Eigene Vorlage

# Dossier zur Nutzenbewertung gemäß § 35a SGB V

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## Separater Anhang 4-G zu Modul 4A

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Table 2.15
Overall Survival by Neoadjuvant Chemotherapy According to eCRF (ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Yes | Time to death (months) [1] [2] | Median (95% CI) | 33.6 (33.6,NE) | NE (NE,NE) |
| | Overall | N | 322 | 167 |
| | Censored Observations | n (%) | 270 (83.9) | 140 (83.8) |
| | Event Rate, Overall | n (%) | 52 (16.1) | 27 (16.2) |
| | p-value [3] | | 0.8987 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.97 (0.608,1.548) | |
| No | Time to death (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 165 | 79 |
| | Censored Observations | n (%) | 144 (87.3) | 67 (84.8) |
| | Event Rate, Overall | n (%) | 21 (12.7) | 12 (15.2) |
| | p-value [3] | | 0.2948 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.69 (0.336,1.395) | |

[1] Time to death is defined as the date of randomization to the date of death by any cause. Patients known to be alive were censored at the last known survival follow-up date.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.16
Overall Survival by Best Response to First Platinum Regimen According to eCRF
(ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| CR | Time to death (months) [1] [2] | Median (95% CI) | NE (33.6,NE) | NE (NE,NE) |
| | Overall | N | 337 | 172 |
| | Censored Observations | n (%) | 300 (89.0) | 150 (87.2) |
| | Event Rate, Overall | n (%) | 37 (11.0) | 22 (12.8) |
| | p-value [3] | | 0.5973 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.87 (0.510,1.474) | |
| PR | Time to death (months) [1] [2] | Median (95% CI) | NE (25.3,NE) | NE (26.1,NE) |
| | Overall | N | 150 | 74 |
| | Censored Observations | n (%) | 114 (76.0) | 57 (77.0) |
| | Event Rate, Overall | n (%) | 36 (24.0) | 17 (23.0) |
| | p-value [3] | | 0.7853 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.92 (0.516,1.647) | |

[1] Time to death is defined as the date of randomization to the date of death by any cause. Patients known to be alive were censored at the last known survival follow-up date.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.18
Overall Survival by Fixed and Individualized Starting Dose Subgroup
(ITT Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Fixed | Time to death (months) [1] [2] | Median (95% CI) | NE (33.6,NE) | NE (NE,NE) |
| | Overall | N | 317 | 158 |
| | Censored Observations | n (%) | 265 (83.6) | 130 (82.3) |
| | Event Rate, Overall | n (%) | 52 (16.4) | 28 (17.7) |
| | p-value [3] | | 0.7243 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.92 (0.580,1.461) | |
| Individualized | Time to death (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 170 | 88 |
| | Censored Observations | n (%) | 149 (87.6) | 77 (87.5) |
| | Event Rate, Overall | n (%) | 21 (12.4) | 11 (12.5) |
| | p-value [3] | | 0.5795 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.81 (0.388,1.698) | |

[1] Time to death is defined as the date of randomization to the date of death by any cause. Patients known to be alive were censored at the last known survival follow-up date.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.42
Progression-Free Survival by Investigator Assessment by Age Category (ITT Population)

| Age Category | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| < 65 years | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.8 (11.3,16.6) | 8.2 (7.6,11.2) |
| | Overall | N | 297 | 147 |
| | Censored Observations | n (%) | 126 (42.4) | 41 (27.9) |
| | Event Rate, Overall | n (%) | 171 (57.6) | 106 (72.1) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 171 (57.6) | 106 (72.1) |
| | p-value [3] | | 0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.62 (0.488,0.798) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.42
Progression-Free Survival by Investigator Assessment by Age Category (ITT Population)

| Age Category | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| >= 65 years | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.8 (11.0,16.1) | 8.3 (5.6,10.9) |
| | Overall | N | 190 | 99 |
| | Censored Observations | n (%) | 73 (38.4) | 20 (20.2) |
| | Event Rate, Overall | n (%) | 117 (61.6) | 79 (79.8) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 117 (61.6) | 79 (79.8) |
| | p-value [3] | | 0.0003 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.58 (0.427,0.776) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.43
Progression-Free Survival by Investigator Assessment by Race (ITT Population)

| Race | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| White | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.8 (11.8,16.4) | 8.3 (7.6,11.0) |
| | Overall | N | 436 | 219 |
| | Censored Observations | n (%) | 174 (39.9) | 55 (25.1) |
| | Event Rate, Overall | n (%) | 262 (60.1) | 164 (74.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 262 (60.1) | 164 (74.9) |
| | p-value [3] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.66 (0.545,0.808) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.43
Progression-Free Survival by Investigator Assessment by Race (ITT Population)

| Race | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Non-White | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.8 (8.2,28.5) | 7.5 (5.6,9.8) |
| | Overall | N | 51 | 27 |
| | Censored Observations | n (%) | 25 (49.0) | 6 (22.2) |
| | Event Rate, Overall | n (%) | 26 (51.0) | 21 (77.8) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 26 (51.0) | 21 (77.8) |
| | p-value [3] | | 0.0178 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.45 (0.232,0.890) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.44
Progression-Free Survival by Investigator Assessment by ECOG Performance Status (ITT Population)

| ECOG Performance | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| 0 | Progression-free Survival (months) [1] [2] | Median (95% CI) | 14.7 (13.7,16.7) | 8.3 (7.4,10.4) |
| | Overall | N | 337 | 174 |
| | Censored Observations | n (%) | 150 (44.5) | 44 (25.3) |
| | Event Rate, Overall | n (%) | 187 (55.5) | 130 (74.7) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 187 (55.5) | 130 (74.7) |
| | p-value [3] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.62 (0.490,0.773) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.44
Progression-Free Survival by Investigator Assessment by ECOG Performance Status (ITT Population)

| ECOG Performance | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| 1 | Progression-free Survival (months) [1] [2] | Median (95% CI) | 11.1 (8.4,14.3) | 8.1 (5.7,11.7) |
| | Overall | N | 150 | 72 |
| | Censored Observations | n (%) | 49 (32.7) | 17 (23.6) |
| | Event Rate, Overall | n (%) | 101 (67.3) | 55 (76.4) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 101 (67.3) | 55 (76.4) |
| | p-value [3] | | 0.0412 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.70 (0.501,0.990) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.45
Progression-Free Survival by Investigator Assessment by Stage of Disease at Initial Diagnosis (ITT Population)

| Stage of Disease | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| III | Progression-free Survival (months) [1] [2] | Median (95% CI) | 16.5 (13.8,19.5) | 8.3 (7.0,11.0) |
| | Overall | N | 318 | 158 |
| | Censored Observations | n (%) | 148 (46.5) | 38 (24.1) |
| | Event Rate, Overall | n (%) | 170 (53.5) | 120 (75.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 170 (53.5) | 120 (75.9) |
| | p-value [3] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.54 (0.424,0.681) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Stage III included IIIA, IIIB, IIIC, and III not otherwise specified.
Note: NE = Not Evaluable.
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Table 2.45
Progression-Free Survival by Investigator Assessment by Stage of Disease at Initial Diagnosis (ITT Population)

| Stage of Disease | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| IV | Progression-free Survival (months) [1] [2] | Median (95% CI) | 11.2 (8.3,13.8) | 8.2 (6.7,11.0) |
| | Overall | N | 169 | 88 |
| | Censored Observations | n (%) | 51 (30.2) | 23 (26.1) |
| | Event Rate, Overall | n (%) | 118 (69.8) | 65 (73.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 118 (69.8) | 65 (73.9) |
| | p-value [3] | | 0.2905 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.85 (0.620,1.155) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Stage III included IIIA, IIIB, IIIC, and III not otherwise specified.
Note: NE = Not Evaluable.
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Table 2.46
Progression-Free Survival by Investigator Assessment by Primary Tumor Site (ITT Population)

| Primary Tumor Site | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Ovarian | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.9 (11.8,16.5) | 8.3 (7.2,11.0) |
| | Overall | N | 388 | 201 |
| | Censored Observations | n (%) | 166 (42.8) | 50 (24.9) |
| | Event Rate, Overall | n (%) | 222 (57.2) | 151 (75.1) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 222 (57.2) | 151 (75.1) |
| | p-value [3] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.61 (0.497,0.754) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.46
Progression-Free Survival by Investigator Assessment by Primary Tumor Site (ITT Population)

| Primary Tumor Site | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Primary Peritoneal | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.6 (7.7,19.1) | 12.6 (5.6,19.4) |
| | Overall | N | 34 | 13 |
| | Censored Observations | n (%) | 10 (29.4) | 3 (23.1) |
| | Event Rate, Overall | n (%) | 24 (70.6) | 10 (76.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 24 (70.6) | 10 (76.9) |
| | p-value [3] | | 0.6998 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.22 (0.440,3.401) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.46
Progression-Free Survival by Investigator Assessment by Primary Tumor Site (ITT Population)

| Primary Tumor Site | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Fallopian Tube | Progression-free Survival (months) [1] [2] | Median (95% CI) | 12.5 (8.3,16.7) | 8.1 (5.6,8.3) |
| | Overall | N | 65 | 32 |
| | Censored Observations | n (%) | 23 (35.4) | 8 (25.0) |
| | Event Rate, Overall | n (%) | 42 (64.6) | 24 (75.0) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 42 (64.6) | 24 (75.0) |
| | p-value [3] | | 0.1540 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.68 (0.394,1.161) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.47
Progression-Free Survival by Investigator Assessment by Neoadjuvant Chemotherapy According to Randomization (ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Yes | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.8 (11.2,16.4) | 8.2 (7.3,10.9) |
| | Overall | N | 326 | 165 |
| | Censored Observations | n (%) | 132 (40.5) | 43 (26.1) |
| | Event Rate, Overall | n (%) | 194 (59.5) | 122 (73.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 194 (59.5) | 122 (73.9) |
| | p-value [3] | | 0.0003 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.66 (0.524,0.827) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR) and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.47
Progression-Free Survival by Investigator Assessment by Neoadjuvant Chemotherapy According to Randomization (ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| No | Progression-free Survival (months) [1] [2] | Median (95% CI) | 14.3 (11.1,16.6) | 8.3 (6.8,11.3) |
| | Overall | N | 161 | 81 |
| | Censored Observations | n (%) | 67 (41.6) | 18 (22.2) |
| | Event Rate, Overall | n (%) | 94 (58.4) | 63 (77.8) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 94 (58.4) | 63 (77.8) |
| | p-value [3] | | 0.0012 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.59 (0.429,0.817) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR) and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.48
Progression-Free Survival by Investigator Assessment by Best Response to First Platinum Regimen According to Randomization (ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| CR | Progression-free Survival (months) [1] [2] | Median (95% CI) | 16.6 (14.0,19.5) | 10.8 (7.9,13.7) |
| | Overall | N | 327 | 165 |
| | Censored Observations | n (%) | 149 (45.6) | 45 (27.3) |
| | Event Rate, Overall | n (%) | 178 (54.4) | 120 (72.7) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 178 (54.4) | 120 (72.7) |
| | p-value [3] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.61 (0.483,0.771) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.48
Progression-Free Survival by Investigator Assessment by Best Response to First Platinum Regimen According to Randomization (ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| PR | Progression-free Survival (months) [1] [2] | Median (95% CI) | 8.5 (8.0,11.1) | 6.8 (5.6,8.2) |
| | Overall | N | 160 | 81 |
| | Censored Observations | n (%) | 50 (31.3) | 16 (19.8) |
| | Event Rate, Overall | n (%) | 110 (68.8) | 65 (80.2) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 110 (68.8) | 65 (80.2) |
| | p-value [3] | | 0.0147 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.68 (0.501,0.930) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.49
Progression-Free Survival by Investigator Assessment by Neoadjuvant Chemotherapy According to eCRF (ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Yes | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.8 (11.2,16.1) | 8.0 (7.0,9.7) |
| | Overall | N | 322 | 167 |
| | Censored Observations | n (%) | 127 (39.4) | 42 (25.1) |
| | Event Rate, Overall | n (%) | 195 (60.6) | 125 (74.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 195 (60.6) | 125 (74.9) |
| | p-value [3] | | 0.0002 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.66 (0.523,0.824) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.49
Progression-Free Survival by Investigator Assessment by Neoadjuvant Chemotherapy According to eCRF (ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| No | Progression-free Survival (months) [1] [2] | Median (95% CI) | 15.2 (11.8,16.6) | 9.0 (7.0,13.6) |
| | Overall | N | 165 | 79 |
| | Censored Observations | n (%) | 72 (43.6) | 19 (24.1) |
| | Event Rate, Overall | n (%) | 93 (56.4) | 60 (75.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 93 (56.4) | 60 (75.9) |
| | p-value [3] | | 0.0021 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.60 (0.434,0.835) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.50
Progression-Free Survival by Investigator Assessment by Best Response to First Platinum Regimen
According to eCRF (ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| CR | Progression-free Survival (months) [1] [2] | Median (95% CI) | 16.6 (14.2,19.6) | 11.0 (8.2,13.7) |
| | Overall | N | 337 | 172 |
| | Censored Observations | n (%) | 156 (46.3) | 50 (29.1) |
| | Event Rate, Overall | n (%) | 181 (53.7) | 122 (70.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 181 (53.7) | 122 (70.9) |
| | p-value [3] | | 0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.64 (0.505,0.801) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.50
Progression-Free Survival by Investigator Assessment by Best Response to First Platinum Regimen
According to eCRF (ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| PR | Progression-free Survival (months) [1] [2] | Median (95% CI) | 8.4 (7.9,11.0) | 5.7 (5.0,8.0) |
| | Overall | N | 150 | 74 |
| | Censored Observations | n (%) | 43 (28.7) | 11 (14.9) |
| | Event Rate, Overall | n (%) | 107 (71.3) | 63 (85.1) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 107 (71.3) | 63 (85.1) |
| | p-value [3] | | 0.0007 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.58 (0.425,0.800) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.51
Progression-Free Survival by Investigator Assessment in tBRCA Subgroup (ITT Population)

| tBRCA status Subtype | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| tBRCAmut | Progression-free Survival (months) [1] [2] | Median (95% CI) | 24.8 (18.7,NE) | 11.5 (8.4,16.6) |
| | Overall | N | 152 | 71 |
| | Censored Observations | n (%) | 85 (55.9) | 20 (28.2) |
| | Event Rate, Overall | n (%) | 67 (44.1) | 51 (71.8) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 67 (44.1) | 51 (71.8) |
| | p-value [3] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.43 (0.297,0.620) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd for tBRCAwt subgroup only).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.51
Progression-Free Survival by Investigator Assessment in tBRCA Subgroup (ITT Population)

| tBRCA status Subtype | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| tBRCAwt | Progression-free Survival (months) [1] [2] | Median (95% CI) | 11.0 (8.5,12.2) | 7.6 (5.7,8.3) |
| | Overall | N | 310 | 163 |
| | Censored Observations | n (%) | 103 (33.2) | 37 (22.7) |
| | Event Rate, Overall | n (%) | 207 (66.8) | 126 (77.3) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 207 (66.8) | 126 (77.3) |
| | p-value [3] | | 0.0035 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.72 (0.572,0.897) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd for tBRCAwt subgroup only).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.52
Progression-Free Survival by Investigator Assessment by Baseline CA-125 Level (ITT Population)

| Baseline CA-125 | Parameter | Statistic | Niraparib (N=484) | Placebo (N=244) |
|---|---|---|---|---|
| <=ULN | Progression-free Survival (months) [1] [2] | Median (95% CI) | 14.7 (13.8,16.6) | 8.4 (7.9,11.2) |
| | Overall | N | 450 | 226 |
| | Censored Observations | n (%) | 194 (43.1) | 58 (25.7) |
| | Event Rate, Overall | n (%) | 256 (56.9) | 168 (74.3) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 256 (56.9) | 168 (74.3) |
| | p-value [3] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.62 (0.508,0.753) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.52
Progression-Free Survival by Investigator Assessment by Baseline CA-125 Level (ITT Population)

| Baseline CA-125 | Parameter | Statistic | Niraparib (N=484) | Placebo (N=244) |
|---|---|---|---|---|
| >ULN | Progression-free Survival (months) [1] [2] | Median (95% CI) | 4.2 (2.8,5.8) | 2.9 (2.1,5.3) |
| | Overall | N | 34 | 18 |
| | Censored Observations | n (%) | 2 (5.9) | 1 (5.6) |
| | Event Rate, Overall | n (%) | 32 (94.1) | 17 (94.4) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 32 (94.1) | 17 (94.4) |
| | p-value [3] | | 0.6362 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.87 (0.432,1.764) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.54
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| HRDpos | Progression-free Survival (months) [1] [2] | Median (95% CI) | 24.2 (16.7,NE) | 11.2 (8.4,13.7) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.87 (0.82,0.91) | 0.74 (0.65,0.81) |
| | 12-month | | 0.70 (0.64,0.76) | 0.47 (0.38,0.55) |
| | 18-month | | 0.56 (0.50,0.63) | 0.34 (0.26,0.43) |
| | 24-month | | 0.51 (0.44,0.58) | 0.24 (0.16,0.34) |
| | 30-month | | 0.45 (0.36,0.53) | 0.16 (0.07,0.29) |
| | Overall | N | 247 | 126 |
| | Censored Observations | n (%) | 138 (55.9) | 36 (28.6) |
| | Event Rate, Overall | n (%) | 109 (44.1) | 90 (71.4) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 109 (44.1) | 90 (71.4) |
| | p-value [4] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.48 (0.360,0.632) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Where the last observation within a treatment and subgroup is an event prior to a time point, the SDF is missing at subsequent time points.
Note: NE = Not Evaluable.
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Table 2.54
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| tBRCAmut | Progression-free Survival (months) [1] [2] | Median (95% CI) | 24.8 (18.7,NE) | 11.5 (8.4,16.6) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.90 (0.84,0.94) | 0.75 (0.63,0.84) |
| | 12-month | | 0.74 (0.67,0.81) | 0.50 (0.37,0.61) |
| | 18-month | | 0.59 (0.51,0.67) | 0.34 (0.23,0.46) |
| | 24-month | | 0.54 (0.45,0.63) | 0.25 (0.15,0.36) |
| | 30-month | | 0.45 (0.34,0.56) | 0.19 (0.08,0.33) |
| | Overall | N | 152 | 71 |
| | Censored Observations | n (%) | 85 (55.9) | 20 (28.2) |
| | Event Rate, Overall | n (%) | 67 (44.1) | 51 (71.8) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 67 (44.1) | 51 (71.8) |
| | p-value [4] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.43 (0.297,0.620) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Where the last observation within a treatment and subgroup is an event prior to a time point, the SDF is missing at subsequent time points.
Note: NE = Not Evaluable.
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Table 2.54
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| non-tBRCAmut and HRDpos | Progression-free Survival (months) [1] [2] | Median (95% CI) | 19.4 (12.5,NE) | 10.4 (7.0,13.7) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.83 (0.73,0.90) | 0.73 (0.59,0.83) |
| | 12-month | | 0.62 (0.51,0.72) | 0.44 (0.30,0.56) |
| | 18-month | | 0.52 (0.41,0.62) | 0.34 (0.22,0.47) |
| | 24-month | | 0.45 (0.32,0.56) | 0.25 (0.13,0.40) |
| | 30-month | | 0.45 (0.32,0.56) | 0.13 (0.01,0.37) |
| | Overall | N | 95 | 55 |
| | Censored Observations | n (%) | 53 (55.8) | 16 (29.1) |
| | Event Rate, Overall | n (%) | 42 (44.2) | 39 (70.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 42 (44.2) | 39 (70.9) |
| | p-value [4] | | 0.0151 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.58 (0.372,0.905) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Where the last observation within a treatment and subgroup is an event prior to a time point, the SDF is missing at subsequent time points.
Note: NE = Not Evaluable.
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Table 2.54
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| HRDneg | Progression-free Survival (months) [1] [2] | Median (95% CI) | 8.3 (7.2,10.5) | 5.4 (4.5,7.0) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.59 (0.51,0.66) | 0.44 (0.33,0.55) |
| | 12-month | | 0.35 (0.27,0.42) | 0.25 (0.16,0.35) |
| | 18-month | | 0.23 (0.17,0.30) | 0.17 (0.10,0.26) |
| | 24-month | | 0.17 (0.11,0.25) | 0.09 (0.03,0.18) |
| | 30-month | | | 0.09 (0.03,0.18) |
| | Overall | N | 169 | 80 |
| | Censored Observations | n (%) | 39 (23.1) | 12 (15.0) |
| | Event Rate, Overall | n (%) | 130 (76.9) | 68 (85.0) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 130 (76.9) | 68 (85.0) |
| | p-value [4] | | 0.0015 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.62 (0.456,0.835) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Where the last observation within a treatment and subgroup is an event prior to a time point, the SDF is missing at subsequent time points.
Note: NE = Not Evaluable.
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Table 2.54
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| HRDnd | Progression-free Survival (months) [1] [2] | Median (95% CI) | 11.0 (7.8,14.2) | 8.3 (5.7,16.5) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.73 (0.61,0.82) | 0.67 (0.50,0.79) |
| | 12-month | | 0.45 (0.33,0.57) | 0.43 (0.27,0.58) |
| | 18-month | | 0.31 (0.20,0.42) | 0.35 (0.20,0.50) |
| | 24-month | | 0.23 (0.12,0.35) | 0.14 (0.01,0.40) |
| | 30-month | | | 0.14 (0.01,0.40) |
| | Overall | N | 71 | 40 |
| | Censored Observations | n (%) | 22 (31.0) | 13 (32.5) |
| | Event Rate, Overall | n (%) | 49 (69.0) | 27 (67.5) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 49 (69.0) | 27 (67.5) |
| | p-value [4] | | 0.9654 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 1.01 (0.622,1.637) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Where the last observation within a treatment and subgroup is an event prior to a time point, the SDF is missing at subsequent time points.
Note: NE = Not Evaluable.
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Table 2.69
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Neoadjuvant Chemotherapy According to eCRF (ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Yes | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (28.7,NE) | NE (27.5,NE) |
| | Overall | N | 322 | 167 |
| | Censored Observations | n (%) | 227 (70.5) | 116 (69.5) |
| | Event Rate, Overall | n (%) | 95 (29.5) | 51 (30.5) |
| | Death | n (%) | 24 (7.5) | 11 (6.6) |
| | Progression | n (%) | 71 (22.0) | 40 (24.0) |
| | p-value [3] | | 0.5698 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.91 (0.643,1.275) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.69
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Neoadjuvant Chemotherapy According to eCRF (ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| No | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | 31.3 (26.2,NE) | NE (23.9,NE) |
| | Overall | N | 165 | 79 |
| | Censored Observations | n (%) | 121 (73.3) | 57 (72.2) |
| | Event Rate, Overall | n (%) | 44 (26.7) | 22 (27.8) |
| | Death | n (%) | 15 (9.1) | 3 (3.8) |
| | Progression | n (%) | 29 (17.6) | 19 (24.1) |
| | p-value [3] | | 0.3245 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.77 (0.461,1.293) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.70
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Best Response to First Platinum Regimen According to eCRF (ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| CR | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (31.3,NE) | NE (NE,NE) |
| | Overall | N | 337 | 172 |
| | Censored Observations | n (%) | 260 (77.2) | 128 (74.4) |
| | Event Rate, Overall | n (%) | 77 (22.8) | 44 (25.6) |
| | Death | n (%) | 16 (4.7) | 6 (3.5) |
| | Progression | n (%) | 61 (18.1) | 38 (22.1) |
| | p-value [3] | | 0.3009 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.82 (0.566,1.193) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.70
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Best Response to First Platinum Regimen According to eCRF (ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| PR | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | 22.2 (19.0,NE) | 23.9 (16.1,NE) |
| | Overall | N | 150 | 74 |
| | Censored Observations | n (%) | 88 (58.7) | 45 (60.8) |
| | Event Rate, Overall | n (%) | 62 (41.3) | 29 (39.2) |
| | Death | n (%) | 23 (15.3) | 8 (10.8) |
| | Progression | n (%) | 39 (26.0) | 21 (28.4) |
| | p-value [3] | | 0.7971 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.94 (0.605,1.472) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.72
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Fixed and Individualized Starting Dose Subgroup (ITT Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Fixed | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (28.7,NE) | NE (24.4,NE) |
| | Overall | N | 317 | 158 |
| | Censored Observations | n (%) | 222 (70.0) | 102 (64.6) |
| | Event Rate, Overall | n (%) | 95 (30.0) | 56 (35.4) |
| | Death | n (%) | 27 (8.5) | 8 (5.1) |
| | Progression | n (%) | 68 (21.5) | 48 (30.4) |
| | p-value [3] | | 0.1631 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.79 (0.566, 1.102) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.72
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Fixed and Individualized Starting Dose Subgroup (ITT Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Individualized | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 170 | 88 |
| | Censored Observations | n (%) | 126 (74.1) | 71 (80.7) |
| | Event Rate, Overall | n (%) | 44 (25.9) | 17 (19.3) |
| | Death | n (%) | 12 (7.1) | 6 (6.8) |
| | Progression | n (%) | 32 (18.8) | 11 (12.5) |
| | p-value [3] | | 0.6724 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.13 (0.639, 2.003) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.87
Time to First Subsequent Therapy by Neoadjuvant Chemotherapy According to eCRF
(ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Yes | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 16.0 (14.5,20.5) | 11.9 (9.7,14.4) |
| | Overall | N | 322 | 167 |
| | Censored Observations | n (%) | 145 (45.0) | 58 (34.7) |
| | Event Rate, Overall | n (%) | 177 (55.0) | 109 (65.3) |
| | p-value [3] | | 0.0061 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.72 (0.563,0.910) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.87
Time to First Subsequent Therapy by Neoadjuvant Chemotherapy According to eCRF
(ITT Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| No | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 19.4 (15.6,25.6) | 12.2 (9.2,17.5) |
| | Overall | N | 165 | 79 |
| | Censored Observations | n (%) | 83 (50.3) | 30 (38.0) |
| | Event Rate, Overall | n (%) | 82 (49.7) | 49 (62.0) |
| | p-value [3] | | 0.0106 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.63 (0.442,0.900) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.88
Time to First Subsequent Therapy by Best Response to First Platinum Regimen
According to eCRF (ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| CR | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 21.9 (17.6,25.2) | 13.9 (11.8,17.1) |
| | Overall | N | 337 | 172 |
| | Censored Observations | n (%) | 175 (51.9) | 67 (39.0) |
| | Event Rate, Overall | n (%) | 162 (48.1) | 105 (61.0) |
| | p-value [3] | | 0.0007 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.65 (0.510,0.836) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.88
Time to First Subsequent Therapy by Best Response to First Platinum Regimen
According to eCRF (ITT Population)

| Best Response | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| PR | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 11.6 (10.2,14.6) | 9.1 (7.1,11.1) |
| | Overall | N | 150 | 74 |
| | Censored Observations | n (%) | 53 (35.3) | 21 (28.4) |
| | Event Rate, Overall | n (%) | 97 (64.7) | 53 (71.6) |
| | p-value [3] | | 0.0478 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.71 (0.509,0.998) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.90
Time to First Subsequent Therapy by Fixed and Individualized Starting Dose Subgroup
(ITT Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Fixed | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 18.3 (15.5,23.2) | 12.0 (9.7,14.4) |
| | Overall | N | 317 | 158 |
| | Censored Observations | n (%) | 148 (46.7) | 54 (34.2) |
| | Event Rate, Overall | n (%) | 169 (53.3) | 104 (65.8) |
| | p-value [3] | | 0.0013 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.67 (0.523,0.856) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.90
Time to First Subsequent Therapy by Fixed and Individualized Starting Dose Subgroup
(ITT Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Individualized | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 16.0 (13.3,NE) | 11.7 (8.7,14.9) |
| | Overall | N | 170 | 88 |
| | Censored Observations | n (%) | 80 (47.1) | 34 (38.6) |
| | Event Rate, Overall | n (%) | 90 (52.9) | 54 (61.4) |
| | p-value [3] | | 0.0879 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.74 (0.527,1.046) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.11
Overall Survival by Neoadjuvant Chemotherapy According to eCRF (ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Yes | Time to death (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 145 | 75 |
| | Censored Observations | n (%) | 124 (85.5) | 66 (88.0) |
| | Event Rate, Overall | n (%) | 21 (14.5) | 9 (12.0) |
| | p-value [3] | | 0.5708 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.26 (0.571,2.763) | |
| No | Time to death (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 83 | 49 |
| | Censored Observations | n (%) | 75 (90.4) | 42 (85.7) |
| | Event Rate, Overall | n (%) | 8 (9.6) | 7 (14.3) |
| | p-value [3] | | 0.2846 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.58 (0.209,1.599) | |

[1] Time to death is defined as the date of randomization to the date of death by any cause. Patients known to be alive were censored at the last known survival follow-up date.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.12
Overall Survival by Best Response to First Platinum Regimen According to eCRF
(ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| CR | Time to death (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 149 | 84 |
| | Censored Observations | n (%) | 139 (93.3) | 74 (88.1) |
| | Event Rate, Overall | n (%) | 10 (6.7) | 10 (11.9) |
| | p-value [3] | | 0.2625 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.61 (0.252,1.465) | |
| PR | Time to death (months) [1] [2] | Median (95% CI) | 25.3 (25.3,NE) | NE (NE,NE) |
| | Overall | N | 79 | 40 |
| | Censored Observations | n (%) | 60 (75.9) | 34 (85.0) |
| | Event Rate, Overall | n (%) | 19 (24.1) | 6 (15.0) |
| | p-value [3] | | 0.3714 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.52 (0.603,3.822) | |

[1] Time to death is defined as the date of randomization to the date of death by any cause. Patients known to be alive were censored at the last known survival follow-up date.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.14
Overall Survival by Fixed and Individualized Starting Dose Subgroup (ITT-GVD Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Fixed | Time to death (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 72 | 42 |
| | Censored Observations | n (%) | 63 (87.5) | 36 (85.7) |
| | Event Rate, Overall | n (%) | 9 (12.5) | 6 (14.3) |
| | p-value [3] | | 0.9639 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.03 (0.349,3.008) | |
| Individualized | Time to death (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 156 | 82 |
| | Censored Observations | n (%) | 136 (87.2) | 72 (87.8) |
| | Event Rate, Overall | n (%) | 20 (12.8) | 10 (12.2) |
| | p-value [3] | | 0.7793 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.90 (0.417,1.928) | |

[1] Time to death is defined as the date of randomization to the date of death by any cause. Patients known to be alive were censored at the last known survival follow-up date.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.30
Progression-Free Survival by Investigator Assessment by Race (ITT-GVD Population)

| Race | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| White | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.8 (11.0,16.6) | 8.3 (7.3,11.0) |
| | Overall | N | 205 | 110 |
| | Censored Observations | n (%) | 87 (42.4) | 27 (24.5) |
| | Event Rate, Overall | n (%) | 118 (57.6) | 83 (75.5) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 118 (57.6) | 83 (75.5) |
| | p-value [3] | | 0.0021 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.64 (0.478,0.851) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.30
Progression-Free Survival by Investigator Assessment by Race (ITT-GVD Population)

| Race | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Non-White | Progression-free Survival (months) [1] [2] | Median (95% CI) | 16.1 (8.3,NE) | 7.7 (2.8,NE) |
| | Overall | N | 23 | 14 |
| | Censored Observations | n (%) | 13 (56.5) | 5 (35.7) |
| | Event Rate, Overall | n (%) | 10 (43.5) | 9 (64.3) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 10 (43.5) | 9 (64.3) |
| | p-value [3] | | 0.1610 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.44 (0.137,1.419) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.31
Progression-Free Survival by Investigator Assessment by ECOG Performance Status (ITT-GVD Population)

| ECOG Performance | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| 0 | Progression-free Survival (months) [1] [2] | Median (95% CI) | 16.4 (12.2,19.6) | 8.3 (6.8,11.2) |
| | Overall | N | 154 | 83 |
| | Censored Observations | n (%) | 75 (48.7) | 20 (24.1) |
| | Event Rate, Overall | n (%) | 79 (51.3) | 63 (75.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 79 (51.3) | 63 (75.9) |
| | p-value [3] | | 0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.51 (0.360,0.714) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.31
Progression-Free Survival by Investigator Assessment by ECOG Performance Status (ITT-GVD Population)

| ECOG Performance | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| 1 | Progression-free Survival (months) [1] [2] | Median (95% CI) | 11.0 (6.8,14.0) | 8.1 (5.7,11.5) |
| | Overall | N | 74 | 41 |
| | Censored Observations | n (%) | 25 (33.8) | 12 (29.3) |
| | Event Rate, Overall | n (%) | 49 (66.2) | 29 (70.7) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 49 (66.2) | 29 (70.7) |
| | p-value [3] | | 0.6908 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.91 (0.564,1.468) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.32
Progression-Free Survival by Investigator Assessment by Stage of Disease at Initial Diagnosis (ITT-GVD Population)

| Stage of Disease | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| III | Progression-free Survival (months) [1] [2] | Median (95% CI) | 16.6 (12.2,19.6) | 7.6 (6.5,9.4) |
| | Overall | N | 155 | 80 |
| | Censored Observations | n (%) | 76 (49.0) | 19 (23.8) |
| | Event Rate, Overall | n (%) | 79 (51.0) | 61 (76.3) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 79 (51.0) | 61 (76.3) |
| | p-value [3] | | 0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.51 (0.357,0.714) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Stage III included IIIA, IIIB, IIIC, and III not otherwise specified.
Note: NE = Not Evaluable.
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Table 2.32
Progression-Free Survival by Investigator Assessment by Stage of Disease at Initial Diagnosis (ITT-GVD Population)

| Stage of Disease | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| IV | Progression-free Survival (months) [1] [2] | Median (95% CI) | 11.0 (7.9,13.9) | 9.7 (8.1,12.7) |
| | Overall | N | 73 | 44 |
| | Censored Observations | n (%) | 24 (32.9) | 13 (29.5) |
| | Event Rate, Overall | n (%) | 49 (67.1) | 31 (70.5) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 49 (67.1) | 31 (70.5) |
| | p-value [3] | | 0.5307 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.85 (0.528,1.377) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: Stage III included IIIA, IIIB, IIIC, and III not otherwise specified.
Note: NE = Not Evaluable.
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Table 2.33
Progression-Free Survival by Investigator Assessment by Primary Tumor Site (ITT-GVD Population)

| Primary Tumor Site | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Ovarian | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.9 (10.9,16.6) | 8.2 (6.5,10.9) |
| | Overall | N | 187 | 99 |
| | Censored Observations | n (%) | 85 (45.5) | 24 (24.2) |
| | Event Rate, Overall | n (%) | 102 (54.5) | 75 (75.8) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 102 (54.5) | 75 (75.8) |
| | p-value [3] | | 0.0006 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.59 (0.439,0.806) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.33
Progression-Free Survival by Investigator Assessment by Primary Tumor Site (ITT-GVD Population)

| Primary Tumor Site | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Primary Peritoneal | Progression-free Survival (months) [1] [2] | Median (95% CI) | 14.3 (7.8,NE) | 18.5 (1.8,NE) |
| | Overall | N | 18 | 8 |
| | Censored Observations | n (%) | 7 (38.9) | 3 (37.5) |
| | Event Rate, Overall | n (%) | 11 (61.1) | 5 (62.5) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 11 (61.1) | 5 (62.5) |
| | p-value [3] | | 0.7004 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.32 (0.321,5.410) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.33
Progression-Free Survival by Investigator Assessment by Primary Tumor Site (ITT-GVD Population)

| Primary Tumor Site | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Fallopian Tube | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.8 (7.3,19.4) | 8.2 (6.1,16.3) |
| | Overall | N | 23 | 17 |
| | Censored Observations | n (%) | 8 (34.8) | 5 (29.4) |
| | Event Rate, Overall | n (%) | 15 (65.2) | 12 (70.6) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 15 (65.2) | 12 (70.6) |
| | p-value [3] | | 0.4218 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.71 (0.306,1.644) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.34
Progression-Free Survival by Investigator Assessment by Neoadjuvant Chemotherapy According to Randomization (ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Yes | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.9 (10.5,16.6) | 8.3 (7.0,12.7) |
| | Overall | N | 146 | 74 |
| | Censored Observations | n (%) | 64 (43.8) | 22 (29.7) |
| | Event Rate, Overall | n (%) | 82 (56.2) | 52 (70.3) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 82 (56.2) | 52 (70.3) |
| | p-value [3] | | 0.0409 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.69 (0.487,0.986) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR) and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.34
Progression-Free Survival by Investigator Assessment by Neoadjuvant Chemotherapy According to Randomization (ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| No | Progression-free Survival (months) [1] [2] | Median (95% CI) | 15.2 (11.1,19.6) | 8.2 (5.7,10.4) |
| | Overall | N | 82 | 50 |
| | Censored Observations | n (%) | 36 (43.9) | 10 (20.0) |
| | Event Rate, Overall | n (%) | 46 (56.1) | 40 (80.0) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 46 (56.1) | 40 (80.0) |
| | p-value [3] | | 0.0020 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.51 (0.330,0.788) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR) and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.35
Progression-Free Survival by Investigator Assessment by Best Response to First Platinum Regimen According to Randomization (ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| CR | Progression-free Survival (months) [1] [2] | Median (95% CI) | 16.5 (12.2,25.7) | 9.0 (7.2,12.7) |
| | Overall | N | 146 | 82 |
| | Censored Observations | n (%) | 72 (49.3) | 21 (25.6) |
| | Event Rate, Overall | n (%) | 74 (50.7) | 61 (74.4) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 74 (50.7) | 61 (74.4) |
| | p-value [3] | | 0.0004 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.54 (0.384,0.766) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.35
Progression-Free Survival by Investigator Assessment by Best Response to First Platinum Regimen According to Randomization (ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| PR | Progression-free Survival (months) [1] [2] | Median (95% CI) | 10.2 (8.2,13.9) | 8.1 (5.7,8.4) |
| | Overall | N | 82 | 42 |
| | Censored Observations | n (%) | 28 (34.1) | 11 (26.2) |
| | Event Rate, Overall | n (%) | 54 (65.9) | 31 (73.8) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 54 (65.9) | 31 (73.8) |
| | p-value [3] | | 0.2227 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.76 (0.482,1.185) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.36

Progression-Free Survival by Investigator Assessment by Neoadjuvant Chemotherapy According to eCRF (ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Yes | Progression-free Survival (months) [1] [2] | Median (95% CI) | 13.9 (10.3,16.6) | 8.2 (6.8,11.2) |
| | Overall | N | 145 | 75 |
| | Censored Observations | n (%) | 63 (43.4) | 21 (28.0) |
| | Event Rate, Overall | n (%) | 82 (56.6) | 54 (72.0) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 82 (56.6) | 54 (72.0) |
| | p-value [3] | | 0.0181 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.66 (0.465,0.934) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.36
Progression-Free Survival by Investigator Assessment by Neoadjuvant Chemotherapy According to eCRF (ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| No | Progression-free Survival (months) [1] [2] | Median (95% CI) | 15.2 (11.1,19.6) | 8.3 (6.5,11.2) |
| | Overall | N | 83 | 49 |
| | Censored Observations | n (%) | 37 (44.6) | 11 (22.4) |
| | Event Rate, Overall | n (%) | 46 (55.4) | 38 (77.6) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 46 (55.4) | 38 (77.6) |
| | p-value [3] | | 0.0120 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.57 (0.370,0.891) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.37
Progression-Free Survival by Investigator Assessment by Best Response to First Platinum Regimen
According to eCRF (ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| CR | Progression-free Survival (months) [1] [2] | Median (95% CI) | 16.5 (12.2,25.7) | 9.7 (7.7,13.7) |
| | Overall | N | 149 | 84 |
| | Censored Observations | n (%) | 74 (49.7) | 25 (29.8) |
| | Event Rate, Overall | n (%) | 75 (50.3) | 59 (70.2) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 75 (50.3) | 59 (70.2) |
| | p-value [3] | | 0.0076 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.63 (0.442,0.886) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.37
Progression-Free Survival by Investigator Assessment by Best Response to First Platinum Regimen
According to eCRF (ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| PR | Progression-free Survival (months) [1] [2] | Median (95% CI) | 10.2 (8.2,13.9) | 6.6 (5.6,8.2) |
| | Overall | N | 79 | 40 |
| | Censored Observations | n (%) | 26 (32.9) | 7 (17.5) |
| | Event Rate, Overall | n (%) | 53 (67.1) | 33 (82.5) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 53 (67.1) | 33 (82.5) |
| | p-value [3] | | 0.0087 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.56 (0.358,0.868) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.39
Progression-Free Survival by Investigator Assessment by Baseline CA-125 Level (ITT-GVD Population)

| Baseline CA-125 | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| <=ULN | Progression-free Survival (months) [1] [2] | Median (95% CI) | 14.5 (11.9,19.1) | 8.3 (7.6,11.2) |
| | Overall | N | 214 | 115 |
| | Censored Observations | n (%) | 98 (45.8) | 32 (27.8) |
| | Event Rate, Overall | n (%) | 116 (54.2) | 83 (72.2) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 116 (54.2) | 83 (72.2) |
| | p-value [3] | | 0.0007 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.61 (0.457,0.812) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.39
Progression-Free Survival by Investigator Assessment by Baseline CA-125 Level (ITT-GVD Population)

| Baseline CA-125 | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| >ULN | Progression-free Survival (months) [1] [2] | Median (95% CI) | 4.0 (2.7,6.6) | 4.9 (1.2,8.5) |
| | Overall | N | 14 | 9 |
| | Censored Observations | n (%) | 2 (14.3) | 0 |
| | Event Rate, Overall | n (%) | 12 (85.7) | 9 (100.0) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 12 (85.7) | 9 (100.0) |
| | p-value [3] | | 0.1433 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.33 (0.068,1.557) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.41
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT-GVD Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| HRDpos | Progression-free Survival (months) [1] [2] | Median (95% CI) | 25.7 (16.6,NE) | 12.1 (9.4,16.1) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.88 (0.80,0.93) | 0.83 (0.70,0.91) |
| | 12-month | | 0.73 (0.64,0.80) | 0.50 (0.36,0.62) |
| | 18-month | | 0.58 (0.48,0.66) | 0.35 (0.22,0.47) |
| | 24-month | | 0.51 (0.39,0.61) | 0.24 (0.12,0.38) |
| | 30-month | | 0.44 (0.29,0.59) | 0.24 (0.12,0.38) |
| | Overall | N | 120 | 56 |
| | Censored Observations | n (%) | 70 (58.3) | 18 (32.1) |
| | Event Rate, Overall | n (%) | 50 (41.7) | 38 (67.9) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 50 (41.7) | 38 (67.9) |
| | p-value [4] | | 0.0003 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.46 (0.302,0.712) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.41
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT-GVD Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| tBRCAmut | Progression-free Survival (months) [1] [2] | Median (95% CI) | 25.7 (16.6,NE) | 11.5 (9.4,14.3) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.90 (0.81,0.95) | 0.83 (0.63,0.92) |
| | 12-month | | 0.81 (0.69,0.88) | 0.48 (0.29,0.65) |
| | 18-month | | 0.61 (0.48,0.71) | 0.27 (0.13,0.44) |
| | 24-month | | 0.58 (0.45,0.69) | 0.19 (0.07,0.35) |
| | 30-month | | 0.48 (0.28,0.66) | 0.19 (0.07,0.35) |
| | Overall | N | 76 | 31 |
| | Censored Observations | n (%) | 47 (61.8) | 8 (25.8) |
| | Event Rate, Overall | n (%) | 29 (38.2) | 23 (74.2) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 29 (38.2) | 23 (74.2) |
| | p-value [4] | | <0.0001 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.33 (0.186,0.570) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.41
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT-GVD Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| non-tBRCAmut and HRDpos | Progression-free Survival (months) [1] [2] | Median (95% CI) | 19.4 (11.1,NE) | 12.1 (7.6,NE) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.83 (0.68,0.92) | 0.84 (0.63,0.94) |
| | 12-month | | 0.60 (0.43,0.73) | 0.52 (0.31,0.69) |
| | 18-month | | 0.52 (0.36,0.66) | 0.44 (0.24,0.62) |
| | 24-month | | 0.36 (0.16,0.57) | 0.29 (0.07,0.56) |
| | 30-month | | 0.36 (0.16,0.57) | 0.29 (0.07,0.56) |
| | Overall | N | 44 | 25 |
| | Censored Observations | n (%) | 23 (52.3) | 10 (40.0) |
| | Event Rate, Overall | n (%) | 21 (47.7) | 15 (60.0) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 21 (47.7) | 15 (60.0) |
| | p-value [4] | | 0.2865 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.69 (0.347,1.370) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.41
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT-GVD Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| HRDneg | Progression-free Survival (months) [1] [2] | Median (95% CI) | 7.3 (5.6,9.7) | 5.7 (4.6,7.6) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.52 (0.40,0.63) | 0.49 (0.34,0.63) |
| | 12-month | | 0.29 (0.19,0.39) | 0.21 (0.10,0.34) |
| | 18-month | | 0.23 (0.14,0.33) | 0.14 (0.06,0.26) |
| | 24-month | | 0.21 (0.12,0.31) | 0.08 (0.02,0.20) |
| | 30-month | | 0.21 (0.12,0.31) | 0.08 (0.02,0.20) |
| | Overall | N | 77 | 45 |
| | Censored Observations | n (%) | 20 (26.0) | 6 (13.3) |
| | Event Rate, Overall | n (%) | 57 (74.0) | 39 (86.7) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 57 (74.0) | 39 (86.7) |
| | p-value [4] | | 0.0247 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.62 (0.408,0.948) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.41
Progression-Free Survival by Investigator Assessment in HRD subgroup (ITT-GVD Population)

| HRD Status Subtype | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| HRDnd | Progression-free Survival (months) [1] [2] | Median (95% CI) | 11.0 (7.4,13.9) | 7.7 (5.6,13.7) |
| | Survival Distribution Function (SDF) [3] | SDF (95% CI) | | |
| | 6-month | | 0.79 (0.59,0.90) | 0.59 (0.36,0.76) |
| | 12-month | | 0.39 (0.22,0.57) | 0.35 (0.16,0.54) |
| | 18-month | | 0.25 (0.11,0.42) | 0.30 (0.12,0.50) |
| | 24-month | | 0.25 (0.11,0.42) | 0.30 (0.12,0.50) |
| | 30-month | | 0.25 (0.11,0.42) | 0.30 (0.12,0.50) |
| | Overall | N | 31 | 23 |
| | Censored Observations | n (%) | 10 (32.3) | 8 (34.8) |
| | Event Rate, Overall | n (%) | 21 (67.7) | 15 (65.2) |
| | Death | n (%) | 0 | 0 |
| | Progression | n (%) | 21 (67.7) | 15 (65.2) |
| | p-value [4] | | 0.3899 | |
| | Hazard Ratio, Niraparib:Placebo [5] | HR (95% CI) | 0.70 (0.336,1.474) | |

[1] Progression-free Survival is defined as the time in months from the date of randomization to progression or death. See section 1.2.5.1 of the statistical analysis plan for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] SDF estimates from product-limit method. Confidence intervals constructed using log-log transformation.
[4] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR).
[5] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.65
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Neoadjuvant Chemotherapy According to eCRF (ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Yes | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (25.3,NE) | NE (23.1,NE) |
| | Overall | N | 145 | 75 |
| | Censored Observations | n (%) | 105 (72.4) | 57 (76.0) |
| | Event Rate, Overall | n (%) | 40 (27.6) | 18 (24.0) |
| | Death | n (%) | 11 (7.6) | 7 (9.3) |
| | Progression | n (%) | 29 (20.0) | 11 (14.7) |
| | p-value [3] | | 0.3690 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.30 (0.733,2.302) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.65
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Neoadjuvant Chemotherapy According to eCRF (ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| No | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (24.3,NE) | NE (25.6,NE) |
| | Overall | N | 83 | 49 |
| | Censored Observations | n (%) | 63 (75.9) | 36 (73.5) |
| | Event Rate, Overall | n (%) | 20 (24.1) | 13 (26.5) |
| | Death | n (%) | 8 (9.6) | 3 (6.1) |
| | Progression | n (%) | 12 (14.5) | 10 (20.4) |
| | p-value [3] | | 0.4092 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.74 (0.365,1.509) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.66
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Best Response to First Platinum Regimen According to eCRF (ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| CR | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (27.2,NE) | NE (NE,NE) |
| | Overall | N | 149 | 84 |
| | Censored Observations | n (%) | 117 (78.5) | 64 (76.2) |
| | Event Rate, Overall | n (%) | 32 (21.5) | 20 (23.8) |
| | Death | n (%) | 4 (2.7) | 5 (6.0) |
| | Progression | n (%) | 28 (18.8) | 15 (17.9) |
| | p-value [3] | | 0.7339 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.91 (0.517,1.593) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.66
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Best Response to First Platinum Regimen According to eCRF (ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| PR | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | 25.3 (20.7,NE) | 25.6 (23.1,NE) |
| | Overall | N | 79 | 40 |
| | Censored Observations | n (%) | 51 (64.6) | 29 (72.5) |
| | Event Rate, Overall | n (%) | 28 (35.4) | 11 (27.5) |
| | Death | n (%) | 15 (19.0) | 5 (12.5) |
| | Progression | n (%) | 13 (16.5) | 6 (15.0) |
| | p-value [3] | | 0.4137 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.35 (0.654,2.797) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.68
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Fixed and Individualized Starting Dose Subgroup (ITT-GVD Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Fixed | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (27.2,NE) | NE (18.7,NE) |
| | Overall | N | 72 | 42 |
| | Censored Observations | n (%) | 53 (73.6) | 26 (61.9) |
| | Event Rate, Overall | n (%) | 19 (26.4) | 16 (38.1) |
| | Death | n (%) | 8 (11.1) | 4 (9.5) |
| | Progression | n (%) | 11 (15.3) | 12 (28.6) |
| | p-value [3] | | 0.2889 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.68 (0.339, 1.383) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.68
Progression-Free Survival-2 (PFS2) by Investigator Assessment by Fixed and Individualized Starting Dose Subgroup (ITT-GVD Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Individualized | Progression-free Survival-2 (months) [1] [2] | Median (95% CI) | NE (NE,NE) | NE (NE,NE) |
| | Overall | N | 156 | 82 |
| | Censored Observations | n (%) | 115 (73.7) | 67 (81.7) |
| | Event Rate, Overall | n (%) | 41 (26.3) | 15 (18.3) |
| | Death | n (%) | 11 (7.1) | 6 (7.3) |
| | Progression | n (%) | 30 (19.2) | 9 (11.0) |
| | p-value [3] | | 0.4396 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 1.27 (0.694, 2.323) | |

[1] PFS2 is defined as the date of randomization in the current study to the earlier date of assessment of progression on the next anti-cancer therapy following study treatment or death by any cause. See section 1.2.5.3 of the SAP for censoring conventions.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.83
Time to First Subsequent Therapy by Neoadjuvant Chemotherapy According to eCRF
(ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Yes | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 16.0 (12.3,NE) | 13.1 (8.7,14.9) |
| | Overall | N | 145 | 75 |
| | Censored Observations | n (%) | 69 (47.6) | 27 (36.0) |
| | Event Rate, Overall | n (%) | 76 (52.4) | 48 (64.0) |
| | p-value [3] | | 0.1525 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.77 (0.532,1.104) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.83
Time to First Subsequent Therapy by Neoadjuvant Chemotherapy According to eCRF
(ITT-GVD Population)

| Neoadjuvant Chemotherapy | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| No | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 19.7 (14.6,NE) | 10.4 (8.8,14.2) |
| | Overall | N | 83 | 49 |
| | Censored Observations | n (%) | 43 (51.8) | 16 (32.7) |
| | Event Rate, Overall | n (%) | 40 (48.2) | 33 (67.3) |
| | p-value [3] | | 0.0087 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.54 (0.338,0.862) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.84
Time to First Subsequent Therapy by Best Response to First Platinum Regimen
According to eCRF (ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| CR | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 20.5 (15.3,NE) | 13.1 (9.2,15.3) |
| | Overall | N | 149 | 84 |
| | Censored Observations | n (%) | 80 (53.7) | 29 (34.5) |
| | Event Rate, Overall | n (%) | 69 (46.3) | 55 (65.5) |
| | p-value [3] | | 0.0036 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.59 (0.413,0.845) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.84
Time to First Subsequent Therapy by Best Response to First Platinum Regimen
According to eCRF (ITT-GVD Population)

| Best Response | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| PR | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 14.3 (10.4,19.7) | 10.9 (7.9,13.7) |
| | Overall | N | 79 | 40 |
| | Censored Observations | n (%) | 32 (40.5) | 14 (35.0) |
| | Event Rate, Overall | n (%) | 47 (59.5) | 26 (65.0) |
| | p-value [3] | | 0.4055 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.82 (0.503,1.323) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.86
Time to First Subsequent Therapy by Fixed and Individualized Starting Dose Subgroup
(ITT-GVD Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Fixed | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | NE (13.9,NE) | 11.1 (8.8,14.5) |
| | Overall | N | 72 | 42 |
| | Censored Observations | n (%) | 40 (55.6) | 12 (28.6) |
| | Event Rate, Overall | n (%) | 32 (44.4) | 30 (71.4) |
| | p-value [3] | | 0.0025 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.46 (0.272,0.767) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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Table 2.86
Time to First Subsequent Therapy by Fixed and Individualized Starting Dose Subgroup
(ITT-GVD Population)

| Starting Dose Subgroup | Parameter | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Individualized | Time to First Subsequent Therapy (months) [1] [2] | Median (95% CI) | 16.0 (13.3,20.6) | 11.7 (8.7,14.9) |
| | Overall | N | 156 | 82 |
| | Censored Observations | n (%) | 72 (46.2) | 31 (37.8) |
| | Event Rate, Overall | n (%) | 84 (53.8) | 51 (62.2) |
| | p-value [3] | | 0.1459 | |
| | Hazard Ratio, Niraparib:Placebo [4] | HR (95% CI) | 0.77 (0.539,1.095) | |

