Dossier zur Nutzenbewertung gemäß § 35a SGB V

Olaparib (Lynparza®)

AstraZeneca GmbH

Modul 4 A – Anhang 4-G

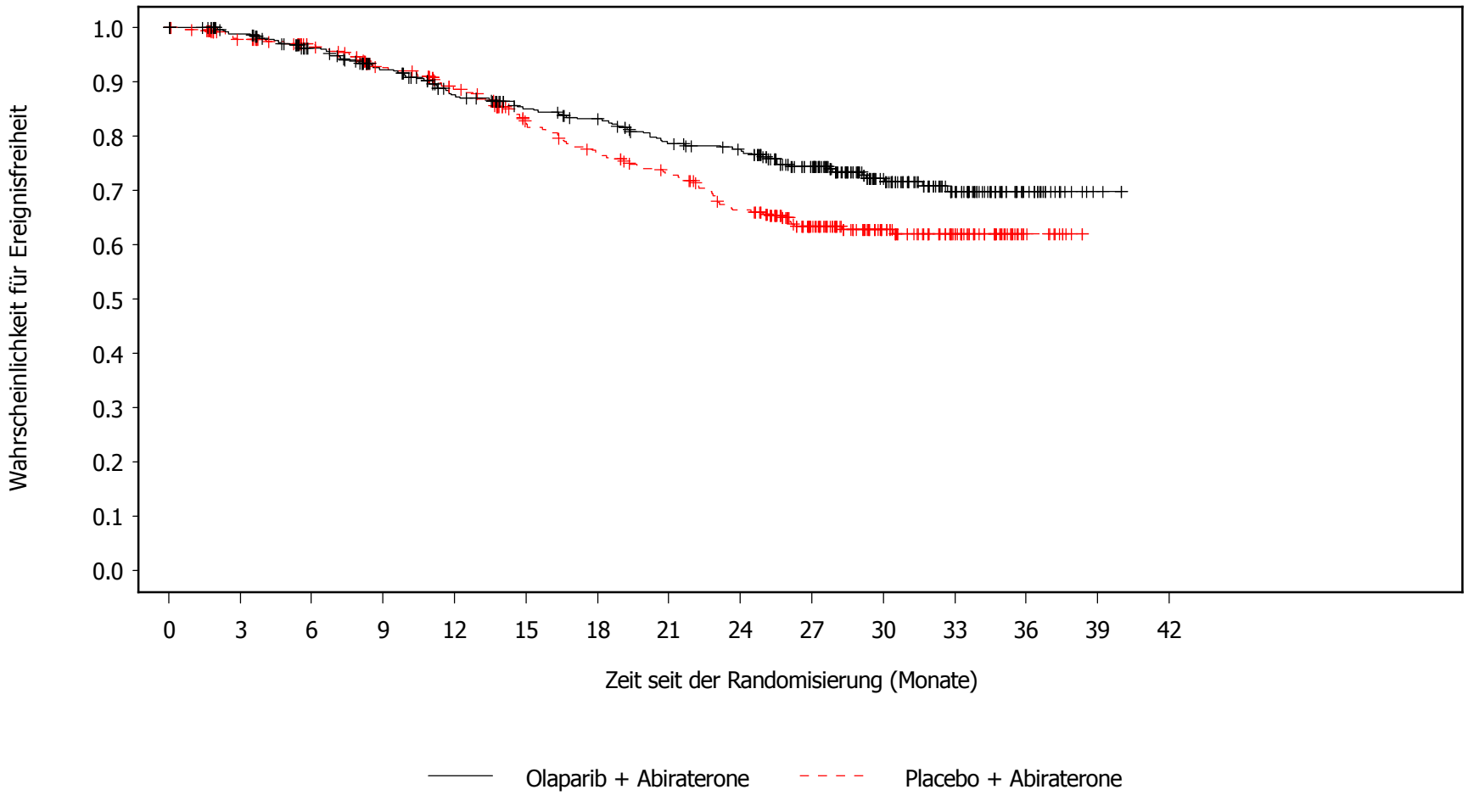
Behandlung von erwachsenen Patienten mit mCRPC, bei denen eine Chemotherapie nicht klinisch indiziert ist

Weitere Analysen und Kaplan-Meier-Plots
zu den in Abschnitt 4.3.1.3 gezeigten Ergebnissen

Stand: 13.01.2023

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.1.2.3 PROpel: Kaplan-Meier plot of time to second progression-free survival (PFS2)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	380	349	319	289	269	259	239	230	186	113	65	22	2	0	Olaparib + Abiraterone
397	373	351	318	293	258	238	221	196	141	85	51	11	0	0	Placebo + Abiraterone

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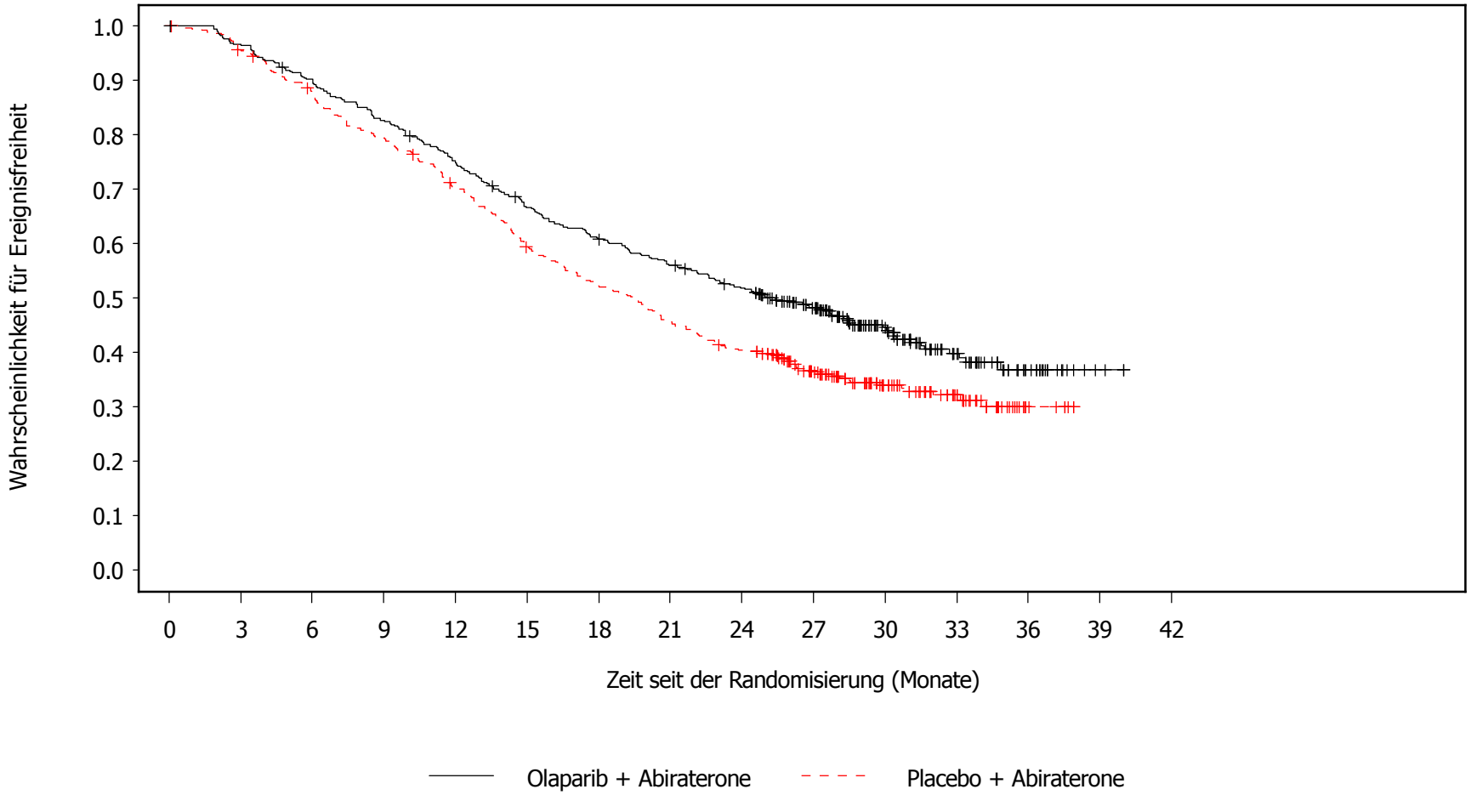
Figure 1.1.2.4 PROpel: Kaplan-Meier plot of time to first subsequent therapy or death (TFST)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	385	358	328	296	262	239	219	200	157	93	49	19	2	0	Olaparib + Abiraterone
397	378	345	313	273	231	203	177	156	112	66	38	6	0	0	Placebo + Abiraterone

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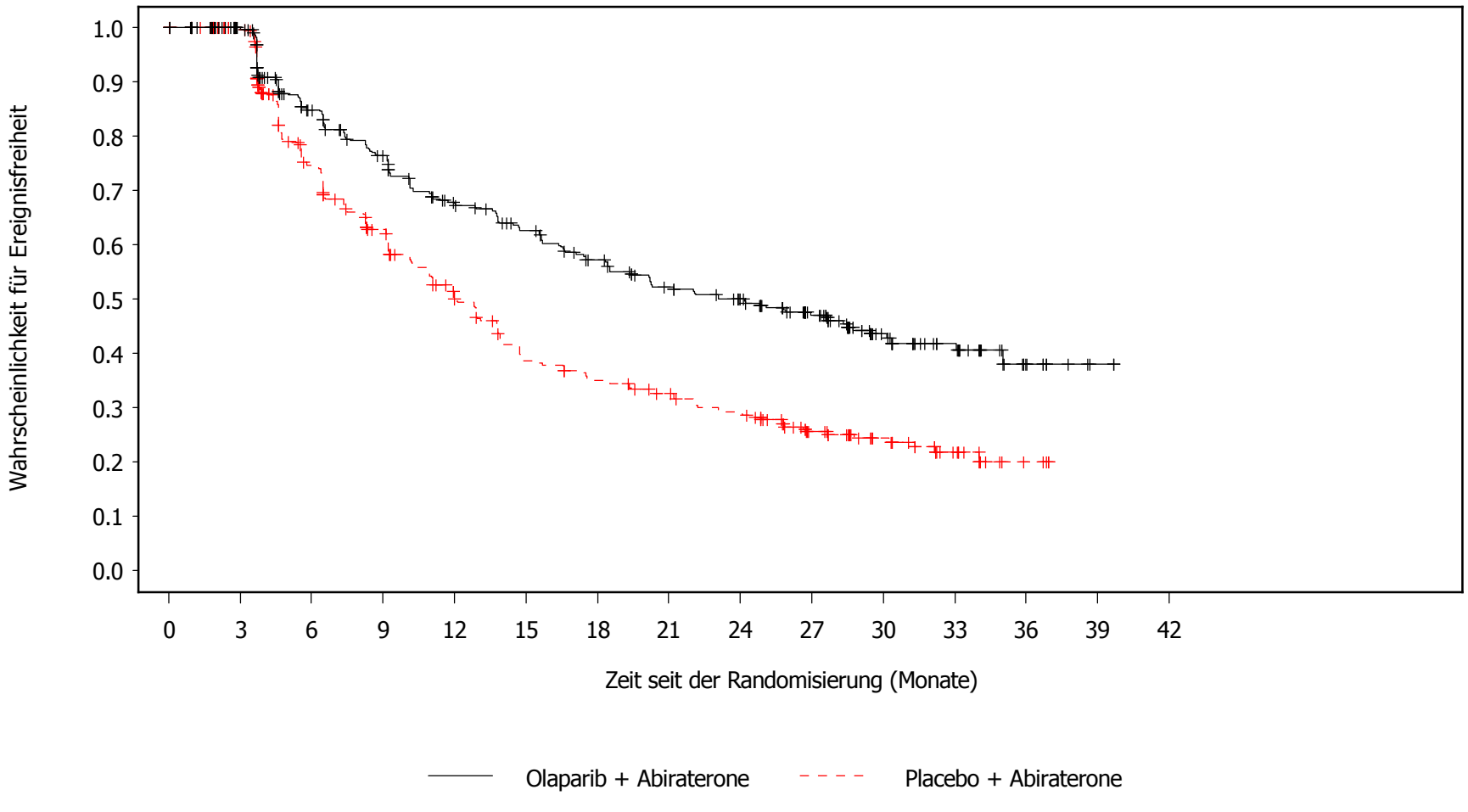
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.1.2.5 PROpel: Kaplan-Meier plot of time to first PSA progression
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	365	284	247	208	187	165	144	130	97	53	32	9	1	0	Olaparib + Abiraterone
397	369	251	200	150	113	101	90	78	51	34	17	3	0	0	Placebo + Abiraterone

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Table 1.2.1.1 PROpel: Summary of subgroup analysis of Gesamtüberleben (OS)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	74 (34,7)	NE [NE; NE]	226	86 (38,1)	NE [NE; NE]	0,89	[0,65; 1,22]	0,4790
Viszeral	67	32 (47,8)	30,5 [24,0; NE]	73	42 (57,5)	23,8 [20,1; NE]	0,79	[0,49; 1,25]	0,3110
andere	119	42 (35,3)	NE [NE; NE]	98	43 (43,9)	NE [NE; NE]	0,77	[0,50; 1,17]	0,2184
Interaktion p-Wert									0,8175
Docetaxel-Behandlung des mHSPC									
Ja	90	38 (42,2)	34,9 [30,1; NE]	90	47 (52,2)	27,4 [23,1; NE]	0,77	[0,50; 1,18]	0,2284
Nein	309	110 (35,6)	NE [NE; NE]	307	124 (40,4)	NE [NE; NE]	0,86	[0,66; 1,11]	0,2474
Interaktion p-Wert									0,6635
Alter bei Randomisierung									
<65 Jahre	130	35 (26,9)	NE [NE; NE]	97	42 (43,3)	NE [NE; NE]	0,57	[0,36; 0,90]	0,0152*
>=65 Jahre	269	113 (42,0)	NE [NE; NE]	300	129 (43,0)	NE [NE; NE]	0,98	[0,76; 1,26]	0,8461
Interaktion p-Wert									0,0435*
Region									
Asien	91	21 (23,1)	NE [NE; NE]	104	37 (35,6)	NE [NE; NE]	0,57	[0,33; 0,96]	0,0358*
Europa	178	78 (43,8)	NE [NE; NE]	172	80 (46,5)	32,2 [26,3; NE]	0,95	[0,69; 1,29]	0,7320
Nord- und Suedamerika	130	49 (37,7)	NE [NE; NE]	121	54 (44,6)	NE [NE; NE]	0,84	[0,57; 1,23]	0,3688
Interaktion p-Wert									0,2675
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	41 (41,8)	33,4 [29,1; NE]	100	54 (54,0)	26,7 [23,7;33,2]	0,72	[0,48; 1,08]	0,1098
Nicht-HRRm	269	100 (37,2)	NE [NE; NE]	267	110 (41,2)	NE [NE; NE]	0,88	[0,67; 1,16]	0,3642
Unbekannt	32	7 (21,9)	NE [NE; NE]	30	7 (23,3)	NE [NE; NE]	0,97	[0,33; 2,84]	0,9580
Interaktion p-Wert									0,6835

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.1 PROpel: Summary of subgroup analysis of Gesamtüberleben (OS)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	21 (33,9)	NE [NE; NE]	56	24 (42,9)	NE [NE; NE]	0,71	[0,39; 1,27]	0,2424
Nicht-HRRm	207	81 (39,1)	NE [NE; NE]	210	83 (39,5)	NE [NE; NE]	1,00	[0,73; 1,35]	0,9760
Unbekannt	130	46 (35,4)	NE [NE; NE]	131	64 (48,9)	32,0 [25,8; NE]	0,69	[0,47; 1,01]	0,0533
Interaktion p-Wert									0,2780
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	9 (31,0)	NE [NE; NE]	22	13 (59,1)	25,7 [14,9; NE]	0,41	[0,17; 0,95]	0,0367*
Nicht-HRRm	330	127 (38,5)	NE [NE; NE]	327	135 (41,3)	NE [NE; NE]	0,93	[0,73; 1,18]	0,5355
Unbekannt	40	12 (30,0)	33,4 [32,7; NE]	48	23 (47,9)	32,2 [22,5; NE]	0,57	[0,27; 1,13]	0,1076
Interaktion p-Wert									0,0971
ECOG-PS zu Baseline									
0	286	102 (35,7)	NE [NE; NE]	272	111 (40,8)	NE [NE; NE]	0,87	[0,67; 1,14]	0,3146
1	112	46 (41,1)	NE [NE; NE]	124	60 (48,4)	28,6 [22,9; NE]	0,77	[0,52; 1,12]	0,1708
Interaktion p-Wert									0,5876
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	55 (28,1)	NE [NE; NE]	200	68 (34,0)	NE [NE; NE]	0,79	[0,55; 1,12]	0,1878
Über medianem PSA-Baselinewert	201	92 (45,8)	NE [NE; NE]	196	102 (52,0)	27,4 [24,2;33,2]	0,87	[0,65; 1,15]	0,3157
Interaktion p-Wert									0,6846
Abstammung									
Kaukasisch	282	114 (40,4)	NE [NE; NE]	275	131 (47,6)	32,2 [26,3; NE]	0,83	[0,64; 1,07]	0,1440
Afroamerikanisch	14	4 (28,6)	NE [NE; NE]	11	4 (36,4)	NE [NE; NE]	0,72	[0,17; 3,04]	0,6425

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.1 PROpel: Summary of subgroup analysis of Gesamtüberleben (OS)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Asiatisch	66	15 (22,7)	NE [NE; NE]	72	22 (30,6)	NE [NE; NE]	0,65	[0,33; 1,24]	0,1940
Andere	15	7 (46,7)	NE [NE; NE]	9	1 (11,1)	NE [NE; NE]	4,91	[0,87; 91,88]	0,0742
Interaktion p-Wert									0,1957
Schmerzen zu baseline									
Symptomatisch	103	62 (60,2)	22,9 [18,4;29,2]	80	49 (61,3)	22,8 [16,4;26,2]	0,95	[0,66; 1,39]	0,8028
Asymptomatisch/mild symptomatisch	266	77 (28,9)	NE [NE; NE]	294	111 (37,8)	NE [NE; NE]	0,73	[0,54; 0,97]	0,0314*
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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.2 PROpel: Summary of subgroup analysis of Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	97 (45,5)	27,8 [24,6;30,5]	226	126 (55,8)	21,2 [19,1;24,6]	0,77	[0,59; 0,9996]	0,0496*
Viszeral	67	43 (64,2)	16,5 [11,4;19,3]	73	56 (76,7)	10,1 [5,8;13,7]	0,69	[0,46; 1,03]	0,0685
andere	119	59 (49,6)	24,8 [16,5;33,2]	98	76 (77,6)	13,7 [11,1;16,4]	0,55	[0,39; 0,77]	0,0005*
Interaktion p-Wert									0,3008
Docetaxel-Behandlung des mHSPC									
Ja	90	43 (47,8)	23,7 [16,4;31,7]	90	57 (63,3)	14,2 [11,5;21,1]	0,69	[0,46; 1,03]	0,0678
Nein	309	156 (50,5)	25,2 [20,6;29,1]	307	201 (65,5)	16,6 [14,3;19,3]	0,70	[0,57; 0,86]	0,0008*
Interaktion p-Wert									0,9672
Alter bei Randomisierung									
<65 Jahre	130	54 (41,5)	33,2 [23,7; NE]	97	64 (66,0)	16,4 [11,7;22,0]	0,52	[0,36; 0,75]	0,0004*
>=65 Jahre	269	145 (53,9)	22,5 [19,3;27,2]	300	194 (64,7)	16,6 [13,9;19,3]	0,80	[0,64; 0,99]	0,0389*
Interaktion p-Wert									0,0476*
Region									
Asien	91	38 (41,8)	33,7 [24,6; NE]	104	61 (58,7)	19,1 [13,8;23,1]	0,55	[0,36; 0,82]	0,0034*
Europa	178	95 (53,4)	21,9 [17,5;27,6]	172	123 (71,5)	13,9 [13,6;16,7]	0,69	[0,53; 0,90]	0,0069*
Nord- und Suedamerika	130	66 (50,8)	24,8 [16,5;31,7]	121	74 (61,2)	19,4 [14,3;22,0]	0,83	[0,59; 1,16]	0,2689
Interaktion p-Wert									0,3052
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	50 (51,0)	25,0 [15,3;30,3]	100	72 (72,0)	13,6 [9,3;16,5]	0,55	[0,38; 0,79]	0,0010*
Nicht-HRRm	269	139 (51,7)	24,8 [19,4;27,6]	267	171 (64,0)	19,0 [14,2;20,9]	0,77	[0,62; 0,97]	0,0251*
Unbekannt	32	10 (31,3)	NE [NE; NE]	30	15 (50,0)	19,3 [13,9; NE]	0,57	[0,25; 1,25]	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 1.2.1.2 PROpel: Summary of subgroup analysis of Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Interaktion p-Wert									0,2471
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	26 (41,9)	NE [NE; NE]	56	42 (75,0)	16,5 [10,8;19,4]	0,42	[0,25; 0,68]	0,0004*
Nicht-HRRm	207	111 (53,6)	22,2 [19,2;27,6]	210	130 (61,9)	16,6 [13,8;19,4]	0,86	[0,67; 1,11]	0,2421
Unbekannt	130	62 (47,7)	27,9 [19,4;33,2]	131	86 (65,6)	16,4 [13,8;21,8]	0,63	[0,46; 0,88]	0,0059*
Interaktion p-Wert									0,0267*
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	12 (41,4)	NE [NE; NE]	22	17 (77,3)	8,6 [5,3;16,4]	0,31	[0,14; 0,64]	0,0017*
Nicht-HRRm	330	167 (50,6)	24,8 [19,4;27,7]	327	208 (63,6)	16,6 [13,9;19,3]	0,75	[0,61; 0,91]	0,0046*
Unbekannt	40	20 (50,0)	27,6 [16,3; NE]	48	33 (68,8)	19,4 [12,3;24,2]	0,67	[0,38; 1,16]	0,1535
Interaktion p-Wert									0,0723
ECOG-PS zu Baseline									
0	286	138 (48,3)	27,6 [22,1;30,2]	272	174 (64,0)	16,7 [14,3;19,4]	0,69	[0,55; 0,86]	0,0011*
1	112	61 (54,5)	17,5 [13,6;27,7]	124	84 (67,7)	14,6 [11,6;19,3]	0,73	[0,52; 1,02]	0,0620
Interaktion p-Wert									0,7758
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	90 (45,9)	27,6 [24,9;32,7]	200	113 (56,5)	22,0 [19,1;26,3]	0,76	[0,58; 1,005]	0,0539
Über medianem PSA-Baselinewert	201	108 (53,7)	19,2 [14,7;27,8]	196	144 (73,5)	13,8 [11,5;15,5]	0,63	[0,49; 0,81]	0,0003*
Interaktion p-Wert									0,3374
Abstammung									
Kaukasisch	282	152 (53,9)	22,2 [19,2;27,6]	275	188 (68,4)	15,0 [13,8;19,1]	0,71	[0,57; 0,88]	0,0017*

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.2 PROpel: Summary of subgroup analysis of Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Afroamerikanisch	14	5 (35,7)	NE [NE; NE]	11	6 (54,5)	21,8 [8,6; NE]	0,70	[0,20; 2,32]	0,5550
Asiatisch	66	24 (36,4)	NE [NE; NE]	72	40 (55,6)	19,3 [13,8;33,1]	0,55	[0,33; 0,90]	0,0178*
Andere	15	9 (60,0)	25,6 [2,6; NE]	9	4 (44,4)	NE [NE; NE]	1,60	[0,52; 5,90]	0,4236
Interaktion p-Wert									0,3953
Schmerzen zu baseline									
Symptomatisch	103	67 (65,0)	14,1 [11,2;19,3]	80	59 (73,8)	13,8 [8,4;16,4]	0,80	[0,57; 1,14]	0,2234
Asymptomatisch/mild symptomatisch	266	119 (44,7)	29,1 [27,6;30,5]	294	185 (62,9)	19,1 [14,6;19,4]	0,62	[0,49; 0,78]	<0,0001*
Interaktion p-Wert									0,2258

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.3 PROpel: Summary of subgroup analysis of Zeit bis zur ersten symptomatischen skelettbezogenen Komplikation (SSRE)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	27 (12,7)	NE [NE; NE]	226	31 (13,7)	NE [NE; NE]	0,89	[0,53; 1,48]	0,6426
Viszeral	67	3 (4,5)	NE [NE; NE]	73	8 (11,0)	NE [NE; NE]	0,34	[0,07; 1,16]	0,0866
andere	119	11 (9,2)	NE [NE; NE]	98	10 (10,2)	NE [NE; NE]	0,78	[0,33; 1,88]	0,5757
Interaktion p-Wert									0,3788
Docetaxel-Behandlung des mHSPC									
Ja	90	20 (22,2)	NE [NE; NE]	90	14 (15,6)	NE [NE; NE]	1,36	[0,69; 2,74]	0,3776
Nein	309	21 (6,8)	NE [NE; NE]	307	35 (11,4)	NE [NE; NE]	0,54	[0,31; 0,92]	0,0234*
Interaktion p-Wert									0,0364*
Alter bei Randomisierung									
<65 Jahre	130	20 (15,4)	NE [NE; NE]	97	9 (9,3)	NE [NE; NE]	1,42	[0,67; 3,29]	0,3708
>=65 Jahre	269	21 (7,8)	NE [NE; NE]	300	40 (13,3)	NE [NE; NE]	0,56	[0,32; 0,93]	0,0253*
Interaktion p-Wert									0,0456*
Region									
Asien	91	7 (7,7)	NE [NE; NE]	104	11 (10,6)	NE [NE; NE]	0,58	[0,21; 1,46]	0,2471
Europa	178	25 (14,0)	NE [NE; NE]	172	21 (12,2)	NE [NE; NE]	1,07	[0,60; 1,93]	0,8218
Nord- und Suedamerika	130	9 (6,9)	NE [NE; NE]	121	17 (14,0)	NE [NE; NE]	0,49	[0,21; 1,08]	0,0783
Interaktion p-Wert									0,2451
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	11 (11,2)	NE [NE; NE]	100	18 (18,0)	NE [NE; NE]	0,50	[0,23; 1,04]	0,0629
Nicht-HRRm	269	27 (10,0)	NE [NE; NE]	267	28 (10,5)	NE [NE; NE]	0,91	[0,54; 1,55]	0,7361
Unbekannt	32	3 (9,4)	NE [NE; NE]	30	3 (10,0)	NE [NE; NE]	0,90	[0,17; 4,86]	0,8966
Interaktion p-Wert									0,4129

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.3 PROpel: Summary of subgroup analysis of Zeit bis zur ersten symptomatischen skelettbezogenen Komplikation (SSRE)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	8 (12,9)	NE [NE; NE]	56	10 (17,9)	NE [NE; NE]	0,58	[0,22; 1,46]	0,2425
Nicht-HRRm	207	21 (10,1)	NE [NE; NE]	210	23 (11,0)	NE [NE; NE]	0,91	[0,50; 1,65]	0,7625
Unbekannt	130	12 (9,2)	NE [NE; NE]	131	16 (12,2)	NE [NE; NE]	0,66	[0,31; 1,40]	0,2798
Interaktion p-Wert									0,6575
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	3 (10,3)	NE [NE; NE]	22	4 (18,2)	NE [NE; NE]	0,35	[0,07; 1,60]	0,1721
Nicht-HRRm	330	31 (9,4)	NE [NE; NE]	327	37 (11,3)	NE [NE; NE]	0,78	[0,48; 1,26]	0,3159
Unbekannt	40	7 (17,5)	NE [NE; NE]	48	8 (16,7)	NE [NE; NE]	0,95	[0,33; 2,66]	0,9261
Interaktion p-Wert									0,5420
ECOG-PS zu Baseline									
0	286	30 (10,5)	NE [NE; NE]	272	29 (10,7)	NE [NE; NE]	0,94	[0,56; 1,57]	0,8088
1	112	11 (9,8)	NE [NE; NE]	124	20 (16,1)	NE [NE; NE]	0,51	[0,23; 1,04]	0,0638
Interaktion p-Wert									0,1721
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	18 (9,2)	NE [NE; NE]	200	19 (9,5)	NE [NE; NE]	0,90	[0,47; 1,73]	0,7554
Über medianem PSA-Baselinewert	201	23 (11,4)	NE [NE; NE]	196	30 (15,3)	NE [NE; NE]	0,66	[0,38; 1,14]	0,1362
Interaktion p-Wert									0,4728
Abstammung									
Kaukasisch	282	31 (11,0)	NE [NE; NE]	275	37 (13,5)	NE [NE; NE]	0,76	[0,47; 1,22]	0,2513
Afroamerikanisch	14	0	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	NC	[NC]	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.3 PROpel: Summary of subgroup analysis of Zeit bis zur ersten symptomatischen skelettbezogenen Komplikation (SSRE)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Asiatisch	66	4 (6,1)	NE [NE; NE]	72	8 (11,1)	NE [NE; NE]	0,45	[0,12; 1,42]	0,1739
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4152
Schmerzen zu baseline									
Symptomatisch	103	15 (14,6)	NE [NE; NE]	80	16 (20,0)	NE [NE; NE]	0,68	[0,33; 1,39]	0,2879
Asymptomatisch/mild symptomatisch	266	23 (8,6)	NE [NE; NE]	294	32 (10,9)	NE [NE; NE]	0,70	[0,40; 1,19]	0,1871
Interaktion p-Wert									0,9573

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.4 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Chemotherapie oder Tod
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=301)			Placebo + Abiraterone (N=296)					
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]
Metastasen zu Baseline									
Nur Knochen	159	65 (40,9)	NE [NE; NE]	164	84 (51,2)	26,3 [23,0; NE]	0,73	[0,53; 1,01]	0,0601
Viszeral	53	33 (62,3)	19,7 [13,8;28,5]	53	37 (69,8)	18,4 [13,2;22,7]	0,81	[0,50; 1,29]	0,3659
andere	89	35 (39,3)	NE [NE; NE]	79	46 (58,2)	21,2 [14,9;31,8]	0,59	[0,38; 0,91]	0,0175*
Interaktion p-Wert									0,6006
Docetaxel-Behandlung des mHSPC									
Nein	301	133 (44,2)	NE [NE; NE]	296	167 (56,4)	23,8 [21,7;27,0]	0,71	[0,57; 0,89]	0,0032*
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	81	26 (32,1)	NE [NE; NE]	59	32 (54,2)	23,7 [17,9; NE]	0,50	[0,29; 0,83]	0,0077*
>=65 Jahre	220	107 (48,6)	30,1 [25,0; NE]	237	135 (57,0)	23,8 [20,9;27,0]	0,80	[0,62; 1,03]	0,0834
Interaktion p-Wert									0,1022
Region									
Asien	80	27 (33,8)	NE [NE; NE]	89	44 (49,4)	26,4 [20,5; NE]	0,55	[0,34; 0,88]	0,0125*
Europa	119	61 (51,3)	27,7 [22,6; NE]	114	76 (66,7)	20,9 [17,1;23,7]	0,69	[0,49; 0,97]	0,0309*
Nord- und Suedamerika	102	45 (44,1)	NE [NE; NE]	93	47 (50,5)	28,1 [21,7; NE]	0,88	[0,59; 1,33]	0,5545
Interaktion p-Wert									0,3232
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	70	32 (45,7)	NE [NE; NE]	77	51 (66,2)	19,9 [14,9;25,5]	0,60	[0,38; 0,92]	0,0196*
Nicht-HRRm	209	95 (45,5)	NE [NE; NE]	198	107 (54,0)	25,5 [22,0;31,8]	0,78	[0,59; 1,03]	0,0837
Unbekannt	22	6 (27,3)	NE [NE; NE]	21	9 (42,9)	NE [NE; NE]	0,55	[0,18; 1,52]	0,2491
Interaktion p-Wert									0,5093

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.4 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Chemotherapie oder Tod
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=301)			Placebo + Abiraterone (N=296)					
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]
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	48	17 (35,4)	NE [NE; NE]	43	23 (53,5)	25,5 [16,7; NE]	0,57	[0,30; 1,05]	0,0722
Nicht-HRRm	154	75 (48,7)	30,1 [24,5; NE]	151	82 (54,3)	23,9 [20,3; NE]	0,84	[0,61; 1,14]	0,2640
Unbekannt	99	41 (41,4)	NE [NE; NE]	102	62 (60,8)	23,0 [20,0;26,4]	0,61	[0,41; 0,91]	0,0138*
Interaktion p-Wert									0,3490
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	22	5 (22,7)	NE [NE; NE]	16	12 (75,0)	14,9 [10,4;26,3]	0,20	[0,06; 0,53]	0,0012*
Nicht-HRRm	246	115 (46,7)	NE [NE; NE]	246	137 (55,7)	25,2 [22,0;28,6]	0,78	[0,61; 1,005]	0,0547
Unbekannt	33	13 (39,4)	32,7 [19,1; NE]	34	18 (52,9)	22,5 [13,7; NE]	0,65	[0,31; 1,32]	0,2338
Interaktion p-Wert									0,0275*
ECOG-PS zu Baseline									
0	224	95 (42,4)	NE [NE; NE]	205	111 (54,1)	26,3 [22,7;32,0]	0,73	[0,55; 0,96]	0,0240*
1	76	38 (50,0)	28,5 [15,9; NE]	90	56 (62,2)	17,5 [13,2;25,2]	0,70	[0,46; 1,05]	0,0845
Interaktion p-Wert									0,8593
PSA zu Baseline									
Unter medianem PSA-Baselinewert	151	56 (37,1)	NE [NE; NE]	149	68 (45,6)	NE [NE; NE]	0,77	[0,54; 1,10]	0,1498
Über medianem PSA-Baselinewert	149	76 (51,0)	27,9 [21,2; NE]	147	99 (67,3)	18,0 [14,9;22,0]	0,64	[0,48; 0,87]	0,0037*
Interaktion p-Wert									0,4440
Abstammung									
Kaukasisch	202	97 (48,0)	32,7 [24,5; NE]	194	121 (62,4)	22,0 [19,9;25,9]	0,70	[0,54; 0,92]	0,0100*
Afroamerikanisch	12	4 (33,3)	NE [NE; NE]	9	3 (33,3)	NE [NE; NE]	1,01	[0,22; 5,12]	0,9910

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.4 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Chemotherapie oder Tod
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=301)			Placebo + Abiraterone (N=296)					
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]
Asiatisch	60	20 (33,3)	NE [NE; NE]	67	32 (47,8)	26,4 [19,8; NE]	0,57	[0,32; 0,99]	0,0446*
Andere	11	5 (45,5)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	4,16	[0,67; 79,62]	0,1359
Interaktion p-Wert									0,2207
Schmerzen zu baseline									
Symptomatisch	64	44 (68,8)	14,9 [11,7;24,1]	61	45 (73,8)	15,0 [12,6;19,9]	0,85	[0,56; 1,28]	0,4307
Asymptomatisch/mild symptomatisch	212	79 (37,3)	NE [NE; NE]	212	109 (51,4)	26,4 [22,7; NE]	0,65	[0,49; 0,87]	0,0035*
Interaktion p-Wert									0,3127

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.5 PROpel: Summary of subgroup analysis of Zeit bis zum ersten chirurgischen Eingriff wegen Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	0	NE [NE; NE]	226	4 (1,8)	NE [NE; NE]	NC	[NC]	NC
Viszeral	67	0	NE [NE; NE]	73	0	NE [NE; NE]	NC	[NC]	NC
andere	119	2 (1,7)	NE [NE; NE]	98	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	0	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Nein	309	2 (0,6)	NE [NE; NE]	307	4 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	2 (1,5)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	269	0	NE [NE; NE]	300	4 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	1 (1,1)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Europa	178	0	NE [NE; NE]	172	3 (1,7)	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	1 (0,8)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	5 (5,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	269	1 (0,4)	NE [NE; NE]	267	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	32	0	NE [NE; NE]	30	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 1.2.1.5 PROpel: Summary of subgroup analysis of Zeit bis zum ersten chirurgischen Eingriff wegen Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	3 (5,4)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	1 (0,5)	NE [NE; NE]	210	2 (1,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	130	0	NE [NE; NE]	131	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	1 (0,3)	NE [NE; NE]	327	4 (1,2)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	40	0	NE [NE; NE]	48	2 (4,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	2 (0,7)	NE [NE; NE]	272	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
1	112	0	NE [NE; NE]	124	4 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	1 (0,5)	NE [NE; NE]	200	3 (1,5)	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	201	1 (0,5)	NE [NE; NE]	196	3 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Kaukasisch	282	2 (0,7)	NE [NE; NE]	275	5 (1,8)	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.5 PROpel: Summary of subgroup analysis of Zeit bis zum ersten chirurgischen Eingriff wegen Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Asiatisch	66	0	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	0	NE [NE; NE]	80	3 (3,8)	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	2 (0,8)	NE [NE; NE]	294	3 (1,0)	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.6 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Strahlentherapie wegen skelettaler Symptome
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	20 (9,4)	NE [NE; NE]	226	26 (11,5)	NE [NE; NE]	0,78	[0,43; 1,39]	0,3979
Viszeral	67	2 (3,0)	NE [NE; NE]	73	5 (6,8)	NE [NE; NE]	0,36	[0,05; 1,67]	0,1973
andere	119	6 (5,0)	NE [NE; NE]	98	9 (9,2)	NE [NE; NE]	0,47	[0,16; 1,31]	0,1473
Interaktion p-Wert									0,5271
Docetaxel-Behandlung des mHSPC									
Ja	90	16 (17,8)	NE [NE; NE]	90	11 (12,2)	NE [NE; NE]	1,37	[0,64; 3,04]	0,4173
Nein	309	12 (3,9)	NE [NE; NE]	307	29 (9,4)	NE [NE; NE]	0,37	[0,18; 0,71]	0,0024*
Interaktion p-Wert									0,0105*
Alter bei Randomisierung									
<65 Jahre	130	15 (11,5)	NE [NE; NE]	97	7 (7,2)	NE [NE; NE]	1,35	[0,57; 3,54]	0,5030
>=65 Jahre	269	13 (4,8)	NE [NE; NE]	300	33 (11,0)	NE [NE; NE]	0,42	[0,21; 0,77]	0,0049*
Interaktion p-Wert									0,0306*
Region									
Asien	91	3 (3,3)	NE [NE; NE]	104	7 (6,7)	NE [NE; NE]	0,38	[0,08; 1,38]	0,1439
Europa	178	18 (10,1)	NE [NE; NE]	172	17 (9,9)	NE [NE; NE]	0,95	[0,49; 1,86]	0,8777
Nord- und Suedamerika	130	7 (5,4)	NE [NE; NE]	121	16 (13,2)	NE [NE; NE]	0,41	[0,16; 0,95]	0,0380*
Interaktion p-Wert									0,2229
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	6 (6,1)	NE [NE; NE]	100	15 (15,0)	NE [NE; NE]	0,32	[0,11; 0,79]	0,0127*
Nicht-HRRm	269	20 (7,4)	NE [NE; NE]	267	22 (8,2)	NE [NE; NE]	0,86	[0,47; 1,58]	0,6226
Unbekannt	32	2 (6,3)	NE [NE; NE]	30	3 (10,0)	NE [NE; NE]	0,60	[0,08; 3,63]	0,5733
Interaktion p-Wert									0,2109

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 1.2.1.6 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Strahlentherapie wegen skelettaler Symptome
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	8 (14,3)	NE [NE; NE]	0,35	[0,09; 1,12]	0,0776
Nicht-HRRm	207	15 (7,2)	NE [NE; NE]	210	19 (9,0)	NE [NE; NE]	0,79	[0,39; 1,54]	0,4859
Unbekannt	130	9 (6,9)	NE [NE; NE]	131	13 (9,9)	NE [NE; NE]	0,61	[0,25; 1,42]	0,2549
Interaktion p-Wert									0,5069
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	0,15	[0,01; 1,19]	0,0728
Nicht-HRRm	330	20 (6,1)	NE [NE; NE]	327	30 (9,2)	NE [NE; NE]	0,62	[0,35; 1,09]	0,0961
Unbekannt	40	7 (17,5)	NE [NE; NE]	48	7 (14,6)	NE [NE; NE]	1,09	[0,37; 3,20]	0,8660
Interaktion p-Wert									0,2409
ECOG-PS zu Baseline									
0	286	18 (6,3)	NE [NE; NE]	272	24 (8,8)	NE [NE; NE]	0,67	[0,36; 1,23]	0,1997
1	112	10 (8,9)	NE [NE; NE]	124	16 (12,9)	NE [NE; NE]	0,59	[0,26; 1,28]	0,1811
Interaktion p-Wert									0,7915
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	15 (7,7)	NE [NE; NE]	200	14 (7,0)	NE [NE; NE]	1,02	[0,49; 2,14]	0,9593
Über medianem PSA-Baselinewert	201	13 (6,5)	NE [NE; NE]	196	26 (13,3)	NE [NE; NE]	0,43	[0,21; 0,82]	0,0100*
Interaktion p-Wert									0,0831
Abstammung									
Kaukasisch	282	22 (7,8)	NE [NE; NE]	275	32 (11,6)	NE [NE; NE]	0,62	[0,35; 1,06]	0,0801
Afroamerikanisch	14	0	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	NC	[NC]	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.6 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Strahlentherapie wegen skelettaler Symptome
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Asiatisch	66	1 (1,5)	NE [NE; NE]	72	4 (5,6)	NE [NE; NE]	0,22	[0,01; 1,50]	0,1299
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3367
Schmerzen zu baseline									
Symptomatisch	103	13 (12,6)	NE [NE; NE]	80	14 (17,5)	NE [NE; NE]	0,68	[0,32; 1,46]	0,3184
Asymptomatisch/mild symptomatisch	266	13 (4,9)	NE [NE; NE]	294	25 (8,5)	NE [NE; NE]	0,50	[0,25; 0,96]	0,0378*
Interaktion p-Wert									0,5506

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.7 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Knochenfraktur aufgrund von Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	8 (3,8)	NE [NE; NE]	226	7 (3,1)	NE [NE; NE]	1,14	[0,41; 3,25]	0,8033
Viszeral	67	1 (1,5)	NE [NE; NE]	73	3 (4,1)	NE [NE; NE]	0,29	[0,01; 2,28]	0,2488
andere	119	6 (5,0)	NE [NE; NE]	98	5 (5,1)	NE [NE; NE]	0,85	[0,26; 2,95]	0,7880
Interaktion p-Wert									0,5209
Docetaxel-Behandlung des mHSPC									
Ja	90	6 (6,7)	NE [NE; NE]	90	4 (4,4)	NE [NE; NE]	1,37	[0,39; 5,37]	0,6214
Nein	309	9 (2,9)	NE [NE; NE]	307	11 (3,6)	NE [NE; NE]	0,73	[0,29; 1,77]	0,4836
Interaktion p-Wert									0,4193
Alter bei Randomisierung									
<65 Jahre	130	6 (4,6)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	1,22	[0,32; 5,80]	0,7735
>=65 Jahre	269	9 (3,3)	NE [NE; NE]	300	12 (4,0)	NE [NE; NE]	0,79	[0,32; 1,88]	0,5987
Interaktion p-Wert									0,5994
Region									
Asien	91	3 (3,3)	NE [NE; NE]	104	5 (4,8)	NE [NE; NE]	0,54	[0,11; 2,21]	0,3923
Europa	178	10 (5,6)	NE [NE; NE]	172	3 (1,7)	NE [NE; NE]	2,95	[0,90; 13,16]	0,0752
Nord- und Suedamerika	130	2 (1,5)	NE [NE; NE]	121	7 (5,8)	NE [NE; NE]	0,26	[0,04; 1,08]	0,0641
Interaktion p-Wert									0,0268*
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	6 (6,1)	NE [NE; NE]	100	6 (6,0)	NE [NE; NE]	0,80	[0,25; 2,55]	0,6960
Nicht-HRRm	269	8 (3,0)	NE [NE; NE]	267	8 (3,0)	NE [NE; NE]	0,93	[0,34; 2,53]	0,8842
Unbekannt	32	1 (3,1)	NE [NE; NE]	30	1 (3,3)	NE [NE; NE]	0,91	[0,04; 23,03]	0,9476
Interaktion p-Wert									0,9796

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.7 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Knochenfraktur aufgrund von Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	3 (4,8)	NE [NE; NE]	56	2 (3,6)	NE [NE; NE]	1,06	[0,18; 8,08]	0,9461
Nicht-HRRm	207	9 (4,3)	NE [NE; NE]	210	7 (3,3)	NE [NE; NE]	1,27	[0,47; 3,57]	0,6298
Unbekannt	130	3 (2,3)	NE [NE; NE]	131	6 (4,6)	NE [NE; NE]	0,43	[0,09; 1,64]	0,2214
Interaktion p-Wert									0,4380
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	13 (3,9)	NE [NE; NE]	327	13 (4,0)	NE [NE; NE]	0,93	[0,43; 2,02]	0,8518
Unbekannt	40	1 (2,5)	NE [NE; NE]	48	2 (4,2)	NE [NE; NE]	0,52	[0,02; 5,48]	0,5878
Interaktion p-Wert									0,6493
ECOG-PS zu Baseline									
0	286	11 (3,8)	NE [NE; NE]	272	8 (2,9)	NE [NE; NE]	1,22	[0,49; 3,15]	0,6670
1	112	4 (3,6)	NE [NE; NE]	124	7 (5,6)	NE [NE; NE]	0,53	[0,14; 1,75]	0,2992
Interaktion p-Wert									0,2766
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	3 (1,5)	NE [NE; NE]	200	6 (3,0)	NE [NE; NE]	0,46	[0,10; 1,75]	0,2602
Über medianem PSA-Baselinewert	201	12 (6,0)	NE [NE; NE]	196	9 (4,6)	NE [NE; NE]	1,15	[0,49; 2,83]	0,7457
Interaktion p-Wert									0,2623
Abstammung									
Kaukasisch	282	11 (3,9)	NE [NE; NE]	275	10 (3,6)	NE [NE; NE]	0,96	[0,41; 2,32]	0,9324
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.7 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Knochenfraktur aufgrund von Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Asiatisch	66	3 (4,5)	NE [NE; NE]	72	4 (5,6)	NE [NE; NE]	0,68	[0,13; 3,07]	0,6057
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6856
Schmerzen zu baseline									
Symptomatisch	103	4 (3,9)	NE [NE; NE]	80	4 (5,0)	NE [NE; NE]	0,71	[0,17; 3,00]	0,6272
Asymptomatisch/mild symptomatisch	266	10 (3,8)	NE [NE; NE]	294	10 (3,4)	NE [NE; NE]	0,96	[0,39; 2,35]	0,9308
Interaktion p-Wert									0,7151

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.8 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Rückenmarkkompression aufgrund von Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	1 (0,5)	NE [NE; NE]	226	5 (2,2)	NE [NE; NE]	NC	[NC]	NC
Viszeral	67	0	NE [NE; NE]	73	2 (2,7)	NE [NE; NE]	NC	[NC]	NC
andere	119	2 (1,7)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	1 (1,1)	NE [NE; NE]	90	4 (4,4)	NE [NE; NE]	NC	[NC]	NC
Nein	309	2 (0,6)	NE [NE; NE]	307	4 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	2 (1,5)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	269	1 (0,4)	NE [NE; NE]	300	6 (2,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	NC	[NC]	NC
Europa	178	2 (1,1)	NE [NE; NE]	172	4 (2,3)	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	1 (0,8)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	6 (6,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	269	2 (0,7)	NE [NE; NE]	267	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	32	0	NE [NE; NE]	30	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.8 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Rückenmarkkompression aufgrund von Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	0	NE [NE; NE]	56	4 (7,1)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	2 (1,0)	NE [NE; NE]	210	3 (1,4)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	130	1 (0,8)	NE [NE; NE]	131	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	1 (0,3)	NE [NE; NE]	327	6 (1,8)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	40	2 (5,0)	NE [NE; NE]	48	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	1 (0,3)	NE [NE; NE]	272	5 (1,8)	NE [NE; NE]	NC	[NC]	NC
1	112	2 (1,8)	NE [NE; NE]	124	3 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	0	NE [NE; NE]	200	4 (2,0)	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	201	3 (1,5)	NE [NE; NE]	196	4 (2,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Kaukasisch	282	2 (0,7)	NE [NE; NE]	275	5 (1,8)	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 1.2.1.8 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Rückenmarkkompression aufgrund von Knochenmetastasen
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Asiatisch	66	0	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	1 (1,0)	NE [NE; NE]	80	4 (5,0)	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	2 (0,8)	NE [NE; NE]	294	4 (1,4)	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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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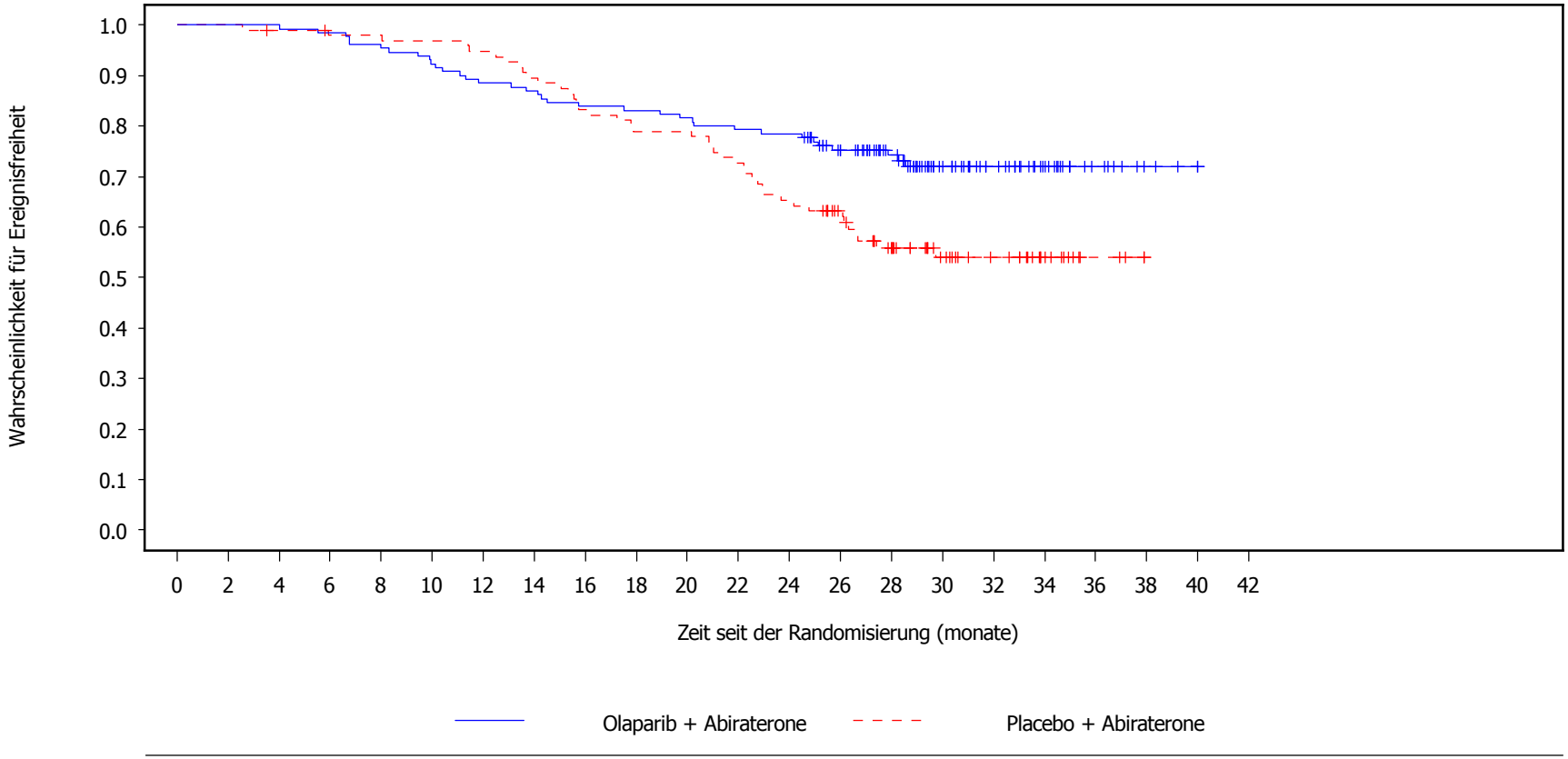
Figure 1.2.2.1 PROpel: Kaplan-Meier plot of Gesamtüberleben (OS) for Alter bei Randomisierung=<65 Jahre
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

130	130	130	128	124	120	115	113	109	108	106	103	102	87	70	48	34	21	9	3	1	0	Olaparib + Abiraterone
97	97	95	93	93	92	90	85	79	75	75	69	62	53	41	27	20	11	3	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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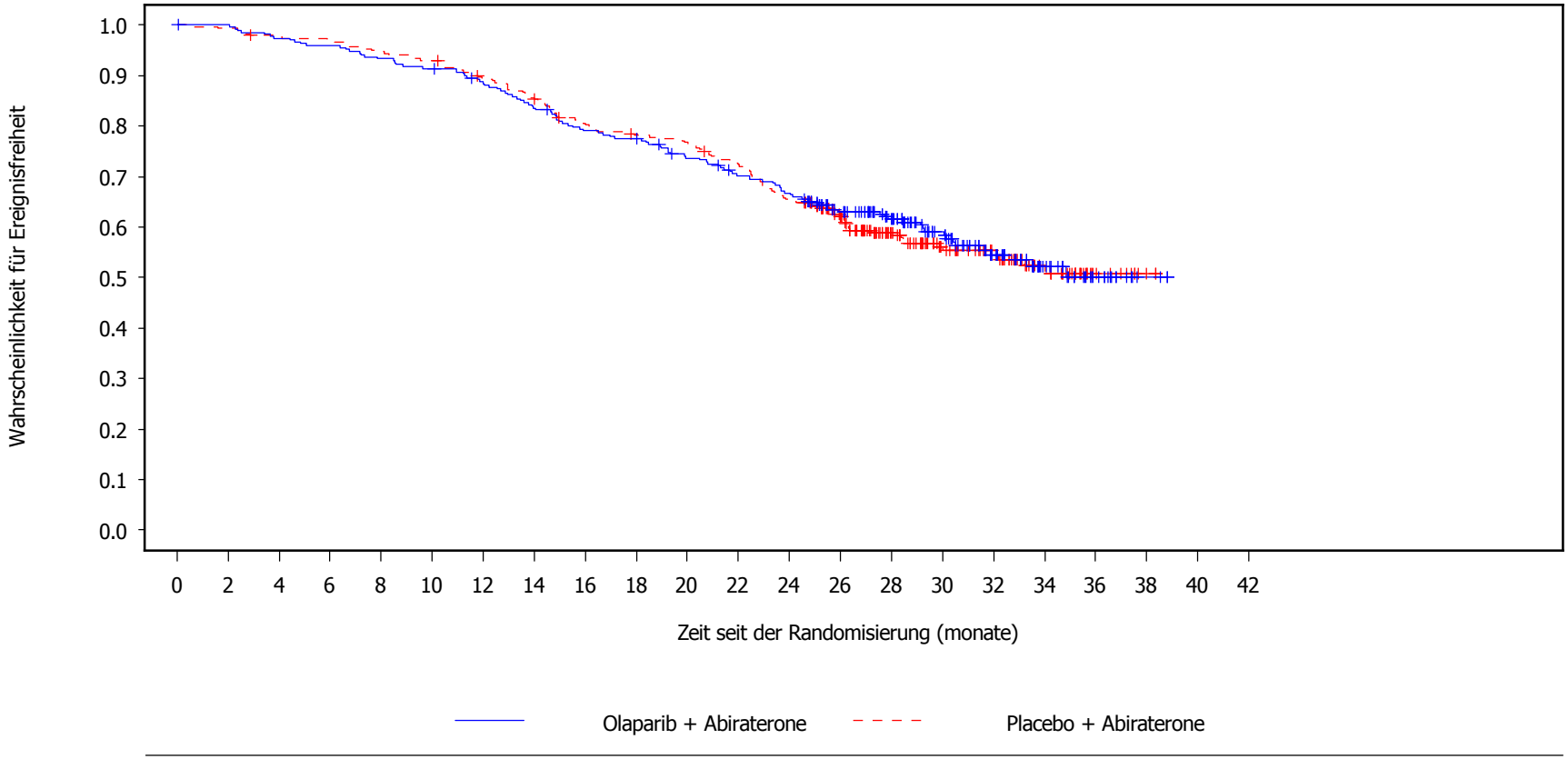
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.2.2.2 PROpel: Kaplan-Meier plot of Gesamtüberleben (OS) for Alter bei Randomisierung=>=65 Jahre
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

269	268	261	257	250	245	235	222	209	205	192	181	172	145	118	87	59	32	14	2	0	0	Olaparib + Abiraterone
300	298	293	290	283	278	265	252	237	229	225	211	191	158	113	79	61	35	10	1	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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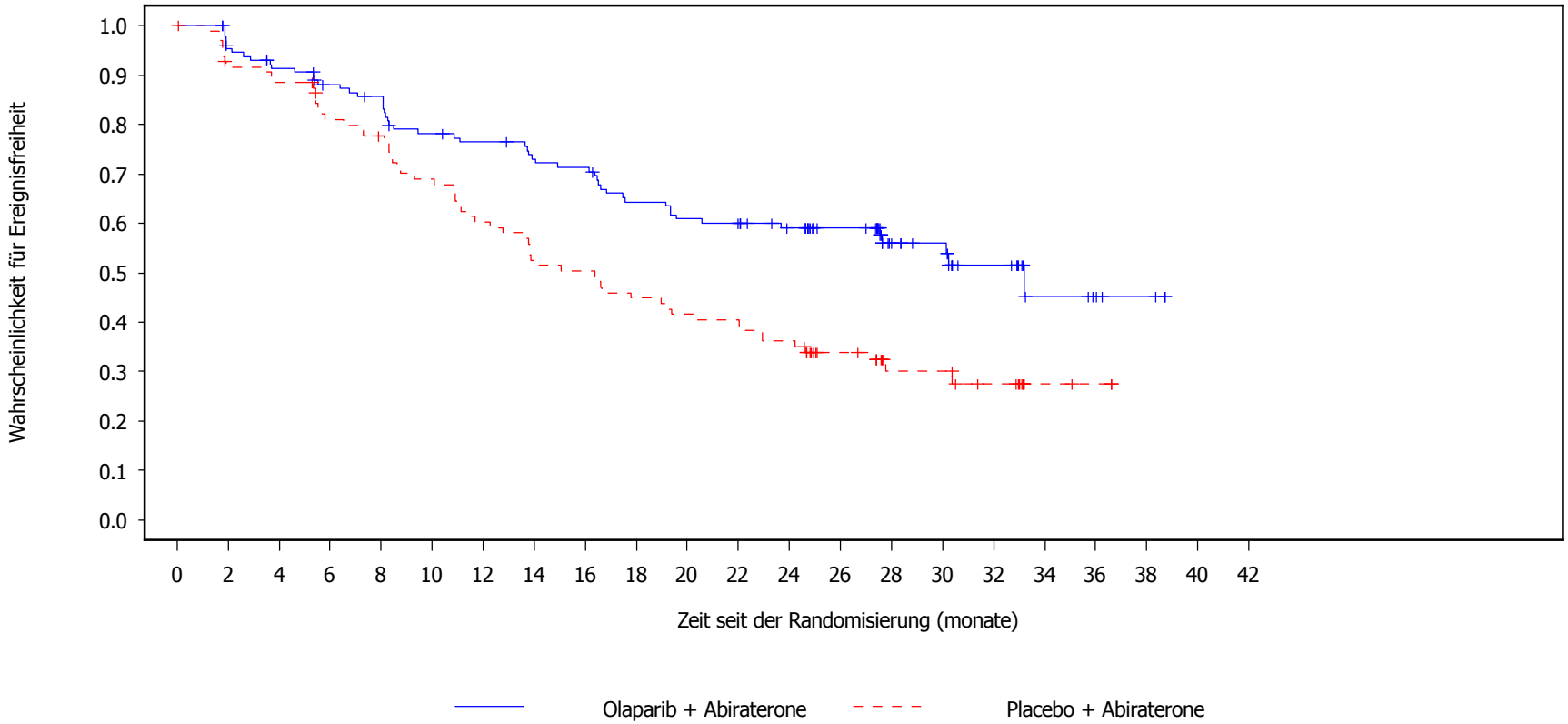
Figure 1.2.2.3 PROpel: Kaplan-Meier plot of Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS) for Alter bei Randomisierung=<65 Jahre
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

130	121	114	107	103	93	90	85	83	74	70	68	61	50	30	27	15	6	4	2	0	0	Olaparib + Abiraterone
97	87	84	75	71	63	55	48	46	41	38	37	33	23	13	13	9	2	1	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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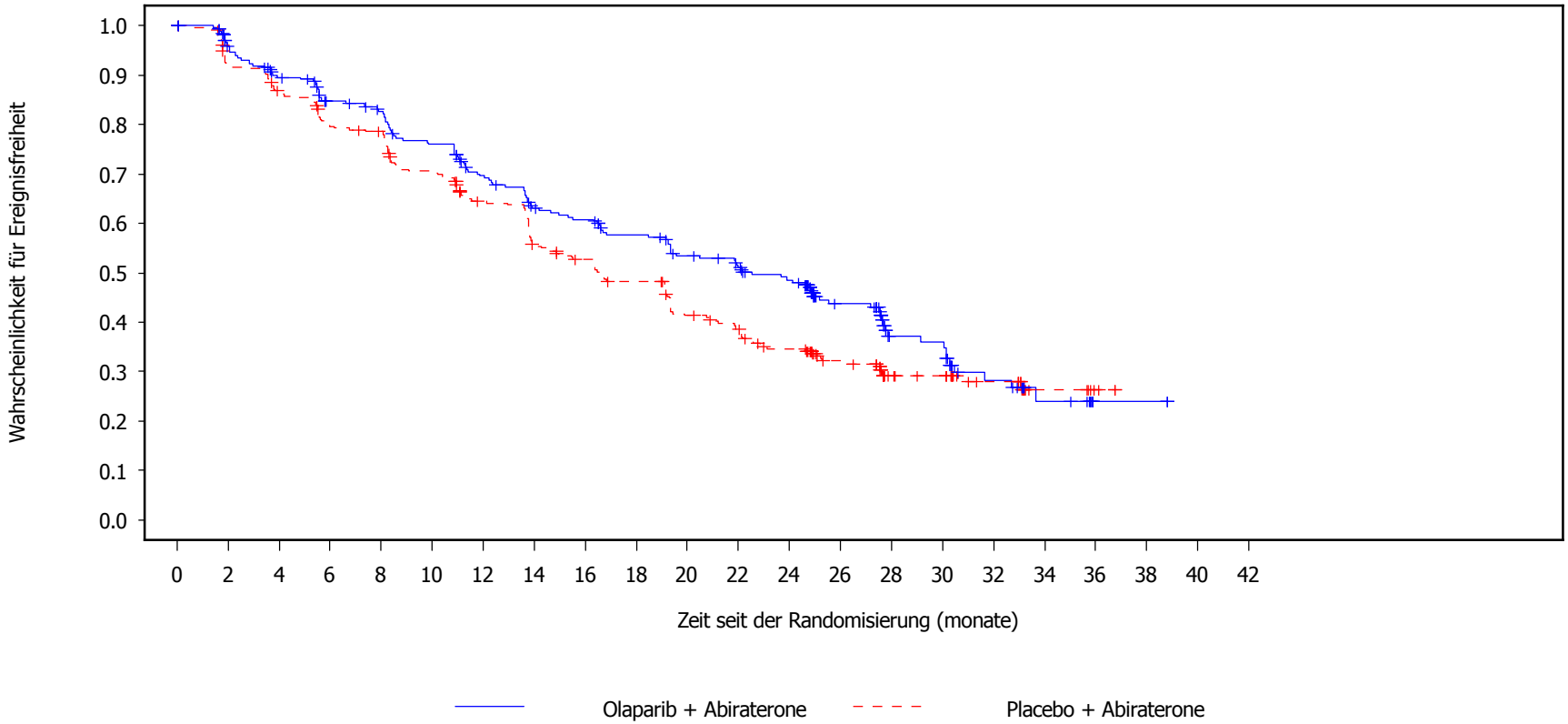
Figure 1.2.2.4 PROpel: Kaplan-Meier plot of Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS) for Alter bei Randomisierung=>=65 Jahre
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

269	246	226	206	198	181	161	143	137	126	114	106	97	60	32	31	18	9	1	1	0	0	Olaparib + Abiraterone
300	272	254	231	226	201	177	151	141	128	107	98	84	61	38	35	21	6	2	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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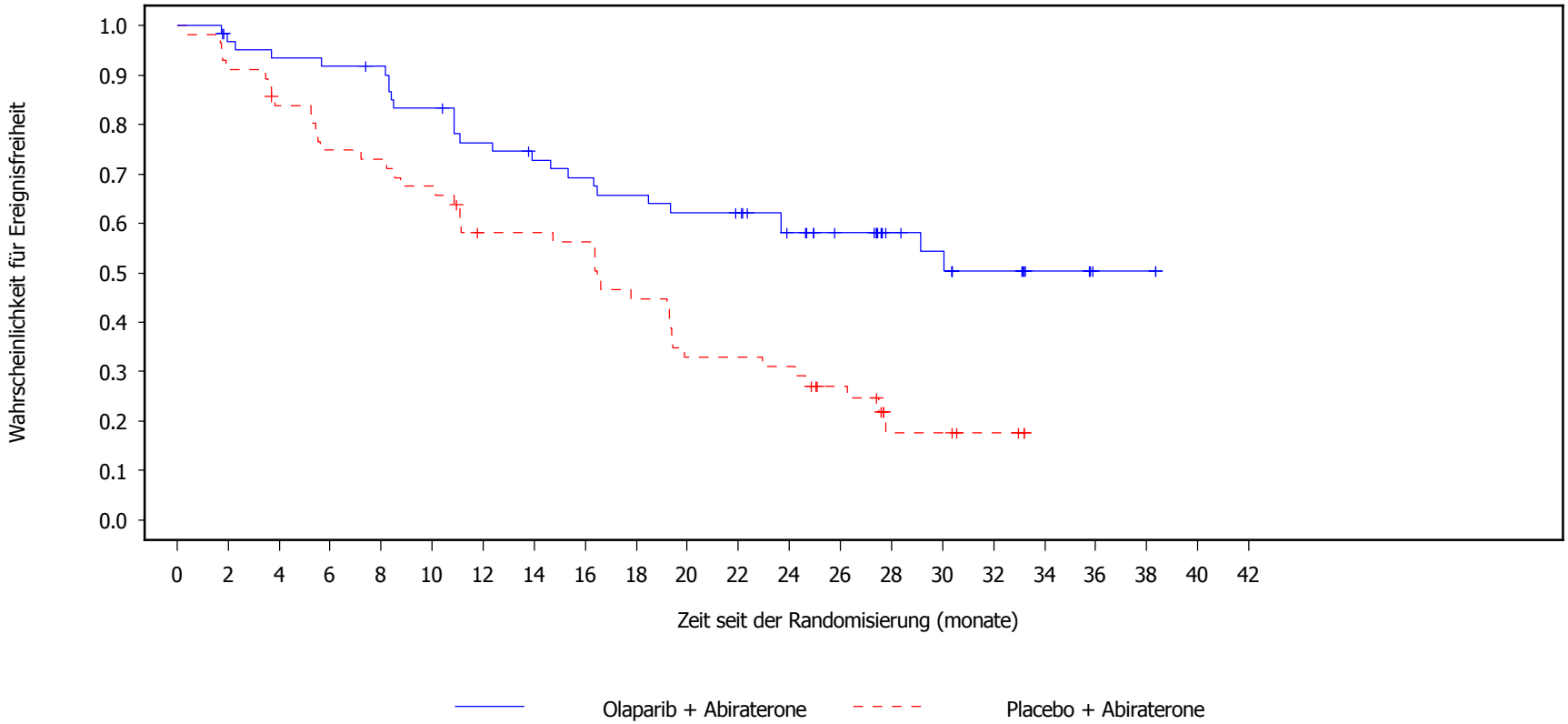
Figure 1.2.2.5 PROpel: Kaplan-Meier plot of Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS) for HRRm-Status basierend auf einem Tumorgewebetest=HRRm
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

62	58	56	55	54	49	44	41	39	37	35	34	28	23	16	14	8	4	1	1	0	0	Olaparib + Abiraterone
56	51	46	41	40	37	30	30	29	23	17	17	16	11	4	4	2	0	0	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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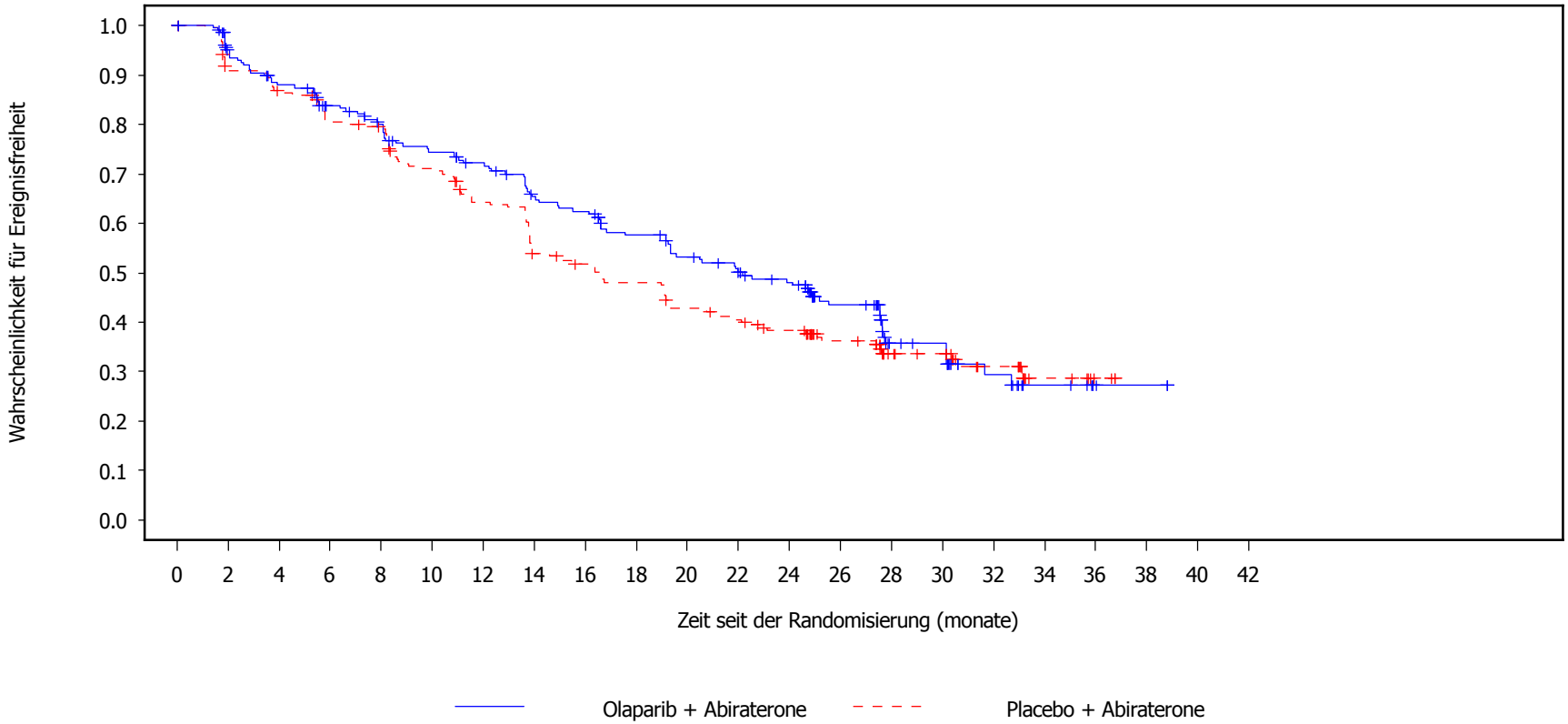
Figure 1.2.2.6 PROpel: Kaplan-Meier plot of Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS) for HRRm-Status basierend auf einem Tumorgewebetest=Nicht-HRRm
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

207	188	171	156	146	134	127	112	107	95	86	78	71	49	27	25	14	7	2	1	0	0	Olaparib + Abiraterone
210	189	178	163	159	140	124	103	97	90	79	74	67	49	32	29	19	7	2	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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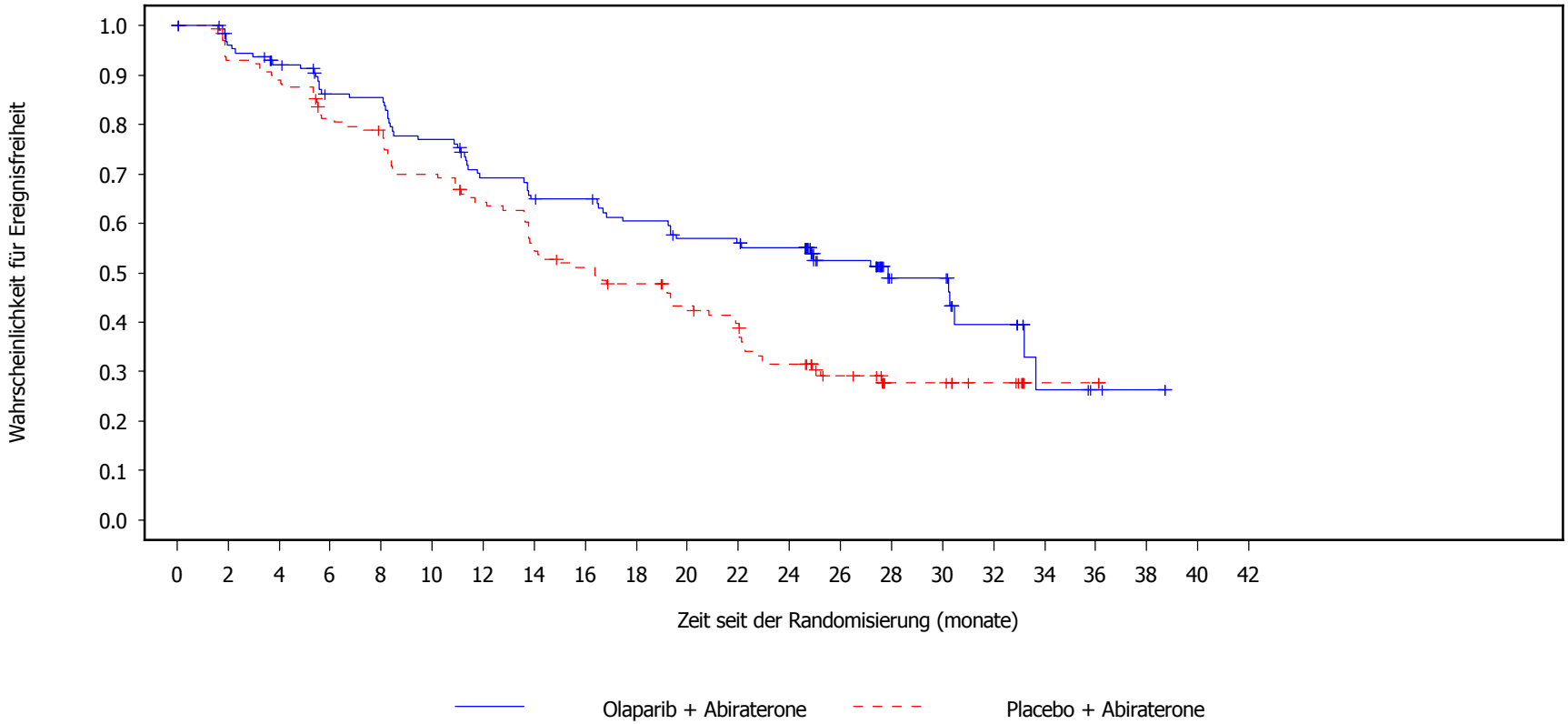
Figure 1.2.2.7 PROpel: Kaplan-Meier plot of Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS) for HRRm-Status basierend auf einem Tumorgewebetest=Unbekannt
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

130	121	113	102	101	91	80	75	74	68	63	62	59	38	19	19	11	4	2	1	0	0	Olaparib + Abiraterone
131	119	114	102	98	87	78	66	61	56	49	44	34	24	15	15	9	1	1	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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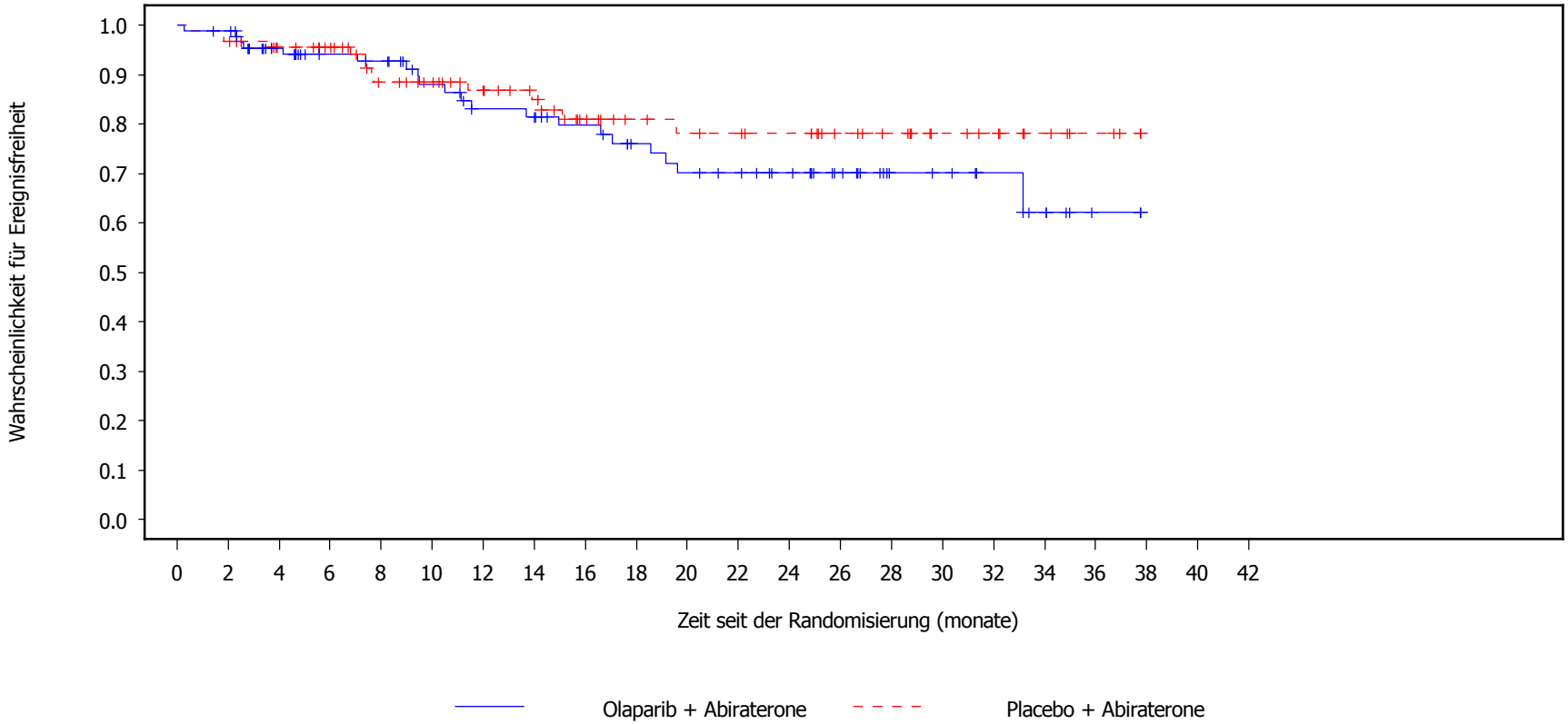
Figure 1.2.2.8 PROpel: Kaplan-Meier plot of Zeit bis zur ersten symptomatischen skelettbezogenen Komplikation (SSRE) for Docetaxel-Behandlung des mHSPC=Ja
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

90	88	75	66	64	56	50	48	44	38	35	33	29	22	14	13	9	6	1	0	0	0	Olaparib + Abiraterone
90	87	79	73	61	57	50	45	36	31	29	28	26	20	17	12	10	6	3	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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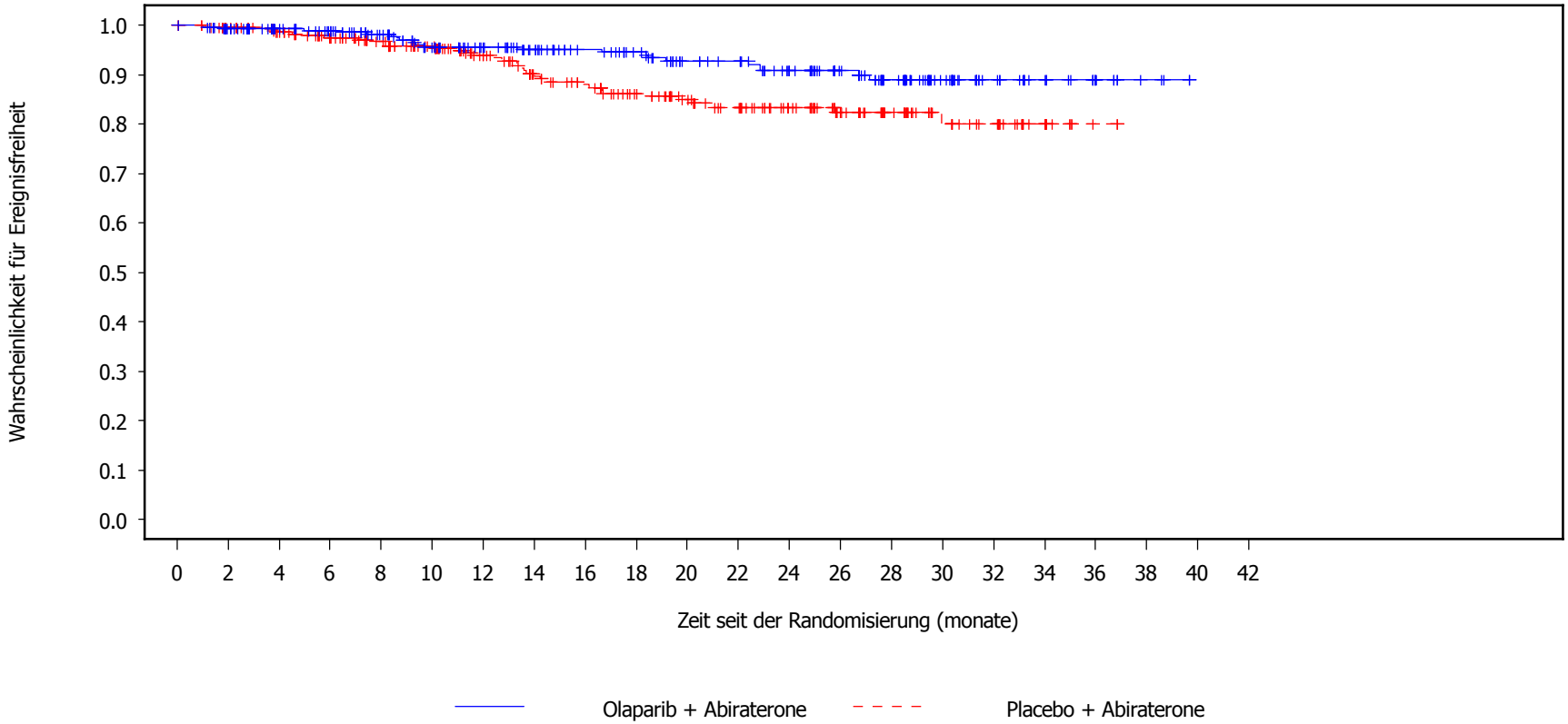
Figure 1.2.2.9 PROpel: Kaplan-Meier plot of Zeit bis zur ersten symptomatischen skelettbezogenen Komplikation (SSRE) for Docetaxel-Behandlung des mHSPC=Nein
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

309	296	274	261	241	218	202	187	173	163	146	142	126	106	80	52	29	20	9	3	0	0	Olaparib + Abiraterone
307	292	270	252	234	211	185	164	153	136	121	110	91	71	54	36	26	12	1	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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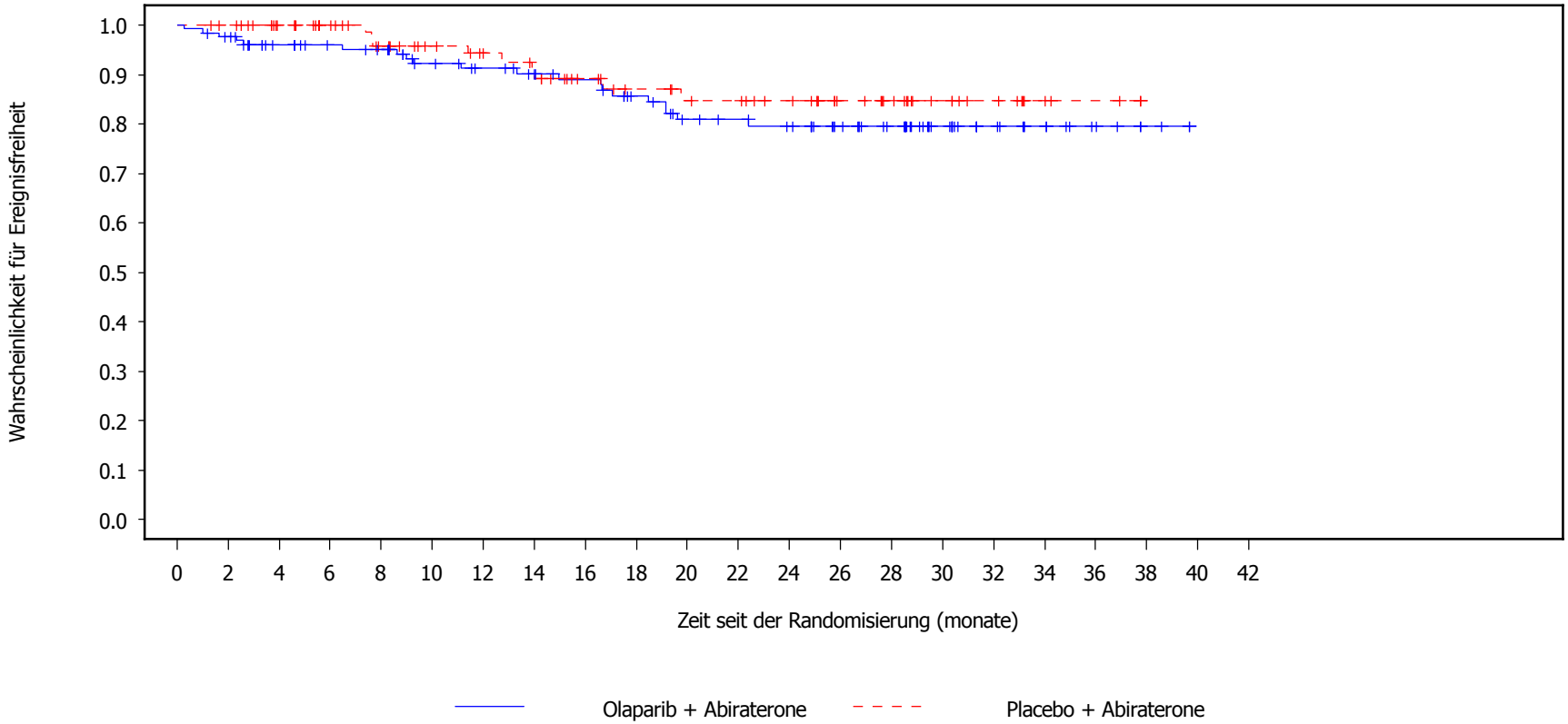
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.2.2.10 PROpel: Kaplan-Meier plot of Zeit bis zur ersten symptomatischen skelettbezogenen Komplikation (SSRE) for Alter bei Randomisierung=<65 Jahre
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

130	125	113	106	103	93	88	83	80	72	64	62	59	50	43	28	16	11	6	2	0	0	Olaparib + Abiraterone
97	95	86	77	68	61	56	52	45	40	37	36	32	24	20	13	9	4	2	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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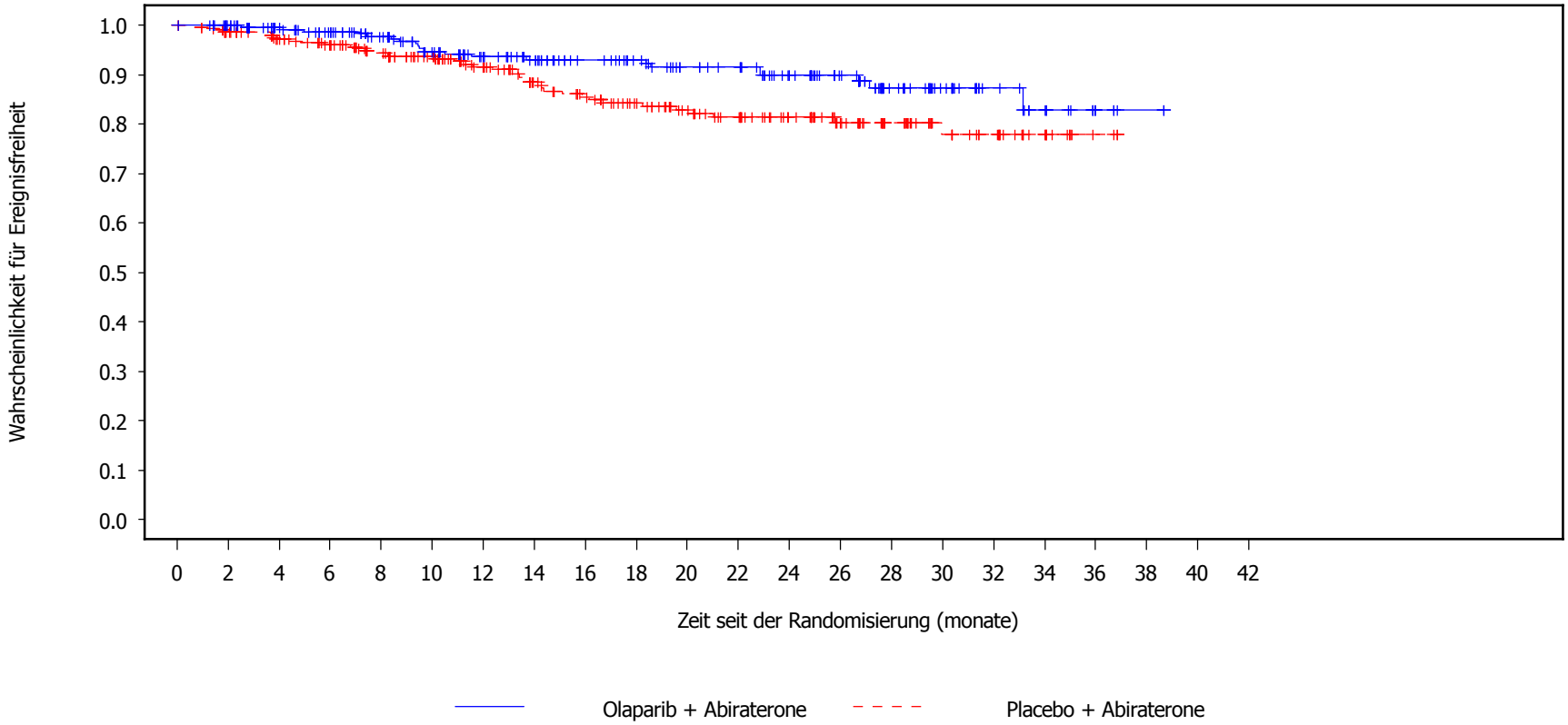
Figure 1.2.2.11 PROpel: Kaplan-Meier plot of Zeit bis zur ersten symptomatischen skelettbezogenen Komplikation (SSRE) for Alter bei Randomisierung=>=65 Jahre
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

269	259	236	221	202	181	164	152	137	129	117	113	96	78	51	37	22	15	4	1	0	0	Olaparib + Abiraterone
300	284	263	248	227	207	179	157	144	127	113	102	85	67	51	35	27	14	2	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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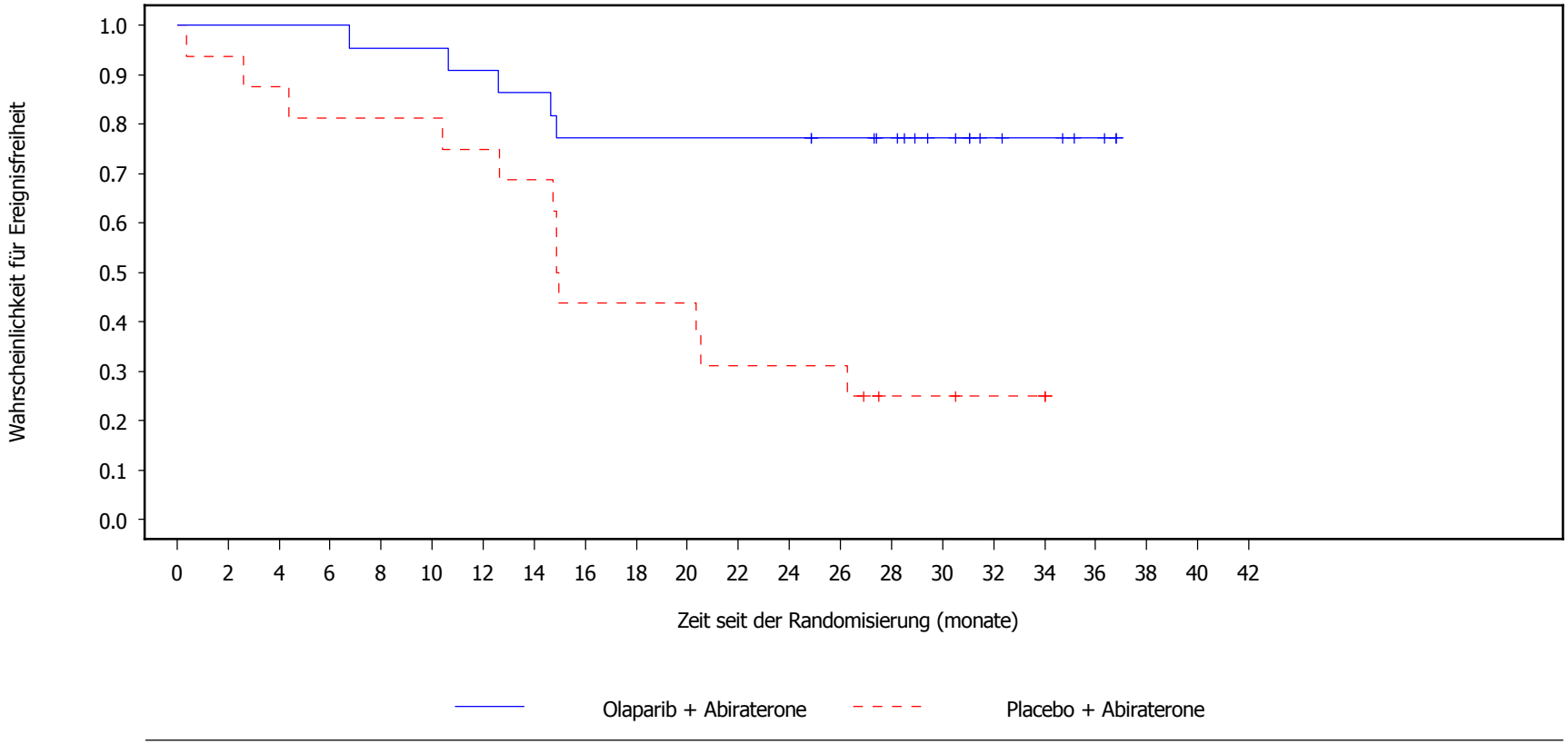
Figure 1.2.2.12 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Chemotherapie oder Tod for HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen=HRRm
Full Analysis Set, DCO 14MAR2022



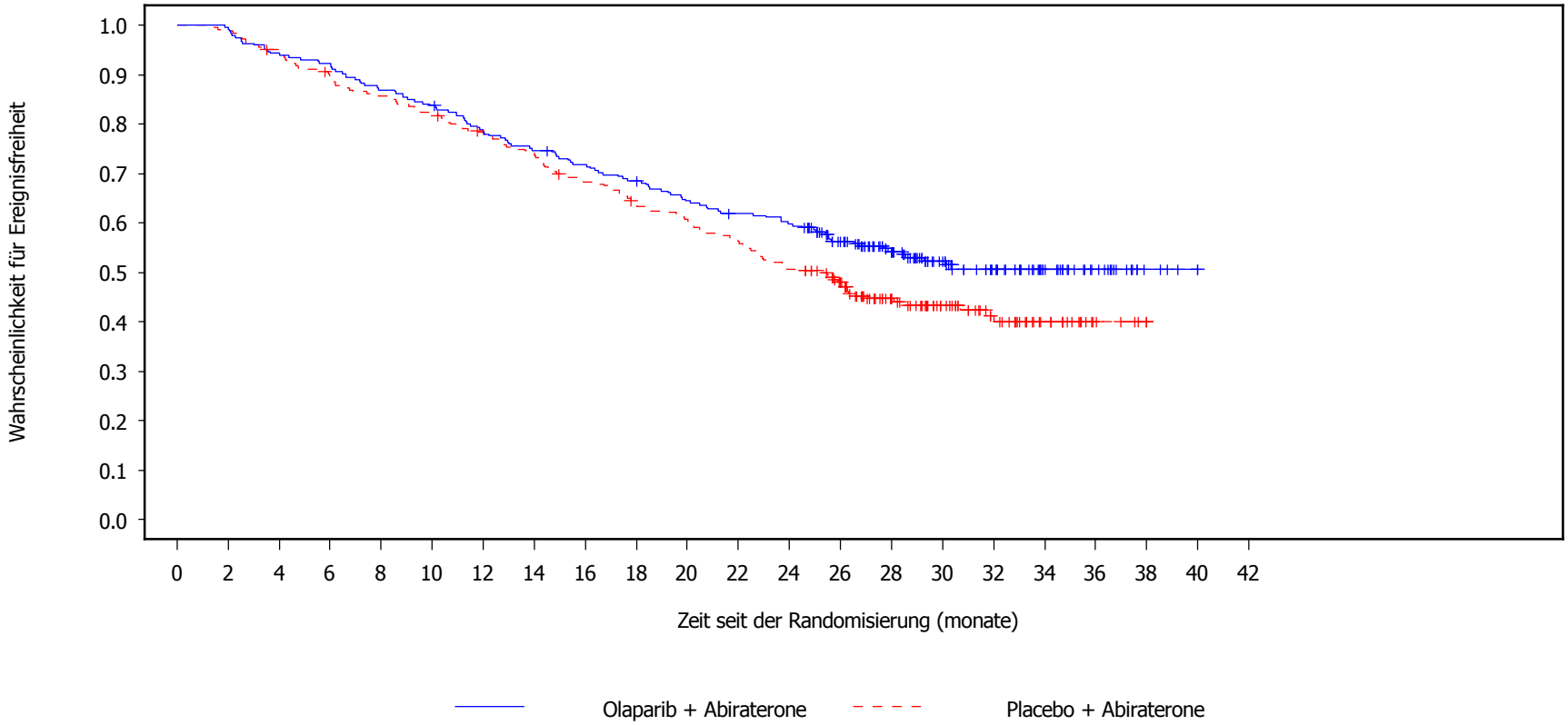
Anzahl an Patienten unter Risiko:

22	22	22	22	21	21	20	19	17	17	17	17	17	15	13	9	5	4	2	0	0	0	Olaparib + Abiraterone
16	15	14	13	13	13	12	11	7	7	7	5	5	5	2	2	1	1	0	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubeff.sas gttesubeffbal 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.2.2.13 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Chemotherapie oder Tod for HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen=Nicht-HRRm
Full Analysis Set, DCO 14MAR2022

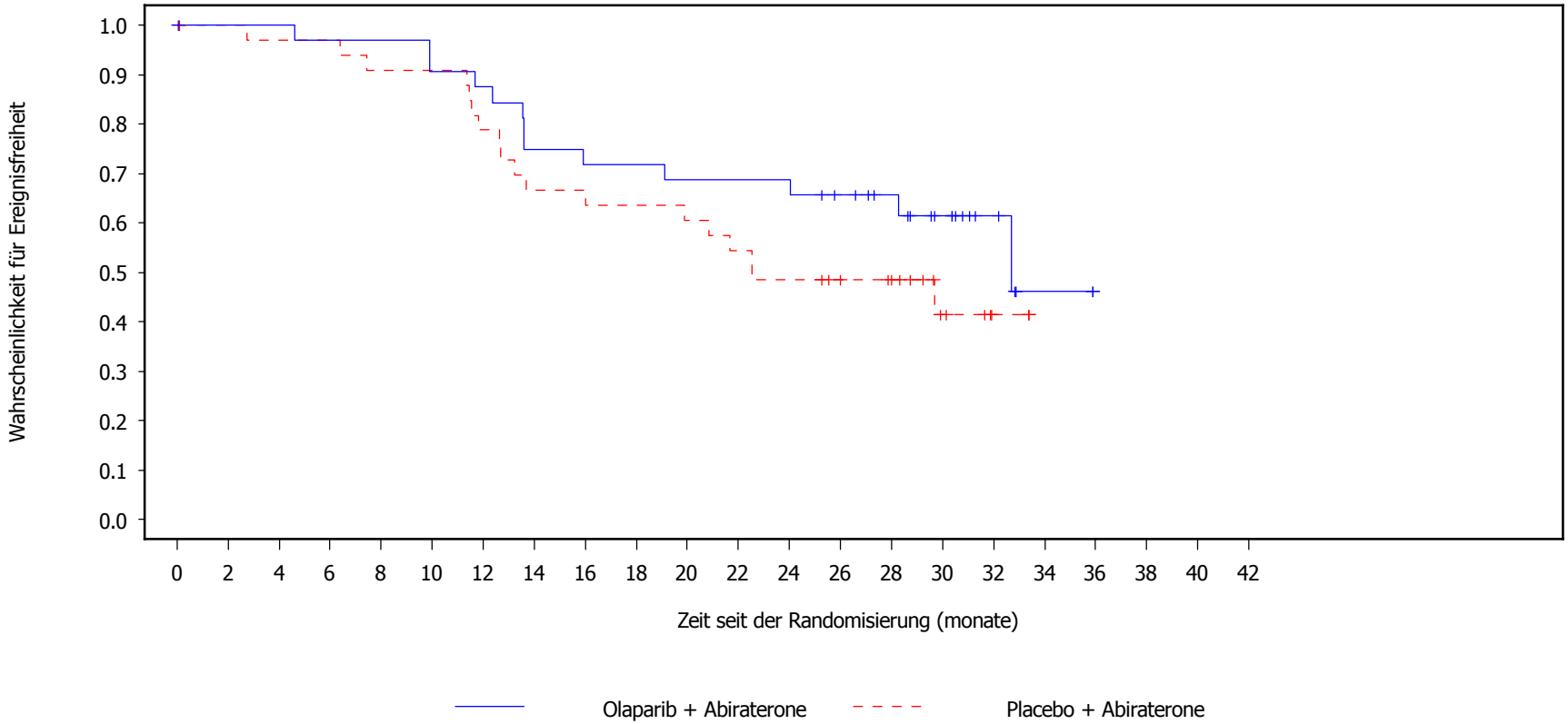


Anzahl an Patienten unter Risiko:

246	245	232	227	214	206	192	183	175	167	156	149	144	120	93	67	49	30	17	4	1	0	Olaparib + Abiraterone
246	243	233	219	209	201	188	178	164	152	145	134	121	103	75	52	35	19	5	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubeff.sas gttesubeffbam 05DEC2022:09:12 khcs324

Figure 1.2.2.14 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Chemotherapie oder Tod for HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen=Unbekannt
Full Analysis Set, DCO 14MAR2022

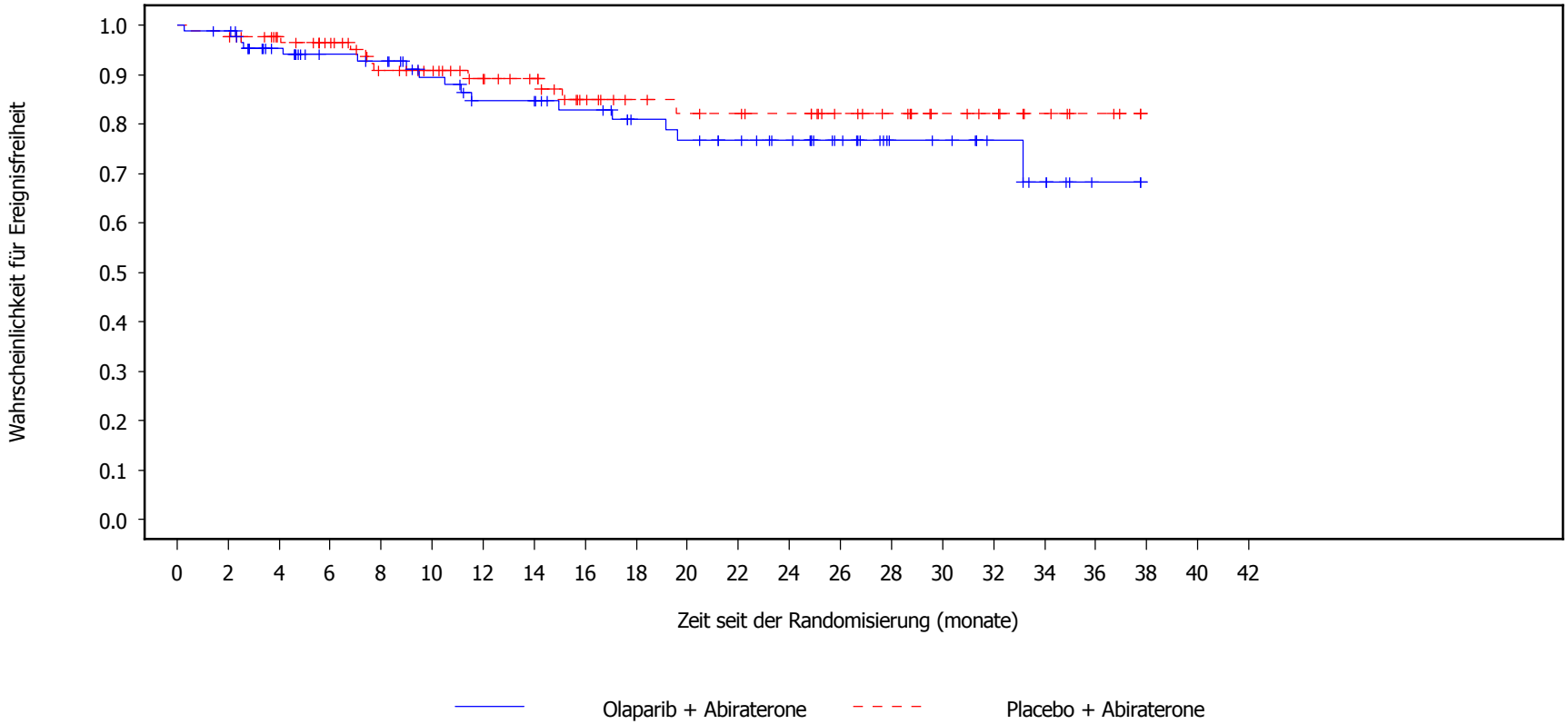


Anzahl an Patienten unter Risiko:

33	32	32	31	31	29	28	24	23	23	22	22	22	19	16	11	5	1	0	0	0	0	Olaparib + Abiraterone
34	33	32	32	30	30	26	22	22	21	20	18	16	13	11	5	1	0	0	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubeff.sas gttesubeffban 05DEC2022:09:12 khcs324

Figure 1.2.2.15 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Strahlentherapie wegen skelettaler Symptome for Docetaxel-Behandlung des mHSPC=Ja
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

90	88	75	66	64	56	50	49	45	39	37	34	30	23	15	14	9	6	1	0	0	0	Olaparib + Abiraterone
90	88	80	73	62	58	50	46	36	31	29	28	26	20	17	12	10	6	3	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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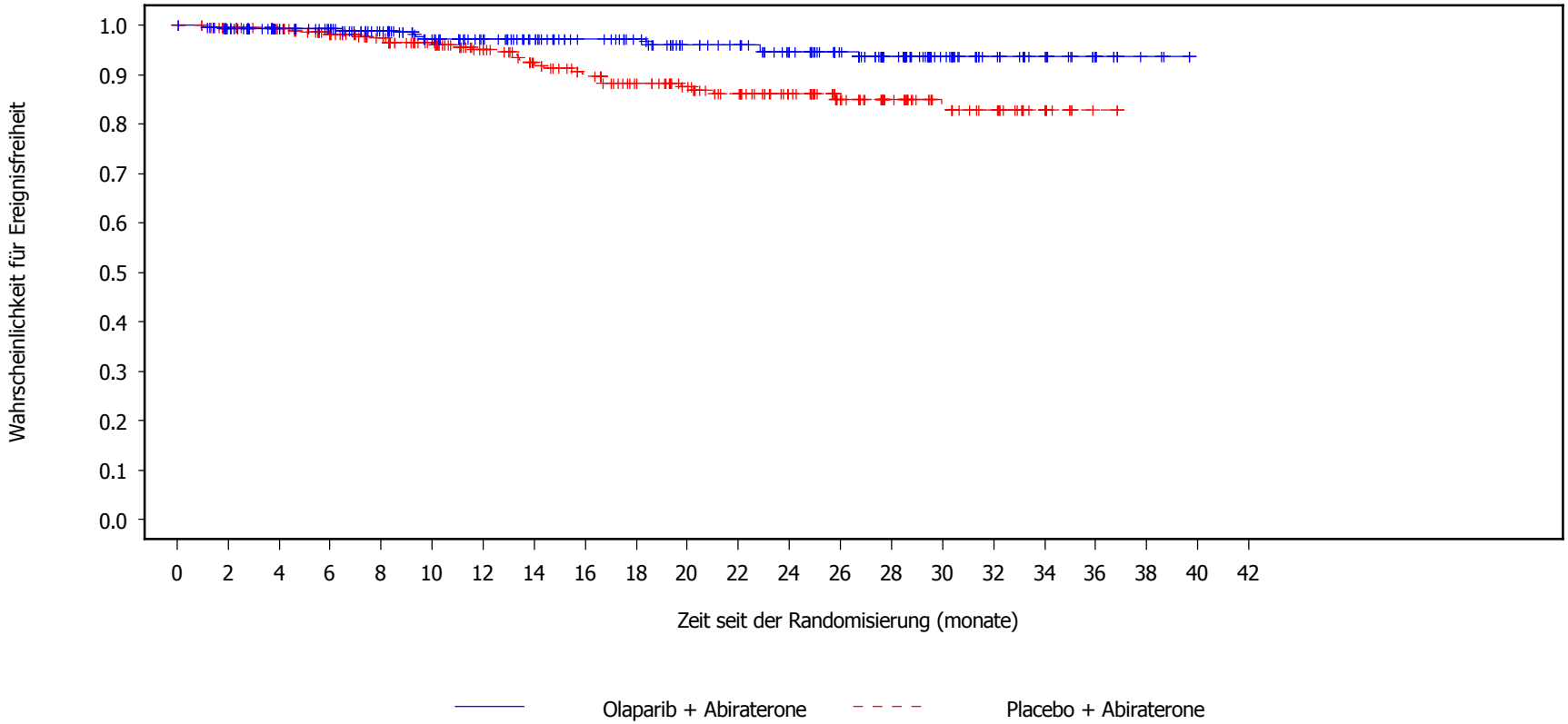
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.2.2.16 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Strahlentherapie wegen skelettaler Symptome for Docetaxel-Behandlung des mHSPC=Nein
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

309	296	274	262	242	219	203	189	175	166	150	145	130	110	84	56	33	23	9	3	0	0	Olaparib + Abiraterone
307	292	271	252	234	211	186	167	155	138	124	112	93	71	54	36	26	12	1	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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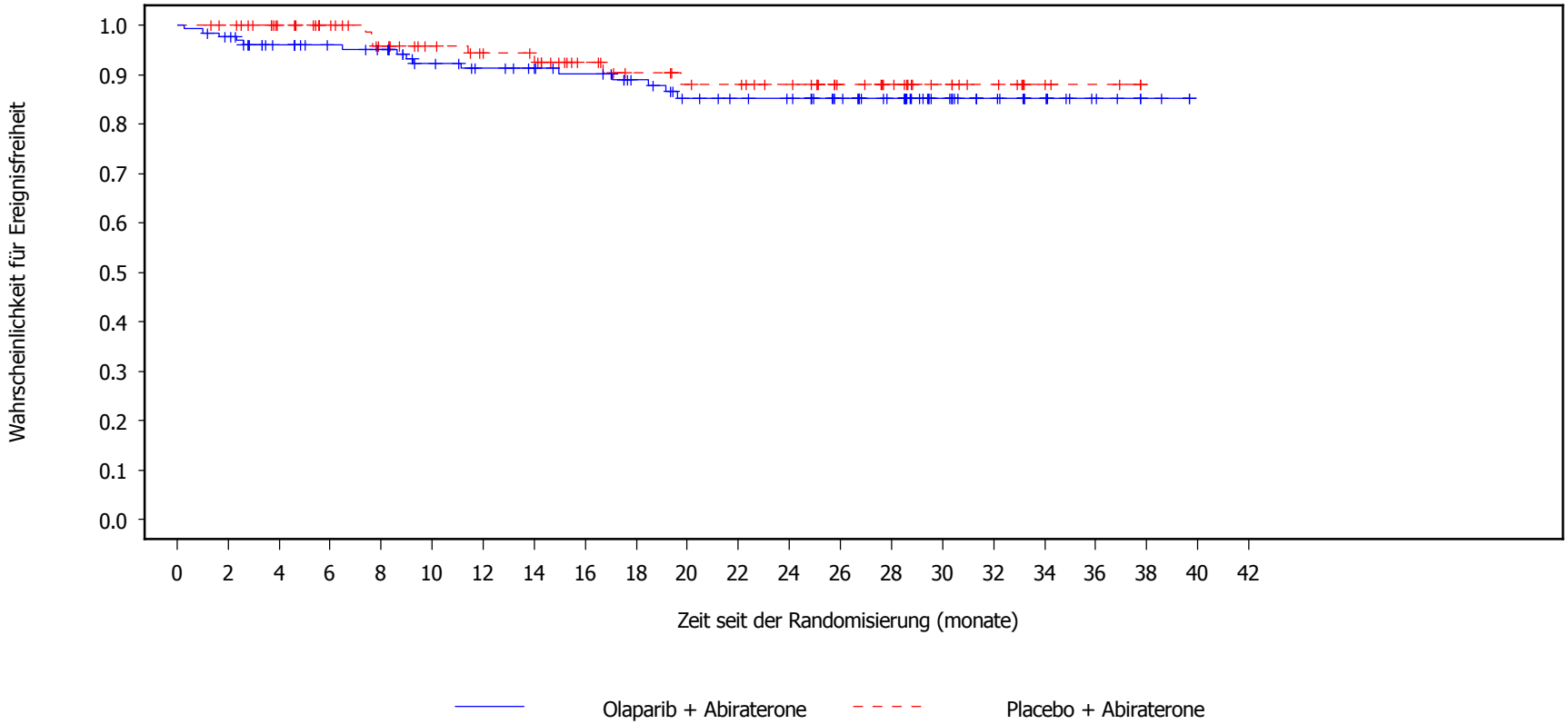
Figure 1.2.2.17 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Strahlentherapie wegen skelettaler Symptome for Alter bei Randomisierung=<65 Jahre
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

130	125	113	106	103	93	88	84	81	74	67	64	62	53	45	30	18	12	6	2	0	0	Olaparib + Abiraterone
97	95	86	77	68	61	56	54	45	40	37	36	32	24	20	13	9	4	2	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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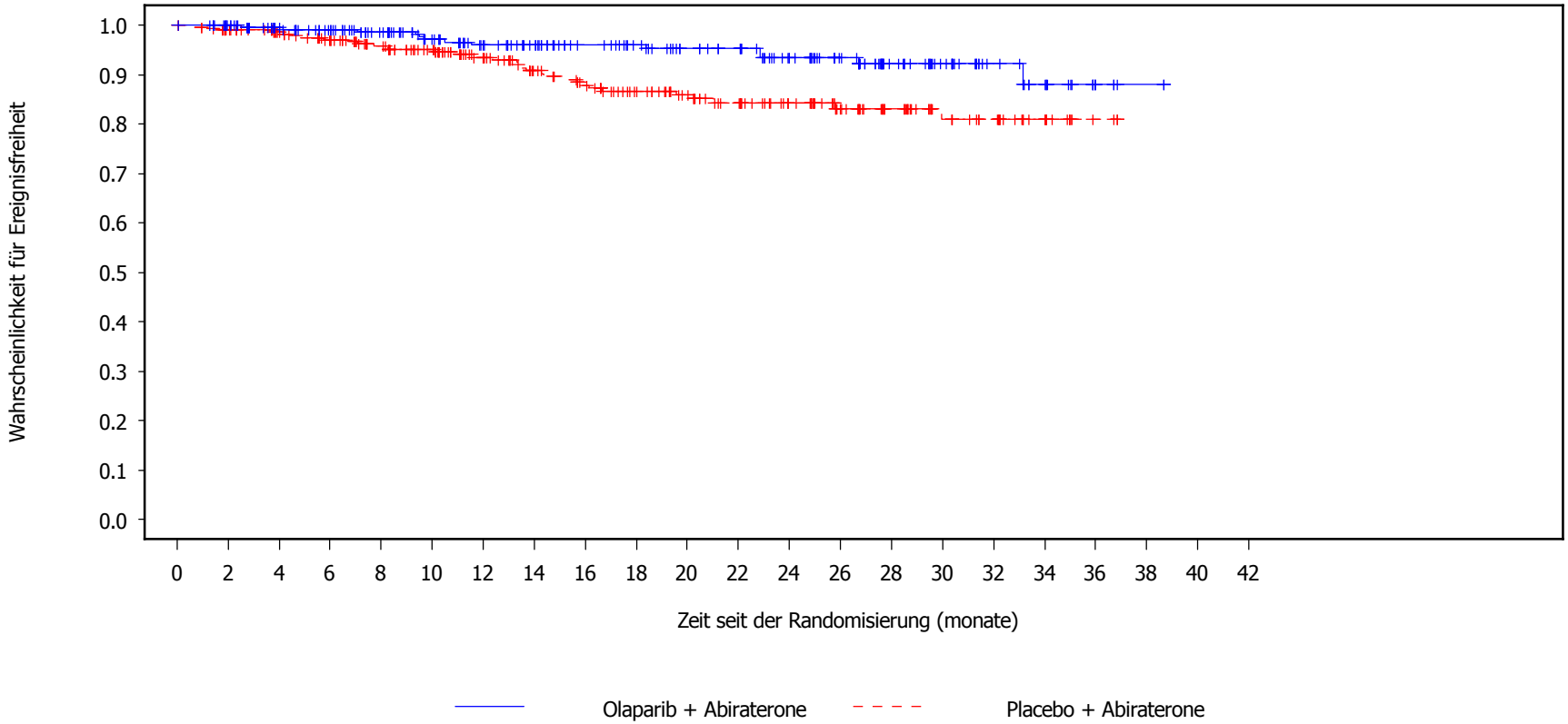
Figure 1.2.2.18 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Strahlentherapie wegen skelettaler Symptome for Alter bei Randomisierung=>=65 Jahre
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

269	259	236	222	203	182	165	154	139	131	120	115	98	80	54	40	24	17	4	1	0	0	Olaparib + Abiraterone
300	285	265	248	228	208	180	159	146	129	116	104	87	67	51	35	27	14	2	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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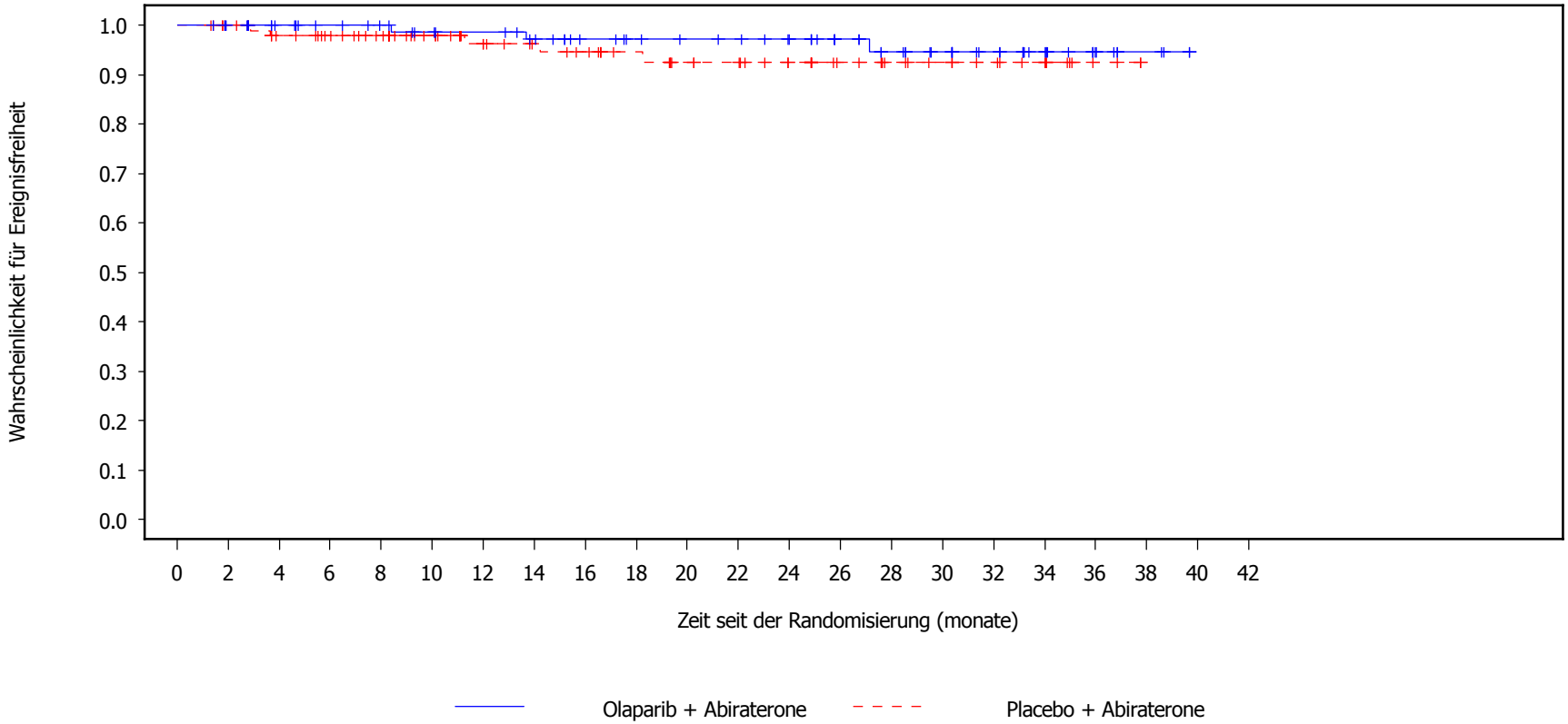
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 1.2.2.19 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Knochenfraktur aufgrund von Knochenmetastasen for Region=Asien
Region=Asien
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

91	88	81	77	74	70	68	64	58	55	53	52	48	40	35	30	23	16	7	3	0	0	Olaparib + Abiraterone
104	99	91	86	80	69	58	54	51	45	40	38	32	24	20	17	13	10	2	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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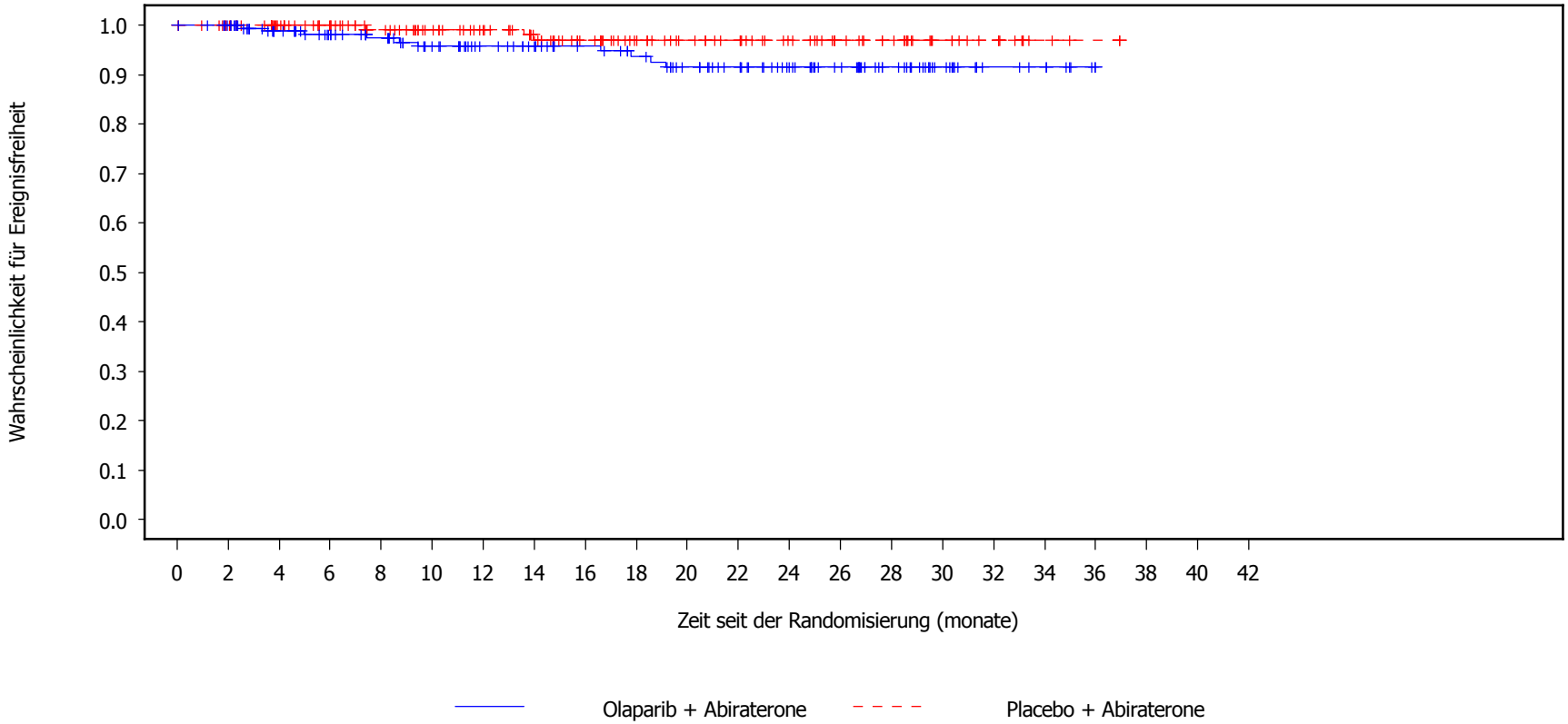
Figure 1.2.2.20 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Knochenfraktur aufgrund von Knochenmetastasen for Region=Europa
Region=Europa
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

178	173	154	142	133	118	106	99	92	86	77	69	57	47	32	19	9	7	0	0	0	0	Olaparib + Abiraterone
172	165	149	137	123	111	101	88	76	64	56	51	42	33	27	16	11	3	1	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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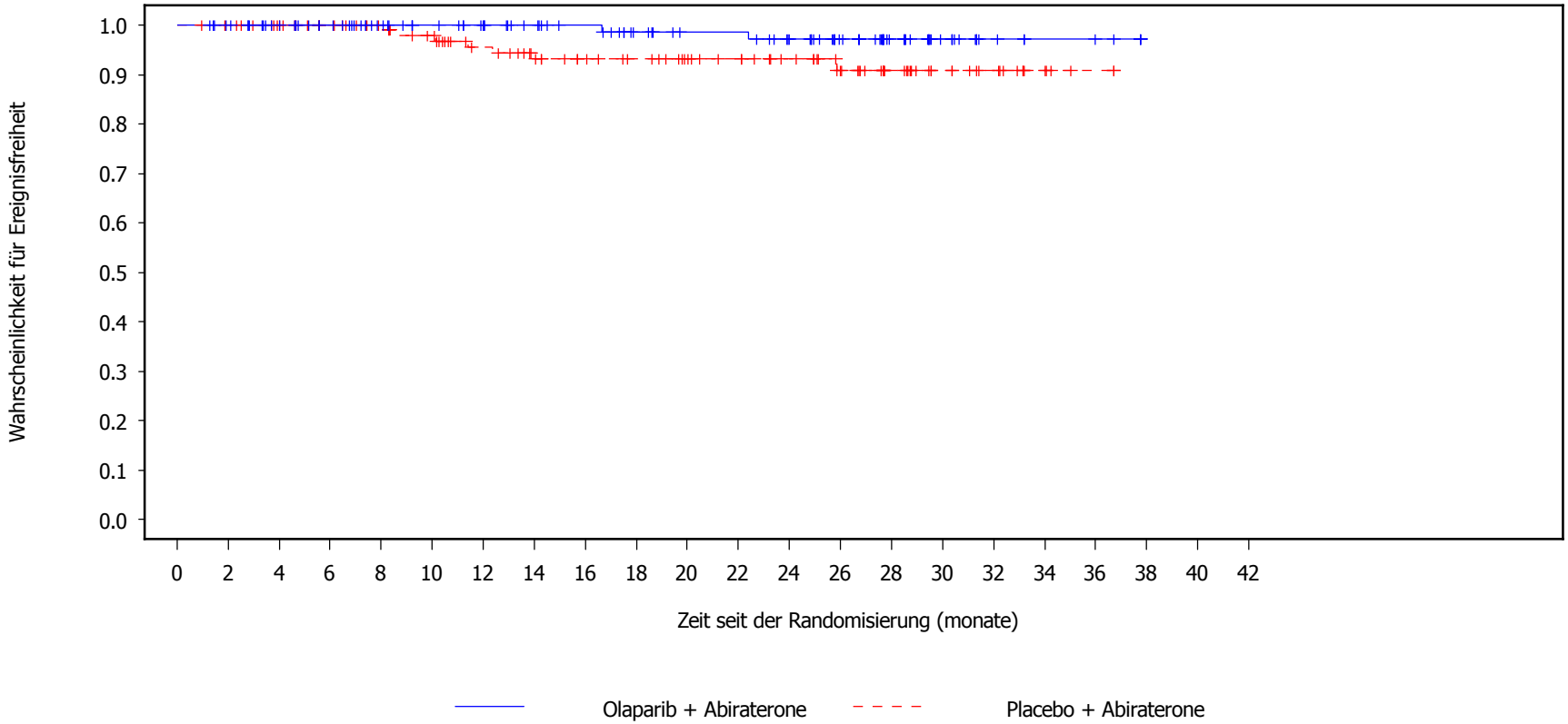
Figure 1.2.2.21 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Knochenfraktur aufgrund von Knochenmetastasen for Region=Nord- und Suedamerika
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

130	126	118	111	101	94	88	82	77	69	64	64	57	46	30	17	7	4	3	0	0	0	Olaparib + Abiraterone
121	119	113	105	99	91	80	72	66	62	56	52	46	37	26	17	12	5	1	0	0	0	Placebo + Abiraterone

[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.

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Table 2.1 PROpel: Summary of observation period (months) for PRO endpoints
Full Analysis Set, DCO 14MAR2022

		Olaparib + Abiraterone (N=399)	Placebo + Abiraterone (N=397)
BPI-SF	n	399	397
	Mediane	15,44	11,76
	Min	0,0	0,0
	Max	39,4	37,5
FACT-P	n	399	397
	Mediane	17,41	13,73
	Min	0,0	0,0
	Max	39,5	37,7
EQ-5D visuelle Analogskala	n	399	397
	Mediane	17,41	11,99
	Min	0,0	0,0
	Max	39,5	37,7

Observation period for PROs is defined as the time from randomisation to the earliest date of the DCO and last assessment for each questionnaire.
Patients without any measurements post randomisation are summarised with duration of 1 day.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/obsperpr.sas gobsperpra 26MAY2022:14:59 klfm426

Table 2.2.1 PROpel: Summary of status at time to deterioration in BPI-SF scores
Full Analysis Set, DCO 14MAR2022

Parameter	Deterioration/censoring reason	Olaparib + Abiraterone (N=399)	Placebo + Abiraterone (N=397)
BPI-SF Schmerzprogression (Frage 3)	Deterioration in score	92 (23,1)	88 (22,2)
	Censored due to last observation (no deterioration)	217 (54,4)	218 (54,9)
	Censored due to last observation (2 or more missed assessments)	4 (1,0)	7 (1,8)
	Censored due to death within 2 visits of last observation	17 (4,3)	19 (4,8)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	69 (17,3)	65 (16,4)
	Total	399 (100)	397 (100)
BPI-SF Schmerze (Frage 3-6)	Deterioration in score	63 (15,8)	60 (15,1)
	Censored due to last observation (no deterioration)	245 (61,4)	247 (62,2)
	Censored due to last observation (2 or more missed assessments)	3 (0,8)	5 (1,3)
	Censored due to death within 2 visits of last observation	19 (4,8)	20 (5,0)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	69 (17,3)	65 (16,4)
	Total	399 (100)	397 (100)
BPI-SF Beeinträchtigung durch Schmerzen (Frage 9a-g)	Deterioration in score	73 (18,3)	78 (19,6)
	Censored due to last observation (no deterioration)	234 (58,6)	231 (58,2)
	Censored due to last observation (2 or more missed assessments)	6 (1,5)	5 (1,3)
	Censored due to death within 2 visits of last observation	17 (4,3)	18 (4,5)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	69 (17,3)	65 (16,4)
	Total	399 (100)	397 (100)

Time to deterioration is defined as the time from date of randomisation until the earliest date of a deterioration in the respective score. Patients who have not met the criteria for deterioration and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events.
Patients with no evaluable baseline or post-baseline data are censored at day 1.
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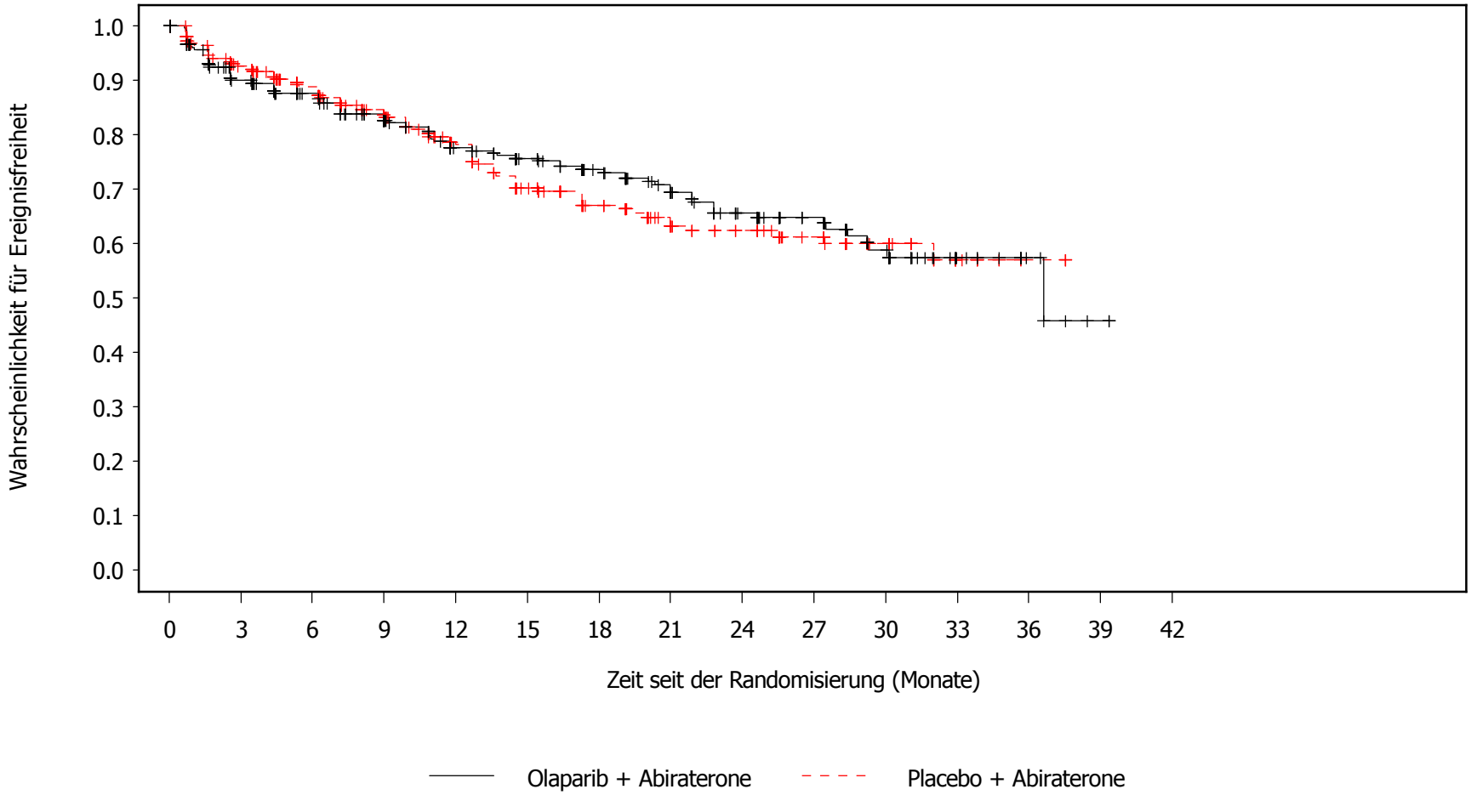
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.2.3.1 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Schmerzprogression (BPI-SF Frage 3) (MID=2)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	264	234	211	172	153	133	109	88	66	41	17	6	1	0	Olaparib + Abiraterone
397	279	236	200	152	125	99	75	65	50	32	11	2	0	0	Placebo + Abiraterone

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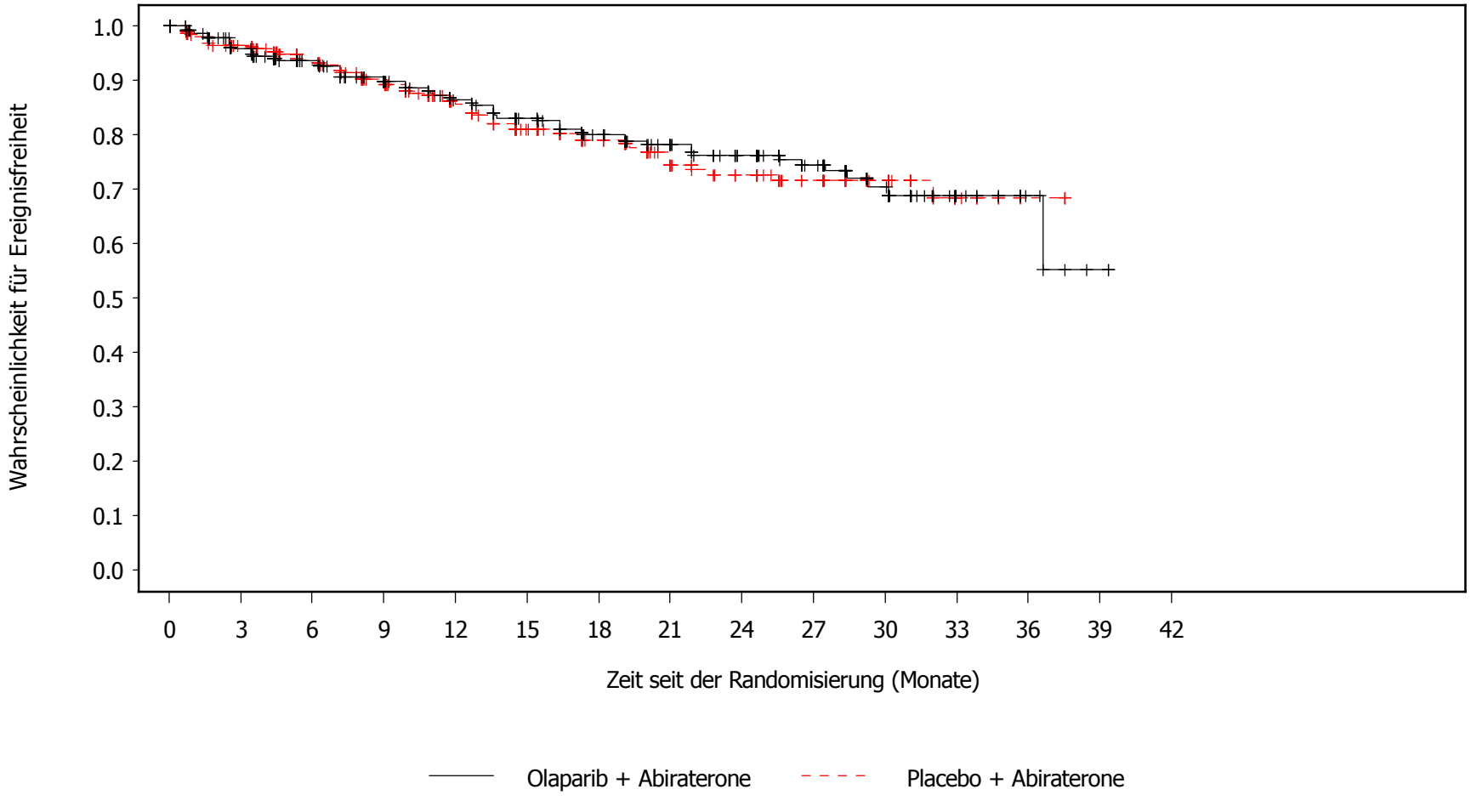
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.2.3.2 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung des Schmerzes (BPI-SF Frage 3-6) (MID=2)
Full Analysis Set, DCO 14MAR2022

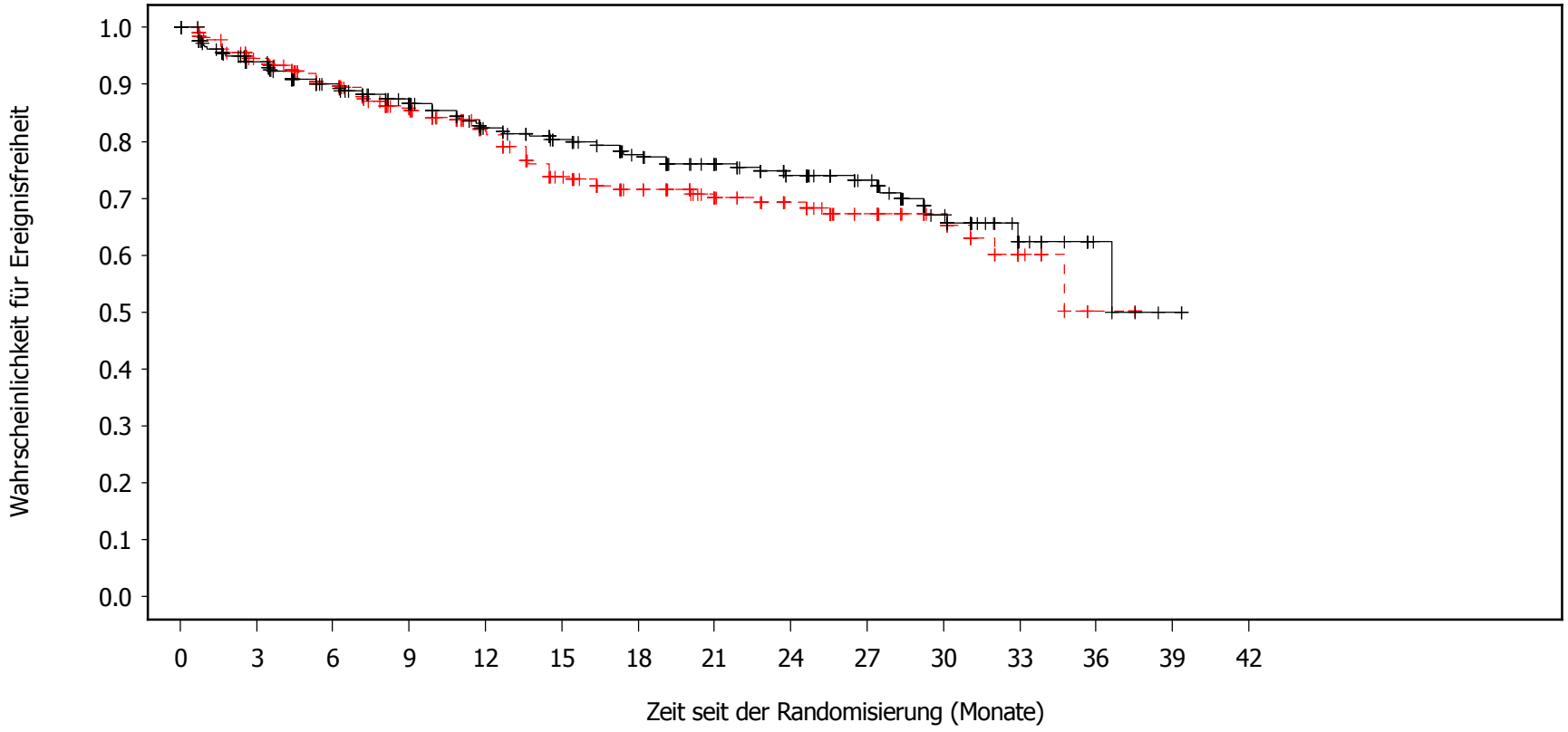


Anzahl an Patienten unter Risiko:

399	282	247	225	189	167	144	123	104	75	45	18	6	1	0	Olaparib + Abiraterone
397	292	251	216	168	142	116	90	76	55	36	12	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainpr.sas gttemainprbab 27MAY2022:08:01 khcs324

Figure 2.2.3.3 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung der Beeinträchtigung durch Schmerzen (BPI-SF Frage 9a-g) (MID=1.5)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	275	238	217	179	160	139	119	99	76	43	16	5	1	0	Olaparib + Abiraterone
397	288	243	206	161	134	111	88	75	53	35	11	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainpr.sas gttemainprbac 27MAY2022:08:01 khcs324

Table 2.2.4.1 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Schmerzprogression (BPI-SF Frage 3) (MID=2)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	53 (24,9)	36,6 [36,6; NE]	226	51 (22,6)	NE [NE; NE]	1,10	[0,75; 1,62]	0,6281
Viszeral	67	15 (22,4)	NE [NE; NE]	73	18 (24,7)	21,0 [12,7; NE]	0,66	[0,33; 1,31]	0,2376
andere	119	24 (20,2)	29,3 [27,5; NE]	98	19 (19,4)	NE [NE; NE]	0,88	[0,48; 1,63]	0,6793
Interaktion p-Wert									0,4304
Docetaxel-Behandlung des mHSPC									
Ja	90	21 (23,3)	NE [NE; NE]	90	18 (20,0)	NE [NE; NE]	1,31	[0,70; 2,48]	0,4027
Nein	309	71 (23,0)	36,6 [36,6; NE]	307	70 (22,8)	NE [NE; NE]	0,87	[0,63; 1,22]	0,4188
Interaktion p-Wert									0,2637
Alter bei Randomisierung									
<65 Jahre	130	33 (25,4)	36,6 [24,6; NE]	97	23 (23,7)	NE [NE; NE]	0,93	[0,55; 1,60]	0,7889
>=65 Jahre	269	59 (21,9)	NE [NE; NE]	300	65 (21,7)	NE [NE; NE]	0,95	[0,67; 1,35]	0,7857
Interaktion p-Wert									0,9410
Region									
Asien	91	19 (20,9)	NE [NE; NE]	104	28 (26,9)	32,0 [19,1; NE]	0,61	[0,33; 1,09]	0,0929
Europa	178	51 (28,7)	28,4 [21,9; NE]	172	38 (22,1)	NE [NE; NE]	1,21	[0,80; 1,85]	0,3771
Nord- und Suedamerika	130	22 (16,9)	NE [NE; NE]	121	22 (18,2)	NE [NE; NE]	0,94	[0,52; 1,71]	0,8388
Interaktion p-Wert									0,1704
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	19 (19,4)	NE [NE; NE]	100	19 (19,0)	NE [NE; NE]	0,85	[0,45; 1,62]	0,6185
Nicht-HRRm	269	67 (24,9)	36,6 [28,4; NE]	267	65 (24,3)	NE [NE; NE]	0,97	[0,69; 1,37]	0,8785

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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Table 2.2.4.1 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Schmerzprogression (BPI-SF Frage 3) (MID=2)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Unbekannt	32	6 (18,8)	NE [NE; NE]	30	4 (13,3)	NE [NE; NE]	1,31	[0,38; 5,14]	0,6705
Interaktion p-Wert									0,8249
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	13 (21,0)	NE [NE; NE]	56	9 (16,1)	NE [NE; NE]	1,03	[0,44; 2,50]	0,9458
Nicht-HRRm	207	46 (22,2)	36,6 [29,3; NE]	210	56 (26,7)	32,0 [20,0; NE]	0,76	[0,51; 1,12]	0,1641
Unbekannt	130	33 (25,4)	NE [NE; NE]	131	23 (17,6)	NE [NE; NE]	1,49	[0,88; 2,56]	0,1421
Interaktion p-Wert									0,1315
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	7 (24,1)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	75 (22,7)	36,6 [29,3; NE]	327	80 (24,5)	NE [NE; NE]	0,90	[0,66; 1,24]	0,5351
Unbekannt	40	10 (25,0)	NE [NE; NE]	48	8 (16,7)	NE [NE; NE]	1,31	[0,52; 3,42]	0,5712
Interaktion p-Wert									0,4615
ECOG-PS zu Baseline									
0	286	67 (23,4)	36,6 [30,2; NE]	272	66 (24,3)	NE [NE; NE]	0,92	[0,66; 1,30]	0,6386
1	112	25 (22,3)	NE [NE; NE]	124	22 (17,7)	NE [NE; NE]	1,06	[0,60; 1,90]	0,8434
Interaktion p-Wert									0,6817
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	50 (25,5)	NE [NE; NE]	200	45 (22,5)	NE [NE; NE]	1,04	[0,69; 1,56]	0,8573
Über medianem PSA-Baselinewert	201	41 (20,4)	36,6 [29,2; NE]	196	43 (21,9)	NE [NE; NE]	0,86	[0,56; 1,32]	0,4962
Interaktion p-Wert									0,5354

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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Table 2.2.4.1 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Schmerzprogression (BPI-SF Frage 3) (MID=2)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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									
Kaukasisch	282	66 (23,4)	36,6 [28,4; NE]	275	57 (20,7)	NE [NE; NE]	1,06	[0,75; 1,52]	0,7311
Afroamerikanisch	14	0	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	17 (25,8)	NE [NE; NE]	72	23 (31,9)	27,4 [14,5; NE]	0,60	[0,31; 1,12]	0,1079
Andere	15	2 (13,3)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1165
Schmerzen zu baseline									
Symptomatisch	103	25 (24,3)	29,3 [17,3; NE]	80	19 (23,8)	NE [NE; NE]	0,96	[0,53; 1,76]	0,8860
Asymptomatisch/mild symptomatisch	266	67 (25,2)	36,6 [36,6; NE]	294	69 (23,5)	NE [NE; NE]	0,93	[0,67; 1,31]	0,6849
Interaktion p-Wert									0,9408

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubpr.sas gttesubpraaa 05DEC2022:09:12 khcs324

Table 2.2.4.2 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung der Beeinträchtigung durch Schmerzen (BPI-SF Frage 9a-g) (MID=1.5)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	40 (18,8)	36,6 [36,6; NE]	226	44 (19,5)	NE [NE; NE]	0,95	[0,61; 1,46]	0,8037
Viszeral	67	14 (20,9)	NE [NE; NE]	73	18 (24,7)	34,8 [13,6; NE]	0,70	[0,34; 1,40]	0,3126
andere	119	19 (16,0)	NE [NE; NE]	98	16 (16,3)	NE [NE; NE]	0,82	[0,42; 1,62]	0,5671
Interaktion p-Wert									0,7594
Docetaxel-Behandlung des mHSPC									
Ja	90	14 (15,6)	NE [NE; NE]	90	13 (14,4)	NE [NE; NE]	1,19	[0,56; 2,57]	0,6454
Nein	309	59 (19,1)	NE [NE; NE]	307	65 (21,2)	34,8 [31,1; NE]	0,80	[0,56; 1,13]	0,2060
Interaktion p-Wert									0,3412
Alter bei Randomisierung									
<65 Jahre	130	22 (16,9)	36,6 [32,9; NE]	97	15 (15,5)	NE [NE; NE]	0,94	[0,49; 1,85]	0,8533
>=65 Jahre	269	51 (19,0)	NE [NE; NE]	300	63 (21,0)	34,8 [31,1; NE]	0,88	[0,60; 1,27]	0,4877
Interaktion p-Wert									0,8587
Region									
Asien	91	14 (15,4)	NE [NE; NE]	104	24 (23,1)	32,0 [30,2; NE]	0,52	[0,26; 0,99]	0,0456*
Europa	178	39 (21,9)	36,6 [29,2; NE]	172	36 (20,9)	34,8 [25,6; NE]	0,95	[0,60; 1,49]	0,8096
Nord- und Suedamerika	130	20 (15,4)	NE [NE; NE]	121	18 (14,9)	NE [NE; NE]	1,15	[0,60; 2,19]	0,6753
Interaktion p-Wert									0,1904
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	13 (13,3)	NE [NE; NE]	100	19 (19,0)	NE [NE; NE]	0,57	[0,27; 1,14]	0,1103
Nicht-HRRm	269	54 (20,1)	36,6 [30,2; NE]	267	55 (20,6)	34,8 [32,0; NE]	0,95	[0,65; 1,39]	0,7893

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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Table 2.2.4.2 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung der Beeinträchtigung durch Schmerzen (BPI-SF Frage 9a-g) (MID=1.5)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Unbekannt	32	6 (18,8)	NE [NE; NE]	30	4 (13,3)	NE [NE; NE]	1,38	[0,39; 5,38]	0,6183
Interaktion p-Wert									0,3369
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	7 (11,3)	NE [NE; NE]	56	8 (14,3)	NE [NE; NE]	0,60	[0,21; 1,66]	0,3170
Nicht-HRRm	207	47 (22,7)	32,9 [29,3; NE]	210	50 (23,8)	32,0 [30,2; NE]	0,97	[0,65; 1,44]	0,8776
Unbekannt	130	19 (14,6)	NE [NE; NE]	131	20 (15,3)	NE [NE; NE]	0,87	[0,46; 1,64]	0,6618
Interaktion p-Wert									0,6767
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	4 (13,8)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	0,85	[0,17; 6,15]	0,8552
Nicht-HRRm	330	62 (18,8)	36,6 [32,9; NE]	327	68 (20,8)	34,8 [32,0; NE]	0,91	[0,64; 1,28]	0,5719
Unbekannt	40	7 (17,5)	NE [NE; NE]	48	8 (16,7)	NE [NE; NE]	0,81	[0,28; 2,25]	0,6771
Interaktion p-Wert									0,9763
ECOG-PS zu Baseline									
0	286	56 (19,6)	36,6 [32,9; NE]	272	57 (21,0)	34,8 [32,0; NE]	0,92	[0,63; 1,33]	0,6430
1	112	17 (15,2)	NE [NE; NE]	124	21 (16,9)	NE [NE; NE]	0,73	[0,38; 1,39]	0,3410
Interaktion p-Wert									0,5536
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	34 (17,3)	NE [NE; NE]	200	36 (18,0)	NE [NE; NE]	0,87	[0,54; 1,39]	0,5498
Über medianem PSA-Baselinewert	201	38 (18,9)	36,6 [29,3; NE]	196	42 (21,4)	31,1 [25,6; NE]	0,84	[0,54; 1,31]	0,4531
Interaktion p-Wert									0,9387

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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Table 2.2.4.2 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung der Beeinträchtigung durch Schmerzen (BPI-SF Frage 9a-g) (MID=1.5)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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									
Kaukasisch	282	55 (19,5)	36,6 [36,6; NE]	275	52 (18,9)	34,8 [34,8; NE]	0,99	[0,68; 1,45]	0,9602
Afroamerikanisch	14	2 (14,3)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	1,21	[0,15; 10,10]	0,8478
Asiatisch	66	11 (16,7)	NE [NE; NE]	72	19 (26,4)	32,0 [24,6; NE]	0,46	[0,21; 0,96]	0,0386*
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1824
Schmerzen zu baseline									
Symptomatisch	103	19 (18,4)	NE [NE; NE]	80	18 (22,5)	NE [NE; NE]	0,79	[0,41; 1,52]	0,4825
Asymptomatisch/mild symptomatisch	266	54 (20,3)	36,6 [36,6; NE]	294	60 (20,4)	NE [NE; NE]	0,87	[0,60; 1,26]	0,4684
Interaktion p-Wert									0,8005

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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Table 2.3.1 PROpel: Summary of status at time to deterioration in FACT-P, overall and subscales
Full Analysis Set, DCO 14MAR2022

Parameter	Deterioration/censoring reason	Olaparib + Abiraterone (N=399)	Placebo + Abiraterone (N=397)
FACT-P Gesamtscore	Deterioration in score	90 (22,6)	97 (24,4)
	Censored due to last observation (no deterioration)	161 (40,4)	179 (45,1)
	Censored due to last observation (2 or more missed assessments)	5 (1,3)	1 (0,3)
	Censored due to death within 2 visits of last observation	21 (5,3)	17 (4,3)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	122 (30,6)	103 (25,9)
	Total	399 (100)	397 (100)
FACT-P Subskala physisches Wohlbefinden (PWB)	Deterioration in score	150 (37,6)	137 (34,5)
	Censored due to last observation (no deterioration)	108 (27,1)	144 (36,3)
	Censored due to last observation (2 or more missed assessments)	6 (1,5)	1 (0,3)
	Censored due to death within 2 visits of last observation	13 (3,3)	12 (3,0)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	122 (30,6)	103 (25,9)
	Total	399 (100)	397 (100)
FACT-P Subskala soziales Wohlbefinden (SWB)	Deterioration in score	141 (35,3)	141 (35,5)
	Censored due to last observation (no deterioration)	120 (30,1)	138 (34,8)
	Censored due to last observation (2 or more missed assessments)	1 (0,3)	1 (0,3)
	Censored due to death within 2 visits of last observation	15 (3,8)	14 (3,5)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	122 (30,6)	103 (25,9)
	Total	399 (100)	397 (100)
FACT-P Subskala funktionales Wohlbefinden (FWB)	Deterioration in score	143 (35,8)	156 (39,3)
	Censored due to last observation (no deterioration)	116 (29,1)	123 (31,0)
	Censored due to last observation (2 or more missed assessments)	5 (1,3)	1 (0,3)
	Censored due to death within 2 visits of last observation	13 (3,3)	14 (3,5)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	122 (30,6)	103 (25,9)
	Total	399 (100)	397 (100)

Time to deterioration is defined as the time from date of randomisation until the earliest date of a deterioration in the respective score. Patients who have not met the criteria for deterioration and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events.
Patients with no evaluable baseline or post-baseline data are censored at day 1.
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Table 2.3.1 PROpel: Summary of status at time to deterioration in FACT-P, overall and subscales
Full Analysis Set, DCO 14MAR2022

Parameter	Deterioration/censoring reason	Olaparib + Abiraterone (N=399)	Placebo + Abiraterone (N=397)
FACT-P Subskala emotionales Wohlbefinden (EWB)	Deterioration in score	113 (28,3)	121 (30,5)
	Censored due to last observation (no deterioration)	144 (36,1)	154 (38,8)
	Censored due to last observation (2 or more missed assessments)	3 (0,8)	1 (0,3)
	Censored due to death within 2 visits of last observation	17 (4,3)	18 (4,5)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	122 (30,6)	103 (25,9)
	Total	399 (100)	397 (100)
FACT-P Prostatakarzinom-spezifische Subskala (PCS)	Deterioration in score	96 (24,1)	100 (25,2)
	Censored due to last observation (no deterioration)	154 (38,6)	172 (43,3)
	Censored due to last observation (2 or more missed assessments)	4 (1,0)	1 (0,3)
	Censored due to death within 2 visits of last observation	23 (5,8)	21 (5,3)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	122 (30,6)	103 (25,9)
	Total	399 (100)	397 (100)

Time to deterioration is defined as the time from date of randomisation until the earliest date of a deterioration in the respective score. Patients who have not met the criteria for deterioration and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events.
Patients with no evaluable baseline or post-baseline data are censored at day 1.
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Table 2.3.2 PROpel: Summary of analysis of time to first deterioration in FACT-P, overall and subscales
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
Verschlechterung FACT-P Gesamtscore (MID=23.4)	399	90 (22,6)	NE [NE; NE]	397	97 (24,4)	NE [NE; NE]	0,95	[0,71; 1,27]	0,7597
Verschlechterung FACT-P Subskala physisches Wohlbefinden (PWB) (MID=4.2)	399	150 (37,6)	11,9 [9,1;19,1]	397	137 (34,5)	17,4 [13,7;24,8]	1,31	[1,04; 1,65]	0,0406*
Verschlechterung FACT-P Subskala soziales Wohlbefinden (SWB) (MID=4.2)	399	141 (35,3)	11,1 [8,2;21,1]	397	141 (35,5)	13,8 [9,1; NE]	1,05	[0,83; 1,33]	0,8098
Verschlechterung FACT-P Subskala funktionales Wohlbefinden (FWB) (MID=4.2)	399	143 (35,8)	15,6 [11,0;23,0]	397	156 (39,3)	11,1 [9,1;17,4]	0,89	[0,71; 1,12]	0,3233
Verschlechterung FACT-P Subskala emotionales Wohlbefinden (EWB) (MID=3.6)	399	113 (28,3)	28,6 [19,3; NE]	397	121 (30,5)	24,8 [17,4; NE]	0,98	[0,76; 1,27]	0,9522
Verschlechterung FACT-P Prostatakarzinom-spezifische Subskala (PCS) (MID=7.2)	399	96 (24,1)	35,8 [24,8; NE]	397	100 (25,2)	NE [NE; NE]	0,94	[0,71; 1,25]	0,5845

Time to deterioration is defined as the time from date of randomisation until the earliest date of a deterioration in the respective score. Patients who have not met the criteria for deterioration and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events.
Patients with no evaluable baseline or post-baseline data are censored at day 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 adjusted for the variables selected in the primary pooling strategy: Metastases, Docetaxel treatment at mHSPC stage. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using log-rank test stratified by the same variables selected in the primary pooling strategy.
Hazard ratio <1 favours olaparib. * p<0.05.
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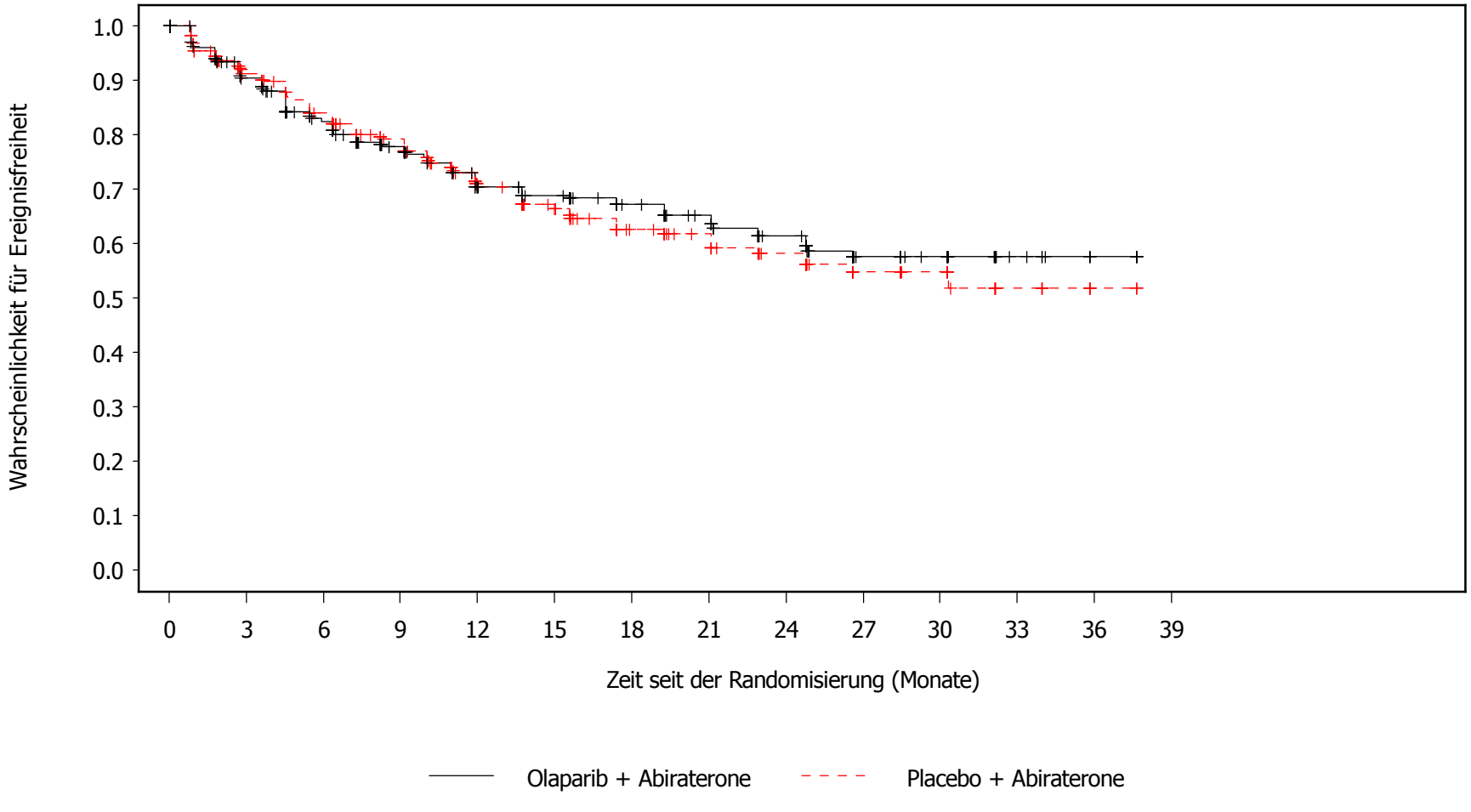
Figure 2.3.3.1 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Gesamtscore (MID=23.4)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	238	197	166	137	125	102	89	72	40	26	10	3	0	Olaparib + Abiraterone
397	250	216	184	131	108	86	70	57	32	25	9	1	0	Placebo + Abiraterone

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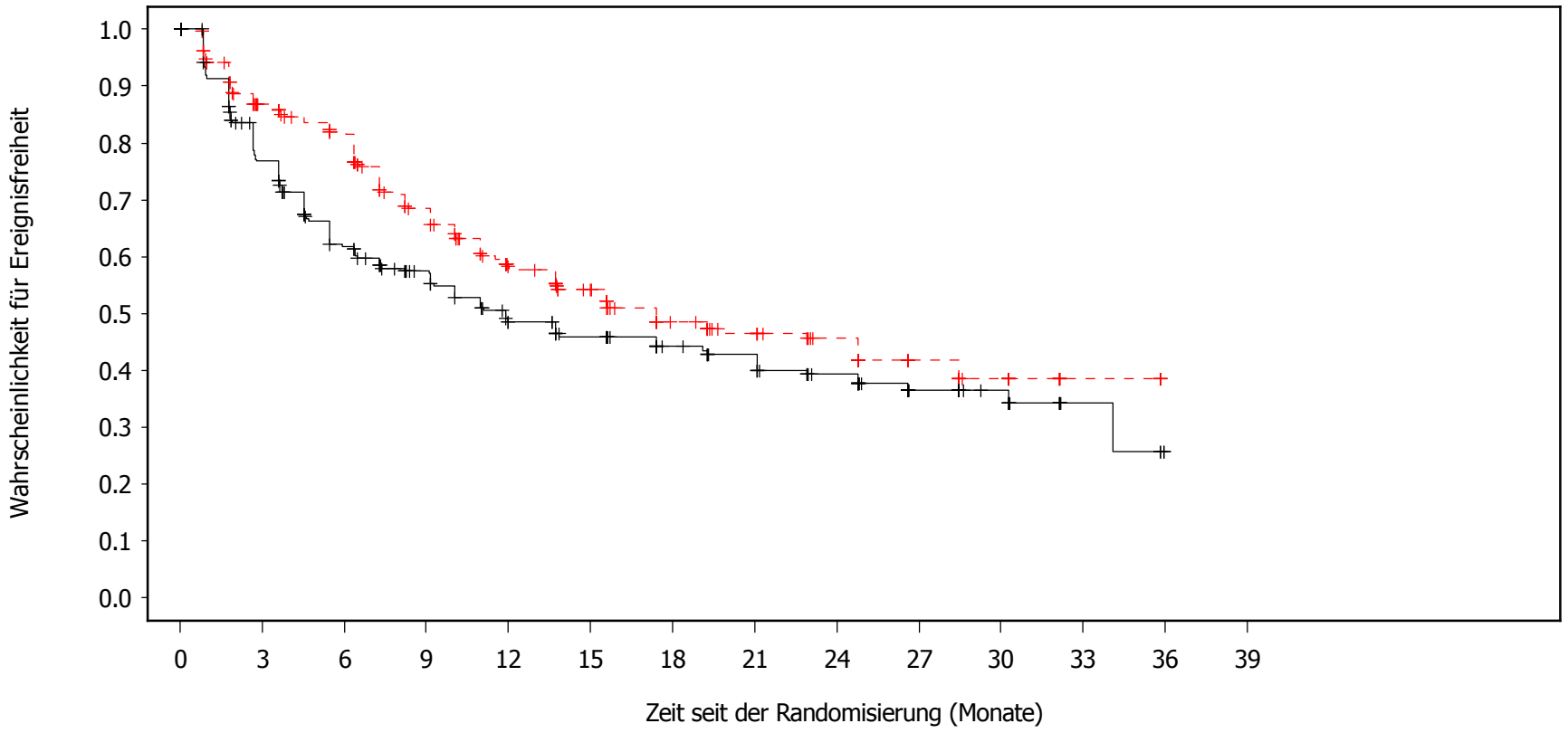
Figure 2.3.3.2 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Subskala physisches Wohlbefinden (PWB) (MID=4.2)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	203	150	125	96	84	68	61	48	26	16	4	0	0	Olaparib + Abiraterone
397	239	214	165	121	100	75	59	48	26	18	3	0	0	Placebo + Abiraterone

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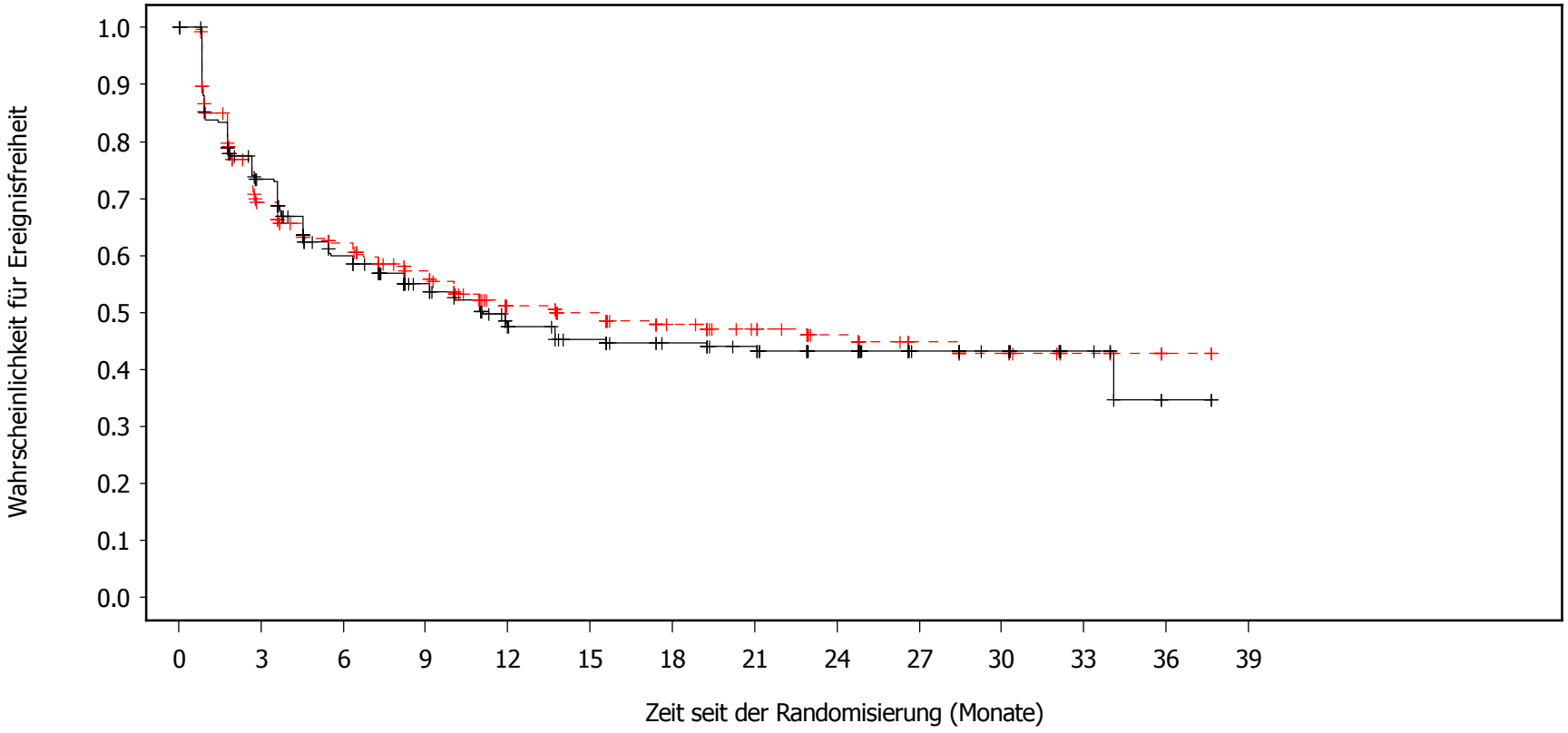
Figure 2.3.3.3 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Subskala soziales Wohlbefinden (SWB) (MID=4.2)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	192	141	115	87	78	66	59	47	24	18	8	1	0	Olaparib + Abiraterone
397	189	157	132	86	76	61	47	37	22	16	8	1	0	Placebo + Abiraterone

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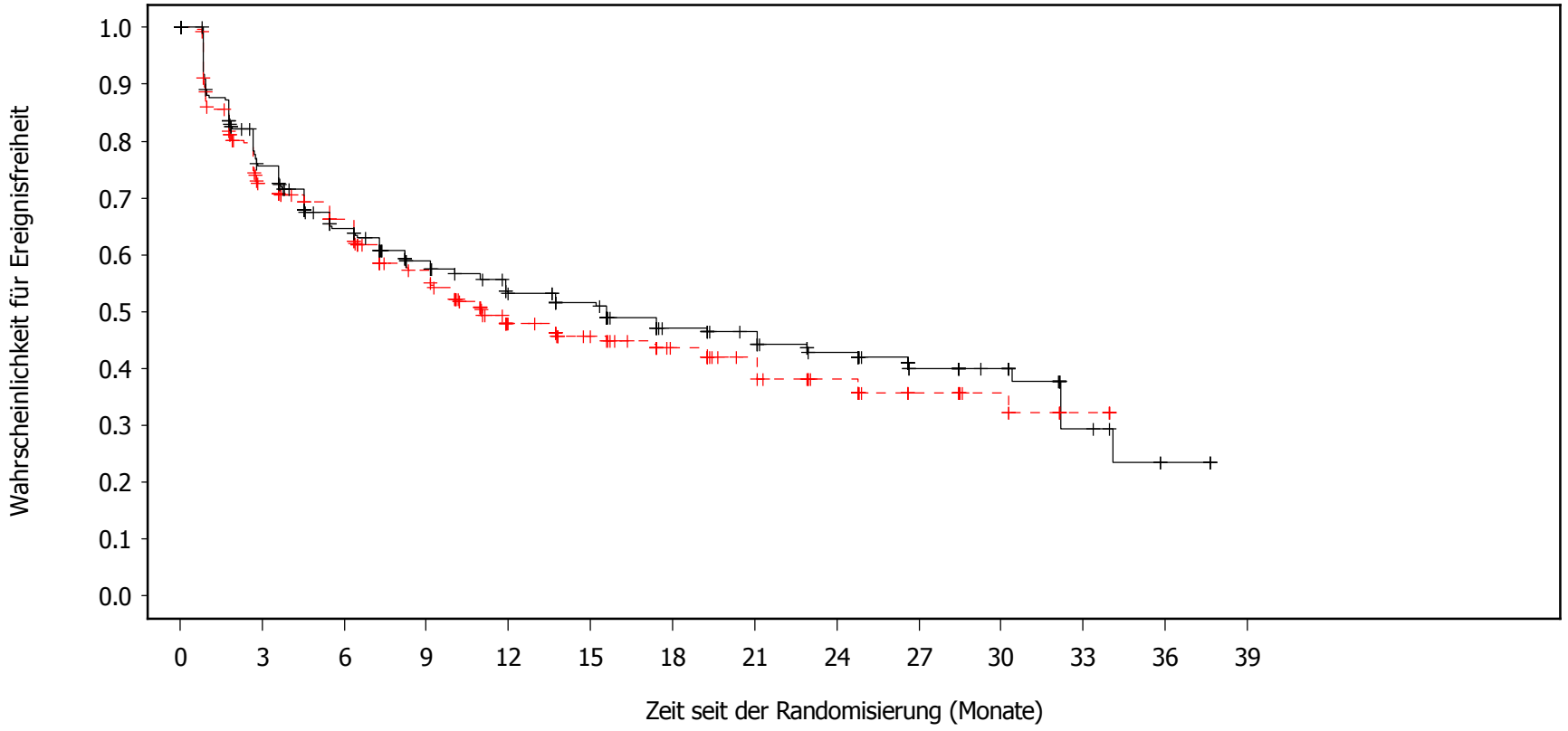
Figure 2.3.3.4 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Subskala funktionales Wohlbefinden (FWB) (MID=4.2)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	199	153	125	105	95	73	66	54	33	23	7	2	0	Olaparib + Abiraterone
397	201	172	137	87	71	55	43	33	16	10	3	0	0	Placebo + Abiraterone

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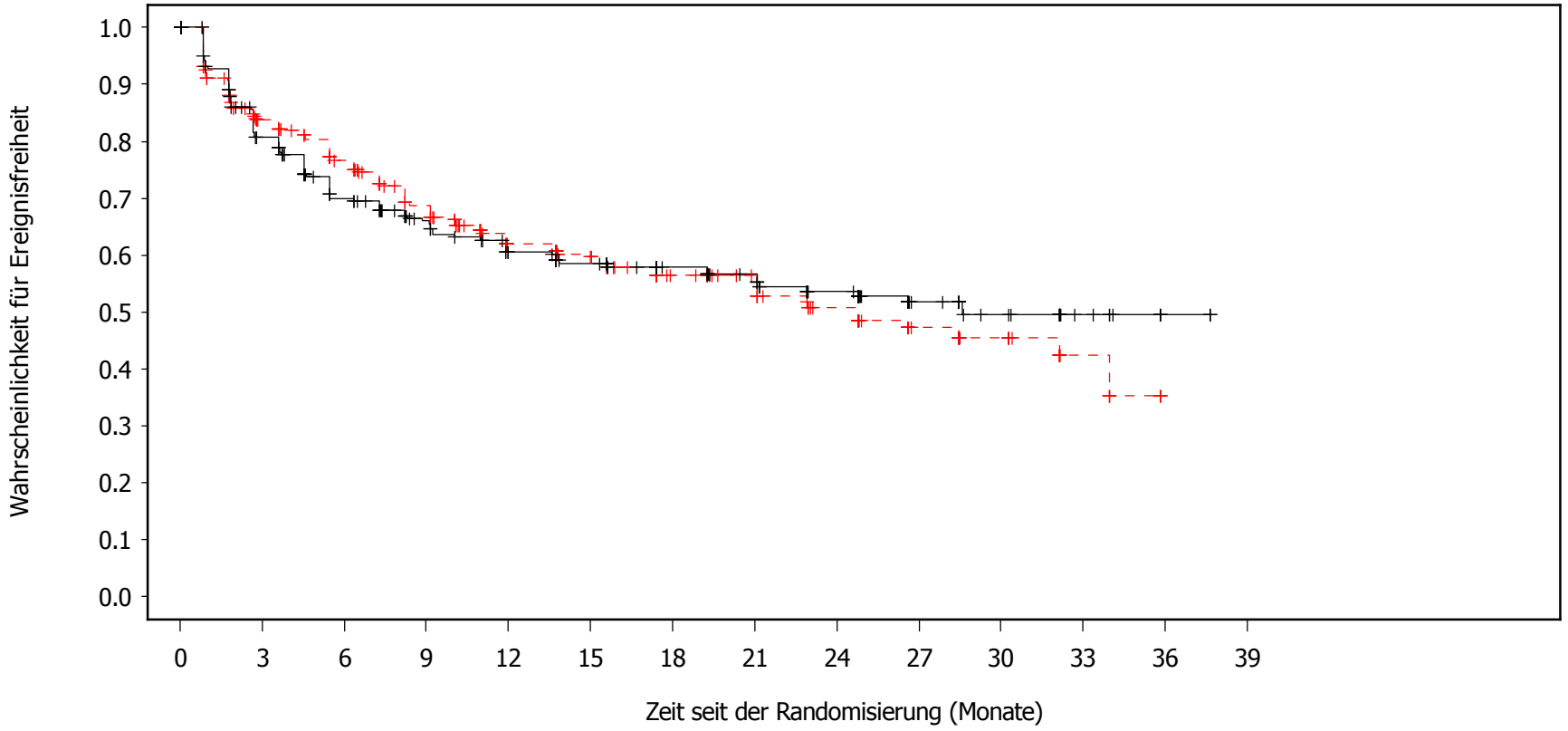
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.3.3.5 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Subskala emotionales Wohlbefinden (EWB) (MID=3.6)
Full Analysis Set, DCO 14MAR2022

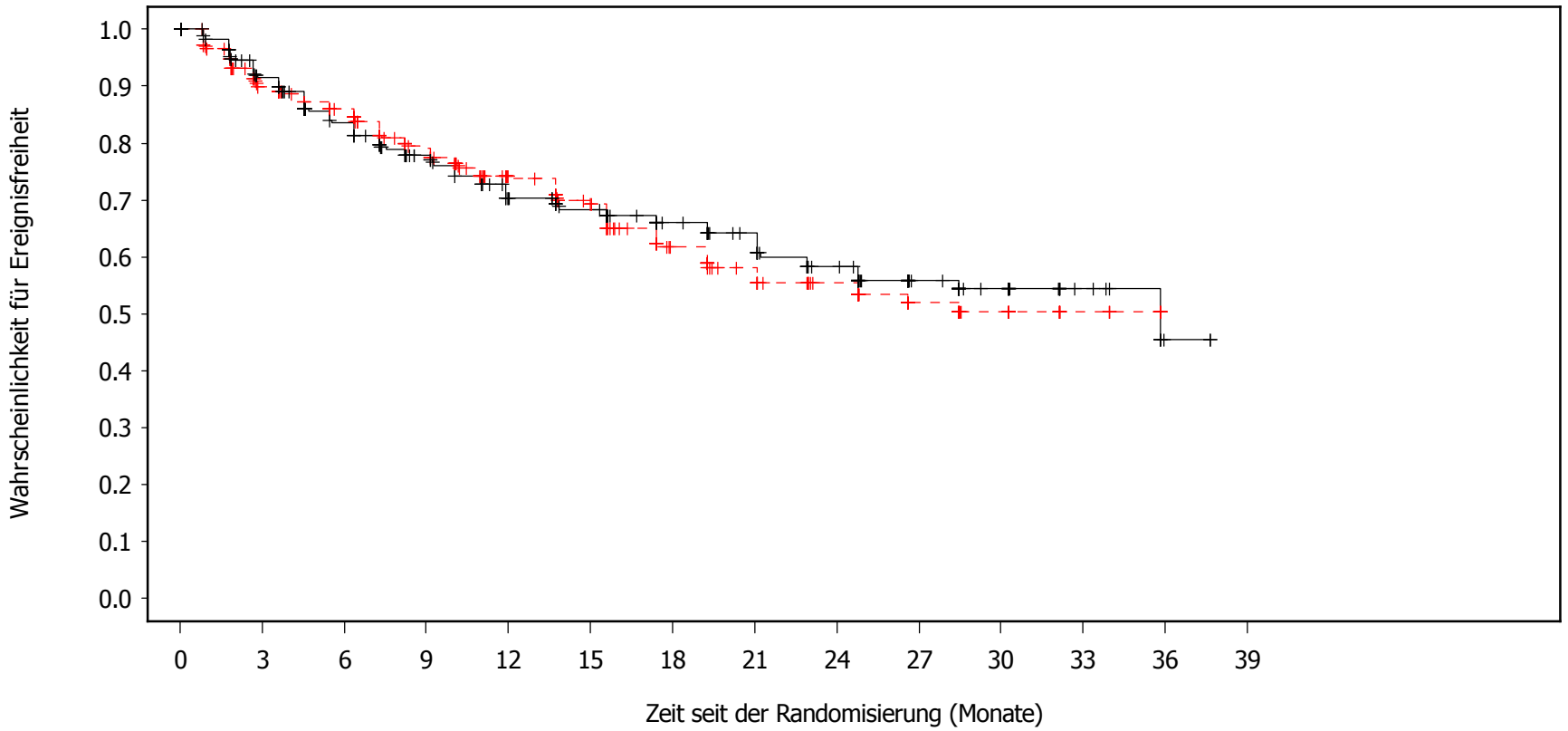


Anzahl an Patienten unter Risiko:

399	211	166	140	119	106	89	79	63	34	20	8	1	0	Olaparib + Abiraterone
397	230	196	162	116	100	77	62	46	27	20	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainpr.sas gttemainprcae 27MAY2022:08:01 khcs324

Figure 2.3.3.6 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Prostatakarzinom-spezifische Subskala (PCS) (MID=7.2)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	238	200	170	141	128	104	92	72	41	24	9	1	0	Olaparib + Abiraterone
397	246	220	183	138	116	86	69	53	31	21	7	0	0	Placebo + Abiraterone

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Table 2.3.4.1 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung FACT-P Gesamtscore (MID=23.4)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	62 (29,1)	26,6 [19,3; NE]	226	53 (23,5)	NE [NE; NE]	1,45	[1,003; 2,09]	0,0482*
Viszeral	67	13 (19,4)	NE [NE; NE]	73	20 (27,4)	17,4 [7,3; NE]	0,45	[0,22; 0,89]	0,0226*
andere	119	15 (12,6)	NE [NE; NE]	98	24 (24,5)	NE [NE; NE]	0,51	[0,26; 0,95]	0,0354*
Interaktion p-Wert									0,0012*
Docetaxel-Behandlung des mHSPC									
Ja	90	16 (17,8)	NE [NE; NE]	90	21 (23,3)	NE [NE; NE]	0,91	[0,47; 1,74]	0,7797
Nein	309	74 (23,9)	NE [NE; NE]	307	76 (24,8)	NE [NE; NE]	0,95	[0,69; 1,31]	0,7510
Interaktion p-Wert									0,9121
Alter bei Randomisierung									
<65 Jahre	130	27 (20,8)	NE [NE; NE]	97	19 (19,6)	NE [NE; NE]	1,09	[0,61; 2,00]	0,7637
>=65 Jahre	269	63 (23,4)	NE [NE; NE]	300	78 (26,0)	30,3 [21,1; NE]	0,92	[0,66; 1,28]	0,6188
Interaktion p-Wert									0,6119
Region									
Asien	91	28 (30,8)	NE [NE; NE]	104	33 (31,7)	30,3 [17,4; NE]	0,92	[0,55; 1,52]	0,7328
Europa	178	33 (18,5)	NE [NE; NE]	172	42 (24,4)	NE [NE; NE]	0,70	[0,44; 1,10]	0,1169
Nord- und Suedamerika	130	29 (22,3)	NE [NE; NE]	121	22 (18,2)	NE [NE; NE]	1,50	[0,87; 2,65]	0,1458
Interaktion p-Wert									0,1051
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	21 (21,4)	NE [NE; NE]	100	22 (22,0)	NE [NE; NE]	0,83	[0,45; 1,52]	0,5483
Nicht-HRRm	269	60 (22,3)	NE [NE; NE]	267	71 (26,6)	30,3 [21,1; NE]	0,89	[0,63; 1,25]	0,4997

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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Table 2.3.4.1 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung FACT-P Gesamtscore (MID=23.4)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Unbekannt	32	9 (28,1)	11,9 [9,1; NE]	30	4 (13,3)	NE [NE; NE]	2,79	[0,91; 10,29]	0,0742
Interaktion p-Wert									0,1459
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	16 (25,8)	NE [NE; NE]	56	17 (30,4)	NE [NE; NE]	0,71	[0,36; 1,41]	0,3280
Nicht-HRRm	207	49 (23,7)	NE [NE; NE]	210	49 (23,3)	NE [NE; NE]	1,21	[0,81; 1,80]	0,3530
Unbekannt	130	25 (19,2)	NE [NE; NE]	131	31 (23,7)	26,6 [17,4; NE]	0,74	[0,43; 1,25]	0,2589
Interaktion p-Wert									0,2270
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	10 (34,5)	NE [NE; NE]	22	4 (18,2)	NE [NE; NE]	1,01	[0,34; 3,69]	0,9855
Nicht-HRRm	330	71 (21,5)	NE [NE; NE]	327	81 (24,8)	NE [NE; NE]	0,93	[0,68; 1,28]	0,6584
Unbekannt	40	9 (22,5)	NE [NE; NE]	48	12 (25,0)	NE [NE; NE]	0,91	[0,37; 2,15]	0,8312
Interaktion p-Wert									0,9891
ECOG-PS zu Baseline									
0	286	67 (23,4)	NE [NE; NE]	272	73 (26,8)	30,3 [21,1; NE]	0,89	[0,64; 1,24]	0,4999
1	112	23 (20,5)	NE [NE; NE]	124	24 (19,4)	NE [NE; NE]	1,11	[0,62; 1,97]	0,7258
Interaktion p-Wert									0,5211
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	55 (28,1)	NE [NE; NE]	200	53 (26,5)	NE [NE; NE]	1,06	[0,73; 1,56]	0,7436
Über medianem PSA-Baselinewert	201	35 (17,4)	NE [NE; NE]	196	44 (22,4)	30,3 [21,1; NE]	0,81	[0,51; 1,25]	0,3401
Interaktion p-Wert									0,3480

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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Table 2.3.4.1 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung FACT-P Gesamtscore (MID=23.4)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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									
Kaukasisch	282	59 (20,9)	NE [NE; NE]	275	67 (24,4)	30,3 [21,1; NE]	0,85	[0,60; 1,21]	0,3653
Afroamerikanisch	14	2 (14,3)	11,9 [4,5; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	25 (37,9)	NE [NE; NE]	72	27 (37,5)	24,8 [12,0; NE]	1,01	[0,58; 1,74]	0,9742
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6055
Schmerzen zu baseline									
Symptomatisch	103	24 (23,3)	22,9 [11,9; NE]	80	16 (20,0)	NE [NE; NE]	1,65	[0,88; 3,16]	0,1170
Asymptomatisch/mild symptomatisch	266	66 (24,8)	NE [NE; NE]	294	80 (27,2)	NE [NE; NE]	0,83	[0,60; 1,15]	0,2546
Interaktion p-Wert									0,0553

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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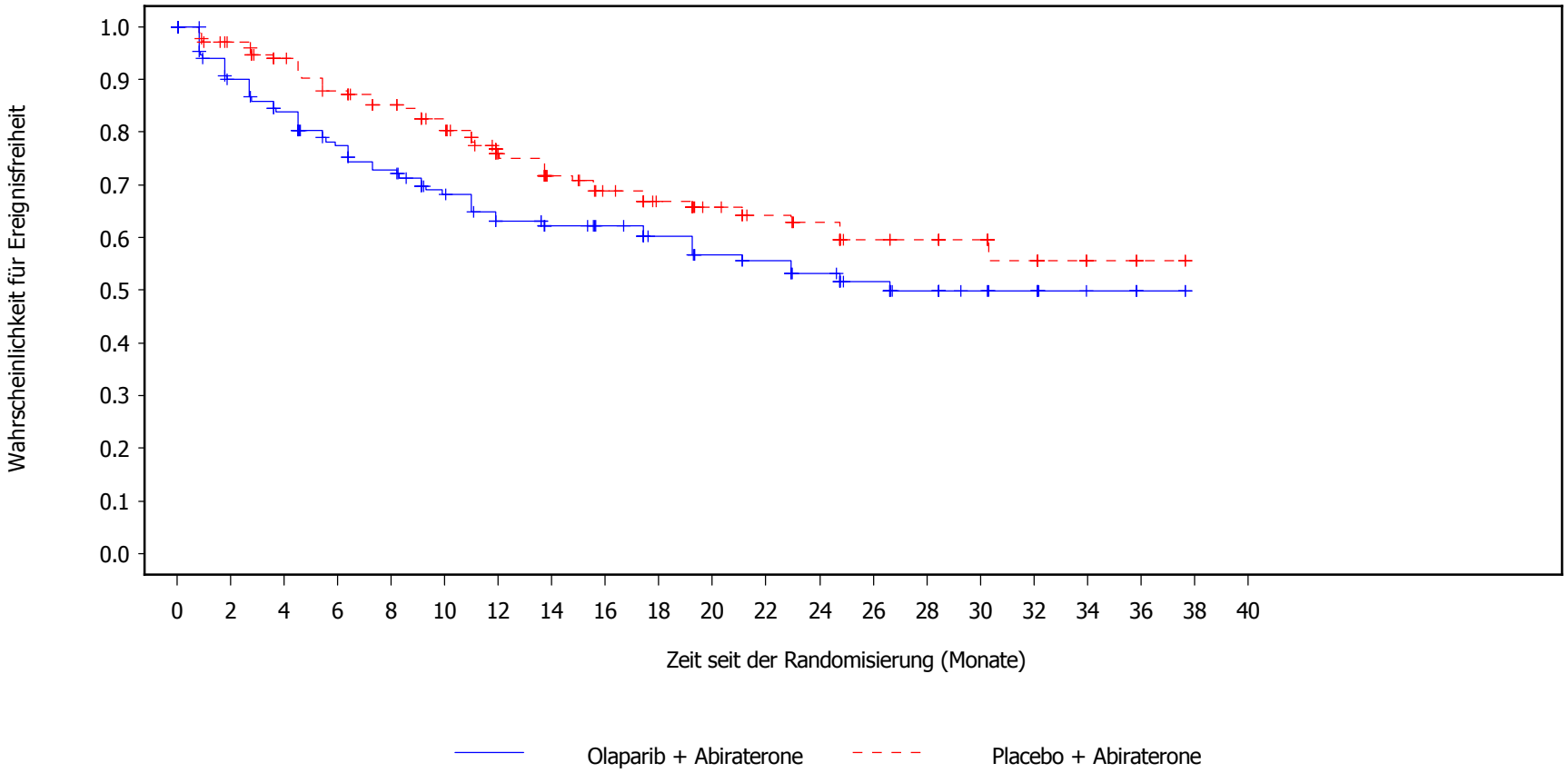
Figure 2.3.5.1 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Gesamtscore (MID=23.4) for Metastasen zu Baseline=Nur Knochen
Full Analysis Set, DCO 14MAR2022

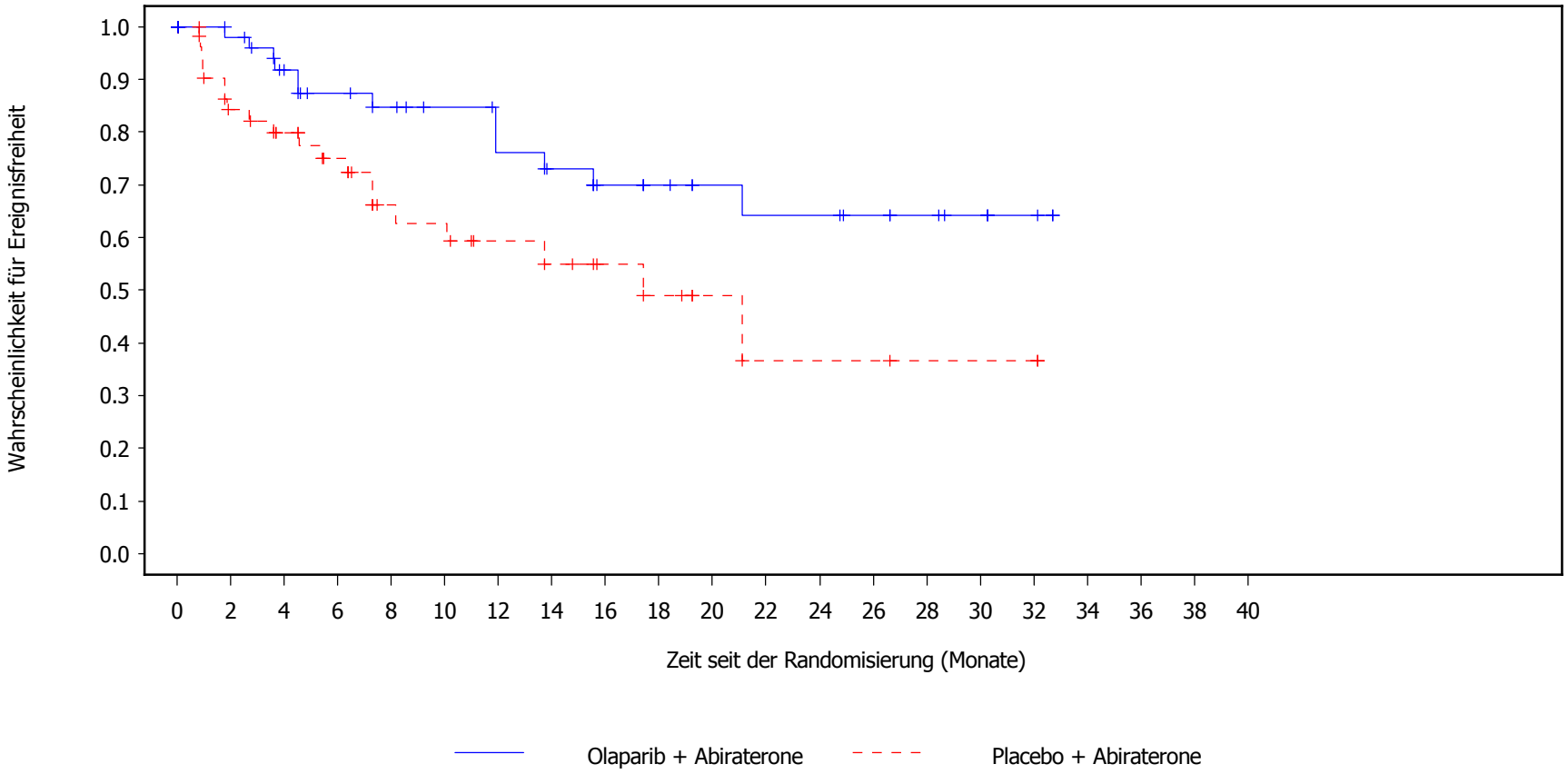


Anzahl an Patienten unter Risiko:

213	132	120	104	96	83	73	66	62	53	47	44	39	30	20	13	10	4	1	0	0	Olaparib + Abiraterone
226	162	150	138	128	118	91	76	68	58	49	43	39	28	26	21	14	4	1	0	0	Placebo + Abiraterone

Time to deterioration is defined as the time from date of randomisation until the earliest date of a deterioration in the respective score. Patients who have not met the criteria for deterioration and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events.
Patients with no evaluable baseline or post-baseline data are censored at day 1.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubpr.sas gttesubpreaa 05DEC2022:09:12 khcs324

Figure 2.3.5.2 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Gesamtscore (MID=23.4) for Metastasen zu Baseline=Viszeral
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

67	49	42	36	33	30	26	23	18	15	12	11	11	9	7	5	2	0	0	0	0	Olaparib + Abiraterone
73	40	34	28	19	18	14	12	9	7	4	2	2	2	1	1	1	0	0	0	0	Placebo + Abiraterone

Time to deterioration is defined as the time from date of randomisation until the earliest date of a deterioration in the respective score. Patients who have not met the criteria for deterioration and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events.
Patients with no evaluable baseline or post-baseline data are censored at day 1.
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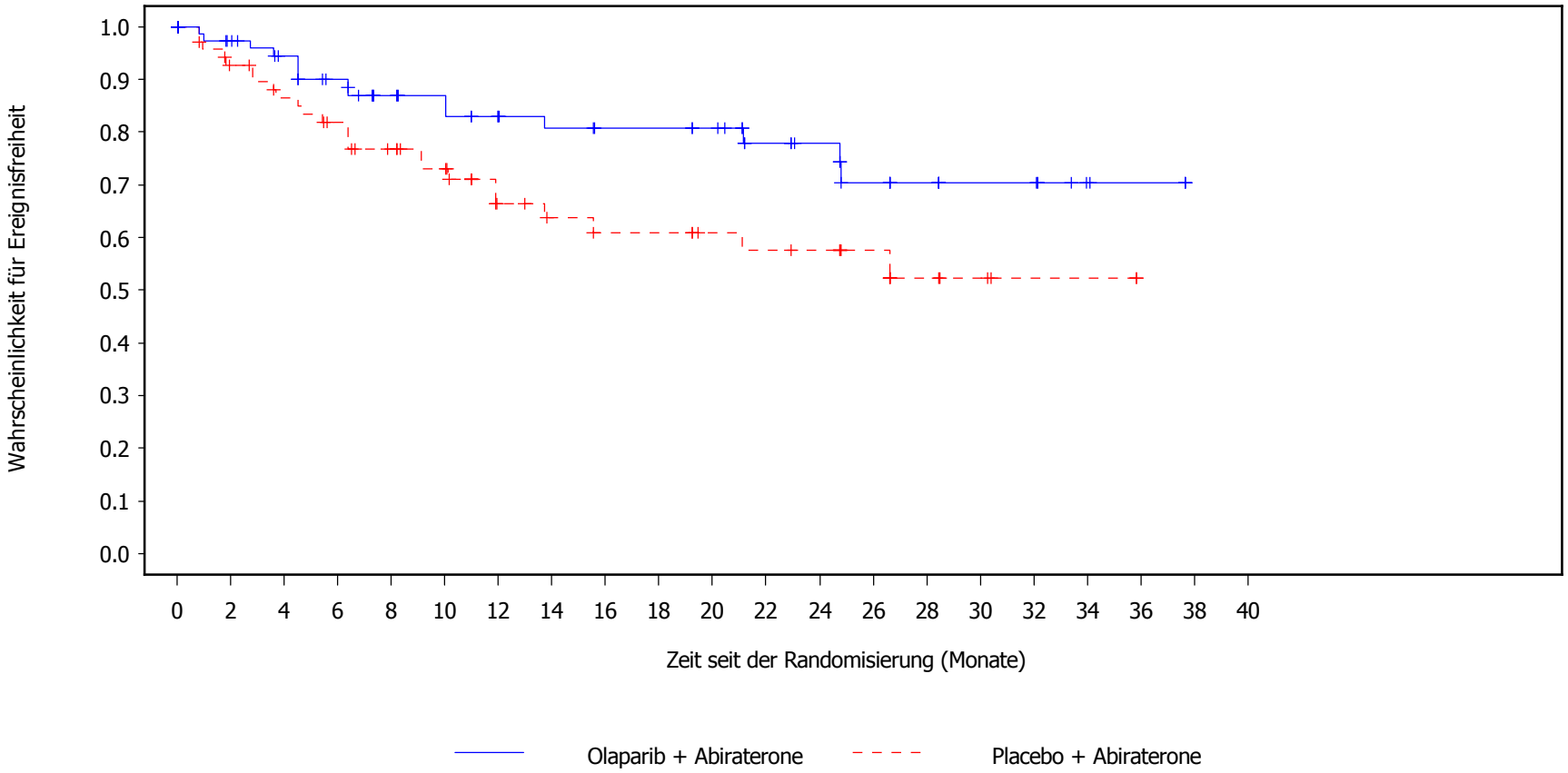
Figure 2.3.5.3 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung FACT-P Gesamtscore (MID=23.4) for Metastasen zu Baseline=andere
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

119	70	64	57	48	44	38	36	34	34	32	25	22	17	13	8	8	3	2	0	0	Olaparib + Abiraterone
98	61	55	50	44	39	26	23	21	21	18	17	16	11	5	3	1	1	0	0	0	Placebo + Abiraterone

Time to deterioration is defined as the time from date of randomisation until the earliest date of a deterioration in the respective score. Patients who have not met the criteria for deterioration and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events.
Patients with no evaluable baseline or post-baseline data are censored at day 1.
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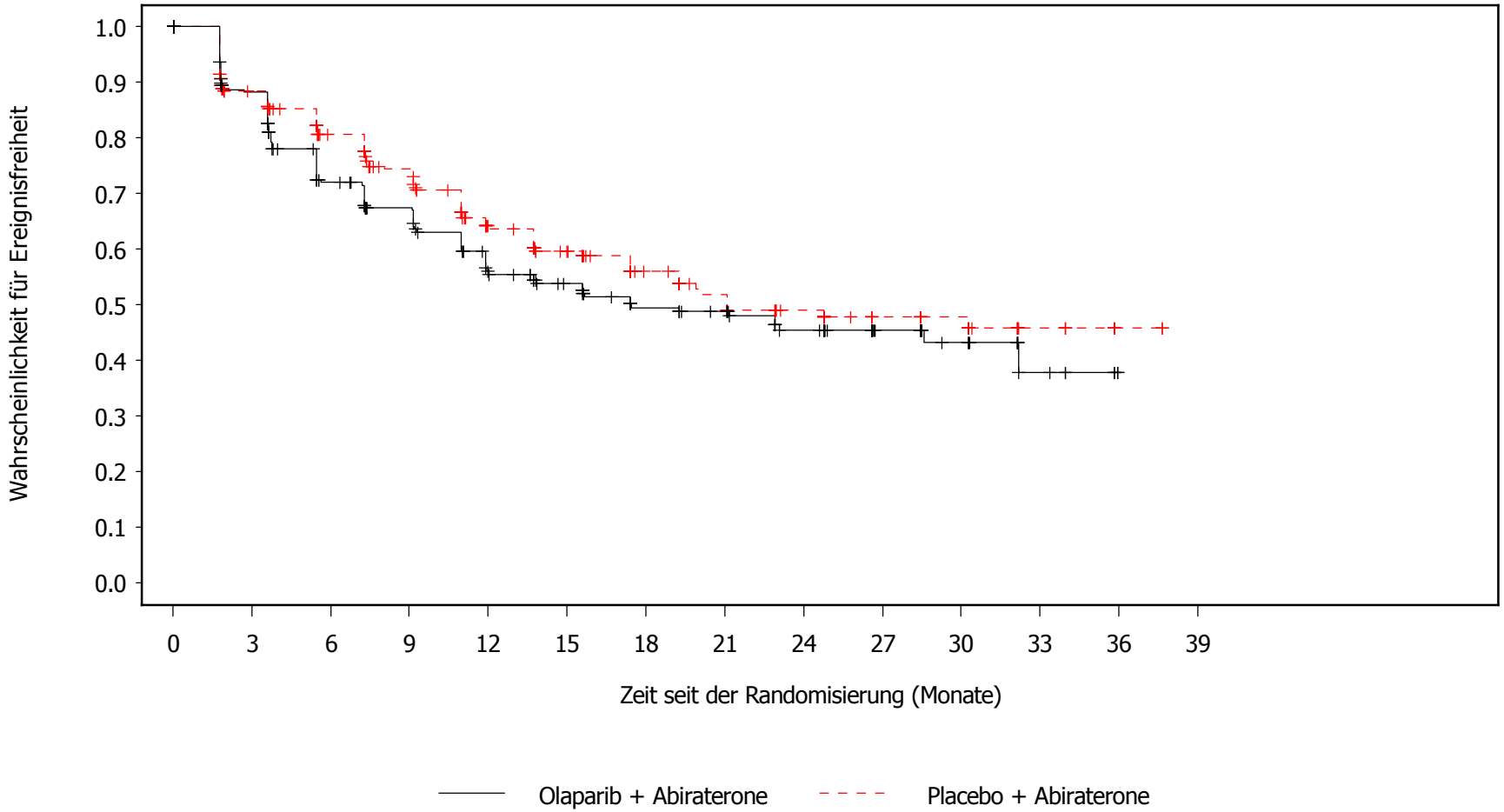
Table 2.4.1 PROpel: Summary of status at time to deterioration in EQ-5D VAS
Full Analysis Set, DCO 14MAR2022

Parameter	Deterioration/censoring reason	Olaparib + Abiraterone (N=399)	Placebo + Abiraterone (N=397)
EQ-5D visuelle Analogskala	Deterioration in score	120 (30,1)	108 (27,2)
	Censored due to last observation (no deterioration)	115 (28,8)	141 (35,5)
	Censored due to last observation (2 or more missed assessments)	6 (1,5)	4 (1,0)
	Censored due to death within 2 visits of last observation	16 (4,0)	16 (4,0)
	Censored due to no evaluable baseline or post-baseline result (Day 1)	142 (35,6)	128 (32,2)
	Total	399 (100)	397 (100)

Time to deterioration is defined as the time from date of randomisation until the earliest date of a deterioration in the respective score. Patients who have not met the criteria for deterioration and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events.
Patients with no evaluable baseline or post-baseline data are censored at day 1.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/cnsrpr.sas gcnsrprc 26MAY2022:21:15 klfm426

Figure 2.4.3 PROpel: Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung EQ-5D visuelle Analogskala (MID=15)
Full Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

399	221	163	139	107	93	72	65	51	29	19	6	0	0	Olaparib + Abiraterone
397	224	185	159	114	93	73	55	42	27	23	8	1	0	Placebo + Abiraterone

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Table 2.4.4 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung EQ-5D visuelle Analogskala (MID=15)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Metastasen zu Baseline									
Nur Knochen	213	74 (34,7)	11,9 [9,2;28,6]	226	69 (30,5)	21,1 [17,4; NE]	1,36	[0,98; 1,90]	0,0636
Viszeral	67	21 (31,3)	19,3 [11,0; NE]	73	15 (20,5)	20,0 [11,0; NE]	1,01	[0,52; 1,99]	0,9794
andere	119	25 (21,0)	22,9 [13,8; NE]	98	24 (24,5)	24,8 [11,9; NE]	0,97	[0,55; 1,71]	0,9204
Interaktion p-Wert									0,4999
Docetaxel-Behandlung des mHSPC									
Ja	90	19 (21,1)	28,6 [9,1; NE]	90	23 (25,6)	19,3 [13,7; NE]	1,00	[0,54; 1,83]	0,9922
Nein	309	101 (32,7)	15,6 [11,9;23,1]	307	85 (27,7)	21,1 [15,6; NE]	1,23	[0,93; 1,65]	0,1524
Interaktion p-Wert									0,5336
Alter bei Randomisierung									
<65 Jahre	130	38 (29,2)	17,4 [11,0; NE]	97	27 (27,8)	30,3 [13,8; NE]	1,20	[0,74; 1,99]	0,4578
>=65 Jahre	269	82 (30,5)	17,4 [11,9; NE]	300	81 (27,0)	21,1 [17,4; NE]	1,20	[0,88; 1,63]	0,2524
Interaktion p-Wert									0,9821
Region									
Asien	91	36 (39,6)	17,4 [11,9; NE]	104	33 (31,7)	21,1 [13,7; NE]	1,23	[0,76; 1,98]	0,3948
Europa	178	51 (28,7)	15,6 [9,1; NE]	172	44 (25,6)	30,3 [13,7; NE]	1,22	[0,81; 1,83]	0,3361
Nord- und Suedamerika	130	33 (25,4)	32,2 [11,9; NE]	121	31 (25,6)	21,1 [13,7; NE]	1,12	[0,68; 1,83]	0,6525
Interaktion p-Wert									0,9561
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	27 (27,6)	NE [NE; NE]	100	22 (22,0)	NE [NE; NE]	1,17	[0,67; 2,07]	0,5894
Nicht-HRRm	269	83 (30,9)	19,3 [11,9; NE]	267	80 (30,0)	19,3 [13,7; NE]	1,13	[0,83; 1,54]	0,4306

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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Table 2.4.4 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung EQ-5D visuelle Analogskala (MID=15)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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]
Unbekannt	32	10 (31,3)	11,0 [3,6;13,8]	30	6 (20,0)	NE [NE; NE]	2,46	[0,91; 7,24]	0,0750
Interaktion p-Wert									0,3398
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	19 (30,6)	22,9 [13,7; NE]	56	18 (32,1)	21,1 [11,0; NE]	1,05	[0,55; 2,01]	0,8930
Nicht-HRRm	207	65 (31,4)	11,9 [9,1;28,6]	210	57 (27,1)	21,1 [15,6; NE]	1,35	[0,94; 1,93]	0,0994
Unbekannt	130	36 (27,7)	22,9 [11,9; NE]	131	33 (25,2)	24,8 [13,7; NE]	1,07	[0,67; 1,72]	0,7787
Interaktion p-Wert									0,6665
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	11 (37,9)	15,6 [5,5; NE]	22	4 (18,2)	NE [NE; NE]	1,33	[0,45; 4,78]	0,6223
Nicht-HRRm	330	97 (29,4)	17,4 [11,9;28,6]	327	92 (28,1)	21,1 [17,4; NE]	1,21	[0,91; 1,61]	0,1882
Unbekannt	40	12 (30,0)	32,2 [7,3; NE]	48	12 (25,0)	NE [NE; NE]	1,07	[0,48; 2,41]	0,8694
Interaktion p-Wert									0,9452
ECOG-PS zu Baseline									
0	286	89 (31,1)	17,4 [11,9; NE]	272	79 (29,0)	21,1 [17,4; NE]	1,16	[0,86; 1,57]	0,3328
1	112	31 (27,7)	22,9 [9,1; NE]	124	29 (23,4)	30,3 [13,7; NE]	1,29	[0,78; 2,16]	0,3194
Interaktion p-Wert									0,7205
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	69 (35,2)	15,6 [11,9;28,6]	200	53 (26,5)	NE [NE; NE]	1,44	[1,01; 2,07]	0,0430*
Über medianem PSA-Baselinewert	201	51 (25,4)	22,9 [11,0; NE]	196	55 (28,1)	19,9 [13,7; NE]	0,97	[0,66; 1,42]	0,8719
Interaktion p-Wert									0,1340

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Table 2.4.4 PROpel: Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung EQ-5D visuelle Analogskala (MID=15)
Full Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=399)			Placebo + Abiraterone (N=397)					
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									
Kaukasisch	282	88 (31,2)	11,9 [9,2; NE]	275	73 (26,5)	21,1 [17,4; NE]	1,27	[0,93; 1,74]	0,1276
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	0,79	[0,03; 20,07]	0,8707
Asiatisch	66	26 (39,4)	22,9 [12,0; NE]	72	29 (40,3)	17,4 [11,0; NE]	0,93	[0,54; 1,58]	0,7811
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5788
Schmerzen zu baseline									
Symptomatisch	103	31 (30,1)	12,0 [7,3;23,1]	80	28 (35,0)	13,7 [9,2;21,1]	1,21	[0,73; 2,03]	0,4607
Asymptomatisch/mild symptomatisch	266	88 (33,1)	22,9 [11,9; NE]	294	80 (27,2)	30,3 [19,3; NE]	1,19	[0,88; 1,61]	0,2659
Interaktion p-Wert									0,9464

Time to det. is defined as the time from date of random. until the earliest date of det. in the respective score. Patients who have not met the criteria for det. and who are alive at the time of the analysis will be censored at the time of the latest evaluable assessment. Deaths are not counted as events. Patients with no evaluable baseline or post-baseline data are censored at day 1. NC = not calculable. [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/treat., results from model including treat., subgroup, treat. 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 treat., results from model for 1 level including treat. only. * Interaction p-value <0.05. HR <1 favours olaparib.
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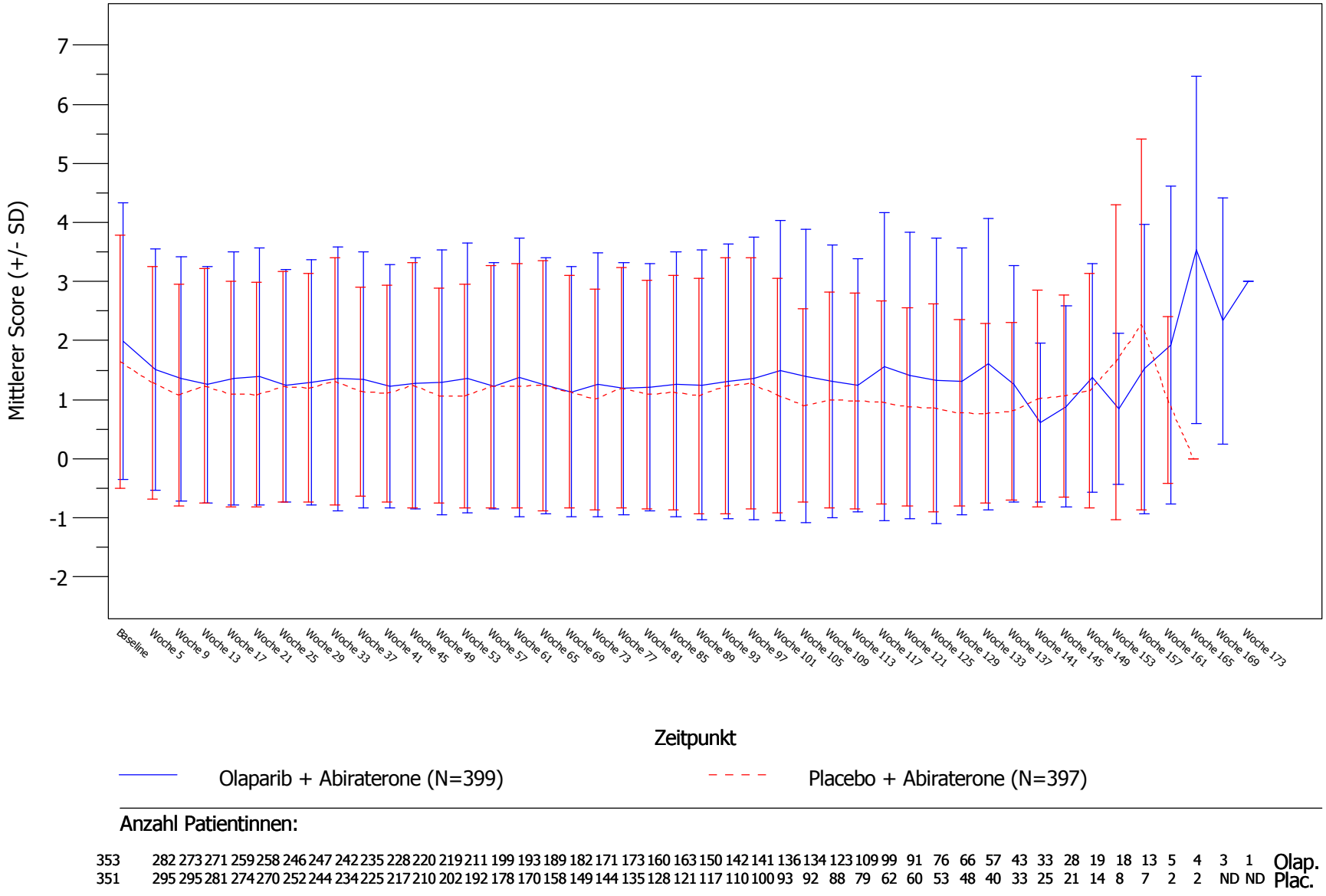
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.1 PROpel: Mean (+/- SD) score for BPI-SF Schmerzprogression (Frage 3) across timepoints, by treatment group
Full Analysis Set, DCO 14MAR2022



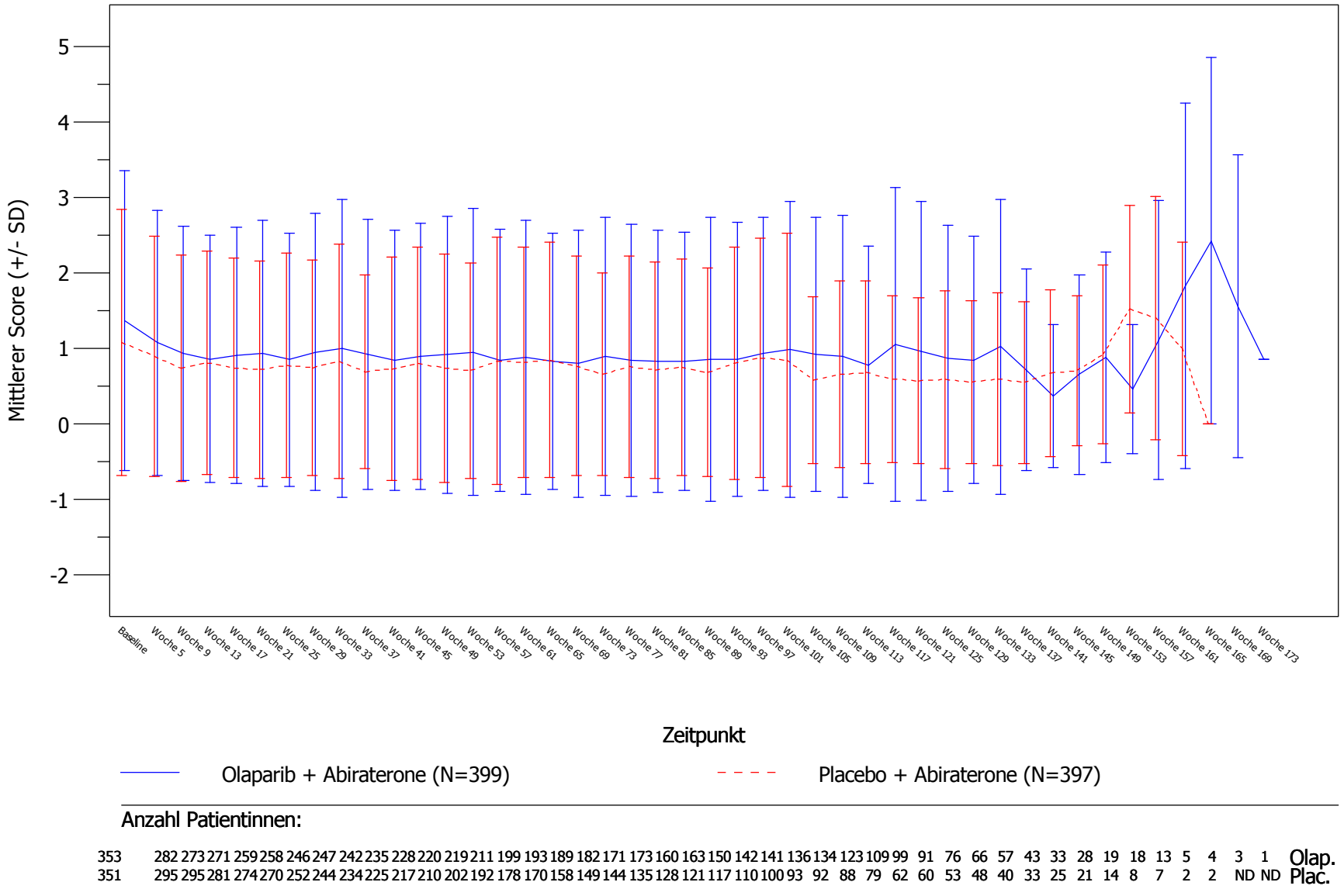
Anzahl Patientinnen:

353	282	273	271	259	258	246	247	242	235	228	220	219	211	199	193	189	182	171	173	160	163	150	142	141	136	134	123	109	99	91	76	66	57	43	33	28	19	18	13	5	4	3	1	Olap.
351	295	295	281	274	270	252	244	234	225	217	210	202	192	178	170	158	149	144	135	128	121	117	110	100	93	92	88	79	62	60	53	48	40	33	25	21	14	8	7	2	2	ND	ND	Plac.

