Dossier zur Nutzenbewertung gemäß § 35a SGB V

Pembrolizumab (KEYTRUDA®)

MSD Sharp & Dohme GmbH

Modul 4 E

Behandlung von Tumoren mit MSI-H oder dMMR nach vorheriger Therapie bei Erwachsenen: Nicht resezierbares oder metastasierendes biliäres Karzinom

> Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Anhang 4-G: Weitere Ergebnisse

Anhang 4-G1: Rücklaufquoten des EORTC QLQ-C30 und EQ-5D VAS

Im Folgenden werden ergänzend zu Abschnitt 4.3.2.3.3.2.1 die Rücklaufquoten des EORTC QLQ-C30 und die Rücklaufquoten des EQ-5D VAS dargestellt.

Alle Ergebnisse beziehen sich auf den Datenschnitt vom 05. Oktober 2020.

Anhang 4-G1.1: Rücklaufquoten des EORTC QLQ-C30

Tabelle 4G-1: Gründe für das Fehlen von Werten im EORTC QLQ-C30

KEYNOTE 158		Pembrolizum
		$N^{b} = 22$
Visit	EORTC QLQ-C30	n (%)
Baseline	Missing by Design	0 (0.0)
	Discontinued due to adverse event	0 (0.0)
	Discontinued due to clinical progression	0 (0.0)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	0 (0.0)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	22 (100.0)
	Not completed	1 (4.5)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	1 (4.5)
	With visit, no record	0 (0.0)
	Completed	21 (95.5)
	Compliance (% in those expected to complete questionnaires) ^d	21 (95.5)
Week 3	Missing by Design	0 (0.0)
	Discontinued due to adverse event	0 (0.0)
	Discontinued due to clinical progression	0 (0.0)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	0 (0.0)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	22 (100.0)
	Not completed	1 (4.5)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	1 (4.5)
	With visit, no record	0 (0.0)
	Completed	21 (95.5)
	Compliance (% in those expected to complete questionnaires) ^d	21 (95.5)
Week 6	Missing by Design	3 (13.6)
	Discontinued due to adverse event	0 (0.0)
	Discontinued due to clinical progression	0 (0.0)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	0 (0.0)
	Subject died	1 (4.5)
	Visit not scheduled	2 (9.1)
	Expected to Complete Questionnaires ^c	19 (86.4)
	Not completed	2 (9.1)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	2 (9.1)
	With visit, no record	0 (0.0)
	Completed	17 (77.3)
		()

Week 9	Missing by Design	4 (18.2)
Week y	Discontinued due to adverse event	0 (0.0)
	Discontinued due to clinical progression	2 (9.1)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	0 (0.0)
	Subject died	0 (0.0)
	Visit not scheduled	2 (9.1)
	Expected to Complete Questionnaires ^c	18 (81.8)
	Not completed	0 (0.0)
	Not completed Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	` ′
	Other	0 (0.0)
	With visit, no record	0 (0.0)
	Completed	0 (0.0)
		18 (81.8)
	Compliance (% in those expected to complete questionnaires) ^d	18 (100.0)
Week 18	Missing by Design	4 (18.2)
	Discontinued due to adverse event	1 (4.5)
	Discontinued due to clinical progression	2 (9.1)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	1 (4.5)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	18 (81.8)
	Not completed	1 (4.5)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	1 (4.5)
	With visit, no record	0 (0.0)
	Completed	17 (77.3)
	Compliance (% in those expected to complete questionnaires) ^d	17 (94.4)
Week 27	Missing by Design	7 (31.8)
	Discontinued due to adverse event	1 (4.5)
	Discontinued due to clinical progression	3 (13.6)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	3 (13.6)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	15 (68.2)
	Not completed	3 (13.6)
	Not completed due to site staff error	1 (4.5)
	Subject refused for other reasons	1 (4.5)
	Other	0 (0.0)
	With visit, no record	1 (4.5)
	Completed	12 (54.5)
	Compliance (% in those expected to complete questionnaires) ^d	
W/1- 20		12 (80.0)
Week 39	Missing by Design Discontinued due to adverse event	9 (40.9)
		1 (4.5)
	Discontinued due to clinical progression Discontinued due to complete response	5 (22.7)
	Discontinued due to complete response Discontinued due to progressive disease	0 (0.0)
		3 (13.6)
	Subject died Visit not scheduled	0 (0.0)
		0 (0.0)
	Expected to Complete Questionnaires ^c	13 (59.1)
	Not completed	2 (9.1)
	Not completed due to site staff error	1 (4.5)
	Subject refused for other reasons	0 (0.0)
	Other	1 (4.5)
	With visit, no record	0 (0.0)
	Completed	11 (50.0)
		44.04.0
	Compliance (% in those expected to complete questionnaires) ^d	11 (84.6)