[1] Time to first subsequent therapy is defined as the time from the date of randomization to the date of first dose of follow-up anti-cancer treatment or death, whichever occurs first. Patients alive and not starting a first follow-up anti-cancer treatment will be censored at the date last known alive.
[2] Quartile estimates from product-limit (Kaplan-Meier) method. Confidence intervals from Brookmeyer and Crowley method with log-log transformation.
[3] Based on stratified log-rank test using randomization stratification factors: Administration of neoadjuvant chemotherapy (yes/no), best response to platinum therapy (CR or PR), and HRD status (HRDpos or HRDneg/HRDnd).
[4] Based on stratified Cox proportional hazards model using randomization stratification factors as above.
Note: NE = Not Evaluable.
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| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Last On-treatment Visit Prior to Progression | Actual | n | 263 | 171 | 434 |
| | | Mean (StdDev) | 25.1 (4.39) | 25.3 (3.92) | 25.2 (4.21) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 23.0, 28.0 | 23.0, 28.0 | 23.0, 28.0 |
| | | Min, Max | 9, 32 | 7, 32 | 7, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| End of Treatment | Actual (All Subjects) | n | 214 | 159 | 373 |
| | | Mean (StdDev) | 23.0 (4.83) | 23.4 (4.70) | 23.2 (4.77) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.0, 26.0 | 21.0, 27.0 | 21.0, 27.0 |
| | | Min, Max | 4, 31 | 4, 32 | 4, 32 |
| | Actual (Subjects with Change at Visit) | n | 209 | 146 | 355 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.2 (4.35) | 25.5 (3.66) | 25.3 (4.08) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 23.0, 28.0 | 24.0, 28.0 | 23.0, 28.0 |
| | | Min, Max | 10, 32 | 14, 32 | 10, 32 |
| | | End of Treatment | | | |
| | | Mean (StdDev) | 23.1 (4.85) | 23.5 (4.73) | 23.2 (4.80) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.0, 26.0 | 21.0, 27.0 | 21.0, 27.0 |
| | | Min, Max | 4, 31 | 4, 32 | 4, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| End of Treatment | Change at Visit | Mean (StdDev) | -2.1 (3.71) | -2.0 (3.49) | -2.1 (3.62) |
| | | Median | -2.0 | -1.0 | -1.3 |
| | | Q1, Q3 | -4.0, 0.0 | -4.0, 0.0 | -4.0, 0.0 |
| | | Min, Max | -14, 8 | -15, 6 | -15, 8 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.46 (0.37, 0.55) |
| | | Delta3 (95% CI) [4] | | | 0.51 (0.41, 0.61) |
| | | LS Mean (SE) | -2.1 (0.24) | -2.0 (0.29) | -2.1 (0.19) |
| | | 95% CI | -2.6, -1.7 | -2.5, -1.4 | -2.4, -1.7 |
| | | p-value[2] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Actual (All Subjects) | n | 135 | 97 | 232 |
| | | Mean (StdDev) | 23.3 (5.65) | 22.9 (4.75) | 23.1 (5.29) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 21.0, 27.0 | 20.0, 26.0 | 20.0, 27.0 |
| | | Min, Max | 1, 32 | 8, 30 | 1, 32 |
| | Actual (Subjects with Change at Visit) | n | 134 | 90 | 224 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.4 (4.15) | 25.2 (3.77) | 25.3 (4.00) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 23.0, 28.0 | 23.0, 28.0 | 23.0, 28.0 |
| | | Min, Max | 10, 32 | 7, 32 | 7, 32 |
| | | Follow-Up Week 4 | | | |
| | | Mean (StdDev) | 23.3 (5.66) | 22.9 (4.82) | 23.1 (5.33) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 21.0, 27.0 | 20.0, 26.0 | 20.0, 27.0 |
| | | Min, Max | 1, 32 | 8, 30 | 1, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Change at Visit | Mean (StdDev) | -2.1 (4.98) | -2.3 (4.28) | -2.2 (4.70) |
| | | Median | -1.0 | -2.0 | -1.3 |
| | | Q1, Q3 | -4.0, 0.0 | -4.0, 0.0 | -4.0, 0.0 |
| | | Min, Max | -25, 10 | -19, 5 | -25, 10 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.47 (0.34, 0.61) |
| | | Delta3 (95% CI) [4] | | | 0.56 (0.39, 0.72) |
| | | LS Mean (SE) | -2.1 (0.39) | -2.4 (0.48) | -2.2 (0.30) |
| | | 95% CI | -2.9, -1.3 | -3.3, -1.4 | -2.8, -1.6 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 215 | 151 | 366 |
| | | LS Mean (SE) | -2.2 (0.38) | -2.6 (0.46) | -2.4 (0.29) |
| | | 95% CI | -3.0, -1.5 | -3.5, -1.7 | -3.0, -1.8 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Actual (All Subjects) | n | 135 | 88 | 223 |
| | | Mean (StdDev) | 23.2 (4.71) | 22.5 (4.77) | 22.9 (4.74) |
| | | Median | 25.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.0, 27.0 | 20.0, 26.0 | 20.0, 26.0 |
| | | Min, Max | 9, 31 | 9, 30 | 9, 31 |
| | Actual (Subjects with Change at Visit) | n | 133 | 83 | 216 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.3 (4.33) | 25.3 (3.60) | 25.3 (4.06) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 23.0, 28.0 | 23.0, 28.0 | 23.0, 28.0 |
| | | Min, Max | 12, 32 | 14, 32 | 12, 32 |
| | | Follow-Up Week 8 | | | |
| | | Mean (StdDev) | 23.3 (4.73) | 22.6 (4.76) | 23.0 (4.74) |
| | | Median | 25.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.0, 27.0 | 20.0, 26.0 | 20.0, 26.0 |
| | | Min, Max | 9, 31 | 9, 30 | 9, 31 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Change at Visit | Mean (StdDev) | -2.0 (4.27) | -2.7 (4.32) | -2.3 (4.30) |
| | | Median | -2.0 | -2.0 | -2.0 |
| | | Q1, Q3 | -4.0, 0.0 | -4.0, 0.0 | -4.0, 0.0 |
| | | Min, Max | -18, 8 | -19, 10 | -19, 10 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.52 (0.38, 0.65) |
| | | Delta3 (95% CI) [4] | | | 0.56 (0.41, 0.71) |
| | | LS Mean (SE) | -2.0 (0.35) | -2.7 (0.44) | -2.3 (0.27) |
| | | 95% CI | -2.7, -1.3 | -3.6, -1.9 | -2.8, -1.7 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 220 | 151 | 371 |
| | | LS Mean (SE) | -1.9 (0.34) | -2.9 (0.42) | -2.3 (0.26) |
| | | 95% CI | -2.6, -1.3 | -3.7, -2.0 | -2.8, -1.8 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Actual (All Subjects) | n | 159 | 103 | 262 |
| | | Mean (StdDev) | 23.2 (5.58) | 23.1 (4.58) | 23.2 (5.20) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.0, 27.0 | 21.0, 26.0 | 21.0, 26.0 |
| | | Min, Max | 3, 32 | 8, 31 | 3, 32 |
| | Actual (Subjects with Change at Visit) | n | 154 | 97 | 251 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.5 (4.29) | 25.3 (3.93) | 25.5 (4.15) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 23.0, 29.0 | 23.0, 28.0 | 23.0, 28.0 |
| | | Min, Max | 10, 32 | 7, 32 | 7, 32 |
| | | Follow-Up Week 12 | | | |
| | | Mean (StdDev) | 23.2 (5.60) | 23.1 (4.65) | 23.2 (5.25) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.0, 27.0 | 21.0, 26.0 | 21.0, 26.0 |
| | | Min, Max | 3, 32 | 8, 31 | 3, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Change at Visit | Mean (StdDev) | -2.3 (4.79) | -2.2 (4.20) | -2.3 (4.56) |
| | | Median | -1.0 | -2.0 | -1.0 |
| | | Q1, Q3 | -4.0, 0.0 | -4.0, 0.0 | -4.0, 0.0 |
| | | Min, Max | -20, 7 | -22, 7 | -22, 7 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.48 (0.36, 0.61) |
| | | Delta3 (95% CI) [4] | | | 0.55 (0.41, 0.70) |
| | | LS Mean (SE) | -2.3 (0.35) | -2.3 (0.45) | -2.3 (0.28) |
| | | 95% CI | -3.0, -1.6 | -3.2, -1.4 | -2.8, -1.7 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 226 | 151 | 377 |
| | | LS Mean (SE) | -2.1 (0.35) | -2.3 (0.44) | -2.2 (0.27) |
| | | 95% CI | -2.8, -1.4 | -3.1, -1.4 | -2.7, -1.6 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Actual (All Subjects) | n | 128 | 83 | 211 |
| | | Mean (StdDev) | 23.8 (5.04) | 24.0 (4.23) | 23.8 (4.73) |
| | | Median | 25.0 | 25.0 | 25.0 |
| | | Q1, Q3 | 21.0, 27.0 | 22.0, 27.0 | 21.0, 27.0 |
| | | Min, Max | 3, 32 | 9, 31 | 3, 32 |
| | Actual (Subjects with Change at Visit) | n | 123 | 77 | 200 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.8 (4.30) | 25.3 (3.39) | 25.7 (3.97) |
| | | Median | 26.3 | 26.0 | 26.0 |
| | | Q1, Q3 | 24.0, 29.0 | 23.0, 28.0 | 23.0, 28.0 |
| | | Min, Max | 9, 32 | 14, 31 | 9, 32 |
| | | Follow-Up Week 24 | | | |
| | | Mean (StdDev) | 24.0 (4.97) | 24.0 (4.32) | 24.0 (4.72) |
| | | Median | 25.0 | 25.0 | 25.0 |
| | | Q1, Q3 | 21.0, 27.0 | 22.0, 27.0 | 21.5, 27.0 |
| | | Min, Max | 3, 32 | 9, 31 | 3, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Change at Visit | Mean (StdDev) | -1.9 (4.85) | -1.4 (3.71) | -1.7 (4.44) |
| | | Median | -1.3 | -1.0 | -1.0 |
| | | Q1, Q3 | -4.0, 0.0 | -3.0, 1.0 | -4.0, 0.0 |
| | | Min, Max | -20, 19 | -14, 7 | -20, 19 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.39 (0.24, 0.53) |
| | | Delta3 (95% CI) [4] | | | 0.43 (0.27, 0.59) |
| | | LS Mean (SE) | -1.8 (0.37) | -1.5 (0.47) | -1.7 (0.29) |
| | | 95% CI | -2.5, -1.1 | -2.4, -0.6 | -2.3, -1.1 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 230 | 152 | 382 |
| | | LS Mean (SE) | -2.0 (0.37) | -1.7 (0.46) | -1.9 (0.29) |
| | | 95% CI | -2.7, -1.2 | -2.6, -0.8 | -2.4, -1.3 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Last On-treatment Visit Prior to Progression | Actual | n | 265 | 172 | 437 |
| | | Mean (StdDev) | 72.3 (19.41) | 73.1 (17.01) | 72.6 (18.48) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 58.3, 83.3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| End of Treatment | Actual (All Subjects) | n | 215 | 162 | 377 |
| | | Mean (StdDev) | 65.2 (21.58) | 65.2 (20.99) | 65.2 (21.30) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 8, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 210 | 149 | 359 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 74.0 (18.46) | 73.5 (16.70) | 73.8 (17.73) |
| | | Median | 83.3 | 75.0 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 17, 100 | 17, 100 |
| | | End of Treatment | | | |
| | | Mean (StdDev) | 65.2 (21.79) | 65.7 (20.68) | 65.4 (21.31) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 8, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| End of Treatment | Change at Visit | Mean (StdDev) | -8.9 (19.81) | -7.8 (16.66) | -8.4 (18.55) |
| | | Median | -8.3 | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -100, 58 | -58, 50 | -100, 58 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.43 (0.33, 0.53) |
| | | Delta3 (95% CI) [4] | | | 0.48 (0.36, 0.59) |
| | | LS Mean (SE) | -8.8 (1.22) | -7.9 (1.45) | -8.4 (0.93) |
| | | 95% CI | -11.2, -6.4 | -10.7, -5.0 | -10.3, -6.6 |
| | | p-value[2] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Actual (All Subjects) | n | 133 | 99 | 232 |
| | | Mean (StdDev) | 65.0 (21.94) | 62.5 (19.58) | 63.9 (20.96) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 133 | 93 | 226 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 75.3 (18.35) | 72.2 (15.06) | 74.0 (17.10) |
| | | Median | 83.3 | 66.7 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 33, 100 | 25, 100 |
| | | Follow-Up Week 4 | | | |
| | | Mean (StdDev) | 65.0 (21.94) | 62.0 (19.71) | 63.8 (21.06) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Change at Visit | Mean (StdDev) | -10.2 (18.88) | -10.2 (15.69) | -10.2 (17.60) |
| | | Median | -8.3 | -8.3 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -83, 42 | -58, 25 | -83, 42 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.53 (0.41, 0.66) |
| | | Delta3 (95% CI) [4] | | | 0.60 (0.45, 0.74) |
| | | LS Mean (SE) | -9.9 (1.48) | -10.7 (1.77) | -10.2 (1.13) |
| | | 95% CI | -12.8, -7.0 | -14.2, -7.2 | -12.4, -8.0 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 216 | 153 | 369 |
| | | LS Mean (SE) | -10.4 (1.46) | -10.4 (1.74) | -10.4 (1.11) |
| | | 95% CI | -13.2, -7.5 | -13.8, -7.0 | -12.6, -8.2 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Actual (All Subjects) | n | 136 | 90 | 226 |
| | | Mean (StdDev) | 64.0 (21.27) | 60.5 (19.93) | 62.6 (20.78) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 135 | 86 | 221 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 74.5 (18.12) | 72.0 (15.23) | 73.5 (17.06) |
| | | Median | 83.3 | 75.0 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 33, 100 | 25, 100 |
| | | Follow-Up Week 8 | | | |
| | | Mean (StdDev) | 63.9 (21.28) | 60.2 (20.19) | 62.4 (20.90) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Change at Visit | Mean (StdDev) | -10.6 (21.51) | -11.8 (19.95) | -11.1 (20.88) |
| | | Median | -8.3 | -8.3 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -100, 42 | -75, 25 | -100, 42 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.58 (0.43, 0.73) |
| | | Delta3 (95% CI) [4] | | | 0.65 (0.48, 0.82) |
| | | LS Mean (SE) | -10.1 (1.65) | -12.6 (2.06) | -11.1 (1.29) |
| | | 95% CI | -13.4, -6.9 | -16.7, -8.5 | -13.6, -8.6 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 219 | 153 | 372 |
| | | LS Mean (SE) | -10.6 (1.59) | -12.0 (1.99) | -11.2 (1.24) |
| | | 95% CI | -13.7, -7.4 | -16.0, -8.1 | -13.6, -8.7 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Actual (All Subjects) | n | 161 | 106 | 267 |
| | | Mean (StdDev) | 62.2 (22.40) | 63.0 (19.28) | 62.5 (21.18) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 157 | 101 | 258 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 74.3 (18.94) | 72.9 (15.62) | 73.7 (17.70) |
| | | Median | 83.3 | 75.0 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 17, 100 | 33, 100 | 17, 100 |
| | | Follow-Up Week 12 | | | |
| | | Mean (StdDev) | 62.5 (22.48) | 63.0 (19.56) | 62.7 (21.35) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Change at Visit | Mean (StdDev) | -11.8 (20.37) | -9.9 (17.07) | -11.0 (19.13) |
| | | Median | -8.3 | -8.3 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -83, 50 | -83, 25 | -83, 50 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.56 (0.44, 0.69) |
| | | Delta3 (95% CI) [4] | | | 0.62 (0.48, 0.77) |
| | | LS Mean (SE) | -11.6 (1.45) | -10.2 (1.80) | -11.0 (1.13) |
| | | 95% CI | -14.4, -8.7 | -13.8, -6.7 | -13.3, -8.8 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 227 | 153 | 380 |
| | | LS Mean (SE) | -11.1 (1.41) | -10.3 (1.76) | -10.8 (1.10) |
| | | 95% CI | -13.9, -8.4 | -13.8, -6.8 | -13.0, -8.6 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Actual (All Subjects) | n | 129 | 84 | 213 |
| | | Mean (StdDev) | 63.6 (20.88) | 64.8 (19.42) | 64.1 (20.28) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 125 | 79 | 204 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 75.3 (18.91) | 74.2 (15.01) | 74.9 (17.48) |
| | | Median | 83.3 | 75.0 | 83.3 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 0, 100 | 33, 100 | 0, 100 |
| | | Follow-Up Week 24 | | | |
| | | Mean (StdDev) | 64.1 (20.97) | 64.5 (19.69) | 64.2 (20.43) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Change at Visit | Mean (StdDev) | -11.3 (21.64) | -9.7 (16.42) | -10.7 (19.76) |
| | | Median | -8.3 | -8.3 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -25.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -100, 100 | -50, 25 | -100, 100 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.56 (0.41, 0.71) |
| | | Delta3 (95% CI) [4] | | | 0.61 (0.44, 0.78) |
| | | LS Mean (SE) | -11.1 (1.63) | -10.0 (2.04) | -10.7 (1.27) |
| | | 95% CI | -14.3, -7.9 | -14.1, -6.0 | -13.2, -8.2 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 231 | 153 | 384 |
| | | LS Mean (SE) | -11.4 (1.60) | -9.6 (2.00) | -10.7 (1.25) |
| | | 95% CI | -14.6, -8.3 | -13.6, -5.7 | -13.2, -8.2 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Last On-treatment Visit Prior to Progression | Actual | n | 264 | 170 | 434 |
| | | Mean (StdDev) | 77.8 (16.79) | 78.5 (15.05) | 78.1 (16.12) |
| | | Median | 80.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 70.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 0, 100 | 30, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| End of Treatment | Actual (All Subjects) | n | 214 | 163 | 377 |
| | | Mean (StdDev) | 70.0 (21.38) | 69.8 (22.72) | 69.9 (21.94) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 55.0, 85.0 | 50.0, 90.0 | 55.0, 90.0 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 209 | 150 | 359 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 78.6 (16.68) | 78.3 (15.14) | 78.5 (16.03) |
| | | Median | 85.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 70.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 100 | 30, 100 |
| | | End of Treatment | | | |
| | | Mean (StdDev) | 70.3 (21.50) | 70.9 (21.93) | 70.5 (21.65) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 55.0, 85.0 | 60.0, 90.0 | 58.0, 90.0 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| End of Treatment | Change at Visit | Mean (StdDev) | -8.3 (16.85) | -7.4 (15.66) | -7.9 (16.35) |
| | | Median | -5.0 | -3.0 | -5.0 |
| | | Q1, Q3 | -15.0, 0.0 | -15.0, 0.0 | -15.0, 0.0 |
| | | Min, Max | -75, 50 | -70, 25 | -75, 50 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.42 (0.32, 0.51) |
| | | Delta3 (95% CI) [4] | | | 0.50 (0.38, 0.61) |
| | | LS Mean (SE) | -8.3 (1.13) | -7.5 (1.33) | -7.9 (0.86) |
| | | 95% CI | -10.5, -6.1 | -10.1, -4.8 | -9.6, -6.3 |
| | | p-value[2] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Actual (All Subjects) | n | 134 | 99 | 233 |
| | | Mean (StdDev) | 71.6 (20.39) | 68.6 (20.44) | 70.3 (20.42) |
| | | Median | 75.0 | 70.0 | 75.0 |
| | | Q1, Q3 | 60.0, 90.0 | 55.0, 85.0 | 55.0, 90.0 |
| | | Min, Max | 0, 100 | 0, 99 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 133 | 93 | 226 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 79.5 (16.41) | 77.6 (13.71) | 78.7 (15.35) |
| | | Median | 85.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 70.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 100 | 30, 100 |
| | | Follow-Up Week 4 | | | |
| | | Mean (StdDev) | 71.6 (20.46) | 68.9 (19.93) | 70.5 (20.24) |
| | | Median | 75.0 | 70.0 | 75.0 |
| | | Q1, Q3 | 60.0, 90.0 | 55.0, 85.0 | 55.0, 90.0 |
| | | Min, Max | 0, 100 | 0, 99 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Change at Visit | Mean (StdDev) | -7.8 (17.16) | -8.7 (16.96) | -8.2 (17.05) |
| | | Median | -3.0 | -5.0 | -5.0 |
| | | Q1, Q3 | -15.0, 0.0 | -15.0, 0.0 | -15.0, 0.0 |
| | | Min, Max | -90, 40 | -90, 23 | -90, 40 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.46 (0.33, 0.59) |
| | | Delta3 (95% CI) [4] | | | 0.53 (0.38, 0.69) |
| | | LS Mean (SE) | -7.7 (1.45) | -9.0 (1.73) | -8.2 (1.11) |
| | | 95% CI | -10.5, -4.8 | -12.4, -5.6 | -10.4, -6.0 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 216 | 154 | 370 |
| | | LS Mean (SE) | -7.9 (1.38) | -9.1 (1.65) | -8.4 (1.06) |
| | | 95% CI | -10.6, -5.2 | -12.3, -5.8 | -10.5, -6.3 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Actual (All Subjects) | n | 136 | 88 | 224 |
| | | Mean (StdDev) | 70.2 (19.79) | 69.4 (19.03) | 69.9 (19.46) |
| | | Median | 70.0 | 70.0 | 70.0 |
| | | Q1, Q3 | 55.0, 90.0 | 57.5, 85.0 | 55.0, 86.0 |
| | | Min, Max | 20, 100 | 25, 99 | 20, 100 |
| | Actual (Subjects with Change at Visit) | n | 135 | 84 | 219 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 78.4 (16.27) | 77.9 (13.86) | 78.2 (15.36) |
| | | Median | 80.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 70.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 100 | 30, 100 |
| | | Follow-Up Week 8 | | | |
| | | Mean (StdDev) | 70.4 (19.79) | 69.1 (19.02) | 69.9 (19.46) |
| | | Median | 70.0 | 70.0 | 70.0 |
| | | Q1, Q3 | 55.0, 90.0 | 57.5, 85.0 | 55.0, 85.0 |
| | | Min, Max | 20, 100 | 25, 99 | 20, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Change at Visit | Mean (StdDev) | -8.0 (15.31) | -8.7 (13.93) | -8.3 (14.77) |
| | | Median | -5.0 | -5.0 | -5.0 |
| | | Q1, Q3 | -15.0, 3.0 | -15.0, 0.0 | -15.0, 0.0 |
| | | Min, Max | -50, 40 | -60, 20 | -60, 40 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.47 (0.35, 0.59) |
| | | Delta3 (95% CI) [4] | | | 0.54 (0.40, 0.68) |
| | | LS Mean (SE) | -8.0 (1.26) | -8.8 (1.60) | -8.3 (0.99) |
| | | 95% CI | -10.4, -5.5 | -11.9, -5.6 | -10.2, -6.3 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 219 | 154 | 373 |
| | | LS Mean (SE) | -8.4 (1.22) | -8.3 (1.53) | -8.3 (0.95) |
| | | 95% CI | -10.8, -6.0 | -11.3, -5.3 | -10.2, -6.5 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Actual (All Subjects) | n | 160 | 104 | 264 |
| | | Mean (StdDev) | 69.3 (20.23) | 73.0 (16.67) | 70.8 (18.96) |
| | | Median | 70.0 | 75.0 | 73.5 |
| | | Q1, Q3 | 60.0, 85.0 | 65.0, 87.0 | 60.0, 85.0 |
| | | Min, Max | 10, 100 | 30, 98 | 10, 100 |
| | Actual (Subjects with Change at Visit) | n | 156 | 99 | 255 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 78.7 (16.02) | 77.9 (14.38) | 78.4 (15.38) |
| | | Median | 82.5 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 70.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 100 | 30, 100 |
| | | Follow-Up Week 12 | | | |
| | | Mean (StdDev) | 69.6 (20.22) | 73.4 (16.49) | 71.1 (18.92) |
| | | Median | 72.5 | 75.0 | 75.0 |
| | | Q1, Q3 | 60.0, 85.0 | 65.0, 85.0 | 60.0, 85.0 |
| | | Min, Max | 10, 100 | 30, 98 | 10, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Change at Visit | Mean (StdDev) | -9.1 (16.66) | -4.5 (12.33) | -7.3 (15.26) |
| | | Median | -5.0 | -5.0 | -5.0 |
| | | Q1, Q3 | -15.0, 0.0 | -10.0, 0.0 | -15.0, 0.0 |
| | | Min, Max | -76, 45 | -50, 35 | -76, 45 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.42 (0.31, 0.54) |
| | | Delta3 (95% CI) [4] | | | 0.48 (0.35, 0.60) |
| | | LS Mean (SE) | -9.0 (1.18) | -4.7 (1.48) | -7.3 (0.92) |
| | | 95% CI | -11.3, -6.7 | -7.6, -1.7 | -9.1, -5.5 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 225 | 154 | 379 |
| | | LS Mean (SE) | -9.1 (1.14) | -4.6 (1.43) | -7.3 (0.89) |
| | | 95% CI | -11.4, -6.9 | -7.4, -1.8 | -9.0, -5.5 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Actual (All Subjects) | n | 129 | 85 | 214 |
| | | Mean (StdDev) | 71.7 (20.20) | 71.7 (18.51) | 71.7 (19.50) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 60.0, 89.0 | 60.0, 85.0 | 60.0, 85.0 |
| | | Min, Max | 5, 100 | 25, 100 | 5, 100 |
| | Actual (Subjects with Change at Visit) | n | 124 | 80 | 204 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 78.4 (16.75) | 78.4 (13.73) | 78.4 (15.60) |
| | | Median | 82.5 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 70.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 50, 100 | 30, 100 |
| | | Follow-Up Week 24 | | | |
| | | Mean (StdDev) | 72.3 (20.21) | 72.1 (18.20) | 72.2 (19.40) |
| | | Median | 76.5 | 75.0 | 75.0 |
| | | Q1, Q3 | 60.0, 90.0 | 60.0, 85.0 | 60.0, 85.0 |
| | | Min, Max | 5, 100 | 25, 100 | 5, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Change at Visit | Mean (StdDev) | -6.1 (15.38) | -6.4 (13.29) | -6.2 (14.56) |
| | | Median | -3.5 | -5.0 | -5.0 |
| | | Q1, Q3 | -13.0, 0.0 | -15.0, 0.0 | -15.0, 0.0 |
| | | Min, Max | -65, 55 | -40, 20 | -65, 55 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.35 (0.23, 0.47) |
| | | Delta3 (95% CI) [4] | | | 0.40 (0.26, 0.53) |
| | | LS Mean (SE) | -6.1 (1.29) | -6.4 (1.61) | -6.2 (1.01) |
| | | 95% CI | -8.7, -3.6 | -9.5, -3.2 | -8.2, -4.2 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 229 | 154 | 383 |
| | | LS Mean (SE) | -7.7 (1.23) | -6.3 (1.52) | -7.1 (0.96) |
| | | 95% CI | -10.1, -5.3 | -9.3, -3.3 | -9.0, -5.2 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Last On-treatment Visit Prior to Progression | Actual | n | 117 | 84 | 201 |
| | | Mean (StdDev) | 24.8 (4.41) | 24.6 (3.95) | 24.7 (4.21) |
| | | Median | 26.0 | 25.5 | 26.0 |
| | | Q1, Q3 | 23.0, 28.0 | 22.0, 28.0 | 22.0, 28.0 |
| | | Min, Max | 10, 32 | 14, 31 | 10, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| End of Treatment | Actual (All Subjects) | n | 89 | 82 | 171 |
| | | Mean (StdDev) | 23.3 (4.65) | 22.7 (4.74) | 23.0 (4.69) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.0, 27.0 | 20.0, 26.0 | 20.0, 26.0 |
| | | Min, Max | 8, 31 | 4, 31 | 4, 31 |
| | Actual (Subjects with Change at Visit) | n | 88 | 75 | 163 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 24.9 (4.49) | 24.7 (3.96) | 24.8 (4.24) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 22.0, 28.0 | 22.0, 28.0 | 22.0, 28.0 |
| | | Min, Max | 10, 32 | 14, 31 | 10, 32 |
| | | End of Treatment | | | |
| | | Mean (StdDev) | 23.2 (4.65) | 22.6 (4.83) | 23.0 (4.73) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.0, 27.0 | 20.0, 26.0 | 20.0, 26.0 |
| | | Min, Max | 8, 31 | 4, 31 | 4, 31 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| End of Treatment | Change at Visit | Mean (StdDev) | -1.7 (3.72) | -2.1 (3.51) | -1.9 (3.62) |
| | | Median | -1.1 | -2.0 | -1.3 |
| | | Q1, Q3 | -4.0, 1.0 | -4.0, 0.0 | -4.0, 0.0 |
| | | Min, Max | -13, 8 | -15, 4 | -15, 8 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.42 (0.29, 0.55) |
| | | Delta3 (95% CI) [4] | | | 0.44 (0.30, 0.58) |
| | | LS Mean (SE) | -1.6 (0.37) | -2.1 (0.40) | -1.9 (0.27) |
| | | 95% CI | -2.4, -0.9 | -2.9, -1.4 | -2.4, -1.3 |
| | | p-value[2] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Actual (All Subjects) | n | 65 | 52 | 117 |
| | | Mean (StdDev) | 23.4 (5.45) | 22.9 (4.16) | 23.2 (4.91) |
| | | Median | 25.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 21.0, 27.0 | 20.0, 26.0 | 20.0, 26.0 |
| | | Min, Max | 6, 32 | 12, 29 | 6, 32 |
| | Actual (Subjects with Change at Visit) | n | 64 | 49 | 113 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.1 (4.35) | 25.2 (3.10) | 25.1 (3.84) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 23.0, 28.0 | 23.0, 27.0 | 23.0, 28.0 |
| | | Min, Max | 10, 32 | 18, 31 | 10, 32 |
| | | Follow-Up Week 4 | | | |
| | | Mean (StdDev) | 23.3 (5.48) | 22.8 (4.21) | 23.1 (4.96) |
| | | Median | 25.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 20.5, 26.5 | 20.0, 26.0 | 20.0, 26.0 |
| | | Min, Max | 6, 32 | 12, 29 | 6, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Change at Visit | Mean (StdDev) | -1.8 (4.99) | -2.4 (3.73) | -2.1 (4.48) |
| | | Median | -1.0 | -3.0 | -2.0 |
| | | Q1, Q3 | -4.0, 1.0 | -5.0, 0.0 | -4.0, 0.0 |
| | | Min, Max | -15, 10 | -11, 5 | -15, 10 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.46 (0.27, 0.66) |
| | | Delta3 (95% CI) [4] | | | 0.54 (0.31, 0.76) |
| | | LS Mean (SE) | -1.8 (0.54) | -2.4 (0.61) | -2.1 (0.40) |
| | | 95% CI | -2.9, -0.7 | -3.6, -1.2 | -2.9, -1.3 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 92 | 77 | 169 |
| | | LS Mean (SE) | -1.8 (0.53) | -2.5 (0.60) | -2.2 (0.40) |
| | | 95% CI | -2.9, -0.8 | -3.7, -1.4 | -2.9, -1.4 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Actual (All Subjects) | n | 60 | 50 | 110 |
| | | Mean (StdDev) | 23.2 (4.98) | 22.0 (4.75) | 22.7 (4.89) |
| | | Median | 24.0 | 23.0 | 24.0 |
| | | Q1, Q3 | 20.0, 26.5 | 19.0, 25.0 | 20.0, 26.0 |
| | | Min, Max | 9, 31 | 9, 30 | 9, 31 |
| | Actual (Subjects with Change at Visit) | n | 59 | 48 | 107 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.3 (4.32) | 24.6 (3.59) | 25.0 (4.01) |
| | | Median | 26.0 | 25.0 | 26.0 |
| | | Q1, Q3 | 23.0, 28.0 | 22.0, 27.0 | 23.0, 28.0 |
| | | Min, Max | 13, 32 | 14, 31 | 13, 32 |
| | | Follow-Up Week 8 | | | |
| | | Mean (StdDev) | 23.2 (5.01) | 21.9 (4.79) | 22.6 (4.93) |
| | | Median | 24.0 | 23.0 | 24.0 |
| | | Q1, Q3 | 20.0, 27.0 | 19.0, 25.0 | 20.0, 26.0 |
| | | Min, Max | 9, 31 | 9, 30 | 9, 31 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Change at Visit | Mean (StdDev) | -2.0 (4.63) | -2.7 (4.03) | -2.3 (4.36) |
| | | Median | -2.0 | -3.0 | -2.0 |
| | | Q1, Q3 | -4.0, 0.0 | -4.0, -1.0 | -4.0, 0.0 |
| | | Min, Max | -18, 8 | -10, 10 | -18, 10 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.52 (0.33, 0.72) |
| | | Delta3 (95% CI) [4] | | | 0.59 (0.36, 0.81) |
| | | LS Mean (SE) | -1.9 (0.54) | -2.8 (0.60) | -2.3 (0.40) |
| | | 95% CI | -3.0, -0.9 | -4.0, -1.7 | -3.1, -1.5 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 96 | 77 | 173 |
| | | LS Mean (SE) | -1.8 (0.51) | -3.0 (0.58) | -2.3 (0.38) |
| | | 95% CI | -2.8, -0.8 | -4.1, -1.8 | -3.1, -1.6 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Actual (All Subjects) | n | 69 | 56 | 125 |
| | | Mean (StdDev) | 23.0 (5.99) | 23.0 (4.35) | 23.0 (5.30) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 21.0, 27.0 | 21.0, 26.0 | 21.0, 26.0 |
| | | Min, Max | 5, 32 | 8, 30 | 5, 32 |
| | Actual (Subjects with Change at Visit) | n | 67 | 54 | 121 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.5 (4.36) | 25.1 (3.43) | 25.3 (3.96) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 23.0, 29.0 | 23.0, 28.0 | 23.0, 28.0 |
| | | Min, Max | 10, 32 | 14, 31 | 10, 32 |
| | | Follow-Up Week 12 | | | |
| | | Mean (StdDev) | 22.9 (6.06) | 23.0 (4.43) | 23.0 (5.37) |
| | | Median | 24.0 | 24.0 | 24.0 |
| | | Q1, Q3 | 19.0, 27.0 | 21.0, 26.0 | 21.0, 26.0 |
| | | Min, Max | 5, 32 | 8, 30 | 5, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Change at Visit | Mean (StdDev) | -2.5 (5.46) | -2.1 (4.46) | -2.3 (5.02) |
| | | Median | -1.0 | -2.0 | -1.0 |
| | | Q1, Q3 | -4.0, 0.0 | -4.0, 1.0 | -4.0, 0.0 |
| | | Min, Max | -20, 7 | -18, 7 | -20, 7 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.49 (0.30, 0.69) |
| | | Delta3 (95% CI) [4] | | | 0.59 (0.35, 0.83) |
| | | LS Mean (SE) | -2.5 (0.59) | -2.2 (0.66) | -2.3 (0.44) |
| | | 95% CI | -3.6, -1.3 | -3.5, -0.9 | -3.2, -1.5 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 99 | 77 | 176 |
| | | LS Mean (SE) | -2.2 (0.58) | -2.2 (0.65) | -2.2 (0.43) |
| | | 95% CI | -3.4, -1.1 | -3.4, -0.9 | -3.1, -1.3 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Actual (All Subjects) | n | 61 | 46 | 107 |
| | | Mean (StdDev) | 23.7 (5.16) | 24.4 (4.10) | 24.0 (4.73) |
| | | Median | 25.0 | 25.0 | 25.0 |
| | | Q1, Q3 | 22.0, 27.0 | 22.0, 27.0 | 22.0, 27.0 |
| | | Min, Max | 3, 32 | 10, 31 | 3, 32 |
| | Actual (Subjects with Change at Visit) | n | 56 | 43 | 99 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 25.6 (4.41) | 25.3 (3.41) | 25.5 (3.99) |
| | | Median | 26.0 | 26.0 | 26.0 |
| | | Q1, Q3 | 23.0, 29.0 | 23.0, 28.0 | 23.0, 28.0 |
| | | Min, Max | 10, 32 | 14, 31 | 10, 32 |
| | | Follow-Up Week 24 | | | |
| | | Mean (StdDev) | 24.1 (5.00) | 24.4 (4.17) | 24.2 (4.64) |
| | | Median | 25.0 | 25.0 | 25.0 |
| | | Q1, Q3 | 22.0, 27.0 | 22.0, 27.0 | 22.0, 27.0 |
| | | Min, Max | 3, 32 | 10, 31 | 3, 32 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Change at Visit | Mean (StdDev) | -1.5 (4.77) | -0.9 (3.77) | -1.3 (4.35) |
| | | Median | -1.0 | 0.0 | -1.0 |
| | | Q1, Q3 | -3.5, 0.5 | -3.0, 1.0 | -3.0, 1.0 |
| | | Min, Max | -19, 11 | -14, 7 | -19, 11 |
| | | p-value[1] | | | 0.0049 |
| | | Delta2 (95% CI) [3] | | | 0.29 (0.09, 0.49) |
| | | Delta3 (95% CI) [4] | | | 0.32 (0.09, 0.54) |
| | | LS Mean (SE) | -1.5 (0.54) | -1.0 (0.62) | -1.3 (0.41) |
| | | 95% CI | -2.5, -0.4 | -2.2, 0.2 | -2.1, -0.4 |
| | | p-value[2] | | | 0.0026 |
| | Change up to Visit | n [5] | 101 | 77 | 178 |
| | | LS Mean (SE) | -1.6 (0.53) | -1.3 (0.60) | -1.5 (0.40) |
| | | 95% CI | -2.7, -0.6 | -2.5, -0.1 | -2.3, -0.7 |
| | | p-value[6] | | | 0.0004 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Last On-treatment Visit Prior to Progression | Actual | n | 118 | 84 | 202 |
| | | Mean (StdDev) | 71.8 (20.27) | 71.4 (18.03) | 71.6 (19.32) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 58.3, 83.3 | 58.3, 83.3 | 58.3, 83.3 |
| | | Min, Max | 25, 100 | 17, 100 | 17, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| End of Treatment | Actual (All Subjects) | n | 91 | 82 | 173 |
| | | Mean (StdDev) | 63.6 (21.96) | 64.9 (20.27) | 64.3 (21.13) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 90 | 74 | 164 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 73.6 (19.84) | 72.5 (17.38) | 73.1 (18.72) |
| | | Median | 83.3 | 75.0 | 75.0 |
| | | Q1, Q3 | 58.3, 83.3 | 58.3, 83.3 | 58.3, 83.3 |
| | | Min, Max | 25, 100 | 33, 100 | 25, 100 |
| | | End of Treatment | | | |
| | | Mean (StdDev) | 63.7 (22.08) | 65.4 (19.83) | 64.5 (21.05) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| End of Treatment | Change at Visit | Mean (StdDev) | -9.9 (22.27) | -7.1 (13.70) | -8.6 (18.89) |
| | | Median | -8.3 | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -100, 58 | -42, 25 | -100, 58 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.43 (0.28, 0.58) |
| | | Delta3 (95% CI) [4] | | | 0.46 (0.30, 0.62) |
| | | LS Mean (SE) | -9.7 (1.85) | -7.3 (2.05) | -8.6 (1.37) |
| | | 95% CI | -13.4, -6.1 | -11.4, -3.3 | -11.4, -5.9 |
| | | p-value[2] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Actual (All Subjects) | n | 65 | 53 | 118 |
| | | Mean (StdDev) | 62.4 (21.71) | 63.4 (17.48) | 62.9 (19.84) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 | 50.0, 75.0 |
| | | Min, Max | 17, 100 | 17, 100 | 17, 100 |
| | Actual (Subjects with Change at Visit) | n | 65 | 50 | 115 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 74.1 (19.61) | 71.3 (16.93) | 72.9 (18.46) |
| | | Median | 83.3 | 75.0 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 58.3, 83.3 | 58.3, 83.3 |
| | | Min, Max | 25, 100 | 33, 100 | 25, 100 |
| | | Follow-Up Week 4 | | | |
| | | Mean (StdDev) | 62.4 (21.71) | 62.7 (17.68) | 62.5 (19.97) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 | 50.0, 75.0 |
| | | Min, Max | 17, 100 | 17, 100 | 17, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Change at Visit | Mean (StdDev) | -11.7 (21.03) | -8.7 (15.79) | -10.4 (18.91) |
| | | Median | -8.3 | -8.3 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -83, 42 | -50, 25 | -83, 42 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.54 (0.35, 0.73) |
| | | Delta3 (95% CI) [4] | | | 0.56 (0.36, 0.76) |
| | | LS Mean (SE) | -11.1 (2.14) | -9.3 (2.44) | -10.4 (1.60) |
| | | 95% CI | -15.4, -6.9 | -14.2, -4.5 | -13.5, -7.2 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 94 | 76 | 170 |
| | | LS Mean (SE) | -11.8 (2.10) | -9.3 (2.40) | -10.7 (1.58) |
| | | 95% CI | -16.0, -7.7 | -14.1, -4.6 | -13.8, -7.6 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Actual (All Subjects) | n | 61 | 50 | 111 |
| | | Mean (StdDev) | 62.7 (21.87) | 59.5 (19.49) | 61.3 (20.80) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 66.7 | 50.0, 75.0 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 61 | 48 | 109 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 74.3 (19.56) | 70.7 (16.40) | 72.7 (18.25) |
| | | Median | 83.3 | 75.0 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 54.2, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 33, 100 | 25, 100 |
| | | Follow-Up Week 8 | | | |
| | | Mean (StdDev) | 62.7 (21.87) | 59.2 (19.84) | 61.2 (20.98) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 70.8 | 50.0, 75.0 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Change at Visit | Mean (StdDev) | -11.6 (24.31) | -11.5 (19.42) | -11.5 (22.19) |
| | | Median | -8.3 | -12.5 | -8.3 |
| | | Q1, Q3 | -25.0, 0.0 | -16.7, 0.0 | -25.0, 0.0 |
| | | Min, Max | -83, 42 | -67, 25 | -83, 42 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.59 (0.37, 0.81) |
| | | Delta3 (95% CI) [4] | | | 0.63 (0.39, 0.88) |
| | | LS Mean (SE) | -10.7 (2.52) | -12.7 (2.85) | -11.5 (1.88) |
| | | 95% CI | -15.7, -5.7 | -18.3, -7.0 | -15.3, -7.8 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 96 | 76 | 172 |
| | | LS Mean (SE) | -11.4 (2.40) | -11.4 (2.74) | -11.4 (1.80) |
| | | 95% CI | -16.2, -6.7 | -16.8, -5.9 | -15.0, -7.8 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Actual (All Subjects) | n | 72 | 57 | 129 |
| | | Mean (StdDev) | 60.1 (23.57) | 62.9 (17.11) | 61.3 (20.93) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 | 50.0, 75.0 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 71 | 55 | 126 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 74.4 (19.64) | 71.1 (17.26) | 72.9 (18.64) |
| | | Median | 83.3 | 75.0 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 50.0, 83.3 | 58.3, 83.3 |
| | | Min, Max | 25, 100 | 33, 100 | 25, 100 |
| | | Follow-Up Week 12 | | | |
| | | Mean (StdDev) | 60.2 (23.70) | 63.0 (17.33) | 61.4 (21.13) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 | 50.0, 75.0 |
| | | Min, Max | 0, 100 | 17, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Change at Visit | Mean (StdDev) | -14.2 (22.77) | -8.0 (15.87) | -11.5 (20.22) |
| | | Median | -8.3 | -8.3 | -8.3 |
| | | Q1, Q3 | -25.0, 0.0 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -83, 25 | -50, 25 | -83, 25 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.58 (0.39, 0.76) |
| | | Delta3 (95% CI) [4] | | | 0.62 (0.41, 0.82) |
| | | LS Mean (SE) | -13.6 (2.19) | -8.9 (2.49) | -11.5 (1.64) |
| | | 95% CI | -17.9, -9.2 | -13.8, -3.9 | -14.8, -8.3 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 100 | 76 | 176 |
| | | LS Mean (SE) | -13.6 (2.12) | -9.2 (2.42) | -11.7 (1.59) |
| | | 95% CI | -17.8, -9.4 | -14.0, -4.5 | -14.8, -8.5 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Actual (All Subjects) | n | 62 | 46 | 108 |
| | | Mean (StdDev) | 63.3 (19.99) | 66.1 (20.29) | 64.5 (20.07) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 17, 100 | 0, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 58 | 43 | 101 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 74.3 (19.01) | 73.6 (16.46) | 74.0 (17.88) |
| | | Median | 83.3 | 75.0 | 83.3 |
| | | Q1, Q3 | 58.3, 83.3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 33, 100 | 25, 100 |
| | | Follow-Up Week 24 | | | |
| | | Mean (StdDev) | 64.2 (20.11) | 65.1 (20.59) | 64.6 (20.22) |
| | | Median | 66.7 | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 17, 100 | 0, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Change at Visit | Mean (StdDev) | -10.1 (17.57) | -8.5 (15.38) | -9.4 (16.61) |
| | | Median | -8.3 | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -25.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -58, 33 | -42, 17 | -58, 33 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.49 (0.31, 0.67) |
| | | Delta3 (95% CI) [4] | | | 0.53 (0.33, 0.72) |
| | | LS Mean (SE) | -10.0 (2.09) | -8.6 (2.43) | -9.4 (1.58) |
| | | 95% CI | -14.1, -5.8 | -13.5, -3.8 | -12.5, -6.3 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 102 | 76 | 178 |
| | | LS Mean (SE) | -11.4 (2.05) | -8.6 (2.38) | -10.2 (1.55) |
| | | 95% CI | -15.5, -7.4 | -13.3, -3.9 | -13.3, -7.1 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Last On-treatment Visit Prior to Progression | Actual | n | 117 | 84 | 201 |
| | | Mean (StdDev) | 77.7 (16.94) | 77.5 (15.74) | 77.6 (16.41) |
| | | Median | 80.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 70.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 100 | 30, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| End of Treatment | Actual (All Subjects) | n | 91 | 82 | 173 |
| | | Mean (StdDev) | 68.9 (21.70) | 69.0 (23.53) | 69.0 (22.52) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 55.0, 85.0 | 50.0, 88.0 | 50.0, 85.0 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 90 | 75 | 165 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 77.8 (17.86) | 77.6 (16.02) | 77.7 (17.00) |
| | | Median | 80.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 93.0 | 68.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 100 | 30, 100 |
| | | End of Treatment | | | |
| | | Mean (StdDev) | 69.0 (21.82) | 70.4 (22.65) | 69.6 (22.14) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 55.0, 85.0 | 55.0, 90.0 | 55.0, 87.0 |
| | | Min, Max | 0, 100 | 0, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| End of Treatment | Change at Visit | Mean (StdDev) | -8.8 (17.59) | -7.2 (16.99) | -8.1 (17.28) |
| | | Median | -5.0 | -2.0 | -5.0 |
| | | Q1, Q3 | -20.0, 0.0 | -15.0, 0.0 | -19.0, 0.0 |
| | | Min, Max | -70, 50 | -70, 25 | -70, 50 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.41 (0.27, 0.55) |
| | | Delta3 (95% CI) [4] | | | 0.48 (0.31, 0.64) |
| | | LS Mean (SE) | -8.8 (1.81) | -7.2 (1.98) | -8.1 (1.33) |
| | | 95% CI | -12.4, -5.2 | -11.1, -3.3 | -10.7, -5.4 |
| | | p-value[2] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Actual (All Subjects) | n | 65 | 54 | 119 |
| | | Mean (StdDev) | 71.0 (21.48) | 68.1 (20.86) | 69.7 (21.16) |
| | | Median | 75.0 | 72.5 | 75.0 |
| | | Q1, Q3 | 55.0, 90.0 | 55.0, 85.0 | 55.0, 85.0 |
| | | Min, Max | 0, 100 | 0, 99 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 64 | 51 | 115 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 79.0 (16.42) | 76.5 (14.77) | 77.9 (15.69) |
| | | Median | 85.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 68.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 100 | 30, 100 |
| | | Follow-Up Week 4 | | | |
| | | Mean (StdDev) | 71.1 (21.64) | 68.5 (20.10) | 70.0 (20.92) |
| | | Median | 75.0 | 70.0 | 75.0 |
| | | Q1, Q3 | 55.0, 90.0 | 55.0, 85.0 | 55.0, 85.0 |
| | | Min, Max | 0, 100 | 0, 99 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Change at Visit | Mean (StdDev) | -7.9 (20.53) | -8.0 (18.13) | -7.9 (19.42) |
| | | Median | 0.0 | -5.0 | -5.0 |
| | | Q1, Q3 | -15.0, 0.0 | -15.0, 0.0 | -15.0, 0.0 |
| | | Min, Max | -90, 40 | -90, 23 | -90, 40 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.43 (0.23, 0.63) |
| | | Delta3 (95% CI) [4] | | | 0.51 (0.27, 0.74) |
| | | LS Mean (SE) | -7.5 (2.34) | -8.5 (2.62) | -7.9 (1.74) |
| | | 95% CI | -12.1, -2.9 | -13.7, -3.3 | -11.4, -4.5 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 94 | 77 | 171 |
| | | LS Mean (SE) | -8.3 (2.24) | -8.2 (2.51) | -8.3 (1.67) |
| | | 95% CI | -12.8, -3.9 | -13.1, -3.2 | -11.6, -4.9 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Actual (All Subjects) | n | 61 | 48 | 109 |
| | | Mean (StdDev) | 71.0 (20.27) | 67.1 (18.69) | 69.3 (19.60) |
| | | Median | 75.0 | 70.0 | 70.0 |
| | | Q1, Q3 | 50.0, 90.0 | 50.0, 80.0 | 50.0, 90.0 |
| | | Min, Max | 20, 100 | 30, 99 | 20, 100 |
| | Actual (Subjects with Change at Visit) | n | 61 | 46 | 107 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 78.1 (17.04) | 76.2 (14.30) | 77.3 (15.87) |
| | | Median | 80.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 70.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 99 | 30, 100 |
| | | Follow-Up Week 8 | | | |
| | | Mean (StdDev) | 71.0 (20.27) | 66.9 (18.47) | 69.2 (19.54) |
| | | Median | 75.0 | 70.0 | 70.0 |
| | | Q1, Q3 | 50.0, 90.0 | 50.0, 80.0 | 50.0, 90.0 |
| | | Min, Max | 20, 100 | 30, 99 | 20, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Change at Visit | Mean (StdDev) | -7.0 (16.83) | -9.4 (12.66) | -8.0 (15.15) |
| | | Median | -5.0 | -6.5 | -5.0 |
| | | Q1, Q3 | -15.0, 5.0 | -15.0, 0.0 | -15.0, 0.0 |
| | | Min, Max | -50, 40 | -40, 20 | -50, 40 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.45 (0.28, 0.62) |
| | | Delta3 (95% CI) [4] | | | 0.51 (0.31, 0.70) |
| | | LS Mean (SE) | -6.9 (1.91) | -9.6 (2.20) | -8.0 (1.44) |
| | | 95% CI | -10.7, -3.1 | -13.9, -5.2 | -10.9, -5.2 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 96 | 77 | 173 |
| | | LS Mean (SE) | -7.9 (1.82) | -8.4 (2.10) | -8.1 (1.38) |
| | | 95% CI | -11.5, -4.3 | -12.5, -4.2 | -10.8, -5.4 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Actual (All Subjects) | n | 71 | 56 | 127 |
| | | Mean (StdDev) | 69.8 (20.76) | 73.1 (16.34) | 71.2 (18.94) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 60.0, 85.0 | 62.5, 85.0 | 60.0, 85.0 |
| | | Min, Max | 10, 100 | 35, 95 | 10, 100 |
| | Actual (Subjects with Change at Visit) | n | 70 | 54 | 124 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 78.2 (16.50) | 76.6 (14.91) | 77.5 (15.79) |
| | | Median | 80.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 68.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 30, 99 | 30, 100 |
| | | Follow-Up Week 12 | | | |
| | | Mean (StdDev) | 69.8 (20.91) | 73.2 (16.18) | 71.2 (19.00) |
| | | Median | 75.0 | 75.0 | 75.0 |
| | | Q1, Q3 | 60.0, 85.0 | 65.0, 85.0 | 60.0, 85.0 |
| | | Min, Max | 10, 100 | 35, 95 | 10, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Change at Visit | Mean (StdDev) | -8.4 (19.12) | -3.4 (13.82) | -6.3 (17.13) |
| | | Median | -5.0 | -5.0 | -5.0 |
| | | Q1, Q3 | -20.0, 0.0 | -10.0, 5.0 | -12.5, 2.0 |
| | | Min, Max | -76, 45 | -40, 35 | -76, 45 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | 0.36 (0.18, 0.53) |
| | | Delta3 (95% CI) [4] | | | 0.40 (0.20, 0.59) |
| | | LS Mean (SE) | -8.2 (1.93) | -3.7 (2.19) | -6.3 (1.45) |
| | | 95% CI | -12.0, -4.4 | -8.1, 0.6 | -9.1, -3.4 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 99 | 77 | 176 |
| | | LS Mean (SE) | -8.7 (1.87) | -3.7 (2.13) | -6.5 (1.40) |
| | | 95% CI | -12.4, -5.0 | -7.9, 0.5 | -9.3, -3.7 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Actual (All Subjects) | n | 63 | 47 | 110 |
| | | Mean (StdDev) | 71.6 (20.18) | 73.1 (18.33) | 72.3 (19.34) |
| | | Median | 75.0 | 80.0 | 75.0 |
| | | Q1, Q3 | 60.0, 88.0 | 70.0, 85.0 | 60.0, 85.0 |
| | | Min, Max | 5, 100 | 25, 100 | 5, 100 |
| | Actual (Subjects with Change at Visit) | n | 58 | 44 | 102 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 76.9 (17.74) | 77.4 (13.44) | 77.1 (15.95) |
| | | Median | 80.0 | 80.0 | 80.0 |
| | | Q1, Q3 | 70.0, 90.0 | 69.0, 90.0 | 70.0, 90.0 |
| | | Min, Max | 30, 100 | 50, 100 | 30, 100 |
| | | Follow-Up Week 24 | | | |
| | | Mean (StdDev) | 72.9 (20.18) | 72.5 (18.53) | 72.7 (19.39) |
| | | Median | 77.5 | 77.5 | 77.5 |
| | | Q1, Q3 | 60.0, 90.0 | 69.5, 85.0 | 60.0, 85.0 |
| | | Min, Max | 5, 100 | 25, 100 | 5, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Change at Visit | Mean (StdDev) | -4.0 (14.83) | -4.9 (13.74) | -4.4 (14.31) |
| | | Median | 0.0 | -2.5 | 0.0 |
| | | Q1, Q3 | -10.0, 5.0 | -10.0, 1.0 | -10.0, 5.0 |
| | | Min, Max | -45, 40 | -37, 20 | -45, 40 |
| | | p-value[1] | | | 0.0024 |
| | | Delta2 (95% CI) [3] | | | 0.25 (0.09, 0.41) |
| | | Delta3 (95% CI) [4] | | | 0.28 (0.10, 0.45) |
| | | LS Mean (SE) | -4.0 (1.86) | -4.9 (2.14) | -4.4 (1.41) |
| | | 95% CI | -7.7, -0.3 | -9.1, -0.6 | -7.2, -1.6 |
| | | p-value[2] | | | 0.0023 |
| | Change up to Visit | n [5] | 101 | 77 | 178 |
| | | LS Mean (SE) | -6.8 (1.76) | -4.9 (2.02) | -6.0 (1.33) |
| | | 95% CI | -10.3, -3.3 | -8.9, -0.9 | -8.6, -3.3 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Last On-treatment Visit Prior to Progression | Actual | n | 265 | 172 | 437 |
| | | Mean (StdDev) | 17.3 (16.31) | 16.1 (16.50) | 16.8 (16.38) |
| | | Median | 14.3 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 23.8 | 4.8, 19.0 | 4.8, 23.8 |
| | | Min, Max | 0, 81 | 0, 81 | 0, 81 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| End of Treatment | Actual (All Subjects) | n | 217 | 162 | 379 |
| | | Mean (StdDev) | 23.3 (20.68) | 20.8 (18.91) | 22.2 (19.96) |
| | | Median | 19.0 | 19.0 | 19.0 |
| | | Q1, Q3 | 9.5, 38.1 | 9.5, 23.8 | 9.5, 33.3 |
| | | Min, Max | 0, 90 | 0, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 212 | 150 | 362 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 16.9 (16.04) | 15.0 (15.51) | 16.1 (15.83) |
| | | Median | 14.3 | 9.5 | 14.3 |
| | | Q1, Q3 | 4.8, 23.8 | 4.8, 19.0 | 4.8, 23.8 |
| | | Min, Max | 0, 81 | 0, 81 | 0, 81 |
| | | End of Treatment | | | |
| | | Mean (StdDev) | 23.2 (20.88) | 20.3 (19.09) | 22.0 (20.18) |
| | | Median | 14.3 | 14.3 | 14.3 |
| | | Q1, Q3 | 7.5, 38.1 | 4.8, 23.8 | 5.6, 33.3 |
| | | Min, Max | 0, 90 | 0, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| End of Treatment | Change at Visit | Mean (StdDev) | 6.3 (16.50) | 5.3 (14.17) | 5.9 (15.57) |
| | | Median | 2.4 | 4.8 | 4.8 |
| | | Q1, Q3 | -4.8, 14.3 | -4.8, 9.5 | -4.8, 9.5 |
| | | Min, Max | -28, 71 | -29, 67 | -29, 71 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | -0.33 (-0.42, -0.23) |
| | | Delta3 (95% CI) [4] | | | -0.37 (-0.48, -0.27) |
| | | LS Mean (SE) | 6.5 (1.06) | 5.1 (1.26) | 5.9 (0.81) |
| | | 95% CI | 4.4, 8.5 | 2.6, 7.6 | 4.3, 7.5 |
| | | p-value[2] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Actual (All Subjects) | n | 133 | 97 | 230 |
| | | Mean (StdDev) | 20.8 (21.35) | 23.0 (19.33) | 21.7 (20.51) |
| | | Median | 14.3 | 19.0 | 14.3 |
| | | Q1, Q3 | 4.8, 33.3 | 9.5, 33.3 | 4.8, 33.3 |
| | | Min, Max | 0, 90 | 0, 86 | 0, 90 |
| | Actual (Subjects with Change at Visit) | n | 133 | 92 | 225 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 15.1 (14.93) | 15.4 (13.87) | 15.2 (14.48) |
| | | Median | 9.5 | 14.3 | 9.5 |
| | | Q1, Q3 | 4.8, 19.0 | 4.8, 19.0 | 4.8, 19.0 |
| | | Min, Max | 0, 67 | 0, 76 | 0, 76 |
| | | Follow-Up Week 4 | | | |
| | | Mean (StdDev) | 20.8 (21.35) | 23.3 (19.76) | 21.8 (20.71) |
| | | Median | 14.3 | 19.0 | 14.3 |
| | | Q1, Q3 | 4.8, 33.3 | 9.5, 33.3 | 4.8, 33.3 |
| | | Min, Max | 0, 90 | 0, 86 | 0, 90 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Change at Visit | Mean (StdDev) | 5.6 (18.98) | 7.9 (16.24) | 6.6 (17.91) |
| | | Median | 4.8 | 7.1 | 4.8 |
| | | Q1, Q3 | -4.8, 9.5 | 0.0, 16.7 | -4.8, 14.3 |
| | | Min, Max | -38, 71 | -29, 62 | -38, 71 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | -0.37 (-0.50, -0.23) |
| | | Delta3 (95% CI) [4] | | | -0.45 (-0.62, -0.29) |
| | | LS Mean (SE) | 5.6 (1.53) | 8.0 (1.84) | 6.6 (1.17) |
| | | 95% CI | 2.6, 8.6 | 4.3, 11.6 | 4.3, 8.9 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 218 | 154 | 372 |
| | | LS Mean (SE) | 6.0 (1.49) | 8.7 (1.79) | 7.1 (1.15) |
| | | 95% CI | 3.0, 8.9 | 5.2, 12.2 | 4.8, 9.4 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Actual (All Subjects) | n | 136 | 90 | 226 |
| | | Mean (StdDev) | 21.4 (19.50) | 21.6 (18.73) | 21.5 (19.15) |
| | | Median | 17.9 | 19.0 | 19.0 |
| | | Q1, Q3 | 4.8, 33.3 | 9.5, 28.6 | 4.8, 28.6 |
| | | Min, Max | 0, 95 | 0, 100 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 135 | 86 | 221 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 16.6 (16.54) | 15.7 (14.66) | 16.2 (15.80) |
| | | Median | 9.5 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 23.8 | 4.8, 19.0 | 4.8, 23.8 |
| | | Min, Max | 0, 67 | 0, 71 | 0, 71 |
| | | Follow-Up Week 8 | | | |
| | | Mean (StdDev) | 21.6 (19.51) | 21.9 (18.98) | 21.7 (19.27) |
| | | Median | 19.0 | 19.0 | 19.0 |
| | | Q1, Q3 | 4.8, 33.3 | 9.5, 28.6 | 4.8, 28.6 |
| | | Min, Max | 0, 95 | 0, 100 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Change at Visit | Mean (StdDev) | 5.0 (17.22) | 6.2 (15.95) | 5.5 (16.71) |
| | | Median | 4.8 | 4.8 | 4.8 |
| | | Q1, Q3 | -4.8, 14.3 | 0.0, 14.3 | -4.8, 14.3 |
| | | Min, Max | -48, 52 | -48, 52 | -48, 52 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | -0.31 (-0.44, -0.18) |
| | | Delta3 (95% CI) [4] | | | -0.35 (-0.49, -0.20) |
| | | LS Mean (SE) | 5.1 (1.38) | 6.0 (1.73) | 5.5 (1.08) |
| | | 95% CI | 2.4, 7.8 | 2.6, 9.4 | 3.3, 7.6 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 221 | 154 | 375 |
| | | LS Mean (SE) | 5.5 (1.31) | 6.9 (1.63) | 6.1 (1.02) |
| | | 95% CI | 2.9, 8.1 | 3.7, 10.1 | 4.1, 8.1 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Actual (All Subjects) | n | 162 | 106 | 268 |
| | | Mean (StdDev) | 22.6 (20.57) | 22.0 (17.96) | 22.4 (19.55) |
| | | Median | 19.0 | 19.0 | 19.0 |
| | | Q1, Q3 | 9.5, 33.3 | 9.5, 33.3 | 9.5, 33.3 |
| | | Min, Max | 0, 100 | 0, 81 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 158 | 101 | 259 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 16.1 (15.33) | 16.0 (15.20) | 16.0 (15.25) |
| | | Median | 9.5 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 23.8 | 4.8, 19.0 | 4.8, 23.8 |
| | | Min, Max | 0, 67 | 0, 76 | 0, 76 |
| | | Follow-Up Week 12 | | | |
| | | Mean (StdDev) | 22.7 (20.67) | 22.3 (18.25) | 22.6 (19.73) |
| | | Median | 19.0 | 19.0 | 19.0 |
| | | Q1, Q3 | 9.5, 33.3 | 9.5, 33.3 | 9.5, 33.3 |
| | | Min, Max | 0, 100 | 0, 81 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Change at Visit | Mean (StdDev) | 6.7 (17.18) | 6.3 (16.24) | 6.5 (16.79) |
| | | Median | 4.8 | 4.8 | 4.8 |
| | | Q1, Q3 | -4.8, 14.3 | 0.0, 9.5 | -4.8, 14.3 |
| | | Min, Max | -29, 86 | -43, 67 | -43, 86 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | -0.37 (-0.49, -0.25) |
| | | Delta3 (95% CI) [4] | | | -0.43 (-0.57, -0.29) |
| | | LS Mean (SE) | 6.7 (1.30) | 6.3 (1.63) | 6.5 (1.02) |
| | | 95% CI | 4.1, 9.2 | 3.1, 9.5 | 4.5, 8.5 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 228 | 154 | 382 |
| | | LS Mean (SE) | 6.0 (1.26) | 6.6 (1.58) | 6.2 (0.99) |
| | | 95% CI | 3.5, 8.4 | 3.5, 9.8 | 4.3, 8.2 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Actual (All Subjects) | n | 129 | 83 | 212 |
| | | Mean (StdDev) | 21.0 (18.61) | 18.9 (16.41) | 20.2 (17.77) |
| | | Median | 19.0 | 14.3 | 14.3 |
| | | Q1, Q3 | 5.6, 28.6 | 4.8, 28.6 | 4.8, 28.6 |
| | | Min, Max | 0, 81 | 0, 90 | 0, 90 |
| | Actual (Subjects with Change at Visit) | n | 124 | 78 | 202 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 15.4 (15.04) | 14.4 (13.38) | 15.0 (14.40) |
| | | Median | 9.5 | 11.9 | 9.5 |
| | | Q1, Q3 | 4.8, 23.8 | 4.8, 19.0 | 4.8, 19.0 |
| | | Min, Max | 0, 67 | 0, 57 | 0, 67 |
| | | Follow-Up Week 24 | | | |
| | | Mean (StdDev) | 20.7 (18.68) | 18.9 (16.47) | 20.0 (17.84) |
| | | Median | 19.0 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 28.6 | 4.8, 28.6 | 4.8, 28.6 |
| | | Min, Max | 0, 81 | 0, 90 | 0, 90 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) | Overall (N=733) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Change at Visit | Mean (StdDev) | 5.3 (18.88) | 4.5 (12.99) | 5.0 (16.82) |
| | | Median | 0.0 | 4.8 | 0.0 |
| | | Q1, Q3 | -4.8, 11.9 | -4.8, 9.5 | -4.8, 9.5 |
| | | Min, Max | -67, 62 | -24, 38 | -67, 62 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | -0.31 (-0.45, -0.16) |
| | | Delta3 (95% CI) [4] | | | -0.35 (-0.51, -0.18) |
| | | LS Mean (SE) | 5.5 (1.42) | 4.2 (1.79) | 5.0 (1.11) |
| | | 95% CI | 2.7, 8.3 | 0.7, 7.7 | 2.8, 7.2 |
| | | p-value[2] | | | <0.0001 |
| | Change up to Visit | n [5] | 232 | 154 | 386 |
| | | LS Mean (SE) | 5.5 (1.37) | 4.2 (1.73) | 5.0 (1.08) |
| | | 95% CI | 2.7, 8.2 | 0.8, 7.6 | 2.8, 7.1 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Last On-treatment Visit Prior to Progression | Actual | n | 118 | 84 | 202 |
| | | Mean (StdDev) | 17.0 (15.14) | 17.7 (18.10) | 17.3 (16.40) |
| | | Median | 14.3 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 23.8 | 4.8, 23.8 | 4.8, 23.8 |
| | | Min, Max | 0, 67 | 0, 81 | 0, 81 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| End of Treatment | Actual (All Subjects) | n | 92 | 82 | 174 |
| | | Mean (StdDev) | 22.6 (19.90) | 22.4 (19.42) | 22.5 (19.62) |
| | | Median | 16.7 | 19.0 | 19.0 |
| | | Q1, Q3 | 9.5, 33.3 | 9.5, 28.6 | 9.5, 28.6 |
| | | Min, Max | 0, 90 | 0, 86 | 0, 90 |
| | Actual (Subjects with Change at Visit) | n | 91 | 75 | 166 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 16.3 (14.69) | 16.6 (17.62) | 16.4 (16.03) |
| | | Median | 14.3 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 23.8 | 4.8, 19.0 | 4.8, 19.0 |
| | | Min, Max | 0, 67 | 0, 81 | 0, 81 |
| | | End of Treatment | | | |
| | | Mean (StdDev) | 22.5 (19.98) | 21.7 (19.76) | 22.1 (19.82) |
| | | Median | 14.3 | 19.0 | 16.7 |
| | | Q1, Q3 | 9.5, 33.3 | 9.5, 23.8 | 9.5, 28.6 |
| | | Min, Max | 0, 90 | 0, 86 | 0, 90 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| End of Treatment | Change at Visit | Mean (StdDev) | 6.2 (17.76) | 5.1 (14.34) | 5.7 (16.27) |
| | | Median | 0.0 | 4.8 | 0.0 |
| | | Q1, Q3 | -4.8, 14.3 | 0.0, 9.5 | -4.8, 9.5 |
| | | Min, Max | -24, 71 | -24, 67 | -24, 71 |
| | | p-value[1] | | | <0.0001 |
| | | Delta2 (95% CI) [3] | | | -0.32 (-0.46, -0.18) |
| | | Delta3 (95% CI) [4] | | | -0.36 (-0.52, -0.20) |
| | | LS Mean (SE) | 6.2 (1.66) | 5.2 (1.83) | 5.7 (1.23) |
| | | 95% CI | 2.9, 9.5 | 1.6, 8.8 | 3.3, 8.2 |
| | | p-value[2] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Actual (All Subjects) | n | 64 | 53 | 117 |
| | | Mean (StdDev) | 21.0 (21.17) | 21.0 (16.90) | 21.0 (19.27) |
| | | Median | 14.3 | 19.0 | 14.3 |
| | | Q1, Q3 | 4.8, 35.7 | 9.5, 28.6 | 4.8, 33.3 |
| | | Min, Max | 0, 90 | 0, 76 | 0, 90 |
| | Actual (Subjects with Change at Visit) | n | 64 | 50 | 114 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 15.6 (14.99) | 14.9 (11.69) | 15.2 (13.59) |
| | | Median | 11.9 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 19.0 | 4.8, 19.0 | 4.8, 19.0 |
| | | Min, Max | 0, 67 | 0, 57 | 0, 67 |
| | | Follow-Up Week 4 | | | |
| | | Mean (StdDev) | 21.0 (21.17) | 21.4 (17.30) | 21.2 (19.49) |
| | | Median | 14.3 | 19.0 | 14.3 |
| | | Q1, Q3 | 4.8, 35.7 | 9.5, 28.6 | 4.8, 33.3 |
| | | Min, Max | 0, 90 | 0, 76 | 0, 90 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 4 | Change at Visit | Mean (StdDev) | 5.4 (17.71) | 6.6 (15.48) | 5.9 (16.71) |
| | | Median | 4.8 | 4.8 | 4.8 |
| | | Q1, Q3 | -4.8, 9.5 | -4.8, 14.3 | -4.8, 14.3 |
| | | Min, Max | -29, 57 | -29, 62 | -29, 62 |
| | | p-value[1] | | | 0.0002 |
| | | Delta2 (95% CI) [3] | | | -0.35 (-0.54, -0.17) |
| | | Delta3 (95% CI) [4] | | | -0.44 (-0.67, -0.20) |
| | | LS Mean (SE) | 5.5 (2.07) | 6.5 (2.34) | 5.9 (1.55) |
| | | 95% CI | 1.4, 9.6 | 1.8, 11.1 | 2.9, 9.0 |
| | | p-value[2] | | | 0.0002 |
| | Change up to Visit | n [5] | 95 | 77 | 172 |
| | | LS Mean (SE) | 6.1 (2.07) | 7.3 (2.34) | 6.6 (1.56) |
| | | 95% CI | 2.0, 10.2 | 2.6, 11.9 | 3.5, 9.7 |
| | | p-value[6] | | | <0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Actual (All Subjects) | n | 61 | 50 | 111 |
| | | Mean (StdDev) | 21.5 (19.92) | 21.0 (17.27) | 21.3 (18.69) |
| | | Median | 16.7 | 19.0 | 19.0 |
| | | Q1, Q3 | 9.5, 28.6 | 9.5, 28.6 | 9.5, 28.6 |
| | | Min, Max | 0, 95 | 0, 90 | 0, 95 |
| | Actual (Subjects with Change at Visit) | n | 61 | 48 | 109 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 15.8 (15.35) | 17.4 (15.20) | 16.5 (15.23) |
| | | Median | 14.3 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 19.0 | 4.8, 19.0 | 4.8, 19.0 |
| | | Min, Max | 0, 67 | 0, 71 | 0, 71 |
| | | Follow-Up Week 8 | | | |
| | | Mean (StdDev) | 21.5 (19.92) | 21.0 (17.57) | 21.3 (18.84) |
| | | Median | 16.7 | 19.0 | 19.0 |
| | | Q1, Q3 | 9.5, 28.6 | 9.5, 28.6 | 9.5, 28.6 |
| | | Min, Max | 0, 95 | 0, 90 | 0, 95 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 8 | Change at Visit | Mean (StdDev) | 5.7 (15.80) | 3.7 (16.79) | 4.8 (16.20) |
| | | Median | 4.8 | 0.0 | 4.8 |
| | | Q1, Q3 | -4.8, 14.3 | -4.8, 11.9 | -4.8, 14.3 |
| | | Min, Max | -19, 52 | -48, 52 | -48, 52 |
| | | p-value[1] | | | 0.0024 |
| | | Delta2 (95% CI) [3] | | | -0.28 (-0.46, -0.10) |
| | | Delta3 (95% CI) [4] | | | -0.32 (-0.52, -0.11) |
| | | LS Mean (SE) | 5.5 (2.01) | 3.9 (2.26) | 4.8 (1.50) |
| | | 95% CI | 1.5, 9.5 | -0.5, 8.4 | 1.9, 7.8 |
| | | p-value[2] | | | 0.0017 |
| | Change up to Visit | n [5] | 97 | 77 | 174 |
| | | LS Mean (SE) | 6.3 (1.93) | 4.9 (2.18) | 5.7 (1.45) |
| | | 95% CI | 2.5, 10.2 | 0.6, 9.3 | 2.9, 8.6 |
| | | p-value[6] | | | 0.0001 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Actual (All Subjects) | n | 72 | 57 | 129 |
| | | Mean (StdDev) | 22.7 (21.91) | 19.6 (14.62) | 21.3 (19.03) |
| | | Median | 19.0 | 14.3 | 19.0 |
| | | Q1, Q3 | 7.1, 28.6 | 9.5, 28.6 | 9.5, 28.6 |
| | | Min, Max | 0, 100 | 0, 57 | 0, 100 |
| | Actual (Subjects with Change at Visit) | n | 71 | 55 | 126 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 15.8 (14.75) | 15.9 (13.66) | 15.8 (14.23) |
| | | Median | 14.3 | 14.3 | 14.3 |
| | | Q1, Q3 | 4.8, 19.0 | 4.8, 19.0 | 4.8, 19.0 |
| | | Min, Max | 0, 67 | 0, 57 | 0, 67 |
| | | Follow-Up Week 12 | | | |
| | | Mean (StdDev) | 22.9 (21.96) | 19.5 (14.84) | 21.4 (19.19) |
| | | Median | 19.0 | 14.3 | 19.0 |
| | | Q1, Q3 | 9.5, 28.6 | 9.5, 28.6 | 9.5, 28.6 |
| | | Min, Max | 0, 100 | 0, 57 | 0, 100 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 12 | Change at Visit | Mean (StdDev) | 7.2 (18.05) | 3.5 (16.55) | 5.6 (17.44) |