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/fmeanpr.sas gfmeanpraaa 26MAY2022:16:20 klfm426

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.2 PROpel: Mean (+/- SD) score for BPI-SF Beeinträchtigung durch Schmerzen (Frage 9a-g) across timepoints, by treatment group
Full Analysis Set, DCO 14MAR2022



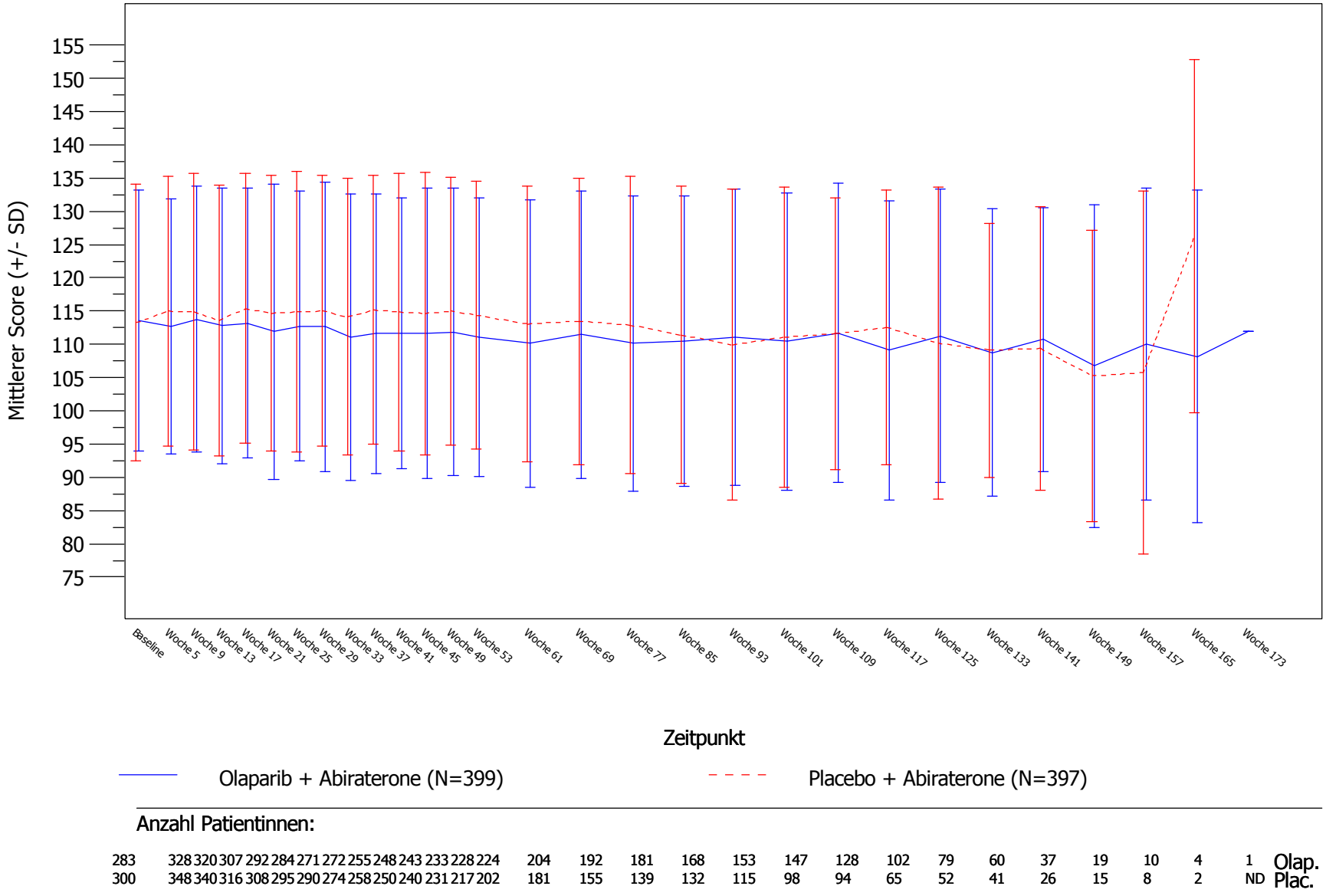
Anzahl Patientinnen:

353	282	273	271	259	258	246	247	242	235	228	220	219	211	199	193	189	182	171	173	160	163	150	142	141	136	134	123	109	99	91	76	66	57	43	33	28	19	18	13	5	4	3	1	Olap.
351	295	295	281	274	270	252	244	234	225	217	210	202	192	178	170	158	149	144	135	128	121	117	110	100	93	92	88	79	62	60	53	48	40	33	25	21	14	8	7	2	2	ND	ND	Plac.

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/fmeanpr.sas gfmeanpraab 26MAY2022:16:20 klfm426

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.6.2 PROpel: Mean (+/- SD) score for FACT-P Gesamtscore across timepoints, by treatment group
Full Analysis Set, DCO 14MAR2022



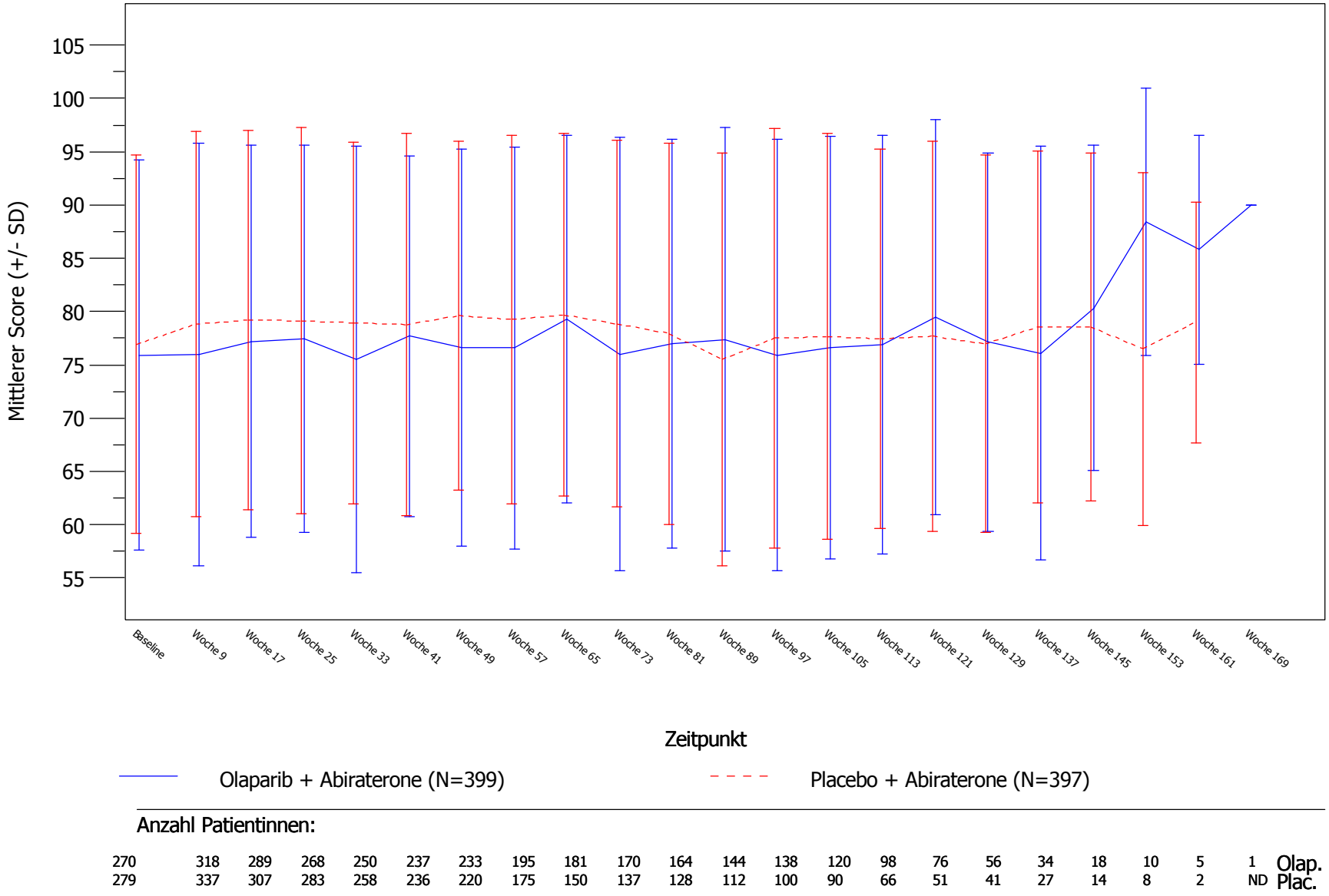
Anzahl Patientinnen:

283	328	320	307	292	284	271	272	255	248	243	233	228	224	204	192	181	168	153	147	128	102	79	60	37	19	10	4	1	Olap.
300	348	340	316	308	295	290	274	258	250	240	231	217	202	181	155	139	132	115	98	94	65	52	41	26	15	8	2	ND	Plac.

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/fmeanpr.sas gfmeanprbaa 26MAY2022:16:20 klfm426

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.7.2 PROpel: Mean (+/- SD) score for EQ-5D visuelle Analogskala across timepoints, by treatment group
Full Analysis Set, DCO 14MAR2022

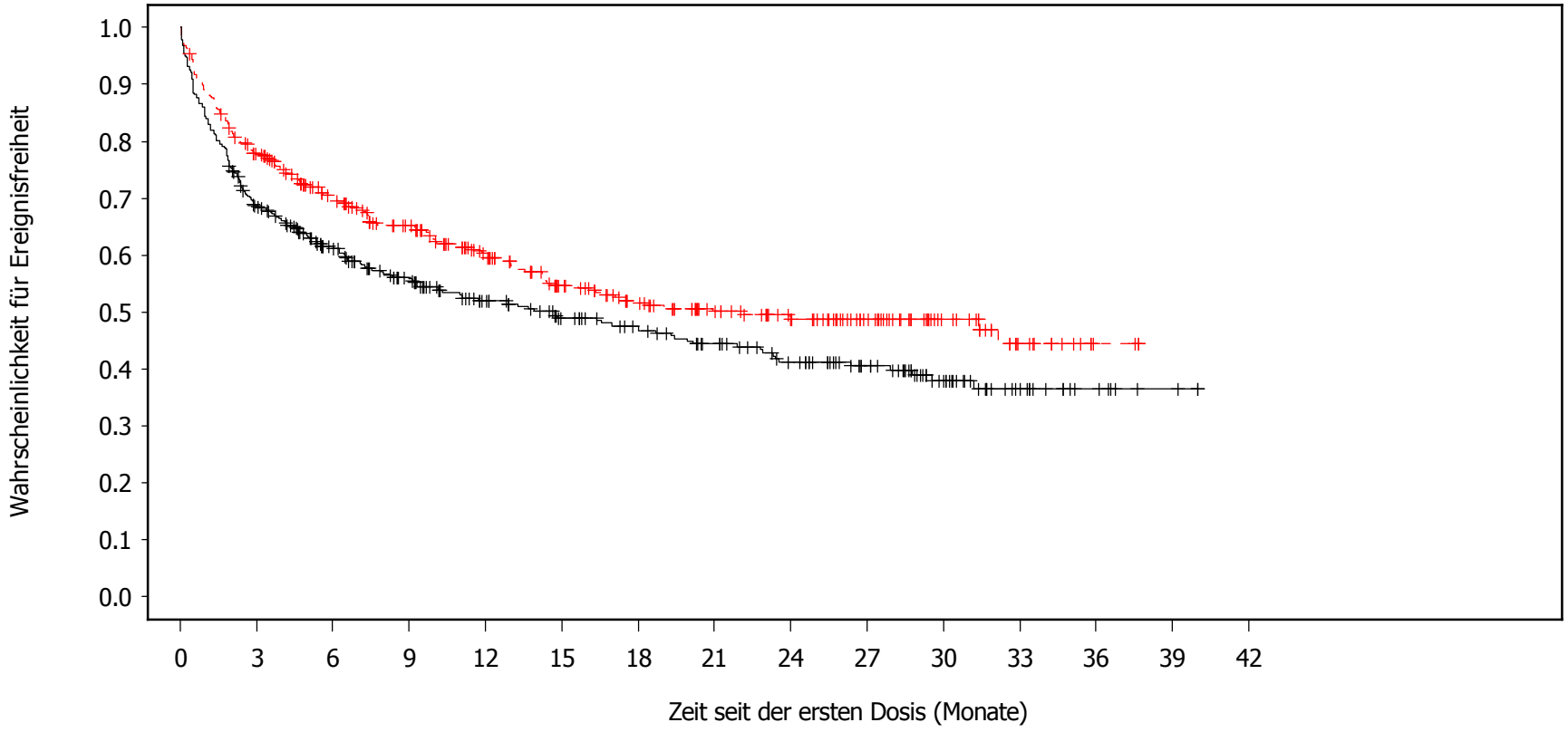


Anzahl Patientinnen:

270	318	289	268	250	237	233	195	181	170	164	144	138	120	98	76	56	34	18	10	5	1	Olap.
279	337	307	283	258	236	220	175	150	137	128	112	100	90	66	51	41	27	14	8	2	ND	Plac.

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/fmeanpr.sas gfmeanprcaa 26MAY2022:16:20 klfm426

Figure 3.3.2 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 14MAR2022



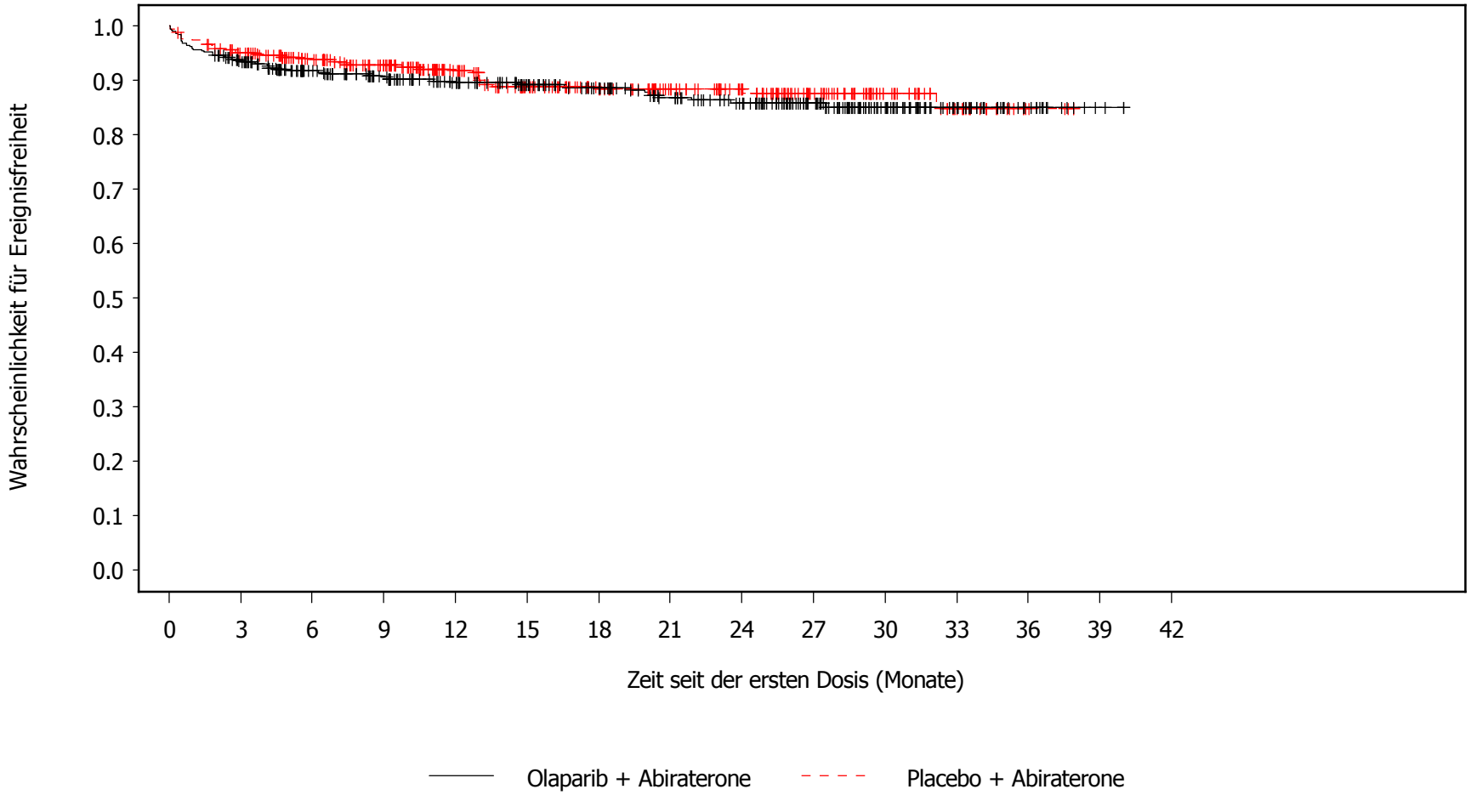
Anzahl an Patienten unter Risiko:

398	266	213	175	141	118	106	91	75	58	35	17	7	2	0	Olaparib + Abiraterone
396	299	245	208	170	132	110	90	73	54	31	13	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebab 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.3 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Asthenie
Safety Analysis Set, DCO 14MAR2022

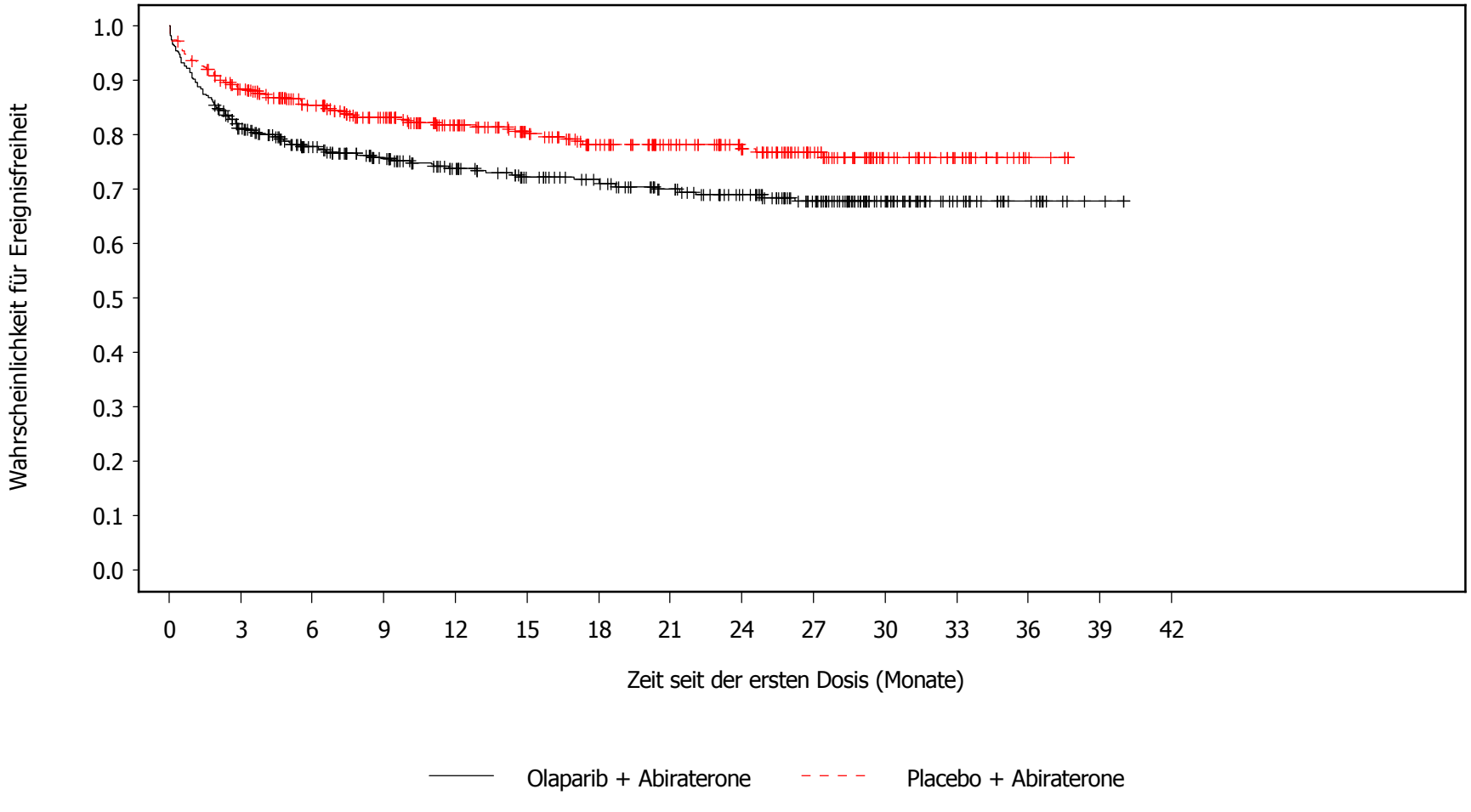


Anzahl an Patienten unter Risiko:

398	362	315	284	250	222	202	178	159	118	72	39	15	2	0	Olaparib + Abiraterone
396	364	326	287	236	196	166	141	116	82	48	24	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebac 06JUN2022:19:52 kvbv306

Figure 3.3.4 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Ermuedung
Safety Analysis Set, DCO 14MAR2022



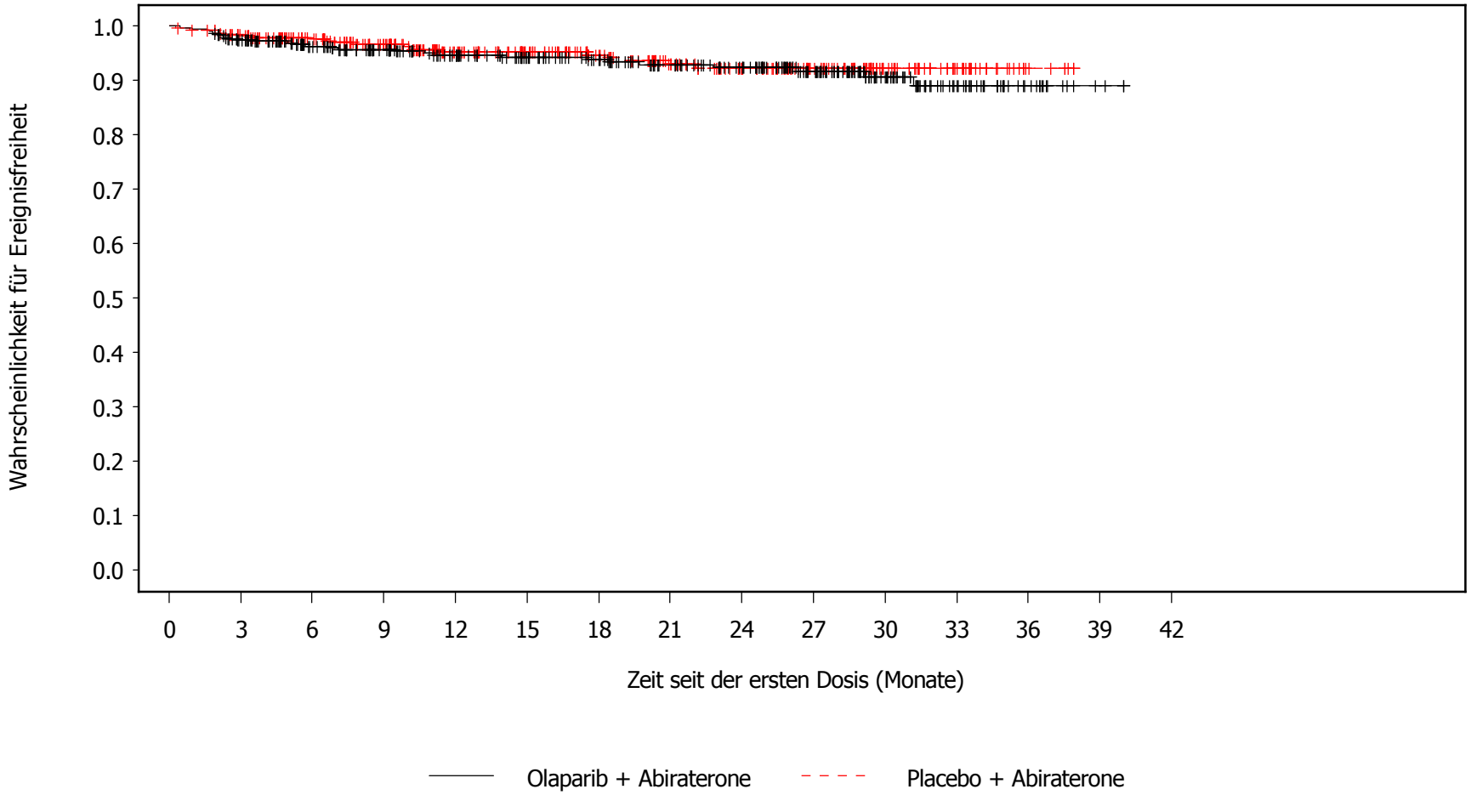
Anzahl an Patienten unter Risiko:

398	312	265	231	200	176	164	143	124	95	52	26	12	2	0	Olaparib + Abiraterone
396	336	290	250	214	179	150	128	105	78	42	23	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebad 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.5 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Fieber
Safety Analysis Set, DCO 14MAR2022

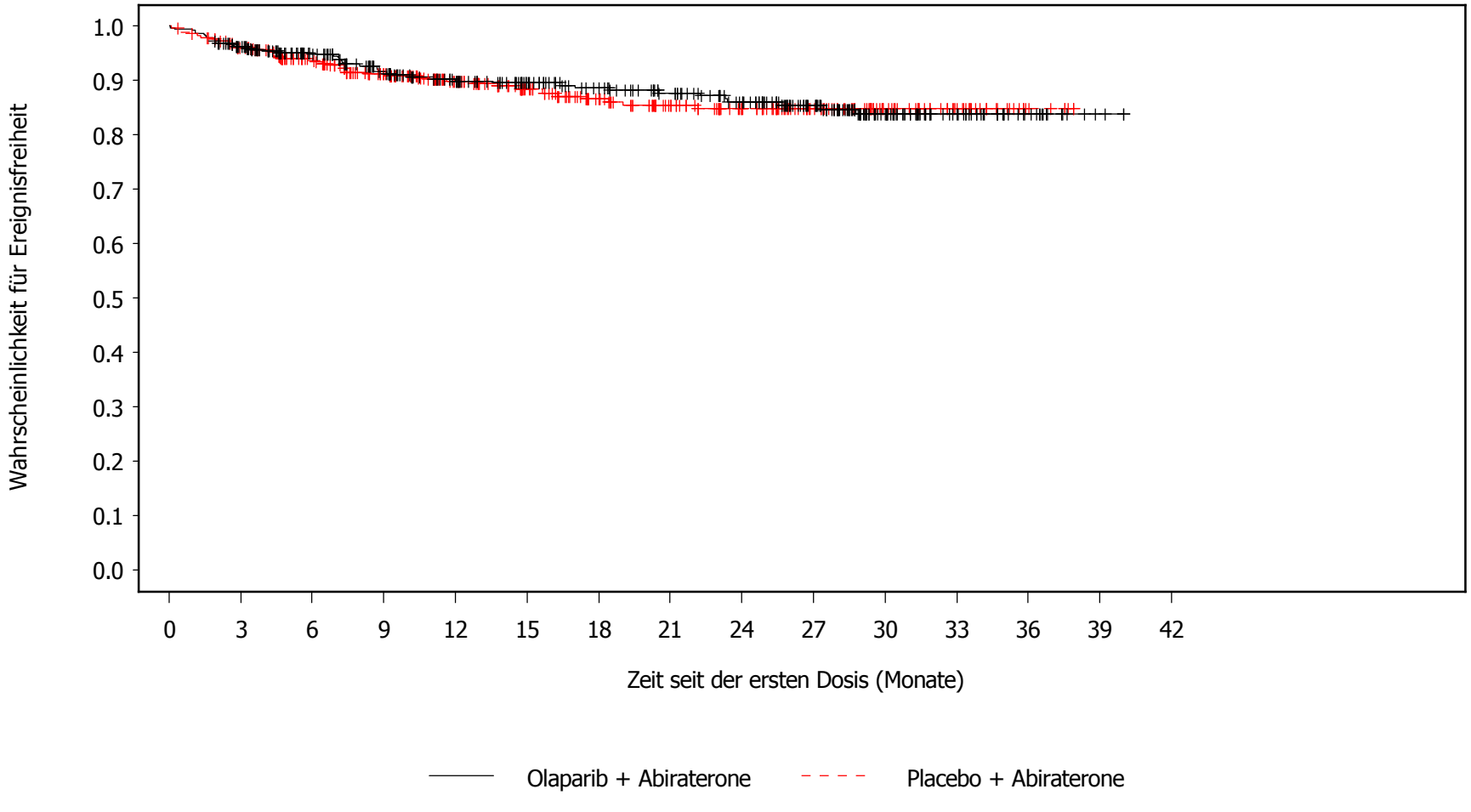


Anzahl an Patienten unter Risiko:

398	376	330	297	263	234	214	187	166	125	70	37	14	2	0	Olaparib + Abiraterone
396	375	334	293	244	209	176	147	123	91	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebae 06JUN2022:19:52 kvbv306

Figure 3.3.6 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Oedem peripher
Safety Analysis Set, DCO 14MAR2022

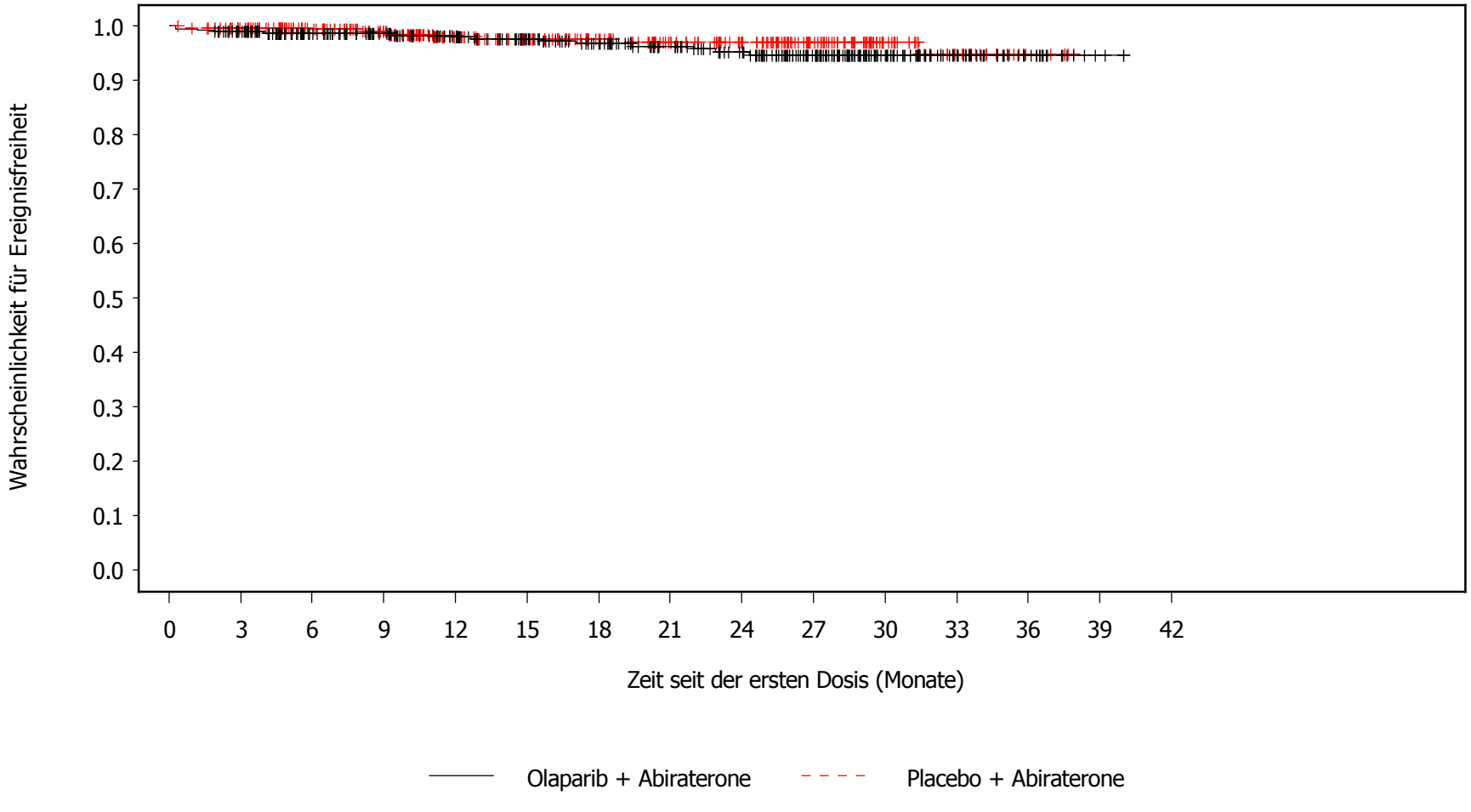


Anzahl an Patienten unter Risiko:

398	369	321	282	247	218	198	179	157	118	67	37	15	2	0	Olaparib + Abiraterone
396	366	322	276	230	194	161	136	111	83	49	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebaf 06JUN2022:19:52 kvbv306

Figure 3.3.7 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Unwohlsein
Safety Analysis Set, DCO 14MAR2022



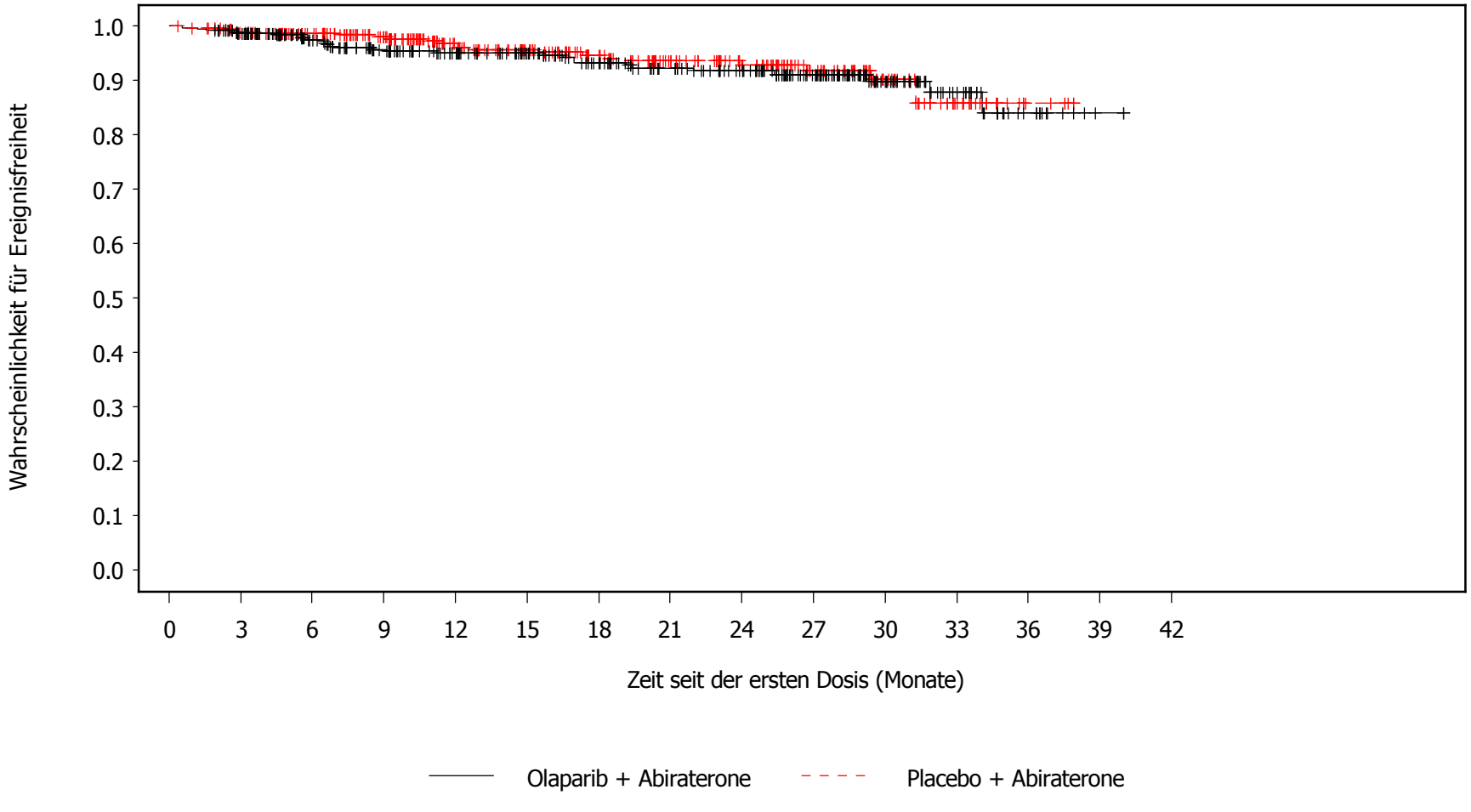
Anzahl an Patienten unter Risiko:

398	381	336	305	272	240	218	192	172	129	71	39	17	2	0	Olaparib + Abiraterone
396	379	339	299	248	212	180	153	128	94	54	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebag 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.8 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Augenerkrankungen
Safety Analysis Set, DCO 14MAR2022

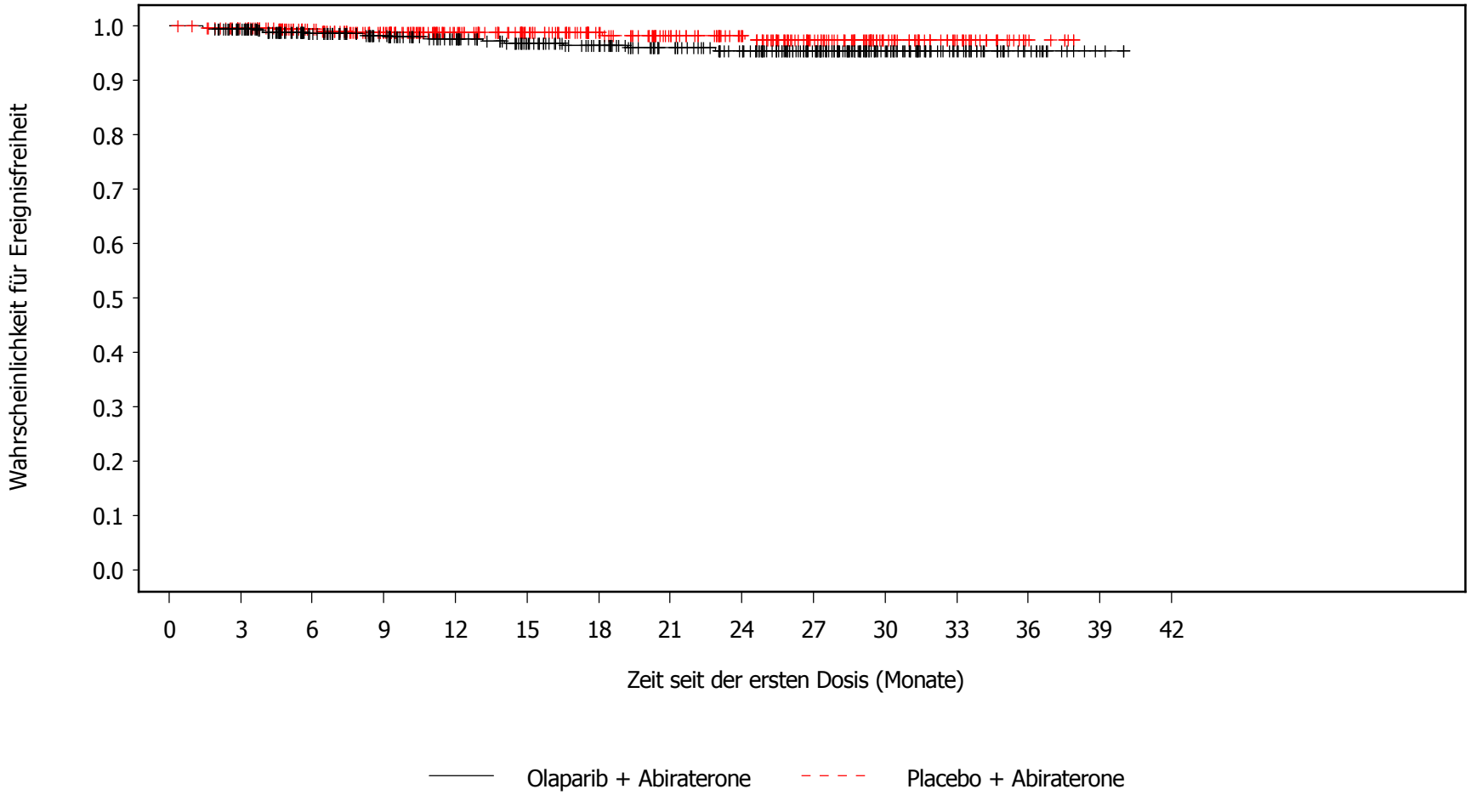


Anzahl an Patienten unter Risiko:

398	379	330	293	259	229	204	179	160	122	66	33	12	1	0	Olaparib + Abiraterone
396	376	336	295	240	205	171	143	118	85	49	24	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebah 06JUN2022:19:52 kvbv306

Figure 3.3.9 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 14MAR2022

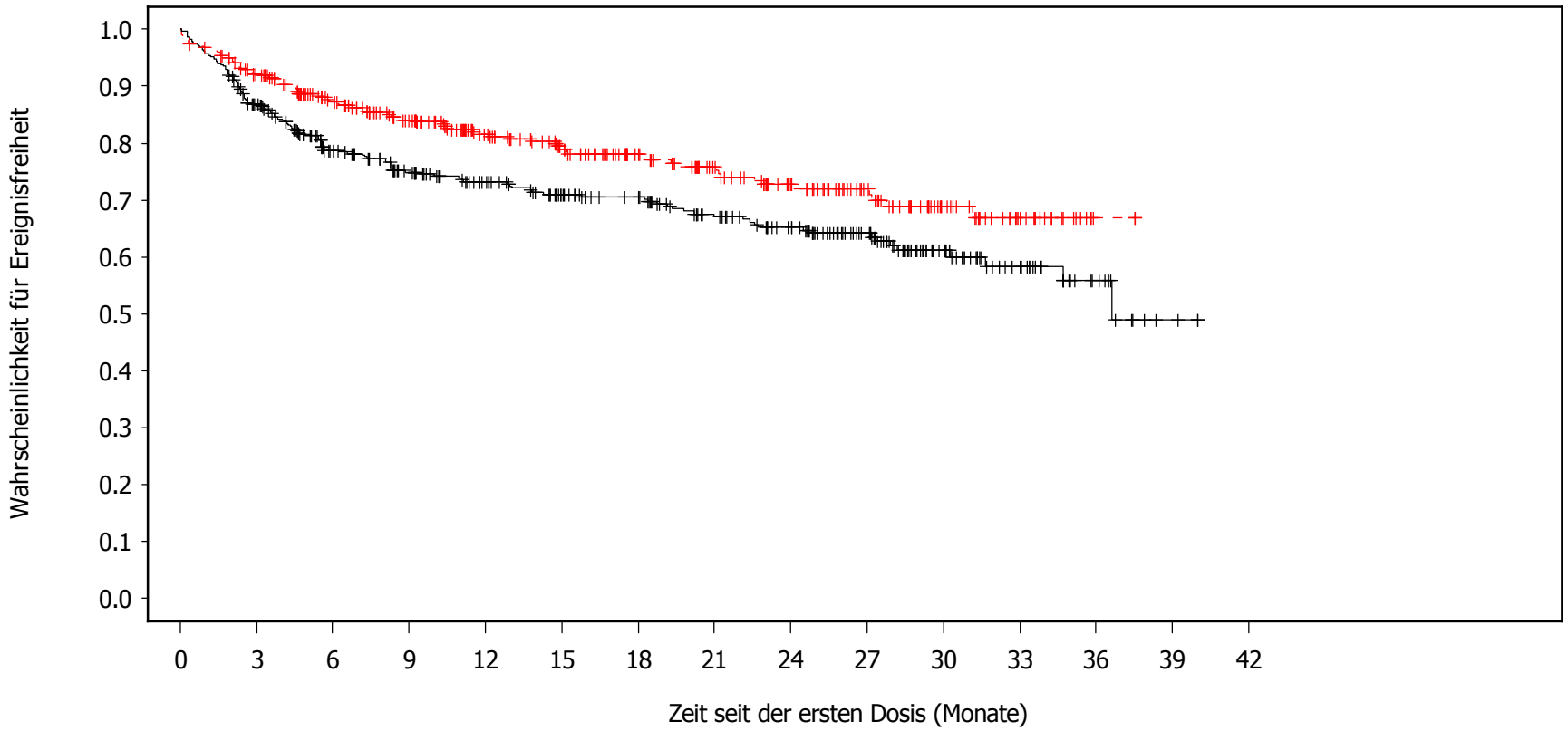


Anzahl an Patienten unter Risiko:

398	382	334	302	268	238	216	191	172	130	73	39	15	2	0	Olaparib + Abiraterone
396	379	339	297	246	211	178	152	127	92	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebai 06JUN2022:19:52 kvbv306

Figure 3.3.10 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

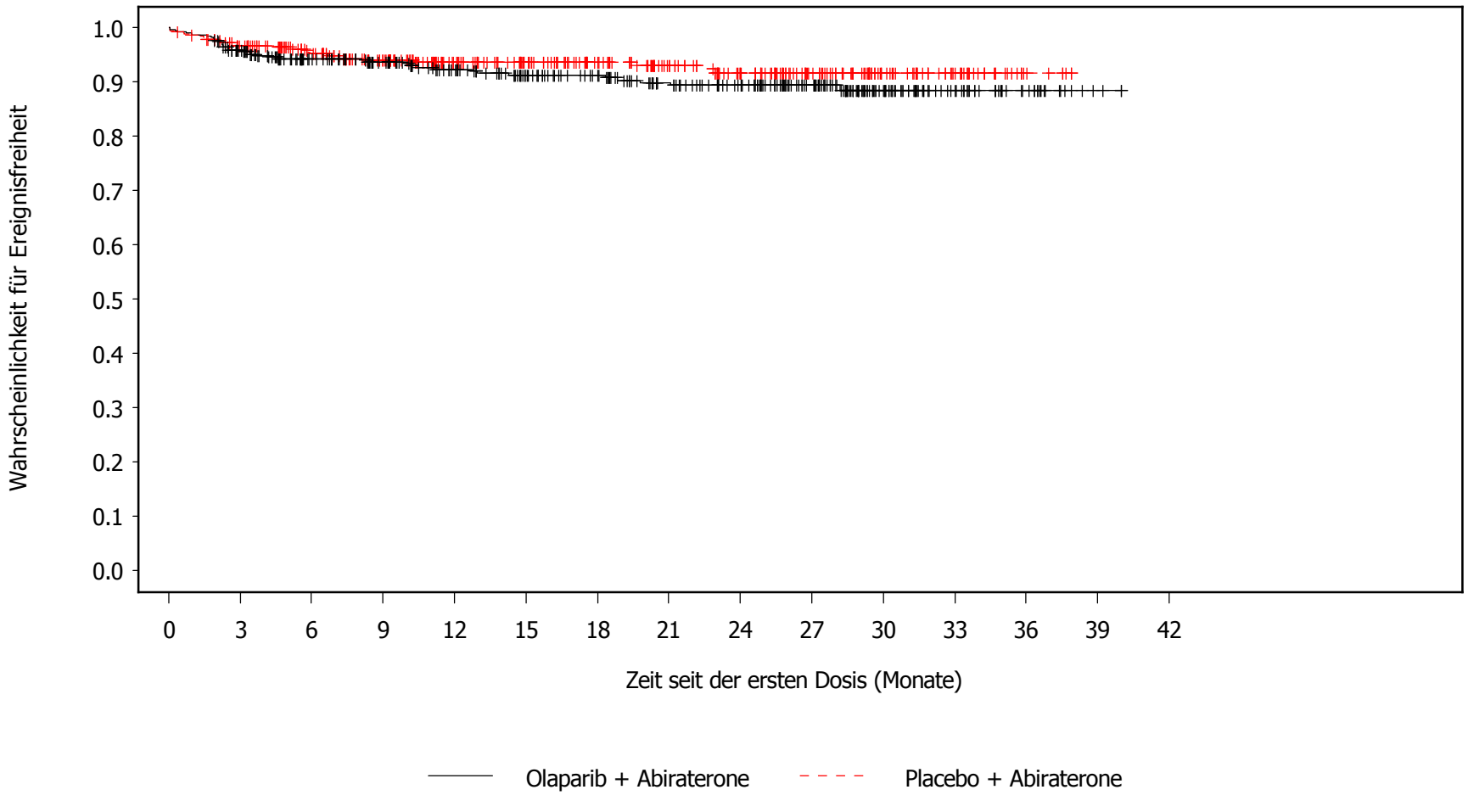


Anzahl an Patienten unter Risiko:

398	335	272	240	210	183	171	146	128	97	57	32	13	2	0	Olaparib + Abiraterone
396	351	299	257	209	177	147	122	96	72	42	21	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebaj 06JUN2022:19:52 kvbv306

Figure 3.3.11 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Dyspnoe
Safety Analysis Set, DCO 14MAR2022

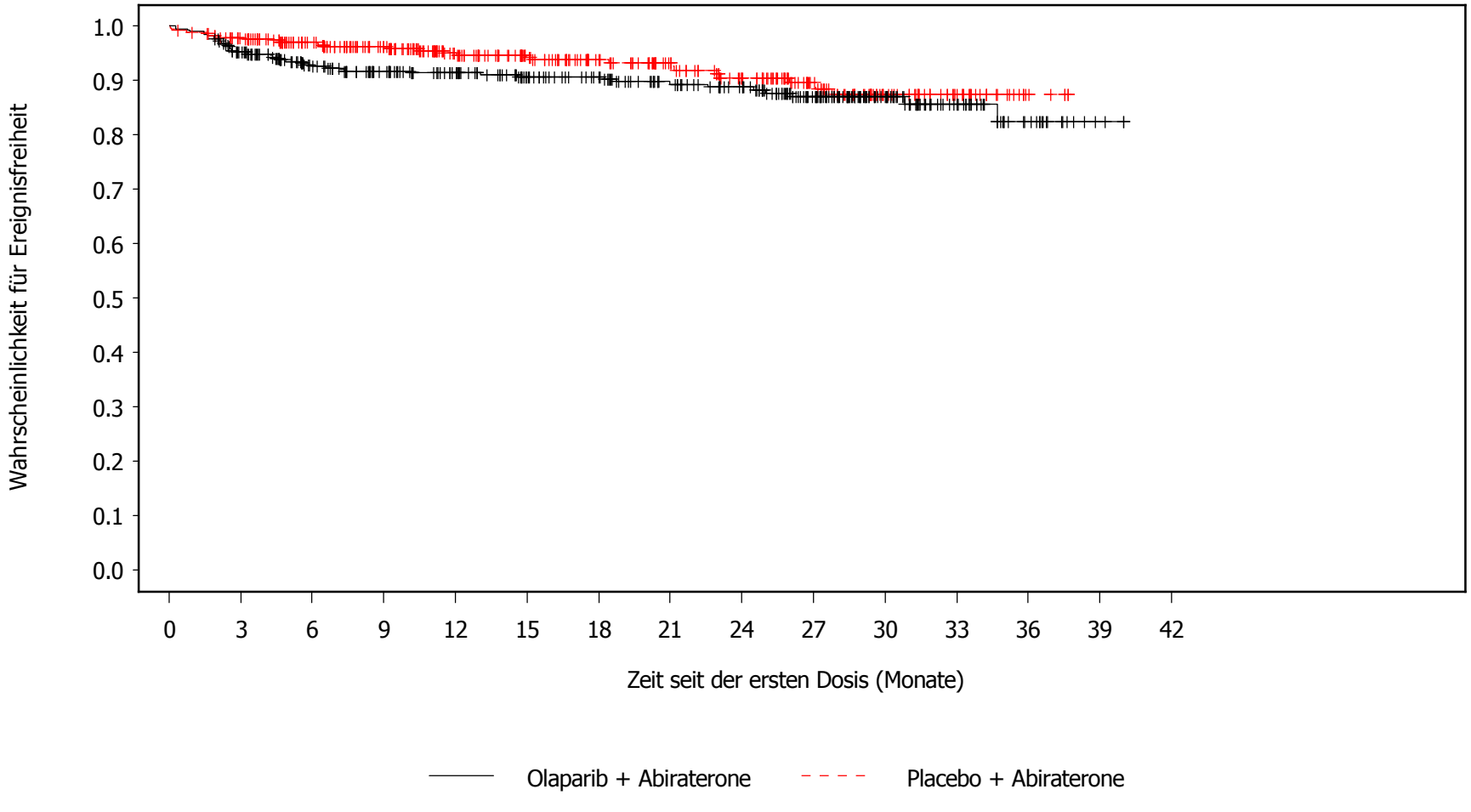


Anzahl an Patienten unter Risiko:

398	369	322	294	259	229	210	183	163	125	70	38	17	2	0	Olaparib + Abiraterone
396	368	328	287	239	207	176	149	121	89	52	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebak 06JUN2022:19:52 kvbv306

Figure 3.3.12 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Husten
Safety Analysis Set, DCO 14MAR2022

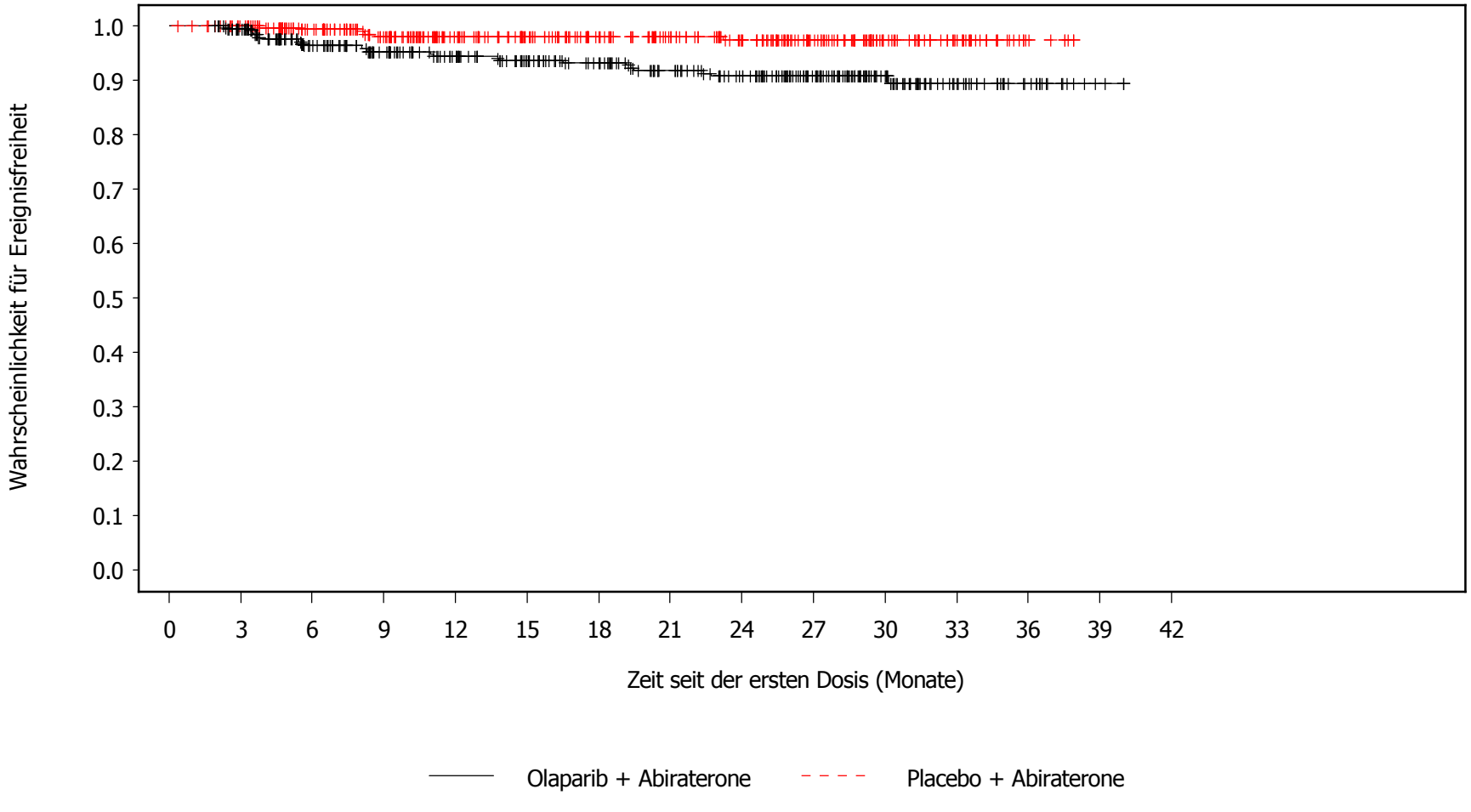


Anzahl an Patienten unter Risiko:

398	366	317	285	257	226	210	185	168	126	73	40	16	2	0	Olaparib + Abiraterone
396	372	330	290	239	202	170	146	118	85	49	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebal 06JUN2022:19:52 kvbv306

Figure 3.3.13 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

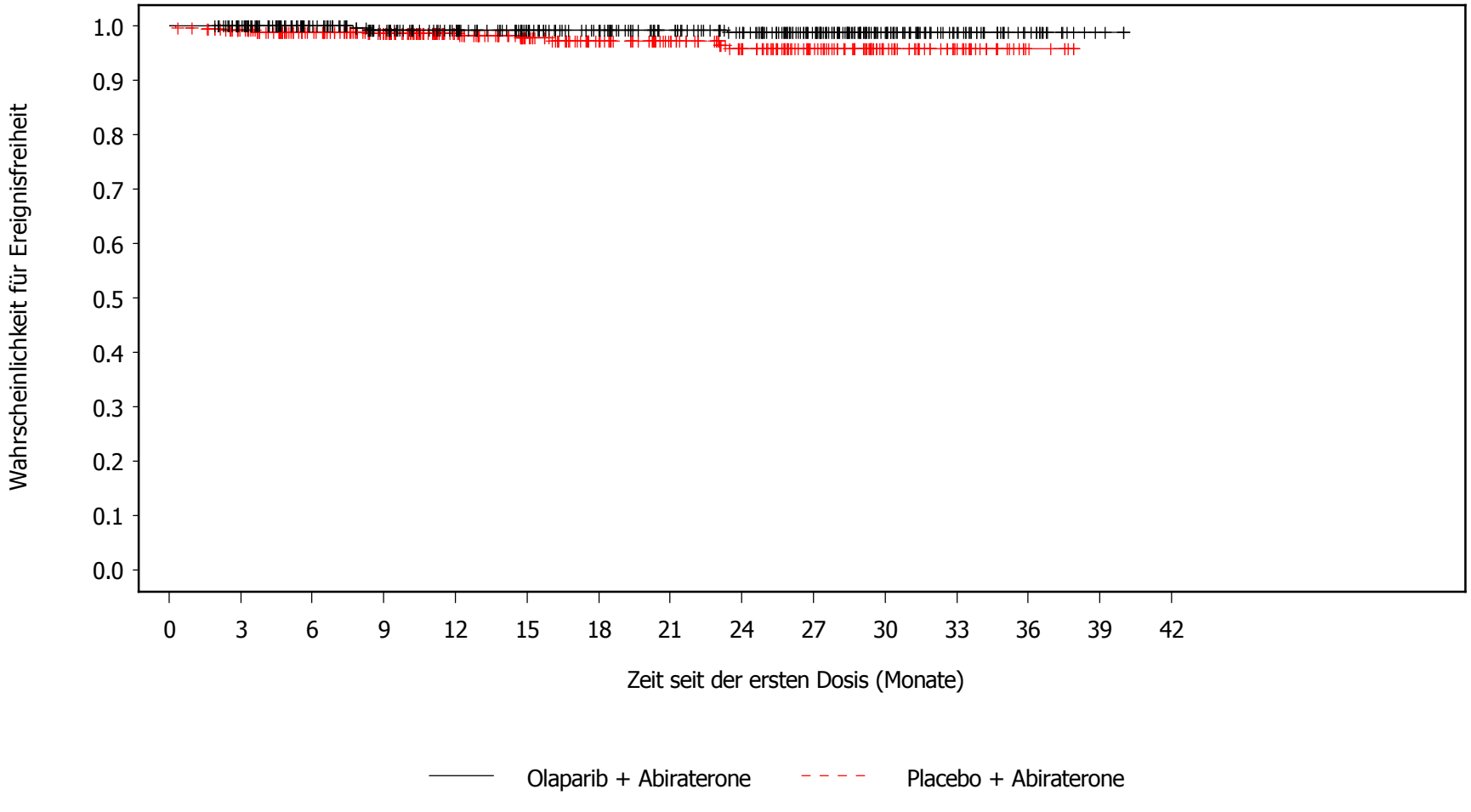


Anzahl an Patienten unter Risiko:

398	382	327	292	260	230	210	184	162	121	71	36	16	2	0	Olaparib + Abiraterone
396	380	339	296	247	212	180	155	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebam 06JUN2022:19:52 kvbv306

Figure 3.3.14 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Nasenverstopfung
Safety Analysis Set, DCO 14MAR2022



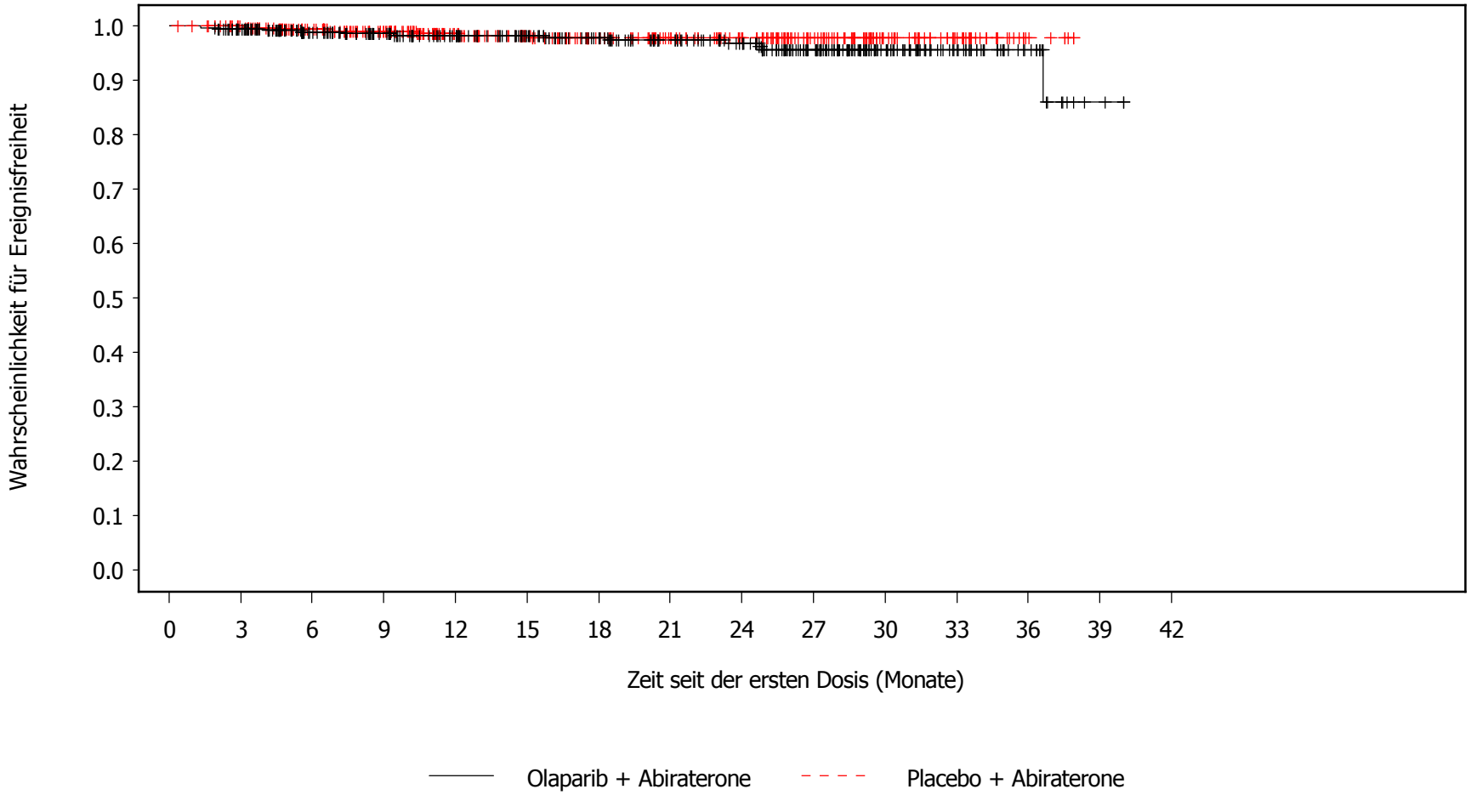
Anzahl an Patienten unter Risiko:

398	384	339	306	274	244	224	199	178	136	77	41	17	2	0	Olaparib + Abiraterone
396	377	337	298	247	209	175	150	122	90	52	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaeban 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.15 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerzen im Oropharynx
Safety Analysis Set, DCO 14MAR2022



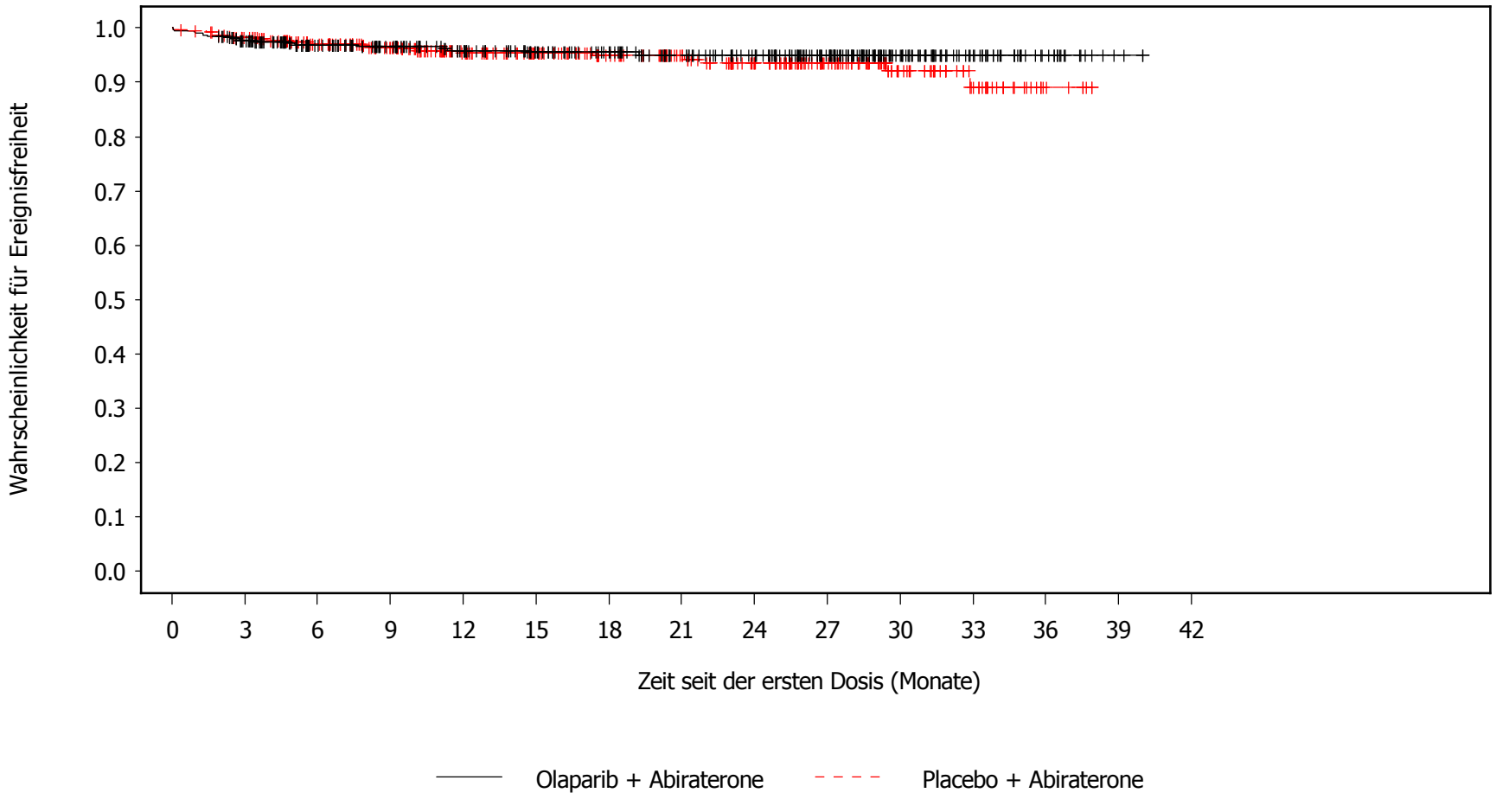
Anzahl an Patienten unter Risiko:

398	382	335	304	271	241	219	194	173	130	74	41	17	2	0	Olaparib + Abiraterone
396	380	339	298	246	209	175	149	124	92	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebao 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.16 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese
Safety Analysis Set, DCO 14MAR2022

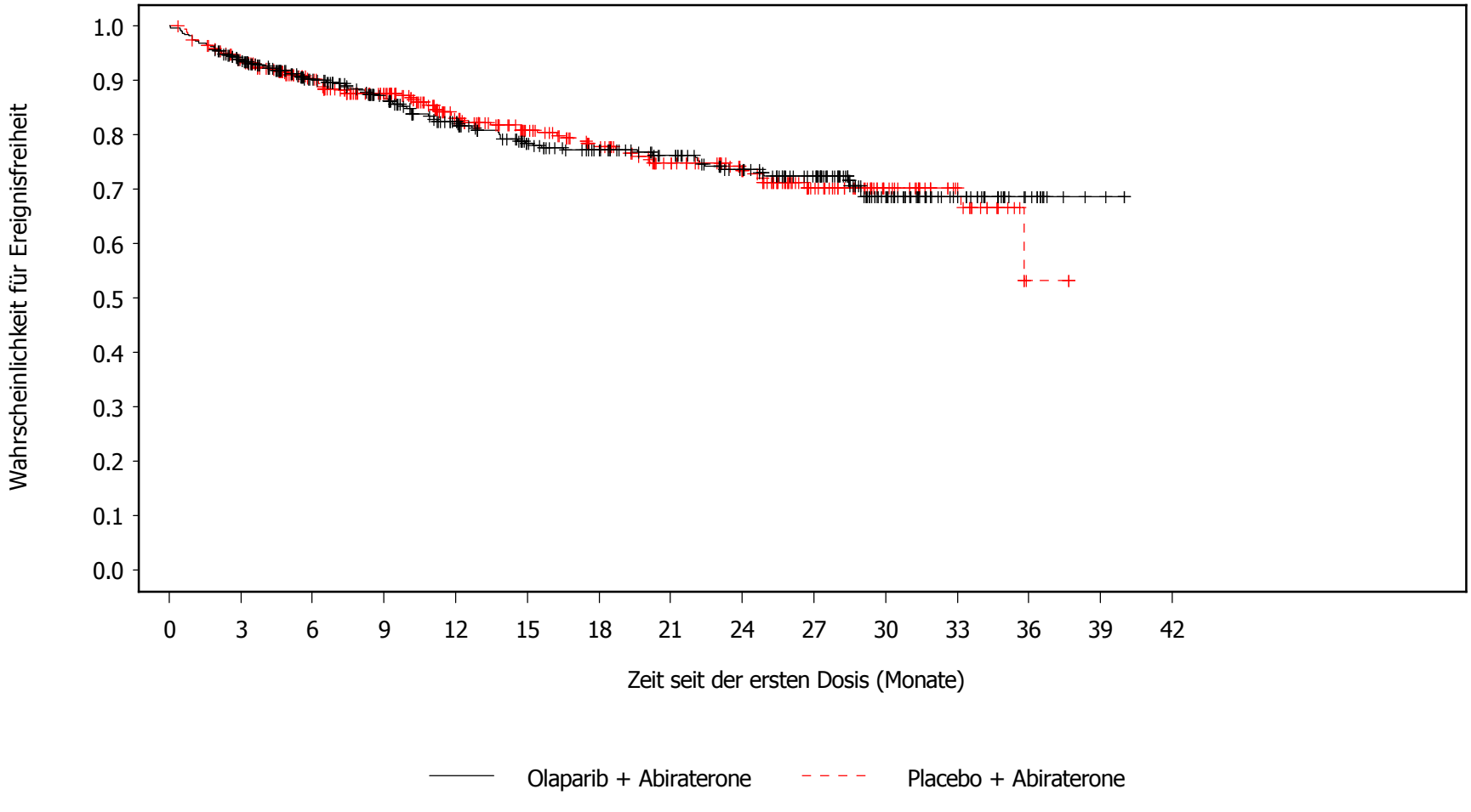


Anzahl an Patienten unter Risiko:

398	375	330	300	267	238	219	194	174	134	75	41	17	2	0	Olaparib + Abiraterone
396	374	333	294	246	210	178	153	126	91	52	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebap 06JUN2022:19:52 kvbv306

Figure 3.3.17 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Haut und des Unterhautgewebes
Safety Analysis Set, DCO 14MAR2022

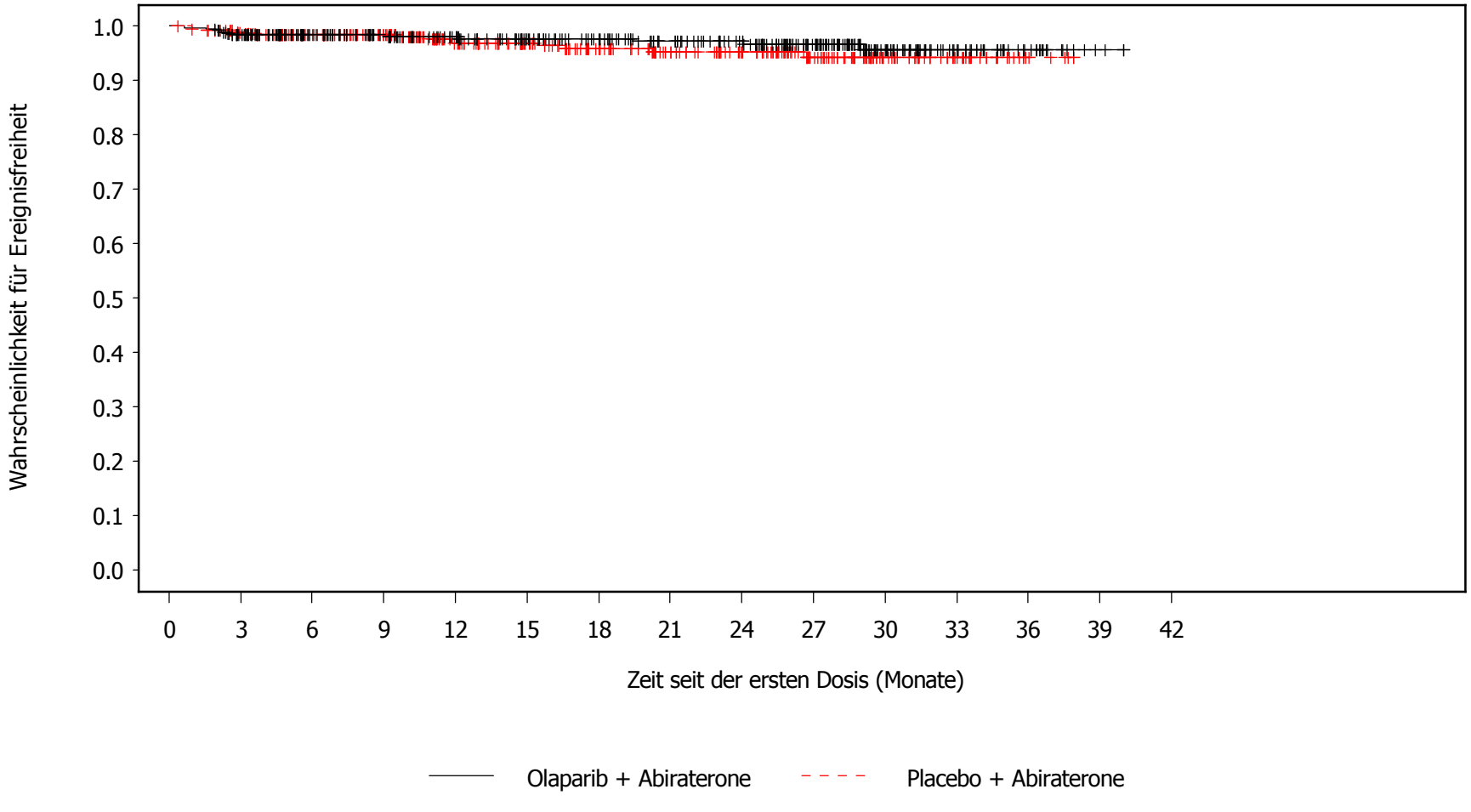


Anzahl an Patienten unter Risiko:

398	360	304	267	224	190	172	154	132	108	56	31	12	2	0	Olaparib + Abiraterone
396	358	308	263	207	171	143	121	100	68	40	20	1	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebaq 06JUN2022:19:52 kvbv306

Figure 3.3.18 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Ausschlag
Safety Analysis Set, DCO 14MAR2022

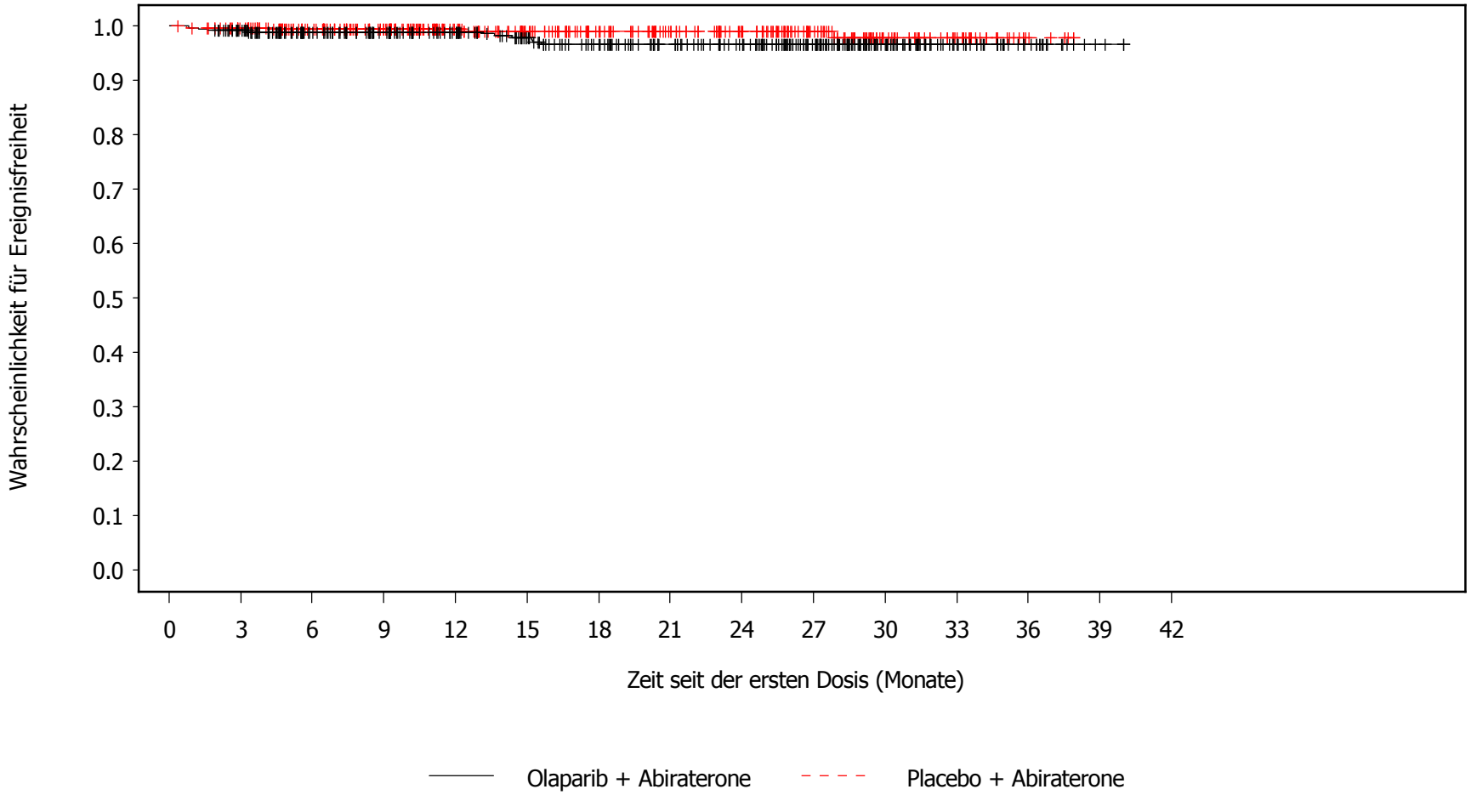


Anzahl an Patienten unter Risiko:

398	378	333	303	271	240	219	195	175	131	72	39	17	2	0	Olaparib + Abiraterone
396	376	336	297	244	208	175	150	126	90	51	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebar 06JUN2022:19:52 kvbv306

Figure 3.3.19 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Ausschlag makulo-papuloes
Safety Analysis Set, DCO 14MAR2022

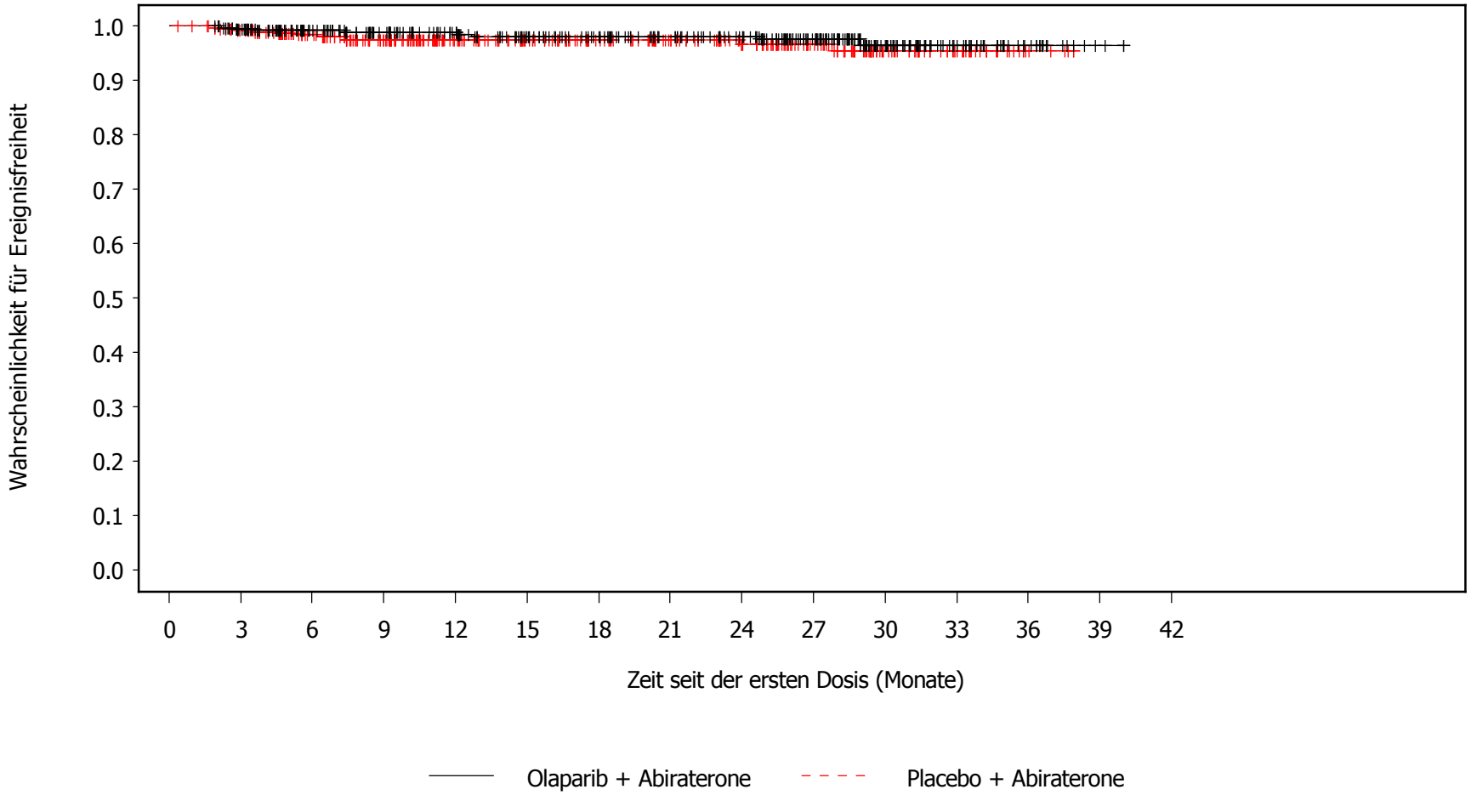


Anzahl an Patienten unter Risiko:

398	381	336	306	274	243	220	195	175	131	75	39	17	2	0	Olaparib + Abiraterone
396	380	340	301	250	213	180	154	128	94	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebas 06JUN2022:19:52 kvbv306

Figure 3.3.20 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Pruritus
Safety Analysis Set, DCO 14MAR2022



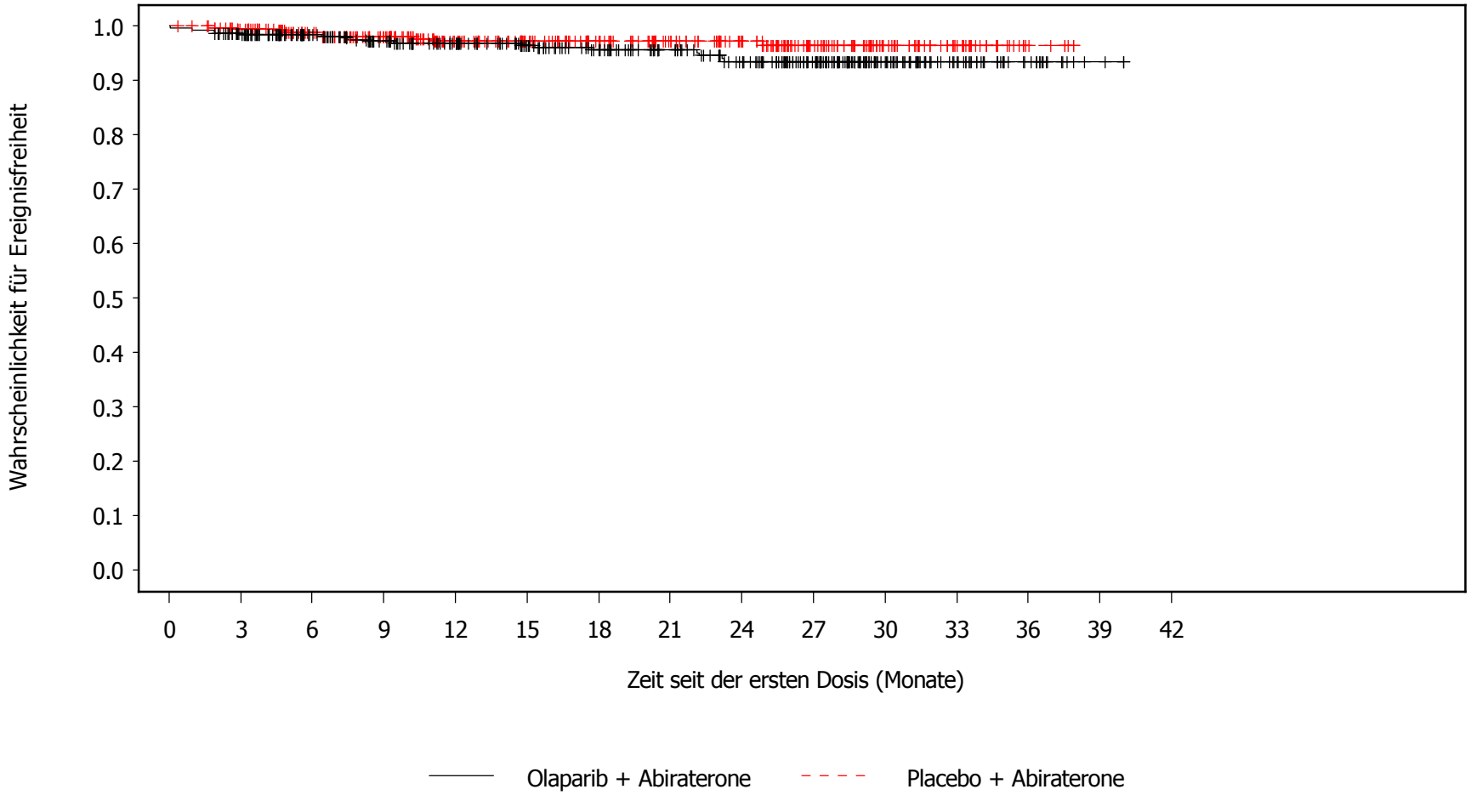
Anzahl an Patienten unter Risiko:

398	382	337	305	273	242	222	198	178	135	75	39	16	2	0	Olaparib + Abiraterone
396	378	336	295	244	208	176	152	125	92	52	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebat 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.21 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Trockene Haut
Safety Analysis Set, DCO 14MAR2022

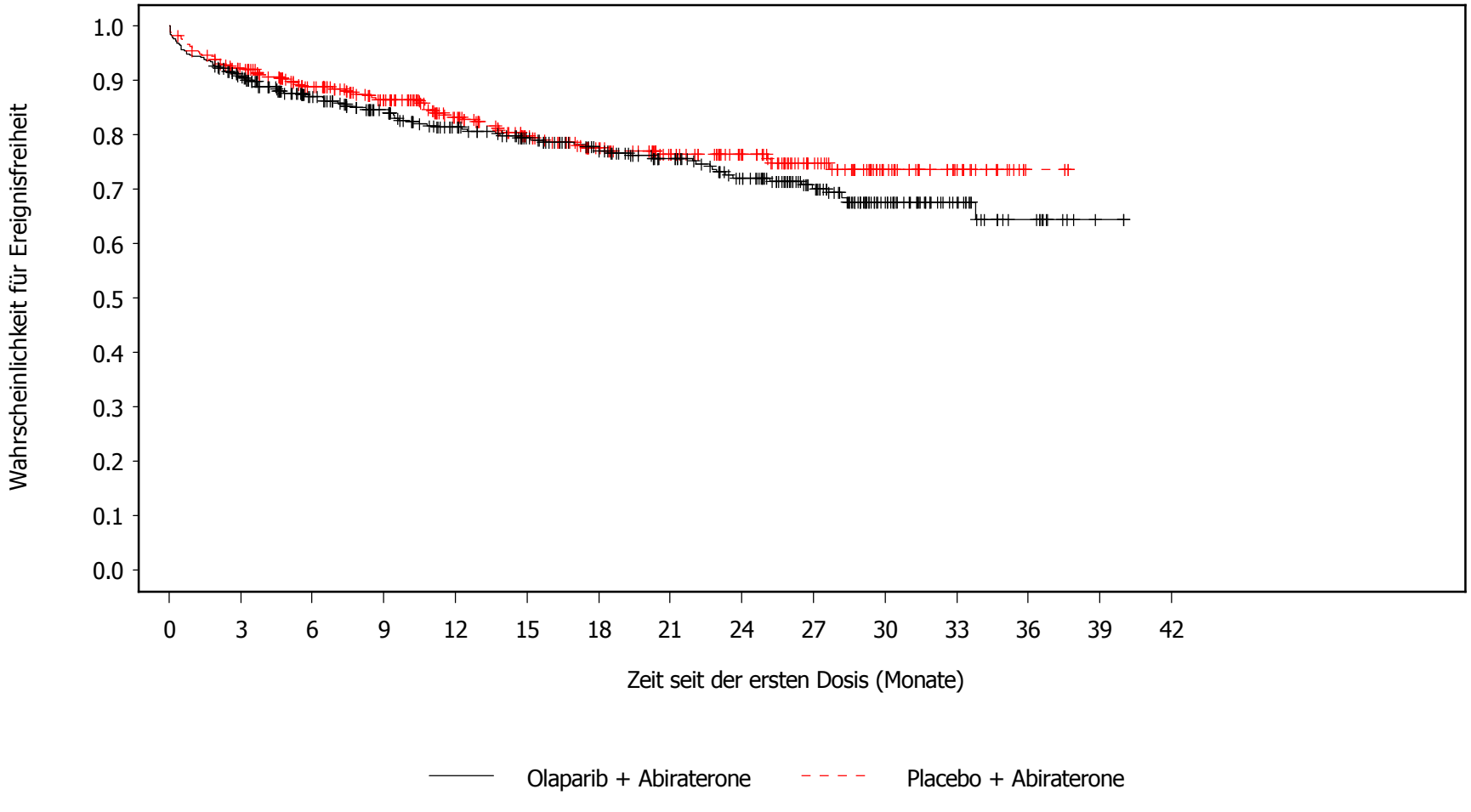


Anzahl an Patienten unter Risiko:

398	379	333	299	267	236	213	189	166	128	71	39	16	2	0	Olaparib + Abiraterone
396	378	337	295	244	208	177	152	126	91	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebau 06JUN2022:19:52 kvbv306

Figure 3.3.22 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 14MAR2022



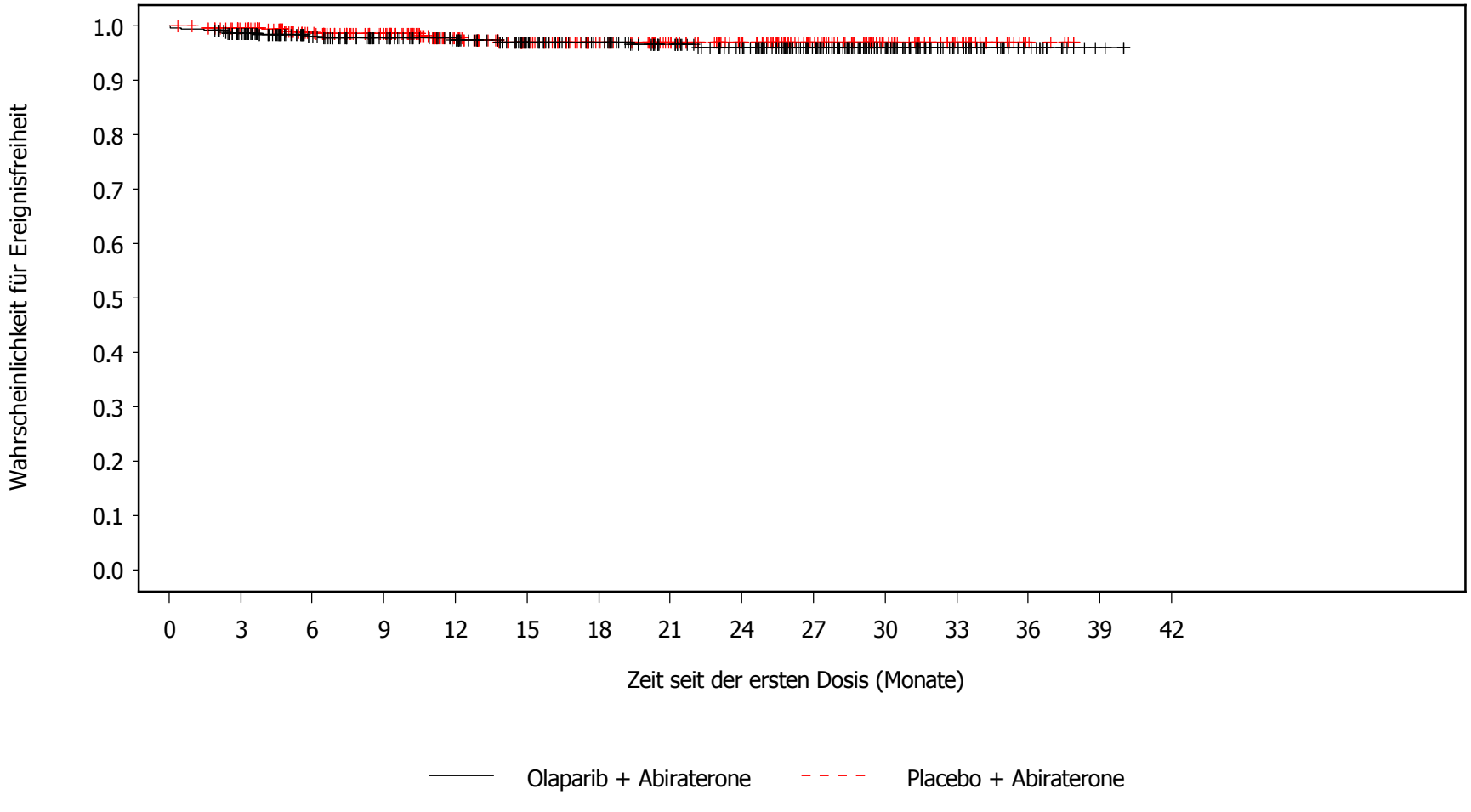
Anzahl an Patienten unter Risiko:

398	351	298	264	228	203	183	158	134	99	56	29	12	1	0	Olaparib + Abiraterone
396	352	305	263	216	177	148	125	102	72	41	22	3	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebav 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.23 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Akute Nierenschaedigung
Safety Analysis Set, DCO 14MAR2022



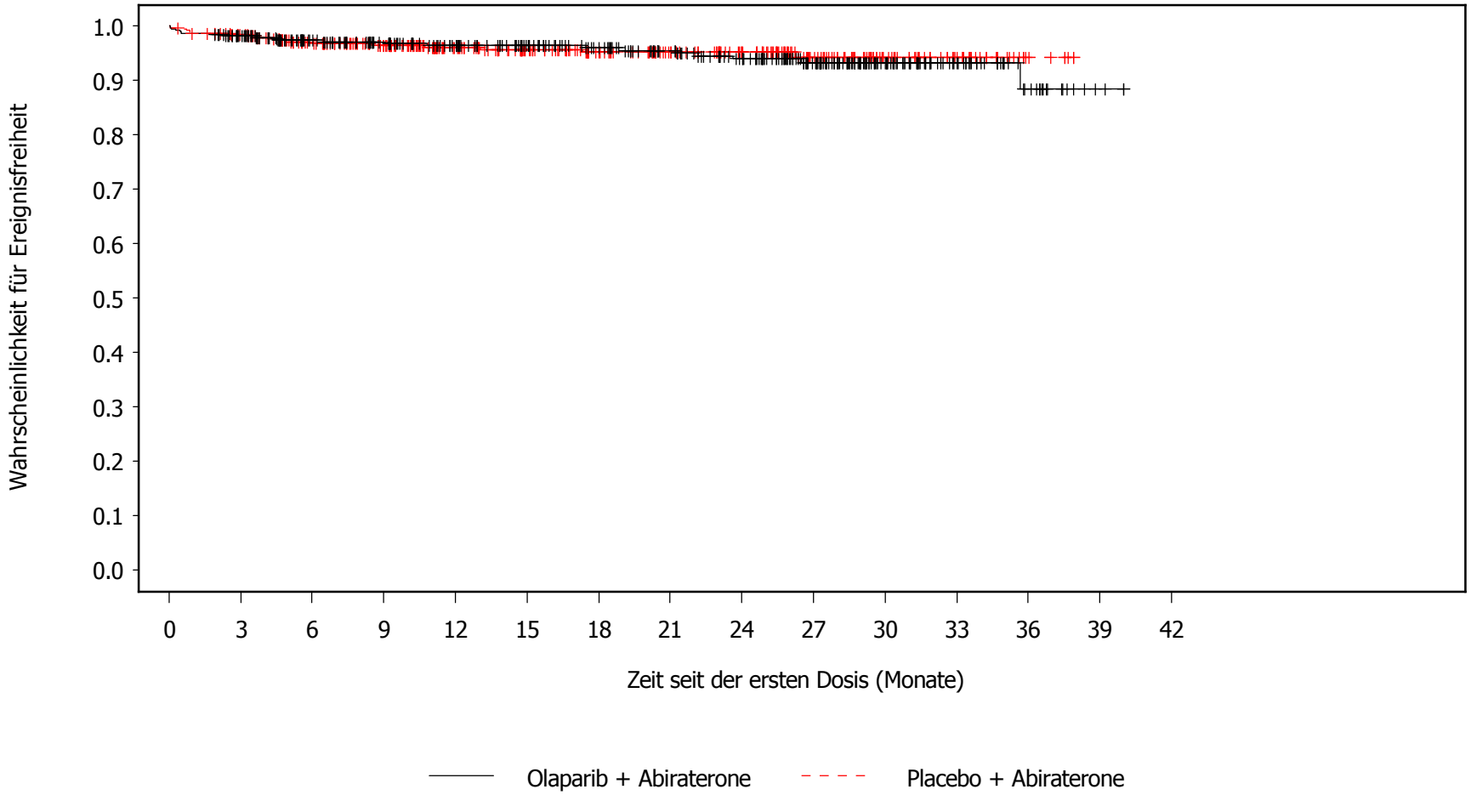
Anzahl an Patienten unter Risiko:

398	379	334	303	272	242	222	198	178	134	77	41	17	2	0	Olaparib + Abiraterone
396	379	338	299	249	212	179	153	127	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebaw 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.24 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Dysurie
Safety Analysis Set, DCO 14MAR2022

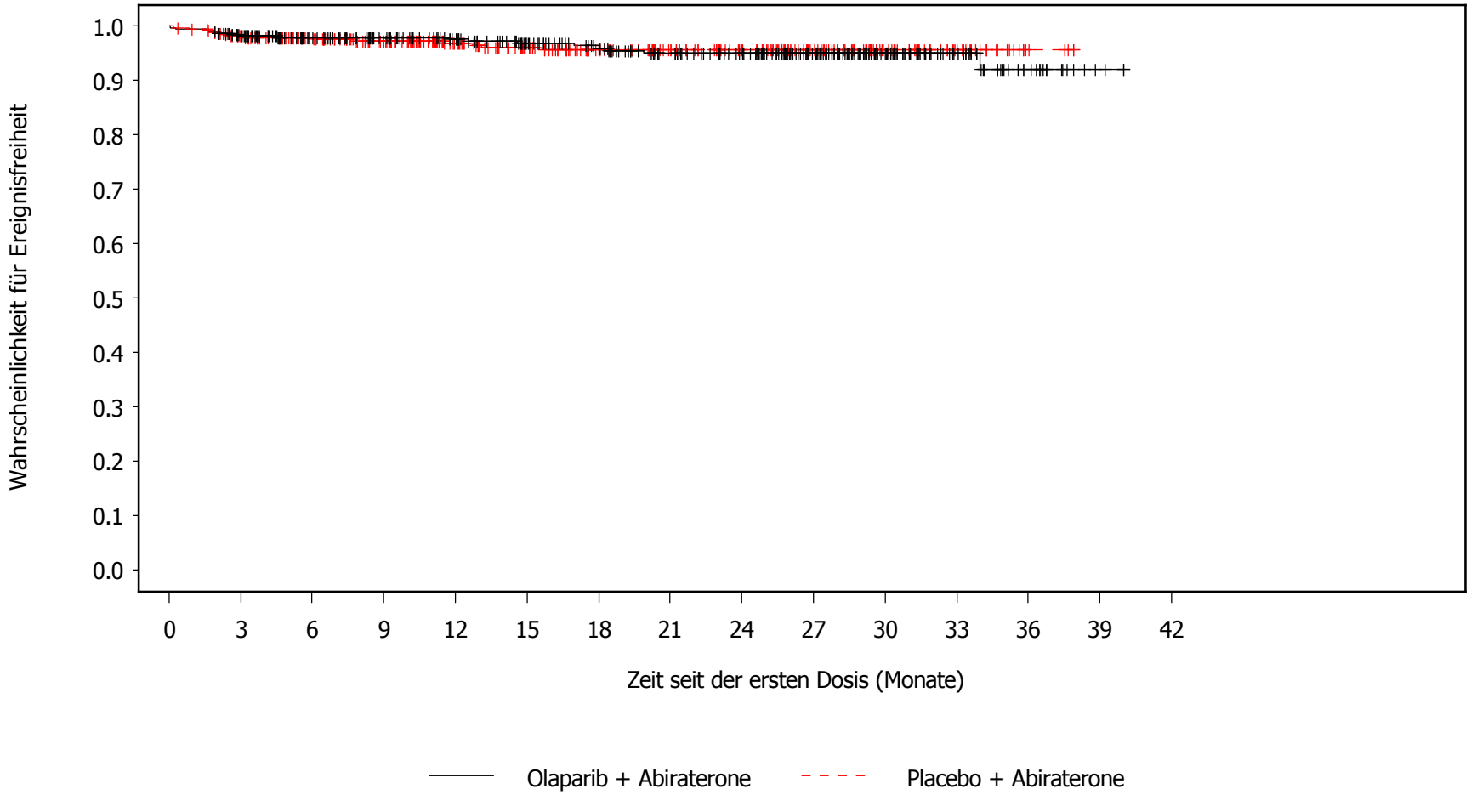


Anzahl an Patienten unter Risiko:

398	377	331	300	268	240	218	193	170	128	74	40	16	2	0	Olaparib + Abiraterone
396	375	332	292	243	206	174	150	125	89	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebax 06JUN2022:19:52 kvbv306

Figure 3.3.25 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Haematurie
Safety Analysis Set, DCO 14MAR2022

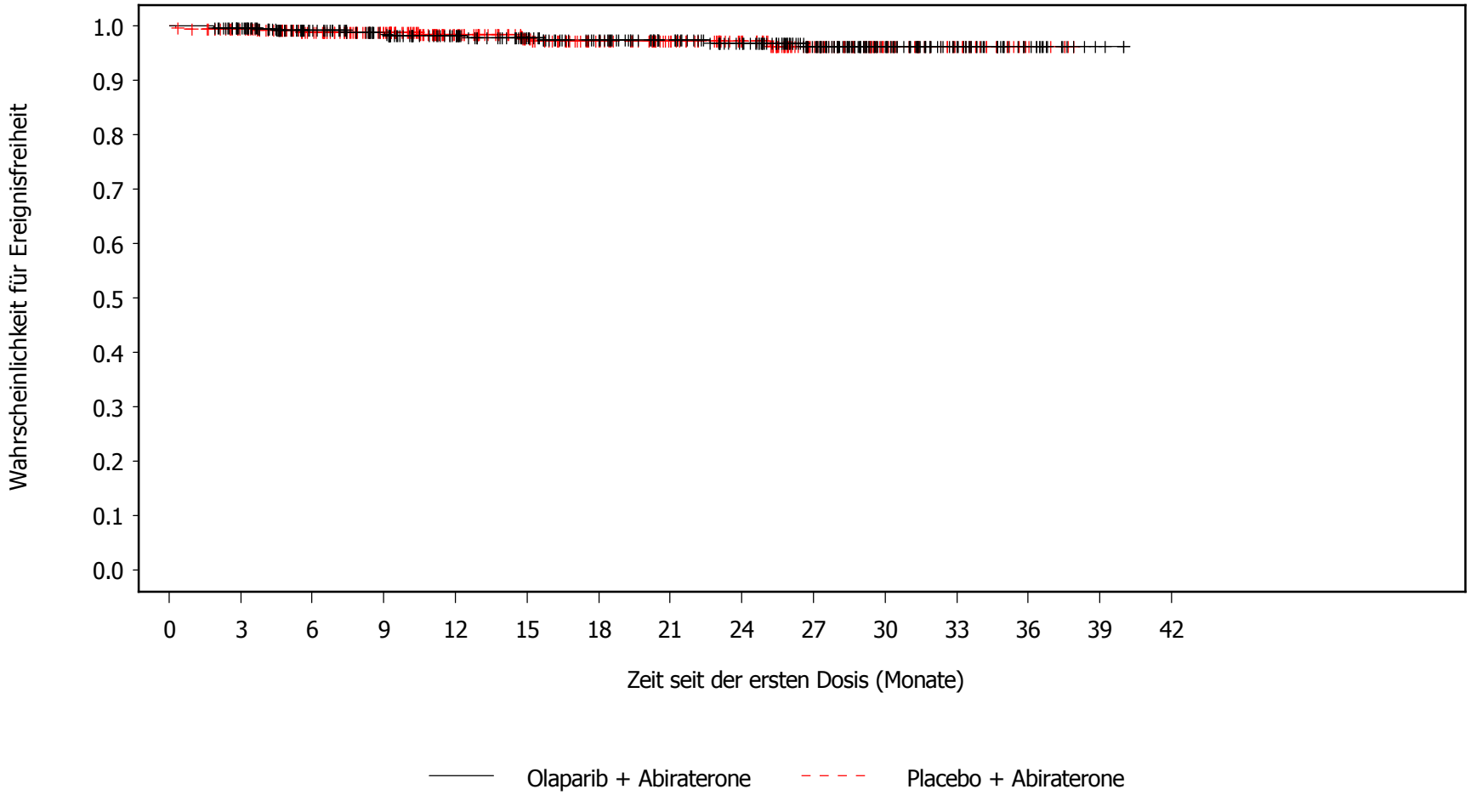


Anzahl an Patienten unter Risiko:

398	378	333	302	270	241	222	194	176	133	76	41	17	2	0	Olaparib + Abiraterone
396	373	334	294	245	208	174	149	123	90	52	28	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebay 06JUN2022:19:52 kvbv306

Figure 3.3.26 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Harninkontinenz
Safety Analysis Set, DCO 14MAR2022



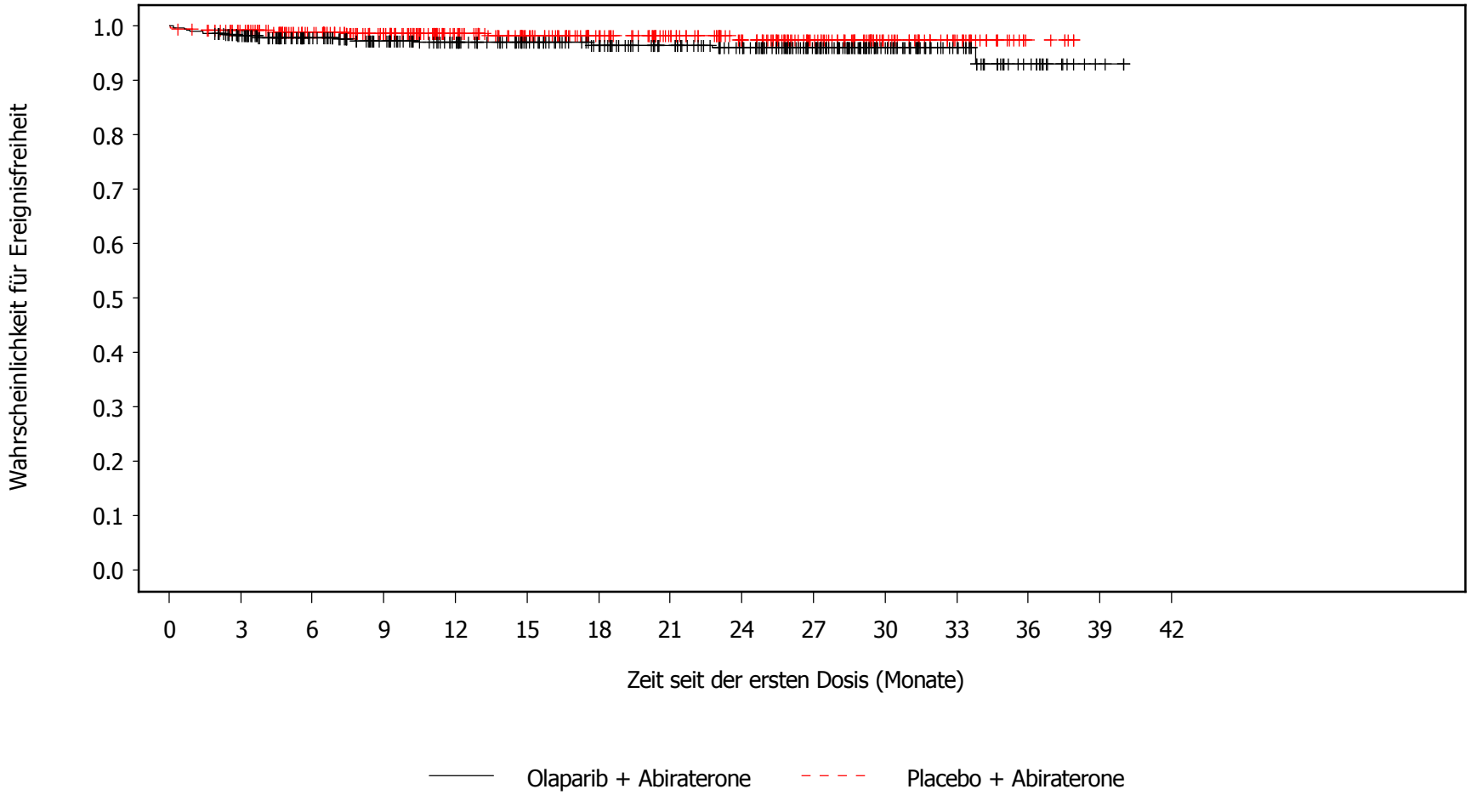
Anzahl an Patienten unter Risiko:

398	383	336	306	272	242	221	196	175	131	75	41	17	2	0	Olaparib + Abiraterone
396	378	338	298	248	210	177	152	126	90	52	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebaz 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.27 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Nykturie
Safety Analysis Set, DCO 14MAR2022

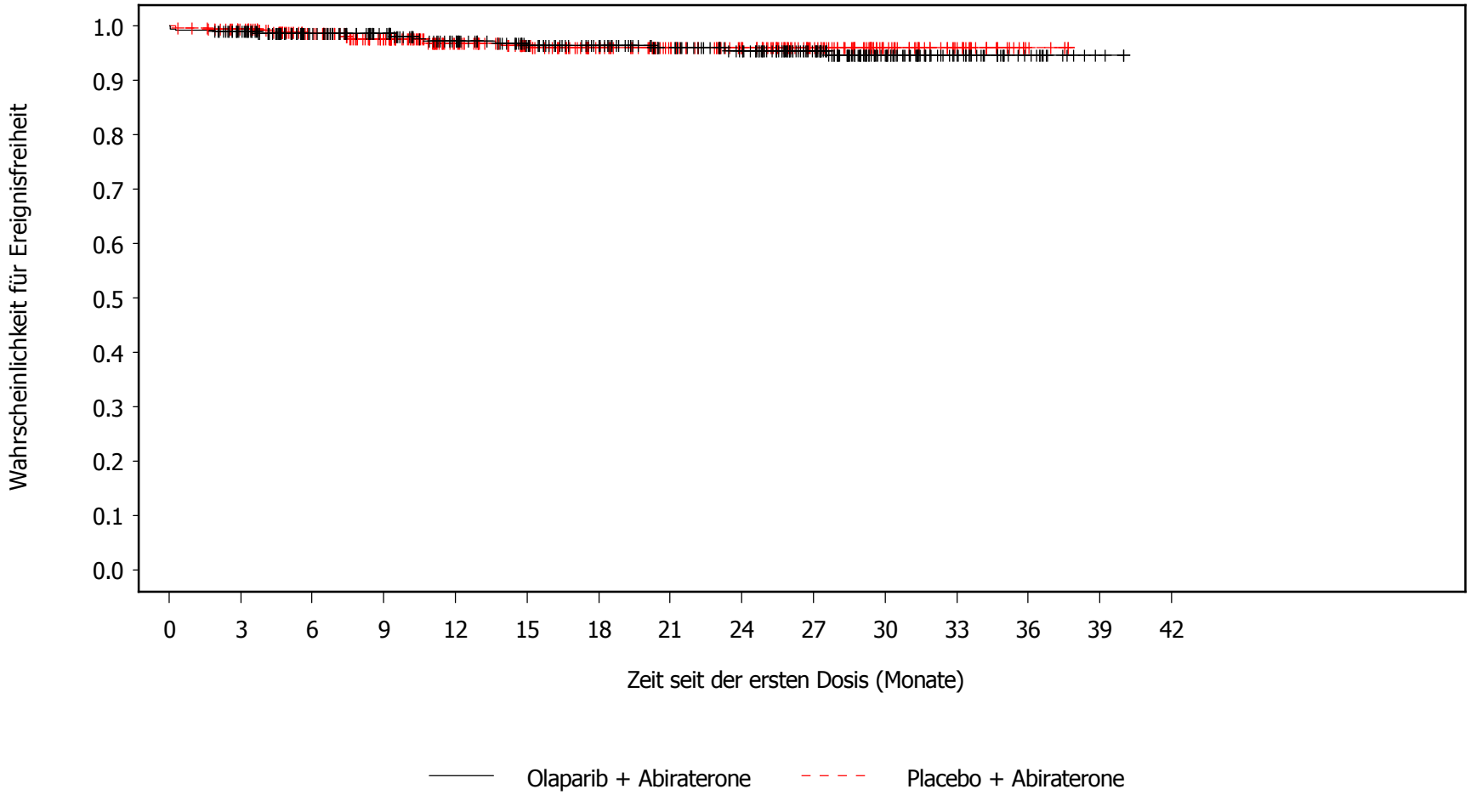


Anzahl an Patienten unter Risiko:

398	378	332	299	266	237	216	193	172	130	73	40	17	2	0	Olaparib + Abiraterone
396	377	337	296	248	211	178	153	126	91	53	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebba 06JUN2022:19:52 kvbv306

Figure 3.3.28 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Pollakisurie
Safety Analysis Set, DCO 14MAR2022

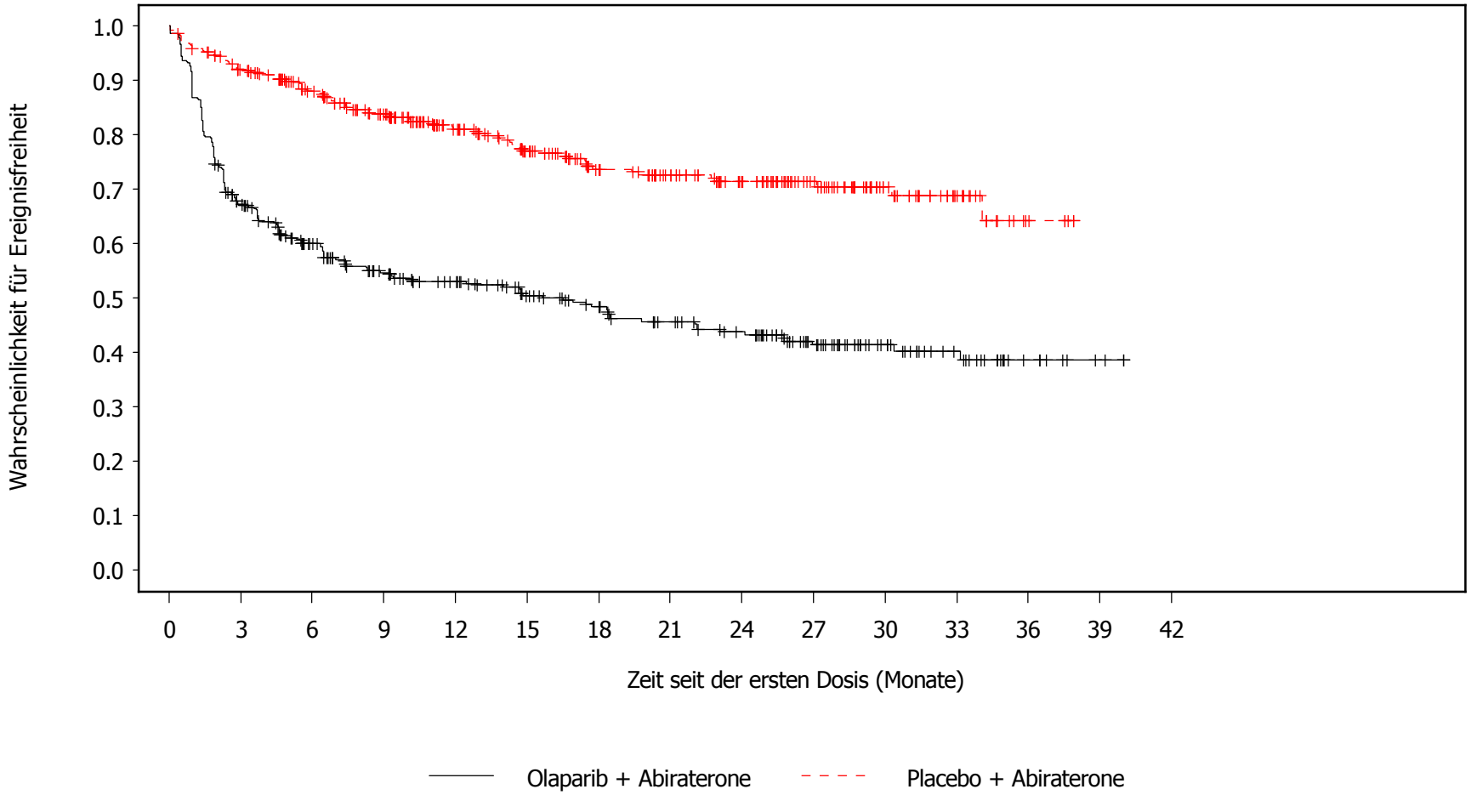


Anzahl an Patienten unter Risiko:

398	380	334	303	268	237	217	192	171	129	72	37	15	2	0	Olaparib + Abiraterone
396	378	336	295	244	208	177	151	125	90	51	28	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbb 06JUN2022:19:52 kvbv306

Figure 3.3.29 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

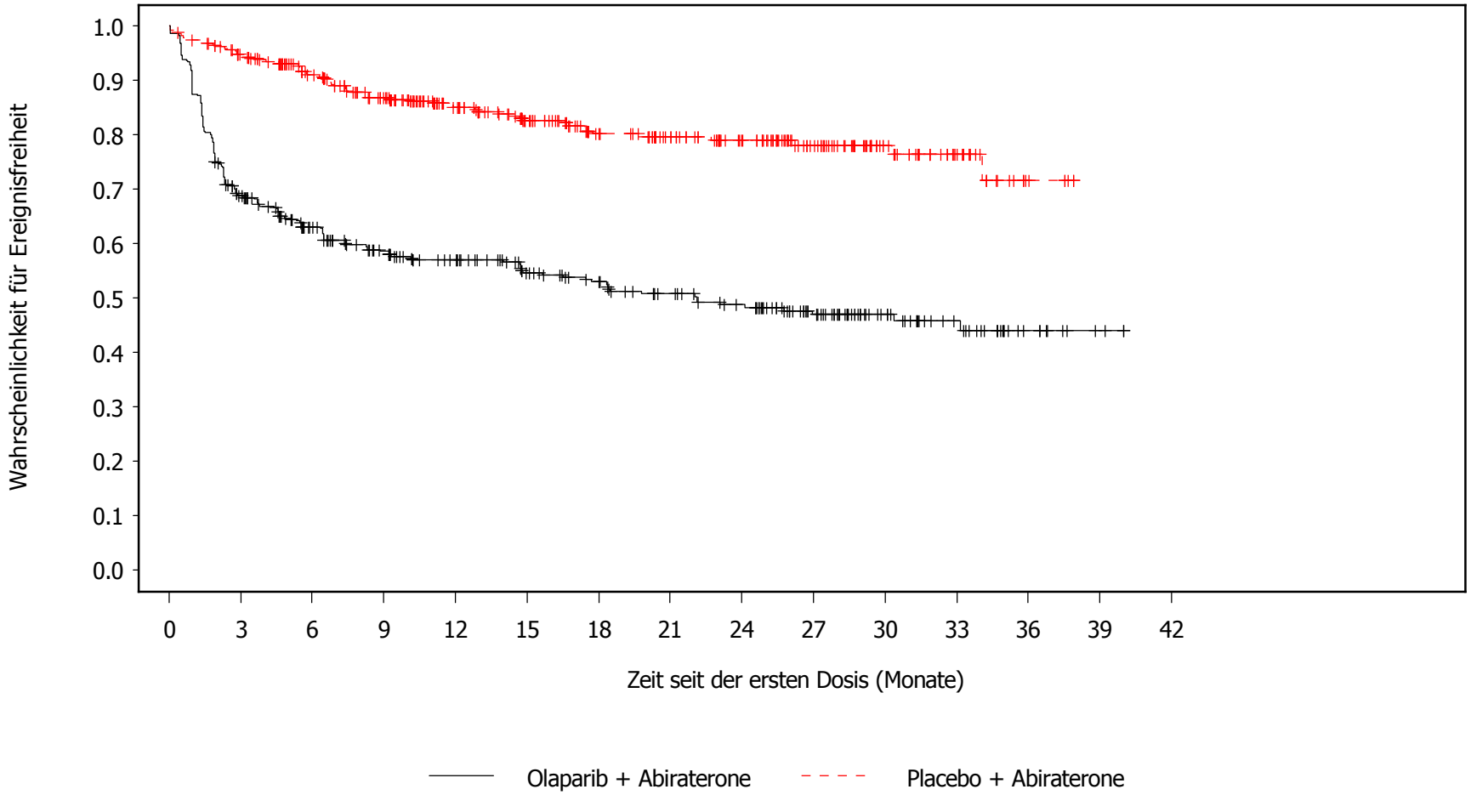


Anzahl an Patienten unter Risiko:

398	260	210	175	152	128	114	99	87	61	38	24	8	2	0	Olaparib + Abiraterone
396	352	308	267	217	179	145	126	101	75	44	23	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbc 06JUN2022:19:52 kvbv306

Figure 3.3.30 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Anaemie
Safety Analysis Set, DCO 14MAR2022



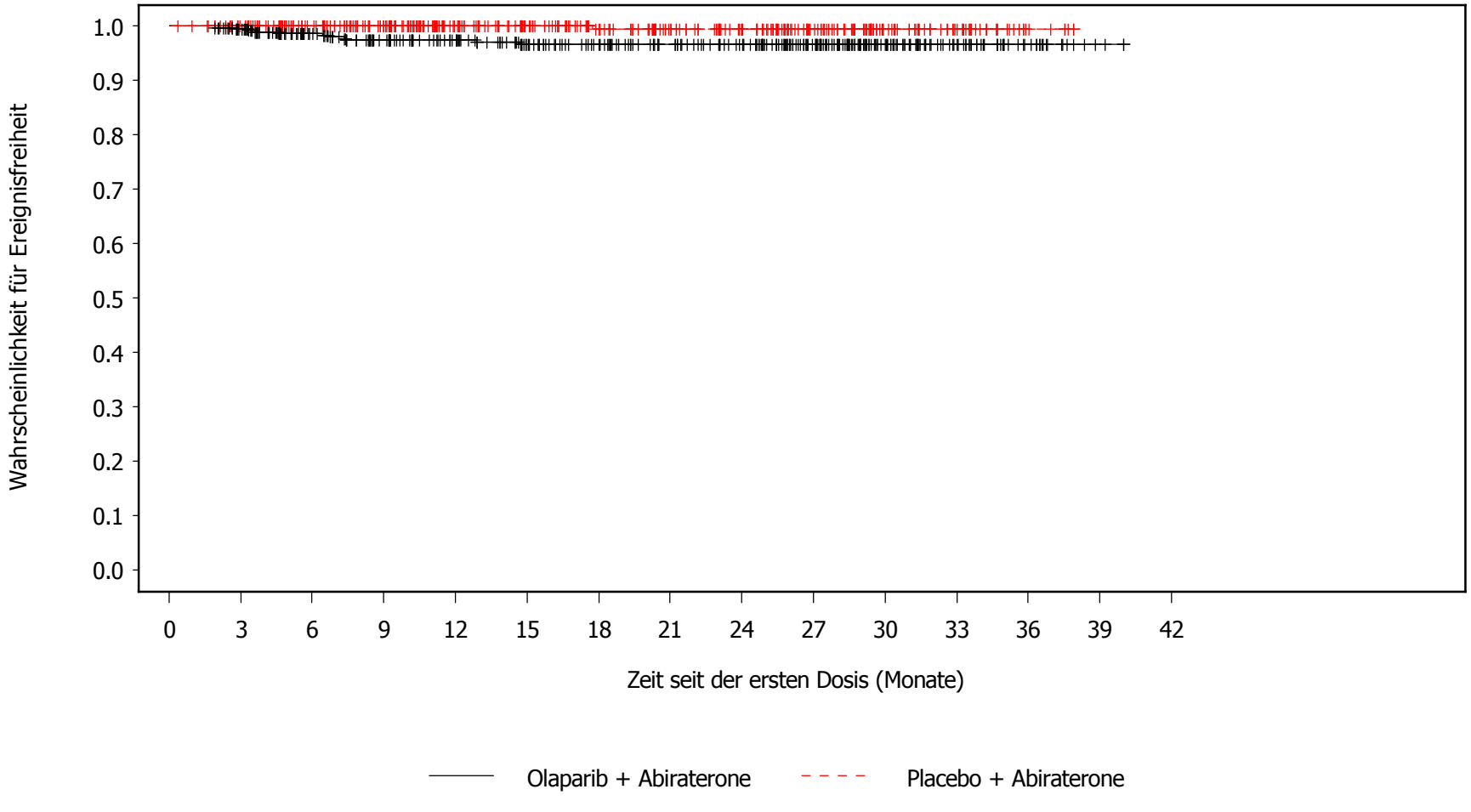
Anzahl an Patienten unter Risiko:

398	265	219	186	162	137	124	108	96	69	41	26	9	2	0	Olaparib + Abiraterone
396	362	318	276	226	188	153	134	110	80	47	25	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbd 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.31 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Leukopenie
Safety Analysis Set, DCO 14MAR2022

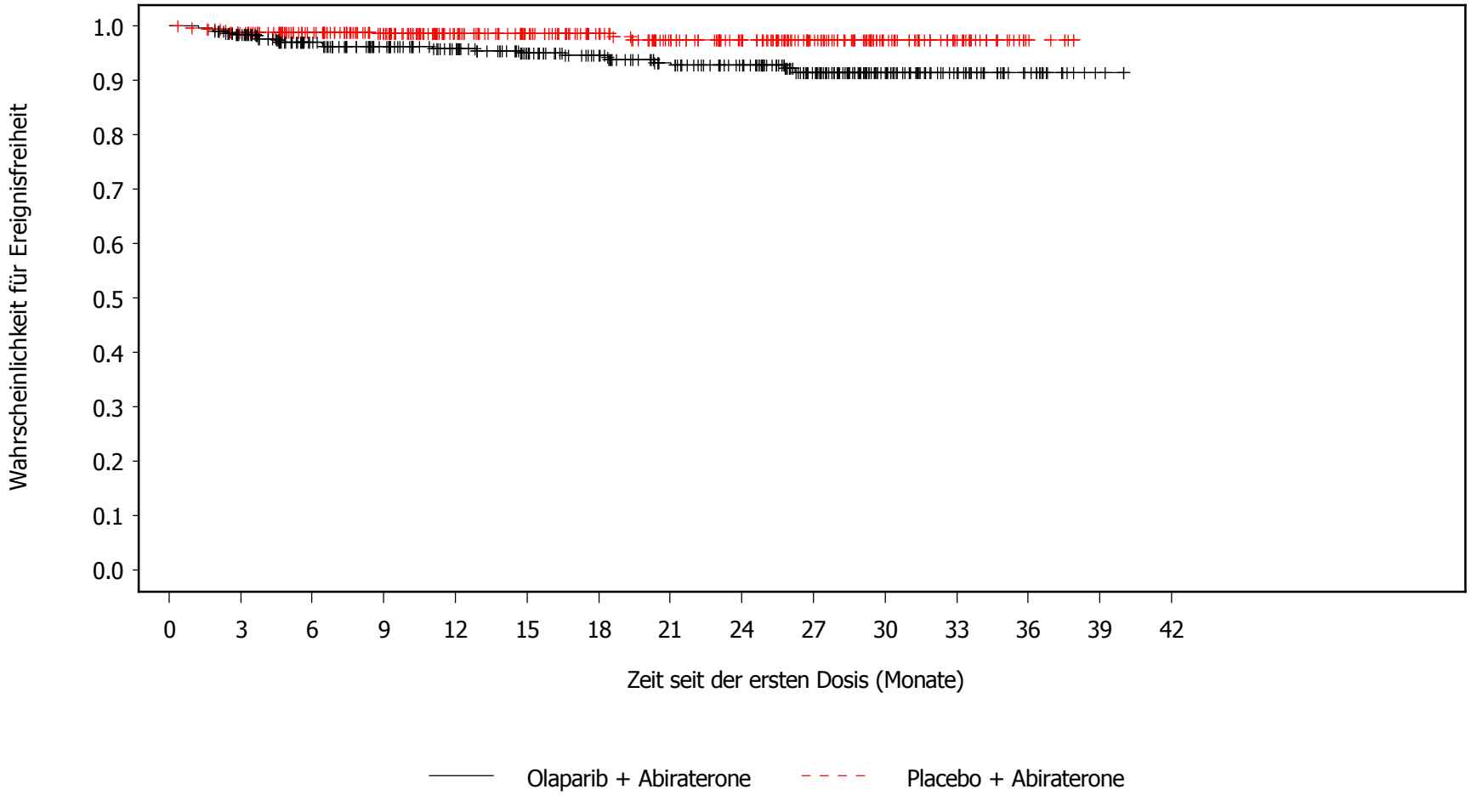


Anzahl an Patienten unter Risiko:

398	382	334	300	270	240	219	195	176	133	76	41	17	2	0	Olaparib + Abiraterone
396	380	341	301	250	214	180	155	129	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbe 06JUN2022:19:52 kvbv306

Figure 3.3.32 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Lymphopenie
Safety Analysis Set, DCO 14MAR2022

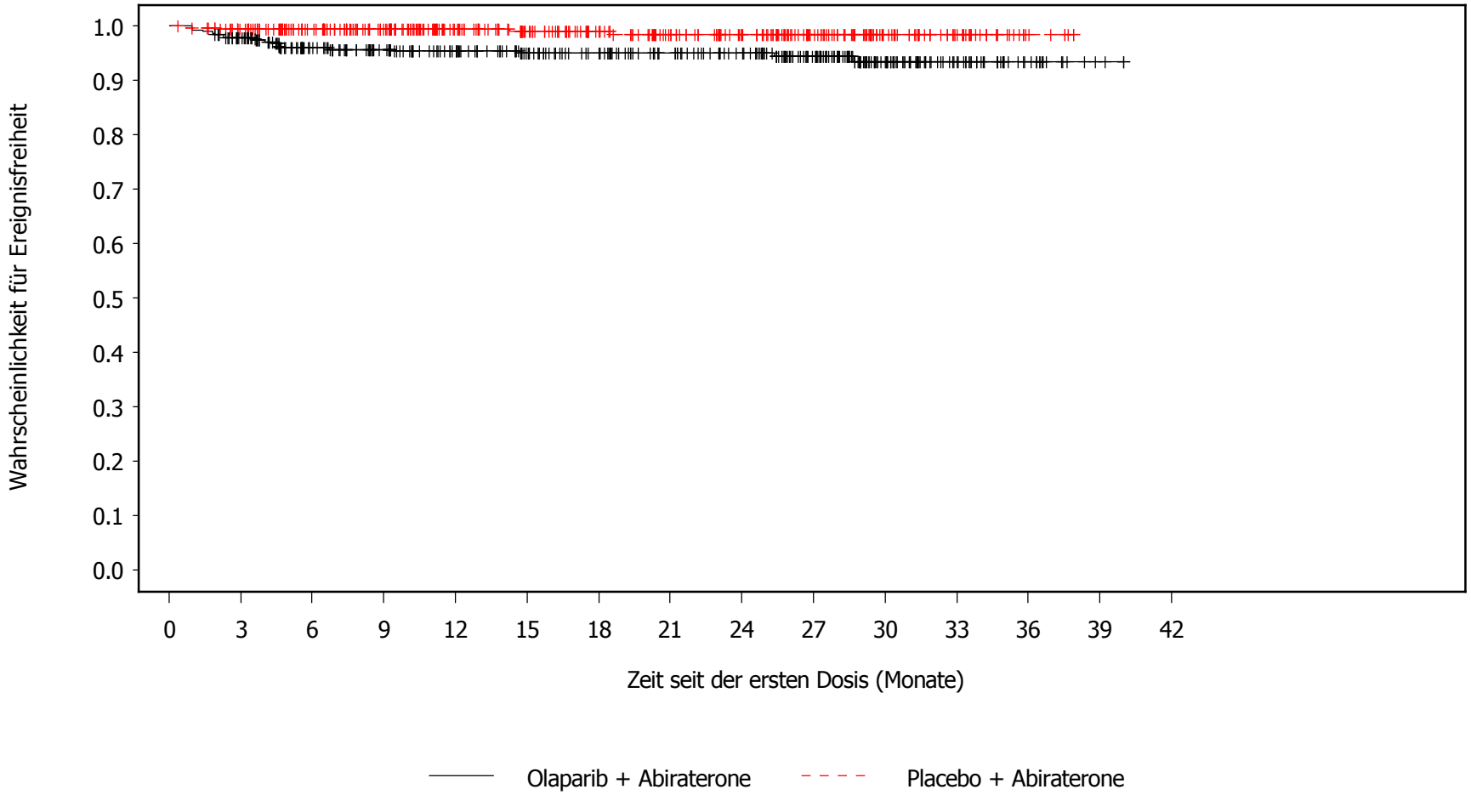


Anzahl an Patienten unter Risiko:

398	378	330	297	265	236	215	190	170	125	69	40	17	2	0	Olaparib + Abiraterone
396	376	339	299	249	214	181	154	128	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbf 06JUN2022:19:52 kvbv306

Figure 3.3.33 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Neutropenie
Safety Analysis Set, DCO 14MAR2022

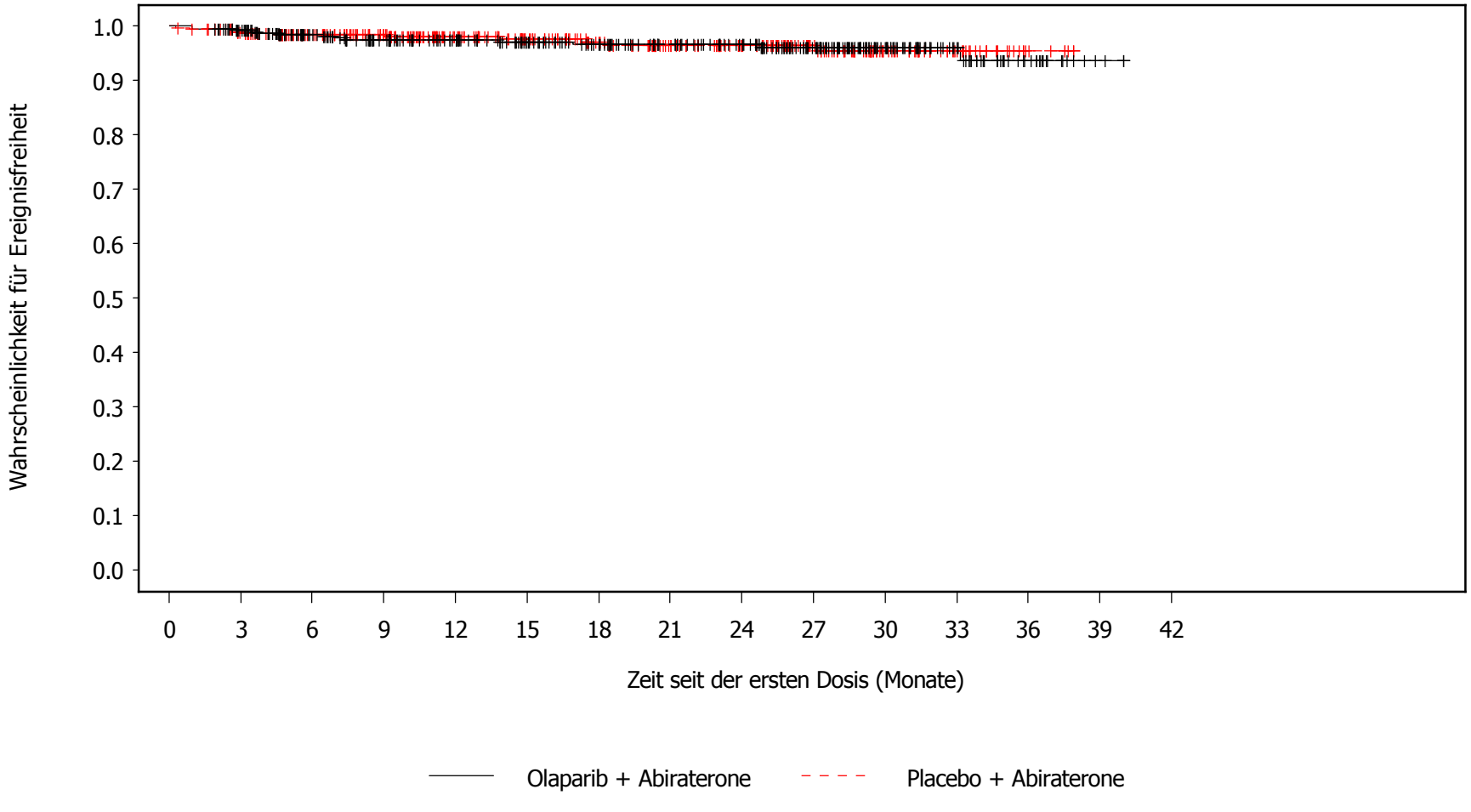


Anzahl an Patienten unter Risiko:

398	377	326	294	263	235	216	192	173	131	74	39	15	2	0	Olaparib + Abiraterone
396	378	339	300	249	213	181	155	129	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbg 06JUN2022:19:52 kvbv306

Figure 3.3.34 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Thrombozytopenie
Safety Analysis Set, DCO 14MAR2022

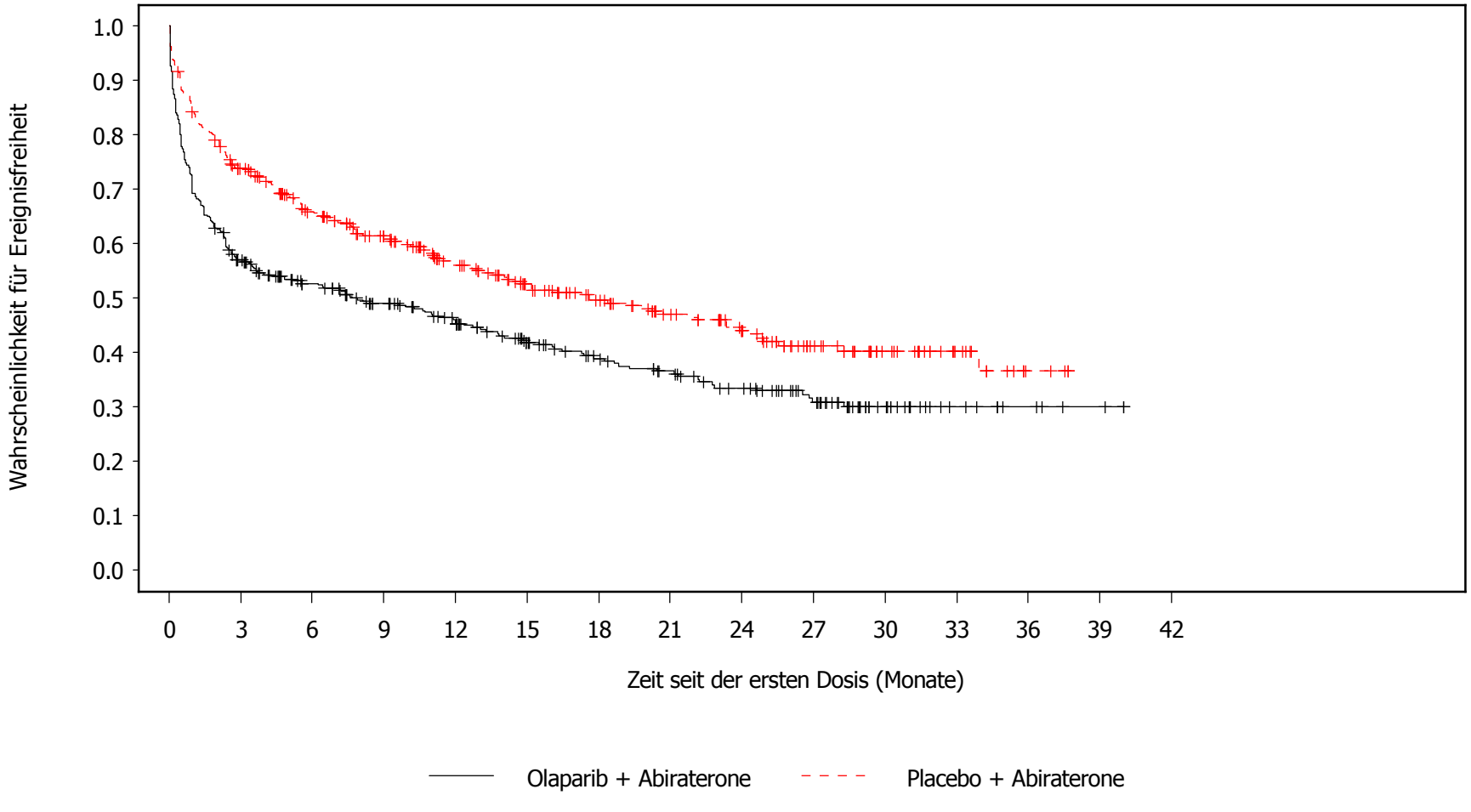


Anzahl an Patienten unter Risiko:

398	381	333	301	269	239	217	194	174	132	77	41	17	2	0	Olaparib + Abiraterone
396	376	337	297	245	209	177	152	126	91	52	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbh 06JUN2022:19:52 kvbv306

Figure 3.3.35 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 14MAR2022

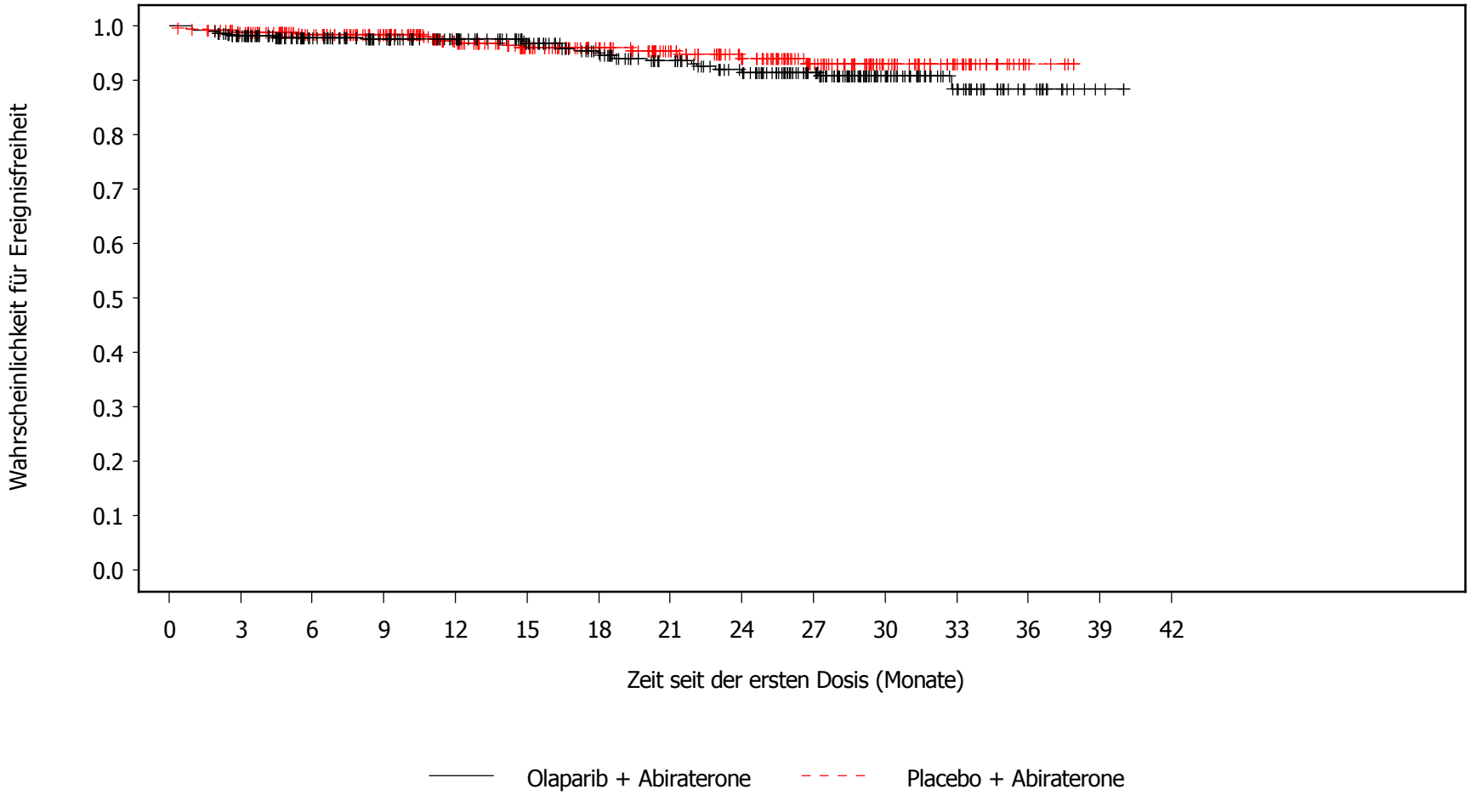


Anzahl an Patienten unter Risiko:

398	220	182	155	131	103	86	75	62	45	23	10	5	2	0	Olaparib + Abiraterone
396	282	231	196	158	127	105	86	67	46	29	15	3	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbi 06JUN2022:19:52 kvbv306

Figure 3.3.36 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Abdominalschmerz
Safety Analysis Set, DCO 14MAR2022

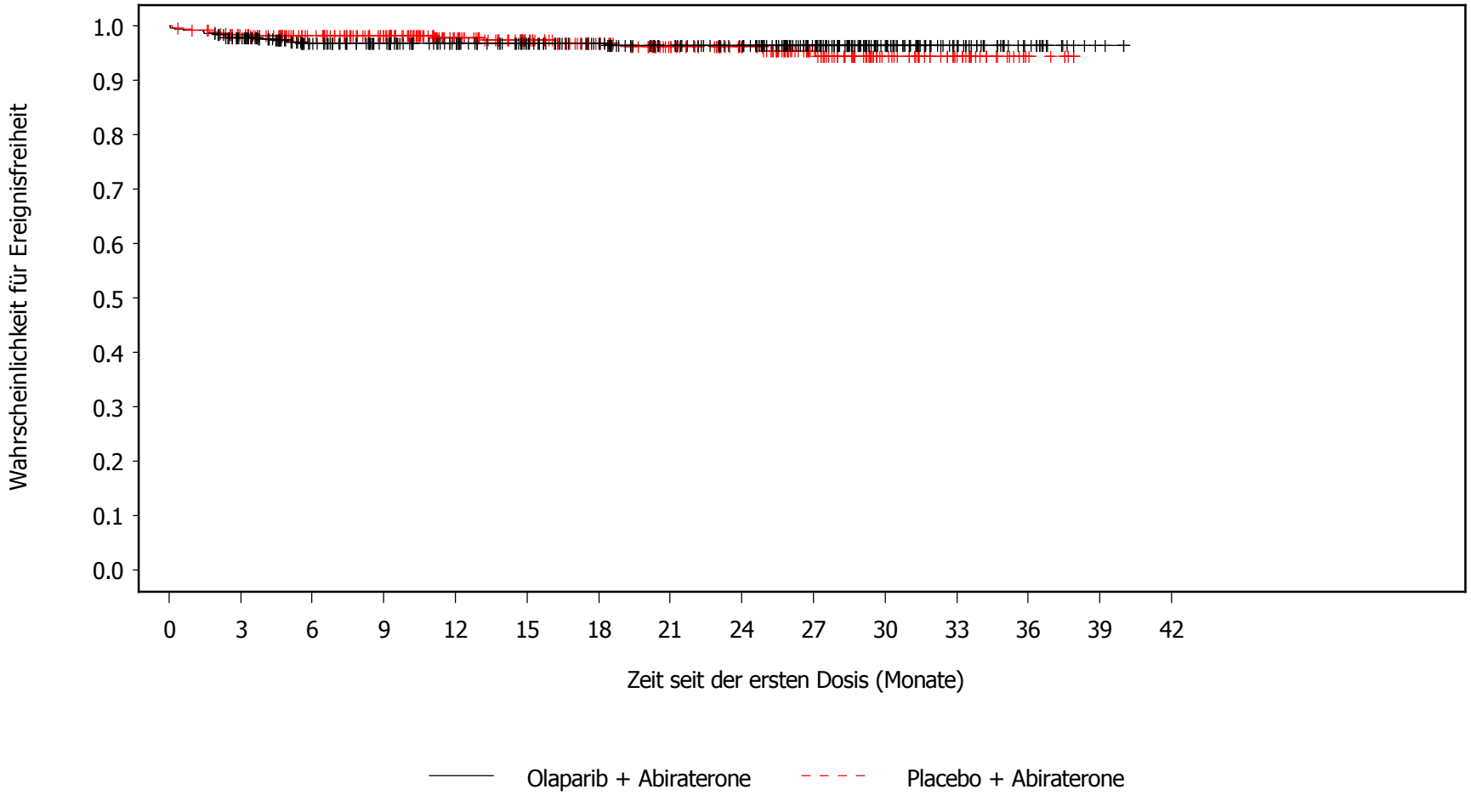


Anzahl an Patienten unter Risiko:

398	377	331	300	270	238	213	187	164	126	69	38	15	2	0	Olaparib + Abiraterone
396	376	336	298	247	210	177	151	124	89	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbj 06JUN2022:19:52 kvbv306

Figure 3.3.37 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Bauch aufgetrieben
Safety Analysis Set, DCO 14MAR2022

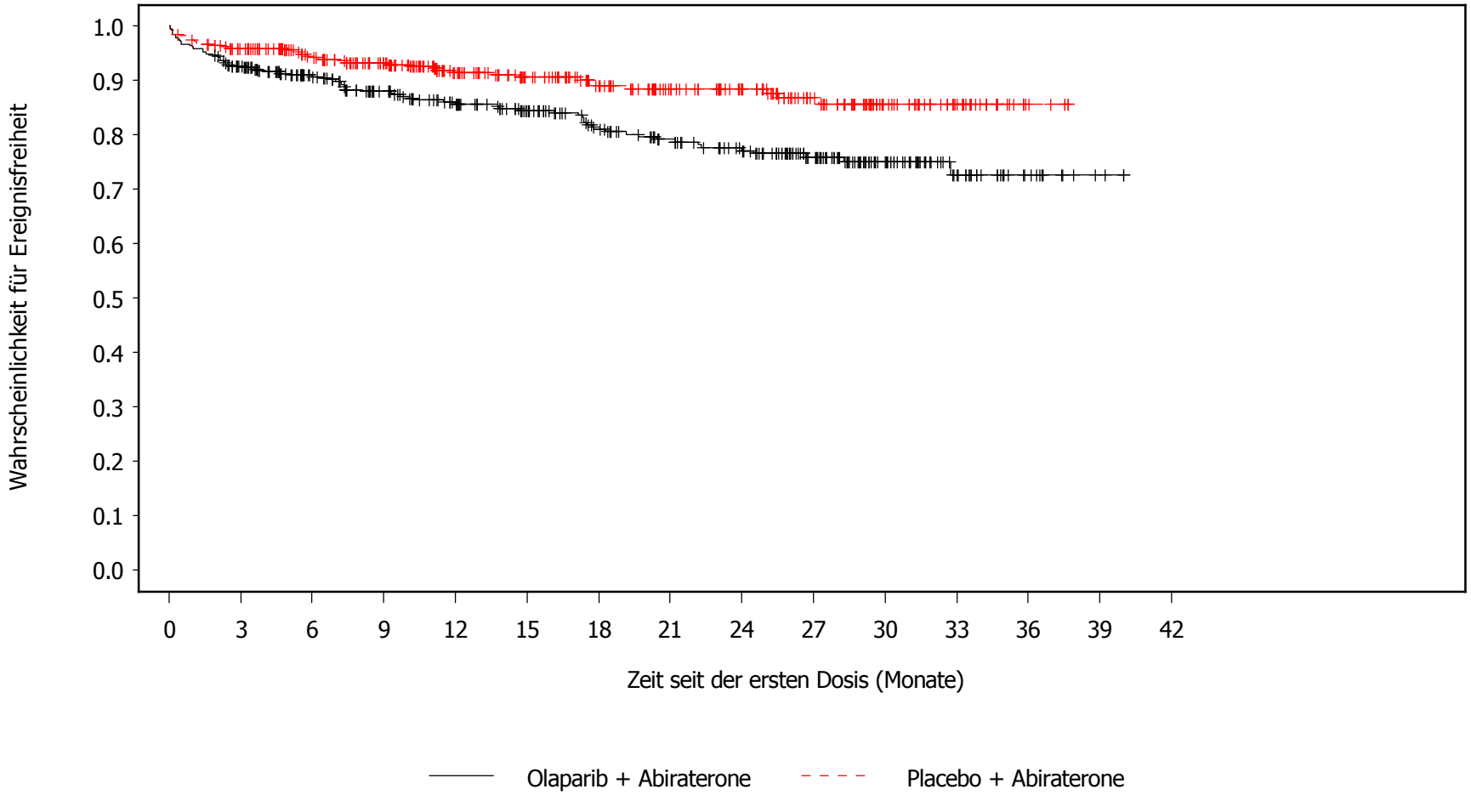


Anzahl an Patienten unter Risiko:

398	376	327	297	267	239	219	195	176	133	76	40	17	2	0	Olaparib + Abiraterone
396	374	334	296	244	207	175	148	122	87	50	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbk 06JUN2022:19:52 kvbv306

Figure 3.3.38 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Diarrhoe
Safety Analysis Set, DCO 14MAR2022

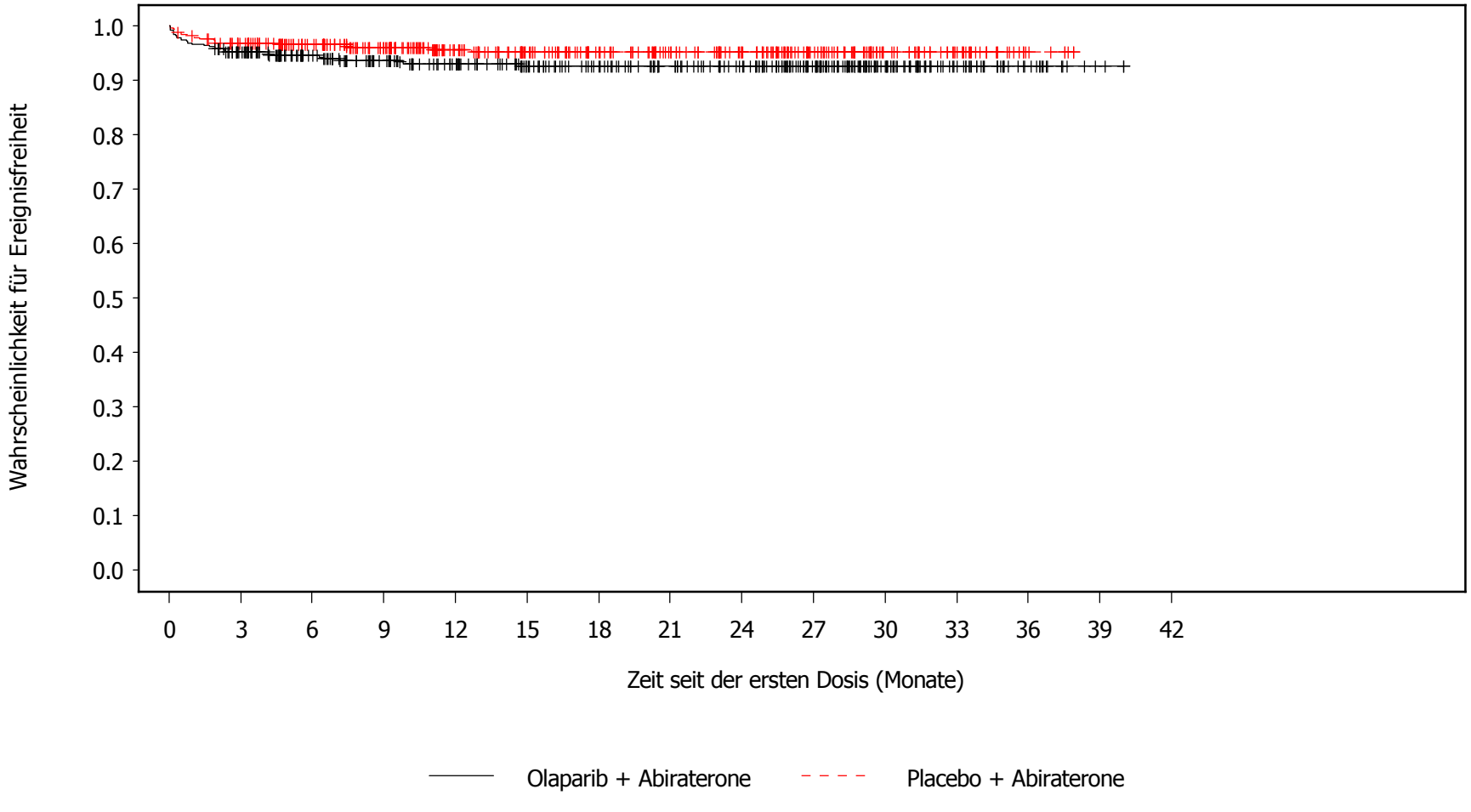


Anzahl an Patienten unter Risiko:

398	357	310	274	241	210	182	162	144	108	62	29	11	2	0	Olaparib + Abiraterone
396	365	321	284	232	198	166	139	116	86	50	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbl 06JUN2022:19:52 kvbv306

Figure 3.3.39 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Dyspepsie
Safety Analysis Set, DCO 14MAR2022

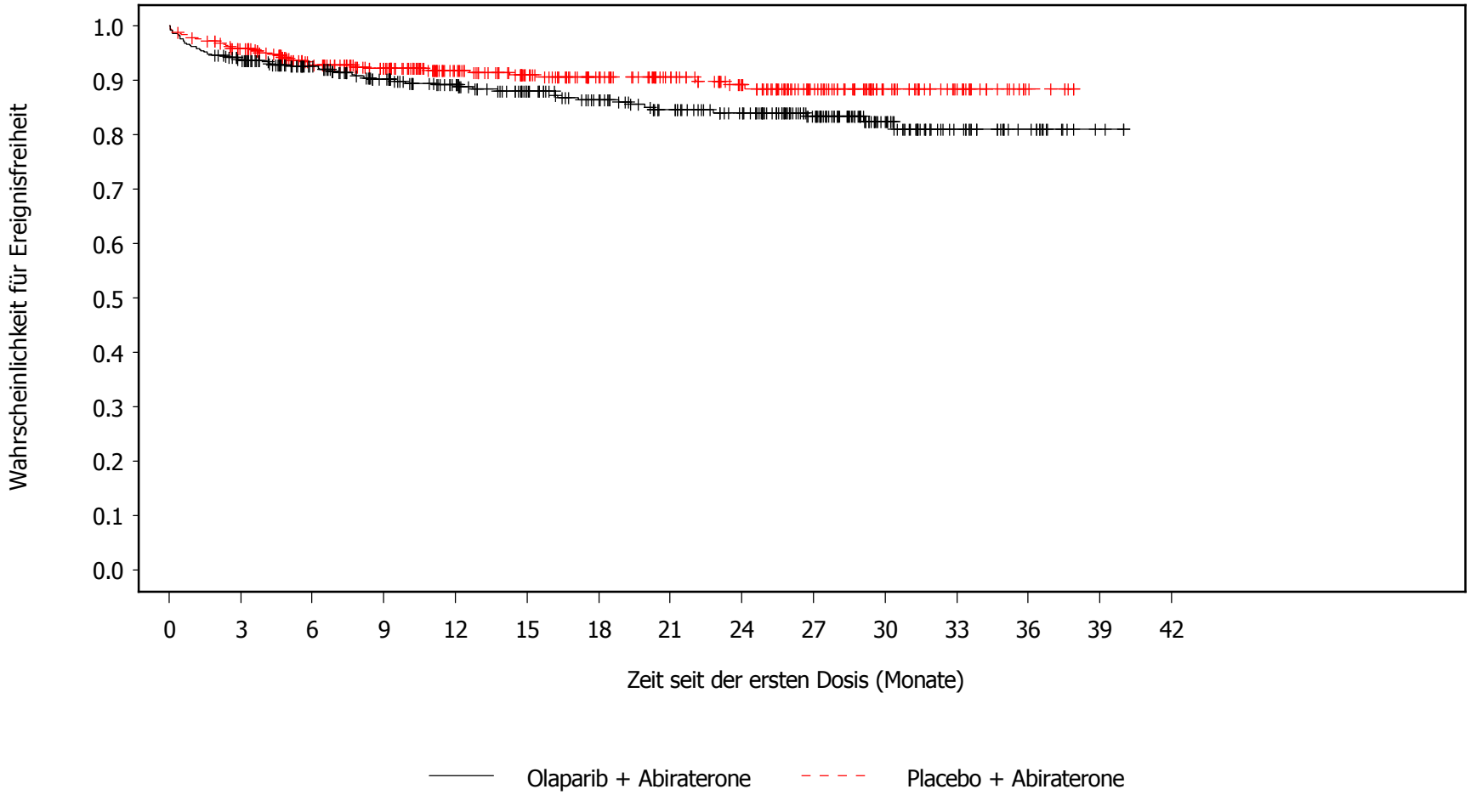


Anzahl an Patienten unter Risiko:

398	365	324	291	259	229	208	186	166	127	73	38	15	2	0	Olaparib + Abiraterone
396	370	330	289	239	204	172	148	123	88	51	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbm 06JUN2022:19:52 kvbv306

Figure 3.3.40 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Erbrechen
Safety Analysis Set, DCO 14MAR2022

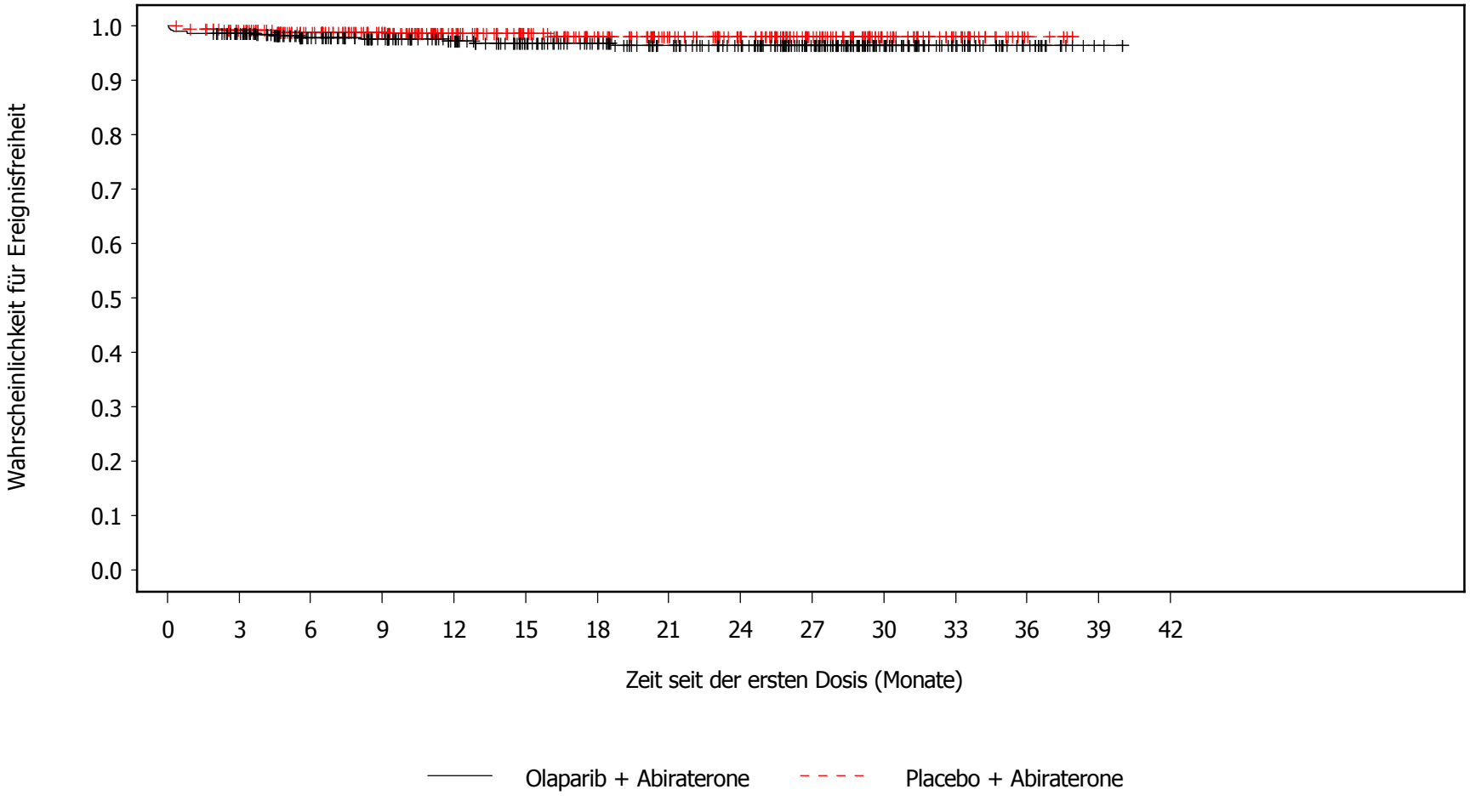


Anzahl an Patienten unter Risiko:

398	364	321	286	255	225	202	180	161	120	64	32	16	2	0	Olaparib + Abiraterone
396	367	321	284	237	201	170	146	120	86	48	27	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbn 06JUN2022:19:52 kvbv306

Figure 3.3.41 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Flatulenz
Safety Analysis Set, DCO 14MAR2022

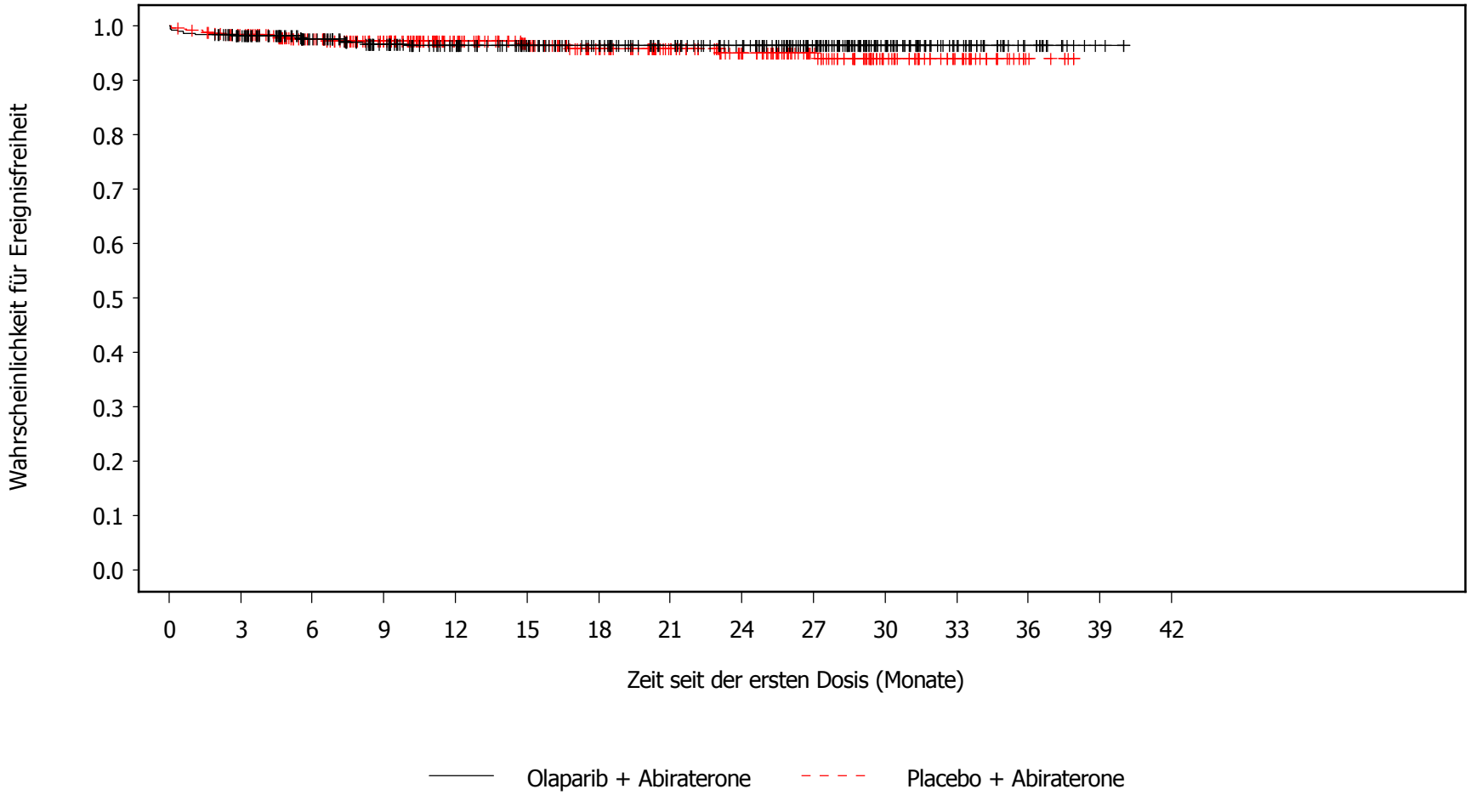


Anzahl an Patienten unter Risiko:

398	379	332	300	269	238	217	192	172	130	74	40	17	2	0	Olaparib + Abiraterone
396	377	337	297	245	210	178	152	126	92	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbo 06JUN2022:19:52 kvbv306

Figure 3.3.42 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Gastrooesophageale Refluxerkrankung
Safety Analysis Set, DCO 14MAR2022

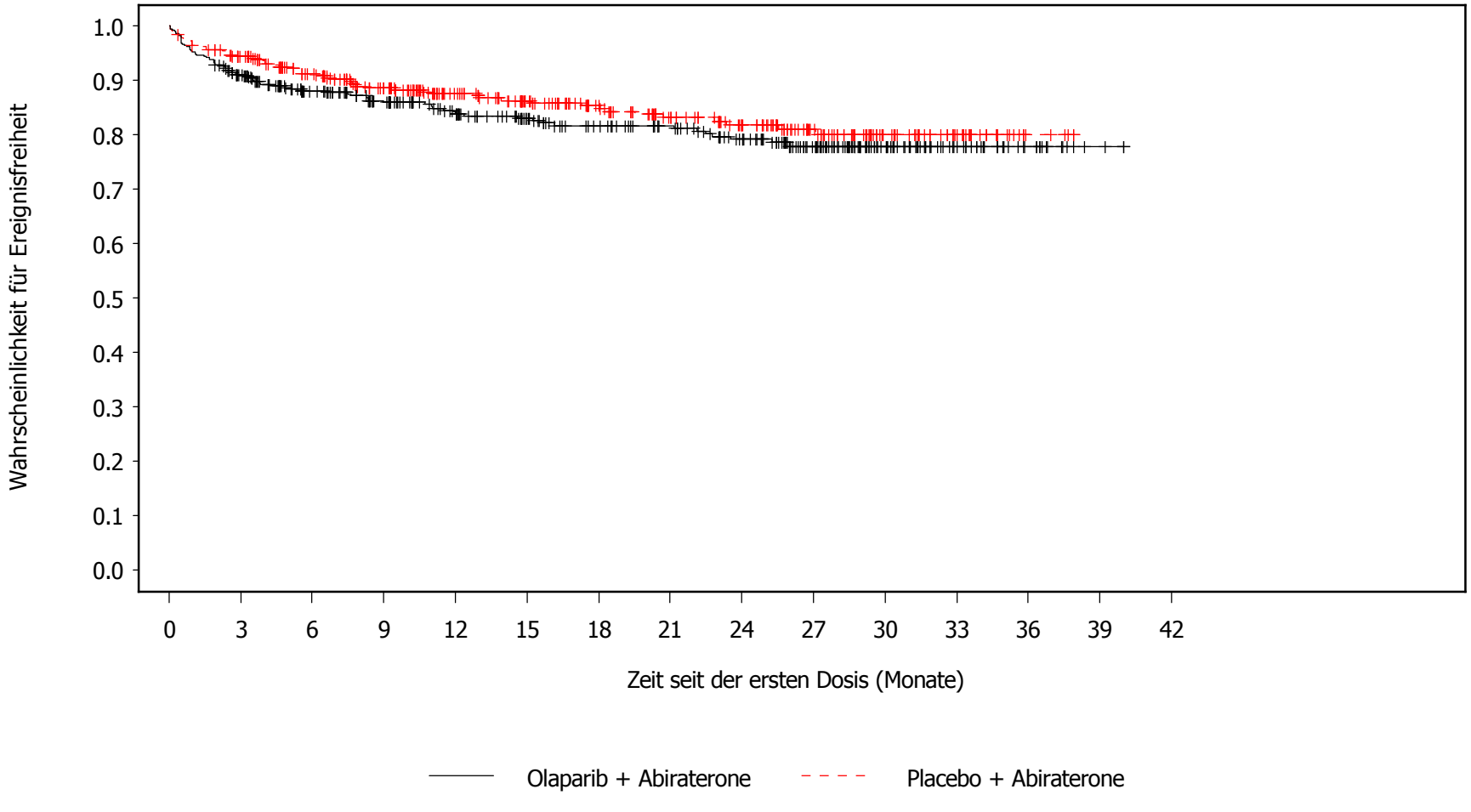


Anzahl an Patienten unter Risiko:

398	377	332	298	265	237	216	192	173	132	76	40	16	2	0	Olaparib + Abiraterone
396	374	332	291	243	205	174	149	122	89	52	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbp 06JUN2022:19:52 kvbv306

