Dossier zur Nutzenbewertung gemäß § 35a SGB V

Olaparib (Lynparza®)

AstraZeneca GmbH

Anhang 4-G: Ergänzende Unterlagen

Behandlung von erwachsenen Patientinnen mit einem fortgeschrittenen (FIGO-Stadien III und IV), BRCA1/2-mutierten (in der Keimbahn und/oder somatisch), high-grade epithelialen Ovarialkarzinom, Eileiterkarzinom oder primären Peritonealkarzinom, die nach einer abgeschlossenen Platin-basierten Erstlinien-Chemotherapie ein Ansprechen (vollständig oder partiell) haben

Stand: 31.03.2023

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1.1: Mortalität: Gesamtüberleben

1.1.1: Subgruppenanalysen

Table 1.4.1.1 SOLO1: Summary of subgroup analysis of Gesamtüberleben
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	66 (29,3)	NE [NE; NE]	112	53 (47,3)	78,7 [61,0; NE]	0,53	[0,37; 0,77]	0,0009*
>=65 Jahre	35	18 (51,4)	80,3 [46,9; NE]	19	12 (63,2)	73,9 [26,3; NE]	0,82	[0,40; 1,74]	0,5871
Interaktion p-Wert									0,3066
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	60 (28,2)	NE [NE; NE]	107	46 (43,0)	97,4 [72,3; NE]	0,60	[0,41; 0,88]	0,0098*
Partielles Ansprechen	47	24 (51,1)	88,2 [37,4; NE]	24	19 (79,2)	45,4 [25,4;60,7]	0,44	[0,24; 0,81]	0,0096*
Interaktion p-Wert									0,4002
ECOG PS Status									
Normale Aktivität	200	57 (28,5)	NE [NE; NE]	105	48 (45,7)	78,7 [64,5; NE]	0,55	[0,37; 0,80]	0,0024*
Eingeschränkte Aktivität	60	27 (45,0)	93,2 [56,7; NE]	25	17 (68,0)	72,3 [44,2;88,6]	0,61	[0,33; 1,13]	0,1149
Interaktion p-Wert									0,7736
Baseline CA-125 Wert									
<=ULN	247	75 (30,4)	NE [NE; NE]	123	58 (47,2)	81,5 [67,4; NE]	0,57	[0,41; 0,81]	0,0018*
>ULN	13	9 (69,2)	43,8 [16,1; NE]	7	7 (100)	26,3 [16,7;56,0]	0,52	[0,19; 1,45]	0,2013
Interaktion p-Wert									0,8472
FIGO Stadium									
III	220	65 (29,5)	NE [NE; NE]	105	53 (50,5)	75,2 [64,5; NE]	0,52	[0,36; 0,75]	0,0005*
IV	40	19 (47,5)	93,2 [63,8; NE]	26	12 (46,2)	NE [NE; NE]	0,89	[0,43; 1,88]	0,7424
Interaktion p-Wert									0,1896
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	68 (36,2)	NE [NE; NE]	91	46 (50,5)	73,9 [59,5; NE]	0,65	[0,45; 0,95]	0,0278*
BRCA2	62	13 (21,0)	NE [NE; NE]	39	18 (46,2)	81,5 [66,1; NE]	0,37	[0,18; 0,74]	0,0055*
Interaktion p-Wert									0,1574
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.4.1.1 SOLO1: Summary of subgroup analysis of Gesamtüberleben
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	26 (47,3)	NE [NE; NE]	29	17 (58,6)	61,0 [28,5; NE]	0,73	[0,40; 1,38]	0,3261
Keine makroskopische Resterkrankung	200	56 (28,0)	NE [NE; NE]	98	45 (45,9)	88,6 [67,4; NE]	0,55	[0,37; 0,81]	0,0030*
Interaktion p-Wert									0,4223
Abstammung									
Weiß	214	69 (32,2)	NE [NE; NE]	106	53 (50,0)	77,0 [65,4; NE]	0,58	[0,40; 0,83]	0,0032*
Andere	46	15 (32,6)	NE [NE; NE]	25	12 (48,0)	68,2 [43,9; NE]	0,55	[0,26; 1,20]	0,1323
Interaktion p-Wert									0,9188
Region									
Europa	101	28 (27,7)	NE [NE; NE]	53	26 (49,1)	88,6 [58,5; NE]	0,50	[0,29; 0,87]	0,0133*
Asien	33	11 (33,3)	NE [NE; NE]	14	5 (35,7)	NE [NE; NE]	0,64	[0,23; 2,02]	0,4153
Rest der Welt	126	45 (35,7)	NE [NE; NE]	64	34 (53,1)	74,1 [60,7; NE]	0,61	[0,39; 0,96]	0,0321*
Interaktion p-Wert									0,8482

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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1.2: Morbidität: Rezidive

1.2.1: Rezidivrate

1.2.1.1: Subgruppenanalysen

Table 1.4.3 SOLO1: Summary of subgroup analysis for recurrence or death rate (odds ratio, relative risk and risk difference)
Patients with a clinical complete response after platinum-based chemotherapy as randomised, DCO 07MAR2022

	Olaparib 300 mg bd (N=213)		Placebo bd (N=107)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter (Jahre)										
<65 Jahre [a][d][g]	185	76(41,1)	94	70(74,5)	0,24[0,14; 0,41]	<0,0001 *	0,55[0,45; 0,68]	<0,0001 *	-0,33[-0,44; -0,22]	<0,0001 *
>=65 Jahre [a][d][g]	28	16(57,1)	13	8(61,5)	0,83[0,21; 3,16]	0,7899	0,93[0,56; 1,74]	0,7899	-0,04[-0,34; 0,28]	0,7899
Int. p-Wert [a][d][g]						0,0992		0,0650		0,0813
ECOG PS Status										
Normale Aktivität [a][d][g]	169	74(43,8)	88	63(71,6)	0,31[0,18; 0,53]	<0,0001 *	0,61[0,49; 0,76]	<0,0001 *	-0,28[-0,39; -0,15]	<0,0001 *
Eingeschränkte Aktivität [a][d][g]	44	18(40,9)	18	15(83,3)	0,14[0,03; 0,49]	0,0016 *	0,49[0,32; 0,74]	0,0016 *	-0,42[-0,62; -0,17]	0,0016 *
Int. p-Wert [a][d][g]						0,2702		0,3497		0,2846
Baseline CA-125 Wert										
<=ULN	211	91(43,1)	105	77(73,3)	ID	ID	ID	ID	ID	ID
>ULN	2	1(50,0)	1	1(100)	ID	ID	ID	ID	ID	ID
Int. p-Wert						ID		ID		ID
FIGO Stadium										
III [a][d][g]	187	79(42,2)	87	66(75,9)	0,23[0,13; 0,41]	<0,0001 *	0,56[0,45; 0,68]	<0,0001 *	-0,34[-0,45; -0,22]	<0,0001 *
IV	26	13(50,0)	20	12(60,0)	0,67[0,20; 2,16]	0,4990	0,83[0,48; 1,45]	0,4990	-0,10[-0,38; 0,19]	0,4990

CI=95% profile likelihood confidence interval. LR=likelihood ratio test p-value. ID=insufficient data. Results for subgroup levels from separate models for each subgroup level including treatment only. Interaction p-values from models including treatment, subgroup and treatment by subgroup. If >=10 patients for all subgroup levels and >=10 events for 1 subgroup level, models for all subgroup levels fitted and interaction p-value calculated. For subgroups with >2 levels, levels with ID were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met ID presented.
[a] Odds ratio (OR) CI, LR via logistic regression. [b] As [a] but Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR) CI, LR via log-binomial regression. [e] RR, CI, p-value via modified poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD) CI, LR via binomial regression. [h] RD NC via [g]. OR and RR <1, and RD <0 favours olaparib. * p<0.05.
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Table 1.4.3 SOLO1: Summary of subgroup analysis for recurrence or death rate (odds ratio, relative risk and risk difference)
Patients with a clinical complete response after platinum-based chemotherapy as randomised, DCO 07MAR2022

	Olaparib 300 mg bd (N=213)		Placebo bd (N=107)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
[a][d][g]										
Int. p-Wert [a][d][g]						0,1189		0,1689		0,1269
BRCA-Mutationstyp (durch Myriad CDx bestätigt)										
BRCA1 [a][d][g]	152	70(46,1)	74	57(77,0)	0,25[0,13; 0,47]	<0,0001 *	0,60[0,48; 0,74]	<0,0001 *	-0,31[-0,43; -0,18]	<0,0001 *
BRCA2 [a][d][g]	53	17(32,1)	32	20(62,5)	0,28[0,11; 0,70]	0,0060 *	0,51[0,31; 0,82]	0,0060 *	-0,30[-0,50; -0,09]	0,0060 *
Int. p-Wert [a][d][g]						0,8508		0,5626		0,9647
Ergebnis der Debulkingoperation vor Studienbeginn										
makroskopische Resterkrankung [a][d][g]	31	15(48,4)	20	16(80,0)	0,23[0,06; 0,81]	0,0207 *	0,60[0,38; 0,92]	0,0207 *	-0,32[-0,54; -0,05]	0,0207 *
Keine makroskopische Resterkrankung [a][d][g]	181	77(42,5)	86	61(70,9)	0,30[0,17; 0,52]	<0,0001 *	0,60[0,48; 0,75]	<0,0001 *	-0,28[-0,40; -0,16]	<0,0001 *
Int. p-Wert [a][d][g]						0,7180		0,9724		0,8199
Abstammung										
Weiß [a][d][g]	176	76(43,2)	88	64(72,7)	0,29[0,16; 0,49]	<0,0001 *	0,59[0,48; 0,73]	<0,0001 *	-0,30[-0,41; -0,17]	<0,0001 *
Andere [a][d][g]	37	16(43,2)	19	14(73,7)	0,27[0,07; 0,87]	0,0280 *	0,59[0,36; 0,94]	0,0280 *	-0,30[-0,54; -0,03]	0,0280 *
Int. p-Wert [a][d][g]						0,9456		0,9638		0,9502

CI=95% profile likelihood confidence interval. LR=likelihood ratio test p-value. ID=insufficient data. Results for subgroup levels from separate models for each subgroup level including treatment only. Interaction p-values from models including treatment, subgroup and treatment by subgroup. If >=10 patients for all subgroup levels and >=10 events for 1 subgroup level, models for all subgroup levels fitted and interaction p-value calculated. For subgroups with >2 levels, levels with ID were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met ID presented.
[a] Odds ratio (OR) CI, LR via logistic regression. [b] As [a] but Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR) CI, LR via log-binomial regression. [e] RR, CI, p-value via modified poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD) CI, LR via binomial regression. [h] RD NC via [g]. OR and RR <1, and RD <0 favours olaparib. * p<0.05.
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Table 1.4.3 SOLO1: Summary of subgroup analysis for recurrence or death rate (odds ratio, relative risk and risk difference)
Patients with a clinical complete response after platinum-based chemotherapy as randomised, DCO 07MAR2022

	Olaparib 300 mg bd (N=213)		Placebo bd (N=107)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Europa [a][d][g]	87	36(41,4)	43	30(69,8)	0,31[0,14; 0,65]	0,0021 *	0,59[0,43; 0,82]	0,0021 *	-0,28[-0,45; -0,11]	0,0021 *
Asien [a][d][g]	26	12(46,2)	10	7(70,0)	0,37[0,07; 1,64]	0,1938	0,66[0,37; 1,29]	0,1938	-0,24[-0,54; 0,12]	0,1938
Rest der Welt [a][d][g]	100	44(44,0)	54	41(75,9)	0,25[0,12; 0,51]	0,0001 *	0,58[0,44; 0,76]	0,0001 *	-0,32[-0,46; -0,16]	0,0001 *
Int. p-Wert [a][d][g]						0,8783		0,9236		0,8947

CI=95% profile likelihood confidence interval. LR=likelihood ratio test p-value. ID=insufficient data. Results for subgroup levels from separate models for each subgroup level including treatment only. Interaction p-values from models including treatment, subgroup and treatment by subgroup. If >=10 patients for all subgroup levels and >=10 events for 1 subgroup level, models for all subgroup levels fitted and interaction p-value calculated. For subgroups with >2 levels, levels with ID were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met ID presented.
[a] Odds ratio (OR) CI, LR via logistic regression. [b] As [a] but Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR) CI, LR via log-binomial regression. [e] RR, CI, p-value via modified poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD) CI, LR via binomial regression. [h] RD NC via [g]. OR and RR <1, and RD <0 favours olaparib. * p<0.05.
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1.2.2: Rezidivfreies Überleben

1.2.2.1: Subgruppenanalysen

Table 1.4.1.6 SOLO1: Summary of subgroup analysis of Time to recurrence or death
Patients with a clinical complete response after platinum-based chemotherapy as randomised, DCO 07MAR2022

	Olaparib 300 mg bd (N=213)			Placebo bd (N=107)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	185	76 (41,1)	78,0 [50,5; NE]	94	70 (74,5)	16,6 [11,3;22,1]	0,35	[0,25; 0,49]	<0,0001*
>=65 Jahre	28	16 (57,1)	40,6 [25,0;77,9]	13	8 (61,5)	30,4 [5,4; NE]	0,86	[0,38; 2,11]	0,7221
Interaktion p-Wert									0,0492*
ECOG PS Status									
Normale Aktivität	169	74 (43,8)	71,6 [44,8; NE]	88	63 (71,6)	19,0 [11,3;24,9]	0,42	[0,30; 0,59]	<0,0001*
Eingeschränkte Aktivität	44	18 (40,9)	NE [NE; NE]	18	15 (83,3)	14,6 [8,2;38,5]	0,31	[0,15; 0,62]	0,0013*
Interaktion p-Wert									0,4267
Baseline CA-125 Wert									
<=ULN	211	91 (43,1)	77,5 [47,2; NE]	105	77 (73,3)	19,0 [11,8;24,9]	0,40	[0,29; 0,54]	<0,0001*
>ULN	2	1 (50,0)	11,7 [NE; NE]	1	1 (100)	2,6 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	187	79 (42,2)	77,9 [47,2; NE]	87	66 (75,9)	15,3 [11,8;24,7]	0,36	[0,26; 0,50]	<0,0001*
IV	26	13 (50,0)	40,6 [24,4; NE]	20	12 (60,0)	18,0 [7,8; NE]	0,66	[0,30; 1,48]	0,3107
Interaktion p-Wert									0,1586
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	152	70 (46,1)	50,5 [33,8; NE]	74	57 (77,0)	19,4 [11,3;30,2]	0,42	[0,30; 0,60]	<0,0001*
BRCA2	53	17 (32,1)	77,9 [64,8; NE]	32	20 (62,5)	14,6 [8,5;64,9]	0,30	[0,15; 0,57]	0,0003*
Interaktion p-Wert									0,3451
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	31	15 (48,4)	77,5 [24,8; NE]	20	16 (80,0)	13,8 [11,1;41,4]	0,40	[0,20; 0,82]	0,0125*
Keine makroskopische Resterkrankung	181	77 (42,5)	71,6 [44,4; NE]	86	61 (70,9)	21,5 [11,2;30,4]	0,41	[0,29; 0,57]	<0,0001*
Interaktion p-Wert									0,9729

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.4.1.6 SOLO1: Summary of subgroup analysis of Time to recurrence or death
Patients with a clinical complete response after platinum-based chemotherapy as randomised, DCO 07MAR2022

	Olaparib 300 mg bd (N=213)			Placebo bd (N=107)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Abstammung									
Weiß	176	76 (43,2)	77,9 [44,4; NE]	88	64 (72,7)	19,4 [11,9;27,7]	0,39	[0,28; 0,55]	<0,0001*
Andere	37	16 (43,2)	77,5 [27,0; NE]	19	14 (73,7)	11,3 [9,2;41,5]	0,42	[0,21; 0,88]	0,0221*
Interaktion p-Wert									0,8456
Region									
Europa	87	36 (41,4)	78,0 [47,2; NE]	43	30 (69,8)	16,6 [11,8;30,4]	0,37	[0,23; 0,61]	0,0001*
Asien	26	12 (46,2)	71,6 [22,0; NE]	10	7 (70,0)	17,9 [5,4; NE]	0,50	[0,20; 1,33]	0,1561
Rest der Welt	100	44 (44,0)	63,3 [33,8; NE]	54	41 (75,9)	19,0 [11,1;30,5]	0,40	[0,26; 0,62]	<0,0001*
Interaktion p-Wert									0,8644

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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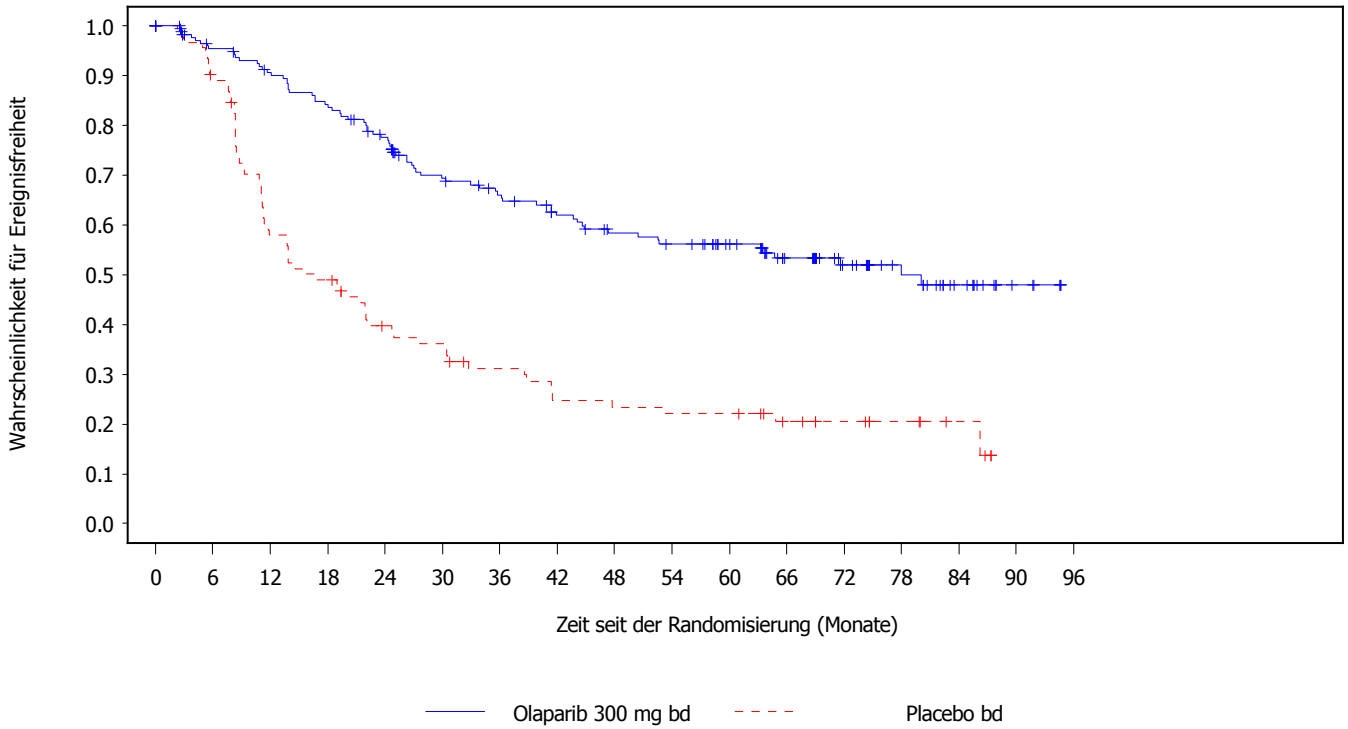
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.9 SOLO1: Kaplan-Meier plot of Rezidivfreies Überleben for Alter (Jahre) = <65 Jahre
Patients with a clinical complete response after platinum-based chemotherapy as randomised, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

185	164	154	143	128	106	98	88	80	76	67	51	35	24	14	4	0	Olaparib 300 mg bd
94	82	52	44	33	30	24	19	18	17	17	12	9	6	3	0	0	Placebo bd

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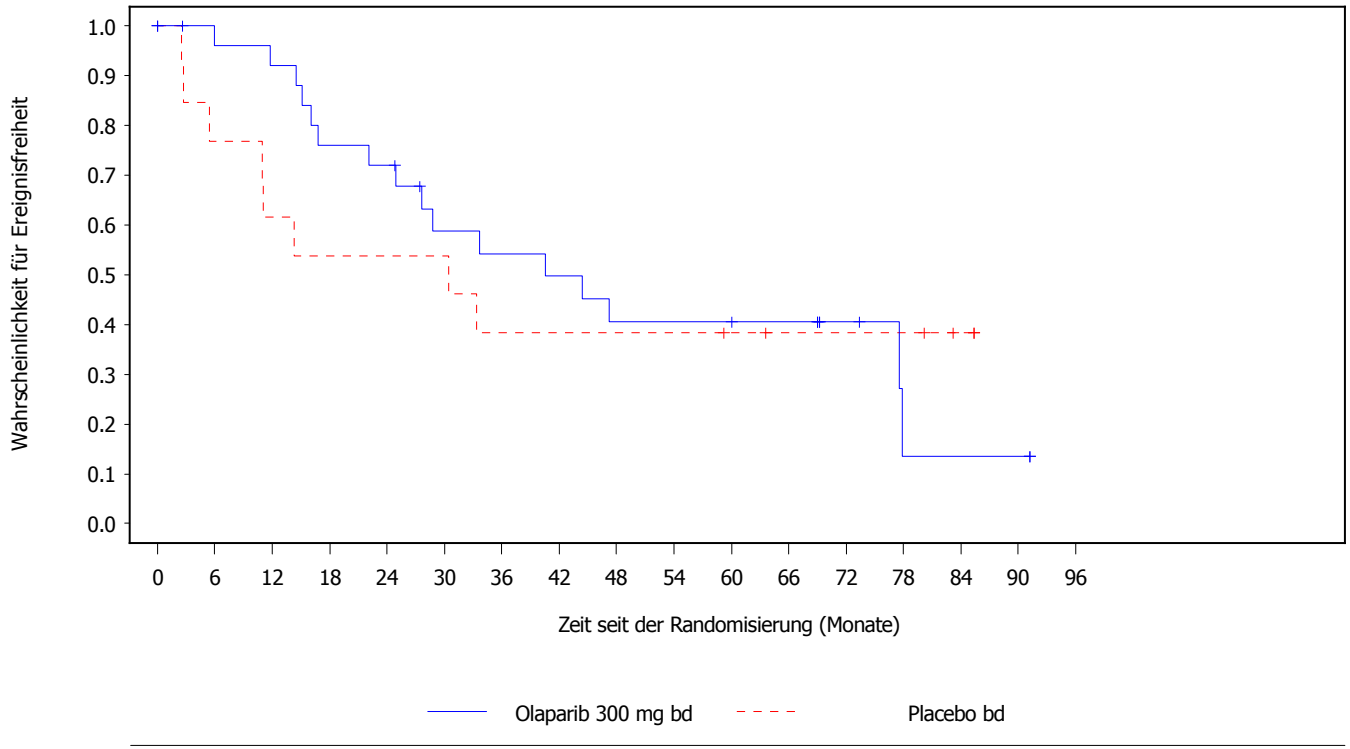
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.10 SOLO1: Kaplan-Meier plot of Rezidivfreies Überleben for Alter (Jahre) = >=65 Jahre
Patients with a clinical complete response after platinum-based chemotherapy as randomised, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

28	24	23	19	18	13	12	11	9	9	9	8	4	1	1	1	0 Olaparib 300 mg bd
13	10	8	7	7	7	5	5	5	5	4	3	3	3	1	0	0 Placebo bd

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1.3: Morbidität: Progressionsfreies Überleben

1.3.1: Progressionsfreies Überleben

1.3.1.1: Subgruppenanalysen

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 1.4.1.2 SOLO1: Summary of subgroup analysis of Progressionsfreies Überleben
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	105 (46,7)	63,5 [43,7; NE]	112	88 (78,6)	13,8 [11,1;19,0]	0,35	[0,27; 0,47]	<0,0001*
>=65 Jahre	35	22 (62,9)	33,6 [16,8;77,5]	19	14 (73,7)	11,1 [5,4;33,4]	0,62	[0,32; 1,23]	0,1661
Interaktion p-Wert									0,1322
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	92 (43,2)	77,5 [44,8; NE]	107	78 (72,9)	16,6 [11,8;24,7]	0,40	[0,30; 0,55]	<0,0001*
Partielles Ansprechen	47	35 (74,5)	28,6 [19,3;55,7]	24	24 (100)	5,6 [4,2; 8,4]	0,19	[0,11; 0,32]	<0,0001*
Interaktion p-Wert									0,0157*
ECOG PS Status									
Normale Aktivität	200	98 (49,0)	57,9 [41,9;78,0]	105	80 (76,2)	13,8 [11,1;19,4]	0,40	[0,30; 0,54]	<0,0001*
Eingeschränkte Aktivität	60	29 (48,3)	56,0 [24,8; NE]	25	22 (88,0)	13,8 [8,2;27,7]	0,31	[0,18; 0,55]	0,0001*
Interaktion p-Wert									0,4436
Baseline CA-125 Wert									
<=ULN	247	115 (46,6)	63,5 [44,4; NE]	123	95 (77,2)	13,9 [11,3;19,4]	0,38	[0,29; 0,50]	<0,0001*
>ULN	13	12 (92,3)	11,0 [7,4;41,9]	7	7 (100)	4,2 [2,2; 8,2]	0,15	[0,06; 0,41]	0,0005*
Interaktion p-Wert									0,0739
FIGO Stadium									
III	220	106 (48,2)	57,9 [43,7;80,1]	105	84 (80,0)	13,8 [11,1;19,4]	0,36	[0,27; 0,48]	<0,0001*
IV	40	21 (52,5)	33,8 [24,4; NE]	26	18 (69,2)	9,6 [5,6;41,4]	0,51	[0,27; 0,97]	0,0395*
Interaktion p-Wert									0,3321
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	99 (52,7)	43,7 [29,4;63,5]	91	74 (81,3)	13,8 [11,1;21,5]	0,42	[0,31; 0,57]	<0,0001*
BRCA2	62	23 (37,1)	77,9 [55,7; NE]	39	27 (69,2)	13,8 [8,3;21,9]	0,29	[0,16; 0,50]	<0,0001*
Interaktion p-Wert									0,2489
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 1.4.1.2 SOLO1: Summary of subgroup analysis of Progressionsfreies Überleben
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	35 (63,6)	29,4 [19,3;77,5]	29	25 (86,2)	11,3 [8,3;14,6]	0,44	[0,26; 0,74]	0,0025*
Keine makroskopische Resterkrankung	200	89 (44,5)	64,3 [44,6; NE]	98	73 (74,5)	15,3 [11,1;22,0]	0,38	[0,28; 0,52]	<0,0001*
Interaktion p-Wert									0,6443
Abstammung									
Weiß	214	104 (48,6)	55,7 [41,4; NE]	106	82 (77,4)	13,8 [11,1;19,4]	0,38	[0,28; 0,51]	<0,0001*
Andere	46	23 (50,0)	71,6 [27,7; NE]	25	20 (80,0)	11,2 [8,3;41,5]	0,41	[0,23; 0,76]	0,0047*
Interaktion p-Wert									0,8010
Region									
Europa	101	46 (45,5)	77,9 [47,2; NE]	53	40 (75,5)	13,9 [11,1;19,4]	0,35	[0,23; 0,54]	<0,0001*
Asien	33	17 (51,5)	71,6 [26,8; NE]	14	11 (78,6)	12,5 [6,4;61,0]	0,46	[0,22; 1,01]	0,0522
Rest der Welt	126	64 (50,8)	41,4 [28,6;77,5]	64	51 (79,7)	11,3 [8,8;21,5]	0,40	[0,27; 0,58]	<0,0001*
Interaktion p-Wert									0,7998

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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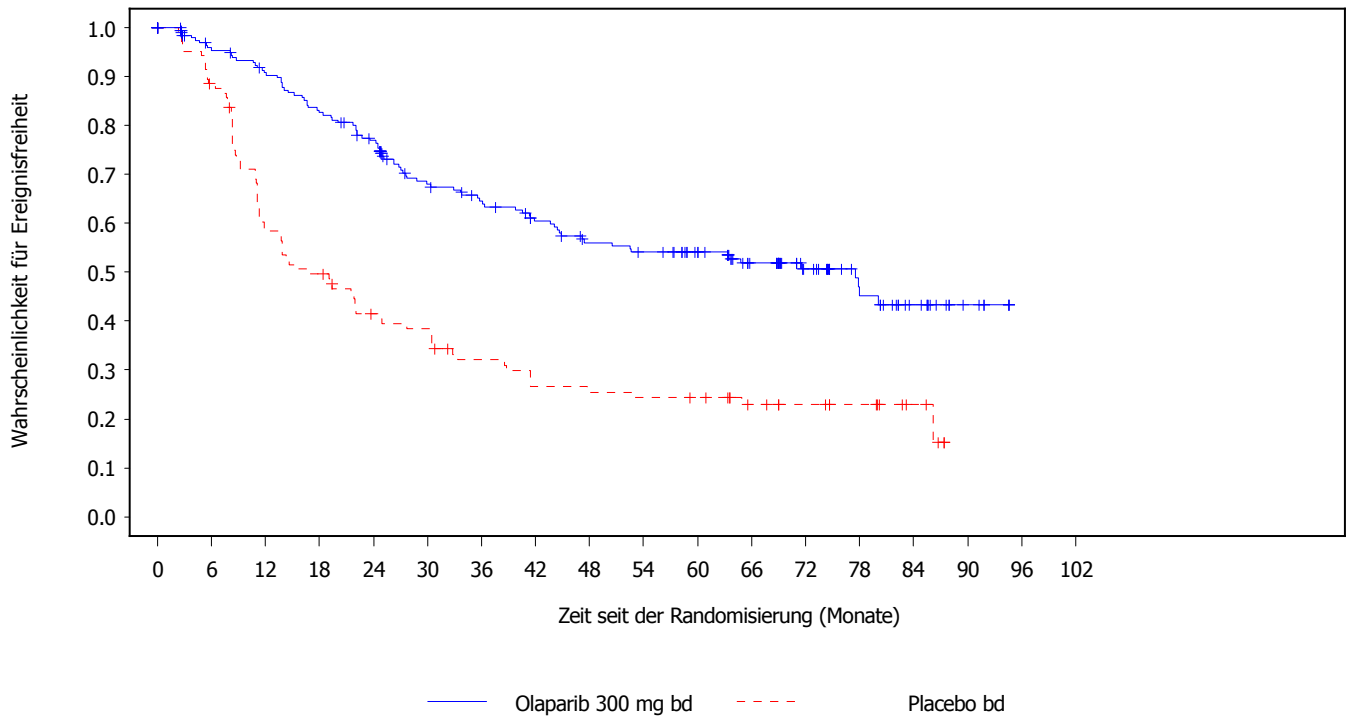
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.1 SOLO1: Kaplan-Meier plot of Progressionsfreies Überleben for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Vollständiges Ansprechen
Full Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

213	188	177	162	146	119	110	99	89	85	76	59	39	25	15	5	0	0	Olaparib 300 mg bd
107	92	60	51	40	37	29	24	23	22	21	15	12	9	4	0	0	0	Placebo bd

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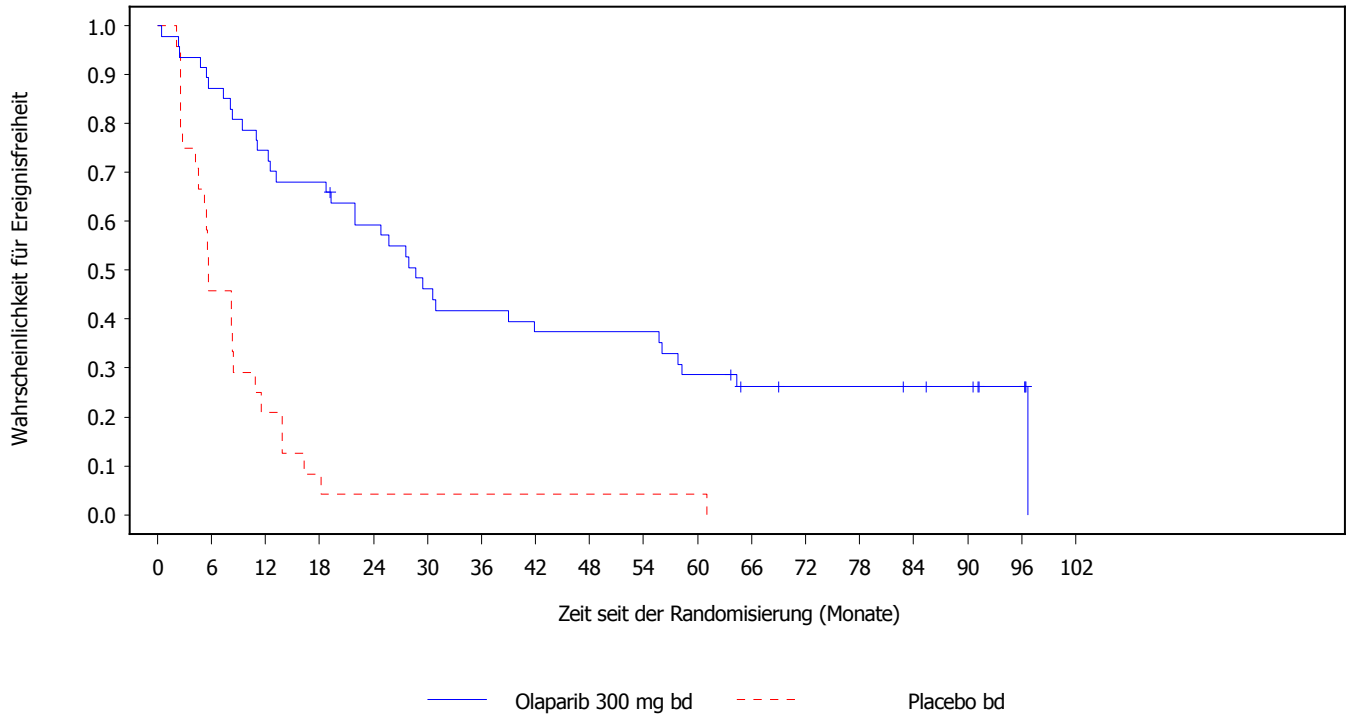
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.2 SOLO1: Kaplan-Meier plot of Progressionsfreies Überleben for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Partielles Ansprechen
Full Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

47	41	35	32	27	21	19	17	17	17	13	10	9	9	8	7	4	0	Olaparib 300 mg bd
24	11	5	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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1.3.2: Progressionsfreies Überleben 2

1.3.2.1: Subgruppenanalysen

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 1.4.1.3 SOLO1: Summary of subgroup analysis of Progressionsfreies Überleben 2
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	72 (32,0)	NE [NE; NE]	112	51 (45,5)	47,9 [36,5;61,0]	0,52	[0,36; 0,75]	0,0006*
>=65 Jahre	35	21 (60,0)	60,7 [31,7;85,3]	19	11 (57,9)	35,5 [11,7; NE]	0,86	[0,42; 1,86]	0,6985
Interaktion p-Wert									0,2176
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	66 (31,0)	88,0 [80,1; NE]	107	45 (42,1)	56,9 [40,3; NE]	0,61	[0,42; 0,90]	0,0124*
Partielles Ansprechen	47	27 (57,4)	40,0 [28,5; NE]	24	17 (70,8)	20,6 [13,3;35,4]	0,30	[0,16; 0,57]	0,0004*
Interaktion p-Wert									0,0602
ECOG PS Status									
Normale Aktivität	200	73 (36,5)	86,8 [77,7; NE]	105	49 (46,7)	47,9 [35,5; NE]	0,60	[0,42; 0,87]	0,0075*
Eingeschränkte Aktivität	60	20 (33,3)	NE [NE; NE]	25	13 (52,0)	40,9 [22,0;61,0]	0,44	[0,22; 0,91]	0,0282*
Interaktion p-Wert									0,4449
Baseline CA-125 Wert									
<=ULN	247	84 (34,0)	91,3 [80,1; NE]	123	57 (46,3)	47,9 [36,5;68,6]	0,57	[0,41; 0,80]	0,0014*
>ULN	13	9 (69,2)	20,3 [11,1; NE]	7	5 (71,4)	8,2 [5,8; NE]	0,14	[0,05; 0,49]	0,0030*
Interaktion p-Wert									0,0334*
FIGO Stadium									
III	220	75 (34,1)	91,3 [77,9; NE]	105	49 (46,7)	47,9 [35,7;61,0]	0,55	[0,38; 0,79]	0,0014*
IV	40	18 (45,0)	66,8 [34,2; NE]	26	13 (50,0)	28,7 [21,2; NE]	0,72	[0,35; 1,50]	0,3740
Interaktion p-Wert									0,4933
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	71 (37,8)	88,0 [66,8; NE]	91	43 (47,3)	47,9 [35,0; NE]	0,65	[0,44; 0,95]	0,0275*
BRCA2	62	19 (30,6)	91,3 [77,7; NE]	39	18 (46,2)	40,3 [29,0; NE]	0,43	[0,22; 0,82]	0,0111*
Interaktion p-Wert									0,2745
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.4.1.3 SOLO1: Summary of subgroup analysis of Progressionsfreies Überleben 2
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	29 (52,7)	60,7 [31,7; NE]	29	14 (48,3)	33,5 [16,8; NE]	0,65	[0,35; 1,27]	0,2000
Keine makroskopische Resterkrankung	200	61 (30,5)	NE [NE; NE]	98	45 (45,9)	52,9 [38,2; NE]	0,54	[0,37; 0,80]	0,0023*
Interaktion p-Wert									0,6303
Abstammung									
Weiß	214	75 (35,0)	88,0 [77,9; NE]	106	51 (48,1)	47,7 [35,4;61,0]	0,55	[0,39; 0,79]	0,0013*
Andere	46	18 (39,1)	80,1 [38,1; NE]	25	11 (44,0)	38,2 [24,7; NE]	0,67	[0,32; 1,47]	0,3096
Interaktion p-Wert									0,6303
Region									
Europa	101	35 (34,7)	88,0 [77,9; NE]	53	25 (47,2)	52,9 [35,4; NE]	0,57	[0,34; 0,96]	0,0348*
Asien	33	11 (33,3)	80,1 [36,8; NE]	14	7 (50,0)	38,2 [27,4; NE]	0,52	[0,20; 1,42]	0,1911
Rest der Welt	126	47 (37,3)	85,3 [47,6; NE]	64	30 (46,9)	40,0 [29,0;68,6]	0,57	[0,36; 0,91]	0,0201*
Interaktion p-Wert									0,9844

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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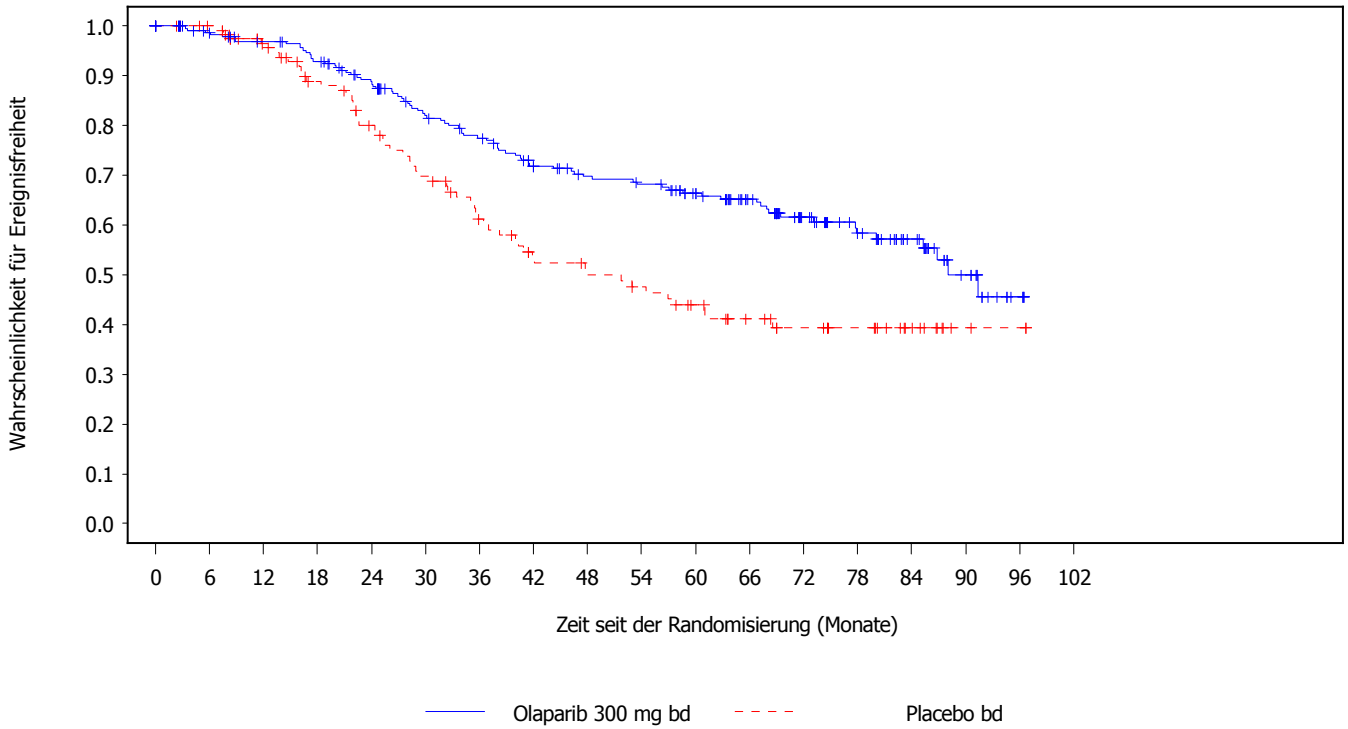
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.3 SOLO1: Kaplan-Meier plot of Progressionsfreies Überleben 2 for Baseline CA-125 Wert = <=ULN
Full Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

247	227	219	208	191	166	155	138	129	125	113	93	66	51	35	16	3	0	Olaparib 300 mg bd
123	118	105	91	79	68	56	46	42	39	33	26	21	17	10	2	1	0	Placebo bd

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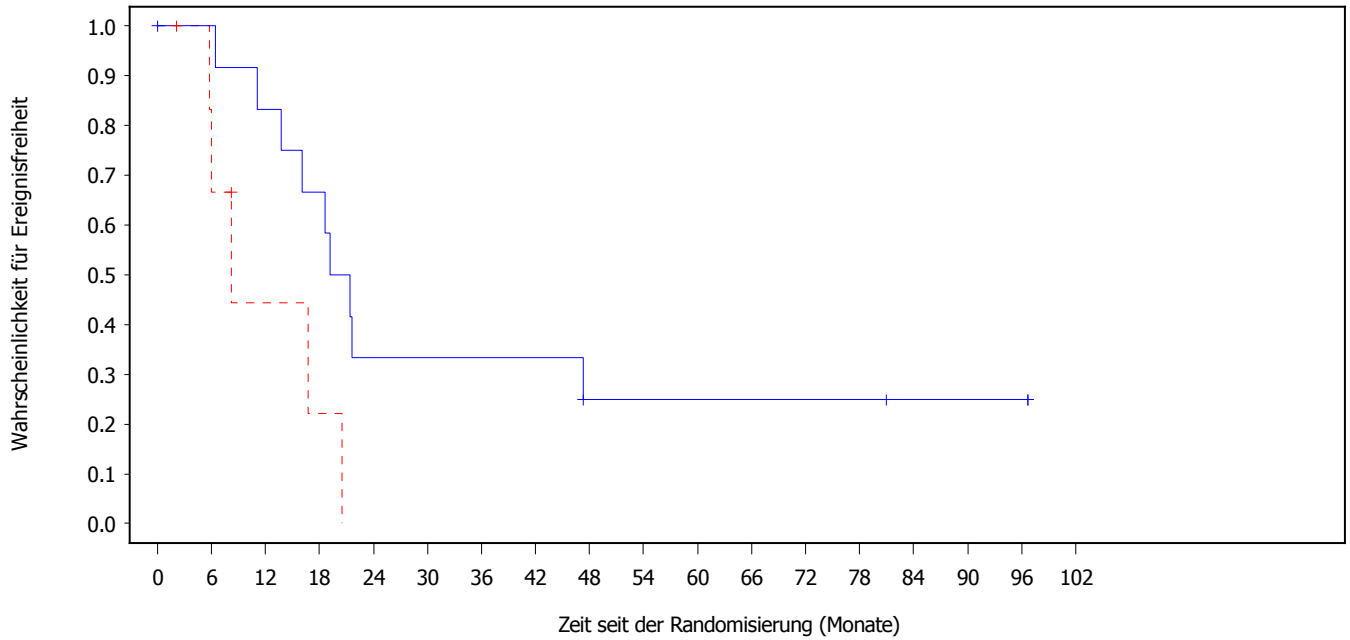
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.4 SOLO1: Kaplan-Meier plot of Progressionsfreies Überleben 2 for Baseline CA-125 Wert = >ULN
Full Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

13	12	10	8	4	4	4	4	2	2	2	2	2	2	1	1	1	0	Olaparib 300 mg bd
7	4	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

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1.4: Morbidität: Zeit bis zur Folgetherapie

1.4.1: Zeit bis zur ersten Folgetherapie

1.4.1.1: Subgruppenanalysen

Table 1.4.1.4 SOLO1: Summary of subgroup analysis of Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	109 (48,4)	75,8 [50,8; NE]	112	84 (75,0)	16,1 [12,7;21,2]	0,37	[0,28; 0,50]	<0,0001*
>=65 Jahre	35	26 (74,3)	46,9 [28,6;77,9]	19	14 (73,7)	14,4 [5,6;33,7]	0,66	[0,35; 1,30]	0,2215
Interaktion p-Wert									0,1074
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	101 (47,4)	81,2 [54,6; NE]	107	76 (71,0)	19,8 [14,8;25,5]	0,42	[0,31; 0,57]	<0,0001*
Partielles Ansprechen	47	34 (72,3)	32,2 [23,7;48,4]	24	22 (91,7)	8,7 [5,8;11,6]	0,21	[0,12; 0,36]	<0,0001*
Interaktion p-Wert									0,0248*
ECOG PS Status									
Normale Aktivität	200	100 (50,0)	72,5 [50,4; NE]	105	77 (73,3)	16,1 [12,4;21,2]	0,41	[0,30; 0,55]	<0,0001*
Eingeschränkte Aktivität	60	35 (58,3)	53,1 [27,6; NE]	25	21 (84,0)	14,5 [9,3;33,6]	0,39	[0,23; 0,68]	0,0012*
Interaktion p-Wert									0,8898
Baseline CA-125 Wert									
<=ULN	247	122 (49,4)	75,8 [51,4; NE]	123	91 (74,0)	16,8 [14,3;22,6]	0,40	[0,30; 0,53]	<0,0001*
>ULN	13	13 (100)	14,5 [9,0;42,2]	7	7 (100)	5,3 [3,6; 8,9]	0,15	[0,06; 0,40]	0,0005*
Interaktion p-Wert									0,0556
FIGO Stadium									
III	220	110 (50,0)	72,5 [48,4; NE]	105	80 (76,2)	15,5 [13,5;23,2]	0,38	[0,29; 0,51]	<0,0001*
IV	40	25 (62,5)	51,8 [28,1;93,2]	26	18 (69,2)	10,8 [6,9;22,0]	0,55	[0,30; 1,02]	0,0568
Interaktion p-Wert									0,2920
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	106 (56,4)	47,7 [33,5;72,5]	91	71 (78,0)	15,1 [12,1;22,6]	0,45	[0,33; 0,61]	<0,0001*
BRCA2	62	24 (38,7)	NE [NE; NE]	39	26 (66,7)	15,5 [10,2;27,4]	0,29	[0,17; 0,51]	<0,0001*
Interaktion p-Wert									0,1907
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 1.4.1.4 SOLO1: Summary of subgroup analysis of Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	38 (69,1)	33,5 [18,9;53,8]	29	24 (82,8)	14,1 [9,2;21,2]	0,53	[0,32; 0,89]	0,0174*
Keine makroskopische Resterkrankung	200	94 (47,0)	82,6 [56,3; NE]	98	71 (72,4)	16,8 [12,4;23,3]	0,38	[0,28; 0,53]	<0,0001*
Interaktion p-Wert									0,2997
Abstammung									
Weiß	214	111 (51,9)	61,7 [46,9;93,2]	106	80 (75,5)	15,1 [12,7;22,0]	0,39	[0,29; 0,53]	<0,0001*
Andere	46	24 (52,2)	77,2 [28,3; NE]	25	18 (72,0)	16,1 [11,2;43,4]	0,47	[0,26; 0,88]	0,0193*
Interaktion p-Wert									0,5941
Region									
Europa	101	46 (45,5)	NE [NE; NE]	53	40 (75,5)	16,8 [13,5;20,5]	0,34	[0,22; 0,52]	<0,0001*
Asien	33	16 (48,5)	81,2 [27,4; NE]	14	9 (64,3)	14,3 [10,0; NE]	0,49	[0,22; 1,17]	0,1044
Rest der Welt	126	73 (57,9)	46,9 [34,3;77,2]	64	49 (76,6)	14,5 [10,8;23,2]	0,44	[0,31; 0,64]	<0,0001*
Interaktion p-Wert									0,5700

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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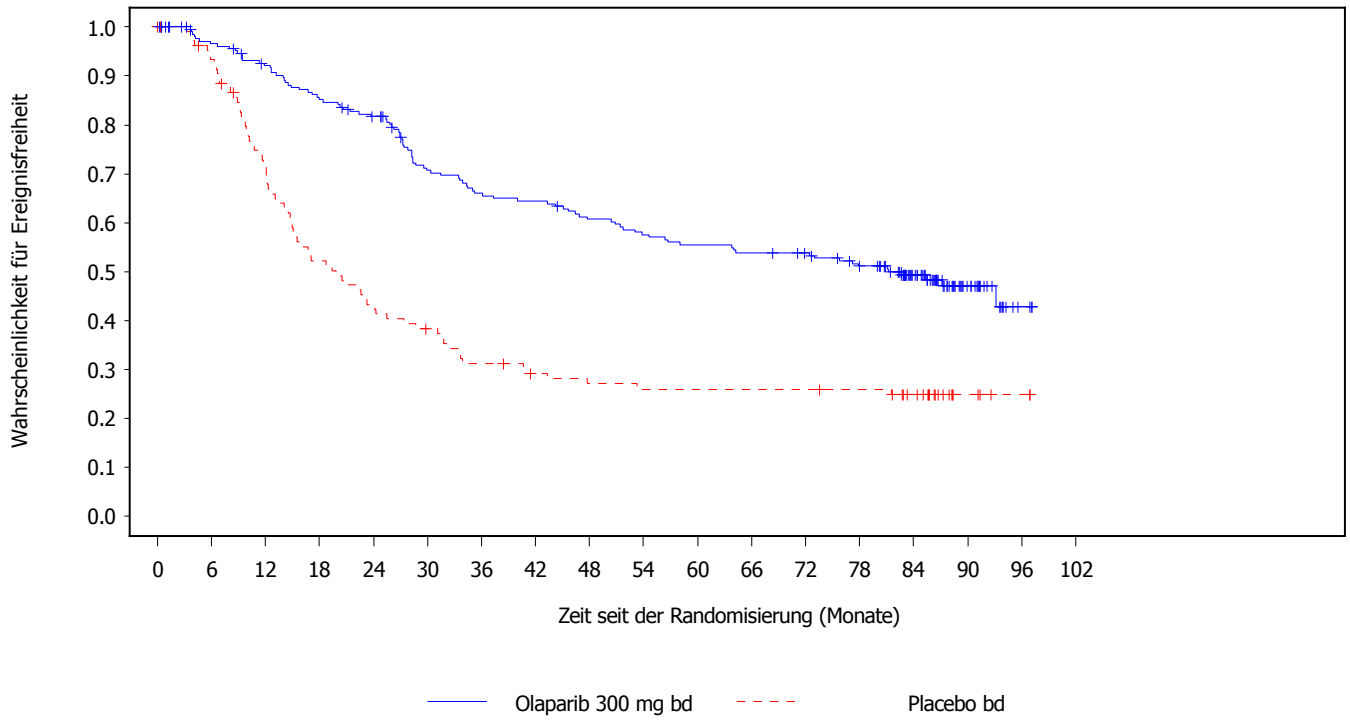
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Vollständiges Ansprechen
Full Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

213	197	185	171	161	135	126	123	115	109	105	102	99	90	63	23	2	0	Olaparib 300 mg bd
107	97	73	53	44	38	31	27	25	24	24	24	24	23	18	4	1	0	Placebo bd

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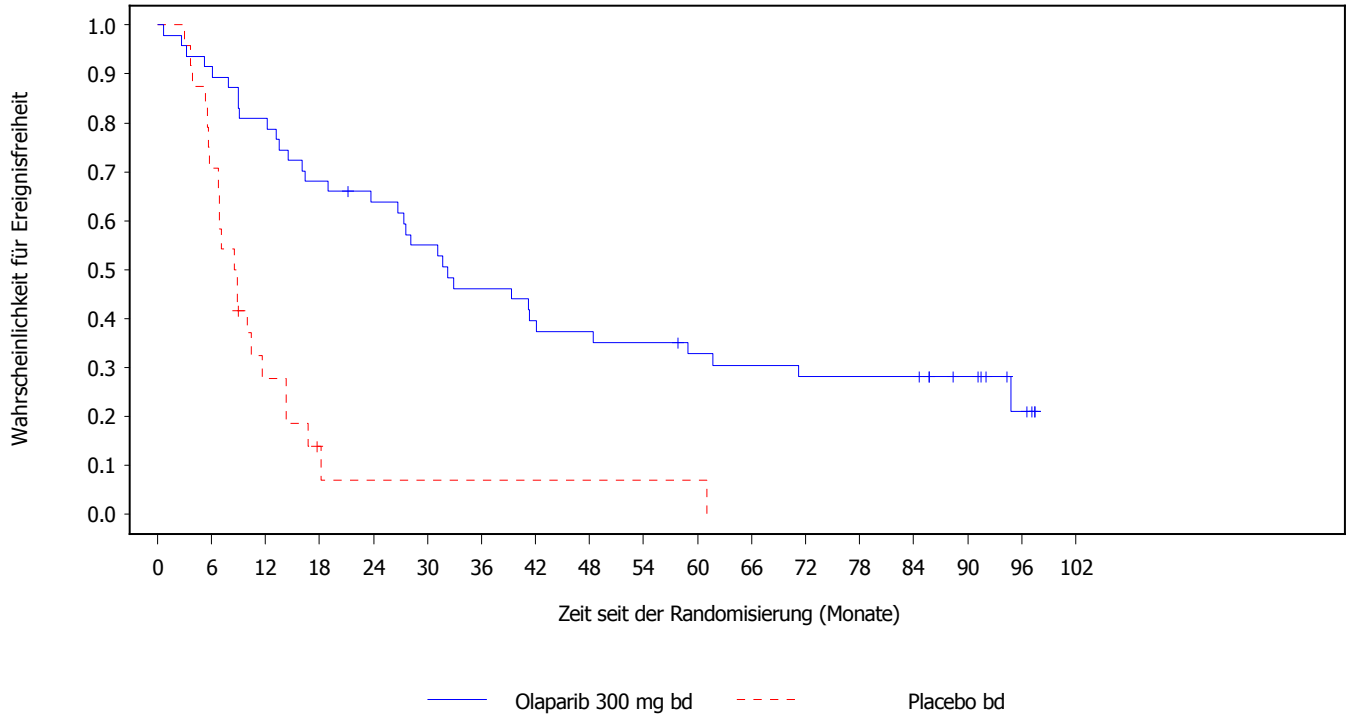
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Partielles Ansprechen
Full Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

47	43	38	32	29	25	21	18	17	16	14	13	12	12	12	8	3	0	Olaparib 300 mg bd
24	17	6	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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1.4.2: Zeit bis zur zweiten Folgetherapie

1.4.2.1: Subgruppenanalysen

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 1.4.1.5 SOLO1: Summary of subgroup analysis of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	86 (38,2)	NE [NE; NE]	112	68 (60,7)	40,7 [35,7;55,3]	0,48	[0,35; 0,66]	<0,0001*
>=65 Jahre	35	24 (68,6)	63,0 [33,4;90,2]	19	12 (63,2)	32,7 [12,6; NE]	0,89	[0,46; 1,85]	0,7512
Interaktion p-Wert									0,1001
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	84 (39,4)	93,2 [87,2; NE]	107	60 (56,1)	49,1 [37,8;74,1]	0,58	[0,41; 0,81]	0,0014*
Partielles Ansprechen	47	26 (55,3)	44,4 [29,2; NE]	24	20 (83,3)	20,9 [14,8;35,7]	0,30	[0,17; 0,55]	0,0002*
Interaktion p-Wert									0,0644
ECOG PS Status									
Normale Aktivität	200	80 (40,0)	NE [NE; NE]	105	59 (56,2)	46,5 [35,8;58,9]	0,57	[0,41; 0,80]	0,0014*
Eingeschränkte Aktivität	60	30 (50,0)	88,1 [38,2; NE]	25	21 (84,0)	26,2 [17,4;46,1]	0,36	[0,21; 0,64]	0,0007*
Interaktion p-Wert									0,1754
Baseline CA-125 Wert									
<=ULN	247	100 (40,5)	93,2 [87,2; NE]	123	73 (59,3)	43,4 [35,7;57,3]	0,53	[0,39; 0,72]	<0,0001*
>ULN	13	10 (76,9)	21,8 [14,4;63,8]	7	7 (100)	13,5 [5,3;17,4]	0,29	[0,11; 0,80]	0,0190*
Interaktion p-Wert									0,2514
FIGO Stadium									
III	220	86 (39,1)	NE [NE; NE]	105	68 (64,8)	40,7 [33,2;50,9]	0,45	[0,33; 0,63]	<0,0001*
IV	40	24 (60,0)	63,8 [32,2; NE]	26	12 (46,2)	NE [NE; NE]	1,07	[0,54; 2,21]	0,8553
Interaktion p-Wert									0,0251*
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	85 (45,2)	90,2 [54,2; NE]	91	59 (64,8)	43,4 [30,1;54,4]	0,56	[0,40; 0,78]	0,0008*
BRCA2	62	20 (32,3)	NE [NE; NE]	39	20 (51,3)	42,3 [31,4; NE]	0,44	[0,23; 0,81]	0,0096*
Interaktion p-Wert									0,4938
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.4.1.5 SOLO1: Summary of subgroup analysis of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod
Full Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	31 (56,4)	48,3 [31,7; NE]	29	22 (75,9)	32,9 [17,4;47,7]	0,55	[0,32; 0,97]	0,0397*
Keine makroskopische Resterkrankung	200	76 (38,0)	NE [NE; NE]	98	55 (56,1)	46,5 [38,5;58,8]	0,53	[0,38; 0,76]	0,0005*
Interaktion p-Wert									0,9002
Abstammung									
Weiß	214	89 (41,6)	93,2 [84,2; NE]	106	65 (61,3)	42,3 [32,9;55,3]	0,52	[0,38; 0,71]	<0,0001*
Andere	46	21 (45,7)	93,0 [36,8; NE]	25	15 (60,0)	39,5 [22,9; NE]	0,60	[0,31; 1,18]	0,1352
Interaktion p-Wert									0,6970
Region									
Europa	101	36 (35,6)	NE [NE; NE]	53	30 (56,6)	50,9 [31,6; NE]	0,50	[0,31; 0,82]	0,0061*
Asien	33	13 (39,4)	NE [NE; NE]	14	7 (50,0)	39,5 [20,2; NE]	0,57	[0,23; 1,51]	0,2406
Rest der Welt	126	61 (48,4)	85,8 [44,4;93,2]	64	43 (67,2)	39,5 [25,8;46,5]	0,53	[0,36; 0,79]	0,0022*
Interaktion p-Wert									0,9642

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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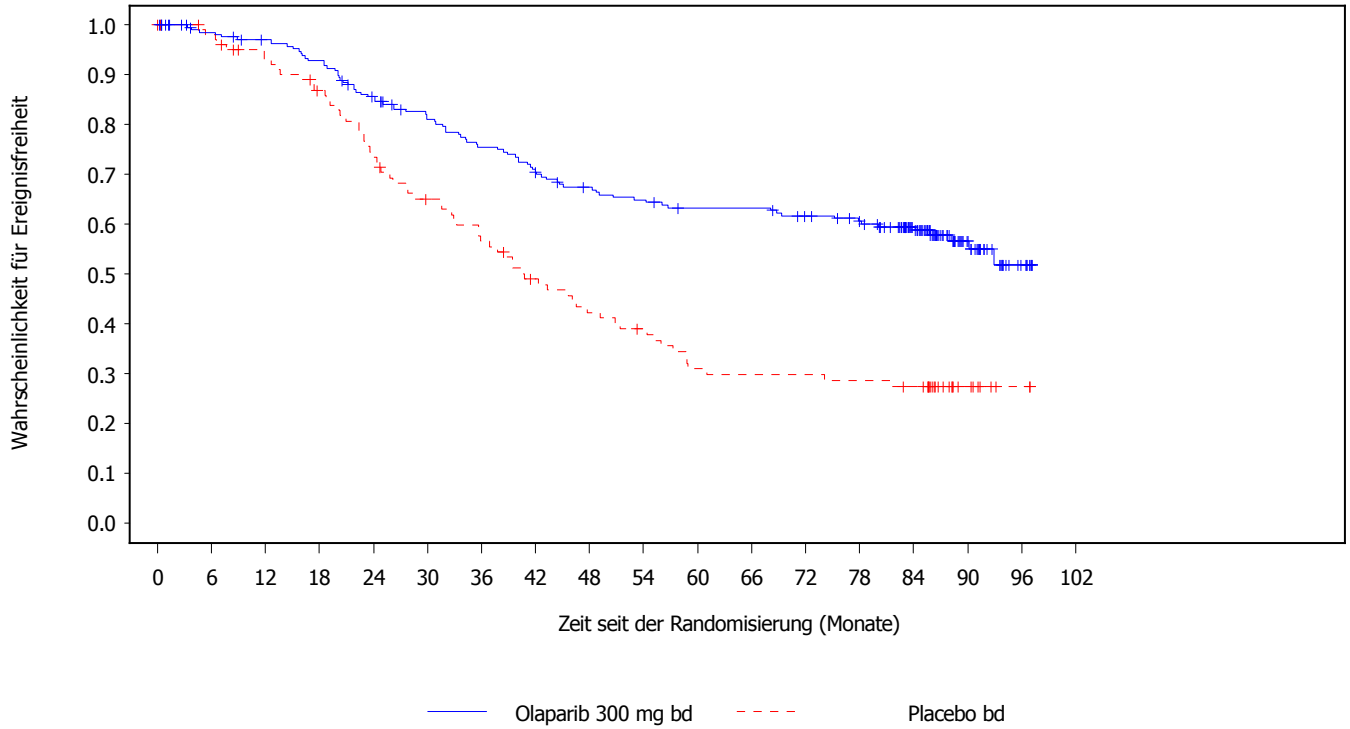
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.7 SOLO1: Kaplan-Meier plot of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod for FIGO Stadium = III
Full Analysis Set, DCO 07MAR2022



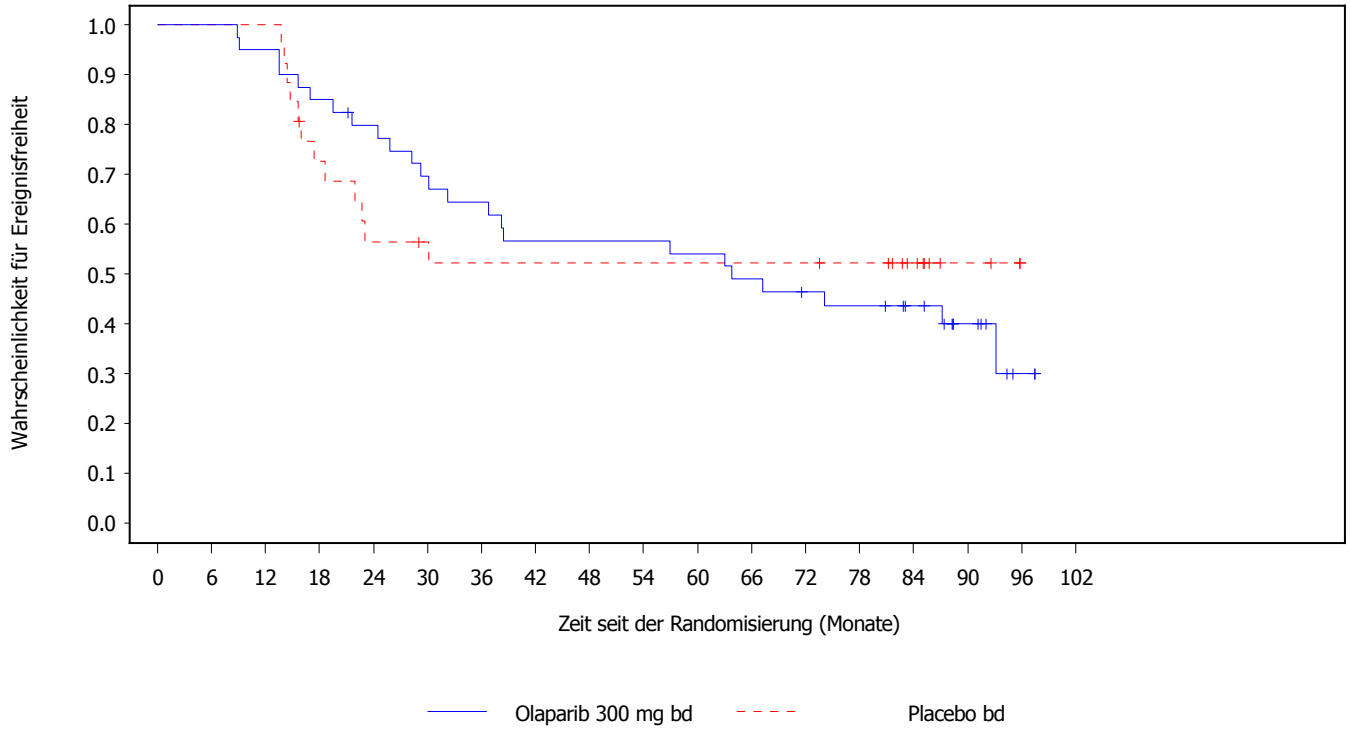
Anzahl an Patienten unter Risiko:

220	208	202	193	175	161	150	140	131	126	121	121	115	109	82	34	7	0	Olaparib 300 mg bd
105	100	92	84	71	61	53	44	38	34	27	26	26	25	23	7	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubef1.sas gttesubef1bag 05JAN2023:14:15 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.4.2.8 SOLO1: Kaplan-Meier plot of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod for FIGO Stadium = IV
Full Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

40	40	38	34	31	27	25	22	22	22	21	19	17	16	13	7	1	0	Olaparib 300 mg bd
26	26	26	18	14	13	12	12	12	12	12	12	12	11	7	2	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubef1.sas gttesubef1bah 05JAN2023:14:15 kvbv306

1.5: Patientenberichtete Morbidität: EQ-5D VAS

1.5.1: Mittelwerte im Zeitverlauf

Table 2.5.3.1 SOLO1: Summary of EQ-5D Visual analogue scale results across timepoints, by treatment group
Full Analysis Set, DCO 17MAY2018

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
EQ-5D visuelle Analogskala	Olaparib 300 mg bd (N=260)	Baseline	244	77,1	15,40	10	80,0	100
		Woche 5 (Tag 29)	233	75,0	16,11	1	80,0	100
		Woche 13 (Tag 85)	220	78,1	14,54	20	80,0	100
		Woche 25 (Tag 169)	214	80,6	13,91	20	80,0	100
		Woche 37 (Tag 253)	211	79,5	15,11	20	80,0	100
		Woche 49 (Tag 337)	200	80,1	15,01	30	80,5	100
		Woche 61 (Tag 421)	192	80,9	14,56	20	85,0	100
		Woche 73 (Tag 505)	177	80,8	14,79	20	85,0	100
		Woche 85 (Tag 589)	182	80,4	14,97	20	85,0	100
		Woche 97 (Tag 673)	168	80,2	16,24	10	85,0	100
		Woche 109 (Tag 757)	170	81,3	14,84	25	85,0	100
		Woche 121 (Tag 841)	132	81,1	15,24	35	85,0	100
		Woche 133 (Tag 925)	126	80,3	17,56	20	85,0	100
		Woche 145 (Tag 1009)	134	81,3	17,10	20	89,0	100
		Woche 157 (Tag 1093)	125	82,2	14,89	35	88,0	100
		Woche 169 (Tag 1177)	80	80,6	16,92	5	85,0	100
		Woche 193 (Tag 1345)	70	83,2	16,77	30	90,0	100
		Woche 217 (Tag 1513)	30	85,3	12,66	50	90,0	98
		Woche 241 (Tag 1681)	2	96,5	2,12	95	96,5	98
EQ-5D visuelle Analogskala	Placebo bd (N=131)	Baseline	128	80,4	13,09	35	80,0	100
		Woche 5 (Tag 29)	119	81,0	12,38	45	80,0	100
		Woche 13 (Tag 85)	117	82,4	11,87	35	85,0	100
		Woche 25 (Tag 169)	113	82,5	13,16	30	80,0	100
		Woche 37 (Tag 253)	102	82,8	12,16	45	82,0	100
		Woche 49 (Tag 337)	96	80,2	14,20	40	80,0	100
		Woche 61 (Tag 421)	84	80,3	15,46	25	85,0	100
		Woche 73 (Tag 505)	75	80,3	16,57	30	85,0	100
		Woche 85 (Tag 589)	75	79,9	16,12	30	80,0	100

Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

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Table 2.5.3.1 SOLO1: Summary of EQ-5D Visual analogue scale results across timepoints, by treatment group
Full Analysis Set, DCO 17MAY2018

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 97 (Tag 673)	65	79,7	19,13	10	80,0	100
		Woche 109 (Tag 757)	65	79,8	19,00	8	80,0	100
		Woche 121 (Tag 841)	56	82,2	13,88	45	85,0	100
		Woche 133 (Tag 925)	54	80,4	16,04	40	84,0	100
		Woche 145 (Tag 1009)	52	82,2	14,86	30	85,0	100
		Woche 157 (Tag 1093)	47	81,2	17,64	20	80,0	100
		Woche 169 (Tag 1177)	43	78,0	18,66	0	80,0	100
		Woche 193 (Tag 1345)	30	82,1	14,26	35	85,0	100
		Woche 217 (Tag 1513)	10	81,5	9,73	65	85,0	90

Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.
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1.5.2: Mittlere Veränderung zum Ausgangswert mittels MMRM

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 2.5.1.1 SOLO1: Summary of analysis of change from baseline in EQ-5D VAS
(mixed model for repeated measures)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)			Behandlungseffekt	
Zeitpunkt [c]	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Woche 5 (Tag 29)	221	77,38 (15,586)	-2,36 (0,886)	118	80,53 (13,069)	1,56 (1,214)	-3,91 [-6,876; -0,952]	0,0097*
Woche 13 (Tag 85)	210	77,05 (15,644)	0,34 (0,847)	116	80,43 (13,374)	3,10 (1,151)	-2,76 [-5,580; 0,054]	0,0545
Woche 25 (Tag 169)	205	77,05 (14,986)	2,93 (0,816)	112	80,80 (13,176)	3,10 (1,113)	-0,17 [-2,891; 2,553]	0,9031
Woche 37 (Tag 253)	202	76,51 (15,747)	2,18 (0,871)	101	80,84 (12,528)	3,43 (1,216)	-1,25 [-4,198; 1,706]	0,4072
Woche 49 (Tag 337)	191	76,77 (15,989)	2,67 (0,895)	95	80,21 (13,143)	0,34 (1,252)	2,32 [-0,711; 5,357]	0,1331
Woche 61 (Tag 421)	183	76,77 (15,119)	3,23 (0,922)	83	81,08 (13,040)	0,15 (1,332)	3,08 [-0,119; 6,275]	0,0591
Woche 73 (Tag 505)	170	77,41 (15,226)	3,01 (0,924)	75	80,80 (14,091)	-0,38 (1,354)	3,40 [0,168; 6,630]	0,0393*
Woche 85 (Tag 589)	174	77,09 (15,087)	2,70 (0,920)	75	81,00 (13,148)	-1,11 (1,363)	3,81 [0,568; 7,056]	0,0214*
Woche 97 (Tag 673)	161	76,94 (15,916)	2,96 (1,119)	64	81,95 (13,077)	-1,93 (1,711)	4,88 [0,846; 8,922]	0,0179*
Woche 109 (Tag 757)	163	76,26 (15,221)	3,06 (1,094)	65	79,98 (13,440)	-0,97 (1,668)	4,03 [0,094; 7,970]	0,0448*
Woche 121 (Tag 841)	127	76,15 (15,058)	3,52 (1,039)	56	81,23 (13,801)	0,60 (1,548)	2,92 [-0,766; 6,611]	0,1199
Woche 133 (Tag 925)	122	77,13 (15,445)	2,41 (1,226)	54	80,63 (13,643)	-0,83 (1,826)	3,25 [-1,095; 7,588]	0,1421
Woche 145 (Tag 1009)	129	76,43 (15,464)	3,38 (1,095)	52	81,23 (13,509)	1,87 (1,676)	1,52 [-2,440; 5,474]	0,4511
Woche 157 (Tag 1093)	123	77,24 (14,912)	3,24 (1,160)	47	79,98 (13,642)	-0,93 (1,806)	4,17 [-0,063; 8,409]	0,0535
Woche 169 (Tag 1177)	78	76,04 (16,323)	3,47 (1,510)	43	81,51 (13,731)	-3,40 (2,101)	6,86 [1,729; 11,996]	0,0091*

[a] = number of patients with change from baseline at each timepoint in the MMRM analysis.
[b] = mean baseline for patients with change from baseline at each timepoint in the MMRM analysis.
Calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit and treatment by visit interaction included as explanatory variables and the baseline score included as a covariate along with the baseline score by visit interaction. Only visits where change from baseline is available for at least one patient in both treatment arms are included in the analysis.
Treatment, visit and treatment by visit interaction are fixed effects in the model, a Toeplitz with heterogeneity covariance matrix is used to model within-subject error. SMD = standardised mean difference. * p<0.05. [c] Based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3).
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/mmrmpr_v2.sas gmmrmpr_v2ba 15NOV2022:10:06 kvbv306

Table 2.5.1.1 SOLO1: Summary of analysis of change from baseline in EQ-5D VAS
(mixed model for repeated measures)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)			Behandlungseffekt	
Zeitpunkt [c]	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Woche 193 (Tag 1345)	68	77,54 (15,877)	3,40 (1,373)	30	78,30 (14,232)	1,12 (2,052)	2,27 [-2,616; 7,157]	0,3598
Woche 217 (Tag 1513)	29	77,97 (15,110)	5,43 (1,613)	10	83,00 (11,595)	-3,28 (2,734)	8,71 [2,345; 15,078]	0,0082*
Hedges' g SMD							0,25 [0,032; 0,463]	0,0246*
Mittelwert über alle Visite	237	77,07 (15,461)	2,68 (0,653)	128	80,37 (13,094)	0,14 (0,934)	2,54 [0,290; 4,785]	0,0270*

[a] = number of patients with change from baseline at each timepoint in the MMRM analysis.
[b] = mean baseline for patients with change from baseline at each timepoint in the MMRM analysis.
Calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit and treatment by visit interaction included as explanatory variables and the baseline score included as a covariate along with the baseline score by visit interaction. Only visits where change from baseline is available for at least one patient in both treatment arms are included in the analysis.
Treatment, visit and treatment by visit interaction are fixed effects in the model, a Toeplitz with heterogeneity covariance matrix is used to model within-subject error. SMD = standardised mean difference. * p<0.05. [c] Based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3).
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/mmrmpr_v2.sas gmmrmpr_v2ba 15NOV2022:10:06 kvbv306

1.5.3: Sensitivitätsanalyse: Zeit bis zur dauerhaften klinisch relevanten Verschlechterung

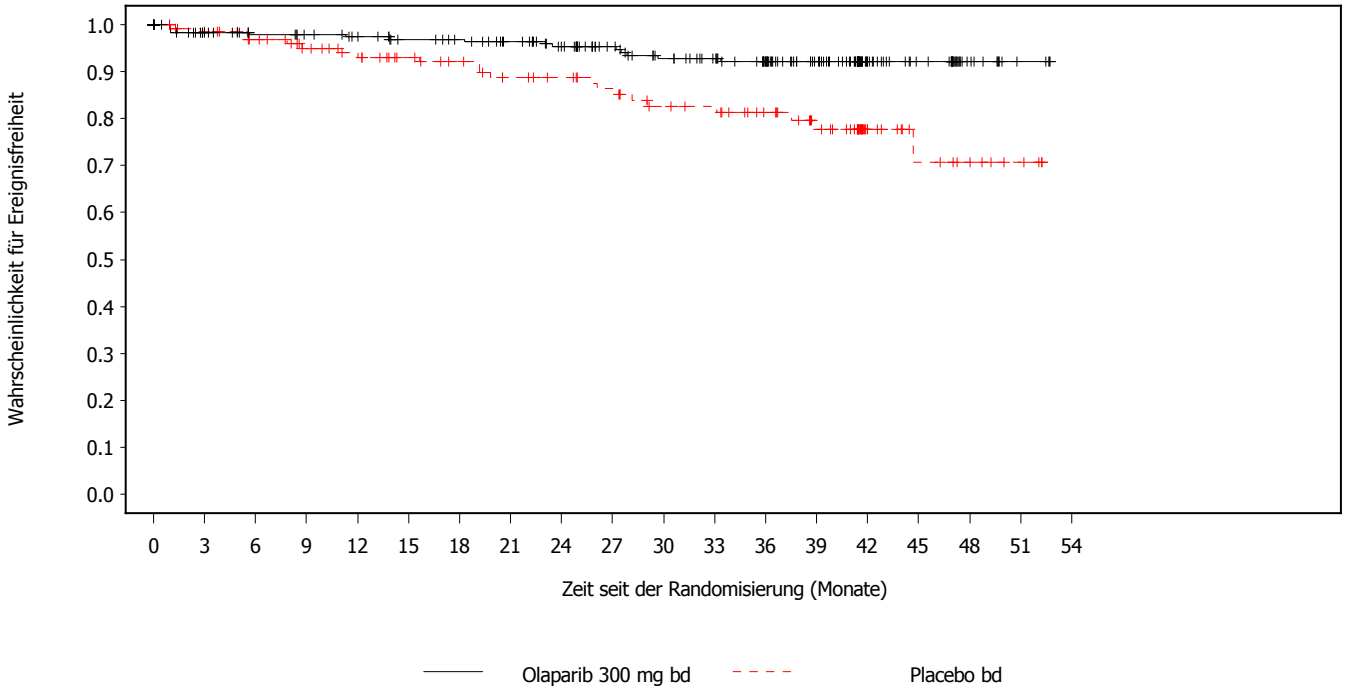
Table 2.9.3 SOLO1: Summary of analysis of Time to sustained deterioration in EQ-5D VAS
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
EQ-5D visuelle Analogskala	260	15 (5,8)	NE [NE; NE]	131	21 (16,0)	NE [NE; NE]	0,32	[0,16; 0,62]	0,0004*

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2ab 15NOV2022:14:11 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.9.4.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

260	225	215	211	206	198	194	186	174	157	145	137	120	97	51	39	13	3	0 Olaparib 300 mg bd
131	121	114	105	99	91	86	79	76	71	63	61	53	43	17	10	7	3	0 Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2caa 15NOV2022:14:11 kpzx329

1.5.4: Subgruppenanalysen

1.5.4.1: Zeit bis zur ersten bestätigten klinisch relevanten Verschlechterung

Table 2.10.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	35 (15,6)	NE [NE; NE]	112	28 (25,0)	NE [NE; NE]	0,61	[0,37; 1,02]	0,0573
>=65 Jahre	35	6 (17,1)	NE [NE; NE]	19	5 (26,3)	NE [NE; NE]	0,81	[0,24; 2,82]	0,7324
Interaktion p-Wert									0,6677
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	30 (14,1)	NE [NE; NE]	107	29 (27,1)	NE [NE; NE]	0,56	[0,33; 0,93]	0,0254*
Partielles Ansprechen	47	11 (23,4)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	1,07	[0,36; 3,86]	0,9112
Interaktion p-Wert									0,2935
ECOG PS Status									
Normale Aktivität	200	33 (16,5)	NE [NE; NE]	105	26 (24,8)	NE [NE; NE]	0,68	[0,41; 1,14]	0,1420
Eingeschränkte Aktivität	60	8 (13,3)	NE [NE; NE]	25	7 (28,0)	NE [NE; NE]	0,49	[0,18; 1,40]	0,1775
Interaktion p-Wert									0,5812
Baseline CA-125 Wert									
<=ULN	247	38 (15,4)	NE [NE; NE]	123	33 (26,8)	NE [NE; NE]	0,59	[0,37; 0,95]	0,0303*
>ULN	13	3 (23,1)	30,8 [12,0; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	34 (15,5)	NE [NE; NE]	105	25 (23,8)	NE [NE; NE]	0,69	[0,41; 1,17]	0,1626
IV	40	7 (17,5)	NE [NE; NE]	26	8 (30,8)	NE [NE; NE]	0,46	[0,16; 1,30]	0,1407
Interaktion p-Wert									0,4979
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	34 (18,1)	NE [NE; NE]	91	23 (25,3)	NE [NE; NE]	0,74	[0,44; 1,26]	0,2618
BRCA2	62	6 (9,7)	NE [NE; NE]	39	10 (25,6)	NE [NE; NE]	0,39	[0,13; 1,04]	0,0594
Interaktion p-Wert									0,2611
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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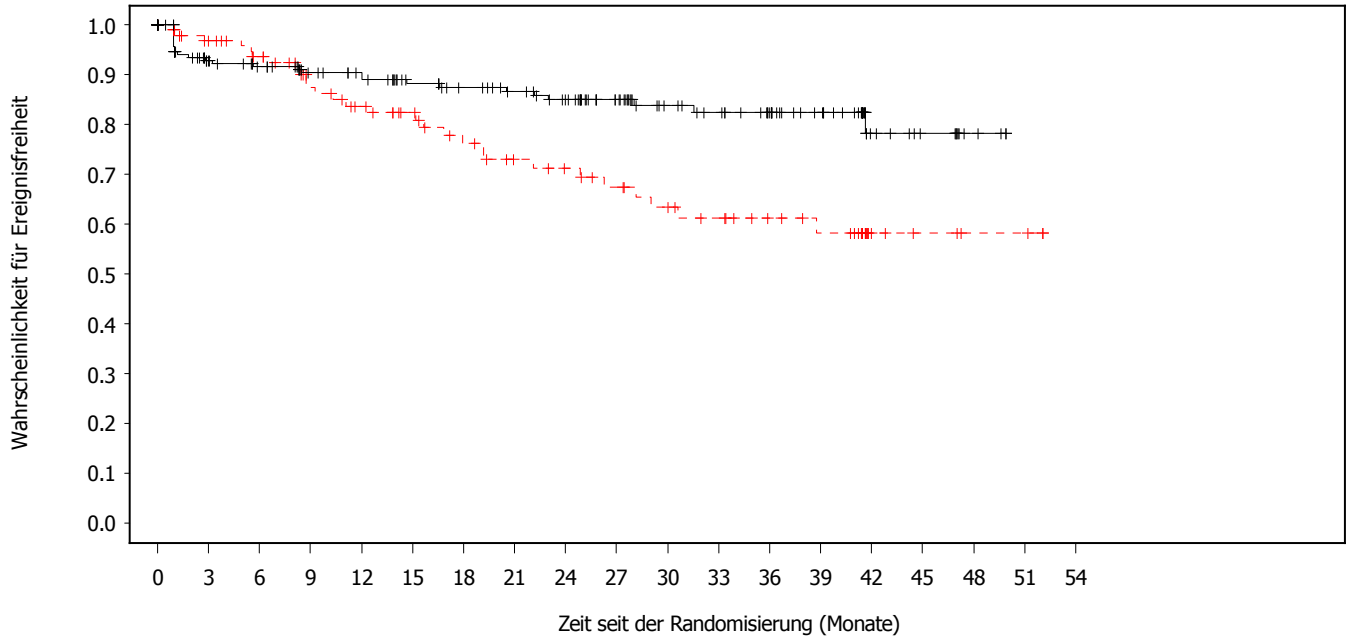
Table 2.10.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	11 (20,0)	NE [NE; NE]	29	8 (27,6)	NE [NE; NE]	0,67	[0,27; 1,74]	0,4039
Keine makroskopische Resterkrankung	200	28 (14,0)	NE [NE; NE]	98	24 (24,5)	NE [NE; NE]	0,61	[0,35; 1,06]	0,0763
Interaktion p-Wert									0,8456
Abstammung									
Weiß	214	27 (12,6)	NE [NE; NE]	106	28 (26,4)	NE [NE; NE]	0,48	[0,28; 0,82]	0,0077*
Andere	46	14 (30,4)	NE [NE; NE]	25	5 (20,0)	41,7 [41,7; NE]	1,54	[0,59; 4,76]	0,3949
Interaktion p-Wert									0,0395*
Region									
Europa	101	9 (8,9)	NE [NE; NE]	53	16 (30,2)	30,6 [18,0; NE]	0,28	[0,12; 0,62]	0,0018*
Asien	33	13 (39,4)	NE [NE; NE]	14	5 (35,7)	41,7 [8,7; NE]	1,16	[0,44; 3,60]	0,7806
Rest der Welt	126	19 (15,1)	NE [NE; NE]	64	12 (18,8)	NE [NE; NE]	0,85	[0,42; 1,80]	0,6584
Interaktion p-Wert									0,0484*

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubpraab 13JAN2023:14:29 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.10.2.3 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala for Abstammung = Weiß
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

214	160	150	136	131	118	111	105	97	81	66	61	52	42	15	10	3	0	0	Olaparib 300 mg bd
106	91	83	70	63	56	48	42	39	35	31	27	22	19	6	4	2	2	0	Placebo bd

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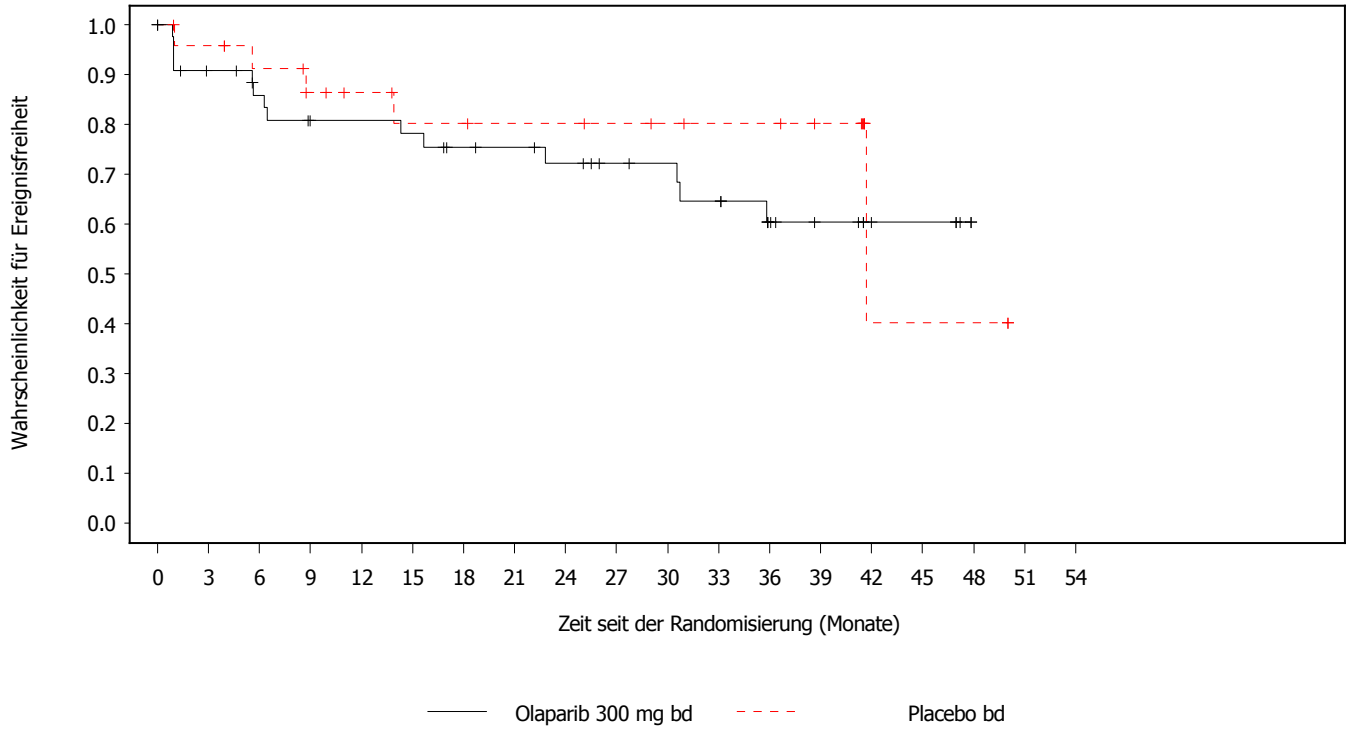
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.10.2.4 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala for Abstammung = Andere
Full Analysis Set, DCO 17MAY2018



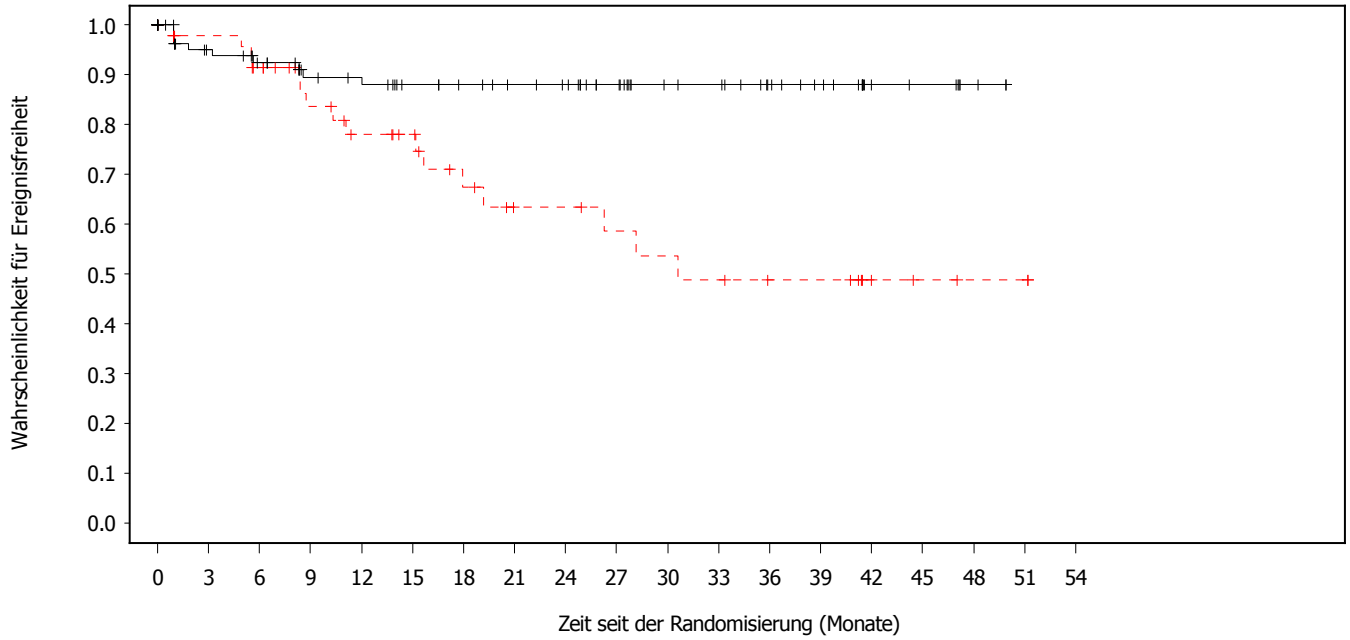
Anzahl an Patienten unter Risiko:

46	38	34	31	30	29	26	25	23	20	19	17	11	8	4	4	0	0	0	Olaparib 300 mg bd
25	23	20	17	15	13	13	12	12	11	10	9	9	7	1	1	1	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubprbad 13JAN2023:14:29 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.10.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala for Region = Europa
Full Analysis Set, DCO 17MAY2018



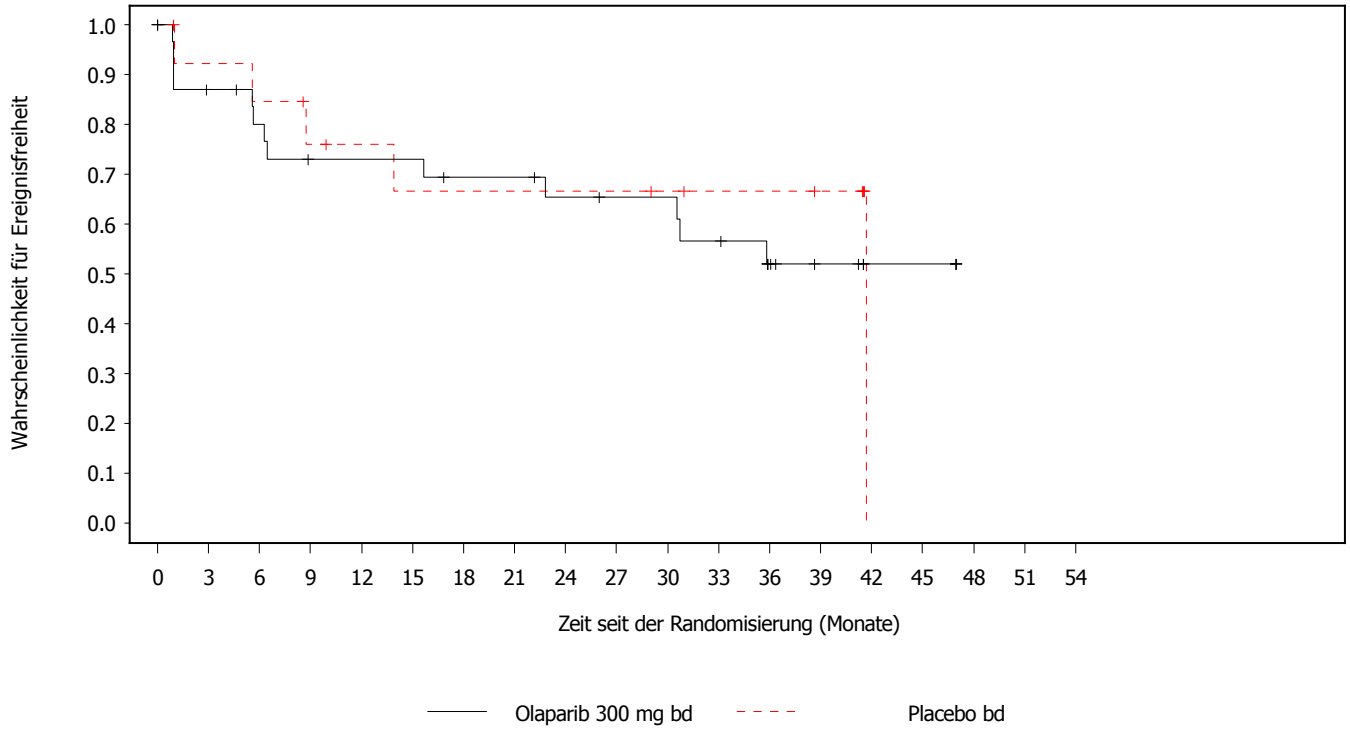
Anzahl an Patienten unter Risiko:

101	74	68	59	57	51	48	45	43	36	28	27	21	17	7	6	2	0	0	Olaparib 300 mg bd
53	45	40	32	27	24	18	14	14	12	11	10	8	8	3	2	1	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubprbae 13JAN2023:14:29 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.10.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala for Region = Asien
Full Analysis Set, DCO 17MAY2018



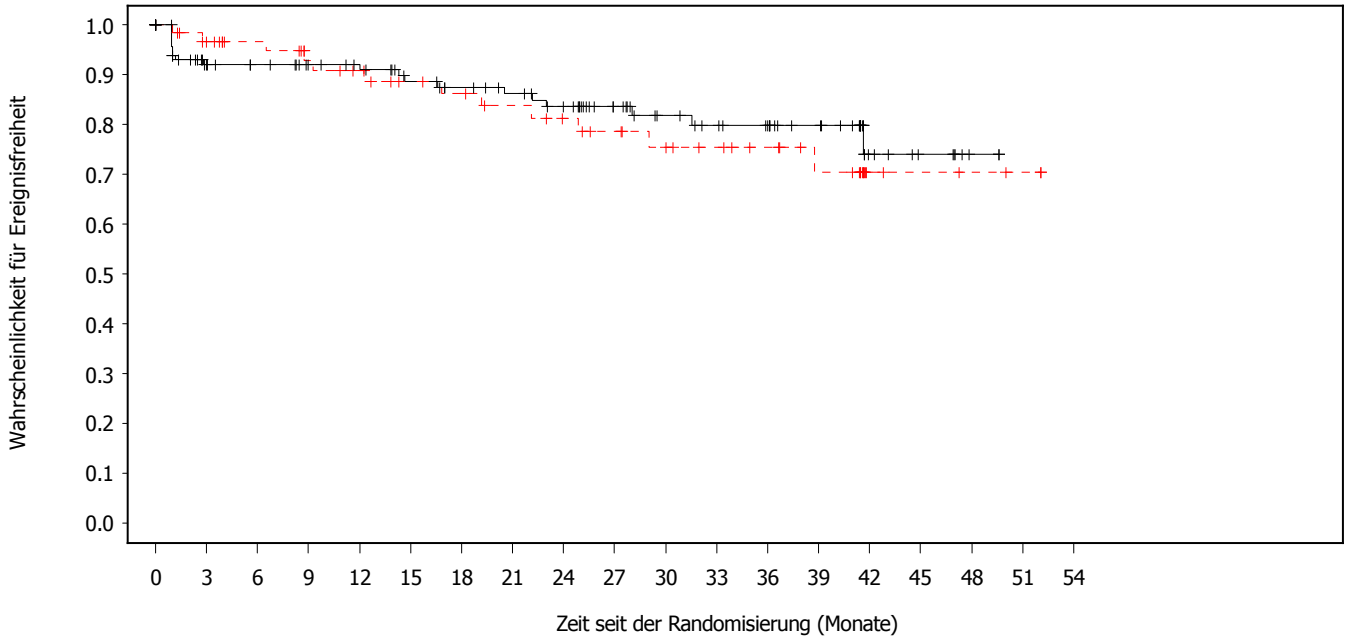
Anzahl an Patienten unter Risiko:

33	26	23	20	20	20	18	18	16	15	15	13	8	5	2	2	0	0	0	Olaparib 300 mg bd
14	12	11	9	8	7	7	7	7	7	6	5	5	4	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubprbaf 13JAN2023:14:29 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.10.2.7 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala for Region = Rest der Welt
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

126	98	93	88	84	76	71	67	61	50	42	38	34	28	10	6	1	0	0	Olaparib 300 mg bd
64	57	52	46	43	38	36	33	30	27	24	21	18	14	4	3	2	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubprbag 13JAN2023:14:29 kvbv306

1.5.4.2: Zeit bis zur dauerhaften klinisch relevanten Verschlechterung

Table 2.11.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	22 (9,8)	NE [NE; NE]	112	27 (24,1)	49,2 [44,7; NE]	0,35	[0,20; 0,62]	0,0003*
>=65 Jahre	35	6 (17,1)	NE [NE; NE]	19	5 (26,3)	NE [NE; NE]	0,66	[0,20; 2,31]	0,5038
Interaktion p-Wert									0,3392
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	19 (8,9)	NE [NE; NE]	107	26 (24,3)	NE [NE; NE]	0,35	[0,19; 0,63]	0,0005*
Partielles Ansprechen	47	9 (19,1)	52,5 [NE; NE]	24	6 (25,0)	49,2 [19,2; NE]	0,46	[0,16; 1,38]	0,1574
Interaktion p-Wert									0,6600
ECOG PS Status									
Normale Aktivität	200	21 (10,5)	NE [NE; NE]	105	24 (22,9)	49,2 [44,7; NE]	0,41	[0,22; 0,74]	0,0034*
Eingeschränkte Aktivität	60	7 (11,7)	NE [NE; NE]	25	8 (32,0)	NE [NE; NE]	0,31	[0,11; 0,87]	0,0272*
Interaktion p-Wert									0,6521
Baseline CA-125 Wert									
<=ULN	247	26 (10,5)	NE [NE; NE]	123	31 (25,2)	49,2 [44,7; NE]	0,37	[0,22; 0,63]	0,0003*
>ULN	13	2 (15,4)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,81	[0,08; 17,45]	0,8651
Interaktion p-Wert									0,5267
FIGO Stadium									
III	220	22 (10,0)	NE [NE; NE]	105	22 (21,0)	NE [NE; NE]	0,42	[0,23; 0,77]	0,0054*
IV	40	6 (15,0)	NE [NE; NE]	26	10 (38,5)	39,8 [26,1; NE]	0,34	[0,12; 0,91]	0,0325*
Interaktion p-Wert									0,7092
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	23 (12,2)	NE [NE; NE]	91	21 (23,1)	NE [NE; NE]	0,48	[0,26; 0,87]	0,0166*
BRCA2	62	4 (6,5)	NE [NE; NE]	39	11 (28,2)	49,2 [37,5; NE]	0,21	[0,06; 0,61]	0,0037*
Interaktion p-Wert									0,1950
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr_sw.sas gttesubpr_swaab 13JAN2023:14:29 kvbv306

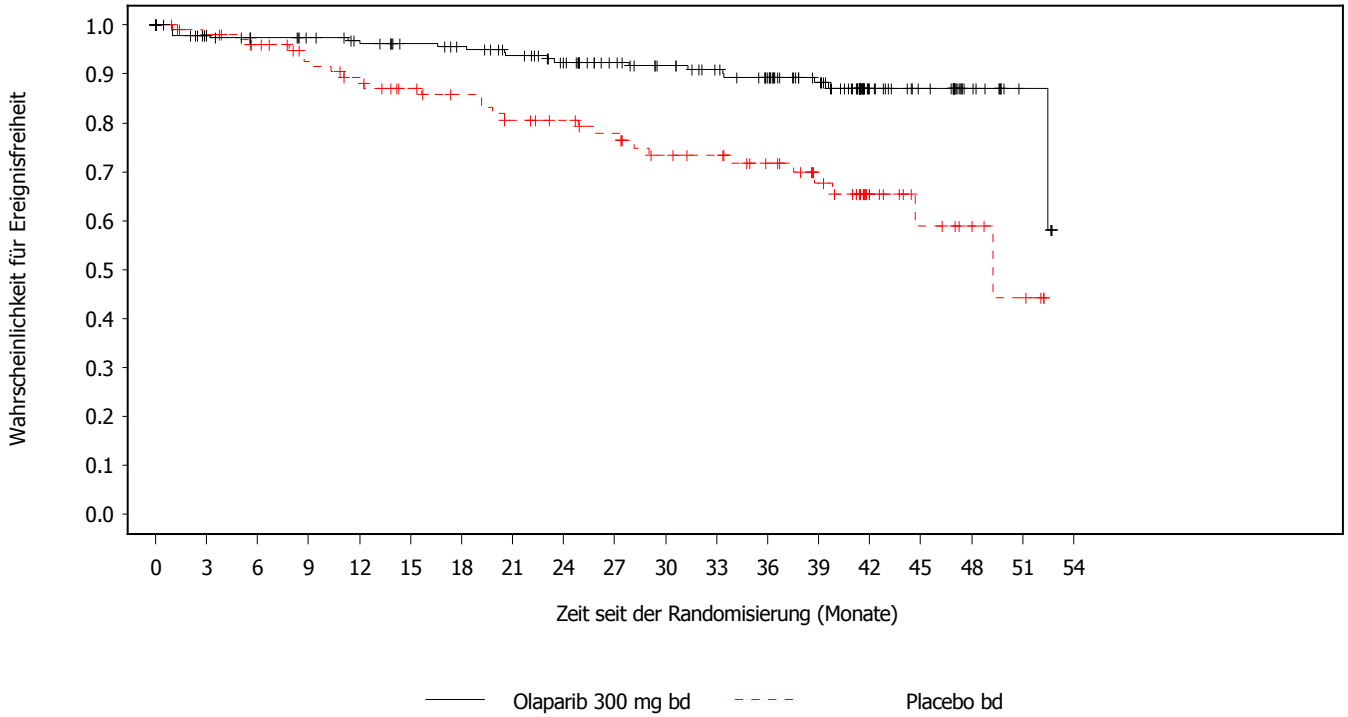
Table 2.11.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	10 (18,2)	52,5 [NE; NE]	29	8 (27,6)	NE [NE; NE]	0,46	[0,18; 1,22]	0,1155
Keine makroskopische Resterkrankung	200	17 (8,5)	NE [NE; NE]	98	22 (22,4)	NE [NE; NE]	0,36	[0,19; 0,68]	0,0016*
Interaktion p-Wert									0,6666
Abstammung									
Weiß	214	20 (9,3)	NE [NE; NE]	106	28 (26,4)	49,2 [44,7; NE]	0,30	[0,16; 0,53]	<0,0001*
Andere	46	8 (17,4)	NE [NE; NE]	25	4 (16,0)	NE [NE; NE]	1,10	[0,35; 4,14]	0,8722
Interaktion p-Wert									0,0488*
Region									
Europa	101	10 (9,9)	NE [NE; NE]	53	17 (32,1)	44,7 [37,5; NE]	0,24	[0,10; 0,52]	0,0003*
Asien	33	7 (21,2)	47,2 [NE; NE]	14	2 (14,3)	NE [NE; NE]	1,39	[0,34; 9,33]	0,6732
Rest der Welt	126	11 (8,7)	NE [NE; NE]	64	13 (20,3)	NE [NE; NE]	0,42	[0,18; 0,93]	0,0333*
Interaktion p-Wert									0,1012

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr_sw.sas gttesubpr_swaab 13JAN2023:14:29 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.11.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala for Abstammung = Weiß
Full Analysis Set, DCO 17MAY2018



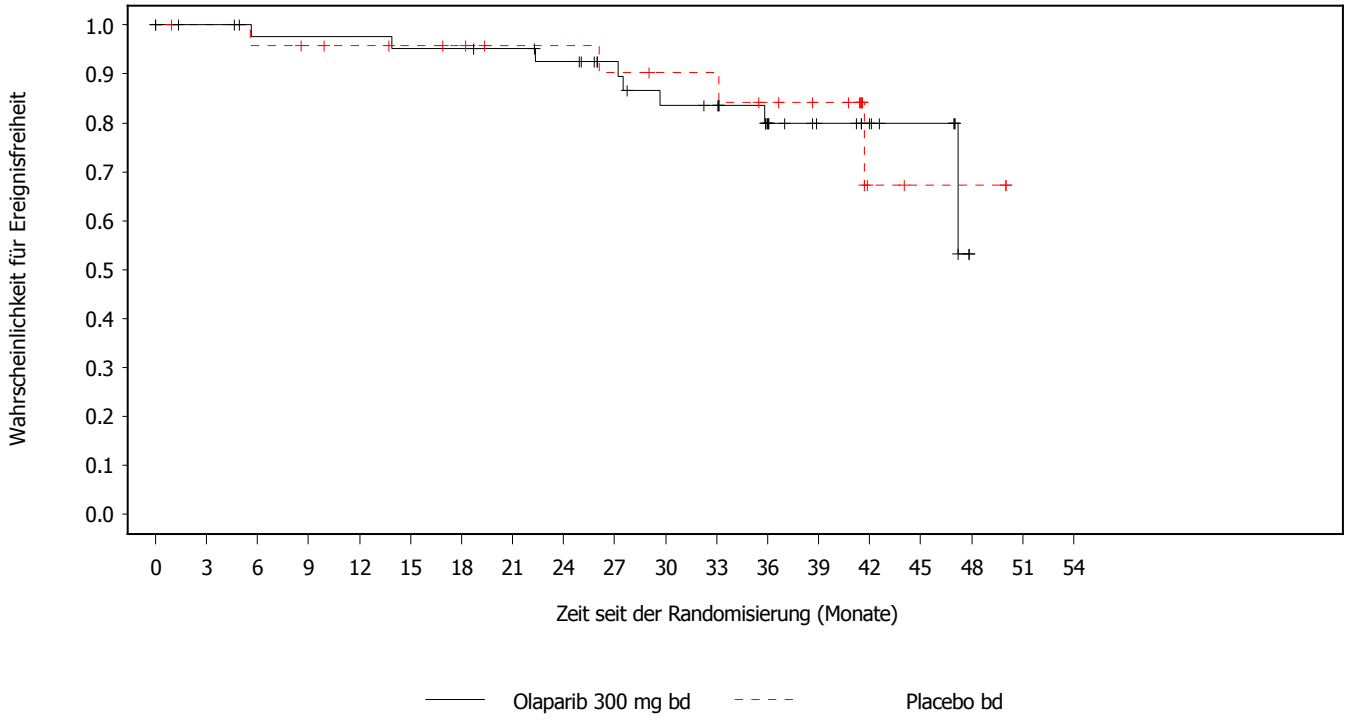
Anzahl an Patienten unter Risiko:

214	182	175	171	166	159	155	148	138	126	118	111	102	85	43	33	13	3	0	Olaparib 300 mg bd
106	97	91	83	78	71	67	62	59	55	48	46	40	32	15	9	6	3	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr_sw.sas gttesubpr_swbaa 13JAN2023:14:29 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.11.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala for Abstammung = Andere
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

46	43	40	40	40	39	39	38	36	31	27	26	18	12	8	6	0	0	0	Olaparib 300 mg bd
25	24	23	22	21	20	19	17	17	16	15	15	13	11	2	1	1	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr_sw.sas gttesubpr_swbab 13JAN2023:14:29 kvbv306

1.5.4.3: Sensitivitätsanalyse: Zeit bis zur dauerhaften klinisch relevanten Verschlechterung

Table 2.12.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	10 (4,4)	NE [NE; NE]	112	17 (15,2)	NE [NE; NE]	0,27	[0,12; 0,58]	0,0007*
>=65 Jahre	35	5 (14,3)	NE [NE; NE]	19	4 (21,1)	NE [NE; NE]	0,69	[0,18; 2,77]	0,5777
Interaktion p-Wert									0,2266
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	10 (4,7)	NE [NE; NE]	107	17 (15,9)	NE [NE; NE]	0,29	[0,13; 0,63]	0,0016*
Partielles Ansprechen	47	5 (10,6)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	0,42	[0,11; 1,70]	0,2104
Interaktion p-Wert									0,6419
ECOG PS Status									
Normale Aktivität	200	12 (6,0)	NE [NE; NE]	105	16 (15,2)	NE [NE; NE]	0,37	[0,17; 0,78]	0,0094*
Eingeschränkte Aktivität	60	3 (5,0)	NE [NE; NE]	25	5 (20,0)	NE [NE; NE]	0,22	[0,04; 0,89]	0,0346*
Interaktion p-Wert									0,5165
Baseline CA-125 Wert									
<=ULN	247	14 (5,7)	NE [NE; NE]	123	20 (16,3)	NE [NE; NE]	0,33	[0,16; 0,64]	0,0013*
>ULN	13	1 (7,7)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,41	[0,02; 10,36]	0,5341
Interaktion p-Wert									0,8802
FIGO Stadium									
III	220	10 (4,5)	NE [NE; NE]	105	14 (13,3)	NE [NE; NE]	0,32	[0,14; 0,71]	0,0054*
IV	40	5 (12,5)	NE [NE; NE]	26	7 (26,9)	NE [NE; NE]	0,42	[0,12; 1,31]	0,1346
Interaktion p-Wert									0,6982
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	12 (6,4)	NE [NE; NE]	91	14 (15,4)	NE [NE; NE]	0,39	[0,18; 0,85]	0,0181*
BRCA2	62	3 (4,8)	NE [NE; NE]	39	7 (17,9)	NE [NE; NE]	0,25	[0,05; 0,90]	0,0331*
Interaktion p-Wert									0,5627

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr_sw2.sas gttesubpr_sw2aab 13JAN2023:14:31 kvbv306

Table 2.12.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	5 (9,1)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	0,53	[0,14; 2,16]	0,3575
Keine makroskopische Resterkrankung	200	9 (4,5)	NE [NE; NE]	98	16 (16,3)	NE [NE; NE]	0,27	[0,11; 0,59]	0,0012*
Interaktion p-Wert									0,3829
Abstammung									
Weiß	214	10 (4,7)	NE [NE; NE]	106	18 (17,0)	NE [NE; NE]	0,25	[0,11; 0,53]	0,0003*
Andere	46	5 (10,9)	NE [NE; NE]	25	3 (12,0)	NE [NE; NE]	0,89	[0,22; 4,35]	0,8746
Interaktion p-Wert									0,1192
Region									
Europa	101	5 (5,0)	NE [NE; NE]	53	10 (18,9)	NE [NE; NE]	0,24	[0,07; 0,67]	0,0065*
Asien	33	4 (12,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	1,55	[0,23; 30,34]	0,6825
Rest der Welt	126	6 (4,8)	NE [NE; NE]	64	10 (15,6)	NE [NE; NE]	0,29	[0,10; 0,78]	0,0141*
Interaktion p-Wert									0,2373

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr_sw2.sas gttesubpr_sw2aab 13JAN2023:14:31 kvbv306

1.6: Patientenberichtete gesundheitsbezogene Lebensqualität: FACT-O

1.6.1: Mittelwerte im Zeitverlauf

Table 2.4.3.1 SOLO1: Summary of FACT-O Total score results across timepoints, by treatment group
Full Analysis Set, DCO 17MAY2018

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
FACT-O Gesamtscore	Olaparib 300 mg bd (N=260)	Baseline	246	113,46	18,229	59,0	115,83	152,0
		Woche 5 (Tag 29)	230	109,95	18,982	58,7	111,03	148,0
		Woche 13 (Tag 85)	219	111,87	20,049	58,0	114,50	148,0
		Woche 25 (Tag 169)	209	113,30	19,553	55,0	114,00	152,0
		Woche 37 (Tag 253)	206	113,56	20,107	51,8	115,00	149,0
		Woche 49 (Tag 337)	200	114,85	20,895	58,2	116,67	147,0
		Woche 61 (Tag 421)	189	114,71	19,964	57,3	115,40	148,0
		Woche 73 (Tag 505)	172	114,88	19,719	64,4	117,25	148,0
		Woche 85 (Tag 589)	176	114,87	21,113	53,5	118,10	149,0
		Woche 97 (Tag 673)	168	114,47	21,263	44,0	117,00	148,0
		Woche 109 (Tag 757)	168	116,20	20,021	46,0	119,00	149,9
		Woche 121 (Tag 841)	134	117,30	20,114	35,7	120,50	148,0
		Woche 133 (Tag 925)	122	116,53	21,017	55,7	121,00	149,0
		Woche 145 (Tag 1009)	129	116,68	20,316	56,3	121,00	146,9
		Woche 157 (Tag 1093)	120	117,97	18,411	72,0	120,10	149,0
		Woche 169 (Tag 1177)	77	116,19	18,679	56,0	119,43	145,0
		Woche 193 (Tag 1345)	71	118,91	19,419	70,8	123,00	146,0
		Woche 217 (Tag 1513)	28	115,32	18,550	66,5	118,50	145,7
		Woche 241 (Tag 1681)	2	139,17	1,886	137,8	139,17	140,5
FACT-O Gesamtscore	Placebo bd (N=131)	Baseline	125	115,83	18,574	68,0	119,00	151,0
		Woche 5 (Tag 29)	118	118,09	15,737	72,5	119,50	152,0
		Woche 13 (Tag 85)	116	119,76	17,233	75,0	121,08	152,0
		Woche 25 (Tag 169)	111	119,10	19,011	63,0	120,00	152,0
		Woche 37 (Tag 253)	97	119,75	18,001	80,0	120,00	152,0
		Woche 49 (Tag 337)	90	117,63	18,600	77,0	121,00	152,0
		Woche 61 (Tag 421)	80	116,58	20,733	67,0	118,00	152,0
		Woche 73 (Tag 505)	74	117,72	20,502	63,8	119,00	152,0
		Woche 85 (Tag 589)	74	118,08	18,575	64,5	116,89	151,0

Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

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Table 2.4.3.1 SOLO1: Summary of FACT-O Total score results across timepoints, by treatment group
Full Analysis Set, DCO 17MAY2018

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 97 (Tag 673)	65	117,82	20,096	63,3	118,00	152,0
		Woche 109 (Tag 757)	64	117,56	20,843	58,8	118,20	152,0
		Woche 121 (Tag 841)	55	117,08	20,229	73,8	119,00	152,0
		Woche 133 (Tag 925)	54	117,09	18,256	66,5	118,00	152,0
		Woche 145 (Tag 1009)	50	116,56	22,135	45,7	119,50	148,0
		Woche 157 (Tag 1093)	46	117,91	18,409	79,2	117,50	152,0
		Woche 169 (Tag 1177)	43	113,91	24,111	47,3	117,00	152,0
		Woche 193 (Tag 1345)	31	114,15	18,534	72,7	118,00	146,0
		Woche 217 (Tag 1513)	9	127,15	9,538	112,0	129,00	142,7

Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/smeanpr.sas gsmeanpra 14FEB2023:12:23 kvbv306

1.6.2: Mittlere Veränderung zum Ausgangswert mittels MMRM

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 2.4.1.1 SOLO1: Summary of analysis of change from baseline in FACT-O Gesamtscore (mixed model for repeated measures)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)			Behandlungseffekt	
Zeitpunkt [c]	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Woche 5 (Tag 29)	219	113,55 (18,050)	-3,49 (0,815)	115	116,43 (18,074)	2,09 (1,124)	-5,59 [-8,320; -2,851]	<0,0001*
Woche 13 (Tag 85)	207	113,52 (18,027)	-2,14 (0,992)	114	116,78 (18,390)	3,59 (1,356)	-5,73 [-9,045; -2,424]	0,0007*
Woche 25 (Tag 169)	201	114,07 (17,689)	-0,11 (0,988)	108	117,72 (17,399)	2,94 (1,361)	-3,05 [-6,364; 0,262]	0,0710
Woche 37 (Tag 253)	199	112,99 (17,158)	0,31 (1,024)	94	117,74 (16,394)	2,96 (1,453)	-2,65 [-6,158; 0,852]	0,1375
Woche 49 (Tag 337)	195	113,23 (17,656)	0,72 (0,974)	88	117,74 (17,555)	1,11 (1,402)	-0,40 [-3,760; 2,968]	0,8171
Woche 61 (Tag 421)	184	113,33 (17,874)	1,20 (0,999)	78	118,33 (17,610)	-1,03 (1,469)	2,23 [-1,271; 5,734]	0,2110
Woche 73 (Tag 505)	168	113,75 (17,633)	0,56 (1,032)	74	116,86 (17,972)	0,56 (1,514)	0,01 [-3,604; 3,616]	0,9973
Woche 85 (Tag 589)	171	113,61 (17,885)	0,71 (0,992)	74	117,60 (16,937)	0,16 (1,471)	0,54 [-2,954; 4,040]	0,7602
Woche 97 (Tag 673)	163	113,53 (17,852)	1,02 (1,080)	64	119,88 (17,265)	-1,47 (1,657)	2,48 [-1,417; 6,386]	0,2111
Woche 109 (Tag 757)	163	113,34 (17,225)	1,74 (1,083)	64	115,17 (18,635)	0,74 (1,659)	1,00 [-2,903; 4,901]	0,6149
Woche 121 (Tag 841)	130	113,99 (17,220)	2,64 (1,159)	55	117,04 (18,718)	-1,78 (1,755)	4,41 [0,268; 8,558]	0,0370*
Woche 133 (Tag 925)	118	114,61 (16,253)	0,30 (1,242)	53	116,96 (18,665)	-1,87 (1,852)	2,17 [-2,221; 6,565]	0,3313
Woche 145 (Tag 1009)	126	114,02 (16,529)	0,86 (1,243)	50	115,06 (19,422)	-1,75 (1,913)	2,62 [-1,874; 7,111]	0,2522
Woche 157 (Tag 1093)	118	114,75 (16,032)	0,66 (1,184)	46	118,27 (15,392)	-2,88 (1,842)	3,54 [-0,774; 7,853]	0,1074
Woche 169 (Tag 1177)	75	114,12 (16,087)	1,20 (1,618)	43	115,35 (18,946)	-4,23 (2,246)	5,42 [-0,043; 10,889]	0,0518

[a] = number of patients with change from baseline at each timepoint in the MMRM analysis.
[b] = mean baseline for patients with change from baseline at each timepoint in the MMRM analysis.
Calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit and treatment by visit interaction included as explanatory variables and the baseline score included as a covariate along with the baseline score by visit interaction. Only visits where change from baseline is available for at least one patient in both treatment arms are included in the analysis.
Treatment, visit and treatment by visit interaction are fixed effects in the model, a Toeplitz with heterogeneity covariance matrix is used to model within-subject error. SMD = standardised mean difference. * p<0.05. [c] Based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3).
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Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 2 von 2

Table 2.4.1.1 SOLO1: Summary of analysis of change from baseline in FACT-O Gesamtscore (mixed model for repeated measures)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)			Behandlungseffekt	
Zeitpunkt [c]	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Woche 193 (Tag 1345)	70	116,54 (15,950)	1,26 (1,492)	31	114,38 (16,377)	-3,34 (2,224)	4,60 [-0,690; 9,897]	0,0878
Woche 217 (Tag 1513)	27	113,23 (14,373)	-0,28 (2,272)	9	120,36 (11,737)	1,92 (3,903)	-2,20 [-11,336; 6,929]	0,6303
Hedges' g SMD							0,05 [-0,169; 0,264]	0,6668
Mittelwert über alle Visite	238	113,42 (18,175)	0,42 (0,739)	125	115,83 (18,574)	-0,13 (1,074)	0,55 [-2,014; 3,121]	0,6719

[a] = number of patients with change from baseline at each timepoint in the MMRM analysis.
[b] = mean baseline for patients with change from baseline at each timepoint in the MMRM analysis.
Calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit and treatment by visit interaction included as explanatory variables and the baseline score included as a covariate along with the baseline score by visit interaction. Only visits where change from baseline is available for at least one patient in both treatment arms are included in the analysis.
Treatment, visit and treatment by visit interaction are fixed effects in the model, a Toeplitz with heterogeneity covariance matrix is used to model within-subject error. SMD = standardised mean difference. * p<0.05. [c] Based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3).
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1.6.3: Sensitivitätsanalyse: Zeit bis zur dauerhaften klinisch relevanten Verschlechterung

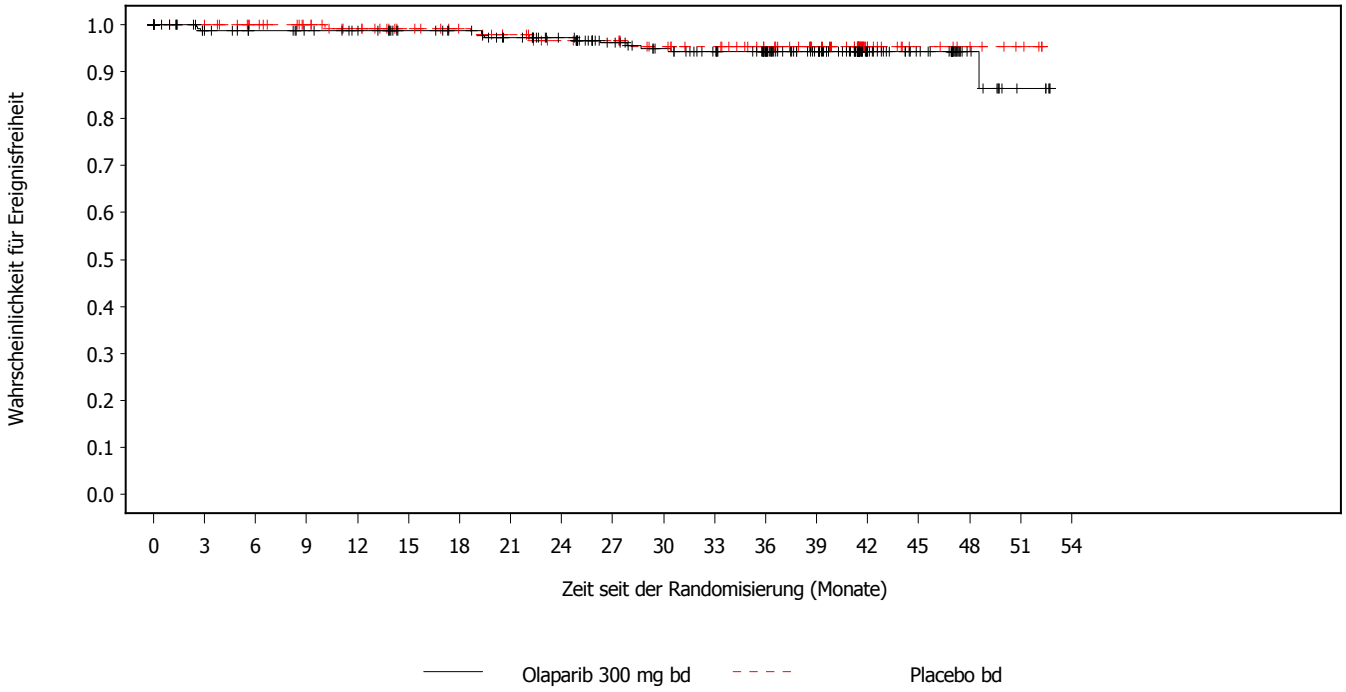
Table 2.9.1 SOLO1: Summary of analysis of Time to sustained deterioration in FACT-O
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
FACT-O Gesamtscore	260	12 (4,6)	NE [NE; NE]	131	4 (3,1)	NE [NE; NE]	1,33	[0,46; 4,78]	0,5539
FACT-O Subskala physisches Wohlbefinden (PWB)	260	18 (6,9)	NE [NE; NE]	131	9 (6,9)	NE [NE; NE]	0,88	[0,40; 2,05]	0,8082
FACT-O Subskala soziales Wohlbefinden (SWB)	260	33 (12,7)	NE [NE; NE]	131	17 (13,0)	NE [NE; NE]	0,93	[0,52; 1,71]	0,8240
FACT-O Subskala funktionales Wohlbefinden (FWB)	260	24 (9,2)	NE [NE; NE]	131	11 (8,4)	NE [NE; NE]	1,01	[0,50; 2,14]	0,9198
FACT-O Subskala emotionales Wohlbefinden (EWB)	260	19 (7,3)	NE [NE; NE]	131	10 (7,6)	NE [NE; NE]	0,90	[0,43; 2,02]	0,8032
FACT-O Eierstockkrebs-spezifische Subskala (OCS)	260	12 (4,6)	NE [NE; NE]	131	6 (4,6)	NE [NE; NE]	0,92	[0,36; 2,67]	0,9470

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2aa 15NOV2022:14:11 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.9.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Full Analysis Set, DCO 17MAY2018



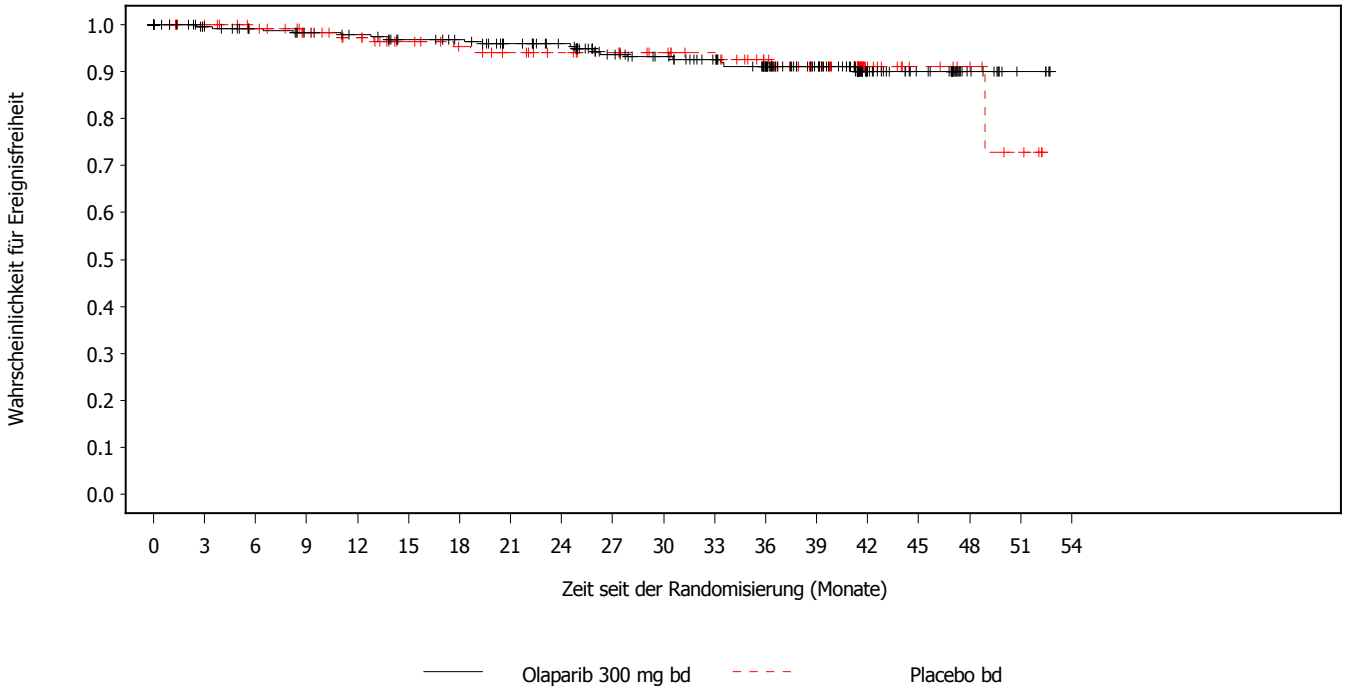
Anzahl an Patienten unter Risiko:

260	227	221	217	213	204	200	191	181	162	152	143	125	101	54	41	13	4	0	Olaparib 300 mg bd
131	120	114	107	100	92	87	82	76	74	68	64	55	46	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2baa 15NOV2022:14:11 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.9.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala physisches Wohlbefinden (PWB)
Full Analysis Set, DCO 17MAY2018



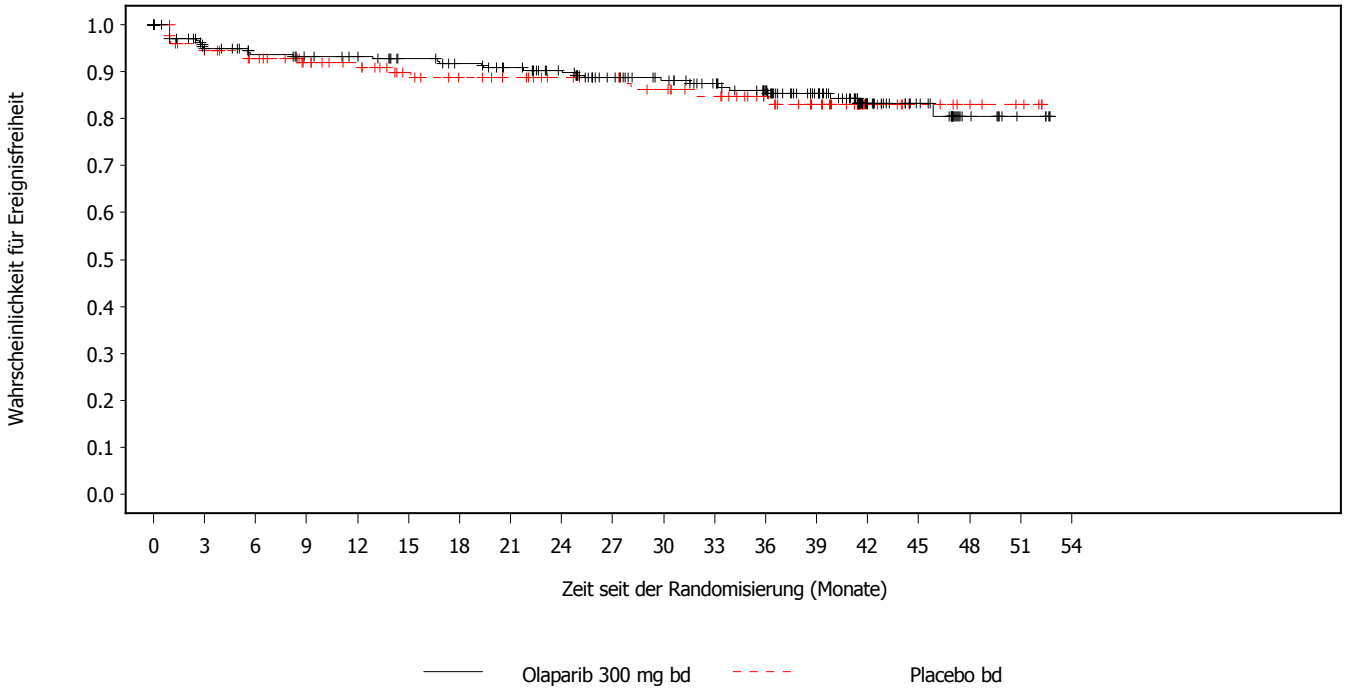
Anzahl an Patienten unter Risiko:

260	231	223	217	213	205	201	191	183	161	153	143	125	101	53	40	13	4	0	Olaparib 300 mg bd
131	122	115	107	100	91	86	81	77	74	69	65	56	45	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2bab 15NOV2022:14:11 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.9.2.3 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala soziales Wohlbefinden (SWB)
Full Analysis Set, DCO 17MAY2018



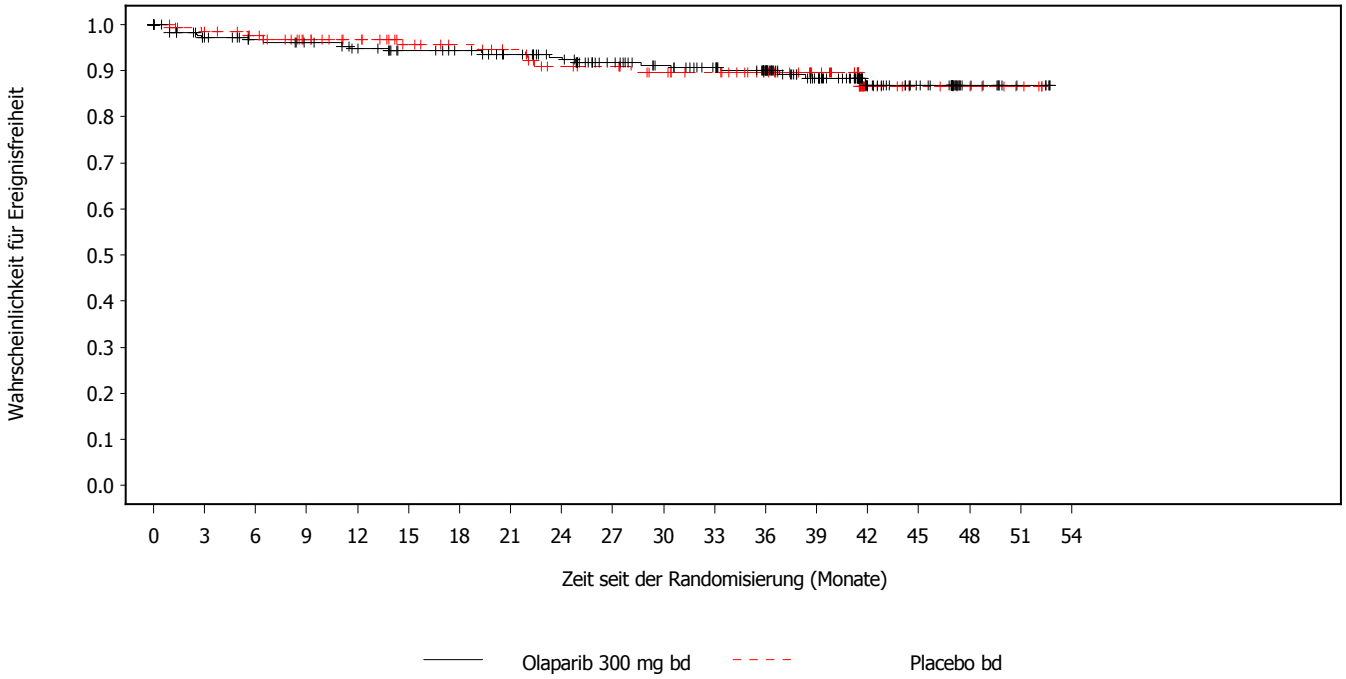
Anzahl an Patienten unter Risiko:

260	220	210	205	202	194	188	181	171	152	143	133	117	95	47	35	11	4	0	Olaparib 300 mg bd
131	115	109	100	94	85	80	77	72	70	64	59	50	42	16	9	6	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2bac 15NOV2022:14:11 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.9.2.4 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala funktionales Wohlbefinden (FWB)
Full Analysis Set, DCO 17MAY2018



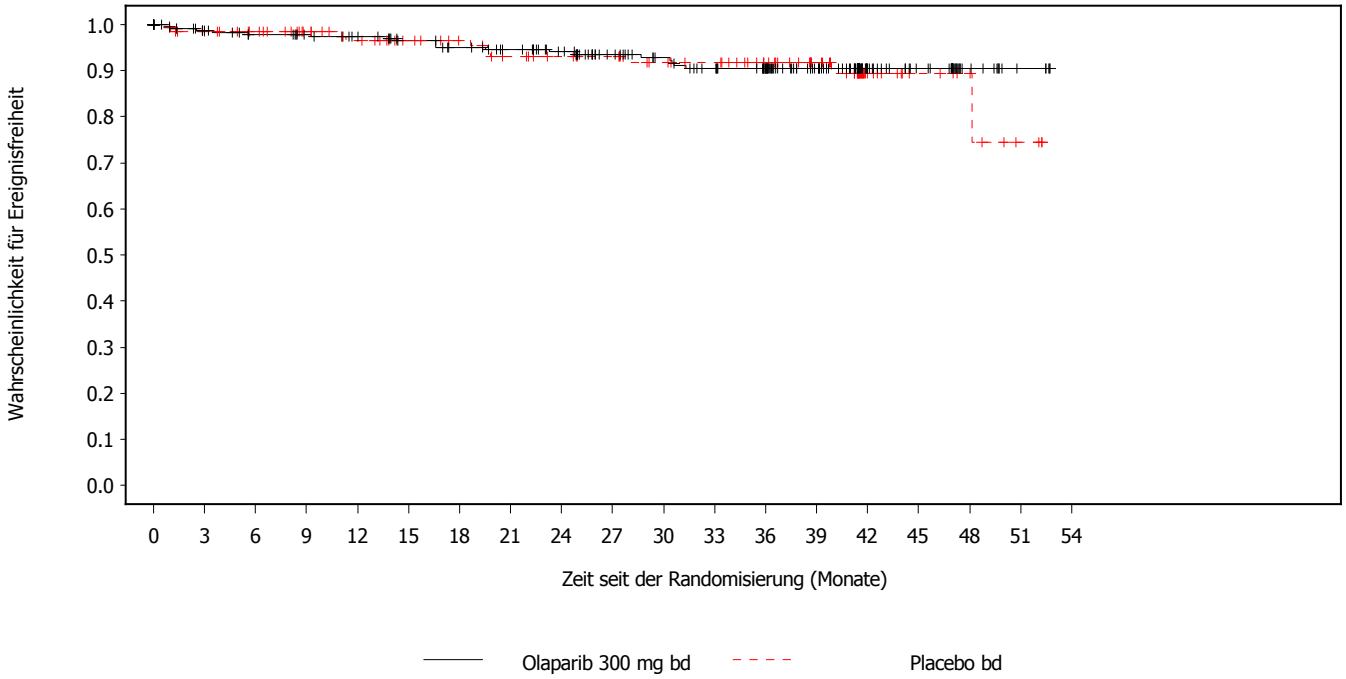
Anzahl an Patienten unter Risiko:

260	226	218	214	207	198	194	186	178	159	149	140	123	96	51	39	12	4	0	Olaparib 300 mg bd
131	120	115	105	99	90	86	81	73	71	65	61	52	42	16	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2bad 15NOV2022:14:11 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.9.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala emotionales Wohlbefinden (EWB)
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

260	230	222	217	212	202	195	188	178	159	149	140	124	97	51	39	13	4	0	Olaparib 300 mg bd
131	120	115	106	98	90	85	79	75	72	66	63	54	44	17	10	7	2	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
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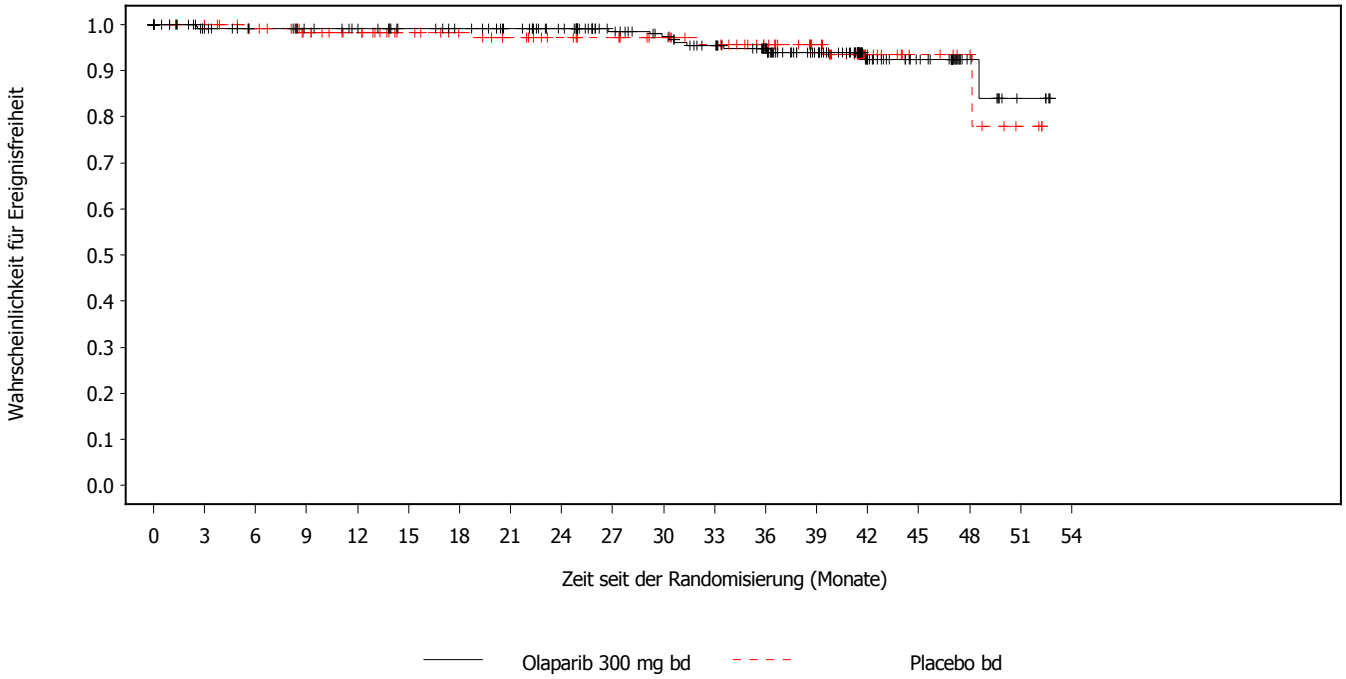
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.9.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Eierstockkrebs-spezifische Subskala (OCS)
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

260	231	224	219	215	207	203	196	186	165	156	146	127	100	53	40	12	4	0	Olaparib 300 mg bd
131	122	116	108	102	93	88	83	78	75	70	65	56	47	17	10	7	2	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2baf 15NOV2022:14:11 kpzx329

1.6.4: Analysen zu den Subskalen des FACT-O

1.6.4.1: Zeit bis zur ersten bestätigten klinisch relevanten Verschlechterung

Table 2.2.1 SOLO1: Summary of analysis of Time to deterioration in FACT-O
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
FACT-O Gesamtscore	260	34 (13,1)	NE [NE; NE]	131	19 (14,5)	NE [NE; NE]	0,89	[0,51; 1,61]	0,7409
FACT-O Subskala physisches Wohlbefinden (PWB)	260	64 (24,6)	NE [NE; NE]	131	25 (19,1)	NE [NE; NE]	1,38	[0,88; 2,23]	0,1907
FACT-O Subskala soziales Wohlbefinden (SWB)	260	67 (25,8)	NE [NE; NE]	131	29 (22,1)	NE [NE; NE]	1,13	[0,74; 1,78]	0,6443
FACT-O Subskala funktionales Wohlbefinden (FWB)	260	47 (18,1)	NE [NE; NE]	131	23 (17,6)	50,7 [44,6; NE]	1,01	[0,62; 1,70]	0,9047
FACT-O Subskala emotionales Wohlbefinden (EWB)	260	54 (20,8)	49,9 [42,1; NE]	131	32 (24,4)	NE [NE; NE]	0,80	[0,52; 1,26]	0,3389
FACT-O Eierstockkrebs-spezifische Subskala (OCS)	260	36 (13,8)	NE [NE; NE]	131	17 (13,0)	48,2 [46,3; NE]	1,06	[0,60; 1,94]	0,7830

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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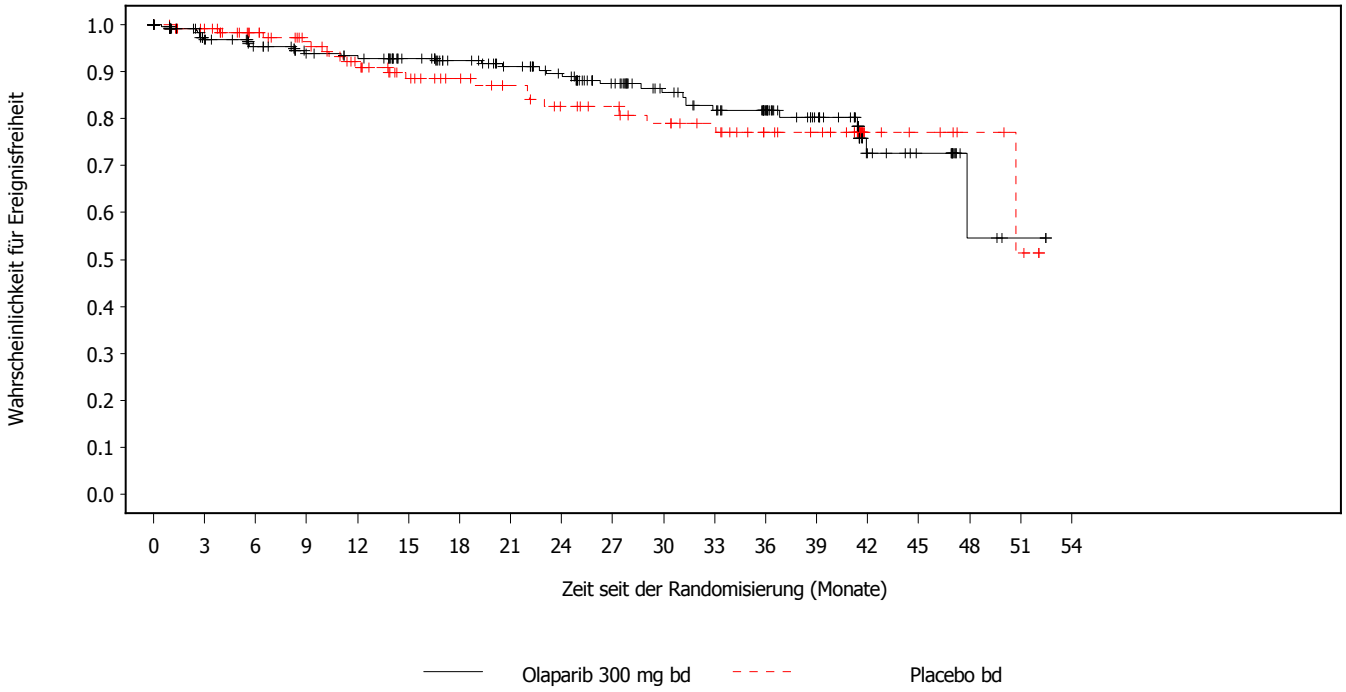
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.2.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Gesamtscore
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

260	209	195	182	177	161	148	138	128	109	92	84	67	49	21	16	3	1	0	Olaparib 300 mg bd
131	114	103	93	82	70	64	58	52	49	44	40	32	29	9	7	4	2	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.

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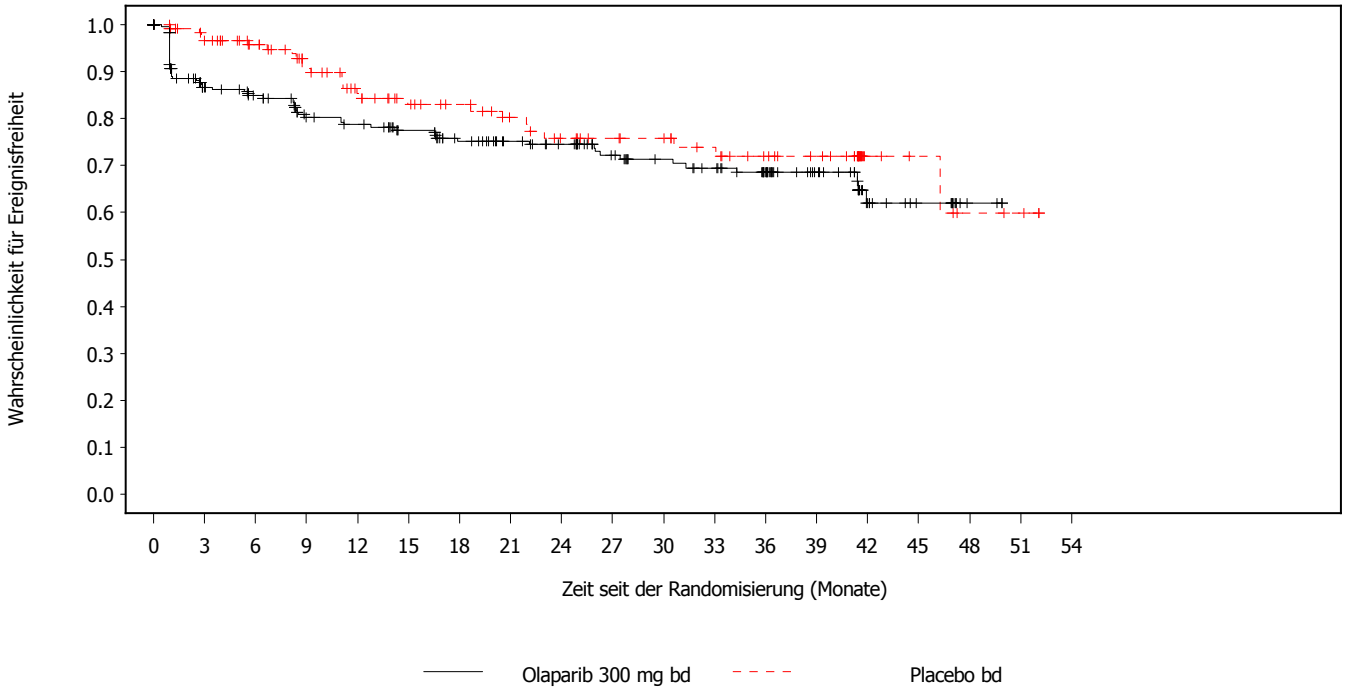
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.2.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Subskala physisches Wohlbefinden (PWB)
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

260	188	174	154	148	135	122	112	105	88	79	74	61	44	20	13	2	0	0	Olaparib 300 mg bd
131	113	102	88	76	67	62	55	49	45	43	38	32	28	8	6	3	2	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.

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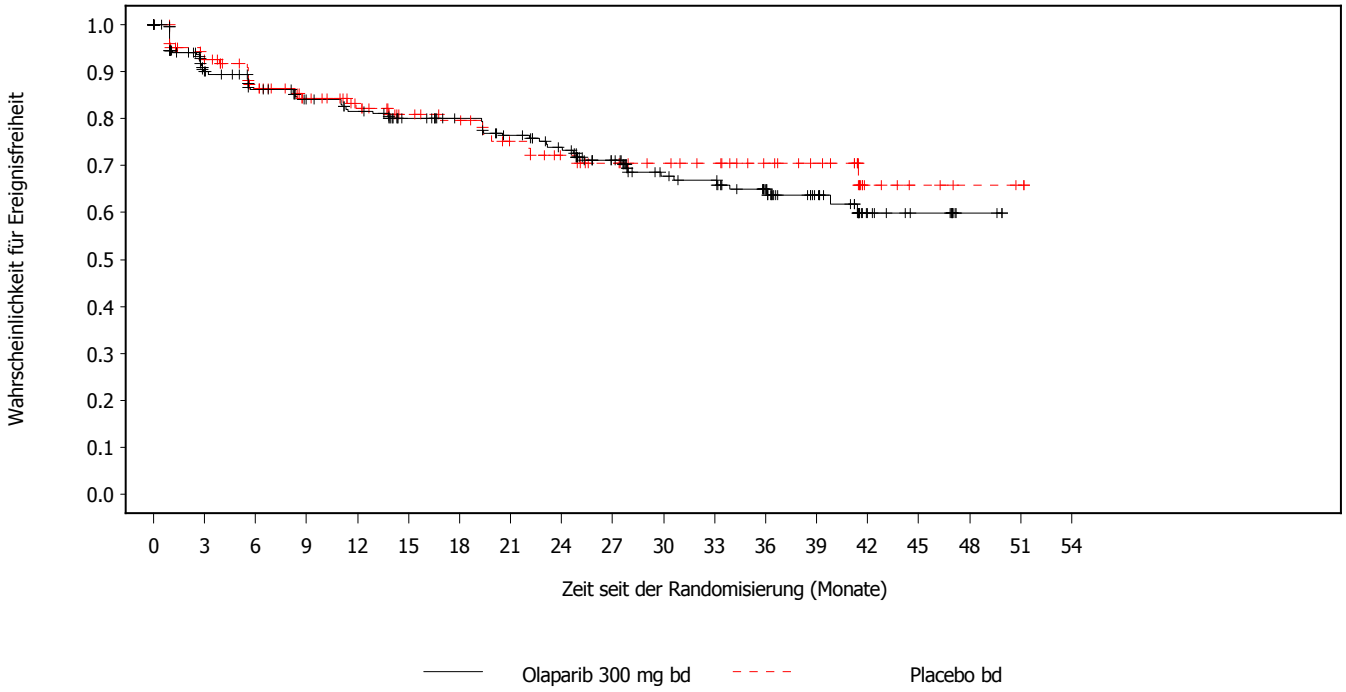
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.2.2.3 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Subskala soziales Wohlbefinden (SWB)
Full Analysis Set, DCO 17MAY2018



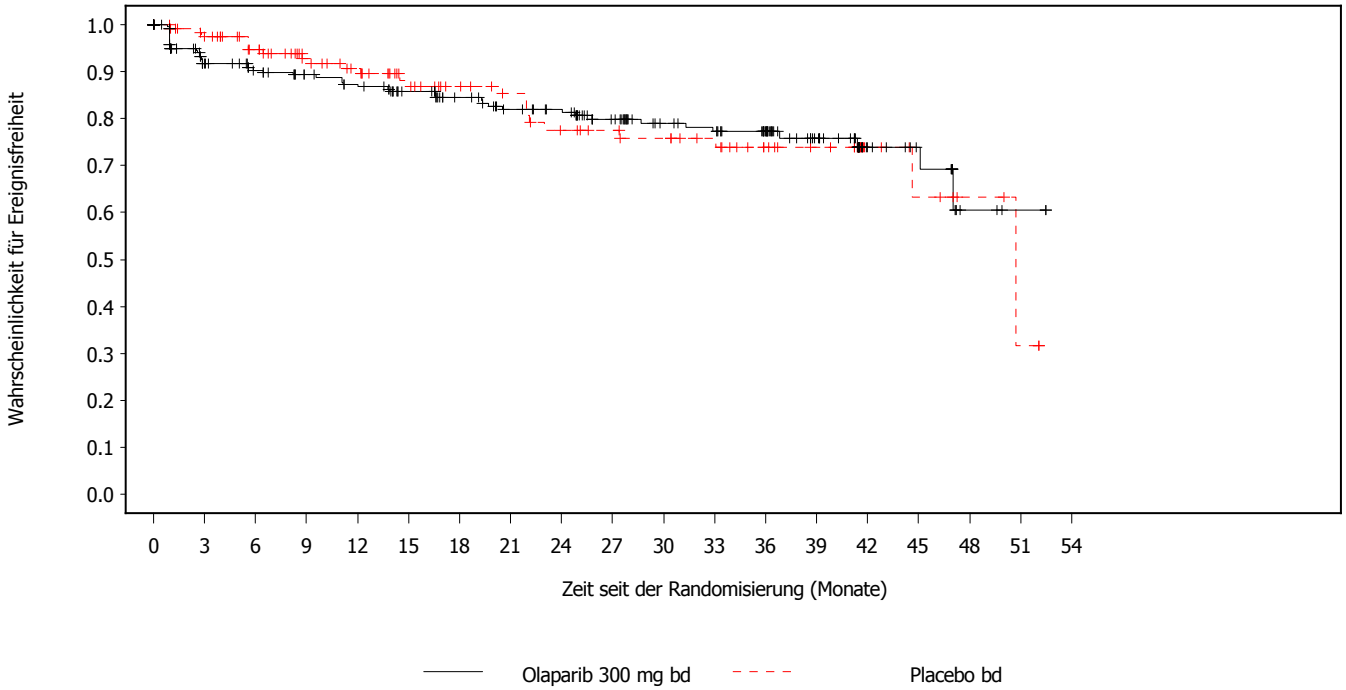
Anzahl an Patienten unter Risiko:

260	194	177	166	157	142	134	124	114	94	75	72	56	39	17	12	2	0	0	Olaparib 300 mg bd
131	109	94	82	72	62	58	50	44	39	35	32	26	22	7	4	2	1	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr.sas gttemainprbac 09NOV2022:11:10 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.2.2.4 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Subskala funktionales Wohlbefinden (FWB)
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

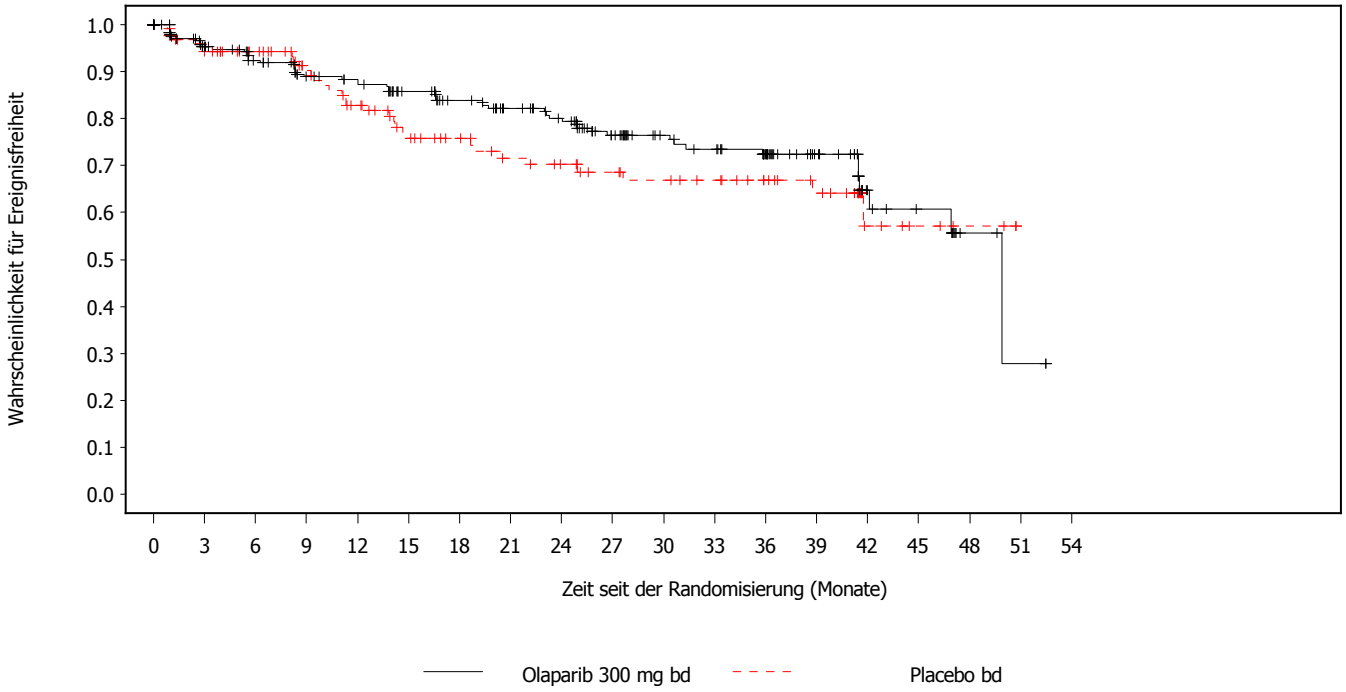
260	199	185	174	167	152	139	128	123	104	87	83	69	48	21	16	3	1	0 Olaparib 300 mg bd
131	114	102	88	80	67	60	55	48	45	42	38	30	26	9	6	3	1	0 Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr.sas gttemainprbad 09NOV2022:11:10 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.2.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Subskala emotionales Wohlbefinden (EWB)
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

260	207	191	174	168	151	138	127	118	95	79	74	59	39	16	12	3	1	0	Olaparib 300 mg bd
131	110	101	87	76	63	57	50	46	41	38	35	29	24	7	4	2	0	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.