| | | Median | 4.8 | 4.8 | 4.8 |
| | | Q1, Q3 | -4.8, 19.0 | -4.8, 9.5 | -4.8, 14.3 |
| | | Min, Max | -24, 71 | -43, 48 | -43, 71 |
| | | p-value[1] | | | 0.0005 |
| | | Delta2 (95% CI) [3] | | | -0.33 (-0.52, -0.15) |
| | | Delta3 (95% CI) [4] | | | -0.39 (-0.61, -0.17) |
| | | LS Mean (SE) | 7.2 (1.99) | 3.6 (2.26) | 5.6 (1.50) |
| | | 95% CI | 3.2, 11.1 | -0.9, 8.1 | 2.6, 8.6 |
| | | p-value[2] | | | 0.0003 |
| | Change up to Visit | n [5] | 100 | 77 | 177 |
| | | LS Mean (SE) | 6.3 (1.93) | 4.5 (2.20) | 5.5 (1.45) |
| | | 95% CI | 2.5, 10.1 | 0.1, 8.8 | 2.6, 8.4 |
| | | p-value[6] | | | 0.0002 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Actual (All Subjects) | n | 62 | 45 | 107 |
| | | Mean (StdDev) | 22.6 (19.22) | 17.9 (13.36) | 20.6 (17.09) |
| | | Median | 19.0 | 14.3 | 19.0 |
| | | Q1, Q3 | 9.5, 33.3 | 4.8, 23.8 | 9.5, 28.6 |
| | | Min, Max | 0, 76 | 0, 52 | 0, 76 |
| | Actual (Subjects with Change at Visit) | n | 57 | 42 | 99 |
| | | Last On-treatment Visit Prior to Progression | | | |
| | | Mean (StdDev) | 15.6 (14.48) | 12.6 (10.77) | 14.3 (13.06) |
| | | Median | 14.3 | 11.9 | 14.3 |
| | | Q1, Q3 | 4.8, 19.0 | 4.8, 19.0 | 4.8, 19.0 |
| | | Min, Max | 0, 67 | 0, 57 | 0, 67 |
| | | Follow-Up Week 24 | | | |
| | | Mean (StdDev) | 22.1 (19.46) | 17.9 (13.17) | 20.3 (17.13) |
| | | Median | 19.0 | 14.3 | 19.0 |
| | | Q1, Q3 | 9.5, 28.6 | 4.8, 23.8 | 4.8, 28.6 |
| | | Min, Max | 0, 76 | 0, 52 | 0, 76 |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) | Overall (N=352) |
|---|---|---|---|---|---|
| Follow-Up Week 24 | Change at Visit | Mean (StdDev) | 6.5 (19.79) | 5.3 (12.09) | 6.0 (16.89) |
| | | Median | 0.0 | 4.8 | 4.8 |
| | | Q1, Q3 | -4.8, 14.3 | -4.8, 9.5 | -4.8, 14.3 |
| | | Min, Max | -38, 62 | -24, 38 | -38, 62 |
| | | p-value[1] | | | 0.0006 |
| | | Delta2 (95% CI) [3] | | | -0.39 (-0.62, -0.17) |
| | | Delta3 (95% CI) [4] | | | -0.46 (-0.72, -0.20) |
| | | LS Mean (SE) | 7.1 (2.10) | 4.5 (2.45) | 6.0 (1.59) |
| | | 95% CI | 3.0, 11.3 | -0.4, 9.3 | 2.9, 9.2 |
| | | p-value[2] | | | 0.0003 |
| | Change up to Visit | n [5] | 102 | 77 | 179 |
| | | LS Mean (SE) | 6.6 (2.03) | 4.6 (2.39) | 5.7 (1.56) |
| | | 95% CI | 2.5, 10.6 | -0.1, 9.4 | 2.6, 8.8 |
| | | p-value[6] | | | 0.0004 |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 476 | 238 |
| | | Mean (StdDev) | 1.4 (1.04) | 1.4 (0.97) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 422 | 221 |
| | | Mean (StdDev) | 1.5 (1.06) | 1.3 (1.08) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 416 | 215 |
| | | Mean (StdDev) | 0.1 (1.08) | -0.1 (1.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -3, 4 |
| | | LS Mean (SE) | 0.1 (0.05) | -0.1 (0.07) |
| | | 95% CI | 0.0, 0.2 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.09) | |
| | | 95% CI | 0.0, 0.4 | |
| | | p-value | 0.0252 | |
| | | Corrected Hedges g (95% CI) [2] | 0.19 (0.02, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 352 | 185 |
| | | Mean (StdDev) | 1.3 (1.03) | 1.3 (1.05) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 345 | 181 |
| | | Mean (StdDev) | -0.1 (1.12) | -0.1 (1.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 3 | -3, 3 |
| | | LS Mean (SE) | -0.1 (0.05) | -0.1 (0.07) |
| | | 95% CI | -0.2, 0.0 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.7965 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.16, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 317 | 159 |
| | | Mean (StdDev) | 1.1 (0.97) | 1.1 (0.93) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 311 | 155 |
| | | Mean (StdDev) | -0.3 (1.08) | -0.3 (1.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.2 (0.05) | -0.2 (0.07) |
| | | 95% CI | -0.3, -0.1 | -0.3, -0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.08) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9311 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.20, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 283 | 125 |
| | | Mean (StdDev) | 1.1 (1.00) | 1.2 (0.98) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 276 | 121 |
| | | Mean (StdDev) | -0.3 (1.02) | -0.2 (1.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.2 (0.05) | -0.2 (0.08) |
| | | 95% CI | -0.3, -0.1 | -0.3, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.8648 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.23, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 254 | 99 |
| | | Mean (StdDev) | 1.1 (0.96) | 1.3 (1.13) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 249 | 95 |
| | | Mean (StdDev) | -0.3 (1.09) | -0.1 (1.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.3 (0.05) | 0.0 (0.08) |
| | | 95% CI | -0.4, -0.2 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.09) | |
| | | 95% CI | -0.4, 0.0 | |
| | | p-value | 0.0181 | |
| | | Corrected Hedges g (95% CI) [2] | -0.28 (-0.52, -0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 231 | 97 |
| | | Mean (StdDev) | 1.0 (0.97) | 1.1 (0.94) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 226 | 93 |
| | | Mean (StdDev) | -0.3 (1.11) | -0.3 (0.96) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 2 |
| | | LS Mean (SE) | -0.3 (0.05) | -0.2 (0.08) |
| | | 95% CI | -0.4, -0.2 | -0.4, -0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.4145 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.34, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 1.0 (0.98) | 1.0 (0.95) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 205 | 80 |
| | | Mean (StdDev) | -0.3 (1.10) | -0.2 (1.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.3 (0.05) | -0.2 (0.08) |
| | | 95% CI | -0.4, -0.2 | -0.3, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.10) | |
| | | 95% CI | -0.3, 0.0 | |
| | | p-value | 0.1216 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.46, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 172 | 71 |
| | | Mean (StdDev) | 1.0 (1.02) | 1.1 (1.05) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 169 | 69 |
| | | Mean (StdDev) | -0.2 (1.22) | -0.3 (1.02) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.3 (0.06) | -0.3 (0.09) |
| | | 95% CI | -0.4, -0.2 | -0.4, -0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.11) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.8053 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.31, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 143 | 54 |
| | | Mean (StdDev) | 1.0 (1.00) | 1.2 (1.20) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 140 | 53 |
| | | Mean (StdDev) | -0.2 (0.99) | -0.1 (1.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.3 (0.07) | -0.1 (0.11) |
| | | 95% CI | -0.4, -0.1 | -0.3, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.13) | |
| | | 95% CI | -0.4, 0.1 | |
| | | p-value | 0.1789 | |
| | | Corrected Hedges g (95% CI) [2] | -0.21 (-0.53, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 87 | 32 |
| | | Mean (StdDev) | 1.0 (1.01) | 1.1 (1.21) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 85 | 31 |
| | | Mean (StdDev) | -0.4 (1.13) | -0.2 (0.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 1 |
| | | LS Mean (SE) | -0.5 (0.08) | -0.2 (0.14) |
| | | 95% CI | -0.6, -0.3 | -0.4, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (0.16) | |
| | | 95% CI | -0.6, 0.0 | |
| | | p-value | 0.0849 | |
| | | Corrected Hedges g (95% CI) [2] | -0.36 (-0.77, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 46 | 16 |
| | | Mean (StdDev) | 1.0 (1.03) | 1.0 (0.89) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.5 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 45 | 15 |
| | | Mean (StdDev) | -0.2 (1.10) | -0.7 (1.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 1 |
| | | LS Mean (SE) | -0.3 (0.10) | -0.4 (0.17) |
| | | 95% CI | -0.4, -0.1 | -0.7, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.19) | |
| | | 95% CI | -0.3, 0.5 | |
| | | p-value | 0.6038 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.43, 0.74) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 1.3 (1.27) | 0.9 (0.99) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 26 | 8 |
| | | Mean (StdDev) | 0.2 (0.90) | -0.6 (0.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | -1.5, 0.0 |
| | | Min, Max | -1, 2 | -2, 0 |
| | | LS Mean (SE) | -0.1 (0.12) | -0.3 (0.21) |
| | | 95% CI | -0.3, 0.2 | -0.7, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.25) | |
| | | 95% CI | -0.3, 0.7 | |
| | | p-value | 0.3967 | |
| | | Corrected Hedges g (95% CI) [2] | 0.33 (-0.46, 1.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 1.2 (1.31) | 0.5 (0.71) |
| | | Median | 1.0 | 0.5 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 1 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.1 (1.21) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.6 (1.34) | 2.0 (2.83) |
| | | Median | 0.0 | 2.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 4.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -0.2 (0.84) | 1.5 (2.12) |
| | | Median | 0.0 | 1.5 |
| | | Q1, Q3 | -1.0, 0.0 | 0.0, 3.0 |
| | | Min, Max | -1, 1 | 0, 3 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 1.0 (NA) | |
| | | Median | 1.0 | |
| | | Q1, Q3 | 1.0, 1.0 | |
| | | Min, Max | 1, 1 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 1.0 (NA) | |
| | | Median | 1.0 | |
| | | Q1, Q3 | 1.0, 1.0 | |
| | | Min, Max | 1, 1 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 285 | 170 |
| | | Mean (StdDev) | 1.5 (1.15) | 1.3 (1.06) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 283 | 167 |
| | | Mean (StdDev) | 0.1 (1.26) | -0.1 (1.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -3, 4 |
| | | LS Mean (SE) | 0.1 (0.06) | -0.1 (0.08) |
| | | 95% CI | 0.0, 0.2 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.10) | |
| | | 95% CI | 0.0, 0.4 | |
| | | p-value | 0.0342 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (0.02, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 149 | 103 |
| | | Mean (StdDev) | 1.4 (1.11) | 1.5 (1.07) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 148 | 101 |
| | | Mean (StdDev) | 0.0 (1.29) | 0.1 (1.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 3 | -2, 4 |
| | | LS Mean (SE) | 0.1 (0.08) | 0.2 (0.09) |
| | | 95% CI | -0.1, 0.2 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.12) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.4405 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.35, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 169 | 96 |
| | | Mean (StdDev) | 1.6 (1.00) | 1.8 (1.09) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 166 | 94 |
| | | Mean (StdDev) | 0.1 (1.23) | 0.4 (1.11) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -2, 4 |
| | | LS Mean (SE) | 0.2 (0.07) | 0.4 (0.09) |
| | | 95% CI | 0.0, 0.3 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.11) | |
| | | 95% CI | -0.4, 0.0 | |
| | | p-value | 0.0505 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.51, 0.00) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 196 | 111 |
| | | Mean (StdDev) | 1.6 (1.07) | 1.6 (1.04) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 195 | 108 |
| | | Mean (StdDev) | 0.2 (1.12) | 0.2 (1.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.07) | 0.2 (0.09) |
| | | 95% CI | 0.0, 0.3 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.11) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.5247 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.31, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 160 | 89 |
| | | Mean (StdDev) | 1.5 (1.04) | 1.6 (1.01) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 158 | 87 |
| | | Mean (StdDev) | 0.1 (1.15) | 0.2 (1.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.08) | 0.2 (0.10) |
| | | 95% CI | 0.0, 0.3 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.13) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.7627 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.30, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -0.1 (0.03) | -0.1 (0.05) |
| | | 95% CI | -0.2, 0.0 | -0.2, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.06) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.5260 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.21, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 240 |
| | | Mean (StdDev) | 0.0 (0.23) | 0.1 (0.39) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 3 |
| Cycle 3 Day 1 | Actual | n | 423 | 220 |
| | | Mean (StdDev) | 0.1 (0.41) | 0.0 (0.19) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 1 |
| | Change from BL | n | 419 | 216 |
| | | Mean (StdDev) | 0.1 (0.39) | -0.1 (0.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 1 |
| | | LS Mean (SE) | 0.1 (0.02) | 0.0 (0.02) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.03) | |
| | | 95% CI | 0.0, 0.2 | |
| | | p-value | 0.0003 | |
| | | Corrected Hedges g (95% CI) [2] | 0.30 (0.14, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 352 | 184 |
| | | Mean (StdDev) | 0.1 (0.39) | 0.0 (0.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 347 | 181 |
| | | Mean (StdDev) | 0.1 (0.43) | -0.1 (0.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 1 |
| | | LS Mean (SE) | 0.1 (0.02) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.03) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.0368 | |
| | | Corrected Hedges g (95% CI) [2] | 0.19 (0.01, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 316 | 157 |
| | | Mean (StdDev) | 0.1 (0.35) | 0.0 (0.26) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 311 | 154 |
| | | Mean (StdDev) | 0.0 (0.40) | -0.1 (0.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -3, 2 |
| | | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.03) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.1345 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.05, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 285 | 125 |
| | | Mean (StdDev) | 0.1 (0.37) | 0.1 (0.32) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 280 | 122 |
| | | Mean (StdDev) | 0.0 (0.42) | -0.1 (0.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 4 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.04) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.1973 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.07, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 254 | 99 |
| | | Mean (StdDev) | 0.1 (0.35) | 0.1 (0.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 1 |
| | Change from BL | n | 250 | 96 |
| | | Mean (StdDev) | 0.0 (0.40) | -0.1 (0.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.04) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.2018 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.08, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 230 | 97 |
| | | Mean (StdDev) | 0.0 (0.21) | 0.1 (0.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 3 |
| | Change from BL | n | 226 | 94 |
| | | Mean (StdDev) | 0.0 (0.27) | -0.1 (0.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 1 | -3, 2 |
| | | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.0 | 0.0, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.03) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.8793 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.22, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 0.0 (0.27) | 0.1 (0.24) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 1 |
| | Change from BL | n | 206 | 81 |
| | | Mean (StdDev) | 0.0 (0.34) | -0.1 (0.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.0 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.04) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.8014 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.22, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 173 | 71 |
| | | Mean (StdDev) | 0.1 (0.31) | 0.0 (0.26) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 2 |
| | Change from BL | n | 171 | 70 |
| | | Mean (StdDev) | 0.1 (0.36) | -0.1 (0.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.04) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.0798 | |
| | | Corrected Hedges g (95% CI) [2] | 0.25 (-0.03, 0.53) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 143 | 55 |
| | | Mean (StdDev) | 0.1 (0.46) | 0.1 (0.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 141 | 54 |
| | | Mean (StdDev) | 0.1 (0.50) | -0.1 (0.58) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.0 (0.06) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.07) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.3127 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.15, 0.48) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 0.1 (0.25) | 0.2 (0.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 2 |
| | Change from BL | n | 87 | 31 |
| | | Mean (StdDev) | 0.1 (0.28) | 0.0 (0.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 1 | -1, 2 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.0 (0.06) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.8828 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.44, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 46 | 16 |
| | | Mean (StdDev) | 0.0 (0.15) | 0.3 (0.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 2 |
| | Change from BL | n | 46 | 15 |
| | | Mean (StdDev) | 0.0 (0.21) | 0.1 (0.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 1 | -1, 2 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.1 (0.06) |
| | | 95% CI | -0.1, 0.1 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.07) | |
| | | 95% CI | -0.3, 0.0 | |
| | | p-value | 0.0432 | |
| | | Corrected Hedges g (95% CI) [2] | -0.62 (-1.21, -0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 26 | 8 |
| | | Mean (StdDev) | 0.0 (0.00) | -0.3 (0.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | -2, 0 |
| | | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.03) |
| | | 95% CI | -0.1, 0.0 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.04) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.6312 | |
| | | Corrected Hedges g (95% CI) [2] | -0.19 (-0.98, 0.60) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 0.1 (0.27) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.1 (0.27) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 286 | 170 |
| | | Mean (StdDev) | 0.1 (0.45) | 0.1 (0.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 284 | 167 |
| | | Mean (StdDev) | 0.1 (0.44) | 0.0 (0.56) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -3, 4 |
| | | LS Mean (SE) | 0.1 (0.03) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.1 | 0.0, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.04) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.3752 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.10, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 149 | 103 |
| | | Mean (StdDev) | 0.2 (0.60) | 0.1 (0.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 2 |
| | Change from BL | n | 149 | 101 |
| | | Mean (StdDev) | 0.1 (0.61) | 0.0 (0.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 4 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.0 (0.05) |
| | | 95% CI | 0.0, 0.2 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.06) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.2658 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.11, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 168 | 96 |
| | | Mean (StdDev) | 0.2 (0.46) | 0.2 (0.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 166 | 94 |
| | | Mean (StdDev) | 0.1 (0.48) | 0.1 (0.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -2, 4 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.2 (0.05) |
| | | 95% CI | 0.0, 0.2 | 0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.07) | |
| | | 95% CI | -0.2, 0.0 | |
| | | p-value | 0.2168 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.41, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 199 | 111 |
| | | Mean (StdDev) | 0.2 (0.62) | 0.1 (0.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 198 | 108 |
| | | Mean (StdDev) | 0.2 (0.63) | 0.1 (0.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 4 | -1, 4 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.1 (0.06) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.08) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.7669 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.20, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 161 | 90 |
| | | Mean (StdDev) | 0.1 (0.40) | 0.1 (0.41) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 160 | 88 |
| | | Mean (StdDev) | 0.1 (0.44) | 0.1 (0.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -1, 3 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.1 (0.05) |
| | | 95% CI | 0.0, 0.1 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.06) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.4856 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.35, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.0 (0.01) | 0.0 (0.02) |
| | | 95% CI | 0.0, 0.1 | 0.0, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.02) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.3505 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.08, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 476 | 240 |
| | | Mean (StdDev) | 0.8 (1.02) | 0.8 (1.02) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 423 | 221 |
| | | Mean (StdDev) | 0.7 (0.93) | 0.9 (1.05) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 416 | 217 |
| | | Mean (StdDev) | -0.1 (0.93) | 0.1 (1.03) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -4, 3 | -3, 3 |
| | | LS Mean (SE) | -0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | -0.2, 0.0 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.07) | |
| | | 95% CI | -0.3, 0.0 | |
| | | p-value | 0.0146 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.37, -0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 351 | 185 |
| | | Mean (StdDev) | 0.7 (0.93) | 0.8 (1.09) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 344 | 182 |
| | | Mean (StdDev) | -0.1 (0.88) | 0.0 (1.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -4, 3 | -4, 4 |
| | | LS Mean (SE) | -0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | -0.2, 0.0 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.08) | |
| | | 95% CI | -0.3, 0.0 | |
| | | p-value | 0.0306 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.38, -0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 315 | 156 |
| | | Mean (StdDev) | 0.8 (0.92) | 0.8 (0.98) |
| | | Median | 0.0 | 0.5 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 309 | 153 |
| | | Mean (StdDev) | 0.0 (1.00) | 0.0 (0.97) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -4, 2 |
| | | LS Mean (SE) | 0.0 (0.05) | 0.0 (0.07) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.08) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.7931 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.22, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 284 | 124 |
| | | Mean (StdDev) | 0.8 (0.97) | 0.9 (1.04) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 278 | 121 |
| | | Mean (StdDev) | 0.0 (0.96) | 0.0 (1.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | 0.0 (0.05) | 0.1 (0.07) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.7274 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.25, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 254 | 99 |
| | | Mean (StdDev) | 0.8 (0.97) | 0.8 (1.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 249 | 96 |
| | | Mean (StdDev) | 0.0 (0.98) | 0.0 (0.99) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.0 (0.05) | 0.0 (0.08) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9931 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.24, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 229 | 97 |
| | | Mean (StdDev) | 0.7 (0.97) | 0.8 (1.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 224 | 94 |
| | | Mean (StdDev) | 0.0 (0.97) | 0.0 (0.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -0.5, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | 0.0 (0.05) | 0.0 (0.07) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.09) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.3815 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.35, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 0.6 (0.92) | 0.7 (0.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 205 | 81 |
| | | Mean (StdDev) | -0.1 (0.94) | 0.0 (0.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | -0.1 (0.05) | 0.0 (0.07) |
| | | 95% CI | -0.1, 0.0 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.09) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.2434 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.41, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 173 | 71 |
| | | Mean (StdDev) | 0.7 (0.99) | 0.8 (1.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 170 | 70 |
| | | Mean (StdDev) | 0.0 (1.02) | 0.0 (0.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -2, 4 | -2, 3 |
| | | LS Mean (SE) | 0.0 (0.06) | 0.1 (0.09) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.11) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.2133 | |
| | | Corrected Hedges g (95% CI) [2] | -0.18 (-0.45, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 143 | 55 |
| | | Mean (StdDev) | 0.7 (0.98) | 0.7 (1.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 140 | 54 |
| | | Mean (StdDev) | 0.0 (1.04) | -0.1 (0.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -0.5, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | 0.0 (0.06) | 0.0 (0.10) |
| | | 95% CI | -0.1, 0.1 | -0.2, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.2, 0.3 | |
| | | p-value | 0.8515 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.28, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 0.6 (0.88) | 0.8 (1.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.5 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 87 | 31 |
| | | Mean (StdDev) | -0.1 (0.94) | -0.1 (0.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 2 |
| | | LS Mean (SE) | -0.1 (0.08) | 0.0 (0.13) |
| | | 95% CI | -0.3, 0.0 | -0.2, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.15) | |
| | | 95% CI | -0.4, 0.2 | |
| | | p-value | 0.4607 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.56, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 46 | 16 |
| | | Mean (StdDev) | 0.6 (0.81) | 0.6 (0.96) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 46 | 15 |
| | | Mean (StdDev) | 0.0 (0.87) | -0.1 (0.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -2, 3 | -1, 2 |
| | | LS Mean (SE) | 0.0 (0.09) | 0.0 (0.15) |
| | | 95% CI | -0.2, 0.2 | -0.3, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.18) | |
| | | 95% CI | -0.4, 0.4 | |
| | | p-value | 0.9827 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.58, 0.59) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 0.7 (0.86) | 0.3 (0.46) |
| | | Median | 1.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.5 |
| | | Min, Max | 0, 3 | 0, 1 |
| | Change from BL | n | 26 | 8 |
| | | Mean (StdDev) | 0.2 (0.83) | -0.3 (0.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -1, 2 | -1, 1 |
| | | LS Mean (SE) | 0.2 (0.13) | -0.1 (0.22) |
| | | 95% CI | -0.1, 0.4 | -0.5, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.25) | |
| | | 95% CI | -0.3, 0.7 | |
| | | p-value | 0.4005 | |
| | | Corrected Hedges g (95% CI) [2] | 0.33 (-0.47, 1.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 0.6 (0.76) | 1.0 (1.41) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 2 | 0, 2 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.4 (0.74) | 0.5 (0.71) |
| | | Median | 0.0 | 0.5 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -1, 2 | 0, 1 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.6 (1.34) | 2.0 (2.83) |
| | | Median | 0.0 | 2.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 4.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.6 (1.34) | 1.5 (2.12) |
| | | Median | 0.0 | 1.5 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 3.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 286 | 171 |
| | | Mean (StdDev) | 1.0 (1.01) | 1.1 (1.06) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 284 | 168 |
| | | Mean (StdDev) | 0.2 (1.08) | 0.3 (1.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -4, 3 |
| | | LS Mean (SE) | 0.2 (0.05) | 0.3 (0.07) |
| | | 95% CI | 0.1, 0.3 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.08) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.3566 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.28, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 149 | 102 |
| | | Mean (StdDev) | 1.0 (1.07) | 1.1 (1.09) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 149 | 100 |
| | | Mean (StdDev) | 0.2 (1.17) | 0.3 (1.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 4 | -4, 4 |
| | | LS Mean (SE) | 0.2 (0.08) | 0.3 (0.09) |
| | | 95% CI | 0.0, 0.3 | 0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.12) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.5108 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.34, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 169 | 96 |
| | | Mean (StdDev) | 1.0 (1.06) | 1.0 (0.96) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.5 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 166 | 94 |
| | | Mean (StdDev) | 0.2 (1.08) | 0.3 (1.03) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | 0.2 (0.06) | 0.2 (0.09) |
| | | 95% CI | 0.1, 0.3 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.11) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9251 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.27, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 198 | 111 |
| | | Mean (StdDev) | 1.0 (1.03) | 1.0 (0.97) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 197 | 108 |
| | | Mean (StdDev) | 0.2 (1.21) | 0.2 (1.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 4 | -4, 3 |
| | | LS Mean (SE) | 0.2 (0.06) | 0.2 (0.09) |
| | | 95% CI | 0.1, 0.3 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.11) | |
| | | 95% CI | -0.2, 0.3 | |
| | | p-value | 0.7233 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.19, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 160 | 90 |
| | | Mean (StdDev) | 1.0 (1.08) | 0.9 (0.94) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 158 | 88 |
| | | Mean (StdDev) | 0.2 (1.12) | 0.1 (1.03) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 3 | -2, 3 |
| | | LS Mean (SE) | 0.3 (0.07) | 0.1 (0.09) |
| | | 95% CI | 0.1, 0.4 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.11) | |
| | | 95% CI | 0.0, 0.4 | |
| | | p-value | 0.0605 | |
| | | Corrected Hedges g (95% CI) [2] | 0.25 (-0.01, 0.51) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.1 (0.03) | 0.1 (0.05) |
| | | 95% CI | 0.0, 0.1 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.06) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.6103 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.20, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 477 | 239 |
| | | Mean (StdDev) | 0.2 (0.55) | 0.3 (0.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 425 | 221 |
| | | Mean (StdDev) | 0.6 (0.85) | 0.3 (0.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 419 | 217 |
| | | Mean (StdDev) | 0.4 (0.87) | 0.0 (0.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | -2, 4 | -3, 3 |
| | | LS Mean (SE) | 0.4 (0.04) | 0.1 (0.05) |
| | | 95% CI | 0.3, 0.5 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (0.06) | |
| | | 95% CI | 0.2, 0.5 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.44 (0.28, 0.61) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 351 | 185 |
| | | Mean (StdDev) | 0.4 (0.74) | 0.2 (0.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 345 | 181 |
| | | Mean (StdDev) | 0.2 (0.77) | 0.0 (0.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 4 | -2, 2 |
| | | LS Mean (SE) | 0.2 (0.04) | 0.0 (0.05) |
| | | 95% CI | 0.1, 0.3 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.06) | |
| | | 95% CI | 0.1, 0.3 | |
| | | p-value | 0.0008 | |
| | | Corrected Hedges g (95% CI) [2] | 0.31 (0.13, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 316 | 159 |
| | | Mean (StdDev) | 0.4 (0.75) | 0.2 (0.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 311 | 156 |
| | | Mean (StdDev) | 0.3 (0.81) | -0.1 (0.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | 0.2 (0.04) | 0.0 (0.05) |
| | | 95% CI | 0.1, 0.3 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.06) | |
| | | 95% CI | 0.1, 0.3 | |
| | | p-value | 0.0009 | |
| | | Corrected Hedges g (95% CI) [2] | 0.33 (0.13, 0.52) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 283 | 123 |
| | | Mean (StdDev) | 0.3 (0.65) | 0.2 (0.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 278 | 120 |
| | | Mean (StdDev) | 0.2 (0.70) | -0.1 (0.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -4, 3 |
| | | LS Mean (SE) | 0.2 (0.03) | 0.0 (0.05) |
| | | 95% CI | 0.1, 0.2 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.06) | |
| | | 95% CI | 0.0, 0.3 | |
| | | p-value | 0.0124 | |
| | | Corrected Hedges g (95% CI) [2] | 0.27 (0.06, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 254 | 98 |
| | | Mean (StdDev) | 0.3 (0.57) | 0.3 (0.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 250 | 95 |
| | | Mean (StdDev) | 0.1 (0.58) | 0.1 (0.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.9287 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.23, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 231 | 97 |
| | | Mean (StdDev) | 0.3 (0.60) | 0.3 (0.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 227 | 94 |
| | | Mean (StdDev) | 0.2 (0.63) | 0.0 (0.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.1, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.07) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.3584 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.13, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 0.2 (0.54) | 0.3 (0.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 206 | 81 |
| | | Mean (StdDev) | 0.1 (0.61) | 0.0 (0.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.7310 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.21, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 173 | 70 |
| | | Mean (StdDev) | 0.3 (0.67) | 0.3 (0.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 171 | 69 |
| | | Mean (StdDev) | 0.2 (0.76) | 0.0 (0.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.1 (0.07) |
| | | 95% CI | 0.1, 0.2 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.09) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.5022 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.18, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 143 | 55 |
| | | Mean (StdDev) | 0.3 (0.65) | 0.3 (0.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 141 | 54 |
| | | Mean (StdDev) | 0.2 (0.66) | 0.1 (0.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -4, 2 |
| | | LS Mean (SE) | 0.2 (0.05) | 0.1 (0.08) |
| | | 95% CI | 0.1, 0.3 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.09) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.5526 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.22, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 87 | 32 |
| | | Mean (StdDev) | 0.3 (0.53) | 0.5 (0.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.5 |
| | | Min, Max | 0, 2 | 0, 3 |
| | Change from BL | n | 86 | 31 |
| | | Mean (StdDev) | 0.1 (0.53) | 0.1 (0.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -3, 2 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.2 (0.10) |
| | | 95% CI | 0.0, 0.3 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.7756 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.47, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 46 | 16 |
| | | Mean (StdDev) | 0.3 (0.57) | 0.4 (0.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.5 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 46 | 15 |
| | | Mean (StdDev) | 0.1 (0.68) | 0.0 (1.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -3, 3 |
| | | LS Mean (SE) | 0.1 (0.09) | 0.2 (0.16) |
| | | 95% CI | -0.1, 0.3 | -0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.18) | |
| | | 95% CI | -0.4, 0.3 | |
| | | p-value | 0.6448 | |
| | | Corrected Hedges g (95% CI) [2] | -0.14 (-0.72, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 0.2 (0.51) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 0 |
| | Change from BL | n | 26 | 8 |
| | | Mean (StdDev) | 0.1 (0.63) | -0.6 (1.41) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -0.5, 0.0 |
| | | Min, Max | -2, 1 | -4, 0 |
| | | LS Mean (SE) | 0.0 (0.10) | 0.0 (0.19) |
| | | 95% CI | -0.2, 0.2 | -0.4, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.21) | |
| | | 95% CI | -0.4, 0.5 | |
| | | p-value | 0.6951 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.63, 0.95) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 0.1 (0.36) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | -0.1 (0.53) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 0 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -0.2 (0.45) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 0 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 285 | 170 |
| | | Mean (StdDev) | 0.5 (0.87) | 0.4 (0.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 282 | 166 |
| | | Mean (StdDev) | 0.3 (0.88) | 0.1 (0.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | -3, 4 | -2, 4 |
| | | LS Mean (SE) | 0.3 (0.05) | 0.2 (0.06) |
| | | 95% CI | 0.2, 0.4 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.08) | |
| | | 95% CI | -0.1, 0.3 | |
| | | p-value | 0.2068 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.07, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 148 | 102 |
| | | Mean (StdDev) | 0.5 (0.89) | 0.6 (0.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 147 | 100 |
| | | Mean (StdDev) | 0.3 (0.92) | 0.3 (0.91) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -1, 3 |
| | | LS Mean (SE) | 0.3 (0.06) | 0.4 (0.08) |
| | | 95% CI | 0.2, 0.4 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.2981 | |
| | | Corrected Hedges g (95% CI) [2] | -0.14 (-0.39, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 167 | 96 |
| | | Mean (StdDev) | 0.4 (0.79) | 0.8 (1.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 164 | 93 |
| | | Mean (StdDev) | 0.2 (0.88) | 0.4 (1.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 4 |
| | | LS Mean (SE) | 0.2 (0.06) | 0.6 (0.08) |
| | | 95% CI | 0.1, 0.3 | 0.4, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (0.10) | |
| | | 95% CI | -0.6, -0.2 | |
| | | p-value | 0.0004 | |
| | | Corrected Hedges g (95% CI) [2] | -0.46 (-0.72, -0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 197 | 112 |
| | | Mean (StdDev) | 0.5 (0.80) | 0.6 (0.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 195 | 108 |
| | | Mean (StdDev) | 0.2 (0.84) | 0.3 (1.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -3, 4 |
| | | LS Mean (SE) | 0.2 (0.05) | 0.4 (0.07) |
| | | 95% CI | 0.1, 0.4 | 0.2, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.09) | |
| | | 95% CI | -0.3, 0.0 | |
| | | p-value | 0.1220 | |
| | | Corrected Hedges g (95% CI) [2] | -0.19 (-0.42, 0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 161 | 90 |
| | | Mean (StdDev) | 0.4 (0.77) | 0.4 (0.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 160 | 87 |
| | | Mean (StdDev) | 0.2 (0.80) | 0.1 (0.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.06) | 0.3 (0.08) |
| | | 95% CI | 0.1, 0.3 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.5475 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.34, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.2 (0.02) | 0.2 (0.04) |
| | | 95% CI | 0.1, 0.2 | 0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.04) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.4819 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.10, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 240 |
| | | Mean (StdDev) | 0.4 (0.76) | 0.3 (0.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 420 | 221 |
| | | Mean (StdDev) | 0.4 (0.85) | 0.3 (0.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 416 | 217 |
| | | Mean (StdDev) | 0.1 (0.75) | 0.0 (0.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.0 (0.05) |
| | | 95% CI | 0.0, 0.2 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.07) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.2354 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.06, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 352 | 184 |
| | | Mean (StdDev) | 0.5 (0.82) | 0.4 (0.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 347 | 181 |
| | | Mean (StdDev) | 0.1 (0.83) | 0.1 (0.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.05) |
| | | 95% CI | 0.1, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.7664 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.15, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 316 | 158 |
| | | Mean (StdDev) | 0.4 (0.80) | 0.4 (0.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 312 | 155 |
| | | Mean (StdDev) | 0.1 (0.81) | 0.1 (0.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.04) | 0.2 (0.06) |
| | | 95% CI | 0.1, 0.2 | 0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.9727 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.20, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 285 | 124 |
| | | Mean (StdDev) | 0.4 (0.77) | 0.5 (0.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 280 | 121 |
| | | Mean (StdDev) | 0.1 (0.77) | 0.1 (0.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.2 (0.06) |
| | | 95% CI | 0.0, 0.2 | 0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.08) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.3306 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.32, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 254 | 98 |
| | | Mean (StdDev) | 0.4 (0.83) | 0.4 (0.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 250 | 95 |
| | | Mean (StdDev) | 0.1 (0.80) | 0.0 (0.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 4 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.1, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.08) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.5991 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.17, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 230 | 97 |
| | | Mean (StdDev) | 0.4 (0.81) | 0.4 (0.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 227 | 94 |
| | | Mean (StdDev) | 0.2 (0.80) | 0.1 (0.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.04) | 0.2 (0.07) |
| | | 95% CI | 0.1, 0.2 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.08) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9664 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.25, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 212 | 82 |
| | | Mean (StdDev) | 0.4 (0.78) | 0.4 (0.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 207 | 81 |
| | | Mean (StdDev) | 0.1 (0.78) | 0.1 (0.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.7677 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.29, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 173 | 71 |
| | | Mean (StdDev) | 0.4 (0.81) | 0.6 (0.86) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 171 | 70 |
| | | Mean (StdDev) | 0.1 (0.82) | 0.2 (0.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.2 (0.08) |
| | | 95% CI | 0.1, 0.2 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.09) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.2636 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.44, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 141 | 55 |
| | | Mean (StdDev) | 0.5 (0.83) | 0.7 (1.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 138 | 54 |
| | | Mean (StdDev) | 0.1 (0.87) | 0.4 (1.03) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -2, 4 |
| | | LS Mean (SE) | 0.2 (0.06) | 0.4 (0.09) |
| | | 95% CI | 0.1, 0.3 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.11) | |
| | | 95% CI | -0.4, 0.0 | |
| | | p-value | 0.1280 | |
| | | Corrected Hedges g (95% CI) [2] | -0.24 (-0.56, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 0.6 (0.95) | 0.7 (1.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 86 | 31 |
| | | Mean (StdDev) | 0.3 (0.83) | 0.3 (1.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 4 | -1, 4 |
| | | LS Mean (SE) | 0.3 (0.07) | 0.3 (0.12) |
| | | 95% CI | 0.1, 0.4 | 0.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.14) | |
| | | 95% CI | -0.4, 0.2 | |
| | | p-value | 0.6000 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.52, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 45 | 16 |
| | | Mean (StdDev) | 0.3 (0.60) | 0.7 (1.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 2 | 0, 3 |
| | Change from BL | n | 44 | 15 |
| | | Mean (StdDev) | 0.2 (0.58) | 0.0 (1.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -1, 2 | -1, 3 |
| | | LS Mean (SE) | 0.2 (0.08) | 0.2 (0.13) |
| | | 95% CI | 0.0, 0.3 | -0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.16) | |
| | | 95% CI | -0.3, 0.3 | |
| | | p-value | 0.9841 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.58, 0.59) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 0.7 (1.18) | 0.4 (0.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 1 |
| | Change from BL | n | 26 | 8 |
| | | Mean (StdDev) | 0.3 (0.89) | 0.0 (0.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | -1, 1 |
| | | LS Mean (SE) | 0.3 (0.10) | 0.2 (0.17) |
| | | 95% CI | 0.1, 0.5 | -0.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.20) | |
| | | 95% CI | -0.3, 0.5 | |
| | | p-value | 0.7415 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.66, 0.92) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 0.3 (0.73) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.3 (0.73) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.6 (1.34) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 0 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.6 (1.34) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 4.0 (NA) | |
| | | Median | 4.0 | |
| | | Q1, Q3 | 4.0, 4.0 | |
| | | Min, Max | 4, 4 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 4.0 (NA) | |
| | | Median | 4.0 | |
| | | Q1, Q3 | 4.0, 4.0 | |
| | | Min, Max | 4, 4 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 284 | 172 |
| | | Mean (StdDev) | 0.7 (1.02) | 0.7 (0.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 282 | 169 |
| | | Mean (StdDev) | 0.4 (0.95) | 0.4 (1.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -2, 4 |
| | | LS Mean (SE) | 0.4 (0.05) | 0.4 (0.07) |
| | | 95% CI | 0.3, 0.5 | 0.3, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.08) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.5682 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.25, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 148 | 103 |
| | | Mean (StdDev) | 0.8 (1.09) | 0.7 (0.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 148 | 101 |
| | | Mean (StdDev) | 0.5 (1.05) | 0.6 (1.04) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -2, 4 |
| | | LS Mean (SE) | 0.4 (0.08) | 0.5 (0.10) |
| | | 95% CI | 0.3, 0.6 | 0.3, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.12) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.4665 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.35, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 168 | 96 |
| | | Mean (StdDev) | 0.6 (0.92) | 0.6 (0.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 166 | 94 |
| | | Mean (StdDev) | 0.3 (0.86) | 0.4 (0.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 2 |
| | | LS Mean (SE) | 0.3 (0.06) | 0.4 (0.08) |
| | | 95% CI | 0.2, 0.4 | 0.3, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.3289 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.38, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 199 | 111 |
| | | Mean (StdDev) | 0.7 (1.02) | 0.6 (0.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 198 | 108 |
| | | Mean (StdDev) | 0.3 (0.99) | 0.4 (0.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -2, 4 |
| | | LS Mean (SE) | 0.3 (0.06) | 0.4 (0.08) |
| | | 95% CI | 0.2, 0.5 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.5966 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.30, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 161 | 90 |
| | | Mean (StdDev) | 0.7 (1.01) | 0.6 (0.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 160 | 88 |
| | | Mean (StdDev) | 0.4 (0.94) | 0.3 (0.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 4 | -2, 3 |
| | | LS Mean (SE) | 0.4 (0.07) | 0.3 (0.09) |
| | | 95% CI | 0.3, 0.5 | 0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.11) | |
| | | 95% CI | -0.1, 0.3 | |
| | | p-value | 0.2840 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.12, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.2 (0.03) | 0.3 (0.04) |
| | | 95% CI | 0.2, 0.3 | 0.2, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.05) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.6444 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.19, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 240 |
| | | Mean (StdDev) | 1.6 (1.29) | 1.7 (1.24) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 424 | 222 |
| | | Mean (StdDev) | 1.6 (1.31) | 1.6 (1.33) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 3.0 | 0.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 420 | 218 |
| | | Mean (StdDev) | -0.1 (1.19) | -0.1 (1.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | -0.1 (0.06) | -0.1 (0.08) |
| | | 95% CI | -0.2, 0.0 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.6164 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.21, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 351 | 185 |
| | | Mean (StdDev) | 1.4 (1.20) | 1.6 (1.19) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 347 | 182 |
| | | Mean (StdDev) | -0.2 (1.08) | -0.1 (1.25) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 3 |
| | | LS Mean (SE) | -0.2 (0.05) | -0.1 (0.07) |
| | | 95% CI | -0.3, -0.1 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.09) | |
| | | 95% CI | -0.3, 0.0 | |
| | | p-value | 0.0684 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.35, 0.01) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 317 | 159 |
| | | Mean (StdDev) | 1.5 (1.16) | 1.6 (1.22) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 313 | 156 |
| | | Mean (StdDev) | -0.1 (1.15) | -0.1 (1.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 4 |
| | | LS Mean (SE) | -0.1 (0.06) | 0.0 (0.08) |
| | | 95% CI | -0.2, 0.0 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.10) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.6131 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.24, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 284 | 125 |
| | | Mean (StdDev) | 1.4 (1.21) | 1.6 (1.19) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 280 | 122 |
| | | Mean (StdDev) | -0.2 (1.14) | -0.1 (1.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 4 | -3, 4 |
| | | LS Mean (SE) | -0.2 (0.06) | -0.1 (0.08) |
| | | 95% CI | -0.3, -0.1 | -0.3, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.3574 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.31, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 253 | 100 |
| | | Mean (StdDev) | 1.4 (1.21) | 1.5 (1.18) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 250 | 97 |
| | | Mean (StdDev) | -0.2 (1.15) | -0.2 (1.28) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 4 | -4, 3 |
| | | LS Mean (SE) | -0.2 (0.06) | -0.1 (0.09) |
| | | 95% CI | -0.3, -0.1 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.11) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.2728 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.36, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 230 | 97 |
| | | Mean (StdDev) | 1.4 (1.19) | 1.5 (1.19) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 227 | 94 |
| | | Mean (StdDev) | -0.2 (1.10) | -0.2 (1.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -3, 4 | -3, 3 |
| | | LS Mean (SE) | -0.2 (0.06) | -0.1 (0.09) |
| | | 95% CI | -0.3, -0.1 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.11) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.3172 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.36, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 210 | 82 |
| | | Mean (StdDev) | 1.4 (1.15) | 1.4 (1.18) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 206 | 81 |
| | | Mean (StdDev) | -0.2 (1.12) | -0.4 (1.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -3, 3 |
| | | LS Mean (SE) | -0.2 (0.06) | -0.2 (0.10) |
| | | 95% CI | -0.3, -0.1 | -0.4, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9841 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.26, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 173 | 70 |
| | | Mean (StdDev) | 1.4 (1.17) | 1.6 (1.30) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 172 | 69 |
| | | Mean (StdDev) | -0.2 (1.03) | -0.2 (1.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 4 |
| | | LS Mean (SE) | -0.2 (0.07) | 0.0 (0.10) |
| | | 95% CI | -0.3, 0.0 | -0.2, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.12) | |
| | | 95% CI | -0.4, 0.1 | |
| | | p-value | 0.2028 | |
| | | Corrected Hedges g (95% CI) [2] | -0.18 (-0.46, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 143 | 55 |
| | | Mean (StdDev) | 1.4 (1.22) | 1.5 (1.23) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 141 | 54 |
| | | Mean (StdDev) | -0.2 (1.05) | -0.3 (1.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 4 |
| | | LS Mean (SE) | -0.1 (0.07) | -0.1 (0.11) |
| | | 95% CI | -0.3, 0.0 | -0.3, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.13) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.5699 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.40, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 87 | 32 |
| | | Mean (StdDev) | 1.4 (1.17) | 1.4 (1.24) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 0.5, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 86 | 31 |
| | | Mean (StdDev) | -0.2 (1.13) | -0.5 (1.29) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -2.0, 0.0 |
| | | Min, Max | -3, 2 | -3, 3 |
| | | LS Mean (SE) | -0.1 (0.08) | -0.1 (0.13) |
| | | 95% CI | -0.3, 0.0 | -0.4, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.16) | |
| | | 95% CI | -0.3, 0.3 | |
| | | p-value | 0.8993 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.44, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 46 | 16 |
| | | Mean (StdDev) | 1.3 (1.05) | 1.3 (1.00) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 0.5, 2.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 46 | 15 |
| | | Mean (StdDev) | 0.0 (1.01) | -0.5 (1.25) |
| | | Median | 0.0 | -1.0 |
| | | Q1, Q3 | -1.0, 0.0 | -2.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 2 |
| | | LS Mean (SE) | -0.1 (0.10) | 0.0 (0.16) |
| | | 95% CI | -0.3, 0.1 | -0.3, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.19) | |
| | | 95% CI | -0.5, 0.2 | |
| | | p-value | 0.4927 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.78, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 1.3 (1.02) | 1.6 (1.60) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 1.0 | 0.5, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 26 | 8 |
| | | Mean (StdDev) | 0.0 (0.72) | -0.4 (1.77) |
| | | Median | 0.0 | -0.5 |
| | | Q1, Q3 | 0.0, 0.0 | -2.0, 0.5 |
| | | Min, Max | -2, 1 | -2, 3 |
| | | LS Mean (SE) | 0.0 (0.16) | 0.2 (0.28) |
| | | 95% CI | -0.3, 0.4 | -0.3, 0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.33) | |
| | | 95% CI | -0.9, 0.5 | |
| | | p-value | 0.5449 | |
| | | Corrected Hedges g (95% CI) [2] | -0.24 (-1.03, 0.56) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 1.0 (1.04) | 1.0 (0.00) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 1.0, 1.0 |
| | | Min, Max | 0, 3 | 1, 1 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | -0.1 (1.35) | -0.5 (0.71) |
| | | Median | 0.0 | -0.5 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -2, 3 | -1, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 1.6 (1.14) | 2.0 (1.41) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 3.0 |
| | | Min, Max | 0, 3 | 1, 3 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.71) | 0.5 (2.12) |
| | | Median | 0.0 | 0.5 |
| | | Q1, Q3 | 0.0, 0.0 | -1.0, 2.0 |
| | | Min, Max | -1, 1 | -1, 2 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 1.0 (NA) | |
| | | Median | 1.0 | |
| | | Q1, Q3 | 1.0, 1.0 | |
| | | Min, Max | 1, 1 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 286 | 172 |
| | | Mean (StdDev) | 2.3 (1.36) | 2.4 (1.26) |
| | | Median | 2.0 | 2.5 |
| | | Q1, Q3 | 1.0, 4.0 | 1.0, 4.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 284 | 169 |
| | | Mean (StdDev) | 0.6 (1.36) | 0.8 (1.45) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | -3, 4 | -3, 4 |
| | | LS Mean (SE) | 0.6 (0.06) | 0.8 (0.08) |
| | | 95% CI | 0.5, 0.7 | 0.6, 0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.10) | |
| | | 95% CI | -0.4, 0.0 | |
| | | p-value | 0.1315 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.34, 0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 149 | 103 |
| | | Mean (StdDev) | 2.2 (1.34) | 2.2 (1.30) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 149 | 101 |
| | | Mean (StdDev) | 0.5 (1.32) | 0.6 (1.32) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -2, 4 |
| | | LS Mean (SE) | 0.5 (0.08) | 0.5 (0.10) |
| | | 95% CI | 0.3, 0.6 | 0.3, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.7125 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.30, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 168 | 96 |
| | | Mean (StdDev) | 2.1 (1.24) | 2.1 (1.31) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 166 | 94 |
| | | Mean (StdDev) | 0.5 (1.32) | 0.5 (1.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 4 | -3, 4 |
| | | LS Mean (SE) | 0.5 (0.07) | 0.5 (0.10) |
| | | 95% CI | 0.3, 0.6 | 0.3, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9379 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.26, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 198 | 111 |
| | | Mean (StdDev) | 2.1 (1.28) | 2.1 (1.26) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 197 | 108 |
| | | Mean (StdDev) | 0.5 (1.37) | 0.5 (1.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 4 | -3, 4 |
| | | LS Mean (SE) | 0.4 (0.07) | 0.4 (0.09) |
| | | 95% CI | 0.3, 0.6 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.2, 0.3 | |
| | | p-value | 0.7498 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.20, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 161 | 90 |
| | | Mean (StdDev) | 2.0 (1.26) | 2.0 (1.26) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 160 | 88 |
| | | Mean (StdDev) | 0.4 (1.34) | 0.4 (1.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -0.5, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -3, 4 |
| | | LS Mean (SE) | 0.4 (0.07) | 0.4 (0.10) |