Figure 3.3.43 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Obstipation
Safety Analysis Set, DCO 14MAR2022



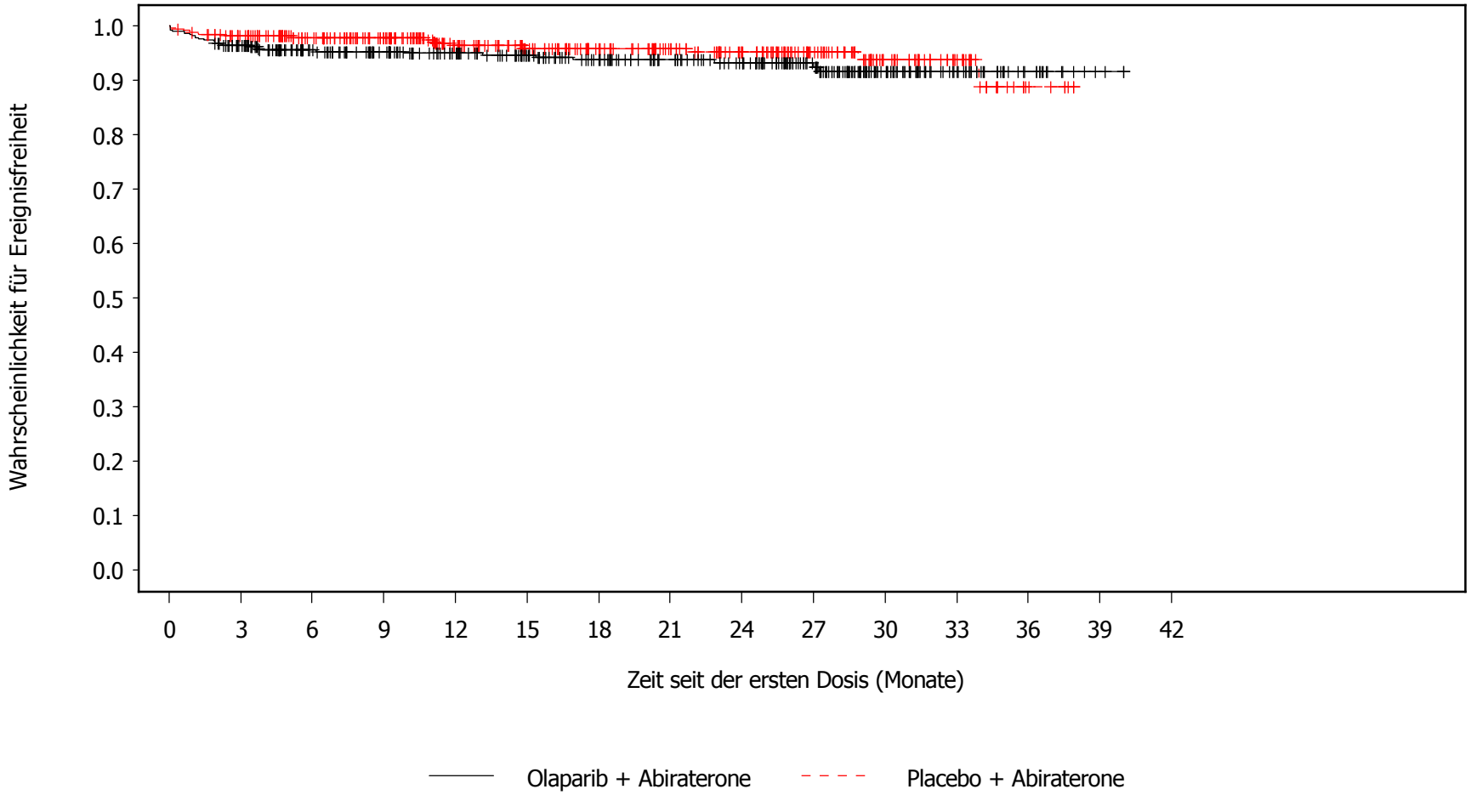
Anzahl an Patienten unter Risiko:

398	350	298	266	229	200	181	166	144	110	63	33	14	2	0	Olaparib + Abiraterone
396	360	318	273	229	194	162	137	113	81	47	27	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbq 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.44 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerzen Oberbauch
Safety Analysis Set, DCO 14MAR2022



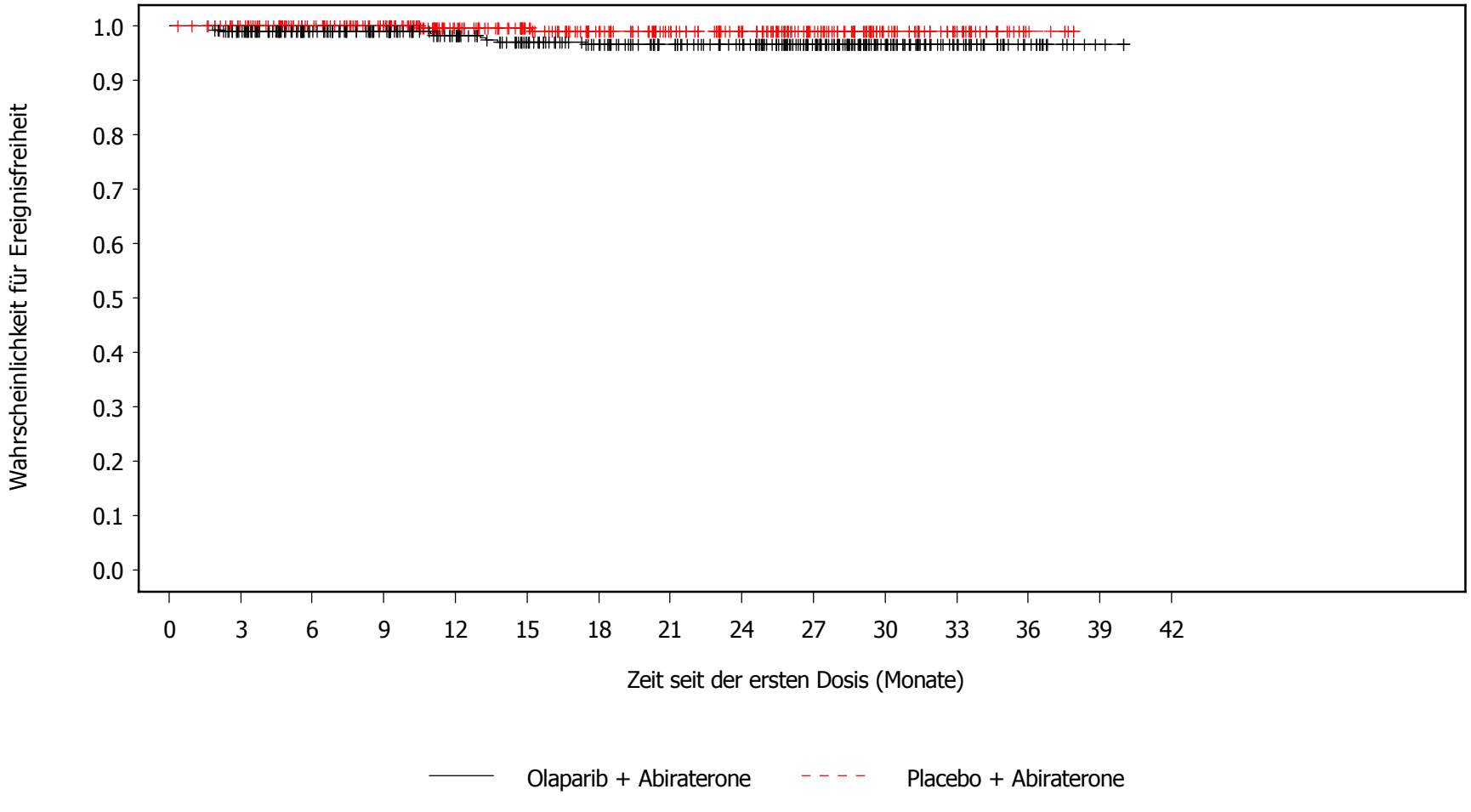
Anzahl an Patienten unter Risiko:

398	371	324	295	263	233	210	187	168	128	72	39	15	2	0	Olaparib + Abiraterone
396	373	334	295	241	204	172	149	122	89	52	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbr 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.45 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Stomatitis
Safety Analysis Set, DCO 14MAR2022

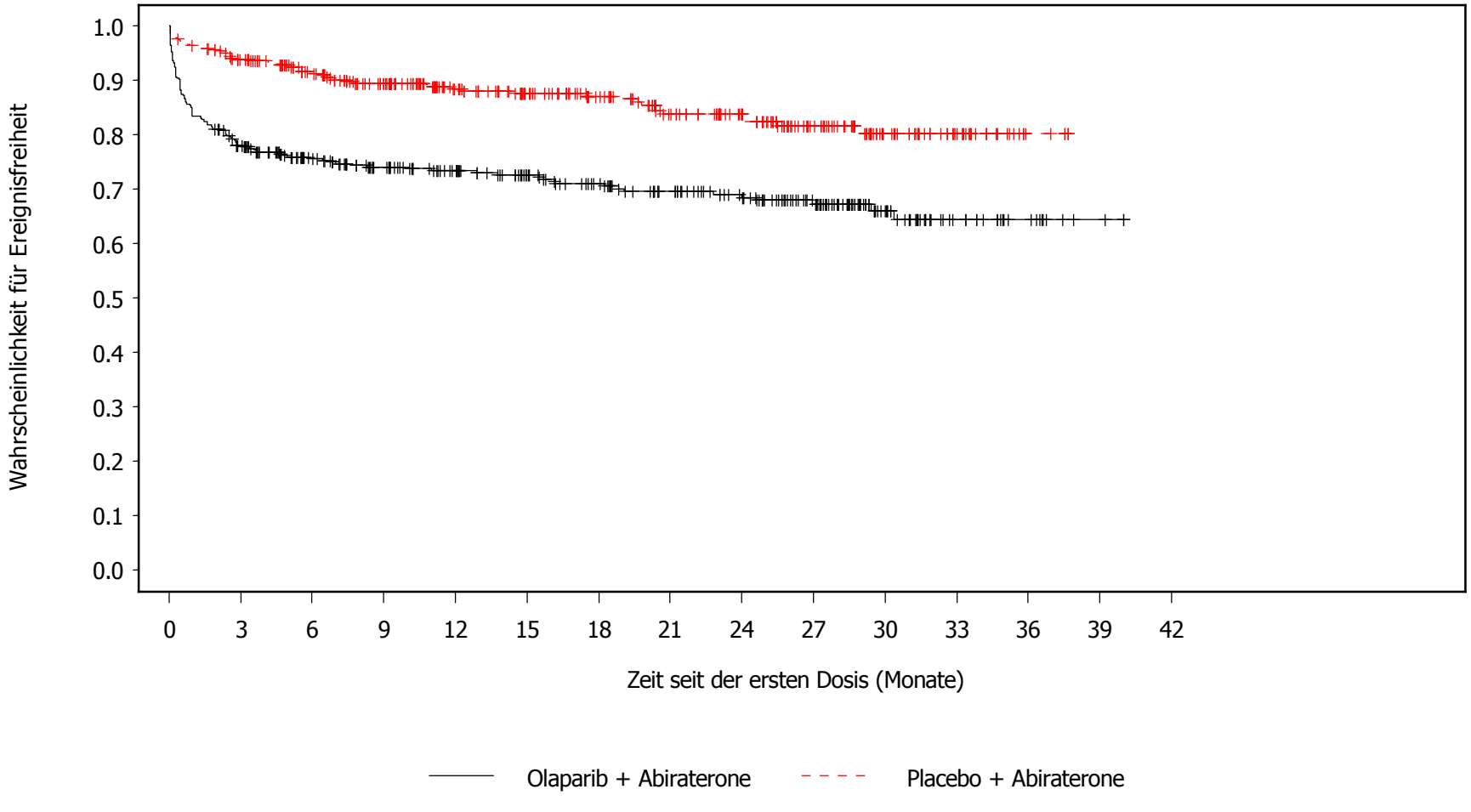


Anzahl an Patienten unter Risiko:

398	381	336	305	271	240	218	194	175	133	75	40	16	2	0	Olaparib + Abiraterone
396	380	341	301	249	213	180	154	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbs 06JUN2022:19:52 kvbv306

Figure 3.3.46 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Uebelkeit
Safety Analysis Set, DCO 14MAR2022

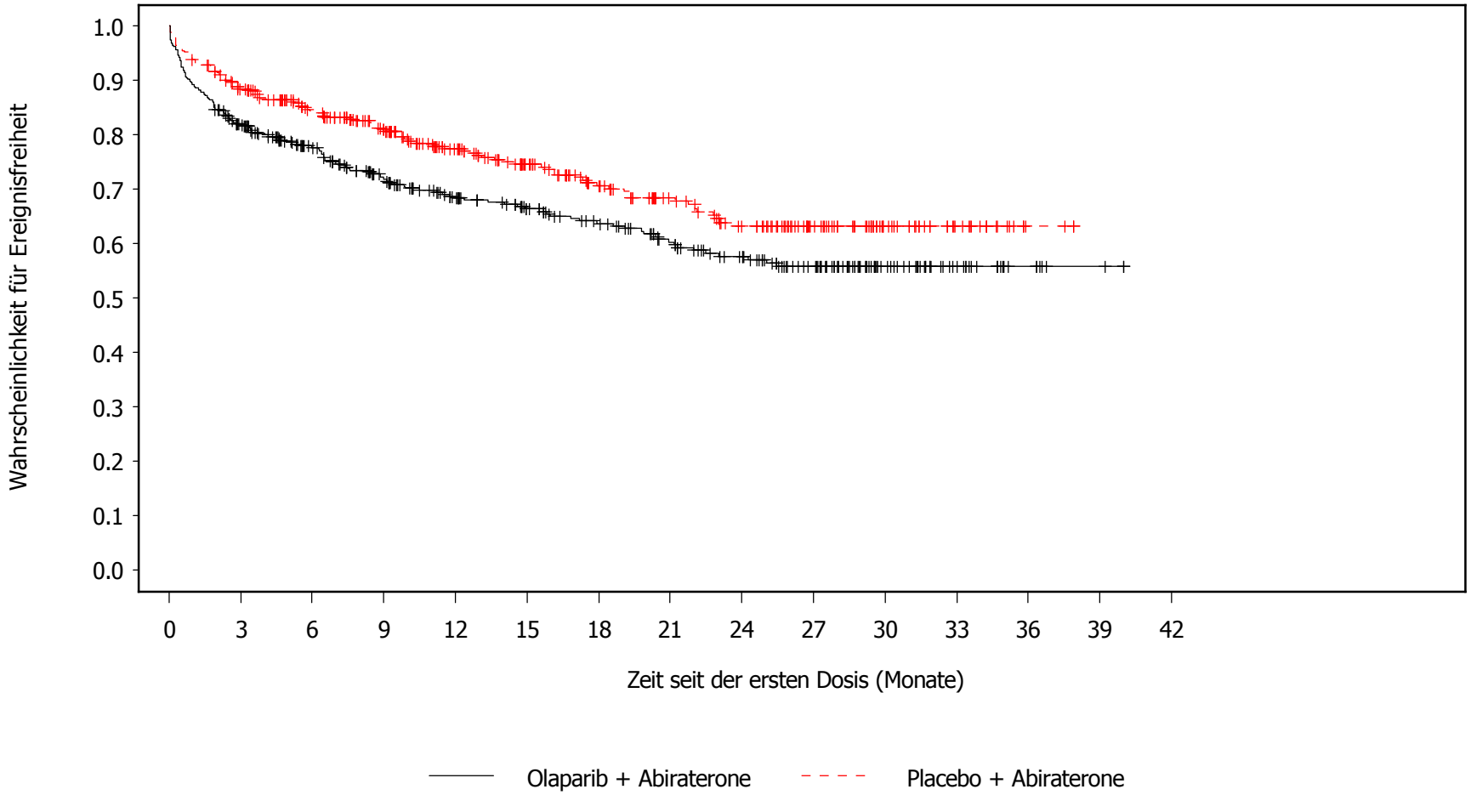


Anzahl an Patienten unter Risiko:

398	302	259	230	205	180	161	141	122	93	47	21	10	2	0	Olaparib + Abiraterone
396	357	315	275	231	199	170	142	119	85	49	27	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbt 06JUN2022:19:52 kvbv306

Figure 3.3.47 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 14MAR2022

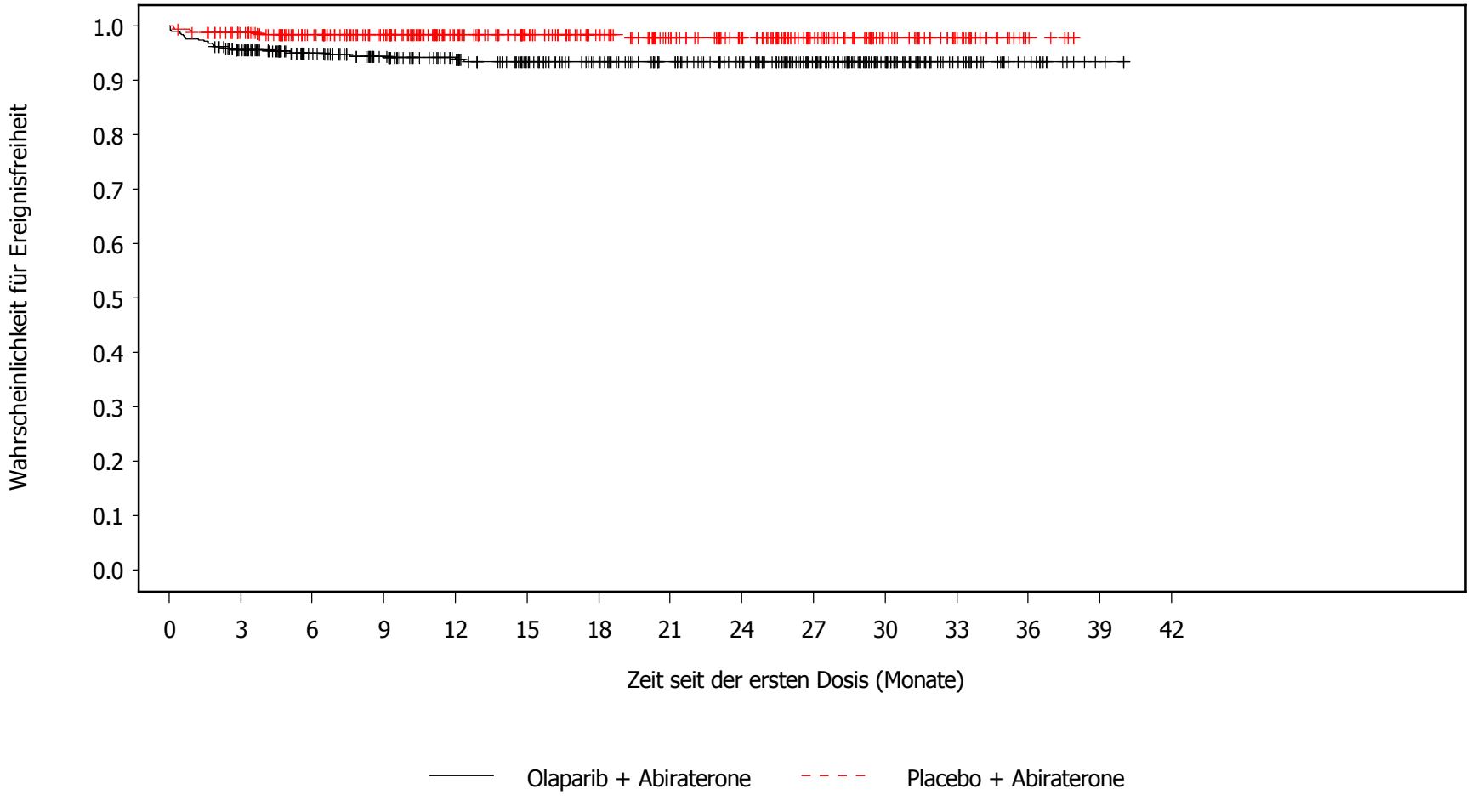


Anzahl an Patienten unter Risiko:

398	314	264	220	183	158	140	119	101	77	41	21	7	2	0	Olaparib + Abiraterone
396	338	290	247	202	165	133	109	89	63	36	18	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbu 06JUN2022:19:52 kvbv306

Figure 3.3.48 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Dysgeusie
Safety Analysis Set, DCO 14MAR2022

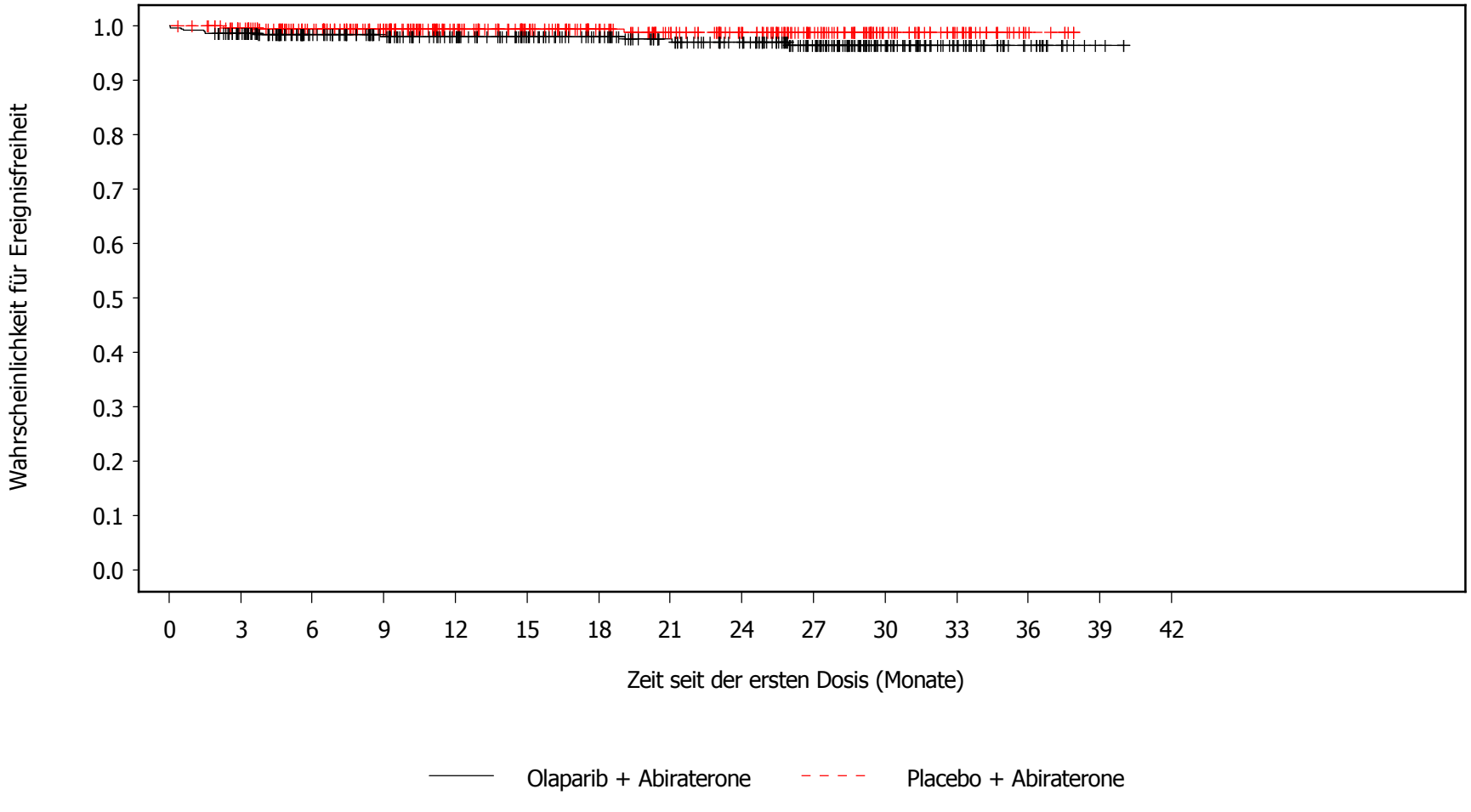


Anzahl an Patienten unter Risiko:

398	367	322	291	257	230	209	186	166	128	72	38	16	2	0	Olaparib + Abiraterone
396	376	337	297	247	212	179	152	127	92	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbv 06JUN2022:19:52 kvbv306

Figure 3.3.49 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Erinnerungsvermoegen eingeschraenkt
Safety Analysis Set, DCO 14MAR2022

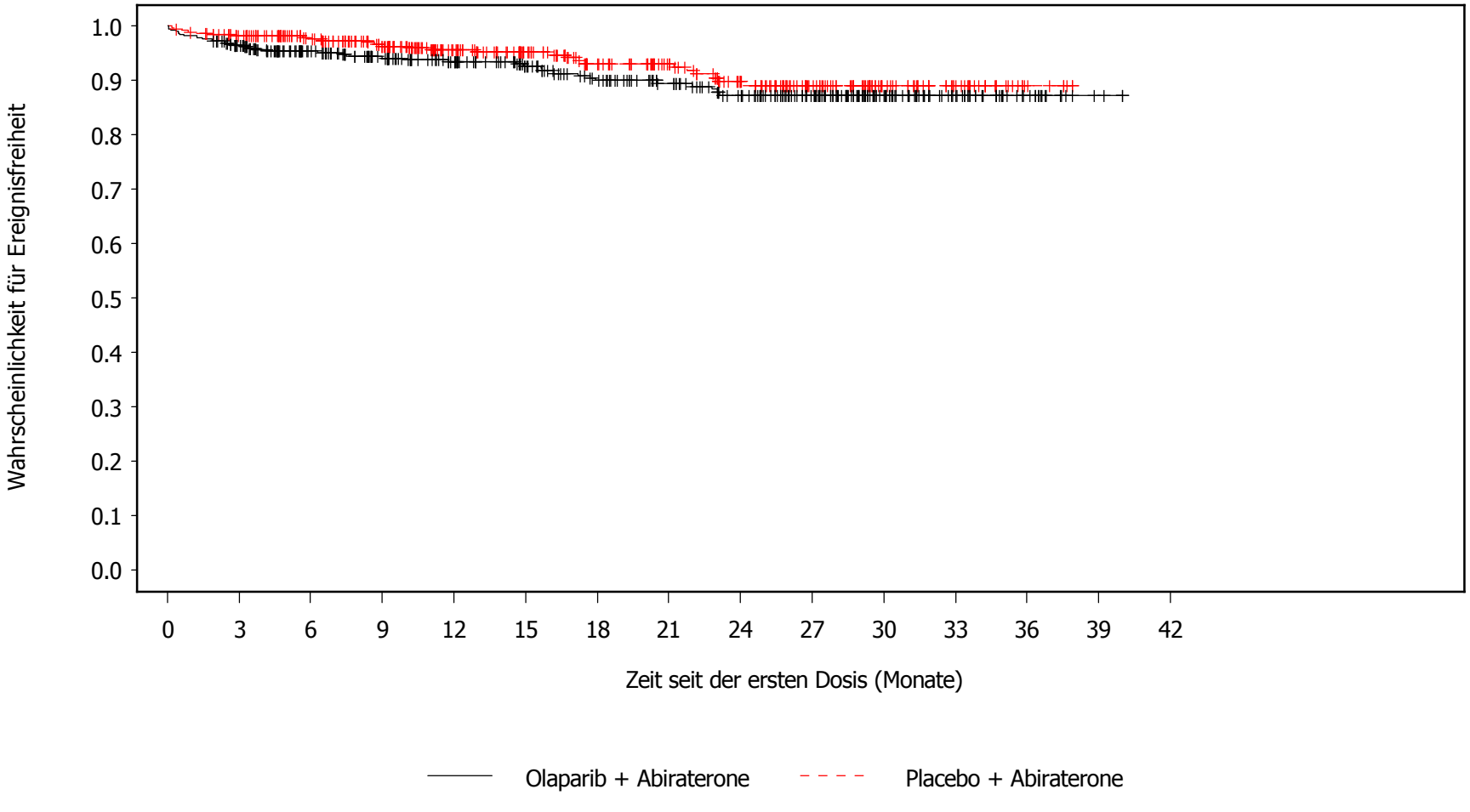


Anzahl an Patienten unter Risiko:

398	379	333	302	271	241	220	195	175	133	74	39	17	2	0	Olaparib + Abiraterone
396	379	339	299	249	213	180	154	128	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbw 06JUN2022:19:52 kvbv306

Figure 3.3.50 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Kopfschmerzen
Safety Analysis Set, DCO 14MAR2022

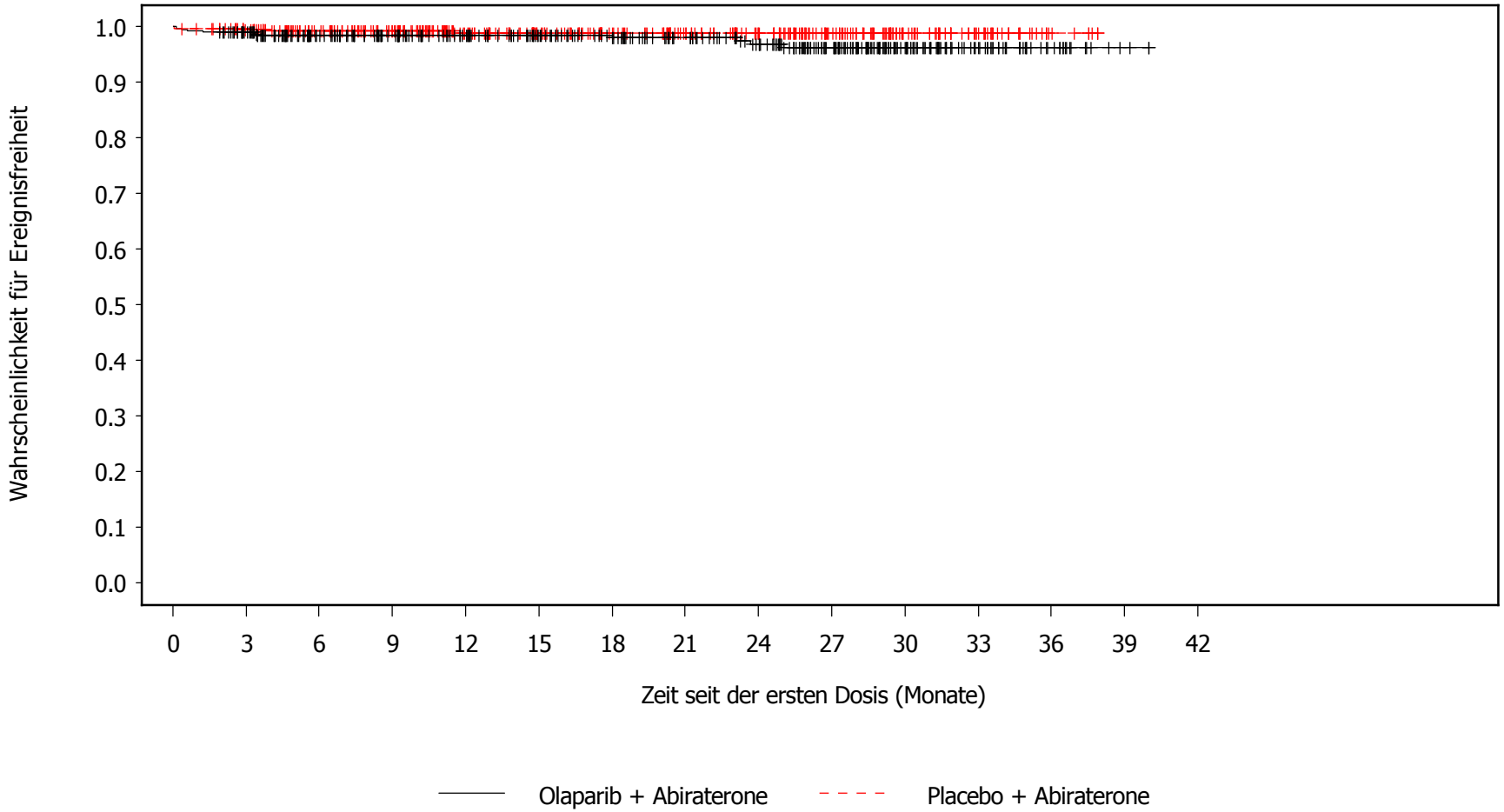


Anzahl an Patienten unter Risiko:

398	370	322	288	256	225	199	175	152	119	69	39	16	2	0	Olaparib + Abiraterone
396	373	333	290	239	203	169	146	117	84	49	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbx 06JUN2022:19:52 kvbv306

Figure 3.3.51 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Paraesthesie
Safety Analysis Set, DCO 14MAR2022

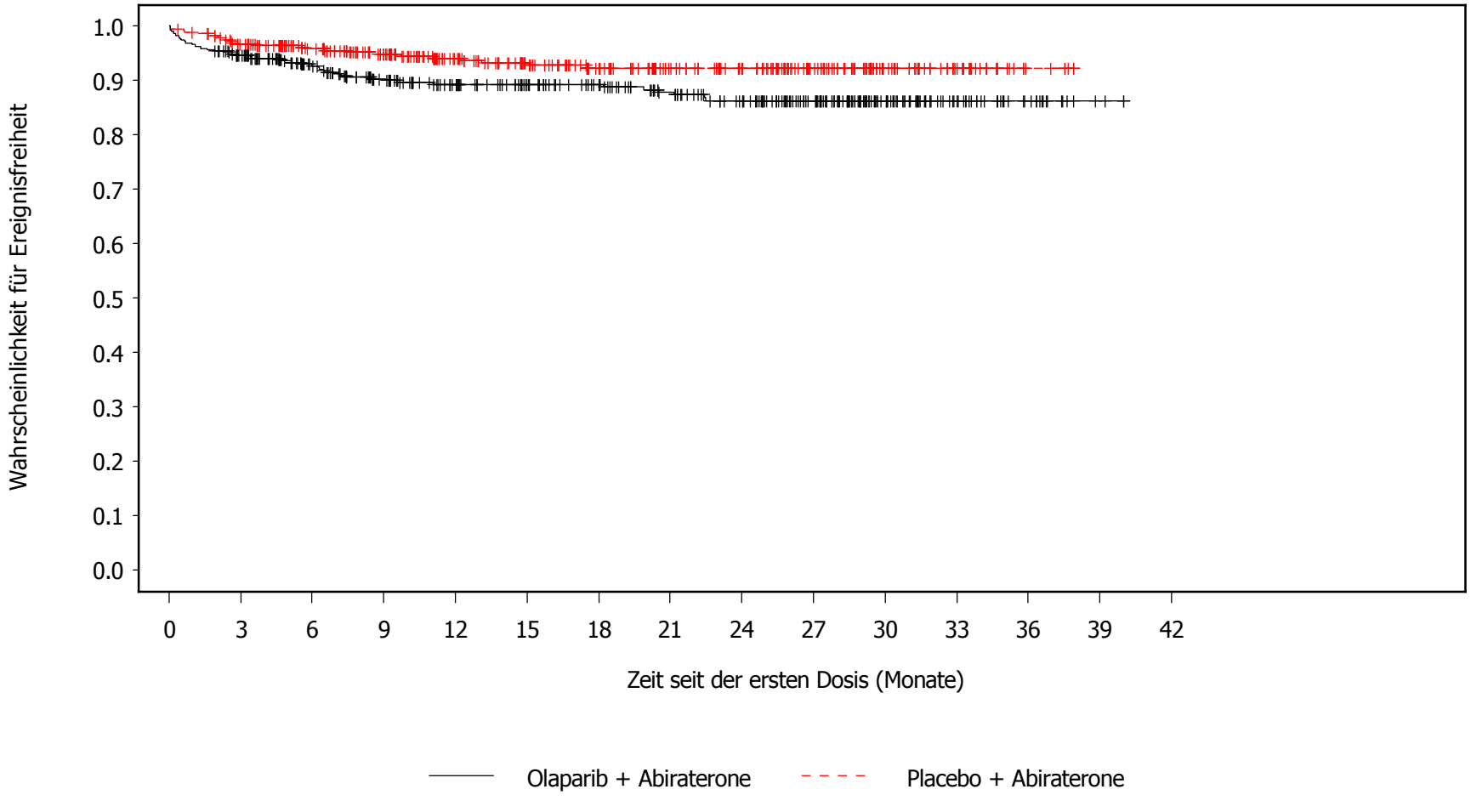


Anzahl an Patienten unter Risiko:

398	380	333	302	271	242	222	196	174	133	76	40	16	2	0	Olaparib + Abiraterone
396	378	338	298	246	210	178	152	126	92	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebby 06JUN2022:19:52 kvbv306

Figure 3.3.52 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Schwindelgefuehl
Safety Analysis Set, DCO 14MAR2022

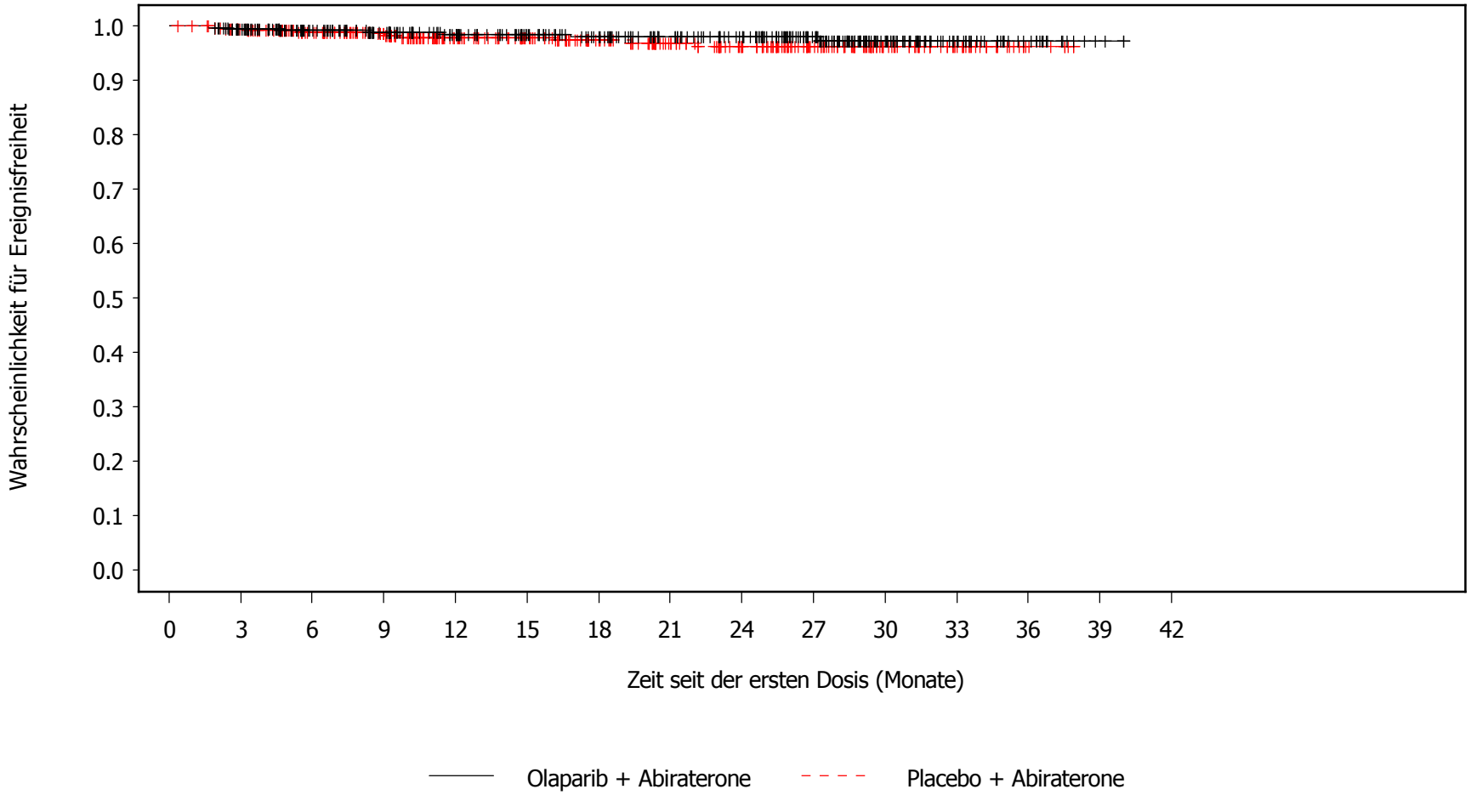


Anzahl an Patienten unter Risiko:

398	364	315	277	244	217	199	176	155	120	68	35	15	2	0	Olaparib + Abiraterone
396	368	327	285	238	203	171	145	122	88	50	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebbz 06JUN2022:19:52 kvbv306

Figure 3.3.53 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Synkope
Safety Analysis Set, DCO 14MAR2022



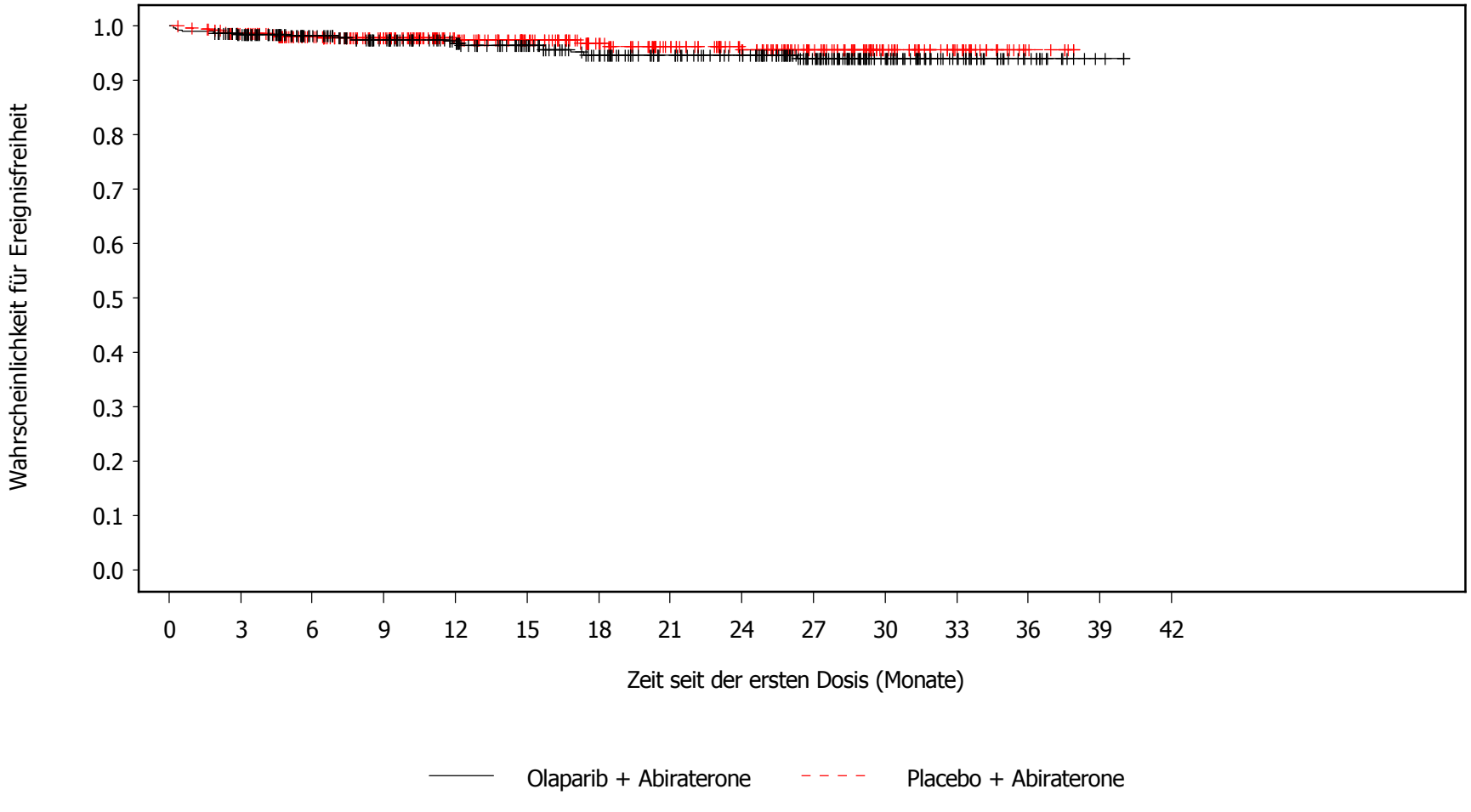
Anzahl an Patienten unter Risiko:

398	382	338	306	273	243	223	198	178	134	74	38	16	2	0	Olaparib + Abiraterone
396	378	337	297	246	212	178	151	125	91	52	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebca 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.54 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Erkrankungen des Ohrs und des Labyrinths
Safety Analysis Set, DCO 14MAR2022



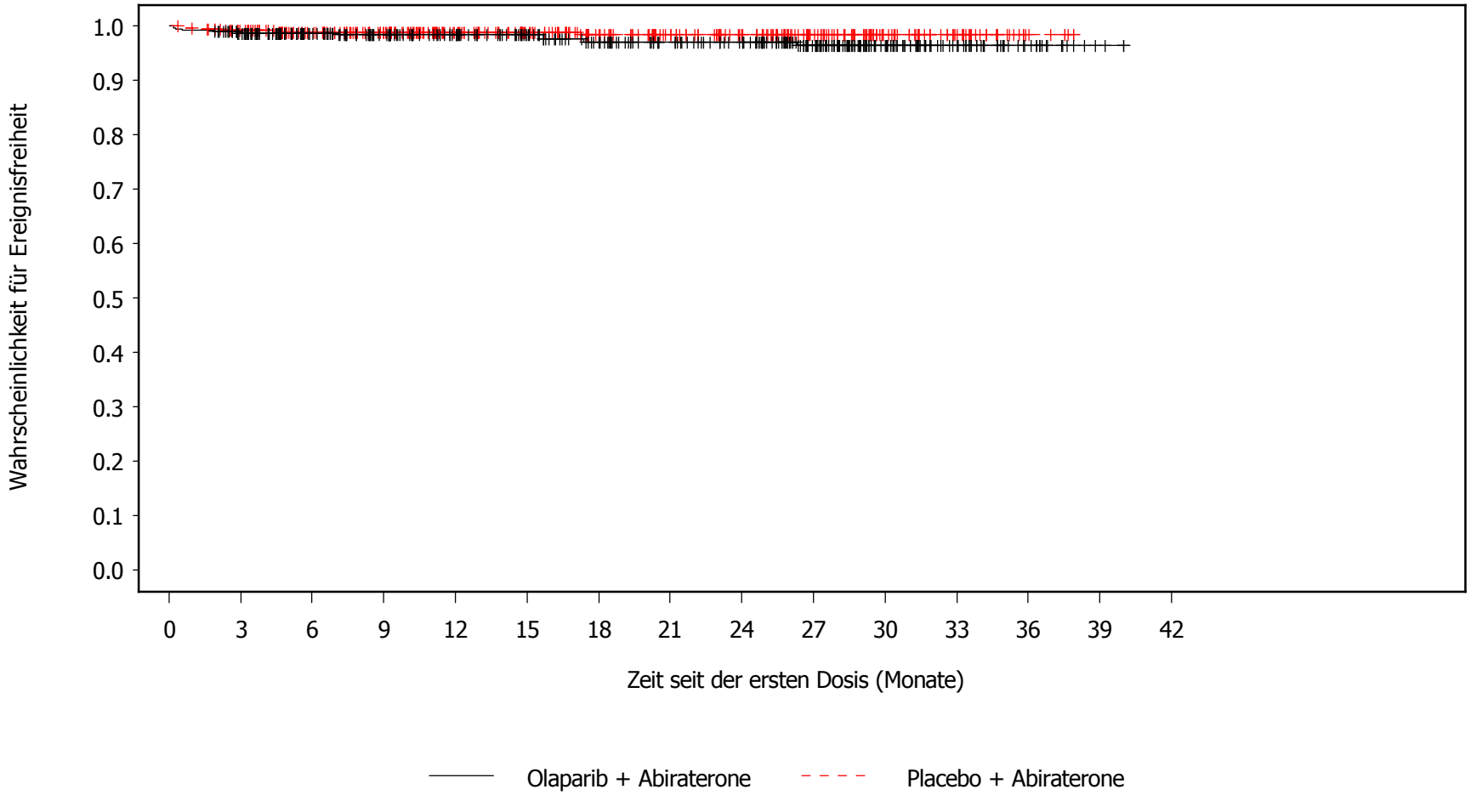
Anzahl an Patienten unter Risiko:

398	378	332	299	265	235	210	187	170	126	71	39	16	2	0	Olaparib + Abiraterone
396	375	335	294	244	207	174	148	122	90	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcb 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.55 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Vertigo
Safety Analysis Set, DCO 14MAR2022



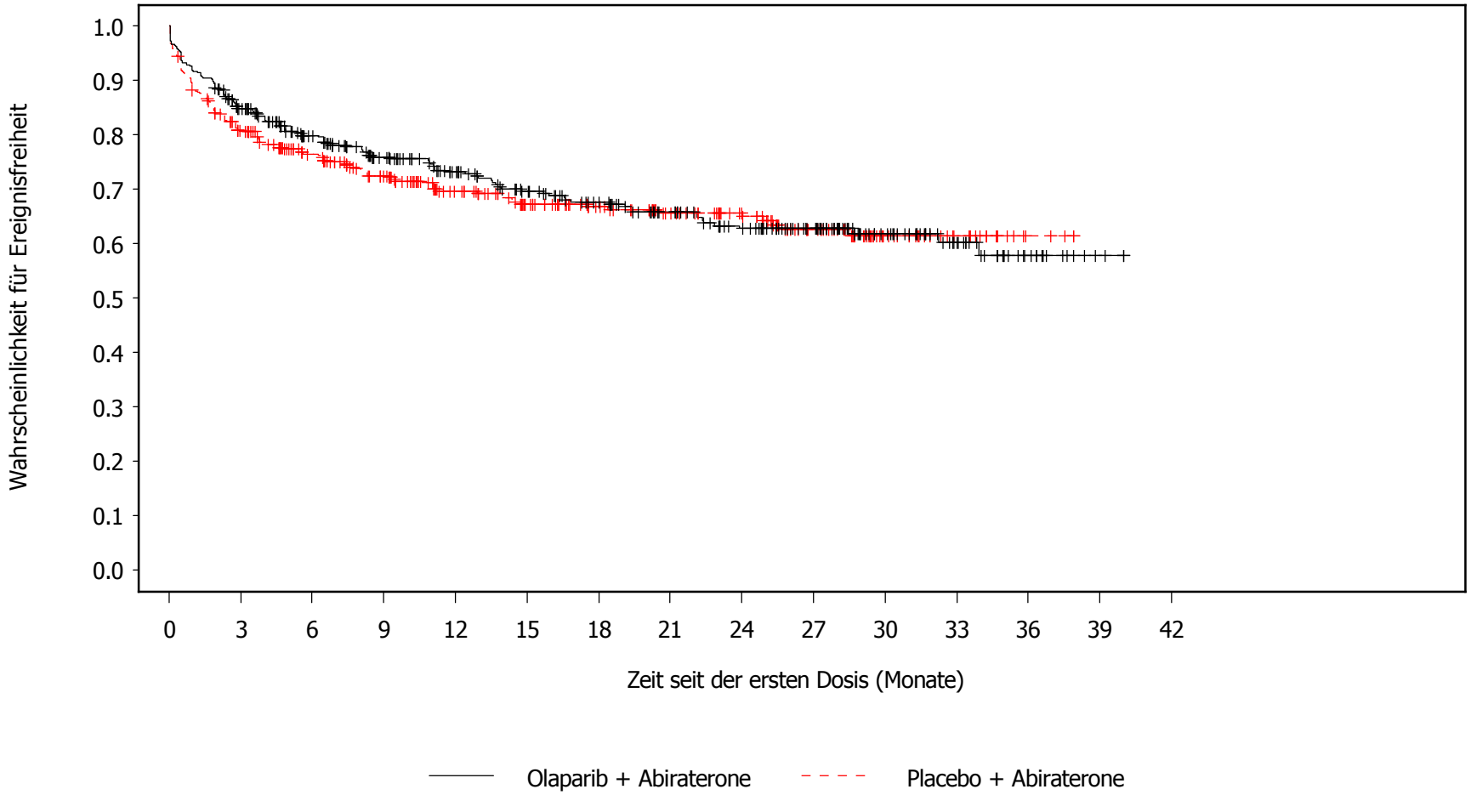
Anzahl an Patienten unter Risiko:

398	379	334	302	270	241	217	193	176	131	74	40	16	2	0	Olaparib + Abiraterone
396	377	338	298	247	211	177	152	127	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcc 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.56 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Gefaesserkrankungen
Safety Analysis Set, DCO 14MAR2022



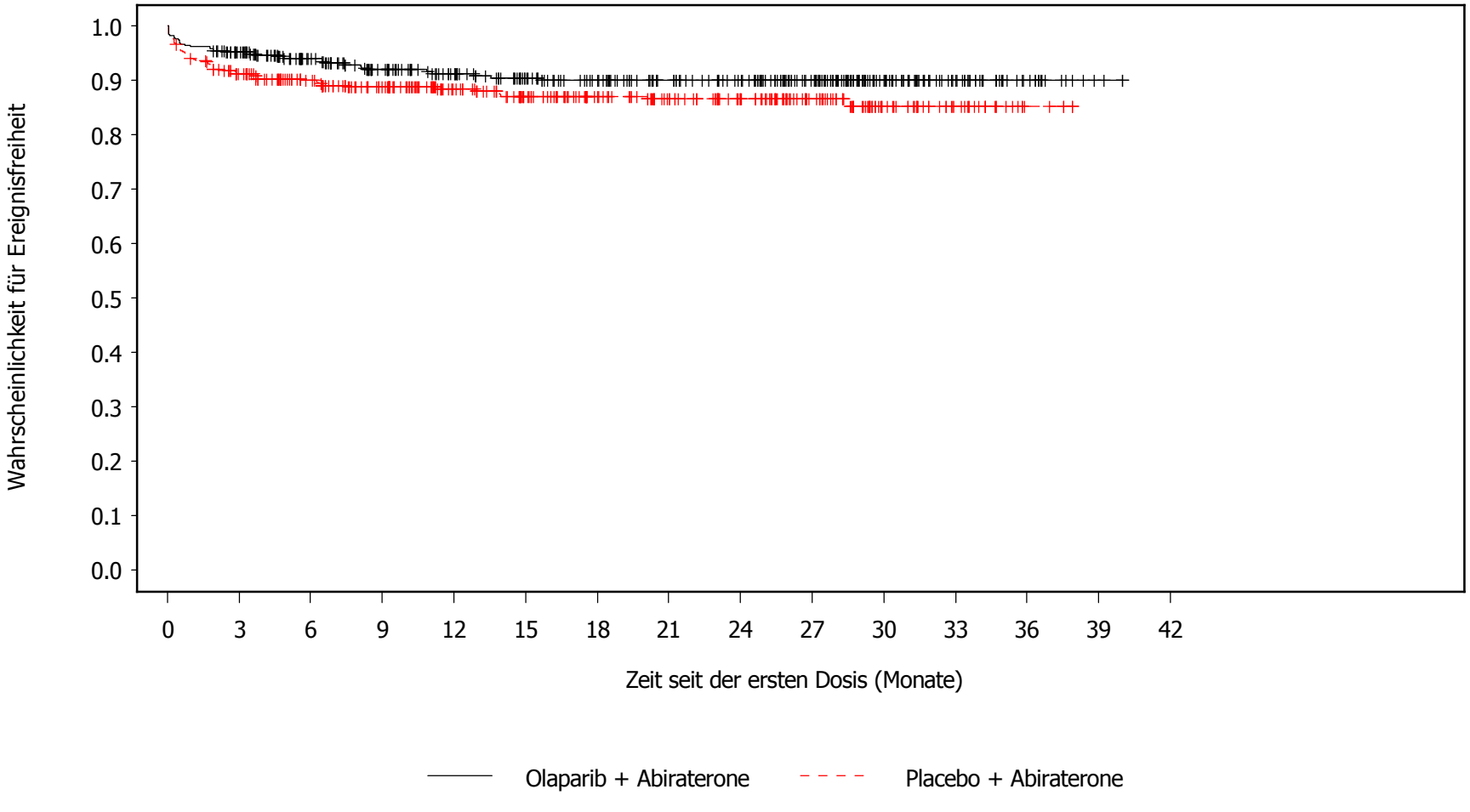
Anzahl an Patienten unter Risiko:

398	324	274	234	202	176	157	135	115	92	55	33	13	2	0	Olaparib + Abiraterone
396	307	261	223	185	153	130	112	93	65	33	18	3	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcd 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.57 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hitzewallung
Safety Analysis Set, DCO 14MAR2022



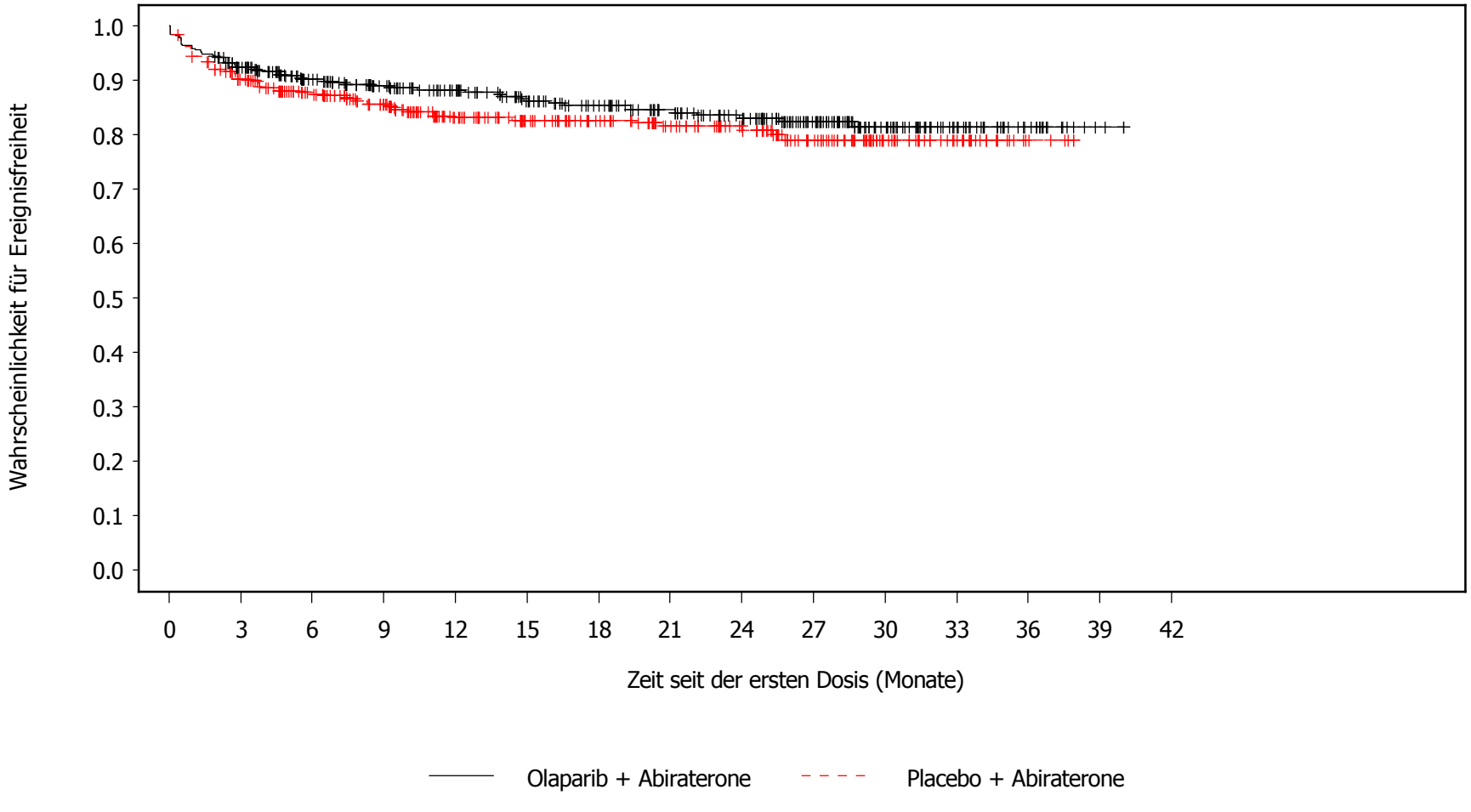
Anzahl an Patienten unter Risiko:

398	365	323	286	254	224	203	178	160	125	71	39	15	2	0	Olaparib + Abiraterone
396	346	306	268	225	193	162	138	114	82	44	23	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebce 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.58 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hypertonie
Safety Analysis Set, DCO 14MAR2022

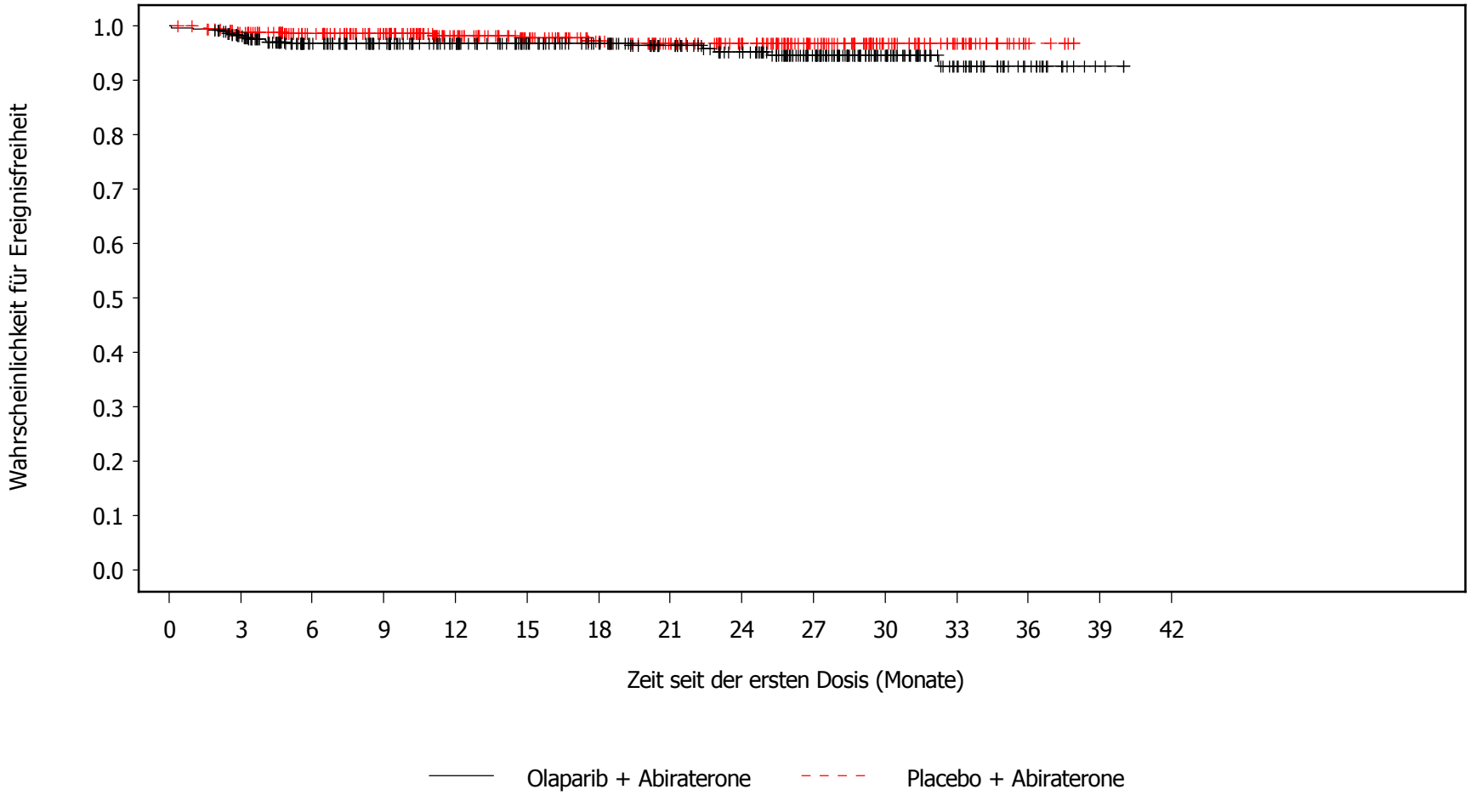


Anzahl an Patienten unter Risiko:

398	354	306	273	244	215	196	173	152	113	68	39	17	2	0	Olaparib + Abiraterone
396	342	300	260	212	179	153	131	110	80	45	26	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcf 06JUN2022:19:52 kvbv306

Figure 3.3.59 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hypotonie
Safety Analysis Set, DCO 14MAR2022



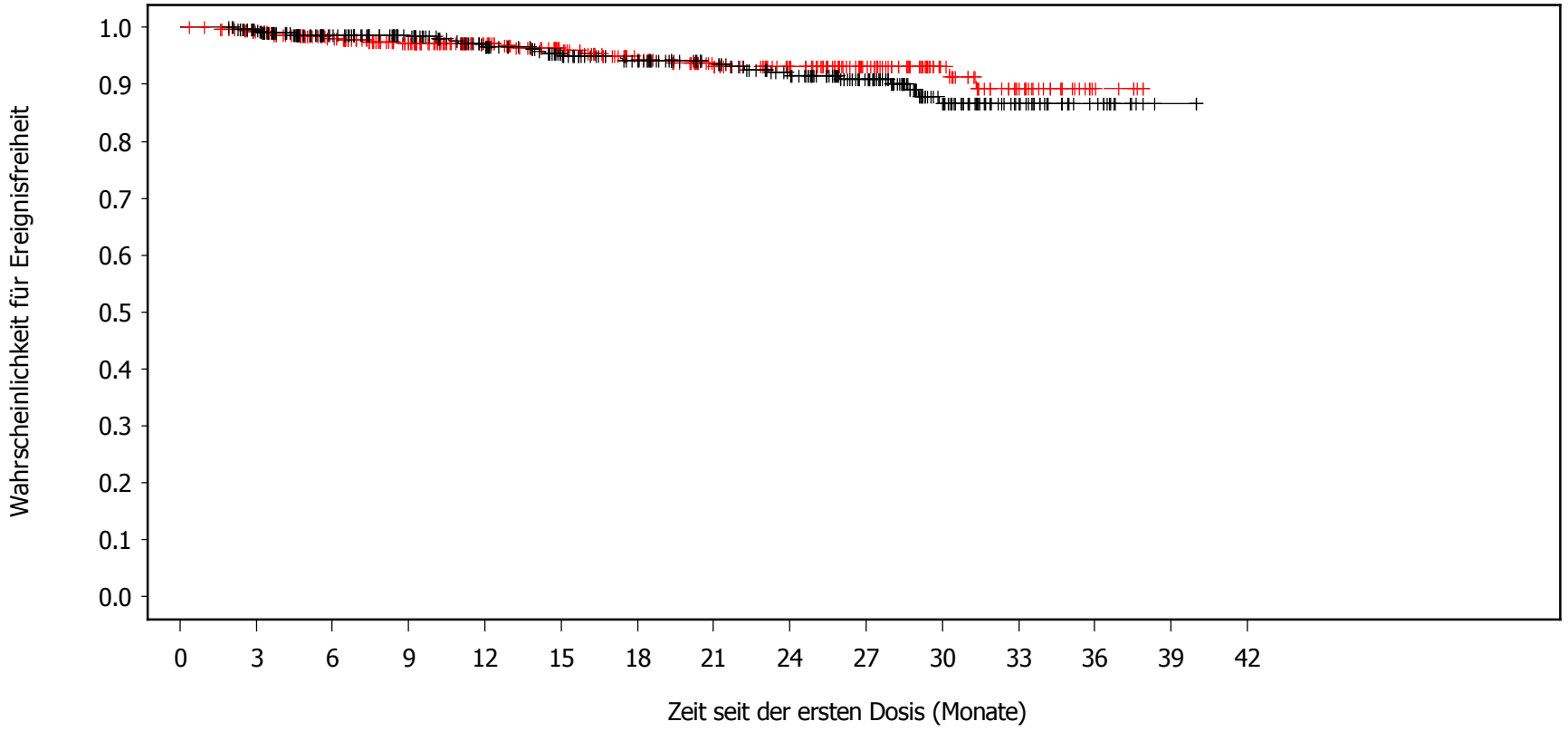
Anzahl an Patienten unter Risiko:

398	377	327	297	266	236	217	193	172	130	77	40	16	2	0	Olaparib + Abiraterone
396	377	338	300	249	212	180	154	128	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcg 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.60 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Gutartige, boesartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)
Safety Analysis Set, DCO 14MAR2022



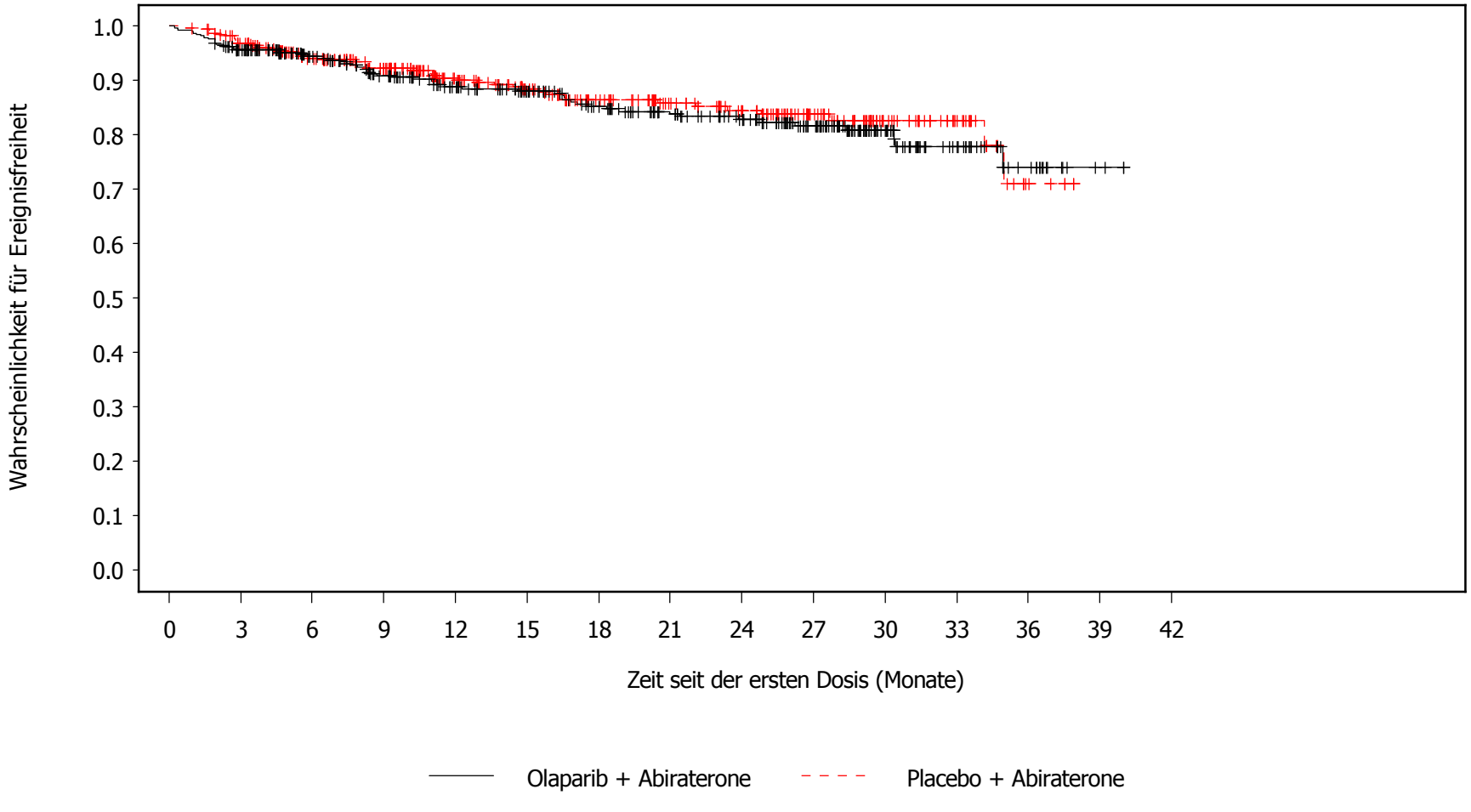
Anzahl an Patienten unter Risiko:

398	382	334	302	265	233	213	188	165	125	67	33	14	1	0	Olaparib + Abiraterone
396	377	336	293	245	209	175	147	122	89	52	27	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebch 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.61 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Herzerkrankungen
Safety Analysis Set, DCO 14MAR2022

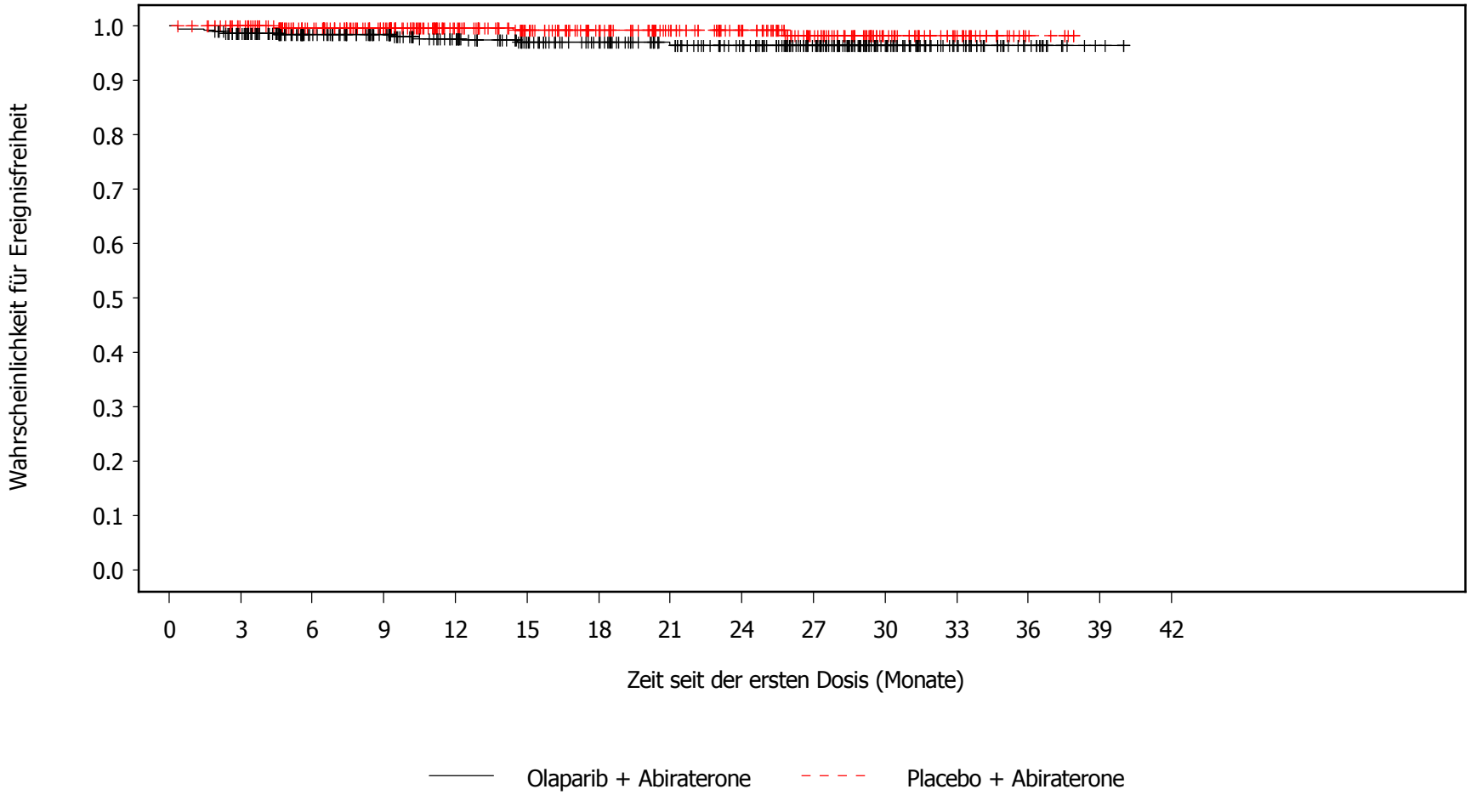


Anzahl an Patienten unter Risiko:

398	369	323	287	251	225	200	175	156	119	64	35	15	2	0	Olaparib + Abiraterone
396	371	326	284	233	196	161	137	116	84	48	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebci 06JUN2022:19:52 kvbv306

Figure 3.3.62 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Palpitationen
Safety Analysis Set, DCO 14MAR2022

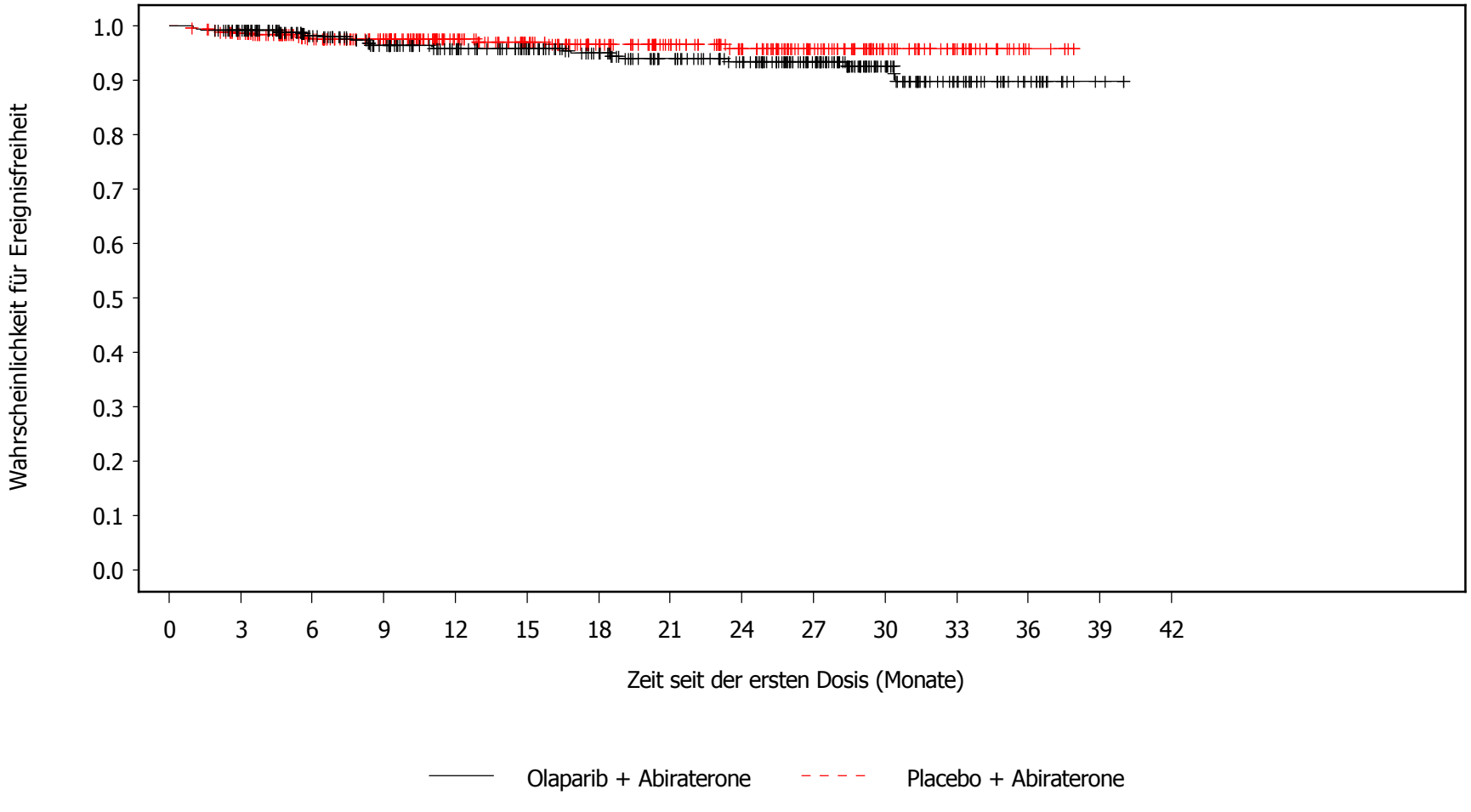


Anzahl an Patienten unter Risiko:

398	379	333	303	269	238	218	192	172	133	75	39	16	2	0	Olaparib + Abiraterone
396	380	340	300	250	213	180	154	128	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcj 06JUN2022:19:52 kvbv306

Figure 3.3.63 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Vorhofflimmern
Safety Analysis Set, DCO 14MAR2022

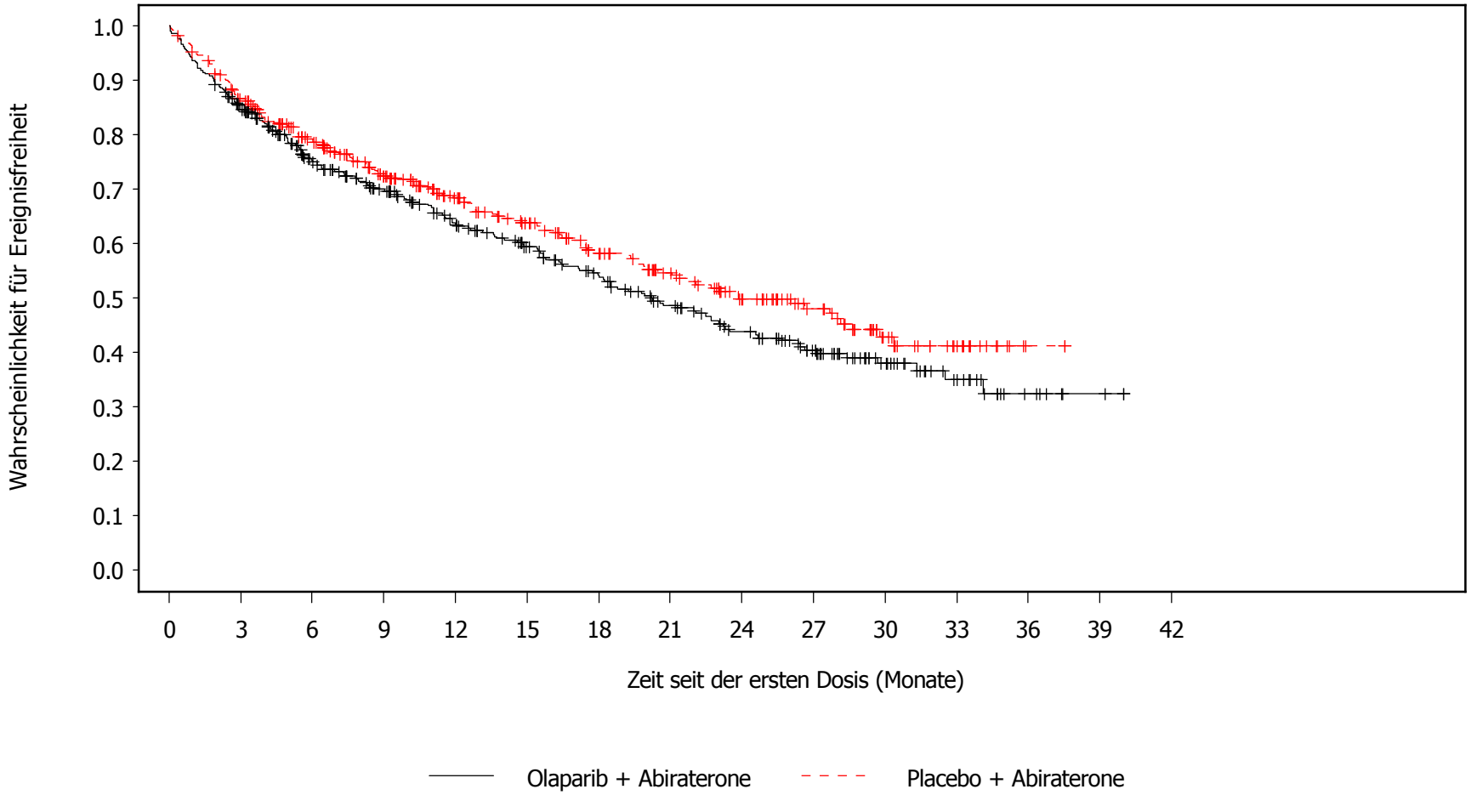


Anzahl an Patienten unter Risiko:

398	382	335	303	269	243	220	194	173	131	73	39	16	2	0	Olaparib + Abiraterone
396	377	335	297	247	212	178	152	126	92	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebck 06JUN2022:19:52 kvbv306

Figure 3.3.64 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Infektionen und parasitaere Erkrankungen
Safety Analysis Set, DCO 14MAR2022



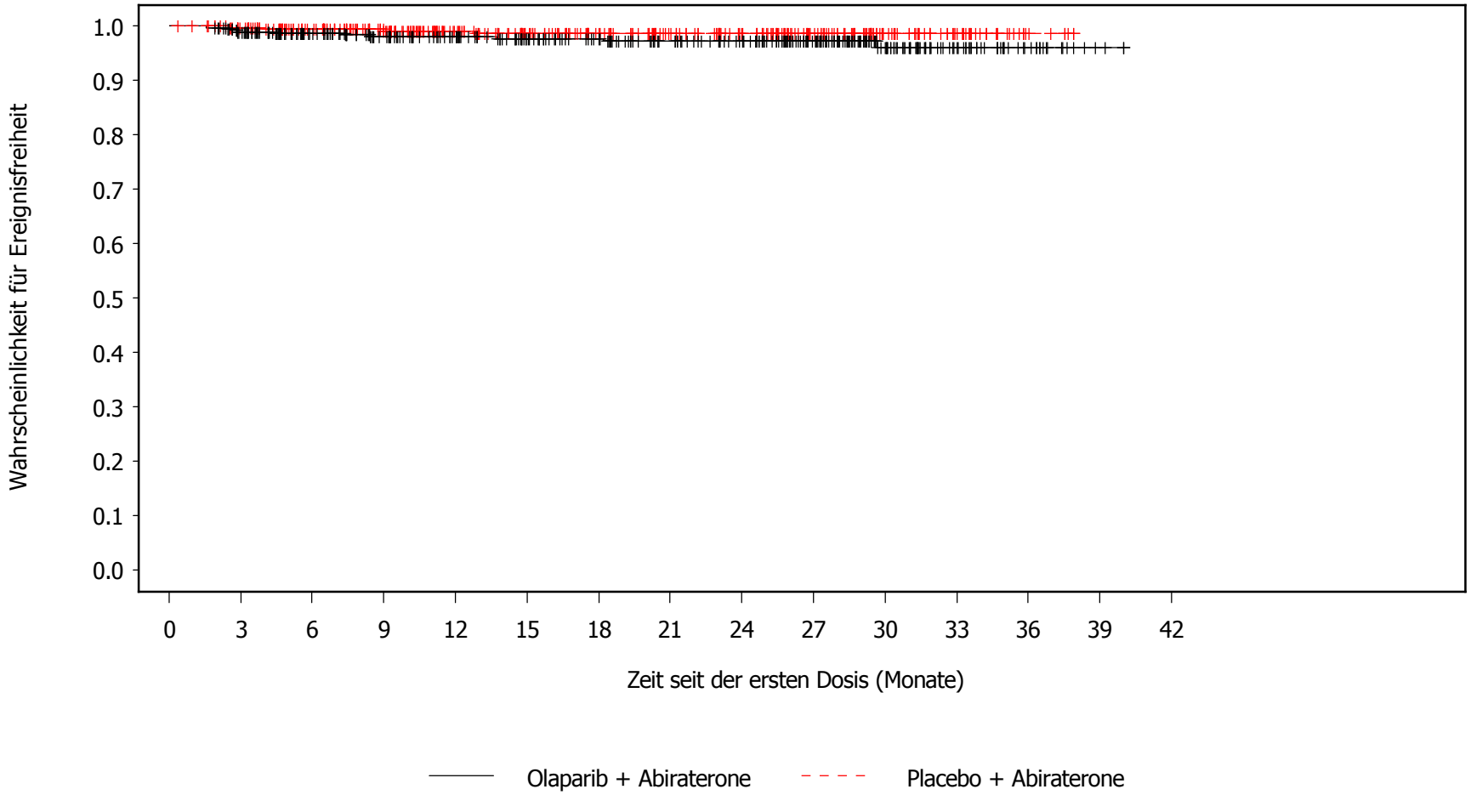
Anzahl an Patienten unter Risiko:

398	329	262	223	182	153	130	107	86	64	37	20	7	2	0	Olaparib + Abiraterone
396	333	277	223	181	150	120	97	73	53	29	16	1	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcl 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.65 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Bronchitis
Safety Analysis Set, DCO 14MAR2022



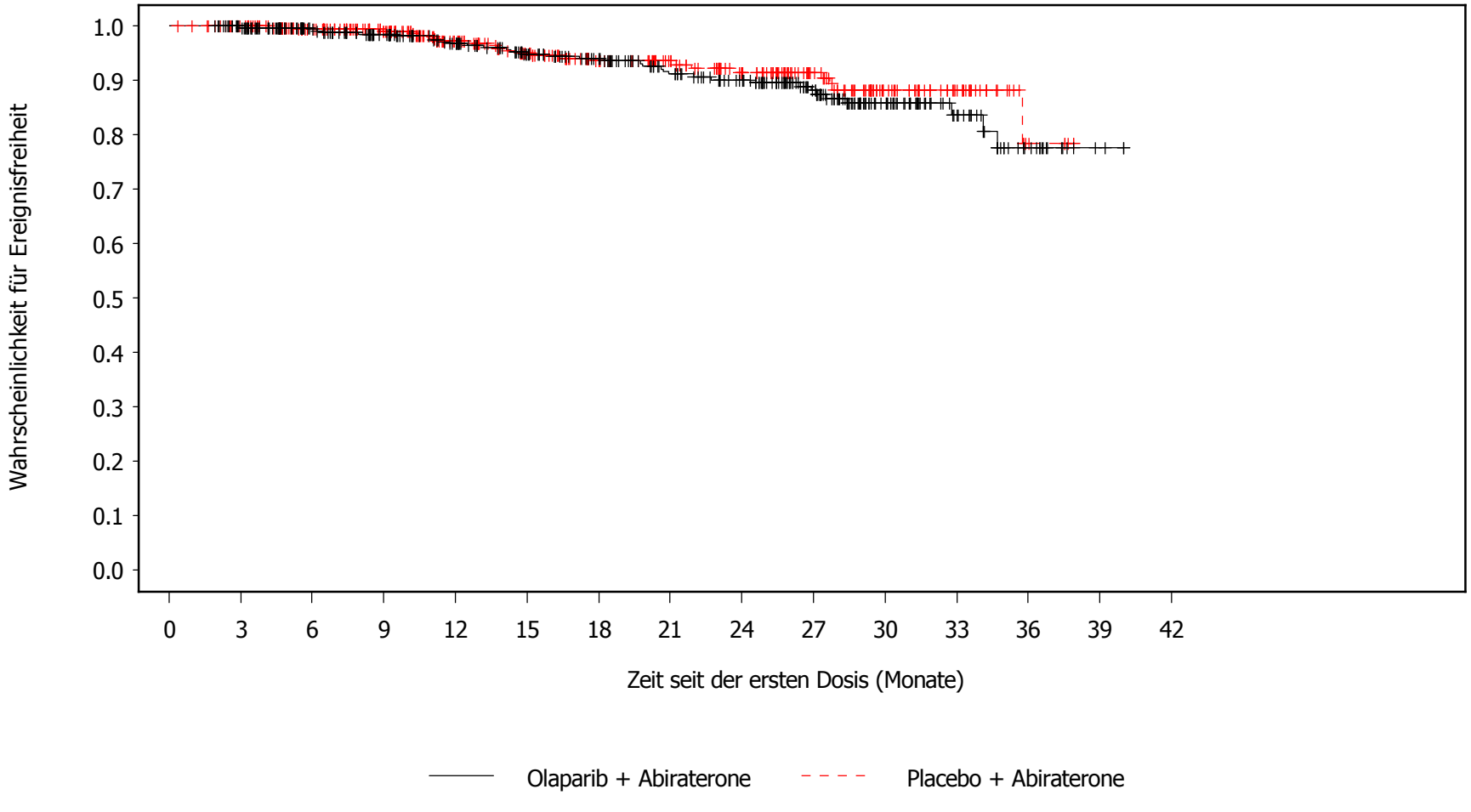
Anzahl an Patienten unter Risiko:

398	380	335	303	271	240	220	195	176	134	74	39	16	2	0	Olaparib + Abiraterone
396	379	339	299	247	212	179	153	129	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcm 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.66 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: COVID-19
Safety Analysis Set, DCO 14MAR2022

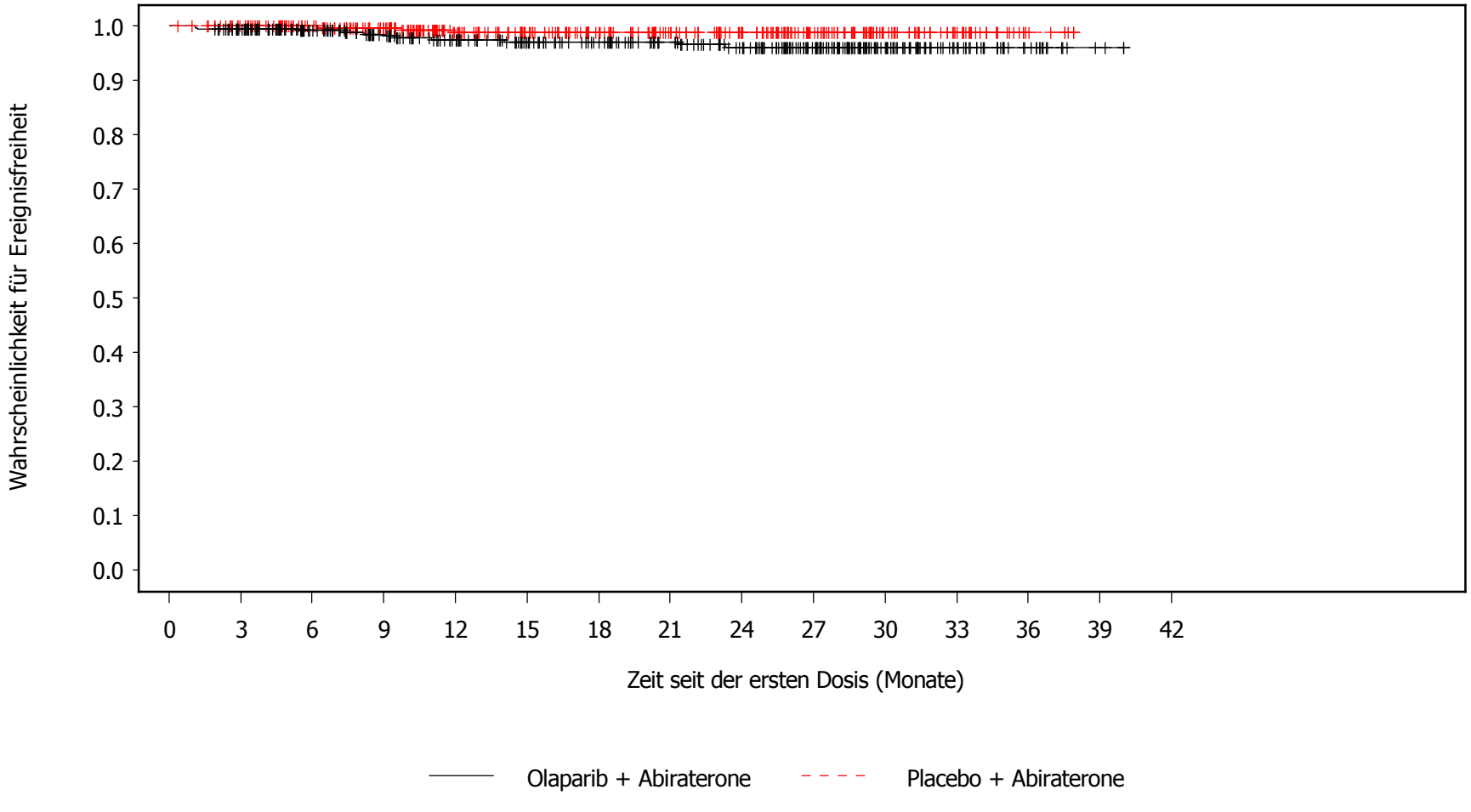


Anzahl an Patienten unter Risiko:

398	383	338	305	270	236	216	188	167	122	71	37	15	2	0	Olaparib + Abiraterone
396	380	339	298	244	207	172	148	121	89	52	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcn 06JUN2022:19:52 kvbv306

Figure 3.3.67 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Gastroenteritis
Safety Analysis Set, DCO 14MAR2022



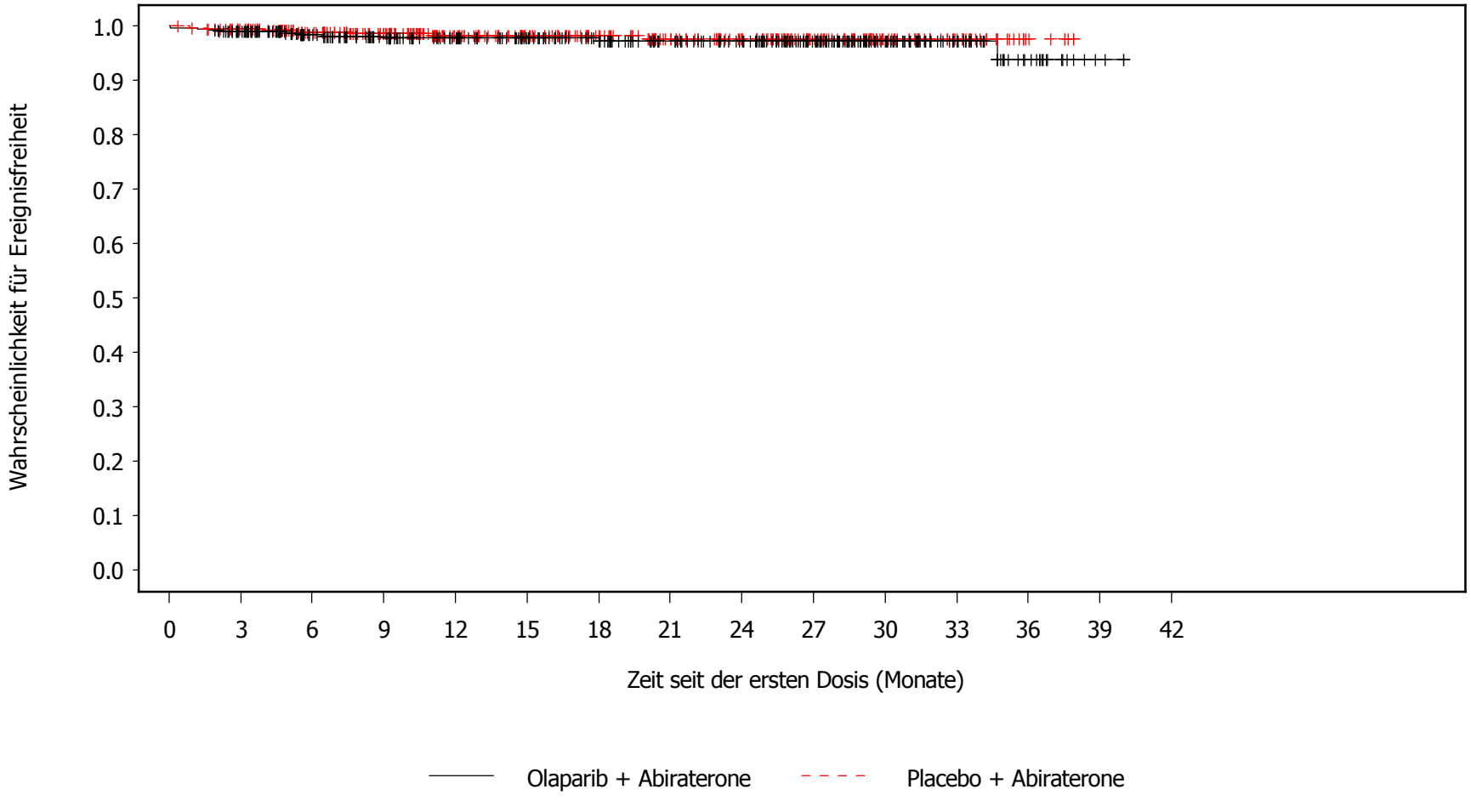
Anzahl an Patienten unter Risiko:

398	382	336	303	268	238	219	195	173	130	73	37	15	2	0	Olaparib + Abiraterone
396	380	341	300	247	213	180	154	129	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebco 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.68 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Grippe
Safety Analysis Set, DCO 14MAR2022

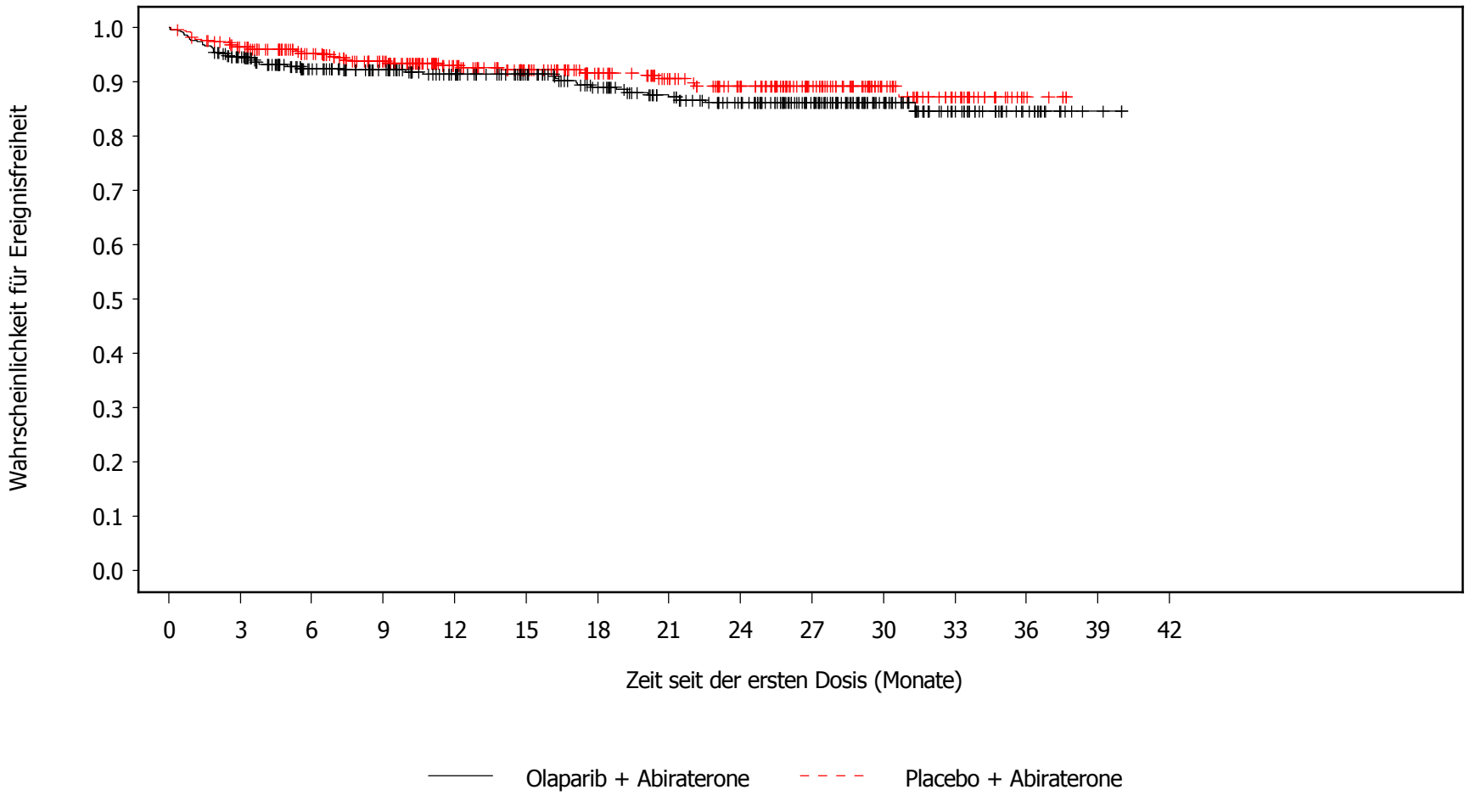


Anzahl an Patienten unter Risiko:

398	380	333	301	269	239	218	193	173	132	76	41	16	2	0	Olaparib + Abiraterone
396	378	338	297	246	210	178	152	126	91	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcp 06JUN2022:19:52 kvbv306

Figure 3.3.69 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Harnwegsinfektion
Safety Analysis Set, DCO 14MAR2022

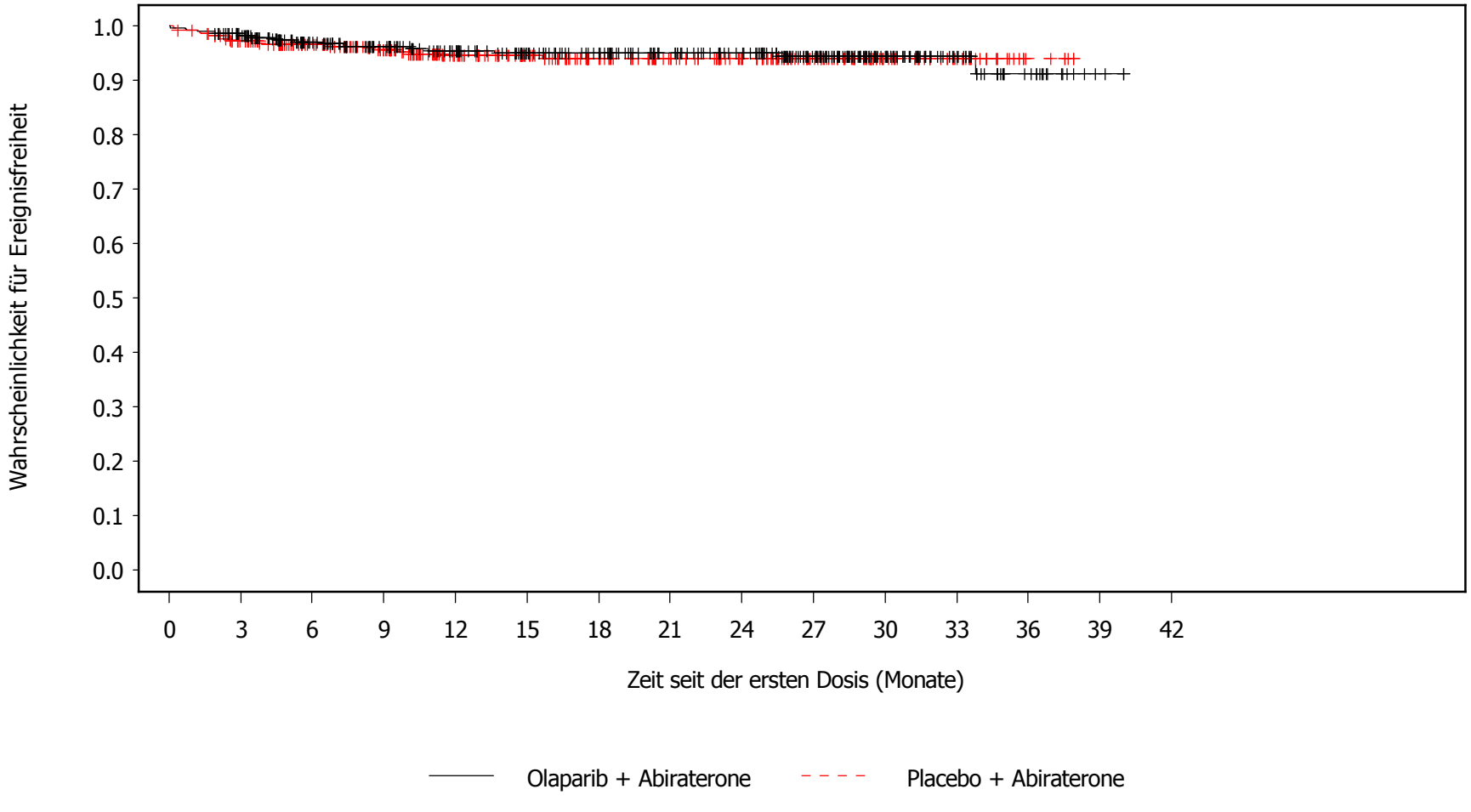


Anzahl an Patienten unter Risiko:

398	365	317	290	258	232	206	182	162	123	72	38	16	2	0	Olaparib + Abiraterone
396	368	330	290	240	204	171	147	122	89	50	28	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcq 06JUN2022:19:52 kvbv306

Figure 3.3.70 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Infektion der oberen Atemwege
Safety Analysis Set, DCO 14MAR2022

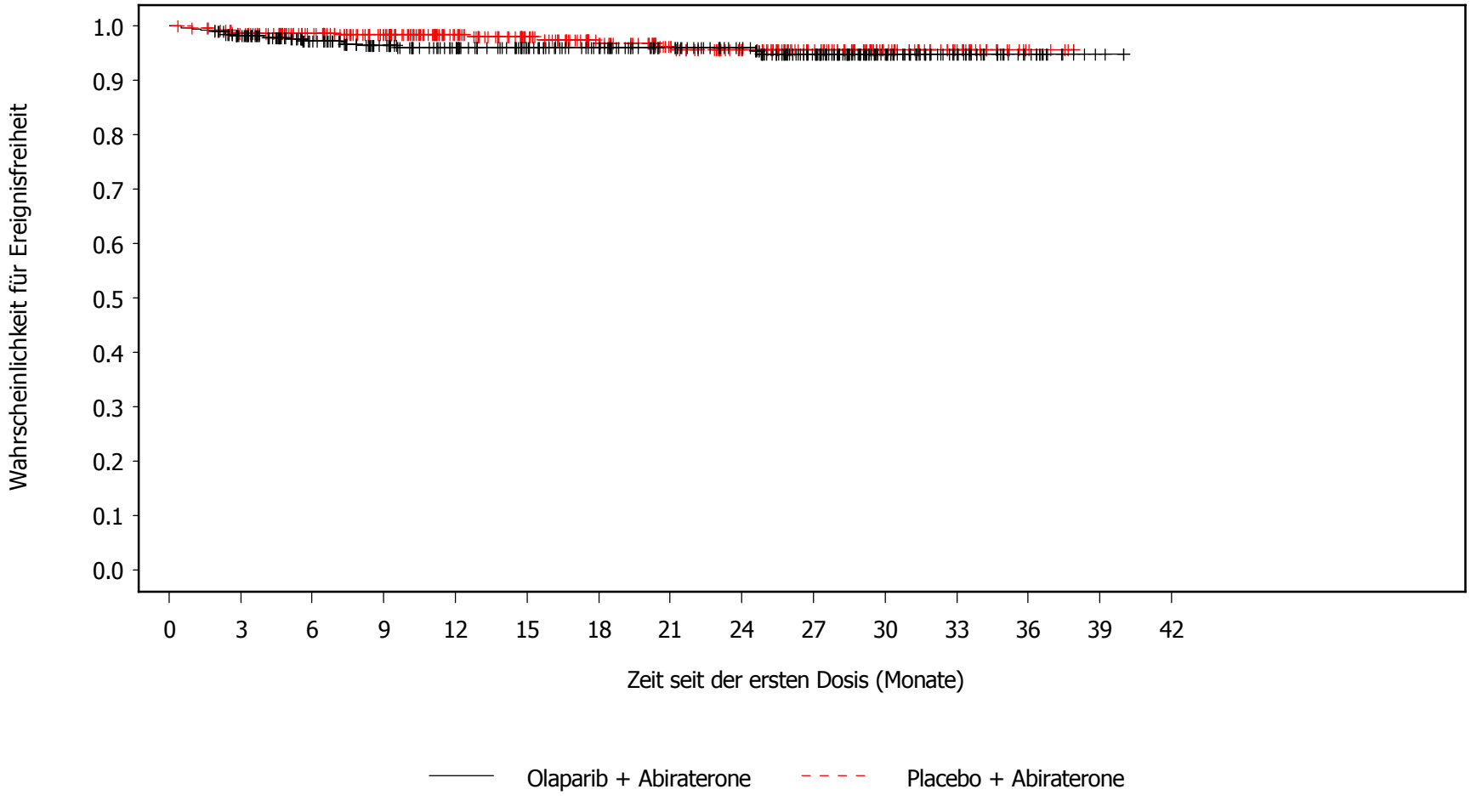


Anzahl an Patienten unter Risiko:

398	378	330	297	264	235	217	192	173	130	72	37	16	2	0	Olaparib + Abiraterone
396	369	330	287	237	203	171	147	123	90	50	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcr 06JUN2022:19:52 kvbv306

Figure 3.3.71 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Nasopharyngitis
Safety Analysis Set, DCO 14MAR2022

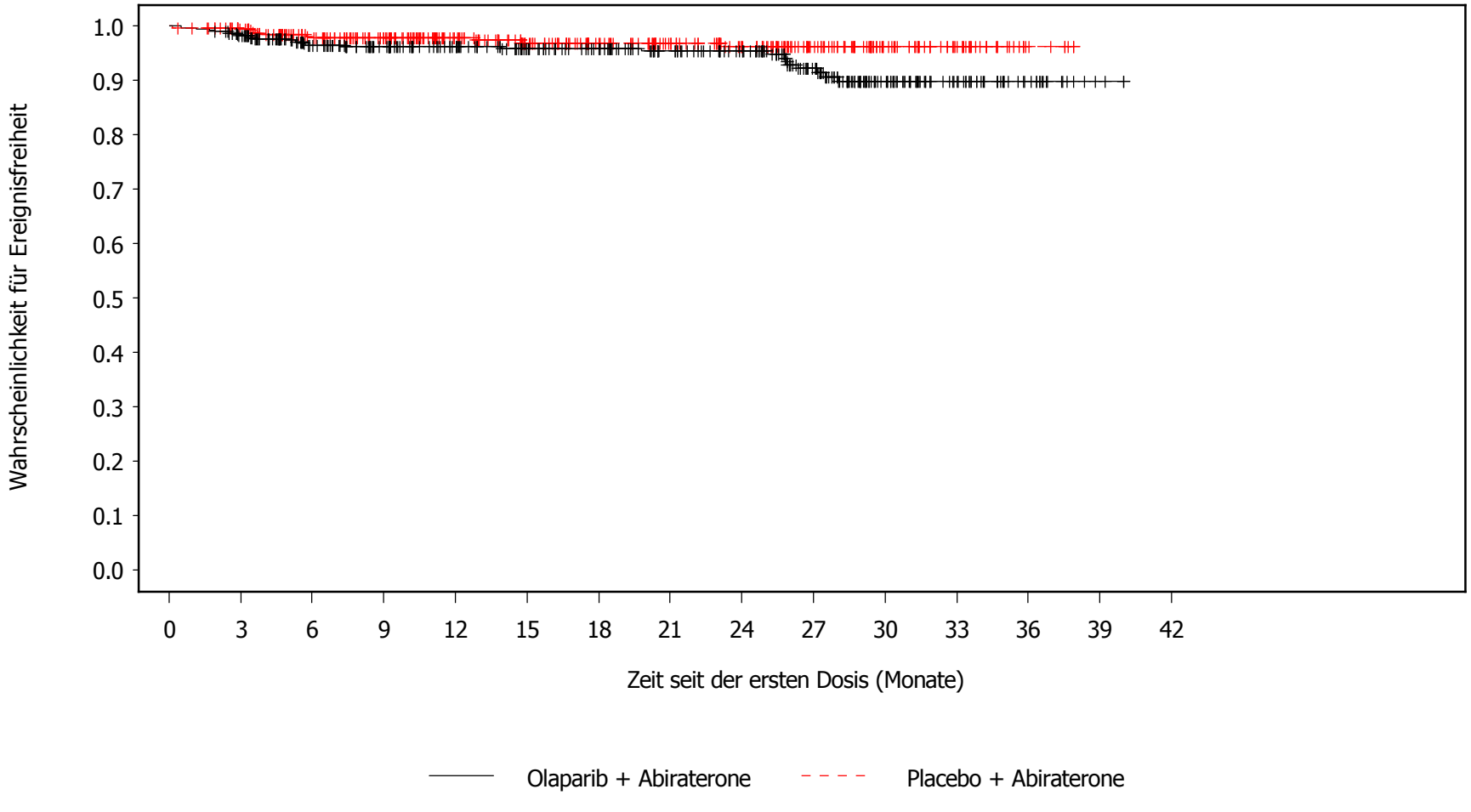


Anzahl an Patienten unter Risiko:

398	377	329	295	264	235	214	190	170	128	72	39	16	2	0	Olaparib + Abiraterone
396	375	336	296	246	209	175	147	120	88	50	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcs 06JUN2022:19:52 kvbv306

Figure 3.3.72 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Pneumonie
Safety Analysis Set, DCO 14MAR2022

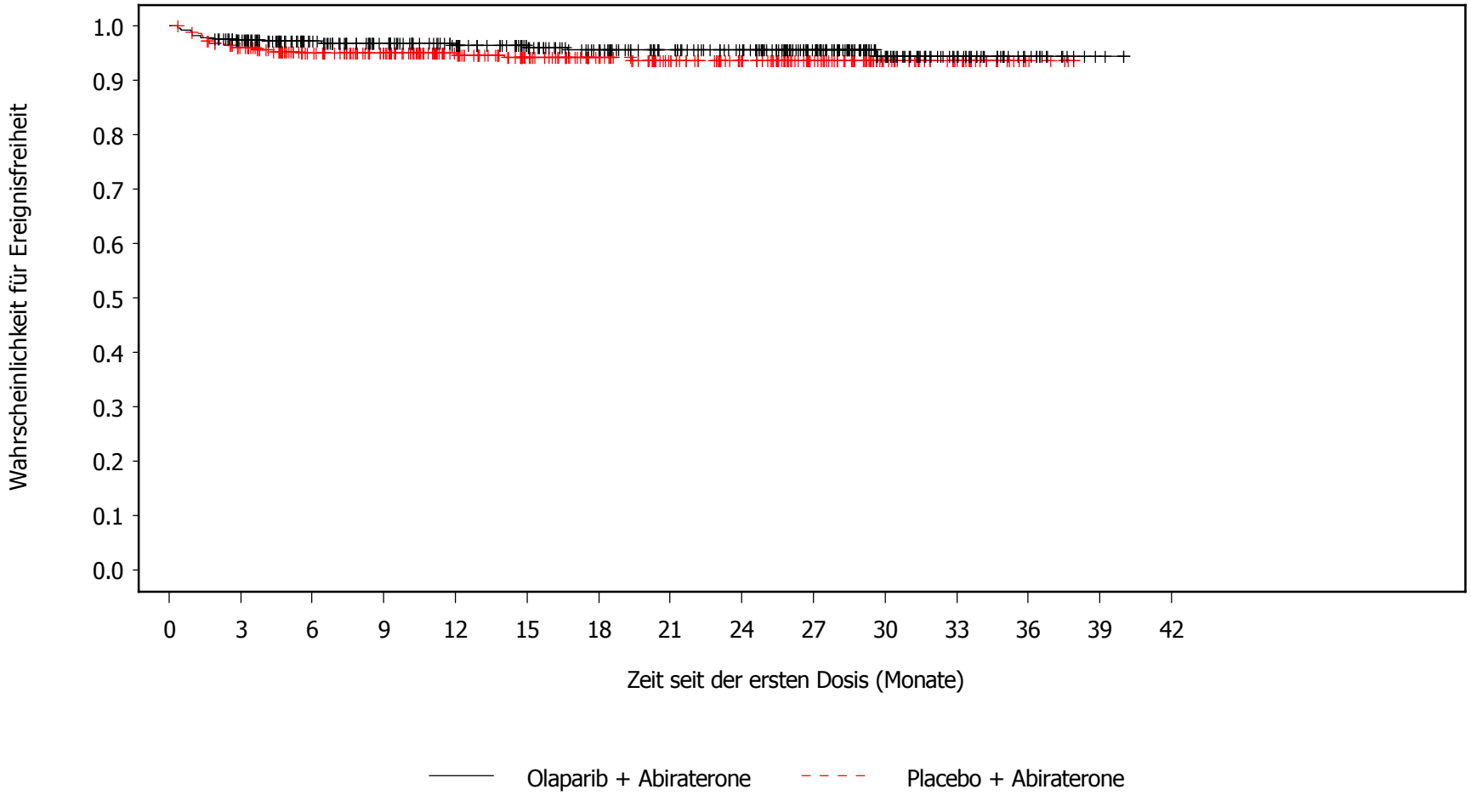


Anzahl an Patienten unter Risiko:

398	381	330	300	268	239	221	195	175	128	73	41	17	2	0	Olaparib + Abiraterone
396	378	335	294	245	209	178	152	126	91	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebct 06JUN2022:19:52 kvbv306

Figure 3.3.73 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Leber- und Gallenerkrankungen
Safety Analysis Set, DCO 14MAR2022

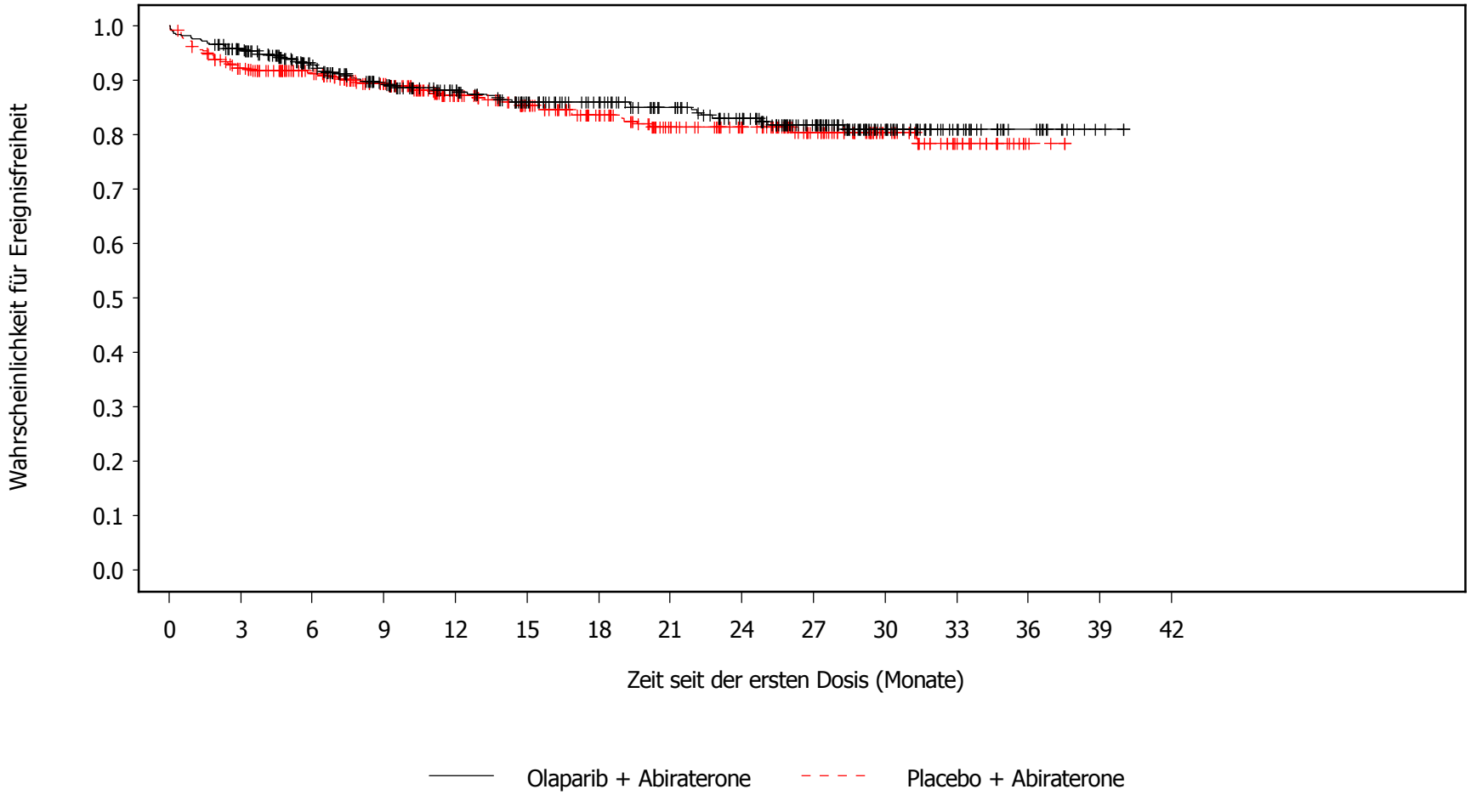


Anzahl an Patienten unter Risiko:

398	374	329	299	268	241	218	194	175	131	73	40	16	2	0	Olaparib + Abiraterone
396	367	325	292	244	208	176	149	123	91	52	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcu 06JUN2022:19:52 kvbv306

Figure 3.3.74 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Psychiatrische Erkrankungen
Safety Analysis Set, DCO 14MAR2022



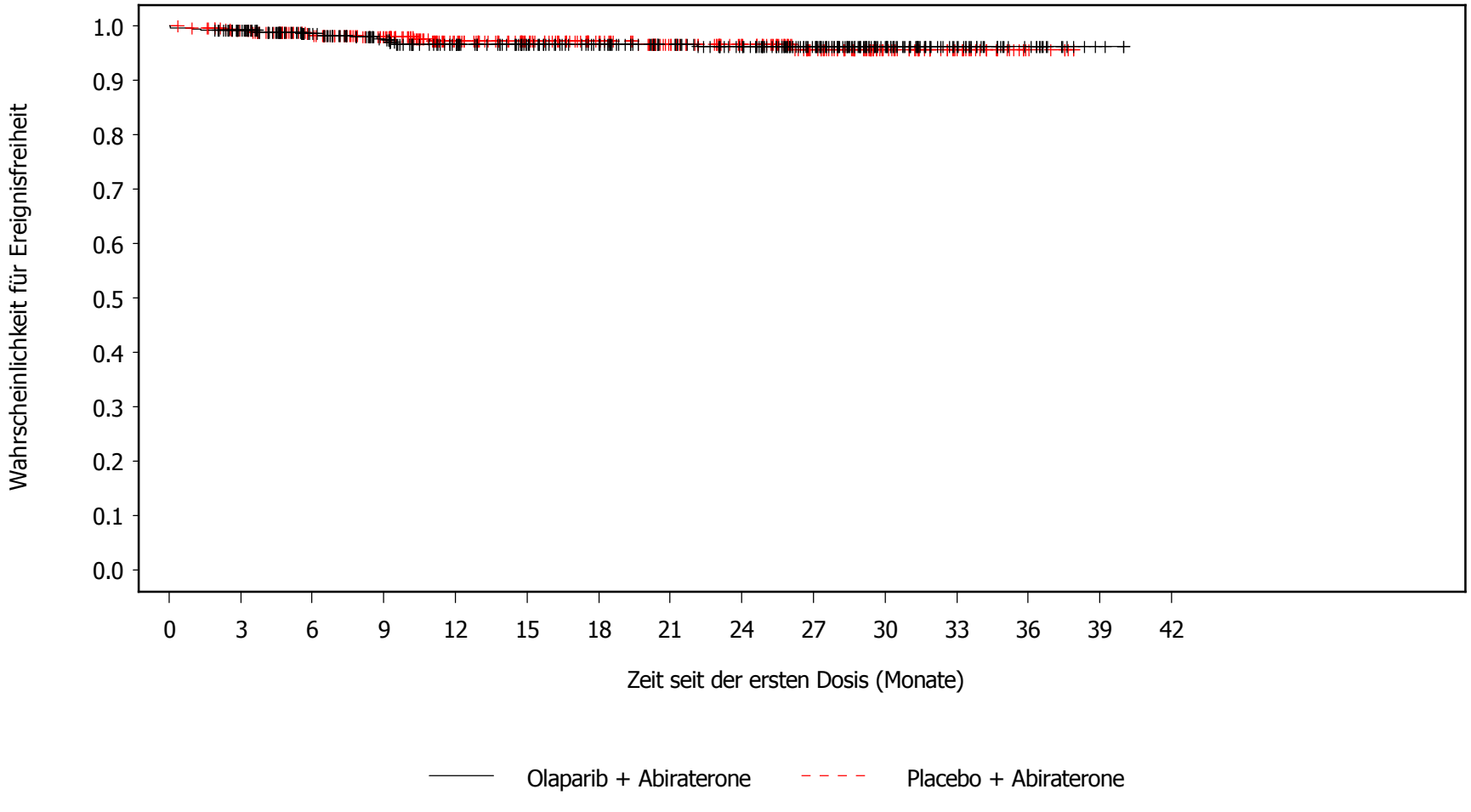
Anzahl an Patienten unter Risiko:

398	368	319	279	246	216	197	174	152	114	63	32	15	2	0	Olaparib + Abiraterone
396	352	313	273	222	188	158	130	110	80	47	24	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcv 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.75 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Angst
Safety Analysis Set, DCO 14MAR2022

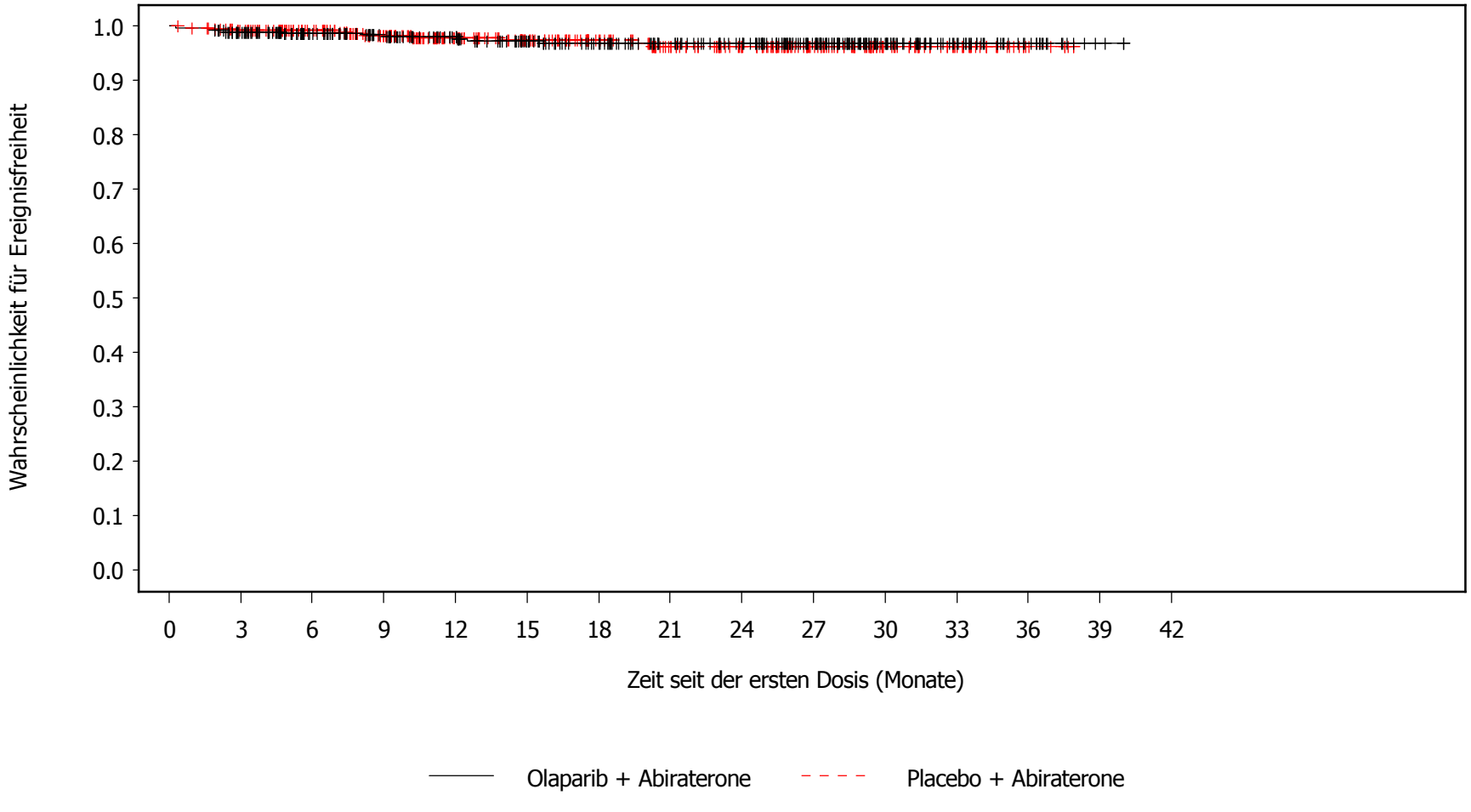


Anzahl an Patienten unter Risiko:

398	381	334	299	266	238	217	193	173	131	74	38	17	2	0	Olaparib + Abiraterone
396	378	337	297	244	208	176	149	124	90	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcw 06JUN2022:19:52 kvbv306

Figure 3.3.76 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Depression
Safety Analysis Set, DCO 14MAR2022

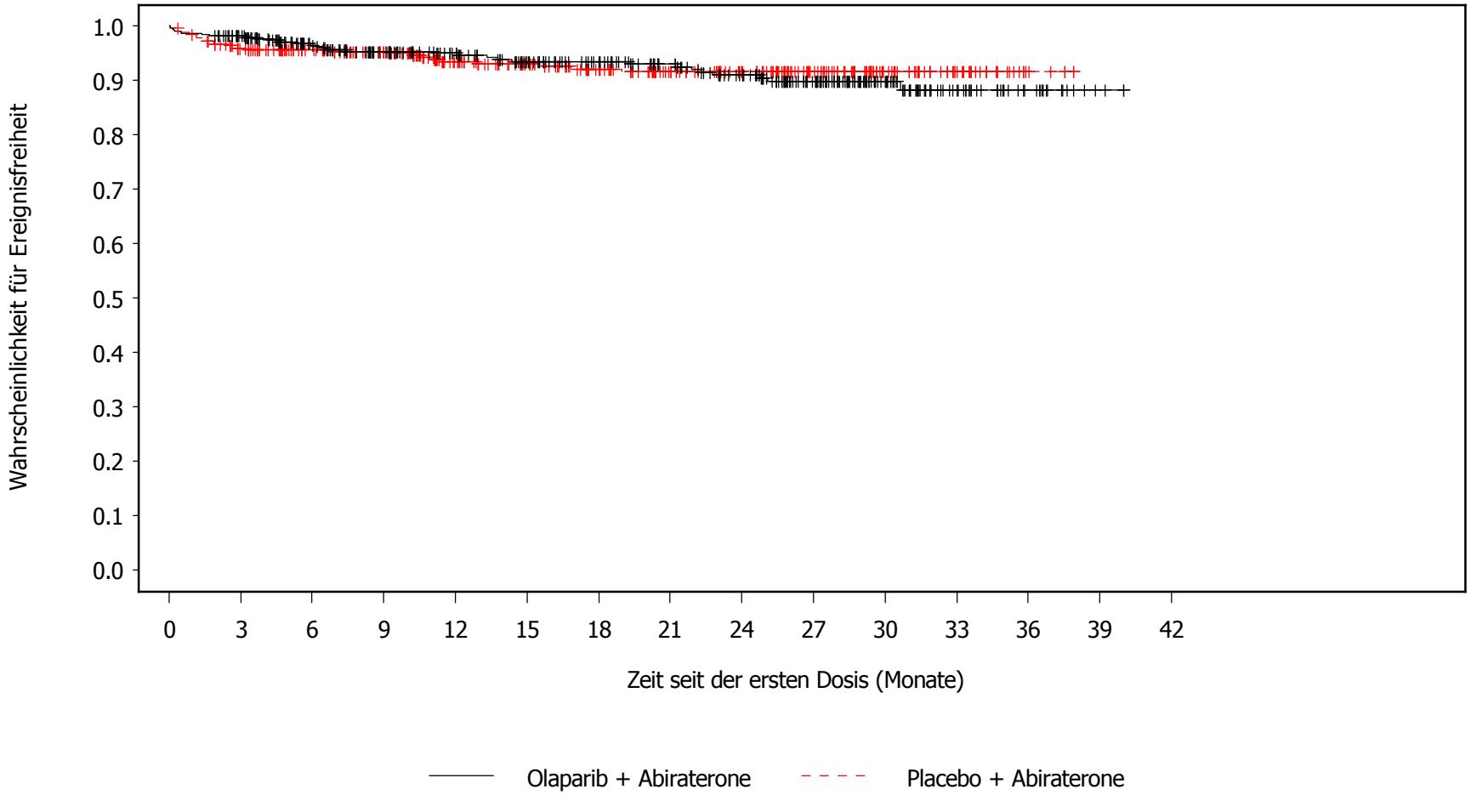


Anzahl an Patienten unter Risiko:

398	380	337	305	273	242	220	195	175	132	74	40	17	2	0	Olaparib + Abiraterone
396	377	338	295	245	208	176	148	124	89	51	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcx 06JUN2022:19:52 kvbv306

Figure 3.3.77 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Schlaflosigkeit
Safety Analysis Set, DCO 14MAR2022

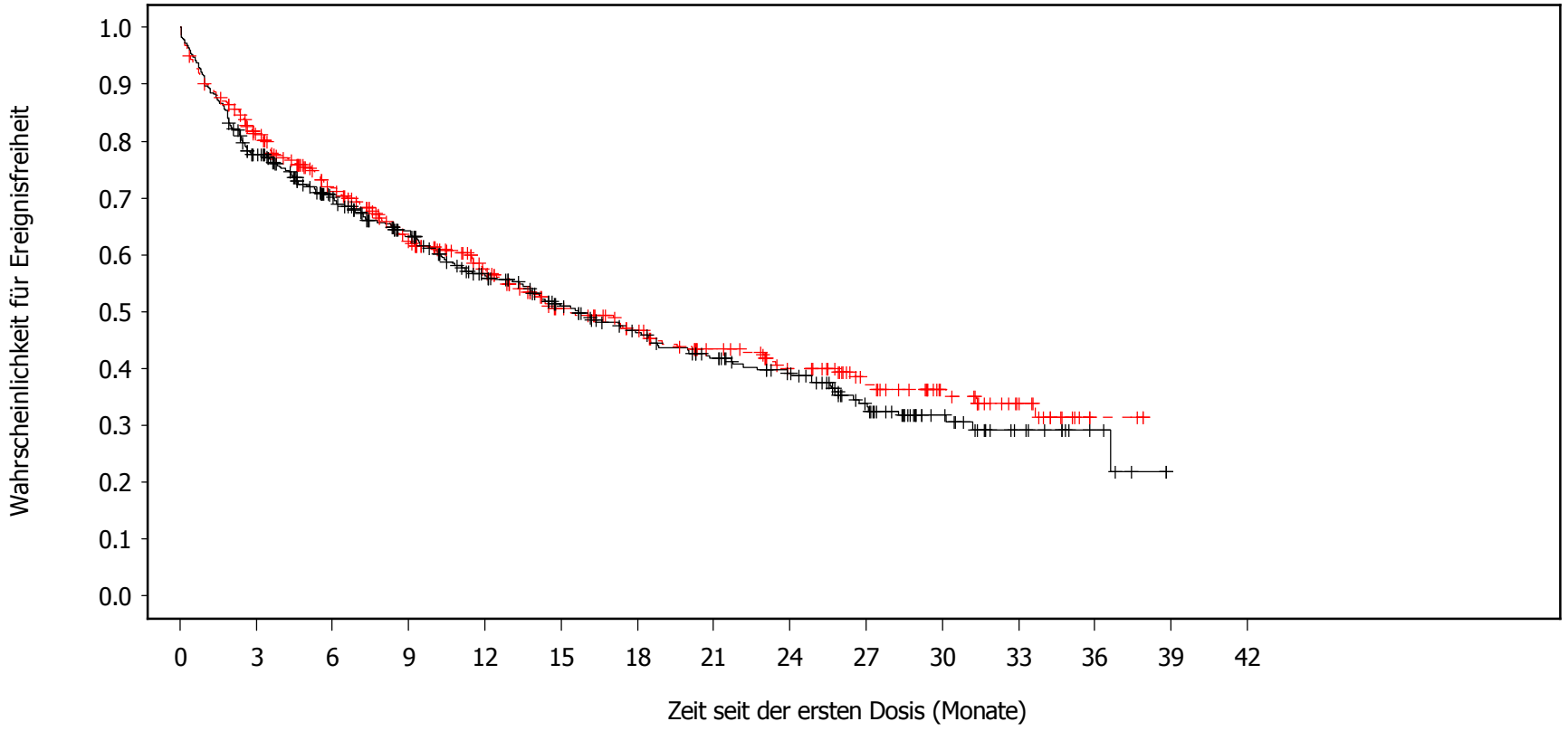


Anzahl an Patienten unter Risiko:

398	377	328	294	263	233	212	188	165	124	70	35	15	2	0	Olaparib + Abiraterone
396	364	327	288	237	203	173	148	123	90	52	28	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcy 06JUN2022:19:52 kvbv306

Figure 3.3.78 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Safety Analysis Set, DCO 14MAR2022



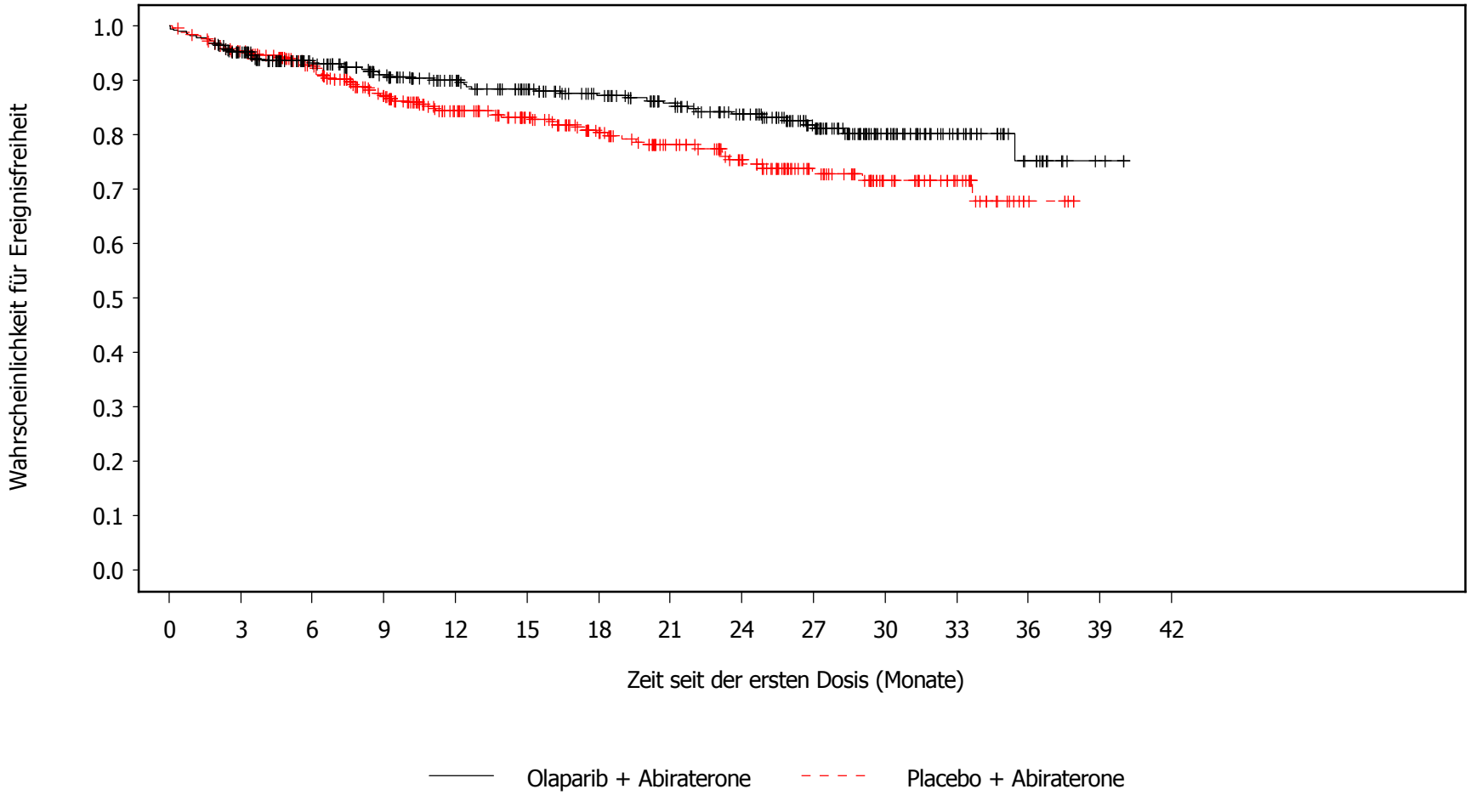
Anzahl an Patienten unter Risiko:

398	299	242	199	156	126	105	89	74	50	27	13	5	0	0	Olaparib + Abiraterone
396	308	248	196	159	123	103	85	67	48	31	17	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebcz 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.79 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Arthralgie
Safety Analysis Set, DCO 14MAR2022

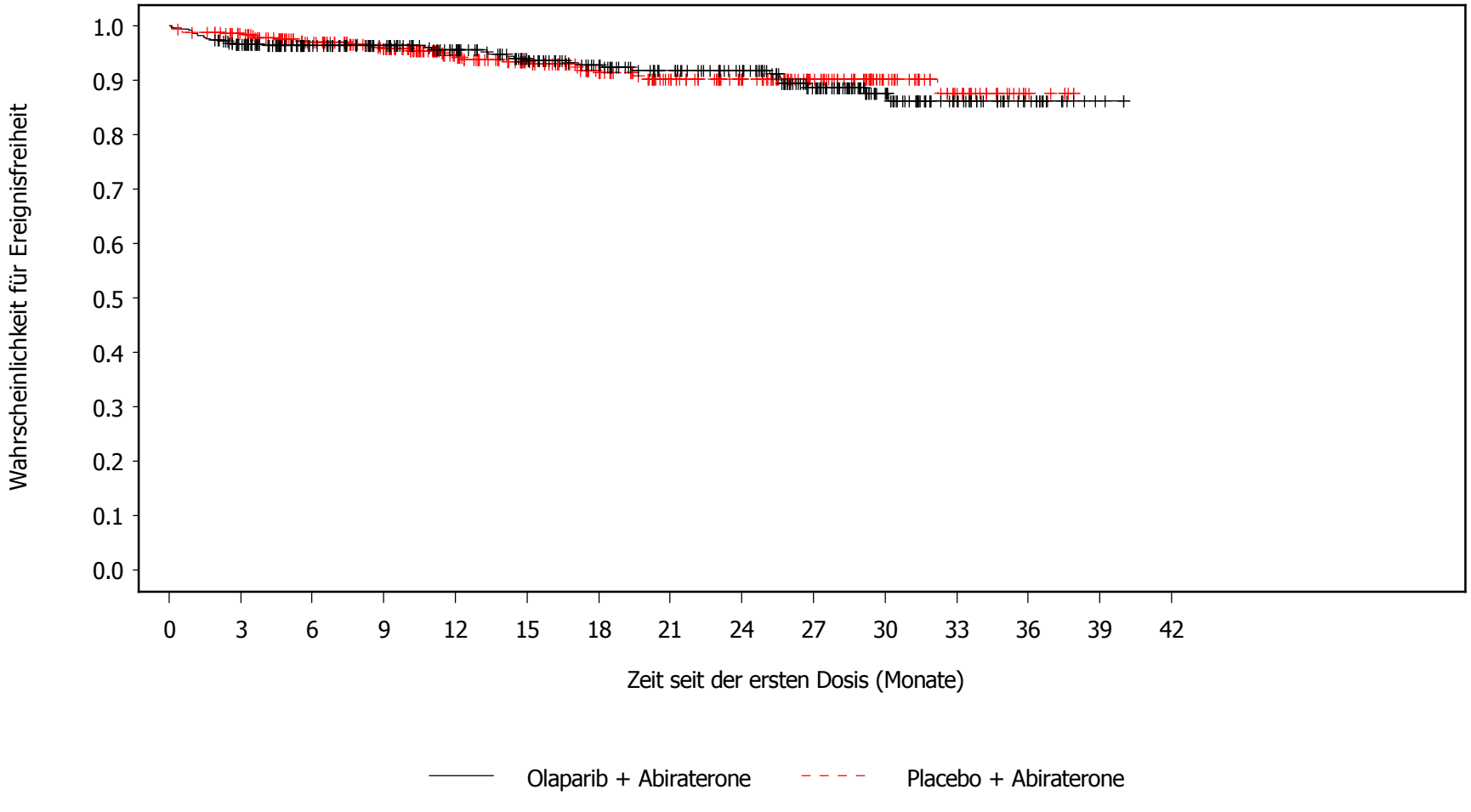


Anzahl an Patienten unter Risiko:

398	365	316	279	246	219	197	175	153	115	65	34	13	2	0	Olaparib + Abiraterone
396	362	317	266	221	186	152	127	103	72	45	26	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebda 06JUN2022:19:52 kvbv306

Figure 3.3.80 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Brustschmerzen die Skelettmuskulatur betreffend
Safety Analysis Set, DCO 14MAR2022

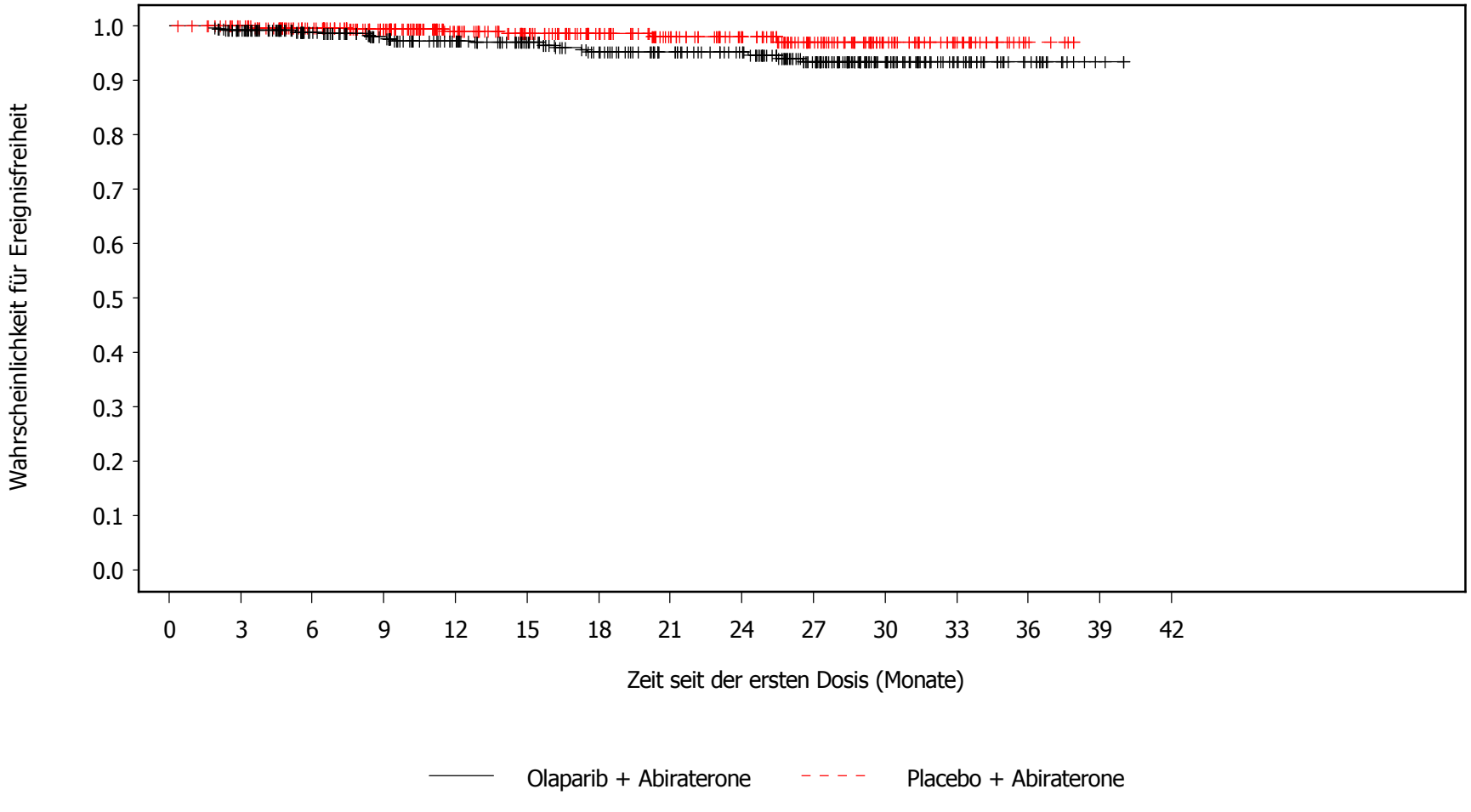


Anzahl an Patienten unter Risiko:

398	371	326	297	263	229	205	182	163	121	70	39	17	2	0	Olaparib + Abiraterone
396	376	333	293	241	203	169	144	119	88	52	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdb 06JUN2022:19:52 kvbv306

Figure 3.3.81 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Knochenschmerzen
Safety Analysis Set, DCO 14MAR2022

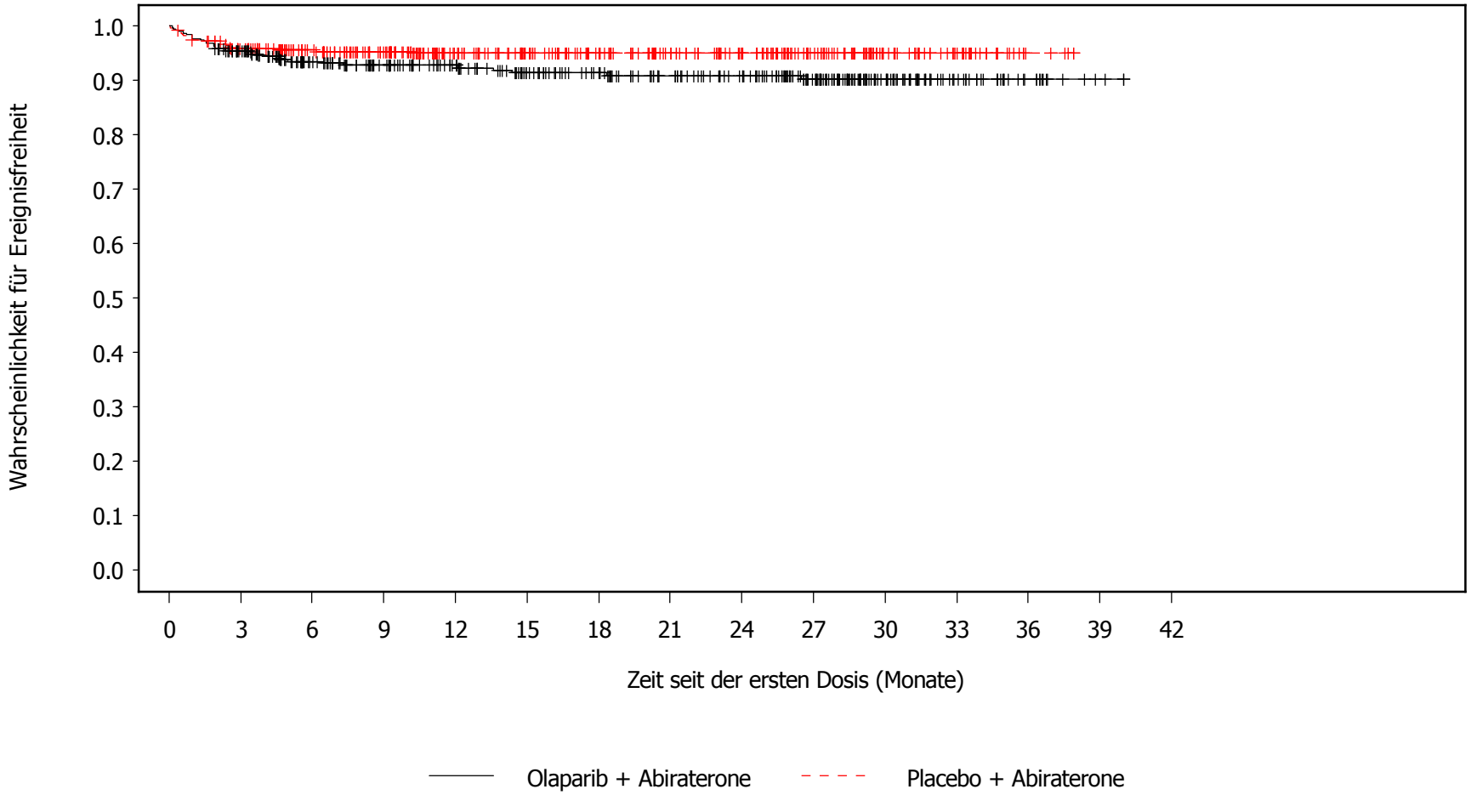


Anzahl an Patienten unter Risiko:

398	381	336	303	269	238	214	192	174	129	73	39	17	2	0	Olaparib + Abiraterone
396	380	341	300	249	212	179	152	127	92	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdc 06JUN2022:19:52 kvbv306

Figure 3.3.82 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Muskelspasmen
Safety Analysis Set, DCO 14MAR2022



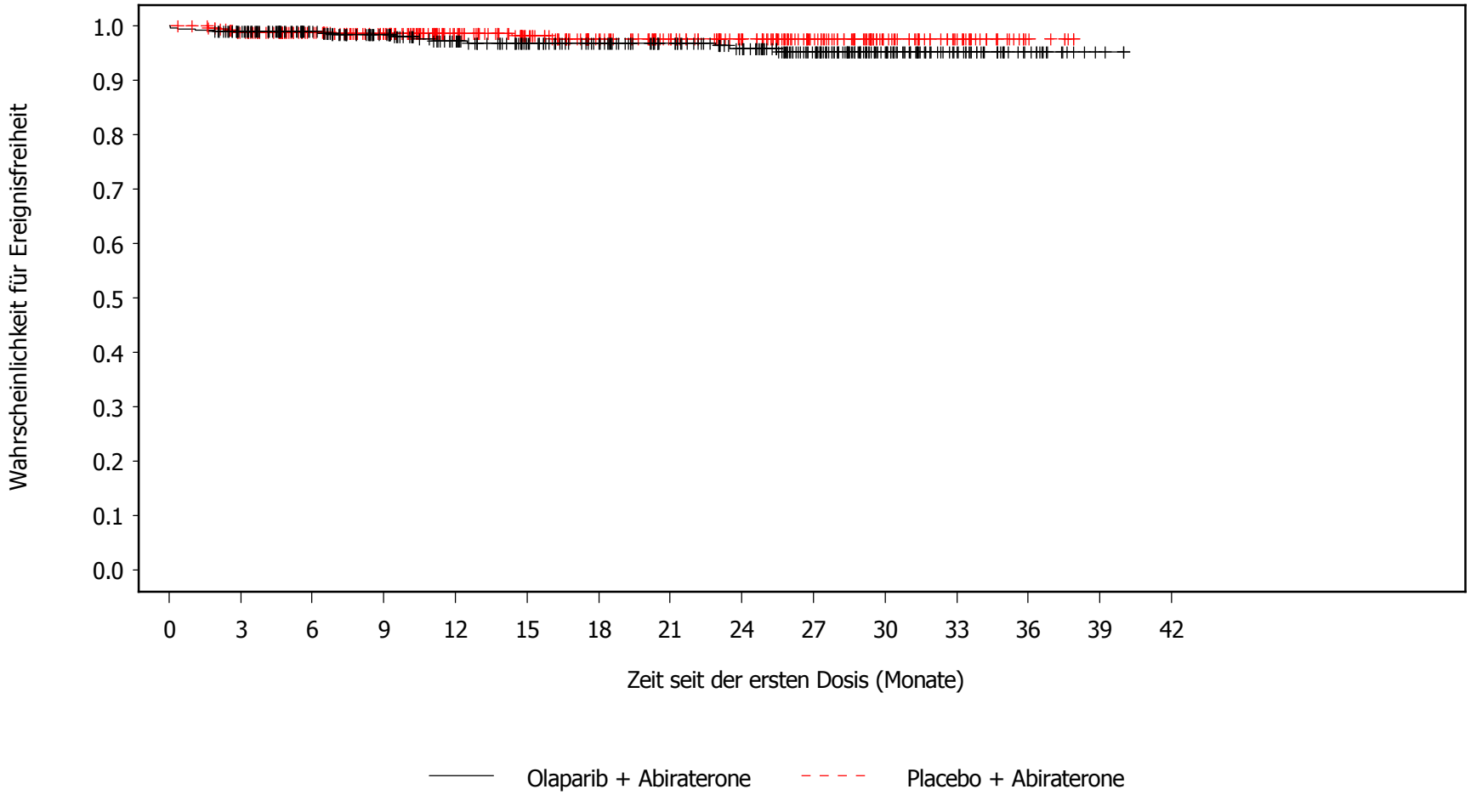
Anzahl an Patienten unter Risiko:

398	366	316	283	254	222	203	180	162	122	67	33	13	2	0	Olaparib + Abiraterone
396	364	324	285	236	201	171	146	120	87	48	28	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdd 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.83 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Muskulaere Schwaeche
Safety Analysis Set, DCO 14MAR2022

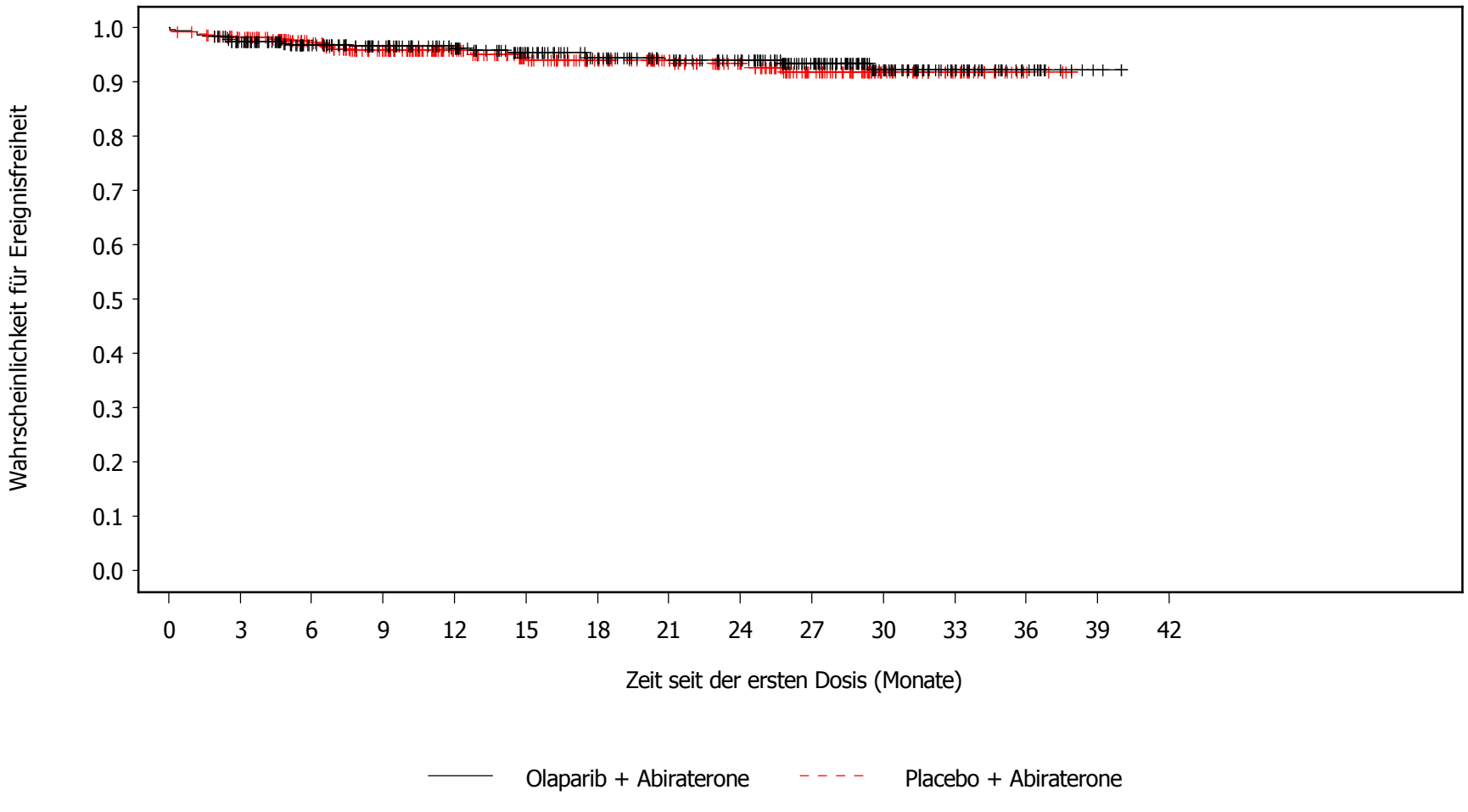


Anzahl an Patienten unter Risiko:

398	380	336	303	269	238	218	194	172	131	76	40	16	2	0	Olaparib + Abiraterone
396	376	337	297	246	209	176	152	126	92	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebde 06JUN2022:19:52 kvbv306

Figure 3.3.84 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Myalgie
Safety Analysis Set, DCO 14MAR2022

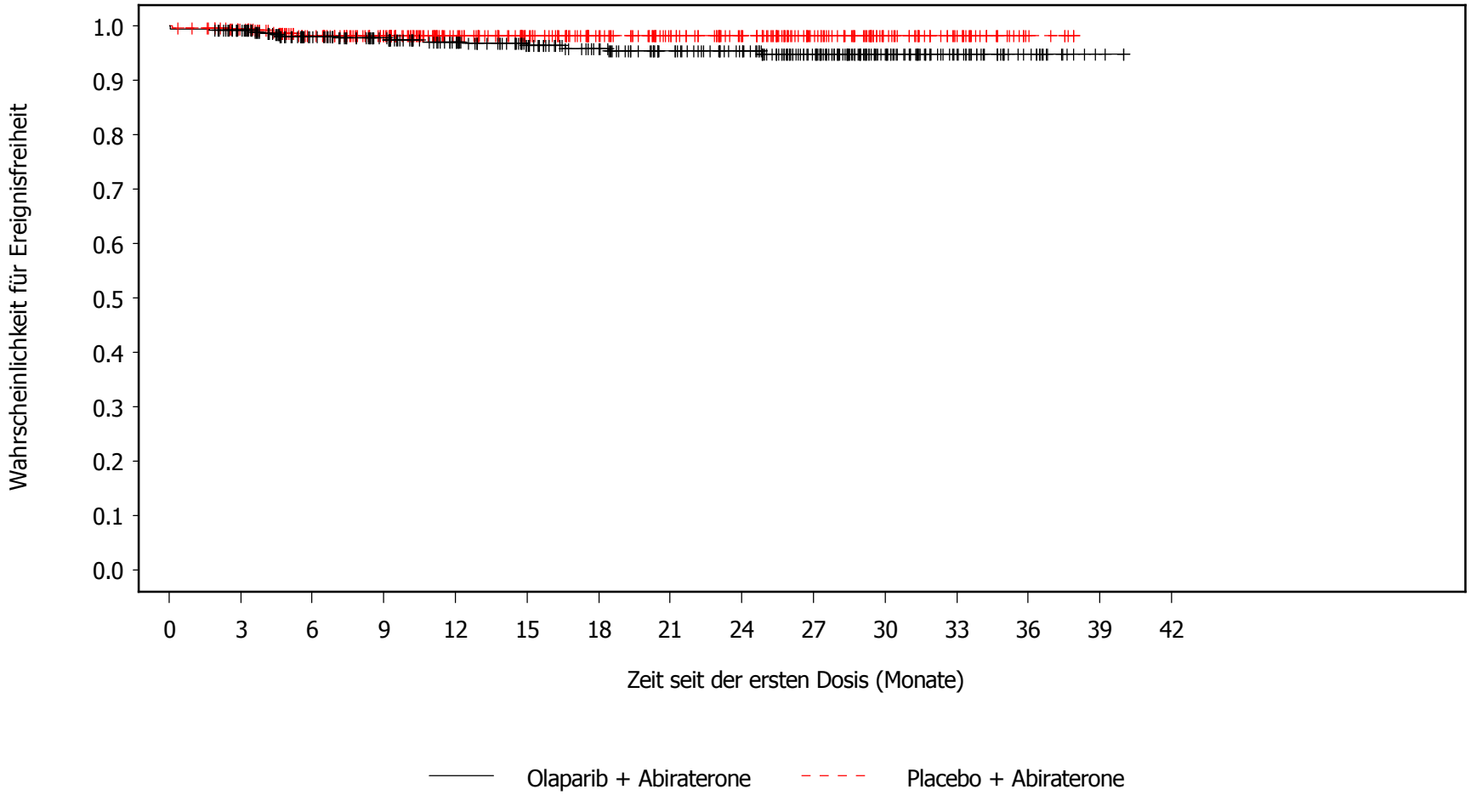


Anzahl an Patienten unter Risiko:

398	374	327	295	263	231	208	184	166	126	72	39	15	2	0	Olaparib + Abiraterone
396	373	332	288	240	203	173	150	124	90	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdf 06JUN2022:19:52 kvbv306

Figure 3.3.85 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Nackenschmerzen
Safety Analysis Set, DCO 14MAR2022



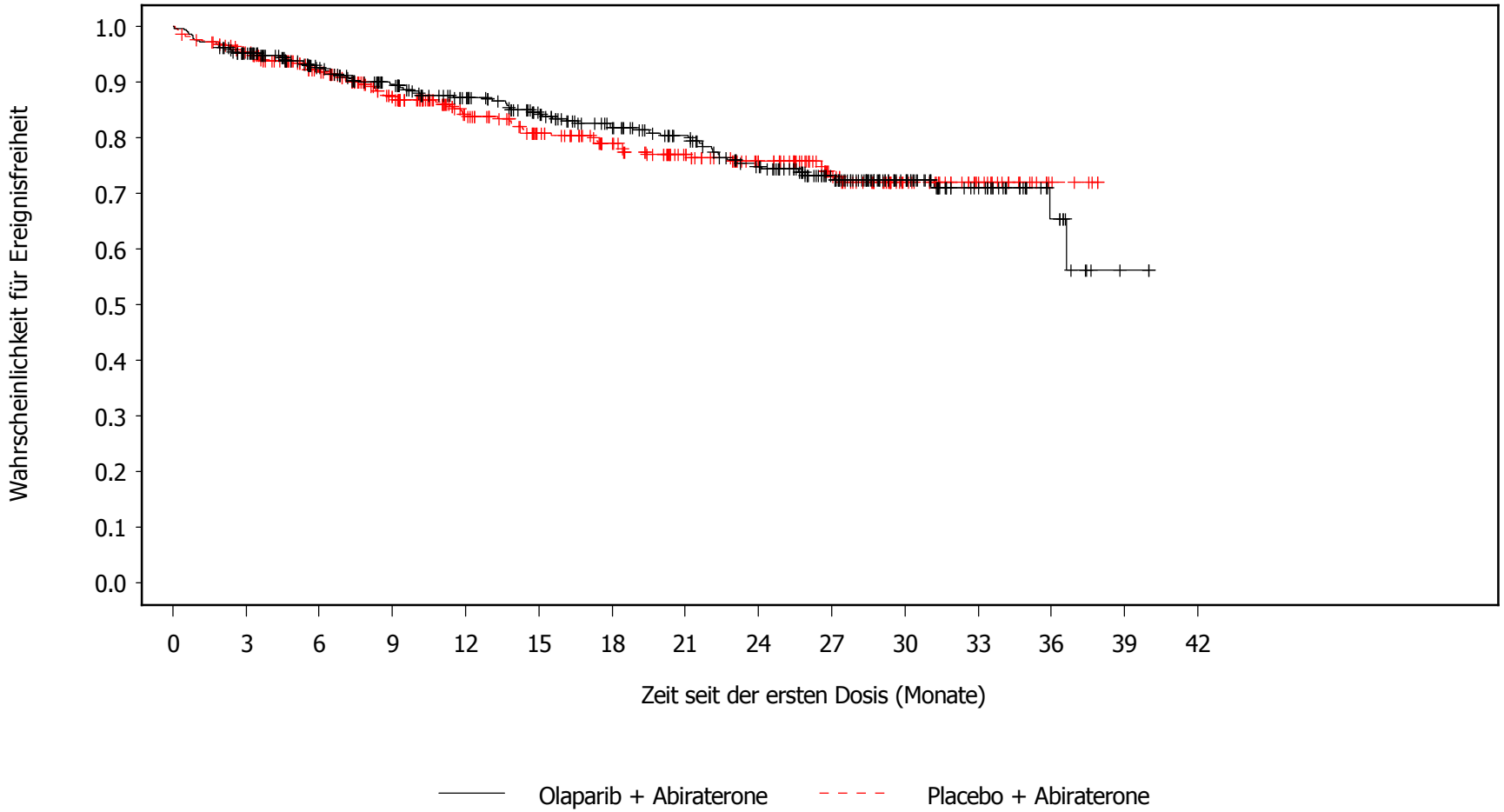
Anzahl an Patienten unter Risiko:

398	382	334	303	270	238	216	192	173	132	74	40	17	2	0	Olaparib + Abiraterone
396	378	335	297	247	211	178	152	126	91	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdg 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.86 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Rueckenschmerzen
Safety Analysis Set, DCO 14MAR2022

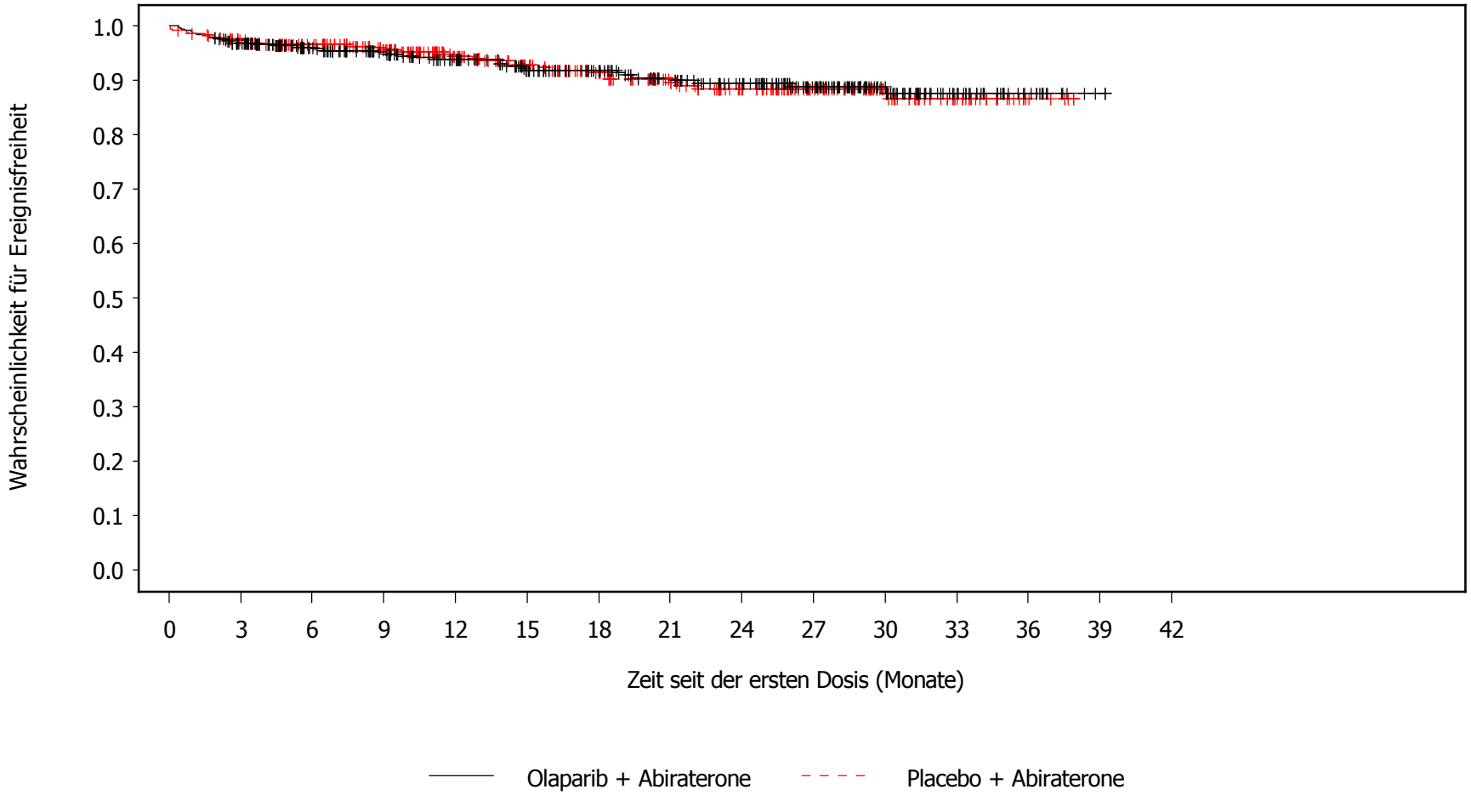


Anzahl an Patienten unter Risiko:

398	366	318	281	246	214	188	167	142	107	63	33	12	1	0	Olaparib + Abiraterone
396	362	318	269	220	186	159	133	106	76	45	25	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdh 06JUN2022:19:52 kvbv306

Figure 3.3.87 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerz in einer Extremitaet
Safety Analysis Set, DCO 14MAR2022



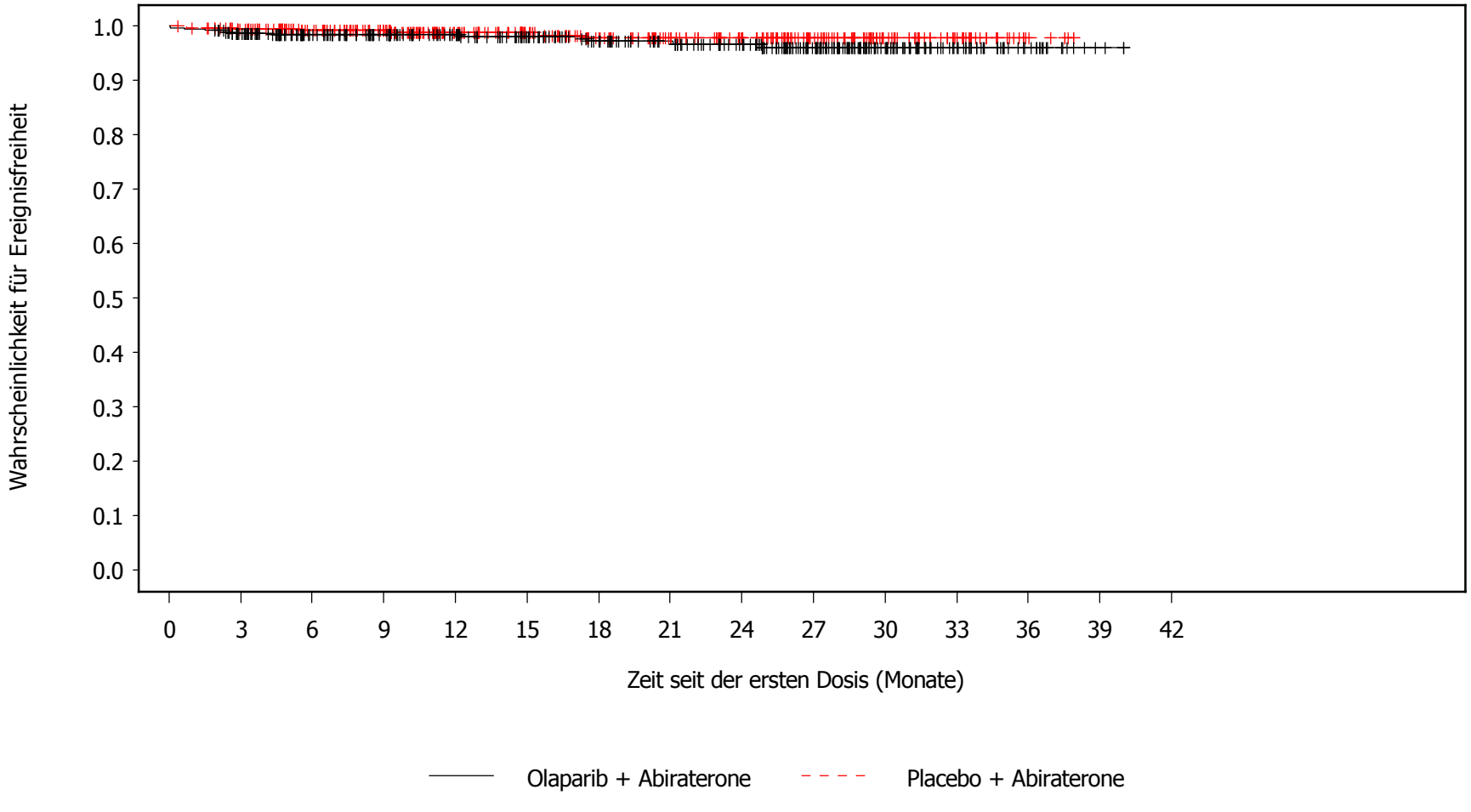
Anzahl an Patienten unter Risiko:

398	374	327	294	260	227	208	183	161	120	71	37	14	1	0	Olaparib + Abiraterone
396	370	334	293	242	204	170	142	117	86	51	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdi 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.88 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Schmerzen des Muskel- und Skelettsystems
Safety Analysis Set, DCO 14MAR2022

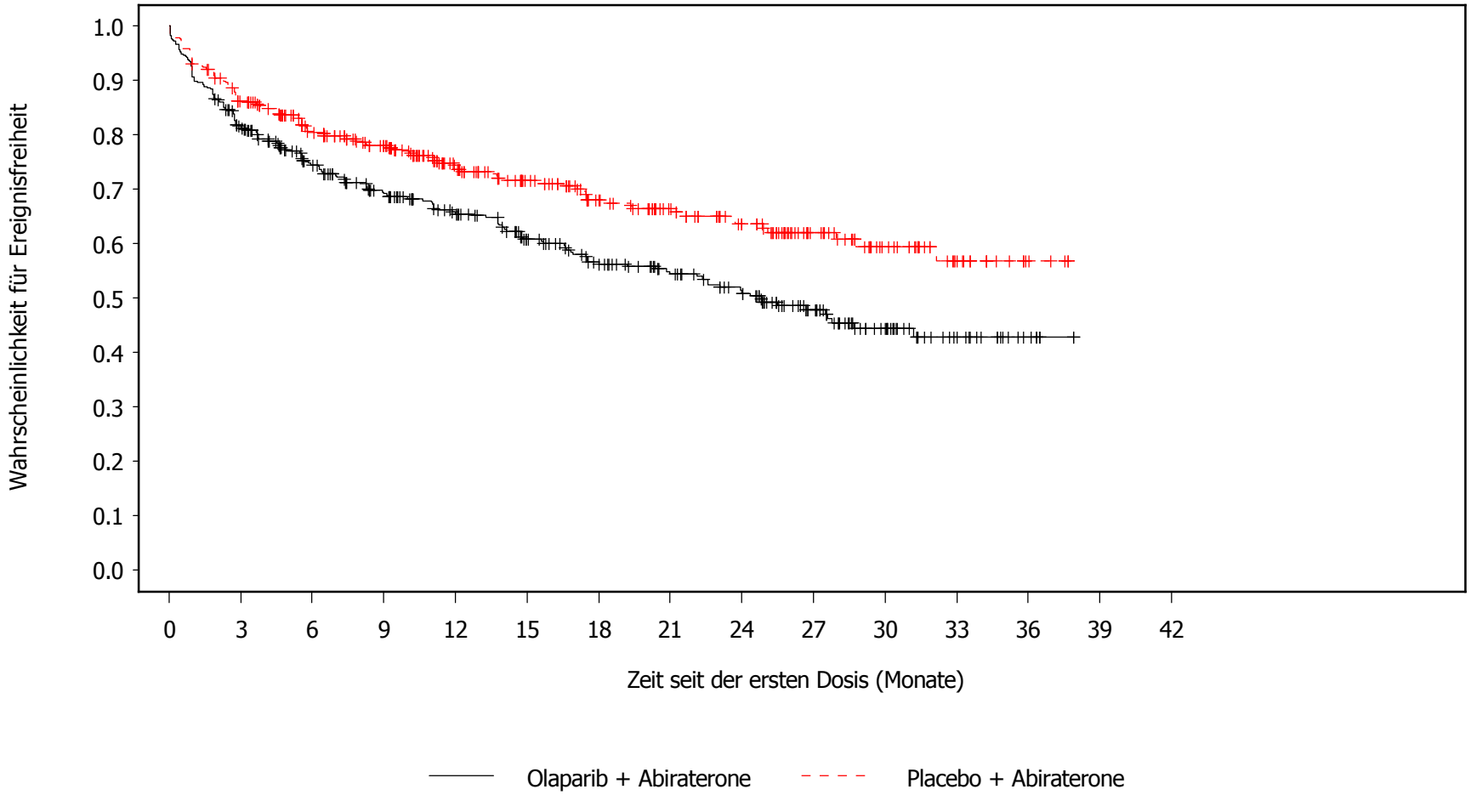


Anzahl an Patienten unter Risiko:

398	379	336	305	273	242	219	197	176	133	76	41	17	2	0	Olaparib + Abiraterone
396	378	338	298	247	211	178	152	127	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdj 06JUN2022:19:52 kvbv306

Figure 3.3.89 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 14MAR2022

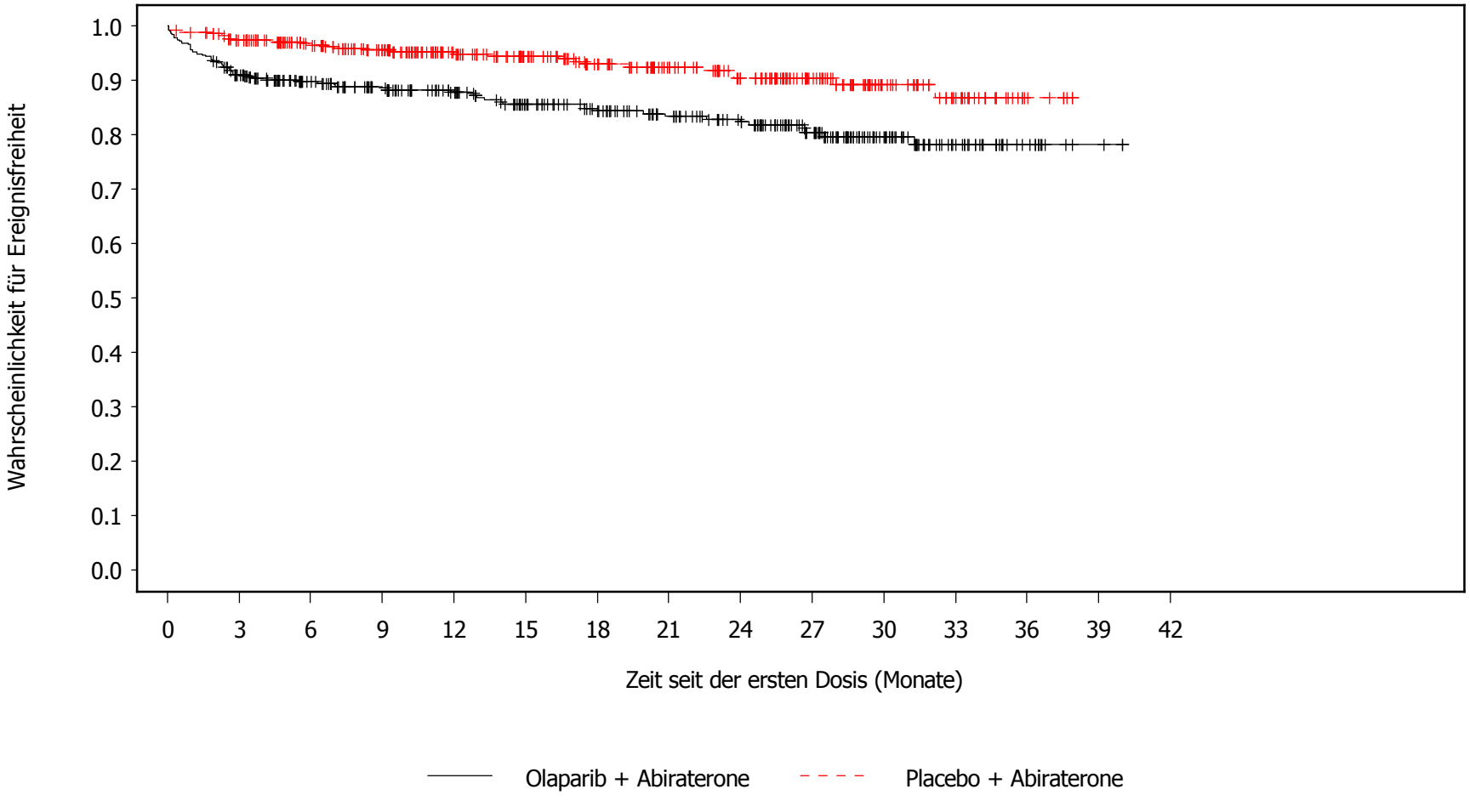


Anzahl an Patienten unter Risiko:

398	316	262	224	190	158	135	114	97	67	38	19	6	0	0	Olaparib + Abiraterone
396	332	279	243	190	156	127	105	84	57	36	17	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdk 06JUN2022:19:52 kvbv306

Figure 3.3.90 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Appetit vermindert
Safety Analysis Set, DCO 14MAR2022



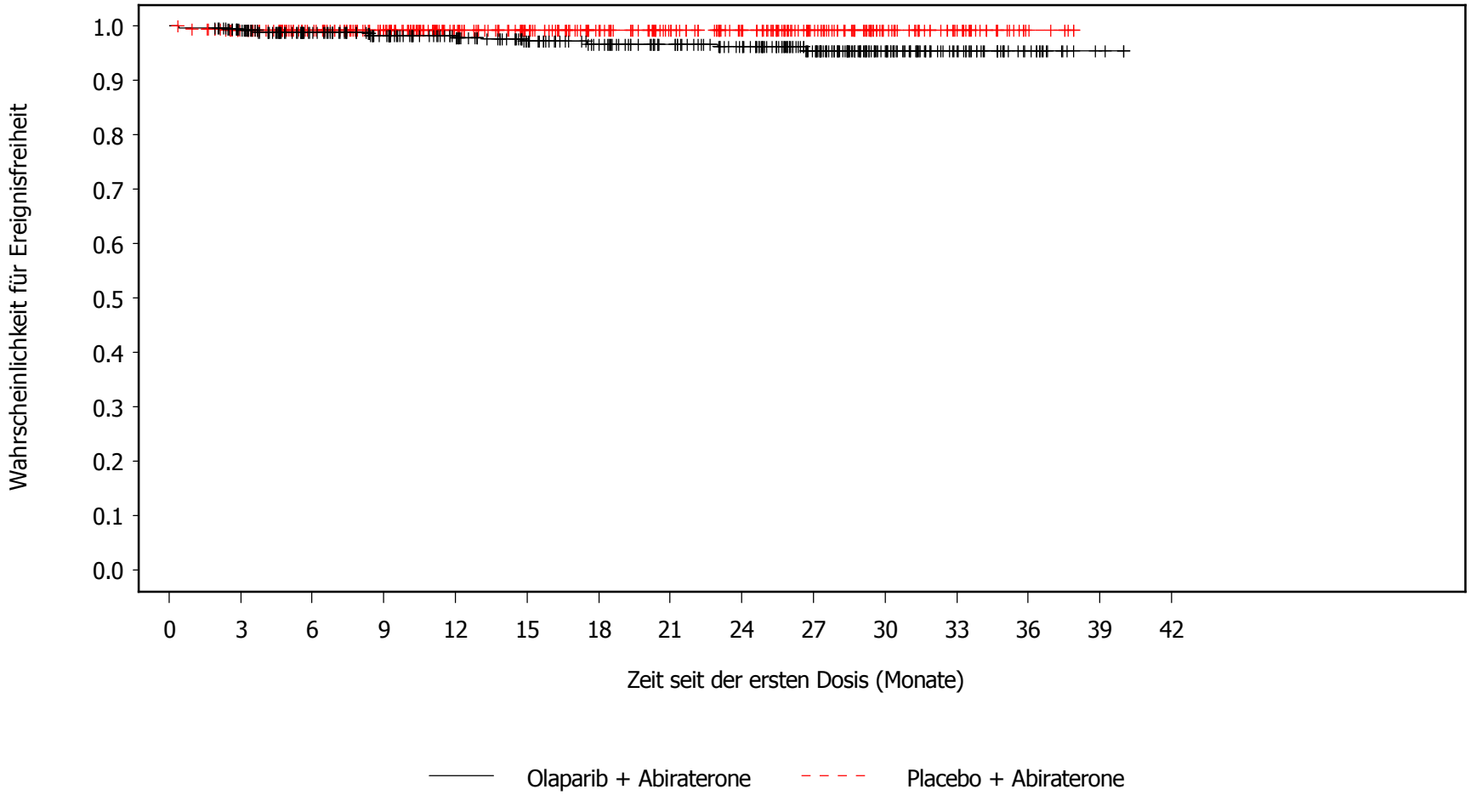
Anzahl an Patienten unter Risiko:

398	353	311	280	247	216	196	172	152	116	67	33	12	2	0	Olaparib + Abiraterone
396	371	330	291	243	209	177	151	123	90	52	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdl 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.91 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Dehydratation
Safety Analysis Set, DCO 14MAR2022



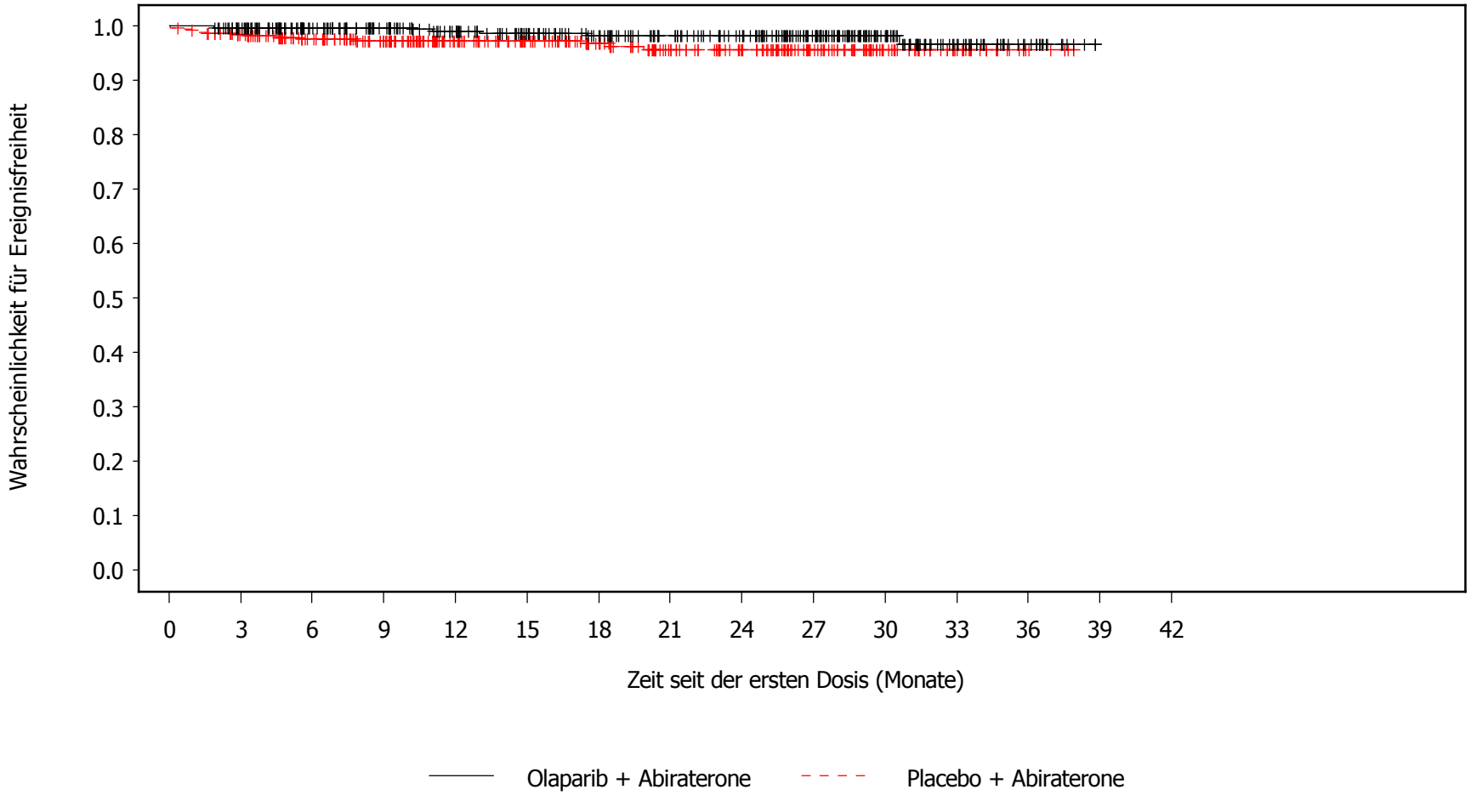
Anzahl an Patienten unter Risiko:

398	382	338	306	273	241	221	199	178	133	75	40	16	2	0	Olaparib + Abiraterone
396	377	338	298	247	212	180	154	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdm 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.92 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Diabetes mellitus
Safety Analysis Set, DCO 14MAR2022

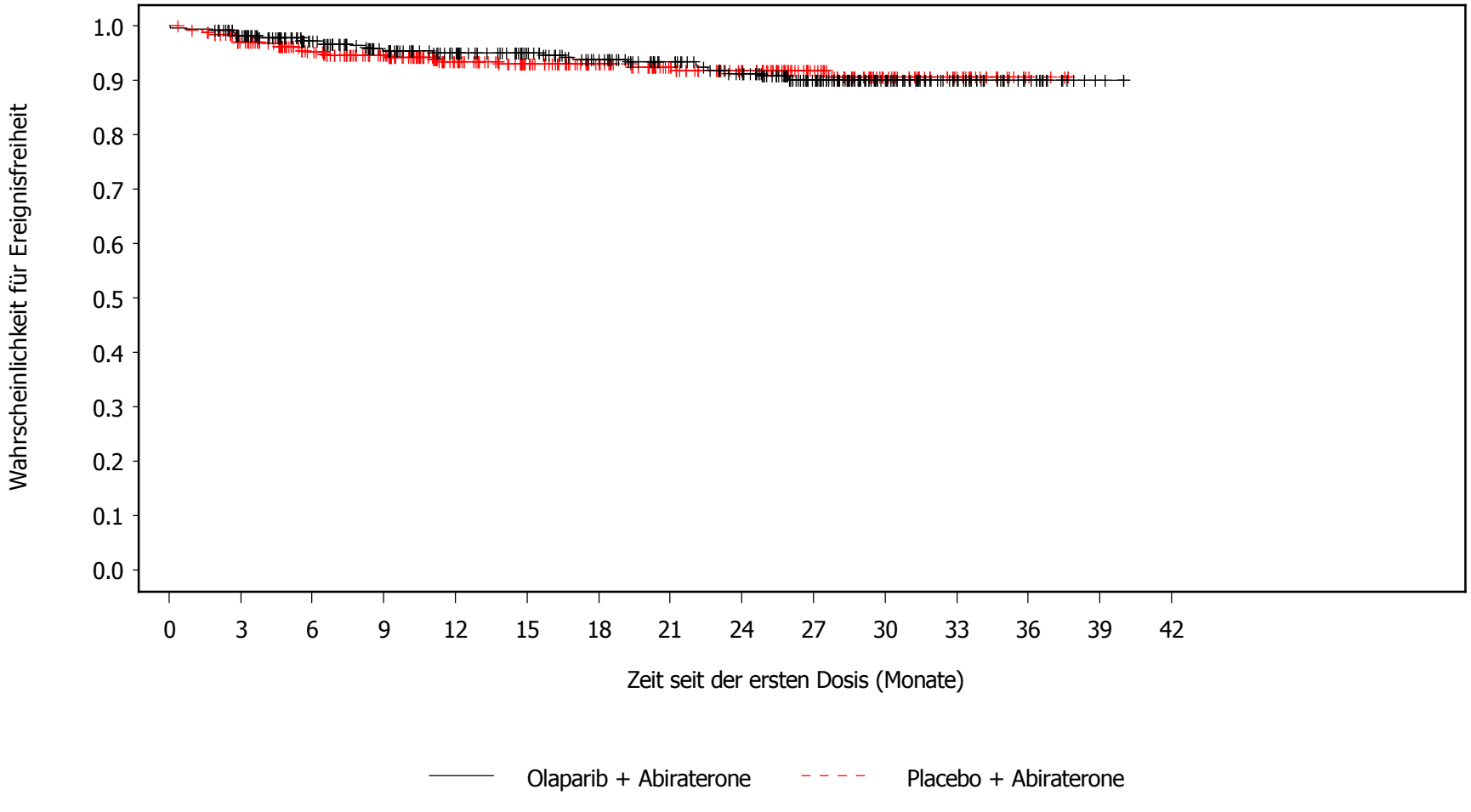


Anzahl an Patienten unter Risiko:

398	383	338	307	273	242	221	196	176	133	75	39	15	0	0	Olaparib + Abiraterone
396	375	336	297	246	210	177	149	124	89	52	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdn 06JUN2022:19:52 kvbv306

Figure 3.3.93 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hyperglykaemie
Safety Analysis Set, DCO 14MAR2022

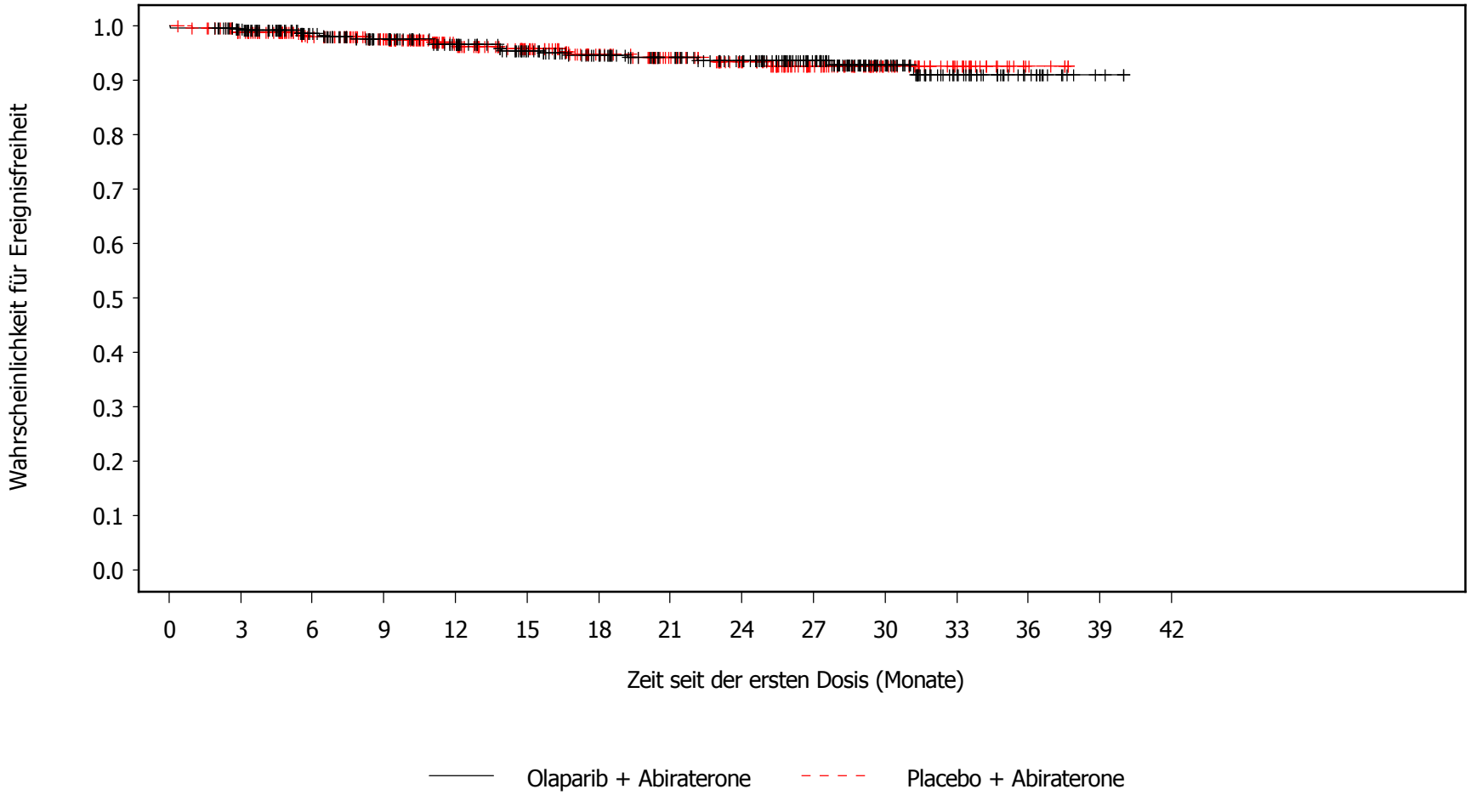


Anzahl an Patienten unter Risiko:

398	377	330	295	263	235	214	190	170	126	74	40	17	2	0	Olaparib + Abiraterone
396	369	324	284	233	196	166	140	116	84	50	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdo 06JUN2022:19:52 kvbv306

Figure 3.3.94 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hypertriglyzeridaemie
Safety Analysis Set, DCO 14MAR2022

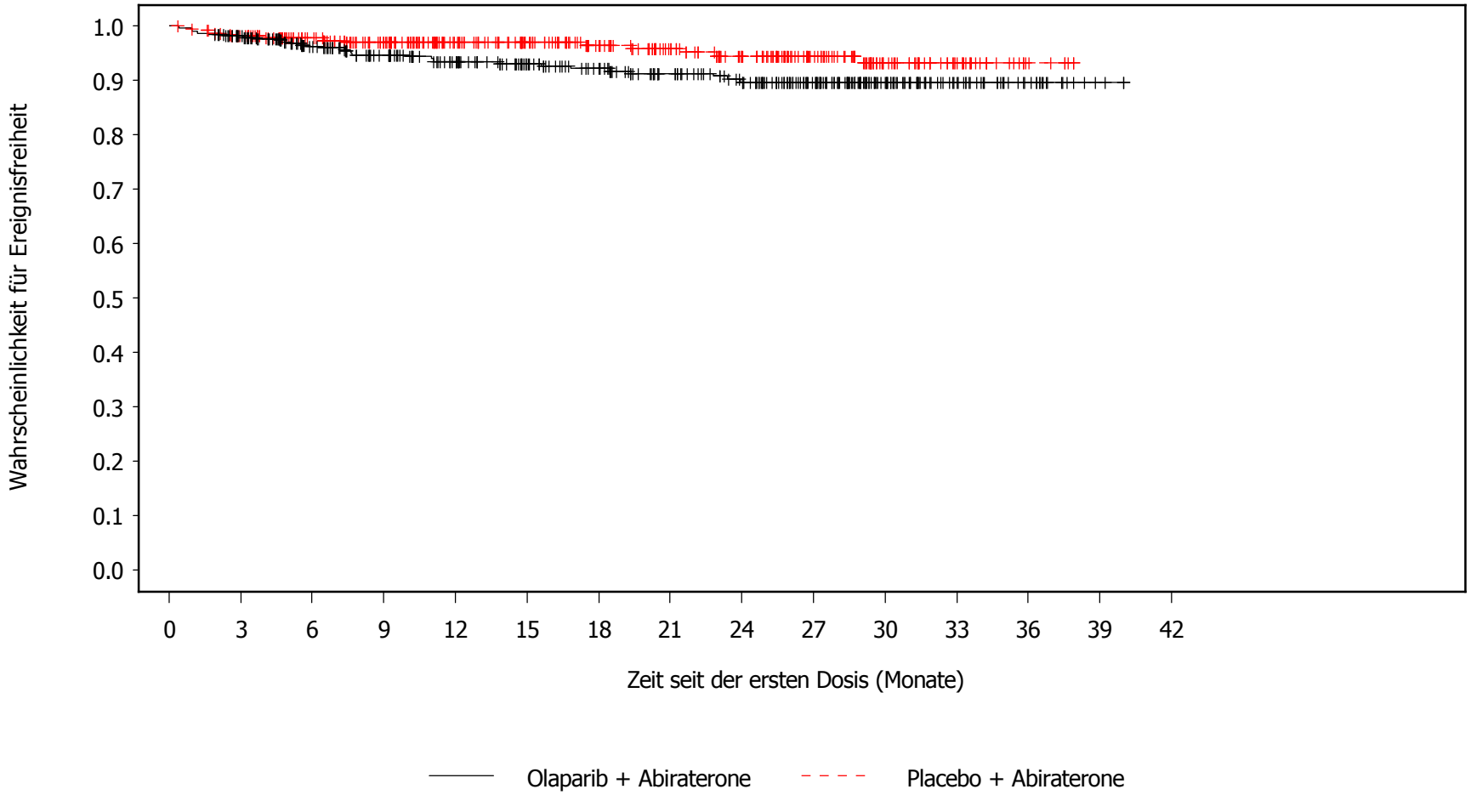


Anzahl an Patienten unter Risiko:

398	382	334	301	268	235	213	189	169	126	71	36	15	2	0	Olaparib + Abiraterone
396	376	334	296	242	205	171	146	121	88	50	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdp 06JUN2022:19:52 kvbv306

Figure 3.3.95 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hypokaliaemie
Safety Analysis Set, DCO 14MAR2022

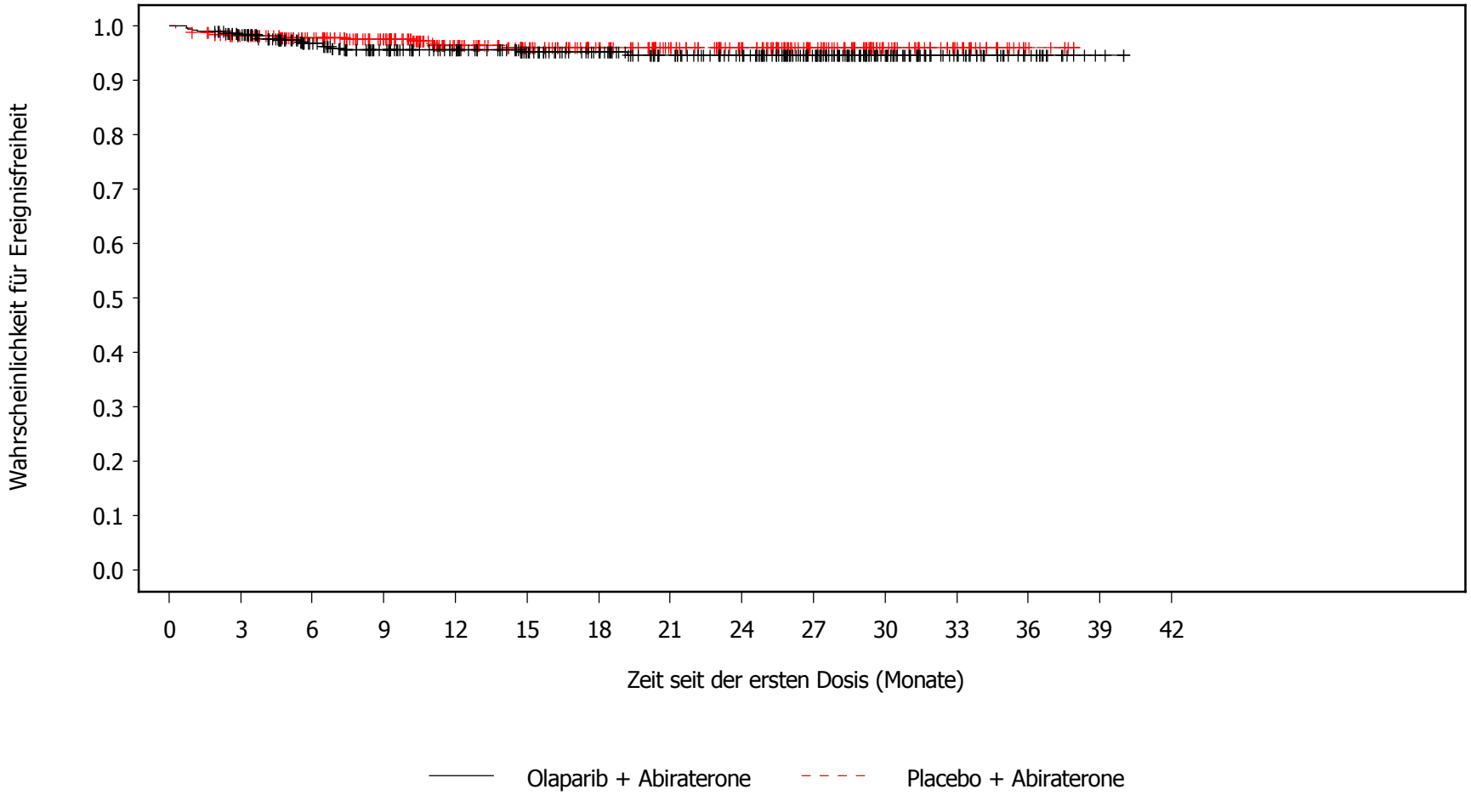


Anzahl an Patienten unter Risiko:

398	377	329	298	265	234	214	188	166	126	71	37	17	2	0	Olaparib + Abiraterone
396	374	334	292	243	208	175	149	123	88	50	26	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdq 06JUN2022:19:52 kvbv306

Figure 3.3.96 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hypokalzaemie
Safety Analysis Set, DCO 14MAR2022

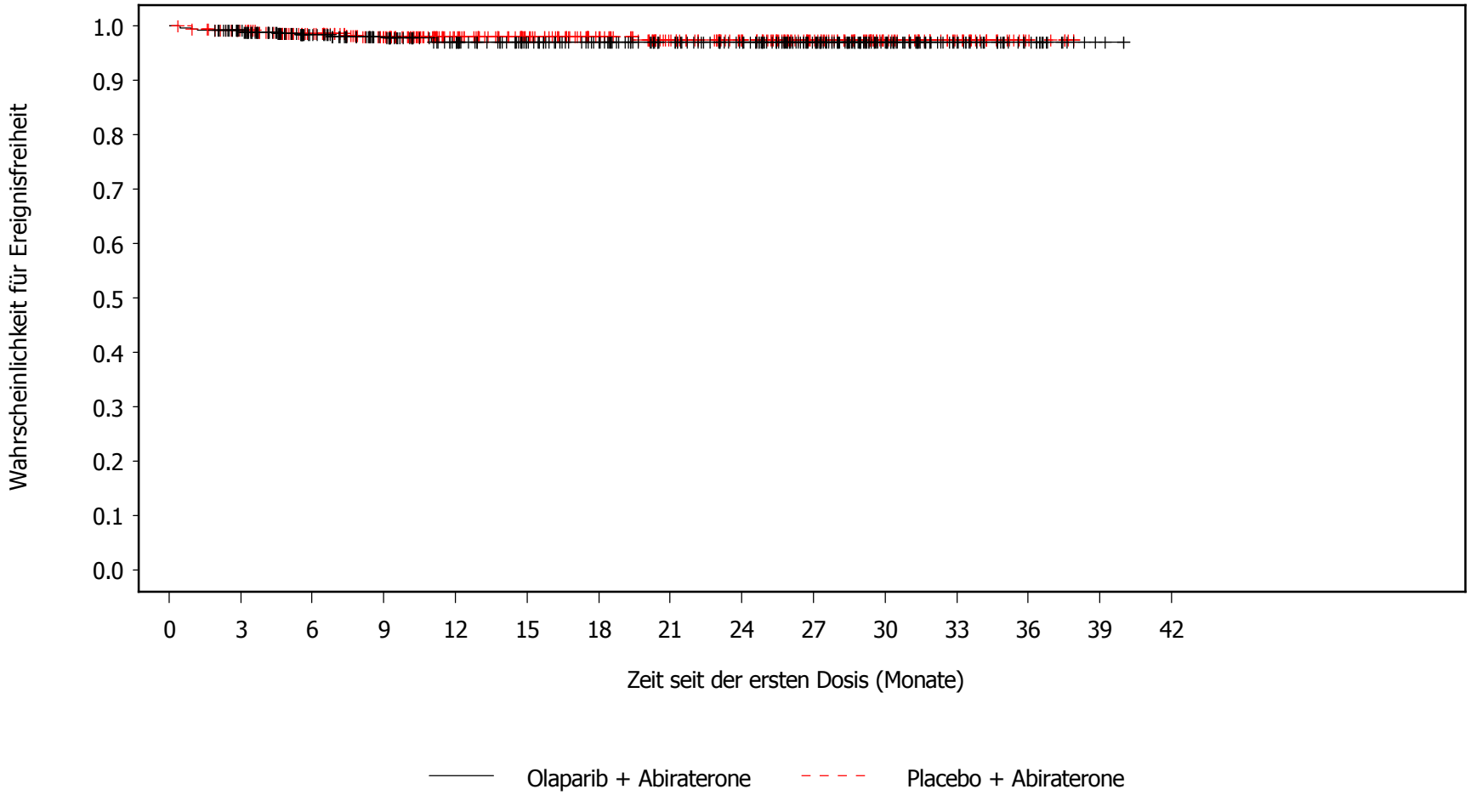


Anzahl an Patienten unter Risiko:

398	378	330	297	266	236	215	190	170	126	72	39	17	2	0	Olaparib + Abiraterone
396	374	335	295	242	207	176	151	125	91	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdr 06JUN2022:19:52 kvbv306

Figure 3.3.97 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hypophosphataemie
Safety Analysis Set, DCO 14MAR2022



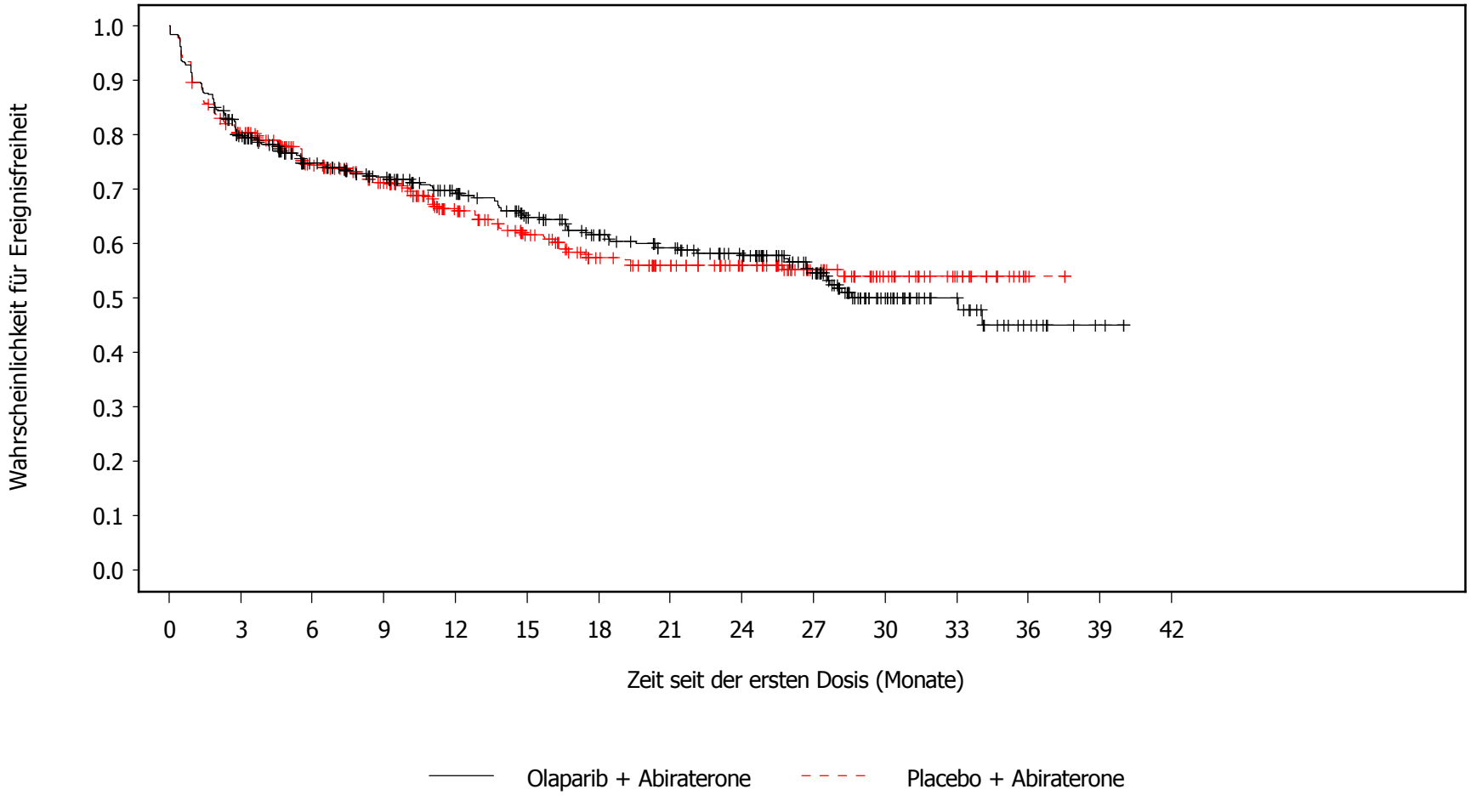
Anzahl an Patienten unter Risiko:

398	381	335	304	272	242	222	197	177	133	76	40	17	2	0	Olaparib + Abiraterone
396	378	338	298	247	211	179	152	127	92	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebds 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.98 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Untersuchungen
Safety Analysis Set, DCO 14MAR2022

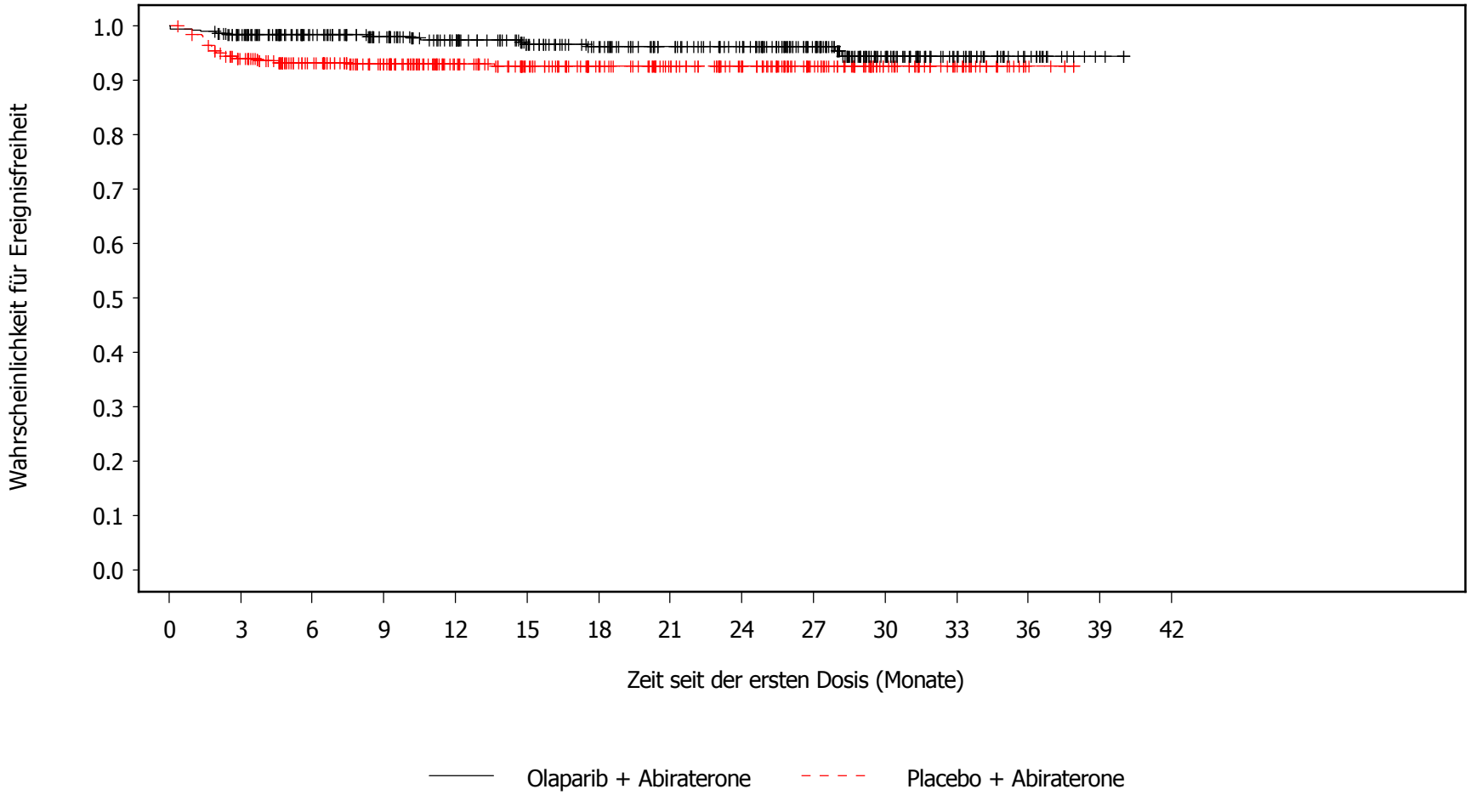


Anzahl an Patienten unter Risiko:

398	307	260	232	200	173	152	135	118	85	41	24	9	2	0	Olaparib + Abiraterone
396	310	259	224	175	142	114	97	80	56	36	20	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdt 06JUN2022:19:52 kvbv306

Figure 3.3.99 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, DCO 14MAR2022



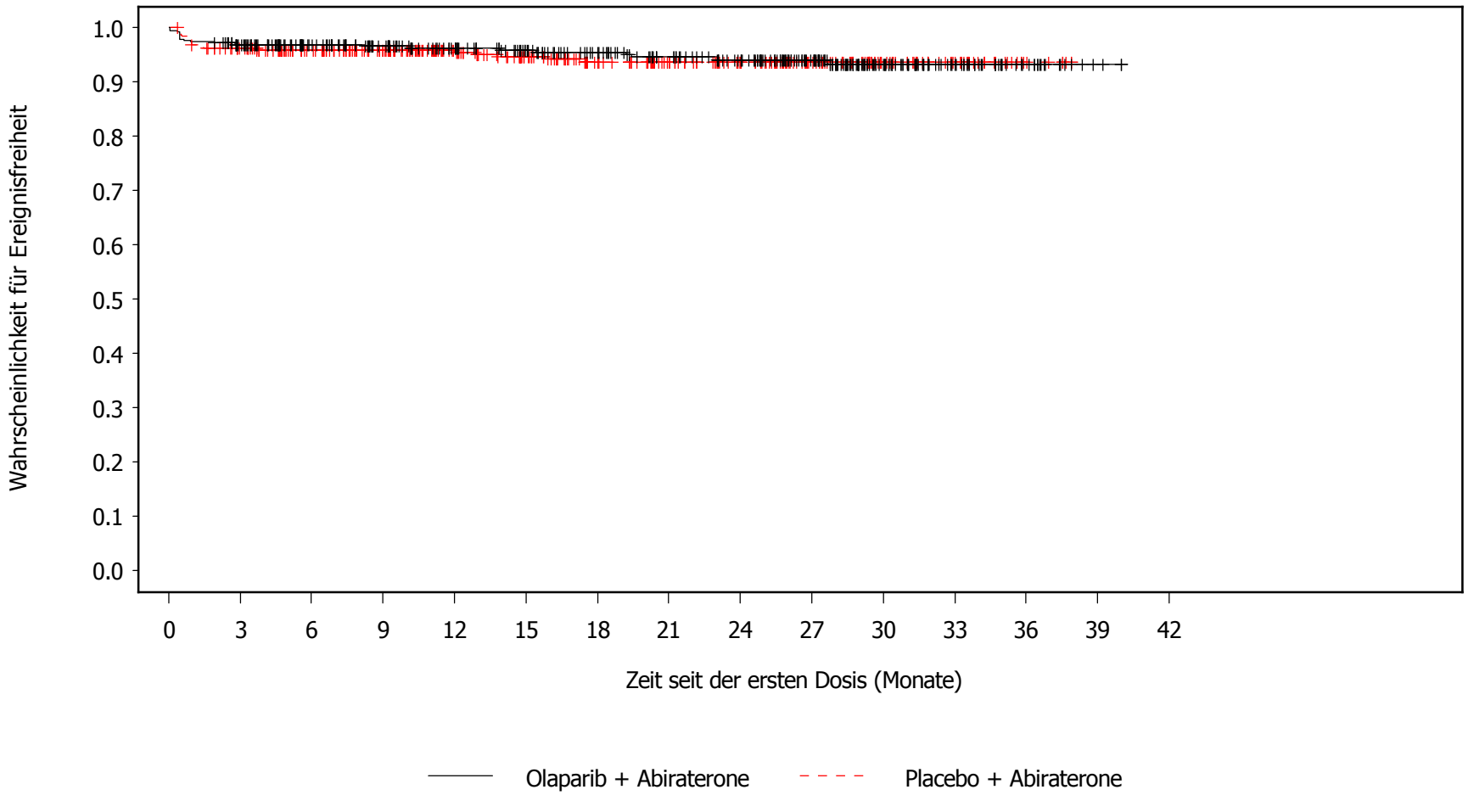
Anzahl an Patienten unter Risiko:

398	378	336	304	270	241	220	197	178	135	75	40	16	2	0	Olaparib + Abiraterone
396	358	318	281	234	201	171	147	121	88	51	28	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdu 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.100 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Alkalische Phosphatase im Blut erhoeht
Safety Analysis Set, DCO 14MAR2022

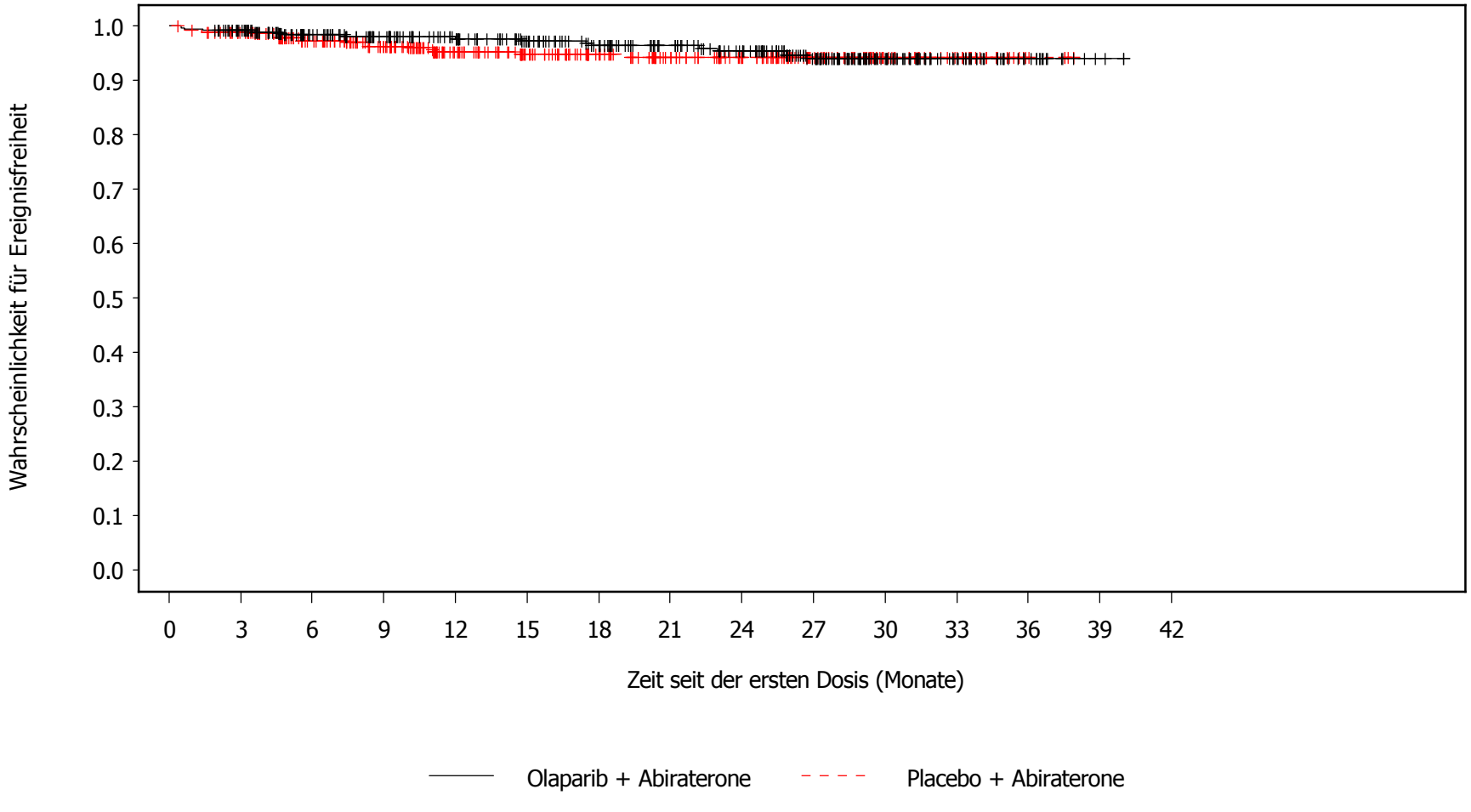


Anzahl an Patienten unter Risiko:

398	374	332	301	269	242	220	197	177	133	75	41	17	2	0	Olaparib + Abiraterone
396	366	328	290	239	205	171	148	122	89	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdv 06JUN2022:19:52 kvbv306

Figure 3.3.101 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Amylase erhoeht
Safety Analysis Set, DCO 14MAR2022

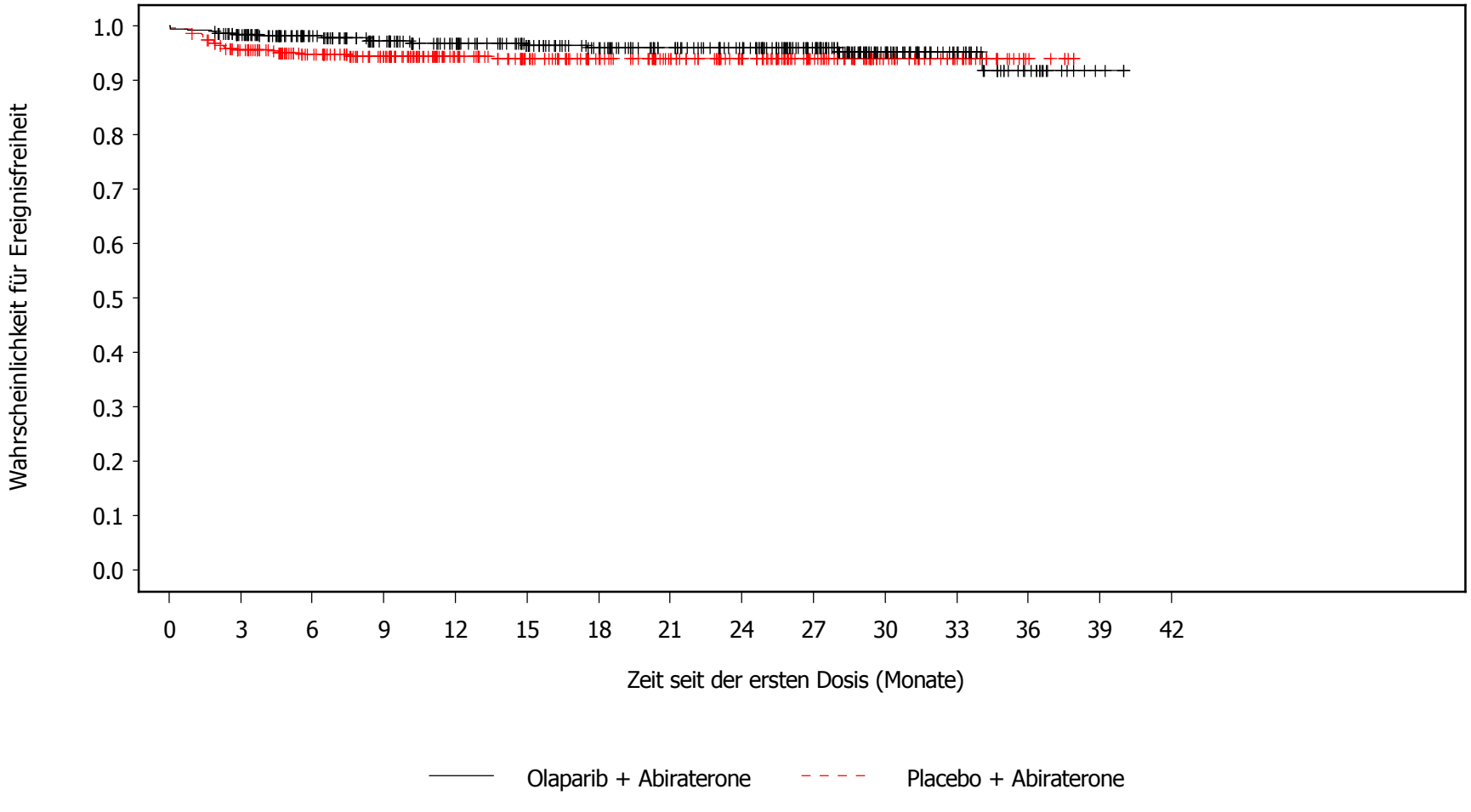


Anzahl an Patienten unter Risiko:

398	381	334	302	270	240	217	193	171	129	74	40	16	2	0	Olaparib + Abiraterone
396	377	332	291	238	202	169	144	119	86	49	28	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdw 06JUN2022:19:52 kvbv306

Figure 3.3.102 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Aspartataminotransferase erhoeht
Safety Analysis Set, DCO 14MAR2022



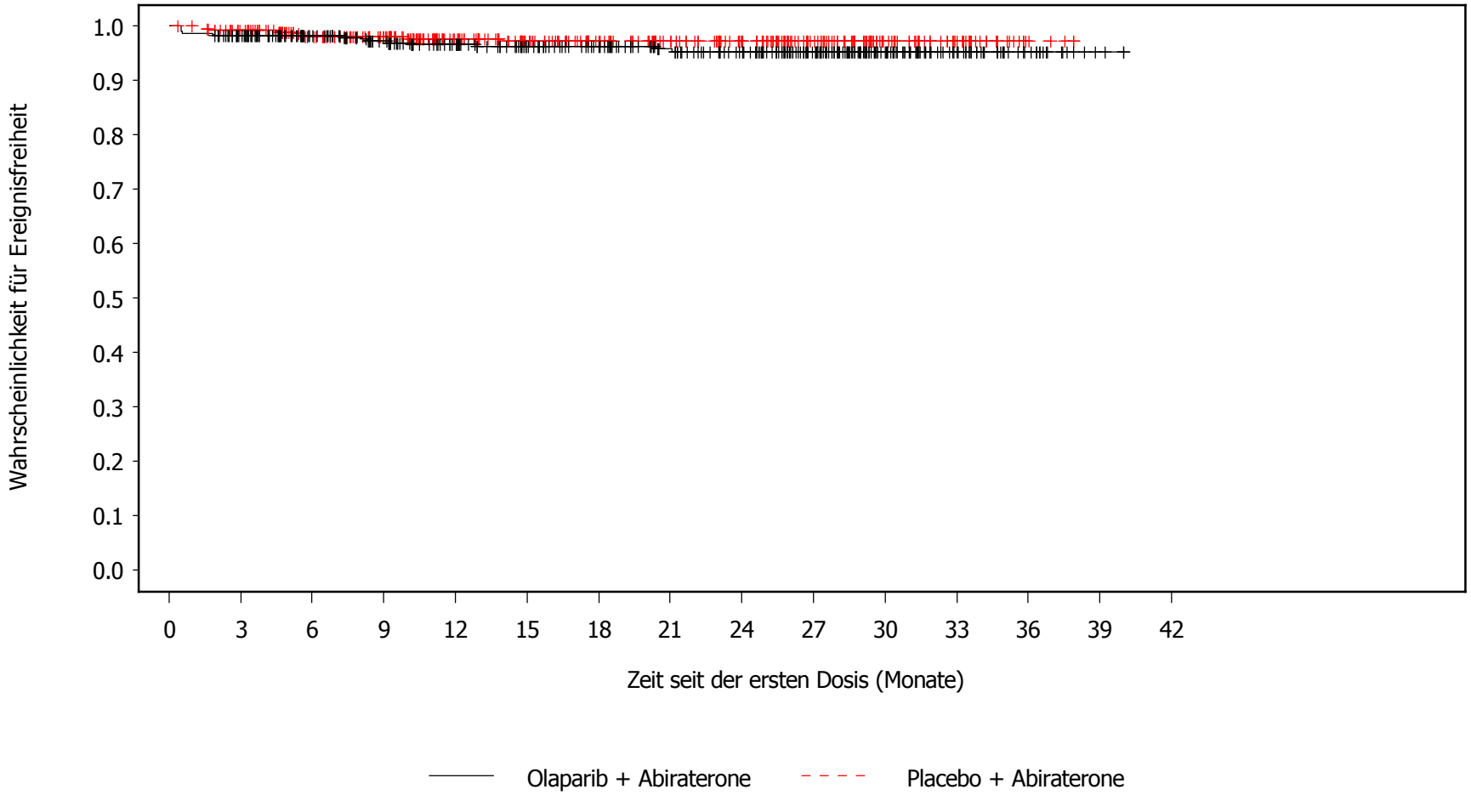
Anzahl an Patienten unter Risiko:

398	378	335	302	270	241	220	196	176	133	73	40	16	2	0	Olaparib + Abiraterone
396	364	324	285	237	205	174	150	124	91	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdx 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.103 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Bilirubin im Blut erhoeht
Safety Analysis Set, DCO 14MAR2022

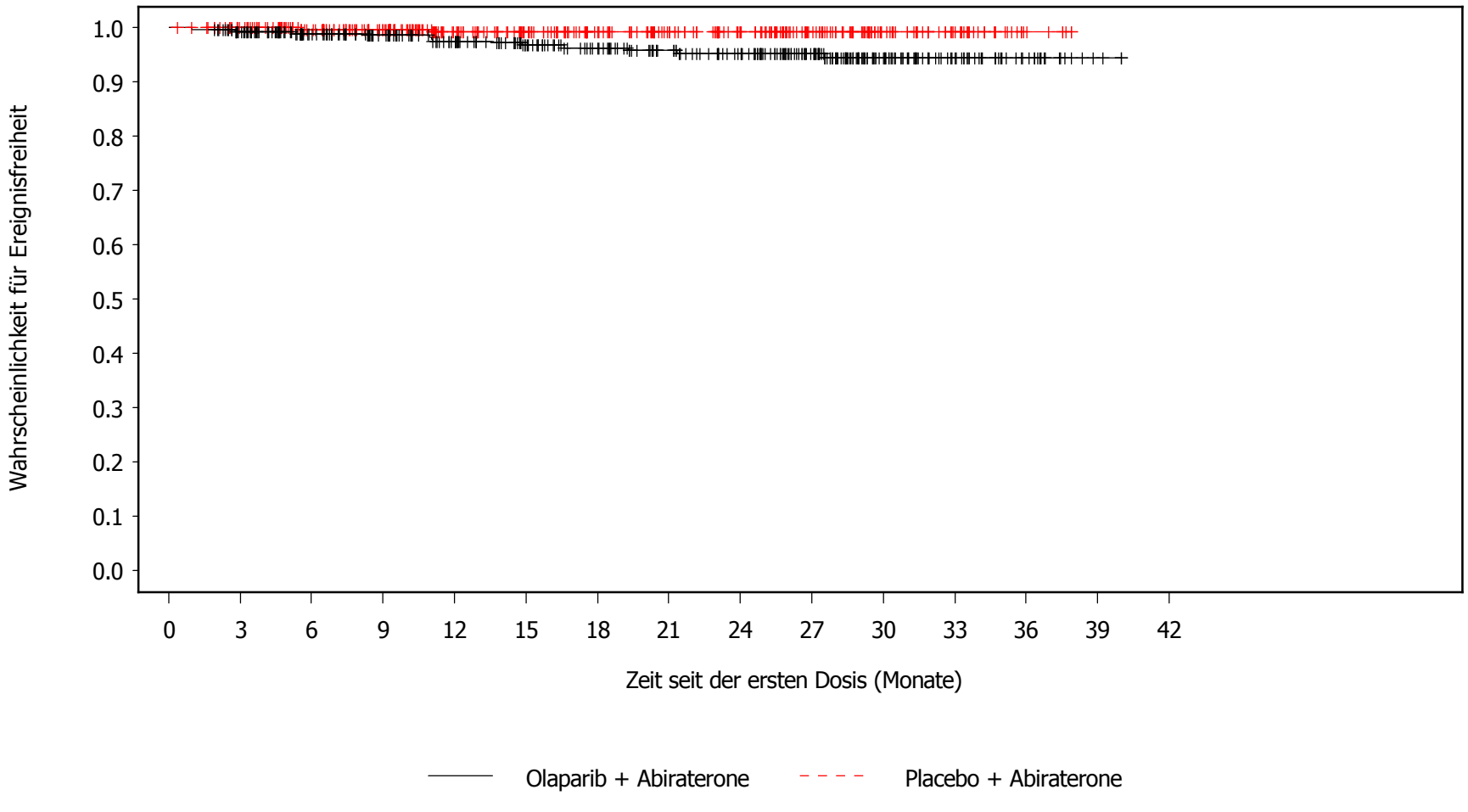


Anzahl an Patienten unter Risiko:

398	377	334	302	268	240	221	196	175	133	75	40	16	2	0	Olaparib + Abiraterone
396	377	334	296	245	208	176	152	126	92	52	28	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdy 06JUN2022:19:52 kvbv306

Figure 3.3.104 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Elektrokardiogramm QT verlaengert
Safety Analysis Set, DCO 14MAR2022

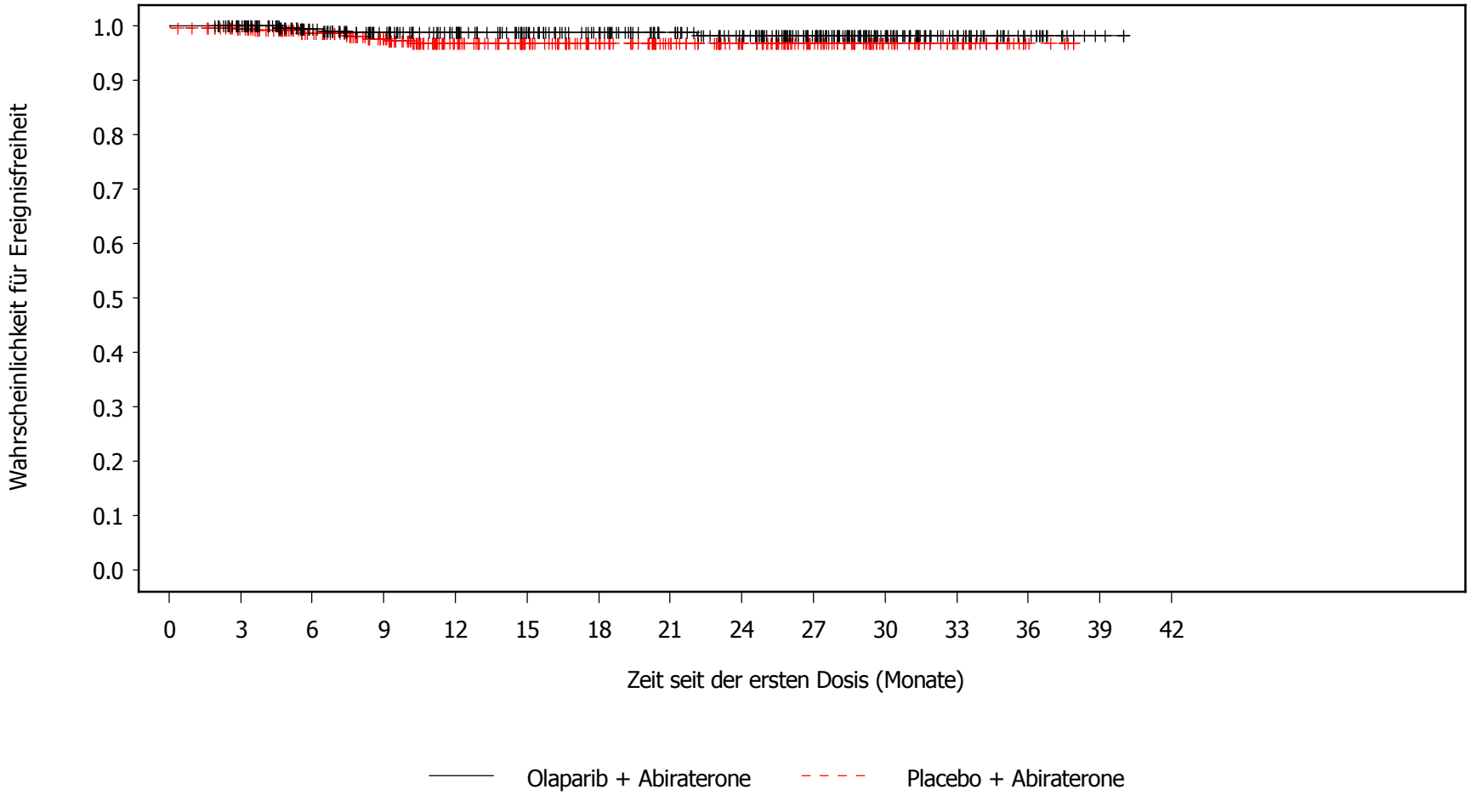


Anzahl an Patienten unter Risiko:

398	381	336	304	269	237	215	191	171	130	71	38	16	2	0	Olaparib + Abiraterone
396	380	340	300	249	213	180	154	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebdz 06JUN2022:19:52 kvbv306

Figure 3.3.105 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Gewicht erhoeht
Safety Analysis Set, DCO 14MAR2022

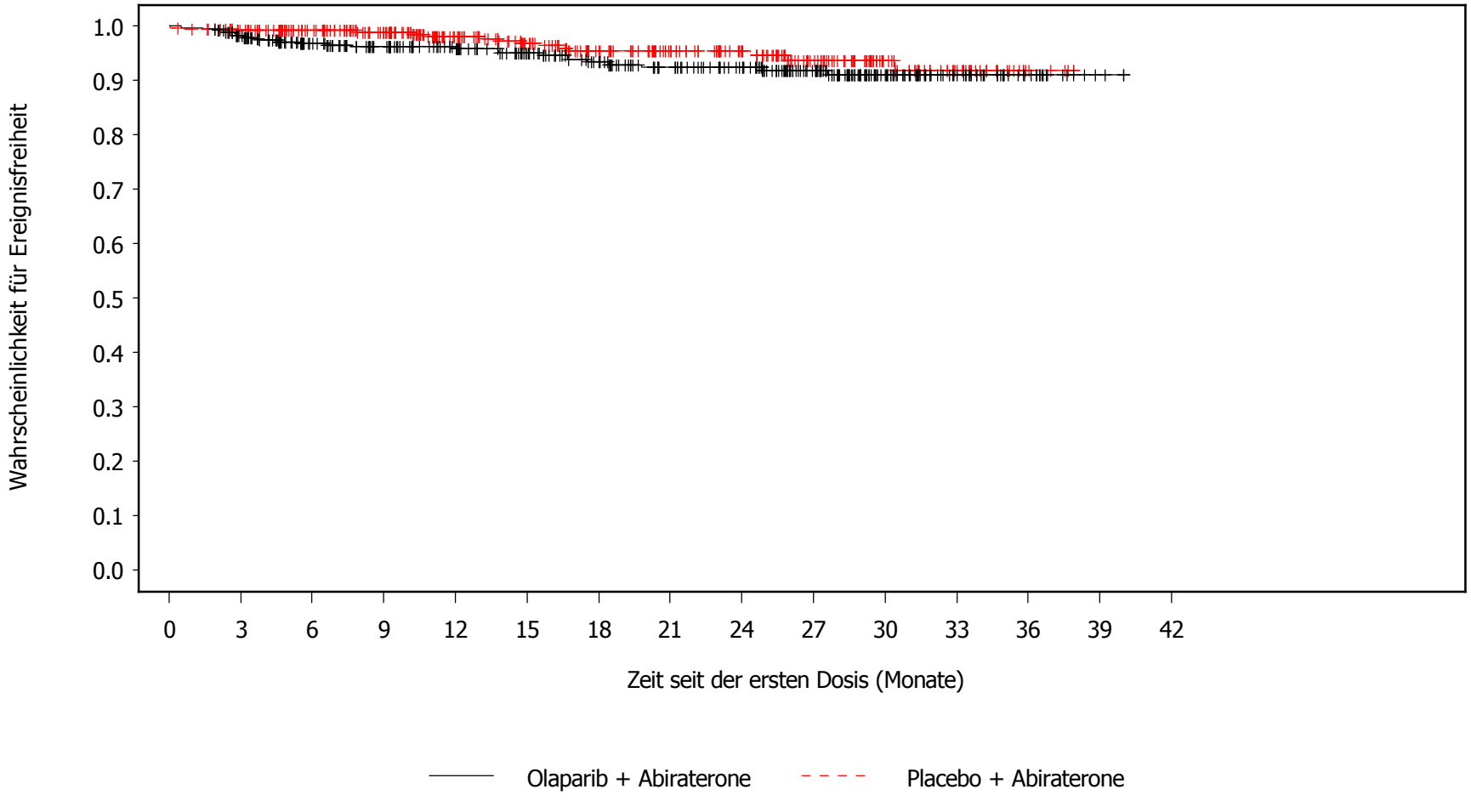


Anzahl an Patienten unter Risiko:

398	384	337	304	275	245	224	199	178	135	76	41	17	2	0	Olaparib + Abiraterone
396	378	336	293	241	206	175	150	125	92	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebea 06JUN2022:19:52 kvbv306

Figure 3.3.106 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Gewicht erniedrigt
Safety Analysis Set, DCO 14MAR2022

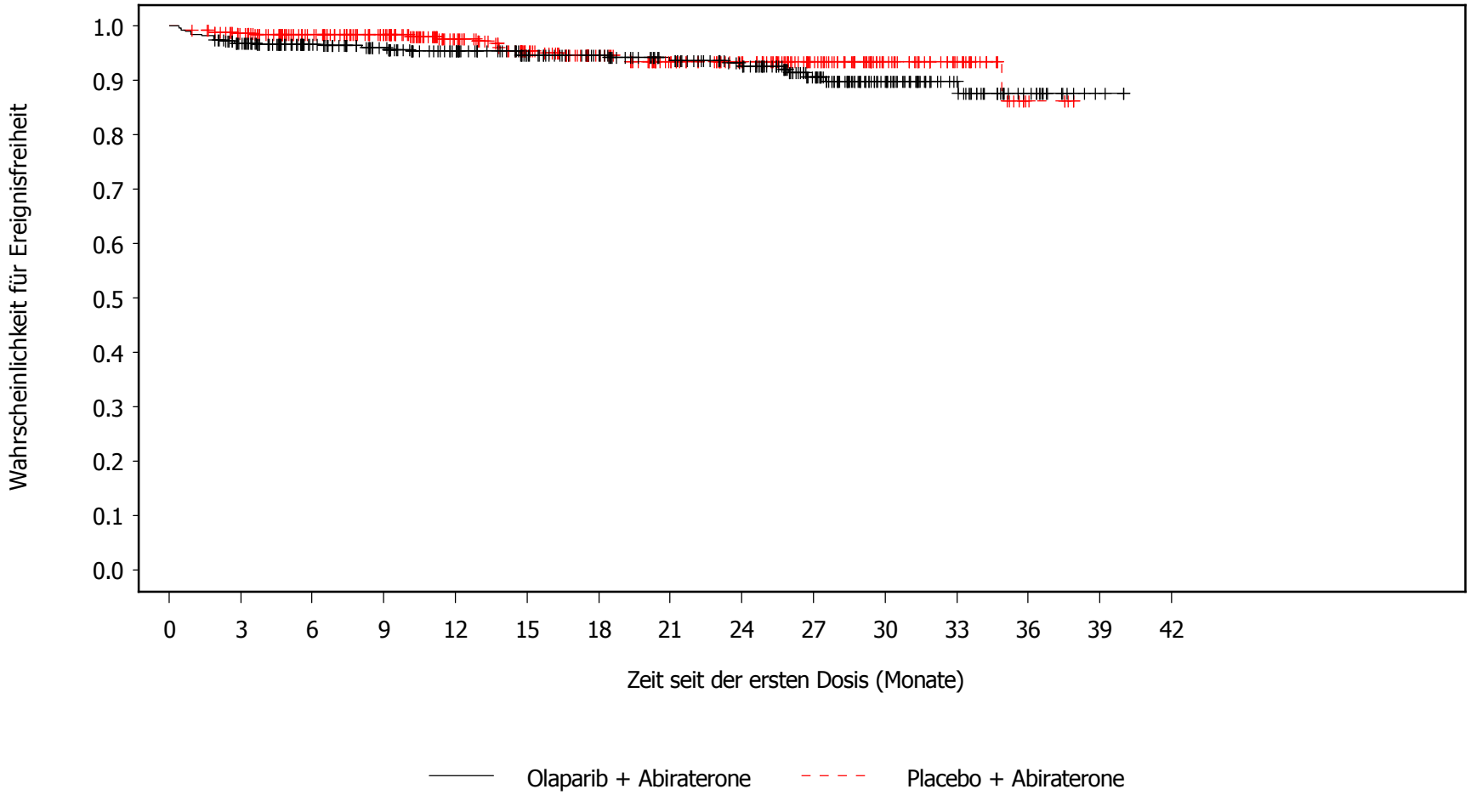


Anzahl an Patienten unter Risiko:

398	377	330	300	267	236	212	187	167	126	71	38	16	2	0	Olaparib + Abiraterone
396	377	339	299	246	209	175	151	125	91	53	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebeb 06JUN2022:19:52 kvbv306

Figure 3.3.107 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Kreatinin im Blut erhoeht
Safety Analysis Set, DCO 14MAR2022

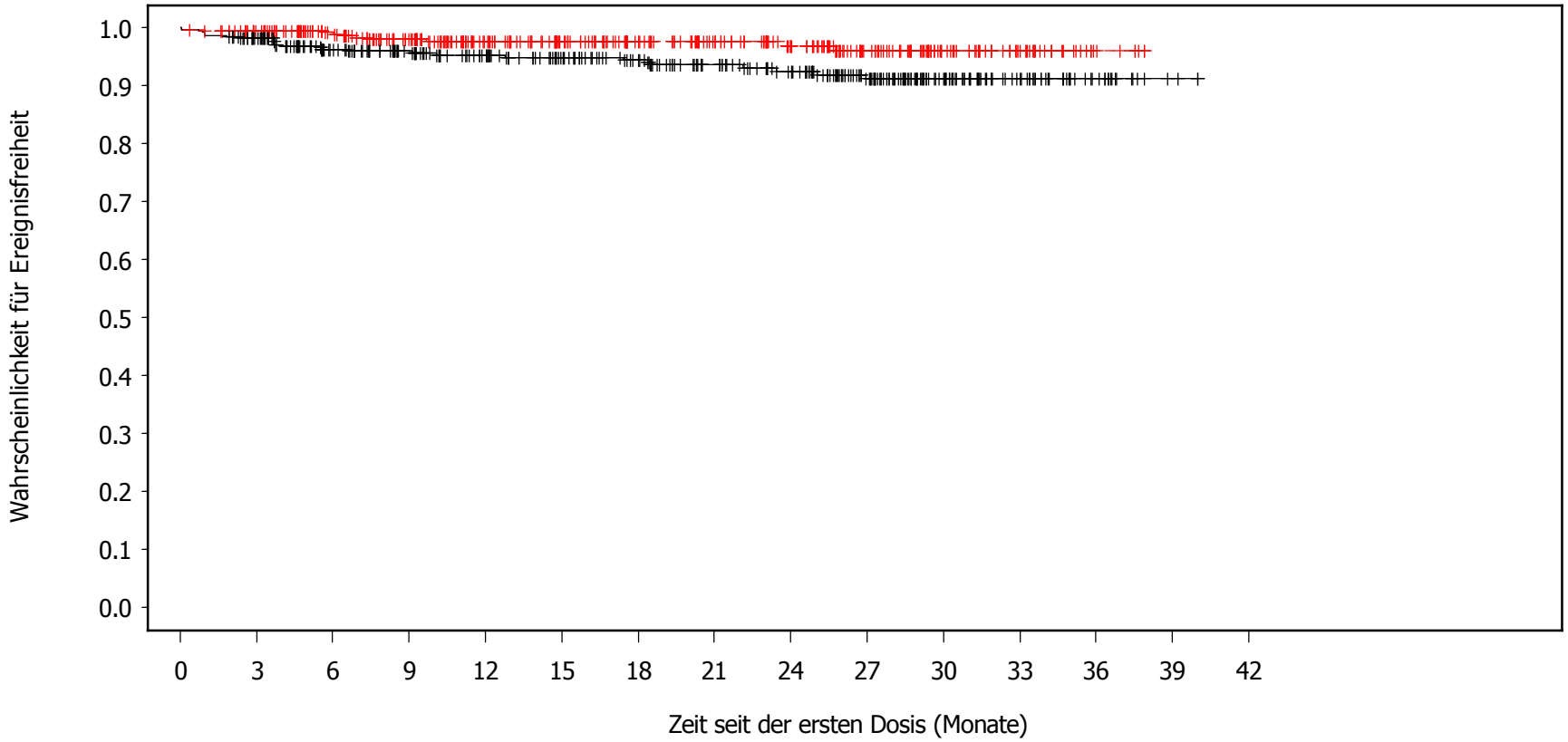


Anzahl an Patienten unter Risiko:

398	372	328	299	267	236	218	194	173	128	74	40	17	2	0	Olaparib + Abiraterone
396	376	336	297	244	204	171	146	124	91	53	30	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebec 06JUN2022:19:52 kvbv306

Figure 3.3.108 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Leukozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

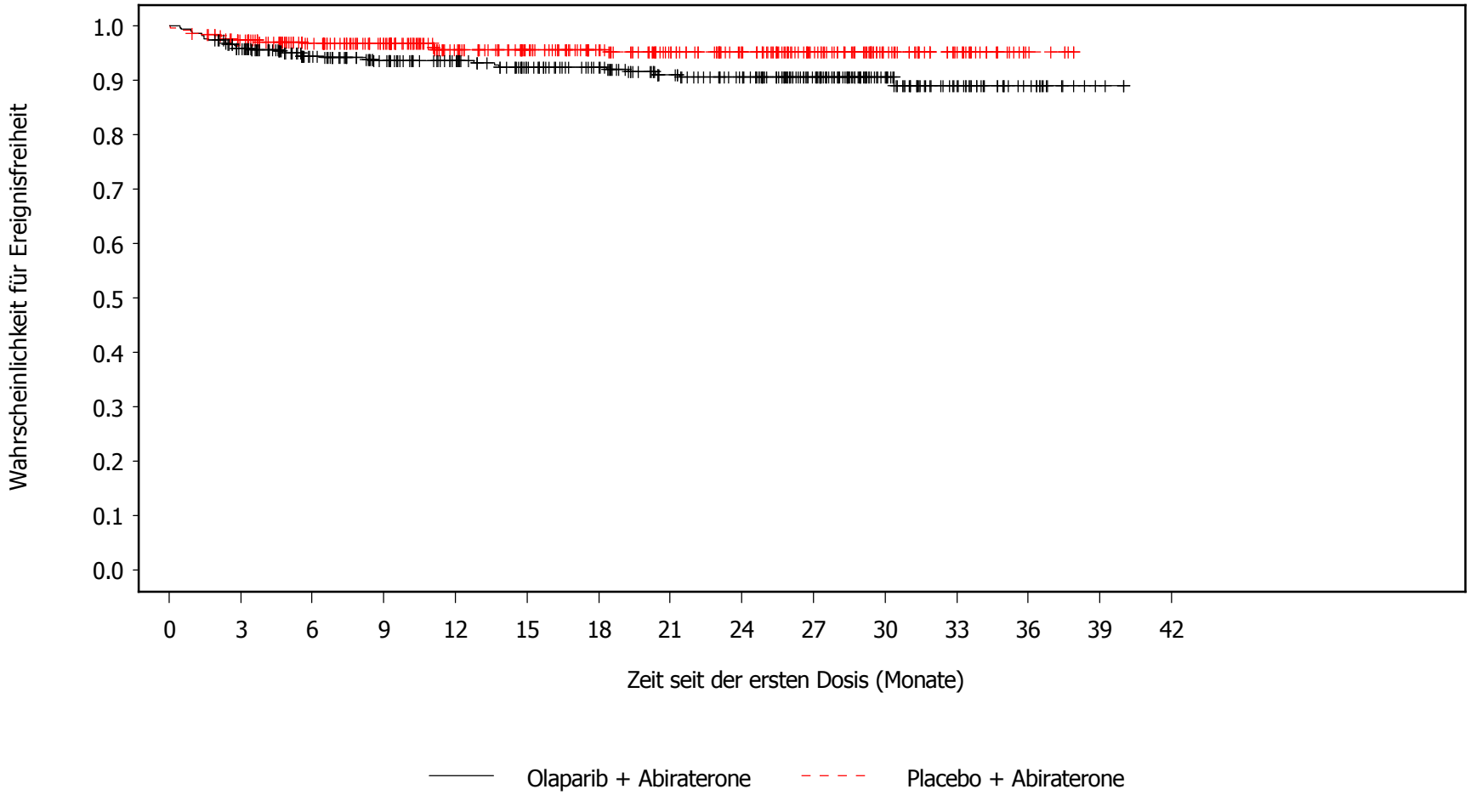


Anzahl an Patienten unter Risiko:

398	377	327	295	264	236	214	187	166	125	72	40	16	2	0	Olaparib + Abiraterone
396	378	338	298	249	213	180	154	127	92	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebed 06JUN2022:19:52 kvbv306

Figure 3.3.109 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Lymphozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

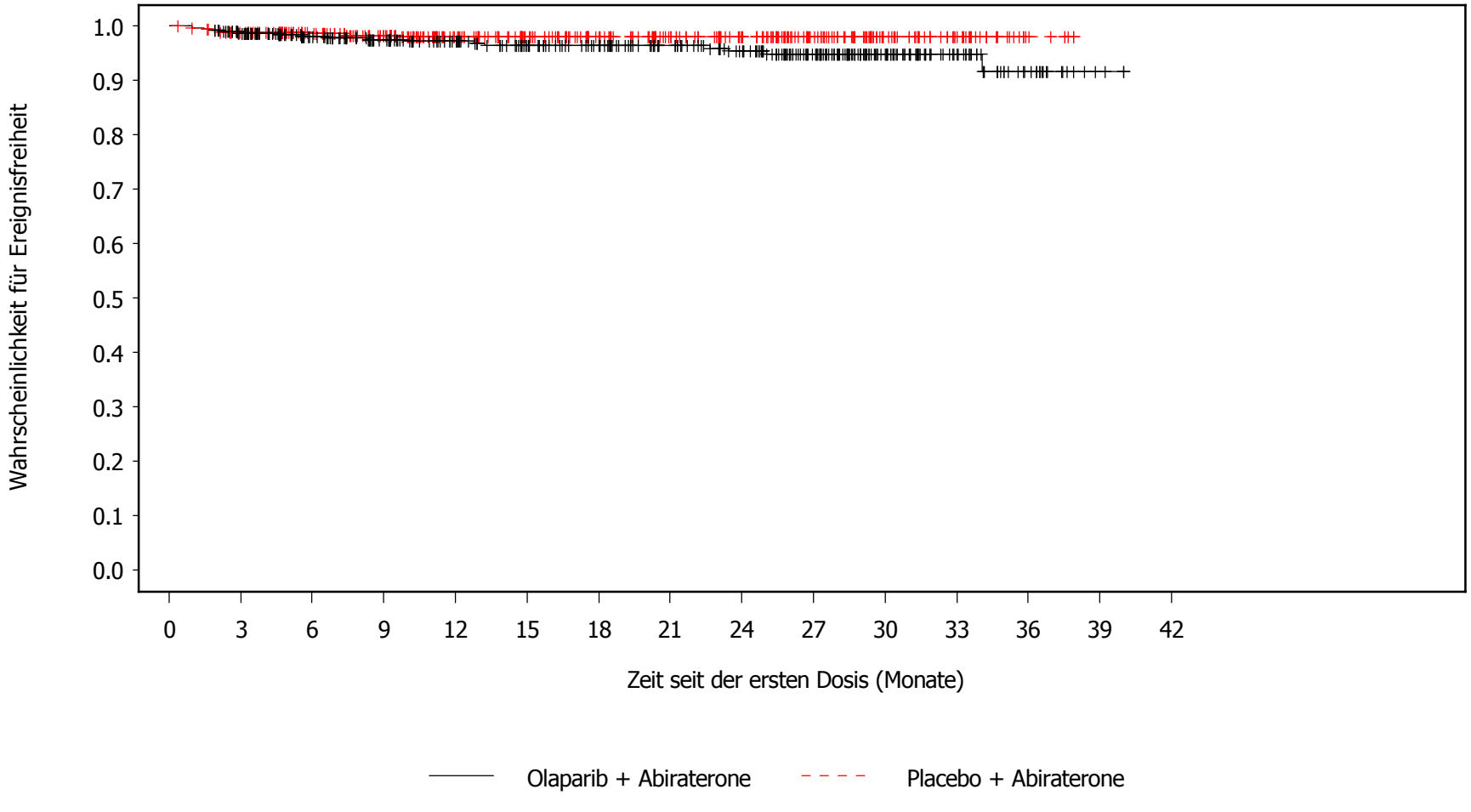


Anzahl an Patienten unter Risiko:

398	369	321	290	261	231	211	183	165	123	68	37	16	2	0	Olaparib + Abiraterone
396	372	333	296	244	210	178	151	125	91	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebee 06JUN2022:19:52 kvbv306

Figure 3.3.110 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Neutrophilenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

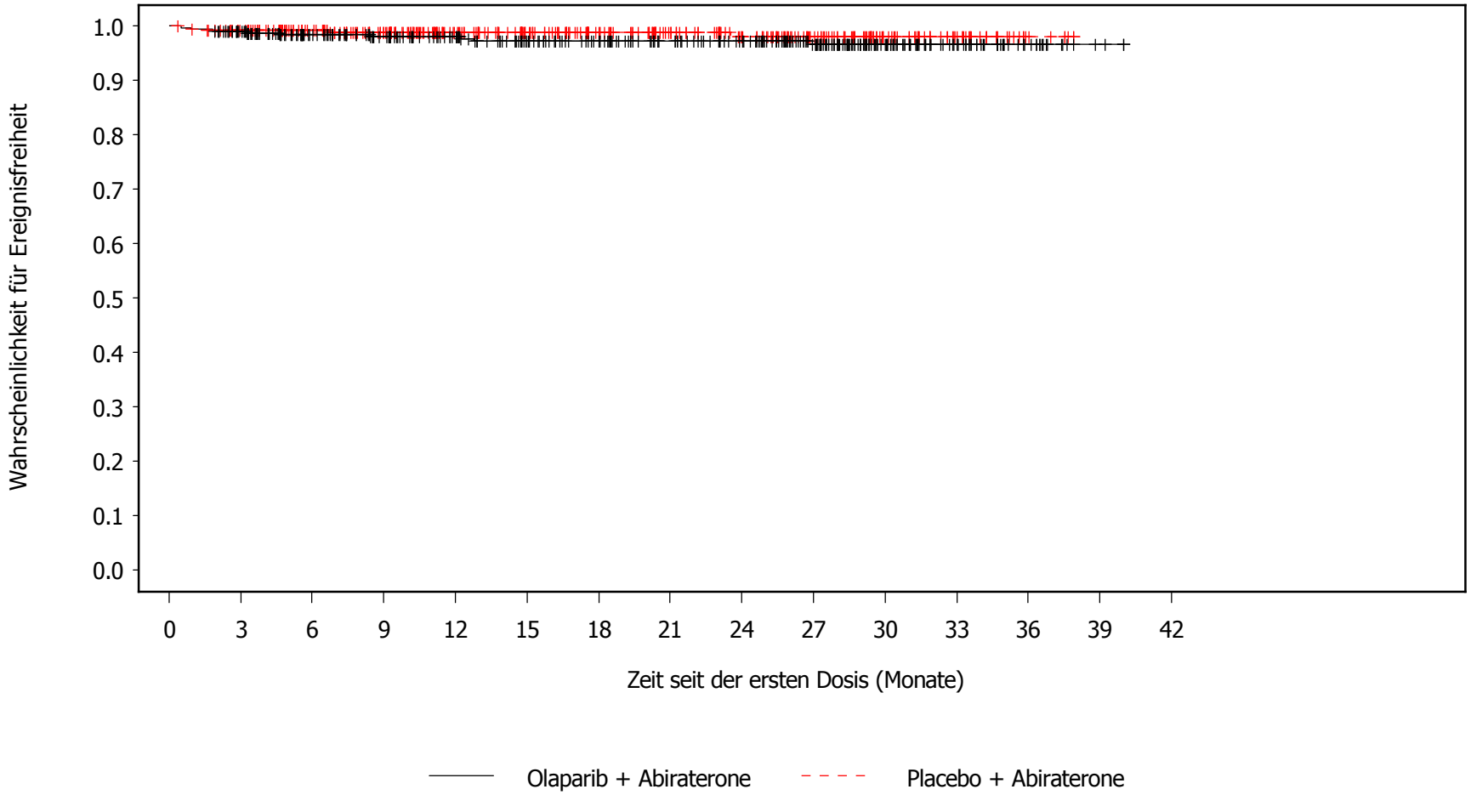


Anzahl an Patienten unter Risiko:

398	379	334	301	269	239	220	195	173	132	76	41	17	2	0	Olaparib + Abiraterone
396	377	338	298	249	213	180	154	129	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebef 06JUN2022:19:52 kvbv306

Figure 3.3.111 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Thrombozytenzahl vermindert
Safety Analysis Set, DCO 14MAR2022

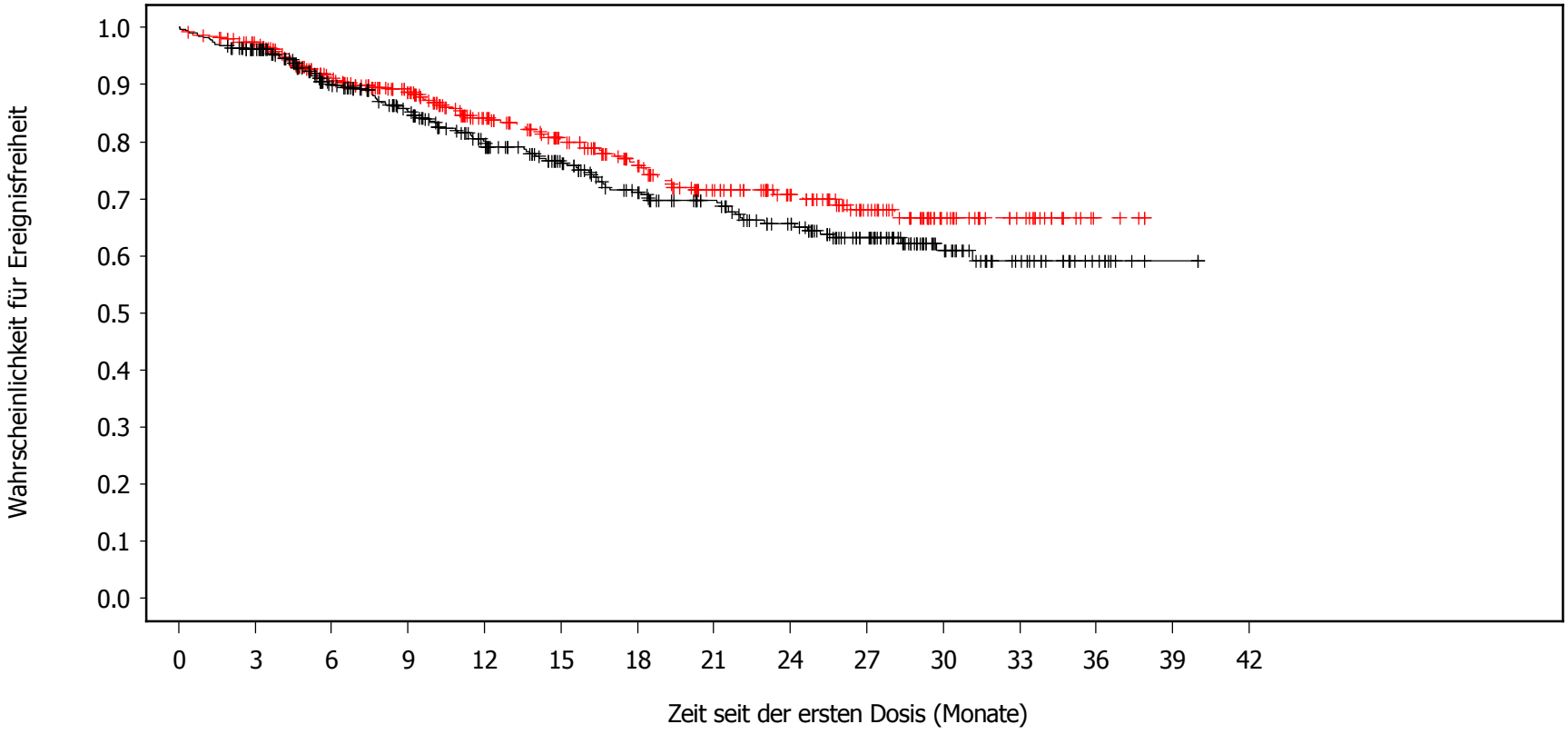


Anzahl an Patienten unter Risiko:

398	380	334	303	272	240	220	195	175	131	73	40	16	2	0	Olaparib + Abiraterone
396	377	338	298	247	212	179	153	127	93	53	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebeg 06JUN2022:19:52 kvbv306

Figure 3.3.112 PROpel: Kaplan-Meier plot of time to first occurrence of UE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Safety Analysis Set, DCO 14MAR2022



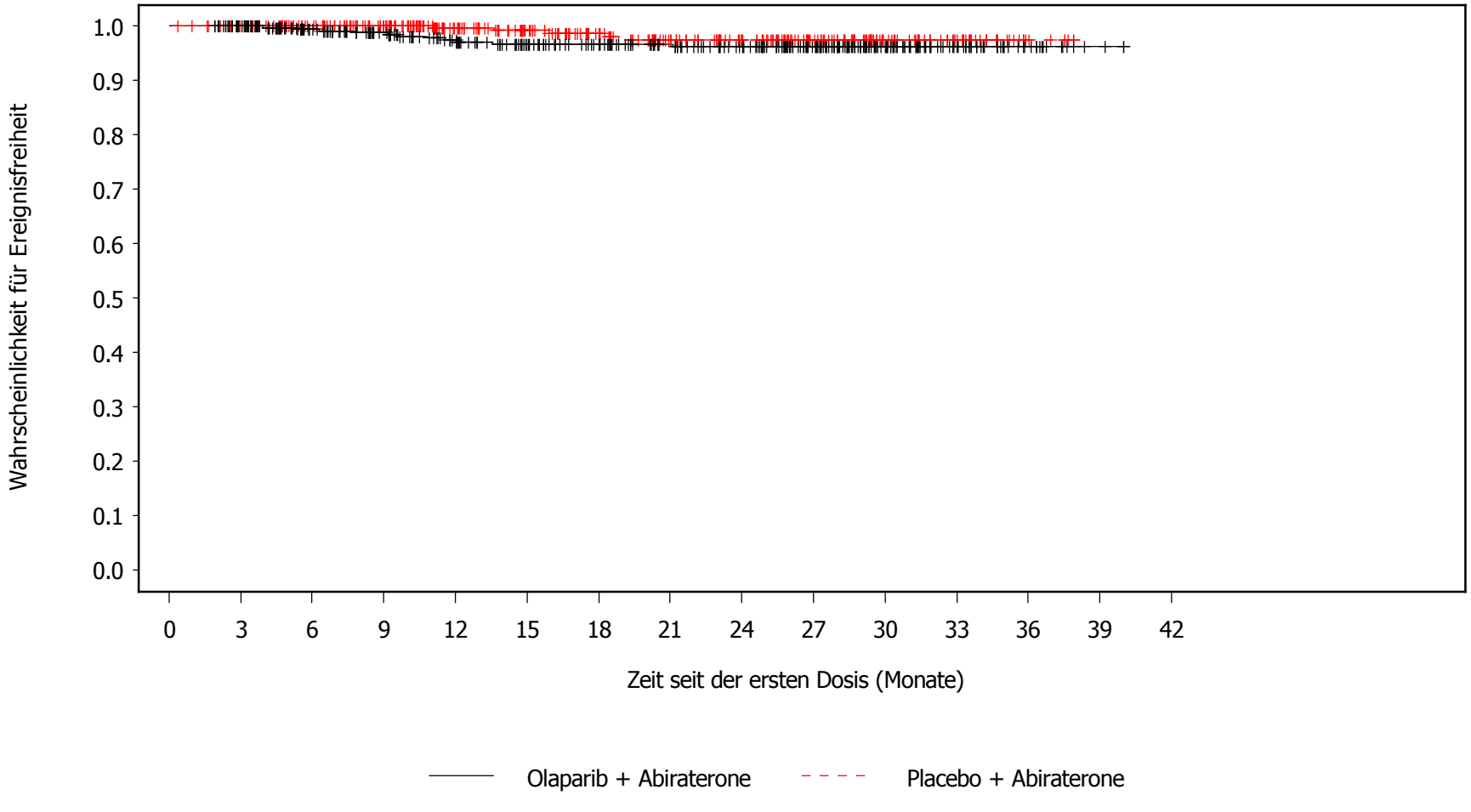
Anzahl an Patienten unter Risiko:

398	370	309	269	224	187	158	139	117	86	44	23	9	1	0	Olaparib + Abiraterone
396	371	310	264	211	174	144	113	90	63	34	19	3	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebeh 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.113 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Hauteinriss
Safety Analysis Set, DCO 14MAR2022

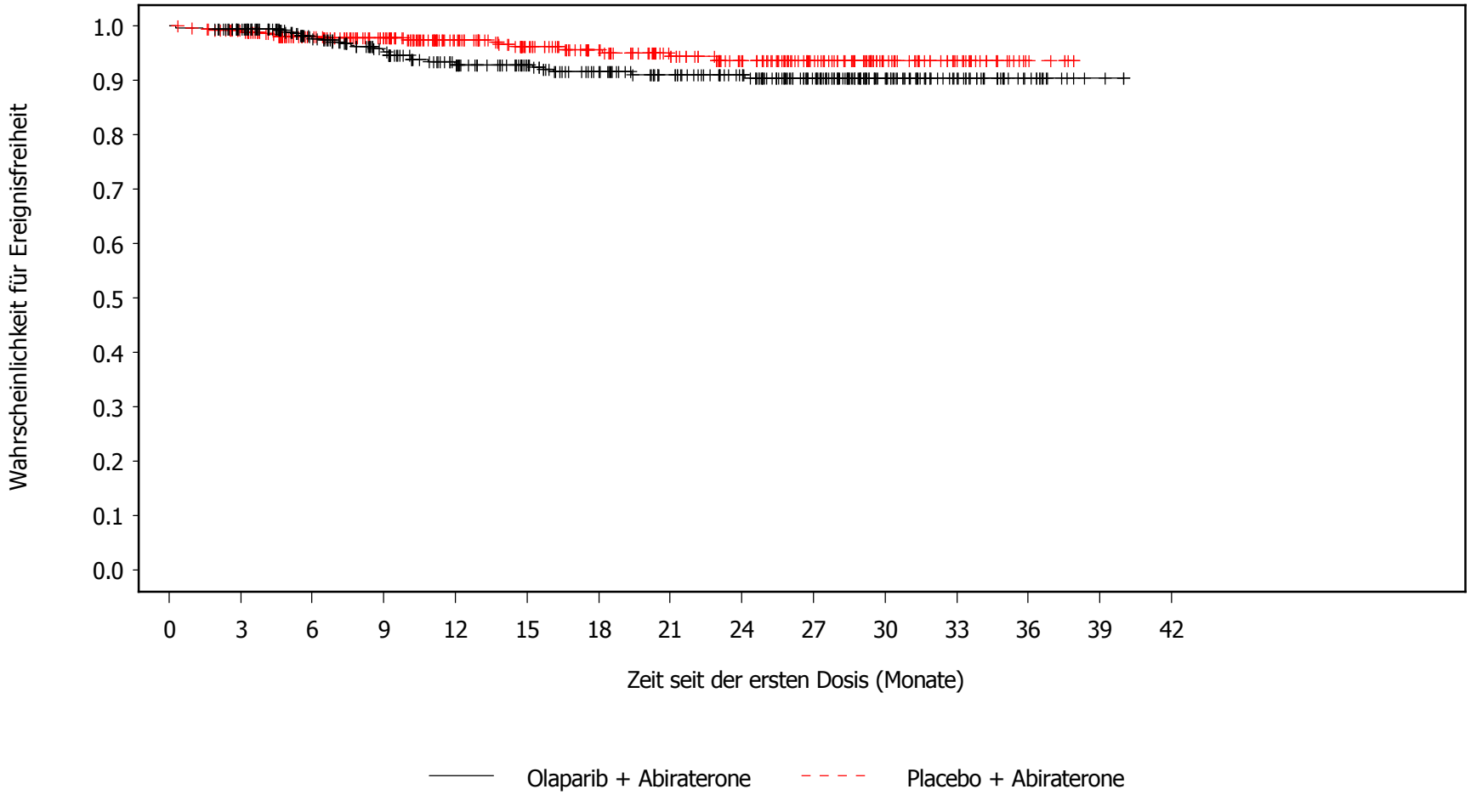


Anzahl an Patienten unter Risiko:

398	384	337	304	269	237	217	193	172	131	74	38	14	2	0	Olaparib + Abiraterone
396	380	341	301	249	213	179	151	125	92	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebei 06JUN2022:19:52 kvbv306

Figure 3.3.114 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Kontusion
Safety Analysis Set, DCO 14MAR2022



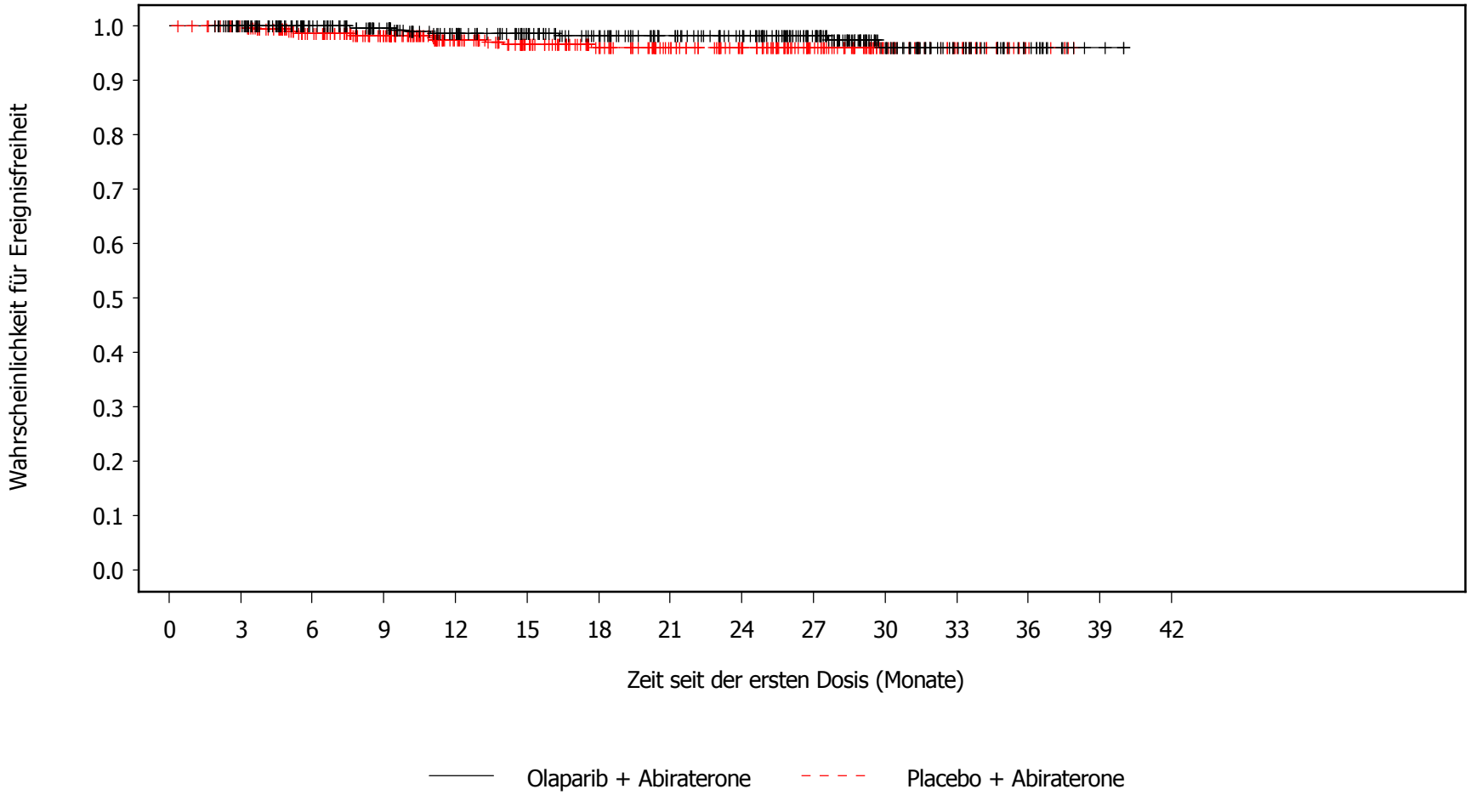
Anzahl an Patienten unter Risiko:

398	382	331	293	257	226	203	181	161	121	68	38	15	2	0	Olaparib + Abiraterone
396	377	334	294	243	204	173	146	120	88	50	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebej 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.115 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Rippenfraktur
Safety Analysis Set, DCO 14MAR2022



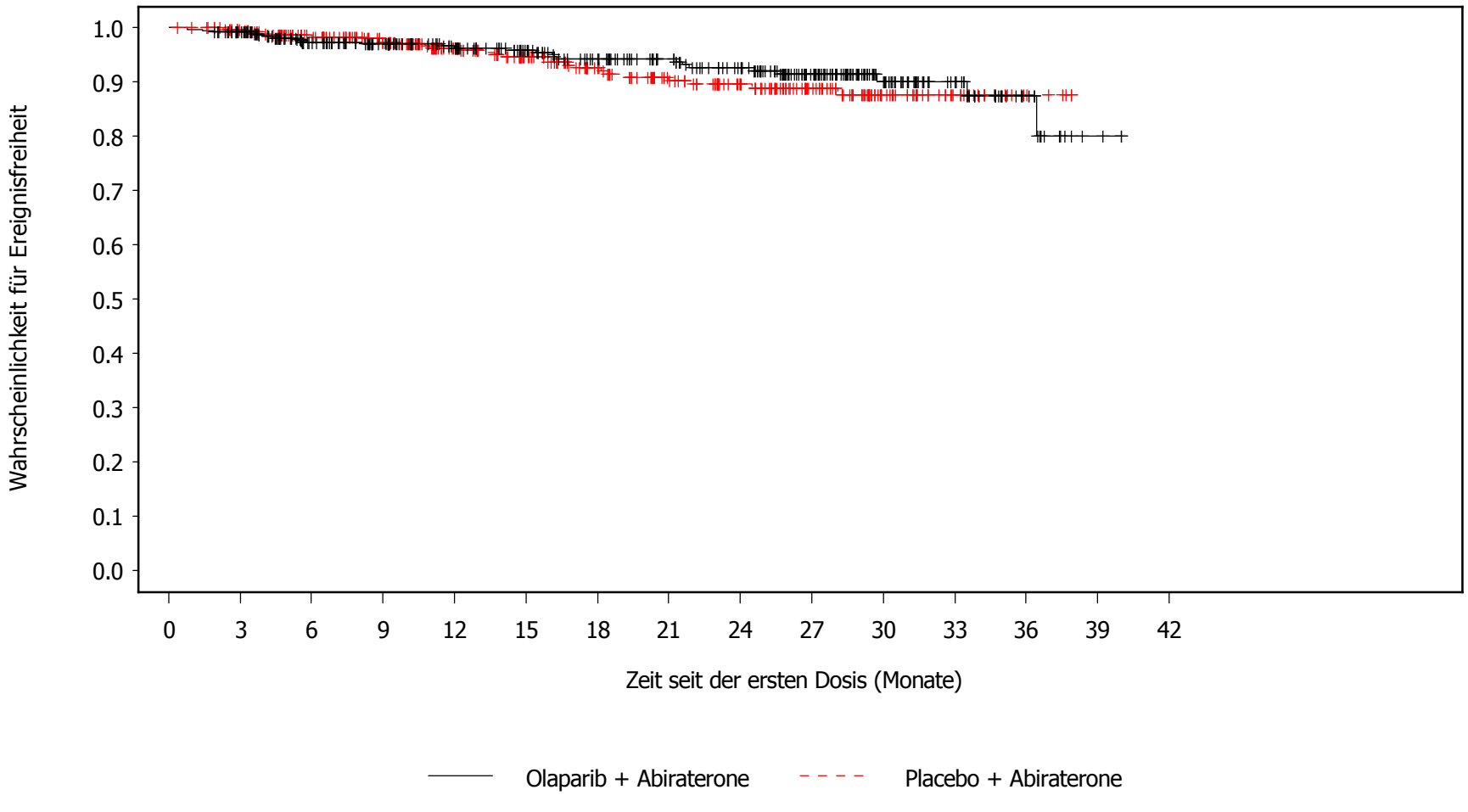
Anzahl an Patienten unter Risiko:

398	384	339	307	272	242	220	196	176	132	72	38	16	2	0	Olaparib + Abiraterone
396	380	336	295	242	205	171	146	122	88	50	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebek 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.116 PROpel: Kaplan-Meier plot of time to first occurrence of UE PT: Sturz
Safety Analysis Set, DCO 14MAR2022

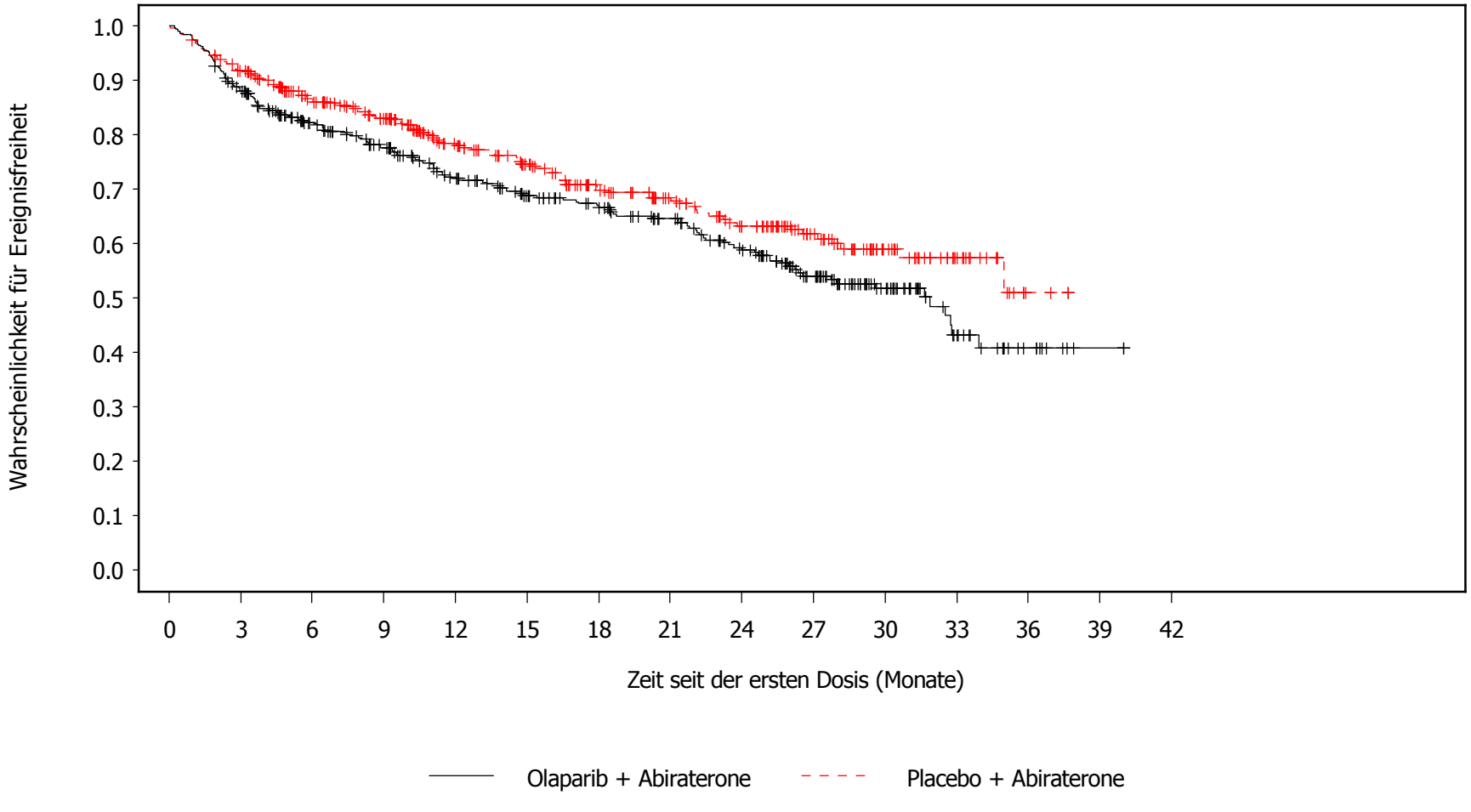


Anzahl an Patienten unter Risiko:

398	382	332	300	266	237	213	190	168	124	68	38	15	2	0	Olaparib + Abiraterone
396	379	336	293	241	204	170	143	117	85	47	24	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebel 06JUN2022:19:52 kvbv306

Figure 3.3.117 PROpel: Kaplan-Meier plot of time to first occurrence of SUE
Safety Analysis Set, DCO 14MAR2022



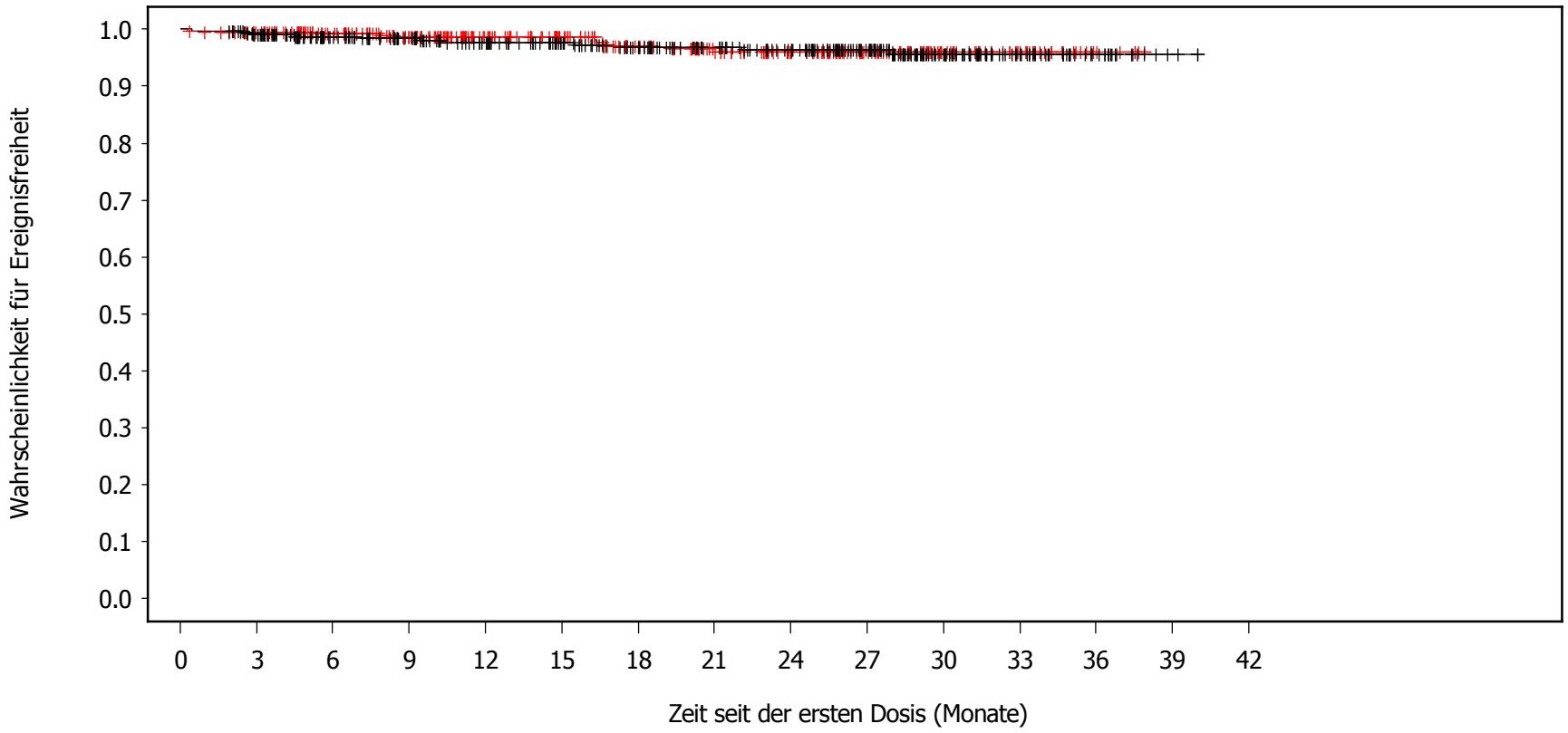
Anzahl an Patienten unter Risiko:

398	346	294	261	219	191	175	153	127	90	52	23	9	1	0	Olaparib + Abiraterone
396	356	304	266	219	185	151	127	102	73	41	20	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebem 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.118 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 14MAR2022

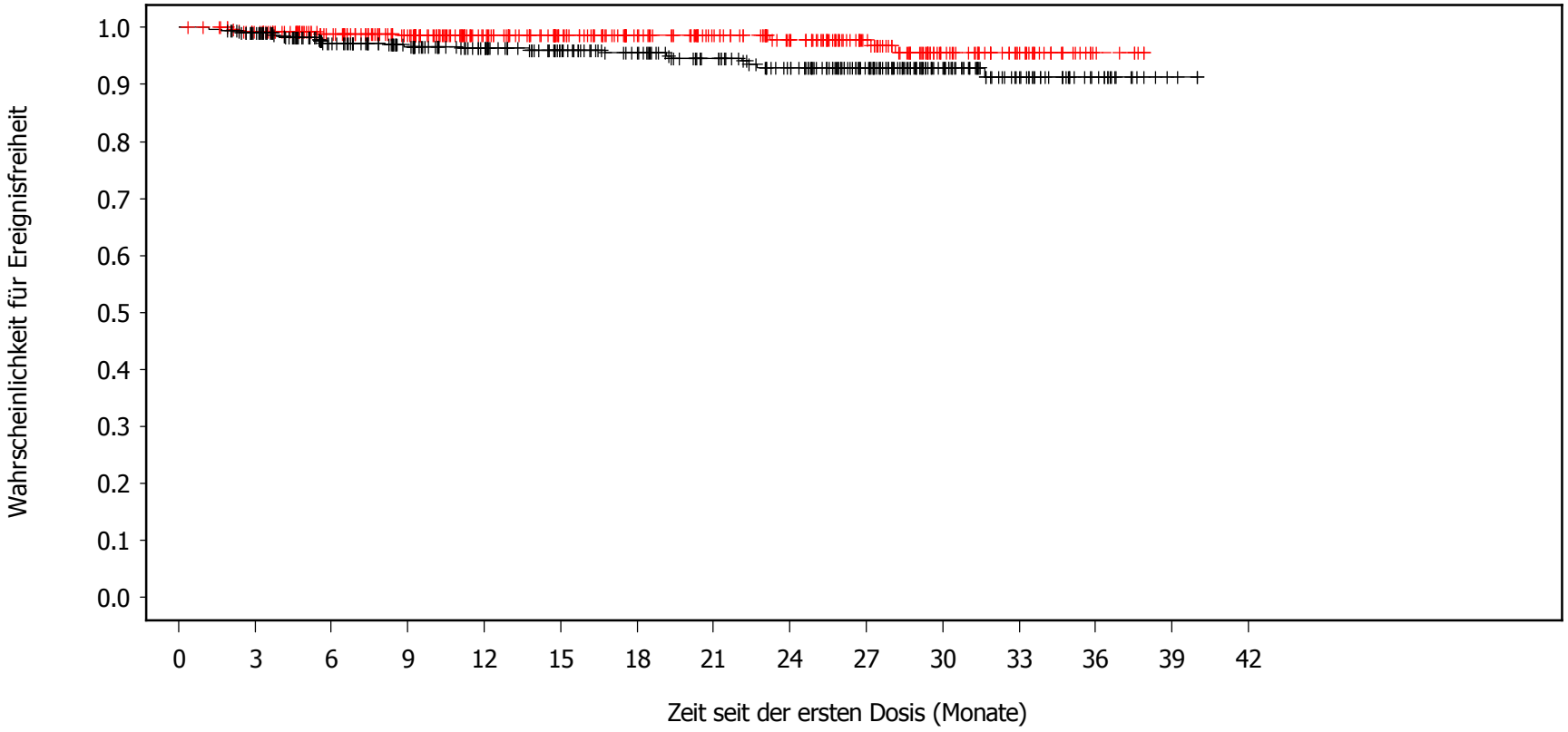


Anzahl an Patienten unter Risiko:

398	381	335	306	273	244	223	198	177	134	76	40	17	2	0	Olaparib + Abiraterone
396	379	339	299	249	214	180	153	127	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaeben 06JUN2022:19:52 kvbv306

Figure 3.3.119 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

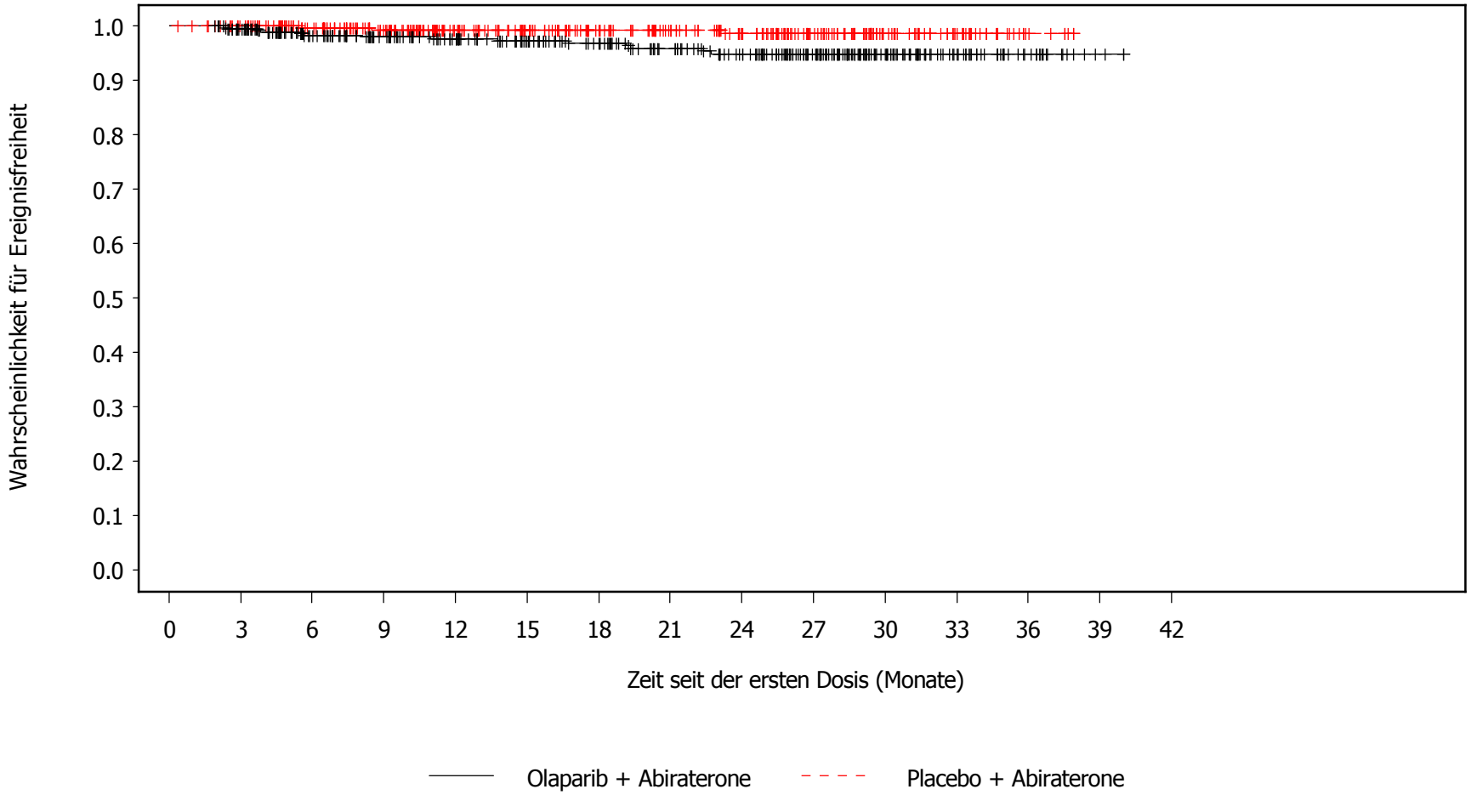


Anzahl an Patienten unter Risiko:

398	381	332	300	267	237	217	193	170	128	75	40	17	2	0	Olaparib + Abiraterone
396	379	339	299	248	212	179	154	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebeo 06JUN2022:19:52 kvbv306

Figure 3.3.120 PROpel: Kaplan-Meier plot of time to first occurrence of SUE PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022



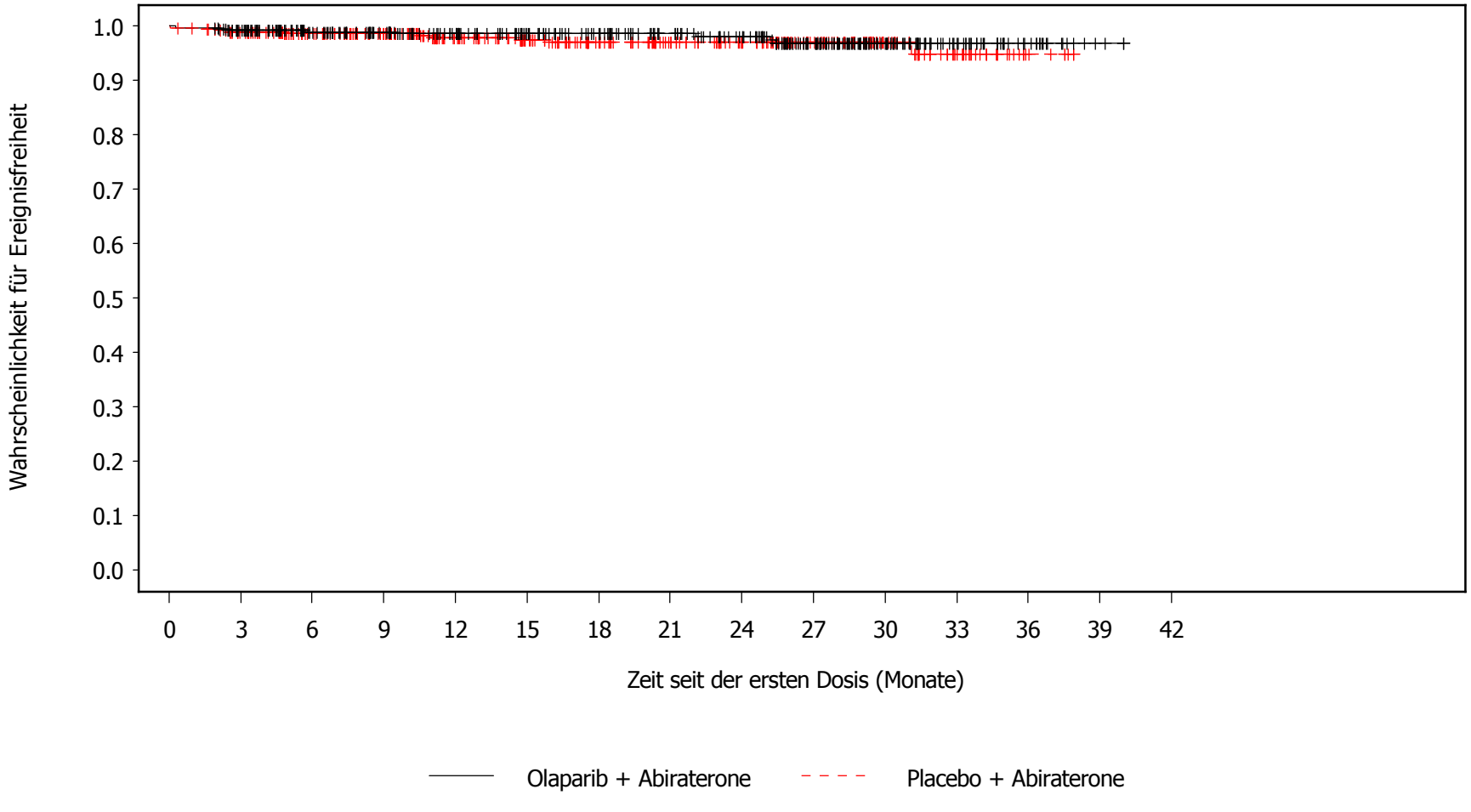
Anzahl an Patienten unter Risiko:

398	382	333	301	268	238	218	193	171	129	75	40	17	2	0	Olaparib + Abiraterone
396	380	340	300	249	213	180	155	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebep 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.121 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 14MAR2022

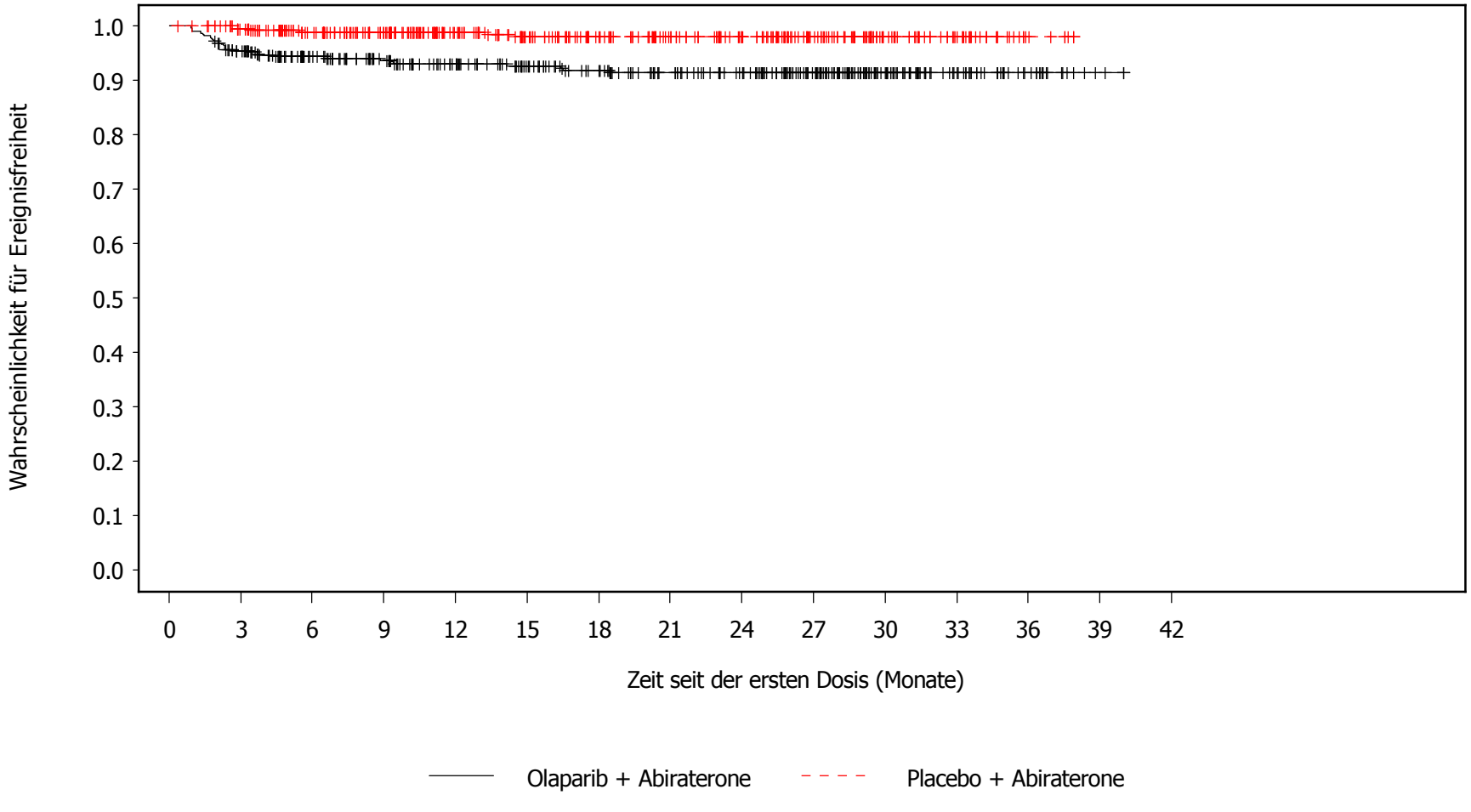


Anzahl an Patienten unter Risiko:

398	381	335	305	273	243	223	198	177	132	77	41	17	2	0	Olaparib + Abiraterone
396	377	337	298	249	212	179	153	128	94	54	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebeq 06JUN2022:19:52 kvbv306

Figure 3.3.122 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

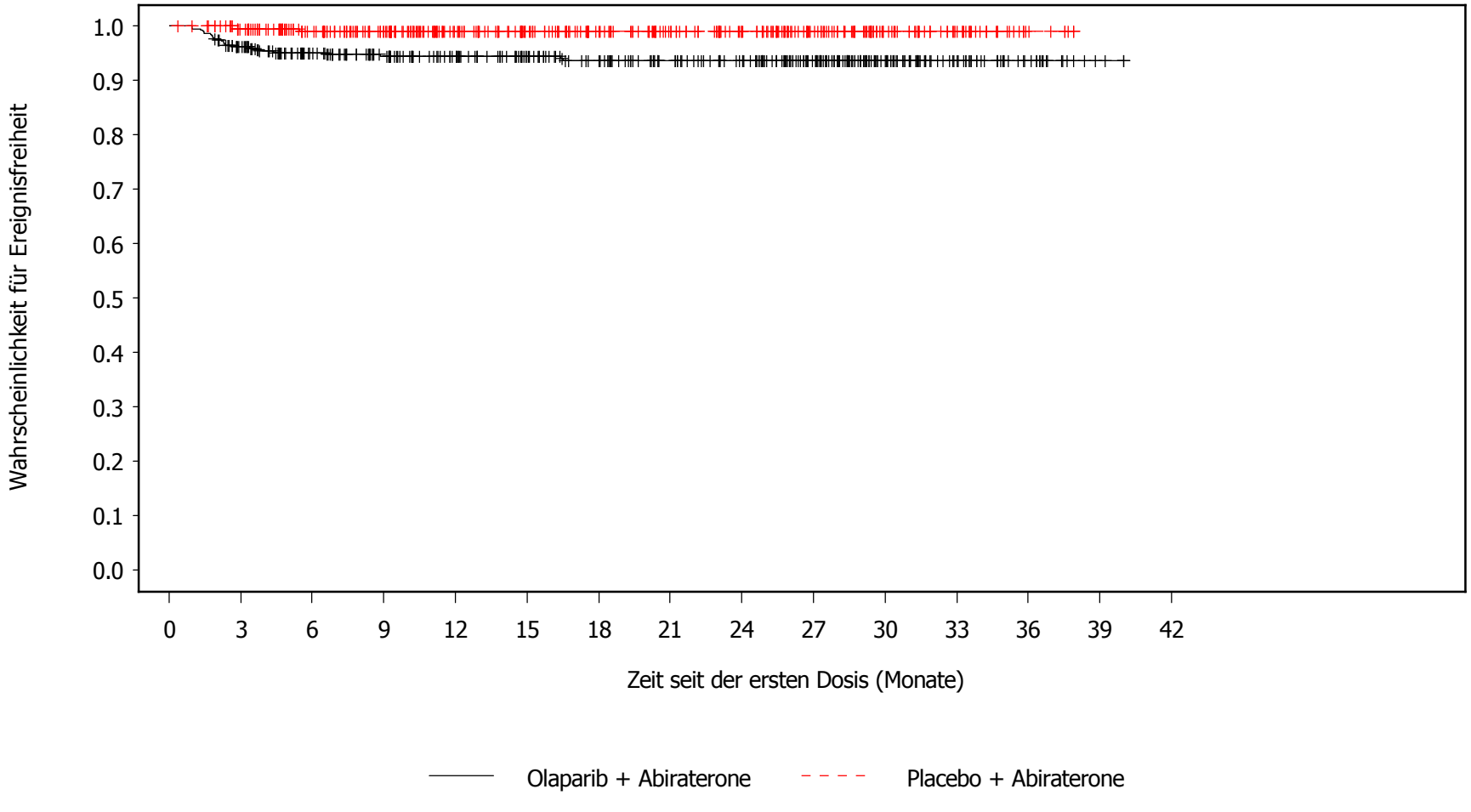


Anzahl an Patienten unter Risiko:

398	369	325	295	262	234	213	189	170	130	73	40	17	2	0	Olaparib + Abiraterone
396	378	338	299	249	212	179	153	127	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaeber 06JUN2022:19:52 kvbv306

Figure 3.3.123 PROpel: Kaplan-Meier plot of time to first occurrence of SUE PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

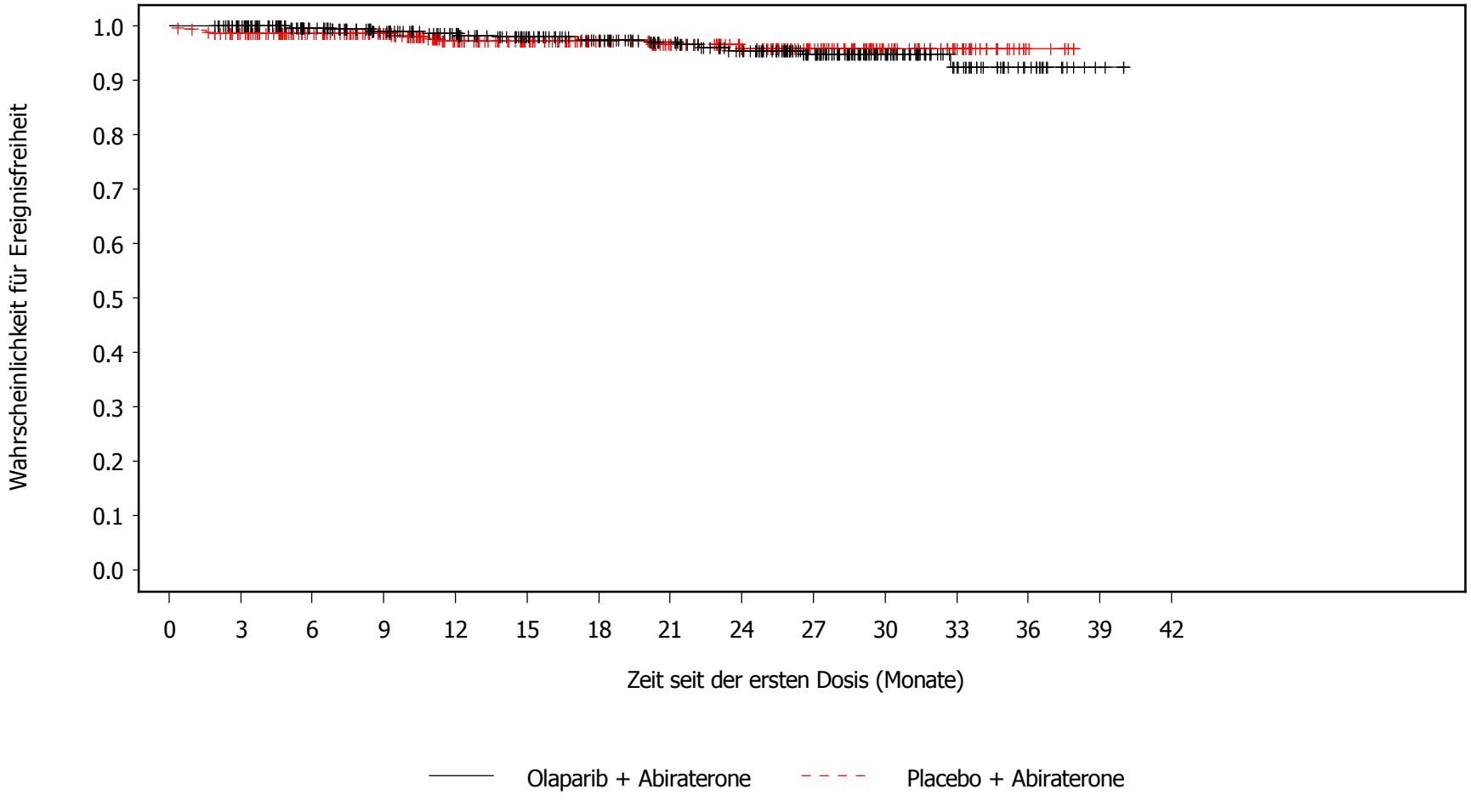


Anzahl an Patienten unter Risiko:

398	370	326	296	265	236	215	191	172	131	74	40	17	2	0	Olaparib + Abiraterone
396	378	339	300	249	213	180	154	128	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebes 06JUN2022:19:52 kvbv306

Figure 3.3.124 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 14MAR2022

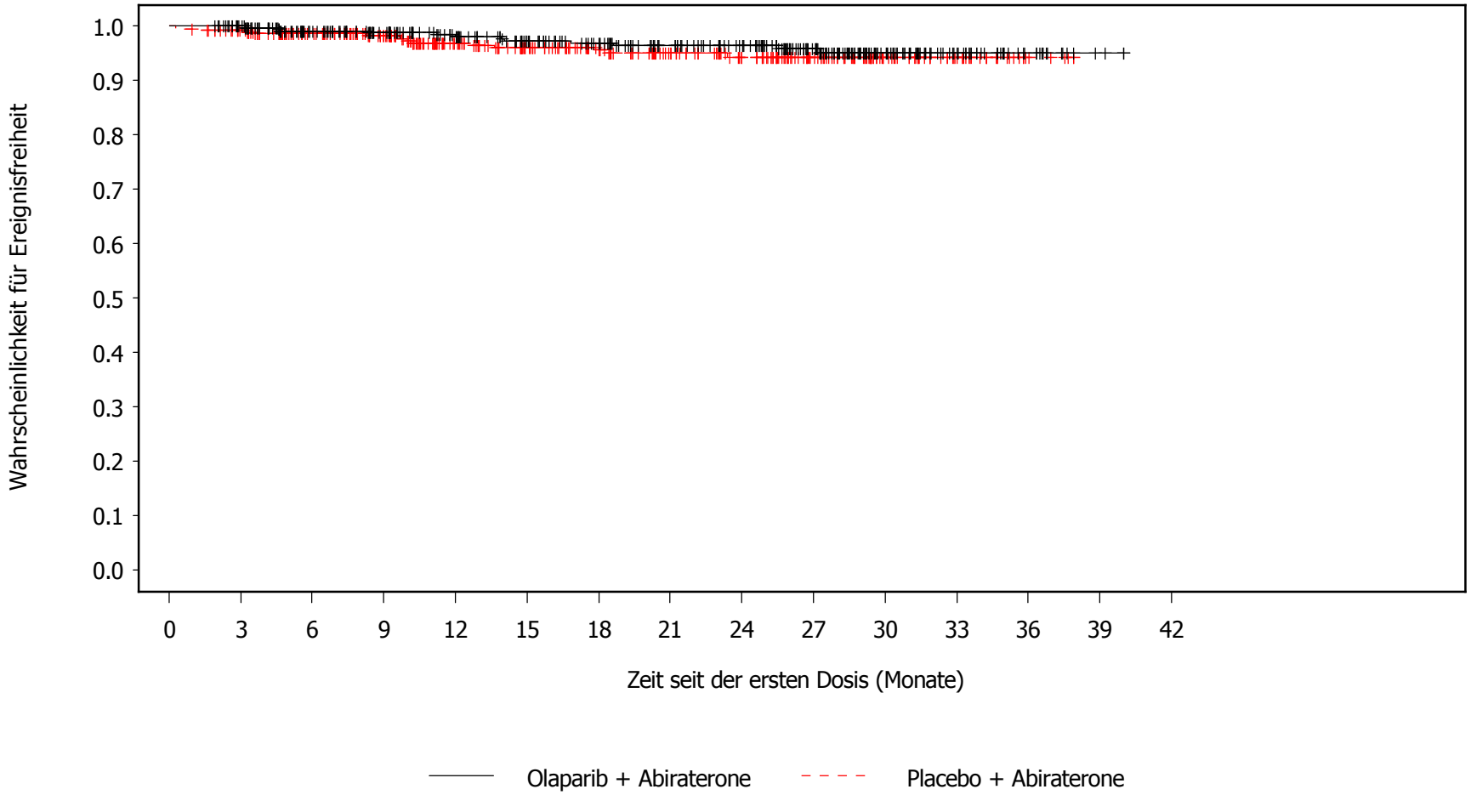


Anzahl an Patienten unter Risiko:

398	384	338	307	275	243	221	196	173	131	76	39	17	2	0	Olaparib + Abiraterone
396	376	337	298	247	211	179	153	126	92	52	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebet 06JUN2022:19:52 kvbv306

Figure 3.3.125 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 14MAR2022



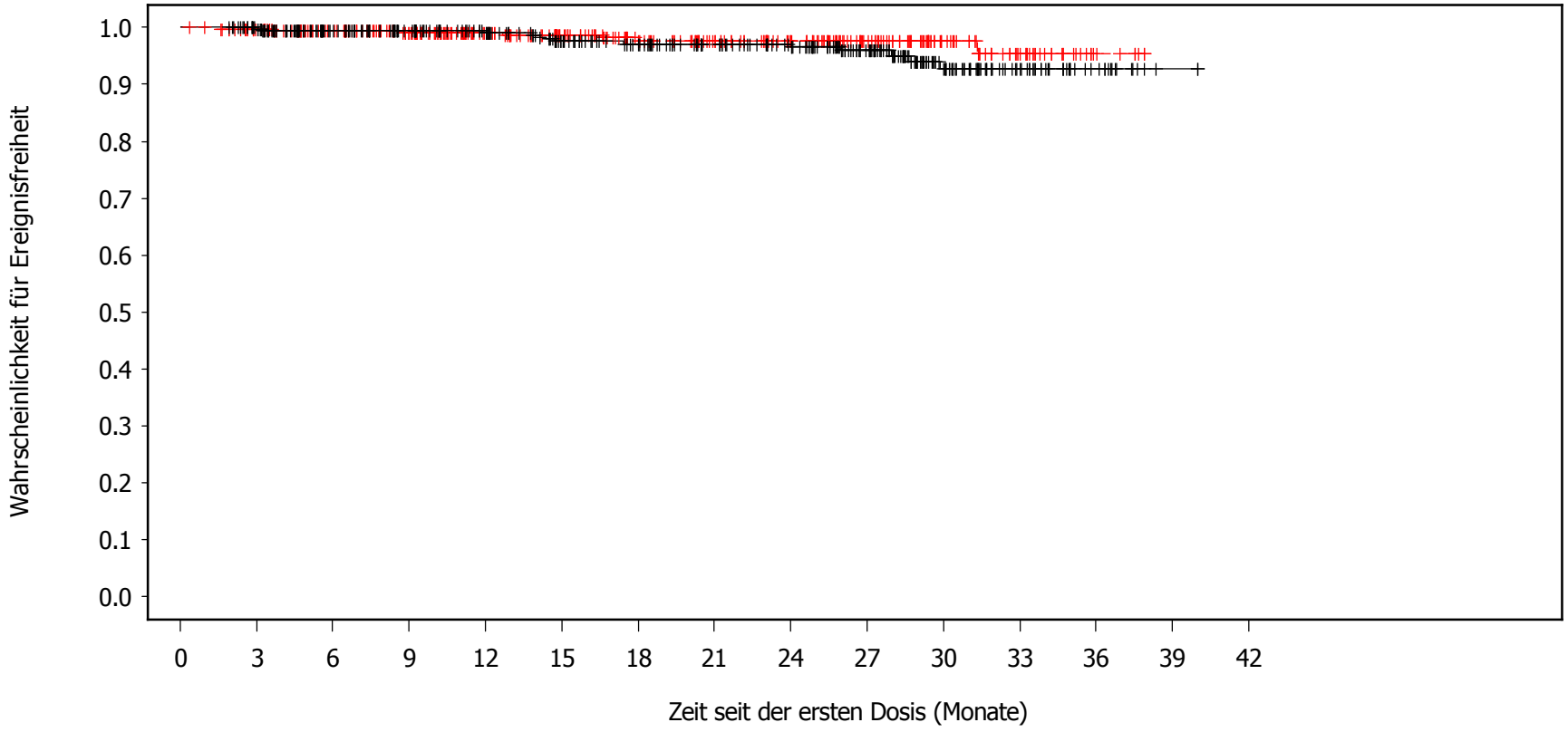
Anzahl an Patienten unter Risiko:

398	384	338	306	272	241	221	195	175	131	73	37	14	2	0	Olaparib + Abiraterone
396	379	339	298	245	209	177	151	124	91	51	27	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebeu 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.126 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Gutartige, boesartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)
Safety Analysis Set, DCO 14MAR2022

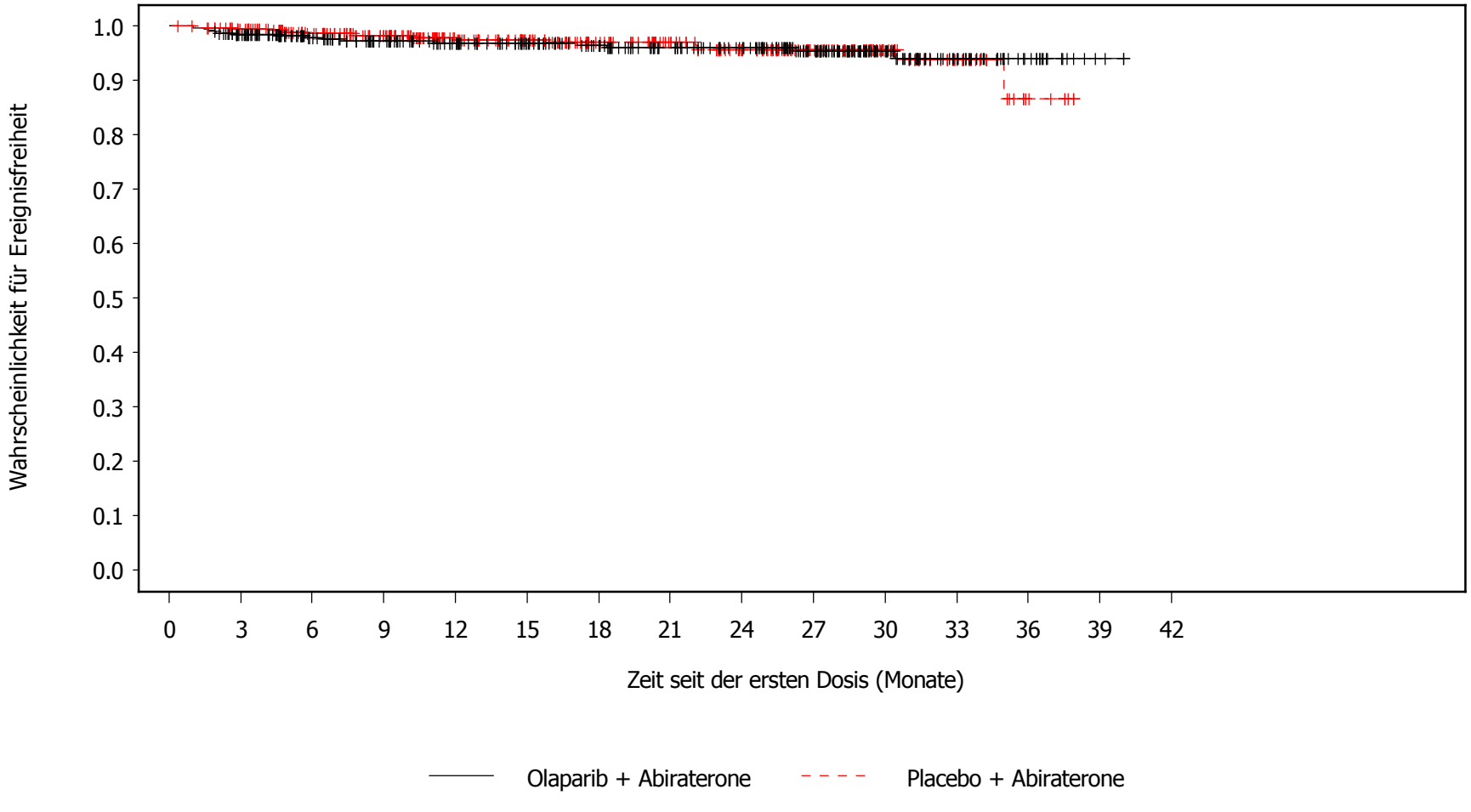


Anzahl an Patienten unter Risiko:

398	383	337	306	273	239	219	195	174	132	72	37	14	1	0	Olaparib + Abiraterone
396	379	339	298	248	213	179	152	126	91	53	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebev 06JUN2022:19:52 kvbv306

Figure 3.3.127 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Herzerkrankungen
Safety Analysis Set, DCO 14MAR2022

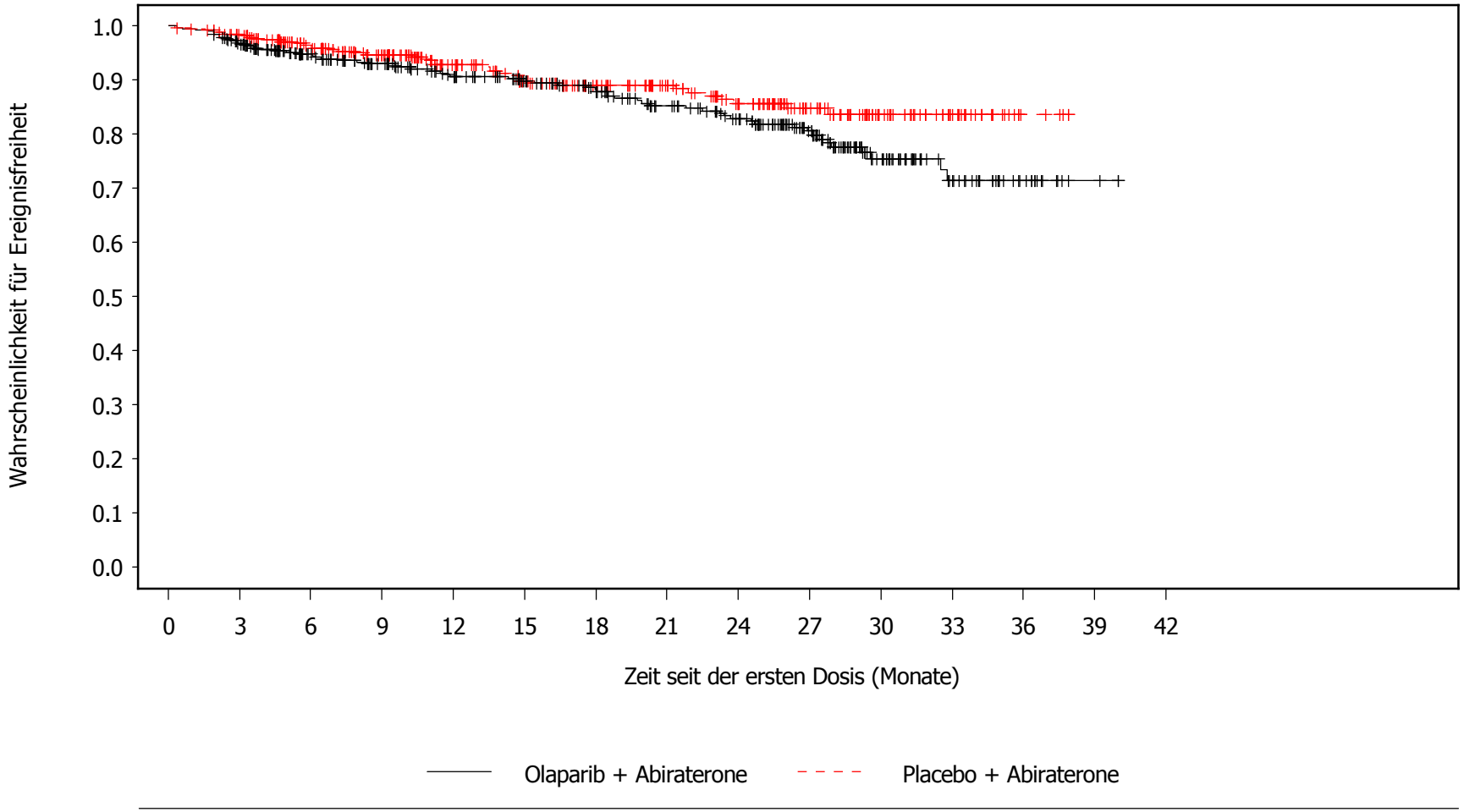


Anzahl an Patienten unter Risiko:

398	379	334	304	271	243	222	197	177	134	76	40	17	2	0	Olaparib + Abiraterone
396	378	338	299	248	213	179	154	128	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebew 06JUN2022:19:52 kvbv306

Figure 3.3.128 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Infektionen und parasitaere Erkrankungen
Safety Analysis Set, DCO 14MAR2022

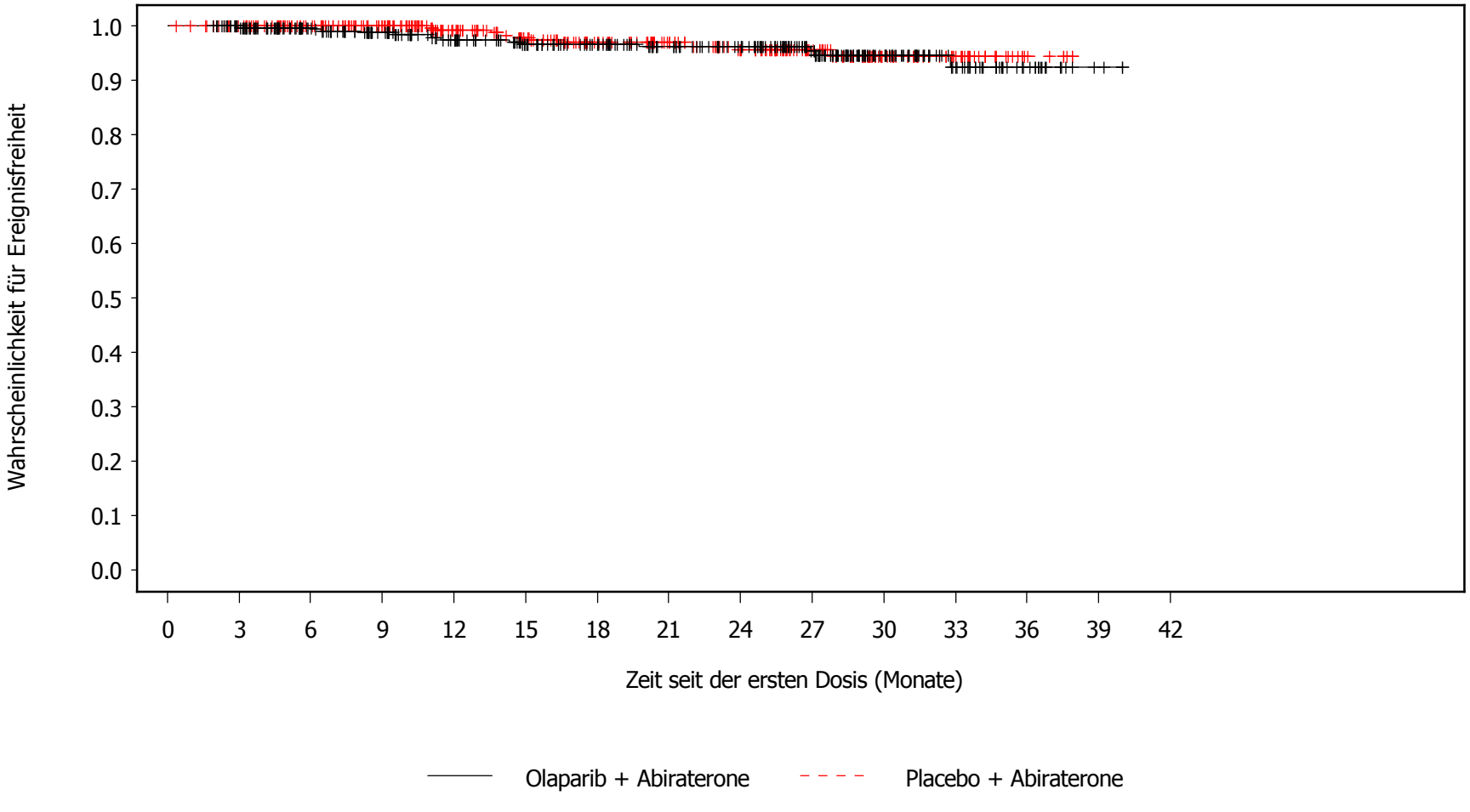


Anzahl an Patienten unter Risiko:

398	376	328	296	260	234	214	187	166	121	64	33	14	2	0	Olaparib + Abiraterone
396	376	331	287	239	202	171	146	119	85	49	27	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebex 06JUN2022:19:52 kvbv306

Figure 3.3.129 PROpel: Kaplan-Meier plot of time to first occurrence of SUE PT: COVID-19
Safety Analysis Set, DCO 14MAR2022

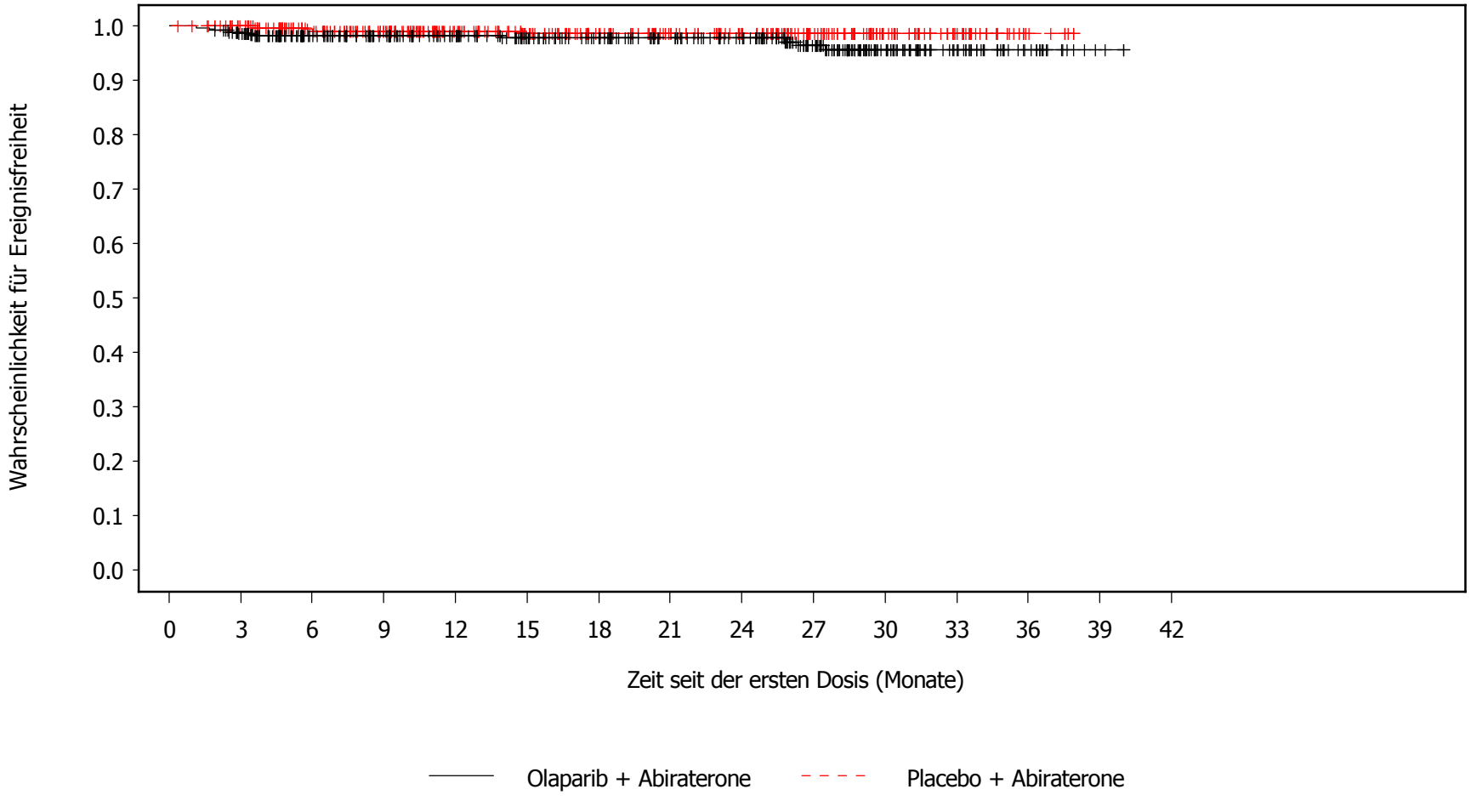


Anzahl an Patienten unter Risiko:

398	383	338	306	272	241	222	197	178	133	76	39	16	2	0	Olaparib + Abiraterone
396	380	341	301	249	213	178	153	127	92	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebey 06JUN2022:19:52 kvbv306

Figure 3.3.130 PROpel: Kaplan-Meier plot of time to first occurrence of SUE PT: Pneumonie
Safety Analysis Set, DCO 14MAR2022



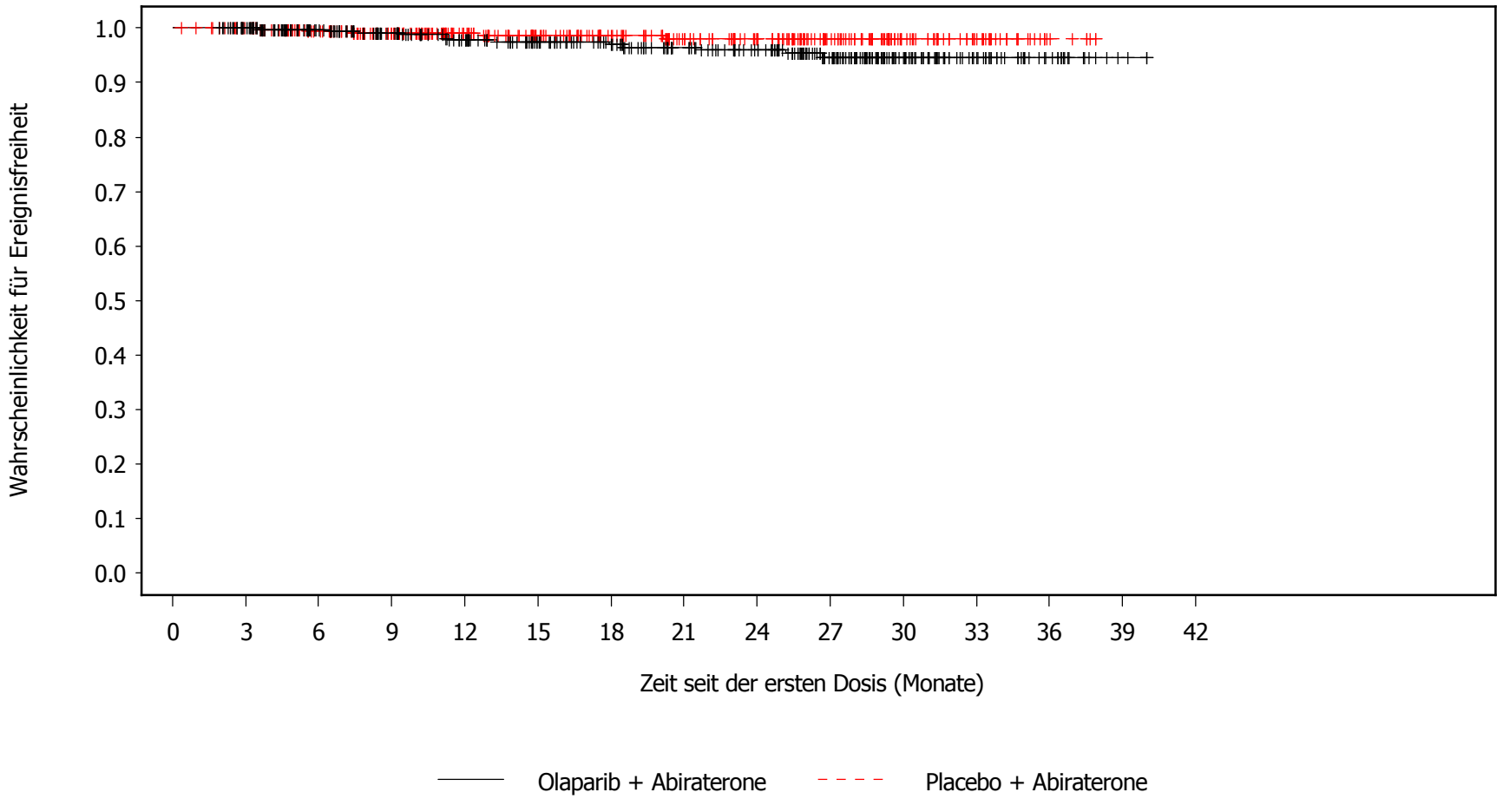
Anzahl an Patienten unter Risiko:

398	382	335	306	274	244	224	199	179	133	75	41	17	2	0	Olaparib + Abiraterone
396	380	339	298	248	211	179	153	127	92	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebez 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.131 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Safety Analysis Set, DCO 14MAR2022



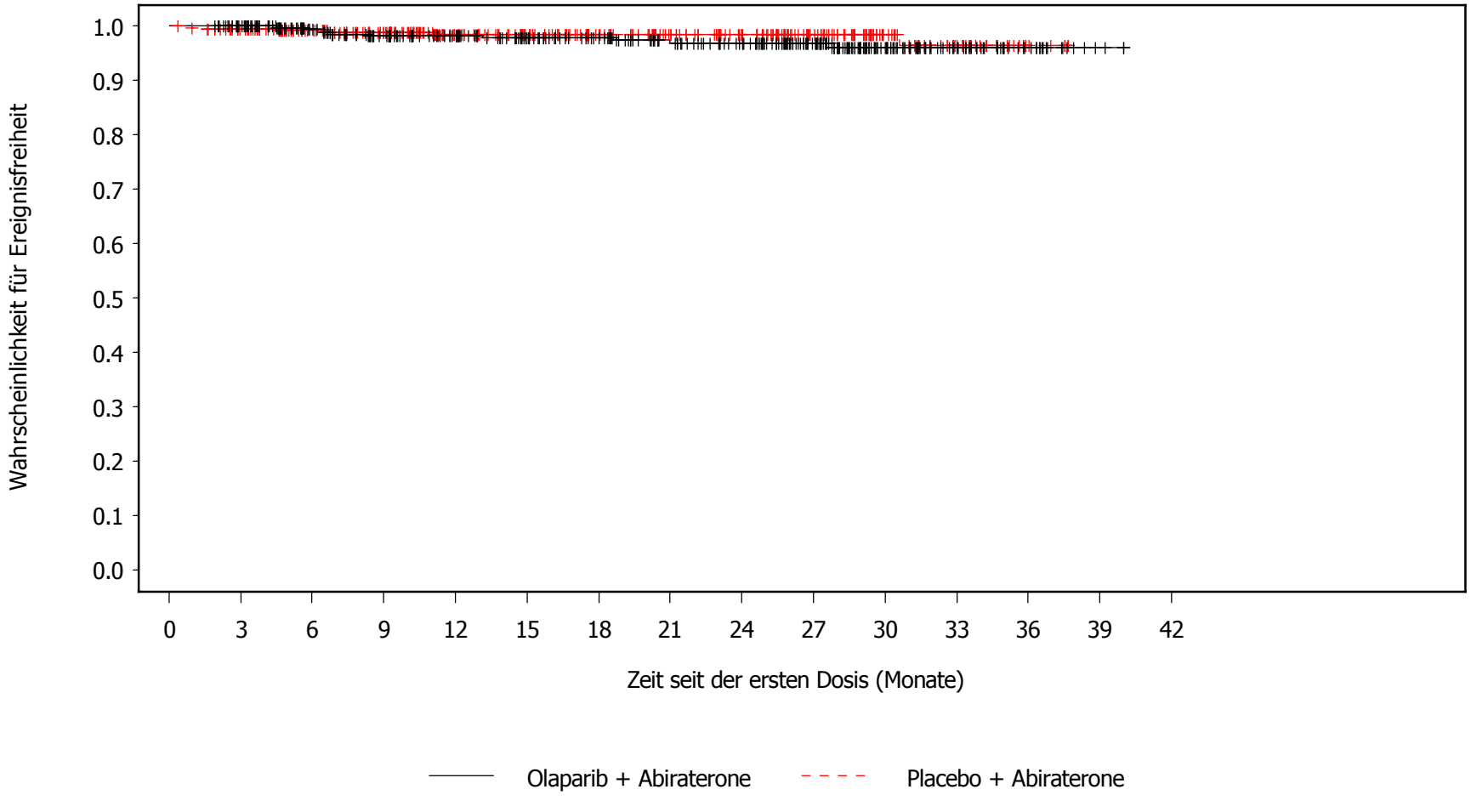
Anzahl an Patienten unter Risiko:

398	384	339	307	273	242	221	195	175	131	74	39	17	2	0	Olaparib + Abiraterone
396	380	341	300	249	212	180	153	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfa 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.132 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 14MAR2022

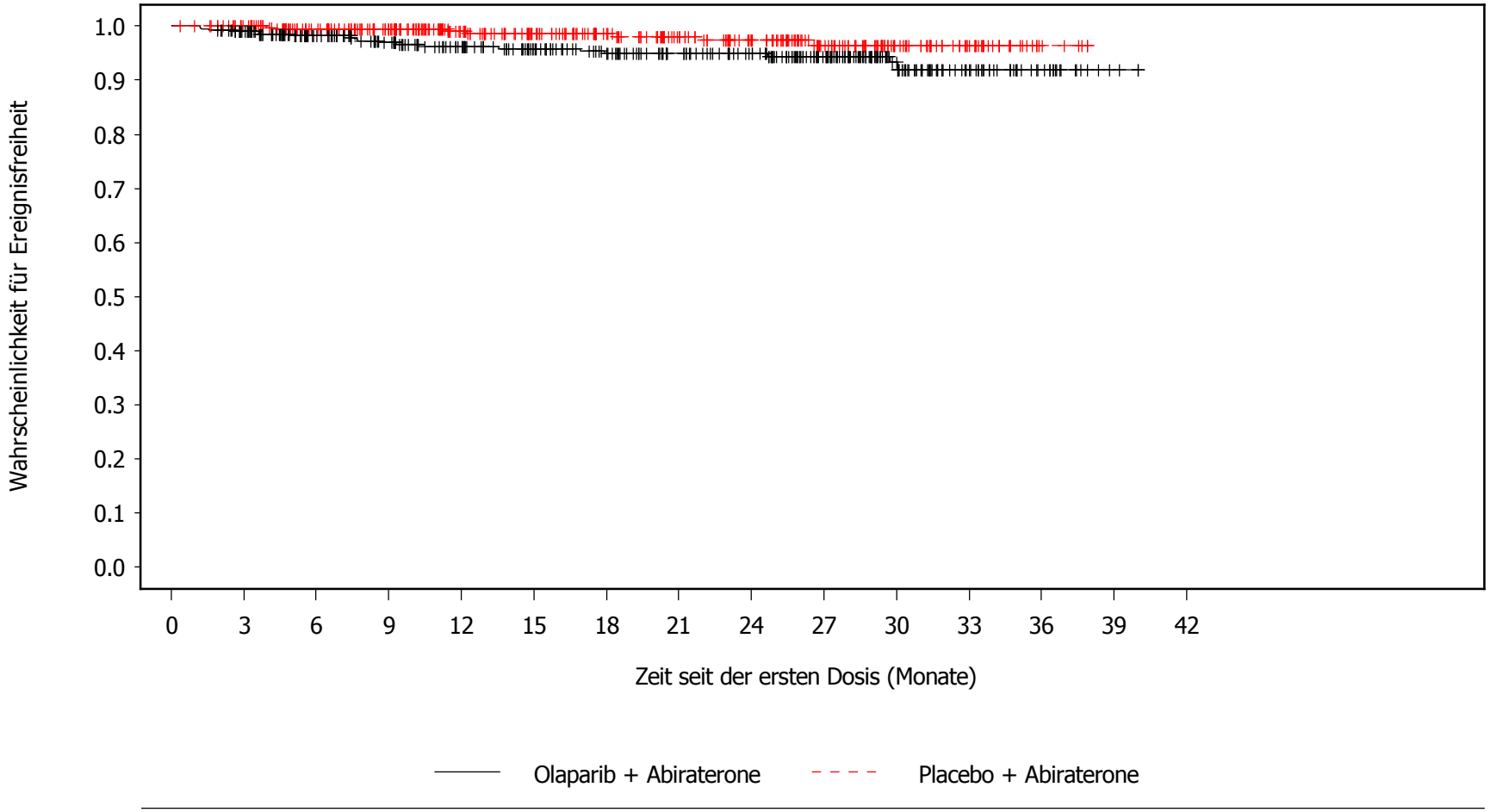


Anzahl an Patienten unter Risiko:

398	384	338	307	275	244	224	198	179	135	77	41	17	2	0	Olaparib + Abiraterone
396	378	338	300	249	213	181	155	129	94	54	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfb 06JUN2022:19:52 kvbv306

Figure 3.3.133 PROpel: Kaplan-Meier plot of time to first occurrence of SUE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Safety Analysis Set, DCO 14MAR2022

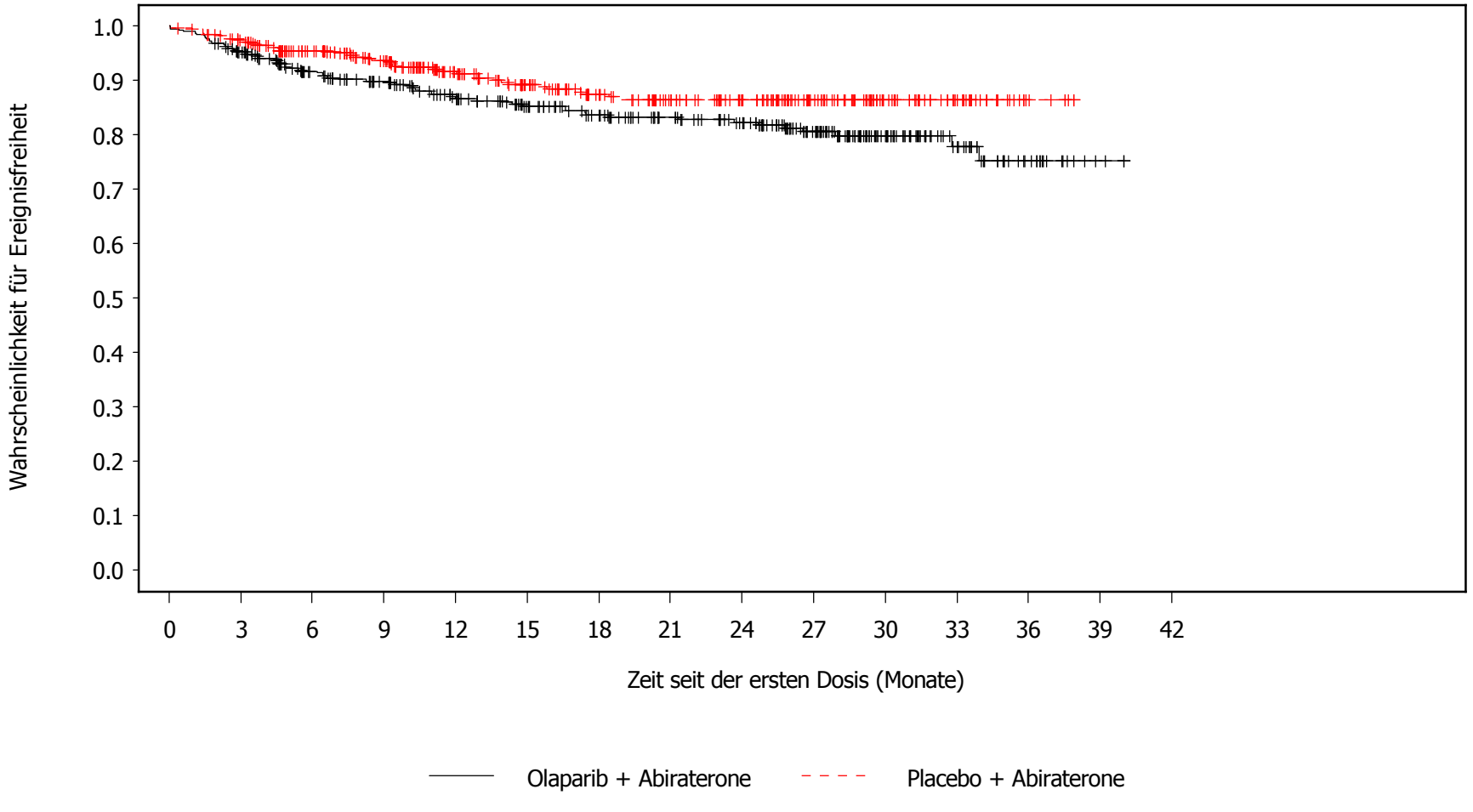


Anzahl an Patienten unter Risiko:

398	381	336	305	272	241	219	194	174	132	75	40	17	2	0	Olaparib + Abiraterone
396	380	339	299	247	212	179	152	125	90	52	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfc 06JUN2022:19:52 kvbv306

Figure 3.3.134 PROpel: Kaplan-Meier plot of time to first occurrence of Abbruch wegen UE
Safety Analysis Set, DCO 14MAR2022

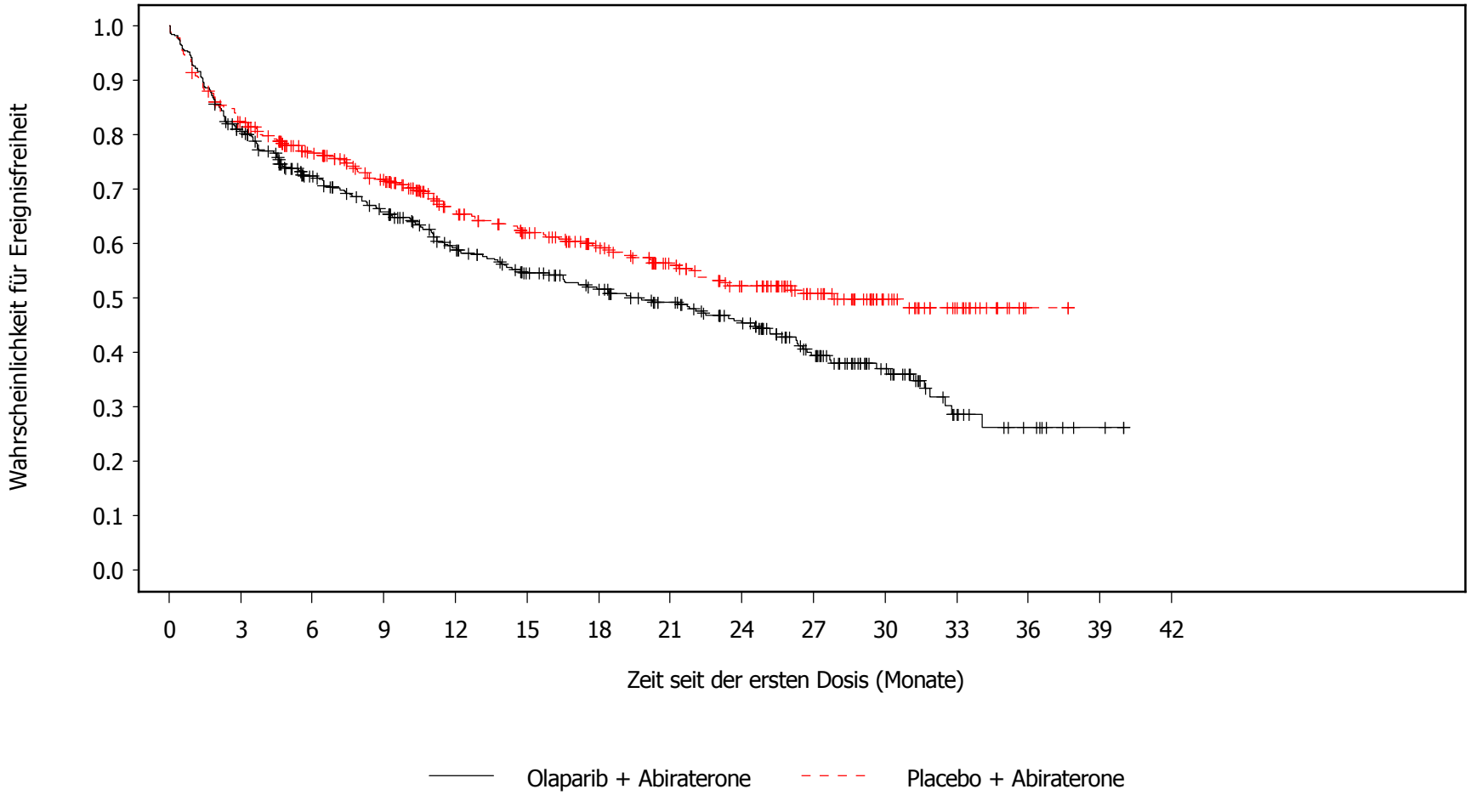


Anzahl an Patienten unter Risiko:

398	369	322	294	257	228	208	185	167	125	70	38	16	2	0	Olaparib + Abiraterone
396	374	333	293	244	207	175	150	125	91	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfd 06JUN2022:19:52 kvbv306

Figure 3.3.135 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, DCO 14MAR2022



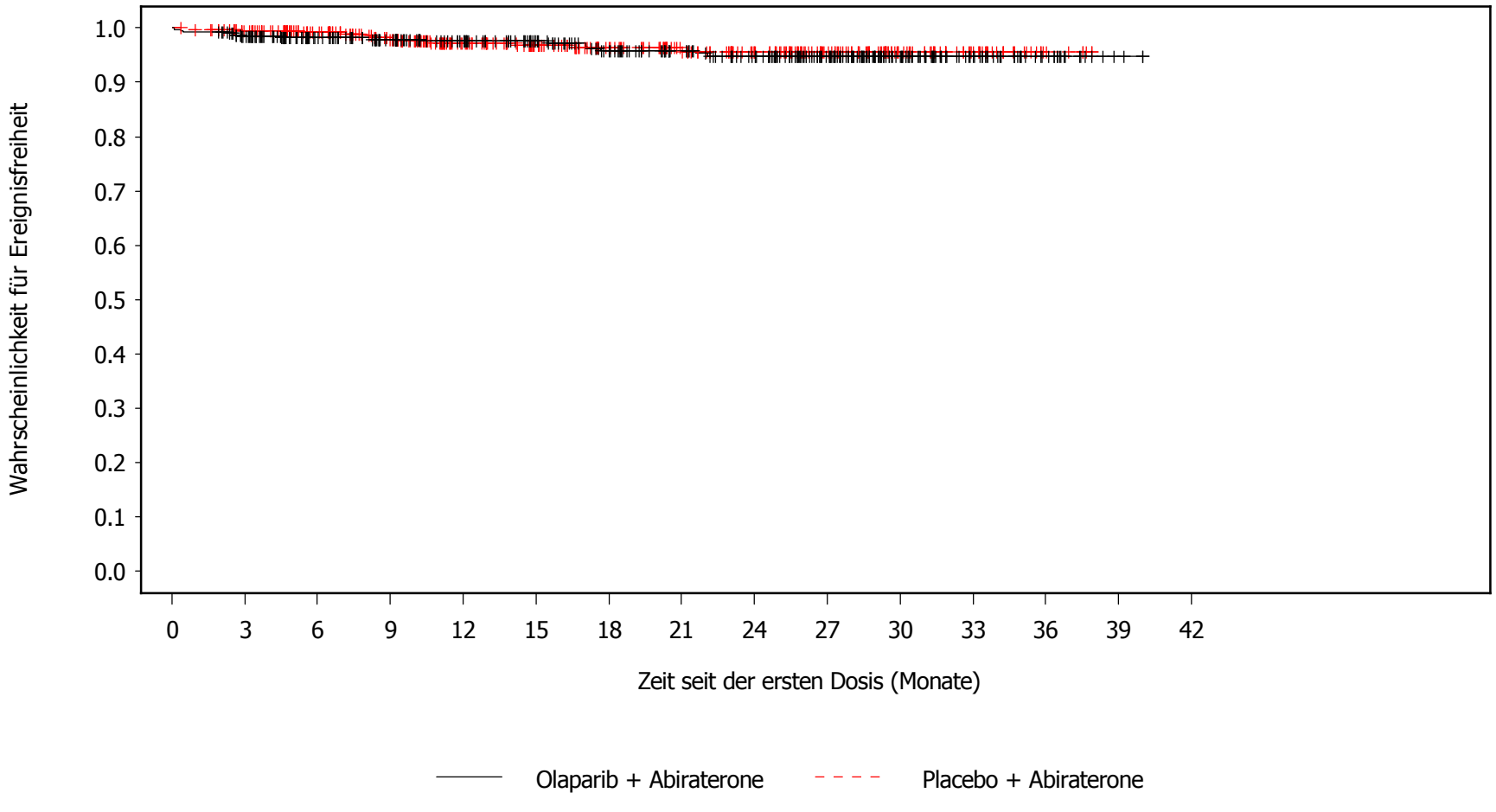
Anzahl an Patienten unter Risiko:

398	315	259	225	184	156	139	120	99	66	38	16	8	2	0	Olaparib + Abiraterone
396	319	271	235	188	161	136	111	89	63	36	19	1	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfe 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.136 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 14MAR2022

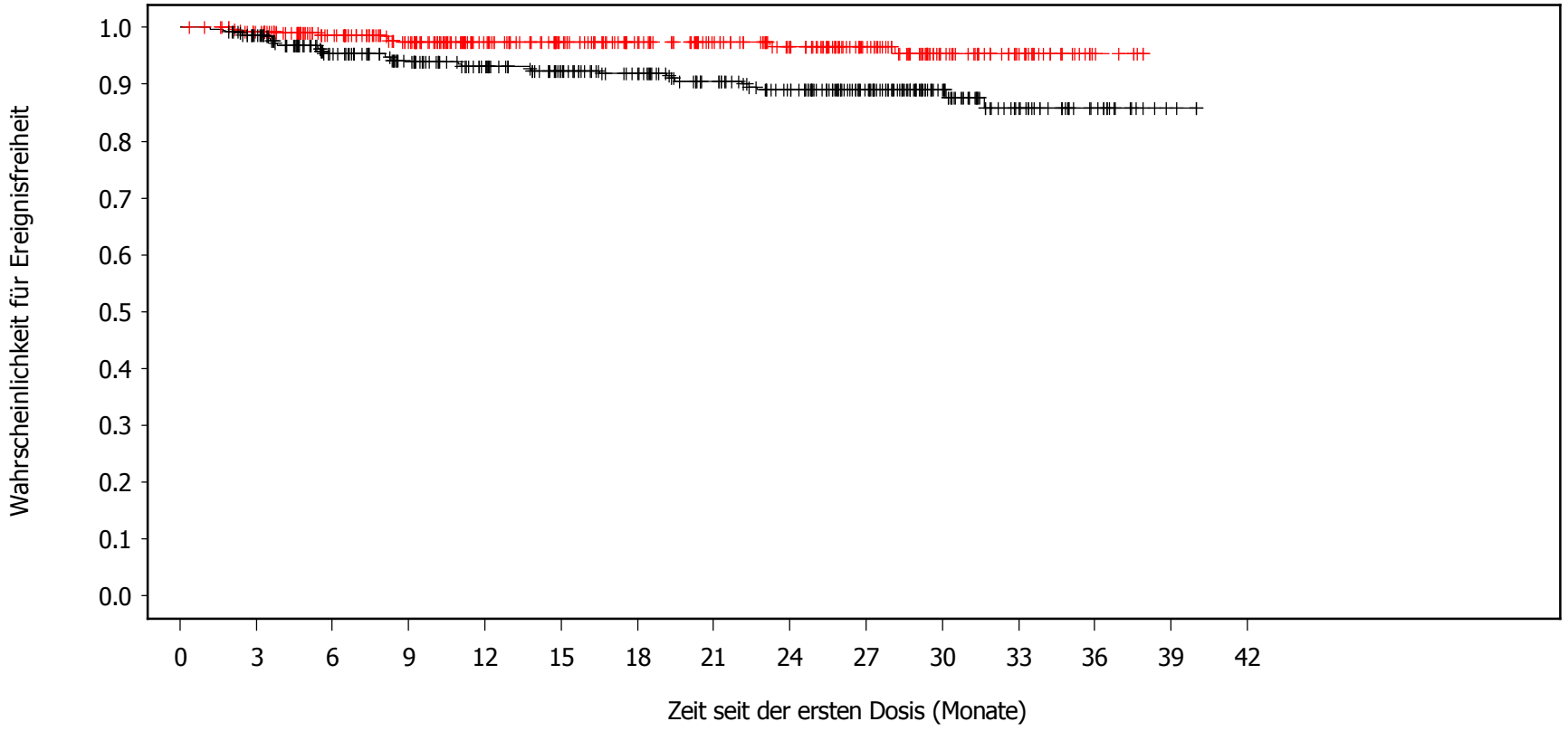


Anzahl an Patienten unter Risiko:

398	379	333	304	273	243	220	196	175	132	75	40	17	2	0	Olaparib + Abiraterone
396	379	340	300	248	211	179	153	127	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebff 06JUN2022:19:52 kvbv306

Figure 3.3.137 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

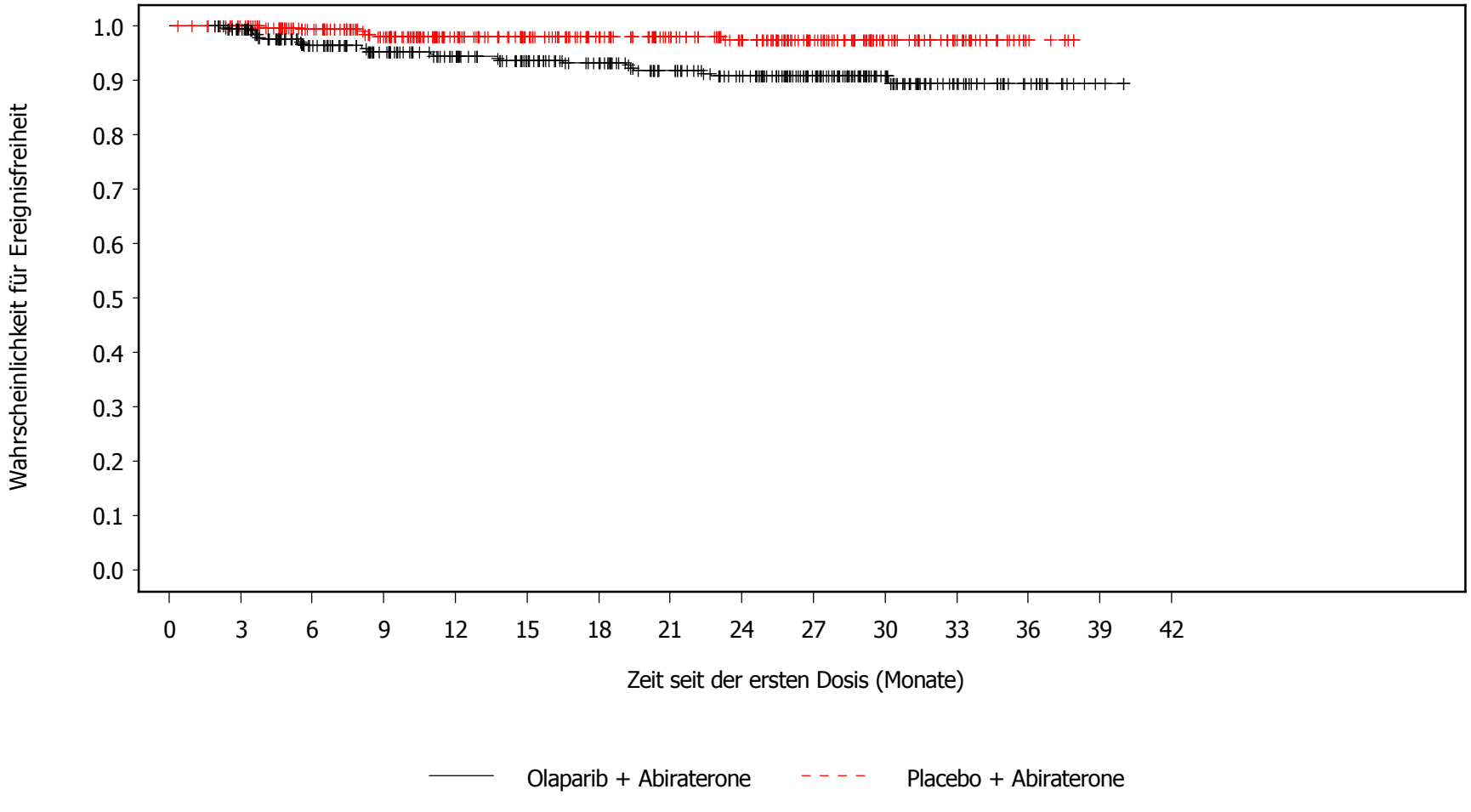


Anzahl an Patienten unter Risiko:

398	380	326	291	259	229	209	184	161	120	71	36	16	2	0	Olaparib + Abiraterone
396	379	338	295	246	211	179	154	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfg 06JUN2022:19:52 kvbv306

Figure 3.3.138 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022



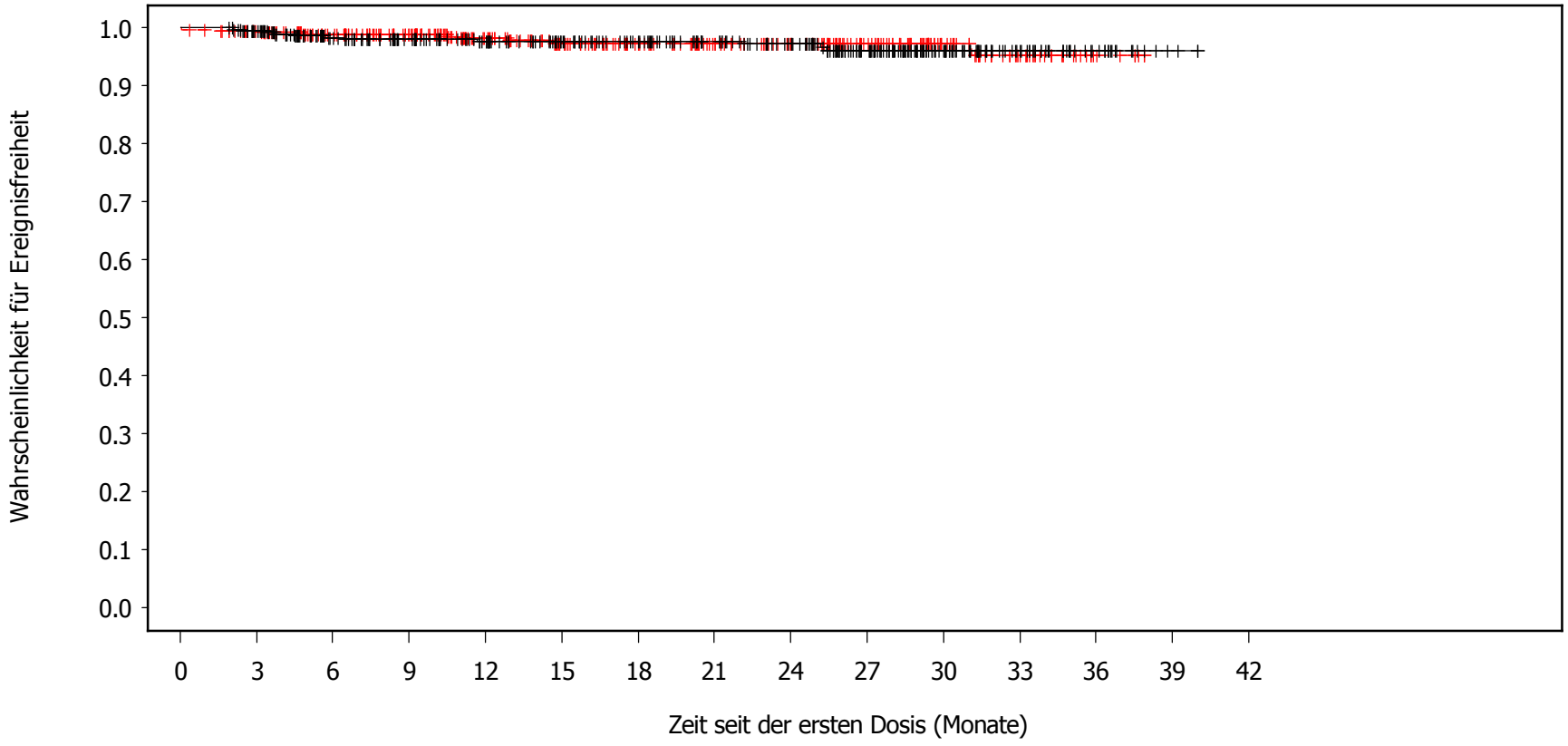
Anzahl an Patienten unter Risiko:

398	382	327	292	260	230	210	184	162	121	71	36	16	2	0	Olaparib + Abiraterone
396	380	339	296	247	212	180	155	128	93	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfh 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.139 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 14MAR2022

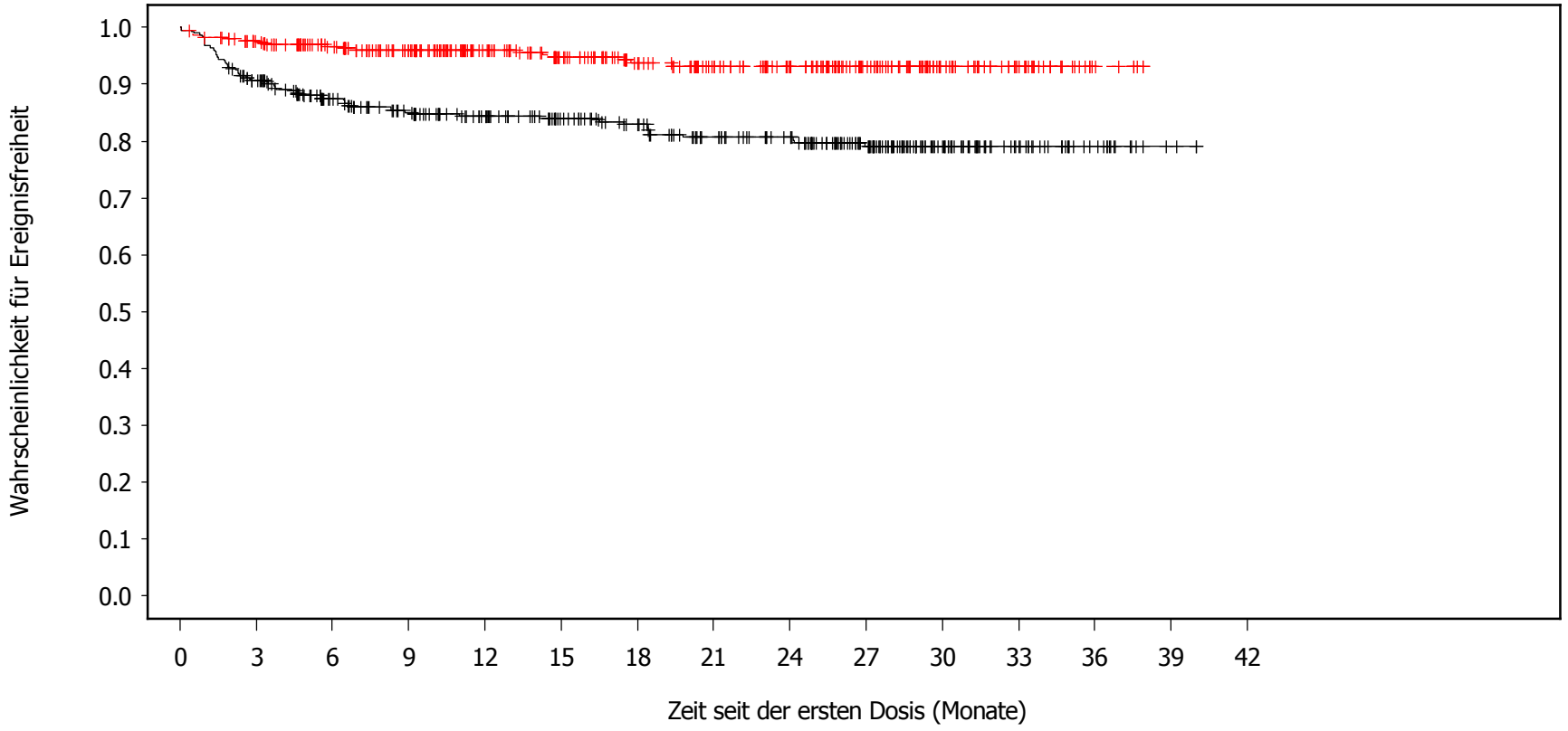


Anzahl an Patienten unter Risiko:

398	382	333	303	271	244	224	199	178	133	77	41	17	2	0	Olaparib + Abiraterone
396	378	338	299	249	212	179	153	128	94	54	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfi 06JUN2022:19:52 kvbv306

Figure 3.3.140 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

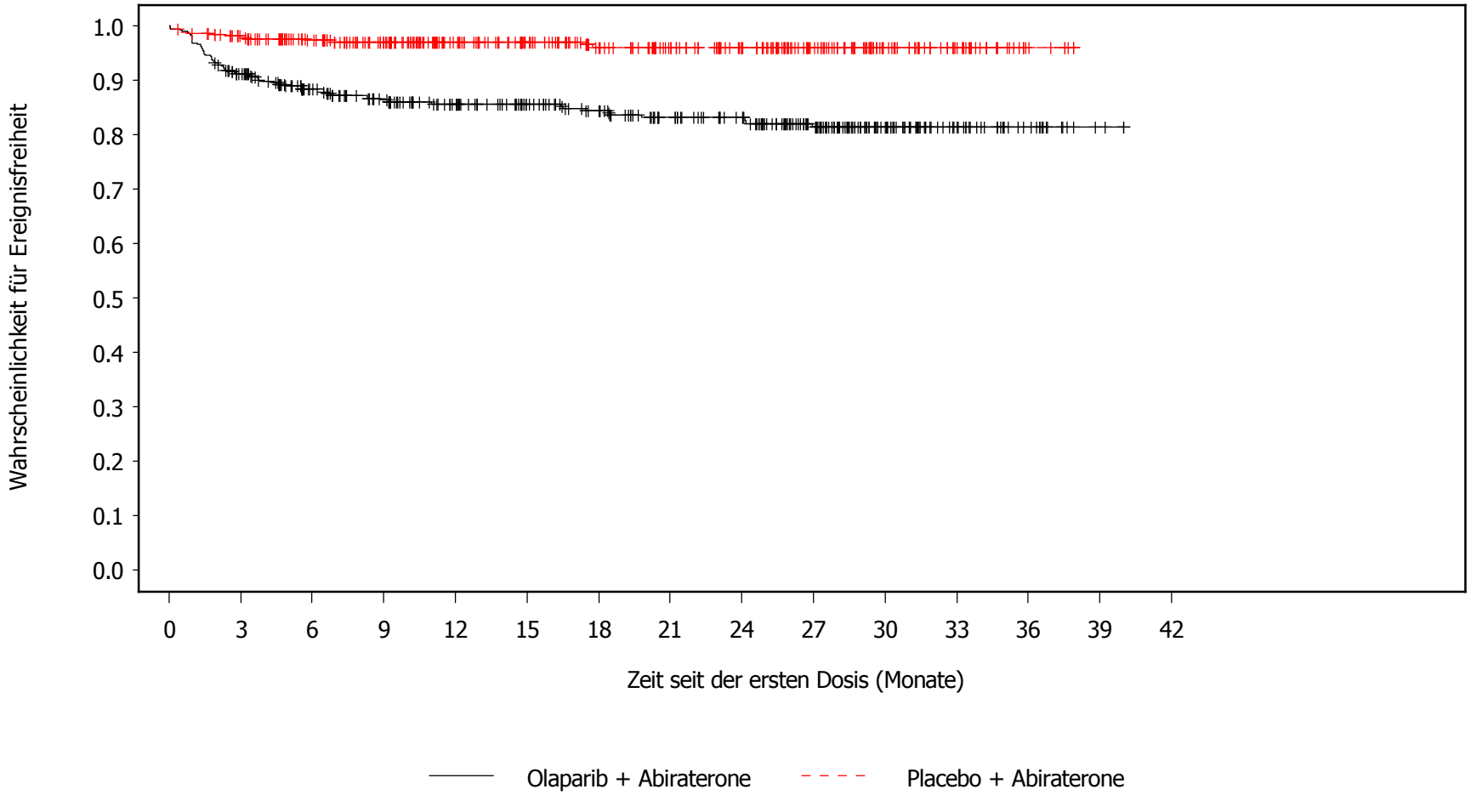


Anzahl an Patienten unter Risiko:

398	351	304	277	246	219	200	174	158	116	66	35	15	2	0	Olaparib + Abiraterone
396	372	335	296	248	212	178	153	127	92	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfj 06JUN2022:19:52 kvbv306

Figure 3.3.141 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

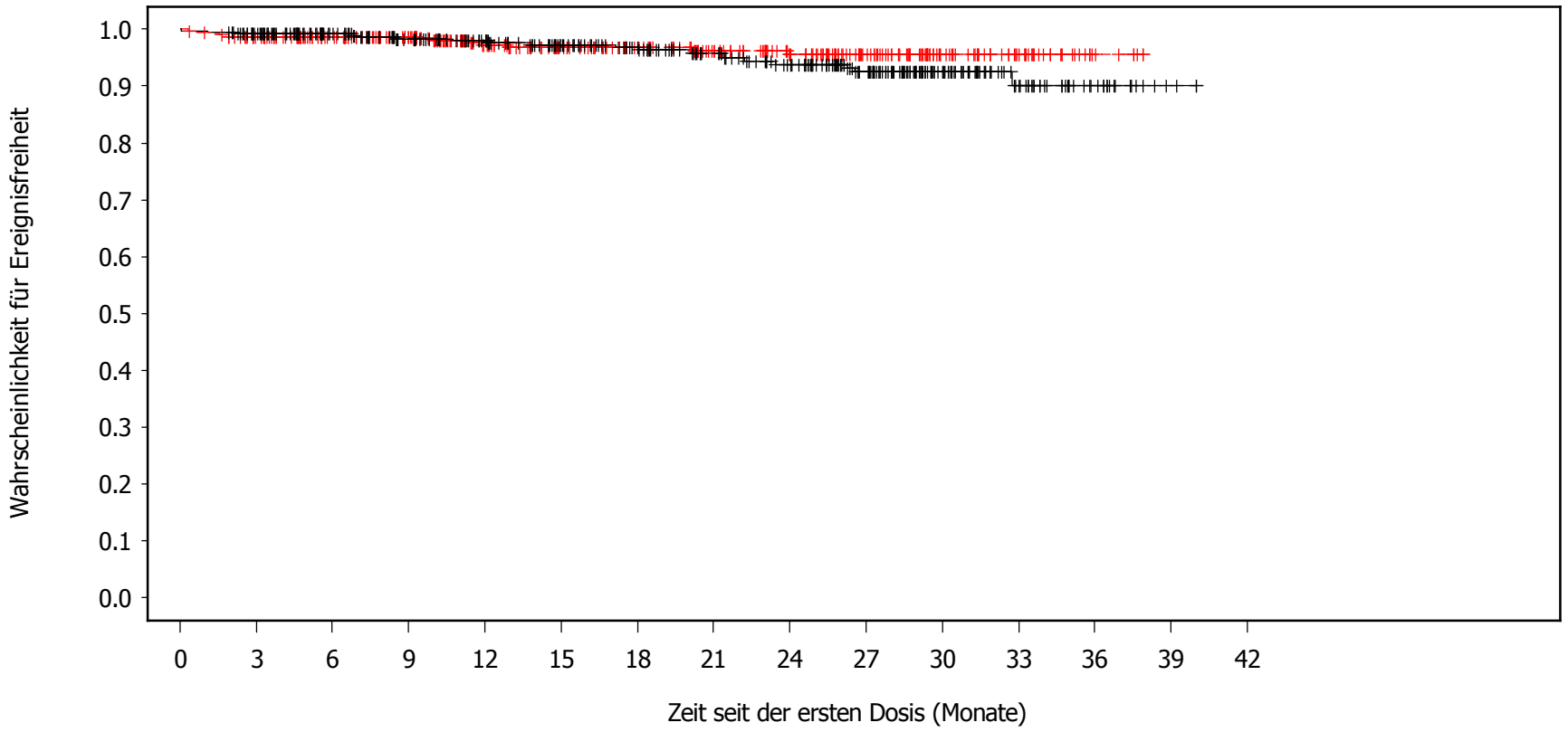


Anzahl an Patienten unter Risiko:

398	352	307	280	248	221	202	177	161	119	67	35	15	2	0	Olaparib + Abiraterone
396	374	337	298	249	214	179	155	129	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfk 06JUN2022:19:52 kvbv306

Figure 3.3.142 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 14MAR2022



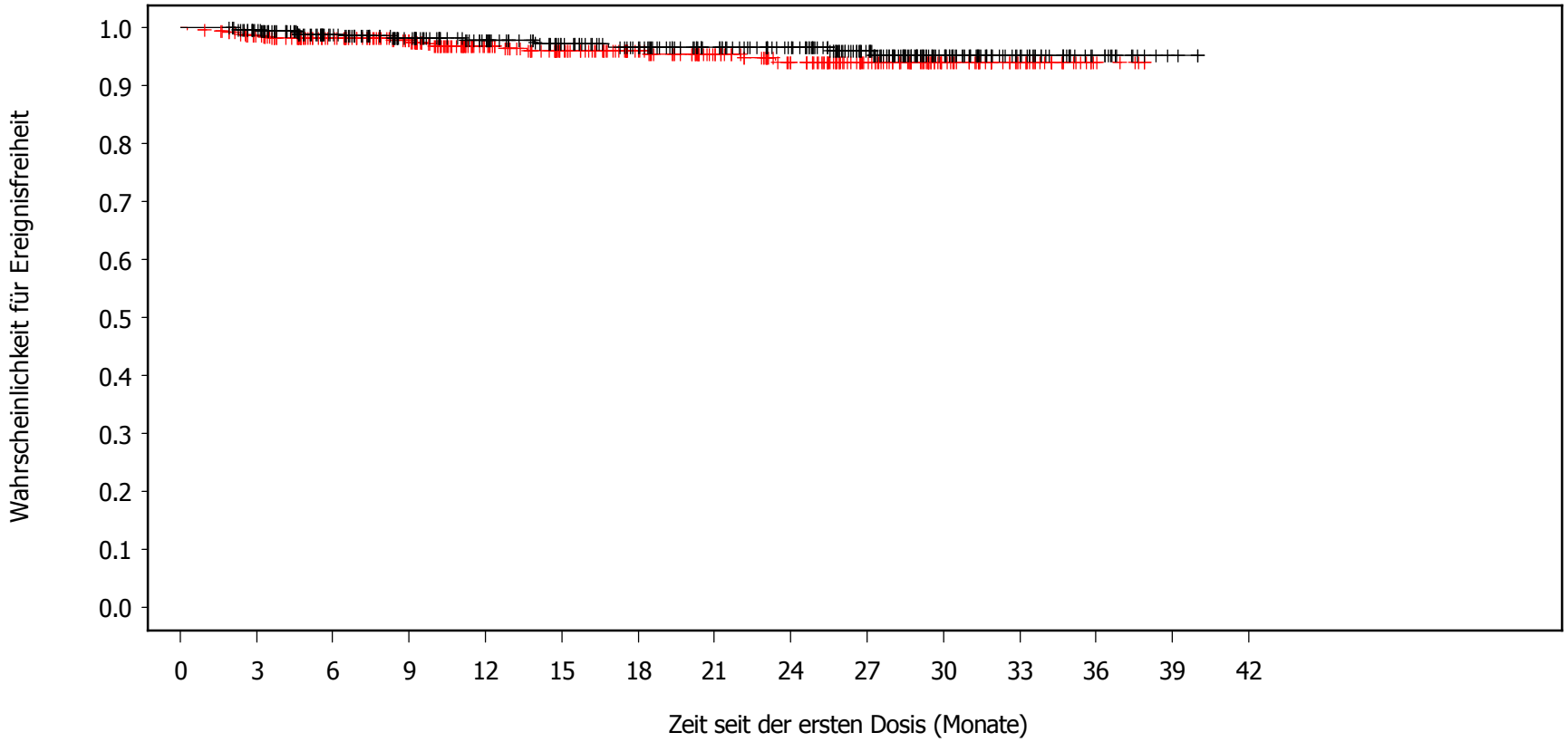
Anzahl an Patienten unter Risiko:

398	381	337	305	274	242	220	194	170	129	74	38	16	2	0	Olaparib + Abiraterone
396	376	337	298	246	209	179	153	126	92	52	29	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfl 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.143 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 14MAR2022