	Discontinued due to clinical progression	5 (22.7)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	3 (13.6)
	Subject died Visit not sekeduled	1 (4.5)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	12 (54.5)
	Not completed	3 (13.6)
	Not completed due to site staff error	1 (4.5)
	Subject refused for other reasons	1 (4.5)
	Other	0 (0.0)
	With visit, no record	1 (4.5)
	Completed	9 (40.9)
	Compliance (% in those expected to complete questionnaires) ^d	9 (75.0)
Week 63	Missing by Design	12 (54.5)
	Discontinued due to adverse event	2 (9.1)
	Discontinued due to clinical progression	6 (27.3)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	4 (18.2)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	10 (45.5)
	Not completed	2 (9.1)
	Not completed due to site staff error	1 (4.5)
	Subject refused for other reasons	0 (0.0)
	Other	0 (0.0)
	With visit, no record	1 (4.5)
	Completed	8 (36.4)
	Compliance (% in those expected to complete questionnaires) ^d	8 (80.0)
Week 75	Missing by Design	14 (63.6)
	Discontinued due to adverse event	2 (9.1)
	Discontinued due to clinical progression	6 (27.3)
	Discontinued due to complete response	1 (4.5)
	Discontinued due to progressive disease	5 (22.7)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	8 (36.4)
	Not completed	0 (0.0)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	0 (0.0)
	With visit, no record	0 (0.0)
	Completed	8 (36.4)
	Compliance (% in those expected to complete questionnaires) ^d	8 (100.0)
Week 87	Missing by Design	15 (68.2)
	Discontinued due to adverse event	2 (9.1)
	Discontinued due to clinical progression	6 (27.3)
	Discontinued due to complete response	1 (4.5)
	Discontinued due to progressive disease	6 (27.3)
	Subject died	0 (0.0)
	V:-i441 41 - 4	0 (0 0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	7 (31.8)
	Expected to Complete Questionnaires ^c Not completed	7 (31.8) 1 (4.5)
	Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error	7 (31.8) 1 (4.5) 0 (0.0)
	Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons	7 (31.8) 1 (4.5) 0 (0.0) 0 (0.0)
	Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons Other	7 (31.8) 1 (4.5) 0 (0.0) 0 (0.0) 1 (4.5)
	Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons Other With visit, no record	7 (31.8) 1 (4.5) 0 (0.0) 0 (0.0) 1 (4.5) 0 (0.0)
	Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons Other With visit, no record Completed	7 (31.8) 1 (4.5) 0 (0.0) 0 (0.0) 1 (4.5) 0 (0.0) 6 (27.3)
	Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons Other With visit, no record	7 (31.8) 1 (4.5) 0 (0.0) 0 (0.0) 1 (4.5) 0 (0.0)

	Discontinued due to clinical progression	6 (27.3)
	Discontinued due to complete response	1 (4.5)
	Discontinued due to progressive disease	7 (31.8)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	6 (27.3)
	Not completed	1 (4.5)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	0 (0.0)
	With visit, no record	1 (4.5)
	Completed	5 (22.7)
	Compliance (% in those expected to complete questionnaires) ^d	5 (83.3)
Week 111	Missing by Design	17 (77.3)
	Discontinued due to adverse event	3 (13.6)
	Discontinued due to clinical progression	6 (27.3)
	Discontinued due to complete response	1 (4.5)
	Discontinued due to progressive disease	7 (31.8)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	5 (22.7)
	Not completed	1 (4.5)
	Not completed due to site staff error	1 (4.5)
	Subject refused for other reasons	0 (0.0)
	Other	0 (0.0)
	With visit, no record	0(0.0)
	With visit, no record Completed	0 (0.0) 4 (18.2)

a: Database Cutoff Date: 05OCT2020

Anhang 4-G12: Rücklaufquoten des EQ-5D VAS

Tabelle 4G-2: Gründe für das Fehlen von Werten im EQ-5D VAS

tudy: KEYNOTE 158 ^a		Pembrolizumab
		N ^b = 22
Visit	EQ-5D-3L	n (%)
Baseline	Missing by Design	0 (0.0)
	Discontinued due to adverse event	0 (0.0)
	Discontinued due to clinical progression	0 (0.0)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	0 (0.0)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	22 (100.0)
	Not completed	1 (4.5)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	1 (4.5)
	With visit, no record	0 (0.0)
	Completed	21 (95.5)
	Compliance (% in those expected to complete questionnaires) ^d	21 (95.5)

b: Number of participants: full-analysis-set population with MSI-H biliary carcinoma, at least one line of prior therapy

c: Expected to complete questionnaire includes all participants who do not have missing data due to a missing by design reason

d: Compliance is the proportion of participants who completed the PRO questionnaire among those who are expected to complete the questionnaire at each time point, excluding those missing by design. All the other percentages are defined as the proportion of participants in the analysis population (N)

EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 items; MSI-H: Microsatellite Instability-High; PRO: Patient Reported Outcome

Week 3	Missing by Design	0 (0.0)
WCCK 3	Discontinued due to adverse event	0 (0.0)
	Discontinued due to clinical progression	0 (0.0)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	0 (0.0)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	22 (100.0)
	Not completed	0 (0.0)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	` '
	With visit, no record	0 (0.0)
	Completed	0 (0.0)
		22 (100.0)
	Compliance (% in those expected to complete questionnaires) ^d	22 (100.0)
Week 6	Missing by Design	3 (13.6)
	Discontinued due to adverse event	0 (0.0)
	Discontinued due to clinical progression	0 (0.0)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	0 (0.0)
	Subject died	1 (4.5)
	Visit not scheduled	2 (9.1)
	Expected to Complete Questionnaires ^c	19 (86.4)
	Not completed	2 (9.1)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	2 (9.1)
	With visit, no record	0 (0.0)
	Completed	17 (77.3)
	Compliance (% in those expected to complete questionnaires) ^d	17 (89.5)
Week 9	Missing by Design	4 (18.2)
	Discontinued due to adverse event	0 (0.0)
	Discontinued due to clinical progression	2 (9.1)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	0 (0.0)
	Subject died	0 (0.0)
	Visit not scheduled	2 (9.1)
	Expected to Complete Questionnaires ^c	18 (81.8)
	Not completed	0 (0.0)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	0 (0.0)
	With visit, no record	0 (0.0)
	Completed	18 (81.8)
	Compliance (% in those expected to complete questionnaires) ^d	18 (100.0)
Week 18	Missing by Design	4 (18.2)
3011 10	Discontinued due to adverse event	1 (4.5)
	Discontinued due to clinical progression	2 (9.1)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to progressive disease	1 (4.5)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	18 (81.8)
	Not completed	1 (4.5)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	` '
	Other	0 (0.0)
		1 (4.5)
	With visit, no record	0 (0.0)
	Completed	17 (77.3)
	Compliance (% in those expected to complete questionnaires) ^d	17 (94.4)
Week 27	Missing by Design	7 (31.8)

Week 75	Compliance (% in those expected to complete questionnaires) ^d Missing by Design	8 (80.0) 14 (63.6)
	Compliance (% in those expected to complete questionnaires) ^d	8 (80.0)
		1
	Completed	8 (36.4)
	With visit, no record	1 (4.5)
	Other	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Not completed due to site staff error	1 (4.5)
	Not completed	2 (9.1)
	Expected to Complete Questionnaires ^c	10 (45.5)
	Visit not scheduled	0 (0.0)
	Subject died	0 (0.0)
	Discontinued due to progressive disease	4 (18.2)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to clinical progression	6 (27.3)
WCCK US	Discontinued due to adverse event	2 (9.1)
Week 63	Missing by Design	12 (54.5)
	Compliance (% in those expected to complete questionnaires) ^d	9 (75.0)
	Completed	9 (40.9)
	With visit, no record	1 (4.5)
	Other	0 (0.0)
	Subject refused for other reasons	1 (4.5)
	Not completed Not completed due to site staff error	1 (4.5)
	Expected to Complete Questionnaires ^c Not completed	12 (54.5) 3 (13.6)
	Visit not scheduled Expected to Complete Questionnairees	0 (0.0)
	Subject died	1 (4.5)
	Discontinued due to progressive disease	3 (13.6)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to clinical progression	5 (22.7)
	Discontinued due to adverse event	1 (4.5)
Week 51	Missing by Design	10 (45.5)
	Compliance (% in those expected to complete questionnaires) ^d	11 (84.6)
	Completed	11 (50.0)
	With visit, no record	0 (0.0)
	Other With visit no record	1 (4.5)
	Subject refused for other reasons	0 (0.0)
	Not completed due to site staff error	1 (4.5)
	Not completed	2 (9.1)
	Expected to Complete Questionnaires ^c	13 (59.1)
	Visit not scheduled	0 (0.0)
	Subject died	0 (0.0)
	Discontinued due to progressive disease	3 (13.6)
	Discontinued due to complete response	0 (0.0)
	Discontinued due to clinical progression	5 (22.7)
	Discontinued due to adverse event	1 (4.5)
Week 39	Missing by Design	9 (40.9)
	Compliance (% in those expected to complete questionnaires) ^d	12 (80.0)
	Completed	12 (54.5)
	With visit, no record	1 (4.5)
	Other	0 (0.0)
	Subject refused for other reasons	1 (4.5)
	Not completed due to site staff error	1 (4.5)
	Not completed	3 (13.6)
	Expected to Complete Questionnaires ^c	15 (68.2)
	Visit not scheduled	0 (0.0)
	Discontinued due to progressive disease Subject died	3 (13.6) 0 (0.0)
	Discontinued due to complete response	0 (0.0)
		` '
	Discontinued due to clinical progression	3 (13.6)