| | | 95% CI | 0.3, 0.6 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.13) | |
| | | 95% CI | -0.2, 0.3 | |
| | | p-value | 0.6929 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.21, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.0 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.0, 0.1 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.07) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.2817 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.24, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 240 |
| | | Mean (StdDev) | 2.2 (1.26) | 2.2 (1.17) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.5, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 424 | 221 |
| | | Mean (StdDev) | 2.3 (1.21) | 2.3 (1.21) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 420 | 217 |
| | | Mean (StdDev) | 0.0 (1.51) | 0.1 (1.16) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.0 (0.06) | 0.1 (0.08) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.3765 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.24, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 350 | 185 |
| | | Mean (StdDev) | 2.3 (1.27) | 2.3 (1.23) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 347 | 182 |
| | | Mean (StdDev) | 0.1 (1.55) | 0.0 (1.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.0 (0.09) |
| | | 95% CI | -0.1, 0.2 | -0.2, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.11) | |
| | | 95% CI | -0.1, 0.3 | |
| | | p-value | 0.4034 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.10, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 317 | 159 |
| | | Mean (StdDev) | 2.3 (1.23) | 2.2 (1.21) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 313 | 156 |
| | | Mean (StdDev) | 0.1 (1.50) | -0.1 (1.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.07) | -0.1 (0.09) |
| | | 95% CI | -0.1, 0.2 | -0.3, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.11) | |
| | | 95% CI | -0.1, 0.4 | |
| | | p-value | 0.2056 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.07, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 284 | 125 |
| | | Mean (StdDev) | 2.3 (1.29) | 2.4 (1.19) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.5, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 280 | 122 |
| | | Mean (StdDev) | 0.0 (1.50) | 0.1 (1.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.07) | 0.1 (0.10) |
| | | 95% CI | -0.1, 0.2 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.7397 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.25, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 254 | 99 |
| | | Mean (StdDev) | 2.3 (1.30) | 2.4 (1.17) |
| | | Median | 3.0 | 3.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 251 | 96 |
| | | Mean (StdDev) | 0.0 (1.56) | 0.1 (1.55) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.07) | 0.1 (0.11) |
| | | 95% CI | -0.1, 0.2 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.14) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.8753 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.25, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 231 | 97 |
| | | Mean (StdDev) | 2.3 (1.31) | 2.5 (1.22) |
| | | Median | 2.0 | 3.0 |
| | | Q1, Q3 | 1.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 228 | 94 |
| | | Mean (StdDev) | 0.0 (1.48) | 0.2 (1.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.0 (0.07) | 0.2 (0.11) |
| | | 95% CI | -0.1, 0.2 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.14) | |
| | | 95% CI | -0.4, 0.1 | |
| | | p-value | 0.2681 | |
| | | Corrected Hedges g (95% CI) [2] | -0.14 (-0.38, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 213 | 82 |
| | | Mean (StdDev) | 2.3 (1.26) | 2.6 (1.03) |
| | | Median | 2.0 | 3.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 209 | 81 |
| | | Mean (StdDev) | 0.1 (1.65) | 0.3 (1.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.0 (0.08) | 0.3 (0.12) |
| | | 95% CI | -0.1, 0.2 | 0.0, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.15) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.1429 | |
| | | Corrected Hedges g (95% CI) [2] | -0.19 (-0.45, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 173 | 71 |
| | | Mean (StdDev) | 2.3 (1.32) | 2.5 (1.08) |
| | | Median | 2.0 | 3.0 |
| | | Q1, Q3 | 1.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 172 | 70 |
| | | Mean (StdDev) | 0.1 (1.53) | 0.3 (1.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.09) | 0.3 (0.14) |
| | | 95% CI | -0.1, 0.3 | 0.0, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.16) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.2829 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.43, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 144 | 55 |
| | | Mean (StdDev) | 2.3 (1.34) | 2.4 (1.18) |
| | | Median | 2.0 | 3.0 |
| | | Q1, Q3 | 1.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 142 | 54 |
| | | Mean (StdDev) | 0.0 (1.77) | 0.2 (1.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 3 |
| | | LS Mean (SE) | 0.0 (0.10) | 0.1 (0.16) |
| | | 95% CI | -0.2, 0.2 | -0.2, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.19) | |
| | | 95% CI | -0.5, 0.2 | |
| | | p-value | 0.5052 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.42, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 2.3 (1.34) | 2.4 (1.13) |
| | | Median | 3.0 | 2.5 |
| | | Q1, Q3 | 1.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 87 | 31 |
| | | Mean (StdDev) | 0.0 (1.49) | 0.2 (1.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 3 | -3, 3 |
| | | LS Mean (SE) | 0.0 (0.13) | 0.2 (0.21) |
| | | 95% CI | -0.3, 0.2 | -0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.25) | |
| | | 95% CI | -0.7, 0.3 | |
| | | p-value | 0.4063 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.58, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 46 | 16 |
| | | Mean (StdDev) | 2.5 (1.43) | 2.7 (1.01) |
| | | Median | 3.0 | 3.0 |
| | | Q1, Q3 | 2.0, 4.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 1, 4 |
| | Change from BL | n | 46 | 15 |
| | | Mean (StdDev) | 0.1 (1.59) | 0.1 (0.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | -4, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.17) | 0.4 (0.30) |
| | | 95% CI | -0.2, 0.5 | -0.2, 1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (0.34) | |
| | | 95% CI | -1.0, 0.4 | |
| | | p-value | 0.4152 | |
| | | Corrected Hedges g (95% CI) [2] | -0.24 (-0.82, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 26 | 8 |
| | | Mean (StdDev) | 2.6 (1.30) | 3.4 (0.52) |
| | | Median | 2.5 | 3.0 |
| | | Q1, Q3 | 2.0, 4.0 | 3.0, 4.0 |
| | | Min, Max | 0, 4 | 3, 4 |
| | Change from BL | n | 25 | 8 |
| | | Mean (StdDev) | 0.2 (1.48) | 0.3 (0.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 2.0 | 0.0, 0.5 |
| | | Min, Max | -3, 2 | 0, 1 |
| | | LS Mean (SE) | 0.2 (0.21) | 0.8 (0.39) |
| | | 95% CI | -0.2, 0.7 | 0.0, 1.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (0.44) | |
| | | 95% CI | -1.5, 0.3 | |
| | | p-value | 0.2119 | |
| | | Corrected Hedges g (95% CI) [2] | -0.52 (-1.32, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 2.6 (1.45) | 2.5 (2.12) |
| | | Median | 2.5 | 2.5 |
| | | Q1, Q3 | 2.0, 4.0 | 1.0, 4.0 |
| | | Min, Max | 0, 4 | 1, 4 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.1 (1.96) | -1.0 (1.41) |
| | | Median | 0.5 | -1.0 |
| | | Q1, Q3 | -1.0, 1.0 | -2.0, 0.0 |
| | | Min, Max | -4, 4 | -2, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 2.2 (1.48) | 1.5 (2.12) |
| | | Median | 2.0 | 1.5 |
| | | Q1, Q3 | 2.0, 3.0 | 0.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -0.2 (1.30) | -2.0 (1.41) |
| | | Median | 0.0 | -2.0 |
| | | Q1, Q3 | -1.0, 1.0 | -3.0, -1.0 |
| | | Min, Max | -2, 1 | -3, -1 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 4.0 (NA) | |
| | | Median | 4.0 | |
| | | Q1, Q3 | 4.0, 4.0 | |
| | | Min, Max | 4, 4 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 285 | 170 |
| | | Mean (StdDev) | 2.0 (1.21) | 1.8 (1.25) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 283 | 167 |
| | | Mean (StdDev) | -0.2 (1.59) | -0.3 (1.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | -0.2 (0.07) | -0.4 (0.09) |
| | | 95% CI | -0.4, -0.1 | -0.6, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.12) | |
| | | 95% CI | -0.1, 0.4 | |
| | | p-value | 0.1429 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.05, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 148 | 103 |
| | | Mean (StdDev) | 2.0 (1.22) | 1.8 (1.15) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 148 | 101 |
| | | Mean (StdDev) | -0.2 (1.49) | -0.4 (1.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | -0.3 (0.09) | -0.4 (0.11) |
| | | 95% CI | -0.4, -0.1 | -0.6, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.14) | |
| | | 95% CI | -0.1, 0.4 | |
| | | p-value | 0.2770 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.11, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 169 | 96 |
| | | Mean (StdDev) | 2.1 (1.14) | 1.8 (1.09) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 167 | 94 |
| | | Mean (StdDev) | -0.1 (1.54) | -0.4 (1.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | -0.2 (0.08) | -0.5 (0.11) |
| | | 95% CI | -0.4, 0.0 | -0.7, -0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (0.13) | |
| | | 95% CI | 0.0, 0.5 | |
| | | p-value | 0.0543 | |
| | | Corrected Hedges g (95% CI) [2] | 0.25 (-0.01, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 199 | 112 |
| | | Mean (StdDev) | 2.0 (1.12) | 1.8 (1.11) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 198 | 109 |
| | | Mean (StdDev) | -0.2 (1.51) | -0.4 (1.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | -0.2 (0.08) | -0.4 (0.10) |
| | | 95% CI | -0.4, -0.1 | -0.6, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.13) | |
| | | 95% CI | 0.0, 0.5 | |
| | | p-value | 0.1078 | |
| | | Corrected Hedges g (95% CI) [2] | 0.19 (-0.04, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 160 | 90 |
| | | Mean (StdDev) | 2.2 (1.14) | 2.0 (1.07) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 159 | 88 |
| | | Mean (StdDev) | 0.0 (1.42) | -0.2 (1.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -3, 4 |
| | | LS Mean (SE) | -0.1 (0.09) | -0.2 (0.11) |
| | | 95% CI | -0.3, 0.0 | -0.4, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.14) | |
| | | 95% CI | -0.2, 0.4 | |
| | | p-value | 0.5368 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.18, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.0 (0.04) | 0.0 (0.06) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.5160 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.21, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 239 |
| | | Mean (StdDev) | 0.3 (0.62) | 0.2 (0.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| Cycle 3 Day 1 | Actual | n | 424 | 221 |
| | | Mean (StdDev) | 0.3 (0.66) | 0.3 (0.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 419 | 216 |
| | | Mean (StdDev) | 0.1 (0.65) | 0.1 (0.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.03) | 0.1 (0.05) |
| | | 95% CI | 0.0, 0.1 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.06) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.7695 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.19, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 352 | 185 |
| | | Mean (StdDev) | 0.3 (0.59) | 0.4 (0.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 347 | 181 |
| | | Mean (StdDev) | 0.0 (0.75) | 0.2 (0.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -4, 3 | -2, 4 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.2 (0.05) |
| | | 95% CI | 0.0, 0.1 | 0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.06) | |
| | | 95% CI | -0.2, 0.0 | |
| | | p-value | 0.0575 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.35, 0.01) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 316 | 158 |
| | | Mean (StdDev) | 0.3 (0.69) | 0.3 (0.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 311 | 154 |
| | | Mean (StdDev) | 0.1 (0.78) | 0.1 (0.58) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -4, 3 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.05) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.06) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.6690 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.24, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 285 | 124 |
| | | Mean (StdDev) | 0.4 (0.73) | 0.3 (0.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 280 | 120 |
| | | Mean (StdDev) | 0.1 (0.80) | 0.1 (0.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 4 | -1, 3 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.1, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.5571 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.15, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 254 | 99 |
| | | Mean (StdDev) | 0.3 (0.66) | 0.2 (0.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 250 | 95 |
| | | Mean (StdDev) | 0.0 (0.71) | 0.1 (0.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.7422 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.20, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 230 | 97 |
| | | Mean (StdDev) | 0.3 (0.71) | 0.3 (0.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 226 | 93 |
| | | Mean (StdDev) | 0.1 (0.84) | 0.1 (0.56) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -4, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.1 (0.06) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.9914 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.24, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 0.3 (0.71) | 0.3 (0.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 206 | 80 |
| | | Mean (StdDev) | 0.1 (0.68) | 0.1 (0.58) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.2 (0.06) |
| | | 95% CI | 0.1, 0.2 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.07) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.7843 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.29, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 173 | 71 |
| | | Mean (StdDev) | 0.3 (0.69) | 0.3 (0.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 171 | 70 |
| | | Mean (StdDev) | 0.0 (0.73) | 0.1 (0.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -1, 2 |
| | | LS Mean (SE) | 0.0 (0.04) | 0.2 (0.06) |
| | | 95% CI | 0.0, 0.1 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.07) | |
| | | 95% CI | -0.2, 0.0 | |
| | | p-value | 0.0931 | |
| | | Corrected Hedges g (95% CI) [2] | -0.24 (-0.51, 0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 144 | 55 |
| | | Mean (StdDev) | 0.4 (0.75) | 0.4 (0.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 141 | 54 |
| | | Mean (StdDev) | 0.1 (0.86) | 0.2 (0.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -1, 2 |
| | | LS Mean (SE) | 0.2 (0.05) | 0.2 (0.08) |
| | | 95% CI | 0.1, 0.3 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.6371 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.39, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 0.3 (0.75) | 0.5 (0.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 86 | 31 |
| | | Mean (StdDev) | 0.0 (0.85) | 0.3 (0.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.3 (0.09) |
| | | 95% CI | 0.0, 0.2 | 0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.10) | |
| | | 95% CI | -0.5, 0.0 | |
| | | p-value | 0.0203 | |
| | | Corrected Hedges g (95% CI) [2] | -0.48 (-0.90, -0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 46 | 16 |
| | | Mean (StdDev) | 0.3 (0.66) | 0.4 (0.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.5 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 46 | 15 |
| | | Mean (StdDev) | 0.0 (0.82) | 0.3 (0.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -1, 3 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.3 (0.11) |
| | | 95% CI | 0.0, 0.2 | 0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.13) | |
| | | 95% CI | -0.5, 0.0 | |
| | | p-value | 0.1027 | |
| | | Corrected Hedges g (95% CI) [2] | -0.48 (-1.07, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 0.2 (0.58) | 0.1 (0.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 1 |
| | Change from BL | n | 25 | 8 |
| | | Mean (StdDev) | 0.0 (0.61) | -0.1 (0.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -0.5, 0.0 |
| | | Min, Max | -2, 2 | -1, 1 |
| | | LS Mean (SE) | 0.0 (0.05) | 0.1 (0.09) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.3858 | |
| | | Corrected Hedges g (95% CI) [2] | -0.34 (-1.14, 0.46) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 0.1 (0.27) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | -0.1 (0.62) | -0.5 (0.71) |
| | | Median | 0.0 | -0.5 |
| | | Q1, Q3 | 0.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -2, 1 | -1, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | -0.5 (0.71) |
| | | Median | 0.0 | -0.5 |
| | | Q1, Q3 | 0.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | 0, 0 | -1, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 285 | 171 |
| | | Mean (StdDev) | 0.6 (0.99) | 0.5 (0.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 283 | 168 |
| | | Mean (StdDev) | 0.4 (0.99) | 0.3 (0.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -2, 4 |
| | | LS Mean (SE) | 0.4 (0.05) | 0.3 (0.06) |
| | | 95% CI | 0.3, 0.5 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.08) | |
| | | 95% CI | 0.0, 0.3 | |
| | | p-value | 0.1033 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.03, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 149 | 103 |
| | | Mean (StdDev) | 0.6 (0.91) | 0.5 (0.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 149 | 101 |
| | | Mean (StdDev) | 0.4 (0.88) | 0.3 (0.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.3 (0.06) | 0.3 (0.07) |
| | | 95% CI | 0.2, 0.5 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.09) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.5327 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.17, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 169 | 96 |
| | | Mean (StdDev) | 0.5 (0.86) | 0.7 (1.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 167 | 94 |
| | | Mean (StdDev) | 0.3 (0.84) | 0.5 (1.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 4 | -2, 4 |
| | | LS Mean (SE) | 0.3 (0.06) | 0.5 (0.08) |
| | | 95% CI | 0.2, 0.4 | 0.3, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.10) | |
| | | 95% CI | -0.4, 0.0 | |
| | | p-value | 0.0321 | |
| | | Corrected Hedges g (95% CI) [2] | -0.28 (-0.53, -0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 199 | 112 |
| | | Mean (StdDev) | 0.5 (0.95) | 0.5 (0.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 198 | 109 |
| | | Mean (StdDev) | 0.3 (0.93) | 0.3 (0.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -3, 4 | -3, 4 |
| | | LS Mean (SE) | 0.3 (0.06) | 0.3 (0.08) |
| | | 95% CI | 0.2, 0.4 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.10) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.8324 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.21, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 161 | 90 |
| | | Mean (StdDev) | 0.4 (0.81) | 0.4 (0.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 160 | 88 |
| | | Mean (StdDev) | 0.2 (0.84) | 0.2 (0.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 4 | -3, 3 |
| | | LS Mean (SE) | 0.2 (0.06) | 0.2 (0.08) |
| | | 95% CI | 0.1, 0.4 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.7373 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.22, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.2 (0.02) | 0.2 (0.04) |
| | | 95% CI | 0.1, 0.2 | 0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.04) | |
| | | 95% CI | -0.1, 0.0 | |
| | | p-value | 0.2745 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.24, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 223 | 121 |
| | | Mean (StdDev) | 1.5 (1.06) | 1.5 (0.91) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 198 | 109 |
| | | Mean (StdDev) | 1.5 (1.05) | 1.4 (1.14) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 194 | 106 |
| | | Mean (StdDev) | 0.1 (1.14) | -0.1 (1.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -3, 4 | -3, 3 |
| | | LS Mean (SE) | 0.1 (0.08) | 0.0 (0.10) |
| | | 95% CI | 0.0, 0.3 | -0.2, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.13) | |
| | | 95% CI | -0.1, 0.4 | |
| | | p-value | 0.2826 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.11, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 164 | 98 |
| | | Mean (StdDev) | 1.3 (1.05) | 1.3 (1.02) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 160 | 96 |
| | | Mean (StdDev) | -0.1 (1.16) | -0.2 (1.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 3 | -3, 3 |
| | | LS Mean (SE) | -0.1 (0.07) | -0.1 (0.10) |
| | | 95% CI | -0.3, 0.0 | -0.3, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9521 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.25, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 147 | 85 |
| | | Mean (StdDev) | 1.1 (0.91) | 1.2 (0.95) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 144 | 83 |
| | | Mean (StdDev) | -0.3 (1.06) | -0.4 (1.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 2 |
| | | LS Mean (SE) | -0.3 (0.07) | -0.2 (0.09) |
| | | 95% CI | -0.4, -0.2 | -0.4, -0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.11) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.6621 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.33, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 130 | 67 |
| | | Mean (StdDev) | 1.1 (1.01) | 1.4 (1.07) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 126 | 65 |
| | | Mean (StdDev) | -0.3 (1.06) | -0.2 (1.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | -0.3 (0.08) | -0.1 (0.11) |
| | | 95% CI | -0.4, -0.1 | -0.3, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.13) | |
| | | 95% CI | -0.5, 0.0 | |
| | | p-value | 0.0974 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.55, 0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 49 |
| | | Mean (StdDev) | 1.0 (0.87) | 1.5 (1.21) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 117 | 47 |
| | | Mean (StdDev) | -0.4 (1.15) | 0.0 (1.15) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | -0.4 (0.07) | 0.1 (0.11) |
| | | 95% CI | -0.5, -0.2 | -0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.5 (0.13) | |
| | | 95% CI | -0.7, -0.2 | |
| | | p-value | 0.0002 | |
| | | Corrected Hedges g (95% CI) [2] | -0.63 (-0.97, -0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 1.0 (0.96) | 1.2 (0.95) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.5, 2.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 106 | 46 |
| | | Mean (StdDev) | -0.4 (1.15) | -0.2 (1.02) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 2 |
| | | LS Mean (SE) | -0.3 (0.08) | -0.1 (0.12) |
| | | 95% CI | -0.5, -0.2 | -0.4, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.14) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.1687 | |
| | | Corrected Hedges g (95% CI) [2] | -0.24 (-0.59, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 0.9 (0.91) | 1.0 (0.94) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 94 | 37 |
| | | Mean (StdDev) | -0.5 (1.20) | -0.3 (0.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 2 |
| | | LS Mean (SE) | -0.4 (0.08) | -0.2 (0.12) |
| | | 95% CI | -0.5, -0.2 | -0.4, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.14) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.1852 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.63, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 82 | 32 |
| | | Mean (StdDev) | 0.9 (0.91) | 1.0 (1.02) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 80 | 31 |
| | | Mean (StdDev) | -0.4 (1.23) | -0.5 (0.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | -0.4 (0.08) | -0.3 (0.13) |
| | | 95% CI | -0.5, -0.2 | -0.6, -0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.15) | |
| | | 95% CI | -0.3, 0.3 | |
| | | p-value | 0.7871 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.47, 0.36) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 22 |
| | | Mean (StdDev) | 1.0 (0.99) | 1.2 (1.22) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 62 | 22 |
| | | Mean (StdDev) | -0.3 (0.92) | -0.2 (1.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 2 | -3, 3 |
| | | LS Mean (SE) | -0.3 (0.11) | -0.2 (0.19) |
| | | 95% CI | -0.5, 0.0 | -0.5, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.22) | |
| | | 95% CI | -0.5, 0.3 | |
| | | p-value | 0.6481 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.60, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 0.7 (0.89) | 1.1 (1.35) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 3.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 24 | 7 |
| | | Mean (StdDev) | -0.8 (1.19) | -0.3 (1.38) |
| | | Median | -0.5 | 0.0 |
| | | Q1, Q3 | -2.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -3, 1 | -3, 1 |
| | | LS Mean (SE) | -0.7 (0.13) | -0.1 (0.24) |
| | | 95% CI | -1.0, -0.4 | -0.6, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (0.27) | |
| | | 95% CI | -1.2, -0.1 | |
| | | p-value | 0.0324 | |
| | | Corrected Hedges g (95% CI) [2] | -0.92 (-1.79, -0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 0.9 (0.86) | 1.5 (1.29) |
| | | Median | 1.0 | 1.5 |
| | | Q1, Q3 | 0.0, 1.0 | 0.5, 2.5 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 12 | 4 |
| | | Mean (StdDev) | -0.3 (1.72) | -0.5 (1.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.5, 0.5 |
| | | Min, Max | -3, 3 | -3, 1 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 7 | 1 |
| | | Mean (StdDev) | 1.0 (1.00) | 0.0 (NA) |
| | | Median | 1.0 | 0.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 0 |
| | Change from BL | n | 7 | 1 |
| | | Mean (StdDev) | 0.4 (1.27) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 2.0 | 0.0, 0.0 |
| | | Min, Max | -1, 2 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 0.8 (0.84) | |
| | | Median | 1.0 | |
| | | Q1, Q3 | 0.0, 1.0 | |
| | | Min, Max | 0, 2 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | -0.2 (1.48) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | -1.0, 0.0 | |
| | | Min, Max | -2, 2 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -1.0 (NA) | |
| | | Median | -1.0 | |
| | | Q1, Q3 | -1.0, -1.0 | |
| | | Min, Max | -1, -1 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 124 | 86 |
| | | Mean (StdDev) | 1.6 (1.20) | 1.4 (1.10) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 124 | 85 |
| | | Mean (StdDev) | 0.0 (1.20) | -0.1 (1.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -2, 4 | -3, 3 |
| | | LS Mean (SE) | 0.0 (0.09) | -0.1 (0.11) |
| | | 95% CI | -0.1, 0.2 | -0.3, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.14) | |
| | | 95% CI | -0.1, 0.4 | |
| | | p-value | 0.3472 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.14, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 75 | 55 |
| | | Mean (StdDev) | 1.5 (1.18) | 1.5 (1.12) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 74 | 54 |
| | | Mean (StdDev) | 0.0 (1.32) | -0.1 (1.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 3 | -2, 3 |
| | | LS Mean (SE) | 0.0 (0.11) | 0.1 (0.14) |
| | | 95% CI | -0.2, 0.2 | -0.2, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.18) | |
| | | 95% CI | -0.5, 0.2 | |
| | | p-value | 0.4852 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.48, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 78 | 54 |
| | | Mean (StdDev) | 1.6 (1.01) | 1.9 (1.15) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 77 | 53 |
| | | Mean (StdDev) | 0.0 (1.25) | 0.4 (1.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.10) | 0.4 (0.12) |
| | | 95% CI | -0.1, 0.2 | 0.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (0.16) | |
| | | 95% CI | -0.7, 0.0 | |
| | | p-value | 0.0321 | |
| | | Corrected Hedges g (95% CI) [2] | -0.38 (-0.74, -0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 87 | 59 |
| | | Mean (StdDev) | 1.6 (1.11) | 1.7 (1.06) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 87 | 58 |
| | | Mean (StdDev) | 0.3 (1.23) | 0.2 (1.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.10) | 0.3 (0.13) |
| | | 95% CI | 0.0, 0.4 | 0.0, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.16) | |
| | | 95% CI | -0.4, 0.3 | |
| | | p-value | 0.6602 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.41, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 78 | 48 |
| | | Mean (StdDev) | 1.5 (0.98) | 1.4 (0.97) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 77 | 47 |
| | | Mean (StdDev) | -0.1 (1.07) | 0.0 (1.09) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -2, 2 | -2, 3 |
| | | LS Mean (SE) | 0.0 (0.09) | 0.1 (0.12) |
| | | 95% CI | -0.2, 0.2 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.15) | |
| | | 95% CI | -0.4, 0.2 | |
| | | p-value | 0.6008 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.46, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -0.2 (0.05) | 0.0 (0.07) |
| | | 95% CI | -0.3, -0.1 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.08) | |
| | | 95% CI | -0.3, 0.0 | |
| | | p-value | 0.0798 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.43, 0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 122 |
| | | Mean (StdDev) | 0.1 (0.33) | 0.1 (0.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 3 |
| Cycle 3 Day 1 | Actual | n | 198 | 108 |
| | | Mean (StdDev) | 0.1 (0.37) | 0.0 (0.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 1 |
| | Change from BL | n | 196 | 106 |
| | | Mean (StdDev) | 0.1 (0.36) | -0.1 (0.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.02) | -0.1 (0.03) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.04) | |
| | | 95% CI | 0.0, 0.2 | |
| | | p-value | 0.0096 | |
| | | Corrected Hedges g (95% CI) [2] | 0.31 (0.08, 0.55) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 164 | 98 |
| | | Mean (StdDev) | 0.1 (0.37) | 0.1 (0.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 162 | 97 |
| | | Mean (StdDev) | 0.0 (0.44) | -0.1 (0.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.0 (0.04) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.05) | |
| | | 95% CI | 0.0, 0.2 | |
| | | p-value | 0.2926 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.12, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 147 | 84 |
| | | Mean (StdDev) | 0.1 (0.34) | 0.0 (0.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 3 |
| | Change from BL | n | 145 | 83 |
| | | Mean (StdDev) | 0.0 (0.42) | -0.1 (0.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -3, 2 |
| | | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.03) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.04) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.1546 | |
| | | Corrected Hedges g (95% CI) [2] | 0.20 (-0.07, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 130 | 67 |
| | | Mean (StdDev) | 0.1 (0.51) | 0.1 (0.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 128 | 66 |
| | | Mean (StdDev) | 0.0 (0.59) | 0.0 (0.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 4 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.04) | 0.0 (0.05) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.06) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.3573 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.16, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 49 |
| | | Mean (StdDev) | 0.1 (0.39) | 0.1 (0.28) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 1 |
| | Change from BL | n | 118 | 48 |
| | | Mean (StdDev) | 0.0 (0.47) | -0.1 (0.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.0 (0.05) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.06) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.4846 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.22, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 0.1 (0.25) | 0.1 (0.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 3 |
| | Change from BL | n | 107 | 47 |
| | | Mean (StdDev) | 0.0 (0.34) | -0.1 (0.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 1 | -3, 2 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.0 (0.04) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.05) | |
| | | 95% CI | -0.1, 0.1 | |
| | | p-value | 0.4766 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.22, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 96 | 38 |
| | | Mean (StdDev) | 0.1 (0.30) | 0.1 (0.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 1 |
| | Change from BL | n | 94 | 38 |
| | | Mean (StdDev) | 0.0 (0.41) | -0.1 (0.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.0 (0.05) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.06) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.5310 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.26, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 82 | 32 |
| | | Mean (StdDev) | 0.1 (0.34) | 0.1 (0.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 2 |
| | Change from BL | n | 81 | 32 |
| | | Mean (StdDev) | 0.1 (0.43) | -0.1 (0.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.0 (0.05) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.06) | |
| | | 95% CI | 0.0, 0.2 | |
| | | p-value | 0.1909 | |
| | | Corrected Hedges g (95% CI) [2] | 0.27 (-0.14, 0.68) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 0.0 (0.21) | 0.0 (0.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 1 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | 0.0 (0.36) | -0.1 (0.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 1 | -2, 0 |
| | | LS Mean (SE) | 0.0 (0.03) | -0.1 (0.05) |
| | | 95% CI | -0.1, 0.1 | -0.2, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.06) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.2868 | |
| | | Corrected Hedges g (95% CI) [2] | 0.26 (-0.22, 0.74) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.3 (0.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 2 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 0.0 (0.20) | 0.1 (0.38) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 0 | 0, 1 |
| | | LS Mean (SE) | 0.0 (0.03) | 0.0 (0.05) |
| | | 95% CI | -0.1, 0.0 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.06) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.2994 | |
| | | Corrected Hedges g (95% CI) [2] | -0.43 (-1.27, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.5 (1.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 0 | 0, 2 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -0.1 (0.28) | 0.3 (0.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.5 |
| | | Min, Max | -1, 0 | 0, 1 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 7 | 1 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 7 | 1 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 0.2 (0.45) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 1 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 0.2 (0.45) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 1 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 125 | 88 |
| | | Mean (StdDev) | 0.2 (0.54) | 0.1 (0.38) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 125 | 87 |
| | | Mean (StdDev) | 0.1 (0.51) | 0.0 (0.58) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -3, 3 |
| | | LS Mean (SE) | 0.1 (0.04) | 0.0 (0.05) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.06) | |
| | | 95% CI | 0.0, 0.2 | |
| | | p-value | 0.1857 | |
| | | Corrected Hedges g (95% CI) [2] | 0.18 (-0.09, 0.46) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 75 | 55 |
| | | Mean (StdDev) | 0.2 (0.64) | 0.0 (0.19) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 1 |
| | Change from BL | n | 75 | 54 |
| | | Mean (StdDev) | 0.1 (0.66) | -0.1 (0.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -2, 1 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.0 (0.07) |
| | | 95% CI | 0.0, 0.2 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.09) | |
| | | 95% CI | 0.0, 0.3 | |
| | | p-value | 0.1391 | |
| | | Corrected Hedges g (95% CI) [2] | 0.26 (-0.09, 0.62) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 78 | 54 |
| | | Mean (StdDev) | 0.1 (0.44) | 0.2 (0.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 2 |
| | Change from BL | n | 78 | 53 |
| | | Mean (StdDev) | 0.1 (0.44) | 0.1 (0.55) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 2 | -2, 2 |
| | | LS Mean (SE) | 0.0 (0.04) | 0.1 (0.05) |
| | | 95% CI | -0.1, 0.1 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.07) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.2781 | |
| | | Corrected Hedges g (95% CI) [2] | -0.19 (-0.54, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 88 | 59 |
| | | Mean (StdDev) | 0.2 (0.62) | 0.2 (0.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 88 | 58 |
| | | Mean (StdDev) | 0.1 (0.61) | 0.1 (0.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -1, 4 |
| | | LS Mean (SE) | 0.1 (0.07) | 0.1 (0.09) |
| | | 95% CI | 0.0, 0.3 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9681 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.32, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 78 | 49 |
| | | Mean (StdDev) | 0.1 (0.49) | 0.1 (0.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 78 | 48 |
| | | Mean (StdDev) | 0.1 (0.55) | 0.1 (0.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -1, 3 |
| | | LS Mean (SE) | 0.0 (0.06) | 0.1 (0.08) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.10) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.7530 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.42, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.0 (0.02) | 0.0 (0.02) |
| | | 95% CI | 0.0, 0.1 | -0.1, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.03) | |
| | | 95% CI | 0.0, 0.1 | |
| | | p-value | 0.1943 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.08, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 223 | 122 |
| | | Mean (StdDev) | 0.8 (1.03) | 1.0 (1.09) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 198 | 109 |
| | | Mean (StdDev) | 0.7 (0.98) | 1.0 (1.13) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 194 | 107 |
| | | Mean (StdDev) | 0.0 (0.96) | 0.0 (1.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.1 (0.06) | 0.1 (0.09) |
| | | 95% CI | -0.2, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.11) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.2135 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.39, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 163 | 98 |
| | | Mean (StdDev) | 0.7 (0.96) | 1.0 (1.16) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 159 | 97 |
| | | Mean (StdDev) | -0.1 (0.82) | 0.1 (1.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 4 |
| | | LS Mean (SE) | -0.1 (0.07) | 0.2 (0.09) |
| | | 95% CI | -0.2, 0.0 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.11) | |
| | | 95% CI | -0.5, 0.0 | |
| | | p-value | 0.0262 | |
| | | Corrected Hedges g (95% CI) [2] | -0.29 (-0.54, -0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 147 | 83 |
| | | Mean (StdDev) | 0.8 (0.94) | 0.9 (1.02) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 144 | 82 |
| | | Mean (StdDev) | 0.1 (1.03) | 0.0 (0.97) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.5 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 2 |
| | | LS Mean (SE) | 0.1 (0.07) | 0.1 (0.09) |
| | | 95% CI | -0.1, 0.2 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9980 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.27, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 130 | 66 |
| | | Mean (StdDev) | 0.8 (0.97) | 0.9 (1.12) |
| | | Median | 0.5 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 127 | 65 |
| | | Mean (StdDev) | 0.0 (0.96) | 0.0 (1.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | 0.0 (0.08) | 0.0 (0.10) |
| | | 95% CI | -0.2, 0.1 | -0.2, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.13) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.6593 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.37, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 49 |
| | | Mean (StdDev) | 0.8 (0.97) | 0.7 (0.97) |
| | | Median | 1.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 117 | 48 |
| | | Mean (StdDev) | 0.1 (1.01) | -0.2 (0.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.0 (0.08) | 0.0 (0.11) |
| | | 95% CI | -0.1, 0.2 | -0.3, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.14) | |
| | | 95% CI | -0.2, 0.3 | |
| | | p-value | 0.5591 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.24, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 108 | 48 |
| | | Mean (StdDev) | 0.8 (1.08) | 0.7 (0.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 105 | 47 |
| | | Mean (StdDev) | 0.0 (1.16) | -0.1 (0.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | 0.0 (0.08) | 0.0 (0.12) |
| | | 95% CI | -0.2, 0.1 | -0.3, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.14) | |
| | | 95% CI | -0.3, 0.3 | |
| | | p-value | 0.8794 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.32, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 0.7 (0.92) | 0.8 (0.90) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 94 | 38 |
| | | Mean (StdDev) | -0.1 (1.11) | -0.1 (0.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | -0.1 (0.07) | 0.1 (0.11) |
| | | 95% CI | -0.2, 0.1 | -0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.13) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.1385 | |
| | | Corrected Hedges g (95% CI) [2] | -0.28 (-0.66, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 82 | 32 |
| | | Mean (StdDev) | 0.7 (1.01) | 0.9 (1.05) |
| | | Median | 0.0 | 0.5 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 80 | 32 |
| | | Mean (StdDev) | -0.1 (1.10) | 0.1 (1.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.0 (0.09) | 0.3 (0.14) |
| | | 95% CI | -0.2, 0.1 | 0.0, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (0.17) | |
| | | 95% CI | -0.6, 0.0 | |
| | | p-value | 0.0724 | |
| | | Corrected Hedges g (95% CI) [2] | -0.37 (-0.78, 0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 0.6 (0.96) | 0.8 (1.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 62 | 23 |
| | | Mean (StdDev) | -0.2 (1.04) | -0.3 (0.96) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.0 |
| | | Min, Max | -3, 2 | -2, 2 |
| | | LS Mean (SE) | -0.1 (0.09) | 0.0 (0.15) |
| | | 95% CI | -0.3, 0.1 | -0.3, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.18) | |
| | | 95% CI | -0.4, 0.3 | |
| | | p-value | 0.5959 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.61, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 0.6 (0.91) | 0.7 (0.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -0.1 (1.15) | 0.0 (1.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 2.0 |
| | | Min, Max | -2, 2 | -2, 2 |
| | | LS Mean (SE) | -0.1 (0.15) | 0.0 (0.27) |
| | | 95% CI | -0.4, 0.2 | -0.6, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.31) | |
| | | 95% CI | -0.7, 0.6 | |
| | | p-value | 0.7953 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.94, 0.73) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 0.6 (0.96) | 1.0 (1.15) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 0.0 (0.82) | 0.3 (1.26) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -0.5, 1.0 |
| | | Min, Max | -1, 1 | -1, 2 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 7 | 1 |
| | | Mean (StdDev) | 1.0 (1.00) | 0.0 (NA) |
| | | Median | 1.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 0 |
| | Change from BL | n | 7 | 1 |
| | | Mean (StdDev) | 0.3 (1.25) | 0.0 (NA) |
| | | Median | 1.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | -1, 2 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 0.6 (0.55) | |
| | | Median | 1.0 | |
| | | Q1, Q3 | 0.0, 1.0 | |
| | | Min, Max | 0, 1 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 0.2 (0.84) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 1.0 | |
| | | Min, Max | -1, 1 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 125 | 88 |
| | | Mean (StdDev) | 1.0 (1.01) | 1.2 (1.10) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 125 | 87 |
| | | Mean (StdDev) | 0.2 (1.02) | 0.1 (1.11) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 2 |
| | | LS Mean (SE) | 0.1 (0.08) | 0.2 (0.09) |
| | | 95% CI | 0.0, 0.3 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.12) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.5904 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.35, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 75 | 54 |
| | | Mean (StdDev) | 1.0 (1.06) | 1.1 (1.13) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 75 | 53 |
| | | Mean (StdDev) | 0.1 (1.23) | 0.1 (1.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 4 | -3, 4 |
| | | LS Mean (SE) | 0.1 (0.11) | 0.2 (0.13) |
| | | 95% CI | -0.1, 0.4 | -0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.17) | |
| | | 95% CI | -0.4, 0.3 | |
| | | p-value | 0.7451 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.41, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 78 | 54 |
| | | Mean (StdDev) | 1.3 (1.18) | 1.1 (1.04) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 77 | 53 |
| | | Mean (StdDev) | 0.3 (1.20) | 0.2 (1.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -3, 3 |
| | | LS Mean (SE) | 0.3 (0.10) | 0.2 (0.12) |
| | | 95% CI | 0.1, 0.5 | -0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.16) | |
| | | 95% CI | -0.2, 0.4 | |
| | | p-value | 0.4010 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.20, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 87 | 58 |
| | | Mean (StdDev) | 1.1 (1.11) | 1.1 (1.00) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 87 | 57 |
| | | Mean (StdDev) | 0.2 (1.28) | 0.2 (1.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | 0.2 (0.11) | 0.2 (0.13) |
| | | 95% CI | 0.0, 0.4 | -0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.17) | |
| | | 95% CI | -0.3, 0.4 | |
| | | p-value | 0.7239 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.27, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 78 | 49 |
| | | Mean (StdDev) | 1.1 (1.12) | 0.9 (0.92) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 77 | 48 |
| | | Mean (StdDev) | 0.2 (1.16) | 0.1 (1.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | -0.5, 1.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.3 (0.09) | 0.1 (0.12) |
| | | 95% CI | 0.1, 0.4 | -0.2, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.15) | |
| | | 95% CI | -0.1, 0.5 | |
| | | p-value | 0.2111 | |
| | | Corrected Hedges g (95% CI) [2] | 0.23 (-0.13, 0.59) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.0 (0.05) | 0.1 (0.07) |
| | | 95% CI | 0.0, 0.1 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.08) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.5431 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.29, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 224 | 121 |
| | | Mean (StdDev) | 0.3 (0.64) | 0.3 (0.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 199 | 109 |
| | | Mean (StdDev) | 0.6 (0.84) | 0.3 (0.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 196 | 107 |
| | | Mean (StdDev) | 0.4 (0.85) | 0.1 (0.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.4 (0.05) | 0.1 (0.07) |
| | | 95% CI | 0.3, 0.5 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (0.09) | |
| | | 95% CI | 0.1, 0.5 | |
| | | p-value | 0.0009 | |
| | | Corrected Hedges g (95% CI) [2] | 0.40 (0.16, 0.64) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 164 | 98 |
| | | Mean (StdDev) | 0.4 (0.76) | 0.2 (0.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 161 | 96 |
| | | Mean (StdDev) | 0.2 (0.81) | 0.0 (0.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 4 | -2, 2 |
| | | LS Mean (SE) | 0.2 (0.05) | 0.0 (0.07) |
| | | 95% CI | 0.1, 0.3 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.09) | |
| | | 95% CI | 0.0, 0.4 | |
| | | p-value | 0.0120 | |
| | | Corrected Hedges g (95% CI) [2] | 0.33 (0.07, 0.58) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 147 | 85 |
| | | Mean (StdDev) | 0.4 (0.73) | 0.2 (0.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 145 | 84 |
| | | Mean (StdDev) | 0.2 (0.71) | -0.1 (0.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -2, 2 |
| | | LS Mean (SE) | 0.2 (0.05) | 0.0 (0.07) |
| | | 95% CI | 0.1, 0.3 | -0.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.08) | |
| | | 95% CI | 0.0, 0.4 | |
| | | p-value | 0.0186 | |
| | | Corrected Hedges g (95% CI) [2] | 0.32 (0.05, 0.59) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 128 | 66 |
| | | Mean (StdDev) | 0.4 (0.71) | 0.3 (0.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 126 | 65 |
| | | Mean (StdDev) | 0.2 (0.72) | 0.0 (0.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.05) | 0.0 (0.07) |
| | | 95% CI | 0.1, 0.3 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.09) | |
| | | 95% CI | 0.0, 0.3 | |
| | | p-value | 0.1202 | |
| | | Corrected Hedges g (95% CI) [2] | 0.24 (-0.06, 0.54) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 48 |
| | | Mean (StdDev) | 0.3 (0.59) | 0.3 (0.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 118 | 47 |
| | | Mean (StdDev) | 0.1 (0.55) | 0.1 (0.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.1 (0.08) |
| | | 95% CI | 0.0, 0.2 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.10) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9976 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.34, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 0.3 (0.62) | 0.2 (0.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 107 | 47 |
| | | Mean (StdDev) | 0.1 (0.63) | 0.0 (0.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.0 (0.08) |
| | | 95% CI | 0.0, 0.2 | -0.2, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.09) | |
| | | 95% CI | -0.1, 0.3 | |
| | | p-value | 0.3704 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.19, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 0.2 (0.58) | 0.3 (0.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 95 | 38 |
| | | Mean (StdDev) | 0.1 (0.65) | 0.1 (0.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | -1, 3 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.0 (0.08) |
| | | 95% CI | 0.0, 0.2 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.10) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.6011 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.28, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 82 | 32 |
| | | Mean (StdDev) | 0.3 (0.72) | 0.4 (0.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 81 | 32 |
| | | Mean (StdDev) | 0.2 (0.84) | 0.2 (0.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.07) | 0.2 (0.10) |
| | | 95% CI | 0.0, 0.2 | -0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.7143 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.48, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 0.4 (0.66) | 0.3 (0.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | 0.2 (0.72) | 0.2 (0.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.1 (0.10) |
| | | 95% CI | 0.0, 0.3 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.12) | |
| | | 95% CI | -0.2, 0.3 | |
| | | p-value | 0.5055 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.32, 0.64) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 0.3 (0.54) | 0.3 (0.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 2 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 0.0 (0.58) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 1 | 0, 0 |
| | | LS Mean (SE) | 0.0 (0.09) | 0.0 (0.17) |
| | | 95% CI | -0.1, 0.2 | -0.4, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.19) | |
| | | 95% CI | -0.3, 0.4 | |
| | | p-value | 0.7744 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.72, 0.96) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 0.4 (0.87) | 0.5 (1.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 0.1 (1.04) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -1, 3 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 7 | 1 |
| | | Mean (StdDev) | 0.4 (0.79) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 2 | 0, 0 |
| | Change from BL | n | 7 | 1 |
| | | Mean (StdDev) | 0.1 (0.69) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | -1, 1 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 0.4 (0.55) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 1.0 | |
| | | Min, Max | 0, 1 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 0.0 (0.00) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -1.0 (NA) | |
| | | Median | -1.0 | |
| | | Q1, Q3 | -1.0, -1.0 | |
| | | Min, Max | -1, -1 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 124 | 88 |
| | | Mean (StdDev) | 0.5 (1.00) | 0.4 (0.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 123 | 86 |
| | | Mean (StdDev) | 0.3 (0.96) | 0.0 (0.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 4 | -2, 4 |
| | | LS Mean (SE) | 0.3 (0.08) | 0.1 (0.09) |
| | | 95% CI | 0.1, 0.4 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.12) | |
| | | 95% CI | -0.1, 0.4 | |
| | | p-value | 0.2714 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.12, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 75 | 55 |
| | | Mean (StdDev) | 0.5 (0.98) | 0.5 (0.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 74 | 54 |
| | | Mean (StdDev) | 0.3 (0.97) | 0.2 (0.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -1, 4 | -1, 2 |
| | | LS Mean (SE) | 0.3 (0.09) | 0.3 (0.11) |
| | | 95% CI | 0.1, 0.5 | 0.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.14) | |
| | | 95% CI | -0.3, 0.3 | |
| | | p-value | 0.9098 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.37, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 77 | 54 |
| | | Mean (StdDev) | 0.4 (0.83) | 0.8 (1.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 76 | 52 |
| | | Mean (StdDev) | 0.1 (0.91) | 0.4 (1.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.10) | 0.6 (0.12) |
| | | 95% CI | 0.0, 0.4 | 0.3, 0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (0.15) | |
| | | 95% CI | -0.7, -0.1 | |
| | | p-value | 0.0068 | |
| | | Corrected Hedges g (95% CI) [2] | -0.49 (-0.85, -0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 87 | 59 |
| | | Mean (StdDev) | 0.5 (0.89) | 0.5 (0.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 86 | 57 |
| | | Mean (StdDev) | 0.2 (0.90) | 0.2 (1.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 4 |
| | | LS Mean (SE) | 0.3 (0.09) | 0.4 (0.11) |
| | | 95% CI | 0.1, 0.4 | 0.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.15) | |
| | | 95% CI | -0.4, 0.2 | |
| | | p-value | 0.4998 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.45, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 78 | 49 |
| | | Mean (StdDev) | 0.4 (0.78) | 0.4 (0.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 78 | 47 |
| | | Mean (StdDev) | 0.2 (0.83) | 0.0 (0.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.09) | 0.2 (0.11) |
| | | 95% CI | 0.0, 0.4 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.14) | |
| | | 95% CI | -0.3, 0.3 | |
| | | p-value | 0.8226 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.40, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.2 (0.03) | 0.1 (0.05) |
| | | 95% CI | 0.1, 0.2 | 0.0, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.06) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.4301 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.13, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 226 | 122 |
| | | Mean (StdDev) | 0.4 (0.77) | 0.4 (0.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 197 | 109 |
| | | Mean (StdDev) | 0.4 (0.77) | 0.4 (0.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 196 | 107 |
| | | Mean (StdDev) | 0.1 (0.65) | 0.0 (0.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.1 (0.07) |
| | | 95% CI | 0.0, 0.2 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.1, 0.2 | |
| | | p-value | 0.6896 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.19, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 164 | 98 |
| | | Mean (StdDev) | 0.4 (0.77) | 0.5 (0.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 163 | 97 |
| | | Mean (StdDev) | 0.1 (0.82) | 0.2 (0.83) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.2 (0.08) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.5741 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.32, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 147 | 85 |
| | | Mean (StdDev) | 0.4 (0.68) | 0.5 (0.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 146 | 84 |
| | | Mean (StdDev) | 0.1 (0.78) | 0.2 (0.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.2 (0.06) | 0.2 (0.07) |
| | | 95% CI | 0.0, 0.3 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.6673 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.33, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 130 | 67 |
| | | Mean (StdDev) | 0.4 (0.67) | 0.5 (0.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 129 | 66 |
| | | Mean (StdDev) | 0.1 (0.74) | 0.1 (0.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -3, 3 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.2 (0.09) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.11) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.4840 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.40, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 49 |
| | | Mean (StdDev) | 0.4 (0.75) | 0.5 (0.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 119 | 48 |
| | | Mean (StdDev) | 0.1 (0.78) | 0.1 (0.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.2 (0.08) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.5724 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.43, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 108 | 48 |
| | | Mean (StdDev) | 0.4 (0.82) | 0.6 (0.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.5 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 107 | 47 |
| | | Mean (StdDev) | 0.1 (0.87) | 0.3 (0.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.3 (0.10) |
| | | 95% CI | 0.0, 0.3 | 0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.12) | |
| | | 95% CI | -0.4, 0.1 | |
| | | p-value | 0.1434 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.60, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 0.3 (0.67) | 0.4 (0.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 0.0 (0.69) | 0.1 (0.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 2 | -2, 2 |
| | | LS Mean (SE) | 0.0 (0.05) | 0.1 (0.08) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.5083 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.50, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 82 | 32 |
| | | Mean (StdDev) | 0.4 (0.75) | 0.6 (0.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 82 | 32 |
| | | Mean (StdDev) | 0.1 (0.84) | 0.2 (0.91) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.07) | 0.3 (0.11) |
| | | 95% CI | 0.0, 0.3 | 0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.13) | |
| | | 95% CI | -0.4, 0.1 | |