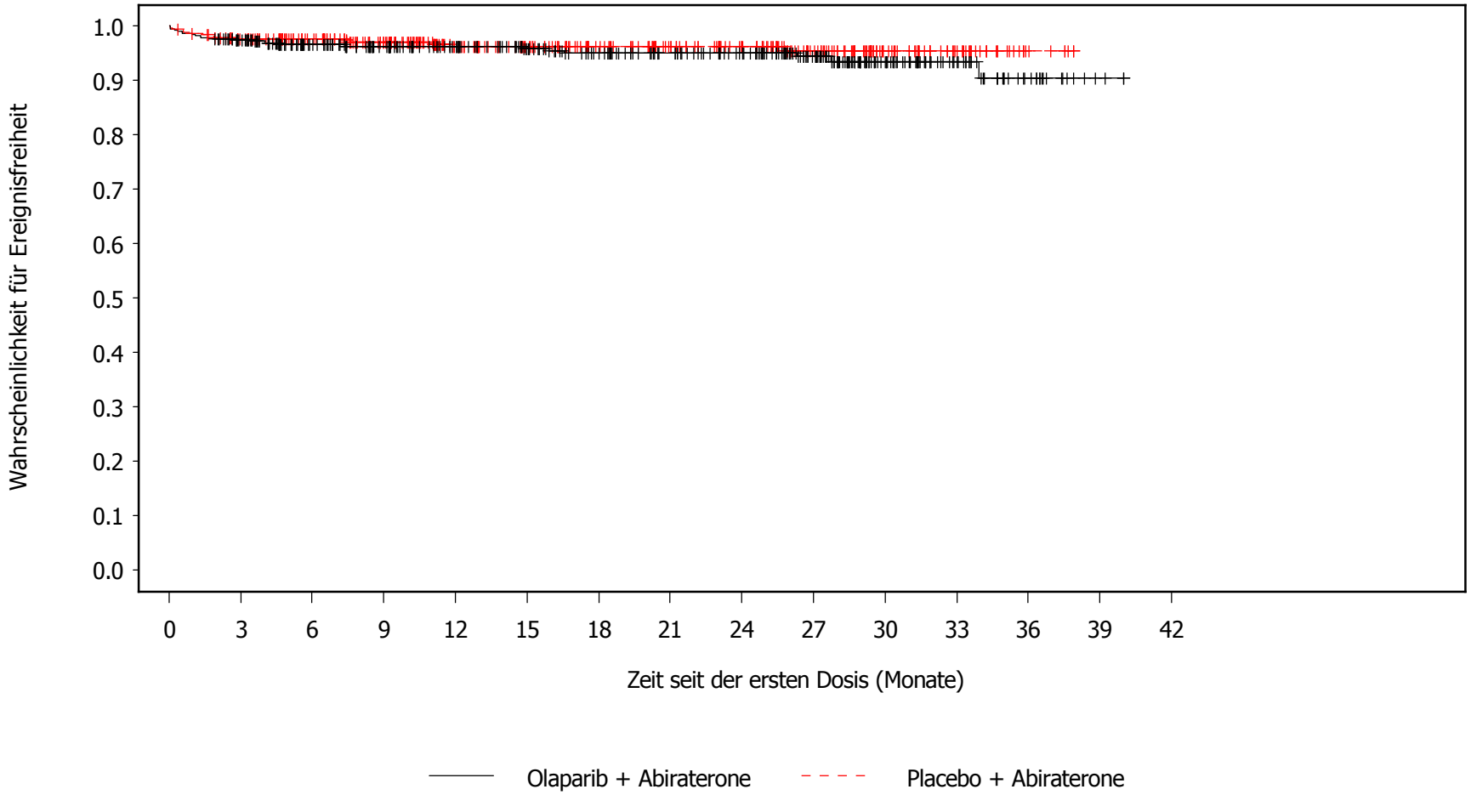
Anzahl an Patienten unter Risiko:

398	383	337	304	271	240	221	196	176	132	74	38	15	2	0	Olaparib + Abiraterone
396	376	336	297	245	211	179	153	125	91	52	28	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfm 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.144 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Gefaesserkrankungen
Safety Analysis Set, DCO 14MAR2022

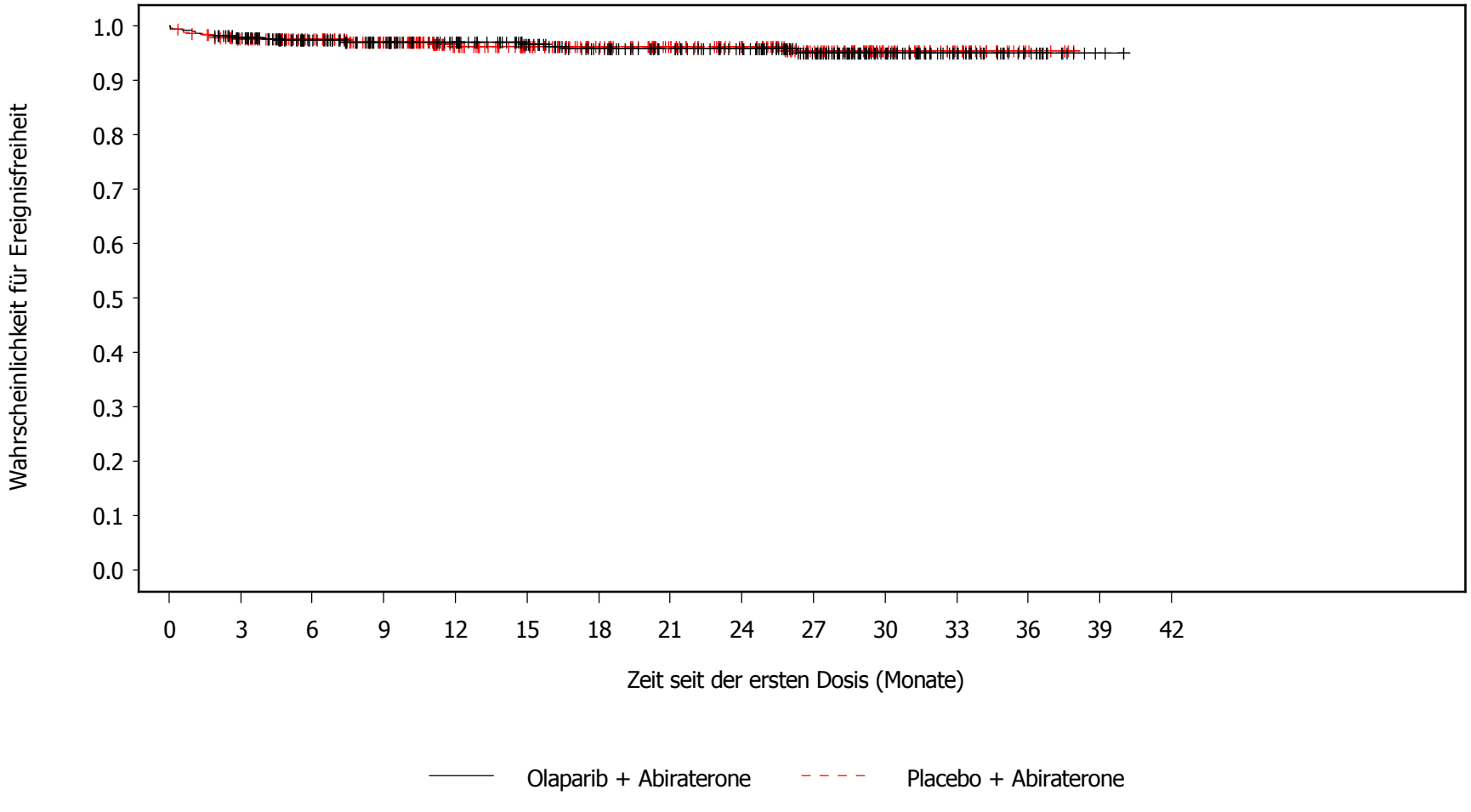


Anzahl an Patienten unter Risiko:

398	374	328	297	265	235	213	190	170	127	71	39	16	2	0	Olaparib + Abiraterone
396	371	332	291	239	205	174	150	126	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfn 06JUN2022:19:52 kvbv306

Figure 3.3.145 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Hypertonie
Safety Analysis Set, DCO 14MAR2022

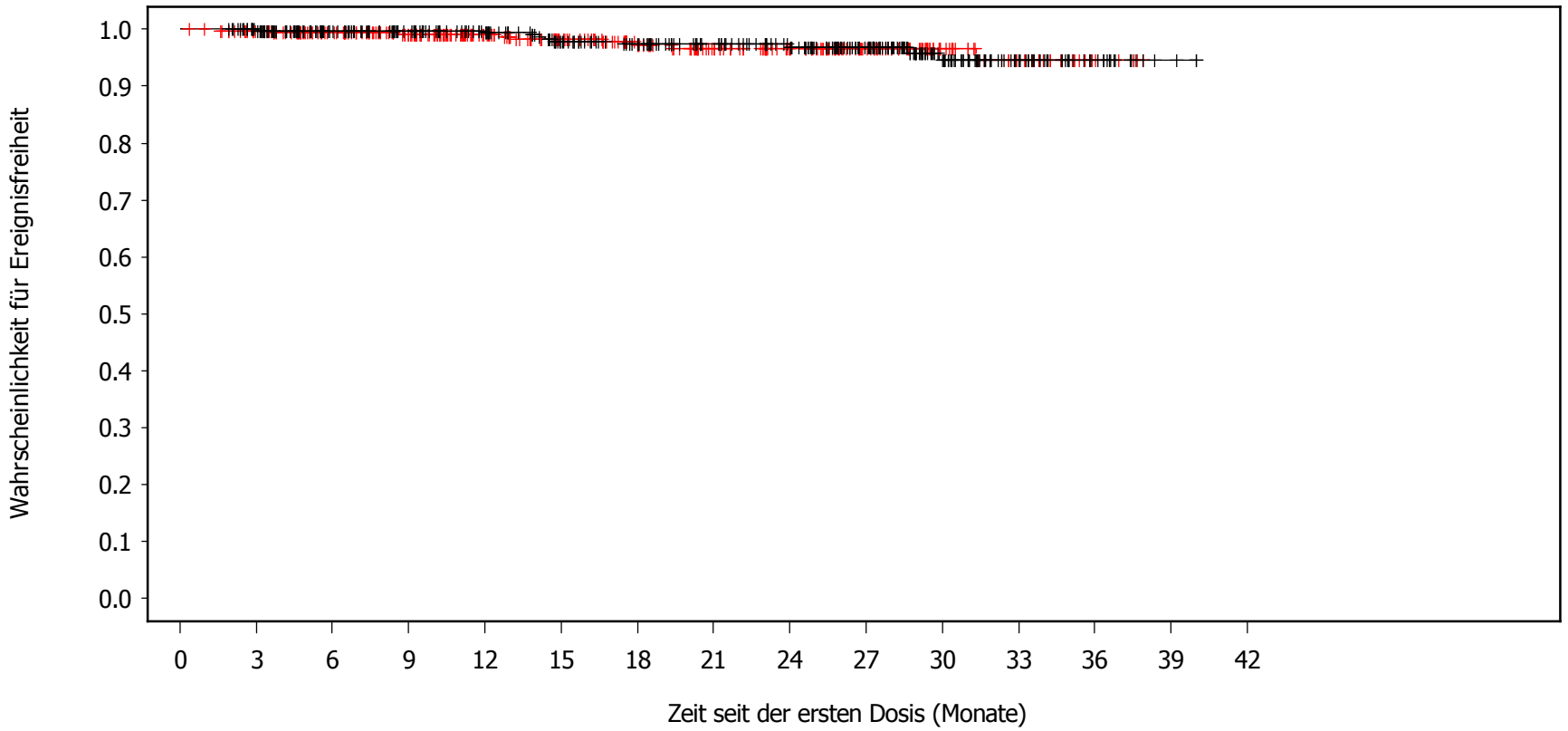


Anzahl an Patienten unter Risiko:

398	376	331	300	268	237	215	192	172	129	73	40	17	2	0	Olaparib + Abiraterone
396	371	332	291	239	205	174	150	126	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfo 06JUN2022:19:52 kvbv306

Figure 3.3.146 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Gutartige, boesartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)
Safety Analysis Set, DCO 14MAR2022

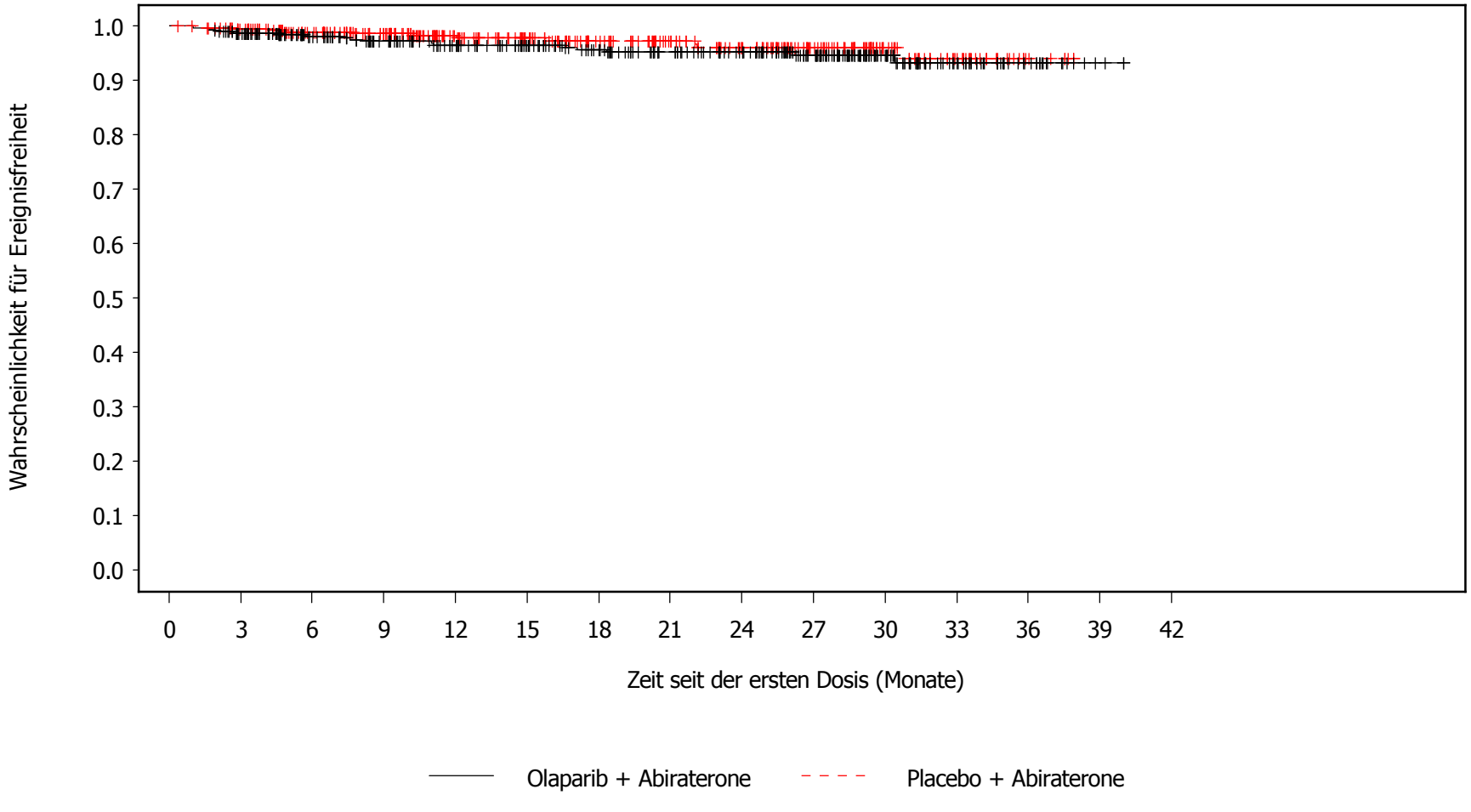


Anzahl an Patienten unter Risiko:

398	383	338	307	274	240	220	196	175	133	74	39	15	2	0	Olaparib + Abiraterone
396	379	339	298	248	212	179	151	125	90	53	28	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfp 06JUN2022:19:52 kvbv306

Figure 3.3.147 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Herzerkrankungen
Safety Analysis Set, DCO 14MAR2022

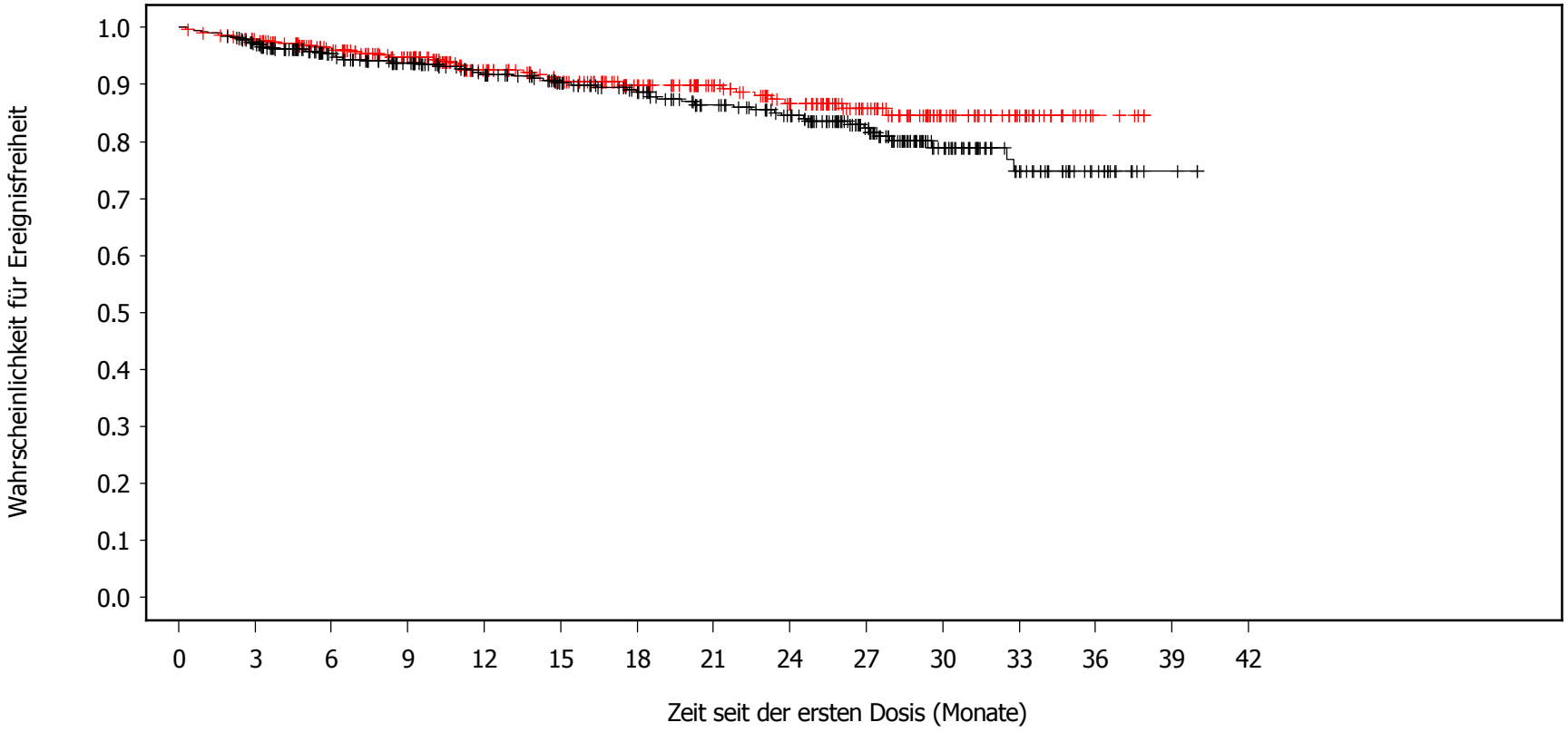


Anzahl an Patienten unter Risiko:

398	380	335	304	271	244	221	196	176	134	77	41	17	2	0	Olaparib + Abiraterone
396	378	339	300	248	213	179	154	128	93	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfq 06JUN2022:19:52 kvbv306

Figure 3.3.148 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Infektionen und parasitaere Erkrankungen
Safety Analysis Set, DCO 14MAR2022



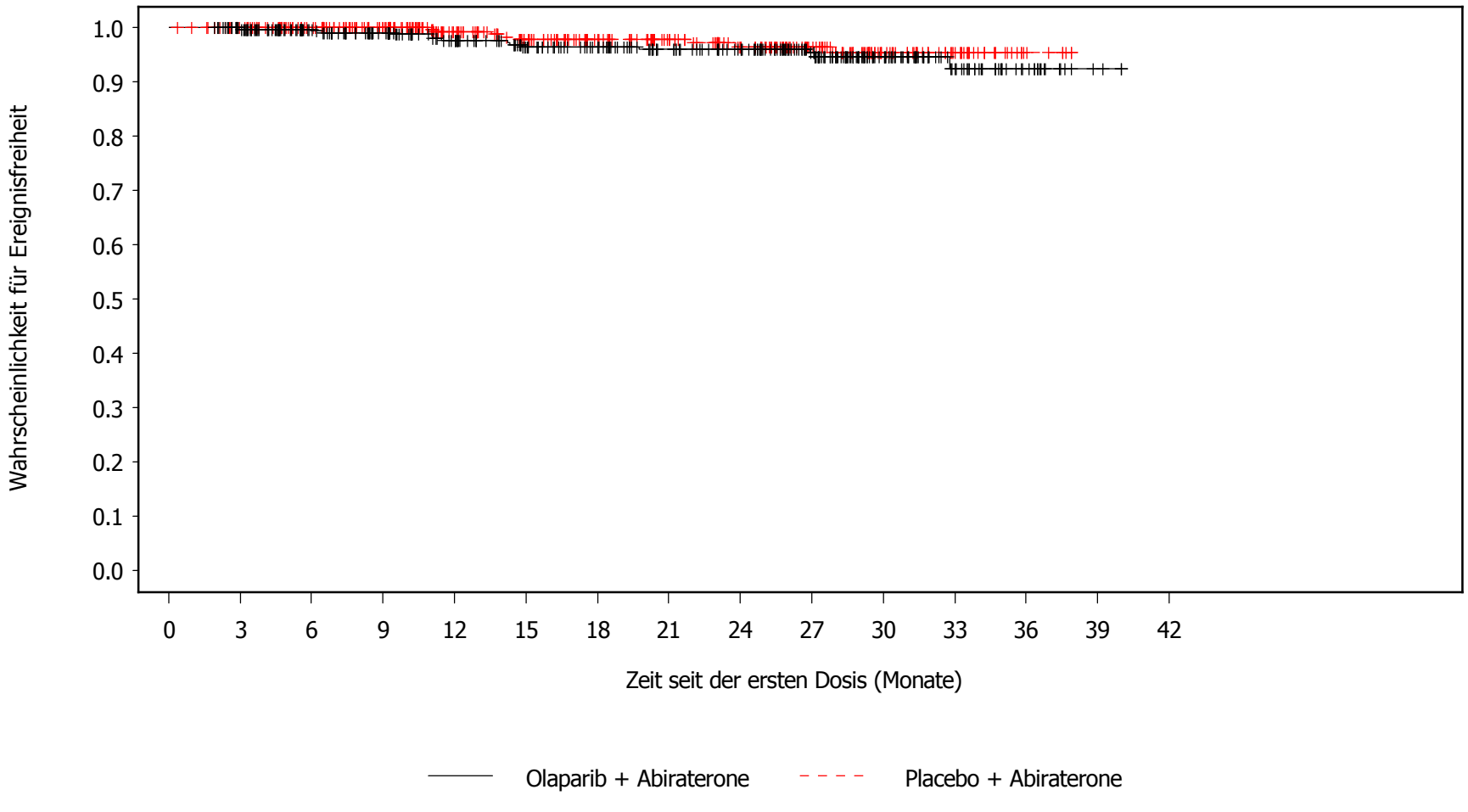
Anzahl an Patienten unter Risiko:

398	376	328	298	263	234	214	188	168	124	68	34	14	2	0	Olaparib + Abiraterone
396	374	331	288	237	203	172	147	120	87	50	27	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfr 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.149 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: COVID-19
Safety Analysis Set, DCO 14MAR2022



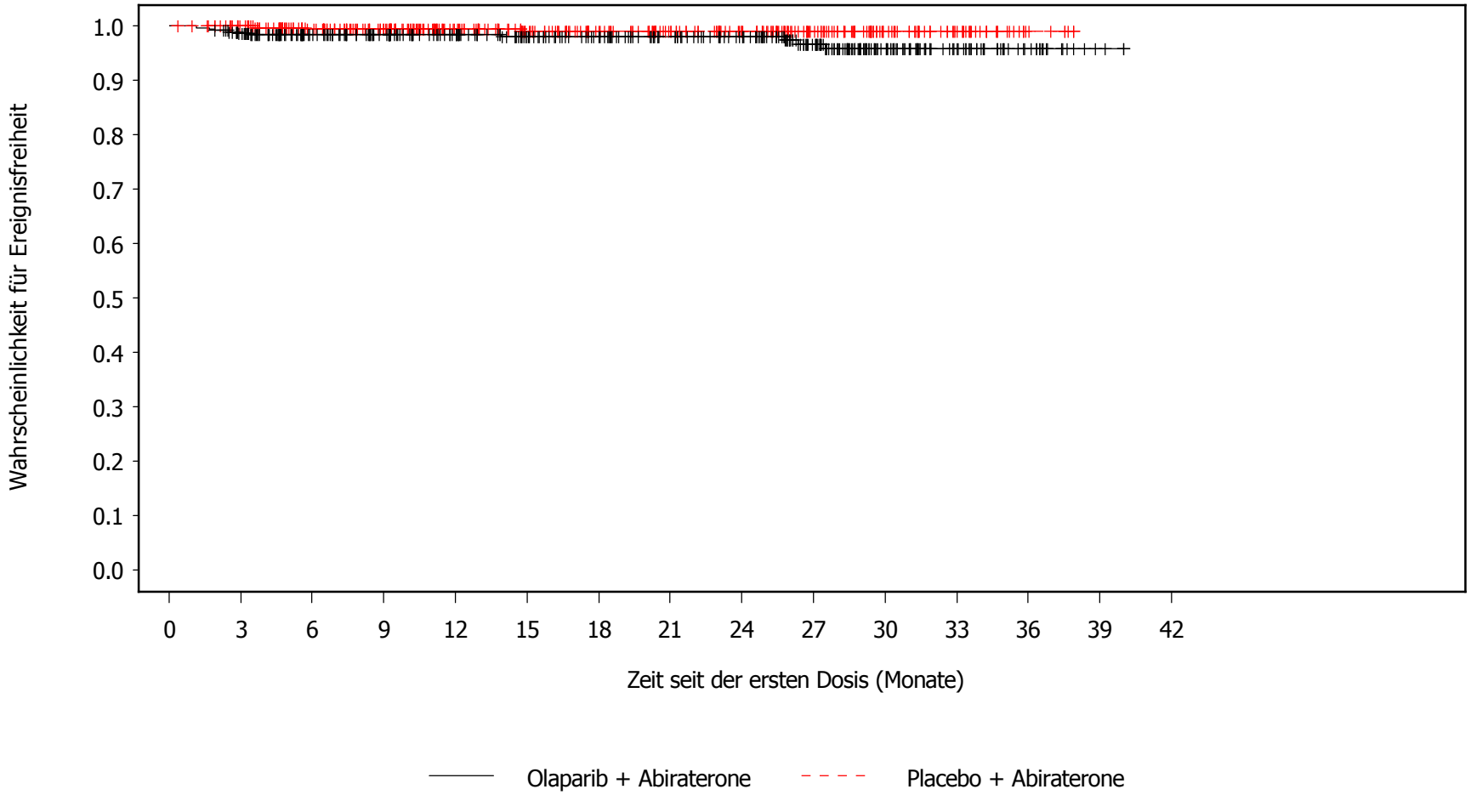
Anzahl an Patienten unter Risiko:

398	383	338	307	273	241	222	197	178	133	76	39	16	2	0	Olaparib + Abiraterone
396	380	341	301	249	213	180	155	129	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfs 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.150 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Pneumonie
Safety Analysis Set, DCO 14MAR2022

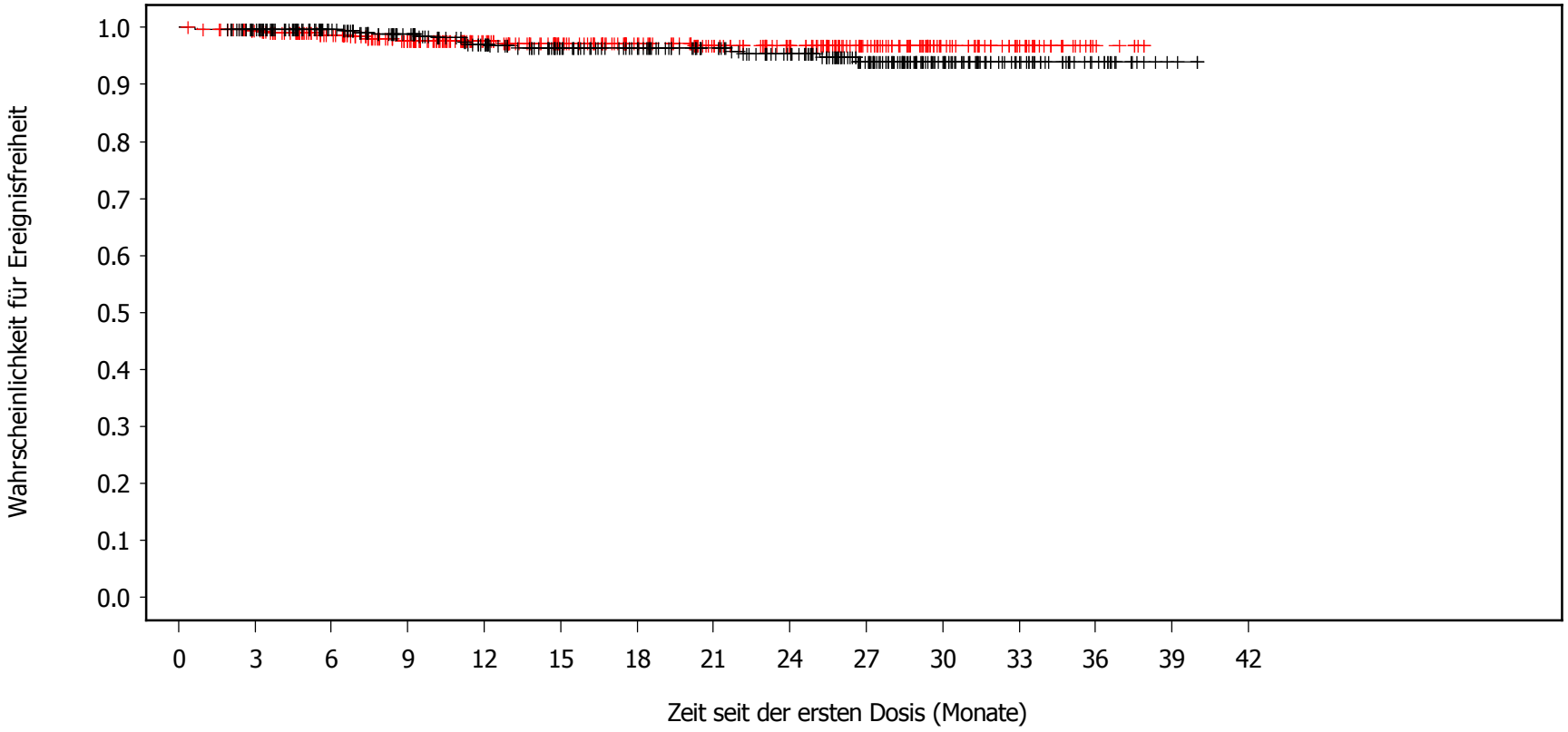


Anzahl an Patienten unter Risiko:

398	382	336	307	275	244	224	199	179	133	75	41	17	2	0	Olaparib + Abiraterone
396	380	339	299	248	211	179	153	127	92	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebft 06JUN2022:19:52 kvbv306

Figure 3.3.151 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Safety Analysis Set, DCO 14MAR2022

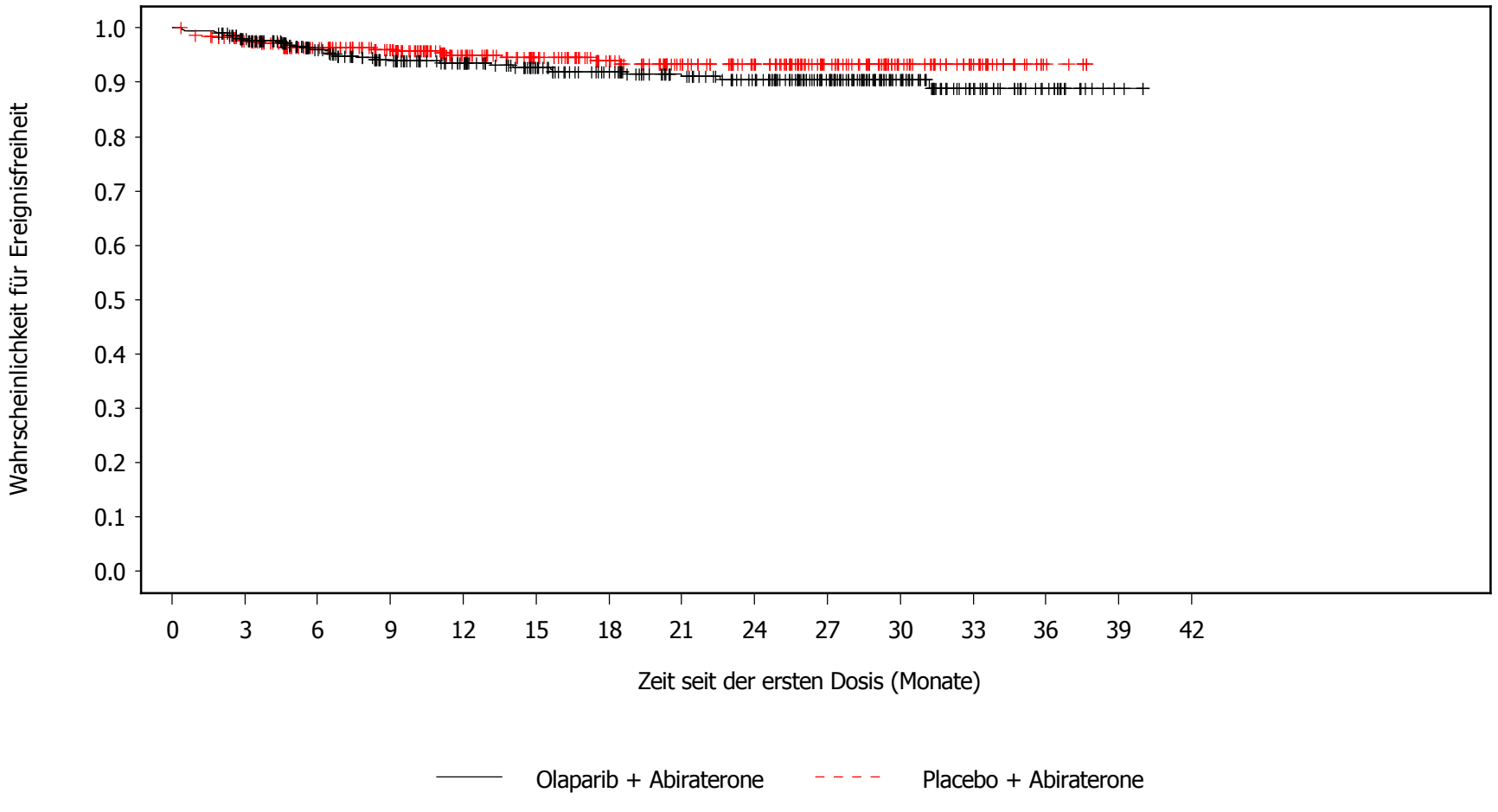


Anzahl an Patienten unter Risiko:

398	383	339	306	271	239	219	195	174	129	73	39	17	2	0	Olaparib + Abiraterone
396	378	338	296	246	209	178	151	126	92	52	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfu 06JUN2022:19:52 kvbv306

Figure 3.3.152 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 14MAR2022

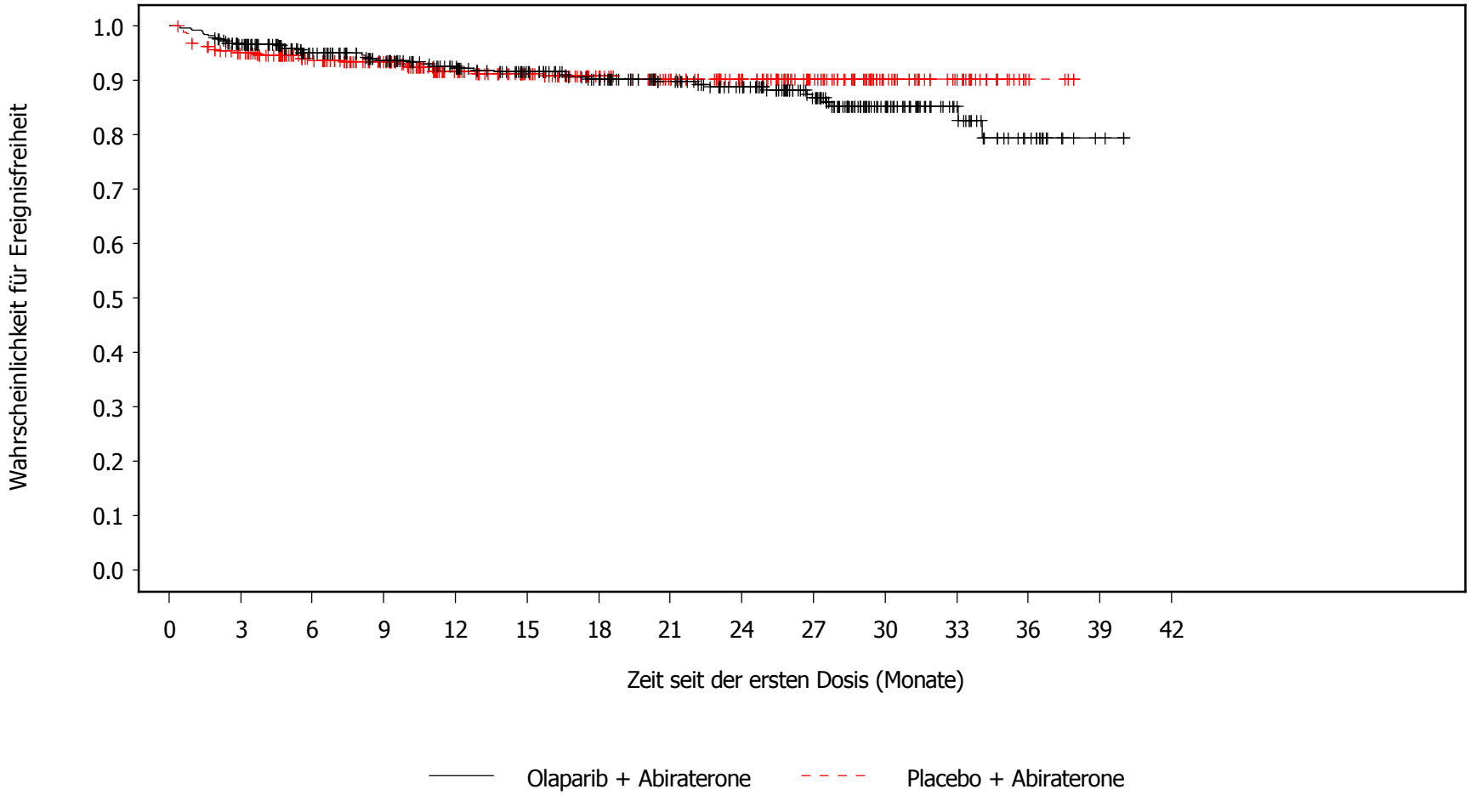


Anzahl an Patienten unter Risiko:

398	376	327	294	263	232	211	187	169	127	73	37	17	2	0	Olaparib + Abiraterone
396	371	329	293	240	204	173	146	122	87	52	28	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfv 06JUN2022:19:52 kvbv306

Figure 3.3.153 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Untersuchungen
Safety Analysis Set, DCO 14MAR2022

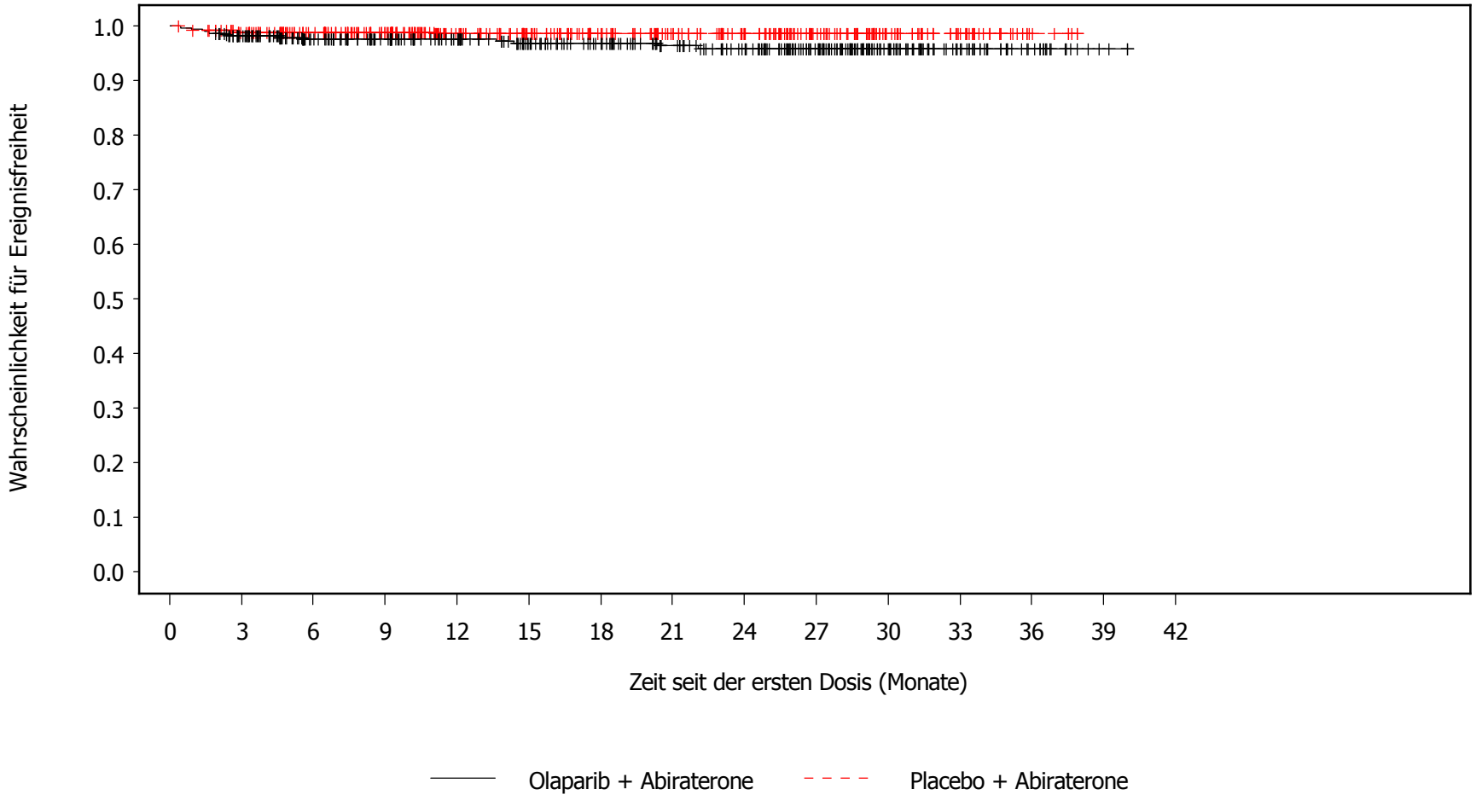


Anzahl an Patienten unter Risiko:

398	371	322	290	258	229	207	183	162	123	67	35	15	2	0	Olaparib + Abiraterone
396	363	321	285	235	202	170	145	119	88	49	28	4	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfw 06JUN2022:19:52 kvbv306

Figure 3.3.154 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Lymphozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

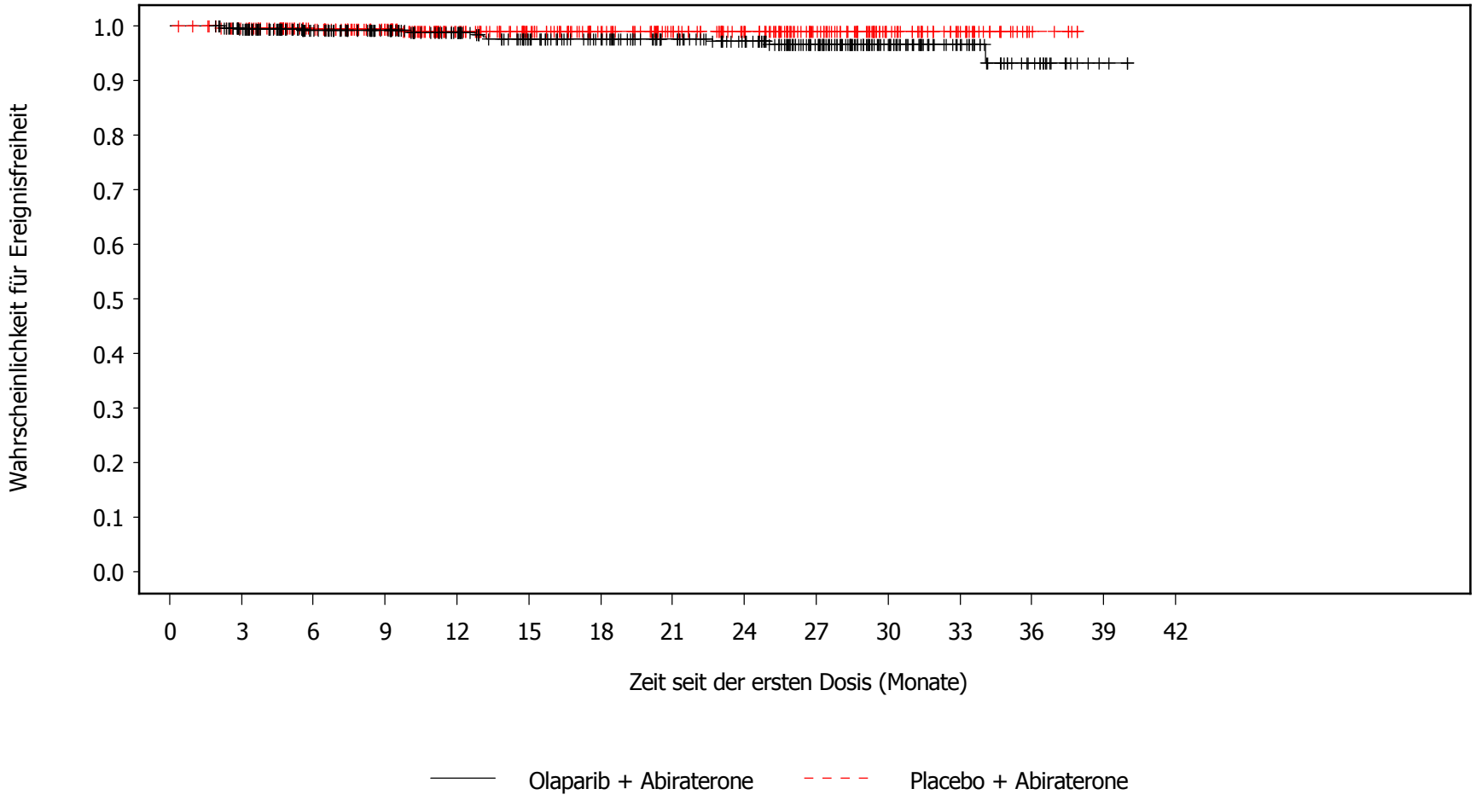


Anzahl an Patienten unter Risiko:

398	377	330	301	270	240	219	193	173	131	73	39	17	2	0	Olaparib + Abiraterone
396	376	337	298	247	212	179	153	127	92	53	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfx 06JUN2022:19:52 kvbv306

Figure 3.3.155 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach PT: Neutrophilenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

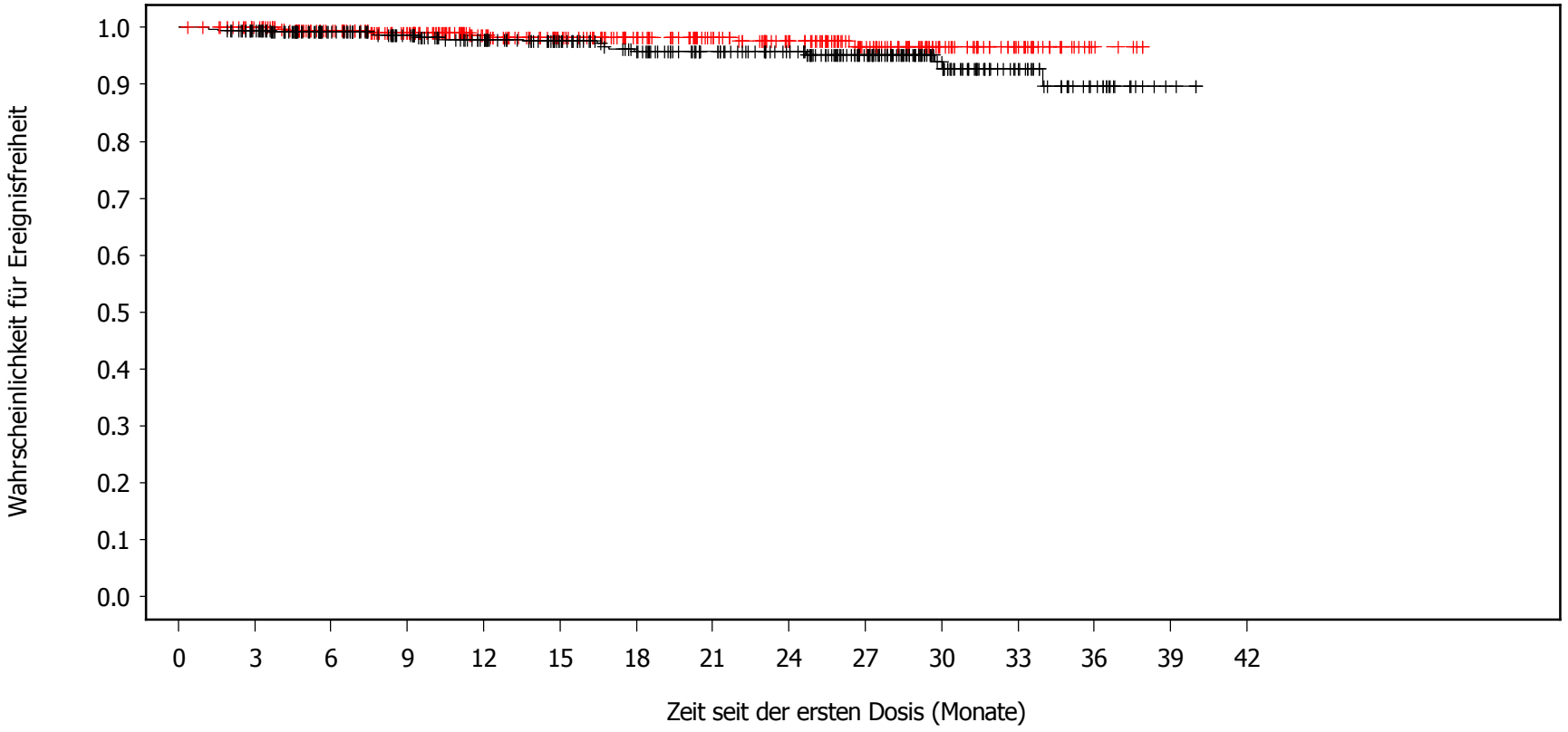


Anzahl an Patienten unter Risiko:

398	382	336	305	273	242	222	197	176	133	76	41	17	2	0	Olaparib + Abiraterone
396	380	341	301	250	214	181	155	129	94	54	30	6	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfy 06JUN2022:19:52 kvbv306

Figure 3.3.156 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UE nach SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Safety Analysis Set, DCO 14MAR2022



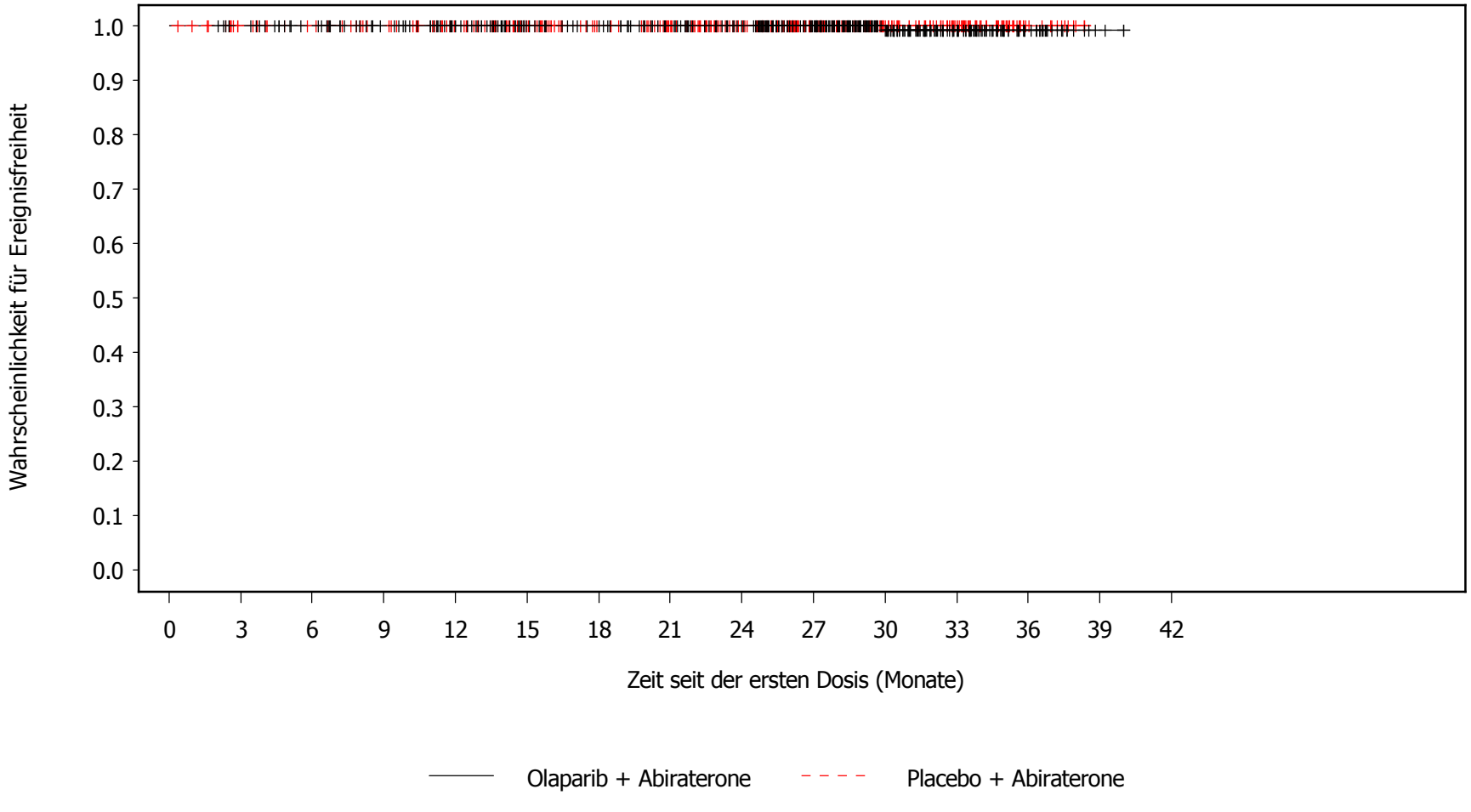
Anzahl an Patienten unter Risiko:

398	383	338	307	273	242	219	194	174	133	75	40	17	2	0	Olaparib + Abiraterone
396	380	339	298	247	212	179	153	126	91	52	29	5	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebfz 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.157 PROpel: Kaplan-Meier plot of time to first occurrence of UESI: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022



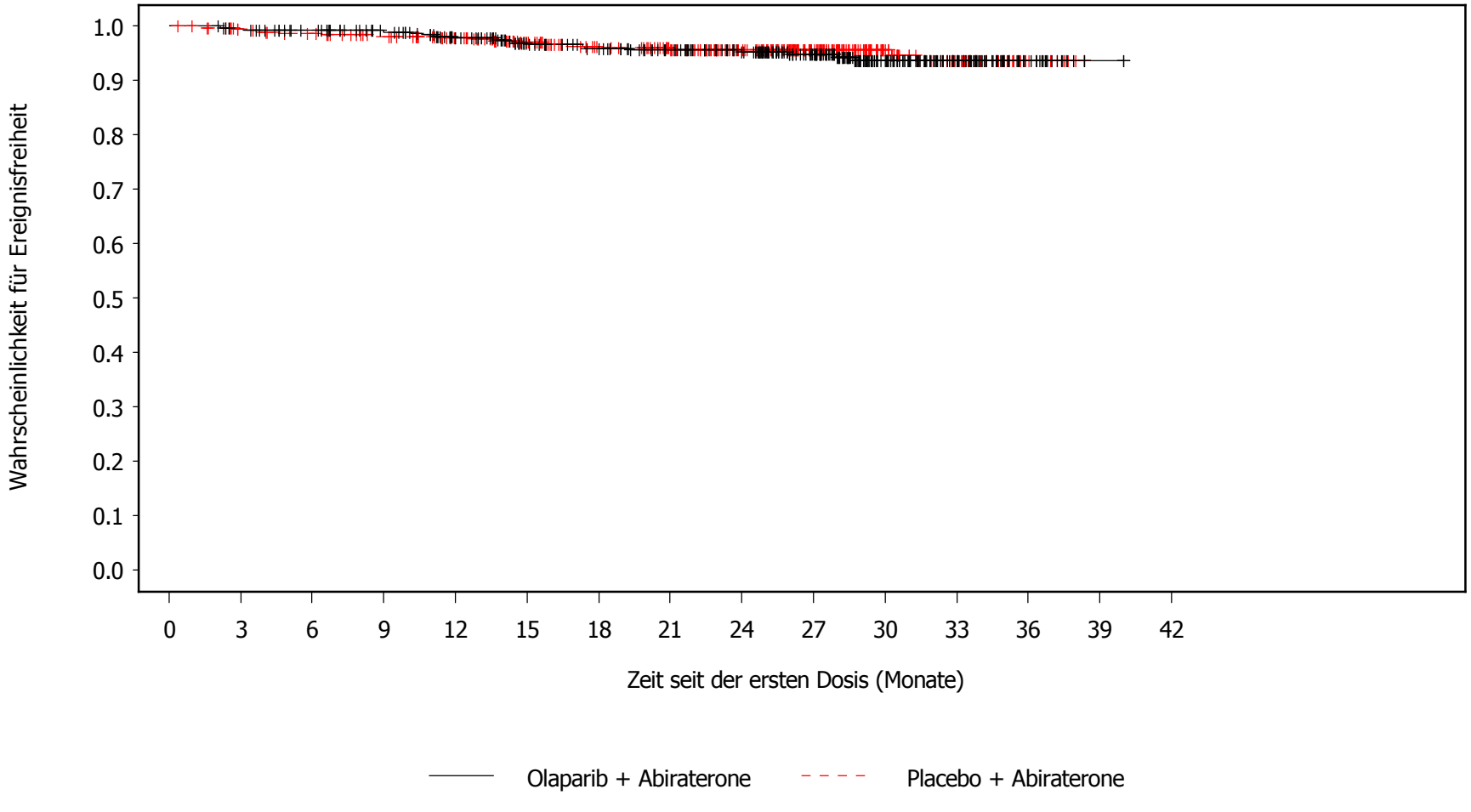
Anzahl an Patienten unter Risiko:

398	394	383	366	346	320	309	292	270	218	133	74	23	2	0	Olaparib + Abiraterone
396	386	380	370	352	323	304	289	253	180	105	66	14	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebga 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.158 PROpel: Kaplan-Meier plot of time to first occurrence of UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

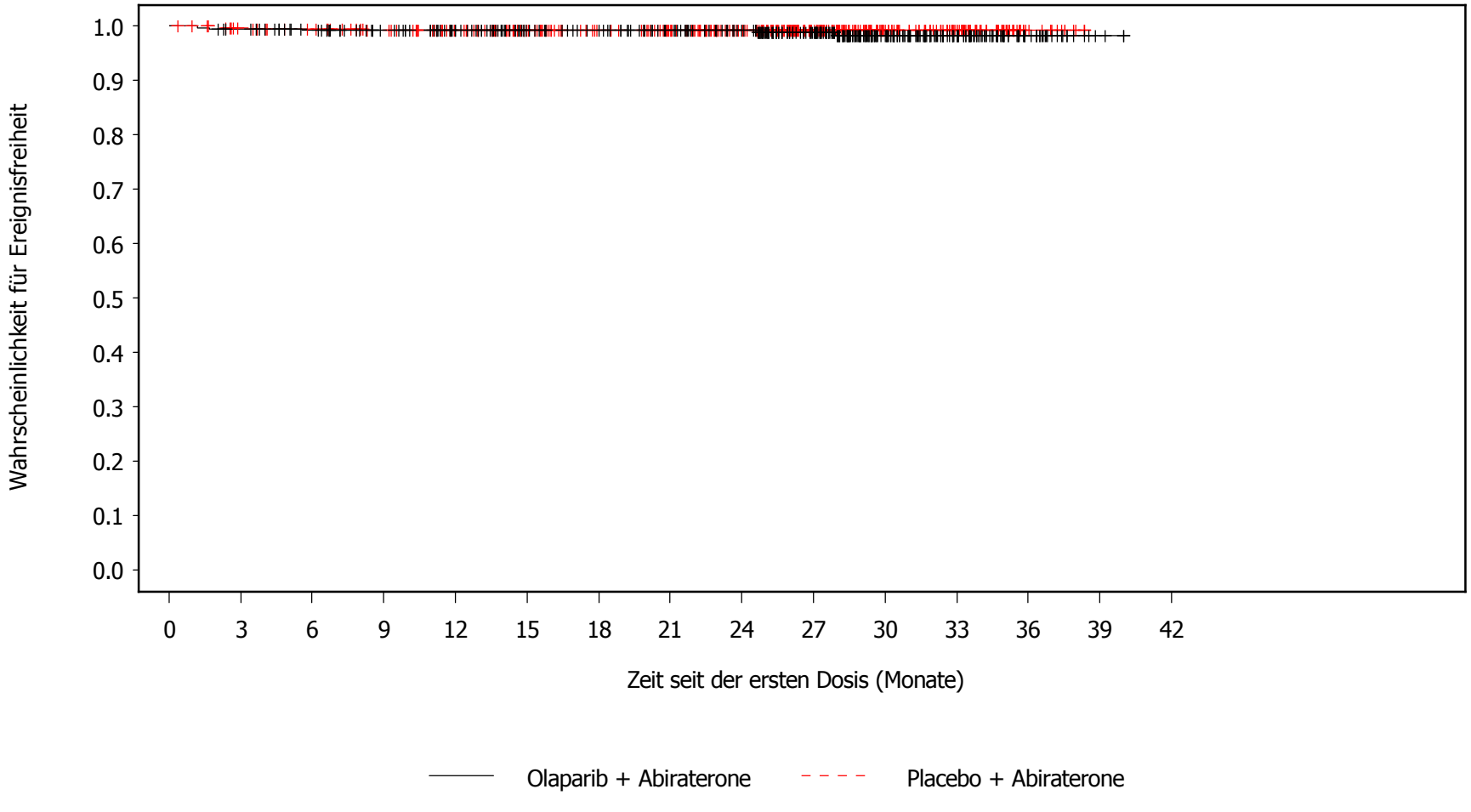


Anzahl an Patienten unter Risiko:

398	392	380	362	338	310	296	278	255	204	124	67	19	1	0	Olaparib + Abiraterone
396	384	376	364	345	316	295	278	244	173	101	62	14	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebgb 06JUN2022:19:52 kvbv306

Figure 3.3.159 PROpel: Kaplan-Meier plot of time to first occurrence of UESI: Pneumonitis
Safety Analysis Set, DCO 14MAR2022



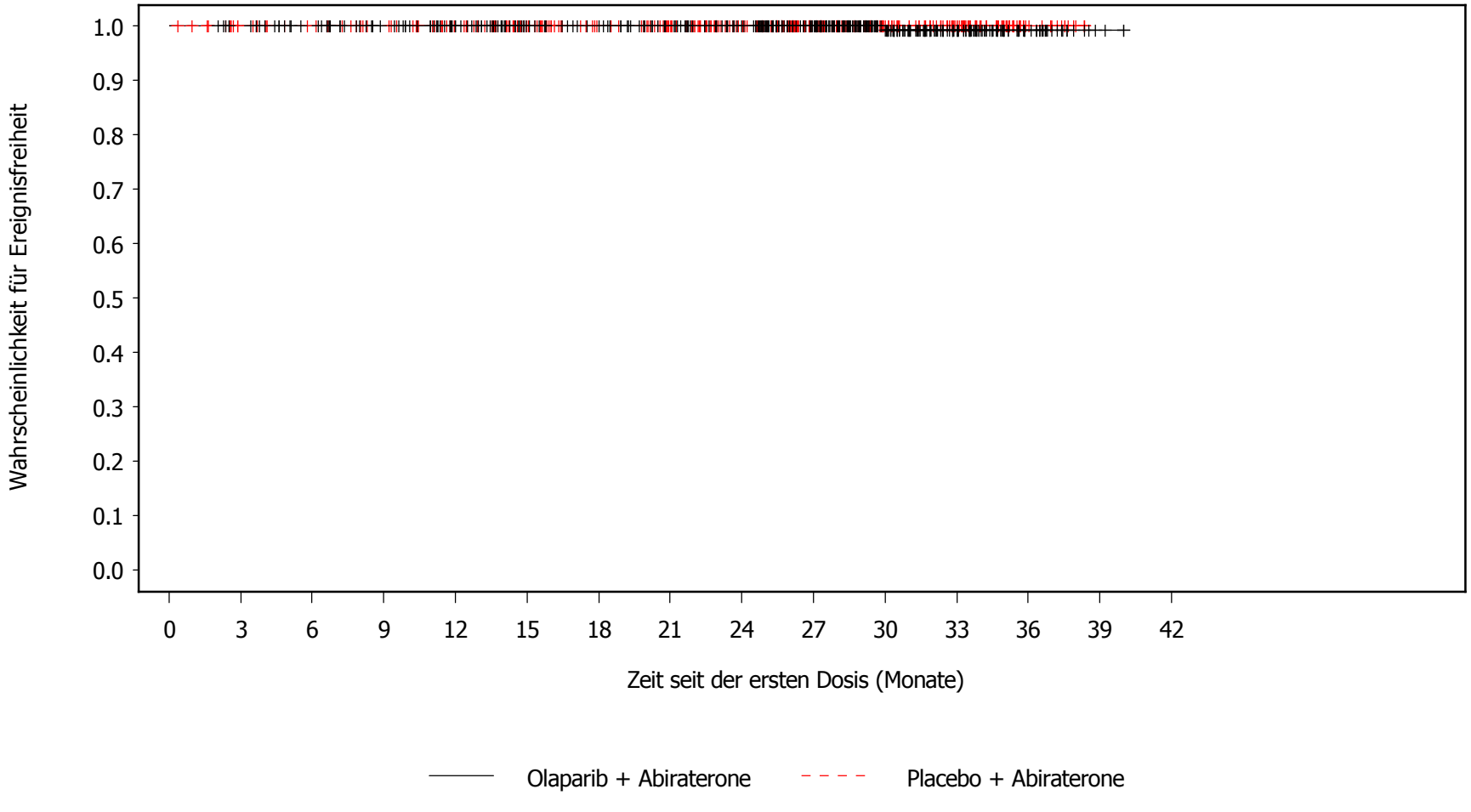
Anzahl an Patienten unter Risiko:

398	393	381	364	345	319	308	291	269	217	132	73	23	2	0	Olaparib + Abiraterone
396	386	379	368	350	321	302	287	251	179	104	65	13	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebgc 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.160 PROpel: Kaplan-Meier plot of time to first occurrence of Schwerwiegende UE: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022



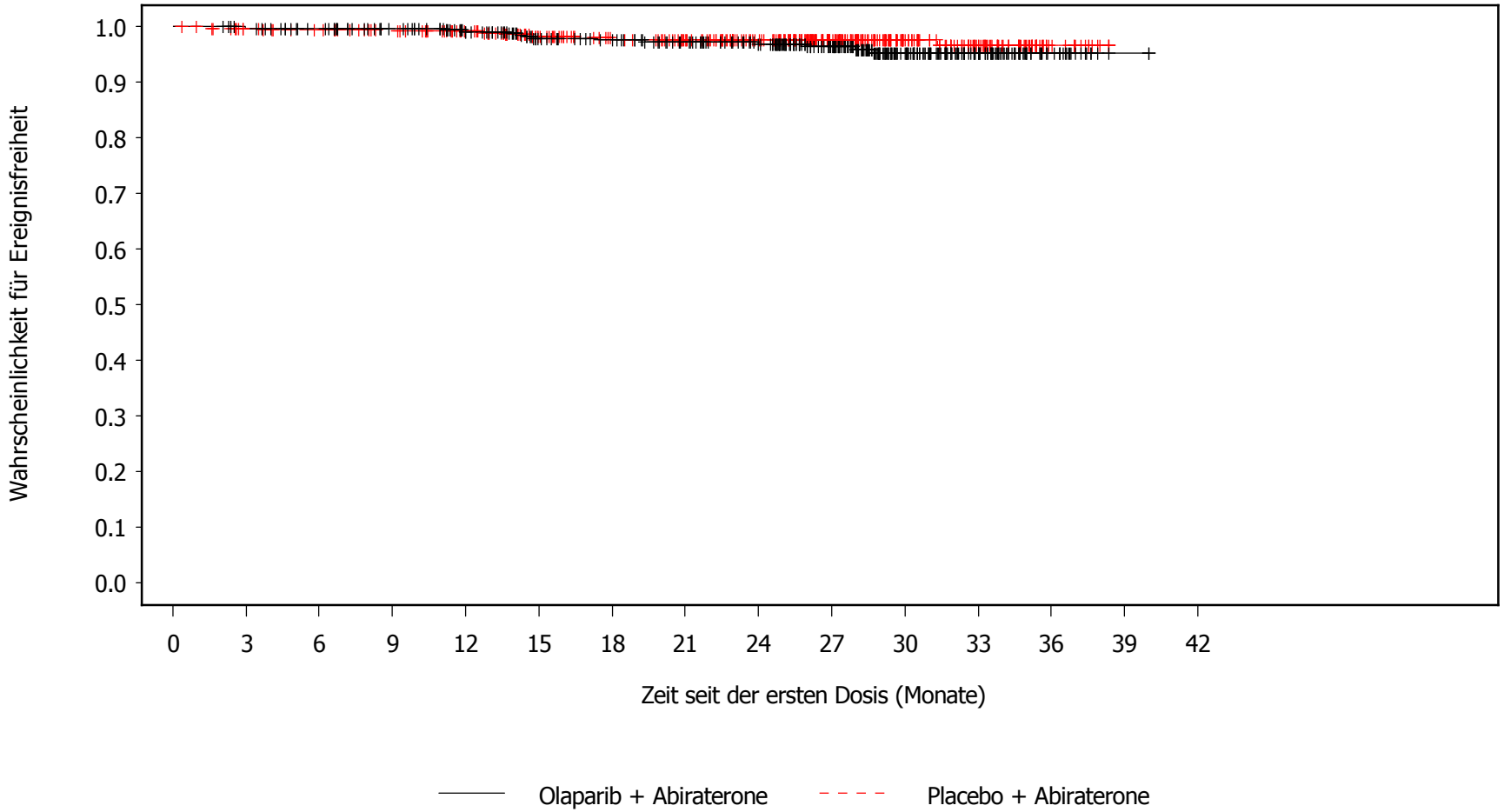
Anzahl an Patienten unter Risiko:

398	394	383	366	346	320	309	292	270	218	133	74	23	2	0	Olaparib + Abiraterone
396	386	380	370	352	323	304	289	253	180	105	66	14	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebgd 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.161 PROpel: Kaplan-Meier plot of time to first occurrence of Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

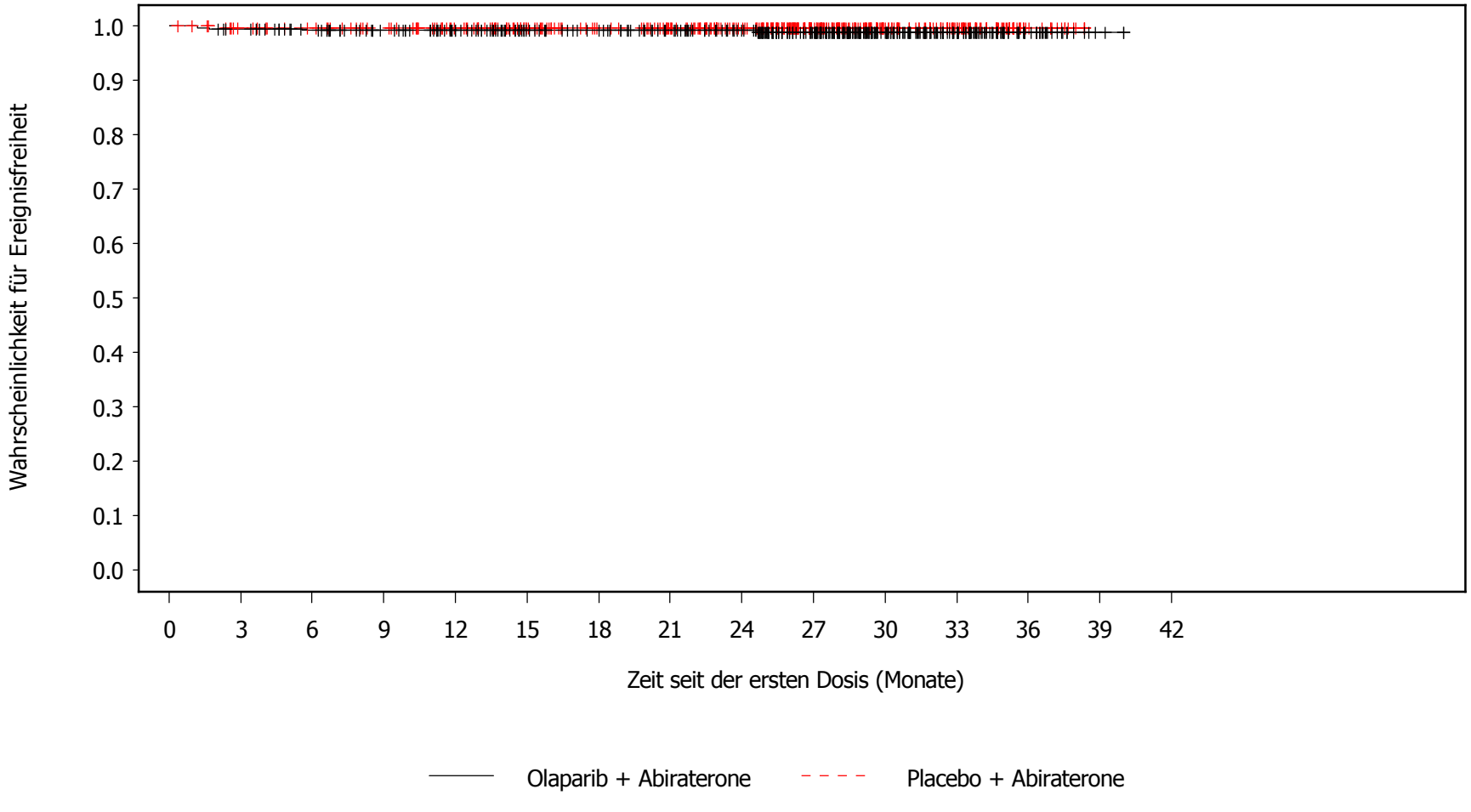


Anzahl an Patienten unter Risiko:

398	393	382	365	343	314	302	284	261	209	126	68	19	1	0	Olaparib + Abiraterone
396	385	378	367	349	320	300	284	249	177	104	64	14	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebge 06JUN2022:19:52 kvbv306

Figure 3.3.162 PROpel: Kaplan-Meier plot of time to first occurrence of Schwerwiegende UE: Pneumonitis
Safety Analysis Set, DCO 14MAR2022



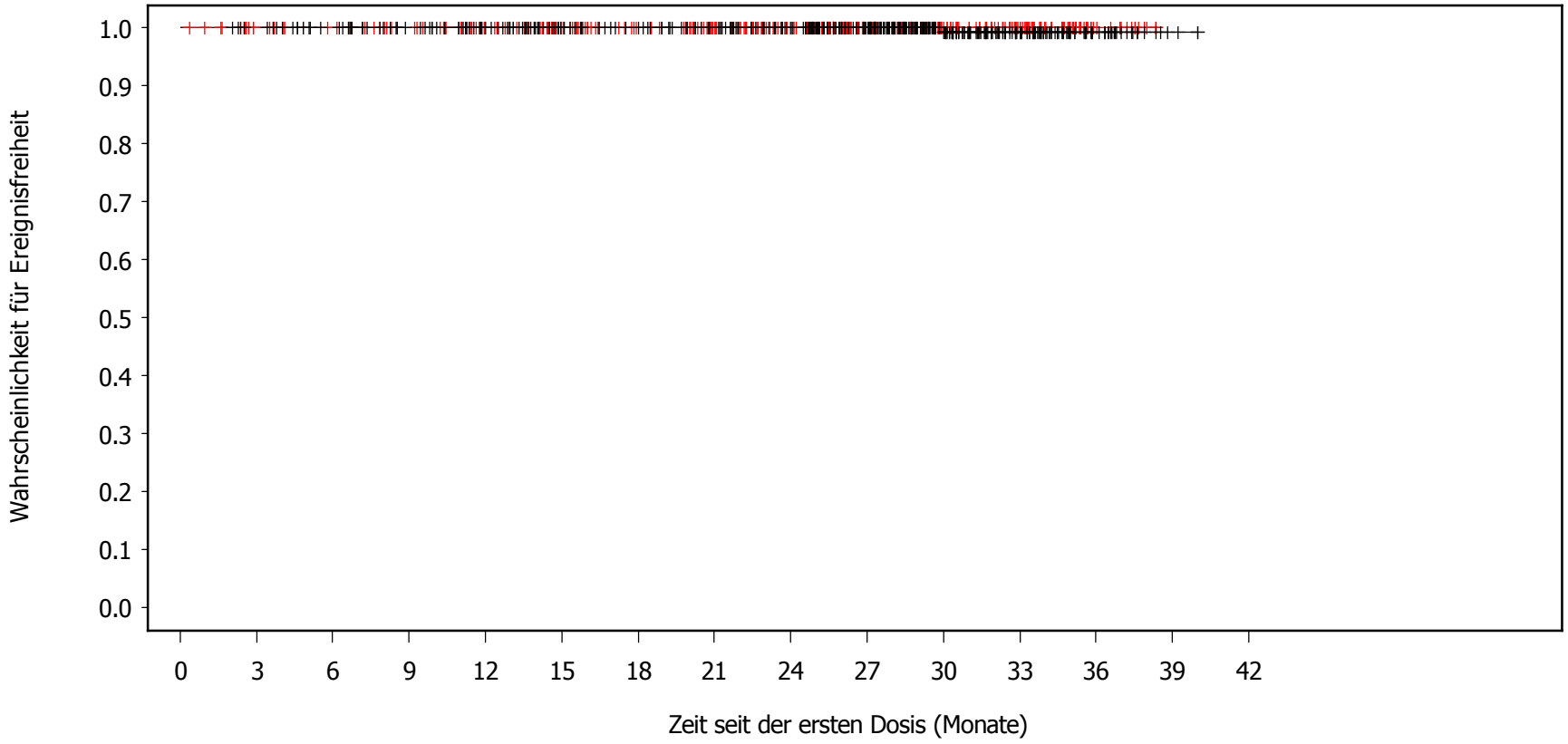
Anzahl an Patienten unter Risiko:

398	393	381	364	345	319	308	291	269	217	133	74	23	2	0	Olaparib + Abiraterone
396	386	380	370	352	323	304	289	253	180	105	66	14	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebgf 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.163 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UESI G>=3: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022



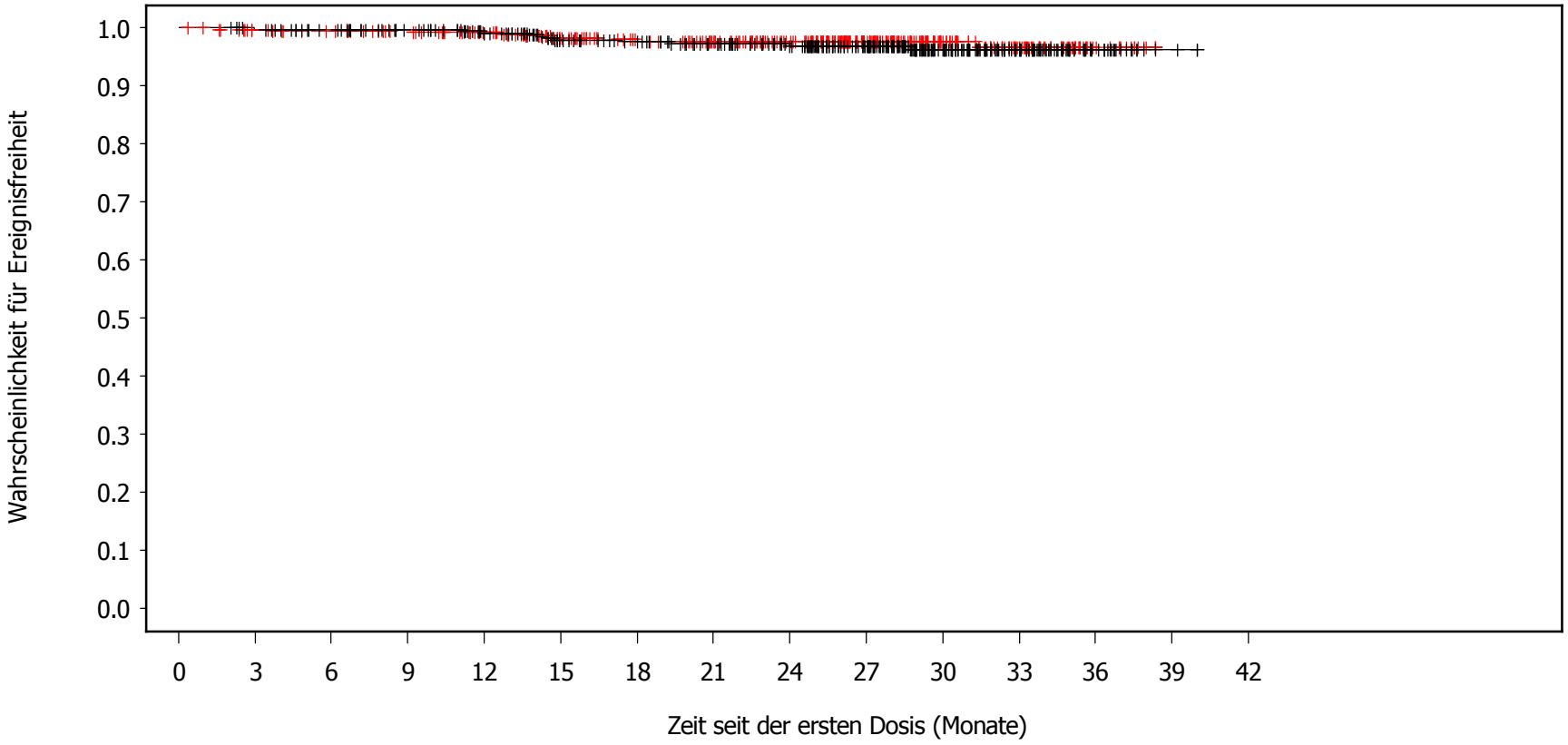
Anzahl an Patienten unter Risiko:

398	394	383	366	346	320	309	292	270	218	133	74	23	2	0	Olaparib + Abiraterone
396	386	380	370	352	323	304	289	253	180	105	66	14	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebgg 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.164 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022



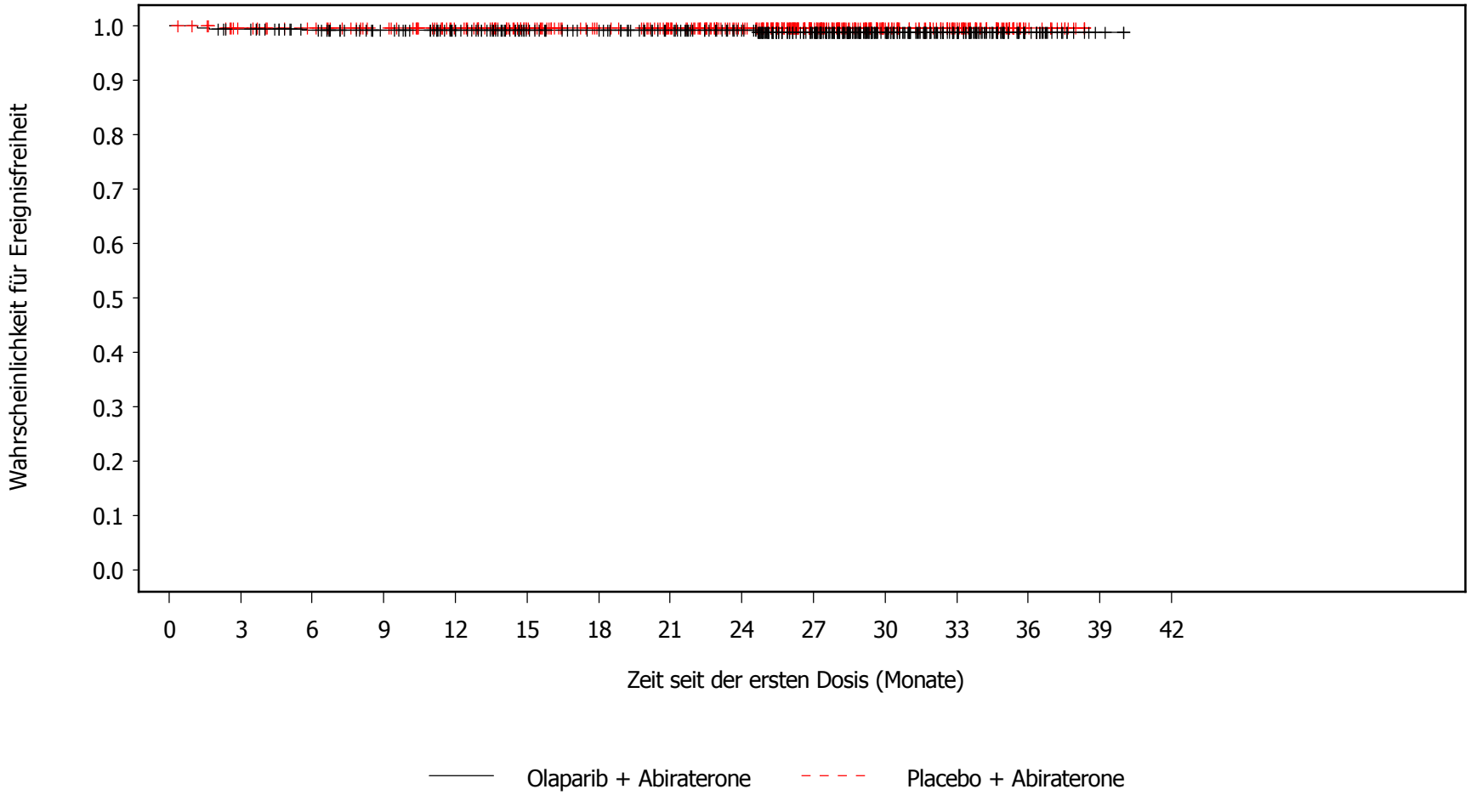
Anzahl an Patienten unter Risiko:

398	393	382	365	343	314	302	284	261	210	128	70	20	2	0	Olaparib + Abiraterone
396	385	378	367	349	320	300	284	249	177	104	64	14	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebgh 06JUN2022:19:52 kvbv306

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.165 PROpel: Kaplan-Meier plot of time to first occurrence of Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

398	393	381	364	345	319	308	291	269	217	133	74	23	2	0	Olaparib + Abiraterone
396	386	380	370	352	323	304	289	253	180	105	66	14	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttemainae.sas gttemainaebgi 06JUN2022:19:52 kvbv306

Table 3.5.1 PROpel: Summary of subgroup analysis of time to UE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	209 (98,1)	0,9 [0,5; 1,2]	226	217 (96,0)	1,0 [0,9; 1,4]	1,33	[1,10; 1,61]	0,0037*
Viszeral	66	62 (93,9)	0,6 [0,5; 1,0]	72	67 (93,1)	0,9 [0,5; 1,4]	0,98	[0,69; 1,38]	0,8913
andere	119	118 (99,2)	0,5 [0,4; 0,5]	98	94 (95,9)	0,8 [0,5; 1,4]	1,55	[1,18; 2,04]	0,0015*
Interaktion p-Wert									0,1197
Docetaxel-Behandlung des mHSPC									
Ja	90	87 (96,7)	0,5 [0,4; 0,8]	90	83 (92,2)	0,8 [0,5; 1,0]	1,16	[0,86; 1,57]	0,3403
Nein	308	302 (98,1)	0,5 [0,5; 0,9]	306	295 (96,4)	1,0 [0,9; 1,4]	1,36	[1,16; 1,60]	0,0002*
Interaktion p-Wert									0,3472
Alter bei Randomisierung									
<65 Jahre	130	125 (96,2)	0,5 [0,4; 0,9]	97	92 (94,8)	0,7 [0,5; 1,3]	1,16	[0,89; 1,53]	0,2712
>=65 Jahre	268	264 (98,5)	0,6 [0,5; 0,9]	299	286 (95,7)	1,0 [0,9; 1,4]	1,38	[1,16; 1,63]	0,0002*
Interaktion p-Wert									0,3002
Region									
Asien	91	91 (100)	0,9 [0,4; 1,4]	104	97 (93,3)	1,4 [1,0; 1,6]	1,45	[1,09; 1,93]	0,0113*
Europa	177	170 (96,0)	0,6 [0,5; 0,9]	171	163 (95,3)	0,7 [0,5; 1,0]	1,12	[0,90; 1,39]	0,3058
Nord- und Suedamerika	130	128 (98,5)	0,5 [0,5; 0,8]	121	118 (97,5)	1,0 [0,7; 1,5]	1,49	[1,16; 1,91]	0,0020*
Interaktion p-Wert									0,1708
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	97 (99,0)	0,5 [0,4; 1,0]	100	93 (93,0)	0,7 [0,5; 1,2]	1,21	[0,91; 1,60]	0,1964
Nicht-HRRm	268	261 (97,4)	0,5 [0,5; 0,8]	267	257 (96,3)	1,0 [0,9; 1,4]	1,37	[1,15; 1,63]	0,0004*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaa 05DEC2022:09:12 khcs324

Table 3.5.1 PROpel: Summary of subgroup analysis of time to UE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	31 (96,9)	0,6 [0,5; 1,9]	29	28 (96,6)	1,1 [0,6; 1,8]	1,22	[0,73; 2,05]	0,4444
Interaktion p-Wert									0,7251
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	61 (98,4)	0,5 [0,4; 1,4]	56	50 (89,3)	1,3 [0,6; 1,7]	1,43	[0,99; 2,09]	0,0592
Nicht-HRRm	207	203 (98,1)	0,6 [0,5; 0,9]	210	202 (96,2)	1,0 [0,7; 1,3]	1,29	[1,06; 1,57]	0,0112*
Unbekannt	129	125 (96,9)	0,5 [0,4; 0,8]	130	126 (96,9)	0,9 [0,6; 1,4]	1,32	[1,03; 1,70]	0,0273*
Interaktion p-Wert									0,8851
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	29 (100)	0,6 [0,3; 1,7]	22	20 (90,9)	0,7 [0,2; 2,3]	1,04	[0,59; 1,87]	0,8909
Nicht-HRRm	330	321 (97,3)	0,5 [0,5; 0,8]	327	312 (95,4)	1,0 [0,9; 1,3]	1,35	[1,15; 1,58]	0,0002*
Unbekannt	39	39 (100)	0,5 [0,3; 0,9]	47	46 (97,9)	0,8 [0,5; 1,4]	1,31	[0,85; 2,01]	0,2200
Interaktion p-Wert									0,6935
ECOG-PS zu Baseline									
0	286	280 (97,9)	0,5 [0,5; 0,9]	272	260 (95,6)	1,2 [0,9; 1,4]	1,34	[1,13; 1,59]	0,0007*
1	112	109 (97,3)	0,5 [0,4; 0,6]	124	118 (95,2)	0,6 [0,5; 1,0]	1,26	[0,97; 1,64]	0,0801
Interaktion p-Wert									0,7050
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	195 (99,5)	0,6 [0,5; 0,8]	199	188 (94,5)	1,2 [0,9; 1,4]	1,46	[1,19; 1,78]	0,0003*
Über medianem PSA-Baselinewert	200	192 (96,0)	0,5 [0,5; 0,9]	196	189 (96,4)	0,9 [0,5; 1,1]	1,18	[0,96; 1,44]	0,1076
Interaktion p-Wert									0,1452

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaa 05DEC2022:09:12 khcs324

Table 3.5.1 PROpel: Summary of subgroup analysis of time to UE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	272 (96,8)	0,5 [0,5; 0,8]	274	266 (97,1)	0,9 [0,6; 1,0]	1,23	[1,03; 1,45]	0,0188*
Afroamerikanisch	14	14 (100)	0,7 [0,1; 1,8]	11	10 (90,9)	1,1 [0,4; 3,2]	2,03	[0,91; 4,73]	0,0850
Asiatisch	66	66 (100)	1,1 [0,5; 1,6]	72	65 (90,3)	1,6 [1,3; 2,6]	1,53	[1,09; 2,17]	0,0147*
Andere	15	15 (100)	0,5 [0,1; 0,7]	9	8 (88,9)	1,1 [0,0; NE]	1,83	[0,79; 4,55]	0,1575
Interaktion p-Wert									0,3690
Schmerzen zu baseline									
Symptomatisch	103	102 (99,0)	0,5 [0,4; 0,5]	80	80 (100)	0,5 [0,5; 1,0]	1,24	[0,93; 1,67]	0,1463
Asymptomatisch/mild symptomatisch	266	258 (97,0)	0,7 [0,5; 1,0]	294	277 (94,2)	1,1 [0,9; 1,4]	1,30	[1,09; 1,54]	0,0029*
Interaktion p-Wert									0,8003

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaa 05DEC2022:09:12 khcs324

Table 3.5.2 PROpel: Summary of subgroup analysis of time to UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	114 (53,5)	14,8 [10,3;22,8]	226	99 (43,8)	31,4 [16,3; NE]	1,35	[1,03; 1,76]	0,0304*
Viszeral	66	33 (50,0)	10,2 [4,4; NE]	72	27 (37,5)	NE [NE; NE]	1,42	[0,85; 2,37]	0,1772
andere	119	63 (52,9)	12,9 [4,8;27,9]	98	50 (51,0)	13,0 [7,4; NE]	1,10	[0,76; 1,59]	0,6283
Interaktion p-Wert									0,6201
Docetaxel-Behandlung des mHSPC									
Ja	90	54 (60,0)	9,0 [4,6;18,7]	90	42 (46,7)	14,4 [7,4; NE]	1,41	[0,94; 2,12]	0,0949
Nein	308	156 (50,6)	17,0 [10,2;26,3]	306	134 (43,8)	31,4 [15,6; NE]	1,26	[0,999; 1,59]	0,0514
Interaktion p-Wert									0,6333
Alter bei Randomisierung									
<65 Jahre	130	65 (50,0)	21,9 [8,3; NE]	97	42 (43,3)	18,4 [12,7; NE]	1,14	[0,77; 1,69]	0,5170
>=65 Jahre	268	145 (54,1)	12,9 [7,1;19,4]	299	134 (44,8)	22,2 [14,3; NE]	1,37	[1,08; 1,73]	0,0089*
Interaktion p-Wert									0,4234
Region									
Asien	91	41 (45,1)	26,3 [9,3; NE]	104	37 (35,6)	NE [NE; NE]	1,33	[0,86; 2,09]	0,2030
Europa	177	98 (55,4)	11,1 [5,6;19,3]	171	84 (49,1)	16,3 [10,1; NE]	1,21	[0,90; 1,62]	0,2023
Nord- und Suedamerika	130	71 (54,6)	13,3 [6,2;28,8]	121	55 (45,5)	18,4 [11,6; NE]	1,35	[0,95; 1,93]	0,0930
Interaktion p-Wert									0,8727
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	49 (50,0)	9,3 [5,4; NE]	100	40 (40,0)	20,9 [12,7; NE]	1,39	[0,91; 2,11]	0,1244
Nicht-HRRm	268	141 (52,6)	16,6 [11,0;23,3]	267	122 (45,7)	22,2 [13,0; NE]	1,23	[0,97; 1,57]	0,0938

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.2 PROpel: Summary of subgroup analysis of time to UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	20 (62,5)	6,5 [1,0;21,9]	29	14 (48,3)	19,0 [2,3; NE]	1,59	[0,81; 3,21]	0,1822
Interaktion p-Wert									0,7351
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	27 (43,5)	NE [NE; NE]	56	23 (41,1)	NE [NE; NE]	1,05	[0,60; 1,85]	0,8623
Nicht-HRRm	207	112 (54,1)	13,7 [7,5;20,1]	210	91 (43,3)	31,4 [14,3; NE]	1,40	[1,07; 1,85]	0,0158*
Unbekannt	129	71 (55,0)	12,9 [6,0;23,4]	130	62 (47,7)	17,1 [11,4; NE]	1,25	[0,89; 1,77]	0,1908
Interaktion p-Wert									0,6379
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	15 (51,7)	19,9 [6,3; NE]	22	10 (45,5)	12,7 [4,2; NE]	0,92	[0,42; 2,12]	0,8439
Nicht-HRRm	330	171 (51,8)	13,9 [9,0;22,8]	327	147 (45,0)	20,9 [14,3; NE]	1,28	[1,03; 1,60]	0,0288*
Unbekannt	39	24 (61,5)	11,0 [2,3;29,5]	47	19 (40,4)	NE [NE; NE]	1,72	[0,94; 3,18]	0,0765
Interaktion p-Wert									0,4627
ECOG-PS zu Baseline									
0	286	145 (50,7)	14,8 [10,2;27,9]	272	115 (42,3)	31,4 [17,1; NE]	1,32	[1,04; 1,69]	0,0242*
1	112	65 (58,0)	8,2 [4,6;19,9]	124	61 (49,2)	13,0 [9,9;18,4]	1,26	[0,88; 1,78]	0,2026
Interaktion p-Wert									0,8071
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	116 (59,2)	9,3 [6,2;19,3]	199	92 (46,2)	31,4 [14,3; NE]	1,43	[1,09; 1,89]	0,0094*
Über medianem PSA-Baselinewert	200	93 (46,5)	18,7 [11,1;27,9]	196	84 (42,9)	17,1 [12,0; NE]	1,14	[0,85; 1,54]	0,3714
Interaktion p-Wert									0,2699

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.2 PROpel: Summary of subgroup analysis of time to UE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	150 (53,4)	13,3 [9,0;19,4]	274	124 (45,3)	18,4 [14,2; NE]	1,29	[1,02; 1,64]	0,0333*
Afroamerikanisch	14	6 (42,9)	NE [NE; NE]	11	5 (45,5)	17,1 [2,0; NE]	1,18	[0,36; 4,10]	0,7831
Asiatisch	66	28 (42,4)	NE [NE; NE]	72	24 (33,3)	NE [NE; NE]	1,34	[0,78; 2,33]	0,2912
Andere	15	10 (66,7)	2,9 [0,5; NE]	9	4 (44,4)	NE [NE; NE]	1,81	[0,61; 6,60]	0,2981
Interaktion p-Wert									0,9487
Schmerzen zu baseline									
Symptomatisch	103	60 (58,3)	7,3 [3,6;12,9]	80	36 (45,0)	16,3 [10,0;31,4]	1,54	[1,02; 2,35]	0,0379*
Asymptomatisch/mild symptomatisch	266	133 (50,0)	19,9 [11,7;28,8]	294	129 (43,9)	32,2 [14,4; NE]	1,19	[0,94; 1,52]	0,1536
Interaktion p-Wert									0,2939

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.3 PROpel: Summary of subgroup analysis of time to UE PT: Ermuedung
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	63 (29,6)	NE [NE; NE]	226	46 (20,4)	NE [NE; NE]	1,50	[1,03; 2,20]	0,0363*
Viszeral	66	18 (27,3)	NE [NE; NE]	72	10 (13,9)	NE [NE; NE]	2,04	[0,96; 4,60]	0,0640
andere	119	31 (26,1)	NE [NE; NE]	98	22 (22,4)	NE [NE; NE]	1,21	[0,71; 2,12]	0,4890
Interaktion p-Wert									0,5511
Docetaxel-Behandlung des mHSPC									
Ja	90	33 (36,7)	NE [NE; NE]	90	25 (27,8)	NE [NE; NE]	1,38	[0,82; 2,35]	0,2202
Nein	308	79 (25,6)	NE [NE; NE]	306	53 (17,3)	NE [NE; NE]	1,53	[1,08; 2,18]	0,0154*
Interaktion p-Wert									0,7489
Alter bei Randomisierung									
<65 Jahre	130	35 (26,9)	NE [NE; NE]	97	20 (20,6)	NE [NE; NE]	1,31	[0,76; 2,31]	0,3329
>=65 Jahre	268	77 (28,7)	NE [NE; NE]	299	58 (19,4)	NE [NE; NE]	1,56	[1,11; 2,20]	0,0103*
Interaktion p-Wert									0,5974
Region									
Asien	91	21 (23,1)	NE [NE; NE]	104	13 (12,5)	NE [NE; NE]	1,89	[0,96; 3,88]	0,0656
Europa	177	45 (25,4)	NE [NE; NE]	171	33 (19,3)	NE [NE; NE]	1,32	[0,84; 2,08]	0,2263
Nord- und Suedamerika	130	46 (35,4)	NE [NE; NE]	121	32 (26,4)	NE [NE; NE]	1,46	[0,93; 2,31]	0,0978
Interaktion p-Wert									0,6860
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	31 (31,6)	NE [NE; NE]	100	16 (16,0)	NE [NE; NE]	2,05	[1,14; 3,85]	0,0162*
Nicht-HRRm	268	71 (26,5)	NE [NE; NE]	267	56 (21,0)	NE [NE; NE]	1,30	[0,92; 1,85]	0,1423

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.3 PROpel: Summary of subgroup analysis of time to UE PT: Ermuedung
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	10 (31,3)	NE [NE; NE]	29	6 (20,7)	NE [NE; NE]	1,68	[0,62; 4,94]	0,3066
Interaktion p-Wert									0,4148
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	17 (27,4)	NE [NE; NE]	56	10 (17,9)	NE [NE; NE]	1,48	[0,69; 3,36]	0,3170
Nicht-HRRm	207	57 (27,5)	NE [NE; NE]	210	43 (20,5)	NE [NE; NE]	1,42	[0,96; 2,13]	0,0786
Unbekannt	129	38 (29,5)	NE [NE; NE]	130	25 (19,2)	NE [NE; NE]	1,59	[0,97; 2,66]	0,0686
Interaktion p-Wert									0,9447
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	8 (27,6)	NE [NE; NE]	22	4 (18,2)	NE [NE; NE]	1,35	[0,43; 5,06]	0,6188
Nicht-HRRm	330	87 (26,4)	NE [NE; NE]	327	66 (20,2)	NE [NE; NE]	1,35	[0,98; 1,86]	0,0670
Unbekannt	39	17 (43,6)	NE [NE; NE]	47	8 (17,0)	NE [NE; NE]	3,06	[1,36; 7,49]	0,0065*
Interaktion p-Wert									0,1823
ECOG-PS zu Baseline									
0	286	75 (26,2)	NE [NE; NE]	272	52 (19,1)	NE [NE; NE]	1,42	[1,003; 2,04]	0,0481*
1	112	37 (33,0)	NE [NE; NE]	124	26 (21,0)	NE [NE; NE]	1,64	[0,997; 2,74]	0,0512
Interaktion p-Wert									0,6527
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	62 (31,6)	NE [NE; NE]	199	39 (19,6)	NE [NE; NE]	1,71	[1,15; 2,57]	0,0080*
Über medianem PSA-Baselinewert	200	50 (25,0)	NE [NE; NE]	196	39 (19,9)	NE [NE; NE]	1,28	[0,84; 1,96]	0,2455
Interaktion p-Wert									0,3312

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.3 PROpel: Summary of subgroup analysis of time to UE PT: Ermuedung
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	87 (31,0)	NE [NE; NE]	274	59 (21,5)	NE [NE; NE]	1,49	[1,08; 2,09]	0,0165*
Afroamerikanisch	14	4 (28,6)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	3,92	[0,58; 76,65]	0,1718
Asiatisch	66	10 (15,2)	NE [NE; NE]	72	4 (5,6)	NE [NE; NE]	2,74	[0,92; 9,99]	0,0719
Andere	15	4 (26,7)	NE [NE; NE]	9	2 (22,2)	NE [NE; NE]	1,32	[0,26; 9,54]	0,7429
Interaktion p-Wert									0,6026
Schmerzen zu baseline									
Symptomatisch	103	34 (33,0)	NE [NE; NE]	80	19 (23,8)	NE [NE; NE]	1,50	[0,86; 2,67]	0,1538
Asymptomatisch/mild symptomatisch	266	68 (25,6)	NE [NE; NE]	294	55 (18,7)	NE [NE; NE]	1,37	[0,96; 1,97]	0,0792
Interaktion p-Wert									0,8020

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.4 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	67 (31,5)	36,6 [31,7; NE]	226	53 (23,5)	NE [NE; NE]	1,33	[0,93; 1,91]	0,1218
Viszeral	66	21 (31,8)	NE [NE; NE]	72	12 (16,7)	NE [NE; NE]	1,93	[0,97; 4,05]	0,0626
andere	119	41 (34,5)	NE [NE; NE]	98	23 (23,5)	NE [NE; NE]	1,42	[0,86; 2,41]	0,1701
Interaktion p-Wert									0,6461
Docetaxel-Behandlung des mHSPC									
Ja	90	26 (28,9)	NE [NE; NE]	90	18 (20,0)	NE [NE; NE]	1,44	[0,80; 2,67]	0,2298
Nein	308	103 (33,4)	36,6 [34,7; NE]	306	70 (22,9)	NE [NE; NE]	1,45	[1,07; 1,97]	0,0162*
Interaktion p-Wert									0,9890
Alter bei Randomisierung									
<65 Jahre	130	44 (33,8)	NE [NE; NE]	97	17 (17,5)	NE [NE; NE]	1,93	[1,12; 3,47]	0,0168*
>=65 Jahre	268	85 (31,7)	36,6 [31,7; NE]	299	71 (23,7)	NE [NE; NE]	1,32	[0,97; 1,82]	0,0806
Interaktion p-Wert									0,2449
Region									
Asien	91	23 (25,3)	NE [NE; NE]	104	21 (20,2)	NE [NE; NE]	1,06	[0,58; 1,93]	0,8519
Europa	177	61 (34,5)	34,7 [27,9; NE]	171	36 (21,1)	NE [NE; NE]	1,65	[1,10; 2,52]	0,0150*
Nord- und Suedamerika	130	45 (34,6)	NE [NE; NE]	121	31 (25,6)	NE [NE; NE]	1,47	[0,93; 2,34]	0,0967
Interaktion p-Wert									0,4791
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	35 (35,7)	34,7 [24,8; NE]	100	26 (26,0)	NE [NE; NE]	1,19	[0,72; 2,00]	0,4913
Nicht-HRRm	268	81 (30,2)	NE [NE; NE]	267	56 (21,0)	NE [NE; NE]	1,45	[1,04; 2,05]	0,0299*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.4 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	13 (40,6)	NE [NE; NE]	29	6 (20,7)	NE [NE; NE]	2,46	[0,97; 7,01]	0,0576
Interaktion p-Wert									0,4144
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	18 (29,0)	NE [NE; NE]	56	12 (21,4)	NE [NE; NE]	1,20	[0,58; 2,56]	0,6262
Nicht-HRRm	207	76 (36,7)	36,6 [22,7; NE]	210	41 (19,5)	NE [NE; NE]	2,05	[1,41; 3,03]	0,0001*
Unbekannt	129	35 (27,1)	NE [NE; NE]	130	35 (26,9)	NE [NE; NE]	0,91	[0,57; 1,46]	0,6896
Interaktion p-Wert									0,0253*
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	10 (34,5)	NE [NE; NE]	22	8 (36,4)	NE [NE; NE]	0,65	[0,26; 1,72]	0,3768
Nicht-HRRm	330	103 (31,2)	36,6 [31,7; NE]	327	70 (21,4)	NE [NE; NE]	1,47	[1,09; 2,00]	0,0117*
Unbekannt	39	16 (41,0)	NE [NE; NE]	47	10 (21,3)	NE [NE; NE]	2,05	[0,94; 4,68]	0,0707
Interaktion p-Wert									0,1806
ECOG-PS zu Baseline									
0	286	90 (31,5)	36,6 [34,7; NE]	272	54 (19,9)	NE [NE; NE]	1,60	[1,15; 2,26]	0,0055*
1	112	39 (34,8)	NE [NE; NE]	124	34 (27,4)	NE [NE; NE]	1,22	[0,77; 1,94]	0,4056
Interaktion p-Wert									0,3445
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	69 (35,2)	36,6 [31,7; NE]	199	44 (22,1)	NE [NE; NE]	1,62	[1,12; 2,39]	0,0111*
Über medianem PSA-Baselinewert	200	60 (30,0)	NE [NE; NE]	196	44 (22,4)	NE [NE; NE]	1,29	[0,87; 1,91]	0,2012
Interaktion p-Wert									0,4029

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.4 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	95 (33,8)	36,6 [30,3; NE]	274	64 (23,4)	NE [NE; NE]	1,43	[1,05; 1,98]	0,0252*
Afroamerikanisch	14	4 (28,6)	NE [NE; NE]	11	3 (27,3)	NE [NE; NE]	1,04	[0,23; 5,27]	0,9601
Asiatisch	66	13 (19,7)	NE [NE; NE]	72	12 (16,7)	NE [NE; NE]	1,03	[0,47; 2,29]	0,9412
Andere	15	6 (40,0)	NE [NE; NE]	9	3 (33,3)	NE [NE; NE]	1,70	[0,45; 8,04]	0,4442
Interaktion p-Wert									0,8489
Schmerzen zu baseline									
Symptomatisch	103	39 (37,9)	31,7 [19,2; NE]	80	20 (25,0)	NE [NE; NE]	1,53	[0,90; 2,68]	0,1145
Asymptomatisch/mild symptomatisch	266	80 (30,1)	36,6 [34,7; NE]	294	61 (20,7)	NE [NE; NE]	1,39	[0,99; 1,94]	0,0540
Interaktion p-Wert									0,7566

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.5 PROpel: Summary of subgroup analysis of time to UE PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	15 (7,0)	NE [NE; NE]	226	2 (0,9)	NE [NE; NE]	7,96	[2,24; 50,48]	0,0005*
Viszeral	66	4 (6,1)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	3,82	[0,56; 74,66]	0,1809
andere	119	9 (7,6)	NE [NE; NE]	98	4 (4,1)	NE [NE; NE]	1,76	[0,57; 6,50]	0,3327
Interaktion p-Wert									0,2694
Docetaxel-Behandlung des mHSPC									
Ja	90	5 (5,6)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	4,88	[0,79; 93,41]	0,0937
Nein	308	23 (7,5)	NE [NE; NE]	306	6 (2,0)	NE [NE; NE]	3,70	[1,60; 10,01]	0,0015*
Interaktion p-Wert									0,8119
Alter bei Randomisierung									
<65 Jahre	130	7 (5,4)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	21 (7,8)	NE [NE; NE]	299	7 (2,3)	NE [NE; NE]	3,36	[1,50; 8,54]	0,0027*
Interaktion p-Wert									NC
Region									
Asien	91	3 (3,3)	NE [NE; NE]	104	3 (2,9)	NE [NE; NE]	1,01	[0,19; 5,46]	0,9912
Europa	177	15 (8,5)	NE [NE; NE]	171	1 (0,6)	NE [NE; NE]	14,05	[2,85;254,06]	0,0002*
Nord- und Suedamerika	130	10 (7,7)	NE [NE; NE]	121	3 (2,5)	NE [NE; NE]	3,23	[0,99; 14,39]	0,0527
Interaktion p-Wert									0,0866
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	6 (6,1)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	5,46	[0,93;103,07]	0,0613
Nicht-HRRm	268	22 (8,2)	NE [NE; NE]	267	6 (2,2)	NE [NE; NE]	3,65	[1,57; 9,90]	0,0019*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.5 PROpel: Summary of subgroup analysis of time to UE PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7230
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	17 (8,2)	NE [NE; NE]	210	4 (1,9)	NE [NE; NE]	4,48	[1,66; 15,57]	0,0022*
Unbekannt	129	7 (5,4)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	2,19	[0,61; 10,16]	0,2366
Interaktion p-Wert									0,4244
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	3 (10,3)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	22 (6,7)	NE [NE; NE]	327	5 (1,5)	NE [NE; NE]	4,32	[1,77; 12,90]	0,0008*
Unbekannt	39	3 (7,7)	NE [NE; NE]	47	2 (4,3)	NE [NE; NE]	1,75	[0,29; 13,32]	0,5341
Interaktion p-Wert									0,3957
ECOG-PS zu Baseline									
0	286	24 (8,4)	NE [NE; NE]	272	3 (1,1)	NE [NE; NE]	7,55	[2,64; 31,78]	<0,0001*
1	112	4 (3,6)	NE [NE; NE]	124	4 (3,2)	NE [NE; NE]	1,03	[0,24; 4,35]	0,9681
Interaktion p-Wert									0,0303*
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	16 (8,2)	NE [NE; NE]	199	2 (1,0)	NE [NE; NE]	8,07	[2,30; 51,05]	0,0004*
Über medianem PSA-Baselinewert	200	12 (6,0)	NE [NE; NE]	196	5 (2,6)	NE [NE; NE]	2,23	[0,83; 7,01]	0,1158
Interaktion p-Wert									0,1428

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.5 PROpel: Summary of subgroup analysis of time to UE PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	20 (7,1)	NE [NE; NE]	274	3 (1,1)	NE [NE; NE]	6,28	[2,15; 26,65]	0,0003*
Afroamerikanisch	14	3 (21,4)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	1,26	[0,21; 9,56]	0,8010
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	1,92	[0,18; 41,28]	0,5840
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3118
Schmerzen zu baseline									
Symptomatisch	103	6 (5,8)	NE [NE; NE]	80	4 (5,0)	NE [NE; NE]	1,14	[0,32; 4,44]	0,8432
Asymptomatisch/mild symptomatisch	266	19 (7,1)	NE [NE; NE]	294	3 (1,0)	NE [NE; NE]	6,56	[2,23; 27,91]	0,0002*
Interaktion p-Wert									0,0488*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaae 05DEC2022:09:12 khcs324

Table 3.5.6 PROpel: Summary of subgroup analysis of time to UE PT: Nasenverstopfung
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	2 (0,9)	NE [NE; NE]	226	9 (4,0)	NE [NE; NE]	0,22	[0,03; 0,84]	0,0253*
Viszeral	66	1 (1,5)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	0,92	[0,04; 23,30]	0,9541
andere	119	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3756
Docetaxel-Behandlung des mHSPC									
Ja	90	2 (2,2)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Nein	308	1 (0,3)	NE [NE; NE]	306	8 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	2 (1,5)	NE [NE; NE]	97	4 (4,1)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	1 (0,4)	NE [NE; NE]	299	6 (2,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Europa	177	1 (0,6)	NE [NE; NE]	171	2 (1,2)	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	2 (1,5)	NE [NE; NE]	121	7 (5,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	2 (0,7)	NE [NE; NE]	267	7 (2,6)	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaf 05DEC2022:09:12 khcs324

Table 3.5.6 PROpel: Summary of subgroup analysis of time to UE PT: Nasenverstopfung
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	1 (0,5)	NE [NE; NE]	210	7 (3,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	1 (0,8)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	3 (0,9)	NE [NE; NE]	327	8 (2,4)	NE [NE; NE]	0,35	[0,08; 1,19]	0,0950
Unbekannt	39	0	NE [NE; NE]	47	2 (4,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	2 (0,7)	NE [NE; NE]	272	7 (2,6)	NE [NE; NE]	NC	[NC]	NC
1	112	1 (0,9)	NE [NE; NE]	124	3 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	2 (1,0)	NE [NE; NE]	199	5 (2,5)	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	1 (0,5)	NE [NE; NE]	196	5 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaf 05DEC2022:09:12 khcs324

Table 3.5.6 PROpel: Summary of subgroup analysis of time to UE PT: Nasenverstopfung
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	2 (0,7)	NE [NE; NE]	274	8 (2,9)	NE [NE; NE]	0,21	[0,03; 0,85]	0,0276*
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	1 (11,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	0	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	3 (1,1)	NE [NE; NE]	294	9 (3,1)	NE [NE; NE]	0,31	[0,07; 1,06]	0,0619
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.7 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	109 (51,2)	17,5 [9,3; NE]	226	50 (22,1)	NE [NE; NE]	2,94	[2,11; 4,14]	<0,0001*
Viszeral	66	32 (48,5)	25,8 [4,6; NE]	72	22 (30,6)	NE [NE; NE]	1,73	[1,01; 3,02]	0,0445*
andere	119	67 (56,3)	6,5 [3,1;24,1]	98	20 (20,4)	34,1 [34,1; NE]	3,74	[2,31; 6,32]	<0,0001*
Interaktion p-Wert									0,1167
Docetaxel-Behandlung des mHSPC									
Ja	90	37 (41,1)	33,1 [14,8; NE]	90	19 (21,1)	NE [NE; NE]	2,15	[1,25; 3,81]	0,0053*
Nein	308	171 (55,5)	10,2 [6,3;18,5]	306	73 (23,9)	NE [NE; NE]	3,08	[2,35; 4,07]	<0,0001*
Interaktion p-Wert									0,2601
Alter bei Randomisierung									
<65 Jahre	130	55 (42,3)	NE [NE; NE]	97	22 (22,7)	NE [NE; NE]	1,97	[1,22; 3,30]	0,0050*
>=65 Jahre	268	153 (57,1)	7,5 [5,1;16,9]	299	70 (23,4)	NE [NE; NE]	3,39	[2,56; 4,52]	<0,0001*
Interaktion p-Wert									0,0698
Region									
Asien	91	40 (44,0)	NE [NE; NE]	104	11 (10,6)	NE [NE; NE]	4,81	[2,56; 9,86]	<0,0001*
Europa	177	96 (54,2)	10,2 [6,3;19,8]	171	47 (27,5)	NE [NE; NE]	2,62	[1,86; 3,75]	<0,0001*
Nord- und Suedamerika	130	72 (55,4)	14,8 [6,4;25,8]	121	34 (28,1)	34,1 [34,1; NE]	2,49	[1,67; 3,79]	<0,0001*
Interaktion p-Wert									0,2008
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	44 (44,9)	30,4 [9,3; NE]	100	19 (19,0)	NE [NE; NE]	2,74	[1,62; 4,80]	0,0001*
Nicht-HRRm	268	146 (54,5)	14,7 [6,5;22,1]	267	65 (24,3)	NE [NE; NE]	2,88	[2,16; 3,88]	<0,0001*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.7 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	18 (56,3)	8,3 [2,3; NE]	29	8 (27,6)	NE [NE; NE]	2,93	[1,32; 7,15]	0,0080*
Interaktion p-Wert									0,9846
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	28 (45,2)	30,4 [10,2; NE]	56	13 (23,2)	NE [NE; NE]	2,04	[1,08; 4,07]	0,0278*
Nicht-HRRm	207	111 (53,6)	14,0 [6,5;22,1]	210	51 (24,3)	NE [NE; NE]	2,87	[2,07; 4,03]	<0,0001*
Unbekannt	129	69 (53,5)	14,7 [3,8; NE]	130	28 (21,5)	NE [NE; NE]	3,32	[2,17; 5,24]	<0,0001*
Interaktion p-Wert									0,4912
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	15 (51,7)	17,7 [5,1; NE]	22	5 (22,7)	NE [NE; NE]	2,43	[0,94; 7,48]	0,0672
Nicht-HRRm	330	167 (50,6)	18,3 [8,3;25,8]	327	69 (21,1)	NE [NE; NE]	3,05	[2,31; 4,06]	<0,0001*
Unbekannt	39	26 (66,7)	7,4 [1,8;25,8]	47	18 (38,3)	23,0 [13,9; NE]	2,39	[1,32; 4,44]	0,0040*
Interaktion p-Wert									0,7320
ECOG-PS zu Baseline									
0	286	143 (50,0)	18,3 [10,2;33,1]	272	52 (19,1)	NE [NE; NE]	3,31	[2,43; 4,59]	<0,0001*
1	112	65 (58,0)	8,3 [3,7;22,1]	124	40 (32,3)	34,1 [22,7; NE]	2,33	[1,58; 3,48]	<0,0001*
Interaktion p-Wert									0,1747
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	101 (51,5)	18,4 [9,3;33,1]	199	42 (21,1)	NE [NE; NE]	3,12	[2,19; 4,51]	<0,0001*
Über medianem PSA-Baselinewert	200	105 (52,5)	14,7 [6,3;23,1]	196	49 (25,0)	NE [NE; NE]	2,63	[1,88; 3,72]	<0,0001*
Interaktion p-Wert									0,5007

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.7 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	153 (54,4)	10,2 [6,5;18,5]	274	74 (27,0)	NE [NE; NE]	2,60	[1,98; 3,45]	<0,0001*
Afroamerikanisch	14	9 (64,3)	4,6 [0,5; NE]	11	2 (18,2)	NE [NE; NE]	5,11	[1,32; 33,51]	0,0165*
Asiatisch	66	28 (42,4)	NE [NE; NE]	72	7 (9,7)	NE [NE; NE]	4,97	[2,30; 12,36]	<0,0001*
Andere	15	9 (60,0)	12,5 [1,2; NE]	9	3 (33,3)	34,1 [5,5; NE]	2,83	[0,84; 12,77]	0,0943
Interaktion p-Wert									0,3981
Schmerzen zu baseline									
Symptomatisch	103	50 (48,5)	16,9 [4,7; NE]	80	22 (27,5)	NE [NE; NE]	2,14	[1,31; 3,60]	0,0020*
Asymptomatisch/mild symptomatisch	266	143 (53,8)	16,5 [7,5;23,1]	294	65 (22,1)	NE [NE; NE]	3,08	[2,31; 4,16]	<0,0001*
Interaktion p-Wert									0,2255

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.8 PROpel: Summary of subgroup analysis of time to UE PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	99 (46,5)	23,1 [14,7; NE]	226	38 (16,8)	NE [NE; NE]	3,45	[2,40; 5,08]	<0,0001*
Viszeral	66	29 (43,9)	30,4 [6,3; NE]	72	17 (23,6)	NE [NE; NE]	2,10	[1,17; 3,91]	0,0129*
andere	119	61 (51,3)	14,8 [5,1; NE]	98	14 (14,3)	NE [NE; NE]	4,77	[2,75; 8,88]	<0,0001*
Interaktion p-Wert									0,1526
Docetaxel-Behandlung des mHSPC									
Ja	90	31 (34,4)	NE [NE; NE]	90	16 (17,8)	NE [NE; NE]	2,11	[1,17; 3,95]	0,0126*
Nein	308	158 (51,3)	17,5 [7,4;25,8]	306	53 (17,3)	NE [NE; NE]	3,89	[2,87; 5,35]	<0,0001*
Interaktion p-Wert									0,0844
Alter bei Randomisierung									
<65 Jahre	130	47 (36,2)	NE [NE; NE]	97	18 (18,6)	NE [NE; NE]	2,04	[1,21; 3,61]	0,0071*
>=65 Jahre	268	142 (53,0)	10,2 [6,3;22,1]	299	51 (17,1)	NE [NE; NE]	4,27	[3,12; 5,94]	<0,0001*
Interaktion p-Wert									0,0264*
Region									
Asien	91	37 (40,7)	NE [NE; NE]	104	10 (9,6)	NE [NE; NE]	4,85	[2,51; 10,31]	<0,0001*
Europa	177	87 (49,2)	15,6 [8,3; NE]	171	35 (20,5)	NE [NE; NE]	3,16	[2,16; 4,75]	<0,0001*
Nord- und Suedamerika	130	65 (50,0)	22,1 [7,5; NE]	121	24 (19,8)	NE [NE; NE]	3,16	[2,01; 5,14]	<0,0001*
Interaktion p-Wert									0,5269
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	39 (39,8)	33,1 [17,7; NE]	100	15 (15,0)	NE [NE; NE]	3,07	[1,73; 5,75]	<0,0001*
Nicht-HRRm	268	133 (49,6)	18,4 [9,2; NE]	267	47 (17,6)	NE [NE; NE]	3,59	[2,59; 5,06]	<0,0001*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.8 PROpel: Summary of subgroup analysis of time to UE PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	17 (53,1)	8,3 [2,3; NE]	29	7 (24,1)	NE [NE; NE]	3,09	[1,33; 7,98]	0,0080*
Interaktion p-Wert									0,8796
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	25 (40,3)	33,1 [17,5; NE]	56	10 (17,9)	NE [NE; NE]	2,41	[1,19; 5,25]	0,0138*
Nicht-HRRm	207	101 (48,8)	18,4 [8,3; NE]	210	40 (19,0)	NE [NE; NE]	3,26	[2,28; 4,76]	<0,0001*
Unbekannt	129	63 (48,8)	18,5 [4,6; NE]	130	19 (14,6)	NE [NE; NE]	4,45	[2,72; 7,64]	<0,0001*
Interaktion p-Wert									0,3744
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	15 (51,7)	17,7 [5,1; NE]	22	4 (18,2)	NE [NE; NE]	3,06	[1,11; 10,74]	0,0295*
Nicht-HRRm	330	150 (45,5)	24,1 [16,5; NE]	327	53 (16,2)	NE [NE; NE]	3,53	[2,60; 4,87]	<0,0001*
Unbekannt	39	24 (61,5)	7,4 [1,8; NE]	47	12 (25,5)	NE [NE; NE]	3,26	[1,66; 6,74]	0,0005*
Interaktion p-Wert									0,9553
ECOG-PS zu Baseline									
0	286	127 (44,4)	33,1 [17,5; NE]	272	36 (13,2)	NE [NE; NE]	4,19	[2,93; 6,16]	<0,0001*
1	112	62 (55,4)	9,2 [4,4;25,8]	124	33 (26,6)	34,1 [30,3; NE]	2,69	[1,78; 4,16]	<0,0001*
Interaktion p-Wert									0,1233
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	92 (46,9)	26,9 [14,7; NE]	199	30 (15,1)	NE [NE; NE]	3,96	[2,66; 6,08]	<0,0001*
Über medianem PSA-Baselinewert	200	95 (47,5)	18,5 [9,2; NE]	196	38 (19,4)	NE [NE; NE]	3,02	[2,09; 4,46]	<0,0001*
Interaktion p-Wert									0,3428

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.8 PROpel: Summary of subgroup analysis of time to UE PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	140 (49,8)	18,4 [9,2;26,9]	274	57 (20,8)	NE [NE; NE]	3,03	[2,24; 4,15]	<0,0001*
Afroamerikanisch	14	8 (57,1)	4,6 [0,5; NE]	11	2 (18,2)	NE [NE; NE]	4,36	[1,09; 28,86]	0,0363*
Asiatisch	66	26 (39,4)	NE [NE; NE]	72	6 (8,3)	NE [NE; NE]	5,41	[2,38; 14,54]	<0,0001*
Andere	15	6 (40,0)	NE [NE; NE]	9	3 (33,3)	34,1 [5,5; NE]	1,68	[0,44; 7,97]	0,4517
Interaktion p-Wert									0,4676
Schmerzen zu baseline									
Symptomatisch	103	45 (43,7)	30,4 [8,3; NE]	80	18 (22,5)	NE [NE; NE]	2,33	[1,38; 4,13]	0,0014*
Asymptomatisch/mild symptomatisch	266	132 (49,6)	18,5 [10,2; NE]	294	50 (17,0)	NE [NE; NE]	3,67	[2,67; 5,12]	<0,0001*
Interaktion p-Wert									0,1714

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.9 PROpel: Summary of subgroup analysis of time to UE PT: Leukopenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	8 (3,8)	NE [NE; NE]	226	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	2 (1,7)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	0	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	11 (3,6)	NE [NE; NE]	306	1 (0,3)	NE [NE; NE]	10,72	[2,09;195,96]	0,0021*
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	2 (1,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	9 (3,4)	NE [NE; NE]	299	1 (0,3)	NE [NE; NE]	10,12	[1,90;186,55]	0,0039*
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	4 (2,3)	NE [NE; NE]	171	1 (0,6)	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	7 (5,4)	NE [NE; NE]	121	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	8 (3,0)	NE [NE; NE]	267	1 (0,4)	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.9 PROpel: Summary of subgroup analysis of time to UE PT: Leukopenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	2 (6,3)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	5 (2,4)	NE [NE; NE]	210	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	5 (3,9)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	9 (2,7)	NE [NE; NE]	327	1 (0,3)	NE [NE; NE]	8,81	[1,65;162,38]	0,0073*
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	7 (2,4)	NE [NE; NE]	272	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
1	112	4 (3,6)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	5 (2,6)	NE [NE; NE]	199	1 (0,5)	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	6 (3,0)	NE [NE; NE]	196	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.9 PROpel: Summary of subgroup analysis of time to UE PT: Leukopenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	10 (3,6)	NE [NE; NE]	274	1 (0,4)	NE [NE; NE]	9,63	[1,84;176,66]	0,0042*
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	5 (4,9)	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	4 (1,5)	NE [NE; NE]	294	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaai 05DEC2022:09:12 khcs324

Table 3.5.10 PROpel: Summary of subgroup analysis of time to UE PT: Lymphopenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	17 (8,0)	NE [NE; NE]	226	4 (1,8)	NE [NE; NE]	4,43	[1,64; 15,40]	0,0024*
Viszeral	66	3 (4,5)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	1,44	[0,24; 10,96]	0,6848
andere	119	4 (3,4)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	2,99	[0,44; 58,52]	0,2813
Interaktion p-Wert									0,5882
Docetaxel-Behandlung des mHSPC									
Ja	90	8 (8,9)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	7,82	[1,43;145,05]	0,0141*
Nein	308	16 (5,2)	NE [NE; NE]	306	6 (2,0)	NE [NE; NE]	2,49	[1,02; 6,95]	0,0439*
Interaktion p-Wert									0,2833
Alter bei Randomisierung									
<65 Jahre	130	7 (5,4)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	2,30	[0,56; 15,47]	0,2657
>=65 Jahre	268	17 (6,3)	NE [NE; NE]	299	5 (1,7)	NE [NE; NE]	3,73	[1,47; 11,34]	0,0045*
Interaktion p-Wert									0,6198
Region									
Asien	91	0	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	12 (6,8)	NE [NE; NE]	171	4 (2,3)	NE [NE; NE]	2,77	[0,97; 9,93]	0,0584
Nord- und Suedamerika	130	12 (9,2)	NE [NE; NE]	121	3 (2,5)	NE [NE; NE]	3,74	[1,19; 16,43]	0,0225*
Interaktion p-Wert									0,7285
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	4 (4,1)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	19 (7,1)	NE [NE; NE]	267	7 (2,6)	NE [NE; NE]	2,63	[1,16; 6,74]	0,0203*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.10 PROpel: Summary of subgroup analysis of time to UE PT: Lymphopenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	1 (3,1)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	2 (3,2)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	13 (6,3)	NE [NE; NE]	210	3 (1,4)	NE [NE; NE]	4,35	[1,40; 18,98]	0,0092*
Unbekannt	129	9 (7,0)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	2,12	[0,69; 7,82]	0,1949
Interaktion p-Wert									0,4093
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	18 (5,5)	NE [NE; NE]	327	6 (1,8)	NE [NE; NE]	2,86	[1,20; 7,90]	0,0167*
Unbekannt	39	6 (15,4)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	7,07	[1,21;133,45]	0,0281*
Interaktion p-Wert									0,4129
ECOG-PS zu Baseline									
0	286	15 (5,2)	NE [NE; NE]	272	5 (1,8)	NE [NE; NE]	2,75	[1,06; 8,45]	0,0361*
1	112	9 (8,0)	NE [NE; NE]	124	2 (1,6)	NE [NE; NE]	4,60	[1,18; 30,21]	0,0259*
Interaktion p-Wert									0,5747
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	14 (7,1)	NE [NE; NE]	199	4 (2,0)	NE [NE; NE]	3,42	[1,23; 12,06]	0,0175*
Über medianem PSA-Baselinewert	200	10 (5,0)	NE [NE; NE]	196	3 (1,5)	NE [NE; NE]	3,05	[0,93; 13,63]	0,0658
Interaktion p-Wert									0,8969

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaj 05DEC2022:09:12 khcs324

Table 3.5.10 PROpel: Summary of subgroup analysis of time to UE PT: Lymphopenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	19 (6,8)	NE [NE; NE]	274	7 (2,6)	NE [NE; NE]	2,55	[1,12; 6,53]	0,0250*
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	4 (26,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	8 (7,8)	NE [NE; NE]	80	3 (3,8)	NE [NE; NE]	1,99	[0,58; 9,11]	0,2865
Asymptomatisch/mild symptomatisch	266	13 (4,9)	NE [NE; NE]	294	2 (0,7)	NE [NE; NE]	6,61	[1,82; 42,25]	0,0025*
Interaktion p-Wert									0,2335

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaj 05DEC2022:09:12 khcs324

Table 3.5.11 PROpel: Summary of subgroup analysis of time to UE PT: Neutropenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	9 (4,2)	NE [NE; NE]	226	3 (1,3)	NE [NE; NE]	3,12	[0,93; 14,07]	0,0660
Viszeral	66	3 (4,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	8 (6,7)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	6,36	[1,17;117,94]	0,0301*
Interaktion p-Wert									0,5557
Docetaxel-Behandlung des mHSPC									
Ja	90	3 (3,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	17 (5,5)	NE [NE; NE]	306	4 (1,3)	NE [NE; NE]	4,08	[1,51; 14,18]	0,0044*
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	4 (3,1)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	16 (6,0)	NE [NE; NE]	299	4 (1,3)	NE [NE; NE]	4,43	[1,62; 15,47]	0,0027*
Interaktion p-Wert									NC
Region									
Asien	91	2 (2,2)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	11 (6,2)	NE [NE; NE]	171	2 (1,2)	NE [NE; NE]	5,25	[1,41; 33,94]	0,0111*
Nord- und Suedamerika	130	7 (5,4)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	3,30	[0,80; 22,15]	0,1032
Interaktion p-Wert									0,6763
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	7 (7,1)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	12 (4,5)	NE [NE; NE]	267	4 (1,5)	NE [NE; NE]	2,98	[1,04; 10,64]	0,0425*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaak 05DEC2022:09:12 khcs324

Table 3.5.11 PROpel: Summary of subgroup analysis of time to UE PT: Neutropenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	1 (3,1)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	10 (4,8)	NE [NE; NE]	210	2 (1,0)	NE [NE; NE]	5,20	[1,37; 33,87]	0,0132*
Unbekannt	129	6 (4,7)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	2,86	[0,66; 19,53]	0,1673
Interaktion p-Wert									0,5959
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	17 (5,2)	NE [NE; NE]	327	3 (0,9)	NE [NE; NE]	5,56	[1,87; 23,83]	0,0012*
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	2,28	[0,22; 49,05]	0,4869
Interaktion p-Wert									0,5313
ECOG-PS zu Baseline									
0	286	14 (4,9)	NE [NE; NE]	272	1 (0,4)	NE [NE; NE]	13,16	[2,65;238,38]	0,0004*
1	112	6 (5,4)	NE [NE; NE]	124	3 (2,4)	NE [NE; NE]	2,11	[0,56; 10,03]	0,2750
Interaktion p-Wert									0,1154
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	8 (4,1)	NE [NE; NE]	199	2 (1,0)	NE [NE; NE]	3,99	[0,998; 26,41]	0,0503
Über medianem PSA-Baselinewert	200	12 (6,0)	NE [NE; NE]	196	2 (1,0)	NE [NE; NE]	5,71	[1,56; 36,69]	0,0064*
Interaktion p-Wert									0,7440

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaak 05DEC2022:09:12 khcs324

Table 3.5.11 PROpel: Summary of subgroup analysis of time to UE PT: Neutropenie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	20 (7,1)	NE [NE; NE]	274	3 (1,1)	NE [NE; NE]	6,41	[2,20; 27,23]	0,0003*
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	8 (7,8)	NE [NE; NE]	80	2 (2,5)	NE [NE; NE]	3,08	[0,77; 20,40]	0,1173
Asymptomatisch/mild symptomatisch	266	10 (3,8)	NE [NE; NE]	294	2 (0,7)	NE [NE; NE]	5,24	[1,38; 34,12]	0,0128*
Interaktion p-Wert									0,6315

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.12 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	134 (62,9)	8,3 [3,5;13,3]	226	110 (48,7)	22,2 [15,2;33,9]	1,59	[1,24; 2,05]	0,0003*
Viszeral	66	31 (47,0)	14,9 [3,4; NE]	72	35 (48,6)	13,2 [7,8; NE]	0,96	[0,59; 1,56]	0,8761
andere	119	77 (64,7)	3,6 [1,7;13,8]	98	50 (51,0)	12,9 [6,3; NE]	1,48	[1,04; 2,12]	0,0307*
Interaktion p-Wert									0,1902
Docetaxel-Behandlung des mHSPC									
Ja	90	57 (63,3)	3,7 [1,8;16,5]	90	46 (51,1)	12,6 [7,5;33,9]	1,45	[0,98; 2,14]	0,0616
Nein	308	185 (60,1)	8,1 [4,0;13,3]	306	149 (48,7)	17,6 [13,2;24,1]	1,45	[1,17; 1,81]	0,0006*
Interaktion p-Wert									0,9808
Alter bei Randomisierung									
<65 Jahre	130	87 (66,9)	4,8 [1,9;13,3]	97	52 (53,6)	16,2 [7,8;24,1]	1,48	[1,05; 2,10]	0,0231*
>=65 Jahre	268	155 (57,8)	9,6 [4,0;14,9]	299	143 (47,8)	19,8 [12,9;28,2]	1,41	[1,12; 1,77]	0,0030*
Interaktion p-Wert									0,8185
Region									
Asien	91	57 (62,6)	8,3 [2,0;13,8]	104	61 (58,7)	12,7 [7,8;21,7]	1,21	[0,84; 1,73]	0,3066
Europa	177	103 (58,2)	11,0 [3,7;17,8]	171	81 (47,4)	18,4 [9,2; NE]	1,36	[1,01; 1,82]	0,0394*
Nord- und Suedamerika	130	82 (63,1)	3,6 [1,5;14,8]	121	53 (43,8)	24,1 [15,2; NE]	1,91	[1,35; 2,71]	0,0002*
Interaktion p-Wert									0,1629
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	57 (58,2)	13,3 [2,8;22,2]	100	50 (50,0)	12,7 [7,5; NE]	1,14	[0,78; 1,67]	0,5113
Nicht-HRRm	268	162 (60,4)	7,9 [3,5;13,0]	267	131 (49,1)	19,2 [13,2;24,9]	1,51	[1,20; 1,90]	0,0004*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.12 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	23 (71,9)	1,0 [0,7;10,6]	29	14 (48,3)	33,9 [5,2; NE]	2,20	[1,14; 4,38]	0,0180*
Interaktion p-Wert									0,1987
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	38 (61,3)	13,0 [5,6;22,8]	56	28 (50,0)	21,7 [7,8; NE]	1,18	[0,73; 1,94]	0,5101
Nicht-HRRm	207	124 (59,9)	6,4 [2,6;14,9]	210	112 (53,3)	12,9 [9,2;19,8]	1,36	[1,05; 1,75]	0,0192*
Unbekannt	129	80 (62,0)	7,2 [2,4;12,7]	130	55 (42,3)	24,9 [17,6; NE]	1,83	[1,30; 2,59]	0,0005*
Interaktion p-Wert									0,2600
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	15 (51,7)	27,0 [1,4; NE]	22	13 (59,1)	5,1 [1,2; NE]	0,63	[0,30; 1,35]	0,2306
Nicht-HRRm	330	198 (60,0)	7,9 [3,7;12,7]	327	157 (48,0)	19,8 [14,2;24,9]	1,52	[1,23; 1,88]	<0,0001*
Unbekannt	39	29 (74,4)	2,4 [0,7;18,8]	47	25 (53,2)	11,2 [7,1; NE]	1,68	[0,99; 2,89]	0,0566
Interaktion p-Wert									0,0796
ECOG-PS zu Baseline									
0	286	171 (59,8)	10,7 [4,9;15,5]	272	133 (48,9)	19,2 [13,2;28,2]	1,44	[1,15; 1,80]	0,0017*
1	112	71 (63,4)	3,4 [1,5;10,3]	124	62 (50,0)	14,0 [10,7;24,8]	1,52	[1,08; 2,14]	0,0157*
Interaktion p-Wert									0,7808
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	127 (64,8)	9,9 [3,4;13,3]	199	105 (52,8)	17,6 [12,7;25,6]	1,50	[1,16; 1,94]	0,0022*
Über medianem PSA-Baselinewert	200	113 (56,5)	7,9 [2,8;18,2]	196	90 (45,9)	17,6 [10,7;24,9]	1,39	[1,05; 1,83]	0,0206*
Interaktion p-Wert									0,6899

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.12 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Gastrointestinaltrakts
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	177 (63,0)	7,2 [2,8;12,7]	274	128 (46,7)	20,2 [12,9; NE]	1,63	[1,30; 2,05]	<0,0001*
Afroamerikanisch	14	8 (57,1)	10,6 [2,3; NE]	11	7 (63,6)	10,0 [1,1; NE]	0,85	[0,30; 2,42]	0,7494
Asiatisch	66	36 (54,5)	13,0 [4,3; NE]	72	38 (52,8)	15,2 [10,9;25,6]	1,14	[0,72; 1,80]	0,5694
Andere	15	8 (53,3)	12,0 [0,1; NE]	9	6 (66,7)	11,9 [0,0; NE]	0,80	[0,28; 2,44]	0,6883
Interaktion p-Wert									0,2306
Schmerzen zu baseline									
Symptomatisch	103	65 (63,1)	5,6 [1,9;11,5]	80	46 (57,5)	11,4 [6,2;20,7]	1,30	[0,90; 1,91]	0,1660
Asymptomatisch/mild symptomatisch	266	161 (60,5)	11,0 [4,8;16,1]	294	141 (48,0)	18,4 [12,9;33,9]	1,46	[1,16; 1,83]	0,0011*
Interaktion p-Wert									0,6207

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.13 PROpel: Summary of subgroup analysis of time to UE PT: Diarrhoe
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	39 (18,3)	NE [NE; NE]	226	21 (9,3)	NE [NE; NE]	1,97	[1,17; 3,41]	0,0101*
Viszeral	66	12 (18,2)	NE [NE; NE]	72	7 (9,7)	NE [NE; NE]	1,70	[0,68; 4,56]	0,2585
andere	119	24 (20,2)	NE [NE; NE]	98	11 (11,2)	NE [NE; NE]	1,75	[0,88; 3,72]	0,1137
Interaktion p-Wert									0,9455
Docetaxel-Behandlung des mHSPC									
Ja	90	18 (20,0)	NE [NE; NE]	90	12 (13,3)	NE [NE; NE]	1,42	[0,69; 3,04]	0,3387
Nein	308	57 (18,5)	NE [NE; NE]	306	27 (8,8)	NE [NE; NE]	2,08	[1,33; 3,34]	0,0012*
Interaktion p-Wert									0,3925
Alter bei Randomisierung									
<65 Jahre	130	23 (17,7)	NE [NE; NE]	97	10 (10,3)	NE [NE; NE]	1,56	[0,76; 3,44]	0,2266
>=65 Jahre	268	52 (19,4)	NE [NE; NE]	299	29 (9,7)	NE [NE; NE]	2,04	[1,30; 3,24]	0,0017*
Interaktion p-Wert									0,5558
Region									
Asien	91	16 (17,6)	NE [NE; NE]	104	11 (10,6)	NE [NE; NE]	1,50	[0,70; 3,34]	0,2937
Europa	177	37 (20,9)	NE [NE; NE]	171	15 (8,8)	NE [NE; NE]	2,41	[1,35; 4,53]	0,0026*
Nord- und Suedamerika	130	22 (16,9)	NE [NE; NE]	121	13 (10,7)	NE [NE; NE]	1,58	[0,81; 3,23]	0,1828
Interaktion p-Wert									0,5387
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	11 (11,2)	NE [NE; NE]	100	12 (12,0)	NE [NE; NE]	0,81	[0,35; 1,85]	0,6191
Nicht-HRRm	268	57 (21,3)	NE [NE; NE]	267	24 (9,0)	NE [NE; NE]	2,40	[1,51; 3,93]	0,0002*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.13 PROpel: Summary of subgroup analysis of time to UE PT: Diarrhoe
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	7 (21,9)	32,8 [NE; NE]	29	3 (10,3)	NE [NE; NE]	2,30	[0,64; 10,68]	0,2074
Interaktion p-Wert									0,0785
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	8 (12,9)	NE [NE; NE]	56	6 (10,7)	NE [NE; NE]	1,01	[0,35; 3,06]	0,9895
Nicht-HRRm	207	41 (19,8)	NE [NE; NE]	210	24 (11,4)	NE [NE; NE]	1,79	[1,09; 3,01]	0,0209*
Unbekannt	129	26 (20,2)	NE [NE; NE]	130	9 (6,9)	NE [NE; NE]	2,86	[1,39; 6,46]	0,0037*
Interaktion p-Wert									0,2784
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	6 (20,7)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	1,67	[0,38; 11,38]	0,5158
Nicht-HRRm	330	62 (18,8)	NE [NE; NE]	327	34 (10,4)	NE [NE; NE]	1,83	[1,21; 2,80]	0,0039*
Unbekannt	39	7 (17,9)	NE [NE; NE]	47	3 (6,4)	NE [NE; NE]	2,60	[0,72; 12,05]	0,1472
Interaktion p-Wert									0,8747
ECOG-PS zu Baseline									
0	286	58 (20,3)	NE [NE; NE]	272	34 (12,5)	NE [NE; NE]	1,62	[1,07; 2,50]	0,0227*
1	112	17 (15,2)	NE [NE; NE]	124	5 (4,0)	NE [NE; NE]	3,56	[1,41; 10,84]	0,0062*
Interaktion p-Wert									0,1372
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	43 (21,9)	NE [NE; NE]	199	22 (11,1)	NE [NE; NE]	2,01	[1,22; 3,43]	0,0060*
Über medianem PSA-Baselinewert	200	32 (16,0)	NE [NE; NE]	196	17 (8,7)	NE [NE; NE]	1,75	[0,98; 3,22]	0,0567
Interaktion p-Wert									0,7247

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.13 PROpel: Summary of subgroup analysis of time to UE PT: Diarrhoe
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	54 (19,2)	NE [NE; NE]	274	27 (9,9)	NE [NE; NE]	1,93	[1,22; 3,10]	0,0043*
Afroamerikanisch	14	2 (14,3)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	0,76	[0,09; 6,33]	0,7836
Asiatisch	66	10 (15,2)	NE [NE; NE]	72	6 (8,3)	NE [NE; NE]	1,69	[0,63; 4,97]	0,3021
Andere	15	1 (6,7)	NE [NE; NE]	9	2 (22,2)	NE [NE; NE]	0,31	[0,01; 3,26]	0,3234
Interaktion p-Wert									0,3955
Schmerzen zu baseline									
Symptomatisch	103	14 (13,6)	NE [NE; NE]	80	6 (7,5)	NE [NE; NE]	1,77	[0,71; 4,99]	0,2282
Asymptomatisch/mild symptomatisch	266	55 (20,7)	NE [NE; NE]	294	32 (10,9)	NE [NE; NE]	1,84	[1,19; 2,87]	0,0054*
Interaktion p-Wert									0,9434

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaam 05DEC2022:09:12 khcs324

Table 3.5.14 PROpel: Summary of subgroup analysis of time to UE PT: Stomatitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	7 (3,3)	NE [NE; NE]	226	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	1 (1,5)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	NC	[NC]	NC
andere	119	2 (1,7)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	2 (2,2)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	8 (2,6)	NE [NE; NE]	306	2 (0,7)	NE [NE; NE]	3,79	[0,95; 25,10]	0,0601
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	4 (3,1)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	6 (2,2)	NE [NE; NE]	299	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	4 (4,4)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Europa	177	4 (2,3)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	2 (1,5)	NE [NE; NE]	121	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	4 (4,1)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	6 (2,2)	NE [NE; NE]	267	1 (0,4)	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.14 PROpel: Summary of subgroup analysis of time to UE PT: Stomatitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	5 (8,1)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	4 (1,9)	NE [NE; NE]	210	2 (1,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	1 (0,8)	NE [NE; NE]	130	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	2 (6,9)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	7 (2,1)	NE [NE; NE]	327	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	39	1 (2,6)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	8 (2,8)	NE [NE; NE]	272	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
1	112	2 (1,8)	NE [NE; NE]	124	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	7 (3,6)	NE [NE; NE]	199	1 (0,5)	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	3 (1,5)	NE [NE; NE]	196	1 (0,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.14 PROpel: Summary of subgroup analysis of time to UE PT: Stomatitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	3 (1,1)	NE [NE; NE]	274	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	4 (6,1)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	3 (2,9)	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	6 (2,3)	NE [NE; NE]	294	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.15 PROpel: Summary of subgroup analysis of time to UE PT: Uebelkeit
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	67 (31,5)	NE [NE; NE]	226	32 (14,2)	NE [NE; NE]	2,57	[1,70; 3,97]	<0,0001*
Viszeral	66	13 (19,7)	NE [NE; NE]	72	11 (15,3)	NE [NE; NE]	1,29	[0,58; 2,94]	0,5338
andere	119	38 (31,9)	NE [NE; NE]	98	12 (12,2)	NE [NE; NE]	2,80	[1,51; 5,60]	0,0008*
Interaktion p-Wert									0,2799
Docetaxel-Behandlung des mHSPC									
Ja	90	32 (35,6)	NE [NE; NE]	90	15 (16,7)	NE [NE; NE]	2,43	[1,34; 4,61]	0,0032*
Nein	308	86 (27,9)	NE [NE; NE]	306	40 (13,1)	NE [NE; NE]	2,35	[1,63; 3,46]	<0,0001*
Interaktion p-Wert									0,9293
Alter bei Randomisierung									
<65 Jahre	130	44 (33,8)	NE [NE; NE]	97	12 (12,4)	NE [NE; NE]	3,03	[1,66; 6,01]	0,0002*
>=65 Jahre	268	74 (27,6)	NE [NE; NE]	299	43 (14,4)	NE [NE; NE]	2,13	[1,47; 3,12]	<0,0001*
Interaktion p-Wert									0,3400
Region									
Asien	91	26 (28,6)	NE [NE; NE]	104	14 (13,5)	NE [NE; NE]	2,25	[1,19; 4,43]	0,0119*
Europa	177	43 (24,3)	NE [NE; NE]	171	22 (12,9)	NE [NE; NE]	1,99	[1,21; 3,39]	0,0068*
Nord- und Suedamerika	130	49 (37,7)	NE [NE; NE]	121	19 (15,7)	NE [NE; NE]	2,95	[1,77; 5,14]	<0,0001*
Interaktion p-Wert									0,5688
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	29 (29,6)	NE [NE; NE]	100	10 (10,0)	NE [NE; NE]	3,04	[1,53; 6,56]	0,0012*
Nicht-HRRm	268	77 (28,7)	NE [NE; NE]	267	41 (15,4)	NE [NE; NE]	2,10	[1,44; 3,09]	<0,0001*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.15 PROpel: Summary of subgroup analysis of time to UE PT: Uebelkeit
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	12 (37,5)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	3,53	[1,23; 12,62]	0,0182*
Interaktion p-Wert									0,5024
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	16 (25,8)	NE [NE; NE]	56	7 (12,5)	NE [NE; NE]	2,01	[0,86; 5,22]	0,1109
Nicht-HRRm	207	58 (28,0)	NE [NE; NE]	210	35 (16,7)	NE [NE; NE]	1,91	[1,26; 2,93]	0,0021*
Unbekannt	129	44 (34,1)	NE [NE; NE]	130	13 (10,0)	NE [NE; NE]	3,89	[2,16; 7,52]	<0,0001*
Interaktion p-Wert									0,1489
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	5 (17,2)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	1,00	[0,25; 4,88]	0,9992
Nicht-HRRm	330	99 (30,0)	NE [NE; NE]	327	45 (13,8)	NE [NE; NE]	2,47	[1,75; 3,54]	<0,0001*
Unbekannt	39	14 (35,9)	NE [NE; NE]	47	7 (14,9)	NE [NE; NE]	2,84	[1,18; 7,50]	0,0192*
Interaktion p-Wert									0,4822
ECOG-PS zu Baseline									
0	286	82 (28,7)	NE [NE; NE]	272	36 (13,2)	NE [NE; NE]	2,41	[1,64; 3,60]	<0,0001*
1	112	36 (32,1)	NE [NE; NE]	124	19 (15,3)	NE [NE; NE]	2,34	[1,36; 4,15]	0,0021*
Interaktion p-Wert									0,9305
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	65 (33,2)	NE [NE; NE]	199	29 (14,6)	NE [NE; NE]	2,60	[1,70; 4,09]	<0,0001*
Über medianem PSA-Baselinewert	200	51 (25,5)	NE [NE; NE]	196	26 (13,3)	NE [NE; NE]	2,06	[1,30; 3,35]	0,0021*
Interaktion p-Wert									0,4762

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.15 PROpel: Summary of subgroup analysis of time to UE PT: Uebelkeit
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	89 (31,7)	NE [NE; NE]	274	45 (16,4)	NE [NE; NE]	2,14	[1,50; 3,08]	<0,0001*
Afroamerikanisch	14	4 (28,6)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	13 (19,7)	NE [NE; NE]	72	6 (8,3)	NE [NE; NE]	2,42	[0,96; 6,90]	0,0622
Andere	15	3 (20,0)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8110
Schmerzen zu baseline									
Symptomatisch	103	35 (34,0)	NE [NE; NE]	80	12 (15,0)	NE [NE; NE]	2,54	[1,36; 5,11]	0,0030*
Asymptomatisch/mild symptomatisch	266	75 (28,2)	NE [NE; NE]	294	42 (14,3)	NE [NE; NE]	2,14	[1,48; 3,15]	<0,0001*
Interaktion p-Wert									0,6553

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.16 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	76 (35,7)	NE [NE; NE]	226	63 (27,9)	NE [NE; NE]	1,36	[0,98; 1,91]	0,0693
Viszeral	66	17 (25,8)	NE [NE; NE]	72	16 (22,2)	NE [NE; NE]	1,16	[0,58; 2,32]	0,6681
andere	119	49 (41,2)	25,0 [14,9; NE]	98	29 (29,6)	NE [NE; NE]	1,46	[0,93; 2,33]	0,1048
Interaktion p-Wert									0,8652
Docetaxel-Behandlung des mHSPC									
Ja	90	39 (43,3)	23,0 [11,2; NE]	90	30 (33,3)	NE [NE; NE]	1,35	[0,84; 2,19]	0,2173
Nein	308	103 (33,4)	NE [NE; NE]	306	78 (25,5)	NE [NE; NE]	1,39	[1,04; 1,87]	0,0282*
Interaktion p-Wert									0,9188
Alter bei Randomisierung									
<65 Jahre	130	48 (36,9)	NE [NE; NE]	97	28 (28,9)	NE [NE; NE]	1,25	[0,79; 2,02]	0,3459
>=65 Jahre	268	94 (35,1)	NE [NE; NE]	299	80 (26,8)	NE [NE; NE]	1,42	[1,05; 1,92]	0,0209*
Interaktion p-Wert									0,6505
Region									
Asien	91	31 (34,1)	NE [NE; NE]	104	23 (22,1)	NE [NE; NE]	1,53	[0,89; 2,65]	0,1204
Europa	177	55 (31,1)	NE [NE; NE]	171	53 (31,0)	NE [NE; NE]	0,97	[0,67; 1,42]	0,8941
Nord- und Suedamerika	130	56 (43,1)	24,3 [15,8; NE]	121	32 (26,4)	NE [NE; NE]	1,98	[1,29; 3,10]	0,0016*
Interaktion p-Wert									0,0468*
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	36 (36,7)	NE [NE; NE]	100	25 (25,0)	NE [NE; NE]	1,38	[0,83; 2,32]	0,2180
Nicht-HRRm	268	95 (35,4)	NE [NE; NE]	267	73 (27,3)	NE [NE; NE]	1,42	[1,05; 1,94]	0,0224*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.16 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	11 (34,4)	NE [NE; NE]	29	10 (34,5)	NE [NE; NE]	1,05	[0,44; 2,52]	0,9110
Interaktion p-Wert									0,8067
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	23 (37,1)	NE [NE; NE]	56	14 (25,0)	NE [NE; NE]	1,42	[0,74; 2,84]	0,2908
Nicht-HRRm	207	71 (34,3)	NE [NE; NE]	210	54 (25,7)	NE [NE; NE]	1,47	[1,04; 2,11]	0,0311*
Unbekannt	129	48 (37,2)	NE [NE; NE]	130	40 (30,8)	NE [NE; NE]	1,24	[0,81; 1,89]	0,3200
Interaktion p-Wert									0,8185
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	6 (20,7)	NE [NE; NE]	22	4 (18,2)	NE [NE; NE]	0,82	[0,24; 3,22]	0,7650
Nicht-HRRm	330	121 (36,7)	NE [NE; NE]	327	90 (27,5)	NE [NE; NE]	1,44	[1,10; 1,90]	0,0081*
Unbekannt	39	15 (38,5)	NE [NE; NE]	47	14 (29,8)	NE [NE; NE]	1,41	[0,68; 2,95]	0,3556
Interaktion p-Wert									0,7086
ECOG-PS zu Baseline									
0	286	105 (36,7)	NE [NE; NE]	272	75 (27,6)	NE [NE; NE]	1,44	[1,08; 1,95]	0,0143*
1	112	37 (33,0)	NE [NE; NE]	124	33 (26,6)	NE [NE; NE]	1,22	[0,77; 1,97]	0,3975
Interaktion p-Wert									0,5601
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	79 (40,3)	NE [NE; NE]	199	55 (27,6)	NE [NE; NE]	1,60	[1,14; 2,27]	0,0067*
Über medianem PSA-Baselinewert	200	62 (31,0)	NE [NE; NE]	196	52 (26,5)	NE [NE; NE]	1,17	[0,81; 1,70]	0,3998
Interaktion p-Wert									0,2231

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.16 PROpel: Summary of subgroup analysis of time to UE SOC: Erkrankungen des Nervensystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	100 (35,6)	NE [NE; NE]	274	77 (28,1)	NE [NE; NE]	1,34	[0,99; 1,80]	0,0554
Afroamerikanisch	14	5 (35,7)	24,3 [11,2; NE]	11	1 (9,1)	NE [NE; NE]	4,39	[0,71; 84,18]	0,1199
Asiatisch	66	17 (25,8)	NE [NE; NE]	72	16 (22,2)	NE [NE; NE]	1,10	[0,55; 2,19]	0,7924
Andere	15	7 (46,7)	NE [NE; NE]	9	3 (33,3)	NE [NE; NE]	2,23	[0,62; 10,33]	0,2267
Interaktion p-Wert									0,4969
Schmerzen zu baseline									
Symptomatisch	103	37 (35,9)	23,0 [20,9; NE]	80	23 (28,8)	NE [NE; NE]	1,30	[0,78; 2,21]	0,3250
Asymptomatisch/mild symptomatisch	266	94 (35,3)	NE [NE; NE]	294	77 (26,2)	NE [NE; NE]	1,39	[1,03; 1,88]	0,0335*
Interaktion p-Wert									0,8279

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.17 PROpel: Summary of subgroup analysis of time to UE PT: Dysgeusie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	12 (5,6)	NE [NE; NE]	226	3 (1,3)	NE [NE; NE]	4,30	[1,37; 18,86]	0,0111*
Viszeral	66	4 (6,1)	NE [NE; NE]	72	3 (4,2)	NE [NE; NE]	1,44	[0,32; 7,30]	0,6319
andere	119	8 (6,7)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	6,62	[1,21;122,79]	0,0261*
Interaktion p-Wert									0,4086
Docetaxel-Behandlung des mHSPC									
Ja	90	5 (5,6)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	5,11	[0,82; 97,85]	0,0834
Nein	308	19 (6,2)	NE [NE; NE]	306	6 (2,0)	NE [NE; NE]	3,16	[1,34; 8,68]	0,0078*
Interaktion p-Wert									0,6761
Alter bei Randomisierung									
<65 Jahre	130	7 (5,4)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	2,56	[0,62; 17,21]	0,2055
>=65 Jahre	268	17 (6,3)	NE [NE; NE]	299	5 (1,7)	NE [NE; NE]	3,87	[1,53; 11,77]	0,0034*
Interaktion p-Wert									0,6707
Region									
Asien	91	3 (3,3)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	14 (7,9)	NE [NE; NE]	171	5 (2,9)	NE [NE; NE]	2,73	[1,04; 8,45]	0,0402*
Nord- und Suedamerika	130	7 (5,4)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	3,33	[0,81; 22,36]	0,1002
Interaktion p-Wert									0,8334
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	6 (6,1)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	14 (5,2)	NE [NE; NE]	267	7 (2,6)	NE [NE; NE]	2,01	[0,83; 5,29]	0,1215

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.17 PROpel: Summary of subgroup analysis of time to UE PT: Dysgeusie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	4 (12,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	6 (9,7)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	11 (5,3)	NE [NE; NE]	210	5 (2,4)	NE [NE; NE]	2,28	[0,83; 7,23]	0,1127
Unbekannt	129	7 (5,4)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	3,48	[0,84; 23,34]	0,0880
Interaktion p-Wert									0,6564
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	2 (6,9)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	20 (6,1)	NE [NE; NE]	327	7 (2,1)	NE [NE; NE]	2,87	[1,27; 7,31]	0,0104*
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	16 (5,6)	NE [NE; NE]	272	5 (1,8)	NE [NE; NE]	3,07	[1,20; 9,40]	0,0177*
1	112	8 (7,1)	NE [NE; NE]	124	2 (1,6)	NE [NE; NE]	4,47	[1,12; 29,62]	0,0329*
Interaktion p-Wert									0,6868
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	15 (7,7)	NE [NE; NE]	199	4 (2,0)	NE [NE; NE]	3,88	[1,41; 13,61]	0,0074*
Über medianem PSA-Baselinewert	200	9 (4,5)	NE [NE; NE]	196	3 (1,5)	NE [NE; NE]	2,94	[0,88; 13,23]	0,0827
Interaktion p-Wert									0,7502

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.17 PROpel: Summary of subgroup analysis of time to UE PT: Dysgeusie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	16 (5,7)	NE [NE; NE]	274	4 (1,5)	NE [NE; NE]	3,93	[1,44; 13,73]	0,0062*
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	7 (6,8)	NE [NE; NE]	80	1 (1,3)	NE [NE; NE]	5,63	[1,002; 105,31]	0,0497*
Asymptomatisch/mild symptomatisch	266	15 (5,6)	NE [NE; NE]	294	6 (2,0)	NE [NE; NE]	2,74	[1,11; 7,68]	0,0276*
Interaktion p-Wert									0,5158

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaq 05DEC2022:09:12 khcs324

Table 3.5.18 PROpel: Summary of subgroup analysis of time to UE PT: Schwindelgefuehl
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	21 (9,9)	NE [NE; NE]	226	13 (5,8)	NE [NE; NE]	1,74	[0,88; 3,57]	0,1103
Viszeral	66	9 (13,6)	NE [NE; NE]	72	6 (8,3)	NE [NE; NE]	1,58	[0,57; 4,72]	0,3780
andere	119	15 (12,6)	NE [NE; NE]	98	6 (6,1)	NE [NE; NE]	2,02	[0,82; 5,68]	0,1280
Interaktion p-Wert									0,9395
Docetaxel-Behandlung des mHSPC									
Ja	90	11 (12,2)	NE [NE; NE]	90	3 (3,3)	NE [NE; NE]	3,72	[1,16; 16,44]	0,0258*
Nein	308	34 (11,0)	NE [NE; NE]	306	22 (7,2)	NE [NE; NE]	1,53	[0,90; 2,66]	0,1141
Interaktion p-Wert									0,1863
Alter bei Randomisierung									
<65 Jahre	130	15 (11,5)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	3,69	[1,22; 15,95]	0,0189*
>=65 Jahre	268	30 (11,2)	NE [NE; NE]	299	22 (7,4)	NE [NE; NE]	1,53	[0,89; 2,69]	0,1244
Interaktion p-Wert									0,1774
Region									
Asien	91	8 (8,8)	NE [NE; NE]	104	7 (6,7)	NE [NE; NE]	1,23	[0,44; 3,52]	0,6833
Europa	177	14 (7,9)	NE [NE; NE]	171	8 (4,7)	NE [NE; NE]	1,66	[0,71; 4,16]	0,2440
Nord- und Suedamerika	130	23 (17,7)	NE [NE; NE]	121	10 (8,3)	NE [NE; NE]	2,30	[1,13; 5,06]	0,0217*
Interaktion p-Wert									0,6101
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	9 (9,2)	NE [NE; NE]	100	7 (7,0)	NE [NE; NE]	1,23	[0,46; 3,43]	0,6841
Nicht-HRRm	268	32 (11,9)	NE [NE; NE]	267	15 (5,6)	NE [NE; NE]	2,17	[1,20; 4,12]	0,0102*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaar 05DEC2022:09:12 khcs324

Table 3.5.18 PROpel: Summary of subgroup analysis of time to UE PT: Schwindelgefuehl
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	4 (12,5)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	1,27	[0,28; 6,44]	0,7549
Interaktion p-Wert									0,5659
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	5 (8,9)	NE [NE; NE]	0,65	[0,16; 2,47]	0,5225
Nicht-HRRm	207	22 (10,6)	NE [NE; NE]	210	13 (6,2)	NE [NE; NE]	1,76	[0,90; 3,59]	0,1002
Unbekannt	129	19 (14,7)	NE [NE; NE]	130	7 (5,4)	NE [NE; NE]	2,78	[1,22; 7,11]	0,0140*
Interaktion p-Wert									0,1916
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	42 (12,7)	NE [NE; NE]	327	19 (5,8)	NE [NE; NE]	2,24	[1,32; 3,94]	0,0024*
Unbekannt	39	3 (7,7)	NE [NE; NE]	47	5 (10,6)	NE [NE; NE]	0,70	[0,14; 2,87]	0,6264
Interaktion p-Wert									0,1299
ECOG-PS zu Baseline									
0	286	28 (9,8)	NE [NE; NE]	272	13 (4,8)	NE [NE; NE]	2,08	[1,10; 4,14]	0,0243*
1	112	17 (15,2)	NE [NE; NE]	124	12 (9,7)	NE [NE; NE]	1,54	[0,74; 3,31]	0,2459
Interaktion p-Wert									0,5572
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	21 (10,7)	NE [NE; NE]	199	13 (6,5)	NE [NE; NE]	1,64	[0,83; 3,35]	0,1575
Über medianem PSA-Baselinewert	200	24 (12,0)	NE [NE; NE]	196	12 (6,1)	NE [NE; NE]	1,98	[1,01; 4,10]	0,0469*
Interaktion p-Wert									0,7022

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaar 05DEC2022:09:12 khcs324

Table 3.5.18 PROpel: Summary of subgroup analysis of time to UE PT: Schwindelgefuehl
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	36 (12,8)	NE [NE; NE]	274	16 (5,8)	NE [NE; NE]	2,22	[1,25; 4,11]	0,0057*
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	7 (9,7)	NE [NE; NE]	0,28	[0,04; 1,17]	0,0836
Andere	15	4 (26,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0077*
Schmerzen zu baseline									
Symptomatisch	103	12 (11,7)	NE [NE; NE]	80	9 (11,3)	NE [NE; NE]	1,01	[0,43; 2,47]	0,9841
Asymptomatisch/mild symptomatisch	266	28 (10,5)	NE [NE; NE]	294	14 (4,8)	NE [NE; NE]	2,17	[1,16; 4,24]	0,0147*
Interaktion p-Wert									0,1662

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.19 PROpel: Summary of subgroup analysis of time to UE PT: Palpitationen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	5 (2,3)	NE [NE; NE]	226	2 (0,9)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	5 (4,2)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	2 (2,2)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	1,88	[0,18; 40,43]	0,5964
Nein	308	9 (2,9)	NE [NE; NE]	306	2 (0,7)	NE [NE; NE]	4,26	[1,10; 27,97]	0,0351*
Interaktion p-Wert									0,5816
Alter bei Randomisierung									
<65 Jahre	130	4 (3,1)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	7 (2,6)	NE [NE; NE]	299	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	1 (1,1)	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	NC	[NC]	NC
Europa	177	7 (4,0)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	3 (2,3)	NE [NE; NE]	121	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	2 (2,0)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	1,76	[0,17; 37,91]	0,6359
Nicht-HRRm	268	8 (3,0)	NE [NE; NE]	267	2 (0,7)	NE [NE; NE]	3,87	[0,97; 25,64]	0,0559

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.19 PROpel: Summary of subgroup analysis of time to UE PT: Palpitationen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	1 (3,1)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5970
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	5 (2,4)	NE [NE; NE]	210	3 (1,4)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	5 (3,9)	NE [NE; NE]	130	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	9 (2,7)	NE [NE; NE]	327	3 (0,9)	NE [NE; NE]	2,86	[0,85; 12,90]	0,0910
Unbekannt	39	1 (2,6)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	8 (2,8)	NE [NE; NE]	272	2 (0,7)	NE [NE; NE]	3,69	[0,92; 24,42]	0,0661
1	112	3 (2,7)	NE [NE; NE]	124	1 (0,8)	NE [NE; NE]	3,04	[0,39; 61,43]	0,3010
Interaktion p-Wert									0,8908
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	6 (3,1)	NE [NE; NE]	199	3 (1,5)	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	5 (2,5)	NE [NE; NE]	196	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.19 PROpel: Summary of subgroup analysis of time to UE PT: Palpitationen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	6 (2,1)	NE [NE; NE]	274	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	1 (1,5)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	4 (3,9)	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	7 (2,6)	NE [NE; NE]	294	3 (1,0)	NE [NE; NE]	2,34	[0,65; 10,90]	0,1977
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.20 PROpel: Summary of subgroup analysis of time to UE PT: Gastroenteritis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	9 (4,2)	NE [NE; NE]	226	2 (0,9)	NE [NE; NE]	4,71	[1,21; 30,91]	0,0234*
Viszeral	66	1 (1,5)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	0,94	[0,04; 23,70]	0,9639
andere	119	1 (0,8)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3263
Docetaxel-Behandlung des mHSPC									
Ja	90	3 (3,3)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	2,89	[0,37; 58,36]	0,3246
Nein	308	8 (2,6)	NE [NE; NE]	306	2 (0,7)	NE [NE; NE]	3,77	[0,94; 24,96]	0,0614
Interaktion p-Wert									0,8506
Alter bei Randomisierung									
<65 Jahre	130	7 (5,4)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	4 (1,5)	NE [NE; NE]	299	3 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	1 (1,1)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	5 (2,8)	NE [NE; NE]	171	2 (1,2)	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	5 (3,8)	NE [NE; NE]	121	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	0	NE [NE; NE]	100	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	11 (4,1)	NE [NE; NE]	267	1 (0,4)	NE [NE; NE]	10,60	[2,06;193,64]	0,0022*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.20 PROpel: Summary of subgroup analysis of time to UE PT: Gastroenteritis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	0	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	6 (2,9)	NE [NE; NE]	210	1 (0,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	5 (3,9)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	9 (2,7)	NE [NE; NE]	327	3 (0,9)	NE [NE; NE]	2,86	[0,85; 12,89]	0,0911
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	7 (2,4)	NE [NE; NE]	272	3 (1,1)	NE [NE; NE]	2,11	[0,59; 9,82]	0,2586
1	112	4 (3,6)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	9 (4,6)	NE [NE; NE]	199	2 (1,0)	NE [NE; NE]	4,40	[1,13; 28,86]	0,0309*
Über medianem PSA-Baselinewert	200	2 (1,0)	NE [NE; NE]	196	1 (0,5)	NE [NE; NE]	1,85	[0,18; 39,83]	0,6052
Interaktion p-Wert									0,5609

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.20 PROpel: Summary of subgroup analysis of time to UE PT: Gastroenteritis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	6 (2,1)	NE [NE; NE]	274	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	3 (2,9)	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	7 (2,6)	NE [NE; NE]	294	3 (1,0)	NE [NE; NE]	2,34	[0,65; 10,88]	0,1981
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaat 05DEC2022:09:12 khcs324

Table 3.5.21 PROpel: Summary of subgroup analysis of time to UE PT: Arthralgie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	38 (17,8)	NE [NE; NE]	226	44 (19,5)	NE [NE; NE]	0,87	[0,56; 1,34]	0,5144
Viszeral	66	6 (9,1)	NE [NE; NE]	72	11 (15,3)	NE [NE; NE]	0,52	[0,18; 1,38]	0,1929
andere	119	12 (10,1)	NE [NE; NE]	98	20 (20,4)	NE [NE; NE]	0,41	[0,19; 0,82]	0,0121*
Interaktion p-Wert									0,1756
Docetaxel-Behandlung des mHSPC									
Ja	90	17 (18,9)	NE [NE; NE]	90	23 (25,6)	NE [NE; NE]	0,69	[0,36; 1,29]	0,2512
Nein	308	39 (12,7)	NE [NE; NE]	306	52 (17,0)	NE [NE; NE]	0,67	[0,44; 1,01]	0,0549
Interaktion p-Wert									0,9173
Alter bei Randomisierung									
<65 Jahre	130	21 (16,2)	NE [NE; NE]	97	19 (19,6)	NE [NE; NE]	0,69	[0,37; 1,29]	0,2367
>=65 Jahre	268	35 (13,1)	NE [NE; NE]	299	56 (18,7)	NE [NE; NE]	0,66	[0,43; 0,996]	0,0479*
Interaktion p-Wert									0,9094
Region									
Asien	91	8 (8,8)	NE [NE; NE]	104	10 (9,6)	NE [NE; NE]	0,75	[0,29; 1,91]	0,5503
Europa	177	25 (14,1)	NE [NE; NE]	171	27 (15,8)	NE [NE; NE]	0,81	[0,47; 1,39]	0,4390
Nord- und Suedamerika	130	23 (17,7)	35,4 [35,4; NE]	121	38 (31,4)	NE [NE; NE]	0,54	[0,32; 0,90]	0,0184*
Interaktion p-Wert									0,5613
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	16 (16,3)	NE [NE; NE]	100	19 (19,0)	NE [NE; NE]	0,74	[0,37; 1,43]	0,3638
Nicht-HRRm	268	37 (13,8)	NE [NE; NE]	267	50 (18,7)	NE [NE; NE]	0,68	[0,44; 1,03]	0,0699

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaau 05DEC2022:09:12 khcs324

Table 3.5.21 PROpel: Summary of subgroup analysis of time to UE PT: Arthralgie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	3 (9,4)	NE [NE; NE]	29	6 (20,7)	NE [NE; NE]	0,43	[0,09; 1,64]	0,2194
Interaktion p-Wert									0,7870
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	10 (16,1)	NE [NE; NE]	56	10 (17,9)	NE [NE; NE]	0,79	[0,32; 1,92]	0,5954
Nicht-HRRm	207	25 (12,1)	NE [NE; NE]	210	32 (15,2)	NE [NE; NE]	0,75	[0,44; 1,27]	0,2881
Unbekannt	129	21 (16,3)	NE [NE; NE]	130	33 (25,4)	NE [NE; NE]	0,54	[0,31; 0,93]	0,0271*
Interaktion p-Wert									0,6410
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	2 (6,9)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	0,35	[0,05; 2,09]	0,2400
Nicht-HRRm	330	45 (13,6)	NE [NE; NE]	327	59 (18,0)	NE [NE; NE]	0,70	[0,47; 1,03]	0,0712
Unbekannt	39	9 (23,1)	NE [NE; NE]	47	13 (27,7)	NE [NE; NE]	0,74	[0,31; 1,73]	0,4936
Interaktion p-Wert									0,7330
ECOG-PS zu Baseline									
0	286	35 (12,2)	NE [NE; NE]	272	45 (16,5)	NE [NE; NE]	0,68	[0,43; 1,05]	0,0831
1	112	21 (18,8)	NE [NE; NE]	124	30 (24,2)	33,7 [33,7; NE]	0,69	[0,39; 1,19]	0,1830
Interaktion p-Wert									0,9736
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	26 (13,3)	NE [NE; NE]	199	39 (19,6)	NE [NE; NE]	0,62	[0,37; 1,005]	0,0522
Über medianem PSA-Baselinewert	200	30 (15,0)	NE [NE; NE]	196	36 (18,4)	NE [NE; NE]	0,73	[0,45; 1,19]	0,2108
Interaktion p-Wert									0,6162

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.21 PROpel: Summary of subgroup analysis of time to UE PT: Arthralgie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	44 (15,7)	NE [NE; NE]	274	68 (24,8)	NE [NE; NE]	0,56	[0,38; 0,82]	0,0028*
Afroamerikanisch	14	3 (21,4)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	1,14	[0,19; 8,69]	0,8823
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	3 (4,2)	NE [NE; NE]	0,62	[0,08; 3,72]	0,5915
Andere	15	3 (20,0)	NE [NE; NE]	9	1 (11,1)	NE [NE; NE]	2,19	[0,28; 44,20]	0,4739
Interaktion p-Wert									0,5555
Schmerzen zu baseline									
Symptomatisch	103	20 (19,4)	NE [NE; NE]	80	23 (28,8)	26,9 [19,5; NE]	0,64	[0,35; 1,16]	0,1430
Asymptomatisch/mild symptomatisch	266	32 (12,0)	NE [NE; NE]	294	46 (15,6)	NE [NE; NE]	0,67	[0,42; 1,05]	0,0777
Interaktion p-Wert									0,9076

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.22 PROpel: Summary of subgroup analysis of time to UE PT: Knochenschmerzen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	11 (5,2)	NE [NE; NE]	226	5 (2,2)	NE [NE; NE]	2,25	[0,82; 7,14]	0,1188
Viszeral	66	2 (3,0)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	4 (3,4)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	2,89	[0,43; 56,58]	0,2976
Interaktion p-Wert									0,8364
Docetaxel-Behandlung des mHSPC									
Ja	90	6 (6,7)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	2,86	[0,66; 19,51]	0,1678
Nein	308	11 (3,6)	NE [NE; NE]	306	4 (1,3)	NE [NE; NE]	2,47	[0,84; 8,91]	0,1018
Interaktion p-Wert									0,8833
Alter bei Randomisierung									
<65 Jahre	130	11 (8,5)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	7,03	[1,37;128,50]	0,0155*
>=65 Jahre	268	6 (2,2)	NE [NE; NE]	299	5 (1,7)	NE [NE; NE]	1,27	[0,38; 4,40]	0,6958
Interaktion p-Wert									0,1138
Region									
Asien	91	3 (3,3)	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	NC	[NC]	NC
Europa	177	7 (4,0)	NE [NE; NE]	171	2 (1,2)	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	7 (5,4)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	3 (3,1)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	2,41	[0,31; 48,70]	0,4190
Nicht-HRRm	268	13 (4,9)	NE [NE; NE]	267	5 (1,9)	NE [NE; NE]	2,44	[0,92; 7,61]	0,0738

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.22 PROpel: Summary of subgroup analysis of time to UE PT: Knochenschmerzen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	1 (3,1)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9910
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	2 (3,2)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	9 (4,3)	NE [NE; NE]	210	4 (1,9)	NE [NE; NE]	2,25	[0,73; 8,31]	0,1600
Unbekannt	129	6 (4,7)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	2,64	[0,61; 18,03]	0,2041
Interaktion p-Wert									0,8743
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	15 (4,5)	NE [NE; NE]	327	4 (1,2)	NE [NE; NE]	3,49	[1,26; 12,23]	0,0143*
Unbekannt	39	1 (2,6)	NE [NE; NE]	47	2 (4,3)	NE [NE; NE]	0,50	[0,02; 5,26]	0,5635
Interaktion p-Wert									0,1361
ECOG-PS zu Baseline									
0	286	10 (3,5)	NE [NE; NE]	272	3 (1,1)	NE [NE; NE]	2,96	[0,91; 13,21]	0,0739
1	112	7 (6,3)	NE [NE; NE]	124	3 (2,4)	NE [NE; NE]	2,26	[0,63; 10,49]	0,2192
Interaktion p-Wert									0,7756
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	10 (5,1)	NE [NE; NE]	199	3 (1,5)	NE [NE; NE]	3,17	[0,97; 14,16]	0,0565
Über medianem PSA-Baselinewert	200	7 (3,5)	NE [NE; NE]	196	3 (1,5)	NE [NE; NE]	2,03	[0,56; 9,41]	0,2880
Interaktion p-Wert									0,6385

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.22 PROpel: Summary of subgroup analysis of time to UE PT: Knochenschmerzen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	12 (4,3)	NE [NE; NE]	274	3 (1,1)	NE [NE; NE]	3,58	[1,14; 15,73]	0,0281*
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	0,94	[0,11; 7,85]	0,9525
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2638
Schmerzen zu baseline									
Symptomatisch	103	9 (8,7)	NE [NE; NE]	80	3 (3,8)	NE [NE; NE]	2,18	[0,65; 9,81]	0,2181
Asymptomatisch/mild symptomatisch	266	8 (3,0)	NE [NE; NE]	294	3 (1,0)	NE [NE; NE]	2,57	[0,74; 11,75]	0,1400
Interaktion p-Wert									0,8602

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.23 PROpel: Summary of subgroup analysis of time to UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	94 (44,1)	24,8 [20,4; NE]	226	67 (29,6)	NE [NE; NE]	1,55	[1,14; 2,13]	0,0056*
Viszeral	66	23 (34,8)	31,2 [17,5; NE]	72	28 (38,9)	23,7 [9,2; NE]	0,74	[0,42; 1,29]	0,2891
andere	119	56 (47,1)	16,6 [11,0; NE]	98	24 (24,5)	NE [NE; NE]	2,11	[1,32; 3,46]	0,0015*
Interaktion p-Wert									0,0159*
Docetaxel-Behandlung des mHSPC									
Ja	90	36 (40,0)	26,7 [22,6; NE]	90	29 (32,2)	NE [NE; NE]	1,22	[0,75; 2,00]	0,4302
Nein	308	137 (44,5)	24,0 [17,5; NE]	306	90 (29,4)	NE [NE; NE]	1,57	[1,21; 2,06]	0,0008*
Interaktion p-Wert									0,3701
Alter bei Randomisierung									
<65 Jahre	130	52 (40,0)	27,6 [22,3; NE]	97	28 (28,9)	NE [NE; NE]	1,24	[0,79; 1,98]	0,3603
>=65 Jahre	268	121 (45,1)	22,6 [15,7;28,7]	299	91 (30,4)	NE [NE; NE]	1,62	[1,24; 2,13]	0,0005*
Interaktion p-Wert									0,3238
Region									
Asien	91	33 (36,3)	NE [NE; NE]	104	26 (25,0)	NE [NE; NE]	1,40	[0,84; 2,36]	0,1973
Europa	177	73 (41,2)	27,8 [16,8; NE]	171	45 (26,3)	NE [NE; NE]	1,64	[1,13; 2,39]	0,0085*
Nord- und Suedamerika	130	67 (51,5)	17,5 [11,9;27,5]	121	48 (39,7)	28,0 [19,4; NE]	1,35	[0,94; 1,97]	0,1081
Interaktion p-Wert									0,7610
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	44 (44,9)	22,6 [13,8; NE]	100	34 (34,0)	NE [NE; NE]	1,26	[0,81; 1,99]	0,3023
Nicht-HRRm	268	114 (42,5)	26,7 [17,5; NE]	267	77 (28,8)	NE [NE; NE]	1,57	[1,18; 2,10]	0,0020*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.23 PROpel: Summary of subgroup analysis of time to UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	15 (46,9)	24,8 [16,9; NE]	29	8 (27,6)	NE [NE; NE]	1,56	[0,68; 3,88]	0,2999
Interaktion p-Wert									0,7237
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	31 (50,0)	20,9 [11,9; NE]	56	21 (37,5)	NE [NE; NE]	1,40	[0,81; 2,47]	0,2297
Nicht-HRRm	207	95 (45,9)	22,6 [15,6;27,6]	210	57 (27,1)	NE [NE; NE]	1,83	[1,32; 2,55]	0,0003*
Unbekannt	129	47 (36,4)	NE [NE; NE]	130	41 (31,5)	NE [NE; NE]	1,08	[0,71; 1,65]	0,7064
Interaktion p-Wert									0,1550
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	14 (48,3)	19,2 [9,1; NE]	22	9 (40,9)	17,5 [7,8; NE]	1,05	[0,46; 2,51]	0,9141
Nicht-HRRm	330	141 (42,7)	24,8 [20,4; NE]	327	95 (29,1)	NE [NE; NE]	1,54	[1,19; 2,00]	0,0010*
Unbekannt	39	18 (46,2)	28,7 [7,4; NE]	47	15 (31,9)	NE [NE; NE]	1,38	[0,70; 2,78]	0,3528
Interaktion p-Wert									0,6839
ECOG-PS zu Baseline									
0	286	122 (42,7)	24,8 [21,0; NE]	272	86 (31,6)	NE [NE; NE]	1,39	[1,06; 1,83]	0,0190*
1	112	51 (45,5)	20,9 [13,8; NE]	124	33 (26,6)	NE [NE; NE]	1,77	[1,14; 2,76]	0,0099*
Interaktion p-Wert									0,3614
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	85 (43,4)	27,5 [22,3; NE]	199	67 (33,7)	NE [NE; NE]	1,32	[0,96; 1,83]	0,0868
Über medianem PSA-Baselinewert	200	87 (43,5)	20,9 [13,8; NE]	196	51 (26,0)	NE [NE; NE]	1,72	[1,22; 2,45]	0,0017*
Interaktion p-Wert									0,2710

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaw 05DEC2022:09:12 khcs324

Table 3.5.23 PROpel: Summary of subgroup analysis of time to UE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	125 (44,5)	24,4 [16,6;28,7]	274	85 (31,0)	NE [NE; NE]	1,45	[1,10; 1,92]	0,0074*
Afroamerikanisch	14	8 (57,1)	16,9 [3,7; NE]	11	4 (36,4)	NE [NE; NE]	1,80	[0,57; 6,75]	0,3243
Asiatisch	66	24 (36,4)	NE [NE; NE]	72	21 (29,2)	NE [NE; NE]	1,22	[0,68; 2,20]	0,5133
Andere	15	10 (66,7)	11,9 [1,0; NE]	9	4 (44,4)	21,5 [5,5; NE]	2,02	[0,68; 7,37]	0,2148
Interaktion p-Wert									0,8487
Schmerzen zu baseline									
Symptomatisch	103	42 (40,8)	17,5 [13,8; NE]	80	28 (35,0)	23,7 [17,5; NE]	1,13	[0,71; 1,84]	0,6110
Asymptomatisch/mild symptomatisch	266	117 (44,0)	26,7 [22,1; NE]	294	81 (27,6)	NE [NE; NE]	1,62	[1,23; 2,16]	0,0007*
Interaktion p-Wert									0,2060

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.24 PROpel: Summary of subgroup analysis of time to UE PT: Appetit vermindert
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	29 (13,6)	NE [NE; NE]	226	14 (6,2)	NE [NE; NE]	2,18	[1,18; 4,26]	0,0130*
Viszeral	66	8 (12,1)	NE [NE; NE]	72	8 (11,1)	NE [NE; NE]	1,00	[0,37; 2,72]	0,9980
andere	119	27 (22,7)	NE [NE; NE]	98	6 (6,1)	NE [NE; NE]	3,79	[1,67; 10,15]	0,0009*
Interaktion p-Wert									0,1332
Docetaxel-Behandlung des mHSPC									
Ja	90	13 (14,4)	NE [NE; NE]	90	6 (6,7)	NE [NE; NE]	2,12	[0,84; 6,04]	0,1146
Nein	308	51 (16,6)	NE [NE; NE]	306	22 (7,2)	NE [NE; NE]	2,30	[1,41; 3,87]	0,0007*
Interaktion p-Wert									0,8844
Alter bei Randomisierung									
<65 Jahre	130	10 (7,7)	NE [NE; NE]	97	4 (4,1)	NE [NE; NE]	1,65	[0,55; 6,03]	0,3813
>=65 Jahre	268	54 (20,1)	NE [NE; NE]	299	24 (8,0)	NE [NE; NE]	2,64	[1,65; 4,34]	<0,0001*
Interaktion p-Wert									0,4772
Region									
Asien	91	13 (14,3)	NE [NE; NE]	104	8 (7,7)	NE [NE; NE]	1,69	[0,71; 4,27]	0,2361
Europa	177	23 (13,0)	NE [NE; NE]	171	10 (5,8)	NE [NE; NE]	2,19	[1,07; 4,81]	0,0315*
Nord- und Suedamerika	130	28 (21,5)	NE [NE; NE]	121	10 (8,3)	NE [NE; NE]	2,80	[1,41; 6,06]	0,0029*
Interaktion p-Wert									0,6833
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	17 (17,3)	NE [NE; NE]	100	8 (8,0)	NE [NE; NE]	2,05	[0,91; 5,03]	0,0834
Nicht-HRRm	268	45 (16,8)	NE [NE; NE]	267	18 (6,7)	NE [NE; NE]	2,53	[1,49; 4,49]	0,0005*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.24 PROpel: Summary of subgroup analysis of time to UE PT: Appetit vermindert
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	2 (6,3)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	0,86	[0,10; 7,18]	0,8814
Interaktion p-Wert									0,5720
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	10 (16,1)	NE [NE; NE]	56	4 (7,1)	NE [NE; NE]	2,06	[0,69; 7,51]	0,2026
Nicht-HRRm	207	35 (16,9)	NE [NE; NE]	210	17 (8,1)	NE [NE; NE]	2,17	[1,23; 3,97]	0,0067*
Unbekannt	129	19 (14,7)	NE [NE; NE]	130	7 (5,4)	NE [NE; NE]	2,64	[1,16; 6,76]	0,0198*
Interaktion p-Wert									0,9190
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	4 (13,8)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	1,16	[0,23; 8,36]	0,8640
Nicht-HRRm	330	55 (16,7)	NE [NE; NE]	327	23 (7,0)	NE [NE; NE]	2,43	[1,51; 4,03]	0,0002*
Unbekannt	39	5 (12,8)	NE [NE; NE]	47	3 (6,4)	NE [NE; NE]	1,83	[0,45; 8,94]	0,3986
Interaktion p-Wert									0,7011
ECOG-PS zu Baseline									
0	286	39 (13,6)	NE [NE; NE]	272	20 (7,4)	NE [NE; NE]	1,86	[1,10; 3,25]	0,0209*
1	112	25 (22,3)	NE [NE; NE]	124	8 (6,5)	NE [NE; NE]	3,41	[1,61; 8,09]	0,0011*
Interaktion p-Wert									0,2067
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	31 (15,8)	NE [NE; NE]	199	14 (7,0)	NE [NE; NE]	2,27	[1,23; 4,40]	0,0081*
Über medianem PSA-Baselinewert	200	33 (16,5)	NE [NE; NE]	196	14 (7,1)	NE [NE; NE]	2,25	[1,23; 4,34]	0,0080*
Interaktion p-Wert									0,9835

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.24 PROpel: Summary of subgroup analysis of time to UE PT: Appetit vermindert
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	47 (16,7)	NE [NE; NE]	274	19 (6,9)	NE [NE; NE]	2,38	[1,42; 4,15]	0,0008*
Afroamerikanisch	14	2 (14,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	7 (10,6)	NE [NE; NE]	72	7 (9,7)	NE [NE; NE]	0,98	[0,34; 2,87]	0,9755
Andere	15	4 (26,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1436
Schmerzen zu baseline									
Symptomatisch	103	11 (10,7)	NE [NE; NE]	80	8 (10,0)	NE [NE; NE]	1,04	[0,42; 2,68]	0,9351
Asymptomatisch/mild symptomatisch	266	45 (16,9)	NE [NE; NE]	294	18 (6,1)	NE [NE; NE]	2,69	[1,58; 4,76]	0,0002*
Interaktion p-Wert									0,0846

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.25 PROpel: Summary of subgroup analysis of time to UE PT: Dehydratation
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	6 (2,8)	NE [NE; NE]	226	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	1 (1,5)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	NC	[NC]	NC
andere	119	5 (4,2)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	2 (2,2)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	10 (3,2)	NE [NE; NE]	306	3 (1,0)	NE [NE; NE]	3,18	[0,97; 14,19]	0,0559
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	3 (2,3)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	1,95	[0,25; 39,50]	0,5427
>=65 Jahre	268	9 (3,4)	NE [NE; NE]	299	2 (0,7)	NE [NE; NE]	4,79	[1,23; 31,43]	0,0218*
Interaktion p-Wert									0,5340
Region									
Asien	91	1 (1,1)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	1 (0,6)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	10 (7,7)	NE [NE; NE]	121	3 (2,5)	NE [NE; NE]	3,04	[0,93; 13,57]	0,0667
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	4 (4,1)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	8 (3,0)	NE [NE; NE]	267	0	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.25 PROpel: Summary of subgroup analysis of time to UE PT: Dehydratation
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	1 (1,8)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	5 (2,4)	NE [NE; NE]	210	2 (1,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	6 (4,7)	NE [NE; NE]	130	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	12 (3,6)	NE [NE; NE]	327	2 (0,6)	NE [NE; NE]	5,62	[1,53; 36,12]	0,0070*
Unbekannt	39	0	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	10 (3,5)	NE [NE; NE]	272	1 (0,4)	NE [NE; NE]	9,00	[1,72;165,06]	0,0058*
1	112	2 (1,8)	NE [NE; NE]	124	2 (1,6)	NE [NE; NE]	0,98	[0,12; 8,20]	0,9867
Interaktion p-Wert									0,1100
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	7 (3,6)	NE [NE; NE]	199	0	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	5 (2,5)	NE [NE; NE]	196	3 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.25 PROpel: Summary of subgroup analysis of time to UE PT: Dehydratation
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	9 (3,2)	NE [NE; NE]	274	3 (1,1)	NE [NE; NE]	2,66	[0,79; 12,02]	0,1168
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	1 (1,0)	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	8 (3,0)	NE [NE; NE]	294	2 (0,7)	NE [NE; NE]	3,92	[0,98; 26,01]	0,0539
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaay 05DEC2022:09:12 khcs324

Table 3.5.26 PROpel: Summary of subgroup analysis of time to UE PT: Hypokaliaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	17 (8,0)	NE [NE; NE]	226	9 (4,0)	NE [NE; NE]	1,94	[0,88; 4,55]	0,0999
Viszeral	66	6 (9,1)	NE [NE; NE]	72	4 (5,6)	NE [NE; NE]	1,46	[0,42; 5,73]	0,5507
andere	119	8 (6,7)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	2,01	[0,58; 9,17]	0,2821
Interaktion p-Wert									0,9253
Docetaxel-Behandlung des mHSPC									
Ja	90	8 (8,9)	NE [NE; NE]	90	4 (4,4)	NE [NE; NE]	1,89	[0,60; 7,10]	0,2835
Nein	308	23 (7,5)	NE [NE; NE]	306	12 (3,9)	NE [NE; NE]	1,80	[0,91; 3,73]	0,0922
Interaktion p-Wert									0,9397
Alter bei Randomisierung									
<65 Jahre	130	9 (6,9)	NE [NE; NE]	97	4 (4,1)	NE [NE; NE]	1,48	[0,48; 5,45]	0,5075
>=65 Jahre	268	22 (8,2)	NE [NE; NE]	299	12 (4,0)	NE [NE; NE]	2,00	[1,01; 4,17]	0,0478*
Interaktion p-Wert									0,6678
Region									
Asien	91	5 (5,5)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	5,03	[0,81; 96,47]	0,0866
Europa	177	20 (11,3)	NE [NE; NE]	171	7 (4,1)	NE [NE; NE]	2,63	[1,16; 6,70]	0,0193*
Nord- und Suedamerika	130	6 (4,6)	NE [NE; NE]	121	8 (6,6)	NE [NE; NE]	0,68	[0,22; 1,96]	0,4774
Interaktion p-Wert									0,0775
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	10 (10,2)	NE [NE; NE]	100	5 (5,0)	NE [NE; NE]	1,78	[0,63; 5,73]	0,2793
Nicht-HRRm	268	19 (7,1)	NE [NE; NE]	267	9 (3,4)	NE [NE; NE]	2,04	[0,95; 4,73]	0,0693

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.26 PROpel: Summary of subgroup analysis of time to UE PT: Hypokaliaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	2 (6,3)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	0,87	[0,10; 7,26]	0,8908
Interaktion p-Wert									0,7374
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	6 (9,7)	NE [NE; NE]	56	1 (1,8)	NE [NE; NE]	4,71	[0,80; 89,03]	0,0911
Nicht-HRRm	207	18 (8,7)	NE [NE; NE]	210	9 (4,3)	NE [NE; NE]	2,03	[0,93; 4,73]	0,0745
Unbekannt	129	7 (5,4)	NE [NE; NE]	130	6 (4,6)	NE [NE; NE]	1,06	[0,35; 3,29]	0,9165
Interaktion p-Wert									0,3768
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	3 (10,3)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	1,70	[0,22; 34,41]	0,6321
Nicht-HRRm	330	27 (8,2)	NE [NE; NE]	327	13 (4,0)	NE [NE; NE]	1,98	[1,04; 3,95]	0,0375*
Unbekannt	39	1 (2,6)	NE [NE; NE]	47	2 (4,3)	NE [NE; NE]	0,56	[0,03; 5,88]	0,6307
Interaktion p-Wert									0,5915
ECOG-PS zu Baseline									
0	286	20 (7,0)	NE [NE; NE]	272	9 (3,3)	NE [NE; NE]	2,02	[0,95; 4,67]	0,0689
1	112	11 (9,8)	NE [NE; NE]	124	7 (5,6)	NE [NE; NE]	1,60	[0,63; 4,36]	0,3234
Interaktion p-Wert									0,7114
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	8 (4,1)	NE [NE; NE]	199	10 (5,0)	NE [NE; NE]	0,75	[0,29; 1,91]	0,5504
Über medianem PSA-Baselinewert	200	23 (11,5)	NE [NE; NE]	196	6 (3,1)	NE [NE; NE]	3,60	[1,56; 9,75]	0,0020*
Interaktion p-Wert									0,0147*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.26 PROpel: Summary of subgroup analysis of time to UE PT: Hypokaliaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	25 (8,9)	NE [NE; NE]	274	15 (5,5)	NE [NE; NE]	1,52	[0,81; 2,95]	0,1941
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	3 (4,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	1 (6,7)	NE [NE; NE]	9	1 (11,1)	NE [NE; NE]	0,71	[0,03; 17,85]	0,8062
Interaktion p-Wert									0,6012
Schmerzen zu baseline									
Symptomatisch	103	9 (8,7)	NE [NE; NE]	80	4 (5,0)	NE [NE; NE]	1,67	[0,54; 6,17]	0,3791
Asymptomatisch/mild symptomatisch	266	20 (7,5)	NE [NE; NE]	294	10 (3,4)	NE [NE; NE]	2,05	[0,98; 4,56]	0,0571
Interaktion p-Wert									0,7790