	Discontinued due to clinical progression	6 (27.3)
	Discontinued due to complete response	1 (4.5)
	Discontinued due to progressive disease	5 (22.7)
	Subject died Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	0 (0.0)
	Not completed	8 (36.4) 0 (0.0)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	0 (0.0)
	With visit, no record	0 (0.0)
	Completed	8 (36.4)
	Compliance (% in those expected to complete questionnaires) ^d	8 (100.0)
Week 87		
week 87	Missing by Design Discontinued due to adverse event	15 (68.2)
	Discontinued due to clinical progression	2 (9.1) 6 (27.3)
		` '
	Discontinued due to complete response	1 (4.5) 6 (27.3)
	Discontinued due to progressive disease	` ′
	Subject died Visit not scheduled	0 (0.0)
		0 (0.0)
	Expected to Complete Questionnaires ^c Not completed	7 (31.8)
		1 (4.5)
	Not completed due to site staff error Subject refused for other reasons	0 (0.0)
	Other	0 (0.0)
	With visit, no record	1 (4.5)
	Completed	0 (0.0)
		6 (27.3)
	Compliance (% in those expected to complete questionnaires) ^d	6 (85.7)
Week 99	Missing by Design	16 (72.7)
	Discontinued due to adverse event Discontinued due to clinical progression	2 (9.1) 6 (27.3)
	Discontinued due to complete response	
	Discontinued due to complete response Discontinued due to progressive disease	1 (4.5) 7 (31.8)
	Subject died	0 (0.0)
	Visit not scheduled	0 (0.0)
	Expected to Complete Questionnaires ^c	6 (27.3)
	Not completed	1 (4.5)
	Not completed due to site staff error	0 (0.0)
	Subject refused for other reasons	0 (0.0)
	Other	0 (0.0)
	With visit, no record	1 (4.5)
	Completed	5 (22.7)
	Compliance (% in those expected to complete questionnaires) ^d	5 (83.3)
		` `
W 1 111	Missing by Design	17 (77.3)
Week 111		
Week 111	Discontinued due to adverse event	3 (13.6)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression	6 (27.3)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response	6 (27.3) 1 (4.5)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease	6 (27.3) 1 (4.5) 7 (31.8)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died Visit not scheduled	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0) 0 (0.0)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died Visit not scheduled Expected to Complete Questionnaires ^c	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0) 0 (0.0) 5 (22.7)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died Visit not scheduled Expected to Complete Questionnaires ^c Not completed	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0) 0 (0.0) 5 (22.7) 1 (4.5)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died Visit not scheduled Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0) 0 (0.0) 5 (22.7) 1 (4.5) 1 (4.5)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died Visit not scheduled Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0) 0 (0.0) 5 (22.7) 1 (4.5) 1 (4.5) 0 (0.0)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died Visit not scheduled Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons Other	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0) 0 (0.0) 5 (22.7) 1 (4.5) 1 (4.5) 0 (0.0) 0 (0.0)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died Visit not scheduled Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons Other With visit, no record	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0) 0 (0.0) 5 (22.7) 1 (4.5) 0 (0.0) 0 (0.0) 0 (0.0)
Week 111	Discontinued due to adverse event Discontinued due to clinical progression Discontinued due to complete response Discontinued due to progressive disease Subject died Visit not scheduled Expected to Complete Questionnaires ^c Not completed Not completed due to site staff error Subject refused for other reasons Other	6 (27.3) 1 (4.5) 7 (31.8) 0 (0.0) 0 (0.0) 5 (22.7) 1 (4.5) 1 (4.5) 0 (0.0) 0 (0.0)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

c: Expected to complete questionnaire includes all participants who do not have missing data due to a missing by design reason

d: Compliance is the proportion of participants who completed the PRO questionnaire among those who are expected to complete the questionnaire at each time point, excluding those missing by design. All the other percentages are defined as the proportion of participants in the analysis population (N)

EQ-5D-3L: 3-level version of the EuroQol-5 Dimension of health questionnaire; MSI-H: Microsatellite Instability-High; PRO: Patient Reported Outcome

Anhang 4-G2: Definition der Immunvermittelten unerwünschten Ereignisse (AEOSI) anhand der zugeordneten PT

Die Definition der Immunvermittelten unerwünschten Ereignisse (AEOSI) anhand der zugeordneten PT in der Studie KEYNOTE 158 sind Anhang 4G des Moduls 4C (Magenkarzinom) zu entnehmen.