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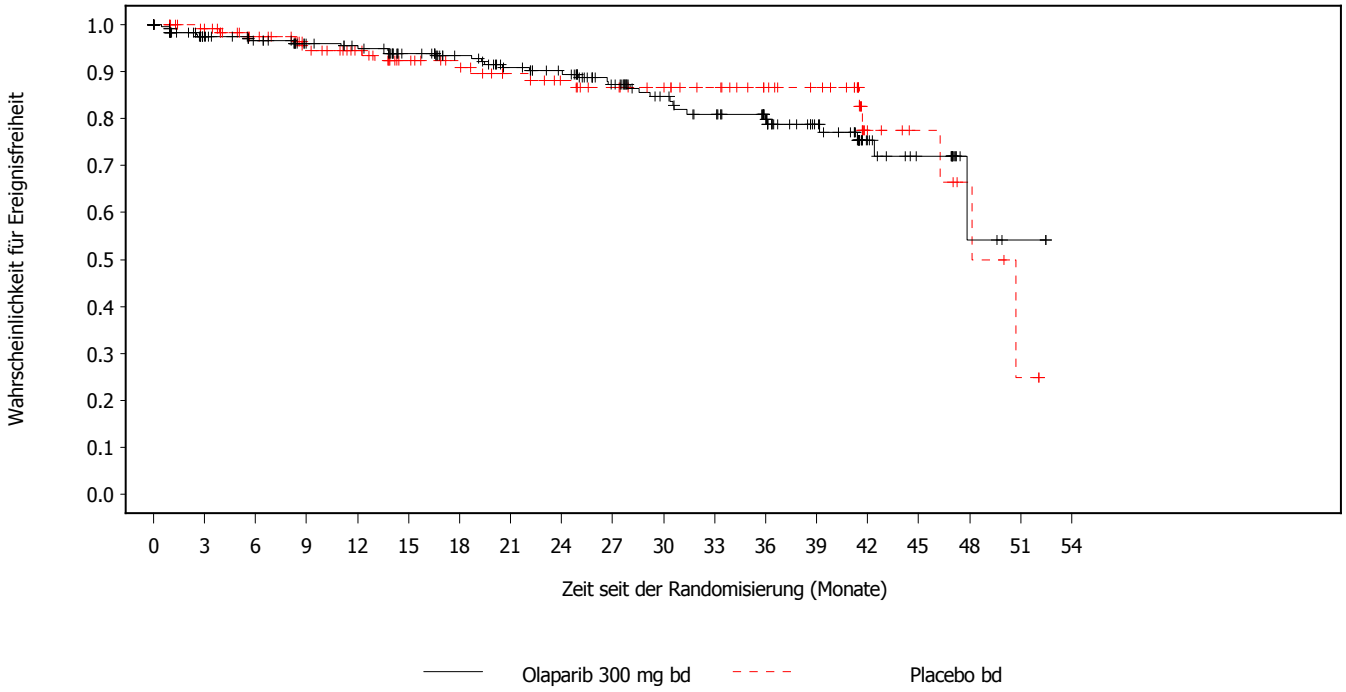
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.2.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Eierstockkrebs-spezifische Subskala (OCS)
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

260	213	201	188	182	165	152	140	132	112	95	87	71	52	25	17	3	1	0	Olaparib 300 mg bd
131	117	106	96	87	75	69	62	57	52	48	43	36	32	10	7	4	1	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr.sas gttemainprbaf 09NOV2022:11:10 kvbv306

1.6.4.2: Zeit bis zur dauerhaften klinisch relevanten Verschlechterung

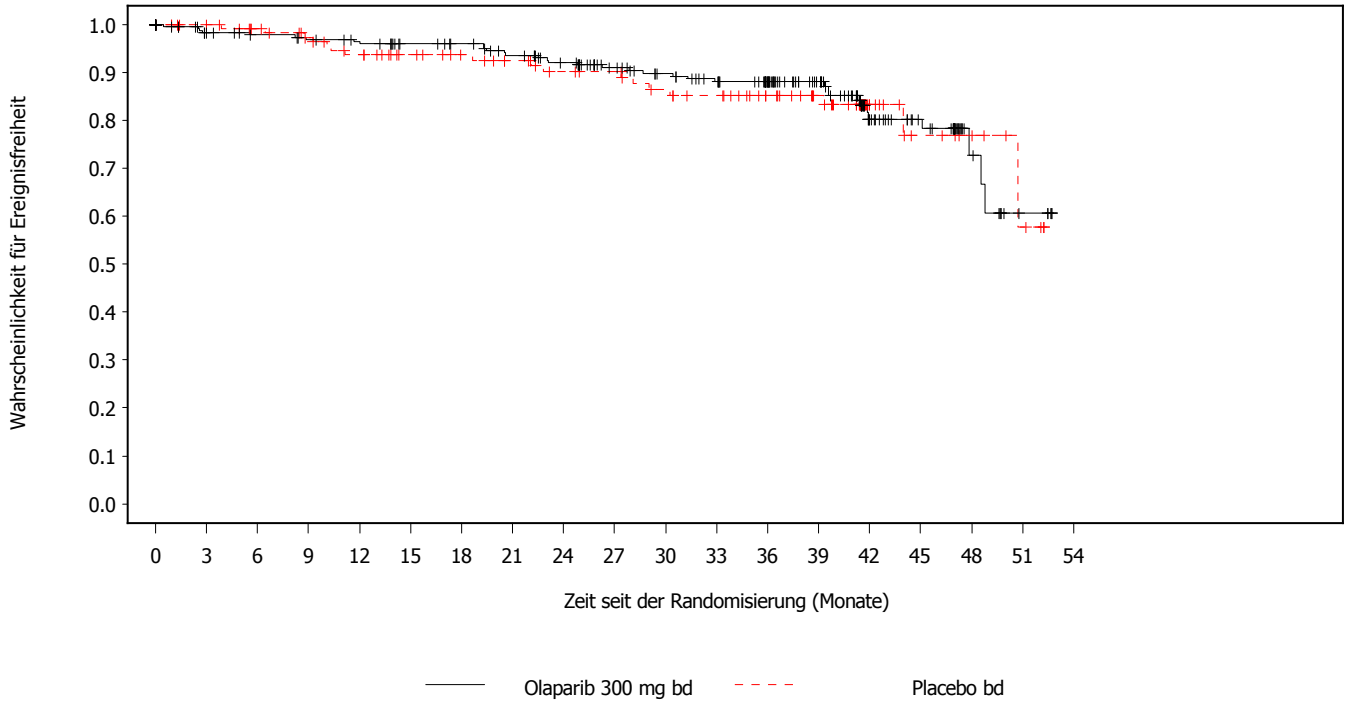
Table 2.8.1 SOLO1: Summary of analysis of Time to sustained deterioration in FACT-O
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
FACT-O Gesamtscore	260	35 (13,5)	NE [NE; NE]	131	17 (13,0)	NE [NE; NE]	0,94	[0,53; 1,72]	0,9837
FACT-O Subskala physisches Wohlbefinden (PWB)	260	34 (13,1)	NE [NE; NE]	131	20 (15,3)	NE [NE; NE]	0,76	[0,44; 1,35]	0,3957
FACT-O Subskala soziales Wohlbefinden (SWB)	260	49 (18,8)	NE [NE; NE]	131	25 (19,1)	52,1 [44,0; NE]	0,89	[0,56; 1,47]	0,7191
FACT-O Subskala funktionales Wohlbefinden (FWB)	260	45 (17,3)	NE [NE; NE]	131	22 (16,8)	NE [NE; NE]	0,89	[0,54; 1,51]	0,7370
FACT-O Subskala emotionales Wohlbefinden (EWB)	260	49 (18,8)	49,9 [48,1; NE]	131	26 (19,8)	NE [NE; NE]	0,83	[0,52; 1,36]	0,4999
FACT-O Eierstockkrebs-spezifische Subskala (OCS)	260	29 (11,2)	NE [NE; NE]	131	19 (14,5)	50,7 [46,3; NE]	0,70	[0,40; 1,28]	0,3099

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swaa 15NOV2022:14:07 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.8.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Full Analysis Set, DCO 17MAY2018



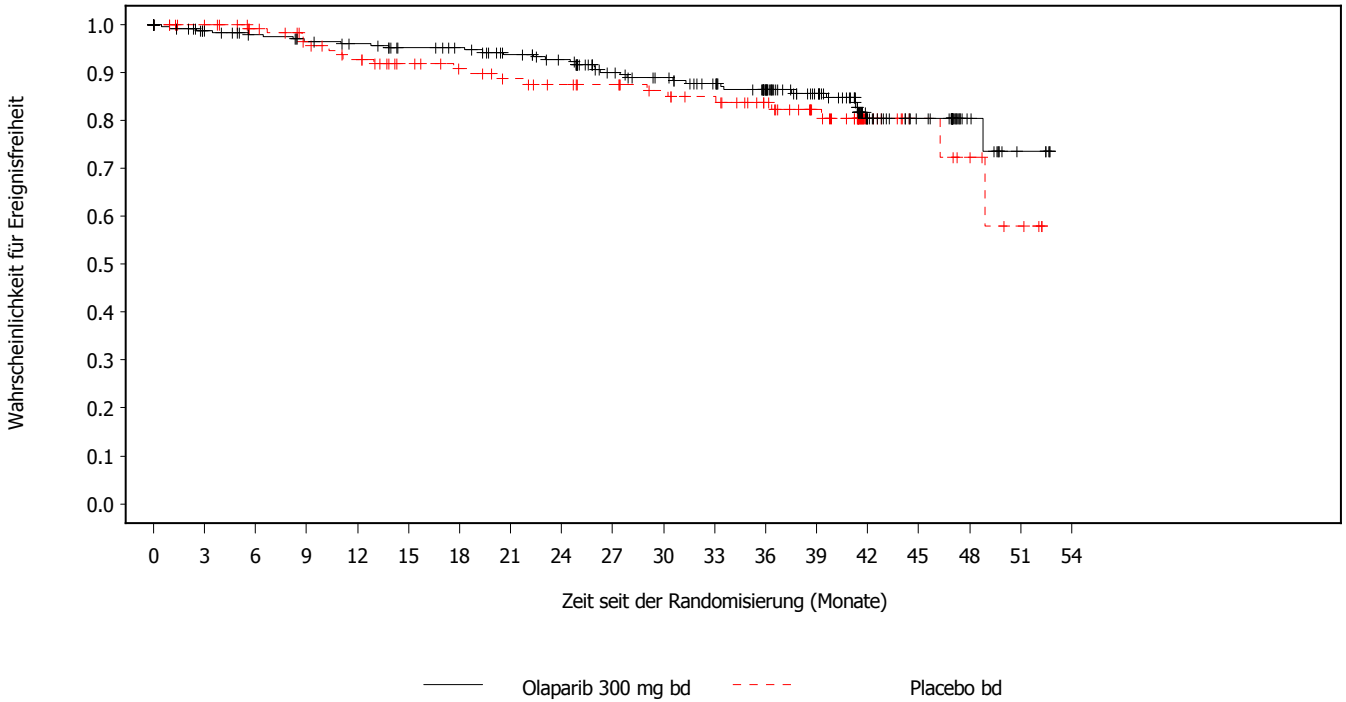
Anzahl an Patienten unter Risiko:

260	227	221	217	213	204	200	191	181	162	152	143	125	101	54	41	13	4	0	Olaparib 300 mg bd
131	120	114	107	100	92	87	82	76	74	68	64	55	46	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbaa 15NOV2022:14:07 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.8.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala physisches Wohlbefinden (PWB)
Full Analysis Set, DCO 17MAY2018



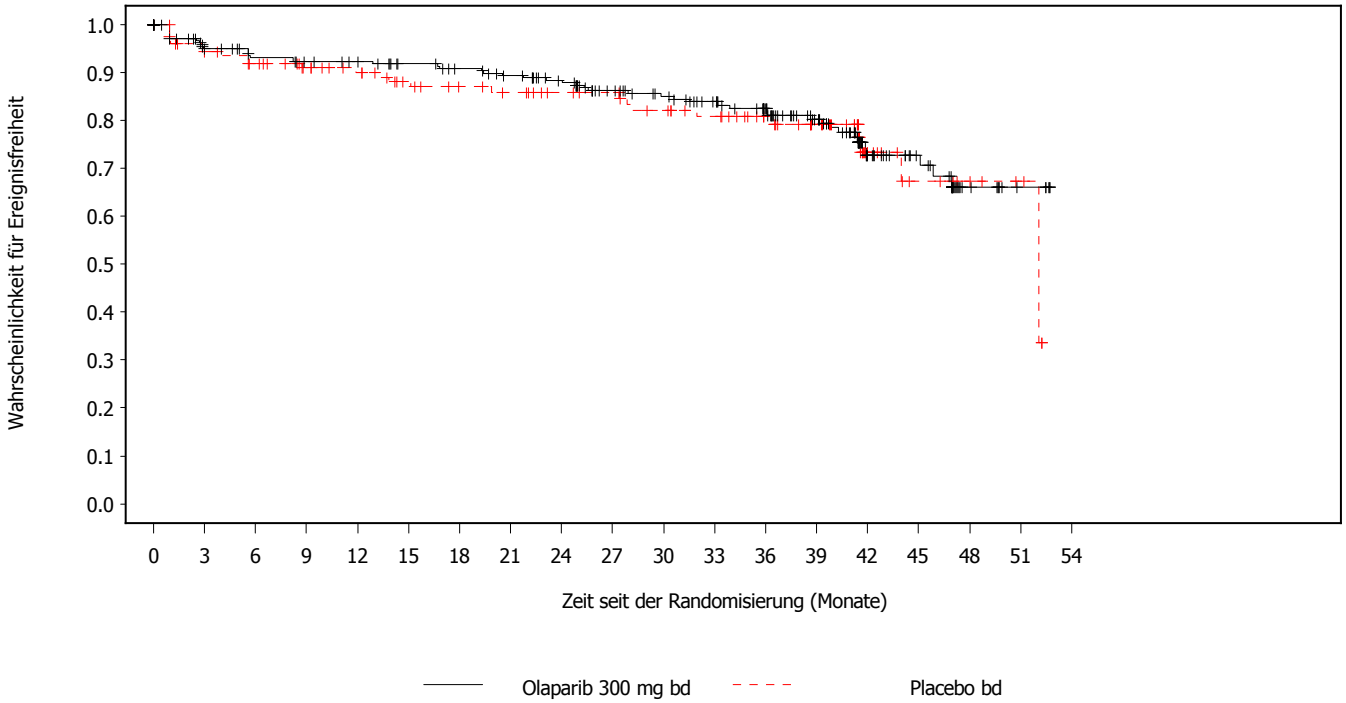
Anzahl an Patienten unter Risiko:

260	231	223	217	213	205	201	191	183	161	153	143	125	101	53	40	13	4	0	Olaparib 300 mg bd
131	122	115	107	100	91	86	81	77	74	69	65	56	45	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbab 15NOV2022:14:07 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.8.2.3 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala soziales Wohlbefinden (SWB)
Full Analysis Set, DCO 17MAY2018



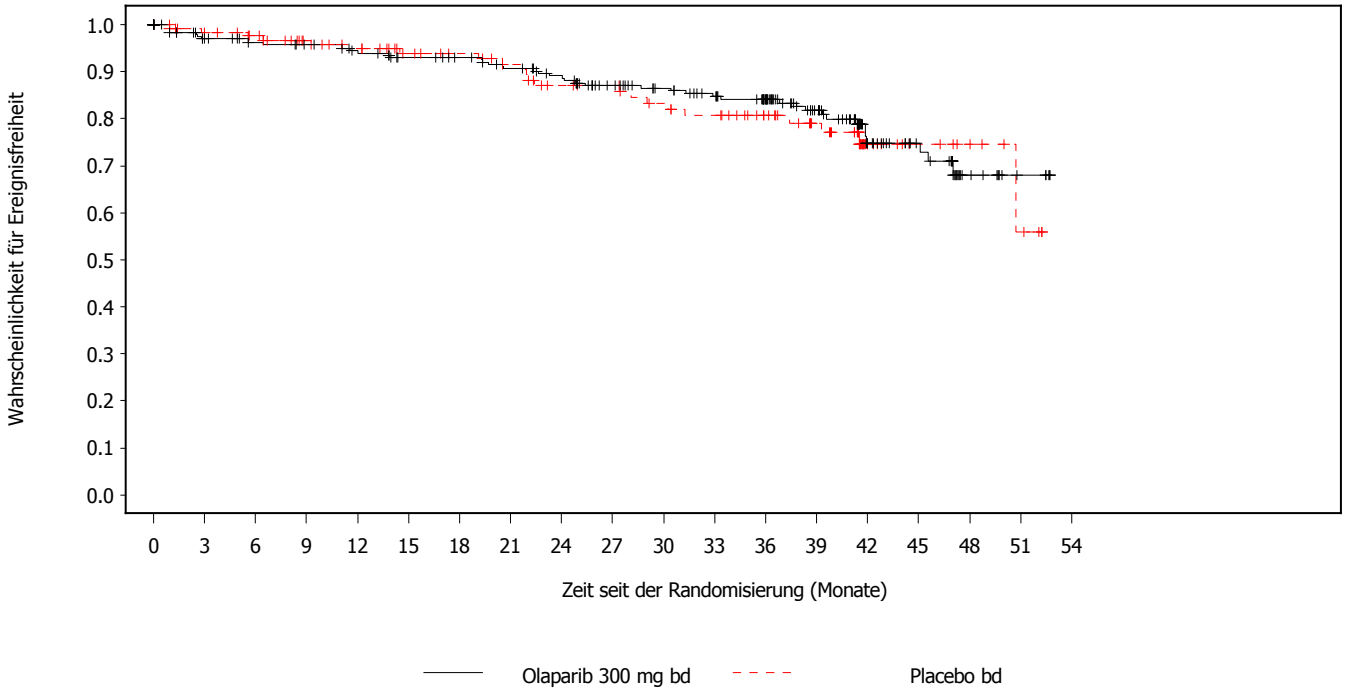
Anzahl an Patienten unter Risiko:

260	220	210	205	202	194	188	181	171	152	143	133	117	95	47	35	11	4	0	Olaparib 300 mg bd
131	115	109	100	94	85	80	77	72	70	64	59	50	42	16	9	6	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbac 15NOV2022:14:07 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.8.2.4 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala funktionales Wohlbefinden (FWB)
Full Analysis Set, DCO 17MAY2018



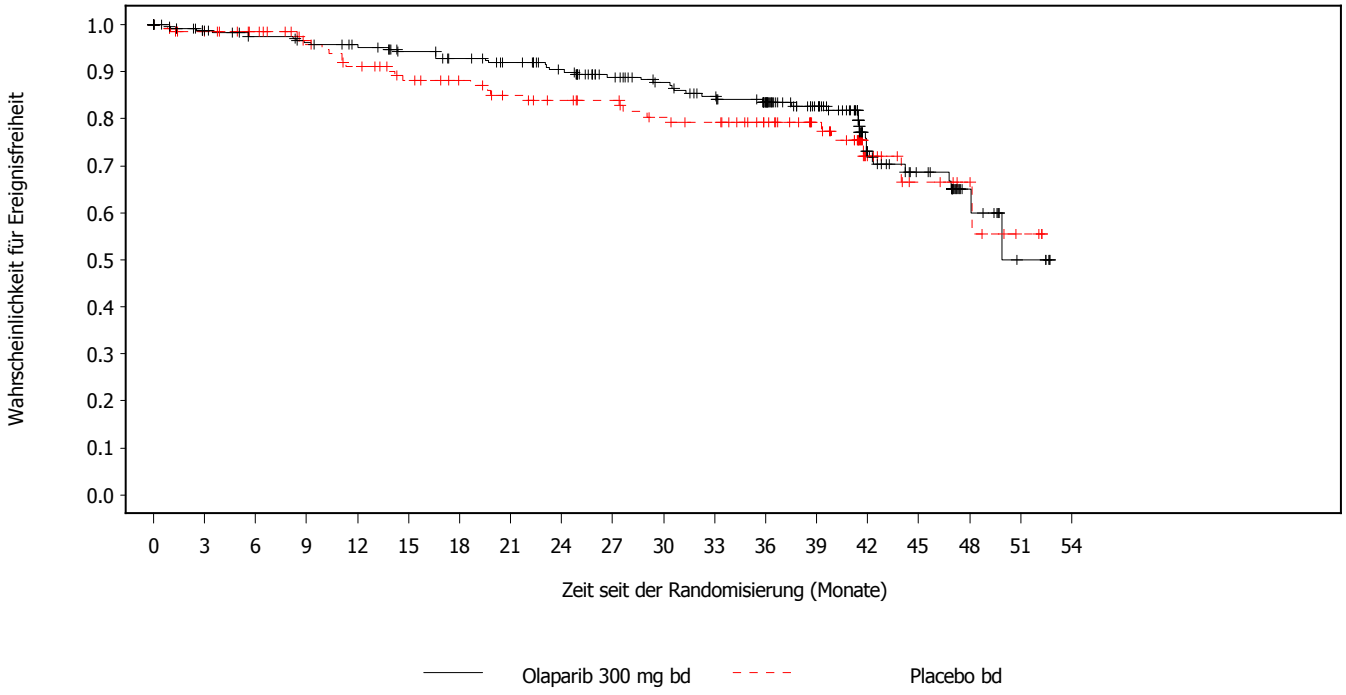
Anzahl an Patienten unter Risiko:

260	226	218	214	207	198	194	186	178	159	149	140	123	96	51	39	12	4	0	Olaparib 300 mg bd
131	120	115	105	99	90	86	81	73	71	65	61	52	42	16	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbad 15NOV2022:14:07 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.8.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala emotionales Wohlbefinden (EWB)
Full Analysis Set, DCO 17MAY2018



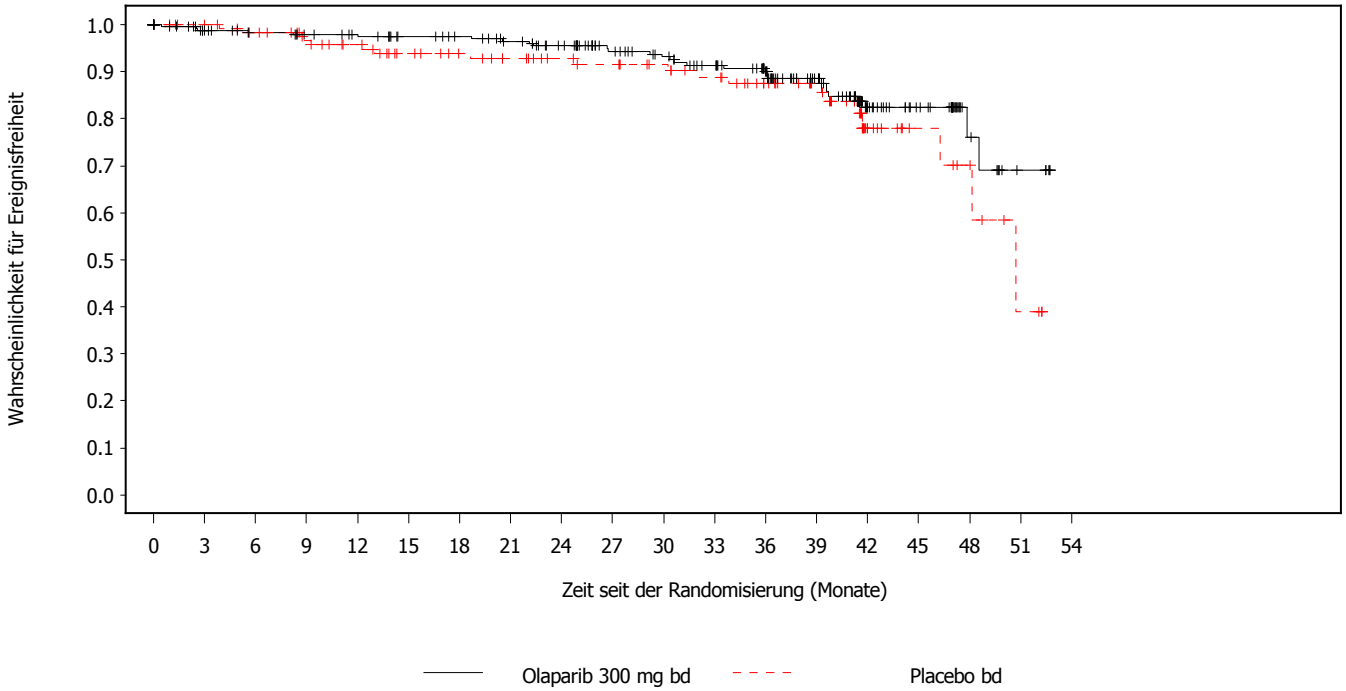
Anzahl an Patienten unter Risiko:

260	230	222	217	212	202	195	188	178	159	149	140	124	97	51	39	13	4	0	Olaparib 300 mg bd
131	120	115	106	98	90	85	79	75	72	66	63	54	44	17	10	7	2	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbae 15NOV2022:14:07 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.8.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Eierstockkrebs-spezifische Subskala (OCS)
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

260	231	224	219	215	207	203	196	186	165	156	146	127	100	53	40	12	4	0	Olaparib 300 mg bd
131	122	116	108	102	93	88	83	78	75	70	65	56	47	17	10	7	2	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbaf 15NOV2022:14:07 kpzx329

1.6.5: Subgruppenanalysen

1.6.5.1: Zeit bis zur ersten bestätigten klinisch relevanten Verschlechterung

Table 2.10.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur Verschlechterung FACT-O Gesamtscore
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	30 (13,3)	NE [NE; NE]	112	15 (13,4)	50,7 [50,7; NE]	0,97	[0,53; 1,85]	0,9165
>=65 Jahre	35	4 (11,4)	47,9 [41,9; NE]	19	4 (21,1)	NE [NE; NE]	0,64	[0,15; 2,76]	0,5395
Interaktion p-Wert									0,6023
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	27 (12,7)	47,9 [47,9; NE]	107	17 (15,9)	NE [NE; NE]	0,85	[0,47; 1,60]	0,6063
Partielles Ansprechen	47	7 (14,9)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	1,21	[0,29; 8,12]	0,8120
Interaktion p-Wert									0,6779
ECOG PS Status									
Normale Aktivität	200	29 (14,5)	47,9 [47,9; NE]	105	11 (10,5)	NE [NE; NE]	1,42	[0,73; 3,01]	0,3141
Eingeschränkte Aktivität	60	5 (8,3)	NE [NE; NE]	25	8 (32,0)	NE [NE; NE]	0,25	[0,07; 0,74]	0,0128*
Interaktion p-Wert									0,0080*
Baseline CA-125 Wert									
<=ULN	247	33 (13,4)	NE [NE; NE]	123	19 (15,4)	NE [NE; NE]	0,88	[0,50; 1,58]	0,6582
>ULN	13	1 (7,7)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	26 (11,8)	NE [NE; NE]	105	16 (15,2)	NE [NE; NE]	0,80	[0,43; 1,53]	0,4917
IV	40	8 (20,0)	41,9 [32,9; NE]	26	3 (11,5)	NE [NE; NE]	1,52	[0,44; 6,93]	0,5267
Interaktion p-Wert									0,3804
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	28 (14,9)	NE [NE; NE]	91	12 (13,2)	NE [NE; NE]	1,25	[0,65; 2,59]	0,5112
BRCA2	62	5 (8,1)	47,9 [41,9; NE]	39	7 (17,9)	NE [NE; NE]	0,35	[0,10; 1,12]	0,0756
Interaktion p-Wert									0,0623
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubpraaa 13JAN2023:14:29 kvbv306

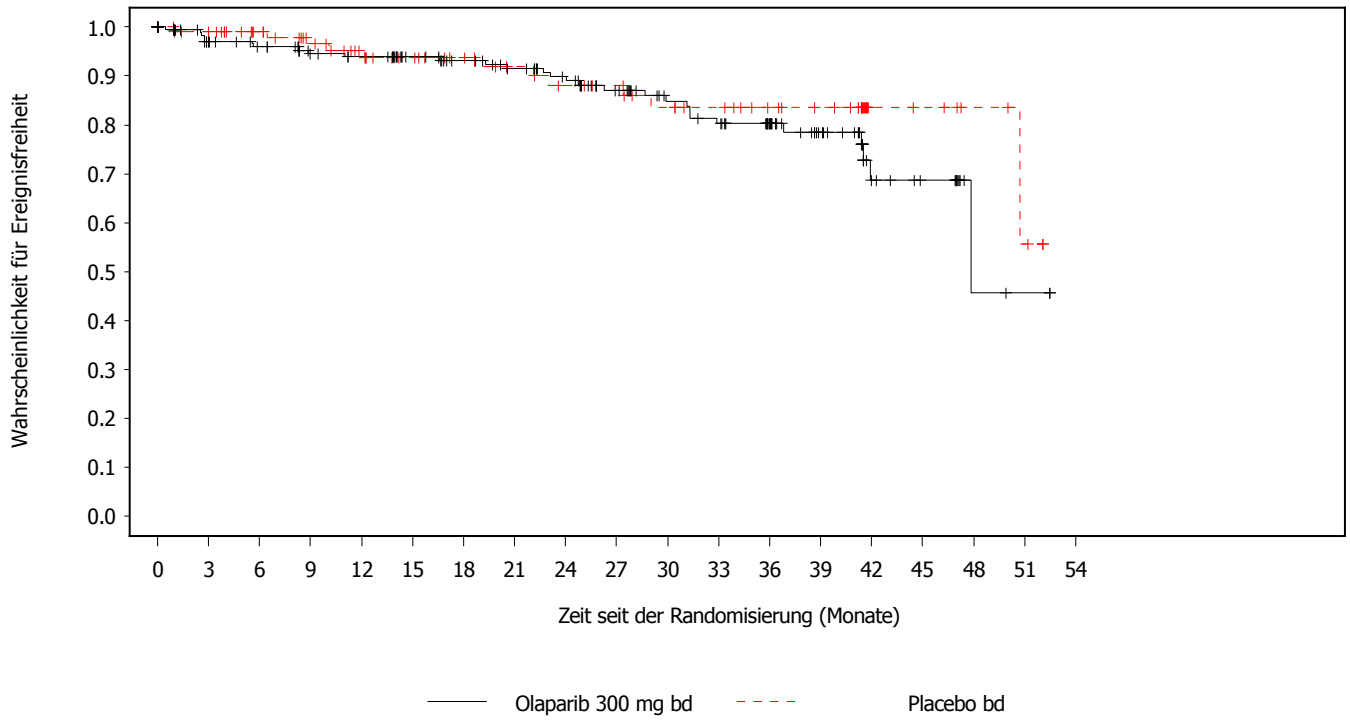
Table 2.10.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur Verschlechterung FACT-O Gesamtscore
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	9 (16,4)	47,9 [41,4; NE]	29	6 (20,7)	NE [NE; NE]	0,63	[0,23; 1,88]	0,3871
Keine makroskopische Resterkrankung	200	24 (12,0)	NE [NE; NE]	98	13 (13,3)	NE [NE; NE]	0,98	[0,50; 2,01]	0,9617
Interaktion p-Wert									0,4818
Abstammung									
Weiß	214	26 (12,1)	NE [NE; NE]	106	15 (14,2)	NE [NE; NE]	0,89	[0,47; 1,73]	0,7154
Andere	46	8 (17,4)	47,9 [41,5; NE]	25	4 (16,0)	NE [NE; NE]	0,95	[0,30; 3,57]	0,9364
Interaktion p-Wert									0,9183
Region									
Europa	101	10 (9,9)	NE [NE; NE]	53	7 (13,2)	50,7 [50,7; NE]	0,77	[0,29; 2,15]	0,6030
Asien	33	7 (21,2)	NE [NE; NE]	14	4 (28,6)	NE [NE; NE]	0,63	[0,19; 2,41]	0,4737
Rest der Welt	126	17 (13,5)	NE [NE; NE]	64	8 (12,5)	NE [NE; NE]	1,13	[0,50; 2,76]	0,7821
Interaktion p-Wert									0,7108

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubpraaa 13JAN2023:14:29 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.10.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Gesamtscore for ECOG PS Status = Normale Aktivität
Full Analysis Set, DCO 17MAY2018



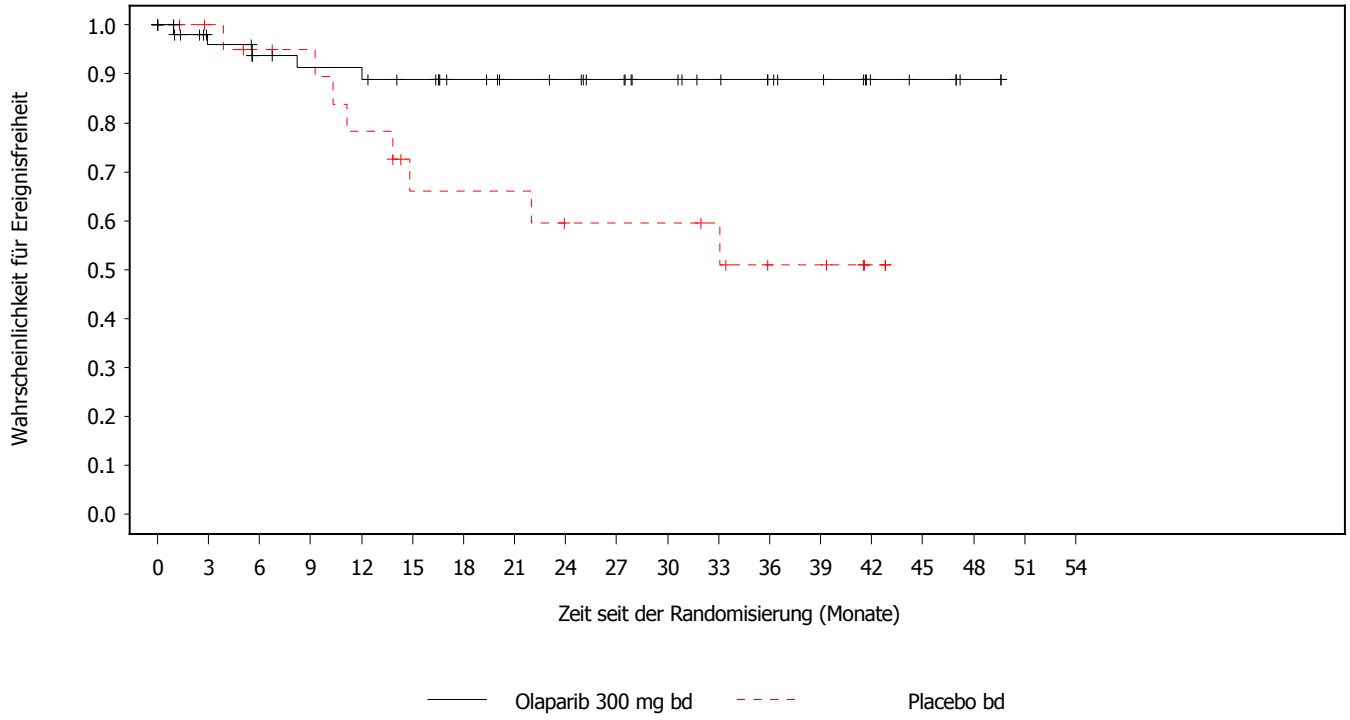
Anzahl an Patienten unter Risiko:

200	164	156	145	140	127	119	112	103	87	74	69	55	39	16	12	2	1	0	Olaparib 300 mg bd
105	94	85	76	68	60	54	48	44	41	36	33	28	25	8	7	4	2	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubprbaa 13JAN2023:14:29 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.10.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Gesamtscore for ECOG PS Status = Eingeschränkte Aktivität
Full Analysis Set, DCO 17MAY2018



Anzahl an Patienten unter Risiko:

60	45	39	37	37	34	29	26	25	22	18	15	12	10	5	4	1	0	0	Olaparib 300 mg bd
25	20	18	17	14	10	10	10	8	8	8	7	4	4	1	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr.sas gttesubprbab 13JAN2023:14:29 kvbv306

1.6.5.2: Zeit bis zur dauerhaften klinisch relevanten Verschlechterung

Table 2.11.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	30 (13,3)	NE [NE; NE]	112	12 (10,7)	NE [NE; NE]	1,10	[0,58; 2,24]	0,7728
>=65 Jahre	35	5 (14,3)	47,9 [41,9; NE]	19	5 (26,3)	NE [NE; NE]	0,54	[0,15; 1,95]	0,3356
Interaktion p-Wert									0,3228
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	29 (13,6)	NE [NE; NE]	107	15 (14,0)	NE [NE; NE]	0,95	[0,52; 1,83]	0,8796
Partielles Ansprechen	47	6 (12,8)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	0,85	[0,19; 5,85]	0,8473
Interaktion p-Wert									0,8998
ECOG PS Status									
Normale Aktivität	200	28 (14,0)	NE [NE; NE]	105	10 (9,5)	NE [NE; NE]	1,33	[0,67; 2,89]	0,4258
Eingeschränkte Aktivität	60	7 (11,7)	NE [NE; NE]	25	7 (28,0)	NE [NE; NE]	0,37	[0,13; 1,10]	0,0725
Interaktion p-Wert									0,0515
Baseline CA-125 Wert									
<=ULN	247	33 (13,4)	NE [NE; NE]	123	17 (13,8)	NE [NE; NE]	0,88	[0,50; 1,63]	0,6830
>ULN	13	2 (15,4)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	27 (12,3)	NE [NE; NE]	105	12 (11,4)	NE [NE; NE]	0,97	[0,50; 2,00]	0,9394
IV	40	8 (20,0)	NE [NE; NE]	26	5 (19,2)	NE [NE; NE]	0,92	[0,31; 3,06]	0,8861
Interaktion p-Wert									0,9337
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	28 (14,9)	NE [NE; NE]	91	11 (12,1)	NE [NE; NE]	1,19	[0,61; 2,49]	0,6282
BRCA2	62	6 (9,7)	NE [NE; NE]	39	6 (15,4)	NE [NE; NE]	0,49	[0,15; 1,57]	0,2220
Interaktion p-Wert									0,1937
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubpr_sw.sas gttesubpr_swaaa 13JAN2023:14:29 kvbv306

Table 2.11.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	10 (18,2)	47,9 [47,9; NE]	29	5 (17,2)	NE [NE; NE]	0,68	[0,24; 2,20]	0,4976
Keine makroskopische Resterkrankung	200	24 (12,0)	NE [NE; NE]	98	12 (12,2)	NE [NE; NE]	0,96	[0,49; 1,99]	0,9086
Interaktion p-Wert									0,6053
Abstammung									
Weiß	214	30 (14,0)	NE [NE; NE]	106	14 (13,2)	NE [NE; NE]	0,93	[0,50; 1,80]	0,8163
Andere	46	5 (10,9)	47,9 [NE; NE]	25	3 (12,0)	NE [NE; NE]	0,93	[0,23; 4,52]	0,9163
Interaktion p-Wert									0,9987
Region									
Europa	101	12 (11,9)	NE [NE; NE]	53	5 (9,4)	50,7 [50,7; NE]	0,95	[0,35; 2,99]	0,9192
Asien	33	4 (12,1)	NE [NE; NE]	14	3 (21,4)	NE [NE; NE]	0,49	[0,11; 2,49]	0,3630
Rest der Welt	126	19 (15,1)	NE [NE; NE]	64	9 (14,1)	NE [NE; NE]	1,12	[0,52; 2,61]	0,7799
Interaktion p-Wert									0,6430

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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1.6.5.3: Sensitivitätsanalyse: Zeit bis zur dauerhaften klinisch relevanten Verschlechterung

Table 2.12.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	11 (4,9)	NE [NE; NE]	112	3 (2,7)	NE [NE; NE]	1,62	[0,51; 7,18]	0,4379
>=65 Jahre	35	1 (2,9)	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	0,59	[0,02; 14,87]	0,7084
Interaktion p-Wert									0,5183
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	8 (3,8)	NE [NE; NE]	107	4 (3,7)	NE [NE; NE]	0,99	[0,31; 3,71]	0,9850
Partielles Ansprechen	47	4 (8,5)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	11 (5,5)	NE [NE; NE]	105	3 (2,9)	NE [NE; NE]	1,77	[0,55; 7,81]	0,3587
Eingeschränkte Aktivität	60	1 (1,7)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	0,38	[0,02; 9,69]	0,5054
Interaktion p-Wert									0,3378
Baseline CA-125 Wert									
<=ULN	247	12 (4,9)	NE [NE; NE]	123	4 (3,3)	NE [NE; NE]	1,38	[0,48; 4,95]	0,5641
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	9 (4,1)	NE [NE; NE]	105	4 (3,8)	NE [NE; NE]	0,94	[0,31; 3,49]	0,9254
IV	40	3 (7,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	10 (5,3)	NE [NE; NE]	91	3 (3,3)	NE [NE; NE]	1,54	[0,47; 6,89]	0,4941
BRCA2	62	2 (3,2)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	1,05	[0,10; 22,64]	0,9664
Interaktion p-Wert									0,7858

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 2.12.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)
Full Analysis Set, DCO 17MAY2018

	Olaparib 300 mg bd (N=260)			Placebo bd (N=131)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	0,19	[0,01; 2,00]	0,1605
Keine makroskopische Resterkrankung	200	10 (5,0)	NE [NE; NE]	98	2 (2,0)	NE [NE; NE]	2,34	[0,62; 15,26]	0,2298
Interaktion p-Wert									0,0705
Abstammung									
Weiß	214	11 (5,1)	NE [NE; NE]	106	3 (2,8)	NE [NE; NE]	1,62	[0,50; 7,15]	0,4422
Andere	46	1 (2,2)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	0,54	[0,02; 13,77]	0,6697
Interaktion p-Wert									0,4898
Region									
Europa	101	3 (3,0)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	1,23	[0,16; 24,90]	0,8571
Asien	33	1 (3,0)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	0,35	[0,01; 8,91]	0,4708
Rest der Welt	126	8 (6,3)	NE [NE; NE]	64	2 (3,1)	NE [NE; NE]	2,15	[0,53; 14,34]	0,3021
Interaktion p-Wert									0,5463

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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1.7: Zensierungsgründe erste bestätigte klinisch relevante Verschlechterung

Table 2.6 SOLO1: Summary of censoring reasons for PRO endpoints
Full Analysis Set, DCO 17MAY2018

Parameter	Deterioration/censoring reason	Olaparib 300mg bd (N=260)	Placebo bd (N=131)
FACT-O Gesamtscore	Deterioration	34 (13,1)	19 (14,5)
	Deterioration confirmed on 2 subsequent visits	21 (8,1)	10 (7,6)
	Deterioration at last observation visit	13 (5,0)	9 (6,9)
	Censored due to last observation (no deterioration)	116 (44,6)	67 (51,1)
	Censored due to 2 or more missed assessments	78 (30,0)	36 (27,5)
	Censored due to PFS-event [a]	12 (4,6)	3 (2,3)
	Censored due to PROs collection limit at 36 months [a]	10 (3,8)	6 (4,6)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	22 (8,5)	6 (4,6)
	Censored due to death	10 (3,8)	3 (2,3)
	Total	260 (100)	131 (100)
FACT-O Subskala physisches Wohlbefinden (PWB)	Deterioration	64 (24,6)	25 (19,1)
	Deterioration confirmed on 2 subsequent visits	54 (20,8)	18 (13,7)
	Deterioration at last observation visit	10 (3,8)	7 (5,3)
	Censored due to last observation (no deterioration)	105 (40,4)	67 (51,1)
	Censored due to 2 or more missed assessments	64 (24,6)	32 (24,4)
	Censored due to PFS-event [a]	10 (3,8)	3 (2,3)
	Censored due to PROs collection limit at 36 months [a]	6 (2,3)	5 (3,8)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	19 (7,3)	4 (3,1)
	Censored due to death	8 (3,1)	3 (2,3)
	Total	260 (100)	131 (100)
FACT-O Subskala soziales Wohlbefinden (SWB)	Deterioration	67 (25,8)	29 (22,1)
	Deterioration confirmed on 2 subsequent visits	59 (22,7)	26 (19,8)
	Deterioration at last observation visit	8 (3,1)	3 (2,3)
	Censored due to last observation (no deterioration)	99 (38,1)	58 (44,3)
	Censored due to 2 or more missed assessments	63 (24,2)	33 (25,2)
	Censored due to PFS-event [a]	8 (3,1)	3 (2,3)
	Censored due to PROs collection limit at 36 months [a]	10 (3,8)	7 (5,3)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	19 (7,3)	4 (3,1)
	Censored due to death	12 (4,6)	7 (5,3)
	Total	260 (100)	131 (100)
FACT-O Subskala funktionales Wohlbefinden (FWB)	Deterioration	47 (18,1)	23 (17,6)
	Deterioration confirmed on 2 subsequent visits	37 (14,2)	17 (13,0)
	Deterioration at last observation visit	10 (3,8)	6 (4,6)
	Censored due to last observation (no deterioration)	113 (43,5)	66 (50,4)
	Censored due to 2 or more missed assessments	71 (27,3)	35 (26,7)
	Censored due to PFS-event [a]	12 (4,6)	3 (2,3)
	Censored due to PROs collection limit at 36 months [a]	10 (3,8)	6 (4,6)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	19 (7,3)	4 (3,1)
	Censored due to death	10 (3,8)	3 (2,3)
	Total	260 (100)	131 (100)

[a] Subject can potentially contribute to either one or both categories.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/cnsrpr_v2.sas gcnsrpr_v2a 18NOV2022:13:12 kvbv306

Table 2.6 SOLO1: Summary of censoring reasons for PRO endpoints
Full Analysis Set, DCO 17MAY2018

Parameter	Deterioration/censoring reason	Olaparib 300mg bd (N=260)	Placebo bd (N=131)
FACT-O Subskala emotionales Wohlbefinden (EWB)	Deterioration	54 (20,8)	32 (24,4)
	Deterioration confirmed on 2 subsequent visits	39 (15,0)	23 (17,6)
	Deterioration at last observation visit	15 (5,8)	9 (6,9)
	Censored due to last observation (no deterioration)	108 (41,5)	60 (45,8)
	Censored due to 2 or more missed assessments	73 (28,1)	32 (24,4)
	Censored due to PFS-event [a]	11 (4,2)	3 (2,3)
	Censored due to PROs collection limit at 36 months [a]	11 (4,2)	4 (3,1)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	18 (6,9)	4 (3,1)
	Censored due to death	7 (2,7)	3 (2,3)
	Total	260 (100)	131 (100)
FACT-O Eierstockkrebs-spezifische Subskala (OCS)	Deterioration	36 (13,8)	17 (13,0)
	Deterioration confirmed on 2 subsequent visits	23 (8,8)	8 (6,1)
	Deterioration at last observation visit	13 (5,0)	9 (6,9)
	Censored due to last observation (no deterioration)	122 (46,9)	69 (52,7)
	Censored due to 2 or more missed assessments	74 (28,5)	36 (27,5)
	Censored due to PFS-event [a]	10 (3,8)	3 (2,3)
	Censored due to PROs collection limit at 36 months [a]	10 (3,8)	6 (4,6)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	18 (6,9)	4 (3,1)
	Censored due to death	10 (3,8)	5 (3,8)
	Total	260 (100)	131 (100)
EQ-5D visuelle Analogskala	Deterioration	41 (15,8)	33 (25,2)
	Deterioration confirmed on 2 subsequent visits	35 (13,5)	26 (19,8)
	Deterioration at last observation visit	6 (2,3)	7 (5,3)
	Censored due to last observation (no deterioration)	112 (43,1)	59 (45,0)
	Censored due to 2 or more missed assessments	71 (27,3)	33 (25,2)
	Censored due to PFS-event [a]	8 (3,1)	3 (2,3)
	Censored due to PROs collection limit at 36 months [a]	10 (3,8)	7 (5,3)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	23 (8,8)	3 (2,3)
	Censored due to death	13 (5,0)	3 (2,3)
	Total	260 (100)	131 (100)

[a] Subject can potentially contribute to either one or both categories.
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1.8: Sicherheit: Unerwünschte Ereignisse

1.8.1: Unerwünschte Ereignisse nach SOC und PT

1.8.1.1: Unerwünschte Ereignisse unabhängig vom Schweregrad nach SOC und PT

Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE	260	256 (98,5)	0,1 [0,1; 0,1]	130	120 (92,3)	0,3 [0,2; 0,4]	1,69	[1,36; 2,11]	<0,0001*
UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	260	199 (76,5)	1,9 [1,0; 3,1]	130	73 (56,2)	12,5 [5,5;15,7]	1,75	[1,34; 2,31]	<0,0001*
UE PT: Asthenie	260	63 (24,2)	NE [NE; NE]	130	16 (12,3)	NE [NE; NE]	2,05	[1,21; 3,67]	0,0090*
UE PT: Ermuedung	260	108 (41,5)	33,9 [33,9; NE]	130	39 (30,0)	NE [NE; NE]	1,46	[1,02; 2,13]	0,0436*
UE PT: Fieber	260	32 (12,3)	NE [NE; NE]	130	12 (9,2)	NE [NE; NE]	1,17	[0,61; 2,37]	0,6507
UE PT: Grippeaehnliche Erkrankung	260	20 (7,7)	NE [NE; NE]	130	11 (8,5)	NE [NE; NE]	0,78	[0,38; 1,68]	0,4999
UE PT: Oedem peripher	260	25 (9,6)	NE [NE; NE]	130	9 (6,9)	NE [NE; NE]	1,34	[0,64; 3,03]	0,4571
UE PT: Schleimhautentzuendung	260	18 (6,9)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	7,88	[1,62;142,01]	0,0174*
UE PT: Unwohlsein	260	11 (4,2)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	2,50	[0,67; 16,18]	0,2194
UE SOC: Augenerkrankungen	260	23 (8,8)	NE [NE; NE]	130	7 (5,4)	NE [NE; NE]	1,37	[0,61; 3,48]	0,4737
UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums	260	98 (37,7)	34,7 [34,7; NE]	130	42 (32,3)	NE [NE; NE]	1,07	[0,75; 1,55]	0,7194

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Allergische Rhinitis	260	10 (3,8)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	2,13	[0,56; 13,90]	0,3196
UE PT: Dyspnoe	260	41 (15,8)	NE [NE; NE]	130	7 (5,4)	NE [NE; NE]	2,56	[1,22; 6,26]	0,0178*
UE PT: Husten	260	44 (16,9)	NE [NE; NE]	130	28 (21,5)	30,1 [30,1; NE]	0,66	[0,41; 1,07]	0,0840
UE PT: Nasenverstopfung	260	10 (3,8)	NE [NE; NE]	130	6 (4,6)	33,1 [33,1; NE]	0,75	[0,28; 2,22]	0,5813
UE PT: Schmerzen im Oropharynx	260	21 (8,1)	NE [NE; NE]	130	12 (9,2)	33,1 [33,1; NE]	0,69	[0,34; 1,45]	0,3049
UE SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese	260	23 (8,8)	NE [NE; NE]	130	8 (6,2)	NE [NE; NE]	1,28	[0,59; 3,06]	0,5493
UE SOC: Erkrankungen der Haut und des Unterhautgewebes	260	84 (32,3)	54,1 [46,9; NE]	130	32 (24,6)	NE [NE; NE]	1,16	[0,78; 1,77]	0,4818
UE PT: Ausschlag	260	17 (6,5)	NE [NE; NE]	130	11 (8,5)	NE [NE; NE]	0,65	[0,30; 1,45]	0,2698
UE PT: Erythem	260	13 (5,0)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	1,36	[0,47; 4,86]	0,5949
UE PT: Pruritus	260	11 (4,2)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	1,09	[0,37; 3,96]	0,8861
UE SOC: Erkrankungen der Nieren und Harnwege	260	37 (14,2)	NE [NE; NE]	130	10 (7,7)	NE [NE; NE]	1,63	[0,84; 3,48]	0,1692

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Dysurie	260	10 (3,8)	NE [NE; NE]	130	0	NE [NE; NE]	NC	NC	0,0333*
UE SOC: Erkrankungen des Blutes und des Lymphsystems	260	129 (49,6)	16,6 [7,3;51,7]	130	24 (18,5)	NE [NE; NE]	3,12	[2,06; 4,94]	<0,0001*
UE PT: Anaemie	260	102 (39,2)	49,7 [44,5; NE]	130	12 (9,2)	NE [NE; NE]	4,87	[2,79; 9,35]	<0,0001*
UE PT: Leukopenie	260	17 (6,5)	NE [NE; NE]	130	5 (3,8)	NE [NE; NE]	1,67	[0,66; 5,09]	0,3071
UE PT: Lymphopenie	260	12 (4,6)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	2,88	[0,78; 18,55]	0,1472
UE PT: Neutropenie	260	41 (15,8)	NE [NE; NE]	130	9 (6,9)	NE [NE; NE]	2,27	[1,16; 4,99]	0,0221*
UE PT: Thrombozytopenie	260	21 (8,1)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	5,13	[1,50; 32,05]	0,0139*
UE SOC: Erkrankungen des Gastrointestinaltrakts	260	240 (92,3)	0,2 [0,1; 0,2]	130	97 (74,6)	3,1 [1,9; 4,6]	2,28	[1,80; 2,90]	<0,0001*
UE PT: Abdominalschmerz	260	67 (25,8)	81,1 [29,3; NE]	130	25 (19,2)	29,3 [29,3; NE]	1,22	[0,78; 1,97]	0,4004
UE PT: Bauch aufgetrieben	260	20 (7,7)	NE [NE; NE]	130	10 (7,7)	NE [NE; NE]	0,83	[0,40; 1,87]	0,6424
UE PT: Diarrhoe	260	90 (34,6)	NE [NE; NE]	130	32 (24,6)	NE [NE; NE]	1,43	[0,96; 2,17]	0,0854
UE PT: Dyspepsie	260	43 (16,5)	NE [NE; NE]	130	16 (12,3)	NE [NE; NE]	1,24	[0,71; 2,26]	0,4719

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO. Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Erbrechen	260	104 (40,0)	NE [NE; NE]	130	19 (14,6)	NE [NE; NE]	3,06	[1,92; 5,14]	<0,0001*
UE PT: Flatulenz	260	12 (4,6)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	2,80	[0,76; 18,02]	0,1602
UE PT: Gastrooesophageale Refluxerkrankung	260	11 (4,2)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	1,28	[0,43; 4,62]	0,6768
UE PT: Haemorrhoiden	260	11 (4,2)	NE [NE; NE]	130	0	NE [NE; NE]	NC	NC	0,0323*
UE PT: Mundtrockenheit	260	10 (3,8)	NE [NE; NE]	130	6 (4,6)	NE [NE; NE]	0,81	[0,30; 2,39]	0,6879
UE PT: Obstipation	260	72 (27,7)	NE [NE; NE]	130	25 (19,2)	NE [NE; NE]	1,42	[0,91; 2,28]	0,1310
UE PT: Schmerzen Oberbauch	260	45 (17,3)	NE [NE; NE]	130	17 (13,1)	NE [NE; NE]	1,29	[0,75; 2,31]	0,3761
UE PT: Stomatitis	260	23 (8,8)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	3,67	[1,28; 15,50]	0,0234*
UE PT: Uebelkeit	260	202 (77,7)	0,3 [0,2; 0,3]	130	49 (37,7)	NE [NE; NE]	3,32	[2,45; 4,60]	<0,0001*
UE SOC: Erkrankungen des Immunsystems	260	14 (5,4)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	2,77	[0,77; 17,69]	0,1624
UE SOC: Erkrankungen des Nervensystems	260	158 (60,8)	6,0 [3,1; 8,2]	130	62 (47,7)	18,4 [7,1; NE]	1,44	[1,08; 1,94]	0,0165*
UE PT: Dysgeusie	260	56 (21,5)	NE [NE; NE]	130	5 (3,8)	NE [NE; NE]	5,97	[2,64; 17,13]	<0,0001*

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO. Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Geschmacksstoerung	260	12 (4,6)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	6,00	[1,18;109,30]	0,0500
UE PT: Kopfschmerzen	260	60 (23,1)	NE [NE; NE]	130	31 (23,8)	NE [NE; NE]	0,88	[0,57; 1,37]	0,5579
UE PT: Paraesthesie	260	10 (3,8)	NE [NE; NE]	130	5 (3,8)	NE [NE; NE]	0,88	[0,31; 2,84]	0,8189
UE PT: Periphere Neuropathie	260	15 (5,8)	NE [NE; NE]	130	7 (5,4)	NE [NE; NE]	0,99	[0,41; 2,60]	0,9803
UE PT: Schwindelgefuehl	260	53 (20,4)	NE [NE; NE]	130	20 (15,4)	NE [NE; NE]	1,23	[0,75; 2,12]	0,4268
UE PT: Somnolenz	260	10 (3,8)	NE [NE; NE]	130	0	NE [NE; NE]	NC	NC	0,0242*
UE SOC: Erkrankungen des Ohrs und des Labyrinths	260	18 (6,9)	NE [NE; NE]	130	10 (7,7)	37,6 [37,6; NE]	0,76	[0,35; 1,72]	0,4877
UE SOC: Gefaesserkrankungen	260	40 (15,4)	NE [NE; NE]	130	23 (17,7)	NE [NE; NE]	0,76	[0,46; 1,29]	0,2897
UE PT: Hitzewallung	260	17 (6,5)	NE [NE; NE]	130	11 (8,5)	NE [NE; NE]	0,71	[0,33; 1,57]	0,3753
UE PT: Hypertonie	260	9 (3,5)	NE [NE; NE]	130	12 (9,2)	NE [NE; NE]	0,30	[0,12; 0,73]	0,0051*
UE SOC: Herzerkrankungen	260	20 (7,7)	NE [NE; NE]	130	7 (5,4)	NE [NE; NE]	1,18	[0,52; 3,02]	0,7127
UE PT: Palpitationen	260	13 (5,0)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	2,60	[0,71; 16,67]	0,1939

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE SOC: Infektionen und parasitaere Erkrankungen	260	148 (56,9)	13,5 [10,0;15,4]	130	67 (51,5)	11,8 [9,4;18,4]	0,95	[0,72; 1,28]	0,7535
UE PT: Bronchitis	260	13 (5,0)	NE [NE; NE]	130	0	NE [NE; NE]	NC	NC	0,0268*
UE PT: Gastroenteritis	260	10 (3,8)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	1,54	[0,40; 10,14]	0,5763
UE PT: Grippe	260	18 (6,9)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	2,53	[0,85; 10,81]	0,1250
UE PT: Harnwegsinfektion	260	31 (11,9)	NE [NE; NE]	130	8 (6,2)	NE [NE; NE]	1,76	[0,85; 4,11]	0,1504
UE PT: Infektion der oberen Atemwege	260	30 (11,5)	NE [NE; NE]	130	12 (9,2)	NE [NE; NE]	0,96	[0,50; 1,97]	0,9063
UE PT: Nasopharyngitis	260	28 (10,8)	NE [NE; NE]	130	17 (13,1)	NE [NE; NE]	0,67	[0,37; 1,25]	0,1882
UE PT: Sinusitis	260	11 (4,2)	NE [NE; NE]	130	8 (6,2)	NE [NE; NE]	0,56	[0,22; 1,45]	0,2074
UE PT: Zystitis	260	15 (5,8)	NE [NE; NE]	130	5 (3,8)	NE [NE; NE]	1,37	[0,53; 4,22]	0,5433
UE SOC: Psychiatrische Erkrankungen	260	53 (20,4)	NE [NE; NE]	130	35 (26,9)	NE [NE; NE]	0,68	[0,45; 1,06]	0,0792
UE PT: Angst	260	17 (6,5)	NE [NE; NE]	130	11 (8,5)	NE [NE; NE]	0,67	[0,31; 1,48]	0,2951
UE PT: Depression	260	14 (5,4)	NE [NE; NE]	130	13 (10,0)	NE [NE; NE]	0,50	[0,23; 1,07]	0,0656
UE PT: Schlaflosigkeit	260	27 (10,4)	NE [NE; NE]	130	16 (12,3)	NE [NE; NE]	0,80	[0,43; 1,52]	0,4772

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	260	146 (56,2)	11,8 [8,4;14,8]	130	63 (48,5)	12,0 [5,0; NE]	1,03	[0,77; 1,39]	0,8435
UE PT: Arthralgie	260	75 (28,8)	NE [NE; NE]	130	39 (30,0)	29,0 [29,0; NE]	0,85	[0,58; 1,26]	0,4033
UE PT: Brustschmerzen die Skelettmuskulatur betreffend	260	12 (4,6)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	0,90	[0,30; 3,30]	0,8572
UE PT: Muskelspasmen	260	18 (6,9)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	7,58	[1,55;136,62]	0,0206*
UE PT: Myalgie	260	26 (10,0)	NE [NE; NE]	130	13 (10,0)	NE [NE; NE]	0,81	[0,42; 1,63]	0,5311
UE PT: Rueckenschmerzen	260	42 (16,2)	NE [NE; NE]	130	16 (12,3)	NE [NE; NE]	1,08	[0,62; 1,99]	0,7855
UE PT: Schmerz in einer Extremitaet	260	30 (11,5)	NE [NE; NE]	130	11 (8,5)	NE [NE; NE]	1,22	[0,63; 2,55]	0,5802
UE SOC: Stoffwechsel- und Ernaehrungsstoerungen	260	90 (34,6)	52,5 [28,3; NE]	130	29 (22,3)	NE [NE; NE]	1,54	[1,03; 2,39]	0,0428*
UE PT: Appetit vermindert	260	53 (20,4)	NE [NE; NE]	130	13 (10,0)	NE [NE; NE]	2,03	[1,14; 3,89]	0,0201*
UE PT: Hypokaliaemie	260	15 (5,8)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	2,45	[0,81; 10,60]	0,1438
UE PT: Hypomagnesiaemie	260	14 (5,4)	NE [NE; NE]	130	9 (6,9)	NE [NE; NE]	0,70	[0,30; 1,68]	0,4020

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE SOC: Untersuchungen	260	79 (30,4)	74,5 [34,9; NE]	130	43 (33,1)	NE [NE; NE]	0,80	[0,55; 1,17]	0,2442
UE PT: Alaninaminotransferase erhoeht	260	12 (4,6)	NE [NE; NE]	130	10 (7,7)	41,6 [NE; NE]	0,32	[0,13; 0,82]	0,0119*
UE PT: Aspartataminotransferase erhoeht	260	13 (5,0)	NE [NE; NE]	130	7 (5,4)	55,4 [NE; NE]	0,62	[0,24; 1,69]	0,3213
UE PT: Gewicht erhoeht	260	14 (5,4)	NE [NE; NE]	130	12 (9,2)	NE [NE; NE]	0,51	[0,23; 1,12]	0,0820
UE PT: Kreatinin im Blut erhoeht	260	22 (8,5)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	4,61	[1,35; 28,86]	0,0237*
UE PT: Leukozytenzahl erniedrigt	260	16 (6,2)	NE [NE; NE]	130	6 (4,6)	NE [NE; NE]	1,16	[0,47; 3,24]	0,7599
UE PT: Neutrophilenzahl erniedrigt	260	20 (7,7)	NE [NE; NE]	130	7 (5,4)	NE [NE; NE]	1,38	[0,61; 3,52]	0,4683
UE PT: Thrombozytenzahl vermindert	260	10 (3,8)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	1,53	[0,46; 6,85]	0,5211
UE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	260	56 (21,5)	NE [NE; NE]	130	25 (19,2)	NE [NE; NE]	0,91	[0,57; 1,49]	0,7027

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Baenderzerrung	260	10 (3,8)	NE [NE; NE]	130	0	NE [NE; NE]	NC	NC	0,0437*

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties.
Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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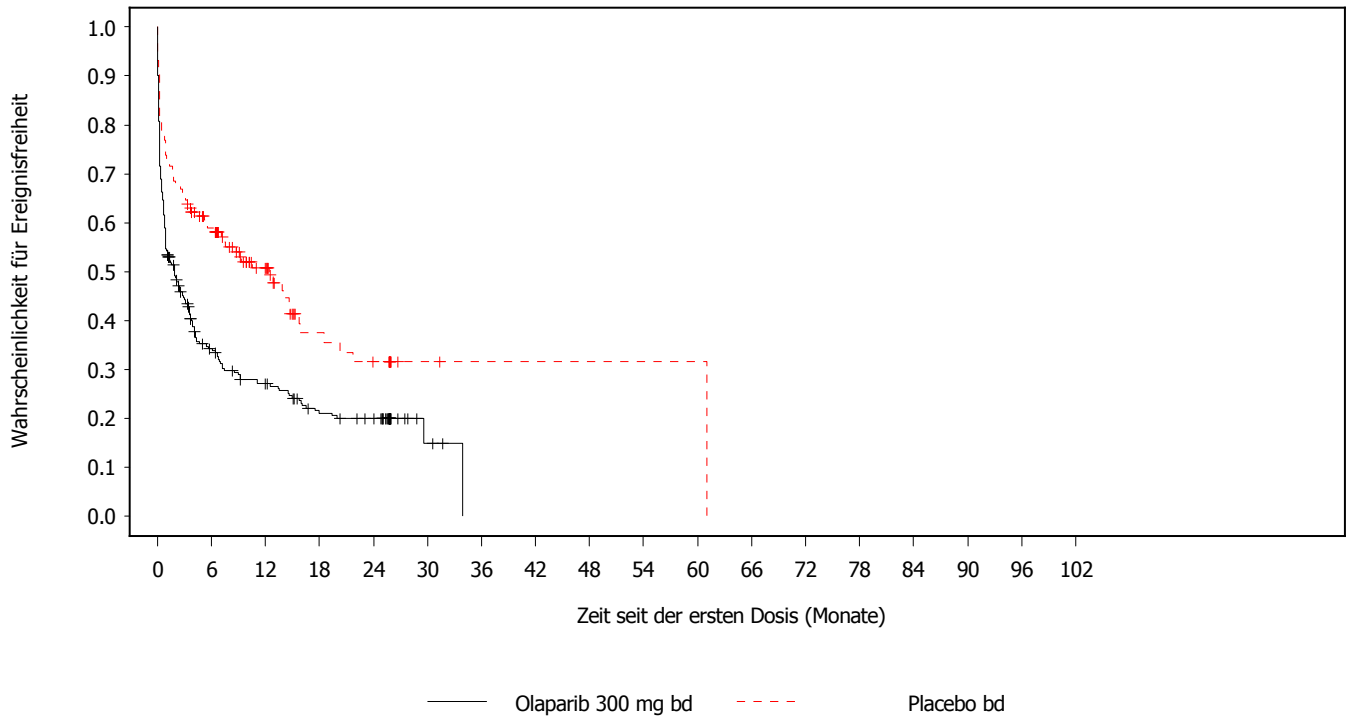
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.2 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

260	77	57	40	35	3	0	0	0	0	0	0	0	0	0	0	0	0	Olaparib 300 mg bd
130	69	39	19	15	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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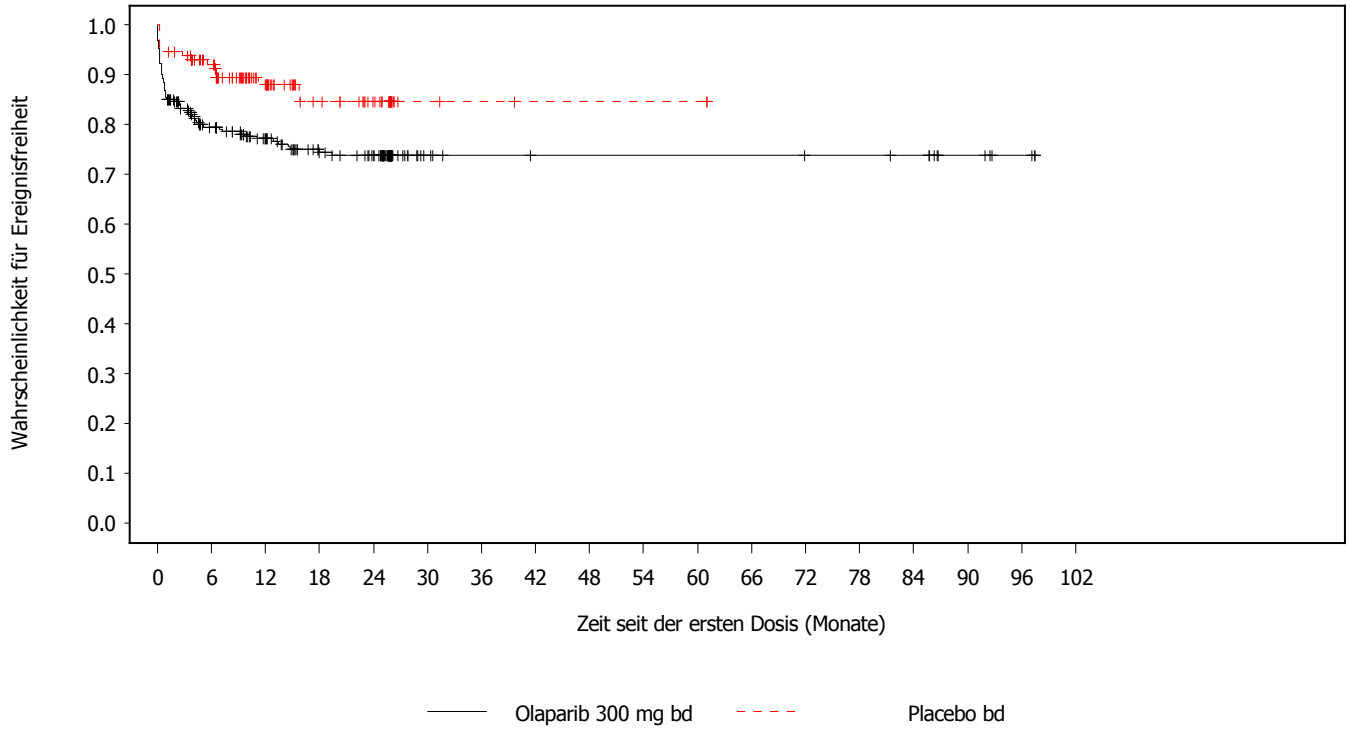
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.3 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Asthenie
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

260	179	153	129	119	16	13	12	12	12	12	12	11	11	10	5	2	0	Olaparib 300 mg bd
130	105	69	46	37	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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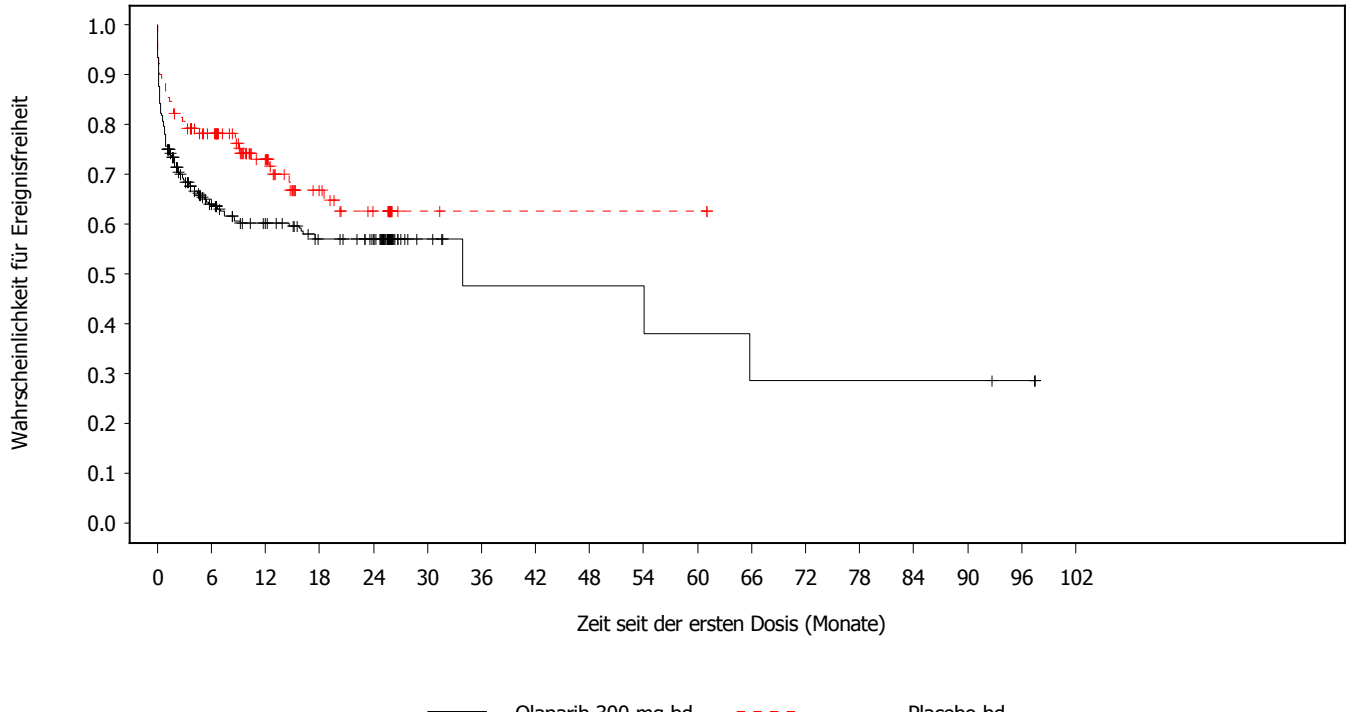
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.4 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Ermuedung
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

260	141	119	104	97	9	5	5	5	5	4	3	3	3	3	3	2	0	Olaparib 300 mg bd
130	90	57	33	24	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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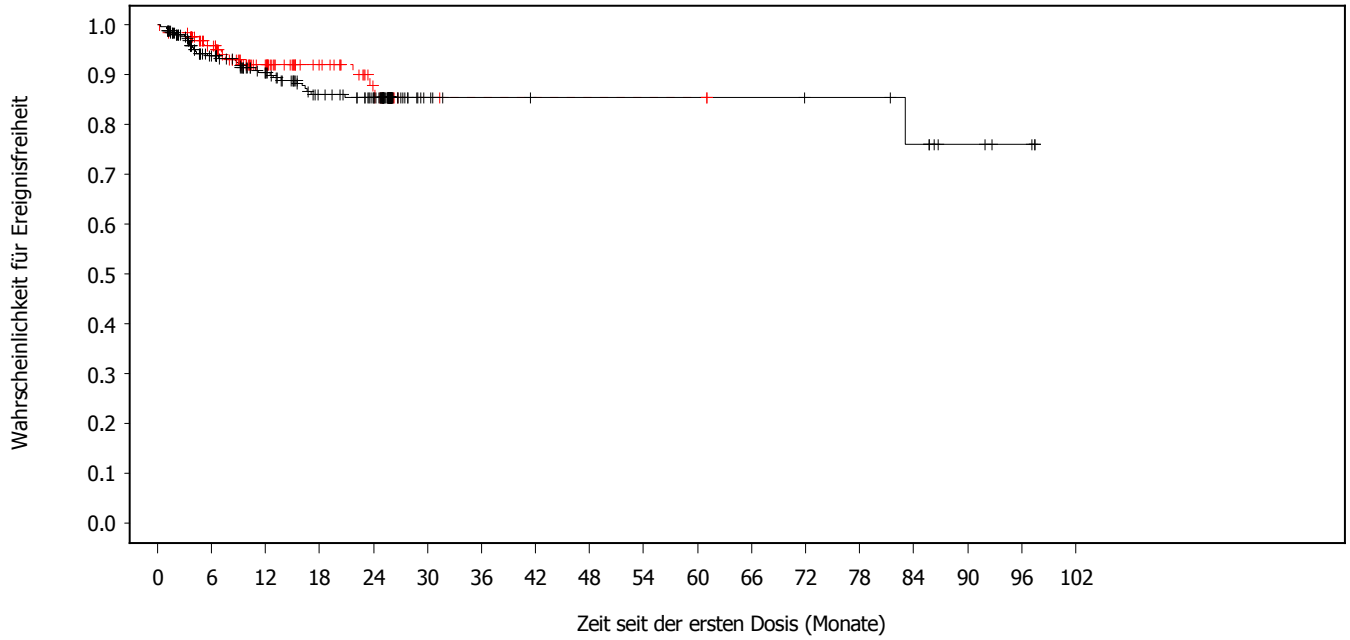
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.5 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Fieber
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

260	210	180	153	140	15	12	11	11	11	11	11	10	10	8	4	2	0	Olaparib 300 mg bd
130	109	76	52	38	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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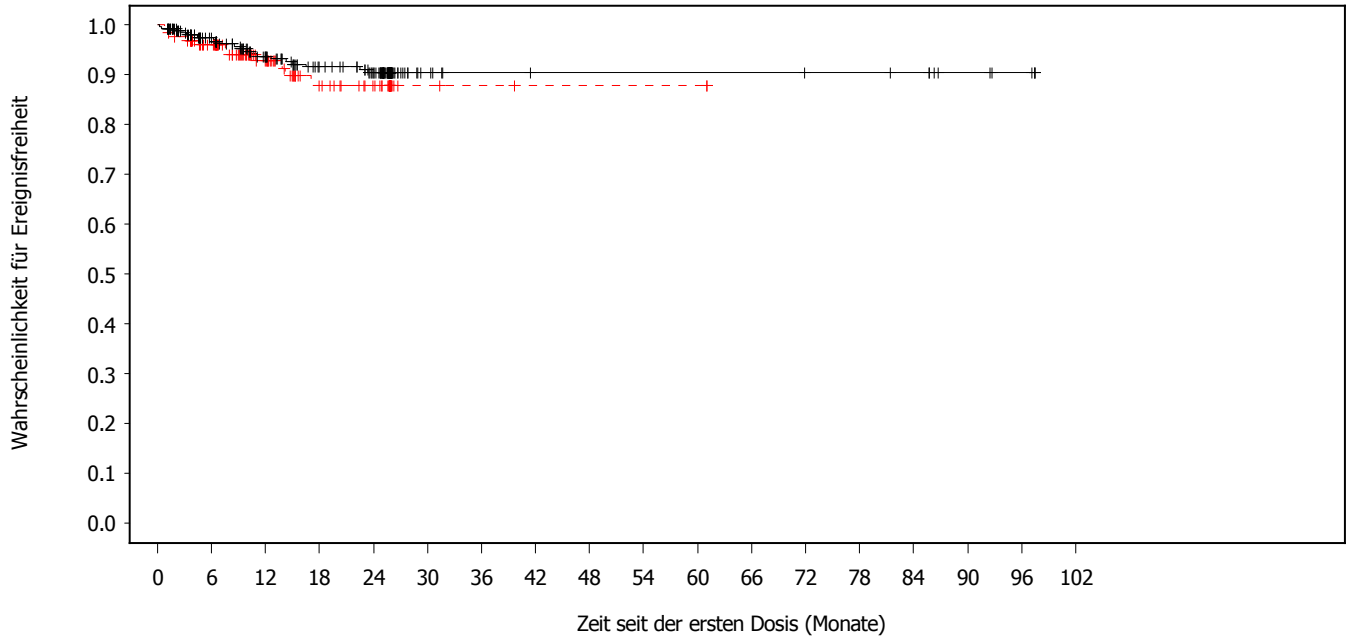
Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.6 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Grippeaehnliche Erkrankung
Safety Analysis Set, DCO 07MAR2022



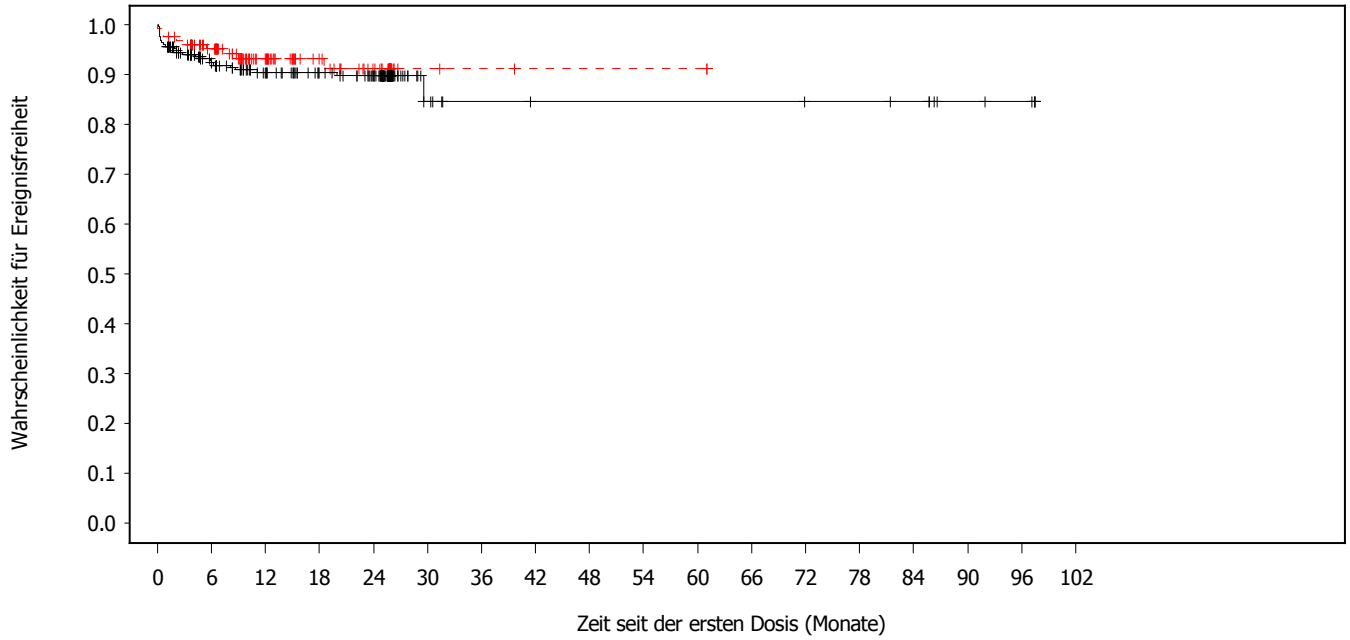
Anzahl an Patienten unter Risiko:

260	218	184	160	144	16	12	11	11	11	11	11	10	10	9	5	3	0	Olaparib 300 mg bd
130	108	72	47	38	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebaf 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.7 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Oedem peripher
Safety Analysis Set, DCO 07MAR2022



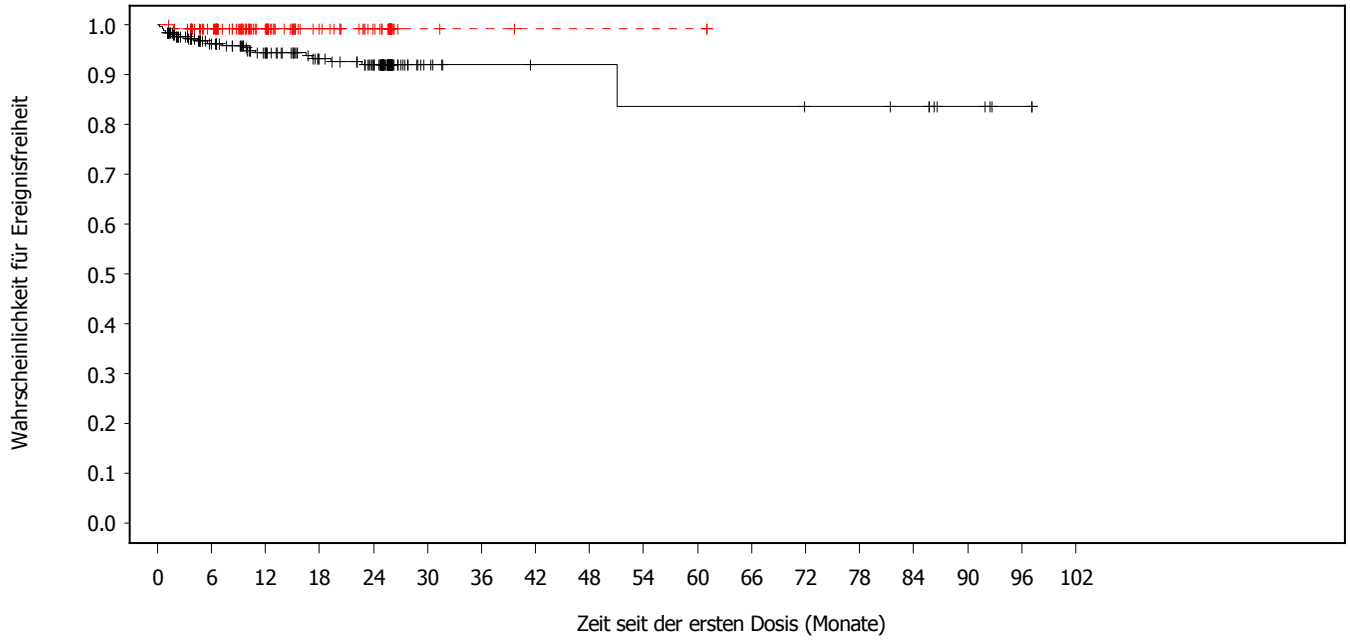
Anzahl an Patienten unter Risiko:

260	209	181	164	150	15	11	10	10	10	10	10	9	9	8	4	3	0	Olaparib 300 mg bd
130	108	74	50	38	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebag 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.8 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schleimhautentzuendung
Safety Analysis Set, DCO 07MAR2022



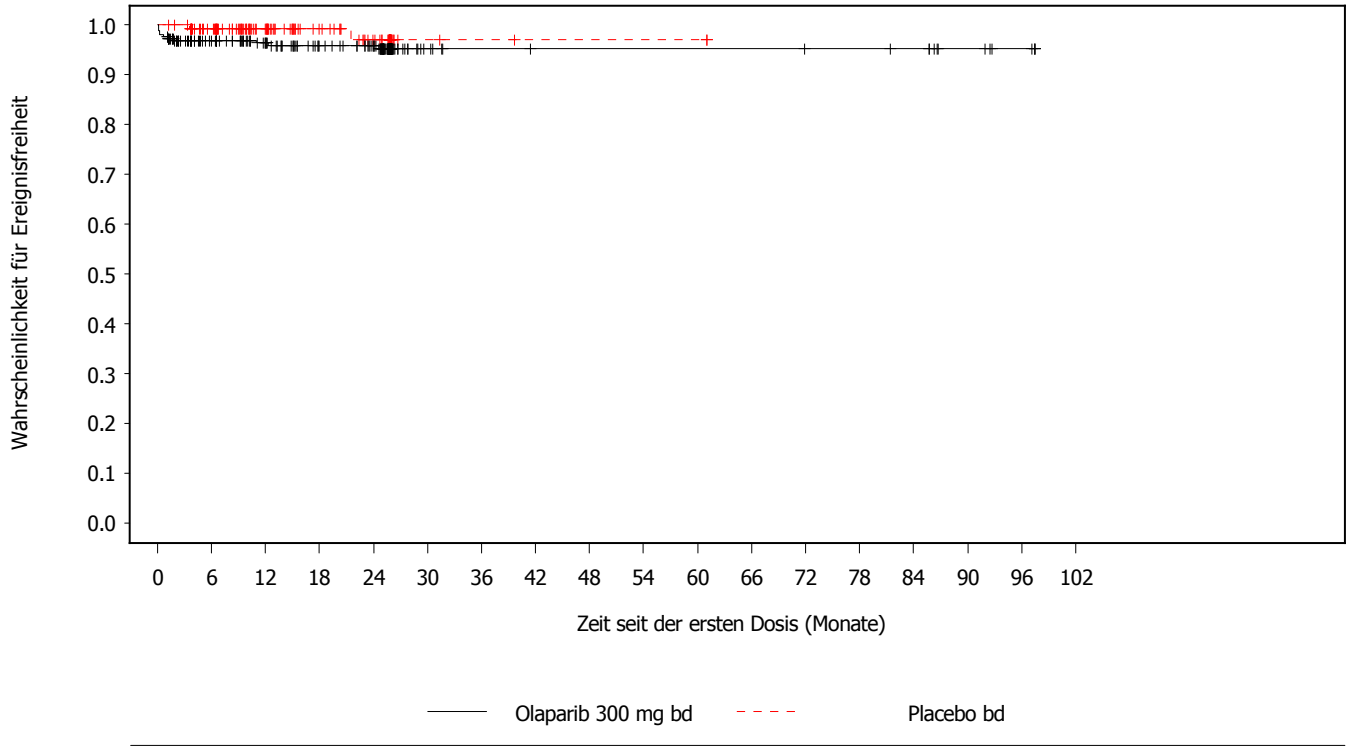
Anzahl an Patienten unter Risiko:

260	216	186	163	148	16	12	11	11	10	10	10	9	9	8	4	1	0	Olaparib 300 mg bd
130	113	79	53	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebah 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.9 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Unwohlsein
Safety Analysis Set, DCO 07MAR2022



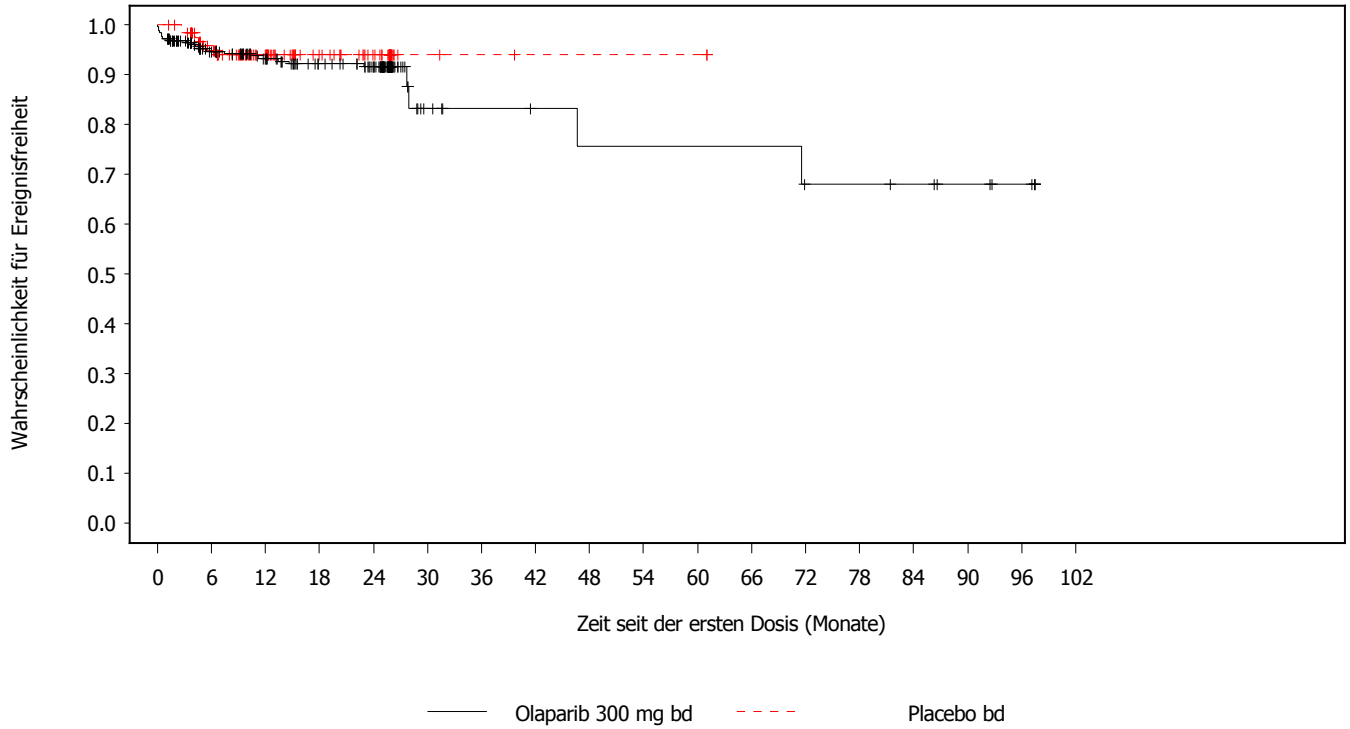
Anzahl an Patienten unter Risiko:

260	220	194	171	158	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	112	78	53	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebai 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.10 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Augenerkrankungen
Safety Analysis Set, DCO 07MAR2022



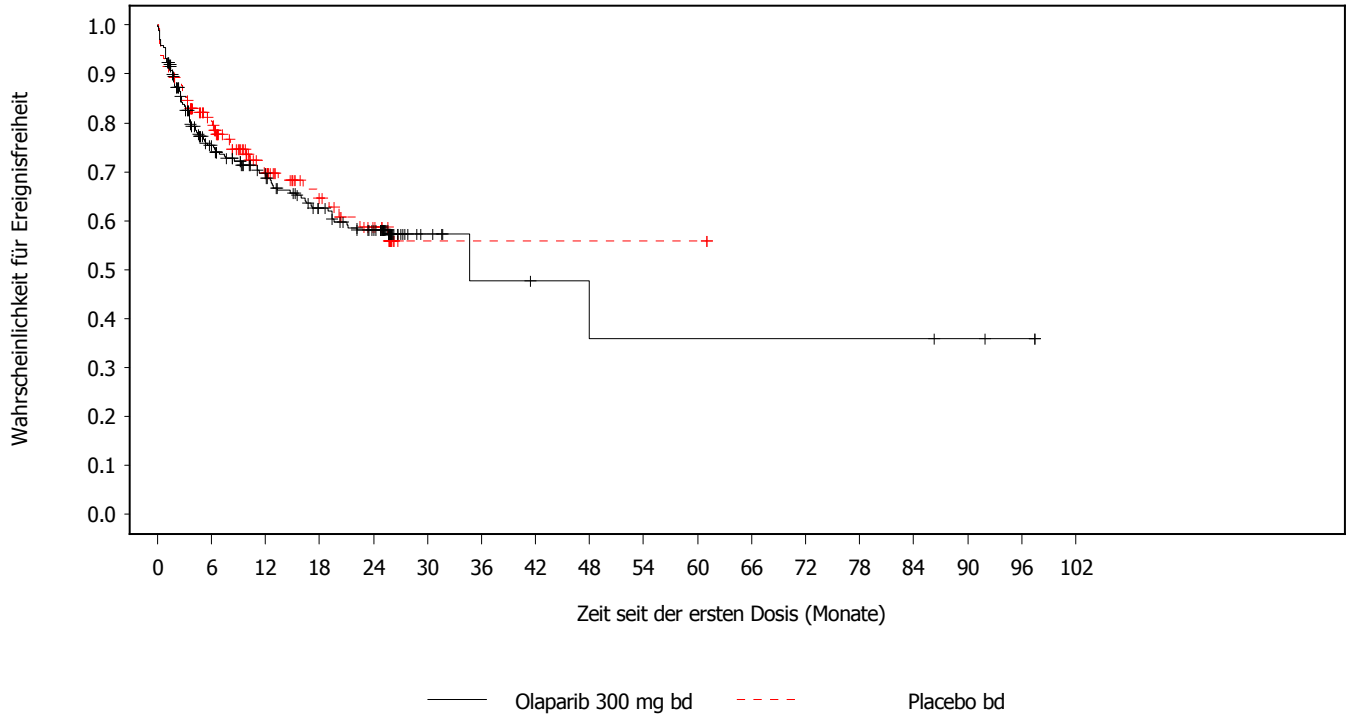
Anzahl an Patienten unter Risiko:

260	211	184	163	150	15	12	11	10	10	10	10	8	8	7	5	3	0	Olaparib 300 mg bd
130	107	73	49	37	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebaj 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.11 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 07MAR2022



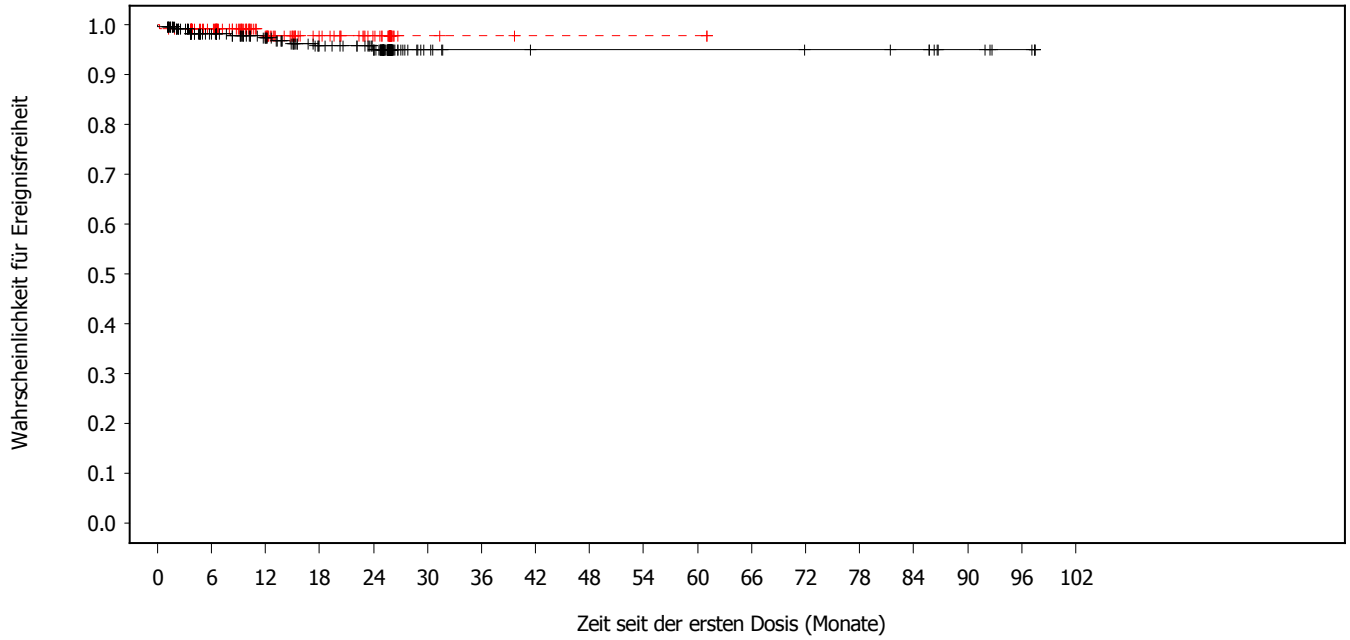
Anzahl an Patienten unter Risiko:

260	170	138	114	97	9	5	4	4	3	3	3	3	3	3	2	1	0	Olaparib 300 mg bd
130	92	54	35	25	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebak 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.12 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Allergische Rhinitis
Safety Analysis Set, DCO 07MAR2022



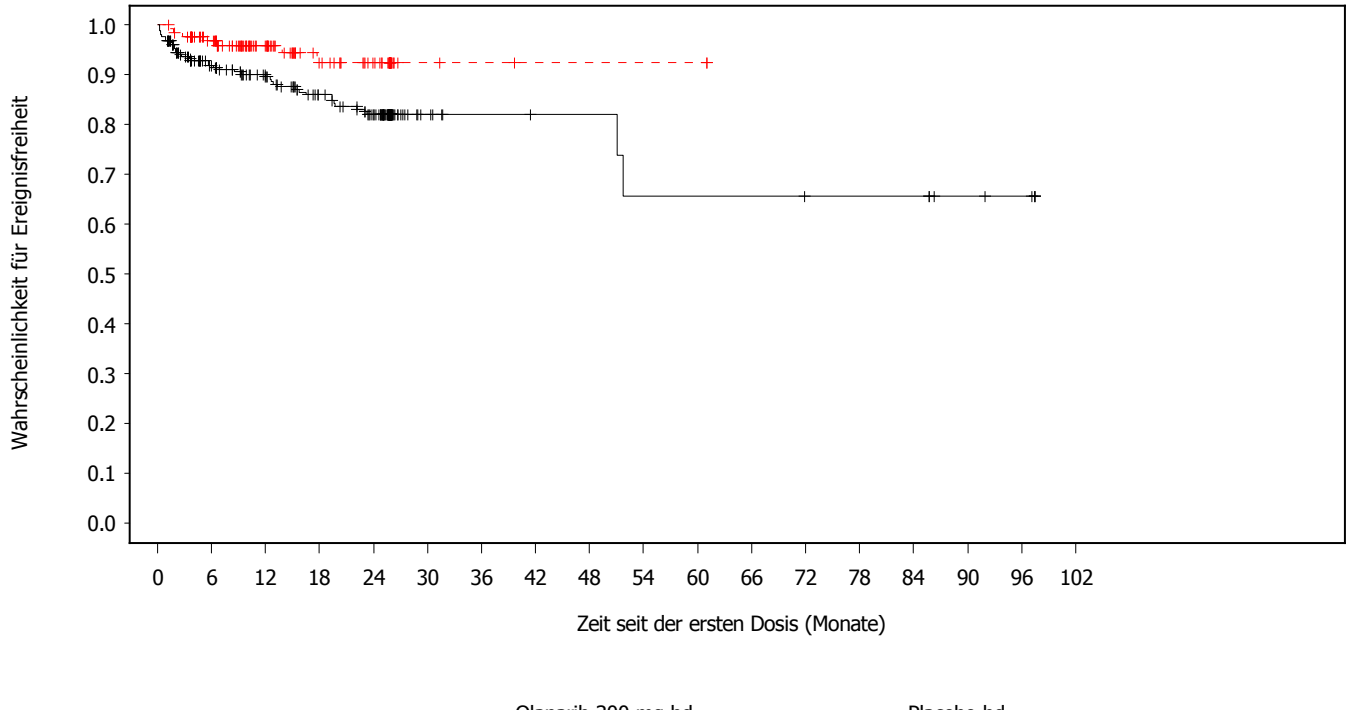
Anzahl an Patienten unter Risiko:

260	220	193	168	154	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	112	77	52	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebal 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.13 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Dyspnoe
Safety Analysis Set, DCO 07MAR2022



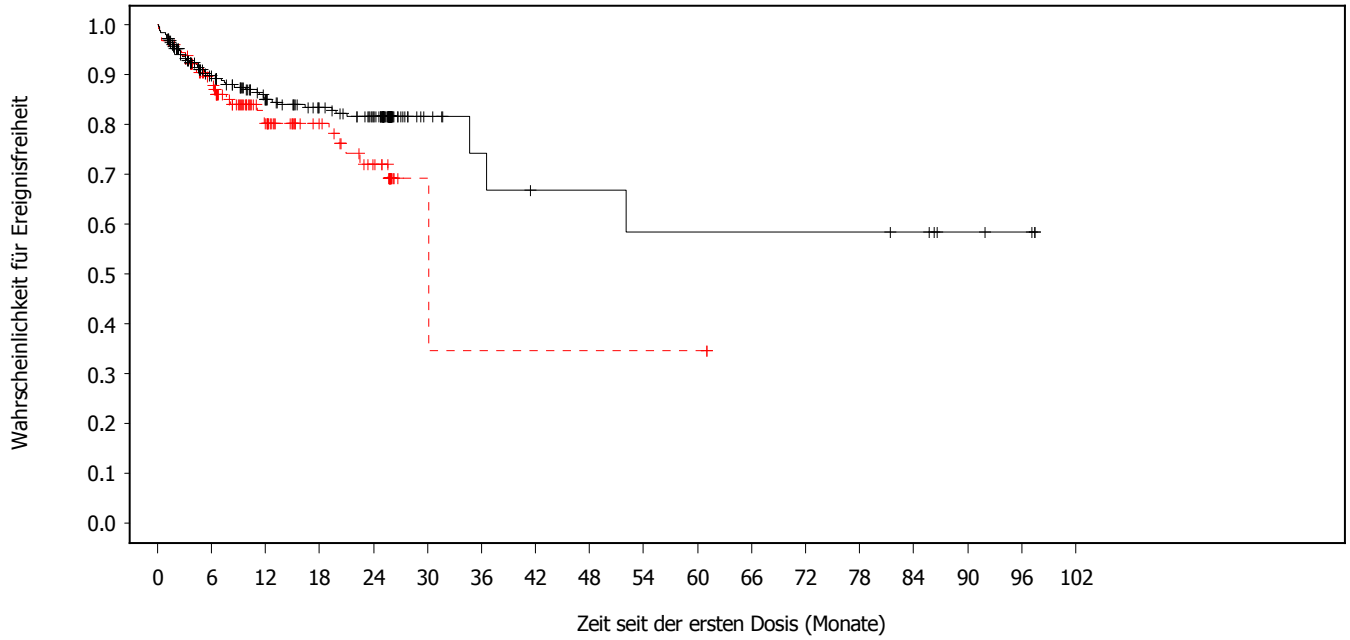
Anzahl an Patienten unter Risiko:

260	207	180	155	136	15	11	10	10	8	8	8	7	7	7	4	3	0	Olaparib 300 mg bd
130	110	76	50	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebam 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.14 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Husten
Safety Analysis Set, DCO 07MAR2022



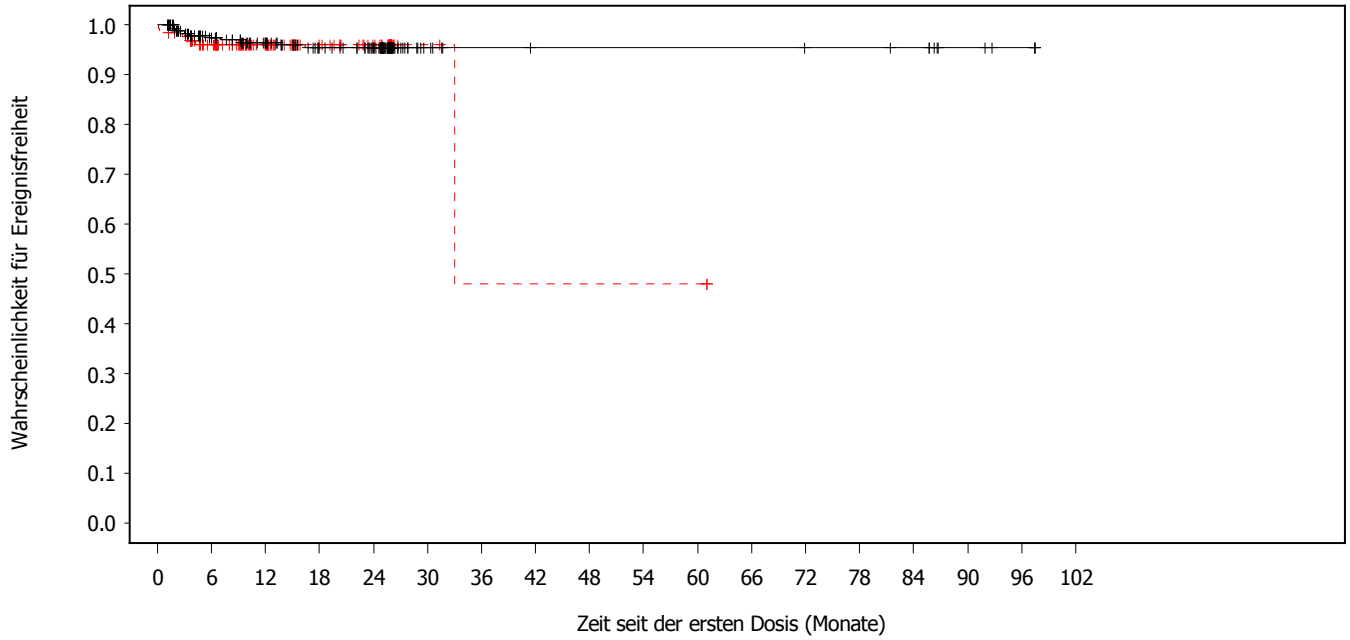
Anzahl an Patienten unter Risiko:

260	202	168	149	133	14	10	8	8	7	7	7	7	7	6	3	2	0	Olaparib 300 mg bd
130	102	62	42	30	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaeban 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.15 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Nasenverstopfung
Safety Analysis Set, DCO 07MAR2022



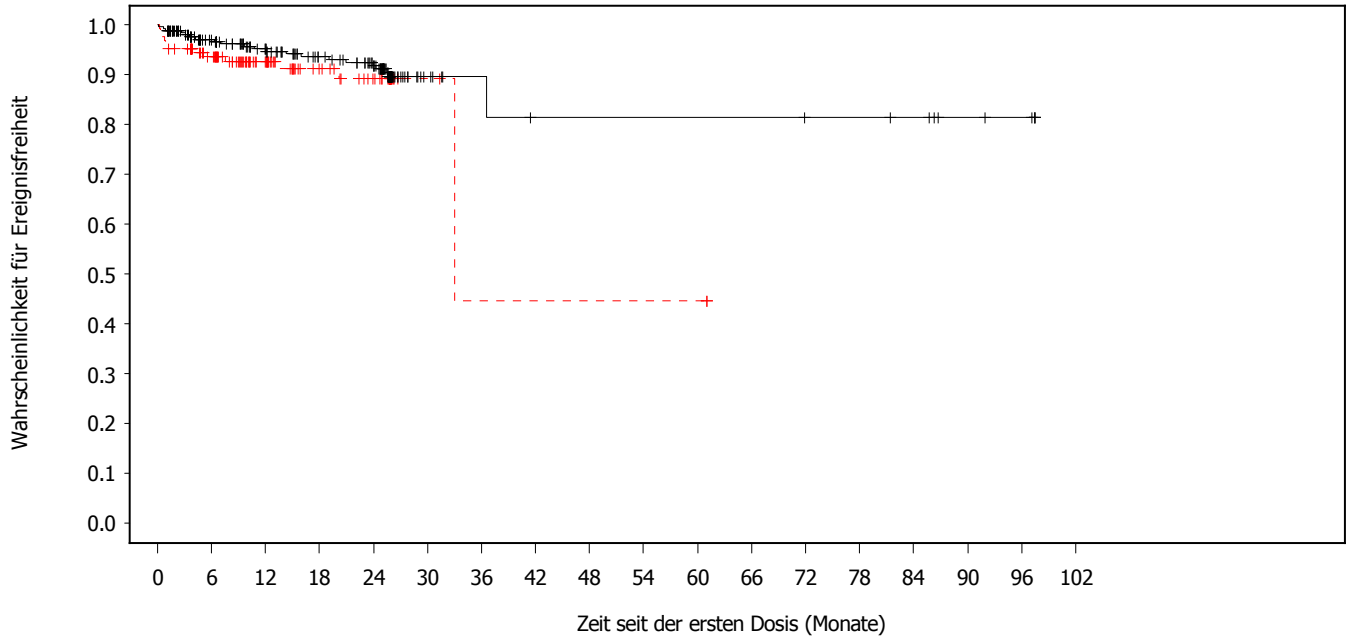
Anzahl an Patienten unter Risiko:

260	218	192	170	156	16	12	11	11	11	11	11	10	10	9	4	2	0	Olaparib 300 mg bd
130	109	77	52	41	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebao 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.16 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerzen im Oropharynx
Safety Analysis Set, DCO 07MAR2022



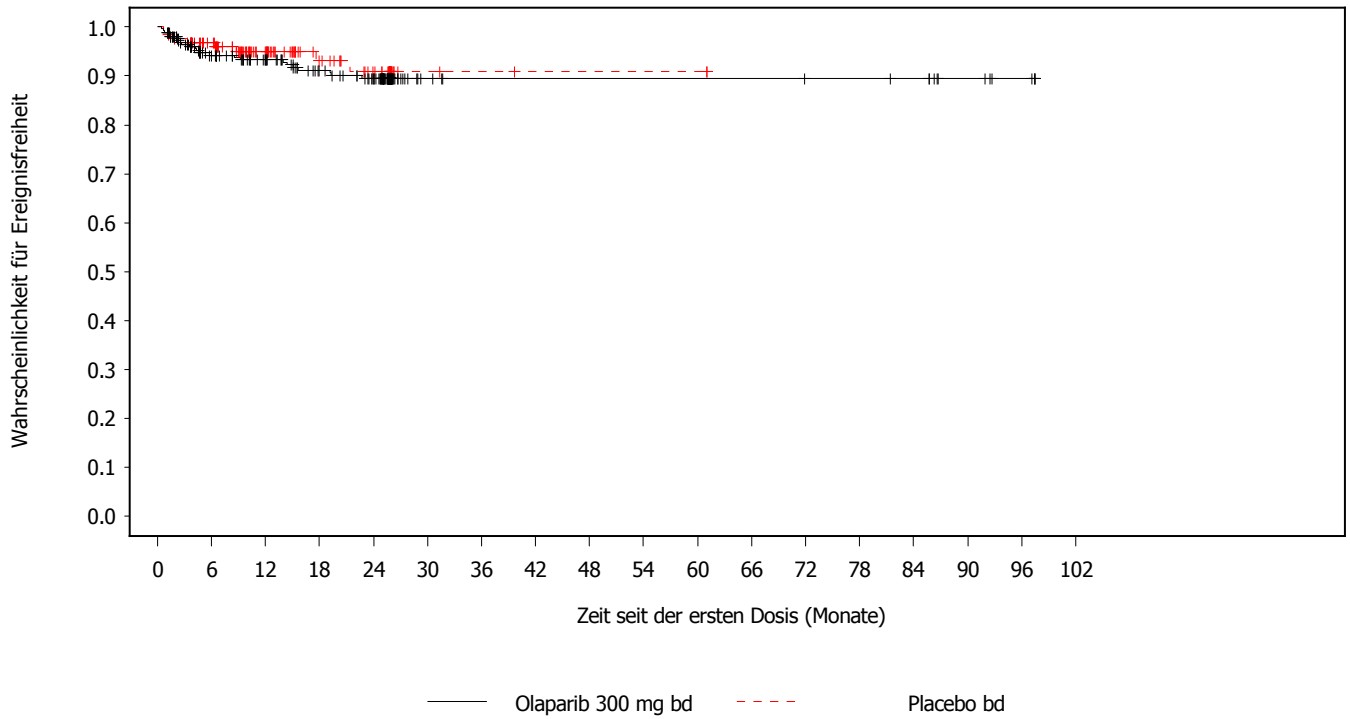
Anzahl an Patienten unter Risiko:

260	217	188	164	148	15	11	9	9	9	9	9	8	8	7	4	3	0	Olaparib 300 mg bd
130	106	74	50	40	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebap 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.17 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese
Safety Analysis Set, DCO 07MAR2022



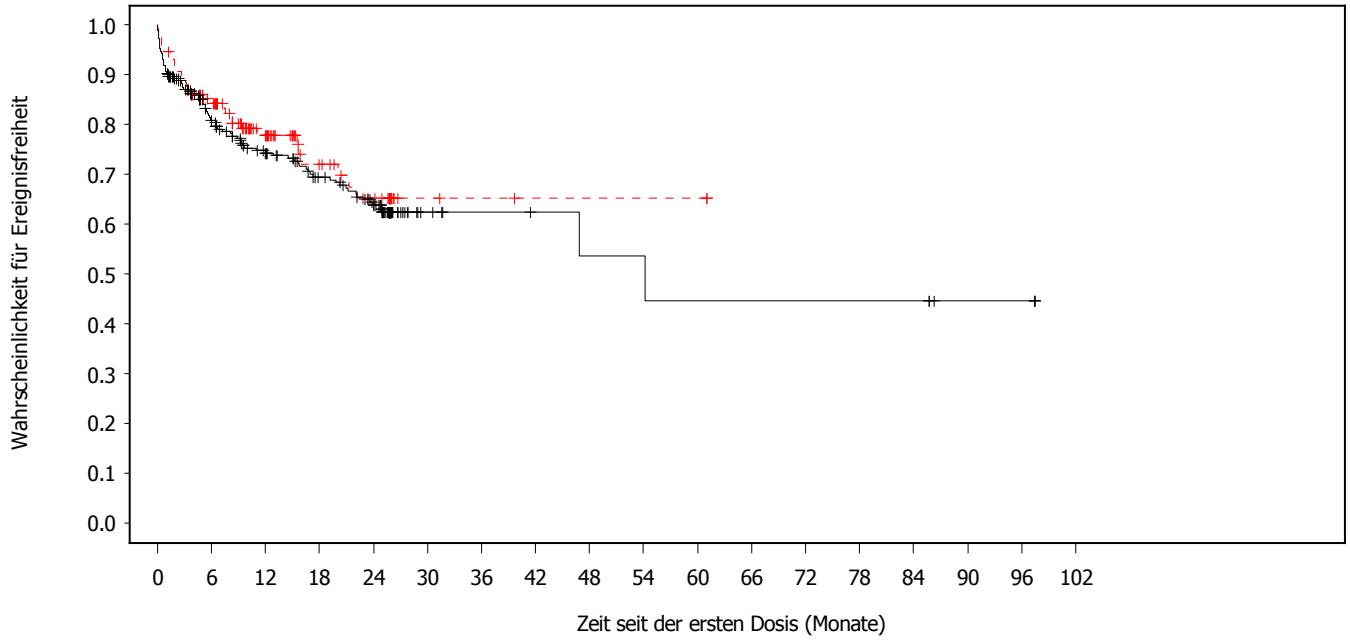
Anzahl an Patienten unter Risiko:

260	210	186	163	148	16	13	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	109	74	48	37	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebaq 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.18 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Haut und des Unterhautgewebes
Safety Analysis Set, DCO 07MAR2022



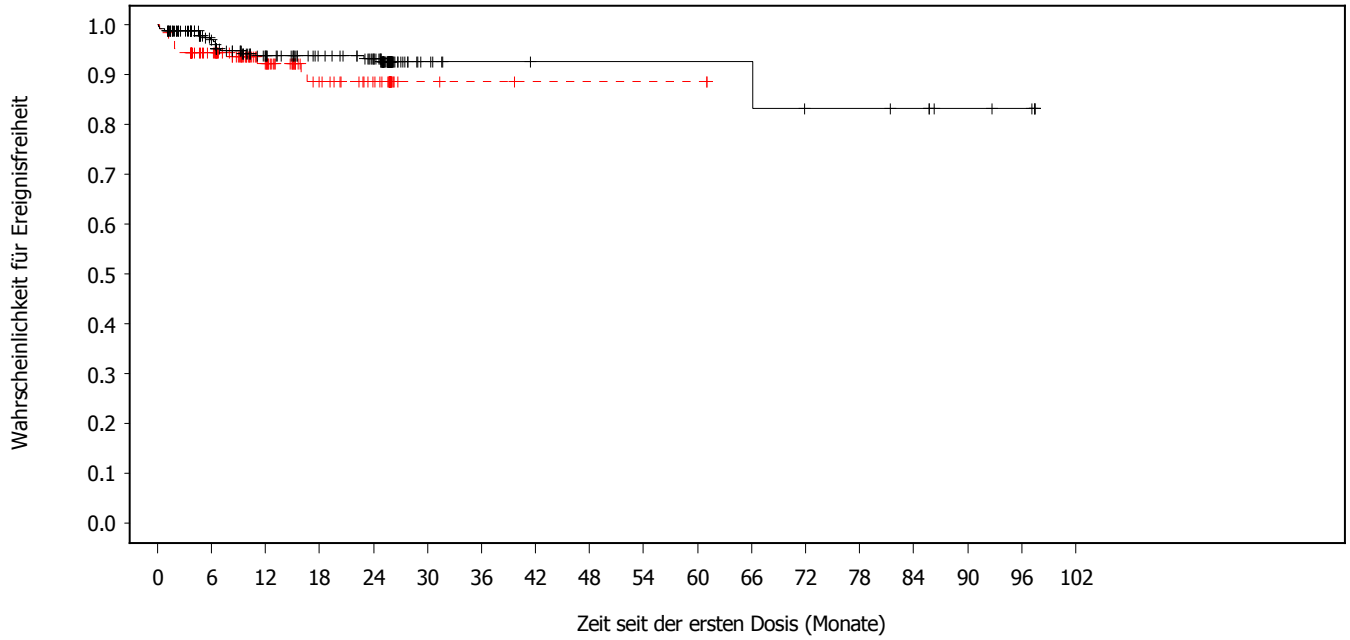
Anzahl an Patienten unter Risiko:

260	181	147	125	107	11	8	7	6	6	5	5	5	5	2	2	0	Olaparib 300 mg bd
130	95	59	35	26	3	2	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebar 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.19 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Ausschlag
Safety Analysis Set, DCO 07MAR2022



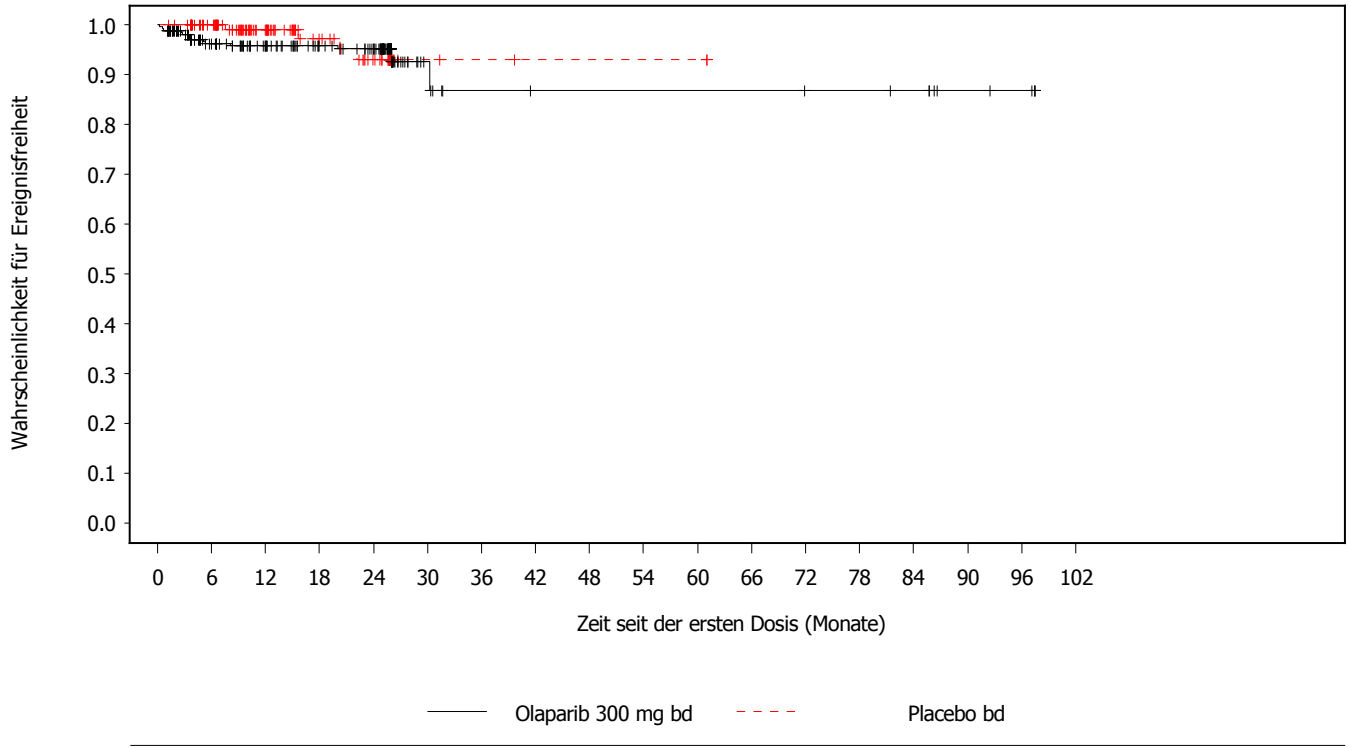
Anzahl an Patienten unter Risiko:

260	217	184	166	153	15	11	10	10	10	10	10	8	8	7	4	3	0	Olaparib 300 mg bd
130	108	72	46	36	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebas 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.20 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Erythem
Safety Analysis Set, DCO 07MAR2022



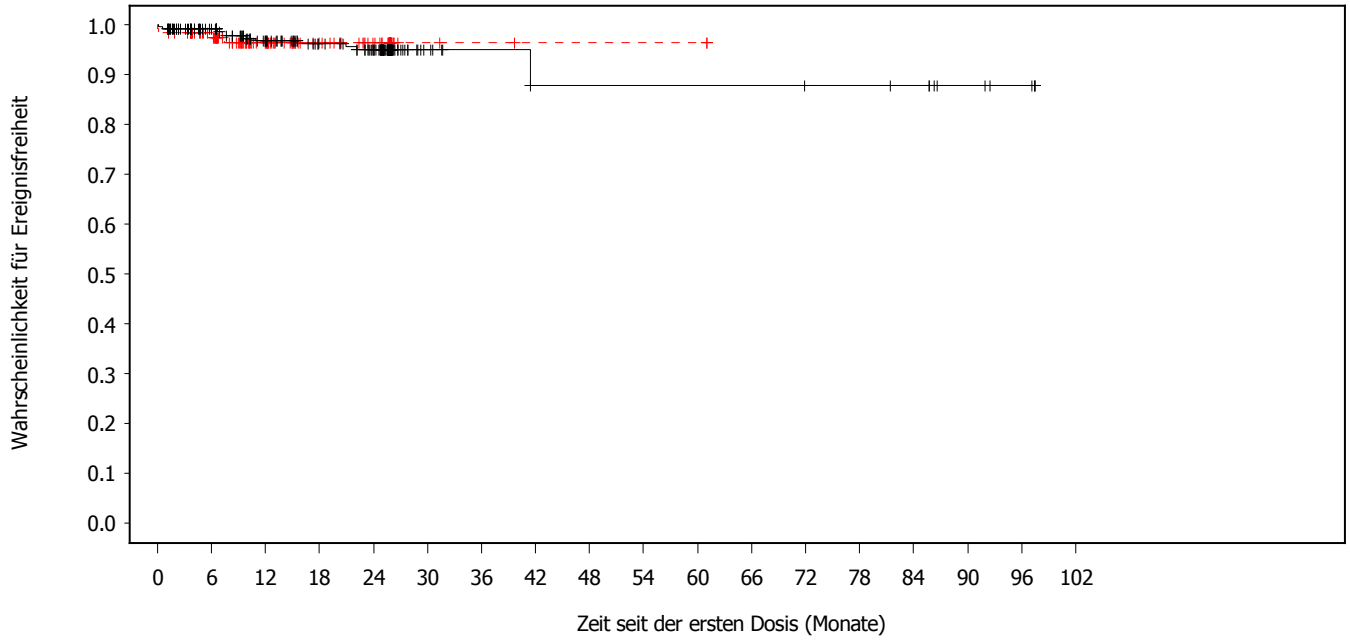
Anzahl an Patienten unter Risiko:

260	215	190	169	157	16	11	10	10	10	10	10	9	9	8	4	3	0	Olaparib 300 mg bd
130	113	78	51	38	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebat 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.21 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Pruritus
Safety Analysis Set, DCO 07MAR2022



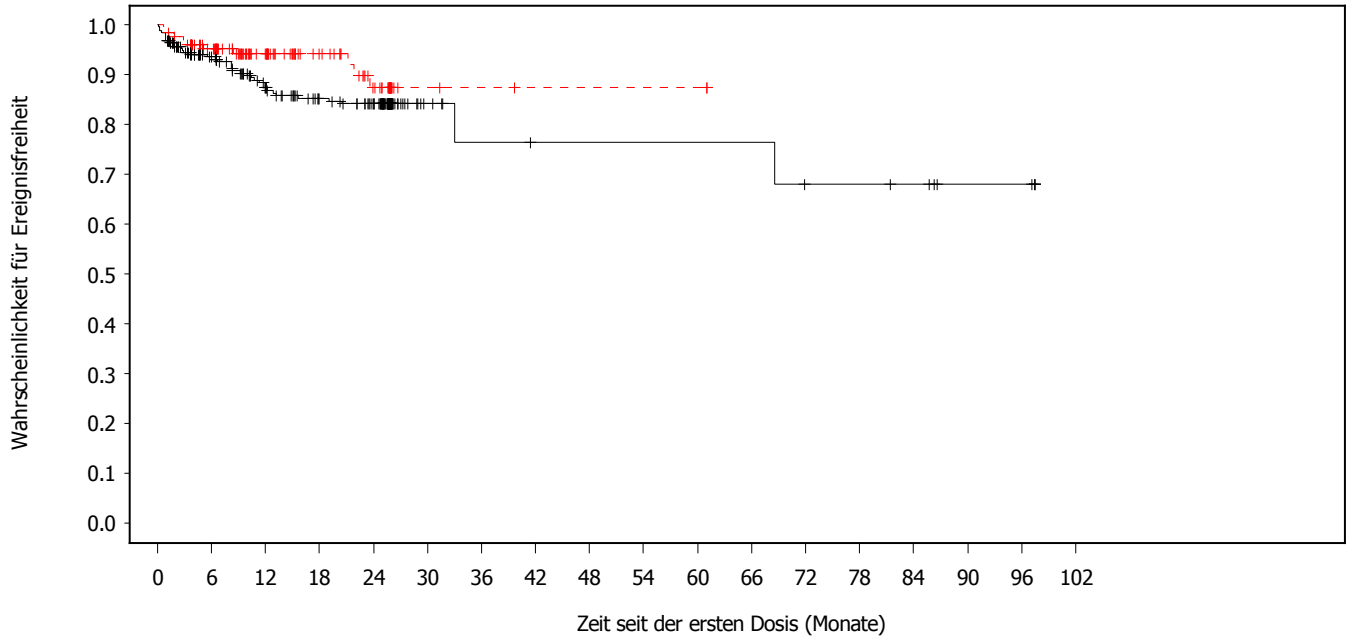
Anzahl an Patienten unter Risiko:

260	224	193	170	156	17	13	11	11	11	11	11	10	10	9	5	3	0	Olaparib 300 mg bd
130	110	76	51	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebau 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.22 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 07MAR2022



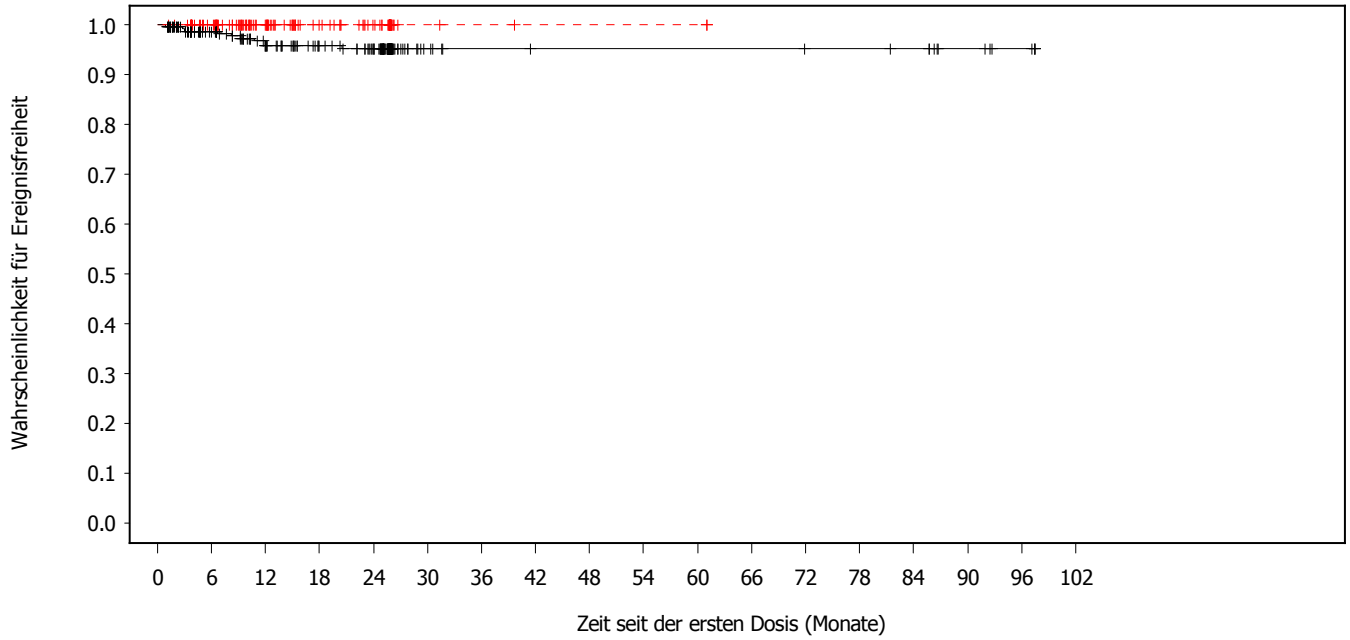
Anzahl an Patienten unter Risiko:

260	211	174	152	138	14	10	9	9	9	9	9	7	7	6	3	3	0	Olaparib 300 mg bd
130	107	74	50	35	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebav 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.23 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Dysurie
Safety Analysis Set, DCO 07MAR2022



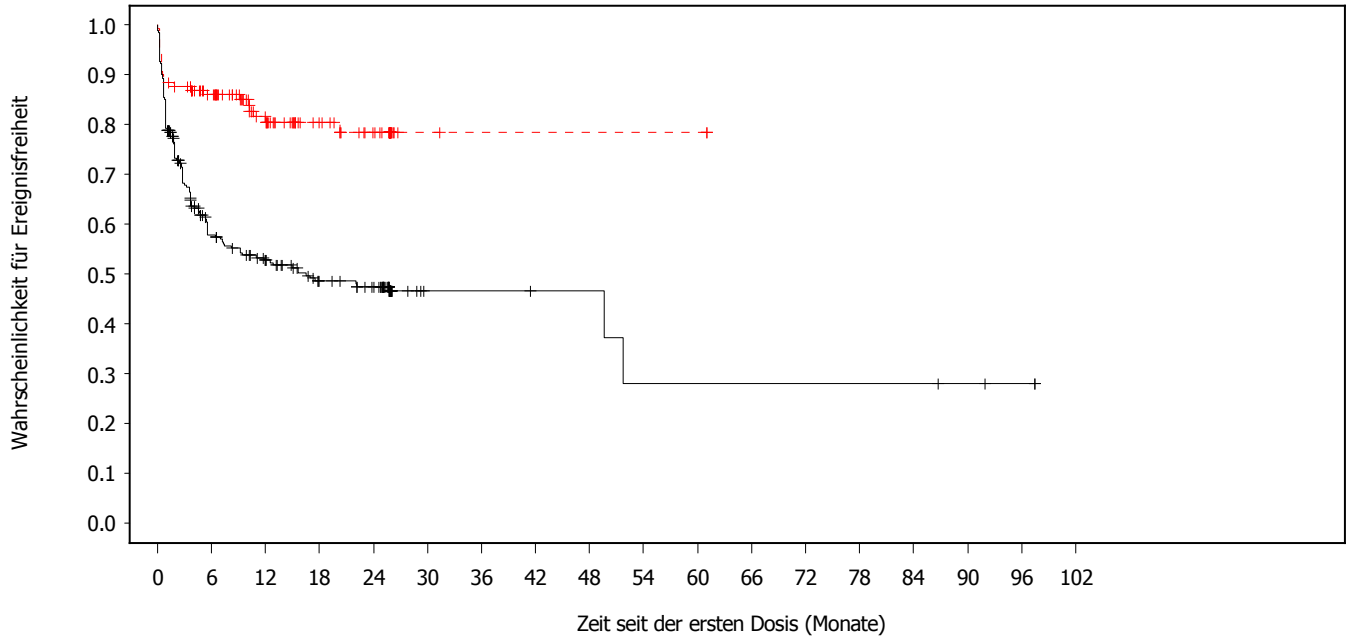
Anzahl an Patienten unter Risiko:

260	221	190	169	154	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	113	79	53	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebaw 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.24 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022



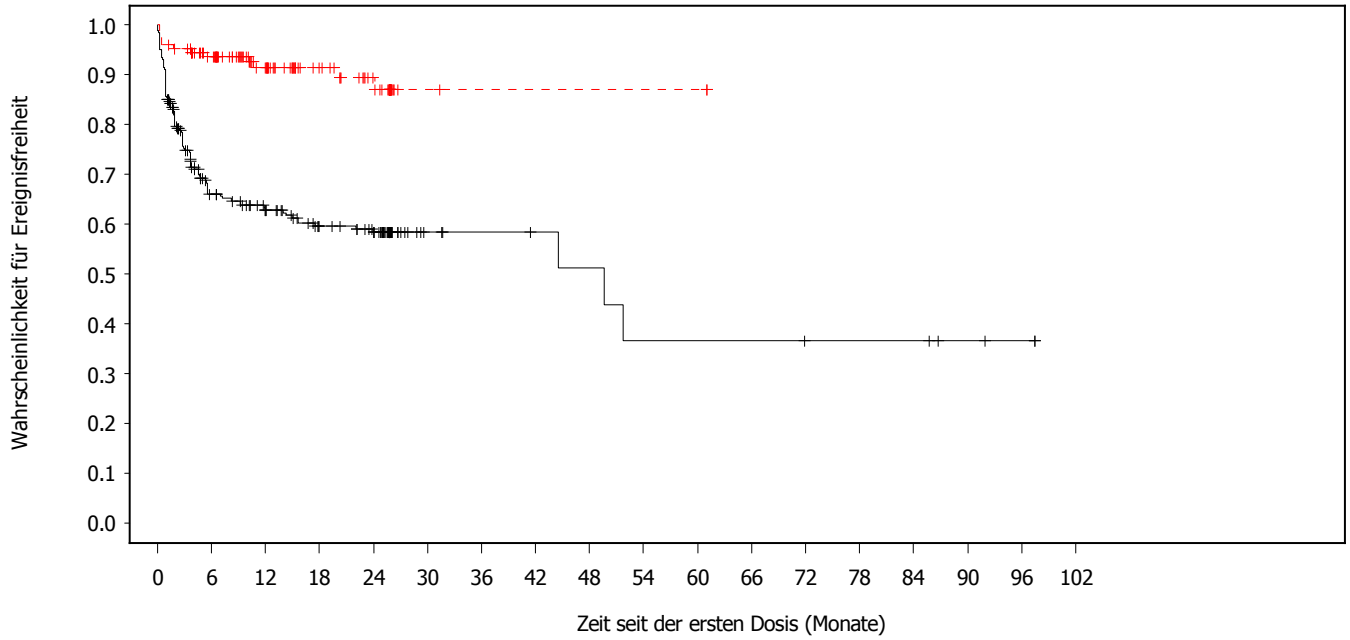
Anzahl an Patienten unter Risiko:

260	130	109	88	79	6	6	5	5	3	3	3	3	3	3	2	1	0	Olaparib 300 mg bd
130	98	68	45	34	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebax 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.25 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Anaemie
Safety Analysis Set, DCO 07MAR2022



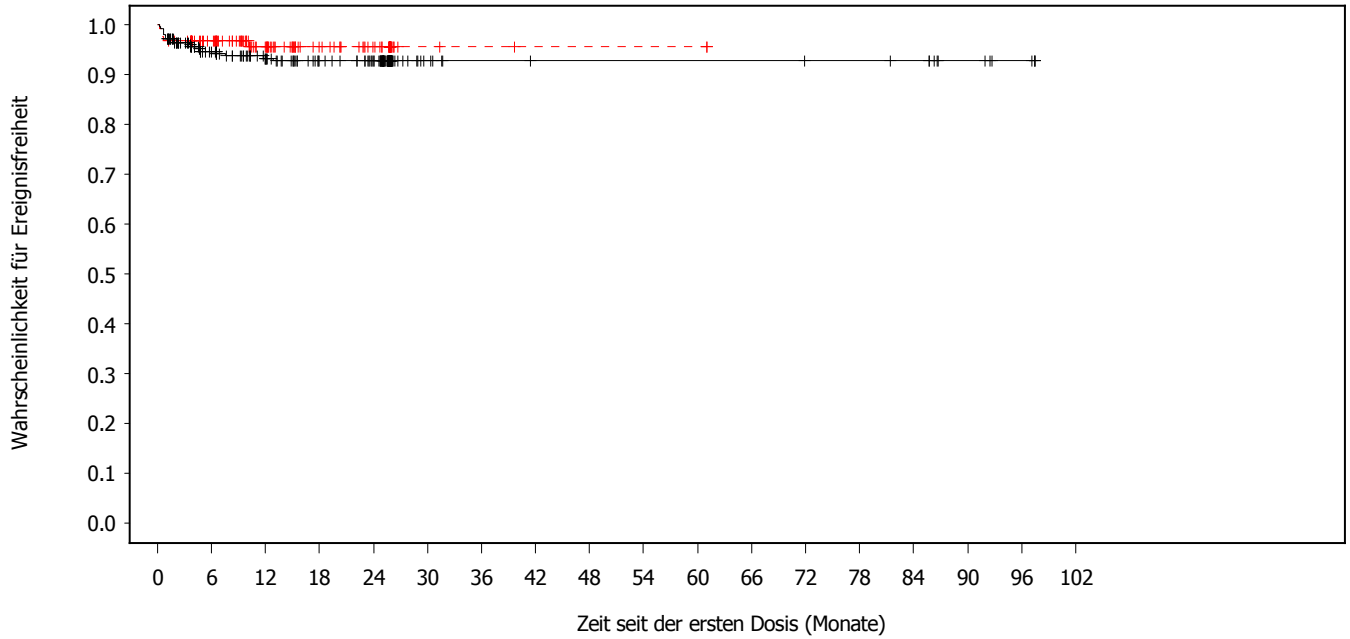
Anzahl an Patienten unter Risiko:

260	147	128	108	98	11	9	8	7	5	5	5	4	4	4	2	1	0	Olaparib 300 mg bd
130	108	76	51	38	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebay 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.26 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Leukopenie
Safety Analysis Set, DCO 07MAR2022



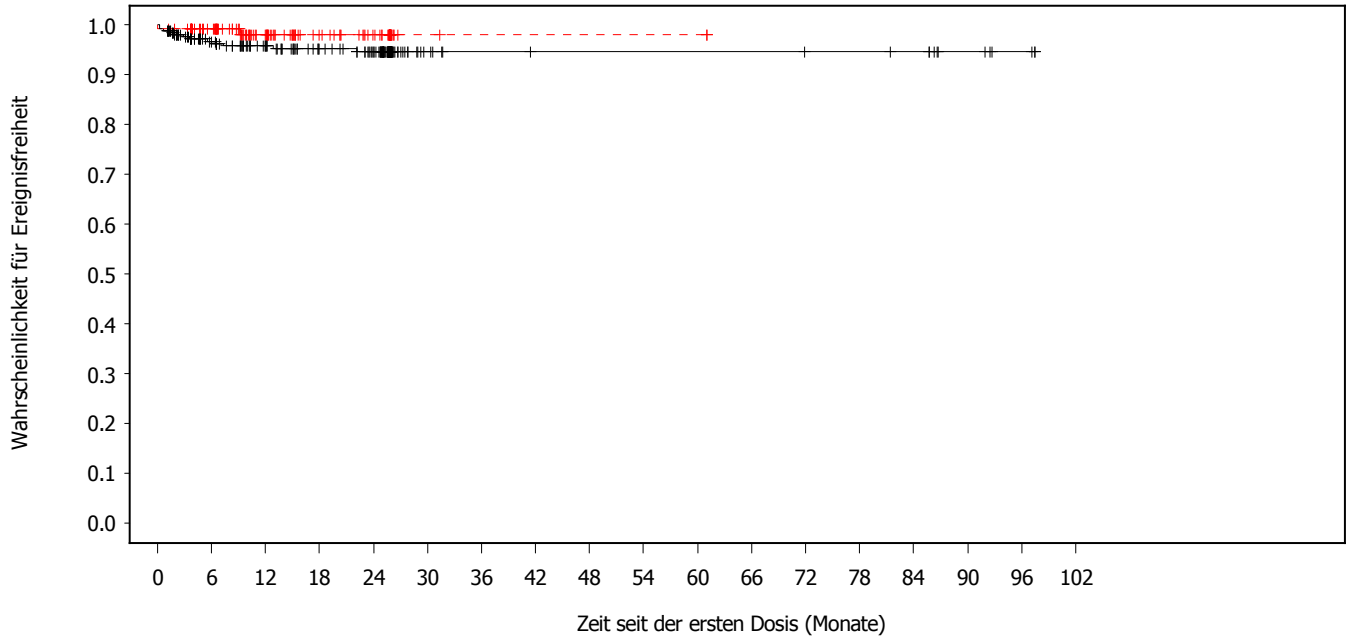
Anzahl an Patienten unter Risiko:

260	211	184	162	149	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	109	76	50	38	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebaz 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.27 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Lymphopenie
Safety Analysis Set, DCO 07MAR2022



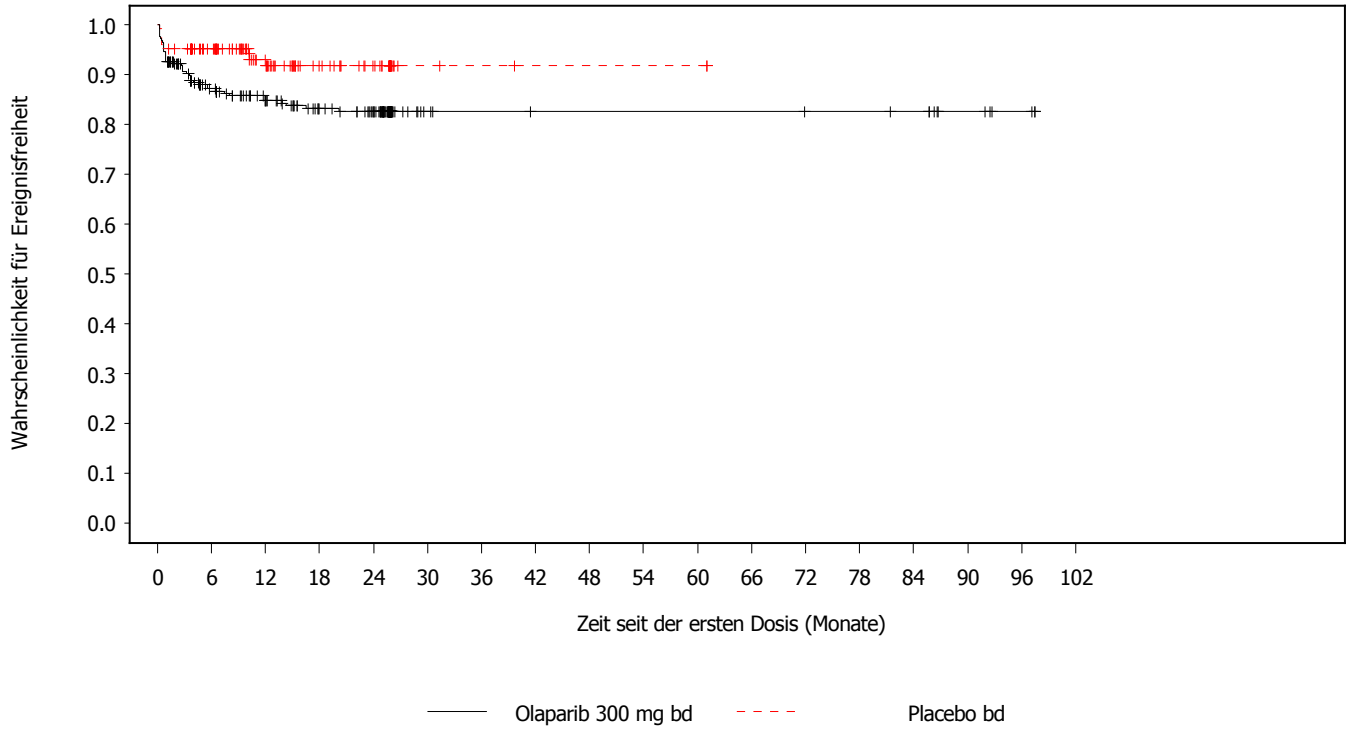
Anzahl an Patienten unter Risiko:

260	216	188	167	152	17	13	12	12	12	12	12	11	11	10	5	2	0	Olaparib 300 mg bd
130	112	77	51	39	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebba 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.28 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Neutropenie
Safety Analysis Set, DCO 07MAR2022



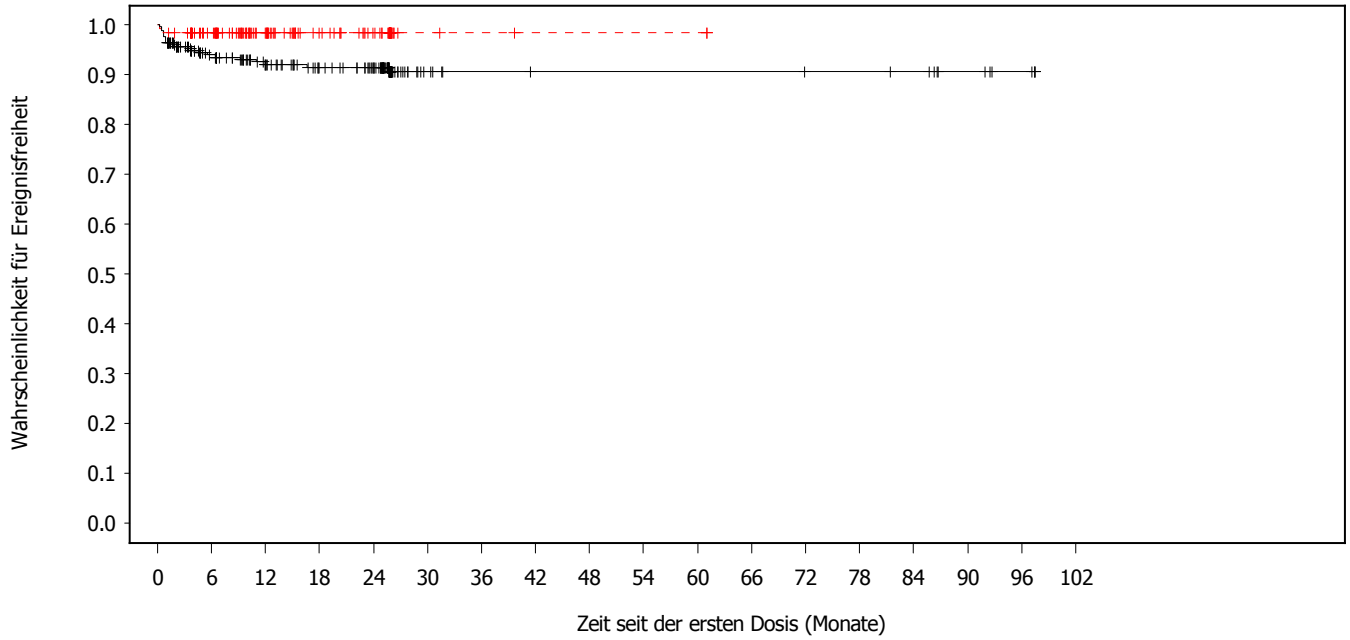
Anzahl an Patienten unter Risiko:

260	195	169	148	135	15	13	12	12	12	12	12	11	11	10	5	2	0	Olaparib 300 mg bd
130	107	74	49	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbb 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.29 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Thrombozytopenie
Safety Analysis Set, DCO 07MAR2022



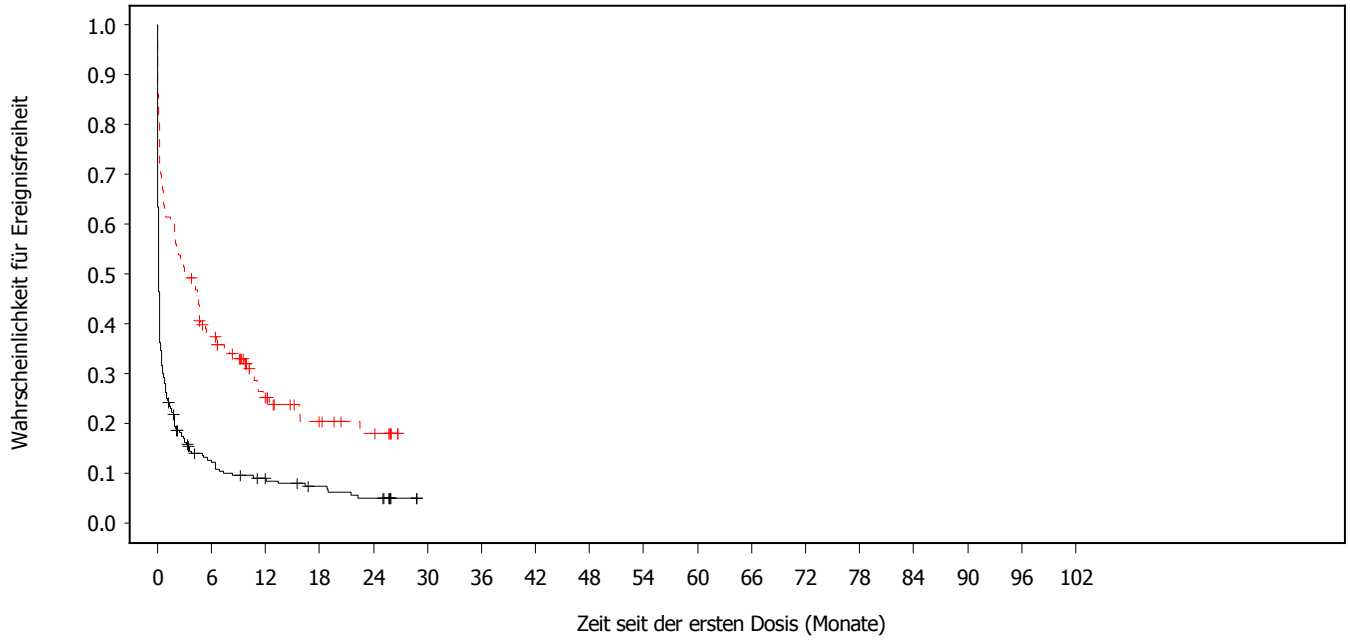
Anzahl an Patienten unter Risiko:

260	210	182	163	149	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
130	112	78	53	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbc 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.30 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 07MAR2022



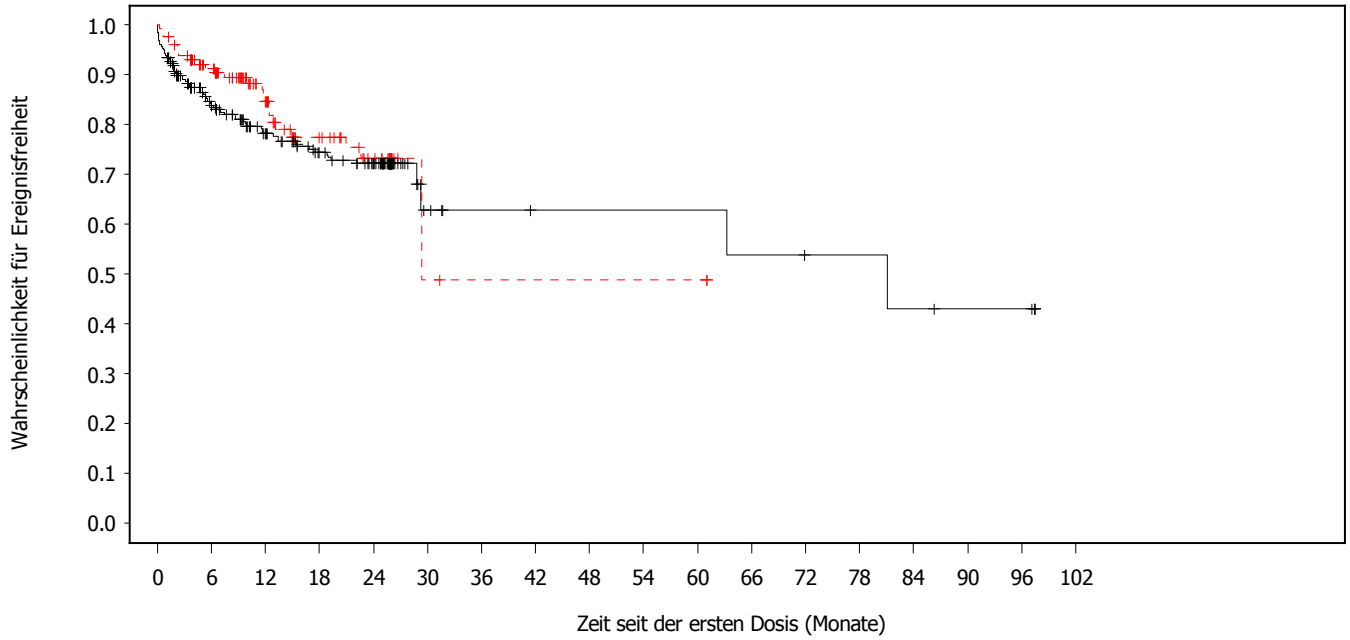
Anzahl an Patienten unter Risiko:

260	28	17	12	8	0	0	0	0	0	0	0	0	0	0	0	0	Olaparib 300 mg bd
130	47	21	11	7	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbd 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.31 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Abdominalschmerz
Safety Analysis Set, DCO 07MAR2022



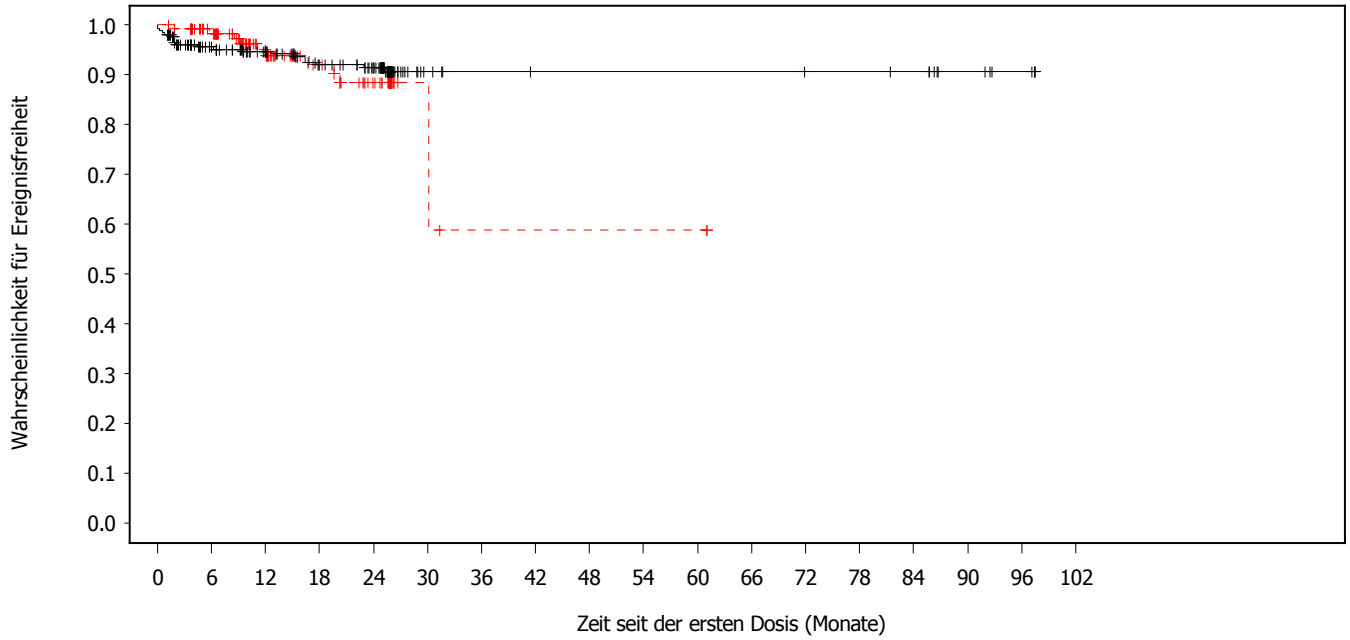
Anzahl an Patienten unter Risiko:

260	191	155	134	119	11	8	7	7	7	7	6	5	5	4	3	3	0	Olaparib 300 mg bd
130	104	68	43	31	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbe 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.32 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Bauch aufgetrieben
Safety Analysis Set, DCO 07MAR2022



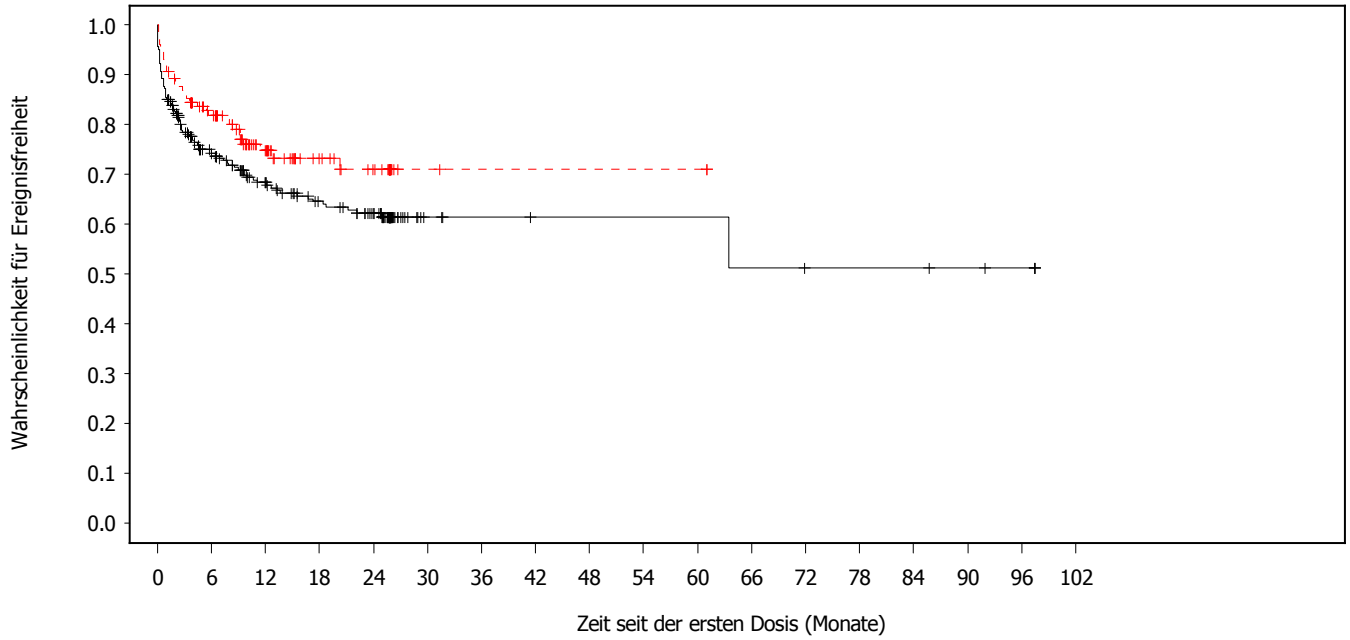
Anzahl an Patienten unter Risiko:

260	214	188	166	152	17	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	112	77	51	38	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbf 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.33 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Diarrhoe
Safety Analysis Set, DCO 07MAR2022



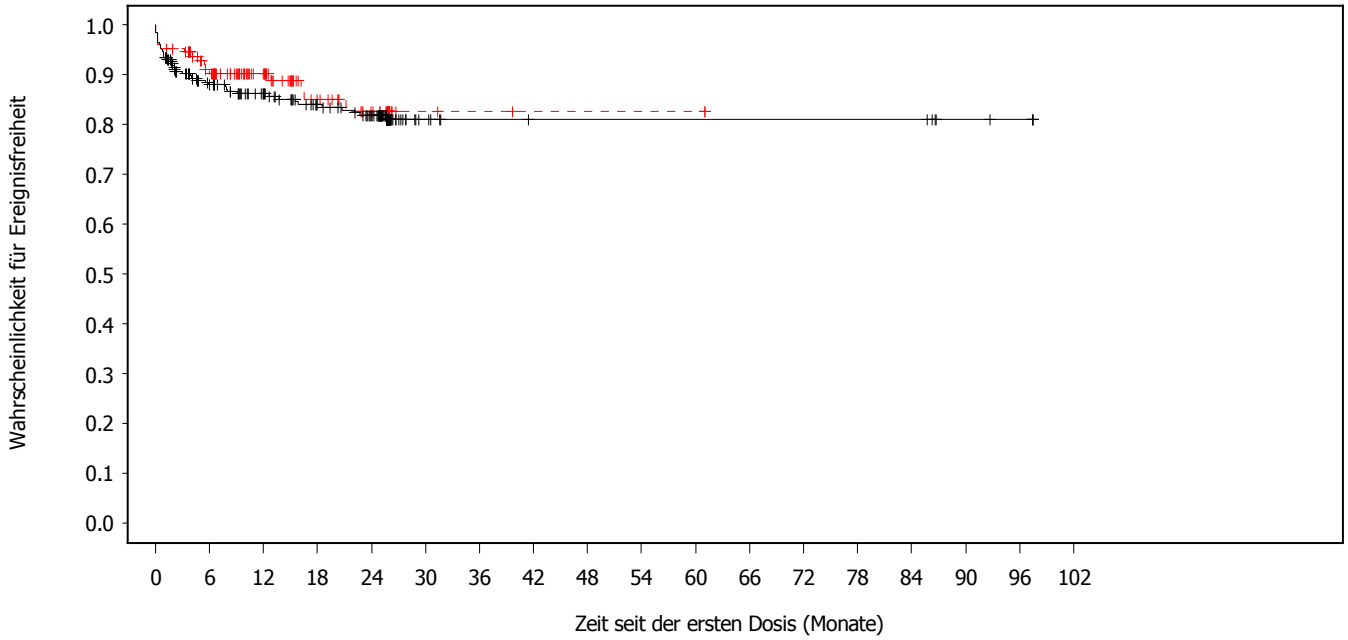
Anzahl an Patienten unter Risiko:

260	167	132	111	98	9	7	6	6	6	6	5	4	4	4	3	2	0	Olaparib 300 mg bd
130	95	59	36	28	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbg 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.34 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Dyspepsie
Safety Analysis Set, DCO 07MAR2022



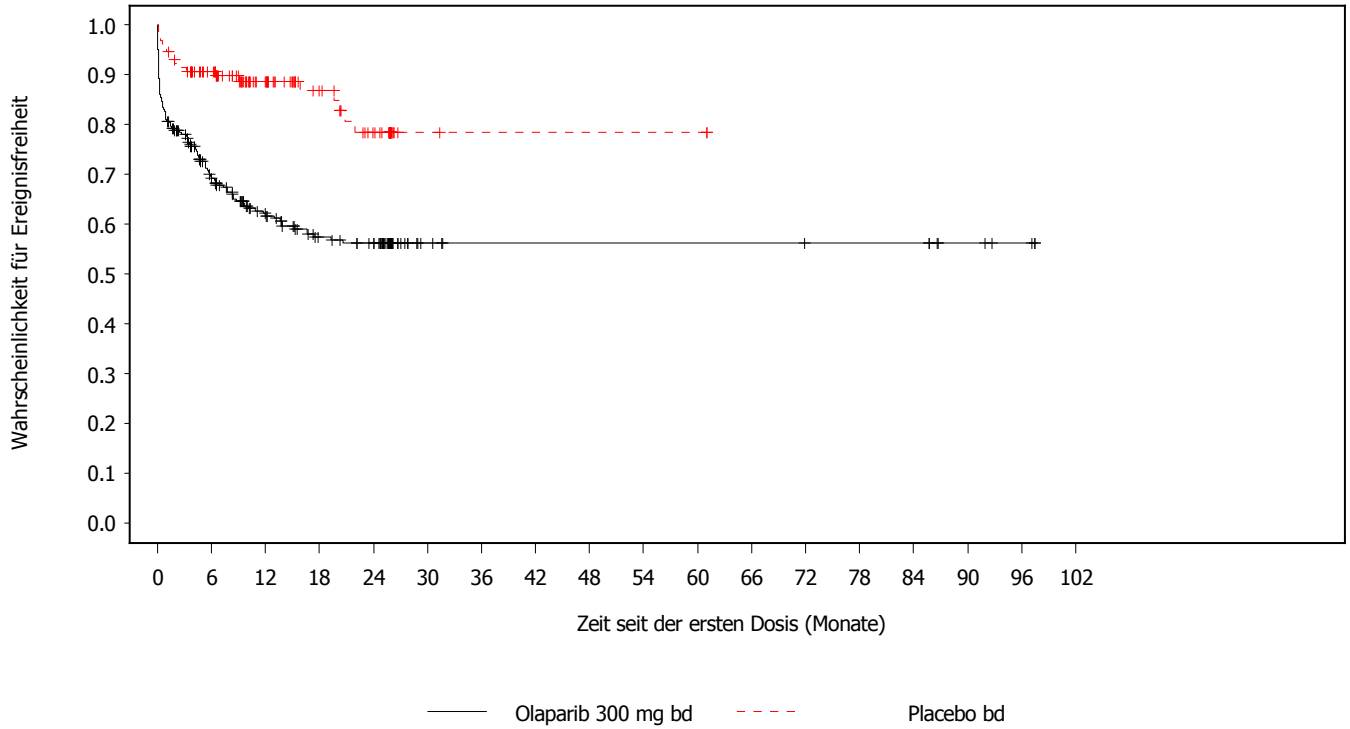
Anzahl an Patienten unter Risiko:

260	199	173	151	135	12	8	7	7	7	7	7	7	7	3	2	0	Olaparib 300 mg bd
130	102	71	43	32	3	2	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbh 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.35 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Erbrechen
Safety Analysis Set, DCO 07MAR2022



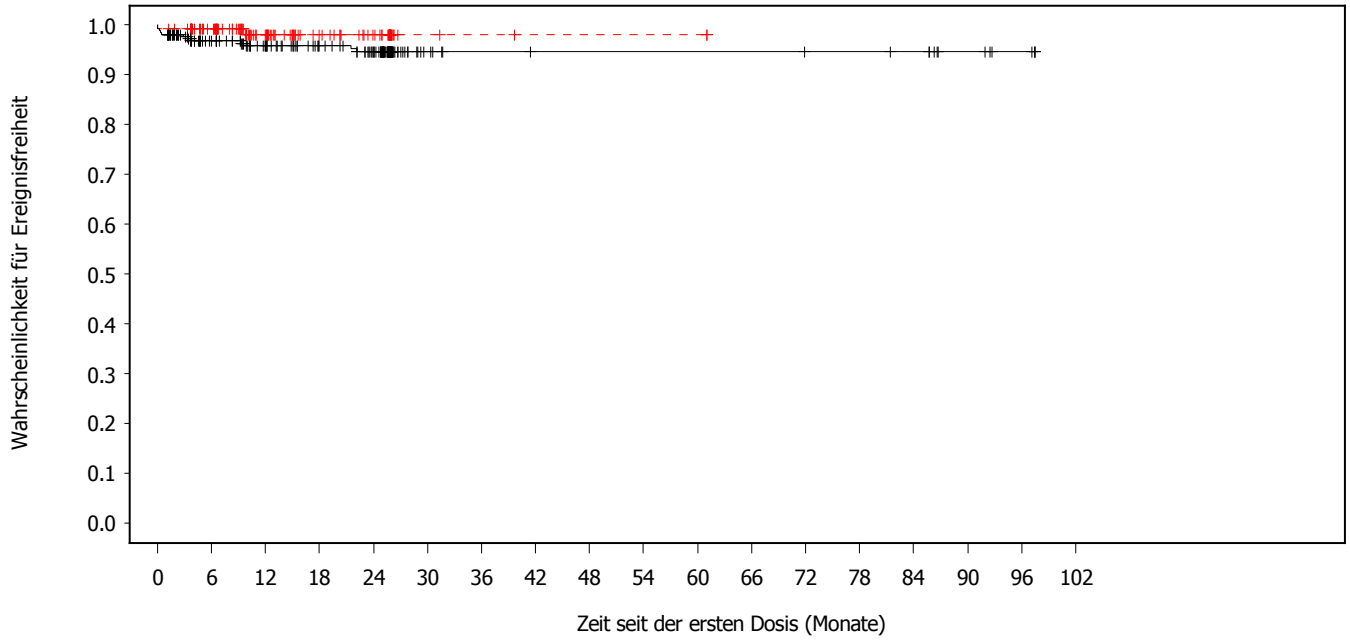
Anzahl an Patienten unter Risiko:

260	160	122	100	93	12	9	9	9	9	9	9	8	8	8	4	2	0	Olaparib 300 mg bd
130	103	68	45	32	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbi 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.36 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Flatulenz
Safety Analysis Set, DCO 07MAR2022



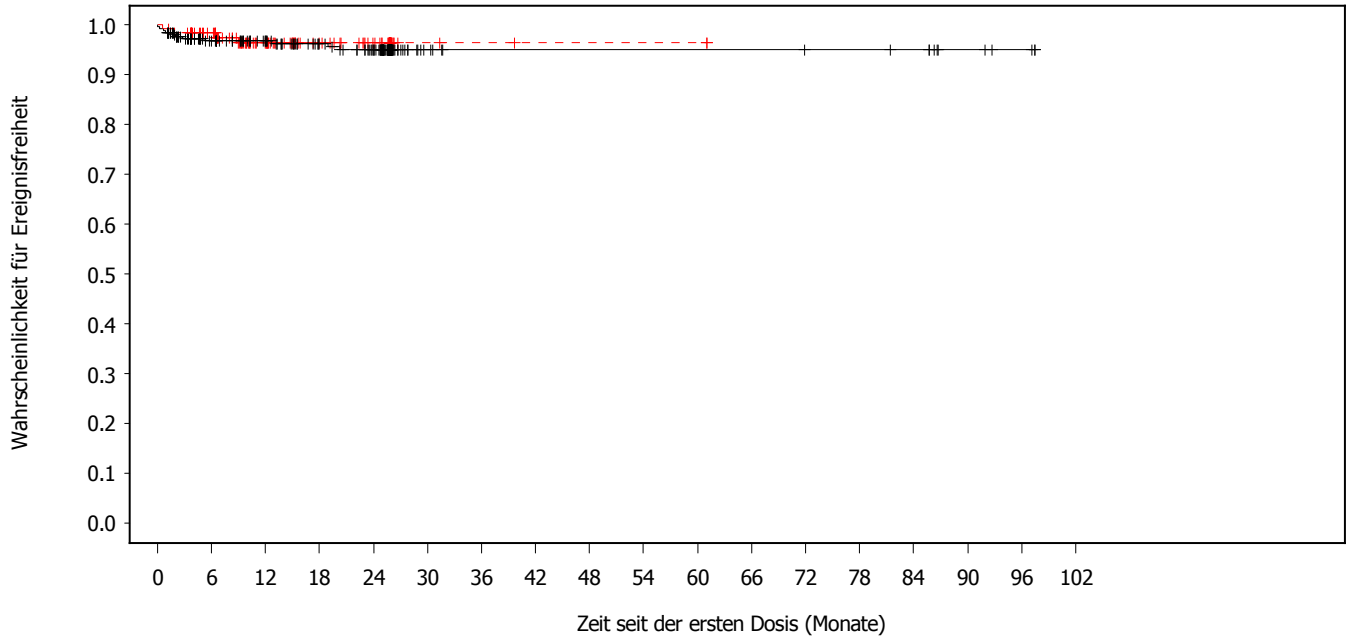
Anzahl an Patienten unter Risiko:

260	216	189	169	153	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	112	77	52	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbj 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.37 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Gastrooesophageale Refluxerkrankung
Safety Analysis Set, DCO 07MAR2022



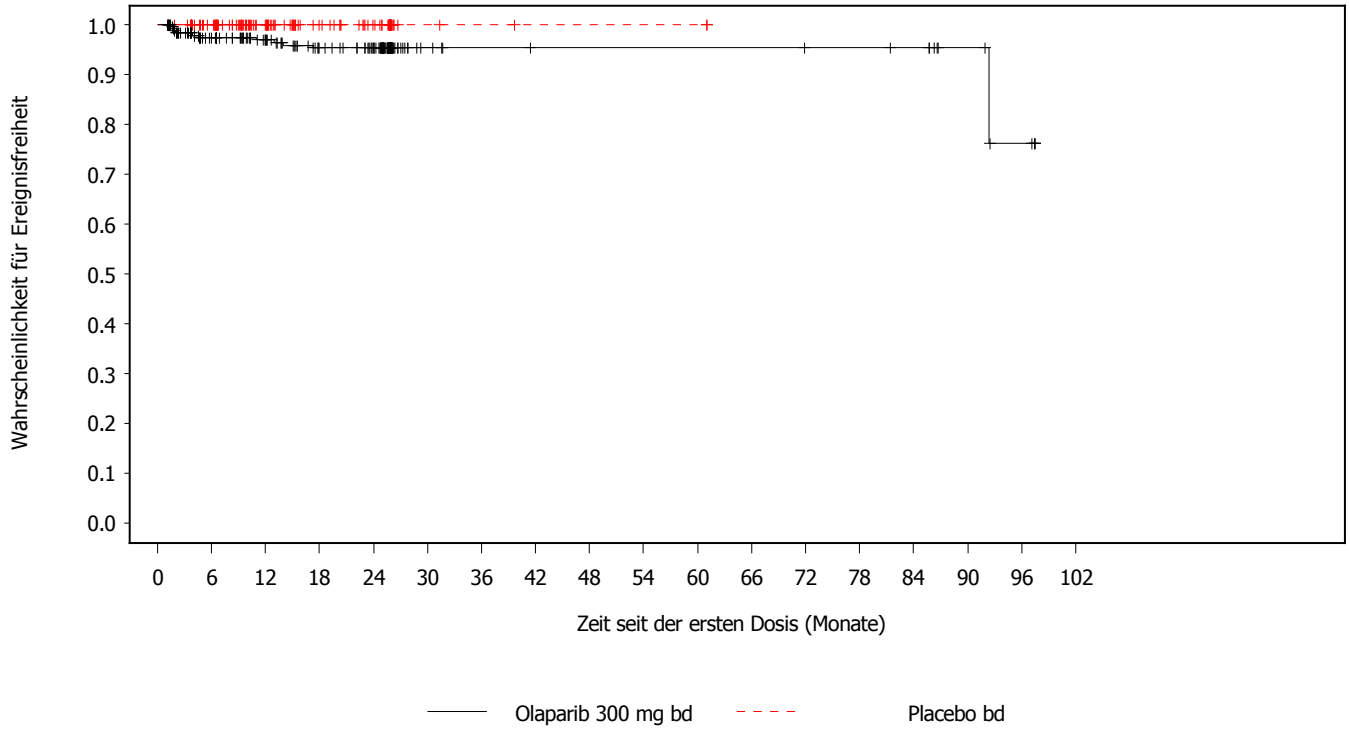
Anzahl an Patienten unter Risiko:

260	217	192	169	153	15	11	11	11	11	11	11	10	10	9	4	2	0	Olaparib 300 mg bd
130	111	76	51	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbk 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.38 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Haemorrhoiden
Safety Analysis Set, DCO 07MAR2022



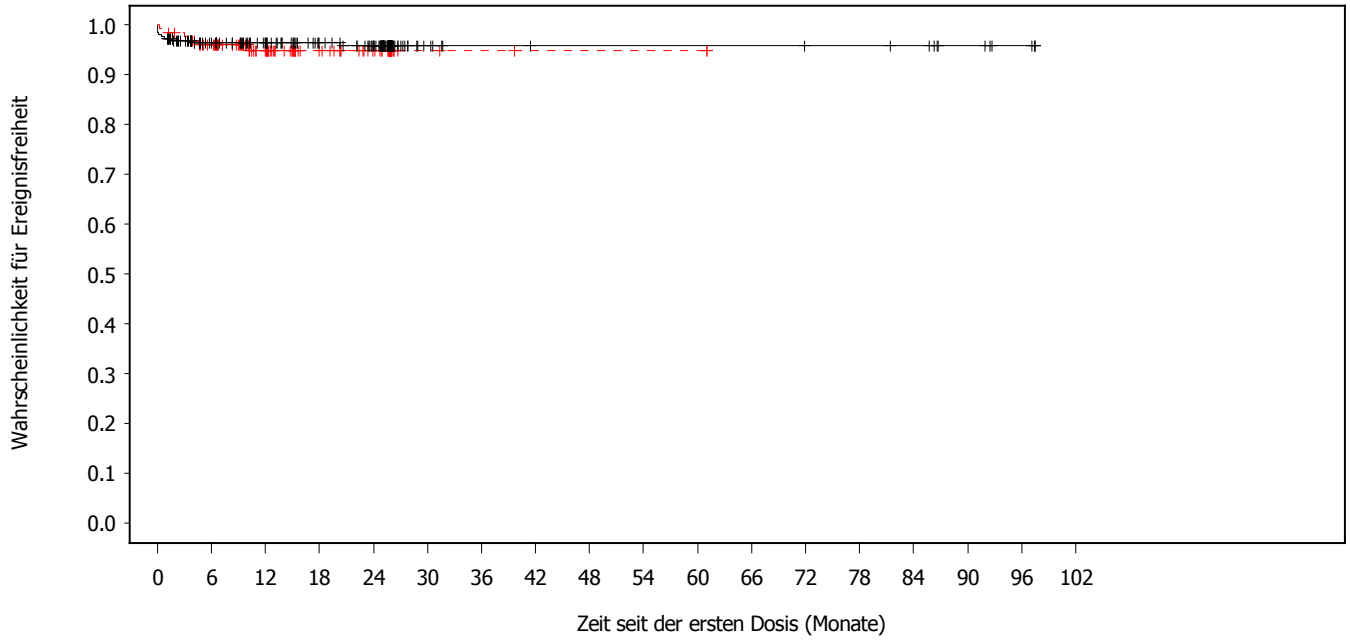
Anzahl an Patienten unter Risiko:

260	218	191	168	154	17	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	113	79	53	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbl 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.39 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Mundtrockenheit
Safety Analysis Set, DCO 07MAR2022



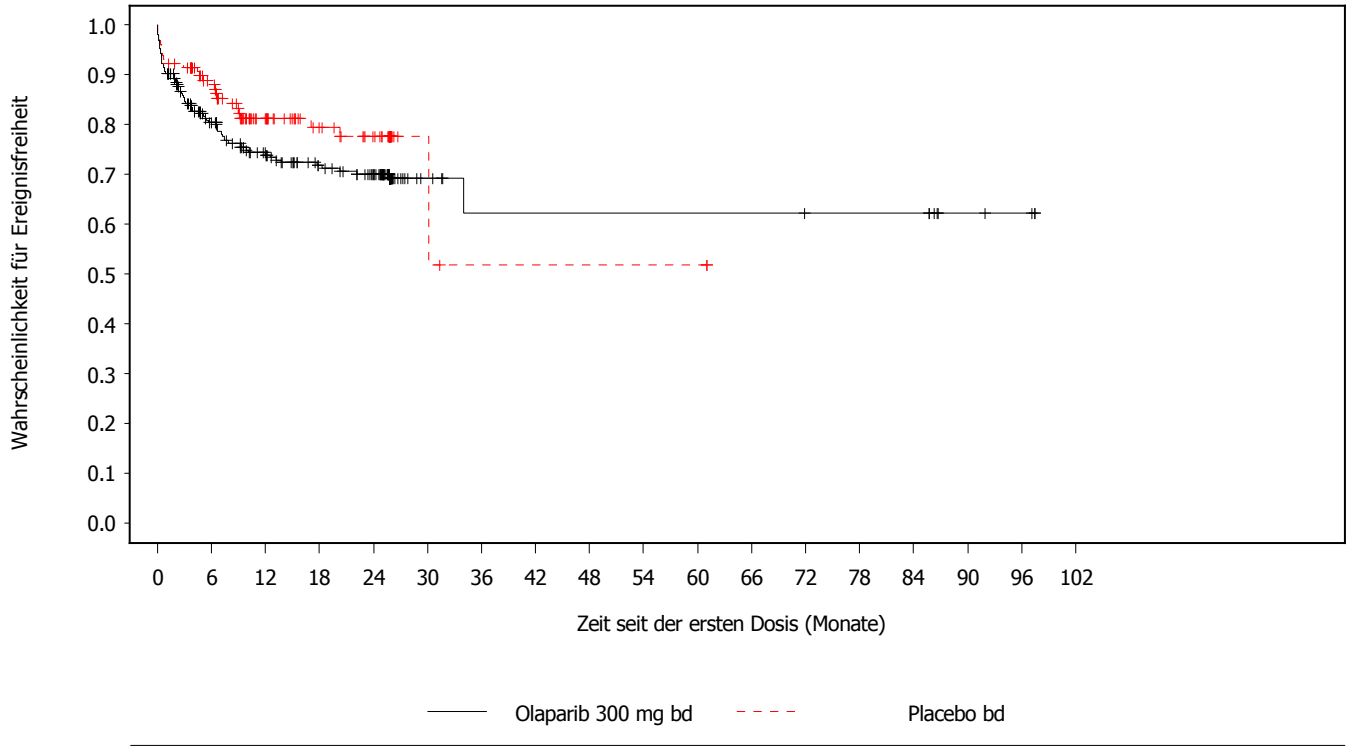
Anzahl an Patienten unter Risiko:

260	218	192	170	156	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
130	108	75	50	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbm 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.40 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Obstipation
Safety Analysis Set, DCO 07MAR2022



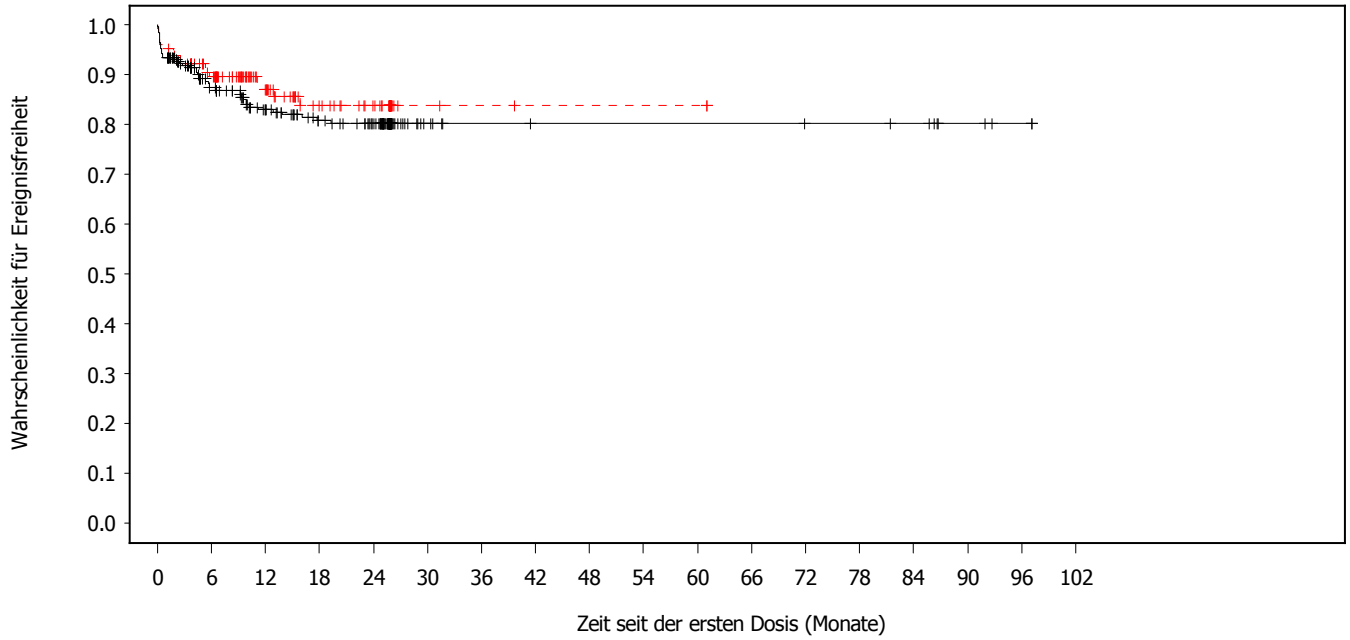
Anzahl an Patienten unter Risiko:

260	182	150	128	114	13	9	9	9	9	9	8	8	8	3	2	0	Olaparib 300 mg bd
130	99	63	44	35	3	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbn 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.41 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerzen Oberbauch
Safety Analysis Set, DCO 07MAR2022



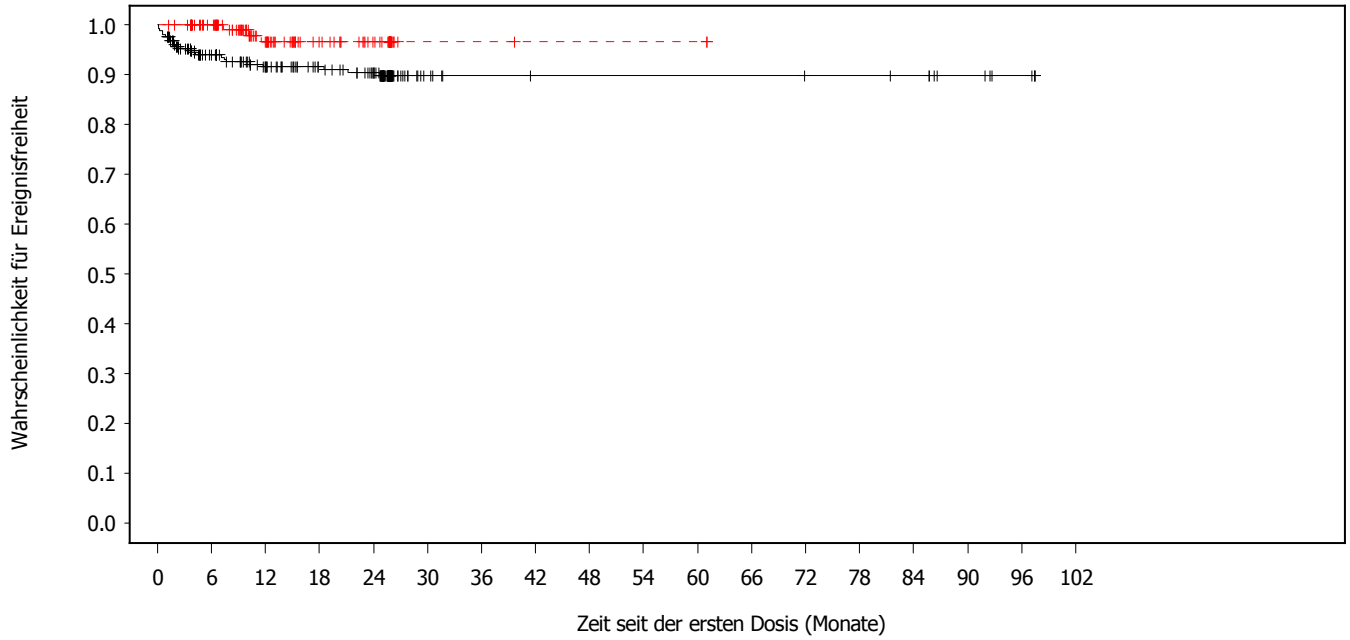
Anzahl an Patienten unter Risiko:

260	193	161	140	127	14	10	9	9	9	9	9	8	8	7	3	1	0	Olaparib 300 mg bd
130	103	68	45	36	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbo 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.42 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Stomatitis
Safety Analysis Set, DCO 07MAR2022



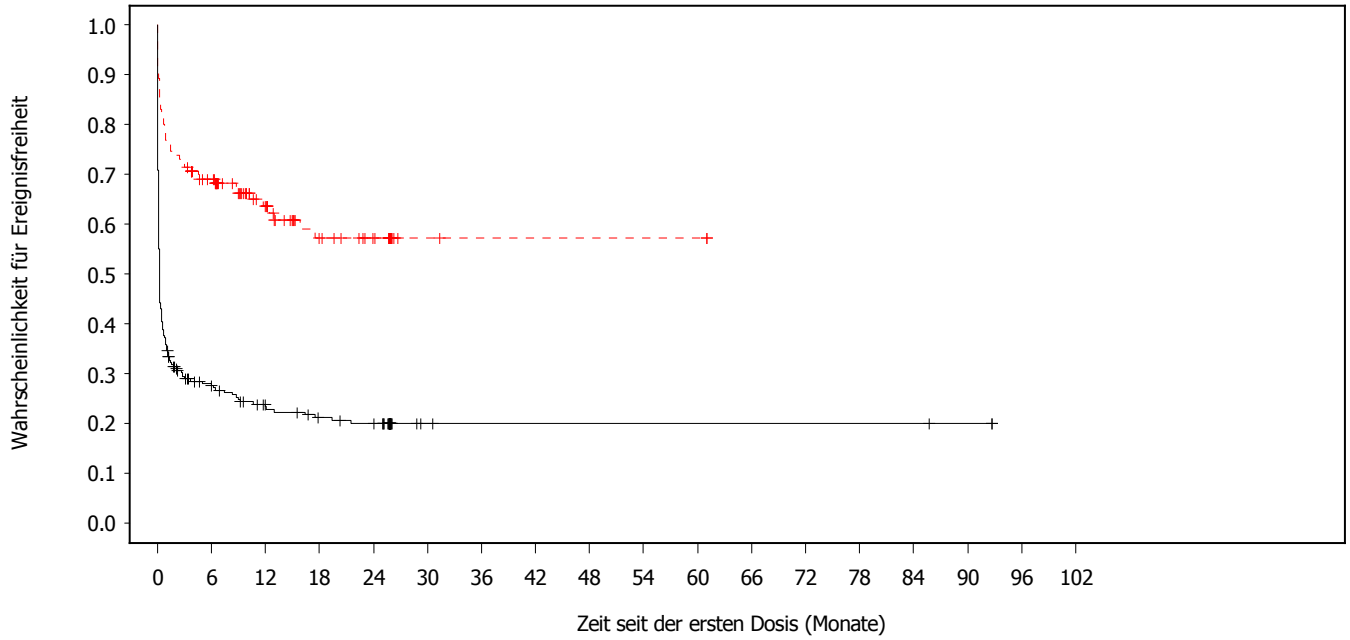
Anzahl an Patienten unter Risiko:

260	209	181	160	147	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
130	113	76	50	38	2	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbp 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.43 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Uebelkeit
Safety Analysis Set, DCO 07MAR2022



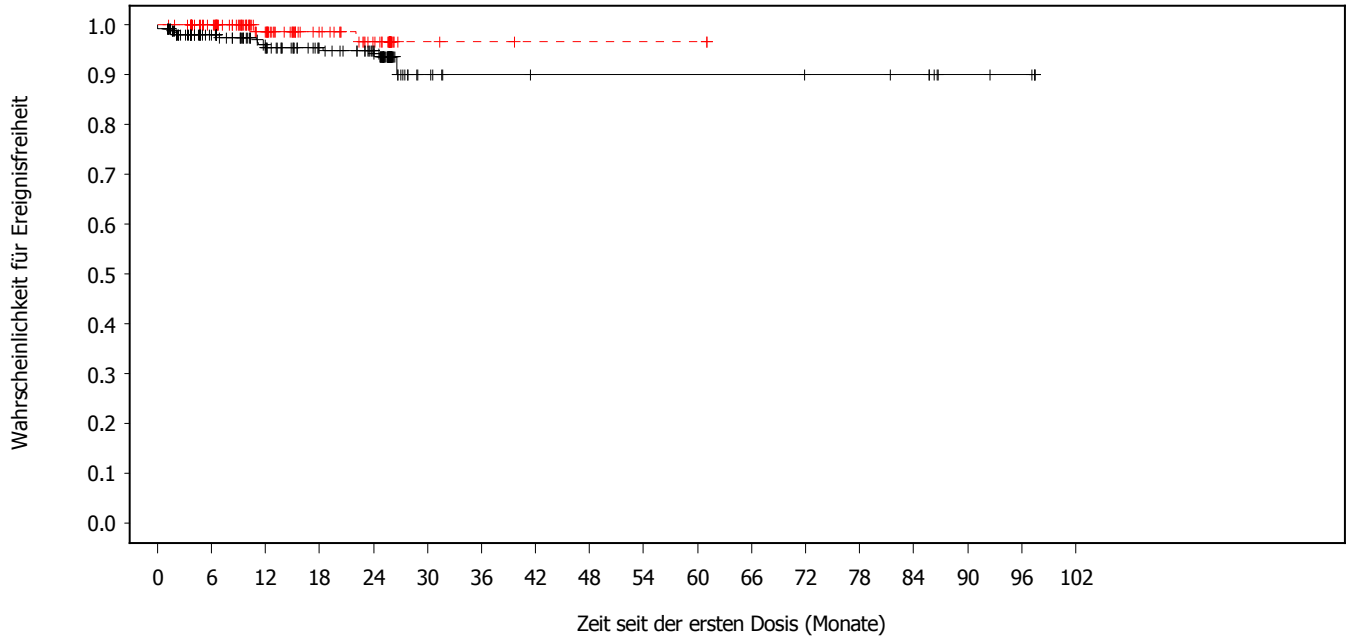
Anzahl an Patienten unter Risiko:

260	62	45	38	35	3	2	2	2	2	2	2	2	2	1	0	0	Olaparib 300 mg bd
130	80	50	31	24	2	1	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbq 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.44 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Immunsystems
Safety Analysis Set, DCO 07MAR2022



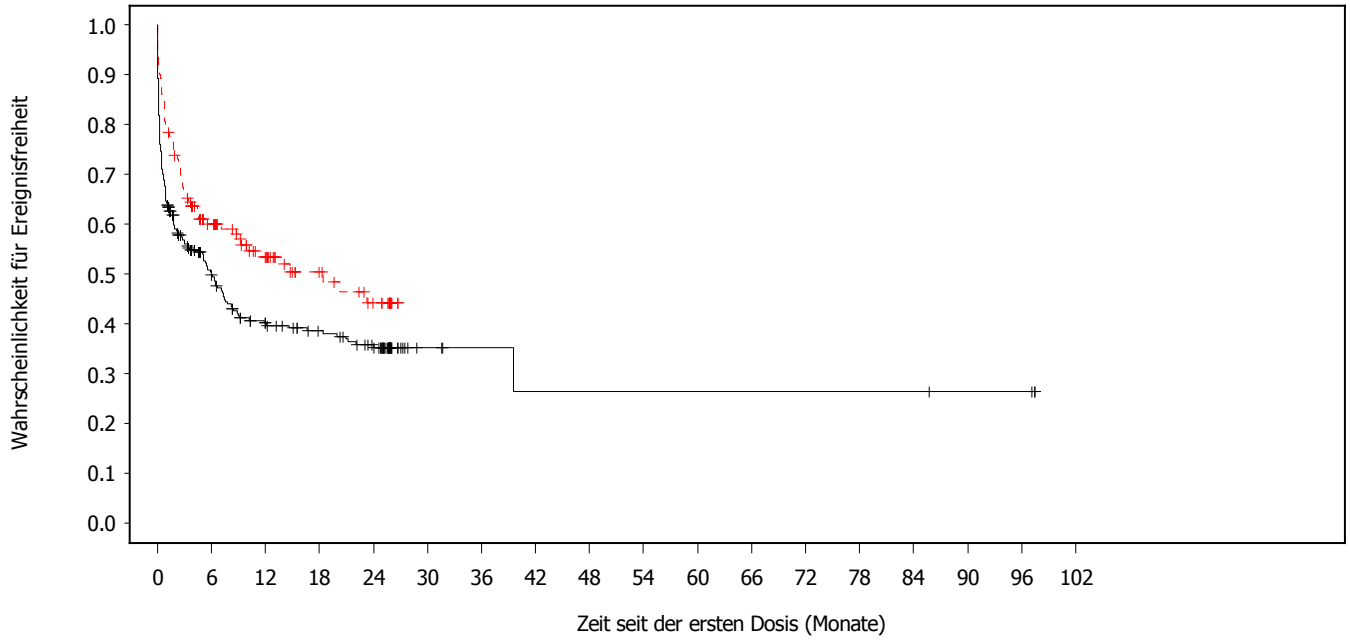
Anzahl an Patienten unter Risiko:

260	219	188	167	152	16	12	11	11	11	11	11	10	10	9	4	3	0	Olaparib 300 mg bd
130	113	78	52	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbr 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.45 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 07MAR2022



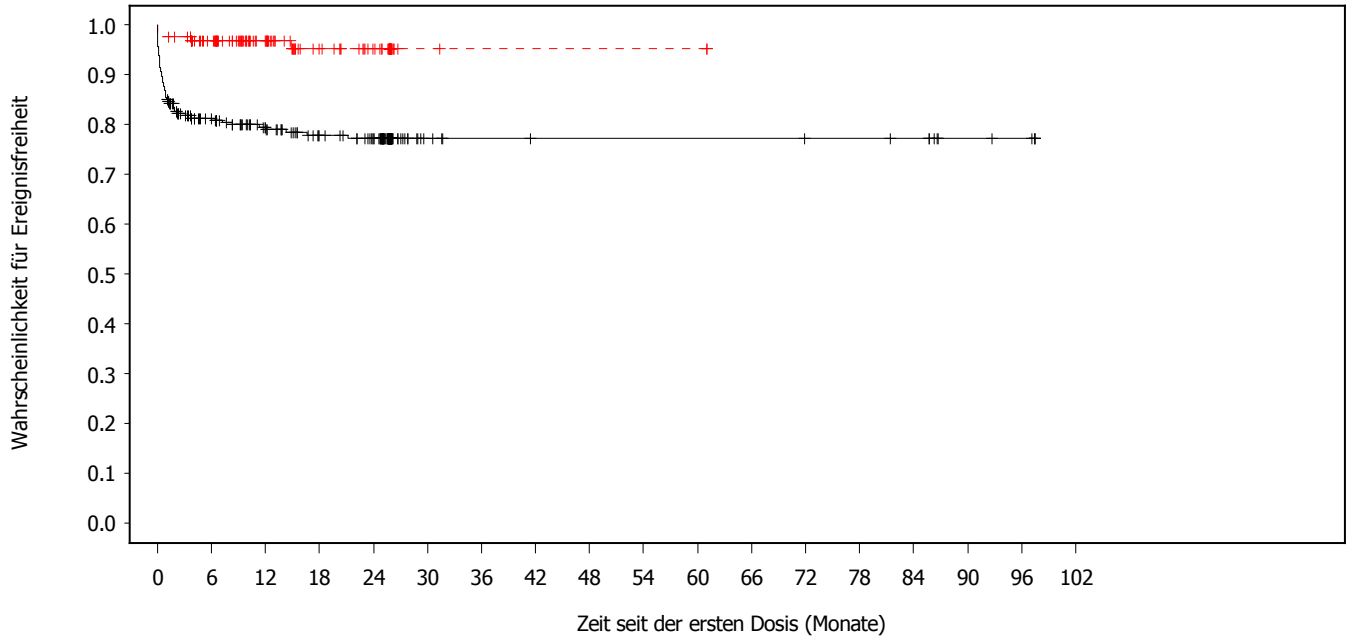
Anzahl an Patienten unter Risiko:

260	111	81	69	58	6	4	3	3	3	3	3	3	3	2	2	0	Olaparib 300 mg bd
130	65	43	27	18	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbs 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.46 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Dysgeusie
Safety Analysis Set, DCO 07MAR2022



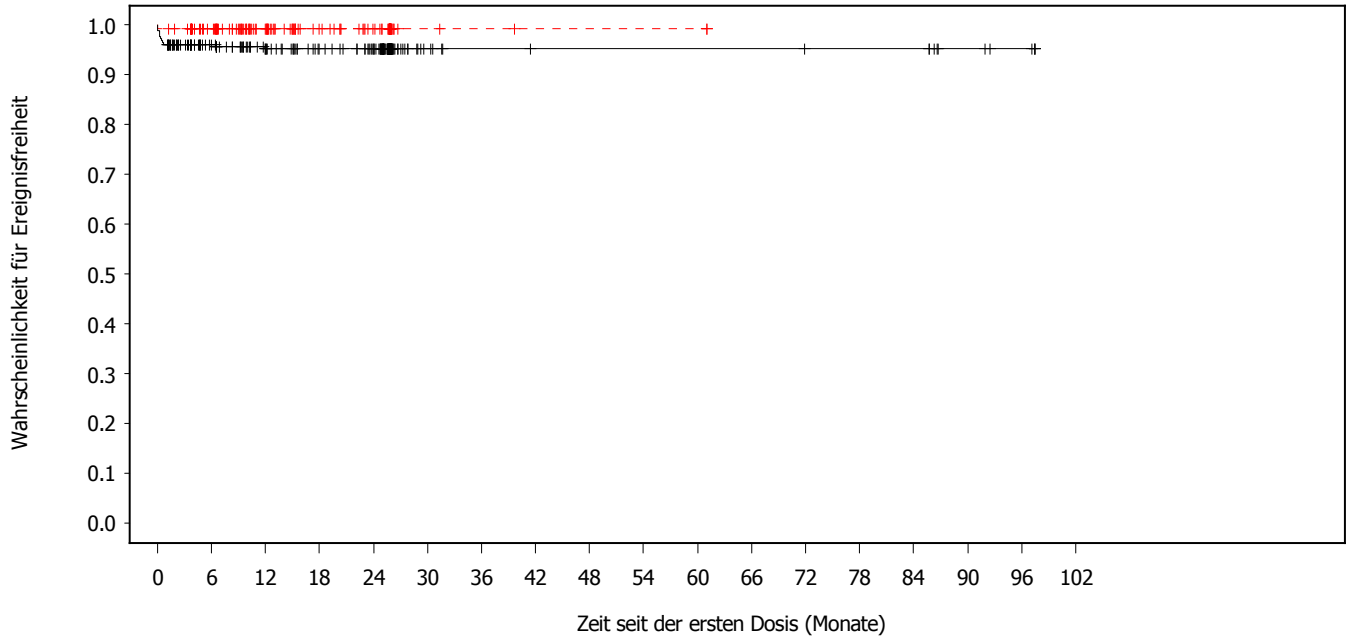
Anzahl an Patienten unter Risiko:

260	184	158	138	126	15	12	11	11	11	11	11	10	10	9	4	3	0	Olaparib 300 mg bd
130	109	76	49	38	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbt 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.47 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Geschmacksstoerung
Safety Analysis Set, DCO 07MAR2022



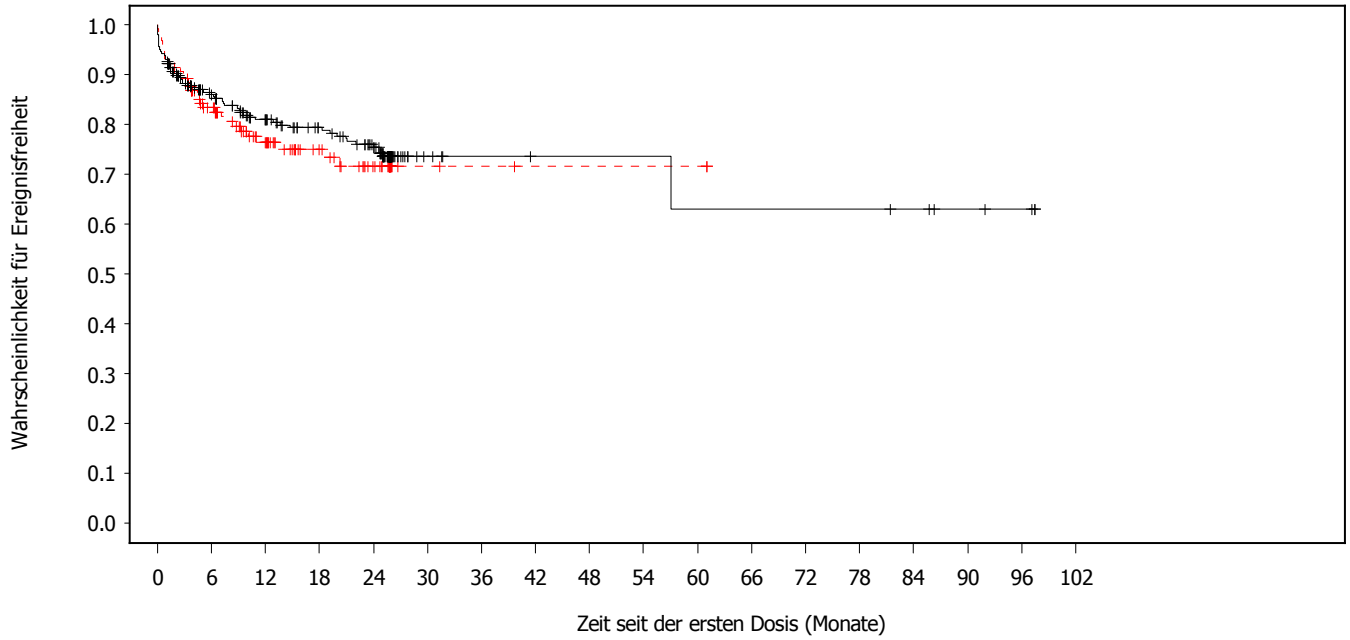
Anzahl an Patienten unter Risiko:

260	214	186	167	153	16	12	11	11	11	11	11	10	10	10	5	3	0	Olaparib 300 mg bd
130	112	78	52	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbu 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.48 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Kopfschmerzen
Safety Analysis Set, DCO 07MAR2022



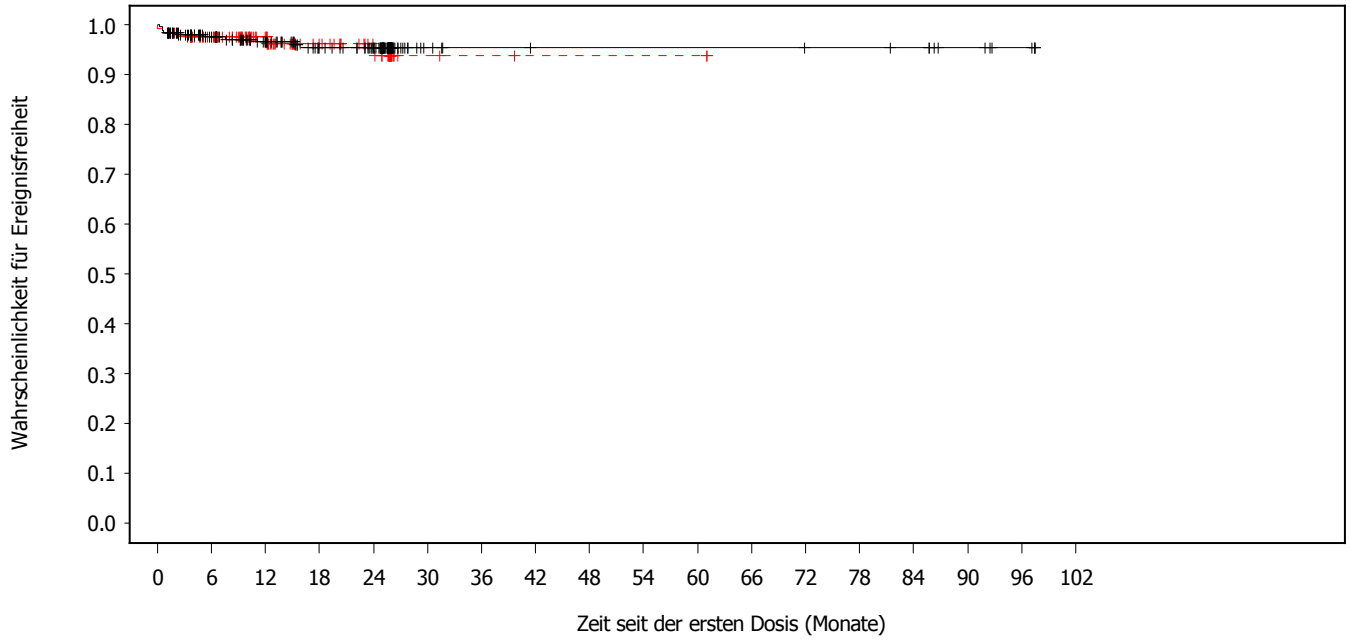
Anzahl an Patienten unter Risiko:

260	193	164	144	128	11	8	7	7	7	6	6	6	6	5	3	2	0	Olaparib 300 mg bd
130	95	67	45	32	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbv 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.49 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Paraesthesie
Safety Analysis Set, DCO 07MAR2022



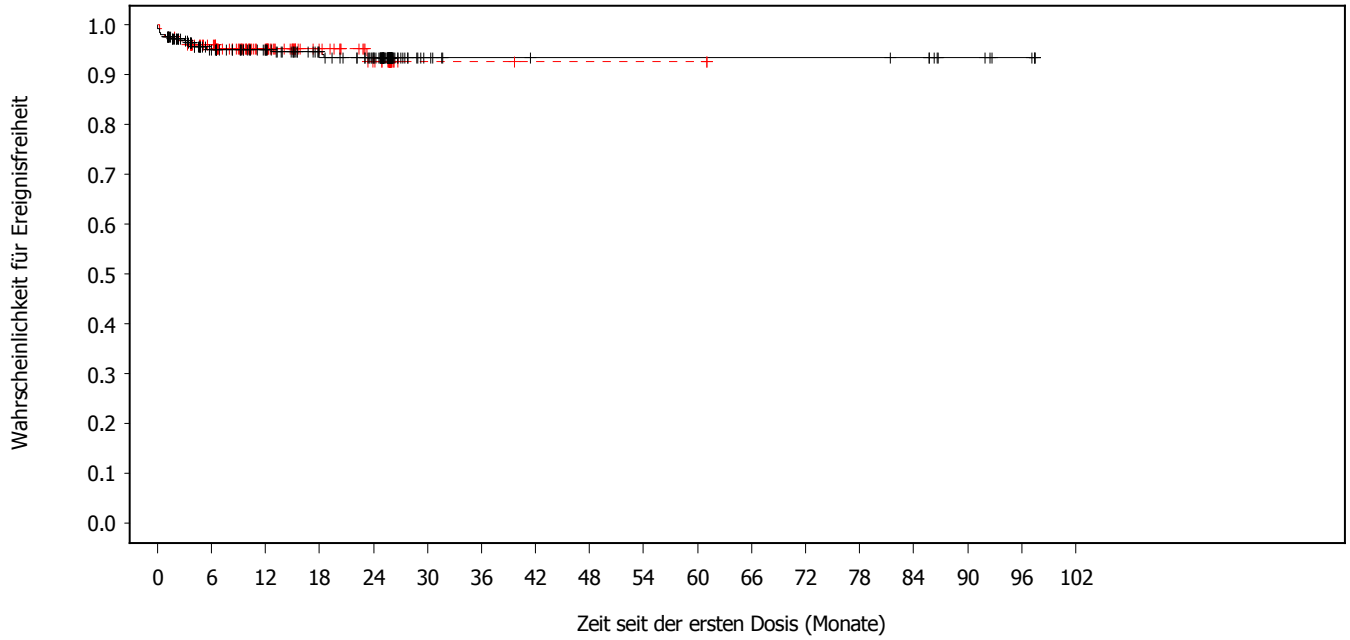
Anzahl an Patienten unter Risiko:

260	219	191	167	153	16	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
130	110	77	51	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbw 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.50 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Periphere Neuropathie
Safety Analysis Set, DCO 07MAR2022



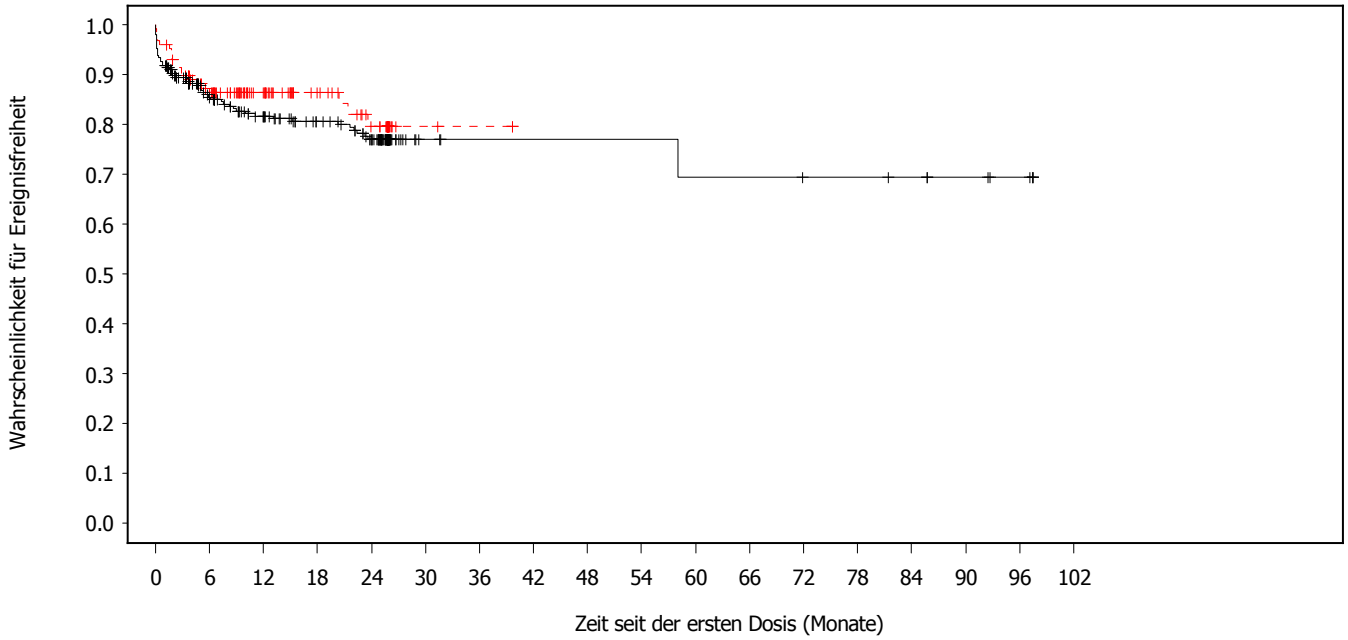
Anzahl an Patienten unter Risiko:

260	213	191	169	153	17	13	12	12	12	12	12	12	11	6	3	0	Olaparib 300 mg bd
130	108	73	47	34	2	2	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbx 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.51 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schwindelgefuehl
Safety Analysis Set, DCO 07MAR2022



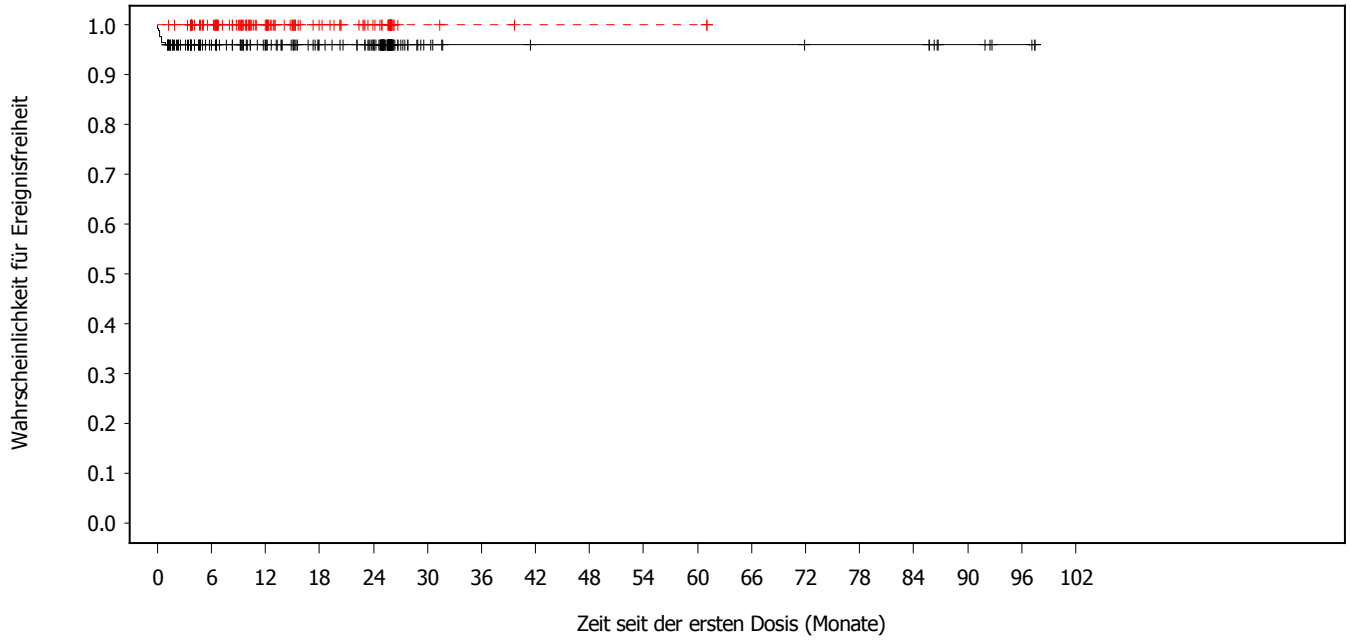
Anzahl an Patienten unter Risiko:

260	190	162	142	125	12	10	10	10	10	9	9	8	8	7	5	3	0	Olaparib 300 mg bd
130	96	66	44	32	2	1	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebby 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.52 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Somnolenz
Safety Analysis Set, DCO 07MAR2022



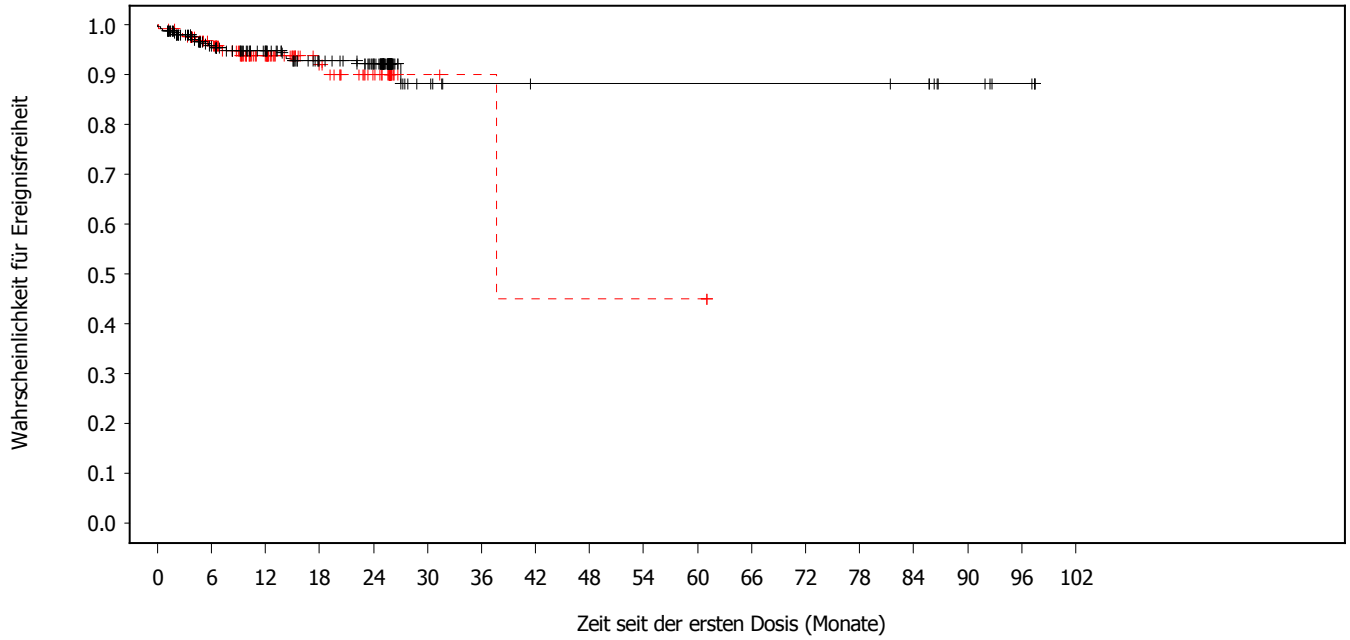
Anzahl an Patienten unter Risiko:

260	215	190	169	155	16	12	11	11	11	11	11	10	10	10	5	2	0	Olaparib 300 mg bd
130	113	79	53	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebbz 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.53 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Ohrs und des Labyrinths
Safety Analysis Set, DCO 07MAR2022



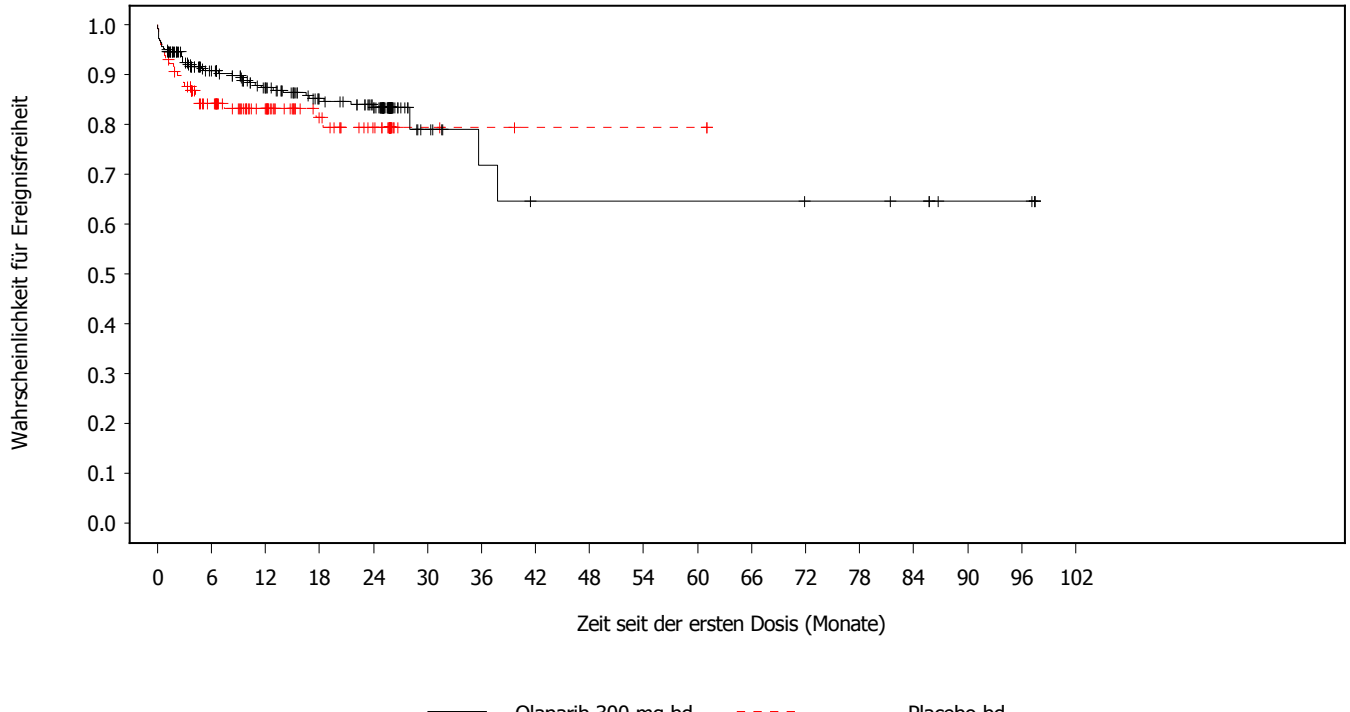
Anzahl an Patienten unter Risiko:

260	214	188	163	148	17	13	12	12	12	12	12	12	12	11	6	3	0	Olaparib 300 mg bd
130	108	75	49	36	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebca 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.54 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Gefaesserkrankungen
Safety Analysis Set, DCO 07MAR2022



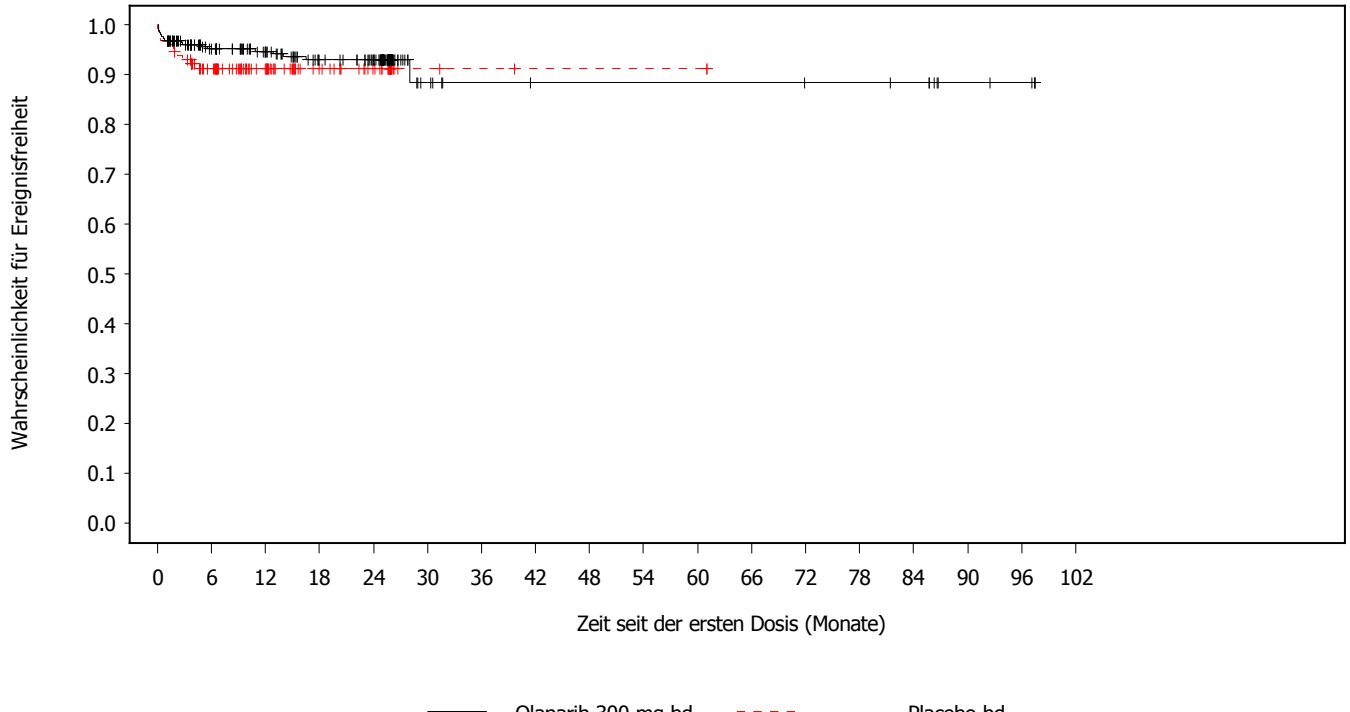
Anzahl an Patienten unter Risiko:

260	203	173	148	132	15	10	8	8	8	8	8	7	7	6	3	3	0	Olaparib 300 mg bd
130	93	68	44	33	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcb 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.55 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hitzewallung
Safety Analysis Set, DCO 07MAR2022



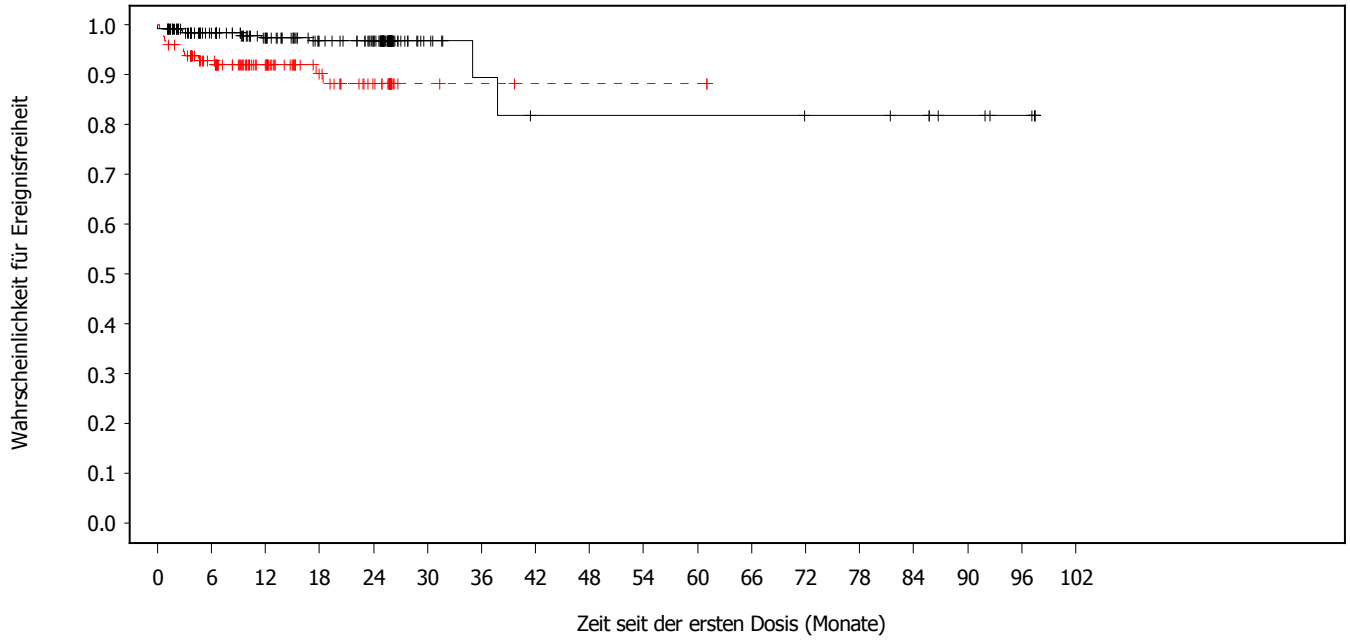
Anzahl an Patienten unter Risiko:

260	213	188	164	151	16	12	11	11	11	11	11	10	10	9	4	3	0	Olaparib 300 mg bd
130	102	74	48	37	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcc 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.56 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hypertonie
Safety Analysis Set, DCO 07MAR2022



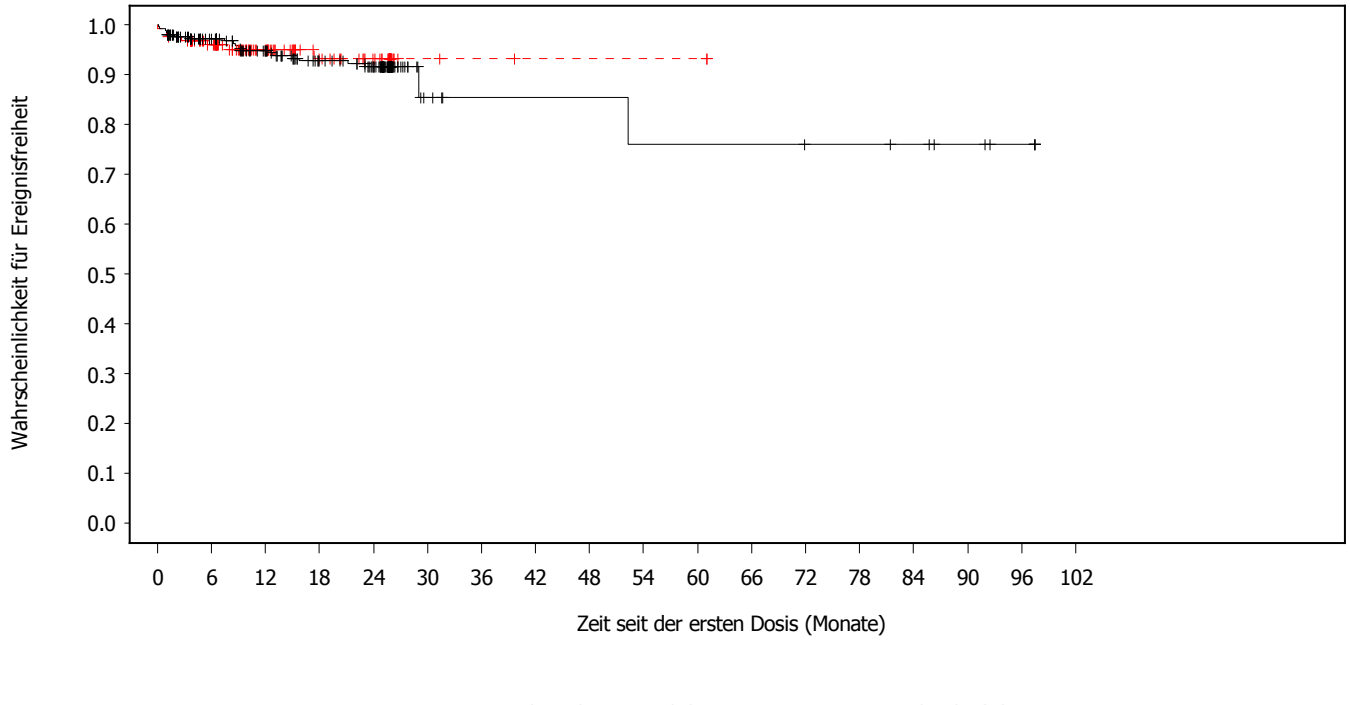
Anzahl an Patienten unter Risiko:

260	220	192	169	155	17	12	10	10	10	10	10	9	9	8	5	3	0	Olaparib 300 mg bd
130	104	74	49	37	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcd 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.57 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Herzerkrankungen
Safety Analysis Set, DCO 07MAR2022



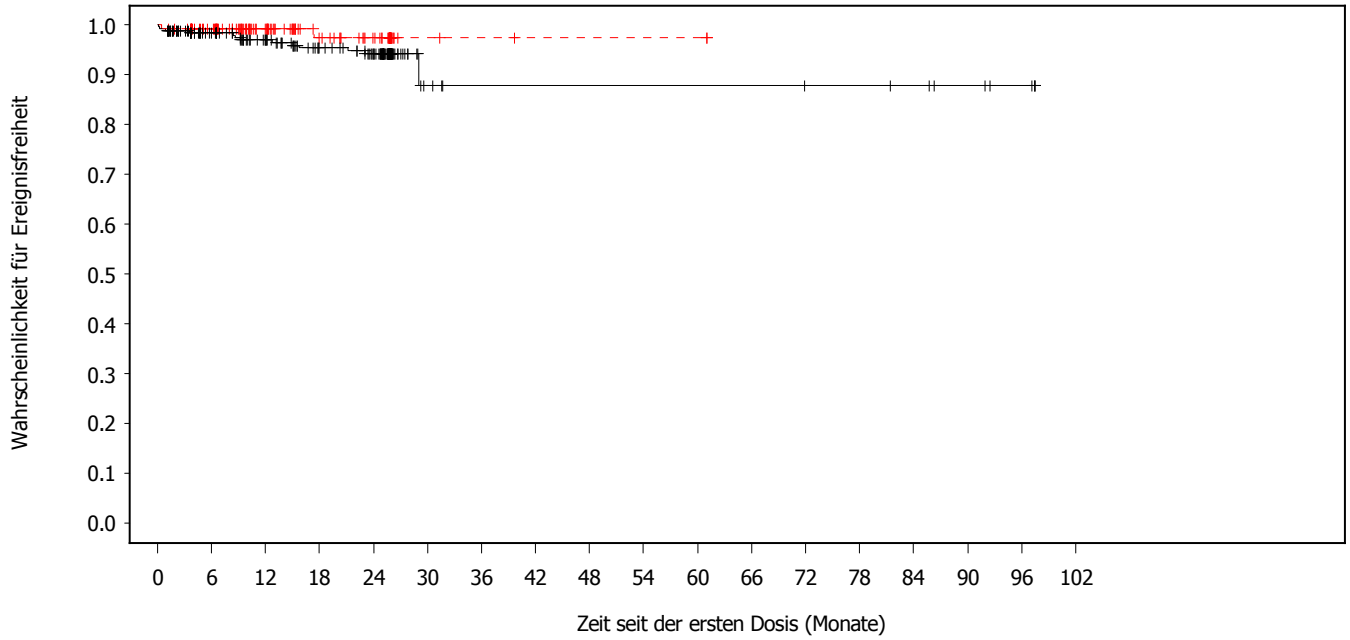
Anzahl an Patienten unter Risiko:

260	219	191	165	149	12	9	9	9	8	8	8	7	7	6	4	2	0	Olaparib 300 mg bd
130	109	74	50	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebce 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.58 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Palpitationen
Safety Analysis Set, DCO 07MAR2022



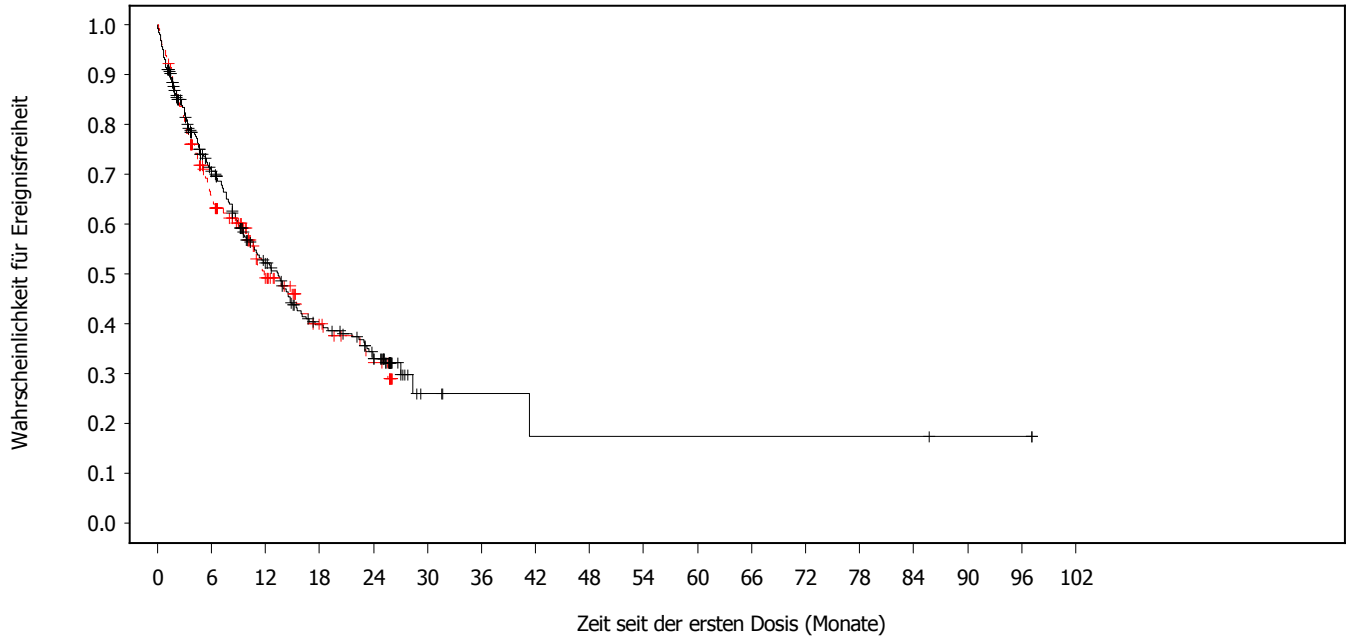
Anzahl an Patienten unter Risiko:

260	221	193	168	152	12	9	9	9	9	9	9	8	8	7	5	3	0	Olaparib 300 mg bd
130	112	78	52	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcf 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.59 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Infektionen und parasitaere Erkrankungen
Safety Analysis Set, DCO 07MAR2022



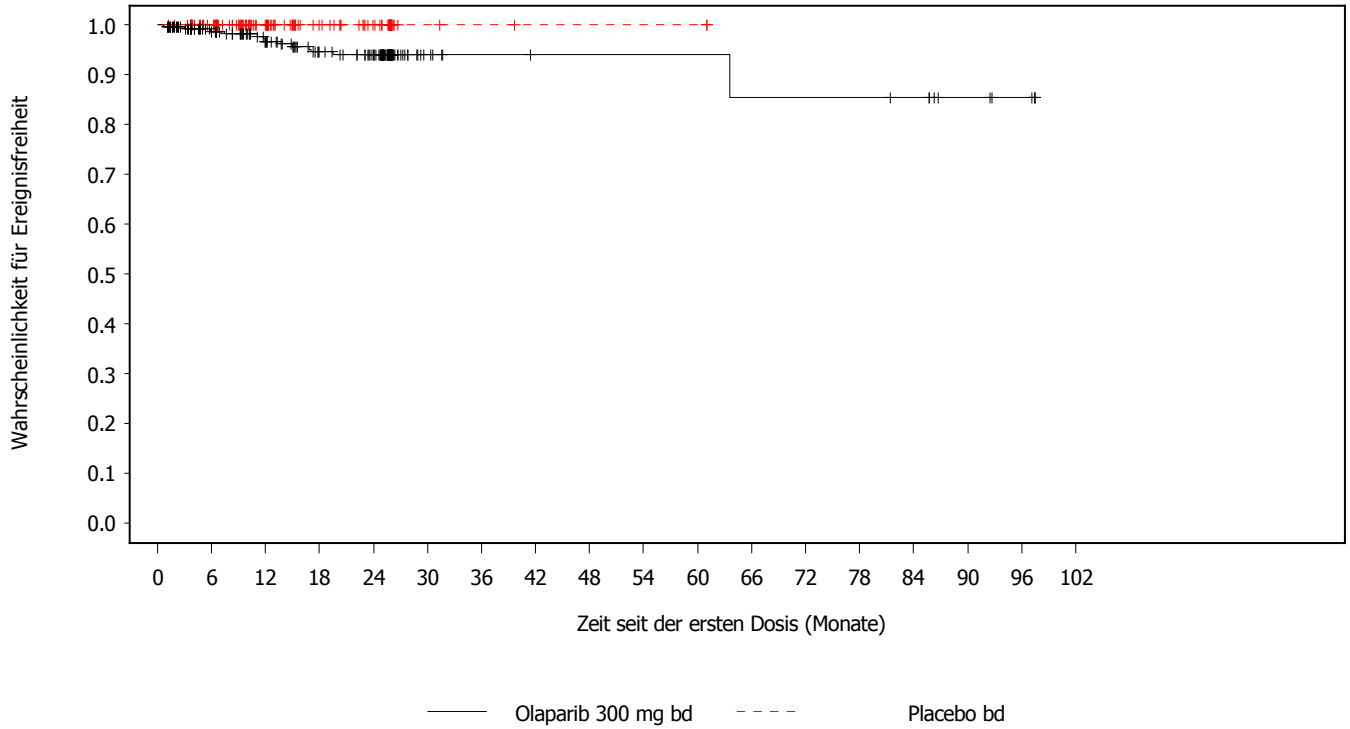
Anzahl an Patienten unter Risiko:

260	157	101	69	51	5	3	2	2	2	2	2	2	2	2	1	1	0	Olaparib 300 mg bd
130	76	37	18	12	0	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcg 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.60 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Bronchitis
Safety Analysis Set, DCO 07MAR2022



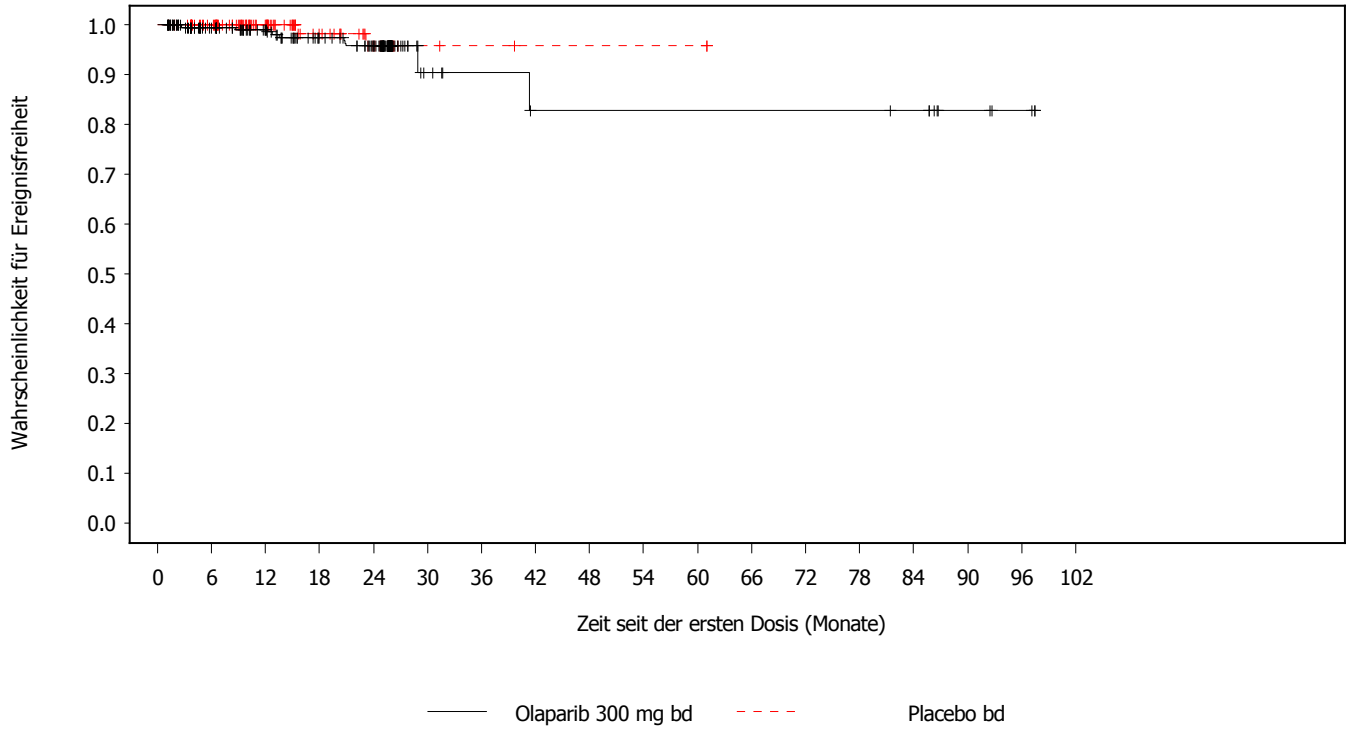
Anzahl an Patienten unter Risiko:

260	221	191	166	152	16	12	11	11	11	11	10	10	10	9	5	3	0	Olaparib 300 mg bd
130	113	79	53	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebch 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.61 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Gastroenteritis
Safety Analysis Set, DCO 07MAR2022



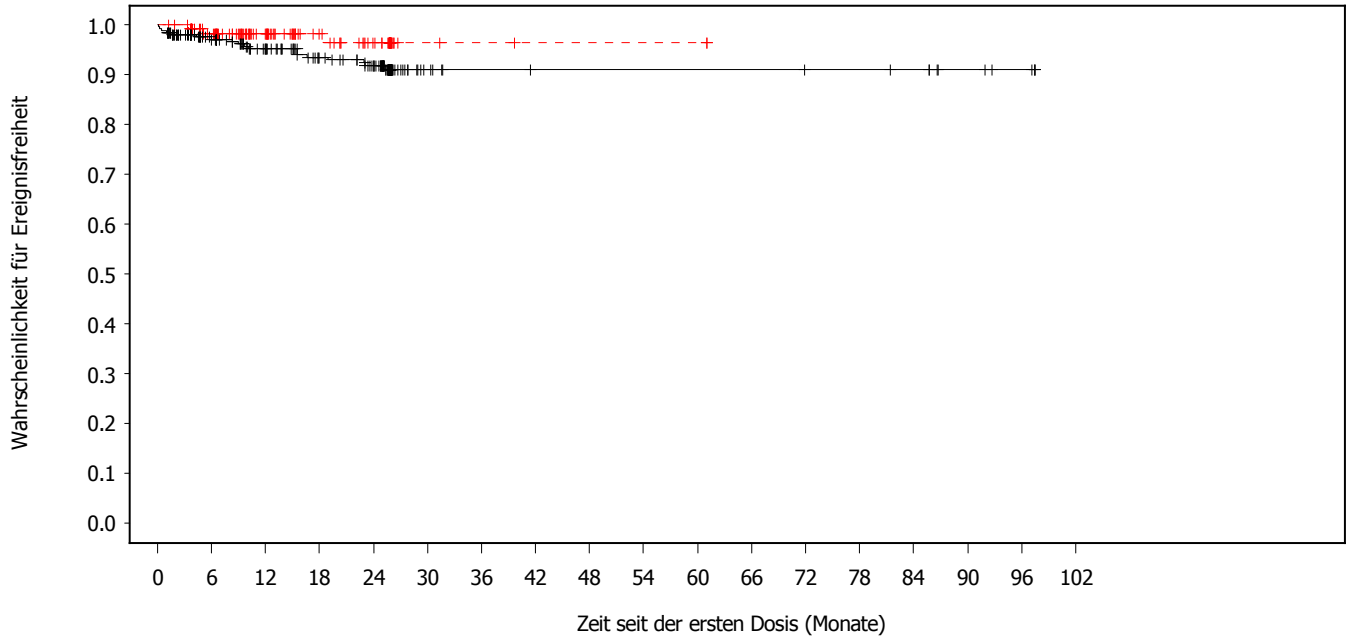
Anzahl an Patienten unter Risiko:

260	223	196	171	154	15	12	10	10	10	10	10	10	10	9	4	2	0	Olaparib 300 mg bd
130	113	79	52	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebci 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.62 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Grippe
Safety Analysis Set, DCO 07MAR2022



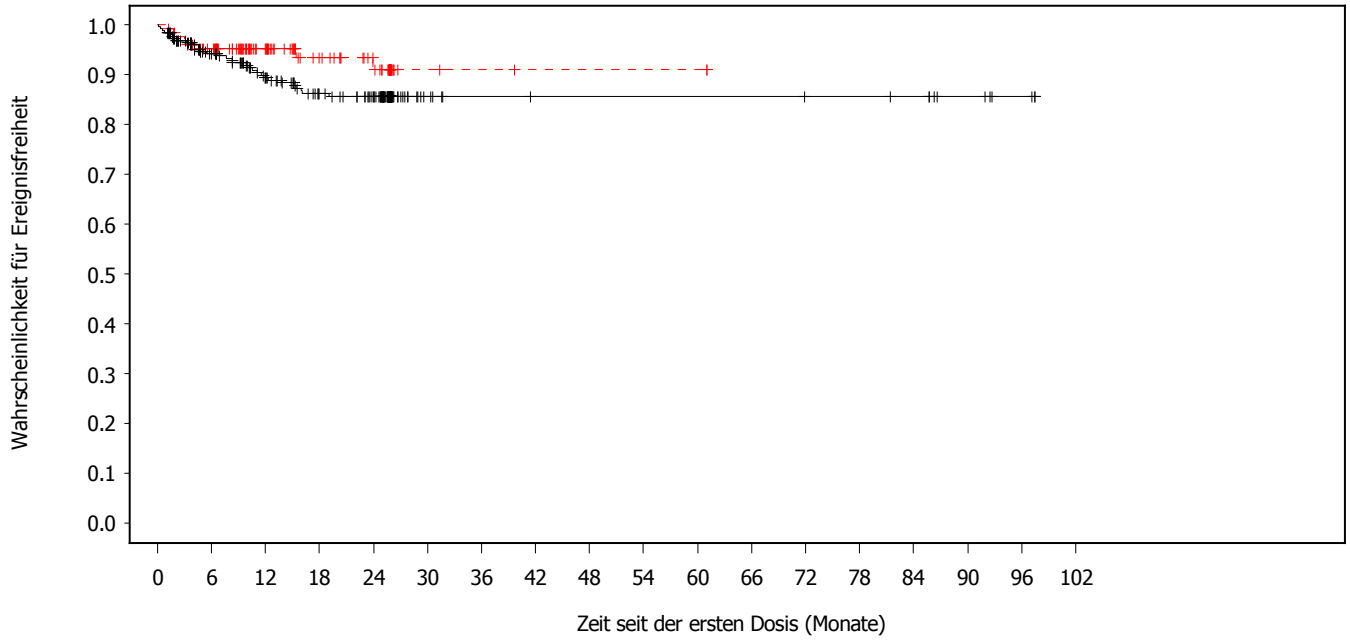
Anzahl an Patienten unter Risiko:

260	217	187	162	147	16	12	11	11	11	11	11	10	10	9	5	3	0	Olaparib 300 mg bd
130	111	78	52	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcj 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.63 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Harnwegsinfektion
Safety Analysis Set, DCO 07MAR2022



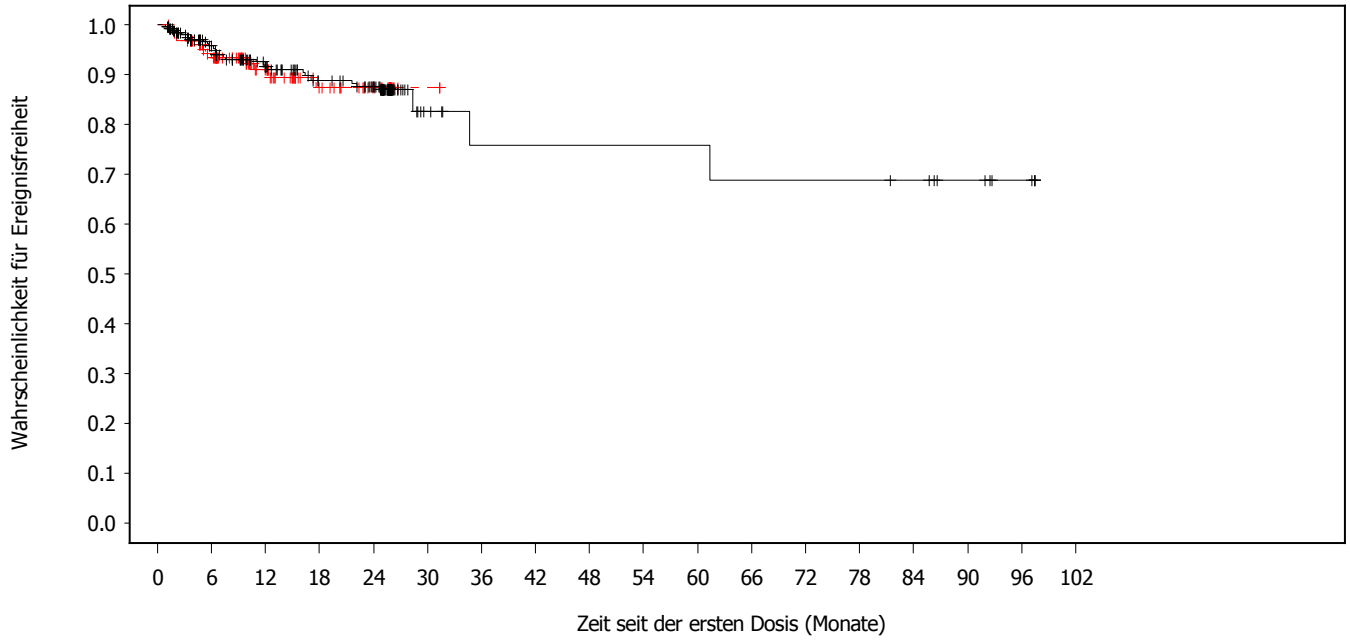
Anzahl an Patienten unter Risiko:

260	211	177	152	138	16	12	11	11	11	11	11	10	10	9	5	2	0	Olaparib 300 mg bd
130	107	74	49	38	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebck 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.64 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Infektion der oberen Atemwege
Safety Analysis Set, DCO 07MAR2022



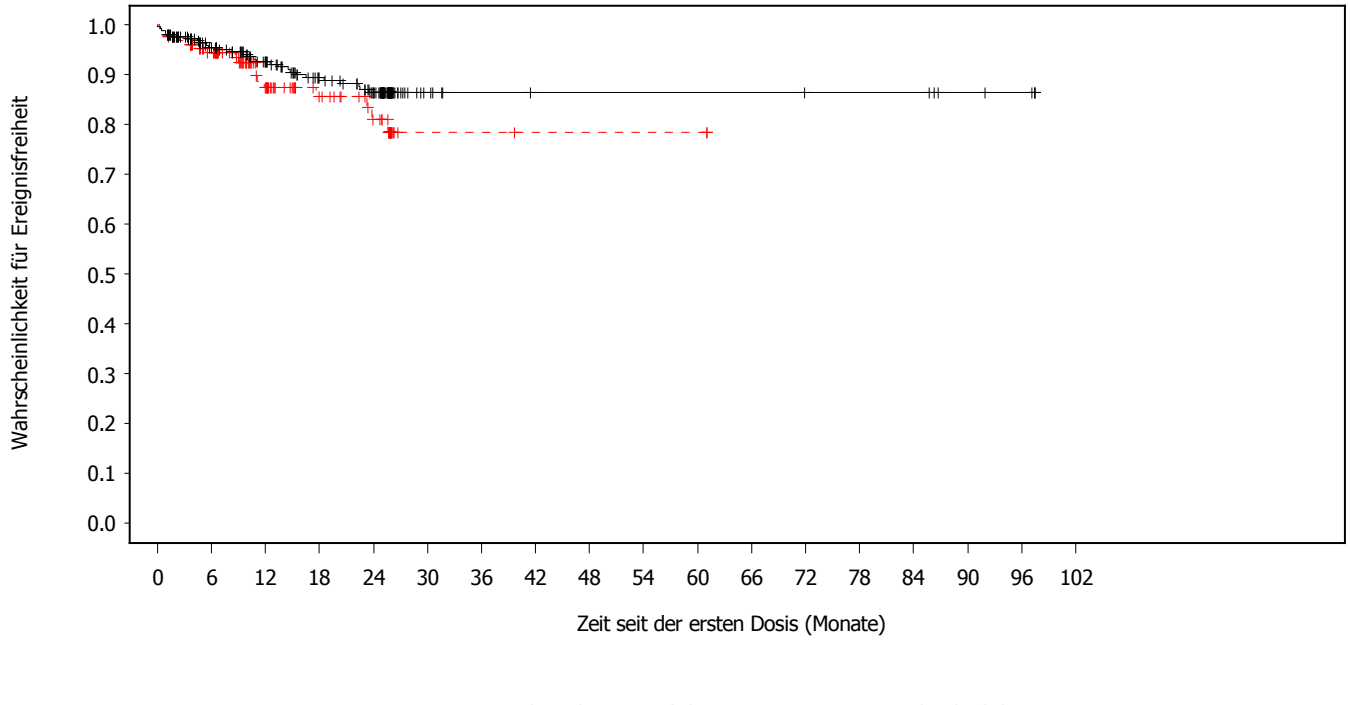
Anzahl an Patienten unter Risiko:

260	214	180	156	144	15	11	11	11	11	11	10	10	10	9	6	3	0	Olaparib 300 mg bd
130	106	69	43	31	1	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcl 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.65 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Nasopharyngitis
Safety Analysis Set, DCO 07MAR2022



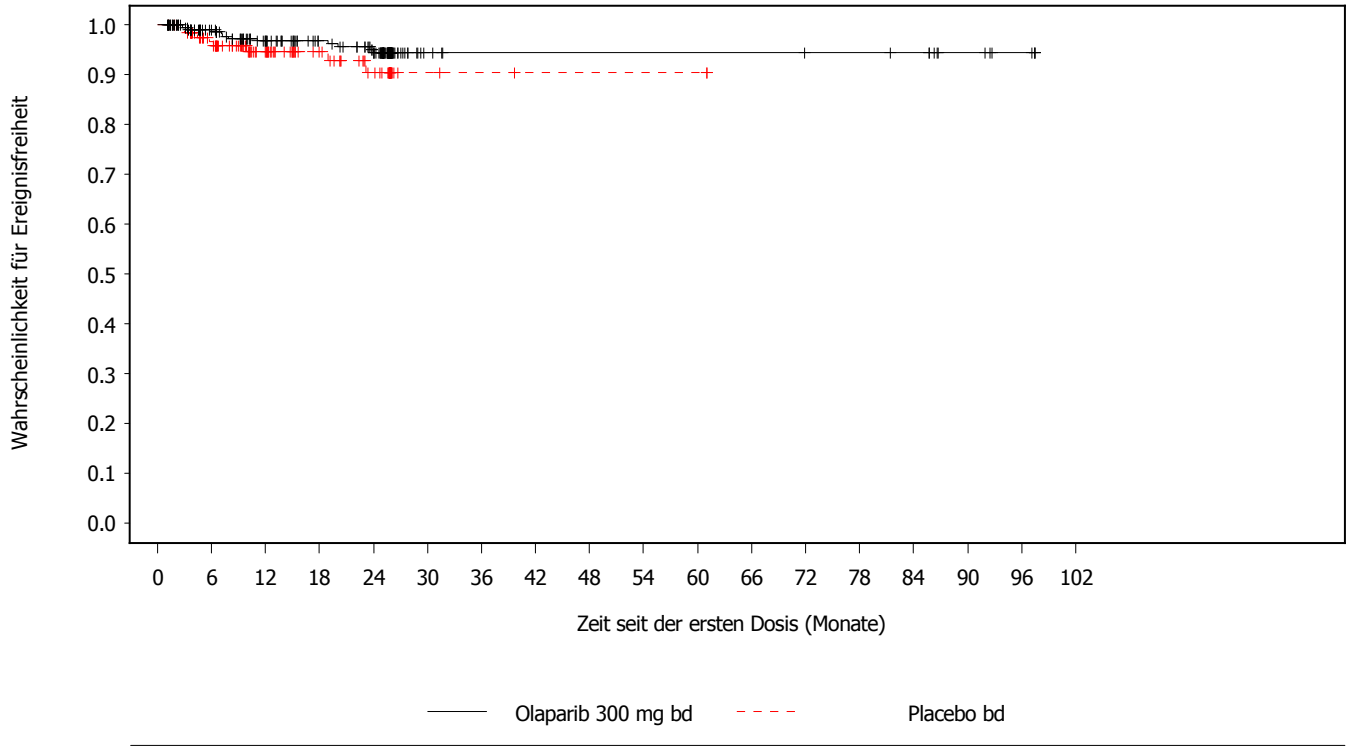
Anzahl an Patienten unter Risiko:

260	215	185	157	138	13	9	8	8	8	8	8	7	7	7	4	3	0	Olaparib 300 mg bd
130	108	69	46	35	2	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcm 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.66 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Sinusitis
Safety Analysis Set, DCO 07MAR2022



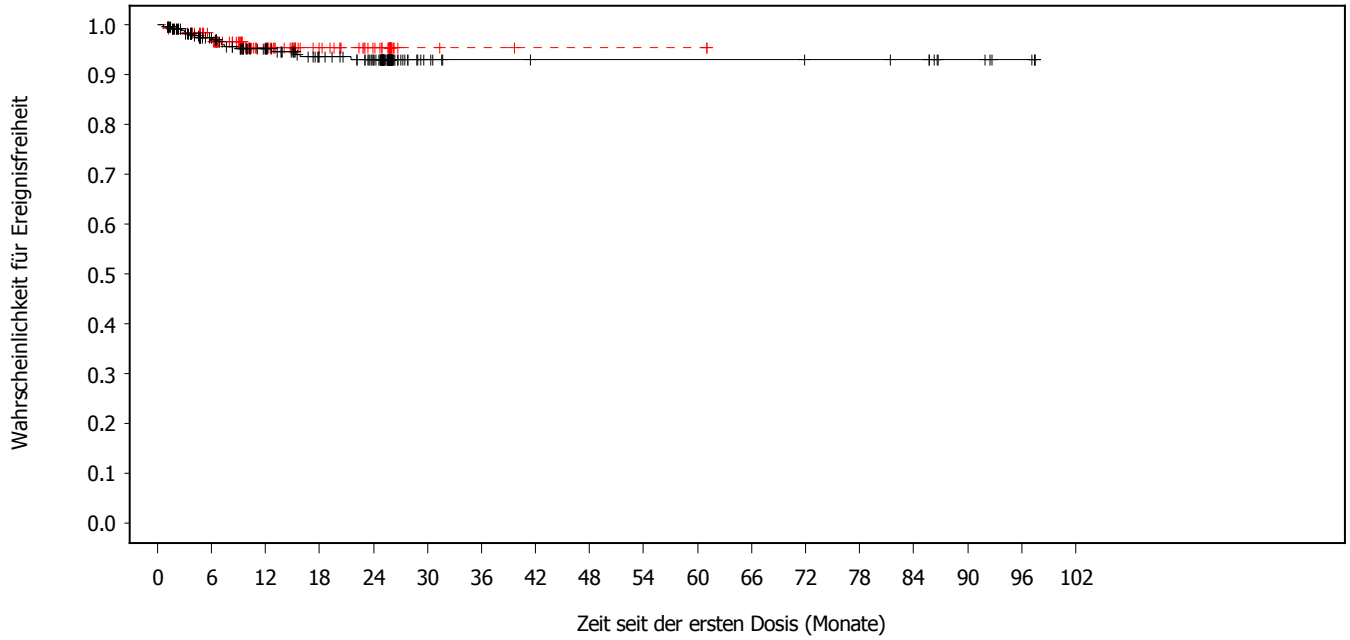
Anzahl an Patienten unter Risiko:

260	222	191	169	154	16	13	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	109	75	52	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcn 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.67 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Zystitis
Safety Analysis Set, DCO 07MAR2022



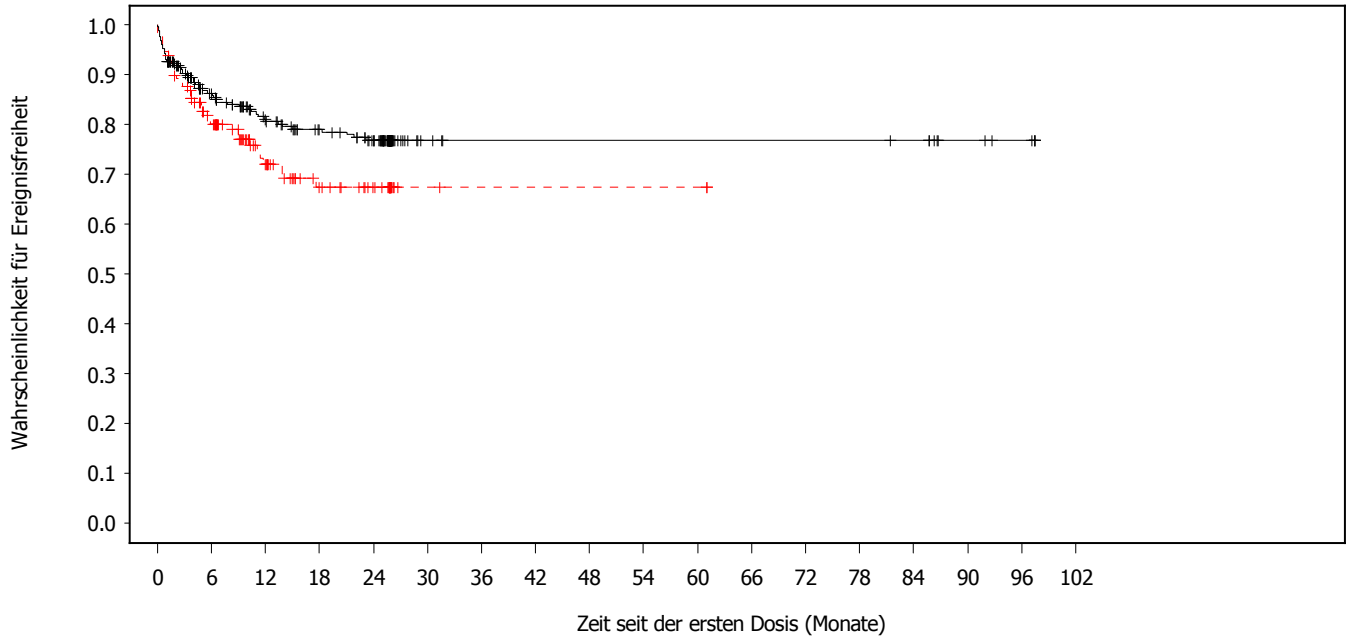
Anzahl an Patienten unter Risiko:

260	219	190	167	152	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	109	74	50	38	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebco 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.68 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Psychiatrische Erkrankungen
Safety Analysis Set, DCO 07MAR2022



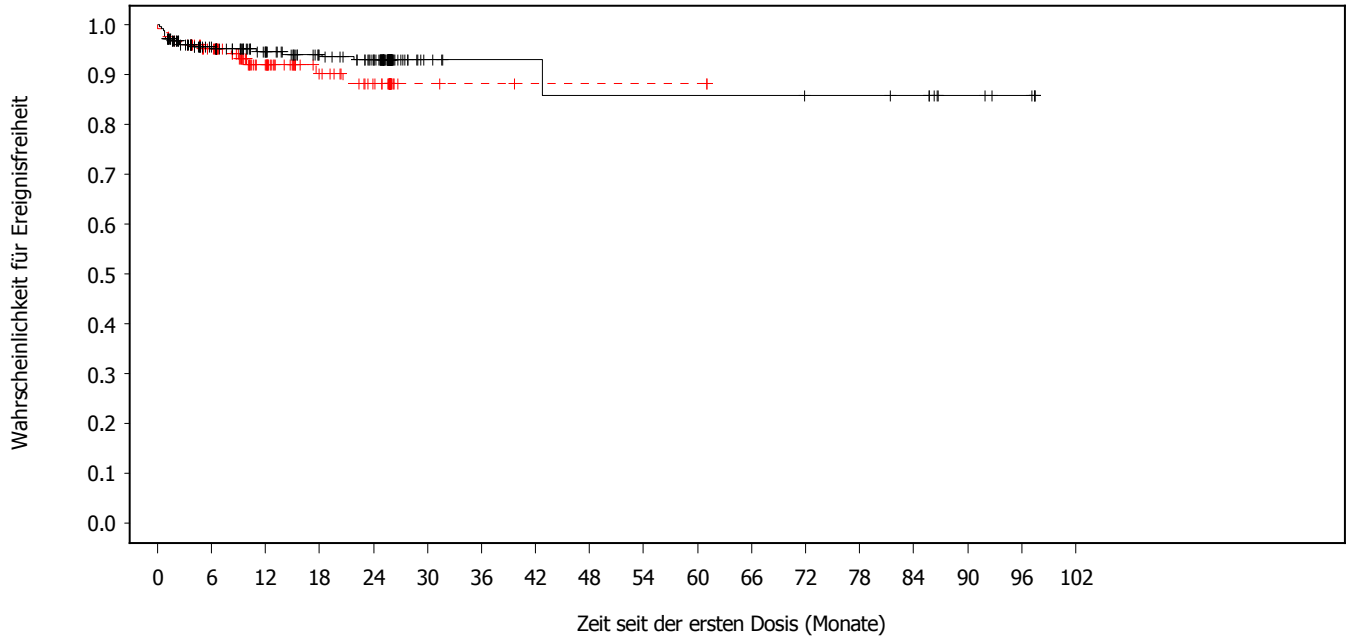
Anzahl an Patienten unter Risiko:

260	194	160	144	130	14	11	11	11	11	11	11	11	11	10	5	3	0	Olaparib 300 mg bd
130	91	57	38	29	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcp 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.69 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Angst
Safety Analysis Set, DCO 07MAR2022



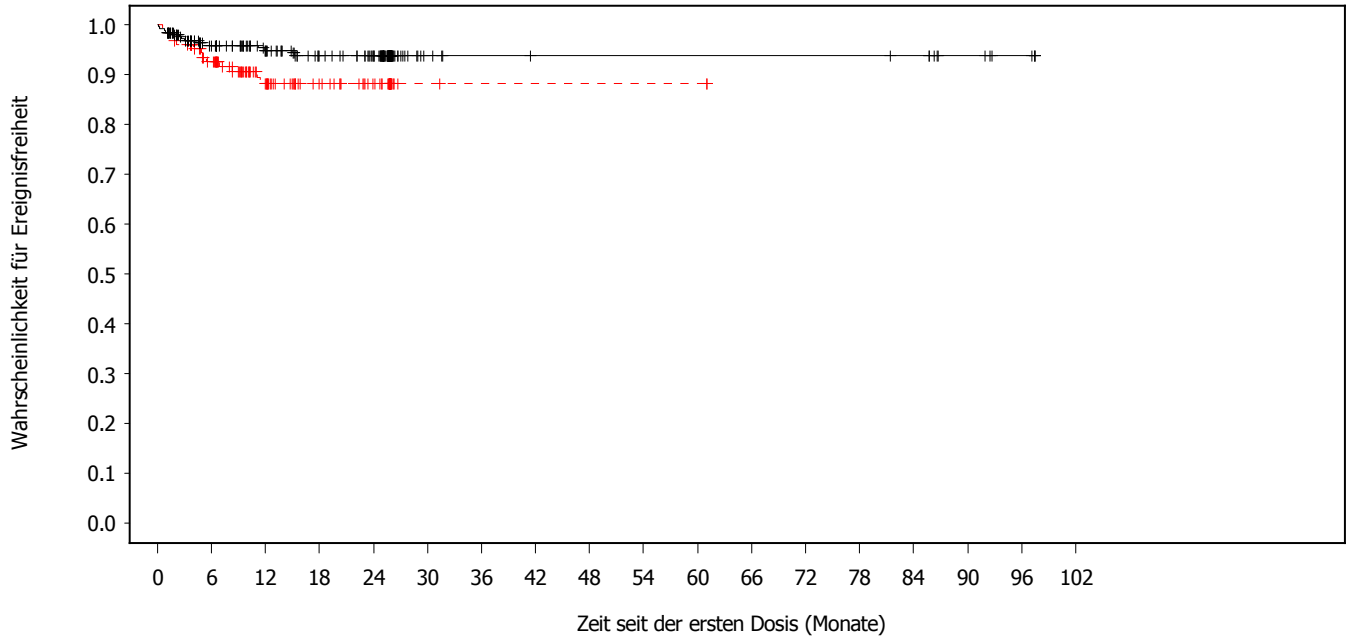
Anzahl an Patienten unter Risiko:

260	214	188	168	153	16	13	13	12	12	12	12	11	11	10	5	3	0	Olaparib 300 mg bd
130	109	73	48	37	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcq 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.70 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Depression
Safety Analysis Set, DCO 07MAR2022



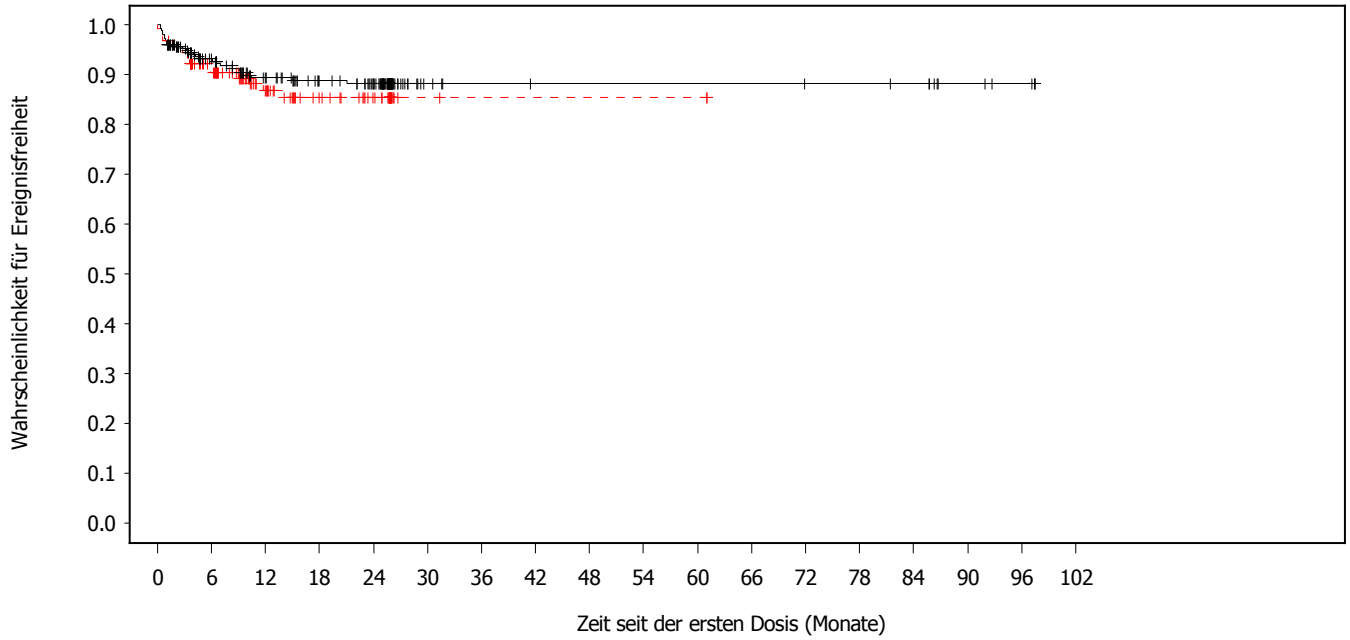
Anzahl an Patienten unter Risiko:

260	216	189	167	153	16	13	12	12	12	12	12	12	12	11	6	3	0	Olaparib 300 mg bd
130	105	69	46	34	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcr 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.71 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schlaflosigkeit
Safety Analysis Set, DCO 07MAR2022



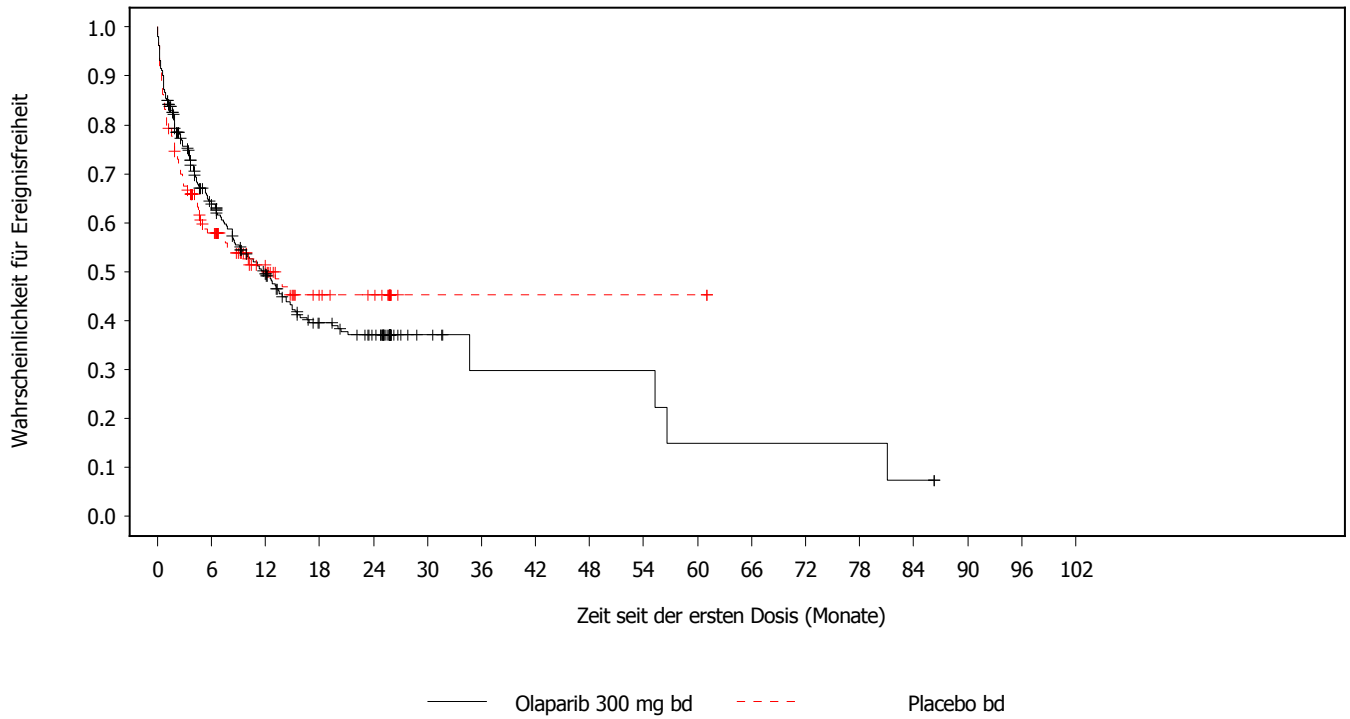
Anzahl an Patienten unter Risiko:

260	207	176	159	146	16	13	12	12	12	12	12	11	11	10	5	3	0	Olaparib 300 mg bd
130	101	67	47	37	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcs 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.72 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Safety Analysis Set, DCO 07MAR2022



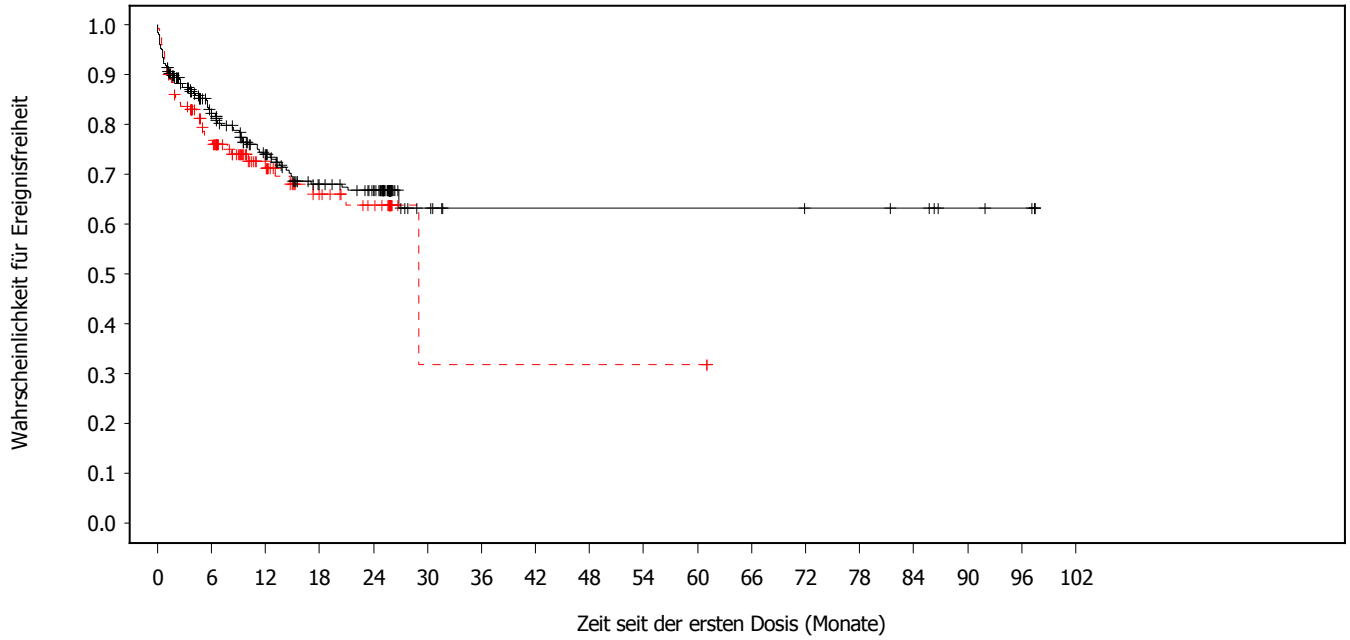
Anzahl an Patienten unter Risiko:

260	143	99	69	57	8	4	4	4	4	2	2	2	2	1	0	0	0	Olaparib 300 mg bd
130	63	37	22	19	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebct 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.73 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Arthralgie
Safety Analysis Set, DCO 07MAR2022



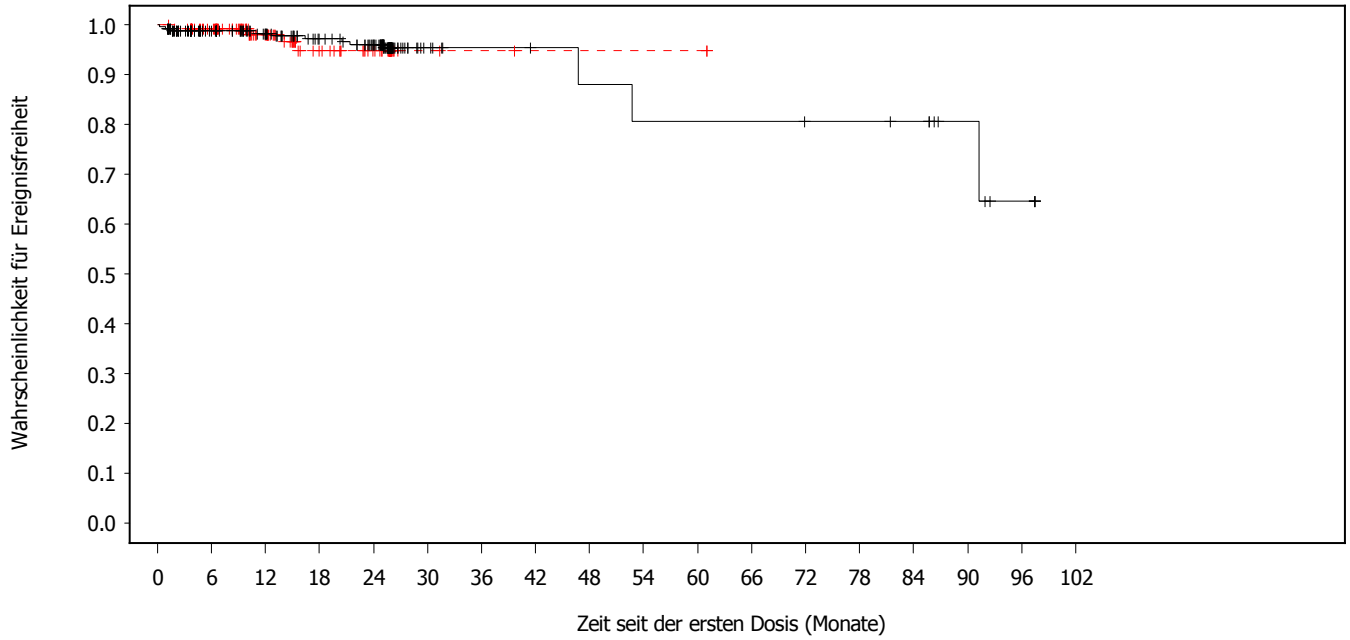
Anzahl an Patienten unter Risiko:

260	184	145	118	107	13	9	9	9	9	9	9	8	8	7	4	3	0	Olaparib 300 mg bd
130	87	51	33	26	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcu 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.74 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Brustschmerzen die Skelettmuskulatur betreffend
Safety Analysis Set, DCO 07MAR2022



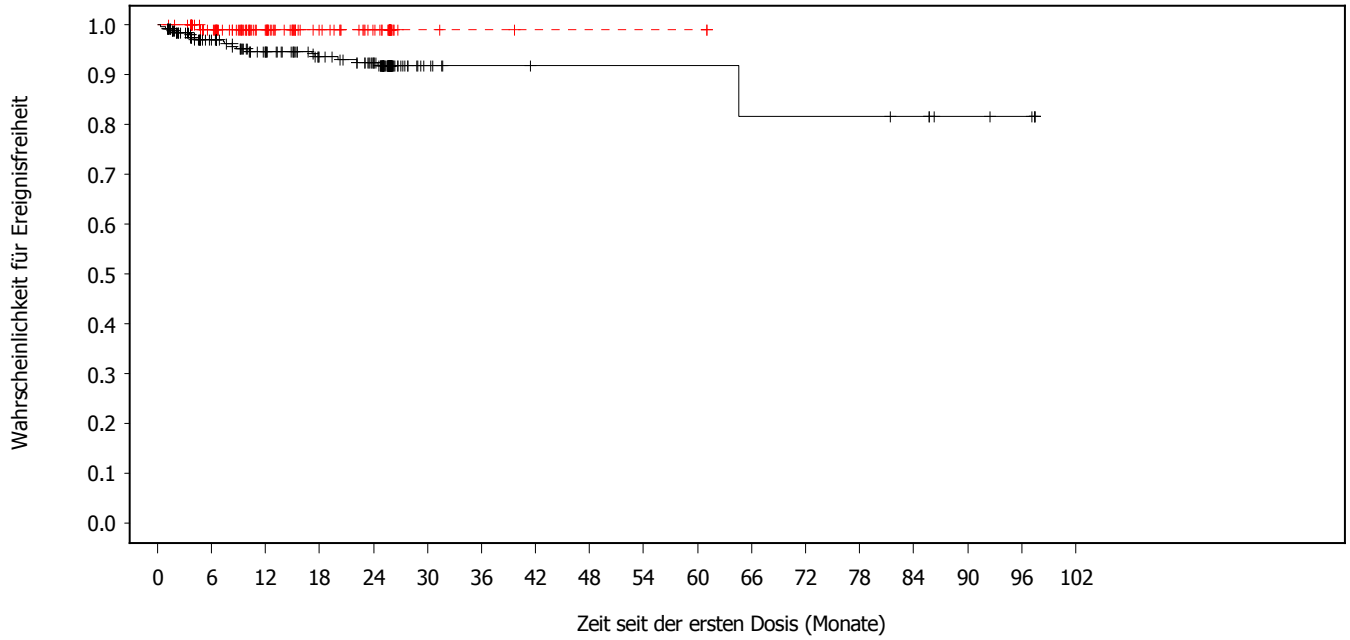
Anzahl an Patienten unter Risiko:

260	221	196	174	158	18	14	13	12	11	11	11	10	10	9	5	2	0	Olaparib 300 mg bd
130	112	77	51	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcv 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.75 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Muskelspasmen
Safety Analysis Set, DCO 07MAR2022



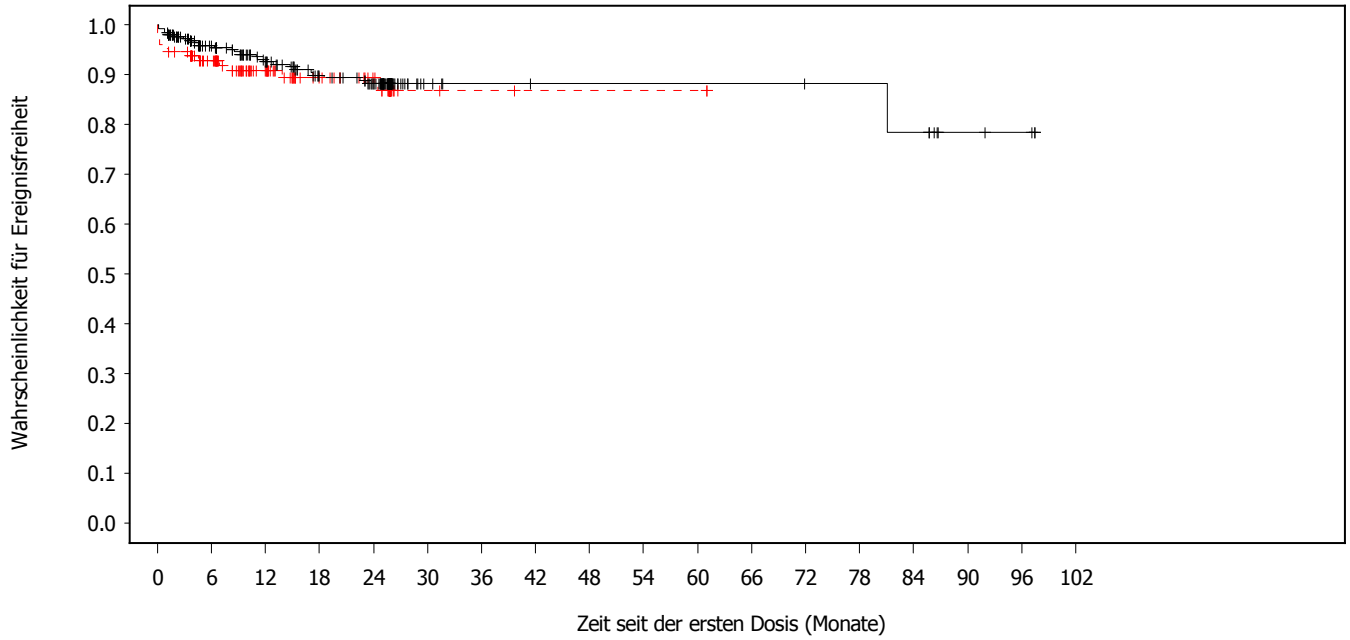
Anzahl an Patienten unter Risiko:

260	217	187	165	149	14	10	9	9	9	9	8	8	8	7	4	3	0	Olaparib 300 mg bd
130	112	78	52	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcw 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.76 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Myalgie
Safety Analysis Set, DCO 07MAR2022



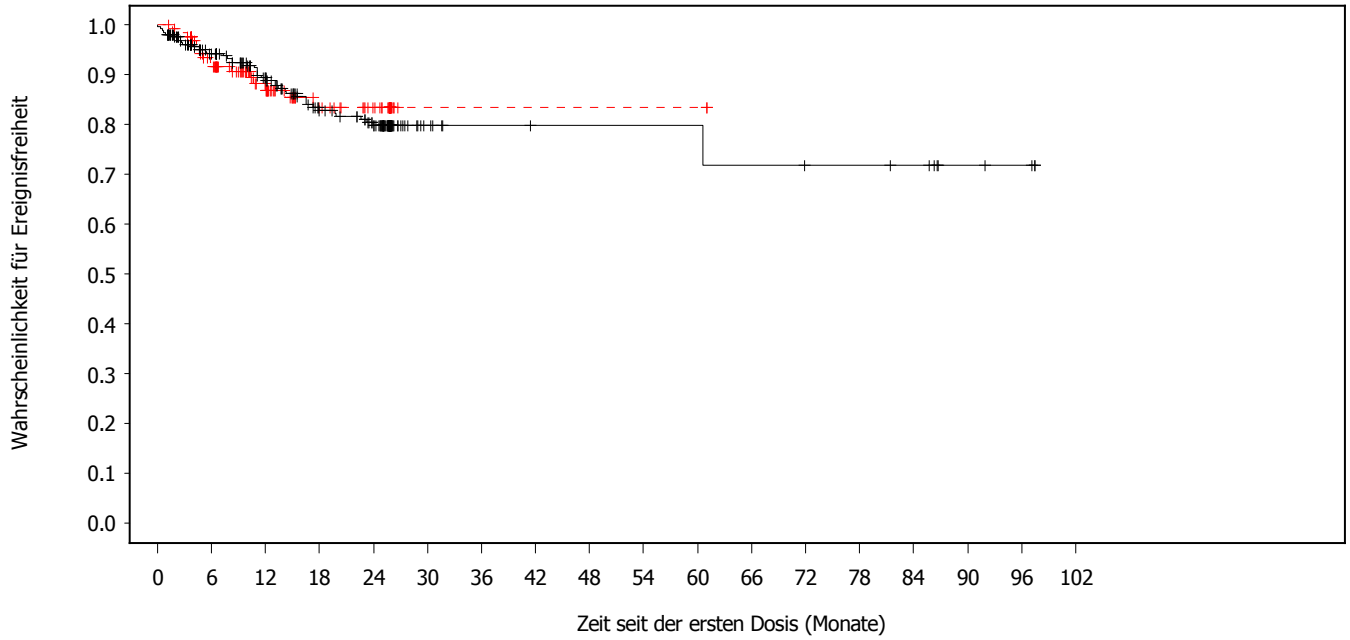
Anzahl an Patienten unter Risiko:

260	216	184	160	145	14	11	10	10	10	10	10	9	9	8	3	2	0	Olaparib 300 mg bd
130	104	71	46	36	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcx 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.77 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Rueckenschmerzen
Safety Analysis Set, DCO 07MAR2022



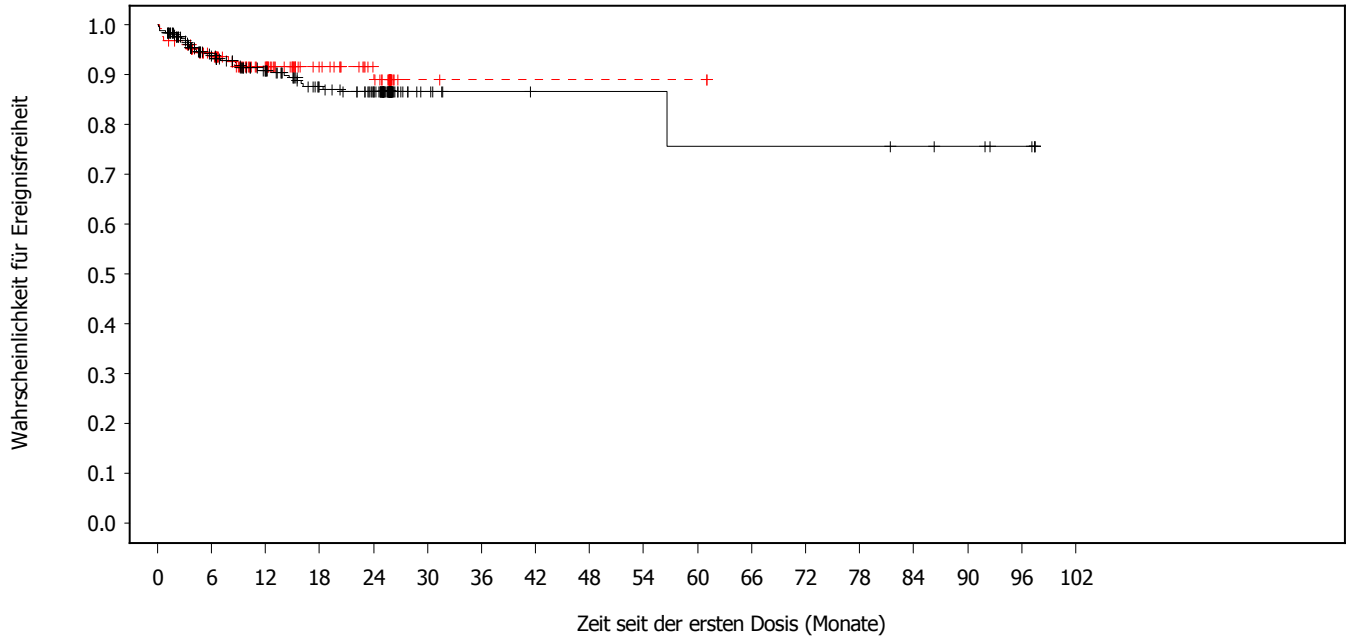
Anzahl an Patienten unter Risiko:

260	211	176	143	125	15	11	10	10	10	10	9	8	8	7	3	2	0	Olaparib 300 mg bd
130	104	69	43	33	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcy 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.78 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerz in einer Extremitaet
Safety Analysis Set, DCO 07MAR2022



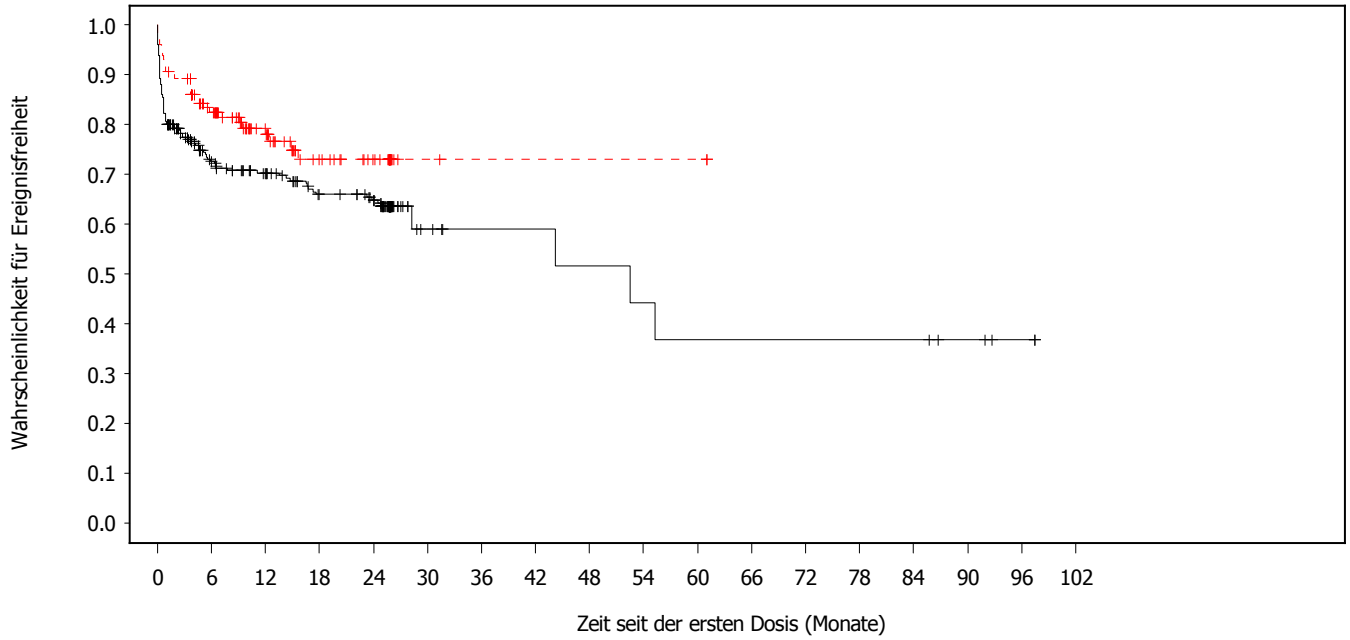
Anzahl an Patienten unter Risiko:

260	210	180	154	138	13	9	8	8	8	7	7	7	7	6	5	3	0	Olaparib 300 mg bd
130	105	74	49	37	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebcz 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.79 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 07MAR2022



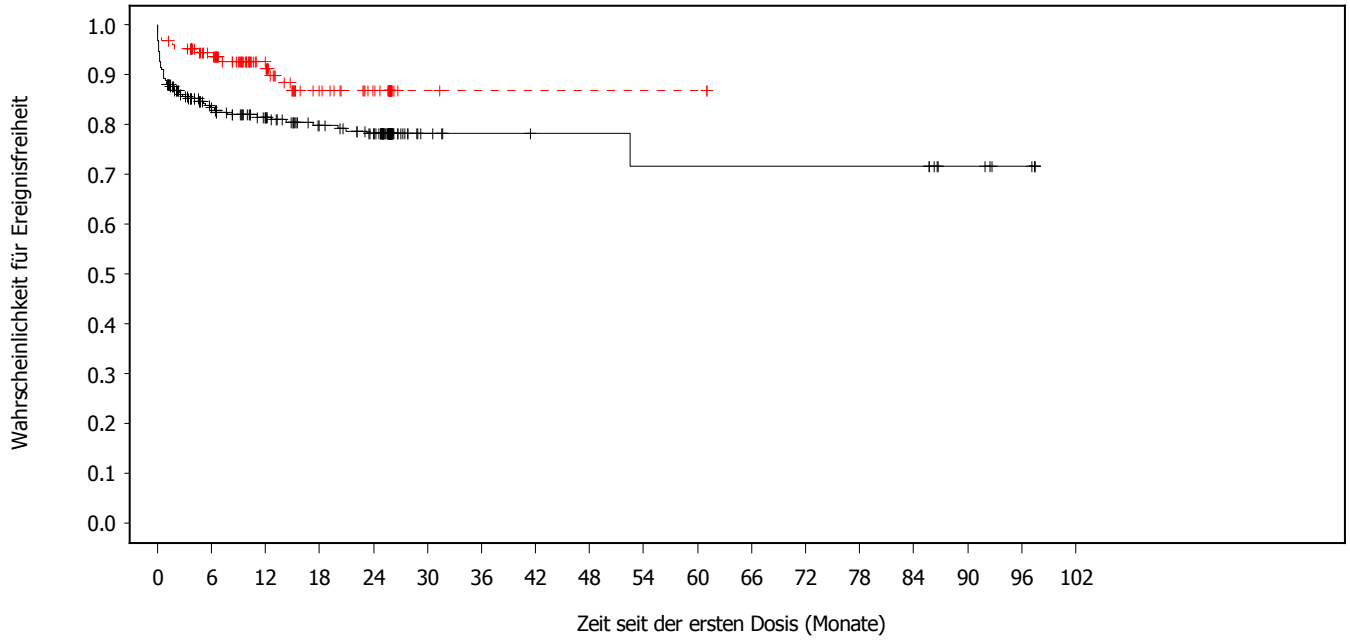
Anzahl an Patienten unter Risiko:

260	160	141	119	110	11	8	8	7	6	5	5	5	5	3	1	0	Olaparib 300 mg bd
130	92	60	35	26	2	1	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebda 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.80 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Appetit vermindert
Safety Analysis Set, DCO 07MAR2022



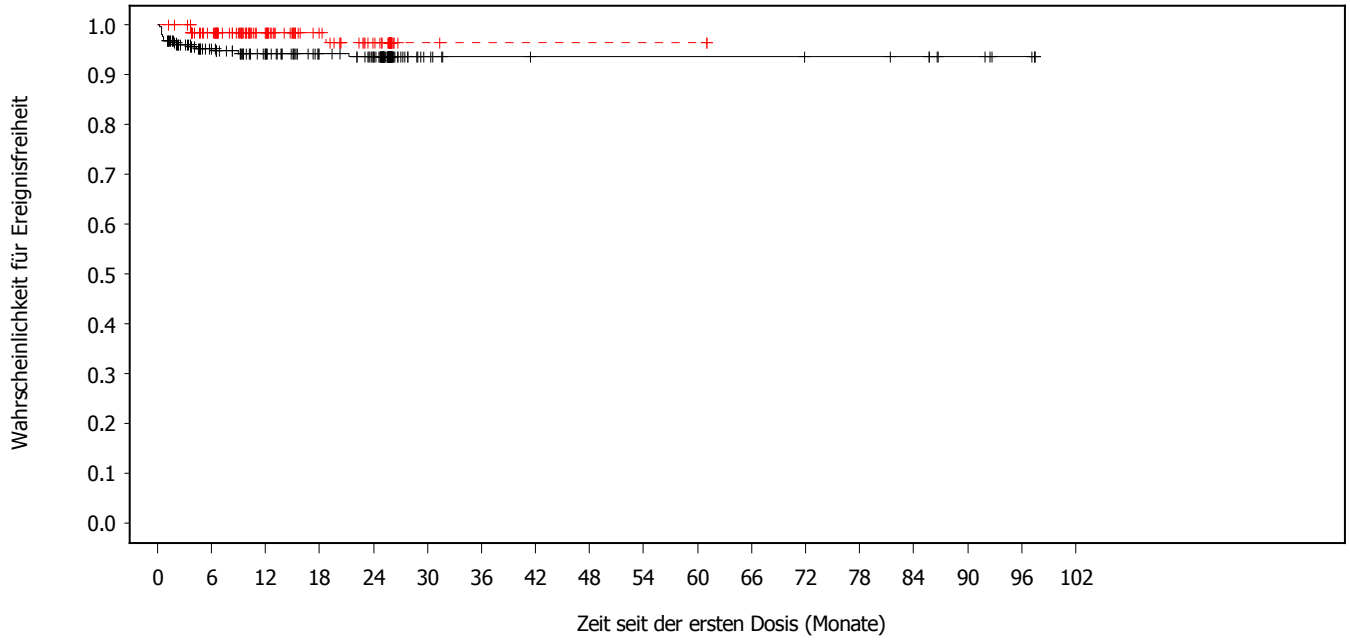
Anzahl an Patienten unter Risiko:

260	185	161	141	129	16	13	12	12	11	11	11	11	11	11	6	3	0	Olaparib 300 mg bd
130	106	72	44	34	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdb 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.81 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hypokaliaemie
Safety Analysis Set, DCO 07MAR2022



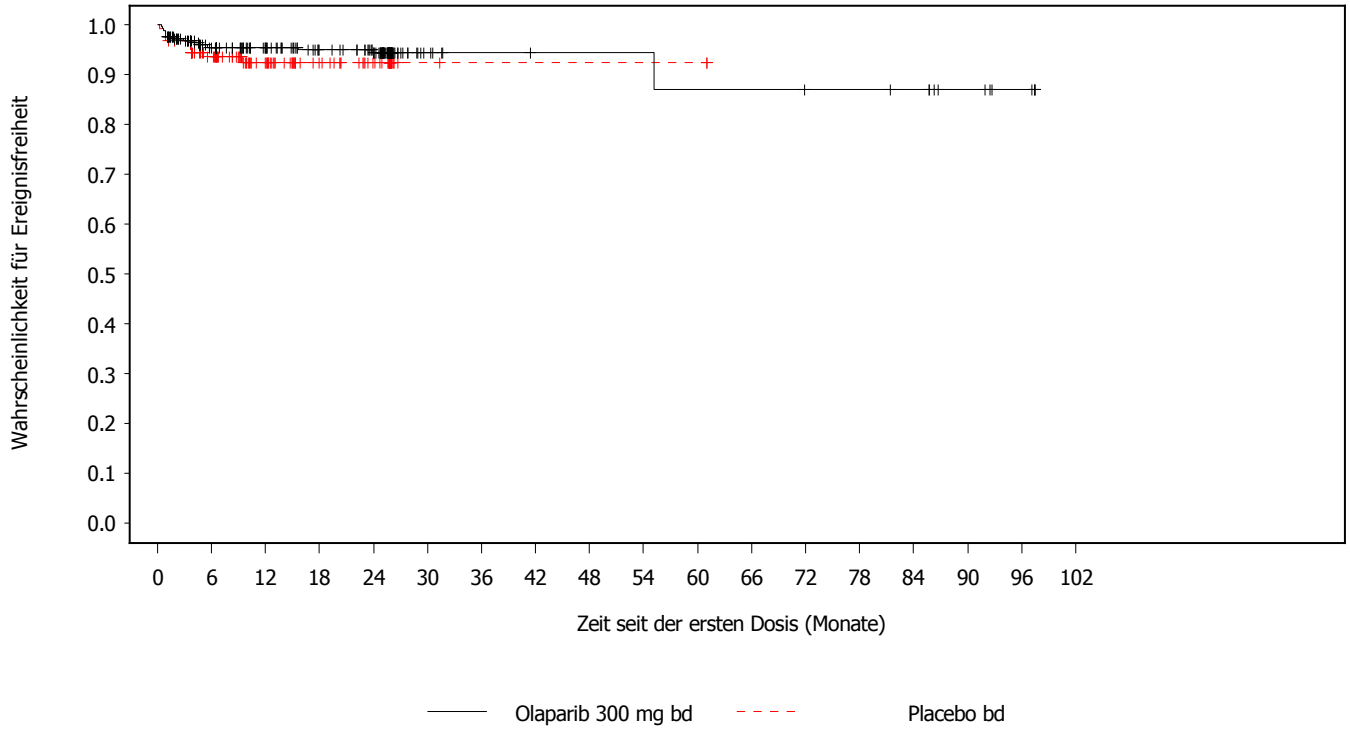
Anzahl an Patienten unter Risiko:

260	212	187	165	153	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
130	111	77	51	38	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdc 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.82 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hypomagnesiaemie
Safety Analysis Set, DCO 07MAR2022



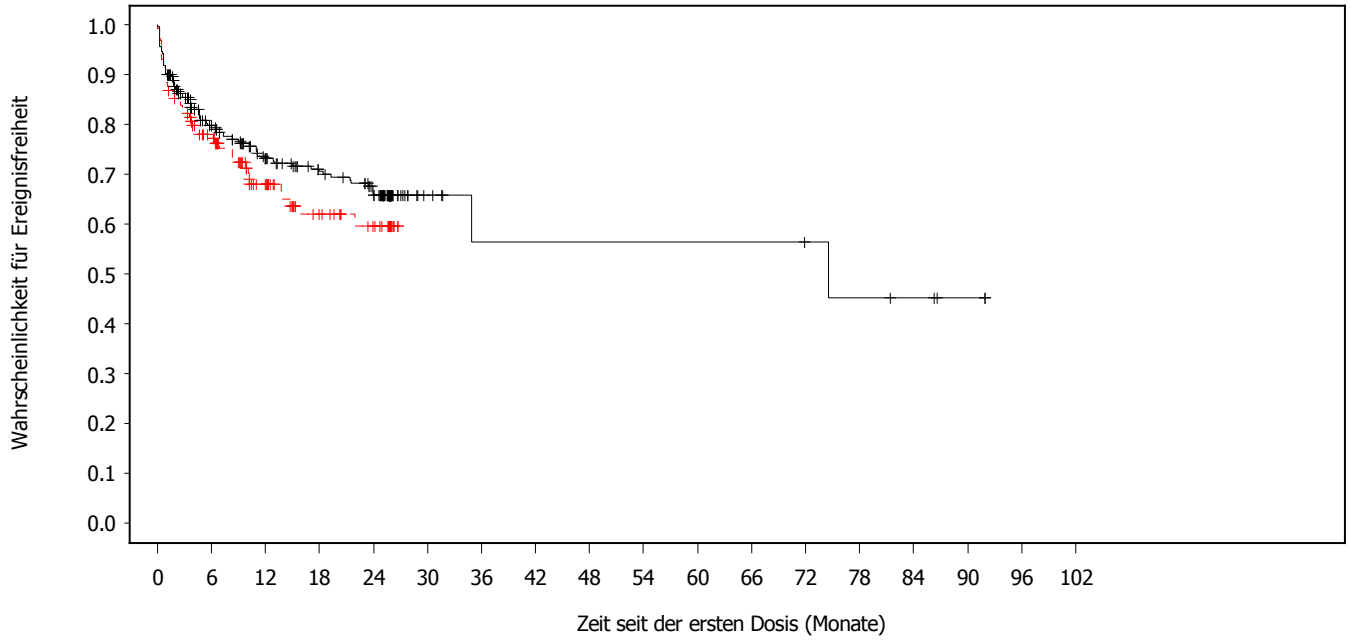
Anzahl an Patienten unter Risiko:

260	215	190	168	154	18	14	13	13	13	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
130	105	73	50	38	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdd 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.83 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Untersuchungen
Safety Analysis Set, DCO 07MAR2022



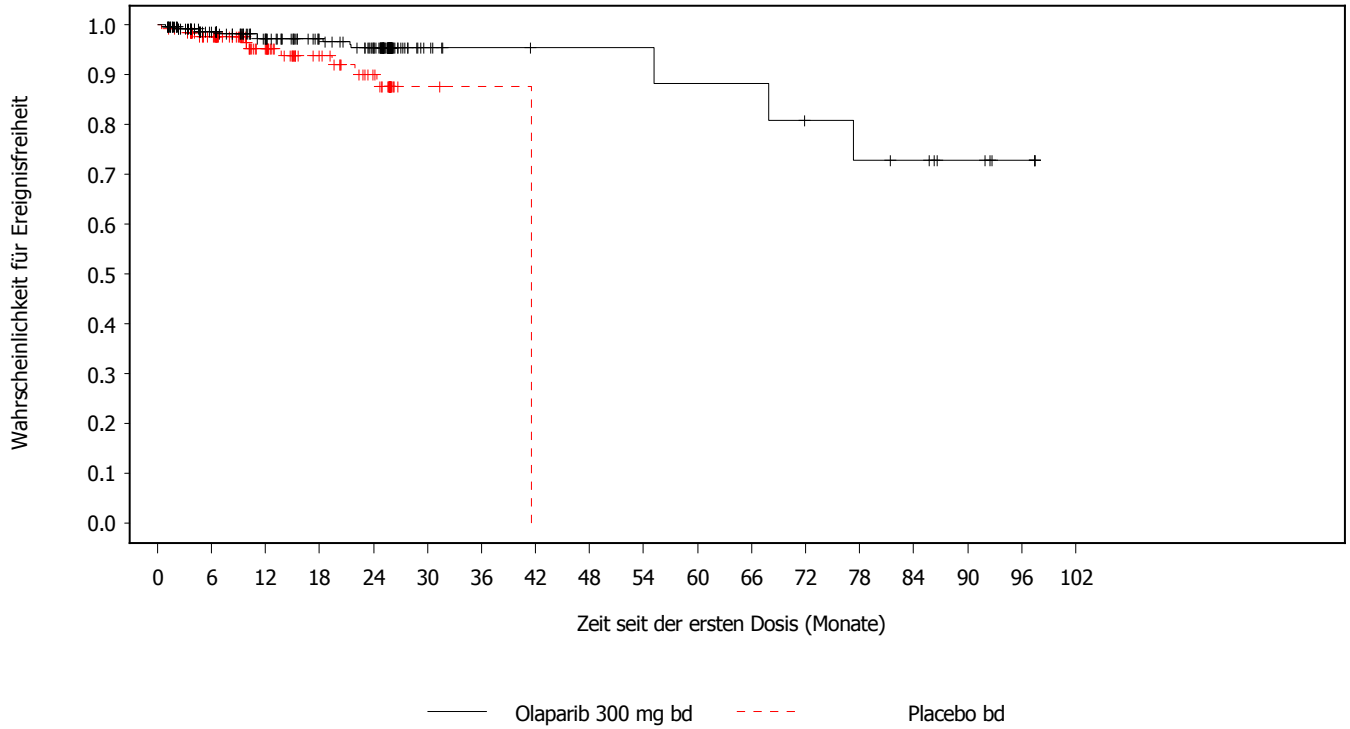
Anzahl an Patienten unter Risiko:

260	179	145	126	110	10	6	6	6	6	6	6	5	4	3	1	0	0	Olaparib 300 mg bd
130	88	56	34	25	0	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebde 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.84 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, DCO 07MAR2022



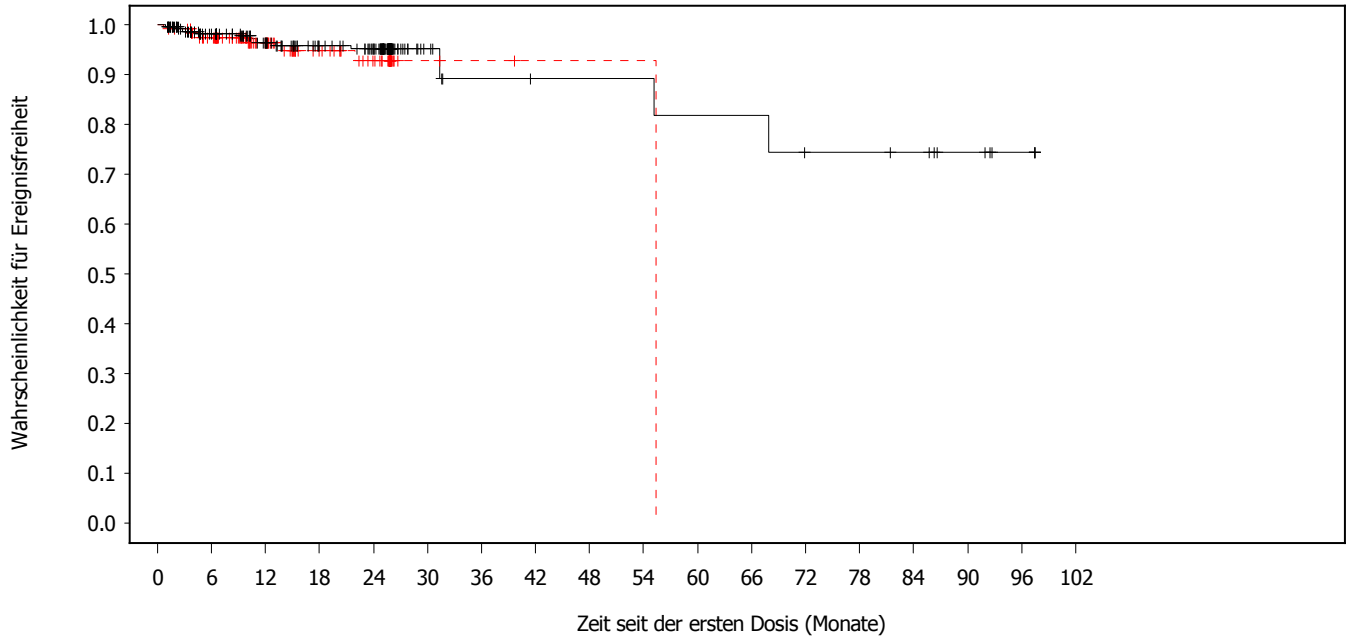
Anzahl an Patienten unter Risiko:

260	221	192	170	154	18	14	13	13	13	12	12	10	9	8	5	2	0	Olaparib 300 mg bd
130	112	77	52	39	2	1	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdf 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.85 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Aspartataminotransferase erhoeht
Safety Analysis Set, DCO 07MAR2022



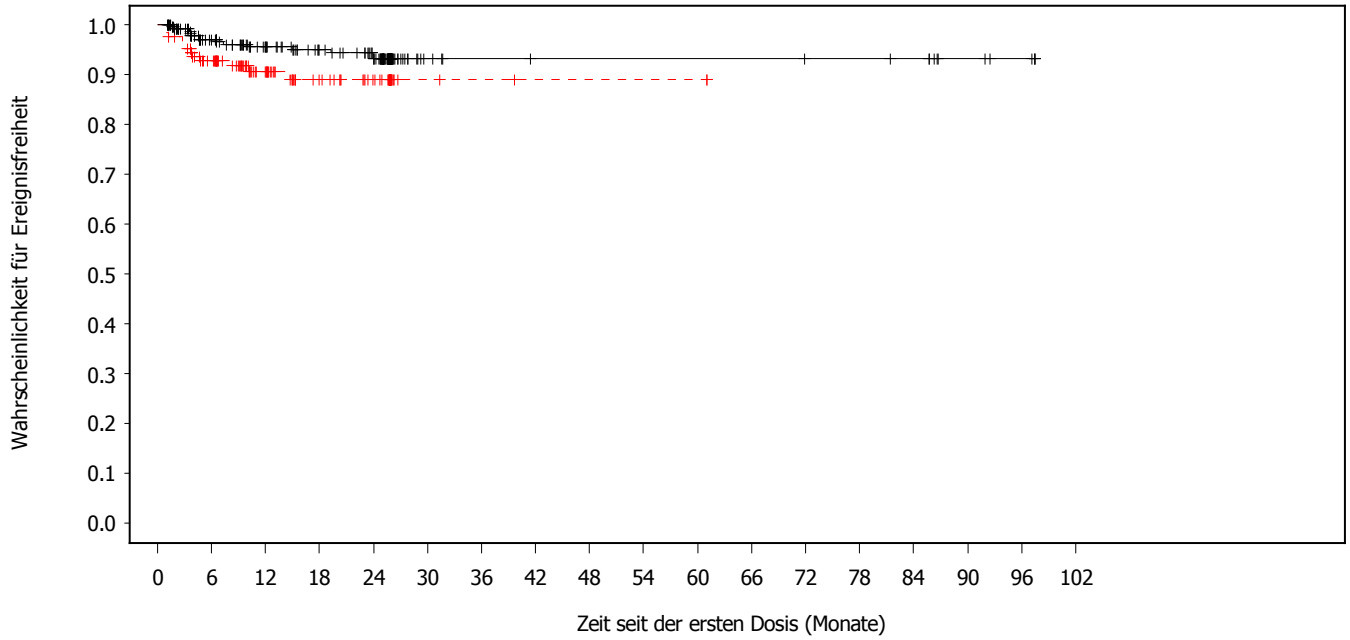
Anzahl an Patienten unter Risiko:

260	221	191	168	154	18	13	12	12	12	11	11	9	9	8	5	2	0	Olaparib 300 mg bd
130	111	76	51	40	3	2	1	1	1	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdg 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.86 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Gewicht erhoeht
Safety Analysis Set, DCO 07MAR2022



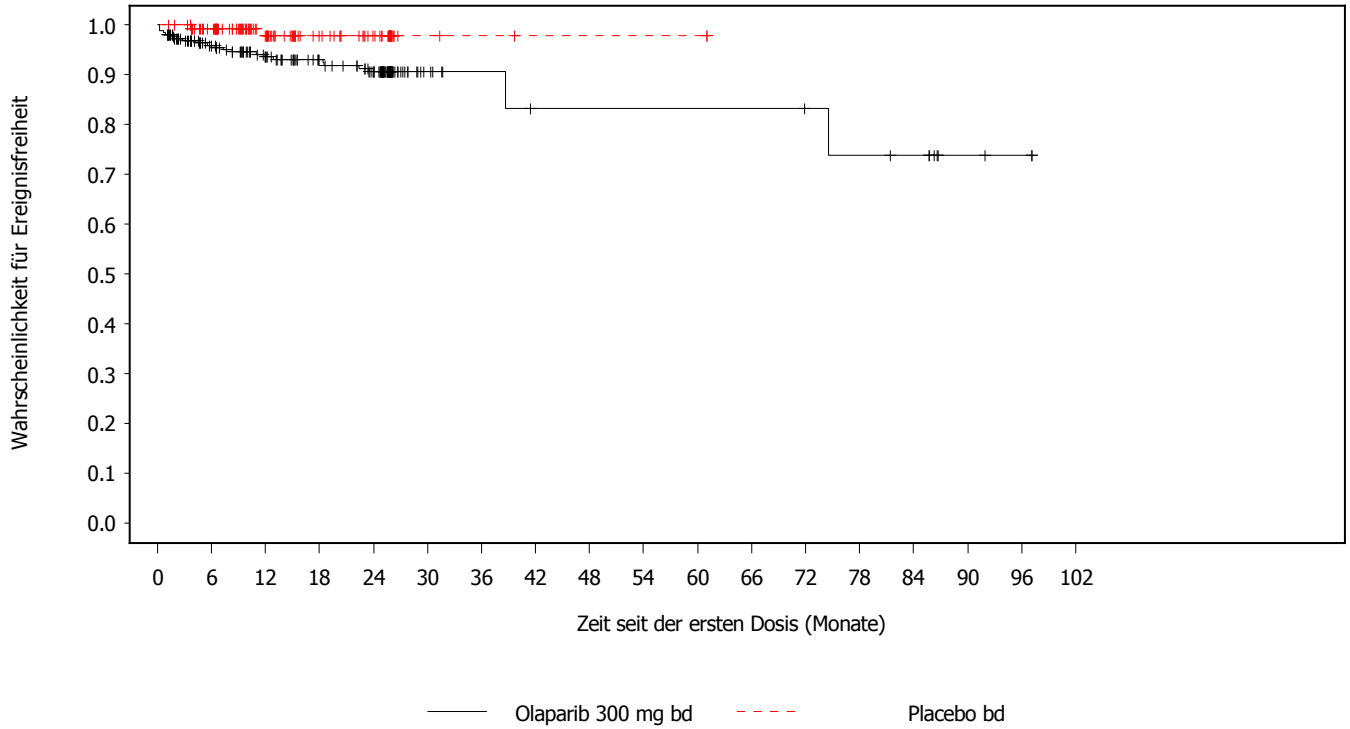
Anzahl an Patienten unter Risiko:

260	217	188	169	153	16	13	12	12	12	12	12	11	11	10	5	3	0	Olaparib 300 mg bd
130	104	70	47	36	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdh 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.87 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Kreatinin im Blut erhoeht
Safety Analysis Set, DCO 07MAR2022



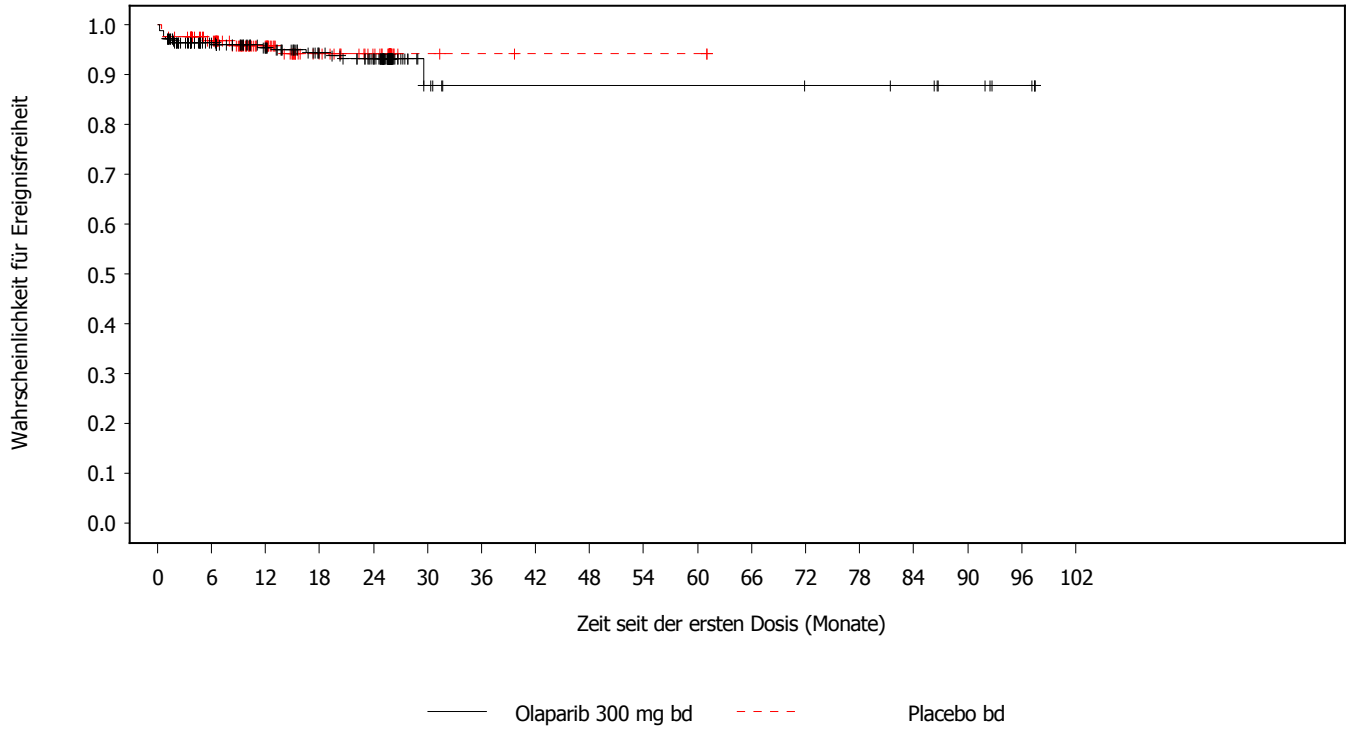
Anzahl an Patienten unter Risiko:

260	215	186	165	149	16	12	10	10	10	10	10	9	8	7	2	1	0	Olaparib 300 mg bd
130	112	77	51	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdi 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.88 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Leukozytenzahl erniedrigt
Safety Analysis Set, DCO 07MAR2022



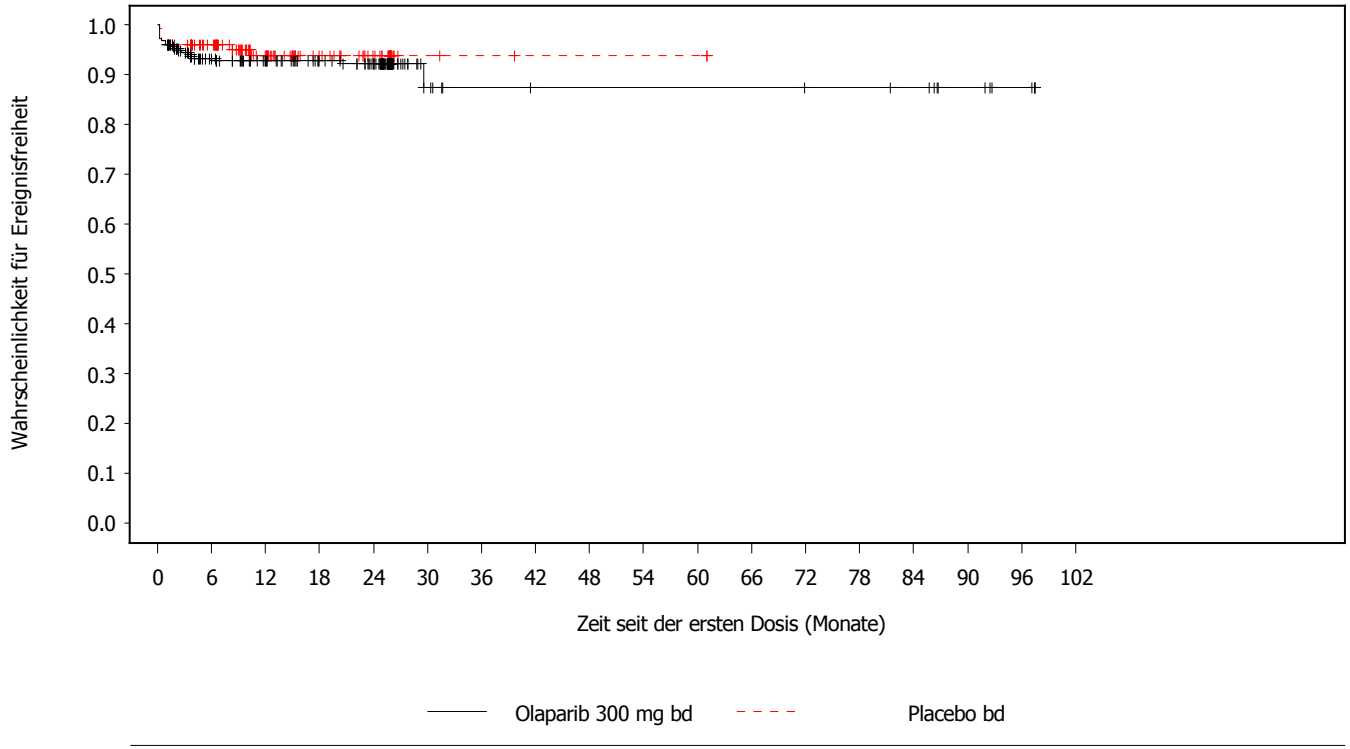
Anzahl an Patienten unter Risiko:

260	216	189	166	151	15	11	11	11	11	11	11	10	10	9	6	3	0	Olaparib 300 mg bd
130	110	76	49	38	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdj 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.89 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Neutrophilenzahl erniedrigt
Safety Analysis Set, DCO 07MAR2022



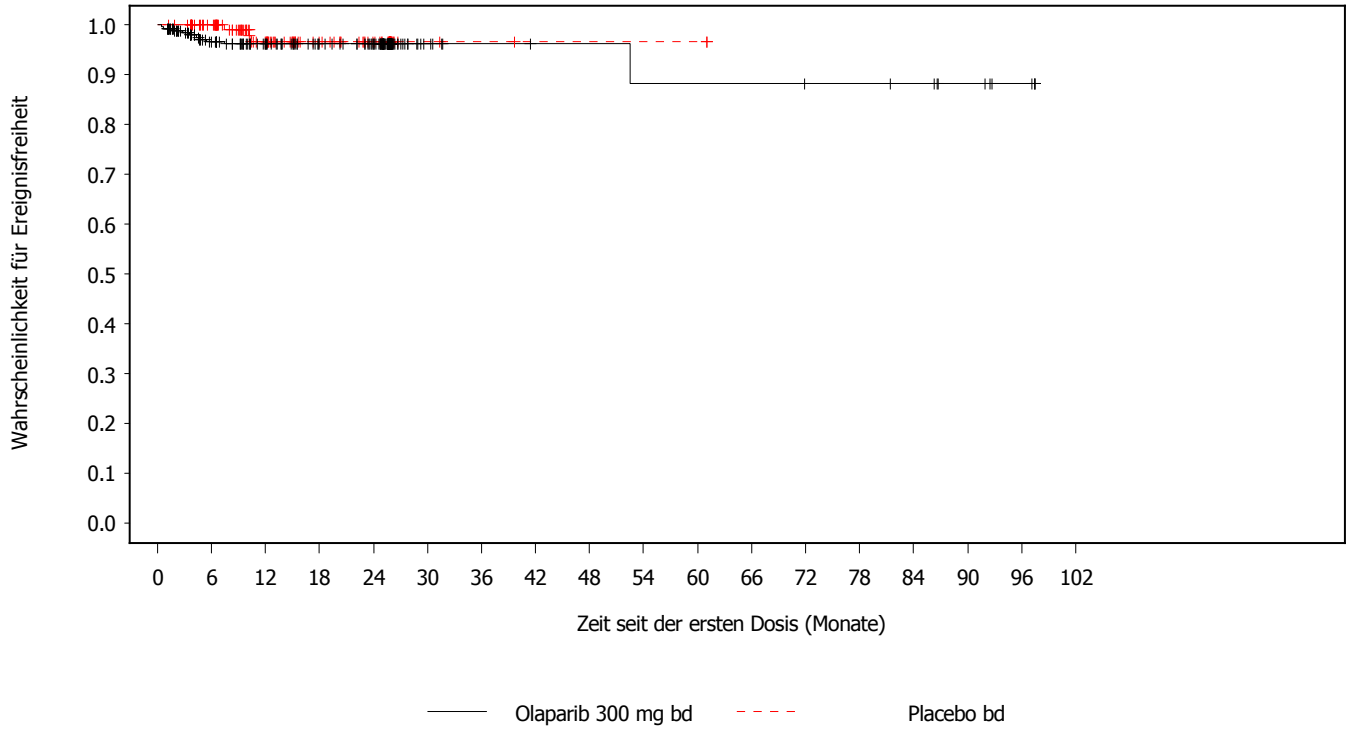
Anzahl an Patienten unter Risiko:

260	210	188	169	155	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
130	109	75	49	37	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdk 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.90 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Thrombozytenzahl vermindert
Safety Analysis Set, DCO 07MAR2022



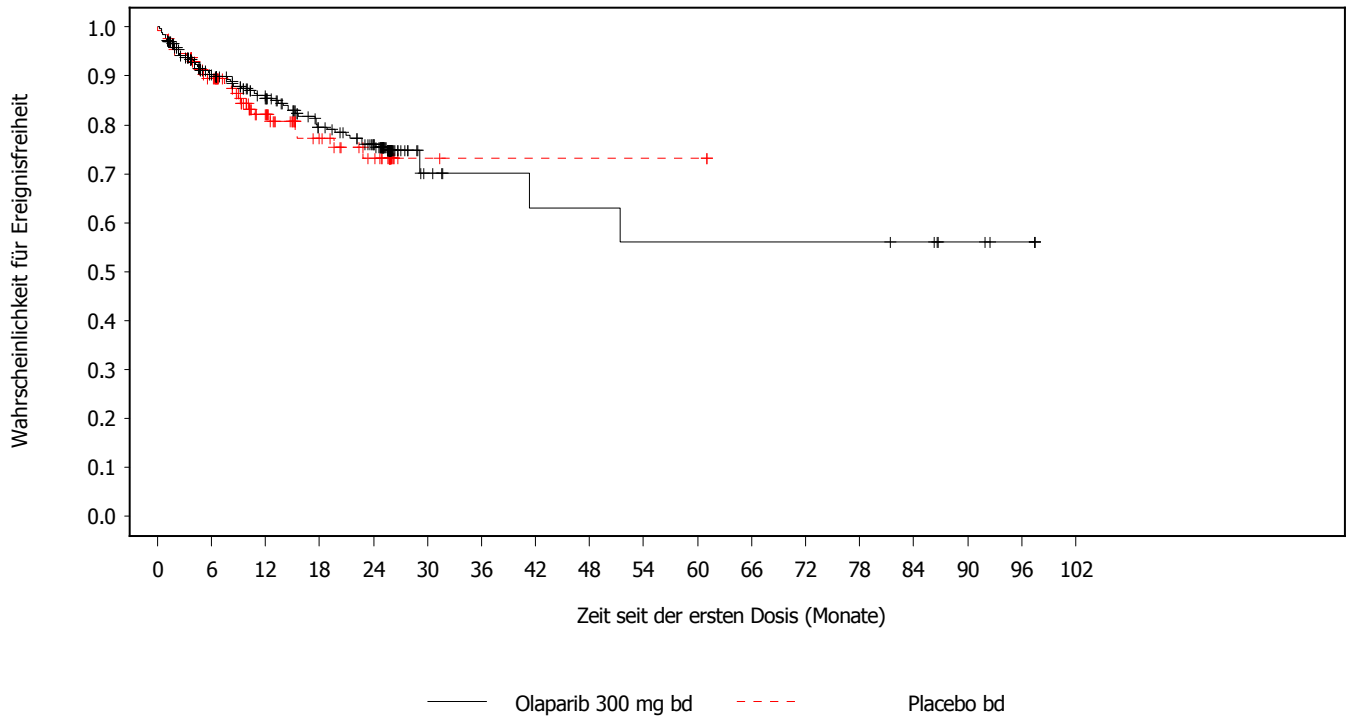
Anzahl an Patienten unter Risiko:

260	219	193	171	157	17	13	12	12	11	11	11	10	10	9	6	3	0	Olaparib 300 mg bd
130	113	78	52	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdl 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.91 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Safety Analysis Set, DCO 07MAR2022



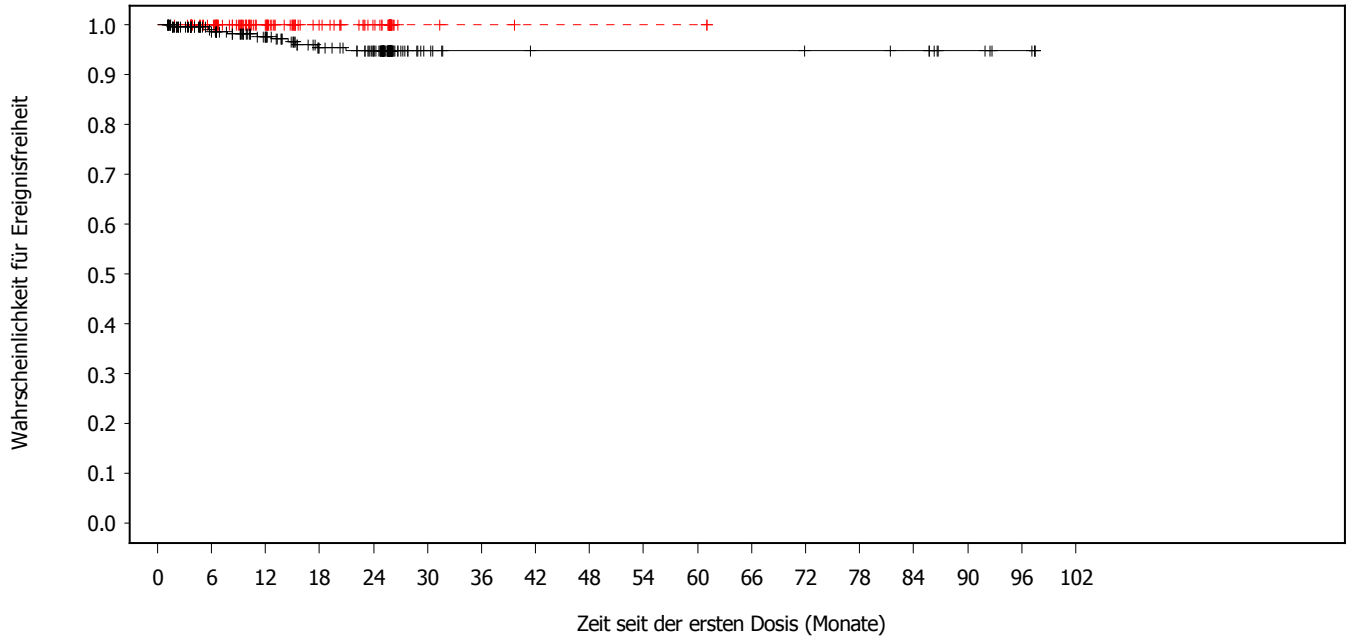
Anzahl an Patienten unter Risiko:

260	204	173	142	125	13	10	9	9	8	8	8	8	8	7	4	2	0	Olaparib 300 mg bd
130	100	65	43	33	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdm 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.92 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Baenderzerrung
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

260	221	193	167	152	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	113	79	53	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdn 28NOV2022:14:52 kvbv306

1.8.1.2: Schwere unerwünschte Ereignisse (CTCAE-Grad $\geq$ 3) nach SOC und PT

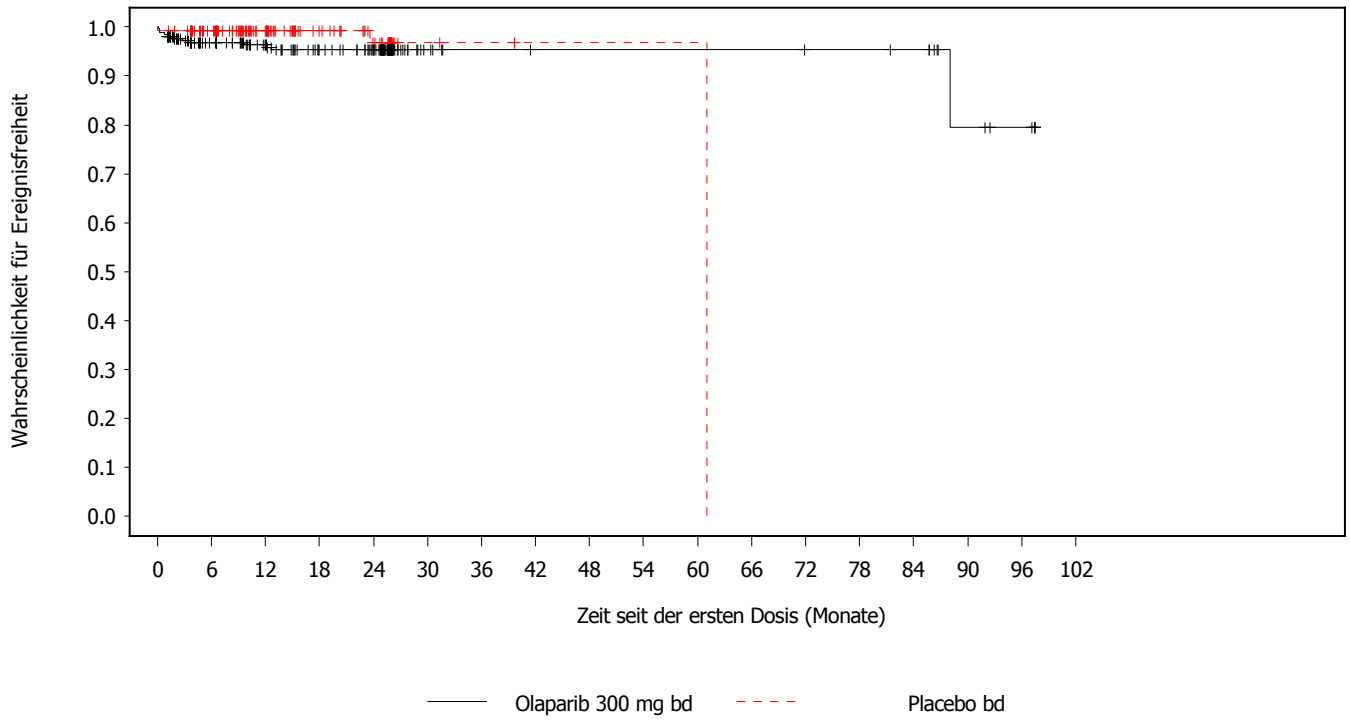
Table 3.2.4 SOLO1: Summary of analysis of time to first occurrence of adverse events with max CTCAE grade >=3
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Schwere UE mit max. CTCAE Grad>=3	260	103 (39,6)	42,1 [41,2; NE]	130	26 (20,0)	61,0 [NE; NE]	2,08	[1,38; 3,28]	0,0007*
Schwere UE nach SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	260	12 (4,6)	NE [NE; NE]	130	3 (2,3)	61,0 [NE; NE]	1,58	[0,49; 7,04]	0,4830
Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems	260	64 (24,6)	NE [NE; NE]	130	8 (6,2)	NE [NE; NE]	4,31	[2,19; 9,75]	<0,0001*
Schwere UE nach PT: Anaemie	260	56 (21,5)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	15,45	[4,82; 94,32]	<0,0001*
Schwere UE nach PT: Neutropenie	260	13 (5,0)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	1,57	[0,55; 5,57]	0,4292
Schwere UE nach SOC: Erkrankungen des Gastrointestinaltrakts	260	17 (6,5)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	2,76	[0,92; 11,82]	0,0916
Schwere UE nach SOC: Untersuchungen	260	12 (4,6)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	1,40	[0,49; 5,03]	0,5593

The time to event endpoint is the time to first AE with max CTCAE grade >=3 or the time to censoring if the AE with max CTCAE grade >=3 has not occurred prior to the date of DCO. Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaead 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.99 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 07MAR2022



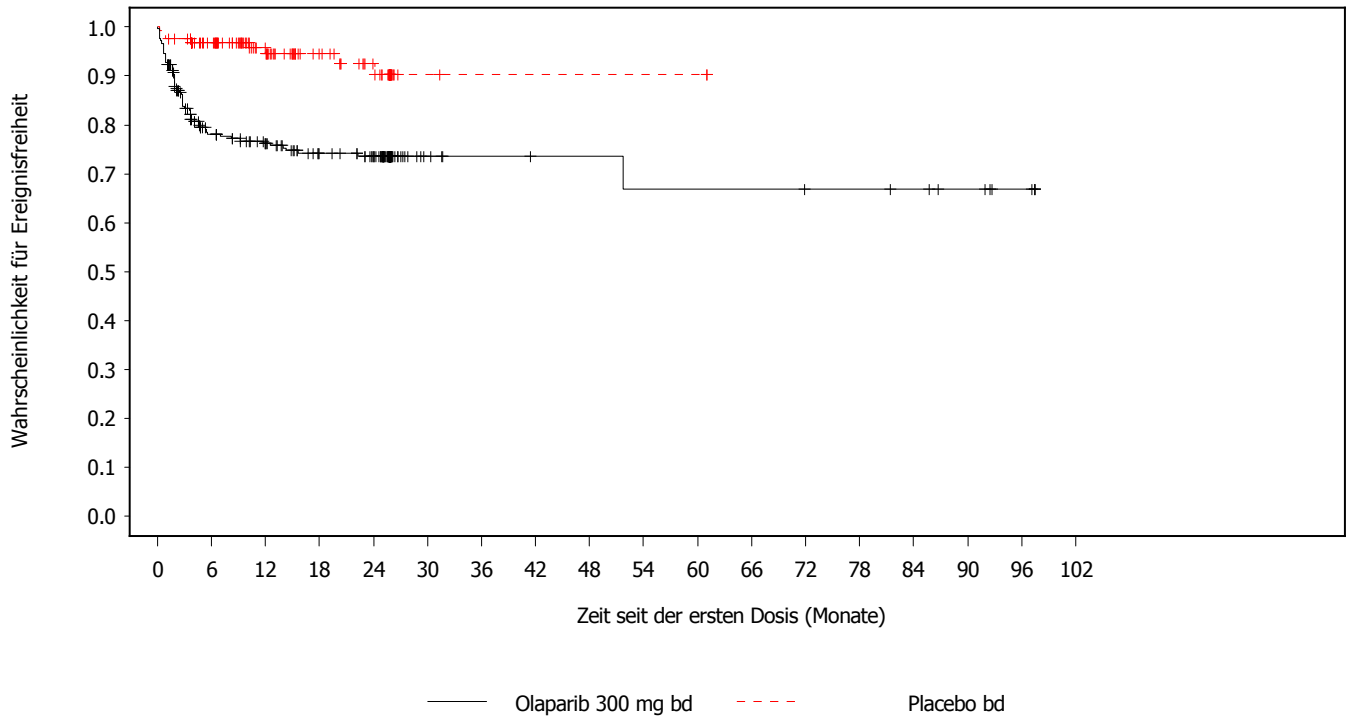
Anzahl an Patienten unter Risiko:

260	218	193	171	157	18	14	13	13	13	13	13	12	12	11	5	3	0	Olaparib 300 mg bd
130	112	78	52	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdu 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.100 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022



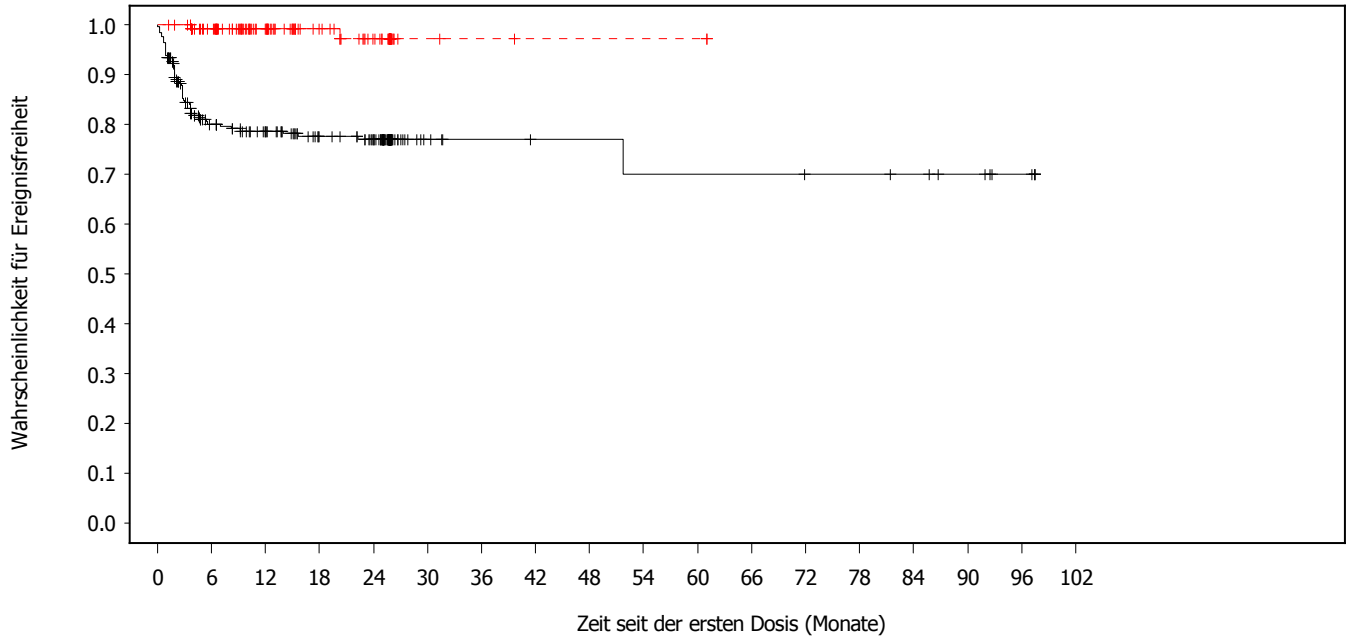
Anzahl an Patienten unter Risiko:

260	174	155	135	124	15	12	11	11	10	10	10	9	9	8	6	3	0	Olaparib 300 mg bd
130	109	77	52	40	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdv 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.101 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Anaemie
Safety Analysis Set, DCO 07MAR2022



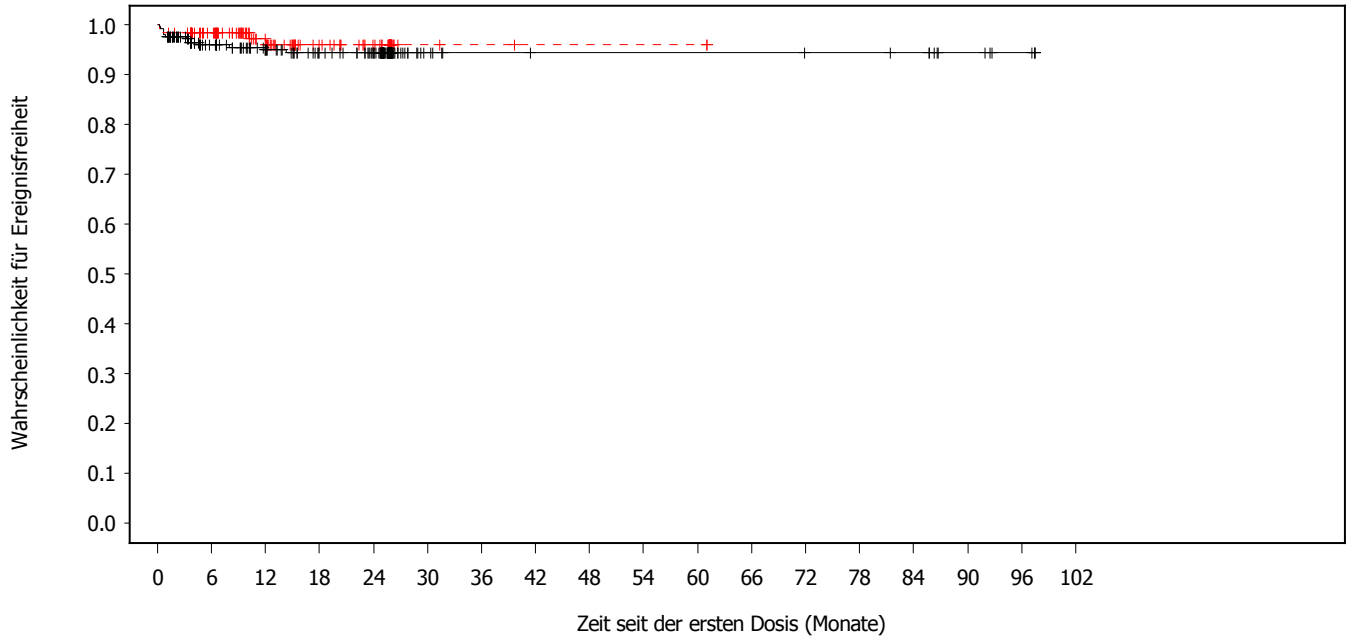
Anzahl an Patienten unter Risiko:

260	178	159	138	126	15	12	11	11	10	10	10	9	9	8	6	3	0	Olaparib 300 mg bd
130	112	79	53	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdw 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.102 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Neutropenie
Safety Analysis Set, DCO 07MAR2022



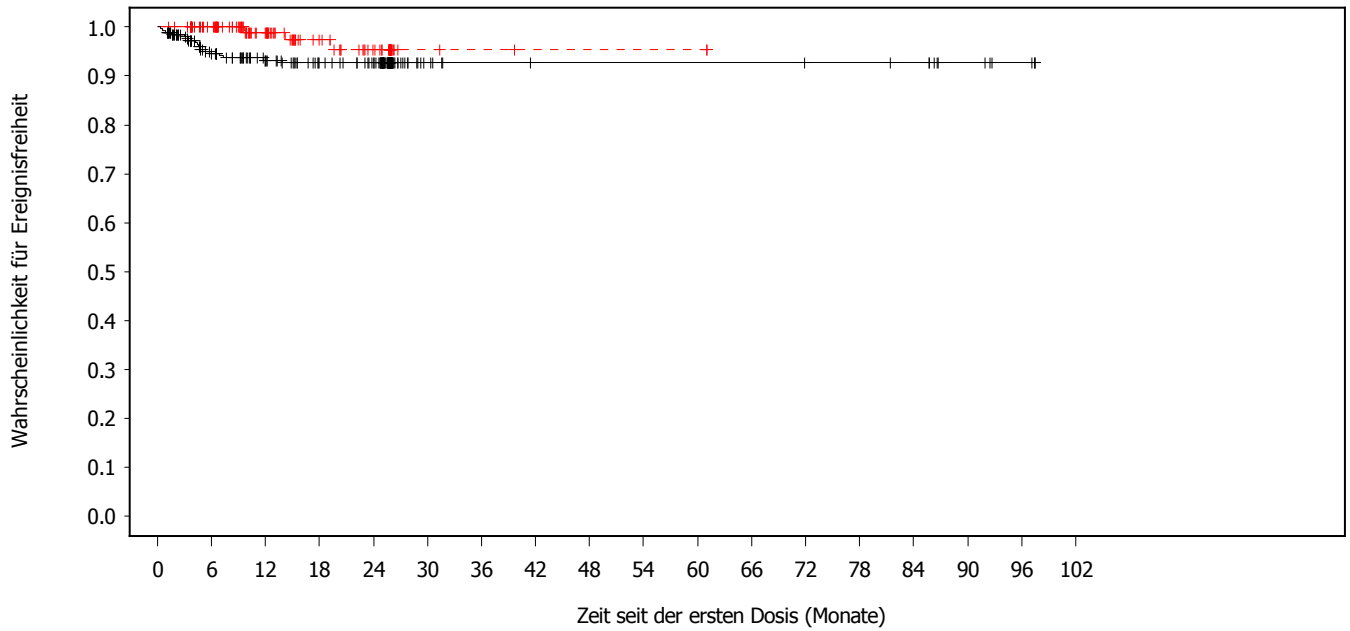
Anzahl an Patienten unter Risiko:

260	214	189	169	155	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	111	77	52	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdx 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.103 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 07MAR2022



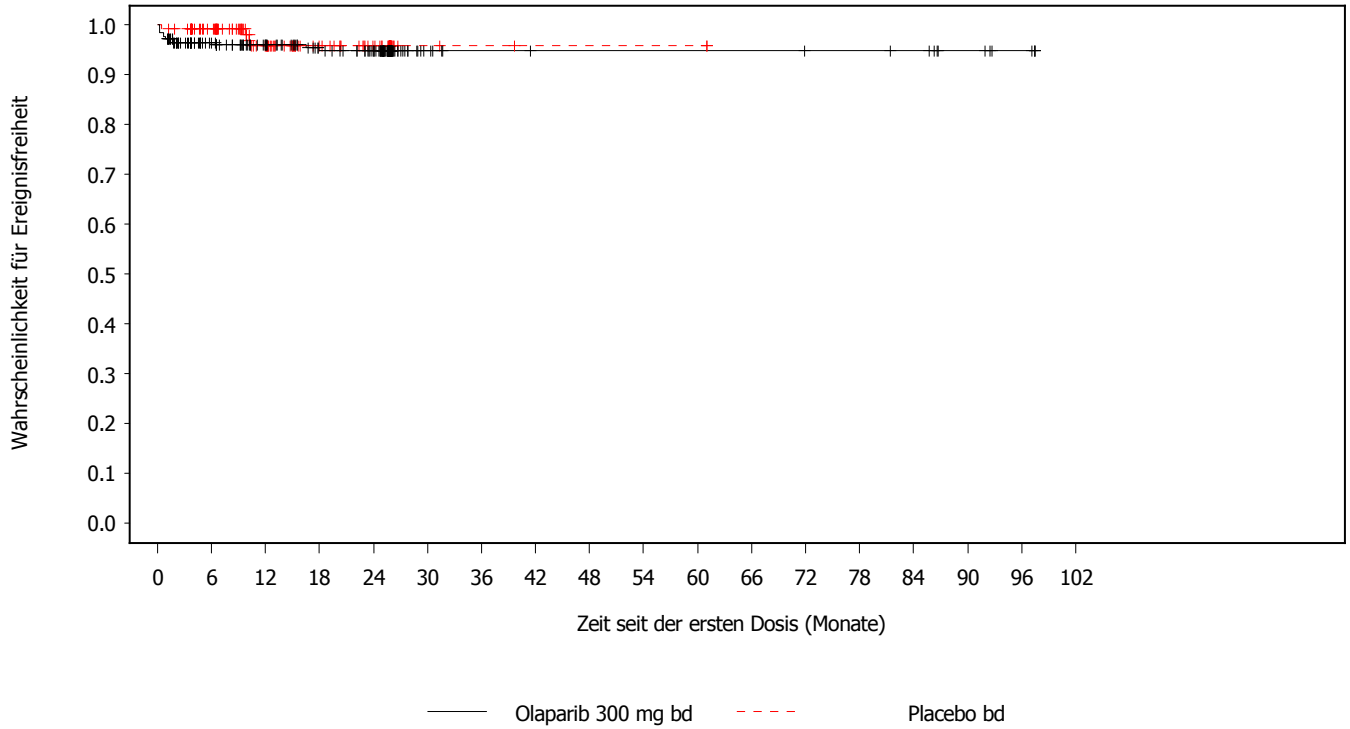
Anzahl an Patienten unter Risiko:

260	213	185	166	155	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
130	113	79	52	39	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdy 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.104 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Untersuchungen
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

260	216	191	170	158	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
130	112	78	52	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdz 28NOV2022:14:52 kvbv306

1.8.1.3: Schwerwiegende unerwünschte Ereignisse nach SOC und PT

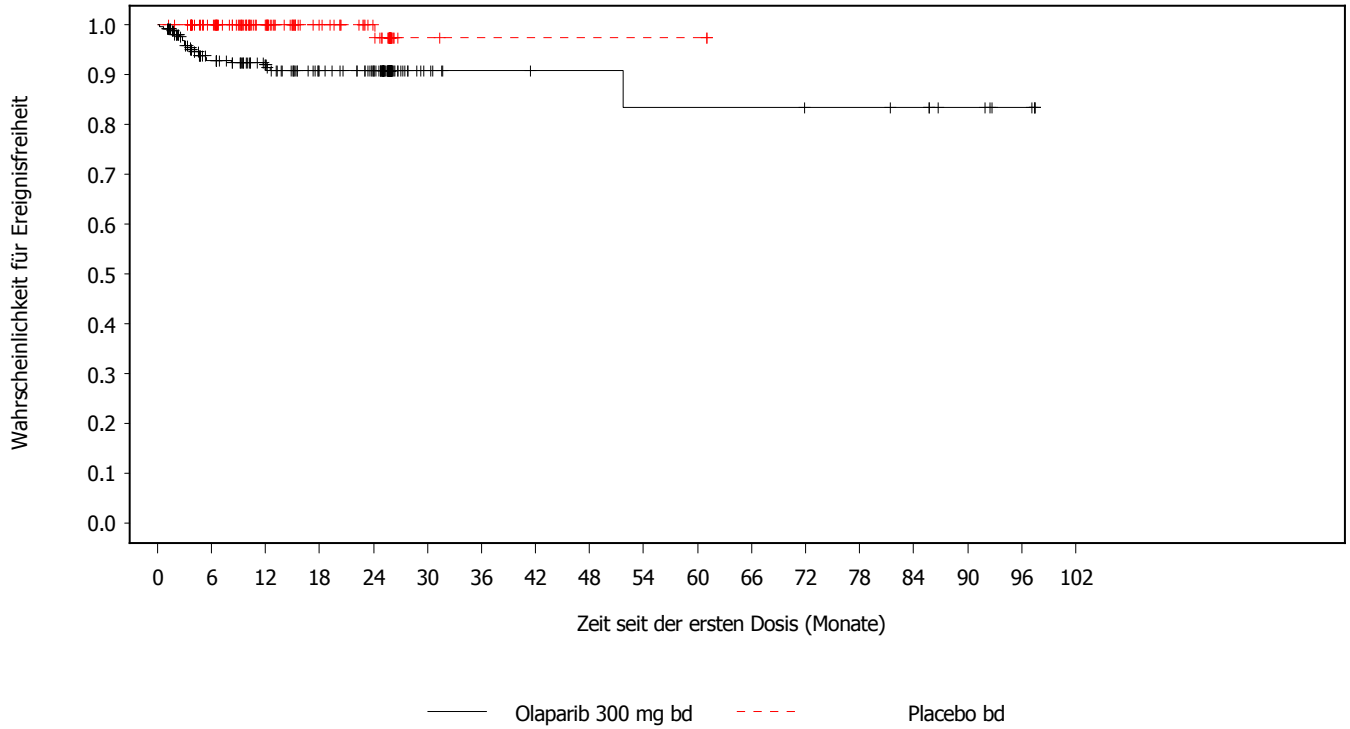
Table 3.2.2 SOLO1: Summary of analysis of time to first occurrence of serious adverse events
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
SUE	260	55 (21,2)	NE [NE; NE]	130	18 (13,8)	61,0 [NE; NE]	1,39	[0,83; 2,43]	0,2319
SUE SOC: Erkrankungen des Blutes und des Lymphsystems	260	22 (8,5)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	10,68	[2,24;191,65]	0,0038*
SUE PT: Anaemie	260	18 (6,9)	NE [NE; NE]	130	0	NE [NE; NE]	NC	NC	0,0025*
SUE SOC: Infektionen und parasitaere Erkrankungen	260	11 (4,2)	NE [NE; NE]	130	5 (3,8)	NE [NE; NE]	0,80	[0,28; 2,60]	0,6914

The time to event endpoint is the time to first serious AE or the time to censoring if the serious AE has not occurred prior to the date of DCO. Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaeab 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.94 SOLO1: Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022



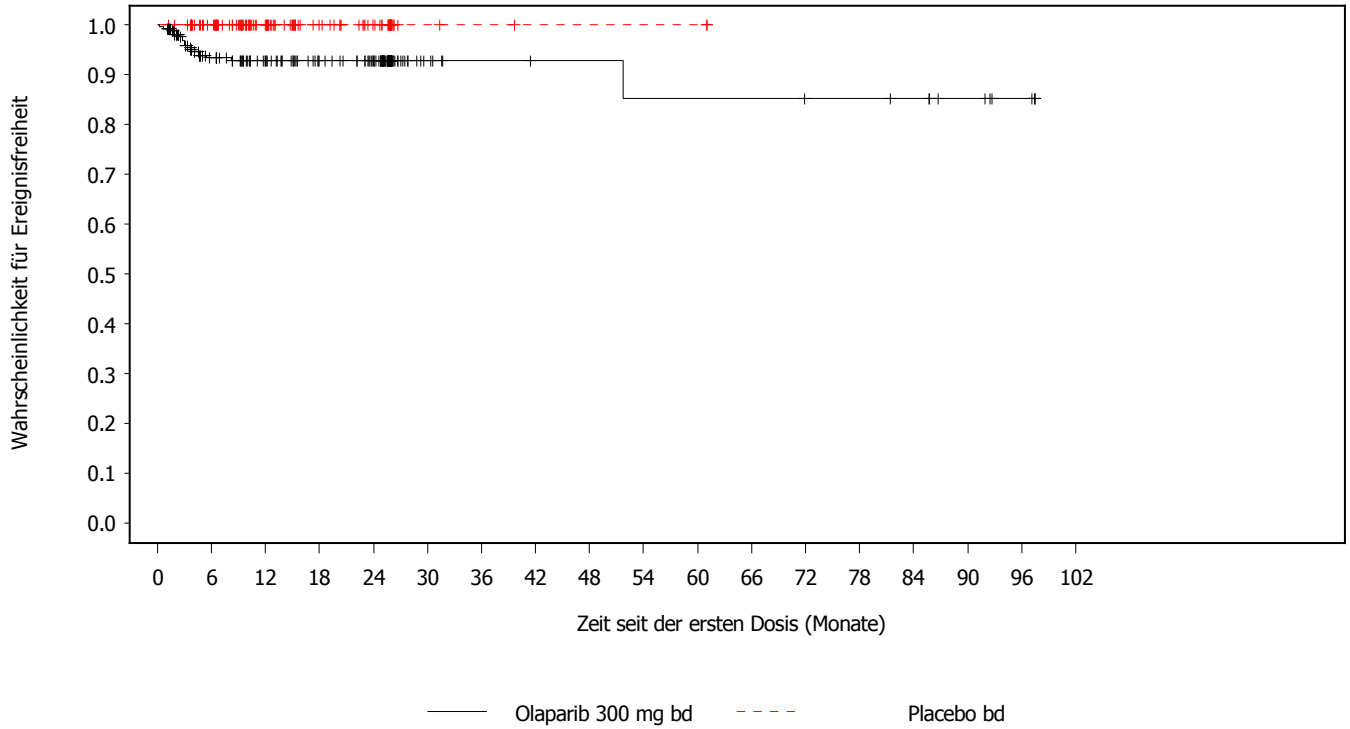
Anzahl an Patienten unter Risiko:

260	209	184	162	149	17	13	12	12	11	11	11	10	10	9	6	3	0	Olaparib 300 mg bd
130	113	79	53	41	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdp 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.95 SOLO1: Kaplan-Meier plot of time to first occurrence of SUE PT: Anaemie
Safety Analysis Set, DCO 07MAR2022



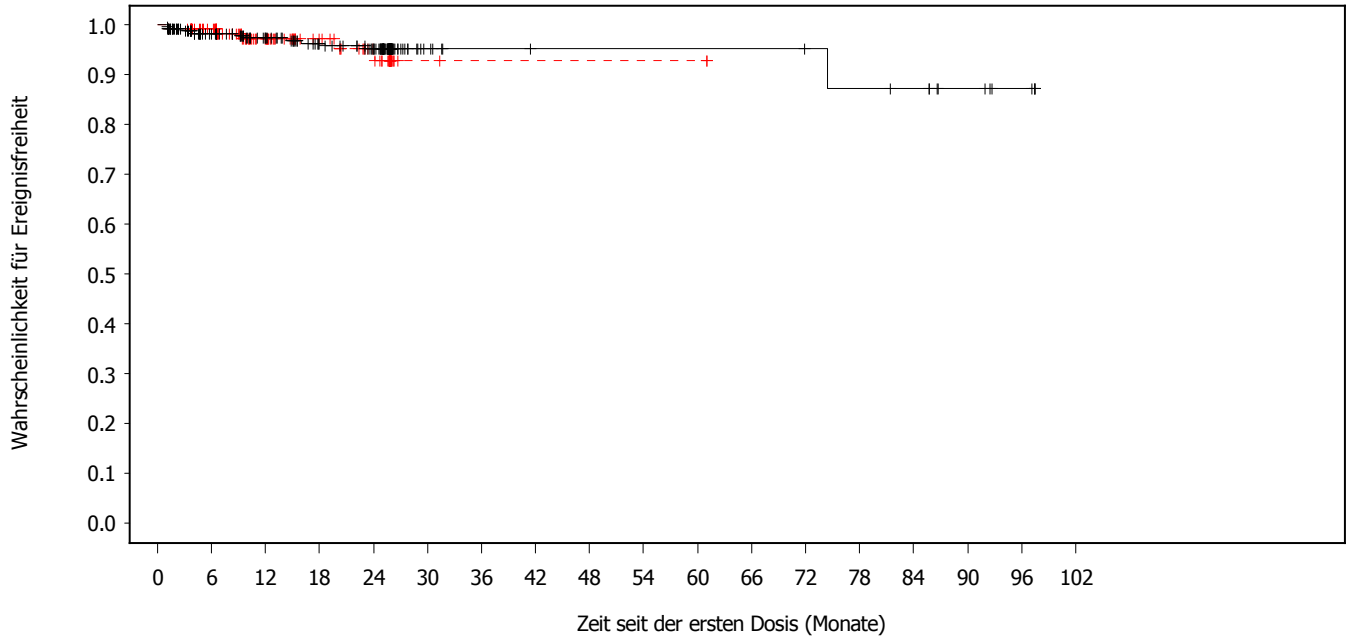
Anzahl an Patienten unter Risiko:

260	209	185	164	150	17	13	12	12	11	11	11	10	10	9	6	3	0	Olaparib 300 mg bd
130	113	79	53	41	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdq 28NOV2022:14:52 kvbv306

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.96 SOLO1: Kaplan-Meier plot of time to first occurrence of SUE SOC: Infektionen und parasitaere Erkrankungen
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

260	220	193	171	156	18	14	13	13	13	13	13	12	11	10	6	3	0	Olaparib 300 mg bd
130	113	77	52	39	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttemainae.sas gttemainaebdr 28NOV2022:14:52 kvbv306

1.8.2: Subgruppenanalysen

1.8.2.1: Unerwünschte Ereignisse unabhängig vom Schweregrad

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 3.4.1 SOLO1: Summary of subgroup analysis of time to first occurrence of UE
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	222 (98,7)	0,1 [0,1; 0,1]	111	103 (92,8)	0,3 [0,2; 0,4]	1,67	[1,32; 2,12]	<0,0001*
>=65 Jahre	35	34 (97,1)	0,1 [0,1; 0,1]	19	17 (89,5)	0,2 [0,1; 0,7]	1,87	[1,06; 3,44]	0,0304*
Interaktion p-Wert									0,7138
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	210 (98,6)	0,1 [0,1; 0,1]	106	99 (93,4)	0,3 [0,2; 0,5]	1,73	[1,36; 2,22]	<0,0001*
Partielles Ansprechen	47	46 (97,9)	0,1 [0,1; 0,2]	24	21 (87,5)	0,3 [0,1; 0,5]	1,56	[0,94; 2,66]	0,0870
Interaktion p-Wert									0,7118
ECOG PS Status									
Normale Aktivität	200	199 (99,5)	0,1 [0,1; 0,1]	105	100 (95,2)	0,3 [0,2; 0,4]	1,56	[1,23; 2,00]	0,0002*
Eingeschränkte Aktivität	60	57 (95,0)	0,1 [0,1; 0,1]	25	20 (80,0)	0,4 [0,1; 2,6]	2,35	[1,43; 4,03]	0,0006*
Interaktion p-Wert									0,1476
Baseline CA-125 Wert									
<=ULN	247	243 (98,4)	0,1 [0,1; 0,1]	123	113 (91,9)	0,3 [0,2; 0,4]	1,77	[1,41; 2,23]	<0,0001*
>ULN	13	13 (100)	0,2 [0,1; 0,3]	7	7 (100)	0,2 [0,0; NE]	0,70	[0,29; 1,87]	0,4624
Interaktion p-Wert									0,0704
FIGO Stadium									
III	220	216 (98,2)	0,1 [0,1; 0,1]	104	97 (93,3)	0,3 [0,2; 0,4]	1,58	[1,24; 2,02]	0,0002*
IV	40	40 (100)	0,1 [0,1; 0,1]	26	23 (88,5)	0,4 [0,1; 0,7]	2,55	[1,53; 4,35]	0,0003*
Interaktion p-Wert									0,0937
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	186 (98,9)	0,1 [0,1; 0,1]	90	83 (92,2)	0,3 [0,2; 0,4]	1,65	[1,28; 2,16]	0,0001*
BRCA2	62	60 (96,8)	0,1 [0,1; 0,2]	39	37 (94,9)	0,3 [0,1; 0,7]	1,57	[1,04; 2,38]	0,0304*
Interaktion p-Wert									0,8276
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.1 SOLO1: Summary of subgroup analysis of time to first occurrence of UE
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	53 (96,4)	0,1 [0,1; 0,2]	29	26 (89,7)	0,3 [0,2; 0,6]	1,54	[0,97; 2,50]	0,0672
Keine makroskopische Resterkrankung	200	198 (99,0)	0,1 [0,1; 0,1]	97	91 (93,8)	0,3 [0,2; 0,4]	1,67	[1,30; 2,16]	<0,0001*
Interaktion p-Wert									0,7550
Abstammung									
Weiß	214	210 (98,1)	0,1 [0,1; 0,1]	105	99 (94,3)	0,3 [0,2; 0,3]	1,54	[1,22; 1,97]	0,0003*
Andere	46	46 (100)	0,1 [0,1; 0,1]	25	21 (84,0)	0,5 [0,2; 1,0]	2,47	[1,49; 4,23]	0,0004*
Interaktion p-Wert									0,1001
Region									
Europa	101	101 (100)	0,1 [0,1; 0,1]	53	51 (96,2)	0,3 [0,2; 0,4]	1,82	[1,30; 2,57]	0,0004*
Asien	33	33 (100)	0,1 [0,1; 0,1]	14	10 (71,4)	1,3 [0,1; NE]	3,20	[1,63; 6,89]	0,0005*
Rest der Welt	126	122 (96,8)	0,1 [0,1; 0,2]	63	59 (93,7)	0,3 [0,1; 0,5]	1,39	[1,03; 1,92]	0,0335*
Interaktion p-Wert									0,0798

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.2 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	169 (75,1)	1,9 [0,9; 3,5]	111	62 (55,9)	12,5 [6,5;15,8]	1,73	[1,30; 2,34]	0,0001*
>=65 Jahre	35	30 (85,7)	2,0 [0,7; 3,6]	19	11 (57,9)	15,7 [0,9; NE]	1,86	[0,96; 3,88]	0,0671
Interaktion p-Wert									0,8554
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	166 (77,9)	1,9 [0,9; 3,0]	106	63 (59,4)	9,3 [4,6;15,7]	1,69	[1,27; 2,28]	0,0002*
Partielles Ansprechen	47	33 (70,2)	2,3 [0,9; 7,2]	24	10 (41,7)	14,2 [2,8; NE]	2,17	[1,08; 4,84]	0,0282*
Interaktion p-Wert									0,5322
ECOG PS Status									
Normale Aktivität	200	151 (75,5)	1,9 [1,0; 3,2]	105	59 (56,2)	9,3 [3,7;15,7]	1,62	[1,20; 2,21]	0,0013*
Eingeschränkte Aktivität	60	48 (80,0)	1,1 [0,6; 4,1]	25	14 (56,0)	12,8 [5,5; NE]	2,34	[1,30; 4,51]	0,0037*
Interaktion p-Wert									0,2841
Baseline CA-125 Wert									
<=ULN	247	192 (77,7)	1,9 [0,9; 2,8]	123	70 (56,9)	12,5 [5,5;15,7]	1,82	[1,39; 2,41]	<0,0001*
>ULN	13	7 (53,8)	17,5 [1,1; NE]	7	3 (42,9)	NE [NE; NE]	0,86	[0,24; 4,00]	0,8303
Interaktion p-Wert									0,3146
FIGO Stadium									
III	220	168 (76,4)	1,9 [0,9; 3,5]	104	58 (55,8)	12,8 [5,5;20,2]	1,80	[1,34; 2,46]	<0,0001*
IV	40	31 (77,5)	2,1 [0,4; 6,1]	26	15 (57,7)	8,8 [2,6;14,2]	1,55	[0,85; 2,95]	0,1557
Interaktion p-Wert									0,6679
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	142 (75,5)	1,9 [1,0; 3,5]	90	48 (53,3)	14,7 [6,5;21,7]	1,83	[1,33; 2,58]	0,0002*
BRCA2	62	48 (77,4)	2,0 [0,6; 7,0]	39	25 (64,1)	7,3 [2,6;12,8]	1,50	[0,94; 2,47]	0,0933
Interaktion p-Wert									0,5063

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.2 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	42 (76,4)	2,0 [0,7; 6,1]	29	15 (51,7)	15,8 [0,9; NE]	1,93	[1,08; 3,66]	0,0264*
Keine makroskopische Resterkrankung	200	153 (76,5)	1,9 [0,9; 3,5]	97	57 (58,8)	9,3 [4,6;14,7]	1,67	[1,24; 2,28]	0,0007*
Interaktion p-Wert									0,6786
Abstammung									
Weiß	214	169 (79,0)	1,9 [0,9; 3,1]	105	62 (59,0)	10,6 [5,2;14,7]	1,71	[1,29; 2,31]	0,0002*
Andere	46	30 (65,2)	1,9 [0,5; 6,1]	25	11 (44,0)	61,0 [1,7; NE]	1,96	[0,99; 4,23]	0,0535
Interaktion p-Wert									0,7285
Region									
Europa	101	86 (85,1)	1,1 [0,8; 3,1]	53	36 (67,9)	7,6 [3,6;14,2]	1,68	[1,14; 2,51]	0,0076*
Asien	33	21 (63,6)	2,4 [0,3; NE]	14	4 (28,6)	61,0 [3,1; NE]	4,39	[1,51; 18,62]	0,0047*
Rest der Welt	126	92 (73,0)	1,9 [0,8; 4,1]	63	33 (52,4)	12,8 [1,8; NE]	1,63	[1,11; 2,46]	0,0126*
Interaktion p-Wert									0,2336

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 3.4.3 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Asthenie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	53 (23,6)	NE [NE; NE]	111	12 (10,8)	NE [NE; NE]	2,27	[1,26; 4,46]	0,0055*
>=65 Jahre	35	10 (28,6)	NE [NE; NE]	19	4 (21,1)	NE [NE; NE]	1,40	[0,47; 5,09]	0,5642
Interaktion p-Wert									0,4778
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	53 (24,9)	NE [NE; NE]	106	15 (14,2)	NE [NE; NE]	1,87	[1,08; 3,43]	0,0246*
Partielles Ansprechen	47	10 (21,3)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	4,88	[0,93; 89,64]	0,0624
Interaktion p-Wert									0,3250
ECOG PS Status									
Normale Aktivität	200	52 (26,0)	NE [NE; NE]	105	15 (14,3)	NE [NE; NE]	1,89	[1,09; 3,47]	0,0224*
Eingeschränkte Aktivität	60	11 (18,3)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	4,89	[0,95; 89,30]	0,0592
Interaktion p-Wert									0,3279
Baseline CA-125 Wert									
<=ULN	247	61 (24,7)	NE [NE; NE]	123	15 (12,2)	NE [NE; NE]	2,14	[1,25; 3,90]	0,0047*
>ULN	13	2 (15,4)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,85	[0,08; 18,31]	0,8963
Interaktion p-Wert									0,4893
FIGO Stadium									
III	220	54 (24,5)	NE [NE; NE]	104	14 (13,5)	NE [NE; NE]	1,90	[1,09; 3,56]	0,0231*
IV	40	9 (22,5)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	3,01	[0,78; 19,76]	0,1177
Interaktion p-Wert									0,5704
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	47 (25,0)	NE [NE; NE]	90	11 (12,2)	NE [NE; NE]	2,13	[1,15; 4,33]	0,0153*
BRCA2	62	16 (25,8)	NE [NE; NE]	39	5 (12,8)	NE [NE; NE]	2,16	[0,84; 6,60]	0,1115
Interaktion p-Wert									0,9830
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.3 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Asthenie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	10 (18,2)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	1,23	[0,41; 4,49]	0,7222
Keine makroskopische Resterkrankung	200	52 (26,0)	NE [NE; NE]	97	11 (11,3)	NE [NE; NE]	2,50	[1,36; 5,05]	0,0025*
Interaktion p-Wert									0,3112
Abstammung									
Weiß	214	62 (29,0)	NE [NE; NE]	105	16 (15,2)	NE [NE; NE]	2,02	[1,20; 3,62]	0,0077*
Andere	46	1 (2,2)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	55 (54,5)	9,7 [3,5; NE]	53	15 (28,3)	NE [NE; NE]	2,36	[1,37; 4,34]	0,0015*
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	8 (6,3)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	3,83	[0,70; 71,07]	0,1349
Interaktion p-Wert									0,6429

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.4 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Ermuedung
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	92 (40,9)	33,9 [33,9; NE]	111	33 (29,7)	NE [NE; NE]	1,45	[0,99; 2,20]	0,0592
>=65 Jahre	35	16 (45,7)	15,7 [2,9; NE]	19	6 (31,6)	NE [NE; NE]	1,50	[0,62; 4,18]	0,3842
Interaktion p-Wert									0,9529
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	88 (41,3)	33,9 [17,5; NE]	106	34 (32,1)	NE [NE; NE]	1,41	[0,96; 2,12]	0,0851
Partielles Ansprechen	47	20 (42,6)	65,8 [5,7; NE]	24	5 (20,8)	NE [NE; NE]	1,84	[0,74; 5,55]	0,2018
Interaktion p-Wert									0,6144
ECOG PS Status									
Normale Aktivität	200	77 (38,5)	54,1 [33,9; NE]	105	28 (26,7)	NE [NE; NE]	1,48	[0,97; 2,33]	0,0676
Eingeschränkte Aktivität	60	31 (51,7)	9,2 [4,5; NE]	25	11 (44,0)	20,2 [8,8; NE]	1,34	[0,69; 2,79]	0,3985
Interaktion p-Wert									0,8033
Baseline CA-125 Wert									
<=ULN	247	105 (42,5)	33,9 [17,5;65,8]	123	37 (30,1)	NE [NE; NE]	1,51	[1,05; 2,23]	0,0265*
>ULN	13	3 (23,1)	NE [NE; NE]	7	2 (28,6)	NE [NE; NE]	0,64	[0,11; 4,87]	0,6321
Interaktion p-Wert									0,3756
FIGO Stadium									
III	220	92 (41,8)	33,9 [17,5; NE]	104	31 (29,8)	NE [NE; NE]	1,50	[1,01; 2,29]	0,0455*
IV	40	16 (40,0)	65,8 [4,8; NE]	26	8 (30,8)	NE [NE; NE]	1,29	[0,57; 3,20]	0,5488
Interaktion p-Wert									0,7629
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	76 (40,4)	33,9 [17,5; NE]	90	25 (27,8)	NE [NE; NE]	1,57	[1,01; 2,51]	0,0439*
BRCA2	62	25 (40,3)	54,1 [9,2; NE]	39	14 (35,9)	NE [NE; NE]	1,11	[0,58; 2,19]	0,7624
Interaktion p-Wert									0,3938
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.4 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Ermuedung
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	29 (52,7)	17,5 [1,9; NE]	29	6 (20,7)	NE [NE; NE]	2,98	[1,33; 7,97]	0,0067*
Keine makroskopische Resterkrankung	200	76 (38,0)	33,9 [33,9; NE]	97	33 (34,0)	NE [NE; NE]	1,14	[0,76; 1,74]	0,5284
Interaktion p-Wert									0,0389*
Abstammung									
Weiß	214	89 (41,6)	33,9 [17,5; NE]	105	34 (32,4)	NE [NE; NE]	1,32	[0,89; 1,99]	0,1655
Andere	46	19 (41,3)	NE [NE; NE]	25	5 (20,0)	NE [NE; NE]	2,45	[0,98; 7,40]	0,0543
Interaktion p-Wert									0,2344
Region									
Europa	101	19 (18,8)	NE [NE; NE]	53	11 (20,8)	NE [NE; NE]	0,88	[0,43; 1,92]	0,7435
Asien	33	11 (33,3)	NE [NE; NE]	14	3 (21,4)	NE [NE; NE]	1,81	[0,56; 8,01]	0,3386
Rest der Welt	126	78 (61,9)	4,8 [1,9; 9,2]	63	25 (39,7)	NE [NE; NE]	1,73	[1,12; 2,78]	0,0129*
Interaktion p-Wert									0,3097

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.5 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Schleimhautentzuendung
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	15 (6,7)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	6,92	[1,40;125,14]	0,0130*
>=65 Jahre	35	3 (8,6)	51,1 [51,1; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	14 (6,6)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	4 (8,5)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	14 (7,0)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	6,17	[1,23;112,13]	0,0234*
Eingeschränkte Aktivität	60	4 (6,7)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	18 (7,3)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	7,98	[1,64;143,83]	0,0057*
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	14 (6,4)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	4 (10,0)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	13 (6,9)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	5,70	[1,13;103,63]	0,0322*
BRCA2	62	5 (8,1)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.5 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Schleimhautentzuendung
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	16 (8,0)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	18 (8,4)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	0	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	16 (15,8)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	2 (1,6)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 3.4.6 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dyspnoe
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	31 (13,8)	NE [NE; NE]	111	3 (2,7)	NE [NE; NE]	4,36	[1,55; 18,19]	0,0032*
>=65 Jahre	35	10 (28,6)	51,1 [19,4; NE]	19	4 (21,1)	NE [NE; NE]	1,31	[0,44; 4,79]	0,6389
Interaktion p-Wert									0,1542
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	31 (14,6)	NE [NE; NE]	106	5 (4,7)	NE [NE; NE]	2,94	[1,25; 8,64]	0,0115*
Partielles Ansprechen	47	10 (21,3)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	1,50	[0,39; 9,84]	0,5877
Interaktion p-Wert									0,4779
ECOG PS Status									
Normale Aktivität	200	29 (14,5)	NE [NE; NE]	105	6 (5,7)	NE [NE; NE]	2,16	[0,96; 5,78]	0,0647
Eingeschränkte Aktivität	60	12 (20,0)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	4,82	[0,95; 87,86]	0,0595
Interaktion p-Wert									0,4458
Baseline CA-125 Wert									
<=ULN	247	39 (15,8)	NE [NE; NE]	123	6 (4,9)	NE [NE; NE]	2,85	[1,30; 7,52]	0,0074*
>ULN	13	2 (15,4)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,72	[0,07; 15,64]	0,7971
Interaktion p-Wert									0,3312
FIGO Stadium									
III	220	34 (15,5)	NE [NE; NE]	104	6 (5,8)	NE [NE; NE]	2,40	[1,08; 6,38]	0,0297*
IV	40	7 (17,5)	51,7 [51,1; NE]	26	1 (3,8)	NE [NE; NE]	3,54	[0,62; 66,36]	0,1725
Interaktion p-Wert									0,7304
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	28 (14,9)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	6,15	[1,85; 38,09]	0,0013*
BRCA2	62	13 (21,0)	NE [NE; NE]	39	5 (12,8)	NE [NE; NE]	1,30	[0,49; 4,09]	0,6112
Interaktion p-Wert									0,0693
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.6 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dyspnoe
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	12 (21,8)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	5,46	[1,07; 99,56]	0,0390*
Keine makroskopische Resterkrankung	200	27 (13,5)	NE [NE; NE]	97	6 (6,2)	NE [NE; NE]	2,02	[0,89; 5,43]	0,0951
Interaktion p-Wert									0,3388
Abstammung									
Weiß	214	37 (17,3)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	2,27	[1,07; 5,59]	0,0313*
Andere	46	4 (8,7)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	15 (14,9)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	3,27	[0,92; 20,81]	0,0704
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	26 (20,6)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	2,32	[0,97; 6,88]	0,0606
Interaktion p-Wert									0,6973

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.7 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dysurie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	9 (4,0)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	1 (2,9)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	10 (4,7)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	8 (4,0)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	9 (3,6)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	1 (7,7)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	10 (4,5)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	0	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	8 (4,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	2 (3,2)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.7 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dysurie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	9 (4,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	9 (4,2)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	1 (2,2)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	6 (5,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.8 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	109 (48,4)	17,5 [8,2; NE]	111	22 (19,8)	NE [NE; NE]	2,79	[1,80; 4,53]	<0,0001*
>=65 Jahre	35	20 (57,1)	4,7 [1,8; NE]	19	2 (10,5)	NE [NE; NE]	7,04	[2,05; 44,16]	0,0007*
Interaktion p-Wert									0,1892
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	104 (48,8)	17,5 [7,2; NE]	106	20 (18,9)	NE [NE; NE]	3,12	[1,98; 5,18]	<0,0001*
Partielles Ansprechen	47	25 (53,2)	11,9 [3,3; NE]	24	4 (16,7)	NE [NE; NE]	3,12	[1,21; 10,61]	0,0163*
Interaktion p-Wert									0,9979
ECOG PS Status									
Normale Aktivität	200	103 (51,5)	12,8 [5,6;51,7]	105	18 (17,1)	NE [NE; NE]	3,47	[2,16; 5,92]	<0,0001*
Eingeschränkte Aktivität	60	26 (43,3)	NE [NE; NE]	25	6 (24,0)	NE [NE; NE]	2,13	[0,94; 5,73]	0,0723
Interaktion p-Wert									0,3642
Baseline CA-125 Wert									
<=ULN	247	119 (48,2)	22,0 [9,2; NE]	123	22 (17,9)	NE [NE; NE]	3,15	[2,04; 5,09]	<0,0001*
>ULN	13	10 (76,9)	3,6 [0,5; 9,2]	7	2 (28,6)	NE [NE; NE]	2,81	[0,74; 18,25]	0,1393
Interaktion p-Wert									0,8886
FIGO Stadium									
III	220	107 (48,6)	22,0 [9,2; NE]	104	19 (18,3)	NE [NE; NE]	3,09	[1,94; 5,19]	<0,0001*
IV	40	22 (55,0)	5,6 [1,8; NE]	26	5 (19,2)	NE [NE; NE]	3,42	[1,40; 10,25]	0,0058*
Interaktion p-Wert									0,8516
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	93 (49,5)	15,7 [6,5; NE]	90	19 (21,1)	NE [NE; NE]	2,67	[1,67; 4,51]	<0,0001*
BRCA2	62	33 (53,2)	11,9 [3,8; NE]	39	5 (12,8)	NE [NE; NE]	5,10	[2,18; 14,91]	<0,0001*
Interaktion p-Wert									0,2139