| | | p-value | 0.3263 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.61, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 0.3 (0.60) | 0.8 (1.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 2.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | -0.1 (0.86) | 0.3 (0.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | 0.0 (0.07) | 0.4 (0.12) |
| | | 95% CI | -0.1, 0.2 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (0.14) | |
| | | 95% CI | -0.7, -0.1 | |
| | | p-value | 0.0056 | |
| | | Corrected Hedges g (95% CI) [2] | -0.67 (-1.15, -0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 0.2 (0.52) | 0.9 (1.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 2.0 |
| | | Min, Max | 0, 2 | 0, 3 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 0.1 (0.33) | 0.1 (0.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 1 | -1, 1 |
| | | LS Mean (SE) | 0.2 (0.07) | 0.1 (0.12) |
| | | 95% CI | 0.0, 0.3 | -0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.14) | |
| | | 95% CI | -0.3, 0.3 | |
| | | p-value | 0.9380 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.81, 0.87) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 0.0 (0.00) | 1.5 (1.29) |
| | | Median | 0.0 | 1.5 |
| | | Q1, Q3 | 0.0, 0.0 | 0.5, 2.5 |
| | | Min, Max | 0, 0 | 0, 3 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -0.1 (0.28) | 0.3 (0.96) |
| | | Median | 0.0 | 0.5 |
| | | Q1, Q3 | 0.0, 0.0 | -0.5, 1.0 |
| | | Min, Max | -1, 0 | -1, 1 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 7 | 1 |
| | | Mean (StdDev) | 0.1 (0.38) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 0 |
| | Change from BL | n | 7 | 1 |
| | | Mean (StdDev) | 0.1 (0.38) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 1 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 0.0 (0.00) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 0.0 (0.00) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 124 | 88 |
| | | Mean (StdDev) | 0.6 (0.94) | 0.7 (1.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 124 | 87 |
| | | Mean (StdDev) | 0.2 (0.81) | 0.4 (1.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 4 |
| | | LS Mean (SE) | 0.2 (0.07) | 0.4 (0.09) |
| | | 95% CI | 0.1, 0.4 | 0.3, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.11) | |
| | | 95% CI | -0.4, 0.0 | |
| | | p-value | 0.0728 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.53, 0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 74 | 55 |
| | | Mean (StdDev) | 0.6 (0.99) | 0.6 (0.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 74 | 54 |
| | | Mean (StdDev) | 0.4 (0.93) | 0.4 (0.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -1, 3 |
| | | LS Mean (SE) | 0.3 (0.09) | 0.5 (0.11) |
| | | 95% CI | 0.1, 0.5 | 0.2, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.14) | |
| | | 95% CI | -0.4, 0.1 | |
| | | p-value | 0.3311 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.53, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 77 | 54 |
| | | Mean (StdDev) | 0.6 (0.95) | 0.7 (0.82) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 77 | 53 |
| | | Mean (StdDev) | 0.3 (0.75) | 0.4 (0.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -1, 2 | -2, 2 |
| | | LS Mean (SE) | 0.3 (0.08) | 0.5 (0.10) |
| | | 95% CI | 0.1, 0.4 | 0.3, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.12) | |
| | | 95% CI | -0.5, 0.0 | |
| | | p-value | 0.0852 | |
| | | Corrected Hedges g (95% CI) [2] | -0.31 (-0.66, 0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 88 | 58 |
| | | Mean (StdDev) | 0.6 (1.07) | 0.4 (0.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 88 | 57 |
| | | Mean (StdDev) | 0.2 (0.94) | 0.3 (0.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 3 | -2, 4 |
| | | LS Mean (SE) | 0.3 (0.08) | 0.3 (0.10) |
| | | 95% CI | 0.1, 0.4 | 0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.13) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.8518 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.37, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 78 | 49 |
| | | Mean (StdDev) | 0.6 (0.97) | 0.3 (0.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 78 | 48 |
| | | Mean (StdDev) | 0.3 (0.97) | 0.1 (0.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | -3, 3 | -2, 2 |
| | | LS Mean (SE) | 0.3 (0.09) | 0.2 (0.12) |
| | | 95% CI | 0.1, 0.5 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.15) | |
| | | 95% CI | -0.2, 0.4 | |
| | | p-value | 0.4266 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.21, 0.51) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.2 (0.04) | 0.3 (0.05) |
| | | 95% CI | 0.1, 0.2 | 0.2, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.07) | |
| | | 95% CI | -0.2, 0.0 | |
| | | p-value | 0.1614 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.38, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 226 | 122 |
| | | Mean (StdDev) | 1.6 (1.31) | 1.7 (1.29) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 198 | 109 |
| | | Mean (StdDev) | 1.6 (1.33) | 1.6 (1.30) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 3.0 | 0.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 197 | 107 |
| | | Mean (StdDev) | 0.0 (1.29) | -0.2 (1.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.0 (0.09) | -0.1 (0.12) |
| | | 95% CI | -0.2, 0.1 | -0.3, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.15) | |
| | | 95% CI | -0.2, 0.4 | |
| | | p-value | 0.5621 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.17, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 164 | 98 |
| | | Mean (StdDev) | 1.4 (1.22) | 1.6 (1.15) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 163 | 97 |
| | | Mean (StdDev) | -0.3 (1.15) | -0.1 (1.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -3, 3 |
| | | LS Mean (SE) | -0.3 (0.08) | -0.1 (0.11) |
| | | 95% CI | -0.4, -0.1 | -0.3, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.13) | |
| | | 95% CI | -0.5, 0.0 | |
| | | p-value | 0.0874 | |
| | | Corrected Hedges g (95% CI) [2] | -0.22 (-0.47, 0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 148 | 85 |
| | | Mean (StdDev) | 1.5 (1.22) | 1.6 (1.21) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 147 | 84 |
| | | Mean (StdDev) | -0.1 (1.18) | 0.0 (1.55) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 4 |
| | | LS Mean (SE) | -0.1 (0.09) | 0.1 (0.12) |
| | | 95% CI | -0.3, 0.1 | -0.2, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.15) | |
| | | 95% CI | -0.4, 0.1 | |
| | | p-value | 0.2860 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.41, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 129 | 67 |
| | | Mean (StdDev) | 1.6 (1.32) | 1.6 (1.17) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 128 | 66 |
| | | Mean (StdDev) | -0.1 (1.25) | -0.1 (1.39) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 4 |
| | | LS Mean (SE) | -0.1 (0.09) | 0.0 (0.12) |
| | | 95% CI | -0.3, 0.1 | -0.3, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.15) | |
| | | 95% CI | -0.4, 0.2 | |
| | | p-value | 0.6958 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.36, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 49 |
| | | Mean (StdDev) | 1.6 (1.37) | 1.5 (1.17) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 119 | 48 |
| | | Mean (StdDev) | -0.1 (1.17) | -0.1 (1.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 0.5 |
| | | Min, Max | -2, 3 | -4, 3 |
| | | LS Mean (SE) | 0.0 (0.09) | 0.0 (0.13) |
| | | 95% CI | -0.2, 0.1 | -0.3, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.16) | |
| | | 95% CI | -0.3, 0.3 | |
| | | p-value | 0.8154 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.37, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 1.5 (1.31) | 1.5 (1.18) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 108 | 47 |
| | | Mean (StdDev) | -0.2 (1.22) | -0.1 (1.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -1.0, 1.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.1 (0.09) | 0.1 (0.14) |
| | | 95% CI | -0.3, 0.0 | -0.2, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.16) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.2257 | |
| | | Corrected Hedges g (95% CI) [2] | -0.21 (-0.55, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 96 | 38 |
| | | Mean (StdDev) | 1.5 (1.24) | 1.4 (1.13) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 95 | 38 |
| | | Mean (StdDev) | -0.2 (1.15) | -0.4 (1.51) |
| | | Median | 0.0 | -0.5 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | -0.1 (0.09) | -0.2 (0.14) |
| | | 95% CI | -0.3, 0.1 | -0.4, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.17) | |
| | | 95% CI | -0.3, 0.4 | |
| | | p-value | 0.7734 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.32, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 82 | 31 |
| | | Mean (StdDev) | 1.5 (1.22) | 1.7 (1.18) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 82 | 31 |
| | | Mean (StdDev) | -0.2 (1.23) | -0.1 (1.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 4 |
| | | LS Mean (SE) | -0.1 (0.09) | 0.2 (0.14) |
| | | 95% CI | -0.2, 0.1 | -0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.17) | |
| | | 95% CI | -0.6, 0.1 | |
| | | p-value | 0.1751 | |
| | | Corrected Hedges g (95% CI) [2] | -0.28 (-0.69, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 1.4 (1.32) | 1.3 (1.23) |
| | | Median | 1.0 | 1.0 |
| | | Q1, Q3 | 0.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | -0.3 (1.26) | -0.4 (1.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 0.0 | -2.0, 0.0 |
| | | Min, Max | -3, 3 | -3, 3 |
| | | LS Mean (SE) | 0.0 (0.11) | -0.1 (0.17) |
| | | 95% CI | -0.2, 0.2 | -0.4, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.20) | |
| | | 95% CI | -0.3, 0.5 | |
| | | p-value | 0.6969 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.39, 0.57) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 1.5 (1.26) | 1.3 (0.95) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 2.0 | 0.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 2 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -0.2 (1.41) | -0.4 (1.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -2.0, 0.0 |
| | | Min, Max | -3, 2 | -2, 1 |
| | | LS Mean (SE) | 0.0 (0.11) | 0.1 (0.20) |
| | | 95% CI | -0.2, 0.2 | -0.3, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.23) | |
| | | 95% CI | -0.5, 0.4 | |
| | | p-value | 0.7494 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.97, 0.71) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 1.2 (1.09) | 1.8 (1.26) |
| | | Median | 1.0 | 2.0 |
| | | Q1, Q3 | 1.0, 2.0 | 1.0, 2.5 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 0.0 (1.00) | -0.5 (1.91) |
| | | Median | 0.0 | -1.0 |
| | | Q1, Q3 | 0.0, 0.0 | -2.0, 1.0 |
| | | Min, Max | -2, 2 | -2, 2 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 7 | 1 |
| | | Mean (StdDev) | 1.3 (1.25) | 0.0 (NA) |
| | | Median | 1.0 | 0.0 |
| | | Q1, Q3 | 1.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 0 |
| | Change from BL | n | 7 | 1 |
| | | Mean (StdDev) | 0.3 (0.76) | -2.0 (NA) |
| | | Median | 0.0 | -2.0 |
| | | Q1, Q3 | 0.0, 1.0 | -2.0, -2.0 |
| | | Min, Max | -1, 1 | -2, -2 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 1.0 (1.22) | |
| | | Median | 1.0 | |
| | | Q1, Q3 | 0.0, 1.0 | |
| | | Min, Max | 0, 3 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 0.4 (1.52) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | -1, 3 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -1.0 (NA) | |
| | | Median | -1.0 | |
| | | Q1, Q3 | -1.0, -1.0 | |
| | | Min, Max | -1, -1 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 125 | 88 |
| | | Mean (StdDev) | 2.3 (1.36) | 2.6 (1.19) |
| | | Median | 2.0 | 3.0 |
| | | Q1, Q3 | 1.0, 4.0 | 2.0, 4.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 125 | 87 |
| | | Mean (StdDev) | 0.6 (1.30) | 1.0 (1.53) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | -3, 4 | -3, 4 |
| | | LS Mean (SE) | 0.5 (0.09) | 0.9 (0.11) |
| | | 95% CI | 0.4, 0.7 | 0.7, 1.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (0.15) | |
| | | 95% CI | -0.7, -0.1 | |
| | | p-value | 0.0103 | |
| | | Corrected Hedges g (95% CI) [2] | -0.36 (-0.64, -0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 75 | 55 |
| | | Mean (StdDev) | 2.3 (1.39) | 2.2 (1.24) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 4.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 75 | 54 |
| | | Mean (StdDev) | 0.5 (1.20) | 0.7 (1.31) |
| | | Median | 0.0 | 0.5 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -1, 4 |
| | | LS Mean (SE) | 0.4 (0.11) | 0.6 (0.13) |
| | | 95% CI | 0.2, 0.6 | 0.3, 0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.17) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.2254 | |
| | | Corrected Hedges g (95% CI) [2] | -0.22 (-0.57, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 78 | 54 |
| | | Mean (StdDev) | 2.2 (1.28) | 2.3 (1.23) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 78 | 53 |
| | | Mean (StdDev) | 0.6 (1.19) | 0.6 (1.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -3, 4 |
| | | LS Mean (SE) | 0.4 (0.10) | 0.5 (0.13) |
| | | 95% CI | 0.2, 0.6 | 0.3, 0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.16) | |
| | | 95% CI | -0.5, 0.2 | |
| | | p-value | 0.4024 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.50, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 87 | 58 |
| | | Mean (StdDev) | 2.2 (1.32) | 2.2 (1.24) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 87 | 57 |
| | | Mean (StdDev) | 0.7 (1.27) | 0.7 (1.39) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | -2, 4 | -3, 4 |
| | | LS Mean (SE) | 0.5 (0.11) | 0.5 (0.14) |
| | | 95% CI | 0.2, 0.7 | 0.3, 0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.17) | |
| | | 95% CI | -0.4, 0.3 | |
| | | p-value | 0.7179 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.40, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 78 | 49 |
| | | Mean (StdDev) | 2.2 (1.31) | 2.0 (1.26) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 78 | 48 |
| | | Mean (StdDev) | 0.6 (1.32) | 0.4 (1.47) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | -0.5, 1.0 |
| | | Min, Max | -2, 4 | -3, 4 |
| | | LS Mean (SE) | 0.5 (0.11) | 0.4 (0.15) |
| | | 95% CI | 0.3, 0.7 | 0.1, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.18) | |
| | | 95% CI | -0.3, 0.5 | |
| | | p-value | 0.5369 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.25, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.1 (0.06) | 0.2 (0.08) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.3451 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.33, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 226 | 122 |
| | | Mean (StdDev) | 2.3 (1.26) | 2.2 (1.15) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 2.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| Cycle 3 Day 1 | Actual | n | 199 | 109 |
| | | Mean (StdDev) | 2.4 (1.29) | 2.4 (1.21) |
| | | Median | 3.0 | 3.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 198 | 107 |
| | | Mean (StdDev) | 0.1 (1.53) | 0.2 (1.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 3 |
| | | LS Mean (SE) | 0.1 (0.09) | 0.2 (0.12) |
| | | 95% CI | -0.1, 0.3 | -0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.15) | |
| | | 95% CI | -0.4, 0.2 | |
| | | p-value | 0.5628 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.30, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 163 | 98 |
| | | Mean (StdDev) | 2.3 (1.35) | 2.3 (1.25) |
| | | Median | 3.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 162 | 97 |
| | | Mean (StdDev) | 0.1 (1.60) | 0.0 (1.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.10) | 0.0 (0.13) |
| | | 95% CI | -0.1, 0.3 | -0.2, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.16) | |
| | | 95% CI | -0.3, 0.4 | |
| | | p-value | 0.8072 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.22, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 147 | 85 |
| | | Mean (StdDev) | 2.5 (1.26) | 2.2 (1.24) |
| | | Median | 3.0 | 2.0 |
| | | Q1, Q3 | 2.0, 4.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 146 | 84 |
| | | Mean (StdDev) | 0.2 (1.44) | -0.1 (1.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 3 |
| | | LS Mean (SE) | 0.2 (0.10) | -0.1 (0.13) |
| | | 95% CI | 0.0, 0.4 | -0.3, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (0.16) | |
| | | 95% CI | 0.0, 0.6 | |
| | | p-value | 0.0943 | |
| | | Corrected Hedges g (95% CI) [2] | 0.23 (-0.04, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 129 | 67 |
| | | Mean (StdDev) | 2.4 (1.26) | 2.6 (1.13) |
| | | Median | 3.0 | 3.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 128 | 66 |
| | | Mean (StdDev) | 0.0 (1.33) | 0.4 (1.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.10) | 0.3 (0.13) |
| | | 95% CI | -0.1, 0.3 | 0.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.17) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.2331 | |
| | | Corrected Hedges g (95% CI) [2] | -0.18 (-0.48, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 49 |
| | | Mean (StdDev) | 2.3 (1.31) | 2.5 (1.16) |
| | | Median | 3.0 | 3.0 |
| | | Q1, Q3 | 1.5, 3.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 119 | 48 |
| | | Mean (StdDev) | 0.0 (1.57) | 0.3 (1.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -0.5, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.0 (0.10) | 0.2 (0.16) |
| | | 95% CI | -0.2, 0.2 | -0.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.19) | |
| | | 95% CI | -0.6, 0.2 | |
| | | p-value | 0.2419 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.53, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 2.4 (1.26) | 2.6 (1.20) |
| | | Median | 2.0 | 3.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 4.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 108 | 47 |
| | | Mean (StdDev) | 0.1 (1.47) | 0.4 (1.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.11) | 0.4 (0.16) |
| | | 95% CI | -0.1, 0.3 | 0.0, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (0.19) | |
| | | 95% CI | -0.6, 0.1 | |
| | | p-value | 0.1503 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.59, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 98 | 38 |
| | | Mean (StdDev) | 2.4 (1.25) | 2.8 (1.08) |
| | | Median | 2.0 | 3.0 |
| | | Q1, Q3 | 2.0, 3.0 | 2.0, 4.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 97 | 38 |
| | | Mean (StdDev) | 0.1 (1.65) | 0.5 (1.47) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | 0.1 (0.11) | 0.4 (0.18) |
| | | 95% CI | -0.1, 0.3 | 0.1, 0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (0.21) | |
| | | 95% CI | -0.8, 0.1 | |
| | | p-value | 0.1047 | |
| | | Corrected Hedges g (95% CI) [2] | -0.31 (-0.69, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 82 | 32 |
| | | Mean (StdDev) | 2.4 (1.30) | 2.9 (0.94) |
| | | Median | 3.0 | 3.0 |
| | | Q1, Q3 | 2.0, 4.0 | 2.5, 3.5 |
| | | Min, Max | 0, 4 | 1, 4 |
| | Change from BL | n | 82 | 32 |
| | | Mean (StdDev) | 0.1 (1.48) | 0.8 (1.50) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 2.0 |
| | | Min, Max | -4, 4 | -2, 4 |
| | | LS Mean (SE) | 0.2 (0.12) | 0.6 (0.20) |
| | | 95% CI | -0.1, 0.4 | 0.2, 1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (0.23) | |
| | | 95% CI | -0.9, 0.0 | |
| | | p-value | 0.0724 | |
| | | Corrected Hedges g (95% CI) [2] | -0.37 (-0.79, 0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 2.4 (1.35) | 2.7 (1.07) |
| | | Median | 3.0 | 3.0 |
| | | Q1, Q3 | 2.0, 4.0 | 2.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | 0.1 (1.79) | 0.6 (1.41) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 4 | -4, 3 |
| | | LS Mean (SE) | 0.2 (0.15) | 0.3 (0.25) |
| | | 95% CI | -0.2, 0.5 | -0.2, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.29) | |
| | | 95% CI | -0.7, 0.5 | |
| | | p-value | 0.7298 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.56, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 2.4 (1.47) | 2.4 (1.40) |
| | | Median | 3.0 | 2.0 |
| | | Q1, Q3 | 1.0, 4.0 | 2.0, 4.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -0.1 (1.73) | 0.4 (1.81) |
| | | Median | 0.0 | 1.0 |
| | | Q1, Q3 | -1.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -4, 2 | -3, 3 |
| | | LS Mean (SE) | 0.0 (0.29) | 0.1 (0.55) |
| | | 95% CI | -0.6, 0.6 | -1.0, 1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.63) | |
| | | 95% CI | -1.4, 1.2 | |
| | | p-value | 0.8579 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.91, 0.76) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 2.3 (1.60) | 2.0 (0.82) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 2.0, 4.0 | 1.5, 2.5 |
| | | Min, Max | 0, 4 | 1, 3 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -0.5 (2.11) | 0.0 (0.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -2.0, 1.0 | -0.5, 0.5 |
| | | Min, Max | -4, 2 | -1, 1 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 7 | 1 |
| | | Mean (StdDev) | 2.1 (1.46) | 3.0 (NA) |
| | | Median | 2.0 | 3.0 |
| | | Q1, Q3 | 1.0, 4.0 | 3.0, 3.0 |
| | | Min, Max | 0, 4 | 3, 3 |
| | Change from BL | n | 7 | 1 |
| | | Mean (StdDev) | -0.4 (2.07) | 0.0 (NA) |
| | | Median | -1.0 | 0.0 |
| | | Q1, Q3 | -2.0, 2.0 | 0.0, 0.0 |
| | | Min, Max | -3, 2 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 2.0 (2.00) | |
| | | Median | 2.0 | |
| | | Q1, Q3 | 0.0, 4.0 | |
| | | Min, Max | 0, 4 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | -1.4 (1.95) | |
| | | Median | -2.0 | |
| | | Q1, Q3 | -2.0, 0.0 | |
| | | Min, Max | -4, 1 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -2.0 (NA) | |
| | | Median | -2.0 | |
| | | Q1, Q3 | -2.0, -2.0 | |
| | | Min, Max | -2, -2 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 125 | 87 |
| | | Mean (StdDev) | 2.1 (1.23) | 1.7 (1.19) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 125 | 86 |
| | | Mean (StdDev) | -0.2 (1.64) | -0.4 (1.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -4, 4 |
| | | LS Mean (SE) | -0.2 (0.11) | -0.5 (0.13) |
| | | 95% CI | -0.4, 0.0 | -0.7, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (0.17) | |
| | | 95% CI | -0.1, 0.6 | |
| | | p-value | 0.1364 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (-0.07, 0.48) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 75 | 55 |
| | | Mean (StdDev) | 2.1 (1.21) | 1.7 (1.12) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 75 | 54 |
| | | Mean (StdDev) | -0.1 (1.71) | -0.5 (1.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -4, 3 |
| | | LS Mean (SE) | -0.2 (0.12) | -0.5 (0.15) |
| | | 95% CI | -0.4, 0.1 | -0.8, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (0.19) | |
| | | 95% CI | 0.0, 0.7 | |
| | | p-value | 0.0713 | |
| | | Corrected Hedges g (95% CI) [2] | 0.32 (-0.03, 0.67) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 78 | 54 |
| | | Mean (StdDev) | 2.2 (1.17) | 1.7 (1.04) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 2.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 78 | 53 |
| | | Mean (StdDev) | -0.1 (1.62) | -0.4 (1.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 4 | -4, 3 |
| | | LS Mean (SE) | -0.1 (0.12) | -0.5 (0.15) |
| | | 95% CI | -0.3, 0.1 | -0.8, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (0.19) | |
| | | 95% CI | 0.0, 0.7 | |
| | | p-value | 0.0573 | |
| | | Corrected Hedges g (95% CI) [2] | 0.34 (-0.01, 0.69) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 88 | 59 |
| | | Mean (StdDev) | 2.1 (1.20) | 1.7 (1.08) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 1.0, 3.0 | 1.0, 2.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 88 | 58 |
| | | Mean (StdDev) | -0.3 (1.43) | -0.5 (1.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 0.0 |
| | | Min, Max | -4, 3 | -4, 3 |
| | | LS Mean (SE) | -0.3 (0.12) | -0.5 (0.14) |
| | | 95% CI | -0.5, 0.0 | -0.8, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (0.19) | |
| | | 95% CI | -0.1, 0.6 | |
| | | p-value | 0.1670 | |
| | | Corrected Hedges g (95% CI) [2] | 0.23 (-0.10, 0.57) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 77 | 49 |
| | | Mean (StdDev) | 2.3 (1.14) | 2.1 (1.10) |
| | | Median | 2.0 | 2.0 |
| | | Q1, Q3 | 2.0, 3.0 | 1.0, 3.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 77 | 48 |
| | | Mean (StdDev) | 0.1 (1.44) | -0.1 (1.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -1.0, 1.0 | -1.0, 1.0 |
| | | Min, Max | -4, 4 | -2, 3 |
| | | LS Mean (SE) | 0.0 (0.12) | -0.1 (0.15) |
| | | 95% CI | -0.2, 0.3 | -0.4, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (0.19) | |
| | | 95% CI | -0.2, 0.5 | |
| | | p-value | 0.3918 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.20, 0.52) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.0 (0.05) | 0.0 (0.08) |
| | | 95% CI | -0.1, 0.1 | -0.1, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.9571 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.23, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 226 | 122 |
| | | Mean (StdDev) | 0.3 (0.61) | 0.2 (0.47) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 2 |
| Cycle 3 Day 1 | Actual | n | 198 | 109 |
| | | Mean (StdDev) | 0.3 (0.67) | 0.3 (0.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 197 | 107 |
| | | Mean (StdDev) | 0.1 (0.58) | 0.1 (0.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -2, 3 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.1 (0.07) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.08) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.6910 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.28, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 164 | 98 |
| | | Mean (StdDev) | 0.3 (0.54) | 0.5 (0.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 163 | 97 |
| | | Mean (StdDev) | 0.0 (0.72) | 0.3 (0.86) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -3, 3 | -2, 4 |
| | | LS Mean (SE) | 0.0 (0.05) | 0.3 (0.07) |
| | | 95% CI | -0.1, 0.1 | 0.2, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (0.09) | |
| | | 95% CI | -0.4, -0.1 | |
| | | p-value | 0.0041 | |
| | | Corrected Hedges g (95% CI) [2] | -0.37 (-0.62, -0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 147 | 85 |
| | | Mean (StdDev) | 0.3 (0.65) | 0.3 (0.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 146 | 84 |
| | | Mean (StdDev) | 0.1 (0.73) | 0.1 (0.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -4, 3 | -2, 2 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.1 (0.07) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.09) | |
| | | 95% CI | -0.2, 0.1 | |
| | | p-value | 0.4753 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.37, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 130 | 67 |
| | | Mean (StdDev) | 0.4 (0.74) | 0.3 (0.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 129 | 66 |
| | | Mean (StdDev) | 0.1 (0.90) | 0.2 (0.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -3, 4 | -1, 3 |
| | | LS Mean (SE) | 0.2 (0.06) | 0.2 (0.09) |
| | | 95% CI | 0.1, 0.3 | 0.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.11) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.7535 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.25, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 49 |
| | | Mean (StdDev) | 0.3 (0.65) | 0.2 (0.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 3 | 0, 3 |
| | Change from BL | n | 119 | 48 |
| | | Mean (StdDev) | 0.1 (0.67) | 0.1 (0.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.1 (0.08) |
| | | 95% CI | 0.0, 0.2 | -0.1, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.09) | |
| | | 95% CI | -0.2, 0.2 | |
| | | p-value | 0.8857 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.36, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 0.3 (0.68) | 0.4 (0.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 4 |
| | Change from BL | n | 108 | 47 |
| | | Mean (StdDev) | 0.1 (0.89) | 0.2 (0.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -4, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.06) | 0.2 (0.09) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.11) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.3436 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.51, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 0.2 (0.59) | 0.3 (0.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 4 | 0, 2 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 0.0 (0.56) | 0.1 (0.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.05) | 0.2 (0.08) |
| | | 95% CI | 0.0, 0.2 | 0.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.10) | |
| | | 95% CI | -0.3, 0.1 | |
| | | p-value | 0.4062 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.53, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 82 | 32 |
| | | Mean (StdDev) | 0.2 (0.61) | 0.3 (0.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 82 | 32 |
| | | Mean (StdDev) | 0.0 (0.67) | 0.2 (0.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 2 | -1, 2 |
| | | LS Mean (SE) | 0.0 (0.05) | 0.3 (0.08) |
| | | 95% CI | -0.1, 0.1 | 0.1, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.09) | |
| | | 95% CI | -0.4, -0.1 | |
| | | p-value | 0.0099 | |
| | | Corrected Hedges g (95% CI) [2] | -0.53 (-0.94, -0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 0.3 (0.69) | 0.6 (0.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | 0.0 (0.90) | 0.4 (0.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -1, 2 |
| | | LS Mean (SE) | 0.1 (0.07) | 0.5 (0.12) |
| | | 95% CI | 0.0, 0.3 | 0.2, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (0.14) | |
| | | 95% CI | -0.6, -0.1 | |
| | | p-value | 0.0194 | |
| | | Corrected Hedges g (95% CI) [2] | -0.57 (-1.05, -0.08) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 0.1 (0.28) | 0.3 (0.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 1 | 0, 1 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -0.2 (0.69) | 0.3 (0.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 1 | 0, 1 |
| | | LS Mean (SE) | 0.0 (0.07) | 0.2 (0.13) |
| | | 95% CI | -0.1, 0.2 | 0.0, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (0.15) | |
| | | 95% CI | -0.5, 0.1 | |
| | | p-value | 0.1680 | |
| | | Corrected Hedges g (95% CI) [2] | -0.58 (-1.43, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.5 (1.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | 0, 0 | 0, 2 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -0.3 (0.75) | 0.5 (1.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 1.0 |
| | | Min, Max | -2, 0 | 0, 2 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 7 | 1 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 7 | 1 |
| | | Mean (StdDev) | -0.3 (0.76) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -2, 0 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 0.0 (0.00) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | -0.4 (0.89) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | -2, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 124 | 88 |
| | | Mean (StdDev) | 0.6 (0.95) | 0.6 (0.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 124 | 87 |
| | | Mean (StdDev) | 0.3 (0.91) | 0.4 (0.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -2, 4 |
| | | LS Mean (SE) | 0.3 (0.07) | 0.4 (0.09) |
| | | 95% CI | 0.2, 0.5 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.11) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.5415 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.36, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 75 | 55 |
| | | Mean (StdDev) | 0.6 (0.89) | 0.5 (0.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 75 | 54 |
| | | Mean (StdDev) | 0.3 (0.92) | 0.4 (0.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -1, 3 |
| | | LS Mean (SE) | 0.3 (0.08) | 0.4 (0.10) |
| | | 95% CI | 0.2, 0.5 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.13) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.8907 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.37, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 78 | 54 |
| | | Mean (StdDev) | 0.6 (0.94) | 0.6 (0.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 4 |
| | Change from BL | n | 78 | 53 |
| | | Mean (StdDev) | 0.3 (0.86) | 0.5 (0.99) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 3 | -2, 4 |
| | | LS Mean (SE) | 0.3 (0.08) | 0.4 (0.10) |
| | | 95% CI | 0.2, 0.5 | 0.2, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.12) | |
| | | 95% CI | -0.3, 0.2 | |
| | | p-value | 0.5326 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.46, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 88 | 59 |
| | | Mean (StdDev) | 0.6 (1.10) | 0.4 (0.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 4 | 0, 3 |
| | Change from BL | n | 88 | 58 |
| | | Mean (StdDev) | 0.4 (0.97) | 0.2 (0.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | -2, 4 | -1, 2 |
| | | LS Mean (SE) | 0.4 (0.09) | 0.3 (0.11) |
| | | 95% CI | 0.2, 0.6 | 0.0, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (0.14) | |
| | | 95% CI | -0.2, 0.4 | |
| | | p-value | 0.4783 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.21, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 78 | 49 |
| | | Mean (StdDev) | 0.5 (0.83) | 0.4 (0.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 |
| | | Min, Max | 0, 3 | 0, 2 |
| | Change from BL | n | 78 | 48 |
| | | Mean (StdDev) | 0.3 (0.81) | 0.2 (0.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 1.0 | 0.0, 0.5 |
| | | Min, Max | -2, 3 | -2, 2 |
| | | LS Mean (SE) | 0.3 (0.08) | 0.3 (0.10) |
| | | 95% CI | 0.2, 0.5 | 0.1, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (0.12) | |
| | | 95% CI | -0.2, 0.3 | |
| | | p-value | 0.7873 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.31, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.2 (0.03) | 0.3 (0.05) |
| | | 95% CI | 0.1, 0.2 | 0.2, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (0.06) | |
| | | 95% CI | -0.2, 0.0 | |
| | | p-value | 0.1308 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.40, 0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 243 |
| | | Mean (StdDev) | 71.5 (18.86) | 70.2 (18.66) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 58.3, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 |
| Cycle 3 Day 1 | Actual | n | 427 | 229 |
| | | Mean (StdDev) | 72.3 (18.66) | 73.9 (19.18) |
| | | Median | 75.0 | 83.3 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 422 | 228 |
| | | Mean (StdDev) | 0.2 (18.07) | 3.3 (16.91) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -50, 50 |
| | | LS Mean (SE) | 0.4 (0.83) | 2.6 (1.14) |
| | | 95% CI | -1.2, 2.0 | 0.3, 4.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.2 (1.41) | |
| | | 95% CI | -4.9, 0.6 | |
| | | p-value | 0.1221 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.29, 0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 359 | 187 |
| | | Mean (StdDev) | 73.5 (18.50) | 74.6 (17.69) |
| | | Median | 75.0 | 83.3 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 25, 100 |
| | Change from BL | n | 354 | 186 |
| | | Mean (StdDev) | 1.5 (18.10) | 2.6 (16.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 16.7 |
| | | Min, Max | -50, 67 | -50, 50 |
| | | LS Mean (SE) | 1.0 (0.82) | 2.4 (1.13) |
| | | 95% CI | -0.6, 2.6 | 0.2, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.4 (1.39) | |
| | | 95% CI | -4.1, 1.4 | |
| | | p-value | 0.3243 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.27, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 322 | 161 |
| | | Mean (StdDev) | 74.7 (17.60) | 76.4 (16.01) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 8, 100 | 17, 100 |
| | Change from BL | n | 318 | 160 |
| | | Mean (StdDev) | 2.7 (17.84) | 4.2 (16.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 16.7 |
| | | Min, Max | -67, 42 | -42, 50 |
| | | LS Mean (SE) | 2.1 (0.81) | 3.6 (1.13) |
| | | 95% CI | 0.5, 3.7 | 1.4, 5.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.5 (1.39) | |
| | | 95% CI | -4.2, 1.2 | |
| | | p-value | 0.2862 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.29, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 126 |
| | | Mean (StdDev) | 75.1 (17.91) | 72.2 (19.01) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 58.3, 83.3 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 285 | 125 |
| | | Mean (StdDev) | 2.6 (16.88) | 0.5 (17.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 8.3 |
| | | Min, Max | -75, 50 | -67, 50 |
| | | LS Mean (SE) | 2.3 (0.85) | 0.1 (1.25) |
| | | 95% CI | 0.6, 4.0 | -2.3, 2.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.1 (1.52) | |
| | | 95% CI | -0.8, 5.1 | |
| | | p-value | 0.1582 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.06, 0.36) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 256 | 102 |
| | | Mean (StdDev) | 77.5 (16.50) | 74.8 (18.26) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 17, 100 |
| | Change from BL | n | 253 | 101 |
| | | Mean (StdDev) | 4.2 (16.91) | 2.1 (18.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 16.7 |
| | | Min, Max | -50, 42 | -50, 50 |
| | | LS Mean (SE) | 4.0 (0.86) | 1.4 (1.31) |
| | | 95% CI | 2.4, 5.7 | -1.2, 3.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.7 (1.57) | |
| | | 95% CI | -0.4, 5.8 | |
| | | p-value | 0.0873 | |
| | | Corrected Hedges g (95% CI) [2] | 0.20 (-0.03, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 236 | 96 |
| | | Mean (StdDev) | 76.9 (17.85) | 75.8 (19.20) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 87.5 | 66.7, 91.7 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 234 | 96 |
| | | Mean (StdDev) | 4.0 (18.55) | 3.6 (20.11) |
| | | Median | 0.0 | 4.2 |
| | | Q1, Q3 | 0.0, 16.7 | -8.3, 16.7 |
| | | Min, Max | -67, 58 | -67, 50 |
| | | LS Mean (SE) | 3.7 (0.92) | 2.9 (1.40) |
| | | 95% CI | 1.9, 5.5 | 0.1, 5.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.8 (1.67) | |
| | | 95% CI | -2.5, 4.1 | |
| | | p-value | 0.6332 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.18, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 212 | 81 |
| | | Mean (StdDev) | 77.4 (18.21) | 77.0 (16.73) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 83.3 |
| | | Min, Max | 17, 100 | 25, 100 |
| | Change from BL | n | 209 | 81 |
| | | Mean (StdDev) | 4.2 (18.04) | 3.1 (18.09) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -8.3, 16.7 |
| | | Min, Max | -58, 67 | -50, 50 |
| | | LS Mean (SE) | 3.7 (0.94) | 2.9 (1.46) |
| | | 95% CI | 1.9, 5.6 | 0.0, 5.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.9 (1.74) | |
| | | 95% CI | -2.6, 4.3 | |
| | | p-value | 0.6227 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.19, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 76.9 (17.99) | 73.6 (16.49) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 17, 100 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | 2.3 (21.03) | 1.5 (20.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 16.7 |
| | | Min, Max | -75, 67 | -50, 50 |
| | | LS Mean (SE) | 2.9 (1.03) | 0.1 (1.58) |
| | | 95% CI | 0.9, 5.0 | -3.0, 3.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.8 (1.89) | |
| | | 95% CI | -0.9, 6.5 | |
| | | p-value | 0.1371 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (-0.07, 0.48) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 144 | 56 |
| | | Mean (StdDev) | 76.9 (19.03) | 75.0 (18.67) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 83.3 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 143 | 56 |
| | | Mean (StdDev) | 2.0 (17.70) | 3.6 (20.77) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 16.7 |
| | | Min, Max | -75, 33 | -50, 50 |
| | | LS Mean (SE) | 2.0 (1.17) | 3.0 (1.82) |
| | | 95% CI | -0.3, 4.3 | -0.6, 6.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.0 (2.17) | |
| | | 95% CI | -5.2, 3.3 | |
| | | p-value | 0.6584 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.38, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 80.2 (16.92) | 75.3 (16.86) |
| | | Median | 83.3 | 79.2 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 83.3 |
| | | Min, Max | 17, 100 | 42, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 4.4 (16.18) | 4.9 (16.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -4.2, 16.7 | 0.0, 16.7 |
| | | Min, Max | -33, 33 | -33, 50 |
| | | LS Mean (SE) | 4.9 (1.20) | 3.4 (1.91) |
| | | 95% CI | 2.5, 7.2 | -0.4, 7.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.5 (2.26) | |
| | | 95% CI | -3.0, 5.9 | |
| | | p-value | 0.5120 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.27, 0.54) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 80.9 (16.11) | 80.4 (15.85) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 91.7 |
| | | Min, Max | 33, 100 | 50, 100 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | 2.3 (18.36) | 9.8 (21.09) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | -8.3, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 42 | -17, 67 |
| | | LS Mean (SE) | 3.9 (1.73) | 9.4 (2.72) |
| | | 95% CI | 0.5, 7.4 | 4.0, 14.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -5.5 (3.24) | |
| | | 95% CI | -12.0, 0.9 | |
| | | p-value | 0.0935 | |
| | | Corrected Hedges g (95% CI) [2] | -0.46 (-1.02, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 77.2 (19.56) | 83.3 (9.96) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 91.7 | 79.2, 87.5 |
| | | Min, Max | 33, 100 | 67, 100 |
| | Change from BL | n | 27 | 8 |
| | | Mean (StdDev) | -0.3 (19.13) | 10.4 (18.77) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | -16.7, 16.7 | -4.2, 29.2 |
| | | Min, Max | -33, 33 | -17, 33 |
| | | LS Mean (SE) | 1.3 (2.28) | 8.5 (3.96) |
| | | 95% CI | -3.3, 5.9 | 0.5, 16.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -7.2 (4.56) | |
| | | 95% CI | -16.4, 2.0 | |
| | | p-value | 0.1232 | |
| | | Corrected Hedges g (95% CI) [2] | -0.60 (-1.40, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 81.0 (16.48) | 83.3 (0.00) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 75.0, 91.7 | 83.3, 83.3 |
| | | Min, Max | 42, 100 | 83, 83 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 2.4 (17.43) | 0.0 (11.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -8.3, 8.3 |
| | | Min, Max | -42, 25 | -8, 8 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 80.0 (12.64) | 50.0 (47.14) |
| | | Median | 75.0 | 50.0 |
| | | Q1, Q3 | 75.0, 83.3 | 16.7, 83.3 |
| | | Min, Max | 67, 100 | 17, 83 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 6.7 (23.12) | -33.3 (35.36) |
| | | Median | 0.0 | -33.3 |
| | | Q1, Q3 | 0.0, 25.0 | -58.3, -8.3 |
| | | Min, Max | -25, 33 | -58, -8 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 91.7 (NA) | |
| | | Median | 91.7 | |
| | | Q1, Q3 | 91.7, 91.7 | |
| | | Min, Max | 92, 92 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -8.3 (NA) | |
| | | Median | -8.3 | |
| | | Q1, Q3 | -8.3, -8.3 | |
| | | Min, Max | -8, -8 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 289 | 174 |
| | | Mean (StdDev) | 63.2 (22.41) | 65.1 (21.01) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 8, 100 |
| | Change from BL | n | 285 | 173 |
| | | Mean (StdDev) | -7.5 (23.45) | -5.0 (20.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 8.3 |
| | | Min, Max | -100, 67 | -75, 50 |
| | | LS Mean (SE) | -7.8 (1.12) | -6.0 (1.46) |
| | | 95% CI | -10.0, -5.6 | -8.8, -3.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.8 (1.84) | |
| | | 95% CI | -5.4, 1.8 | |
| | | p-value | 0.3175 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.29, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 149 | 105 |
| | | Mean (StdDev) | 65.1 (21.76) | 62.9 (19.30) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 148 | 104 |
| | | Mean (StdDev) | -6.5 (22.65) | -7.7 (20.34) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -83, 42 |
| | | LS Mean (SE) | -7.3 (1.32) | -8.4 (1.62) |
| | | 95% CI | -9.9, -4.7 | -11.6, -5.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.1 (2.09) | |
| | | 95% CI | -3.0, 5.2 | |
| | | p-value | 0.5898 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.18, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 98 |
| | | Mean (StdDev) | 64.8 (20.43) | 60.9 (19.97) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 166 | 98 |
| | | Mean (StdDev) | -4.9 (22.23) | -9.9 (20.91) |
| | | Median | -4.2 | -8.3 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -100, 83 | -67, 33 |
| | | LS Mean (SE) | -6.4 (1.33) | -9.6 (1.74) |
| | | 95% CI | -9.0, -3.8 | -13.0, -6.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.2 (2.19) | |
| | | 95% CI | -1.1, 7.5 | |
| | | p-value | 0.1439 | |
| | | Corrected Hedges g (95% CI) [2] | 0.19 (-0.06, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 201 | 115 |
| | | Mean (StdDev) | 64.4 (21.39) | 63.3 (18.98) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | -6.0 (22.86) | -6.9 (18.19) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -92, 83 | -50, 33 |
| | | LS Mean (SE) | -6.9 (1.21) | -7.8 (1.60) |
| | | 95% CI | -9.3, -4.5 | -11.0, -4.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.9 (2.00) | |
| | | 95% CI | -3.0, 4.8 | |
| | | p-value | 0.6450 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.18, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 162 | 91 |
| | | Mean (StdDev) | 65.1 (20.27) | 65.6 (19.05) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 160 | 90 |
| | | Mean (StdDev) | -4.9 (21.71) | -5.5 (21.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 8.3 |
| | | Min, Max | -92, 83 | -67, 50 |
| | | LS Mean (SE) | -6.9 (1.33) | -6.5 (1.77) |
| | | 95% CI | -9.5, -4.3 | -9.9, -3.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (2.21) | |
| | | 95% CI | -4.8, 3.9 | |
| | | p-value | 0.8451 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.28, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -0.2 (0.59) | 0.1 (0.86) |
| | | 95% CI | -1.3, 1.0 | -1.6, 1.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (1.04) | |
| | | 95% CI | -2.3, 1.8 | |
| | | p-value | 0.7811 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.18, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 244 |
| | | Mean (StdDev) | 81.0 (16.52) | 78.7 (18.27) |
| | | Median | 86.7 | 80.0 |
| | | Q1, Q3 | 73.3, 93.3 | 66.7, 93.3 |
| | | Min, Max | 13, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 426 | 229 |
| | | Mean (StdDev) | 82.0 (16.46) | 81.4 (16.80) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 73.3, 93.3 | 73.3, 93.3 |
| | | Min, Max | 13, 100 | 33, 100 |
| | Change from BL | n | 423 | 229 |
| | | Mean (StdDev) | 0.1 (13.34) | 2.7 (10.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 6.7 | 0.0, 6.7 |
| | | Min, Max | -67, 53 | -27, 40 |
| | | LS Mean (SE) | 0.4 (0.62) | 1.9 (0.85) |
| | | 95% CI | -0.8, 1.6 | 0.2, 3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.5 (1.05) | |
| | | 95% CI | -3.5, 0.6 | |
| | | p-value | 0.1612 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.28, 0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 187 |
| | | Mean (StdDev) | 83.3 (15.51) | 82.8 (16.78) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 73.3, 93.3 | 73.3, 93.3 |
| | | Min, Max | 20, 100 | 27, 100 |
| | Change from BL | n | 354 | 187 |
| | | Mean (StdDev) | 1.7 (13.56) | 3.4 (12.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 6.7 | 0.0, 13.3 |
| | | Min, Max | -67, 47 | -27, 53 |
| | | LS Mean (SE) | 1.3 (0.65) | 2.8 (0.90) |
| | | 95% CI | 0.0, 2.6 | 1.1, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.5 (1.11) | |
| | | 95% CI | -3.7, 0.7 | |
| | | p-value | 0.1737 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.30, 0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 319 | 160 |
| | | Mean (StdDev) | 84.1 (13.90) | 84.4 (15.44) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 73.3, 93.3 | 80.0, 100.0 |
| | | Min, Max | 40, 100 | 27, 100 |
| | Change from BL | n | 316 | 160 |
| | | Mean (StdDev) | 2.2 (13.03) | 4.3 (12.24) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 6.7 | 0.0, 13.3 |
| | | Min, Max | -40, 47 | -27, 40 |
| | | LS Mean (SE) | 2.1 (0.61) | 3.7 (0.85) |
| | | 95% CI | 0.9, 3.3 | 2.0, 5.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.6 (1.05) | |
| | | 95% CI | -3.7, 0.4 | |
| | | p-value | 0.1209 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.34, 0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 127 |
| | | Mean (StdDev) | 85.8 (14.28) | 83.1 (16.09) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 73.3, 93.3 |
| | | Min, Max | 20, 100 | 20, 100 |
| | Change from BL | n | 285 | 127 |
| | | Mean (StdDev) | 3.5 (13.31) | 4.1 (12.43) |
| | | Median | 0.0 | 6.7 |
| | | Q1, Q3 | 0.0, 13.3 | 0.0, 13.3 |
| | | Min, Max | -33, 53 | -33, 40 |
| | | LS Mean (SE) | 3.3 (0.62) | 3.5 (0.90) |
| | | 95% CI | 2.1, 4.5 | 1.7, 5.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (1.09) | |
| | | 95% CI | -2.3, 2.0 | |
| | | p-value | 0.9034 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.22, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 255 | 102 |
| | | Mean (StdDev) | 86.1 (13.98) | 82.8 (16.45) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 73.3, 93.3 |
| | | Min, Max | 27, 100 | 27, 100 |
| | Change from BL | n | 252 | 102 |
| | | Mean (StdDev) | 3.5 (14.06) | 3.2 (13.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 13.3 | 0.0, 13.3 |
| | | Min, Max | -47, 67 | -40, 40 |
| | | LS Mean (SE) | 3.4 (0.68) | 2.5 (1.03) |
| | | 95% CI | 2.1, 4.7 | 0.5, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.8 (1.23) | |
| | | 95% CI | -1.6, 3.3 | |
| | | p-value | 0.4917 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.15, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 235 | 95 |
| | | Mean (StdDev) | 85.7 (15.08) | 82.1 (18.20) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 73.3, 93.3 |
| | | Min, Max | 20, 100 | 20, 100 |
| | Change from BL | n | 233 | 95 |
| | | Mean (StdDev) | 3.4 (14.51) | 3.8 (12.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 13.3 | 0.0, 13.3 |
| | | Min, Max | -40, 53 | -33, 40 |
| | | LS Mean (SE) | 3.1 (0.65) | 3.1 (0.99) |
| | | 95% CI | 1.8, 4.4 | 1.1, 5.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (1.19) | |
| | | 95% CI | -2.3, 2.4 | |
| | | p-value | 0.9804 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.24, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 86.2 (14.64) | 85.4 (15.73) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 80.0, 100.0 |
| | | Min, Max | 27, 100 | 40, 100 |
| | Change from BL | n | 208 | 82 |
| | | Mean (StdDev) | 3.6 (14.12) | 5.1 (12.80) |
| | | Median | 0.0 | 6.7 |
| | | Q1, Q3 | 0.0, 6.7 | 0.0, 13.3 |
| | | Min, Max | -47, 60 | -40, 40 |
| | | LS Mean (SE) | 3.5 (0.66) | 4.1 (1.01) |
| | | 95% CI | 2.2, 4.8 | 2.2, 6.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.7 (1.21) | |
| | | 95% CI | -3.0, 1.7 | |
| | | p-value | 0.5842 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.33, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 175 | 71 |
| | | Mean (StdDev) | 86.3 (14.58) | 83.1 (16.41) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 73.3, 100.0 |
| | | Min, Max | 27, 100 | 40, 100 |
| | Change from BL | n | 175 | 71 |
| | | Mean (StdDev) | 3.1 (14.99) | 3.8 (11.80) |
| | | Median | 0.0 | 6.7 |
| | | Q1, Q3 | -6.7, 13.3 | 0.0, 13.3 |
| | | Min, Max | -47, 60 | -33, 40 |
| | | LS Mean (SE) | 3.2 (0.75) | 1.9 (1.15) |
| | | 95% CI | 1.7, 4.6 | -0.4, 4.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (1.37) | |
| | | 95% CI | -1.4, 4.0 | |
| | | p-value | 0.3569 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.15, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 85.6 (14.90) | 81.3 (19.16) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 73.3, 100.0 |
| | | Min, Max | 33, 100 | 33, 100 |
| | Change from BL | n | 146 | 56 |
| | | Mean (StdDev) | 2.4 (15.31) | 2.8 (14.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 13.3 | -3.3, 13.3 |
| | | Min, Max | -47, 53 | -47, 47 |
| | | LS Mean (SE) | 3.0 (0.84) | 1.8 (1.31) |
| | | 95% CI | 1.4, 4.7 | -0.8, 4.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (1.56) | |
| | | 95% CI | -1.9, 4.3 | |
| | | p-value | 0.4389 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.19, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 86.0 (15.36) | 83.5 (17.26) |
| | | Median | 93.3 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 76.7, 100.0 |
| | | Min, Max | 27, 100 | 40, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 2.9 (15.42) | 4.3 (11.92) |
| | | Median | 0.0 | 6.7 |
| | | Q1, Q3 | -6.7, 6.7 | -3.3, 6.7 |
| | | Min, Max | -40, 53 | -13, 47 |
| | | LS Mean (SE) | 3.4 (1.01) | 4.0 (1.64) |
| | | 95% CI | 1.4, 5.4 | 0.8, 7.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (1.93) | |
| | | 95% CI | -4.4, 3.3 | |
| | | p-value | 0.7733 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.46, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 46 | 16 |
| | | Mean (StdDev) | 89.1 (12.36) | 84.6 (17.68) |
| | | Median | 93.3 | 93.3 |
| | | Q1, Q3 | 86.7, 100.0 | 73.3, 100.0 |
| | | Min, Max | 53, 100 | 40, 100 |
| | Change from BL | n | 46 | 16 |
| | | Mean (StdDev) | 2.3 (14.48) | 7.9 (14.45) |
| | | Median | 0.0 | 6.7 |
| | | Q1, Q3 | 0.0, 6.7 | 0.0, 16.7 |
| | | Min, Max | -33, 47 | -13, 40 |
| | | LS Mean (SE) | 2.8 (1.19) | 5.3 (1.93) |
| | | 95% CI | 0.4, 5.2 | 1.5, 9.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.5 (2.30) | |
| | | 95% CI | -7.1, 2.0 | |
| | | p-value | 0.2730 | |
| | | Corrected Hedges g (95% CI) [2] | -0.31 (-0.88, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 85.4 (17.64) | 87.5 (19.98) |
| | | Median | 93.3 | 93.3 |
| | | Q1, Q3 | 80.0, 100.0 | 86.7, 100.0 |
| | | Min, Max | 20, 100 | 40, 100 |
| | Change from BL | n | 27 | 8 |
| | | Mean (StdDev) | -1.0 (17.51) | 4.2 (11.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 6.7 | -3.3, 10.0 |
| | | Min, Max | -60, 40 | -7, 27 |
| | | LS Mean (SE) | -0.2 (2.87) | 3.0 (4.98) |
| | | 95% CI | -6.0, 5.6 | -7.1, 13.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.2 (5.71) | |
| | | 95% CI | -14.8, 8.4 | |
| | | p-value | 0.5802 | |
| | | Corrected Hedges g (95% CI) [2] | -0.21 (-1.00, 0.58) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 90.7 (9.08) | 90.0 (14.14) |
| | | Median | 93.3 | 90.0 |
| | | Q1, Q3 | 83.3, 100.0 | 80.0, 100.0 |
| | | Min, Max | 73, 100 | 80, 100 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.2 (8.72) | -3.3 (4.71) |
| | | Median | 0.0 | -3.3 |
| | | Q1, Q3 | -6.7, 3.3 | -6.7, 0.0 |
| | | Min, Max | -13, 20 | -7, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 88.0 (14.45) | 80.0 (28.28) |
| | | Median | 93.3 | 80.0 |
| | | Q1, Q3 | 80.0, 100.0 | 60.0, 100.0 |
| | | Min, Max | 67, 100 | 60, 100 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -5.3 (17.26) | -13.3 (18.86) |
| | | Median | 0.0 | -13.3 |
| | | Q1, Q3 | -6.7, 0.0 | -26.7, 0.0 |
| | | Min, Max | -33, 13 | -27, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 86.7 (NA) | |
| | | Median | 86.7 | |
| | | Q1, Q3 | 86.7, 86.7 | |
| | | Min, Max | 87, 87 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -13.3 (NA) | |
| | | Median | -13.3 | |
| | | Q1, Q3 | -13.3, -13.3 | |
| | | Min, Max | -13, -13 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 286 | 173 |
| | | Mean (StdDev) | 79.5 (17.91) | 80.8 (19.80) |
| | | Median | 80.0 | 86.7 |
| | | Q1, Q3 | 66.7, 93.3 | 73.3, 100.0 |
| | | Min, Max | 20, 100 | 7, 100 |
| | Change from BL | n | 283 | 173 |
| | | Mean (StdDev) | -1.3 (16.01) | 1.5 (16.15) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -13.3, 6.7 | 0.0, 6.7 |
| | | Min, Max | -60, 36 | -80, 47 |
| | | LS Mean (SE) | -0.7 (0.82) | 0.8 (1.07) |
| | | 95% CI | -2.3, 0.9 | -1.3, 2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.5 (1.34) | |
| | | 95% CI | -4.2, 1.1 | |
| | | p-value | 0.2499 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.30, 0.08) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 151 | 104 |
| | | Mean (StdDev) | 78.0 (21.24) | 78.7 (20.78) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 66.7, 93.3 | 66.7, 93.3 |
| | | Min, Max | 7, 100 | 13, 100 |
| | Change from BL | n | 150 | 104 |
| | | Mean (StdDev) | -3.0 (19.39) | -1.3 (18.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -13.3, 6.7 | -6.7, 6.7 |
| | | Min, Max | -80, 33 | -73, 33 |
| | | LS Mean (SE) | -2.6 (1.30) | -2.5 (1.60) |
| | | 95% CI | -5.2, -0.1 | -5.6, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (2.06) | |
| | | 95% CI | -4.2, 3.9 | |
| | | p-value | 0.9490 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.26, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 97 |
| | | Mean (StdDev) | 76.5 (18.90) | 75.9 (22.80) |
| | | Median | 80.0 | 86.7 |
| | | Q1, Q3 | 66.7, 93.3 | 66.7, 93.3 |
| | | Min, Max | 13, 100 | 13, 100 |
| | Change from BL | n | 167 | 97 |
| | | Mean (StdDev) | -2.3 (18.37) | -3.8 (19.15) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -13.3, 6.7 | -13.3, 6.7 |
| | | Min, Max | -53, 40 | -67, 27 |
| | | LS Mean (SE) | -2.7 (1.14) | -3.9 (1.51) |
| | | 95% CI | -4.9, -0.4 | -6.9, -1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (1.89) | |
| | | 95% CI | -2.5, 5.0 | |
| | | p-value | 0.5101 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.17, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 202 | 115 |
| | | Mean (StdDev) | 77.0 (19.40) | 77.8 (18.18) |
| | | Median | 80.0 | 80.0 |
| | | Q1, Q3 | 66.7, 93.3 | 66.7, 93.3 |
| | | Min, Max | 7, 100 | 27, 100 |
| | Change from BL | n | 199 | 115 |
| | | Mean (StdDev) | -2.6 (18.22) | -3.0 (15.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -13.3, 6.7 | -6.7, 6.7 |
| | | Min, Max | -73, 40 | -47, 27 |
| | | LS Mean (SE) | -2.4 (1.02) | -2.9 (1.36) |
| | | 95% CI | -4.4, -0.4 | -5.6, -0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.5 (1.70) | |
| | | 95% CI | -2.8, 3.9 | |
| | | p-value | 0.7524 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.19, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 163 | 91 |
| | | Mean (StdDev) | 78.1 (19.35) | 78.2 (19.84) |
| | | Median | 80.0 | 80.0 |
| | | Q1, Q3 | 66.7, 93.3 | 66.7, 93.3 |
| | | Min, Max | 0, 100 | 7, 100 |
| | Change from BL | n | 161 | 91 |
| | | Mean (StdDev) | -1.8 (16.72) | -2.2 (16.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 6.7 | -6.7, 6.7 |
| | | Min, Max | -73, 40 | -73, 40 |
| | | LS Mean (SE) | -2.1 (1.14) | -3.6 (1.53) |
| | | 95% CI | -4.3, 0.2 | -6.6, -0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.6 (1.90) | |
| | | 95% CI | -2.2, 5.3 | |
| | | p-value | 0.4024 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.15, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 1.1 (0.51) | 1.5 (0.75) |
| | | 95% CI | 0.1, 2.1 | 0.0, 3.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (0.91) | |
| | | 95% CI | -2.2, 1.4 | |
| | | p-value | 0.6669 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.19, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 244 |
| | | Mean (StdDev) | 80.2 (22.80) | 77.3 (24.35) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 427 | 229 |
| | | Mean (StdDev) | 81.0 (23.88) | 81.6 (23.51) |
| | | Median | 83.3 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 423 | 229 |
| | | Mean (StdDev) | 0.2 (21.16) | 4.1 (21.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -100, 67 |