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaaz 05DEC2022:09:12 khcs324

Table 3.5.27 PROpel: Summary of subgroup analysis of time to UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	10 (4,7)	NE [NE; NE]	226	16 (7,1)	NE [NE; NE]	0,64	[0,28; 1,38]	0,2542
Viszeral	66	3 (4,5)	NE [NE; NE]	72	4 (5,6)	NE [NE; NE]	0,76	[0,15; 3,45]	0,7198
andere	119	1 (0,8)	NE [NE; NE]	98	8 (8,2)	NE [NE; NE]	0,09	[0,01; 0,51]	0,0036*
Interaktion p-Wert									0,1119
Docetaxel-Behandlung des mHSPC									
Ja	90	2 (2,2)	NE [NE; NE]	90	8 (8,9)	NE [NE; NE]	0,24	[0,04; 0,94]	0,0399*
Nein	308	12 (3,9)	NE [NE; NE]	306	20 (6,5)	NE [NE; NE]	0,56	[0,27; 1,13]	0,1067
Interaktion p-Wert									0,2950
Alter bei Randomisierung									
<65 Jahre	130	5 (3,8)	NE [NE; NE]	97	4 (4,1)	NE [NE; NE]	0,87	[0,23; 3,50]	0,8304
>=65 Jahre	268	9 (3,4)	NE [NE; NE]	299	24 (8,0)	NE [NE; NE]	0,40	[0,17; 0,83]	0,0125*
Interaktion p-Wert									0,3126
Region									
Asien	91	5 (5,5)	NE [NE; NE]	104	11 (10,6)	NE [NE; NE]	0,46	[0,14; 1,25]	0,1305
Europa	177	6 (3,4)	NE [NE; NE]	171	8 (4,7)	NE [NE; NE]	0,69	[0,23; 2,00]	0,4959
Nord- und Suedamerika	130	3 (2,3)	NE [NE; NE]	121	9 (7,4)	NE [NE; NE]	0,30	[0,07; 1,01]	0,0519
Interaktion p-Wert									0,6102
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	10 (10,0)	NE [NE; NE]	0,09	[0,00; 0,47]	0,0020*
Nicht-HRRm	268	13 (4,9)	NE [NE; NE]	267	16 (6,0)	NE [NE; NE]	0,77	[0,37; 1,61]	0,4926

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.27 PROpel: Summary of subgroup analysis of time to UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0186*
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	7 (12,5)	NE [NE; NE]	0,11	[0,01; 0,62]	0,0095*
Nicht-HRRm	207	9 (4,3)	NE [NE; NE]	210	18 (8,6)	NE [NE; NE]	0,48	[0,21; 1,05]	0,0674
Unbekannt	129	4 (3,1)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	1,28	[0,28; 6,52]	0,7427
Interaktion p-Wert									0,1160
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	4 (18,2)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	12 (3,6)	NE [NE; NE]	327	21 (6,4)	NE [NE; NE]	0,54	[0,26; 1,08]	0,0832
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	3 (6,4)	NE [NE; NE]	0,74	[0,10; 4,45]	0,7366
Interaktion p-Wert									0,7546
ECOG-PS zu Baseline									
0	286	10 (3,5)	NE [NE; NE]	272	20 (7,4)	NE [NE; NE]	0,45	[0,20; 0,94]	0,0341*
1	112	4 (3,6)	NE [NE; NE]	124	8 (6,5)	NE [NE; NE]	0,51	[0,14; 1,62]	0,2583
Interaktion p-Wert									0,8666
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	6 (3,1)	NE [NE; NE]	199	12 (6,0)	NE [NE; NE]	0,48	[0,17; 1,24]	0,1333
Über medianem PSA-Baselinewert	200	8 (4,0)	NE [NE; NE]	196	16 (8,2)	NE [NE; NE]	0,45	[0,18; 1,03]	0,0600
Interaktion p-Wert									0,9267

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.27 PROpel: Summary of subgroup analysis of time to UE PT: Alaninaminotransferase erhoeht
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	8 (2,8)	NE [NE; NE]	274	25 (9,1)	NE [NE; NE]	0,29	[0,12; 0,61]	0,0009*
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	5 (7,6)	NE [NE; NE]	72	3 (4,2)	NE [NE; NE]	1,70	[0,42; 8,27]	0,4623
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0301*
Schmerzen zu baseline									
Symptomatisch	103	2 (1,9)	NE [NE; NE]	80	6 (7,5)	NE [NE; NE]	0,25	[0,04; 1,06]	0,0610
Asymptomatisch/mild symptomatisch	266	11 (4,1)	NE [NE; NE]	294	21 (7,1)	NE [NE; NE]	0,54	[0,25; 1,09]	0,0865
Interaktion p-Wert									0,3652

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.28 PROpel: Summary of subgroup analysis of time to UE PT: Elektrokardiogramm QT verlaengert
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	8 (3,8)	NE [NE; NE]	226	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	2 (3,0)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	4 (3,4)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	7 (7,8)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	7 (2,3)	NE [NE; NE]	306	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	12 (9,2)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	2 (0,7)	NE [NE; NE]	299	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	2 (2,2)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Europa	177	7 (4,0)	NE [NE; NE]	171	1 (0,6)	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	5 (3,8)	NE [NE; NE]	121	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	5 (5,1)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	6 (2,2)	NE [NE; NE]	267	2 (0,7)	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.28 PROpel: Summary of subgroup analysis of time to UE PT: Elektrokardiogramm QT verlaengert
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	3 (9,4)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	3 (4,8)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	5 (2,4)	NE [NE; NE]	210	2 (1,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	6 (4,7)	NE [NE; NE]	130	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	11 (3,3)	NE [NE; NE]	327	2 (0,6)	NE [NE; NE]	5,14	[1,38; 33,25]	0,0123*
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	9 (3,1)	NE [NE; NE]	272	1 (0,4)	NE [NE; NE]	8,18	[1,54;150,84]	0,0101*
1	112	5 (4,5)	NE [NE; NE]	124	1 (0,8)	NE [NE; NE]	4,92	[0,79; 94,30]	0,0920
Interaktion p-Wert									0,7388
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	6 (3,1)	NE [NE; NE]	199	0	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	8 (4,0)	NE [NE; NE]	196	2 (1,0)	NE [NE; NE]	3,63	[0,91; 24,11]	0,0699
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.28 PROpel: Summary of subgroup analysis of time to UE PT: Elektrokardiogramm QT verlaengert
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	11 (3,9)	NE [NE; NE]	274	1 (0,4)	NE [NE; NE]	10,14	[1,97;185,28]	0,0028*
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	1,93	[0,18; 41,47]	0,5813
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3117
Schmerzen zu baseline									
Symptomatisch	103	6 (5,8)	NE [NE; NE]	80	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	8 (3,0)	NE [NE; NE]	294	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabb 05DEC2022:09:12 khcs324

Table 3.5.29 PROpel: Summary of subgroup analysis of time to UE PT: Leukozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	14 (6,6)	NE [NE; NE]	226	8 (3,5)	NE [NE; NE]	1,79	[0,77; 4,48]	0,1814
Viszeral	66	2 (3,0)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	0,98	[0,12; 8,14]	0,9809
andere	119	9 (7,6)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5815
Docetaxel-Behandlung des mHSPC									
Ja	90	6 (6,7)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	5,95	[1,01;112,29]	0,0479*
Nein	308	19 (6,2)	NE [NE; NE]	306	9 (2,9)	NE [NE; NE]	1,99	[0,92; 4,62]	0,0797
Interaktion p-Wert									0,2993
Alter bei Randomisierung									
<65 Jahre	130	7 (5,4)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	2,31	[0,56; 15,50]	0,2642
>=65 Jahre	268	18 (6,7)	NE [NE; NE]	299	8 (2,7)	NE [NE; NE]	2,50	[1,12; 6,08]	0,0247*
Interaktion p-Wert									0,9321
Region									
Asien	91	3 (3,3)	NE [NE; NE]	104	3 (2,9)	NE [NE; NE]	0,99	[0,18; 5,33]	0,9862
Europa	177	10 (5,6)	NE [NE; NE]	171	2 (1,2)	NE [NE; NE]	4,68	[1,23; 30,47]	0,0213*
Nord- und Suedamerika	130	12 (9,2)	NE [NE; NE]	121	5 (4,1)	NE [NE; NE]	2,27	[0,84; 7,13]	0,1079
Interaktion p-Wert									0,3647
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	9 (9,2)	NE [NE; NE]	100	3 (3,0)	NE [NE; NE]	2,79	[0,83; 12,59]	0,0995
Nicht-HRRm	268	14 (5,2)	NE [NE; NE]	267	7 (2,6)	NE [NE; NE]	1,94	[0,81; 5,13]	0,1398

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.29 PROpel: Summary of subgroup analysis of time to UE PT: Leukozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	2 (6,3)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6523
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	7 (11,3)	NE [NE; NE]	56	1 (1,8)	NE [NE; NE]	5,68	[1,01;106,23]	0,0485*
Nicht-HRRm	207	12 (5,8)	NE [NE; NE]	210	6 (2,9)	NE [NE; NE]	2,05	[0,80; 5,89]	0,1388
Unbekannt	129	6 (4,7)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	1,83	[0,48; 8,69]	0,3792
Interaktion p-Wert									0,5954
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	2 (6,9)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	16 (4,8)	NE [NE; NE]	327	7 (2,1)	NE [NE; NE]	2,18	[0,93; 5,68]	0,0733
Unbekannt	39	7 (17,9)	NE [NE; NE]	47	3 (6,4)	NE [NE; NE]	2,86	[0,80; 13,29]	0,1090
Interaktion p-Wert									0,7400
ECOG-PS zu Baseline									
0	286	16 (5,6)	NE [NE; NE]	272	6 (2,2)	NE [NE; NE]	2,47	[1,02; 6,88]	0,0461*
1	112	9 (8,0)	NE [NE; NE]	124	4 (3,2)	NE [NE; NE]	2,30	[0,75; 8,51]	0,1489
Interaktion p-Wert									0,9277
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	17 (8,7)	NE [NE; NE]	199	5 (2,5)	NE [NE; NE]	3,39	[1,34; 10,32]	0,0087*
Über medianem PSA-Baselinewert	200	8 (4,0)	NE [NE; NE]	196	5 (2,6)	NE [NE; NE]	1,46	[0,49; 4,84]	0,4998
Interaktion p-Wert									0,2716

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabc 05DEC2022:09:12 khcs324

Table 3.5.29 PROpel: Summary of subgroup analysis of time to UE PT: Leukozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	20 (7,1)	NE [NE; NE]	274	7 (2,6)	NE [NE; NE]	2,68	[1,18; 6,82]	0,0171*
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	3 (4,5)	NE [NE; NE]	72	3 (4,2)	NE [NE; NE]	0,96	[0,18; 5,19]	0,9605
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2723
Schmerzen zu baseline									
Symptomatisch	103	7 (6,8)	NE [NE; NE]	80	5 (6,3)	NE [NE; NE]	1,06	[0,34; 3,59]	0,9186
Asymptomatisch/mild symptomatisch	266	17 (6,4)	NE [NE; NE]	294	5 (1,7)	NE [NE; NE]	3,46	[1,37; 10,55]	0,0076*
Interaktion p-Wert									0,1279

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabc 05DEC2022:09:12 khcs324

Table 3.5.30 PROpel: Summary of subgroup analysis of time to UE PT: Lymphozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	20 (9,4)	NE [NE; NE]	226	9 (4,0)	NE [NE; NE]	2,35	[1,10; 5,44]	0,0263*
Viszeral	66	6 (9,1)	NE [NE; NE]	72	3 (4,2)	NE [NE; NE]	2,08	[0,55; 9,87]	0,2849
andere	119	6 (5,0)	NE [NE; NE]	98	4 (4,1)	NE [NE; NE]	1,18	[0,34; 4,60]	0,8005
Interaktion p-Wert									0,6648
Docetaxel-Behandlung des mHSPC									
Ja	90	3 (3,3)	NE [NE; NE]	90	4 (4,4)	NE [NE; NE]	0,72	[0,14; 3,28]	0,6708
Nein	308	29 (9,4)	NE [NE; NE]	306	12 (3,9)	NE [NE; NE]	2,36	[1,24; 4,81]	0,0086*
Interaktion p-Wert									0,1556
Alter bei Randomisierung									
<65 Jahre	130	9 (6,9)	NE [NE; NE]	97	5 (5,2)	NE [NE; NE]	1,26	[0,43; 4,09]	0,6797
>=65 Jahre	268	23 (8,6)	NE [NE; NE]	299	11 (3,7)	NE [NE; NE]	2,34	[1,17; 4,99]	0,0162*
Interaktion p-Wert									0,3586
Region									
Asien	91	8 (8,8)	NE [NE; NE]	104	5 (4,8)	NE [NE; NE]	1,69	[0,56; 5,59]	0,3519
Europa	177	16 (9,0)	NE [NE; NE]	171	9 (5,3)	NE [NE; NE]	1,70	[0,77; 4,02]	0,1929
Nord- und Suedamerika	130	8 (6,2)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	3,76	[0,94; 24,90]	0,0617
Interaktion p-Wert									0,6232
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	7 (7,1)	NE [NE; NE]	100	5 (5,0)	NE [NE; NE]	1,32	[0,42; 4,45]	0,6361
Nicht-HRRm	268	21 (7,8)	NE [NE; NE]	267	11 (4,1)	NE [NE; NE]	1,89	[0,93; 4,07]	0,0791

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabd 05DEC2022:09:12 khcs324

Table 3.5.30 PROpel: Summary of subgroup analysis of time to UE PT: Lymphozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	4 (12,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6039
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	4 (7,1)	NE [NE; NE]	0,82	[0,19; 3,46]	0,7766
Nicht-HRRm	207	21 (10,1)	NE [NE; NE]	210	9 (4,3)	NE [NE; NE]	2,43	[1,15; 5,59]	0,0198*
Unbekannt	129	7 (5,4)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	2,23	[0,62; 10,34]	0,2258
Interaktion p-Wert									0,4038
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	2 (6,9)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	0,62	[0,07; 5,16]	0,6326
Nicht-HRRm	330	25 (7,6)	NE [NE; NE]	327	12 (3,7)	NE [NE; NE]	2,05	[1,05; 4,22]	0,0350*
Unbekannt	39	5 (12,8)	NE [NE; NE]	47	2 (4,3)	NE [NE; NE]	2,97	[0,64; 20,72]	0,1689
Interaktion p-Wert									0,4638
ECOG-PS zu Baseline									
0	286	22 (7,7)	NE [NE; NE]	272	10 (3,7)	NE [NE; NE]	2,06	[1,001; 4,55]	0,0496*
1	112	10 (8,9)	NE [NE; NE]	124	6 (4,8)	NE [NE; NE]	1,81	[0,67; 5,32]	0,2434
Interaktion p-Wert									0,8392
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	16 (8,2)	NE [NE; NE]	199	3 (1,5)	NE [NE; NE]	5,37	[1,79; 23,09]	0,0017*
Über medianem PSA-Baselinewert	200	16 (8,0)	NE [NE; NE]	196	13 (6,6)	NE [NE; NE]	1,16	[0,56; 2,46]	0,6828
Interaktion p-Wert									0,0244*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabd 05DEC2022:09:12 khcs324

Table 3.5.30 PROpel: Summary of subgroup analysis of time to UE PT: Lymphozytenzahl erniedrigt
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	20 (7,1)	NE [NE; NE]	274	10 (3,6)	NE [NE; NE]	1,92	[0,92; 4,27]	0,0844
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	9 (13,6)	NE [NE; NE]	72	5 (6,9)	NE [NE; NE]	1,87	[0,64; 6,08]	0,2527
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9700
Schmerzen zu baseline									
Symptomatisch	103	6 (5,8)	NE [NE; NE]	80	6 (7,5)	NE [NE; NE]	0,76	[0,24; 2,44]	0,6415
Asymptomatisch/mild symptomatisch	266	26 (9,8)	NE [NE; NE]	294	9 (3,1)	NE [NE; NE]	3,10	[1,51; 7,01]	0,0017*
Interaktion p-Wert									0,0448*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabd 05DEC2022:09:12 khcs324

Table 3.5.31 PROpel: Summary of subgroup analysis of time to SUE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	80 (37,6)	31,9 [25,5; NE]	226	68 (30,1)	NE [NE; NE]	1,25	[0,91; 1,74]	0,1695
Viszeral	66	23 (34,8)	32,5 [14,8; NE]	72	19 (26,4)	35,0 [23,8; NE]	1,17	[0,64; 2,16]	0,6193
andere	119	51 (42,9)	26,3 [22,1; NE]	98	30 (30,6)	NE [NE; NE]	1,31	[0,84; 2,08]	0,2330
Interaktion p-Wert									0,9543
Docetaxel-Behandlung des mHSPC									
Ja	90	32 (35,6)	31,7 [22,4; NE]	90	26 (28,9)	30,6 [21,0; NE]	1,25	[0,75; 2,11]	0,3989
Nein	308	122 (39,6)	31,9 [25,2; NE]	306	91 (29,7)	35,0 [35,0; NE]	1,28	[0,98; 1,69]	0,0705
Interaktion p-Wert									0,9273
Alter bei Randomisierung									
<65 Jahre	130	32 (24,6)	NE [NE; NE]	97	23 (23,7)	NE [NE; NE]	0,91	[0,53; 1,57]	0,7189
>=65 Jahre	268	122 (45,5)	25,5 [21,4;31,7]	299	94 (31,4)	35,0 [27,2; NE]	1,51	[1,15; 1,97]	0,0027*
Interaktion p-Wert									0,1007
Region									
Asien	91	37 (40,7)	33,9 [22,1; NE]	104	29 (27,9)	NE [NE; NE]	1,26	[0,78; 2,07]	0,3505
Europa	177	71 (40,1)	25,2 [22,4;32,8]	171	46 (26,9)	35,0 [27,2; NE]	1,51	[1,05; 2,20]	0,0277*
Nord- und Suedamerika	130	46 (35,4)	32,5 [26,3; NE]	121	42 (34,7)	NE [NE; NE]	1,03	[0,68; 1,58]	0,8756
Interaktion p-Wert									0,4130
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	31 (31,6)	32,8 [23,7; NE]	100	33 (33,0)	NE [NE; NE]	0,79	[0,48; 1,30]	0,3518
Nicht-HRRm	268	115 (42,9)	26,3 [23,4;32,5]	267	76 (28,5)	35,0 [30,6; NE]	1,54	[1,16; 2,07]	0,0030*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.31 PROpel: Summary of subgroup analysis of time to SUE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	8 (25,0)	32,8 [32,8; NE]	29	8 (27,6)	NE [NE; NE]	0,93	[0,34; 2,52]	0,8817
Interaktion p-Wert									0,0577
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	21 (33,9)	32,8 [22,5; NE]	56	18 (32,1)	NE [NE; NE]	0,85	[0,45; 1,62]	0,6187
Nicht-HRRm	207	90 (43,5)	26,0 [21,4;32,8]	210	61 (29,0)	NE [NE; NE]	1,62	[1,17; 2,24]	0,0035*
Unbekannt	129	43 (33,3)	NE [NE; NE]	130	38 (29,2)	NE [NE; NE]	1,04	[0,67; 1,61]	0,8726
Interaktion p-Wert									0,1081
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	9 (31,0)	NE [NE; NE]	22	9 (40,9)	20,2 [7,8; NE]	0,49	[0,19; 1,26]	0,1361
Nicht-HRRm	330	130 (39,4)	31,7 [24,0; NE]	327	95 (29,1)	NE [NE; NE]	1,36	[1,05; 1,78]	0,0214*
Unbekannt	39	15 (38,5)	32,5 [24,7; NE]	47	13 (27,7)	NE [NE; NE]	1,35	[0,64; 2,88]	0,4264
Interaktion p-Wert									0,1224
ECOG-PS zu Baseline									
0	286	106 (37,1)	32,5 [26,2; NE]	272	83 (30,5)	35,0 [30,6; NE]	1,20	[0,90; 1,61]	0,2061
1	112	48 (42,9)	26,3 [22,1;32,8]	124	34 (27,4)	NE [NE; NE]	1,48	[0,95; 2,31]	0,0809
Interaktion p-Wert									0,4462
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	72 (36,7)	32,8 [29,6; NE]	199	55 (27,6)	NE [NE; NE]	1,29	[0,91; 1,83]	0,1579
Über medianem PSA-Baselinewert	200	81 (40,5)	24,7 [21,7; NE]	196	61 (31,1)	NE [NE; NE]	1,28	[0,92; 1,79]	0,1492
Interaktion p-Wert									0,9730

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.31 PROpel: Summary of subgroup analysis of time to SUE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	110 (39,1)	31,7 [24,5; NE]	274	83 (30,3)	35,0 [28,1; NE]	1,28	[0,96; 1,71]	0,0882
Afroamerikanisch	14	7 (50,0)	22,2 [10,6; NE]	11	3 (27,3)	NE [NE; NE]	1,91	[0,53; 8,84]	0,3329
Asiatisch	66	23 (34,8)	NE [NE; NE]	72	22 (30,6)	NE [NE; NE]	0,97	[0,54; 1,74]	0,9086
Andere	15	4 (26,7)	NE [NE; NE]	9	1 (11,1)	NE [NE; NE]	3,48	[0,51; 68,03]	0,2158
Interaktion p-Wert									0,5403
Schmerzen zu baseline									
Symptomatisch	103	43 (41,7)	26,5 [18,7; NE]	80	24 (30,0)	26,1 [16,3; NE]	1,35	[0,82; 2,25]	0,2383
Asymptomatisch/mild symptomatisch	266	100 (37,6)	32,5 [26,0; NE]	294	82 (27,9)	NE [NE; NE]	1,28	[0,96; 1,72]	0,0958
Interaktion p-Wert									0,8668

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.32 PROpel: Summary of subgroup analysis of time to SUE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	9 (4,2)	NE [NE; NE]	226	5 (2,2)	NE [NE; NE]	1,80	[0,62; 5,85]	0,2834
Viszeral	66	4 (6,1)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	8 (6,7)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	1,92	[0,56; 8,80]	0,3140
Interaktion p-Wert									0,9379
Docetaxel-Behandlung des mHSPC									
Ja	90	6 (6,7)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	5,69	[0,97;107,50]	0,0544
Nein	308	15 (4,9)	NE [NE; NE]	306	7 (2,3)	NE [NE; NE]	1,96	[0,83; 5,14]	0,1283
Interaktion p-Wert									0,3260
Alter bei Randomisierung									
<65 Jahre	130	3 (2,3)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	18 (6,7)	NE [NE; NE]	299	8 (2,7)	NE [NE; NE]	2,42	[1,09; 5,91]	0,0298*
Interaktion p-Wert									NC
Region									
Asien	91	2 (2,2)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	1,85	[0,18; 39,92]	0,6050
Europa	177	13 (7,3)	NE [NE; NE]	171	4 (2,3)	NE [NE; NE]	2,97	[1,05; 10,55]	0,0396*
Nord- und Suedamerika	130	6 (4,6)	NE [NE; NE]	121	3 (2,5)	NE [NE; NE]	1,84	[0,49; 8,72]	0,3761
Interaktion p-Wert									0,8503
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	4 (4,1)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	3,47	[0,51; 67,79]	0,2176
Nicht-HRRm	268	15 (5,6)	NE [NE; NE]	267	6 (2,2)	NE [NE; NE]	2,36	[0,96; 6,63]	0,0616

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.32 PROpel: Summary of subgroup analysis of time to SUE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	2 (6,3)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	1,83	[0,17; 39,27]	0,6138
Interaktion p-Wert									0,9214
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	2 (3,2)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	14 (6,8)	NE [NE; NE]	210	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	5 (3,9)	NE [NE; NE]	130	8 (6,2)	NE [NE; NE]	0,54	[0,16; 1,62]	0,2702
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	2 (6,9)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	1,02	[0,10; 21,99]	0,9869
Nicht-HRRm	330	15 (4,5)	NE [NE; NE]	327	6 (1,8)	NE [NE; NE]	2,35	[0,96; 6,60]	0,0629
Unbekannt	39	4 (10,3)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	4,47	[0,66; 87,43]	0,1317
Interaktion p-Wert									0,6762
ECOG-PS zu Baseline									
0	286	15 (5,2)	NE [NE; NE]	272	5 (1,8)	NE [NE; NE]	2,70	[1,05; 8,32]	0,0393*
1	112	6 (5,4)	NE [NE; NE]	124	3 (2,4)	NE [NE; NE]	1,97	[0,52; 9,33]	0,3259
Interaktion p-Wert									0,7170
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	8 (4,1)	NE [NE; NE]	199	3 (1,5)	NE [NE; NE]	2,55	[0,74; 11,65]	0,1433
Über medianem PSA-Baselinewert	200	13 (6,5)	NE [NE; NE]	196	5 (2,6)	NE [NE; NE]	2,30	[0,86; 7,16]	0,0974
Interaktion p-Wert									0,9017

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.32 PROpel: Summary of subgroup analysis of time to SUE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	16 (5,7)	NE [NE; NE]	274	7 (2,6)	NE [NE; NE]	2,02	[0,86; 5,27]	0,1072
Afroamerikanisch	14	2 (14,3)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	1,69	[0,16; 36,31]	0,6625
Asiatisch	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8901
Schmerzen zu baseline									
Symptomatisch	103	9 (8,7)	NE [NE; NE]	80	2 (2,5)	NE [NE; NE]	3,34	[0,86; 21,91]	0,0848
Asymptomatisch/mild symptomatisch	266	11 (4,1)	NE [NE; NE]	294	5 (1,7)	NE [NE; NE]	2,16	[0,78; 6,86]	0,1390
Interaktion p-Wert									0,6407

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.33 PROpel: Summary of subgroup analysis of time to SUE PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	7 (3,3)	NE [NE; NE]	226	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	6 (5,0)	NE [NE; NE]	98	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	3 (3,3)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	11 (3,6)	NE [NE; NE]	306	3 (1,0)	NE [NE; NE]	3,43	[1,07; 15,16]	0,0374*
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	2 (1,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	12 (4,5)	NE [NE; NE]	299	3 (1,0)	NE [NE; NE]	4,32	[1,37; 18,96]	0,0109*
Interaktion p-Wert									NC
Region									
Asien	91	2 (2,2)	NE [NE; NE]	104	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Europa	177	10 (5,6)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	2 (1,5)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	3 (3,1)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	11 (4,1)	NE [NE; NE]	267	3 (1,1)	NE [NE; NE]	3,49	[1,09; 15,42]	0,0346*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.33 PROpel: Summary of subgroup analysis of time to SUE PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	2 (3,2)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	8 (3,9)	NE [NE; NE]	210	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	4 (3,1)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	2 (6,9)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	10 (3,0)	NE [NE; NE]	327	2 (0,6)	NE [NE; NE]	4,68	[1,23; 30,46]	0,0213*
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	2,32	[0,22; 49,89]	0,4778
Interaktion p-Wert									0,6343
ECOG-PS zu Baseline									
0	286	12 (4,2)	NE [NE; NE]	272	2 (0,7)	NE [NE; NE]	5,46	[1,49; 35,06]	0,0081*
1	112	2 (1,8)	NE [NE; NE]	124	1 (0,8)	NE [NE; NE]	1,96	[0,19; 42,24]	0,5714
Interaktion p-Wert									0,4920
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	5 (2,6)	NE [NE; NE]	199	1 (0,5)	NE [NE; NE]	4,76	[0,77; 91,17]	0,0993
Über medianem PSA-Baselinewert	200	9 (4,5)	NE [NE; NE]	196	2 (1,0)	NE [NE; NE]	4,06	[1,04; 26,61]	0,0426*
Interaktion p-Wert									0,9046

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.33 PROpel: Summary of subgroup analysis of time to SUE PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	11 (3,9)	NE [NE; NE]	274	2 (0,7)	NE [NE; NE]	4,95	[1,33; 32,01]	0,0148*
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	0,77	[0,03; 19,44]	0,8530
Asiatisch	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2595
Schmerzen zu baseline									
Symptomatisch	103	4 (3,9)	NE [NE; NE]	80	2 (2,5)	NE [NE; NE]	1,49	[0,29; 10,74]	0,6400
Asymptomatisch/mild symptomatisch	266	9 (3,4)	NE [NE; NE]	294	1 (0,3)	NE [NE; NE]	8,96	[1,68;165,27]	0,0069*
Interaktion p-Wert									0,1727

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.34 PROpel: Summary of subgroup analysis of time to SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	18 (8,5)	NE [NE; NE]	226	2 (0,9)	NE [NE; NE]	9,76	[2,82; 61,41]	<0,0001*
Viszeral	66	4 (6,1)	NE [NE; NE]	72	3 (4,2)	NE [NE; NE]	1,38	[0,30; 6,98]	0,6749
andere	119	8 (6,7)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	6,54	[1,20;121,33]	0,0272*
Interaktion p-Wert									0,1681
Docetaxel-Behandlung des mHSPC									
Ja	90	5 (5,6)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	5,00	[0,81; 95,79]	0,0879
Nein	308	25 (8,1)	NE [NE; NE]	306	5 (1,6)	NE [NE; NE]	4,99	[2,08; 14,78]	0,0001*
Interaktion p-Wert									0,9983
Alter bei Randomisierung									
<65 Jahre	130	4 (3,1)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	26 (9,7)	NE [NE; NE]	299	6 (2,0)	NE [NE; NE]	4,98	[2,19; 13,36]	<0,0001*
Interaktion p-Wert									NC
Region									
Asien	91	6 (6,6)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	10 (5,6)	NE [NE; NE]	171	2 (1,2)	NE [NE; NE]	4,89	[1,29; 31,84]	0,0174*
Nord- und Suedamerika	130	14 (10,8)	NE [NE; NE]	121	4 (3,3)	NE [NE; NE]	3,40	[1,22; 11,98]	0,0181*
Interaktion p-Wert									0,7004
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	6 (6,1)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	5,87	[1,002; 110,88]	0,0497*
Nicht-HRRm	268	22 (8,2)	NE [NE; NE]	267	5 (1,9)	NE [NE; NE]	4,46	[1,83; 13,31]	0,0006*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.34 PROpel: Summary of subgroup analysis of time to SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	2 (6,3)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8127
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	18 (8,7)	NE [NE; NE]	210	3 (1,4)	NE [NE; NE]	6,31	[2,14; 26,96]	0,0004*
Unbekannt	129	8 (6,2)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	2,61	[0,75; 11,90]	0,1341
Interaktion p-Wert									0,3391
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	26 (7,9)	NE [NE; NE]	327	6 (1,8)	NE [NE; NE]	4,36	[1,92; 11,72]	0,0002*
Unbekannt	39	4 (10,3)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	22 (7,7)	NE [NE; NE]	272	6 (2,2)	NE [NE; NE]	3,50	[1,51; 9,52]	0,0027*
1	112	8 (7,1)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	13 (6,6)	NE [NE; NE]	199	3 (1,5)	NE [NE; NE]	4,40	[1,42; 19,18]	0,0087*
Über medianem PSA-Baselinewert	200	17 (8,5)	NE [NE; NE]	196	3 (1,5)	NE [NE; NE]	5,60	[1,88; 23,97]	0,0011*
Interaktion p-Wert									0,7880

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabh 05DEC2022:09:12 khcs324

Table 3.5.34 PROpel: Summary of subgroup analysis of time to SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	25 (8,9)	NE [NE; NE]	274	4 (1,5)	NE [NE; NE]	6,22	[2,41; 21,11]	<0,0001*
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	4 (6,1)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	12 (11,7)	NE [NE; NE]	80	2 (2,5)	NE [NE; NE]	4,74	[1,29; 30,48]	0,0163*
Asymptomatisch/mild symptomatisch	266	15 (5,6)	NE [NE; NE]	294	4 (1,4)	NE [NE; NE]	4,07	[1,48; 14,26]	0,0055*
Interaktion p-Wert									0,8699

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.35 PROpel: Summary of subgroup analysis of time to SUE PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	15 (7,0)	NE [NE; NE]	226	1 (0,4)	NE [NE; NE]	16,43	[3,33;296,89]	<0,0001*
Viszeral	66	4 (6,1)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	2,13	[0,42; 15,35]	0,3681
andere	119	4 (3,4)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1158
Docetaxel-Behandlung des mHSPC									
Ja	90	4 (4,4)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	19 (6,2)	NE [NE; NE]	306	3 (1,0)	NE [NE; NE]	6,34	[2,16; 26,98]	0,0003*
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	2 (1,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	21 (7,8)	NE [NE; NE]	299	3 (1,0)	NE [NE; NE]	8,03	[2,77; 34,01]	<0,0001*
Interaktion p-Wert									NC
Region									
Asien	91	4 (4,4)	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	7 (4,0)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	12 (9,2)	NE [NE; NE]	121	3 (2,5)	NE [NE; NE]	3,90	[1,24; 17,13]	0,0183*
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	4 (4,1)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	3,97	[0,59; 77,53]	0,1680
Nicht-HRRm	268	17 (6,3)	NE [NE; NE]	267	2 (0,7)	NE [NE; NE]	8,65	[2,48; 54,56]	0,0002*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.35 PROpel: Summary of subgroup analysis of time to SUE PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	2 (6,3)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5751
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	3 (4,8)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	13 (6,3)	NE [NE; NE]	210	1 (0,5)	NE [NE; NE]	13,67	[2,72;248,33]	0,0003*
Unbekannt	129	7 (5,4)	NE [NE; NE]	130	2 (1,5)	NE [NE; NE]	3,47	[0,84; 23,28]	0,0888
Interaktion p-Wert									0,2788
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	22 (6,7)	NE [NE; NE]	327	3 (0,9)	NE [NE; NE]	7,40	[2,57; 31,27]	<0,0001*
Unbekannt	39	1 (2,6)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	16 (5,6)	NE [NE; NE]	272	3 (1,1)	NE [NE; NE]	5,10	[1,70; 21,94]	0,0024*
1	112	7 (6,3)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	9 (4,6)	NE [NE; NE]	199	1 (0,5)	NE [NE; NE]	9,18	[1,73;169,30]	0,0061*
Über medianem PSA-Baselinewert	200	14 (7,0)	NE [NE; NE]	196	2 (1,0)	NE [NE; NE]	6,97	[1,95; 44,37]	0,0015*
Interaktion p-Wert									0,8296

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.35 PROpel: Summary of subgroup analysis of time to SUE PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	20 (7,1)	NE [NE; NE]	274	3 (1,1)	NE [NE; NE]	6,61	[2,27; 28,05]	0,0002*
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	10 (9,7)	NE [NE; NE]	80	2 (2,5)	NE [NE; NE]	4,02	[1,06; 26,16]	0,0400*
Asymptomatisch/mild symptomatisch	266	10 (3,8)	NE [NE; NE]	294	1 (0,3)	NE [NE; NE]	10,94	[2,09;200,67]	0,0022*
Interaktion p-Wert									0,4291

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabi 05DEC2022:09:12 khcs324

Table 3.5.36 PROpel: Summary of subgroup analysis of time to SUE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	8 (3,8)	NE [NE; NE]	226	6 (2,7)	NE [NE; NE]	1,32	[0,46; 4,00]	0,6085
Viszeral	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	10 (8,4)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	7,32	[1,40;134,33]	0,0144*
Interaktion p-Wert									0,1012
Docetaxel-Behandlung des mHSPC									
Ja	90	5 (5,6)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	2,32	[0,50; 16,21]	0,2912
Nein	308	14 (4,5)	NE [NE; NE]	306	5 (1,6)	NE [NE; NE]	2,53	[0,97; 7,82]	0,0594
Interaktion p-Wert									0,9318
Alter bei Randomisierung									
<65 Jahre	130	2 (1,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	17 (6,3)	NE [NE; NE]	299	7 (2,3)	NE [NE; NE]	2,57	[1,11; 6,65]	0,0274*
Interaktion p-Wert									NC
Region									
Asien	91	6 (6,6)	NE [NE; NE]	104	3 (2,9)	NE [NE; NE]	1,84	[0,48; 8,72]	0,3791
Europa	177	7 (4,0)	NE [NE; NE]	171	3 (1,8)	NE [NE; NE]	2,09	[0,58; 9,68]	0,2679
Nord- und Suedamerika	130	6 (4,6)	NE [NE; NE]	121	1 (0,8)	NE [NE; NE]	5,53	[0,94;104,36]	0,0591
Interaktion p-Wert									0,6388
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	4 (4,1)	NE [NE; NE]	100	2 (2,0)	NE [NE; NE]	1,67	[0,33; 12,07]	0,5446

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.36 PROpel: Summary of subgroup analysis of time to SUE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Nicht-HRRm	268	14 (5,2)	NE [NE; NE]	267	5 (1,9)	NE [NE; NE]	2,62	[0,9999; 8,10]	0,0500
Unbekannt	32	1 (3,1)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6616
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	3 (5,4)	NE [NE; NE]	0,95	[0,21; 4,83]	0,9456
Nicht-HRRm	207	9 (4,3)	NE [NE; NE]	210	3 (1,4)	NE [NE; NE]	2,99	[0,89; 13,48]	0,0773
Unbekannt	129	6 (4,7)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	5,30	[0,90;100,17]	0,0666
Interaktion p-Wert									0,3455
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	18 (5,5)	NE [NE; NE]	327	5 (1,5)	NE [NE; NE]	3,41	[1,36; 10,33]	0,0077*
Unbekannt	39	1 (2,6)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	14 (4,9)	NE [NE; NE]	272	7 (2,6)	NE [NE; NE]	1,78	[0,74; 4,69]	0,2028
1	112	5 (4,5)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	7 (3,6)	NE [NE; NE]	199	5 (2,5)	NE [NE; NE]	1,32	[0,42; 4,46]	0,6330

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.36 PROpel: Summary of subgroup analysis of time to SUE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Über medianem PSA-Baselinewert	200	12 (6,0)	NE [NE; NE]	196	2 (1,0)	NE [NE; NE]	5,24	[1,43; 33,70]	0,0101*
Interaktion p-Wert									0,1345
Abstammung									
Kaukasisch	281	13 (4,6)	NE [NE; NE]	274	2 (0,7)	NE [NE; NE]	5,84	[1,61; 37,37]	0,0051*
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	3 (4,5)	NE [NE; NE]	72	3 (4,2)	NE [NE; NE]	0,91	[0,17; 4,94]	0,9111
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0883
Schmerzen zu baseline									
Symptomatisch	103	6 (5,8)	NE [NE; NE]	80	1 (1,3)	NE [NE; NE]	4,31	[0,73; 81,47]	0,1142
Asymptomatisch/mild symptomatisch	266	12 (4,5)	NE [NE; NE]	294	5 (1,7)	NE [NE; NE]	2,35	[0,87; 7,40]	0,0928
Interaktion p-Wert									0,6001

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.37 PROpel: Summary of subgroup analysis of time to Abbruch wegen UE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	35 (16,4)	NE [NE; NE]	226	23 (10,2)	NE [NE; NE]	1,59	[0,95; 2,73]	0,0793
Viszeral	66	11 (16,7)	NE [NE; NE]	72	6 (8,3)	NE [NE; NE]	1,83	[0,69; 5,30]	0,2254
andere	119	19 (16,0)	NE [NE; NE]	98	12 (12,2)	NE [NE; NE]	1,22	[0,60; 2,58]	0,5895
Interaktion p-Wert									0,7734
Docetaxel-Behandlung des mHSPC									
Ja	90	5 (5,6)	NE [NE; NE]	90	6 (6,7)	NE [NE; NE]	0,80	[0,23; 2,65]	0,7105
Nein	308	60 (19,5)	NE [NE; NE]	306	35 (11,4)	NE [NE; NE]	1,65	[1,09; 2,52]	0,0171*
Interaktion p-Wert									0,2591
Alter bei Randomisierung									
<65 Jahre	130	8 (6,2)	NE [NE; NE]	97	6 (6,2)	NE [NE; NE]	0,88	[0,31; 2,68]	0,8177
>=65 Jahre	268	57 (21,3)	NE [NE; NE]	299	35 (11,7)	NE [NE; NE]	1,83	[1,21; 2,81]	0,0043*
Interaktion p-Wert									0,2191
Region									
Asien	91	18 (19,8)	NE [NE; NE]	104	8 (7,7)	NE [NE; NE]	2,32	[1,04; 5,66]	0,0390*
Europa	177	27 (15,3)	NE [NE; NE]	171	15 (8,8)	NE [NE; NE]	1,68	[0,91; 3,24]	0,1007
Nord- und Suedamerika	130	20 (15,4)	NE [NE; NE]	121	18 (14,9)	NE [NE; NE]	1,05	[0,55; 2,00]	0,8850
Interaktion p-Wert									0,2965
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	15 (15,3)	NE [NE; NE]	100	11 (11,0)	NE [NE; NE]	1,25	[0,58; 2,80]	0,5665
Nicht-HRRm	268	44 (16,4)	NE [NE; NE]	267	27 (10,1)	NE [NE; NE]	1,59	[0,99; 2,59]	0,0553

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.37 PROpel: Summary of subgroup analysis of time to Abbruch wegen UE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	6 (18,8)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	1,92	[0,51; 9,11]	0,3418
Interaktion p-Wert									0,8286
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	10 (16,1)	NE [NE; NE]	56	6 (10,7)	NE [NE; NE]	1,31	[0,49; 3,85]	0,6004
Nicht-HRRm	207	41 (19,8)	NE [NE; NE]	210	19 (9,0)	NE [NE; NE]	2,28	[1,34; 4,01]	0,0021*
Unbekannt	129	14 (10,9)	NE [NE; NE]	130	16 (12,3)	NE [NE; NE]	0,80	[0,38; 1,64]	0,5375
Interaktion p-Wert									0,0681
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	4 (13,8)	NE [NE; NE]	22	5 (22,7)	NE [NE; NE]	0,45	[0,11; 1,69]	0,2300
Nicht-HRRm	330	52 (15,8)	NE [NE; NE]	327	32 (9,8)	NE [NE; NE]	1,58	[1,02; 2,47]	0,0401*
Unbekannt	39	9 (23,1)	NE [NE; NE]	47	4 (8,5)	NE [NE; NE]	2,71	[0,88; 10,01]	0,0822
Interaktion p-Wert									0,1172
ECOG-PS zu Baseline									
0	286	44 (15,4)	NE [NE; NE]	272	29 (10,7)	NE [NE; NE]	1,41	[0,89; 2,28]	0,1432
1	112	21 (18,8)	NE [NE; NE]	124	12 (9,7)	NE [NE; NE]	1,82	[0,91; 3,81]	0,0932
Interaktion p-Wert									0,5642
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	37 (18,9)	NE [NE; NE]	199	16 (8,0)	NE [NE; NE]	2,31	[1,31; 4,27]	0,0034*
Über medianem PSA-Baselinewert	200	28 (14,0)	NE [NE; NE]	196	25 (12,8)	NE [NE; NE]	1,03	[0,60; 1,79]	0,9018
Interaktion p-Wert									0,0456*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.37 PROpel: Summary of subgroup analysis of time to Abbruch wegen UE
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	46 (16,4)	NE [NE; NE]	274	33 (12,0)	NE [NE; NE]	1,31	[0,84; 2,07]	0,2284
Afroamerikanisch	14	1 (7,1)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	13 (19,7)	NE [NE; NE]	72	5 (6,9)	NE [NE; NE]	2,61	[0,98; 8,14]	0,0539
Andere	15	0	NE [NE; NE]	9	1 (11,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2173
Schmerzen zu baseline									
Symptomatisch	103	17 (16,5)	NE [NE; NE]	80	8 (10,0)	NE [NE; NE]	1,63	[0,73; 4,00]	0,2407
Asymptomatisch/mild symptomatisch	266	46 (17,3)	NE [NE; NE]	294	30 (10,2)	NE [NE; NE]	1,60	[1,01; 2,55]	0,0440*
Interaktion p-Wert									0,9621

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabk 05DEC2022:09:12 khcs324

Table 3.5.38 PROpel: Summary of subgroup analysis of time to Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	110 (51,6)	23,4 [17,1;26,9]	226	105 (46,5)	22,1 [18,0; NE]	1,10	[0,84; 1,44]	0,4872
Viszeral	66	36 (54,5)	14,8 [8,8;21,7]	72	17 (23,6)	NE [NE; NE]	2,42	[1,38; 4,42]	0,0018*
andere	119	64 (53,8)	14,1 [10,9;26,7]	98	38 (38,8)	30,5 [12,9; NE]	1,43	[0,96; 2,15]	0,0773
Interaktion p-Wert									0,0397*
Docetaxel-Behandlung des mHSPC									
Ja	90	39 (43,3)	30,2 [19,8;32,8]	90	41 (45,6)	21,0 [11,5; NE]	0,94	[0,61; 1,46]	0,7900
Nein	308	171 (55,5)	17,1 [13,3;23,7]	306	119 (38,9)	NE [NE; NE]	1,45	[1,15; 1,84]	0,0017*
Interaktion p-Wert									0,0886
Alter bei Randomisierung									
<65 Jahre	130	55 (42,3)	30,2 [24,5; NE]	97	33 (34,0)	NE [NE; NE]	1,18	[0,77; 1,83]	0,4512
>=65 Jahre	268	155 (57,8)	15,9 [11,4;20,3]	299	127 (42,5)	23,4 [18,5; NE]	1,44	[1,14; 1,82]	0,0024*
Interaktion p-Wert									0,4340
Region									
Asien	91	51 (56,0)	17,1 [11,0;31,9]	104	48 (46,2)	20,2 [10,8; NE]	1,05	[0,70; 1,56]	0,8214
Europa	177	88 (49,7)	22,1 [14,8;25,2]	171	62 (36,3)	30,5 [21,9; NE]	1,41	[1,02; 1,95]	0,0387*
Nord- und Suedamerika	130	71 (54,6)	16,6 [11,7;26,5]	121	50 (41,3)	27,8 [18,0; NE]	1,48	[1,03; 2,14]	0,0324*
Interaktion p-Wert									0,3969
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	46 (46,9)	23,7 [13,3; NE]	100	41 (41,0)	26,1 [11,1; NE]	1,00	[0,66; 1,53]	0,9932
Nicht-HRRm	268	151 (56,3)	17,5 [12,8;24,0]	267	109 (40,8)	27,8 [21,0; NE]	1,46	[1,14; 1,87]	0,0025*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabl 05DEC2022:09:12 khcs324

Table 3.5.38 PROpel: Summary of subgroup analysis of time to Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	13 (40,6)	31,2 [10,6; NE]	29	10 (34,5)	NE [NE; NE]	1,26	[0,55; 2,95]	0,5838
Interaktion p-Wert									0,3192
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	27 (43,5)	32,8 [14,7; NE]	56	26 (46,4)	22,0 [11,1; NE]	0,73	[0,42; 1,25]	0,2516
Nicht-HRRm	207	118 (57,0)	14,1 [10,6;19,3]	210	82 (39,0)	NE [NE; NE]	1,67	[1,26; 2,22]	0,0003*
Unbekannt	129	65 (50,4)	25,5 [16,6;27,7]	130	52 (40,0)	27,8 [21,9; NE]	1,20	[0,83; 1,73]	0,3278
Interaktion p-Wert									0,0232*
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	11 (37,9)	NE [NE; NE]	22	11 (50,0)	20,2 [4,4; NE]	0,54	[0,23; 1,26]	0,1519
Nicht-HRRm	330	178 (53,9)	18,4 [13,9;24,0]	327	128 (39,1)	NE [NE; NE]	1,44	[1,15; 1,81]	0,0016*
Unbekannt	39	21 (53,8)	24,7 [8,1; NE]	47	21 (44,7)	30,5 [11,1; NE]	1,17	[0,64; 2,16]	0,6026
Interaktion p-Wert									0,0845
ECOG-PS zu Baseline									
0	286	149 (52,1)	19,3 [13,8;26,3]	272	109 (40,1)	30,5 [21,9; NE]	1,35	[1,06; 1,74]	0,0159*
1	112	61 (54,5)	19,8 [11,1;26,3]	124	51 (41,1)	22,0 [12,9; NE]	1,26	[0,87; 1,83]	0,2287
Interaktion p-Wert									0,7444
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	106 (54,1)	23,4 [14,1;26,9]	199	74 (37,2)	NE [NE; NE]	1,49	[1,11; 2,02]	0,0075*
Über medianem PSA-Baselinewert	200	103 (51,5)	16,6 [12,8;22,4]	196	85 (43,4)	22,1 [14,2; NE]	1,18	[0,89; 1,58]	0,2508
Interaktion p-Wert									0,2676

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.38 PROpel: Summary of subgroup analysis of time to Schwere UE mit max. CTCAE Grad>=3
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	144 (51,2)	21,7 [14,7;26,5]	274	111 (40,5)	26,5 [20,2; NE]	1,28	[0,997; 1,64]	0,0530
Afroamerikanisch	14	12 (85,7)	8,1 [2,7;16,5]	11	4 (36,4)	NE [NE; NE]	3,12	[1,09; 11,18]	0,0340*
Asiatisch	66	36 (54,5)	17,1 [10,5;34,1]	72	35 (48,6)	16,7 [9,9; NE]	0,97	[0,61; 1,54]	0,8857
Andere	15	7 (46,7)	13,9 [3,7; NE]	9	1 (11,1)	NE [NE; NE]	6,63	[1,18;124,22]	0,0293*
Interaktion p-Wert									0,0574
Schmerzen zu baseline									
Symptomatisch	103	56 (54,4)	12,8 [8,1;23,7]	80	36 (45,0)	16,3 [10,8; NE]	1,16	[0,76; 1,77]	0,4977
Asymptomatisch/mild symptomatisch	266	137 (51,5)	22,4 [16,6;26,7]	294	115 (39,1)	NE [NE; NE]	1,29	[1,01; 1,66]	0,0429*
Interaktion p-Wert									0,6549

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.39 PROpel: Summary of subgroup analysis of time to Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	18 (8,5)	NE [NE; NE]	226	5 (2,2)	NE [NE; NE]	3,80	[1,52; 11,51]	0,0035*
Viszeral	66	6 (9,1)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	5,87	[1,004; 111,10]	0,0493*
andere	119	11 (9,2)	NE [NE; NE]	98	5 (5,1)	NE [NE; NE]	1,68	[0,61; 5,35]	0,3205
Interaktion p-Wert									0,4196
Docetaxel-Behandlung des mHSPC									
Ja	90	8 (8,9)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	3,94	[0,99; 26,12]	0,0524
Nein	308	27 (8,8)	NE [NE; NE]	306	9 (2,9)	NE [NE; NE]	2,87	[1,40; 6,47]	0,0033*
Interaktion p-Wert									0,7135
Alter bei Randomisierung									
<65 Jahre	130	8 (6,2)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	27 (10,1)	NE [NE; NE]	299	11 (3,7)	NE [NE; NE]	2,75	[1,40; 5,78]	0,0029*
Interaktion p-Wert									NC
Region									
Asien	91	3 (3,3)	NE [NE; NE]	104	3 (2,9)	NE [NE; NE]	0,98	[0,18; 5,30]	0,9793
Europa	177	18 (10,2)	NE [NE; NE]	171	4 (2,3)	NE [NE; NE]	4,23	[1,58; 14,64]	0,0030*
Nord- und Suedamerika	130	14 (10,8)	NE [NE; NE]	121	4 (3,3)	NE [NE; NE]	3,41	[1,22; 12,02]	0,0178*
Interaktion p-Wert									0,3247
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	6 (6,1)	NE [NE; NE]	100	2 (2,0)	NE [NE; NE]	2,73	[0,63; 18,66]	0,1875

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.39 PROpel: Summary of subgroup analysis of time to Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Nicht-HRRm	268	26 (9,7)	NE [NE; NE]	267	8 (3,0)	NE [NE; NE]	3,20	[1,52; 7,57]	0,0018*
Unbekannt	32	3 (9,4)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	2,80	[0,36; 56,60]	0,3392
Interaktion p-Wert									0,9816
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	23 (11,1)	NE [NE; NE]	210	4 (1,9)	NE [NE; NE]	6,04	[2,32; 20,61]	<0,0001*
Unbekannt	129	8 (6,2)	NE [NE; NE]	130	7 (5,4)	NE [NE; NE]	1,07	[0,38; 3,05]	0,8977
Interaktion p-Wert									0,0173*
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	3 (10,3)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	1,63	[0,21; 33,06]	0,6592
Nicht-HRRm	330	27 (8,2)	NE [NE; NE]	327	8 (2,4)	NE [NE; NE]	3,31	[1,58; 7,81]	0,0012*
Unbekannt	39	5 (12,8)	NE [NE; NE]	47	2 (4,3)	NE [NE; NE]	2,88	[0,62; 20,14]	0,1812
Interaktion p-Wert									0,8572
ECOG-PS zu Baseline									
0	286	28 (9,8)	NE [NE; NE]	272	5 (1,8)	NE [NE; NE]	5,26	[2,21; 15,48]	<0,0001*
1	112	7 (6,3)	NE [NE; NE]	124	6 (4,8)	NE [NE; NE]	1,20	[0,40; 3,73]	0,7429
Interaktion p-Wert									0,0435*
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	20 (10,2)	NE [NE; NE]	199	3 (1,5)	NE [NE; NE]	6,74	[2,31; 28,60]	0,0002*
Über medianem PSA-Baselinewert	200	15 (7,5)	NE [NE; NE]	196	8 (4,1)	NE [NE; NE]	1,72	[0,75; 4,28]	0,2057

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.39 PROpel: Summary of subgroup analysis of time to Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Interaktion p-Wert									0,0586
Abstammung									
Kaukasisch	281	25 (8,9)	NE [NE; NE]	274	7 (2,6)	NE [NE; NE]	3,33	[1,52; 8,36]	0,0020*
Afroamerikanisch	14	4 (28,6)	22,7 [16,5; NE]	11	2 (18,2)	NE [NE; NE]	1,77	[0,34; 12,77]	0,5008
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	1,89	[0,18; 40,60]	0,5940
Andere	15	2 (13,3)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7671
Schmerzen zu baseline									
Symptomatisch	103	10 (9,7)	NE [NE; NE]	80	4 (5,0)	NE [NE; NE]	1,89	[0,63; 6,89]	0,2642
Asymptomatisch/mild symptomatisch	266	22 (8,3)	NE [NE; NE]	294	6 (2,0)	NE [NE; NE]	3,78	[1,63; 10,26]	0,0014*
Interaktion p-Wert									0,3620

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.40 PROpel: Summary of subgroup analysis of time to Schwere UE nach PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	15 (7,0)	NE [NE; NE]	226	2 (0,9)	NE [NE; NE]	7,96	[2,24; 50,48]	0,0005*
Viszeral	66	4 (6,1)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	3,82	[0,56; 74,66]	0,1809
andere	119	9 (7,6)	NE [NE; NE]	98	4 (4,1)	NE [NE; NE]	1,76	[0,57; 6,50]	0,3327
Interaktion p-Wert									0,2694
Docetaxel-Behandlung des mHSPC									
Ja	90	5 (5,6)	NE [NE; NE]	90	1 (1,1)	NE [NE; NE]	4,88	[0,79; 93,41]	0,0937
Nein	308	23 (7,5)	NE [NE; NE]	306	6 (2,0)	NE [NE; NE]	3,70	[1,60; 10,01]	0,0015*
Interaktion p-Wert									0,8119
Alter bei Randomisierung									
<65 Jahre	130	7 (5,4)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	21 (7,8)	NE [NE; NE]	299	7 (2,3)	NE [NE; NE]	3,36	[1,50; 8,54]	0,0027*
Interaktion p-Wert									NC
Region									
Asien	91	3 (3,3)	NE [NE; NE]	104	3 (2,9)	NE [NE; NE]	1,01	[0,19; 5,46]	0,9912
Europa	177	15 (8,5)	NE [NE; NE]	171	1 (0,6)	NE [NE; NE]	14,05	[2,85;254,06]	0,0002*
Nord- und Suedamerika	130	10 (7,7)	NE [NE; NE]	121	3 (2,5)	NE [NE; NE]	3,23	[0,99; 14,39]	0,0527
Interaktion p-Wert									0,0866
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	6 (6,1)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	5,46	[0,93;103,07]	0,0613
Nicht-HRRm	268	22 (8,2)	NE [NE; NE]	267	6 (2,2)	NE [NE; NE]	3,65	[1,57; 9,90]	0,0019*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.40 PROpel: Summary of subgroup analysis of time to Schwere UE nach PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7230
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	17 (8,2)	NE [NE; NE]	210	4 (1,9)	NE [NE; NE]	4,48	[1,66; 15,57]	0,0022*
Unbekannt	129	7 (5,4)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	2,19	[0,61; 10,16]	0,2366
Interaktion p-Wert									0,4244
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	3 (10,3)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	22 (6,7)	NE [NE; NE]	327	5 (1,5)	NE [NE; NE]	4,32	[1,77; 12,90]	0,0008*
Unbekannt	39	3 (7,7)	NE [NE; NE]	47	2 (4,3)	NE [NE; NE]	1,75	[0,29; 13,32]	0,5341
Interaktion p-Wert									0,3957
ECOG-PS zu Baseline									
0	286	24 (8,4)	NE [NE; NE]	272	3 (1,1)	NE [NE; NE]	7,55	[2,64; 31,78]	<0,0001*
1	112	4 (3,6)	NE [NE; NE]	124	4 (3,2)	NE [NE; NE]	1,03	[0,24; 4,35]	0,9681
Interaktion p-Wert									0,0303*
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	16 (8,2)	NE [NE; NE]	199	2 (1,0)	NE [NE; NE]	8,07	[2,30; 51,05]	0,0004*
Über medianem PSA-Baselinewert	200	12 (6,0)	NE [NE; NE]	196	5 (2,6)	NE [NE; NE]	2,23	[0,83; 7,01]	0,1158
Interaktion p-Wert									0,1428

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.40 PROpel: Summary of subgroup analysis of time to Schwere UE nach PT: Lungenembolie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	20 (7,1)	NE [NE; NE]	274	3 (1,1)	NE [NE; NE]	6,28	[2,15; 26,65]	0,0003*
Afroamerikanisch	14	3 (21,4)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	1,26	[0,21; 9,56]	0,8010
Asiatisch	66	2 (3,0)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	1,92	[0,18; 41,28]	0,5840
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3118
Schmerzen zu baseline									
Symptomatisch	103	6 (5,8)	NE [NE; NE]	80	4 (5,0)	NE [NE; NE]	1,14	[0,32; 4,44]	0,8432
Asymptomatisch/mild symptomatisch	266	19 (7,1)	NE [NE; NE]	294	3 (1,0)	NE [NE; NE]	6,56	[2,23; 27,91]	0,0002*
Interaktion p-Wert									0,0488*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.41 PROpel: Summary of subgroup analysis of time to Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	38 (17,8)	NE [NE; NE]	226	10 (4,4)	NE [NE; NE]	4,18	[2,17; 8,88]	<0,0001*
Viszeral	66	9 (13,6)	NE [NE; NE]	72	6 (8,3)	NE [NE; NE]	1,56	[0,56; 4,66]	0,3930
andere	119	24 (20,2)	NE [NE; NE]	98	5 (5,1)	NE [NE; NE]	4,01	[1,66; 11,91]	0,0013*
Interaktion p-Wert									0,2867
Docetaxel-Behandlung des mHSPC									
Ja	90	18 (20,0)	NE [NE; NE]	90	4 (4,4)	NE [NE; NE]	4,73	[1,76; 16,36]	0,0013*
Nein	308	53 (17,2)	NE [NE; NE]	306	17 (5,6)	NE [NE; NE]	3,13	[1,85; 5,57]	<0,0001*
Interaktion p-Wert									0,4964
Alter bei Randomisierung									
<65 Jahre	130	16 (12,3)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	3,77	[1,26; 16,21]	0,0158*
>=65 Jahre	268	55 (20,5)	NE [NE; NE]	299	18 (6,0)	NE [NE; NE]	3,60	[2,16; 6,30]	<0,0001*
Interaktion p-Wert									0,9460
Region									
Asien	91	16 (17,6)	NE [NE; NE]	104	4 (3,8)	NE [NE; NE]	4,38	[1,61; 15,30]	0,0030*
Europa	177	30 (16,9)	NE [NE; NE]	171	9 (5,3)	NE [NE; NE]	3,32	[1,64; 7,42]	0,0006*
Nord- und Suedamerika	130	25 (19,2)	NE [NE; NE]	121	8 (6,6)	NE [NE; NE]	3,07	[1,45; 7,27]	0,0029*
Interaktion p-Wert									0,8680
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	13 (13,3)	NE [NE; NE]	100	4 (4,0)	NE [NE; NE]	3,21	[1,13; 11,39]	0,0270*
Nicht-HRRm	268	54 (20,1)	NE [NE; NE]	267	17 (6,4)	NE [NE; NE]	3,29	[1,95; 5,85]	<0,0001*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.41 PROpel: Summary of subgroup analysis of time to Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	4 (12,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9671
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	7 (11,3)	NE [NE; NE]	56	3 (5,4)	NE [NE; NE]	1,96	[0,54; 9,09]	0,3123
Nicht-HRRm	207	45 (21,7)	NE [NE; NE]	210	12 (5,7)	NE [NE; NE]	4,05	[2,22; 8,02]	<0,0001*
Unbekannt	129	19 (14,7)	NE [NE; NE]	130	6 (4,6)	NE [NE; NE]	3,18	[1,34; 8,72]	0,0075*
Interaktion p-Wert									0,6373
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	5 (17,2)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	3,33	[0,54; 63,88]	0,2154
Nicht-HRRm	330	61 (18,5)	NE [NE; NE]	327	19 (5,8)	NE [NE; NE]	3,28	[2,00; 5,64]	<0,0001*
Unbekannt	39	5 (12,8)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	6,11	[0,99;117,08]	0,0520
Interaktion p-Wert									0,8421
ECOG-PS zu Baseline									
0	286	46 (16,1)	NE [NE; NE]	272	12 (4,4)	NE [NE; NE]	3,72	[2,04; 7,36]	<0,0001*
1	112	25 (22,3)	NE [NE; NE]	124	9 (7,3)	NE [NE; NE]	3,16	[1,53; 7,17]	0,0015*
Interaktion p-Wert									0,7490
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	32 (16,3)	NE [NE; NE]	199	10 (5,0)	NE [NE; NE]	3,30	[1,68; 7,07]	0,0004*
Über medianem PSA-Baselinewert	200	39 (19,5)	NE [NE; NE]	196	11 (5,6)	NE [NE; NE]	3,57	[1,89; 7,32]	<0,0001*
Interaktion p-Wert									0,8737

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabo 05DEC2022:09:12 khcs324

Table 3.5.41 PROpel: Summary of subgroup analysis of time to Schwere UE nach SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	52 (18,5)	NE [NE; NE]	274	16 (5,8)	NE [NE; NE]	3,26	[1,91; 5,90]	<0,0001*
Afroamerikanisch	14	3 (21,4)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	11 (16,7)	NE [NE; NE]	72	3 (4,2)	NE [NE; NE]	3,83	[1,20; 16,92]	0,0225*
Andere	15	3 (20,0)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8211
Schmerzen zu baseline									
Symptomatisch	103	22 (21,4)	NE [NE; NE]	80	6 (7,5)	NE [NE; NE]	2,97	[1,28; 8,05]	0,0100*
Asymptomatisch/mild symptomatisch	266	43 (16,2)	NE [NE; NE]	294	15 (5,1)	NE [NE; NE]	3,14	[1,78; 5,84]	<0,0001*
Interaktion p-Wert									0,9185

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabo 05DEC2022:09:12 khcs324

Table 3.5.42 PROpel: Summary of subgroup analysis of time to Schwere UE nach PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	34 (16,0)	NE [NE; NE]	226	6 (2,7)	NE [NE; NE]	6,25	[2,82; 16,53]	<0,0001*
Viszeral	66	8 (12,1)	NE [NE; NE]	72	4 (5,6)	NE [NE; NE]	2,13	[0,67; 7,96]	0,2039
andere	119	21 (17,6)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	5,80	[2,00; 24,55]	0,0005*
Interaktion p-Wert									0,3576
Docetaxel-Behandlung des mHSPC									
Ja	90	15 (16,7)	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	7,78	[2,19; 49,36]	0,0006*
Nein	308	48 (15,6)	NE [NE; NE]	306	11 (3,6)	NE [NE; NE]	4,41	[2,38; 8,94]	<0,0001*
Interaktion p-Wert									0,4700
Alter bei Randomisierung									
<65 Jahre	130	15 (11,5)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	5,36	[1,51; 34,03]	0,0067*
>=65 Jahre	268	48 (17,9)	NE [NE; NE]	299	11 (3,7)	NE [NE; NE]	5,12	[2,76; 10,39]	<0,0001*
Interaktion p-Wert									0,9554
Region									
Asien	91	14 (15,4)	NE [NE; NE]	104	3 (2,9)	NE [NE; NE]	5,17	[1,69; 22,45]	0,0029*
Europa	177	27 (15,3)	NE [NE; NE]	171	6 (3,5)	NE [NE; NE]	4,45	[1,97; 11,93]	0,0002*
Nord- und Suedamerika	130	22 (16,9)	NE [NE; NE]	121	4 (3,3)	NE [NE; NE]	5,41	[2,07; 18,49]	0,0002*
Interaktion p-Wert									0,9582
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	12 (12,2)	NE [NE; NE]	100	3 (3,0)	NE [NE; NE]	3,99	[1,27; 17,51]	0,0164*
Nicht-HRRm	268	47 (17,5)	NE [NE; NE]	267	10 (3,7)	NE [NE; NE]	4,86	[2,57; 10,21]	<0,0001*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.42 PROpel: Summary of subgroup analysis of time to Schwere UE nach PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	4 (12,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7891
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	7 (11,3)	NE [NE; NE]	56	2 (3,6)	NE [NE; NE]	3,00	[0,73; 20,14]	0,1357
Nicht-HRRm	207	38 (18,4)	NE [NE; NE]	210	7 (3,3)	NE [NE; NE]	5,81	[2,76; 14,21]	<0,0001*
Unbekannt	129	18 (14,0)	NE [NE; NE]	130	4 (3,1)	NE [NE; NE]	4,56	[1,70; 15,78]	0,0017*
Interaktion p-Wert									0,7668
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	5 (17,2)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	3,41	[0,55; 65,32]	0,2063
Nicht-HRRm	330	54 (16,4)	NE [NE; NE]	327	11 (3,4)	NE [NE; NE]	5,02	[2,73; 10,12]	<0,0001*
Unbekannt	39	4 (10,3)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	4,88	[0,72; 95,32]	0,1089
Interaktion p-Wert									0,9485
ECOG-PS zu Baseline									
0	286	40 (14,0)	NE [NE; NE]	272	6 (2,2)	NE [NE; NE]	6,47	[2,96; 16,99]	<0,0001*
1	112	23 (20,5)	NE [NE; NE]	124	7 (5,6)	NE [NE; NE]	3,77	[1,70; 9,50]	0,0008*
Interaktion p-Wert									0,3789
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	26 (13,3)	NE [NE; NE]	199	5 (2,5)	NE [NE; NE]	5,34	[2,23; 15,80]	<0,0001*
Über medianem PSA-Baselinewert	200	37 (18,5)	NE [NE; NE]	196	8 (4,1)	NE [NE; NE]	4,67	[2,29; 10,81]	<0,0001*
Interaktion p-Wert									0,8300

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabp 05DEC2022:09:12 khcs324

Table 3.5.42 PROpel: Summary of subgroup analysis of time to Schwere UE nach PT: Anaemie
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	48 (17,1)	NE [NE; NE]	274	11 (4,0)	NE [NE; NE]	4,38	[2,37; 8,89]	<0,0001*
Afroamerikanisch	14	2 (14,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	9 (13,6)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	4,71	[1,21; 30,91]	0,0233*
Andere	15	2 (13,3)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9319
Schmerzen zu baseline									
Symptomatisch	103	20 (19,4)	NE [NE; NE]	80	4 (5,0)	NE [NE; NE]	4,07	[1,54; 14,01]	0,0033*
Asymptomatisch/mild symptomatisch	266	38 (14,3)	NE [NE; NE]	294	9 (3,1)	NE [NE; NE]	4,63	[2,34; 10,21]	<0,0001*
Interaktion p-Wert									0,8471

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabp 05DEC2022:09:12 khcs324

Table 3.5.43 PROpel: Summary of subgroup analysis of time to UESI: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	1 (0,5)	NE [NE; NE]	226	0	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	1 (1,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	0	NE [NE; NE]	306	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	1 (0,4)	NE [NE; NE]	299	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	1 (0,6)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	0	NE [NE; NE]	121	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	0	NE [NE; NE]	267	0	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.43 PROpel: Summary of subgroup analysis of time to UESI: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	0	NE [NE; NE]	210	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	0	NE [NE; NE]	130	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	0	NE [NE; NE]	327	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	39	0	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	0	NE [NE; NE]	272	0	NE [NE; NE]	NC	[NC]	NC
1	112	1 (0,9)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	1 (0,5)	NE [NE; NE]	199	0	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	0	NE [NE; NE]	196	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.43 PROpel: Summary of subgroup analysis of time to UESI: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	1 (0,4)	NE [NE; NE]	274	0	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	0	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	1 (0,4)	NE [NE; NE]	294	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabq 05DEC2022:09:12 khcs324

Table 3.5.44 PROpel: Summary of subgroup analysis of time to UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	12 (5,6)	NE [NE; NE]	226	10 (4,4)	NE [NE; NE]	1,28	[0,55; 3,04]	0,5619
Viszeral	66	1 (1,5)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	0,50	[0,02; 5,26]	0,5649
andere	119	6 (5,0)	NE [NE; NE]	98	5 (5,1)	NE [NE; NE]	0,97	[0,29; 3,35]	0,9542
Interaktion p-Wert									0,7391
Docetaxel-Behandlung des mHSPC									
Ja	90	2 (2,2)	NE [NE; NE]	90	5 (5,6)	NE [NE; NE]	0,39	[0,06; 1,81]	0,2362
Nein	308	17 (5,5)	NE [NE; NE]	306	12 (3,9)	NE [NE; NE]	1,40	[0,67; 3,00]	0,3720
Interaktion p-Wert									0,1454
Alter bei Randomisierung									
<65 Jahre	130	3 (2,3)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	2,16	[0,28; 43,64]	0,4811
>=65 Jahre	268	16 (6,0)	NE [NE; NE]	299	16 (5,4)	NE [NE; NE]	1,12	[0,56; 2,26]	0,7408
Interaktion p-Wert									0,5736
Region									
Asien	91	8 (8,8)	NE [NE; NE]	104	5 (4,8)	NE [NE; NE]	1,67	[0,56; 5,53]	0,3619
Europa	177	9 (5,1)	NE [NE; NE]	171	7 (4,1)	NE [NE; NE]	1,26	[0,47; 3,52]	0,6478
Nord- und Suedamerika	130	2 (1,5)	NE [NE; NE]	121	5 (4,1)	NE [NE; NE]	0,38	[0,05; 1,76]	0,2206
Interaktion p-Wert									0,2952
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	3 (3,1)	NE [NE; NE]	100	3 (3,0)	NE [NE; NE]	0,99	[0,18; 5,37]	0,9942
Nicht-HRRm	268	14 (5,2)	NE [NE; NE]	267	13 (4,9)	NE [NE; NE]	1,06	[0,50; 2,29]	0,8717

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabr 05DEC2022:09:12 khcs324

Table 3.5.44 PROpel: Summary of subgroup analysis of time to UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	2 (6,3)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	1,84	[0,18; 39,56]	0,6092
Interaktion p-Wert									0,9014
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	7 (11,3)	NE [NE; NE]	56	2 (3,6)	NE [NE; NE]	3,15	[0,76; 21,16]	0,1179
Nicht-HRRm	207	6 (2,9)	NE [NE; NE]	210	10 (4,8)	NE [NE; NE]	0,60	[0,20; 1,62]	0,3172
Unbekannt	129	6 (4,7)	NE [NE; NE]	130	5 (3,8)	NE [NE; NE]	1,19	[0,36; 4,13]	0,7725
Interaktion p-Wert									0,1768
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	16 (4,8)	NE [NE; NE]	327	15 (4,6)	NE [NE; NE]	1,06	[0,52; 2,17]	0,8655
Unbekannt	39	3 (7,7)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	3,51	[0,45; 70,91]	0,2396
Interaktion p-Wert									0,2924
ECOG-PS zu Baseline									
0	286	12 (4,2)	NE [NE; NE]	272	13 (4,8)	NE [NE; NE]	0,89	[0,40; 1,96]	0,7689
1	112	7 (6,3)	NE [NE; NE]	124	4 (3,2)	NE [NE; NE]	1,82	[0,55; 6,95]	0,3299
Interaktion p-Wert									0,3294
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	11 (5,6)	NE [NE; NE]	199	10 (5,0)	NE [NE; NE]	1,09	[0,46; 2,63]	0,8368
Über medianem PSA-Baselinewert	200	8 (4,0)	NE [NE; NE]	196	7 (3,6)	NE [NE; NE]	1,12	[0,40; 3,19]	0,8265
Interaktion p-Wert									0,9724

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.44 PROpel: Summary of subgroup analysis of time to UESI: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	11 (3,9)	NE [NE; NE]	274	13 (4,7)	NE [NE; NE]	0,82	[0,36; 1,83]	0,6255
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	5 (7,6)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	2,49	[0,54; 17,39]	0,2512
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2140
Schmerzen zu baseline									
Symptomatisch	103	1 (1,0)	NE [NE; NE]	80	5 (6,3)	NE [NE; NE]	0,15	[0,01; 0,91]	0,0383*
Asymptomatisch/mild symptomatisch	266	16 (6,0)	NE [NE; NE]	294	12 (4,1)	NE [NE; NE]	1,47	[0,70; 3,17]	0,3139
Interaktion p-Wert									0,0213*

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabr 05DEC2022:09:12 khcs324

Table 3.5.45 PROpel: Summary of subgroup analysis of time to UESI: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	0	NE [NE; NE]	226	2 (0,9)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	4 (3,4)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	1 (1,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	4 (1,3)	NE [NE; NE]	306	3 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	1 (0,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	4 (1,5)	NE [NE; NE]	299	3 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	NC	[NC]	NC
Europa	177	3 (1,7)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	2 (1,5)	NE [NE; NE]	121	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	4 (1,5)	NE [NE; NE]	267	2 (0,7)	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabs 05DEC2022:09:12 khcs324

Table 3.5.45 PROpel: Summary of subgroup analysis of time to UESI: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	0	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	4 (1,9)	NE [NE; NE]	210	2 (1,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	1 (0,8)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	3 (0,9)	NE [NE; NE]	327	3 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	3 (1,0)	NE [NE; NE]	272	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
1	112	2 (1,8)	NE [NE; NE]	124	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	2 (1,0)	NE [NE; NE]	199	2 (1,0)	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	3 (1,5)	NE [NE; NE]	196	1 (0,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabs 05DEC2022:09:12 khcs324

Table 3.5.45 PROpel: Summary of subgroup analysis of time to UESI: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	3 (1,1)	NE [NE; NE]	274	2 (0,7)	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	NC	[NC]	NC
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	2 (1,9)	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	3 (1,1)	NE [NE; NE]	294	3 (1,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.46 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	1 (0,5)	NE [NE; NE]	226	0	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	1 (1,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	0	NE [NE; NE]	306	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	1 (0,4)	NE [NE; NE]	299	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	1 (0,6)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	0	NE [NE; NE]	121	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	0	NE [NE; NE]	267	0	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.46 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	0	NE [NE; NE]	210	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	0	NE [NE; NE]	130	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	0	NE [NE; NE]	327	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	39	0	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	0	NE [NE; NE]	272	0	NE [NE; NE]	NC	[NC]	NC
1	112	1 (0,9)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	1 (0,5)	NE [NE; NE]	199	0	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	0	NE [NE; NE]	196	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.46 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	1 (0,4)	NE [NE; NE]	274	0	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	0	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	1 (0,4)	NE [NE; NE]	294	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabt 05DEC2022:09:12 khcs324

Table 3.5.47 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	9 (4,2)	NE [NE; NE]	226	5 (2,2)	NE [NE; NE]	1,93	[0,67; 6,27]	0,2290
Viszeral	66	1 (1,5)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	0,99	[0,04; 25,11]	0,9964
andere	119	3 (2,5)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	0,80	[0,15; 4,33]	0,7867
Interaktion p-Wert									0,6523
Docetaxel-Behandlung des mHSPC									
Ja	90	0	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Nein	308	13 (4,2)	NE [NE; NE]	306	7 (2,3)	NE [NE; NE]	1,82	[0,75; 4,85]	0,1896
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	2 (1,5)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	1,42	[0,14; 30,48]	0,7720
>=65 Jahre	268	11 (4,1)	NE [NE; NE]	299	8 (2,7)	NE [NE; NE]	1,55	[0,63; 4,01]	0,3414
Interaktion p-Wert									0,9455
Region									
Asien	91	7 (7,7)	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	3,64	[0,88; 24,44]	0,0766
Europa	177	5 (2,8)	NE [NE; NE]	171	5 (2,9)	NE [NE; NE]	0,97	[0,27; 3,50]	0,9661
Nord- und Suedamerika	130	1 (0,8)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	0,47	[0,02; 4,96]	0,5306
Interaktion p-Wert									0,2448
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	0,98	[0,04; 24,86]	0,9907
Nicht-HRRm	268	11 (4,1)	NE [NE; NE]	267	7 (2,6)	NE [NE; NE]	1,56	[0,61; 4,23]	0,3541

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.47 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	1 (3,1)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	0,91	[0,04; 22,94]	0,9456
Interaktion p-Wert									0,9037
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	4 (6,5)	NE [NE; NE]	56	1 (1,8)	NE [NE; NE]	3,49	[0,52; 68,16]	0,2149
Nicht-HRRm	207	6 (2,9)	NE [NE; NE]	210	5 (2,4)	NE [NE; NE]	1,22	[0,37; 4,23]	0,7439
Unbekannt	129	3 (2,3)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	0,98	[0,18; 5,31]	0,9835
Interaktion p-Wert									0,5998
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	11 (3,3)	NE [NE; NE]	327	7 (2,1)	NE [NE; NE]	1,57	[0,62; 4,26]	0,3457
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	2,27	[0,22; 48,79]	0,4896
Interaktion p-Wert									0,7765
ECOG-PS zu Baseline									
0	286	8 (2,8)	NE [NE; NE]	272	8 (2,9)	NE [NE; NE]	0,97	[0,36; 2,63]	0,9450
1	112	5 (4,5)	NE [NE; NE]	124	1 (0,8)	NE [NE; NE]	5,12	[0,83; 98,13]	0,0829
Interaktion p-Wert									0,1250
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	8 (4,1)	NE [NE; NE]	199	8 (4,0)	NE [NE; NE]	0,98	[0,36; 2,68]	0,9754
Über medianem PSA-Baselinewert	200	5 (2,5)	NE [NE; NE]	196	1 (0,5)	NE [NE; NE]	4,94	[0,80; 94,57]	0,0908
Interaktion p-Wert									0,1391

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.47 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	6 (2,1)	NE [NE; NE]	274	5 (1,8)	NE [NE; NE]	1,16	[0,35; 4,04]	0,8030
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	5 (7,6)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	2,46	[0,53; 17,14]	0,2594
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4617
Schmerzen zu baseline									
Symptomatisch	103	1 (1,0)	NE [NE; NE]	80	3 (3,8)	NE [NE; NE]	0,25	[0,01; 1,92]	0,1861
Asymptomatisch/mild symptomatisch	266	11 (4,1)	NE [NE; NE]	294	6 (2,0)	NE [NE; NE]	2,02	[0,77; 5,86]	0,1565
Interaktion p-Wert									0,0709

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabu 05DEC2022:09:12 khcs324

Table 3.5.48 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	0	NE [NE; NE]	226	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	3 (2,5)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	1 (1,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	3 (1,0)	NE [NE; NE]	306	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	1 (0,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	3 (1,1)	NE [NE; NE]	299	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	2 (1,1)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	2 (1,5)	NE [NE; NE]	121	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	0	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	4 (1,5)	NE [NE; NE]	267	1 (0,4)	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabv 05DEC2022:09:12 khcs324

Table 3.5.48 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	0	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	3 (1,4)	NE [NE; NE]	210	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	1 (0,8)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	2 (0,6)	NE [NE; NE]	327	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	2 (0,7)	NE [NE; NE]	272	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
1	112	2 (1,8)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	1 (0,5)	NE [NE; NE]	199	0	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	3 (1,5)	NE [NE; NE]	196	1 (0,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.48 PROpel: Summary of subgroup analysis of time to Schwerwiegende UE: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	2 (0,7)	NE [NE; NE]	274	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	2 (1,9)	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	2 (0,8)	NE [NE; NE]	294	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabv 05DEC2022:09:12 khcs324

Table 3.5.49 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	1 (0,5)	NE [NE; NE]	226	0	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	1 (1,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	0	NE [NE; NE]	306	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	1 (0,4)	NE [NE; NE]	299	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	1 (0,6)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	0	NE [NE; NE]	121	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	0	NE [NE; NE]	267	0	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.49 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	1 (1,6)	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	0	NE [NE; NE]	210	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	0	NE [NE; NE]	130	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	1 (3,4)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	0	NE [NE; NE]	327	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	39	0	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	0	NE [NE; NE]	272	0	NE [NE; NE]	NC	[NC]	NC
1	112	1 (0,9)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	1 (0,5)	NE [NE; NE]	199	0	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	0	NE [NE; NE]	196	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.49 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: hohes potentielles Risiko von MDS/AML
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	1 (0,4)	NE [NE; NE]	274	0	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	0	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	1 (0,4)	NE [NE; NE]	294	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabw 05DEC2022:09:12 khcs324

Table 3.5.50 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	8 (3,8)	NE [NE; NE]	226	5 (2,2)	NE [NE; NE]	1,72	[0,57; 5,70]	0,3334
Viszeral	66	1 (1,5)	NE [NE; NE]	72	1 (1,4)	NE [NE; NE]	1,01	[0,04; 25,49]	0,9951
andere	119	2 (1,7)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	0,54	[0,07; 3,24]	0,4908
Interaktion p-Wert									0,5434
Docetaxel-Behandlung des mHSPC									
Ja	90	0	NE [NE; NE]	90	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Nein	308	11 (3,6)	NE [NE; NE]	306	7 (2,3)	NE [NE; NE]	1,55	[0,61; 4,22]	0,3574
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	1 (0,8)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	0,72	[0,03; 18,15]	0,8154
>=65 Jahre	268	10 (3,7)	NE [NE; NE]	299	8 (2,7)	NE [NE; NE]	1,41	[0,56; 3,70]	0,4632
Interaktion p-Wert									0,6519
Region									
Asien	91	6 (6,6)	NE [NE; NE]	104	2 (1,9)	NE [NE; NE]	NC	[NC]	NC
Europa	177	4 (2,3)	NE [NE; NE]	171	5 (2,9)	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	1 (0,8)	NE [NE; NE]	121	2 (1,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	1 (1,0)	NE [NE; NE]	100	1 (1,0)	NE [NE; NE]	1,00	[0,04; 25,22]	0,9990
Nicht-HRRm	268	9 (3,4)	NE [NE; NE]	267	7 (2,6)	NE [NE; NE]	1,28	[0,48; 3,59]	0,6215

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabx 05DEC2022:09:12 khcs324

Table 3.5.50 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	1 (3,1)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	0,90	[0,04; 22,84]	0,9430
Interaktion p-Wert									0,9638
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	3 (4,8)	NE [NE; NE]	56	1 (1,8)	NE [NE; NE]	2,65	[0,34; 53,52]	0,3673
Nicht-HRRm	207	5 (2,4)	NE [NE; NE]	210	5 (2,4)	NE [NE; NE]	1,02	[0,28; 3,67]	0,9739
Unbekannt	129	3 (2,3)	NE [NE; NE]	130	3 (2,3)	NE [NE; NE]	0,99	[0,18; 5,35]	0,9897
Interaktion p-Wert									0,7235
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	10 (3,0)	NE [NE; NE]	327	7 (2,1)	NE [NE; NE]	1,43	[0,55; 3,94]	0,4631
Unbekannt	39	1 (2,6)	NE [NE; NE]	47	1 (2,1)	NE [NE; NE]	1,14	[0,05; 28,84]	0,9256
Interaktion p-Wert									0,8798
ECOG-PS zu Baseline									
0	286	8 (2,8)	NE [NE; NE]	272	8 (2,9)	NE [NE; NE]	0,97	[0,36; 2,64]	0,9534
1	112	3 (2,7)	NE [NE; NE]	124	1 (0,8)	NE [NE; NE]	3,11	[0,40; 62,87]	0,2900
Interaktion p-Wert									0,3288
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	6 (3,1)	NE [NE; NE]	199	8 (4,0)	NE [NE; NE]	0,74	[0,24; 2,13]	0,5792
Über medianem PSA-Baselinewert	200	5 (2,5)	NE [NE; NE]	196	1 (0,5)	NE [NE; NE]	4,98	[0,80; 95,42]	0,0888
Interaktion p-Wert									0,0822

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabx 05DEC2022:09:12 khcs324

Table 3.5.50 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: neue primäre Malignität (außer MDS/AML)
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	5 (1,8)	NE [NE; NE]	274	5 (1,8)	NE [NE; NE]	0,98	[0,27; 3,52]	0,9747
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	4 (6,1)	NE [NE; NE]	72	2 (2,8)	NE [NE; NE]	2,00	[0,39; 14,45]	0,4091
Andere	15	0	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4996
Schmerzen zu baseline									
Symptomatisch	103	1 (1,0)	NE [NE; NE]	80	3 (3,8)	NE [NE; NE]	0,25	[0,01; 1,92]	0,1869
Asymptomatisch/mild symptomatisch	266	10 (3,8)	NE [NE; NE]	294	6 (2,0)	NE [NE; NE]	1,84	[0,68; 5,40]	0,2304
Interaktion p-Wert									0,0863

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeabx 05DEC2022:09:12 khcs324

Table 3.5.51 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Metastasen zu Baseline									
Nur Knochen	213	0	NE [NE; NE]	226	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Viszeral	66	1 (1,5)	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
andere	119	3 (2,5)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Docetaxel-Behandlung des mHSPC									
Ja	90	1 (1,1)	NE [NE; NE]	90	0	NE [NE; NE]	NC	[NC]	NC
Nein	308	3 (1,0)	NE [NE; NE]	306	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter bei Randomisierung									
<65 Jahre	130	1 (0,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
>=65 Jahre	268	3 (1,1)	NE [NE; NE]	299	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	91	0	NE [NE; NE]	104	0	NE [NE; NE]	NC	[NC]	NC
Europa	177	2 (1,1)	NE [NE; NE]	171	0	NE [NE; NE]	NC	[NC]	NC
Nord- und Suedamerika	130	2 (1,5)	NE [NE; NE]	121	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem ctDNA-Test									
HRRm	98	0	NE [NE; NE]	100	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	268	4 (1,5)	NE [NE; NE]	267	1 (0,4)	NE [NE; NE]	NC	[NC]	NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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Table 3.5.51 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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]
Unbekannt	32	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Tumorgewebetest									
HRRm	62	0	NE [NE; NE]	56	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	207	3 (1,4)	NE [NE; NE]	210	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	129	1 (0,8)	NE [NE; NE]	130	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRRm-Status basierend auf einem Bluttest für Keimbahnmutationen									
HRRm	29	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	330	2 (0,6)	NE [NE; NE]	327	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	39	2 (5,1)	NE [NE; NE]	47	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG-PS zu Baseline									
0	286	2 (0,7)	NE [NE; NE]	272	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
1	112	2 (1,8)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PSA zu Baseline									
Unter medianem PSA-Baselinewert	196	1 (0,5)	NE [NE; NE]	199	0	NE [NE; NE]	NC	[NC]	NC
Über medianem PSA-Baselinewert	200	3 (1,5)	NE [NE; NE]	196	1 (0,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
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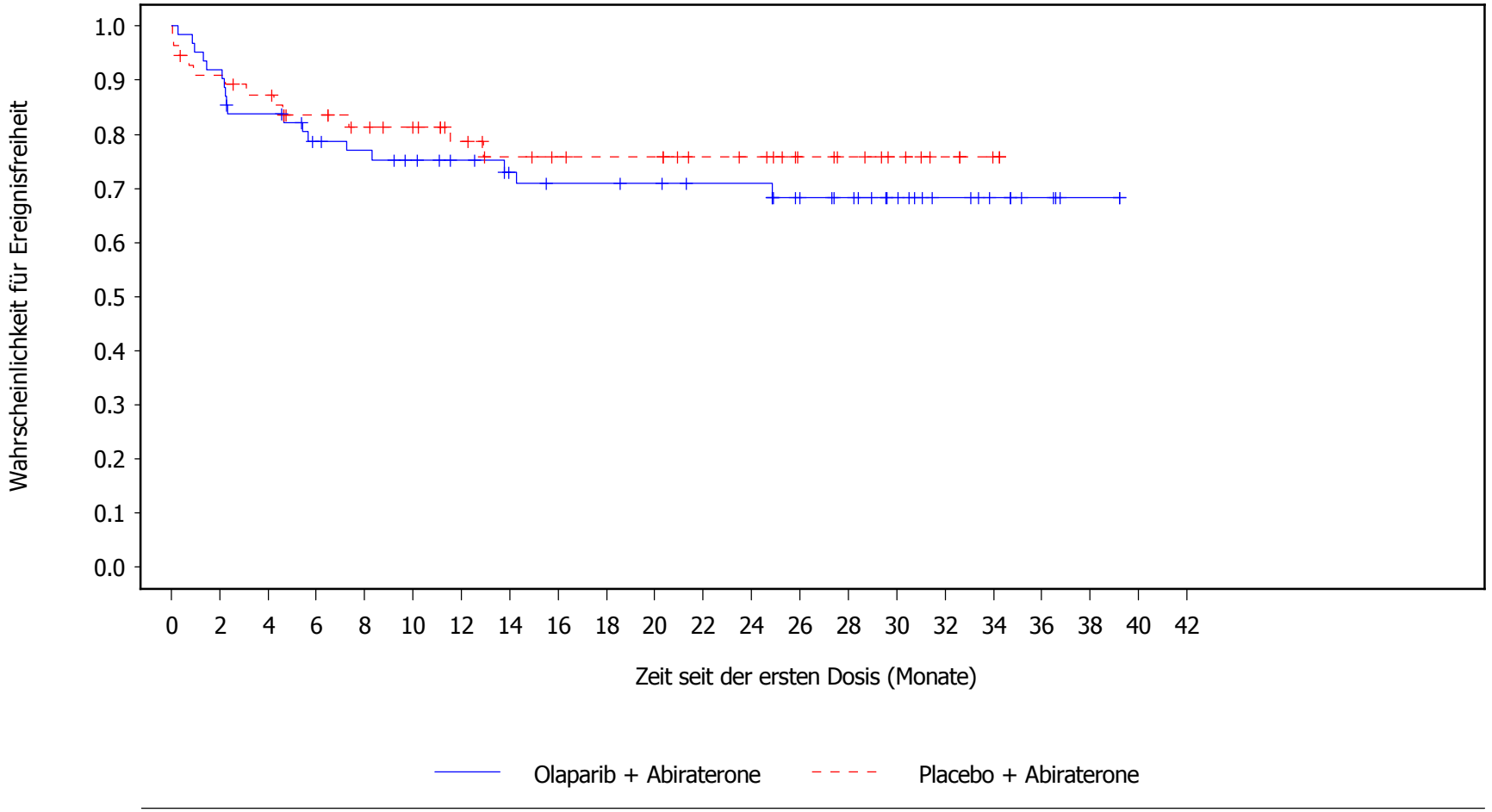
Table 3.5.51 PROpel: Summary of subgroup analysis of time to Schwere UESI G>=3: Pneumonitis
Safety Analysis Set, DCO 14MAR2022

	Olaparib + Abiraterone (N=398)			Placebo + Abiraterone (N=396)					
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									
Kaukasisch	281	2 (0,7)	NE [NE; NE]	274	1 (0,4)	NE [NE; NE]	NC	[NC]	NC
Afroamerikanisch	14	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	66	0	NE [NE; NE]	72	0	NE [NE; NE]	NC	[NC]	NC
Andere	15	1 (6,7)	NE [NE; NE]	9	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Schmerzen zu baseline									
Symptomatisch	103	2 (1,9)	NE [NE; NE]	80	0	NE [NE; NE]	NC	[NC]	NC
Asymptomatisch/mild symptomatisch	266	2 (0,8)	NE [NE; NE]	294	1 (0,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first AE or time to censoring if the AE has not occurred by 30 days after last dose of olaparib/placebo. Includes AEs with onset date >=date of first dose and <=30 days after last dose of olaparib/placebo. MedDRA version 24.0.
[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.
* Interaction p-value <0.05. HR <1 favours olaparib. NC = not calculable.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeaby 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.1 PROpel: Kaplan-Meier plot of UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums for HRRm-Status basierend auf einem Tumorgewebetest=HRRm
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

62	57	51	45	43	40	37	33	31	31	30	28	28	22	20	15	10	7	4	1	0	0	Olaparib + Abiraterone
56	50	47	41	37	34	29	25	23	22	22	18	17	12	10	7	4	1	0	0	0	0	Placebo + Abiraterone

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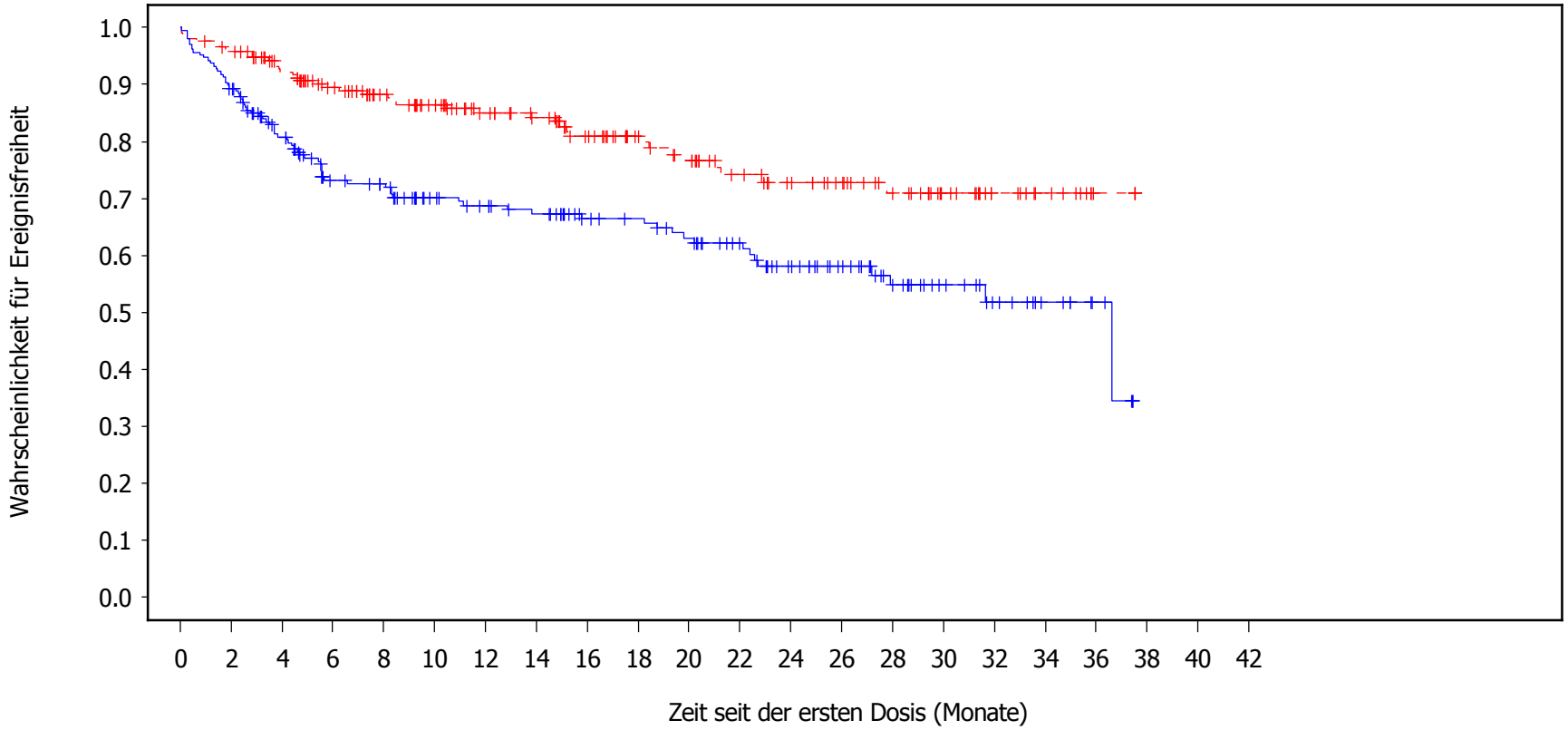
Figure 3.6.2 PROpel: Kaplan-Meier plot of UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums for HRRm-Status basierend auf einem Tumorgewebetest=Nicht-HRRm
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

207	184	155	127	122	105	99	93	81	78	72	62	51	42	30	22	15	9	4	0	0	0	Olaparib + Abiraterone
210	199	179	160	143	130	115	107	93	77	69	58	51	45	36	25	15	10	2	0	0	0	Placebo + Abiraterone

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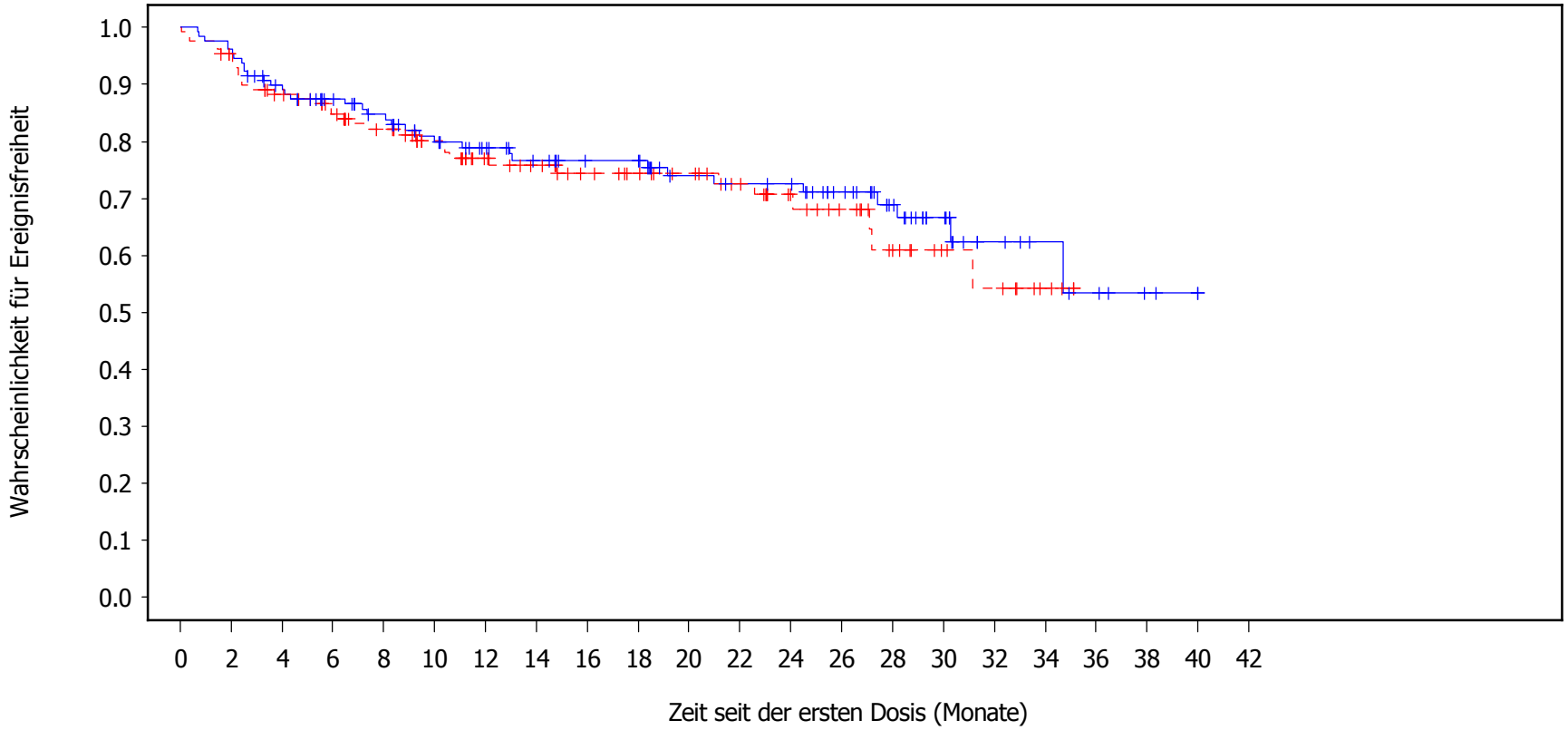
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.3 PROpel: Kaplan-Meier plot of UE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums for HRRm-Status basierend auf einem Tumorgewebetest=Unbekannt
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

129	124	111	100	91	81	74	67	62	62	52	50	49	40	30	20	10	7	5	2	1	0	Olaparib + Abiraterone
130	121	108	98	88	76	65	59	52	48	44	38	28	23	16	10	8	3	0	0	0	0	Placebo + Abiraterone

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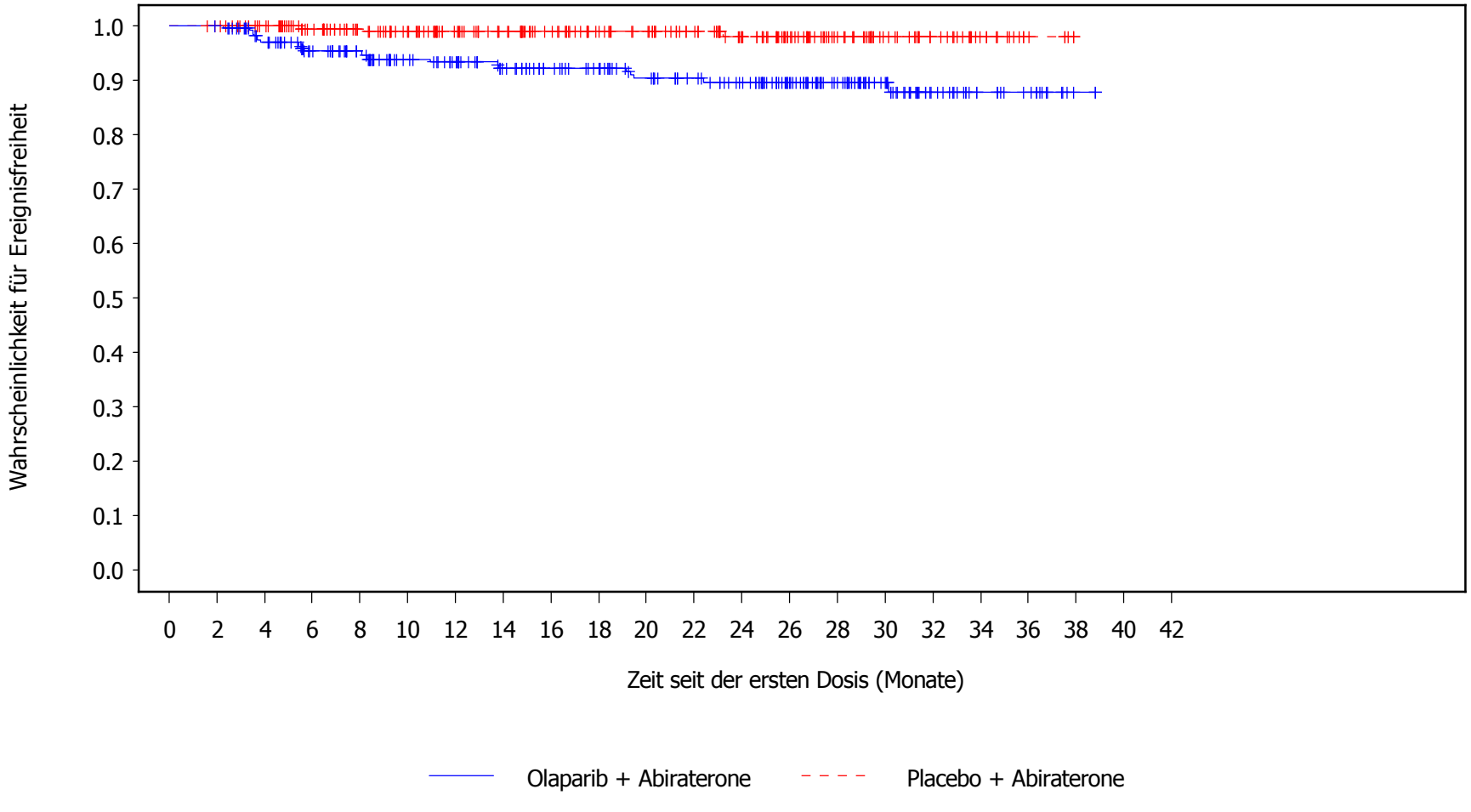
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.4 PROpel: Kaplan-Meier plot of UE PT: Lungenembolie for ECOG-PS zu Baseline=0
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

286	285	266	243	227	203	193	175	162	154	141	131	121	98	76	53	29	17	12	1	0	0	Olaparib + Abiraterone
272	270	258	238	217	202	184	169	152	137	130	116	98	79	60	41	27	15	5	0	0	0	Placebo + Abiraterone

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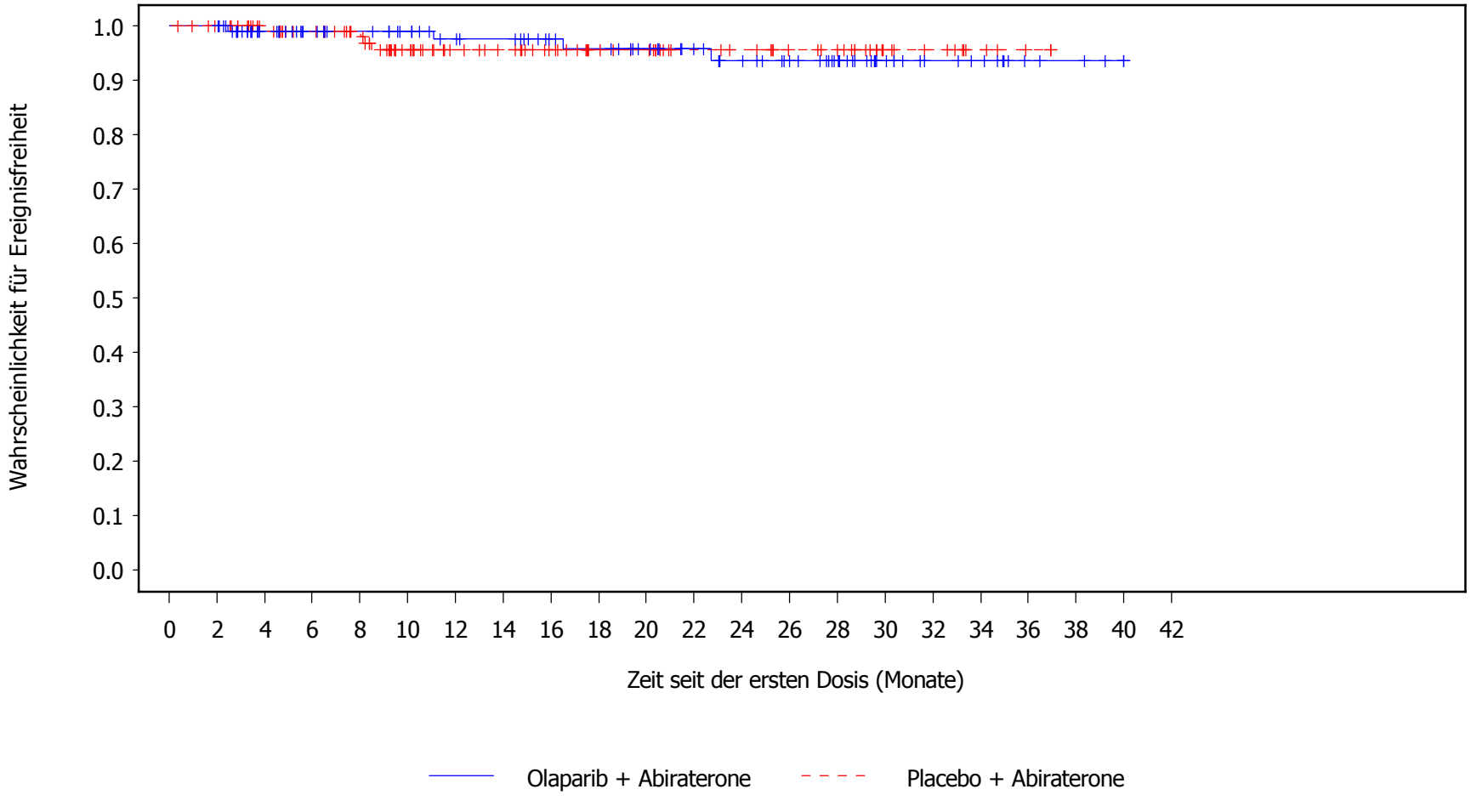
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.5 PROpel: Kaplan-Meier plot of UE PT: Lungenembolie for ECOG-PS zu Baseline=1
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

112	112	94	84	80	74	67	65	58	56	51	45	41	35	29	18	12	10	4	3	1	0	Olaparib + Abiraterone
124	120	108	101	92	75	63	59	52	43	40	32	30	25	22	12	9	4	1	0	0	0	Placebo + Abiraterone

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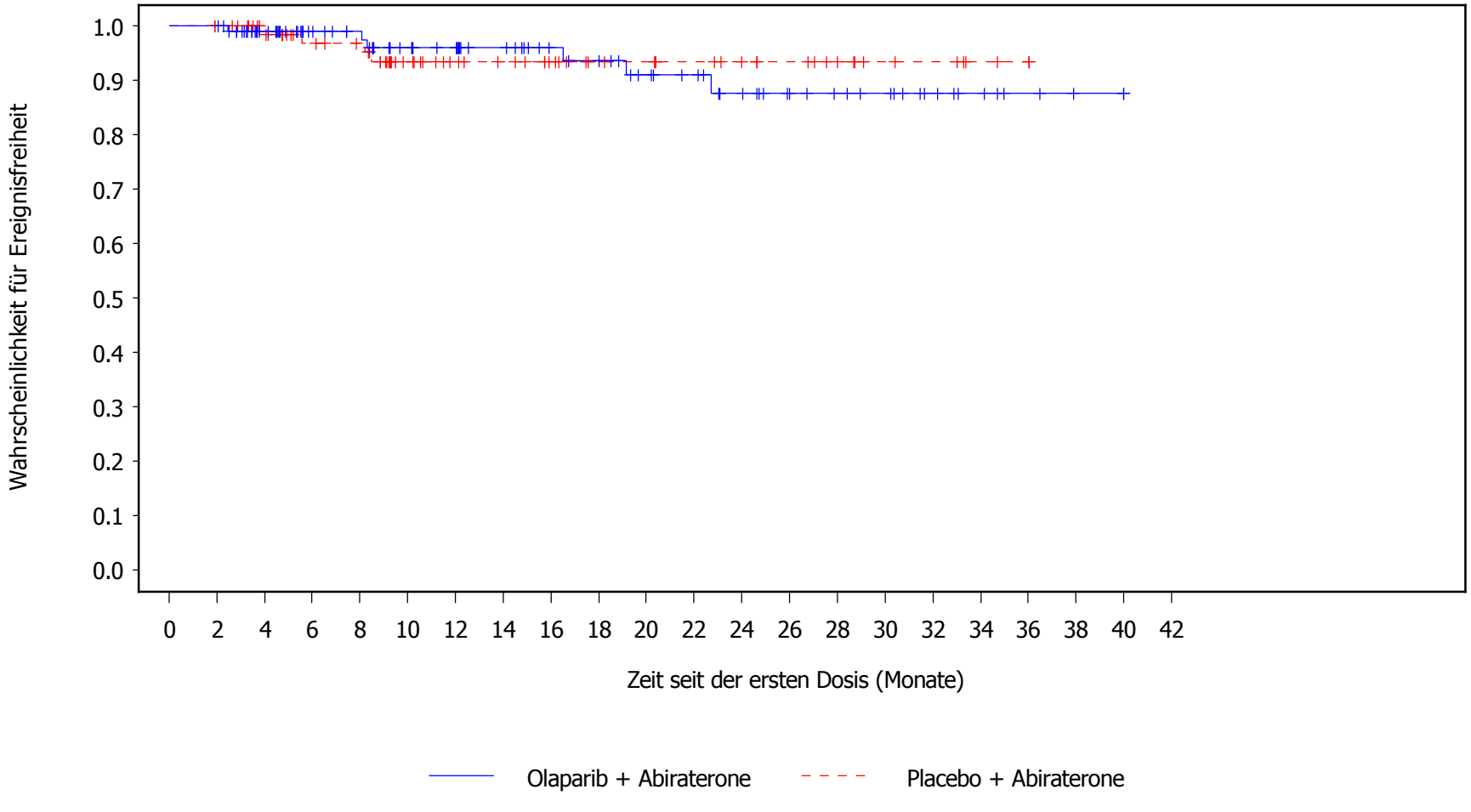
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.6 PROpel: Kaplan-Meier plot of UE PT: Lungenembolie for Schmerzen zu baseline=Symptomatisch
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

103	103	87	73	68	59	55	47	40	38	32	29	24	18	16	14	9	6	3	1	1	0	Olaparib + Abiraterone
80	78	69	60	57	42	35	32	27	22	21	18	15	13	9	6	5	2	1	0	0	0	Placebo + Abiraterone

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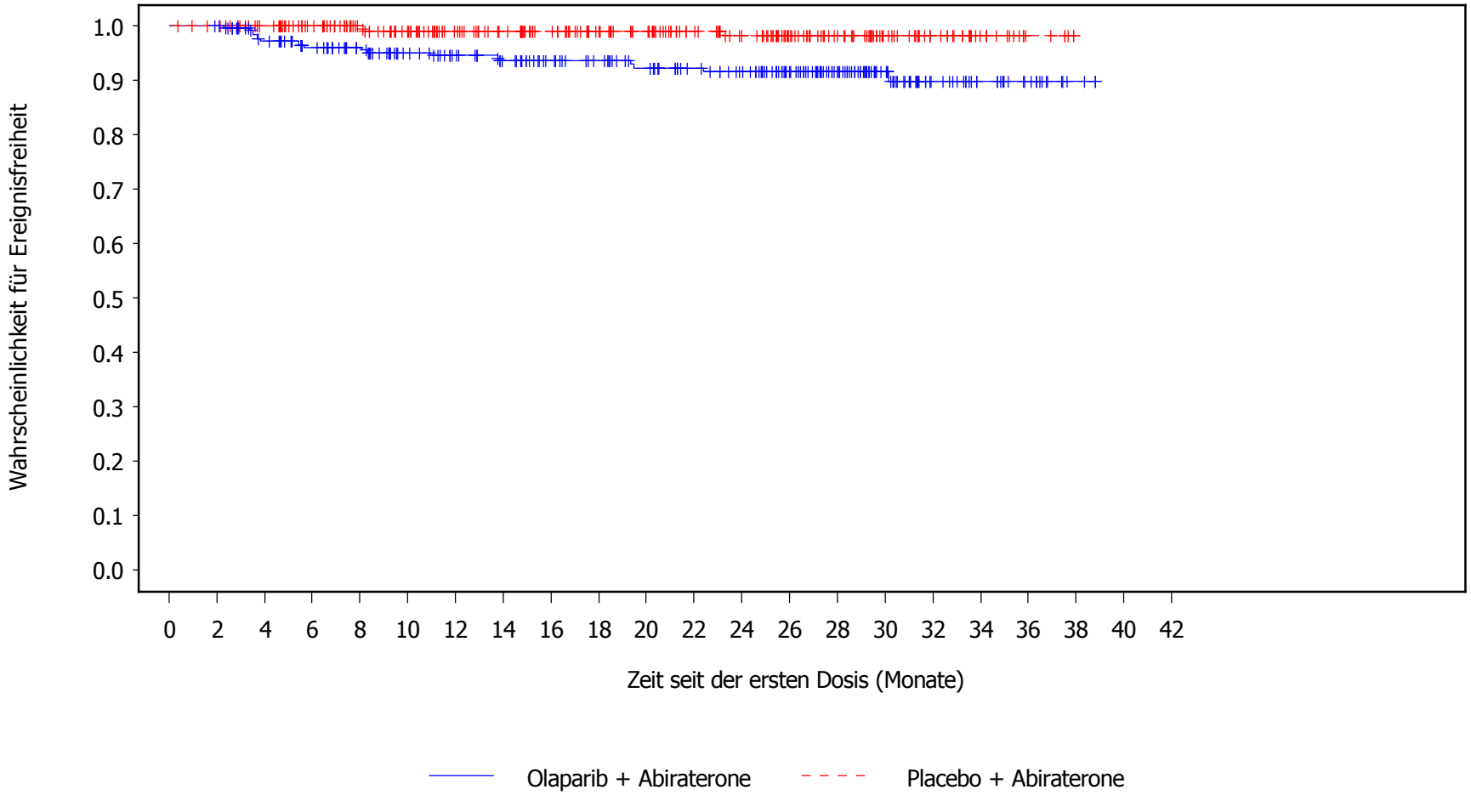
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.7 PROpel: Kaplan-Meier plot of UE PT: Lungenembolie for Schmerzen zu baseline=Asymptomatisch/mild symptomatisch
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

266	265	246	232	219	200	189	177	165	157	147	135	127	105	82	55	31	20	12	2	0	0	Olaparib + Abiraterone
294	291	278	260	235	218	197	182	164	145	136	117	102	82	67	45	29	16	5	0	0	0	Placebo + Abiraterone

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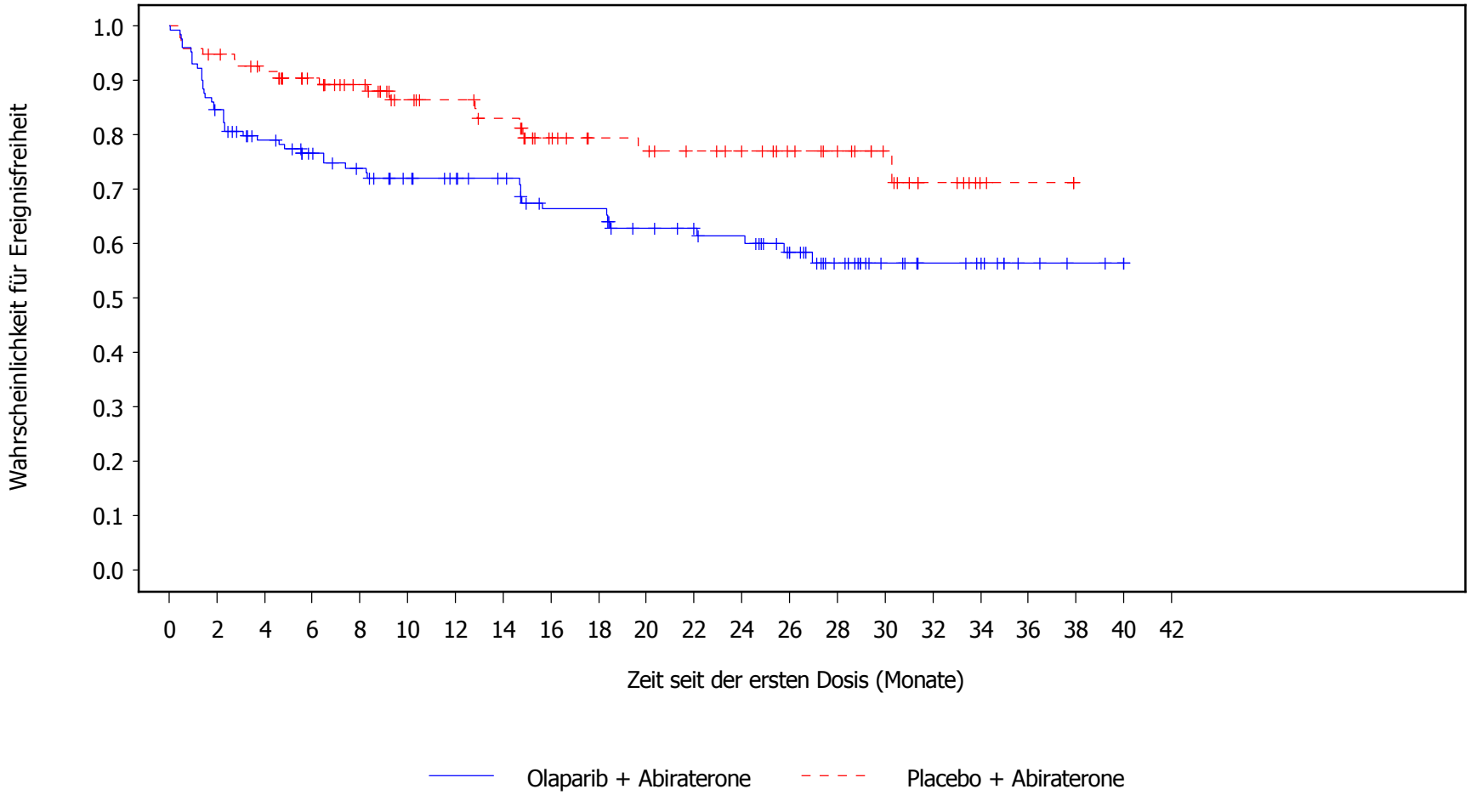
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.8 PROpel: Kaplan-Meier plot of UE PT: Anaemie for Alter bei Randomisierung=<65 Jahre
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

130	109	96	87	81	73	69	65	56	56	49	46	44	34	25	16	12	10	4	2	1	0	Olaparib + Abiraterone
97	91	85	75	66	55	52	48	38	33	32	29	26	22	19	13	7	2	1	0	0	0	Placebo + Abiraterone

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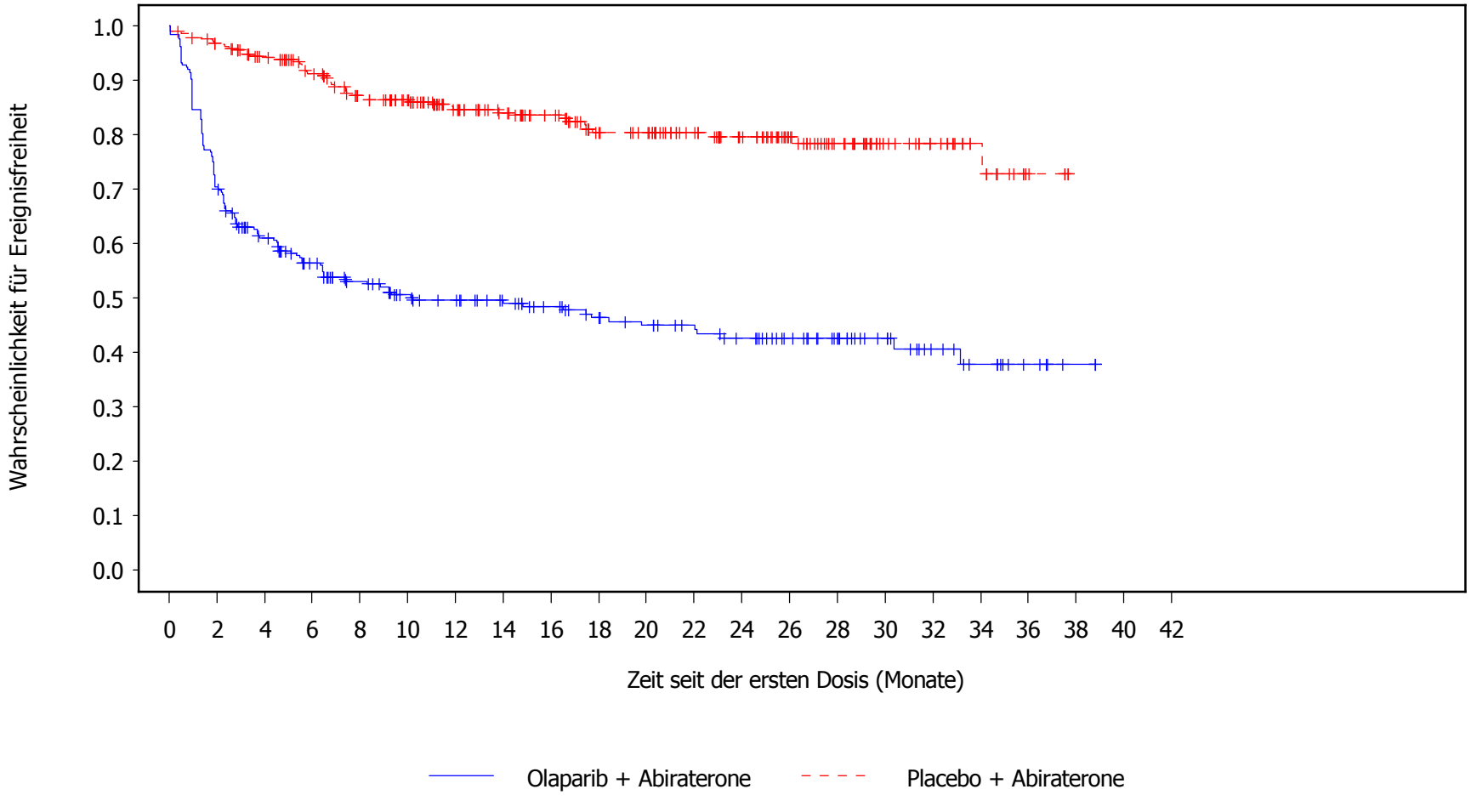
Figure 3.6.9 PROpel: Kaplan-Meier plot of UE PT: Anaemie for Alter bei Randomisierung=>=65 Jahre
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

268	189	154	132	114	100	93	84	76	68	63	58	52	43	34	25	16	11	5	1	0	0	Olaparib + Abiraterone
299	284	264	243	220	201	174	159	142	120	115	98	84	67	51	34	24	14	4	0	0	0	Placebo + Abiraterone

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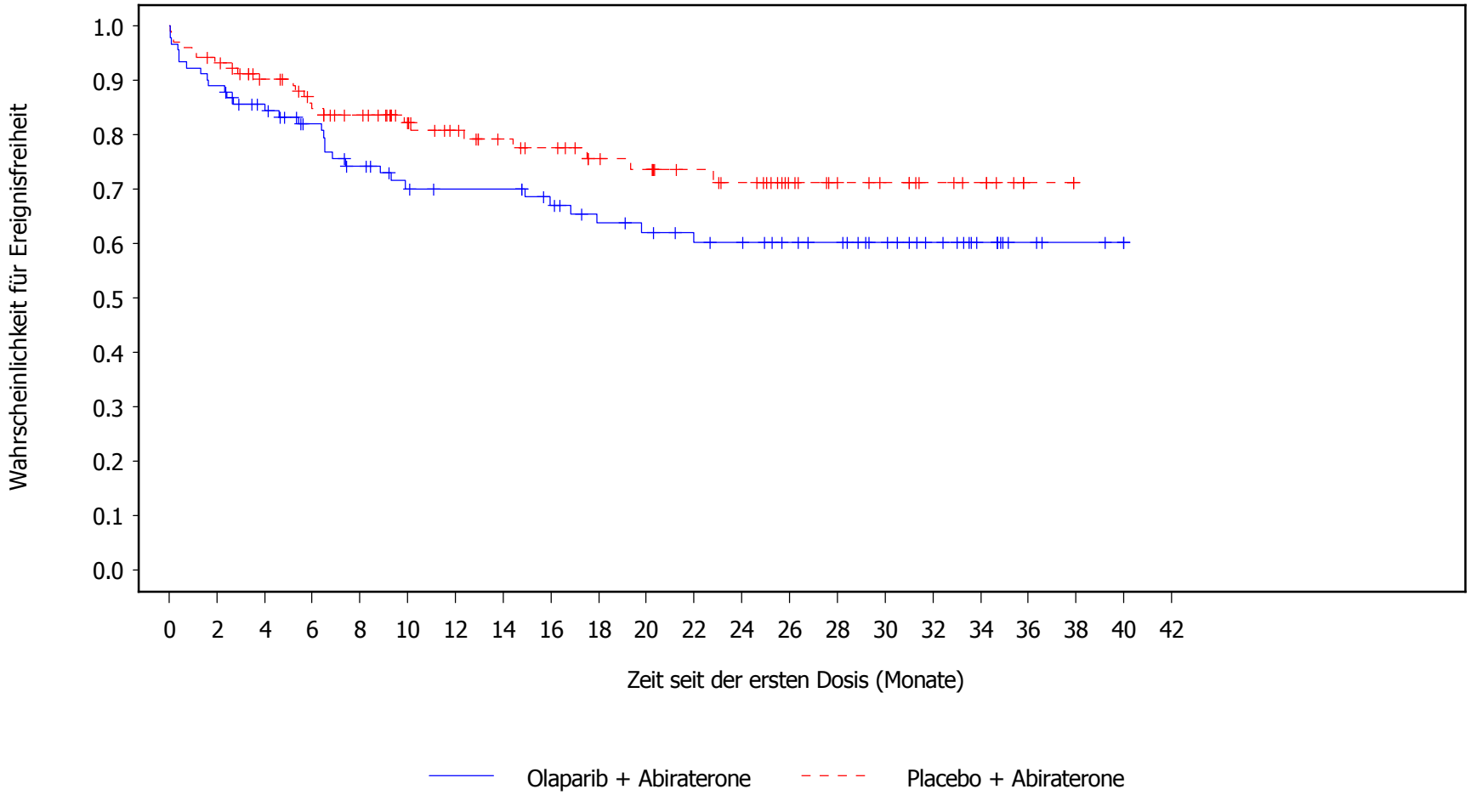
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.10 PROpel: Kaplan-Meier plot of UE SOC: Erkrankungen des Nervensystems for Region=Asien
Safety Analysis Set, DCO 14MAR2022

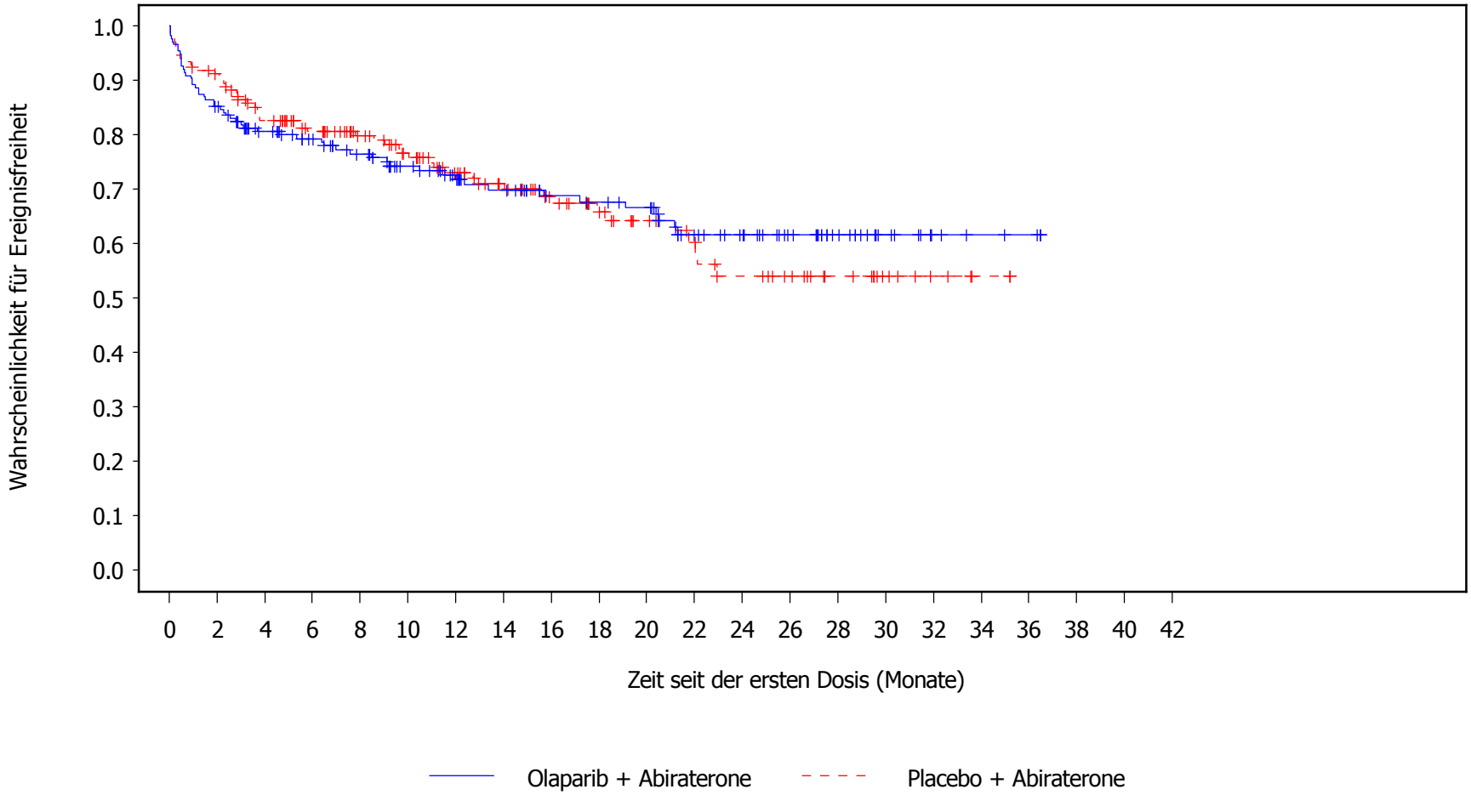


Anzahl an Patienten unter Risiko:

91	81	73	64	56	50	48	48	43	38	36	33	32	28	26	21	16	10	4	2	1	0	Olaparib + Abiraterone
104	96	86	77	71	59	53	47	44	38	36	31	28	20	16	13	9	7	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebaj 05DEC2022:09:12 khcs324

Figure 3.6.11 PROpel: Kaplan-Meier plot of UE SOC: Erkrankungen des Nervensystems for Region=Europa
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

177	150	129	118	107	92	81	74	64	62	59	44	39	30	21	12	5	3	2	0	0	0	Olaparib + Abiraterone
171	153	132	117	103	91	78	66	53	43	35	30	24	20	14	8	4	1	0	0	0	0	Placebo + Abiraterone

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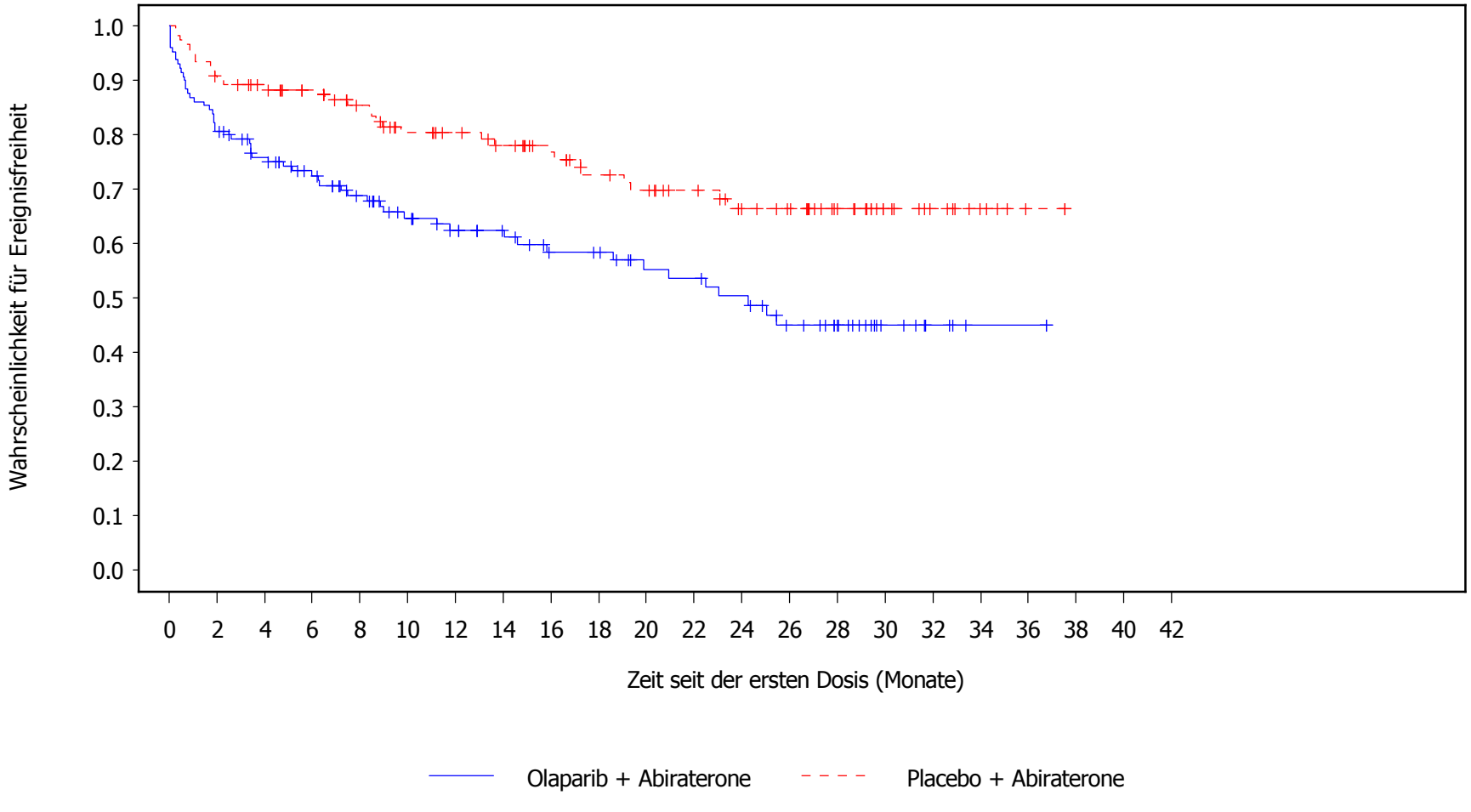
Figure 3.6.12 PROpel: Kaplan-Meier plot of UE SOC: Erkrankungen des Nervensystems for Region=Nord- und Suedamerika
Safety Analysis Set, DCO 14MAR2022



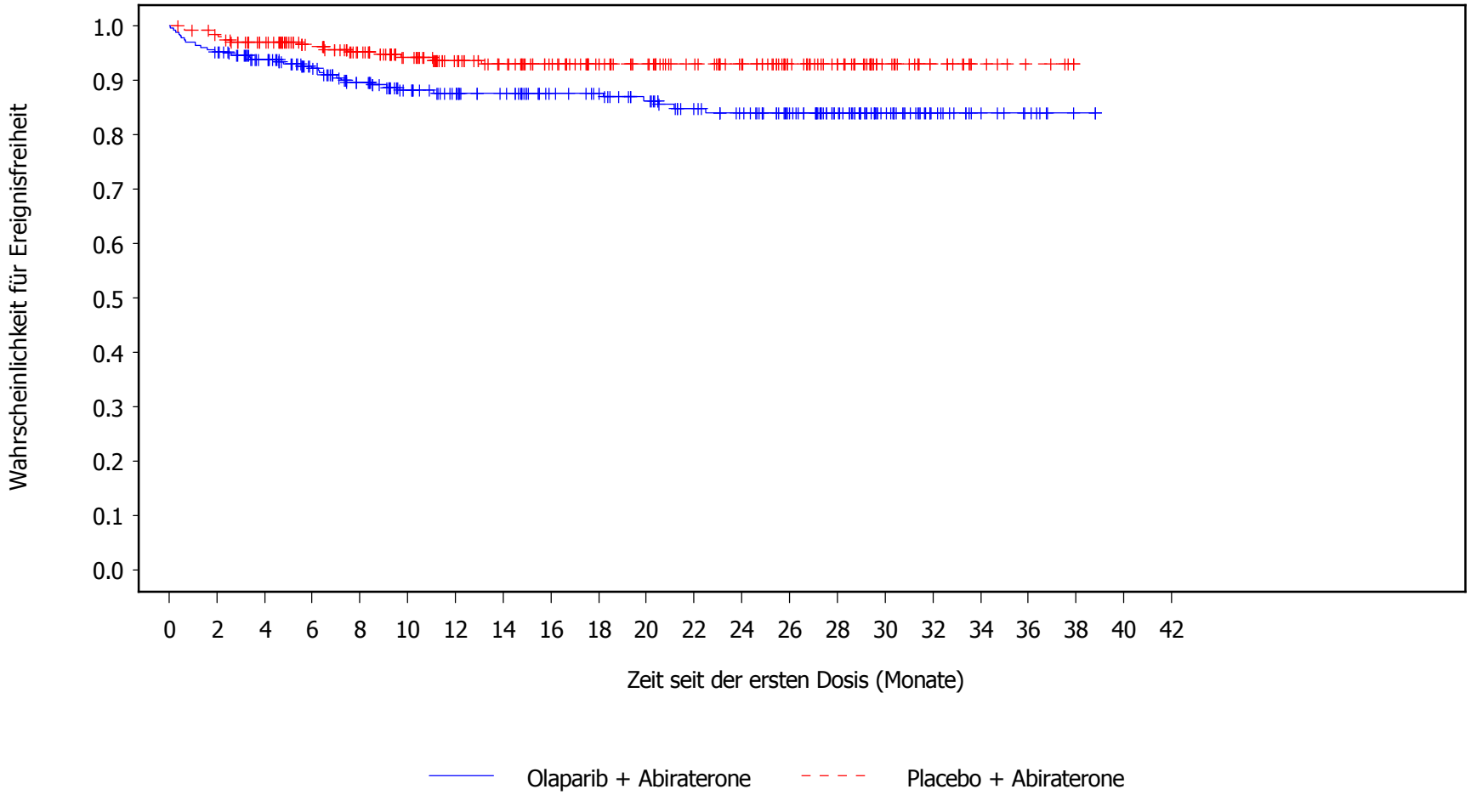
Anzahl an Patienten unter Risiko:

130	105	93	82	71	61	54	48	41	40	34	33	30	23	17	8	4	1	1	0	0	0	Olaparib + Abiraterone
121	109	103	96	85	75	71	66	59	52	49	44	37	34	24	15	10	5	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebal 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.13 PROpel: Kaplan-Meier plot of UE PT: Schwindelgefuehl for Abstammung=Kaukasisch
Safety Analysis Set, DCO 14MAR2022



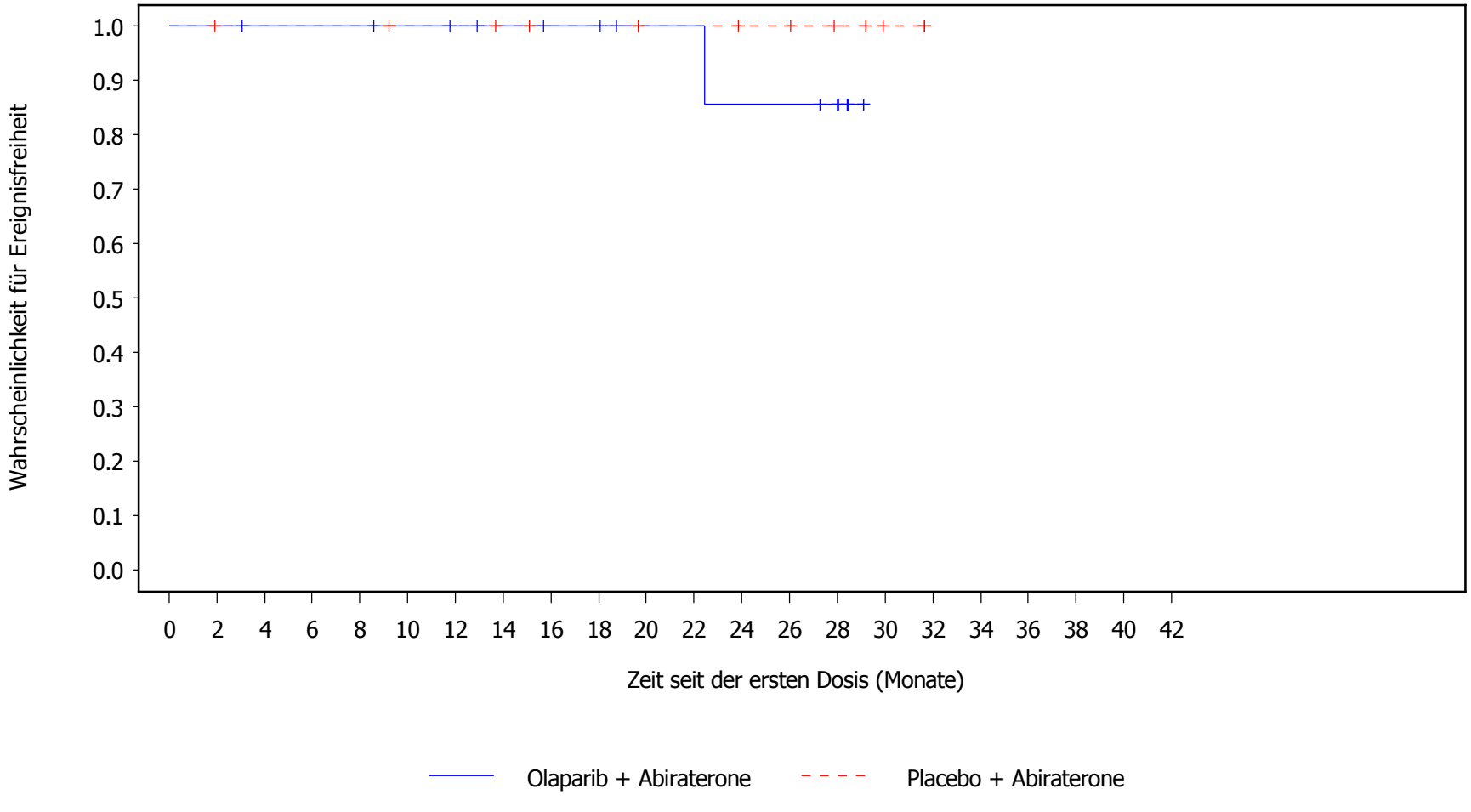
Anzahl an Patienten unter Risiko:

281	267	246	221	199	176	163	152	136	131	121	107	99	83	63	40	21	12	7	1	0	0	Olaparib + Abiraterone
274	266	249	224	204	178	157	143	128	111	103	90	78	61	48	27	16	8	4	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebam 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.14 PROpel: Kaplan-Meier plot of UE PT: Schwindelgefuehl for Abstammung=Afroamerikanisch
Safety Analysis Set, DCO 14MAR2022

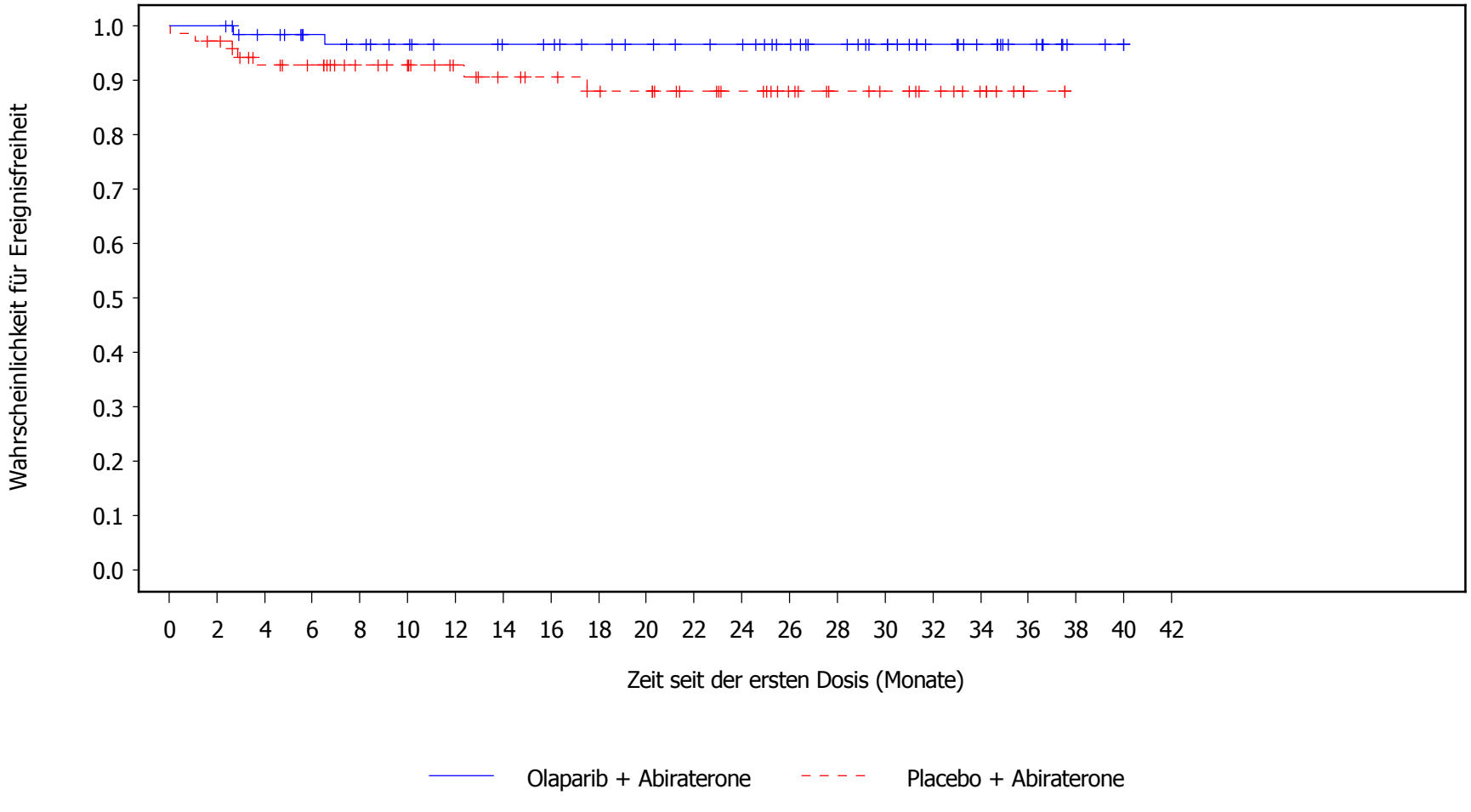


Anzahl an Patienten unter Risiko:

14	14	13	13	13	12	11	10	9	9	7	7	6	6	4	0	0	0	0	0	0	0	Olaparib + Abiraterone
11	10	10	10	10	9	9	8	7	7	6	6	5	5	3	1	0	0	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaeban 05DEC2022:09:12 khcs324

Figure 3.6.15 PROpel: Kaplan-Meier plot of UE PT: Schwindelgefuehl for Abstammung=Asiatisch
Safety Analysis Set, DCO 14MAR2022



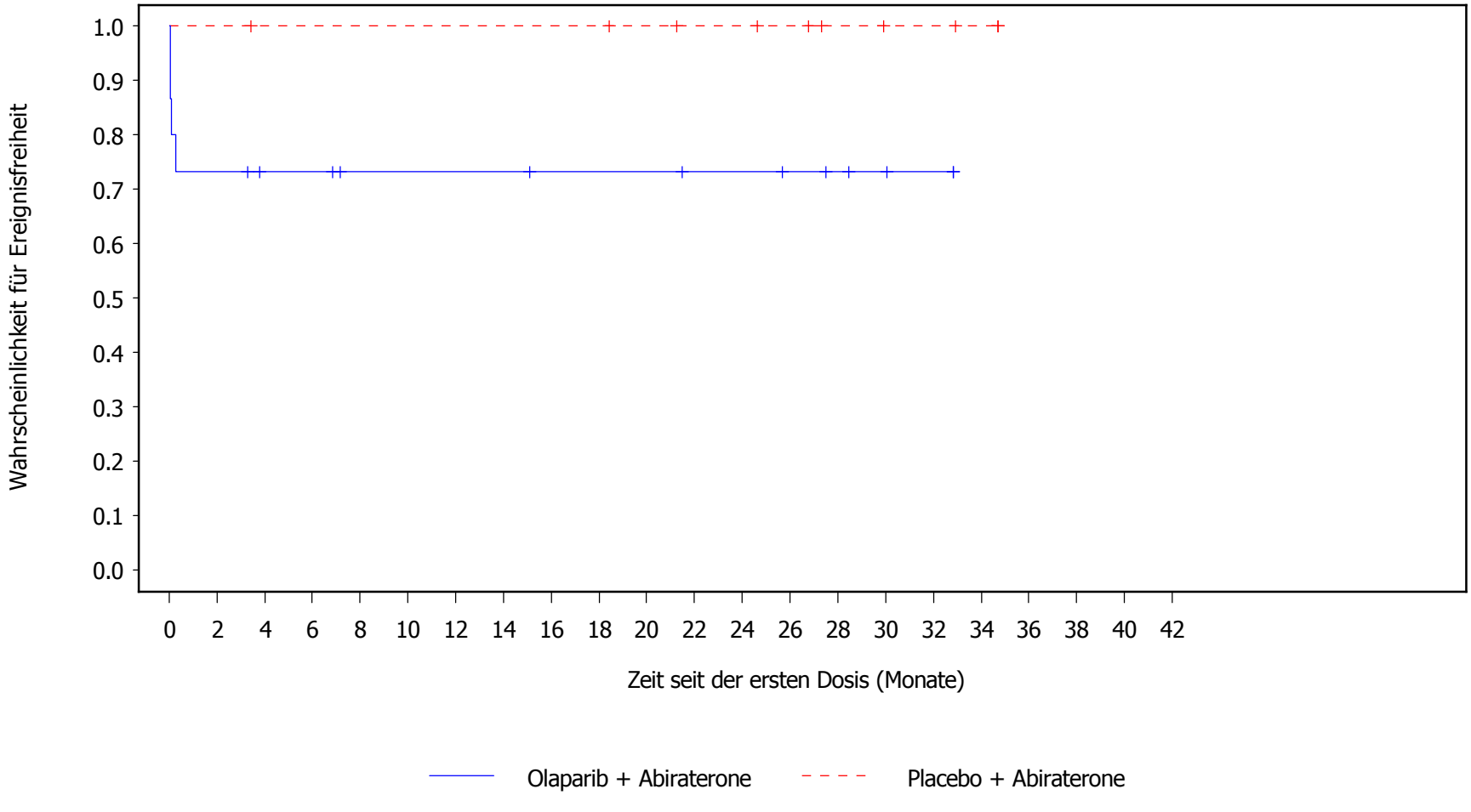
Anzahl an Patienten unter Risiko:

66	66	61	56	54	51	48	46	45	42	40	38	37	32	28	24	17	13	8	2	1	0	Olaparib + Abiraterone
72	69	61	58	51	48	43	39	37	34	33	28	25	20	16	14	11	7	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebao 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.16 PROpel: Kaplan-Meier plot of UE PT: Schwindelgefuehl for Abstammung=Andere
Safety Analysis Set, DCO 14MAR2022



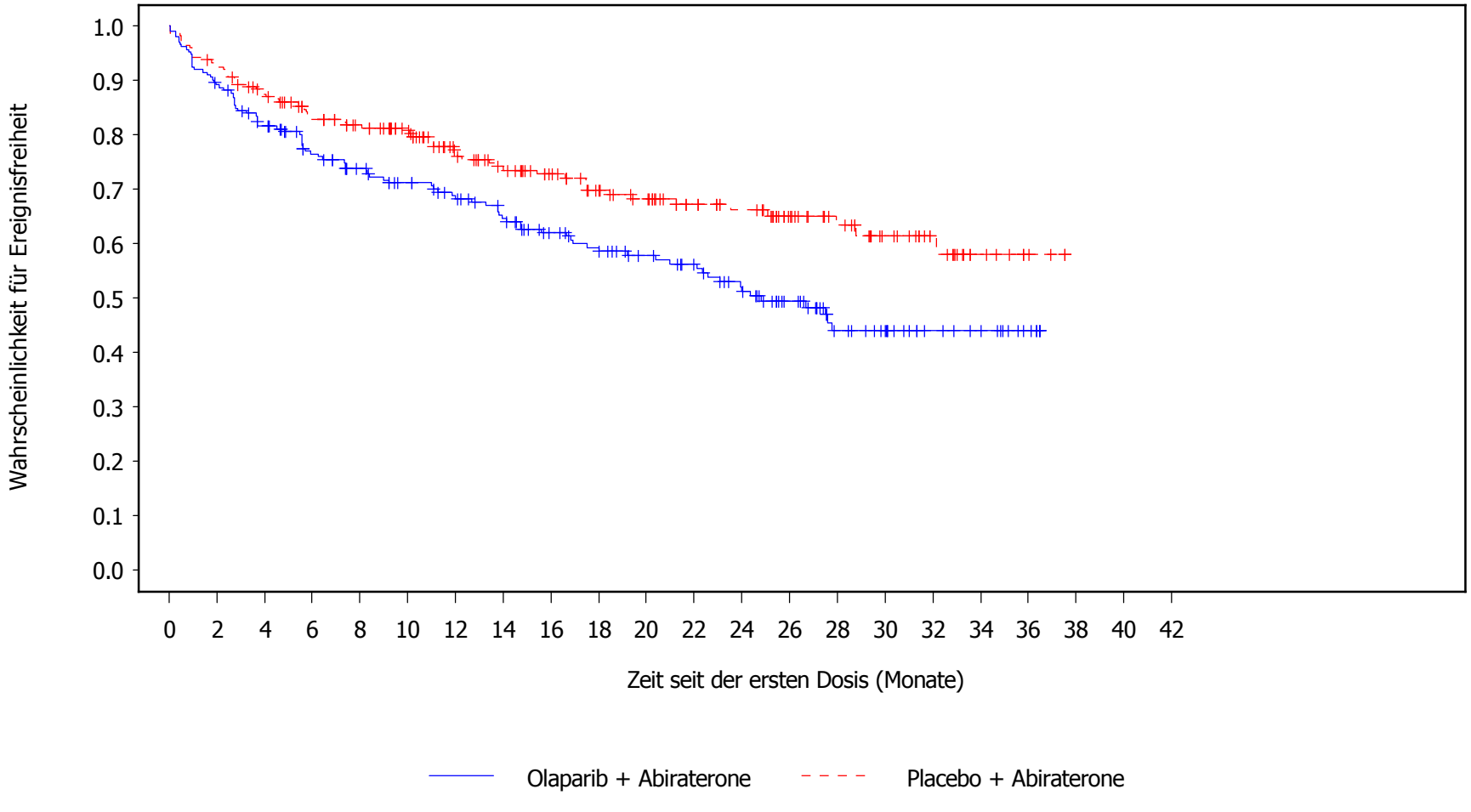
Anzahl an Patienten unter Risiko:

15	11	9	9	7	7	7	7	6	6	6	5	5	4	3	2	1	0	0	0	0	0	Olaparib + Abiraterone
9	9	8	8	8	8	8	8	8	8	7	6	6	5	3	2	2	1	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebap 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.17 PROpel: Kaplan-Meier plot of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Metastasen zu Baseline=Nur Knochen
Safety Analysis Set, DCO 14MAR2022

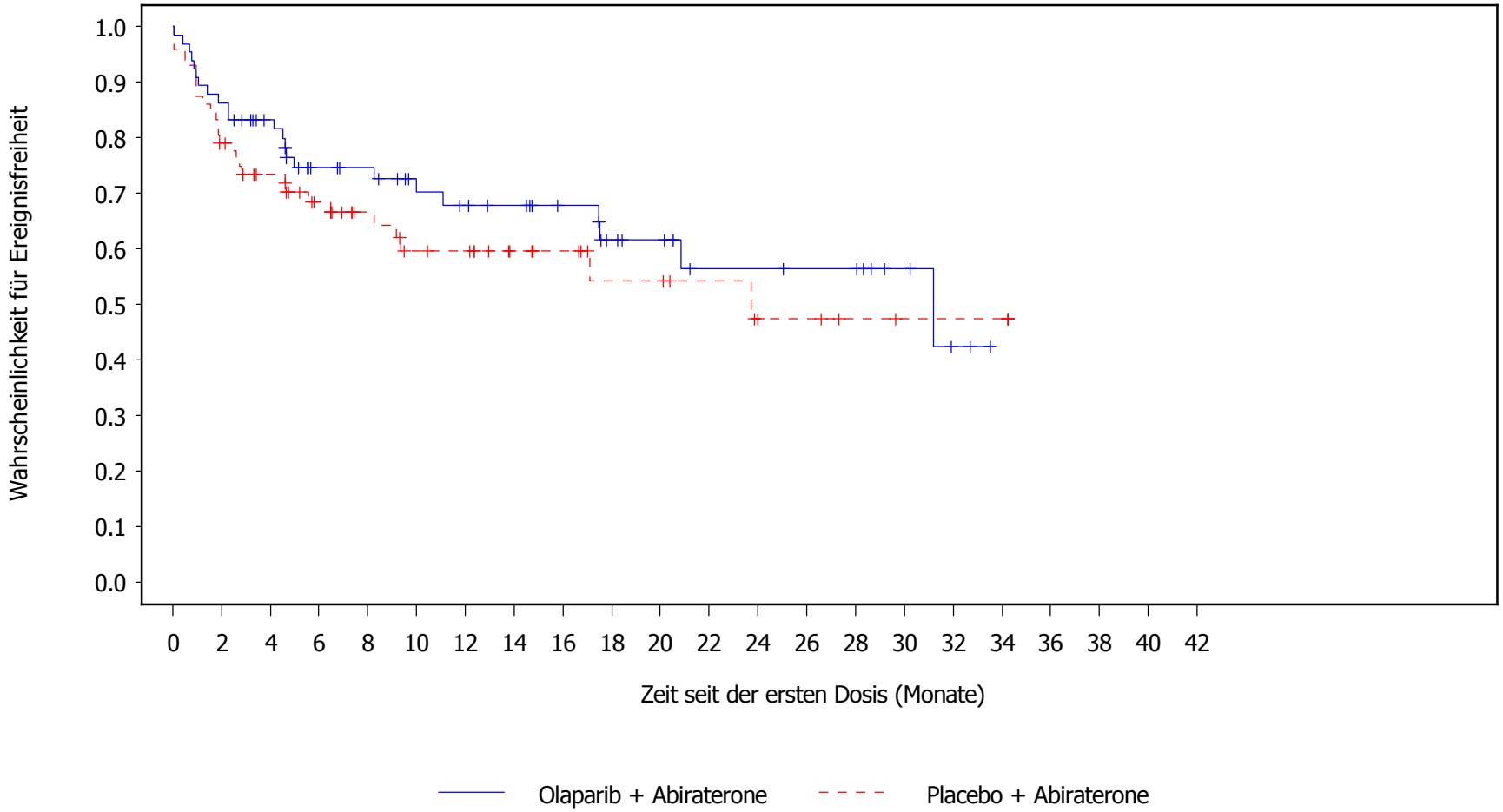


Anzahl an Patienten unter Risiko:

213	189	169	149	137	126	116	105	92	85	76	69	59	46	30	24	15	12	5	0	0	0	Olaparib + Abiraterone
226	208	192	174	163	148	125	112	101	89	81	68	61	48	38	27	18	8	3	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebaq 05DEC2022:09:12 khcs324

Figure 3.6.18 PROpel: Kaplan-Meier plot of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Metastasen zu Baseline=Viszeral
Safety Analysis Set, DCO 14MAR2022

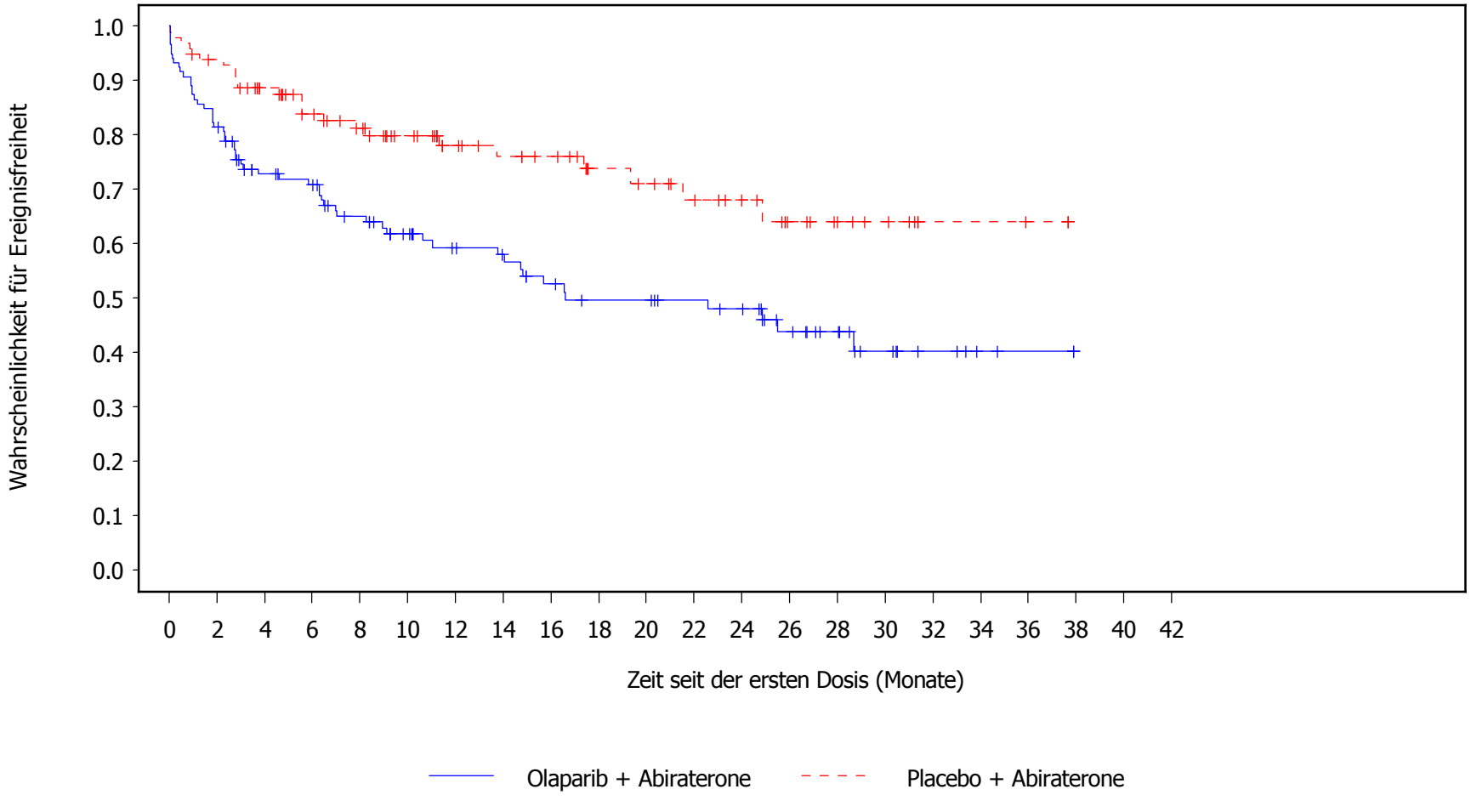


Anzahl an Patienten unter Risiko:

66	57	49	38	36	30	28	26	22	17	15	10	10	9	9	5	2	0	0	0	0	0	Olaparib + Abiraterone
72	56	46	37	29	24	23	17	14	10	10	8	5	5	3	2	2	2	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebar 05DEC2022:09:12 khcs324

Figure 3.6.19 PROpel: Kaplan-Meier plot of UE SOC: Stoffwechsel- und Ernaehrungsstoerungen for Metastasen zu Baseline=andere
Safety Analysis Set, DCO 14MAR2022



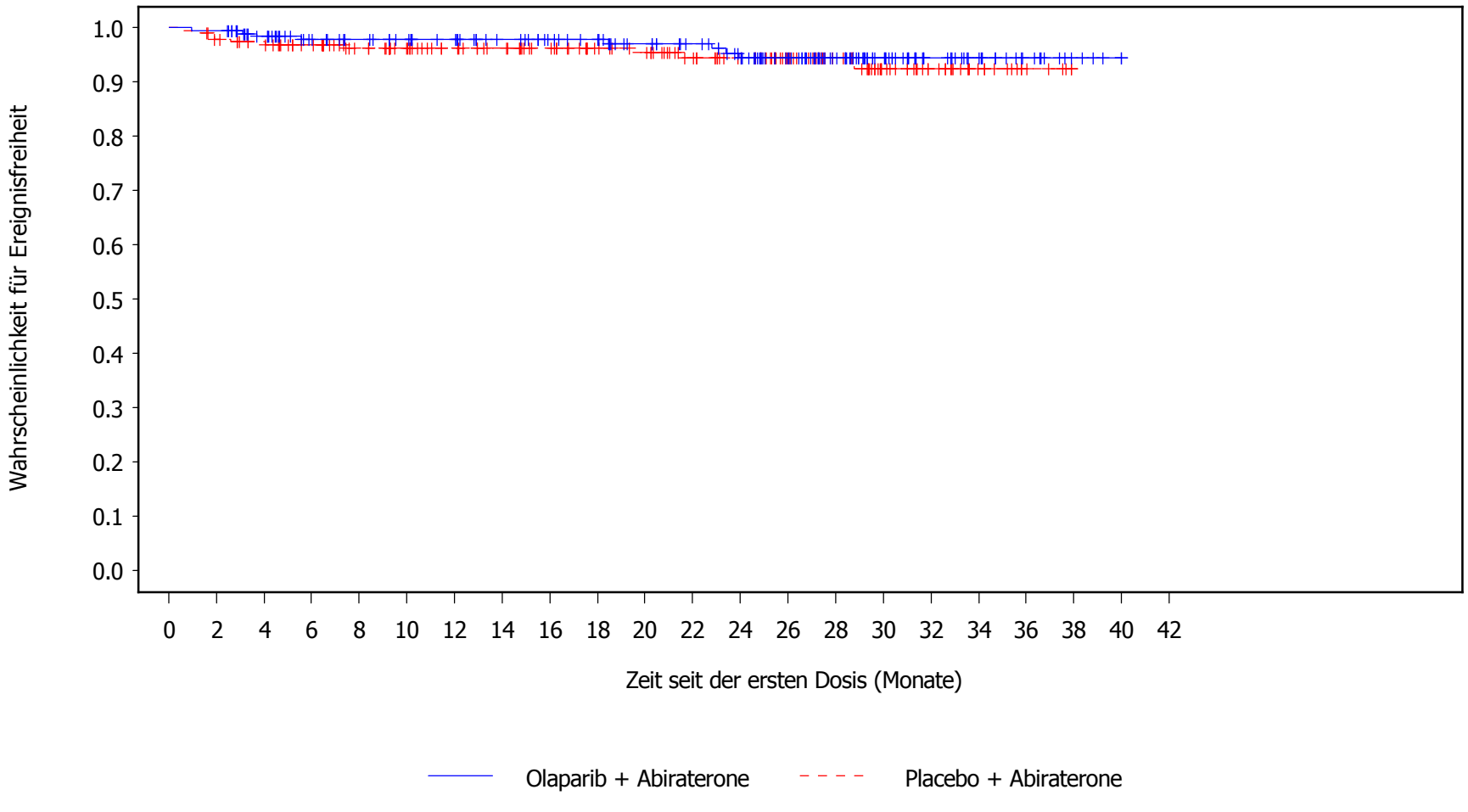
Anzahl an Patienten unter Risiko:

119	97	79	75	64	53	46	43	37	33	33	30	28	20	15	9	5	2	1	0	0	0	Olaparib + Abiraterone
98	90	79	68	61	52	42	38	35	28	26	22	18	13	10	7	2	2	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebas 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.20 PROpel: Kaplan-Meier plot of UE PT: Hypokaliaemie for PSA zu Baseline=Unter medianem PSA-Baselinewert
Safety Analysis Set, DCO 14MAR2022



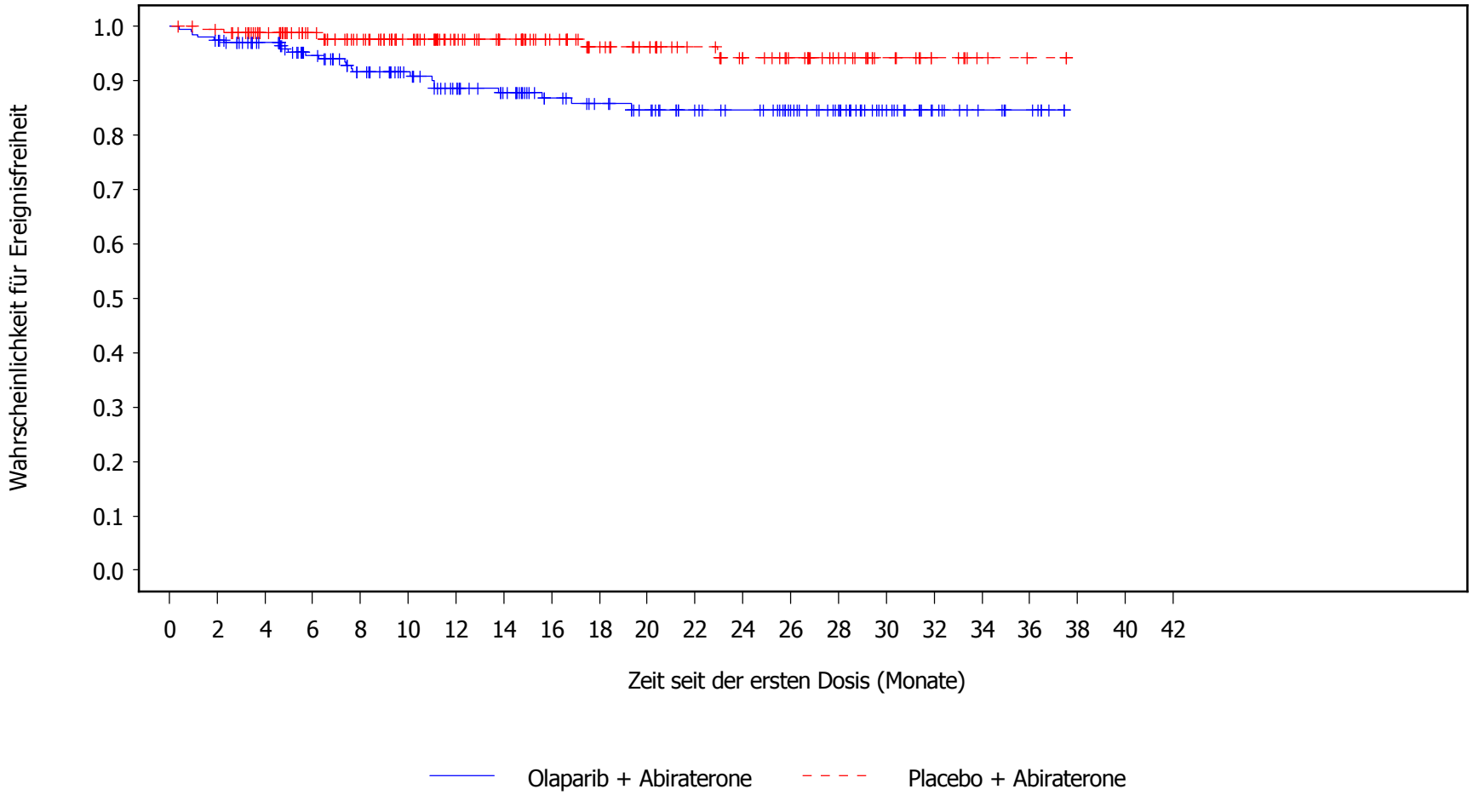
Anzahl an Patienten unter Risiko:

196	195	182	168	162	157	152	143	136	132	122	115	105	88	67	46	28	20	11	4	1	0	Olaparib + Abiraterone
199	192	185	175	160	148	138	131	122	110	105	93	83	65	53	35	24	13	5	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebat 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.21 PROpel: Kaplan-Meier plot of UE PT: Hypokaliaemie for PSA zu Baseline=Über medianem PSA-Baselinewert
Safety Analysis Set, DCO 14MAR2022

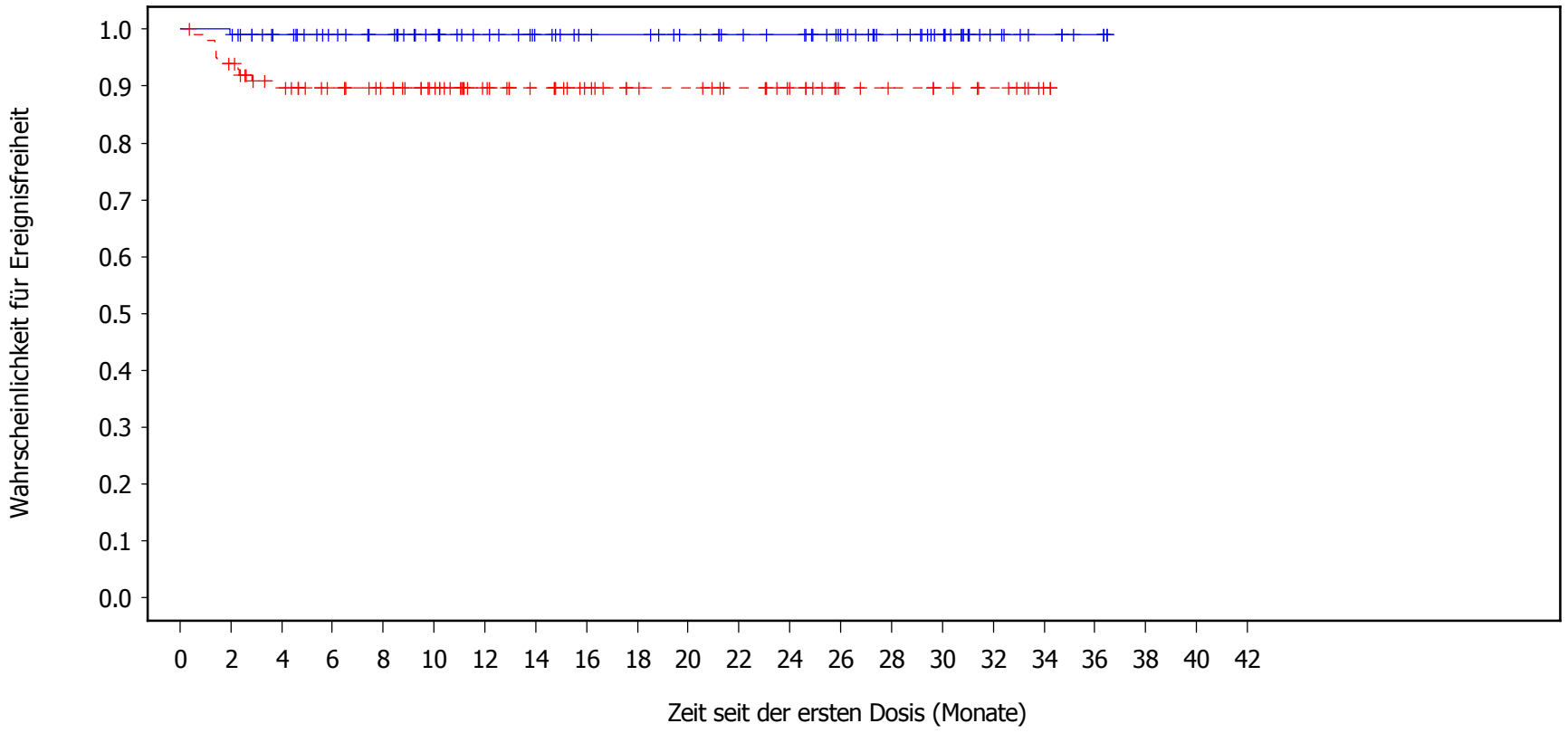


Anzahl an Patienten unter Risiko:

200	194	179	159	141	125	112	101	87	81	74	64	60	50	40	25	15	9	6	0	0	0	Olaparib + Abiraterone
196	192	176	159	142	125	105	93	78	65	58	48	40	34	25	15	8	3	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebau 05DEC2022:09:12 khcs324

Figure 3.6.22 PROpel: Kaplan-Meier plot of UE PT: Alaninaminotransferase erhoeht for HRRm-Status basierend auf einem ctDNA-Test=HRRm
Safety Analysis Set, DCO 14MAR2022

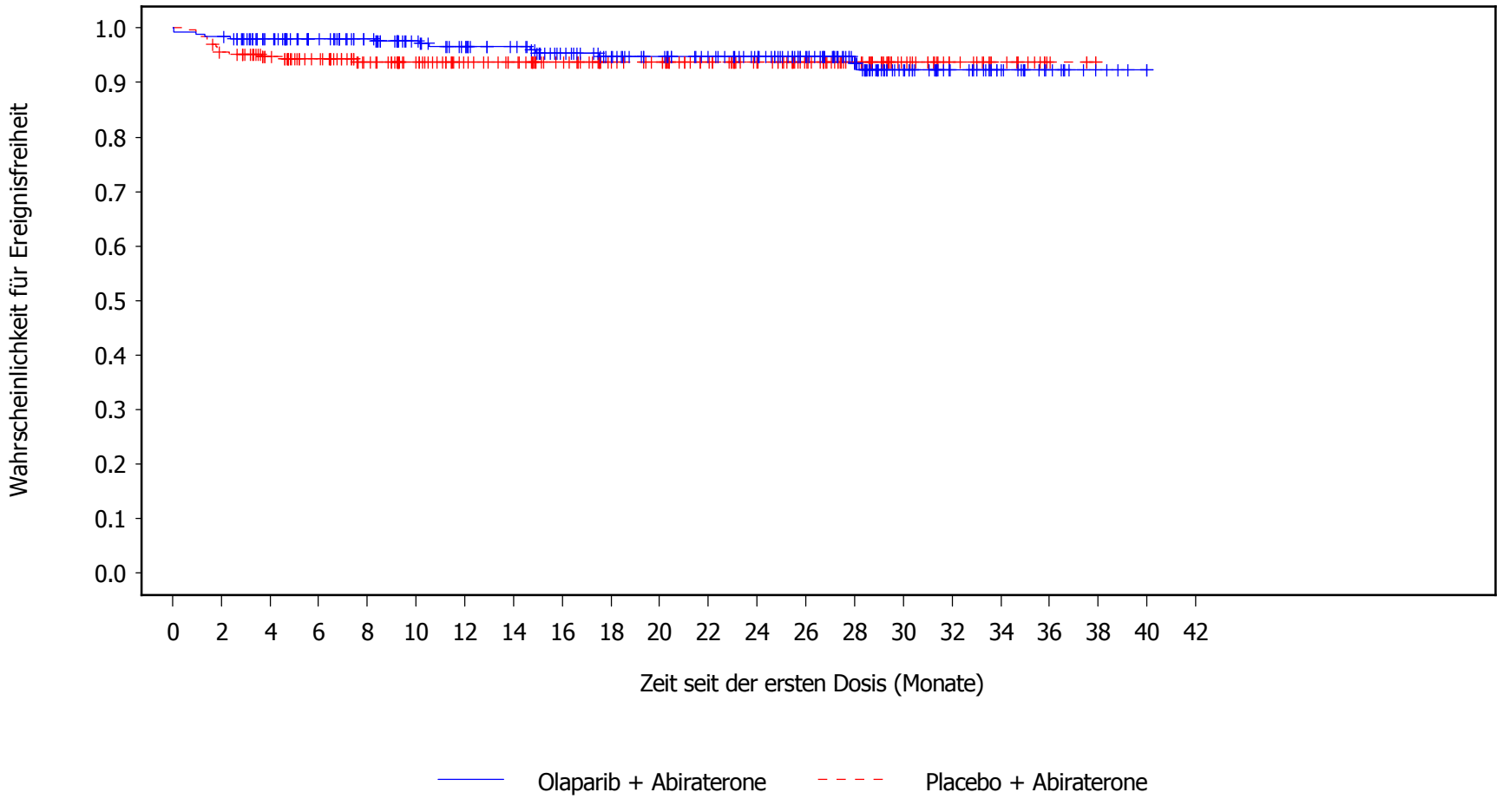


Anzahl an Patienten unter Risiko:

98	97	89	82	78	71	65	59	54	53	49	45	43	34	28	21	10	6	3	0	0	0	Olaparib + Abiraterone
100	92	82	74	68	60	49	43	36	31	30	26	21	14	12	10	7	1	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebav 05DEC2022:09:12 khcs324

Figure 3.6.23 PROpel: Kaplan-Meier plot of UE PT: Alaninaminotransferase erhoeht for HRRm-Status basierend auf einem ctDNA-Test=Nicht-HRRm
Safety Analysis Set, DCO 14MAR2022



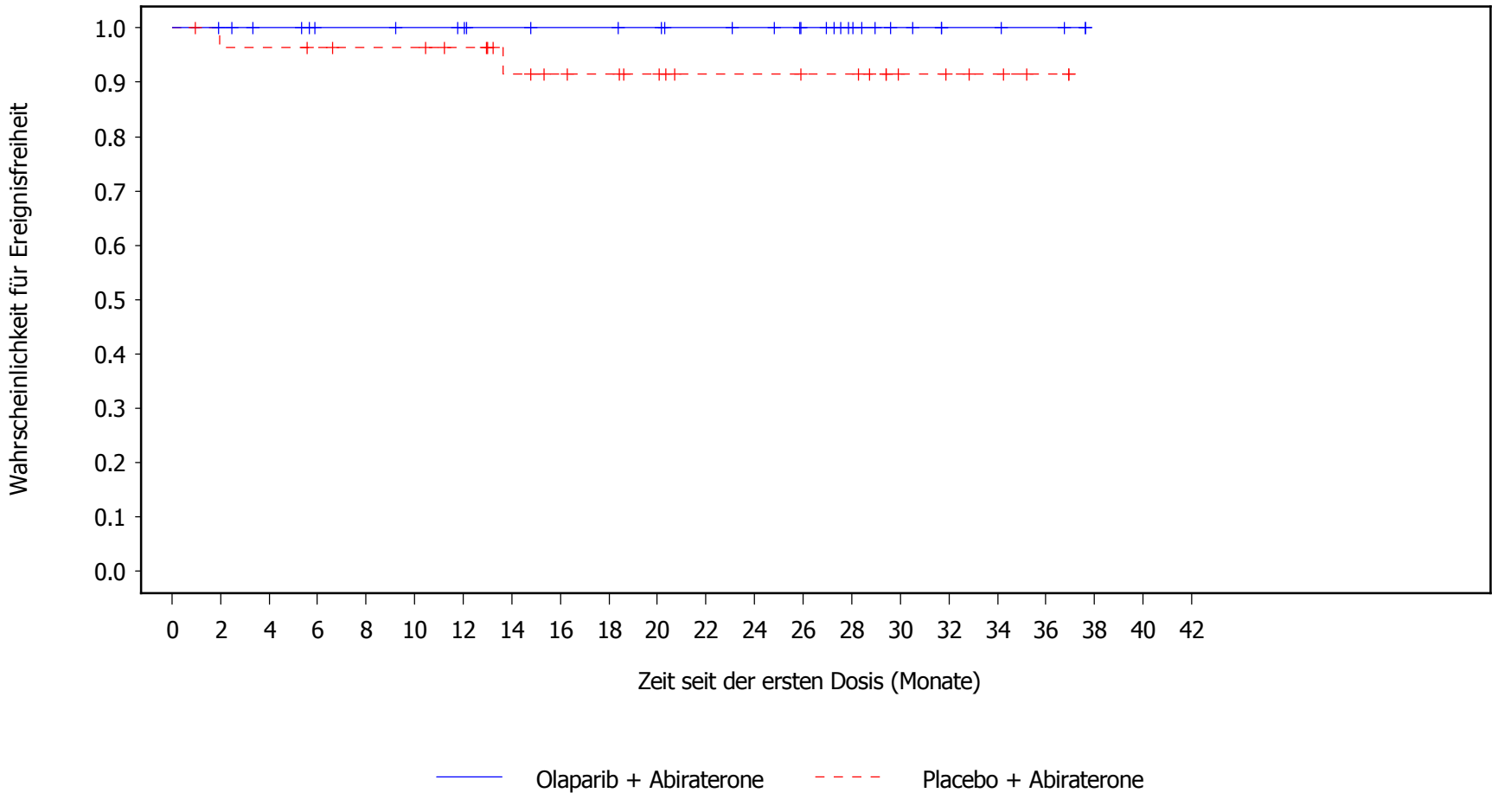
Anzahl an Patienten unter Risiko:

268	264	245	228	212	192	181	172	157	146	136	127	118	99	75	48	32	21	11	4	1	0	Olaparib + Abiraterone
267	253	235	218	197	178	162	154	140	124	118	103	89	74	56	36	22	14	4	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebaw 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.24 PROpel: Kaplan-Meier plot of UE PT: Alaninaminotransferase erhoeht for HRRm-Status basierend auf einem ctDNA-Test=Unbekannt
Safety Analysis Set, DCO 14MAR2022



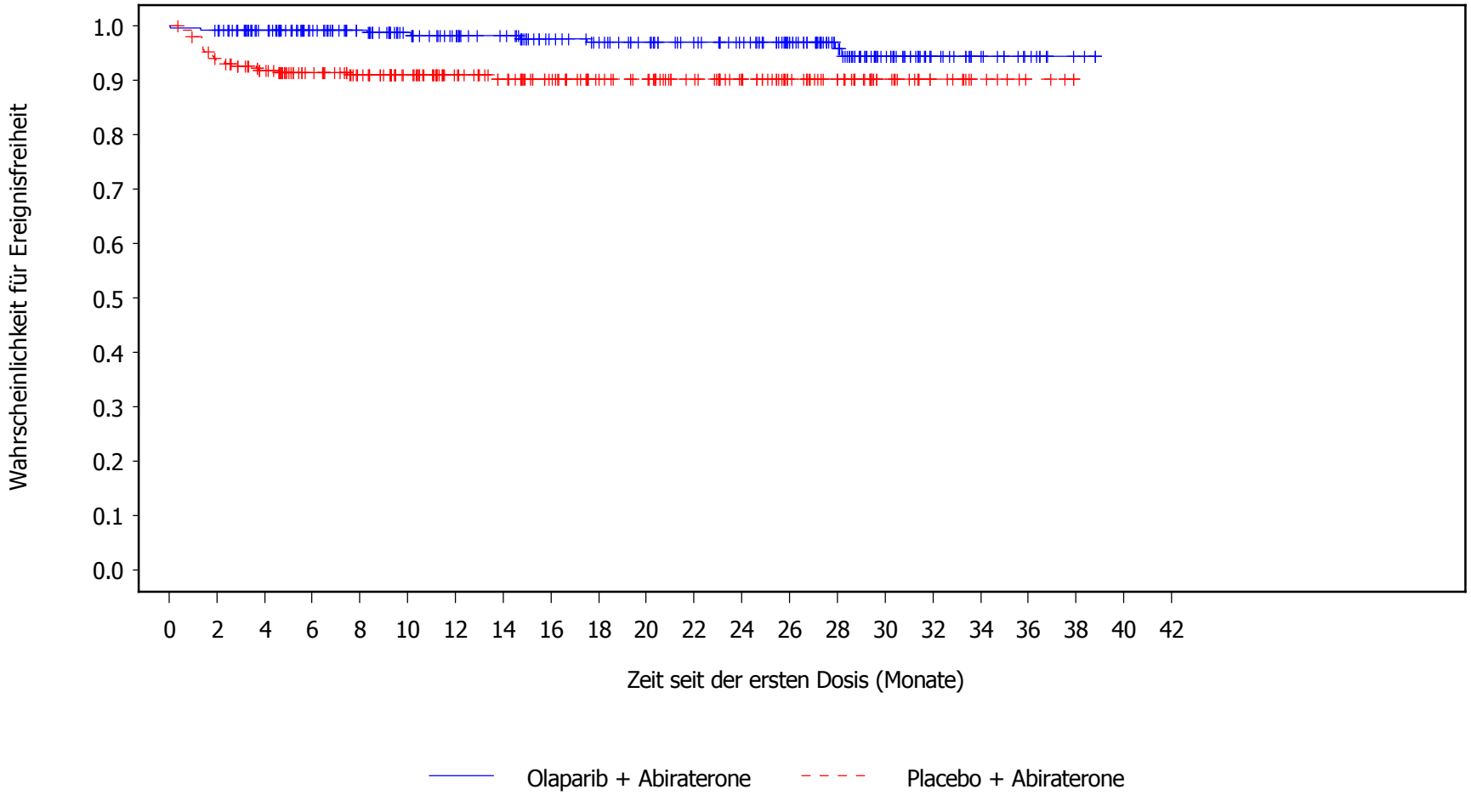
Anzahl an Patienten unter Risiko:

32	31	29	26	26	25	24	22	21	21	20	18	17	14	10	6	3	3	2	0	0	0	Olaparib + Abiraterone
29	27	27	26	25	25	23	19	17	16	14	11	11	10	10	5	4	3	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebax 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.25 PROpel: Kaplan-Meier plot of UE PT: Alaninaminotransferase erhoeht for Abstammung=Kaukasisch
Safety Analysis Set, DCO 14MAR2022



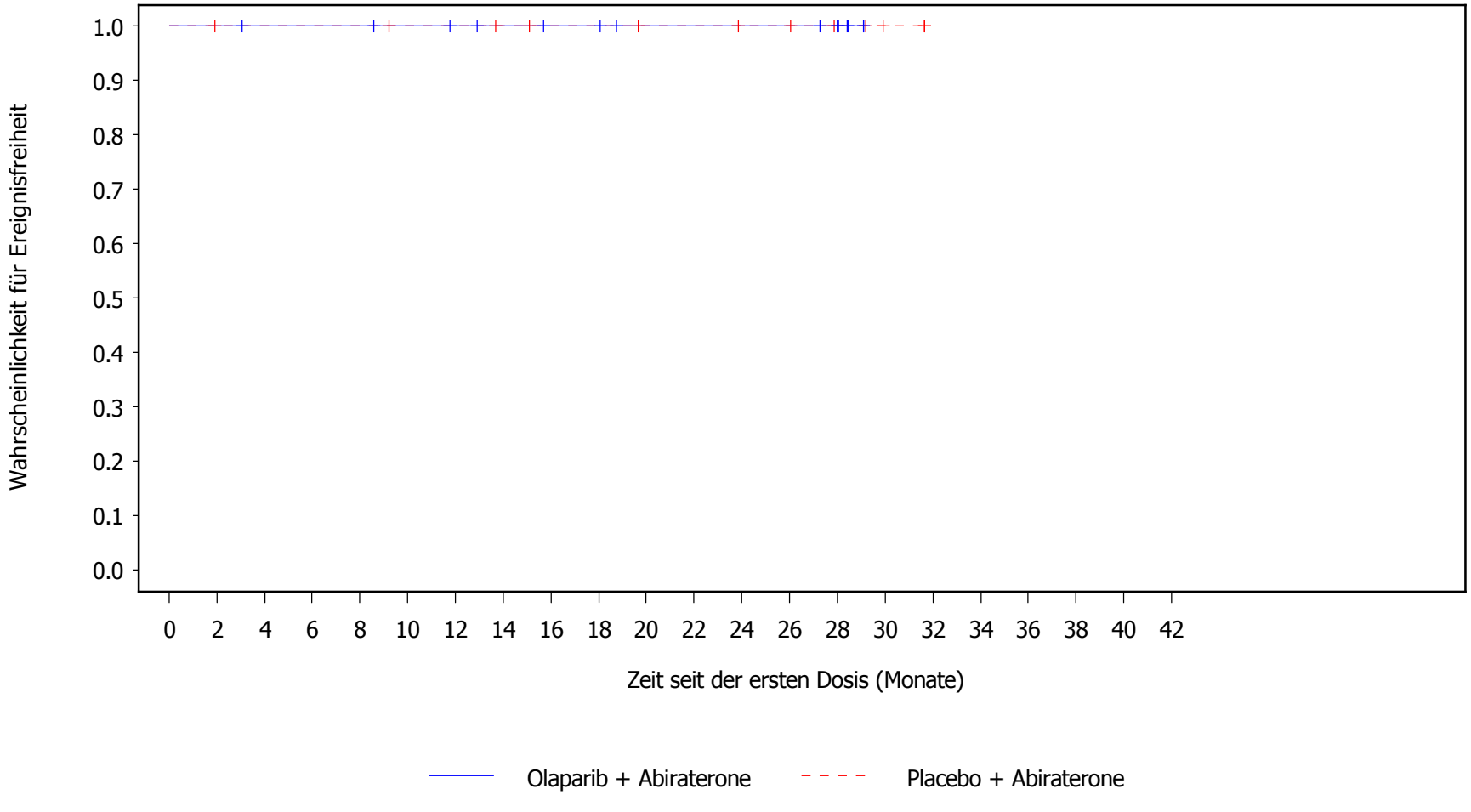
Anzahl an Patienten unter Risiko:

281	278	259	237	220	197	184	173	156	149	140	129	120	100	74	48	26	17	9	2	0	0	Olaparib + Abiraterone
274	253	235	212	195	173	152	140	124	108	102	88	74	58	46	27	15	8	3	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebay 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.26 PROpel: Kaplan-Meier plot of UE PT: Alaninaminotransferase erhoeht for Abstammung=Afroamerikanisch
Safety Analysis Set, DCO 14MAR2022

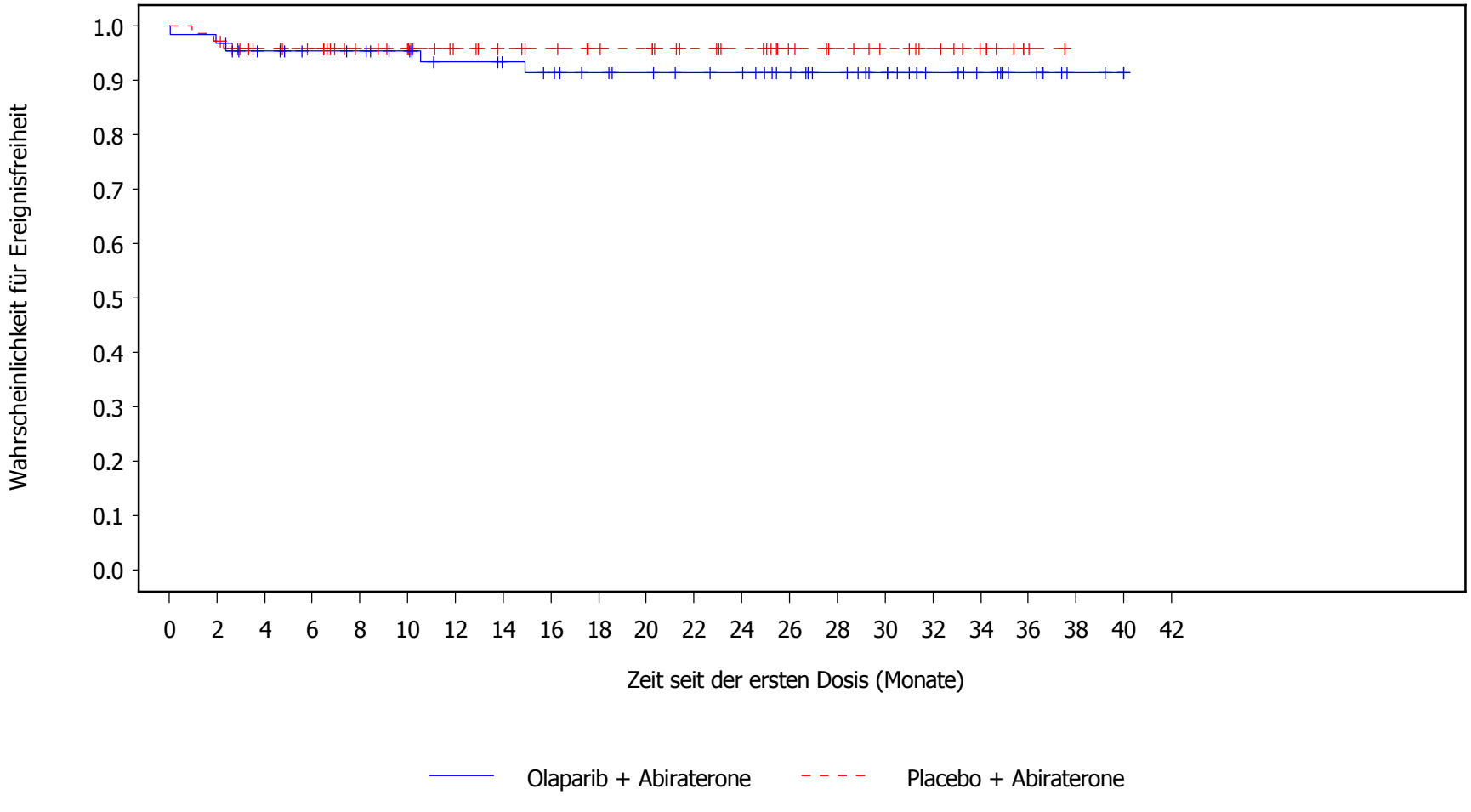


Anzahl an Patienten unter Risiko:

14	14	13	13	13	12	11	10	9	9	7	7	7	7	4	0	0	0	0	0	0	0	Olaparib + Abiraterone
11	10	10	10	10	9	9	8	7	7	6	6	5	5	3	1	0	0	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebaz 05DEC2022:09:12 khcs324

Figure 3.6.27 PROpel: Kaplan-Meier plot of UE PT: Alaninaminotransferase erhoeht for Abstammung=Asiatisch
Safety Analysis Set, DCO 14MAR2022