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.8 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	27 (49,1)	16,6 [7,0; NE]	29	5 (17,2)	NE [NE; NE]	2,92	[1,22; 8,62]	0,0138*
Keine makroskopische Resterkrankung	200	99 (49,5)	17,0 [5,6; NE]	97	18 (18,6)	NE [NE; NE]	3,26	[2,02; 5,57]	<0,0001*
Interaktion p-Wert									0,8430
Abstammung									
Weiß	214	102 (47,7)	22,0 [8,2; NE]	105	21 (20,0)	NE [NE; NE]	2,68	[1,71; 4,41]	<0,0001*
Andere	46	27 (58,7)	5,6 [1,9; NE]	25	3 (12,0)	NE [NE; NE]	6,51	[2,30; 27,27]	0,0001*
Interaktion p-Wert									0,1422
Region									
Europa	101	58 (57,4)	5,4 [3,3;22,1]	53	11 (20,8)	NE [NE; NE]	3,55	[1,94; 7,15]	<0,0001*
Asien	33	17 (51,5)	9,2 [3,6; NE]	14	1 (7,1)	NE [NE; NE]	10,01	[2,05;180,58]	0,0016*
Rest der Welt	126	54 (42,9)	49,7 [16,6; NE]	63	12 (19,0)	NE [NE; NE]	2,33	[1,29; 4,56]	0,0041*
Interaktion p-Wert									0,2496

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 3.4.9 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Anaemie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	85 (37,8)	44,5 [44,5; NE]	111	11 (9,9)	NE [NE; NE]	4,34	[2,42; 8,62]	<0,0001*
>=65 Jahre	35	17 (48,6)	49,7 [1,9; NE]	19	1 (5,3)	NE [NE; NE]	11,23	[2,30;202,46]	0,0008*
Interaktion p-Wert									0,3235
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	80 (37,6)	49,7 [49,7; NE]	106	9 (8,5)	NE [NE; NE]	5,30	[2,81; 11,35]	<0,0001*
Partielles Ansprechen	47	22 (46,8)	44,5 [7,0; NE]	24	3 (12,5)	NE [NE; NE]	3,53	[1,22; 14,94]	0,0174*
Interaktion p-Wert									0,5780
ECOG PS Status									
Normale Aktivität	200	78 (39,0)	49,7 [44,5; NE]	105	8 (7,6)	NE [NE; NE]	5,66	[2,91; 12,74]	<0,0001*
Eingeschränkte Aktivität	60	24 (40,0)	NE [NE; NE]	25	4 (16,0)	NE [NE; NE]	3,27	[1,26; 11,14]	0,0126*
Interaktion p-Wert									0,4157
Baseline CA-125 Wert									
<=ULN	247	93 (37,7)	49,7 [44,5; NE]	123	10 (8,1)	NE [NE; NE]	5,34	[2,92; 10,95]	<0,0001*
>ULN	13	9 (69,2)	3,6 [0,5; 9,2]	7	2 (28,6)	NE [NE; NE]	2,40	[0,62; 15,71]	0,2240
Interaktion p-Wert									0,3758
FIGO Stadium									
III	220	83 (37,7)	44,5 [44,5; NE]	104	11 (10,6)	NE [NE; NE]	4,05	[2,26; 8,04]	<0,0001*
IV	40	19 (47,5)	15,7 [2,8; NE]	26	1 (3,8)	NE [NE; NE]	15,36	[3,18;276,78]	<0,0001*
Interaktion p-Wert									0,1464
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	71 (37,8)	NE [NE; NE]	90	8 (8,9)	NE [NE; NE]	4,94	[2,53; 11,13]	<0,0001*
BRCA2	62	30 (48,4)	44,5 [5,4; NE]	39	4 (10,3)	NE [NE; NE]	5,45	[2,15; 18,38]	0,0001*
Interaktion p-Wert									0,8782
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.9 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Anaemie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	23 (41,8)	49,7 [11,9; NE]	29	3 (10,3)	NE [NE; NE]	4,08	[1,42; 17,22]	0,0066*
Keine makroskopische Resterkrankung	200	76 (38,0)	44,5 [44,5; NE]	97	9 (9,3)	NE [NE; NE]	4,89	[2,58; 10,49]	<0,0001*
Interaktion p-Wert									0,8022
Abstammung									
Weiß	214	78 (36,4)	51,7 [44,5; NE]	105	11 (10,5)	NE [NE; NE]	3,88	[2,15; 7,73]	<0,0001*
Andere	46	24 (52,2)	15,7 [1,9; NE]	25	1 (4,0)	NE [NE; NE]	17,03	[3,61;305,06]	<0,0001*
Interaktion p-Wert									0,0984
Region									
Europa	101	43 (42,6)	44,5 [5,6; NE]	53	4 (7,5)	NE [NE; NE]	6,78	[2,74; 22,57]	<0,0001*
Asien	33	15 (45,5)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	44 (34,9)	49,7 [49,7; NE]	63	8 (12,7)	NE [NE; NE]	2,89	[1,44; 6,63]	0,0020*
Interaktion p-Wert									0,1763

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.10 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Neutropenie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	34 (15,1)	NE [NE; NE]	111	8 (7,2)	NE [NE; NE]	2,08	[1,01; 4,83]	0,0463*
>=65 Jahre	35	7 (20,0)	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	3,96	[0,70; 74,03]	0,1307
Interaktion p-Wert									0,5480
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	36 (16,9)	NE [NE; NE]	106	8 (7,5)	NE [NE; NE]	2,32	[1,13; 5,37]	0,0198*
Partielles Ansprechen	47	5 (10,6)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	2,15	[0,35; 41,33]	0,4476
Interaktion p-Wert									0,9513
ECOG PS Status									
Normale Aktivität	200	33 (16,5)	NE [NE; NE]	105	8 (7,6)	NE [NE; NE]	2,17	[1,05; 5,05]	0,0348*
Eingeschränkte Aktivität	60	8 (13,3)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	3,27	[0,60; 60,66]	0,1951
Interaktion p-Wert									0,7063
Baseline CA-125 Wert									
<=ULN	247	39 (15,8)	NE [NE; NE]	123	9 (7,3)	NE [NE; NE]	2,16	[1,10; 4,77]	0,0247*
>ULN	13	2 (15,4)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	37 (16,8)	NE [NE; NE]	104	6 (5,8)	NE [NE; NE]	2,94	[1,34; 7,75]	0,0057*
IV	40	4 (10,0)	NE [NE; NE]	26	3 (11,5)	NE [NE; NE]	0,83	[0,18; 4,21]	0,8070
Interaktion p-Wert									0,1609
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	28 (14,9)	NE [NE; NE]	90	8 (8,9)	NE [NE; NE]	1,65	[0,79; 3,89]	0,1899
BRCA2	62	12 (19,4)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	7,92	[1,56;144,27]	0,0084*
Interaktion p-Wert									0,1043
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.10 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Neutropenie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	4 (7,3)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	0,95	[0,19; 6,84]	0,9519
Keine makroskopische Resterkrankung	200	36 (18,0)	NE [NE; NE]	97	6 (6,2)	NE [NE; NE]	3,03	[1,38; 8,01]	0,0044*
Interaktion p-Wert									0,2549
Abstammung									
Weiß	214	37 (17,3)	NE [NE; NE]	105	8 (7,6)	NE [NE; NE]	2,27	[1,11; 5,25]	0,0228*
Andere	46	4 (8,7)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	2,14	[0,32; 41,81]	0,4662
Interaktion p-Wert									0,9604
Region									
Europa	101	24 (23,8)	NE [NE; NE]	53	6 (11,3)	NE [NE; NE]	2,20	[0,96; 5,93]	0,0641
Asien	33	2 (6,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	0,84	[0,08; 18,15]	0,8909
Rest der Welt	126	15 (11,9)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	3,62	[1,02; 22,97]	0,0459*
Interaktion p-Wert									0,6081

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.11 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Thrombozytopenie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	17 (7,6)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	8,19	[1,68;147,64]	0,0050*
>=65 Jahre	35	4 (11,4)	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	2,11	[0,31; 41,30]	0,4738
Interaktion p-Wert									0,3829
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	17 (8,0)	NE [NE; NE]	106	1 (0,9)	NE [NE; NE]	8,54	[1,76;154,01]	0,0039*
Partielles Ansprechen	47	4 (8,5)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	1,68	[0,25; 32,87]	0,6276
Interaktion p-Wert									0,2996
ECOG PS Status									
Normale Aktivität	200	19 (9,5)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	9,81	[2,03;176,20]	0,0016*
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	0,79	[0,08; 17,01]	0,8503
Interaktion p-Wert									0,1346
Baseline CA-125 Wert									
<=ULN	247	21 (8,5)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	10,38	[2,17;186,29]	0,0009*
>ULN	13	0	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	20 (9,1)	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	4,62	[1,35; 28,92]	0,0116*
IV	40	1 (2,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	16 (8,5)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	3,82	[1,09; 24,17]	0,0350*
BRCA2	62	3 (4,8)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.11 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Thrombozytopenie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	4 (7,3)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	17 (8,5)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	4,05	[1,16; 25,53]	0,0258*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	20 (9,3)	NE [NE; NE]	105	2 (1,9)	NE [NE; NE]	4,81	[1,40; 30,13]	0,0092*
Andere	46	1 (2,2)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	12 (11,9)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	6,25	[1,23;113,87]	0,0233*
Asien	33	1 (3,0)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	8 (6,3)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	3,84	[0,70; 71,26]	0,1342
Interaktion p-Wert									0,7439

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1aak 09JAN2023:12:30 kpzx329

Table 3.4.12 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	208 (92,4)	0,2 [0,1; 0,2]	111	80 (72,1)	3,0 [1,4; 4,8]	2,40	[1,85; 3,13]	<0,0001*
>=65 Jahre	35	32 (91,4)	0,2 [0,1; 0,5]	19	17 (89,5)	4,1 [0,5; 7,4]	1,71	[0,96; 3,15]	0,0701
Interaktion p-Wert									0,3067
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	197 (92,5)	0,1 [0,1; 0,2]	106	78 (73,6)	3,0 [0,8; 4,7]	2,35	[1,81; 3,08]	<0,0001*
Partielles Ansprechen	47	43 (91,5)	0,2 [0,1; 0,3]	24	19 (79,2)	4,1 [1,0;10,8]	1,99	[1,18; 3,50]	0,0099*
Interaktion p-Wert									0,5961
ECOG PS Status									
Normale Aktivität	200	187 (93,5)	0,2 [0,1; 0,3]	105	78 (74,3)	2,3 [0,8; 4,7]	2,28	[1,75; 3,00]	<0,0001*
Eingeschränkte Aktivität	60	53 (88,3)	0,2 [0,1; 0,3]	25	19 (76,0)	4,5 [2,9;10,8]	2,28	[1,37; 3,96]	0,0012*
Interaktion p-Wert									0,9947
Baseline CA-125 Wert									
<=ULN	247	229 (92,7)	0,1 [0,1; 0,2]	123	91 (74,0)	4,1 [1,9; 4,8]	2,39	[1,87; 3,07]	<0,0001*
>ULN	13	11 (84,6)	0,3 [0,1; 0,9]	7	6 (85,7)	0,8 [0,0; 4,1]	0,89	[0,34; 2,60]	0,8273
Interaktion p-Wert									0,0754
FIGO Stadium									
III	220	203 (92,3)	0,2 [0,1; 0,3]	104	79 (76,0)	2,4 [0,7; 4,5]	2,10	[1,62; 2,75]	<0,0001*
IV	40	37 (92,5)	0,1 [0,1; 0,2]	26	18 (69,2)	6,5 [2,2;12,5]	3,25	[1,87; 5,87]	<0,0001*
Interaktion p-Wert									0,1645
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	175 (93,1)	0,2 [0,1; 0,2]	90	63 (70,0)	4,2 [1,9; 8,0]	2,53	[1,90; 3,41]	<0,0001*
BRCA2	62	55 (88,7)	0,2 [0,1; 0,6]	39	34 (87,2)	2,3 [0,3; 4,6]	1,61	[1,06; 2,50]	0,0270*
Interaktion p-Wert									0,0890
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.12 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	48 (87,3)	0,3 [0,1; 0,5]	29	18 (62,1)	11,2 [1,0;15,8]	2,56	[1,51; 4,53]	0,0003*
Keine makroskopische Resterkrankung	200	187 (93,5)	0,1 [0,1; 0,2]	97	77 (79,4)	2,6 [0,7; 4,6]	2,13	[1,63; 2,80]	<0,0001*
Interaktion p-Wert									0,5451
Abstammung									
Weiß	214	196 (91,6)	0,2 [0,1; 0,3]	105	84 (80,0)	2,3 [0,5; 4,5]	1,89	[1,46; 2,46]	<0,0001*
Andere	46	44 (95,7)	0,1 [0,1; 0,2]	25	13 (52,0)	15,8 [4,4; NE]	5,07	[2,81; 9,83]	<0,0001*
Interaktion p-Wert									0,0023*
Region									
Europa	101	97 (96,0)	0,1 [0,1; 0,2]	53	42 (79,2)	1,9 [0,3; 4,6]	2,37	[1,65; 3,44]	<0,0001*
Asien	33	31 (93,9)	0,1 [0,1; 0,2]	14	7 (50,0)	15,8 [4,4; NE]	4,74	[2,21; 11,75]	<0,0001*
Rest der Welt	126	112 (88,9)	0,2 [0,1; 0,3]	63	48 (76,2)	2,9 [0,8; 4,6]	1,92	[1,37; 2,72]	0,0001*
Interaktion p-Wert									0,1028

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.13 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Erbrechen
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	89 (39,6)	NE [NE; NE]	111	18 (16,2)	NE [NE; NE]	2,67	[1,65; 4,58]	<0,0001*
>=65 Jahre	35	15 (42,9)	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	10,43	[2,12;188,76]	0,0014*
Interaktion p-Wert									0,1288
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	87 (40,8)	NE [NE; NE]	106	17 (16,0)	NE [NE; NE]	2,99	[1,83; 5,20]	<0,0001*
Partielles Ansprechen	47	17 (36,2)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	3,85	[1,10; 24,31]	0,0325*
Interaktion p-Wert									0,7426
ECOG PS Status									
Normale Aktivität	200	76 (38,0)	NE [NE; NE]	105	14 (13,3)	NE [NE; NE]	3,13	[1,83; 5,78]	<0,0001*
Eingeschränkte Aktivität	60	28 (46,7)	17,4 [5,4; NE]	25	5 (20,0)	NE [NE; NE]	2,74	[1,15; 8,08]	0,0205*
Interaktion p-Wert									0,8156
Baseline CA-125 Wert									
<=ULN	247	103 (41,7)	NE [NE; NE]	123	19 (15,4)	NE [NE; NE]	3,07	[1,93; 5,17]	<0,0001*
>ULN	13	1 (7,7)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	85 (38,6)	NE [NE; NE]	104	16 (15,4)	NE [NE; NE]	2,76	[1,66; 4,88]	<0,0001*
IV	40	19 (47,5)	16,6 [5,4; NE]	26	3 (11,5)	NE [NE; NE]	5,03	[1,71; 21,41]	0,0020*
Interaktion p-Wert									0,3536
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	75 (39,9)	NE [NE; NE]	90	13 (14,4)	NE [NE; NE]	3,08	[1,77; 5,81]	<0,0001*
BRCA2	62	26 (41,9)	NE [NE; NE]	39	6 (15,4)	NE [NE; NE]	3,12	[1,37; 8,37]	0,0054*
Interaktion p-Wert									0,9825
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.13 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Erbrechen
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	21 (38,2)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	2,85	[1,09; 9,79]	0,0320*
Keine makroskopische Resterkrankung	200	82 (41,0)	NE [NE; NE]	97	15 (15,5)	NE [NE; NE]	3,08	[1,83; 5,55]	<0,0001*
Interaktion p-Wert									0,9025
Abstammung									
Weiß	214	87 (40,7)	NE [NE; NE]	105	15 (14,3)	NE [NE; NE]	3,16	[1,88; 5,68]	<0,0001*
Andere	46	17 (37,0)	NE [NE; NE]	25	4 (16,0)	NE [NE; NE]	2,66	[0,98; 9,25]	0,0541
Interaktion p-Wert									0,7852
Region									
Europa	101	48 (47,5)	16,6 [9,6; NE]	53	9 (17,0)	NE [NE; NE]	3,25	[1,68; 7,09]	0,0002*
Asien	33	11 (33,3)	NE [NE; NE]	14	2 (14,3)	NE [NE; NE]	2,75	[0,74; 17,77]	0,1425
Rest der Welt	126	45 (35,7)	NE [NE; NE]	63	8 (12,7)	NE [NE; NE]	3,02	[1,50; 6,91]	0,0012*
Interaktion p-Wert									0,9772

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.14 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Haemorrhoiden
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	11 (4,9)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	0	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	8 (3,8)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	3 (6,4)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	9 (4,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	10 (4,0)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	1 (7,7)	92,3 [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	8 (3,6)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	3 (7,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	10 (5,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	0	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.14 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Haemorrhoiden
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	2 (3,6)	92,3 [92,3; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	7 (3,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	9 (4,2)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	2 (4,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	3 (3,0)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	1 (3,0)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	7 (5,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.15 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Stomatitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	19 (8,4)	NE [NE; NE]	111	3 (2,7)	NE [NE; NE]	2,96	[1,004; 12,61]	0,0490*
>=65 Jahre	35	4 (11,4)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	17 (8,0)	NE [NE; NE]	106	3 (2,8)	NE [NE; NE]	2,78	[0,93; 11,90]	0,0691
Partielles Ansprechen	47	6 (12,8)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	18 (9,0)	NE [NE; NE]	105	3 (2,9)	NE [NE; NE]	2,95	[0,99; 12,60]	0,0515
Eingeschränkte Aktivität	60	5 (8,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	21 (8,5)	NE [NE; NE]	123	3 (2,4)	NE [NE; NE]	3,35	[1,15; 14,20]	0,0242*
>ULN	13	2 (15,4)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	16 (7,3)	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	3,61	[1,02; 22,82]	0,0453*
IV	40	7 (17,5)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	4,54	[0,81; 84,99]	0,0921
Interaktion p-Wert									0,8581
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	15 (8,0)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	3,54	[0,999; 22,49]	0,0503
BRCA2	62	7 (11,3)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	4,27	[0,76; 79,85]	0,1088
Interaktion p-Wert									0,8859

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.15 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Stomatitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	6 (10,9)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	14 (7,0)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	2,17	[0,71; 9,43]	0,1888
Interaktion p-Wert									NC
Abstammung									
Weiß	214	17 (7,9)	NE [NE; NE]	105	2 (1,9)	NE [NE; NE]	3,97	[1,14; 25,08]	0,0282*
Andere	46	6 (13,0)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	3,19	[0,54; 60,36]	0,2219
Interaktion p-Wert									0,8691
Region									
Europa	101	9 (8,9)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	4,49	[0,84; 82,87]	0,0844
Asien	33	4 (12,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	1,73	[0,26; 33,77]	0,6071
Rest der Welt	126	10 (7,9)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	4,74	[0,91; 87,02]	0,0684
Interaktion p-Wert									0,7822

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 2

Table 3.4.16 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Uebelkeit
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	178 (79,1)	0,3 [0,1; 0,3]	111	44 (39,6)	NE [NE; NE]	3,24	[2,34; 4,56]	<0,0001*
>=65 Jahre	35	24 (68,6)	0,5 [0,1; 3,7]	19	5 (26,3)	NE [NE; NE]	4,03	[1,67; 11,97]	0,0012*
Interaktion p-Wert									0,6672
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	166 (77,9)	0,3 [0,1; 0,5]	106	43 (40,6)	NE [NE; NE]	3,15	[2,27; 4,47]	<0,0001*
Partielles Ansprechen	47	36 (76,6)	0,2 [0,1; 0,5]	24	6 (25,0)	NE [NE; NE]	4,54	[2,06; 12,02]	<0,0001*
Interaktion p-Wert									0,4231
ECOG PS Status									
Normale Aktivität	200	157 (78,5)	0,3 [0,2; 0,5]	105	39 (37,1)	NE [NE; NE]	3,35	[2,38; 4,83]	<0,0001*
Eingeschränkte Aktivität	60	45 (75,0)	0,2 [0,1; 0,9]	25	10 (40,0)	17,5 [4,5; NE]	3,22	[1,69; 6,77]	0,0002*
Interaktion p-Wert									0,9198
Baseline CA-125 Wert									
<=ULN	247	193 (78,1)	0,3 [0,2; 0,3]	123	46 (37,4)	NE [NE; NE]	3,45	[2,52; 4,83]	<0,0001*
>ULN	13	9 (69,2)	0,3 [0,1; NE]	7	3 (42,9)	NE [NE; NE]	1,61	[0,48; 7,26]	0,4592
Interaktion p-Wert									0,2964
FIGO Stadium									
III	220	168 (76,4)	0,3 [0,2; 0,5]	104	39 (37,5)	NE [NE; NE]	3,18	[2,27; 4,57]	<0,0001*
IV	40	34 (85,0)	0,1 [0,1; 0,3]	26	10 (38,5)	15,8 [8,8; NE]	4,25	[2,18; 9,11]	<0,0001*
Interaktion p-Wert									0,4616
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	149 (79,3)	0,2 [0,1; 0,3]	90	32 (35,6)	NE [NE; NE]	3,82	[2,64; 5,71]	<0,0001*
BRCA2	62	46 (74,2)	0,7 [0,1; 3,7]	39	17 (43,6)	NE [NE; NE]	2,34	[1,37; 4,20]	0,0016*
Interaktion p-Wert									0,1609
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.16 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Uebelkeit
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	37 (67,3)	0,4 [0,2; 2,2]	29	8 (27,6)	NE [NE; NE]	3,44	[1,69; 7,98]	0,0004*
Keine makroskopische Resterkrankung	200	161 (80,5)	0,2 [0,1; 0,3]	97	41 (42,3)	NE [NE; NE]	3,19	[2,28; 4,56]	<0,0001*
Interaktion p-Wert									0,8552
Abstammung									
Weiß	214	167 (78,0)	0,3 [0,2; 0,5]	105	43 (41,0)	NE [NE; NE]	2,97	[2,14; 4,22]	<0,0001*
Andere	46	35 (76,1)	0,2 [0,1; 0,7]	25	6 (24,0)	NE [NE; NE]	5,80	[2,62; 15,34]	<0,0001*
Interaktion p-Wert									0,1365
Region									
Europa	101	84 (83,2)	0,2 [0,1; 0,3]	53	23 (43,4)	NE [NE; NE]	3,37	[2,16; 5,48]	<0,0001*
Asien	33	25 (75,8)	0,2 [0,1; 1,2]	14	3 (21,4)	NE [NE; NE]	6,33	[2,22; 26,59]	0,0002*
Rest der Welt	126	93 (73,8)	0,3 [0,2; 1,0]	63	23 (36,5)	NE [NE; NE]	2,99	[1,93; 4,83]	<0,0001*
Interaktion p-Wert									0,4689

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.17 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	135 (60,0)	6,0 [2,8; 8,3]	111	55 (49,5)	14,8 [5,6; NE]	1,36	[0,997; 1,87]	0,0519
>=65 Jahre	35	23 (65,7)	5,6 [0,8;20,9]	19	7 (36,8)	NE [NE; NE]	2,08	[0,94; 5,25]	0,0722
Interaktion p-Wert									0,3405
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	130 (61,0)	5,6 [2,3; 8,8]	106	50 (47,2)	18,4 [8,8; NE]	1,55	[1,12; 2,16]	0,0070*
Partielles Ansprechen	47	28 (59,6)	7,2 [1,6;39,5]	24	12 (50,0)	NE [NE; NE]	1,00	[0,52; 2,04]	0,9901
Interaktion p-Wert									0,2621
ECOG PS Status									
Normale Aktivität	200	120 (60,0)	6,6 [5,1; 9,1]	105	50 (47,6)	18,4 [5,6; NE]	1,38	[0,996; 1,93]	0,0531
Eingeschränkte Aktivität	60	38 (63,3)	1,6 [0,5; 7,8]	25	12 (48,0)	NE [NE; NE]	1,67	[0,90; 3,33]	0,1098
Interaktion p-Wert									0,6057
Baseline CA-125 Wert									
<=ULN	247	152 (61,5)	5,8 [3,1; 7,5]	123	60 (48,8)	14,8 [7,1; NE]	1,44	[1,07; 1,95]	0,0152*
>ULN	13	6 (46,2)	NE [NE; NE]	7	2 (28,6)	NE [NE; NE]	1,50	[0,35; 10,26]	0,6075
Interaktion p-Wert									0,9572
FIGO Stadium									
III	220	129 (58,6)	7,1 [3,1;10,2]	104	47 (45,2)	23,3 [9,3; NE]	1,49	[1,07; 2,10]	0,0167*
IV	40	29 (72,5)	5,1 [1,6; 6,3]	26	15 (57,7)	5,6 [1,9; NE]	1,33	[0,72; 2,56]	0,3609
Interaktion p-Wert									0,7629
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	113 (60,1)	6,1 [2,3; 9,0]	90	43 (47,8)	18,4 [4,5; NE]	1,41	[0,999; 2,02]	0,0504
BRCA2	62	36 (58,1)	6,4 [1,8;20,0]	39	19 (48,7)	14,8 [2,6; NE]	1,31	[0,76; 2,33]	0,3390
Interaktion p-Wert									0,8236
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.17 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	33 (60,0)	7,2 [2,1;16,6]	29	11 (37,9)	NE [NE; NE]	1,80	[0,94; 3,73]	0,0776
Keine makroskopische Resterkrankung	200	121 (60,5)	5,6 [1,9; 8,8]	97	50 (51,5)	11,0 [3,7; NE]	1,34	[0,97; 1,88]	0,0772
Interaktion p-Wert									0,4375
Abstammung									
Weiß	214	133 (62,1)	5,6 [2,1; 7,5]	105	52 (49,5)	13,8 [4,5; NE]	1,45	[1,06; 2,02]	0,0197*
Andere	46	25 (54,3)	8,2 [2,3; NE]	25	10 (40,0)	20,3 [1,8; NE]	1,37	[0,68; 2,99]	0,3940
Interaktion p-Wert									0,8827
Region									
Europa	101	64 (63,4)	5,6 [1,9;11,9]	53	23 (43,4)	23,3 [8,8; NE]	1,75	[1,10; 2,88]	0,0166*
Asien	33	14 (42,4)	NE [NE; NE]	14	3 (21,4)	NE [NE; NE]	1,98	[0,65; 8,58]	0,2508
Rest der Welt	126	80 (63,5)	3,4 [1,3; 7,5]	63	36 (57,1)	4,5 [1,8; NE]	1,24	[0,84; 1,85]	0,2867
Interaktion p-Wert									0,4726

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.18 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dysgeusie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	48 (21,3)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	5,08	[2,23; 14,64]	<0,0001*
>=65 Jahre	35	8 (22,9)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	48 (22,5)	NE [NE; NE]	106	4 (3,8)	NE [NE; NE]	6,50	[2,65; 21,54]	<0,0001*
Partielles Ansprechen	47	8 (17,0)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	3,96	[0,73; 73,50]	0,1244
Interaktion p-Wert									0,6874
ECOG PS Status									
Normale Aktivität	200	41 (20,5)	NE [NE; NE]	105	4 (3,8)	NE [NE; NE]	5,70	[2,30; 18,97]	<0,0001*
Eingeschränkte Aktivität	60	15 (25,0)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	6,78	[1,37;122,63]	0,0140*
Interaktion p-Wert									0,8785
Baseline CA-125 Wert									
<=ULN	247	53 (21,5)	NE [NE; NE]	123	5 (4,1)	NE [NE; NE]	5,64	[2,49; 16,19]	<0,0001*
>ULN	13	3 (23,1)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	44 (20,0)	NE [NE; NE]	104	4 (3,8)	NE [NE; NE]	5,46	[2,21; 18,12]	<0,0001*
IV	40	12 (30,0)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	9,11	[1,79;165,98]	0,0042*
Interaktion p-Wert									0,6463
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	44 (23,4)	NE [NE; NE]	90	4 (4,4)	NE [NE; NE]	5,72	[2,32; 19,01]	<0,0001*
BRCA2	62	9 (14,5)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	5,62	[1,06;103,75]	0,0417*
Interaktion p-Wert									0,9884
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.18 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dysgeusie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	8 (14,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	47 (23,5)	NE [NE; NE]	97	5 (5,2)	NE [NE; NE]	4,93	[2,16; 14,20]	<0,0001*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	47 (22,0)	NE [NE; NE]	105	4 (3,8)	NE [NE; NE]	6,18	[2,51; 20,47]	<0,0001*
Andere	46	9 (19,6)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	5,10	[0,96; 93,94]	0,0576
Interaktion p-Wert									0,8721
Region									
Europa	101	23 (22,8)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	12,77	[2,69;228,37]	0,0002*
Asien	33	6 (18,2)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	27 (21,4)	NE [NE; NE]	63	4 (6,3)	NE [NE; NE]	3,61	[1,41; 12,23]	0,0054*
Interaktion p-Wert									0,2299

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.19 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Somnolenz
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	8 (3,6)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	2 (5,7)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	9 (4,2)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	1 (2,1)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	8 (4,0)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	10 (4,0)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	8 (3,6)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	2 (5,0)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	5 (2,7)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	4 (6,5)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.19 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Somnolenz
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	3 (5,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	7 (3,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	8 (3,7)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	2 (4,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	6 (5,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	1 (3,0)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1aas 09JAN2023:12:30 kpzx329

Table 3.4.20 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Hypertonie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	8 (3,6)	NE [NE; NE]	111	10 (9,0)	NE [NE; NE]	0,32	[0,12; 0,83]	0,0193*
>=65 Jahre	35	1 (2,9)	NE [NE; NE]	19	2 (10,5)	NE [NE; NE]	0,20	[0,01; 2,16]	0,1802
Interaktion p-Wert									0,7200
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	7 (3,3)	NE [NE; NE]	106	10 (9,4)	NE [NE; NE]	0,32	[0,12; 0,84]	0,0206*
Partielles Ansprechen	47	2 (4,3)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	0,25	[0,03; 2,21]	0,1960
Interaktion p-Wert									0,8384
ECOG PS Status									
Normale Aktivität	200	6 (3,0)	NE [NE; NE]	105	10 (9,5)	NE [NE; NE]	0,24	[0,08; 0,66]	0,0056*
Eingeschränkte Aktivität	60	3 (5,0)	NE [NE; NE]	25	2 (8,0)	NE [NE; NE]	0,64	[0,10; 4,87]	0,6299
Interaktion p-Wert									0,3480
Baseline CA-125 Wert									
<=ULN	247	8 (3,2)	NE [NE; NE]	123	11 (8,9)	NE [NE; NE]	0,30	[0,11; 0,74]	0,0096*
>ULN	13	1 (7,7)	35,0 [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,32	[0,01; 8,17]	0,4339
Interaktion p-Wert									0,9615
FIGO Stadium									
III	220	8 (3,6)	NE [NE; NE]	104	12 (11,5)	NE [NE; NE]	0,26	[0,10; 0,64]	0,0035*
IV	40	1 (2,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	6 (3,2)	NE [NE; NE]	90	5 (5,6)	NE [NE; NE]	0,51	[0,15; 1,77]	0,2754
BRCA2	62	3 (4,8)	NE [NE; NE]	39	7 (17,9)	NE [NE; NE]	0,17	[0,04; 0,65]	0,0091*
Interaktion p-Wert									0,2379
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.20 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Hypertonie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	2 (3,6)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	0,34	[0,04; 2,89]	0,2961
Keine makroskopische Resterkrankung	200	7 (3,5)	NE [NE; NE]	97	10 (10,3)	NE [NE; NE]	0,30	[0,11; 0,79]	0,0149*
Interaktion p-Wert									0,9190
Abstammung									
Weiß	214	7 (3,3)	NE [NE; NE]	105	11 (10,5)	NE [NE; NE]	0,25	[0,09; 0,64]	0,0041*
Andere	46	2 (4,3)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	0,91	[0,09; 19,70]	0,9421
Interaktion p-Wert									0,3073
Region									
Europa	101	4 (4,0)	NE [NE; NE]	53	7 (13,2)	NE [NE; NE]	0,22	[0,05; 0,74]	0,0145*
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	5 (4,0)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	0,40	[0,11; 1,47]	0,1618
Interaktion p-Wert									0,4808

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.21 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Bronchitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	8 (3,6)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	5 (14,3)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	12 (5,6)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	1 (2,1)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	11 (5,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	13 (5,3)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	12 (5,5)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	1 (2,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	7 (3,7)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	3 (4,8)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.21 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Bronchitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	12 (6,0)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	13 (6,1)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	0	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	6 (5,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	7 (5,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1aau 09JAN2023:12:30 kpzx329

Table 3.4.22 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Muskelspasmen
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	14 (6,2)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	6,16	[1,23;111,72]	0,0228*
>=65 Jahre	35	4 (11,4)	64,6 [64,6; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	14 (6,6)	NE [NE; NE]	106	1 (0,9)	NE [NE; NE]	6,47	[1,30;117,38]	0,0183*
Partielles Ansprechen	47	4 (8,5)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	15 (7,5)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	6,61	[1,32;119,82]	0,0169*
Eingeschränkte Aktivität	60	3 (5,0)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	16 (6,5)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	6,65	[1,34;120,38]	0,0157*
>ULN	13	2 (15,4)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	15 (6,8)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	3 (7,5)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	12 (6,4)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	5 (8,1)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.22 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Muskelspasmen
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	5 (9,1)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	11 (5,5)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	4,93	[0,95; 90,18]	0,0583
Interaktion p-Wert									NC
Abstammung									
Weiß	214	18 (8,4)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	7,52	[1,54;135,62]	0,0080*
Andere	46	0	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	9 (8,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	9 (7,1)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	4,11	[0,77; 75,79]	0,1089
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1aav 09JAN2023:12:30 kpzx329

Table 3.4.23 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	75 (33,3)	52,5 [28,3; NE]	111	24 (21,6)	NE [NE; NE]	1,54	[0,99; 2,50]	0,0574
>=65 Jahre	35	15 (42,9)	23,3 [11,1; NE]	19	5 (26,3)	NE [NE; NE]	1,57	[0,61; 4,83]	0,3665
Interaktion p-Wert									0,9737
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	66 (31,0)	52,5 [28,3; NE]	106	29 (27,4)	NE [NE; NE]	1,13	[0,74; 1,78]	0,5721
Partielles Ansprechen	47	24 (51,1)	24,4 [4,6; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	64 (32,0)	55,3 [28,3; NE]	105	21 (20,0)	NE [NE; NE]	1,56	[0,97; 2,62]	0,0700
Eingeschränkte Aktivität	60	26 (43,3)	44,2 [5,8; NE]	25	8 (32,0)	NE [NE; NE]	1,43	[0,67; 3,38]	0,3646
Interaktion p-Wert									0,8564
Baseline CA-125 Wert									
<=ULN	247	85 (34,4)	52,5 [28,3; NE]	123	29 (23,6)	NE [NE; NE]	1,45	[0,96; 2,26]	0,0750
>ULN	13	5 (38,5)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	73 (33,2)	44,2 [28,3; NE]	104	25 (24,0)	NE [NE; NE]	1,37	[0,88; 2,21]	0,1635
IV	40	17 (42,5)	55,3 [6,3; NE]	26	4 (15,4)	NE [NE; NE]	2,76	[1,01; 9,61]	0,0468*
Interaktion p-Wert									0,2268
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	68 (36,2)	44,2 [44,2; NE]	90	17 (18,9)	NE [NE; NE]	1,97	[1,18; 3,46]	0,0080*
BRCA2	62	20 (32,3)	28,3 [28,3; NE]	39	12 (30,8)	NE [NE; NE]	0,97	[0,48; 2,06]	0,9432
Interaktion p-Wert									0,1248
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1aaw 09JAN2023:12:30 kpzx329

Table 3.4.23 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	21 (38,2)	44,2 [17,6; NE]	29	2 (6,9)	NE [NE; NE]	5,59	[1,64; 34,95]	0,0035*
Keine makroskopische Resterkrankung	200	66 (33,0)	52,5 [28,3; NE]	97	27 (27,8)	NE [NE; NE]	1,18	[0,76; 1,88]	0,4603
Interaktion p-Wert									0,0184*
Abstammung									
Weiß	214	74 (34,6)	52,5 [28,3; NE]	105	25 (23,8)	NE [NE; NE]	1,41	[0,91; 2,27]	0,1285
Andere	46	16 (34,8)	44,2 [23,9; NE]	25	4 (16,0)	NE [NE; NE]	2,36	[0,86; 8,24]	0,0973
Interaktion p-Wert									0,3804
Region									
Europa	101	30 (29,7)	55,3 [52,5; NE]	53	7 (13,2)	NE [NE; NE]	2,24	[1,04; 5,56]	0,0388*
Asien	33	9 (27,3)	44,2 [23,9; NE]	14	1 (7,1)	NE [NE; NE]	4,22	[0,79; 77,75]	0,1006
Rest der Welt	126	51 (40,5)	28,3 [23,3; NE]	63	21 (33,3)	NE [NE; NE]	1,16	[0,71; 1,98]	0,5575
Interaktion p-Wert									0,2051

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.24 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Appetit vermindert
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	44 (19,6)	NE [NE; NE]	111	11 (9,9)	NE [NE; NE]	1,97	[1,05; 4,01]	0,0332*
>=65 Jahre	35	9 (25,7)	NE [NE; NE]	19	2 (10,5)	NE [NE; NE]	2,41	[0,62; 15,84]	0,2196
Interaktion p-Wert									0,8075
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	40 (18,8)	NE [NE; NE]	106	13 (12,3)	NE [NE; NE]	1,53	[0,84; 2,99]	0,1681
Partielles Ansprechen	47	13 (27,7)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	36 (18,0)	NE [NE; NE]	105	9 (8,6)	NE [NE; NE]	2,08	[1,04; 4,60]	0,0368*
Eingeschränkte Aktivität	60	17 (28,3)	NE [NE; NE]	25	4 (16,0)	NE [NE; NE]	1,79	[0,66; 6,23]	0,2665
Interaktion p-Wert									0,8278
Baseline CA-125 Wert									
<=ULN	247	51 (20,6)	NE [NE; NE]	123	13 (10,6)	NE [NE; NE]	1,96	[1,10; 3,77]	0,0217*
>ULN	13	2 (15,4)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	46 (20,9)	NE [NE; NE]	104	11 (10,6)	NE [NE; NE]	1,98	[1,06; 4,02]	0,0309*
IV	40	7 (17,5)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	2,23	[0,54; 15,00]	0,2860
Interaktion p-Wert									0,8876
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	42 (22,3)	NE [NE; NE]	90	8 (8,9)	NE [NE; NE]	2,56	[1,27; 5,89]	0,0072*
BRCA2	62	11 (17,7)	NE [NE; NE]	39	5 (12,8)	NE [NE; NE]	1,32	[0,48; 4,19]	0,6037
Interaktion p-Wert									0,3236
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.24 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Appetit vermindert
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	9 (16,4)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	4,57	[0,86; 84,27]	0,0804
Keine makroskopische Resterkrankung	200	43 (21,5)	NE [NE; NE]	97	12 (12,4)	NE [NE; NE]	1,76	[0,96; 3,49]	0,0707
Interaktion p-Wert									0,3386
Abstammung									
Weiß	214	44 (20,6)	NE [NE; NE]	105	13 (12,4)	NE [NE; NE]	1,60	[0,89; 3,10]	0,1229
Andere	46	9 (19,6)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	22 (21,8)	NE [NE; NE]	53	4 (7,5)	NE [NE; NE]	2,88	[1,10; 9,85]	0,0300*
Asien	33	5 (15,2)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	26 (20,6)	NE [NE; NE]	63	9 (14,3)	NE [NE; NE]	1,39	[0,68; 3,15]	0,3816
Interaktion p-Wert									0,2649

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1aax 09JAN2023:12:30 kpzx329

Table 3.4.25 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	11 (4,9)	NE [NE; NE]	111	9 (8,1)	41,6 [NE; NE]	0,33	[0,12; 0,86]	0,0245*
>=65 Jahre	35	1 (2,9)	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	0,28	[0,01; 7,34]	0,3930
Interaktion p-Wert									0,9232
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	9 (4,2)	NE [NE; NE]	106	8 (7,5)	NE [NE; NE]	0,39	[0,14; 1,07]	0,0674
Partielles Ansprechen	47	3 (6,4)	NE [NE; NE]	24	2 (8,3)	41,6 [NE; NE]	0,13	[0,02; 1,09]	0,0589
Interaktion p-Wert									0,3073
ECOG PS Status									
Normale Aktivität	200	10 (5,0)	NE [NE; NE]	105	6 (5,7)	NE [NE; NE]	0,47	[0,16; 1,44]	0,1777
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	4 (16,0)	41,6 [24,4; NE]	0,13	[0,02; 0,68]	0,0160*
Interaktion p-Wert									0,1900
Baseline CA-125 Wert									
<=ULN	247	12 (4,9)	NE [NE; NE]	123	10 (8,1)	41,6 [NE; NE]	0,33	[0,13; 0,84]	0,0200*
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	9 (4,1)	NE [NE; NE]	104	7 (6,7)	41,6 [NE; NE]	0,36	[0,13; 1,04]	0,0593
IV	40	3 (7,5)	NE [NE; NE]	26	3 (11,5)	NE [NE; NE]	0,26	[0,04; 1,53]	0,1296
Interaktion p-Wert									0,7384
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	8 (4,3)	NE [NE; NE]	90	7 (7,8)	41,6 [NE; NE]	0,35	[0,12; 1,03]	0,0557
BRCA2	62	2 (3,2)	NE [NE; NE]	39	3 (7,7)	NE [NE; NE]	0,17	[0,02; 1,13]	0,0664
Interaktion p-Wert									0,5111
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.25 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	2 (3,6)	NE [NE; NE]	29	4 (13,8)	41,6 [NE; NE]	0,10	[0,01; 0,56]	0,0093*
Keine makroskopische Resterkrankung	200	9 (4,5)	NE [NE; NE]	97	6 (6,2)	NE [NE; NE]	0,49	[0,17; 1,51]	0,2043
Interaktion p-Wert									0,1087
Abstammung									
Weiß	214	7 (3,3)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	0,28	[0,09; 0,85]	0,0249*
Andere	46	5 (10,9)	NE [NE; NE]	25	3 (12,0)	41,6 [21,9; NE]	0,49	[0,11; 2,49]	0,3618
Interaktion p-Wert									0,5280
Region									
Europa	101	4 (4,0)	NE [NE; NE]	53	4 (7,5)	NE [NE; NE]	NC	[NC]	NC
Asien	33	4 (12,1)	77,3 [77,3; NE]	14	2 (14,3)	41,6 [21,9; NE]	NC	[NC]	NC
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	4 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.26 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Kreatinin im Blut erhoeht
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	19 (8,4)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	3,85	[1,10; 24,27]	0,0323*
>=65 Jahre	35	3 (8,6)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	16 (7,5)	NE [NE; NE]	106	2 (1,9)	NE [NE; NE]	3,69	[1,05; 23,40]	0,0409*
Partielles Ansprechen	47	6 (12,8)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	13 (6,5)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	5,64	[1,11;102,56]	0,0340*
Eingeschränkte Aktivität	60	9 (15,0)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	3,39	[0,63; 62,65]	0,1770
Interaktion p-Wert									0,7323
Baseline CA-125 Wert									
<=ULN	247	21 (8,5)	NE [NE; NE]	123	2 (1,6)	NE [NE; NE]	4,59	[1,33; 28,75]	0,0122*
>ULN	13	1 (7,7)	38,7 [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	16 (7,3)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	6,49	[1,32;117,29]	0,0167*
IV	40	6 (15,0)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	3,07	[0,51; 58,44]	0,2439
Interaktion p-Wert									0,6197
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	15 (8,0)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	4 (6,5)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.26 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Kreatinin im Blut erhoeht
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	3 (5,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	19 (9,5)	74,5 [74,5; NE]	97	2 (2,1)	NE [NE; NE]	4,11	[1,18; 25,90]	0,0233*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	18 (8,4)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	7,48	[1,54;134,81]	0,0080*
Andere	46	4 (8,7)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	1,73	[0,25; 33,95]	0,6079
Interaktion p-Wert									0,3474
Region									
Europa	101	11 (10,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	4 (12,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	7 (5,6)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1aaz 09JAN2023:12:30 kpzx329

Table 3.4.27 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Baenderzerrung
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	9 (4,0)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	1 (2,9)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	9 (4,2)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	1 (2,1)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	4 (2,0)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	6 (10,0)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	10 (4,0)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	9 (4,1)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	1 (2,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	8 (4,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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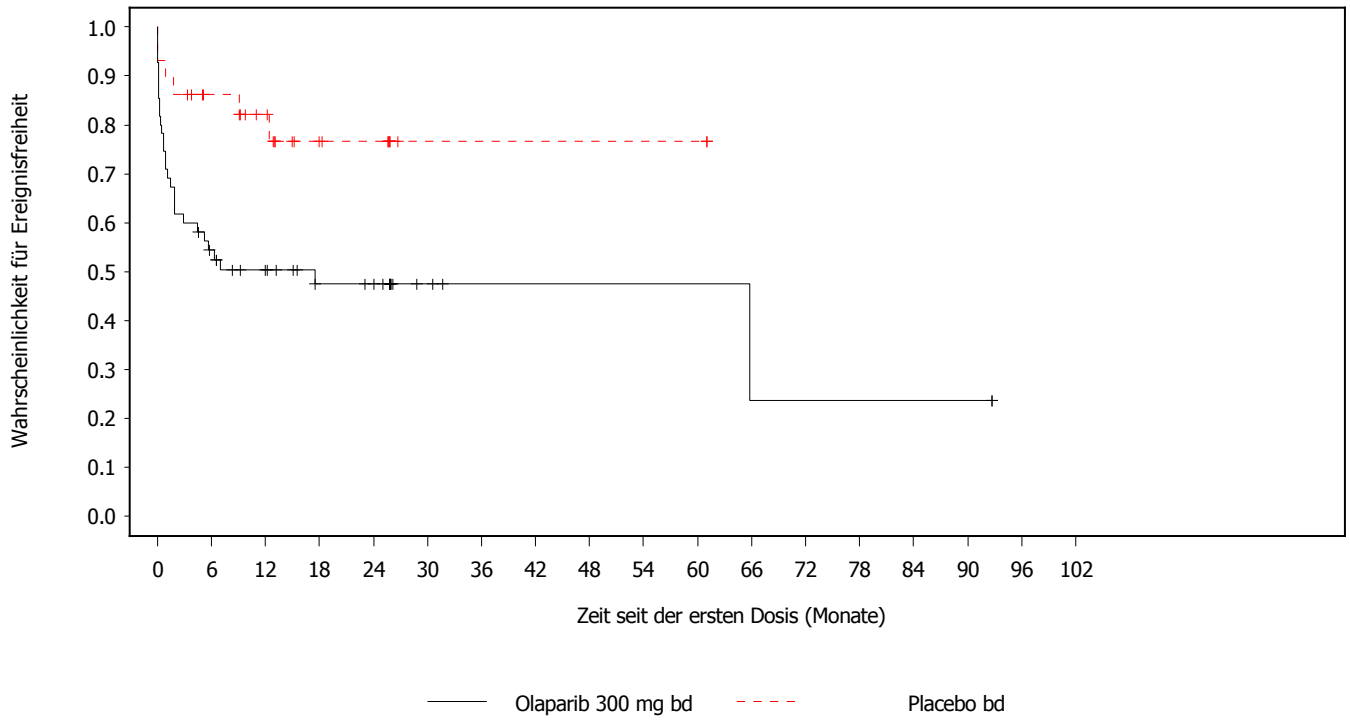
Table 3.4.27 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Baenderzerrung
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	10 (5,0)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	8 (3,7)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	2 (4,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	4 (4,0)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	2 (6,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1aba 09JAN2023:12:30 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.5.1 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Ermuedung for Ergebnis der Debulkingoperation vor Studienbeginn = makroskopische Resterkrankung
Safety Analysis Set, DCO 07MAR2022



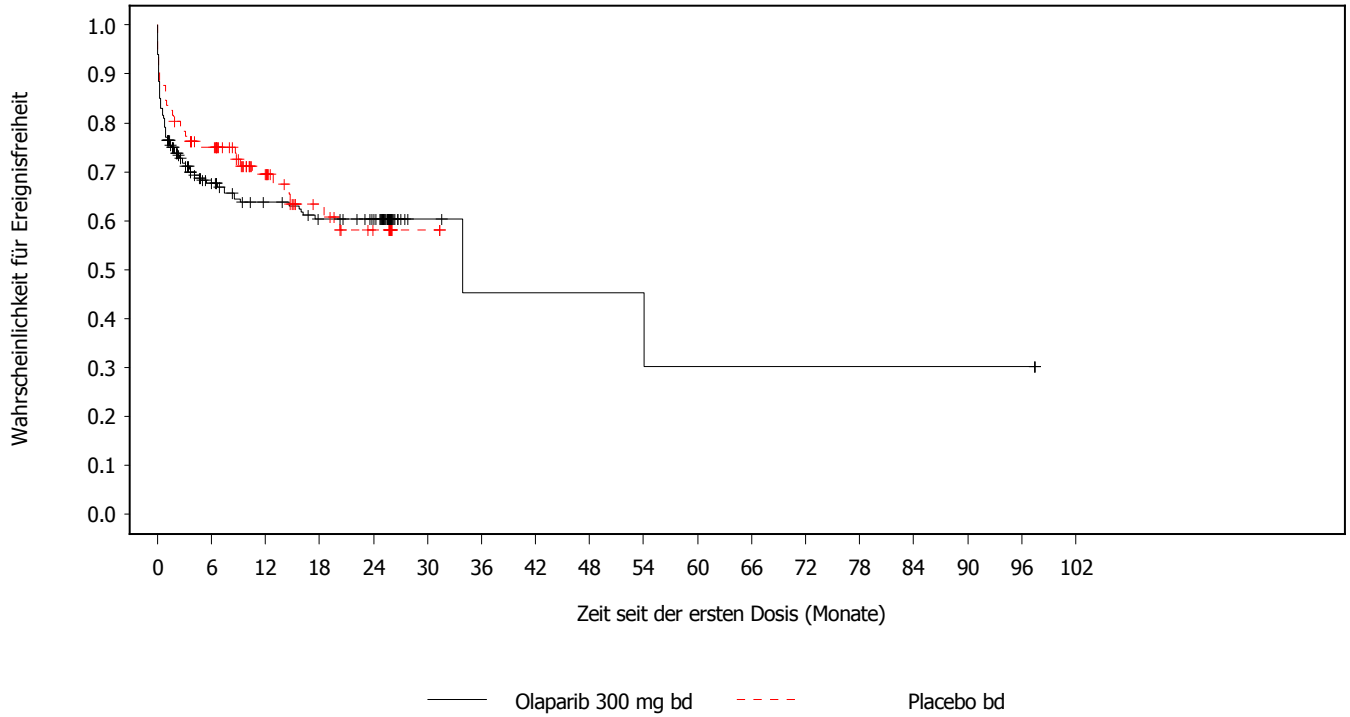
Anzahl an Patienten unter Risiko:

55	28	21	15	14	4	2	2	2	2	2	1	1	1	1	1	0	0	Olaparib 300 mg bd
29	21	16	8	7	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1baa 09JAN2023:12:30 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.5.2 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Ermuedung for Ergebnis der Debulkingoperation vor Studienbeginn = Keine makroskopische Resterkrankung
Safety Analysis Set, DCO 07MAR2022



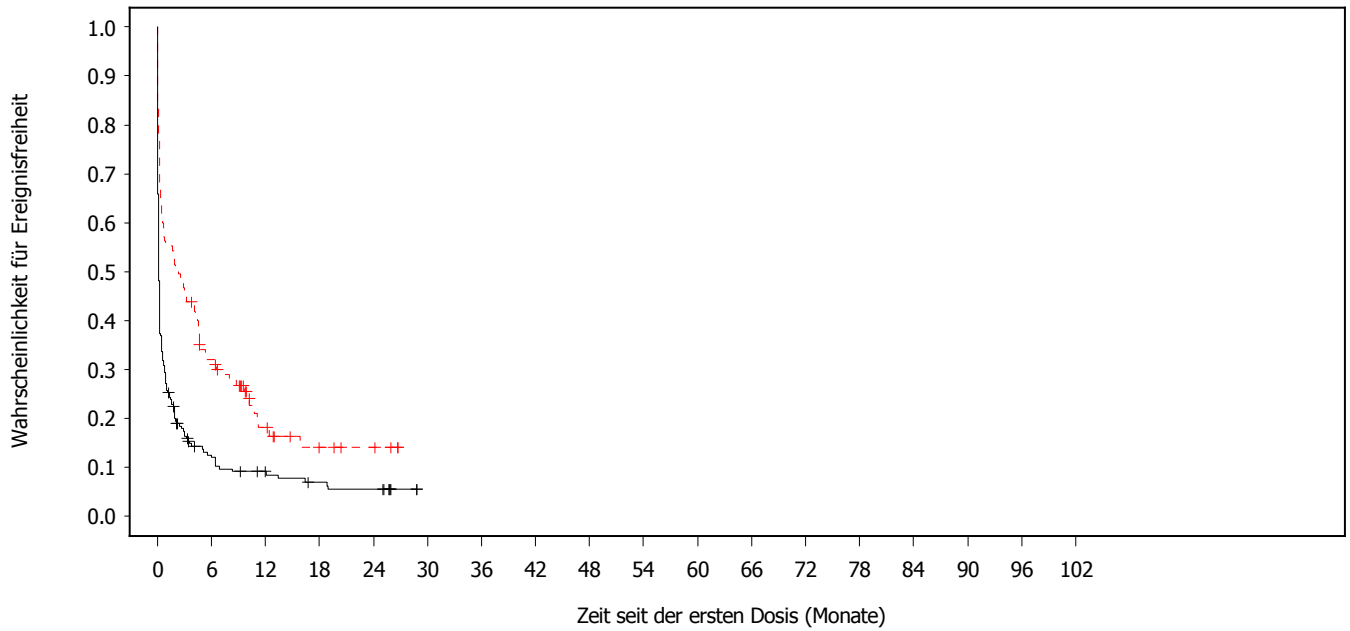
Anzahl an Patienten unter Risiko:

200	111	96	88	82	5	3	3	3	3	2	2	2	2	2	2	2	0	Olaparib 300 mg bd
97	67	41	25	17	1	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1bab 09JAN2023:12:30 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.5.3 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts for Abstammung = Weiß
Safety Analysis Set, DCO 07MAR2022



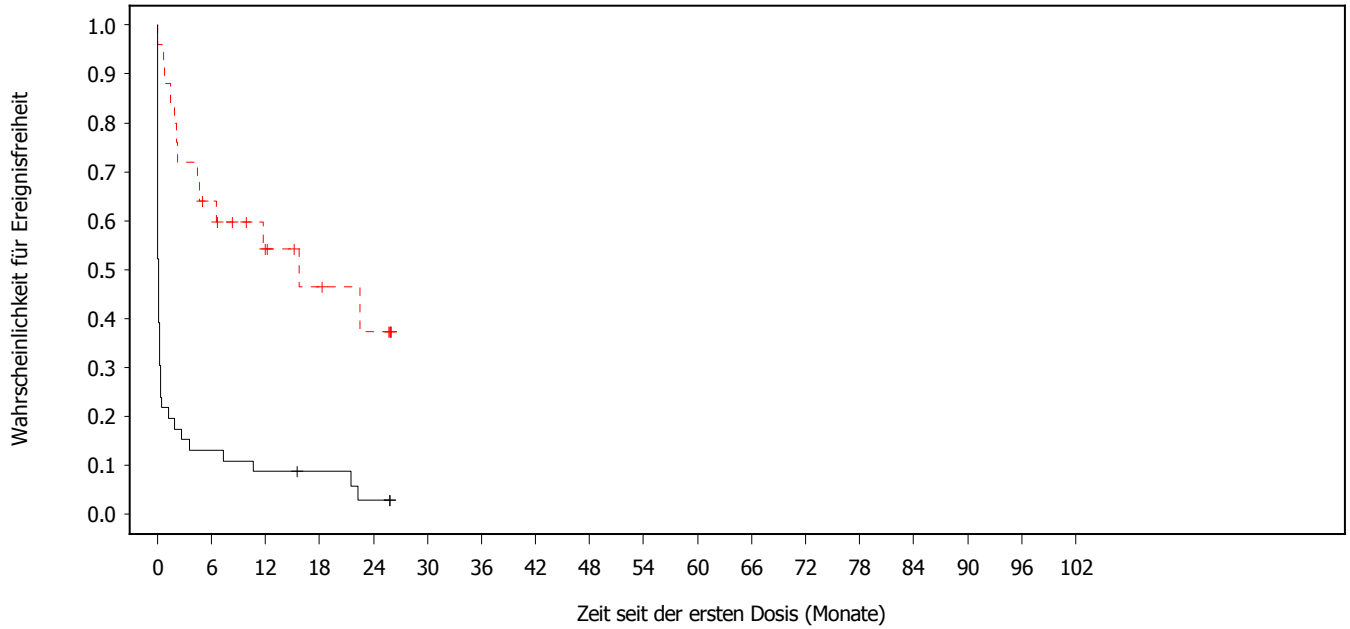
Anzahl an Patienten unter Risiko:

214	22	13	9	7	0	0	0	0	0	0	0	0	0	0	0	0	Olaparib 300 mg bd
105	32	12	5	3	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1bac 09JAN2023:12:30 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.5.4 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts for Abstammung = Andere
Safety Analysis Set, DCO 07MAR2022



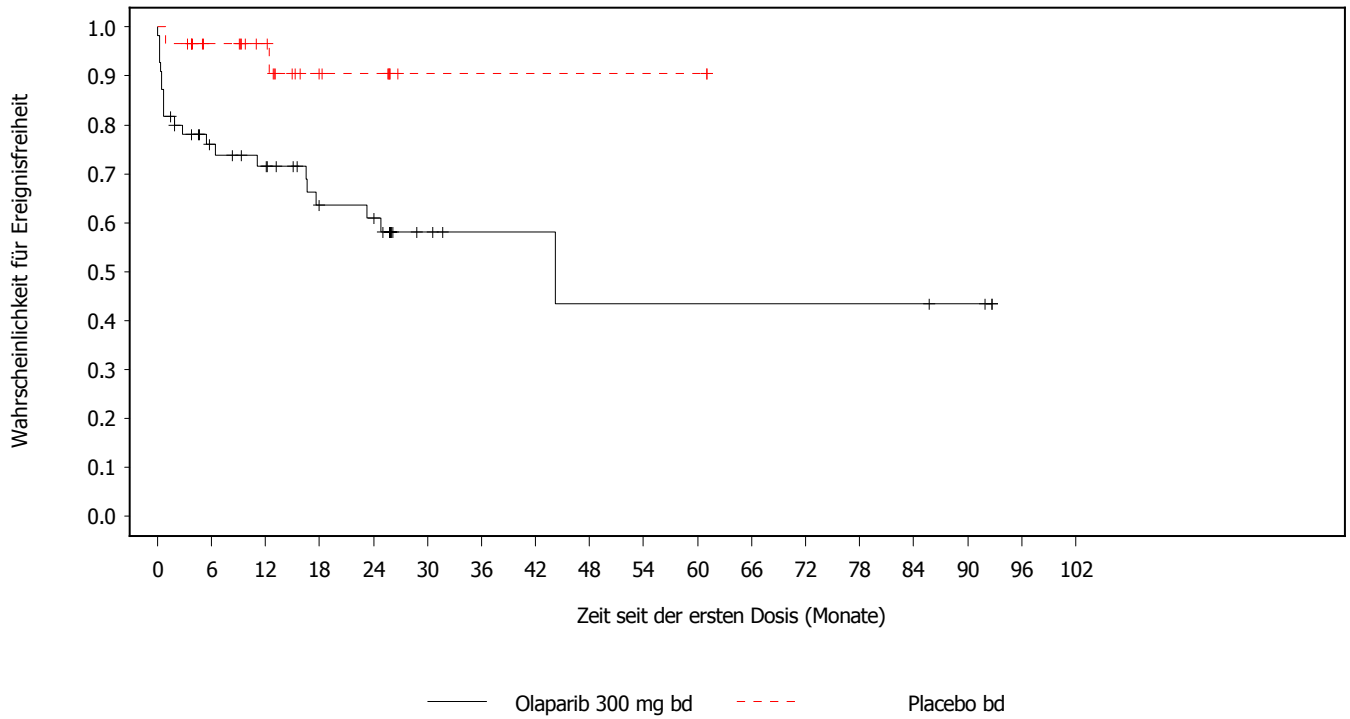
Anzahl an Patienten unter Risiko:

46	6	4	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	Olaparib 300 mg bd
25	15	9	6	4	0	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1bad 09JAN2023:12:30 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.5.5 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Ergebnis der Debulkingoperation vor Studienbeginn = makroskopische Resterkrankung
Safety Analysis Set, DCO 07MAR2022



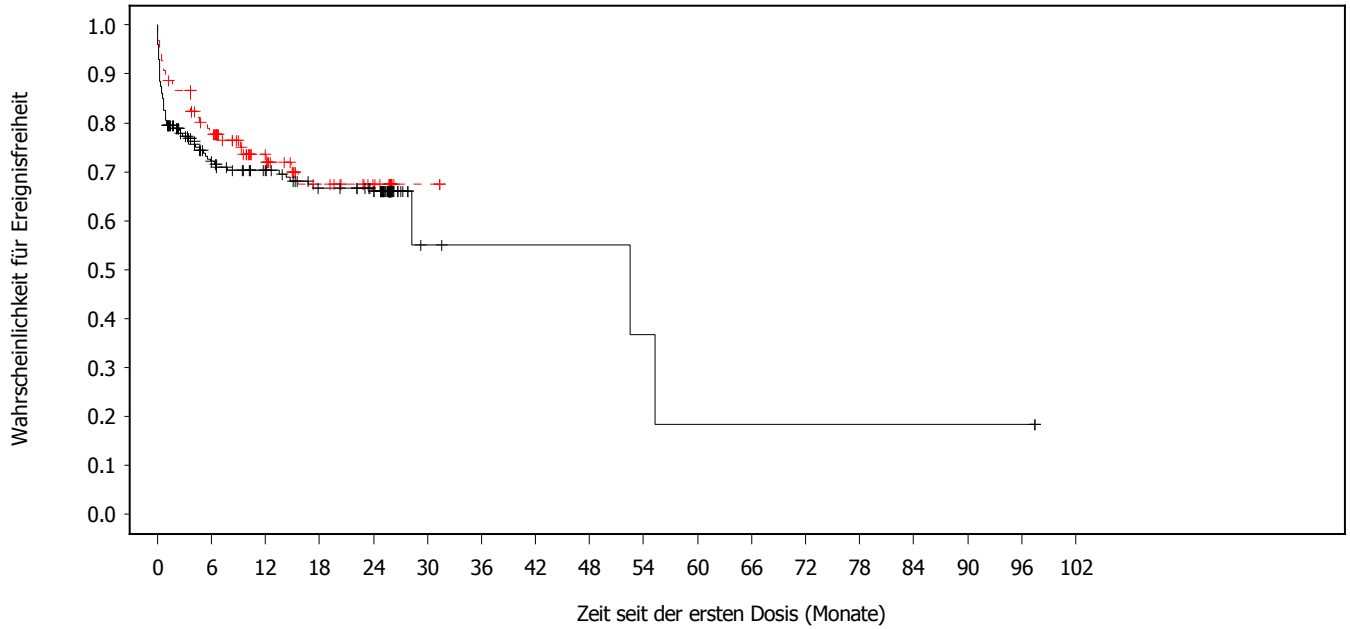
Anzahl an Patienten unter Risiko:

55	36	32	24	22	6	4	4	3	3	3	3	3	3	3	2	0	0	Olaparib 300 mg bd
29	22	17	8	7	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1bae 09JAN2023:12:30 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.5.6 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Ergebnis der Debulkingoperation vor Studienbeginn = Keine makroskopische Resterkrankung
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

200	121	106	92	85	4	3	3	3	2	1	1	1	1	1	1	1	0	Olaparib 300 mg bd
97	68	43	27	19	1	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1baf 09JAN2023:12:30 kpzx329

1.8.2.2: Schwere unerwünschte Ereignisse (CTCAE-Grad $\geq$ 3)

Table 3.4.32 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	89 (39,6)	42,1 [41,2; NE]	111	22 (19,8)	61,0 [NE; NE]	2,12	[1,35; 3,47]	0,0008*
>=65 Jahre	35	14 (40,0)	NE [NE; NE]	19	4 (21,1)	NE [NE; NE]	1,90	[0,68; 6,70]	0,2344
Interaktion p-Wert									0,8578
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	82 (38,5)	51,7 [51,7; NE]	106	23 (21,7)	NE [NE; NE]	1,98	[1,27; 3,22]	0,0022*
Partielles Ansprechen	47	21 (44,7)	41,2 [12,9; NE]	24	3 (12,5)	61,0 [NE; NE]	2,92	[0,9999; 12,39]	0,0500
Interaktion p-Wert									0,5437
ECOG PS Status									
Normale Aktivität	200	77 (38,5)	51,7 [42,1; NE]	105	15 (14,3)	NE [NE; NE]	2,80	[1,66; 5,07]	<0,0001*
Eingeschränkte Aktivität	60	26 (43,3)	41,2 [11,1; NE]	25	11 (44,0)	19,2 [8,8; NE]	1,08	[0,55; 2,29]	0,8250
Interaktion p-Wert									0,0417*
Baseline CA-125 Wert									
<=ULN	247	97 (39,3)	51,7 [41,2; NE]	123	25 (20,3)	61,0 [NE; NE]	2,05	[1,34; 3,26]	0,0007*
>ULN	13	6 (46,2)	42,1 [5,4; NE]	7	1 (14,3)	NE [NE; NE]	2,76	[0,47; 52,09]	0,2937
Interaktion p-Wert									0,7835
FIGO Stadium									
III	220	82 (37,3)	42,1 [41,2; NE]	104	21 (20,2)	61,0 [NE; NE]	1,93	[1,22; 3,20]	0,0043*
IV	40	21 (52,5)	6,5 [3,0; NE]	26	5 (19,2)	NE [NE; NE]	3,08	[1,25; 9,26]	0,0132*
Interaktion p-Wert									0,3901
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	78 (41,5)	42,1 [16,8; NE]	90	18 (20,0)	61,0 [NE; NE]	2,29	[1,41; 3,95]	0,0006*
BRCA2	62	23 (37,1)	41,2 [18,0; NE]	39	8 (20,5)	NE [NE; NE]	1,70	[0,79; 4,07]	0,1798
Interaktion p-Wert									0,5444

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.32 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	24 (43,6)	41,2 [13,9; NE]	29	4 (13,8)	61,0 [19,2; NE]	3,22	[1,24; 10,98]	0,0137*
Keine makroskopische Resterkrankung	200	77 (38,5)	51,7 [51,7; NE]	97	22 (22,7)	NE [NE; NE]	1,82	[1,15; 2,99]	0,0098*
Interaktion p-Wert									0,3108
Abstammung									
Weiß	214	79 (36,9)	42,1 [41,2; NE]	105	21 (20,0)	NE [NE; NE]	1,87	[1,17; 3,10]	0,0074*
Andere	46	24 (52,2)	6,9 [2,8; NE]	25	5 (20,0)	61,0 [21,9; NE]	3,33	[1,38; 9,90]	0,0060*
Interaktion p-Wert									0,2753
Region									
Europa	101	46 (45,5)	NE [NE; NE]	53	11 (20,8)	NE [NE; NE]	2,43	[1,30; 4,94]	0,0042*
Asien	33	20 (60,6)	5,6 [1,9; NE]	14	5 (35,7)	61,0 [12,0; NE]	2,40	[0,97; 7,21]	0,0588
Rest der Welt	126	37 (29,4)	42,1 [41,2; NE]	63	10 (15,9)	NE [NE; NE]	1,76	[0,91; 3,74]	0,0961
Interaktion p-Wert									0,7838

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.33 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	53 (23,6)	NE [NE; NE]	111	8 (7,2)	NE [NE; NE]	3,45	[1,74; 7,87]	0,0002*
>=65 Jahre	35	11 (31,4)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	53 (24,9)	51,7 [51,7; NE]	106	8 (7,5)	NE [NE; NE]	3,64	[1,83; 8,30]	<0,0001*
Partielles Ansprechen	47	11 (23,4)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	52 (26,0)	NE [NE; NE]	105	5 (4,8)	NE [NE; NE]	5,82	[2,56; 16,72]	<0,0001*
Eingeschränkte Aktivität	60	12 (20,0)	NE [NE; NE]	25	3 (12,0)	NE [NE; NE]	1,87	[0,59; 8,20]	0,3054
Interaktion p-Wert									0,1733
Baseline CA-125 Wert									
<=ULN	247	60 (24,3)	NE [NE; NE]	123	8 (6,5)	NE [NE; NE]	4,04	[2,05; 9,15]	<0,0001*
>ULN	13	4 (30,8)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	51 (23,2)	NE [NE; NE]	104	6 (5,8)	NE [NE; NE]	4,31	[2,00; 11,22]	<0,0001*
IV	40	13 (32,5)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	4,76	[1,31; 30,48]	0,0149*
Interaktion p-Wert									0,9079
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	47 (25,0)	NE [NE; NE]	90	6 (6,7)	NE [NE; NE]	4,09	[1,89; 10,69]	0,0001*
BRCA2	62	16 (25,8)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	5,27	[1,50; 33,33]	0,0069*
Interaktion p-Wert									0,7672

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1abg 09JAN2023:12:30 kpzx329

Table 3.4.33 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	13 (23,6)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	6,78	[1,35;123,23]	0,0156*
Keine makroskopische Resterkrankung	200	49 (24,5)	NE [NE; NE]	97	7 (7,2)	NE [NE; NE]	3,75	[1,82; 9,09]	0,0001*
Interaktion p-Wert									0,5724
Abstammung									
Weiß	214	47 (22,0)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	3,46	[1,67; 8,39]	0,0004*
Andere	46	17 (37,0)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	11,18	[2,29;201,30]	0,0008*
Interaktion p-Wert									0,2330
Region									
Europa	101	29 (28,7)	NE [NE; NE]	53	4 (7,5)	NE [NE; NE]	4,27	[1,68; 14,42]	0,0013*
Asien	33	13 (39,4)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	7,00	[1,39;127,05]	0,0136*
Rest der Welt	126	22 (17,5)	NE [NE; NE]	63	3 (4,8)	NE [NE; NE]	3,67	[1,27; 15,52]	0,0136*
Interaktion p-Wert									0,8550

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1abg 09JAN2023:12:30 kpzx329

Table 3.4.34 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE nach PT: Anaemie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	48 (21,3)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	12,92	[4,00; 79,05]	<0,0001*
>=65 Jahre	35	8 (22,9)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	46 (21,6)	NE [NE; NE]	106	2 (1,9)	NE [NE; NE]	12,96	[4,01; 79,42]	<0,0001*
Partielles Ansprechen	47	10 (21,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	44 (22,0)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	25,02	[5,46;443,49]	<0,0001*
Eingeschränkte Aktivität	60	12 (20,0)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	5,89	[1,16;107,34]	0,0292*
Interaktion p-Wert									0,3358
Baseline CA-125 Wert									
<=ULN	247	53 (21,5)	NE [NE; NE]	123	2 (1,6)	NE [NE; NE]	14,62	[4,55; 89,37]	<0,0001*
>ULN	13	3 (23,1)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	45 (20,5)	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	11,53	[3,56; 70,68]	<0,0001*
IV	40	11 (27,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	42 (22,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	13 (21,0)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	4,28	[1,16; 27,55]	0,0266*
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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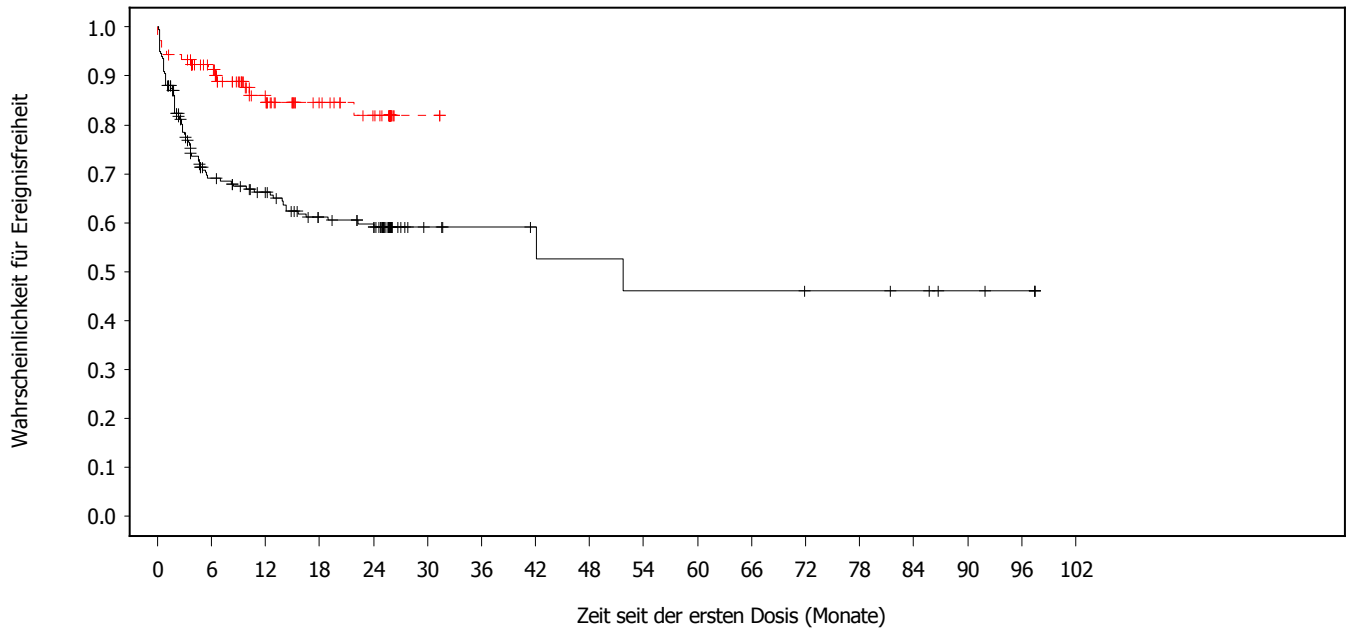
Table 3.4.34 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE nach PT: Anaemie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	11 (20,0)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	43 (21,5)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	11,58	[3,57; 71,05]	<0,0001*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	40 (18,7)	NE [NE; NE]	105	2 (1,9)	NE [NE; NE]	10,57	[3,25; 65,00]	<0,0001*
Andere	46	16 (34,8)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	24 (23,8)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	7,14	[2,12; 44,43]	0,0005*
Asien	33	12 (36,4)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	20 (15,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1abh 09JAN2023:12:30 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.5.7 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3 for ECOG PS Status = Normale Aktivität
Safety Analysis Set, DCO 07MAR2022



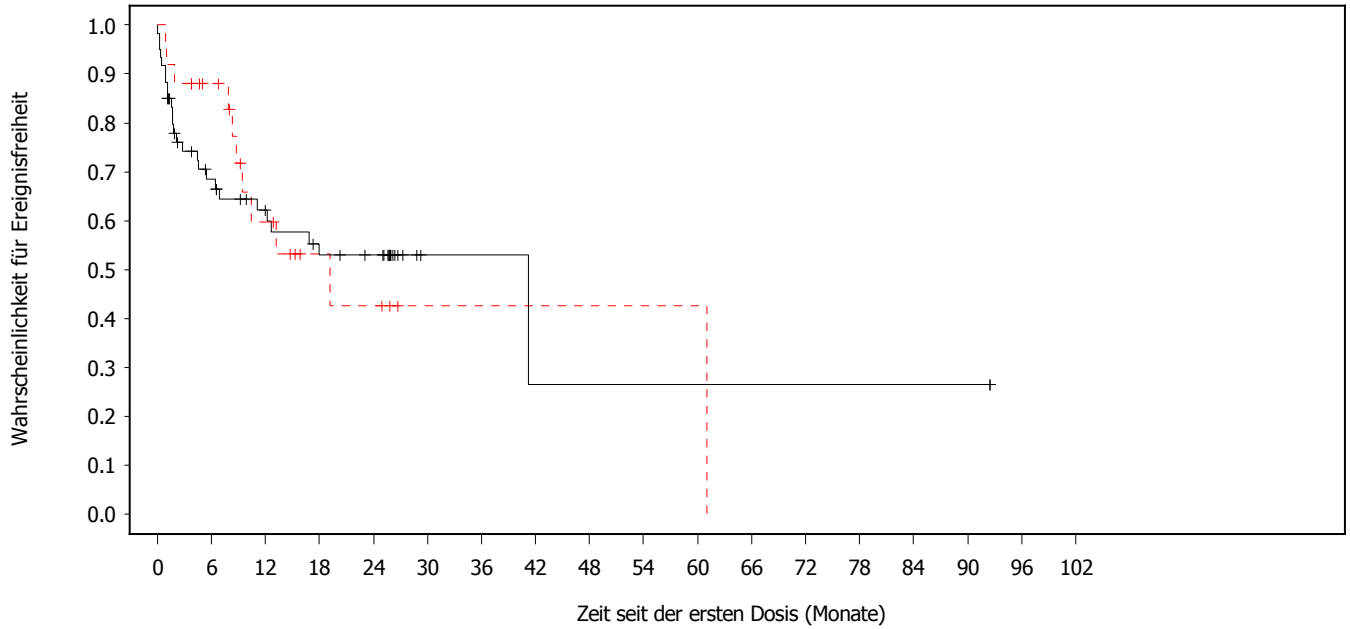
Anzahl an Patienten unter Risiko:

200	121	109	92	87	12	10	9	8	7	7	7	6	6	5	3	2	0	Olaparib 300 mg bd
105	84	56	38	30	1	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1bag 09JAN2023:12:30 kpzx329

Olaparib SOLO1, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.5.8 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3 for ECOG PS Status = Eingeschränkte Aktivität
Safety Analysis Set, DCO 07MAR2022



Anzahl an Patienten unter Risiko:

60	35	27	22	20	2	2	1	1	1	1	1	1	1	1	0	0	Olaparib 300 mg bd
25	18	10	5	4	1	1	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1bah 09JAN2023:12:30 kpzx329

1.8.2.3: Schwerwiegende unerwünschte Ereignisse

Table 3.4.28 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	47 (20,9)	NE [NE; NE]	111	17 (15,3)	61,0 [NE; NE]	1,24	[0,73; 2,23]	0,4388
>=65 Jahre	35	8 (22,9)	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	3,86	[0,70; 71,70]	0,1334
Interaktion p-Wert									0,2449
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	42 (19,7)	NE [NE; NE]	106	16 (15,1)	NE [NE; NE]	1,28	[0,73; 2,34]	0,4003
Partielles Ansprechen	47	13 (27,7)	NE [NE; NE]	24	2 (8,3)	61,0 [NE; NE]	2,21	[0,60; 14,20]	0,2565
Interaktion p-Wert									0,4819
ECOG PS Status									
Normale Aktivität	200	43 (21,5)	NE [NE; NE]	105	11 (10,5)	NE [NE; NE]	1,82	[0,97; 3,72]	0,0646
Eingeschränkte Aktivität	60	12 (20,0)	41,2 [41,2; NE]	25	7 (28,0)	61,0 [13,9; NE]	0,72	[0,29; 1,93]	0,4926
Interaktion p-Wert									0,1184
Baseline CA-125 Wert									
<=ULN	247	52 (21,1)	NE [NE; NE]	123	17 (13,8)	61,0 [NE; NE]	1,41	[0,83; 2,51]	0,2147
>ULN	13	3 (23,1)	42,1 [14,3; NE]	7	1 (14,3)	NE [NE; NE]	0,96	[0,12; 19,54]	0,9745
Interaktion p-Wert									0,7581
FIGO Stadium									
III	220	45 (20,5)	51,7 [41,2; NE]	104	13 (12,5)	61,0 [NE; NE]	1,54	[0,85; 2,97]	0,1593
IV	40	10 (25,0)	NE [NE; NE]	26	5 (19,2)	NE [NE; NE]	1,02	[0,36; 3,31]	0,9749
Interaktion p-Wert									0,5231
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	39 (20,7)	NE [NE; NE]	90	13 (14,4)	61,0 [NE; NE]	1,37	[0,75; 2,66]	0,3208
BRCA2	62	15 (24,2)	51,7 [41,2; NE]	39	5 (12,8)	NE [NE; NE]	1,57	[0,60; 4,87]	0,3666
Interaktion p-Wert									0,8140
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.28 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	15 (27,3)	42,1 [41,2; NE]	29	4 (13,8)	61,0 [19,2; NE]	1,79	[0,65; 6,29]	0,2768
Keine makroskopische Resterkrankung	200	39 (19,5)	NE [NE; NE]	97	14 (14,4)	NE [NE; NE]	1,25	[0,69; 2,38]	0,4737
Interaktion p-Wert									0,5674
Abstammung									
Weiß	214	45 (21,0)	NE [NE; NE]	105	14 (13,3)	NE [NE; NE]	1,41	[0,79; 2,68]	0,2513
Andere	46	10 (21,7)	NE [NE; NE]	25	4 (16,0)	61,0 [21,9; NE]	1,31	[0,44; 4,77]	0,6450
Interaktion p-Wert									0,9089
Region									
Europa	101	22 (21,8)	NE [NE; NE]	53	8 (15,1)	NE [NE; NE]	1,31	[0,60; 3,15]	0,5053
Asien	33	7 (21,2)	NE [NE; NE]	14	3 (21,4)	61,0 [21,9; NE]	1,10	[0,30; 5,11]	0,8912
Rest der Welt	126	26 (20,6)	51,7 [41,2; NE]	63	7 (11,1)	NE [NE; NE]	1,60	[0,73; 4,02]	0,2488
Interaktion p-Wert									0,8834

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.29 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	16 (7,1)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	7,45	[1,51;134,65]	0,0089*
>=65 Jahre	35	6 (17,1)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	19 (8,9)	NE [NE; NE]	106	1 (0,9)	NE [NE; NE]	9,35	[1,93;168,30]	0,0022*
Partielles Ansprechen	47	3 (6,4)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	19 (9,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	3 (5,0)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	21 (8,5)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	10,26	[2,14;184,22]	0,0011*
>ULN	13	1 (7,7)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	17 (7,7)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	7,61	[1,56;137,20]	0,0076*
IV	40	5 (12,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	13 (6,9)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	6,25	[1,24;113,59]	0,0221*
BRCA2	62	8 (12,9)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.29 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	5 (9,1)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	16 (8,0)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	7,31	[1,48;132,19]	0,0100*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	19 (8,9)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	9,00	[1,86;161,94]	0,0028*
Andere	46	3 (6,5)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	11 (10,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	2 (6,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	9 (7,1)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	3,69	[0,67; 68,62]	0,1488
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1abc 09JAN2023:12:30 kpzx329

Table 3.4.30 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE PT: Anaemie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	14 (6,2)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	4 (11,4)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	16 (7,5)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	2 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	15 (7,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	3 (5,0)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	18 (7,3)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	14 (6,4)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	4 (10,0)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	11 (5,9)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	7 (11,3)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae1.sas gttesubae1abd 09JAN2023:12:30 kpzx329

Table 3.4.30 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE PT: Anaemie
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	4 (7,3)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	13 (6,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	16 (7,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	2 (4,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	10 (9,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	1 (3,0)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	7 (5,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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1.8.2.4: Therapieabbrüche aufgrund von unerwünschten Ereignissen

Table 3.4.31 SOLO1: Summary of subgroup analysis of time to first occurrence of Abbruch wegen UE
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	24 (10,7)	NE [NE; NE]	111	4 (3,6)	61,0 [NE; NE]	2,58	[0,99; 8,83]	0,0537
>=65 Jahre	35	7 (20,0)	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	26 (12,2)	NE [NE; NE]	106	3 (2,8)	NE [NE; NE]	4,22	[1,48; 17,70]	0,0047*
Partielles Ansprechen	47	5 (10,6)	NE [NE; NE]	24	1 (4,2)	61,0 [NE; NE]	1,52	[0,22; 29,95]	0,6978
Interaktion p-Wert									0,4537
ECOG PS Status									
Normale Aktivität	200	22 (11,0)	NE [NE; NE]	105	3 (2,9)	NE [NE; NE]	3,46	[1,19; 14,66]	0,0199*
Eingeschränkte Aktivität	60	9 (15,0)	NE [NE; NE]	25	1 (4,0)	61,0 [NE; NE]	3,52	[0,66; 64,89]	0,1613
Interaktion p-Wert									0,9901
Baseline CA-125 Wert									
<=ULN	247	29 (11,7)	NE [NE; NE]	123	4 (3,3)	61,0 [NE; NE]	3,41	[1,34; 11,52]	0,0081*
>ULN	13	2 (15,4)	91,7 [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	25 (11,4)	NE [NE; NE]	104	3 (2,9)	61,0 [NE; NE]	3,64	[1,27; 15,33]	0,0131*
IV	40	6 (15,0)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	3,26	[0,55; 61,95]	0,2172
Interaktion p-Wert									0,9293
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	23 (12,2)	NE [NE; NE]	90	2 (2,2)	61,0 [NE; NE]	5,09	[1,50; 31,73]	0,0059*
BRCA2	62	8 (12,9)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	2,19	[0,54; 14,63]	0,2896
Interaktion p-Wert									0,4410
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.31 SOLO1: Summary of subgroup analysis of time to first occurrence of Abbruch wegen UE
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	5 (9,1)	NE [NE; NE]	29	1 (3,4)	61,0 [NE; NE]	2,11	[0,34; 40,67]	0,4627
Keine makroskopische Resterkrankung	200	26 (13,0)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	3,95	[1,39; 16,59]	0,0076*
Interaktion p-Wert									0,6322
Abstammung									
Weiß	214	27 (12,6)	NE [NE; NE]	105	2 (1,9)	NE [NE; NE]	5,99	[1,78; 37,21]	0,0017*
Andere	46	4 (8,7)	NE [NE; NE]	25	2 (8,0)	61,0 [21,9; NE]	1,01	[0,20; 7,26]	0,9945
Interaktion p-Wert									0,1247
Region									
Europa	101	11 (10,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	4 (12,1)	NE [NE; NE]	14	2 (14,3)	61,0 [21,9; NE]	0,84	[0,16; 6,08]	0,8450
Rest der Welt	126	16 (12,7)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	3,46	[0,97; 22,04]	0,0562
Interaktion p-Wert									0,2240

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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1.8.2.5: Unerwünschte Ereignisse von speziellem Interesse

Table 3.6.1 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: MDS/AML
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	4 (1,8)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	0	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	3 (1,4)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	1 (2,1)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	2 (1,0)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	4 (1,6)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	4 (1,8)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
IV	40	0	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	3 (1,6)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.1 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: MDS/AML
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	3 (1,5)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Andere	46	0	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	1 (1,0)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae2.sas gttesubae2aaa 09JAN2023:12:35 kpzx329

Table 3.6.2 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	14 (6,2)	NE [NE; NE]	111	7 (6,3)	NE [NE; NE]	0,85	[0,35; 2,24]	0,7220
>=65 Jahre	35	0	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	11 (5,2)	NE [NE; NE]	106	7 (6,6)	NE [NE; NE]	0,72	[0,28; 1,95]	0,4985
Partielles Ansprechen	47	3 (6,4)	98,5 [NE; NE]	24	1 (4,2)	NE [NE; NE]	1,02	[0,13; 20,68]	0,9894
Interaktion p-Wert									0,7776
ECOG PS Status									
Normale Aktivität	200	12 (6,0)	NE [NE; NE]	105	5 (4,8)	NE [NE; NE]	1,07	[0,39; 3,38]	0,8996
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	3 (12,0)	NE [NE; NE]	0,27	[0,04; 1,69]	0,1572
Interaktion p-Wert									0,1989
Baseline CA-125 Wert									
<=ULN	247	13 (5,3)	NE [NE; NE]	123	7 (5,7)	NE [NE; NE]	0,81	[0,33; 2,15]	0,6498
>ULN	13	1 (7,7)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,42	[0,02; 10,75]	0,5502
Interaktion p-Wert									0,6682
FIGO Stadium									
III	220	13 (5,9)	NE [NE; NE]	104	6 (5,8)	NE [NE; NE]	0,92	[0,36; 2,62]	0,8657
IV	40	1 (2,5)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	0,25	[0,01; 2,62]	0,2399
Interaktion p-Wert									0,3080
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	13 (6,9)	NE [NE; NE]	90	6 (6,7)	NE [NE; NE]	0,93	[0,37; 2,66]	0,8870
BRCA2	62	1 (1,6)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	0,25	[0,01; 2,66]	0,2450
Interaktion p-Wert									0,3089
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.2 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	3 (5,5)	98,5 [NE; NE]	29	2 (6,9)	NE [NE; NE]	0,64	[0,11; 4,91]	0,6355
Keine makroskopische Resterkrankung	200	11 (5,5)	NE [NE; NE]	97	6 (6,2)	NE [NE; NE]	0,81	[0,31; 2,34]	0,6756
Interaktion p-Wert									0,8287
Abstammung									
Weiß	214	12 (5,6)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	0,74	[0,30; 2,01]	0,5406
Andere	46	2 (4,3)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	0,90	[0,09; 19,42]	0,9337
Interaktion p-Wert									0,8818
Region									
Europa	101	8 (7,9)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	1,71	[0,42; 11,44]	0,4792
Asien	33	2 (6,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	0,60	[0,06; 12,90]	0,6850
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	0,39	[0,10; 1,47]	0,1594
Interaktion p-Wert									0,3291

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae2.sas gttesubae2aab 09JAN2023:12:35 kpzx329

Table 3.6.3 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: Pneumonitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	5 (2,2)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	0	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	3 (1,4)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	2 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	4 (2,0)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	1 (1,7)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	5 (2,0)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	4 (1,8)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	1 (2,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	2 (1,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	3 (4,8)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae2.sas gttesubae2aac 09JAN2023:12:35 kpzx329

Table 3.6.3 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: Pneumonitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	4 (2,0)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	1 (2,2)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	2 (2,0)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	1 (3,0)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	2 (1,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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1.8.2.6: Schwere unerwünschte Ereignisse von speziellem Interesse (CTCAE-Grad $\geq$ 3)

Table 3.6.7 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: MDS/AML
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	4 (1,8)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	0	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	3 (1,4)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	1 (2,1)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	2 (1,0)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	4 (1,6)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	4 (1,8)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
IV	40	0	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	3 (1,6)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.7 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: MDS/AML
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	3 (1,5)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Andere	46	0	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	1 (1,0)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae2.sas gttesubae2aag 09JAN2023:12:35 kpzx329

Table 3.6.8 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	13 (5,8)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	1,10	[0,41; 3,43]	0,8626
>=65 Jahre	35	0	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	10 (4,7)	NE [NE; NE]	106	6 (5,7)	NE [NE; NE]	0,78	[0,29; 2,29]	0,6288
Partielles Ansprechen	47	3 (6,4)	98,5 [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	11 (5,5)	NE [NE; NE]	105	4 (3,8)	NE [NE; NE]	1,20	[0,41; 4,37]	0,7520
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	2 (8,0)	NE [NE; NE]	0,43	[0,05; 3,62]	0,4051
Interaktion p-Wert									0,3811
Baseline CA-125 Wert									
<=ULN	247	12 (4,9)	NE [NE; NE]	123	6 (4,9)	NE [NE; NE]	0,88	[0,34; 2,53]	0,7955
>ULN	13	1 (7,7)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	12 (5,5)	NE [NE; NE]	104	5 (4,8)	NE [NE; NE]	1,01	[0,37; 3,19]	0,9844
IV	40	1 (2,5)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	0,50	[0,02; 12,62]	0,6262
Interaktion p-Wert									0,6421
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	12 (6,4)	NE [NE; NE]	90	5 (5,6)	NE [NE; NE]	1,02	[0,38; 3,23]	0,9663
BRCA2	62	1 (1,6)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	0,51	[0,02; 12,78]	0,6328
Interaktion p-Wert									0,6429

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.8 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	3 (5,5)	98,5 [NE; NE]	29	1 (3,4)	NE [NE; NE]	1,29	[0,16; 26,18]	0,8228
Keine makroskopische Resterkrankung	200	10 (5,0)	NE [NE; NE]	97	5 (5,2)	NE [NE; NE]	0,87	[0,31; 2,81]	0,8060
Interaktion p-Wert									0,7559
Abstammung									
Weiß	214	11 (5,1)	NE [NE; NE]	105	5 (4,8)	NE [NE; NE]	0,95	[0,34; 3,02]	0,9195
Andere	46	2 (4,3)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	0,89	[0,09; 19,18]	0,9255
Interaktion p-Wert									0,9641
Region									
Europa	101	8 (7,9)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	1,66	[0,41; 11,15]	0,5054
Asien	33	2 (6,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	0,58	[0,05; 12,46]	0,6657
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	3 (4,8)	NE [NE; NE]	0,49	[0,09; 2,67]	0,3911
Interaktion p-Wert									0,5187

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.9 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	1 (0,4)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	0	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	1 (0,5)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	1 (0,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	0	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	1 (0,4)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	1 (0,5)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	0	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	1 (0,5)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	0	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.9 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	1 (0,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	0	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	0	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	1 (0,8)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae2.sas gttesubae2aai 09JAN2023:12:35 kpzx329

1.8.2.7: Schwerwiegende unerwünschte Ereignisse von speziellem Interesse

Table 3.6.4 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: MDS/AML
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	4 (1,8)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	0	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	3 (1,4)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	1 (2,1)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	2 (1,0)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	4 (1,6)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	4 (1,8)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
IV	40	0	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	3 (1,6)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae2.sas gttesubae2aad 09JAN2023:12:35 kpzx329

Table 3.6.4 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: MDS/AML
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	3 (1,5)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Andere	46	0	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	1 (1,0)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_s2/tlf/prod/program/ttesubae2.sas gttesubae2aad 09JAN2023:12:35 kpzx329

Table 3.6.5 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	14 (6,2)	NE [NE; NE]	111	7 (6,3)	NE [NE; NE]	0,85	[0,35; 2,24]	0,7238
>=65 Jahre	35	0	NE [NE; NE]	19	1 (5,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	11 (5,2)	NE [NE; NE]	106	7 (6,6)	NE [NE; NE]	0,72	[0,28; 1,95]	0,5002
Partielles Ansprechen	47	3 (6,4)	98,5 [NE; NE]	24	1 (4,2)	NE [NE; NE]	1,02	[0,13; 20,68]	0,9893
Interaktion p-Wert									0,7784
ECOG PS Status									
Normale Aktivität	200	12 (6,0)	NE [NE; NE]	105	5 (4,8)	NE [NE; NE]	1,07	[0,39; 3,39]	0,8986
Eingeschränkte Aktivität	60	2 (3,3)	NE [NE; NE]	25	3 (12,0)	NE [NE; NE]	0,27	[0,04; 1,69]	0,1581
Interaktion p-Wert									0,1996
Baseline CA-125 Wert									
<=ULN	247	13 (5,3)	NE [NE; NE]	123	7 (5,7)	NE [NE; NE]	0,81	[0,33; 2,15]	0,6515
>ULN	13	1 (7,7)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,42	[0,02; 10,75]	0,5502
Interaktion p-Wert									0,6677
FIGO Stadium									
III	220	13 (5,9)	NE [NE; NE]	104	6 (5,8)	NE [NE; NE]	0,92	[0,36; 2,63]	0,8670
IV	40	1 (2,5)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	0,25	[0,01; 2,62]	0,2407
Interaktion p-Wert									0,3086
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	13 (6,9)	NE [NE; NE]	90	6 (6,7)	NE [NE; NE]	0,93	[0,37; 2,66]	0,8874
BRCA2	62	1 (1,6)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	0,25	[0,01; 2,67]	0,2461
Interaktion p-Wert									0,3100

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.5 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	55	3 (5,5)	98,5 [NE; NE]	29	2 (6,9)	NE [NE; NE]	0,64	[0,11; 4,91]	0,6355
Keine makroskopische Resterkrankung	200	11 (5,5)	NE [NE; NE]	97	6 (6,2)	NE [NE; NE]	0,81	[0,31; 2,35]	0,6775
Interaktion p-Wert									0,8277
Abstammung									
Weiß	214	12 (5,6)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	0,74	[0,30; 2,01]	0,5424
Andere	46	2 (4,3)	NE [NE; NE]	25	1 (4,0)	NE [NE; NE]	0,90	[0,09; 19,42]	0,9337
Interaktion p-Wert									0,8826
Region									
Europa	101	8 (7,9)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	1,71	[0,42; 11,46]	0,4781
Asien	33	2 (6,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	0,60	[0,06; 12,90]	0,6851
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	0,39	[0,10; 1,47]	0,1599
Interaktion p-Wert									0,3289

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.6 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: Pneumonitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	225	2 (0,9)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	35	0	NE [NE; NE]	19	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	213	1 (0,5)	NE [NE; NE]	106	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	47	1 (2,1)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	200	1 (0,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	60	1 (1,7)	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	247	2 (0,8)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
>ULN	13	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	220	1 (0,5)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
IV	40	1 (2,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	1 (0,5)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ergebnis der Debulkingoperation vor Studienbeginn									

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.6 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: Pneumonitis
Safety Analysis Set, DCO 07MAR2022

	Olaparib 300 mg bd (N=260)			Placebo bd (N=130)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
makroskopische Resterkrankung	55	1 (1,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	200	1 (0,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	2 (0,9)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	46	0	NE [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	0	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	33	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	2 (1,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Anhang 4-G 2: Gepoolte Kohorte

2.1: Wirksamkeit

2.1.1: Gesamtpopulation

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 1.1.1 SOLO1: Summary of observation period (months) for efficacy endpoints (PFS, PFS2, TFST, TSST, OS)
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

		Olaparib 300 mg bd (N=300)	Placebo bd (N=150)
Progressionsfreies Überleben	n	300	150
	Median	30,51	11,86
	Min	0,0	0,0
	Max	96,7	87,4
Progressionsfreies Überleben 2	n	300	150
	Median	40,30	30,41
	Min	0,0	0,0
	Max	96,7	96,7
Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod	n	300	150
	Median	35,12	14,64
	Min	0,2	0,0
	Max	97,5	96,9
Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod	n	300	150
	Median	49,84	32,07
	Min	0,2	0,0
	Max	97,5	96,9
Gesamtüberleben	n	300	150
	Median	84,48	58,99
	Min	0,3	0,7
	Max	99,4	99,5

Observation period for time-to-event efficacy endpoints is defined as the time from randomisation until the last date endpoint data are collected for the respective endpoint.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 1.1.2 SOLO1: Summary of observation period (months) for recurrence or death free survival
Patients with a clinical complete response after platinum-based chemotherapy as randomised
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

		Olaparib 300 mg bd (N=247)	Placebo bd (N=124)
Rezidivfreies Überleben	n	247	124
	Median	32,92	14,44
	Min	0,0	0,0
	Max	94,6	87,4

Observation period for time-to-event efficacy endpoints is defined as the time from randomisation until the last date endpoint data are collected for the respective endpoint.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/obsperef2.sas gobsperef2a 25JAN2023:08:54 kdqm145

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 1.2.1.1 SOLO1: Summary of Overall Survival
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Gesamtüberleben	300	92 (30,7)	NE [NE; NE]	150	70 (46,7)	75,2 [64,5; NE]	0,56	[0,41; 0,77]	0,0004*

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.2.1.2 SOLO1: Summary of Progression-free Survival
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Progressionsfreies Überleben	300	143 (47,7)	55,7 [41,4;77,9]	150	114 (76,0)	13,8 [11,1;18,2]	0,36	[0,28; 0,46]	<0,0001*

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.2.1.3 SOLO1: Summary of Second Progression-free Survival
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Progressionsfreies Überleben 2	300	104 (34,7)	88,0 [77,7; NE]	150	70 (46,7)	42,1 [35,5;61,0]	0,52	[0,38; 0,71]	<0,0001*

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.2.1.4 SOLO1: Summary of Time to First Subsequent Cancer Therapy or Death
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod	300	153 (51,0)	58,9 [45,7;82,6]	150	109 (72,7)	15,1 [12,4;19,8]	0,39	[0,31; 0,51]	<0,0001*

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainef1.sas gttemainef1d 25JAN2023:10:05 kvbv306

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

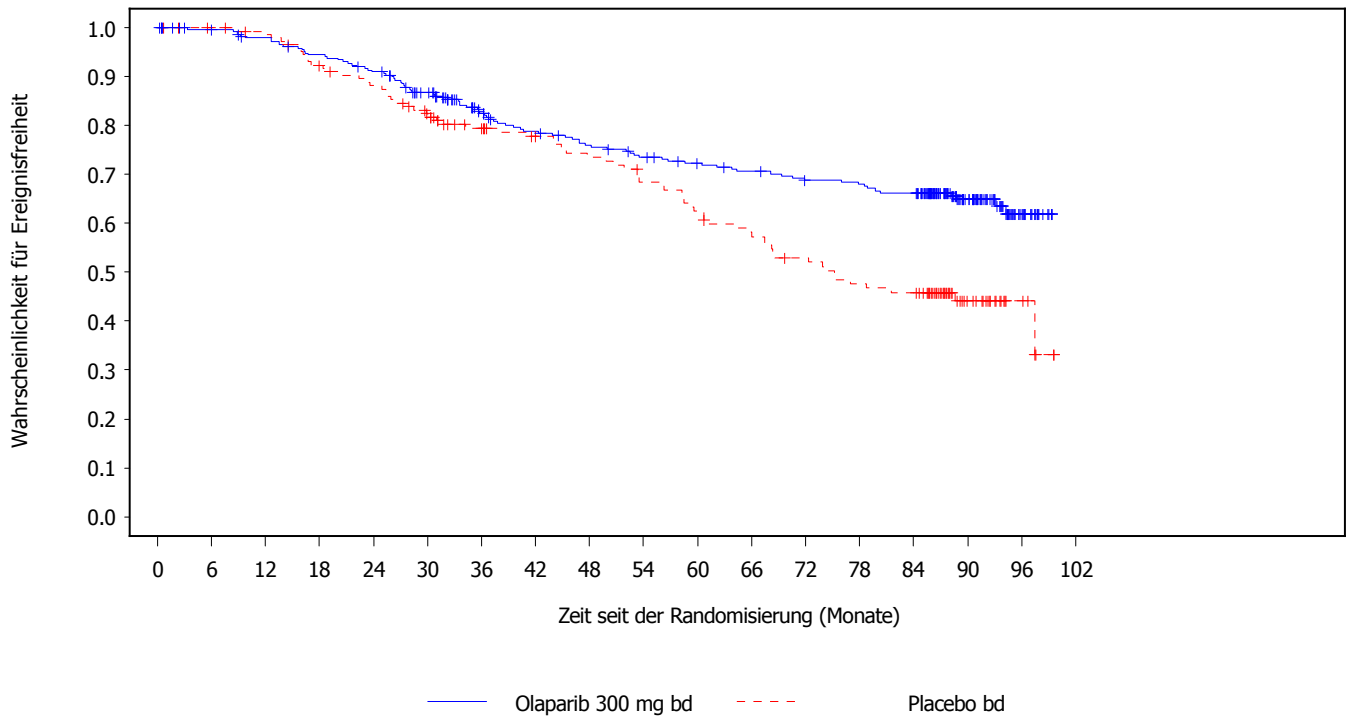
Table 1.2.1.5 SOLO1: Summary of Time to Second Subsequent Cancer Therapy or Death
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod	300	121 (40,3)	93,0 [80,1; NE]	150	90 (60,0)	39,5 [32,7;50,9]	0,50	[0,38; 0,66]	<0,0001*

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainef1.sas gttemainef1e 25JAN2023:10:05 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.2.2.1 SOLO1: Kaplan-Meier plot of Overall Survival
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	291	284	273	262	240	207	194	185	177	170	165	159	157	153	79	21	0	Olaparib 300 mg bd
150	147	143	132	125	113	99	92	87	80	73	67	60	54	52	21	6	0	Placebo bd

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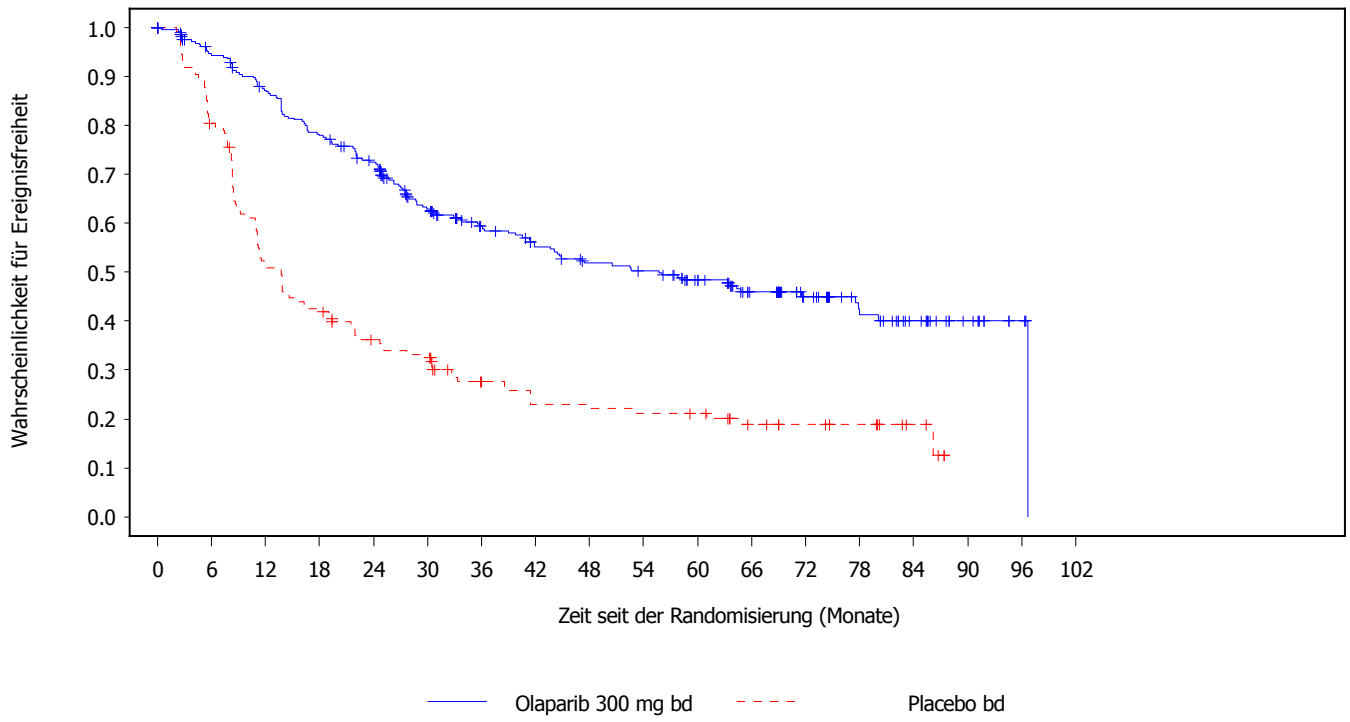
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.2.2.2 SOLO1: Kaplan-Meier plot of Progression-free Survival
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	267	244	219	198	157	129	116	106	102	89	69	48	34	23	12	4	0	Olaparib 300 mg bd
150	118	74	62	49	45	31	25	24	23	22	15	12	9	4	0	0	0	Placebo bd

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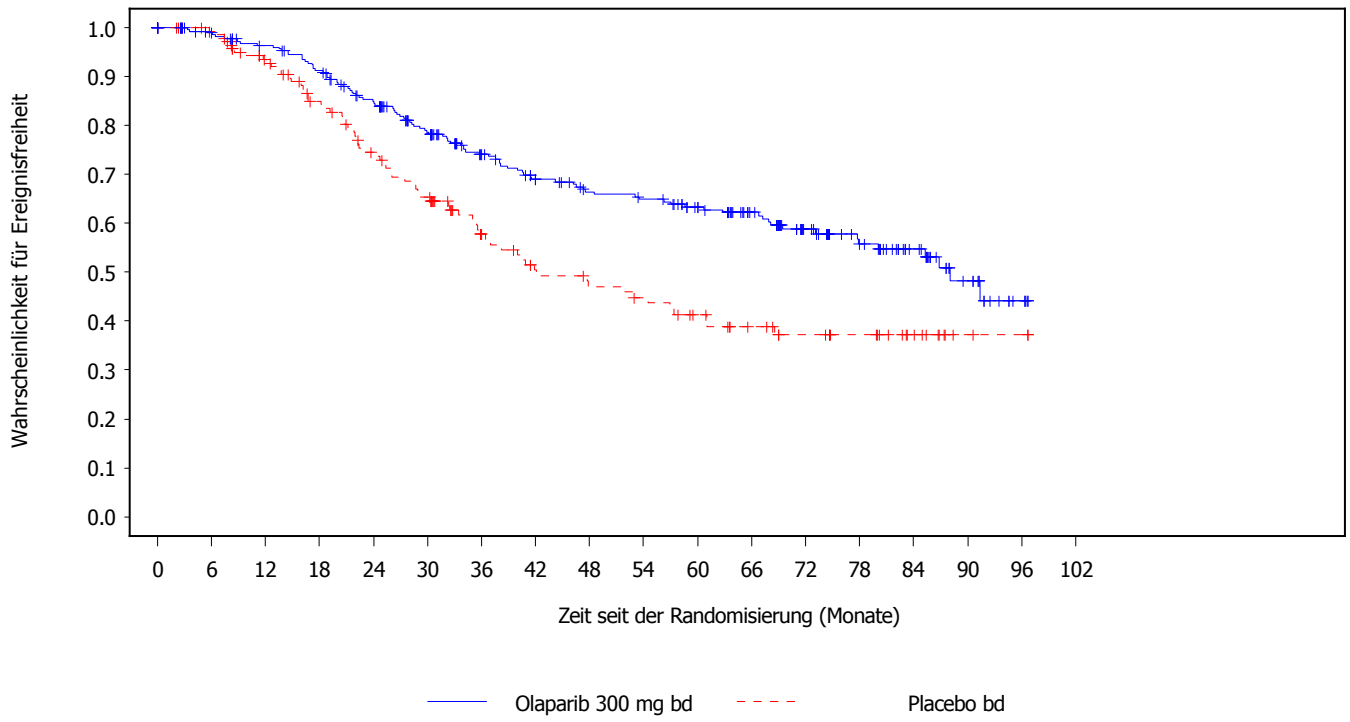
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.2.2.3 SOLO1: Kaplan-Meier plot of Second Progression-free Survival
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	278	266	250	225	192	159	142	131	127	115	95	68	53	36	17	4	0	Olaparib 300 mg bd
150	141	124	107	90	78	57	46	42	39	33	26	21	17	10	2	1	0	Placebo bd

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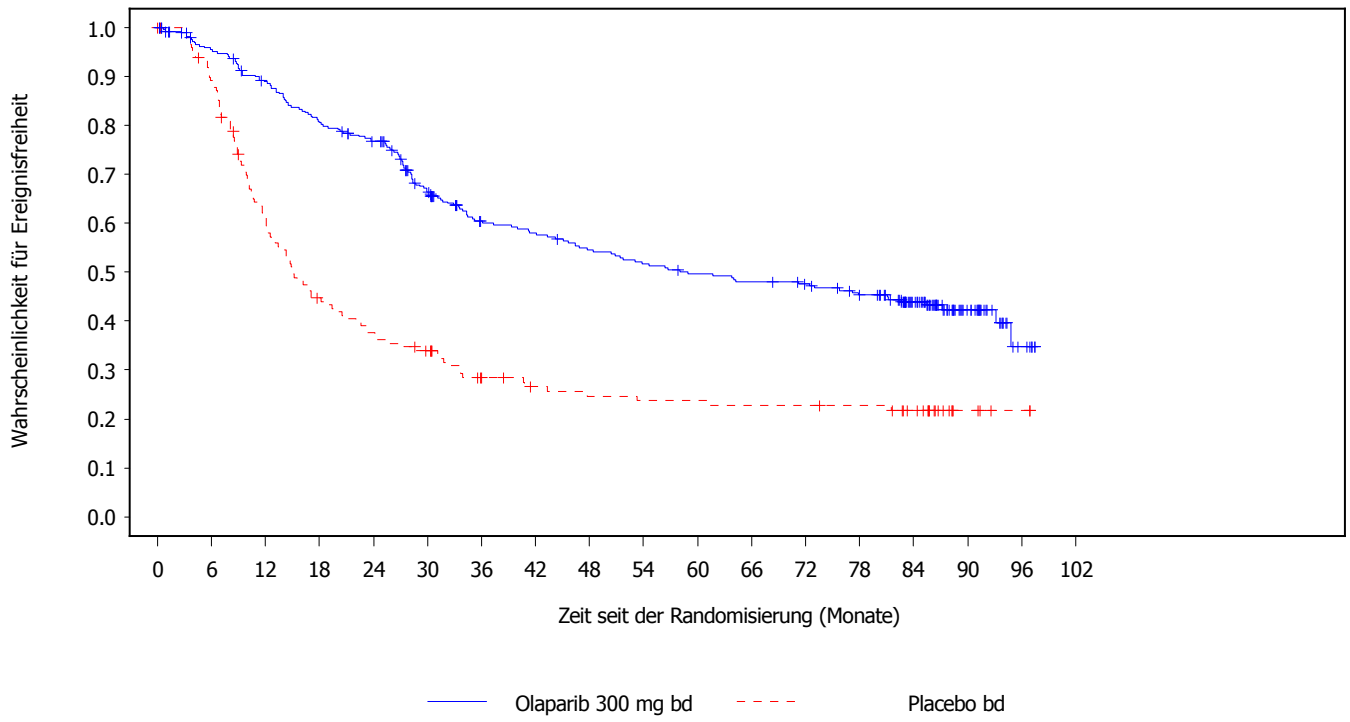
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.2.2.4 SOLO1: Kaplan-Meier plot of Time to First Subsequent Cancer Therapy or Death
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



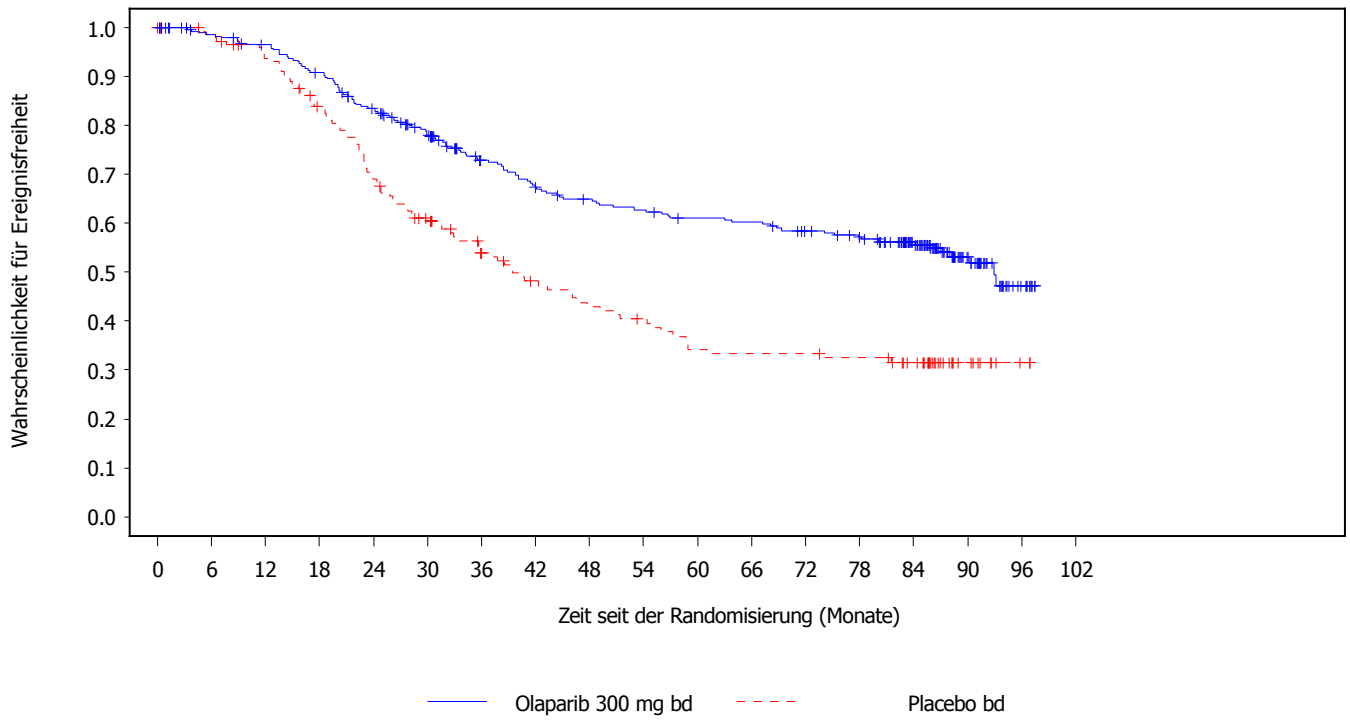
Anzahl an Patienten unter Risiko:

300	277	255	231	216	177	147	141	132	125	119	115	111	102	75	31	5	0	Olaparib 300 mg bd
150	131	88	63	53	46	33	28	26	25	25	24	24	23	18	4	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainef1.sas gttemainef1da 25JAN2023:10:05 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.2.2.5 SOLO1: Kaplan-Meier plot of Time to Second Subsequent Cancer Therapy or Death
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	286	277	260	235	209	175	162	153	148	142	140	132	125	95	41	8	0	Olaparib 300 mg bd
150	145	135	118	97	82	66	56	50	46	39	38	38	36	30	9	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainef1.sas gttemainef1ea 25JAN2023:10:05 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

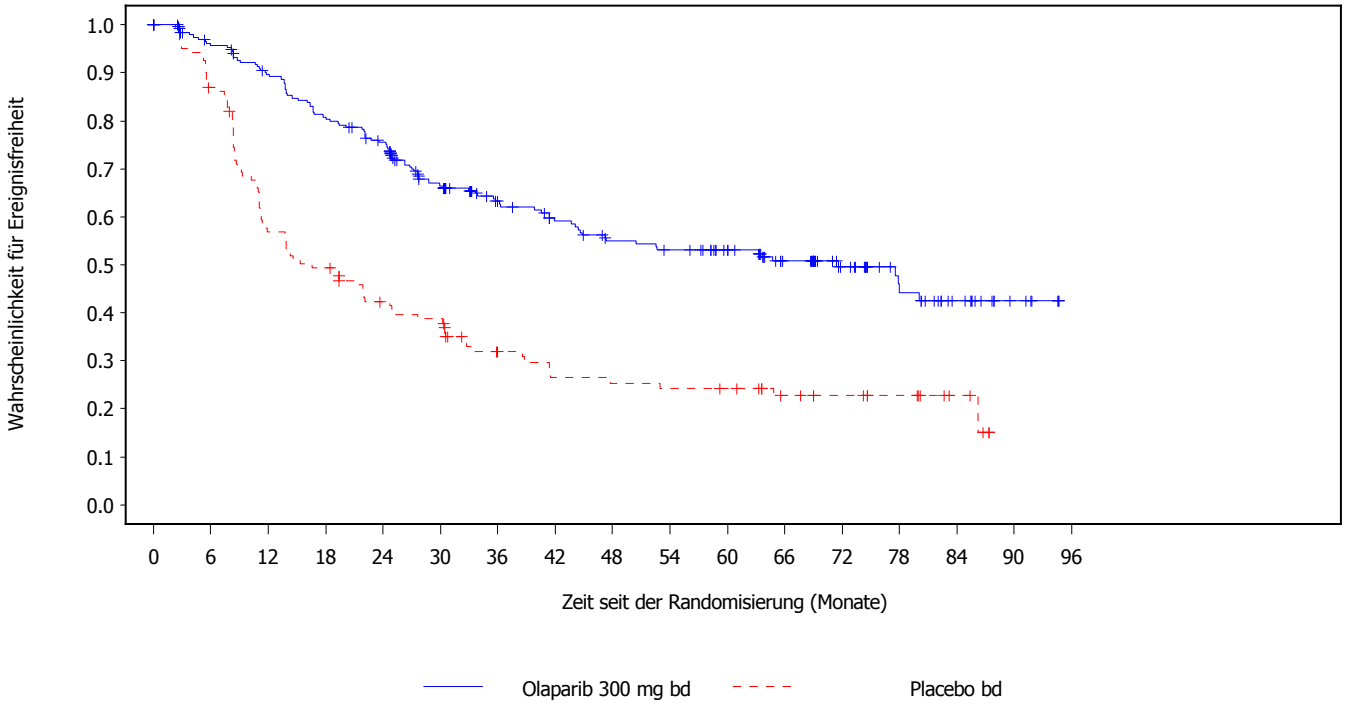
Table 1.3.1.1 SOLO1: Summary of time to recurrence or death
Patients with a clinical complete response after platinum-based chemotherapy as randomised
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=247)			Placebo bd (N=124)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Rezidivfreies Überleben	247	106 (42,9)	71,6 [44,6; NE]	124	89 (71,8)	16,6 [11,3;24,9]	0,41	[0,31; 0,54]	<0,0001*

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment as a covariate.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties.
Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainef2.sas gttemainef2a 25JAN2023:10:06 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.3.2.1 SOLO1: Kaplan-Meier plot of recurrence or death free survival
Patients with a clinical complete response after platinum-based chemotherapy as randomised
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

247	221	204	184	168	134	110	99	89	85	76	59	39	25	15	5	0	Olaparib 300 mg bd
124	105	68	59	47	43	30	24	23	22	21	15	12	9	4	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainef2.sas gttemainef2aa 25JAN2023:10:06 kvbv306

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.3.3.1 SOLO1: Summary of recurrence or death rate (odds ratio, relative risk and risk difference)
Patients with a clinical complete response after platinum-based chemotherapy as randomised
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=247)		Placebo bd (N=124)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Rezidiv oder Todesrate [a][d][h]	247	106(42,9)	124	89(71,8)	0,30[0,18; 0,47]	<0,0001 *	0,60[0,50; 0,72]	<0,0001 *	-0,29[-0,39; -0,19]	<0,0001 *

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. Model includes treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR <1, and RD <0 favours olaparib. * p<0.05.
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2.1.2: Subgruppen

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.1.1 SOLO1: Summary of subgroup analysis of Gesamtüberleben
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	72 (27,4)	NE [NE; NE]	130	57 (43,8)	78,7 [61,0; NE]	0,55	[0,39; 0,78]	0,0008*
>=65 Jahre	37	20 (54,1)	79,8 [40,6; NE]	20	13 (65,0)	70,7 [26,3; NE]	0,84	[0,42; 1,74]	0,6308
Interaktion p-Wert									0,2750
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	68 (27,5)	NE [NE; NE]	124	50 (40,3)	97,4 [68,6; NE]	0,63	[0,44; 0,91]	0,0142*
Partielles Ansprechen	53	24 (45,3)	88,8 [38,7; NE]	26	20 (76,9)	45,4 [25,4;60,7]	0,42	[0,23; 0,76]	0,0052*
Interaktion p-Wert									0,2515
ECOG PS Status									
Normale Aktivität	221	61 (27,6)	NE [NE; NE]	115	52 (45,2)	75,2 [60,7; NE]	0,54	[0,37; 0,78]	0,0013*
Eingeschränkte Aktivität	79	31 (39,2)	93,2 [56,7; NE]	34	18 (52,9)	75,2 [47,7;97,4]	0,69	[0,39; 1,26]	0,2199
Interaktion p-Wert									0,4772
Baseline CA-125 Wert									
<=ULN	286	83 (29,0)	NE [NE; NE]	142	63 (44,4)	78,7 [67,4; NE]	0,59	[0,42; 0,82]	0,0019*
>ULN	14	9 (64,3)	43,8 [16,1; NE]	7	7 (100)	26,3 [16,7;56,0]	0,49	[0,18; 1,37]	0,1682
Interaktion p-Wert									0,7303
FIGO Stadium									
III	254	71 (28,0)	NE [NE; NE]	123	58 (47,2)	74,1 [64,5; NE]	0,53	[0,37; 0,75]	0,0004*
IV	46	21 (45,7)	93,2 [56,7; NE]	27	12 (44,4)	NE [NE; NE]	0,95	[0,47; 1,98]	0,8773
Interaktion p-Wert									0,1393
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	68 (36,2)	NE [NE; NE]	91	46 (50,5)	73,9 [59,5; NE]	0,65	[0,45; 0,95]	0,0278*
BRCA2	62	13 (21,0)	NE [NE; NE]	39	18 (46,2)	81,5 [66,1; NE]	0,37	[0,18; 0,74]	0,0055*
Interaktion p-Wert									0,1574

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 1.4.1.1 SOLO1: Summary of subgroup analysis of Gesamtüberleben
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	30 (44,8)	78,9 [45,3; NE]	34	18 (52,9)	75,2 [38,0; NE]	0,79	[0,44; 1,45]	0,4356
Keine makroskopische Resterkrankung	228	60 (26,3)	NE [NE; NE]	112	49 (43,8)	78,7 [67,4; NE]	0,54	[0,37; 0,79]	0,0018*
Interaktion p-Wert									0,2832
Abstammung									
Weiß	214	69 (32,2)	NE [NE; NE]	106	53 (50,0)	77,0 [65,4; NE]	0,58	[0,40; 0,83]	0,0032*
Andere	86	23 (26,7)	NE [NE; NE]	44	17 (38,6)	68,2 [43,9; NE]	0,61	[0,33; 1,17]	0,1325
Interaktion p-Wert									0,8710
Region									
Europa	101	28 (27,7)	NE [NE; NE]	53	26 (49,1)	88,6 [58,5; NE]	0,50	[0,30; 0,87]	0,0135*
Asien	73	19 (26,0)	NE [NE; NE]	33	10 (30,3)	61,0 [34,3; NE]	0,67	[0,32; 1,50]	0,3133
Rest der Welt	126	45 (35,7)	NE [NE; NE]	64	34 (53,1)	74,1 [60,7; NE]	0,61	[0,39; 0,96]	0,0322*
Interaktion p-Wert									0,8032

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.1.2 SOLO1: Summary of subgroup analysis of Progressionsfreies Überleben
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	119 (45,2)	63,5 [43,7; NE]	130	99 (76,2)	13,8 [11,1;19,4]	0,37	[0,28; 0,48]	<0,0001*
>=65 Jahre	37	24 (64,9)	28,8 [16,0;55,7]	20	15 (75,0)	11,0 [5,4;33,4]	0,63	[0,33; 1,23]	0,1685
Interaktion p-Wert									0,1248
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	106 (42,9)	71,6 [44,6; NE]	124	89 (71,8)	16,6 [11,3;24,9]	0,41	[0,31; 0,55]	<0,0001*
Partielles Ansprechen	53	37 (69,8)	28,6 [19,3;55,7]	26	25 (96,2)	6,5 [4,5; 8,4]	0,21	[0,13; 0,36]	<0,0001*
Interaktion p-Wert									0,0316*
ECOG PS Status									
Normale Aktivität	221	106 (48,0)	55,7 [41,9;77,9]	115	87 (75,7)	11,8 [10,9;18,2]	0,39	[0,30; 0,53]	<0,0001*
Eingeschränkte Aktivität	79	37 (46,8)	56,0 [25,2; NE]	34	27 (79,4)	13,9 [8,2;32,7]	0,39	[0,24; 0,65]	0,0004*
Interaktion p-Wert									0,9781
Baseline CA-125 Wert									
<=ULN	286	130 (45,5)	63,3 [44,1;80,1]	142	107 (75,4)	13,8 [11,1;19,4]	0,39	[0,30; 0,50]	<0,0001*
>ULN	14	13 (92,9)	11,1 [8,0;39,0]	7	7 (100)	4,2 [2,2; 8,2]	0,14	[0,06; 0,40]	0,0004*
Interaktion p-Wert									0,0597
FIGO Stadium									
III	254	118 (46,5)	57,9 [43,7;80,1]	123	95 (77,2)	13,8 [11,1;19,4]	0,37	[0,28; 0,49]	<0,0001*
IV	46	25 (54,3)	33,6 [24,4; NE]	27	19 (70,4)	8,4 [5,5;41,4]	0,52	[0,29; 0,96]	0,0377*
Interaktion p-Wert									0,3111
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	99 (52,7)	43,7 [29,4;63,5]	91	74 (81,3)	13,8 [11,1;21,5]	0,42	[0,31; 0,57]	<0,0001*
BRCA2	62	23 (37,1)	77,9 [55,7; NE]	39	27 (69,2)	13,8 [8,3;21,9]	0,29	[0,16; 0,50]	<0,0001*
Interaktion p-Wert									0,2489

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.1.2 SOLO1: Summary of subgroup analysis of Progressionsfreies Überleben
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	42 (62,7)	27,9 [18,7;55,7]	34	29 (85,3)	11,3 [8,2;14,6]	0,45	[0,28; 0,74]	0,0017*
Keine makroskopische Resterkrankung	228	98 (43,0)	64,3 [44,6; NE]	112	81 (72,3)	15,3 [11,1;22,0]	0,39	[0,29; 0,52]	<0,0001*
Interaktion p-Wert									0,5744
Abstammung									
Weiß	214	104 (48,6)	55,7 [41,4; NE]	106	82 (77,4)	13,8 [11,1;19,4]	0,38	[0,28; 0,51]	<0,0001*
Andere	86	39 (45,3)	71,6 [28,6; NE]	44	32 (72,7)	11,1 [8,3;32,7]	0,43	[0,27; 0,70]	0,0007*
Interaktion p-Wert									0,6302
Region									
Europa	101	46 (45,5)	77,9 [47,2; NE]	53	40 (75,5)	13,9 [11,1;19,4]	0,35	[0,23; 0,54]	<0,0001*
Asien	73	33 (45,2)	71,6 [27,7; NE]	33	23 (69,7)	11,1 [8,3;41,5]	0,46	[0,27; 0,80]	0,0061*
Rest der Welt	126	64 (50,8)	41,4 [28,6;77,5]	64	51 (79,7)	11,3 [8,8;21,5]	0,40	[0,28; 0,58]	<0,0001*
Interaktion p-Wert									0,7276

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.1.3 SOLO1: Summary of subgroup analysis of Progressionsfreies Überleben 2
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	81 (30,8)	NE [NE; NE]	130	58 (44,6)	47,9 [36,5;61,0]	0,53	[0,38; 0,74]	0,0003*
>=65 Jahre	37	23 (62,2)	60,7 [31,7;85,3]	20	12 (60,0)	32,3 [11,7; NE]	0,86	[0,43; 1,78]	0,6666
Interaktion p-Wert									0,2132
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	76 (30,8)	88,0 [80,1; NE]	124	52 (41,9)	54,5 [40,0; NE]	0,61	[0,43; 0,88]	0,0080*
Partielles Ansprechen	53	28 (52,8)	40,6 [31,7; NE]	26	18 (69,2)	20,6 [13,3;35,4]	0,31	[0,17; 0,57]	0,0003*
Interaktion p-Wert									0,0565
ECOG PS Status									
Normale Aktivität	221	80 (36,2)	86,8 [69,5; NE]	115	55 (47,8)	41,9 [35,0;68,6]	0,59	[0,42; 0,83]	0,0028*
Eingeschränkte Aktivität	79	24 (30,4)	NE [NE; NE]	34	15 (44,1)	47,7 [22,3; NE]	0,52	[0,28; 1,02]	0,0574
Interaktion p-Wert									0,7657
Baseline CA-125 Wert									
<=ULN	286	95 (33,2)	88,0 [77,9; NE]	142	65 (45,8)	47,9 [36,5;61,0]	0,57	[0,42; 0,79]	0,0008*
>ULN	14	9 (64,3)	21,4 [13,8; NE]	7	5 (71,4)	8,2 [5,8; NE]	0,14	[0,05; 0,46]	0,0023*
Interaktion p-Wert									0,0257*
FIGO Stadium									
III	254	83 (32,7)	88,0 [77,9; NE]	123	56 (45,5)	47,7 [35,7;61,0]	0,54	[0,39; 0,77]	0,0006*
IV	46	21 (45,7)	66,8 [34,0; NE]	27	14 (51,9)	28,7 [21,2; NE]	0,75	[0,38; 1,50]	0,4031
Interaktion p-Wert									0,4068
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	71 (37,8)	88,0 [66,8; NE]	91	43 (47,3)	47,9 [35,0; NE]	0,65	[0,44; 0,95]	0,0275*
BRCA2	62	19 (30,6)	91,3 [77,7; NE]	39	18 (46,2)	40,3 [29,0; NE]	0,43	[0,22; 0,82]	0,0111*
Interaktion p-Wert									0,2745

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 1.4.1.3 SOLO1: Summary of subgroup analysis of Progressionsfreies Überleben 2
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	34 (50,7)	60,7 [32,2;91,3]	34	16 (47,1)	33,5 [16,8; NE]	0,68	[0,38; 1,27]	0,2169
Keine makroskopische Resterkrankung	228	67 (29,4)	NE [NE; NE]	112	51 (45,5)	51,7 [37,0; NE]	0,53	[0,37; 0,77]	0,0009*
Interaktion p-Wert									0,4862
Abstammung									
Weiß	214	75 (35,0)	88,0 [77,9; NE]	106	51 (48,1)	47,7 [35,4;61,0]	0,55	[0,39; 0,79]	0,0014*
Andere	86	29 (33,7)	73,1 [36,8; NE]	44	19 (43,2)	38,2 [24,7; NE]	0,63	[0,36; 1,15]	0,1302
Interaktion p-Wert									0,6850
Region									
Europa	101	35 (34,7)	88,0 [77,9; NE]	53	25 (47,2)	52,9 [35,4; NE]	0,57	[0,34; 0,96]	0,0362*
Asien	73	22 (30,1)	80,1 [36,8; NE]	33	15 (45,5)	38,2 [26,0; NE]	0,54	[0,28; 1,07]	0,0750
Rest der Welt	126	47 (37,3)	85,3 [47,6; NE]	64	30 (46,9)	40,0 [29,0;68,6]	0,57	[0,36; 0,92]	0,0205*
Interaktion p-Wert									0,9900

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.1.4 SOLO1: Summary of subgroup analysis of Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	125 (47,5)	71,2 [47,7; NE]	130	94 (72,3)	15,1 [12,6;21,2]	0,39	[0,30; 0,52]	<0,0001*
>=65 Jahre	37	28 (75,7)	43,3 [28,3;61,7]	20	15 (75,0)	13,2 [5,6;33,7]	0,67	[0,36; 1,29]	0,2271
Interaktion p-Wert									0,1159
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	118 (47,8)	75,8 [51,4; NE]	124	86 (69,4)	18,7 [14,5;24,2]	0,45	[0,34; 0,59]	<0,0001*
Partielles Ansprechen	53	35 (66,0)	32,9 [27,4;58,9]	26	23 (88,5)	8,7 [6,7;11,6]	0,23	[0,13; 0,39]	<0,0001*
Interaktion p-Wert									0,0289*
ECOG PS Status									
Normale Aktivität	221	109 (49,3)	64,0 [46,9; NE]	115	84 (73,0)	15,1 [12,3;19,8]	0,41	[0,30; 0,54]	<0,0001*
Eingeschränkte Aktivität	79	44 (55,7)	48,4 [27,9;93,2]	34	25 (73,5)	14,5 [9,9;40,7]	0,48	[0,29; 0,79]	0,0049*
Interaktion p-Wert									0,5671
Baseline CA-125 Wert									
<=ULN	286	139 (48,6)	64,2 [48,4;93,2]	142	102 (71,8)	16,1 [13,5;22,0]	0,42	[0,32; 0,54]	<0,0001*
>ULN	14	14 (100)	15,3 [9,0;42,2]	7	7 (100)	5,3 [3,6; 8,9]	0,16	[0,06; 0,43]	0,0007*
Interaktion p-Wert									0,0613
FIGO Stadium									
III	254	124 (48,8)	64,0 [46,9; NE]	123	90 (73,2)	15,1 [12,7;22,6]	0,40	[0,31; 0,53]	<0,0001*
IV	46	29 (63,0)	43,3 [26,9;93,2]	27	19 (70,4)	9,9 [6,8;22,0]	0,56	[0,31; 1,01]	0,0543
Interaktion p-Wert									0,3131
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	106 (56,4)	47,7 [33,5;72,5]	91	71 (78,0)	15,1 [12,1;22,6]	0,45	[0,33; 0,61]	<0,0001*
BRCA2	62	24 (38,7)	NE [NE; NE]	39	26 (66,7)	15,5 [10,2;27,4]	0,29	[0,17; 0,51]	<0,0001*
Interaktion p-Wert									0,1907

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 1.4.1.4 SOLO1: Summary of subgroup analysis of Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	44 (65,7)	31,7 [26,7;53,8]	34	28 (82,4)	13,3 [8,8;18,7]	0,50	[0,31; 0,82]	0,0059*
Keine makroskopische Resterkrankung	228	106 (46,5)	75,8 [53,1; NE]	112	78 (69,6)	16,8 [12,6;24,2]	0,41	[0,31; 0,55]	<0,0001*
Interaktion p-Wert									0,4807
Abstammung									
Weiß	214	111 (51,9)	61,7 [46,9;93,2]	106	80 (75,5)	15,1 [12,7;22,0]	0,40	[0,30; 0,53]	<0,0001*
Andere	86	42 (48,8)	73,0 [29,9; NE]	44	29 (65,9)	12,6 [10,0;43,4]	0,51	[0,32; 0,83]	0,0072*
Interaktion p-Wert									0,3621
Region									
Europa	101	46 (45,5)	NE [NE; NE]	53	40 (75,5)	16,8 [13,5;20,5]	0,34	[0,22; 0,53]	<0,0001*
Asien	73	34 (46,6)	73,0 [29,9; NE]	33	20 (60,6)	12,6 [10,0; NE]	0,53	[0,31; 0,93]	0,0282*
Rest der Welt	126	73 (57,9)	46,9 [34,3;77,2]	64	49 (76,6)	14,5 [10,8;23,2]	0,45	[0,31; 0,65]	<0,0001*
Interaktion p-Wert									0,4455

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.1.5 SOLO1: Summary of subgroup analysis of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	95 (36,1)	NE [NE; NE]	130	77 (59,2)	40,4 [33,2;54,4]	0,48	[0,35; 0,64]	<0,0001*
>=65 Jahre	37	26 (70,3)	56,9 [31,7;87,2]	20	13 (65,0)	32,1 [12,6; NE]	0,89	[0,47; 1,80]	0,7439
Interaktion p-Wert									0,0844
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	95 (38,5)	93,0 [85,8; NE]	124	69 (55,6)	46,5 [35,8;58,8]	0,58	[0,42; 0,79]	0,0007*
Partielles Ansprechen	53	26 (49,1)	48,3 [31,7; NE]	26	21 (80,8)	20,9 [14,8;35,7]	0,29	[0,16; 0,53]	<0,0001*
Interaktion p-Wert									0,0436*
ECOG PS Status									
Normale Aktivität	221	86 (38,9)	93,0 [84,2; NE]	115	66 (57,4)	43,4 [32,7;58,7]	0,55	[0,40; 0,76]	0,0003*
Eingeschränkte Aktivität	79	35 (44,3)	88,1 [41,4; NE]	34	24 (70,6)	32,9 [23,0;46,1]	0,43	[0,26; 0,73]	0,0023*
Interaktion p-Wert									0,4396
Baseline CA-125 Wert									
<=ULN	286	111 (38,8)	93,2 [85,8; NE]	142	83 (58,5)	40,7 [33,2;54,4]	0,53	[0,40; 0,71]	<0,0001*
>ULN	14	10 (71,4)	21,8 [14,4;63,8]	7	7 (100)	13,5 [5,3;17,4]	0,27	[0,10; 0,75]	0,0132*
Interaktion p-Wert									0,1988
FIGO Stadium									
III	254	94 (37,0)	NE [NE; NE]	123	77 (62,6)	39,5 [32,9;49,1]	0,45	[0,34; 0,61]	<0,0001*
IV	46	27 (58,7)	63,0 [30,2;93,2]	27	13 (48,1)	NE [NE; NE]	1,07	[0,56; 2,14]	0,8478
Interaktion p-Wert									0,0181*
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	85 (45,2)	90,2 [54,2; NE]	91	59 (64,8)	43,4 [30,1;54,4]	0,56	[0,40; 0,78]	0,0008*
BRCA2	62	20 (32,3)	NE [NE; NE]	39	20 (51,3)	42,3 [31,4; NE]	0,44	[0,23; 0,81]	0,0096*
Interaktion p-Wert									0,4938

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 1.4.1.5 SOLO1: Summary of subgroup analysis of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	36 (53,7)	44,4 [31,7;93,0]	34	25 (73,5)	31,6 [18,7;47,7]	0,57	[0,35; 0,97]	0,0381*
Keine makroskopische Resterkrankung	228	82 (36,0)	NE [NE; NE]	112	62 (55,4)	46,1 [37,8;58,7]	0,52	[0,37; 0,72]	0,0001*
Interaktion p-Wert									0,7416
Abstammung									
Weiß	214	89 (41,6)	93,2 [84,2; NE]	106	65 (61,3)	42,3 [32,9;55,3]	0,52	[0,38; 0,72]	<0,0001*
Andere	86	32 (37,2)	93,0 [38,4; NE]	44	25 (56,8)	35,8 [24,8;74,1]	0,56	[0,33; 0,96]	0,0339*
Interaktion p-Wert									0,7947
Region									
Europa	101	36 (35,6)	NE [NE; NE]	53	30 (56,6)	50,9 [31,6; NE]	0,50	[0,31; 0,82]	0,0063*
Asien	73	24 (32,9)	NE [NE; NE]	33	17 (51,5)	35,8 [22,9; NE]	0,51	[0,28; 0,97]	0,0414*
Rest der Welt	126	61 (48,4)	85,8 [44,4;93,2]	64	43 (67,2)	39,5 [25,8;46,5]	0,54	[0,36; 0,80]	0,0023*
Interaktion p-Wert									0,9777

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.1.6 SOLO1: Summary of subgroup analysis of Time to recurrence or death
Patients with a clinical complete response after platinum-based chemotherapy as randomised, Global Cohort DCO 07Mar2022, China Cohor

	Olaparib 300 mg bd (N=247)			Placebo bd (N=124)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	217	88 (40,6)	78,0 [47,4; NE]	110	80 (72,7)	16,6 [11,3;24,7]	0,36	[0,27; 0,49]	<0,0001*
>=65 Jahre	30	18 (60,0)	40,6 [16,8;77,5]	14	9 (64,3)	22,3 [5,4; NE]	0,86	[0,39; 2,00]	0,7063
Interaktion p-Wert									0,0449*
ECOG PS Status									
Normale Aktivität	186	81 (43,5)	71,6 [44,8; NE]	97	70 (72,2)	14,3 [11,1;22,1]	0,40	[0,29; 0,56]	<0,0001*
Eingeschränkte Aktivität	61	25 (41,0)	NE [NE; NE]	26	19 (73,1)	25,1 [8,4;38,5]	0,42	[0,23; 0,77]	0,0058*
Interaktion p-Wert									0,9162
Baseline CA-125 Wert									
<=ULN	244	104 (42,6)	77,5 [44,8; NE]	122	88 (72,1)	16,6 [11,3;24,9]	0,41	[0,31; 0,54]	<0,0001*
>ULN	3	2 (66,7)	20,2 [11,7; NE]	1	1 (100)	2,6 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	216	89 (41,2)	77,9 [47,2; NE]	103	76 (73,8)	15,3 [11,3;24,9]	0,37	[0,27; 0,50]	<0,0001*
IV	31	17 (54,8)	33,8 [24,3; NE]	21	13 (61,9)	16,6 [7,8; NE]	0,72	[0,35; 1,52]	0,3826
Interaktion p-Wert									0,0909
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	152	70 (46,1)	50,5 [33,8; NE]	74	57 (77,0)	19,4 [11,3;30,2]	0,42	[0,30; 0,60]	<0,0001*
BRCA2	53	17 (32,1)	77,9 [64,8; NE]	32	20 (62,5)	14,6 [8,5;64,9]	0,30	[0,15; 0,57]	0,0003*
Interaktion p-Wert									0,3451
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	39	20 (51,3)	52,7 [22,1; NE]	24	19 (79,2)	13,8 [11,1;25,1]	0,46	[0,24; 0,87]	0,0171*

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef2.sas gttesubef2aaa 27FEB2023:11:59 kpzx329

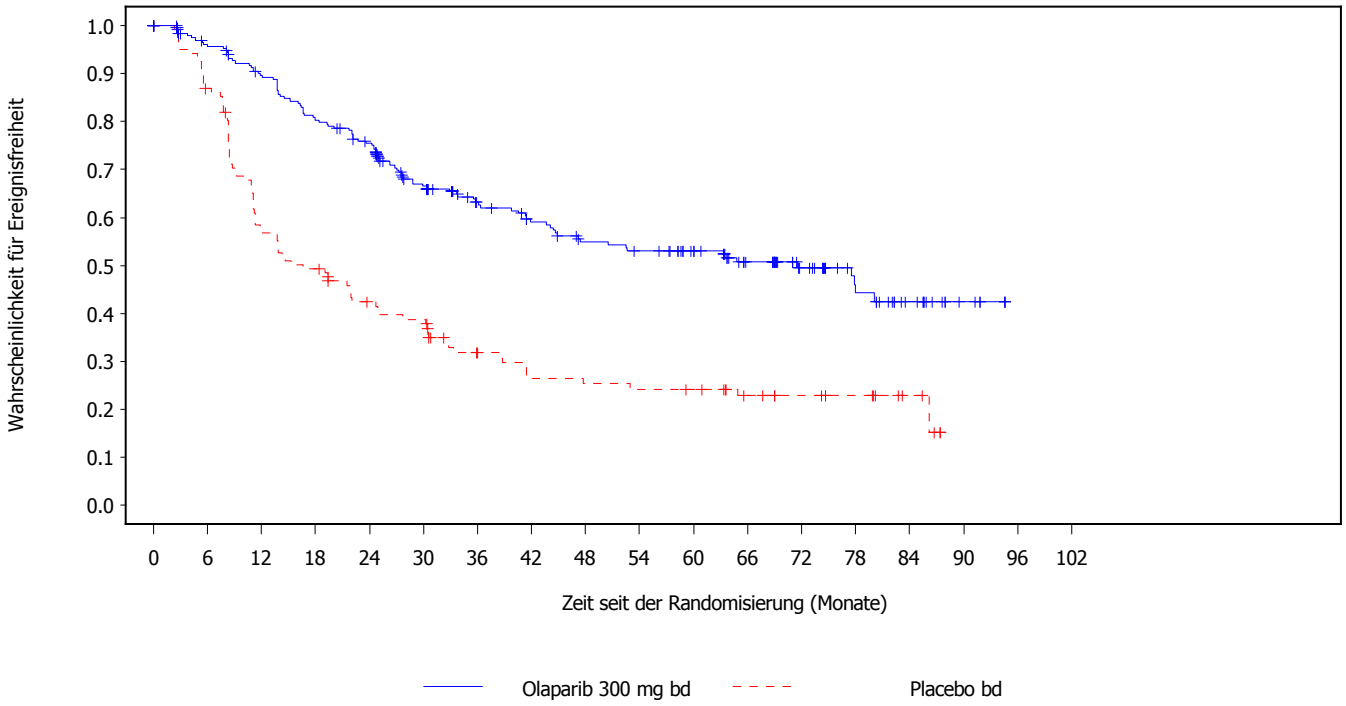
Table 1.4.1.6 SOLO1: Summary of subgroup analysis of Time to recurrence or death
Patients with a clinical complete response after platinum-based chemotherapy as randomised, Global Cohort DCO 07Mar2022, China Cohor

	Olaparib 300 mg bd (N=247)			Placebo bd (N=124)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Keine makroskopische Resterkrankung	207	86 (41,5)	71,6 [44,4; NE]	99	69 (69,7)	19,4 [11,1;30,4]	0,41	[0,30; 0,56]	<0,0001*
Interaktion p-Wert									0,7397
Abstammung									
Weiß	176	76 (43,2)	77,9 [44,4; NE]	88	64 (72,7)	19,4 [11,9;27,7]	0,40	[0,28; 0,55]	<0,0001*
Andere	71	30 (42,3)	77,5 [27,7;80,1]	36	25 (69,4)	11,3 [8,4;41,5]	0,44	[0,26; 0,76]	0,0032*
Interaktion p-Wert									0,7369
Region									
Europa	87	36 (41,4)	78,0 [47,2; NE]	43	30 (69,8)	16,6 [11,8;30,4]	0,38	[0,23; 0,62]	0,0001*
Asien	60	26 (43,3)	71,6 [27,0; NE]	27	18 (66,7)	11,1 [7,7;41,5]	0,47	[0,26; 0,86]	0,0159*
Rest der Welt	100	44 (44,0)	63,3 [33,8; NE]	54	41 (75,9)	19,0 [11,1;30,5]	0,41	[0,27; 0,63]	<0,0001*
Interaktion p-Wert									0,8695

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef2.sas gttesubef2aaa 27FEB2023:11:59 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.1 SOLO1: Kaplan-Meier plot of Progressionsfreies Überleben for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Vollständiges Ansprechen
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



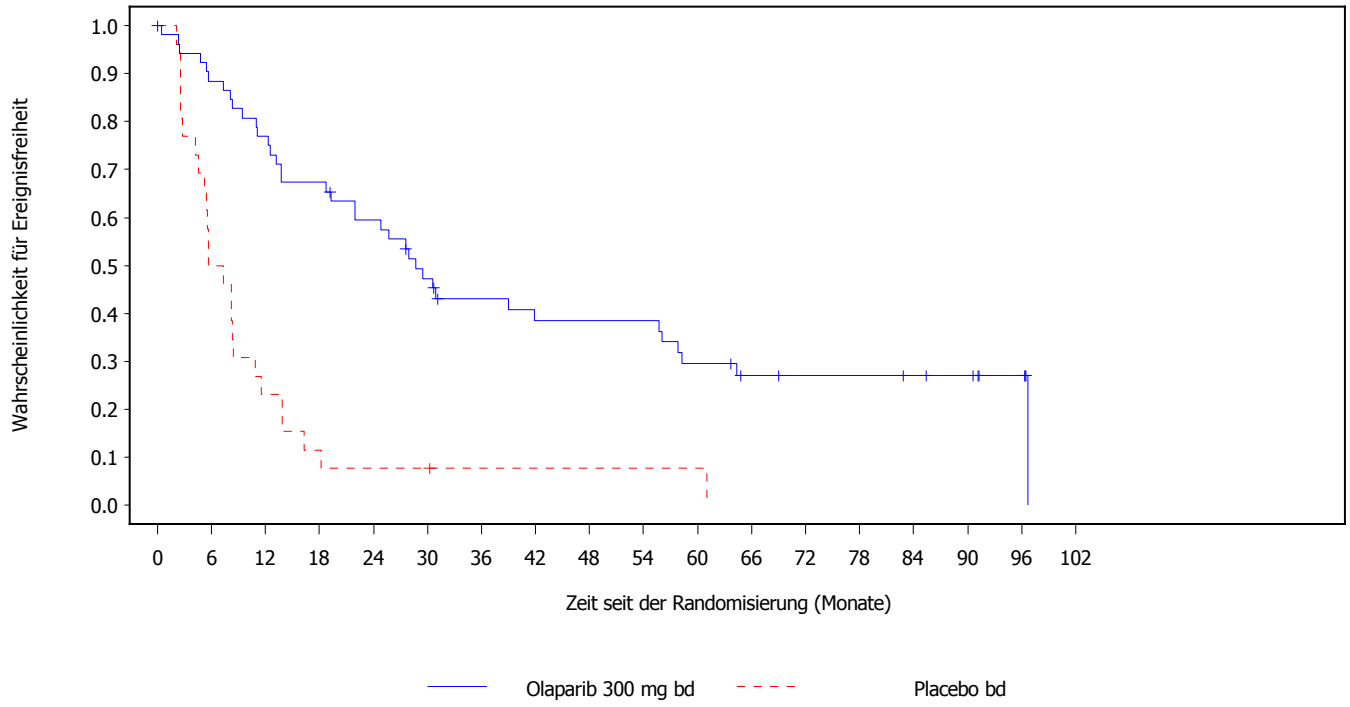
Anzahl an Patienten unter Risiko:

247	221	204	184	168	134	110	99	89	85	76	59	39	25	15	5	0	0	Olaparib 300 mg bd
124	105	68	59	47	43	30	24	23	22	21	15	12	9	4	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1baa 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.2 SOLO1: Kaplan-Meier plot of Progressionsfreies Überleben for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Partielles Ansprechen
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



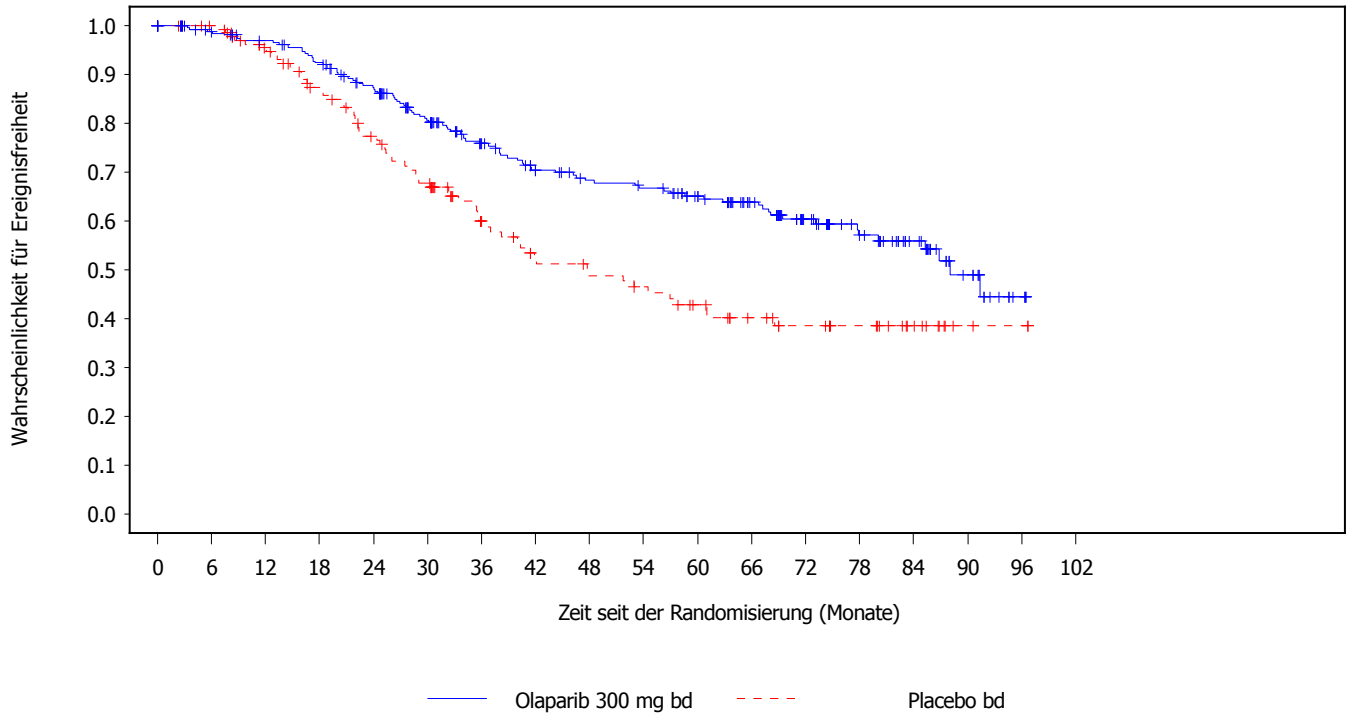
Anzahl an Patienten unter Risiko:

53	46	40	35	30	23	19	17	17	17	13	10	9	9	8	7	4	0	Olaparib 300 mg bd
26	13	6	3	2	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1bab 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.3 SOLO1: Kaplan-Meier plot of Progressionsfreies Überleben 2 for Baseline CA-125 Wert = <=ULN
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



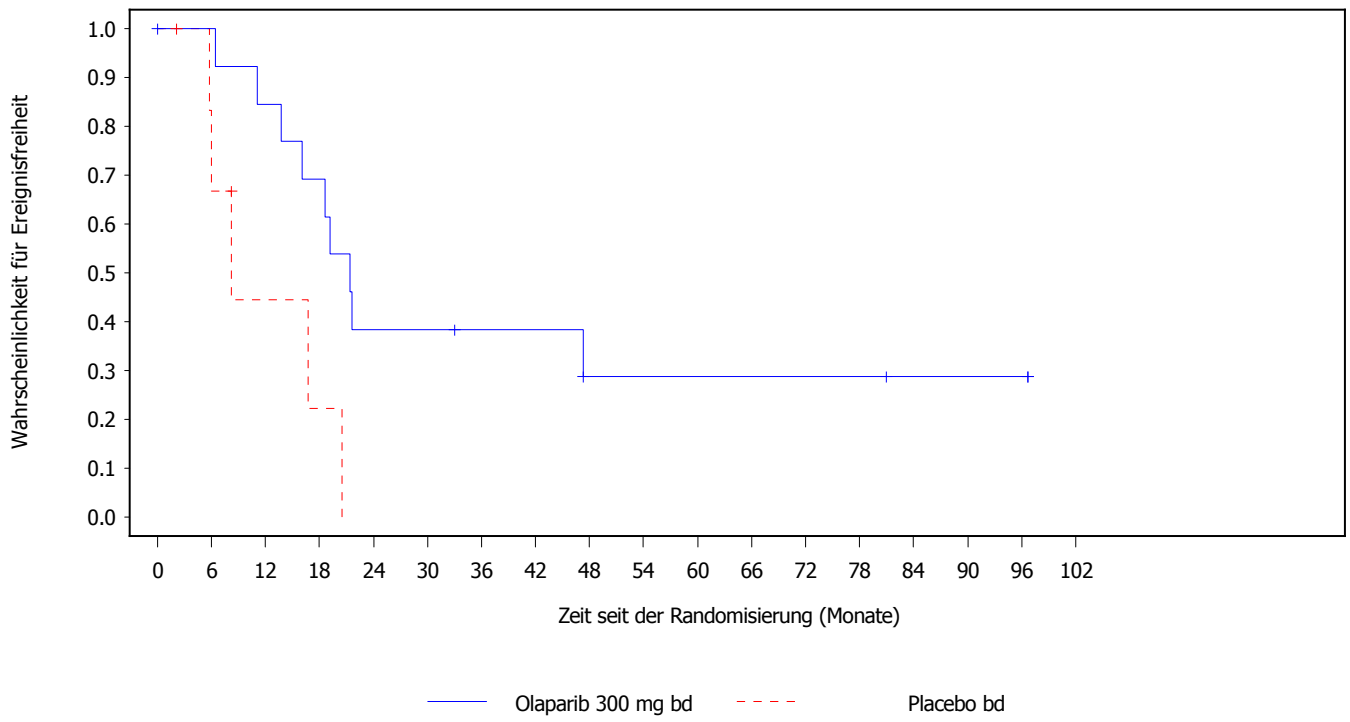
Anzahl an Patienten unter Risiko:

286	265	255	241	220	187	155	138	129	125	113	93	66	51	35	16	3	0	Olaparib 300 mg bd
142	137	122	106	90	78	57	46	42	39	33	26	21	17	10	2	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1bac 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.4 SOLO1: Kaplan-Meier plot of Progressionsfreies Überleben 2 for Baseline CA-125 Wert = >ULN
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



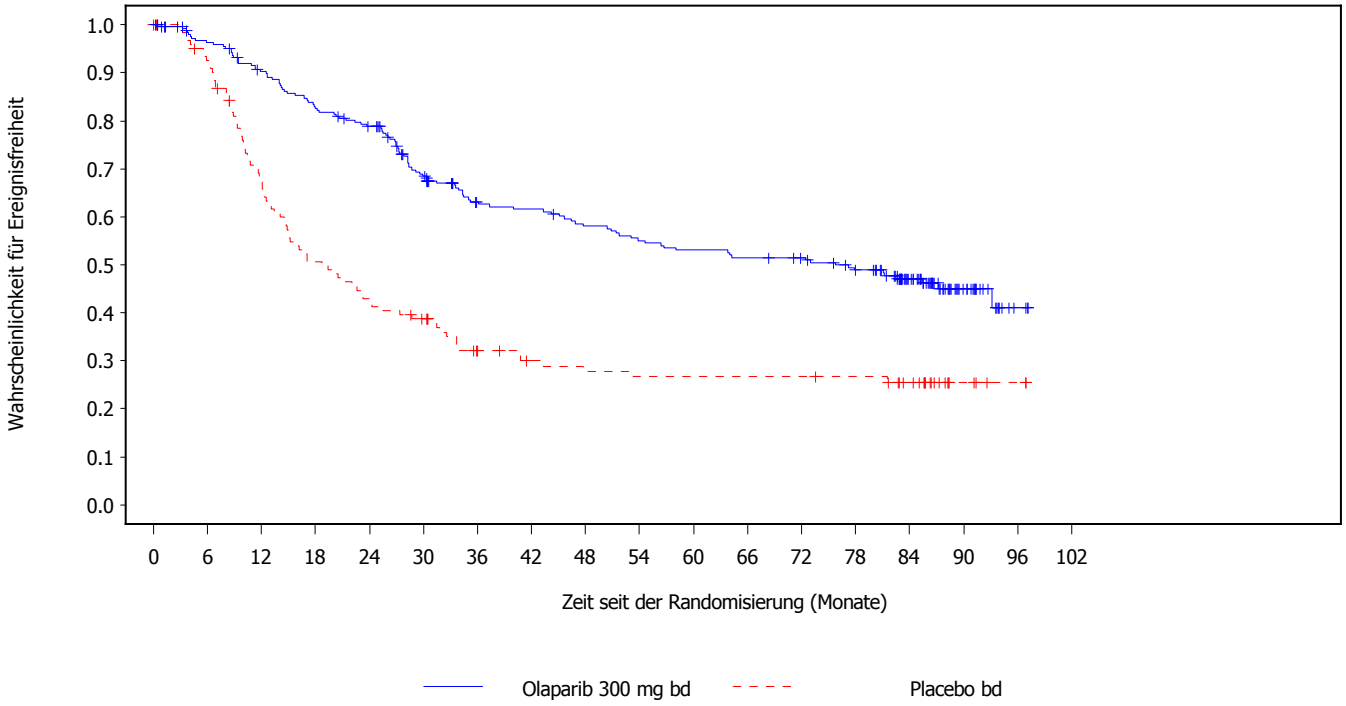
Anzahl an Patienten unter Risiko:

14	13	11	9	5	5	4	4	2	2	2	2	2	2	1	1	1	0	Olaparib 300 mg bd
7	4	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1bad 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Vollständiges Ansprechen
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



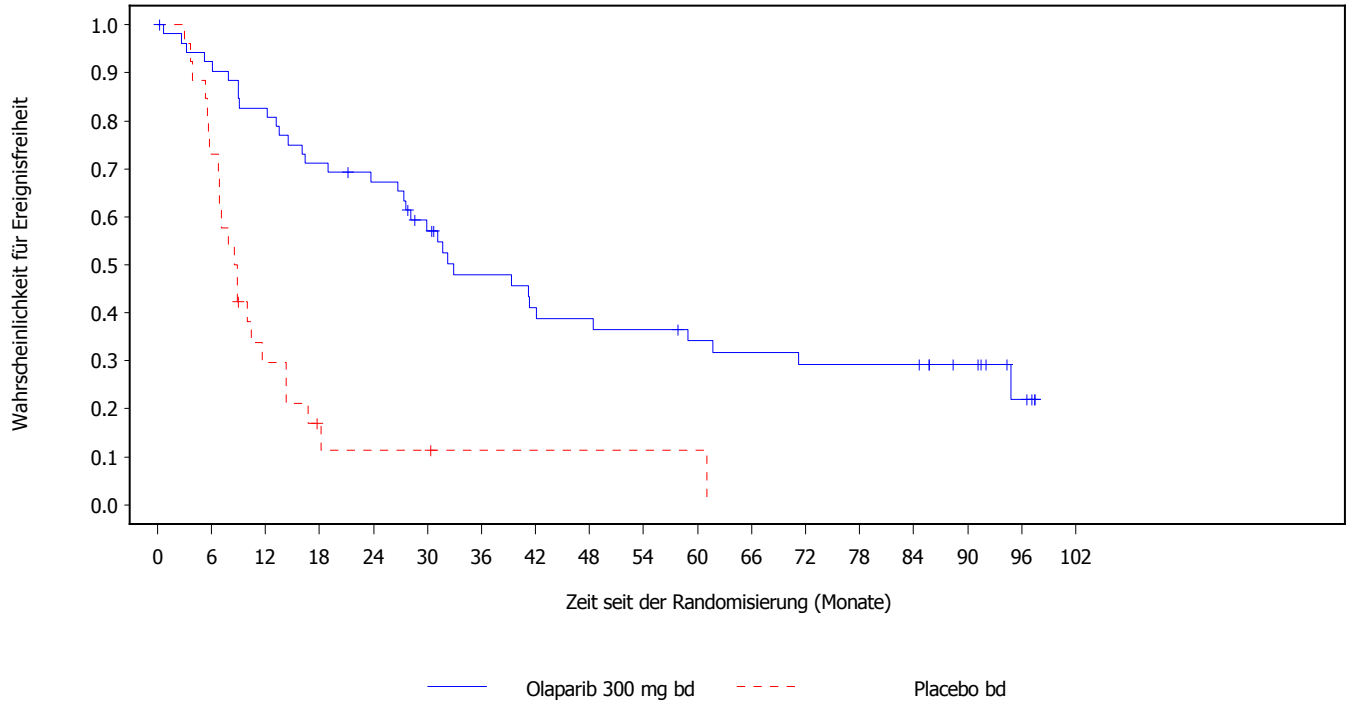
Anzahl an Patienten unter Risiko:

247	229	212	194	182	150	126	123	115	109	105	102	99	90	63	23	2	0	Olaparib 300 mg bd
124	112	81	60	51	44	32	27	25	24	24	24	24	23	18	4	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1bae 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Partielles Ansprechen
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

53	48	43	37	34	27	21	18	17	16	14	13	12	12	12	8	3	0	Olaparib 300 mg bd
26	19	7	3	2	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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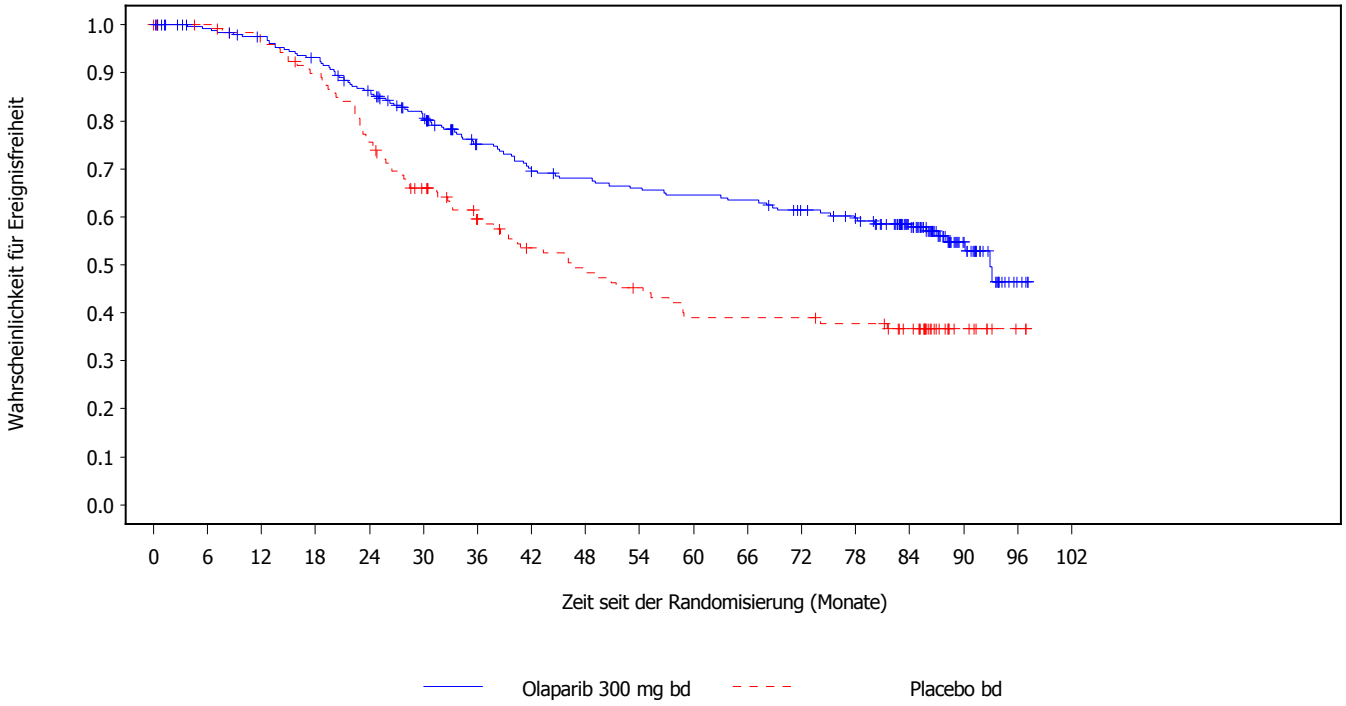
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.7 SOLO1: Kaplan-Meier plot of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Vollständiges Ansprechen
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



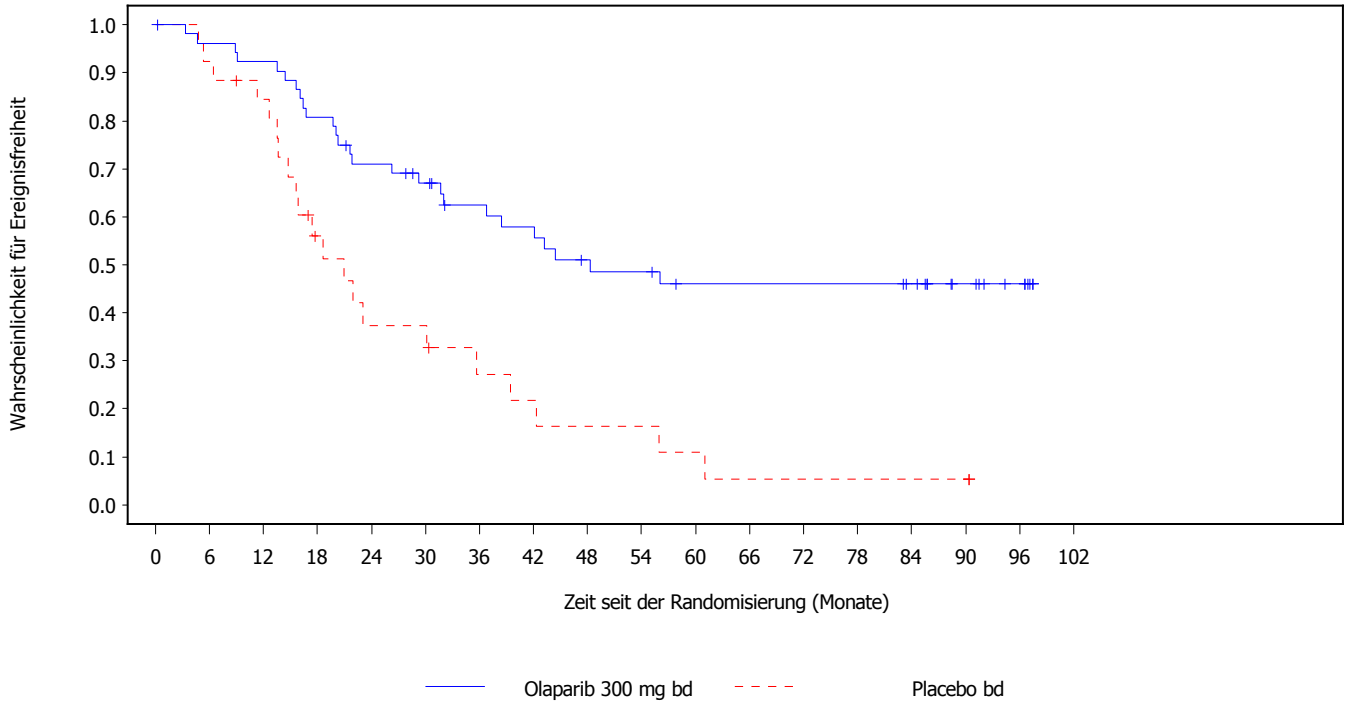
Anzahl an Patienten unter Risiko:

247	236	229	218	199	177	148	137	132	128	125	123	115	108	80	32	3	0	Olaparib 300 mg bd
124	121	114	106	89	74	61	52	47	43	37	37	37	35	29	8	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1bag 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.8 SOLO1: Kaplan-Meier plot of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Partielles Ansprechen
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



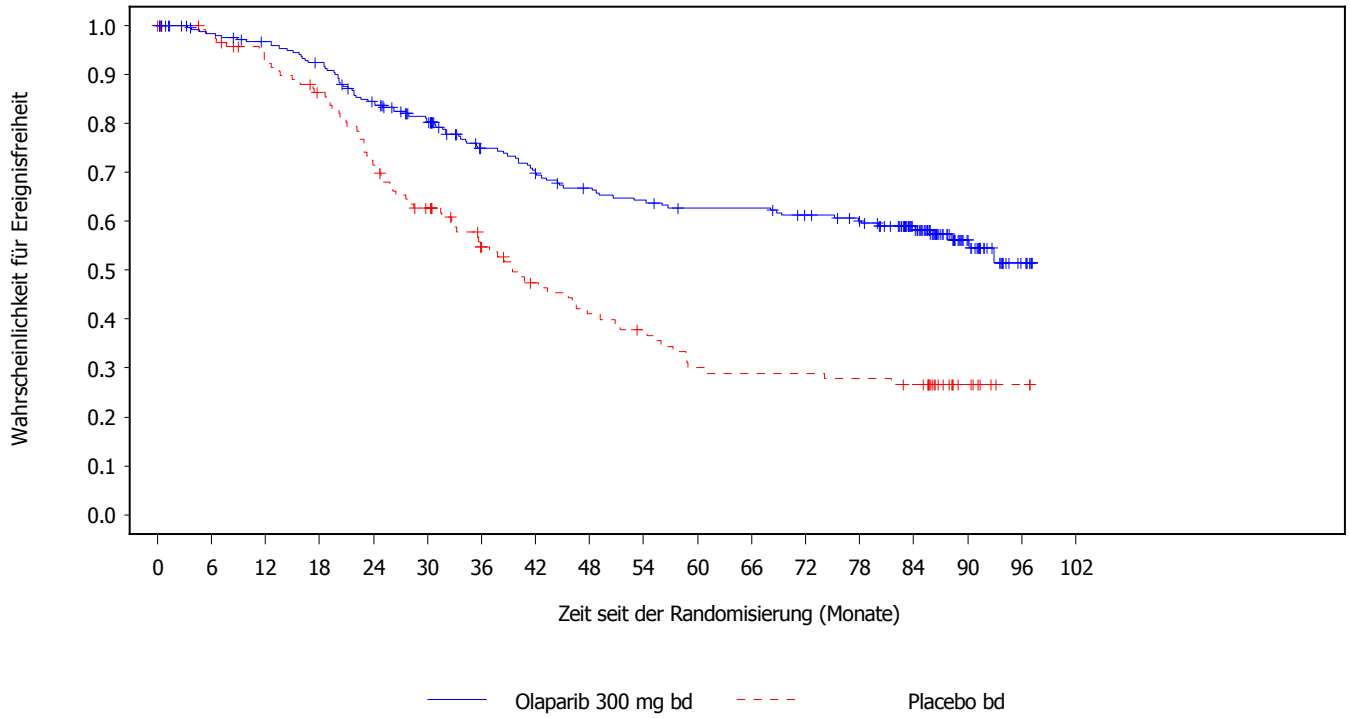
Anzahl an Patienten unter Risiko:

53	50	48	42	36	32	27	25	21	20	17	17	17	17	15	9	5	0	Olaparib 300 mg bd
26	24	21	12	8	8	5	4	3	3	2	1	1	1	1	1	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1bah 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.9 SOLO1: Kaplan-Meier plot of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod for FIGO Stadium = III
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



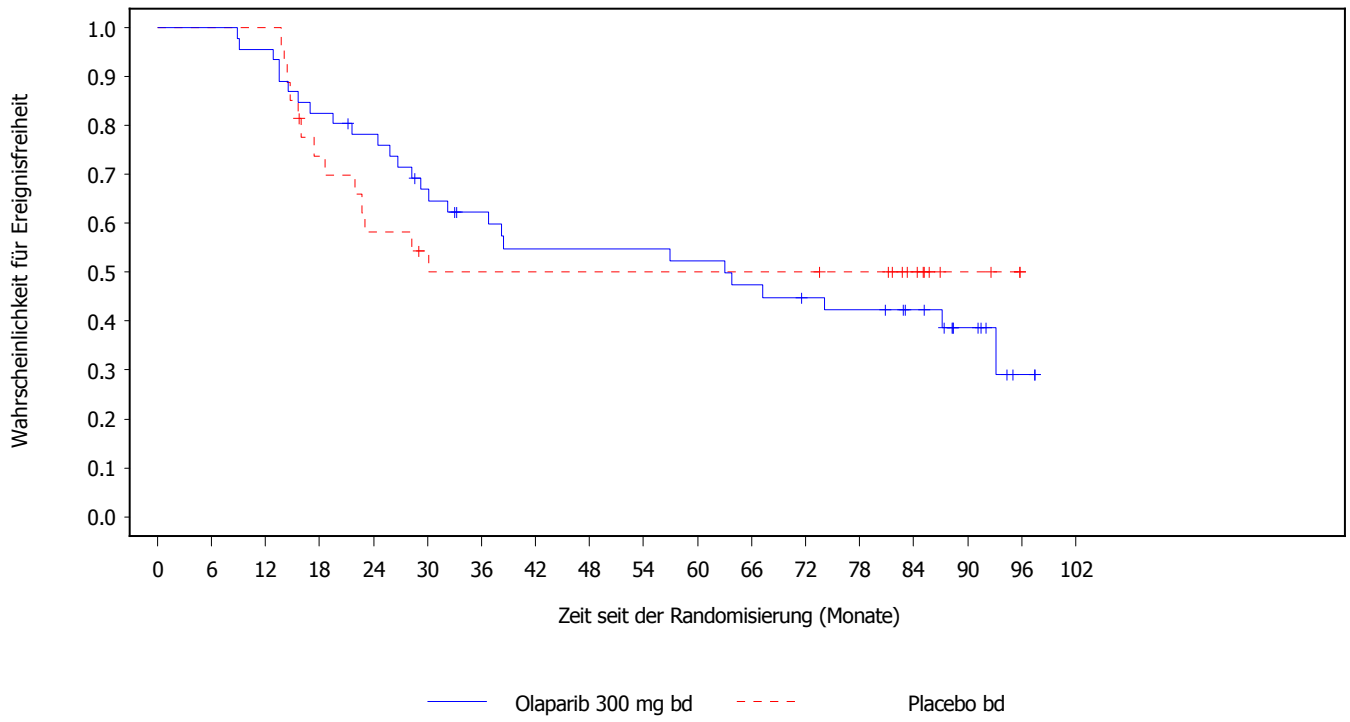
Anzahl an Patienten unter Risiko:

254	240	233	222	200	180	150	140	131	126	121	121	115	109	82	34	7	0	Olaparib 300 mg bd
123	118	108	99	82	69	54	44	38	34	27	26	26	25	23	7	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1bai 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.10 SOLO1: Kaplan-Meier plot of Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod for FIGO Stadium = IV
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



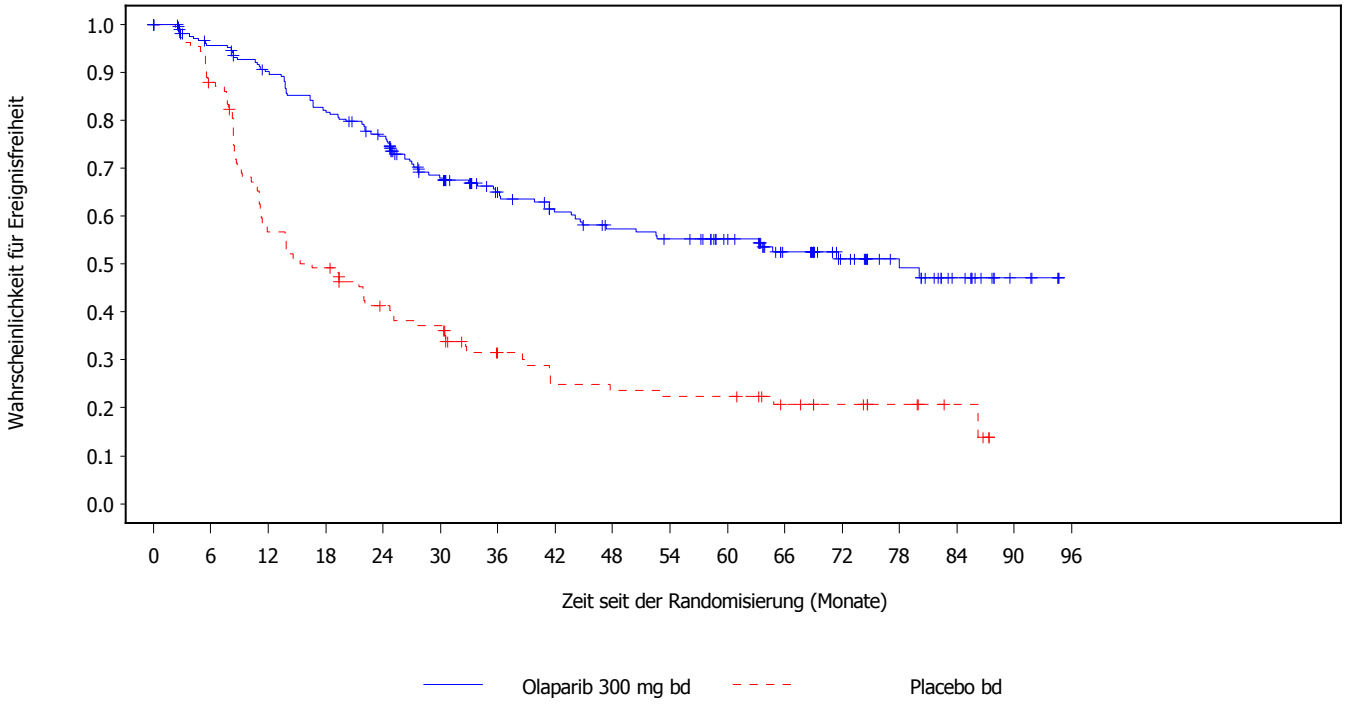
Anzahl an Patienten unter Risiko:

46	46	44	38	35	29	25	22	22	22	21	19	17	16	13	7	1	0	Olaparib 300 mg bd
27	27	27	19	15	13	12	12	12	12	12	12	12	11	7	2	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef1.sas gttesubef1baj 27FEB2023:11:56 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.11 SOLO1: Kaplan-Meier plot of Rezidivfreies Überleben for Alter (Jahre) = <65 Jahre
Patients with a clinical complete response after platinum-based chemotherapy as randomised, Global Cohort DCO 07Mar2022, China Cohor



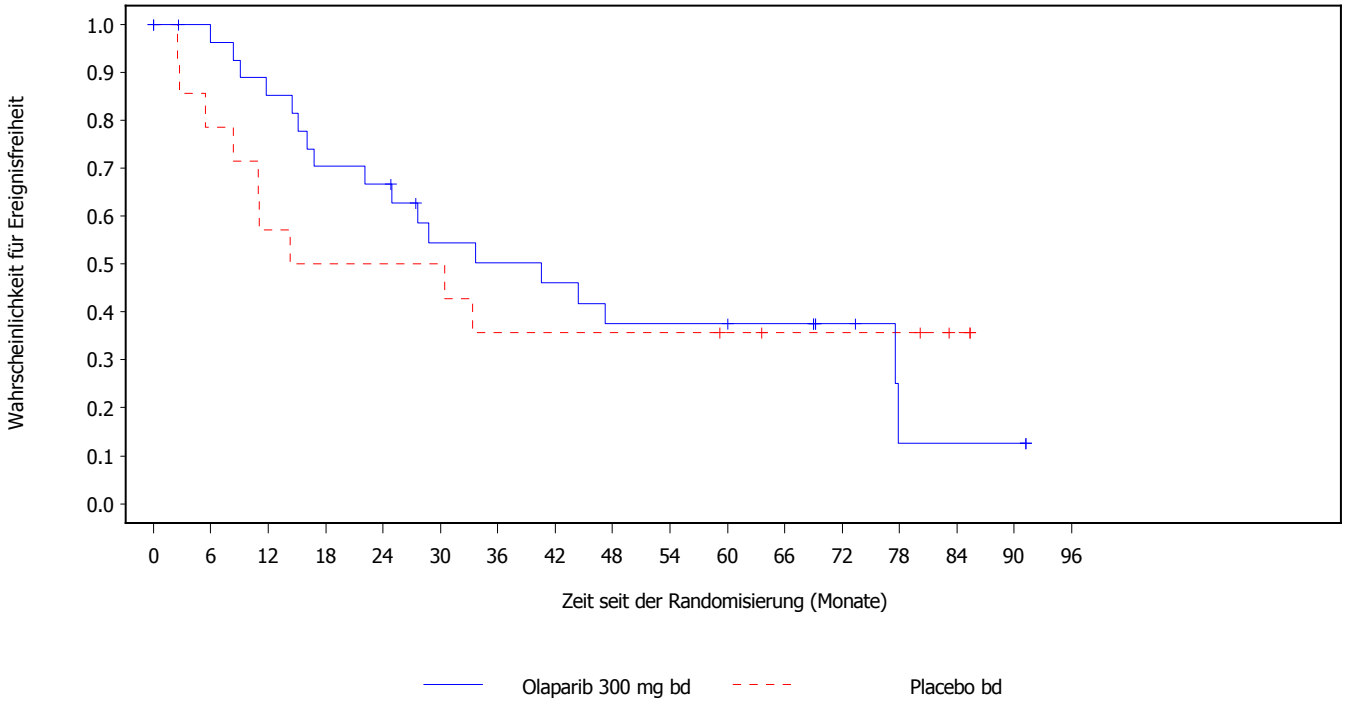
Anzahl an Patienten unter Risiko:

217	195	181	165	150	121	98	88	80	76	67	51	35	24	14	4	0	Olaparib 300 mg bd
110	94	60	52	40	36	25	19	18	17	17	12	9	6	3	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef2.sas gttesubef2baa 27FEB2023:11:59 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 1.4.2.12 SOLO1: Kaplan-Meier plot of Rezidivfreies Überleben for Alter (Jahre) = >=65 Jahre
Patients with a clinical complete response after platinum-based chemotherapy as randomised, Global Cohort DCO 07Mar2022, China Cohor



Anzahl an Patienten unter Risiko:

30	26	23	19	18	13	12	11	9	9	9	8	4	1	1	1	0 Olaparib 300 mg bd
14	11	8	7	7	7	5	5	5	5	4	3	3	3	1	0	0 Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubef2.sas gttesubef2bab 27FEB2023:11:59 kpzx329

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.3 SOLO1: Summary of subgroup analysis for recurrence or death rate (odds ratio, relative risk and risk difference)
Patients with a clinical complete response after platinum-based chemotherapy as randomised, Global Cohort DCO 07Mar2022, China Cohor

	Olaparib 300 mg bd (N=247)		Placebo bd (N=124)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter (Jahre)										
<65 Jahre [a][d][g]	217	88(40,6)	110	80(72,7)	0,26[0,15; 0,42]	<0,0001 *	0,56[0,46; 0,68]	<0,0001 *	-0,32[-0,42; -0,21]	<0,0001 *
>=65 Jahre [a][d][g]	30	18(60,0)	14	9(64,3)	0,83[0,21; 3,05]	0,7851	0,93[0,59; 1,65]	0,7851	-0,04[-0,33; 0,27]	0,7851
Int. p-Wert [a][d][g]						0,1084		0,0461 *		0,0764
ECOG PS Status										
Normale Aktivität [a][d][g]	186	81(43,5)	97	70(72,2)	0,30[0,17; 0,50]	<0,0001 *	0,60[0,49; 0,74]	<0,0001 *	-0,29[-0,40; -0,17]	<0,0001 *
Eingeschränkte Aktivität [a][d][g]	61	25(41,0)	26	19(73,1)	0,26[0,09; 0,68]	0,0054 *	0,56[0,38; 0,83]	0,0054 *	-0,32[-0,51; -0,10]	0,0054 *
Int. p-Wert [a][d][g]						0,7939		0,7401		0,7775
Baseline CA-125 Wert										
<=ULN	244	104(42,6)	122	88(72,1)	ID	ID	ID	ID	ID	ID
>ULN	3	2(66,7)	1	1(100)	ID	ID	ID	ID	ID	ID
Int. p-Wert						ID		ID		ID
FIGO Stadium										
III	216	89(41,2)	103	76(73,8)	0,25[0,15; 0,41]	<0,0001	0,56[0,46; 0,68]	<0,0001	-0,33[-0,43; -0,21]	<0,0001

CI=95% profile likelihood confidence interval. LR=likelihood ratio test p-value. ID=insufficient data. Results for subgroup levels from separate models for each subgroup level including treatment only. Interaction p-values from models including treatment, subgroup and treatment by subgroup. If >=10 patients for all subgroup levels and >=10 events for 1 subgroup level, models for all subgroup levels fitted and interaction p-value calculated. For subgroups with >2 levels, levels with ID were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met ID presented.
[a] Odds ratio (OR) CI, LR via logistic regression. [b] As [a] but Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR) CI, LR via log-binomial regression. [e] RR, CI, p-value via modified poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD) CI, LR via binomial regression. [h] RD NC via [g]. OR and RR <1, and RD <0 favours olaparib. * p<0.05.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/orrardsubef1.sas gorrardsubef1a 27FEB2023:11:51 kpzx329

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.3 SOLO1: Summary of subgroup analysis for recurrence or death rate (odds ratio, relative risk and risk difference)
Patients with a clinical complete response after platinum-based chemotherapy as randomised, Global Cohort DCO 07Mar2022, China Cohor

	Olaparib 300 mg bd (N=247)		Placebo bd (N=124)		Behandlungseffekt								
					Odds Ratio			Relatives Risiko			Risikodifferenz		
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]		2-seitiger p-Wert	Schätzer [95%-KI]		2-seitiger p-Wert	Schätzer [95%-KI]		2-seitiger p-Wert
[a][d][g]							*			*			*
IV [a][d][g]	31	17(54,8)	21	13(61,9)	0,75[0,24;	2,30]	0,6121	0,89[0,55;	1,46]	0,6121	-0,07[-0,33;	0,20]	0,6121
Int. p-Wert [a][d][g]							0,0867			0,0743			0,0789
BRCA-Mutationstyp (durch Myriad CDx bestätigt)													
BRCA1 [a][d][g]	152	70(46,1)	74	57(77,0)	0,25[0,13;	0,47]	<0,0001 *	0,60[0,48;	0,74]	<0,0001 *	-0,31[-0,43;	-0,18]	<0,0001 *
BRCA2 [a][d][g]	53	17(32,1)	32	20(62,5)	0,28[0,11;	0,70]	0,0060 *	0,51[0,31;	0,82]	0,0060 *	-0,30[-0,50;	-0,09]	0,0060 *
Int. p-Wert [a][d][g]							0,8508			0,5626			0,9647
Ergebnis der Debulkingoperation vor Studienbeginn													
makroskopische Resterkrankung [a][d][g]	39	20(51,3)	24	19(79,2)	0,28[0,08;	0,85]	0,0236 *	0,65[0,44;	0,94]	0,0236 *	-0,28[-0,49;	-0,04]	0,0236 *
Keine makroskopische Resterkrankung [a][d][g]	207	86(41,5)	99	69(69,7)	0,31[0,18;	0,51]	<0,0001 *	0,60[0,48;	0,73]	<0,0001 *	-0,28[-0,39;	-0,17]	<0,0001 *
Int. p-Wert [a][d][g]							0,8660			0,7016			0,9835
Abstammung													
Weiß	176	76(43,2)	88	64(72,7)	0,29[0,16;	0,49]	<0,0001	0,59[0,48;	0,73]	<0,0001	-0,30[-0,41;	-0,17]	<0,0001

CI=95% profile likelihood confidence interval. LR=likelihood ratio test p-value. ID=insufficient data. Results for subgroup levels from separate models for each subgroup level including treatment only. Interaction p-values from models including treatment, subgroup and treatment by subgroup. If >=10 patients for all subgroup levels and >=10 events for 1 subgroup level, models for all subgroup levels fitted and interaction p-value calculated. For subgroups with >2 levels, levels with ID were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met ID presented.
[a] Odds ratio (OR) CI, LR via logistic regression. [b] As [a] but Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR) CI, LR via log-binomial regression. [e] RR, CI, p-value via modified poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD) CI, LR via binomial regression. [h] RD NC via [g]. OR and RR <1, and RD <0 favours olaparib. * p<0.05.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 1.4.3 SOLO1: Summary of subgroup analysis for recurrence or death rate (odds ratio, relative risk and risk difference)
Patients with a clinical complete response after platinum-based chemotherapy as randomised, Global Cohort DCO 07Mar2022, China Cohor

	Olaparib 300 mg bd (N=247)		Placebo bd (N=124)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
[a][d][g]						*		*		*
Andere	71	30(42,3)	36	25(69,4)	0,32[0,13; 0,74]	0,0072	0,61[0,43; 0,87]	0,0072	-0,27[-0,45; -0,08]	0,0072
[a][d][g]						*		*		*
Int. p-Wert						0,8145		0,9064		0,8358
[a][d][g]										
Region										
Europa	87	36(41,4)	43	30(69,8)	0,31[0,14; 0,65]	0,0021	0,59[0,43; 0,82]	0,0021	-0,28[-0,45; -0,11]	0,0021
[a][d][g]						*		*		*
Asien	60	26(43,3)	27	18(66,7)	0,38[0,14; 0,97]	0,0425	0,65[0,44; 0,98]	0,0425	-0,23[-0,44; -0,01]	0,0425
[a][d][g]						*		*		*
Rest der Welt	100	44(44,0)	54	41(75,9)	0,25[0,12; 0,51]	0,0001	0,58[0,44; 0,76]	0,0001	-0,32[-0,46; -0,16]	0,0001
[a][d][g]						*		*		*
Int. p-Wert						0,7810		0,8917		0,8124
[a][d][g]										

CI=95% profile likelihood confidence interval. LR=likelihood ratio test p-value. ID=insufficient data. Results for subgroup levels from separate models for each subgroup level including treatment only. Interaction p-values from models including treatment, subgroup and treatment by subgroup. If >=10 patients for all subgroup levels and >=10 events for 1 subgroup level, models for all subgroup levels fitted and interaction p-value calculated. For subgroups with >2 levels, levels with ID were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met ID presented.
[a] Odds ratio (OR) CI, LR via logistic regression. [b] As [a] but Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR) CI, LR via log-binomial regression. [e] RR, CI, p-value via modified poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD) CI, LR via binomial regression. [h] RD NC via [g]. OR and RR <1, and RD <0 favours olaparib. * p<0.05.
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2.2: Patientenberichtete Endpunkte

2.2.1: Gesamtpopulation

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.1 SOLO1: Summary of observation period (months) for PRO endpoints
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

		Olaparib 300 mg bd (N=300)	Placebo bd (N=150)
FACT-O	n	300	150
	Median	34,69	30,51
	Min	0,0	0,0
	Max	52,7	52,2
EQ-5D visuelle Analogskala	n	300	150
	Median	34,69	30,51
	Min	0,0	0,0
	Max	52,7	52,2

Observation period includes the time from randomisation until the last date data are collected for the respective questionnaire, death or primary DCO, whichever comes first.