| | | LS Mean (SE) | 0.5 (0.98) | 3.0 (1.34) |
| | | 95% CI | -1.4, 2.4 | 0.4, 5.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.5 (1.66) | |
| | | 95% CI | -5.8, 0.7 | |
| | | p-value | 0.1267 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.29, 0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 188 |
| | | Mean (StdDev) | 82.3 (22.89) | 82.9 (21.90) |
| | | Median | 100.0 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 354 | 188 |
| | | Mean (StdDev) | 1.9 (23.79) | 4.9 (20.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 100 | -100, 50 |
| | | LS Mean (SE) | 1.5 (1.03) | 3.5 (1.42) |
| | | 95% CI | -0.5, 3.5 | 0.7, 6.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.0 (1.76) | |
| | | 95% CI | -5.4, 1.5 | |
| | | p-value | 0.2586 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.28, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 319 | 160 |
| | | Mean (StdDev) | 84.6 (20.24) | 84.4 (20.87) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 316 | 160 |
| | | Mean (StdDev) | 3.6 (21.19) | 6.6 (21.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 3.5 (0.99) | 4.6 (1.39) |
| | | 95% CI | 1.5, 5.4 | 1.8, 7.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.1 (1.71) | |
| | | 95% CI | -4.4, 2.3 | |
| | | p-value | 0.5297 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.25, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 128 |
| | | Mean (StdDev) | 85.1 (21.37) | 80.9 (24.67) |
| | | Median | 100.0 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 285 | 128 |
| | | Mean (StdDev) | 3.6 (22.13) | 4.2 (22.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 67 | -67, 67 |
| | | LS Mean (SE) | 3.7 (1.07) | 2.7 (1.57) |
| | | 95% CI | 1.6, 5.8 | -0.4, 5.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.0 (1.91) | |
| | | 95% CI | -2.7, 4.8 | |
| | | p-value | 0.5887 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.15, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 255 | 102 |
| | | Mean (StdDev) | 87.8 (19.28) | 81.5 (24.25) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 252 | 102 |
| | | Mean (StdDev) | 5.6 (21.36) | 2.1 (23.41) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 6.0 (1.00) | 1.4 (1.51) |
| | | 95% CI | 4.1, 8.0 | -1.5, 4.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.6 (1.81) | |
| | | 95% CI | 1.1, 8.2 | |
| | | p-value | 0.0111 | |
| | | Corrected Hedges g (95% CI) [2] | 0.29 (0.06, 0.52) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 235 | 96 |
| | | Mean (StdDev) | 86.3 (20.40) | 84.0 (23.44) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 233 | 96 |
| | | Mean (StdDev) | 4.6 (21.73) | 5.7 (22.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -50, 67 |
| | | LS Mean (SE) | 4.4 (1.08) | 4.5 (1.65) |
| | | 95% CI | 2.3, 6.5 | 1.3, 7.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (1.97) | |
| | | 95% CI | -4.0, 3.8 | |
| | | p-value | 0.9528 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.24, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 87.0 (19.33) | 86.4 (20.97) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 208 | 82 |
| | | Mean (StdDev) | 4.2 (21.59) | 6.5 (20.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -33, 67 |
| | | LS Mean (SE) | 4.7 (1.04) | 5.3 (1.60) |
| | | 95% CI | 2.6, 6.7 | 2.2, 8.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (1.90) | |
| | | 95% CI | -4.4, 3.1 | |
| | | p-value | 0.7382 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.30, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 86.9 (20.69) | 84.3 (21.06) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | 3.2 (23.82) | 6.6 (23.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -83, 67 | -67, 83 |
| | | LS Mean (SE) | 4.5 (1.20) | 3.2 (1.85) |
| | | 95% CI | 2.2, 6.9 | -0.5, 6.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (2.21) | |
| | | 95% CI | -3.0, 5.7 | |
| | | p-value | 0.5358 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.19, 0.36) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 85.5 (21.75) | 78.3 (27.69) |
| | | Median | 100.0 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 146 | 56 |
| | | Mean (StdDev) | 1.6 (24.71) | 2.4 (27.97) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -83, 100 | -83, 67 |
| | | LS Mean (SE) | 3.5 (1.45) | -0.5 (2.29) |
| | | 95% CI | 0.7, 6.4 | -5.0, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.0 (2.72) | |
| | | 95% CI | -1.4, 9.3 | |
| | | p-value | 0.1446 | |
| | | Corrected Hedges g (95% CI) [2] | 0.23 (-0.08, 0.54) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 87.1 (20.49) | 82.3 (21.97) |
| | | Median | 100.0 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 2.7 (19.88) | 6.3 (21.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 50 | -33, 67 |
| | | LS Mean (SE) | 5.6 (1.66) | 4.0 (2.68) |
| | | 95% CI | 2.3, 8.8 | -1.3, 9.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.6 (3.17) | |
| | | 95% CI | -4.7, 7.9 | |
| | | p-value | 0.6157 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.30, 0.51) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 86.5 (21.32) | 86.3 (16.91) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 50, 100 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | -3.5 (19.33) | 10.8 (22.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -67, 33 | -33, 67 |
| | | LS Mean (SE) | 0.7 (2.24) | 8.0 (3.46) |
| | | 95% CI | -3.8, 5.1 | 1.1, 14.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -7.3 (4.19) | |
| | | 95% CI | -15.6, 1.1 | |
| | | p-value | 0.0858 | |
| | | Corrected Hedges g (95% CI) [2] | -0.48 (-1.04, 0.08) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 81.5 (23.72) | 91.7 (12.60) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 83.3, 100.0 |
| | | Min, Max | 17, 100 | 67, 100 |
| | Change from BL | n | 27 | 8 |
| | | Mean (StdDev) | -8.0 (16.90) | 8.3 (15.43) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -50, 17 | -17, 33 |
| | | LS Mean (SE) | -2.9 (2.45) | 8.1 (4.08) |
| | | 95% CI | -7.9, 2.0 | -0.1, 16.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -11.0 (4.71) | |
| | | 95% CI | -20.6, -1.5 | |
| | | p-value | 0.0245 | |
| | | Corrected Hedges g (95% CI) [2] | -0.86 (-1.68, -0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 85.7 (23.44) | 75.0 (35.36) |
| | | Median | 100.0 | 75.0 |
| | | Q1, Q3 | 83.3, 100.0 | 50.0, 100.0 |
| | | Min, Max | 17, 100 | 50, 100 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | -8.3 (14.25) | -25.0 (35.36) |
| | | Median | 0.0 | -25.0 |
| | | Q1, Q3 | -16.7, 0.0 | -50.0, 0.0 |
| | | Min, Max | -33, 17 | -50, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 90.0 (14.91) | 58.3 (58.93) |
| | | Median | 100.0 | 58.3 |
| | | Q1, Q3 | 83.3, 100.0 | 16.7, 100.0 |
| | | Min, Max | 67, 100 | 17, 100 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -3.3 (18.26) | -41.7 (58.93) |
| | | Median | 0.0 | -41.7 |
| | | Q1, Q3 | 0.0, 0.0 | -83.3, 0.0 |
| | | Min, Max | -33, 17 | -83, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 289 | 173 |
| | | Mean (StdDev) | 75.8 (28.79) | 79.2 (25.68) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 286 | 173 |
| | | Mean (StdDev) | -3.8 (28.72) | 1.3 (25.86) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 83 | -100, 67 |
| | | LS Mean (SE) | -3.6 (1.38) | 0.0 (1.79) |
| | | 95% CI | -6.3, -0.9 | -3.5, 3.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.6 (2.26) | |
| | | 95% CI | -8.1, 0.8 | |
| | | p-value | 0.1078 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.34, 0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 151 | 104 |
| | | Mean (StdDev) | 76.7 (26.11) | 74.8 (27.67) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 150 | 104 |
| | | Mean (StdDev) | -4.0 (27.49) | -1.6 (26.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -100, 50 |
| | | LS Mean (SE) | -3.7 (1.76) | -5.0 (2.17) |
| | | 95% CI | -7.2, -0.2 | -9.2, -0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (2.80) | |
| | | 95% CI | -4.2, 6.8 | |
| | | p-value | 0.6522 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.19, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 97 |
| | | Mean (StdDev) | 71.1 (26.86) | 69.6 (29.85) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 167 | 97 |
| | | Mean (StdDev) | -7.1 (26.22) | -8.4 (29.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -33.3, 0.0 |
| | | Min, Max | -100, 83 | -100, 50 |
| | | LS Mean (SE) | -7.4 (1.76) | -9.6 (2.33) |
| | | 95% CI | -10.8, -3.9 | -14.2, -5.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.3 (2.92) | |
| | | 95% CI | -3.5, 8.0 | |
| | | p-value | 0.4365 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.15, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 202 | 115 |
| | | Mean (StdDev) | 72.0 (27.17) | 73.8 (28.36) |
| | | Median | 66.7 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 50.0, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 199 | 115 |
| | | Mean (StdDev) | -7.2 (26.82) | -4.1 (26.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -83, 50 |
| | | LS Mean (SE) | -7.1 (1.63) | -5.6 (2.16) |
| | | 95% CI | -10.3, -3.9 | -9.9, -1.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.4 (2.70) | |
| | | 95% CI | -6.7, 3.9 | |
| | | p-value | 0.5983 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.29, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 163 | 91 |
| | | Mean (StdDev) | 75.1 (25.48) | 73.6 (25.95) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 161 | 91 |
| | | Mean (StdDev) | -4.0 (23.48) | -3.7 (25.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -100, 67 |
| | | LS Mean (SE) | -5.0 (1.72) | -6.5 (2.30) |
| | | 95% CI | -8.4, -1.6 | -11.0, -2.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.5 (2.87) | |
| | | 95% CI | -4.1, 7.2 | |
| | | p-value | 0.5953 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.19, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.5 (0.72) | 1.2 (1.03) |
| | | 95% CI | -0.9, 1.9 | -0.8, 3.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.7 (1.26) | |
| | | 95% CI | -3.2, 1.8 | |
| | | p-value | 0.5720 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.20, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 243 |
| | | Mean (StdDev) | 78.8 (20.03) | 76.3 (20.58) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 91.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 426 | 229 |
| | | Mean (StdDev) | 78.5 (19.84) | 78.6 (20.99) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 421 | 228 |
| | | Mean (StdDev) | -0.1 (17.93) | 2.4 (16.38) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -75, 58 | -42, 67 |
| | | LS Mean (SE) | 0.0 (0.86) | 1.5 (1.18) |
| | | 95% CI | -1.7, 1.7 | -0.8, 3.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.5 (1.46) | |
| | | 95% CI | -4.4, 1.3 | |
| | | p-value | 0.2892 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.25, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 357 | 186 |
| | | Mean (StdDev) | 80.1 (20.08) | 77.9 (20.81) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 91.7 |
| | | Min, Max | 8, 100 | 0, 100 |
| | Change from BL | n | 352 | 185 |
| | | Mean (StdDev) | 1.5 (17.81) | 1.0 (17.86) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -67, 75 | -42, 75 |
| | | LS Mean (SE) | 1.4 (0.85) | 0.2 (1.18) |
| | | 95% CI | -0.3, 3.1 | -2.1, 2.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (1.45) | |
| | | 95% CI | -1.6, 4.1 | |
| | | p-value | 0.4016 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.10, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 321 | 161 |
| | | Mean (StdDev) | 79.0 (19.82) | 78.2 (19.56) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 91.7 |
| | | Min, Max | 8, 100 | 0, 100 |
| | Change from BL | n | 317 | 160 |
| | | Mean (StdDev) | 0.1 (18.49) | 1.7 (17.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -58, 83 | -42, 67 |
| | | LS Mean (SE) | 0.2 (0.87) | 0.2 (1.21) |
| | | 95% CI | -1.5, 1.9 | -2.1, 2.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (1.49) | |
| | | 95% CI | -2.9, 2.9 | |
| | | p-value | 0.9976 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.19, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 125 |
| | | Mean (StdDev) | 79.3 (19.97) | 78.0 (22.51) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 8, 100 | 0, 100 |
| | Change from BL | n | 285 | 124 |
| | | Mean (StdDev) | -0.3 (18.12) | 1.0 (20.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -75, 92 | -50, 67 |
| | | LS Mean (SE) | 0.3 (0.93) | -0.3 (1.36) |
| | | 95% CI | -1.5, 2.1 | -2.9, 2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (1.65) | |
| | | 95% CI | -2.7, 3.8 | |
| | | p-value | 0.7285 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.17, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 256 | 102 |
| | | Mean (StdDev) | 80.6 (19.42) | 80.1 (18.69) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 25, 100 |
| | Change from BL | n | 253 | 101 |
| | | Mean (StdDev) | 0.3 (17.39) | 4.1 (16.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -67, 75 | -33, 67 |
| | | LS Mean (SE) | 0.9 (0.87) | 0.4 (1.31) |
| | | 95% CI | -0.8, 2.6 | -2.2, 3.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.5 (1.57) | |
| | | 95% CI | -2.6, 3.6 | |
| | | p-value | 0.7460 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.19, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 236 | 96 |
| | | Mean (StdDev) | 79.6 (20.03) | 81.9 (18.24) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 234 | 96 |
| | | Mean (StdDev) | 0.0 (18.31) | 5.5 (17.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 16.7 |
| | | Min, Max | -50, 83 | -33, 58 |
| | | LS Mean (SE) | 0.5 (0.93) | 1.8 (1.41) |
| | | 95% CI | -1.3, 2.3 | -1.0, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (1.69) | |
| | | 95% CI | -4.6, 2.0 | |
| | | p-value | 0.4417 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.33, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 212 | 81 |
| | | Mean (StdDev) | 79.6 (21.17) | 81.3 (19.39) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 209 | 81 |
| | | Mean (StdDev) | -0.6 (20.23) | 4.4 (18.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | 0.0, 16.7 |
| | | Min, Max | -67, 92 | -42, 50 |
| | | LS Mean (SE) | -0.3 (0.97) | 1.4 (1.51) |
| | | 95% CI | -2.2, 1.6 | -1.6, 4.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.7 (1.79) | |
| | | 95% CI | -5.2, 1.8 | |
| | | p-value | 0.3394 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.38, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 80.1 (19.94) | 79.7 (22.26) |
| | | Median | 83.3 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | -0.4 (19.55) | 4.1 (18.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | 0.0, 16.7 |
| | | Min, Max | -50, 83 | -50, 58 |
| | | LS Mean (SE) | -0.3 (1.08) | 0.4 (1.65) |
| | | 95% CI | -2.4, 1.8 | -2.9, 3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.7 (1.98) | |
| | | 95% CI | -4.5, 3.2 | |
| | | p-value | 0.7410 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.32, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 144 | 56 |
| | | Mean (StdDev) | 78.5 (20.16) | 79.1 (21.53) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 8, 100 |
| | Change from BL | n | 143 | 56 |
| | | Mean (StdDev) | -2.2 (17.63) | 5.0 (19.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -5.6, 8.3 |
| | | Min, Max | -58, 58 | -25, 67 |
| | | LS Mean (SE) | -2.0 (1.13) | 1.4 (1.77) |
| | | 95% CI | -4.2, 0.2 | -2.1, 4.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.4 (2.11) | |
| | | 95% CI | -7.6, 0.7 | |
| | | p-value | 0.1057 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.56, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 79.9 (19.31) | 74.0 (24.48) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 62.5, 91.7 |
| | | Min, Max | 33, 100 | 8, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | -0.7 (19.75) | 1.6 (22.24) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -50, 92 | -42, 67 |
| | | LS Mean (SE) | -0.3 (1.41) | -2.1 (2.29) |
| | | 95% CI | -3.1, 2.5 | -6.7, 2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.9 (2.70) | |
| | | 95% CI | -3.5, 7.2 | |
| | | p-value | 0.4929 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.26, 0.55) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 81.0 (17.78) | 82.4 (18.61) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 42, 100 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | -4.1 (17.19) | 5.4 (25.16) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 8.3 | -8.3, 8.3 |
| | | Min, Max | -50, 42 | -33, 67 |
| | | LS Mean (SE) | -1.0 (1.93) | 0.4 (3.04) |
| | | 95% CI | -4.9, 2.8 | -5.7, 6.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.4 (3.61) | |
| | | 95% CI | -8.6, 5.8 | |
| | | p-value | 0.7042 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.66, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 78.7 (22.21) | 81.3 (25.10) |
| | | Median | 83.3 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 75.0, 95.8 |
| | | Min, Max | 25, 100 | 25, 100 |
| | Change from BL | n | 27 | 8 |
| | | Mean (StdDev) | -6.8 (15.16) | 6.3 (12.40) |
| | | Median | -8.3 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -50, 17 | -8, 25 |
| | | LS Mean (SE) | -5.2 (2.03) | -0.3 (3.46) |
| | | 95% CI | -9.2, -1.1 | -7.3, 6.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.9 (4.04) | |
| | | 95% CI | -13.0, 3.3 | |
| | | p-value | 0.2362 | |
| | | Corrected Hedges g (95% CI) [2] | -0.46 (-1.25, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 82.7 (15.83) | 79.2 (17.68) |
| | | Median | 83.3 | 79.2 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 91.7 |
| | | Min, Max | 58, 100 | 67, 92 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | -3.0 (13.32) | -4.2 (5.89) |
| | | Median | 0.0 | -4.2 |
| | | Q1, Q3 | -16.7, 8.3 | -8.3, 0.0 |
| | | Min, Max | -25, 17 | -8, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 83.3 (16.67) | 62.5 (41.25) |
| | | Median | 91.7 | 62.5 |
| | | Q1, Q3 | 75.0, 91.7 | 33.3, 91.7 |
| | | Min, Max | 58, 100 | 33, 92 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (13.18) | -20.8 (17.68) |
| | | Median | 0.0 | -20.8 |
| | | Q1, Q3 | -8.3, 8.3 | -33.3, -8.3 |
| | | Min, Max | -17, 17 | -33, -8 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 25.0 (NA) | |
| | | Median | 25.0 | |
| | | Q1, Q3 | 25.0, 25.0 | |
| | | Min, Max | 25, 25 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 290 | 174 |
| | | Mean (StdDev) | 66.1 (24.76) | 69.1 (22.24) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 58.3, 91.7 |
| | | Min, Max | 0, 100 | 8, 100 |
| | Change from BL | n | 286 | 173 |
| | | Mean (StdDev) | -12.4 (22.06) | -8.0 (21.92) |
| | | Median | -8.3 | -8.3 |
| | | Q1, Q3 | -25.0, 0.0 | -25.0, 0.0 |
| | | Min, Max | -92, 92 | -92, 75 |
| | | LS Mean (SE) | -12.3 (1.11) | -8.2 (1.45) |
| | | 95% CI | -14.5, -10.2 | -11.0, -5.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.1 (1.82) | |
| | | 95% CI | -7.7, -0.6 | |
| | | p-value | 0.0231 | |
| | | Corrected Hedges g (95% CI) [2] | -0.22 (-0.41, -0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 105 |
| | | Mean (StdDev) | 69.5 (23.27) | 69.6 (21.21) |
| | | Median | 75.0 | 66.7 |
| | | Q1, Q3 | 58.3, 91.7 | 58.3, 83.3 |
| | | Min, Max | 8, 100 | 0, 100 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | -9.5 (22.35) | -7.8 (22.01) |
| | | Median | -8.3 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 58 | -100, 75 |
| | | LS Mean (SE) | -8.4 (1.38) | -7.0 (1.70) |
| | | 95% CI | -11.1, -5.7 | -10.4, -3.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.4 (2.19) | |
| | | 95% CI | -5.7, 3.0 | |
| | | p-value | 0.5370 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.33, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 98 |
| | | Mean (StdDev) | 71.7 (22.10) | 71.2 (22.20) |
| | | Median | 75.0 | 75.0 |
| | | Q1, Q3 | 58.3, 91.7 | 58.3, 83.3 |
| | | Min, Max | 8, 100 | 8, 100 |
| | Change from BL | n | 166 | 98 |
| | | Mean (StdDev) | -6.5 (21.42) | -6.8 (20.63) |
| | | Median | 0.0 | -4.2 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -92, 50 | -92, 42 |
| | | LS Mean (SE) | -6.6 (1.28) | -5.2 (1.69) |
| | | 95% CI | -9.1, -4.1 | -8.5, -1.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.5 (2.12) | |
| | | 95% CI | -5.6, 2.7 | |
| | | p-value | 0.4924 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.34, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 201 | 115 |
| | | Mean (StdDev) | 70.7 (21.88) | 72.0 (22.52) |
| | | Median | 75.0 | 75.0 |
| | | Q1, Q3 | 58.3, 83.3 | 58.3, 91.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | -7.7 (20.72) | -5.1 (22.73) |
| | | Median | -8.3 | -8.3 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 8.3 |
| | | Min, Max | -75, 58 | -75, 67 |
| | | LS Mean (SE) | -7.7 (1.23) | -5.5 (1.63) |
| | | 95% CI | -10.1, -5.3 | -8.7, -2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.2 (2.04) | |
| | | 95% CI | -6.2, 1.8 | |
| | | p-value | 0.2749 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.36, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 162 | 91 |
| | | Mean (StdDev) | 72.0 (22.32) | 74.7 (20.50) |
| | | Median | 75.0 | 75.0 |
| | | Q1, Q3 | 58.3, 91.7 | 66.7, 91.7 |
| | | Min, Max | 8, 100 | 8, 100 |
| | Change from BL | n | 160 | 90 |
| | | Mean (StdDev) | -6.3 (18.78) | -2.4 (20.91) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -8.3, 8.3 |
| | | Min, Max | -75, 50 | -75, 58 |
| | | LS Mean (SE) | -6.9 (1.23) | -3.0 (1.65) |
| | | 95% CI | -9.3, -4.5 | -6.2, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.0 (2.05) | |
| | | 95% CI | -8.0, 0.1 | |
| | | p-value | 0.0544 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.51, 0.01) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -2.8 (0.64) | -1.4 (0.93) |
| | | 95% CI | -4.1, -1.5 | -3.2, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.4 (1.14) | |
| | | 95% CI | -3.6, 0.8 | |
| | | p-value | 0.2170 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.25, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 243 |
| | | Mean (StdDev) | 83.1 (19.03) | 81.3 (19.09) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| Cycle 3 Day 1 | Actual | n | 426 | 229 |
| | | Mean (StdDev) | 83.5 (18.79) | 80.7 (20.78) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 421 | 228 |
| | | Mean (StdDev) | -0.2 (15.85) | -0.9 (16.83) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -67, 50 |
| | | LS Mean (SE) | 0.2 (0.83) | -1.5 (1.14) |
| | | 95% CI | -1.5, 1.8 | -3.7, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.7 (1.41) | |
| | | 95% CI | -1.1, 4.5 | |
| | | p-value | 0.2345 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.06, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 359 | 186 |
| | | Mean (StdDev) | 83.4 (18.69) | 81.2 (20.54) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 354 | 185 |
| | | Mean (StdDev) | -0.1 (16.48) | -0.4 (17.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 16.7 |
| | | Min, Max | -50, 50 | -67, 67 |
| | | LS Mean (SE) | 0.5 (0.81) | -1.2 (1.13) |
| | | 95% CI | -1.1, 2.1 | -3.5, 1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (1.39) | |
| | | 95% CI | -0.9, 4.5 | |
| | | p-value | 0.2004 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.06, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 322 | 161 |
| | | Mean (StdDev) | 82.8 (19.94) | 82.3 (19.43) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 318 | 160 |
| | | Mean (StdDev) | -1.1 (17.70) | 0.3 (18.55) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 16.7 |
| | | Min, Max | -50, 67 | -50, 33 |
| | | LS Mean (SE) | -0.2 (0.87) | -0.4 (1.23) |
| | | 95% CI | -2.0, 1.5 | -2.8, 2.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (1.51) | |
| | | 95% CI | -2.8, 3.1 | |
| | | p-value | 0.9218 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.18, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 125 |
| | | Mean (StdDev) | 82.1 (19.97) | 84.3 (17.87) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 83.3, 100.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 285 | 124 |
| | | Mean (StdDev) | -2.4 (18.90) | 3.4 (17.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -83, 50 | -33, 67 |
| | | LS Mean (SE) | -0.9 (0.86) | 2.4 (1.27) |
| | | 95% CI | -2.6, 0.8 | -0.1, 4.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.3 (1.53) | |
| | | 95% CI | -6.3, -0.3 | |
| | | p-value | 0.0330 | |
| | | Corrected Hedges g (95% CI) [2] | -0.23 (-0.44, -0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 256 | 102 |
| | | Mean (StdDev) | 84.2 (19.03) | 81.9 (19.78) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 253 | 101 |
| | | Mean (StdDev) | -1.2 (19.04) | 0.8 (19.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 |
| | | Min, Max | -83, 67 | -50, 67 |
| | | LS Mean (SE) | 0.2 (0.94) | -0.6 (1.42) |
| | | 95% CI | -1.6, 2.1 | -3.4, 2.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.9 (1.71) | |
| | | 95% CI | -2.5, 4.2 | |
| | | p-value | 0.6139 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.17, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 236 | 96 |
| | | Mean (StdDev) | 83.2 (19.26) | 82.5 (19.85) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 234 | 96 |
| | | Mean (StdDev) | -1.7 (18.96) | 1.9 (18.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -50, 67 | -50, 67 |
| | | LS Mean (SE) | -0.6 (0.93) | -0.4 (1.41) |
| | | 95% CI | -2.4, 1.2 | -3.2, 2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (1.69) | |
| | | 95% CI | -3.5, 3.1 | |
| | | p-value | 0.9128 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.25, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 212 | 81 |
| | | Mean (StdDev) | 83.6 (20.07) | 85.0 (18.93) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 209 | 81 |
| | | Mean (StdDev) | -1.7 (18.95) | 3.1 (18.09) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -33, 67 |
| | | LS Mean (SE) | -1.0 (0.99) | 1.5 (1.53) |
| | | 95% CI | -2.9, 1.0 | -1.5, 4.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.5 (1.82) | |
| | | 95% CI | -6.0, 1.1 | |
| | | p-value | 0.1778 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.43, 0.08) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 83.2 (18.13) | 82.4 (22.69) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | -2.6 (17.77) | 1.2 (17.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -67, 50 | -50, 67 |
| | | LS Mean (SE) | -1.3 (1.00) | -0.8 (1.51) |
| | | 95% CI | -3.2, 0.7 | -3.8, 2.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (1.82) | |
| | | 95% CI | -4.0, 3.1 | |
| | | p-value | 0.8166 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.31, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 144 | 56 |
| | | Mean (StdDev) | 81.5 (20.59) | 83.0 (18.67) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 143 | 56 |
| | | Mean (StdDev) | -4.4 (19.07) | 3.6 (19.26) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -67, 50 | -33, 50 |
| | | LS Mean (SE) | -2.5 (1.21) | 1.4 (1.88) |
| | | 95% CI | -4.8, -0.1 | -2.3, 5.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.9 (2.24) | |
| | | 95% CI | -8.3, 0.5 | |
| | | p-value | 0.0857 | |
| | | Corrected Hedges g (95% CI) [2] | -0.27 (-0.58, 0.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 81.8 (19.68) | 77.1 (25.31) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | -2.1 (17.84) | -0.5 (17.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 16.7 |
| | | Min, Max | -67, 50 | -50, 33 |
| | | LS Mean (SE) | -1.2 (1.41) | -4.1 (2.31) |
| | | 95% CI | -4.0, 1.6 | -8.6, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.8 (2.72) | |
| | | 95% CI | -2.5, 8.2 | |
| | | p-value | 0.2988 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (-0.19, 0.62) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 84.0 (16.65) | 80.4 (17.91) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 33, 100 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | -1.1 (14.08) | 4.9 (21.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 16.7 |
| | | Min, Max | -50, 33 | -33, 50 |
| | | LS Mean (SE) | -1.3 (1.56) | -3.2 (2.59) |
| | | 95% CI | -4.4, 1.8 | -8.4, 1.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.9 (3.04) | |
| | | 95% CI | -4.2, 7.9 | |
| | | p-value | 0.5365 | |
| | | Corrected Hedges g (95% CI) [2] | 0.17 (-0.38, 0.73) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 76.5 (22.29) | 81.3 (24.30) |
| | | Median | 83.3 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 33, 100 |
| | Change from BL | n | 27 | 8 |
| | | Mean (StdDev) | -5.6 (19.61) | 14.6 (24.30) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -50, 33 | -17, 67 |
| | | LS Mean (SE) | -3.8 (2.54) | -1.5 (4.92) |
| | | 95% CI | -9.0, 1.3 | -11.5, 8.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.3 (5.51) | |
| | | 95% CI | -13.5, 8.9 | |
| | | p-value | 0.6747 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.96, 0.62) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 86.9 (18.70) | 83.3 (23.57) |
| | | Median | 91.7 | 83.3 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 67, 100 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.0 (19.61) | 8.3 (11.79) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 16.7 |
| | | Min, Max | -50, 33 | 0, 17 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 86.7 (13.94) | 66.7 (47.14) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 83.3, 100.0 | 33.3, 100.0 |
| | | Min, Max | 67, 100 | 33, 100 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -3.3 (24.72) | -8.3 (35.36) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 0.0 | -33.3, 16.7 |
| | | Min, Max | -33, 33 | -33, 17 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 83.3 (NA) | |
| | | Median | 83.3 | |
| | | Q1, Q3 | 83.3, 83.3 | |
| | | Min, Max | 83, 83 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -16.7 (NA) | |
| | | Median | -16.7 | |
| | | Q1, Q3 | -16.7, -16.7 | |
| | | Min, Max | -17, -17 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 290 | 174 |
| | | Mean (StdDev) | 80.9 (22.10) | 82.3 (19.97) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 286 | 173 |
| | | Mean (StdDev) | -2.1 (21.66) | -0.3 (19.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -83, 67 | -100, 67 |
| | | LS Mean (SE) | -2.6 (1.03) | -0.4 (1.35) |
| | | 95% CI | -4.7, -0.6 | -3.0, 2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.3 (1.70) | |
| | | 95% CI | -5.6, 1.0 | |
| | | p-value | 0.1785 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.32, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 105 |
| | | Mean (StdDev) | 82.2 (20.40) | 79.2 (22.85) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | -1.6 (21.43) | -2.2 (18.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 0.0 |
| | | Min, Max | -100, 67 | -67, 67 |
| | | LS Mean (SE) | -1.7 (1.28) | -3.0 (1.58) |
| | | 95% CI | -4.2, 0.8 | -6.1, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (2.03) | |
| | | 95% CI | -2.7, 5.3 | |
| | | p-value | 0.5173 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.17, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 169 | 98 |
| | | Mean (StdDev) | 79.1 (22.50) | 81.5 (20.43) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 165 | 98 |
| | | Mean (StdDev) | -1.9 (20.36) | -1.4 (18.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 50 | -50, 67 |
| | | LS Mean (SE) | -3.5 (1.23) | -2.0 (1.61) |
| | | 95% CI | -5.9, -1.1 | -5.1, 1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.5 (2.02) | |
| | | 95% CI | -5.5, 2.4 | |
| | | p-value | 0.4439 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.35, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 201 | 115 |
| | | Mean (StdDev) | 80.5 (21.74) | 80.7 (21.47) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | -1.2 (19.89) | -0.4 (21.32) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 16.7 |
| | | Min, Max | -67, 50 | -50, 67 |
| | | LS Mean (SE) | -2.2 (1.18) | -1.5 (1.57) |
| | | 95% CI | -4.5, 0.1 | -4.6, 1.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.7 (1.96) | |
| | | 95% CI | -4.6, 3.1 | |
| | | p-value | 0.7093 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.27, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 162 | 91 |
| | | Mean (StdDev) | 82.1 (19.71) | 78.4 (23.37) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 160 | 90 |
| | | Mean (StdDev) | -0.2 (19.33) | -3.1 (18.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -16.7, 0.0 |
| | | Min, Max | -67, 50 | -50, 67 |
| | | LS Mean (SE) | -1.0 (1.17) | -3.7 (1.58) |
| | | 95% CI | -3.3, 1.3 | -6.8, -0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.7 (1.96) | |
| | | 95% CI | -1.2, 6.5 | |
| | | p-value | 0.1762 | |
| | | Corrected Hedges g (95% CI) [2] | 0.18 (-0.08, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -1.3 (0.63) | -1.1 (0.93) |
| | | 95% CI | -2.6, -0.1 | -2.9, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (1.13) | |
| | | 95% CI | -2.4, 2.0 | |
| | | p-value | 0.8369 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.17, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 243 |
| | | Mean (StdDev) | 79.1 (25.24) | 76.6 (24.54) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 425 | 229 |
| | | Mean (StdDev) | 83.7 (22.09) | 85.2 (20.12) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 421 | 228 |
| | | Mean (StdDev) | 3.6 (25.51) | 8.5 (21.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 100 | -50, 83 |
| | | LS Mean (SE) | 4.0 (0.98) | 6.7 (1.35) |
| | | 95% CI | 2.1, 6.0 | 4.1, 9.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.7 (1.67) | |
| | | 95% CI | -6.0, 0.6 | |
| | | p-value | 0.1088 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.29, 0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 187 |
| | | Mean (StdDev) | 85.0 (20.96) | 84.8 (20.76) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 353 | 186 |
| | | Mean (StdDev) | 5.1 (23.98) | 8.1 (23.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 83 | -50, 83 |
| | | LS Mean (SE) | 5.0 (0.99) | 6.3 (1.37) |
| | | 95% CI | 3.1, 7.0 | 3.6, 9.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.2 (1.70) | |
| | | 95% CI | -4.5, 2.1 | |
| | | p-value | 0.4727 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.24, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 322 | 161 |
| | | Mean (StdDev) | 86.3 (18.81) | 85.3 (22.62) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 318 | 160 |
| | | Mean (StdDev) | 5.3 (23.85) | 8.4 (24.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -100, 100 |
| | | LS Mean (SE) | 5.9 (1.03) | 6.6 (1.44) |
| | | 95% CI | 3.9, 7.9 | 3.8, 9.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.7 (1.77) | |
| | | 95% CI | -4.2, 2.8 | |
| | | p-value | 0.6874 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.23, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 126 |
| | | Mean (StdDev) | 87.9 (18.62) | 84.3 (22.04) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 285 | 125 |
| | | Mean (StdDev) | 6.8 (23.92) | 8.8 (23.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 7.5 (1.02) | 5.8 (1.50) |
| | | 95% CI | 5.5, 9.5 | 2.9, 8.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.7 (1.82) | |
| | | 95% CI | -1.9, 5.2 | |
| | | p-value | 0.3617 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.11, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 256 | 102 |
| | | Mean (StdDev) | 87.9 (18.75) | 84.3 (23.90) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 0, 100 |
| | Change from BL | n | 253 | 101 |
| | | Mean (StdDev) | 5.7 (24.74) | 6.9 (23.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 6.7 (1.09) | 4.1 (1.67) |
| | | 95% CI | 4.6, 8.9 | 0.8, 7.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (2.00) | |
| | | 95% CI | -1.3, 6.5 | |
| | | p-value | 0.1915 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.08, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 236 | 96 |
| | | Mean (StdDev) | 88.7 (18.94) | 86.1 (22.38) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 83.3, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 234 | 96 |
| | | Mean (StdDev) | 7.3 (24.75) | 9.4 (22.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -50, 67 |
| | | LS Mean (SE) | 8.0 (1.03) | 6.6 (1.56) |
| | | 95% CI | 5.9, 10.0 | 3.5, 9.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (1.88) | |
| | | 95% CI | -2.3, 5.1 | |
| | | p-value | 0.4627 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.15, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 81 |
| | | Mean (StdDev) | 88.2 (20.18) | 89.5 (19.97) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 83.3, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 208 | 81 |
| | | Mean (StdDev) | 5.8 (23.71) | 11.5 (24.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 100 | -67, 83 |
| | | LS Mean (SE) | 6.6 (1.14) | 9.0 (1.76) |
| | | 95% CI | 4.4, 8.8 | 5.5, 12.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.4 (2.09) | |
| | | 95% CI | -6.5, 1.8 | |
| | | p-value | 0.2610 | |
| | | Corrected Hedges g (95% CI) [2] | -0.14 (-0.40, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 70 |
| | | Mean (StdDev) | 87.3 (21.23) | 86.4 (23.10) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 176 | 70 |
| | | Mean (StdDev) | 4.2 (26.46) | 10.2 (26.96) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 6.0 (1.26) | 6.2 (1.94) |
| | | 95% CI | 3.5, 8.5 | 2.4, 10.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (2.32) | |
| | | 95% CI | -4.8, 4.3 | |
| | | p-value | 0.9250 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.29, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 144 | 56 |
| | | Mean (StdDev) | 87.0 (19.95) | 79.5 (24.82) |
| | | Median | 100.0 | 83.3 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 143 | 56 |
| | | Mean (StdDev) | 3.5 (26.30) | 4.5 (29.56) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 83 | -67, 100 |
| | | LS Mean (SE) | 6.1 (1.43) | 1.5 (2.24) |
| | | 95% CI | 3.3, 8.9 | -2.9, 5.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.6 (2.67) | |
| | | 95% CI | -0.6, 9.9 | |
| | | p-value | 0.0850 | |
| | | Corrected Hedges g (95% CI) [2] | 0.27 (-0.04, 0.58) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 87.3 (19.57) | 87.0 (16.79) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 50, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 2.8 (25.30) | 12.0 (27.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -83, 83 | -33, 67 |
| | | LS Mean (SE) | 5.6 (1.61) | 9.2 (2.59) |
| | | 95% CI | 2.4, 8.8 | 4.1, 14.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.6 (3.06) | |
| | | 95% CI | -9.7, 2.4 | |
| | | p-value | 0.2378 | |
| | | Corrected Hedges g (95% CI) [2] | -0.24 (-0.65, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 90.4 (15.83) | 93.1 (13.25) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 100.0, 100.0 |
| | | Min, Max | 50, 100 | 67, 100 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | 3.2 (22.69) | 15.7 (30.32) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -50, 67 | -33, 67 |
| | | LS Mean (SE) | 5.9 (2.02) | 12.4 (3.23) |
| | | 95% CI | 1.8, 9.9 | 6.0, 18.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -6.6 (3.83) | |
| | | 95% CI | -14.2, 1.0 | |
| | | p-value | 0.0898 | |
| | | Corrected Hedges g (95% CI) [2] | -0.47 (-1.03, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 87.0 (18.10) | 95.8 (11.79) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 100.0, 100.0 |
| | | Min, Max | 50, 100 | 67, 100 |
| | Change from BL | n | 27 | 8 |
| | | Mean (StdDev) | 1.2 (18.45) | 14.6 (22.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -50, 33 | 0, 50 |
| | | LS Mean (SE) | 3.5 (2.25) | 11.6 (3.92) |
| | | 95% CI | -1.0, 8.1 | 3.6, 19.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -8.0 (4.51) | |
| | | 95% CI | -17.1, 1.1 | |
| | | p-value | 0.0832 | |
| | | Corrected Hedges g (95% CI) [2] | -0.68 (-1.48, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 85.7 (21.54) | 100.0 (0.00) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 100.0, 100.0 |
| | | Min, Max | 33, 100 | 100, 100 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.0 (31.35) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | 0.0, 0.0 |
| | | Min, Max | -67, 50 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 83.3 (23.57) | 66.7 (47.14) |
| | | Median | 100.0 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 33.3, 100.0 |
| | | Min, Max | 50, 100 | 33, 100 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (20.41) | -33.3 (47.14) |
| | | Median | 0.0 | -33.3 |
| | | Q1, Q3 | 0.0, 16.7 | -66.7, 0.0 |
| | | Min, Max | -33, 17 | -67, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 290 | 174 |
| | | Mean (StdDev) | 77.6 (27.99) | 80.5 (24.40) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 286 | 173 |
| | | Mean (StdDev) | -0.9 (28.38) | 2.8 (23.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 83 | -83, 67 |
| | | LS Mean (SE) | -1.0 (1.29) | 1.7 (1.68) |
| | | 95% CI | -3.5, 1.5 | -1.6, 5.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.7 (2.12) | |
| | | 95% CI | -6.8, 1.5 | |
| | | p-value | 0.2086 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.31, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 105 |
| | | Mean (StdDev) | 76.7 (27.44) | 75.1 (26.57) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | -2.9 (30.19) | -4.2 (26.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | -4.3 (1.78) | -4.3 (2.19) |
| | | 95% CI | -7.8, -0.8 | -8.6, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (2.82) | |
| | | 95% CI | -5.6, 5.5 | |
| | | p-value | 0.9983 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.25, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 98 |
| | | Mean (StdDev) | 74.0 (28.49) | 72.6 (27.42) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 166 | 98 |
| | | Mean (StdDev) | -2.3 (30.09) | -6.8 (28.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 0.0 |
| | | Min, Max | -100, 67 | -100, 50 |
| | | LS Mean (SE) | -4.6 (1.75) | -6.5 (2.28) |
| | | 95% CI | -8.1, -1.2 | -11.0, -2.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (2.87) | |
| | | 95% CI | -3.8, 7.5 | |
| | | p-value | 0.5246 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.17, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 201 | 115 |
| | | Mean (StdDev) | 75.0 (25.56) | 71.7 (26.14) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 50.0, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | -2.7 (28.84) | -5.4 (27.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -100, 50 |
| | | LS Mean (SE) | -3.7 (1.55) | -7.2 (2.05) |
| | | 95% CI | -6.7, -0.6 | -11.2, -3.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.5 (2.57) | |
| | | 95% CI | -1.6, 8.5 | |
| | | p-value | 0.1779 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.07, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 162 | 91 |
| | | Mean (StdDev) | 78.3 (27.43) | 74.4 (27.70) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 160 | 90 |
| | | Mean (StdDev) | 0.8 (26.55) | -2.6 (25.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | -1.2 (1.69) | -5.4 (2.26) |
| | | 95% CI | -4.5, 2.2 | -9.8, -0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.2 (2.81) | |
| | | 95% CI | -1.3, 9.7 | |
| | | p-value | 0.1372 | |
| | | Corrected Hedges g (95% CI) [2] | 0.20 (-0.06, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 3.3 (0.73) | 3.8 (1.05) |
| | | 95% CI | 1.9, 4.7 | 1.7, 5.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.5 (1.28) | |
| | | 95% CI | -3.0, 2.0 | |
| | | p-value | 0.7021 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.19, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 243 |
| | | Mean (StdDev) | 29.9 (21.28) | 32.8 (22.74) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 11.1, 33.3 | 22.2, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 427 | 229 |
| | | Mean (StdDev) | 32.7 (21.89) | 30.0 (22.47) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 44.4 | 11.1, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 423 | 228 |
| | | Mean (StdDev) | 3.6 (20.55) | -2.1 (20.56) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -78, 78 | -67, 67 |
| | | LS Mean (SE) | 3.3 (0.97) | -0.9 (1.33) |
| | | 95% CI | 1.4, 5.2 | -3.5, 1.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.2 (1.65) | |
| | | 95% CI | 0.9, 7.4 | |
| | | p-value | 0.0115 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (0.05, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 188 |
| | | Mean (StdDev) | 29.7 (21.23) | 28.8 (21.67) |
| | | Median | 33.3 | 22.2 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 100 | 0, 89 |
| | Change from BL | n | 354 | 187 |
| | | Mean (StdDev) | 0.2 (20.16) | -3.2 (20.26) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -78, 89 | -89, 44 |
| | | LS Mean (SE) | 0.6 (0.98) | -1.7 (1.36) |
| | | 95% CI | -1.3, 2.5 | -4.4, 0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.4 (1.67) | |
| | | 95% CI | -0.9, 5.6 | |
| | | p-value | 0.1583 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.05, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 319 | 160 |
| | | Mean (StdDev) | 27.9 (20.49) | 28.0 (19.66) |
| | | Median | 22.2 | 33.3 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 89 | 0, 100 |
| | Change from BL | n | 316 | 159 |
| | | Mean (StdDev) | -1.4 (19.30) | -3.8 (20.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -78, 67 | -89, 44 |
| | | LS Mean (SE) | -1.0 (0.91) | -2.1 (1.28) |
| | | 95% CI | -2.8, 0.7 | -4.6, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.1 (1.57) | |
| | | 95% CI | -2.0, 4.2 | |
| | | p-value | 0.4809 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.12, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 288 | 127 |
| | | Mean (StdDev) | 27.4 (20.59) | 28.7 (22.46) |
| | | Median | 22.2 | 22.2 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 100 | 0, 89 |
| | Change from BL | n | 284 | 126 |
| | | Mean (StdDev) | -1.1 (20.75) | -3.1 (20.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -89, 78 | -56, 78 |
| | | LS Mean (SE) | -1.0 (0.99) | -2.2 (1.45) |
| | | 95% CI | -3.0, 0.9 | -5.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (1.76) | |
| | | 95% CI | -2.3, 4.6 | |
| | | p-value | 0.5096 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.14, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 255 | 102 |
| | | Mean (StdDev) | 26.1 (20.38) | 30.0 (23.70) |
| | | Median | 22.2 | 33.3 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 252 | 101 |
| | | Mean (StdDev) | -2.0 (21.40) | -1.5 (21.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 0.0 |
| | | Min, Max | -89, 67 | -67, 56 |
| | | LS Mean (SE) | -2.0 (1.01) | -0.2 (1.54) |
| | | 95% CI | -4.0, -0.1 | -3.2, 2.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.8 (1.84) | |
| | | 95% CI | -5.5, 1.8 | |
| | | p-value | 0.3178 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.35, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 235 | 96 |
| | | Mean (StdDev) | 25.6 (20.69) | 27.4 (23.64) |
| | | Median | 22.2 | 22.2 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 89 | 0, 100 |
| | Change from BL | n | 233 | 95 |
| | | Mean (StdDev) | -2.6 (21.98) | -4.4 (19.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 0.0 |
| | | Min, Max | -89, 67 | -67, 44 |
| | | LS Mean (SE) | -2.4 (1.02) | -2.9 (1.55) |
| | | 95% CI | -4.4, -0.4 | -5.9, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (1.86) | |
| | | 95% CI | -3.2, 4.1 | |
| | | p-value | 0.8121 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.21, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 24.8 (21.24) | 25.8 (21.87) |
| | | Median | 22.2 | 22.2 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 208 | 81 |
| | | Mean (StdDev) | -2.3 (20.20) | -3.9 (18.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 0.0 |
| | | Min, Max | -67, 56 | -67, 44 |
| | | LS Mean (SE) | -2.2 (1.04) | -3.3 (1.60) |
| | | 95% CI | -4.3, -0.2 | -6.5, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.1 (1.91) | |
| | | 95% CI | -2.7, 4.8 | |
| | | p-value | 0.5733 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.18, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 24.1 (20.44) | 28.0 (22.53) |
| | | Median | 22.2 | 22.2 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 100 | 0, 89 |
| | Change from BL | n | 176 | 70 |
| | | Mean (StdDev) | -2.9 (21.60) | -3.8 (19.28) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 5.6 | -11.1, 11.1 |
| | | Min, Max | -56, 78 | -67, 44 |
| | | LS Mean (SE) | -3.5 (1.13) | -2.2 (1.74) |
| | | 95% CI | -5.7, -1.2 | -5.6, 1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (2.07) | |
| | | 95% CI | -5.4, 2.8 | |
| | | p-value | 0.5349 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.36, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 25.0 (20.89) | 31.9 (27.79) |
| | | Median | 22.2 | 33.3 |
| | | Q1, Q3 | 11.1, 33.3 | 5.6, 44.4 |
| | | Min, Max | 0, 89 | 0, 100 |
| | Change from BL | n | 146 | 55 |
| | | Mean (StdDev) | -1.5 (19.98) | -1.0 (24.03) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -56, 78 | -78, 78 |
| | | LS Mean (SE) | -2.4 (1.36) | -0.1 (2.16) |
| | | 95% CI | -5.1, 0.3 | -4.3, 4.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.3 (2.56) | |
| | | 95% CI | -7.4, 2.7 | |
| | | p-value | 0.3654 | |
| | | Corrected Hedges g (95% CI) [2] | -0.14 (-0.45, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 24.0 (19.35) | 28.1 (25.40) |
| | | Median | 22.2 | 33.3 |
| | | Q1, Q3 | 5.6, 33.3 | 0.0, 44.4 |
| | | Min, Max | 0, 67 | 0, 89 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | -2.3 (20.85) | -4.5 (21.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -22.2, 0.0 |
| | | Min, Max | -44, 44 | -67, 56 |
| | | LS Mean (SE) | -4.6 (1.59) | -4.1 (2.57) |
| | | 95% CI | -7.8, -1.5 | -9.2, 0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.5 (3.04) | |
| | | 95% CI | -6.5, 5.5 | |
| | | p-value | 0.8737 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.44, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 22.9 (20.65) | 30.7 (26.51) |
| | | Median | 22.2 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 11.1, 44.4 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | -1.7 (19.10) | -7.2 (21.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 0.0 | -22.2, 0.0 |
| | | Min, Max | -44, 56 | -67, 22 |
| | | LS Mean (SE) | -1.4 (1.87) | -3.7 (3.06) |
| | | 95% CI | -5.1, 2.3 | -9.8, 2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.4 (3.65) | |
| | | 95% CI | -4.9, 9.6 | |
| | | p-value | 0.5214 | |
| | | Corrected Hedges g (95% CI) [2] | 0.18 (-0.37, 0.74) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 28 | 8 |
| | | Mean (StdDev) | 26.2 (20.78) | 25.0 (28.94) |
| | | Median | 27.8 | 16.7 |
| | | Q1, Q3 | 5.6, 33.3 | 5.6, 33.3 |
| | | Min, Max | 0, 78 | 0, 89 |
| | Change from BL | n | 28 | 8 |
| | | Mean (StdDev) | 2.4 (12.96) | -4.2 (10.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -5.6, 11.1 | -11.1, 0.0 |
| | | Min, Max | -22, 22 | -22, 11 |
| | | LS Mean (SE) | 0.8 (1.74) | -3.5 (3.04) |
| | | 95% CI | -2.7, 4.3 | -9.7, 2.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.3 (3.50) | |
| | | 95% CI | -2.7, 11.4 | |
| | | p-value | 0.2217 | |
| | | Corrected Hedges g (95% CI) [2] | 0.47 (-0.33, 1.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 19.8 (23.54) | 22.2 (15.71) |
| | | Median | 22.2 | 22.2 |
| | | Q1, Q3 | 0.0, 22.2 | 11.1, 33.3 |
| | | Min, Max | 0, 78 | 11, 33 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.0 (16.31) | 5.6 (7.86) |
| | | Median | 0.0 | 5.6 |
| | | Q1, Q3 | -11.1, 22.2 | 0.0, 11.1 |
| | | Min, Max | -22, 22 | 0, 11 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 20.0 (21.37) | 50.0 (39.28) |
| | | Median | 11.1 | 50.0 |
| | | Q1, Q3 | 11.1, 22.2 | 22.2, 77.8 |
| | | Min, Max | 0, 56 | 22, 78 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 6.7 (18.59) | 33.3 (15.71) |
| | | Median | 11.1 | 33.3 |
| | | Q1, Q3 | 0.0, 22.2 | 22.2, 44.4 |
| | | Min, Max | -22, 22 | 22, 44 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 22.2 (NA) | |
| | | Median | 22.2 | |
| | | Q1, Q3 | 22.2, 22.2 | |
| | | Min, Max | 22, 22 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 22.2 (NA) | |
| | | Median | 22.2 | |
| | | Q1, Q3 | 22.2, 22.2 | |
| | | Min, Max | 22, 22 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 288 | 174 |
| | | Mean (StdDev) | 34.8 (25.76) | 30.4 (24.25) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 11.1, 44.4 | 11.1, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 285 | 173 |
| | | Mean (StdDev) | 4.3 (24.95) | -1.7 (23.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -89, 89 | -67, 89 |
| | | LS Mean (SE) | 4.2 (1.24) | -0.3 (1.62) |
| | | 95% CI | 1.8, 6.6 | -3.5, 2.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.6 (2.04) | |
| | | 95% CI | 0.6, 8.6 | |
| | | p-value | 0.0256 | |
| | | Corrected Hedges g (95% CI) [2] | 0.22 (0.03, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 104 |
| | | Mean (StdDev) | 33.3 (24.94) | 36.0 (23.96) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 11.1, 44.4 | 22.2, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | 2.5 (24.81) | 4.5 (24.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -56, 100 | -44, 89 |
| | | LS Mean (SE) | 3.5 (1.68) | 6.9 (2.06) |
| | | 95% CI | 0.2, 6.8 | 2.8, 10.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.4 (2.66) | |
| | | 95% CI | -8.6, 1.8 | |
| | | p-value | 0.2013 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.41, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 97 |
| | | Mean (StdDev) | 36.7 (23.35) | 37.9 (23.00) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 55.6 | 22.2, 55.6 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 167 | 97 |
| | | Mean (StdDev) | 4.4 (24.39) | 8.2 (25.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 22.2 | -11.1, 22.2 |
| | | Min, Max | -56, 100 | -44, 89 |
| | | LS Mean (SE) | 6.2 (1.49) | 8.5 (1.97) |
| | | 95% CI | 3.3, 9.1 | 4.6, 12.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.3 (2.47) | |
| | | 95% CI | -7.1, 2.6 | |
| | | p-value | 0.3602 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.37, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 202 | 115 |
| | | Mean (StdDev) | 36.8 (24.27) | 38.7 (21.74) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 55.6 | 22.2, 55.6 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 199 | 115 |
| | | Mean (StdDev) | 5.6 (24.87) | 8.0 (21.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 22.2 | 0.0, 22.2 |
| | | Min, Max | -56, 78 | -67, 78 |
| | | LS Mean (SE) | 6.1 (1.42) | 8.7 (1.89) |
| | | 95% CI | 3.3, 8.9 | 5.0, 12.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.6 (2.36) | |
| | | 95% CI | -7.2, 2.0 | |
| | | p-value | 0.2698 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.36, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 162 | 91 |
| | | Mean (StdDev) | 35.0 (24.34) | 37.7 (22.21) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 44.4 | 22.2, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 160 | 91 |
| | | Mean (StdDev) | 3.5 (22.45) | 7.6 (21.72) |
| | | Median | 0.0 | 11.1 |
| | | Q1, Q3 | -11.1, 11.1 | 0.0, 22.2 |
| | | Min, Max | -67, 78 | -44, 89 |
| | | LS Mean (SE) | 5.3 (1.54) | 9.3 (2.05) |
| | | 95% CI | 2.3, 8.4 | 5.3, 13.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.0 (2.57) | |
| | | 95% CI | -9.0, 1.1 | |
| | | p-value | 0.1229 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.46, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.6 (0.69) | 0.4 (0.99) |
| | | 95% CI | -0.8, 1.9 | -1.6, 2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (1.21) | |
| | | 95% CI | -2.2, 2.6 | |
| | | p-value | 0.8686 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.14, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 244 |
| | | Mean (StdDev) | 3.4 (9.27) | 4.8 (13.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 83 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 429 | 229 |
| | | Mean (StdDev) | 9.9 (14.22) | 4.2 (10.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 425 | 229 |
| | | Mean (StdDev) | 6.7 (14.75) | -0.1 (11.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -50, 50 |
| | | LS Mean (SE) | 6.5 (0.60) | 0.4 (0.83) |
| | | 95% CI | 5.3, 7.7 | -1.2, 2.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 6.1 (1.02) | |
| | | 95% CI | 4.1, 8.1 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.49 (0.33, 0.65) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 188 |
| | | Mean (StdDev) | 7.2 (13.31) | 3.7 (10.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 83 | 0, 100 |
| | Change from BL | n | 354 | 188 |
| | | Mean (StdDev) | 4.4 (13.48) | -1.0 (10.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -50, 67 | -67, 33 |
| | | LS Mean (SE) | 4.0 (0.60) | -0.3 (0.83) |
| | | 95% CI | 2.8, 5.1 | -1.9, 1.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.2 (1.02) | |
| | | 95% CI | 2.2, 6.2 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.37 (0.20, 0.55) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 319 | 160 |
| | | Mean (StdDev) | 7.3 (14.13) | 3.3 (8.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 83 | 0, 50 |
| | Change from BL | n | 316 | 160 |
| | | Mean (StdDev) | 4.8 (14.81) | -1.4 (12.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 83 | -83, 50 |
| | | LS Mean (SE) | 3.9 (0.69) | -0.3 (0.97) |
| | | 95% CI | 2.5, 5.2 | -2.2, 1.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.2 (1.19) | |
| | | 95% CI | 1.8, 6.5 | |
| | | p-value | 0.0005 | |
| | | Corrected Hedges g (95% CI) [2] | 0.34 (0.15, 0.53) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 127 |
| | | Mean (StdDev) | 6.3 (12.80) | 3.8 (11.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 285 | 127 |
| | | Mean (StdDev) | 3.7 (13.55) | -1.6 (15.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 100 | -100, 67 |
| | | LS Mean (SE) | 3.1 (0.66) | -0.1 (0.97) |
| | | 95% CI | 1.8, 4.4 | -2.0, 1.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.2 (1.18) | |
| | | 95% CI | 0.8, 5.5 | |
| | | p-value | 0.0075 | |
| | | Corrected Hedges g (95% CI) [2] | 0.29 (0.08, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 255 | 102 |
| | | Mean (StdDev) | 4.9 (10.51) | 6.0 (11.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 16.7 |
| | | Min, Max | 0, 67 | 0, 50 |
| | Change from BL | n | 252 | 102 |
| | | Mean (StdDev) | 2.9 (11.15) | 0.2 (14.55) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -67, 50 |
| | | LS Mean (SE) | 2.3 (0.60) | 1.8 (0.92) |
| | | 95% CI | 1.1, 3.5 | 0.0, 3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.5 (1.10) | |
| | | 95% CI | -1.7, 2.6 | |
| | | p-value | 0.6744 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.18, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 235 | 96 |
| | | Mean (StdDev) | 5.2 (10.12) | 4.5 (10.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 50 | 0, 50 |