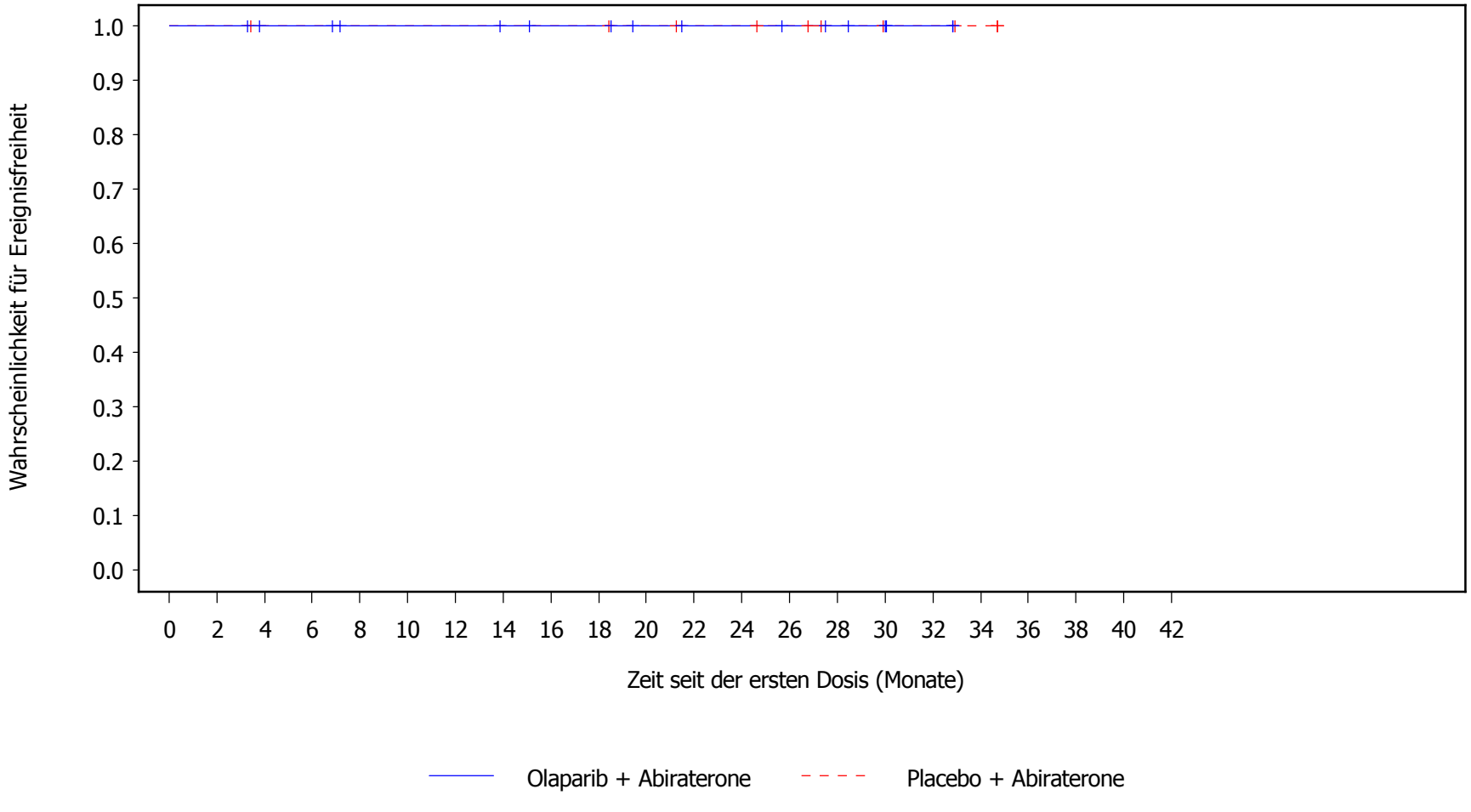
Anzahl an Patienten unter Risiko:

66	64	59	56	55	52	48	46	44	41	39	37	36	31	27	23	16	12	7	2	1	0	Olaparib + Abiraterone
72	70	63	60	53	50	44	41	39	36	35	30	27	21	18	15	12	8	2	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebba 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.28 PROpel: Kaplan-Meier plot of UE PT: Alaninaminotransferase erhoeht for Abstammung=Andere
Safety Analysis Set, DCO 14MAR2022



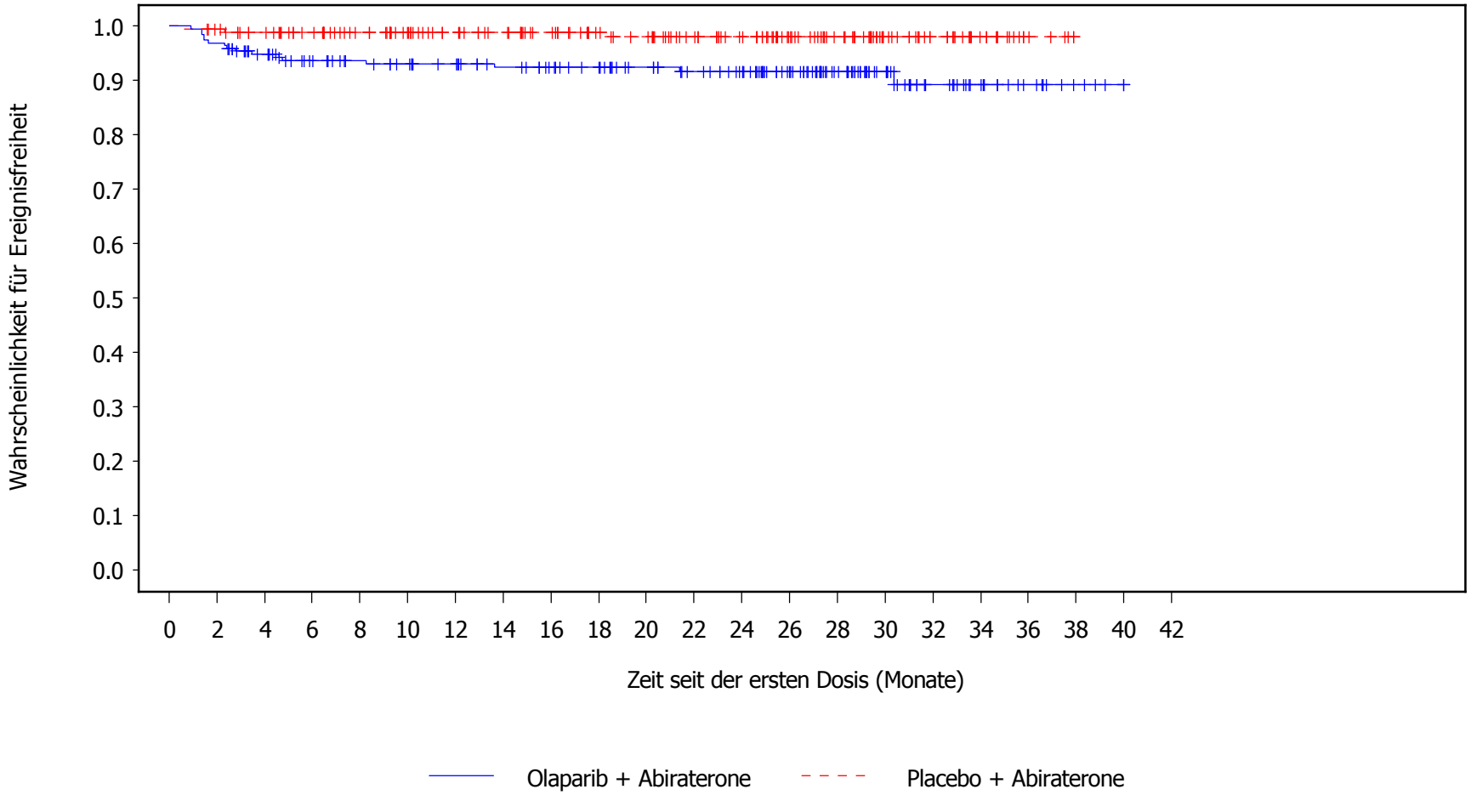
Anzahl an Patienten unter Risiko:

15	15	13	13	11	11	11	10	9	9	7	6	6	5	4	2	1	0	0	0	0	0	Olaparib + Abiraterone
9	9	8	8	8	8	8	8	8	8	7	6	6	5	3	2	2	1	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbb 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.29 PROpel: Kaplan-Meier plot of UE PT: Lymphozytenzahl erniedrigt for PSA zu Baseline=Unter medianem PSA-Baselinewert
Safety Analysis Set, DCO 14MAR2022



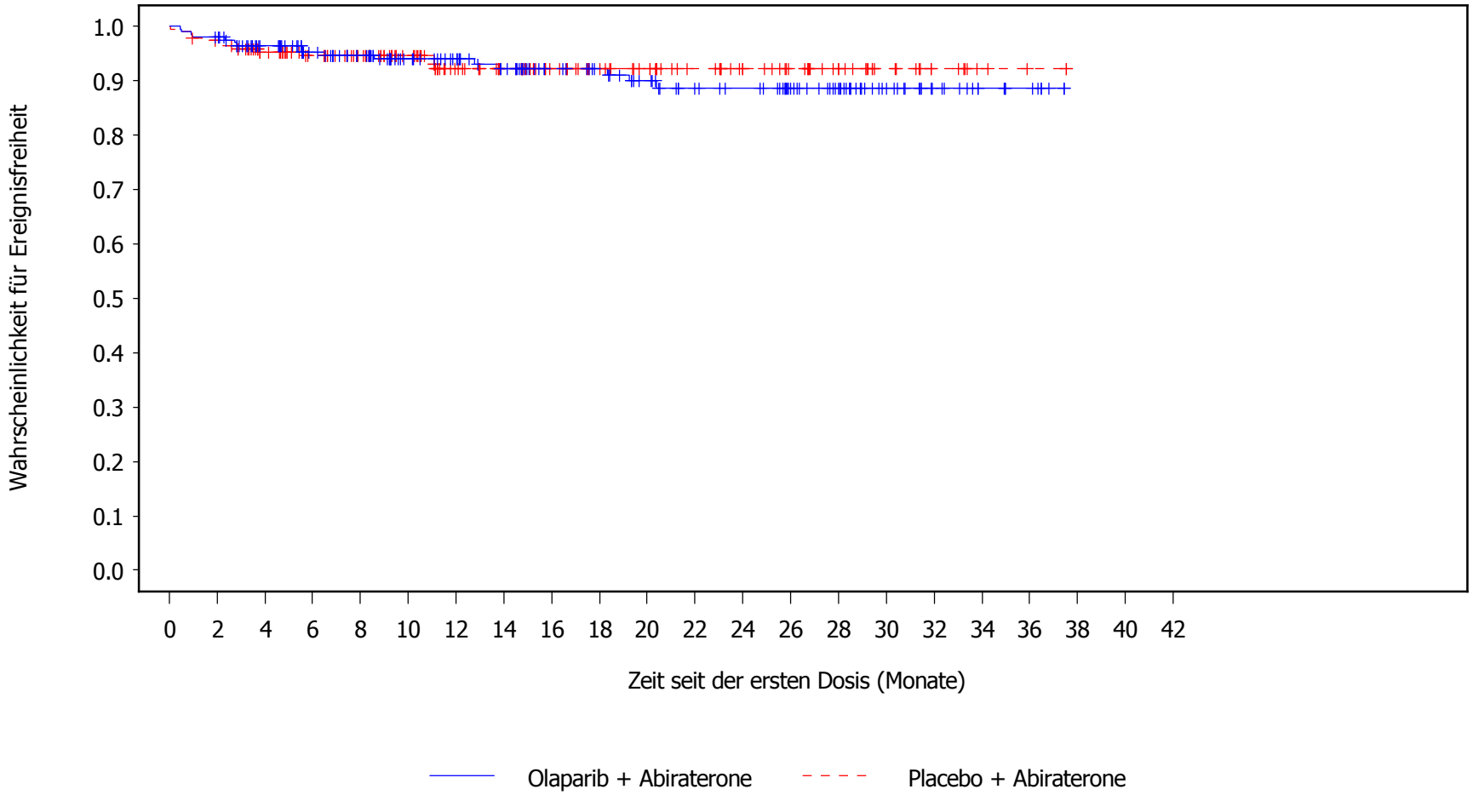
Anzahl an Patienten unter Risiko:

196	190	176	163	156	151	146	138	132	127	118	110	103	84	63	43	26	18	10	4	1	0	Olaparib + Abiraterone
199	195	187	178	165	152	142	135	126	113	108	96	86	69	57	38	27	16	5	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbc 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.30 PROpel: Kaplan-Meier plot of UE PT: Lymphozytenzahl erniedrigt for PSA zu Baseline=Über medianem PSA-Baselinewert
Safety Analysis Set, DCO 14MAR2022



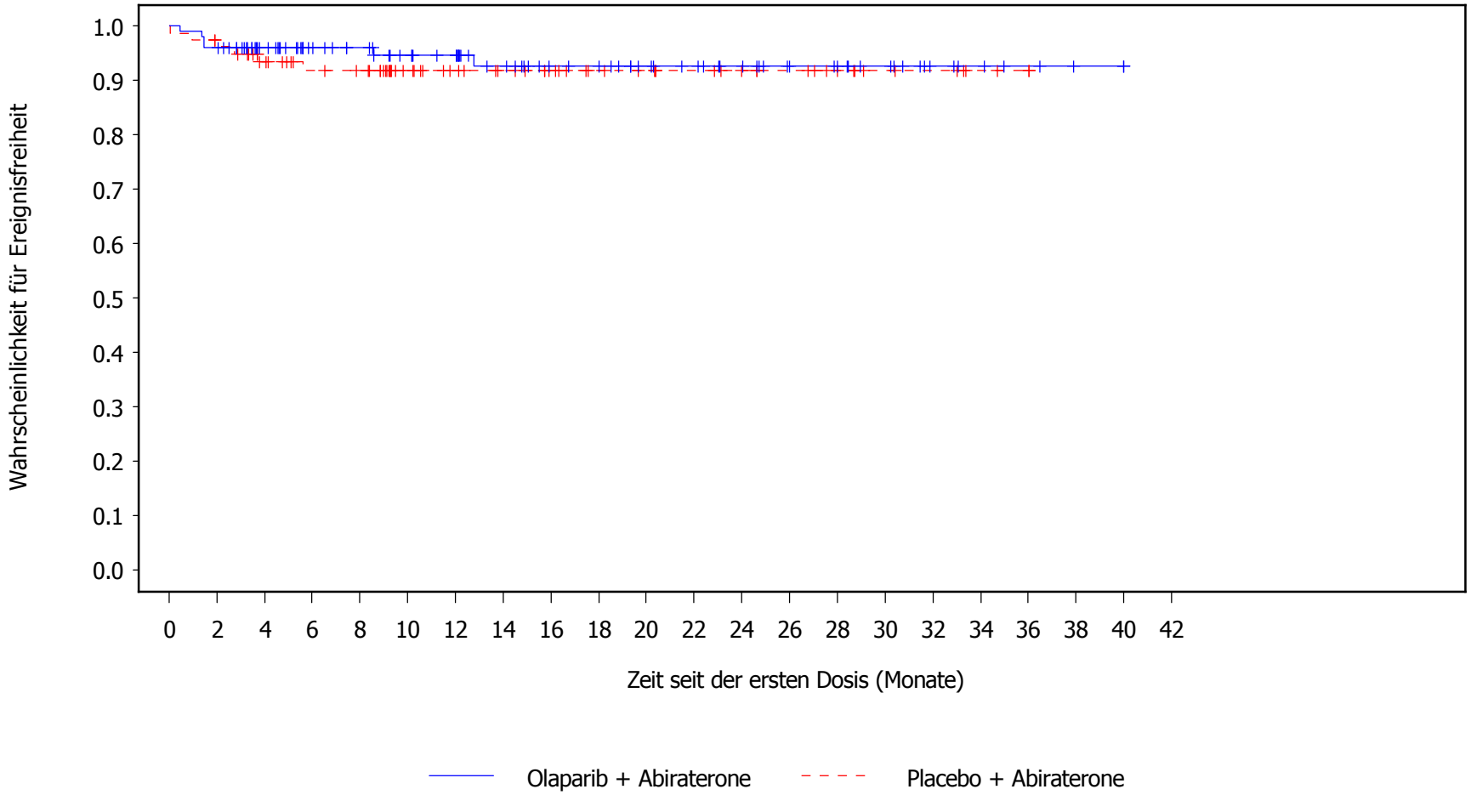
Anzahl an Patienten unter Risiko:

200	195	175	156	143	123	114	103	89	83	74	64	61	50	40	25	16	9	6	0	0	0	Olaparib + Abiraterone
196	189	171	155	141	124	102	91	76	65	58	48	39	33	24	15	8	3	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbd 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.31 PROpel: Kaplan-Meier plot of UE PT: Lymphozytenzahl erniedrigt for Schmerzen zu baseline=Symptomatisch
Safety Analysis Set, DCO 14MAR2022



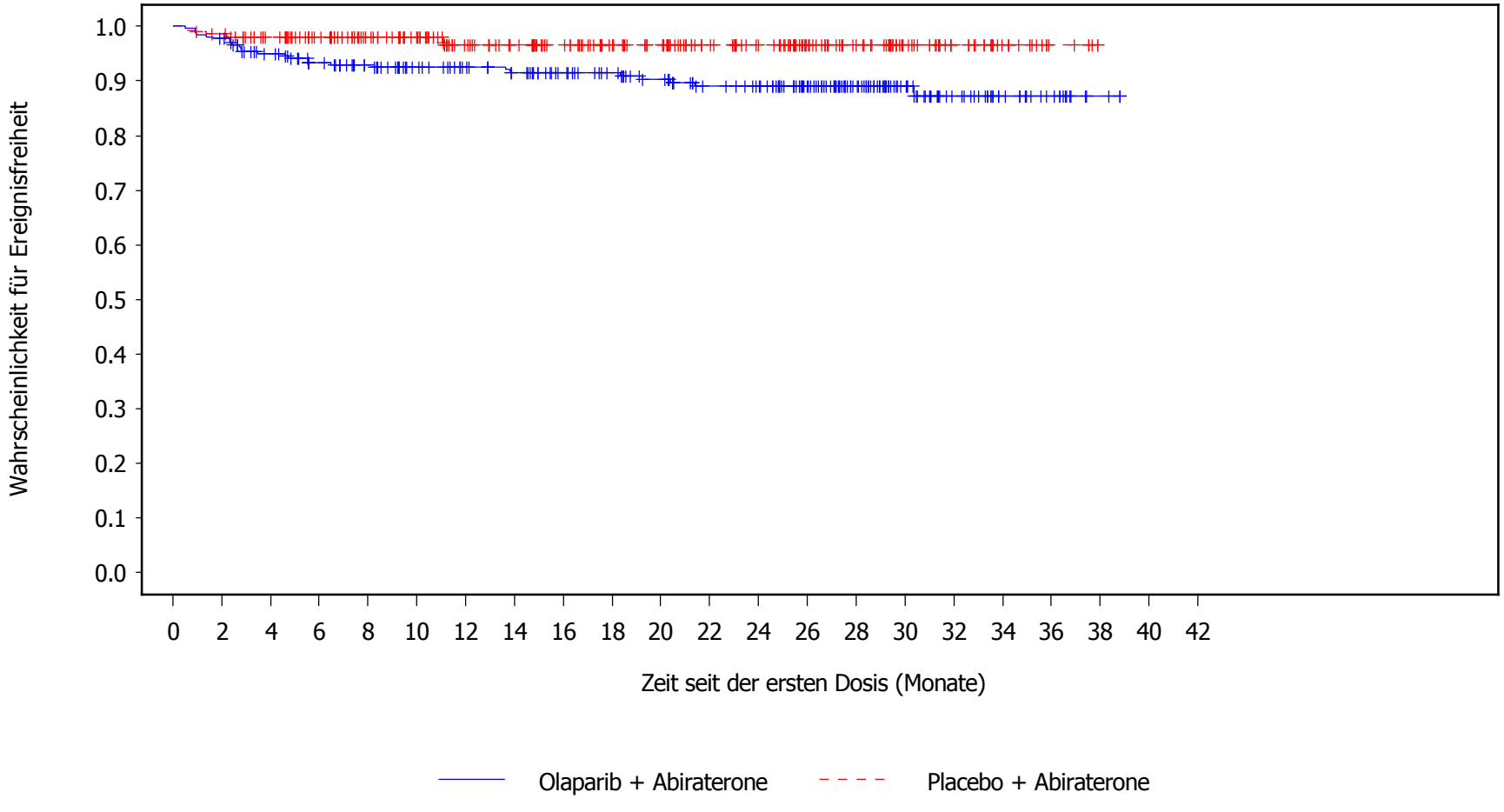
Anzahl an Patienten unter Risiko:

103	99	84	71	66	59	55	45	38	37	31	28	24	18	16	13	7	5	3	1	1	0	Olaparib + Abiraterone
80	76	66	59	57	43	37	33	28	23	21	18	15	13	9	6	5	2	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbe 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.32 PROpel: Kaplan-Meier plot of UE PT: Lymphozytenzahl erniedrigt for Schmerzen zu baseline=Asymptomatisch/mild symptomatisch
Safety Analysis Set, DCO 14MAR2022



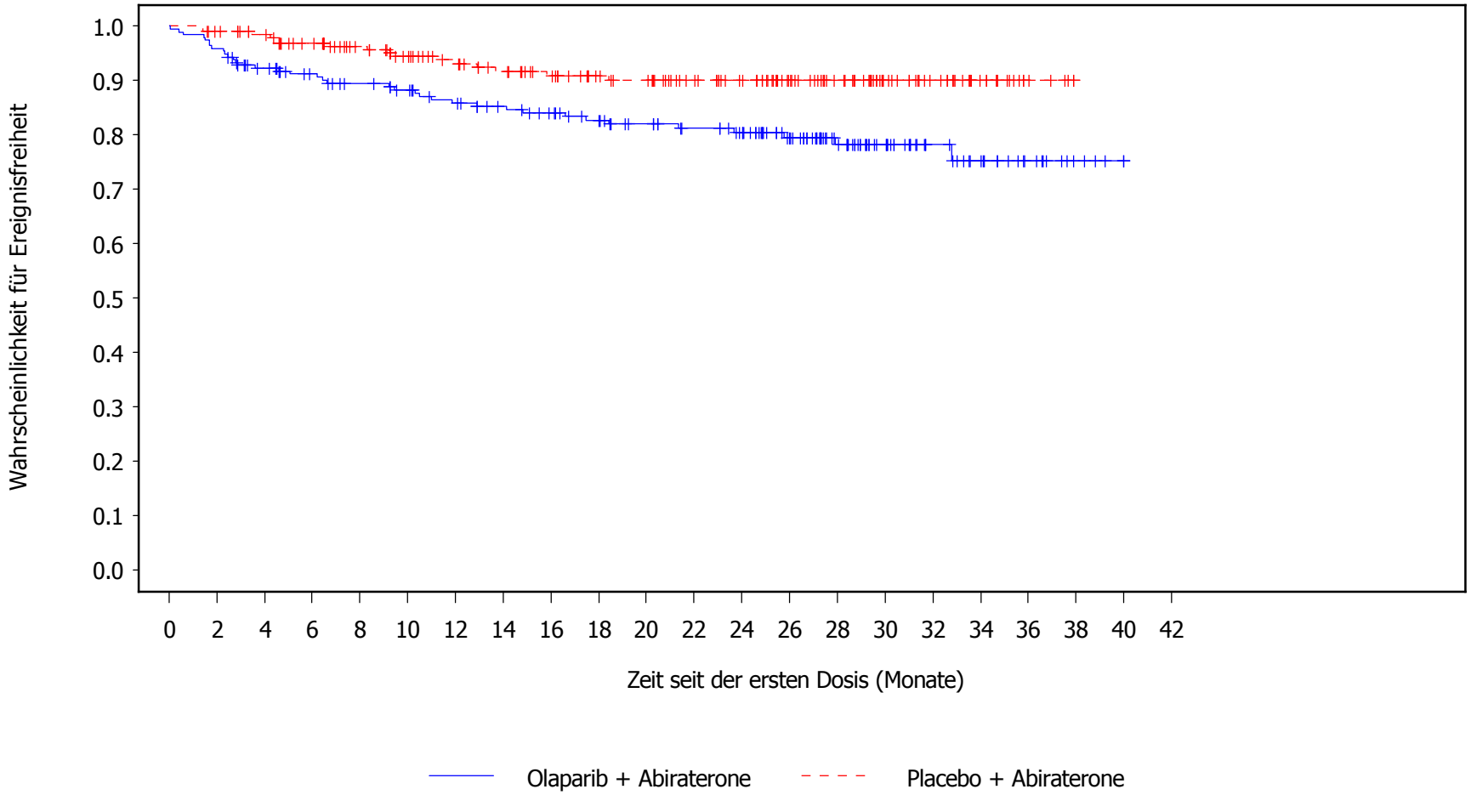
Anzahl an Patienten unter Risiko:

266	259	241	226	213	197	187	178	166	157	147	133	128	105	80	52	33	20	12	2	0	0	Olaparib + Abiraterone
294	288	273	255	232	216	192	179	161	142	133	114	100	80	66	45	28	16	5	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbf 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.33 PROpel: Kaplan-Meier plot of Abbruch wegen UE for PSA zu Baseline=Unter medianem PSA-Baselinewert
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

196	188	173	163	156	150	142	135	129	122	114	107	101	83	61	43	27	20	11	4	1	0	Olaparib + Abiraterone
199	194	187	176	161	148	139	130	122	111	107	95	86	69	57	38	28	16	5	0	0	0	Placebo + Abiraterone

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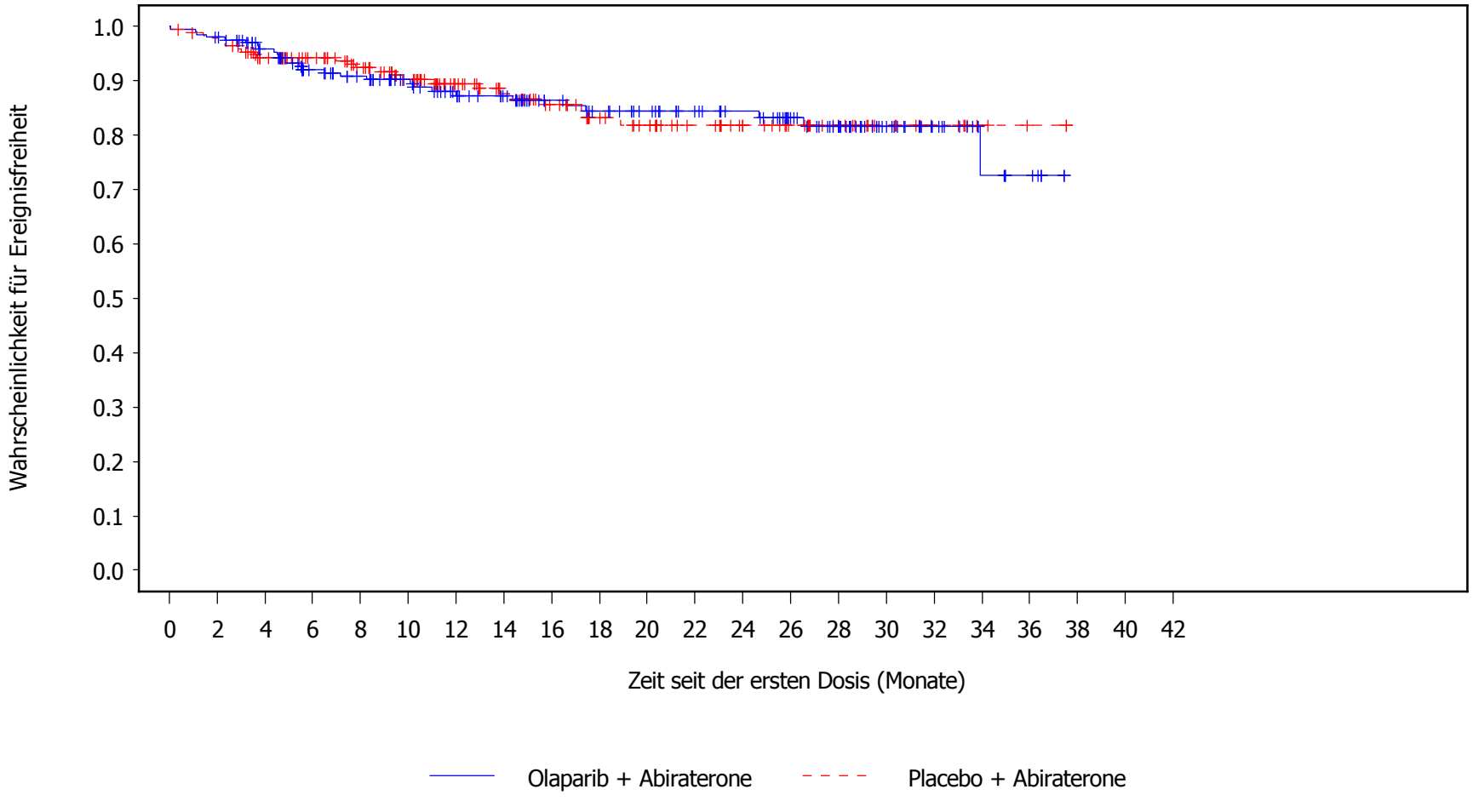
Figure 3.6.34 PROpel: Kaplan-Meier plot of Abbruch wegen UE for PSA zu Baseline=Über medianem PSA-Baselinewert
Safety Analysis Set, DCO 14MAR2022



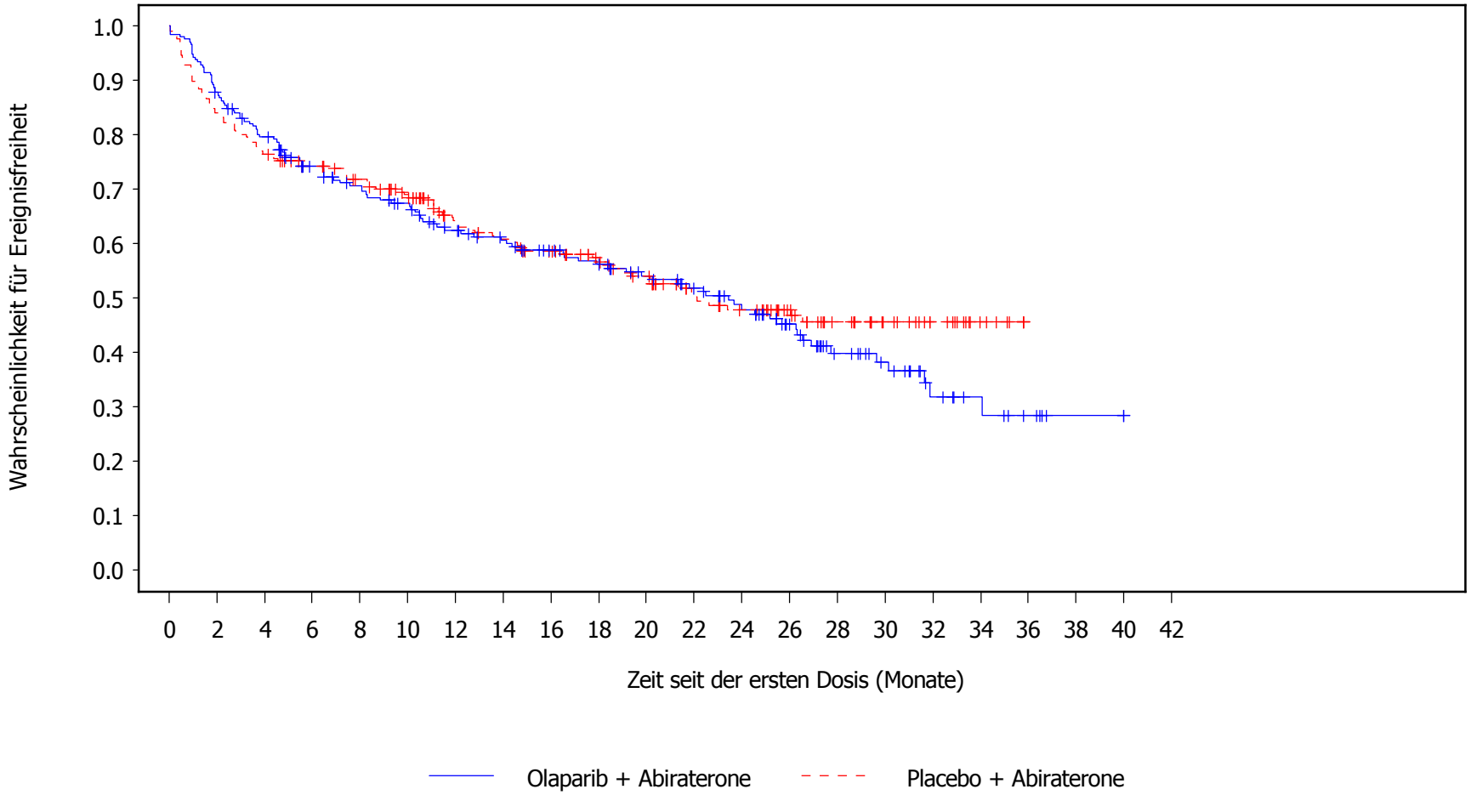
Anzahl an Patienten unter Risiko:

200	195	178	157	145	127	114	105	91	85	78	70	65	53	42	27	17	8	5	0	0	0	Olaparib + Abiraterone
196	190	173	157	141	124	105	91	76	64	58	48	39	33	24	15	8	3	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbh 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.35 PROpel: Kaplan-Meier plot of Schwere UE mit max. CTCAE Grad>=3 for Metastasen zu Baseline=Nur Knochen
Safety Analysis Set, DCO 14MAR2022



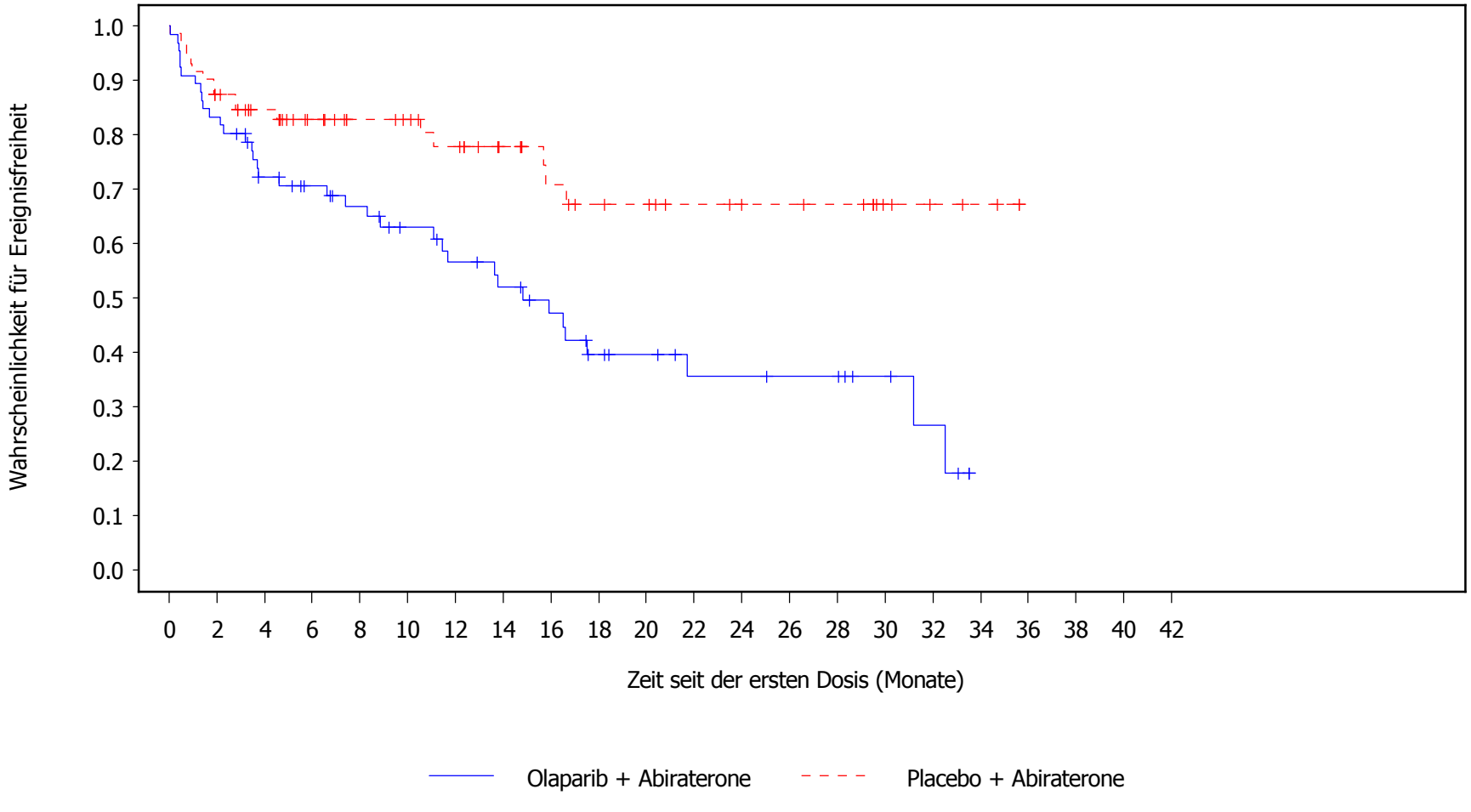
Anzahl an Patienten unter Risiko:

213	186	166	144	133	123	109	101	91	85	76	68	59	45	30	23	13	9	5	1	1	0	Olaparib + Abiraterone
226	190	173	161	151	138	116	108	100	89	79	64	57	45	33	23	15	6	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbi 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.36 PROpel: Kaplan-Meier plot of Schwere UE mit max. CTCAE Grad>=3 for Metastasen zu Baseline=Viszeral
Safety Analysis Set, DCO 14MAR2022

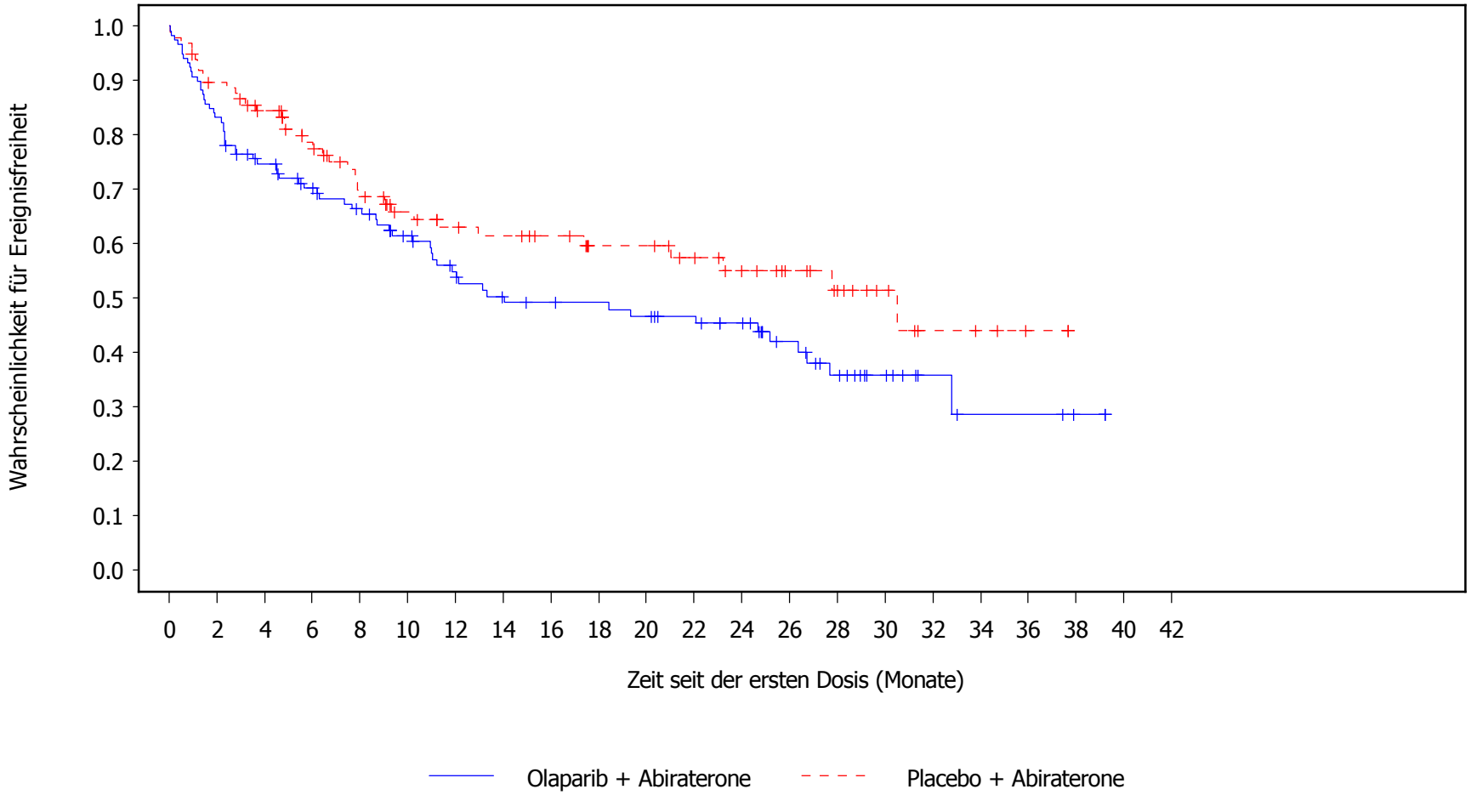


Anzahl an Patienten unter Risiko:

66	55	44	39	35	30	26	23	19	14	12	9	9	8	8	5	3	0	0	0	0	0	Olaparib + Abiraterone
72	61	52	44	37	35	31	25	20	17	16	13	11	11	10	5	3	2	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbj 05DEC2022:09:12 khcs324

Figure 3.6.37 PROpel: Kaplan-Meier plot of Schwere UE mit max. CTCAE Grad>=3 for Metastasen zu Baseline=andere
Safety Analysis Set, DCO 14MAR2022



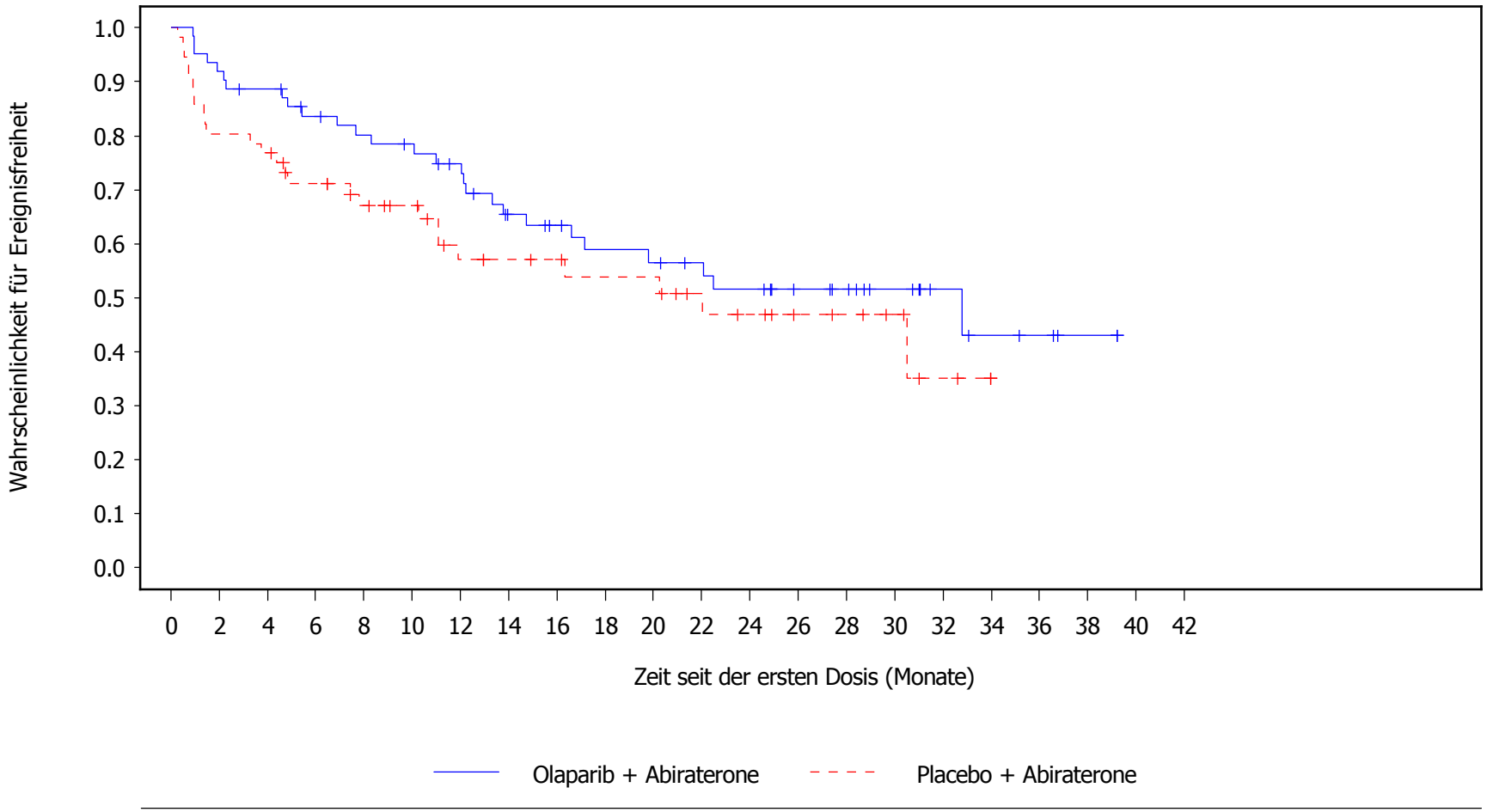
Anzahl an Patienten unter Risiko:

119	99	85	76	69	58	49	43	41	40	38	35	31	22	16	10	5	3	3	1	0	0	Olaparib + Abiraterone
98	86	77	66	55	46	41	39	36	30	30	26	21	17	13	8	4	3	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbk 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.38 PROpel: Kaplan-Meier plot of Schwere UE mit max. CTCAE Grad>=3 for HRRm-Status basierend auf einem Tumorgewebetest=HRRm
Safety Analysis Set, DCO 14MAR2022



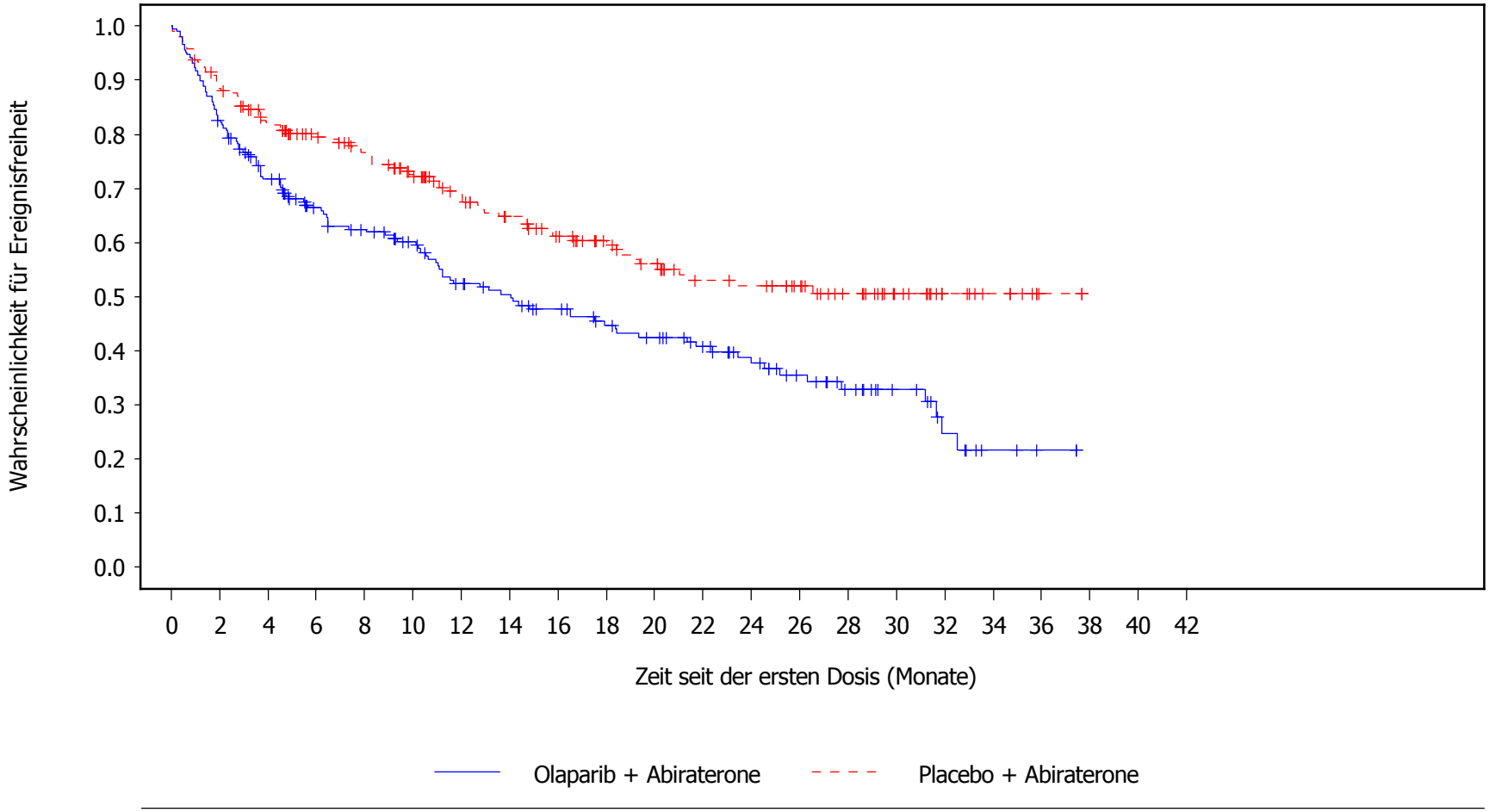
Anzahl an Patienten unter Risiko:

62	57	54	49	46	44	40	32	29	26	25	23	21	16	14	10	6	4	3	1	0	0	Olaparib + Abiraterone
56	45	43	37	32	29	22	20	19	17	17	13	11	8	7	5	2	0	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbl 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.39 PROpel: Kaplan-Meier plot of Schwere UE mit max. CTCAE Grad>=3 for HRRm-Status basierend auf einem Tumorgewebetest=Nicht-HRRm
Safety Analysis Set, DCO 14MAR2022



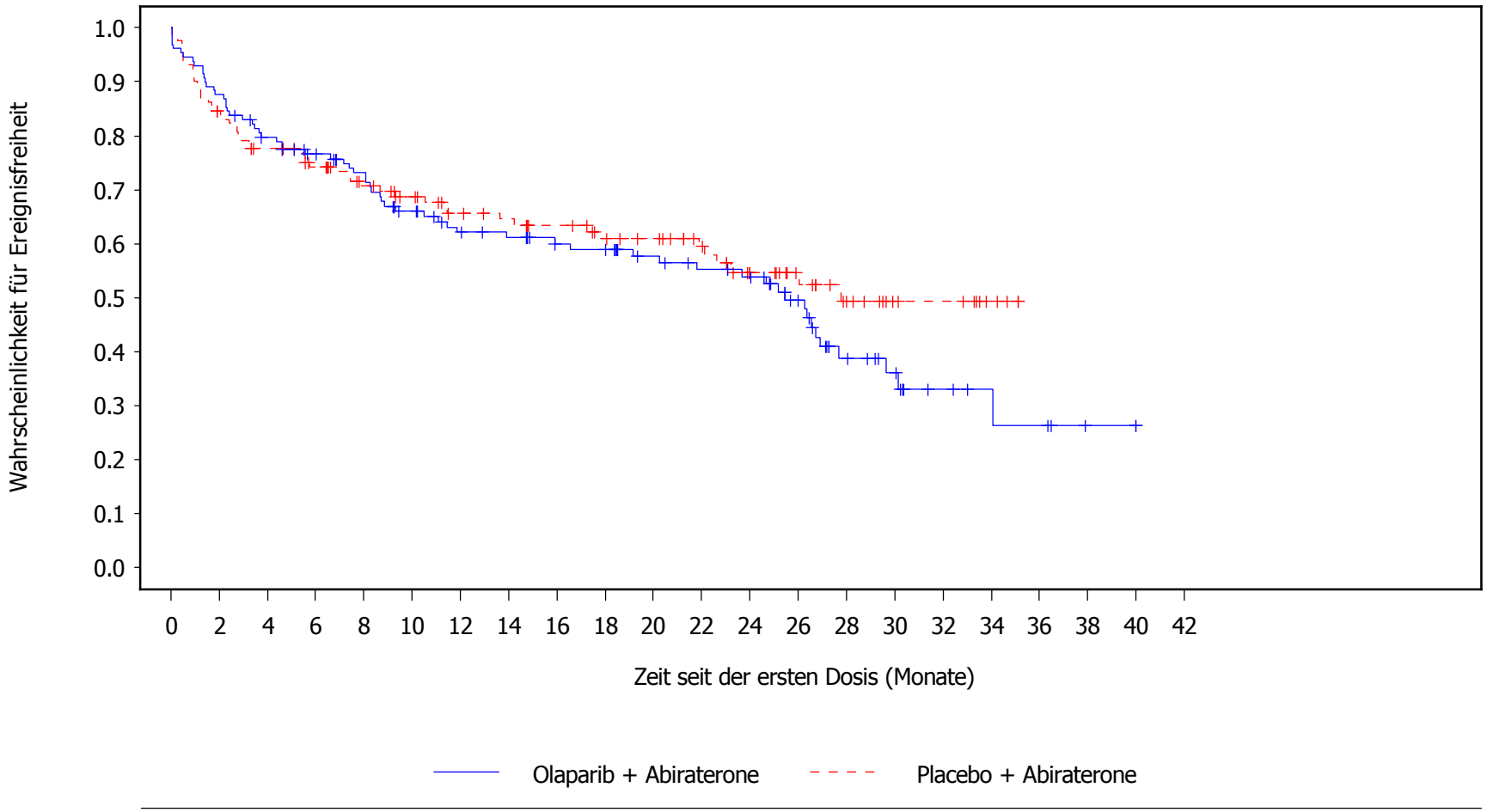
Anzahl an Patienten unter Risiko:

207	170	141	118	108	96	81	75	67	59	54	46	37	29	22	15	8	3	1	0	0	0	Olaparib + Abiraterone
210	184	163	146	134	120	104	93	82	70	62	51	49	42	33	22	12	8	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbm 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.40 PROpel: Kaplan-Meier plot of Schwere UE mit max. CTCAE Grad>=3 for HRRm-Status basierend auf einem Tumorgewebetest=Unbekannt
Safety Analysis Set, DCO 14MAR2022

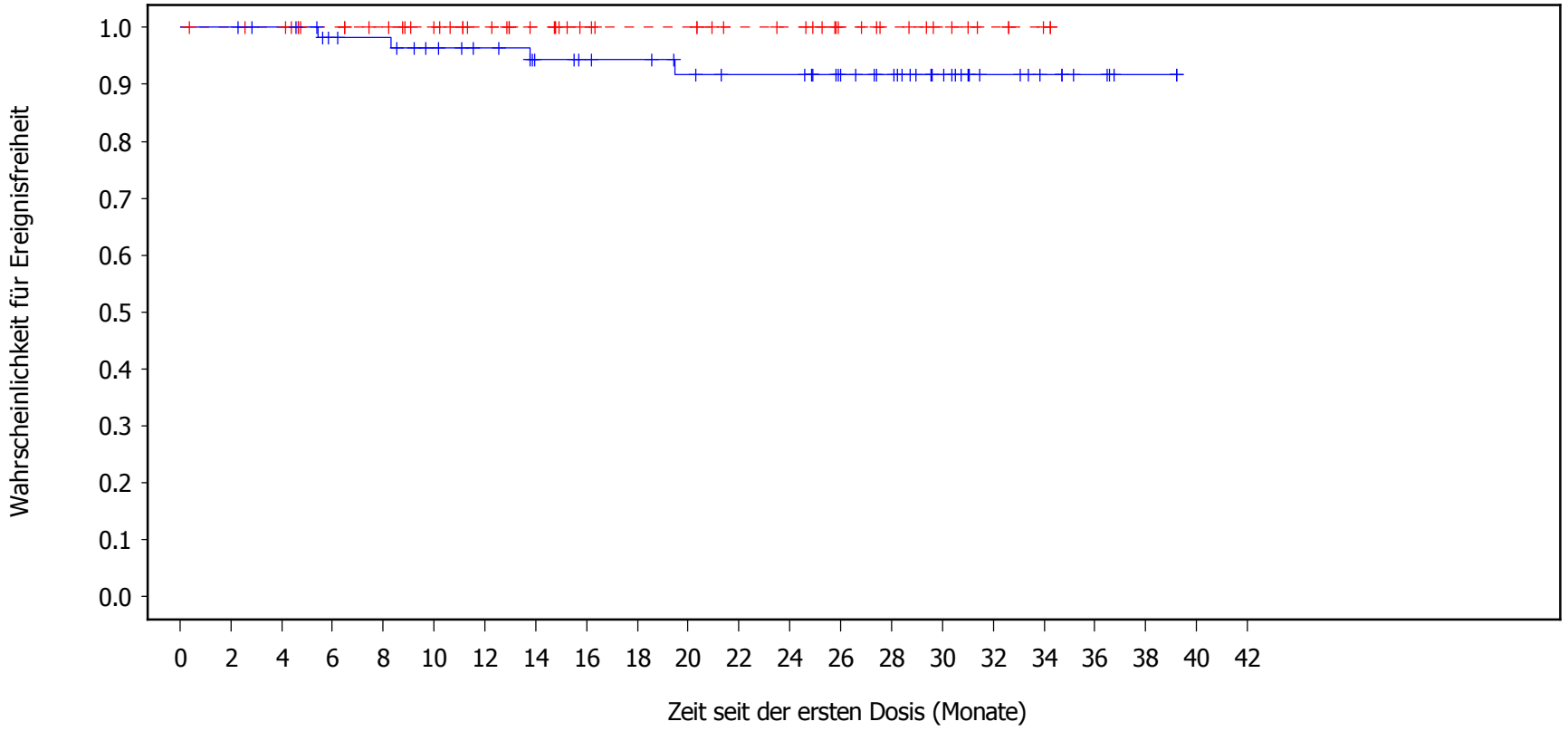


Anzahl an Patienten unter Risiko:

129	113	100	92	83	71	63	60	55	54	47	43	41	30	18	13	7	5	4	1	1	0	Olaparib + Abiraterone
130	108	96	88	77	70	62	59	55	49	46	39	29	23	16	9	8	3	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbn 05DEC2022:09:12 khcs324

Figure 3.6.41 PROpel: Kaplan-Meier plot of Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums for HRRm-Status basierend auf einem Tumorgewebetest=HRRm
Safety Analysis Set, DCO 14MAR2022

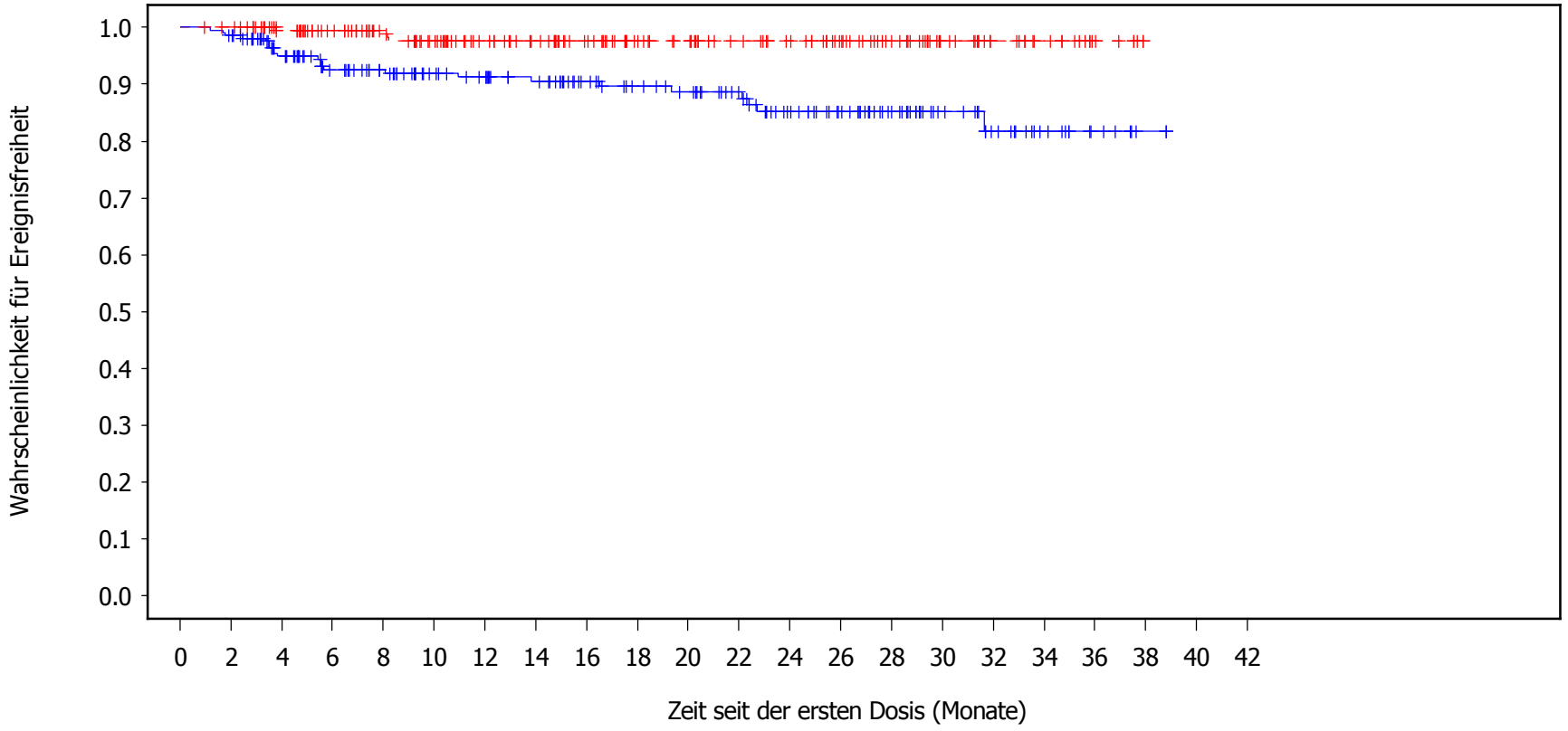


Anzahl an Patienten unter Risiko:

62	62	60	55	54	50	47	42	40	39	36	34	34	27	24	17	10	7	4	1	0	0	Olaparib + Abiraterone
56	55	54	49	46	41	36	31	26	24	24	20	19	13	10	7	4	1	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbo 05DEC2022:09:12 khcs324

Figure 3.6.42 PROpel: Kaplan-Meier plot of Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums for HRRm-Status basierend auf einem Tumorgewebetest=Nicht-HRRm
Safety Analysis Set, DCO 14MAR2022



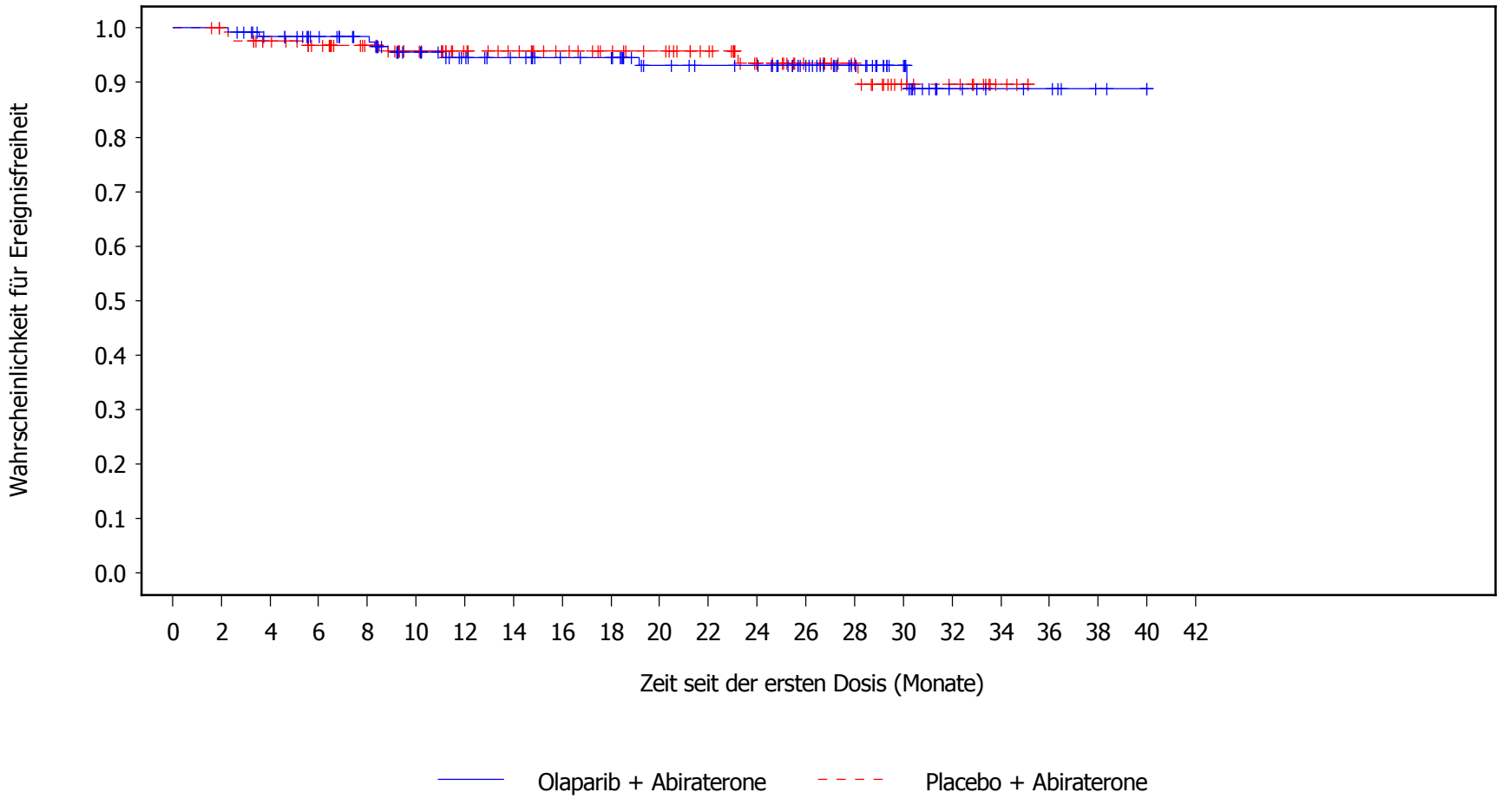
Anzahl an Patienten unter Risiko:

207	203	179	158	147	132	126	116	103	95	90	80	66	56	43	30	21	13	6	1	0	0	Olaparib + Abiraterone
210	208	192	177	160	146	131	122	109	92	86	76	70	59	47	32	21	15	6	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbp 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.43 PROpel: Kaplan-Meier plot of Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums for HRRm-Status basierend auf einem Tumorgewebetest=Unbekannt
Safety Analysis Set, DCO 14MAR2022



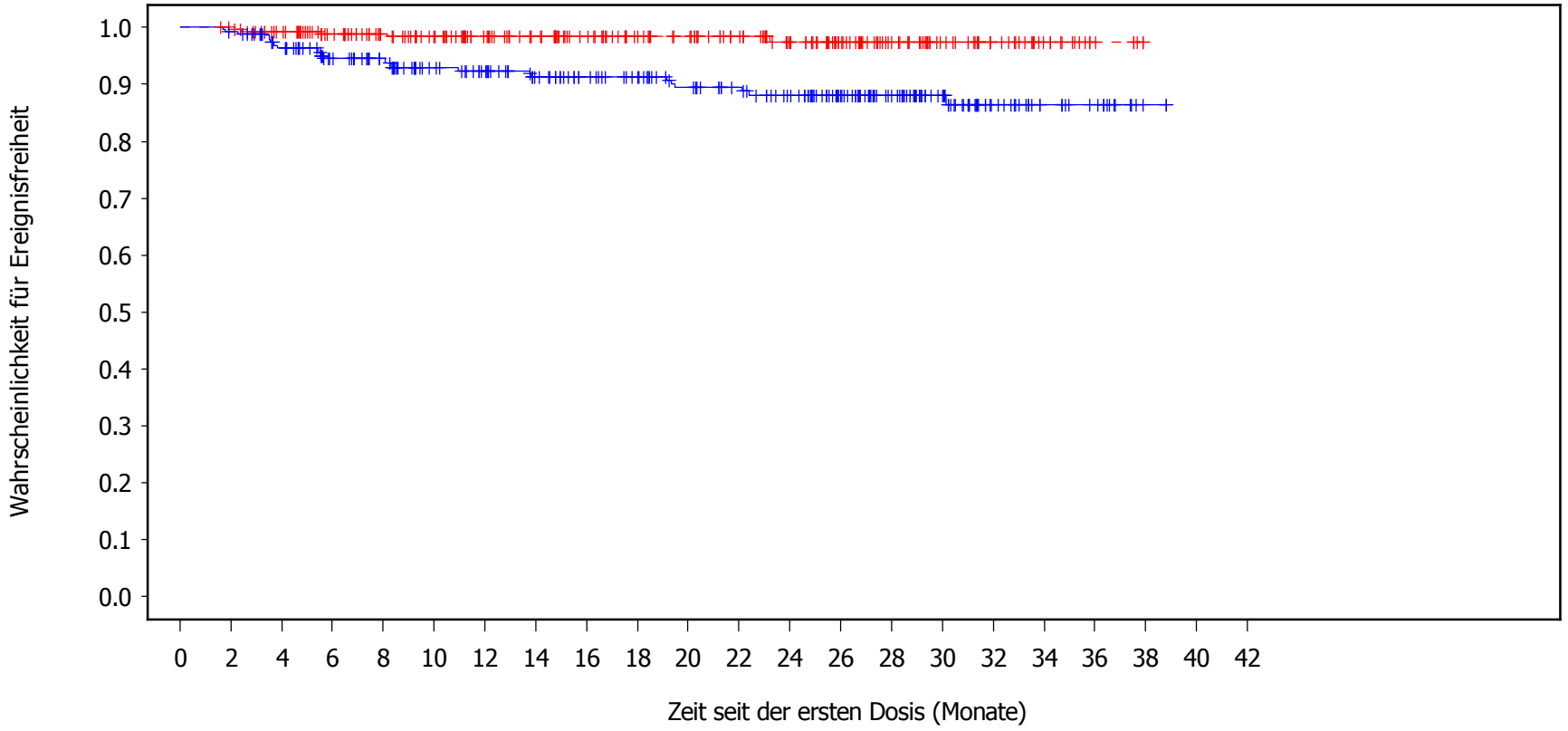
Anzahl an Patienten unter Risiko:

129	129	121	113	106	94	86	81	76	75	65	62	61	49	37	24	10	7	6	2	1	0	Olaparib + Abiraterone
130	127	119	112	102	89	79	74	68	63	59	52	39	32	25	14	11	3	0	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbq 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.44 PROpel: Kaplan-Meier plot of Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums for ECOG-PS zu Baseline=0
Safety Analysis Set, DCO 14MAR2022

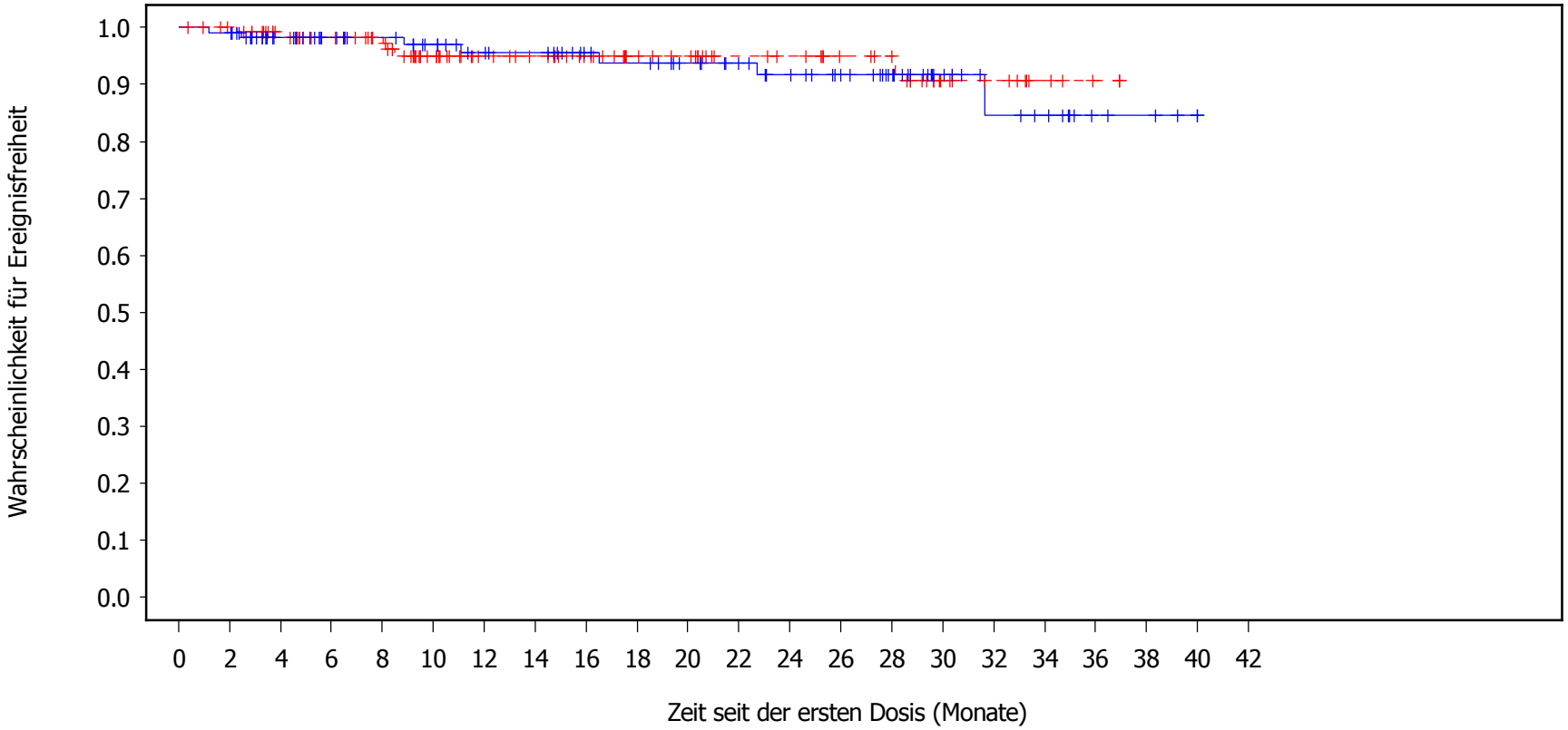


Anzahl an Patienten unter Risiko:

286	283	266	242	227	203	193	175	162	154	141	131	120	97	75	53	29	17	12	1	0	0	Olaparib + Abiraterone
272	270	257	237	216	201	183	168	151	136	129	116	98	79	60	41	27	15	5	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbr 05DEC2022:09:12 khcs324

Figure 3.6.45 PROpel: Kaplan-Meier plot of Schwere UE nach SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums for ECOG-PS zu Baseline=1
Safety Analysis Set, DCO 14MAR2022



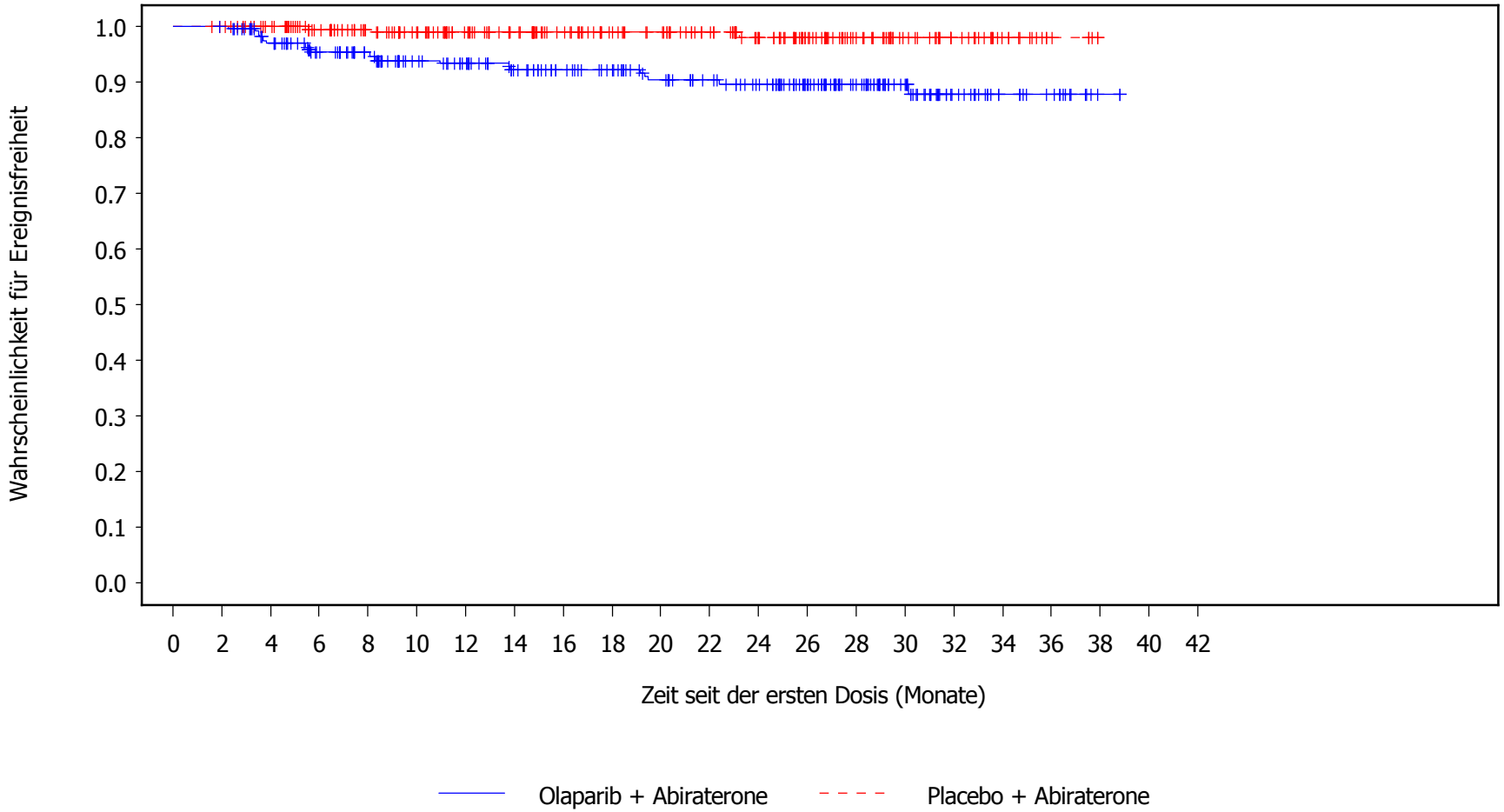
Anzahl an Patienten unter Risiko:

112	111	94	84	80	73	66	64	57	55	50	45	41	35	29	18	12	10	4	3	1	0	Olaparib + Abiraterone
124	120	108	101	92	75	63	59	52	43	40	32	30	25	22	12	9	4	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbs 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.46 PROpel: Kaplan-Meier plot of Schwere UE nach PT: Lungenembolie for ECOG-PS zu Baseline=0
Safety Analysis Set, DCO 14MAR2022



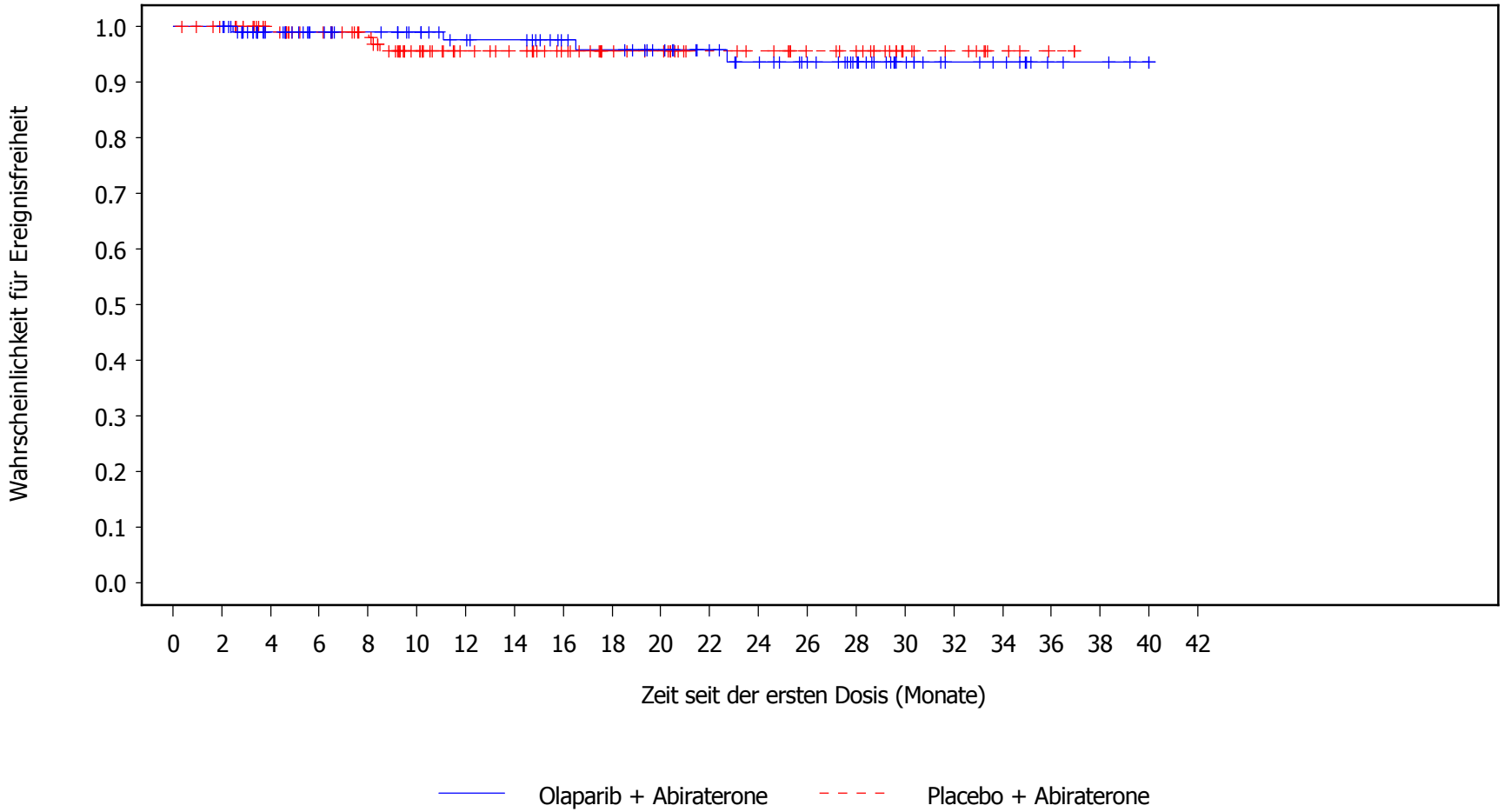
Anzahl an Patienten unter Risiko:

286	285	266	243	227	203	193	175	162	154	141	131	121	98	76	53	29	17	12	1	0	0	Olaparib + Abiraterone
272	270	258	238	217	202	184	169	152	137	130	116	98	79	60	41	27	15	5	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbt 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.47 PROpel: Kaplan-Meier plot of Schwere UE nach PT: Lungenembolie for ECOG-PS zu Baseline=1
Safety Analysis Set, DCO 14MAR2022



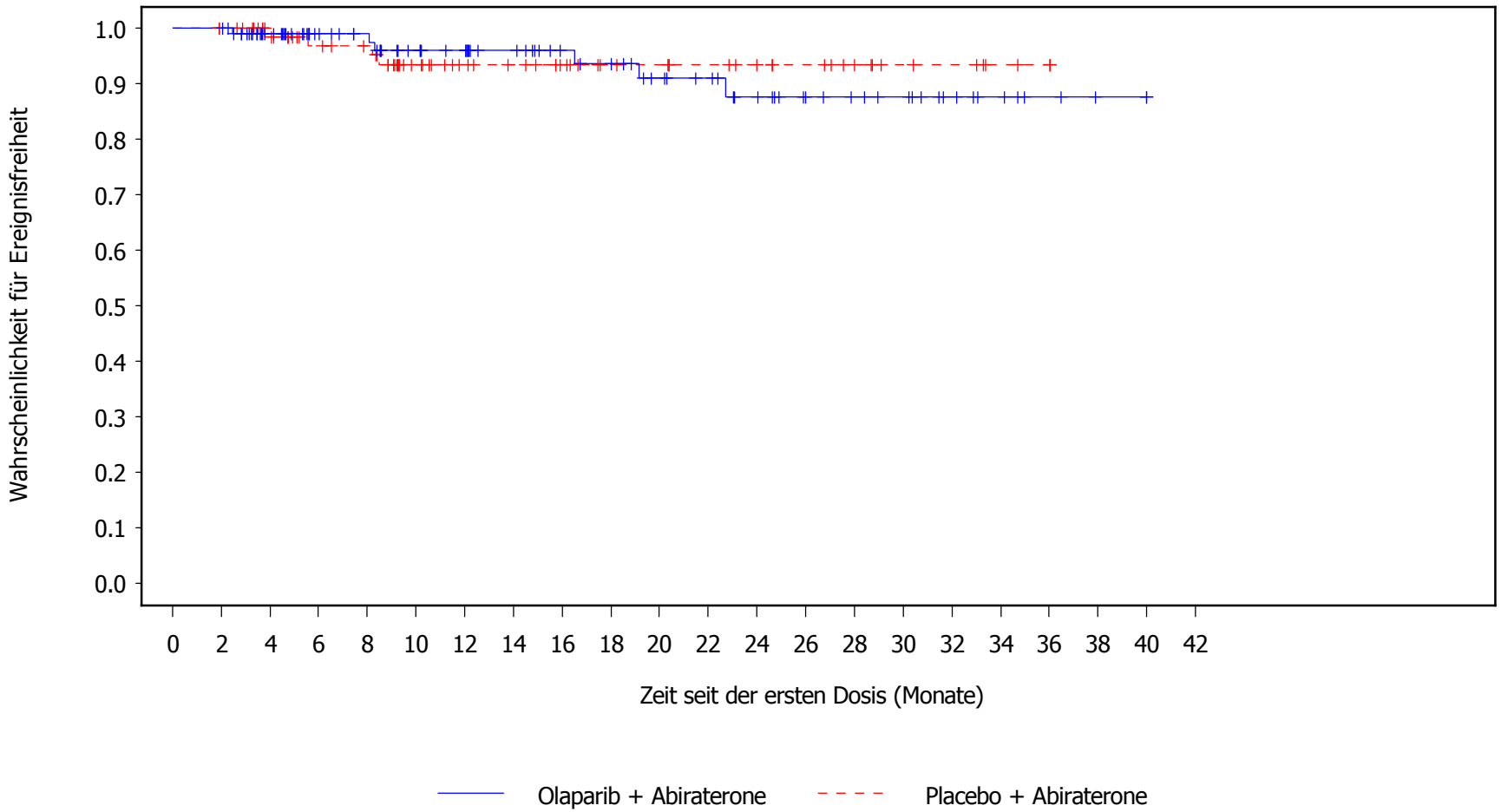
Anzahl an Patienten unter Risiko:

112	112	94	84	80	74	67	65	58	56	51	45	41	35	29	18	12	10	4	3	1	0	Olaparib + Abiraterone
124	120	108	101	92	75	63	59	52	43	40	32	30	25	22	12	9	4	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbu 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.48 PROpel: Kaplan-Meier plot of Schwere UE nach PT: Lungenembolie for Schmerzen zu baseline=Symptomatisch
Safety Analysis Set, DCO 14MAR2022



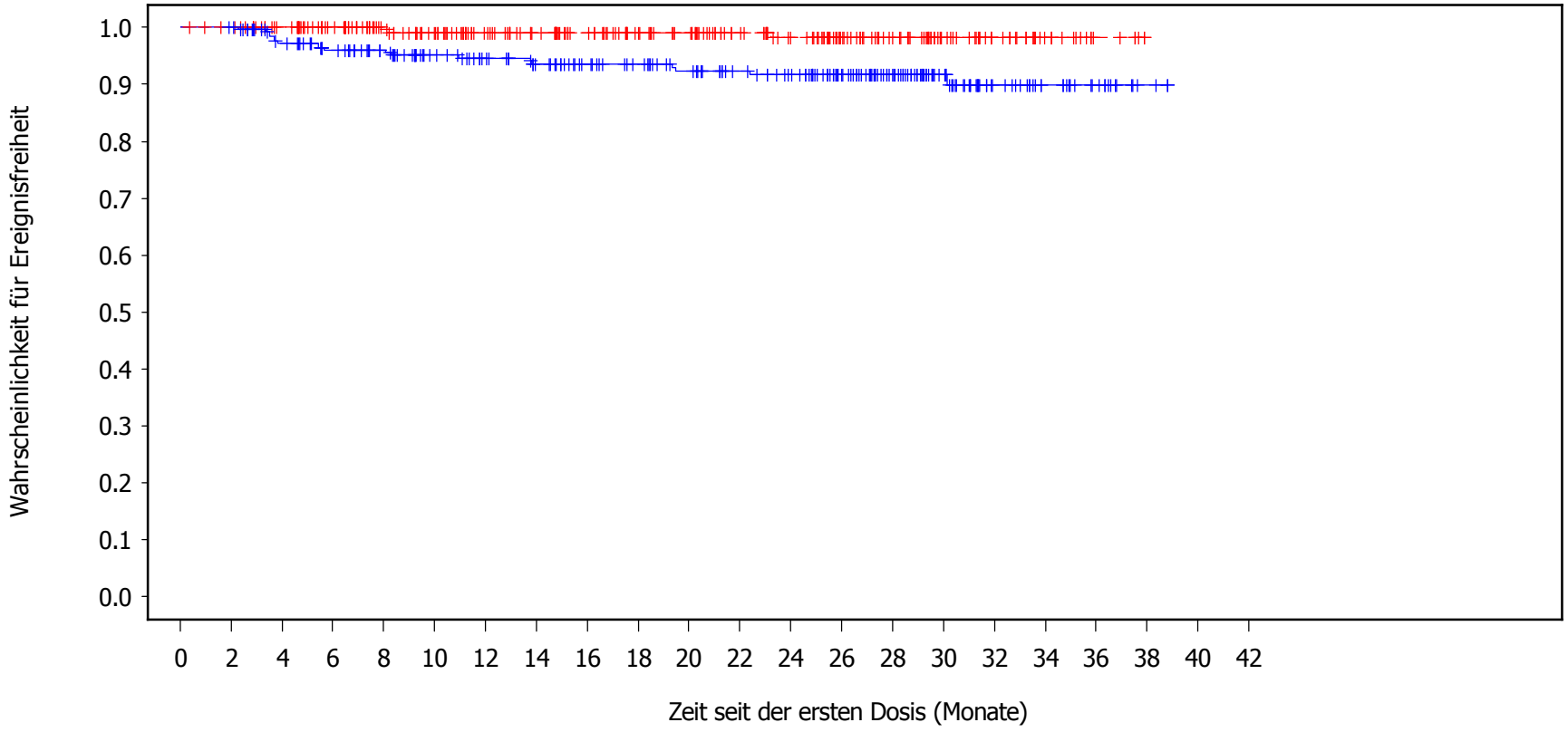
Anzahl an Patienten unter Risiko:

103	103	87	73	68	59	55	47	40	38	32	29	24	18	16	14	9	6	3	1	1	0	Olaparib + Abiraterone
80	78	69	60	57	42	35	32	27	22	21	18	15	13	9	6	5	2	1	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbv 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.49 PROpel: Kaplan-Meier plot of Schwere UE nach PT: Lungenembolie for Schmerzen zu baseline=Asymptomatisch/mild symptomatisch
Safety Analysis Set, DCO 14MAR2022



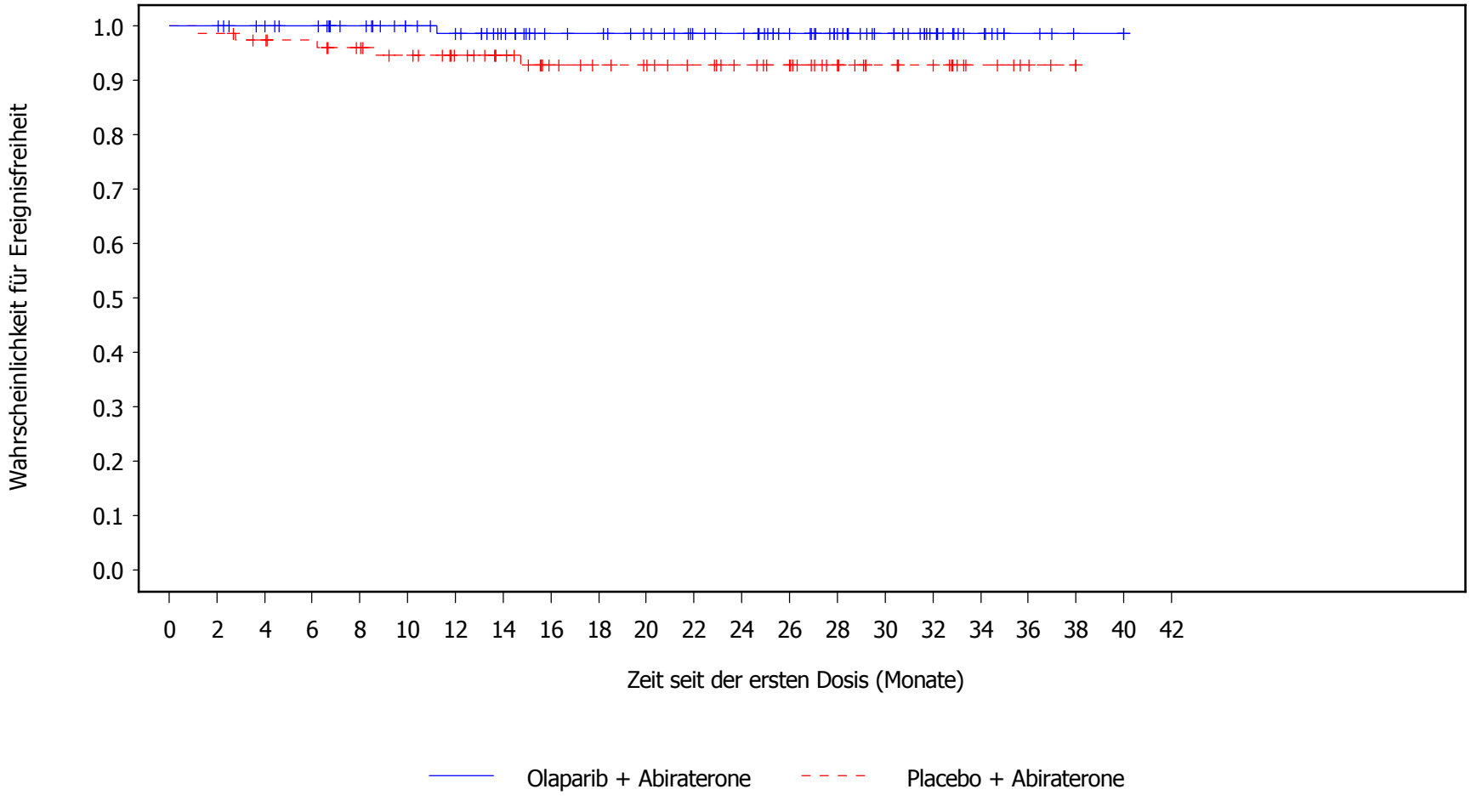
Anzahl an Patienten unter Risiko:

266	265	246	232	219	200	189	177	165	157	147	135	127	105	82	55	31	20	12	2	0	0	Olaparib + Abiraterone
294	291	278	260	235	218	197	182	164	145	136	117	102	82	67	45	29	16	5	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbw 05DEC2022:09:12 khcs324

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.6.50 PROpel: Kaplan-Meier plot of UESI: neue primäre Malignität (außer MDS/AML) for Schmerzen zu baseline=Symptomatisch
Safety Analysis Set, DCO 14MAR2022

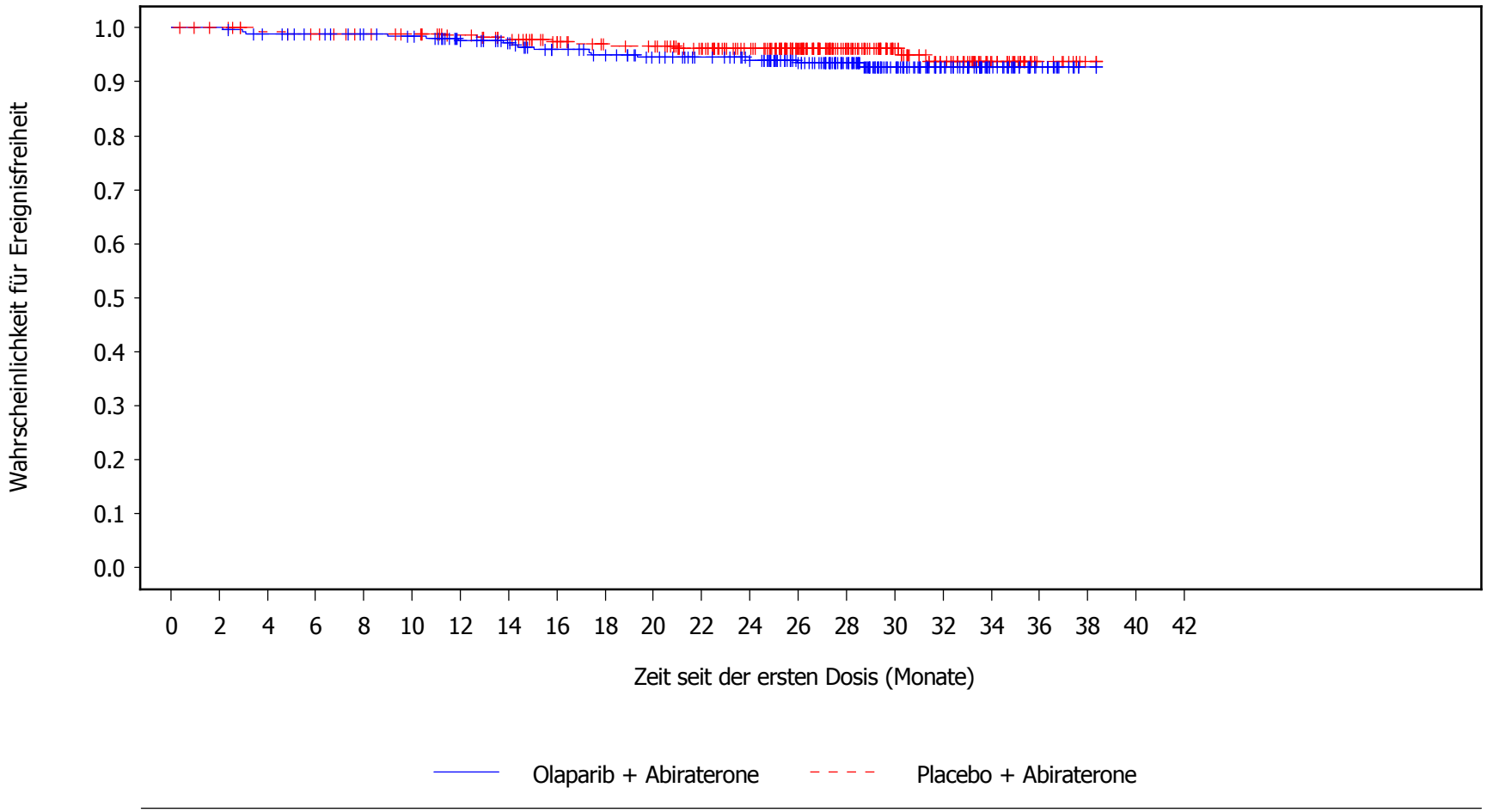


Anzahl an Patienten unter Risiko:

103	103	99	96	90	83	79	72	64	63	59	53	51	42	34	27	17	10	4	1	1	0	Olaparib + Abiraterone
80	79	76	74	70	66	60	54	46	43	41	37	33	29	21	15	13	6	3	0	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebbx 05DEC2022:09:12 khcs324

Figure 3.6.51 PROpel: Kaplan-Meier plot of UESI: neue primäre Malignität (außer MDS/AML) for Schmerzen zu baseline=Asymptomatisch/mild symptomatisch
Safety Analysis Set, DCO 14MAR2022



Anzahl an Patienten unter Risiko:

266	266	260	256	251	248	235	227	216	210	201	193	184	157	129	92	64	34	15	1	0	0	Olaparib + Abiraterone
294	291	285	282	278	275	267	258	246	237	234	218	198	163	120	84	62	36	11	2	0	0	Placebo + Abiraterone

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/ttesubae.sas gttesubaebby 05DEC2022:09:12 khcs324

Ergänzende Angaben zu Patienten mit asymptomatischem/mild symptomatischem Verlauf der Erkrankung

Table 4.1 PROpel: Summary of observation period (months) for efficacy endpoints
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)
Gesamtüberleben (OS)	n	266	294
	Mediane	28,44	26,84
	Min	2,4	0,4
	Max	38,8	38,3
Radiologisches progressionsfreies Überleben nach Prüfarzt (rPFS)	n	266	294
	Mediane	22,16	16,59
	Min	1,4	0,0
	Max	38,8	36,8
Zeit bis zur ersten Chemotherapie oder Tod	n	212	212
	Mediane	27,45	25,36
	Min	1,9	0,4
	Max	38,8	37,7
Zeit bis zur ersten symptomatischen skelettbezogenen Komplikation (SSRE)	n	266	294
	Mediane	22,09	16,59
	Min	1,0	0,0
	Max	38,7	37,7

The observation period for the endpoints will include the time from randomisation until the last date endpoint data are collected for the respective endpoint.

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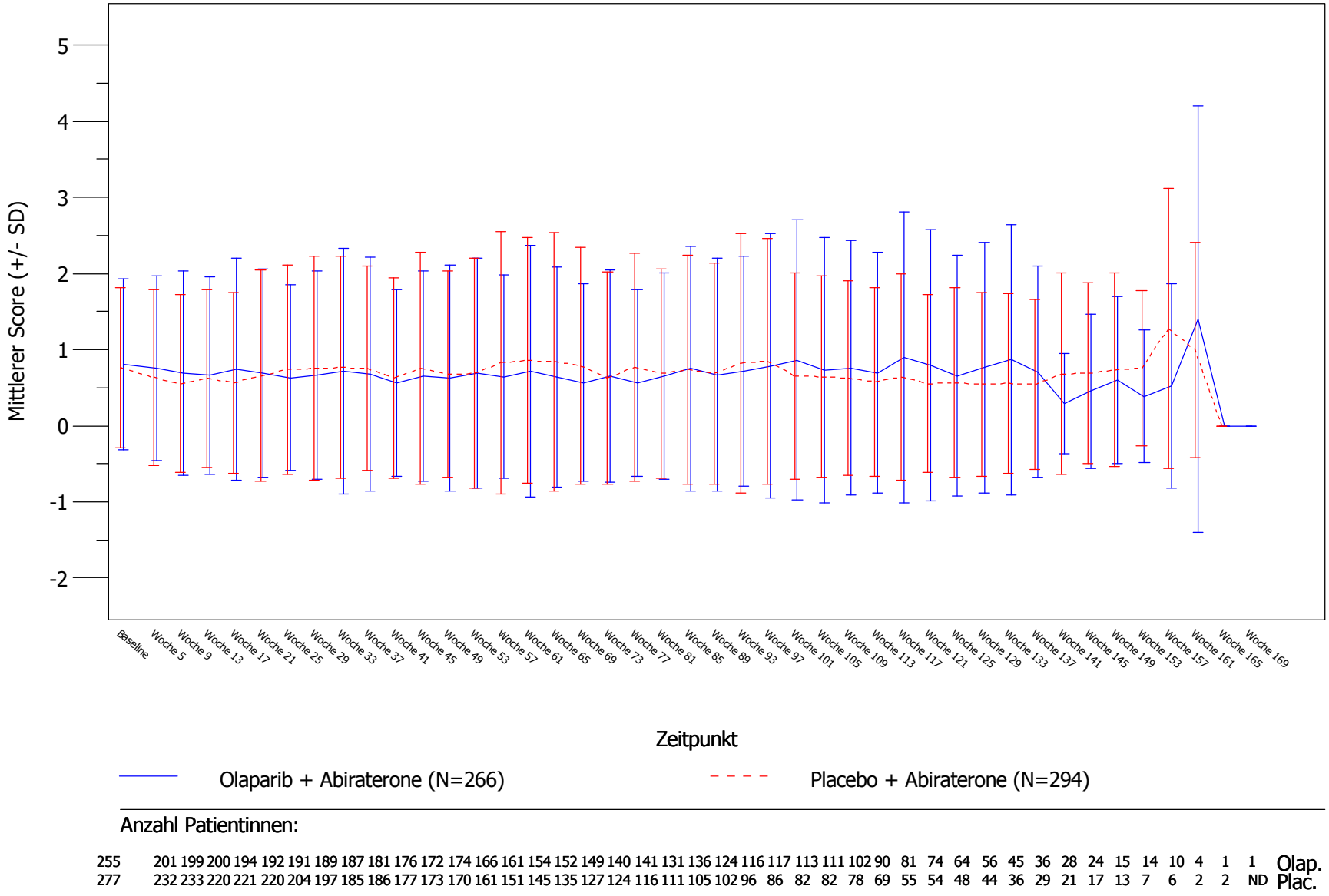
Table 5.1 PROpel: Summary of observation period (months) for PRO endpoints
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)
BPI-SF	n	266	294
	Mediane	20,19	13,67
	Min	0,0	0,0
	Max	38,4	37,5
FACT-P	n	266	294
	Mediane	21,09	14,74
	Min	0,0	0,0
	Max	37,7	37,7
EQ-5D visuelle Analogskala	n	266	294
	Mediane	21,09	13,85
	Min	0,0	0,0
	Max	37,7	37,7

Observation period for PROs is defined as the time from randomisation to the earliest date of the DCO and last assessment for each questionnaire.
Patients without any measurements post randomisation are summarised with duration of 1 day.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/obsperpr_s2.sas gobsperpr_s2a 09JUN2022:16:32 klfm426

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 5.2.1 PROpel: Mean (+/- SD) score for BPI-SF Schmerzprogression (Frage 3) across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022



Anzahl Patientinnen:

255	201	199	200	194	192	191	189	187	181	176	172	174	166	161	154	152	149	140	141	131	136	124	116	117	113	111	102	90	81	74	64	56	45	36	28	24	15	14	10	4	1	1	Olap.
277	232	233	220	221	220	204	197	185	186	177	173	170	161	151	145	135	127	124	116	111	105	102	96	86	82	82	78	69	55	54	48	44	36	29	21	17	13	7	6	2	2	ND	Plac.

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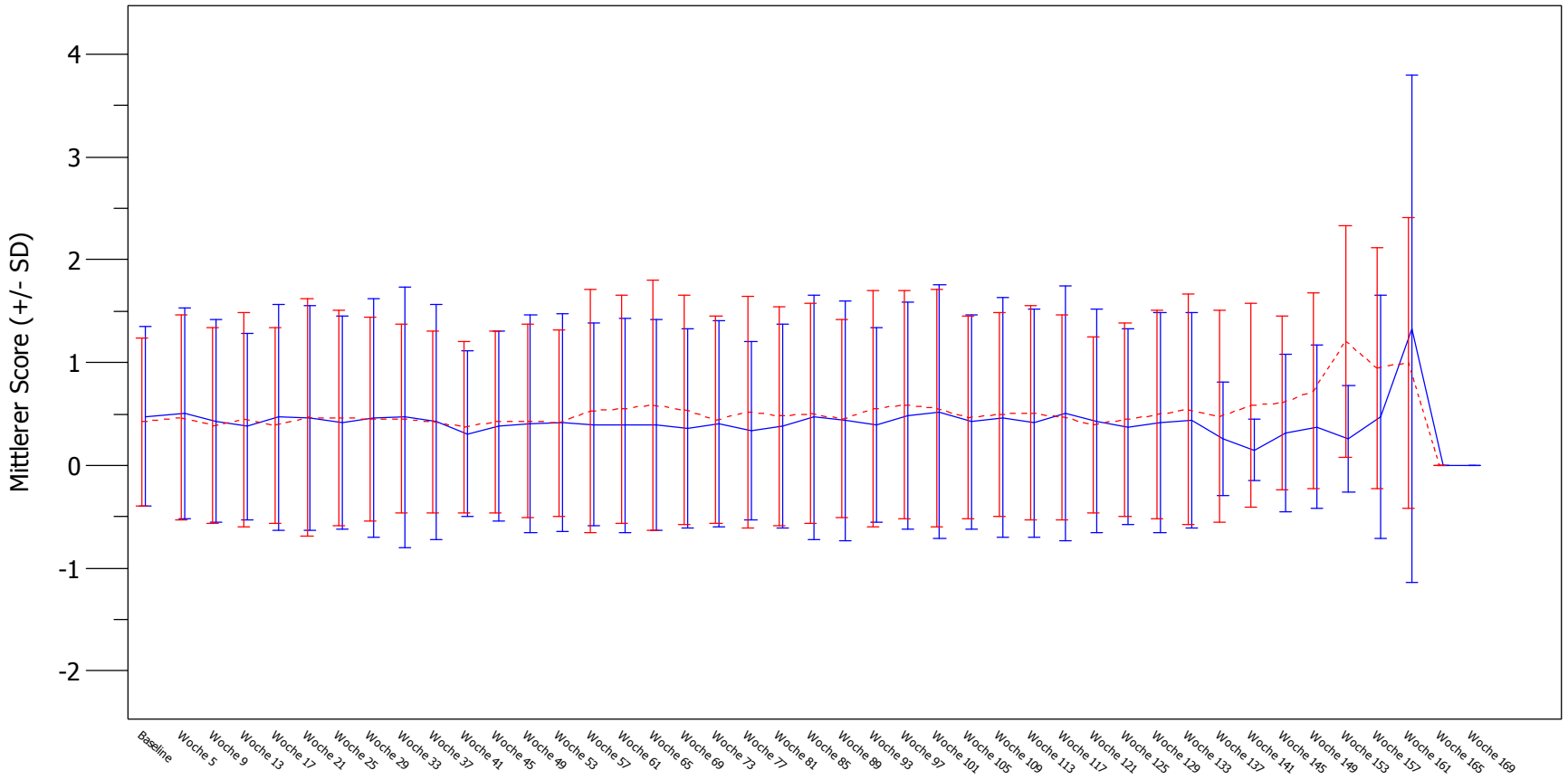
Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 5.2.2 PROpel: Mean (+/- SD) score for BPI-SF Beeinträchtigung durch Schmerzen (Frage 9a-g) across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022



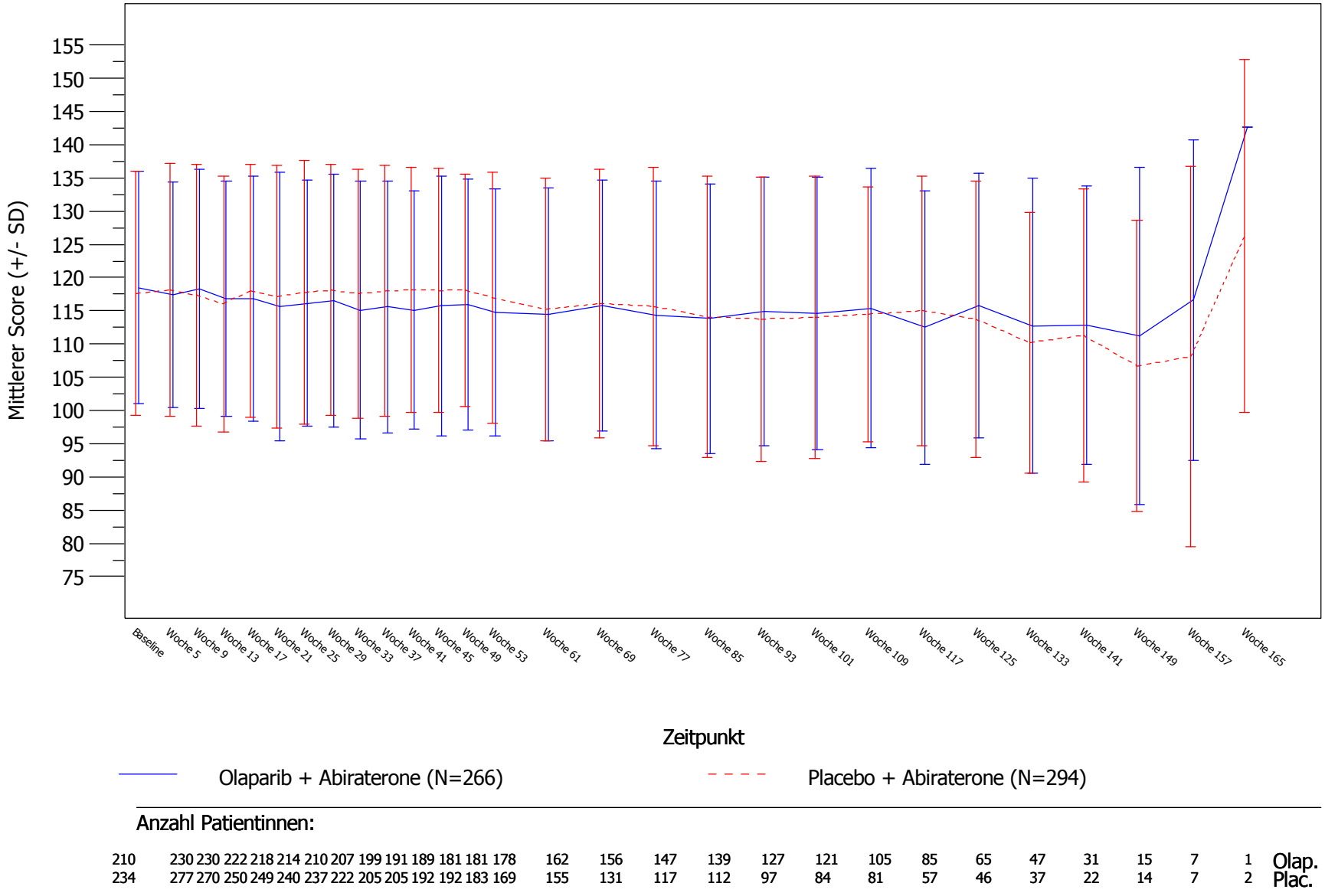
Anzahl Patientinnen:

255	201	199	200	194	192	191	189	187	181	176	172	174	166	161	154	152	149	140	141	131	136	124	116	117	113	111	102	90	81	74	64	56	45	36	28	24	15	14	10	4	1	1	Olap.
277	232	233	220	221	220	204	197	185	186	177	173	170	161	151	145	135	127	124	116	111	105	102	96	86	82	82	78	69	55	54	48	44	36	29	21	17	13	7	6	2	2	ND	Plac.

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/fmeanpr_s2.sas gfmeanpr_s2aab 09JUN2022:16:30 klfm426

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 5.3.1 PROpel: Mean (+/- SD) score for FACT-P Gesamtscore across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022



Anzahl Patientinnen:

210	230	230	222	218	214	210	207	199	191	189	181	181	178	162	156	147	139	127	121	105	85	65	47	31	15	7	1	Olap.
234	277	270	250	249	240	237	222	205	205	192	192	183	169	155	131	117	112	97	84	81	57	46	37	22	14	7	2	Plac.

root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/fmeanpr_s2.sas gfmeanpr_s2baa 09JUN2022:16:30 klfm426

Table 5.3.2 PROpel: Summary of FACT-P Total score results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
FACT-P Gesamtscore	Olaparib + Abiraterone (N=266)	Baseline [a]	210	118,48	17,465	61,0	120,00	154,0
		Woche 5	230	117,47	16,953	69,0	118,00	152,0
		Woche 9	230	118,24	17,987	72,0	119,42	154,0
		Woche 13	222	116,81	17,725	66,5	118,83	152,0
		Woche 17	218	116,79	18,418	61,0	119,00	152,0
		Woche 21	214	115,67	20,167	39,0	118,00	152,0
		Woche 25	210	116,16	18,548	64,0	119,00	152,0
		Woche 29	207	116,53	19,066	55,0	117,50	155,0
		Woche 33	199	115,11	19,393	61,0	117,00	152,0
		Woche 37	191	115,57	18,910	60,5	116,83	156,0
		Woche 41	189	115,10	17,960	55,0	116,00	151,0
		Woche 45	181	115,73	19,520	63,0	117,00	152,0
		Woche 49	181	116,00	18,890	59,7	116,00	150,0
		Woche 53	178	114,82	18,587	64,0	115,00	149,0
		Woche 61	162	114,46	19,004	73,0	113,17	148,0
		Woche 69	156	115,86	18,891	72,0	116,00	148,8
		Woche 77	147	114,36	20,143	53,0	117,00	149,5
		Woche 85	139	113,81	20,261	54,0	117,50	152,0
		Woche 93	127	114,93	20,161	63,0	116,00	150,0
		Woche 101	121	114,61	20,508	65,0	117,00	151,0
		Woche 109	105	115,37	21,035	65,0	119,83	147,0
		Woche 117	85	112,50	20,613	65,0	113,00	147,0
		Woche 125	65	115,82	19,943	67,0	118,00	152,0
		Woche 133	47	112,76	22,167	58,0	111,00	149,0
		Woche 141	31	112,80	20,979	60,0	113,83	147,0
		Woche 149	15	111,21	25,363	55,0	115,00	152,0
		Woche 157	7	116,64	24,111	80,0	114,33	152,0
		Woche 165	1	142,67	NC	142,7	142,67	142,7
	Placebo + Abiraterone (N=294)	Baseline [a]	234	117,60	18,393	56,0	120,67	152,0

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/smeanpr_s2.sas gsmeanpr_s2c 10JUN2022:16:07 ksfr675

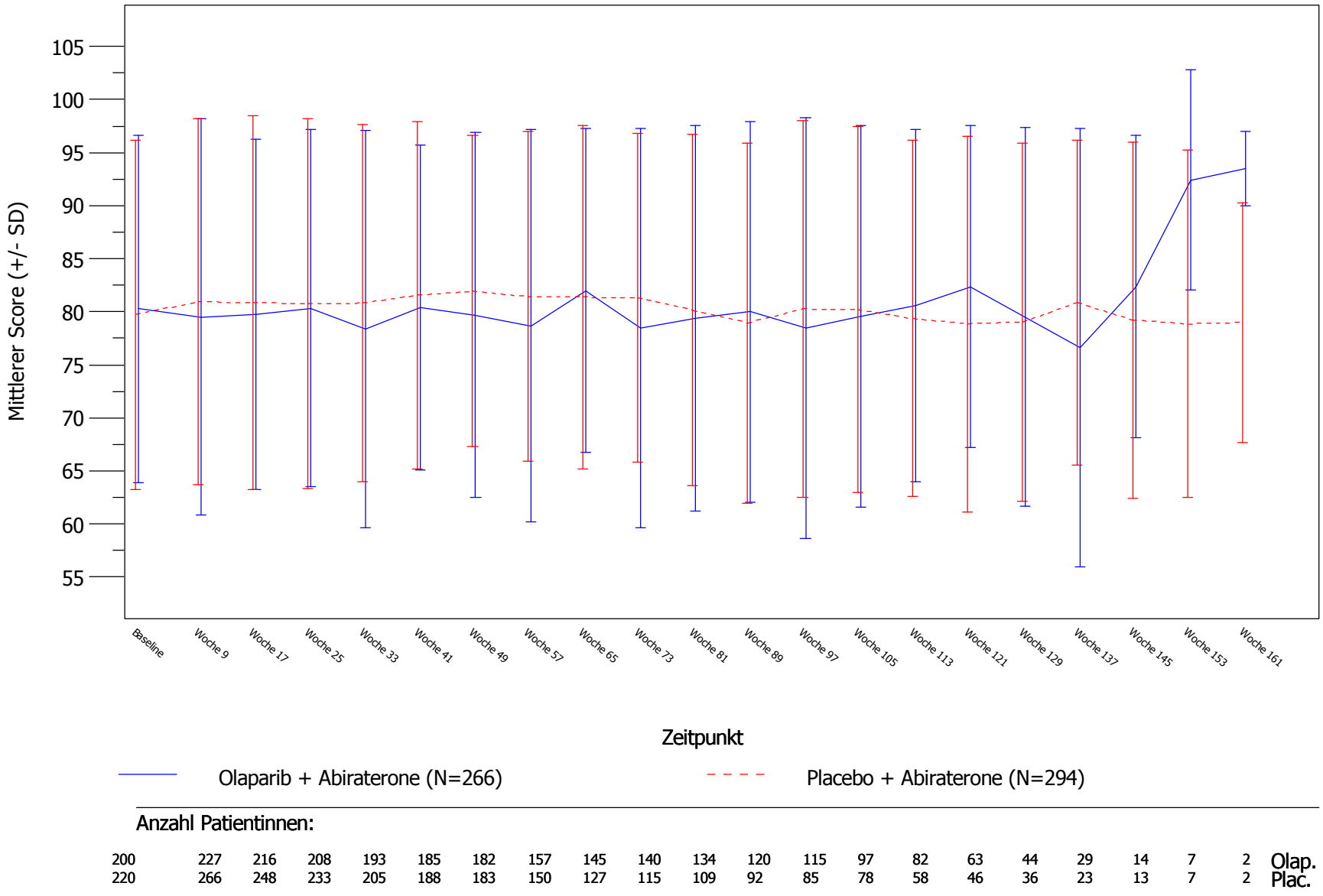
Table 5.3.2 PROpel: Summary of FACT-P Total score results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 5	277	118,14	19,056	48,0	121,67	156,0
		Woche 9	270	117,36	19,706	57,0	120,00	156,0
		Woche 13	250	116,04	19,283	53,0	118,00	156,0
		Woche 17	249	118,02	18,986	47,2	120,00	156,0
		Woche 21	240	117,18	19,769	50,0	119,50	156,0
		Woche 25	237	117,77	19,815	45,0	119,50	156,0
		Woche 29	222	118,09	18,886	63,0	119,00	156,0
		Woche 33	205	117,59	18,740	59,0	119,00	156,0
		Woche 37	205	117,95	18,878	38,0	120,00	155,0
		Woche 41	192	118,16	18,393	67,8	121,00	153,0
		Woche 45	192	118,07	18,362	62,0	121,58	155,0
		Woche 49	183	118,09	17,493	71,0	119,00	156,0
		Woche 53	169	117,00	18,864	74,0	118,67	156,0
		Woche 61	155	115,22	19,770	49,0	115,67	154,0
		Woche 69	131	116,09	20,255	46,0	116,17	153,0
		Woche 77	117	115,69	20,951	51,0	118,50	156,0
		Woche 85	112	114,09	21,235	56,0	117,00	156,0
		Woche 93	97	113,76	21,384	73,0	115,33	151,0
		Woche 101	84	114,02	21,183	51,0	116,50	152,0
		Woche 109	81	114,50	19,198	74,0	116,67	152,0
		Woche 117	57	115,01	20,284	78,0	112,00	152,0
		Woche 125	46	113,77	20,777	77,2	115,92	154,0
		Woche 133	37	110,22	19,622	73,0	108,67	148,0
		Woche 141	22	111,31	22,020	74,0	114,33	152,0
		Woche 149	14	106,70	21,919	66,3	109,58	138,7
		Woche 157	7	108,12	28,591	74,5	110,50	153,0
		Woche 165	2	126,25	26,517	107,5	126,25	145,0

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/smeanpr_s2.sas gsmeanpr_s2c 10JUN2022:16:07 ksfr675

Olaparib PROpel, Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 5.4.1 PROpel: Mean (+/- SD) score for EQ-5D visuelle Analogskala across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022



root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/fmeanpr_s2.sas gfmeanpr_s2caa 09JUN2022:16:30 klfm426

Table 5.4.2 PROpel: Summary of EQ-5D Visual analogue scale results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
EQ-5D visuelle Analogskala	Olaparib + Abiraterone (N=266)	Baseline [a]	200	80,3	16,37	18	83,5	100
		Woche 9	227	79,5	18,68	10	83,0	100
		Woche 17	216	79,7	16,51	8	83,5	100
		Woche 25	208	80,3	16,81	16	85,0	100
		Woche 33	193	78,4	18,73	18	83,0	100
		Woche 41	185	80,4	15,30	33	85,0	100
		Woche 49	182	79,7	17,21	3	84,0	100
		Woche 57	157	78,7	18,48	0	83,0	100
		Woche 65	145	82,0	15,24	0	85,0	100
		Woche 73	140	78,5	18,83	0	81,5	100
		Woche 81	134	79,4	18,14	3	85,0	100
		Woche 89	120	80,0	17,94	0	85,0	100
		Woche 97	115	78,5	19,84	0	81,0	100
		Woche 105	97	79,6	18,00	3	82,0	100
		Woche 113	82	80,5	16,59	21	84,5	100
		Woche 121	63	82,3	15,17	4	85,0	100
		Woche 129	44	79,5	17,81	0	80,5	100
		Woche 137	29	76,6	20,65	4	81,0	100
		Woche 145	14	82,4	14,24	50	82,5	100
		Woche 153	7	92,4	10,41	70	96,0	100
		Woche 161	2	93,5	3,54	91	93,5	96
	Placebo + Abiraterone (N=294)	Baseline [a]	220	79,7	16,44	22	82,0	100
		Woche 9	266	80,9	17,23	0	86,0	100
		Woche 17	248	80,9	17,58	0	86,5	100
		Woche 25	233	80,8	17,42	0	86,0	100
		Woche 33	205	80,8	16,80	17	84,0	100
		Woche 41	188	81,6	16,34	7	85,0	100
		Woche 49	183	81,9	14,66	35	85,0	100
		Woche 57	150	81,4	15,54	10	85,5	100

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/smeanpr_s2.sas gsmeanpr_s2d 10JUN2022:16:07 ksfr675

Table 5.4.2 PROpel: Summary of EQ-5D Visual analogue scale results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 65	127	81,4	16,18	27	86,0	100
		Woche 73	115	81,3	15,49	24	86,0	100
		Woche 81	109	80,2	16,57	20	85,0	100
		Woche 89	92	78,9	16,98	25	82,0	100
		Woche 97	85	80,3	17,75	20	84,0	100
		Woche 105	78	80,2	17,26	30	85,0	100
		Woche 113	58	79,4	16,78	27	85,0	100
		Woche 121	46	78,9	17,70	24	83,5	100
		Woche 129	36	79,1	16,88	34	83,0	100
		Woche 137	23	80,9	15,27	50	86,0	100
		Woche 145	13	79,2	16,78	51	87,0	100
		Woche 153	7	78,9	16,38	57	82,0	100
		Woche 161	2	79,0	11,31	71	79,0	87

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/smeanpr_s2.sas gsmeanpr_s2d 10JUN2022:16:07 ksfr675

Table 5.5.2.3 PROpel: Summary of BPI-SF Worst Pain (Item 3) results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
BPI-SF Schmerzprogression (Frage 3)	Olaparib + Abiraterone (N=266)	Baseline [a]	255	0,81	1,119	0,0	0,00	3,9
		Woche 5	201	0,76	1,217	0,0	0,00	6,3
		Woche 9	199	0,69	1,340	0,0	0,00	8,0
		Woche 13	200	0,66	1,299	0,0	0,00	6,4
		Woche 17	194	0,74	1,460	0,0	0,00	7,9
		Woche 21	192	0,69	1,371	0,0	0,00	8,6
		Woche 25	191	0,63	1,220	0,0	0,00	6,7
		Woche 29	189	0,66	1,369	0,0	0,00	8,0
		Woche 33	187	0,71	1,611	0,0	0,00	10,0
		Woche 37	181	0,68	1,539	0,0	0,00	8,9
		Woche 41	176	0,56	1,227	0,0	0,00	8,2
		Woche 45	172	0,65	1,380	0,0	0,00	8,0
		Woche 49	174	0,63	1,484	0,0	0,00	9,2
		Woche 53	166	0,69	1,510	0,0	0,00	8,6
		Woche 57	161	0,65	1,336	0,0	0,00	6,7
		Woche 61	154	0,71	1,652	0,0	0,00	10,0
		Woche 65	152	0,64	1,443	0,0	0,00	9,1
		Woche 69	149	0,57	1,299	0,0	0,00	7,6
		Woche 73	140	0,66	1,393	0,0	0,00	7,9
		Woche 77	141	0,56	1,226	0,0	0,00	6,1
		Woche 81	131	0,65	1,354	0,0	0,00	6,7
		Woche 85	136	0,75	1,607	0,0	0,00	8,0
		Woche 89	124	0,67	1,529	0,0	0,00	9,0
		Woche 93	116	0,72	1,513	0,0	0,00	8,6
		Woche 97	117	0,78	1,736	0,0	0,00	8,3
		Woche 101	113	0,86	1,841	0,0	0,00	9,0
		Woche 105	111	0,73	1,741	0,0	0,00	8,3
		Woche 109	102	0,76	1,670	0,0	0,00	8,3
		Woche 113	90	0,69	1,581	0,0	0,00	8,0
		Woche 117	81	0,90	1,911	0,0	0,00	8,3
		Woche 121	74	0,80	1,783	0,0	0,00	8,0

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/smeanpr_s2.sas gsmeanpr_s2a 10JUN2022:16:07 ksfr675

Table 5.5.2.3 PROpel: Summary of BPI-SF Worst Pain (Item 3) results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 125	64	0,66	1,584	0,0	0,00	8,0
		Woche 129	56	0,76	1,646	0,0	0,00	8,0
		Woche 133	45	0,87	1,775	0,0	0,00	8,0
		Woche 137	36	0,71	1,385	0,0	0,00	5,7
		Woche 141	28	0,29	0,658	0,0	0,00	2,4
		Woche 145	24	0,46	1,012	0,0	0,00	4,0
		Woche 149	15	0,60	1,092	0,0	0,00	3,1
		Woche 153	14	0,39	0,874	0,0	0,00	3,0
		Woche 157	10	0,53	1,346	0,0	0,00	4,3
		Woche 161	4	1,40	2,800	0,0	0,00	5,6
		Woche 165	1	0,00	NC	0,0	0,00	0,0
		Woche 169	1	0,00	NC	0,0	0,00	0,0
	Placebo + Abiraterone (N=294)	Baseline [a]	277	0,76	1,057	0,0	0,14	3,9
		Woche 5	232	0,63	1,155	0,0	0,00	8,0
		Woche 9	233	0,55	1,164	0,0	0,00	7,8
		Woche 13	220	0,62	1,170	0,0	0,00	5,7
		Woche 17	221	0,56	1,187	0,0	0,00	7,1
		Woche 21	220	0,66	1,386	0,0	0,00	8,3
		Woche 25	204	0,74	1,372	0,0	0,00	6,0
		Woche 29	197	0,75	1,472	0,0	0,00	6,7
		Woche 33	185	0,77	1,461	0,0	0,00	7,9
		Woche 37	186	0,75	1,342	0,0	0,00	7,3
		Woche 41	177	0,63	1,317	0,0	0,00	8,3
		Woche 45	173	0,75	1,519	0,0	0,00	8,5
		Woche 49	170	0,68	1,357	0,0	0,00	8,2
		Woche 53	161	0,69	1,512	0,0	0,00	8,3
		Woche 57	151	0,83	1,720	0,0	0,00	8,4
		Woche 61	145	0,86	1,615	0,0	0,00	7,3
		Woche 65	135	0,84	1,697	0,0	0,00	7,7
		Woche 69	127	0,79	1,557	0,0	0,00	7,9

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/smeanpr_s2.sas gsmeanpr_s2a 10JUN2022:16:07 ksfr675

Table 5.5.2.3 PROpel: Summary of BPI-SF Worst Pain (Item 3) results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 73	124	0,63	1,396	0,0	0,00	8,0
		Woche 77	116	0,77	1,496	0,0	0,00	7,7
		Woche 81	111	0,69	1,372	0,0	0,00	7,4
		Woche 85	105	0,74	1,507	0,0	0,00	7,8
		Woche 89	102	0,69	1,456	0,0	0,00	8,3
		Woche 93	96	0,82	1,705	0,0	0,00	8,4
		Woche 97	86	0,85	1,617	0,0	0,00	8,2
		Woche 101	82	0,66	1,356	0,0	0,00	5,1
		Woche 105	82	0,64	1,322	0,0	0,00	5,0
		Woche 109	78	0,63	1,278	0,0	0,00	5,0
		Woche 113	69	0,58	1,240	0,0	0,00	5,0
		Woche 117	55	0,64	1,353	0,0	0,00	5,3
		Woche 121	54	0,55	1,167	0,0	0,00	4,2
		Woche 125	48	0,56	1,246	0,0	0,00	4,2
		Woche 129	44	0,55	1,206	0,0	0,00	4,4
		Woche 133	36	0,56	1,181	0,0	0,00	4,3
		Woche 137	29	0,54	1,122	0,0	0,00	3,9
		Woche 141	21	0,68	1,326	0,0	0,00	5,3
		Woche 145	17	0,69	1,186	0,0	0,00	3,3
		Woche 149	13	0,74	1,268	0,0	0,00	4,1
		Woche 153	7	0,76	1,019	0,0	0,00	2,3
		Woche 157	6	1,28	1,843	0,0	0,50	4,7
		Woche 161	2	1,00	1,414	0,0	1,00	2,0
		Woche 165	2	0,00	0,000	0,0	0,00	0,0

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 5.5.2.4 PROpel: Summary of BPI-SF Pain Interference (Item 9a-g) results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
BPI-SF Beeinträchtigung durch Schmerzen (Frage 9a-g)	Olaparib + Abiraterone (N=266)	Baseline [a]	255	0,48	0,875	0,0	0,00	5,9
		Woche 5	201	0,50	1,028	0,0	0,00	6,5
		Woche 9	199	0,43	0,984	0,0	0,00	7,4
		Woche 13	200	0,38	0,905	0,0	0,00	6,3
		Woche 17	194	0,47	1,101	0,0	0,00	6,6
		Woche 21	192	0,46	1,092	0,0	0,00	8,4
		Woche 25	191	0,42	1,038	0,0	0,00	7,6
		Woche 29	189	0,46	1,163	0,0	0,00	8,5
		Woche 33	187	0,47	1,267	0,0	0,00	8,8
		Woche 37	181	0,42	1,144	0,0	0,00	8,6
		Woche 41	176	0,31	0,803	0,0	0,00	5,1
		Woche 45	172	0,38	0,924	0,0	0,00	5,8
		Woche 49	174	0,41	1,055	0,0	0,00	8,3
		Woche 53	166	0,41	1,061	0,0	0,00	6,7
		Woche 57	161	0,40	0,987	0,0	0,00	6,4
		Woche 61	154	0,39	1,044	0,0	0,00	5,9
		Woche 65	152	0,40	1,026	0,0	0,00	5,8
		Woche 69	149	0,36	0,973	0,0	0,00	5,7
		Woche 73	140	0,40	1,003	0,0	0,00	5,8
		Woche 77	141	0,34	0,865	0,0	0,00	5,7
		Woche 81	131	0,38	0,989	0,0	0,00	5,7
		Woche 85	136	0,47	1,190	0,0	0,00	6,9
		Woche 89	124	0,44	1,164	0,0	0,00	7,7
		Woche 93	116	0,40	0,947	0,0	0,00	5,8
		Woche 97	117	0,48	1,100	0,0	0,00	5,8
		Woche 101	113	0,52	1,229	0,0	0,00	6,8
		Woche 105	111	0,42	1,041	0,0	0,00	6,2
		Woche 109	102	0,46	1,165	0,0	0,00	5,9
		Woche 113	90	0,41	1,111	0,0	0,00	6,9
		Woche 117	81	0,51	1,242	0,0	0,00	6,1
		Woche 121	74	0,43	1,088	0,0	0,00	5,7

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 5.5.2.4 PROpel: Summary of BPI-SF Pain Interference (Item 9a-g) results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 125	64	0,37	0,955	0,0	0,00	5,8
		Woche 129	56	0,41	1,070	0,0	0,00	6,2
		Woche 133	45	0,44	1,046	0,0	0,00	5,8
		Woche 137	36	0,26	0,551	0,0	0,00	2,6
		Woche 141	28	0,15	0,298	0,0	0,00	1,0
		Woche 145	24	0,32	0,767	0,0	0,00	3,1
		Woche 149	15	0,38	0,790	0,0	0,00	2,6
		Woche 153	14	0,26	0,517	0,0	0,00	1,6
		Woche 157	10	0,47	1,182	0,0	0,00	3,7
		Woche 161	4	1,33	2,470	0,0	0,14	5,0
		Woche 165	1	0,00	NC	0,0	0,00	0,0
		Woche 169	1	0,00	NC	0,0	0,00	0,0
	Placebo + Abiraterone (N=294)	Baseline [a]	277	0,42	0,813	0,0	0,00	5,1
		Woche 5	232	0,47	0,999	0,0	0,00	6,9
		Woche 9	233	0,39	0,949	0,0	0,00	7,8
		Woche 13	220	0,44	1,039	0,0	0,00	6,3
		Woche 17	221	0,39	0,950	0,0	0,00	5,7
		Woche 21	220	0,47	1,149	0,0	0,00	8,2
		Woche 25	204	0,47	1,047	0,0	0,00	5,8
		Woche 29	197	0,45	0,994	0,0	0,00	5,7
		Woche 33	185	0,45	0,919	0,0	0,00	4,8
		Woche 37	186	0,42	0,885	0,0	0,00	4,8
		Woche 41	177	0,37	0,833	0,0	0,00	5,5
		Woche 45	173	0,42	0,883	0,0	0,00	5,2
		Woche 49	170	0,43	0,939	0,0	0,00	6,3
		Woche 53	161	0,41	0,909	0,0	0,00	4,6
		Woche 57	151	0,53	1,186	0,0	0,00	7,6
		Woche 61	145	0,55	1,109	0,0	0,00	5,6
		Woche 65	135	0,59	1,215	0,0	0,00	6,8
		Woche 69	127	0,54	1,118	0,0	0,00	6,1

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 5.5.2.4 PROpel: Summary of BPI-SF Pain Interference (Item 9a-g) results across timepoints, by treatment group
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
		Woche 73	124	0,44	1,008	0,0	0,00	6,3
		Woche 77	116	0,52	1,127	0,0	0,00	7,1
		Woche 81	111	0,48	1,065	0,0	0,00	6,4
		Woche 85	105	0,50	1,071	0,0	0,00	5,3
		Woche 89	102	0,45	0,964	0,0	0,00	4,5
		Woche 93	96	0,55	1,148	0,0	0,00	5,7
		Woche 97	86	0,59	1,112	0,0	0,00	4,2
		Woche 101	82	0,56	1,157	0,0	0,00	5,7
		Woche 105	82	0,47	0,984	0,0	0,00	3,6
		Woche 109	78	0,50	0,990	0,0	0,00	3,7
		Woche 113	69	0,51	1,038	0,0	0,00	3,7
		Woche 117	55	0,47	0,999	0,0	0,00	3,9
		Woche 121	54	0,40	0,855	0,0	0,00	3,5
		Woche 125	48	0,45	0,938	0,0	0,00	3,8
		Woche 129	44	0,49	1,015	0,0	0,00	4,1
		Woche 133	36	0,54	1,125	0,0	0,00	4,4
		Woche 137	29	0,47	1,032	0,0	0,00	4,5
		Woche 141	21	0,58	0,990	0,0	0,00	3,5
		Woche 145	17	0,61	0,849	0,0	0,00	2,3
		Woche 149	13	0,72	0,951	0,0	0,00	2,3
		Woche 153	7	1,21	1,129	0,0	1,00	2,7
		Woche 157	6	0,95	1,170	0,0	0,50	2,7
		Woche 161	2	1,00	1,414	0,0	1,00	2,0
		Woche 165	2	0,00	0,000	0,0	0,00	0,0

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 5.8.1 PROpel: Summary of BPI-SF compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		COMPLIANCE						
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Overall	Olaparib + Abiraterone (N=266)	NA	259	259	238	89.5	100	91.9
	Placebo + Abiraterone (N=294)	NA	291	291	264	89.8	100	90.7
Baseline	Olaparib + Abiraterone (N=266)	266 (100)	266	266	255	95.9	100	95.9
	Placebo + Abiraterone (N=294)	294 (100)	294	294	277	94.2	100	94.2
Week 5	Olaparib + Abiraterone (N=266)	266 (100)	246	246	201	75.6	100	81.7
	Placebo + Abiraterone (N=294)	294 (100)	283	283	232	78.9	100	82.0
Week 9	Olaparib + Abiraterone (N=266)	266 (100)	237	237	199	74.8	100	84.0
	Placebo + Abiraterone (N=294)	292 (99.3)	277	277	233	79.8	100	84.1
Week 13	Olaparib + Abiraterone (N=266)	266 (100)	232	232	200	75.2	100	86.2
	Placebo + Abiraterone (N=294)	291 (99.0)	262	262	220	75.6	100	84.0
Week 17	Olaparib + Abiraterone (N=266)	265 (99.6)	226	226	194	73.2	100	85.8
	Placebo + Abiraterone (N=294)	287 (97.6)	264	264	221	77.0	100	83.7
Week 21	Olaparib + Abiraterone (N=266)	261 (98.1)	226	226	192	73.6	100	85.0
	Placebo + Abiraterone (N=294)	286 (97.3)	250	250	220	76.9	100	88.0
Week 25	Olaparib + Abiraterone (N=266)	254 (95.5)	216	216	191	75.2	100	88.4
	Placebo + Abiraterone (N=294)	283 (96.3)	243	243	204	72.1	100	84.0

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.1 PROpel: Summary of BPI-SF compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		COMPLIANCE						
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Week 29	Olaparib + Abiraterone (N=266)	249 (93.6)	219	219	189	75.9	100	86.3
	Placebo + Abiraterone (N=294)	279 (94.9)	232	232	197	70.6	100	84.9
Week 33	Olaparib + Abiraterone (N=266)	244 (91.7)	216	216	187	76.6	100	86.6
	Placebo + Abiraterone (N=294)	267 (90.8)	217	217	185	69.3	100	85.3
Week 37	Olaparib + Abiraterone (N=266)	239 (89.8)	207	207	181	75.7	100	87.4
	Placebo + Abiraterone (N=294)	263 (89.5)	217	217	186	70.7	100	85.7
Week 41	Olaparib + Abiraterone (N=266)	231 (86.8)	202	202	176	76.2	100	87.1
	Placebo + Abiraterone (N=294)	251 (85.4)	207	207	177	70.5	100	85.5
Week 45	Olaparib + Abiraterone (N=266)	228 (85.7)	194	194	172	75.4	100	88.7
	Placebo + Abiraterone (N=294)	244 (83.0)	203	203	173	70.9	100	85.2
Week 49	Olaparib + Abiraterone (N=266)	221 (83.1)	188	188	174	78.7	100	92.6
	Placebo + Abiraterone (N=294)	239 (81.3)	195	195	170	71.1	100	87.2
Week 53	Olaparib + Abiraterone (N=266)	212 (79.7)	186	186	166	78.3	100	89.2
	Placebo + Abiraterone (N=294)	228 (77.6)	181	181	161	70.6	100	89.0
Week 57	Olaparib + Abiraterone (N=266)	205 (77.1)	179	179	161	78.5	100	89.9
	Placebo + Abiraterone (N=294)	221 (75.2)	172	172	151	68.3	100	87.8

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.1 PROpel: Summary of BPI-SF compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			COMPLIANCE					
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Week 61	Olaparib + Abiraterone (N=266)	201 (75.6)	173	173	154	76.6	100	89.0
	Placebo + Abiraterone (N=294)	208 (70.7)	166	166	145	69.7	100	87.3
Week 65	Olaparib + Abiraterone (N=266)	198 (74.4)	170	170	152	76.8	100	89.4
	Placebo + Abiraterone (N=294)	199 (67.7)	148	148	135	67.8	100	91.2
Week 69	Olaparib + Abiraterone (N=266)	193 (72.6)	163	163	149	77.2	100	91.4
	Placebo + Abiraterone (N=294)	190 (64.6)	138	138	127	66.8	100	92.0
Week 73	Olaparib + Abiraterone (N=266)	189 (71.1)	157	157	140	74.1	100	89.2
	Placebo + Abiraterone (N=294)	186 (63.3)	140	140	124	66.7	100	88.6
Week 77	Olaparib + Abiraterone (N=266)	181 (68.0)	155	155	141	77.9	100	91.0
	Placebo + Abiraterone (N=294)	171 (58.2)	126	126	116	67.8	100	92.1
Week 81	Olaparib + Abiraterone (N=266)	177 (66.5)	140	140	131	74.0	100	93.6
	Placebo + Abiraterone (N=294)	169 (57.5)	122	122	111	65.7	100	91.0
Week 85	Olaparib + Abiraterone (N=266)	173 (65.0)	145	145	136	78.6	100	93.8
	Placebo + Abiraterone (N=294)	163 (55.4)	119	119	105	64.4	100	88.2
Week 89	Olaparib + Abiraterone (N=266)	168 (63.2)	135	135	124	73.8	100	91.9
	Placebo + Abiraterone (N=294)	151 (51.4)	111	111	102	67.5	100	91.9

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.1 PROpel: Summary of BPI-SF compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		COMPLIANCE						
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Week 93	Olaparib + Abiraterone (N=266)	161 (60.5)	130	130	116	72.0	100	89.2
	Placebo + Abiraterone (N=294)	146 (49.7)	104	104	96	65.8	100	92.3
Week 97	Olaparib + Abiraterone (N=266)	158 (59.4)	129	129	117	74.1	100	90.7
	Placebo + Abiraterone (N=294)	140 (47.6)	97	97	86	61.4	100	88.7
Week 101	Olaparib + Abiraterone (N=266)	151 (56.8)	124	124	113	74.8	100	91.1
	Placebo + Abiraterone (N=294)	126 (42.9)	90	90	82	65.1	100	91.1
Week 105	Olaparib + Abiraterone (N=266)	148 (55.6)	121	121	111	75.0	100	91.7
	Placebo + Abiraterone (N=294)	117 (39.8)	87	87	82	70.1	100	94.3
Week 109	Olaparib + Abiraterone (N=266)	147 (55.3)	111	111	102	69.4	100	91.9
	Placebo + Abiraterone (N=294)	116 (39.5)	83	83	78	67.2	100	94.0
Week 113	Olaparib + Abiraterone (N=266)	133 (50.0)	95	95	90	67.7	100	94.7
	Placebo + Abiraterone (N=294)	101 (34.4)	75	75	69	68.3	100	92.0
Week 117	Olaparib + Abiraterone (N=266)	120 (45.1)	87	87	81	67.5	100	93.1
	Placebo + Abiraterone (N=294)	86 (29.3)	62	62	55	64.0	100	88.7
Week 121	Olaparib + Abiraterone (N=266)	108 (40.6)	79	79	74	68.5	100	93.7
	Placebo + Abiraterone (N=294)	79 (26.9)	61	61	54	68.4	100	88.5

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.1 PROpel: Summary of BPI-SF compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		COMPLIANCE						
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Week 125	Olaparib + Abiraterone (N=266)	93 (35.0)	68	68	64	68.8	100	94.1
	Placebo + Abiraterone (N=294)	70 (23.8)	51	51	48	68.6	100	94.1
Week 129	Olaparib + Abiraterone (N=266)	79 (29.7)	58	58	56	70.9	100	96.6
	Placebo + Abiraterone (N=294)	64 (21.8)	47	47	44	68.8	100	93.6
Week 133	Olaparib + Abiraterone (N=266)	67 (25.2)	47	47	45	67.2	100	95.7
	Placebo + Abiraterone (N=294)	51 (17.3)	38	38	36	70.6	100	94.7
Week 137	Olaparib + Abiraterone (N=266)	55 (20.7)	40	40	36	65.5	100	90.0
	Placebo + Abiraterone (N=294)	44 (15.0)	32	32	29	65.9	100	90.6
Week 141	Olaparib + Abiraterone (N=266)	44 (16.5)	31	31	28	63.6	100	90.3
	Placebo + Abiraterone (N=294)	36 (12.2)	22	22	21	58.3	100	95.5
Week 145	Olaparib + Abiraterone (N=266)	39 (14.7)	26	26	24	61.5	100	92.3
	Placebo + Abiraterone (N=294)	29 (9.9)	19	19	17	58.6	100	89.5
Week 149	Olaparib + Abiraterone (N=266)	29 (10.9)	21	21	15	51.7	100	71.4
	Placebo + Abiraterone (N=294)	19 (6.5)	14	14	13	68.4	100	92.9
Week 153	Olaparib + Abiraterone (N=266)	25 (9.4)	15	15	14	56.0	100	93.3
	Placebo + Abiraterone (N=294)	14 (4.8)	9	9	7	50.0	100	77.8

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.1 PROpel: Summary of BPI-SF compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		COMPLIANCE						
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Week 157	Olaparib + Abiraterone (N=266)	18 (6.8)	11	11	10	55.6	100	90.9
	Placebo + Abiraterone (N=294)	9 (3.1)	7	7	6	66.7	100	85.7
Week 161	Olaparib + Abiraterone (N=266)	14 (5.3)	5	5	4	28.6	100	80.0
	Placebo + Abiraterone (N=294)	5 (1.7)	3	3	2	40.0	100	66.7
Week 165	Olaparib + Abiraterone (N=266)	5 (1.9)	3	3	1	20.0	100	33.3
	Placebo + Abiraterone (N=294)	4 (1.4)	3	3	2	50.0	100	66.7
Week 169	Olaparib + Abiraterone (N=266)	2 (0.8)	1	1	1	50.0	100	100
	Placebo + Abiraterone (N=294)	0	0	0	0	NC	NC	NC

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.2 PROpel: Summary of FACT-P compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			COMPLIANCE					
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Overall	Olaparib + Abiraterone (N=266)	NA	205	111	205	77.1	54.1	100
	Placebo + Abiraterone (N=294)	NA	231	142	231	78.6	61.5	100
Baseline	Olaparib + Abiraterone (N=266)	266 (100)	210	127	210	78.9	60.5	100
	Placebo + Abiraterone (N=294)	294 (100)	234	154	234	79.6	65.8	100
Week 5	Olaparib + Abiraterone (N=266)	266 (100)	230	127	230	86.5	55.2	100
	Placebo + Abiraterone (N=294)	294 (100)	277	181	277	94.2	65.3	100
Week 9	Olaparib + Abiraterone (N=266)	266 (100)	230	138	230	86.5	60.0	100
	Placebo + Abiraterone (N=294)	292 (99.3)	270	189	270	92.5	70.0	100
Week 13	Olaparib + Abiraterone (N=266)	266 (100)	222	133	222	83.5	59.9	100
	Placebo + Abiraterone (N=294)	291 (99.0)	250	178	250	85.9	71.2	100
Week 17	Olaparib + Abiraterone (N=266)	265 (99.6)	218	137	218	82.3	62.8	100
	Placebo + Abiraterone (N=294)	287 (97.6)	249	168	249	86.8	67.5	100
Week 21	Olaparib + Abiraterone (N=266)	261 (98.1)	214	124	214	82.0	57.9	100
	Placebo + Abiraterone (N=294)	286 (97.3)	240	155	240	83.9	64.6	100
Week 25	Olaparib + Abiraterone (N=266)	254 (95.5)	210	136	210	82.7	64.8	100
	Placebo + Abiraterone (N=294)	283 (96.3)	237	157	237	83.7	66.2	100

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.2 PROpel: Summary of FACT-P compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			COMPLIANCE					
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Week 29	Olaparib + Abiraterone (N=266)	249 (93.6)	207	128	207	83.1	61.8	100
	Placebo + Abiraterone (N=294)	279 (94.9)	222	152	222	79.6	68.5	100
Week 33	Olaparib + Abiraterone (N=266)	244 (91.7)	199	125	199	81.6	62.8	100
	Placebo + Abiraterone (N=294)	267 (90.8)	205	139	205	76.8	67.8	100
Week 37	Olaparib + Abiraterone (N=266)	239 (89.8)	191	123	191	79.9	64.4	100
	Placebo + Abiraterone (N=294)	263 (89.5)	205	139	205	77.9	67.8	100
Week 41	Olaparib + Abiraterone (N=266)	231 (86.8)	189	122	189	81.8	64.6	100
	Placebo + Abiraterone (N=294)	251 (85.4)	192	128	192	76.5	66.7	100
Week 45	Olaparib + Abiraterone (N=266)	228 (85.7)	181	120	181	79.4	66.3	100
	Placebo + Abiraterone (N=294)	244 (83.0)	192	129	192	78.7	67.2	100
Week 49	Olaparib + Abiraterone (N=266)	221 (83.1)	181	117	181	81.9	64.6	100
	Placebo + Abiraterone (N=294)	239 (81.3)	183	123	183	76.6	67.2	100
Week 53	Olaparib + Abiraterone (N=266)	212 (79.7)	178	115	178	84.0	64.6	100
	Placebo + Abiraterone (N=294)	228 (77.6)	169	112	169	74.1	66.3	100
Week 61	Olaparib + Abiraterone (N=266)	202 (75.9)	162	108	162	80.2	66.7	100
	Placebo + Abiraterone (N=294)	217 (73.8)	155	97	155	71.4	62.6	100

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.2 PROpel: Summary of FACT-P compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			COMPLIANCE					
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Week 69	Olaparib + Abiraterone (N=266)	193 (72.6)	156	101	156	80.8	64.7	100
	Placebo + Abiraterone (N=294)	193 (65.6)	131	83	131	67.9	63.4	100
Week 77	Olaparib + Abiraterone (N=266)	184 (69.2)	147	98	147	79.9	66.7	100
	Placebo + Abiraterone (N=294)	178 (60.5)	117	76	117	65.7	65.0	100
Week 85	Olaparib + Abiraterone (N=266)	174 (65.4)	139	96	139	79.9	69.1	100
	Placebo + Abiraterone (N=294)	168 (57.1)	112	76	112	66.7	67.9	100
Week 93	Olaparib + Abiraterone (N=266)	164 (61.7)	127	88	127	77.4	69.3	100
	Placebo + Abiraterone (N=294)	148 (50.3)	97	67	97	65.5	69.1	100
Week 101	Olaparib + Abiraterone (N=266)	155 (58.3)	121	83	121	78.1	68.6	100
	Placebo + Abiraterone (N=294)	132 (44.9)	84	57	84	63.6	67.9	100
Week 109	Olaparib + Abiraterone (N=266)	147 (55.3)	105	69	105	71.4	65.7	100
	Placebo + Abiraterone (N=294)	116 (39.5)	81	51	81	69.8	63.0	100
Week 117	Olaparib + Abiraterone (N=266)	125 (47.0)	85	54	85	68.0	63.5	100
	Placebo + Abiraterone (N=294)	92 (31.3)	57	41	57	62.0	71.9	100
Week 125	Olaparib + Abiraterone (N=266)	100 (37.6)	65	34	65	65.0	52.3	100
	Placebo + Abiraterone (N=294)	75 (25.5)	46	34	46	61.3	73.9	100

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.2 PROpel: Summary of FACT-P compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			COMPLIANCE					
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Evaluable forms	Compliance rate (%) [a]	Completion rate (%) [b]	Evaluability rate (%) [c]
Week 133	Olaparib + Abiraterone (N=266)	72 (27.1)	47	25	47	65.3	53.2	100
	Placebo + Abiraterone (N=294)	55 (18.7)	37	27	37	67.3	73.0	100
Week 141	Olaparib + Abiraterone (N=266)	49 (18.4)	31	17	31	63.3	54.8	100
	Placebo + Abiraterone (N=294)	39 (13.3)	22	16	22	56.4	72.7	100
Week 149	Olaparib + Abiraterone (N=266)	33 (12.4)	15	7	15	45.5	46.7	100
	Placebo + Abiraterone (N=294)	26 (8.8)	14	7	14	53.8	50.0	100
Week 157	Olaparib + Abiraterone (N=266)	20 (7.5)	7	3	7	35.0	42.9	100
	Placebo + Abiraterone (N=294)	13 (4.4)	7	3	7	53.8	42.9	100
Week 165	Olaparib + Abiraterone (N=266)	5 (1.9)	1	0	1	20.0	NC	100
	Placebo + Abiraterone (N=294)	5 (1.7)	2	0	2	40.0	NC	100
Week 173	Olaparib + Abiraterone (N=266)	1 (0.4)	0	0	0	NC	NC	NC
	Placebo + Abiraterone (N=294)	0	0	0	0	NC	NC	NC

NA = Not applicable.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with an evaluable baseline and at least one evaluable follow-up form divided by the number of patients expected to have completed at least a baseline and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with an evaluable form at that time point divided by number of patients still expected to complete forms at that visit. [b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms. [c] The evaluability rate over time is calculated separately for each visit, including baseline, as the number of evaluable forms divided by the number of received forms.
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Table 5.8.3 PROpel: Summary of EQ-5D-5L compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

			COMPLIANCE			
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Compliance rate (%) [a]	Completion rate (%) [b]
Overall	Olaparib + Abiraterone (N=266)	NA	194	194	72.9	100
	Placebo + Abiraterone (N=294)	NA	213	213	72.4	100
Baseline	Olaparib + Abiraterone (N=266)	266 (100)	200	200	75.2	100
	Placebo + Abiraterone (N=294)	294 (100)	220	220	74.8	100
Week 9	Olaparib + Abiraterone (N=266)	266 (100)	227	227	85.3	100
	Placebo + Abiraterone (N=294)	294 (100)	266	266	90.5	100
Week 17	Olaparib + Abiraterone (N=266)	265 (99.6)	216	216	81.5	100
	Placebo + Abiraterone (N=294)	289 (98.3)	248	248	85.8	100
Week 25	Olaparib + Abiraterone (N=266)	258 (97.0)	208	208	80.6	100
	Placebo + Abiraterone (N=294)	286 (97.3)	233	233	81.5	100
Week 33	Olaparib + Abiraterone (N=266)	247 (92.9)	193	193	78.1	100
	Placebo + Abiraterone (N=294)	272 (92.5)	205	205	75.4	100
Week 41	Olaparib + Abiraterone (N=266)	236 (88.7)	185	185	78.4	100
	Placebo + Abiraterone (N=294)	256 (87.1)	188	188	73.4	100
Week 49	Olaparib + Abiraterone (N=266)	224 (84.2)	182	182	81.3	100
	Placebo + Abiraterone (N=294)	242 (82.3)	183	183	75.6	100

n = the number of evaluable patients. NA = Not applicable. NC = Not calculated.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with a baseline form and at least one follow-up form divided by the number of patients expected to have completed at least a baseline form and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with a form at that time point divided by number of patients still expected to complete forms at that visit.
[b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms.
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Table 5.8.3 PROpel: Summary of EQ-5D-5L compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		COMPLIANCE				
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Compliance rate (%) [a]	Completion rate (%) [b]
Week 57	Olaparib + Abiraterone (N=266)	208 (78.2)	157	157	75.5	100
	Placebo + Abiraterone (N=294)	224 (76.2)	150	150	67.0	100
Week 65	Olaparib + Abiraterone (N=266)	199 (74.8)	145	145	72.9	100
	Placebo + Abiraterone (N=294)	206 (70.1)	127	127	61.7	100
Week 73	Olaparib + Abiraterone (N=266)	190 (71.4)	140	140	73.7	100
	Placebo + Abiraterone (N=294)	187 (63.6)	115	115	61.5	100
Week 81	Olaparib + Abiraterone (N=266)	179 (67.3)	134	134	74.9	100
	Placebo + Abiraterone (N=294)	171 (58.2)	109	109	63.7	100
Week 89	Olaparib + Abiraterone (N=266)	169 (63.5)	120	120	71.0	100
	Placebo + Abiraterone (N=294)	156 (53.1)	92	92	59.0	100
Week 97	Olaparib + Abiraterone (N=266)	160 (60.2)	115	115	71.9	100
	Placebo + Abiraterone (N=294)	141 (48.0)	85	85	60.3	100
Week 105	Olaparib + Abiraterone (N=266)	151 (56.8)	97	97	64.2	100
	Placebo + Abiraterone (N=294)	123 (41.8)	78	78	63.4	100
Week 113	Olaparib + Abiraterone (N=266)	137 (51.5)	82	82	59.9	100
	Placebo + Abiraterone (N=294)	108 (36.7)	58	58	53.7	100

n = the number of evaluable patients. NA = Not applicable. NC = Not calculated.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with a baseline form and at least one follow-up form divided by the number of patients expected to have completed at least a baseline form and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with a form at that time point divided by number of patients still expected to complete forms at that visit.
[b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms.

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Table 5.8.3 PROpel: Summary of EQ-5D-5L compliance by treatment group and visit
Full Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		COMPLIANCE				
Time point	Treatment Group	Expected forms (n,%)*	Received forms	Completed forms	Compliance rate (%) [a]	Completion rate (%) [b]
Week 121	Olaparib + Abiraterone (N=266)	115 (43.2)	63	63	54.8	100
	Placebo + Abiraterone (N=294)	82 (27.9)	46	46	56.1	100
Week 129	Olaparib + Abiraterone (N=266)	85 (32.0)	44	44	51.8	100
	Placebo + Abiraterone (N=294)	66 (22.4)	36	36	54.5	100
Week 137	Olaparib + Abiraterone (N=266)	62 (23.3)	29	29	46.8	100
	Placebo + Abiraterone (N=294)	47 (16.0)	23	23	48.9	100
Week 145	Olaparib + Abiraterone (N=266)	42 (15.8)	14	14	33.3	100
	Placebo + Abiraterone (N=294)	32 (10.9)	13	13	40.6	100
Week 153	Olaparib + Abiraterone (N=266)	26 (9.8)	7	7	26.9	100
	Placebo + Abiraterone (N=294)	17 (5.8)	7	7	41.2	100
Week 161	Olaparib + Abiraterone (N=266)	15 (5.6)	2	2	13.3	100
	Placebo + Abiraterone (N=294)	5 (1.7)	2	2	40.0	100
Week 169	Olaparib + Abiraterone (N=266)	2 (0.8)	0	0	NC	NC
	Placebo + Abiraterone (N=294)	1 (0.3)	0	0	NC	NC

n = the number of evaluable patients. NA = Not applicable. NC = Not calculated.
* Unexpected forms due to progression or other reasons excludes patients who are still expected to complete PRO assessments.
[a] The overall compliance rate is calculated as the number of patients with a baseline form and at least one follow-up form divided by the number of patients expected to have completed at least a baseline form and one follow-up form. Also, the compliance rate over time is calculated separately for each visit, including baseline, as the number of patients with a form at that time point divided by number of patients still expected to complete forms at that visit.
[b] The completion rate over time is calculated separately for each visit, including baseline, as the number of completed forms divided by the number of received forms.
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Table 6.1 PROpel: Summary of observation period (months) for adverse events
Safety Analysis Set, Asymptomatic patients at baseline. DCO 14MAR2022

		Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)
UE	n	266	294
	Mediane	24,77	17,58
	Min	1,9	0,4
	Max	38,8	37,9
UESI	n	266	294
	Mediane	28,37	26,84
	Min	2,4	0,4
	Max	38,8	38,3

Observation period for AEs is defined as the time from first dose to the earliest date of the DCO, study treatment discontinuation + 30 days or death.
Observation period for AESIs is defined as the time from first dose to the earliest date of the DCO, study discontinuation/completion or death.
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Table 7.1 PROpel: Patient disposition
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Patients enrolled [a]			560
Patients randomised	266 (100)	294 (100)	560 (100)
Full analysis set	266 (100)	294 (100)	560 (100)
Patients who received treatment	266 (100)	294 (100)	560 (100)
Patients ongoing treatment at data cut-off [b]	107 (40.2)	85 (28.9)	192 (34.3)
Patients ongoing both Olaparib/Placebo and Abiraterone [b]	101 (38.0)	83 (28.2)	184 (32.9)
Patients who discontinued Olaparib/Placebo alone [b]	6 (2.3)	2 (0.7)	8 (1.4)
Patient decision	1 (0.4)	0	1 (0.2)
Adverse event	5 (1.9)	2 (0.7)	7 (1.3)
Due to COVID-19 pandemic	0	0	0
Patients who discontinued treatment [b]	159 (59.8)	209 (71.1)	368 (65.7)
Olaparib/Placebo [b]			
Patient decision	18 (6.8)	14 (4.8)	32 (5.7)
Adverse event	36 (13.5)	18 (6.1)	54 (9.6)
Severe non-compliance to protocol	2 (0.8)	2 (0.7)	4 (0.7)
Objective disease progression	70 (26.3)	124 (42.2)	194 (34.6)
Patient lost to follow-up	0	1 (0.3)	1 (0.2)
Other [c]	33 (12.4)	50 (17.0)	83 (14.8)
Due to COVID-19 pandemic	0	0	0
Abiraterone [b]			
Patient decision	20 (7.5)	15 (5.1)	35 (6.3)
Adverse event	22 (8.3)	21 (7.1)	43 (7.7)

[a] Informed consent received.
[b] Percentages are calculated from number of patients who received treatment.
[c] Other reason for discontinuation of treatment as provided by the investigator includes clinical progression, PSA progression, death, etc.
Unless otherwise stated, percentages are calculated from the number of patients randomised.
Asymptomatic at Baseline - all randomised patients with treatment groups assigned in accordance with the randomisation, regardless of the treatment actually received.
Due to COVID-19 pandemic refers to site closure due to pandemic impacting all patients at affected sites.
COVID-19 Coronavirus Disease 2019.
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Table 7.1 PROpel: Patient disposition
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Severe non-compliance to protocol	3 (1.1)	2 (0.7)	5 (0.9)
Objective disease progression	74 (27.8)	122 (41.5)	196 (35.0)
Patient lost to follow-up	0	1 (0.3)	1 (0.2)
Other [c]	40 (15.0)	48 (16.3)	88 (15.7)
Due to COVID-19 pandemic	0	0	0
Patients ongoing study at data cut off [b]	179 (67.3)	177 (60.2)	356 (63.6)
Patients who terminated study [b]	87 (32.7)	117 (39.8)	204 (36.4)
Death	75 (28.2)	111 (37.8)	186 (33.2)
Failure to meet randomisation criteria	0	1 (0.3)	1 (0.2)
Patient decision	10 (3.8)	4 (1.4)	14 (2.5)
Patient lost to follow-up	1 (0.4)	0	1 (0.2)
Other	1 (0.4)	1 (0.3)	2 (0.4)
Due to COVID-19 pandemic	0	0	0

[a] Informed consent received.
[b] Percentages are calculated from number of patients who received treatment.
[c] Other reason for discontinuation of treatment as provided by the investigator includes clinical progression, PSA progression, death, etc.
Unless otherwise stated, percentages are calculated from the number of patients randomised.
Asymptomatic at Baseline - all randomised patients with treatment groups assigned in accordance with the randomisation, regardless of the treatment actually received.
Due to COVID-19 pandemic refers to site closure due to pandemic impacting all patients at affected sites.
COVID-19 Coronavirus Disease 2019.
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Table 7.2 PROpel: Stratification factors at randomisation
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

		Number (%) of patients		
Metastases	Docetaxel treatment at mHSPC stage	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
As randomised (IWRS)				
Bone only	Yes	32 (12.0)	43 (14.6)	75 (13.4)
	No	112 (42.1)	117 (39.8)	229 (40.9)
Visceral	Yes	6 (2.3)	9 (3.1)	15 (2.7)
	No	26 (9.8)	26 (8.8)	52 (9.3)
Other	Yes	14 (5.3)	25 (8.5)	39 (7.0)
	No	76 (28.6)	74 (25.2)	150 (26.8)
Derived from eCRF data				
Bone only	Yes	31 (11.7)	44 (15.0)	75 (13.4)
	No	111 (41.7)	119 (40.5)	230 (41.1)
Visceral	Yes	6 (2.3)	13 (4.4)	19 (3.4)
	No	38 (14.3)	38 (12.9)	76 (13.6)
Other	Yes	12 (4.5)	16 (5.4)	28 (5.0)
	No	68 (25.6)	64 (21.8)	132 (23.6)

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Table 7.3 PROpel: Demographic characteristics
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Demographic characteristic		Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Age (years)	n	266	294	560
	Mean	68.4	69.7	69.1
	sd	7.89	7.84	7.88
	Min	45	48	45
	Median	69.0	70.0	69.0
	Max	91	87	91
Age group (years) n (%)	<65	81 (30.5)	74 (25.2)	155 (27.7)
	>=65	185 (69.5)	220 (74.8)	405 (72.3)
	Total	266 (100)	294 (100)	560 (100)
Race n (%)	White	186 (69.9)	197 (67.0)	383 (68.4)
	Black or African American	5 (1.9)	5 (1.7)	10 (1.8)
	Asian	58 (21.8)	62 (21.1)	120 (21.4)
	Native Hawaiian or Other Pacific Islander	2 (0.8)	0	2 (0.4)
	Other	3 (1.1)	2 (0.7)	5 (0.9)
	Missing	12 (4.5)	28 (9.5)	40 (7.1)
	Total	266 (100)	294 (100)	560 (100)
Ethnic group n (%)	Hispanic or Latino	35 (13.2)	34 (11.6)	69 (12.3)
	Not Hispanic or Latino	219 (82.3)	233 (79.3)	452 (80.7)
	Missing	12 (4.5)	27 (9.2)	39 (7.0)
	Total	266 (100)	294 (100)	560 (100)
Country n (%)	Australia	18 (6.8)	24 (8.2)	42 (7.5)
	Belgium	2 (0.8)	0	2 (0.4)
	Brazil	24 (9.0)	17 (5.8)	41 (7.3)
	Canada	12 (4.5)	12 (4.1)	24 (4.3)
	Chile	13 (4.9)	18 (6.1)	31 (5.5)
	Czech Republic	15 (5.6)	10 (3.4)	25 (4.5)

N = Number of patients in treatment group. n = Number of patients included in analysis. SD = Standard deviation.
Min = Minimum. Max = Maximum.
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Table 7.3 PROpel: Demographic characteristics
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Demographic characteristic		Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Country n (%)	France	6 (2.3)	23 (7.8)	29 (5.2)
	Germany	9 (3.4)	11 (3.7)	20 (3.6)
	Italy	19 (7.1)	17 (5.8)	36 (6.4)
	Japan	34 (12.8)	36 (12.2)	70 (12.5)
	Netherlands	12 (4.5)	11 (3.7)	23 (4.1)
	Slovakia	3 (1.1)	9 (3.1)	12 (2.1)
	South Korea	21 (7.9)	24 (8.2)	45 (8.0)
	Spain	9 (3.4)	14 (4.8)	23 (4.1)
	Turkey	28 (10.5)	25 (8.5)	53 (9.5)
	United Kingdom	12 (4.5)	17 (5.8)	29 (5.2)
	United States	29 (10.9)	26 (8.8)	55 (9.8)
	Total	266 (100)	294 (100)	560 (100)

N = Number of patients in treatment group. n = Number of patients included in analysis. SD = Standard deviation.
Min = Minimum. Max = Maximum.
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Table 7.4 PROpel: Previous disease-related treatment modalities
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
Previous treatment modalities	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Patients with any previous treatment modalities	245 (92.1)	283 (96.3)	528 (94.3)
Immunotherapy	3 (1.1)	3 (1.0)	6 (1.1)
Hormonal therapy	206 (77.4)	239 (81.3)	445 (79.5)
Cytotoxic Chemotherapy	54 (20.3)	82 (27.9)	136 (24.3)
Targeted therapy	0	1 (0.3)	1 (0.2)
Radiotherapy	135 (50.8)	140 (47.6)	275 (49.1)
Other	4 (1.5)	4 (1.4)	8 (1.4)

N = Number of patients in treatment group.
Patients can be counted in more than one previous disease related treatment modality.
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Table 7.5 PROpel: Disease characteristics at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Disease characteristic	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Primary Tumour Location			
Prostate Gland	263 (98.9)	290 (98.6)	553 (98.8)
Other	3 (1.1)	4 (1.4)	7 (1.3)
Histology Type			
Adenocarcinoma	266 (100)	294 (100)	560 (100)
Other	0	0	0
Total Gleason Score			
1	0	0	0
2	0	0	0
3	0	0	0
4	0	0	0
5	1 (0.4)	4 (1.4)	5 (0.9)
6	13 (4.9)	12 (4.1)	25 (4.5)
7	65 (24.4)	81 (27.6)	146 (26.1)
8	83 (31.2)	53 (18.0)	136 (24.3)
9	85 (32.0)	126 (42.9)	211 (37.7)
10	15 (5.6)	15 (5.1)	30 (5.4)
Missing	4 (1.5)	3 (1.0)	7 (1.3)
T2a	10 (3.8)	7 (2.4)	17 (3.0)
Primary Tumour TNM Classification at diagnosis			
T0	0	1 (0.3)	1 (0.2)
T2b	13 (4.9)	6 (2.0)	19 (3.4)

PC = prostate cancer. CRPC = Castration resistant prostate cancer.
mCRPC = metastatic castration resistant prostate cancer. mHSPC = metastatic hormone-sensitive prostate cancer.
SD = Standard deviation. Q1 = Lower quartile. Q3 = Upper quartile. Min = Minimum. Max = Maximum.
Prior local therapy with curative intent for PC categories are not mutually exclusive.
Prior chemotherapy for prostate cancer categories are not mutually exclusive.
[a] Counts patients with definitive radiotherapy on prostate as a site.
[b] As long as no signs of failure or disease progression occurred during or immediately after docetaxel treatment.
[c] Baseline pain score is based on a patient completing the BPI-SF questionnaire item (worst pain) at least once during the seven day baseline period and is an average.
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Table 7.5 PROpel: Disease characteristics at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Disease characteristic	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
T2c	19 (7.1)	33 (11.2)	52 (9.3)
Tis	1 (0.4)	0	1 (0.2)
T3	23 (8.6)	37 (12.6)	60 (10.7)
Tis (DCIS)	0	0	0
T3a	30 (11.3)	42 (14.3)	72 (12.9)
Tis (LCIS)	0	0	0
T3b	53 (19.9)	62 (21.1)	115 (20.5)
Tis (Paget's)	0	0	0
T3c	0	2 (0.7)	2 (0.4)
Ta	0	0	0
T4	29 (10.9)	37 (12.6)	66 (11.8)
TX	52 (19.5)	36 (12.2)	88 (15.7)
Missing	3 (1.1)	1 (0.3)	4 (0.7)
T1	2 (0.8)	2 (0.7)	4 (0.7)
T1a	1 (0.4)	1 (0.3)	2 (0.4)
T1b	2 (0.8)	0	2 (0.4)
T1c	17 (6.4)	12 (4.1)	29 (5.2)
T1 (mic)	0	0	0
T2	11 (4.1)	15 (5.1)	26 (4.6)
Regional Lymph Node Classification			
N0	110 (41.4)	120 (40.8)	230 (41.1)
N1	90 (33.8)	121 (41.2)	211 (37.7)
NX	63 (23.7)	53 (18.0)	116 (20.7)
Missing	3 (1.1)	0	3 (0.5)

PC = prostate cancer. CRPC = Castration resistant prostate cancer.
mCRPC = metastatic castration resistant prostate cancer. mHSPC = metastatic hormone-sensitive prostate cancer.
SD = Standard deviation. Q1 = Lower quartile. Q3 = Upper quartile. Min = Minimum. Max = Maximum.
Prior local therapy with curative intent for PC categories are not mutually exclusive.
Prior chemotherapy for prostate cancer categories are not mutually exclusive.
[a] Counts patients with definitive radiotherapy on prostate as a site.
[b] As long as no signs of failure or disease progression occurred during or immediately after docetaxel treatment.
[c] Baseline pain score is based on a patient completing the BPI-SF questionnaire item (worst pain) at least once during the seven day baseline period and is an average.
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Table 7.5 PROpel: Disease characteristics at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Disease characteristic	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Distant metastases TNM Classification			
M0	80 (30.1)	100 (34.0)	180 (32.1)
MX	22 (8.3)	17 (5.8)	39 (7.0)
M1	79 (29.7)	96 (32.7)	175 (31.3)
M1a	10 (3.8)	8 (2.7)	18 (3.2)
M1b	65 (24.4)	62 (21.1)	127 (22.7)
M1c	9 (3.4)	11 (3.7)	20 (3.6)
Missing	1 (0.4)	0	1 (0.2)
Time from initial diagnosis to randomisation (months)			
n	266	294	560
Mean	57.3	58.8	58.1
SD	48.75	52.04	50.47
Median	41.3	39.9	40.4
Min	4	5	4
Max	288	279	288
Time from mCRPC to randomisation (months)			
n	266	294	560
Mean	5.6	6.1	5.8
SD	10.12	12.07	11.18
Median	1.9	2.2	2.0
Min	0	0	0
Max	74	108	108

PC = prostate cancer. CRPC = Castration resistant prostate cancer.
mCRPC = metastatic castration resistant prostate cancer. mHSPC = metastatic hormone-sensitive prostate cancer.
SD = Standard deviation. Q1 = Lower quartile. Q3 = Upper quartile. Min = Minimum. Max = Maximum.
Prior local therapy with curative intent for PC categories are not mutually exclusive.
Prior chemotherapy for prostate cancer categories are not mutually exclusive.
[a] Counts patients with definitive radiotherapy on prostate as a site.
[b] As long as no signs of failure or disease progression occurred during or immediately after docetaxel treatment.
[c] Baseline pain score is based on a patient completing the BPI-SF questionnaire item (worst pain) at least once during the seven day baseline period and is an average.
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Table 7.5 PROpel: Disease characteristics at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Disease characteristic	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Prior local therapy with curative intent for PC			
Yes	98 (36.8)	115 (39.1)	213 (38.0)
Radical prostatectomy	86 (32.3)	105 (35.7)	191 (34.1)
Definitive radiotherapy on prostate [a]	18 (6.8)	14 (4.8)	32 (5.7)
No	168 (63.2)	179 (60.9)	347 (62.0)
Prior treatment with first-generation antiandrogen agents			
Yes	144 (54.1)	150 (51.0)	294 (52.5)
Bicalutamide	141 (53.0)	147 (50.0)	288 (51.4)
Flutamide	8 (3.0)	11 (3.7)	19 (3.4)
Nilutamide	0	3 (1.0)	3 (0.5)
No	122 (45.9)	144 (49.0)	266 (47.5)
Prior treatment with second-generation antiandrogen agents prior to mCRPC stage			
Yes	1 (0.4)	0	1 (0.2)
Apalutamide	0	0	0
Enzalutamide	1 (0.4)	0	1 (0.2)
Darolutamide	0	0	0
No	265 (99.6)	294 (100)	559 (99.8)
Prior docetaxel treatment during neoadjuvant/adjuvant treatment for localised prostate cancer [b]			
Yes	5 (1.9)	11 (3.7)	16 (2.9)

PC = prostate cancer. CRPC = Castration resistant prostate cancer.
mCRPC = metastatic castration resistant prostate cancer. mHSPC = metastatic hormone-sensitive prostate cancer.
SD = Standard deviation. Q1 = Lower quartile. Q3 = Upper quartile. Min = Minimum. Max = Maximum.
Prior local therapy with curative intent for PC categories are not mutually exclusive.
Prior chemotherapy for prostate cancer categories are not mutually exclusive.
[a] Counts patients with definitive radiotherapy on prostate as a site.
[b] As long as no signs of failure or disease progression occurred during or immediately after docetaxel treatment.
[c] Baseline pain score is based on a patient completing the BPI-SF questionnaire item (worst pain) at least once during the seven day baseline period and is an average.

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Table 7.5 PROpel: Disease characteristics at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Disease characteristic	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
No	261 (98.1)	283 (96.3)	544 (97.1)
Prior docetaxel treatment at mHSPC stage [b]			
Yes	49 (18.4)	73 (24.8)	122 (21.8)
No	217 (81.6)	221 (75.2)	438 (78.2)
Prior docetaxel treatment during neoadjuvant/adjuvant treatment for localised prostate cancer or at mHSPC stage [b]			
Yes	53 (19.9)	81 (27.6)	134 (23.9)
No	213 (80.1)	213 (72.4)	426 (76.1)
Type of prostate cancer progression			
PSA progression	112 (42.1)	131 (44.6)	243 (43.4)
Radiographic progression	63 (23.7)	56 (19.0)	119 (21.3)
Both	91 (34.2)	107 (36.4)	198 (35.4)
ECOG performance status			
(0) Normal activity	215 (80.8)	225 (76.5)	440 (78.6)
(1) Restricted activity	51 (19.2)	69 (23.5)	120 (21.4)
(2) In bed less than or equal to 50% of the time	0	0	0
(3) In bed more than 50% of the time	0	0	0
(4) 100% bedridden	0	0	0
Missing	0	0	0
Baseline pain score (BPI-SF Item 3 score) [c]			

PC = prostate cancer. CRPC = Castration resistant prostate cancer.
mCRPC = metastatic castration resistant prostate cancer. mHSPC = metastatic hormone-sensitive prostate cancer.
SD = Standard deviation. Q1 = Lower quartile. Q3 = Upper quartile. Min = Minimum. Max = Maximum.
Prior local therapy with curative intent for PC categories are not mutually exclusive.
Prior chemotherapy for prostate cancer categories are not mutually exclusive.
[a] Counts patients with definitive radiotherapy on prostate as a site.
[b] As long as no signs of failure or disease progression occurred during or immediately after docetaxel treatment.
[c] Baseline pain score is based on a patient completing the BPI-SF questionnaire item (worst pain) at least once during the seven day baseline period and is an average.
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Table 7.5 PROpel: Disease characteristics at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Disease characteristic	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
0 (no pain)	133 (50.0)	136 (46.3)	269 (48.0)
>0-<4 (mild pain)	133 (50.0)	158 (53.7)	291 (52.0)
4-<6 (moderate pain)	0	0	0
>=6 (severe pain)	0	0	0
Missing	0	0	0
Baseline S-Prostate Specific Antigen (ug/L)			
n	264	293	557
Mean	67.830	58.989	63.179
SD	156.7283	168.7695	163.0873
Min	0.07	0.47	0.07
Q1	5.129	5.590	5.440
Median	15.335	13.200	14.190
Q3	50.170	45.670	49.320
Max	1011.13	1888.00	1888.00
Baseline B-Hemoglobin (g/L)			
n	265	294	559
Mean	132.4	132.4	132.4
SD	10.11	11.90	11.08
Min	95	97	95
Q1	127.0	125.6	126.0
Median	133.0	133.0	133.0
Q3	139.0	140.0	140.0
Max	157	162	162

PC = prostate cancer. CRPC = Castration resistant prostate cancer.
mCRPC = metastatic castration resistant prostate cancer. mHSPC = metastatic hormone-sensitive prostate cancer.
SD = Standard deviation. Q1 = Lower quartile. Q3 = Upper quartile. Min = Minimum. Max = Maximum.
Prior local therapy with curative intent for PC categories are not mutually exclusive.
Prior chemotherapy for prostate cancer categories are not mutually exclusive.
[a] Counts patients with definitive radiotherapy on prostate as a site.
[b] As long as no signs of failure or disease progression occurred during or immediately after docetaxel treatment.
[c] Baseline pain score is based on a patient completing the BPI-SF questionnaire item (worst pain) at least once during the seven day baseline period and is an average.
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Table 7.5 PROpel: Disease characteristics at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Disease characteristic	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Baseline S/P-Alkaline Phosphatase (ukat/L)			
n	264	294	558
Mean	2.75	2.52	2.63
SD	3.500	2.298	2.928
Min	0.4	0.6	0.4
Q1	1.32	1.25	1.28
Median	1.77	1.72	1.74
Q3	3.02	2.78	2.92
Max	45.3	16.1	45.3
Baseline S/P-Lactate Dehydrogenase (ukat/L)			
n	259	290	549
Mean	4.18	3.75	3.95
SD	2.204	1.224	1.767
Min	1.8	0.8	0.8
Q1	3.00	2.92	2.95
Median	3.55	3.47	3.50
Q3	4.52	4.13	4.33
Max	23.6	8.7	23.6
Baseline Albumin (g/L)			
n	264	294	558
Mean	42.4	42.1	42.3
SD	3.86	3.84	3.85

PC = prostate cancer. CRPC = Castration resistant prostate cancer.
mCRPC = metastatic castration resistant prostate cancer. mHSPC = metastatic hormone-sensitive prostate cancer.
SD = Standard deviation. Q1 = Lower quartile. Q3 = Upper quartile. Min = Minimum. Max = Maximum.
Prior local therapy with curative intent for PC categories are not mutually exclusive.
Prior chemotherapy for prostate cancer categories are not mutually exclusive.
[a] Counts patients with definitive radiotherapy on prostate as a site.
[b] As long as no signs of failure or disease progression occurred during or immediately after docetaxel treatment.
[c] Baseline pain score is based on a patient completing the BPI-SF questionnaire item (worst pain) at least once during the seven day baseline period and is an average.
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Table 7.5 PROpel: Disease characteristics at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Disease characteristic	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Min	30	30	30
Q1	40.0	40.0	40.0
Median	43.0	42.7	42.9
Q3	45.0	45.0	45.0
Max	54	53	54
Baseline Creatinine (umol/L)			
n	265	293	558
Mean	81.1	80.7	80.9
SD	18.86	19.24	19.04
Min	54	45	45
Q1	69.0	69.0	69.0
Median	76.9	77.8	77.0
Q3	87.5	89.3	88.4
Max	153	221	221

PC = prostate cancer. CRPC = Castration resistant prostate cancer.
mCRPC = metastatic castration resistant prostate cancer. mHSPC = metastatic hormone-sensitive prostate cancer.
SD = Standard deviation. Q1 = Lower quartile. Q3 = Upper quartile. Min = Minimum. Max = Maximum.
Prior local therapy with curative intent for PC categories are not mutually exclusive.
Prior chemotherapy for prostate cancer categories are not mutually exclusive.
[a] Counts patients with definitive radiotherapy on prostate as a site.
[b] As long as no signs of failure or disease progression occurred during or immediately after docetaxel treatment.
[c] Baseline pain score is based on a patient completing the BPI-SF questionnaire item (worst pain) at least once during the seven day baseline period and is an average.
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Table 7.6 PROpel: Extent of disease at baseline
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
Site of disease	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Total	265 (99.6)	294 (100)	559 (99.8)
Prostate and adjacent structures	31 (11.7)	36 (12.2)	67 (12.0)
Locoregional lymph nodes	51 (19.2)	66 (22.4)	117 (20.9)
Distant lymph nodes	89 (33.5)	91 (31.0)	180 (32.1)
Bone	223 (83.8)	246 (83.7)	469 (83.8)
Respiratory	27 (10.2)	32 (10.9)	59 (10.5)
Liver	6 (2.3)	11 (3.7)	17 (3.0)
Other locally advanced sites	6 (2.3)	3 (1.0)	9 (1.6)
Other distant sites	16 (6.0)	20 (6.8)	36 (6.4)
Other	19 (7.1)	19 (6.5)	38 (6.8)

Patients with multiple sites of disease within the same category of extent of disease are counted only once in that category.
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Table 7.7 PROpel: Relevant surgical history
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

System Organ Class / MedDRA preferred term	Number (%) of patients: Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
INVESTIGATIONS	44 (16.5)	33 (11.2)	77 (13.8)
Angiocardiogram	4 (1.5)	0	4 (0.7)
Angiogram	0	2 (0.7)	2 (0.4)
Arthroscopy	1 (0.4)	0	1 (0.2)
Biopsy	4 (1.5)	3 (1.0)	7 (1.3)
Biopsy Bone	1 (0.4)	1 (0.3)	2 (0.4)
Biopsy Breast	1 (0.4)	0	1 (0.2)
Biopsy Lung	2 (0.8)	0	2 (0.4)
Biopsy Lymph Gland	2 (0.8)	1 (0.3)	3 (0.5)
Biopsy Pleura	1 (0.4)	0	1 (0.2)
Biopsy Prostate	24 (9.0)	20 (6.8)	44 (7.9)
Catheterisation Cardiac	1 (0.4)	0	1 (0.2)
Colonoscopy	2 (0.8)	3 (1.0)	5 (0.9)
Cystoscopy	5 (1.9)	4 (1.4)	9 (1.6)
Cytology	0	1 (0.3)	1 (0.2)
Diagnostic Aspiration	2 (0.8)	1 (0.3)	3 (0.5)
Endoscopic Retrograde Cholangiopancreatography	0	1 (0.3)	1 (0.2)
Oesophagogastroduodenoscopy	0	1 (0.3)	1 (0.2)
Ultrasound Prostate	1 (0.4)	0	1 (0.2)
Ureteroscopy	0	2 (0.7)	2 (0.4)
SURGICAL AND MEDICAL PROCEDURES	173 (65.0)	200 (68.0)	373 (66.6)
Abdominal Hernia Repair	1 (0.4)	2 (0.7)	3 (0.5)
Abdominal Operation	1 (0.4)	1 (0.3)	2 (0.4)
Abscess Drainage	0	2 (0.7)	2 (0.4)
Acrochordon Excision	1 (0.4)	0	1 (0.2)
Adenoidectomy	1 (0.4)	1 (0.3)	2 (0.4)
Adrenalectomy	0	1 (0.3)	1 (0.2)
Anal Fissure Excision	0	1 (0.3)	1 (0.2)

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Number (%) of patients are sorted alphabetically by SOC and PT.
A patient can have one or more PTs reported under a given SOC.
MedDRA version 24.1.
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Table 7.7 PROpel: Relevant surgical history
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

System Organ Class / MedDRA preferred term	Number (%) of patients: Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Anal Fistula Repair	0	1 (0.3)	1 (0.2)
Ankle Operation	0	1 (0.3)	1 (0.2)
Aortic Aneurysm Repair	1 (0.4)	1 (0.3)	2 (0.4)
Aortic Valve Replacement	0	2 (0.7)	2 (0.4)
Appendicectomy	9 (3.4)	17 (5.8)	26 (4.6)
Artificial Urinary Sphincter Implant	0	2 (0.7)	2 (0.4)
Atrial Appendage Resection	1 (0.4)	0	1 (0.2)
Atrial Septal Defect Repair	1 (0.4)	0	1 (0.2)
Benign Tumour Excision	2 (0.8)	0	2 (0.4)
Bilateral Orchidectomy	13 (4.9)	11 (3.7)	24 (4.3)
Biliary Fistula Repair	0	1 (0.3)	1 (0.2)
Bladder Calculus Removal	0	2 (0.7)	2 (0.4)
Bladder Catheterisation	2 (0.8)	5 (1.7)	7 (1.3)
Bladder Neck Resection	0	1 (0.3)	1 (0.2)
Bladder Operation	1 (0.4)	0	1 (0.2)
Blepharoplasty	1 (0.4)	0	1 (0.2)
Bone Graft	0	2 (0.7)	2 (0.4)
Brachytherapy	0	1 (0.3)	1 (0.2)
Brachytherapy To Prostate	2 (0.8)	0	2 (0.4)
Brain Tumour Operation	1 (0.4)	0	1 (0.2)
Caecectomy	0	1 (0.3)	1 (0.2)
Calcific Deposits Removal	1 (0.4)	0	1 (0.2)
Cancer Surgery	0	3 (1.0)	3 (0.5)
Cardiac Ablation	2 (0.8)	0	2 (0.4)
Cardiac Pacemaker Insertion	1 (0.4)	4 (1.4)	5 (0.9)
Carpal Tunnel Decompression	1 (0.4)	2 (0.7)	3 (0.5)
Cartilage Operation	0	1 (0.3)	1 (0.2)
Cataract Operation	8 (3.0)	5 (1.7)	13 (2.3)
Central Venous Catheterisation	1 (0.4)	0	1 (0.2)

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A patient can have one or more PTs reported under a given SOC.
MedDRA version 24.1.
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Table 7.7 PROpel: Relevant surgical history
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

System Organ Class / MedDRA preferred term	Number (%) of patients: Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Cervix Operation	0	1 (0.3)	1 (0.2)
Cholecystectomy	9 (3.4)	16 (5.4)	25 (4.5)
Cholelithotomy	1 (0.4)	0	1 (0.2)
Cholesteatoma Removal	0	1 (0.3)	1 (0.2)
Chondrectomy	0	1 (0.3)	1 (0.2)
Circumcision	0	2 (0.7)	2 (0.4)
Colectomy	1 (0.4)	3 (1.0)	4 (0.7)
Colon Operation	1 (0.4)	0	1 (0.2)
Colostomy	1 (0.4)	1 (0.3)	2 (0.4)
Coronary Angioplasty	0	1 (0.3)	1 (0.2)
Coronary Arterial Stent Insertion	1 (0.4)	1 (0.3)	2 (0.4)
Coronary Artery Bypass	1 (0.4)	0	1 (0.2)
Cryotherapy	1 (0.4)	0	1 (0.2)
Cyst Removal	0	1 (0.3)	1 (0.2)
Cystoprostatectomy	2 (0.8)	0	2 (0.4)
Cystostomy	1 (0.4)	0	1 (0.2)
Duodenal Ulcer Repair	1 (0.4)	1 (0.3)	2 (0.4)
Electrocoagulation	0	1 (0.3)	1 (0.2)
Endodontic Procedure	1 (0.4)	0	1 (0.2)
Enterostomy	0	1 (0.3)	1 (0.2)
Eye Excision	0	1 (0.3)	1 (0.2)
Eye Laser Surgery	0	1 (0.3)	1 (0.2)
Eye Operation	0	1 (0.3)	1 (0.2)
Fasciectomy	1 (0.4)	0	1 (0.2)
Femoral Hernia Repair	0	1 (0.3)	1 (0.2)
Fiducial Marker Placement	1 (0.4)	0	1 (0.2)
Finger Amputation	0	2 (0.7)	2 (0.4)
Foot Operation	1 (0.4)	0	1 (0.2)
Fracture Treatment	3 (1.1)	2 (0.7)	5 (0.9)

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Number (%) of patients are sorted alphabetically by SOC and PT.
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MedDRA version 24.1.
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Table 7.7 PROpel: Relevant surgical history
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

System Organ Class / MedDRA preferred term	Number (%) of patients: Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Functional Endoscopic Sinus Surgery	0	2 (0.7)	2 (0.4)
Gastrectomy	2 (0.8)	1 (0.3)	3 (0.5)
Gastric Operation	0	1 (0.3)	1 (0.2)
Haemorrhoid Operation	5 (1.9)	1 (0.3)	6 (1.1)
Hernia Hiatus Repair	0	2 (0.7)	2 (0.4)
Hernia Repair	5 (1.9)	6 (2.0)	11 (2.0)
High Intensity Focused Ultrasound	1 (0.4)	0	1 (0.2)
Hip Arthroplasty	6 (2.3)	8 (2.7)	14 (2.5)
Hip Surgery	0	3 (1.0)	3 (0.5)
Hydrocele Operation	1 (0.4)	3 (1.0)	4 (0.7)
Ileal Operation	0	2 (0.7)	2 (0.4)
Ileectomy	0	1 (0.3)	1 (0.2)
Inguinal Hernia Repair	10 (3.8)	19 (6.5)	29 (5.2)
Internal Fixation Of Fracture	1 (0.4)	1 (0.3)	2 (0.4)
Intervertebral Disc Operation	0	2 (0.7)	2 (0.4)
Intestinal Polypectomy	0	1 (0.3)	1 (0.2)
Intramedullary Rod Insertion	0	2 (0.7)	2 (0.4)
Intraocular Lens Implant	1 (0.4)	0	1 (0.2)
Joint Arthroplasty	2 (0.8)	1 (0.3)	3 (0.5)
Knee Arthroplasty	2 (0.8)	2 (0.7)	4 (0.7)
Knee Operation	3 (1.1)	5 (1.7)	8 (1.4)
Laparotomy	0	1 (0.3)	1 (0.2)
Large Intestinal Polypectomy	0	2 (0.7)	2 (0.4)
Leg Amputation	1 (0.4)	0	1 (0.2)
Lens Extraction	2 (0.8)	0	2 (0.4)
Ligament Operation	1 (0.4)	1 (0.3)	2 (0.4)
Limb Operation	0	1 (0.3)	1 (0.2)
Lipoma Excision	0	2 (0.7)	2 (0.4)
Lithotripsy	0	4 (1.4)	4 (0.7)

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MedDRA version 24.1.
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Table 7.7 PROpel: Relevant surgical history
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

System Organ Class / MedDRA preferred term	Number (%) of patients: Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Liver Transplant	0	1 (0.3)	1 (0.2)
Lung Lobectomy	1 (0.4)	0	1 (0.2)
Lymphadenectomy	13 (4.9)	15 (5.1)	28 (5.0)
Mammoplasty	0	1 (0.3)	1 (0.2)
Mass Excision	1 (0.4)	0	1 (0.2)
Maxillofacial Operation	0	1 (0.3)	1 (0.2)
Meniscus Operation	5 (1.9)	2 (0.7)	7 (1.3)
Meniscus Removal	1 (0.4)	0	1 (0.2)
Metabolic Surgery	1 (0.4)	0	1 (0.2)
Mitral Valve Repair	1 (0.4)	0	1 (0.2)
Mitral Valve Replacement	1 (0.4)	0	1 (0.2)
Nasal Septal Operation	2 (0.8)	3 (1.0)	5 (0.9)
Nephrectomy	2 (0.8)	4 (1.4)	6 (1.1)
Nephrostomy	0	2 (0.7)	2 (0.4)
Oesophagogastric Fundoplasty	0	1 (0.3)	1 (0.2)
Open Reduction Of Fracture	1 (0.4)	0	1 (0.2)
Orchidectomy	6 (2.3)	4 (1.4)	10 (1.8)
Orchidopexy	2 (0.8)	0	2 (0.4)
Osteotomy	1 (0.4)	0	1 (0.2)
Pancreatectomy	1 (0.4)	0	1 (0.2)
Parathyroidectomy	1 (0.4)	0	1 (0.2)
Parotidectomy	0	1 (0.3)	1 (0.2)
Pelvic Operation	1 (0.4)	0	1 (0.2)
Penile Prosthesis Insertion	1 (0.4)	1 (0.3)	2 (0.4)
Percutaneous Coronary Intervention	2 (0.8)	1 (0.3)	3 (0.5)
Phlebectomy	1 (0.4)	0	1 (0.2)
Polypectomy	0	3 (1.0)	3 (0.5)
Proctectomy	0	1 (0.3)	1 (0.2)
Proctocolectomy	0	1 (0.3)	1 (0.2)

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MedDRA version 24.1.
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Table 7.7 PROpel: Relevant surgical history
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

System Organ Class / MedDRA preferred term	Number (%) of patients: Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Prostate Cryoablation	1 (0.4)	0	1 (0.2)
Prostatectomy	19 (7.1)	25 (8.5)	44 (7.9)
Prostatic Operation	0	1 (0.3)	1 (0.2)
Pulmonary Resection	0	1 (0.3)	1 (0.2)
Radical Prostatectomy	50 (18.8)	54 (18.4)	104 (18.6)
Radiotherapy To Lymph Nodes	0	1 (0.3)	1 (0.2)
Renal Artery Stent Placement	0	1 (0.3)	1 (0.2)
Renal Stone Removal	3 (1.1)	4 (1.4)	7 (1.3)
Renal Surgery	0	1 (0.3)	1 (0.2)
Retinopexy	0	1 (0.3)	1 (0.2)
Retro-Pubic Prostatectomy	1 (0.4)	1 (0.3)	2 (0.4)
Rhinoplasty	0	1 (0.3)	1 (0.2)
Rotator Cuff Repair	2 (0.8)	0	2 (0.4)
Salvage Therapy	1 (0.4)	0	1 (0.2)
Sebaceous Cyst Excision	1 (0.4)	1 (0.3)	2 (0.4)
Seminal Vesicle Operation	0	1 (0.3)	1 (0.2)
Shoulder Arthroplasty	2 (0.8)	0	2 (0.4)
Shoulder Operation	2 (0.8)	0	2 (0.4)
Sinus Operation	0	1 (0.3)	1 (0.2)
Skin Lesion Removal	0	1 (0.3)	1 (0.2)
Skin Neoplasm Excision	2 (0.8)	2 (0.7)	4 (0.7)
Small Intestinal Resection	1 (0.4)	0	1 (0.2)
Spinal Decompression	1 (0.4)	0	1 (0.2)
Spinal Fusion Surgery	1 (0.4)	3 (1.0)	4 (0.7)
Spinal Laminectomy	4 (1.5)	2 (0.7)	6 (1.1)
Spinal Operation	2 (0.8)	2 (0.7)	4 (0.7)
Spinal Rod Insertion	0	1 (0.3)	1 (0.2)
Splenectomy	0	1 (0.3)	1 (0.2)
Splint Application	1 (0.4)	0	1 (0.2)

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A patient can have one or more PTs reported under a given SOC.
MedDRA version 24.1.
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Table 7.7 PROpel: Relevant surgical history
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

System Organ Class / MedDRA preferred term	Number (%) of patients: Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Stent Placement	0	1 (0.3)	1 (0.2)
Tendon Sheath Incision	0	1 (0.3)	1 (0.2)
Tenoplasty	2 (0.8)	1 (0.3)	3 (0.5)
Testicular Cyst Excision	0	1 (0.3)	1 (0.2)
Thoracic Cavity Drainage	1 (0.4)	0	1 (0.2)
Thoracic Operation	1 (0.4)	0	1 (0.2)
Thyroid Operation	1 (0.4)	0	1 (0.2)
Thyroidectomy	1 (0.4)	2 (0.7)	3 (0.5)
Tonsillectomy	8 (3.0)	9 (3.1)	17 (3.0)
Transurethral Bladder Resection	2 (0.8)	0	2 (0.4)
Transurethral Prostatectomy	16 (6.0)	26 (8.8)	42 (7.5)
Tricuspid Valve Repair	1 (0.4)	0	1 (0.2)
Tumour Excision	1 (0.4)	0	1 (0.2)
Turbinectomy	1 (0.4)	0	1 (0.2)
Tympanoplasty	1 (0.4)	0	1 (0.2)
Umbilical Hernia Repair	2 (0.8)	3 (1.0)	5 (0.9)
Ureteral Stent Insertion	1 (0.4)	6 (2.0)	7 (1.3)
Ureteric Calculus Removal	0	1 (0.3)	1 (0.2)
Ureteric Operation	1 (0.4)	0	1 (0.2)
Ureterolithotomy	1 (0.4)	0	1 (0.2)
Urethral Calculus Removal	0	1 (0.3)	1 (0.2)
Urethral Dilation Procedure	2 (0.8)	0	2 (0.4)
Urethrotomy	3 (1.1)	0	3 (0.5)
Urinary Bladder Suspension	0	1 (0.3)	1 (0.2)
Urinary Cystectomy	0	1 (0.3)	1 (0.2)
Varicocele Repair	0	1 (0.3)	1 (0.2)
Vasectomy	4 (1.5)	3 (1.0)	7 (1.3)
Vena Cava Filter Insertion	1 (0.4)	0	1 (0.2)
Vesicoureteral Reflux Surgery	1 (0.4)	0	1 (0.2)

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A patient can have one or more PTs reported under a given SOC.
MedDRA version 24.1.
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Table 7.7 PROpel: Relevant surgical history
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

System Organ Class / MedDRA preferred term	Number (%) of patients: Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Vocal Cord Operation	0	1 (0.3)	1 (0.2)
Wrist Surgery	0	1 (0.3)	1 (0.2)

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Number (%) of patients are sorted alphabetically by SOC and PT.
A patient can have one or more PTs reported under a given SOC.
MedDRA version 24.1.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslsurgh_s2.sas ebslsurgh_s2a 10JUN2022:19:42 klfm426

Table 7.8 PROpel: Post-discontinuation anticancer therapy
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
Anticancer therapy [a]	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Patients with any post-discontinuation anticancer therapy	98 (36.8)	151 (51.4)	249 (44.5)
Immunotherapy	12 (4.5)	13 (4.4)	25 (4.5)
Atezolizumab	0	1 (0.3)	1 (0.2)
Blinded Therapy	2 (0.8)	4 (1.4)	6 (1.1)
Investigational Antineoplastic Drugs	0	2 (0.7)	2 (0.4)
Investigational Drug	1 (0.4)	0	1 (0.2)
Ipilimumab	2 (0.8)	1 (0.3)	3 (0.5)
Nivolumab	3 (1.1)	1 (0.3)	4 (0.7)
Pembrolizumab	4 (1.5)	5 (1.7)	9 (1.6)
Sipuleucel-T	2 (0.8)	0	2 (0.4)
Hormonal Therapy	41 (15.4)	56 (19.0)	97 (17.3)
Abiraterone	11 (4.1)	14 (4.8)	25 (4.5)
Abiraterone Acetate	5 (1.9)	3 (1.0)	8 (1.4)
Apalutamide	1 (0.4)	1 (0.3)	2 (0.4)
Bicalutamide	1 (0.4)	0	1 (0.2)
Cyproterone Acetate	0	1 (0.3)	1 (0.2)
Darolutamide	1 (0.4)	1 (0.3)	2 (0.4)
Enzalutamide	24 (9.0)	35 (11.9)	59 (10.5)
Goserelin Acetate	0	1 (0.3)	1 (0.2)
Leuprorelin	0	2 (0.7)	2 (0.4)
Leuprorelin Acetate	0	4 (1.4)	4 (0.7)
Prednisone	1 (0.4)	0	1 (0.2)
Triptorelin	0	1 (0.3)	1 (0.2)
Cytotoxic Chemotherapy	61 (22.9)	112 (38.1)	173 (30.9)
Blinded Therapy	0	1 (0.3)	1 (0.2)
Cabazitaxel	21 (7.9)	40 (13.6)	61 (10.9)
Carboplatin	5 (1.9)	7 (2.4)	12 (2.1)
Cisplatin	0	3 (1.0)	3 (0.5)

[a] Therapies post discontinuation of study treatment.
Patients can be counted in more than one anticancer therapy.