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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.2.1 SOLO1: Summary of analysis of Time to deterioration in FACT-O
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
FACT-O Gesamtscore	300	43 (14,3)	NE [NE; NE]	150	24 (16,0)	50,7 [50,7; NE]	0,89	[0,54; 1,50]	0,7178
FACT-O Subskala physisches Wohlbefinden (PWB)	300	74 (24,7)	NE [NE; NE]	150	32 (21,3)	NE [NE; NE]	1,23	[0,82; 1,88]	0,3483
FACT-O Subskala soziales Wohlbefinden (SWB)	300	81 (27,0)	NE [NE; NE]	150	35 (23,3)	NE [NE; NE]	1,16	[0,79; 1,75]	0,5177
FACT-O Subskala funktionales Wohlbefinden (FWB)	300	65 (21,7)	NE [NE; NE]	150	29 (19,3)	50,7 [44,6; NE]	1,12	[0,73; 1,76]	0,5376
FACT-O Subskala emotionales Wohlbefinden (EWB)	300	66 (22,0)	49,9 [42,1; NE]	150	39 (26,0)	NE [NE; NE]	0,81	[0,55; 1,22]	0,3172
FACT-O Eierstockkrebs-spezifische Subskala (OCS)	300	44 (14,7)	NE [NE; NE]	150	23 (15,3)	48,2 [46,3; NE]	0,96	[0,58; 1,63]	0,9501

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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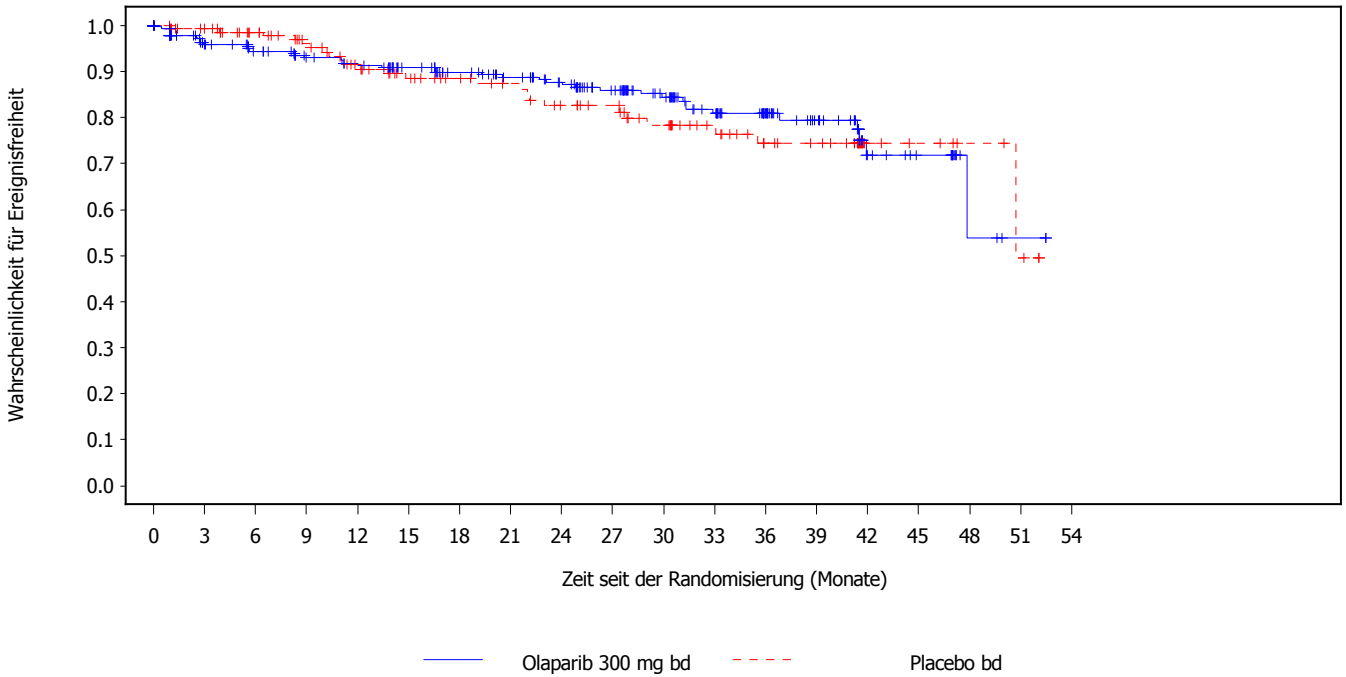
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.2.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Gesamtscore
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	244	229	215	208	191	177	167	155	135	112	90	67	49	21	16	3	1	0	Olaparib 300 mg bd
150	132	121	109	97	85	79	73	66	62	53	42	32	29	9	7	4	2	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
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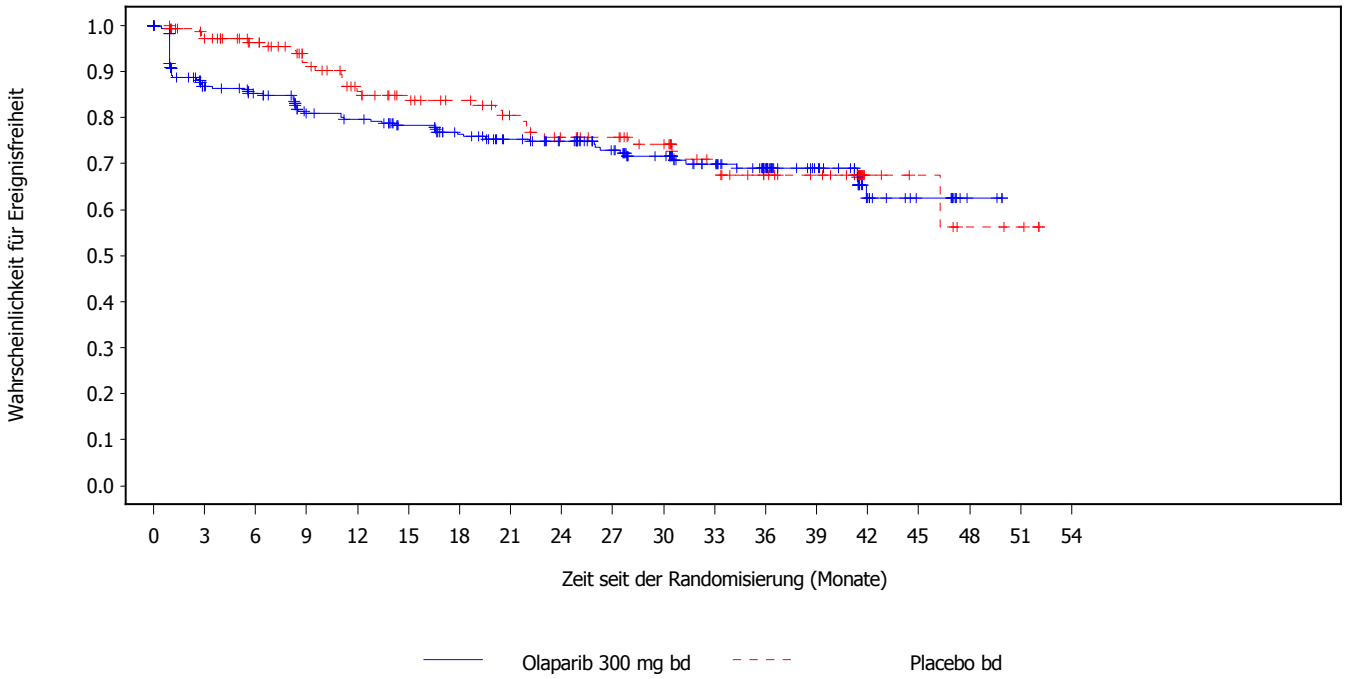
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.2.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Subskala physisches Wohlbefinden (PWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	222	208	186	180	166	153	141	132	114	99	81	61	44	20	13	2	0	0	Olaparib 300 mg bd
150	131	120	105	91	82	77	69	62	57	51	40	32	28	8	6	3	2	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.

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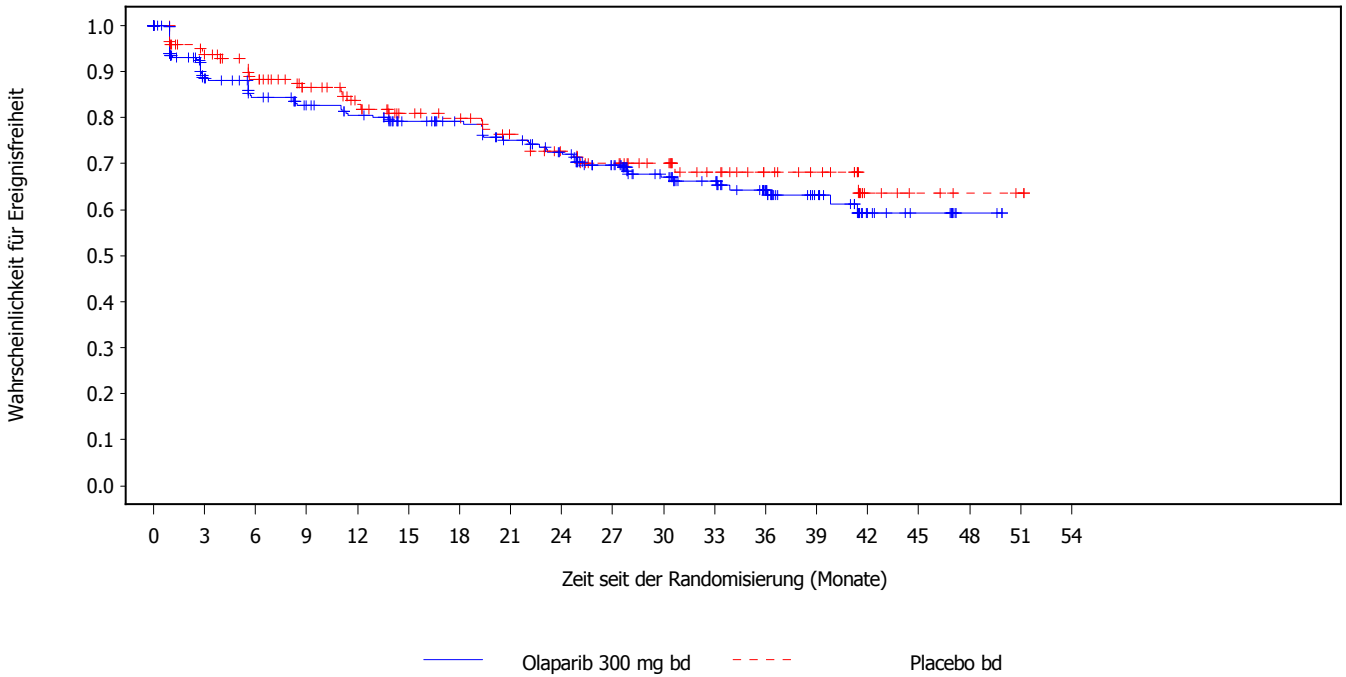
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.2.2.3 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Subskala soziales Wohlbefinden (SWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	224	205	193	183	167	159	147	135	114	89	77	56	39	17	12	2	0	0	Olaparib 300 mg bd
150	127	112	99	87	76	72	64	57	50	43	33	26	22	7	4	2	1	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
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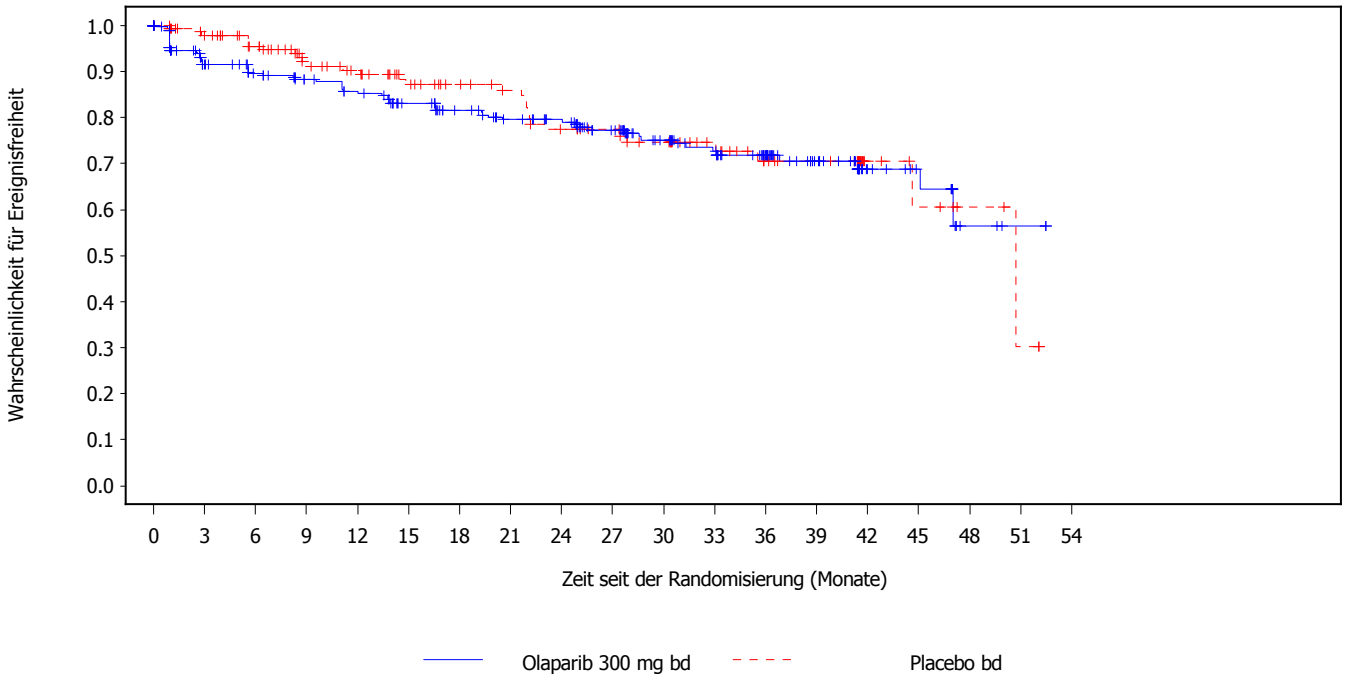
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.2.2.4 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Subskala funktionales Wohlbefinden (FWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	234	218	205	196	178	164	153	147	126	102	89	69	48	21	16	3	1	0	Olaparib 300 mg bd
150	132	120	103	95	82	75	70	61	57	51	40	30	26	9	6	3	1	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.

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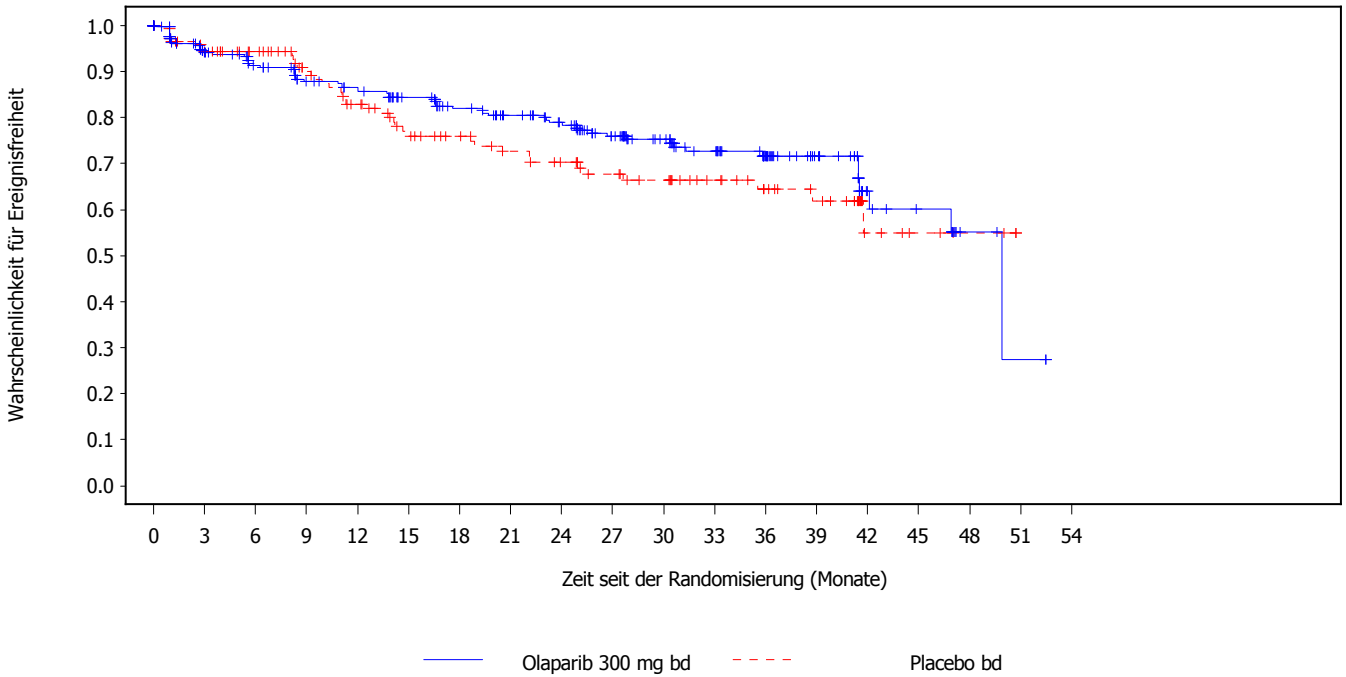
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.2.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Subskala emotionales Wohlbefinden (EWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



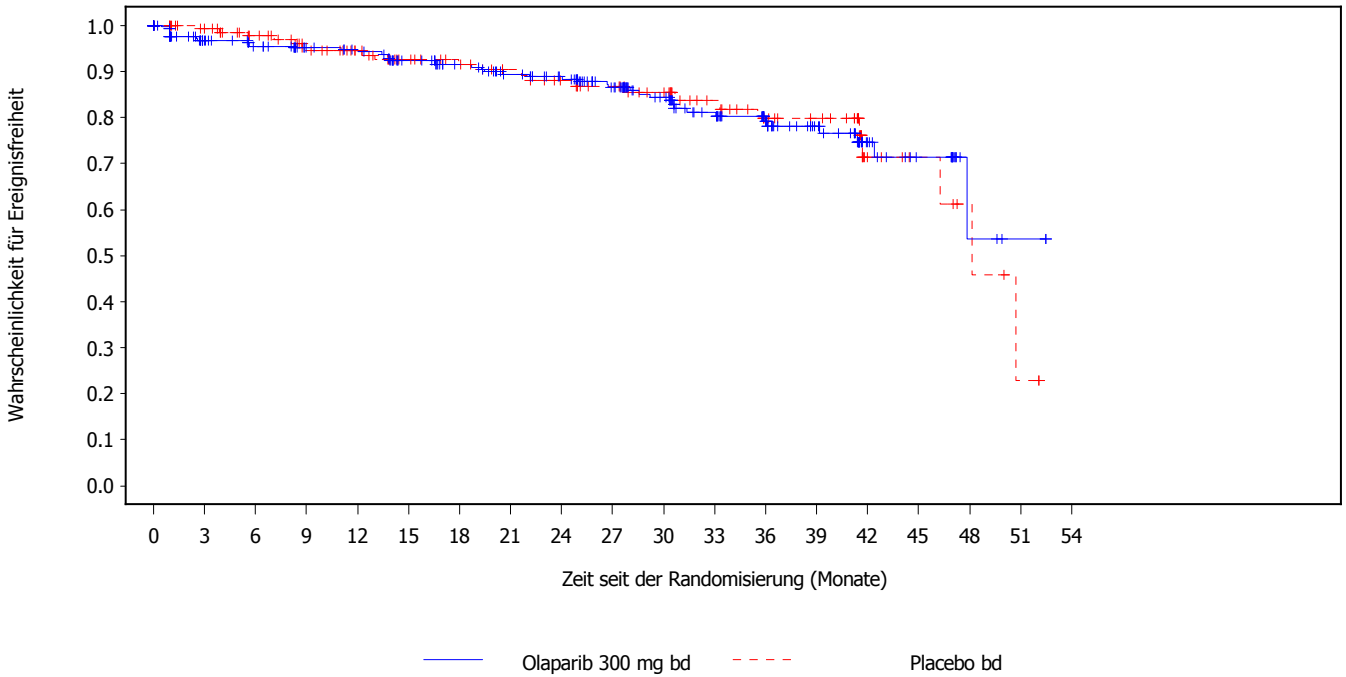
Anzahl an Patienten unter Risiko:

300	241	224	205	197	180	165	154	143	119	97	80	59	39	16	12	3	1	0	Olaparib 300 mg bd
150	127	118	102	90	76	70	63	58	51	46	37	29	24	7	4	2	0	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr.sas gttemainprbae 07FEB2023:09:26 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.2.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Eierstockkrebs-spezifische Subskala (OCS)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	248	235	221	215	196	182	170	160	139	115	94	71	52	25	17	3	1	0 Olaparib 300 mg bd
150	135	124	112	102	90	84	77	71	65	58	46	36	32	10	7	4	1	0 Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr.sas gttemainprbaf 07FEB2023:09:26 kvbv306

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.3.1 SOLO1: Summary of analysis of Time to deterioration in EQ-5D VAS
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
EQ-5D visuelle Analogskala	300	53 (17,7)	NE [NE; NE]	150	41 (27,3)	NE [NE; NE]	0,64	[0,43; 0,97]	0,0295*

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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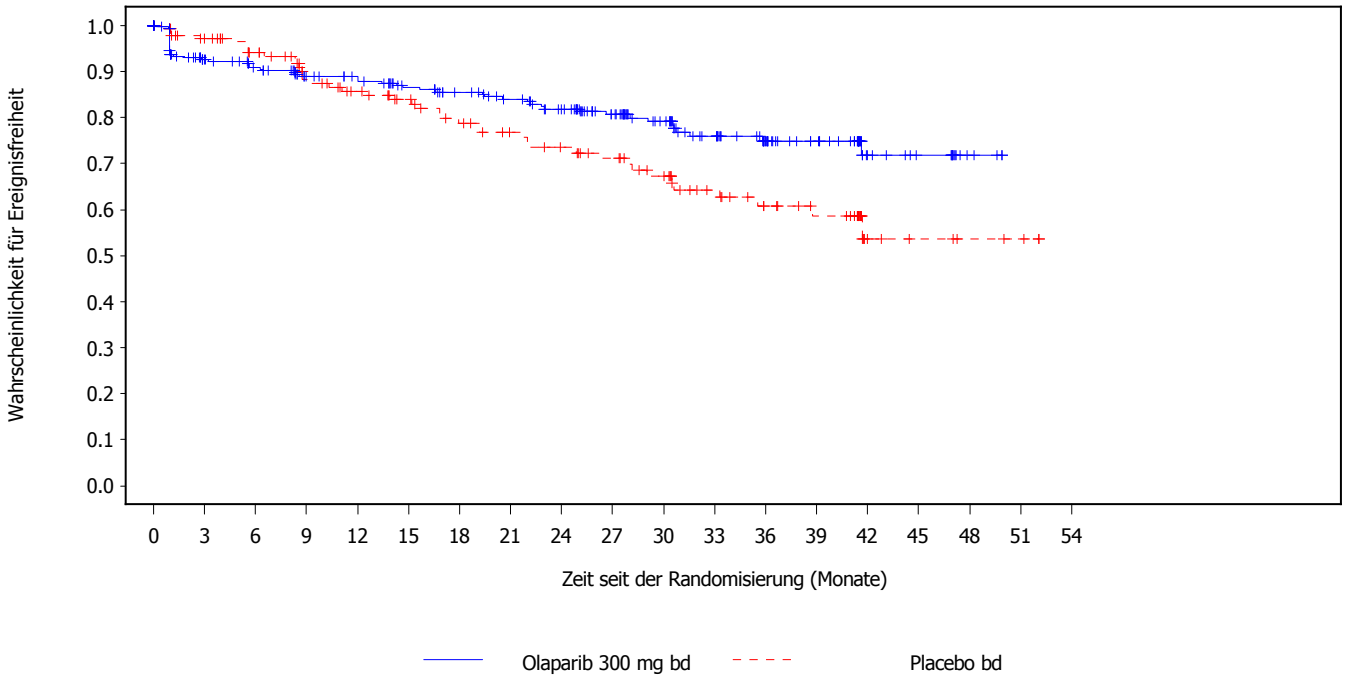
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.3.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	234	220	201	195	180	170	161	149	127	106	85	63	50	19	14	3	0	0	Olaparib 300 mg bd
150	132	121	104	95	86	77	70	65	59	51	39	31	26	7	5	3	2	0	Placebo bd

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr.sas gttemainprcaa 07FEB2023:09:26 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 2
Nutzenbewertung nach AMNOG

Table 2.4.1.1 SOLO1: Summary of analysis of change from baseline in FACT-O Gesamtscore (mixed model for repeated measures)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)			Behandlungseffekt	
Zeitpunkt [c]	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Woche 5 (Tag 29)	258	114,05 (18,446)	-3,96 (0,820)	134	117,02 (18,120)	2,71 (1,139)	-6,67 [-9,432; -3,905]	<0,0001*
Woche 13 (Tag 85)	241	113,97 (18,380)	-1,95 (0,941)	132	117,22 (18,418)	4,40 (1,293)	-6,35 [-9,495; -3,197]	<0,0001*
Woche 25 (Tag 169)	239	114,31 (18,225)	0,04 (0,956)	126	118,05 (17,557)	3,45 (1,327)	-3,40 [-6,623; -0,183]	0,0384*
Woche 37 (Tag 253)	238	113,48 (17,819)	0,48 (1,016)	113	118,21 (16,709)	3,38 (1,443)	-2,90 [-6,376; 0,581]	0,1023
Woche 49 (Tag 337)	232	113,48 (18,150)	0,94 (1,005)	106	118,65 (17,237)	1,61 (1,445)	-0,67 [-4,141; 2,800]	0,7043
Woche 61 (Tag 421)	221	113,58 (18,350)	1,16 (1,014)	95	119,26 (17,307)	0,71 (1,487)	0,45 [-3,099; 3,997]	0,8037
Woche 73 (Tag 505)	203	113,80 (18,227)	1,75 (1,017)	91	118,11 (17,667)	2,30 (1,487)	-0,54 [-4,091; 3,007]	0,7642
Woche 85 (Tag 589)	207	113,77 (18,416)	1,96 (1,016)	91	118,71 (16,775)	2,71 (1,500)	-0,74 [-4,311; 2,829]	0,6835
Woche 97 (Tag 673)	199	113,72 (18,411)	1,91 (1,111)	82	120,08 (17,539)	-0,35 (1,676)	2,26 [-1,702; 6,230]	0,2625
Woche 109 (Tag 757)	196	113,93 (17,653)	1,97 (1,092)	81	116,09 (18,638)	2,04 (1,647)	-0,07 [-3,960; 3,823]	0,9724
Woche 121 (Tag 841)	161	114,69 (17,521)	2,65 (1,160)	68	117,91 (18,244)	-1,87 (1,750)	4,51 [0,377; 8,649]	0,0325*
Woche 133 (Tag 925)	143	115,12 (16,112)	0,49 (1,223)	65	117,61 (18,178)	-0,90 (1,815)	1,39 [-2,917; 5,702]	0,5254
Woche 145 (Tag 1009)	136	114,30 (16,433)	1,30 (1,287)	54	115,41 (19,208)	-2,40 (1,975)	3,70 [-0,939; 8,342]	0,1176
Woche 157 (Tag 1093)	123	114,94 (15,756)	0,87 (1,212)	49	118,47 (15,015)	-3,13 (1,872)	4,00 [-0,397; 8,394]	0,0744
Woche 169 (Tag 1177)	75	114,12 (16,087)	1,76 (1,626)	43	115,35 (18,946)	-4,27 (2,249)	6,03 [0,550; 11,511]	0,0312*

[a] = number of patients with change from baseline at each timepoint in the MMRM analysis.
[b] = mean baseline for patients with change from baseline at each timepoint in the MMRM analysis.
Calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit and treatment by visit interaction included as explanatory variables and the baseline score included as a covariate along with the baseline score by visit interaction. Only visits where change from baseline is available for at least one patient in both treatment arms are included in the analysis.
Treatment, visit and treatment by visit interaction are fixed effects in the model, a Toeplitz with heterogeneity covariance matrix is used to model within-subject error. SMD = standardised mean difference. * p<0.05. [c] Based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3).
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 2.4.1.1 SOLO1: Summary of analysis of change from baseline in FACT-O Gesamtscore (mixed model for repeated measures)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)			Behandlungseffekt	
Zeitpunkt [c]	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Woche 193 (Tag 1345)	70	116,54 (15,950)	1,38 (1,516)	31	114,38 (16,377)	-3,36 (2,258)	4,74 [-0,642; 10,114]	0,0839
Woche 217 (Tag 1513)	27	113,23 (14,373)	-0,20 (2,326)	9	120,36 (11,737)	2,21 (3,978)	-2,41 [-11,751; 6,922]	0,6058
Hedges' g SMD							0,02 [-0,186; 0,217]	0,8784
Mittelwert über alle Visite	278	113,82 (18,545)	0,74 (0,736)	144	116,45 (18,567)	0,54 (1,069)	0,20 [-2,359; 2,751]	0,8802

[a] = number of patients with change from baseline at each timepoint in the MMRM analysis.
[b] = mean baseline for patients with change from baseline at each timepoint in the MMRM analysis.
Calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit and treatment by visit interaction included as explanatory variables and the baseline score included as a covariate along with the baseline score by visit interaction. Only visits where change from baseline is available for at least one patient in both treatment arms are included in the analysis.
Treatment, visit and treatment by visit interaction are fixed effects in the model, a Toeplitz with heterogeneity covariance matrix is used to model within-subject error. SMD = standardised mean difference. * p<0.05. [c] Based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3).
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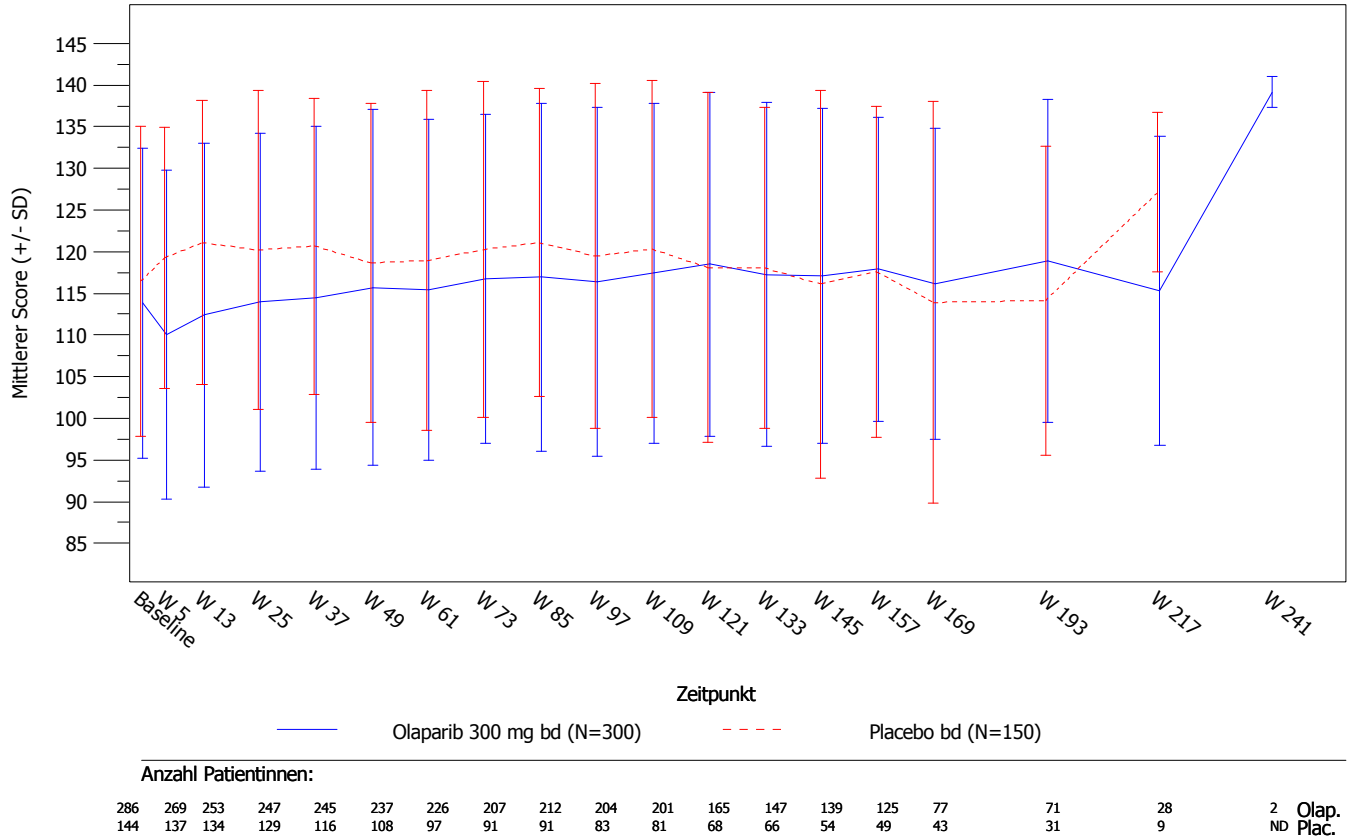
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.4.2.1 SOLO1: Mean (+/- SD) score for FACT-O Gesamtscore across timepoints, by treatment group
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

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Table 2.4.3.1 SOLO1: Summary of FACT-O Total score results across timepoints, by treatment group
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
FACT-O Gesamtscore	Olaparib 300 mg bd (N=300)	Baseline	286	113,84	18,579	59,0	117,17	152,0
		Woche 5 (Tag 29)	269	110,06	19,790	58,7	112,00	148,9
		Woche 13 (Tag 85)	253	112,43	20,639	58,0	114,80	148,0
		Woche 25 (Tag 169)	247	113,97	20,288	55,0	114,67	152,0
		Woche 37 (Tag 253)	245	114,50	20,554	51,8	117,00	149,0
		Woche 49 (Tag 337)	237	115,72	21,351	58,0	117,83	148,0
		Woche 61 (Tag 421)	226	115,44	20,456	47,5	116,33	148,0
		Woche 73 (Tag 505)	207	116,74	19,733	64,4	120,00	148,0
		Woche 85 (Tag 589)	212	116,93	20,896	53,5	120,00	150,0
		Woche 97 (Tag 673)	204	116,37	20,963	44,0	119,30	148,0
		Woche 109 (Tag 757)	201	117,43	20,421	46,0	121,00	149,9
		Woche 121 (Tag 841)	165	118,50	20,636	35,7	122,00	149,0
		Woche 133 (Tag 925)	147	117,28	20,643	55,7	122,00	149,0
		Woche 145 (Tag 1009)	139	117,10	20,143	56,3	122,00	146,9
		Woche 157 (Tag 1093)	125	117,91	18,236	72,0	120,00	149,0
		Woche 169 (Tag 1177)	77	116,19	18,679	56,0	119,43	145,0
		Woche 193 (Tag 1345)	71	118,91	19,419	70,8	123,00	146,0
		Woche 217 (Tag 1513)	28	115,32	18,550	66,5	118,50	145,7
		Woche 241 (Tag 1681)	2	139,17	1,886	137,8	139,17	140,5
FACT-O Gesamtscore	Placebo bd (N=150)	Baseline	144	116,45	18,567	68,0	119,22	151,0
		Woche 5 (Tag 29)	137	119,27	15,684	72,5	121,00	152,0
		Woche 13 (Tag 85)	134	121,09	17,030	75,0	122,00	152,0
		Woche 25 (Tag 169)	129	120,20	19,122	63,0	121,00	152,0
		Woche 37 (Tag 253)	116	120,68	17,771	80,0	121,00	152,0
		Woche 49 (Tag 337)	108	118,67	19,151	68,0	121,83	152,0
		Woche 61 (Tag 421)	97	118,94	20,383	67,0	121,00	152,0
		Woche 73 (Tag 505)	91	120,26	20,196	63,8	120,00	152,0

Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

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Table 2.4.3.1 SOLO1: Summary of FACT-O Total score results across timepoints, by treatment group
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

				Result				
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 85 (Tag 589)	91	121,10	18,491	64,5	121,50	151,0
		Woche 97 (Tag 673)	83	119,47	20,701	58,5	122,00	152,0
		Woche 109 (Tag 757)	81	120,32	20,189	58,8	120,00	152,0
		Woche 121 (Tag 841)	68	118,10	21,033	73,0	119,58	152,0
		Woche 133 (Tag 925)	66	118,06	19,273	56,0	119,50	152,0
		Woche 145 (Tag 1009)	54	116,09	23,298	45,7	120,17	148,0
		Woche 157 (Tag 1093)	49	117,60	19,884	63,8	118,00	152,0
		Woche 169 (Tag 1177)	43	113,91	24,111	47,3	117,00	152,0
		Woche 193 (Tag 1345)	31	114,15	18,534	72,7	118,00	146,0
		Woche 217 (Tag 1513)	9	127,15	9,538	112,0	129,00	142,7

Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/smeanpr.sas gsmeanpra 02FEB2023:12:30 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 2
Nutzenbewertung nach AMNOG

Table 2.5.1.1 SOLO1: Summary of analysis of change from baseline in EQ-5D Visual analogue scale
(mixed model for repeated measures)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)			Behandlungseffekt	
Zeitpunkt [c]	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Woche 5 (Tag 29)	260	78,99 (15,454)	-2,76 (0,802)	137	81,69 (13,067)	1,64 (1,106)	-4,40 [-7,089; -1,709]	0,0014*
Woche 13 (Tag 85)	244	78,47 (15,512)	0,06 (0,762)	134	81,53 (13,336)	3,22 (1,040)	-3,17 [-5,707; -0,626]	0,0147*
Woche 25 (Tag 169)	243	78,69 (14,916)	2,70 (0,756)	130	81,88 (13,135)	2,75 (1,040)	-0,04 [-2,576; 2,488]	0,9730
Woche 37 (Tag 253)	241	78,35 (15,639)	1,85 (0,808)	120	82,13 (12,578)	2,91 (1,133)	-1,06 [-3,802; 1,681]	0,4475
Woche 49 (Tag 337)	228	78,53 (15,805)	2,30 (0,798)	114	81,67 (13,145)	0,24 (1,119)	2,06 [-0,651; 4,765]	0,1362
Woche 61 (Tag 421)	220	78,59 (15,067)	2,37 (0,873)	101	82,43 (12,970)	0,44 (1,259)	1,93 [-1,087; 4,951]	0,2092
Woche 73 (Tag 505)	205	79,15 (15,128)	2,33 (0,819)	93	82,31 (13,839)	-0,30 (1,193)	2,63 [-0,221; 5,480]	0,0705
Woche 85 (Tag 589)	210	78,90 (15,031)	2,31 (0,804)	93	82,47 (13,052)	-0,91 (1,184)	3,22 [0,403; 6,041]	0,0252*
Woche 97 (Tag 673)	197	78,90 (15,717)	1,98 (0,976)	82	83,41 (12,879)	-1,47 (1,473)	3,46 [-0,027; 6,940]	0,0518
Woche 109 (Tag 757)	196	78,20 (15,257)	1,81 (1,009)	82	81,63 (13,295)	-0,67 (1,520)	2,48 [-1,118; 6,078]	0,1760
Woche 121 (Tag 841)	158	78,40 (15,114)	2,50 (0,919)	69	82,67 (13,556)	0,22 (1,375)	2,28 [-0,984; 5,544]	0,1703
Woche 133 (Tag 925)	147	78,62 (15,248)	1,53 (1,111)	66	81,65 (13,203)	-1,07 (1,645)	2,60 [-1,317; 6,512]	0,1927
Woche 145 (Tag 1009)	139	76,88 (15,511)	2,50 (1,073)	56	81,32 (13,442)	0,03 (1,633)	2,46 [-1,398; 6,320]	0,2104
Woche 157 (Tag 1093)	128	77,50 (14,707)	2,21 (1,141)	50	80,18 (13,484)	-2,39 (1,758)	4,59 [0,460; 8,729]	0,0296*

[a] = number of patients with change from baseline at each timepoint in the MMRM analysis.
[b] = mean baseline for patients with change from baseline at each timepoint in the MMRM analysis.
Calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit and treatment by visit interaction included as explanatory variables and the baseline score included as a covariate along with the baseline score by visit interaction. Only visits where change from baseline is available for at least one patient in both treatment arms are included in the analysis.
Treatment, visit and treatment by visit interaction are fixed effects in the model, a Toeplitz with heterogeneity covariance matrix is used to model within-subject error. SMD = standardised mean difference. * p<0.05. [c] Based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3).
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

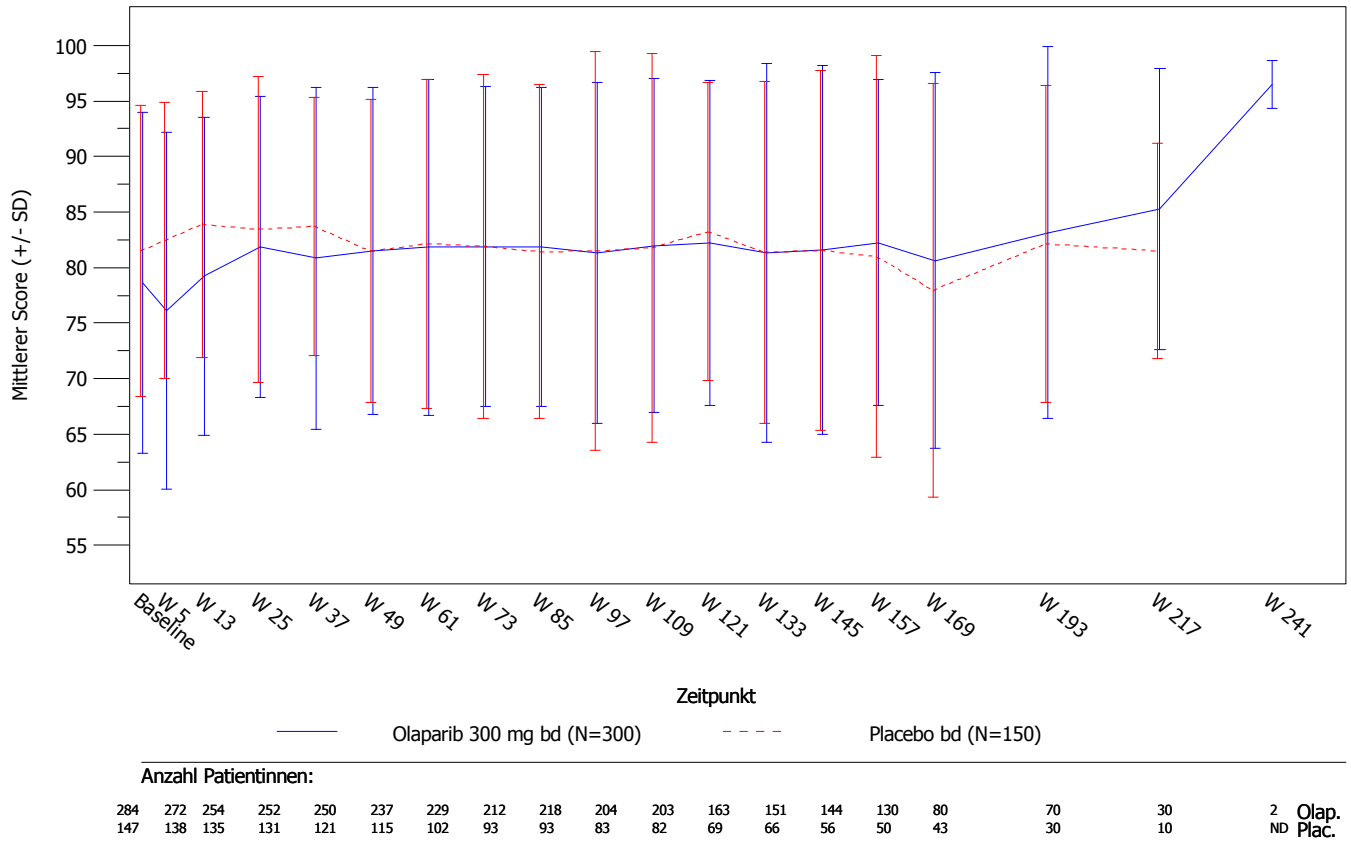
Table 2.5.1.1 SOLO1: Summary of analysis of change from baseline in EQ-5D Visual analogue scale (mixed model for repeated measures)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)			Behandlungseffekt	
Zeitpunkt [c]	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Woche 169 (Tag 1177)	78	76,04 (16,323)	2,52 (1,509)	43	81,51 (13,731)	-4,48 (2,071)	7,00 [1,914; 12,078]	0,0072*
Woche 193 (Tag 1345)	68	77,54 (15,877)	2,63 (1,368)	30	78,30 (14,232)	0,49 (2,035)	2,14 [-2,702; 6,983]	0,3837
Woche 217 (Tag 1513)	29	77,97 (15,110)	4,45 (1,626)	10	83,00 (11,595)	-3,80 (2,730)	8,25 [1,850; 14,649]	0,0125*
Hedges' g SMD							0,21 [0,013; 0,414]	0,0372*
Mittelwert über alle Visite	277	78,63 (15,358)	1,96 (0,594)	147	81,48 (13,104)	-0,19 (0,851)	2,14 [0,099; 4,186]	0,0399*

[a] = number of patients with change from baseline at each timepoint in the MMRM analysis.
[b] = mean baseline for patients with change from baseline at each timepoint in the MMRM analysis.
Calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit and treatment by visit interaction included as explanatory variables and the baseline score included as a covariate along with the baseline score by visit interaction. Only visits where change from baseline is available for at least one patient in both treatment arms are included in the analysis.
Treatment, visit and treatment by visit interaction are fixed effects in the model, a Toeplitz with heterogeneity covariance matrix is used to model within-subject error. SMD = standardised mean difference. * p<0.05. [c] Based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3).
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/mmrmpr.sas gmmrmprba 07FEB2023:09:26 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.5.2.1 SOLO1: Mean (+/- SD) score for EQ-5D visuelle Analogskala across timepoints, by treatment group
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/fmeanpr.sas gfmeanprbaa 02FEB2023:12:31 kvbv306

Table 2.5.3.1 SOLO1: Summary of EQ-5D Visual analogue scale results across timepoints, by treatment group
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
EQ-5D visuelle Analogskala	Olaparib 300 mg bd (N=300)	Baseline	284	78,6	15,30	10	80,0	100
		Woche 5 (Tag 29)	272	76,1	16,05	1	80,0	100
		Woche 13 (Tag 85)	254	79,2	14,33	20	80,0	100
		Woche 25 (Tag 169)	252	81,9	13,55	20	85,0	100
		Woche 37 (Tag 253)	250	80,8	15,38	10	85,0	100
		Woche 49 (Tag 337)	237	81,5	14,71	30	85,0	100
		Woche 61 (Tag 421)	229	81,8	15,14	0	85,0	100
		Woche 73 (Tag 505)	212	81,9	14,38	20	85,0	100
		Woche 85 (Tag 589)	218	81,9	14,40	20	85,0	100
		Woche 97 (Tag 673)	204	81,3	15,36	10	85,0	100
		Woche 109 (Tag 757)	203	82,0	15,05	10	85,0	100
		Woche 121 (Tag 841)	163	82,2	14,65	35	85,0	100
		Woche 133 (Tag 925)	151	81,3	17,02	20	85,0	100
		Woche 145 (Tag 1009)	144	81,6	16,62	20	89,0	100
		Woche 157 (Tag 1093)	130	82,3	14,67	35	86,5	100
		Woche 169 (Tag 1177)	80	80,6	16,92	5	85,0	100
		Woche 193 (Tag 1345)	70	83,2	16,77	30	90,0	100
		Woche 217 (Tag 1513)	30	85,3	12,66	50	90,0	98
		Woche 241 (Tag 1681)	2	96,5	2,12	95	96,5	98
EQ-5D visuelle Analogskala	Placebo bd (N=150)	Baseline	147	81,5	13,10	35	80,0	100
		Woche 5 (Tag 29)	138	82,4	12,46	45	85,0	100
		Woche 13 (Tag 85)	135	83,9	12,01	35	85,0	100
		Woche 25 (Tag 169)	131	83,4	13,74	30	85,0	100
		Woche 37 (Tag 253)	121	83,7	11,63	45	85,0	100
		Woche 49 (Tag 337)	115	81,5	13,63	40	85,0	100
		Woche 61 (Tag 421)	102	82,1	14,82	25	85,0	100
		Woche 73 (Tag 505)	93	81,9	15,45	30	85,0	100

Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.
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Table 2.5.3.1 SOLO1: Summary of EQ-5D Visual analogue scale results across timepoints, by treatment group
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 85 (Tag 589)	93	81,4	15,02	30	85,0	100
		Woche 97 (Tag 673)	83	81,5	17,93	10	85,0	100
		Woche 109 (Tag 757)	82	81,8	17,52	8	87,0	100
		Woche 121 (Tag 841)	69	83,2	13,44	45	90,0	100
		Woche 133 (Tag 925)	66	81,4	15,39	40	85,0	100
		Woche 145 (Tag 1009)	56	81,6	16,17	30	85,0	100
		Woche 157 (Tag 1093)	50	81,0	18,10	20	82,5	100
		Woche 169 (Tag 1177)	43	78,0	18,66	0	80,0	100
		Woche 193 (Tag 1345)	30	82,1	14,26	35	85,0	100
		Woche 217 (Tag 1513)	10	81,5	9,73	65	85,0	90

Timepoint based on the windowing algorithm applied to all the visits (incl. post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/smeanpr.sas gsmeanprb 02FEB2023:12:30 kvbv306

Table 2.6 SOLO1: Summary of censoring reasons for PRO endpoints
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Parameter	Deterioration/censoring reason	Olaparib 300mg bd (N=300)	Placebo bd (N=150)
FACT-O Gesamtscore	Deterioration	43 (14,3)	24 (16,0)
	Deterioration confirmed on 2 subsequent visits	28 (9,3)	12 (8,0)
	Deterioration at last observation visit	15 (5,0)	12 (8,0)
	Censored due to last observation (no deterioration)	142 (47,3)	79 (52,7)
	Censored due to 2 or more missed assessments	79 (26,3)	38 (25,3)
	Censored due to PFS-event [a]	12 (4,0)	4 (2,7)
	Censored due to PROs collection limit at 36 months [a]	10 (3,3)	6 (4,0)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	22 (7,3)	6 (4,0)
	Censored due to death	14 (4,7)	3 (2,0)
	Total	300 (100)	150 (100)
FACT-O Subskala physisches Wohlbefinden (PWB)	Deterioration	74 (24,7)	32 (21,3)
	Deterioration confirmed on 2 subsequent visits	60 (20,0)	21 (14,0)
	Deterioration at last observation visit	14 (4,7)	11 (7,3)
	Censored due to last observation (no deterioration)	130 (43,3)	77 (51,3)
	Censored due to 2 or more missed assessments	65 (21,7)	34 (22,7)
	Censored due to PFS-event [a]	10 (3,3)	4 (2,7)
	Censored due to PROs collection limit at 36 months [a]	6 (2,0)	5 (3,3)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	19 (6,3)	4 (2,7)
	Censored due to death	12 (4,0)	3 (2,0)
	Total	300 (100)	150 (100)
FACT-O Subskala soziales Wohlbefinden (SWB)	Deterioration	81 (27,0)	35 (23,3)
	Deterioration confirmed on 2 subsequent visits	73 (24,3)	29 (19,3)
	Deterioration at last observation visit	8 (2,7)	6 (4,0)
	Censored due to last observation (no deterioration)	118 (39,3)	69 (46,0)
	Censored due to 2 or more missed assessments	64 (21,3)	35 (23,3)
	Censored due to PFS-event [a]	8 (2,7)	4 (2,7)
	Censored due to PROs collection limit at 36 months [a]	10 (3,3)	7 (4,7)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	19 (6,3)	4 (2,7)
	Censored due to death	18 (6,0)	7 (4,7)
	Total	300 (100)	150 (100)
FACT-O Subskala funktionales Wohlbefinden (FWB)	Deterioration	65 (21,7)	29 (19,3)
	Deterioration confirmed on 2 subsequent visits	49 (16,3)	21 (14,0)
	Deterioration at last observation visit	16 (5,3)	8 (5,3)
	Censored due to last observation (no deterioration)	132 (44,0)	77 (51,3)
	Censored due to 2 or more missed assessments	72 (24,0)	37 (24,7)
	Censored due to PFS-event [a]	12 (4,0)	4 (2,7)
	Censored due to PROs collection limit at 36 months [a]	10 (3,3)	6 (4,0)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	19 (6,3)	4 (2,7)
	Censored due to death	12 (4,0)	3 (2,0)
	Total	300 (100)	150 (100)

[a] Subject can potentially contribute to either one or both categories.
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Table 2.6 SOLO1: Summary of censoring reasons for PRO endpoints
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Parameter	Deterioration/censoring reason	Olaparib 300mg bd (N=300)	Placebo bd (N=150)
FACT-O Subskala emotionales Wohlbefinden (EWB)	Deterioration	66 (22,0)	39 (26,0)
	Deterioration confirmed on 2 subsequent visits	49 (16,3)	28 (18,7)
	Deterioration at last observation visit	17 (5,7)	11 (7,3)
	Censored due to last observation (no deterioration)	133 (44,3)	70 (46,7)
	Censored due to 2 or more missed assessments	74 (24,7)	34 (22,7)
	Censored due to PFS-event [a]	11 (3,7)	4 (2,7)
	Censored due to PROs collection limit at 36 months [a]	11 (3,7)	4 (2,7)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	18 (6,0)	4 (2,7)
	Censored due to death	9 (3,0)	3 (2,0)
	Total	300 (100)	150 (100)
FACT-O Eierstockkrebs-spezifische Subskala (OCS)	Deterioration	44 (14,7)	23 (15,3)
	Deterioration confirmed on 2 subsequent visits	29 (9,7)	9 (6,0)
	Deterioration at last observation visit	15 (5,0)	14 (9,3)
	Censored due to last observation (no deterioration)	148 (49,3)	79 (52,7)
	Censored due to 2 or more missed assessments	75 (25,0)	38 (25,3)
	Censored due to PFS-event [a]	10 (3,3)	4 (2,7)
	Censored due to PROs collection limit at 36 months [a]	10 (3,3)	6 (4,0)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	18 (6,0)	4 (2,7)
	Censored due to death	15 (5,0)	6 (4,0)
	Total	300 (100)	150 (100)
EQ-5D visuelle Analogskala	Deterioration	53 (17,7)	41 (27,3)
	Deterioration confirmed on 2 subsequent visits	42 (14,0)	30 (20,0)
	Deterioration at last observation visit	11 (3,7)	11 (7,3)
	Censored due to last observation (no deterioration)	137 (45,7)	68 (45,3)
	Censored due to 2 or more missed assessments	72 (24,0)	34 (22,7)
	Censored due to PFS-event [a]	8 (2,7)	3 (2,0)
	Censored due to PROs collection limit at 36 months [a]	10 (3,3)	7 (4,7)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	23 (7,7)	3 (2,0)
	Censored due to death	15 (5,0)	4 (2,7)
	Total	300 (100)	150 (100)

[a] Subject can potentially contribute to either one or both categories.
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Table 2.7.1 SOLO1: Summary of compliance with Total FACT-O by planned visit
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Group	Analysis visit [f]	Expected [a]	Received [b]	Evaluable [c]	Compliance rate (%) [d]	Evaluability rate (%) [e]
Olaparib 300 mg bd (N=300)	Baseline	298	286	286	96,0	100,0
	Wk 5 (D29)	298	269	269	90,3	100,0
	Wk 13 (D85)	291	253	253	86,9	100,0
	Wk 25 (D169)	288	247	247	85,8	100,0
	Wk 37 (D253)	284	245	245	86,3	100,0
	Wk 49 (D337)	276	237	237	85,9	100,0
	Wk 61 (D421)	273	226	226	82,8	100,0
	Wk 73 (D505)	266	207	207	77,8	100,0
	Wk 85 (D589)	263	212	212	80,6	100,0
	Wk 97 (D673)	255	204	204	80,0	100,0
	Wk 109 (D757)	244	201	201	82,4	100,0
	Wk 121 (D841)	232	165	165	71,1	100,0
	Wk 133 (D925)	216	147	147	68,1	100,0
	Wk 145 (D1009)	200	139	139	69,5	100,0
	Wk 157 (D1093)	185	125	125	67,6	100,0
	Wk 169 (D1177)	178	77	77	43,3	100,0
	Wk 193 (D1345)	117	71	71	60,7	100,0
	Wk 217 (D1513)	49	28	28	57,1	100,0
	Wk 241 (D1681)	3	2	2	66,7	100,0

[a] Expected = number of patients still on study.
[b] Received = any part of FACT-O form received back.
[c] Evaluable = FACT-O Total score could be calculated.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
[f] Based on the windowing algorithm applied to all the visits (including post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

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Table 2.7.1 SOLO1: Summary of compliance with Total FACT-O by planned visit
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Group	Analysis visit [f]	Expected [a]	Received [b]	Evaluable [c]	Compliance rate (%) [d]	Evaluability rate (%) [e]
Placebo bd (N=150)	Baseline	149	144	144	96,6	100,0
	Wk 5 (D29)	149	137	137	91,9	100,0
	Wk 13 (D85)	148	134	134	90,5	100,0
	Wk 25 (D169)	147	129	129	87,8	100,0
	Wk 37 (D253)	143	116	116	81,1	100,0
	Wk 49 (D337)	141	108	108	76,6	100,0
	Wk 61 (D421)	130	97	97	74,6	100,0
	Wk 73 (D505)	129	91	91	70,5	100,0
	Wk 85 (D589)	126	91	91	72,2	100,0
	Wk 97 (D673)	118	83	83	70,3	100,0
	Wk 109 (D757)	119	81	81	68,1	100,0
	Wk 121 (D841)	110	68	68	61,8	100,0
	Wk 133 (D925)	104	66	66	63,5	100,0
	Wk 145 (D1009)	91	54	54	59,3	100,0
	Wk 157 (D1093)	89	49	49	55,1	100,0
	Wk 169 (D1177)	84	43	43	51,2	100,0
	Wk 193 (D1345)	54	31	31	57,4	100,0
	Wk 217 (D1513)	17	9	9	52,9	100,0

[a] Expected = number of patients still on study.
[b] Received = any part of FACT-O form received back.
[c] Evaluable = FACT-O Total score could be calculated.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
[f] Based on the windowing algorithm applied to all the visits (including post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

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Table 2.7.1 SOLO1: Summary of compliance with Total FACT-O by planned visit
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Group	Analysis visit [f]	Expected [a]	Received [b]	Evaluable [c]	Compliance rate (%) [d]	Evaluability rate (%) [e]

[a] Expected = number of patients still on study.
[b] Received = any part of FACT-O form received back.
[c] Evaluable = FACT-O Total score could be calculated.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
[f] Based on the windowing algorithm applied to all the visits (including post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.
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Table 2.7.2 SOLO1: Summary of compliance with EQ-5D VAS by planned visit
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Group	Analysis visit [f]	Expected [a]	Received [b]	Evaluable [c]	Compliance rate (%) [d]	Evaluability rate (%) [e]
Olaparib 300 mg bd (N=300)	Baseline	298	284	284	95,3	100,0
	Wk 5 (D29)	298	272	272	91,3	100,0
	Wk 13 (D85)	291	254	254	87,3	100,0
	Wk 25 (D169)	288	252	252	87,5	100,0
	Wk 37 (D253)	284	250	250	88,0	100,0
	Wk 49 (D337)	276	237	237	85,9	100,0
	Wk 61 (D421)	273	229	229	83,9	100,0
	Wk 73 (D505)	266	212	212	79,7	100,0
	Wk 85 (D589)	263	218	218	82,9	100,0
	Wk 97 (D673)	255	204	204	80,0	100,0
	Wk 109 (D757)	244	203	203	83,2	100,0
	Wk 121 (D841)	232	163	163	70,3	100,0
	Wk 133 (D925)	216	151	151	69,9	100,0
	Wk 145 (D1009)	200	144	144	72,0	100,0
	Wk 157 (D1093)	185	130	130	70,3	100,0
	Wk 169 (D1177)	178	80	80	44,9	100,0
	Wk 193 (D1345)	117	70	70	59,8	100,0
	Wk 217 (D1513)	49	30	30	61,2	100,0
	Wk 241 (D1681)	3	2	2	66,7	100,0

[a] Expected = number of patients still on study.
[b] Received = any part of EQ-5D-5L form received back.
[c] Evaluable = EQ-5D VAS score could be calculated.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
[f] Based on the windowing algorithm applied to all the visits (including post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

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Table 2.7.2 SOLO1: Summary of compliance with EQ-5D VAS by planned visit
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Group	Analysis visit [f]	Expected [a]	Received [b]	Evaluable [c]	Compliance rate (%) [d]	Evaluability rate (%) [e]
Placebo bd (N=150)	Baseline	149	147	147	98,7	100,0
	Wk 5 (D29)	149	138	138	92,6	100,0
	Wk 13 (D85)	148	135	135	91,2	100,0
	Wk 25 (D169)	147	131	131	89,1	100,0
	Wk 37 (D253)	143	121	121	84,6	100,0
	Wk 49 (D337)	141	115	115	81,6	100,0
	Wk 61 (D421)	130	102	102	78,5	100,0
	Wk 73 (D505)	129	93	93	72,1	100,0
	Wk 85 (D589)	126	93	93	73,8	100,0
	Wk 97 (D673)	118	83	83	70,3	100,0
	Wk 109 (D757)	119	82	82	68,9	100,0
	Wk 121 (D841)	110	69	69	62,7	100,0
	Wk 133 (D925)	104	66	66	63,5	100,0
	Wk 145 (D1009)	91	56	56	61,5	100,0
	Wk 157 (D1093)	89	50	50	56,2	100,0
	Wk 169 (D1177)	84	43	43	51,2	100,0
	Wk 193 (D1345)	54	30	30	55,6	100,0
	Wk 217 (D1513)	17	10	10	58,8	100,0

[a] Expected = number of patients still on study.
[b] Received = any part of EQ-5D-5L form received back.
[c] Evaluable = EQ-5D VAS score could be calculated.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
[f] Based on the windowing algorithm applied to all the visits (including post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.

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Table 2.7.2 SOLO1: Summary of compliance with EQ-5D VAS by planned visit
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Group	Analysis visit [f]	Expected [a]	Received [b]	Evaluable [c]	Compliance rate (%) [d]	Evaluability rate (%) [e]

[a] Expected = number of patients still on study.
[b] Received = any part of EQ-5D-5L form received back.
[c] Evaluable = EQ-5D VAS score could be calculated.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
[f] Based on the windowing algorithm applied to all the visits (including post-treatment follow-up visits) constructed as per the safety visit windows (SAP section 3.3.3). For example: Week 5 (D29), days: 2 – 57, Week 13 (D85), days: 58 – 127, Week 25 (D169), days: 128 – 211, etc.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.8.1 SOLO1: Summary of analysis of Time to sustained deterioration in FACT-O
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
FACT-O Gesamtscore	300	39 (13,0)	NE [NE; NE]	150	22 (14,7)	NE [NE; NE]	0,81	[0,49; 1,40]	0,5659
FACT-O Subskala physisches Wohlbefinden (PWB)	300	41 (13,7)	NE [NE; NE]	150	26 (17,3)	NE [NE; NE]	0,71	[0,44; 1,18]	0,2251
FACT-O Subskala soziales Wohlbefinden (SWB)	300	58 (19,3)	NE [NE; NE]	150	30 (20,0)	52,1 [44,0; NE]	0,89	[0,58; 1,40]	0,6606
FACT-O Subskala funktionales Wohlbefinden (FWB)	300	54 (18,0)	NE [NE; NE]	150	28 (18,7)	NE [NE; NE]	0,85	[0,54; 1,37]	0,5699
FACT-O Subskala emotionales Wohlbefinden (EWB)	300	57 (19,0)	49,9 [48,1; NE]	150	31 (20,7)	NE [NE; NE]	0,82	[0,54; 1,29]	0,4452
FACT-O Eierstockkrebs-spezifische Subskala (OCS)	300	34 (11,3)	NE [NE; NE]	150	24 (16,0)	50,7 [46,3; NE]	0,66	[0,39; 1,13]	0,1654

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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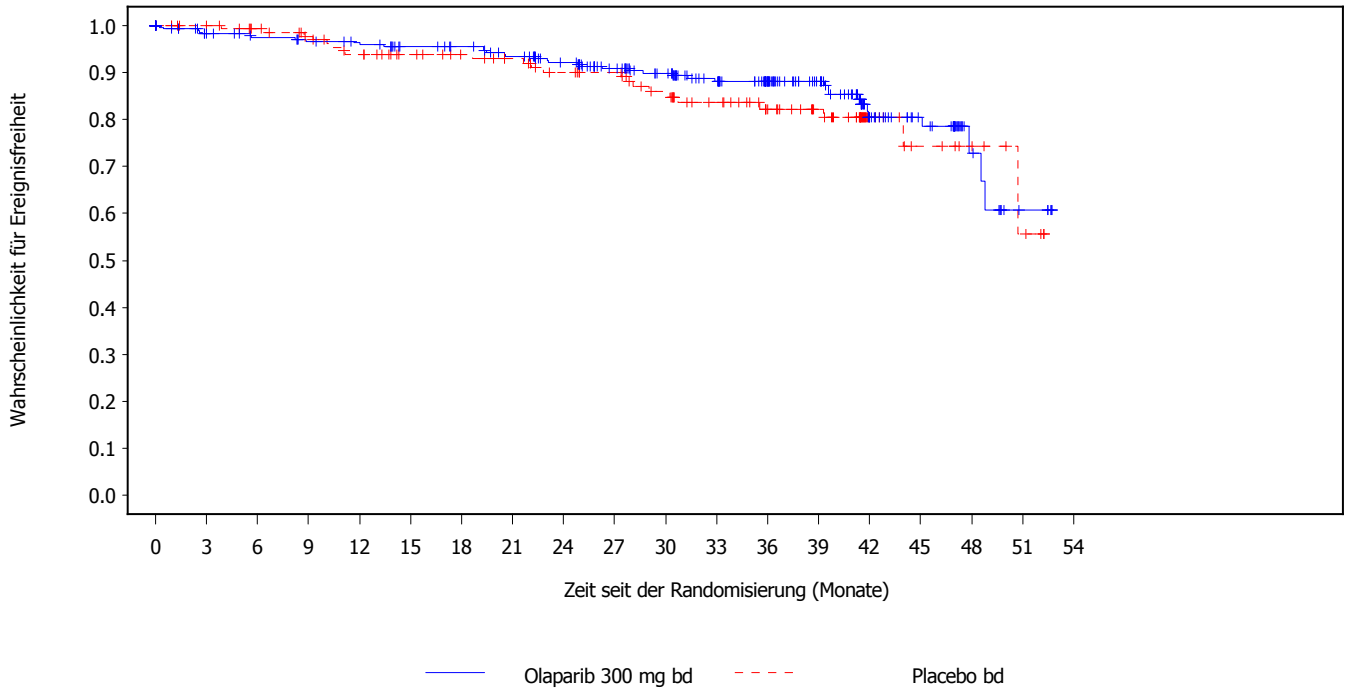
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.8.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	266	259	254	250	240	236	227	214	193	177	153	125	101	54	41	13	4	0	Olaparib 300 mg bd
150	139	133	126	118	110	105	100	93	89	79	67	56	46	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
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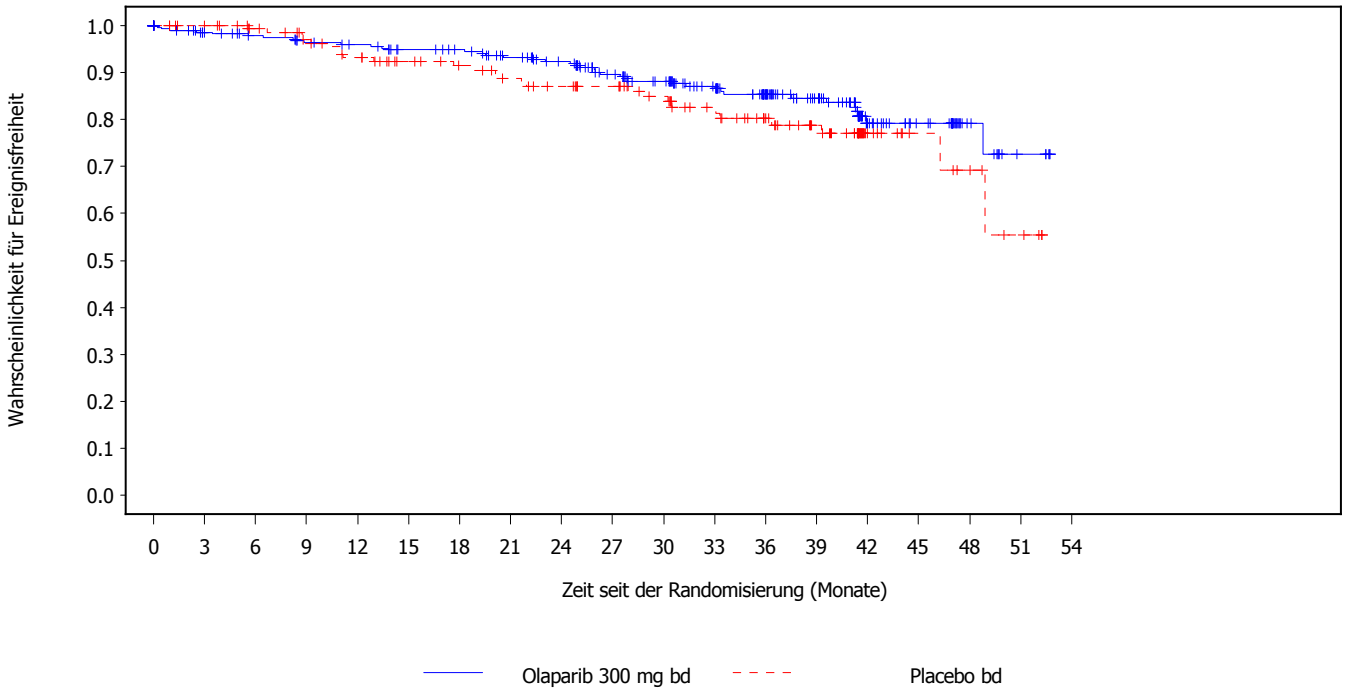
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.8.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala physisches Wohlbefinden (PWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	270	262	254	250	241	237	226	215	191	177	152	125	101	53	40	13	4	0	Olaparib 300 mg bd
150	141	134	126	118	109	104	98	93	88	79	68	57	45	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
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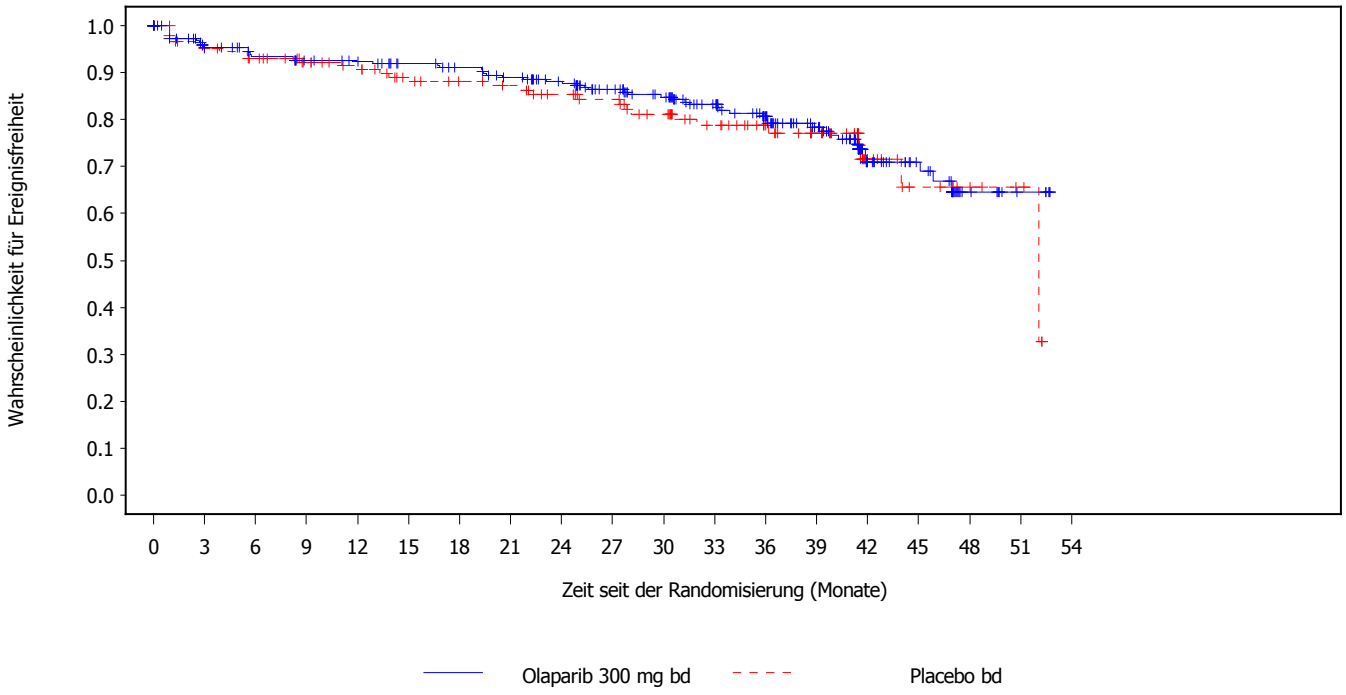
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.8.2.3 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala soziales Wohlbefinden (SWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



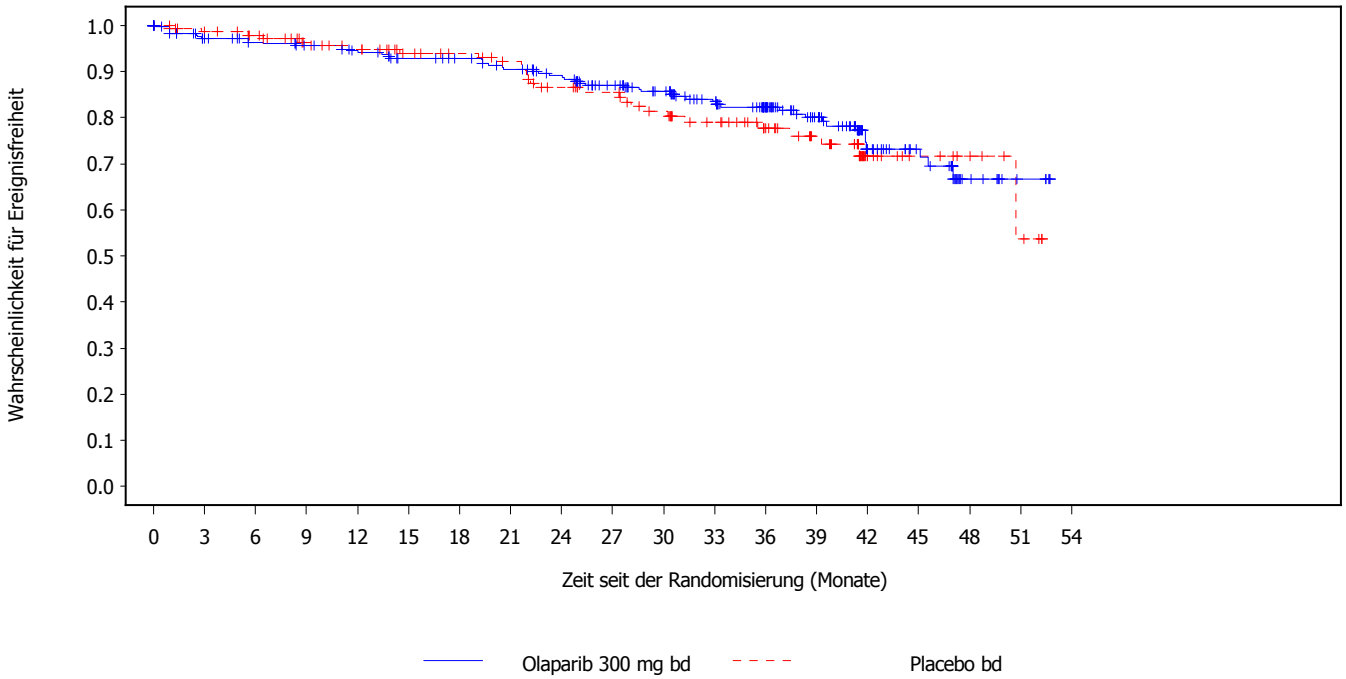
Anzahl an Patienten unter Risiko:

300	258	247	240	236	227	221	212	200	180	165	142	117	95	47	35	11	4	0	Olaparib 300 mg bd
150	134	128	119	112	103	98	95	88	83	74	61	51	42	16	9	6	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbac 07FEB2023:09:28 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.8.2.4 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala funktionales Wohlbefinden (FWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



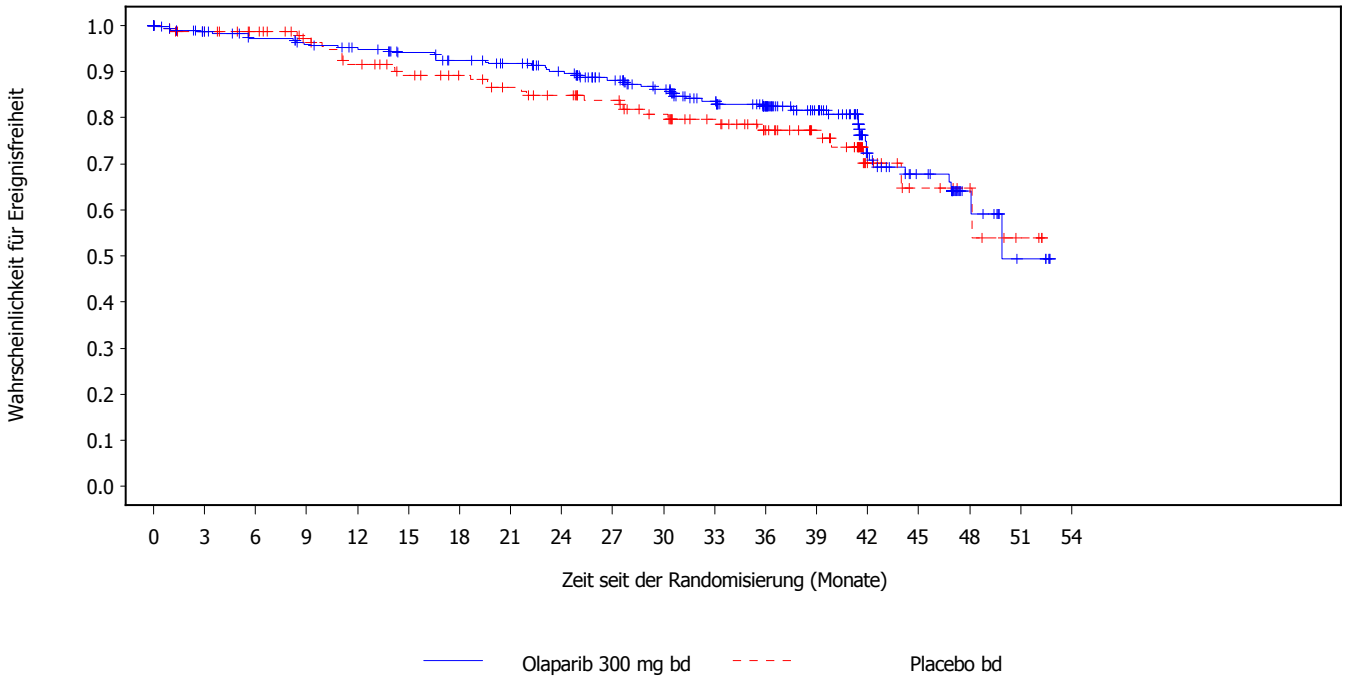
Anzahl an Patienten unter Risiko:

300	265	257	251	244	234	230	221	211	190	173	150	123	96	51	39	12	4	0	Olaparib 300 mg bd
150	139	134	123	117	108	104	99	89	84	75	64	53	42	16	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbad 07FEB2023:09:28 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.8.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala emotionales Wohlbefinden (EWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



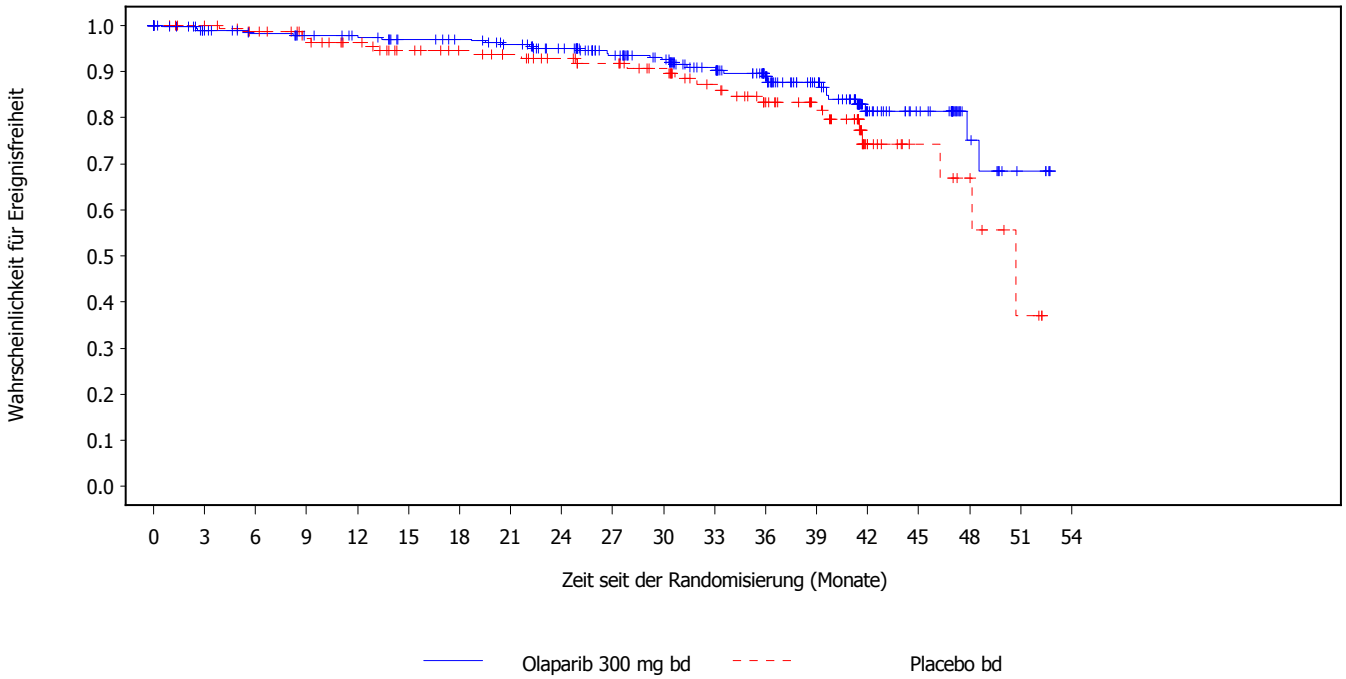
Anzahl an Patienten unter Risiko:

300	269	260	254	248	238	230	223	210	189	172	150	124	97	51	39	13	4	0	Olaparib 300 mg bd
150	139	134	125	116	108	103	97	92	86	77	67	55	44	17	10	7	2	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swbae 07FEB2023:09:28 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.8.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Eierstockkrebs-spezifische Subskala (OCS)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	270	262	256	252	243	239	231	218	195	180	156	127	100	53	40	12	4	0	Olaparib 300 mg bd
150	141	135	127	120	111	106	101	95	90	82	69	57	47	17	10	7	2	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

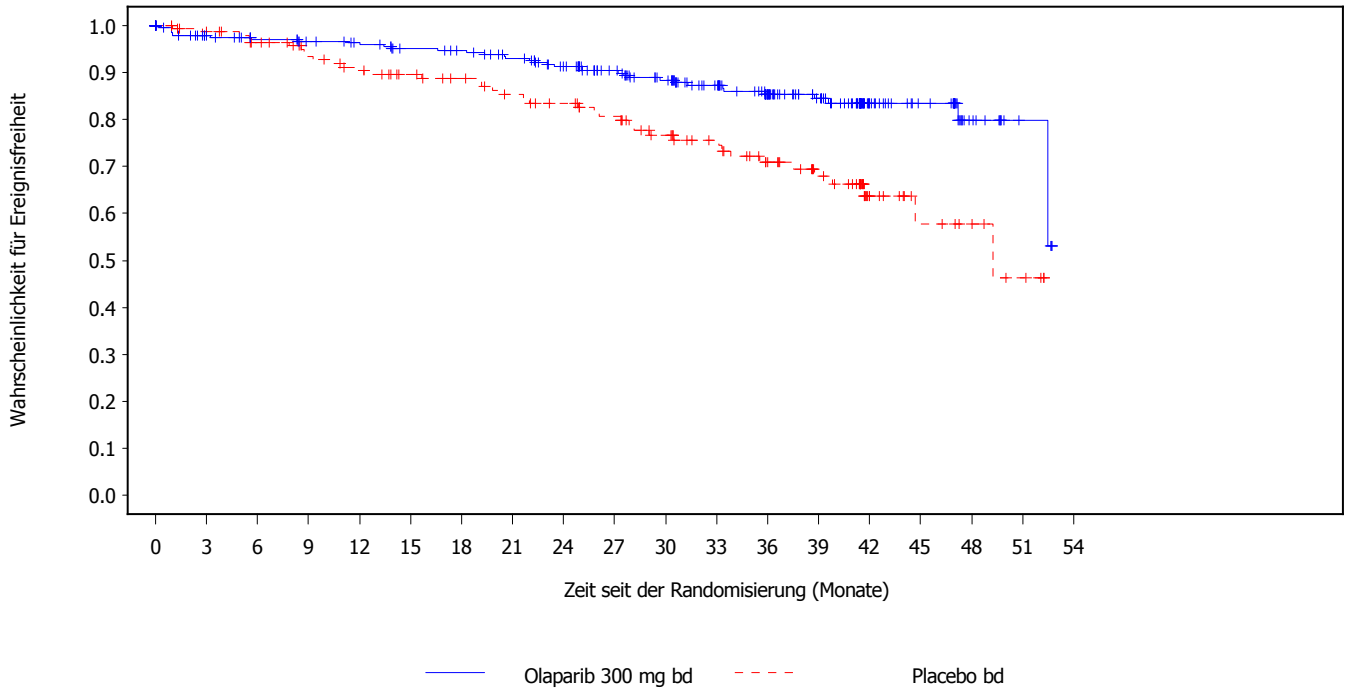
Table 2.8.3 SOLO1: Summary of analysis of Time to sustained deterioration in EQ-5D VAS
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
EQ-5D visuelle Analogskala	300	37 (12,3)	NE [NE; NE]	150	39 (26,0)	49,2 [44,7; NE]	0,42	[0,26; 0,66]	0,0001*

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr_sw.sas gttemainpr_swab 07FEB2023:09:28 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.8.4.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	263	253	247	242	233	229	220	206	186	170	147	120	97	51	39	13	3	0	Olaparib 300 mg bd
150	140	133	123	117	109	104	97	92	85	74	65	54	43	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 2.9.1 SOLO1: Summary of analysis of Time to sustained deterioration in FACT-O
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
FACT-O Gesamtscore	300	13 (4,3)	NE [NE; NE]	150	6 (4,0)	NE [NE; NE]	0,99	[0,39; 2,81]	0,9569
FACT-O Subskala physisches Wohlbefinden (PWB)	300	20 (6,7)	NE [NE; NE]	150	11 (7,3)	NE [NE; NE]	0,81	[0,39; 1,75]	0,6185
FACT-O Subskala soziales Wohlbefinden (SWB)	300	39 (13,0)	NE [NE; NE]	150	19 (12,7)	NE [NE; NE]	0,98	[0,58; 1,74]	0,9665
FACT-O Subskala funktionales Wohlbefinden (FWB)	300	26 (8,7)	NE [NE; NE]	150	15 (10,0)	NE [NE; NE]	0,80	[0,43; 1,55]	0,5544
FACT-O Subskala emotionales Wohlbefinden (EWB)	300	23 (7,7)	NE [NE; NE]	150	11 (7,3)	NE [NE; NE]	1,00	[0,50; 2,14]	0,9716
FACT-O Eierstockkrebs-spezifische Subskala (OCS)	300	14 (4,7)	NE [NE; NE]	150	6 (4,0)	NE [NE; NE]	1,10	[0,44; 3,12]	0,7924

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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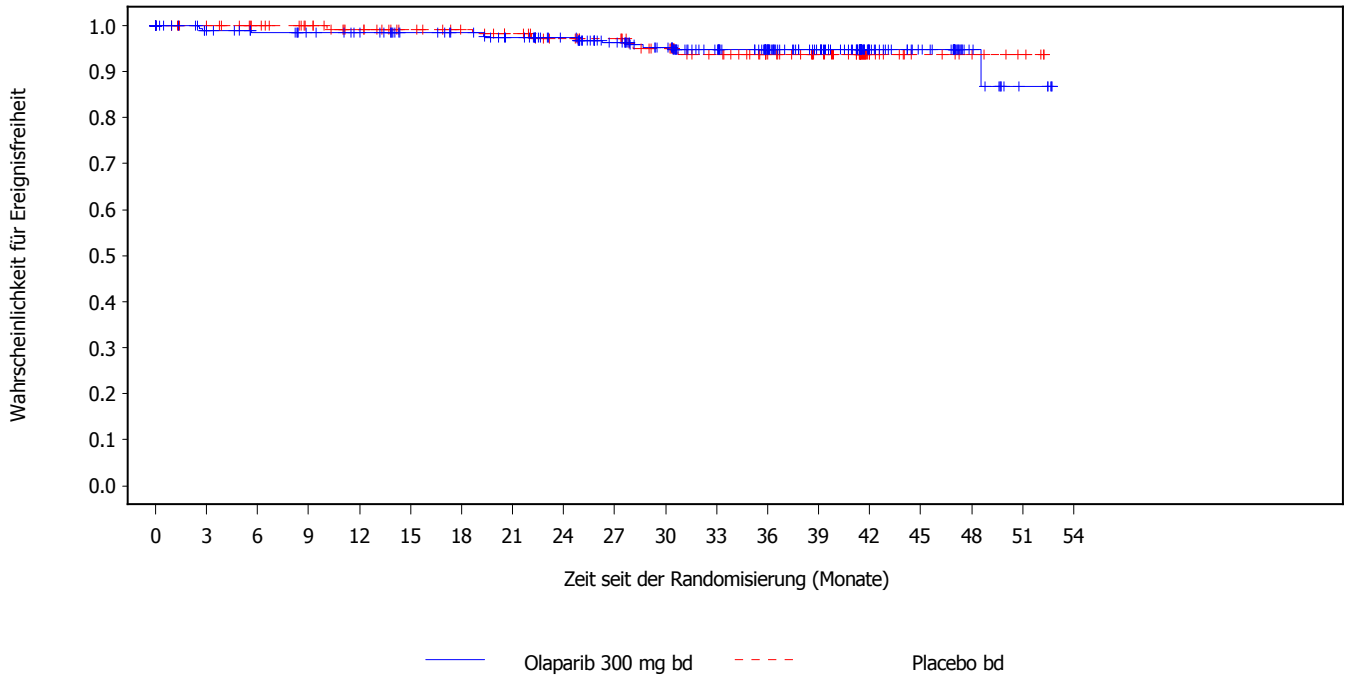
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.9.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	266	259	254	250	240	236	227	214	193	177	153	125	101	54	41	13	4	0	Olaparib 300 mg bd
150	139	133	126	118	110	105	100	93	89	79	67	56	46	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
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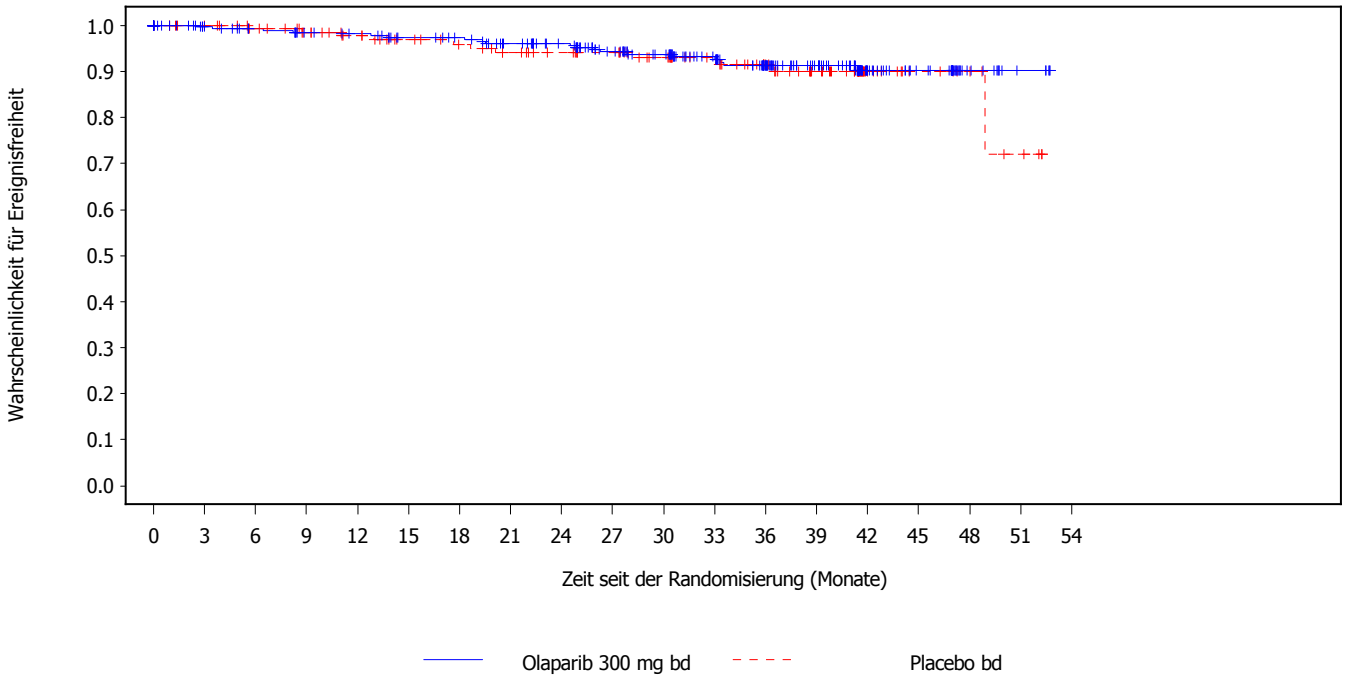
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.9.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala physisches Wohlbefinden (PWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	270	262	254	250	241	237	226	215	191	177	152	125	101	53	40	13	4	0	Olaparib 300 mg bd
150	141	134	126	118	109	104	98	93	88	79	68	57	45	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
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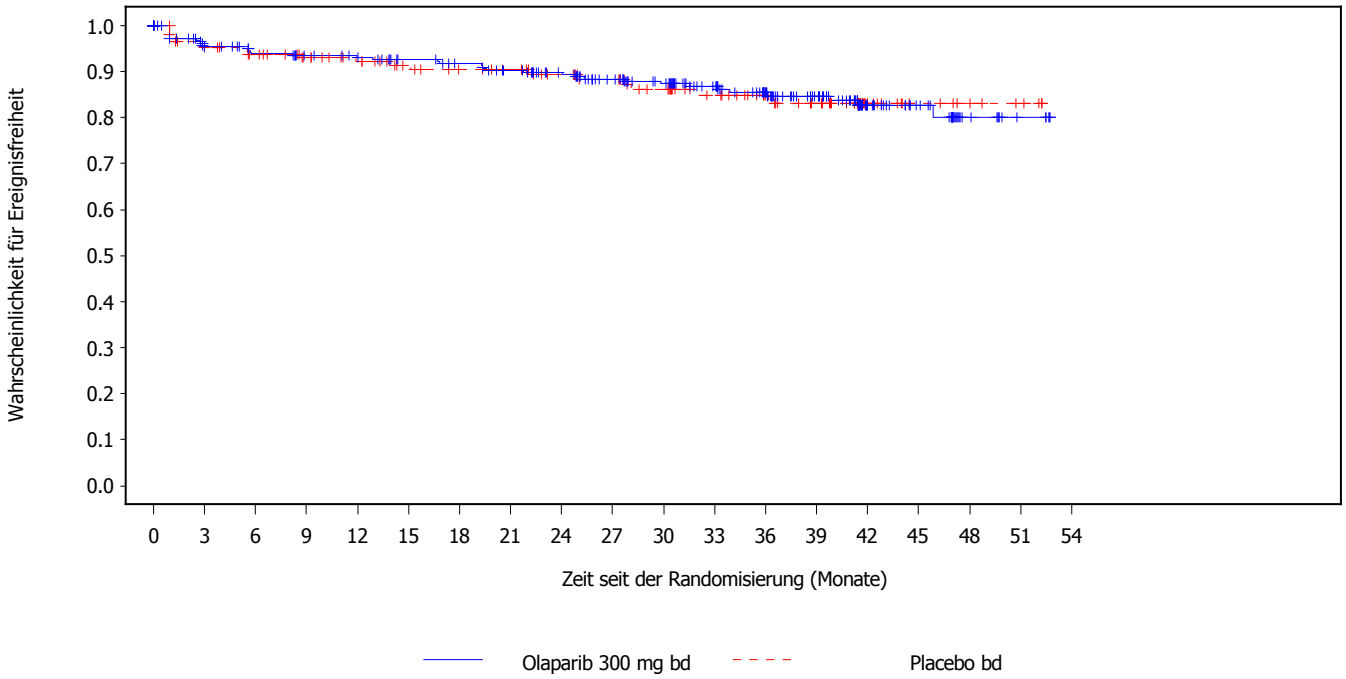
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.9.2.3 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala soziales Wohlbefinden (SWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	258	247	240	236	227	221	212	200	180	165	142	117	95	47	35	11	4	0	Olaparib 300 mg bd
150	134	128	119	112	103	98	95	88	83	74	61	51	42	16	9	6	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
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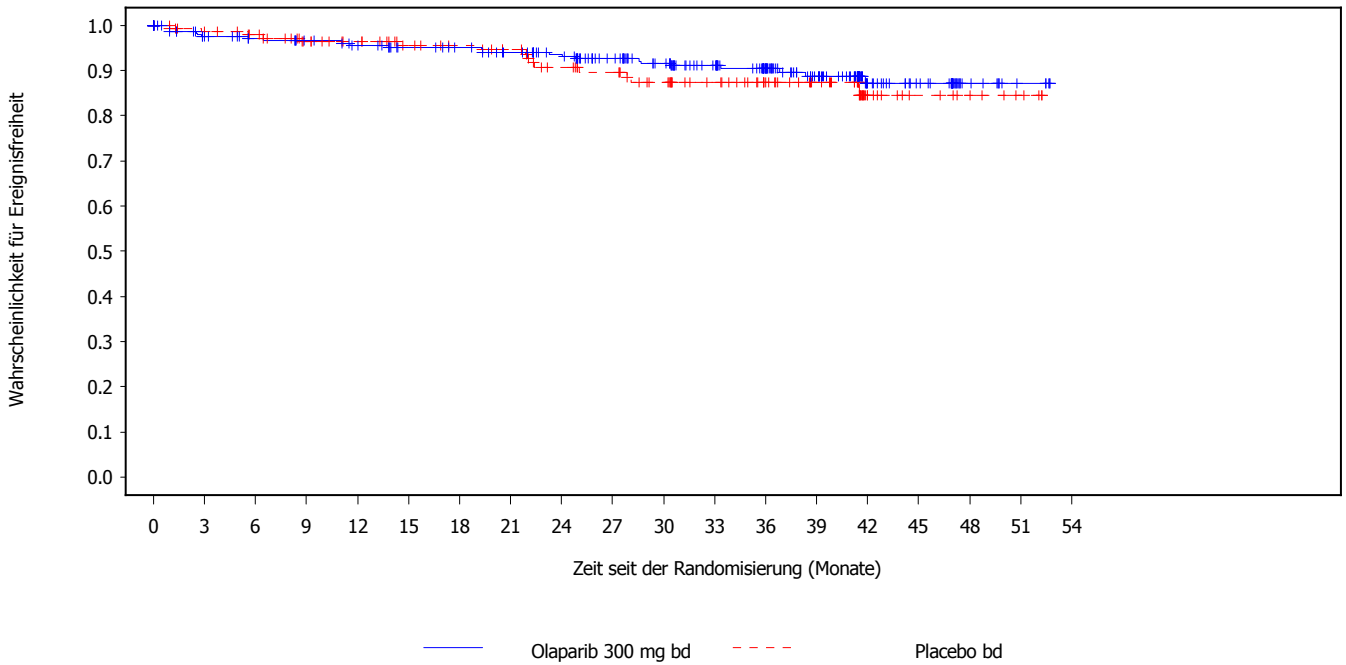
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.9.2.4 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala funktionales Wohlbefinden (FWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



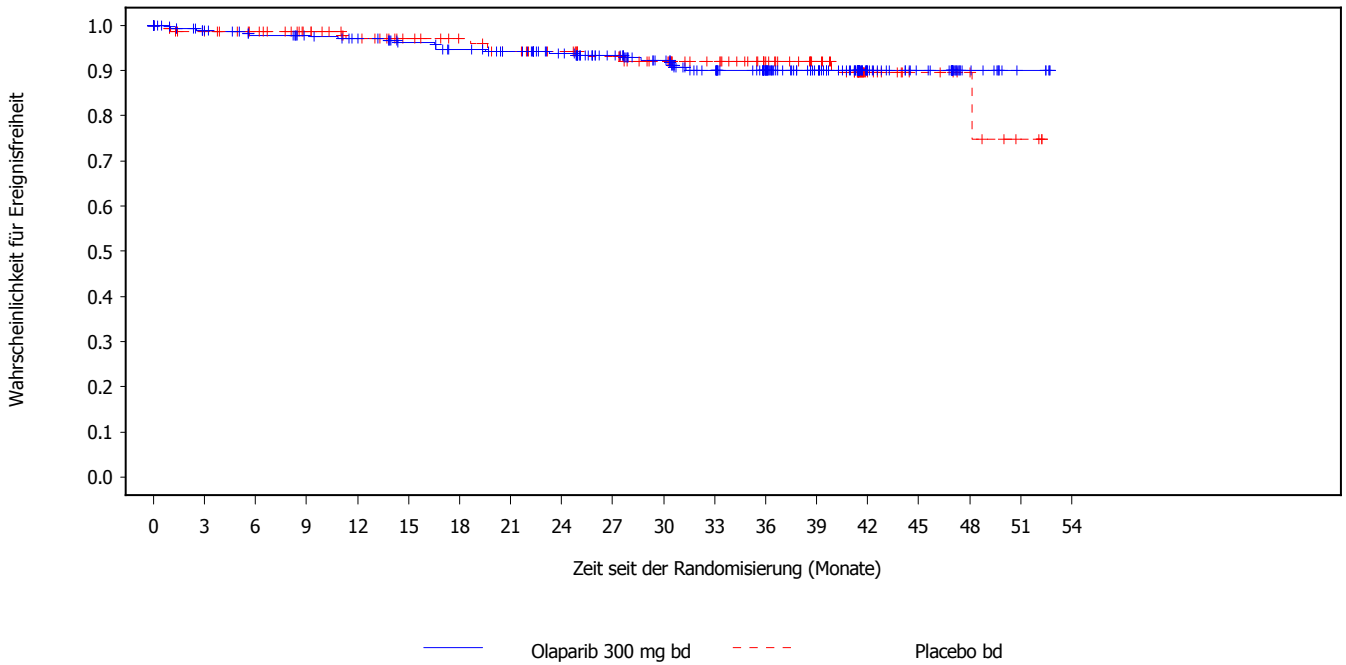
Anzahl an Patienten unter Risiko:

300	265	257	251	244	234	230	221	211	190	173	150	123	96	51	39	12	4	0	Olaparib 300 mg bd
150	139	134	123	117	108	104	99	89	84	75	64	53	42	16	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2bad 07FEB2023:09:29 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.9.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Subskala emotionales Wohlbefinden (EWB)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	269	260	254	248	238	230	223	210	189	172	150	124	97	51	39	13	4	0 Olaparib 300 mg bd
150	139	134	125	116	108	103	97	92	86	77	67	55	44	17	10	7	2	0 Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
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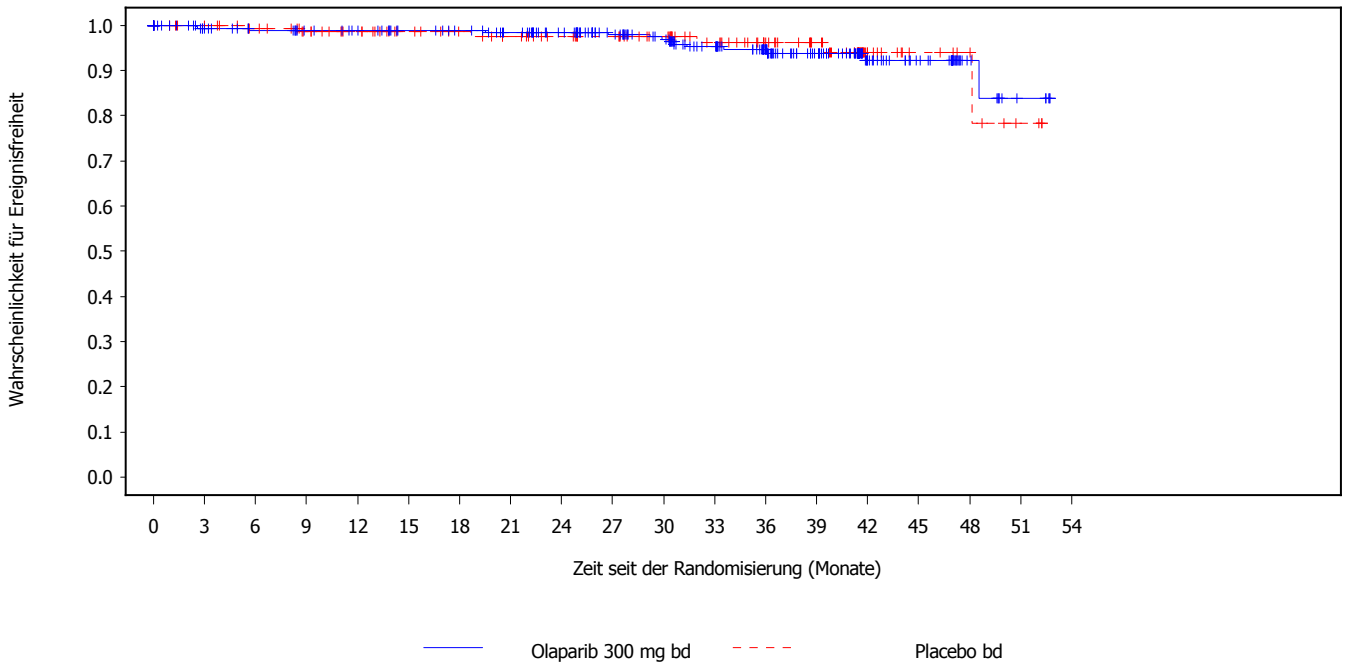
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.9.2.6 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung FACT-O Eierstockkrebs-spezifische Subskala (OCS)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	270	262	256	252	243	239	231	218	195	180	156	127	100	53	40	12	4	0	Olaparib 300 mg bd
150	141	135	127	120	111	106	101	95	90	82	69	57	47	17	10	7	2	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2baf 07FEB2023:09:29 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

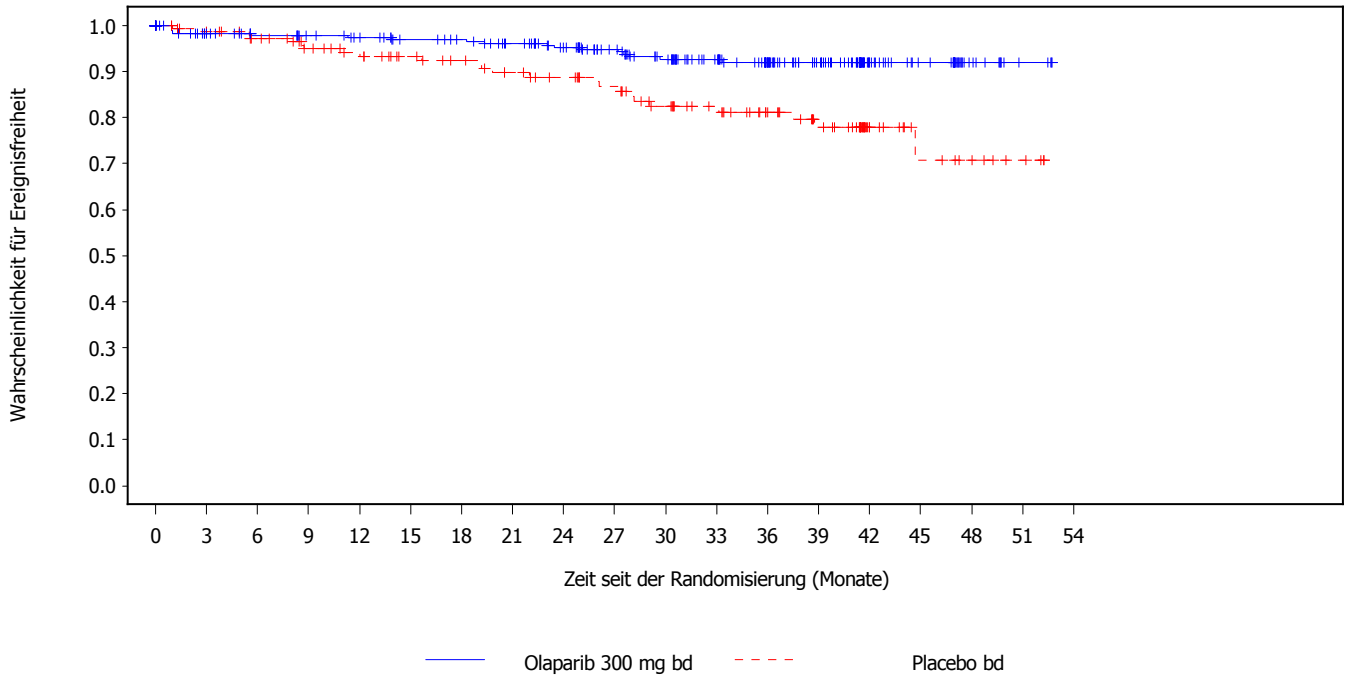
Table 2.9.3 SOLO1: Summary of analysis of Time to sustained deterioration in EQ-5D VAS
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
EQ-5D visuelle Analogskala	300	18 (6,0)	NE [NE; NE]	150	24 (16,0)	NE [NE; NE]	0,34	[0,18; 0,63]	0,0003*

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainpr_sw2.sas gttemainpr_sw2ab 07FEB2023:09:29 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.9.4.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	263	253	247	242	233	229	220	206	186	170	147	120	97	51	39	13	3	0	Olaparib 300 mg bd
150	140	133	123	117	109	104	97	92	85	74	65	54	43	17	10	7	3	0	Placebo bd

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
Sensitivity Analysis - censoring patients with only one worsening post baseline and no subsequent observations.
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2.2.2: Subgruppen

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.10.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur Verschlechterung FACT-O Gesamtscore
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	39 (14,8)	NE [NE; NE]	130	19 (14,6)	50,7 [50,7; NE]	1,00	[0,59; 1,78]	0,9906
>=65 Jahre	37	4 (10,8)	47,9 [41,9; NE]	20	5 (25,0)	NE [NE; NE]	0,48	[0,12; 1,82]	0,2734
Interaktion p-Wert									0,3075
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	34 (13,8)	47,9 [47,9; NE]	124	22 (17,7)	50,7 [50,7; NE]	0,82	[0,48; 1,43]	0,4789
Partielles Ansprechen	53	9 (17,0)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	1,57	[0,40; 10,31]	0,5465
Interaktion p-Wert									0,4121
ECOG PS Status									
Normale Aktivität	221	35 (15,8)	47,9 [47,9; NE]	115	15 (13,0)	NE [NE; NE]	1,24	[0,69; 2,36]	0,4781
Eingeschränkte Aktivität	79	8 (10,1)	NE [NE; NE]	34	9 (26,5)	NE [NE; NE]	0,37	[0,14; 0,98]	0,0451*
Interaktion p-Wert									0,0374*
Baseline CA-125 Wert									
<=ULN	286	42 (14,7)	NE [NE; NE]	142	24 (16,9)	50,7 [50,7; NE]	0,89	[0,54; 1,49]	0,6437
>ULN	14	1 (7,1)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	35 (13,8)	NE [NE; NE]	123	21 (17,1)	50,7 [50,7; NE]	0,83	[0,49; 1,46]	0,5091
IV	46	8 (17,4)	NE [NE; NE]	27	3 (11,1)	NE [NE; NE]	1,39	[0,40; 6,33]	0,6221
Interaktion p-Wert									0,4738
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	28 (14,9)	NE [NE; NE]	91	12 (13,2)	NE [NE; NE]	1,25	[0,65; 2,59]	0,5112
BRCA2	62	5 (8,1)	47,9 [41,9; NE]	39	7 (17,9)	NE [NE; NE]	0,35	[0,10; 1,12]	0,0756
Interaktion p-Wert									0,0623

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 2.10.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur Verschlechterung FACT-O Gesamtscore
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	12 (17,9)	47,9 [41,4; NE]	34	6 (17,6)	NE [NE; NE]	0,87	[0,34; 2,50]	0,7802
Keine makroskopische Resterkrankung	228	30 (13,2)	NE [NE; NE]	112	18 (16,1)	50,7 [50,7; NE]	0,87	[0,49; 1,61]	0,6558
Interaktion p-Wert									0,9921
Abstammung									
Weiß	214	26 (12,1)	NE [NE; NE]	106	15 (14,2)	NE [NE; NE]	0,89	[0,47; 1,73]	0,7165
Andere	86	17 (19,8)	47,9 [41,5; NE]	44	9 (20,5)	NE [NE; NE]	0,92	[0,42; 2,16]	0,8415
Interaktion p-Wert									0,9442
Region									
Europa	101	10 (9,9)	NE [NE; NE]	53	7 (13,2)	50,7 [50,7; NE]	0,77	[0,29; 2,17]	0,6131
Asien	73	16 (21,9)	NE [NE; NE]	33	9 (27,3)	NE [NE; NE]	0,76	[0,34; 1,81]	0,5243
Rest der Welt	126	17 (13,5)	NE [NE; NE]	64	8 (12,5)	NE [NE; NE]	1,12	[0,50; 2,76]	0,7843
Interaktion p-Wert									0,7739

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 2.10.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	47 (17,9)	NE [NE; NE]	130	35 (26,9)	NE [NE; NE]	0,65	[0,42; 1,01]	0,0574
>=65 Jahre	37	6 (16,2)	NE [NE; NE]	20	6 (30,0)	41,7 [29,0; NE]	0,67	[0,21; 2,13]	0,4850
Interaktion p-Wert									0,9664
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	40 (16,2)	NE [NE; NE]	124	37 (29,8)	NE [NE; NE]	0,57	[0,37; 0,90]	0,0154*
Partielles Ansprechen	53	13 (24,5)	NE [NE; NE]	26	4 (15,4)	NE [NE; NE]	1,21	[0,43; 4,31]	0,7329
Interaktion p-Wert									0,2036
ECOG PS Status									
Normale Aktivität	221	41 (18,6)	NE [NE; NE]	115	32 (27,8)	NE [NE; NE]	0,67	[0,42; 1,07]	0,0892
Eingeschränkte Aktivität	79	12 (15,2)	NE [NE; NE]	34	9 (26,5)	38,8 [30,5; NE]	0,60	[0,26; 1,48]	0,2608
Interaktion p-Wert									0,8443
Baseline CA-125 Wert									
<=ULN	286	49 (17,1)	NE [NE; NE]	142	41 (28,9)	NE [NE; NE]	0,61	[0,40; 0,92]	0,0199*
>ULN	14	4 (28,6)	29,1 [12,0; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	43 (16,9)	NE [NE; NE]	123	33 (26,8)	NE [NE; NE]	0,66	[0,42; 1,05]	0,0774
IV	46	10 (21,7)	NE [NE; NE]	27	8 (29,6)	NE [NE; NE]	0,60	[0,24; 1,57]	0,2848
Interaktion p-Wert									0,8480
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	34 (18,1)	NE [NE; NE]	91	23 (25,3)	NE [NE; NE]	0,74	[0,44; 1,26]	0,2618
BRCA2	62	6 (9,7)	NE [NE; NE]	39	10 (25,6)	NE [NE; NE]	0,39	[0,13; 1,04]	0,0594
Interaktion p-Wert									0,2611

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 2.10.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	13 (19,4)	NE [NE; NE]	34	9 (26,5)	NE [NE; NE]	0,68	[0,29; 1,64]	0,3737
Keine makroskopische Resterkrankung	228	38 (16,7)	NE [NE; NE]	112	31 (27,7)	NE [NE; NE]	0,63	[0,39; 1,02]	0,0618
Interaktion p-Wert									0,8945
Abstammung									
Weiß	214	27 (12,6)	NE [NE; NE]	106	28 (26,4)	NE [NE; NE]	0,48	[0,28; 0,81]	0,0063*
Andere	86	26 (30,2)	NE [NE; NE]	44	13 (29,5)	41,7 [33,3; NE]	1,05	[0,55; 2,10]	0,8896
Interaktion p-Wert									0,0648
Region									
Europa	101	9 (8,9)	NE [NE; NE]	53	16 (30,2)	30,6 [18,0; NE]	0,27	[0,11; 0,60]	0,0013*
Asien	73	25 (34,2)	NE [NE; NE]	33	13 (39,4)	35,5 [27,8; NE]	0,91	[0,48; 1,84]	0,7929
Rest der Welt	126	19 (15,1)	NE [NE; NE]	64	12 (18,8)	NE [NE; NE]	0,85	[0,42; 1,79]	0,6504
Interaktion p-Wert									0,0465*

Deterioration is defined as two visits with worsening response minimum of 28 days apart without an intervening visit response of Improved/No change. If after the first visit with worsening response there is no subsequent assessment up to the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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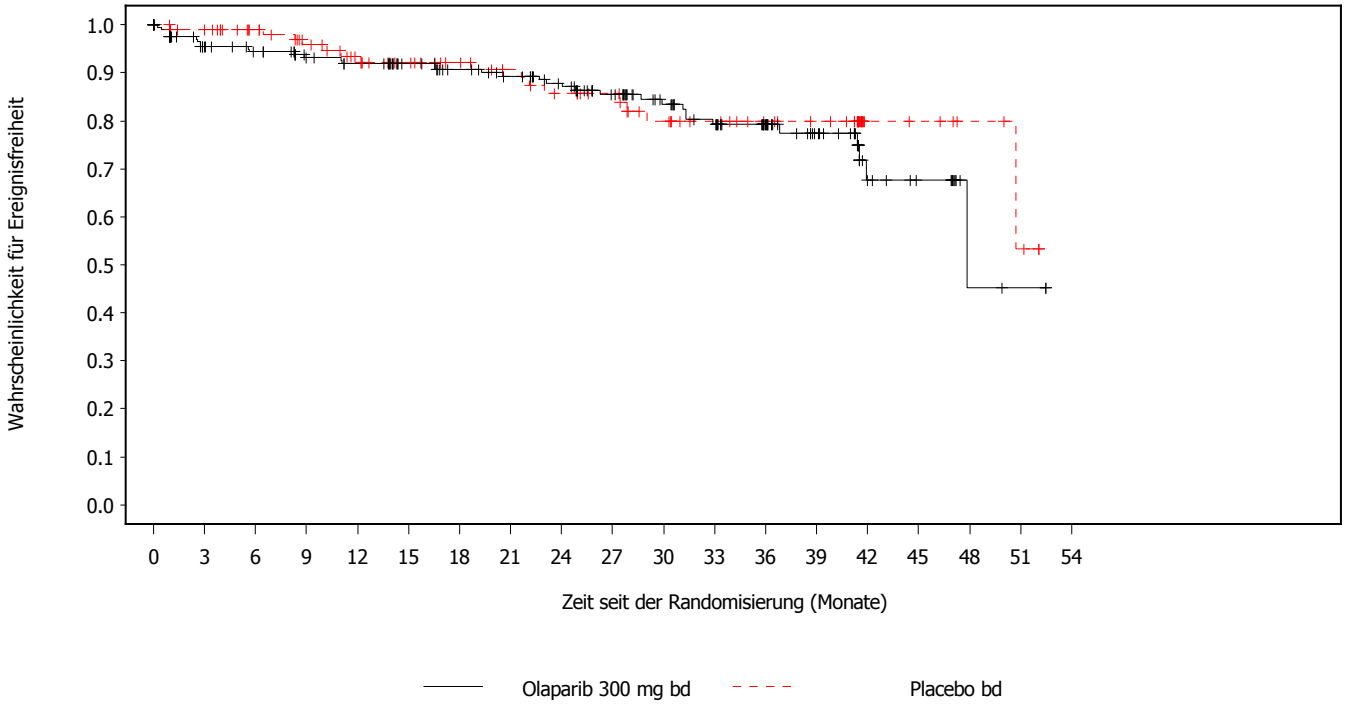
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.10.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Gesamtscore for ECOG PS Status = Normale Aktivität
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

221	180	172	161	155	142	133	126	116	100	84	73	55	39	16	12	2	1	0	Olaparib 300 mg bd
115	104	95	85	76	68	62	56	51	47	39	33	28	25	8	7	4	2	0	Placebo bd

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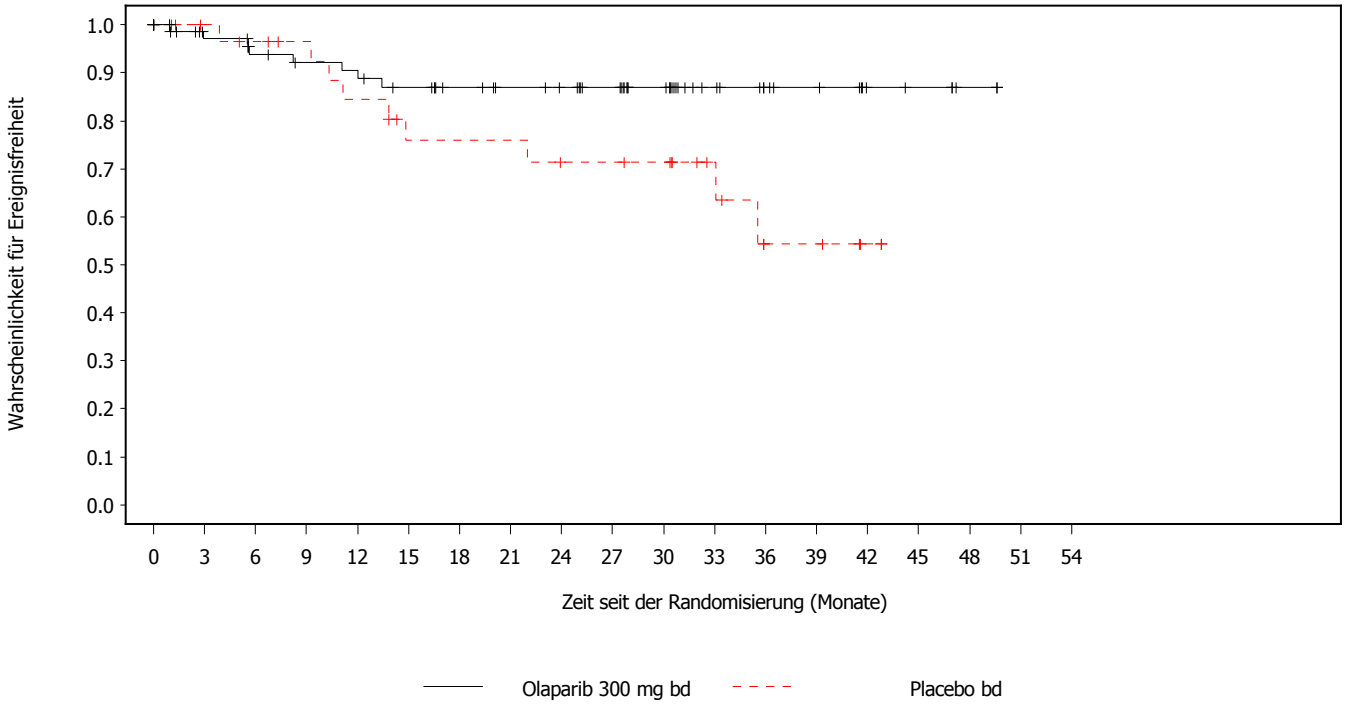
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.10.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung FACT-O Gesamtscore for ECOG PS Status = Eingeschränkte Aktivität
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

79	64	57	54	53	49	44	41	39	35	28	17	12	10	5	4	1	0	0	Olaparib 300 mg bd
34	28	26	24	21	17	17	17	15	15	14	9	4	4	1	0	0	0	0	Placebo bd

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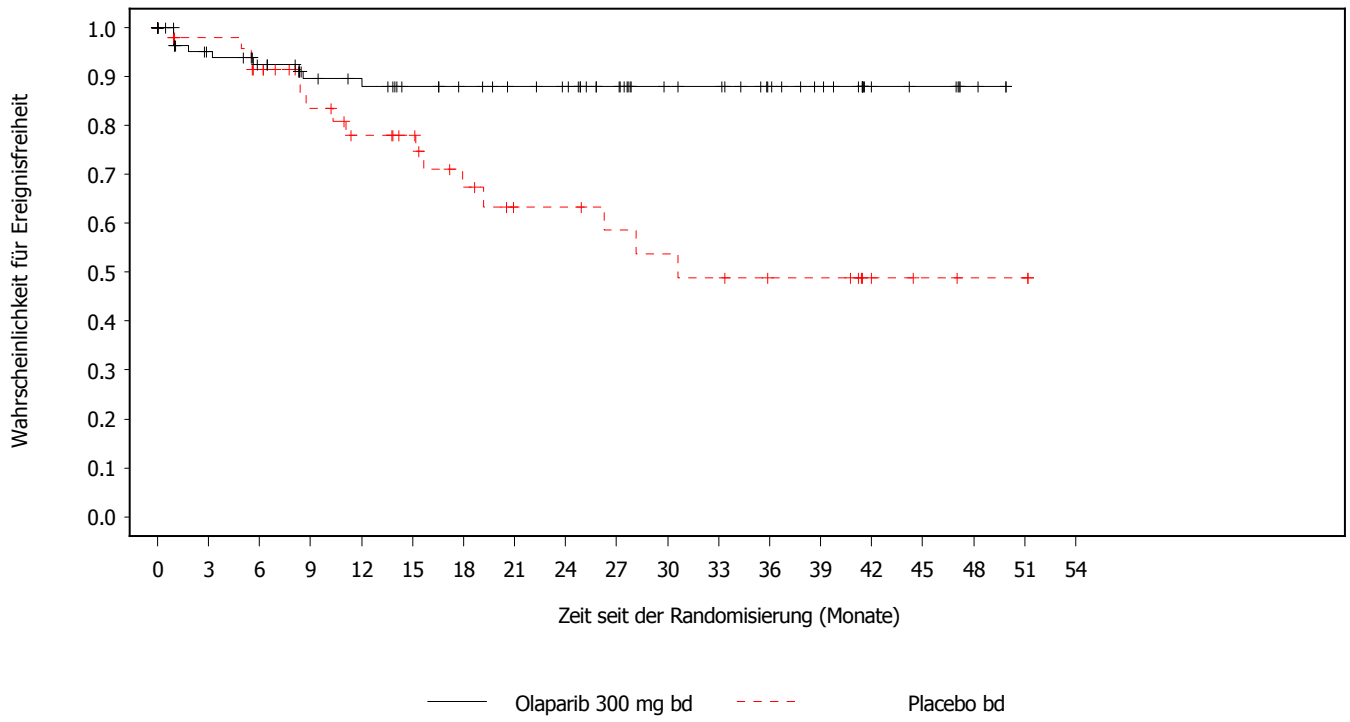
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.10.2.3 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala for Region = Europa
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



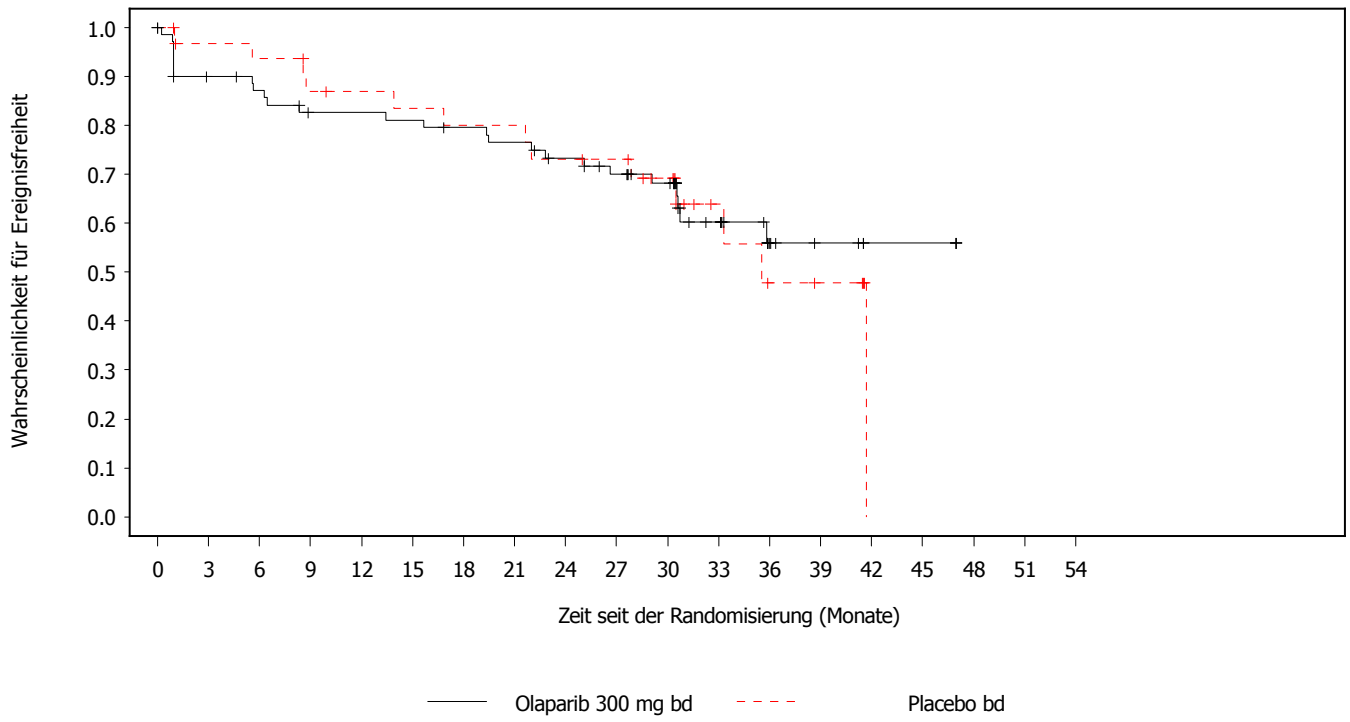
Anzahl an Patienten unter Risiko:

101	74	68	59	57	51	48	45	43	36	28	27	21	17	7	6	2	0	0	Olaparib 300 mg bd
53	45	40	32	27	24	18	14	14	12	11	10	8	8	3	2	1	1	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubpr.sas gttesubprbac 21FEB2023:13:19 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.10.2.4 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala for Region = Asien
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



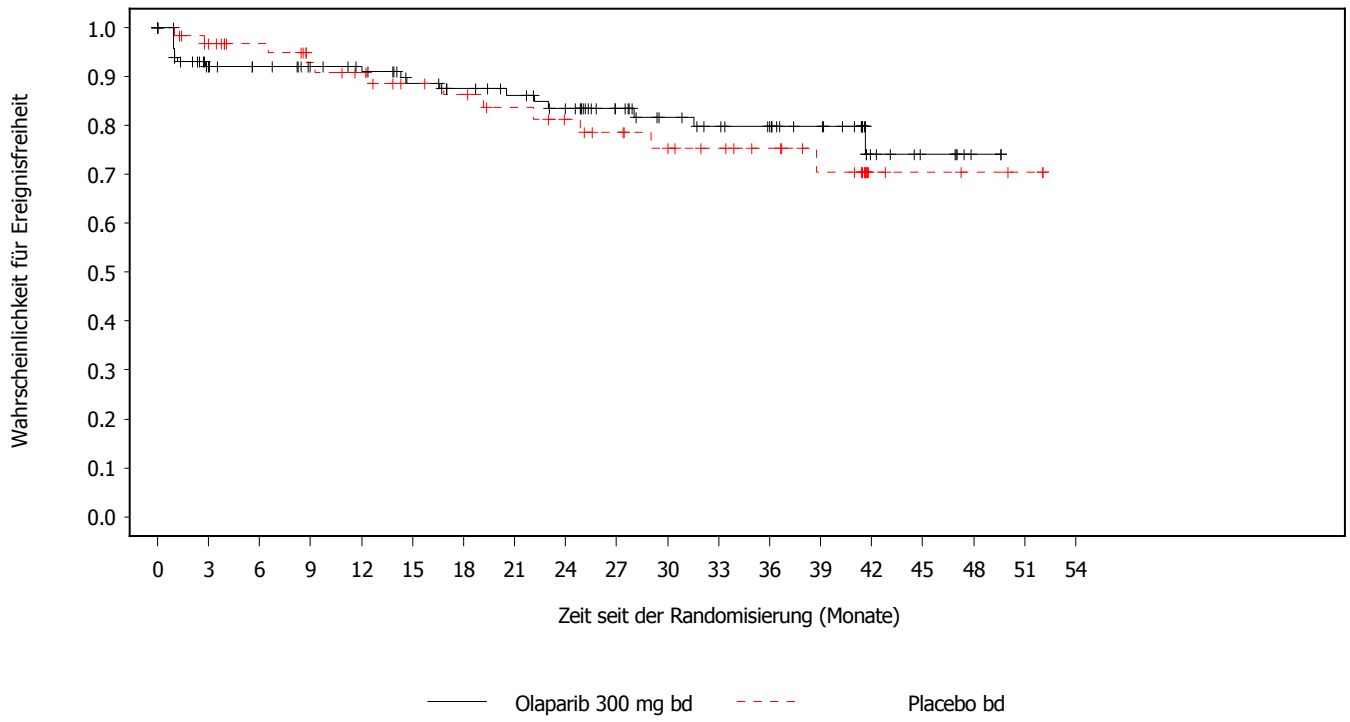
Anzahl an Patienten unter Risiko:

73	62	59	54	54	53	51	49	45	41	36	20	8	5	2	2	0	0	0	Olaparib 300 mg bd
33	30	29	26	25	24	23	23	21	20	16	8	5	4	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubpr.sas gttesubprbad 21FEB2023:13:19 kpzx329

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.10.2.5 SOLO1: Kaplan-Meier plot of Zeit bis zur Verschlechterung EQ-5D visuelle Analogskala for Region = Rest der Welt
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

126	98	93	88	84	76	71	67	61	50	42	38	34	28	10	6	1	0	0	Olaparib 300 mg bd
64	57	52	46	43	38	36	33	30	27	24	21	18	14	4	3	2	1	0	Placebo bd

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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.11.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	34 (12,9)	NE [NE; NE]	130	16 (12,3)	NE [NE; NE]	0,95	[0,53; 1,76]	0,8602
>=65 Jahre	37	5 (13,5)	47,9 [41,9; NE]	20	6 (30,0)	44,0 [28,1; NE]	0,45	[0,13; 1,51]	0,1914
Interaktion p-Wert									0,2734
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	32 (13,0)	NE [NE; NE]	124	20 (16,1)	NE [NE; NE]	0,79	[0,45; 1,40]	0,4138
Partielles Ansprechen	53	7 (13,2)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	1,03	[0,25; 6,93]	0,9733
Interaktion p-Wert									0,7543
ECOG PS Status									
Normale Aktivität	221	30 (13,6)	NE [NE; NE]	115	14 (12,2)	NE [NE; NE]	1,01	[0,55; 1,97]	0,9720
Eingeschränkte Aktivität	79	9 (11,4)	NE [NE; NE]	34	8 (23,5)	NE [NE; NE]	0,46	[0,18; 1,24]	0,1217
Interaktion p-Wert									0,1841
Baseline CA-125 Wert									
<=ULN	286	37 (12,9)	NE [NE; NE]	142	22 (15,5)	NE [NE; NE]	0,77	[0,46; 1,33]	0,3498
>ULN	14	2 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	30 (11,8)	NE [NE; NE]	123	17 (13,8)	NE [NE; NE]	0,78	[0,44; 1,45]	0,4280
IV	46	9 (19,6)	NE [NE; NE]	27	5 (18,5)	NE [NE; NE]	0,96	[0,33; 3,14]	0,9459
Interaktion p-Wert									0,7449
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	28 (14,9)	NE [NE; NE]	91	11 (12,1)	NE [NE; NE]	1,19	[0,61; 2,49]	0,6282
BRCA2	62	6 (9,7)	NE [NE; NE]	39	6 (15,4)	NE [NE; NE]	0,49	[0,15; 1,57]	0,2220
Interaktion p-Wert									0,1937

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated. the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 2.11.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	12 (17,9)	47,9 [47,9; NE]	34	5 (14,7)	NE [NE; NE]	0,86	[0,32; 2,71]	0,7797
Keine makroskopische Resterkrankung	228	26 (11,4)	NE [NE; NE]	112	17 (15,2)	NE [NE; NE]	0,74	[0,40; 1,38]	0,3349
Interaktion p-Wert									0,8026
Abstammung									
Weiß	214	30 (14,0)	NE [NE; NE]	106	14 (13,2)	NE [NE; NE]	0,93	[0,50; 1,80]	0,8139
Andere	86	9 (10,5)	47,9 [NE; NE]	44	8 (18,2)	NE [NE; NE]	0,60	[0,23; 1,59]	0,2916
Interaktion p-Wert									0,4505
Region									
Europa	101	12 (11,9)	NE [NE; NE]	53	5 (9,4)	50,7 [50,7; NE]	0,94	[0,35; 2,97]	0,9139
Asien	73	8 (11,0)	NE [NE; NE]	33	8 (24,2)	NE [NE; NE]	0,43	[0,16; 1,16]	0,0948
Rest der Welt	126	19 (15,1)	NE [NE; NE]	64	9 (14,1)	NE [NE; NE]	1,12	[0,52; 2,61]	0,7790
Interaktion p-Wert									0,3106

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated. the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.11.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	31 (11,8)	NE [NE; NE]	130	33 (25,4)	49,2 [44,7; NE]	0,41	[0,25; 0,68]	0,0005*
>=65 Jahre	37	6 (16,2)	NE [NE; NE]	20	6 (30,0)	NE [NE; NE]	0,56	[0,17; 1,79]	0,3177
Interaktion p-Wert									0,6276
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	27 (10,9)	NE [NE; NE]	124	33 (26,6)	NE [NE; NE]	0,40	[0,24; 0,66]	0,0004*
Partielles Ansprechen	53	10 (18,9)	52,5 [NE; NE]	26	6 (23,1)	49,2 [26,1; NE]	0,51	[0,19; 1,51]	0,2138
Interaktion p-Wert									0,6613
ECOG PS Status									
Normale Aktivität	221	26 (11,8)	NE [NE; NE]	115	29 (25,2)	49,2 [44,7; NE]	0,42	[0,24; 0,71]	0,0014*
Eingeschränkte Aktivität	79	11 (13,9)	NE [NE; NE]	34	10 (29,4)	NE [NE; NE]	0,45	[0,19; 1,08]	0,0722
Interaktion p-Wert									0,8869
Baseline CA-125 Wert									
<=ULN	286	35 (12,2)	NE [NE; NE]	142	38 (26,8)	49,2 [44,7; NE]	0,42	[0,26; 0,67]	0,0003*
>ULN	14	2 (14,3)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,71	[0,07; 15,32]	0,7854
Interaktion p-Wert									0,6648
FIGO Stadium									
III	254	29 (11,4)	NE [NE; NE]	123	29 (23,6)	49,2 [44,7; NE]	0,44	[0,26; 0,74]	0,0022*
IV	46	8 (17,4)	NE [NE; NE]	27	10 (37,0)	39,8 [26,1; NE]	0,42	[0,16; 1,05]	0,0641
Interaktion p-Wert									0,9181
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	23 (12,2)	NE [NE; NE]	91	21 (23,1)	NE [NE; NE]	0,48	[0,26; 0,87]	0,0166*
BRCA2	62	4 (6,5)	NE [NE; NE]	39	11 (28,2)	49,2 [37,5; NE]	0,21	[0,06; 0,61]	0,0037*
Interaktion p-Wert									0,1950

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated. the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 2.11.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	12 (17,9)	52,5 [NE; NE]	34	9 (26,5)	NE [NE; NE]	0,50	[0,21; 1,24]	0,1323
Keine makroskopische Resterkrankung	228	24 (10,5)	NE [NE; NE]	112	28 (25,0)	49,2 [44,7; NE]	0,41	[0,23; 0,70]	0,0013*
Interaktion p-Wert									0,6749
Abstammung									
Weiß	214	20 (9,3)	NE [NE; NE]	106	28 (26,4)	49,2 [44,7; NE]	0,30	[0,16; 0,53]	<0,0001*
Andere	86	17 (19,8)	NE [NE; NE]	44	11 (25,0)	NE [NE; NE]	0,82	[0,39; 1,80]	0,6074
Interaktion p-Wert									0,0364*
Region									
Europa	101	10 (9,9)	NE [NE; NE]	53	17 (32,1)	44,7 [37,5; NE]	0,23	[0,10; 0,51]	0,0003*
Asien	73	16 (21,9)	47,2 [NE; NE]	33	9 (27,3)	41,7 [33,3; NE]	0,80	[0,36; 1,88]	0,5877
Rest der Welt	126	11 (8,7)	NE [NE; NE]	64	13 (20,3)	NE [NE; NE]	0,41	[0,18; 0,93]	0,0325*
Interaktion p-Wert									0,1025

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value. Patients with only one worsening post baseline and no subsequent observation also qualify as deteriorated. the end of collection of PRO this first worsening also qualifies as a deterioration.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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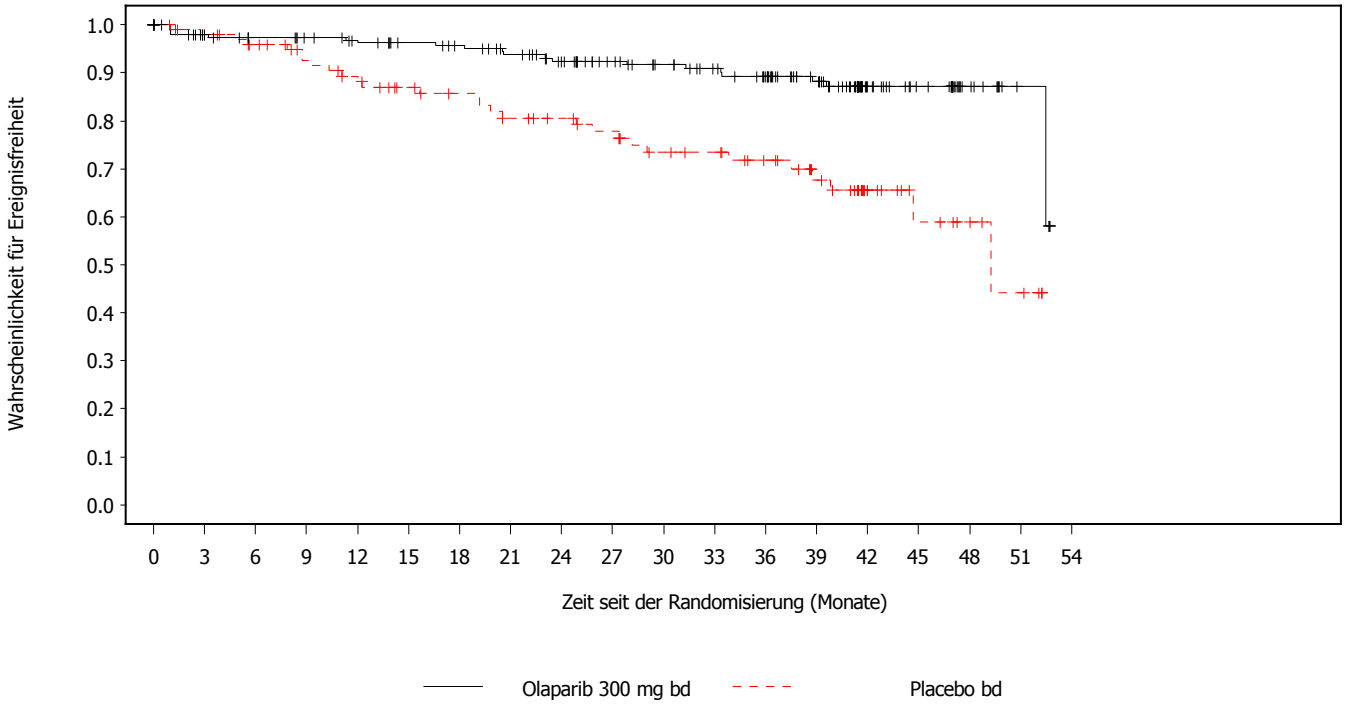
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.11.2.1 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala for Abstammung = Weiß
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

214	182	175	171	166	159	155	148	138	126	118	111	102	85	43	33	13	3	0	Olaparib 300 mg bd
106	97	91	83	78	71	67	62	59	55	48	46	40	32	15	9	6	3	0	Placebo bd

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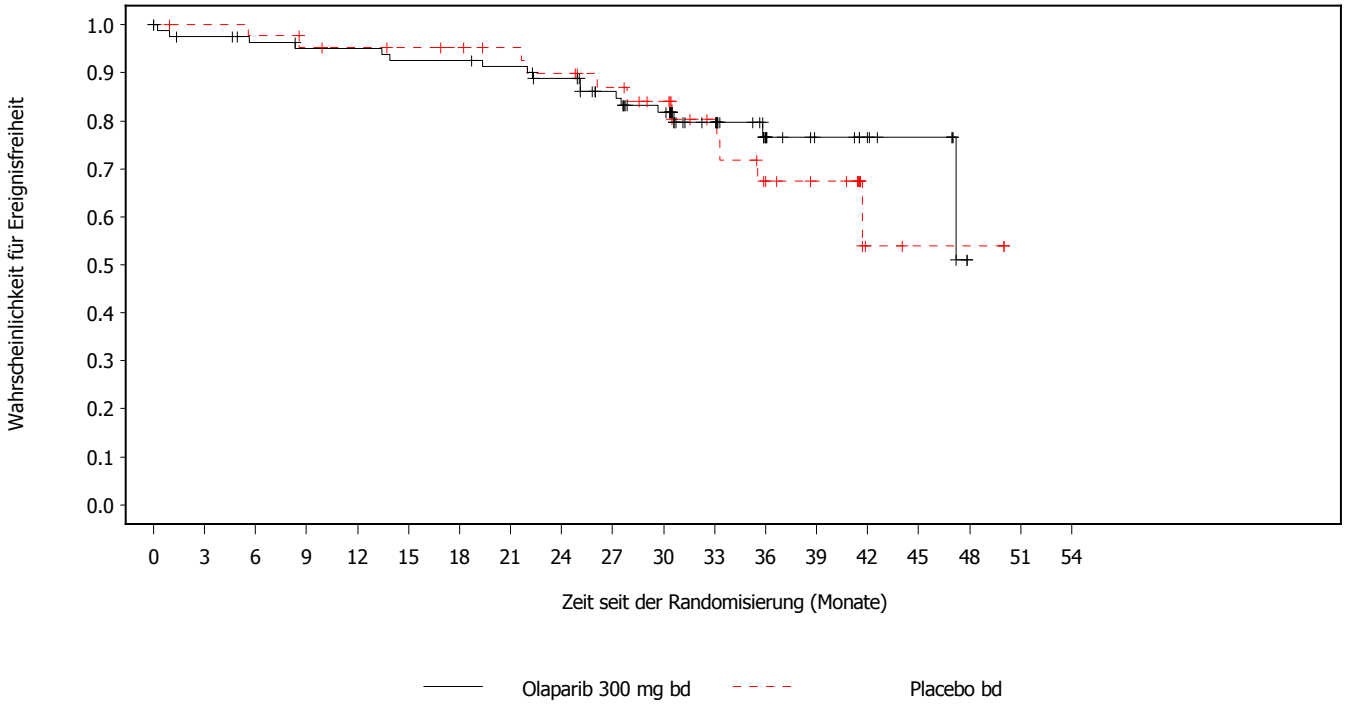
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 2.11.2.2 SOLO1: Kaplan-Meier plot of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala for Abstammung = Andere
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

86	81	78	76	76	74	74	72	68	60	52	36	18	12	8	6	0	0	0 Olaparib 300 mg bd
44	43	42	40	39	38	37	35	33	30	26	19	14	11	2	1	1	0	0 Placebo bd

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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.12.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	12 (4,6)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	1,35	[0,47; 4,82]	0,5977
>=65 Jahre	37	1 (2,7)	NE [NE; NE]	20	2 (10,0)	NE [NE; NE]	0,30	[0,01; 3,14]	0,3071
Interaktion p-Wert									0,2507
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	9 (3,6)	NE [NE; NE]	124	6 (4,8)	NE [NE; NE]	0,75	[0,27; 2,23]	0,5851
Partielles Ansprechen	53	4 (7,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	11 (5,0)	NE [NE; NE]	115	5 (4,3)	NE [NE; NE]	1,05	[0,38; 3,33]	0,9287
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	0,86	[0,08; 18,52]	0,9033
Interaktion p-Wert									0,8832
Baseline CA-125 Wert									
<=ULN	286	13 (4,5)	NE [NE; NE]	142	6 (4,2)	NE [NE; NE]	1,02	[0,40; 2,89]	0,9752
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	10 (3,9)	NE [NE; NE]	123	6 (4,9)	NE [NE; NE]	0,73	[0,27; 2,15]	0,5502
IV	46	3 (6,5)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	10 (5,3)	NE [NE; NE]	91	3 (3,3)	NE [NE; NE]	1,54	[0,47; 6,89]	0,4941
BRCA2	62	2 (3,2)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	1,05	[0,10; 22,64]	0,9664
Interaktion p-Wert									0,7858

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.12.1.1 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung FACT-O Gesamtscore
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	2 (5,9)	NE [NE; NE]	0,20	[0,01; 2,10]	0,1740
Keine makroskopische Resterkrankung	228	11 (4,8)	NE [NE; NE]	112	4 (3,6)	NE [NE; NE]	1,30	[0,44; 4,70]	0,6453
Interaktion p-Wert									0,1539
Abstammung									
Weiß	214	11 (5,1)	NE [NE; NE]	106	3 (2,8)	NE [NE; NE]	1,62	[0,51; 7,16]	0,4402
Andere	86	2 (2,3)	NE [NE; NE]	44	3 (6,8)	NE [NE; NE]	0,35	[0,05; 2,10]	0,2419
Interaktion p-Wert									0,1609
Region									
Europa	101	3 (3,0)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	1,23	[0,16; 24,96]	0,8554
Asien	73	2 (2,7)	NE [NE; NE]	33	3 (9,1)	NE [NE; NE]	0,28	[0,04; 1,72]	0,1651
Rest der Welt	126	8 (6,3)	NE [NE; NE]	64	2 (3,1)	NE [NE; NE]	2,16	[0,54; 14,40]	0,2991
Interaktion p-Wert									0,2192

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.12.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	13 (4,9)	NE [NE; NE]	130	20 (15,4)	NE [NE; NE]	0,30	[0,14; 0,59]	0,0006*
>=65 Jahre	37	5 (13,5)	NE [NE; NE]	20	4 (20,0)	NE [NE; NE]	0,69	[0,18; 2,80]	0,5858
Interaktion p-Wert									0,2670
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	13 (5,3)	NE [NE; NE]	124	20 (16,1)	NE [NE; NE]	0,32	[0,16; 0,65]	0,0014*
Partielles Ansprechen	53	5 (9,4)	NE [NE; NE]	26	4 (15,4)	NE [NE; NE]	0,42	[0,11; 1,69]	0,2080
Interaktion p-Wert									0,7388
ECOG PS Status									
Normale Aktivität	221	14 (6,3)	NE [NE; NE]	115	19 (16,5)	NE [NE; NE]	0,36	[0,18; 0,71]	0,0036*
Eingeschränkte Aktivität	79	4 (5,1)	NE [NE; NE]	34	5 (14,7)	NE [NE; NE]	0,33	[0,08; 1,25]	0,1017
Interaktion p-Wert									0,9159
Baseline CA-125 Wert									
<=ULN	286	17 (5,9)	NE [NE; NE]	142	23 (16,2)	NE [NE; NE]	0,35	[0,18; 0,65]	0,0010*
>ULN	14	1 (7,1)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,36	[0,01; 9,08]	0,4779
Interaktion p-Wert									0,9865
FIGO Stadium									
III	254	12 (4,7)	NE [NE; NE]	123	17 (13,8)	NE [NE; NE]	0,32	[0,15; 0,67]	0,0026*
IV	46	6 (13,0)	NE [NE; NE]	27	7 (25,9)	NE [NE; NE]	0,46	[0,15; 1,38]	0,1620
Interaktion p-Wert									0,6025
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	12 (6,4)	NE [NE; NE]	91	14 (15,4)	NE [NE; NE]	0,39	[0,18; 0,85]	0,0181*
BRCA2	62	3 (4,8)	NE [NE; NE]	39	7 (17,9)	NE [NE; NE]	0,25	[0,05; 0,90]	0,0331*
Interaktion p-Wert									0,5627

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 2.12.1.2 SOLO1: Summary of subgroup analysis of Zeit bis zur dauerhaften Verschlechterung EQ-5D visuelle Analogskala
Sensitivity Analysis (censoring patients with only one worsening post baseline and no subsequent observations)

	Olaparib 300 mg bd (N=300)			Placebo bd (N=150)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	5 (7,5)	NE [NE; NE]	34	5 (14,7)	NE [NE; NE]	0,42	[0,12; 1,52]	0,1792
Keine makroskopische Resterkrankung	228	12 (5,3)	NE [NE; NE]	112	18 (16,1)	NE [NE; NE]	0,32	[0,15; 0,66]	0,0021*
Interaktion p-Wert									0,7116
Abstammung									
Weiß	214	10 (4,7)	NE [NE; NE]	106	18 (17,0)	NE [NE; NE]	0,25	[0,11; 0,53]	0,0003*
Andere	86	8 (9,3)	NE [NE; NE]	44	6 (13,6)	NE [NE; NE]	0,69	[0,24; 2,09]	0,4942
Interaktion p-Wert									0,1259
Region									
Europa	101	5 (5,0)	NE [NE; NE]	53	10 (18,9)	NE [NE; NE]	0,24	[0,07; 0,67]	0,0063*
Asien	73	7 (9,6)	NE [NE; NE]	33	4 (12,1)	NE [NE; NE]	0,78	[0,23; 2,96]	0,6903
Rest der Welt	126	6 (4,8)	NE [NE; NE]	64	10 (15,6)	NE [NE; NE]	0,29	[0,10; 0,78]	0,0139*
Interaktion p-Wert									0,3063

A sustained deterioration is defined as a worsening of response without any recovery above response threshold compared to baseline value.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment and response to first line platinum chemotherapy as covariates. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by response to first line platinum chemotherapy. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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2.3: Sicherheit

2.3.1: Gesamtpopulation

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 3.1 SOLO1: Summary of observation period (months) for adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

		Olaparib 300 mg bd (N=300)	Placebo bd (N=149)
UE	n	300	149
	Median	25,63	14,06
	Min	1,1	1,3
	Max	97,5	61,0
Spezifische UE	n	300	149
	Median	80,02	58,48
	Min	0,3	4,4
	Max	99,4	99,5

Observation period for AEs is defined as the time from first dose to the earliest of the DCO, study treatment discontinuation + 30 days or death i.e. the safety follow-up period for the analysis.
Observation period for AESI of pneumonitis is defined identically as for the AEs.
Observation period for remaining AESIs is defined as the time from first dose to the earliest of the DCO, death or study discontinuation.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE	300	295 (98,3)	0,1 [0,1; 0,1]	149	139 (93,3)	0,3 [0,2; 0,4]	1,71	[1,39; 2,10]	<0,0001*
UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	300	222 (74,0)	2,0 [1,0; 3,5]	149	80 (53,7)	12,8 [8,8;15,8]	1,79	[1,39; 2,33]	<0,0001*
UE PT: Asthenie	300	66 (22,0)	NE [NE; NE]	149	17 (11,4)	NE [NE; NE]	1,99	[1,20; 3,50]	0,0101*
UE PT: Ermuedung	300	121 (40,3)	33,9 [33,9; NE]	149	42 (28,2)	NE [NE; NE]	1,53	[1,08; 2,20]	0,0184*
UE PT: Fieber	300	39 (13,0)	NE [NE; NE]	149	14 (9,4)	NE [NE; NE]	1,21	[0,67; 2,31]	0,5471
UE PT: Grippeaehnliche Erkrankung	300	20 (6,7)	NE [NE; NE]	149	11 (7,4)	NE [NE; NE]	0,76	[0,37; 1,65]	0,4719
UE PT: Oedem peripher	300	25 (8,3)	NE [NE; NE]	149	9 (6,0)	NE [NE; NE]	1,33	[0,64; 3,01]	0,4672
UE PT: Schleimhautentzuendung	300	18 (6,0)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	7,76	[1,59;139,79]	0,0185*
UE PT: Unwohlsein	300	13 (4,3)	NE [NE; NE]	149	3 (2,0)	NE [NE; NE]	1,99	[0,64; 8,68]	0,2760
UE SOC: Augenerkrankungen	300	24 (8,0)	NE [NE; NE]	149	8 (5,4)	NE [NE; NE]	1,24	[0,57; 2,97]	0,6077

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Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums	300	108 (36,0)	34,7 [34,7; NE]	149	47 (31,5)	NE [NE; NE]	1,02	[0,73; 1,45]	0,9065
UE PT: Allergische Rhinitis	300	11 (3,7)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	2,23	[0,60; 14,48]	0,2854
UE PT: Dyspnoe	300	41 (13,7)	NE [NE; NE]	149	7 (4,7)	NE [NE; NE]	2,52	[1,20; 6,16]	0,0199*
UE PT: Husten	300	48 (16,0)	NE [NE; NE]	149	30 (20,1)	30,1 [30,1; NE]	0,66	[0,42; 1,05]	0,0708
UE PT: Nasenverstopfung	300	10 (3,3)	NE [NE; NE]	149	7 (4,7)	33,1 [33,1; NE]	0,64	[0,24; 1,77]	0,3647
UE PT: Schmerzen im Oropharynx	300	24 (8,0)	NE [NE; NE]	149	14 (9,4)	33,1 [33,1; NE]	0,66	[0,34; 1,31]	0,2108
UE SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese	300	28 (9,3)	NE [NE; NE]	149	8 (5,4)	NE [NE; NE]	1,49	[0,71; 3,52]	0,3157
UE SOC: Erkrankungen der Haut und des Unterhautgewebes	300	91 (30,3)	54,1 [46,9; NE]	149	34 (22,8)	NE [NE; NE]	1,18	[0,80; 1,78]	0,4161
UE PT: Ausschlag	300	19 (6,3)	NE [NE; NE]	149	12 (8,1)	NE [NE; NE]	0,67	[0,33; 1,44]	0,2861
UE PT: Erythem	300	13 (4,3)	NE [NE; NE]	149	4 (2,7)	NE [NE; NE]	1,37	[0,48; 4,90]	0,5817

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Pruritus	300	12 (4,0)	NE [NE; NE]	149	4 (2,7)	NE [NE; NE]	1,20	[0,41; 4,32]	0,7575
UE SOC: Erkrankungen der Nieren und Harnwege	300	39 (13,0)	NE [NE; NE]	149	10 (6,7)	NE [NE; NE]	1,69	[0,87; 3,59]	0,1377
UE PT: Dysurie	300	10 (3,3)	NE [NE; NE]	149	0	NE [NE; NE]	NC	NC	0,0354*
UE SOC: Erkrankungen des Blutes und des Lymphsystems	300	162 (54,0)	9,2 [5,4;22,0]	149	30 (20,1)	NE [NE; NE]	3,21	[2,21; 4,84]	<0,0001*
UE PT: Anaemie	300	126 (42,0)	44,5 [23,0; NE]	149	15 (10,1)	NE [NE; NE]	4,86	[2,94; 8,67]	<0,0001*
UE PT: Leukopenie	300	32 (10,7)	NE [NE; NE]	149	7 (4,7)	NE [NE; NE]	2,17	[1,02; 5,37]	0,0568
UE PT: Lymphopenie	300	12 (4,0)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	2,85	[0,77; 18,32]	0,1525
UE PT: Neutropenie	300	57 (19,0)	NE [NE; NE]	149	10 (6,7)	NE [NE; NE]	2,85	[1,52; 5,93]	0,0015*
UE PT: Thrombozytopenie	300	34 (11,3)	NE [NE; NE]	149	5 (3,4)	NE [NE; NE]	3,31	[1,42; 9,66]	0,0081*
UE SOC: Erkrankungen des Gastrointestinaltrakts	300	268 (89,3)	0,2 [0,1; 0,2]	149	110 (73,8)	4,1 [1,9; 4,8]	2,09	[1,68; 2,63]	<0,0001*
UE PT: Abdominale Beschwerden	300	12 (4,0)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	2,92	[0,80; 18,77]	0,1417

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Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Abdominalschmerz	300	68 (22,7)	81,1 [63,3; NE]	149	27 (18,1)	NE [NE; NE]	1,12	[0,73; 1,79]	0,6104
UE PT: Bauch aufgetrieben	300	22 (7,3)	NE [NE; NE]	149	12 (8,1)	NE [NE; NE]	0,77	[0,39; 1,62]	0,4710
UE PT: Diarrhoe	300	96 (32,0)	NE [NE; NE]	149	36 (24,2)	NE [NE; NE]	1,31	[0,90; 1,95]	0,1710
UE PT: Dyspepsie	300	45 (15,0)	NE [NE; NE]	149	17 (11,4)	NE [NE; NE]	1,20	[0,70; 2,17]	0,5160
UE PT: Erbrechen	300	121 (40,3)	NE [NE; NE]	149	22 (14,8)	NE [NE; NE]	3,10	[2,01; 5,01]	<0,0001*
UE PT: Flatulenz	300	13 (4,3)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	2,92	[0,80; 18,73]	0,1397
UE PT: Gastrooesophageale Refluxerkrankung	300	12 (4,0)	NE [NE; NE]	149	4 (2,7)	NE [NE; NE]	1,39	[0,48; 4,99]	0,5659
UE PT: Haemorrhoiden	300	11 (3,7)	NE [NE; NE]	149	0	NE [NE; NE]	NC	NC	0,0336*
UE PT: Mundtrockenheit	300	11 (3,7)	NE [NE; NE]	149	7 (4,7)	NE [NE; NE]	0,76	[0,30; 2,07]	0,5730
UE PT: Mundulzeration	300	11 (3,7)	NE [NE; NE]	149	0	NE [NE; NE]	NC	NC	0,0327*
UE PT: Obstipation	300	79 (26,3)	NE [NE; NE]	149	26 (17,4)	NE [NE; NE]	1,48	[0,96; 2,36]	0,0807
UE PT: Schmerzen Oberbauch	300	52 (17,3)	NE [NE; NE]	149	17 (11,4)	NE [NE; NE]	1,46	[0,86; 2,59]	0,1774
UE PT: Stomatitis	300	23 (7,7)	NE [NE; NE]	149	3 (2,0)	NE [NE; NE]	3,60	[1,25; 15,21]	0,0258*

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Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties.
Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Uebelkeit	300	228 (76,0)	0,3 [0,2; 0,3]	149	54 (36,2)	NE [NE; NE]	3,36	[2,51; 4,57]	<0,0001*
UE PT: Zahnschmerzen	300	11 (3,7)	NE [NE; NE]	149	6 (4,0)	NE [NE; NE]	0,69	[0,26; 2,02]	0,4684
UE SOC: Erkrankungen des Immunsystems	300	15 (5,0)	NE [NE; NE]	149	4 (2,7)	NE [NE; NE]	1,51	[0,54; 5,31]	0,4666
UE SOC: Erkrankungen des Nervensystems	300	171 (57,0)	7,4 [5,5;12,1]	149	70 (47,0)	16,5 [9,1; NE]	1,30	[0,99; 1,73]	0,0654
UE PT: Dysgeusie	300	59 (19,7)	NE [NE; NE]	149	5 (3,4)	NE [NE; NE]	6,20	[2,75; 17,75]	<0,0001*
UE PT: Geschmacksstoerung	300	12 (4,0)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	5,93	[1,17;107,99]	0,0520
UE PT: Hypoaesthesie	300	10 (3,3)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	2,11	[0,55; 13,82]	0,3288
UE PT: Kopfschmerzen	300	66 (22,0)	NE [NE; NE]	149	34 (22,8)	NE [NE; NE]	0,87	[0,58; 1,34]	0,5177
UE PT: Paraesthesie	300	10 (3,3)	NE [NE; NE]	149	5 (3,4)	NE [NE; NE]	0,87	[0,31; 2,81]	0,8032
UE PT: Periphere Neuropathie	300	15 (5,0)	NE [NE; NE]	149	7 (4,7)	NE [NE; NE]	0,99	[0,41; 2,59]	0,9750
UE PT: Schwindelgefuehl	300	60 (20,0)	NE [NE; NE]	149	26 (17,4)	NE [NE; NE]	1,05	[0,67; 1,70]	0,8278
UE PT: Somnolenz	300	10 (3,3)	NE [NE; NE]	149	0	NE [NE; NE]	NC	NC	0,0249*

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[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE SOC: Erkrankungen des Ohrs und des Labyrinths	300	20 (6,7)	NE [NE; NE]	149	10 (6,7)	37,6 [37,6; NE]	0,85	[0,40; 1,91]	0,6790
UE SOC: Gefaesserkrankungen	300	43 (14,3)	NE [NE; NE]	149	23 (15,4)	NE [NE; NE]	0,81	[0,49; 1,36]	0,4045
UE PT: Hitzewallung	300	17 (5,7)	NE [NE; NE]	149	11 (7,4)	NE [NE; NE]	0,71	[0,33; 1,56]	0,3724
UE PT: Hypertonie	300	10 (3,3)	NE [NE; NE]	149	12 (8,1)	NE [NE; NE]	0,33	[0,14; 0,78]	0,0084*
UE SOC: Gutartige, boesartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)	300	10 (3,3)	NE [NE; NE]	149	7 (4,7)	NE [NE; NE]	0,52	[0,19; 1,45]	0,1858
UE SOC: Herzerkrankungen	300	26 (8,7)	NE [NE; NE]	149	8 (5,4)	NE [NE; NE]	1,34	[0,63; 3,18]	0,4718
UE PT: Palpitationen	300	15 (5,0)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	3,02	[0,85; 19,21]	0,1238
UE SOC: Infektionen und parasitaere Erkrankungen	300	168 (56,0)	13,6 [10,7;15,5]	149	77 (51,7)	11,8 [10,1;16,9]	0,91	[0,70; 1,20]	0,5087
UE PT: Bronchitis	300	14 (4,7)	NE [NE; NE]	149	0	NE [NE; NE]	NC	NC	0,0215*
UE PT: Gastroenteritis	300	11 (3,7)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	1,71	[0,45; 11,11]	0,4844

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[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Grippe	300	18 (6,0)	NE [NE; NE]	149	3 (2,0)	NE [NE; NE]	2,50	[0,84; 10,69]	0,1301
UE PT: Harnwegsinfektion	300	35 (11,7)	NE [NE; NE]	149	10 (6,7)	NE [NE; NE]	1,55	[0,80; 3,32]	0,2162
UE PT: Infektion der oberen Atemwege	300	45 (15,0)	NE [NE; NE]	149	18 (12,1)	NE [NE; NE]	0,95	[0,56; 1,70]	0,8715
UE PT: Nasopharyngitis	300	31 (10,3)	NE [NE; NE]	149	20 (13,4)	NE [NE; NE]	0,63	[0,36; 1,13]	0,1066
UE PT: Pharyngitis	300	11 (3,7)	NE [NE; NE]	149	3 (2,0)	NE [NE; NE]	1,55	[0,48; 6,87]	0,4995
UE PT: Sinusitis	300	11 (3,7)	NE [NE; NE]	149	8 (5,4)	NE [NE; NE]	0,56	[0,22; 1,44]	0,2034
UE PT: Zystitis	300	15 (5,0)	NE [NE; NE]	149	5 (3,4)	NE [NE; NE]	1,35	[0,52; 4,16]	0,5602
UE SOC: Leber- und Gallenerkrankungen	300	10 (3,3)	NE [NE; NE]	149	0	NE [NE; NE]	NC	NC	0,0435*
UE SOC: Psychiatrische Erkrankungen	300	58 (19,3)	NE [NE; NE]	149	38 (25,5)	NE [NE; NE]	0,69	[0,46; 1,04]	0,0705
UE PT: Angst	300	18 (6,0)	NE [NE; NE]	149	11 (7,4)	NE [NE; NE]	0,71	[0,33; 1,55]	0,3644
UE PT: Depression	300	16 (5,3)	NE [NE; NE]	149	13 (8,7)	NE [NE; NE]	0,57	[0,27; 1,21]	0,1296
UE PT: Schlaflosigkeit	300	30 (10,0)	NE [NE; NE]	149	19 (12,8)	NE [NE; NE]	0,74	[0,42; 1,33]	0,2934

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Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	300	153 (51,0)	14,3 [11,3;20,1]	149	68 (45,6)	13,8 [7,6; NE]	0,98	[0,74; 1,31]	0,8972
UE PT: Arthralgie	300	77 (25,7)	NE [NE; NE]	149	42 (28,2)	29,0 [29,0; NE]	0,80	[0,55; 1,17]	0,2358
UE PT: Brustschmerzen die Skelettmuskulatur betreffend	300	12 (4,0)	NE [NE; NE]	149	4 (2,7)	NE [NE; NE]	0,89	[0,30; 3,26]	0,8438
UE PT: Muskelspasmen	300	19 (6,3)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	7,88	[1,62;141,88]	0,0173*
UE PT: Muskulaere Schwaeche	300	11 (3,7)	NE [NE; NE]	149	5 (3,4)	NE [NE; NE]	1,03	[0,37; 3,28]	0,9573
UE PT: Myalgie	300	28 (9,3)	NE [NE; NE]	149	13 (8,7)	NE [NE; NE]	0,85	[0,45; 1,71]	0,6368
UE PT: Rueckenschmerzen	300	44 (14,7)	NE [NE; NE]	149	18 (12,1)	NE [NE; NE]	0,99	[0,58; 1,76]	0,9719
UE PT: Schmerz in einer Extremitaet	300	30 (10,0)	NE [NE; NE]	149	13 (8,7)	NE [NE; NE]	1,02	[0,54; 2,02]	0,9640
UE SOC: Stoffwechsel- und Ernaehrungsstoerungen	300	109 (36,3)	52,5 [28,3; NE]	149	35 (23,5)	NE [NE; NE]	1,60	[1,11; 2,39]	0,0150*
UE PT: Appetit vermindert	300	70 (23,3)	NE [NE; NE]	149	14 (9,4)	NE [NE; NE]	2,59	[1,50; 4,79]	0,0008*

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Hypokaliaemie	300	18 (6,0)	NE [NE; NE]	149	6 (4,0)	NE [NE; NE]	1,44	[0,60; 3,98]	0,4367
UE PT: Hypomagnesiaemie	300	14 (4,7)	NE [NE; NE]	149	10 (6,7)	NE [NE; NE]	0,62	[0,28; 1,46]	0,2589
UE SOC: Untersuchungen	300	101 (33,7)	74,5 [34,9; NE]	149	49 (32,9)	NE [NE; NE]	0,91	[0,65; 1,30]	0,6076
UE PT: Alaninaminotransferase erhoeht	300	18 (6,0)	NE [NE; NE]	149	14 (9,4)	41,6 [NE; NE]	0,42	[0,20; 0,89]	0,0174*
UE PT: Aspartataminotransferase erhoeht	300	18 (6,0)	NE [NE; NE]	149	10 (6,7)	55,4 [NE; NE]	0,63	[0,29; 1,43]	0,2432
UE PT: Gamma-Glutamyltransferase erhoeht	300	10 (3,3)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	2,11	[0,55; 13,83]	0,3283
UE PT: Gewicht erhoeht	300	14 (4,7)	NE [NE; NE]	149	12 (8,1)	NE [NE; NE]	0,51	[0,23; 1,12]	0,0804
UE PT: Kreatinin im Blut erhoeht	300	24 (8,0)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	4,96	[1,46; 30,99]	0,0162*
UE PT: Leukozytenzahl erniedrigt	300	24 (8,0)	NE [NE; NE]	149	8 (5,4)	NE [NE; NE]	1,33	[0,62; 3,17]	0,4849
UE PT: Neutrophilenzahl erniedrigt	300	25 (8,3)	NE [NE; NE]	149	9 (6,0)	NE [NE; NE]	1,35	[0,65; 3,07]	0,4374

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Table 3.2.1 SOLO1: Summary of analysis of time to first occurrence of adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE PT: Thrombozytenzahl vermindert	300	16 (5,3)	NE [NE; NE]	149	3 (2,0)	NE [NE; NE]	2,47	[0,82; 10,64]	0,1398
UE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	300	59 (19,7)	NE [NE; NE]	149	26 (17,4)	NE [NE; NE]	0,92	[0,58; 1,48]	0,7143
UE PT: Baenderzerrung	300	11 (3,7)	NE [NE; NE]	149	0	NE [NE; NE]	NC	NC	0,0378*
UE PT: Schmerzen waehrend eines Eingriffes	300	10 (3,3)	NE [NE; NE]	149	3 (2,0)	32,5 [32,5; NE]	1,39	[0,42; 6,25]	0,6160

The time to event endpoint is the time to first AE or the time to censoring if the AE has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties.
Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.2.2 SOLO1: Summary of analysis of time to first occurrence of serious adverse events
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
SUE	300	67 (22,3)	NE [NE; NE]	149	21 (14,1)	61,0 [NE; NE]	1,47	[0,91; 2,46]	0,1273
SUE SOC: Erkrankungen des Blutes und des Lymphsystems	300	31 (10,3)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	15,36	[3,30;273,39]	0,0003*
SUE PT: Anaemie	300	26 (8,7)	NE [NE; NE]	149	0	NE [NE; NE]	NC	NC	0,0003*
SUE SOC: Infektionen und parasitaere Erkrankungen	300	13 (4,3)	NE [NE; NE]	149	6 (4,0)	NE [NE; NE]	0,78	[0,30; 2,26]	0,6234

The time to event endpoint is the time to first serious AE or the time to censoring if the serious AE has not occurred prior to the date of DCO. Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.2.3 SOLO1: Summary of analysis of time to first occurrence of adverse events leading to discontinuation of treatment
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Abbruch wegen UE	300	34 (11,3)	NE [NE; NE]	149	4 (2,7)	61,0 [NE; NE]	3,82	[1,51; 12,83]	0,0067*