| | Change from BL | n | 233 | 96 |
| | | Mean (StdDev) | 3.4 (11.06) | -1.6 (15.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 50 | -83, 50 |
| | | LS Mean (SE) | 2.7 (0.63) | 1.0 (0.96) |
| | | 95% CI | 1.4, 3.9 | -0.9, 2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.7 (1.16) | |
| | | 95% CI | -0.6, 3.9 | |
| | | p-value | 0.1527 | |
| | | Corrected Hedges g (95% CI) [2] | 0.17 (-0.06, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 4.2 (9.74) | 4.7 (11.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 50 |
| | Change from BL | n | 208 | 82 |
| | | Mean (StdDev) | 2.6 (10.85) | -1.0 (14.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -67, 50 |
| | | LS Mean (SE) | 1.9 (0.67) | 1.3 (1.05) |
| | | 95% CI | 0.6, 3.2 | -0.7, 3.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (1.26) | |
| | | 95% CI | -1.9, 3.0 | |
| | | p-value | 0.6511 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.20, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 4.5 (10.15) | 3.3 (8.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 50 | 0, 50 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | 2.9 (10.80) | -2.6 (12.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 50 | -67, 17 |
| | | LS Mean (SE) | 2.4 (0.73) | -0.2 (1.13) |
| | | 95% CI | 0.9, 3.8 | -2.5, 2.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (1.36) | |
| | | 95% CI | -0.1, 5.3 | |
| | | p-value | 0.0561 | |
| | | Corrected Hedges g (95% CI) [2] | 0.27 (-0.01, 0.55) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 6.3 (13.98) | 6.0 (15.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 8.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 146 | 56 |
| | | Mean (StdDev) | 4.8 (14.11) | 0.0 (20.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 100 | -100, 83 |
| | | LS Mean (SE) | 4.0 (1.11) | 2.5 (1.76) |
| | | 95% CI | 1.9, 6.2 | -1.0, 6.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.5 (2.10) | |
| | | 95% CI | -2.6, 5.7 | |
| | | p-value | 0.4726 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.20, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 5.3 (10.88) | 7.8 (17.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 50 | 0, 67 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 3.6 (10.85) | 1.6 (20.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 50 | -67, 67 |
| | | LS Mean (SE) | 3.0 (1.32) | 2.8 (2.18) |
| | | 95% CI | 0.4, 5.6 | -1.5, 7.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (2.57) | |
| | | 95% CI | -4.9, 5.2 | |
| | | p-value | 0.9485 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.39, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 4.6 (9.00) | 8.8 (18.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 67 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | 2.5 (10.41) | 1.0 (23.91) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 33 | -67, 67 |
| | | LS Mean (SE) | 2.1 (1.47) | 3.5 (2.45) |
| | | 95% CI | -0.8, 5.0 | -1.4, 8.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.4 (2.88) | |
| | | 95% CI | -7.2, 4.3 | |
| | | p-value | 0.6227 | |
| | | Corrected Hedges g (95% CI) [2] | -0.14 (-0.69, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 28 | 8 |
| | | Mean (StdDev) | 3.6 (8.31) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 28 | 8 |
| | | Mean (StdDev) | 1.2 (8.99) | -12.5 (35.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 17 | -100, 0 |
| | | LS Mean (SE) | 1.2 (1.49) | -1.3 (2.81) |
| | | 95% CI | -1.8, 4.2 | -7.0, 4.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.5 (3.20) | |
| | | 95% CI | -4.0, 9.0 | |
| | | p-value | 0.4405 | |
| | | Corrected Hedges g (95% CI) [2] | 0.31 (-0.48, 1.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 2.4 (8.91) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | -1.2 (7.91) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 17 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 16.7 (23.57) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 0 | 0, 33 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -3.3 (7.45) | 16.7 (23.57) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | -17, 0 | 0, 33 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 288 | 174 |
| | | Mean (StdDev) | 7.8 (14.45) | 6.2 (15.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 285 | 174 |
| | | Mean (StdDev) | 4.0 (15.94) | 2.0 (18.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -50, 100 | -83, 100 |
| | | LS Mean (SE) | 3.9 (0.85) | 2.4 (1.09) |
| | | 95% CI | 2.2, 5.5 | 0.3, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (1.38) | |
| | | 95% CI | -1.3, 4.1 | |
| | | p-value | 0.3038 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.09, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 104 |
| | | Mean (StdDev) | 9.8 (17.72) | 10.3 (15.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 83 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | 5.4 (18.81) | 6.1 (17.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -33, 100 | -33, 83 |
| | | LS Mean (SE) | 6.0 (1.26) | 7.0 (1.53) |
| | | 95% CI | 3.5, 8.5 | 3.9, 10.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.0 (1.98) | |
| | | 95% CI | -4.9, 2.9 | |
| | | p-value | 0.6174 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.31, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 97 |
| | | Mean (StdDev) | 9.1 (15.18) | 14.1 (20.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | 0, 83 | 0, 100 |
| | Change from BL | n | 167 | 97 |
| | | Mean (StdDev) | 4.3 (16.15) | 9.3 (21.24) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 16.7 |
| | | Min, Max | -33, 83 | -33, 100 |
| | | LS Mean (SE) | 4.8 (1.25) | 10.2 (1.64) |
| | | 95% CI | 2.4, 7.3 | 7.0, 13.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -5.4 (2.05) | |
| | | 95% CI | -9.4, -1.4 | |
| | | p-value | 0.0089 | |
| | | Corrected Hedges g (95% CI) [2] | -0.33 (-0.59, -0.08) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 202 | 115 |
| | | Mean (StdDev) | 9.2 (16.54) | 9.7 (14.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 199 | 115 |
| | | Mean (StdDev) | 4.8 (16.18) | 5.7 (16.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -33, 100 | -33, 100 |
| | | LS Mean (SE) | 5.1 (1.05) | 6.0 (1.39) |
| | | 95% CI | 3.0, 7.1 | 3.2, 8.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.9 (1.74) | |
| | | 95% CI | -4.3, 2.5 | |
| | | p-value | 0.6095 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.29, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 163 | 91 |
| | | Mean (StdDev) | 7.1 (15.59) | 7.1 (12.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 50 |
| | Change from BL | n | 161 | 91 |
| | | Mean (StdDev) | 3.2 (15.31) | 2.9 (15.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 50 |
| | | LS Mean (SE) | 3.3 (1.17) | 3.9 (1.56) |
| | | 95% CI | 1.0, 5.6 | 0.8, 6.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (1.95) | |
| | | 95% CI | -4.4, 3.2 | |
| | | p-value | 0.7556 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.30, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 3.5 (0.41) | 2.4 (0.60) |
| | | 95% CI | 2.7, 4.3 | 1.2, 3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.1 (0.73) | |
| | | 95% CI | -0.3, 2.6 | |
| | | p-value | 0.1208 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.03, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 480 | 244 |
| | | Mean (StdDev) | 16.5 (21.51) | 20.0 (22.86) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 428 | 229 |
| | | Mean (StdDev) | 15.4 (20.49) | 18.9 (22.62) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 425 | 229 |
| | | Mean (StdDev) | -0.4 (20.55) | -0.9 (20.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -83, 67 |
| | | LS Mean (SE) | -0.7 (0.94) | 0.6 (1.29) |
| | | 95% CI | -2.5, 1.2 | -1.9, 3.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (1.60) | |
| | | 95% CI | -4.4, 1.8 | |
| | | p-value | 0.4141 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.23, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 188 |
| | | Mean (StdDev) | 15.4 (20.89) | 20.7 (22.63) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 355 | 188 |
| | | Mean (StdDev) | -0.8 (17.65) | 1.2 (23.41) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 16.7 |
| | | Min, Max | -67, 50 | -83, 67 |
| | | LS Mean (SE) | -0.9 (0.95) | 3.1 (1.31) |
| | | 95% CI | -2.7, 1.0 | 0.5, 5.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.0 (1.62) | |
| | | 95% CI | -7.2, -0.8 | |
| | | p-value | 0.0139 | |
| | | Corrected Hedges g (95% CI) [2] | -0.22 (-0.40, -0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 321 | 161 |
| | | Mean (StdDev) | 16.9 (21.73) | 17.4 (21.36) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 83 |
| | Change from BL | n | 319 | 161 |
| | | Mean (StdDev) | 1.1 (19.97) | -1.3 (21.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -83, 67 |
| | | LS Mean (SE) | 1.0 (1.01) | 0.0 (1.41) |
| | | 95% CI | -0.9, 3.0 | -2.8, 2.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.0 (1.74) | |
| | | 95% CI | -2.4, 4.4 | |
| | | p-value | 0.5502 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.13, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 127 |
| | | Mean (StdDev) | 16.7 (21.18) | 19.3 (23.80) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 286 | 127 |
| | | Mean (StdDev) | 1.9 (19.66) | 0.1 (22.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | -67, 83 | -83, 67 |
| | | LS Mean (SE) | 1.2 (1.02) | 0.9 (1.49) |
| | | 95% CI | -0.8, 3.2 | -2.1, 3.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (1.80) | |
| | | 95% CI | -3.2, 3.9 | |
| | | p-value | 0.8285 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.19, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 256 | 102 |
| | | Mean (StdDev) | 17.3 (22.42) | 18.5 (24.92) |
| | | Median | 8.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 253 | 102 |
| | | Mean (StdDev) | 2.5 (20.85) | -0.5 (24.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 16.7 |
| | | Min, Max | -67, 100 | -83, 67 |
| | | LS Mean (SE) | 2.5 (1.13) | 0.7 (1.72) |
| | | 95% CI | 0.3, 4.7 | -2.7, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (2.06) | |
| | | 95% CI | -2.2, 5.9 | |
| | | p-value | 0.3792 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.13, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 236 | 96 |
| | | Mean (StdDev) | 16.2 (21.85) | 18.1 (23.28) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 234 | 96 |
| | | Mean (StdDev) | 1.1 (19.50) | -0.7 (22.02) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 83 | -83, 67 |
| | | LS Mean (SE) | 1.2 (1.08) | 0.4 (1.65) |
| | | 95% CI | -0.9, 3.3 | -2.8, 3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.8 (1.97) | |
| | | 95% CI | -3.1, 4.7 | |
| | | p-value | 0.6891 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.19, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 212 | 82 |
| | | Mean (StdDev) | 14.9 (21.21) | 16.7 (20.79) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 83 |
| | Change from BL | n | 209 | 82 |
| | | Mean (StdDev) | 0.2 (19.54) | -1.0 (20.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -83, 50 |
| | | LS Mean (SE) | 0.6 (1.04) | 0.1 (1.60) |
| | | 95% CI | -1.5, 2.6 | -3.1, 3.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.5 (1.90) | |
| | | 95% CI | -3.2, 4.3 | |
| | | p-value | 0.7869 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.22, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 14.5 (21.16) | 16.2 (23.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 25.0 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | 0.9 (21.66) | -1.2 (22.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 100 | -83, 67 |
| | | LS Mean (SE) | 0.2 (1.24) | -0.2 (1.91) |
| | | 95% CI | -2.2, 2.7 | -4.0, 3.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (2.28) | |
| | | 95% CI | -4.0, 4.9 | |
| | | p-value | 0.8465 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.25, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 14.9 (19.22) | 19.0 (25.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 146 | 56 |
| | | Mean (StdDev) | 0.7 (18.76) | 0.9 (24.29) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 8.3 |
| | | Min, Max | -67, 50 | -50, 67 |
| | | LS Mean (SE) | 0.5 (1.32) | 0.7 (2.07) |
| | | 95% CI | -2.1, 3.1 | -3.4, 4.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (2.46) | |
| | | 95% CI | -5.0, 4.7 | |
| | | p-value | 0.9471 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.32, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 14.2 (19.00) | 16.1 (23.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 1.1 (20.65) | -2.6 (22.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -33, 67 | -50, 67 |
| | | LS Mean (SE) | -0.7 (1.69) | -1.7 (2.72) |
| | | 95% CI | -4.1, 2.6 | -7.1, 3.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.0 (3.22) | |
| | | 95% CI | -5.4, 7.3 | |
| | | p-value | 0.7614 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.34, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 16.0 (19.02) | 15.7 (23.91) |
| | | Median | 16.7 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | 5.3 (20.00) | 1.0 (22.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 0.0 |
| | | Min, Max | -33, 67 | -17, 67 |
| | | LS Mean (SE) | 4.3 (2.26) | -0.4 (3.60) |
| | | 95% CI | -0.2, 8.8 | -7.6, 6.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.7 (4.22) | |
| | | 95% CI | -3.7, 13.1 | |
| | | p-value | 0.2693 | |
| | | Corrected Hedges g (95% CI) [2] | 0.30 (-0.25, 0.86) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 28 | 8 |
| | | Mean (StdDev) | 16.7 (21.75) | 4.2 (7.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 8.3 |
| | | Min, Max | 0, 67 | 0, 17 |
| | Change from BL | n | 28 | 8 |
| | | Mean (StdDev) | 7.1 (17.23) | -6.3 (12.40) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 0.0 |
| | | Min, Max | -17, 50 | -17, 17 |
| | | LS Mean (SE) | 5.9 (3.16) | -4.0 (5.49) |
| | | 95% CI | -0.5, 12.2 | -15.2, 7.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 9.9 (6.17) | |
| | | 95% CI | -2.6, 22.4 | |
| | | p-value | 0.1169 | |
| | | Corrected Hedges g (95% CI) [2] | 0.59 (-0.21, 1.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 10.7 (14.03) | 16.7 (23.57) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | 0, 33 | 0, 33 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 7.1 (14.19) | 8.3 (11.79) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -17, 33 | 0, 17 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 13.3 (29.81) | 50.0 (70.71) |
| | | Median | 0.0 | 50.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 100.0 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 13.3 (29.81) | 41.7 (58.93) |
| | | Median | 0.0 | 41.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 83.3 |
| | | Min, Max | 0, 67 | 0, 83 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 291 | 175 |
| | | Mean (StdDev) | 22.1 (23.85) | 23.7 (23.66) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 289 | 175 |
| | | Mean (StdDev) | 5.9 (24.53) | 4.0 (23.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -83, 83 |
| | | LS Mean (SE) | 5.4 (1.14) | 5.4 (1.50) |
| | | 95% CI | 3.1, 7.6 | 2.5, 8.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (1.88) | |
| | | 95% CI | -3.7, 3.7 | |
| | | p-value | 0.9892 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.19, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 151 | 105 |
| | | Mean (StdDev) | 23.8 (26.77) | 25.2 (24.36) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 151 | 105 |
| | | Mean (StdDev) | 7.9 (30.17) | 5.9 (26.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -83, 83 |
| | | LS Mean (SE) | 7.6 (1.75) | 7.4 (2.16) |
| | | 95% CI | 4.2, 11.1 | 3.1, 11.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (2.78) | |
| | | 95% CI | -5.2, 5.7 | |
| | | p-value | 0.9230 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.24, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 98 |
| | | Mean (StdDev) | 25.4 (24.74) | 23.3 (21.50) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 83 |
| | Change from BL | n | 168 | 98 |
| | | Mean (StdDev) | 8.2 (24.27) | 5.4 (21.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 83 | -50, 67 |
| | | LS Mean (SE) | 7.7 (1.43) | 5.6 (1.89) |
| | | 95% CI | 4.9, 10.5 | 1.9, 9.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.1 (2.37) | |
| | | 95% CI | -2.6, 6.7 | |
| | | p-value | 0.3837 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.14, 0.36) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 202 | 115 |
| | | Mean (StdDev) | 24.4 (24.83) | 24.1 (22.75) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 83 |
| | Change from BL | n | 200 | 115 |
| | | Mean (StdDev) | 7.8 (27.04) | 5.8 (23.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -83, 67 |
| | | LS Mean (SE) | 7.9 (1.40) | 6.1 (1.87) |
| | | 95% CI | 5.2, 10.7 | 2.5, 9.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (2.34) | |
| | | 95% CI | -2.8, 6.4 | |
| | | p-value | 0.4408 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.14, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 164 | 91 |
| | | Mean (StdDev) | 22.4 (25.21) | 21.2 (23.18) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 163 | 91 |
| | | Mean (StdDev) | 7.3 (24.22) | 3.8 (24.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 16.7 |
| | | Min, Max | -67, 67 | -50, 83 |
| | | LS Mean (SE) | 7.1 (1.55) | 4.1 (2.08) |
| | | 95% CI | 4.1, 10.2 | 0.1, 8.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.0 (2.59) | |
| | | 95% CI | -2.1, 8.1 | |
| | | p-value | 0.2477 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.11, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 3.0 (0.73) | 1.7 (1.06) |
| | | 95% CI | 1.6, 4.4 | -0.4, 3.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (1.29) | |
| | | 95% CI | -1.2, 3.8 | |
| | | p-value | 0.3105 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.07, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 244 |
| | | Mean (StdDev) | 14.4 (20.99) | 17.5 (23.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 425 | 229 |
| | | Mean (StdDev) | 19.4 (24.94) | 15.3 (23.03) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 422 | 229 |
| | | Mean (StdDev) | 4.9 (24.25) | -1.5 (21.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 4.8 (1.08) | -0.6 (1.47) |
| | | 95% CI | 2.7, 6.9 | -3.5, 2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.4 (1.83) | |
| | | 95% CI | 1.8, 9.0 | |
| | | p-value | 0.0033 | |
| | | Corrected Hedges g (95% CI) [2] | 0.24 (0.08, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 355 | 187 |
| | | Mean (StdDev) | 17.7 (23.80) | 14.6 (22.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 351 | 187 |
| | | Mean (StdDev) | 2.8 (24.13) | -1.4 (20.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 3.2 (1.11) | -1.1 (1.52) |
| | | 95% CI | 1.0, 5.3 | -4.0, 1.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.2 (1.88) | |
| | | 95% CI | 0.5, 7.9 | |
| | | p-value | 0.0257 | |
| | | Corrected Hedges g (95% CI) [2] | 0.20 (0.02, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 318 | 160 |
| | | Mean (StdDev) | 13.8 (21.61) | 12.3 (19.29) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 315 | 160 |
| | | Mean (StdDev) | -1.0 (20.84) | -3.3 (19.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | -0.4 (1.00) | -2.8 (1.39) |
| | | 95% CI | -2.4, 1.5 | -5.6, -0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.4 (1.71) | |
| | | 95% CI | -1.0, 5.8 | |
| | | p-value | 0.1637 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.06, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 288 | 127 |
| | | Mean (StdDev) | 13.1 (20.88) | 16.5 (22.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 284 | 127 |
| | | Mean (StdDev) | -0.5 (18.79) | -0.8 (22.41) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -67, 67 |
| | | LS Mean (SE) | -0.8 (1.06) | -0.2 (1.56) |
| | | 95% CI | -2.9, 1.3 | -3.3, 2.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (1.89) | |
| | | 95% CI | -4.3, 3.2 | |
| | | p-value | 0.7702 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.24, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 255 | 102 |
| | | Mean (StdDev) | 10.8 (18.94) | 14.7 (24.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 252 | 102 |
| | | Mean (StdDev) | -1.2 (20.25) | -1.6 (23.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | -1.9 (1.10) | -0.6 (1.67) |
| | | 95% CI | -4.1, 0.3 | -3.9, 2.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (2.00) | |
| | | 95% CI | -5.2, 2.6 | |
| | | p-value | 0.5192 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.30, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 235 | 96 |
| | | Mean (StdDev) | 12.2 (20.50) | 15.6 (22.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 233 | 96 |
| | | Mean (StdDev) | 0.0 (19.57) | -2.1 (22.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -67, 33 |
| | | LS Mean (SE) | -0.7 (1.08) | -0.8 (1.65) |
| | | 95% CI | -2.9, 1.4 | -4.0, 2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (1.98) | |
| | | 95% CI | -3.8, 4.0 | |
| | | p-value | 0.9687 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.23, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 13.4 (20.93) | 15.0 (21.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 208 | 82 |
| | | Mean (StdDev) | 1.3 (20.16) | -2.0 (21.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 0.6 (1.13) | 0.0 (1.75) |
| | | 95% CI | -1.6, 2.9 | -3.4, 3.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (2.09) | |
| | | 95% CI | -3.5, 4.7 | |
| | | p-value | 0.7690 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.22, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 12.1 (19.64) | 17.8 (23.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | 1.1 (22.79) | -0.5 (26.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | -0.2 (1.31) | 3.7 (2.01) |
| | | 95% CI | -2.8, 2.3 | -0.2, 7.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.0 (2.41) | |
| | | 95% CI | -8.7, 0.8 | |
| | | p-value | 0.0992 | |
| | | Corrected Hedges g (95% CI) [2] | -0.23 (-0.51, 0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 14.5 (20.30) | 20.8 (25.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 146 | 56 |
| | | Mean (StdDev) | 4.1 (21.04) | 1.2 (25.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -33, 100 |
| | | LS Mean (SE) | 2.7 (1.46) | 4.0 (2.29) |
| | | 95% CI | -0.2, 5.5 | -0.5, 8.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (2.74) | |
| | | 95% CI | -6.7, 4.1 | |
| | | p-value | 0.6239 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.38, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 12.5 (19.78) | 15.6 (23.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 2.7 (19.72) | -1.0 (21.56) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 33 | -67, 67 |
| | | LS Mean (SE) | 0.4 (1.51) | -0.1 (2.41) |
| | | 95% CI | -2.6, 3.4 | -4.9, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.5 (2.86) | |
| | | 95% CI | -5.1, 6.2 | |
| | | p-value | 0.8601 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.37, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 8.5 (17.68) | 15.7 (26.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | 0.0 (20.85) | -3.9 (20.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 33 |
| | | LS Mean (SE) | -0.8 (1.85) | -2.2 (2.96) |
| | | 95% CI | -4.4, 2.9 | -8.1, 3.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (3.54) | |
| | | 95% CI | -5.6, 8.4 | |
| | | p-value | 0.6921 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.44, 0.67) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 28 | 8 |
| | | Mean (StdDev) | 13.1 (20.96) | 16.7 (25.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 28 | 8 |
| | | Mean (StdDev) | 2.4 (22.09) | -12.5 (17.25) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -33, 67 | -33, 0 |
| | | LS Mean (SE) | 0.9 (2.77) | -2.8 (5.22) |
| | | 95% CI | -4.7, 6.5 | -13.4, 7.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.7 (6.02) | |
| | | 95% CI | -8.5, 15.9 | |
| | | p-value | 0.5412 | |
| | | Corrected Hedges g (95% CI) [2] | 0.25 (-0.54, 1.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 4.8 (12.10) | 16.7 (23.57) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 33 | 0, 33 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.0 (18.49) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 33 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 16.7 (23.57) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 0 | 0, 33 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -13.3 (18.26) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 0 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -33.3 (NA) | |
| | | Median | -33.3 | |
| | | Q1, Q3 | -33.3, -33.3 | |
| | | Min, Max | -33, -33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 286 | 172 |
| | | Mean (StdDev) | 21.9 (25.93) | 19.8 (23.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 283 | 172 |
| | | Mean (StdDev) | 6.6 (26.70) | 1.9 (24.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 100 |
| | | LS Mean (SE) | 6.1 (1.29) | 3.8 (1.67) |
| | | 95% CI | 3.6, 8.6 | 0.5, 7.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.3 (2.11) | |
| | | 95% CI | -1.8, 6.5 | |
| | | p-value | 0.2672 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.08, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 151 | 104 |
| | | Mean (StdDev) | 20.8 (27.95) | 19.9 (24.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 150 | 104 |
| | | Mean (StdDev) | 3.1 (26.57) | 1.6 (24.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 100 |
| | | LS Mean (SE) | 3.5 (1.71) | 3.2 (2.10) |
| | | 95% CI | 0.1, 6.8 | -0.9, 7.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (2.70) | |
| | | 95% CI | -5.0, 5.6 | |
| | | p-value | 0.9191 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.24, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 97 |
| | | Mean (StdDev) | 19.4 (25.04) | 23.0 (27.37) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 167 | 97 |
| | | Mean (StdDev) | 3.2 (26.94) | 4.5 (27.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | 3.4 (1.62) | 6.7 (2.14) |
| | | 95% CI | 0.2, 6.6 | 2.5, 10.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.3 (2.68) | |
| | | 95% CI | -8.6, 1.9 | |
| | | p-value | 0.2142 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.41, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 202 | 115 |
| | | Mean (StdDev) | 21.1 (25.42) | 21.7 (25.76) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 199 | 115 |
| | | Mean (StdDev) | 4.9 (27.30) | 5.5 (24.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | 5.3 (1.53) | 6.2 (2.03) |
| | | 95% CI | 2.3, 8.3 | 2.3, 10.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.0 (2.54) | |
| | | 95% CI | -6.0, 4.0 | |
| | | p-value | 0.7001 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.27, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 163 | 91 |
| | | Mean (StdDev) | 20.0 (25.54) | 24.2 (26.79) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 161 | 91 |
| | | Mean (StdDev) | 3.3 (27.18) | 6.6 (26.86) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 4.2 (1.80) | 8.6 (2.41) |
| | | 95% CI | 0.6, 7.7 | 3.9, 13.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.4 (3.00) | |
| | | 95% CI | -10.3, 1.5 | |
| | | p-value | 0.1424 | |
| | | Corrected Hedges g (95% CI) [2] | -0.19 (-0.45, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 1.8 (0.70) | 1.5 (1.02) |
| | | 95% CI | 0.4, 3.1 | -0.5, 3.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (1.24) | |
| | | 95% CI | -2.1, 2.7 | |
| | | p-value | 0.8116 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.14, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 244 |
| | | Mean (StdDev) | 26.6 (28.82) | 29.1 (30.02) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 427 | 229 |
| | | Mean (StdDev) | 35.0 (30.56) | 31.1 (31.22) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 423 | 229 |
| | | Mean (StdDev) | 9.4 (31.53) | 2.0 (25.09) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 100 |
| | | LS Mean (SE) | 9.4 (1.33) | 3.2 (1.82) |
| | | 95% CI | 6.8, 12.0 | -0.3, 6.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 6.2 (2.25) | |
| | | 95% CI | 1.7, 10.6 | |
| | | p-value | 0.0063 | |
| | | Corrected Hedges g (95% CI) [2] | 0.22 (0.06, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 359 | 187 |
| | | Mean (StdDev) | 31.5 (28.02) | 28.9 (29.70) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 355 | 187 |
| | | Mean (StdDev) | 5.2 (29.35) | 0.4 (29.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 5.0 (1.32) | 1.8 (1.83) |
| | | 95% CI | 2.4, 7.6 | -1.8, 5.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.1 (2.26) | |
| | | 95% CI | -1.3, 7.6 | |
| | | p-value | 0.1671 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.05, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 320 | 160 |
| | | Mean (StdDev) | 30.9 (28.02) | 25.6 (28.03) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 317 | 160 |
| | | Mean (StdDev) | 4.6 (29.64) | -0.8 (31.04) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -16.7, 0.0 |
| | | Min, Max | -100, 67 | -100, 100 |
| | | LS Mean (SE) | 4.7 (1.36) | -0.4 (1.90) |
| | | 95% CI | 2.0, 7.4 | -4.1, 3.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.1 (2.34) | |
| | | 95% CI | 0.5, 9.7 | |
| | | p-value | 0.0295 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (0.02, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 127 |
| | | Mean (StdDev) | 32.1 (29.96) | 30.4 (30.29) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 285 | 127 |
| | | Mean (StdDev) | 7.8 (28.48) | 3.4 (30.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | 6.8 (1.40) | 2.9 (2.05) |
| | | 95% CI | 4.0, 9.5 | -1.2, 6.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.9 (2.49) | |
| | | 95% CI | -0.9, 8.8 | |
| | | p-value | 0.1134 | |
| | | Corrected Hedges g (95% CI) [2] | 0.17 (-0.04, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 255 | 102 |
| | | Mean (StdDev) | 29.3 (27.37) | 30.7 (33.06) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 252 | 102 |
| | | Mean (StdDev) | 6.1 (30.32) | 5.2 (31.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 100 |
| | | LS Mean (SE) | 4.9 (1.55) | 4.2 (2.36) |
| | | 95% CI | 1.9, 8.0 | -0.5, 8.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.8 (2.82) | |
| | | 95% CI | -4.8, 6.3 | |
| | | p-value | 0.7896 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.20, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 235 | 96 |
| | | Mean (StdDev) | 29.2 (26.64) | 28.1 (29.94) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 233 | 96 |
| | | Mean (StdDev) | 6.4 (31.13) | 2.1 (30.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 5.0 (1.56) | 1.4 (2.37) |
| | | 95% CI | 2.0, 8.1 | -3.2, 6.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.6 (2.83) | |
| | | 95% CI | -2.0, 9.2 | |
| | | p-value | 0.2030 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.09, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 27.3 (26.34) | 27.6 (28.11) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 208 | 82 |
| | | Mean (StdDev) | 5.3 (30.19) | 2.8 (29.72) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 100 |
| | | LS Mean (SE) | 3.8 (1.52) | 2.5 (2.34) |
| | | 95% CI | 0.8, 6.7 | -2.1, 7.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (2.79) | |
| | | 95% CI | -4.2, 6.7 | |
| | | p-value | 0.6559 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.20, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 25.0 (24.82) | 30.0 (30.42) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | 2.5 (29.39) | 3.8 (32.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 67 | -100, 100 |
| | | LS Mean (SE) | 1.4 (1.67) | 3.8 (2.56) |
| | | 95% CI | -1.9, 4.7 | -1.2, 8.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.4 (3.06) | |
| | | 95% CI | -8.4, 3.6 | |
| | | p-value | 0.4334 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.38, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 29.0 (28.21) | 31.0 (31.69) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 146 | 56 |
| | | Mean (StdDev) | 5.3 (29.73) | 1.2 (33.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 33.3 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | 4.9 (1.85) | 2.0 (2.93) |
| | | 95% CI | 1.2, 8.5 | -3.8, 7.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.9 (3.47) | |
| | | 95% CI | -3.9, 9.7 | |
| | | p-value | 0.4061 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.18, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 26.5 (29.10) | 34.4 (29.92) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 3.0 (30.59) | 0.0 (32.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -67, 100 |
| | | LS Mean (SE) | 1.4 (2.22) | 0.6 (3.65) |
| | | 95% CI | -3.0, 5.8 | -6.6, 7.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.8 (4.29) | |
| | | 95% CI | -7.7, 9.3 | |
| | | p-value | 0.8482 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.37, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 31.9 (31.05) | 35.3 (29.98) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 33.3, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | 11.3 (33.53) | -7.8 (27.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -100, 100 | -67, 33 |
| | | LS Mean (SE) | 9.9 (2.97) | -0.1 (5.02) |
| | | 95% CI | 4.0, 15.8 | -10.1, 9.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 10.0 (5.94) | |
| | | 95% CI | -1.9, 21.8 | |
| | | p-value | 0.0974 | |
| | | Corrected Hedges g (95% CI) [2] | 0.48 (-0.08, 1.04) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 28 | 8 |
| | | Mean (StdDev) | 35.7 (33.86) | 41.7 (34.50) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 16.7, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 28 | 8 |
| | | Mean (StdDev) | 11.9 (37.64) | -4.2 (21.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -16.7, 0.0 |
| | | Min, Max | -100, 100 | -33, 33 |
| | | LS Mean (SE) | 7.8 (3.85) | 0.6 (7.34) |
| | | 95% CI | 0.1, 15.6 | -14.3, 15.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 7.3 (8.35) | |
| | | 95% CI | -9.7, 24.2 | |
| | | p-value | 0.3901 | |
| | | Corrected Hedges g (95% CI) [2] | 0.35 (-0.44, 1.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 28.6 (36.65) | 50.0 (23.57) |
| | | Median | 16.7 | 50.0 |
| | | Q1, Q3 | 0.0, 33.3 | 33.3, 66.7 |
| | | Min, Max | 0, 100 | 33, 67 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 2.4 (40.22) | 0.0 (47.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 33.3 |
| | | Min, Max | -100, 67 | -33, 33 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 13.3 (18.26) | 66.7 (0.00) |
| | | Median | 0.0 | 66.7 |
| | | Q1, Q3 | 0.0, 33.3 | 66.7, 66.7 |
| | | Min, Max | 0, 33 | 67, 67 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 6.7 (27.89) | 16.7 (23.57) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -33, 33 | 0, 33 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 287 | 173 |
| | | Mean (StdDev) | 33.2 (28.36) | 30.6 (29.73) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 284 | 173 |
| | | Mean (StdDev) | 6.5 (34.11) | 2.5 (31.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 6.1 (1.47) | 4.3 (1.91) |
| | | 95% CI | 3.3, 9.0 | 0.6, 8.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (2.41) | |
| | | 95% CI | -2.9, 6.5 | |
| | | p-value | 0.4546 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.12, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 104 |
| | | Mean (StdDev) | 30.4 (27.29) | 34.0 (30.80) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | 3.4 (28.14) | 3.5 (34.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 67 | -100, 100 |
| | | LS Mean (SE) | 3.8 (1.88) | 6.1 (2.32) |
| | | 95% CI | 0.1, 7.5 | 1.5, 10.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.2 (2.98) | |
| | | 95% CI | -8.1, 3.6 | |
| | | p-value | 0.4573 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.35, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 169 | 97 |
| | | Mean (StdDev) | 28.4 (27.13) | 35.1 (29.02) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 166 | 97 |
| | | Mean (StdDev) | 0.0 (30.48) | 5.8 (28.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 2.4 (1.77) | 8.8 (2.34) |
| | | 95% CI | -1.1, 5.8 | 4.2, 13.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -6.5 (2.93) | |
| | | 95% CI | -12.2, -0.7 | |
| | | p-value | 0.0277 | |
| | | Corrected Hedges g (95% CI) [2] | -0.28 (-0.53, -0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 202 | 115 |
| | | Mean (StdDev) | 30.2 (29.10) | 27.2 (28.47) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 199 | 115 |
| | | Mean (StdDev) | 2.0 (34.92) | -2.6 (33.38) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 33.3 | -33.3, 0.0 |
| | | Min, Max | -100, 100 | -100, 100 |
| | | LS Mean (SE) | 3.2 (1.76) | -0.3 (2.34) |
| | | 95% CI | -0.2, 6.7 | -4.9, 4.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.5 (2.93) | |
| | | 95% CI | -2.2, 9.3 | |
| | | p-value | 0.2280 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.09, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 163 | 91 |
| | | Mean (StdDev) | 29.7 (26.96) | 27.5 (27.03) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 161 | 91 |
| | | Mean (StdDev) | -0.2 (28.01) | -2.9 (27.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 33.3 | -33.3, 0.0 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 1.9 (1.73) | -0.6 (2.32) |
| | | 95% CI | -1.5, 5.3 | -5.2, 3.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.5 (2.89) | |
| | | 95% CI | -3.1, 8.2 | |
| | | p-value | 0.3821 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.14, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 4.9 (0.92) | 2.4 (1.36) |
| | | 95% CI | 3.1, 6.6 | -0.3, 5.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.5 (1.64) | |
| | | 95% CI | -0.8, 5.7 | |
| | | p-value | 0.1355 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.03, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 479 | 244 |
| | | Mean (StdDev) | 8.1 (17.94) | 8.7 (18.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 427 | 229 |
| | | Mean (StdDev) | 14.5 (22.08) | 7.1 (17.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 423 | 229 |
| | | Mean (StdDev) | 6.5 (22.41) | -1.3 (21.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 100 |
| | | LS Mean (SE) | 6.8 (0.93) | -0.5 (1.28) |
| | | 95% CI | 4.9, 8.6 | -3.0, 2.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 7.2 (1.58) | |
| | | 95% CI | 4.1, 10.3 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.37 (0.21, 0.54) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 357 | 187 |
| | | Mean (StdDev) | 10.9 (19.88) | 5.9 (17.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 353 | 187 |
| | | Mean (StdDev) | 2.8 (21.86) | -1.6 (18.38) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 3.3 (0.90) | -1.5 (1.24) |
| | | 95% CI | 1.5, 5.0 | -3.9, 1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.8 (1.54) | |
| | | 95% CI | 1.7, 7.8 | |
| | | p-value | 0.0020 | |
| | | Corrected Hedges g (95% CI) [2] | 0.28 (0.10, 0.46) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 319 | 160 |
| | | Mean (StdDev) | 7.8 (17.07) | 5.8 (14.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 316 | 160 |
| | | Mean (StdDev) | 0.7 (20.82) | -1.5 (19.19) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 1.0 (0.89) | -1.0 (1.25) |
| | | 95% CI | -0.7, 2.8 | -3.5, 1.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.1 (1.53) | |
| | | 95% CI | -0.9, 5.1 | |
| | | p-value | 0.1786 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.06, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 127 |
| | | Mean (StdDev) | 8.1 (18.53) | 7.6 (19.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 285 | 127 |
| | | Mean (StdDev) | 2.3 (20.03) | 0.3 (22.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -100, 100 |
| | | LS Mean (SE) | 1.9 (1.10) | 0.3 (1.62) |
| | | 95% CI | -0.2, 4.1 | -2.9, 3.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.6 (1.96) | |
| | | 95% CI | -2.2, 5.5 | |
| | | p-value | 0.4111 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.12, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 255 | 101 |
| | | Mean (StdDev) | 7.1 (17.06) | 7.9 (19.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 252 | 101 |
| | | Mean (StdDev) | 1.2 (18.90) | 0.0 (23.09) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 100 |
| | | LS Mean (SE) | 1.4 (0.99) | 0.0 (1.52) |
| | | 95% CI | -0.6, 3.3 | -2.9, 3.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (1.81) | |
| | | 95% CI | -2.2, 4.9 | |
| | | p-value | 0.4638 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.15, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 235 | 96 |
| | | Mean (StdDev) | 6.4 (15.77) | 5.2 (15.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 233 | 96 |
| | | Mean (StdDev) | 1.1 (18.53) | -2.4 (22.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -100, 67 |
| | | LS Mean (SE) | 0.7 (0.97) | -2.4 (1.47) |
| | | 95% CI | -1.2, 2.6 | -5.3, 0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.1 (1.76) | |
| | | 95% CI | -0.4, 6.5 | |
| | | p-value | 0.0839 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (-0.03, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 6.6 (17.46) | 4.9 (13.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 208 | 82 |
| | | Mean (StdDev) | 1.8 (18.01) | -0.4 (18.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 1.6 (1.10) | -2.3 (1.71) |
| | | 95% CI | -0.5, 3.8 | -5.6, 1.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.9 (2.03) | |
| | | 95% CI | -0.1, 7.9 | |
| | | p-value | 0.0552 | |
| | | Corrected Hedges g (95% CI) [2] | 0.25 (-0.01, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 5.3 (13.70) | 4.2 (12.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | 0.8 (17.44) | -1.4 (16.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -33, 67 |
| | | LS Mean (SE) | -0.2 (0.97) | -2.8 (1.48) |
| | | 95% CI | -2.1, 1.7 | -5.7, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (1.76) | |
| | | 95% CI | -0.9, 6.0 | |
| | | p-value | 0.1474 | |
| | | Corrected Hedges g (95% CI) [2] | 0.20 (-0.08, 0.48) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 9.5 (19.89) | 8.9 (23.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 146 | 56 |
| | | Mean (StdDev) | 5.0 (23.27) | 3.6 (24.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | 4.2 (1.65) | 1.1 (2.62) |
| | | 95% CI | 0.9, 7.4 | -4.1, 6.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.1 (3.08) | |
| | | 95% CI | -3.0, 9.1 | |
| | | p-value | 0.3198 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.15, 0.46) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 8.0 (16.76) | 7.3 (14.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 33 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 4.2 (19.45) | 3.1 (15.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 33 |
| | | LS Mean (SE) | 2.3 (1.52) | -2.0 (2.44) |
| | | 95% CI | -0.7, 5.3 | -6.8, 2.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.3 (2.84) | |
| | | 95% CI | -1.4, 9.9 | |
| | | p-value | 0.1359 | |
| | | Corrected Hedges g (95% CI) [2] | 0.30 (-0.11, 0.71) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 7.1 (15.44) | 7.8 (18.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | 4.3 (19.18) | 5.9 (21.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 67 |
| | | LS Mean (SE) | 1.3 (1.81) | -1.4 (2.88) |
| | | 95% CI | -2.3, 4.9 | -7.1, 4.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.7 (3.24) | |
| | | 95% CI | -3.7, 9.2 | |
| | | p-value | 0.4061 | |
| | | Corrected Hedges g (95% CI) [2] | 0.22 (-0.34, 0.77) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 28 | 8 |
| | | Mean (StdDev) | 10.7 (15.85) | 4.2 (11.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 33 |
| | Change from BL | n | 28 | 8 |
| | | Mean (StdDev) | 8.3 (14.70) | 4.2 (11.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 33 |
| | | LS Mean (SE) | 6.0 (2.61) | -1.2 (4.56) |
| | | 95% CI | 0.7, 11.2 | -10.5, 8.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 7.2 (4.77) | |
| | | 95% CI | -2.5, 16.9 | |
| | | p-value | 0.1407 | |
| | | Corrected Hedges g (95% CI) [2] | 0.52 (-0.28, 1.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 2.4 (8.91) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 2.4 (8.91) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 16.7 (23.57) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 0 | 0, 33 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 16.7 (23.57) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 0 | 0, 33 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 288 | 172 |
| | | Mean (StdDev) | 17.4 (27.40) | 11.4 (22.04) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 285 | 172 |
| | | Mean (StdDev) | 8.2 (29.52) | 2.1 (24.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | 9.1 (1.35) | 3.8 (1.75) |
| | | 95% CI | 6.4, 11.8 | 0.4, 7.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.3 (2.21) | |
| | | 95% CI | 0.9, 9.6 | |
| | | p-value | 0.0170 | |
| | | Corrected Hedges g (95% CI) [2] | 0.23 (0.04, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 104 |
| | | Mean (StdDev) | 17.1 (28.05) | 12.5 (23.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | 6.9 (32.48) | 3.5 (30.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 100 |
| | | LS Mean (SE) | 10.0 (2.00) | 6.0 (2.42) |
| | | 95% CI | 6.1, 13.9 | 1.2, 10.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.0 (3.13) | |
| | | 95% CI | -2.1, 10.2 | |
| | | p-value | 0.1991 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.09, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 97 |
| | | Mean (StdDev) | 15.1 (24.07) | 15.8 (24.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 167 | 97 |
| | | Mean (StdDev) | 3.8 (27.48) | 6.9 (28.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | 6.6 (1.74) | 8.6 (2.27) |
| | | 95% CI | 3.2, 10.0 | 4.2, 13.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.0 (2.85) | |
| | | 95% CI | -7.7, 3.6 | |
| | | p-value | 0.4734 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.34, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 202 | 114 |
| | | Mean (StdDev) | 16.2 (26.02) | 12.0 (19.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 199 | 114 |
| | | Mean (StdDev) | 6.0 (28.57) | 2.9 (21.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 7.5 (1.58) | 5.4 (2.08) |
| | | 95% CI | 4.4, 10.6 | 1.3, 9.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.2 (2.61) | |
| | | 95% CI | -3.0, 7.3 | |
| | | p-value | 0.4065 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.13, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 163 | 91 |
| | | Mean (StdDev) | 14.7 (26.99) | 13.6 (24.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 161 | 91 |
| | | Mean (StdDev) | 3.7 (28.14) | 5.1 (27.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | 6.5 (1.95) | 7.2 (2.58) |
| | | 95% CI | 2.7, 10.4 | 2.2, 12.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.7 (3.23) | |
| | | 95% CI | -7.1, 5.7 | |
| | | p-value | 0.8290 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.29, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 4.1 (0.64) | 1.0 (0.93) |
| | | 95% CI | 2.9, 5.4 | -0.8, 2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.1 (1.11) | |
| | | 95% CI | 0.9, 5.3 | |
| | | p-value | 0.0058 | |
| | | Corrected Hedges g (95% CI) [2] | 0.22 (0.06, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 244 |
| | | Mean (StdDev) | 16.7 (24.59) | 18.4 (25.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 428 | 228 |
| | | Mean (StdDev) | 30.9 (31.81) | 14.3 (23.82) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 424 | 228 |
| | | Mean (StdDev) | 14.2 (33.20) | -3.7 (21.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 14.0 (1.37) | -3.3 (1.88) |
| | | 95% CI | 11.4, 16.7 | -7.0, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 17.4 (2.33) | |
| | | 95% CI | 12.8, 21.9 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.61 (0.45, 0.78) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 188 |
| | | Mean (StdDev) | 27.3 (29.69) | 14.9 (24.19) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 354 | 188 |
| | | Mean (StdDev) | 10.8 (30.71) | -3.5 (24.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 10.9 (1.30) | -2.3 (1.79) |
| | | 95% CI | 8.3, 13.4 | -5.8, 1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 13.2 (2.21) | |
| | | 95% CI | 8.8, 17.5 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.54 (0.36, 0.72) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 320 | 160 |
| | | Mean (StdDev) | 25.1 (30.64) | 13.3 (22.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 316 | 160 |
| | | Mean (StdDev) | 9.2 (29.99) | -5.4 (24.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 8.7 (1.35) | -4.0 (1.89) |
| | | 95% CI | 6.0, 11.3 | -7.7, -0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 12.6 (2.33) | |
| | | 95% CI | 8.1, 17.2 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.52 (0.33, 0.72) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 127 |
| | | Mean (StdDev) | 25.0 (28.87) | 16.0 (26.18) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 285 | 127 |
| | | Mean (StdDev) | 9.8 (28.47) | -4.2 (23.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 9.5 (1.35) | -3.0 (1.98) |
| | | 95% CI | 6.8, 12.1 | -6.8, 0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 12.4 (2.40) | |
| | | 95% CI | 7.7, 17.1 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.55 (0.34, 0.76) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 254 | 102 |
| | | Mean (StdDev) | 23.9 (27.77) | 17.0 (26.43) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 251 | 102 |
| | | Mean (StdDev) | 8.5 (27.46) | -4.2 (18.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -33, 100 | -33, 67 |
| | | LS Mean (SE) | 8.8 (1.32) | -2.6 (2.01) |
| | | 95% CI | 6.2, 11.3 | -6.6, 1.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 11.4 (2.41) | |
| | | 95% CI | 6.7, 16.1 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.55 (0.32, 0.78) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 235 | 96 |
| | | Mean (StdDev) | 24.5 (29.04) | 16.3 (26.49) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 233 | 96 |
| | | Mean (StdDev) | 8.4 (28.37) | -3.8 (23.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 100 |
| | | LS Mean (SE) | 8.6 (1.44) | -2.4 (2.19) |
| | | 95% CI | 5.7, 11.4 | -6.7, 1.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 11.0 (2.62) | |
| | | 95% CI | 5.8, 16.1 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.50 (0.26, 0.74) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 82 |
| | | Mean (StdDev) | 26.1 (29.99) | 15.4 (27.81) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 208 | 82 |
| | | Mean (StdDev) | 9.5 (28.40) | -4.9 (24.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 10.2 (1.50) | -3.3 (2.34) |
| | | 95% CI | 7.3, 13.2 | -7.9, 1.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 13.5 (2.78) | |
| | | 95% CI | 8.1, 19.0 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.63 (0.37, 0.89) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 21.6 (28.53) | 16.0 (26.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | 4.7 (28.89) | -4.7 (24.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -67, 100 |
| | | LS Mean (SE) | 6.5 (1.61) | -2.6 (2.49) |
| | | 95% CI | 3.4, 9.7 | -7.5, 2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 9.1 (2.96) | |
| | | 95% CI | 3.3, 15.0 | |
| | | p-value | 0.0022 | |
| | | Corrected Hedges g (95% CI) [2] | 0.43 (0.15, 0.71) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 147 | 56 |
| | | Mean (StdDev) | 21.8 (29.36) | 17.9 (28.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 146 | 56 |
| | | Mean (StdDev) | 5.3 (30.50) | -4.8 (29.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -67, 100 |
| | | LS Mean (SE) | 6.6 (1.87) | 0.0 (2.98) |
| | | 95% CI | 2.9, 10.2 | -5.9, 5.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 6.6 (3.52) | |
| | | 95% CI | -0.3, 13.5 | |
| | | p-value | 0.0623 | |
| | | Corrected Hedges g (95% CI) [2] | 0.29 (-0.02, 0.60) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 23.1 (30.05) | 10.4 (21.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | 5.3 (34.97) | -7.3 (27.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 6.5 (2.20) | -4.5 (3.59) |
| | | 95% CI | 2.1, 10.8 | -11.6, 2.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 11.0 (4.21) | |
| | | 95% CI | 2.7, 19.3 | |
| | | p-value | 0.0099 | |
| | | Corrected Hedges g (95% CI) [2] | 0.53 (0.12, 0.94) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 17.0 (21.84) | 15.7 (17.15) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 33 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | -1.4 (29.45) | -2.0 (29.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | -33.3, 33.3 |
| | | Min, Max | -67, 100 | -67, 33 |
| | | LS Mean (SE) | 4.7 (2.43) | 0.9 (3.99) |
| | | 95% CI | -0.1, 9.6 | -7.1, 8.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.9 (4.67) | |
| | | 95% CI | -5.4, 13.2 | |
| | | p-value | 0.4100 | |
| | | Corrected Hedges g (95% CI) [2] | 0.23 (-0.33, 0.79) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 28 | 8 |
| | | Mean (StdDev) | 19.0 (29.30) | 12.5 (24.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 28 | 8 |
| | | Mean (StdDev) | 2.4 (33.86) | -16.7 (17.82) |
| | | Median | 0.0 | -16.7 |
| | | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 |
| | | Min, Max | -33, 100 | -33, 0 |
| | | LS Mean (SE) | 4.5 (2.47) | -3.7 (4.53) |
| | | 95% CI | -0.5, 9.5 | -12.8, 5.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 8.1 (5.17) | |
| | | 95% CI | -2.3, 18.6 | |
| | | p-value | 0.1230 | |
| | | Corrected Hedges g (95% CI) [2] | 0.61 (-0.19, 1.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 11.9 (28.06) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | -4.8 (38.91) | -16.7 (23.57) |
| | | Median | 0.0 | -16.7 |
| | | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -33, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 6.7 (14.91) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (23.57) | -16.7 (23.57) |
| | | Median | 0.0 | -16.7 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -33, 33 | -33, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 33.3 (NA) | |
| | | Median | 33.3 | |
| | | Q1, Q3 | 33.3, 33.3 | |
| | | Min, Max | 33, 33 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 33.3 (NA) | |
| | | Median | 33.3 | |
| | | Q1, Q3 | 33.3, 33.3 | |
| | | Min, Max | 33, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 287 | 174 |
| | | Mean (StdDev) | 28.7 (32.29) | 19.3 (25.64) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 284 | 174 |
| | | Mean (StdDev) | 12.0 (36.18) | 1.3 (27.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 100 |
| | | LS Mean (SE) | 10.4 (1.63) | 1.5 (2.10) |
| | | 95% CI | 7.2, 13.6 | -2.6, 5.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 8.9 (2.66) | |
| | | 95% CI | 3.7, 14.1 | |
| | | p-value | 0.0009 | |
| | | Corrected Hedges g (95% CI) [2] | 0.32 (0.13, 0.51) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 104 |
| | | Mean (StdDev) | 18.0 (25.51) | 22.1 (28.86) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | 0.2 (33.89) | 5.8 (30.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 100 |
| | | LS Mean (SE) | -1.2 (1.99) | 5.0 (2.45) |
| | | 95% CI | -5.1, 2.7 | 0.2, 9.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -6.2 (3.16) | |
| | | 95% CI | -12.4, 0.0 | |
| | | p-value | 0.0508 | |
| | | Corrected Hedges g (95% CI) [2] | -0.25 (-0.50, 0.00) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 96 |
| | | Mean (StdDev) | 16.5 (24.93) | 23.3 (28.25) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 167 | 96 |
| | | Mean (StdDev) | -2.0 (29.66) | 8.0 (30.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 100 |
| | | LS Mean (SE) | -1.1 (1.83) | 7.1 (2.42) |
| | | 95% CI | -4.7, 2.5 | 2.4, 11.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -8.2 (3.04) | |
| | | 95% CI | -14.2, -2.2 | |
| | | p-value | 0.0072 | |
| | | Corrected Hedges g (95% CI) [2] | -0.35 (-0.60, -0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 201 | 115 |
| | | Mean (StdDev) | 20.9 (28.77) | 24.1 (29.14) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 198 | 115 |
| | | Mean (StdDev) | 3.2 (32.84) | 8.7 (28.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 100 |
| | | LS Mean (SE) | 3.0 (1.82) | 7.7 (2.41) |
| | | 95% CI | -0.6, 6.6 | 2.9, 12.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.7 (3.03) | |
| | | 95% CI | -10.6, 1.3 | |
| | | p-value | 0.1223 | |
| | | Corrected Hedges g (95% CI) [2] | -0.18 (-0.41, 0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 163 | 91 |
| | | Mean (StdDev) | 14.7 (23.74) | 17.6 (26.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 161 | 91 |
| | | Mean (StdDev) | -2.7 (31.62) | 2.9 (27.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 100 |
| | | LS Mean (SE) | -2.5 (1.86) | 1.5 (2.49) |
| | | 95% CI | -6.1, 1.2 | -3.4, 6.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.0 (3.11) | |
| | | 95% CI | -10.1, 2.1 | |
| | | p-value | 0.2004 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.43, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 6.4 (0.89) | -0.5 (1.30) |
| | | 95% CI | 4.6, 8.1 | -3.0, 2.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 6.8 (1.57) | |
| | | 95% CI | 3.7, 9.9 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.35 (0.19, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 478 | 243 |
| | | Mean (StdDev) | 7.3 (16.68) | 8.8 (20.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 424 | 229 |
| | | Mean (StdDev) | 4.5 (13.50) | 8.7 (19.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 420 | 228 |
| | | Mean (StdDev) | -2.0 (16.57) | -0.3 (17.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | -2.3 (0.69) | 0.9 (0.94) |
| | | 95% CI | -3.6, -0.9 | -0.9, 2.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.2 (1.17) | |
| | | 95% CI | -5.5, -0.9 | |
| | | p-value | 0.0064 | |
| | | Corrected Hedges g (95% CI) [2] | -0.23 (-0.39, -0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 186 |
| | | Mean (StdDev) | 5.2 (15.10) | 7.9 (17.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 353 | 185 |
| | | Mean (StdDev) | -2.7 (18.35) | 0.0 (19.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | -2.1 (0.78) | 1.0 (1.08) |
| | | 95% CI | -3.7, -0.6 | -1.2, 3.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.1 (1.33) | |
| | | 95% CI | -5.7, -0.5 | |
| | | p-value | 0.0210 | |
| | | Corrected Hedges g (95% CI) [2] | -0.21 (-0.39, -0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 321 | 161 |
| | | Mean (StdDev) | 5.5 (14.22) | 7.0 (18.03) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 317 | 160 |