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Table 7.8 PROpel: Post-discontinuation anticancer therapy
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
Anticancer therapy [a]	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Cyclophosphamide	1 (0.4)	0	1 (0.2)
Docetaxel	49 (18.4)	94 (32.0)	143 (25.5)
Etoposide	0	4 (1.4)	4 (0.7)
Irinotecan Hydrochloride	0	2 (0.7)	2 (0.4)
Mitoxantrone Hydrochloride	0	1 (0.3)	1 (0.2)
Paclitaxel	1 (0.4)	0	1 (0.2)
Systemic Therapy	1 (0.4)	5 (1.7)	6 (1.1)
Blinded Therapy	1 (0.4)	1 (0.3)	2 (0.4)
Cyclophosphamide	0	1 (0.3)	1 (0.2)
Docetaxel	0	1 (0.3)	1 (0.2)
Investigational Drug	0	1 (0.3)	1 (0.2)
Zoledronic Acid	0	1 (0.3)	1 (0.2)
Targeted Therapy	5 (1.9)	19 (6.5)	24 (4.3)
Bevacizumab	0	1 (0.3)	1 (0.2)
Cabozantinib	0	1 (0.3)	1 (0.2)
Cabozantinib S-Malate	0	1 (0.3)	1 (0.2)
Capivasertib	0	1 (0.3)	1 (0.2)
Everolimus	0	1 (0.3)	1 (0.2)
Investigational Antineoplastic Drugs	0	1 (0.3)	1 (0.2)
Ipatasertib	0	2 (0.7)	2 (0.4)
Lutetium (177lu) Psma-617	0	3 (1.0)	3 (0.5)
Lutetium (lu 177)	1 (0.4)	0	1 (0.2)
Radium Ra 223 Dichloride	4 (1.5)	9 (3.1)	13 (2.3)
Parp Inhibitor	0	1 (0.3)	1 (0.2)
Niraparib	0	1 (0.3)	1 (0.2)
Other	2 (0.8)	7 (2.4)	9 (1.6)
Blinded Therapy	1 (0.4)	0	1 (0.2)
Dexamethasone	0	4 (1.4)	4 (0.7)

[a] Therapies post discontinuation of study treatment.
Patients can be counted in more than one anticancer therapy.

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Table 7.8 PROpel: Post-discontinuation anticancer therapy
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
Anticancer therapy [a]	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Enzalutamide	1 (0.4)	0	1 (0.2)
Prednisone	0	2 (0.7)	2 (0.4)
Various Therapeutic Radiopharmaceuticals	0	1 (0.3)	1 (0.2)

[a] Therapies post discontinuation of study treatment.
Patients can be counted in more than one anticancer therapy.

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Table 7.9 PROpel: Allowed concomitant medications during study, opioids given for cancer pain
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Number of patients with allowed concomitant medication, opioids given for cancer pain	41 (15.4)	35 (11.9)	76 (13.6)
ANILIDES	1 (0.4)	0	1 (0.2)
Paracetamol	1 (0.4)	0	1 (0.2)
NATURAL OPIUM ALKALOIDS	11 (4.1)	12 (4.1)	23 (4.1)
Codeine	0	1 (0.3)	1 (0.2)
Hydromorphone	1 (0.4)	1 (0.3)	2 (0.4)
Hydromorphone Hydrochloride	0	3 (1.0)	3 (0.5)
Morphine	1 (0.4)	2 (0.7)	3 (0.5)
Morphine Hydrochloride	1 (0.4)	0	1 (0.2)
Morphine Sulfate	3 (1.1)	2 (0.7)	5 (0.9)
Naloxone Hydrochloride;Oxycodone Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Oxycodone	1 (0.4)	1 (0.3)	2 (0.4)
Oxycodone Hydrochloride	7 (2.6)	4 (1.4)	11 (2.0)
Oxycodone Hydrochloride Trihydrate	0	1 (0.3)	1 (0.2)
OPIOID ANESTHETICS	4 (1.5)	1 (0.3)	5 (0.9)
Fentanyl	1 (0.4)	1 (0.3)	2 (0.4)
Fentanyl Citrate	2 (0.8)	0	2 (0.4)
Remifentanil Hydrochloride	1 (0.4)	0	1 (0.2)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	16 (6.0)	18 (6.1)	34 (6.1)
Caffeine;Codeine Phosphate;Paracetamol	1 (0.4)	5 (1.7)	6 (1.1)
Codeine Phosphate Hemihydrate;Paracetamol	0	1 (0.3)	1 (0.2)
Codeine Phosphate;Ibuprofen;Paracetamol	1 (0.4)	0	1 (0.2)
Codeine Phosphate;Paracetamol	4 (1.5)	3 (1.0)	7 (1.3)
Codeine;Paracetamol	0	1 (0.3)	1 (0.2)
Hydrocodone Bitartrate;Paracetamol	1 (0.4)	1 (0.3)	2 (0.4)

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A patient can have one or more Generic term reported under a given ATC text.
Includes medications that began prior to randomisation and were ongoing after randomisation.
A concomitant medication is only classed as such up to 30 days following discontinuation of randomised treatment.
WHO Drug September 2021.
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Table 7.9 PROpel: Allowed concomitant medications during study, opioids given for cancer pain
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Hydrocodone;Paracetamol	1 (0.4)	2 (0.7)	3 (0.5)
Paracetamol;Tramadol Hydrochloride	9 (3.4)	6 (2.0)	15 (2.7)
OTHER OPIOIDS	19 (7.1)	11 (3.7)	30 (5.4)
Naloxone Hydrochloride;Tilidine Hydrochloride	0	1 (0.3)	1 (0.2)
Tapentadol	1 (0.4)	0	1 (0.2)
Tapentadol Hydrochloride	3 (1.1)	1 (0.3)	4 (0.7)
Tramadol	9 (3.4)	5 (1.7)	14 (2.5)
Tramadol Hydrochloride	8 (3.0)	5 (1.7)	13 (2.3)
PHENYLPIPERIDINE DERIVATIVES	10 (3.8)	5 (1.7)	15 (2.7)
Fentanyl	8 (3.0)	5 (1.7)	13 (2.3)
Fentanyl Citrate	1 (0.4)	0	1 (0.2)
Pethidine Hydrochloride	2 (0.8)	0	2 (0.4)

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WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Number of patients with allowed concomitant medication	262 (98.5)	291 (99.0)	553 (98.8)
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	5 (1.9)	2 (0.7)	7 (1.3)
Amlodipine Besilate;Perindopril Arginine	3 (1.1)	2 (0.7)	5 (0.9)
Amlodipine;Enalapril	1 (0.4)	0	1 (0.2)
Felodipine;Ramipril	1 (0.4)	0	1 (0.2)
ACE INHIBITORS AND DIURETICS	1 (0.4)	7 (2.4)	8 (1.4)
Hydrochlorothiazide;Quinapril Hydrochloride	0	1 (0.3)	1 (0.2)
Hydrochlorothiazide;Ramipril	0	1 (0.3)	1 (0.2)
Hydrochlorothiazide;Zofenopril Calcium	0	1 (0.3)	1 (0.2)
Indapamide;Perindopril	1 (0.4)	1 (0.3)	2 (0.4)
Indapamide;Perindopril Arginine	0	1 (0.3)	1 (0.2)
Indapamide;Perindopril Erbumine	0	2 (0.7)	2 (0.4)
ACE INHIBITORS, OTHER COMBINATIONS	3 (1.1)	2 (0.7)	5 (0.9)
Amlodipine Besilate;Indapamide;Perindopril Arginine	2 (0.8)	1 (0.3)	3 (0.5)
Amlodipine Besilate;Indapamide;Perindopril Erbumine	1 (0.4)	0	1 (0.2)
Amlodipine;Indapamide;Perindopril	0	1 (0.3)	1 (0.2)
ACE INHIBITORS, PLAIN	59 (22.2)	53 (18.0)	112 (20.0)
Captopril	6 (2.3)	2 (0.7)	8 (1.4)
Delapril	1 (0.4)	0	1 (0.2)
Enalapril	11 (4.1)	17 (5.8)	28 (5.0)
Enalapril Maleate	1 (0.4)	2 (0.7)	3 (0.5)
Imidapril Hydrochloride	1 (0.4)	0	1 (0.2)
Lisinopril	10 (3.8)	8 (2.7)	18 (3.2)
Perindopril	9 (3.4)	10 (3.4)	19 (3.4)
Perindopril Arginine	2 (0.8)	0	2 (0.4)
Perindopril Erbumine	1 (0.4)	1 (0.3)	2 (0.4)

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WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Quinapril	1 (0.4)	1 (0.3)	2 (0.4)
Quinapril Hydrochloride	0	1 (0.3)	1 (0.2)
Ramipril	18 (6.8)	11 (3.7)	29 (5.2)
Trandolapril	1 (0.4)	2 (0.7)	3 (0.5)
Zofenopril Calcium	0	1 (0.3)	1 (0.2)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	31 (11.7)	30 (10.2)	61 (10.9)
Aceclofenac	6 (2.3)	4 (1.4)	10 (1.8)
Diclofenac	12 (4.5)	13 (4.4)	25 (4.5)
Diclofenac Deanol	0	2 (0.7)	2 (0.4)
Diclofenac Epolamine	0	2 (0.7)	2 (0.4)
Diclofenac Potassium	1 (0.4)	0	1 (0.2)
Diclofenac Sodium	8 (3.0)	8 (2.7)	16 (2.9)
Indometacin	1 (0.4)	0	1 (0.2)
Ketorolac	2 (0.8)	2 (0.7)	4 (0.7)
Ketorolac Tromethamine	5 (1.9)	2 (0.7)	7 (1.3)
ACID PREPARATIONS	1 (0.4)	0	1 (0.2)
Hydrochloric Acid	1 (0.4)	0	1 (0.2)
ACIDIFIERS	0	1 (0.3)	1 (0.2)
Methionine	0	1 (0.3)	1 (0.2)
ACTH	1 (0.4)	0	1 (0.2)
Tetracosactide Acetate	1 (0.4)	0	1 (0.2)
ADRENERGIC AND DOPAMINERGIC AGENTS	5 (1.9)	11 (3.7)	16 (2.9)
Dobutamine	1 (0.4)	0	1 (0.2)
Dopamine Hydrochloride	0	3 (1.0)	3 (0.5)
Ephedrine	0	1 (0.3)	1 (0.2)

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WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Ephedrine Hydrochloride	2 (0.8)	5 (1.7)	7 (1.3)
Epinephrine	0	2 (0.7)	2 (0.4)
Epinephrine Bitartrate	0	1 (0.3)	1 (0.2)
Norepinephrine	2 (0.8)	4 (1.4)	6 (1.1)
Norepinephrine Bitartrate	2 (0.8)	0	2 (0.4)
Phenylephrine	1 (0.4)	1 (0.3)	2 (0.4)
Phenylephrine Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
ADRENERGICS AND OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	1 (0.4)	0	1 (0.2)
Ipratropium Bromide;Salbutamol Sulfate	1 (0.4)	0	1 (0.2)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	6 (2.3)	7 (2.4)	13 (2.3)
Beclometasone Dipropionate;Formoterol Fumarate	0	3 (1.0)	3 (0.5)
Budesonide;Formoterol Fumarate	3 (1.1)	2 (0.7)	5 (0.9)
Fluticasone Furoate;Vilanterol Trifenatate	0	1 (0.3)	1 (0.2)
Fluticasone Propionate;Salmeterol Xinafoate	3 (1.1)	2 (0.7)	5 (0.9)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	7 (2.6)	5 (1.7)	12 (2.1)
Beclometasone;Formoterol;Glycopyrronium	0	1 (0.3)	1 (0.2)
Fenoterol Hydrobromide;Ipratropium Bromide	0	2 (0.7)	2 (0.4)
Fluticasone Furoate;Umeclidinium Bromide;Vilanterol Trifenatate	1 (0.4)	0	1 (0.2)
Glycopyrronium Bromide;Indacaterol Maleate	1 (0.4)	1 (0.3)	2 (0.4)
Ipratropium Bromide;Salbutamol Sulfate	2 (0.8)	0	2 (0.4)
Ipratropium;Salbutamol	1 (0.4)	0	1 (0.2)
Umeclidinium Bromide;Vilanterol Trifenatate	2 (0.8)	1 (0.3)	3 (0.5)
ALDOSTERONE ANTAGONISTS	11 (4.1)	15 (5.1)	26 (4.6)
Canrenone	1 (0.4)	0	1 (0.2)
Eplerenone	1 (0.4)	3 (1.0)	4 (0.7)

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WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Potassium Canrenoate	1 (0.4)	0	1 (0.2)
Spironolactone	9 (3.4)	12 (4.1)	21 (3.8)
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.4)	0	1 (0.2)
All Other Therapeutic Products	1 (0.4)	0	1 (0.2)
ALPHA AND BETA BLOCKING AGENTS	6 (2.3)	5 (1.7)	11 (2.0)
Carvedilol	6 (2.3)	4 (1.4)	10 (1.8)
Labetalol	0	1 (0.3)	1 (0.2)
ALPHA GLUCOSIDASE INHIBITORS	0	2 (0.7)	2 (0.4)
Voglibose	0	2 (0.7)	2 (0.4)
ALPHA- AND BETA-ADRENORECEPTOR AGONISTS	0	1 (0.3)	1 (0.2)
Epinephrine	0	1 (0.3)	1 (0.2)
ALPHA-ADRENORECEPTOR ANTAGONISTS	41 (15.4)	54 (18.4)	95 (17.0)
Alfuzosin	0	3 (1.0)	3 (0.5)
Alfuzosin Hydrochloride	1 (0.4)	3 (1.0)	4 (0.7)
Doxazosin	3 (1.1)	3 (1.0)	6 (1.1)
Doxazosin Mesilate	2 (0.8)	0	2 (0.4)
Naftopidil	4 (1.5)	0	4 (0.7)
Silodosin	7 (2.6)	10 (3.4)	17 (3.0)
Solifenacin Succinate;Tamsulosin Hydrochloride	1 (0.4)	0	1 (0.2)
Tamsulosin	9 (3.4)	24 (8.2)	33 (5.9)
Tamsulosin Hydrochloride	15 (5.6)	14 (4.8)	29 (5.2)
Terazosin Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Urapidil	1 (0.4)	0	1 (0.2)
AMIDES	16 (6.0)	18 (6.1)	34 (6.1)
Alkonium Bromide;Trimecaine Hydrochloride	0	1 (0.3)	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Articaine Hydrochloride;Epinephrine Hydrochloride	1 (0.4)	0	1 (0.2)
Bupivacaine	0	1 (0.3)	1 (0.2)
Bupivacaine Hydrochloride	1 (0.4)	0	1 (0.2)
Chlorhexidine Gluconate;Lidocaine Hydrochloride	1 (0.4)	0	1 (0.2)
Cinchocaine Hydrochloride	1 (0.4)	0	1 (0.2)
Epinephrine Bitartrate;Lidocaine Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Epinephrine;Lidocaine	1 (0.4)	2 (0.7)	3 (0.5)
Levobupivacaine Hydrochloride	0	1 (0.3)	1 (0.2)
Lidocaine	10 (3.8)	12 (4.1)	22 (3.9)
Lidocaine Hydrochloride	3 (1.1)	3 (1.0)	6 (1.1)
Mepivacaine Hydrochloride	2 (0.8)	0	2 (0.4)
Ropivacaine Hydrochloride	0	1 (0.3)	1 (0.2)
Trimecaine Hydrochloride	0	1 (0.3)	1 (0.2)
AMINO ACIDS	10 (3.8)	5 (1.7)	15 (2.7)
Alanine;Arginine;Aspartic Acid;Cysteine;Glutamic Acid;Histidine;Isoleucine;Leucine;Lysine Acetate;Methionine;Phenylalanine;Proline;Serine;Threonine;Tryptophan, L-;Tyrosine;Valine	0	1 (0.3)	1 (0.2)
Amino Acids Nos	1 (0.4)	1 (0.3)	2 (0.4)
Tranexamic Acid	10 (3.8)	3 (1.0)	13 (2.3)
AMINO ACIDS AND DERIVATIVES	2 (0.8)	1 (0.3)	3 (0.5)
Acetylcysteine	0	1 (0.3)	1 (0.2)
Betaine	1 (0.4)	0	1 (0.2)
Levoglutamide	1 (0.4)	0	1 (0.2)
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES	1 (0.4)	1 (0.3)	2 (0.4)
Asparagine;Levoglutamide;Pyridoxine Hydrochloride;Serine Phosphate	1 (0.4)	1 (0.3)	2 (0.4)

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WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
AMINOALKYL ETHERS	2 (0.8)	1 (0.3)	3 (0.5)
Diphenhydramine Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Diphenhydramine Salicylate	1 (0.4)	0	1 (0.2)
AMINOQUINOLINES	0	3 (1.0)	3 (0.5)
Hydroxychloroquine	0	2 (0.7)	2 (0.4)
Hydroxychloroquine Sulfate	0	1 (0.3)	1 (0.2)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	1 (0.4)	4 (1.4)	5 (0.9)
Mesalazine	1 (0.4)	4 (1.4)	5 (0.9)
ANALGESICS	1 (0.4)	0	1 (0.2)
Analgesics	1 (0.4)	0	1 (0.2)
ANESTHETICS FOR TOPICAL USE	1 (0.4)	1 (0.3)	2 (0.4)
Chlorhexidine Gluconate;Lidocaine Hydrochloride	0	1 (0.3)	1 (0.2)
Dexpanthenol;Lidocaine Hydrochloride;Mepyramine Maleate	1 (0.4)	0	1 (0.2)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND CALCIUM CHANNEL BLOCKERS	12 (4.5)	5 (1.7)	17 (3.0)
Amlodipine Adipate;Valsartan	2 (0.8)	0	2 (0.4)
Amlodipine Besilate;Candesartan Cilexetil	1 (0.4)	0	1 (0.2)
Amlodipine Besilate;Fimasartan Potassium Trihydrate	1 (0.4)	1 (0.3)	2 (0.4)
Amlodipine Besilate;Irbesartan	0	1 (0.3)	1 (0.2)
Amlodipine Besilate;Olmesartan Medoxomil	3 (1.1)	0	3 (0.5)
Amlodipine Besilate;Telmisartan	4 (1.5)	3 (1.0)	7 (1.3)
Amlodipine Besilate;Valsartan	3 (1.1)	0	3 (0.5)
Levamlodipine Besilate;Telmisartan	1 (0.4)	0	1 (0.2)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS	12 (4.5)	16 (5.4)	28 (5.0)
Candesartan Cilexetil;Hydrochlorothiazide	1 (0.4)	2 (0.7)	3 (0.5)

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WHO Drug September 2021.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Hydrochlorothiazide;Irbesartan	0	2 (0.7)	2 (0.4)
Hydrochlorothiazide;Losartan	0	1 (0.3)	1 (0.2)
Hydrochlorothiazide;Losartan Potassium	7 (2.6)	5 (1.7)	12 (2.1)
Hydrochlorothiazide;Olmesartan	0	1 (0.3)	1 (0.2)
Hydrochlorothiazide;Olmesartan Medoxomil	1 (0.4)	1 (0.3)	2 (0.4)
Hydrochlorothiazide;Telmisartan	1 (0.4)	2 (0.7)	3 (0.5)
Hydrochlorothiazide;Valsartan	2 (0.8)	3 (1.0)	5 (0.9)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	37 (13.9)	64 (21.8)	101 (18.0)
Azilsartan	0	2 (0.7)	2 (0.4)
Candesartan	3 (1.1)	4 (1.4)	7 (1.3)
Candesartan Cilexetil	2 (0.8)	2 (0.7)	4 (0.7)
Fimasartan Potassium Trihydrate	1 (0.4)	0	1 (0.2)
Irbesartan	3 (1.1)	6 (2.0)	9 (1.6)
Irbesartan Hydrochloride	0	1 (0.3)	1 (0.2)
Losartan	11 (4.1)	17 (5.8)	28 (5.0)
Losartan Potassium	2 (0.8)	6 (2.0)	8 (1.4)
Olmesartan	4 (1.5)	2 (0.7)	6 (1.1)
Olmesartan Medoxomil	5 (1.9)	7 (2.4)	12 (2.1)
Telmisartan	4 (1.5)	8 (2.7)	12 (2.1)
Valsartan	4 (1.5)	12 (4.1)	16 (2.9)
ANILIDES	103 (38.7)	115 (39.1)	218 (38.9)
Apronal;Caffeine;Paracetamol;Propyphenazone	1 (0.4)	0	1 (0.2)
Caffeine;Cinnamomum Verum;Glycyrrhiza Glabra Extract;Methylephedrine Hydrochloride-Dl;Paracetamol;Zingiber Officinale	1 (0.4)	0	1 (0.2)
Caffeine;Guaifenesin;Paracetamol	0	1 (0.3)	1 (0.2)
Caffeine;Paracetamol;Phenylephrine Hydrochloride	0	1 (0.3)	1 (0.2)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Caffeine;Paracetamol;Promethazine Methylene Disalicylate;Salicylamide	0	1 (0.3)	1 (0.2)
Caffeine;Paracetamol;Propyphenazone	1 (0.4)	0	1 (0.2)
Chlorphenamine Maleate;Paracetamol;Pseudoephedrine Hydrochloride	0	1 (0.3)	1 (0.2)
Dexketoprofen Trometamol;Paracetamol	1 (0.4)	0	1 (0.2)
Dextromethorphan Hydrobromide Monohydrate;Paracetamol;Phenylephrine Hydrochloride	0	1 (0.3)	1 (0.2)
Dextromethorphan Hydrobromide;Guaifenesin;Paracetamol;Phenylephrine Hydrochloride	0	1 (0.3)	1 (0.2)
Dextromethorphan Hydrobromide;Paracetamol;Phenylephrine Hydrochloride	0	1 (0.3)	1 (0.2)
Ibuprofen;Paracetamol	1 (0.4)	0	1 (0.2)
Paracetamol	97 (36.5)	112 (38.1)	209 (37.3)
Paracetamol;Phenylephrine	1 (0.4)	0	1 (0.2)
Paracetamol;Pseudoephedrine Hydrochloride	0	1 (0.3)	1 (0.2)
Propacetamol Hydrochloride	1 (0.4)	2 (0.7)	3 (0.5)
ANTACIDS WITH ANTIFLATULENTS	2 (0.8)	2 (0.7)	4 (0.7)
Aluminium Hydroxide;Magnesium Hydroxide;Simeticone	1 (0.4)	1 (0.3)	2 (0.4)
Calcium Carbonate;Dimeticone;Magnesium Carbonate;Magnesium Hydroxide	1 (0.4)	0	1 (0.2)
Calcium Carbonate;Magnesium Hydroxide;Simeticone	0	1 (0.3)	1 (0.2)
ANTACIDS WITH SODIUM BICARBONATE	4 (1.5)	2 (0.7)	6 (1.1)
Aluminium Hydroxide;Magnesium Carbonate;Sodium Bicarbonate	1 (0.4)	0	1 (0.2)
Sodium Alginate;Sodium Bicarbonate	2 (0.8)	1 (0.3)	3 (0.5)
Sodium Bicarbonate	1 (0.4)	1 (0.3)	2 (0.4)
ANTI-GONADOTROPIN-RELEASING HORMONES	1 (0.4)	0	1 (0.2)
Relugolix	1 (0.4)	0	1 (0.2)
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS	1 (0.4)	2 (0.7)	3 (0.5)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Azelastine Hydrochloride	0	1 (0.3)	1 (0.2)
Cromoglicate Sodium	1 (0.4)	1 (0.3)	2 (0.4)
ANTIANDROGENS, PLAIN	3 (1.1)	0	3 (0.5)
Cyproterone	2 (0.8)	0	2 (0.4)
Cyproterone Acetate	1 (0.4)	0	1 (0.2)
ANTIARRHYTHMICS, CLASS IB	1 (0.4)	0	1 (0.2)
Lidocaine	1 (0.4)	0	1 (0.2)
ANTIARRHYTHMICS, CLASS IC	4 (1.5)	1 (0.3)	5 (0.9)
Flecainide	1 (0.4)	0	1 (0.2)
Flecainide Acetate	2 (0.8)	0	2 (0.4)
Pilsicainide	0	1 (0.3)	1 (0.2)
Propafenone Hydrochloride	1 (0.4)	0	1 (0.2)
ANTIARRHYTHMICS, CLASS III	4 (1.5)	5 (1.7)	9 (1.6)
Amiodarone	3 (1.1)	3 (1.0)	6 (1.1)
Amiodarone Hydrochloride	1 (0.4)	2 (0.7)	3 (0.5)
ANTIBACTERIALS FOR SYSTEMIC USE	2 (0.8)	0	2 (0.4)
Antibiotics	2 (0.8)	0	2 (0.4)
ANTIBIOTICS	10 (3.8)	9 (3.1)	19 (3.4)
Amphotericin B	0	1 (0.3)	1 (0.2)
Chloramphenicol	1 (0.4)	0	1 (0.2)
Fidaxomicin	0	1 (0.3)	1 (0.2)
Fusidic Acid	1 (0.4)	0	1 (0.2)
Gentamicin	1 (0.4)	0	1 (0.2)
Gramicidin;Polymyxin B Sulfate	0	1 (0.3)	1 (0.2)
Nystatin	5 (1.9)	3 (1.0)	8 (1.4)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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Polymyxin B Sulfate	0	1 (0.3)	1 (0.2)
Rifampicin	0	1 (0.3)	1 (0.2)
Rifaximin	2 (0.8)	2 (0.7)	4 (0.7)
ANTICHOLINERGICS	11 (4.1)	11 (3.7)	22 (3.9)
Atropine	0	1 (0.3)	1 (0.2)
Ipratropium	4 (1.5)	0	4 (0.7)
Ipratropium Bromide	2 (0.8)	3 (1.0)	5 (0.9)
Phenylephrine Hydrochloride;Tropicamide	2 (0.8)	1 (0.3)	3 (0.5)
Tiotropium	0	2 (0.7)	2 (0.4)
Tiotropium Bromide Monohydrate	2 (0.8)	3 (1.0)	5 (0.9)
Tropicamide	0	1 (0.3)	1 (0.2)
Umeclidinium Bromide	1 (0.4)	0	1 (0.2)
ANTICHOLINESTERASES	2 (0.8)	3 (1.0)	5 (0.9)
Donepezil Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Neostigmine	1 (0.4)	2 (0.7)	3 (0.5)
Pyridostigmine	0	1 (0.3)	1 (0.2)
Pyridostigmine Bromide	0	1 (0.3)	1 (0.2)
ANTIDIARRHEAL MICROORGANISMS	5 (1.9)	4 (1.4)	9 (1.6)
Antibiotics-Resistant Lactic Acid Bacteriae	0	1 (0.3)	1 (0.2)
Bacillus Clausii	1 (0.4)	0	1 (0.2)
Bacillus Mesentericus;Clostridium Butyricum;Enterococcus Faecalis	0	1 (0.3)	1 (0.2)
Bacillus Subtilis;Enterococcus Faecium	1 (0.4)	0	1 (0.2)
Bifidobacterium Lactis;Enterococcus Faecium;Fructooligosaccharides;Inulin;Lactobacillus Acidophilus;Lactobacillus Paracasei;Lactobacillus Plantarum;Lactobacillus Salivarius;Streptococcus Lactis	0	1 (0.3)	1 (0.2)
Bifidobacterium Nos	1 (0.4)	0	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Enterococcus Faecalis;Escherichia Coli;Lactobacillus Acidophilus;Lactobacillus Helveticus	1 (0.4)	0	1 (0.2)
Lactobacillus Nos	0	1 (0.3)	1 (0.2)
Probiotics Nos	0	1 (0.3)	1 (0.2)
Saccharomyces Boulardii	1 (0.4)	0	1 (0.2)
ANTIDOTES	7 (2.6)	8 (2.7)	15 (2.7)
Acetylcysteine	1 (0.4)	0	1 (0.2)
Flumazenil	3 (1.1)	1 (0.3)	4 (0.7)
Glutathione	0	2 (0.7)	2 (0.4)
Glycopyrronium	0	1 (0.3)	1 (0.2)
Glycopyrronium Bromide	0	1 (0.3)	1 (0.2)
Naloxone Hydrochloride	1 (0.4)	0	1 (0.2)
Protamine	1 (0.4)	0	1 (0.2)
Sugammadex Sodium	2 (0.8)	4 (1.4)	6 (1.1)
ANTIEMETICS AND ANTINAUSEANTS	3 (1.1)	3 (1.0)	6 (1.1)
Metoclopramide	2 (0.8)	0	2 (0.4)
Metoclopramide Hydrochloride	1 (0.4)	3 (1.0)	4 (0.7)
ANTIFUNGALS FOR TOPICAL USE	1 (0.4)	0	1 (0.2)
Liranaftate	1 (0.4)	0	1 (0.2)
ANTIHIDROTICS	1 (0.4)	0	1 (0.2)
Salvia Officinalis	1 (0.4)	0	1 (0.2)
ANTIHISTAMINES FOR TOPICAL USE	2 (0.8)	1 (0.3)	3 (0.5)
Diphenhydramine	1 (0.4)	0	1 (0.2)
Diphenhydramine Hydrochloride	0	1 (0.3)	1 (0.2)
Diphenhydramine Laurilsulfate	1 (0.4)	0	1 (0.2)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
ANTIHYPERTENSIVES	1 (0.4)	0	1 (0.2)
Hydracarbazine	1 (0.4)	0	1 (0.2)
ANTIINFECTIVES	1 (0.4)	2 (0.7)	3 (0.5)
Ciprofloxacin Hydrochloride	1 (0.4)	0	1 (0.2)
Ofloxacin	0	1 (0.3)	1 (0.2)
Taurolidine	0	1 (0.3)	1 (0.2)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	8 (3.0)	7 (2.4)	15 (2.7)
Amphotericin B	1 (0.4)	0	1 (0.2)
Benzydamine Hydrochloride;Chlorhexidine Gluconate	1 (0.4)	0	1 (0.2)
Chlorhexidine	1 (0.4)	0	1 (0.2)
Miconazole	1 (0.4)	0	1 (0.2)
Minocycline Hydrochloride	0	1 (0.3)	1 (0.2)
Nystatin	3 (1.1)	4 (1.4)	7 (1.3)
Povidone-Iodine	2 (0.8)	2 (0.7)	4 (0.7)
ANTIINFECTIVES FOR TREATMENT OF ACNE	2 (0.8)	1 (0.3)	3 (0.5)
Nadifloxacin	2 (0.8)	1 (0.3)	3 (0.5)
ANTIINFLAMMATORY AGENTS, NON-STEROIDS	7 (2.6)	3 (1.0)	10 (1.8)
Bromfenac Sodium	4 (1.5)	1 (0.3)	5 (0.9)
Diclofenac	1 (0.4)	0	1 (0.2)
Ketorolac Tromethamine	0	2 (0.7)	2 (0.4)
Nepafenac	1 (0.4)	0	1 (0.2)
Pranoprofen	1 (0.4)	0	1 (0.2)
ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE	12 (4.5)	13 (4.4)	25 (4.5)
Bendazac	1 (0.4)	0	1 (0.2)
Dexketoprofen Trometamol;Thiocolchicoside	1 (0.4)	0	1 (0.2)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Diclofenac	1 (0.4)	2 (0.7)	3 (0.5)
Diclofenac Diethylamine	0	1 (0.3)	1 (0.2)
Diclofenac Epolamine	0	1 (0.3)	1 (0.2)
Diclofenac Sodium	1 (0.4)	4 (1.4)	5 (0.9)
Esflurbiprofen;Mentha Spp. Oil	1 (0.4)	1 (0.3)	2 (0.4)
Felbinac	2 (0.8)	0	2 (0.4)
Indometacin	1 (0.4)	0	1 (0.2)
Ketoprofen	3 (1.1)	2 (0.7)	5 (0.9)
Loxoprofen Sodium	2 (0.8)	2 (0.7)	4 (0.7)
Loxoprofen Sodium Dihydrate	2 (0.8)	2 (0.7)	4 (0.7)
ANTINEOVASCULARISATION AGENTS	1 (0.4)	0	1 (0.2)
Ranibizumab	1 (0.4)	0	1 (0.2)
ANTIPROPULSIVES	17 (6.4)	8 (2.7)	25 (4.5)
Atropine;Diphenoxylate	0	1 (0.3)	1 (0.2)
Loperamide	8 (3.0)	3 (1.0)	11 (2.0)
Loperamide Hydrochloride	10 (3.8)	4 (1.4)	14 (2.5)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	0	1 (0.3)	1 (0.2)
Diphenhydramine	0	1 (0.3)	1 (0.2)
ANTISEPTICS	3 (1.1)	5 (1.7)	8 (1.4)
Benzethonium Chloride	0	2 (0.7)	2 (0.4)
Chlorhexidine	0	1 (0.3)	1 (0.2)
Dequalinium Chloride	1 (0.4)	0	1 (0.2)
Hexetidine	0	1 (0.3)	1 (0.2)
Sodium Bicarbonate;Sodium Gualenate	2 (0.8)	0	2 (0.4)
Sodium Gualenate Hydrate	0	1 (0.3)	1 (0.2)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
ANTIVERTIGO PREPARATIONS	2 (0.8)	1 (0.3)	3 (0.5)
Betahistine	1 (0.4)	0	1 (0.2)
Cinnarizine	1 (0.4)	0	1 (0.2)
Meclozine	0	1 (0.3)	1 (0.2)
ANTIVIRALS	1 (0.4)	2 (0.7)	3 (0.5)
Ganciclovir	0	1 (0.3)	1 (0.2)
Imiquimod	0	1 (0.3)	1 (0.2)
Vidarabine	1 (0.4)	0	1 (0.2)
APPETITE STIMULANTS	4 (1.5)	2 (0.7)	6 (1.1)
Choline Citrate;Cyproheptadine Hydrochloride	1 (0.4)	0	1 (0.2)
Megestrol Acetate	3 (1.1)	2 (0.7)	5 (0.9)
ASCORBIC ACID (VITAMIN C), COMBINATIONS	1 (0.4)	0	1 (0.2)
Ascorbic Acid;Zinc	1 (0.4)	0	1 (0.2)
ASCORBIC ACID (VITAMIN C), PLAIN	10 (3.8)	10 (3.4)	20 (3.6)
Ascorbic Acid	10 (3.8)	10 (3.4)	20 (3.6)
AVERMECTINES	1 (0.4)	0	1 (0.2)
Ivermectin	1 (0.4)	0	1 (0.2)
BARBITURATES, PLAIN	1 (0.4)	0	1 (0.2)
Thiopental Sodium	1 (0.4)	0	1 (0.2)
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS	6 (2.3)	3 (1.0)	9 (1.6)
Hyoscine Butylbromide	6 (2.3)	3 (1.0)	9 (1.6)
BENZAMIDES	1 (0.4)	0	1 (0.2)
Sulpiride	1 (0.4)	0	1 (0.2)

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BENZIMIDAZOLE DERIVATIVES	1 (0.4)	0	1 (0.2)
Mebendazole	1 (0.4)	0	1 (0.2)
BENZODIAZEPINE DERIVATIVES	30 (11.3)	28 (9.5)	58 (10.4)
Alprazolam	7 (2.6)	2 (0.7)	9 (1.6)
Bromazepam	3 (1.1)	3 (1.0)	6 (1.1)
Brotizolam	1 (0.4)	2 (0.7)	3 (0.5)
Clonazepam	3 (1.1)	3 (1.0)	6 (1.1)
Clotiazepam	0	1 (0.3)	1 (0.2)
Diazepam	0	1 (0.3)	1 (0.2)
Etizolam	0	1 (0.3)	1 (0.2)
Lorazepam	4 (1.5)	6 (2.0)	10 (1.8)
Midazolam	12 (4.5)	3 (1.0)	15 (2.7)
Midazolam Hydrochloride	1 (0.4)	2 (0.7)	3 (0.5)
Oxazepam	2 (0.8)	2 (0.7)	4 (0.7)
Prazepam	1 (0.4)	0	1 (0.2)
Temazepam	1 (0.4)	5 (1.7)	6 (1.1)
Tofisopam	1 (0.4)	0	1 (0.2)
Triazolam	1 (0.4)	0	1 (0.2)
BENZODIAZEPINE RELATED DRUGS	11 (4.1)	11 (3.7)	22 (3.9)
Eszopiclone	2 (0.8)	1 (0.3)	3 (0.5)
Zolpidem	1 (0.4)	4 (1.4)	5 (0.9)
Zolpidem Tartrate	5 (1.9)	2 (0.7)	7 (1.3)
Zopiclone	4 (1.5)	5 (1.7)	9 (1.6)
BENZOMORPHAN DERIVATIVES	1 (0.4)	1 (0.3)	2 (0.4)
Pentazocine	1 (0.4)	1 (0.3)	2 (0.4)
BENZOTHIAZEPINE DERIVATIVES	5 (1.9)	2 (0.7)	7 (1.3)

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WHO Drug September 2021.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Diltiazem	4 (1.5)	1 (0.3)	5 (0.9)
Diltiazem Hydrochloride	1 (0.4)	2 (0.7)	3 (0.5)
BETA BLOCKING AGENTS	4 (1.5)	7 (2.4)	11 (2.0)
Betaxolol Hydrochloride	0	1 (0.3)	1 (0.2)
Bimatoprost;Timolol	0	1 (0.3)	1 (0.2)
Brimonidine Tartrate;Timolol Maleate	0	1 (0.3)	1 (0.2)
Carteolol Hydrochloride;Latanoprost	1 (0.4)	0	1 (0.2)
Dorzolamide Hydrochloride;Timolol Maleate	0	3 (1.0)	3 (0.5)
Dorzolamide;Timolol	0	1 (0.3)	1 (0.2)
Latanoprost;Timolol Maleate	1 (0.4)	1 (0.3)	2 (0.4)
Timolol	1 (0.4)	0	1 (0.2)
Timolol Maleate	1 (0.4)	1 (0.3)	2 (0.4)
Timolol Maleate;Travoprost	0	1 (0.3)	1 (0.2)
BETA BLOCKING AGENTS, NON-SELECTIVE	1 (0.4)	1 (0.3)	2 (0.4)
Propranolol	0	1 (0.3)	1 (0.2)
Sotalol	1 (0.4)	0	1 (0.2)
BETA BLOCKING AGENTS, SELECTIVE	52 (19.5)	47 (16.0)	99 (17.7)
Acebutolol	1 (0.4)	0	1 (0.2)
Atenolol	6 (2.3)	6 (2.0)	12 (2.1)
Betaxolol Hydrochloride	1 (0.4)	0	1 (0.2)
Bisoprolol	6 (2.3)	11 (3.7)	17 (3.0)
Bisoprolol Fumarate	13 (4.9)	11 (3.7)	24 (4.3)
Celiprolol Hydrochloride	1 (0.4)	0	1 (0.2)
Landiolol Hydrochloride	0	1 (0.3)	1 (0.2)
Metoprolol	10 (3.8)	13 (4.4)	23 (4.1)
Metoprolol Succinate	8 (3.0)	4 (1.4)	12 (2.1)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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Metoprolol Tartrate	7 (2.6)	3 (1.0)	10 (1.8)
Nebivolol	1 (0.4)	0	1 (0.2)
Nebivolol Hydrochloride	3 (1.1)	3 (1.0)	6 (1.1)
BETA BLOCKING AGENTS, SELECTIVE, AND OTHER DIURETICS	1 (0.4)	0	1 (0.2)
Atenolol;Chlortalidone	1 (0.4)	0	1 (0.2)
BETA BLOCKING AGENTS, SELECTIVE, AND THIAZIDES	3 (1.1)	0	3 (0.5)
Atenolol;Hydrochlorothiazide	1 (0.4)	0	1 (0.2)
Bisoprolol Fumarate;Hydrochlorothiazide	1 (0.4)	0	1 (0.2)
Bisoprolol;Hydrochlorothiazide	1 (0.4)	0	1 (0.2)
BETA-LACTAM ANTIBACTERIALS, PENICILLINS	1 (0.4)	1 (0.3)	2 (0.4)
Penicillin Nos	1 (0.4)	1 (0.3)	2 (0.4)
BETA-LACTAMASE INHIBITORS	4 (1.5)	4 (1.4)	8 (1.4)
Clavulanate Potassium	1 (0.4)	1 (0.3)	2 (0.4)
Clavulanic Acid	3 (1.1)	2 (0.7)	5 (0.9)
Tazobactam	1 (0.4)	0	1 (0.2)
Tazobactam Sodium	0	1 (0.3)	1 (0.2)
BETA-LACTAMASE RESISTANT PENICILLINS	3 (1.1)	0	3 (0.5)
Dicloxacillin	1 (0.4)	0	1 (0.2)
Flucloxacillin	2 (0.8)	0	2 (0.4)
BETA-LACTAMASE SENSITIVE PENICILLINS	2 (0.8)	0	2 (0.4)
Benzathine Benzylpenicillin	1 (0.4)	0	1 (0.2)
Benzylpenicillin	1 (0.4)	0	1 (0.2)
BIGUANIDES	42 (15.8)	42 (14.3)	84 (15.0)
Metformin	23 (8.6)	27 (9.2)	50 (8.9)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Metformin Hydrochloride	19 (7.1)	15 (5.1)	34 (6.1)
BIGUANIDES AND AMIDINES	1 (0.4)	1 (0.3)	2 (0.4)
Chlorhexidine Gluconate	1 (0.4)	1 (0.3)	2 (0.4)
BILE ACIDS AND DERIVATIVES	10 (3.8)	13 (4.4)	23 (4.1)
Ursodeoxycholic Acid	10 (3.8)	13 (4.4)	23 (4.1)
BIOFLAVONOIDS	6 (2.3)	1 (0.3)	7 (1.3)
Aesculus Hippocastanum;Diosmin;Hesperidin;Magnesium	1 (0.4)	0	1 (0.2)
Ascorbic Acid;Rutoside	1 (0.4)	0	1 (0.2)
Diosmin	0	1 (0.3)	1 (0.2)
Diosmin;Hesperidin	4 (1.5)	0	4 (0.7)
Troxerutin	1 (0.4)	0	1 (0.2)
BISMUTH PREPARATIONS	1 (0.4)	0	1 (0.2)
Bismuth Subsalicylate	1 (0.4)	0	1 (0.2)
BISPHOSPHONATES	33 (12.4)	32 (10.9)	65 (11.6)
Alendronate Sodium	2 (0.8)	2 (0.7)	4 (0.7)
Alendronic Acid	4 (1.5)	6 (2.0)	10 (1.8)
Ibandronate Sodium	0	1 (0.3)	1 (0.2)
Ibandronic Acid	1 (0.4)	0	1 (0.2)
Pamidronate Disodium	1 (0.4)	1 (0.3)	2 (0.4)
Risedronate Sodium	2 (0.8)	3 (1.0)	5 (0.9)
Zoledronic Acid	11 (4.1)	7 (2.4)	18 (3.2)
Zoledronic Acid Monohydrate	13 (4.9)	13 (4.4)	26 (4.6)
BLOOD COAGULATION FACTORS	1 (0.4)	0	1 (0.2)
Thrombin	1 (0.4)	0	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	0	2 (0.7)	2 (0.4)
Blood Glucose Lowering Drugs, Excl. Insulins	0	1 (0.3)	1 (0.2)
Cinnamomum Cassia Twig	0	1 (0.3)	1 (0.2)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	3 (1.1)	8 (2.7)	11 (2.0)
Carbohydrates Nos;Potassium Chloride;Sodium Chloride;Sodium Lactate	3 (1.1)	8 (2.7)	11 (2.0)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS	3 (1.1)	3 (1.0)	6 (1.1)
Albumin Human	2 (0.8)	3 (1.0)	5 (0.9)
Hetastarch	1 (0.4)	0	1 (0.2)
BULK-FORMING LAXATIVES	6 (2.3)	1 (0.3)	7 (1.3)
Methylcellulose	1 (0.4)	0	1 (0.2)
Plantago Ovata Husk	1 (0.4)	0	1 (0.2)
Plantago Spp.	1 (0.4)	0	1 (0.2)
Polycarbophil Calcium	2 (0.8)	0	2 (0.4)
Psyllium Hydrophilic Mucilloid	1 (0.4)	1 (0.3)	2 (0.4)
BUTYROPHENONE DERIVATIVES	2 (0.8)	1 (0.3)	3 (0.5)
Haloperidol	1 (0.4)	0	1 (0.2)
Melperone Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
CALCIUM	33 (12.4)	32 (10.9)	65 (11.6)
Calcium	18 (6.8)	14 (4.8)	32 (5.7)
Calcium Carbonate	12 (4.5)	15 (5.1)	27 (4.8)
Calcium Citrate	1 (0.4)	0	1 (0.2)
Calcium Gluconate;Calcium Laevulinate	1 (0.4)	1 (0.3)	2 (0.4)
Calcium Lactate	1 (0.4)	2 (0.7)	3 (0.5)
CALCIUM COMPOUNDS	4 (1.5)	0	4 (0.7)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Calcium Carbonate	4 (1.5)	0	4 (0.7)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	66 (24.8)	59 (20.1)	125 (22.3)
Calcium Carbonate;Colecalciferol	30 (11.3)	32 (10.9)	62 (11.1)
Calcium Carbonate;Colecalciferol;Magnesium Carbonate	14 (5.3)	13 (4.4)	27 (4.8)
Calcium Carbonate;Ergocalciferol	3 (1.1)	2 (0.7)	5 (0.9)
Calcium Carbonate;Vitamin D Nos	3 (1.1)	3 (1.0)	6 (1.1)
Calcium;Colecalciferol	15 (5.6)	5 (1.7)	20 (3.6)
Calcium;Magnesium;Vitamin D Nos	0	1 (0.3)	1 (0.2)
Calcium;Magnesium;Zinc	1 (0.4)	0	1 (0.2)
Calcium;Vitamin D Nos	2 (0.8)	4 (1.4)	6 (1.1)
CAPSAICIN AND SIMILAR AGENTS	0	1 (0.3)	1 (0.2)
Nonivamide	0	1 (0.3)	1 (0.2)
CARBAMIC ACID ESTERS	3 (1.1)	1 (0.3)	4 (0.7)
Methocarbamol	2 (0.8)	1 (0.3)	3 (0.5)
Methocarbamol;Paracetamol	1 (0.4)	0	1 (0.2)
CARBAMIDE PRODUCTS	0	2 (0.7)	2 (0.4)
Urea	0	2 (0.7)	2 (0.4)
CARBAPENEMS	11 (4.1)	5 (1.7)	16 (2.9)
Cilastatin Sodium;Imipenem	1 (0.4)	0	1 (0.2)
Ertapenem Sodium	0	1 (0.3)	1 (0.2)
Imipenem	1 (0.4)	0	1 (0.2)
Meropenem	7 (2.6)	2 (0.7)	9 (1.6)
Meropenem Trihydrate	5 (1.9)	3 (1.0)	8 (1.4)
CARBONIC ANHYDRASE INHIBITORS	2 (0.8)	1 (0.3)	3 (0.5)
Brimonidine Tartrate;Brinzolamide	0	1 (0.3)	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Brinzolamide	1 (0.4)	0	1 (0.2)
Dorzolamide Hydrochloride	1 (0.4)	0	1 (0.2)
CARDIOVASCULAR SYSTEM	0	1 (0.3)	1 (0.2)
Betaine Hydrochloride;Bioflavonoids Nos;Choline Bitartrate;Cyanocobalamin;Folic Acid;Hesperidin;Inositol;Pyridoxine Hydrochloride	0	1 (0.3)	1 (0.2)
CARIES PROPHYLACTIC AGENTS	1 (0.4)	0	1 (0.2)
Calcium Chloride Dihydrate;Magnesium Chloride;Potassium Chloride;Potassium Phosphate Dibasic;Sodium Chloride	1 (0.4)	0	1 (0.2)
CENTRALLY ACTING SYMPATHOMIMETICS	1 (0.4)	2 (0.7)	3 (0.5)
Methylphenidate	1 (0.4)	0	1 (0.2)
Methylphenidate Hydrochloride	0	2 (0.7)	2 (0.4)
CHARCOAL PREPARATIONS	1 (0.4)	1 (0.3)	2 (0.4)
Charcoal, Activated	1 (0.4)	1 (0.3)	2 (0.4)
CHOLINE ESTERS	1 (0.4)	2 (0.7)	3 (0.5)
Bethanechol	0	1 (0.3)	1 (0.2)
Bethanechol Chloride	1 (0.4)	1 (0.3)	2 (0.4)
COLONY STIMULATING FACTORS	6 (2.3)	6 (2.0)	12 (2.1)
Filgrastim	4 (1.5)	3 (1.0)	7 (1.3)
Granulocyte Colony Stimulating Factor	1 (0.4)	0	1 (0.2)
Lenograstim	2 (0.8)	1 (0.3)	3 (0.5)
Pegfilgrastim	0	2 (0.7)	2 (0.4)
COLOURING AGENTS	0	1 (0.3)	1 (0.2)
Fluorescein	0	1 (0.3)	1 (0.2)

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	4 (1.5)	4 (1.4)	8 (1.4)
Almagate	2 (0.8)	2 (0.7)	4 (0.7)
Calcium Carbonate;Magnesium Carbonate	1 (0.4)	0	1 (0.2)
Calcium Carbonate;Magnesium Hydroxide	1 (0.4)	0	1 (0.2)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds	0	1 (0.3)	1 (0.2)
Hydrotalcite	0	1 (0.3)	1 (0.2)
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	6 (2.3)	9 (3.1)	15 (2.7)
Alogliptin Benzoate;Metformin Hydrochloride	1 (0.4)	0	1 (0.2)
Canagliflozin Hemihydrate;Teneligliptin Hydrobromide	2 (0.8)	0	2 (0.4)
Dapagliflozin Propanediol Monohydrate;Metformin Hydrochloride	0	1 (0.3)	1 (0.2)
Empagliflozin;Metformin Hydrochloride	1 (0.4)	0	1 (0.2)
Linagliptin;Metformin Hydrochloride	0	1 (0.3)	1 (0.2)
Metformin Hydrochloride;Sitagliptin Phosphate	1 (0.4)	0	1 (0.2)
Metformin Hydrochloride;Sitagliptin Phosphate Monohydrate	1 (0.4)	3 (1.0)	4 (0.7)
Metformin Hydrochloride;Teneligliptin Hydrobromide	0	1 (0.3)	1 (0.2)
Metformin Hydrochloride;Vildagliptin	0	2 (0.7)	2 (0.4)
Metformin;Sitagliptin	0	1 (0.3)	1 (0.2)
Mitiglinide Calcium;Voglibose	1 (0.4)	0	1 (0.2)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	36 (13.5)	31 (10.5)	67 (12.0)
Amoxicillin Sodium;Clavulanate Potassium	0	1 (0.3)	1 (0.2)
Amoxicillin Trihydrate;Clavulanate Potassium	19 (7.1)	13 (4.4)	32 (5.7)
Amoxicillin;Clavulanate Potassium	3 (1.1)	3 (1.0)	6 (1.1)
Amoxicillin;Clavulanic Acid	12 (4.5)	6 (2.0)	18 (3.2)
Ampicillin Sodium;Sulbactam Sodium	2 (0.8)	3 (1.0)	5 (0.9)
Ampicillin;Cloxacillin Sodium	0	1 (0.3)	1 (0.2)
Piperacillin Sodium;Tazobactam Sodium	10 (3.8)	10 (3.4)	20 (3.6)

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Piperacillin;Tazobactam	1 (0.4)	1 (0.3)	2 (0.4)
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES	13 (4.9)	5 (1.7)	18 (3.2)
Sulfamethoxazole;Trimethoprim	13 (4.9)	5 (1.7)	18 (3.2)
COMBINATIONS OF VARIOUS LIPID MODIFYING AGENTS	3 (1.1)	4 (1.4)	7 (1.3)
Atorvastatin Calcium;Ezetimibe	1 (0.4)	0	1 (0.2)
Ezetimibe;Rosuvastatin	0	1 (0.3)	1 (0.2)
Ezetimibe;Rosuvastatin Calcium	2 (0.8)	0	2 (0.4)
Ezetimibe;Simvastatin	0	3 (1.0)	3 (0.5)
COMBINATIONS OF VITAMINS	0	2 (0.7)	2 (0.4)
Combinations Of Vitamins	0	1 (0.3)	1 (0.2)
Vitamins Nos	0	1 (0.3)	1 (0.2)
CONTACT LAXATIVES	24 (9.0)	29 (9.9)	53 (9.5)
Bisacodyl	7 (2.6)	3 (1.0)	10 (1.8)
Docusate Sodium;Senna Alexandrina	0	1 (0.3)	1 (0.2)
Docusate Sodium;Sennoside A+b	4 (1.5)	1 (0.3)	5 (0.9)
Docusate;Senna Alexandrina	0	1 (0.3)	1 (0.2)
Senna Alexandrina Leaf	0	1 (0.3)	1 (0.2)
Senna Spp.	1 (0.4)	1 (0.3)	2 (0.4)
Sennoside A+b	10 (3.8)	13 (4.4)	23 (4.1)
Sennoside A+b Calcium	2 (0.8)	2 (0.7)	4 (0.7)
Sodium Picosulfate	3 (1.1)	7 (2.4)	10 (1.8)
Sodium Picosulfate Monohydrate	1 (0.4)	0	1 (0.2)
CORTICOSTEROIDS	12 (4.5)	11 (3.7)	23 (4.1)
Beclometasone Dipropionate	2 (0.8)	0	2 (0.4)
Budesonide	2 (0.8)	0	2 (0.4)

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WHO Drug September 2021.
root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Dexamethasone Sodium Phosphate	1 (0.4)	0	1 (0.2)
Diflucortolone Valerate;Lidocaine	2 (0.8)	0	2 (0.4)
Escherichia Coli;Hydrocortisone	0	1 (0.3)	1 (0.2)
Fluticasone	0	1 (0.3)	1 (0.2)
Fluticasone Furoate	1 (0.4)	3 (1.0)	4 (0.7)
Fluticasone Propionate	1 (0.4)	3 (1.0)	4 (0.7)
Framycetin Sulfate;Naphazoline Nitrate;Prednisolone Acetate	1 (0.4)	0	1 (0.2)
Hydrocortisone	1 (0.4)	1 (0.3)	2 (0.4)
Hydrocortisone Acetate	1 (0.4)	0	1 (0.2)
Mometasone	0	2 (0.7)	2 (0.4)
Mometasone Furoate	0	1 (0.3)	1 (0.2)
Triamcinolone Acetonide	0	1 (0.3)	1 (0.2)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	1 (0.4)	4 (1.4)	5 (0.9)
Betamethasone Sodium Phosphate;Neomycin Sulfate	0	1 (0.3)	1 (0.2)
Ciprofloxacin;Dexamethasone	0	1 (0.3)	1 (0.2)
Ciprofloxacin;Hydrocortisone	1 (0.4)	0	1 (0.2)
Dexamethasone;Oxytetracycline	0	1 (0.3)	1 (0.2)
Gramicidin;Neomycin Sulfate;Nystatin;Triamcinolone Acetonide	0	1 (0.3)	1 (0.2)
CORTICOSTEROIDS FOR LOCAL ORAL TREATMENT	3 (1.1)	0	3 (0.5)
Dexamethasone	2 (0.8)	0	2 (0.4)
Triamcinolone Acetonide	1 (0.4)	0	1 (0.2)
CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATIONS	2 (0.8)	0	2 (0.4)
Betamethasone;Chlorphenamine Maleate	1 (0.4)	0	1 (0.2)
Betamethasone;Dexchlorpheniramine Maleate	1 (0.4)	0	1 (0.2)
Betamethasone;Loratadine	1 (0.4)	0	1 (0.2)
CORTICOSTEROIDS, COMBINATIONS FOR TREATMENT OF ACNE	1 (0.4)	0	1 (0.2)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Dexamethasone Valerate	1 (0.4)	0	1 (0.2)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (0.4)	0	1 (0.2)
Steroids	1 (0.4)	0	1 (0.2)
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	2 (0.8)	4 (1.4)	6 (1.1)
Dexamethasone Propionate	1 (0.4)	0	1 (0.2)
Fluorometholone	0	1 (0.3)	1 (0.2)
Hydrocortisone Butyrate	0	1 (0.3)	1 (0.2)
Triamcinolone	0	1 (0.3)	1 (0.2)
Triamcinolone Acetonide	1 (0.4)	1 (0.3)	2 (0.4)
CORTICOSTEROIDS, MODERATELY POTENT, OTHER COMBINATIONS	1 (0.4)	0	1 (0.2)
Dexamethasone;Salicylic Acid	1 (0.4)	0	1 (0.2)
CORTICOSTEROIDS, PLAIN	7 (2.6)	3 (1.0)	10 (1.8)
Betamethasone Sodium Phosphate	2 (0.8)	0	2 (0.4)
Dexamethasone	1 (0.4)	0	1 (0.2)
Dexamethasone Sodium Metasulfobenzoate	1 (0.4)	0	1 (0.2)
Dexamethasone Sodium Phosphate	0	1 (0.3)	1 (0.2)
Fluorometholone	3 (1.1)	2 (0.7)	5 (0.9)
Loteprednol Etabonate	1 (0.4)	0	1 (0.2)
Prednisolone	1 (0.4)	0	1 (0.2)
CORTICOSTEROIDS, POTENT (GROUP III)	11 (4.1)	14 (4.8)	25 (4.5)
Betamethasone	1 (0.4)	2 (0.7)	3 (0.5)
Betamethasone Butyrate Propionate	3 (1.1)	4 (1.4)	7 (1.3)
Betamethasone Dipropionate	0	2 (0.7)	2 (0.4)
Betamethasone Valerate	2 (0.8)	2 (0.7)	4 (0.7)
Diflorasone Diacetate	1 (0.4)	1 (0.3)	2 (0.4)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Diflucortolone Valerate	0	1 (0.3)	1 (0.2)
Difluprednate	3 (1.1)	1 (0.3)	4 (0.7)
Fludroxycortide	2 (0.8)	0	2 (0.4)
Fluocinonide	0	1 (0.3)	1 (0.2)
Methylprednisolone Aceponate	2 (0.8)	0	2 (0.4)
Mometasone Furoate	0	1 (0.3)	1 (0.2)
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIOTICS	3 (1.1)	1 (0.3)	4 (0.7)
Betamethasone Valerate;Gentamicin Sulfate	3 (1.1)	1 (0.3)	4 (0.7)
CORTICOSTEROIDS, VERY POTENT (GROUP IV)	3 (1.1)	1 (0.3)	4 (0.7)
Clobetasol Propionate	3 (1.1)	1 (0.3)	4 (0.7)
CORTICOSTEROIDS, WEAK (GROUP I)	2 (0.8)	0	2 (0.4)
Hydrocortisone	1 (0.4)	0	1 (0.2)
Prednisolone Acetate	1 (0.4)	0	1 (0.2)
Prednisolone Valeroacetate	1 (0.4)	0	1 (0.2)
COUGH AND COLD PREPARATIONS	2 (0.8)	0	2 (0.4)
Cough And Cold Preparations	1 (0.4)	0	1 (0.2)
Herbal Nos;Honey	1 (0.4)	0	1 (0.2)
COXIBS	12 (4.5)	14 (4.8)	26 (4.6)
Celecoxib	12 (4.5)	12 (4.1)	24 (4.3)
Etoricoxib	0	1 (0.3)	1 (0.2)
Polmacoxib	0	1 (0.3)	1 (0.2)
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	4 (1.5)	1 (0.3)	5 (0.9)
Olanzapine	1 (0.4)	0	1 (0.2)
Quetiapine	1 (0.4)	0	1 (0.2)
Quetiapine Fumarate	3 (1.1)	1 (0.3)	4 (0.7)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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DIGITALIS GLYCOSIDES	1 (0.4)	5 (1.7)	6 (1.1)
Digitoxin	0	1 (0.3)	1 (0.2)
Digoxin	0	3 (1.0)	3 (0.5)
Lanatosides	0	1 (0.3)	1 (0.2)
Metildigoxin	1 (0.4)	0	1 (0.2)
DIHYDROPYRIDINE DERIVATIVES	61 (22.9)	78 (26.5)	139 (24.8)
Amlodipine	21 (7.9)	42 (14.3)	63 (11.3)
Amlodipine Besilate	23 (8.6)	15 (5.1)	38 (6.8)
Azelnidipine	0	2 (0.7)	2 (0.4)
Cilnidipine	0	3 (1.0)	3 (0.5)
Felodipine	1 (0.4)	0	1 (0.2)
Lacidipine	2 (0.8)	0	2 (0.4)
Lercanidipine	3 (1.1)	7 (2.4)	10 (1.8)
Lercanidipine Hydrochloride	3 (1.1)	0	3 (0.5)
Levamlodipine	1 (0.4)	0	1 (0.2)
Nicardipine	0	2 (0.7)	2 (0.4)
Nicardipine Hydrochloride	4 (1.5)	1 (0.3)	5 (0.9)
Nifedipine	7 (2.6)	9 (3.1)	16 (2.9)
Nitrendipine	2 (0.8)	2 (0.7)	4 (0.7)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	15 (5.6)	17 (5.8)	32 (5.7)
Alogliptin	0	1 (0.3)	1 (0.2)
Alogliptin Benzoate	2 (0.8)	2 (0.7)	4 (0.7)
Gemigliptin Tartrate	0	1 (0.3)	1 (0.2)
Linagliptin	3 (1.1)	1 (0.3)	4 (0.7)
Saxagliptin Hydrochloride	0	1 (0.3)	1 (0.2)
Sitagliptin	4 (1.5)	2 (0.7)	6 (1.1)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Sitagliptin Phosphate	1 (0.4)	6 (2.0)	7 (1.3)
Sitagliptin Phosphate Monohydrate	0	2 (0.7)	2 (0.4)
Teneligliptin Hydrobromide	2 (0.8)	1 (0.3)	3 (0.5)
Teneligliptin Hydrobromide Hydrate	2 (0.8)	0	2 (0.4)
Vildagliptin	2 (0.8)	2 (0.7)	4 (0.7)
DIRECT FACTOR XA INHIBITORS	35 (13.2)	17 (5.8)	52 (9.3)
Apixaban	12 (4.5)	11 (3.7)	23 (4.1)
Edoxaban	4 (1.5)	0	4 (0.7)
Edoxaban Tosilate	4 (1.5)	1 (0.3)	5 (0.9)
Edoxaban Tosilate Monohydrate	2 (0.8)	0	2 (0.4)
Rivaroxaban	16 (6.0)	5 (1.7)	21 (3.8)
DIRECT THROMBIN INHIBITORS	3 (1.1)	2 (0.7)	5 (0.9)
Dabigatran	1 (0.4)	1 (0.3)	2 (0.4)
Dabigatran Etexilate	0	1 (0.3)	1 (0.2)
Dabigatran Etexilate Mesilate	2 (0.8)	0	2 (0.4)
DIURETICS	1 (0.4)	0	1 (0.2)
Diuretics	1 (0.4)	0	1 (0.2)
DOPA AND DOPA DERIVATIVES	2 (0.8)	0	2 (0.4)
Benserazide Hydrochloride;Levodopa	1 (0.4)	0	1 (0.2)
Carbidopa;Levodopa	1 (0.4)	0	1 (0.2)
DOPAMINE AGONISTS	2 (0.8)	0	2 (0.4)
Pramipexole	1 (0.4)	0	1 (0.2)
Pramipexole Dihydrochloride Monohydrate	1 (0.4)	0	1 (0.2)
DRUGS FOR CONSTIPATION	1 (0.4)	1 (0.3)	2 (0.4)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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Aloe Vera;Citrus Aurantium;Curcuma Zedoaria;Glycyrrhiza Glabra;Rheum Officinale;Senna Alexandrina	1 (0.4)	0	1 (0.2)
Drugs For Constipation	0	1 (0.3)	1 (0.2)
DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	4 (1.5)	0	4 (0.7)
Teprenone	4 (1.5)	0	4 (0.7)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	26 (9.8)	32 (10.9)	58 (10.4)
Darifenacin	0	1 (0.3)	1 (0.2)
Duloxetine	1 (0.4)	0	1 (0.2)
Duloxetine Hydrochloride	0	2 (0.7)	2 (0.4)
Fesoterodine Fumarate	2 (0.8)	1 (0.3)	3 (0.5)
Flavoxate Hydrochloride	0	1 (0.3)	1 (0.2)
Imidafenacin	1 (0.4)	3 (1.0)	4 (0.7)
Imipramine	1 (0.4)	2 (0.7)	3 (0.5)
Mirabegron	14 (5.3)	12 (4.1)	26 (4.6)
Oxybutynin	3 (1.1)	1 (0.3)	4 (0.7)
Propiverine Hydrochloride	2 (0.8)	1 (0.3)	3 (0.5)
Solifenacin	2 (0.8)	4 (1.4)	6 (1.1)
Solifenacin Succinate	1 (0.4)	3 (1.0)	4 (0.7)
Solifenacin Tartrate	1 (0.4)	1 (0.3)	2 (0.4)
Tolterodine	1 (0.4)	1 (0.3)	2 (0.4)
Trospium Chloride	1 (0.4)	7 (2.4)	8 (1.4)
DRUGS USED IN ERECTILE DYSFUNCTION	8 (3.0)	6 (2.0)	14 (2.5)
Alprostadil	1 (0.4)	0	1 (0.2)
Sildenafil	3 (1.1)	2 (0.7)	5 (0.9)
Sildenafil Citrate	1 (0.4)	2 (0.7)	3 (0.5)
Tadalafil	3 (1.1)	3 (1.0)	6 (1.1)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
DRUGS USED IN OPIOID DEPENDENCE	1 (0.4)	0	1 (0.2)
Naloxone Hydrochloride	1 (0.4)	0	1 (0.2)
ELECTROLYTE SOLUTIONS	34 (12.8)	26 (8.8)	60 (10.7)
Calcium Chloride	1 (0.4)	0	1 (0.2)
Calcium Chloride Dihydrate;Magnesium Chloride Hexahydrate;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride;Sodium Citrate Dihydrate	1 (0.4)	1 (0.3)	2 (0.4)
Calcium Chloride;Magnesium Chloride;Potassium Chloride;Sodium Acetate;Sodium Chloride	0	1 (0.3)	1 (0.2)
Calcium Gluconate	2 (0.8)	0	2 (0.4)
Chromic Chloride;Copper Chloride Dihydrate;Ferric Chloride Hexahydrate;Manganese Chloride Tetrahydrate;Potassium Iodide;Sodium Fluoride;Sodium Molybdate Dihydrate;Sodium Selenite;Zinc Chloride	1 (0.4)	0	1 (0.2)
Copper Sulfate Pentahydrate;Ferric Chloride Hexahydrate;Manganese Chloride Tetrahydrate;Potassium Iodide;Zinc Sulfate Heptahydrate	1 (0.4)	0	1 (0.2)
Copper Sulfate;Ferric Chloride;Manganese Chloride;Potassium Iodide;Zinc Sulfate	0	1 (0.3)	1 (0.2)
Magnesium Sulfate	5 (1.9)	3 (1.0)	8 (1.4)
Potassium	0	1 (0.3)	1 (0.2)
Potassium Chloride	11 (4.1)	4 (1.4)	15 (2.7)
Potassium Phosphate Dibasic;Potassium Phosphate Monobasic	0	2 (0.7)	2 (0.4)
Potassium Phosphate Monobasic	1 (0.4)	0	1 (0.2)
Sodium Bicarbonate	1 (0.4)	3 (1.0)	4 (0.7)
Sodium Chloride	21 (7.9)	19 (6.5)	40 (7.1)
Sodium Phosphate	1 (0.4)	0	1 (0.2)
Sodium Phosphate;Sodium Phosphate Monobasic (dihydrate)	0	1 (0.3)	1 (0.2)
Zinc Sulfate	0	1 (0.3)	1 (0.2)
ENEMAS	7 (2.6)	6 (2.0)	13 (2.3)
Bisacodyl	1 (0.4)	3 (1.0)	4 (0.7)

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Enemas	0	1 (0.3)	1 (0.2)
Glycerol	3 (1.1)	1 (0.3)	4 (0.7)
Glycerol;Polysorbate 80;Sodium Citrate;Sorbitol	0	1 (0.3)	1 (0.2)
Phosphoric Acid Sodium;Sodium Phosphate Dibasic	1 (0.4)	0	1 (0.2)
Sodium Chloride	1 (0.4)	0	1 (0.2)
Sodium Phosphate Dibasic;Sodium Phosphate Monobasic	1 (0.4)	0	1 (0.2)
ENZYME PREPARATIONS	5 (1.9)	3 (1.0)	8 (1.4)
Bromelains;Dimeticone;Pancreatin	1 (0.4)	0	1 (0.2)
Bromelains;Rutoside;Trypsin	0	1 (0.3)	1 (0.2)
Dimeticone;Hemicellulase;Ox Bile;Pancreatin	0	1 (0.3)	1 (0.2)
Dimeticone;Pancreatin	1 (0.4)	0	1 (0.2)
Pancreatin	1 (0.4)	0	1 (0.2)
Pancreatin;Simeticone;Ursodeoxycholic Acid	2 (0.8)	0	2 (0.4)
Pancrelipase	0	1 (0.3)	1 (0.2)
ENZYMES	9 (3.4)	2 (0.7)	11 (2.0)
Alteplase	1 (0.4)	0	1 (0.2)
Bromelains	1 (0.4)	0	1 (0.2)
Bromelains;Tocopheryl Acetate	1 (0.4)	0	1 (0.2)
Kallidinogenase	1 (0.4)	0	1 (0.2)
Pronase	4 (1.5)	2 (0.7)	6 (1.1)
Streptodornase;Streptokinase	2 (0.8)	0	2 (0.4)
ERGOT ALKALOIDS	1 (0.4)	0	1 (0.2)
Caffeine;Dihydroergotamine Mesilate;Metamizole Sodium	1 (0.4)	0	1 (0.2)
ETHERS, CHEMICALLY CLOSE TO ANTIHISTAMINES	2 (0.8)	0	2 (0.4)
Caffeine;Metamizole Sodium;Orphenadrine Citrate	1 (0.4)	0	1 (0.2)
Orphenadrine Citrate	1 (0.4)	0	1 (0.2)

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EXPECTORANTS	3 (1.1)	1 (0.3)	4 (0.7)
Guaifenesin	2 (0.8)	1 (0.3)	3 (0.5)
Myrtol	1 (0.4)	0	1 (0.2)
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMBINATIONS	1 (0.4)	2 (0.7)	3 (0.5)
Ascorbic Acid;Biotin;Calcium Citrate;Calcium Pantothenate;Cyanocobalamin;Ferrous Sulfate;Fibre, Dietary;Folic Acid;Glycine Max Seed Oil;Magnesium Carbonate;Maltodextrin;Nicotinamide;Potassium Citrate;Proteins Nos;Pyridoxine Hydrochloride;Retinol;Riboflavin;Sodium Chloride;Sucrose;Thiamine Hydrochloride;Tocopheryl Acetate;Whey Protein;Zea Mays Starch	0	1 (0.3)	1 (0.2)
Carbohydrates Nos;Choline;Fats Nos;Minerals Nos;Proteins Nos;Uridine Phosphate;Vitamins Nos	1 (0.4)	0	1 (0.2)
Carbohydrates Nos;Fats Nos;Minerals Nos;Protein;Vitamins Nos	0	1 (0.3)	1 (0.2)
FATTY ACID DERIVATIVES	1 (0.4)	0	1 (0.2)
Valproate Sodium;Valproic Acid	1 (0.4)	0	1 (0.2)
FIBRATES	5 (1.9)	8 (2.7)	13 (2.3)
Bezafibrate	1 (0.4)	2 (0.7)	3 (0.5)
Ciprofibrate	1 (0.4)	1 (0.3)	2 (0.4)
Fenofibrate	2 (0.8)	5 (1.7)	7 (1.3)
Gemfibrozil	1 (0.4)	0	1 (0.2)
Pemafibrate	1 (0.4)	0	1 (0.2)
FIRST-GENERATION CEPHALOSPORINS	27 (10.2)	18 (6.1)	45 (8.0)
Cefadroxil	1 (0.4)	1 (0.3)	2 (0.4)
Cefalexin	11 (4.1)	6 (2.0)	17 (3.0)
Cefalexin Monohydrate	2 (0.8)	0	2 (0.4)
Cefazedone Sodium	2 (0.8)	1 (0.3)	3 (0.5)
Cefazolin	4 (1.5)	2 (0.7)	6 (1.1)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Cefazolin Sodium	10 (3.8)	8 (2.7)	18 (3.2)
Cefroxadine	0	1 (0.3)	1 (0.2)
FLUOROQUINOLONES	38 (14.3)	27 (9.2)	65 (11.6)
Ciprofloxacin	15 (5.6)	8 (2.7)	23 (4.1)
Ciprofloxacin Hydrochloride	0	2 (0.7)	2 (0.4)
Ciprofloxacin Hydrochloride Monohydrate	0	1 (0.3)	1 (0.2)
Gatifloxacin	0	3 (1.0)	3 (0.5)
Levofloxacin	17 (6.4)	12 (4.1)	29 (5.2)
Moxifloxacin	3 (1.1)	1 (0.3)	4 (0.7)
Moxifloxacin Hydrochloride	5 (1.9)	3 (1.0)	8 (1.4)
Ofloxacin	5 (1.9)	2 (0.7)	7 (1.3)
Sitafloxacin	1 (0.4)	0	1 (0.2)
FOLIC ACID AND DERIVATIVES	23 (8.6)	8 (2.7)	31 (5.5)
Folic Acid	23 (8.6)	8 (2.7)	31 (5.5)
FOURTH-GENERATION CEPHALOSPORINS	4 (1.5)	6 (2.0)	10 (1.8)
Cefepime	1 (0.4)	4 (1.4)	5 (0.9)
Cefepime Hydrochloride	3 (1.1)	2 (0.7)	5 (0.9)
Cefozopran Hydrochloride	0	1 (0.3)	1 (0.2)
GENERAL NUTRIENTS	1 (0.4)	1 (0.3)	2 (0.4)
General Nutrients	1 (0.4)	0	1 (0.2)
Nutrients Nos	0	1 (0.3)	1 (0.2)
GINKGO REMEDIES	0	2 (0.7)	2 (0.4)
Ginkgo Biloba	0	1 (0.3)	1 (0.2)
Ginkgo Biloba Extract	0	1 (0.3)	1 (0.2)
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES	4 (1.5)	2 (0.7)	6 (1.1)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Dulaglutide	1 (0.4)	1 (0.3)	2 (0.4)
Exenatide	1 (0.4)	0	1 (0.2)
Semaglutide	2 (0.8)	1 (0.3)	3 (0.5)
GLUCOCORTICOIDS	56 (21.1)	66 (22.4)	122 (21.8)
Beclometasone Dipropionate	1 (0.4)	1 (0.3)	2 (0.4)
Betamethasone	1 (0.4)	2 (0.7)	3 (0.5)
Betamethasone Sodium Phosphate	0	1 (0.3)	1 (0.2)
Budesonide	3 (1.1)	2 (0.7)	5 (0.9)
Cortisone	2 (0.8)	1 (0.3)	3 (0.5)
Cortisone Acetate	0	1 (0.3)	1 (0.2)
Deflazacort	1 (0.4)	0	1 (0.2)
Dexamethasone	12 (4.5)	19 (6.5)	31 (5.5)
Dexamethasone Sodium Phosphate	7 (2.6)	6 (2.0)	13 (2.3)
Fluticasone	0	1 (0.3)	1 (0.2)
Fluticasone Propionate	1 (0.4)	2 (0.7)	3 (0.5)
Glucocorticoids	0	1 (0.3)	1 (0.2)
Hydrocortisone	8 (3.0)	6 (2.0)	14 (2.5)
Hydrocortisone Sodium Phosphate	2 (0.8)	1 (0.3)	3 (0.5)
Hydrocortisone Sodium Succinate	5 (1.9)	4 (1.4)	9 (1.6)
Methylprednisolone	6 (2.3)	4 (1.4)	10 (1.8)
Methylprednisolone Acetate	0	1 (0.3)	1 (0.2)
Methylprednisolone Sodium Succinate	7 (2.6)	1 (0.3)	8 (1.4)
Prednisolone	14 (5.3)	20 (6.8)	34 (6.1)
Prednisolone Sodium Succinate	2 (0.8)	0	2 (0.4)
Prednisone	7 (2.6)	7 (2.4)	14 (2.5)
Triamcinolone Acetonide	1 (0.4)	1 (0.3)	2 (0.4)
GLYCOGENOLYTIC HORMONES	2 (0.8)	0	2 (0.4)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Glucagon	2 (0.8)	0	2 (0.4)
GLYCOPEPTIDE ANTIBACTERIALS	11 (4.1)	2 (0.7)	13 (2.3)
Teicoplanin	2 (0.8)	0	2 (0.4)
Vancomycin	7 (2.6)	1 (0.3)	8 (1.4)
Vancomycin Hydrochloride	3 (1.1)	1 (0.3)	4 (0.7)
GONADOTROPIN RELEASING HORMONE ANALOGUES	159 (59.8)	157 (53.4)	316 (56.4)
Buserelin Acetate	3 (1.1)	1 (0.3)	4 (0.7)
Goserelin	16 (6.0)	7 (2.4)	23 (4.1)
Goserelin Acetate	34 (12.8)	38 (12.9)	72 (12.9)
Leuprorelin	24 (9.0)	27 (9.2)	51 (9.1)
Leuprorelin Acetate	78 (29.3)	72 (24.5)	150 (26.8)
Triptorelin	10 (3.8)	18 (6.1)	28 (5.0)
Triptorelin Acetate	0	2 (0.7)	2 (0.4)
Triptorelin Embonate	2 (0.8)	2 (0.7)	4 (0.7)
GONADOTROPIN-RELEASING HORMONES	0	1 (0.3)	1 (0.2)
Leuprorelin Acetate	0	1 (0.3)	1 (0.2)
H2-RECEPTOR ANTAGONISTS	16 (6.0)	20 (6.8)	36 (6.4)
Cimetidine	0	1 (0.3)	1 (0.2)
Famotidine	13 (4.9)	14 (4.8)	27 (4.8)
Lafutidine	0	1 (0.3)	1 (0.2)
Nizatidine	1 (0.4)	2 (0.7)	3 (0.5)
Ranitidine	1 (0.4)	0	1 (0.2)
Ranitidine Hydrochloride	3 (1.1)	2 (0.7)	5 (0.9)
HALOGENATED HYDROCARBONS	1 (0.4)	5 (1.7)	6 (1.1)
Desflurane	0	4 (1.4)	4 (0.7)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Sevoflurane	1 (0.4)	1 (0.3)	2 (0.4)
HEPARIN GROUP	41 (15.4)	36 (12.2)	77 (13.8)
Antithrombin Iii	0	1 (0.3)	1 (0.2)
Bemiparin Sodium	0	1 (0.3)	1 (0.2)
Dalteparin	2 (0.8)	1 (0.3)	3 (0.5)
Dalteparin Sodium	2 (0.8)	1 (0.3)	3 (0.5)
Enoxaparin	5 (1.9)	10 (3.4)	15 (2.7)
Enoxaparin Sodium	16 (6.0)	13 (4.4)	29 (5.2)
Heparin	4 (1.5)	3 (1.0)	7 (1.3)
Heparin Calcium	2 (0.8)	0	2 (0.4)
Heparin Sodium	3 (1.1)	3 (1.0)	6 (1.1)
Heparinoid	1 (0.4)	0	1 (0.2)
Low Molecular Weight Heparin	0	1 (0.3)	1 (0.2)
Nadroparin	1 (0.4)	1 (0.3)	2 (0.4)
Nadroparin Calcium	6 (2.3)	3 (1.0)	9 (1.6)
Sulodexide	2 (0.8)	0	2 (0.4)
Tinzaparin	2 (0.8)	2 (0.7)	4 (0.7)
HERBAL ANTIEMETICS, OTHER	2 (0.8)	0	2 (0.4)
Atractylodes Spp. Rhizome;Citrus Aurantium Peel;Glycyrrhiza Spp. Root;Panax Ginseng Root;Pinellia Ternata Tuber;Poria Cocos Sclerotium;Zingiber Officinale Rhizome;Ziziphus Jujuba Fruit	1 (0.4)	0	1 (0.2)
Zingiber Officinale	1 (0.4)	0	1 (0.2)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	6 (2.3)	6 (2.0)	12 (2.1)
Clematis Spp. Extract;Prunella Vulgaris Extract;Trichosanthes Kirilowii Extract	0	1 (0.3)	1 (0.2)
Curcuma Longa	0	1 (0.3)	1 (0.2)
Glycyrrhiza Spp. Root;Paeonia Lactiflora Root	6 (2.3)	4 (1.4)	10 (1.8)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
HERBAL ANTISPASMODIC AGENTS, OTHER	2 (0.8)	1 (0.3)	3 (0.5)
Corydalis Yanhusuo Tuber;Ipomoea Nil Seed	2 (0.8)	1 (0.3)	3 (0.5)
HERBAL ANTIVERTIGO PREPARATIONS	1 (0.4)	0	1 (0.2)
Ginkgo Biloba Extract	1 (0.4)	0	1 (0.2)
HERBAL APPETITE STIMULANTS	1 (0.4)	0	1 (0.2)
Cannabis Sativa	1 (0.4)	0	1 (0.2)
HERBAL CHOLESTEROL AND TRIGLYCERIDE REDUCERS	1 (0.4)	0	1 (0.2)
Monascus Purpureus	1 (0.4)	0	1 (0.2)
HERBAL DIGESTIVES, OTHER	1 (0.4)	2 (0.7)	3 (0.5)
Monascus Purpureus	0	1 (0.3)	1 (0.2)
Silybum Marianum	1 (0.4)	1 (0.3)	2 (0.4)
HERBAL DIURETICS, OTHER	1 (0.4)	0	1 (0.2)
Alisma Orientale Tuber;Atractylodes Spp. Rhizome;Cinnamomum Cassia Bark;Polyporus Umbellatus Sclerotium;Poria Cocos Sclerotium	1 (0.4)	0	1 (0.2)
HERBAL DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (0.4)	1 (0.3)	2 (0.4)
Chimaphila Umbellata Extract;Equisetum Arvense Extract;Populus Tremuloides Extract;Pulsatilla Vulgaris;Triticum Aestivum Oil	1 (0.4)	1 (0.3)	2 (0.4)
HERBAL EMOLLIENTS AND PROTECTIVES CONTAINING OR CONSTITUTING OIL	1 (0.4)	0	1 (0.2)
Olea Europaea Oil	1 (0.4)	0	1 (0.2)
HERBAL EMOLLIENTS AND PROTECTIVES, OTHER	1 (0.4)	0	1 (0.2)
Agrimonia Eupatoria	1 (0.4)	0	1 (0.2)
HERBAL EXPECTORANTS AND EMOLLIENTS	4 (1.5)	2 (0.7)	6 (1.1)
Cinnamomum Cassia Bark;Ephedra Spp. Herb;Glycyrrhiza Spp. Root;Paeonia Lactiflora Root;Pueraria Lobata Root;Zingiber Officinale Rhizome;Ziziphus Jujuba Fruit	1 (0.4)	1 (0.3)	2 (0.4)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Coptis Spp. Rhizome;Hedera Helix Leaf	2 (0.8)	1 (0.3)	3 (0.5)
Herbal Expectorants And Emollients	1 (0.4)	0	1 (0.2)
HERBAL IMMUNOMODULATORS	1 (0.4)	1 (0.3)	2 (0.4)
Angelica Acutiloba Root;Astragalus Spp. Root;Atractylodes Lancea Rhizome;Cinnamomum Cassia Bark;Cnidium Officinale Rhizome;Glycyrrhiza Spp. Root;Paeonia Lactiflora Root;Panax Ginseng Root;Poria Cocos Sclerotium;Rehmannia Glutinosa Root	0	1 (0.3)	1 (0.2)
Angelica Acutiloba Root;Astragalus Spp. Root;Atractylodes Spp. Rhizome;Cinnamomum Cassia Bark;Citrus Aurantium Peel;Glycyrrhiza Spp. Root;Paeonia Lactiflora Root;Panax Ginseng Root;Polygala Tenuifoliaroot;Poria Cocos Sclerotium;Rehmannia Glutinosa Root;Schisandra Chinensis Fruit	1 (0.4)	0	1 (0.2)
HERBAL INTESTINAL ADSORBENTS	1 (0.4)	0	1 (0.2)
Plantago Ovata	1 (0.4)	0	1 (0.2)
HERBAL REMEDIES FOR TREATMENT OF PEPTIC ULCER, OTHER	2 (0.8)	3 (1.0)	5 (0.9)
Artemisia Argyi	0	2 (0.7)	2 (0.4)
Artemisia Argyi Leaf	2 (0.8)	0	2 (0.4)
Coptis Spp. Rhizome;Glycyrrhiza Spp. Root;Panax Ginseng Root;Pinellia Ternata Tuber;Scutellaria Baicalensis Root;Zingiber Officinale Rhizome;Ziziphus Jujuba Fruit	0	1 (0.3)	1 (0.2)
HERBAL URINARY ANTISEPTICS AND ANTIINFECTIVES	1 (0.4)	0	1 (0.2)
Arctostaphylos Uva-Ursi;D-Mannose;Vaccinium Macrocarpon;Zinc Chelate	1 (0.4)	0	1 (0.2)
HMG COA REDUCTASE INHIBITORS	91 (34.2)	90 (30.6)	181 (32.3)
Atorvastatin	22 (8.3)	28 (9.5)	50 (8.9)
Atorvastatin Calcium	24 (9.0)	14 (4.8)	38 (6.8)
Atorvastatin Calcium Trihydrate	2 (0.8)	0	2 (0.4)
Fluvastatin Sodium	0	1 (0.3)	1 (0.2)
Lovastatin	0	1 (0.3)	1 (0.2)

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Pitavastatin	0	1 (0.3)	1 (0.2)
Pitavastatin Calcium	6 (2.3)	5 (1.7)	11 (2.0)
Pravastatin	4 (1.5)	4 (1.4)	8 (1.4)
Pravastatin Sodium	3 (1.1)	1 (0.3)	4 (0.7)
Rosuvastatin	11 (4.1)	13 (4.4)	24 (4.3)
Rosuvastatin Calcium	10 (3.8)	12 (4.1)	22 (3.9)
Simvastatin	16 (6.0)	14 (4.8)	30 (5.4)
HOMEOPATHIC PREPARATION	1 (0.4)	2 (0.7)	3 (0.5)
Achillea Millefolium;Aconitum Spp.;Arnica Spp.;Atropa Belladonna;Bellis Perennis;Calendula Spp.;Echinacea Angustifolia;Echinacea Purpurea;Hamamelis Spp.;Herbal Nos;Hypericum Spp.;Sulfurated Potash;Symphytum Spp.	0	1 (0.3)	1 (0.2)
Aconitum Napellus;Cinchona Officinalis;Gnaphalium Polycephalum;Magnesium Phosphate;Rhododendron Tomentosum;Toxicodendron Pubescens;Viscum Album	1 (0.4)	0	1 (0.2)
Histamine	0	1 (0.3)	1 (0.2)
HYDRAZIDES	0	1 (0.3)	1 (0.2)
Isoniazid	0	1 (0.3)	1 (0.2)
HYDRAZINOPHTHALAZINE DERIVATIVES	1 (0.4)	4 (1.4)	5 (0.9)
Hydralazine	1 (0.4)	3 (1.0)	4 (0.7)
Hydralazine Hydrochloride	0	1 (0.3)	1 (0.2)
I.V. SOLUTION ADDITIVES	2 (0.8)	0	2 (0.4)
Calcium Chloride Dihydrate;Glucose;Potassium Chloride;Sodium Acetate;Sodium Chloride	2 (0.8)	0	2 (0.4)
I.V. SOLUTIONS	1 (0.4)	1 (0.3)	2 (0.4)
Calcium Gluconate Monohydrate;Glucose;Magnesium Chloride;Sodium Chloride;Sodium L-Lactate;Zinc Sulfate Monohydrate	1 (0.4)	1 (0.3)	2 (0.4)

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IMIDAZOLE AND TRIAZOLE DERIVATIVES	8 (3.0)	2 (0.7)	10 (1.8)
Clotrimazole	1 (0.4)	0	1 (0.2)
Efinaconazole	2 (0.8)	1 (0.3)	3 (0.5)
Isoconazole Nitrate	2 (0.8)	0	2 (0.4)
Luliconazole	2 (0.8)	1 (0.3)	3 (0.5)
Miconazole	1 (0.4)	0	1 (0.2)
Miconazole Nitrate	0	1 (0.3)	1 (0.2)
IMIDAZOLE DERIVATIVES	9 (3.4)	6 (2.0)	15 (2.7)
Ketoconazole	0	1 (0.3)	1 (0.2)
Metronidazole	9 (3.4)	5 (1.7)	14 (2.5)
IMIDAZOLINE RECEPTOR AGONISTS	0	3 (1.0)	3 (0.5)
Clonidine	0	1 (0.3)	1 (0.2)
Moxonidine	0	3 (1.0)	3 (0.5)
IMMUNOGLOBULINS, NORMAL HUMAN	0	1 (0.3)	1 (0.2)
Immunoglobulin G Human	0	1 (0.3)	1 (0.2)
INDIFFERENT PREPARATIONS	1 (0.4)	0	1 (0.2)
Hydroxyquinoline Borate;Trolamine	1 (0.4)	0	1 (0.2)
INFLUENZA VACCINES	41 (15.4)	24 (8.2)	65 (11.6)
Influenza Vaccine	34 (12.8)	19 (6.5)	53 (9.5)
Influenza Vaccine Inact Sag 3v	1 (0.4)	2 (0.7)	3 (0.5)
Influenza Vaccine Inact Sag 4v	4 (1.5)	1 (0.3)	5 (0.9)
Influenza Vaccine Inact Split 3v	4 (1.5)	3 (1.0)	7 (1.3)
Influenza Vaccine Inact Split 4v	0	1 (0.3)	1 (0.2)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	18 (6.8)	14 (4.8)	32 (5.7)
Insulin	7 (2.6)	3 (1.0)	10 (1.8)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Insulin Aspart	1 (0.4)	5 (1.7)	6 (1.1)
Insulin Glulisine	0	1 (0.3)	1 (0.2)
Insulin Human	7 (2.6)	5 (1.7)	12 (2.1)
Insulin Lispro	5 (1.9)	2 (0.7)	7 (1.3)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	2 (0.8)	2 (0.7)	4 (0.7)
Insulin Aspart;Insulin Aspart Protamine (crystalline)	1 (0.4)	0	1 (0.2)
Insulin Aspart;Insulin Degludec	0	1 (0.3)	1 (0.2)
Insulin Human;Insulin Human Injection, Isophane	1 (0.4)	1 (0.3)	2 (0.4)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	5 (1.9)	3 (1.0)	8 (1.4)
Insulin Human Injection, Isophane	3 (1.1)	2 (0.7)	5 (0.9)
Isophane Insulin	2 (0.8)	1 (0.3)	3 (0.5)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	4 (1.5)	10 (3.4)	14 (2.5)
Insulin Degludec	1 (0.4)	2 (0.7)	3 (0.5)
Insulin Glargine	3 (1.1)	8 (2.7)	11 (2.0)
INTERLEUKIN INHIBITORS	1 (0.4)	0	1 (0.2)
Tocilizumab	1 (0.4)	0	1 (0.2)
INVESTIGATIONAL DRUG	1 (0.4)	0	1 (0.2)
Sulforaphane	1 (0.4)	0	1 (0.2)
IODINE PRODUCTS	2 (0.8)	0	2 (0.4)
Povidone-Iodine	2 (0.8)	0	2 (0.4)
IRON BIVALENT, ORAL PREPARATIONS	19 (7.1)	8 (2.7)	27 (4.8)
Ascorbic Acid;Ferrous Sulfate	1 (0.4)	0	1 (0.2)
Ferrous Fumarate	2 (0.8)	2 (0.7)	4 (0.7)
Ferrous Glycine Sulfate	1 (0.4)	0	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Ferrous Sodium Citrate	2 (0.8)	1 (0.3)	3 (0.5)
Ferrous Sulfate	12 (4.5)	5 (1.7)	17 (3.0)
Ferrous Sulfate Exsiccated	1 (0.4)	0	1 (0.2)
Ferrous Sulfate Exsiccated;Sodium Ascorbate	1 (0.4)	0	1 (0.2)
Ferrous Sulfate;Protease Nos	1 (0.4)	0	1 (0.2)
IRON IN COMBINATION WITH FOLIC ACID	1 (0.4)	0	1 (0.2)
Ferrous Bisglycinate;Folic Acid	1 (0.4)	0	1 (0.2)
IRON IN OTHER COMBINATIONS	1 (0.4)	1 (0.3)	2 (0.4)
Ascorbic Acid;Cyanocobalamin;Ferrous Fumarate;Folic Acid	1 (0.4)	0	1 (0.2)
Ferrous Gluconate;Herbal Nos;Vitamins Nos	0	1 (0.3)	1 (0.2)
IRON PREPARATIONS	3 (1.1)	4 (1.4)	7 (1.3)
Iron	3 (1.1)	4 (1.4)	7 (1.3)
IRON TRIVALENT, ORAL PREPARATIONS	3 (1.1)	1 (0.3)	4 (0.7)
Ascorbic Acid;Ferrous Sulfate	1 (0.4)	0	1 (0.2)
Ferric Hydroxide Polymaltose Complex	1 (0.4)	0	1 (0.2)
Iron	1 (0.4)	1 (0.3)	2 (0.4)
Saccharated Iron Oxide	1 (0.4)	0	1 (0.2)
IRON, PARENTERAL PREPARATIONS	2 (0.8)	1 (0.3)	3 (0.5)
Ferric Carboxymaltose	1 (0.4)	1 (0.3)	2 (0.4)
Saccharated Iron Oxide	1 (0.4)	0	1 (0.2)
ISOTONIC SOLUTIONS	0	1 (0.3)	1 (0.2)
Isotonic Solutions	0	1 (0.3)	1 (0.2)
LEUKOTRIENE RECEPTOR ANTAGONISTS	2 (0.8)	2 (0.7)	4 (0.7)
Desloratadine;Montelukast Sodium	0	1 (0.3)	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Montelukast	1 (0.4)	1 (0.3)	2 (0.4)
Montelukast Sodium	1 (0.4)	0	1 (0.2)
LINCOSAMIDES	4 (1.5)	1 (0.3)	5 (0.9)
Clindamycin	3 (1.1)	1 (0.3)	4 (0.7)
Clindamycin Hydrochloride	1 (0.4)	0	1 (0.2)
LIPID MODIFYING AGENTS IN COMBINATION WITH OTHER DRUGS	2 (0.8)	2 (0.7)	4 (0.7)
Amlodipine Besilate;Atorvastatin Calcium	2 (0.8)	1 (0.3)	3 (0.5)
Amlodipine Besilate;Atorvastatin L-Lysine	0	1 (0.3)	1 (0.2)
LIVER THERAPY	6 (2.3)	4 (1.4)	10 (1.8)
Adenine Hydrochloride;Bifendate;Carnitine Orotate;Cyanocobalamin;Liver Extract;Pyridoxine Hydrochloride;Riboflavin	2 (0.8)	1 (0.3)	3 (0.5)
Cysteine Hydrochloride;Glycine;Glycyrrhizic Acid	1 (0.4)	0	1 (0.2)
Cysteine;Glycine;Glycyrrhizic Acid, Ammonium Salt	0	1 (0.3)	1 (0.2)
Dl-Methionine;Glycine;Glycyrrhizic Acid, Ammonium Salt	1 (0.4)	1 (0.3)	2 (0.4)
Glycine;Glycyrrhizic Acid, Ammonium Salt;Methionine	1 (0.4)	0	1 (0.2)
Ornithine	1 (0.4)	0	1 (0.2)
Silybum Marianum	1 (0.4)	1 (0.3)	2 (0.4)
LOCAL ANESTHETICS	7 (2.6)	1 (0.3)	8 (1.4)
Cinchocaine Hydrochloride;Policresulen	2 (0.8)	0	2 (0.4)
Lidocaine	0	1 (0.3)	1 (0.2)
Lidocaine Hydrochloride	2 (0.8)	0	2 (0.4)
Lidocaine Hydrochloride;Tribenoside	1 (0.4)	0	1 (0.2)
Lidocaine;Tribenoside	0	1 (0.3)	1 (0.2)
Oxybuprocaine Hydrochloride	3 (1.1)	0	3 (0.5)
LOCAL HEMOSTATICS	1 (0.4)	2 (0.7)	3 (0.5)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Epinephrine	0	2 (0.7)	2 (0.4)
Thrombin	1 (0.4)	0	1 (0.2)
LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	2 (0.8)	2 (0.7)	4 (0.7)
Amiloride Hydrochloride;Hydrochlorothiazide	1 (0.4)	1 (0.3)	2 (0.4)
Hydrochlorothiazide;Spironolactone	0	1 (0.3)	1 (0.2)
Hydrochlorothiazide;Triamterene	1 (0.4)	0	1 (0.2)
MACROLIDES	18 (6.8)	17 (5.8)	35 (6.3)
Azithromycin	13 (4.9)	11 (3.7)	24 (4.3)
Azithromycin Monohydrate	1 (0.4)	0	1 (0.2)
Clarithromycin	3 (1.1)	5 (1.7)	8 (1.4)
Roxithromycin	2 (0.8)	1 (0.3)	3 (0.5)
Spiramycin	1 (0.4)	0	1 (0.2)
MAGNESIUM	19 (7.1)	16 (5.4)	35 (6.3)
Magnesium	16 (6.0)	9 (3.1)	25 (4.5)
Magnesium Amino Acid Chelate;Magnesium Oxide	1 (0.4)	0	1 (0.2)
Magnesium Aspartate	0	1 (0.3)	1 (0.2)
Magnesium Carbonate	0	3 (1.0)	3 (0.5)
Magnesium Chloride	1 (0.4)	0	1 (0.2)
Magnesium Gluconate	0	2 (0.7)	2 (0.4)
Magnesium Lactate	0	1 (0.3)	1 (0.2)
Magnesium Oxide	2 (0.8)	1 (0.3)	3 (0.5)
Magnesium;Pyridoxine	1 (0.4)	0	1 (0.2)
MAGNESIUM COMPOUNDS	2 (0.8)	0	2 (0.4)
Magnesium Hydroxide	2 (0.8)	0	2 (0.4)
MEDICAL GASES	5 (1.9)	2 (0.7)	7 (1.3)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Oxygen	5 (1.9)	2 (0.7)	7 (1.3)
MEDICATED DRESSINGS WITH ANTIINFECTIVES	1 (0.4)	0	1 (0.2)
Povidone-Iodine;Sucrose	1 (0.4)	0	1 (0.2)
MELATONIN RECEPTOR AGONISTS	4 (1.5)	3 (1.0)	7 (1.3)
Melatonin	4 (1.5)	3 (1.0)	7 (1.3)
MENINGOCOCCAL VACCINES	0	1 (0.3)	1 (0.2)
Meningococcal Vaccine B	0	1 (0.3)	1 (0.2)
Meningococcal Vaccine Polysacch	0	1 (0.3)	1 (0.2)
METHYLDOPA	0	1 (0.3)	1 (0.2)
Methyldopa	0	1 (0.3)	1 (0.2)
MINERAL SUPPLEMENTS	2 (0.8)	0	2 (0.4)
Magnesium Citrate;Magnesium Gluconate;Magnesium Lactate;Potassium Citrate	1 (0.4)	0	1 (0.2)
Minerals Nos	1 (0.4)	0	1 (0.2)
MONOCLONAL ANTIBODIES	2 (0.8)	0	2 (0.4)
Nivolumab	1 (0.4)	0	1 (0.2)
Pembrolizumab	1 (0.4)	0	1 (0.2)
MUCOLYTICS	22 (8.3)	14 (4.8)	36 (6.4)
Acetylcysteine	7 (2.6)	5 (1.7)	12 (2.1)
Acetylcysteine;Ascorbic Acid	1 (0.4)	0	1 (0.2)
Acetylcysteine;Lactoferrin;Resveratrol	1 (0.4)	0	1 (0.2)
Ambroxol	2 (0.8)	1 (0.3)	3 (0.5)
Ambroxol Hydrochloride	4 (1.5)	2 (0.7)	6 (1.1)
Bromhexine Hydrochloride	3 (1.1)	2 (0.7)	5 (0.9)
Carbocisteine	3 (1.1)	3 (1.0)	6 (1.1)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Erdosteine	1 (0.4)	3 (1.0)	4 (0.7)
L-Carbocisteine	3 (1.1)	0	3 (0.5)
MULTIVITAMINS WITH MINERALS	4 (1.5)	3 (1.0)	7 (1.3)
Ascorbic Acid;Betacarotene;Biotin;Calcium Carbonate;Calcium Pantothenate;Calcium Phosphate;Calcium Phosphate Dibasic;Chromic Chloride;Cupric Oxide;Cyanocobalamin;Dl-Alpha Tocopheryl Acetate;Ergocalciferol;Ferrous Fumarate;Folic Acid;Magnesium Oxide;Manganese Sulfate;Nicotinamide;Phytomenadione;Potassium Iodide;Potassium Sulfate;Pyridoxine Hydrochloride;Retinol Acetate;Riboflavin;Thiamine Mononitrate;Zinc Oxide	1 (0.4)	0	1 (0.2)
Ascorbic Acid;Betacarotene;Biotin;Calcium;Chromium;Copper;Folic Acid;Iodine;Iron;Magnesium;Manganese;Molybdenum;Nicotinic Acid;Pantothenic Acid;Phosphorus;Pyridoxine Hydrochloride;Retinol;Riboflavin;Selenium;Thiamine;Vitamin B12 Nos;Vitamin D Nos;Vitamin E Nos;Vitamin K Nos;Zinc	1 (0.4)	0	1 (0.2)
Ascorbic Acid;Biotin;Calcium Pantothenate;Choline Bitartrate;Colecalciferol;Folic Acid;Inositol;Potassium Iodide;Pyridoxine Hydrochloride;Retinol Acetate;Sodium Selenate;Tocopheryl Acetate;Vitamin B12nos;Zinc Sulfate	1 (0.4)	0	1 (0.2)
Ascorbic Acid;Biotin;Calcium;Calcium Pantothenate;Colecalciferol;Copper;Folic Acid;Iron;Magnesium;Manganese;Nicotinamide;Phosphorus;Pyridoxine Hydrochloride;Retinol;Riboflavin;Vitamin B1 Nos;Vitamin B12 Nos;Vitamin E Nos;Zinc	0	1 (0.3)	1 (0.2)
Ascorbic Acid;Calcium;Minerals Nos;Retinol;Tocopheryl Acetate;Vitamin B Nos;Vitamins Nos;Zinc	1 (0.4)	0	1 (0.2)
Calcium Carbonate;Vitamin D Nos	0	1 (0.3)	1 (0.2)
Minerals Nos;Vitamins Nos	0	1 (0.3)	1 (0.2)
MULTIVITAMINS, OTHER COMBINATIONS	1 (0.4)	1 (0.3)	2 (0.4)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Ascorbic Acid;Betacarotene;Biotin;Calcium Carbonate;Calcium Pantothenate;Calcium Phosphate Dibasic;Chromic Chloride;Colecalciferol;Copper Sulfate;Cyanocobalamin;Ferrous Fumarate;Folic Acid;Magnesium Oxide;Manganese Sulfate;Nicotinamide;Phytomenadione;Potassium Iodide;Pyridoxine Hydrochloride;Retinol Acetate;Riboflavin;Sodium Molybdate;Sodium Selenate;Thiamine Mononitrate;Tocopheryl Acetate;Zinc Oxide	1 (0.4)	1 (0.3)	2 (0.4)
MULTIVITAMINS, PLAIN	13 (4.9)	7 (2.4)	20 (3.6)
Ascorbic Acid;Biotin;Colecalciferol;Cyanocobalamin;Folic Acid;Nicotinamide;Panthenol;Phytomenadione;Pyridoxine Hydrochloride;Retinol;Riboflavin Sodium Phosphate;Thiamine Hydrochloride;Tocopheryl Acetate	0	1 (0.3)	1 (0.2)
Ascorbic Acid;Biotin;Cyanocobalamin;Ergocalciferol;Folic Acid;Nicotinamide;Panthenol;Phytomenadione;Pyridoxine Hydrochloride;Retinol Palmitate;Riboflavin Sodium Phosphate;Thiamine Hydrochloride;Tocopheryl Acetate	1 (0.4)	0	1 (0.2)
Vitamins Nos	12 (4.5)	6 (2.0)	18 (3.2)
NATURAL OPIUM ALKALOIDS	23 (8.6)	42 (14.3)	65 (11.6)
Codeine	0	4 (1.4)	4 (0.7)
Codeine Phosphate	1 (0.4)	5 (1.7)	6 (1.1)
Hydrocodone	0	2 (0.7)	2 (0.4)
Hydromorphone	1 (0.4)	2 (0.7)	3 (0.5)
Hydromorphone Hydrochloride	1 (0.4)	5 (1.7)	6 (1.1)
Morphine	3 (1.1)	7 (2.4)	10 (1.8)
Morphine Hydrochloride	2 (0.8)	2 (0.7)	4 (0.7)
Morphine Sulfate	5 (1.9)	6 (2.0)	11 (2.0)
Naloxone Hydrochloride;Oxycodone Hydrochloride	2 (0.8)	5 (1.7)	7 (1.3)
Naloxone;Oxycodone	0	1 (0.3)	1 (0.2)
Oxycodone	4 (1.5)	8 (2.7)	12 (2.1)
Oxycodone Hydrochloride	13 (4.9)	10 (3.4)	23 (4.1)
Oxycodone Hydrochloride Trihydrate	0	1 (0.3)	1 (0.2)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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NEURAMINIDASE INHIBITORS	2 (0.8)	6 (2.0)	8 (1.4)
Laninamivir Octanoate Monohydrate	0	1 (0.3)	1 (0.2)
Oseltamivir	0	2 (0.7)	2 (0.4)
Oseltamivir Phosphate	2 (0.8)	3 (1.0)	5 (0.9)
NICOTINIC ACID AND DERIVATIVES	0	1 (0.3)	1 (0.2)
Tocopheryl Nicotinate	0	1 (0.3)	1 (0.2)
NITROFURAN DERIVATIVES	6 (2.3)	4 (1.4)	10 (1.8)
Nitrofurantoin	6 (2.3)	4 (1.4)	10 (1.8)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	2 (0.8)	3 (1.0)	5 (0.9)
Amitriptyline	1 (0.4)	2 (0.7)	3 (0.5)
Amitriptyline Hydrochloride	0	1 (0.3)	1 (0.2)
Nortriptyline Hydrochloride	1 (0.4)	0	1 (0.2)
NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS	1 (0.4)	0	1 (0.2)
Tenofovir	1 (0.4)	0	1 (0.2)
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	13 (4.9)	6 (2.0)	19 (3.4)
Aciclovir	2 (0.8)	2 (0.7)	4 (0.7)
Famciclovir	2 (0.8)	0	2 (0.4)
Ganciclovir	1 (0.4)	1 (0.3)	2 (0.4)
Remdesivir	3 (1.1)	1 (0.3)	4 (0.7)
Valaciclovir	4 (1.5)	1 (0.3)	5 (0.9)
Valaciclovir Hydrochloride	2 (0.8)	1 (0.3)	3 (0.5)
OPIOID ANESTHETICS	12 (4.5)	14 (4.8)	26 (4.6)
Fentanyl	6 (2.3)	10 (3.4)	16 (2.9)
Fentanyl Citrate	4 (1.5)	3 (1.0)	7 (1.3)

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Remifentanil	2 (0.8)	2 (0.7)	4 (0.7)
Remifentanil Hydrochloride	1 (0.4)	3 (1.0)	4 (0.7)
Sufentanil	1 (0.4)	0	1 (0.2)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	33 (12.4)	33 (11.2)	66 (11.8)
Benfotiamine;Caffeine;Clemastine Fumarate;Dihydrocodeine Phosphate;Methylephedrine Hydrochloride-Dl;Noscapine;Paracetamol;Sulfogaiacol	0	1 (0.3)	1 (0.2)
Caffeine;Codeine Phosphate;Paracetamol	2 (0.8)	6 (2.0)	8 (1.4)
Codeine Phosphate Hemihydrate;Paracetamol	0	1 (0.3)	1 (0.2)
Codeine Phosphate;Ibuprofen;Paracetamol	3 (1.1)	0	3 (0.5)
Codeine Phosphate;Paracetamol	10 (3.8)	8 (2.7)	18 (3.2)
Codeine Phosphate;Paracetamol;Pseudoephedrine Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Codeine;Paracetamol	1 (0.4)	1 (0.3)	2 (0.4)
Hydrocodone Bitartrate;Paracetamol	4 (1.5)	2 (0.7)	6 (1.1)
Hydrocodone;Paracetamol	2 (0.8)	3 (1.0)	5 (0.9)
Paracetamol;Tramadol Hydrochloride	13 (4.9)	12 (4.1)	25 (4.5)
OPIUM ALKALOIDS AND DERIVATIVES	10 (3.8)	6 (2.0)	16 (2.9)
Ammonium Chloride;Chlorphenamine Maleate;Dihydrocodeine Bitartrate;Methylephedrine Hydrochloride-Dl	0	2 (0.7)	2 (0.4)
Cetylpyridinium Chloride;Pholcodine	0	1 (0.3)	1 (0.2)
Codeine	1 (0.4)	1 (0.3)	2 (0.4)
Codeine Phosphate	1 (0.4)	1 (0.3)	2 (0.4)
Dextromethorphan	1 (0.4)	0	1 (0.2)
Dextromethorphan Hydrobromide	1 (0.4)	1 (0.3)	2 (0.4)
Dextromethorphan Hydrobromide Monohydrate	4 (1.5)	1 (0.3)	5 (0.9)
Dextromethorphan;Promethazine	1 (0.4)	0	1 (0.2)
Dihydrocodeine Bitartrate	1 (0.4)	0	1 (0.2)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
OPIUM DERIVATIVES AND EXPECTORANTS	1 (0.4)	2 (0.7)	3 (0.5)
Caffeine;Chlorphenamine Maleate;Dextromethorphan Hydrobromide;Guaifenesin	1 (0.4)	0	1 (0.2)
Codeine Phosphate;Guaifenesin;Pheniramine Maleate	0	1 (0.3)	1 (0.2)
Dextromethorphan Hydrobromide;Guaifenesin	0	1 (0.3)	1 (0.2)
ORAL REHYDRATION SALT FORMULATIONS	3 (1.1)	0	3 (0.5)
Chloride;Citric Acid;Glucose;Potassium;Sodium	2 (0.8)	0	2 (0.4)
Citric Acid;Glucose;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride	1 (0.4)	0	1 (0.2)
ORGANIC NITRATES	7 (2.6)	7 (2.4)	14 (2.5)
Glyceryl Trinitrate	5 (1.9)	6 (2.0)	11 (2.0)
Isosorbide Dinitrate	0	1 (0.3)	1 (0.2)
Isosorbide Mononitrate	2 (0.8)	1 (0.3)	3 (0.5)
ORIPAVINE DERIVATIVES	2 (0.8)	2 (0.7)	4 (0.7)
Buprenorphine	2 (0.8)	2 (0.7)	4 (0.7)
OSMOTICALLY ACTING LAXATIVES	45 (16.9)	29 (9.9)	74 (13.2)
Ascorbic Acid;Macrogol 3350;Potassium Chloride;Sodium Ascorbate;Sodium Chloride;Sodium Sulfate	1 (0.4)	0	1 (0.2)
Ascorbic Acid;Macrogol 4000;Potassium Chloride;Sodium Ascorbate;Sodium Chloride;Sodium Sulfate Anhydrous	1 (0.4)	0	1 (0.2)
Electrolytes Nos;Macrogol	1 (0.4)	0	1 (0.2)
Lactulose	10 (3.8)	7 (2.4)	17 (3.0)
Macrogol	6 (2.3)	7 (2.4)	13 (2.3)
Macrogol 3350	6 (2.3)	2 (0.7)	8 (1.4)
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride	2 (0.8)	1 (0.3)	3 (0.5)
Macrogol;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride	4 (1.5)	3 (1.0)	7 (1.3)
Magnesium Citrate	1 (0.4)	1 (0.3)	2 (0.4)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Magnesium Hydroxide	6 (2.3)	2 (0.7)	8 (1.4)
Magnesium Oxide	10 (3.8)	9 (3.1)	19 (3.4)
Potassium Chloride;Sodium Bicarbonate;Sodium Chloride;Sodium Sulfate Anhydrous	0	1 (0.3)	1 (0.2)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	3 (1.1)	5 (1.7)	8 (1.4)
Aluminium Hydroxide;Diphenhydramine;Lidocaine;Magnesium Hydroxide	0	1 (0.3)	1 (0.2)
Benzydamine Hydrochloride	1 (0.4)	0	1 (0.2)
Other Agents For Local Oral Treatment	0	1 (0.3)	1 (0.2)
Sodium Gualenate Hydrate	2 (0.8)	3 (1.0)	5 (0.9)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	2 (0.8)	1 (0.3)	3 (0.5)
Bismuth Subgallate;Titanium Dioxide	1 (0.4)	0	1 (0.2)
Paraffin, Liquid;Petrolatum;Phenylephrine Hydrochloride	0	1 (0.3)	1 (0.2)
Tribenoside	1 (0.4)	0	1 (0.2)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	5 (1.9)	0	5 (0.9)
Clostridium Butyricum	5 (1.9)	0	5 (0.9)
OTHER AMINOGLYCOSIDES	4 (1.5)	4 (1.4)	8 (1.4)
Amikacin	0	1 (0.3)	1 (0.2)
Amikacin Sulfate	1 (0.4)	0	1 (0.2)
Gentamicin	4 (1.5)	3 (1.0)	7 (1.3)
Gentamicin Sulfate	0	1 (0.3)	1 (0.2)
OTHER ANALGESICS AND ANTIPYRETICS	22 (8.3)	23 (7.8)	45 (8.0)
Amitriptyline	1 (0.4)	0	1 (0.2)
Amitriptyline Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Artemisia Argyi Leaf	0	1 (0.3)	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Cannabidiol	2 (0.8)	1 (0.3)	3 (0.5)
Clonidine	1 (0.4)	0	1 (0.2)
Duloxetine Hydrochloride	0	1 (0.3)	1 (0.2)
Gabapentin	4 (1.5)	7 (2.4)	11 (2.0)
Mirogabalin Besilate	0	4 (1.4)	4 (0.7)
Nefopam Hydrochloride	1 (0.4)	3 (1.0)	4 (0.7)
Other Analgesics And Antipyretics	0	1 (0.3)	1 (0.2)
Pregabalin	13 (4.9)	8 (2.7)	21 (3.8)
OTHER ANTI-DEMENTIA DRUGS	2 (0.8)	1 (0.3)	3 (0.5)
Cistanche Tinctoria;Ginkgo Biloba	0	1 (0.3)	1 (0.2)
Ginkgo Biloba	1 (0.4)	0	1 (0.2)
Memantine	1 (0.4)	0	1 (0.2)
OTHER ANTIANEMIC PREPARATIONS	2 (0.8)	0	2 (0.4)
Epoetin Alfa	2 (0.8)	0	2 (0.4)
OTHER ANTIBACTERIALS	3 (1.1)	4 (1.4)	7 (1.3)
Fosfomycin	1 (0.4)	1 (0.3)	2 (0.4)
Fosfomycin Trometamol	1 (0.4)	1 (0.3)	2 (0.4)
Linezolid	1 (0.4)	2 (0.7)	3 (0.5)
OTHER ANTIBIOTICS FOR TOPICAL USE	14 (5.3)	3 (1.0)	17 (3.0)
Bacitracin Zinc;Gramicidin;Polymyxin B Sulfate	0	1 (0.3)	1 (0.2)
Bacitracin;Neomycin	1 (0.4)	0	1 (0.2)
Bacitracin;Neomycin Sulfate	2 (0.8)	0	2 (0.4)
Bacitracin;Neomycin Sulfate;Polymyxin B Sulfate	1 (0.4)	0	1 (0.2)
Chloramphenicol	1 (0.4)	0	1 (0.2)
Fusidate Sodium	0	1 (0.3)	1 (0.2)
Fusidic Acid	3 (1.1)	0	3 (0.5)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Gentamicin Sulfate	5 (1.9)	2 (0.7)	7 (1.3)
Mupirocin Calcium	1 (0.4)	0	1 (0.2)
OTHER ANTIDEPRESSANTS	3 (1.1)	12 (4.1)	15 (2.7)
Bupropion	0	1 (0.3)	1 (0.2)
Desvenlafaxine	1 (0.4)	0	1 (0.2)
Duloxetine	0	3 (1.0)	3 (0.5)
Duloxetine Hydrochloride	1 (0.4)	2 (0.7)	3 (0.5)
Mirtazapine	0	3 (1.0)	3 (0.5)
Trazodone	1 (0.4)	2 (0.7)	3 (0.5)
Trazodone Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Venlafaxine Hydrochloride	1 (0.4)	2 (0.7)	3 (0.5)
OTHER ANTIDIARRHEALS	3 (1.1)	1 (0.3)	4 (0.7)
Citrus Aurantium Peel;Creosote;Glycyrrhiza Spp. Root;Phellodendron Spp. Bark;Uncaria Gambir Leaf With Twig	0	1 (0.3)	1 (0.2)
Other Antidiarrheals	1 (0.4)	0	1 (0.2)
Racecadotril	2 (0.8)	0	2 (0.4)
OTHER ANTIEMETICS	10 (3.8)	6 (2.0)	16 (2.9)
Cyclizine	1 (0.4)	0	1 (0.2)
Dimenhydrinate	1 (0.4)	2 (0.7)	3 (0.5)
Diphenhydramine Hydrochloride	0	1 (0.3)	1 (0.2)
Hyoscine	0	1 (0.3)	1 (0.2)
Prochlorperazine	3 (1.1)	3 (1.0)	6 (1.1)
Prochlorperazine Maleate	3 (1.1)	0	3 (0.5)
Prochlorperazine Mesilate	1 (0.4)	0	1 (0.2)
Promethazine	1 (0.4)	0	1 (0.2)
OTHER ANTIEPILEPTICS	4 (1.5)	1 (0.3)	5 (0.9)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Lacosamide	1 (0.4)	0	1 (0.2)
Lamotrigine	1 (0.4)	0	1 (0.2)
Levetiracetam	3 (1.1)	1 (0.3)	4 (0.7)
Pregabalin	1 (0.4)	0	1 (0.2)
Topiramate	1 (0.4)	0	1 (0.2)
OTHER ANTIFUNGALS FOR TOPICAL USE	2 (0.8)	2 (0.7)	4 (0.7)
Salicylic Acid;White Soft Paraffin	0	1 (0.3)	1 (0.2)
Terbinafine	1 (0.4)	0	1 (0.2)
Terbinafine Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Urea	0	1 (0.3)	1 (0.2)
OTHER ANTIGLAUCOMA PREPARATIONS	1 (0.4)	0	1 (0.2)
Ripasudil Hydrochloride Dihydrate	1 (0.4)	0	1 (0.2)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	12 (4.5)	19 (6.5)	31 (5.5)
Bepotastine Besilate	1 (0.4)	3 (1.0)	4 (0.7)
Bilastine	0	1 (0.3)	1 (0.2)
Bisulepin Hydrochloride	0	2 (0.7)	2 (0.4)
Desloratadine	3 (1.1)	1 (0.3)	4 (0.7)
Dimenhydrinate;Pyridoxine Hydrochloride	1 (0.4)	0	1 (0.2)
Epinastine Hydrochloride	1 (0.4)	0	1 (0.2)
Fexofenadine	2 (0.8)	1 (0.3)	3 (0.5)
Fexofenadine Hydrochloride	1 (0.4)	6 (2.0)	7 (1.3)
Loratadine	3 (1.1)	5 (1.7)	8 (1.4)
Olopatadine	1 (0.4)	0	1 (0.2)
Olopatadine Hydrochloride	1 (0.4)	0	1 (0.2)
Rupatadine Fumarate	1 (0.4)	1 (0.3)	2 (0.4)
OTHER ANTIINFECTIVES	0	1 (0.3)	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Picloxydine Dihydrochloride	0	1 (0.3)	1 (0.2)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	18 (6.8)	12 (4.1)	30 (5.4)
Benzydamine Hydrochloride	2 (0.8)	0	2 (0.4)
Chondroitin	2 (0.8)	0	2 (0.4)
Chondroitin Sulfate Sodium	0	1 (0.3)	1 (0.2)
Chondroitin;Glucosamine	0	2 (0.7)	2 (0.4)
Clonixin Lysinate	1 (0.4)	0	1 (0.2)
Glucosamine	7 (2.6)	4 (1.4)	11 (2.0)
Glucosamine Sulfate	1 (0.4)	1 (0.3)	2 (0.4)
Glucosamine Sulfate Sodium Chloride	1 (0.4)	0	1 (0.2)
Glycine Max;Persea Americana Extract	1 (0.4)	0	1 (0.2)
Methylsulfonylmethane	0	1 (0.3)	1 (0.2)
Nimesulide	5 (1.9)	3 (1.0)	8 (1.4)
Rabbit Vaccinia Extract	2 (0.8)	0	2 (0.4)
Shark Cartilage	1 (0.4)	0	1 (0.2)
Sulfasalazine	0	1 (0.3)	1 (0.2)
OTHER ANTIINFLAMMATORY/ANTIRHEUMATIC AGENTS IN COMBINATION WITH OTHER DRUGS	0	2 (0.7)	2 (0.4)
Diphenhydramine;Ibuprofen	0	1 (0.3)	1 (0.2)
Other Antiinflammatory/antirheumatic Agents In Combination With Other Drugs	0	1 (0.3)	1 (0.2)
OTHER ANTIMIGRAINE PREPARATIONS	2 (0.8)	2 (0.7)	4 (0.7)
Venlafaxine	2 (0.8)	1 (0.3)	3 (0.5)
Venlafaxine Hydrochloride	0	1 (0.3)	1 (0.2)
OTHER ANTIOBESITY DRUGS	1 (0.4)	0	1 (0.2)
Liraglutide	1 (0.4)	0	1 (0.2)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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OTHER ANTIPRURITICS	1 (0.4)	1 (0.3)	2 (0.4)
Crotamiton	1 (0.4)	0	1 (0.2)
Levomenthol	0	1 (0.3)	1 (0.2)
OTHER ANTIPSORIATICS FOR TOPICAL USE	1 (0.4)	0	1 (0.2)
Maxacalcitol	1 (0.4)	0	1 (0.2)
OTHER ANTIPSYCHOTICS	1 (0.4)	2 (0.7)	3 (0.5)
Perospirone Hydrochloride	1 (0.4)	0	1 (0.2)
Risperidone	0	2 (0.7)	2 (0.4)
OTHER ANTISEPTICS AND DISINFECTANTS	1 (0.4)	1 (0.3)	2 (0.4)
Allantoin;Chlorhexidine Gluconate;Cinchocaine Hydrochloride;Tocopheryl Acetate;Zinc Oxide	0	1 (0.3)	1 (0.2)
Sodium Hypochlorite	1 (0.4)	0	1 (0.2)
OTHER ANTITHROMBOTIC AGENTS	0	1 (0.3)	1 (0.2)
Thrombomodulin Alfa	0	1 (0.3)	1 (0.2)
OTHER ANTIVIRALS	6 (2.3)	4 (1.4)	10 (1.8)
Amenamevir	0	2 (0.7)	2 (0.4)
Bamlanivimab	1 (0.4)	0	1 (0.2)
Casirivimab;Imdevimab	1 (0.4)	0	1 (0.2)
Favipiravir	4 (1.5)	2 (0.7)	6 (1.1)
OTHER ANXIOLYTICS	7 (2.6)	8 (2.7)	15 (2.7)
Duloxetine Hydrochloride	0	1 (0.3)	1 (0.2)
Escitalopram Oxalate	2 (0.8)	1 (0.3)	3 (0.5)
Etifoxine Hydrochloride	0	1 (0.3)	1 (0.2)
Fluoxetine Hydrochloride	0	1 (0.3)	1 (0.2)
Paroxetine	0	2 (0.7)	2 (0.4)

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Pregabalin	1 (0.4)	0	1 (0.2)
Propranolol	1 (0.4)	0	1 (0.2)
Sertraline	1 (0.4)	0	1 (0.2)
Venlafaxine	1 (0.4)	0	1 (0.2)
Venlafaxine Hydrochloride	1 (0.4)	2 (0.7)	3 (0.5)
OTHER BETA-LACTAM ANTIBACTERIALS	1 (0.4)	0	1 (0.2)
Other Beta-Lactam Antibacterials	1 (0.4)	0	1 (0.2)
OTHER BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	1 (0.4)	1 (0.3)	2 (0.4)
Repaglinide	1 (0.4)	1 (0.3)	2 (0.4)
OTHER BLOOD PRODUCTS	2 (0.8)	0	2 (0.4)
Blood Plasma	1 (0.4)	0	1 (0.2)
Blood, Whole	1 (0.4)	0	1 (0.2)
OTHER CAPILLARY STABILIZING AGENTS	1 (0.4)	0	1 (0.2)
Escin	1 (0.4)	0	1 (0.2)
OTHER CARDIAC PREPARATIONS	2 (0.8)	2 (0.7)	4 (0.7)
Adenosine	1 (0.4)	0	1 (0.2)
Trimetazidine Hydrochloride	0	2 (0.7)	2 (0.4)
Ubidecarenone	1 (0.4)	0	1 (0.2)
OTHER CARDIAC STIMULANTS	0	1 (0.3)	1 (0.2)
Atropine Sulfate Monohydrate	0	1 (0.3)	1 (0.2)
OTHER CENTRALLY ACTING AGENTS	13 (4.9)	10 (3.4)	23 (4.1)
Baclofen	1 (0.4)	1 (0.3)	2 (0.4)
Cyclobenzaprine Hydrochloride	0	1 (0.3)	1 (0.2)
Diazepam	2 (0.8)	1 (0.3)	3 (0.5)

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Diclofenac Diethylamine;Thiocolchicoside	2 (0.8)	1 (0.3)	3 (0.5)
Diclofenac Sodium;Thiocolchicoside	1 (0.4)	0	1 (0.2)
Eperisone Hydrochloride	4 (1.5)	3 (1.0)	7 (1.3)
Pridinol	0	1 (0.3)	1 (0.2)
Thiocolchicoside	1 (0.4)	0	1 (0.2)
Tizanidine	1 (0.4)	1 (0.3)	2 (0.4)
Tizanidine Hydrochloride	2 (0.8)	0	2 (0.4)
Tolperisone Hydrochloride	0	1 (0.3)	1 (0.2)
OTHER CICATRIZANTS	1 (0.4)	1 (0.3)	2 (0.4)
Alprostadil	0	1 (0.3)	1 (0.2)
Phenoxyethanol;Triticum Aestivum	1 (0.4)	0	1 (0.2)
OTHER COLD PREPARATIONS	0	1 (0.3)	1 (0.2)
Chlorphenamine Maleate;Paracetamol;Phenylephrine Hydrochloride	0	1 (0.3)	1 (0.2)
OTHER COMBINATIONS OF NUTRIENTS	8 (3.0)	8 (2.7)	16 (2.9)
Carbohydrates Nos;Fatty Acids Nos;Fibre Soluble;Minerals Nos;Proteins Nos	1 (0.4)	0	1 (0.2)
Fish Oil	7 (2.6)	7 (2.4)	14 (2.5)
Other Combinations Of Nutrients	0	1 (0.3)	1 (0.2)
OTHER COUGH SUPPRESSANTS	4 (1.5)	6 (2.0)	10 (1.8)
Benzonatate	2 (0.8)	2 (0.7)	4 (0.7)
Butamirate Citrate	1 (0.4)	0	1 (0.2)
Glycyrrhiza Spp. Root;Ophiopogon Japonicus Tuber;Oryza Sativa Fruit;Panax Ginseng Root;Pinellia Ternata Tuber;Ziziphus Jujuba Fruit	0	1 (0.3)	1 (0.2)
Levodropropizine	1 (0.4)	2 (0.7)	3 (0.5)
Tipepidine Hibenzate	0	1 (0.3)	1 (0.2)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
OTHER DERMATOLOGICALS	3 (1.1)	3 (1.0)	6 (1.1)
Ascorbic Acid;Bromelains;Escin;Nicotinamide;Vaccinium Myrtillus	0	1 (0.3)	1 (0.2)
Guaiazulene	3 (1.1)	2 (0.7)	5 (0.9)
OTHER DIAGNOSTIC AGENTS	1 (0.4)	0	1 (0.2)
Pralmorelin Dihydrochloride	1 (0.4)	0	1 (0.2)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	45 (16.9)	43 (14.6)	88 (15.7)
Denosumab	45 (16.9)	42 (14.3)	87 (15.5)
Other Drugs Affecting Bone Structure And Mineralization	1 (0.4)	0	1 (0.2)
Romosozumab	0	1 (0.3)	1 (0.2)
OTHER DRUGS FOR BILE THERAPY	1 (0.4)	1 (0.3)	2 (0.4)
Fenipentol	1 (0.4)	1 (0.3)	2 (0.4)
OTHER DRUGS FOR CONSTIPATION	4 (1.5)	5 (1.7)	9 (1.6)
Glycyrrhiza Spp. Root;Rheum Spp. Rhizome	0	1 (0.3)	1 (0.2)
Linaclotide	1 (0.4)	2 (0.7)	3 (0.5)
Lubiprostone	1 (0.4)	1 (0.3)	2 (0.4)
Panax Ginseng Root;Zanthoxylum Piperitum Pericarp;Zingiber Officinale Processed Rhizome	2 (0.8)	1 (0.3)	3 (0.5)
Potassium Chloride;Sodium Bicarbonate;Sodium Sulfate	0	1 (0.3)	1 (0.2)
Sodium Bicarbonate;Sodium Phosphate Monobasic (anhydrous)	0	1 (0.3)	1 (0.2)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	2 (0.8)	0	2 (0.4)
Chondroitin Sulfate Sodium;Hyaluronate Sodium	1 (0.4)	0	1 (0.2)
Hyaluronate Sodium	1 (0.4)	0	1 (0.2)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	8 (3.0)	11 (3.7)	19 (3.4)
Alverine Citrate;Simeticone	0	1 (0.3)	1 (0.2)
Dimeticone	4 (1.5)	5 (1.7)	9 (1.6)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Phloroglucinol	2 (0.8)	1 (0.3)	3 (0.5)
Simeticone	2 (0.8)	5 (1.7)	7 (1.3)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	22 (8.3)	16 (5.4)	38 (6.8)
Alginic Acid;Aluminium Hydroxide;Sodium Bicarbonate	1 (0.4)	0	1 (0.2)
Althaea Officinalis;Dexpanthenol;Magnesium Alginate;Papaver Rhoeas;Simeticone;Sodium Bicarbonate;Zinc Oxide	0	1 (0.3)	1 (0.2)
Bismuth Subsalicylate	0	1 (0.3)	1 (0.2)
Calcium Carbonate;Potassium Bicarbonate;Sodium Alginate	1 (0.4)	0	1 (0.2)
Calcium Carbonate;Sodium Alginate	0	1 (0.3)	1 (0.2)
Calcium Carbonate;Sodium Alginate;Sodium Bicarbonate	2 (0.8)	1 (0.3)	3 (0.5)
Irsogladine Maleate	0	1 (0.3)	1 (0.2)
Levoglutamide;Sodium Gualenate Hydrate	1 (0.4)	0	1 (0.2)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (gord)	1 (0.4)	2 (0.7)	3 (0.5)
Polaprezinc	1 (0.4)	0	1 (0.2)
Ranitidine Hydrochloride;Sucralfate;Tripotassium Dicitratobismuthate	1 (0.4)	0	1 (0.2)
Rebamipide	14 (5.3)	7 (2.4)	21 (3.8)
Sodium Alginate	3 (1.1)	0	3 (0.5)
Sucralfate	2 (0.8)	2 (0.7)	4 (0.7)
OTHER DRUGS FOR TREATMENT OF TUBERCULOSIS	0	1 (0.3)	1 (0.2)
Ethambutol Dihydrochloride	0	1 (0.3)	1 (0.2)
Pyrazinamide	0	1 (0.3)	1 (0.2)
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	0	2 (0.7)	2 (0.4)
Alanine;Glutamic Acid;Glycine;Prunus Africana	0	1 (0.3)	1 (0.2)
Tadalafil	0	1 (0.3)	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
OTHER ECTOPARASITICIDES, INCL. SCABICIDES	1 (0.4)	0	1 (0.2)
Dimeticone	1 (0.4)	0	1 (0.2)
OTHER EMOLLIENTS AND PROTECTIVES	16 (6.0)	5 (1.7)	21 (3.8)
Ammonium Lactate	1 (0.4)	0	1 (0.2)
Heparinoid	8 (3.0)	4 (1.4)	12 (2.1)
Ichthammol	1 (0.4)	0	1 (0.2)
Mucopolysaccharide Polysulfuric Acid Ester	6 (2.3)	1 (0.3)	7 (1.3)
Other Emollients And Protectives	1 (0.4)	0	1 (0.2)
OTHER GENERAL ANESTHETICS	5 (1.9)	9 (3.1)	14 (2.5)
Ketamine Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Propofol	5 (1.9)	9 (3.1)	14 (2.5)
OTHER HORMONE ANTAGONISTS AND RELATED AGENTS	14 (5.3)	17 (5.8)	31 (5.5)
Abiraterone Acetate	0	1 (0.3)	1 (0.2)
Degarelix	1 (0.4)	0	1 (0.2)
Degarelix Acetate	13 (4.9)	16 (5.4)	29 (5.2)
OTHER HYPNOTICS AND SEDATIVES	3 (1.1)	6 (2.0)	9 (1.6)
Dexmedetomidine Hydrochloride	0	4 (1.4)	4 (0.7)
Diphenhydramine Hydrochloride	0	1 (0.3)	1 (0.2)
Suvorexant	3 (1.1)	1 (0.3)	4 (0.7)
OTHER IMMUNOSTIMULANTS	0	1 (0.3)	1 (0.2)
Andrographis Paniculata;Curcuma Longa;Echinacea Purpurea;Eleutherococcus Senticosus;Retinol Acetate;Zinc Sulfate Monohydrate	0	1 (0.3)	1 (0.2)
OTHER IMMUNOSUPPRESSANTS	0	1 (0.3)	1 (0.2)
Hydroxychloroquine Sulfate	0	1 (0.3)	1 (0.2)
Methotrexate	0	1 (0.3)	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
OTHER INTESTINAL ADSORBENTS	2 (0.8)	0	2 (0.4)
Diosmectite	2 (0.8)	0	2 (0.4)
OTHER INTESTINAL ANTIINFECTIVES	2 (0.8)	0	2 (0.4)
Chloroxine	2 (0.8)	0	2 (0.4)
OTHER IRRIGATING SOLUTIONS	0	1 (0.3)	1 (0.2)
Mannitol;Sorbitol	0	1 (0.3)	1 (0.2)
OTHER LIPID MODIFYING AGENTS	16 (6.0)	6 (2.0)	22 (3.9)
Astaxanthin;Berberine;Folic Acid;Monascus Purpureus;Policosanol;Ubidecarenone	1 (0.4)	0	1 (0.2)
Eicosapentaenoic Acid Ethyl Ester	0	1 (0.3)	1 (0.2)
Ezetimibe	5 (1.9)	2 (0.7)	7 (1.3)
Fish Oil;Vitamin D Nos	1 (0.4)	0	1 (0.2)
Omega-3 Triglycerides	1 (0.4)	0	1 (0.2)
Omega-3-Acid Ethyl Ester	5 (1.9)	3 (1.0)	8 (1.4)
Probucol	1 (0.4)	0	1 (0.2)
Salmon Oil	2 (0.8)	0	2 (0.4)
OTHER MINERAL PRODUCTS	3 (1.1)	4 (1.4)	7 (1.3)
Boron Citrate;Calcium Citrate;Colecalciferol;Magnesium Oxide;Phytomenadione;Strontium Citrate	0	2 (0.7)	2 (0.4)
Herbal Nos;Minerals Nos	0	1 (0.3)	1 (0.2)
Phosphoric Acid Sodium;Sodium Phosphate Dibasic	1 (0.4)	0	1 (0.2)
Potassium Phosphate Dibasic;Potassium Phosphate Monobasic;Sodium Phosphate Dibasic;Sodium Phosphate Monobasic	1 (0.4)	0	1 (0.2)
Potassium Phosphate Monobasic;Sodium Phosphate Dibasic;Sodium Phosphate Monobasic (anhydrous)	0	1 (0.3)	1 (0.2)
Sodium Phosphate	1 (0.4)	0	1 (0.2)
Sodium Phosphate Monobasic (anhydrous)	1 (0.4)	0	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
OTHER MINERAL SUPPLEMENTS	1 (0.4)	0	1 (0.2)
Citric Acid;Magnesium Citrate;Sodium Citrate	1 (0.4)	0	1 (0.2)
OTHER NASAL PREPARATIONS	2 (0.8)	3 (1.0)	5 (0.9)
Acetylcysteine	0	1 (0.3)	1 (0.2)
Ipratropium Bromide	1 (0.4)	0	1 (0.2)
Other Nasal Preparations	0	1 (0.3)	1 (0.2)
Sodium Chloride	1 (0.4)	1 (0.3)	2 (0.4)
OTHER NERVOUS SYSTEM DRUGS	0	3 (1.0)	3 (0.5)
Edaravone	0	1 (0.3)	1 (0.2)
Propranolol Hydrochloride	0	1 (0.3)	1 (0.2)
Thioctic Acid	0	1 (0.3)	1 (0.2)
OTHER NUTRIENTS	2 (0.8)	0	2 (0.4)
Other Nutrients	2 (0.8)	0	2 (0.4)
OTHER OPHTHALMOLOGICALS	8 (3.0)	11 (3.7)	19 (3.4)
Allantoin;Chamaemelum Nobile;Dexpanthenol;Melaleuca Alternifolia;Taurine	0	1 (0.3)	1 (0.2)
Ascorbic Acid;Copper Citrate;Tocopheryl Acetate;Xantofyl;Zeaxanthin;Zinc Oxide	0	1 (0.3)	1 (0.2)
Calcium Chloride Dihydrate;Cyanocobalamin;Hyaluronic Acid;Macrogol;Magnesium Chloride;Potassium Chloride	0	1 (0.3)	1 (0.2)
Carbomer	1 (0.4)	0	1 (0.2)
Cetalkonium Chloride;Glycerol;Poloxalcol;Trometamol;Tyloxapol	0	1 (0.3)	1 (0.2)
Chlorphenamine Maleate;Neostigmine Metilsulfate;Potassium Aspartate;Pyridoxine Hydrochloride;Retinol Palmitate;Tetryzoline Hydrochloride;Tocopheryl Acetate	1 (0.4)	0	1 (0.2)
Cyanocobalamin	0	1 (0.3)	1 (0.2)
Dexpanthenol	0	1 (0.3)	1 (0.2)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Diquafosol Tetrasodium	3 (1.1)	1 (0.3)	4 (0.7)
Glycerol;Hypromellose;Macrogol	0	1 (0.3)	1 (0.2)
Hyaluronate Sodium	3 (1.1)	2 (0.7)	5 (0.9)
Hypromellose	2 (0.8)	1 (0.3)	3 (0.5)
Other Ophthalmologicals	1 (0.4)	0	1 (0.2)
Pirenoxine	1 (0.4)	2 (0.7)	3 (0.5)
Pirenoxine Sodium	0	1 (0.3)	1 (0.2)
OTHER OPIOIDS	34 (12.8)	24 (8.2)	58 (10.4)
Naloxone Hydrochloride;Tilidine Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Tapentadol	3 (1.1)	0	3 (0.5)
Tapentadol Hydrochloride	3 (1.1)	1 (0.3)	4 (0.7)
Tramadol	17 (6.4)	13 (4.4)	30 (5.4)
Tramadol Hydrochloride	15 (5.6)	10 (3.4)	25 (4.5)
OTHER PARASYMPATHOMIMETICS	5 (1.9)	3 (1.0)	8 (1.4)
Choline Alfoscerate	5 (1.9)	3 (1.0)	8 (1.4)
Pilocarpine Hydrochloride	2 (0.8)	2 (0.7)	4 (0.7)
OTHER PERIPHERAL VASODILATORS	1 (0.4)	1 (0.3)	2 (0.4)
Coumarin;Proxyphylline	1 (0.4)	0	1 (0.2)
Naftidrofuryl Oxalate	0	1 (0.3)	1 (0.2)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	0	2 (0.7)	2 (0.4)
Acetylcarnitine Hydrochloride	0	1 (0.3)	1 (0.2)
Piracetam	0	1 (0.3)	1 (0.2)
OTHER QUATERNARY AMMONIUM COMPOUNDS	5 (1.9)	8 (2.7)	13 (2.3)
Gallamine Triethiodide	0	1 (0.3)	1 (0.2)
Rocuronium	1 (0.4)	0	1 (0.2)

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Rocuronium Bromide	4 (1.5)	7 (2.4)	11 (2.0)
OTHER RESPIRATORY SYSTEM PRODUCTS	0	1 (0.3)	1 (0.2)
Other Respiratory System Products	0	1 (0.3)	1 (0.2)
OTHER SYSTEMIC HEMOSTATICS	6 (2.3)	1 (0.3)	7 (1.3)
Batroxobin	1 (0.4)	0	1 (0.2)
Carbazochrome	1 (0.4)	0	1 (0.2)
Carbazochrome Sodium Sulfonate	3 (1.1)	0	3 (0.5)
Etamsilate	1 (0.4)	1 (0.3)	2 (0.4)
OTHER THERAPEUTIC PRODUCTS	1 (0.4)	1 (0.3)	2 (0.4)
Arsenic	1 (0.4)	0	1 (0.2)
Water	0	1 (0.3)	1 (0.2)
OTHER THROAT PREPARATIONS	1 (0.4)	0	1 (0.2)
Benzydamine	1 (0.4)	0	1 (0.2)
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	3 (1.1)	3 (1.0)	6 (1.1)
Achillea Millefolium;Aconitum Napellus;Arnica Montana;Atropa Belladonna;Bellis Perennis;Calcium Sulfide;Calendula Officinalis;Echinacea Angustifolia;Echinacea Purpurea;Hamamelis Virginiana;Hypericum Perforatum;Matricaria Recutita;Mercurius Solubilis Hahnemanni;Symphytum Officinale	1 (0.4)	0	1 (0.2)
Benzyl Nicotinate	0	1 (0.3)	1 (0.2)
Camphor	1 (0.4)	0	1 (0.2)
Camphor;Eucalyptus Globulus Oil;Mentha X Piperita Oil;Menthol;Methyl Salicylate;Pinus Mugo Oil;Pinus Pinaster Oil	0	1 (0.3)	1 (0.2)
Heparinoid	1 (0.4)	0	1 (0.2)
Other Topical Products For Joint And Muscular Pain	0	1 (0.3)	1 (0.2)
OTHER UROLOGICALS	2 (0.8)	1 (0.3)	3 (0.5)
Citric Acid;Sodium Bicarbonate;Sodium Citrate;Tartaric Acid	1 (0.4)	0	1 (0.2)

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Escherichia Coli	0	1 (0.3)	1 (0.2)
Pentosan Polysulfate Sodium	1 (0.4)	1 (0.3)	2 (0.4)
OTHER VASODILATORS USED IN CARDIAC DISEASES	1 (0.4)	3 (1.0)	4 (0.7)
Nicorandil	1 (0.4)	1 (0.3)	2 (0.4)
Sacubitril	0	1 (0.3)	1 (0.2)
Treprostinil	0	1 (0.3)	1 (0.2)
OTHER VIRAL VACCINES	99 (37.2)	73 (24.8)	172 (30.7)
Covid-19 Vaccine	4 (1.5)	7 (2.4)	11 (2.0)
Covid-19 Vaccine Inact (vero) Cz02	18 (6.8)	17 (5.8)	35 (6.3)
Covid-19 Vaccine Mrna	6 (2.3)	1 (0.3)	7 (1.3)
Covid-19 Vaccine Nrvv Ad (chadox1 Ncov-19)	27 (10.2)	11 (3.7)	38 (6.8)
Elasomeran	17 (6.4)	11 (3.7)	28 (5.0)
Tozinameran	49 (18.4)	45 (15.3)	94 (16.8)
OXICAMS	4 (1.5)	5 (1.7)	9 (1.6)
Meloxicam	4 (1.5)	4 (1.4)	8 (1.4)
Piroxicam Betadex	0	1 (0.3)	1 (0.2)
PAPAVERINE AND DERIVATIVES	0	2 (0.7)	2 (0.4)
Drotaverine Hydrochloride	0	2 (0.7)	2 (0.4)
PARAMAGNETIC CONTRAST MEDIA	1 (0.4)	0	1 (0.2)
Gadobutrol	1 (0.4)	0	1 (0.2)
PARASYMPATHOMIMETICS	1 (0.4)	2 (0.7)	3 (0.5)
Pilocarpine	1 (0.4)	0	1 (0.2)
Pilocarpine Hydrochloride	0	2 (0.7)	2 (0.4)
PARATHYROID HORMONES AND ANALOGUES	2 (0.8)	0	2 (0.4)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Teriparatide	1 (0.4)	0	1 (0.2)
Teriparatide Acetate	1 (0.4)	0	1 (0.2)
PENICILLINS WITH EXTENDED SPECTRUM	27 (10.2)	27 (9.2)	54 (9.6)
Amoxicillin	17 (6.4)	14 (4.8)	31 (5.5)
Amoxicillin Trihydrate	8 (3.0)	10 (3.4)	18 (3.2)
Ampicillin	1 (0.4)	2 (0.7)	3 (0.5)
Ampicillin Sodium	2 (0.8)	1 (0.3)	3 (0.5)
Piperacillin	3 (1.1)	0	3 (0.5)
Piperacillin Sodium	0	1 (0.3)	1 (0.2)
PERCHLORATES	0	1 (0.3)	1 (0.2)
Sodium Perchlorate	0	1 (0.3)	1 (0.2)
PERIPHERAL OPIOID RECEPTOR ANTAGONISTS	0	2 (0.7)	2 (0.4)
Naldemedine Tosilate	0	1 (0.3)	1 (0.2)
Naloxegol	0	1 (0.3)	1 (0.2)
PERTUSSIS VACCINES	1 (0.4)	1 (0.3)	2 (0.4)
Diphtheria Vaccine Toxoid;Pertussis Vaccine Acellular 3-Component;Tetanus Vaccine Toxoid	1 (0.4)	0	1 (0.2)
Diphtheria Vaccine;Pertussis Vaccine;Tetanus Vaccine	0	1 (0.3)	1 (0.2)
PHENOTHIAZINES WITH PIPERAZINE STRUCTURE	1 (0.4)	0	1 (0.2)
Prochlorperazine	1 (0.4)	0	1 (0.2)
PHENYLALKYLAMINE DERIVATIVES	2 (0.8)	0	2 (0.4)
Verapamil Hydrochloride	2 (0.8)	0	2 (0.4)
PHENYLPIPERIDINE DERIVATIVES	16 (6.0)	9 (3.1)	25 (4.5)
Fentanyl	12 (4.5)	6 (2.0)	18 (3.2)
Fentanyl Citrate	1 (0.4)	0	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Pethidine	1 (0.4)	2 (0.7)	3 (0.5)
Pethidine Hydrochloride	4 (1.5)	1 (0.3)	5 (0.9)
PIPERAZINE DERIVATIVES	5 (1.9)	10 (3.4)	15 (2.7)
Cetirizine	1 (0.4)	5 (1.7)	6 (1.1)
Cetirizine Hydrochloride	2 (0.8)	4 (1.4)	6 (1.1)
Levocetirizine Dihydrochloride	2 (0.8)	1 (0.3)	3 (0.5)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	53 (19.9)	54 (18.4)	107 (19.1)
Acetylsalicylate Lysine	1 (0.4)	2 (0.7)	3 (0.5)
Acetylsalicylic Acid	42 (15.8)	42 (14.3)	84 (15.0)
Acetylsalicylic Acid;Dipyridamole	1 (0.4)	0	1 (0.2)
Acetylsalicylic Acid;Glycine	2 (0.8)	1 (0.3)	3 (0.5)
Cilostazol	2 (0.8)	1 (0.3)	3 (0.5)
Cilostazol;Ginkgo Biloba	1 (0.4)	0	1 (0.2)
Clopidogrel	5 (1.9)	8 (2.7)	13 (2.3)
Clopidogrel Bisulfate	10 (3.8)	5 (1.7)	15 (2.7)
Clopidogrel Hydrochloride	0	1 (0.3)	1 (0.2)
Clopidogrel Resinate	3 (1.1)	0	3 (0.5)
Dipyridamole	0	1 (0.3)	1 (0.2)
Prasugrel Hydrochloride	0	1 (0.3)	1 (0.2)
Sarpogrelate Hydrochloride	1 (0.4)	0	1 (0.2)
Ticagrelor	1 (0.4)	3 (1.0)	4 (0.7)
Triflusal	1 (0.4)	0	1 (0.2)
PNEUMOCOCCAL VACCINES	6 (2.3)	8 (2.7)	14 (2.5)
Pneumococcal Vaccine	4 (1.5)	2 (0.7)	6 (1.1)
Pneumococcal Vaccine Conj 13v (crm197)	0	2 (0.7)	2 (0.4)
Pneumococcal Vaccine Polysacch 23v	2 (0.8)	4 (1.4)	6 (1.1)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
POTASSIUM	26 (9.8)	16 (5.4)	42 (7.5)
Ascorbic Acid;Potassium Bicarbonate	1 (0.4)	0	1 (0.2)
Potassium	3 (1.1)	0	3 (0.5)
Potassium Aspartate	2 (0.8)	0	2 (0.4)
Potassium Bicarbonate	0	1 (0.3)	1 (0.2)
Potassium Bicarbonate;Potassium Chloride	2 (0.8)	1 (0.3)	3 (0.5)
Potassium Chloride	19 (7.1)	13 (4.4)	32 (5.7)
Potassium Gluconate	1 (0.4)	1 (0.3)	2 (0.4)
PREGNADIEN DERIVATIVES	1 (0.4)	0	1 (0.2)
Megestrol Acetate	1 (0.4)	0	1 (0.2)
PREGNEN (4) DERIVATIVES	0	2 (0.7)	2 (0.4)
Medroxyprogesterone Acetate	0	2 (0.7)	2 (0.4)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	1 (0.4)	1 (0.3)	2 (0.4)
Povidone-Iodine;Sucrose	1 (0.4)	1 (0.3)	2 (0.4)
PREPARATIONS INCREASING URIC ACID EXCRETION	1 (0.4)	0	1 (0.2)
Benzbromarone	1 (0.4)	0	1 (0.2)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	15 (5.6)	12 (4.1)	27 (4.8)
Allopurinol	11 (4.1)	9 (3.1)	20 (3.6)
Febuxostat	4 (1.5)	3 (1.0)	7 (1.3)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM	2 (0.8)	2 (0.7)	4 (0.7)
Colchicine	2 (0.8)	2 (0.7)	4 (0.7)
PREPARATIONS WITH SALICYLIC ACID DERIVATIVES	1 (0.4)	2 (0.7)	3 (0.5)
Glycol Salicylate	0	1 (0.3)	1 (0.2)
Menthol;Methyl Salicylate	0	1 (0.3)	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Methyl Salicylate	1 (0.4)	0	1 (0.2)
PROPIONIC ACID DERIVATIVES	77 (28.9)	72 (24.5)	149 (26.6)
Apronal;Caffeine;Ibuprofen;Magnesium Oxide	1 (0.4)	0	1 (0.2)
Dexibuprofen	1 (0.4)	0	1 (0.2)
Dexketoprofen	1 (0.4)	0	1 (0.2)
Dexketoprofen Trometamol	3 (1.1)	5 (1.7)	8 (1.4)
Esomeprazole Magnesium Dihydrate;Naproxen	1 (0.4)	0	1 (0.2)
Esomeprazole Magnesium;Naproxen	3 (1.1)	0	3 (0.5)
Esomeprazole;Naproxen	1 (0.4)	0	1 (0.2)
Flurbiprofen	1 (0.4)	1 (0.3)	2 (0.4)
Flurbiprofen Axetil	1 (0.4)	2 (0.7)	3 (0.5)
Hydrocodone;Ibuprofen	0	1 (0.3)	1 (0.2)
Ibuprofen	36 (13.5)	43 (14.6)	79 (14.1)
Ibuprofen Arginine	1 (0.4)	0	1 (0.2)
Ketoprofen	7 (2.6)	3 (1.0)	10 (1.8)
Loxoprofen	3 (1.1)	2 (0.7)	5 (0.9)
Loxoprofen Sodium	3 (1.1)	3 (1.0)	6 (1.1)
Loxoprofen Sodium Dihydrate	13 (4.9)	9 (3.1)	22 (3.9)
Naproxen	7 (2.6)	6 (2.0)	13 (2.3)
Naproxen Sodium	6 (2.3)	4 (1.4)	10 (1.8)
Pelubiprofen	4 (1.5)	2 (0.7)	6 (1.1)
Zaltoprofen	2 (0.8)	0	2 (0.4)
PROPULSIVES	49 (18.4)	24 (8.2)	73 (13.0)
Domperidone	7 (2.6)	3 (1.0)	10 (1.8)
Itopride Hydrochloride	1 (0.4)	0	1 (0.2)
Levosulpiride	0	1 (0.3)	1 (0.2)
Metoclopramide	24 (9.0)	11 (3.7)	35 (6.3)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Metoclopramide Hydrochloride	14 (5.3)	9 (3.1)	23 (4.1)
Mosapride Citrate	6 (2.3)	1 (0.3)	7 (1.3)
PROSTAGLANDIN ANALOGUES	4 (1.5)	5 (1.7)	9 (1.6)
Bimatoprost	1 (0.4)	1 (0.3)	2 (0.4)
Latanoprost	3 (1.1)	4 (1.4)	7 (1.3)
Latanoprostene Bunod	0	1 (0.3)	1 (0.2)
Unoprostone Isopropyl	0	1 (0.3)	1 (0.2)
PROSTAGLANDINS	2 (0.8)	1 (0.3)	3 (0.5)
Dinoprostone	1 (0.4)	0	1 (0.2)
Limaprost	0	1 (0.3)	1 (0.2)
Limaprost Alfadex	1 (0.4)	0	1 (0.2)
PROTEINASE INHIBITORS	1 (0.4)	0	1 (0.2)
Ulinastatin	1 (0.4)	0	1 (0.2)
PROTON PUMP INHIBITORS	105 (39.5)	107 (36.4)	212 (37.9)
Dexlansoprazole	1 (0.4)	1 (0.3)	2 (0.4)
Esomeprazole	6 (2.3)	6 (2.0)	12 (2.1)
Esomeprazole Magnesium	2 (0.8)	7 (2.4)	9 (1.6)
Esomeprazole Magnesium Dihydrate	2 (0.8)	0	2 (0.4)
Esomeprazole Magnesium Trihydrate	0	1 (0.3)	1 (0.2)
Esomeprazole Sodium	1 (0.4)	0	1 (0.2)
Ilaprazole	1 (0.4)	2 (0.7)	3 (0.5)
Lansoprazole	21 (7.9)	19 (6.5)	40 (7.1)
Omeprazole	31 (11.7)	27 (9.2)	58 (10.4)
Omeprazole Sodium	2 (0.8)	1 (0.3)	3 (0.5)
Pantoprazole	28 (10.5)	26 (8.8)	54 (9.6)
Pantoprazole Sodium Sesquihydrate	23 (8.6)	15 (5.1)	38 (6.8)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Rabeprazole	1 (0.4)	3 (1.0)	4 (0.7)
Rabeprazole Sodium	3 (1.1)	2 (0.7)	5 (0.9)
Tegoprazan	0	1 (0.3)	1 (0.2)
Vonoprazan Fumarate	7 (2.6)	2 (0.7)	9 (1.6)
PYRAZOLONES	16 (6.0)	21 (7.1)	37 (6.6)
Adiphenine Hydrochloride;Metamizole Sodium;Promethazine Hydrochloride	0	1 (0.3)	1 (0.2)
Caffeine;Isometheptene;Metamizole Sodium	0	1 (0.3)	1 (0.2)
Fenpiverinium Bromide;Metamizole Sodium;Pitofenone Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Hyoscine Butylbromide;Metamizole Sodium	1 (0.4)	0	1 (0.2)
Metamizole	2 (0.8)	5 (1.7)	7 (1.3)
Metamizole Sodium	12 (4.5)	11 (3.7)	23 (4.1)
Metamizole Sodium Monohydrate	2 (0.8)	3 (1.0)	5 (0.9)
PYRIMIDINE ANALOGUES	1 (0.4)	1 (0.3)	2 (0.4)
Fluorouracil	0	1 (0.3)	1 (0.2)
Gemcitabine	1 (0.4)	0	1 (0.2)
QUATERNARY AMMONIUM COMPOUNDS	2 (0.8)	0	2 (0.4)
Benzalkonium Chloride	1 (0.4)	0	1 (0.2)
Benzethonium Chloride	1 (0.4)	0	1 (0.2)
RABIES VACCINES	0	1 (0.3)	1 (0.2)
Rabies Vaccine	0	1 (0.3)	1 (0.2)
RETINOIDS FOR TOPICAL USE IN ACNE	0	1 (0.3)	1 (0.2)
Retinol	0	1 (0.3)	1 (0.2)
SALICYLIC ACID AND DERIVATIVES	8 (3.0)	5 (1.7)	13 (2.3)
Acetylsalicylic Acid	4 (1.5)	5 (1.7)	9 (1.6)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Acetylsalicylic Acid;Aluminium Glycinate;Magnesium Carbonate	2 (0.8)	0	2 (0.4)
Acetylsalicylic Acid;Hydrotalcite	1 (0.4)	0	1 (0.2)
Calcium Bromide;Cinchocaine Hydrochloride;Salicylate Sodium	1 (0.4)	0	1 (0.2)
Salicylamide	1 (0.4)	0	1 (0.2)
Salicylate Sodium	1 (0.4)	0	1 (0.2)
SALICYLIC ACID PREPARATIONS	2 (0.8)	0	2 (0.4)
Salicylic Acid	2 (0.8)	0	2 (0.4)
SALT SOLUTIONS	1 (0.4)	0	1 (0.2)
Sodium Chloride	1 (0.4)	0	1 (0.2)
SECOND-GENERATION CEPHALOSPORINS	14 (5.3)	11 (3.7)	25 (4.5)
Cefaclor	5 (1.9)	3 (1.0)	8 (1.4)
Cefmetazole Sodium	1 (0.4)	1 (0.3)	2 (0.4)
Cefotetan Disodium	1 (0.4)	0	1 (0.2)
Cefprozil	0	1 (0.3)	1 (0.2)
Cefuroxime	7 (2.6)	3 (1.0)	10 (1.8)
Cefuroxime Axetil	2 (0.8)	2 (0.7)	4 (0.7)
Cefuroxime Sodium	0	1 (0.3)	1 (0.2)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	9 (3.4)	16 (5.4)	25 (4.5)
Formoterol	0	1 (0.3)	1 (0.2)
Formoterol Fumarate	0	3 (1.0)	3 (0.5)
Formoterol Fumarate Dihydrate	0	1 (0.3)	1 (0.2)
Procaterol Hydrochloride	0	1 (0.3)	1 (0.2)
Salbutamol	4 (1.5)	8 (2.7)	12 (2.1)
Salbutamol Sulfate	4 (1.5)	3 (1.0)	7 (1.3)
Salmeterol	0	1 (0.3)	1 (0.2)
Salmeterol Xinafoate	0	1 (0.3)	1 (0.2)

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Terbutaline Sulfate	1 (0.4)	0	1 (0.2)
SELECTIVE IMMUNOSUPPRESSANTS	0	1 (0.3)	1 (0.2)
Mycophenolate Mofetil	0	1 (0.3)	1 (0.2)
SELECTIVE SEROTONIN (5HT1) AGONISTS	0	1 (0.3)	1 (0.2)
Sumatriptan	0	1 (0.3)	1 (0.2)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	16 (6.0)	10 (3.4)	26 (4.6)
Citalopram	1 (0.4)	1 (0.3)	2 (0.4)
Citalopram Hydrobromide	2 (0.8)	0	2 (0.4)
Escitalopram	2 (0.8)	3 (1.0)	5 (0.9)
Escitalopram Oxalate	5 (1.9)	0	5 (0.9)
Fluoxetine Hydrochloride	0	1 (0.3)	1 (0.2)
Paroxetine	0	3 (1.0)	3 (0.5)
Sertraline	5 (1.9)	2 (0.7)	7 (1.3)
Sertraline Hydrochloride	2 (0.8)	0	2 (0.4)
SELENIUM	0	1 (0.3)	1 (0.2)
Selenium	0	1 (0.3)	1 (0.2)
SEROTONIN (5HT3) ANTAGONISTS	18 (6.8)	12 (4.1)	30 (5.4)
Granisetron	0	2 (0.7)	2 (0.4)
Granisetron Hydrochloride	6 (2.3)	0	6 (1.1)
Ondansetron	8 (3.0)	9 (3.1)	17 (3.0)
Ondansetron Hydrochloride	3 (1.1)	0	3 (0.5)
Ramosetron	1 (0.4)	0	1 (0.2)
Ramosetron Hydrochloride	3 (1.1)	1 (0.3)	4 (0.7)
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS	2 (0.8)	6 (2.0)	8 (1.4)
Dapagliflozin Propanediol Monohydrate	0	2 (0.7)	2 (0.4)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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Empagliflozin	2 (0.8)	4 (1.4)	6 (1.1)
SOFT PARAFFIN AND FAT PRODUCTS	10 (3.8)	1 (0.3)	11 (2.0)
Cetyl Alcohol;Glycerol;Paraffin	1 (0.4)	0	1 (0.2)
Isopropyl Myristate;Paraffin, Liquid	1 (0.4)	0	1 (0.2)
Paraffin	1 (0.4)	0	1 (0.2)
Paraffin Soft	1 (0.4)	0	1 (0.2)
Paraffin, Liquid;White Soft Paraffin	1 (0.4)	0	1 (0.2)
Petrolatum	1 (0.4)	0	1 (0.2)
White Soft Paraffin	5 (1.9)	1 (0.3)	6 (1.1)
SOFTENERS, EMOLLIENTS	9 (3.4)	6 (2.0)	15 (2.7)
Docusate	0	2 (0.7)	2 (0.4)
Docusate Sodium	7 (2.6)	4 (1.4)	11 (2.0)
Paraffin, Liquid	2 (0.8)	0	2 (0.4)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	16 (6.0)	18 (6.1)	34 (6.1)
Calcium Chloride Dihydrate;Glucose;Potassium Chloride;Sodium Acetate;Sodium Chloride	0	1 (0.3)	1 (0.2)
Calcium Chloride Dihydrate;Glucose;Potassium Chloride;Sodium Chloride;Sodium Lactate	0	1 (0.3)	1 (0.2)
Calcium Chloride Dihydrate;Magnesium Chloride Hexahydrate;Malic Acid;Potassium Chloride;Sodium Acetate Trihydrate;Sodium Chloride	2 (0.8)	0	2 (0.4)
Calcium Chloride Dihydrate;Potassium Chloride;Sodium Acetate Trihydrate;Sodium Chloride	4 (1.5)	4 (1.4)	8 (1.4)
Calcium Chloride Dihydrate;Potassium Chloride;Sodium Chloride;Sodium Lactate	5 (1.9)	5 (1.7)	10 (1.8)
Calcium Chloride;Magnesium Chloride;Potassium Chloride;Sodium Chloride;Sodium Lactate	0	1 (0.3)	1 (0.2)
Calcium Chloride;Potassium Chloride;Sodium Acetate	1 (0.4)	0	1 (0.2)
Calcium Chloride;Potassium Chloride;Sodium Chloride;Sodium Lactate	0	1 (0.3)	1 (0.2)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Calcium Chloride;Potassium Chloride;Sodium Lactate	1 (0.4)	3 (1.0)	4 (0.7)
Calcium Gluconate Monohydrate;Glucose;Magnesium Chloride Hexahydrate;Potassium Chloride;Sodium Acetate;Sodium Chloride;Sodium Citrate Dihydrate	2 (0.8)	0	2 (0.4)
Gluconate Sodium;Magnesium Chloride;Potassium Chloride;Sodium Acetate;Sodium Chloride	3 (1.1)	1 (0.3)	4 (0.7)
Glucose;Magnesium Chloride Hexahydrate;Potassium Chloride;Potassium Phosphate Monobasic;Sodium Acetate Trihydrate;Sodium Chloride	1 (0.4)	1 (0.3)	2 (0.4)
Glucose;Potassium Chloride;Sodium Chloride;Sodium Lactate	1 (0.4)	2 (0.7)	3 (0.5)
Glucose;Sodium Chloride	2 (0.8)	1 (0.3)	3 (0.5)
Glucose;Sodium Chloride;Sodium Lactate	1 (0.4)	3 (1.0)	4 (0.7)
Magnesium Chloride Hexahydrate;Potassium Chloride;Sodium Acetate Trihydrate;Sodium Chloride	0	1 (0.3)	1 (0.2)
Potassium Chloride;Sodium Chloride;Sodium Lactate	1 (0.4)	0	1 (0.2)
Solutions Affecting The Electrolyte Balance	2 (0.8)	0	2 (0.4)
SOLUTIONS FOR PARENTERAL NUTRITION	17 (6.4)	7 (2.4)	24 (4.3)
Acetylcysteine;Alanine;Arginine;Ascorbic Acid;Aspartic Acid;Biotin;Calcium Chloride Dihydrate;Cyanocobalamin;Folic Acid;Glucose;Glutamic Acid;Glycine;Histidine;Isoleucine;Leucine;Lysine Hydrochloride;Magnesium Sulfate Heptahydrate;Methionine;Nicotinamide;Panthenol;Phenylalanine;Potassium Phosphate Dibasic;Proline;Pyridoxine Hydrochloride;Riboflavin Sodium Phosphate;Serine;Sodium Chloride;Sodium Lactate;Thiamine Hydrochloride;Threonine;Tryptophan, L-;Tyrosine;Valine;Zinc Sulfate Heptahydrate	0	1 (0.3)	1 (0.2)
Alanine;Arginine;Aspartic Acid;Calcium Chloride Dihydrate;Glucose Monohydrate;Glutamic Acid;Glycine;Glycine Max Seed Oil;Histidine;Isoleucine;Leucine;Lysine Hydrochloride;Magnesium Sulfate Heptahydrate;Methionine;Phenylalanine;Potassium Chloride;Proline;Serine;Sodium Acetate Trihydrate;Sodium Glycerophosphate;Threonine;Tryptophan, L-;Tyrosine;Valine	0	1 (0.3)	1 (0.2)

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root/cdar/d081/_iemt/ar/iemt_payer_propel_germany/tlf/prod/program/bslcm_s2.sas ebslcm_s2a 20JUN2022:13:11 khcs324

Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Alanine;Arginine;Aspartic Acid;Calcium Chloride;Glucose Monohydrate;Glutamic Acid;Glycine;Glycine Max Seed Oil;Histidine Hydrochloride;Isoleucine;Leucine;Lysine Hydrochloride;Magnesium Acetate Tetrahydrate;Medium-Chain Triglycerides;Methionine;Phenylalanine;Potassium Acetate;Proline;Serine;Sodium Acetate;Sodium Chloride;Sodium Hydroxide;Sodium Phosphate Monobasic (dihydrate);Threonine;Tryptophan, L-;Valine;Zinc Acetate Dihydrate	1 (0.4)	0	1 (0.2)
Alanine;Arginine;Aspartic Acid;Cysteine;Glutamic Acid;Glycine;Histidine;Isoleucine;Leucine;Lysine Acetate;Methionine;Phenylalanine;Proline;Serine;Threonine;Tryptophan, L-;Tyrosine;Valine	1 (0.4)	0	1 (0.2)
Alanine;Arginine;Calcium Chloride Dihydrate;Fish Oil;Glucose Monohydrate;Glycine;Glycine Max Oil;Histidine;Isoleucine;Leucine;Lysine Hydrochloride;Magnesium Sulfate Heptahydrate;Medium-Chain Triglycerides;Methionine;Olea Europaea Oil;Phenylalanine;Potassium Chloride;Proline;Serine;Sodium Acetate Trihydrate;Sodium Glycerophosphate;Threonine;Tryptophan, L-;Tyrosine;Valine;Zinc Sulfate Heptahydrate	1 (0.4)	0	1 (0.2)
Alanine;Arginine;Calcium Chloride;Fish Oil;Glucose Monohydrate;Glycine;Glycine Max Seed Oil;Histidine;Isoleucine;Leucine;Lysine Acetate;Magnesium Sulfate;Medium-Chain Triglycerides;Methionine;Olea Europaea Oil;Phenylalanine;Potassium Chloride;Proline;Serine;Sodium Acetate;Sodium Glycerophosphate;Taurine;Threonine;Tryptophan, L-;Tyrosine;Valine;Zinc Sulfate	1 (0.4)	0	1 (0.2)
Alanine;Arginine;Cysteine Hydrochloride;Glycine;Histidine;Isoleucine;Leucine;Lysine Acetate;Methionine;Phenylalanine;Proline;Serine;Threonine;Tryptophan, L-;Valine	1 (0.4)	0	1 (0.2)
Amino Acids Nos;Carbohydrates Nos;Electrolytes Nos;Lipids Nos	1 (0.4)	0	1 (0.2)
Amino Acids Nos;Copper;Electrolytes Nos;Glucose;Iodine;Iron;Manganese;Vitamins Nos;Zinc	2 (0.8)	0	2 (0.4)
Amino Acids Nos;Electrolytes Nos;Glucose;Glycine Max Seed Oil;Olea Europaea Oil	1 (0.4)	0	1 (0.2)
Amino Acids Nos;Electrolytes Nos;Glucose;Lipids Nos	1 (0.4)	0	1 (0.2)
Amino Acids Nos;Electrolytes Nos;Glucose;Thiamine Hydrochloride	3 (1.1)	3 (1.0)	6 (1.1)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Amino Acids Nos;Glucose;Lipids Nos	2 (0.8)	1 (0.3)	3 (0.5)
Fish Oil;Glycine Max Seed Oil;Olea Europaea Oil;Triglycerides	1 (0.4)	0	1 (0.2)
Glucose	10 (3.8)	2 (0.7)	12 (2.1)
Solutions For Parenteral Nutrition	1 (0.4)	1 (0.3)	2 (0.4)
SOLUTIONS PRODUCING OSMOTIC DIURESIS	0	1 (0.3)	1 (0.2)
Fructose;Glycerol	0	1 (0.3)	1 (0.2)
SOLVENTS AND DILUTING AGENTS, INCL. IRRIGATING SOLUTIONS	0	1 (0.3)	1 (0.2)
Sodium Chloride	0	1 (0.3)	1 (0.2)
SPECIFIC IMMUNOGLOBULINS	1 (0.4)	0	1 (0.2)
Immunoglobulin Human Anti-Tetanus	1 (0.4)	0	1 (0.2)
SUBSTITUTED ALKYLAMINES	11 (4.1)	5 (1.7)	16 (2.9)
Chlorphenamine	1 (0.4)	0	1 (0.2)
Chlorphenamine Maleate	9 (3.4)	2 (0.7)	11 (2.0)
Dexchlorpheniramine	1 (0.4)	1 (0.3)	2 (0.4)
Dexchlorpheniramine Maleate	1 (0.4)	1 (0.3)	2 (0.4)
Pheniramine	1 (0.4)	1 (0.3)	2 (0.4)
SULFONAMIDES	1 (0.4)	0	1 (0.2)
Sulfadiazine Silver	1 (0.4)	0	1 (0.2)
SULFONAMIDES, PLAIN	34 (12.8)	33 (11.2)	67 (12.0)
Azosemide	1 (0.4)	1 (0.3)	2 (0.4)
Bumetanide	1 (0.4)	0	1 (0.2)
Chlortalidone	4 (1.5)	3 (1.0)	7 (1.3)
Furosemide	24 (9.0)	24 (8.2)	48 (8.6)
Indapamide	5 (1.9)	5 (1.7)	10 (1.8)
Mefruside	1 (0.4)	0	1 (0.2)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Torasemide	1 (0.4)	3 (1.0)	4 (0.7)
Xipamide	1 (0.4)	0	1 (0.2)
SULFONYLUREAS	10 (3.8)	22 (7.5)	32 (5.7)
Glibenclamide	1 (0.4)	3 (1.0)	4 (0.7)
Gliclazide	6 (2.3)	12 (4.1)	18 (3.2)
Glimepiride	4 (1.5)	8 (2.7)	12 (2.1)
Glipizide	1 (0.4)	0	1 (0.2)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	0	1 (0.3)	1 (0.2)
Thiamazole	0	1 (0.3)	1 (0.2)
SYMPATHOMIMETICS	4 (1.5)	3 (1.0)	7 (1.3)
Atropa Belladonna Extract;Caffeine;Carbinoxamine Maleate;Lysozyme Chloride;Pseudoephedrine Hydrochloride	1 (0.4)	0	1 (0.2)
Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride	1 (0.4)	0	1 (0.2)
Phenylephrine Hydrochloride	0	1 (0.3)	1 (0.2)
Pseudoephedrine	0	2 (0.7)	2 (0.4)
Pseudoephedrine Hydrochloride	2 (0.8)	0	2 (0.4)
SYMPATHOMIMETICS IN GLAUCOMA THERAPY	2 (0.8)	2 (0.7)	4 (0.7)
Brimonidine Tartrate	2 (0.8)	2 (0.7)	4 (0.7)
SYMPATHOMIMETICS, PLAIN	1 (0.4)	1 (0.3)	2 (0.4)
Naphazoline	1 (0.4)	0	1 (0.2)
Oxymetazoline Hydrochloride	0	1 (0.3)	1 (0.2)
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP	0	2 (0.7)	2 (0.4)
Pargeverine	0	1 (0.3)	1 (0.2)
Trimebutine Maleate	0	1 (0.3)	1 (0.2)
SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS	2 (0.8)	3 (1.0)	5 (0.9)

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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Glycopyrronium	1 (0.4)	0	1 (0.2)
Glycopyrronium Bromide	1 (0.4)	1 (0.3)	2 (0.4)
Otilonium Bromide	0	1 (0.3)	1 (0.2)
Tiquizium Bromide	0	1 (0.3)	1 (0.2)
SYNTHETIC ANTISPASMODICS, AMIDES WITH TERTIARY AMINES	0	1 (0.3)	1 (0.2)
Tiropramide Hydrochloride	0	1 (0.3)	1 (0.2)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS	0	1 (0.3)	1 (0.2)
Adrenal Gland	0	1 (0.3)	1 (0.2)
TAXANES	0	2 (0.7)	2 (0.4)
Docetaxel	0	2 (0.7)	2 (0.4)
TECHNETIUM (99MTC) COMPOUNDS	4 (1.5)	9 (3.1)	13 (2.3)
Technetium Tc 99m	0	6 (2.0)	6 (1.1)
Technetium Tc 99m Medronate	2 (0.8)	7 (2.4)	9 (1.6)
Technetium Tc 99m Oxidronate	4 (1.5)	4 (1.4)	8 (1.4)
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	2 (0.8)	4 (1.4)	6 (1.1)
Dutasteride	1 (0.4)	4 (1.4)	5 (0.9)
Finasteride	1 (0.4)	0	1 (0.2)
TETANUS VACCINES	2 (0.8)	1 (0.3)	3 (0.5)
Diphtheria Vaccine Toxoid;Tetanus Vaccine Toxoid	1 (0.4)	0	1 (0.2)
Diphtheria Vaccine;Tetanus Vaccine	1 (0.4)	0	1 (0.2)
Tetanus Vaccine	0	1 (0.3)	1 (0.2)
TETRACYCLINE AND DERIVATIVES	2 (0.8)	1 (0.3)	3 (0.5)
Minocycline Hydrochloride	1 (0.4)	1 (0.3)	2 (0.4)
Tetracycline Hydrochloride	1 (0.4)	0	1 (0.2)

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Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

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TETRACYCLINES	6 (2.3)	6 (2.0)	12 (2.1)
Doxycycline	3 (1.1)	4 (1.4)	7 (1.3)
Doxycycline Hyclate	1 (0.4)	1 (0.3)	2 (0.4)
Minocycline Hydrochloride	2 (0.8)	0	2 (0.4)
Tigecycline	0	1 (0.3)	1 (0.2)
THIAZIDES, PLAIN	17 (6.4)	19 (6.5)	36 (6.4)
Bendroflumethiazide	1 (0.4)	0	1 (0.2)
Hydrochlorothiazide	16 (6.0)	18 (6.1)	34 (6.1)
Trichlormethiazide	0	1 (0.3)	1 (0.2)
THIAZOLIDINEDIONES	0	1 (0.3)	1 (0.2)
Pioglitazone	0	1 (0.3)	1 (0.2)
THIRD-GENERATION CEPHALOSPORINS	27 (10.2)	31 (10.5)	58 (10.4)
Cefcapene Pivoxil Hydrochloride	5 (1.9)	0	5 (0.9)
Cefcapene Pivoxil Hydrochloride Hydrate	1 (0.4)	2 (0.7)	3 (0.5)
Cefdinir	3 (1.1)	3 (1.0)	6 (1.1)
Cefditoren Pivoxil	0	2 (0.7)	2 (0.4)
Cefixime	5 (1.9)	3 (1.0)	8 (1.4)
Cefmenoxime Hydrochloride	1 (0.4)	0	1 (0.2)
Cefoperazone Sodium;Sulbactam Sodium	1 (0.4)	0	1 (0.2)
Cefotaxime	1 (0.4)	0	1 (0.2)
Cefotaxime Sodium	1 (0.4)	2 (0.7)	3 (0.5)
Cefpodoxime Proxetil	1 (0.4)	0	1 (0.2)
Ceftazidime	2 (0.8)	1 (0.3)	3 (0.5)
Cefteram Pivoxil	0	1 (0.3)	1 (0.2)
Ceftriaxone	7 (2.6)	11 (3.7)	18 (3.2)
Ceftriaxone Sodium	8 (3.0)	7 (2.4)	15 (2.7)

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Ceftriaxone Sodium Sesquaterhydrate	1 (0.4)	2 (0.7)	3 (0.5)
THYROID HORMONES	7 (2.6)	9 (3.1)	16 (2.9)
Levothyroxine	2 (0.8)	1 (0.3)	3 (0.5)
Levothyroxine Sodium	5 (1.9)	7 (2.4)	12 (2.1)
Levothyroxine Sodium;Potassium Iodide	0	1 (0.3)	1 (0.2)
TONICS	2 (0.8)	4 (1.4)	6 (1.1)
Andrographis Paniculata;Ascorbic Acid;Echinacea Purpurea;Olea Europaea;Zinc Amino Acid Chelate	0	1 (0.3)	1 (0.2)
Curcuma Longa	1 (0.4)	0	1 (0.2)
Curcumin	0	2 (0.7)	2 (0.4)
Glycerophosphoric Acid	1 (0.4)	0	1 (0.2)
Tonics	0	1 (0.3)	1 (0.2)
TRIAZOLE DERIVATIVES	4 (1.5)	3 (1.0)	7 (1.3)
Fluconazole	4 (1.5)	3 (1.0)	7 (1.3)
TRIMETHOPRIM AND DERIVATIVES	3 (1.1)	3 (1.0)	6 (1.1)
Trimethoprim	3 (1.1)	3 (1.0)	6 (1.1)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	3 (1.1)	17 (5.8)	20 (3.6)
Agaricus Blazei	0	1 (0.3)	1 (0.2)
Angelica Acutiloba Root;Astragalus Spp. Root;Atractylodes Spp. Rhizome;Bupleurum Falcatum Root;Cimicifuga Spp. Rhizome;Citrus Aurantium Peel;Glycyrrhiza Spp. Root;Panax Ginseng Root;Zingiber Officinale Rhizome;Ziziphus Jujuba Fruit	0	1 (0.3)	1 (0.2)
Brassica Oleracea;Camellia Sinensis;Curcuma Longa;Punica Granatum	0	1 (0.3)	1 (0.2)
Cannabis Sativa	0	1 (0.3)	1 (0.2)
Cimicifuga Racemosa	0	1 (0.3)	1 (0.2)

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Cinnamomum Cassia Bark;Paeonia Lactiflora Root;Paeonia X Suffruticosa Root Bark;Poria Cocos Sclerotium;Prunus Spp. Seed	1 (0.4)	0	1 (0.2)
Curcuma Longa	0	2 (0.7)	2 (0.4)
Echinacea Spp.	1 (0.4)	0	1 (0.2)
Herbal Extract Nos	0	1 (0.3)	1 (0.2)
Krill Oil	0	1 (0.3)	1 (0.2)
Lentinus Edodes Mycelium	0	1 (0.3)	1 (0.2)
Linum Usitatissimum Seed	0	1 (0.3)	1 (0.2)
Oenothera Biennis Oil	1 (0.4)	1 (0.3)	2 (0.4)
Panax Ginseng	0	1 (0.3)	1 (0.2)
Plantago Ovata Fibre	0	2 (0.7)	2 (0.4)
Sesamum Indicum Seed Oil	0	1 (0.3)	1 (0.2)
Silybum Marianum Seed	0	1 (0.3)	1 (0.2)
Unspecified Herbal And Traditional Medicine	0	3 (1.0)	3 (0.5)
URINARY CONCREMENT SOLVENTS	1 (0.4)	0	1 (0.2)
Potassium Citrate;Sodium Citrate Dihydrate	1 (0.4)	0	1 (0.2)
VARICELLA ZOSTER VACCINES	2 (0.8)	2 (0.7)	4 (0.7)
Varicella Zoster Vaccine	0	1 (0.3)	1 (0.2)
Varicella Zoster Vaccine Rge (cho)	2 (0.8)	1 (0.3)	3 (0.5)
VARIOUS	0	1 (0.3)	1 (0.2)
Radiotherapy	0	1 (0.3)	1 (0.2)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	10 (3.8)	11 (3.7)	21 (3.8)
Acetylcarnitine;Citicoline;Pantothenic Acid;Pyridoxine Hydrochloride;Riboflavin;Thioctic Acid;Vitamin B1 Nos;Vitamin B12 Nos	0	1 (0.3)	1 (0.2)
Anethole Trithione	0	1 (0.3)	1 (0.2)
Citric Acid;Sodium Citrate	0	1 (0.3)	1 (0.2)

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WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Phosphorus	1 (0.4)	0	1 (0.2)
Polaprezinc	1 (0.4)	0	1 (0.2)
Probiotics Nos	1 (0.4)	1 (0.3)	2 (0.4)
Sodium Bicarbonate	4 (1.5)	1 (0.3)	5 (0.9)
Sucralfate	1 (0.4)	0	1 (0.2)
Thioctic Acid	0	1 (0.3)	1 (0.2)
Ubidecarenone	1 (0.4)	6 (2.0)	7 (1.3)
Ubiquinol	1 (0.4)	0	1 (0.2)
Zinc Acetate	1 (0.4)	0	1 (0.2)
Zinc Acetate Dihydrate	1 (0.4)	0	1 (0.2)
VASOPRESSIN AND ANALOGUES	4 (1.5)	2 (0.7)	6 (1.1)
Desmopressin	1 (0.4)	0	1 (0.2)
Desmopressin Acetate	2 (0.8)	1 (0.3)	3 (0.5)
Vasopressin	1 (0.4)	1 (0.3)	2 (0.4)
VASOPRESSIN ANTAGONISTS	1 (0.4)	0	1 (0.2)
Tolvaptan	1 (0.4)	0	1 (0.2)
VITAMIN B-COMPLEX WITH MINERALS	1 (0.4)	0	1 (0.2)
Yeast Dried	1 (0.4)	0	1 (0.2)
VITAMIN B-COMPLEX, PLAIN	9 (3.4)	4 (1.4)	13 (2.3)
Biotin;Calcium Pantothenate;Cyanocobalamin;Folic Acid;Nicotinamide;Pyridoxine Hydrochloride;Riboflavin;Thiamine Mononitrate	1 (0.4)	0	1 (0.2)
Calcium Pantothenate;Nicotinamide;Pyridoxine Hydrochloride;Riboflavin;Thiamine Hydrochloride	1 (0.4)	0	1 (0.2)
Vitamin B Complex	5 (1.9)	0	5 (0.9)
Vitamin B Nos	2 (0.8)	4 (1.4)	6 (1.1)

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A concomitant medication is only classed as such up to 30 days following discontinuation of randomised treatment.
WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12	5 (1.9)	1 (0.3)	6 (1.1)
Benfotiamine;Cyanocobalamin;Pyridoxine Hydrochloride	0	1 (0.3)	1 (0.2)
Cyanocobalamin;Pyridoxine Hydrochloride;Thiamine Hydrochloride	5 (1.9)	0	5 (0.9)
VITAMIN B1, PLAIN	3 (1.1)	5 (1.7)	8 (1.4)
Benfotiamine	0	2 (0.7)	2 (0.4)
Fursultiamine Hydrochloride	2 (0.8)	0	2 (0.4)
Thiamine	0	3 (1.0)	3 (0.5)
Thiamine Hydrochloride	1 (0.4)	0	1 (0.2)
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	27 (10.2)	7 (2.4)	34 (6.1)
Cobamamide	1 (0.4)	0	1 (0.2)
Cyanocobalamin	10 (3.8)	3 (1.0)	13 (2.3)
Hydroxocobalamin	2 (0.8)	0	2 (0.4)
Mecobalamin	5 (1.9)	2 (0.7)	7 (1.3)
Vitamin B12 Nos	12 (4.5)	2 (0.7)	14 (2.5)
VITAMIN D AND ANALOGUES	60 (22.6)	55 (18.7)	115 (20.5)
Alfacalcidol	3 (1.1)	3 (1.0)	6 (1.1)
Calcifediol	0	1 (0.3)	1 (0.2)
Calcitriol	1 (0.4)	0	1 (0.2)
Colecalciferol	34 (12.8)	29 (9.9)	63 (11.3)
Ergocalciferol	1 (0.4)	2 (0.7)	3 (0.5)
Vitamin D Nos	23 (8.6)	21 (7.1)	44 (7.9)
VITAMIN K	1 (0.4)	2 (0.7)	3 (0.5)
Phytomenadione	0	2 (0.7)	2 (0.4)
Vitamin K Nos	1 (0.4)	0	1 (0.2)
VITAMIN K ANTAGONISTS	7 (2.6)	4 (1.4)	11 (2.0)

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WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Acenocoumarol	0	2 (0.7)	2 (0.4)
Phenprocoumon	1 (0.4)	1 (0.3)	2 (0.4)
Warfarin	5 (1.9)	1 (0.3)	6 (1.1)
Warfarin Potassium	1 (0.4)	0	1 (0.2)
VITAMINS	3 (1.1)	1 (0.3)	4 (0.7)
Vitamins Nos	3 (1.1)	1 (0.3)	4 (0.7)
VITAMINS WITH MINERALS	2 (0.8)	2 (0.7)	4 (0.7)
Ascorbic Acid;Betacarotene;Cupric Oxide;Tocopheryl Acetate;Zinc Oxide	1 (0.4)	2 (0.7)	3 (0.5)
Magnesium Glycinate;Pyridoxine Hydrochloride	1 (0.4)	0	1 (0.2)
Minerals Nos;Vitamins Nos	0	1 (0.3)	1 (0.2)
VITAMINS, OTHER COMBINATIONS	1 (0.4)	5 (1.7)	6 (1.1)
Ascorbic Acid;Benfotiamine;Biotin;Calcium Pantothenate;Choline Bitartrate;Cyanocobalamin;Folic Acid;Inositol;Nicotinamide;Pyridoxine Hydrochloride;Riboflavin;Zinc Oxide	1 (0.4)	1 (0.3)	2 (0.4)
Ascorbic Acid;Cupric Oxide;Omega-3 Fatty Acids;Tocopherol;Xantofyl;Zinc Oxide	0	1 (0.3)	1 (0.2)
Biotin;Chromium Picolinate;Pantothenic Acid;Pyridoxine Hydrochloride;Selenium;Thioctic Acid;Vitamin B1 Nos;Vitamin E Nos;Zinc	0	1 (0.3)	1 (0.2)
Herbal Nos;Minerals Nos;Vitamins Nos	0	1 (0.3)	1 (0.2)
Vitamins, Other Combinations	0	1 (0.3)	1 (0.2)
WART AND ANTI-CORN PREPARATIONS	2 (0.8)	0	2 (0.4)
Salicylic Acid	2 (0.8)	0	2 (0.4)
WATERSOLUBLE, NEPHROTROPIC, HIGH OSMOLAR X-RAY CONTRAST MEDIA	0	1 (0.3)	1 (0.2)
Meglumine Amidotrizoate;Sodium Amidotrizoate	0	1 (0.3)	1 (0.2)

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WHO Drug September 2021.
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Table 7.10 PROpel: Allowed concomitant medications during study
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

ATC classification / Generic term	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA	5 (1.9)	8 (2.7)	13 (2.3)
Iobitridol	1 (0.4)	0	1 (0.2)
Iohexol	2 (0.8)	6 (2.0)	8 (1.4)
Iomeprol	0	3 (1.0)	3 (0.5)
Iopamidol	2 (0.8)	3 (1.0)	5 (0.9)
Iopromide	1 (0.4)	0	1 (0.2)
Ioversol	2 (0.8)	2 (0.7)	4 (0.7)
XANTHINES	3 (1.1)	0	3 (0.5)
Ambroxol Acefyllinate	1 (0.4)	0	1 (0.2)
Diphenhydramine Salicylate;Diprophylline	1 (0.4)	0	1 (0.2)
Doxofylline	1 (0.4)	0	1 (0.2)
ZINC	2 (0.8)	0	2 (0.4)
Zinc	2 (0.8)	0	2 (0.4)
ZINC PRODUCTS	2 (0.8)	0	2 (0.4)
Zinc Oxide	2 (0.8)	0	2 (0.4)

ATC = Anatomical Therapeutic Chemical.
A patient can have one or more Generic term reported under a given ATC text.
Includes medications that began prior to randomisation and were ongoing after randomisation.
A concomitant medication is only classed as such up to 30 days following discontinuation of randomised treatment.
WHO Drug September 2021.
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Table 7.11 PROpel: Duration of Olaparib/Placebo exposure (months)
Safety Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Treatment duration (months)	Statistic	Olaparib (N=266)	Abiraterone [c] (N=266)	Placebo (N=294)	Abiraterone [d] (N=294)
Total treatment duration [a]	Mean	19.84	20.84	17.71	17.85
	SD	10.927	10.534	10.355	10.404
	Median	22.47	24.56	16.57	16.59
	Min	0.4	1.0	0.4	0.4
	Max	38.8	38.8	37.9	37.9
	Total treatment months	5276.6	5544.4	5206.7	5246.9
Actual treatment duration [b]	Mean	19.14	20.40	17.40	17.66
	SD	10.684	10.396	10.230	10.389
	Median	21.45	23.38	16.33	16.54
	Min	0.4	0.9	0.3	0.3
	Max	38.4	38.4	37.9	37.9
	Total treatment months	5090.7	5427.3	5116.0	5191.3

SD = Standard deviation. Min = Minimum. Max = Maximum.
[a] Total treatment duration = (last dose date - first dose date +1).
[b] Actual treatment duration = (last dose date - first dose date +1) excluding dose interruptions.
[c] Abiraterone for patients that receive Olaparib treatment group.
[d] Abiraterone for patients that receive Placebo treatment group.
If patient is ongoing, data-cut-off has been used to calculate duration.
Dose interruptions include those where the patient forgot to take a dose.
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Table 7.12 PROpel: Radiotherapy prior to study treatment
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Previous radiotherapy for prostate cancer			
Yes	135 (50.8)	140 (47.6)	275 (49.1)
No	131 (49.2)	154 (52.4)	285 (50.9)
Treatment setting			
Adjuvant	60 (22.6)	58 (19.7)	118 (21.1)
Neo-adjuvant	7 (2.6)	18 (6.1)	25 (4.5)
Palliative	41 (15.4)	39 (13.3)	80 (14.3)
Definitive	19 (7.1)	17 (5.8)	36 (6.4)
Not applicable	12 (4.5)	9 (3.1)	21 (3.8)
Other	6 (2.3)	13 (4.4)	19 (3.4)
Missing	1 (0.4)	0	1 (0.2)
Radiotherapy Site / Region treated			
Bone - Spine	22 (8.3)	14 (4.8)	36 (6.4)
Bone - Calva	1 (0.4)	1 (0.3)	2 (0.4)
Prostate Gland	89 (33.5)	102 (34.7)	191 (34.1)
Pelvic Bone	22 (8.3)	21 (7.1)	43 (7.7)
Other	36 (13.5)	38 (12.9)	74 (13.2)
Missing	1 (0.4)	0	1 (0.2)
Radiotherapy Site / Region laterality			
Left	15 (5.6)	15 (5.1)	30 (5.4)
Right	5 (1.9)	5 (1.7)	10 (1.8)
Contralateral	0	2 (0.7)	2 (0.4)
Ipsilateral	4 (1.5)	3 (1.0)	7 (1.3)
Not applicable	121 (45.5)	126 (42.9)	247 (44.1)
Missing	2 (0.8)	1 (0.3)	3 (0.5)

N = Number of patients in treatment group.
Patients can be counted in more than one treatment setting or radiotherapy site.
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Table 7.13 PROpel: Time from most recent disease progression to randomisation (months)
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

Time (months)		Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Most recent progression to randomisation	n	265	293	558
	Mean	3.35	2.33	2.81
	SD	9.760	3.877	7.300
	Median	1.15	1.28	1.18
	Min	0.0	0.0	0.0
	Max	99.9	29.5	99.9

N = Number of patients in treatment group. n = Number of patients included in analysis. SD = Standard deviation.
Min = Minimum. Max = Maximum.
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Table 7.14 PROpel: HRR gene mutation status based on ctDNA test
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
HRR gene mutation status	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
HRRm [a]	54 (20.3)	71 (24.1)	125 (22.3)
Non-HRRm [b]	189 (71.1)	198 (67.3)	387 (69.1)
HRRm unknown [c]	23 (8.6)	25 (8.5)	48 (8.6)
Total	266 (100)	294 (100)	560 (100)

HRR: Homologous Recombination Repair Gene (BRCA1, BRCA2, ATM, BRIP1, PALB2, RAD51C, BARD1, CDK12, CHEK1, CHEK2, FANCL, RAD51B RAD51D, RAD54L). [a] Any deleterious or suspected deleterious HRR gene mutation detected. [b] No deleterious or suspected deleterious HRR gene mutation detected. [c] Patients where mutation testing was not performed or where mutation testing failed. ctDNA-based test used to derive HRR gene mutation status is FoundationOne®Liquid CDx.
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Table 7.15 PROpel: Current radiotherapy while on study treatment
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Current radiotherapy for prostate cancer			
Yes	15 (5.6)	20 (6.8)	35 (6.3)
No	251 (94.4)	274 (93.2)	525 (93.8)
Palliative and Other			
Palliative	13 (4.9)	15 (5.1)	28 (5.0)
Other	1 (0.4)	4 (1.4)	5 (0.9)
Missing	1 (0.4)	2 (0.7)	3 (0.5)
Radiotherapy Site / Region treated			
Bone - Spine	1 (0.4)	5 (1.7)	6 (1.1)
Bone - Calva	0	2 (0.7)	2 (0.4)
Pelvic Bone	5 (1.9)	4 (1.4)	9 (1.6)
Other	8 (3.0)	9 (3.1)	17 (3.0)
Missing	1 (0.4)	2 (0.7)	3 (0.5)
Radiotherapy Site / Region laterality			
Left	5 (1.9)	4 (1.4)	9 (1.6)
Right	4 (1.5)	3 (1.0)	7 (1.3)
Ipsilateral	0	1 (0.3)	1 (0.2)
Not applicable	6 (2.3)	12 (4.1)	18 (3.2)
Missing	1 (0.4)	2 (0.7)	3 (0.5)

N = Number of patients in treatment group.
Patients can be counted in more than one treatment setting or radiotherapy site.
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Table 7.16 PROpel: Radiotherapy post study treatment discontinuation
Full Analysis Set, Asymptomatic patients at baseline, DCO 14MAR2022

	Number (%) of patients		
	Olaparib + Abiraterone (N=266)	Placebo + Abiraterone (N=294)	Total (N=560)
Post radiotherapy for prostate cancer			
Yes	22 (8.3)	39 (13.3)	61 (10.9)
No	244 (91.7)	255 (86.7)	499 (89.1)
Palliative and Other			
Palliative	21 (7.9)	34 (11.6)	55 (9.8)
Other	1 (0.4)	5 (1.7)	6 (1.1)
Radiotherapy Site / Region treated			
Bone - Spine	9 (3.4)	13 (4.4)	22 (3.9)
Bone - Calva	1 (0.4)	0	1 (0.2)
Prostate Gland	1 (0.4)	4 (1.4)	5 (0.9)
Pelvic Bone	3 (1.1)	7 (2.4)	10 (1.8)
Other	12 (4.5)	18 (6.1)	30 (5.4)
Radiotherapy Site / Region laterality			
Left	1 (0.4)	10 (3.4)	11 (2.0)
Right	9 (3.4)	5 (1.7)	14 (2.5)
Contralateral	1 (0.4)	5 (1.7)	6 (1.1)
Ipsilateral	0	1 (0.3)	1 (0.2)
Not applicable	14 (5.3)	21 (7.1)	35 (6.3)

N = Number of patients in treatment group.
Patients can be counted in more than one treatment setting or radiotherapy site.
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