The time to event endpoint is the time to first AE leading to discontinuation of treatment or the time to censoring if the AE leading to discontinuation of treatment has not occurred prior to the date of DCO.
Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties.
Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 3.2.4 SOLO1: Summary of analysis of time to first occurrence of adverse events with max CTCAE grade >=3
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Schwere UE mit max. CTCAE Grad>=3	300	126 (42,0)	42,1 [21,2; NE]	149	32 (21,5)	61,0 [NE; NE]	2,10	[1,44; 3,15]	0,0001*
Schwere UE nach SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	300	12 (4,0)	NE [NE; NE]	149	3 (2,0)	61,0 [NE; NE]	1,56	[0,48; 6,94]	0,4965
Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems	300	84 (28,0)	NE [NE; NE]	149	10 (6,7)	NE [NE; NE]	4,58	[2,50; 9,42]	<0,0001*
Schwere UE nach PT: Anaemie	300	71 (23,7)	NE [NE; NE]	149	2 (1,3)	NE [NE; NE]	19,51	[6,13;118,74]	<0,0001*
Schwere UE nach PT: Neutropenie	300	20 (6,7)	NE [NE; NE]	149	4 (2,7)	NE [NE; NE]	2,41	[0,91; 8,29]	0,0977
Schwere UE nach SOC: Erkrankungen des Gastrointestinaltrakts	300	20 (6,7)	NE [NE; NE]	149	3 (2,0)	NE [NE; NE]	3,16	[1,08; 13,43]	0,0500
Schwere UE nach SOC: Infektionen und parasitaere Erkrankungen	300	12 (4,0)	NE [NE; NE]	149	6 (4,0)	NE [NE; NE]	0,75	[0,28; 2,18]	0,5662
Schwere UE nach SOC: Untersuchungen	300	15 (5,0)	NE [NE; NE]	149	6 (4,0)	NE [NE; NE]	1,15	[0,47; 3,24]	0,7713

The time to event endpoint is the time to first AE with max CTCAE grade >=3 or the time to censoring if the AE with max CTCAE grade >=3 has not occurred prior to the date of DCO. Includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 3.2.5 SOLO1: Summary of analysis of time to first occurrence of adverse events of special interest
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UESI: MDS/AML	300	4 (1,3)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	1,72	[0,25; 33,75]	0,6229
UESI: neue primäre Malignität (außer MDS/AML)	300	14 (4,7)	NE [NE; NE]	149	8 (5,4)	NE [NE; NE]	0,76	[0,33; 1,91]	0,5409
UESI: Pneumonitis	300	5 (1,7)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	2,61	[0,42; 50,06]	0,3622

The time to event endpoint is the time to first AE of special interest or the time to censoring if the AE of special interest has not occurred prior to the date of DCO. For AESI of pneumonitis, includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. For remaining AESIs, includes AEs with an onset date on or after the date of first dose. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 3.2.6 SOLO1: Summary of analysis of time to first occurrence of serious adverse events of special interest
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Schwerwiegende UE: MDS/AML	300	4 (1,3)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	1,72	[0,25; 33,75]	0,6229
Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)	300	14 (4,7)	NE [NE; NE]	149	8 (5,4)	NE [NE; NE]	0,76	[0,33; 1,92]	0,5423
Schwerwiegende UE: Pneumonitis	300	2 (0,7)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	1,04	[0,10; 22,29]	0,9765

The time to event endpoint is the time to first serious AE of special interest or the time to censoring if the serious AE of special interest has not occurred prior to the date of DCO. For AESI of pneumonitis, includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. For remaining AESIs, includes AEs with an onset date on or after the date of first dose. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 3.2.7 SOLO1: Summary of analysis of time to first occurrence of adverse events of special interest with max CTCAE grade>=3
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Schwere UESI G>=3: MDS/AML	300	4 (1,3)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	1,72	[0,25; 33,75]	0,6229
Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)	300	13 (4,3)	NE [NE; NE]	149	6 (4,0)	NE [NE; NE]	0,94	[0,37; 2,67]	0,8940
Schwere UESI G>=3: Pneumonitis	300	1 (0,3)	NE [NE; NE]	149	1 (0,7)	NE [NE; NE]	0,52	[0,02; 13,03]	0,6336

The time to event endpoint is the time to first AE of special interest with max CTCAE grade>=3 or the time to censoring if the AE of special interest with max CTCAE grade>=3 has not occurred prior to the date of DCO. For AESI of pneumonitis, includes AEs with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. For remaining AESIs, includes AEs with an onset date on or after the date of first dose. MedDRA version 24.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] Estimated from Cox proportional hazards model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test. Breslow method for handling ties. Hazard ratio <1 favours olaparib. * p<0.05. NC = not calculable.
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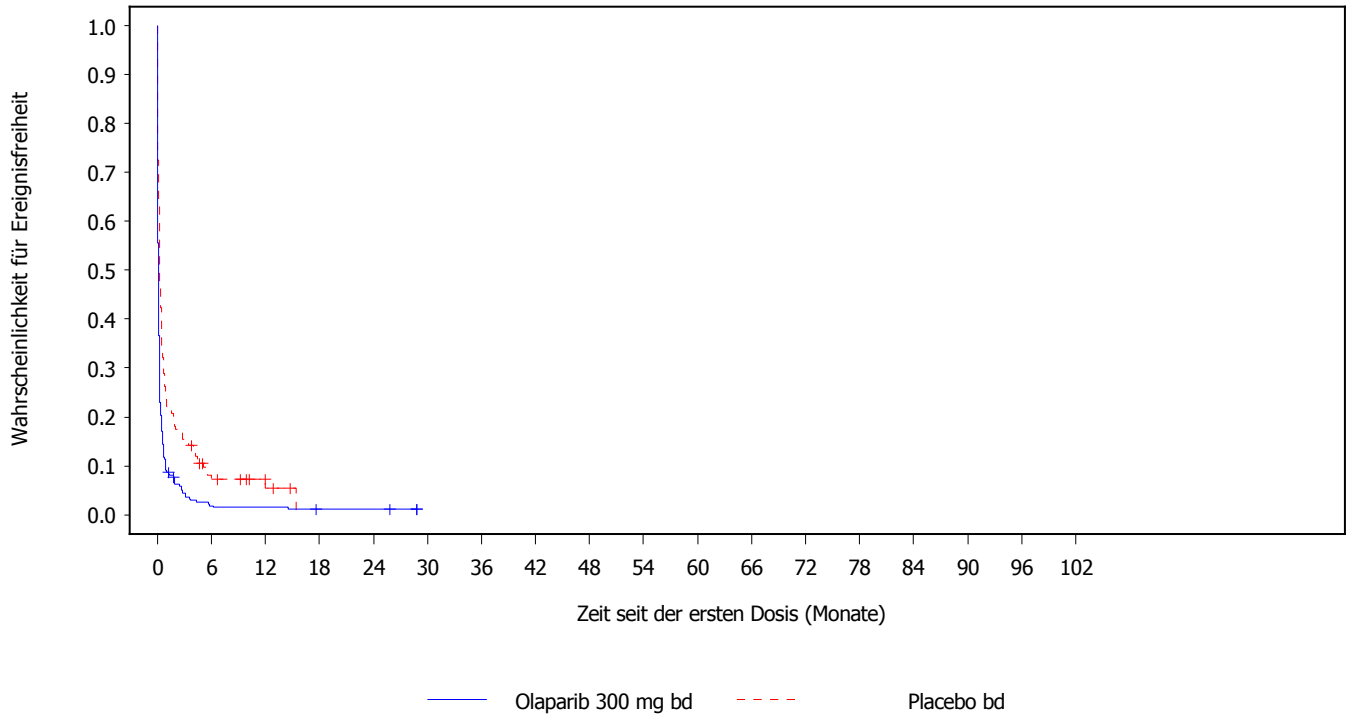
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.1 SOLO1: Kaplan-Meier plot of time to first occurrence of UE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	5	4	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	Olaparib 300 mg bd
149	10	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

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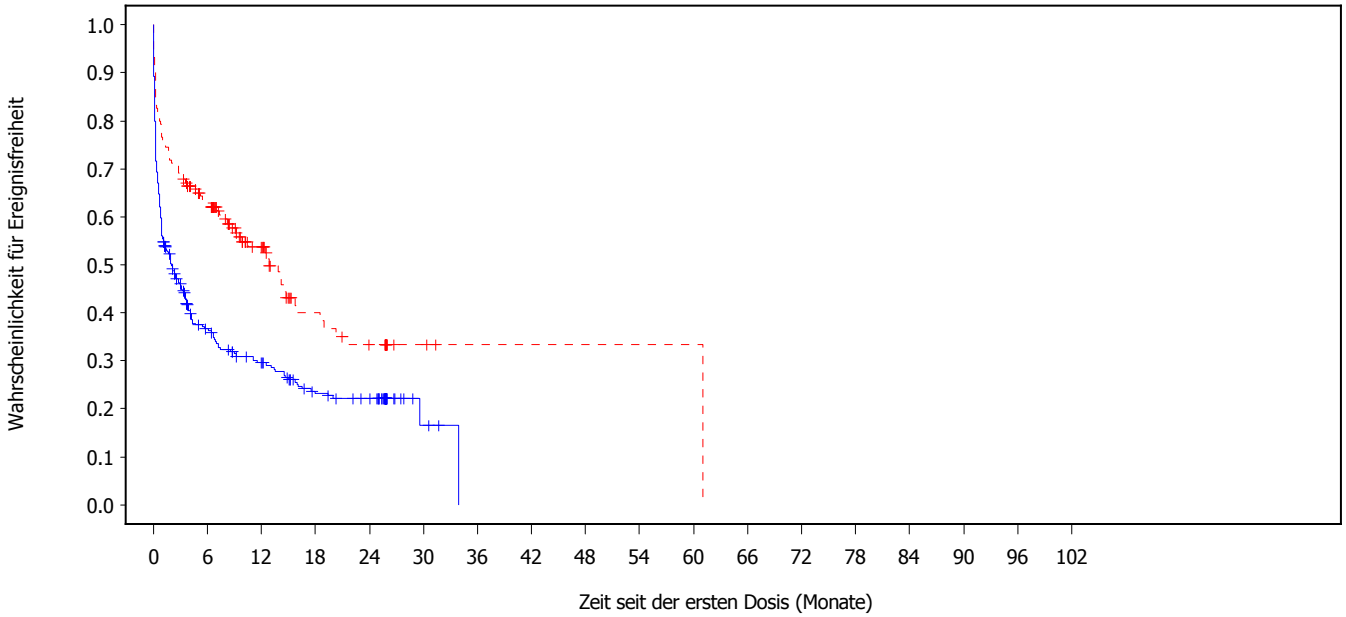
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.2 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	95	70	47	41	3	0	0	0	0	0	0	0	0	0	0	0	Olaparib 300 mg bd
149	85	47	25	19	3	1	1	1	1	1	0	0	0	0	0	0	Placebo bd

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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
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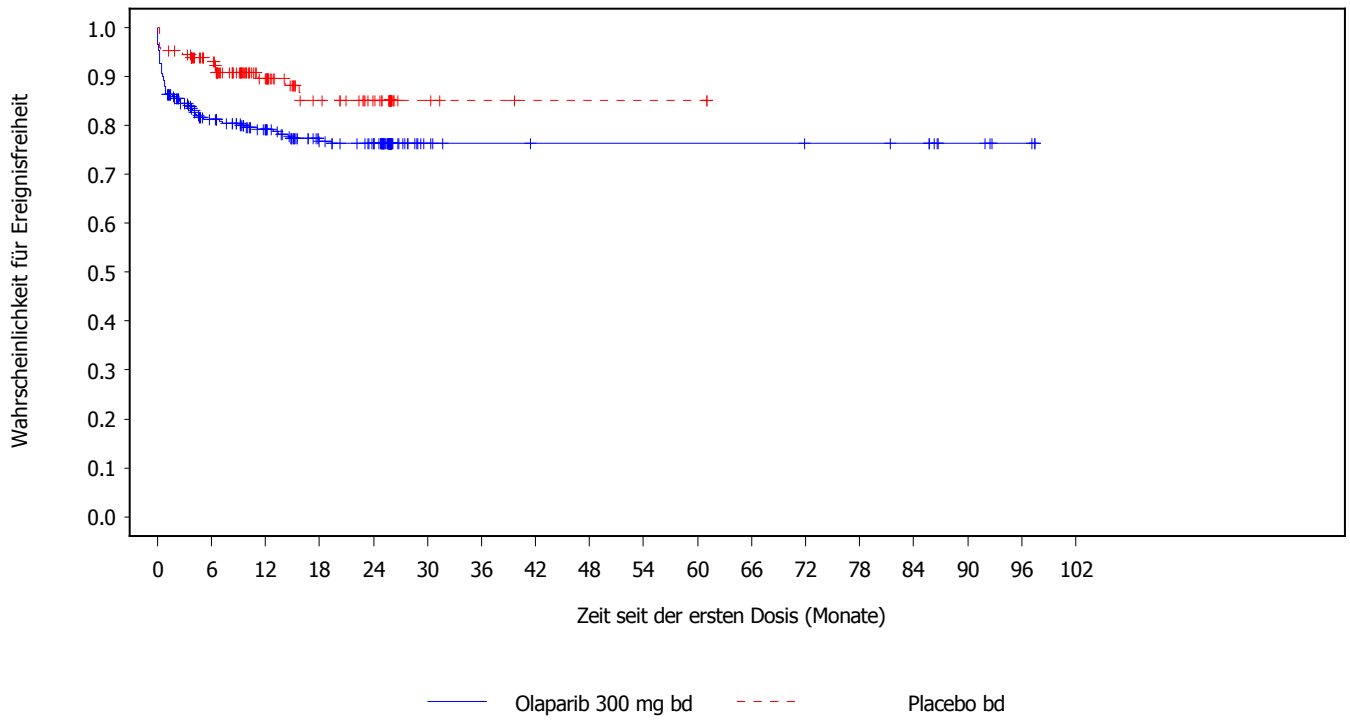
Figure 3.3.3 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Asthenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	212	182	151	140	16	13	12	12	12	12	12	11	11	10	5	2	0	Olaparib 300 mg bd
149	122	77	53	43	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
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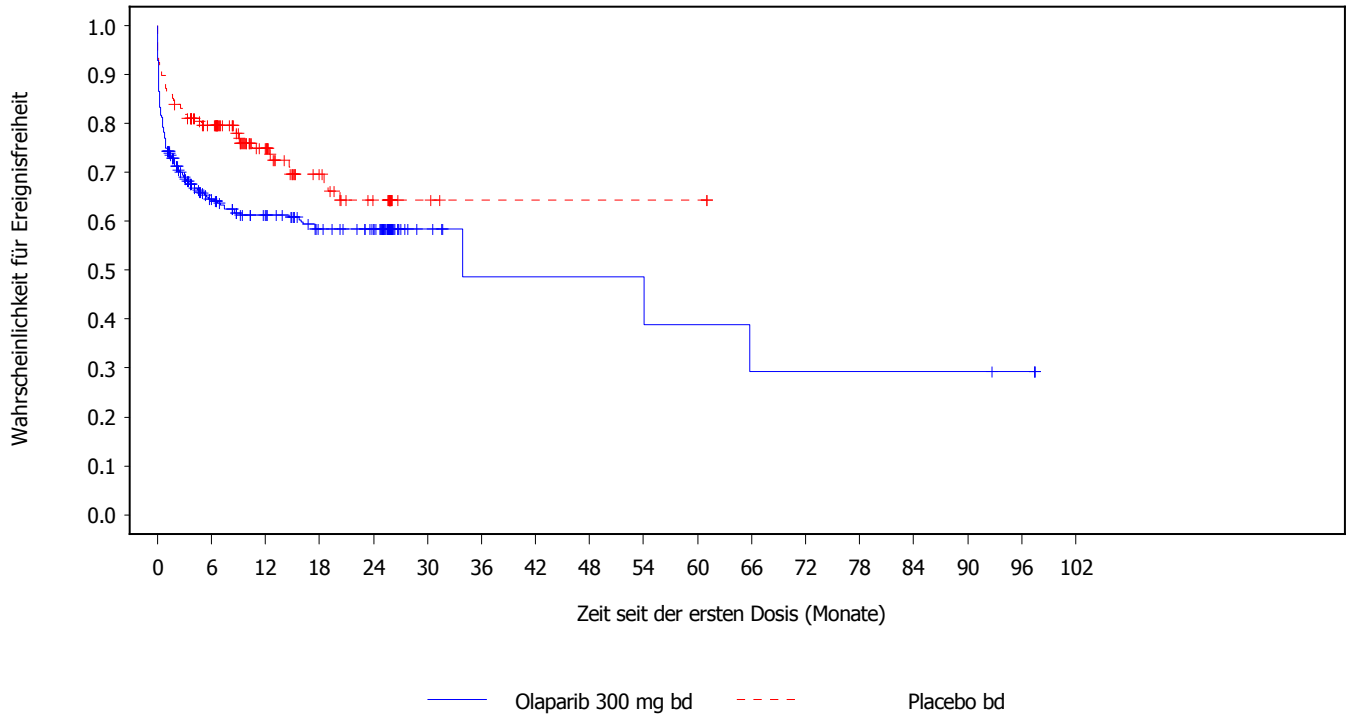
Figure 3.3.4 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Ermuedung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



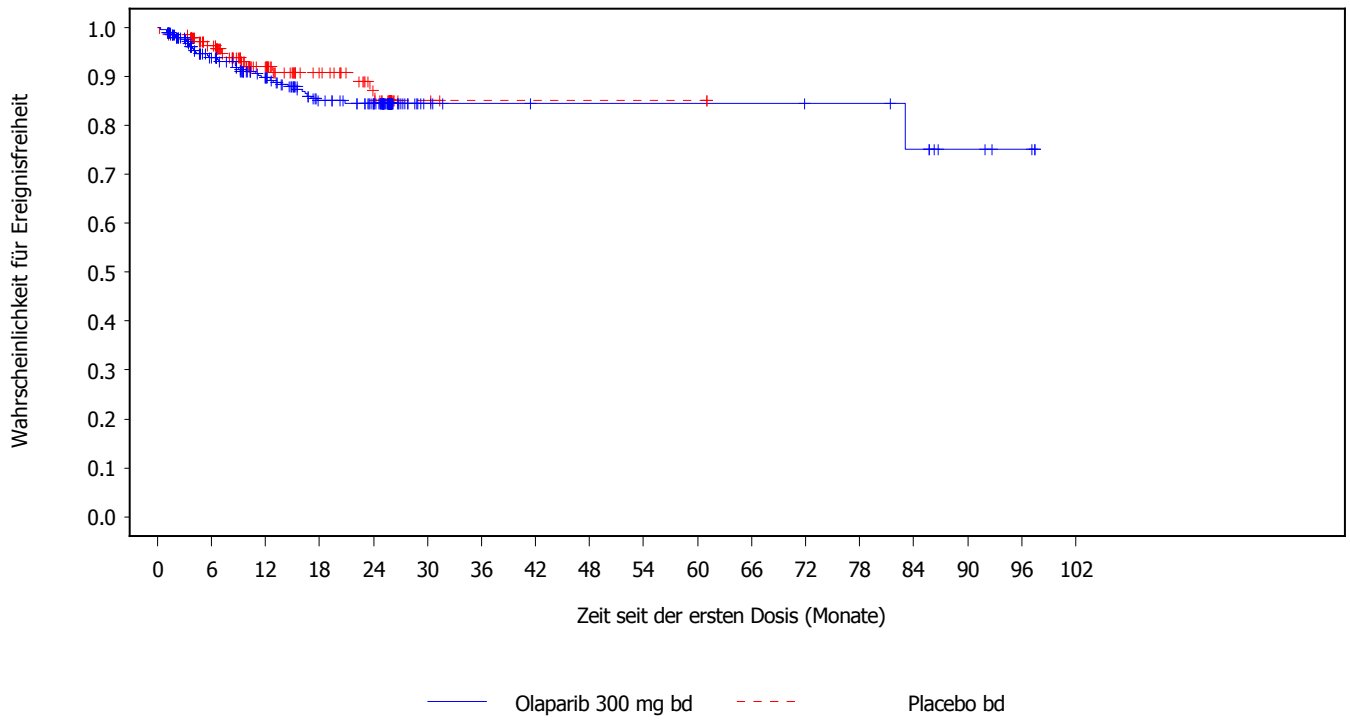
Anzahl an Patienten unter Risiko:

300	165	140	120	111	9	5	5	5	5	4	3	3	3	3	3	2	0	Olaparib 300 mg bd
149	106	65	41	30	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebad 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.5 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Fieber
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



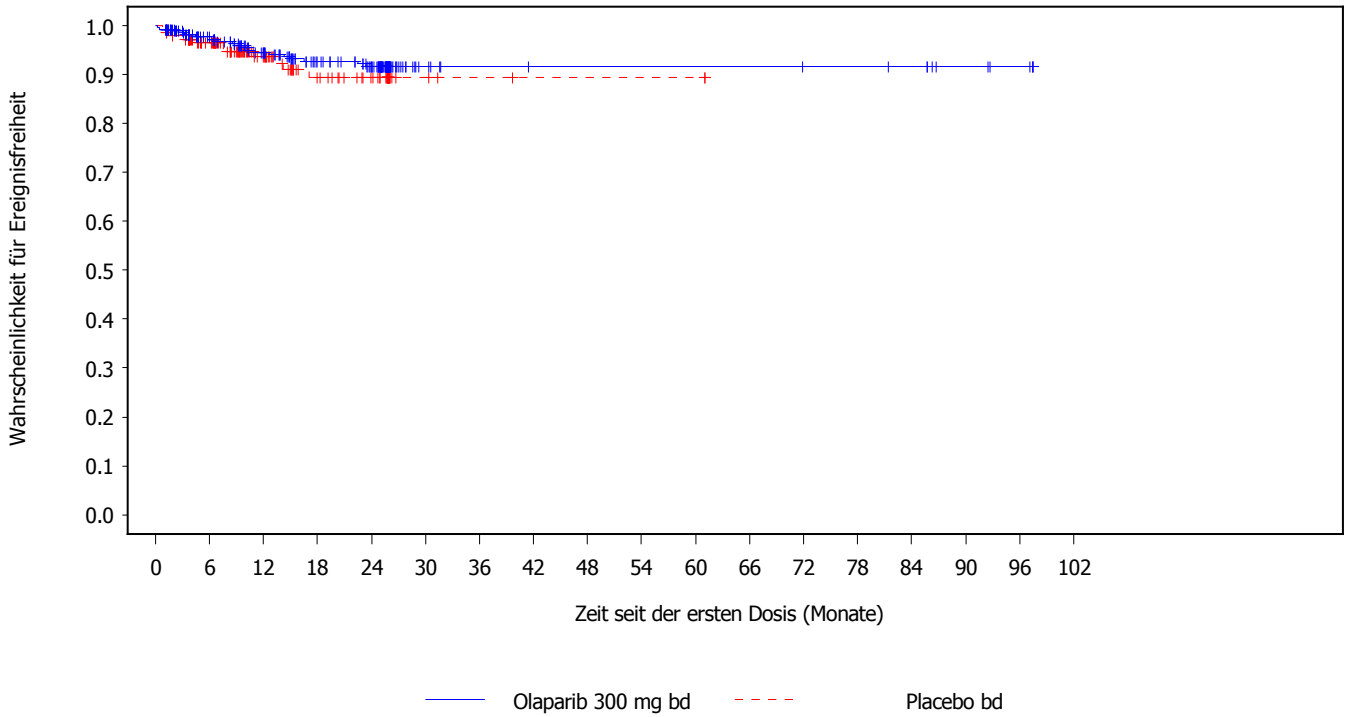
Anzahl an Patienten unter Risiko:

300	244	207	172	158	15	12	11	11	11	11	11	10	10	8	4	2	0	Olaparib 300 mg bd
149	126	84	59	44	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebae 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.6 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Grippeaehnliche Erkrankung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



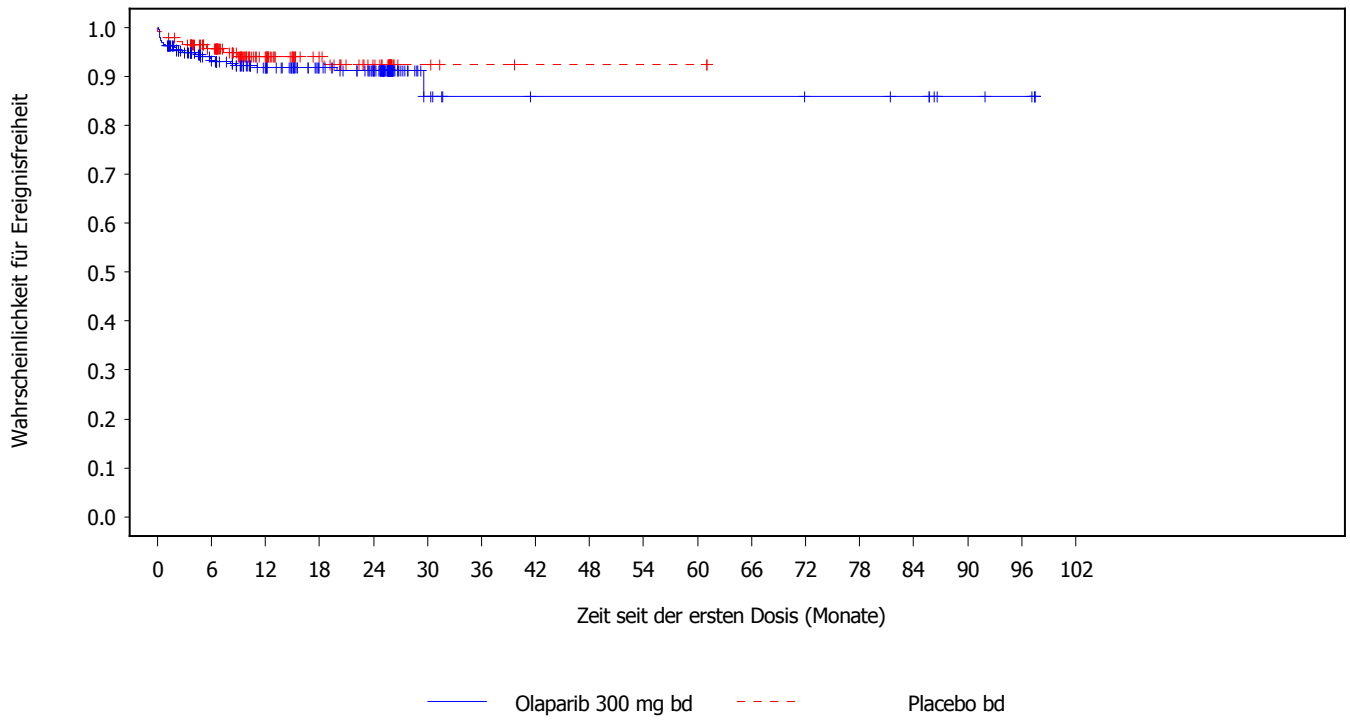
Anzahl an Patienten unter Risiko:

300	254	216	185	167	16	12	11	11	11	11	11	10	10	9	5	3	0	Olaparib 300 mg bd
149	125	80	55	45	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebaf 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.7 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Oedem peripher
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



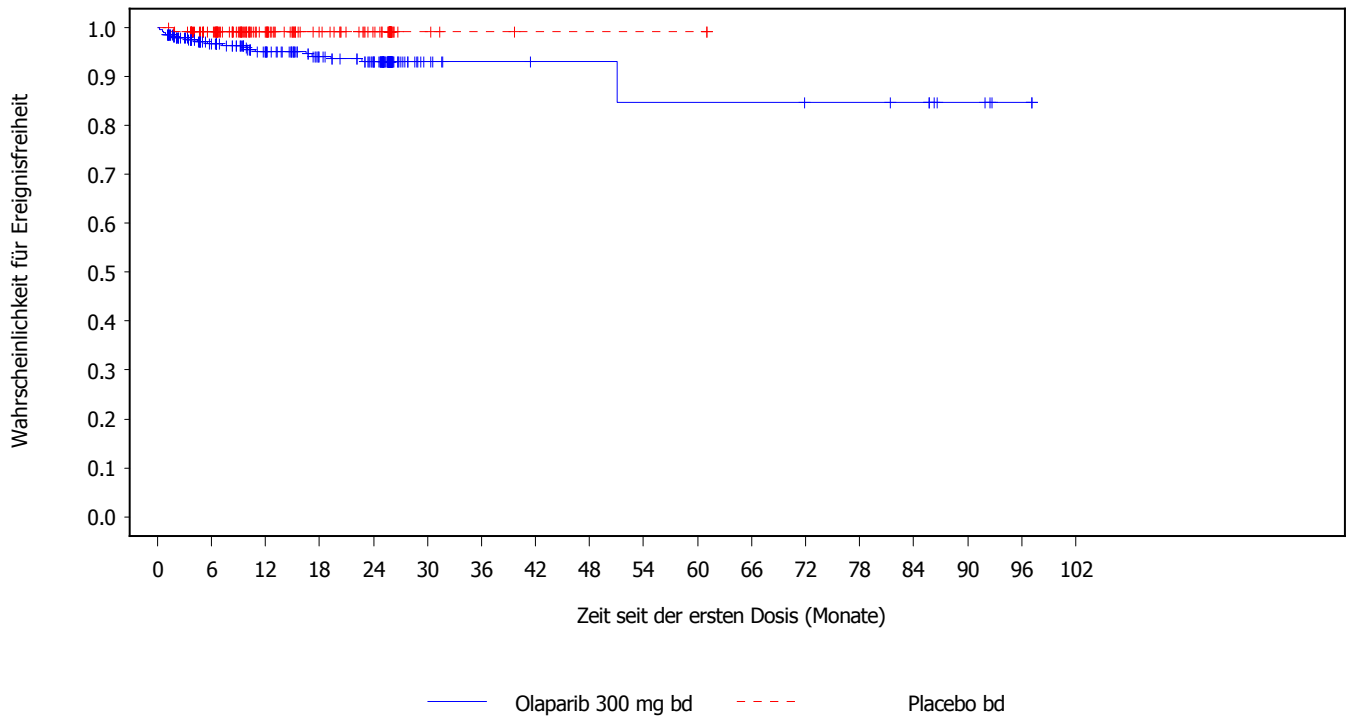
Anzahl an Patienten unter Risiko:

300	245	213	189	173	15	11	10	10	10	10	10	9	9	8	4	3	0	Olaparib 300 mg bd
149	125	82	58	45	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebag 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.8 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schleimhautentzuendung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



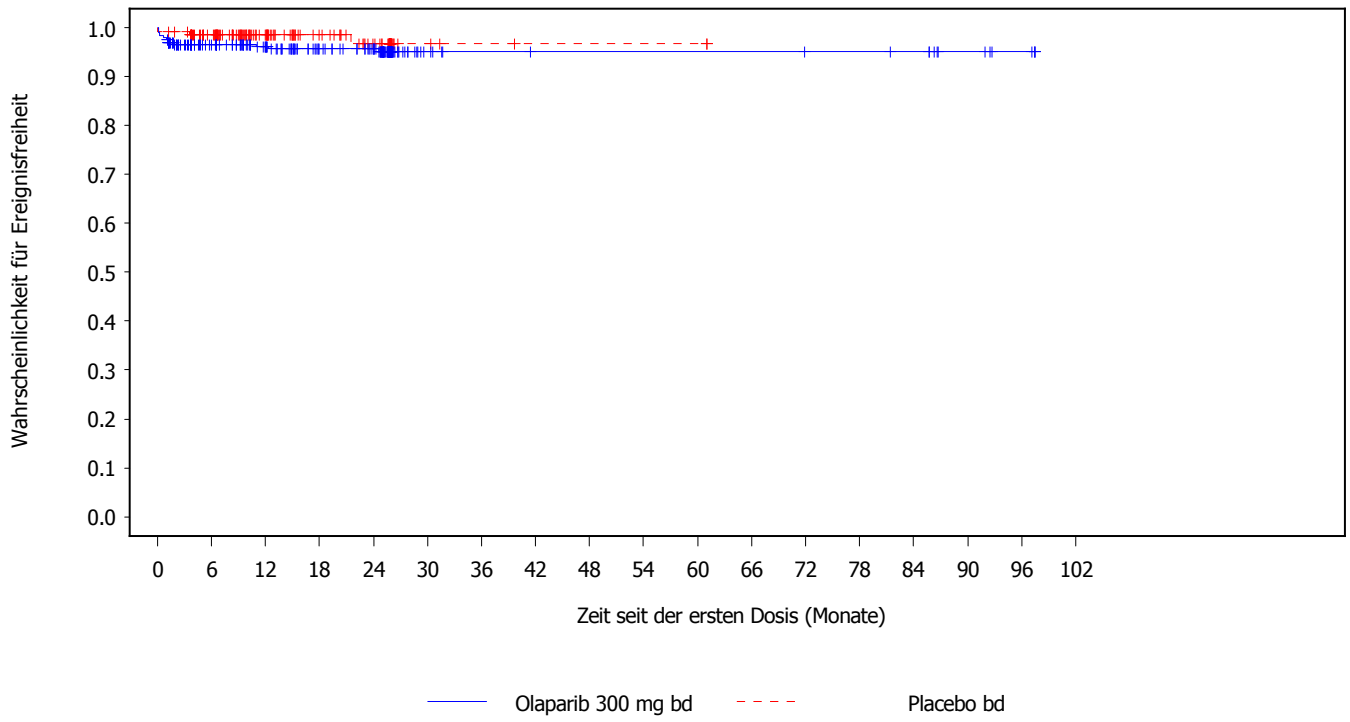
Anzahl an Patienten unter Risiko:

300	252	218	188	171	16	12	11	11	10	10	10	9	9	8	4	1	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebah 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.9 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Unwohlsein
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



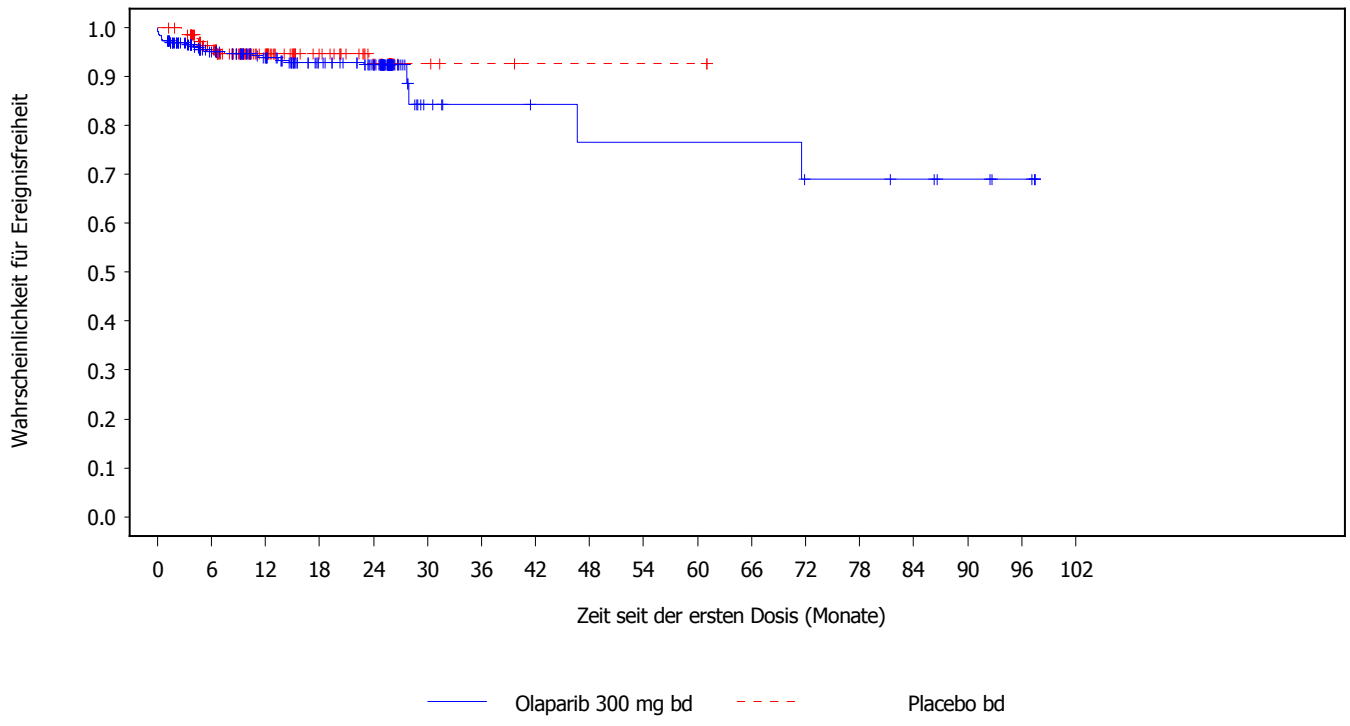
Anzahl an Patienten unter Risiko:

300	254	224	194	179	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	128	86	61	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebai 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.10 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Augenerkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



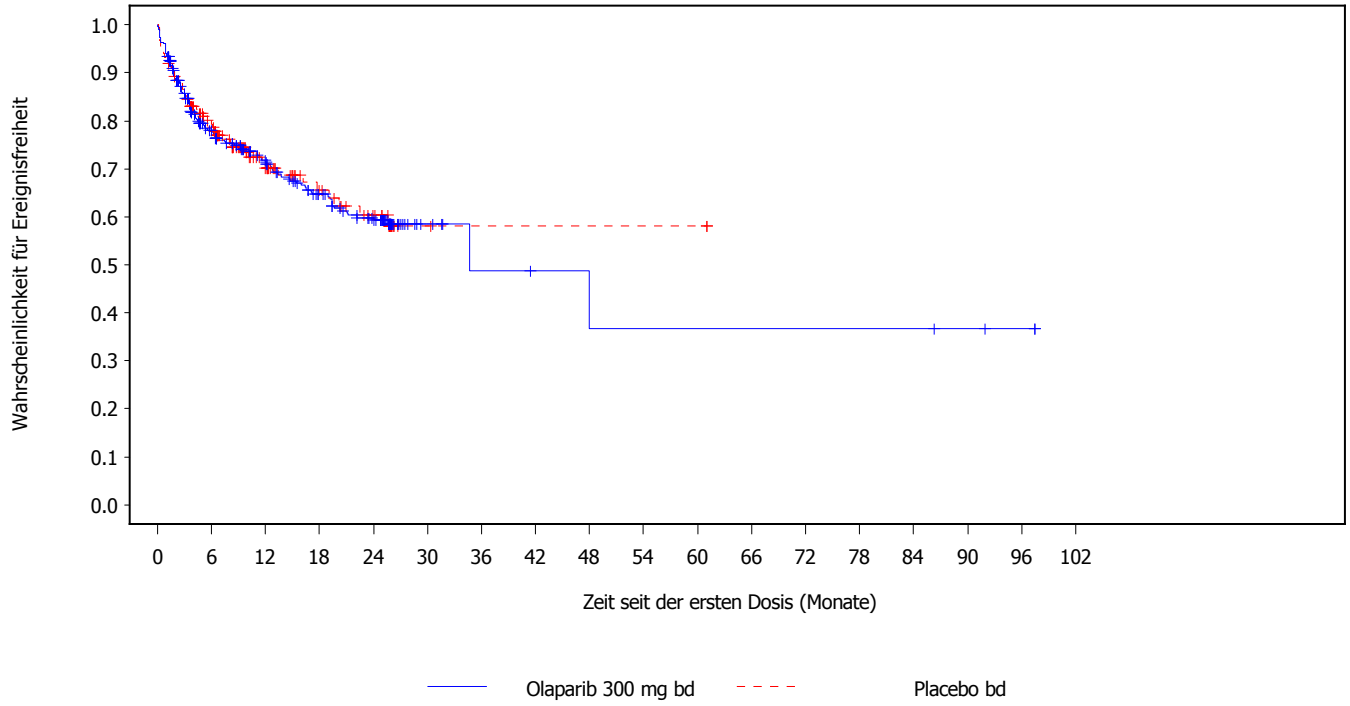
Anzahl an Patienten unter Risiko:

300	246	215	187	172	15	12	11	10	10	10	10	8	8	7	5	3	0	Olaparib 300 mg bd
149	124	81	57	43	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebaj 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.11 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



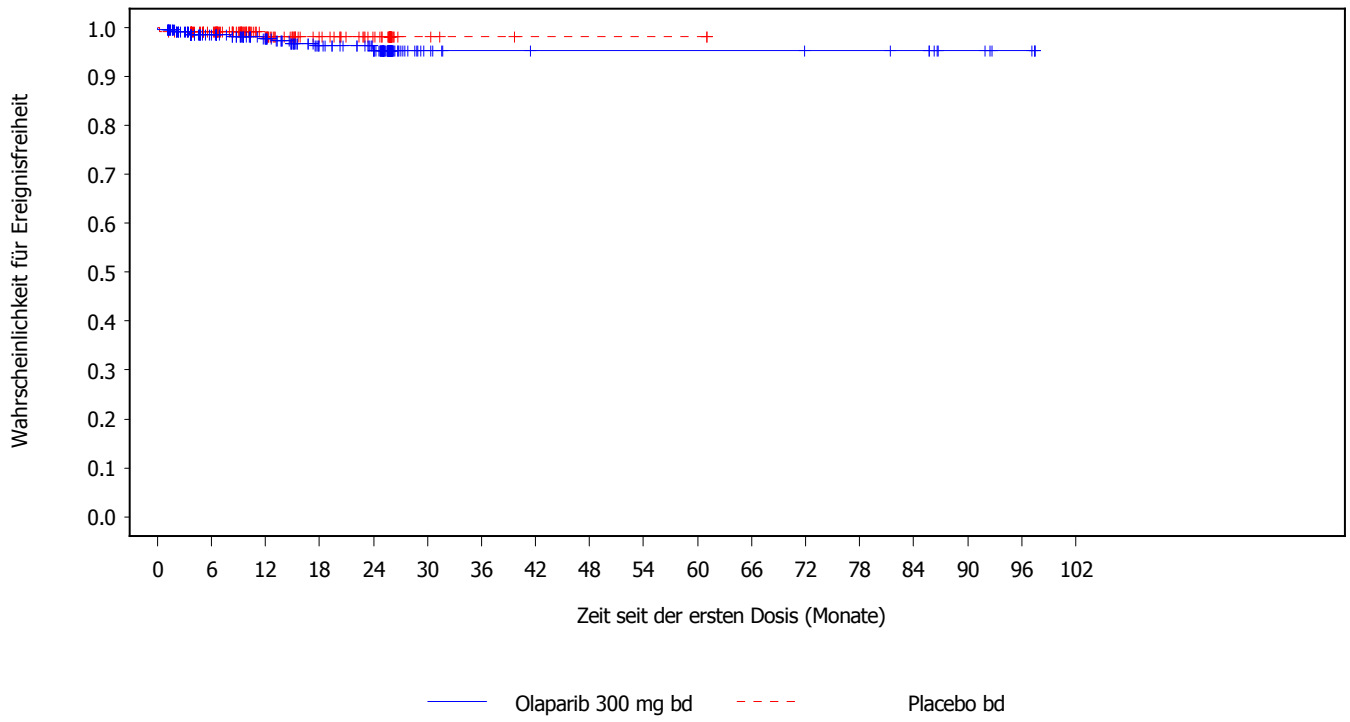
Anzahl an Patienten unter Risiko:

300	204	165	135	114	9	5	4	4	3	3	3	3	3	3	2	1	0	Olaparib 300 mg bd
149	105	60	41	30	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebak 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.12 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Allergische Rhinitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



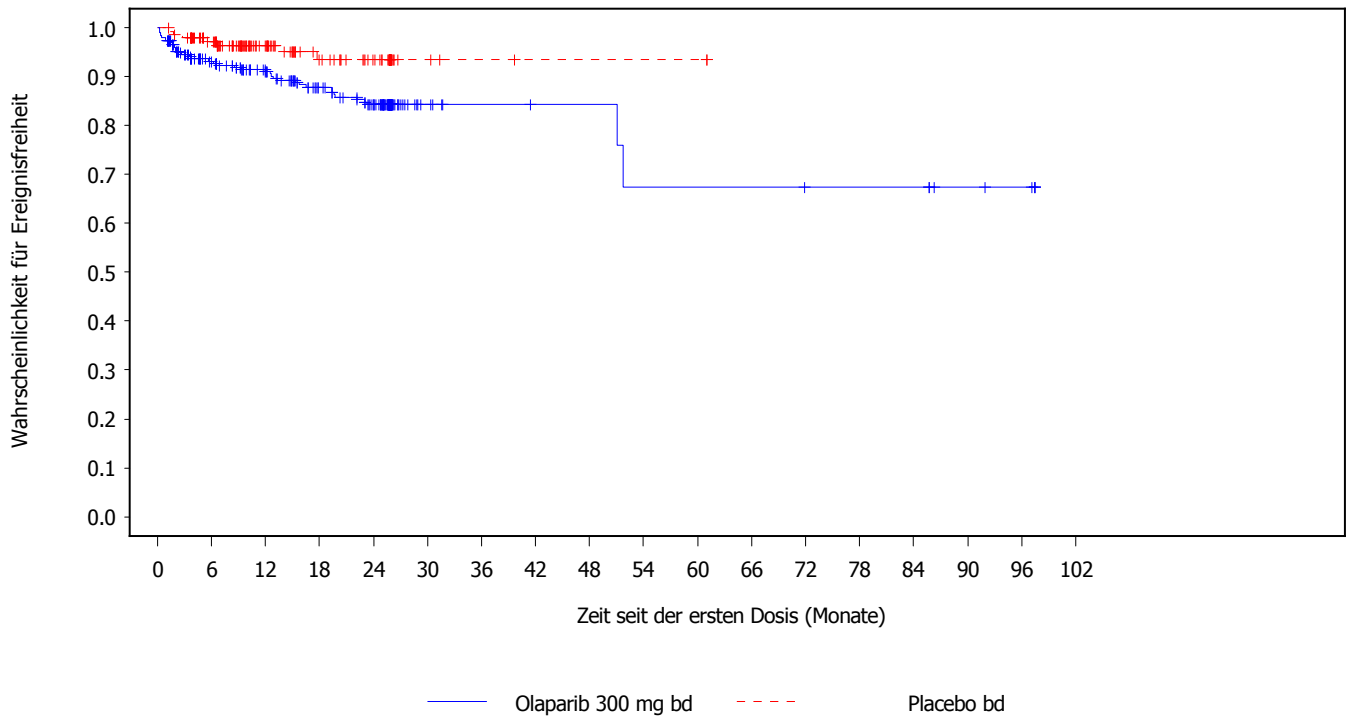
Anzahl an Patienten unter Risiko:

300	256	225	193	177	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	129	85	60	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebal 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.13 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Dyspnoe
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



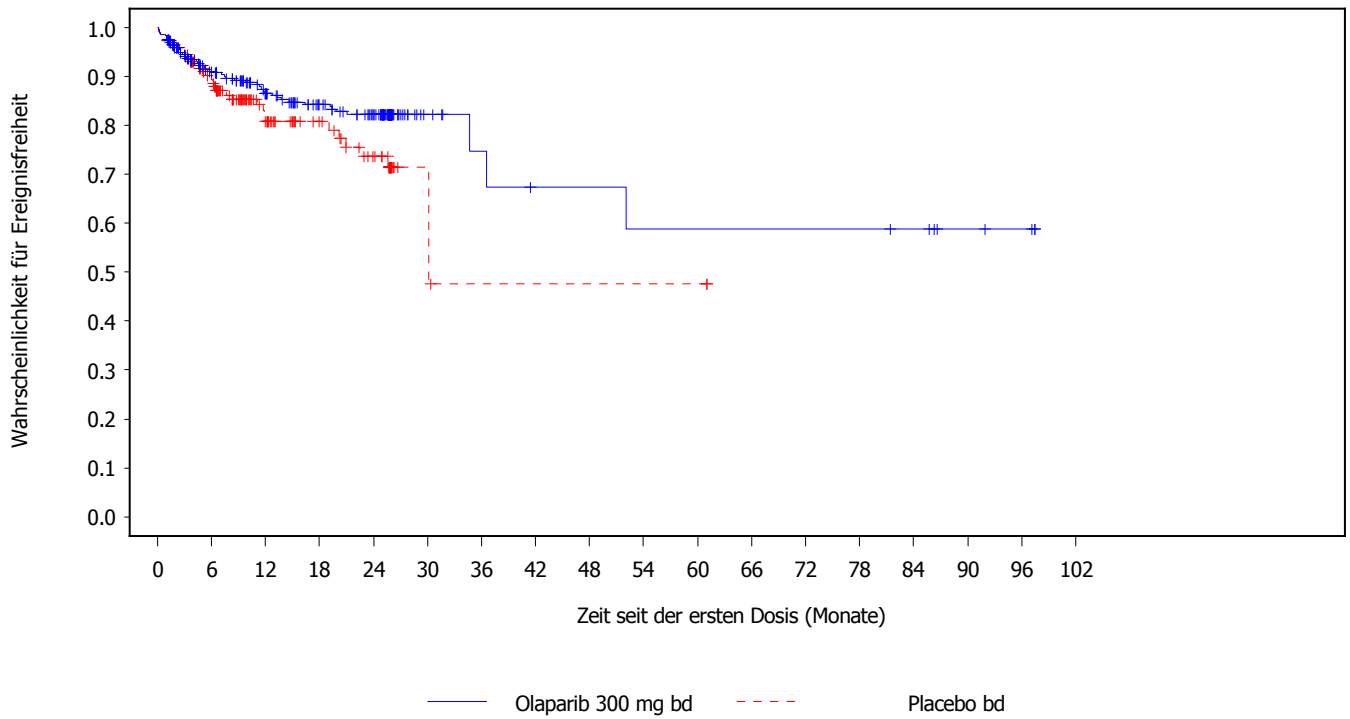
Anzahl an Patienten unter Risiko:

300	243	212	180	159	15	11	10	10	8	8	8	7	7	7	4	3	0	Olaparib 300 mg bd
149	127	84	58	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebam 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.14 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Husten
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



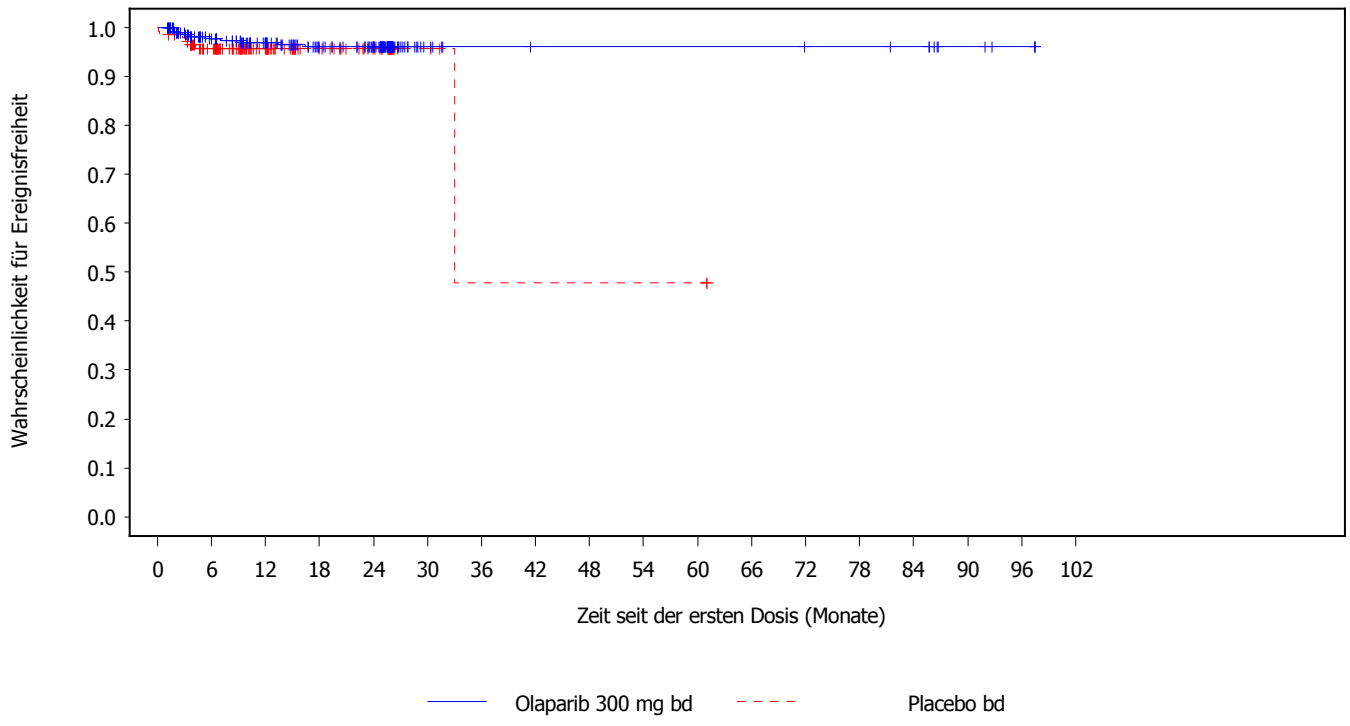
Anzahl an Patienten unter Risiko:

300	238	199	171	152	14	10	8	8	7	7	7	7	7	6	3	2	0	Olaparib 300 mg bd
149	118	69	49	36	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaeban 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.15 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Nasenverstopfung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



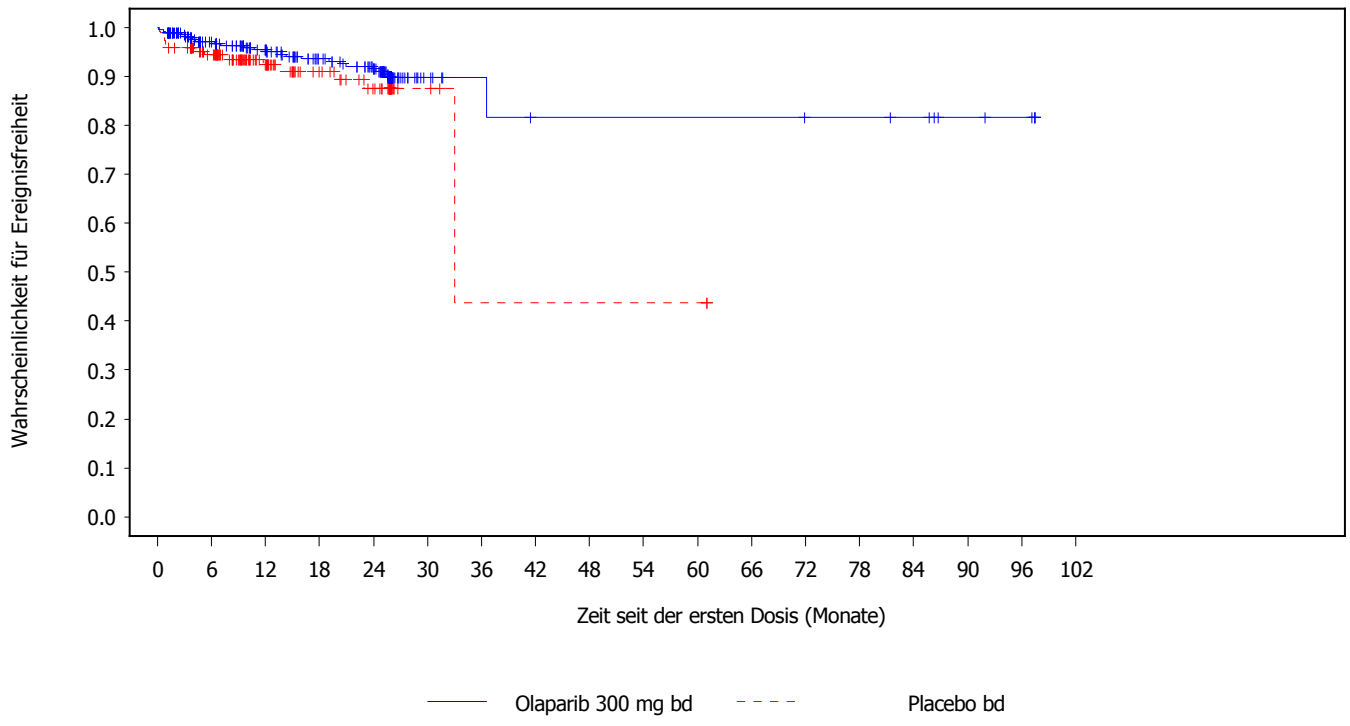
Anzahl an Patienten unter Risiko:

300	254	224	195	179	16	12	11	11	11	11	11	10	10	9	4	2	0	Olaparib 300 mg bd
149	125	84	59	47	4	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebao 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.16 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerzen im Oropharynx
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



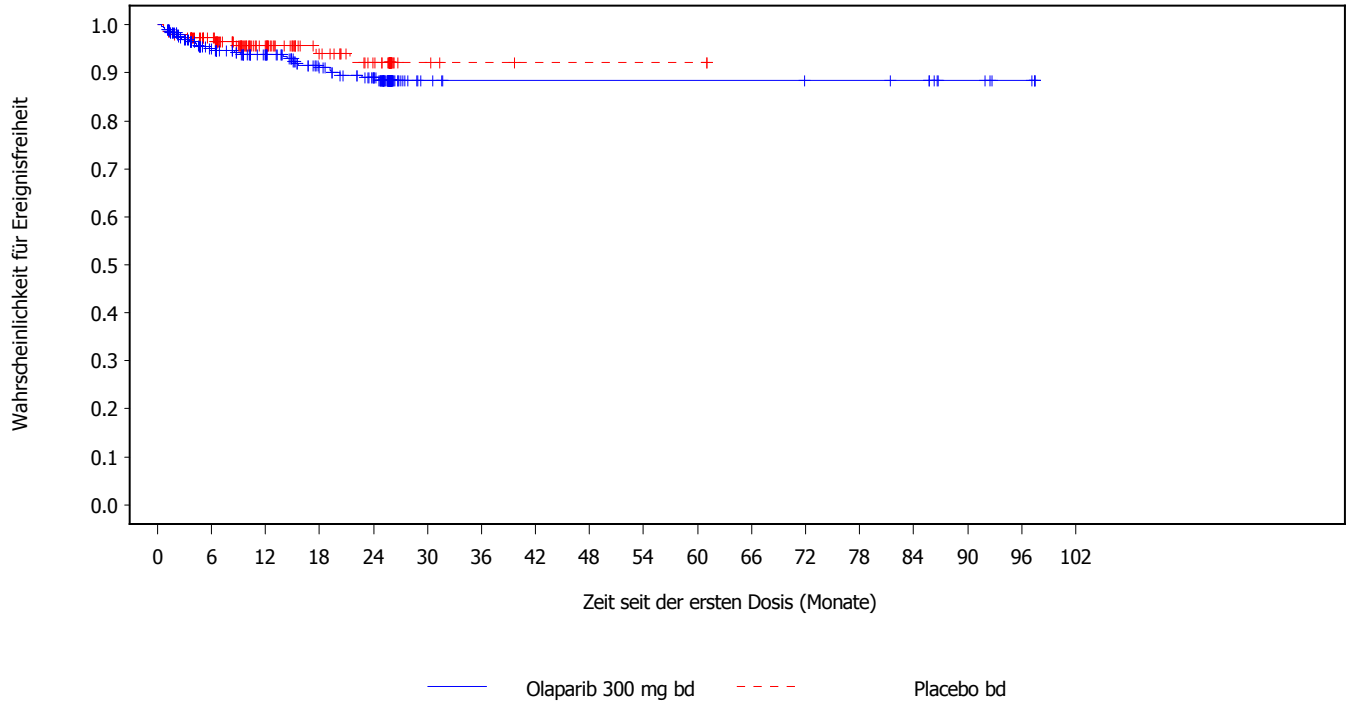
Anzahl an Patienten unter Risiko:

300	252	219	189	170	15	11	9	9	9	9	9	8	8	7	4	3	0	Olaparib 300 mg bd
149	123	81	57	45	4	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebap 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.17 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



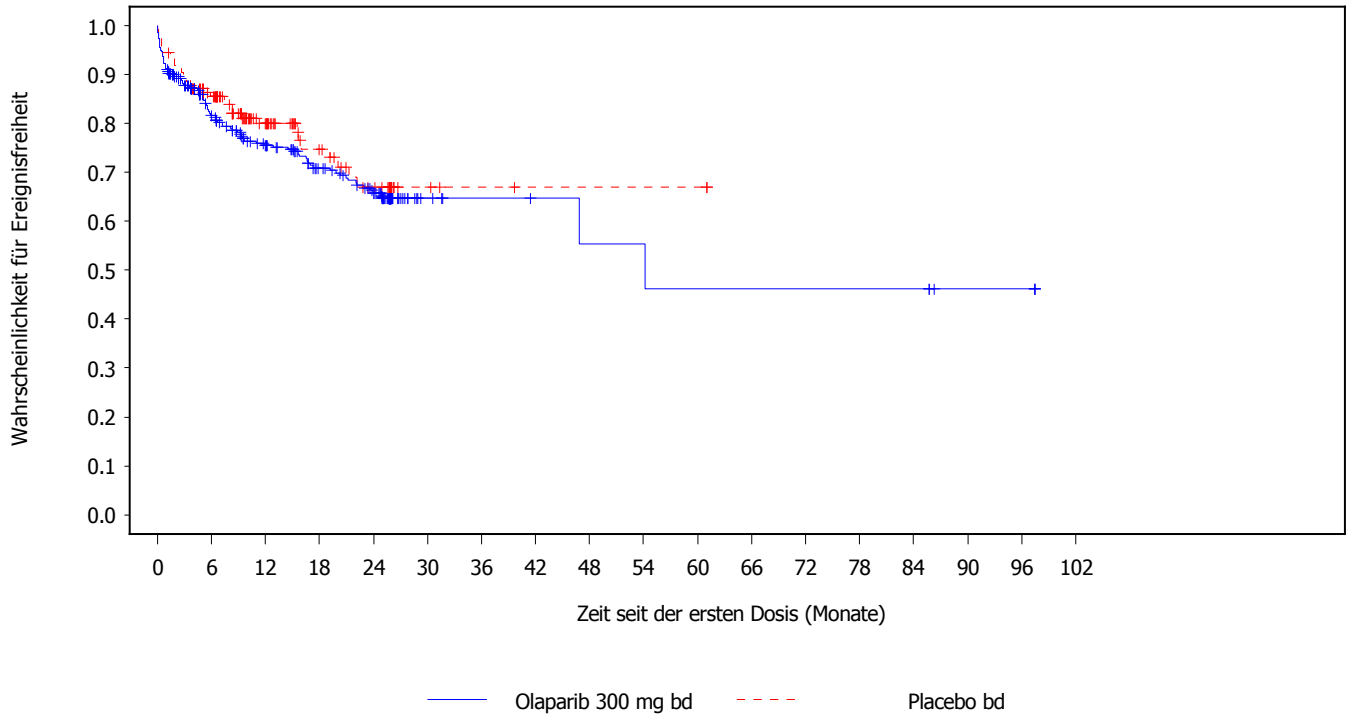
Anzahl an Patienten unter Risiko:

300	246	217	185	167	16	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	126	82	56	44	4	2	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebaq 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.18 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Haut und des Unterhautgewebes
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



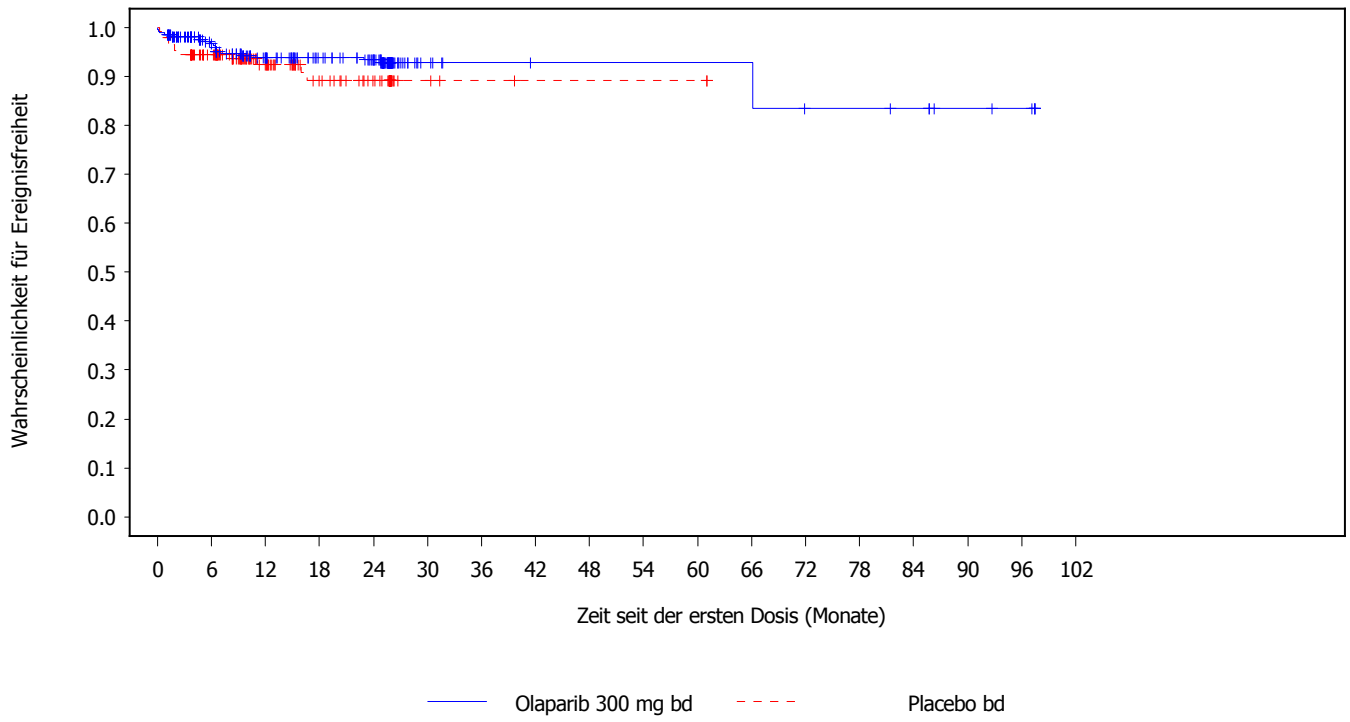
Anzahl an Patienten unter Risiko:

300	212	173	144	124	11	8	7	6	6	5	5	5	5	2	2	0	Olaparib 300 mg bd
149	111	66	42	31	4	2	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebar 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.19 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Ausschlag
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



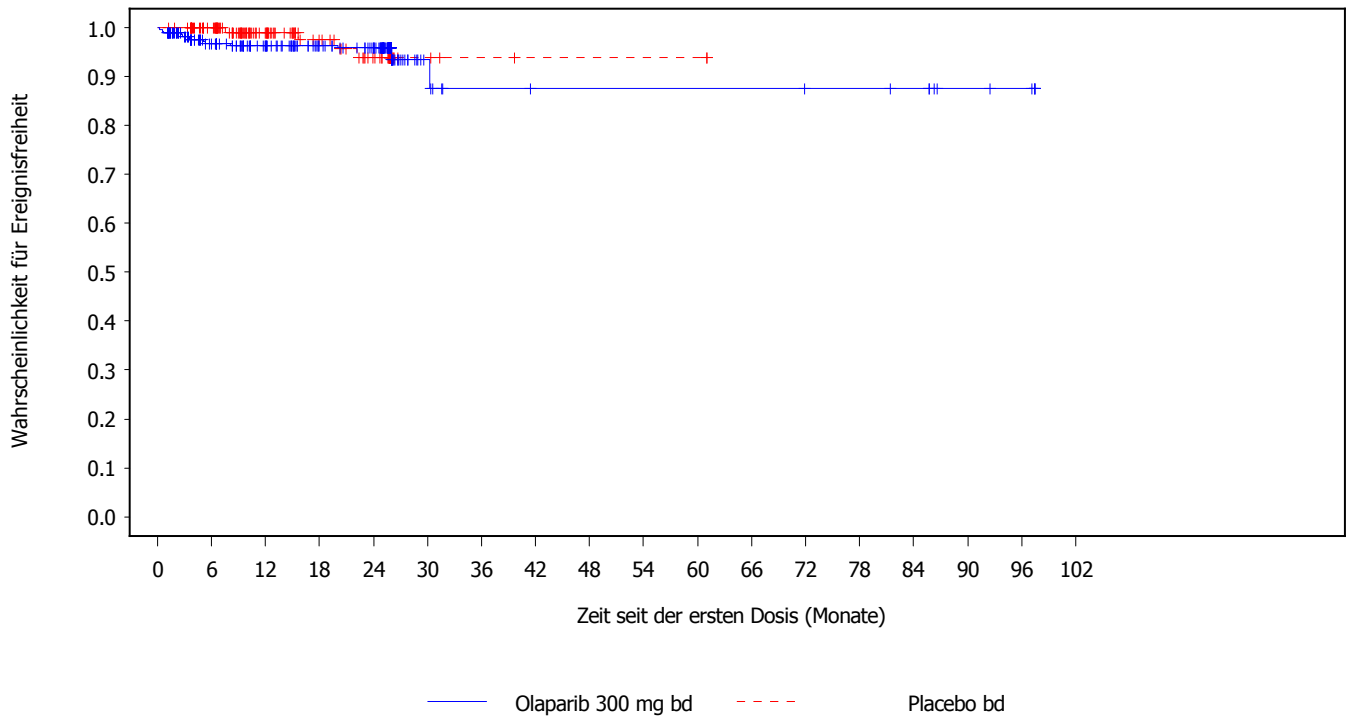
Anzahl an Patienten unter Risiko:

300	251	214	189	174	15	11	10	10	10	10	10	8	8	7	4	3	0	Olaparib 300 mg bd
149	124	79	53	42	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebas 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.20 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Erythem
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



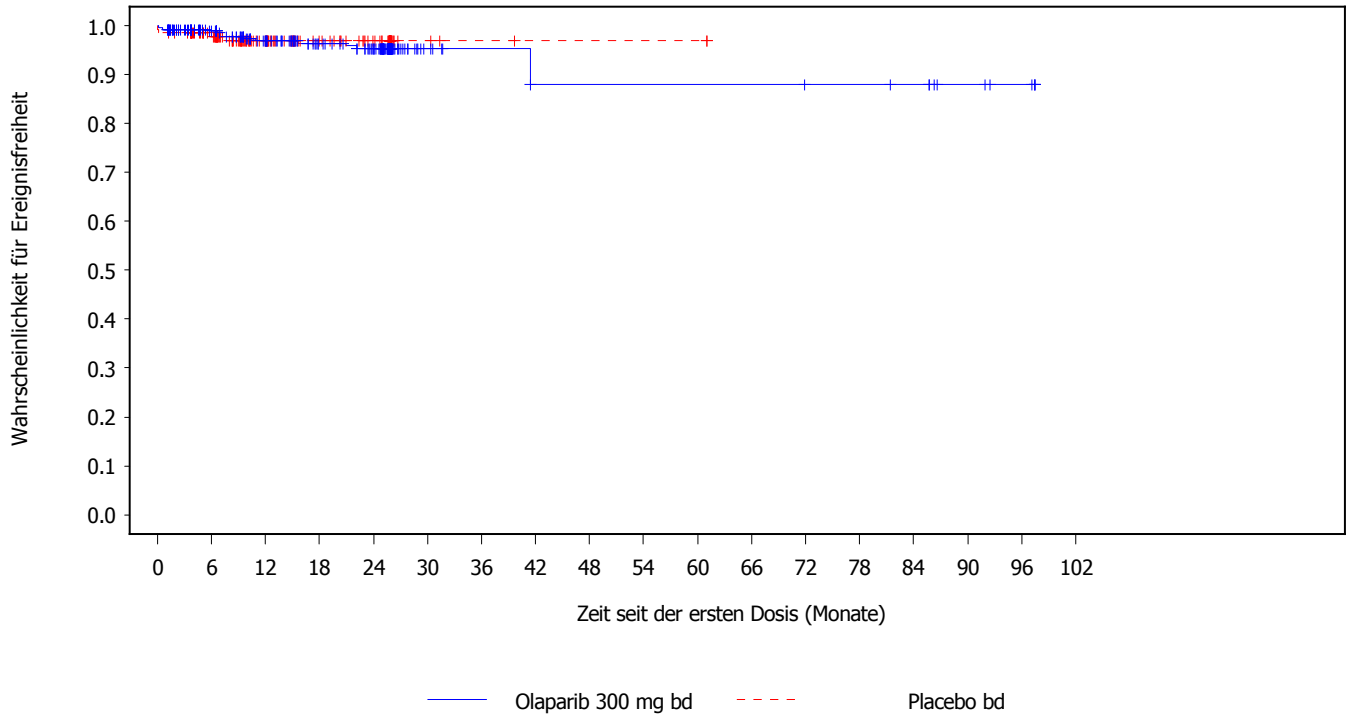
Anzahl an Patienten unter Risiko:

300	251	222	194	180	16	11	10	10	10	10	10	9	9	8	4	3	0	Olaparib 300 mg bd
149	130	86	59	45	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebat 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.21 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Pruritus
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



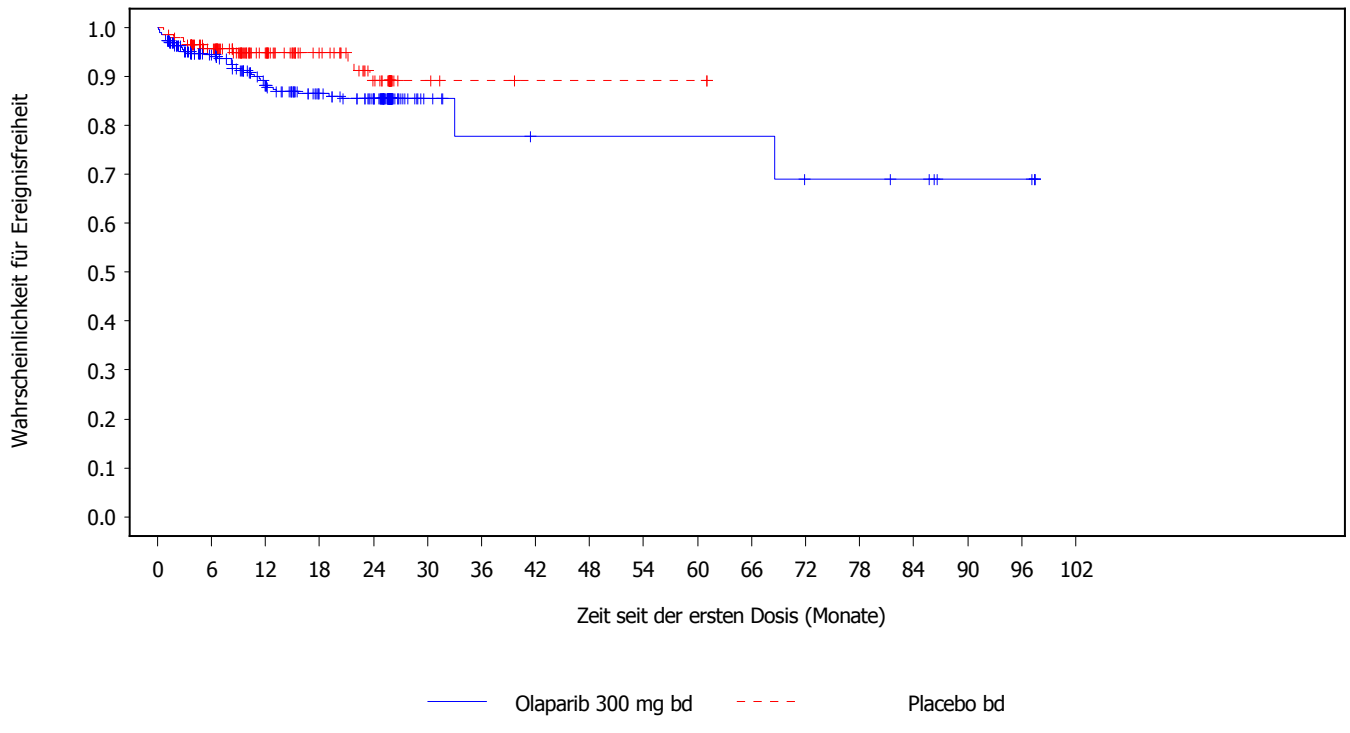
Anzahl an Patienten unter Risiko:

300	259	224	194	178	17	13	11	11	11	11	11	10	10	9	5	3	0	Olaparib 300 mg bd
149	127	84	59	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebau 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.22 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



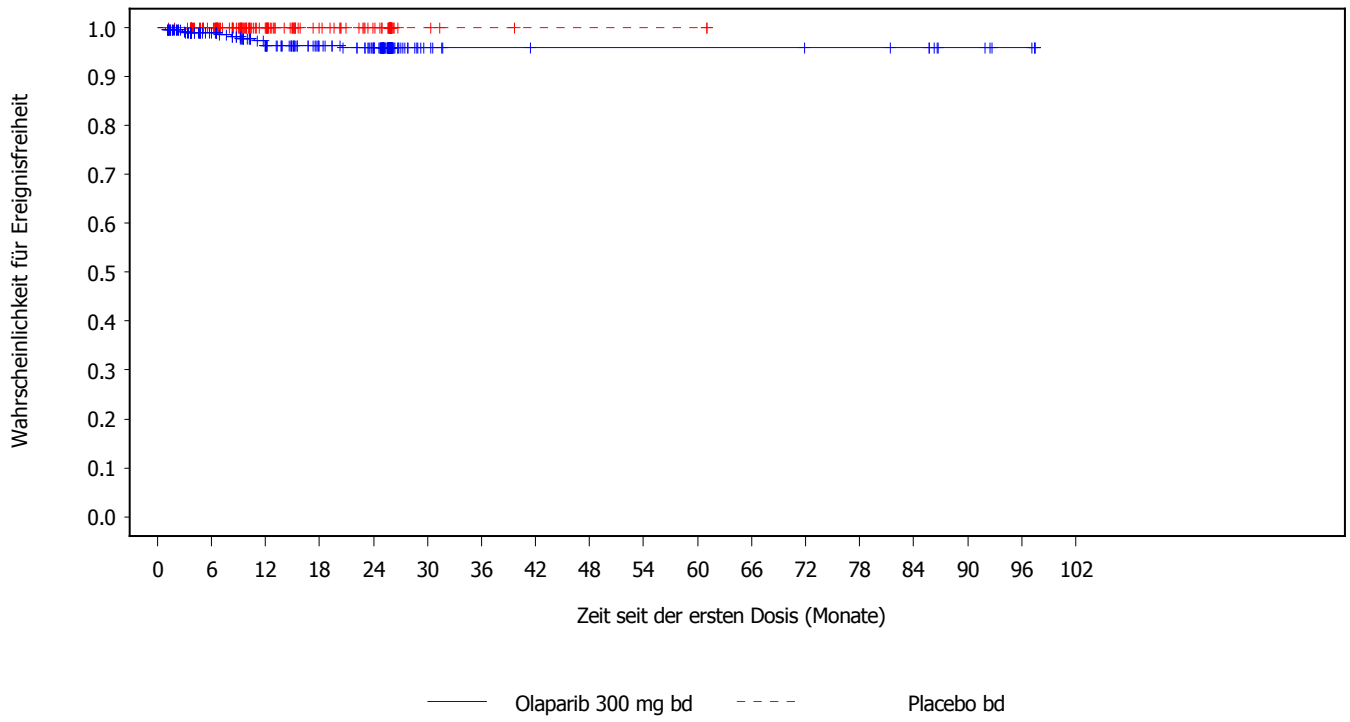
Anzahl an Patienten unter Risiko:

300	247	205	176	160	14	10	9	9	9	9	9	7	7	6	3	3	0	Olaparib 300 mg bd
149	124	82	58	42	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebav 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.23 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Dysurie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



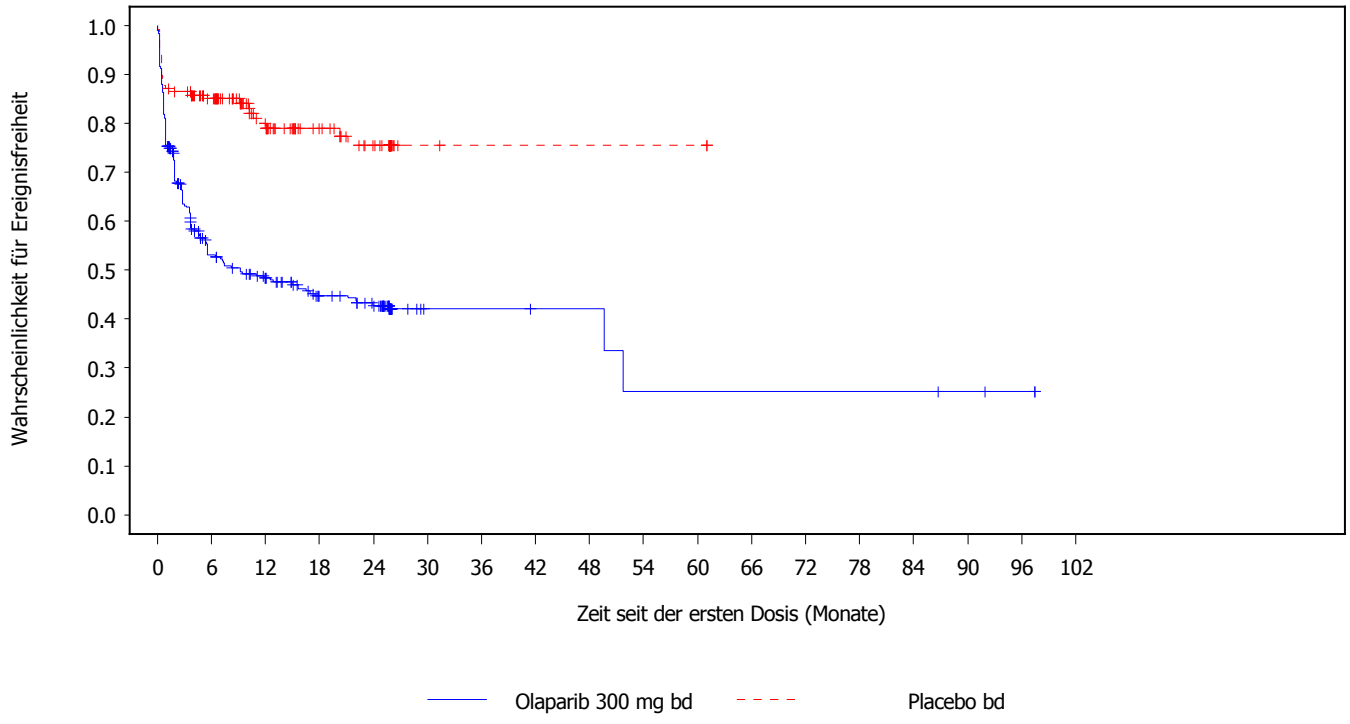
Anzahl an Patienten unter Risiko:

300	257	222	194	177	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebaw 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.24 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



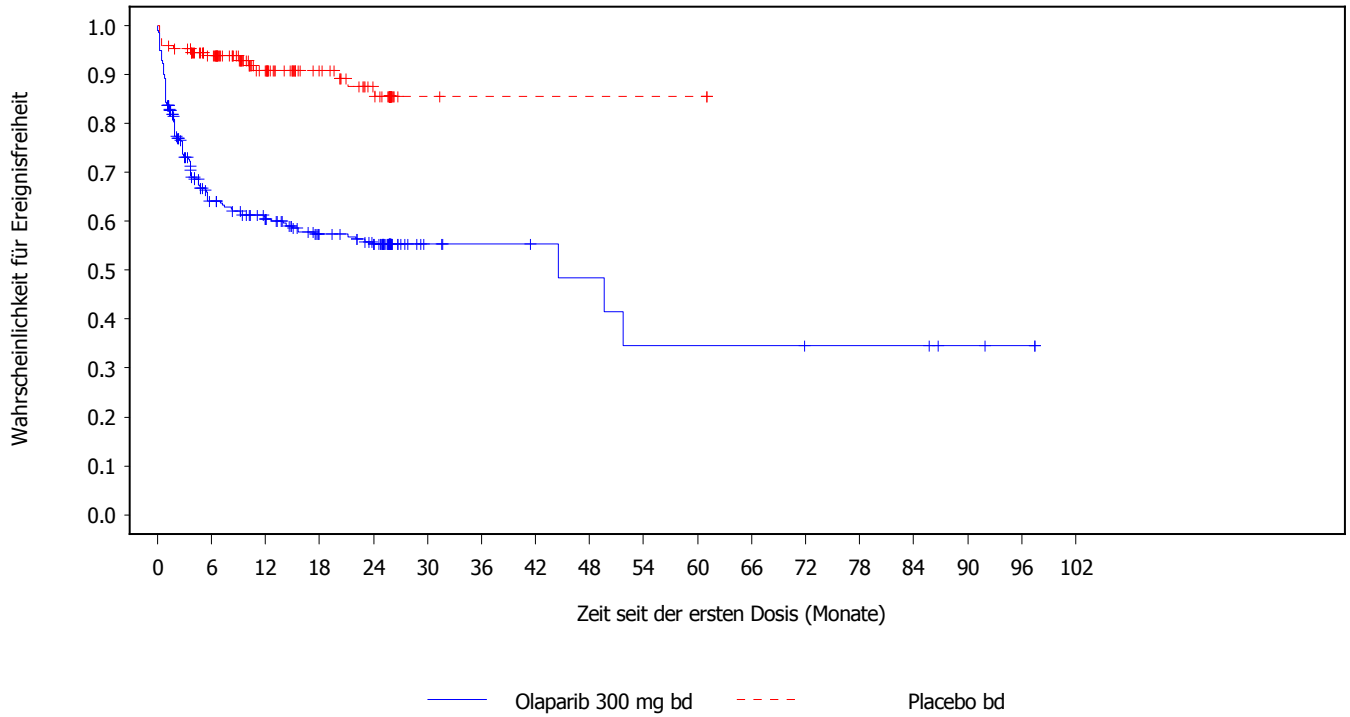
Anzahl an Patienten unter Risiko:

300	138	116	93	82	6	6	5	5	3	3	3	3	3	3	2	1	0	Olaparib 300 mg bd
149	111	75	52	39	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebax 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.25 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



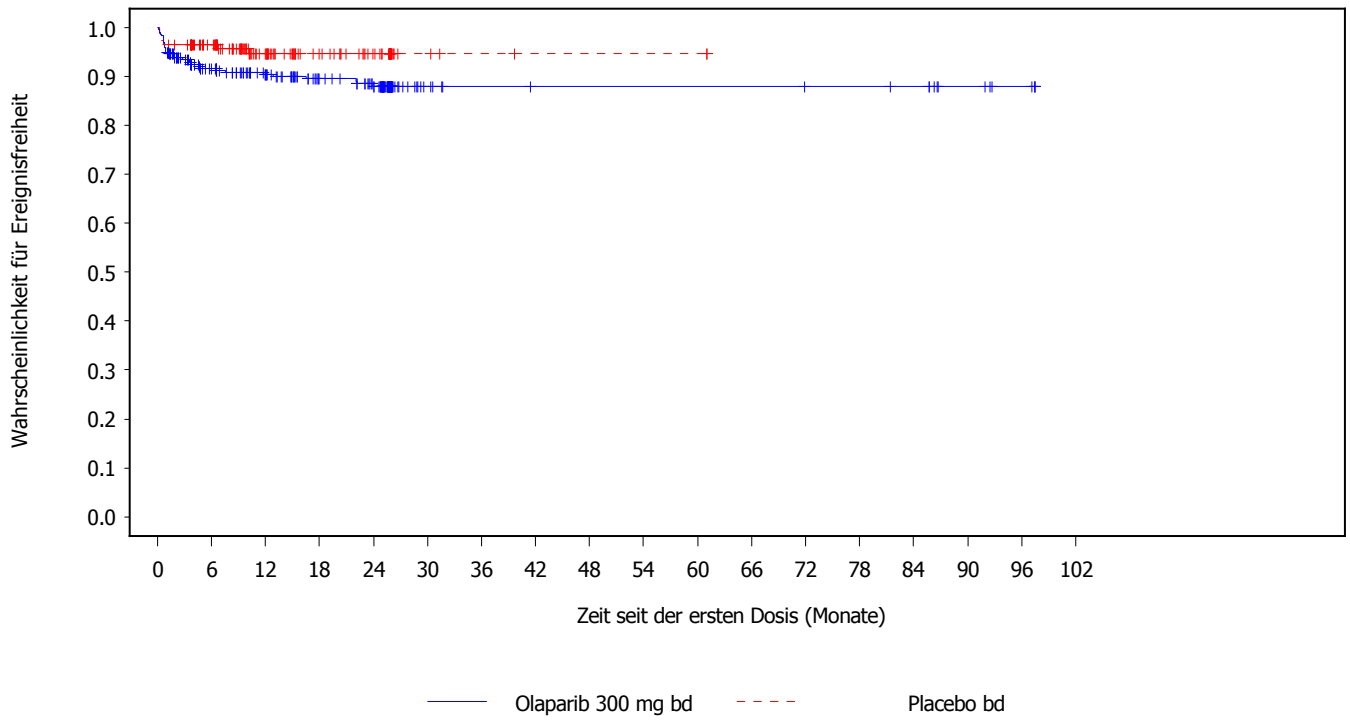
Anzahl an Patienten unter Risiko:

300	165	144	120	108	11	9	8	7	5	5	5	4	4	4	2	1	0	Olaparib 300 mg bd
149	124	84	59	44	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebay 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.26 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Leukopenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



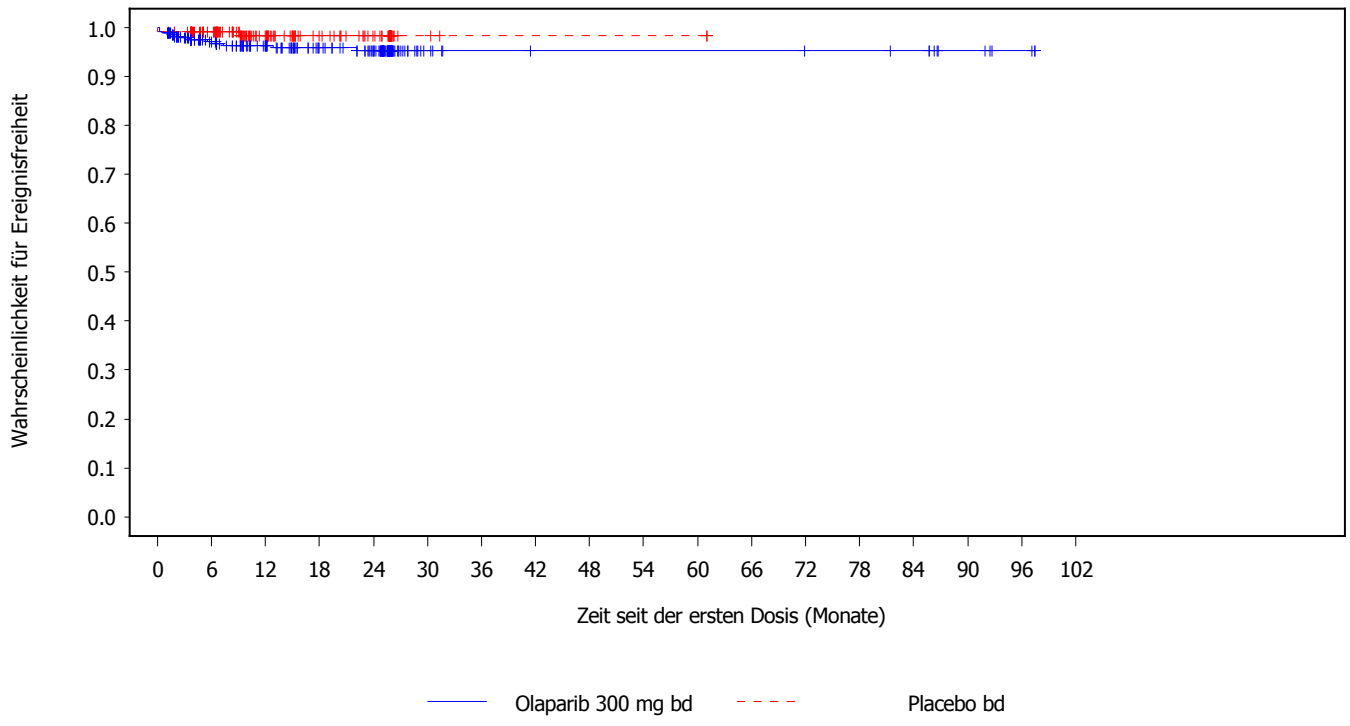
Anzahl an Patienten unter Risiko:

300	237	207	179	163	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	125	83	57	44	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebaz 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.27 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Lymphopenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



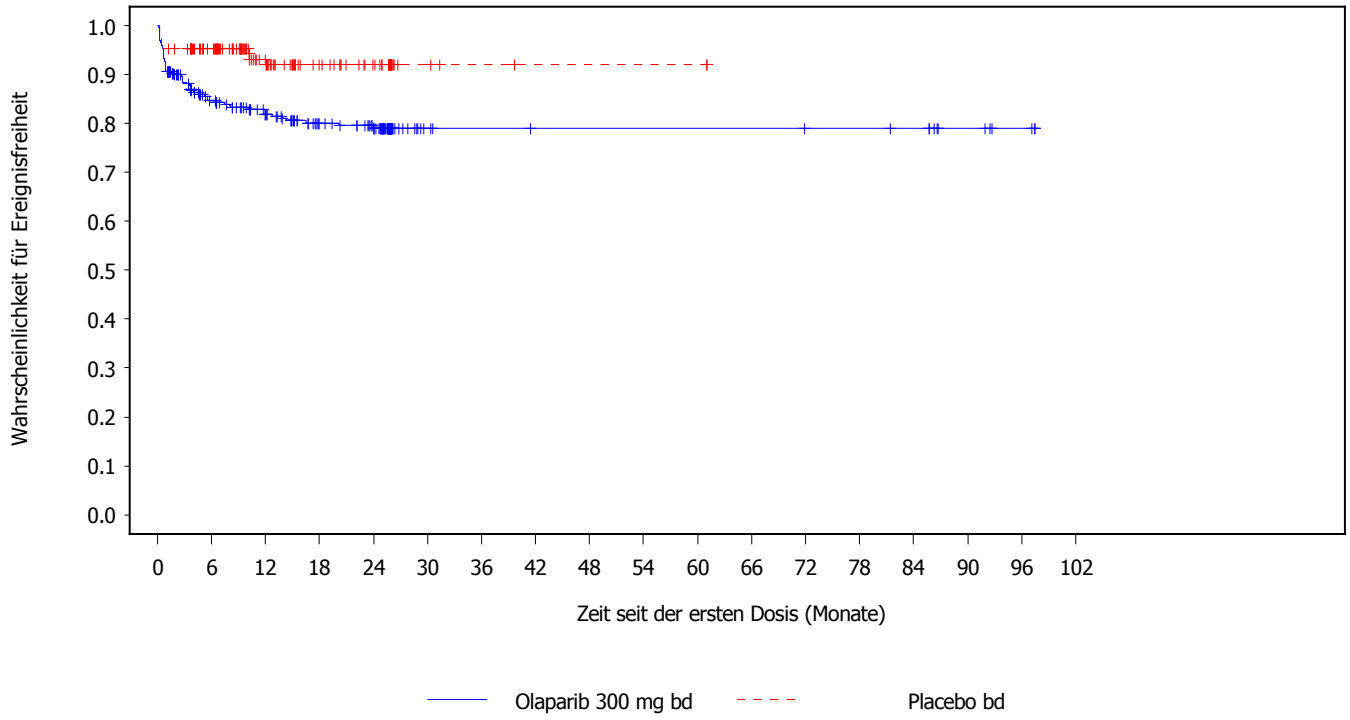
Anzahl an Patienten unter Risiko:

300	252	220	192	175	17	13	12	12	12	12	12	11	11	10	5	2	0	Olaparib 300 mg bd
149	129	85	59	46	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebba 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.28 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Neutropenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



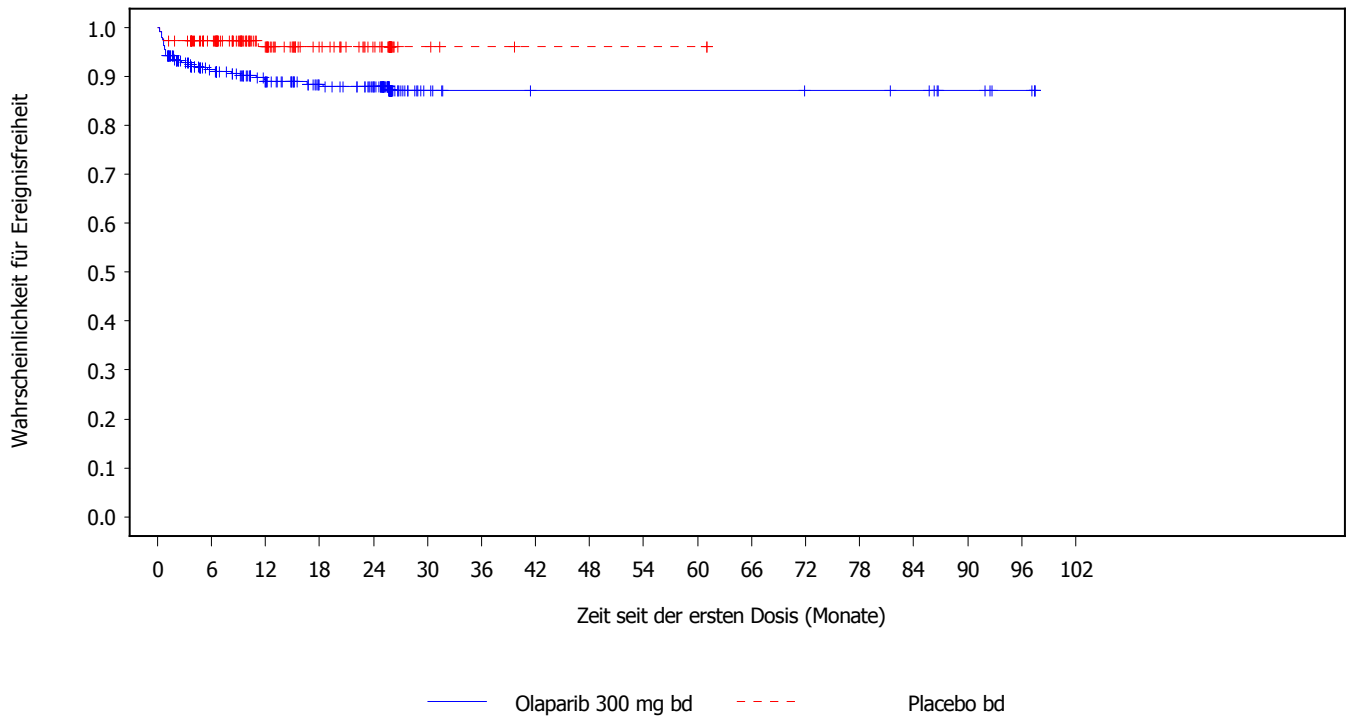
Anzahl an Patienten unter Risiko:

300	220	190	163	149	15	13	12	12	12	12	12	11	11	10	5	2	0	Olaparib 300 mg bd
149	123	81	56	45	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbb 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.29 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Thrombozytopenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



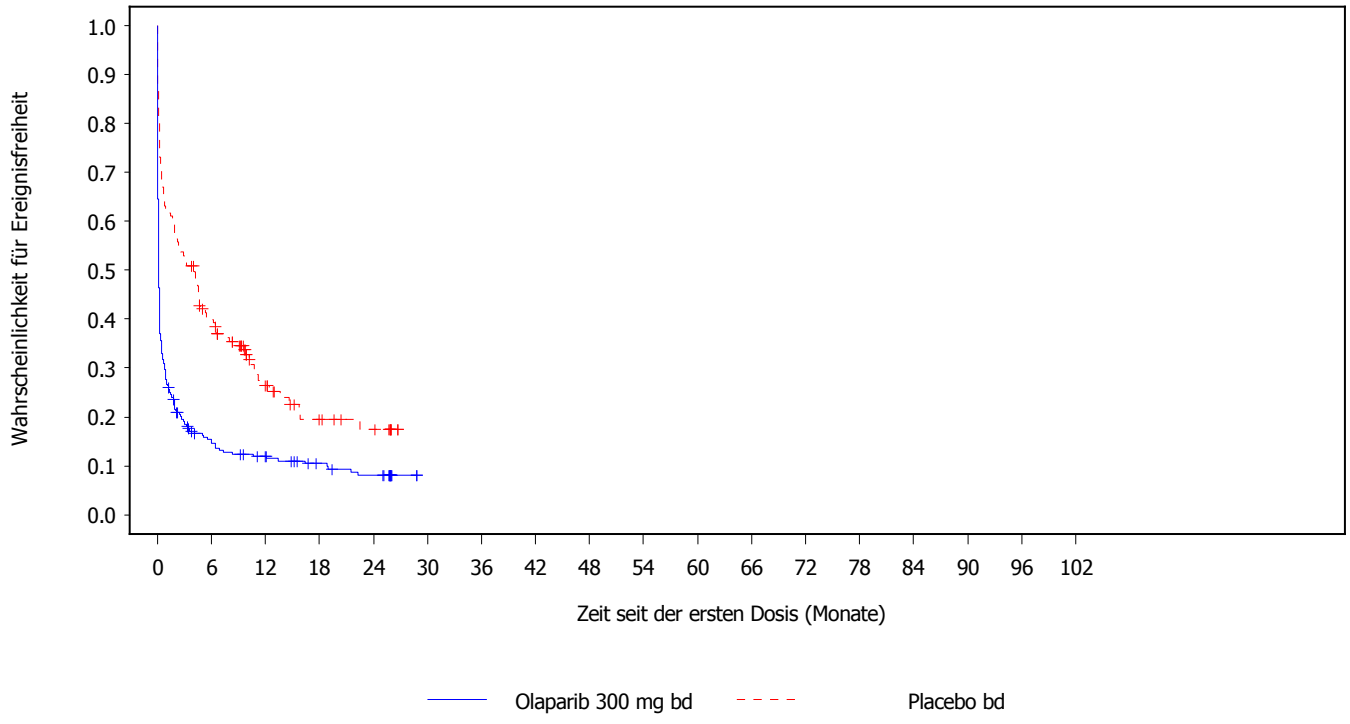
Anzahl an Patienten unter Risiko:

300	238	206	181	166	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	127	86	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbc 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.30 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



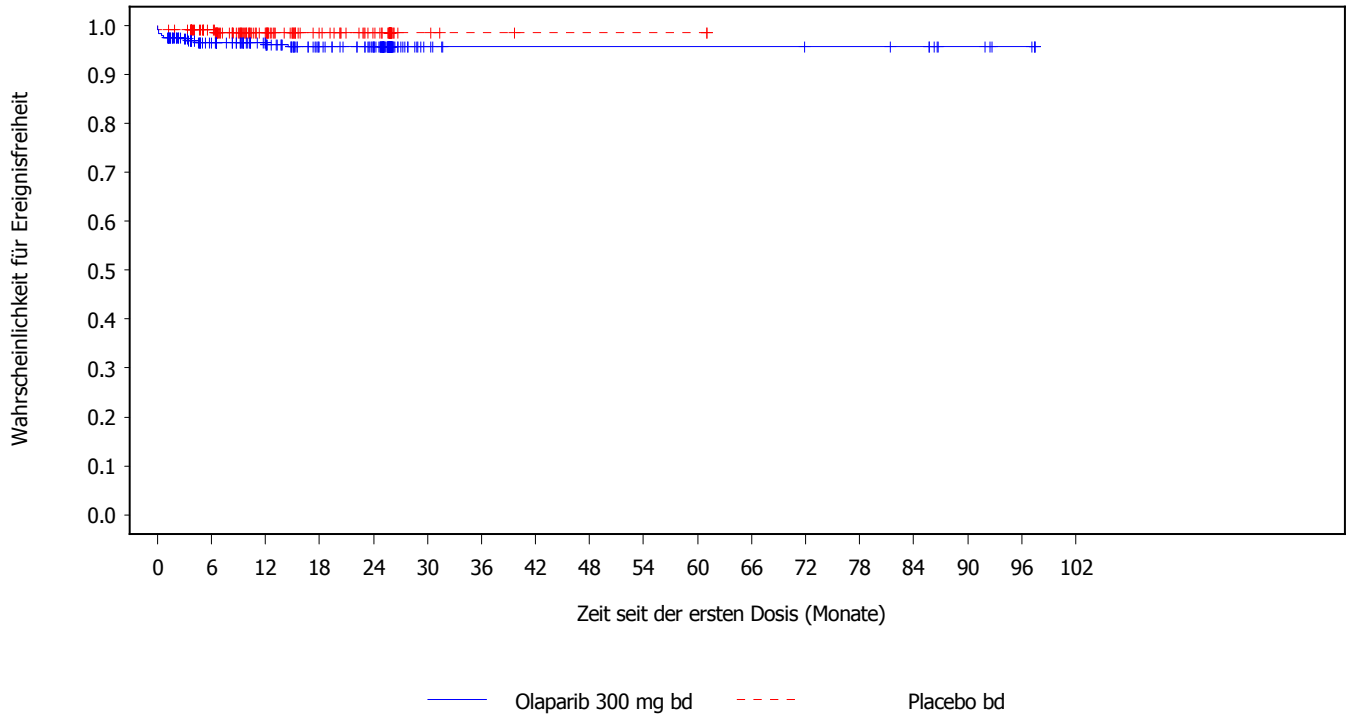
Anzahl an Patienten unter Risiko:

300	40	27	18	13	0	0	0	0	0	0	0	0	0	0	0	0	Olaparib 300 mg bd
149	56	24	12	8	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbd 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.31 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Abdominale Beschwerden
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



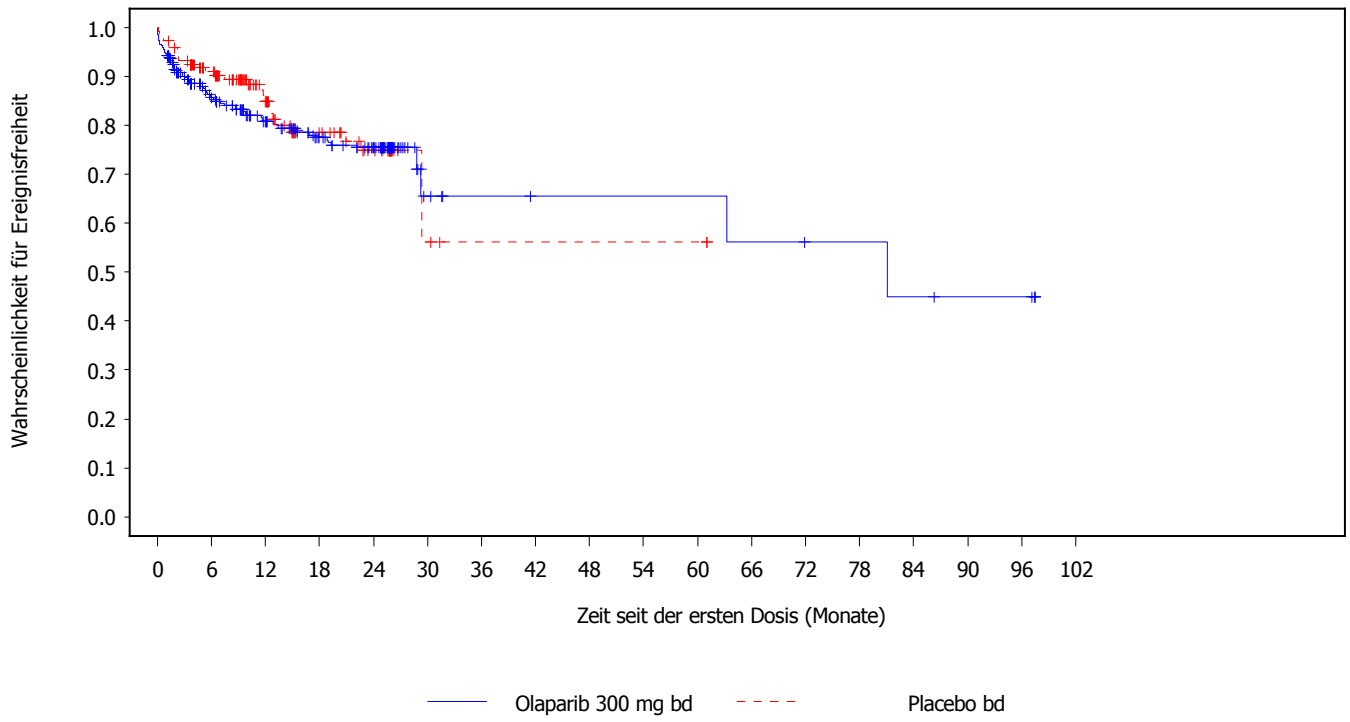
Anzahl an Patienten unter Risiko:

300	251	222	192	176	17	13	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	129	86	60	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbe 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.32 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Abdominalschmerz
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



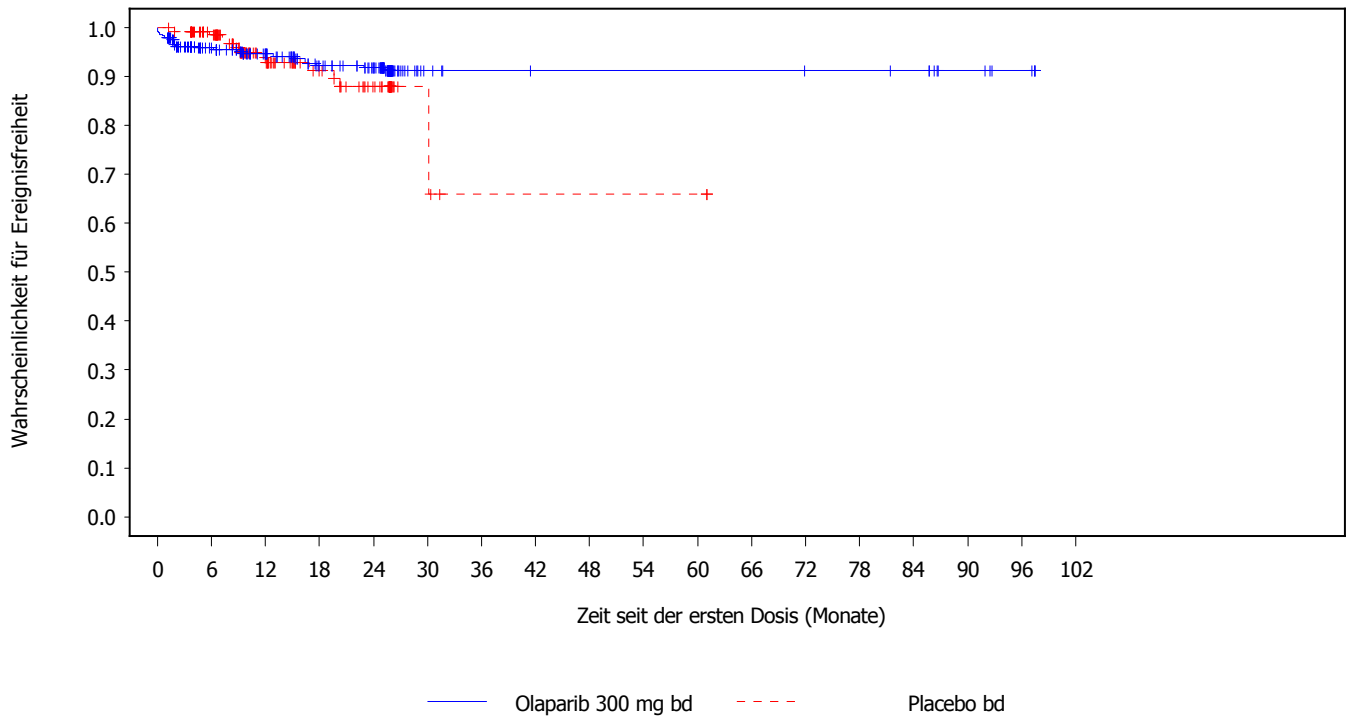
Anzahl an Patienten unter Risiko:

300	226	186	158	141	11	8	7	7	7	7	6	5	5	4	3	3	0	Olaparib 300 mg bd
149	119	75	50	37	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbf 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.33 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Bauch aufgetrieben
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



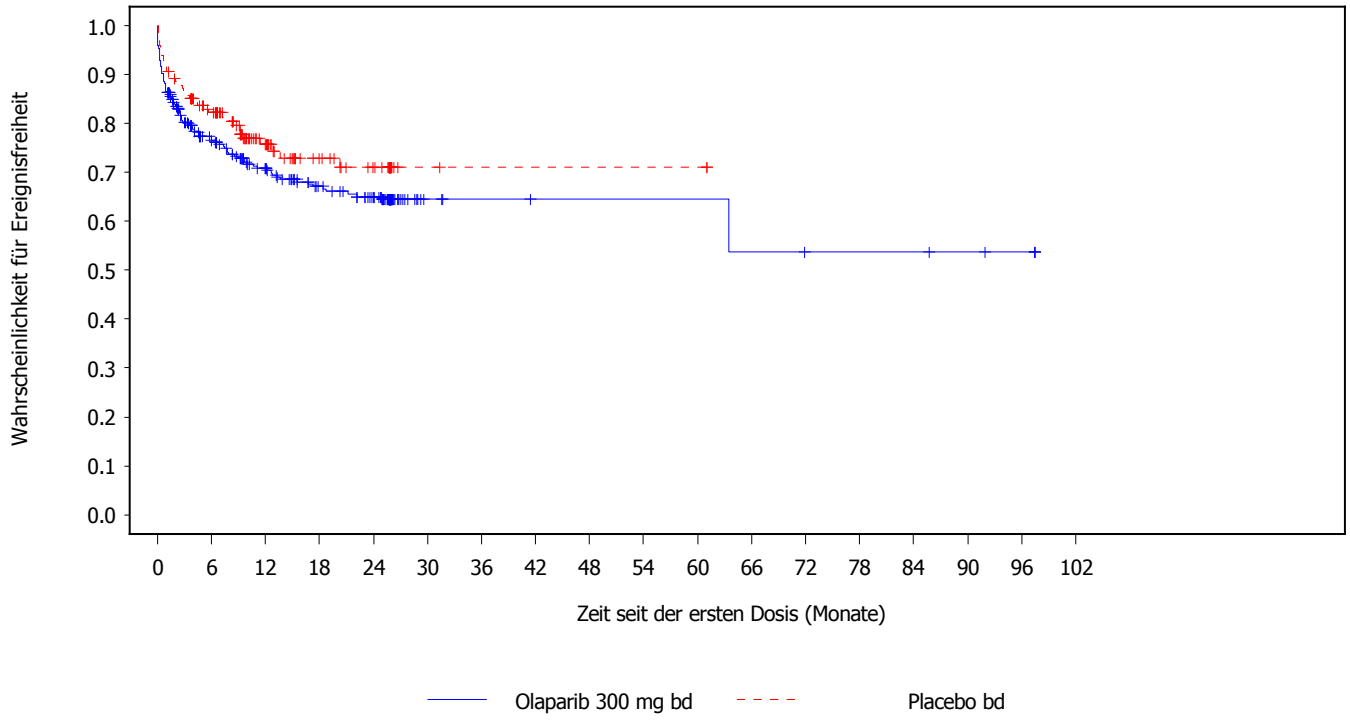
Anzahl an Patienten unter Risiko:

300	249	218	189	173	17	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	129	84	58	44	4	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbg 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.34 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Diarrhoe
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



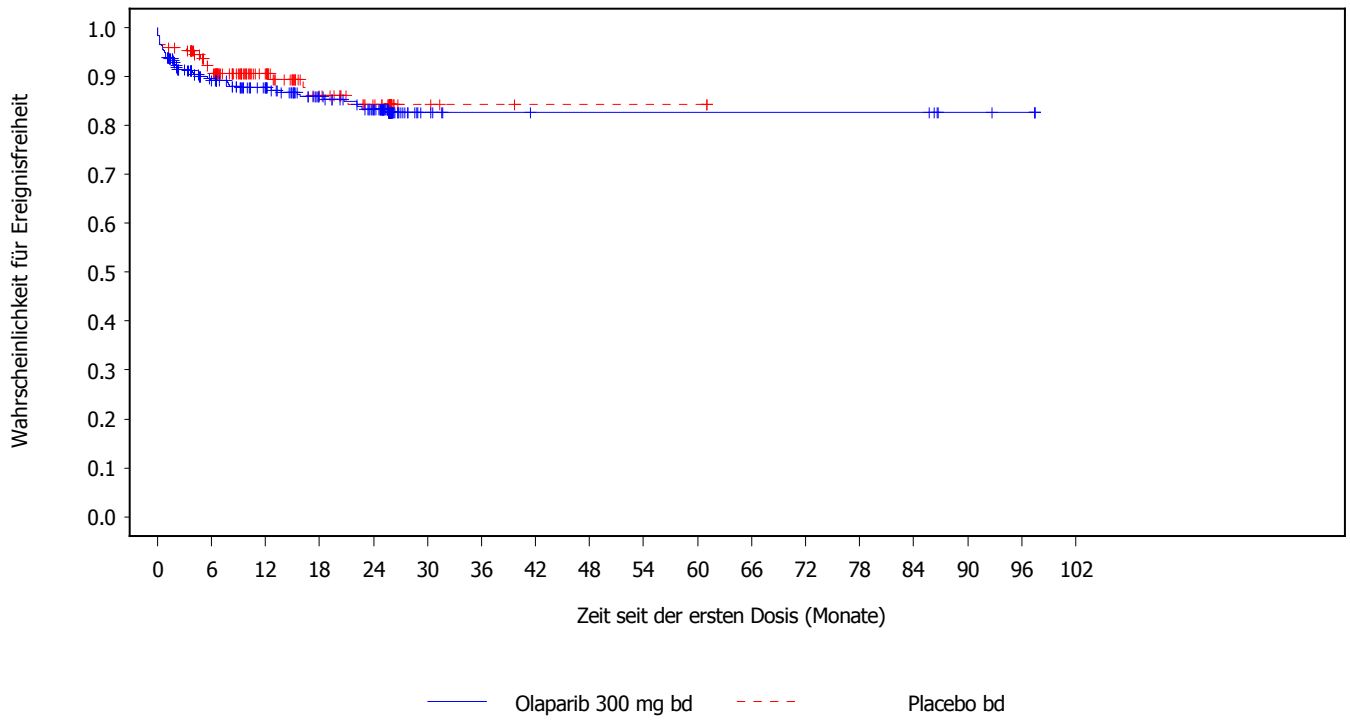
Anzahl an Patienten unter Risiko:

300	200	161	133	118	9	7	6	6	6	6	5	4	4	4	3	2	0	Olaparib 300 mg bd
149	110	65	41	32	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbh 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.35 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Dyspepsie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



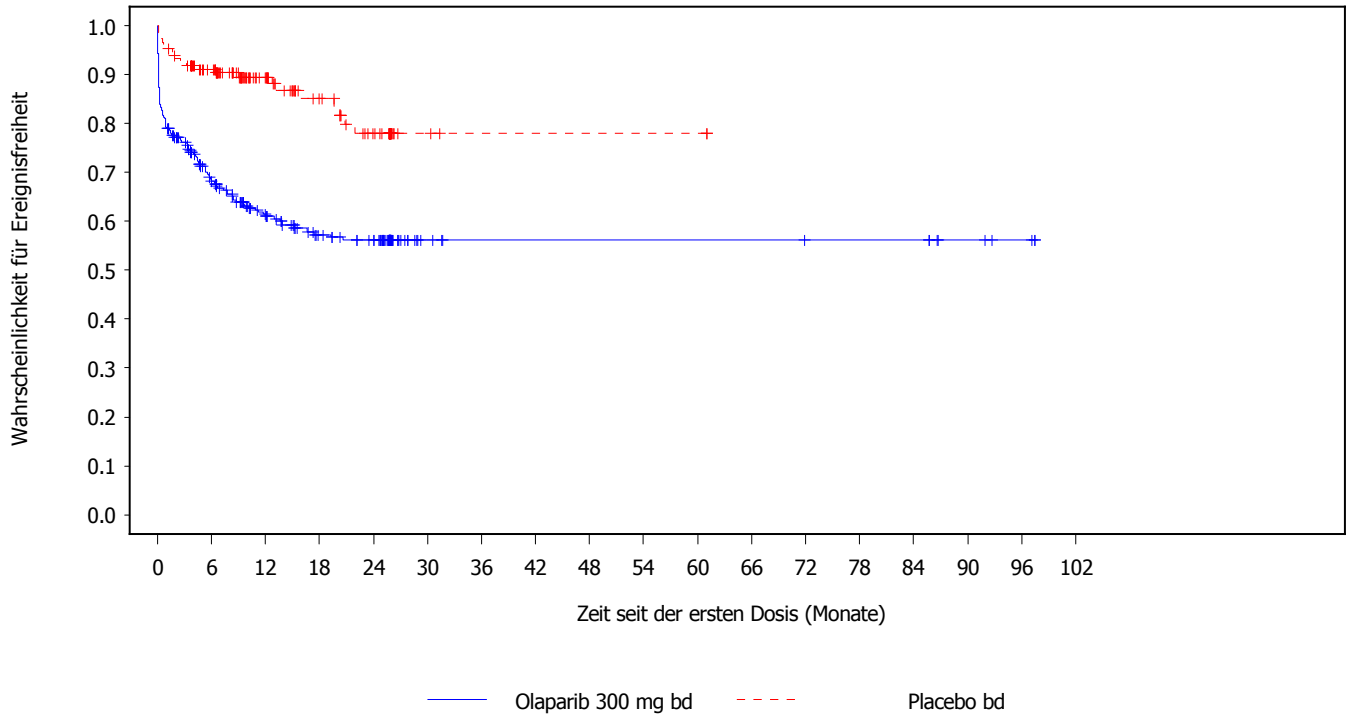
Anzahl an Patienten unter Risiko:

300	234	204	175	156	12	8	7	7	7	7	7	7	7	3	2	0	Olaparib 300 mg bd
149	119	79	51	39	4	2	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbi 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.36 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Erbrechen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



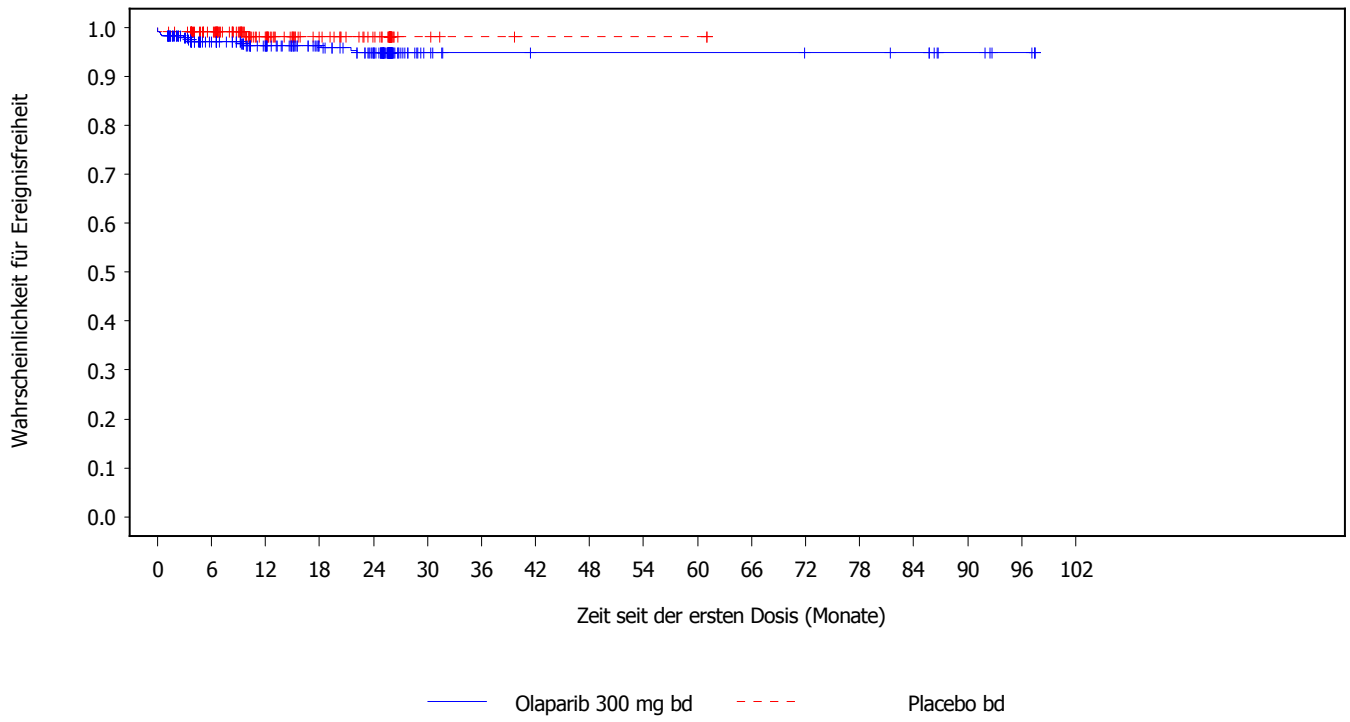
Anzahl an Patienten unter Risiko:

300	183	140	114	105	12	9	9	9	9	9	9	8	8	8	4	2	0	Olaparib 300 mg bd
149	120	76	51	37	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbj 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.37 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Flatulenz
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



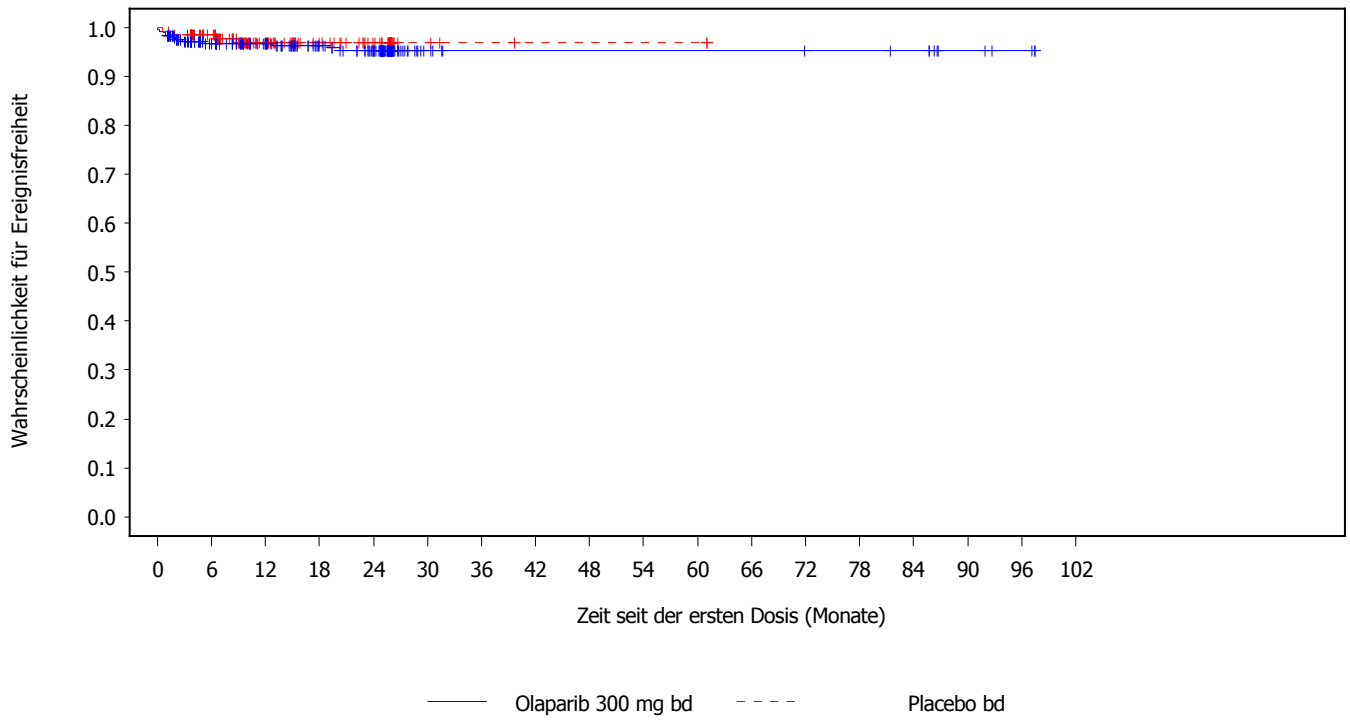
Anzahl an Patienten unter Risiko:

300	252	221	194	175	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	129	85	60	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbk 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.38 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Gastrooesophageale Refluxerkrankung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



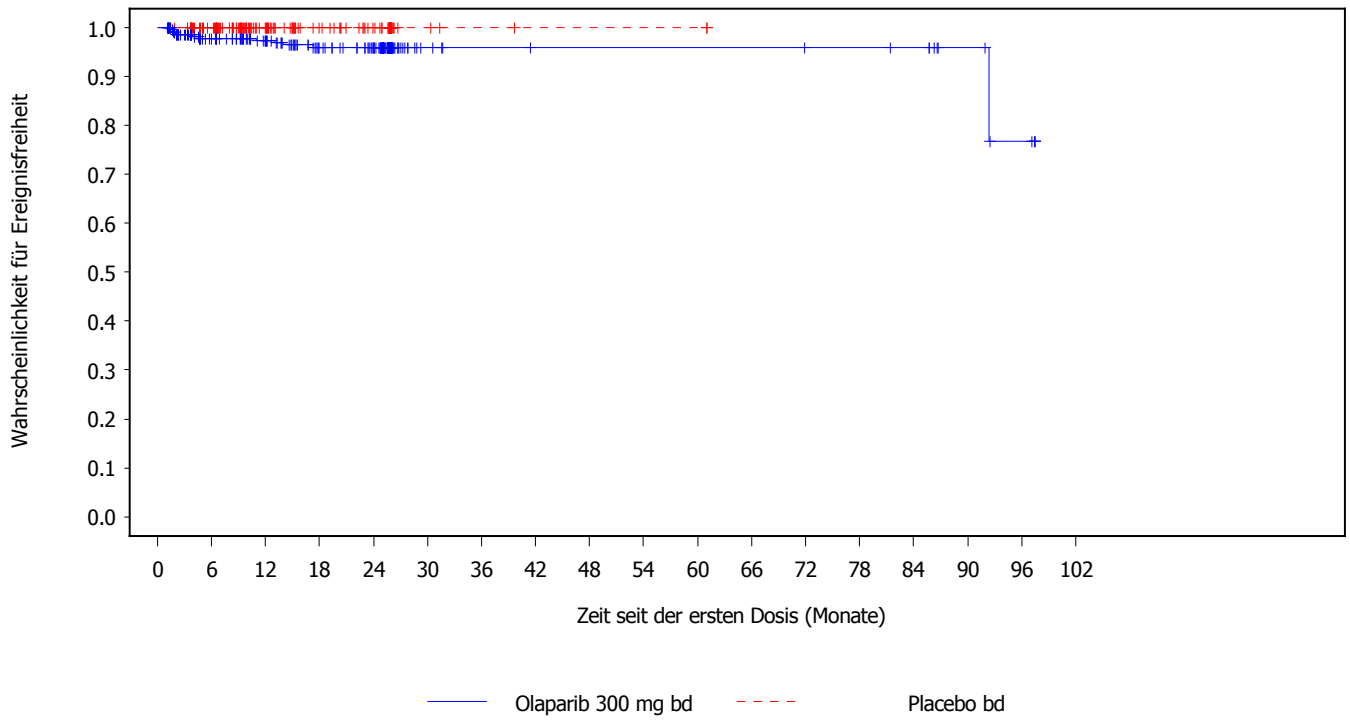
Anzahl an Patienten unter Risiko:

300	252	223	193	175	15	11	11	11	11	11	11	10	10	9	4	2	0	Olaparib 300 mg bd
149	128	84	59	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbl 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.39 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Haemorrhoiden
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



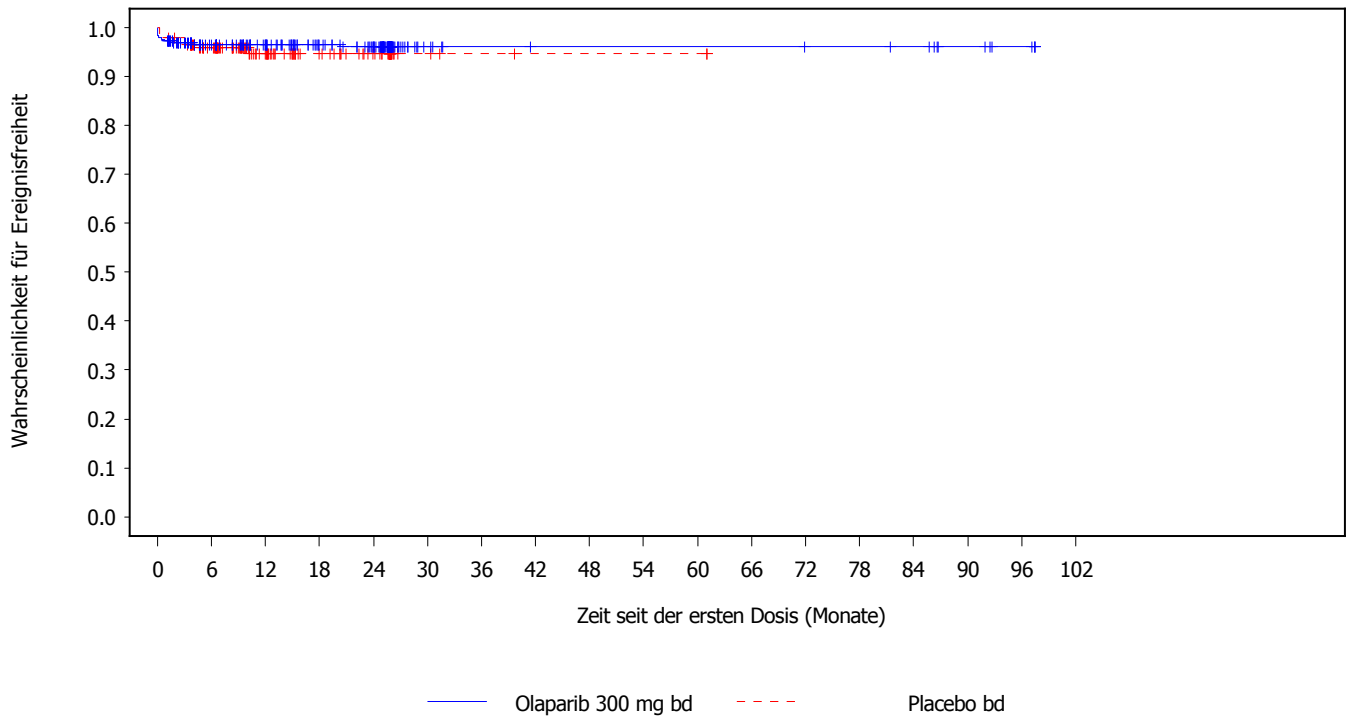
Anzahl an Patienten unter Risiko:

300	254	223	193	177	17	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbm 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.40 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Mundtrockenheit
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



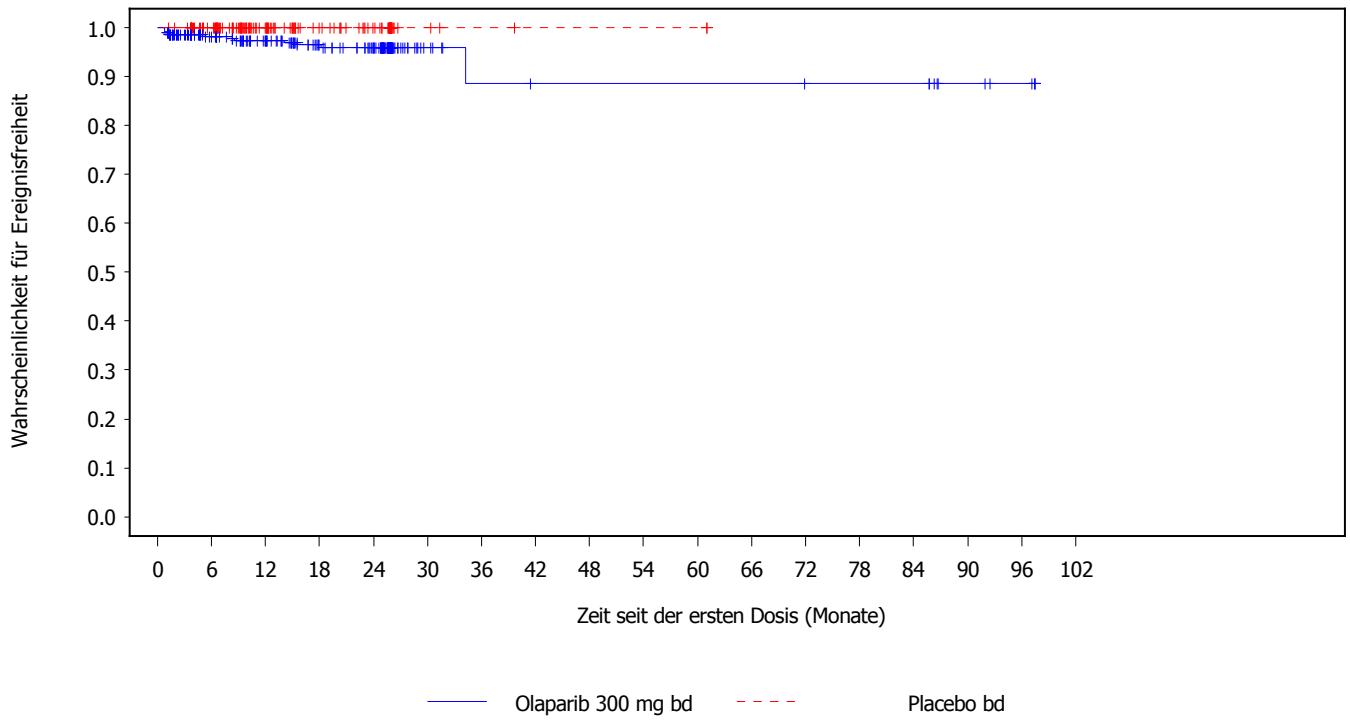
Anzahl an Patienten unter Risiko:

300	253	224	195	179	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	124	82	57	45	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbn 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.41 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Mundulzeration
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



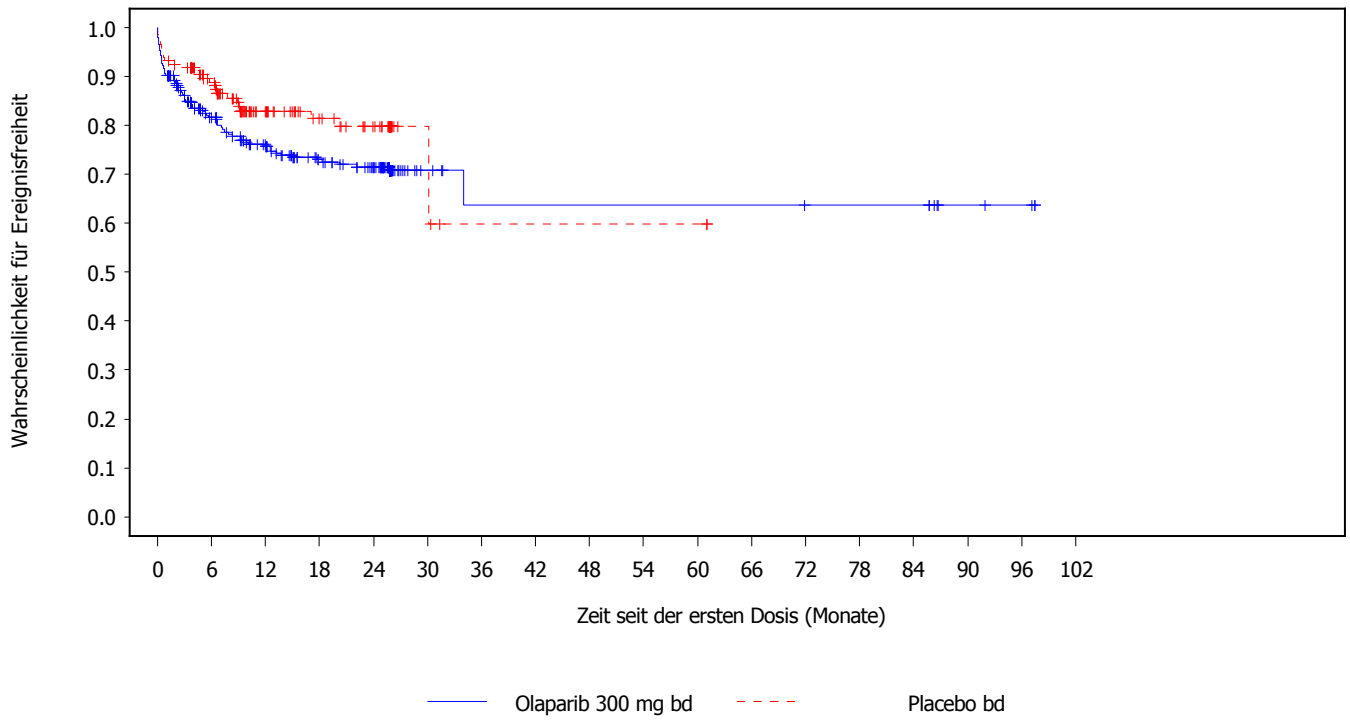
Anzahl an Patienten unter Risiko:

300	255	224	193	176	17	12	11	11	11	11	11	10	10	10	5	3	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbo 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.42 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Obstipation
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



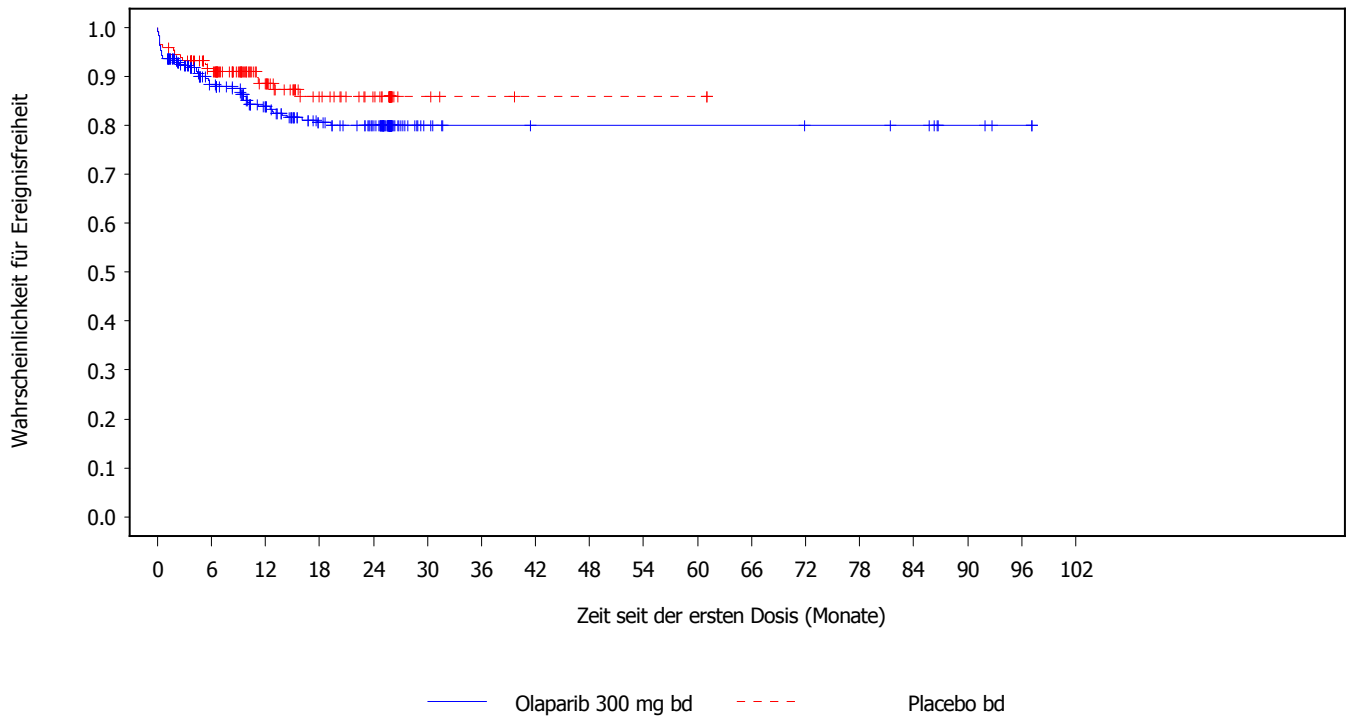
Anzahl an Patienten unter Risiko:

300	214	179	149	133	13	9	9	9	9	9	8	8	8	3	2	0	Olaparib 300 mg bd
149	115	71	52	42	4	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbp 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.43 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerzen Oberbauch
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



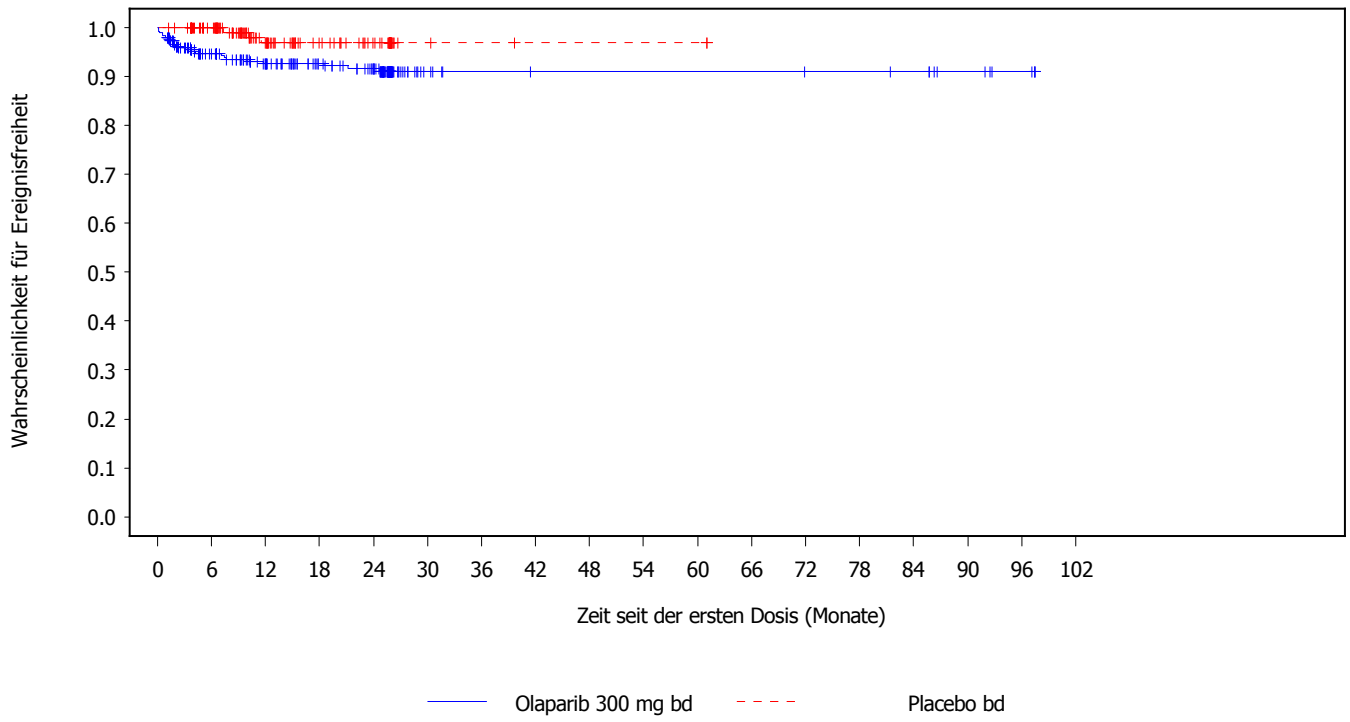
Anzahl an Patienten unter Risiko:

300	227	191	160	145	14	10	9	9	9	9	9	8	8	7	3	1	0	Olaparib 300 mg bd
149	120	76	53	43	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbq 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.44 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Stomatitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



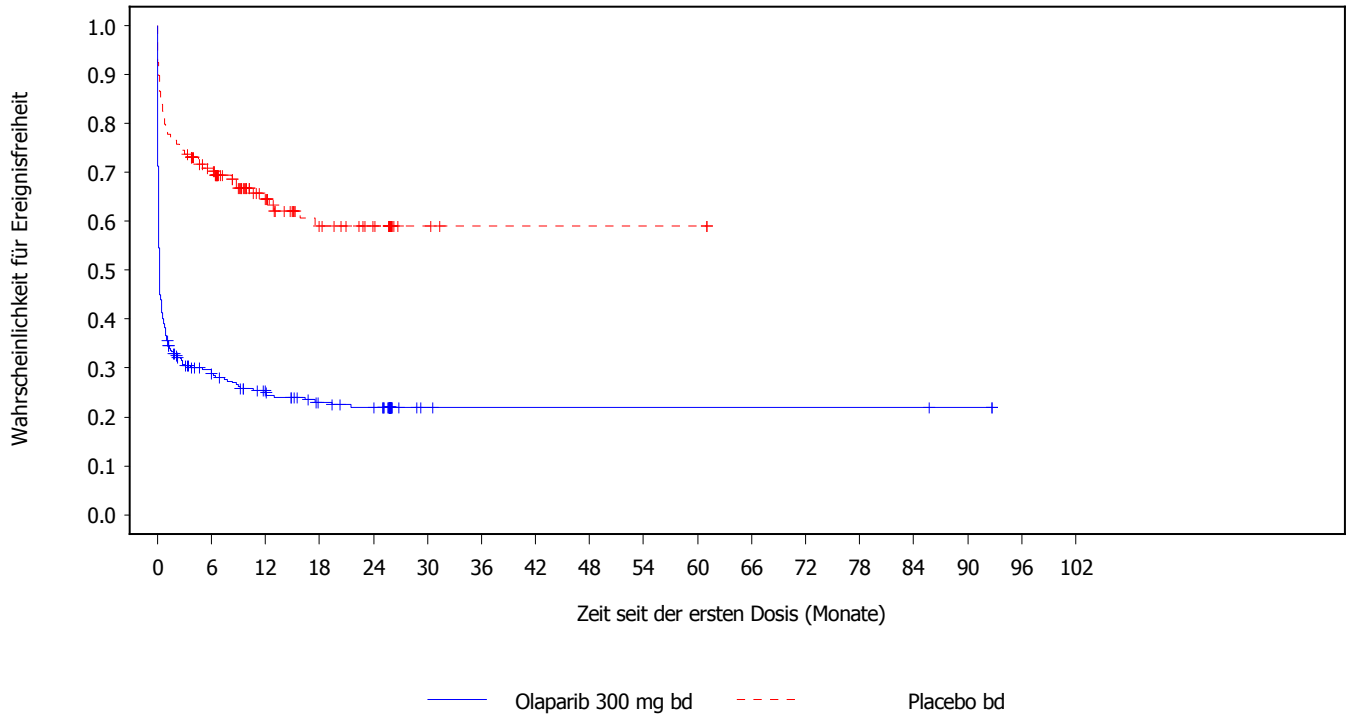
Anzahl an Patienten unter Risiko:

300	245	213	185	170	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	130	84	58	45	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbr 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.45 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Uebelkeit
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



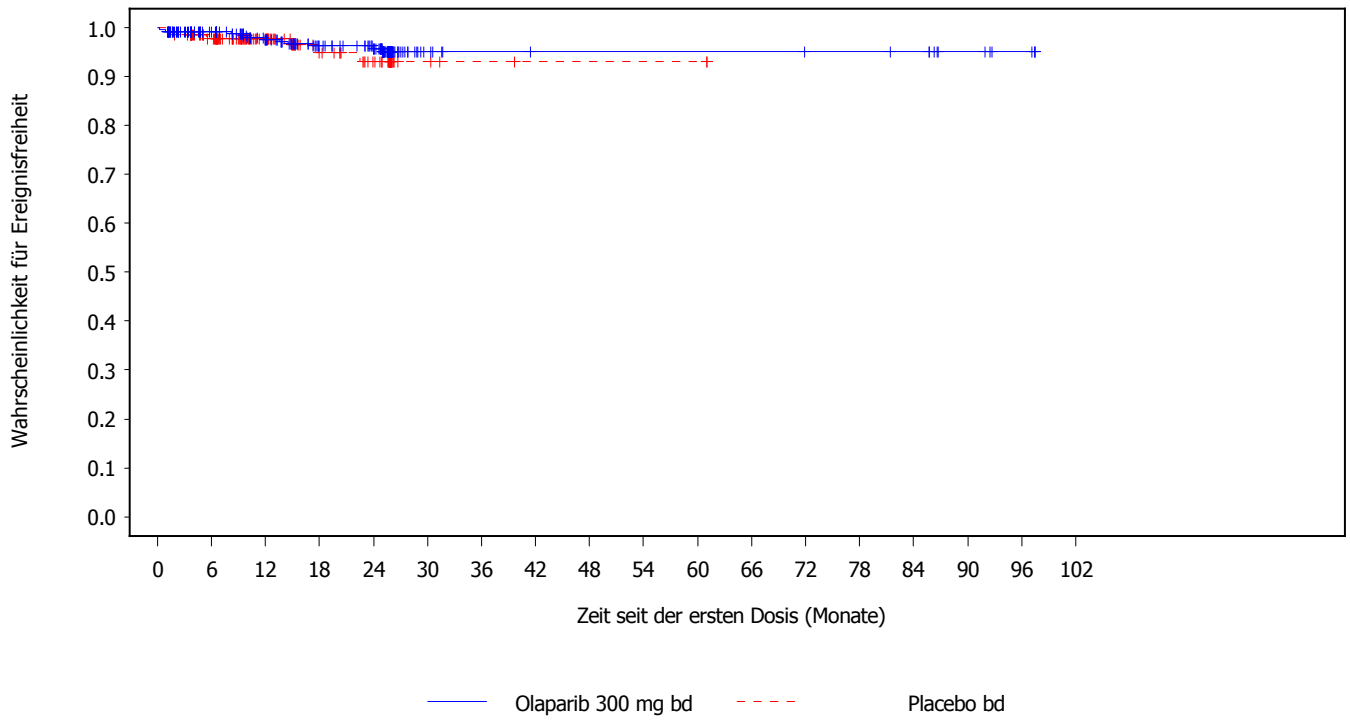
Anzahl an Patienten unter Risiko:

300	77	57	45	41	3	2	2	2	2	2	2	2	2	1	0	0	Olaparib 300 mg bd
149	95	57	38	30	3	1	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbs 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.46 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Zahnschmerzen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



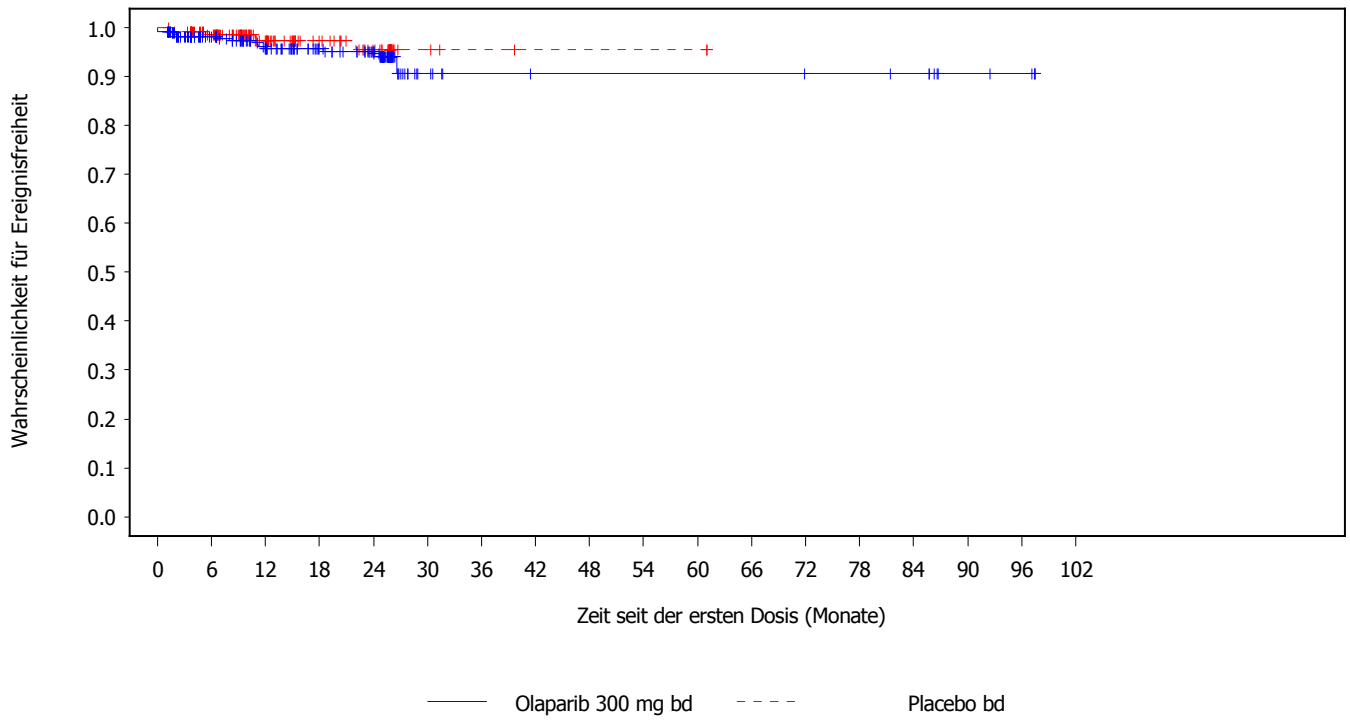
Anzahl an Patienten unter Risiko:

300	259	226	195	179	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	127	85	57	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbt 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.47 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Immunsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



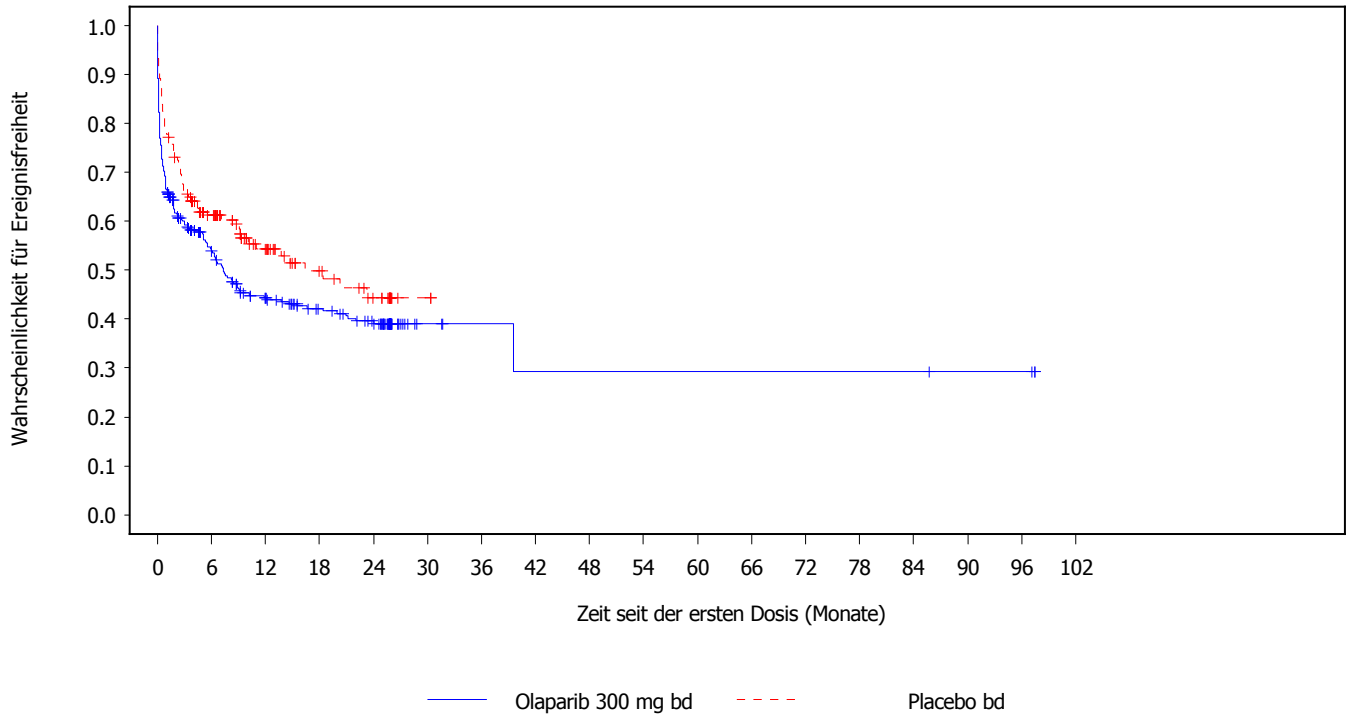
Anzahl an Patienten unter Risiko:

300	255	220	192	175	16	12	11	11	11	11	11	10	10	9	4	3	0	Olaparib 300 mg bd
149	128	85	59	45	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbu 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.48 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



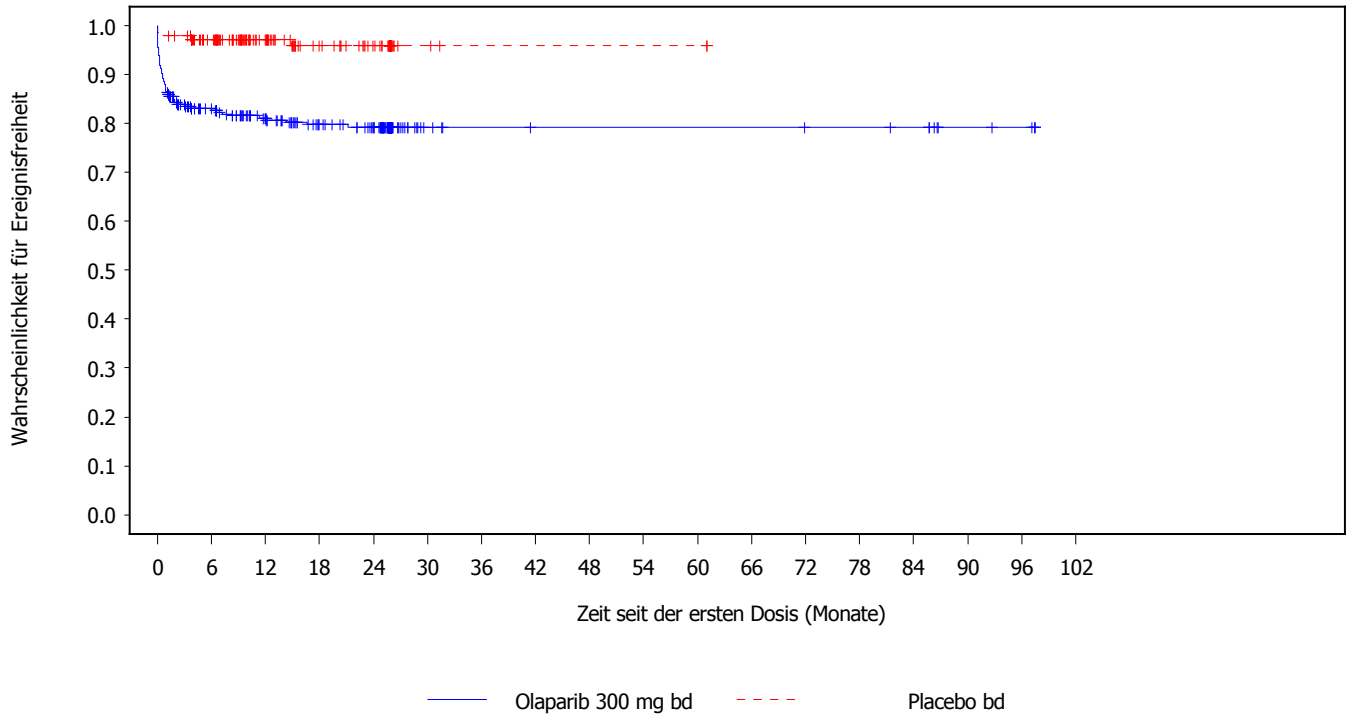
Anzahl an Patienten unter Risiko:

300	140	104	84	72	6	4	3	3	3	3	3	3	3	2	2	0	Olaparib 300 mg bd
149	77	47	30	21	1	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbv 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.49 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Dysgeusie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



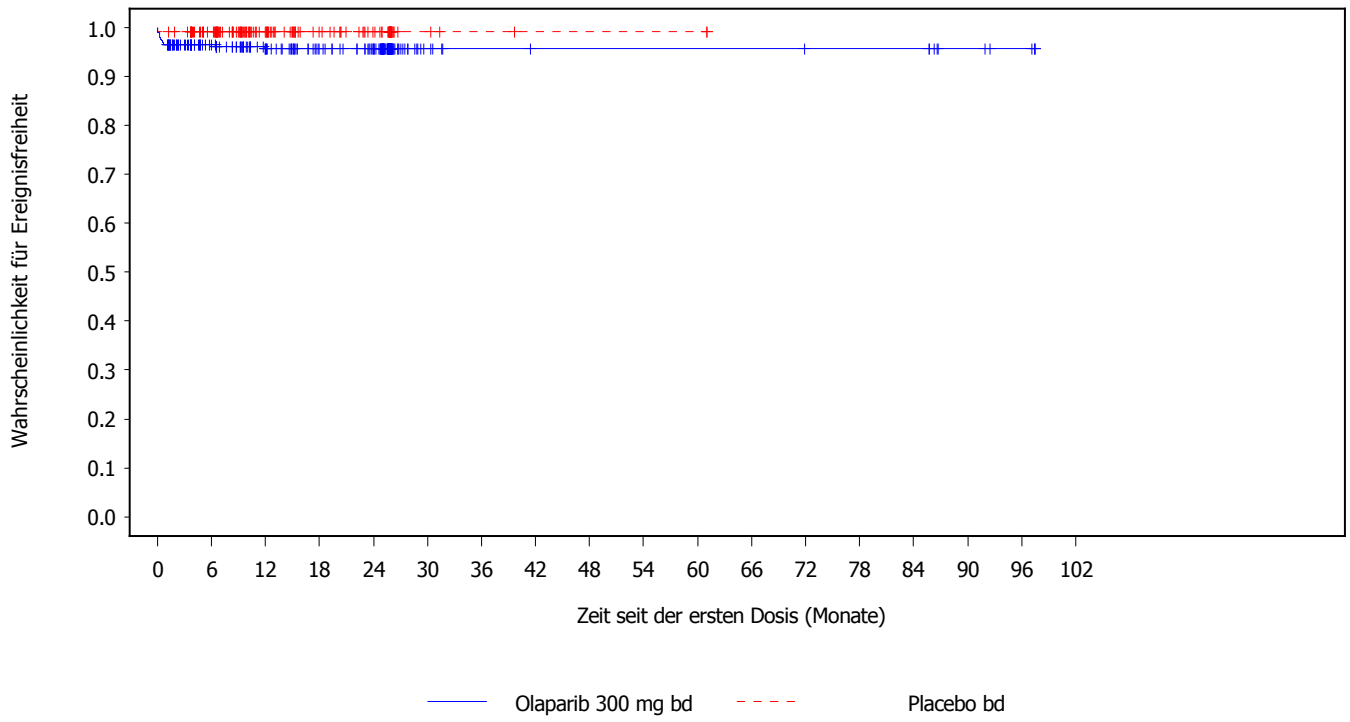
Anzahl an Patienten unter Risiko:

300	218	187	161	147	15	12	11	11	11	11	11	10	10	9	4	3	0	Olaparib 300 mg bd
149	126	84	57	45	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbw 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.50 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Geschmacksstoerung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



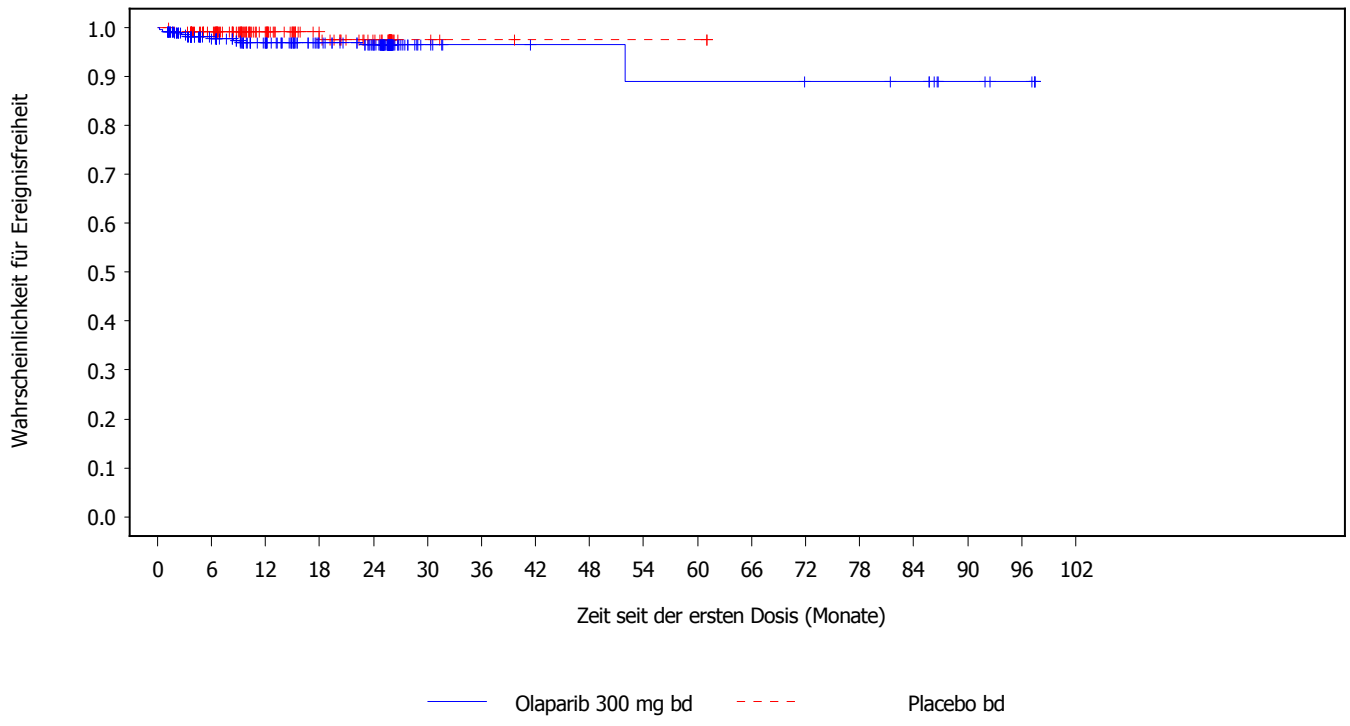
Anzahl an Patienten unter Risiko:

300	250	218	192	176	16	12	11	11	11	11	11	10	10	10	5	3	0	Olaparib 300 mg bd
149	129	86	60	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbx 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.51 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hypoaesthesie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



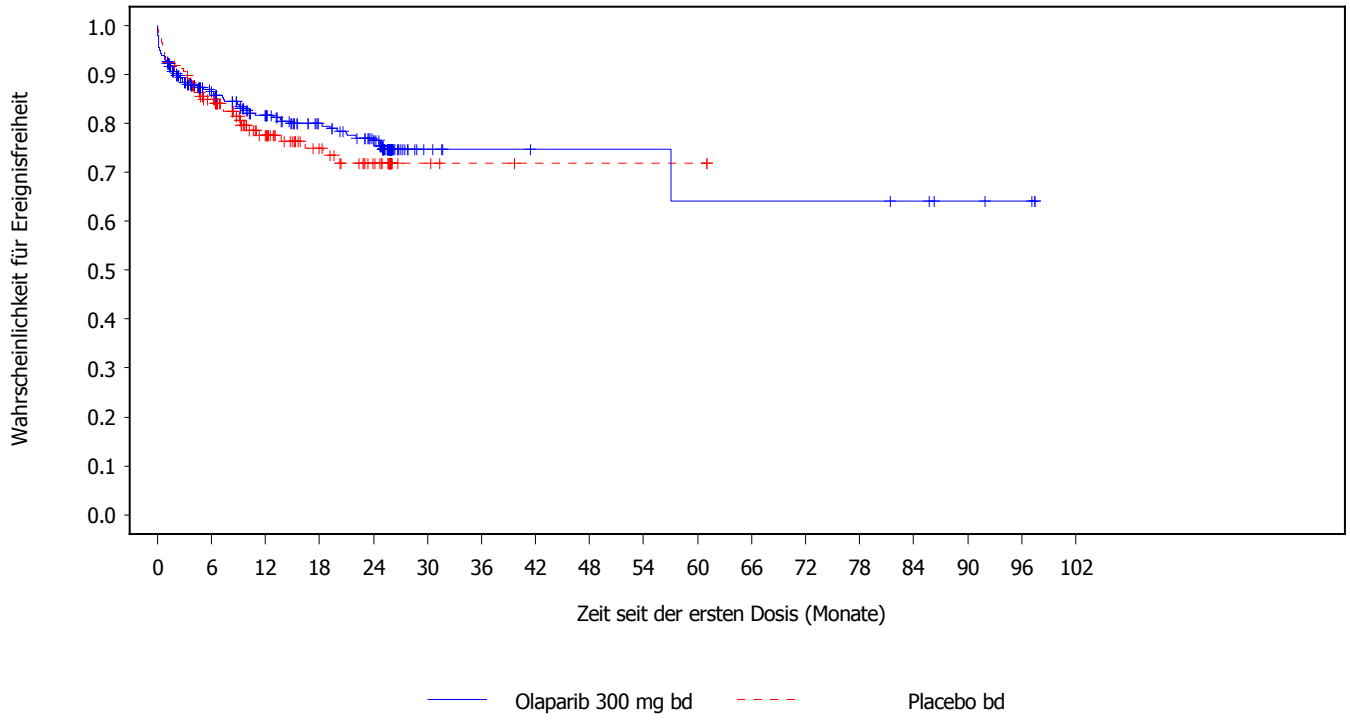
Anzahl an Patienten unter Risiko:

300	256	225	196	179	18	14	13	13	12	12	12	11	11	10	5	3	0	Olaparib 300 mg bd
149	129	86	60	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebby 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.52 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Kopfschmerzen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



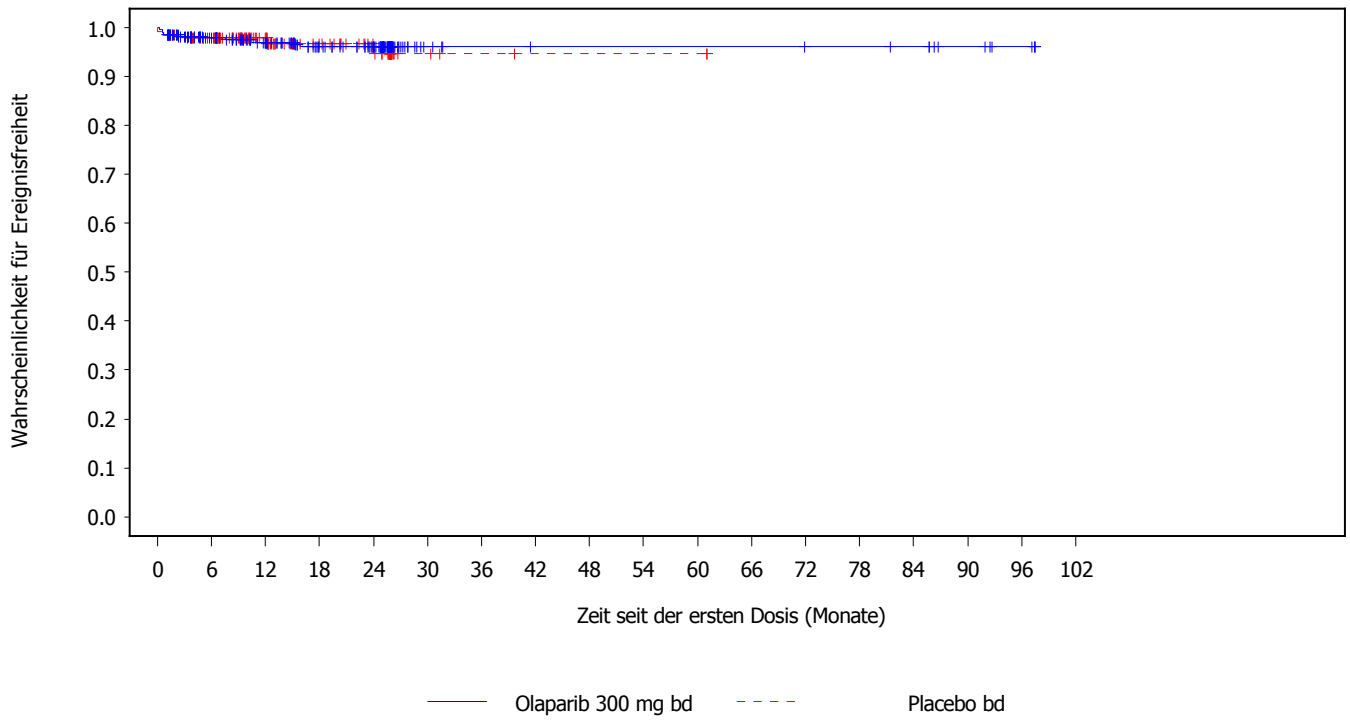
Anzahl an Patienten unter Risiko:

300	225	192	164	147	11	8	7	7	7	6	6	6	6	5	3	2	0	Olaparib 300 mg bd
149	111	73	50	37	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebbz 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.53 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Paraesthesie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



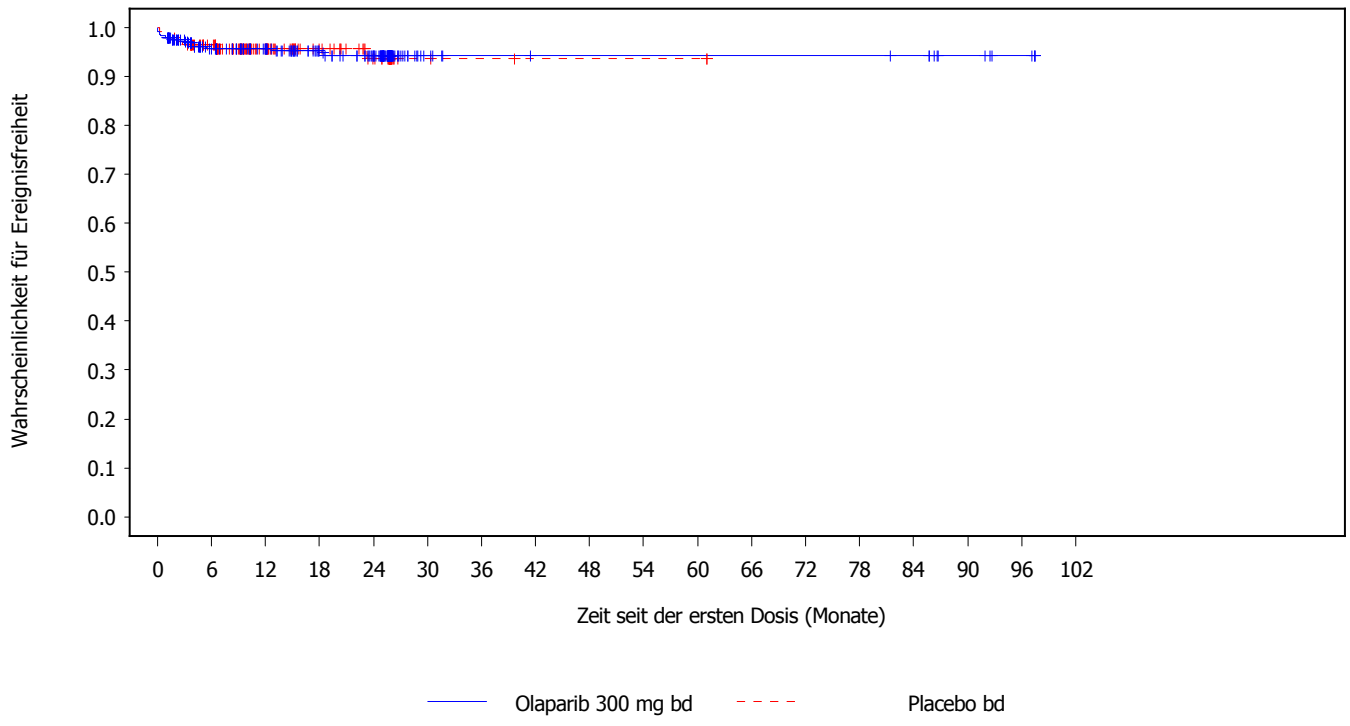
Anzahl an Patienten unter Risiko:

300	255	223	192	176	16	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	127	85	59	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebca 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.54 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Periphere Neuropathie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



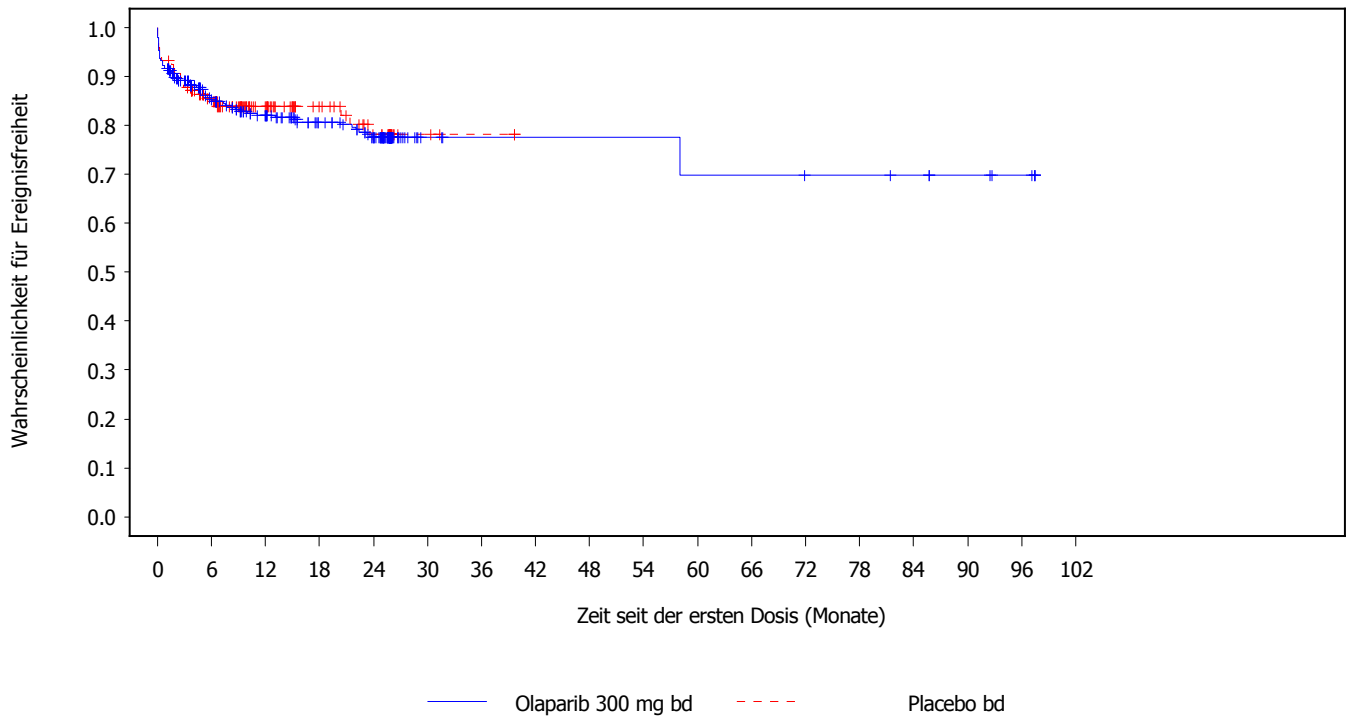
Anzahl an Patienten unter Risiko:

300	249	223	194	176	17	13	12	12	12	12	12	12	11	6	3	0	Olaparib 300 mg bd
149	125	81	55	41	3	2	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcb 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.55 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schwindelgefuehl
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



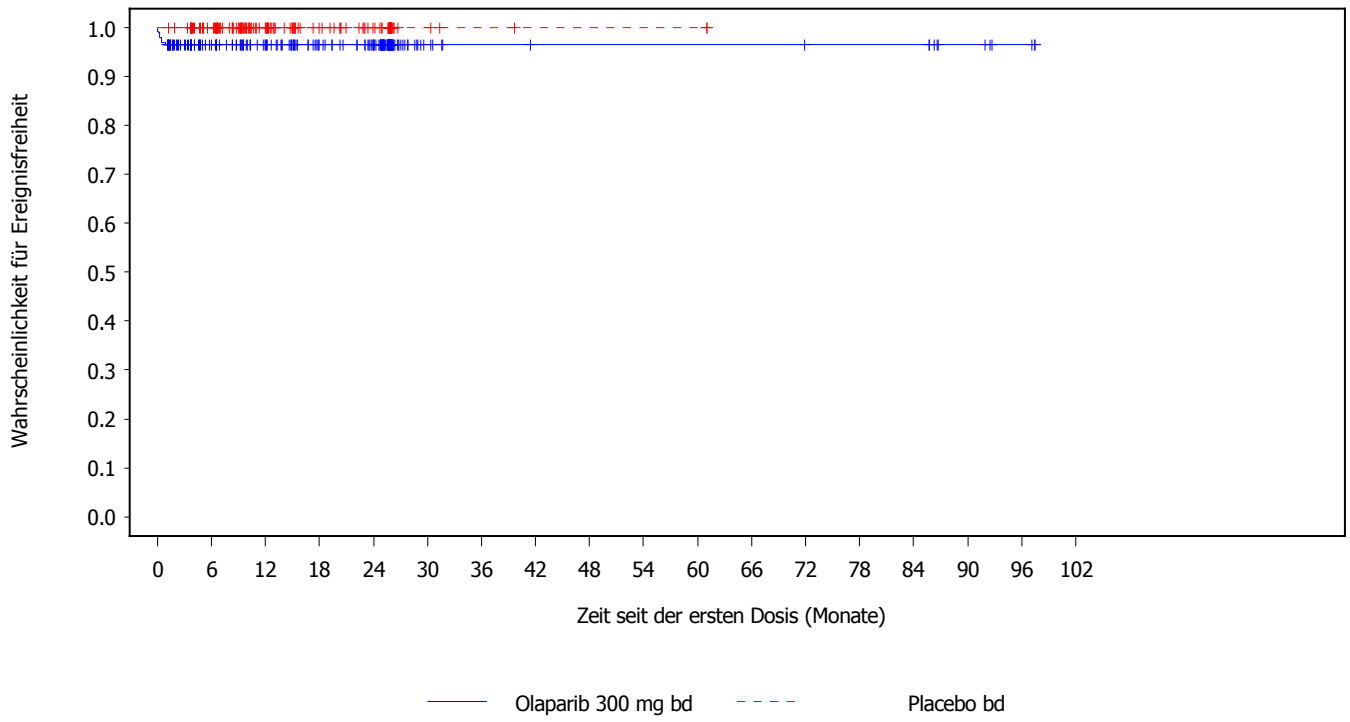
Anzahl an Patienten unter Risiko:

300	220	189	161	143	12	10	10	10	10	9	9	8	8	7	5	3	0	Olaparib 300 mg bd
149	109	71	49	36	3	1	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcc 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.56 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Somnolenz
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



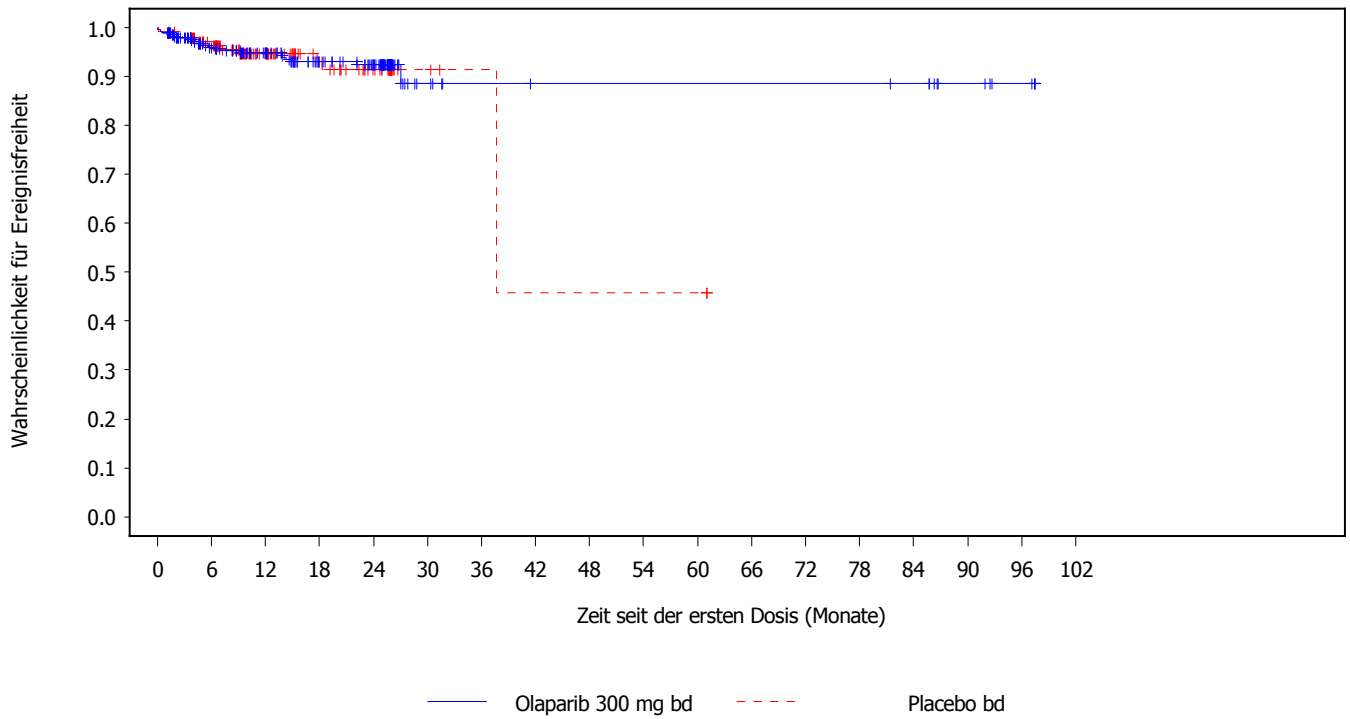
Anzahl an Patienten unter Risiko:

300	251	222	194	178	16	12	11	11	11	11	11	10	10	10	5	2	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcd 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.57 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Ohrs und des Labyrinths
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



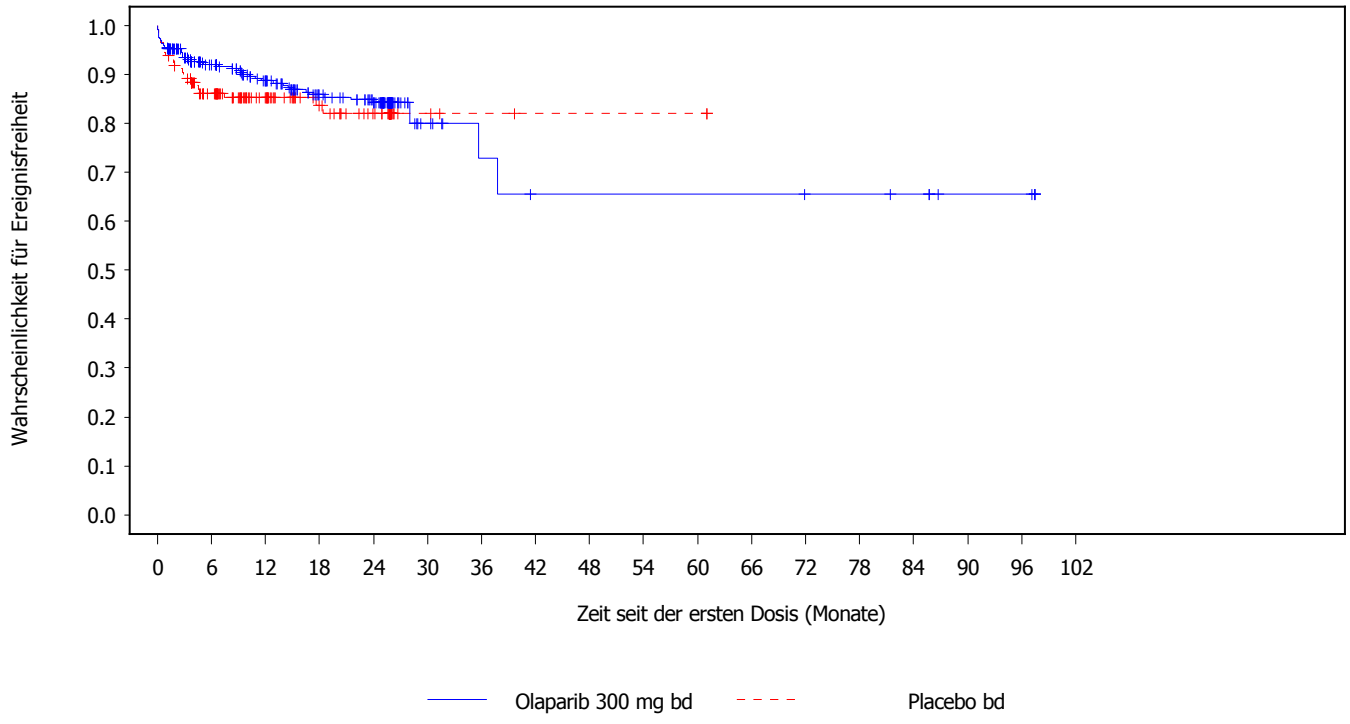
Anzahl an Patienten unter Risiko:

300	249	218	186	169	17	13	12	12	12	12	12	12	12	11	6	3	0	Olaparib 300 mg bd
149	125	83	57	43	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebce 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.58 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Gefaesserkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



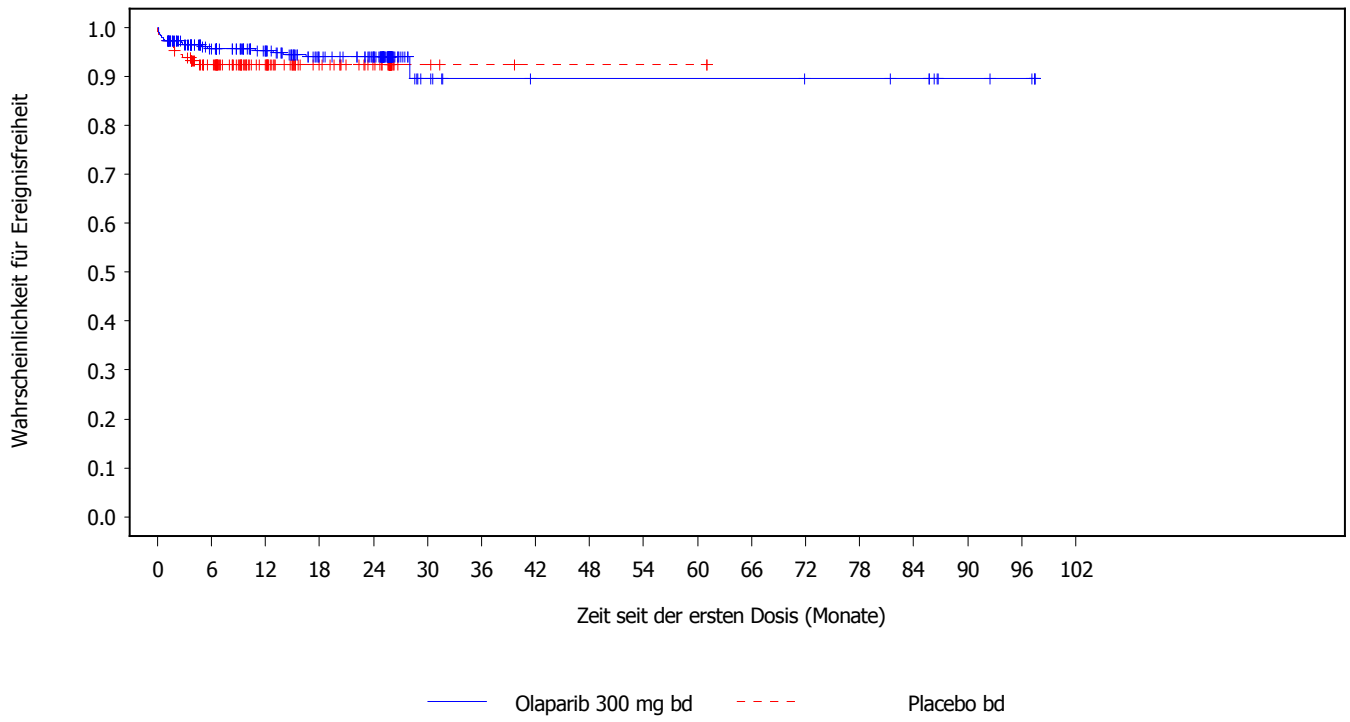
Anzahl an Patienten unter Risiko:

300	239	205	171	153	15	10	8	8	8	8	8	7	7	6	3	3	0	Olaparib 300 mg bd
149	110	76	52	40	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcf 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.59 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hitzewallung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



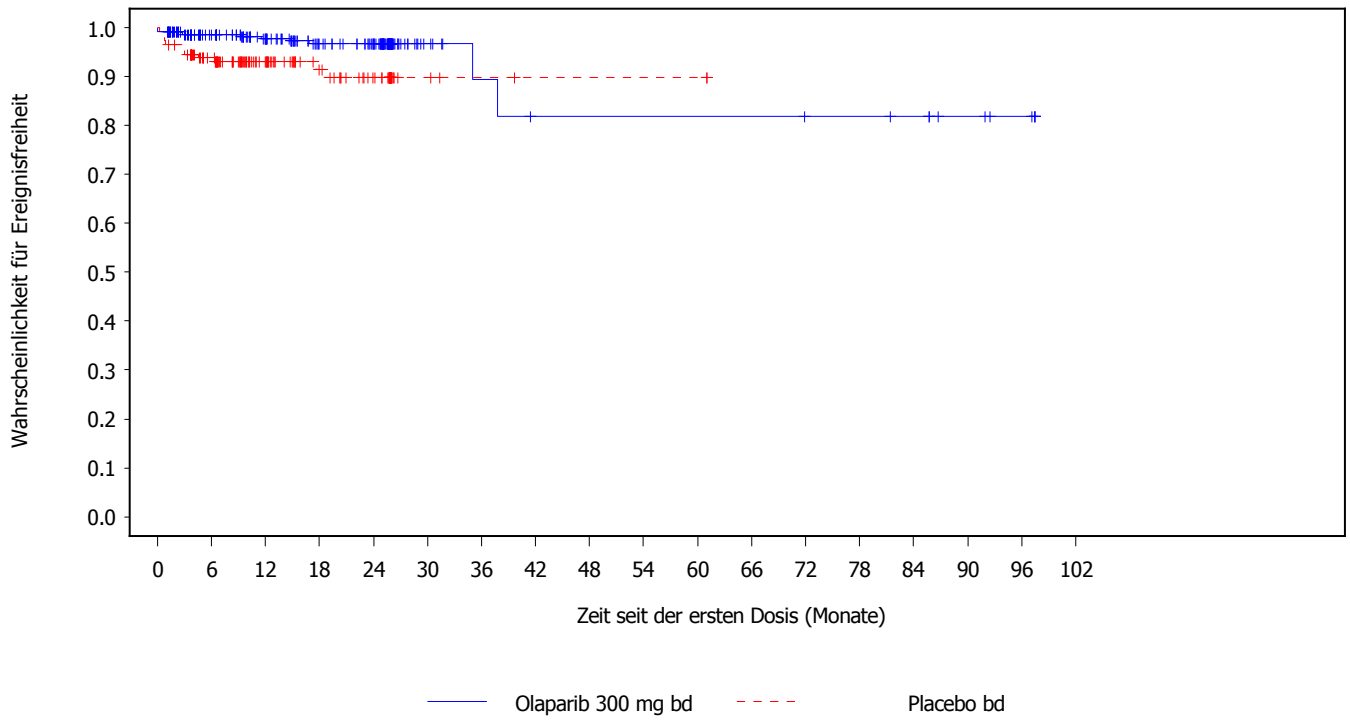
Anzahl an Patienten unter Risiko:

300	249	220	189	174	16	12	11	11	11	11	11	10	10	9	4	3	0	Olaparib 300 mg bd
149	119	82	56	44	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcg 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.60 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hypertonie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



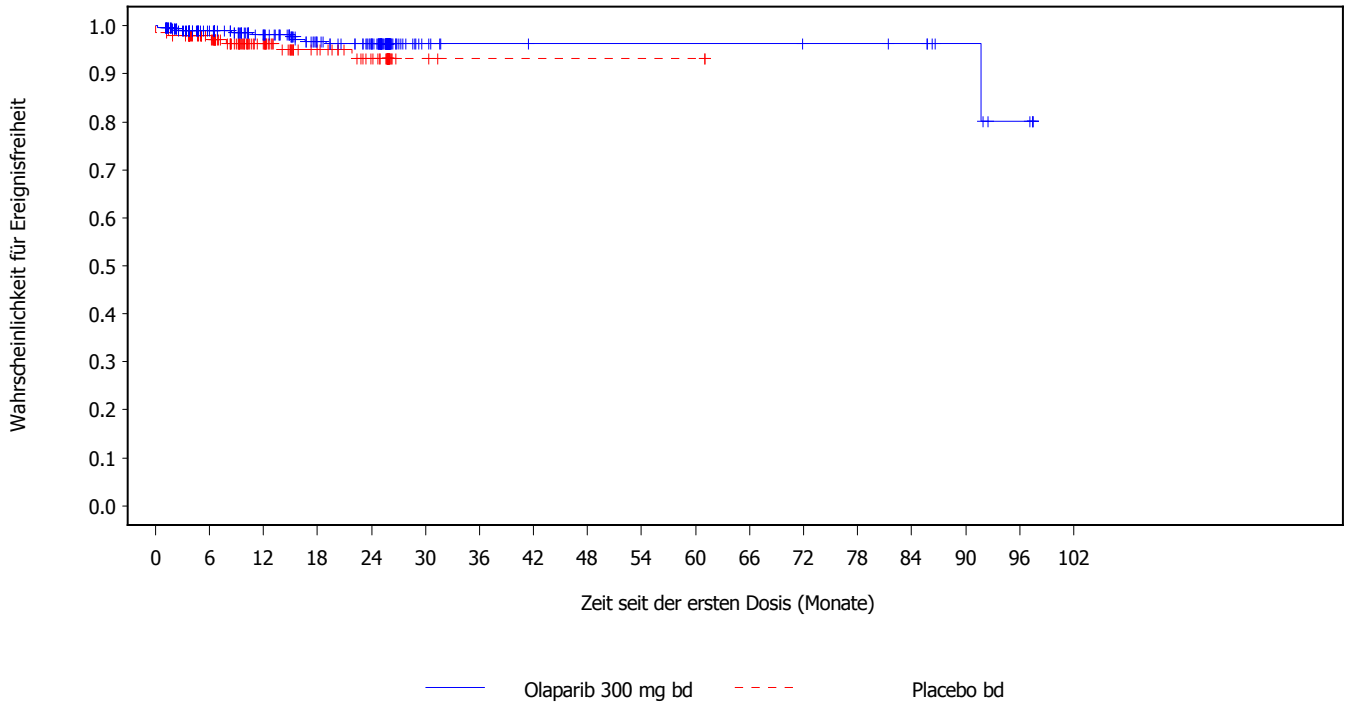
Anzahl an Patienten unter Risiko:

300	256	224	193	177	17	12	10	10	10	10	10	9	9	8	5	3	0	Olaparib 300 mg bd
149	121	82	57	44	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebch 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.61 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Gutartige, boesartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



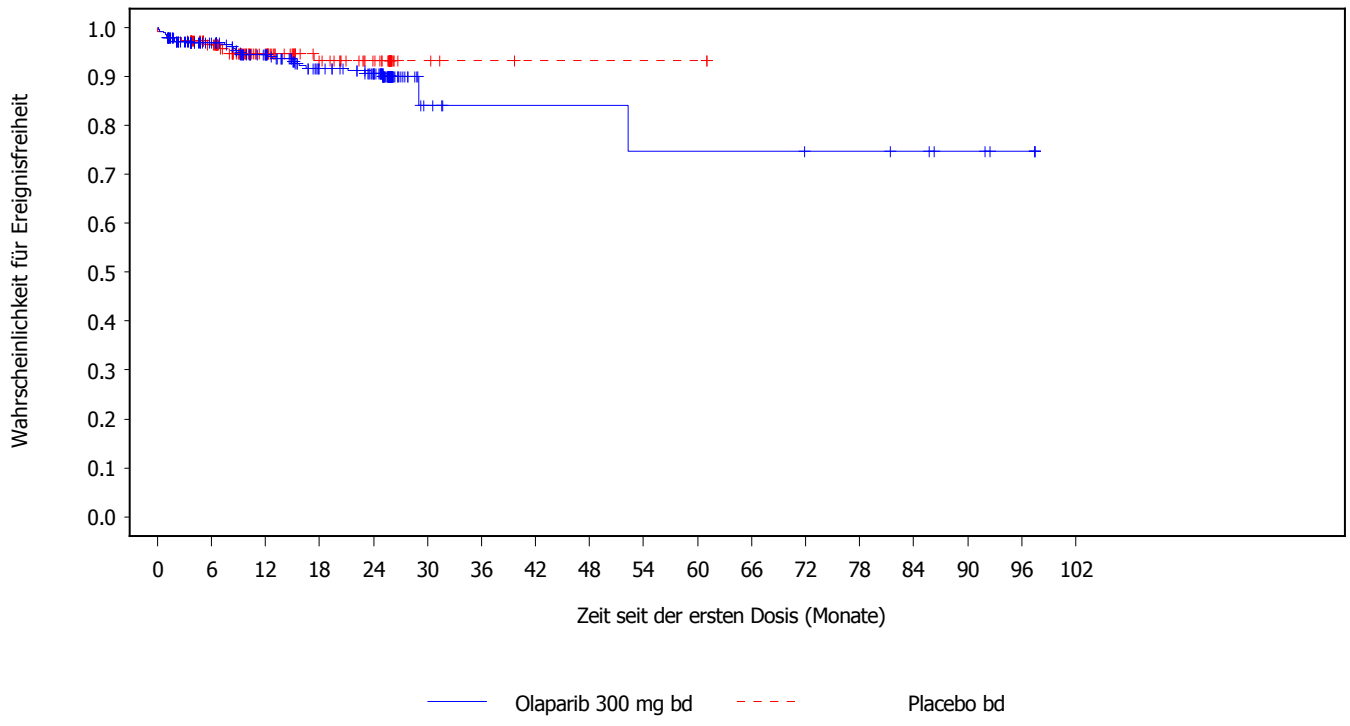
Anzahl an Patienten unter Risiko:

300	258	227	196	179	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	127	84	58	46	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebci 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.62 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Herzerkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



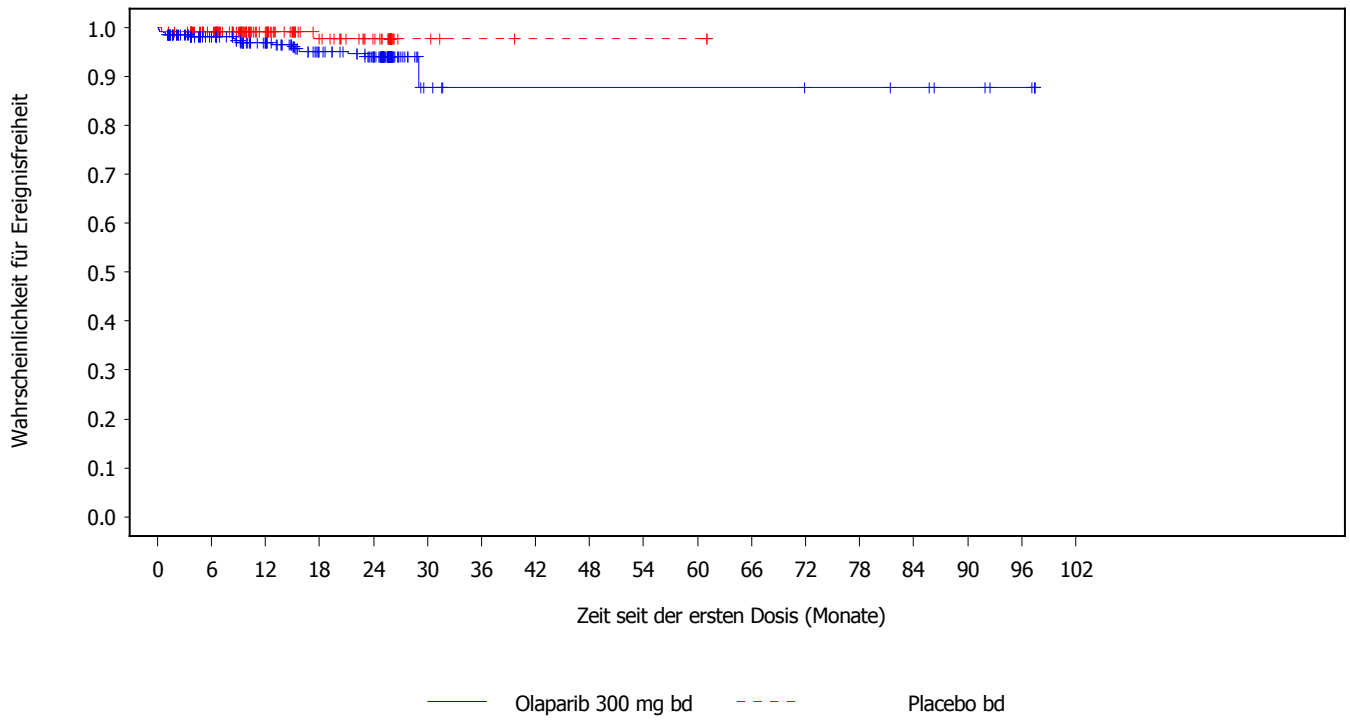
Anzahl an Patienten unter Risiko:

300	253	220	185	168	12	9	9	9	8	8	8	7	7	6	4	2	0	Olaparib 300 mg bd
149	126	82	58	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcj 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.63 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Palpitationen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



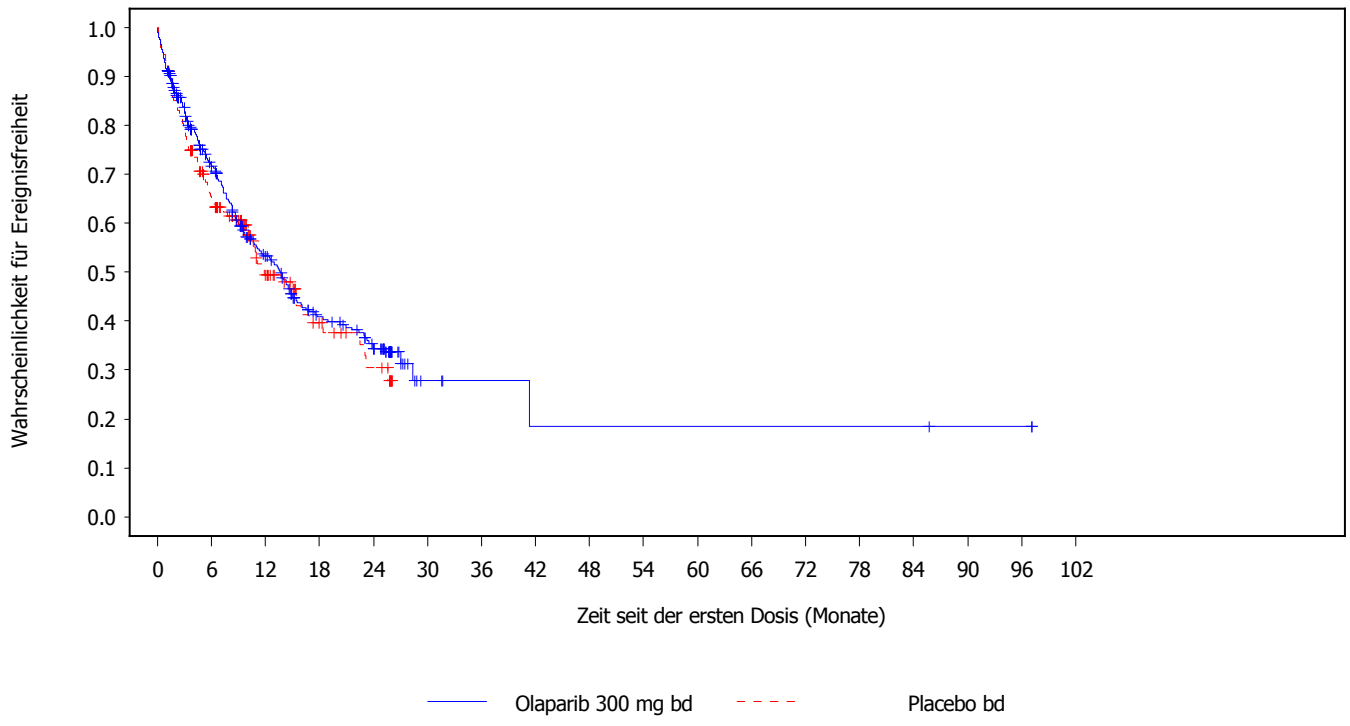
Anzahl an Patienten unter Risiko:

300	256	224	191	173	12	9	9	9	9	9	9	8	8	7	5	3	0	Olaparib 300 mg bd
149	129	86	60	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebck 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.64 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Infektionen und parasitaere Erkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



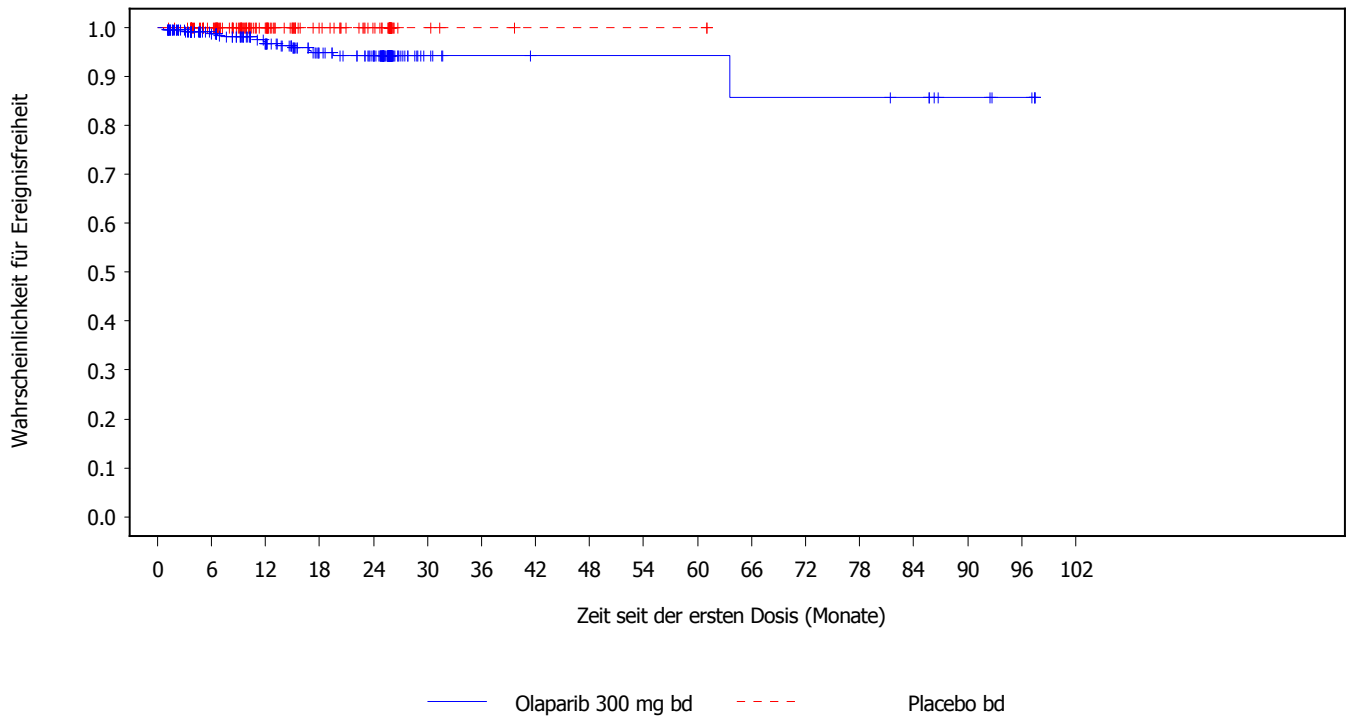
Anzahl an Patienten unter Risiko:

300	186	121	80	61	5	3	2	2	2	2	2	2	2	1	1	0	Olaparib 300 mg bd
149	87	41	21	13	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcl 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.65 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Bronchitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



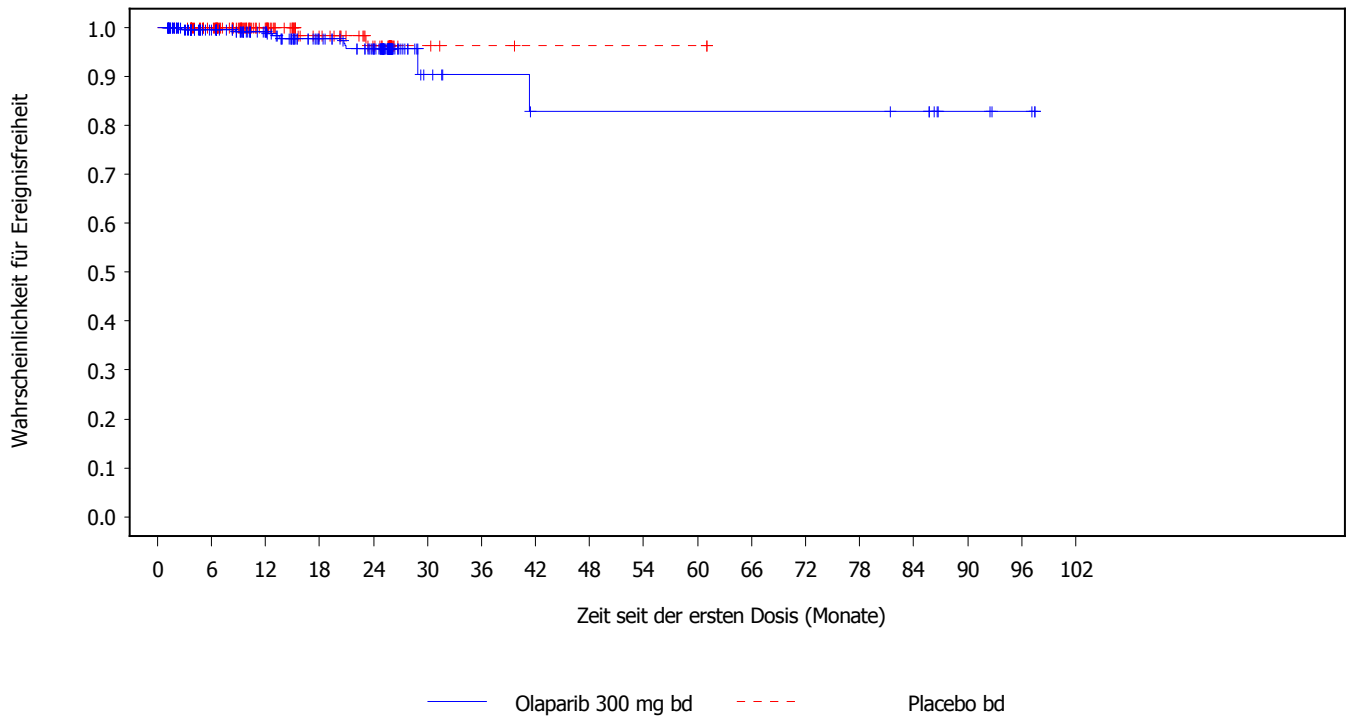
Anzahl an Patienten unter Risiko:

300	257	223	191	175	16	12	11	11	11	11	10	10	10	9	5	3	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcm 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.66 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Gastroenteritis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



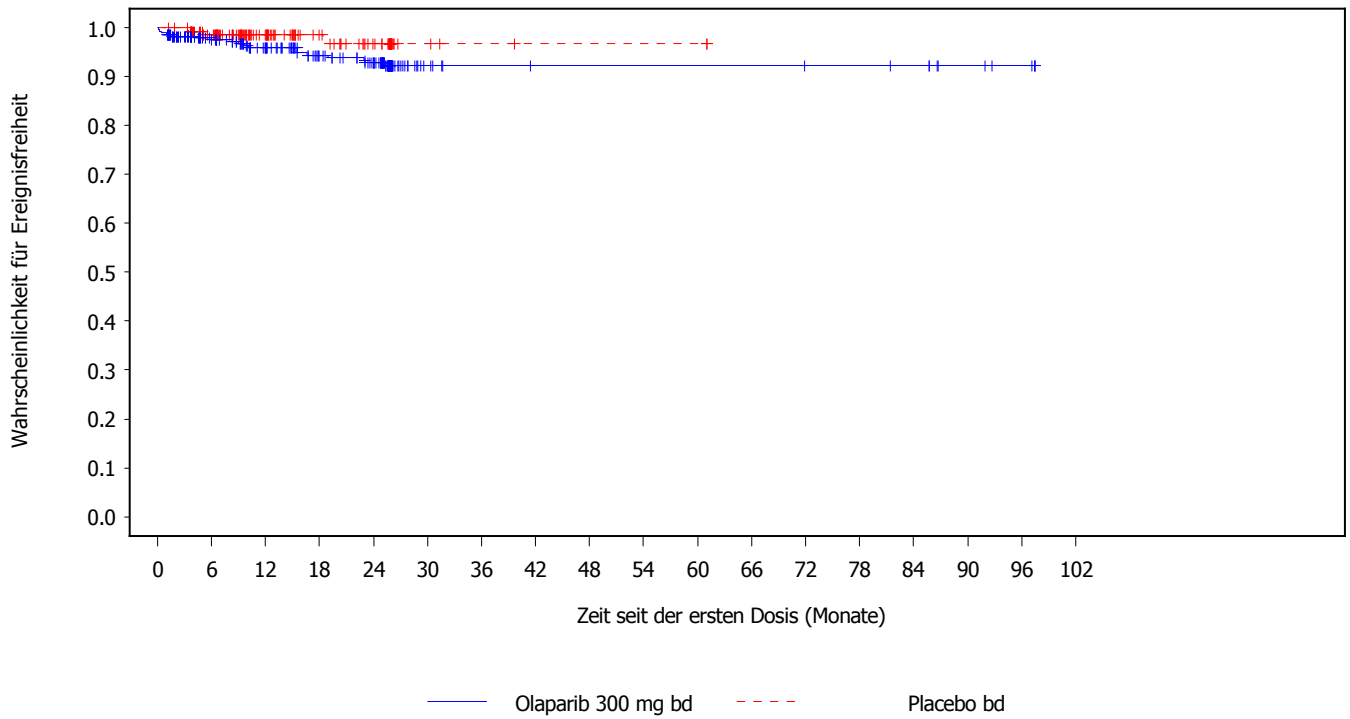
Anzahl an Patienten unter Risiko:

300	259	228	196	176	15	12	10	10	10	10	10	10	10	9	4	2	0	Olaparib 300 mg bd
149	130	87	60	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcn 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.67 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Grippe
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



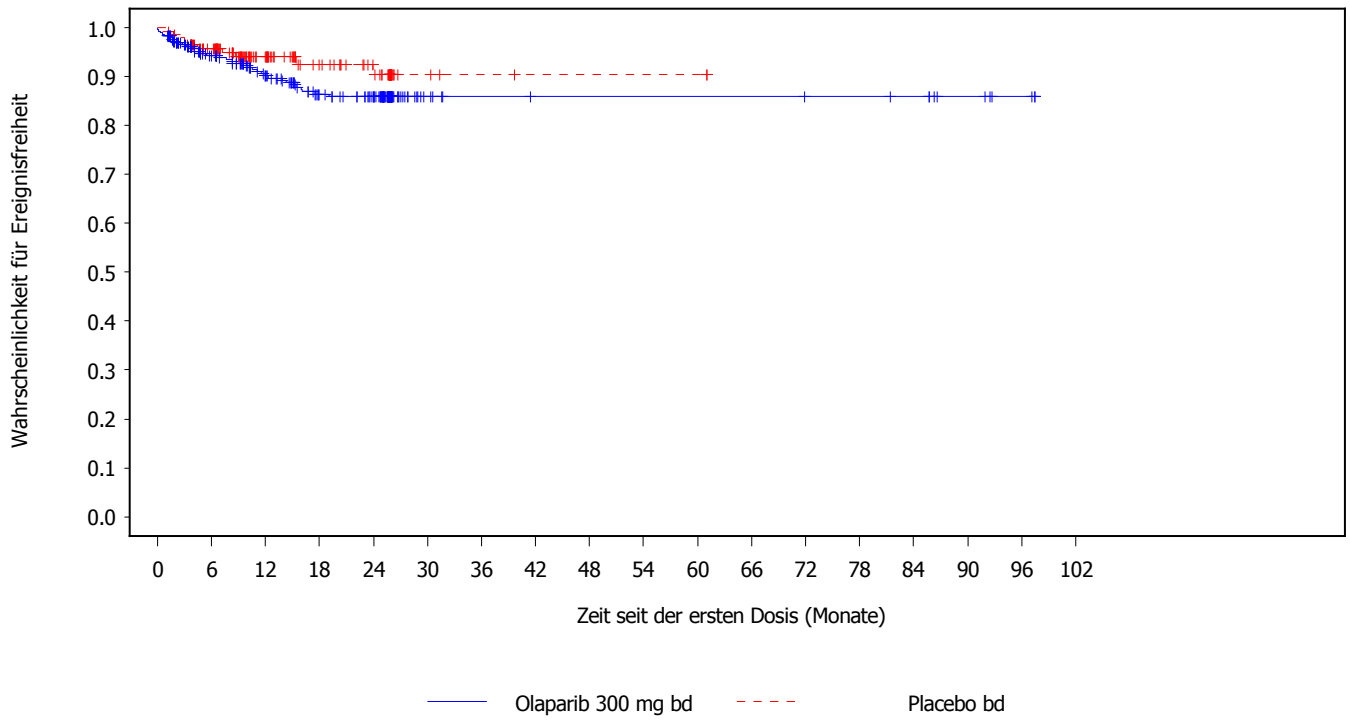
Anzahl an Patienten unter Risiko:

300	253	219	187	170	16	12	11	11	11	11	11	10	10	9	5	3	0	Olaparib 300 mg bd
149	128	86	60	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebco 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.68 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Harnwegsinfektion
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



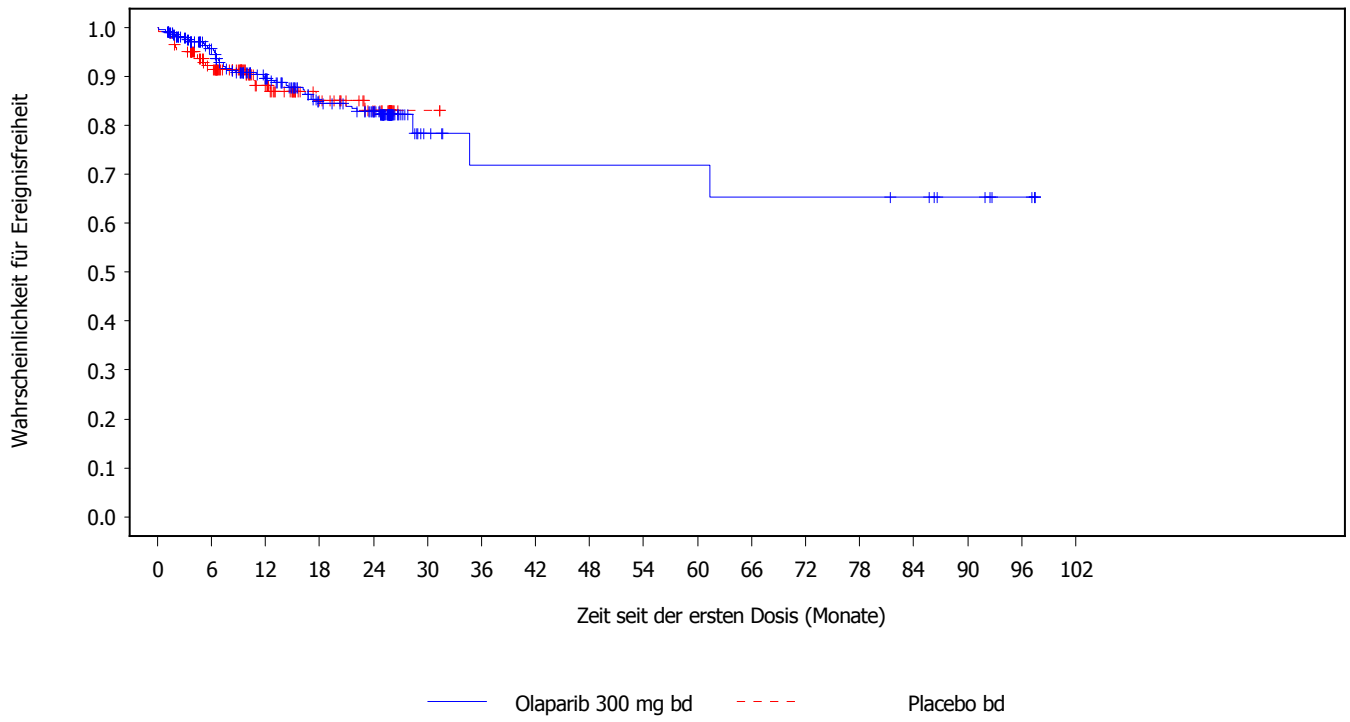
Anzahl an Patienten unter Risiko:

300	245	207	174	159	16	12	11	11	11	11	11	10	10	9	5	2	0	Olaparib 300 mg bd
149	124	81	56	44	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcp 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.69 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Infektion der oberen Atemwege
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



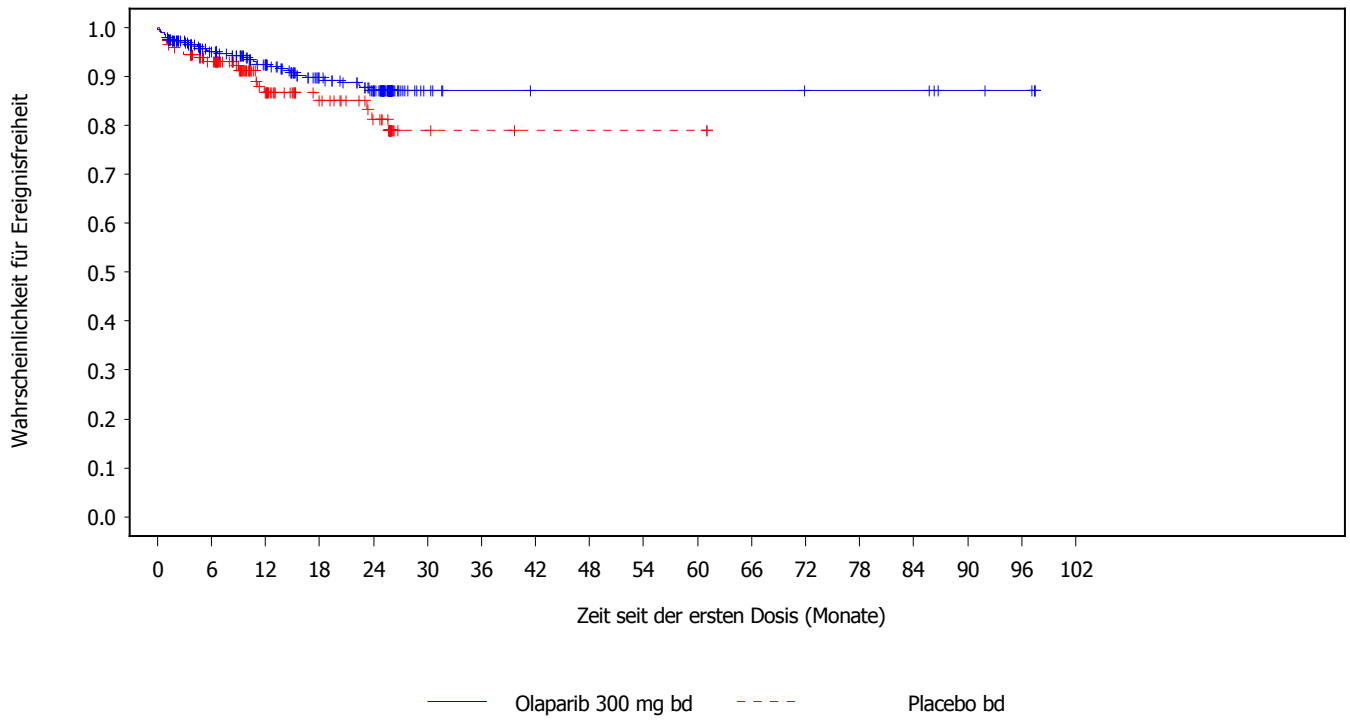
Anzahl an Patienten unter Risiko:

300	249	206	171	156	15	11	11	11	11	11	10	10	10	9	6	3	0	Olaparib 300 mg bd
149	119	75	49	35	1	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcq 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.70 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Nasopharyngitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



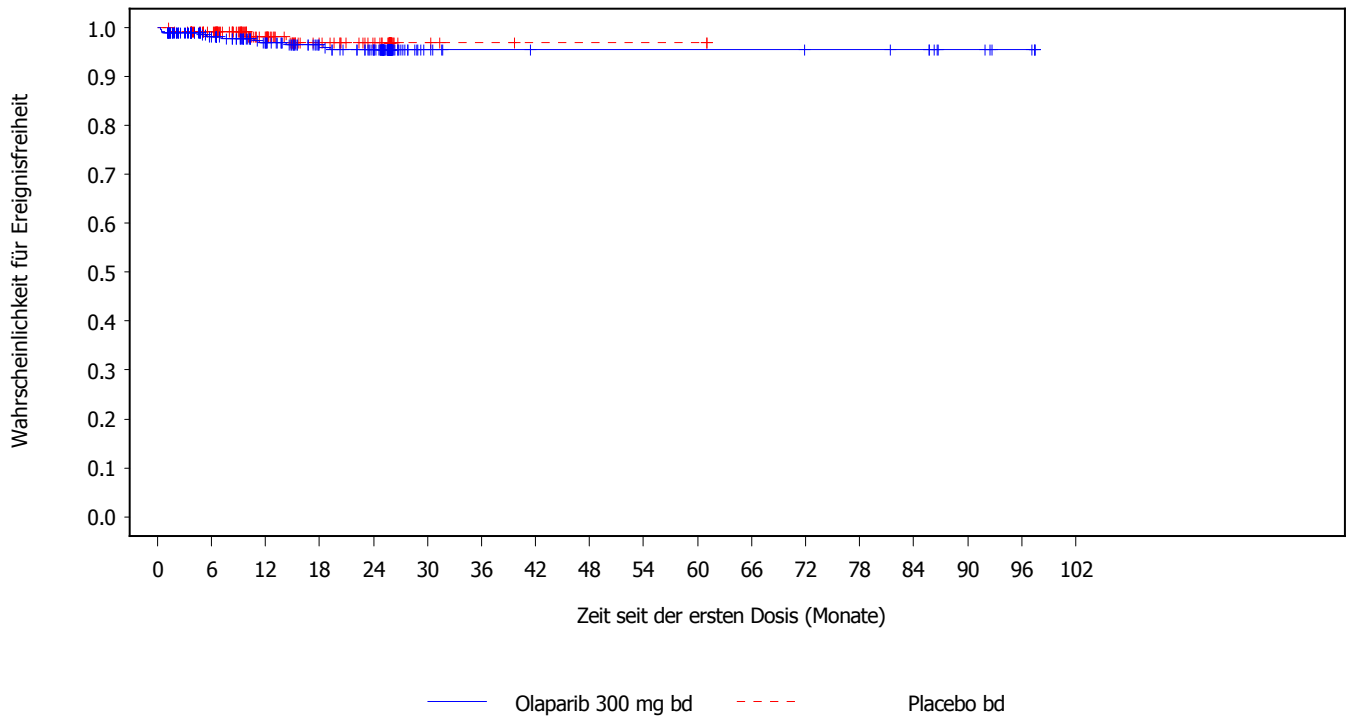
Anzahl an Patienten unter Risiko:

300	248	214	179	158	13	9	8	8	8	8	8	7	7	7	4	3	0	Olaparib 300 mg bd
149	123	75	52	40	3	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcr 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.71 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Pharyngitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



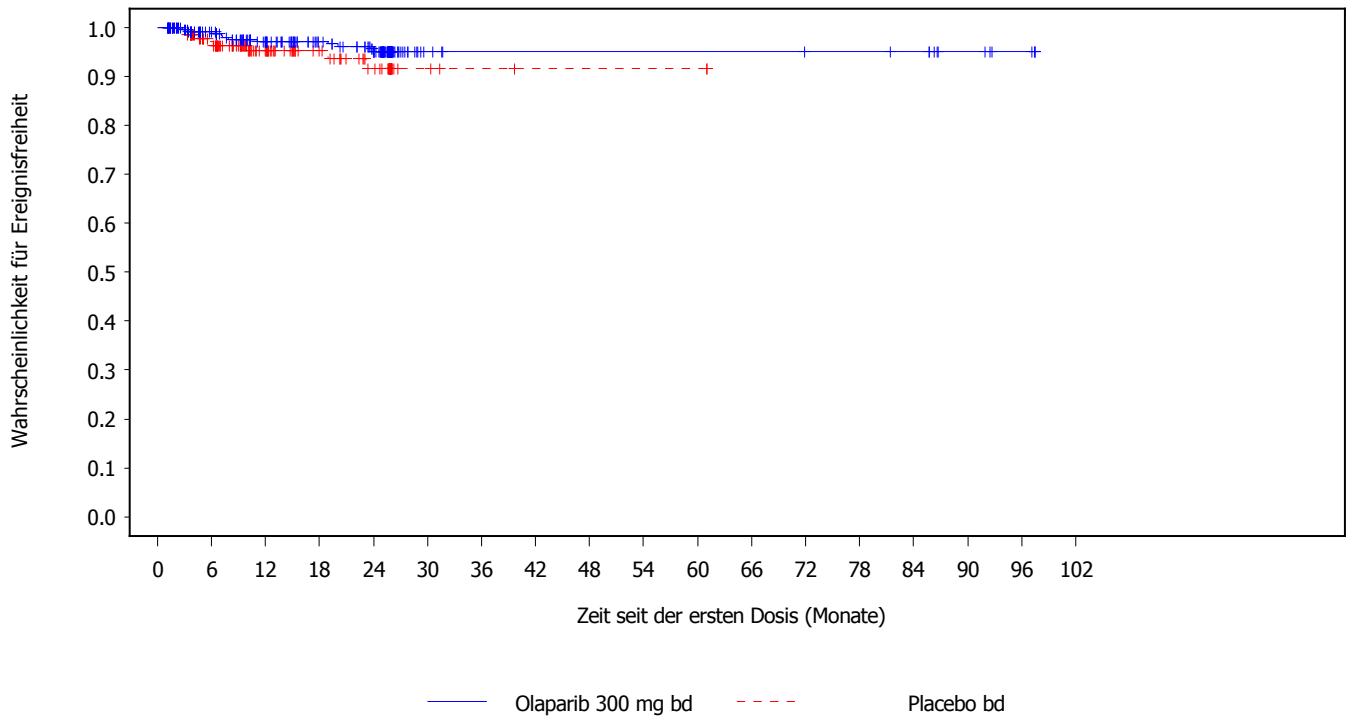
Anzahl an Patienten unter Risiko:

300	255	222	194	178	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	129	85	58	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcs 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.72 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Sinusitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



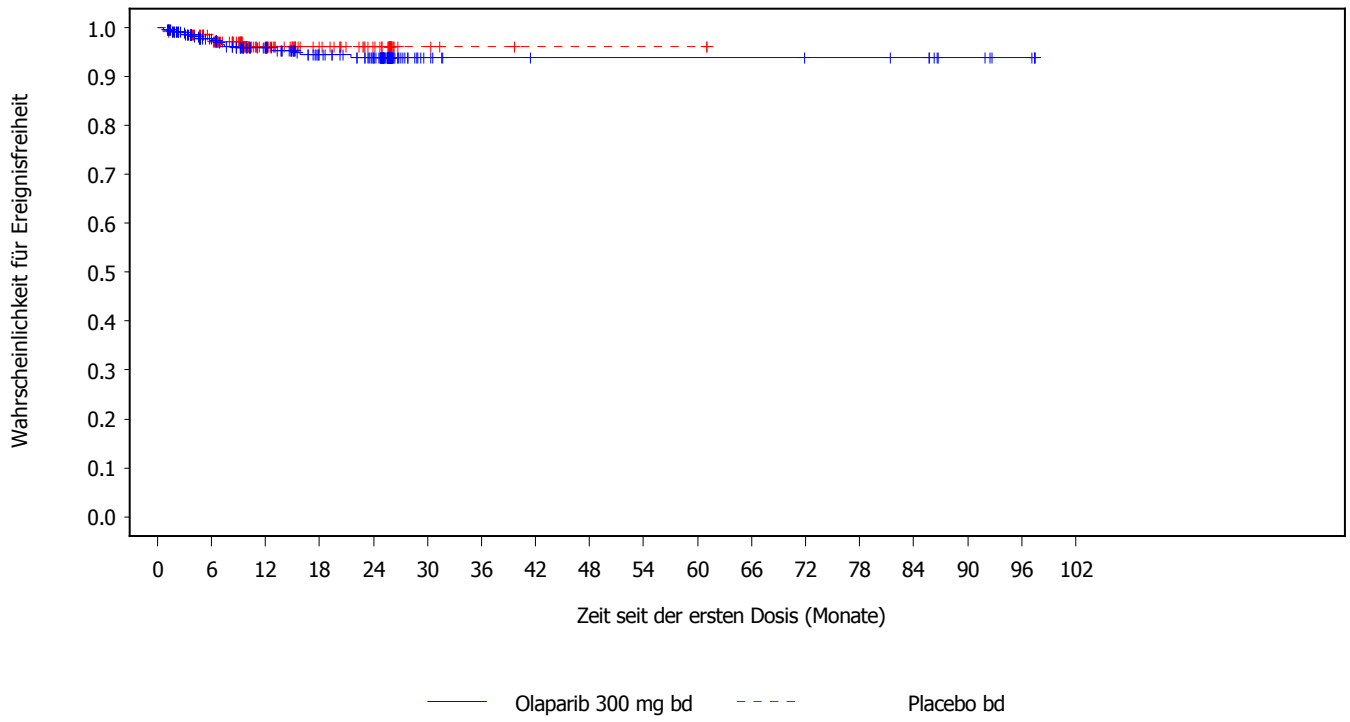
Anzahl an Patienten unter Risiko:

300	258	223	194	177	16	13	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	126	83	60	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebct 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.73 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Zystitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



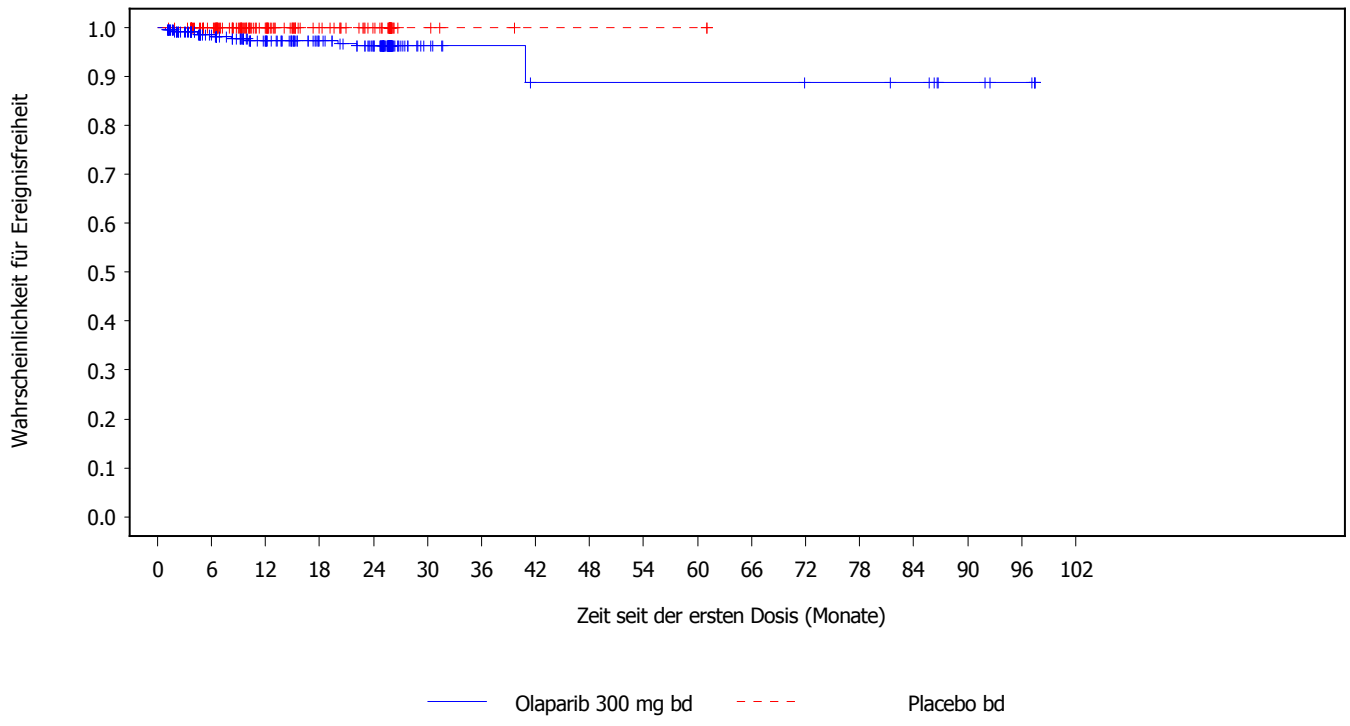
Anzahl an Patienten unter Risiko:

300	255	222	192	175	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	126	82	58	45	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcu 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.74 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Leber- und Gallenerkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



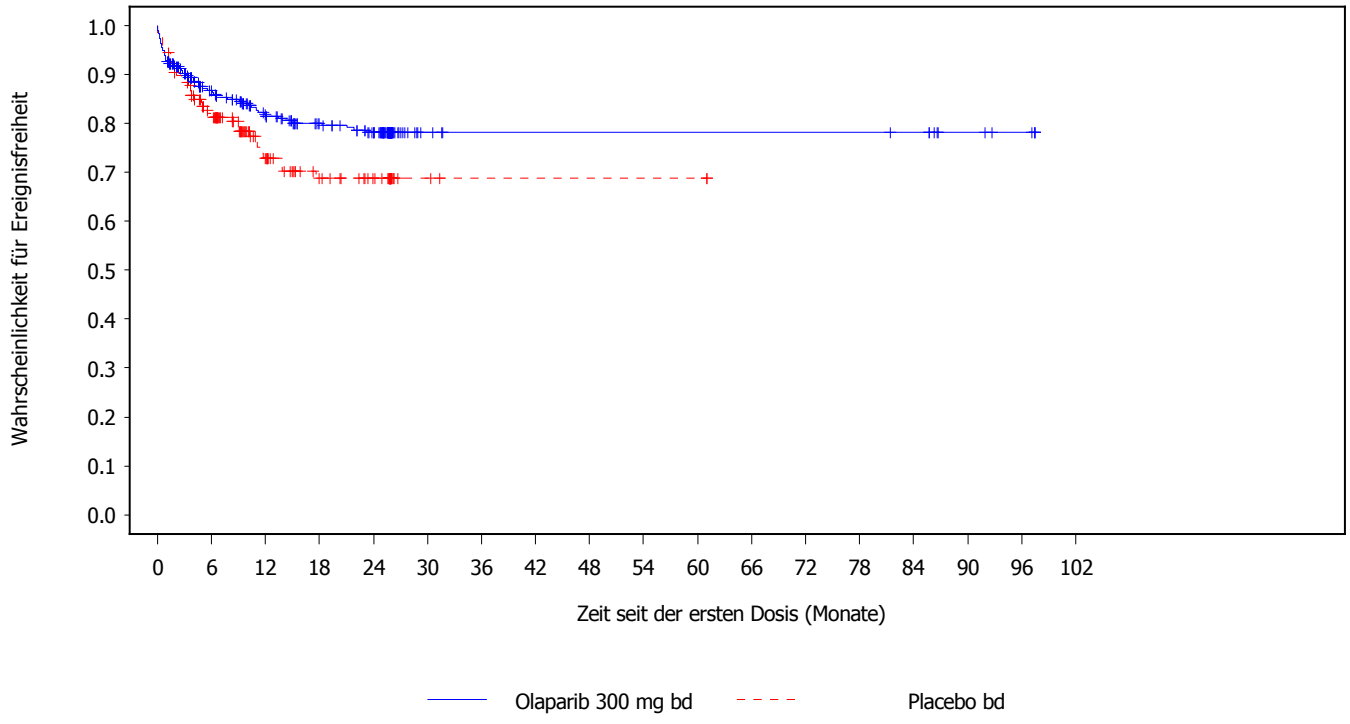
Anzahl an Patienten unter Risiko:

300	256	224	195	177	17	13	11	11	11	11	11	10	10	9	5	3	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcv 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.75 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Psychiatrische Erkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



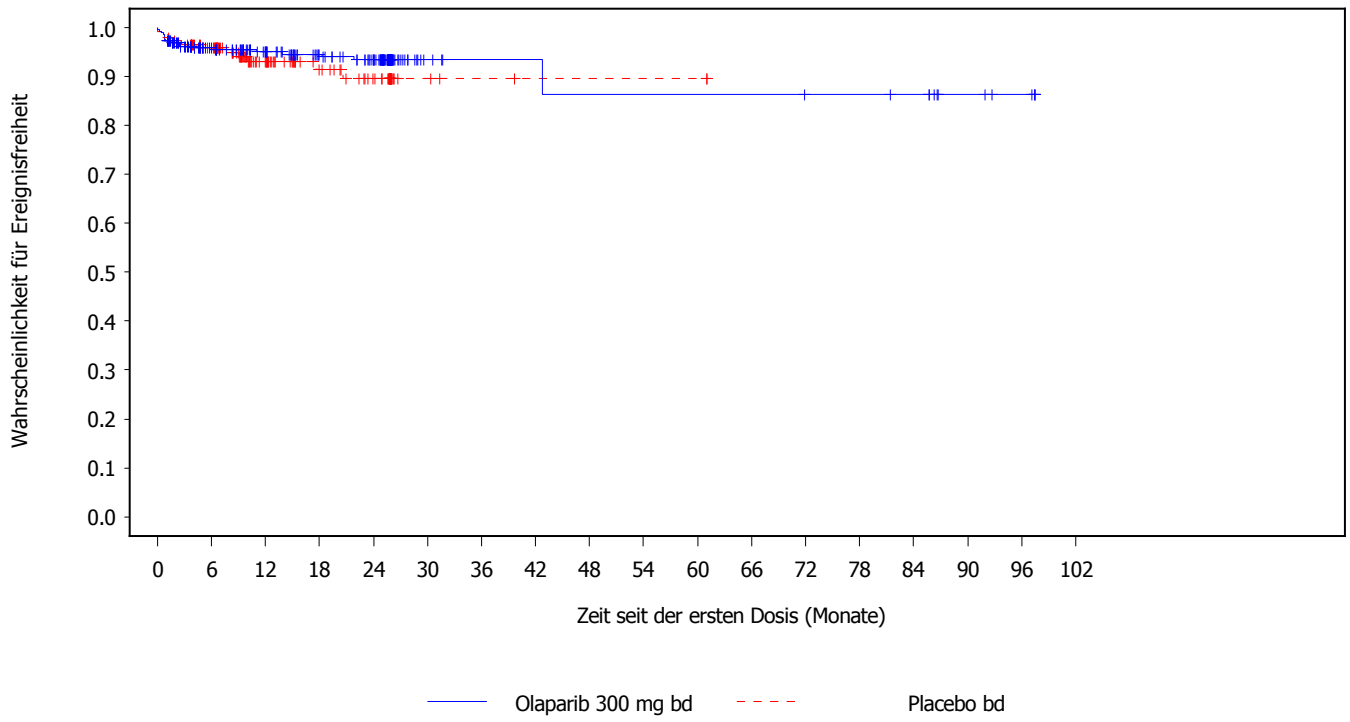
Anzahl an Patienten unter Risiko:

300	226	188	166	150	14	11	11	11	11	11	11	11	11	10	5	3	0	Olaparib 300 mg bd
149	106	63	44	35	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcw 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.76 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Angst
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



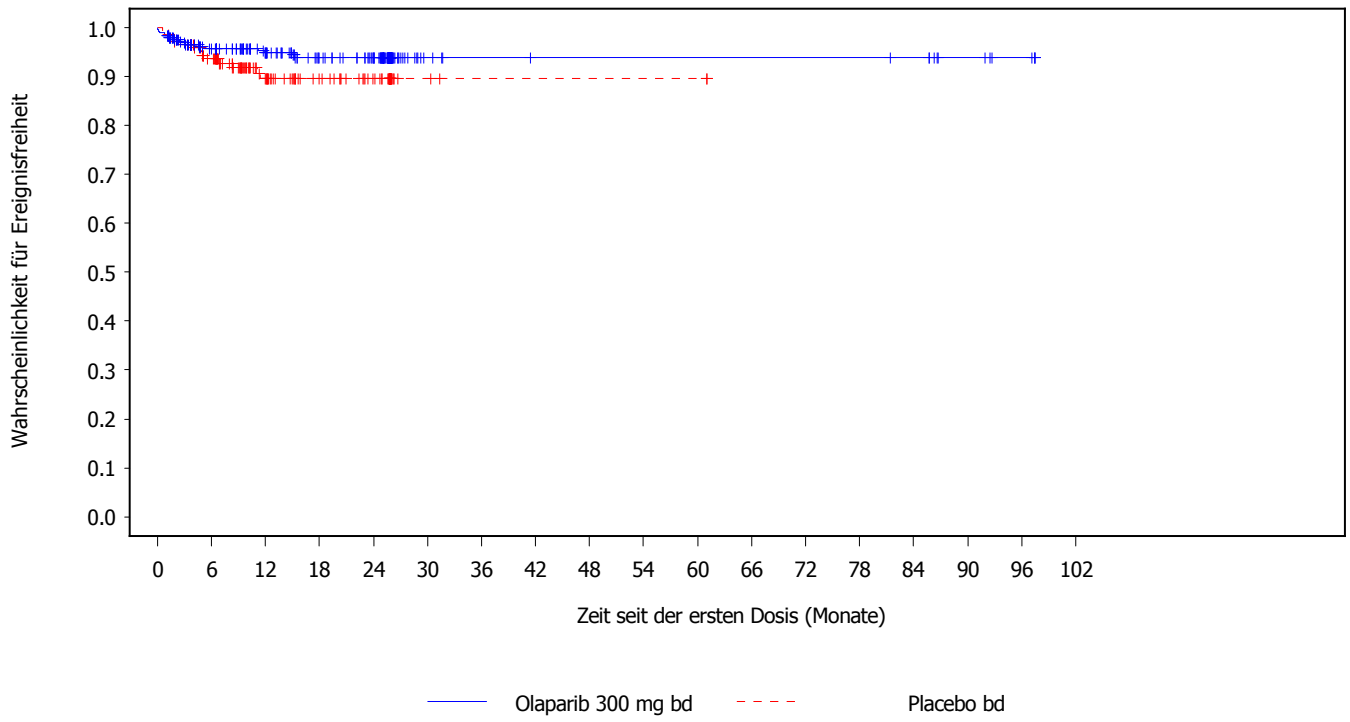
Anzahl an Patienten unter Risiko:

300	249	219	193	176	16	13	13	12	12	12	12	11	11	10	5	3	0	Olaparib 300 mg bd
149	126	81	56	44	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcx 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.77 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Depression
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



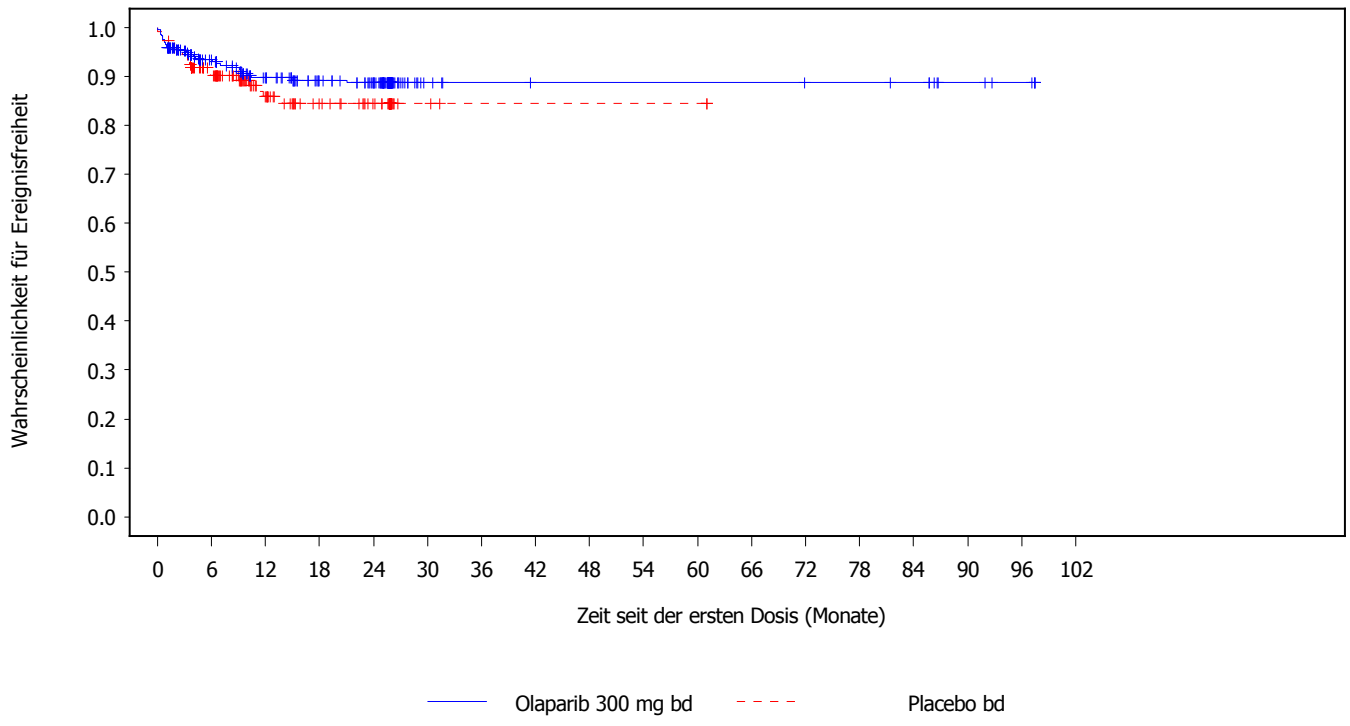
Anzahl an Patienten unter Risiko:

300	250	219	191	175	16	13	12	12	12	12	12	12	12	11	6	3	0	Olaparib 300 mg bd
149	122	77	54	41	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcy 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.78 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schlaflosigkeit
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



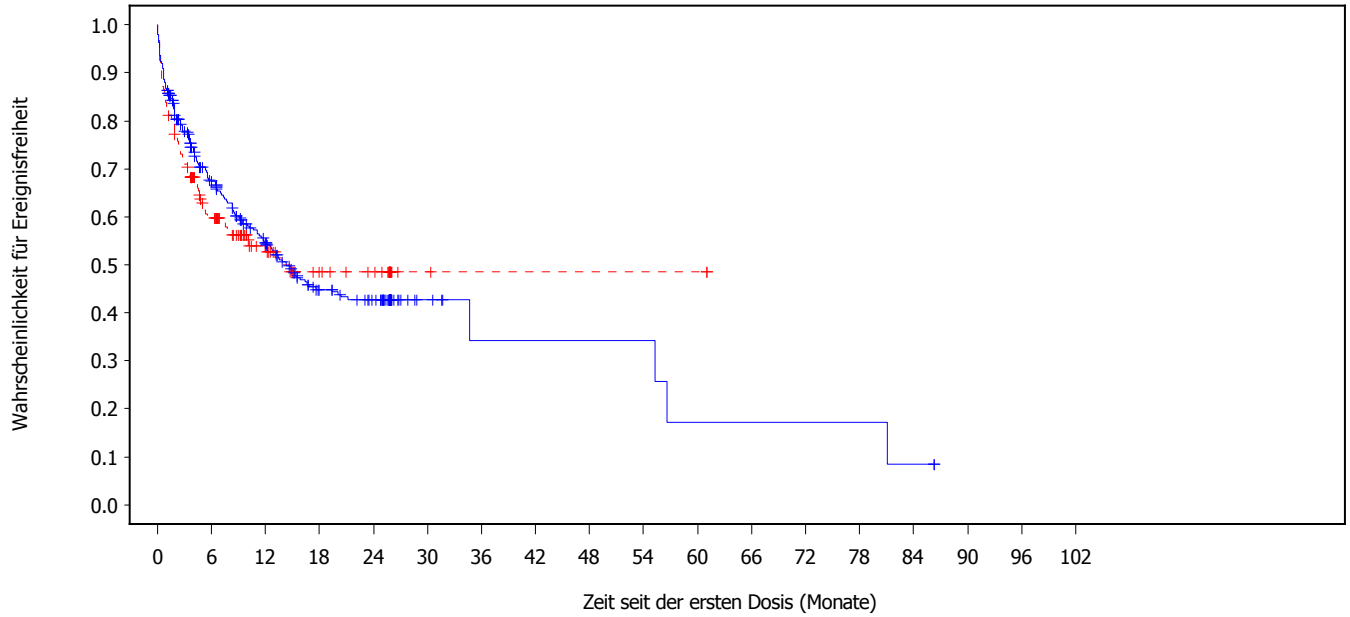
Anzahl an Patienten unter Risiko:

300	241	206	182	167	16	13	12	12	12	12	12	11	11	10	5	3	0	Olaparib 300 mg bd
149	116	73	53	43	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebcz 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.79 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



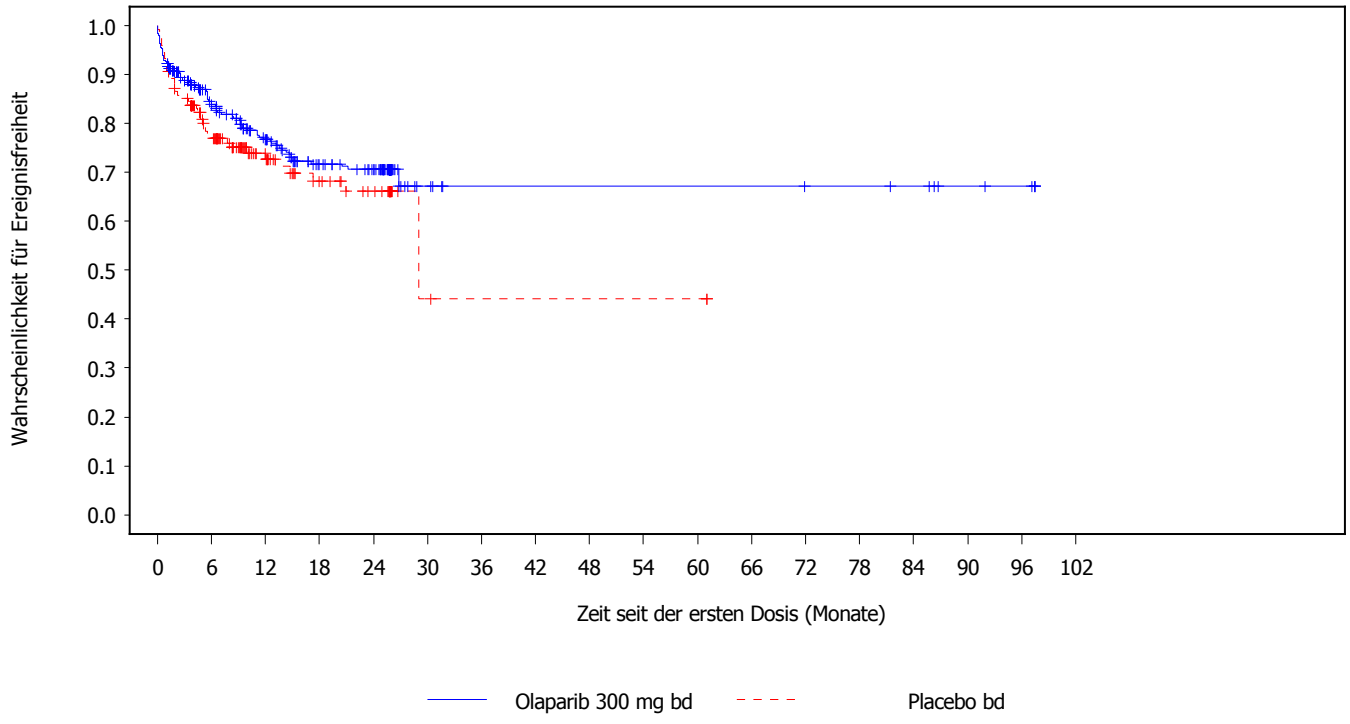
Anzahl an Patienten unter Risiko:

300	175	126	88	75	8	4	4	4	4	2	2	2	2	1	0	0	0	Olaparib 300 mg bd
149	76	43	28	24	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebda 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.80 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Arthralgie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



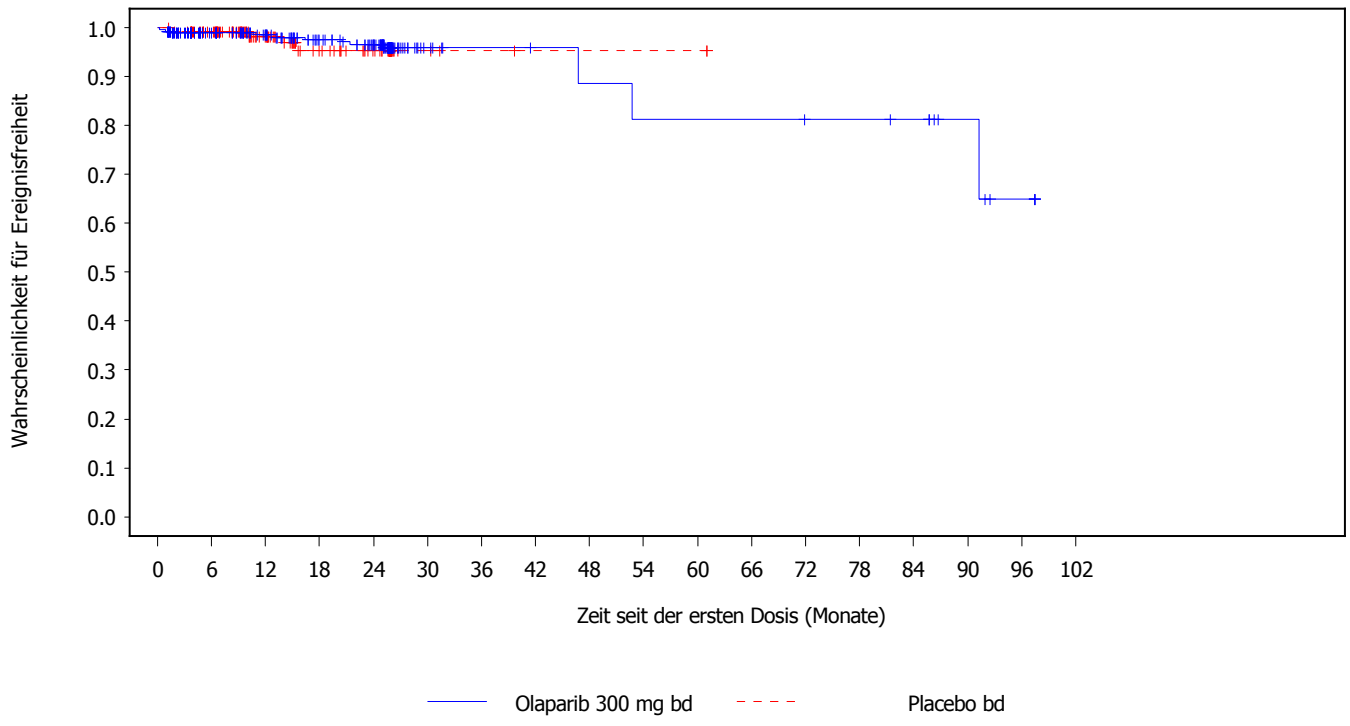
Anzahl an Patienten unter Risiko:

300	218	175	141	128	13	9	9	9	9	9	9	8	8	7	4	3	0	Olaparib 300 mg bd
149	101	57	39	31	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdb 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.81 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Brustschmerzen die Skelettmuskulatur betreffend
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



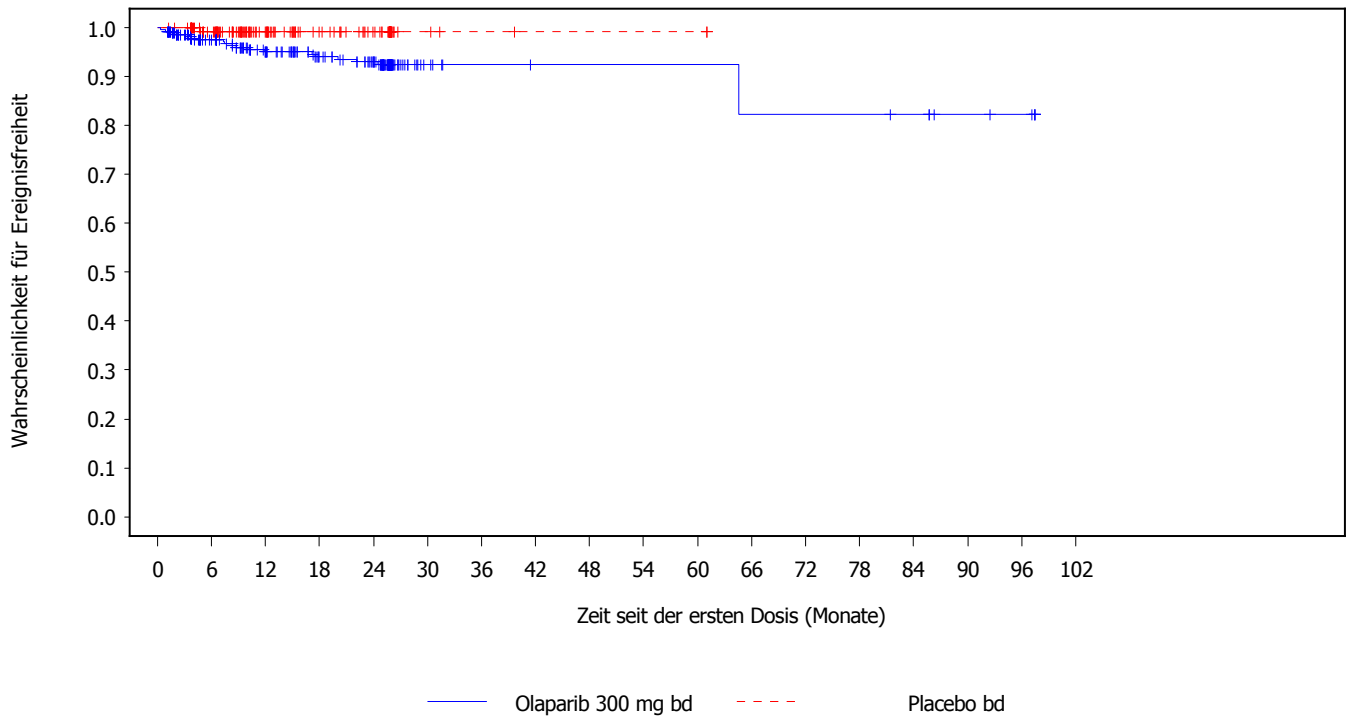
Anzahl an Patienten unter Risiko:

300	257	228	199	181	18	14	13	12	11	11	11	10	10	9	5	2	0	Olaparib 300 mg bd
149	129	85	59	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdc 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.82 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Muskelspasmen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



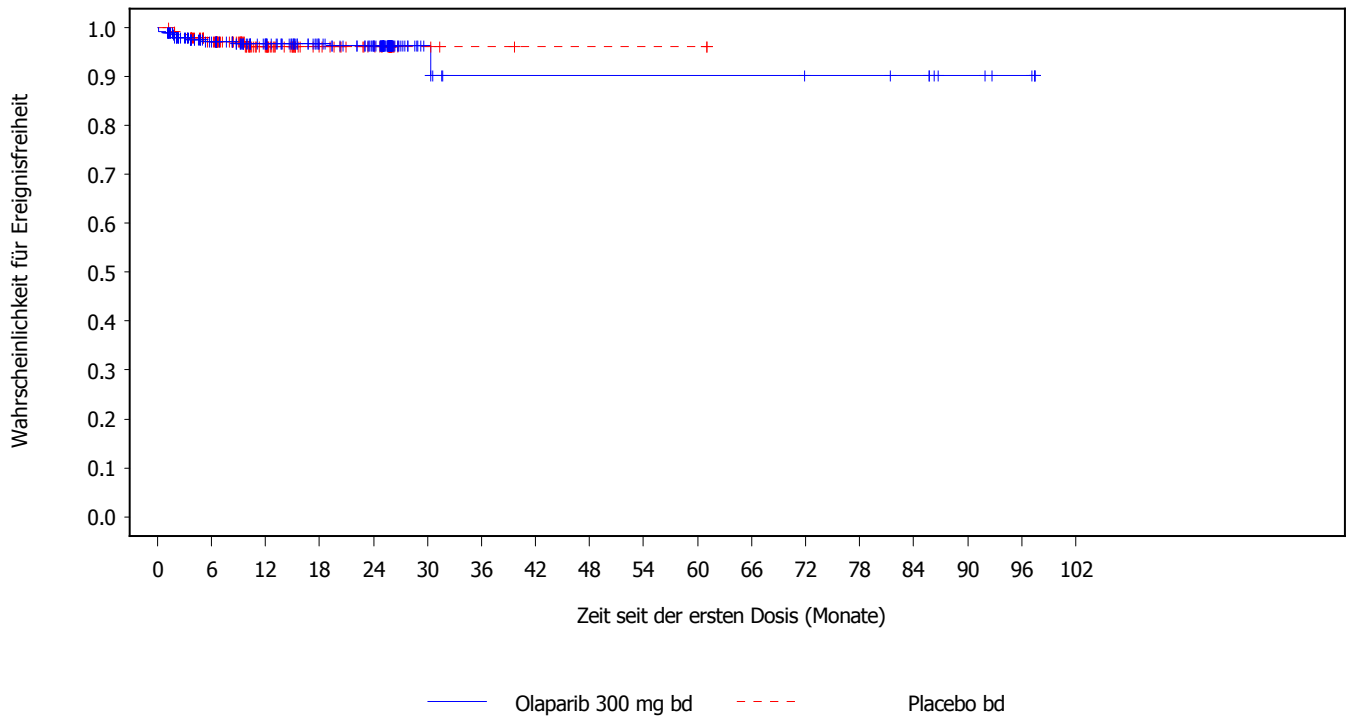
Anzahl an Patienten unter Risiko:

300	253	218	189	171	14	10	9	9	9	9	8	8	8	7	4	3	0	Olaparib 300 mg bd
149	129	86	60	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdd 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.83 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Muskulaere Schwaeche
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



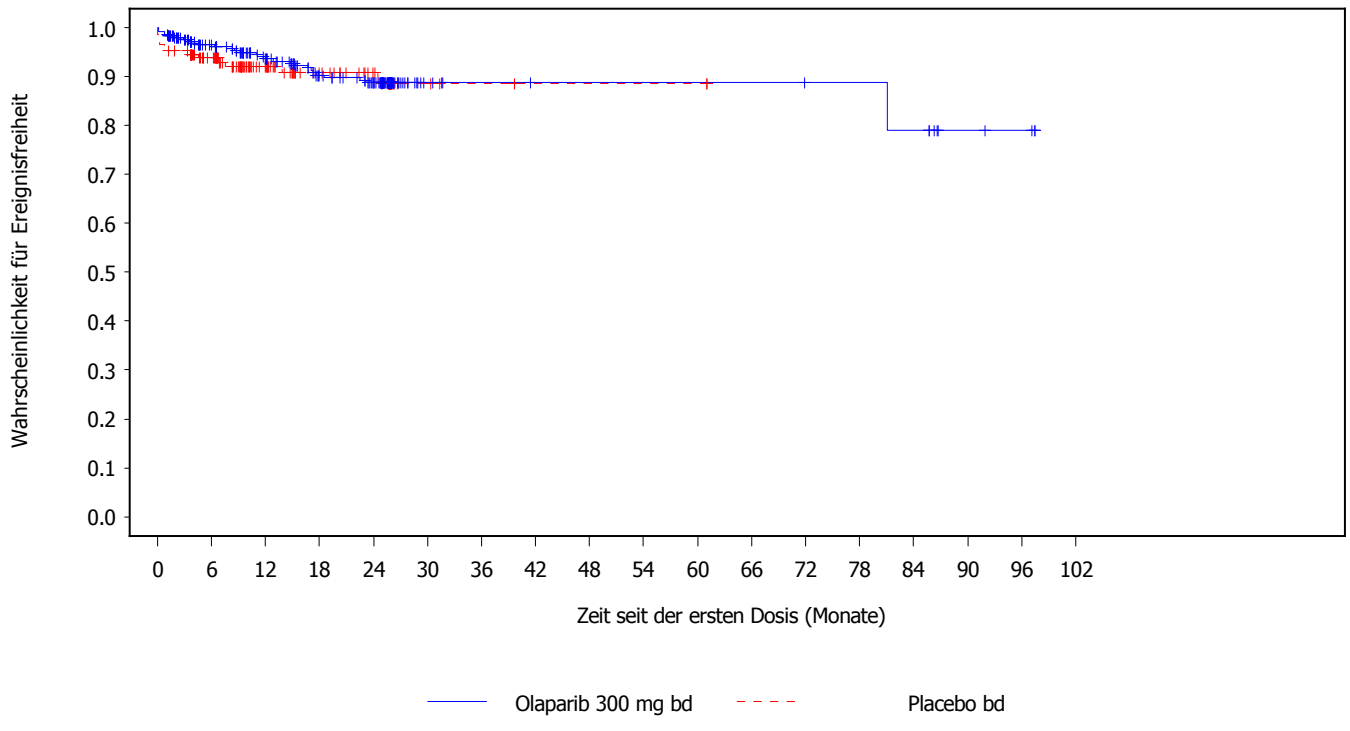
Anzahl an Patienten unter Risiko:

300	254	223	195	178	16	11	11	11	11	11	11	10	10	9	5	3	0	Olaparib 300 mg bd
149	126	82	56	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebde 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.84 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Myalgie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



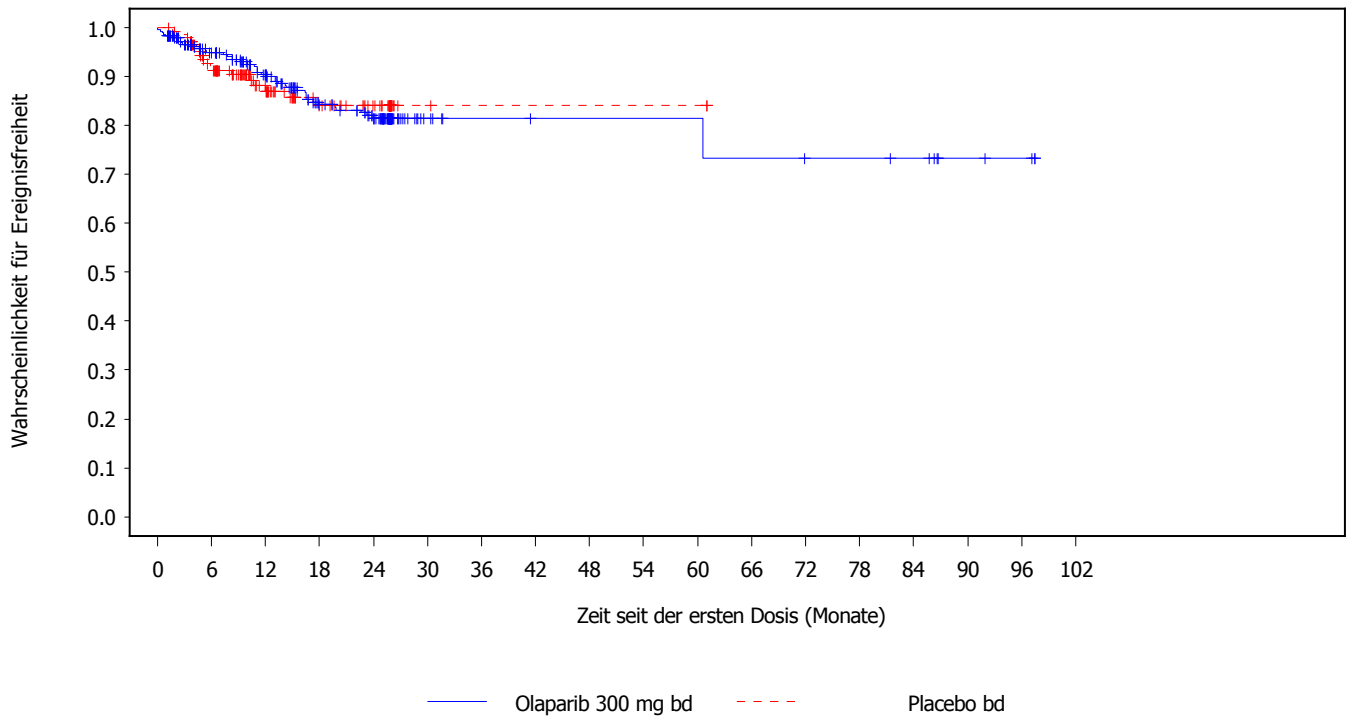
Anzahl an Patienten unter Risiko:

300	252	216	183	166	14	11	10	10	10	10	10	9	9	8	3	2	0	Olaparib 300 mg bd
149	121	79	54	43	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdf 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.85 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Rueckenschmerzen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



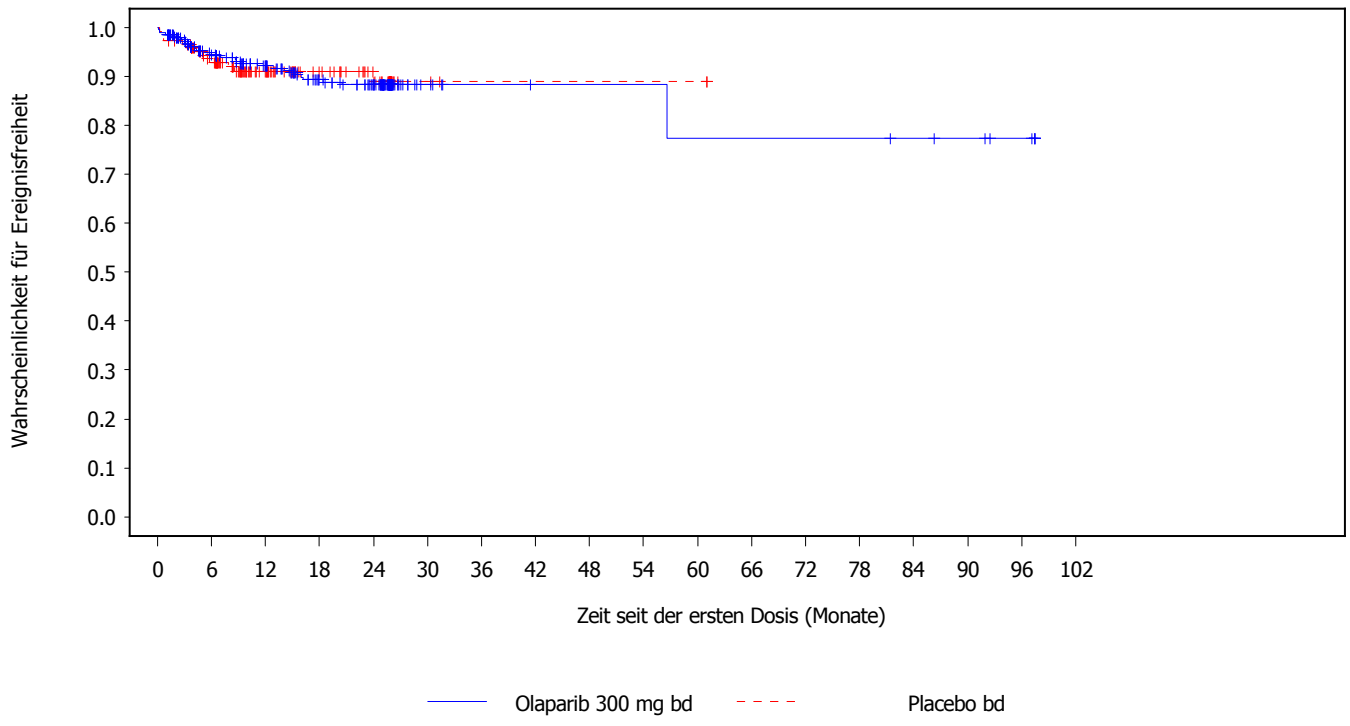
Anzahl an Patienten unter Risiko:

300	247	207	166	147	15	11	10	10	10	10	9	8	8	7	3	2	0	Olaparib 300 mg bd
149	119	76	50	39	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdg 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.86 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerz in einer Extremitaet
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



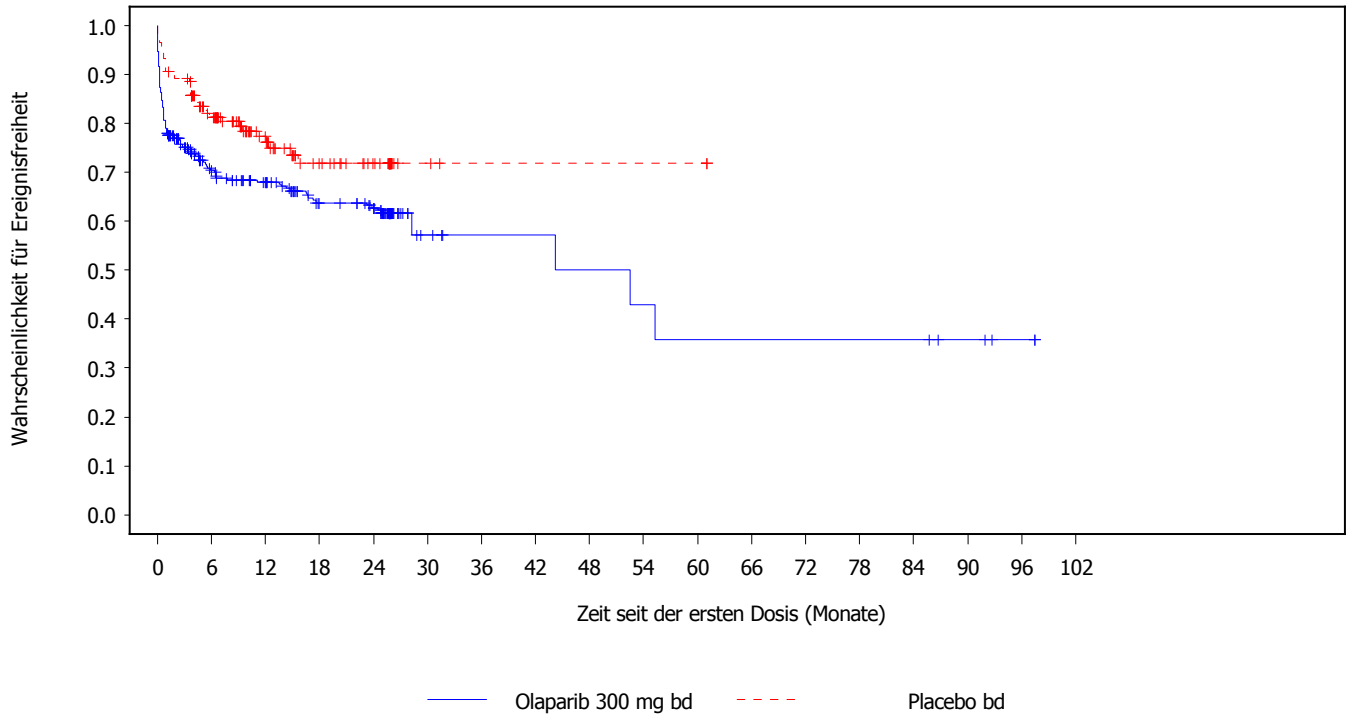
Anzahl an Patienten unter Risiko:

300	246	212	179	161	13	9	8	8	8	7	7	7	7	6	5	3	0	Olaparib 300 mg bd
149	121	81	56	43	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdh 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.87 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



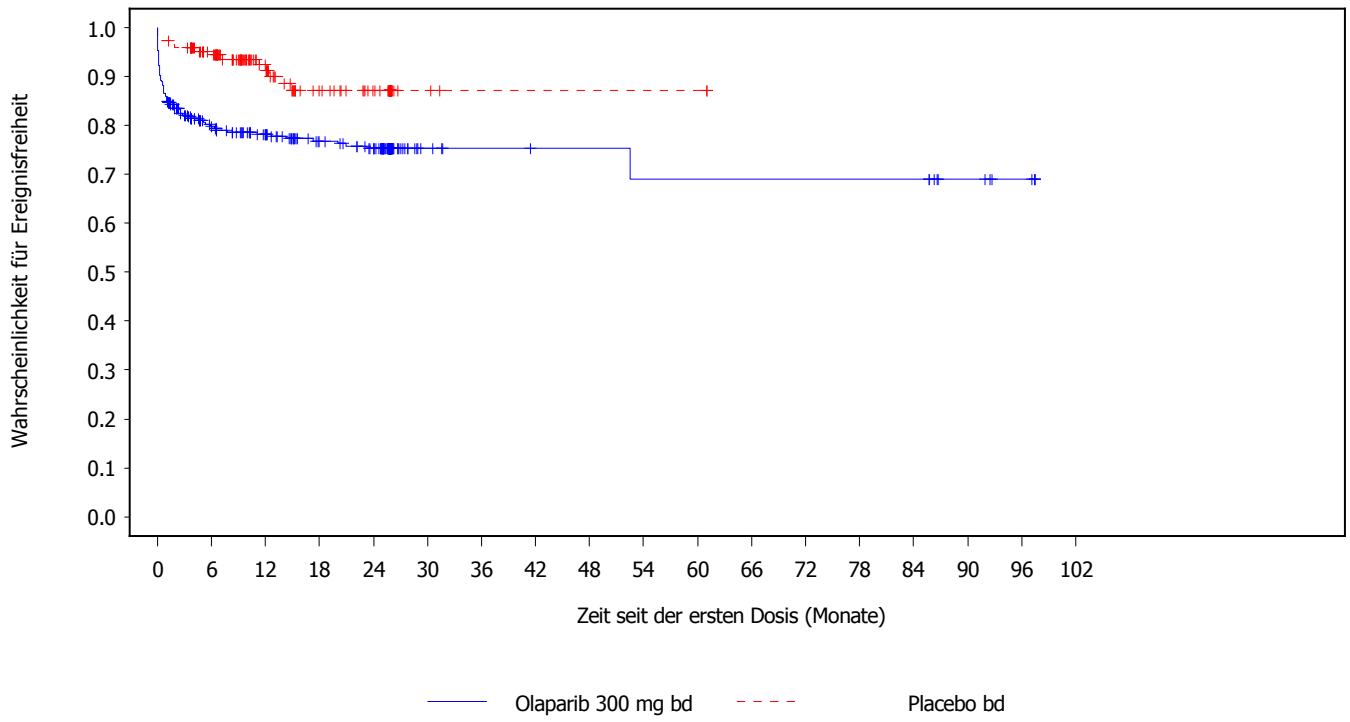
Anzahl an Patienten unter Risiko:

300	179	157	128	119	11	8	8	7	6	5	5	5	5	3	1	0	Olaparib 300 mg bd
149	105	66	41	31	3	1	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdi 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.88 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Appetit vermindert
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



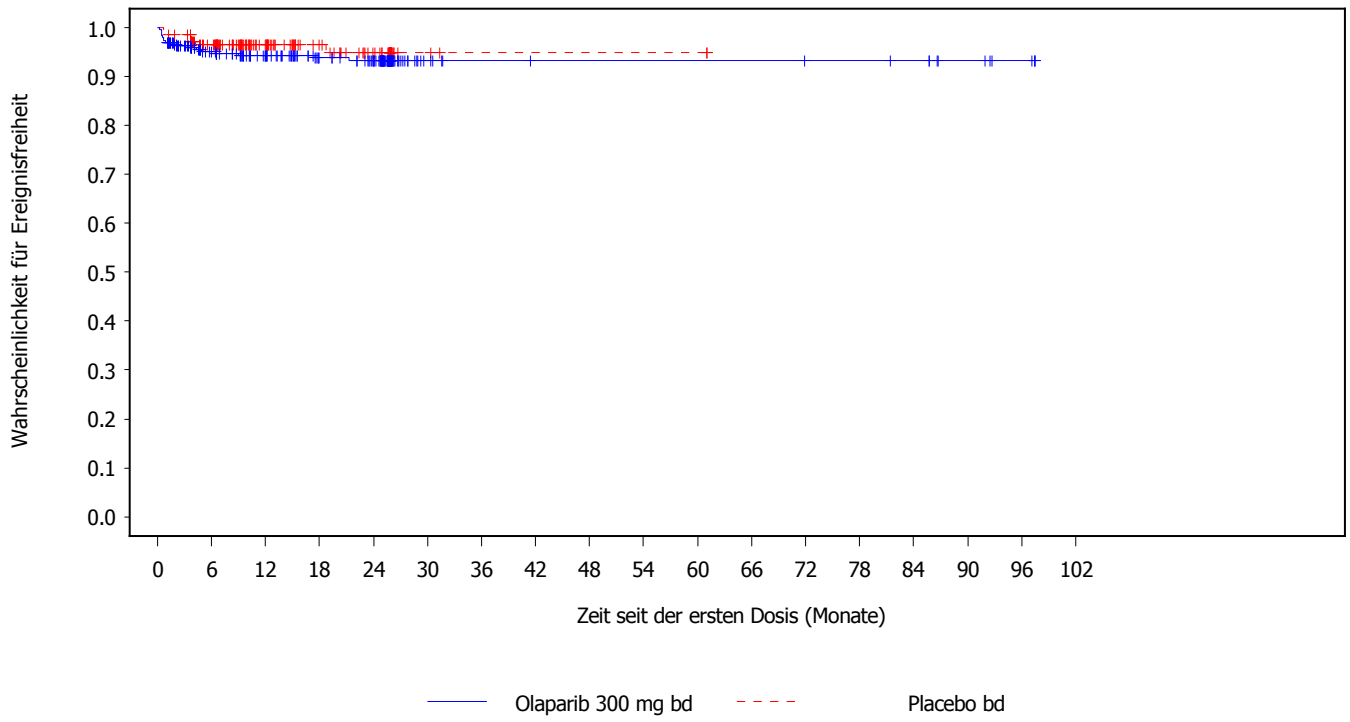
Anzahl an Patienten unter Risiko:

300	204	178	152	140	16	13	12	12	11	11	11	11	11	11	6	3	0	Olaparib 300 mg bd
149	123	79	51	40	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdj 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.89 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hypokaliaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



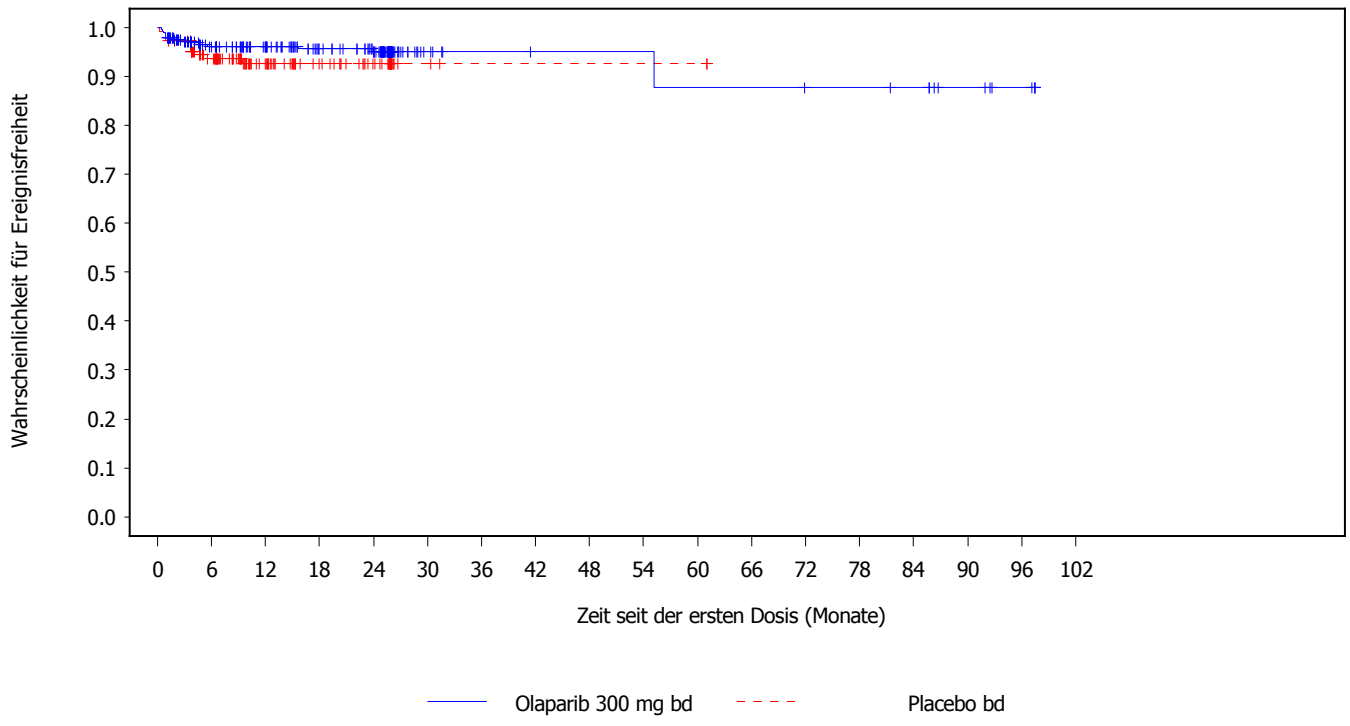
Anzahl an Patienten unter Risiko:

300	246	218	188	175	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	126	85	59	45	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdk 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.90 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Hypomagnesiaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



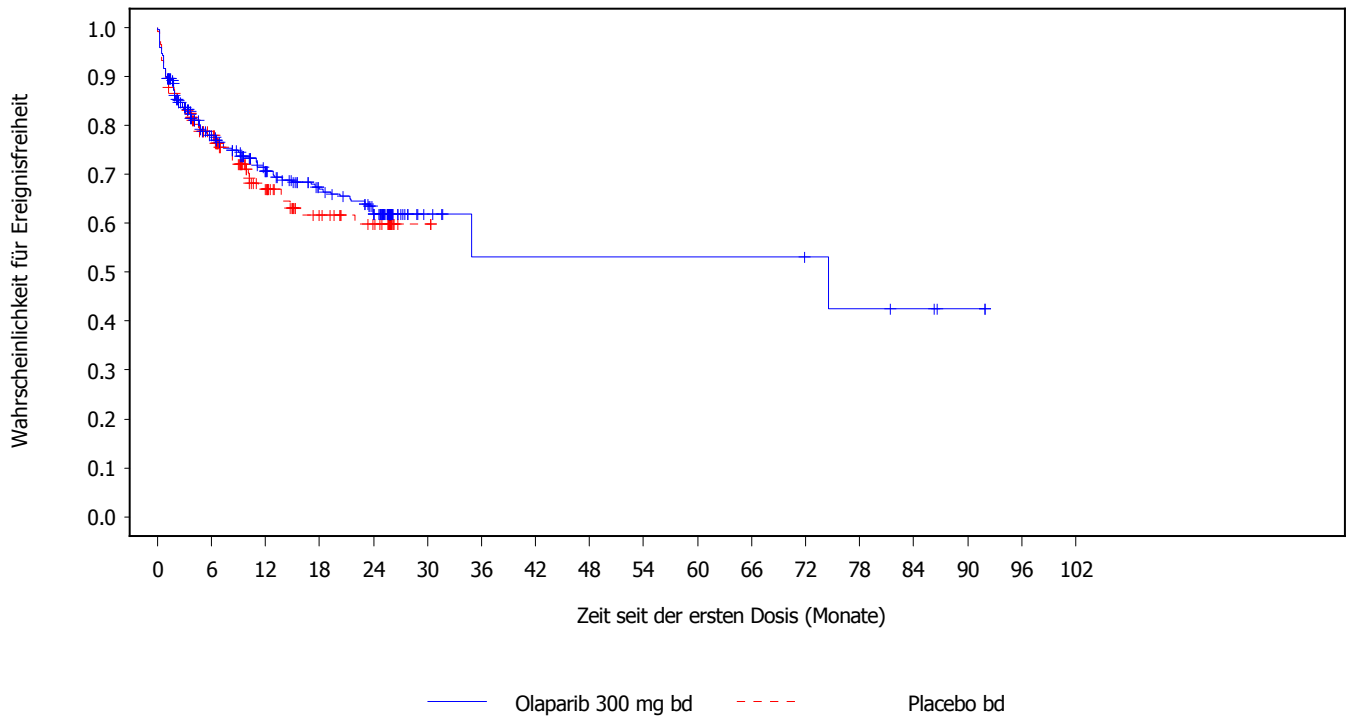
Anzahl an Patienten unter Risiko:

300	251	222	193	177	18	14	13	13	13	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	122	81	58	45	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdl 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.91 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Untersuchungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



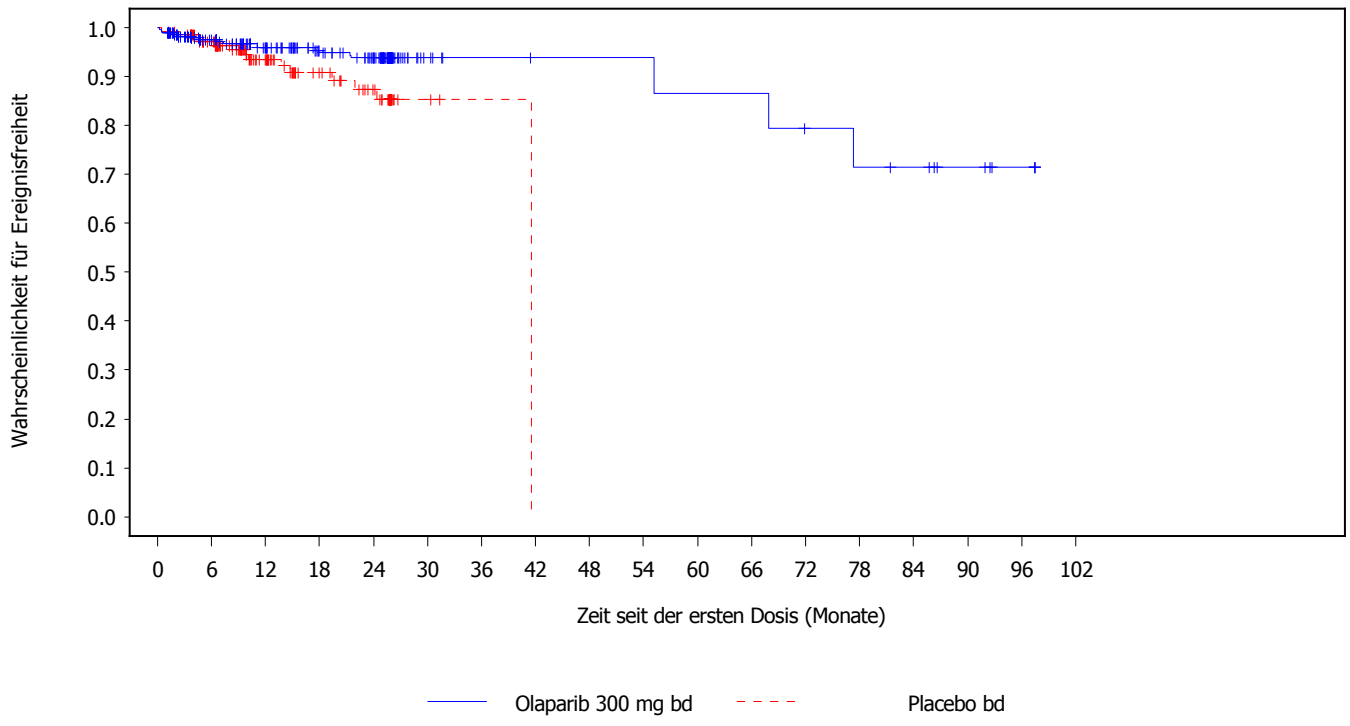
Anzahl an Patienten unter Risiko:

300	203	162	136	117	10	6	6	6	6	6	6	5	4	3	1	0	0	Olaparib 300 mg bd
149	102	61	39	30	1	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdm 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.92 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



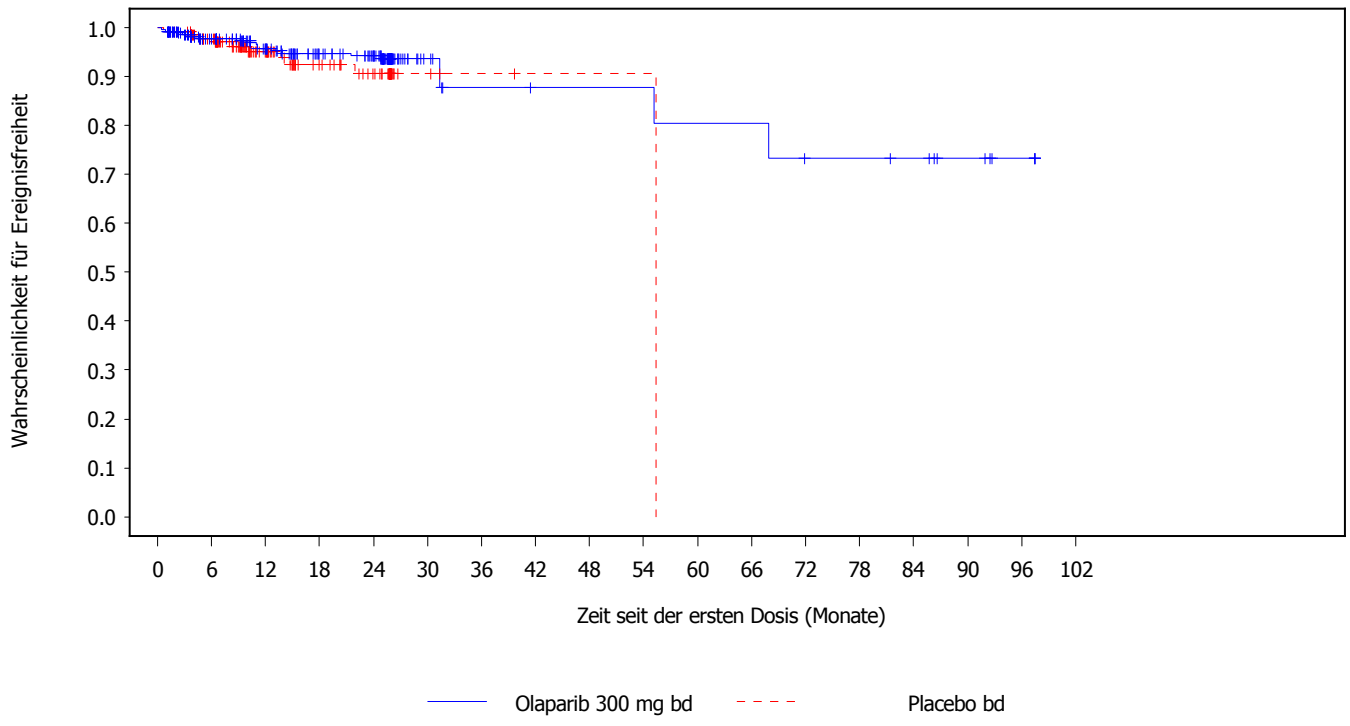
Anzahl an Patienten unter Risiko:

300	253	219	189	171	18	14	13	13	13	12	12	10	9	8	5	2	0	Olaparib 300 mg bd
149	128	83	57	44	3	1	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdn 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.93 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Aspartataminotransferase erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



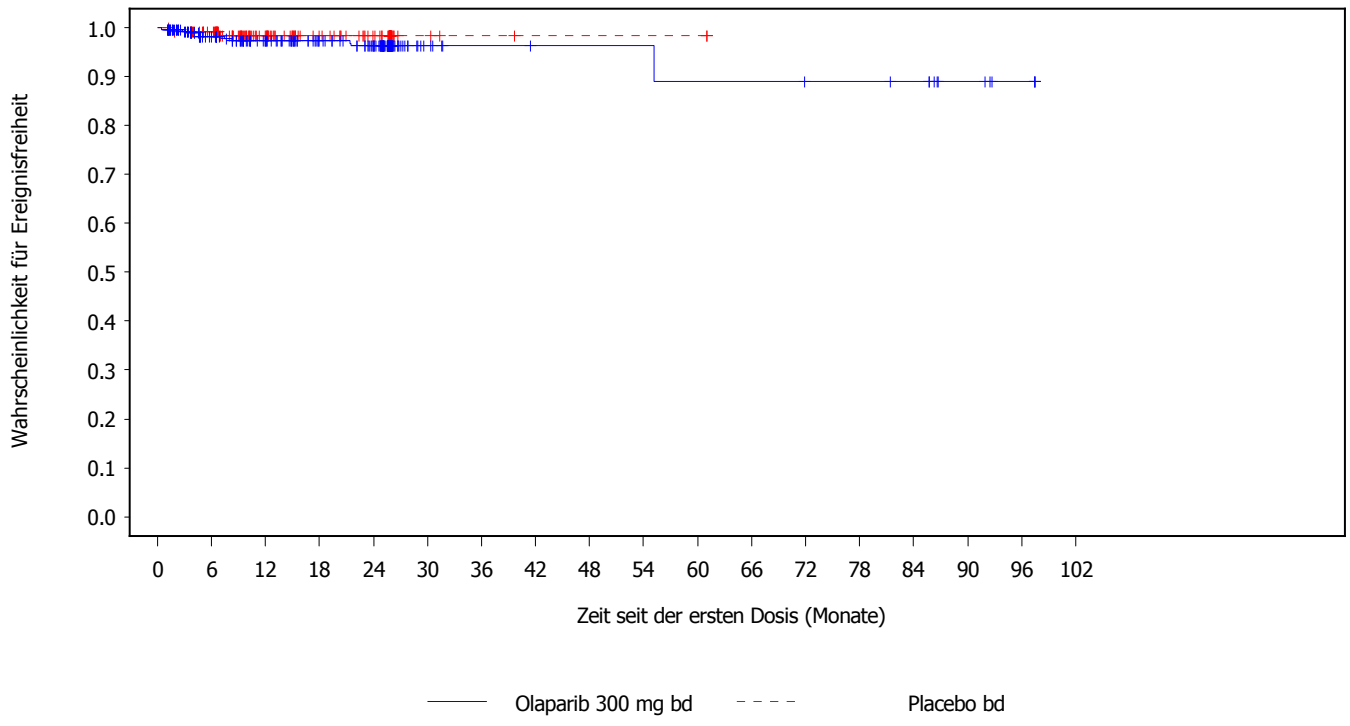
Anzahl an Patienten unter Risiko:

300	255	220	189	173	18	13	12	12	12	11	11	9	9	8	5	2	0	Olaparib 300 mg bd
149	128	82	56	45	4	2	1	1	1	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdo 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.94 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Gamma-Glutamyltransferase erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



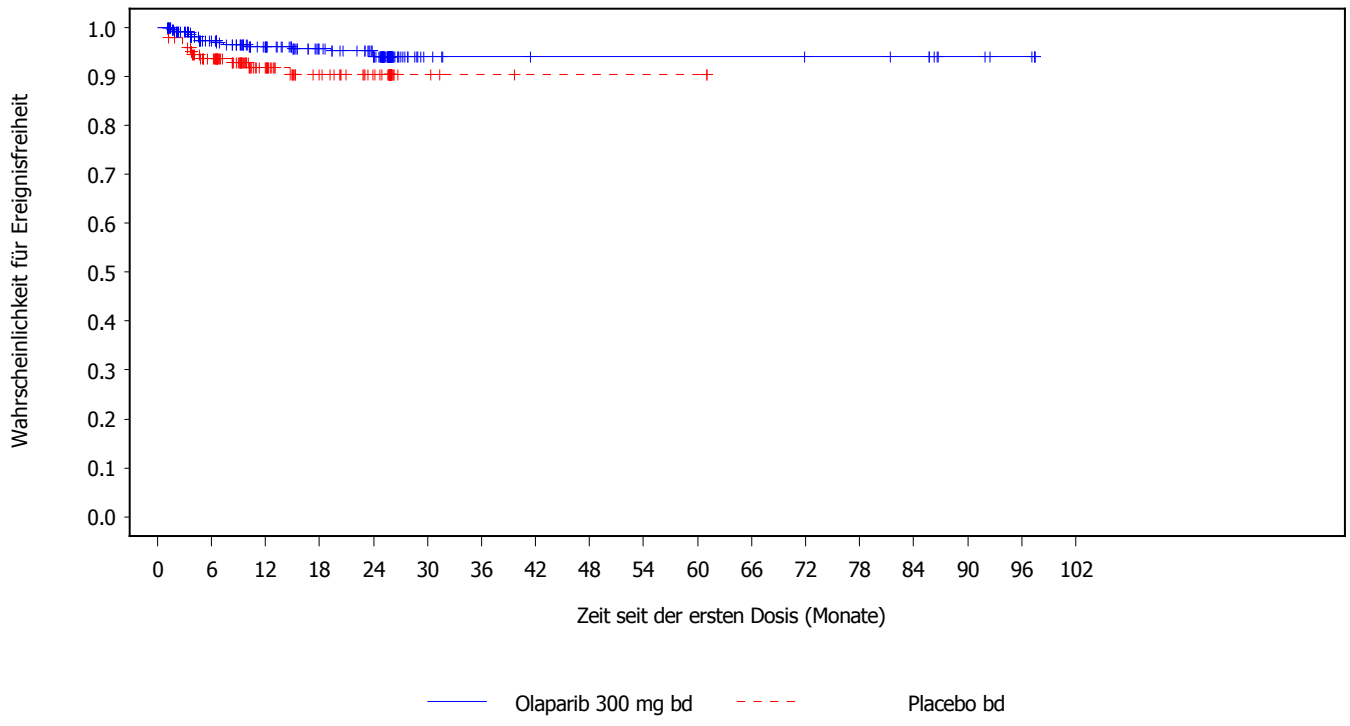
Anzahl an Patienten unter Risiko:

300	255	223	195	177	18	14	13	13	13	12	12	11	11	10	5	2	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdp 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.95 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Gewicht erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



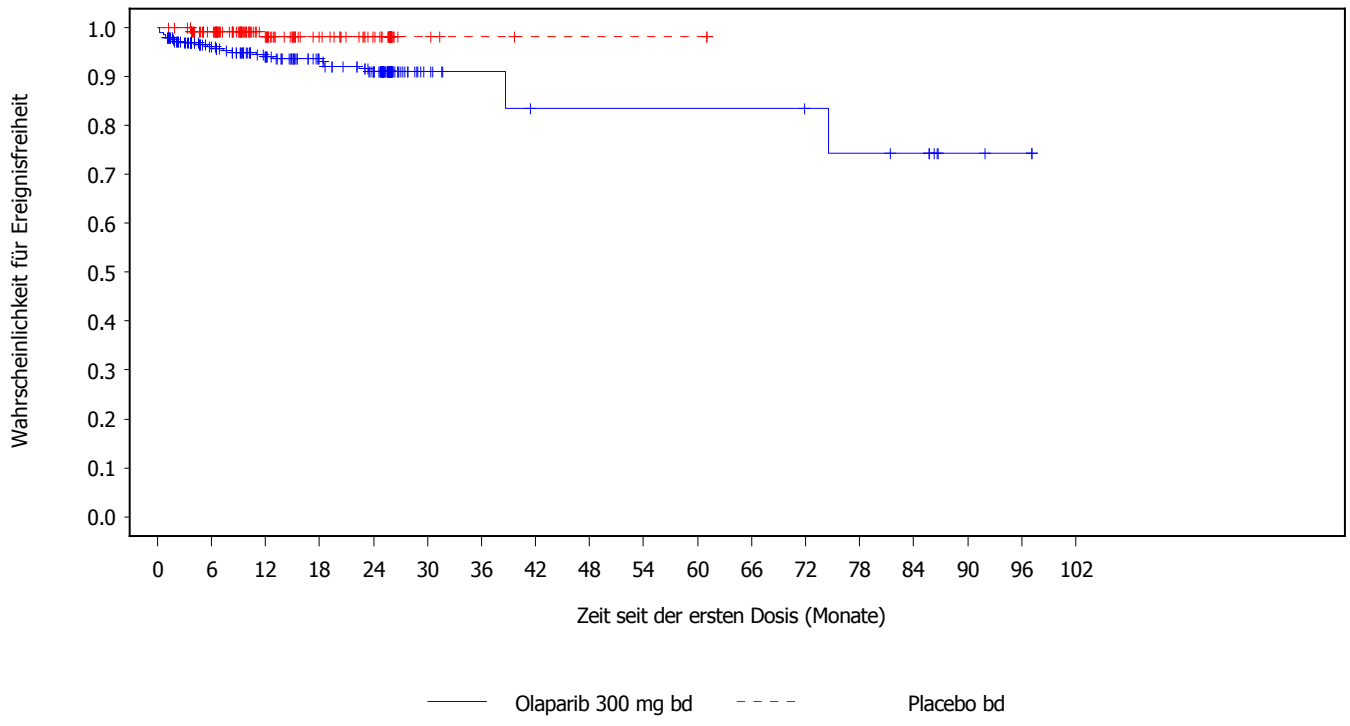
Anzahl an Patienten unter Risiko:

300	253	220	194	176	16	13	12	12	12	12	12	11	11	10	5	3	0	Olaparib 300 mg bd
149	121	78	55	43	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdq 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.96 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Kreatinin im Blut erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



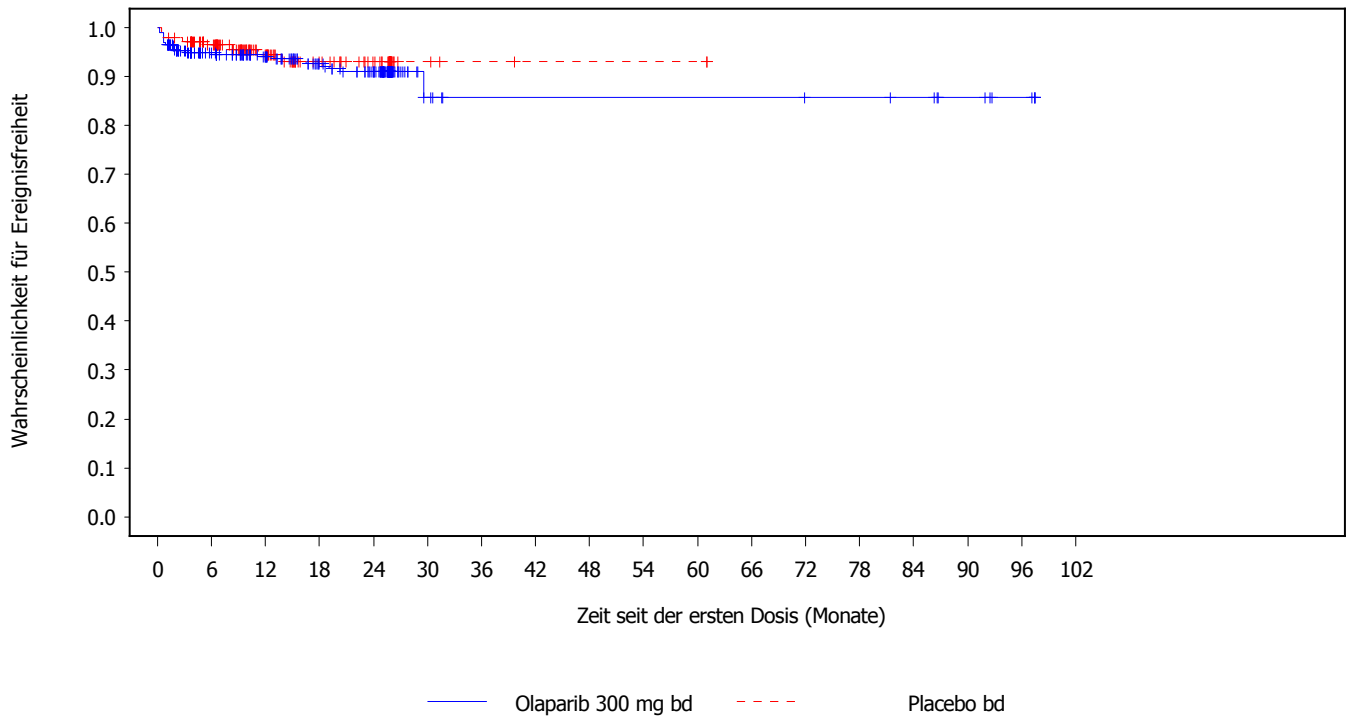
Anzahl an Patienten unter Risiko:

300	250	217	189	170	16	12	10	10	10	10	10	9	8	7	2	1	0	Olaparib 300 mg bd
149	129	85	59	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdr 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.97 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Leukozytenzahl erniedrigt
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



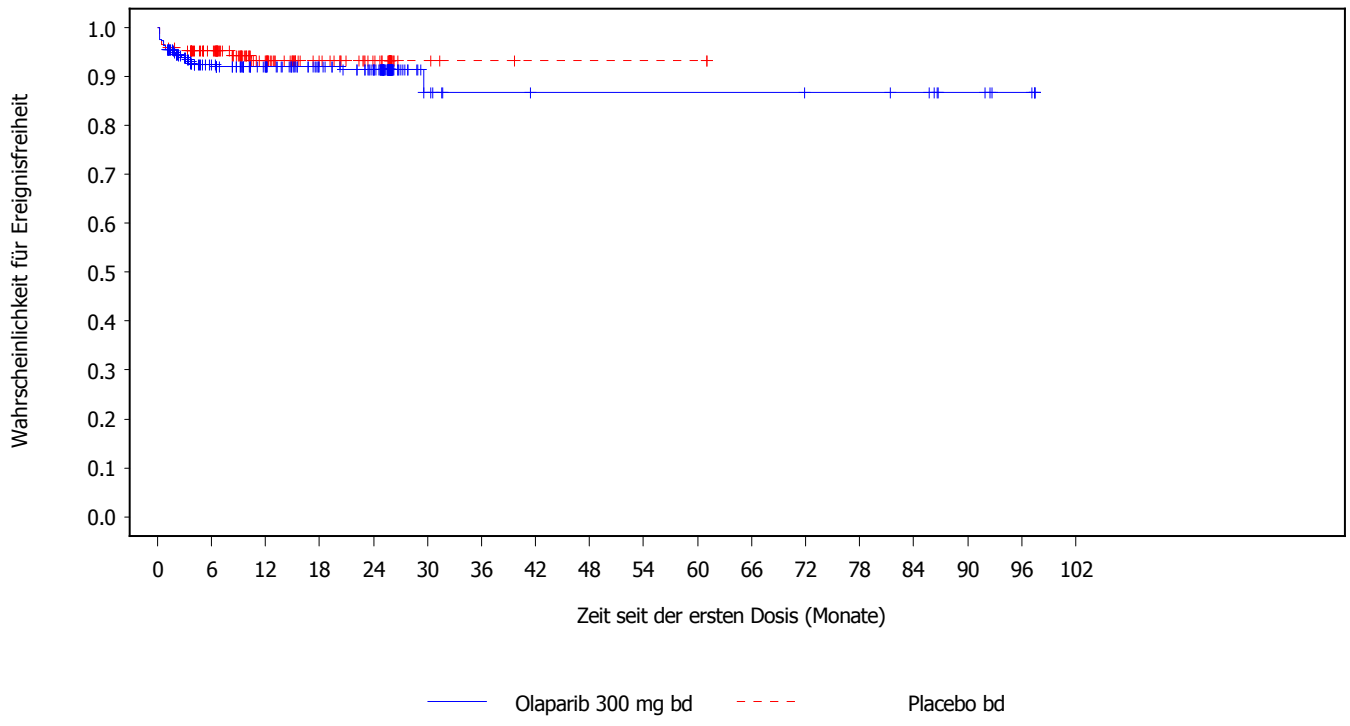
Anzahl an Patienten unter Risiko:

300	246	215	186	168	15	11	11	11	11	11	11	10	10	9	6	3	0	Olaparib 300 mg bd
149	126	83	56	44	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebds 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.98 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Neutrophilenzahl erniedrigt
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



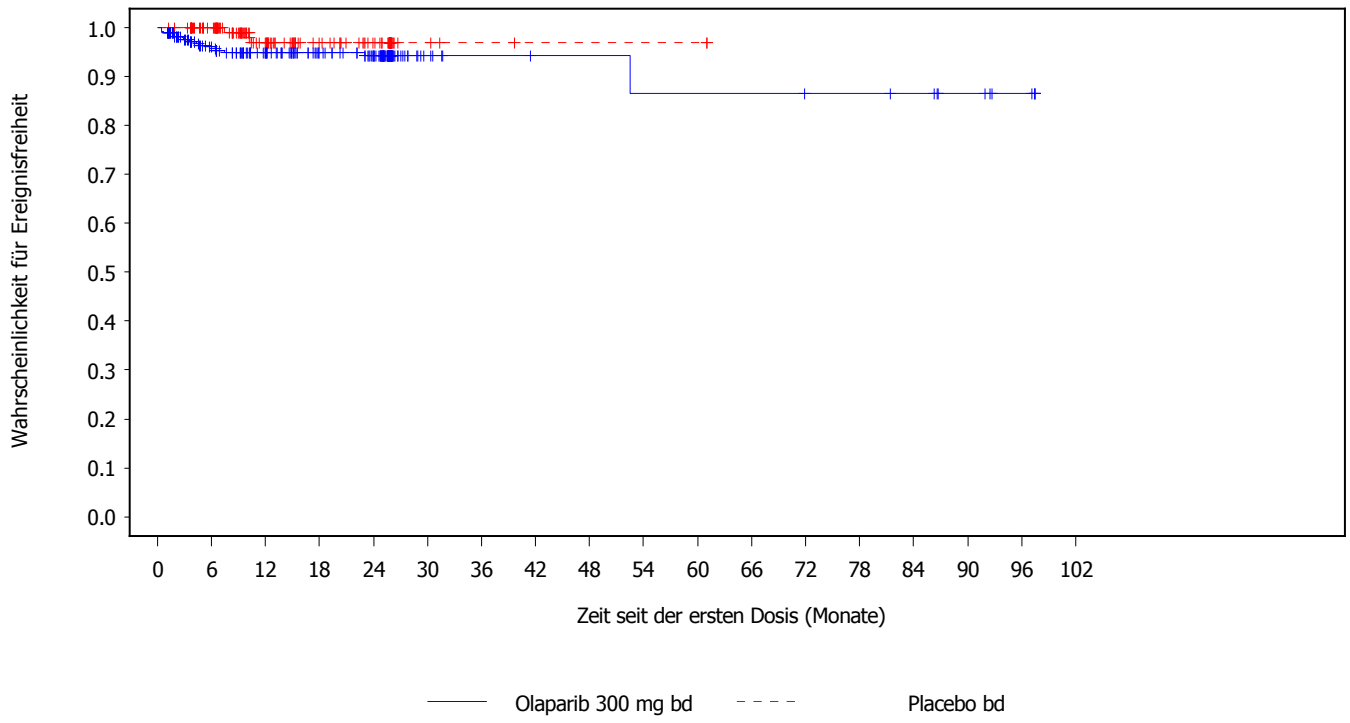
Anzahl an Patienten unter Risiko:

300	241	215	190	174	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	124	82	56	43	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdt 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.99 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Thrombozytenzahl vermindert
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



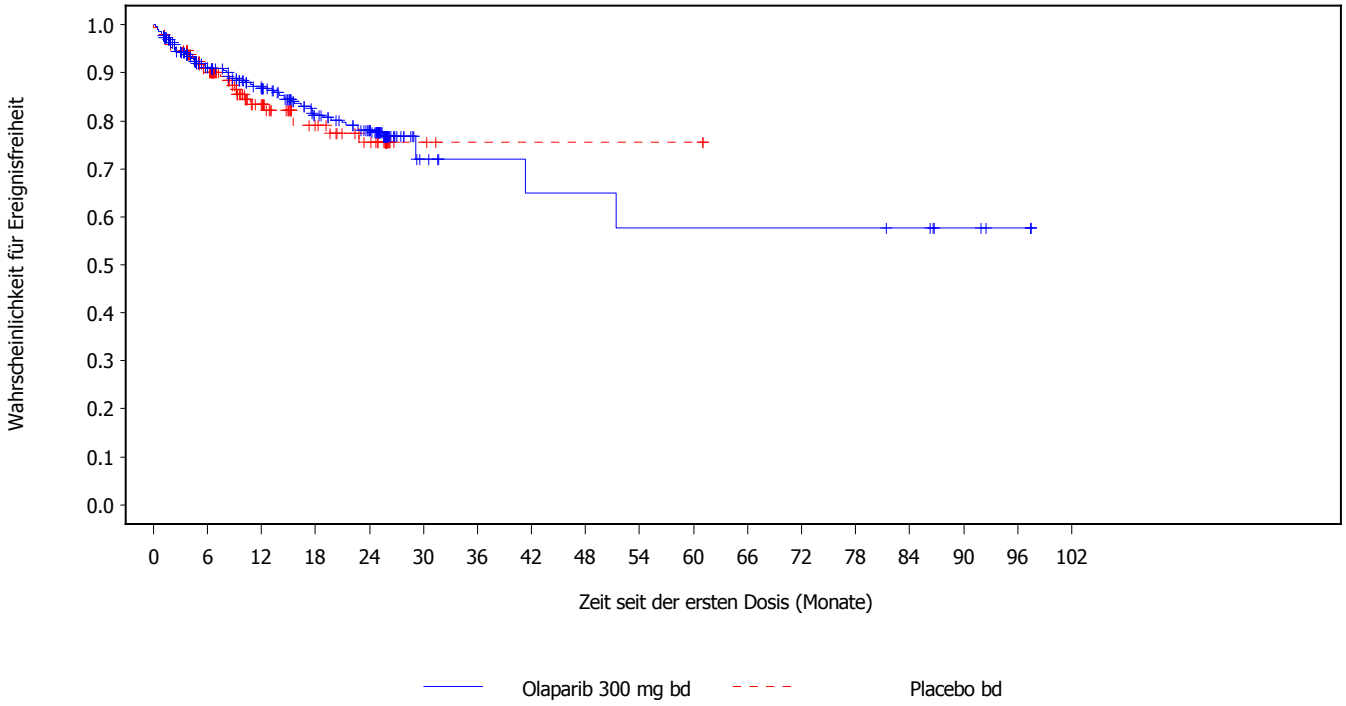
Anzahl an Patienten unter Risiko:

300	252	220	192	175	17	13	12	12	11	11	11	10	10	9	6	3	0	Olaparib 300 mg bd
149	130	86	60	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdu 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.100 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



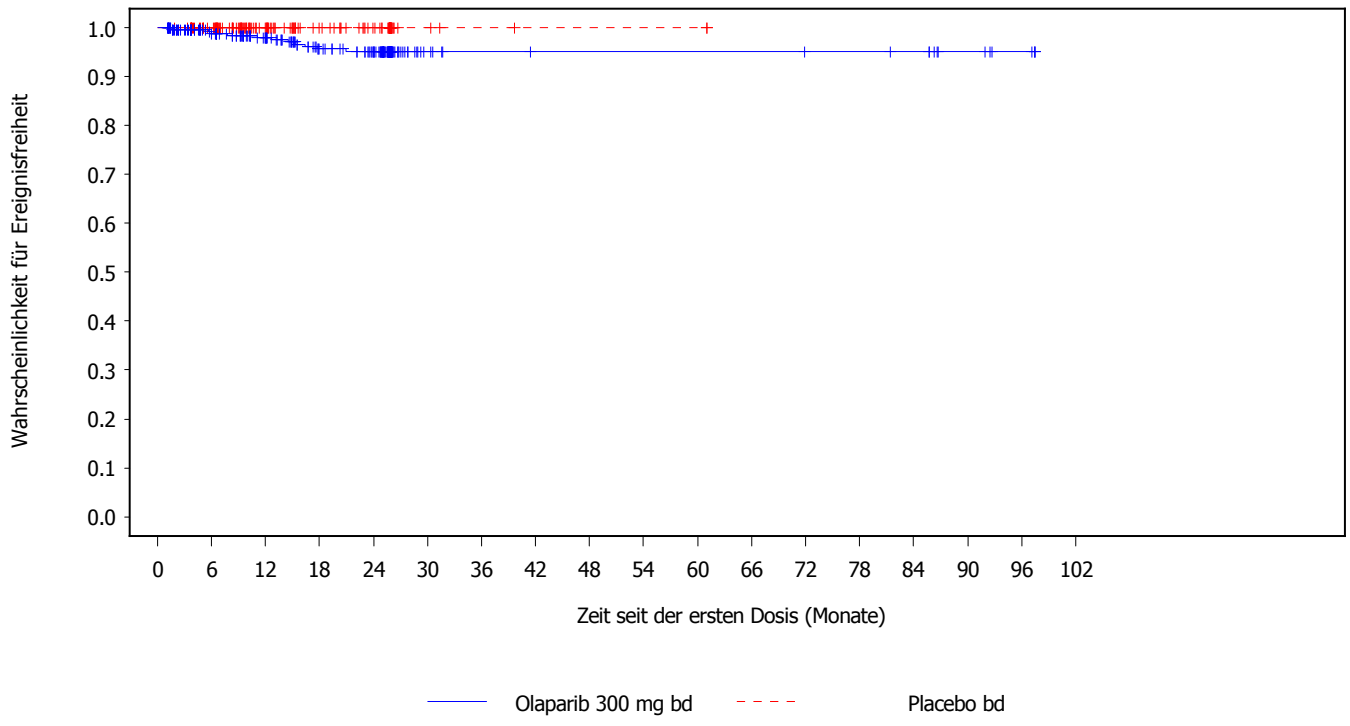
Anzahl an Patienten unter Risiko:

300	239	204	165	146	13	10	9	9	8	8	8	8	8	7	4	2	0	Olaparib 300 mg bd
149	116	72	50	39	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdv 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.101 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Baenderzerrung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



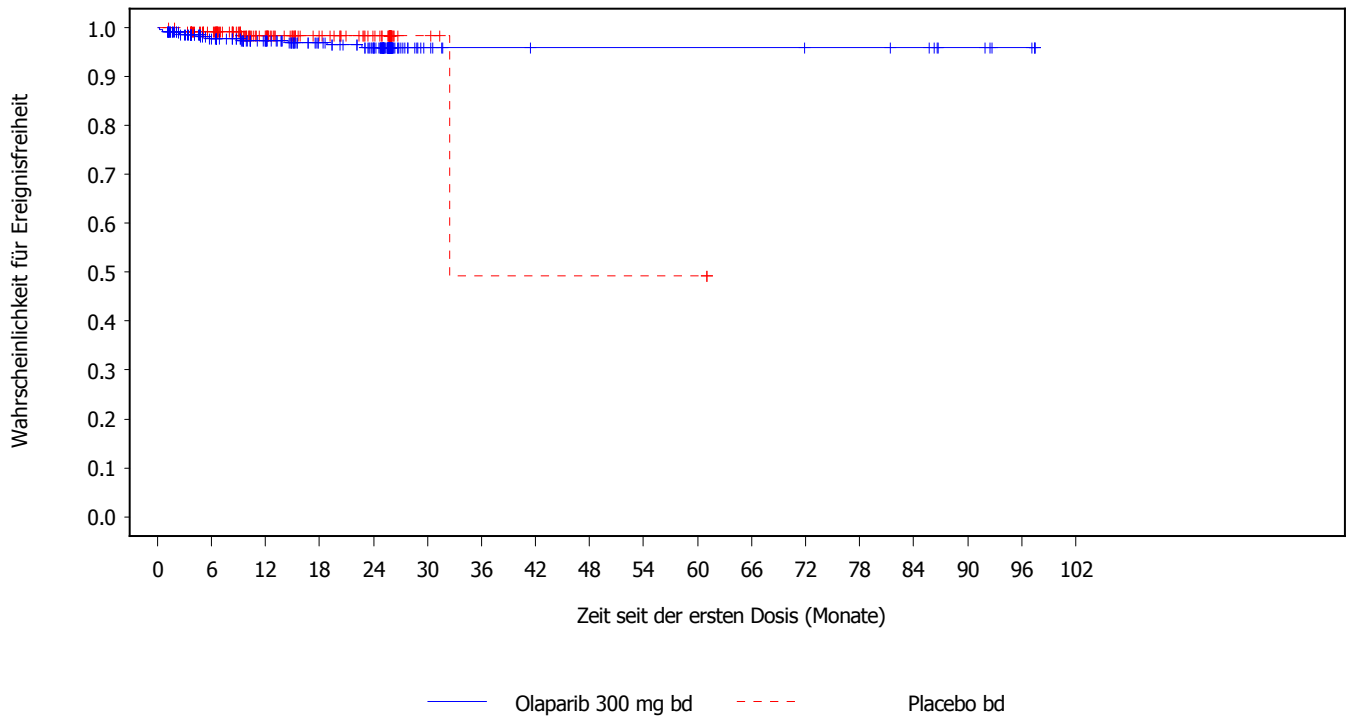
Anzahl an Patienten unter Risiko:

300	257	225	191	174	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdw 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.102 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerzen waehrend eines Eingriffes
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



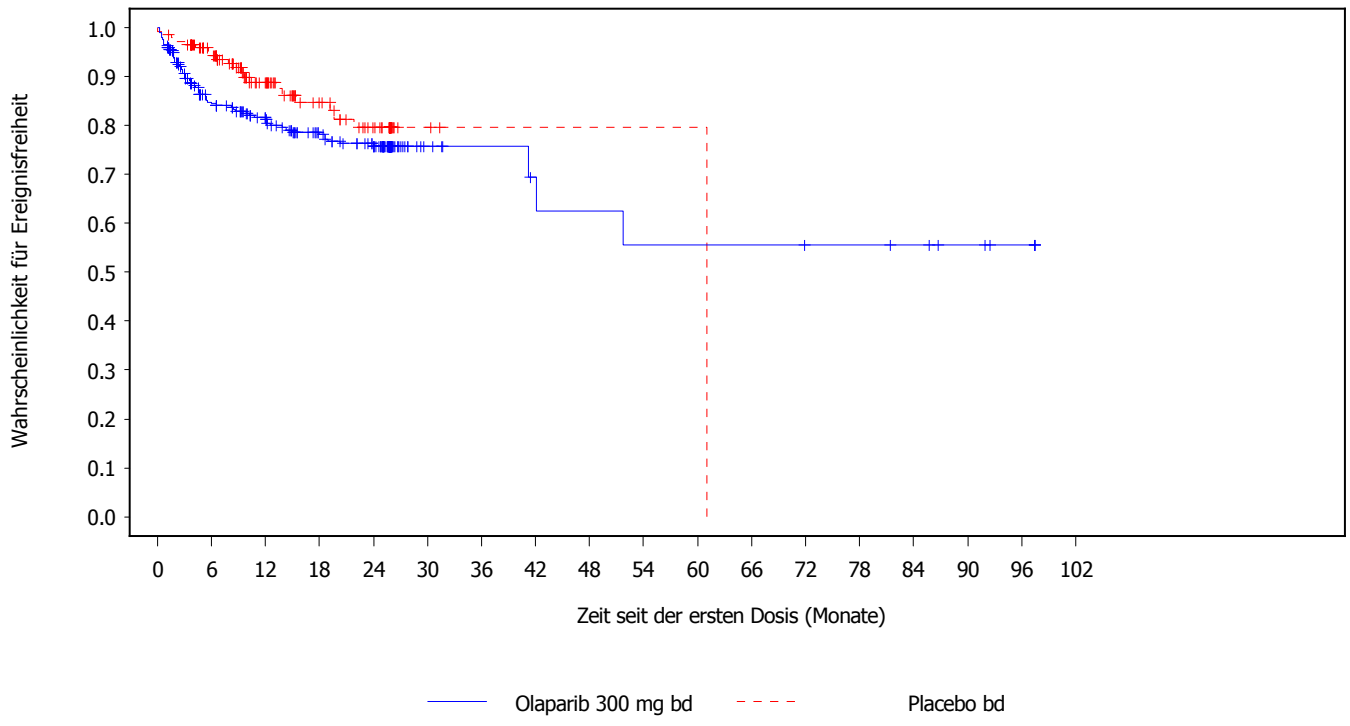
Anzahl an Patienten unter Risiko:

300	255	225	196	179	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	129	86	61	48	4	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdx 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.103 SOLO1: Kaplan-Meier plot of time to first occurrence of SUE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



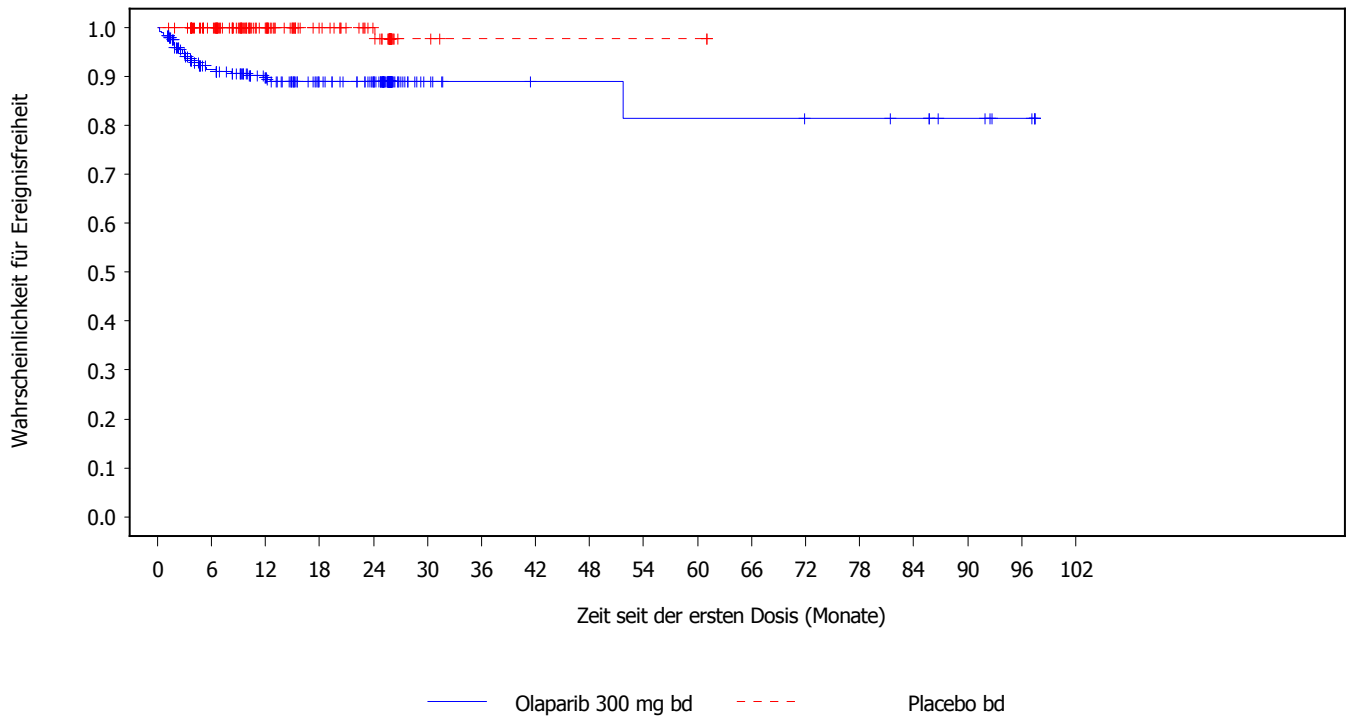
Anzahl an Patienten unter Risiko:

300	223	196	165	149	15	12	10	9	8	8	8	7	7	6	4	2	0	Olaparib 300 mg bd
149	123	80	53	39	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdy 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.104 SOLO1: Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



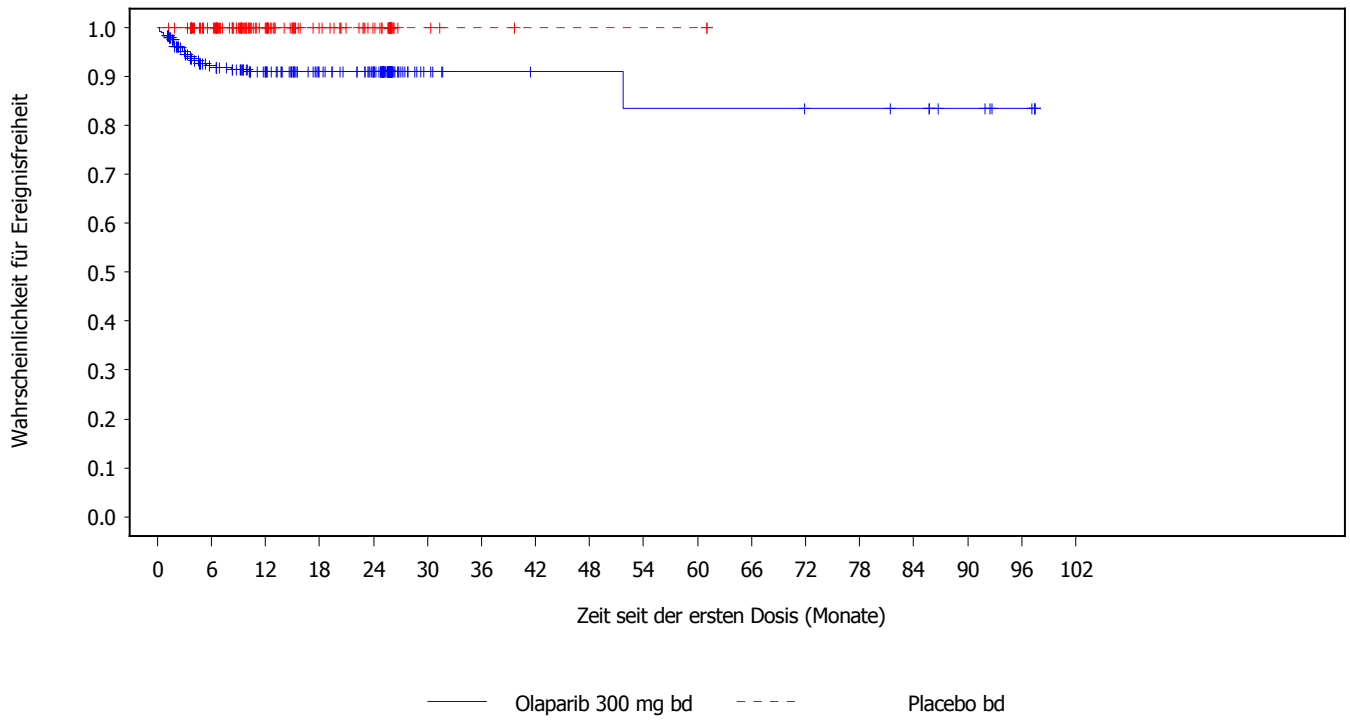
Anzahl an Patienten unter Risiko:

300	239	210	182	167	17	13	12	12	11	11	11	10	10	9	6	3	0	Olaparib 300 mg bd
149	130	87	61	48	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebdz 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.105 SOLO1: Kaplan-Meier plot of time to first occurrence of SUE PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



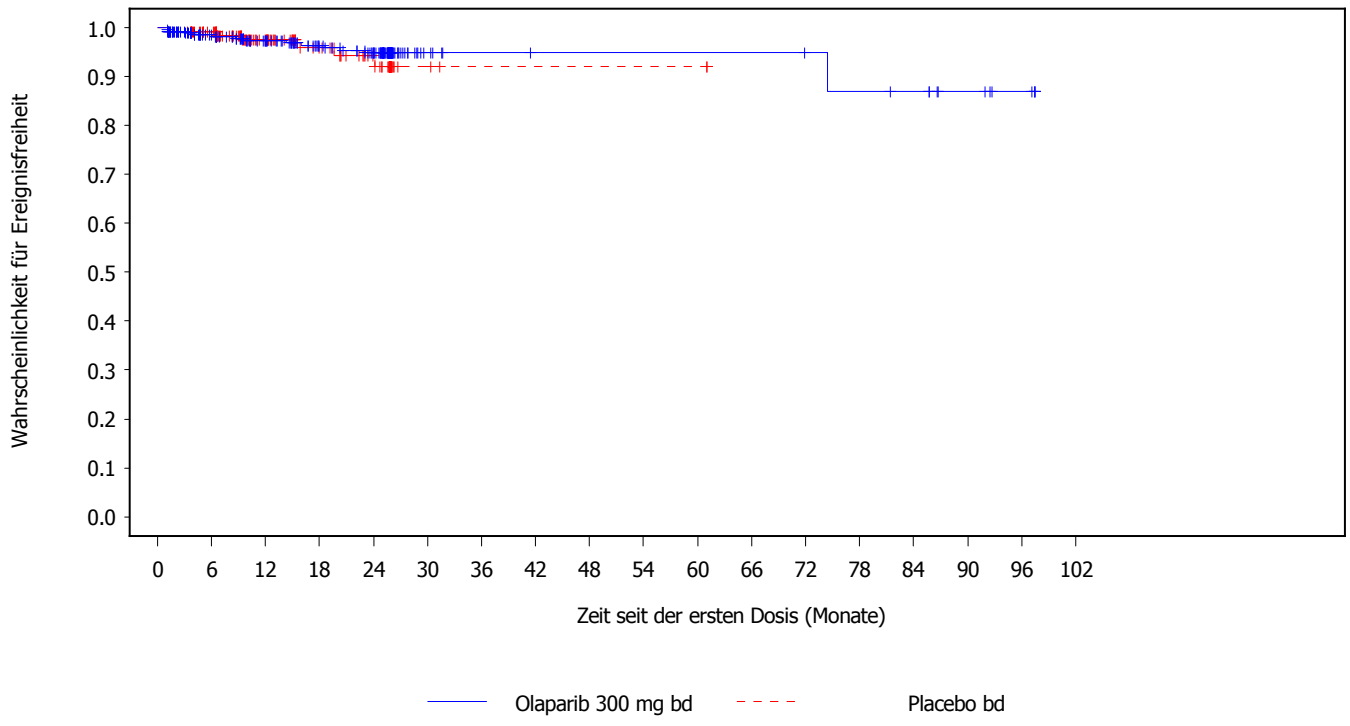
Anzahl an Patienten unter Risiko:

300	240	212	185	169	17	13	12	12	11	11	11	10	10	9	6	3	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebea 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.106 SOLO1: Kaplan-Meier plot of time to first occurrence of SUE SOC: Infektionen und parasitaere Erkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



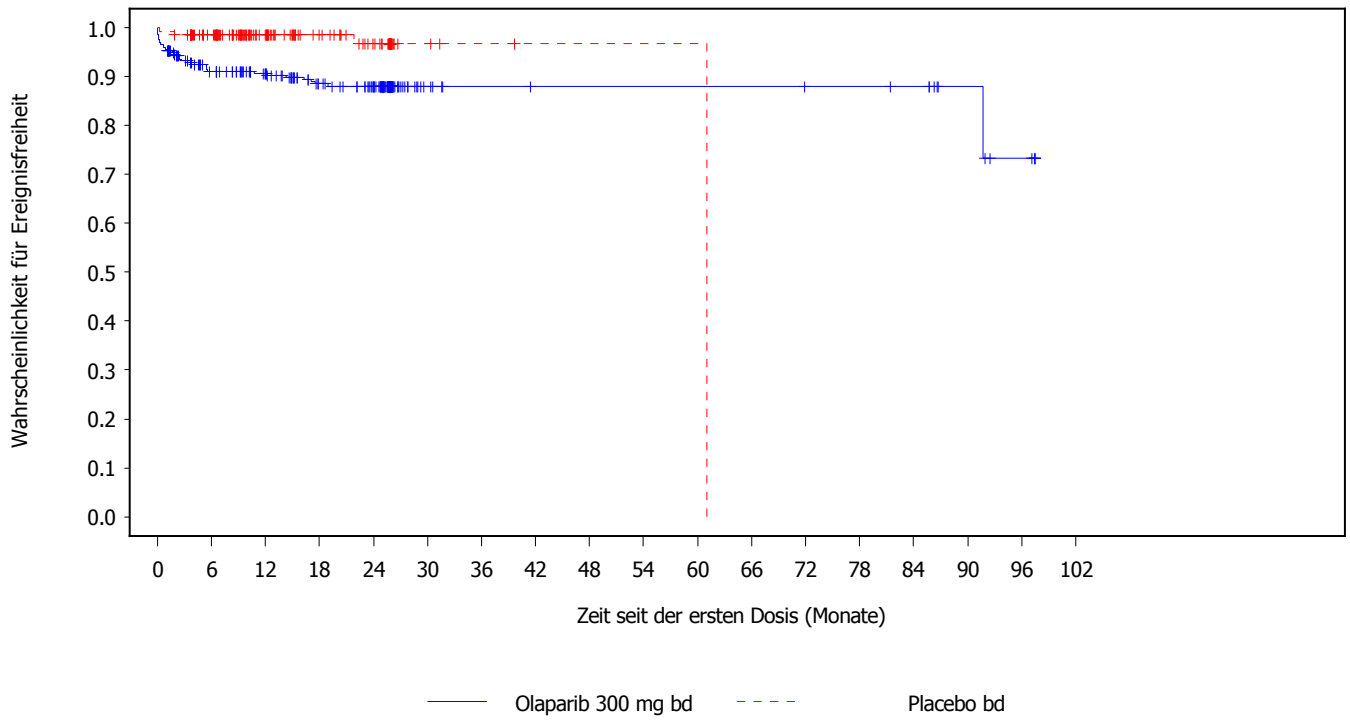
Anzahl an Patienten unter Risiko:

300	256	224	195	177	18	14	13	13	13	13	13	12	11	10	6	3	0	Olaparib 300 mg bd
149	130	85	59	45	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebeb 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.107 SOLO1: Kaplan-Meier plot of time to first occurrence of Abbruch wegen UE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



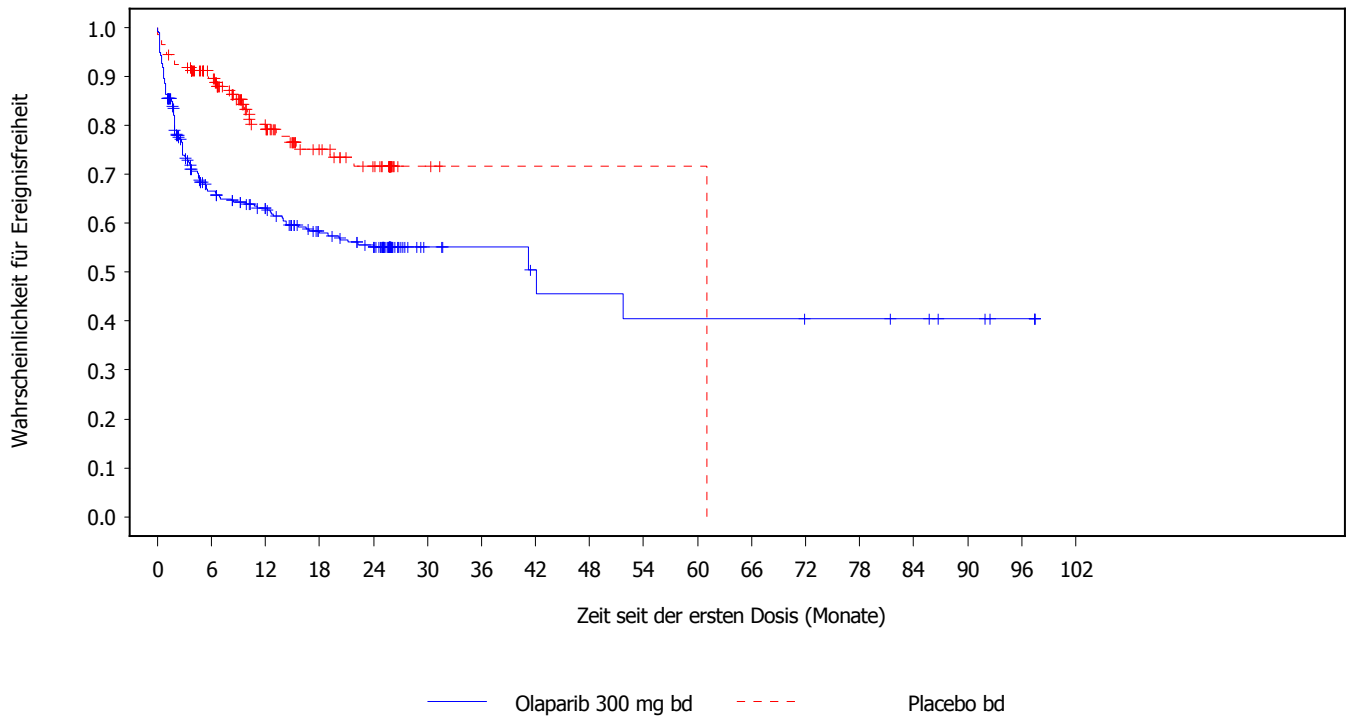
Anzahl an Patienten unter Risiko:

300	250	227	199	184	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	130	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebec 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.108 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



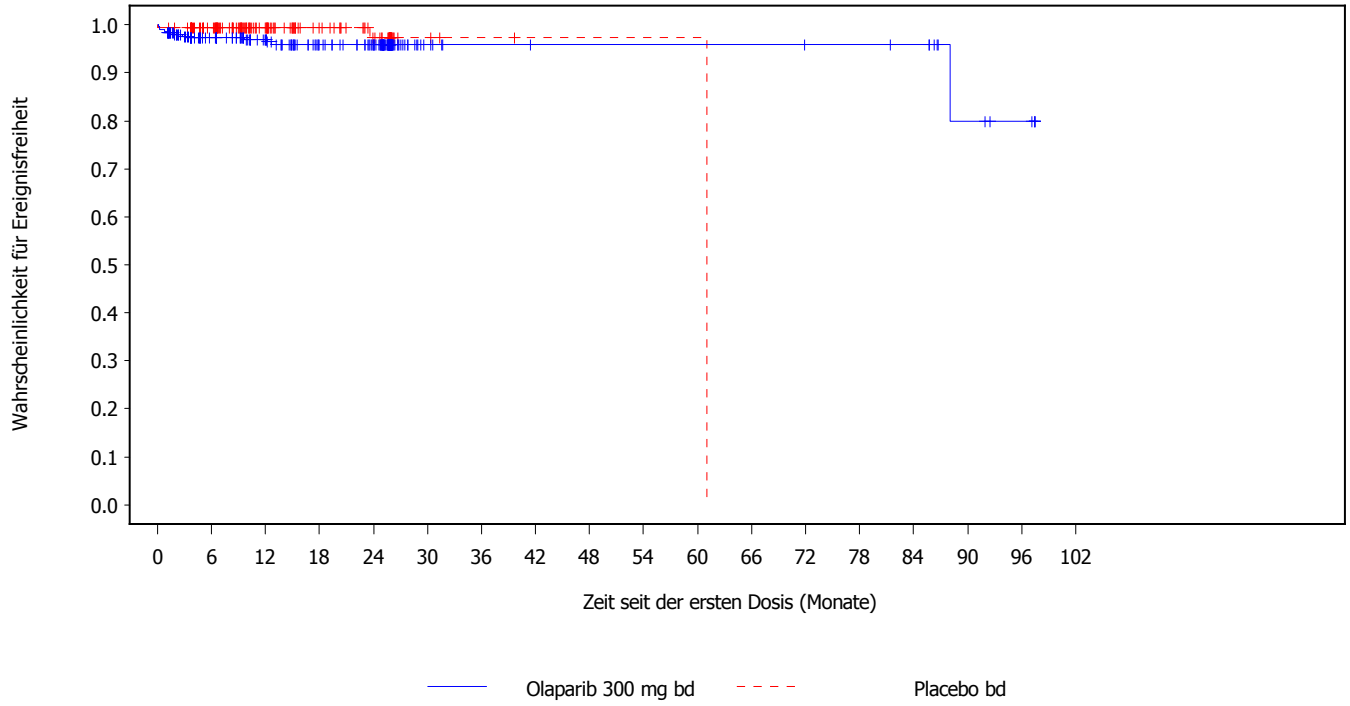
Anzahl an Patienten unter Risiko:

300	175	154	127	117	14	12	10	9	8	8	8	7	7	6	4	2	0	Olaparib 300 mg bd
149	116	73	48	38	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebed 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.109 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



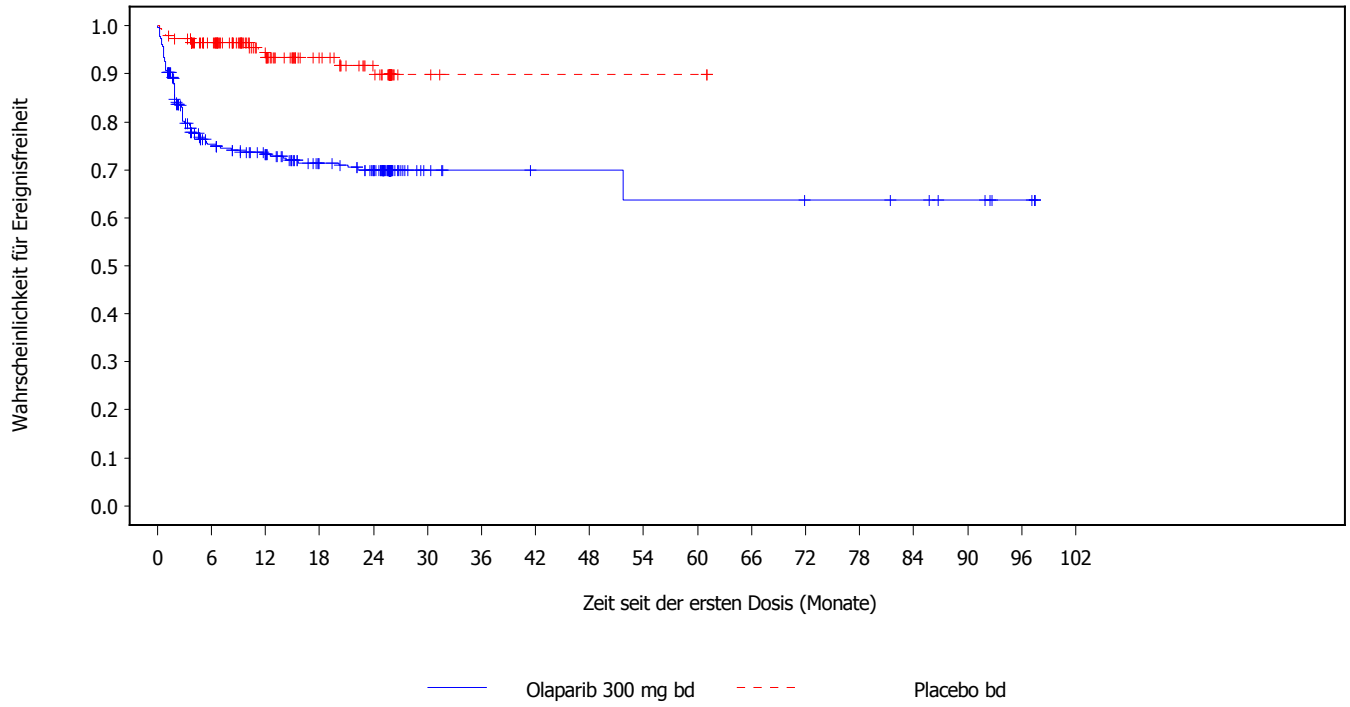
Anzahl an Patienten unter Risiko:

300	254	225	196	180	18	14	13	13	13	13	13	12	12	11	5	3	0	Olaparib 300 mg bd
149	129	86	60	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebee 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.110 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



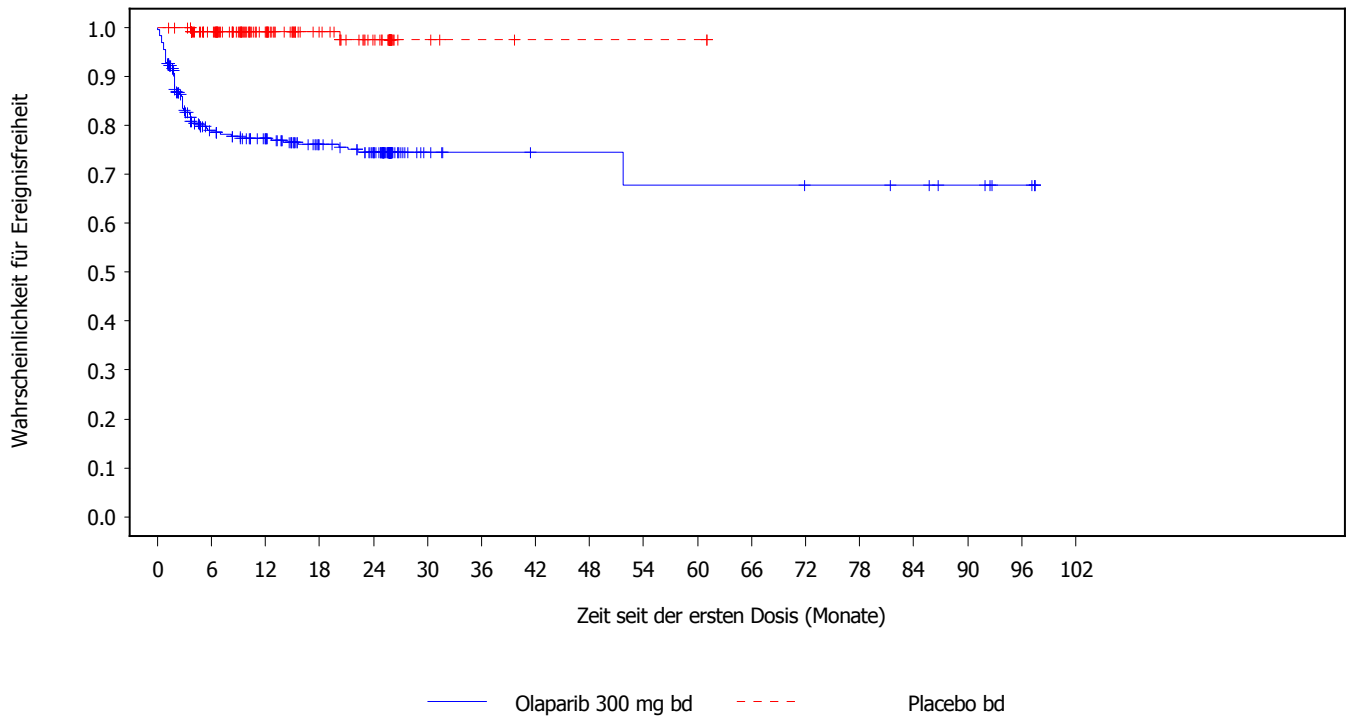
Anzahl an Patienten unter Risiko:

300	195	175	149	136	15	12	11	11	10	10	10	9	9	8	6	3	0	Olaparib 300 mg bd
149	125	85	60	47	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebef 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.111 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



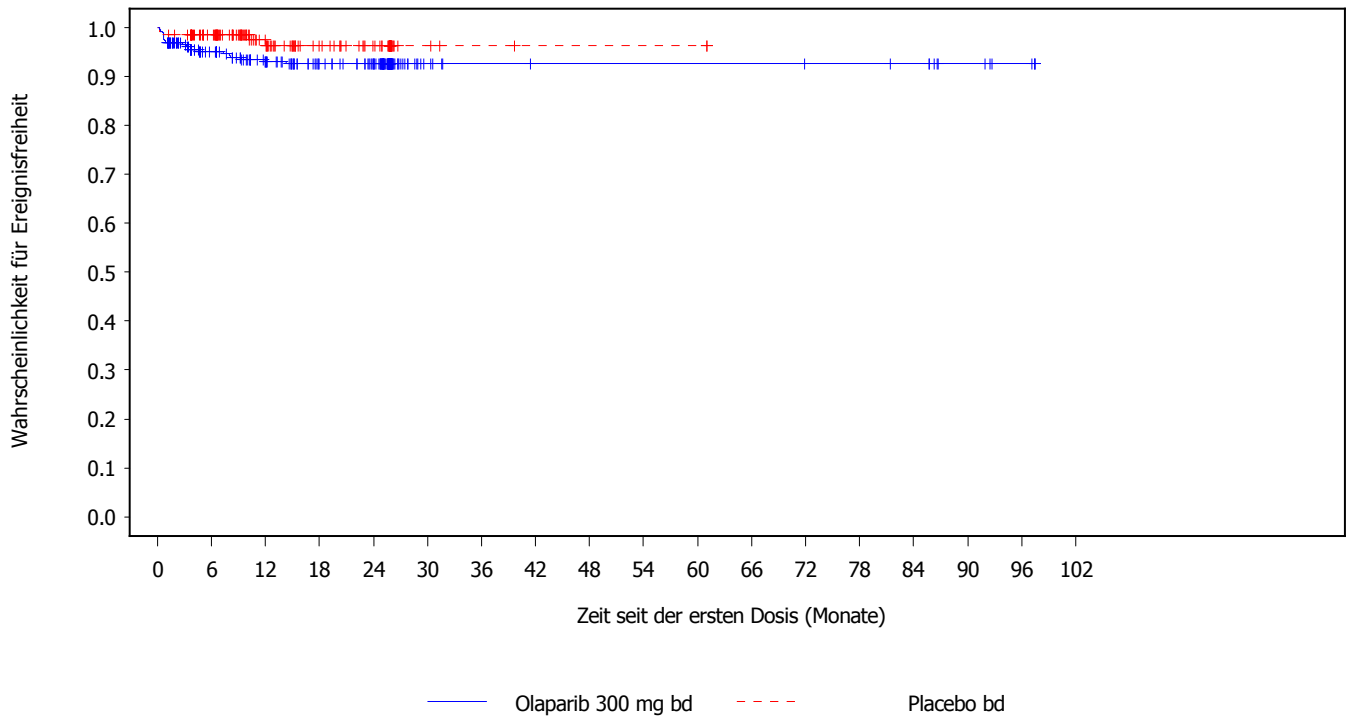
Anzahl an Patienten unter Risiko:

300	204	183	155	140	15	12	11	11	10	10	10	9	9	8	6	3	0	Olaparib 300 mg bd
149	129	87	61	47	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebeg 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.112 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Neutropenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



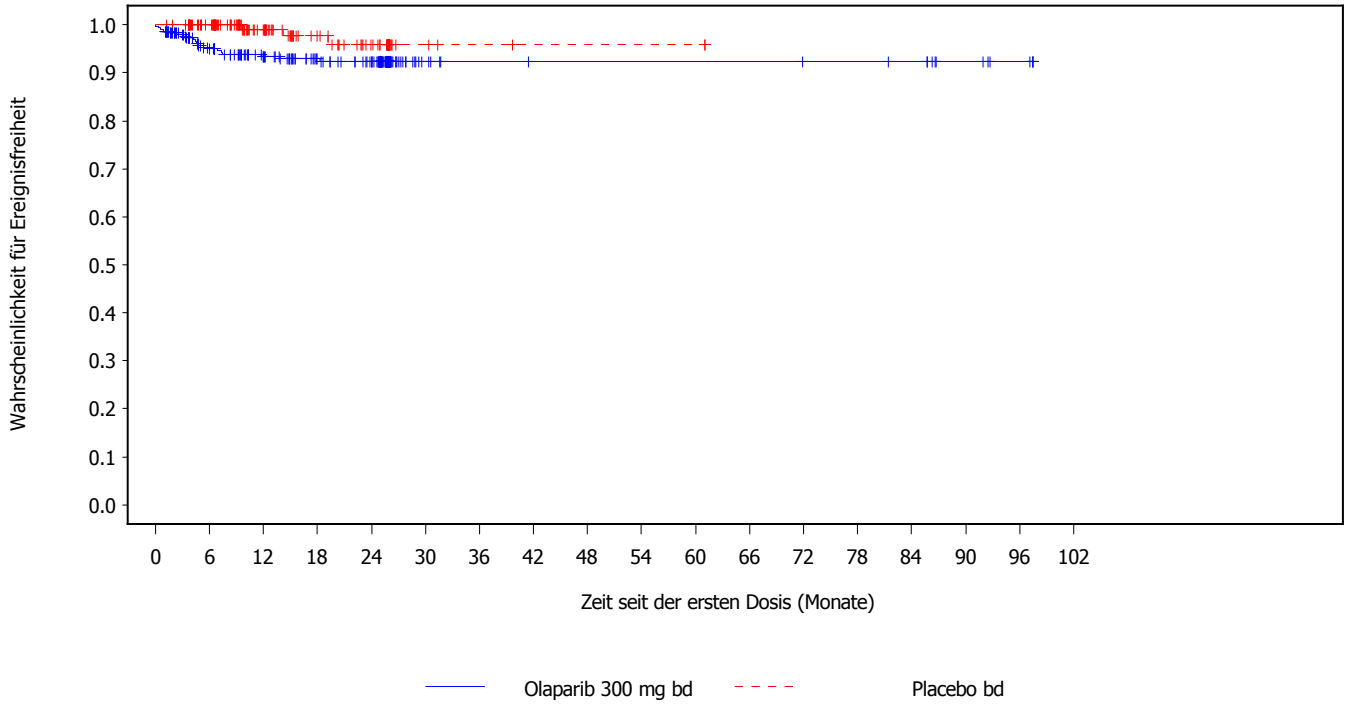
Anzahl an Patienten unter Risiko:

300	247	217	190	175	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	128	85	60	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebeh 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.113 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



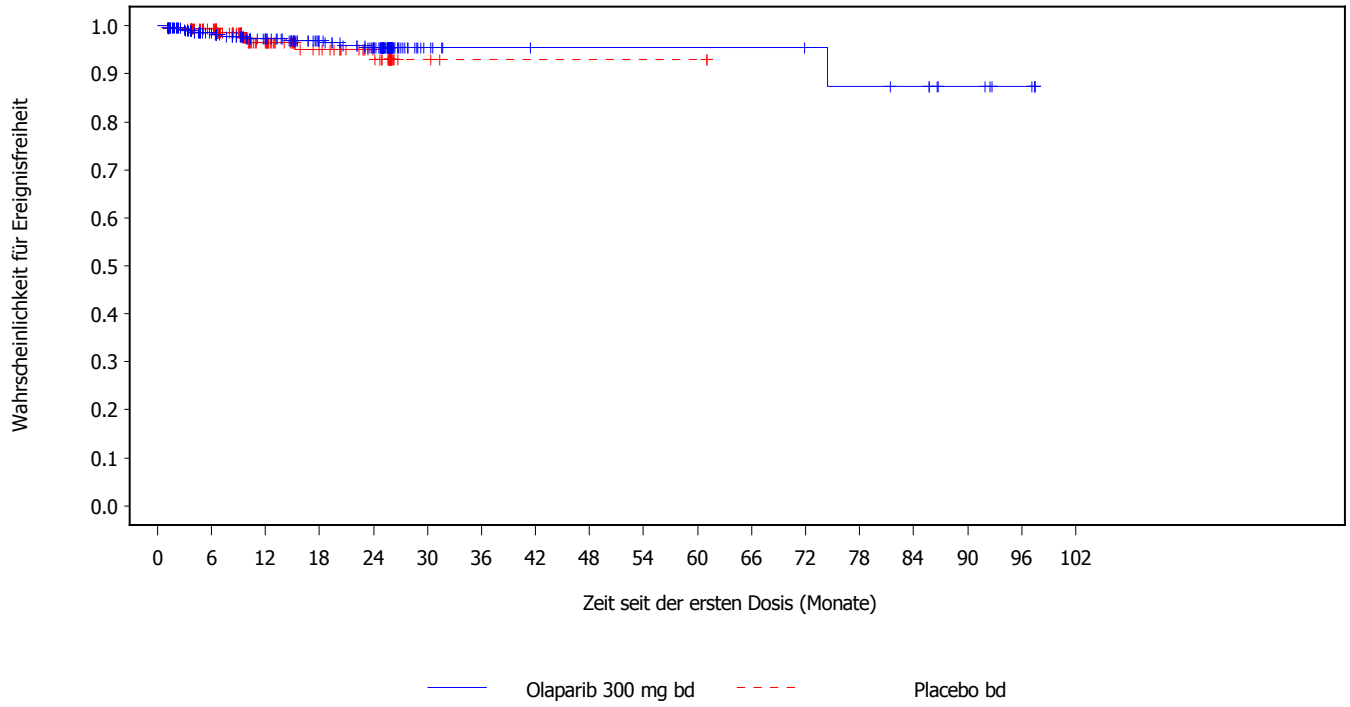
Anzahl an Patienten unter Risiko:

300	248	216	190	176	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	130	87	60	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebei 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.114 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Infektionen und parasitaere Erkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



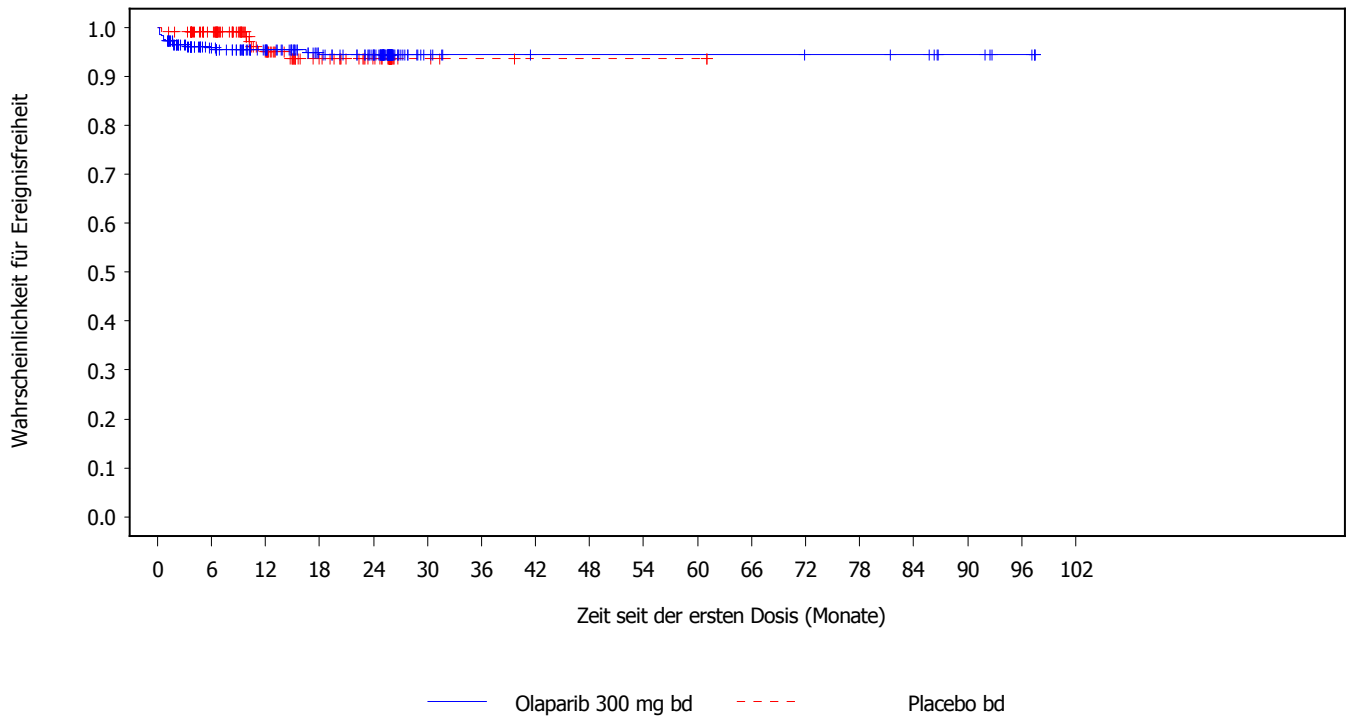
Anzahl an Patienten unter Risiko:

300	256	223	196	178	18	14	13	13	13	13	13	12	11	10	6	3	0	Olaparib 300 mg bd
149	130	85	59	46	3	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebej 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.115 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Untersuchungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



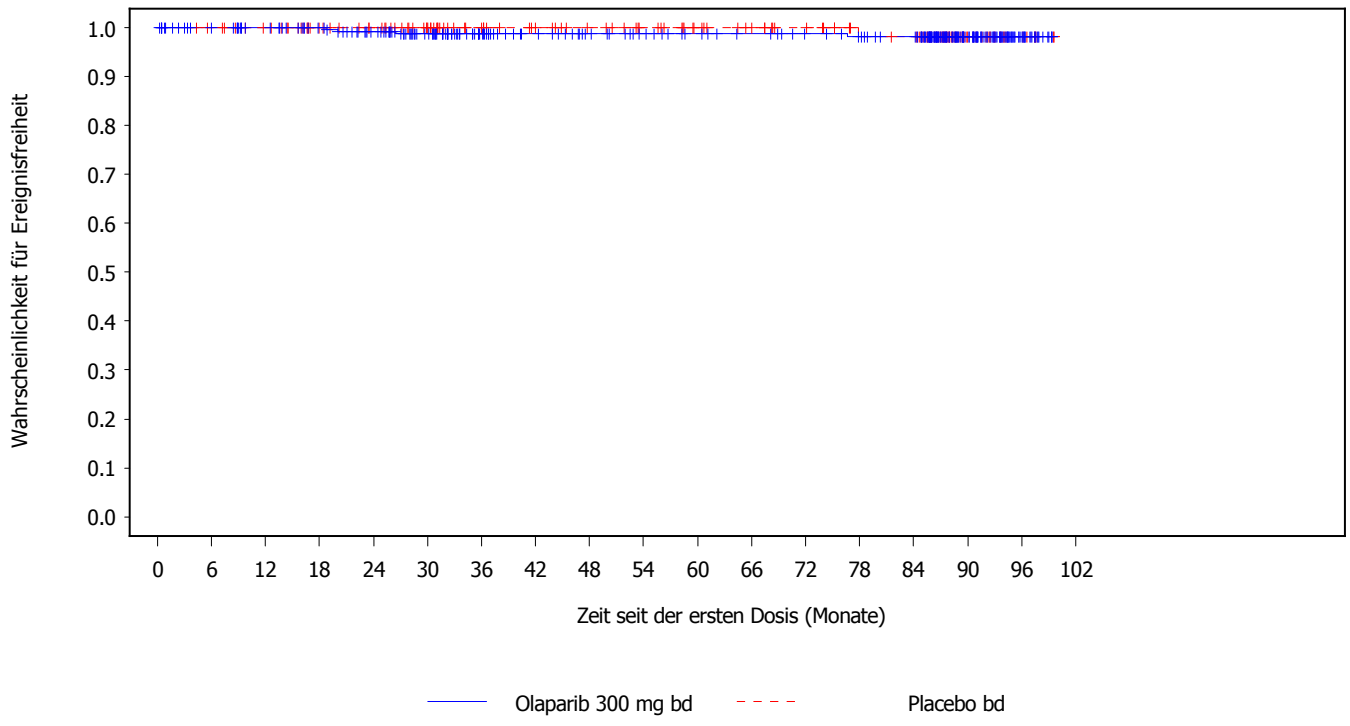
Anzahl an Patienten unter Risiko:

300	249	220	192	178	17	13	12	12	12	12	12	11	11	10	6	3	0	Olaparib 300 mg bd
149	129	86	59	46	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebek 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.116 SOLO1: Kaplan-Meier plot of time to first occurrence of UESI: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



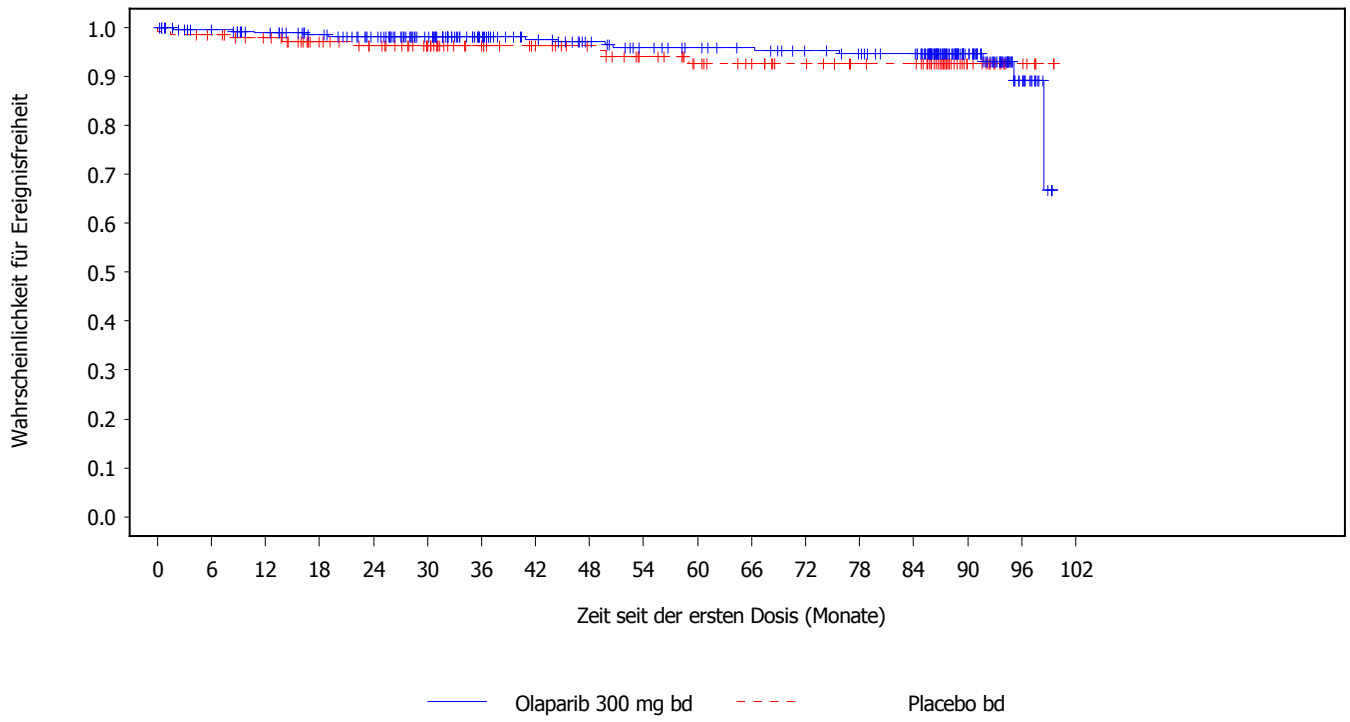
Anzahl an Patienten unter Risiko:

300	288	280	269	255	232	201	188	179	172	166	162	157	153	148	74	20	0	Olaparib 300 mg bd
149	147	142	130	124	111	98	91	86	80	72	67	61	53	52	20	6	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebel 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.117 SOLO1: Kaplan-Meier plot of time to first occurrence of UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



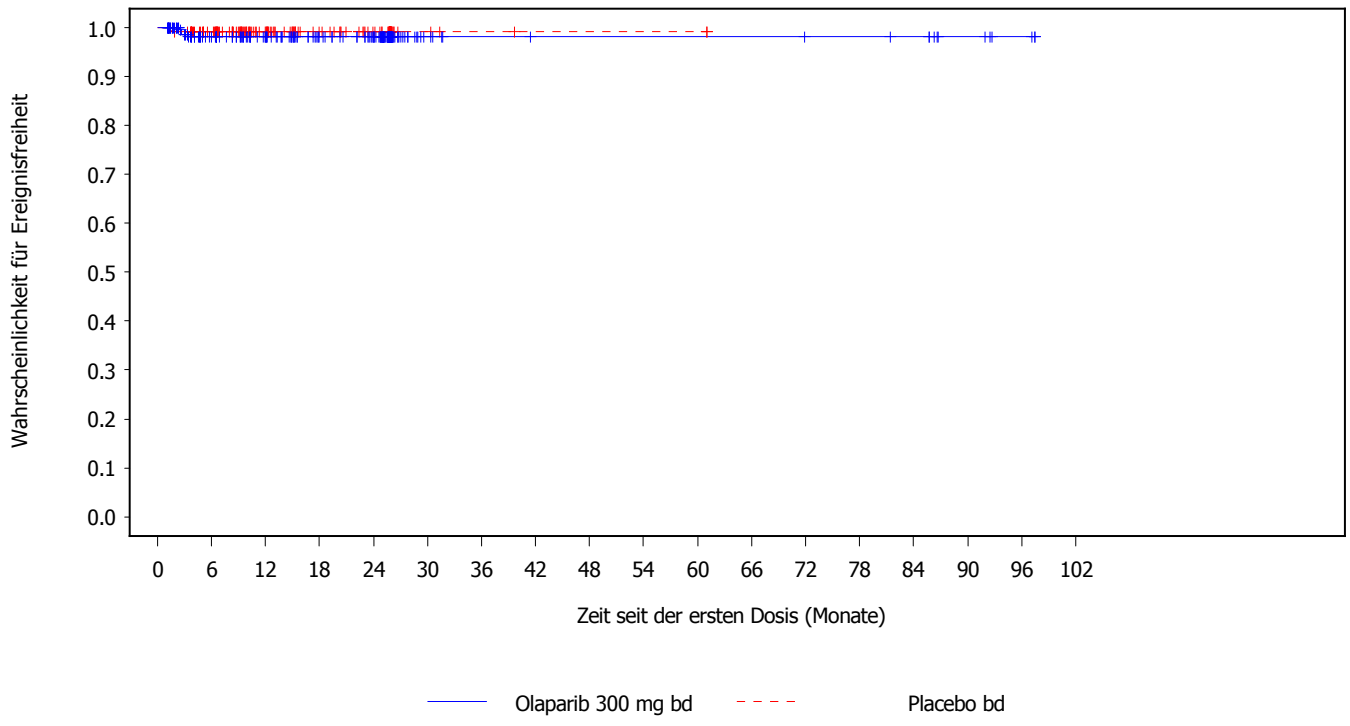
Anzahl an Patienten unter Risiko:

300	287	278	267	254	230	198	184	174	165	160	156	150	146	141	71	18	0	Olaparib 300 mg bd
149	145	139	126	119	107	94	87	82	74	66	61	55	49	48	19	6	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebem 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.118 SOLO1: Kaplan-Meier plot of time to first occurrence of UESI: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



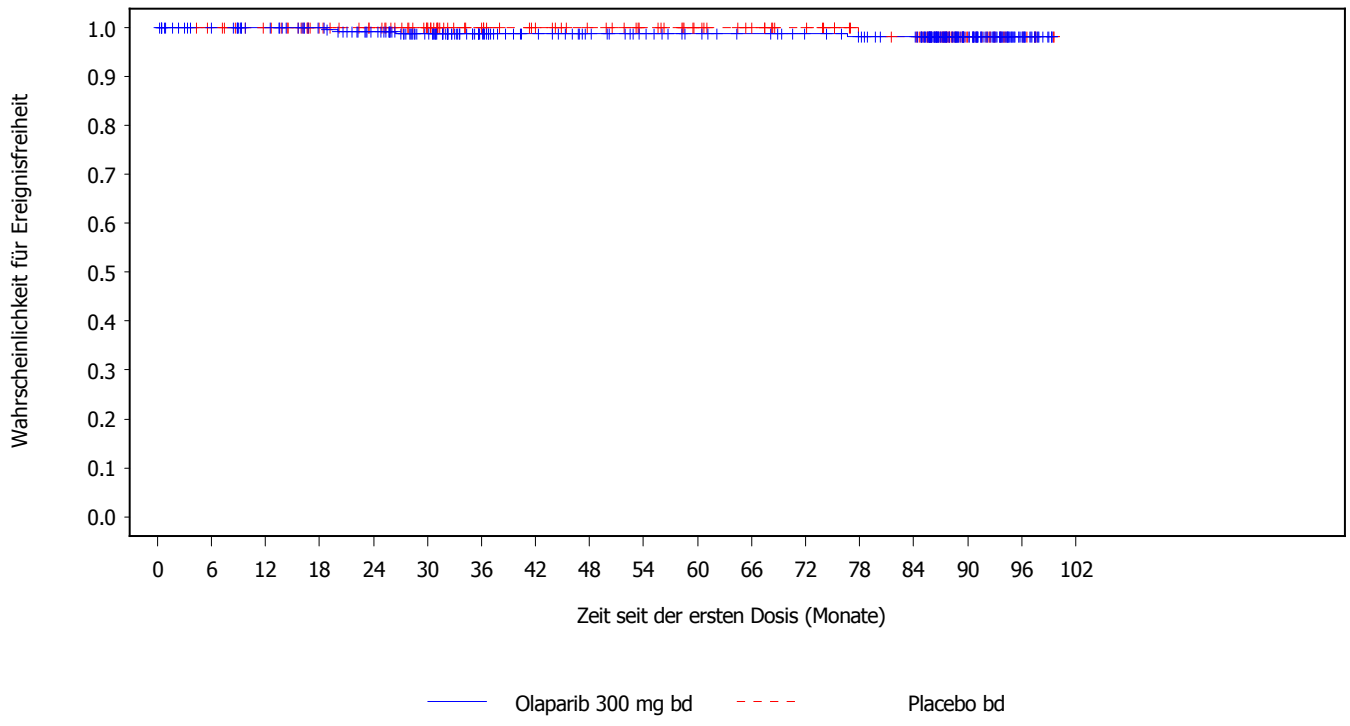
Anzahl an Patienten unter Risiko:

300	258	229	200	184	17	13	12	12	12	12	12	11	11	10	5	2	0	Olaparib 300 mg bd
149	129	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaeben 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.119 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwerwiegende UE: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



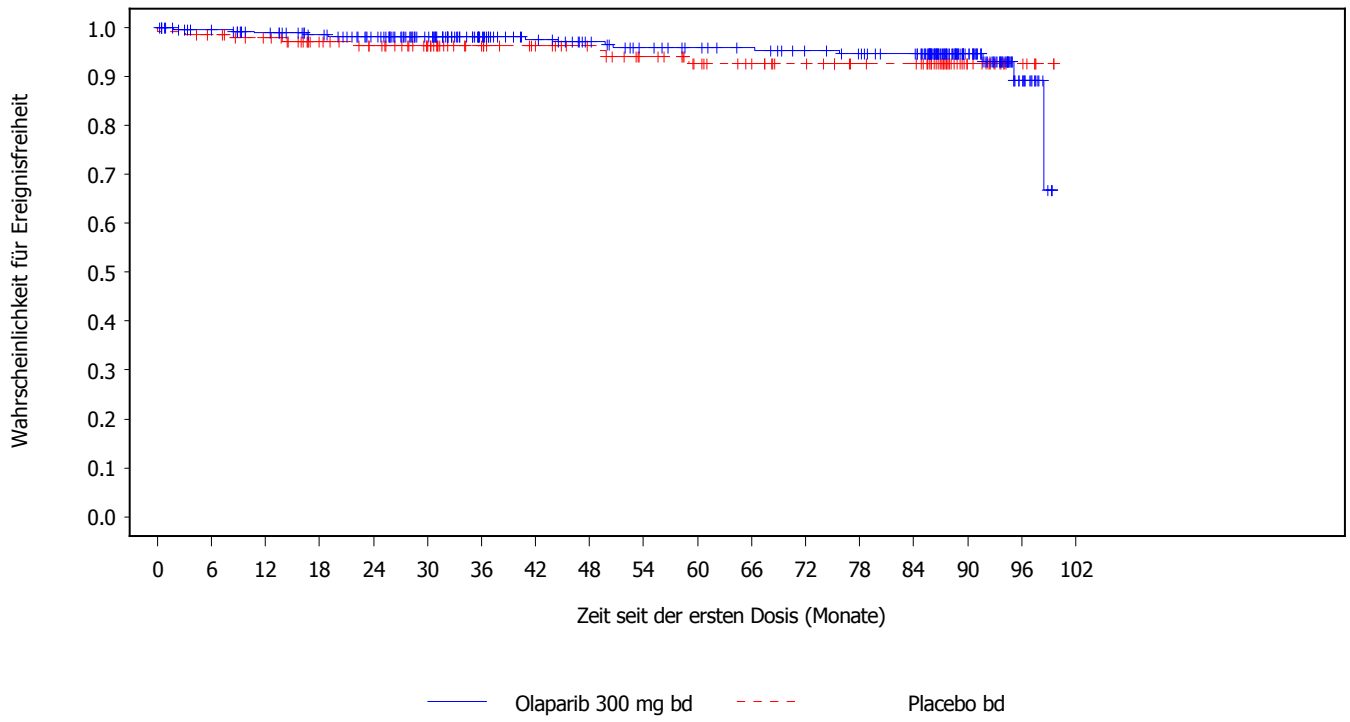
Anzahl an Patienten unter Risiko:

300	288	280	269	255	232	201	188	179	172	166	162	157	153	148	74	20	0	Olaparib 300 mg bd
149	147	142	130	124	111	98	91	86	80	72	67	61	53	52	20	6	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebeo 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.120 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



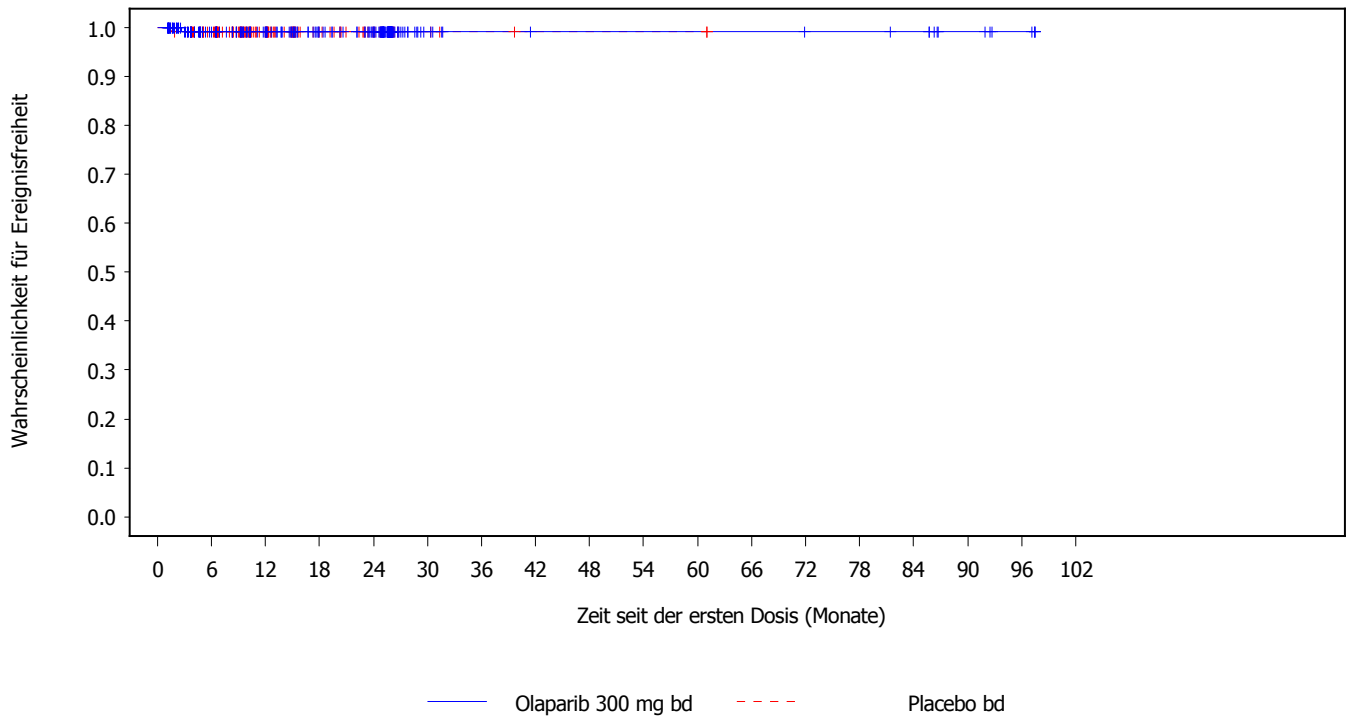
Anzahl an Patienten unter Risiko:

300	287	278	267	254	230	198	184	174	165	160	156	150	146	141	71	18	0	Olaparib 300 mg bd
149	145	139	126	119	107	94	87	82	74	66	61	55	49	48	19	6	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebep 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.121 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwerwiegende UE: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	259	230	201	185	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	129	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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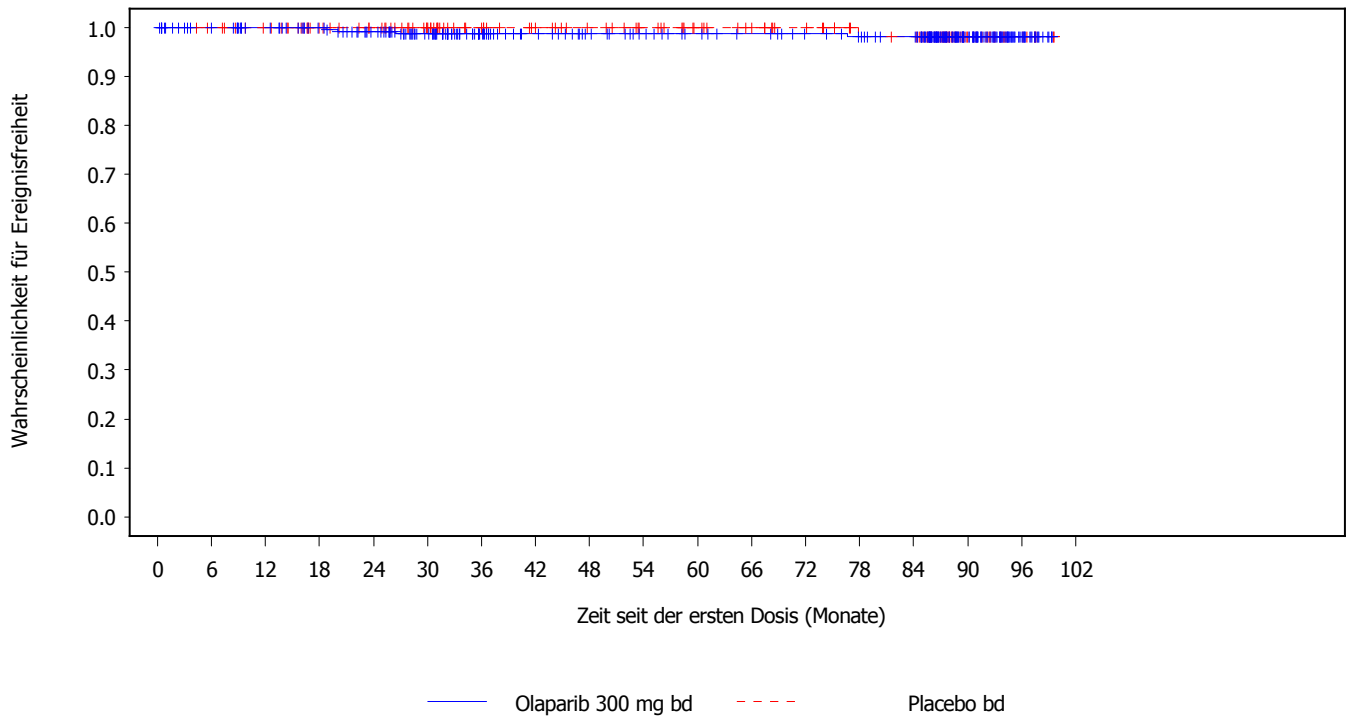
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.122 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UESI G>=3: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



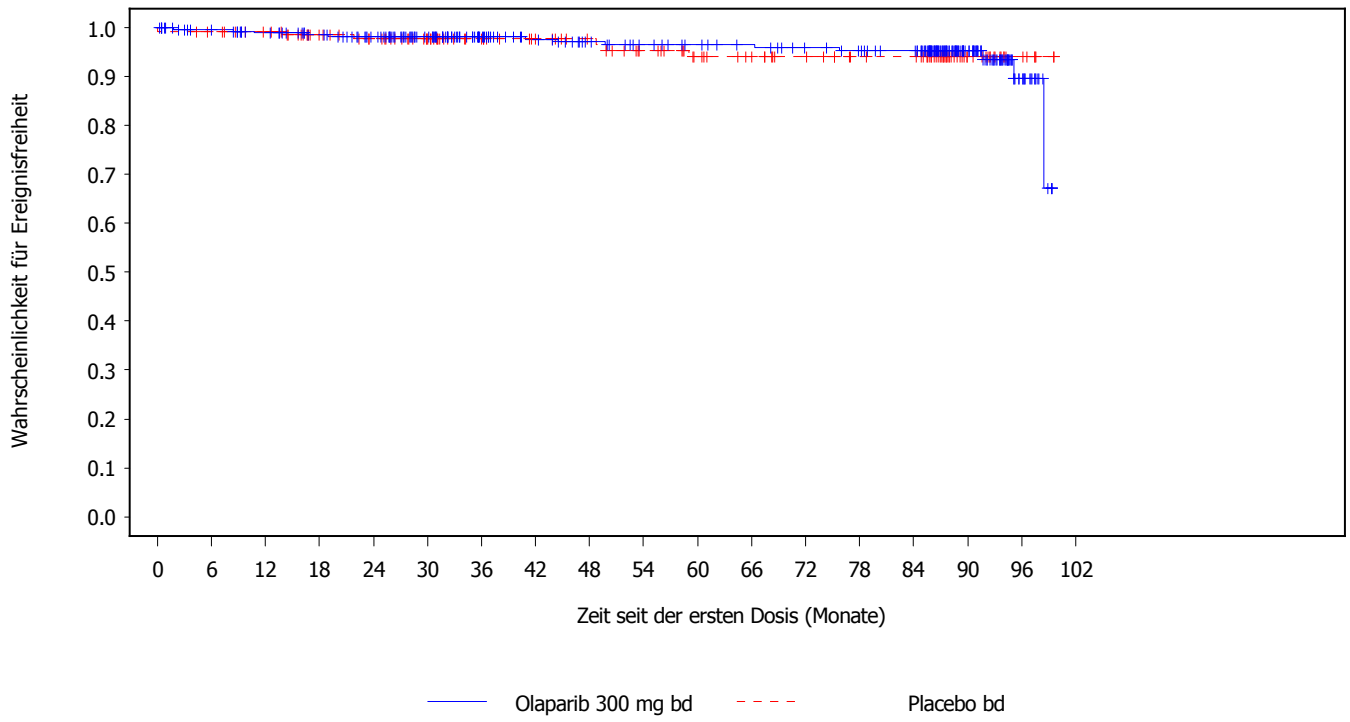
Anzahl an Patienten unter Risiko:

300	288	280	269	255	232	201	188	179	172	166	162	157	153	148	74	20	0	Olaparib 300 mg bd
149	147	142	130	124	111	98	91	86	80	72	67	61	53	52	20	6	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaeber 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.123 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



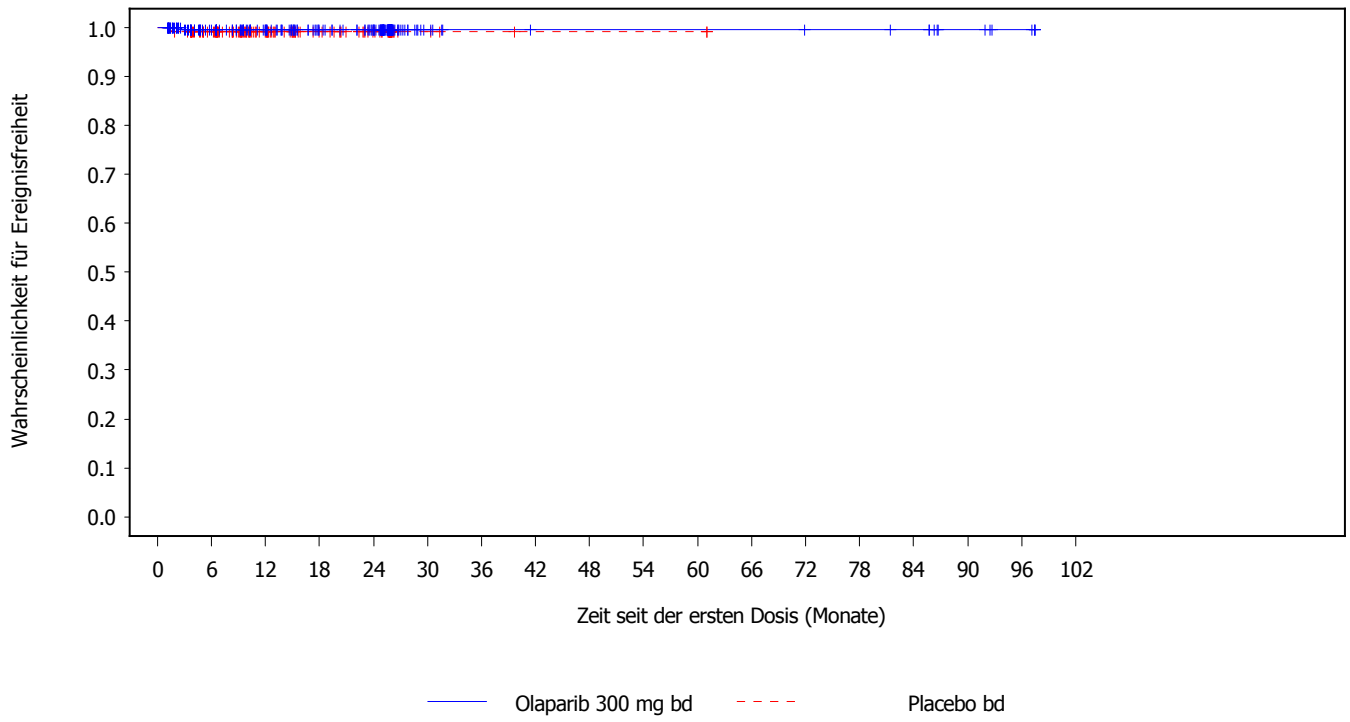
Anzahl an Patienten unter Risiko:

300	287	278	267	254	230	198	184	174	166	161	157	151	147	142	72	18	0	Olaparib 300 mg bd
149	146	141	128	121	108	95	88	83	75	66	61	55	49	48	19	6	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebes 15FEB2023:09:58 kvbv306

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.3.124 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

300	260	230	201	185	18	14	13	13	13	13	13	12	12	11	6	3	0	Olaparib 300 mg bd
149	129	87	61	48	4	2	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttemainae.sas gttemainaebet 15FEB2023:09:58 kvbv306

2.3.2: Subgruppen

Table 3.4.1 SOLO1: Summary of subgroup analysis of time to first occurrence of UE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	259 (98,5)	0,1 [0,1; 0,1]	129	121 (93,8)	0,3 [0,2; 0,4]	1,67	[1,34; 2,08]	<0,0001*
>=65 Jahre	37	36 (97,3)	0,1 [0,1; 0,1]	20	18 (90,0)	0,3 [0,1; 0,8]	2,05	[1,18; 3,70]	0,0109*
Interaktion p-Wert									0,5041
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	243 (98,4)	0,1 [0,1; 0,1]	123	116 (94,3)	0,3 [0,2; 0,5]	1,75	[1,40; 2,20]	<0,0001*
Partielles Ansprechen	53	52 (98,1)	0,1 [0,1; 0,2]	26	23 (88,5)	0,3 [0,1; 0,5]	1,56	[0,97; 2,60]	0,0688
Interaktion p-Wert									0,6756
ECOG PS Status									
Normale Aktivität	221	219 (99,1)	0,1 [0,1; 0,1]	115	110 (95,7)	0,3 [0,2; 0,4]	1,58	[1,26; 2,00]	<0,0001*
Eingeschränkte Aktivität	79	76 (96,2)	0,1 [0,1; 0,1]	34	29 (85,3)	0,3 [0,1; 0,8]	2,20	[1,45; 3,44]	0,0002*
Interaktion p-Wert									0,1795
Baseline CA-125 Wert									
<=ULN	286	281 (98,3)	0,1 [0,1; 0,1]	142	132 (93,0)	0,3 [0,2; 0,4]	1,77	[1,44; 2,19]	<0,0001*
>ULN	14	14 (100)	0,2 [0,1; 0,3]	7	7 (100)	0,2 [0,0; NE]	0,74	[0,31; 1,95]	0,5218
Interaktion p-Wert									0,0815
FIGO Stadium									
III	254	250 (98,4)	0,1 [0,1; 0,1]	122	115 (94,3)	0,3 [0,2; 0,4]	1,63	[1,31; 2,05]	<0,0001*
IV	46	45 (97,8)	0,1 [0,1; 0,1]	27	24 (88,9)	0,5 [0,1; 0,8]	2,17	[1,33; 3,63]	0,0018*
Interaktion p-Wert									0,2967
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	186 (98,9)	0,1 [0,1; 0,1]	90	83 (92,2)	0,3 [0,2; 0,4]	1,65	[1,28; 2,16]	0,0001*
BRCA2	62	60 (96,8)	0,1 [0,1; 0,2]	39	37 (94,9)	0,3 [0,1; 0,7]	1,57	[1,04; 2,38]	0,0304*
Interaktion p-Wert									0,8276

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.1 SOLO1: Summary of subgroup analysis of time to first occurrence of UE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	65 (97,0)	0,1 [0,1; 0,2]	34	31 (91,2)	0,3 [0,2; 0,5]	1,57	[1,03; 2,43]	0,0361*
Keine makroskopische Resterkrankung	228	225 (98,7)	0,1 [0,1; 0,1]	111	105 (94,6)	0,3 [0,2; 0,4]	1,70	[1,35; 2,16]	<0,0001*
Interaktion p-Wert									0,7445
Abstammung									
Weiß	214	210 (98,1)	0,1 [0,1; 0,1]	105	99 (94,3)	0,3 [0,2; 0,3]	1,54	[1,22; 1,97]	0,0003*
Andere	86	85 (98,8)	0,1 [0,1; 0,1]	44	40 (90,9)	0,5 [0,3; 0,9]	2,13	[1,47; 3,15]	<0,0001*
Interaktion p-Wert									0,1530
Region									
Europa	101	101 (100)	0,1 [0,1; 0,1]	53	51 (96,2)	0,3 [0,2; 0,4]	1,83	[1,31; 2,58]	0,0004*
Asien	73	72 (98,6)	0,1 [0,1; 0,1]	33	29 (87,9)	0,5 [0,3; 2,0]	2,29	[1,50; 3,59]	<0,0001*
Rest der Welt	126	122 (96,8)	0,1 [0,1; 0,2]	63	59 (93,7)	0,3 [0,1; 0,5]	1,39	[1,02; 1,91]	0,0358*
Interaktion p-Wert									0,1639

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.2 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	192 (73,0)	1,9 [1,0; 3,5]	129	68 (52,7)	13,8 [8,8;18,5]	1,81	[1,38; 2,41]	<0,0001*
>=65 Jahre	37	30 (81,1)	2,1 [0,9; 4,1]	20	12 (60,0)	8,2 [0,9; NE]	1,69	[0,88; 3,42]	0,1147
Interaktion p-Wert									0,8427
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	184 (74,5)	1,9 [0,9; 3,2]	123	70 (56,9)	12,7 [7,3;15,7]	1,71	[1,30; 2,26]	<0,0001*
Partielles Ansprechen	53	38 (71,7)	3,2 [0,9; 7,0]	26	10 (38,5)	61,0 [5,5; NE]	2,49	[1,26; 5,50]	0,0077*
Interaktion p-Wert									0,3292
ECOG PS Status									
Normale Aktivität	221	166 (75,1)	1,9 [1,0; 3,1]	115	64 (55,7)	9,9 [5,5;15,7]	1,66	[1,25; 2,23]	0,0004*
Eingeschränkte Aktivität	79	56 (70,9)	3,5 [0,9; 6,7]	34	16 (47,1)	15,8 [10,6; NE]	2,35	[1,37; 4,32]	0,0016*
Interaktion p-Wert									0,2778
Baseline CA-125 Wert									
<=ULN	286	214 (74,8)	1,9 [1,0; 3,1]	142	77 (54,2)	12,8 [8,8;15,8]	1,84	[1,43; 2,41]	<0,0001*
>ULN	14	8 (57,1)	17,5 [0,2; NE]	7	3 (42,9)	NE [NE; NE]	0,98	[0,28; 4,47]	0,9731
Interaktion p-Wert									0,3809
FIGO Stadium									
III	254	187 (73,6)	1,9 [1,0; 3,6]	122	64 (52,5)	14,2 [9,2;20,2]	1,87	[1,42; 2,51]	<0,0001*
IV	46	35 (76,1)	2,1 [0,4; 3,6]	27	16 (59,3)	8,8 [2,6;14,2]	1,47	[0,83; 2,74]	0,1897
Interaktion p-Wert									0,4790
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	142 (75,5)	1,9 [1,0; 3,5]	90	48 (53,3)	14,7 [6,5;21,7]	1,83	[1,33; 2,58]	0,0002*
BRCA2	62	48 (77,4)	2,0 [0,6; 7,0]	39	25 (64,1)	7,3 [2,6;12,8]	1,50	[0,94; 2,47]	0,0933
Interaktion p-Wert									0,5063

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.2 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	49 (73,1)	2,9 [0,9; 6,7]	34	16 (47,1)	15,8 [5,2; NE]	2,08	[1,20; 3,85]	0,0087*
Keine makroskopische Resterkrankung	228	169 (74,1)	1,9 [0,9; 3,5]	111	63 (56,8)	12,7 [7,3;14,7]	1,69	[1,27; 2,28]	0,0002*
Interaktion p-Wert									0,5276
Abstammung									
Weiß	214	169 (79,0)	1,9 [0,9; 3,1]	105	62 (59,0)	10,6 [5,2;14,7]	1,70	[1,28; 2,29]	0,0002*
Andere	86	53 (61,6)	3,2 [1,0;11,6]	44	18 (40,9)	61,0 [9,9; NE]	2,09	[1,24; 3,72]	0,0053*
Interaktion p-Wert									0,5109
Region									
Europa	101	86 (85,1)	1,1 [0,8; 3,1]	53	36 (67,9)	7,6 [3,6;14,2]	1,67	[1,14; 2,50]	0,0080*
Asien	73	44 (60,3)	3,5 [1,0;14,5]	33	11 (33,3)	61,0 [12,7; NE]	2,91	[1,53; 6,13]	0,0008*
Rest der Welt	126	92 (73,0)	1,9 [0,8; 4,1]	63	33 (52,4)	12,8 [1,8; NE]	1,62	[1,10; 2,45]	0,0139*
Interaktion p-Wert									0,2912

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.3 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Asthenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	56 (21,3)	NE [NE; NE]	129	13 (10,1)	NE [NE; NE]	2,18	[1,23; 4,16]	0,0065*
>=65 Jahre	37	10 (27,0)	NE [NE; NE]	20	4 (20,0)	NE [NE; NE]	1,40	[0,47; 5,11]	0,5591
Interaktion p-Wert									0,5169
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	56 (22,7)	NE [NE; NE]	123	16 (13,0)	NE [NE; NE]	1,83	[1,08; 3,29]	0,0251*
Partielles Ansprechen	53	10 (18,9)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	4,67	[0,89; 85,78]	0,0715
Interaktion p-Wert									0,3368
ECOG PS Status									
Normale Aktivität	221	53 (24,0)	NE [NE; NE]	115	15 (13,0)	NE [NE; NE]	1,88	[1,09; 3,46]	0,0230*
Eingeschränkte Aktivität	79	13 (16,5)	NE [NE; NE]	34	2 (5,9)	NE [NE; NE]	2,99	[0,83; 19,12]	0,1016
Interaktion p-Wert									0,5522
Baseline CA-125 Wert									
<=ULN	286	64 (22,4)	NE [NE; NE]	142	16 (11,3)	NE [NE; NE]	2,07	[1,23; 3,71]	0,0053*
>ULN	14	2 (14,3)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,78	[0,07; 16,75]	0,8403
Interaktion p-Wert									0,4631
FIGO Stadium									
III	254	57 (22,4)	NE [NE; NE]	122	15 (12,3)	NE [NE; NE]	1,90	[1,10; 3,47]	0,0197*
IV	46	9 (19,6)	NE [NE; NE]	27	2 (7,4)	NE [NE; NE]	2,64	[0,68; 17,33]	0,1727
Interaktion p-Wert									0,6832
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	47 (25,0)	NE [NE; NE]	90	11 (12,2)	NE [NE; NE]	2,13	[1,15; 4,33]	0,0153*
BRCA2	62	16 (25,8)	NE [NE; NE]	39	5 (12,8)	NE [NE; NE]	2,16	[0,84; 6,60]	0,1115
Interaktion p-Wert									0,9830

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.3 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Asthenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	11 (16,4)	NE [NE; NE]	34	4 (11,8)	NE [NE; NE]	1,31	[0,45; 4,74]	0,6335
Keine makroskopische Resterkrankung	228	54 (23,7)	NE [NE; NE]	111	12 (10,8)	NE [NE; NE]	2,35	[1,30; 4,61]	0,0036*
Interaktion p-Wert									0,3946
Abstammung									
Weiß	214	62 (29,0)	NE [NE; NE]	105	16 (15,2)	NE [NE; NE]	2,02	[1,19; 3,62]	0,0077*
Andere	86	4 (4,7)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	1,97	[0,29; 38,60]	0,5170
Interaktion p-Wert									0,9851
Region									
Europa	101	55 (54,5)	9,7 [3,5; NE]	53	15 (28,3)	NE [NE; NE]	2,35	[1,36; 4,32]	0,0016*
Asien	73	3 (4,1)	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	1,32	[0,17; 26,59]	0,8083
Rest der Welt	126	8 (6,3)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	3,82	[0,70; 70,94]	0,1355
Interaktion p-Wert									0,7926

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.4 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Ermuedung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	105 (39,9)	33,9 [33,9; NE]	129	36 (27,9)	NE [NE; NE]	1,53	[1,06; 2,27]	0,0232*
>=65 Jahre	37	16 (43,2)	NE [NE; NE]	20	6 (30,0)	NE [NE; NE]	1,50	[0,62; 4,19]	0,3808
Interaktion p-Wert									0,9711
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	98 (39,7)	33,9 [33,9; NE]	123	37 (30,1)	NE [NE; NE]	1,45	[0,9998; 2,14]	0,0501
Partielles Ansprechen	53	23 (43,4)	65,8 [5,7; NE]	26	5 (19,2)	NE [NE; NE]	2,12	[0,87; 6,34]	0,1027
Interaktion p-Wert									0,4583
ECOG PS Status									
Normale Aktivität	221	87 (39,4)	54,1 [33,9; NE]	115	31 (27,0)	NE [NE; NE]	1,52	[1,02; 2,33]	0,0395*
Eingeschränkte Aktivität	79	34 (43,0)	NE [NE; NE]	34	11 (32,4)	NE [NE; NE]	1,52	[0,79; 3,14]	0,2135
Interaktion p-Wert									0,9954
Baseline CA-125 Wert									
<=ULN	286	117 (40,9)	33,9 [33,9;65,8]	142	40 (28,2)	NE [NE; NE]	1,57	[1,10; 2,27]	0,0117*
>ULN	14	4 (28,6)	NE [NE; NE]	7	2 (28,6)	NE [NE; NE]	0,85	[0,17; 6,18]	0,8571
Interaktion p-Wert									0,5097
FIGO Stadium									
III	254	101 (39,8)	33,9 [33,9; NE]	122	33 (27,0)	NE [NE; NE]	1,58	[1,08; 2,38]	0,0181*
IV	46	20 (43,5)	65,8 [4,1; NE]	27	9 (33,3)	NE [NE; NE]	1,35	[0,63; 3,12]	0,4532
Interaktion p-Wert									0,7221
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	76 (40,4)	33,9 [17,5; NE]	90	25 (27,8)	NE [NE; NE]	1,57	[1,01; 2,51]	0,0439*
BRCA2	62	25 (40,3)	54,1 [9,2; NE]	39	14 (35,9)	NE [NE; NE]	1,11	[0,58; 2,19]	0,7624
Interaktion p-Wert									0,3938

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.4 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Ermuedung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	33 (49,3)	65,8 [2,9; NE]	34	7 (20,6)	NE [NE; NE]	2,80	[1,32; 6,91]	0,0062*
Keine makroskopische Resterkrankung	228	85 (37,3)	33,9 [33,9; NE]	111	35 (31,5)	NE [NE; NE]	1,22	[0,83; 1,84]	0,3082
Interaktion p-Wert									0,0596
Abstammung									
Weiß	214	89 (41,6)	33,9 [17,5; NE]	105	34 (32,4)	NE [NE; NE]	1,31	[0,89; 1,98]	0,1717
Andere	86	32 (37,2)	NE [NE; NE]	44	8 (18,2)	NE [NE; NE]	2,42	[1,17; 5,66]	0,0154*
Interaktion p-Wert									0,1541
Region									
Europa	101	19 (18,8)	NE [NE; NE]	53	11 (20,8)	NE [NE; NE]	0,88	[0,43; 1,92]	0,7407
Asien	73	24 (32,9)	NE [NE; NE]	33	6 (18,2)	NE [NE; NE]	2,13	[0,93; 5,76]	0,0759
Rest der Welt	126	78 (61,9)	4,8 [1,9; 9,2]	63	25 (39,7)	NE [NE; NE]	1,72	[1,11; 2,76]	0,0142*
Interaktion p-Wert									0,2447

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.5 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Schleimhautentzuendung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	15 (5,7)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	6,81	[1,38;123,22]	0,0139*
>=65 Jahre	37	3 (8,1)	51,1 [51,1; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	14 (5,7)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	4 (7,5)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	14 (6,3)	NE [NE; NE]	115	1 (0,9)	NE [NE; NE]	6,01	[1,19;109,26]	0,0261*
Eingeschränkte Aktivität	79	4 (5,1)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	18 (6,3)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	7,87	[1,62;141,87]	0,0061*
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	14 (5,5)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	4 (8,7)	NE [NE; NE]	27	1 (3,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	13 (6,9)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	5,70	[1,13;103,63]	0,0322*
BRCA2	62	5 (8,1)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.5 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Schleimhautentzuendung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	16 (7,0)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	18 (8,4)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	0	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	16 (15,8)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	0	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	2 (1,6)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.6 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dyspnoe
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	31 (11,8)	NE [NE; NE]	129	3 (2,3)	NE [NE; NE]	4,28	[1,52; 17,89]	0,0036*
>=65 Jahre	37	10 (27,0)	51,1 [19,4; NE]	20	4 (20,0)	NE [NE; NE]	1,33	[0,44; 4,84]	0,6266
Interaktion p-Wert									0,1635
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	31 (12,6)	NE [NE; NE]	123	5 (4,1)	NE [NE; NE]	2,89	[1,23; 8,47]	0,0132*
Partielles Ansprechen	53	10 (18,9)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	1,50	[0,39; 9,82]	0,5887
Interaktion p-Wert									0,4891
ECOG PS Status									
Normale Aktivität	221	29 (13,1)	NE [NE; NE]	115	6 (5,2)	NE [NE; NE]	2,10	[0,93; 5,62]	0,0765
Eingeschränkte Aktivität	79	12 (15,2)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	5,02	[0,99; 91,35]	0,0522
Interaktion p-Wert									0,4057
Baseline CA-125 Wert									
<=ULN	286	39 (13,6)	NE [NE; NE]	142	6 (4,2)	NE [NE; NE]	2,81	[1,28; 7,42]	0,0082*
>ULN	14	2 (14,3)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,64	[0,06; 13,92]	0,7279
Interaktion p-Wert									0,2991
FIGO Stadium									
III	254	34 (13,4)	NE [NE; NE]	122	6 (4,9)	NE [NE; NE]	2,43	[1,09; 6,43]	0,0279*
IV	46	7 (15,2)	51,7 [51,1; NE]	27	1 (3,7)	NE [NE; NE]	3,11	[0,55; 58,25]	0,2275
Interaktion p-Wert									0,8277
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	28 (14,9)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	6,15	[1,85; 38,09]	0,0013*
BRCA2	62	13 (21,0)	NE [NE; NE]	39	5 (12,8)	NE [NE; NE]	1,30	[0,49; 4,09]	0,6112
Interaktion p-Wert									0,0693

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.6 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dyspnoe
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	12 (17,9)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	5,21	[1,03; 95,08]	0,0459*
Keine makroskopische Resterkrankung	228	27 (11,8)	NE [NE; NE]	111	6 (5,4)	NE [NE; NE]	2,01	[0,88; 5,38]	0,0994
Interaktion p-Wert									0,3588
Abstammung									
Weiß	214	37 (17,3)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	2,27	[1,07; 5,59]	0,0313*
Andere	86	4 (4,7)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	15 (14,9)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	3,27	[0,92; 20,81]	0,0704
Asien	73	0	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	26 (20,6)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	2,32	[0,97; 6,88]	0,0606
Interaktion p-Wert									0,6973

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.7 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dysurie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	9 (3,4)	NE [NE; NE]	129	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	1 (2,7)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	10 (4,0)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	0	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	8 (3,6)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	9 (3,1)	NE [NE; NE]	142	0	NE [NE; NE]	NC	[NC]	NC
>ULN	14	1 (7,1)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	10 (3,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	0	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	8 (4,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	2 (3,2)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 3.4.7 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dysurie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	9 (3,9)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	9 (4,2)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	1 (1,2)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	6 (5,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	0	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.8 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	141 (53,6)	10,9 [5,5;22,1]	129	28 (21,7)	NE [NE; NE]	2,92	[1,98; 4,47]	<0,0001*
>=65 Jahre	37	21 (56,8)	4,7 [1,9; NE]	20	2 (10,0)	NE [NE; NE]	7,44	[2,18; 46,54]	0,0004*
Interaktion p-Wert									0,1764
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	132 (53,4)	9,2 [4,7;25,8]	123	24 (19,5)	NE [NE; NE]	3,42	[2,26; 5,42]	<0,0001*
Partielles Ansprechen	53	30 (56,6)	9,2 [3,6; NE]	26	6 (23,1)	21,1 [21,1; NE]	2,39	[1,07; 6,37]	0,0332*
Interaktion p-Wert									0,4827
ECOG PS Status									
Normale Aktivität	221	119 (53,8)	9,5 [5,3;25,8]	115	22 (19,1)	NE [NE; NE]	3,26	[2,11; 5,28]	<0,0001*
Eingeschränkte Aktivität	79	43 (54,4)	6,5 [2,8; NE]	34	8 (23,5)	NE [NE; NE]	3,05	[1,52; 7,02]	0,0011*
Interaktion p-Wert									0,8832
Baseline CA-125 Wert									
<=ULN	286	152 (53,1)	11,9 [5,5;24,0]	142	28 (19,7)	NE [NE; NE]	3,26	[2,21; 4,98]	<0,0001*
>ULN	14	10 (71,4)	3,6 [0,5; 9,2]	7	2 (28,6)	NE [NE; NE]	2,42	[0,64; 15,72]	0,2124
Interaktion p-Wert									0,7176
FIGO Stadium									
III	254	136 (53,5)	10,9 [5,4;24,0]	122	25 (20,5)	NE [NE; NE]	3,13	[2,08; 4,90]	<0,0001*
IV	46	26 (56,5)	5,5 [1,0; NE]	27	5 (18,5)	NE [NE; NE]	3,73	[1,55; 11,04]	0,0022*
Interaktion p-Wert									0,7398
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	93 (49,5)	15,7 [6,5; NE]	90	19 (21,1)	NE [NE; NE]	2,67	[1,67; 4,51]	<0,0001*
BRCA2	62	33 (53,2)	11,9 [3,8; NE]	39	5 (12,8)	NE [NE; NE]	5,10	[2,18; 14,91]	<0,0001*
Interaktion p-Wert									0,2139

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.8 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	38 (56,7)	9,2 [3,7; NE]	34	7 (20,6)	NE [NE; NE]	2,95	[1,40; 7,21]	0,0033*
Keine makroskopische Resterkrankung	228	121 (53,1)	9,5 [4,6;25,8]	111	22 (19,8)	NE [NE; NE]	3,36	[2,18; 5,44]	<0,0001*
Interaktion p-Wert									0,7815
Abstammung									
Weiß	214	102 (47,7)	22,0 [8,2; NE]	105	21 (20,0)	NE [NE; NE]	2,67	[1,70; 4,38]	<0,0001*
Andere	86	60 (69,8)	2,7 [1,8; 5,5]	44	9 (20,5)	NE [NE; NE]	4,98	[2,60; 10,77]	<0,0001*
Interaktion p-Wert									0,1368
Region									
Europa	101	58 (57,4)	5,4 [3,3;22,1]	53	11 (20,8)	NE [NE; NE]	3,52	[1,92; 7,08]	<0,0001*
Asien	73	50 (68,5)	2,8 [1,8; 5,6]	33	7 (21,2)	NE [NE; NE]	4,85	[2,35; 11,74]	<0,0001*
Rest der Welt	126	54 (42,9)	49,7 [16,6; NE]	63	12 (19,0)	NE [NE; NE]	2,31	[1,28; 4,54]	0,0044*
Interaktion p-Wert									0,3373

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.9 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	108 (41,1)	44,5 [23,0; NE]	129	14 (10,9)	NE [NE; NE]	4,38	[2,60; 8,00]	<0,0001*
>=65 Jahre	37	18 (48,6)	49,7 [1,9; NE]	20	1 (5,0)	NE [NE; NE]	12,10	[2,50;217,80]	0,0004*
Interaktion p-Wert									0,2786
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	99 (40,1)	49,7 [49,7; NE]	123	10 (8,1)	NE [NE; NE]	6,00	[3,29; 12,28]	<0,0001*
Partielles Ansprechen	53	27 (50,9)	15,7 [5,6; NE]	26	5 (19,2)	21,1 [21,1; NE]	2,50	[1,05; 7,38]	0,0384*
Interaktion p-Wert									0,1547
ECOG PS Status									
Normale Aktivität	221	89 (40,3)	49,7 [44,5; NE]	115	9 (7,8)	NE [NE; NE]	5,71	[3,04; 12,21]	<0,0001*
Eingeschränkte Aktivität	79	37 (46,8)	17,5 [5,6; NE]	34	6 (17,6)	NE [NE; NE]	3,58	[1,63; 9,45]	0,0009*
Interaktion p-Wert									0,4134
Baseline CA-125 Wert									
<=ULN	286	117 (40,9)	44,5 [44,5; NE]	142	13 (9,2)	NE [NE; NE]	5,25	[3,07; 9,78]	<0,0001*
>ULN	14	9 (64,3)	3,6 [0,5; NE]	7	2 (28,6)	NE [NE; NE]	2,08	[0,53; 13,62]	0,3154
Interaktion p-Wert									0,3050
FIGO Stadium									
III	254	104 (40,9)	44,5 [23,9;51,7]	122	14 (11,5)	NE [NE; NE]	4,13	[2,45; 7,55]	<0,0001*
IV	46	22 (47,8)	15,7 [3,4; NE]	27	1 (3,7)	NE [NE; NE]	15,90	[3,33;284,78]	<0,0001*
Interaktion p-Wert									0,1321
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	71 (37,8)	NE [NE; NE]	90	8 (8,9)	NE [NE; NE]	4,94	[2,53; 11,13]	<0,0001*
BRCA2	62	30 (48,4)	44,5 [5,4; NE]	39	4 (10,3)	NE [NE; NE]	5,45	[2,15; 18,38]	0,0001*
Interaktion p-Wert									0,8782

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 3.4.9 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	34 (50,7)	21,2 [8,2; NE]	34	4 (11,8)	NE [NE; NE]	4,63	[1,85; 15,53]	0,0004*
Keine makroskopische Resterkrankung	228	89 (39,0)	44,5 [44,5; NE]	111	11 (9,9)	NE [NE; NE]	4,72	[2,64; 9,37]	<0,0001*
Interaktion p-Wert									0,9754
Abstammung									
Weiß	214	78 (36,4)	51,7 [44,5; NE]	105	11 (10,5)	NE [NE; NE]	3,86	[2,15; 7,69]	<0,0001*
Andere	86	48 (55,8)	8,3 [3,4; NE]	44	4 (9,1)	NE [NE; NE]	8,16	[3,32; 27,04]	<0,0001*
Interaktion p-Wert									0,2036
Region									
Europa	101	43 (42,6)	44,5 [5,6; NE]	53	4 (7,5)	NE [NE; NE]	6,85	[2,77; 22,77]	<0,0001*
Asien	73	39 (53,4)	9,2 [3,7; NE]	33	3 (9,1)	NE [NE; NE]	7,79	[2,82; 32,22]	<0,0001*
Rest der Welt	126	44 (34,9)	49,7 [49,7; NE]	63	8 (12,7)	NE [NE; NE]	2,90	[1,44; 6,66]	0,0019*
Interaktion p-Wert									0,2499

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.10 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Neutropenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	50 (19,0)	NE [NE; NE]	129	9 (7,0)	NE [NE; NE]	2,72	[1,41; 5,93]	0,0021*
>=65 Jahre	37	7 (18,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	3,96	[0,71; 74,18]	0,1300
Interaktion p-Wert									0,7295
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	52 (21,1)	NE [NE; NE]	123	9 (7,3)	NE [NE; NE]	3,00	[1,55; 6,51]	0,0006*
Partielles Ansprechen	53	5 (9,4)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	2,08	[0,34; 39,94]	0,4693
Interaktion p-Wert									0,7608
ECOG PS Status									
Normale Aktivität	221	38 (17,2)	NE [NE; NE]	115	9 (7,8)	NE [NE; NE]	2,16	[1,09; 4,76]	0,0258*
Eingeschränkte Aktivität	79	19 (24,1)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	8,79	[1,83;157,96]	0,0030*
Interaktion p-Wert									0,1341
Baseline CA-125 Wert									
<=ULN	286	55 (19,2)	NE [NE; NE]	142	10 (7,0)	NE [NE; NE]	2,76	[1,47; 5,76]	0,0010*
>ULN	14	2 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	51 (20,1)	NE [NE; NE]	122	7 (5,7)	NE [NE; NE]	3,56	[1,73; 8,61]	0,0002*
IV	46	6 (13,0)	NE [NE; NE]	27	3 (11,1)	NE [NE; NE]	1,12	[0,29; 5,30]	0,8743
Interaktion p-Wert									0,1723
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	28 (14,9)	NE [NE; NE]	90	8 (8,9)	NE [NE; NE]	1,65	[0,79; 3,89]	0,1899
BRCA2	62	12 (19,4)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	7,92	[1,56;144,27]	0,0084*
Interaktion p-Wert									0,1043

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.10 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Neutropenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	7 (10,4)	NE [NE; NE]	34	3 (8,8)	NE [NE; NE]	1,06	[0,30; 4,94]	0,9281
Keine makroskopische Resterkrankung	228	49 (21,5)	NE [NE; NE]	111	6 (5,4)	NE [NE; NE]	4,18	[1,94; 10,92]	<0,0001*
Interaktion p-Wert									0,1105
Abstammung									
Weiß	214	37 (17,3)	NE [NE; NE]	105	8 (7,6)	NE [NE; NE]	2,26	[1,11; 5,22]	0,0236*
Andere	86	20 (23,3)	NE [NE; NE]	44	2 (4,5)	NE [NE; NE]	5,28	[1,54; 33,07]	0,0052*
Interaktion p-Wert									0,2818
Region									
Europa	101	24 (23,8)	NE [NE; NE]	53	6 (11,3)	NE [NE; NE]	2,18	[0,95; 5,90]	0,0664
Asien	73	18 (24,7)	NE [NE; NE]	33	2 (6,1)	NE [NE; NE]	4,24	[1,22; 26,68]	0,0196*
Rest der Welt	126	15 (11,9)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	3,60	[1,02; 22,86]	0,0467*
Interaktion p-Wert									0,6905

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.11 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Thrombozytopenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	30 (11,4)	NE [NE; NE]	129	4 (3,1)	NE [NE; NE]	3,61	[1,42; 12,15]	0,0049*
>=65 Jahre	37	4 (10,8)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	2,12	[0,31; 41,38]	0,4725
Interaktion p-Wert									0,6779
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	30 (12,1)	NE [NE; NE]	123	4 (3,3)	NE [NE; NE]	3,77	[1,49; 12,71]	0,0034*
Partielles Ansprechen	53	4 (7,5)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	1,65	[0,24; 32,21]	0,6406
Interaktion p-Wert									0,5271
ECOG PS Status									
Normale Aktivität	221	24 (10,9)	NE [NE; NE]	115	3 (2,6)	NE [NE; NE]	4,08	[1,42; 17,17]	0,0064*
Eingeschränkte Aktivität	79	10 (12,7)	NE [NE; NE]	34	2 (5,9)	NE [NE; NE]	2,10	[0,55; 13,66]	0,3005
Interaktion p-Wert									0,5102
Baseline CA-125 Wert									
<=ULN	286	34 (11,9)	NE [NE; NE]	142	4 (2,8)	NE [NE; NE]	4,20	[1,67; 14,08]	0,0012*
>ULN	14	0	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	31 (12,2)	NE [NE; NE]	122	5 (4,1)	NE [NE; NE]	2,91	[1,24; 8,54]	0,0123*
IV	46	3 (6,5)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	16 (8,5)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	3,82	[1,09; 24,17]	0,0350*
BRCA2	62	3 (4,8)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.11 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Thrombozytopenie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	7 (10,4)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	27 (11,8)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	2,61	[1,10; 7,72]	0,0288*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	20 (9,3)	NE [NE; NE]	105	2 (1,9)	NE [NE; NE]	4,82	[1,41; 30,16]	0,0091*
Andere	86	14 (16,3)	NE [NE; NE]	44	3 (6,8)	NE [NE; NE]	2,33	[0,76; 10,13]	0,1472
Interaktion p-Wert									0,4536
Region									
Europa	101	12 (11,9)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	6,26	[1,23;113,93]	0,0232*
Asien	73	14 (19,2)	NE [NE; NE]	33	3 (9,1)	NE [NE; NE]	2,09	[0,68; 9,08]	0,2112
Rest der Welt	126	8 (6,3)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	3,84	[0,70; 71,33]	0,1337
Interaktion p-Wert									0,6258

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.12 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	234 (89,0)	0,2 [0,1; 0,2]	129	92 (71,3)	4,1 [1,7; 6,2]	2,16	[1,70; 2,77]	<0,0001*
>=65 Jahre	37	34 (91,9)	0,2 [0,1; 0,5]	20	18 (90,0)	4,1 [0,5; 5,4]	1,75	[0,998; 3,17]	0,0509
Interaktion p-Wert									0,5078
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	220 (89,1)	0,1 [0,1; 0,2]	123	90 (73,2)	3,3 [1,4; 4,8]	2,10	[1,65; 2,70]	<0,0001*
Partielles Ansprechen	53	48 (90,6)	0,2 [0,1; 0,4]	26	20 (76,9)	4,4 [1,9;10,8]	2,05	[1,23; 3,54]	0,0051*
Interaktion p-Wert									0,9388
ECOG PS Status									
Normale Aktivität	221	200 (90,5)	0,2 [0,1; 0,3]	115	85 (73,9)	4,1 [1,7; 5,3]	2,07	[1,61; 2,68]	<0,0001*
Eingeschränkte Aktivität	79	68 (86,1)	0,1 [0,1; 0,2]	34	25 (73,5)	4,3 [0,7;10,8]	2,17	[1,39; 3,50]	0,0005*
Interaktion p-Wert									0,8534
Baseline CA-125 Wert									
<=ULN	286	256 (89,5)	0,1 [0,1; 0,2]	142	104 (73,2)	4,2 [2,0; 5,4]	2,17	[1,73; 2,74]	<0,0001*
>ULN	14	12 (85,7)	0,3 [0,1; 0,9]	7	6 (85,7)	0,8 [0,0; 4,1]	0,94	[0,37; 2,71]	0,9066
Interaktion p-Wert									0,1233
FIGO Stadium									
III	254	229 (90,2)	0,2 [0,1; 0,2]	122	91 (74,6)	2,8 [0,8; 4,6]	2,03	[1,59; 2,61]	<0,0001*
IV	46	39 (84,8)	0,1 [0,1; 0,3]	27	19 (70,4)	6,5 [2,2;11,8]	2,34	[1,37; 4,15]	0,0017*
Interaktion p-Wert									0,6354
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	175 (93,1)	0,2 [0,1; 0,2]	90	63 (70,0)	4,2 [1,9; 8,0]	2,53	[1,90; 3,41]	<0,0001*
BRCA2	62	55 (88,7)	0,2 [0,1; 0,6]	39	34 (87,2)	2,3 [0,3; 4,6]	1,61	[1,06; 2,50]	0,0270*
Interaktion p-Wert									0,0890

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.12 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	57 (85,1)	0,2 [0,1; 0,5]	34	21 (61,8)	9,8 [1,0;15,8]	2,42	[1,49; 4,10]	0,0003*
Keine makroskopische Resterkrankung	228	206 (90,4)	0,1 [0,1; 0,2]	111	87 (78,4)	3,0 [0,8; 4,6]	1,94	[1,52; 2,52]	<0,0001*
Interaktion p-Wert									0,4346
Abstammung									
Weiß	214	196 (91,6)	0,2 [0,1; 0,3]	105	84 (80,0)	2,3 [0,5; 4,5]	1,86	[1,44; 2,42]	<0,0001*
Andere	86	72 (83,7)	0,1 [0,1; 0,2]	44	26 (59,1)	11,8 [4,2;22,5]	2,79	[1,80; 4,45]	<0,0001*
Interaktion p-Wert									0,1181
Region									
Europa	101	97 (96,0)	0,1 [0,1; 0,2]	53	42 (79,2)	1,9 [0,3; 4,6]	2,31	[1,62; 3,36]	<0,0001*
Asien	73	59 (80,8)	0,1 [0,1; 0,3]	33	20 (60,6)	9,8 [4,4;14,6]	2,40	[1,47; 4,08]	0,0004*
Rest der Welt	126	112 (88,9)	0,2 [0,1; 0,3]	63	48 (76,2)	2,9 [0,8; 4,6]	1,88	[1,35; 2,67]	0,0002*
Interaktion p-Wert									0,6363

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.13 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Erbrechen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	104 (39,5)	NE [NE; NE]	129	21 (16,3)	NE [NE; NE]	2,70	[1,73; 4,44]	<0,0001*
>=65 Jahre	37	17 (45,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	12,07	[2,48;217,74]	0,0005*
Interaktion p-Wert									0,0845
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	102 (41,3)	NE [NE; NE]	123	20 (16,3)	NE [NE; NE]	3,00	[1,90; 4,99]	<0,0001*
Partielles Ansprechen	53	19 (35,8)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	4,31	[1,25; 27,06]	0,0174*
Interaktion p-Wert									0,6310
ECOG PS Status									
Normale Aktivität	221	84 (38,0)	NE [NE; NE]	115	16 (13,9)	NE [NE; NE]	3,00	[1,81; 5,32]	<0,0001*
Eingeschränkte Aktivität	79	37 (46,8)	20,6 [5,4; NE]	34	6 (17,6)	NE [NE; NE]	3,30	[1,50; 8,69]	0,0020*
Interaktion p-Wert									0,8568
Baseline CA-125 Wert									
<=ULN	286	119 (41,6)	NE [NE; NE]	142	22 (15,5)	NE [NE; NE]	3,09	[2,00; 5,00]	<0,0001*
>ULN	14	2 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	101 (39,8)	NE [NE; NE]	122	18 (14,8)	NE [NE; NE]	3,03	[1,89; 5,18]	<0,0001*
IV	46	20 (43,5)	20,6 [6,3; NE]	27	4 (14,8)	NE [NE; NE]	3,45	[1,30; 11,85]	0,0107*
Interaktion p-Wert									0,8316
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	75 (39,9)	NE [NE; NE]	90	13 (14,4)	NE [NE; NE]	3,08	[1,77; 5,81]	<0,0001*
BRCA2	62	26 (41,9)	NE [NE; NE]	39	6 (15,4)	NE [NE; NE]	3,12	[1,37; 8,37]	0,0054*
Interaktion p-Wert									0,9825

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.13 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Erbrechen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	27 (40,3)	NE [NE; NE]	34	5 (14,7)	NE [NE; NE]	2,89	[1,21; 8,54]	0,0146*
Keine makroskopische Resterkrankung	228	93 (40,8)	NE [NE; NE]	111	17 (15,3)	NE [NE; NE]	3,13	[1,92; 5,43]	<0,0001*
Interaktion p-Wert									0,8899
Abstammung									
Weiß	214	87 (40,7)	NE [NE; NE]	105	15 (14,3)	NE [NE; NE]	3,15	[1,88; 5,66]	<0,0001*
Andere	86	34 (39,5)	NE [NE; NE]	44	7 (15,9)	NE [NE; NE]	3,00	[1,41; 7,38]	0,0032*
Interaktion p-Wert									0,9231
Region									
Europa	101	48 (47,5)	16,6 [9,6; NE]	53	9 (17,0)	NE [NE; NE]	3,24	[1,67; 7,07]	0,0003*
Asien	73	28 (38,4)	NE [NE; NE]	33	5 (15,2)	NE [NE; NE]	3,10	[1,31; 9,14]	0,0085*
Rest der Welt	126	45 (35,7)	NE [NE; NE]	63	8 (12,7)	NE [NE; NE]	3,01	[1,50; 6,89]	0,0012*
Interaktion p-Wert									0,9898

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.14 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Haemorrhoiden
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	11 (4,2)	NE [NE; NE]	129	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	8 (3,2)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	3 (5,7)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	9 (4,1)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	10 (3,5)	NE [NE; NE]	142	0	NE [NE; NE]	NC	[NC]	NC
>ULN	14	1 (7,1)	92,3 [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	8 (3,1)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	3 (6,5)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	10 (5,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	0	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.14 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Haemorrhoiden
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	2 (3,0)	92,3 [92,3; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	7 (3,1)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	9 (4,2)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	2 (2,3)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	3 (3,0)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	1 (1,4)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	7 (5,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.15 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Mundulzeration
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	10 (3,8)	NE [NE; NE]	129	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	1 (2,7)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	9 (3,6)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	2 (3,8)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	6 (2,7)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	5 (6,3)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	10 (3,5)	NE [NE; NE]	142	0	NE [NE; NE]	NC	[NC]	NC
>ULN	14	1 (7,1)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	11 (4,3)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	0	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	3 (1,6)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	2 (3,2)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.15 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Mundulzeration
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	4 (6,0)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	7 (3,1)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	5 (2,3)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	6 (7,0)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	3 (3,0)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	5 (6,8)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubae1.sas gttesubae1aao 01MAR2023:11:31 kfrh585

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.16 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Stomatitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	19 (7,2)	NE [NE; NE]	129	3 (2,3)	NE [NE; NE]	2,90	[0,98; 12,35]	0,0539
>=65 Jahre	37	4 (10,8)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	17 (6,9)	NE [NE; NE]	123	3 (2,4)	NE [NE; NE]	2,72	[0,91; 11,66]	0,0754
Partielles Ansprechen	53	6 (11,3)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	18 (8,1)	NE [NE; NE]	115	3 (2,6)	NE [NE; NE]	2,87	[0,97; 12,27]	0,0584
Eingeschränkte Aktivität	79	5 (6,3)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	21 (7,3)	NE [NE; NE]	142	3 (2,1)	NE [NE; NE]	3,29	[1,13; 13,96]	0,0266*
>ULN	14	2 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	16 (6,3)	NE [NE; NE]	122	2 (1,6)	NE [NE; NE]	3,63	[1,03; 22,97]	0,0440*
IV	46	7 (15,2)	NE [NE; NE]	27	1 (3,7)	NE [NE; NE]	3,94	[0,70; 73,64]	0,1328
Interaktion p-Wert									0,9501
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	15 (8,0)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	3,54	[0,999; 22,49]	0,0503
BRCA2	62	7 (11,3)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	4,27	[0,76; 79,85]	0,1088
Interaktion p-Wert									0,8859

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.16 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Stomatitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	6 (9,0)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	14 (6,1)	NE [NE; NE]	111	3 (2,7)	NE [NE; NE]	2,15	[0,70; 9,35]	0,1939
Interaktion p-Wert									NC
Abstammung									
Weiß	214	17 (7,9)	NE [NE; NE]	105	2 (1,9)	NE [NE; NE]	3,97	[1,14; 25,08]	0,0283*
Andere	86	6 (7,0)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	2,86	[0,49; 53,96]	0,2749
Interaktion p-Wert									0,8043
Region									
Europa	101	9 (8,9)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	4,49	[0,84; 82,89]	0,0844
Asien	73	4 (5,5)	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	1,69	[0,25; 33,07]	0,6217
Rest der Welt	126	10 (7,9)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	4,74	[0,91; 87,05]	0,0683
Interaktion p-Wert									0,7744

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.17 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Uebelkeit
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	202 (76,8)	0,3 [0,2; 0,3]	129	48 (37,2)	NE [NE; NE]	3,30	[2,43; 4,58]	<0,0001*
>=65 Jahre	37	26 (70,3)	0,4 [0,1; 3,7]	20	6 (30,0)	NE [NE; NE]	3,73	[1,64; 10,02]	0,0011*
Interaktion p-Wert									0,7986
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	188 (76,1)	0,3 [0,2; 0,5]	123	48 (39,0)	NE [NE; NE]	3,16	[2,32; 4,40]	<0,0001*
Partielles Ansprechen	53	40 (75,5)	0,2 [0,1; 0,8]	26	6 (23,1)	NE [NE; NE]	4,92	[2,25; 12,93]	<0,0001*
Interaktion p-Wert									0,3254
ECOG PS Status									
Normale Aktivität	221	169 (76,5)	0,3 [0,2; 0,5]	115	42 (36,5)	NE [NE; NE]	3,27	[2,35; 4,64]	<0,0001*
Eingeschränkte Aktivität	79	59 (74,7)	0,2 [0,1; 0,3]	34	12 (35,3)	NE [NE; NE]	3,66	[2,04; 7,15]	<0,0001*
Interaktion p-Wert									0,7513
Baseline CA-125 Wert									
<=ULN	286	218 (76,2)	0,3 [0,2; 0,4]	142	51 (35,9)	NE [NE; NE]	3,46	[2,57; 4,75]	<0,0001*
>ULN	14	10 (71,4)	0,3 [0,1; NE]	7	3 (42,9)	NE [NE; NE]	1,75	[0,53; 7,79]	0,3760
Interaktion p-Wert									0,3398
FIGO Stadium									
III	254	192 (75,6)	0,3 [0,2; 0,5]	122	43 (35,2)	NE [NE; NE]	3,39	[2,45; 4,78]	<0,0001*
IV	46	36 (78,3)	0,2 [0,1; 0,3]	27	11 (40,7)	12,5 [8,8; NE]	3,31	[1,74; 6,83]	0,0002*
Interaktion p-Wert									0,9513
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	149 (79,3)	0,2 [0,1; 0,3]	90	32 (35,6)	NE [NE; NE]	3,82	[2,64; 5,71]	<0,0001*
BRCA2	62	46 (74,2)	0,7 [0,1; 3,7]	39	17 (43,6)	NE [NE; NE]	2,34	[1,37; 4,20]	0,0016*
Interaktion p-Wert									0,1609

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.17 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Uebelkeit
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	46 (68,7)	0,4 [0,2; 1,4]	34	9 (26,5)	NE [NE; NE]	3,73	[1,92; 8,16]	<0,0001*
Keine makroskopische Resterkrankung	228	178 (78,1)	0,2 [0,1; 0,3]	111	45 (40,5)	NE [NE; NE]	3,18	[2,31; 4,47]	<0,0001*
Interaktion p-Wert									0,6862
Abstammung									
Weiß	214	167 (78,0)	0,3 [0,2; 0,5]	105	43 (41,0)	NE [NE; NE]	2,96	[2,14; 4,20]	<0,0001*
Andere	86	61 (70,9)	0,2 [0,1; 0,8]	44	11 (25,0)	NE [NE; NE]	4,84	[2,65; 9,73]	<0,0001*
Interaktion p-Wert									0,1705
Region									
Europa	101	84 (83,2)	0,2 [0,1; 0,3]	53	23 (43,4)	NE [NE; NE]	3,36	[2,15; 5,46]	<0,0001*
Asien	73	51 (69,9)	0,3 [0,1; 1,2]	33	8 (24,2)	NE [NE; NE]	4,82	[2,42; 11,00]	<0,0001*
Rest der Welt	126	93 (73,8)	0,3 [0,2; 1,0]	63	23 (36,5)	NE [NE; NE]	2,98	[1,92; 4,81]	<0,0001*
Interaktion p-Wert									0,5380

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.18 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dysgeusie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	51 (19,4)	NE [NE; NE]	129	5 (3,9)	NE [NE; NE]	5,32	[2,34; 15,29]	<0,0001*
>=65 Jahre	37	8 (21,6)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	50 (20,2)	NE [NE; NE]	123	4 (3,3)	NE [NE; NE]	6,67	[2,73; 22,09]	<0,0001*
Partielles Ansprechen	53	9 (17,0)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	4,36	[0,82; 80,35]	0,0920
Interaktion p-Wert									0,7263
ECOG PS Status									
Normale Aktivität	221	44 (19,9)	NE [NE; NE]	115	4 (3,5)	NE [NE; NE]	6,04	[2,45; 20,05]	<0,0001*
Eingeschränkte Aktivität	79	15 (19,0)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	6,87	[1,39;124,21]	0,0132*
Interaktion p-Wert									0,9097
Baseline CA-125 Wert									
<=ULN	286	56 (19,6)	NE [NE; NE]	142	5 (3,5)	NE [NE; NE]	5,89	[2,60; 16,90]	<0,0001*
>ULN	14	3 (21,4)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	47 (18,5)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	5,90	[2,40; 19,57]	<0,0001*
IV	46	12 (26,1)	NE [NE; NE]	27	1 (3,7)	NE [NE; NE]	7,92	[1,56;144,30]	0,0084*
Interaktion p-Wert									0,7957
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	44 (23,4)	NE [NE; NE]	90	4 (4,4)	NE [NE; NE]	5,72	[2,32; 19,01]	<0,0001*
BRCA2	62	9 (14,5)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	5,62	[1,06;103,75]	0,0417*
Interaktion p-Wert									0,9884

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubae1.sas gttesubae1aar 01MAR2023:11:31 kfrh585

Table 3.4.18 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Dysgeusie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	9 (13,4)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	49 (21,5)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	5,10	[2,24; 14,69]	<0,0001*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	47 (22,0)	NE [NE; NE]	105	4 (3,8)	NE [NE; NE]	6,17	[2,51; 20,47]	<0,0001*
Andere	86	12 (14,0)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	6,29	[1,24;114,60]	0,0226*
Interaktion p-Wert									0,9869
Region									
Europa	101	23 (22,8)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	12,77	[2,69;228,37]	0,0002*
Asien	73	9 (12,3)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	27 (21,4)	NE [NE; NE]	63	4 (6,3)	NE [NE; NE]	3,61	[1,41; 12,23]	0,0054*
Interaktion p-Wert									0,2299

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.19 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Somnolenz
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	8 (3,0)	NE [NE; NE]	129	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	2 (5,4)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	9 (3,6)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	1 (1,9)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	8 (3,6)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	10 (3,5)	NE [NE; NE]	142	0	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	8 (3,1)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	2 (4,3)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	5 (2,7)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	4 (6,5)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.19 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Somnolenz
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	3 (4,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	7 (3,1)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	8 (3,7)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	2 (2,3)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	6 (5,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	1 (1,4)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.20 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Hypertonie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	9 (3,4)	NE [NE; NE]	129	10 (7,8)	NE [NE; NE]	0,36	[0,14; 0,90]	0,0296*
>=65 Jahre	37	1 (2,7)	NE [NE; NE]	20	2 (10,0)	NE [NE; NE]	0,20	[0,01; 2,14]	0,1773
Interaktion p-Wert									0,6514
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	8 (3,2)	NE [NE; NE]	123	10 (8,1)	NE [NE; NE]	0,36	[0,14; 0,92]	0,0325*
Partielles Ansprechen	53	2 (3,8)	NE [NE; NE]	26	2 (7,7)	NE [NE; NE]	0,25	[0,03; 2,14]	0,1873
Interaktion p-Wert									0,7395
ECOG PS Status									
Normale Aktivität	221	7 (3,2)	NE [NE; NE]	115	10 (8,7)	NE [NE; NE]	0,27	[0,09; 0,72]	0,0090*
Eingeschränkte Aktivität	79	3 (3,8)	NE [NE; NE]	34	2 (5,9)	NE [NE; NE]	0,65	[0,11; 4,96]	0,6455
Interaktion p-Wert									0,3940
Baseline CA-125 Wert									
<=ULN	286	9 (3,1)	NE [NE; NE]	142	11 (7,7)	NE [NE; NE]	0,33	[0,13; 0,81]	0,0156*
>ULN	14	1 (7,1)	35,0 [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,28	[0,01; 7,13]	0,3837
Interaktion p-Wert									0,9067
FIGO Stadium									
III	254	9 (3,5)	NE [NE; NE]	122	12 (9,8)	NE [NE; NE]	0,30	[0,12; 0,71]	0,0068*
IV	46	1 (2,2)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	6 (3,2)	NE [NE; NE]	90	5 (5,6)	NE [NE; NE]	0,51	[0,15; 1,77]	0,2754
BRCA2	62	3 (4,8)	NE [NE; NE]	39	7 (17,9)	NE [NE; NE]	0,17	[0,04; 0,65]	0,0091*
Interaktion p-Wert									0,2379

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.20 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Hypertonie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	2 (3,0)	NE [NE; NE]	34	2 (5,9)	NE [NE; NE]	0,33	[0,04; 2,82]	0,2865
Keine makroskopische Resterkrankung	228	8 (3,5)	NE [NE; NE]	111	10 (9,0)	NE [NE; NE]	0,34	[0,13; 0,87]	0,0247*
Interaktion p-Wert									0,9782
Abstammung									
Weiß	214	7 (3,3)	NE [NE; NE]	105	11 (10,5)	NE [NE; NE]	0,24	[0,09; 0,63]	0,0037*
Andere	86	3 (3,5)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	1,31	[0,17; 26,58]	0,8093
Interaktion p-Wert									0,1495
Region									
Europa	101	4 (4,0)	NE [NE; NE]	53	7 (13,2)	NE [NE; NE]	0,22	[0,05; 0,74]	0,0145*
Asien	73	1 (1,4)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	5 (4,0)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	0,40	[0,11; 1,47]	0,1618
Interaktion p-Wert									0,4808

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.21 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Bronchitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	9 (3,4)	NE [NE; NE]	129	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	5 (13,5)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	13 (5,3)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	1 (1,9)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	12 (5,4)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	14 (4,9)	NE [NE; NE]	142	0	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	12 (4,7)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	2 (4,3)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	7 (3,7)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	3 (4,8)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.21 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Bronchitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	13 (5,7)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	13 (6,1)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	1 (1,2)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	6 (5,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	1 (1,4)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	7 (5,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.22 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Leber- und Gallenerkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	9 (3,4)	NE [NE; NE]	129	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	1 (2,7)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	6 (2,4)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	4 (7,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	7 (3,2)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	3 (3,8)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	9 (3,1)	NE [NE; NE]	142	0	NE [NE; NE]	NC	[NC]	NC
>ULN	14	1 (7,1)	40,9 [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	9 (3,5)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	1 (2,2)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	4 (2,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	0	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.22 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Leber- und Gallenerkrankungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	5 (7,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	5 (2,2)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	6 (7,0)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	2 (2,0)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	6 (8,2)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	2 (1,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 2
Nutzenbewertung nach AMNOG

Table 3.4.23 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Muskelspasmen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	15 (5,7)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	6,44	[1,30;116,63]	0,0179*
>=65 Jahre	37	4 (10,8)	64,6 [64,6; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	14 (5,7)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	6,37	[1,28;115,56]	0,0196*
Partielles Ansprechen	53	5 (9,4)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	16 (7,2)	NE [NE; NE]	115	1 (0,9)	NE [NE; NE]	6,86	[1,38;124,14]	0,0136*
Eingeschränkte Aktivität	79	3 (3,8)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	17 (5,9)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	7,01	[1,43;126,58]	0,0117*
>ULN	14	2 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	16 (6,3)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	3 (6,5)	NE [NE; NE]	27	1 (3,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	12 (6,4)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	5 (8,1)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.23 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Muskelspasmen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	6 (9,0)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	11 (4,8)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	4,91	[0,95; 89,91]	0,0588
Interaktion p-Wert									NC
Abstammung									
Weiß	214	18 (8,4)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	7,52	[1,54;135,62]	0,0080*
Andere	86	1 (1,2)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	9 (8,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	1 (1,4)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	9 (7,1)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	4,11	[0,77; 75,79]	0,1089
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubae1.sas gttesubae1aaw 01MAR2023:11:31 kfrh585

Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.24 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	94 (35,7)	44,2 [28,3; NE]	129	30 (23,3)	NE [NE; NE]	1,60	[1,08; 2,46]	0,0195*
>=65 Jahre	37	15 (40,5)	NE [NE; NE]	20	5 (25,0)	NE [NE; NE]	1,61	[0,62; 4,95]	0,3410
Interaktion p-Wert									0,9997
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	82 (33,2)	52,5 [28,3; NE]	123	34 (27,6)	NE [NE; NE]	1,26	[0,85; 1,90]	0,2534
Partielles Ansprechen	53	27 (50,9)	24,4 [4,6; NE]	26	1 (3,8)	NE [NE; NE]	13,50	[2,87;240,97]	<0,0001*
Interaktion p-Wert									0,0014*
ECOG PS Status									
Normale Aktivität	221	77 (34,8)	52,5 [28,3; NE]	115	24 (20,9)	NE [NE; NE]	1,71	[1,09; 2,76]	0,0180*
Eingeschränkte Aktivität	79	32 (40,5)	44,2 [13,6; NE]	34	11 (32,4)	NE [NE; NE]	1,35	[0,70; 2,81]	0,3793
Interaktion p-Wert									0,5837
Baseline CA-125 Wert									
<=ULN	286	104 (36,4)	44,2 [28,3; NE]	142	35 (24,6)	NE [NE; NE]	1,54	[1,06; 2,29]	0,0236*
>ULN	14	5 (35,7)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	89 (35,0)	44,2 [28,3; NE]	122	30 (24,6)	NE [NE; NE]	1,48	[0,99; 2,28]	0,0551
IV	46	20 (43,5)	55,3 [6,5; NE]	27	5 (18,5)	NE [NE; NE]	2,40	[0,97; 7,24]	0,0591
Interaktion p-Wert									0,3599
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	68 (36,2)	44,2 [44,2; NE]	90	17 (18,9)	NE [NE; NE]	1,97	[1,18; 3,46]	0,0080*
BRCA2	62	20 (32,3)	28,3 [28,3; NE]	39	12 (30,8)	NE [NE; NE]	0,97	[0,48; 2,06]	0,9432
Interaktion p-Wert									0,1248

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.24 SOLO1: Summary of subgroup analysis of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	28 (41,8)	44,2 [16,6; NE]	34	4 (11,8)	NE [NE; NE]	3,79	[1,49; 12,82]	0,0036*
Keine makroskopische Resterkrankung	228	78 (34,2)	52,5 [28,3; NE]	111	31 (27,9)	NE [NE; NE]	1,27	[0,85; 1,96]	0,2518
Interaktion p-Wert									0,0376*
Abstammung									
Weiß	214	74 (34,6)	52,5 [28,3; NE]	105	25 (23,8)	NE [NE; NE]	1,43	[0,92; 2,29]	0,1164
Andere	86	35 (40,7)	44,2 [13,8; NE]	44	10 (22,7)	NE [NE; NE]	2,12	[1,09; 4,53]	0,0255*
Interaktion p-Wert									0,3458
Region									
Europa	101	30 (29,7)	55,3 [52,5; NE]	53	7 (13,2)	NE [NE; NE]	2,27	[1,05; 5,63]	0,0353*
Asien	73	28 (38,4)	44,2 [17,6; NE]	33	7 (21,2)	NE [NE; NE]	2,17	[1,001; 5,39]	0,0498*
Rest der Welt	126	51 (40,5)	28,3 [23,3; NE]	63	21 (33,3)	NE [NE; NE]	1,18	[0,72; 2,01]	0,5222
Interaktion p-Wert									0,2712

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.25 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Appetit vermindert
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	61 (23,2)	NE [NE; NE]	129	12 (9,3)	NE [NE; NE]	2,61	[1,46; 5,09]	0,0008*
>=65 Jahre	37	9 (24,3)	NE [NE; NE]	20	2 (10,0)	NE [NE; NE]	2,45	[0,63; 16,09]	0,2106
Interaktion p-Wert									0,9426
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	55 (22,3)	NE [NE; NE]	123	14 (11,4)	NE [NE; NE]	2,04	[1,17; 3,83]	0,0111*
Partielles Ansprechen	53	15 (28,3)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	48 (21,7)	NE [NE; NE]	115	10 (8,7)	NE [NE; NE]	2,57	[1,36; 5,39]	0,0029*
Eingeschränkte Aktivität	79	22 (27,8)	NE [NE; NE]	34	4 (11,8)	NE [NE; NE]	2,54	[0,97; 8,69]	0,0577
Interaktion p-Wert									0,9866
Baseline CA-125 Wert									
<=ULN	286	68 (23,8)	NE [NE; NE]	142	14 (9,9)	NE [NE; NE]	2,53	[1,47; 4,69]	0,0005*
>ULN	14	2 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	61 (24,0)	NE [NE; NE]	122	12 (9,8)	NE [NE; NE]	2,56	[1,43; 4,99]	0,0011*
IV	46	9 (19,6)	NE [NE; NE]	27	2 (7,4)	NE [NE; NE]	2,66	[0,68; 17,46]	0,1701
Interaktion p-Wert									0,9630
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	42 (22,3)	NE [NE; NE]	90	8 (8,9)	NE [NE; NE]	2,56	[1,27; 5,89]	0,0072*
BRCA2	62	11 (17,7)	NE [NE; NE]	39	5 (12,8)	NE [NE; NE]	1,32	[0,48; 4,19]	0,6037
Interaktion p-Wert									0,3236

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.25 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Appetit vermindert
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	14 (20,9)	NE [NE; NE]	34	2 (5,9)	NE [NE; NE]	3,66	[1,02; 23,29]	0,0461*
Keine makroskopische Resterkrankung	228	55 (24,1)	NE [NE; NE]	111	12 (10,8)	NE [NE; NE]	2,34	[1,30; 4,59]	0,0037*
Interaktion p-Wert									0,5736
Abstammung									
Weiß	214	44 (20,6)	NE [NE; NE]	105	13 (12,4)	NE [NE; NE]	1,64	[0,91; 3,18]	0,1017
Andere	86	26 (30,2)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	15,68	[3,33;279,89]	<0,0001*
Interaktion p-Wert									0,0060*
Region									
Europa	101	22 (21,8)	NE [NE; NE]	53	4 (7,5)	NE [NE; NE]	2,93	[1,12; 10,02]	0,0269*
Asien	73	22 (30,1)	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	11,79	[2,48;211,28]	0,0004*
Rest der Welt	126	26 (20,6)	NE [NE; NE]	63	9 (14,3)	NE [NE; NE]	1,42	[0,69; 3,22]	0,3477
Interaktion p-Wert									0,0555

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.26 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	17 (6,5)	NE [NE; NE]	129	13 (10,1)	41,6 [NE; NE]	0,42	[0,20; 0,91]	0,0290*
>=65 Jahre	37	1 (2,7)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	0,34	[0,01; 8,75]	0,4616
Interaktion p-Wert									0,8879
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	13 (5,3)	NE [NE; NE]	123	12 (9,8)	NE [NE; NE]	0,43	[0,19; 0,96]	0,0406*
Partielles Ansprechen	53	5 (9,4)	NE [NE; NE]	26	2 (7,7)	41,6 [NE; NE]	0,37	[0,07; 2,73]	0,2889
Interaktion p-Wert									0,8680
ECOG PS Status									
Normale Aktivität	221	14 (6,3)	NE [NE; NE]	115	8 (7,0)	NE [NE; NE]	0,58	[0,24; 1,48]	0,2427
Eingeschränkte Aktivität	79	4 (5,1)	NE [NE; NE]	34	6 (17,6)	41,6 [NE; NE]	0,22	[0,05; 0,77]	0,0184*
Interaktion p-Wert									0,2075
Baseline CA-125 Wert									
<=ULN	286	17 (5,9)	NE [NE; NE]	142	14 (9,9)	41,6 [NE; NE]	0,39	[0,18; 0,84]	0,0169*
>ULN	14	1 (7,1)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	13 (5,1)	NE [NE; NE]	122	11 (9,0)	41,6 [NE; NE]	0,40	[0,17; 0,92]	0,0316*
IV	46	5 (10,9)	NE [NE; NE]	27	3 (11,1)	NE [NE; NE]	0,54	[0,12; 2,74]	0,4283
Interaktion p-Wert									0,7125
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	8 (4,3)	NE [NE; NE]	90	7 (7,8)	41,6 [NE; NE]	0,35	[0,12; 1,03]	0,0557
BRCA2	62	2 (3,2)	NE [NE; NE]	39	3 (7,7)	NE [NE; NE]	0,17	[0,02; 1,13]	0,0664
Interaktion p-Wert									0,5111

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.26 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	5 (7,5)	NE [NE; NE]	34	6 (17,6)	41,6 [NE; NE]	0,23	[0,06; 0,80]	0,0213*
Keine makroskopische Resterkrankung	228	12 (5,3)	NE [NE; NE]	111	8 (7,2)	NE [NE; NE]	0,57	[0,23; 1,47]	0,2357
Interaktion p-Wert									0,2296
Abstammung									
Weiß	214	7 (3,3)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	0,31	[0,10; 0,94]	0,0394*
Andere	86	11 (12,8)	NE [NE; NE]	44	7 (15,9)	41,6 [NE; NE]	0,55	[0,21; 1,52]	0,2390
Interaktion p-Wert									0,4393
Region									
Europa	101	4 (4,0)	NE [NE; NE]	53	4 (7,5)	NE [NE; NE]	0,32	[0,07; 1,39]	0,1245
Asien	73	10 (13,7)	77,3 [77,3; NE]	33	6 (18,2)	41,6 [21,9; NE]	0,55	[0,20; 1,65]	0,2726
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	4 (6,3)	NE [NE; NE]	0,31	[0,07; 1,34]	0,1123
Interaktion p-Wert									0,7396

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.27 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Kreatinin im Blut erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	21 (8,0)	NE [NE; NE]	129	2 (1,6)	NE [NE; NE]	4,21	[1,22; 26,43]	0,0195*
>=65 Jahre	37	3 (8,1)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	18 (7,3)	NE [NE; NE]	123	2 (1,6)	NE [NE; NE]	4,08	[1,17; 25,69]	0,0241*
Partielles Ansprechen	53	6 (11,3)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	14 (6,3)	NE [NE; NE]	115	1 (0,9)	NE [NE; NE]	5,89	[1,17;106,87]	0,0276*
Eingeschränkte Aktivität	79	10 (12,7)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	3,96	[0,75; 72,86]	0,1157
Interaktion p-Wert									0,7891
Baseline CA-125 Wert									
<=ULN	286	23 (8,0)	NE [NE; NE]	142	2 (1,4)	NE [NE; NE]	4,96	[1,46; 30,96]	0,0072*
>ULN	14	1 (7,1)	38,7 [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	18 (7,1)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	7,37	[1,52;132,80]	0,0084*
IV	46	6 (13,0)	NE [NE; NE]	27	1 (3,7)	NE [NE; NE]	2,69	[0,45; 51,19]	0,3093
Interaktion p-Wert									0,5060
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	15 (8,0)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	4 (6,5)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.27 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Kreatinin im Blut erhoeht
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	3 (4,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	21 (9,2)	74,5 [74,5; NE]	111	2 (1,8)	NE [NE; NE]	4,53	[1,32; 28,40]	0,0130*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	18 (8,4)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	7,40	[1,52;133,27]	0,0085*
Andere	86	6 (7,0)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	2,52	[0,43; 47,74]	0,3430
Interaktion p-Wert									0,4778
Region									
Europa	101	11 (10,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	6 (8,2)	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	7 (5,6)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.28 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Baenderzerrung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	10 (3,8)	NE [NE; NE]	129	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	1 (2,7)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	9 (3,6)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	2 (3,8)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	5 (2,3)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	6 (7,6)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	11 (3,8)	NE [NE; NE]	142	0	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	10 (3,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	1 (2,2)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	8 (4,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.28 SOLO1: Summary of subgroup analysis of time to first occurrence of UE PT: Baenderzerrung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	10 (4,4)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	8 (3,7)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	3 (3,5)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	4 (4,0)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	3 (4,1)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.29 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	59 (22,4)	NE [NE; NE]	129	20 (15,5)	61,0 [NE; NE]	1,34	[0,82; 2,29]	0,2491
>=65 Jahre	37	8 (21,6)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	3,97	[0,73; 73,68]	0,1243
Interaktion p-Wert									0,2637
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	51 (20,6)	NE [NE; NE]	123	19 (15,4)	NE [NE; NE]	1,31	[0,78; 2,27]	0,3125
Partielles Ansprechen	53	16 (30,2)	NE [NE; NE]	26	2 (7,7)	61,0 [NE; NE]	2,88	[0,81; 18,32]	0,1091
Interaktion p-Wert									0,2850
ECOG PS Status									
Normale Aktivität	221	52 (23,5)	NE [NE; NE]	115	12 (10,4)	NE [NE; NE]	2,04	[1,12; 4,01]	0,0183*
Eingeschränkte Aktivität	79	15 (19,0)	41,2 [41,2; NE]	34	9 (26,5)	61,0 [15,4; NE]	0,72	[0,32; 1,72]	0,4447
Interaktion p-Wert									0,0533
Baseline CA-125 Wert									
<=ULN	286	64 (22,4)	NE [NE; NE]	142	20 (14,1)	61,0 [NE; NE]	1,49	[0,92; 2,54]	0,1090
>ULN	14	3 (21,4)	42,1 [14,3; NE]	7	1 (14,3)	NE [NE; NE]	0,92	[0,12; 18,73]	0,9462
Interaktion p-Wert									0,6971
FIGO Stadium									
III	254	55 (21,7)	51,7 [41,2; NE]	122	16 (13,1)	61,0 [NE; NE]	1,57	[0,92; 2,84]	0,1000
IV	46	12 (26,1)	NE [NE; NE]	27	5 (18,5)	NE [NE; NE]	1,14	[0,42; 3,63]	0,8008
Interaktion p-Wert									0,6063
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	39 (20,7)	NE [NE; NE]	90	13 (14,4)	61,0 [NE; NE]	1,37	[0,75; 2,66]	0,3208
BRCA2	62	15 (24,2)	51,7 [41,2; NE]	39	5 (12,8)	NE [NE; NE]	1,57	[0,60; 4,87]	0,3666
Interaktion p-Wert									0,8140

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.29 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	22 (32,8)	42,1 [41,2; NE]	34	6 (17,6)	61,0 [19,2; NE]	1,75	[0,75; 4,77]	0,2012
Keine makroskopische Resterkrankung	228	44 (19,3)	NE [NE; NE]	111	15 (13,5)	NE [NE; NE]	1,34	[0,76; 2,49]	0,3208
Interaktion p-Wert									0,6190
Abstammung									
Weiß	214	45 (21,0)	NE [NE; NE]	105	14 (13,3)	NE [NE; NE]	1,42	[0,79; 2,69]	0,2462
Andere	86	22 (25,6)	NE [NE; NE]	44	7 (15,9)	61,0 [NE; NE]	1,61	[0,72; 4,06]	0,2584
Interaktion p-Wert									0,8131
Region									
Europa	101	22 (21,8)	NE [NE; NE]	53	8 (15,1)	NE [NE; NE]	1,31	[0,60; 3,14]	0,5090
Asien	73	19 (26,0)	NE [NE; NE]	33	6 (18,2)	61,0 [21,9; NE]	1,52	[0,64; 4,18]	0,3557
Rest der Welt	126	26 (20,6)	51,7 [41,2; NE]	63	7 (11,1)	NE [NE; NE]	1,61	[0,74; 4,05]	0,2421
Interaktion p-Wert									0,9359

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.30 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	25 (9,5)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	12,02	[2,54;214,70]	0,0003*
>=65 Jahre	37	6 (16,2)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	27 (10,9)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	13,57	[2,88;242,12]	<0,0001*
Partielles Ansprechen	53	4 (7,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	25 (11,3)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	6 (7,6)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	30 (10,5)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	14,99	[3,21;267,01]	<0,0001*
>ULN	14	1 (7,1)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	25 (9,8)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	11,80	[2,50;210,84]	0,0003*
IV	46	6 (13,0)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	13 (6,9)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	6,25	[1,24;113,59]	0,0221*
BRCA2	62	8 (12,9)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.30 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	10 (14,9)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	20 (8,8)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	9,33	[1,94;167,72]	0,0021*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	19 (8,9)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	9,00	[1,86;161,94]	0,0028*
Andere	86	12 (14,0)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	11 (10,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	11 (15,1)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	9 (7,1)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	3,69	[0,67; 68,62]	0,1488
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.31 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	22 (8,4)	NE [NE; NE]	129	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	4 (10,8)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	23 (9,3)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	3 (5,7)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	20 (9,0)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	6 (7,6)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	26 (9,1)	NE [NE; NE]	142	0	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	21 (8,3)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
IV	46	5 (10,9)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	11 (5,9)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	7 (11,3)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 3.4.31 SOLO1: Summary of subgroup analysis of time to first occurrence of SUE PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	9 (13,4)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	16 (7,0)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	16 (7,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	10 (11,6)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	10 (9,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	9 (12,3)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	7 (5,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.32 SOLO1: Summary of subgroup analysis of time to first occurrence of Abbruch wegen UE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	27 (10,3)	NE [NE; NE]	129	4 (3,1)	61,0 [NE; NE]	2,89	[1,12; 9,82]	0,0264*
>=65 Jahre	37	7 (18,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	29 (11,7)	NE [NE; NE]	123	3 (2,4)	NE [NE; NE]	4,65	[1,65; 19,43]	0,0020*
Partielles Ansprechen	53	5 (9,4)	NE [NE; NE]	26	1 (3,8)	61,0 [NE; NE]	1,48	[0,22; 29,20]	0,7151
Interaktion p-Wert									0,4050
ECOG PS Status									
Normale Aktivität	221	22 (10,0)	NE [NE; NE]	115	3 (2,6)	NE [NE; NE]	3,39	[1,17; 14,35]	0,0224*
Eingeschränkte Aktivität	79	12 (15,2)	NE [NE; NE]	34	1 (2,9)	61,0 [NE; NE]	4,94	[0,97; 90,01]	0,0554
Interaktion p-Wert									0,7498
Baseline CA-125 Wert									
<=ULN	286	32 (11,2)	NE [NE; NE]	142	4 (2,8)	61,0 [NE; NE]	3,72	[1,47; 12,54]	0,0037*
>ULN	14	2 (14,3)	91,7 [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	28 (11,0)	NE [NE; NE]	122	3 (2,5)	61,0 [NE; NE]	4,13	[1,46; 17,31]	0,0051*
IV	46	6 (13,0)	NE [NE; NE]	27	1 (3,7)	NE [NE; NE]	2,91	[0,49; 55,17]	0,2701
Interaktion p-Wert									0,7813
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	23 (12,2)	NE [NE; NE]	90	2 (2,2)	61,0 [NE; NE]	5,09	[1,50; 31,73]	0,0059*
BRCA2	62	8 (12,9)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	2,19	[0,54; 14,63]	0,2896
Interaktion p-Wert									0,4410

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.32 SOLO1: Summary of subgroup analysis of time to first occurrence of Abbruch wegen UE
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	6 (9,0)	NE [NE; NE]	34	1 (2,9)	61,0 [NE; NE]	2,51	[0,42; 47,60]	0,3468
Keine makroskopische Resterkrankung	228	28 (12,3)	NE [NE; NE]	111	3 (2,7)	NE [NE; NE]	4,23	[1,49; 17,73]	0,0043*
Interaktion p-Wert									0,6843
Abstammung									
Weiß	214	27 (12,6)	NE [NE; NE]	105	2 (1,9)	NE [NE; NE]	5,95	[1,77; 36,96]	0,0018*
Andere	86	7 (8,1)	NE [NE; NE]	44	2 (4,5)	61,0 [NE; NE]	1,67	[0,40; 11,20]	0,5052
Interaktion p-Wert									0,2506
Region									
Europa	101	11 (10,9)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	7 (9,6)	NE [NE; NE]	33	2 (6,1)	61,0 [NE; NE]	1,52	[0,37; 10,24]	0,5854
Rest der Welt	126	16 (12,7)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	3,41	[0,96; 21,74]	0,0597
Interaktion p-Wert									0,4668

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.33 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	111 (42,2)	41,2 [21,2; NE]	129	28 (21,7)	61,0 [NE; NE]	2,10	[1,40; 3,24]	0,0002*
>=65 Jahre	37	15 (40,5)	NE [NE; NE]	20	4 (20,0)	NE [NE; NE]	2,10	[0,76; 7,37]	0,1607
Interaktion p-Wert									0,9986
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	102 (41,3)	51,7 [21,2; NE]	123	29 (23,6)	NE [NE; NE]	1,97	[1,32; 3,03]	0,0007*
Partielles Ansprechen	53	24 (45,3)	41,2 [12,9; NE]	26	3 (11,5)	61,0 [NE; NE]	3,40	[1,18; 14,34]	0,0206*
Interaktion p-Wert									0,3735
ECOG PS Status									
Normale Aktivität	221	89 (40,3)	51,7 [42,1; NE]	115	17 (14,8)	NE [NE; NE]	2,87	[1,75; 5,00]	<0,0001*
Eingeschränkte Aktivität	79	37 (46,8)	21,2 [6,9; NE]	34	15 (44,1)	19,2 [9,4; NE]	1,19	[0,67; 2,24]	0,5581
Interaktion p-Wert									0,0321*
Baseline CA-125 Wert									
<=ULN	286	120 (42,0)	51,7 [21,2; NE]	142	31 (21,8)	61,0 [NE; NE]	2,08	[1,42; 3,15]	0,0001*
>ULN	14	6 (42,9)	42,1 [5,4; NE]	7	1 (14,3)	NE [NE; NE]	2,54	[0,43; 47,93]	0,3391
Interaktion p-Wert									0,8545
FIGO Stadium									
III	254	102 (40,2)	42,1 [41,2; NE]	122	27 (22,1)	61,0 [NE; NE]	1,94	[1,29; 3,02]	0,0012*
IV	46	24 (52,2)	6,5 [3,0; NE]	27	5 (18,5)	NE [NE; NE]	3,17	[1,31; 9,45]	0,0090*
Interaktion p-Wert									0,3428
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	78 (41,5)	42,1 [16,8; NE]	90	18 (20,0)	61,0 [NE; NE]	2,29	[1,41; 3,95]	0,0006*
BRCA2	62	23 (37,1)	41,2 [18,0; NE]	39	8 (20,5)	NE [NE; NE]	1,70	[0,79; 4,07]	0,1798
Interaktion p-Wert									0,5444

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.33 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	33 (49,3)	20,3 [7,0; NE]	34	6 (17,6)	61,0 [19,2; NE]	2,95	[1,33; 7,83]	0,0062*
Keine makroskopische Resterkrankung	228	91 (39,9)	51,7 [24,0; NE]	111	26 (23,4)	NE [NE; NE]	1,85	[1,21; 2,92]	0,0038*
Interaktion p-Wert									0,3298
Abstammung									
Weiß	214	79 (36,9)	42,1 [41,2; NE]	105	21 (20,0)	NE [NE; NE]	1,86	[1,17; 3,09]	0,0078*
Andere	86	47 (54,7)	6,5 [2,8; NE]	44	11 (25,0)	61,0 [15,4; NE]	2,77	[1,49; 5,63]	0,0009*
Interaktion p-Wert									0,3325
Region									
Europa	101	46 (45,5)	NE [NE; NE]	53	11 (20,8)	NE [NE; NE]	2,41	[1,29; 4,90]	0,0047*
Asien	73	43 (58,9)	5,6 [1,9;21,2]	33	11 (33,3)	61,0 [12,0; NE]	2,33	[1,25; 4,76]	0,0070*
Rest der Welt	126	37 (29,4)	42,1 [41,2; NE]	63	10 (15,9)	NE [NE; NE]	1,76	[0,91; 3,73]	0,0977
Interaktion p-Wert									0,7860

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.4.34 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	72 (27,4)	NE [NE; NE]	129	10 (7,8)	NE [NE; NE]	3,81	[2,06; 7,87]	<0,0001*
>=65 Jahre	37	12 (32,4)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	71 (28,7)	51,7 [51,7; NE]	123	10 (8,1)	NE [NE; NE]	3,96	[2,14; 8,19]	<0,0001*
Partielles Ansprechen	53	13 (24,5)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	61 (27,6)	NE [NE; NE]	115	6 (5,2)	NE [NE; NE]	5,69	[2,67; 14,76]	<0,0001*
Eingeschränkte Aktivität	79	23 (29,1)	NE [NE; NE]	34	4 (11,8)	NE [NE; NE]	2,88	[1,11; 9,83]	0,0282*
Interaktion p-Wert									0,3352
Baseline CA-125 Wert									
<=ULN	286	80 (28,0)	NE [NE; NE]	142	10 (7,0)	NE [NE; NE]	4,38	[2,38; 9,02]	<0,0001*
>ULN	14	4 (28,6)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	69 (27,2)	NE [NE; NE]	122	8 (6,6)	NE [NE; NE]	4,54	[2,32; 10,24]	<0,0001*
IV	46	15 (32,6)	NE [NE; NE]	27	2 (7,4)	NE [NE; NE]	4,95	[1,39; 31,43]	0,0105*
Interaktion p-Wert									0,9172
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	47 (25,0)	NE [NE; NE]	90	6 (6,7)	NE [NE; NE]	4,09	[1,89; 10,69]	0,0001*
BRCA2	62	16 (25,8)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	5,27	[1,50; 33,33]	0,0069*
Interaktion p-Wert									0,7672

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.34 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	20 (29,9)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	10,73	[2,24;192,84]	0,0008*
Keine makroskopische Resterkrankung	228	62 (27,2)	NE [NE; NE]	111	9 (8,1)	NE [NE; NE]	3,73	[1,95; 8,06]	<0,0001*
Interaktion p-Wert									0,2718
Abstammung									
Weiß	214	47 (22,0)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	3,44	[1,66; 8,34]	0,0004*
Andere	86	37 (43,0)	NE [NE; NE]	44	3 (6,8)	NE [NE; NE]	7,92	[2,86; 32,82]	<0,0001*
Interaktion p-Wert									0,2325
Region									
Europa	101	29 (28,7)	NE [NE; NE]	53	4 (7,5)	NE [NE; NE]	4,22	[1,66; 14,26]	0,0014*
Asien	73	33 (45,2)	NE [NE; NE]	33	3 (9,1)	NE [NE; NE]	6,41	[2,30; 26,67]	<0,0001*
Rest der Welt	126	22 (17,5)	NE [NE; NE]	63	3 (4,8)	NE [NE; NE]	3,66	[1,27; 15,47]	0,0139*
Interaktion p-Wert									0,7856

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.35 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE nach PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	62 (23,6)	NE [NE; NE]	129	2 (1,6)	NE [NE; NE]	16,58	[5,19;101,07]	<0,0001*
>=65 Jahre	37	9 (24,3)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	59 (23,9)	51,7 [51,7; NE]	123	2 (1,6)	NE [NE; NE]	16,60	[5,18;101,26]	<0,0001*
Partielles Ansprechen	53	12 (22,6)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	52 (23,5)	NE [NE; NE]	115	1 (0,9)	NE [NE; NE]	29,23	[6,43;517,61]	<0,0001*
Eingeschränkte Aktivität	79	19 (24,1)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	9,69	[2,01;174,10]	0,0017*
Interaktion p-Wert									0,4527
Baseline CA-125 Wert									
<=ULN	286	68 (23,8)	NE [NE; NE]	142	2 (1,4)	NE [NE; NE]	18,77	[5,89;114,32]	<0,0001*
>ULN	14	3 (21,4)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	58 (22,8)	NE [NE; NE]	122	2 (1,6)	NE [NE; NE]	15,18	[4,74; 92,63]	<0,0001*
IV	46	13 (28,3)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	42 (22,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	13 (21,0)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	4,28	[1,16; 27,55]	0,0266*
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.4.35 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UE nach PT: Anaemie
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	18 (26,9)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	51 (22,4)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	13,63	[4,23; 83,33]	<0,0001*
Interaktion p-Wert									NC
Abstammung									
Weiß	214	40 (18,7)	NE [NE; NE]	105	2 (1,9)	NE [NE; NE]	10,57	[3,25; 65,00]	<0,0001*
Andere	86	31 (36,0)	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	24 (23,8)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	7,14	[2,12; 44,43]	0,0005*
Asien	73	27 (37,0)	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	20 (15,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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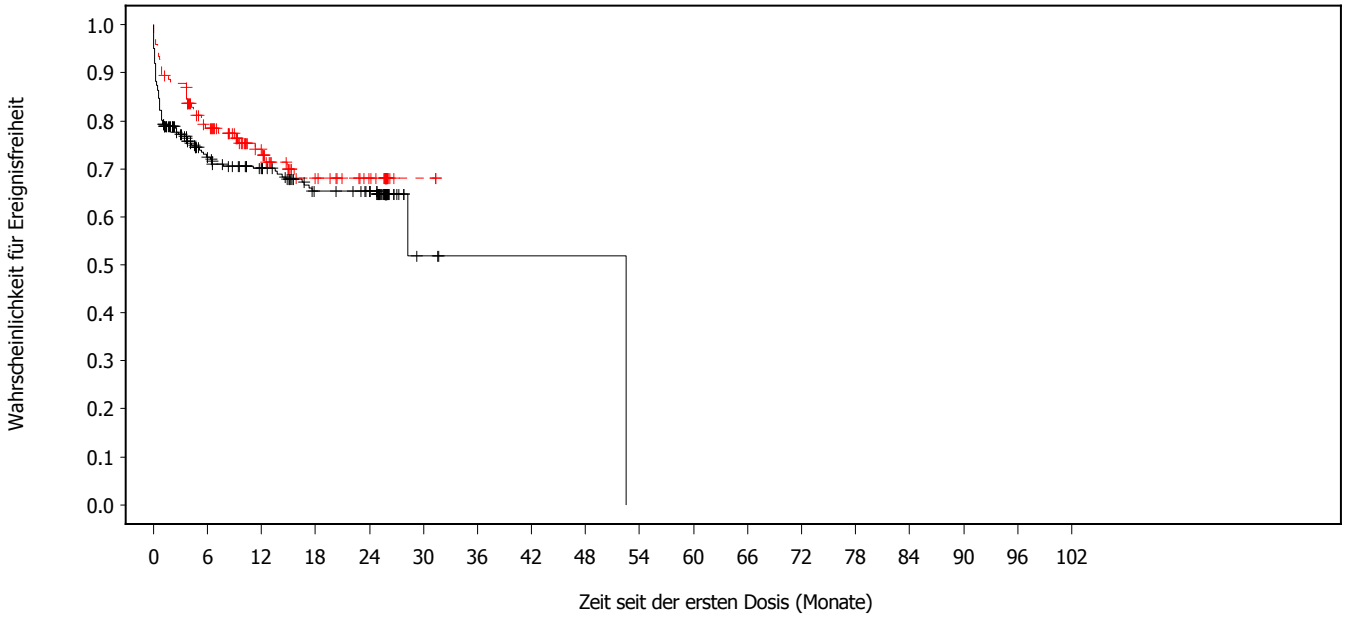
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.5.1 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Vollständiges Ansprechen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

247	151	132	107	102	3	1	1	1	0	0	0	0	0	0	0	0	Olaparib 300 mg bd
123	87	58	38	29	1	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

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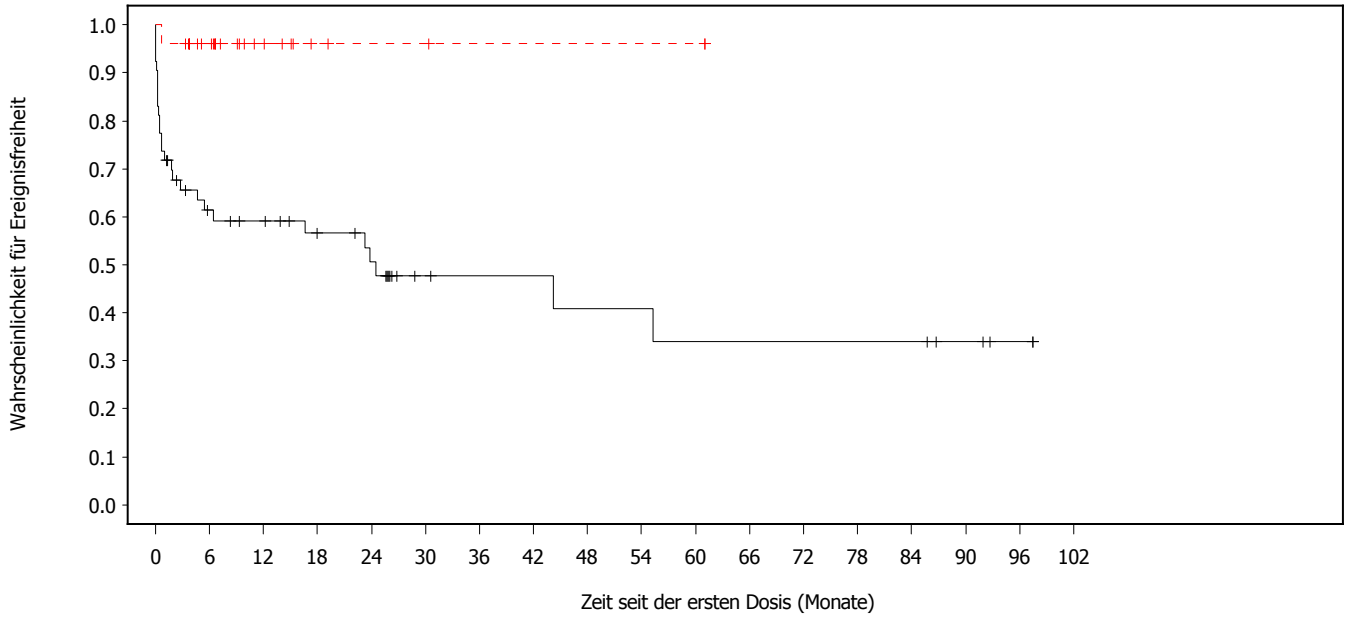
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.5.2 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Ansprechen auf vorangegangene Platin-basierte Chemotherapie = Partielles Ansprechen
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

53	28	25	21	17	8	7	7	6	6	5	5	5	5	5	3	1	0	Olaparib 300 mg bd
26	18	8	3	2	2	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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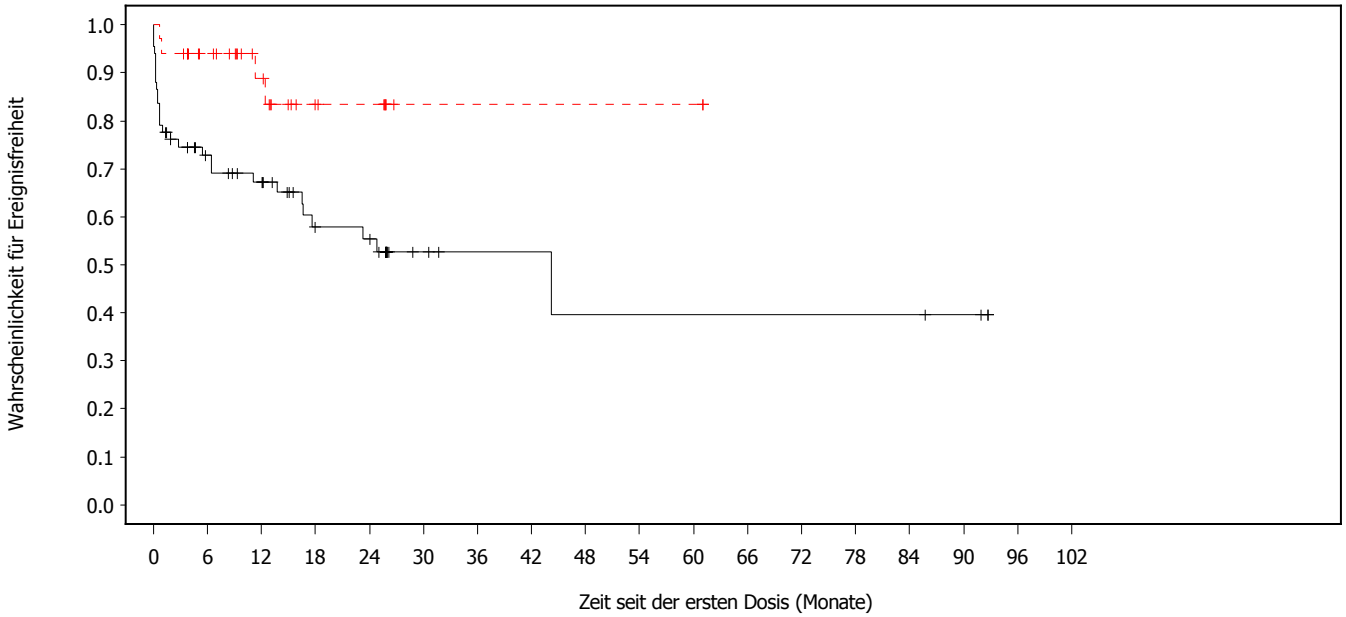
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.5.3 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Ergebnis der Debulkingoperation vor Studienbeginn = makroskopische Resterkrankung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

67	41	35	24	22	6	4	4	3	3	3	3	3	3	3	2	0	0	Olaparib 300 mg bd
34	26	17	8	7	1	1	1	1	1	1	0	0	0	0	0	0	0	Placebo bd

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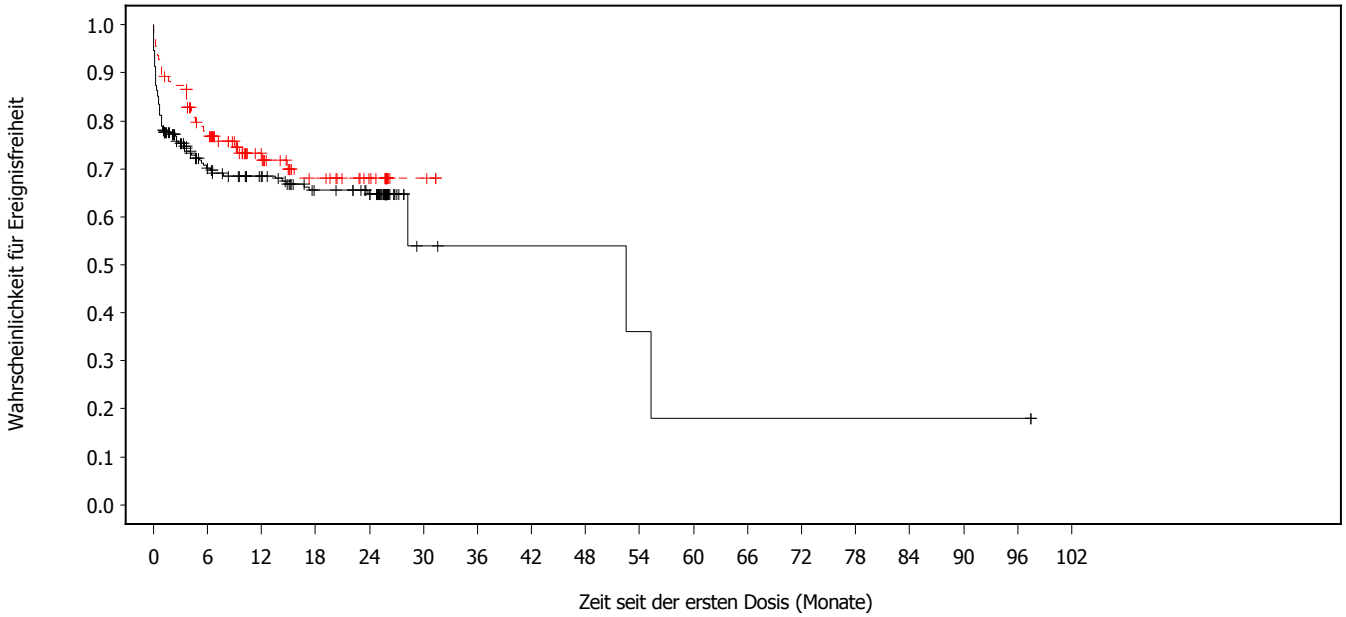
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.5.4 SOLO1: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Ergebnis der Debulkingoperation vor Studienbeginn = Keine makroskopische Resterkrankung
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

228	135	119	101	94	4	3	3	3	2	1	1	1	1	1	1	1	0	Olaparib 300 mg bd
111	77	49	33	24	2	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

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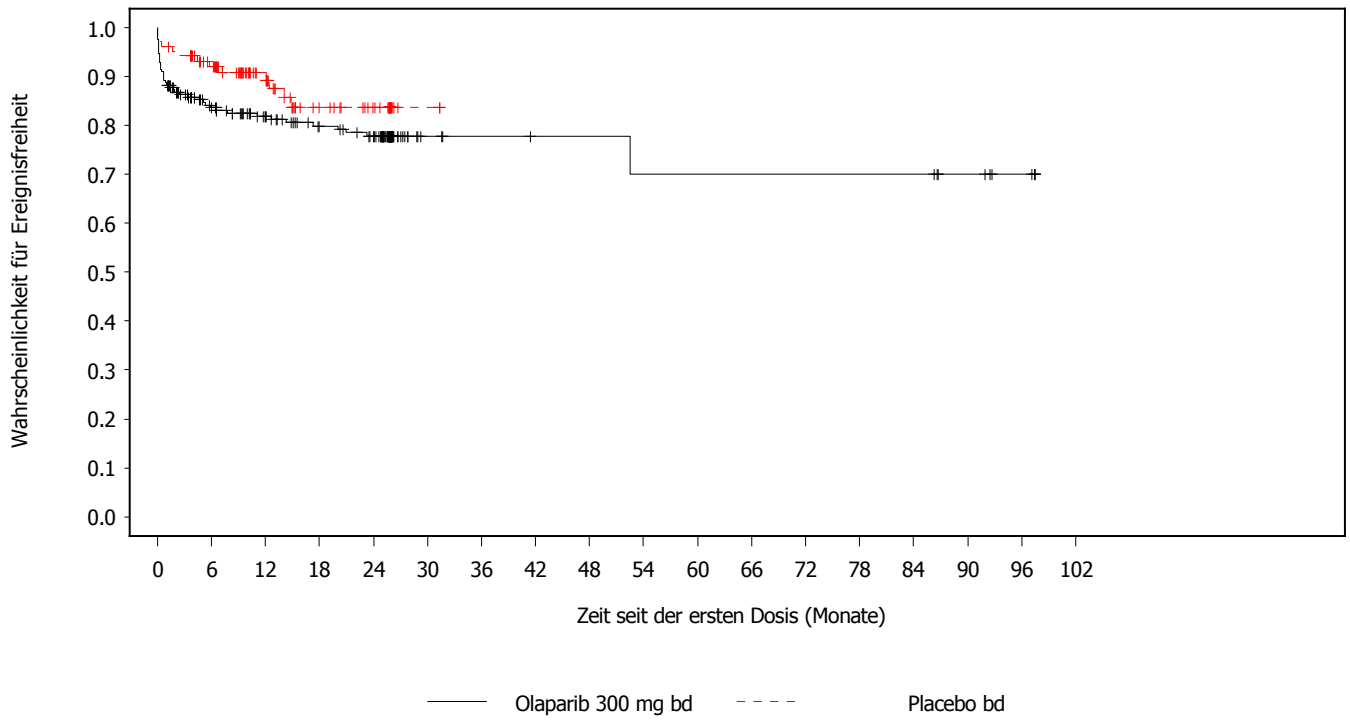
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.5.5 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Appetit vermindert for Abstammung = Weiß
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

214	153	131	116	107	13	11	10	10	9	9	9	9	9	9	6	3	0	Olaparib 300 mg bd
105	84	57	34	26	1	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

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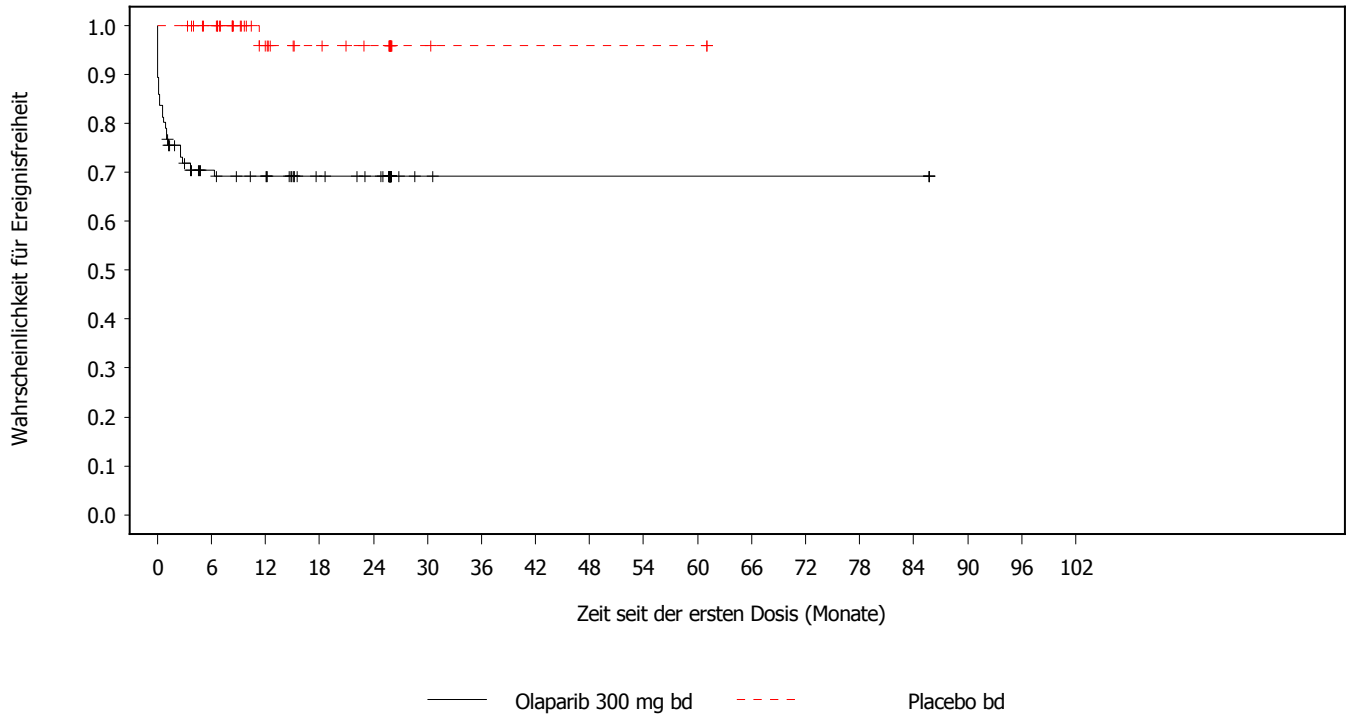
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.5.6 SOLO1: Kaplan-Meier plot of time to first occurrence of UE PT: Appetit vermindert for Abstammung = Andere
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

86	51	47	36	33	3	2	2	2	2	2	2	2	2	0	0	0	Olaparib 300 mg bd
44	39	22	17	14	2	1	1	1	1	1	0	0	0	0	0	0	Placebo bd

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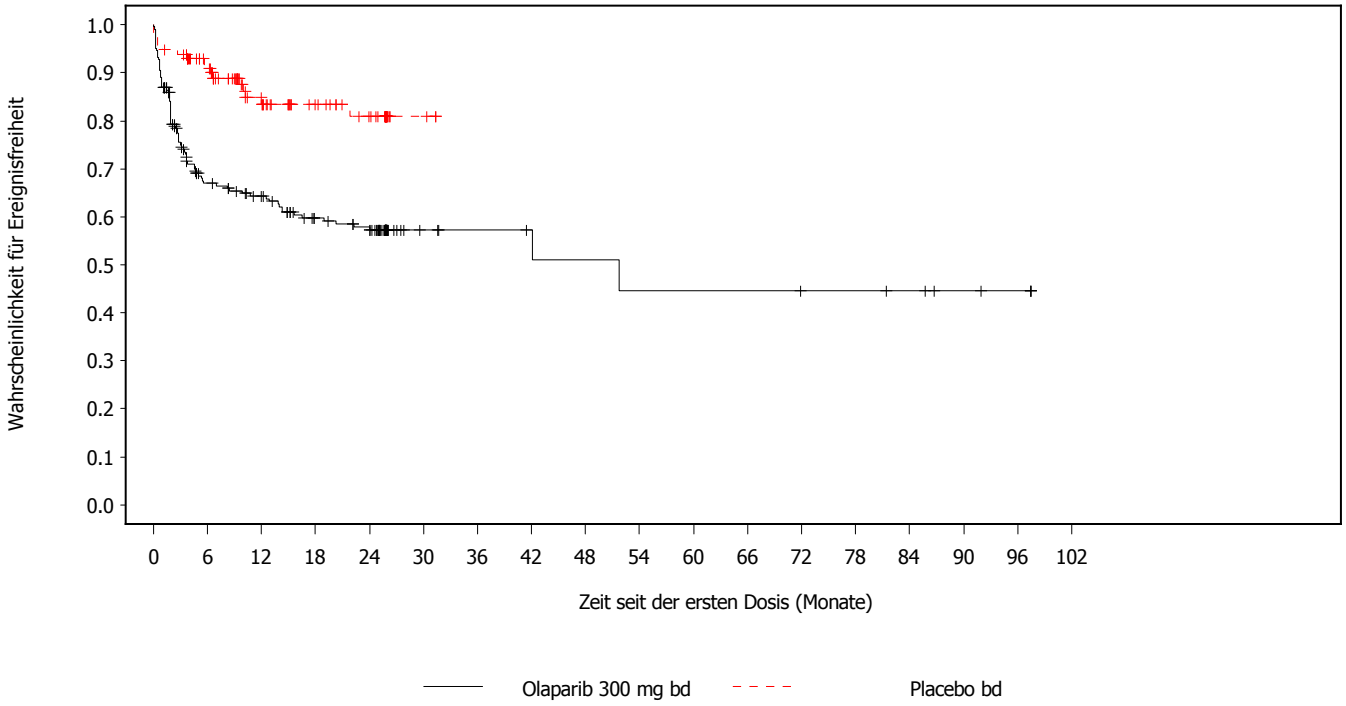
Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.5.7 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3 for ECOG PS Status = Normale Aktivität
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



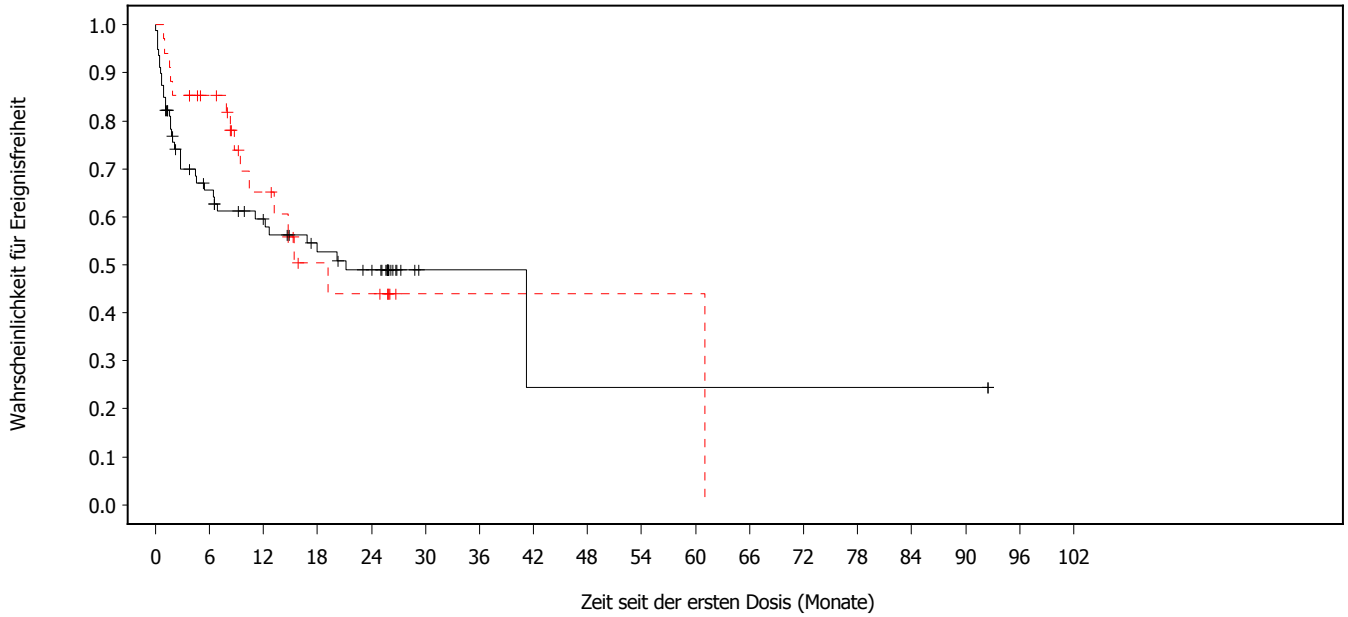
Anzahl an Patienten unter Risiko:

221	130	118	98	92	12	10	9	8	7	7	7	6	6	5	3	2	0	Olaparib 300 mg bd
115	91	58	40	31	2	0	0	0	0	0	0	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubae1.sas gttesubae1bag 01MAR2023:11:31 kfrh585

Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Figure 3.5.8 SOLO1: Kaplan-Meier plot of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3 for ECOG PS Status = Eingeschränkte Aktivität
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018



Anzahl an Patienten unter Risiko:

79	45	36	29	25	2	2	1	1	1	1	1	1	1	1	0	0	Olaparib 300 mg bd
34	25	15	8	7	1	1	1	1	1	1	0	0	0	0	0	0	Placebo bd

root/cdar/d081/_iemt/ar/iemt_payer_solo1_germany_p1/tlf/prod/program/ttesubae1.sas gttesubae1bah 01MAR2023:11:31 kfrh585

Table 3.6.1 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	4 (1,5)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	3 (1,2)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	1 (1,9)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	2 (0,9)	NE [NE; NE]	115	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	4 (1,4)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	4 (1,6)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
IV	46	0	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	3 (1,6)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.1 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	3 (1,3)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Andere	86	0	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	1 (1,0)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Asien	73	0	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.2 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	14 (5,3)	NE [NE; NE]	129	7 (5,4)	NE [NE; NE]	0,85	[0,35; 2,24]	0,7226
>=65 Jahre	37	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	11 (4,5)	NE [NE; NE]	123	7 (5,7)	NE [NE; NE]	0,72	[0,28; 1,95]	0,5003
Partielles Ansprechen	53	3 (5,7)	98,5 [NE; NE]	26	1 (3,8)	NE [NE; NE]	0,99	[0,13; 20,26]	0,9963
Interaktion p-Wert									0,7918
ECOG PS Status									
Normale Aktivität	221	12 (5,4)	NE [NE; NE]	115	5 (4,3)	NE [NE; NE]	1,06	[0,39; 3,35]	0,9133
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	3 (8,8)	NE [NE; NE]	0,28	[0,04; 1,74]	0,1669
Interaktion p-Wert									0,2122
Baseline CA-125 Wert									
<=ULN	286	13 (4,5)	NE [NE; NE]	142	7 (4,9)	NE [NE; NE]	0,81	[0,33; 2,15]	0,6522
>ULN	14	1 (7,1)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,39	[0,02; 9,87]	0,5124
Interaktion p-Wert									0,6270
FIGO Stadium									
III	254	13 (5,1)	NE [NE; NE]	122	6 (4,9)	NE [NE; NE]	0,93	[0,37; 2,65]	0,8820
IV	46	1 (2,2)	NE [NE; NE]	27	2 (7,4)	NE [NE; NE]	0,24	[0,01; 2,48]	0,2220
Interaktion p-Wert									0,2845
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	13 (6,9)	NE [NE; NE]	90	6 (6,7)	NE [NE; NE]	0,93	[0,37; 2,66]	0,8870
BRCA2	62	1 (1,6)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	0,25	[0,01; 2,66]	0,2450
Interaktion p-Wert									0,3089

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 3.6.2 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	3 (4,5)	98,5 [NE; NE]	34	2 (5,9)	NE [NE; NE]	0,63	[0,10; 4,85]	0,6266
Keine makroskopische Resterkrankung	228	11 (4,8)	NE [NE; NE]	111	6 (5,4)	NE [NE; NE]	0,81	[0,31; 2,35]	0,6794
Interaktion p-Wert									0,8180
Abstammung									
Weiß	214	12 (5,6)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	0,74	[0,30; 2,00]	0,5372
Andere	86	2 (2,3)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	0,92	[0,09; 19,76]	0,9449
Interaktion p-Wert									0,8695
Region									
Europa	101	8 (7,9)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	1,70	[0,42; 11,38]	0,4838
Asien	73	2 (2,7)	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	0,73	[0,07; 15,64]	0,7975
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	0,39	[0,10; 1,47]	0,1590
Interaktion p-Wert									0,3374

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.3 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	5 (1,9)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	3 (1,2)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	2 (3,8)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	4 (1,8)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	1 (1,3)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	5 (1,7)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	4 (1,6)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
IV	46	1 (2,2)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	2 (1,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	3 (4,8)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.3 SOLO1: Summary of subgroup analysis of time to first occurrence of UESI: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	4 (1,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	1 (1,2)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	2 (2,0)	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	1 (1,4)	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	2 (1,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.4 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	4 (1,5)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	3 (1,2)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	1 (1,9)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	2 (0,9)	NE [NE; NE]	115	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	4 (1,4)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	4 (1,6)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
IV	46	0	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	3 (1,6)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.4 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	3 (1,3)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Andere	86	0	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	1 (1,0)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Asien	73	0	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.5 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	14 (5,3)	NE [NE; NE]	129	7 (5,4)	NE [NE; NE]	0,85	[0,35; 2,24]	0,7241
>=65 Jahre	37	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	11 (4,5)	NE [NE; NE]	123	7 (5,7)	NE [NE; NE]	0,72	[0,28; 1,96]	0,5018
Partielles Ansprechen	53	3 (5,7)	98,5 [NE; NE]	26	1 (3,8)	NE [NE; NE]	0,99	[0,13; 20,26]	0,9964
Interaktion p-Wert									0,7924
ECOG PS Status									
Normale Aktivität	221	12 (5,4)	NE [NE; NE]	115	5 (4,3)	NE [NE; NE]	1,06	[0,39; 3,36]	0,9124
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	3 (8,8)	NE [NE; NE]	0,28	[0,04; 1,74]	0,1677
Interaktion p-Wert									0,2128
Baseline CA-125 Wert									
<=ULN	286	13 (4,5)	NE [NE; NE]	142	7 (4,9)	NE [NE; NE]	0,81	[0,33; 2,16]	0,6536
>ULN	14	1 (7,1)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	0,39	[0,02; 9,87]	0,5124
Interaktion p-Wert									0,6266
FIGO Stadium									
III	254	13 (5,1)	NE [NE; NE]	122	6 (4,9)	NE [NE; NE]	0,93	[0,37; 2,65]	0,8831
IV	46	1 (2,2)	NE [NE; NE]	27	2 (7,4)	NE [NE; NE]	0,24	[0,01; 2,48]	0,2227
Interaktion p-Wert									0,2850
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	13 (6,9)	NE [NE; NE]	90	6 (6,7)	NE [NE; NE]	0,93	[0,37; 2,66]	0,8874
BRCA2	62	1 (1,6)	NE [NE; NE]	39	2 (5,1)	NE [NE; NE]	0,25	[0,01; 2,67]	0,2461
Interaktion p-Wert									0,3100

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.5 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	3 (4,5)	98,5 [NE; NE]	34	2 (5,9)	NE [NE; NE]	0,63	[0,10; 4,85]	0,6267
Keine makroskopische Resterkrankung	228	11 (4,8)	NE [NE; NE]	111	6 (5,4)	NE [NE; NE]	0,81	[0,31; 2,35]	0,6811
Interaktion p-Wert									0,8171
Abstammung									
Weiß	214	12 (5,6)	NE [NE; NE]	105	7 (6,7)	NE [NE; NE]	0,74	[0,30; 2,00]	0,5389
Andere	86	2 (2,3)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	0,92	[0,09; 19,76]	0,9449
Interaktion p-Wert									0,8703
Region									
Europa	101	8 (7,9)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	1,71	[0,42; 11,40]	0,4828
Asien	73	2 (2,7)	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	0,73	[0,07; 15,64]	0,7976
Rest der Welt	126	4 (3,2)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	0,39	[0,10; 1,47]	0,1595
Interaktion p-Wert									0,3373

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.6 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	2 (0,8)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	1 (0,4)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	1 (1,9)	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	1 (0,5)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	1 (1,3)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	2 (0,7)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	1 (0,4)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
IV	46	1 (2,2)	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	1 (0,5)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.6 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwerwiegende UE: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	1 (0,4)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	2 (0,9)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	0	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	0	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	0	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	2 (1,6)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.7 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	4 (1,5)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	3 (1,2)	NE [NE; NE]	123	0	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	1 (1,9)	NE [NE; NE]	26	1 (3,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	2 (0,9)	NE [NE; NE]	115	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	4 (1,4)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	4 (1,6)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
IV	46	0	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	3 (1,6)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	1 (1,6)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.7 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: MDS/AML
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	0	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	3 (1,3)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	4 (1,9)	NE [NE; NE]	105	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Andere	86	0	NE [NE; NE]	44	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	1 (1,0)	NE [NE; NE]	53	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Asien	73	0	NE [NE; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.8 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	13 (4,9)	NE [NE; NE]	129	5 (3,9)	NE [NE; NE]	1,09	[0,41; 3,42]	0,8634
>=65 Jahre	37	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	10 (4,0)	NE [NE; NE]	123	6 (4,9)	NE [NE; NE]	0,78	[0,29; 2,29]	0,6299
Partielles Ansprechen	53	3 (5,7)	98,5 [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	11 (5,0)	NE [NE; NE]	115	4 (3,5)	NE [NE; NE]	1,19	[0,40; 4,33]	0,7643
Eingeschränkte Aktivität	79	2 (2,5)	NE [NE; NE]	34	2 (5,9)	NE [NE; NE]	0,44	[0,05; 3,71]	0,4189
Interaktion p-Wert									0,3968
Baseline CA-125 Wert									
<=ULN	286	12 (4,2)	NE [NE; NE]	142	6 (4,2)	NE [NE; NE]	0,88	[0,34; 2,53]	0,7974
>ULN	14	1 (7,1)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	12 (4,7)	NE [NE; NE]	122	5 (4,1)	NE [NE; NE]	1,02	[0,38; 3,22]	0,9705
IV	46	1 (2,2)	NE [NE; NE]	27	1 (3,7)	NE [NE; NE]	0,47	[0,02; 11,97]	0,6007
Interaktion p-Wert									0,6135
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	12 (6,4)	NE [NE; NE]	90	5 (5,6)	NE [NE; NE]	1,02	[0,38; 3,23]	0,9663
BRCA2	62	1 (1,6)	NE [NE; NE]	39	1 (2,6)	NE [NE; NE]	0,51	[0,02; 12,78]	0,6328
Interaktion p-Wert									0,6429

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.8 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	3 (4,5)	98,5 [NE; NE]	34	1 (2,9)	NE [NE; NE]	1,27	[0,16; 25,87]	0,8310
Keine makroskopische Resterkrankung	228	10 (4,4)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	0,87	[0,31; 2,81]	0,8087
Interaktion p-Wert									0,7644
Abstammung									
Weiß	214	11 (5,1)	NE [NE; NE]	105	5 (4,8)	NE [NE; NE]	0,94	[0,34; 3,01]	0,9144
Andere	86	2 (2,3)	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	0,91	[0,09; 19,54]	0,9377
Interaktion p-Wert									0,9775
Region									
Europa	101	8 (7,9)	NE [NE; NE]	53	2 (3,8)	NE [NE; NE]	1,65	[0,40; 11,08]	0,5115
Asien	73	2 (2,7)	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	0,70	[0,07; 15,18]	0,7795
Rest der Welt	126	3 (2,4)	NE [NE; NE]	63	3 (4,8)	NE [NE; NE]	0,49	[0,09; 2,66]	0,3900
Interaktion p-Wert									0,5453

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 3.6.9 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Alter (Jahre)									
<65 Jahre	263	1 (0,4)	NE [NE; NE]	129	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	37	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Ansprechen auf vorangegangene Platin-basierte Chemotherapie									
Vollständiges Ansprechen	247	1 (0,4)	NE [NE; NE]	123	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Partielles Ansprechen	53	0	NE [NE; NE]	26	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG PS Status									
Normale Aktivität	221	1 (0,5)	NE [NE; NE]	115	0	NE [NE; NE]	NC	[NC]	NC
Eingeschränkte Aktivität	79	0	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Baseline CA-125 Wert									
<=ULN	286	1 (0,3)	NE [NE; NE]	142	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
>ULN	14	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium									
III	254	1 (0,4)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
IV	46	0	NE [NE; NE]	27	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
BRCA-Mutationstyp (durch Myriad CDx bestätigt)									
BRCA1	188	1 (0,5)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
BRCA2	62	0	NE [NE; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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Table 3.6.9 SOLO1: Summary of subgroup analysis of time to first occurrence of Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Olaparib 300 mg bd (N=300)			Placebo bd (N=149)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Ergebnis der Debulkingoperation vor Studienbeginn									
makroskopische Resterkrankung	67	1 (1,5)	NE [NE; NE]	34	1 (2,9)	NE [NE; NE]	NC	[NC]	NC
Keine makroskopische Resterkrankung	228	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	214	1 (0,5)	NE [NE; NE]	105	0	NE [NE; NE]	NC	[NC]	NC
Andere	86	0	NE [NE; NE]	44	1 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Europa	101	0	NE [NE; NE]	53	0	NE [NE; NE]	NC	[NC]	NC
Asien	73	0	NE [NE; NE]	33	1 (3,0)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	126	1 (0,8)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgroup levels, >=10 events for 1 subgroup level, >0 events for all subgroup levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgroups with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only.
* p-value <0.05. HR <1 favours olaparib. NC = not calculable. MedDRA version 24.1.
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2.3.3: Zusammenfassung der unerwünschten Ereignisse, die zum Abbruch der Studienbehandlung führten

Olaparib SOLO1 gepoolte Population, Seite 1 von 2
Nutzenbewertung nach AMNOG

Table 3.7 SOLO1: Summary of adverse events leading to discontinuation of study treatment (total, and by SOC and PT)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

System organ class / MedDRA Preferred term	Number (%) of patients [a] Olaparib 300mg bd (N=300)	Placebo bd (N=149)
Patienten mit Abbruch wegen UE	34 (11,3)	4 (2,7)
Infektionen und parasitaere Erkrankungen	1 (0,3)	0
Infektion der oberen Atemwege	1 (0,3)	0
Gutartige, boesartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)	4 (1,3)	1 (0,7)
Adenokarzinom der Gallenblase	1 (0,3)	0
Brustkrebs	1 (0,3)	0
Brustkrebs der Frau	0	1 (0,7)
Invasives duktales Mammakarzinom	1 (0,3)	0
Karzinom der Lippe und/oder der Mundhoehle	1 (0,3)	0
Erkrankungen des Blutes und des Lymphsystems	10 (3,3)	0
Anaemie	8 (2,7)	0
Leukopenie	1 (0,3)	0
Lymphopenie	1 (0,3)	0
Neutropenie	1 (0,3)	0
Stoffwechsel- und Ernaehrungsstoerungen	1 (0,3)	0
Appetit vermindert	1 (0,3)	0
Psychiatrische Erkrankungen	1 (0,3)	0
Depression	1 (0,3)	0
Schlaflosigkeit	1 (0,3)	0
Erkrankungen des Nervensystems	2 (0,7)	0
Erinnerungsvermoegen eingeschraenkt	1 (0,3)	0

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Patients with multiple events in the same category are counted only once in that category.
Patients with events in more than one category are counted once in each of those categories.
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Olaparib SOLO1 gepoolte Population, Seite 2 von 2
Nutzenbewertung nach AMNOG

Table 3.7 SOLO1: Summary of adverse events leading to discontinuation of study treatment
(total, and by SOC and PT)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

System organ class / MedDRA Preferred term	Number (%) of patients [a] Olaparib 300mg bd (N=300)	Placebo bd (N=149)
Periphere Neuropathie	1 (0,3)	0
Erkrankungen der Atemwege, des Brustraums und Mediastinums	3 (1,0)	0
Dyspnoe	1 (0,3)	0
Interstitielle Lungenerkrankung	1 (0,3)	0
Pneumonitis	1 (0,3)	0
Erkrankungen des Gastrointestinaltrakts	6 (2,0)	1 (0,7)
Dyspepsie	1 (0,3)	0
Erbrechen	2 (0,7)	0
Uebelkeit	6 (2,0)	1 (0,7)
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	10 (3,3)	2 (1,3)
Asthenie	2 (0,7)	0
Ermuedung	4 (1,3)	1 (0,7)
Fieber	1 (0,3)	0
Inkarzerierte Hernie	1 (0,3)	0
Tod	0	1 (0,7)
Unwohlsein	2 (0,7)	0
Untersuchungen	2 (0,7)	1 (0,7)
Alaninaminotransferase erhoeht	0	1 (0,7)
Aspartataminotransferase erhoeht	0	1 (0,7)
Gamma-Glutamyltransferase erhoeht	0	1 (0,7)
Leukozytenzahl erniedrigt	1 (0,3)	0
Thrombozytenzahl vermindert	1 (0,3)	0

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.1.
[a] Patients with multiple events in the same category are counted only once in that category.
Patients with events in more than one category are counted once in each of those categories.
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2.4: Baseline- und weitere deskriptive Charakteristika und Angaben

Table 4.1 SOLO1: Number of patients unblinded (Full analysis set)
Full Analysis Set, Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Number (%) of patients	
	Olaparib 300 mg bd (N=300)	Placebo bd (N=150)
Unblinded subjects	43 (14,3)	52 (34,7)
Unblinded before PFS event/censoring	8 (2,7)	1 (0,7)
Unblinded before RECIST progression	1 (0,3)	1 (0,7)
Unblinded before death	1 (0,3)	0
Unblinded before censoring	6 (2,0)	0
Unblinded on or after PFS event/censoring	35 (11,7)	51 (34,0)

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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 4.2 SOLO1: Demographic characteristics including ethnic group (Full analysis set)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

Demographic characteristic		Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
Age (years)	n	300	150	450
	Mean	53,2	53,1	53,2
	SD	9,16	9,59	9,29
	Minimum	29	31	29
	Q1	47,0	47,0	47,0
	Median	53,0	53,0	53,0
	Q3	59,0	59,0	59,0
	Maximum	82	84	84
Age group (years) n (%)	<50	111 (37,0)	57 (38,0)	168 (37,3)
	>=50-<65	152 (50,7)	73 (48,7)	225 (50,0)
	>=65	37 (12,3)	20 (13,3)	57 (12,7)
	Total	300 (100)	150 (100)	450 (100)
Sex n (%)	Female	300 (100)	150 (100)	450 (100)
Race n (%)	White	214 (71,3)	106 (70,7)	320 (71,1)
	Black or African American	2 (0,7)	2 (1,3)	4 (0,9)
	Asian	79 (26,3)	39 (26,0)	118 (26,2)
	American Indian or Alaska	0	1 (0,7)	1 (0,2)
	Native Hawaiian or Other	1 (0,3)	1 (0,7)	2 (0,4)
	Other	4 (1,3)	1 (0,7)	5 (1,1)
	Middle Eastern	1 (0,3)	0	1 (0,2)
	More Than One Race	1 (0,3)	0	1 (0,2)
	North Africa	1 (0,3)	0	1 (0,2)
	Puerto Rican	1 (0,3)	1 (0,7)	2 (0,4)
	Total	300 (100)	150 (100)	450 (100)
Ethnicity n (%)	Hispanic or Latino	11 (3,7)	7 (4,7)	18 (4,0)
	Not Hispanic or Latino	289 (96,3)	143 (95,3)	432 (96,0)
	Total	300 (100)	150 (100)	450 (100)

SD = standard deviation; Q1 = first quartile; Q3 = third quartile.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 5
Nutzenbewertung nach AMNOG

Table 4.3 SOLO1: Disease characteristics at baseline (Full analysis set)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Number (%) of patients		
	Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
ECOG performance status			
(0) Normal activity	221 (73,7)	115 (76,7)	336 (74,7)
(1) Restricted activity	79 (26,3)	34 (22,7)	113 (25,1)
(2) In bed =50% of the time	0	0	0
(3) In bed >50% of the time	0	0	0
(4) 100% Bedridden	0	0	0
Missing	0	1 (0,7)	1 (0,2)
BRCA status previously known			
Known	145 (48,3)	78 (52,0)	223 (49,6)
Unknown	155 (51,7)	72 (48,0)	227 (50,4)
Previously confirmed BRCA gene name			
BRCA1	108 (36,0)	54 (36,0)	162 (36,0)
BRCA2	34 (11,3)	24 (16,0)	58 (12,9)
Both	3 (1,0)	0	3 (0,7)
BRCA mutation locally reported or confirmed by Myriad testing			
Yes	265 (88,3)	134 (89,3)	399 (88,7)
No	2 (0,7)	0	2 (0,4)
Missing	33 (11,0)	16 (10,7)	49 (10,9)
Myriad confirmed BRCA gene name			
BRCA1	188 (62,7)	91 (60,7)	279 (62,0)
BRCA2	62 (20,7)	39 (26,0)	101 (22,4)

[a] Metastatic disease - Patient has any metastatic site of disease.
[b] Locally advanced - Patient has only locally advanced sites of disease.
[c] Patients with unknown gBRCA status at study entry and Myriad test performed to allow entry or patients with a local BRCA test (not germline).
[d] gBRCAm patients reported using Myriad/BGI test are considered first before then considering locally reported BRCA gene name. The randomised patients from China have a BGI test rather than a Myriad test
[e] This patient was randomised but did not receive treatment.
ECOG = Eastern Cooperative Oncology Group; BRCA = Breast cancer gene (type); gBRCA = germline BRCA; tBRCA = tumour BRCA.
FIGO = Federation of Gynecology and Obstetrics; FIGO stage is determined at initial diagnosis.
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Table 4.3 SOLO1: Disease characteristics at baseline (Full analysis set)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Number (%) of patients		
	Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
Both	3 (1,0)	0	3 (0,7)
Missing	47 (15,7)	20 (13,3)	67 (14,9)
Locally reported gBRCA status			
BRCA mutated	141 (47,0)	78 (52,0)	219 (48,7)
BRCA VUS	0	0	0
BRCA wildtype	0	0	0
Missing [c]	159 (53,0)	72 (48,0)	231 (51,3)
Myriad confirmed gBRCA status			
BRCA mutated	253 (84,3)	130 (86,7)	383 (85,1)
BRCA VUS	1 (0,3)	0	1 (0,2)
BRCA wildtype	2 (0,7)	0	2 (0,4)
Missing	44 (14,7)	20 (13,3)	64 (14,2)
Myriad/BGI or locally reported BRCA gene name [d]			
BRCA1	225 (75,0)	105 (70,0)	330 (73,3)
BRCA2	72 (24,0)	45 (30,0)	117 (26,0)
Both	3 (1,0)	0	3 (0,7)
Missing	0	0	0
Foundation Medicine confirmed tBRCA status			
BRCA mutated	214 (71,3)	110 (73,3)	324 (72,0)
BRCA VUS	3 (1,0)	2 (1,3)	5 (1,1)
BRCA wildtype	10 (3,3)	2 (1,3)	12 (2,7)

[a] Metastatic disease - Patient has any metastatic site of disease.
[b] Locally advanced - Patient has only locally advanced sites of disease.
[c] Patients with unknown gBRCA status at study entry and Myriad test performed to allow entry or patients with a local BRCA test (not germline).
[d] gBRCAm patients reported using Myriad/BGI test are considered first before then considering locally reported BRCA gene name. The randomised patients from China have a BGI test rather than a Myriad test
[e] This patient was randomised but did not receive treatment.
ECOG = Eastern Cooperative Oncology Group; BRCA = Breast cancer gene (type); gBRCA = germline BRCA; tBRCA = tumour BRCA.
FIGO = Federation of Gynecology and Obstetrics; FIGO stage is determined at initial diagnosis.
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Table 4.3 SOLO1: Disease characteristics at baseline (Full analysis set)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Number (%) of patients		
	Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
Missing	73 (24,3)	36 (24,0)	109 (24,2)
Foundation Medicine reported BRCA gene name			
BRCA1	158 (52,7)	75 (50,0)	233 (51,8)
BRCA2	51 (17,0)	35 (23,3)	86 (19,1)
Both	5 (1,7)	0	5 (1,1)
Missing	86 (28,7)	40 (26,7)	126 (28,0)
Primary tumour location			
Ovary	259 (86,3)	131 (87,3)	390 (86,7)
Fallopian tubes	22 (7,3)	12 (8,0)	34 (7,6)
Primary peritoneal	16 (5,3)	7 (4,7)	23 (5,1)
Other	3 (1,0)	0	3 (0,7)
Ovary, falloppian tube, peritoneum, omentum	1 (0,3)	0	1 (0,2)
Peritoneal and ovarian	1 (0,3)	0	1 (0,2)
Tubo-ovary	1 (0,3)	0	1 (0,2)
Tumour grade			
Well differentiated (G1)	0	0	0
Mod. differentiated (G2)	29 (9,7)	14 (9,3)	43 (9,6)
Poorly differentiated (G3)	245 (81,7)	120 (80,0)	365 (81,1)
Undifferentiated (G4)	5 (1,7)	4 (2,7)	9 (2,0)
Unassessable (GX)	21 (7,0)	12 (8,0)	33 (7,3)
Missing	0	0	0

[a] Metastatic disease - Patient has any metastatic site of disease.
[b] Locally advanced - Patient has only locally advanced sites of disease.
[c] Patients with unknown gBRCA status at study entry and Myriad test performed to allow entry or patients with a local BRCA test (not germline).
[d] gBRCAm patients reported using Myriad/BGI test are considered first before then considering locally reported BRCA gene name. The randomised patients from China have a BGI test rather than a Myriad test
[e] This patient was randomised but did not receive treatment.
ECOG = Eastern Cooperative Oncology Group; BRCA = Breast cancer gene (type); gBRCA = germline BRCA; tBRCA = tumour BRCA.
FIGO = Federation of Gynecology and Obstetrics; FIGO stage is determined at initial diagnosis.
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Table 4.3 SOLO1: Disease characteristics at baseline (Full analysis set)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Number (%) of patients		
	Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
FIGO stage			
Stage 0	0	0	0
Stage I	0	0	0
Stage IA	0	0	0
Stage IB	0	0	0
Stage IC	0	0	0
Stage II	0	0	0
Stage IIA	0	0	0
Stage IIB	0	0	0
Stage IIC	0	0	0
Stage III	5 (1,7)	2 (1,3)	7 (1,6)
Stage IIIA	10 (3,3)	6 (4,0)	16 (3,6)
Stage IIIB	28 (9,3)	10 (6,7)	38 (8,4)
Stage IIIC	211 (70,3)	105 (70,0)	316 (70,2)
Stage IV	46 (15,3)	27 (18,0)	73 (16,2)
Missing	0	0	0
Histology type			
Serous	284 (94,7)	148 (98,7)	432 (96,0)
Endometrioid	9 (3,0)	1 (0,7)	10 (2,2)
Mixed, epithelial	6 (2,0)	1 (0,7)	7 (1,6)
Other	1 (0,3)	0	1 (0,2)
Serous papillary	1 (0,3)	0	1 (0,2)
Time from previous platinum chemotherapy to randomisation			

[a] Metastatic disease - Patient has any metastatic site of disease.
[b] Locally advanced - Patient has only locally advanced sites of disease.
[c] Patients with unknown gBRCA status at study entry and Myriad test performed to allow entry or patients with a local BRCA test (not germline).
[d] gBRCAm patients reported using Myriad/BGI test are considered first before then considering locally reported BRCA gene name. The randomised patients from China have a BGI test rather than a Myriad test
[e] This patient was randomised but did not receive treatment.
ECOG = Eastern Cooperative Oncology Group; BRCA = Breast cancer gene (type); gBRCA = germline BRCA; tBRCA = tumour BRCA.
FIGO = Federation of Gynecology and Obstetrics; FIGO stage is determined at initial diagnosis.
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Table 4.3 SOLO1: Disease characteristics at baseline (Full analysis set)
Full Analysis Set, Global Cohort DCO 17May2018, China Cohort DCO 17May2018

	Number (%) of patients		
	Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
<=8 weeks	277 (92,3)	143 (95,3)	420 (93,3)
>8 weeks	23 (7,7)	7 (4,7)	30 (6,7)
>8 to <=9 weeks	16 (5,3)	5 (3,3)	21 (4,7)
>9 to <=10 weeks	3 (1,0)	1 (0,7)	4 (0,9)
>10 to <=11 weeks	1 (0,3)	0	1 (0,2)
>11 to <=12 weeks	1 (0,3)	0	1 (0,2)
>12 weeks	2 (0,7)	1 (0,7)	3 (0,7)
Overall disease classification at study entry			
Metastatic [a]	42 (14,0)	22 (14,7)	64 (14,2)
Locally advanced [b]	15 (5,0)	6 (4,0)	21 (4,7)
Patient has no sites of disease	241 (80,3)	121 (80,7)	362 (80,4)
Unknown	2 (0,7)	1 (0,7)	3 (0,7)
Baseline CA-125 value			
<=ULN	286 (95,3)	142 (94,7)	428 (95,1)
>ULN	14 (4,7)	7 (4,7)	21 (4,7)
Missing [e]	0	1 (0,7)	1 (0,2)

[a] Metastatic disease - Patient has any metastatic site of disease.
[b] Locally advanced - Patient has only locally advanced sites of disease.
[c] Patients with unknown gBRCA status at study entry and Myriad test performed to allow entry or patients with a local BRCA test (not germline).
[d] gBRCAm patients reported using Myriad/BGI test are considered first before then considering locally reported BRCA gene name. The randomised patients from China have a BGI test rather than a Myriad test
[e] This patient was randomised but did not receive treatment.
ECOG = Eastern Cooperative Oncology Group; BRCA = Breast cancer gene (type); gBRCA = germline BRCA; tBRCA = tumour BRCA.
FIGO = Federation of Gynecology and Obstetrics; FIGO stage is determined at initial diagnosis.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 4.4 SOLO1: Patient disposition (All patients)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Number (%) of patients		
	Olaparib 300 mg bd	Placebo bd	Total
Patients enrolled[a]			1280
Patients randomised	300 (100)	150 (100)	450 (100)
Patients who were not randomised			830
Subject decision			15 (1.8)
Eligibility criteria not fulfilled			808 (97.3)
Death			2 (0.2)
Subject lost to follow-up			3 (0.4)
Other			2 (0.2)
Full analysis set[b]	300 (100)	150 (100)	450 (100)
Patients who did not receive study treatment	0	1 (0.7)	1 (0.2)
Patients who did receive study treatment	300 (100)	149 (99.3)	449 (99.8)
Patients ongoing study treatment at data cut-off[c]	8 (2.7)	1 (0.7)	9 (2.0)
Patients who discontinued study treatment[c]	292 (97.3)	148 (99.3)	440 (98.0)
Subject decision	29 (9.7)	5 (3.4)	34 (7.6)
Adverse event	35 (11.7)	3 (2.0)	38 (8.5)
Severe non-compliance to protocol	3 (1.0)	0	3 (0.7)
Objective Disease Progression	64 (21.3)	87 (58.4)	151 (33.6)
Development of study-specific discontinuation criteria	98 (32.7)	27 (18.1)	125 (27.8)
Patient lost to follow-up	0	1 (0.7)	1 (0.2)
Other	62 (20.7)	25 (16.8)	87 (19.4)
Unknown	1 (0.3)	0	1 (0.2)

[a] Informed consent received.
[b] Percentages are calculated from number of patients randomised.
[c] Percentages are calculated from number of patients who received treatment.
[d] May include patients who never received study treatment.
Percentages for reasons patients were not randomised are calculated from the number of patients who were not randomised.
Patient E7822006 only provided genetic informed consent and not main informed consent.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 4.4 SOLO1: Patient disposition (All patients)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

	Number (%) of patients		
	Olaparib 300 mg bd	Placebo bd	Total
Patient discontinued treatment at two years as per protocol[c]	144 (48.0)	41 (27.5)	185 (41.2)
Patient continued treatment post two years as per protocol[c]	14 (4.7)	3 (2.0)	17 (3.8)
Patients with NED or CR who continued past two years in error[c]	13 (4.3)	1 (0.7)	14 (3.1)
Patients continuing study off treatment at data cut-off[b, d]	170 (56.7)	61 (40.7)	231 (51.3)
Patients who withdraw from the study[b, d]	122 (40.7)	88 (58.7)	210 (46.7)
Subject decision	30 (10.0)	16 (10.7)	46 (10.2)
Death	91 (30.3)	69 (46.0)	160 (35.6)
Severe non-compliance to protocol	1 (0.3)	0	1 (0.2)
Subject lost to follow-up	0	2 (1.3)	2 (0.4)
Other	0	1 (0.7)	1 (0.2)

[a] Informed consent received.
[b] Percentages are calculated from number of patients randomised.
[c] Percentages are calculated from number of patients who received treatment.
[d] May include patients who never received study treatment.
Percentages for reasons patients were not randomised are calculated from the number of patients who were not randomised.
Patient E7822006 only provided genetic informed consent and not main informed consent.
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Olaparib SOLO1 gepoolte Population, Nutzenbewertung nach AMNOG

Table 4.5 SOLO1: Duration of exposure (Safety analysis set)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

Treatment duration		Olaparib 300 mg bd (N=300)	Placebo bd (N=149)
Total treatment duration (weeks) [a]	Mean	94,2	65,5
	SD	73,03	40,99
	Median	107,1	56,9
	Min	0	1
	Max	424	265
	Total treatment weeks	28246	9757
Actual treatment duration (weeks) [b]	Mean	91,6	64,6
	SD	72,62	40,94
	Median	101,3	52,9
	Min	0	1
	Max	422	264
	Total treatment weeks	27469	9632

[a] Total treatment duration (days) = (last dose date - first dose date + 1).
[b] Actual treatment duration (days) = total treatment duration - total duration of dose interruptions.
Dose interruptions include those where the patient forgot to take all doses on a given day.
If patient is ongoing, data-cut-off has been used to calculate duration.
SD = standard deviation.
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Table 4.6 SOLO1: Post-discontinuation anticancer therapy modalities (Full analysis set)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

Subsequent Regimen Number	Post-discontinuation treatment modalities	Number (%) of patients: Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
Any	Total	139 (46,3)	108 (72,0)	247 (54,9)
	Platinum containing regimen	91 (30,3)	62 (41,3)	153 (34,0)
	Platinum in combination with bevacizumab	31 (10,3)	21 (14,0)	52 (11,6)
	Other Bevacizumab containing regimen	16 (5,3)	12 (8,0)	28 (6,2)
	Any other chemotherapy regimen (excluding plat or bev containing)	55 (18,3)	40 (26,7)	95 (21,1)
	PARP Inhibitor	39 (13,0)	58 (38,7)	97 (21,6)
	Hormonal agent	4 (1,3)	5 (3,3)	9 (2,0)
	Other investigational agents	5 (1,7)	5 (3,3)	10 (2,2)
1st	Total	139 (46,3)	106 (70,7)	245 (54,4)
	Platinum containing regimen	75 (25,0)	41 (27,3)	116 (25,8)
	Platinum in combination with bevacizumab	25 (8,3)	16 (10,7)	41 (9,1)
	Other Bevacizumab containing regimen	5 (1,7)	0	5 (1,1)
	Any other chemotherapy regimen (excluding plat or bev containing)	12 (4,0)	12 (8,0)	24 (5,3)
	PARP Inhibitor	22 (7,3)	36 (24,0)	58 (12,9)
	Hormonal agent	2 (0,7)	2 (1,3)	4 (0,9)
	Other investigational agents	1 (0,3)	0	1 (0,2)
2nd	Total	76 (25,3)	67 (44,7)	143 (31,8)
	Platinum containing regimen	23 (7,7)	18 (12,0)	41 (9,1)
	Platinum in combination with bevacizumab	5 (1,7)	4 (2,7)	9 (2,0)
	Other Bevacizumab containing regimen	5 (1,7)	7 (4,7)	12 (2,7)
	Any other chemotherapy regimen (excluding plat or bev containing)	32 (10,7)	20 (13,3)	52 (11,6)
	PARP Inhibitor	11 (3,7)	16 (10,7)	27 (6,0)
	Hormonal agent	0	1 (0,7)	1 (0,2)
	Other investigational agents	2 (0,7)	1 (0,7)	3 (0,7)

Regimen number as assessed by AstraZeneca medical review.
Patients who received subsequent therapy will be counted at least once under the category of Any and at least once under the relevant regimen number.
Patients may appear under more than one subsequent treatment type.
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Table 4.6 SOLO1: Post-discontinuation anticancer therapy modalities (Full analysis set)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

Subsequent Regimen Number	Post-discontinuation treatment modalities	Number (%) of patients: Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
3rd	Total	35 (11,7)	31 (20,7)	66 (14,7)
	Platinum containing regimen	13 (4,3)	9 (6,0)	22 (4,9)
	Platinum in combination with bevacizumab	1 (0,3)	1 (0,7)	2 (0,4)
	Other Bevacizumab containing regimen	3 (1,0)	2 (1,3)	5 (1,1)
	Any other chemotherapy regimen (excluding plat or bev containing)	12 (4,0)	14 (9,3)	26 (5,8)
	PARP Inhibitor	4 (1,3)	5 (3,3)	9 (2,0)
	Hormonal agent	1 (0,3)	1 (0,7)	2 (0,4)
	Other investigational agents	1 (0,3)	0	1 (0,2)
4th	Total	16 (5,3)	23 (15,3)	39 (8,7)
	Platinum containing regimen	5 (1,7)	5 (3,3)	10 (2,2)
	Platinum in combination with bevacizumab	0	1 (0,7)	1 (0,2)
	Other Bevacizumab containing regimen	2 (0,7)	0	2 (0,4)
	Any other chemotherapy regimen (excluding plat or bev containing)	8 (2,7)	10 (6,7)	18 (4,0)
	PARP Inhibitor	0	4 (2,7)	4 (0,9)
	Hormonal agent	1 (0,3)	0	1 (0,2)
	Other investigational agents	0	3 (2,0)	3 (0,7)
5th	Total	13 (4,3)	13 (8,7)	26 (5,8)
	Platinum containing regimen	2 (0,7)	1 (0,7)	3 (0,7)
	Other Bevacizumab containing regimen	2 (0,7)	4 (2,7)	6 (1,3)
	Any other chemotherapy regimen (excluding plat or bev containing)	6 (2,0)	6 (4,0)	12 (2,7)
	PARP Inhibitor	3 (1,0)	2 (1,3)	5 (1,1)

Regimen number as assessed by AstraZeneca medical review.
Patients who received subsequent therapy will be counted at least once under the category of Any and at least once under the relevant regimen number.
Patients may appear under more than one subsequent treatment type.
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Table 4.6 SOLO1: Post-discontinuation anticancer therapy modalities (Full analysis set)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

Subsequent Regimen Number	Post-discontinuation treatment modalities	Number (%) of patients: Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
6th	Total	8 (2,7)	7 (4,7)	15 (3,3)
	Platinum containing regimen	1 (0,3)	1 (0,7)	2 (0,4)
	Platinum in combination with bevacizumab	1 (0,3)	0	1 (0,2)
	Any other chemotherapy regimen (excluding plat or bev containing)	5 (1,7)	3 (2,0)	8 (1,8)
	PARP Inhibitor	0	2 (1,3)	2 (0,4)
	Hormonal agent	0	1 (0,7)	1 (0,2)
	Other investigational agents	1 (0,3)	1 (0,7)	2 (0,4)
7th	Total	7 (2,3)	4 (2,7)	11 (2,4)
	Platinum containing regimen	1 (0,3)	2 (1,3)	3 (0,7)
	Other Bevacizumab containing regimen	1 (0,3)	1 (0,7)	2 (0,4)
	Any other chemotherapy regimen (excluding plat or bev containing)	4 (1,3)	0	4 (0,9)
	PARP Inhibitor	1 (0,3)	1 (0,7)	2 (0,4)
8th	Total	3 (1,0)	3 (2,0)	6 (1,3)
	Platinum containing regimen	1 (0,3)	1 (0,7)	2 (0,4)
	Any other chemotherapy regimen (excluding plat or bev containing)	0	2 (1,3)	2 (0,4)
	PARP Inhibitor	2 (0,7)	0	2 (0,4)
9th	Total	1 (0,3)	0	1 (0,2)
	Any other chemotherapy regimen (excluding plat or bev containing)	1 (0,3)	0	1 (0,2)

Regimen number as assessed by AstraZeneca medical review.
Patients who received subsequent therapy will be counted at least once under the category of Any and at least once under the relevant regimen number.
Patients may appear under more than one subsequent treatment type.
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Olaparib SOLO1 gepoolte Population, Seite 1 von 1
Nutzenbewertung nach AMNOG

Table 4.7 SOLO1 Stratification factors (Full analysis set)
Global Cohort DCO 07Mar2022, China Cohort DCO 17May2018

Response to previous platinum chemotherapy	Olaparib 300 mg bd (N=300)	Placebo bd (N=150)	Total (N=450)
As randomised			
CR	247 (82,3)	124 (82,7)	371 (82,4)
PR	53 (17,7)	26 (17,3)	79 (17,6)
Recorded on eCRF			
CR	222 (74,0)	117 (78,0)	339 (75,3)
PR	78 (26,0)	33 (22,0)	111 (24,7)

CR = Complete Response, PR = Partial Response.
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