| | | Mean (StdDev) | -2.2 (16.94) | -0.6 (18.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | -1.7 (0.79) | 0.2 (1.11) |
| | | 95% CI | -3.2, -0.1 | -2.0, 2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.8 (1.37) | |
| | | 95% CI | -4.5, 0.9 | |
| | | p-value | 0.1803 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.32, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 125 |
| | | Mean (StdDev) | 5.5 (14.70) | 7.7 (15.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 285 | 124 |
| | | Mean (StdDev) | -2.1 (18.65) | 0.5 (18.03) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 67 |
| | | LS Mean (SE) | -1.3 (0.81) | 0.8 (1.21) |
| | | 95% CI | -2.9, 0.3 | -1.6, 3.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.1 (1.46) | |
| | | 95% CI | -5.0, 0.8 | |
| | | p-value | 0.1479 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.37, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 256 | 102 |
| | | Mean (StdDev) | 4.2 (12.17) | 8.8 (18.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 253 | 101 |
| | | Mean (StdDev) | -2.2 (16.78) | 2.6 (18.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | -2.3 (0.84) | 2.5 (1.31) |
| | | 95% CI | -4.0, -0.7 | -0.1, 5.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.8 (1.56) | |
| | | 95% CI | -7.9, -1.8 | |
| | | p-value | 0.0020 | |
| | | Corrected Hedges g (95% CI) [2] | -0.36 (-0.59, -0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 236 | 96 |
| | | Mean (StdDev) | 4.0 (12.04) | 6.3 (15.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 234 | 96 |
| | | Mean (StdDev) | -2.8 (18.57) | 1.0 (16.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 67 |
| | | LS Mean (SE) | -2.5 (0.87) | -0.7 (1.34) |
| | | 95% CI | -4.2, -0.8 | -3.3, 2.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.8 (1.60) | |
| | | 95% CI | -4.9, 1.3 | |
| | | p-value | 0.2628 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.37, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 212 | 81 |
| | | Mean (StdDev) | 3.0 (10.08) | 5.8 (16.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 209 | 81 |
| | | Mean (StdDev) | -3.3 (16.81) | 1.6 (18.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 33 | -67, 100 |
| | | LS Mean (SE) | -2.9 (0.84) | -0.1 (1.32) |
| | | 95% CI | -4.6, -1.3 | -2.7, 2.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.8 (1.56) | |
| | | 95% CI | -5.9, 0.3 | |
| | | p-value | 0.0738 | |
| | | Corrected Hedges g (95% CI) [2] | -0.23 (-0.49, 0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 3.8 (12.78) | 6.6 (14.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 176 | 71 |
| | | Mean (StdDev) | -2.3 (16.94) | 2.8 (16.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -33, 67 |
| | | LS Mean (SE) | -2.4 (0.95) | 1.1 (1.49) |
| | | 95% CI | -4.3, -0.6 | -1.8, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.6 (1.77) | |
| | | 95% CI | -7.0, -0.1 | |
| | | p-value | 0.0442 | |
| | | Corrected Hedges g (95% CI) [2] | -0.28 (-0.56, -0.01) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 145 | 56 |
| | | Mean (StdDev) | 4.6 (14.50) | 4.8 (13.38) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 144 | 56 |
| | | Mean (StdDev) | -1.4 (20.81) | 2.4 (12.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -33, 67 |
| | | LS Mean (SE) | -1.5 (1.18) | -1.3 (1.90) |
| | | 95% CI | -3.8, 0.8 | -5.1, 2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (2.23) | |
| | | 95% CI | -4.6, 4.2 | |
| | | p-value | 0.9442 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.32, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 3.8 (10.64) | 6.3 (13.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 33 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | -0.4 (16.37) | 6.3 (13.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 33 | 0, 33 |
| | | LS Mean (SE) | -2.4 (1.24) | 0.9 (2.09) |
| | | 95% CI | -4.9, 0.0 | -3.2, 5.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.4 (2.35) | |
| | | 95% CI | -8.0, 1.3 | |
| | | p-value | 0.1543 | |
| | | Corrected Hedges g (95% CI) [2] | -0.29 (-0.69, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 2.1 (8.24) | 5.9 (17.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 67 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | -2.1 (14.59) | 5.9 (17.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 33 | 0, 67 |
| | | LS Mean (SE) | -4.3 (1.44) | 0.1 (2.46) |
| | | 95% CI | -7.2, -1.5 | -4.8, 5.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.4 (2.75) | |
| | | 95% CI | -9.9, 1.1 | |
| | | p-value | 0.1152 | |
| | | Corrected Hedges g (95% CI) [2] | -0.44 (-1.00, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 2.5 (8.90) | 4.2 (11.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 33 |
| | Change from BL | n | 27 | 8 |
| | | Mean (StdDev) | -1.2 (14.56) | 4.2 (11.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 33 | 0, 33 |
| | | LS Mean (SE) | -4.2 (2.14) | -1.2 (3.95) |
| | | 95% CI | -8.6, 0.1 | -9.2, 6.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.0 (4.30) | |
| | | 95% CI | -11.7, 5.7 | |
| | | p-value | 0.4903 | |
| | | Corrected Hedges g (95% CI) [2] | -0.26 (-1.05, 0.53) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 7.1 (14.19) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 4.8 (17.82) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 33 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 288 | 174 |
| | | Mean (StdDev) | 7.3 (16.37) | 8.2 (16.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 284 | 173 |
| | | Mean (StdDev) | 0.4 (20.87) | -1.2 (23.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | 0.5 (0.90) | 0.6 (1.17) |
| | | 95% CI | -1.3, 2.2 | -1.7, 2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.2 (1.48) | |
| | | 95% CI | -3.1, 2.7 | |
| | | p-value | 0.9173 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.20, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 150 | 105 |
| | | Mean (StdDev) | 9.1 (18.88) | 8.3 (15.18) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 149 | 104 |
| | | Mean (StdDev) | 2.5 (20.17) | 1.0 (22.97) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 2.0 (1.25) | 1.1 (1.52) |
| | | 95% CI | -0.4, 4.5 | -1.9, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.9 (1.97) | |
| | | 95% CI | -2.9, 4.8 | |
| | | p-value | 0.6346 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.19, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 170 | 98 |
| | | Mean (StdDev) | 11.6 (21.53) | 9.9 (19.86) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 166 | 98 |
| | | Mean (StdDev) | 2.4 (25.04) | 2.0 (26.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 3.7 (1.44) | 2.8 (1.87) |
| | | 95% CI | 0.8, 6.5 | -0.9, 6.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.9 (2.35) | |
| | | 95% CI | -3.8, 5.5 | |
| | | p-value | 0.7157 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.20, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 201 | 115 |
| | | Mean (StdDev) | 11.3 (20.95) | 9.0 (17.28) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | 2.9 (23.75) | 1.8 (20.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 3.5 (1.22) | 1.7 (1.61) |
| | | 95% CI | 1.1, 5.9 | -1.4, 4.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.7 (2.02) | |
| | | 95% CI | -2.3, 5.7 | |
| | | p-value | 0.3951 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.13, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 161 | 91 |
| | | Mean (StdDev) | 9.9 (21.36) | 9.9 (18.25) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 159 | 90 |
| | | Mean (StdDev) | 2.5 (25.03) | 1.9 (19.58) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 2.6 (1.48) | 2.7 (1.97) |
| | | 95% CI | -0.3, 5.5 | -1.2, 6.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (2.46) | |
| | | 95% CI | -5.0, 4.7 | |
| | | p-value | 0.9609 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.27, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -1.0 (0.48) | 0.8 (0.71) |
| | | 95% CI | -2.0, -0.1 | -0.6, 2.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.8 (0.85) | |
| | | 95% CI | -3.5, -0.1 | |
| | | p-value | 0.0328 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.33, -0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Baseline | Actual | n | 475 | 243 |
| | | Mean (StdDev) | 18.8 (29.08) | 21.3 (29.86) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 423 | 229 |
| | | Mean (StdDev) | 16.2 (27.23) | 16.3 (26.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 417 | 228 |
| | | Mean (StdDev) | -2.4 (21.55) | -4.8 (22.37) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 100 |
| | | LS Mean (SE) | -2.6 (1.12) | -4.0 (1.53) |
| | | 95% CI | -4.8, -0.4 | -7.0, -1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (1.89) | |
| | | 95% CI | -2.3, 5.1 | |
| | | p-value | 0.4615 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.10, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 358 | 187 |
| | | Mean (StdDev) | 14.1 (24.91) | 19.6 (30.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 351 | 186 |
| | | Mean (StdDev) | -4.6 (22.21) | -3.0 (26.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 100 |
| | | LS Mean (SE) | -4.9 (1.10) | -1.7 (1.52) |
| | | 95% CI | -7.1, -2.7 | -4.7, 1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.2 (1.88) | |
| | | 95% CI | -6.9, 0.5 | |
| | | p-value | 0.0919 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.33, 0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 322 | 161 |
| | | Mean (StdDev) | 15.1 (25.77) | 16.1 (26.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 317 | 160 |
| | | Mean (StdDev) | -3.3 (24.73) | -7.7 (23.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | -3.7 (1.08) | -5.4 (1.51) |
| | | 95% CI | -5.8, -1.5 | -8.4, -2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.7 (1.86) | |
| | | 95% CI | -1.9, 5.4 | |
| | | p-value | 0.3503 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.10, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 289 | 126 |
| | | Mean (StdDev) | 13.6 (25.45) | 18.0 (28.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 284 | 125 |
| | | Mean (StdDev) | -4.3 (22.78) | -4.0 (24.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 100 |
| | | LS Mean (SE) | -4.7 (1.13) | -3.1 (1.65) |
| | | 95% CI | -6.9, -2.5 | -6.3, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.7 (2.00) | |
| | | 95% CI | -5.6, 2.3 | |
| | | p-value | 0.4078 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.30, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 256 | 102 |
| | | Mean (StdDev) | 13.5 (25.20) | 16.0 (27.24) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 252 | 101 |
| | | Mean (StdDev) | -3.8 (22.43) | -6.6 (22.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -100, 67 |
| | | LS Mean (SE) | -4.2 (1.06) | -4.3 (1.60) |
| | | 95% CI | -6.3, -2.1 | -7.5, -1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (1.92) | |
| | | 95% CI | -3.7, 3.9 | |
| | | p-value | 0.9673 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.23, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 236 | 96 |
| | | Mean (StdDev) | 13.6 (26.54) | 13.2 (23.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 233 | 96 |
| | | Mean (StdDev) | -4.6 (25.11) | -10.4 (24.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | -5.0 (1.09) | -7.0 (1.63) |
| | | 95% CI | -7.2, -2.9 | -10.2, -3.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.9 (1.96) | |
| | | 95% CI | -1.9, 5.8 | |
| | | p-value | 0.3221 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.12, 0.36) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 211 | 81 |
| | | Mean (StdDev) | 12.8 (25.40) | 11.1 (24.15) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 207 | 81 |
| | | Mean (StdDev) | -3.4 (23.09) | -12.3 (24.41) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -100, 67 | -100, 33 |
| | | LS Mean (SE) | -4.8 (1.10) | -8.5 (1.67) |
| | | 95% CI | -7.0, -2.7 | -11.8, -5.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.6 (2.00) | |
| | | 95% CI | -0.3, 7.6 | |
| | | p-value | 0.0713 | |
| | | Corrected Hedges g (95% CI) [2] | 0.23 (-0.03, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 176 | 71 |
| | | Mean (StdDev) | 14.4 (25.60) | 11.7 (27.08) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 175 | 71 |
| | | Mean (StdDev) | -2.7 (25.13) | -9.4 (25.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | -3.5 (1.30) | -7.1 (1.99) |
| | | 95% CI | -6.1, -1.0 | -11.1, -3.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.6 (2.38) | |
| | | 95% CI | -1.1, 8.3 | |
| | | p-value | 0.1309 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (-0.07, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 144 | 56 |
| | | Mean (StdDev) | 14.1 (26.61) | 16.7 (29.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 142 | 56 |
| | | Mean (StdDev) | -0.9 (28.06) | -7.7 (22.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | -3.2 (1.39) | -4.5 (2.15) |
| | | 95% CI | -6.0, -0.5 | -8.7, -0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (2.57) | |
| | | 95% CI | -3.8, 6.3 | |
| | | p-value | 0.6378 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.24, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 88 | 32 |
| | | Mean (StdDev) | 14.8 (28.53) | 13.5 (22.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 88 | 32 |
| | | Mean (StdDev) | -0.8 (26.25) | -11.5 (28.85) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -67, 67 | -100, 33 |
| | | LS Mean (SE) | -2.3 (1.77) | -9.3 (2.87) |
| | | 95% CI | -5.8, 1.2 | -15.0, -3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 7.0 (3.39) | |
| | | 95% CI | 0.3, 13.7 | |
| | | p-value | 0.0401 | |
| | | Corrected Hedges g (95% CI) [2] | 0.42 (0.01, 0.83) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 47 | 17 |
| | | Mean (StdDev) | 12.1 (22.44) | 9.8 (19.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 47 | 17 |
| | | Mean (StdDev) | 0.7 (22.51) | -11.8 (28.73) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -67, 67 | -100, 33 |
| | | LS Mean (SE) | -2.1 (1.80) | -10.4 (2.86) |
| | | 95% CI | -5.7, 1.4 | -16.0, -4.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 8.2 (3.39) | |
| | | 95% CI | 1.5, 15.0 | |
| | | p-value | 0.0170 | |
| | | Corrected Hedges g (95% CI) [2] | 0.67 (0.10, 1.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 27 | 8 |
| | | Mean (StdDev) | 11.1 (20.67) | 8.3 (23.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 27 | 8 |
| | | Mean (StdDev) | 3.7 (23.27) | -12.5 (39.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -100, 33 |
| | | LS Mean (SE) | -4.4 (1.74) | -9.8 (2.83) |
| | | 95% CI | -7.8, -0.9 | -15.4, -4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.4 (3.34) | |
| | | 95% CI | -1.3, 12.1 | |
| | | p-value | 0.1117 | |
| | | Corrected Hedges g (95% CI) [2] | 0.60 (-0.20, 1.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 14 | 2 |
| | | Mean (StdDev) | 11.9 (21.11) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 0 |
| | Change from BL | n | 14 | 2 |
| | | Mean (StdDev) | 0.0 (22.65) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 33 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 5 | 2 |
| | | Mean (StdDev) | 6.7 (14.91) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 5 | 2 |
| | | Mean (StdDev) | -6.7 (36.51) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 33 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Cycle 39 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 290 | 174 |
| | | Mean (StdDev) | 16.9 (27.90) | 17.0 (27.47) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 284 | 173 |
| | | Mean (StdDev) | -2.1 (25.29) | -2.3 (22.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | -2.0 (1.17) | -2.6 (1.54) |
| | | 95% CI | -4.3, 0.3 | -5.6, 0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (1.94) | |
| | | 95% CI | -3.2, 4.4 | |
| | | p-value | 0.7702 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.16, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 149 | 105 |
| | | Mean (StdDev) | 17.7 (27.28) | 19.7 (31.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 147 | 104 |
| | | Mean (StdDev) | -0.9 (25.86) | 2.6 (21.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | -0.7 (1.45) | 1.0 (1.81) |
| | | 95% CI | -3.5, 2.2 | -2.6, 4.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.6 (2.32) | |
| | | 95% CI | -6.2, 2.9 | |
| | | p-value | 0.4772 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.34, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 169 | 96 |
| | | Mean (StdDev) | 20.3 (29.35) | 17.0 (29.02) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 164 | 96 |
| | | Mean (StdDev) | -1.0 (25.69) | 0.7 (21.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 0.8 (1.39) | -0.6 (1.84) |
| | | 95% CI | -1.9, 3.5 | -4.2, 3.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (2.30) | |
| | | 95% CI | -3.1, 5.9 | |
| | | p-value | 0.5492 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.17, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 201 | 114 |
| | | Mean (StdDev) | 20.2 (28.67) | 18.1 (28.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 196 | 113 |
| | | Mean (StdDev) | 0.9 (27.10) | -0.3 (22.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 1.4 (1.37) | -0.6 (1.83) |
| | | 95% CI | -1.3, 4.1 | -4.2, 2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.1 (2.29) | |
| | | 95% CI | -2.4, 6.6 | |
| | | p-value | 0.3638 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.12, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 162 | 91 |
| | | Mean (StdDev) | 20.6 (30.21) | 16.5 (26.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 160 | 90 |
| | | Mean (StdDev) | 0.4 (28.47) | 0.7 (22.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 2.4 (1.48) | 0.2 (1.99) |
| | | 95% CI | -0.5, 5.3 | -3.7, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.2 (2.48) | |
| | | 95% CI | -2.7, 7.0 | |
| | | p-value | 0.3819 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.14, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=487) | Placebo (N=246) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -2.6 (0.80) | -4.6 (1.14) |
| | | 95% CI | -4.1, -1.0 | -6.8, -2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.0 (1.39) | |
| | | 95% CI | -0.7, 4.7 | |
| | | p-value | 0.1513 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.04, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 69.4 (20.14) | 69.4 (19.00) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 58.3, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 |
| Cycle 3 Day 1 | Actual | n | 200 | 114 |
| | | Mean (StdDev) | 73.4 (19.21) | 72.4 (19.71) |
| | | Median | 75.0 | 75.0 |
| | | Q1, Q3 | 66.7, 83.3 | 58.3, 83.3 |
| | | Min, Max | 0, 100 | 8, 100 |
| | Change from BL | n | 198 | 114 |
| | | Mean (StdDev) | 2.7 (17.41) | 2.9 (16.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 67 | -42, 50 |
| | | LS Mean (SE) | 2.7 (1.17) | 2.5 (1.54) |
| | | 95% CI | 0.4, 5.0 | -0.5, 5.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (1.93) | |
| | | 95% CI | -3.6, 4.0 | |
| | | p-value | 0.9062 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.22, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 168 | 98 |
| | | Mean (StdDev) | 73.5 (19.29) | 73.0 (18.80) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 58.3, 83.3 | 66.7, 83.3 |
| | | Min, Max | 25, 100 | 25, 100 |
| | Change from BL | n | 166 | 98 |
| | | Mean (StdDev) | 3.1 (19.08) | 2.9 (15.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 16.7 |
| | | Min, Max | -50, 67 | -50, 50 |
| | | LS Mean (SE) | 2.4 (1.24) | 2.2 (1.62) |
| | | 95% CI | -0.1, 4.8 | -1.0, 5.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (2.04) | |
| | | 95% CI | -3.9, 4.1 | |
| | | p-value | 0.9446 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.24, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 150 | 87 |
| | | Mean (StdDev) | 75.8 (17.99) | 76.6 (15.81) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 83.3 |
| | | Min, Max | 8, 100 | 17, 100 |
| | Change from BL | n | 149 | 87 |
| | | Mean (StdDev) | 4.6 (16.96) | 5.9 (16.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -8.3, 16.7 |
| | | Min, Max | -33, 42 | -33, 50 |
| | | LS Mean (SE) | 3.6 (1.29) | 4.9 (1.69) |
| | | 95% CI | 1.1, 6.2 | 1.6, 8.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (2.12) | |
| | | 95% CI | -5.4, 2.9 | |
| | | p-value | 0.5501 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.34, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 66 |
| | | Mean (StdDev) | 75.9 (18.37) | 72.3 (18.67) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 66.7, 87.5 | 58.3, 83.3 |
| | | Min, Max | 25, 100 | 17, 100 |
| | Change from BL | n | 131 | 66 |
| | | Mean (StdDev) | 4.5 (17.12) | 3.5 (14.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 16.7 |
| | | Min, Max | -33, 50 | -25, 50 |
| | | LS Mean (SE) | 3.5 (1.35) | 2.2 (1.86) |
| | | 95% CI | 0.9, 6.2 | -1.4, 5.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (2.30) | |
| | | 95% CI | -3.3, 5.8 | |
| | | p-value | 0.5855 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.21, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 76.7 (17.48) | 75.2 (18.89) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 91.7 |
| | | Min, Max | 25, 100 | 17, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 5.4 (17.28) | 3.9 (19.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -8.3, 16.7 |
| | | Min, Max | -33, 42 | -50, 50 |
| | | LS Mean (SE) | 4.0 (1.40) | 1.9 (2.05) |
| | | 95% CI | 1.2, 6.7 | -2.2, 5.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.1 (2.48) | |
| | | 95% CI | -2.8, 7.0 | |
| | | p-value | 0.3991 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.19, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 110 | 48 |
| | | Mean (StdDev) | 76.4 (17.69) | 77.4 (18.59) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 83.3 | 66.7, 91.7 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 109 | 48 |
| | | Mean (StdDev) | 5.8 (18.89) | 5.9 (21.54) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 58 | -67, 50 |
| | | LS Mean (SE) | 3.8 (1.44) | 4.4 (2.10) |
| | | 95% CI | 1.0, 6.6 | 0.3, 8.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (2.54) | |
| | | 95% CI | -5.6, 4.4 | |
| | | p-value | 0.8083 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.38, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 37 |
| | | Mean (StdDev) | 77.6 (18.02) | 79.3 (17.96) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 91.7 |
| | | Min, Max | 17, 100 | 25, 100 |
| | Change from BL | n | 96 | 37 |
| | | Mean (StdDev) | 7.1 (19.19) | 6.3 (19.88) |
| | | Median | 8.3 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 67 | -50, 50 |
| | | LS Mean (SE) | 4.6 (1.51) | 3.9 (2.33) |
| | | 95% CI | 1.6, 7.5 | -0.6, 8.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (2.77) | |
| | | 95% CI | -4.8, 6.1 | |
| | | p-value | 0.8146 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.34, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 77.6 (17.65) | 74.7 (17.90) |
| | | Median | 83.3 | 79.2 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 83.3 |
| | | Min, Max | 33, 100 | 17, 100 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | 6.0 (20.51) | 5.2 (18.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | -4.2, 16.7 |
| | | Min, Max | -42, 67 | -50, 50 |
| | | LS Mean (SE) | 4.5 (1.62) | 0.3 (2.50) |
| | | 95% CI | 1.4, 7.7 | -4.6, 5.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.3 (2.98) | |
| | | 95% CI | -1.6, 10.1 | |
| | | p-value | 0.1538 | |
| | | Corrected Hedges g (95% CI) [2] | 0.29 (-0.12, 0.70) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 62 | 23 |
| | | Mean (StdDev) | 78.2 (17.88) | 79.0 (17.74) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 62 | 23 |
| | | Mean (StdDev) | 5.9 (14.74) | 9.4 (20.61) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -25, 33 | -50, 50 |
| | | LS Mean (SE) | 4.2 (1.83) | 5.9 (2.91) |
| | | 95% CI | 0.6, 7.8 | 0.2, 11.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.7 (3.44) | |
| | | 95% CI | -8.5, 5.0 | |
| | | p-value | 0.6178 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.60, 0.36) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 82.3 (20.03) | 73.8 (21.75) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 75.0, 100.0 | 50.0, 91.7 |
| | | Min, Max | 17, 100 | 42, 100 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 7.7 (16.83) | 9.5 (26.97) |
| | | Median | 8.3 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -33, 33 | -33, 50 |
| | | LS Mean (SE) | 6.4 (2.74) | 0.2 (5.03) |
| | | 95% CI | 1.0, 11.8 | -9.6, 10.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 6.2 (5.78) | |
| | | 95% CI | -5.2, 17.5 | |
| | | p-value | 0.2856 | |
| | | Corrected Hedges g (95% CI) [2] | 0.44 (-0.40, 1.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 83.3 (15.96) | 75.0 (21.52) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 75.0, 100.0 | 58.3, 91.7 |
| | | Min, Max | 50, 100 | 50, 100 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 2.6 (23.91) | 18.8 (34.94) |
| | | Median | 0.0 | 12.5 |
| | | Q1, Q3 | -8.3, 16.7 | -4.2, 41.7 |
| | | Min, Max | -50, 42 | -17, 67 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 80.2 (19.89) | 91.7 (NA) |
| | | Median | 79.2 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 91.7, 91.7 |
| | | Min, Max | 50, 100 | 92, 92 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -5.2 (27.07) | 8.3 (NA) |
| | | Median | -8.3 | 8.3 |
| | | Q1, Q3 | -29.2, 16.7 | 8.3, 8.3 |
| | | Min, Max | -33, 33 | 8, 8 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 90.0 (9.13) | |
| | | Median | 83.3 | |
| | | Q1, Q3 | 83.3, 100.0 | |
| | | Min, Max | 83, 100 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 1.7 (12.36) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 8.3 | |
| | | Min, Max | -17, 17 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 33.3 (NA) | |
| | | Median | 33.3 | |
| | | Q1, Q3 | 33.3, 33.3 | |
| | | Min, Max | 33, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 128 | 88 |
| | | Mean (StdDev) | 60.7 (23.01) | 65.1 (20.25) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 127 | 88 |
| | | Mean (StdDev) | -8.3 (22.88) | -5.1 (20.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 8.3 |
| | | Min, Max | -100, 58 | -67, 50 |
| | | LS Mean (SE) | -7.8 (1.39) | -5.0 (1.70) |
| | | 95% CI | -10.5, -5.1 | -8.4, -1.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.8 (2.19) | |
| | | 95% CI | -7.1, 1.5 | |
| | | p-value | 0.2034 | |
| | | Corrected Hedges g (95% CI) [2] | -0.18 (-0.45, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 56 |
| | | Mean (StdDev) | 62.9 (21.62) | 64.3 (17.46) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 76 | 56 |
| | | Mean (StdDev) | -6.9 (23.70) | -7.4 (20.52) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -67, 42 |
| | | LS Mean (SE) | -7.4 (1.66) | -6.8 (1.99) |
| | | 95% CI | -10.7, -4.2 | -10.7, -2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (2.59) | |
| | | 95% CI | -5.7, 4.4 | |
| | | p-value | 0.8022 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.39, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 63.3 (20.74) | 59.7 (19.94) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | -5.9 (20.20) | -9.7 (20.78) |
| | | Median | -4.2 | -8.3 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -67, 33 | -50, 33 |
| | | LS Mean (SE) | -6.2 (1.66) | -8.8 (2.03) |
| | | 95% CI | -9.4, -2.9 | -12.8, -4.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (2.62) | |
| | | 95% CI | -2.5, 7.8 | |
| | | p-value | 0.3149 | |
| | | Corrected Hedges g (95% CI) [2] | 0.18 (-0.17, 0.52) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 62.6 (22.13) | 62.9 (17.25) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 75.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | -6.9 (21.84) | -6.9 (17.30) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -92, 33 | -50, 33 |
| | | LS Mean (SE) | -7.3 (1.61) | -7.2 (1.98) |
| | | 95% CI | -10.4, -4.1 | -11.1, -3.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (2.55) | |
| | | 95% CI | -5.1, 5.0 | |
| | | p-value | 0.9847 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.33, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 79 | 49 |
| | | Mean (StdDev) | 64.8 (19.56) | 66.7 (19.98) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 50.0, 83.3 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 78 | 49 |
| | | Mean (StdDev) | -3.5 (17.59) | -4.6 (19.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 8.3 |
| | | Min, Max | -42, 42 | -50, 42 |
| | | LS Mean (SE) | -4.8 (1.71) | -5.0 (2.15) |
| | | 95% CI | -8.2, -1.5 | -9.2, -0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (2.75) | |
| | | 95% CI | -5.2, 5.6 | |
| | | p-value | 0.9514 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.35, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 0.4 (0.86) | -0.3 (1.20) |
| | | 95% CI | -1.3, 2.1 | -2.6, 2.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.7 (1.47) | |
| | | 95% CI | -2.2, 3.6 | |
| | | p-value | 0.6349 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.17, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 79.3 (17.44) | 76.3 (20.74) |
| | | Median | 80.0 | 80.0 |
| | | Q1, Q3 | 73.3, 93.3 | 63.3, 93.3 |
| | | Min, Max | 13, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 200 | 114 |
| | | Mean (StdDev) | 80.7 (16.82) | 78.9 (18.08) |
| | | Median | 86.7 | 80.0 |
| | | Q1, Q3 | 73.3, 93.3 | 66.7, 93.3 |
| | | Min, Max | 27, 100 | 33, 100 |
| | Change from BL | n | 198 | 114 |
| | | Mean (StdDev) | 0.2 (13.83) | 2.3 (11.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 6.7 | -2.2, 6.7 |
| | | Min, Max | -33, 53 | -27, 40 |
| | | LS Mean (SE) | 0.6 (0.96) | 1.4 (1.28) |
| | | 95% CI | -1.3, 2.5 | -1.2, 3.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.8 (1.60) | |
| | | 95% CI | -3.9, 2.4 | |
| | | p-value | 0.6291 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.29, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 99 |
| | | Mean (StdDev) | 82.7 (16.05) | 81.5 (16.99) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 73.3, 93.3 | 73.3, 93.3 |
| | | Min, Max | 27, 100 | 33, 100 |
| | Change from BL | n | 165 | 99 |
| | | Mean (StdDev) | 2.4 (14.04) | 4.6 (13.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -6.7, 6.7 | 0.0, 13.3 |
| | | Min, Max | -67, 47 | -27, 53 |
| | | LS Mean (SE) | 2.2 (1.01) | 3.2 (1.33) |
| | | 95% CI | 0.2, 4.2 | 0.6, 5.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.9 (1.67) | |
| | | 95% CI | -4.2, 2.3 | |
| | | p-value | 0.5710 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.32, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 84.8 (13.48) | 84.3 (14.86) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 93.3 | 73.3, 100.0 |
| | | Min, Max | 40, 100 | 33, 100 |
| | Change from BL | n | 147 | 87 |
| | | Mean (StdDev) | 3.8 (13.20) | 6.1 (13.50) |
| | | Median | 0.0 | 6.7 |
| | | Q1, Q3 | 0.0, 6.7 | 0.0, 13.3 |
| | | Min, Max | -33, 47 | -27, 40 |
| | | LS Mean (SE) | 3.6 (1.05) | 4.0 (1.38) |
| | | 95% CI | 1.6, 5.7 | 1.3, 6.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (1.74) | |
| | | 95% CI | -3.7, 3.1 | |
| | | p-value | 0.8491 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.29, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 68 |
| | | Mean (StdDev) | 86.1 (14.37) | 82.2 (17.18) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 73.3, 93.3 |
| | | Min, Max | 20, 100 | 20, 100 |
| | Change from BL | n | 130 | 68 |
| | | Mean (StdDev) | 4.8 (14.81) | 5.4 (13.15) |
| | | Median | 3.3 | 6.7 |
| | | Q1, Q3 | 0.0, 13.3 | -3.3, 13.3 |
| | | Min, Max | -33, 53 | -27, 40 |
| | | LS Mean (SE) | 4.2 (1.10) | 3.6 (1.48) |
| | | 95% CI | 2.1, 6.4 | 0.7, 6.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (1.85) | |
| | | 95% CI | -3.1, 4.2 | |
| | | p-value | 0.7562 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.25, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 86.7 (14.02) | 84.2 (14.36) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 73.3, 93.3 |
| | | Min, Max | 40, 100 | 27, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 4.8 (15.61) | 6.1 (13.78) |
| | | Median | 6.7 | 6.7 |
| | | Q1, Q3 | 0.0, 13.3 | 0.0, 13.3 |
| | | Min, Max | -47, 67 | -33, 40 |
| | | LS Mean (SE) | 4.2 (1.13) | 3.8 (1.63) |
| | | 95% CI | 1.9, 6.4 | 0.6, 7.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (1.99) | |
| | | 95% CI | -3.5, 4.3 | |
| | | p-value | 0.8380 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.29, 0.36) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 47 |
| | | Mean (StdDev) | 86.9 (14.73) | 82.6 (17.28) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 86.7, 100.0 | 73.3, 93.3 |
| | | Min, Max | 20, 100 | 20, 100 |
| | Change from BL | n | 108 | 47 |
| | | Mean (StdDev) | 5.1 (14.66) | 6.4 (13.90) |
| | | Median | 6.7 | 6.7 |
| | | Q1, Q3 | 0.0, 13.3 | 0.0, 13.3 |
| | | Min, Max | -33, 53 | -33, 40 |
| | | LS Mean (SE) | 4.1 (1.17) | 3.7 (1.69) |
| | | 95% CI | 1.8, 6.3 | 0.3, 7.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (2.06) | |
| | | 95% CI | -3.6, 4.5 | |
| | | p-value | 0.8438 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.31, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 86.6 (13.39) | 87.0 (13.33) |
| | | Median | 86.7 | 93.3 |
| | | Q1, Q3 | 80.0, 100.0 | 80.0, 100.0 |
| | | Min, Max | 33, 100 | 53, 100 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 5.1 (15.38) | 7.9 (16.02) |
| | | Median | 0.0 | 6.7 |
| | | Q1, Q3 | 0.0, 6.7 | 0.0, 13.3 |
| | | Min, Max | -27, 60 | -40, 40 |
| | | LS Mean (SE) | 4.2 (1.21) | 4.1 (1.82) |
| | | 95% CI | 1.8, 6.6 | 0.5, 7.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (2.19) | |
| | | 95% CI | -4.2, 4.4 | |
| | | p-value | 0.9678 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.37, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 87.1 (13.27) | 84.5 (13.95) |
| | | Median | 86.7 | 86.7 |
| | | Q1, Q3 | 80.0, 100.0 | 73.3, 96.7 |
| | | Min, Max | 53, 100 | 50, 100 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | 5.3 (15.84) | 7.2 (9.80) |
| | | Median | 6.7 | 6.7 |
| | | Q1, Q3 | 0.0, 13.3 | 0.0, 13.3 |
| | | Min, Max | -27, 60 | -10, 40 |
| | | LS Mean (SE) | 4.2 (1.29) | 1.9 (1.97) |
| | | 95% CI | 1.6, 6.7 | -2.0, 5.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.2 (2.36) | |
| | | 95% CI | -2.4, 6.9 | |
| | | p-value | 0.3422 | |
| | | Corrected Hedges g (95% CI) [2] | 0.19 (-0.22, 0.60) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 86.4 (13.98) | 81.8 (16.81) |
| | | Median | 93.3 | 80.0 |
| | | Q1, Q3 | 80.0, 96.7 | 73.3, 100.0 |
| | | Min, Max | 40, 100 | 47, 100 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | 3.8 (16.23) | 5.9 (16.80) |
| | | Median | 3.3 | 6.7 |
| | | Q1, Q3 | -6.7, 13.3 | 0.0, 13.3 |
| | | Min, Max | -27, 53 | -47, 47 |
| | | LS Mean (SE) | 4.4 (1.44) | 2.4 (2.29) |
| | | 95% CI | 1.6, 7.3 | -2.1, 6.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.1 (2.72) | |
| | | 95% CI | -3.3, 7.4 | |
| | | p-value | 0.4471 | |
| | | Corrected Hedges g (95% CI) [2] | 0.18 (-0.30, 0.66) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 84.8 (18.00) | 87.6 (14.10) |
| | | Median | 93.3 | 93.3 |
| | | Q1, Q3 | 86.7, 93.3 | 73.3, 100.0 |
| | | Min, Max | 27, 100 | 67, 100 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 5.6 (17.71) | 12.4 (18.23) |
| | | Median | 6.7 | 6.7 |
| | | Q1, Q3 | 0.0, 6.7 | 0.0, 26.7 |
| | | Min, Max | -20, 53 | -7, 47 |
| | | LS Mean (SE) | 2.5 (2.08) | 6.9 (3.83) |
| | | 95% CI | -1.6, 6.6 | -0.6, 14.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.4 (4.36) | |
| | | 95% CI | -13.0, 4.1 | |
| | | p-value | 0.3102 | |
| | | Corrected Hedges g (95% CI) [2] | -0.42 (-1.26, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 12 | 4 |
| | | Mean (StdDev) | 86.7 (15.83) | 76.7 (17.64) |
| | | Median | 93.3 | 73.3 |
| | | Q1, Q3 | 80.0, 100.0 | 63.3, 90.0 |
| | | Min, Max | 53, 100 | 60, 100 |
| | Change from BL | n | 12 | 4 |
| | | Mean (StdDev) | 1.7 (19.92) | 13.3 (24.34) |
| | | Median | 0.0 | 13.3 |
| | | Q1, Q3 | -6.7, 10.0 | -6.7, 33.3 |
| | | Min, Max | -33, 47 | -13, 40 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 79.2 (26.29) | 100.0 (NA) |
| | | Median | 86.7 | 100.0 |
| | | Q1, Q3 | 73.3, 96.7 | 100.0, 100.0 |
| | | Min, Max | 20, 100 | 100, 100 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -11.7 (21.01) | 0.0 (NA) |
| | | Median | -6.7 | 0.0 |
| | | Q1, Q3 | -13.3, 0.0 | 0.0, 0.0 |
| | | Min, Max | -60, 7 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 84.7 (9.89) | |
| | | Median | 83.3 | |
| | | Q1, Q3 | 80.0, 86.7 | |
| | | Min, Max | 73, 100 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | -3.3 (6.67) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | -6.7, 0.0 | |
| | | Min, Max | -13, 3 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 13.3 (NA) | |
| | | Median | 13.3 | |
| | | Q1, Q3 | 13.3, 13.3 | |
| | | Min, Max | 13, 13 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 126 | 89 |
| | | Mean (StdDev) | 77.6 (18.26) | 79.5 (22.12) |
| | | Median | 80.0 | 86.7 |
| | | Q1, Q3 | 66.7, 93.3 | 66.7, 100.0 |
| | | Min, Max | 20, 100 | 7, 100 |
| | Change from BL | n | 125 | 89 |
| | | Mean (StdDev) | -0.7 (16.14) | 2.1 (16.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -13.3, 6.7 | 0.0, 6.7 |
| | | Min, Max | -40, 36 | -60, 47 |
| | | LS Mean (SE) | 0.3 (1.13) | 1.9 (1.39) |
| | | 95% CI | -2.0, 2.5 | -0.8, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.6 (1.79) | |
| | | 95% CI | -5.1, 1.9 | |
| | | p-value | 0.3605 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.40, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 55 |
| | | Mean (StdDev) | 75.8 (23.06) | 78.1 (21.57) |
| | | Median | 80.0 | 80.0 |
| | | Q1, Q3 | 60.0, 93.3 | 66.7, 93.3 |
| | | Min, Max | 7, 100 | 13, 100 |
| | Change from BL | n | 75 | 55 |
| | | Mean (StdDev) | -1.9 (21.34) | 0.5 (18.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -13.3, 13.3 | -6.7, 13.3 |
| | | Min, Max | -80, 33 | -67, 33 |
| | | LS Mean (SE) | -1.6 (1.32) | -1.3 (1.60) |
| | | 95% CI | -4.2, 1.0 | -4.4, 1.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (2.07) | |
| | | 95% CI | -4.5, 3.7 | |
| | | p-value | 0.8523 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.38, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 74.8 (19.38) | 73.7 (24.55) |
| | | Median | 73.3 | 83.3 |
| | | Q1, Q3 | 60.0, 93.3 | 53.3, 93.3 |
| | | Min, Max | 13, 100 | 13, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | -0.7 (18.27) | -2.7 (19.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -13.3, 13.3 | -6.7, 6.7 |
| | | Min, Max | -42, 40 | -67, 27 |
| | | LS Mean (SE) | -1.2 (1.34) | -3.2 (1.63) |
| | | 95% CI | -3.8, 1.4 | -6.4, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.0 (2.10) | |
| | | 95% CI | -2.1, 6.1 | |
| | | p-value | 0.3456 | |
| | | Corrected Hedges g (95% CI) [2] | 0.17 (-0.18, 0.51) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 76.3 (18.65) | 77.0 (18.14) |
| | | Median | 80.0 | 80.0 |
| | | Q1, Q3 | 66.7, 86.7 | 66.7, 86.7 |
| | | Min, Max | 7, 100 | 27, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | -1.4 (18.52) | -2.3 (16.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -13.3, 6.7 | -10.0, 6.7 |
| | | Min, Max | -40, 40 | -47, 27 |
| | | LS Mean (SE) | -1.5 (1.30) | -1.7 (1.61) |
| | | 95% CI | -4.0, 1.1 | -4.8, 1.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.2 (2.07) | |
| | | 95% CI | -3.9, 4.3 | |
| | | p-value | 0.9198 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.31, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 74.9 (20.42) | 77.7 (20.83) |
| | | Median | 80.0 | 80.0 |
| | | Q1, Q3 | 60.0, 86.7 | 73.3, 93.3 |
| | | Min, Max | 7, 100 | 20, 100 |
| | Change from BL | n | 80 | 49 |
| | | Mean (StdDev) | -0.3 (17.53) | -1.9 (14.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -9.2, 13.3 | -6.7, 6.7 |
| | | Min, Max | -47, 40 | -53, 27 |
| | | LS Mean (SE) | -1.7 (1.38) | -3.4 (1.74) |
| | | 95% CI | -4.4, 1.0 | -6.8, 0.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.7 (2.22) | |
| | | 95% CI | -2.7, 6.0 | |
| | | p-value | 0.4495 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.22, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 1.9 (0.74) | 1.8 (1.02) |
| | | 95% CI | 0.4, 3.3 | -0.2, 3.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (1.26) | |
| | | 95% CI | -2.4, 2.5 | |
| | | p-value | 0.9508 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.21, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 77.5 (24.68) | 75.4 (25.37) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 200 | 114 |
| | | Mean (StdDev) | 79.9 (23.94) | 79.4 (25.41) |
| | | Median | 83.3 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 198 | 114 |
| | | Mean (StdDev) | 1.5 (20.65) | 3.7 (23.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 67 | -100, 67 |
| | | LS Mean (SE) | 1.6 (1.48) | 2.6 (1.97) |
| | | 95% CI | -1.3, 4.5 | -1.2, 6.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.1 (2.46) | |
| | | 95% CI | -5.9, 3.8 | |
| | | p-value | 0.6658 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.28, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 99 |
| | | Mean (StdDev) | 83.0 (23.17) | 81.6 (23.14) |
| | | Median | 100.0 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 165 | 99 |
| | | Mean (StdDev) | 5.6 (26.12) | 6.2 (21.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 100 | -100, 50 |
| | | LS Mean (SE) | 4.5 (1.57) | 4.1 (2.05) |
| | | 95% CI | 1.4, 7.6 | 0.1, 8.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (2.59) | |
| | | 95% CI | -4.7, 5.5 | |
| | | p-value | 0.8699 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.23, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 85.1 (19.58) | 83.7 (22.01) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 0, 100 |
| | Change from BL | n | 147 | 87 |
| | | Mean (StdDev) | 6.9 (22.06) | 10.0 (23.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 5.5 (1.65) | 5.5 (2.15) |
| | | 95% CI | 2.3, 8.7 | 1.3, 9.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (2.71) | |
| | | 95% CI | -5.3, 5.3 | |
| | | p-value | 0.9947 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.27, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 68 |
| | | Mean (StdDev) | 85.5 (20.43) | 79.2 (25.33) |
| | | Median | 100.0 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 130 | 68 |
| | | Mean (StdDev) | 6.0 (24.20) | 7.1 (21.99) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 4.5 (1.71) | 2.7 (2.33) |
| | | 95% CI | 1.2, 7.9 | -1.9, 7.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (2.90) | |
| | | 95% CI | -3.9, 7.5 | |
| | | p-value | 0.5300 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.20, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 88.8 (17.97) | 83.0 (21.47) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 75.0, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 8.5 (22.01) | 5.9 (22.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 67 | -67, 67 |
| | | LS Mean (SE) | 7.0 (1.77) | 2.1 (2.58) |
| | | 95% CI | 3.5, 10.4 | -3.0, 7.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.9 (3.13) | |
| | | 95% CI | -1.2, 11.1 | |
| | | p-value | 0.1166 | |
| | | Corrected Hedges g (95% CI) [2] | 0.26 (-0.07, 0.59) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 88.1 (18.16) | 85.8 (22.01) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 108 | 48 |
| | | Mean (StdDev) | 8.5 (21.91) | 9.4 (24.04) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -50, 67 | -50, 67 |
| | | LS Mean (SE) | 5.6 (1.82) | 5.3 (2.65) |
| | | 95% CI | 2.0, 9.2 | 0.1, 10.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (3.22) | |
| | | 95% CI | -6.1, 6.6 | |
| | | p-value | 0.9366 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.33, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 87.6 (17.06) | 87.7 (18.04) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 7.6 (22.93) | 9.2 (22.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 67 | -33, 67 |
| | | LS Mean (SE) | 5.4 (1.91) | 4.8 (2.89) |
| | | 95% CI | 1.6, 9.1 | -0.9, 10.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (3.46) | |
| | | 95% CI | -6.2, 7.4 | |
| | | p-value | 0.8584 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.34, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 88.2 (18.13) | 87.0 (16.25) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 50, 100 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | 7.6 (24.04) | 12.0 (22.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 67 | -33, 83 |
| | | LS Mean (SE) | 5.9 (2.03) | 4.5 (3.13) |
| | | 95% CI | 1.9, 9.9 | -1.6, 10.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (3.74) | |
| | | 95% CI | -6.0, 8.7 | |
| | | p-value | 0.7134 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.33, 0.48) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 89.8 (16.70) | 79.7 (26.57) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 0, 100 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | 8.9 (26.05) | 6.5 (30.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -33, 100 | -83, 67 |
| | | LS Mean (SE) | 8.1 (2.28) | -0.1 (3.66) |
| | | 95% CI | 3.6, 12.6 | -7.3, 7.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 8.2 (4.33) | |
| | | 95% CI | -0.3, 16.7 | |
| | | p-value | 0.0579 | |
| | | Corrected Hedges g (95% CI) [2] | 0.45 (-0.03, 0.93) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 90.0 (19.25) | 88.1 (20.89) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 100.0, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 50, 100 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 9.3 (21.56) | 16.7 (28.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -33, 50 | -17, 67 |
| | | LS Mean (SE) | 6.9 (3.39) | 4.9 (6.25) |
| | | 95% CI | 0.3, 13.5 | -7.3, 17.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.0 (7.14) | |
| | | 95% CI | -12.0, 16.0 | |
| | | p-value | 0.7821 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.72, 0.95) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 87.2 (20.59) | 79.2 (15.96) |
| | | Median | 100.0 | 75.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 91.7 |
| | | Min, Max | 33, 100 | 67, 100 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -3.8 (24.68) | 20.8 (31.55) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 41.7 |
| | | Min, Max | -67, 33 | 0, 67 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 81.3 (18.77) | 100.0 (NA) |
| | | Median | 83.3 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 100.0, 100.0 |
| | | Min, Max | 50, 100 | 100, 100 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -16.7 (21.82) | 0.0 (NA) |
| | | Median | -16.7 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | 0.0, 0.0 |
| | | Min, Max | -50, 17 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 90.0 (14.91) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 83.3, 100.0 | |
| | | Min, Max | 67, 100 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | -6.7 (19.00) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | -16.7, 0.0 | |
| | | Min, Max | -33, 17 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 16.7 (NA) | |
| | | Median | 16.7 | |
| | | Q1, Q3 | 16.7, 16.7 | |
| | | Min, Max | 17, 17 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 128 | 89 |
| | | Mean (StdDev) | 73.8 (30.50) | 78.1 (24.82) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 127 | 89 |
| | | Mean (StdDev) | -3.1 (33.25) | 1.5 (25.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 83 | -83, 50 |
| | | LS Mean (SE) | -1.8 (1.76) | 1.3 (2.14) |
| | | 95% CI | -5.2, 1.6 | -2.9, 5.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.1 (2.77) | |
| | | 95% CI | -8.6, 2.3 | |
| | | p-value | 0.2566 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.43, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 55 |
| | | Mean (StdDev) | 75.4 (27.01) | 74.8 (27.75) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 75 | 55 |
| | | Mean (StdDev) | -3.1 (28.96) | -0.6 (27.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -100, 50 |
| | | LS Mean (SE) | -1.0 (2.10) | -4.1 (2.53) |
| | | 95% CI | -5.1, 3.2 | -9.1, 0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.1 (3.29) | |
| | | 95% CI | -3.3, 9.6 | |
| | | p-value | 0.3413 | |
| | | Corrected Hedges g (95% CI) [2] | 0.17 (-0.18, 0.52) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 69.4 (28.30) | 68.8 (29.50) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | -7.7 (26.55) | -6.5 (27.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 83 | -83, 50 |
| | | LS Mean (SE) | -5.7 (2.12) | -6.1 (2.60) |
| | | 95% CI | -9.9, -1.5 | -11.1, -1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (3.35) | |
| | | 95% CI | -6.2, 6.9 | |
| | | p-value | 0.9165 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.33, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 69.2 (28.54) | 73.9 (25.92) |
| | | Median | 66.7 | 83.3 |
| | | Q1, Q3 | 50.0, 100.0 | 58.3, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | -7.6 (27.95) | -3.6 (24.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -83, 67 | -67, 50 |
| | | LS Mean (SE) | -6.6 (2.05) | -4.2 (2.53) |
| | | 95% CI | -10.6, -2.6 | -9.1, 0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.4 (3.25) | |
| | | 95% CI | -8.8, 4.0 | |
| | | p-value | 0.4572 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.45, 0.20) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 73.7 (24.70) | 74.1 (24.78) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 80 | 49 |
| | | Mean (StdDev) | -1.7 (21.96) | -4.8 (21.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -50, 67 | -67, 33 |
| | | LS Mean (SE) | -2.9 (2.18) | -5.8 (2.76) |
| | | 95% CI | -7.2, 1.4 | -11.2, -0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.8 (3.52) | |
| | | 95% CI | -4.0, 9.7 | |
| | | p-value | 0.4181 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.21, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 2.5 (1.08) | 1.2 (1.50) |
| | | 95% CI | 0.3, 4.6 | -1.8, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (1.85) | |
| | | 95% CI | -2.3, 4.9 | |
| | | p-value | 0.4861 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.14, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 77.2 (21.15) | 75.9 (20.35) |
| | | Median | 83.3 | 75.0 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 91.7 |
| | | Min, Max | 0, 100 | 25, 100 |
| Cycle 3 Day 1 | Actual | n | 199 | 114 |
| | | Mean (StdDev) | 78.2 (20.76) | 78.7 (20.39) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | 0.8 (19.65) | 2.9 (16.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -75, 58 | -42, 58 |
| | | LS Mean (SE) | 0.6 (1.26) | 2.2 (1.67) |
| | | 95% CI | -1.8, 3.1 | -1.1, 5.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.6 (2.09) | |
| | | 95% CI | -5.7, 2.5 | |
| | | p-value | 0.4457 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.32, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 98 |
| | | Mean (StdDev) | 79.4 (21.49) | 77.2 (20.47) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 91.7 |
| | | Min, Max | 8, 100 | 0, 100 |
| | Change from BL | n | 165 | 98 |
| | | Mean (StdDev) | 1.1 (17.95) | 1.4 (16.99) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -67, 58 | -42, 58 |
| | | LS Mean (SE) | 1.1 (1.32) | -0.1 (1.74) |
| | | 95% CI | -1.5, 3.7 | -3.5, 3.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (2.19) | |
| | | 95% CI | -3.1, 5.5 | |
| | | p-value | 0.5842 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.18, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 77.6 (21.46) | 78.3 (19.58) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 91.7 | 66.7, 100.0 |
| | | Min, Max | 8, 100 | 0, 100 |
| | Change from BL | n | 148 | 87 |
| | | Mean (StdDev) | -0.9 (17.46) | 2.0 (18.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -58, 33 | -33, 67 |
| | | LS Mean (SE) | -1.2 (1.38) | 0.1 (1.81) |
| | | 95% CI | -4.0, 1.5 | -3.5, 3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (2.28) | |
| | | 95% CI | -5.8, 3.1 | |
| | | p-value | 0.5591 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.34, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 66 |
| | | Mean (StdDev) | 77.7 (21.87) | 78.4 (20.93) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 8, 100 | 17, 100 |
| | Change from BL | n | 131 | 66 |
| | | Mean (StdDev) | -1.3 (18.99) | 1.3 (20.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -75, 33 | -50, 50 |
| | | LS Mean (SE) | -1.0 (1.44) | -0.6 (1.97) |
| | | 95% CI | -3.8, 1.9 | -4.5, 3.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (2.44) | |
| | | 95% CI | -5.1, 4.4 | |
| | | p-value | 0.8815 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.32, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 78.6 (21.60) | 79.2 (20.03) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 33, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 0.1 (18.20) | 3.1 (16.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -8.3, 8.3 |
| | | Min, Max | -67, 50 | -33, 50 |
| | | LS Mean (SE) | -0.5 (1.49) | -1.6 (2.16) |
| | | 95% CI | -3.4, 2.4 | -5.8, 2.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.1 (2.63) | |
| | | 95% CI | -4.1, 6.2 | |
| | | p-value | 0.6767 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.26, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 110 | 48 |
| | | Mean (StdDev) | 78.3 (21.92) | 81.8 (18.33) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 109 | 48 |
| | | Mean (StdDev) | 0.5 (18.37) | 4.9 (17.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | -4.2, 12.5 |
| | | Min, Max | -50, 42 | -33, 58 |
| | | LS Mean (SE) | 0.0 (1.53) | 0.4 (2.23) |
| | | 95% CI | -3.0, 3.0 | -4.0, 4.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.4 (2.70) | |
| | | 95% CI | -5.7, 4.9 | |
| | | p-value | 0.8902 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.36, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 37 |
| | | Mean (StdDev) | 79.2 (21.20) | 84.2 (14.93) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 75.0, 100.0 |
| | | Min, Max | 0, 100 | 50, 100 |
| | Change from BL | n | 96 | 37 |
| | | Mean (StdDev) | 0.8 (20.93) | 7.4 (18.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 47 | -33, 50 |
| | | LS Mean (SE) | -0.3 (1.61) | 2.9 (2.46) |
| | | 95% CI | -3.4, 2.9 | -1.9, 7.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.2 (2.94) | |
| | | 95% CI | -8.9, 2.6 | |
| | | p-value | 0.2800 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.58, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 81.1 (18.77) | 82.0 (20.20) |
| | | Median | 83.3 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 70.8, 100.0 |
| | | Min, Max | 25, 100 | 33, 100 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | 2.3 (20.05) | 6.3 (20.41) |
| | | Median | 0.0 | 8.3 |
| | | Q1, Q3 | -8.3, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 42 | -33, 58 |
| | | LS Mean (SE) | 0.5 (1.71) | 0.9 (2.63) |
| | | 95% CI | -2.8, 3.9 | -4.3, 6.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (3.14) | |
| | | 95% CI | -6.5, 5.8 | |
| | | p-value | 0.9122 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.43, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 77.9 (20.26) | 84.1 (19.29) |
| | | Median | 83.3 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | -1.6 (18.08) | 8.3 (18.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 8.3 | 0.0, 8.3 |
| | | Min, Max | -58, 33 | -25, 67 |
| | | LS Mean (SE) | -2.8 (1.91) | 3.6 (3.05) |
| | | 95% CI | -6.5, 1.0 | -2.4, 9.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -6.4 (3.61) | |
| | | 95% CI | -13.5, 0.7 | |
| | | p-value | 0.0763 | |
| | | Corrected Hedges g (95% CI) [2] | -0.42 (-0.90, 0.06) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 80.3 (23.18) | 76.2 (27.82) |
| | | Median | 91.7 | 91.7 |
| | | Q1, Q3 | 66.7, 100.0 | 41.7, 100.0 |
| | | Min, Max | 33, 100 | 42, 100 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 1.7 (15.40) | -1.2 (35.82) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | 0.0, 8.3 | -33.3, 16.7 |
| | | Min, Max | -33, 42 | -42, 67 |
| | | LS Mean (SE) | 1.1 (2.78) | -8.0 (5.12) |
| | | 95% CI | -4.3, 6.6 | -18.0, 2.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 9.1 (5.82) | |
| | | 95% CI | -2.3, 20.5 | |
| | | p-value | 0.1176 | |
| | | Corrected Hedges g (95% CI) [2] | 0.64 (-0.21, 1.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 78.8 (20.30) | 68.8 (27.53) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 45.8, 91.7 |
| | | Min, Max | 33, 100 | 42, 100 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -6.4 (23.11) | -2.1 (37.50) |
| | | Median | 0.0 | -12.5 |
| | | Q1, Q3 | -16.7, 0.0 | -29.2, 25.0 |
| | | Min, Max | -50, 42 | -33, 50 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 79.2 (26.35) | 100.0 (NA) |
| | | Median | 91.7 | 100.0 |
| | | Q1, Q3 | 58.3, 100.0 | 100.0, 100.0 |
| | | Min, Max | 33, 100 | 100, 100 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -11.5 (20.38) | 0.0 (NA) |
| | | Median | -8.3 | 0.0 |
| | | Q1, Q3 | -20.8, 0.0 | 0.0, 0.0 |
| | | Min, Max | -50, 17 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 91.7 (11.79) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 83.3, 100.0 | |
| | | Min, Max | 75, 100 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | -6.7 (13.69) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | -16.7, 0.0 | |
| | | Min, Max | -25, 8 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 128 | 88 |
| | | Mean (StdDev) | 63.7 (26.63) | 66.9 (21.10) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 41.7, 83.3 | 50.0, 83.3 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 127 | 88 |
| | | Mean (StdDev) | -13.5 (22.33) | -10.1 (20.97) |
| | | Median | -8.3 | -8.3 |
| | | Q1, Q3 | -25.0, 0.0 | -25.0, 0.0 |
| | | Min, Max | -92, 56 | -58, 33 |
| | | LS Mean (SE) | -12.3 (1.48) | -9.5 (1.82) |
| | | 95% CI | -15.2, -9.4 | -13.1, -5.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.9 (2.35) | |
| | | 95% CI | -7.5, 1.7 | |
| | | p-value | 0.2238 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.44, 0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 56 |
| | | Mean (StdDev) | 65.5 (24.95) | 72.2 (17.14) |
| | | Median | 66.7 | 66.7 |
| | | Q1, Q3 | 50.0, 83.3 | 66.7, 83.3 |
| | | Min, Max | 8, 100 | 17, 100 |
| | Change from BL | n | 76 | 56 |
| | | Mean (StdDev) | -11.0 (24.68) | -7.9 (17.37) |
| | | Median | -8.3 | -8.3 |
| | | Q1, Q3 | -25.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 58 | -42, 42 |
| | | LS Mean (SE) | -10.3 (1.74) | -5.4 (2.11) |
| | | 95% CI | -13.8, -6.9 | -9.5, -1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -5.0 (2.74) | |
| | | 95% CI | -10.3, 0.4 | |
| | | p-value | 0.0695 | |
| | | Corrected Hedges g (95% CI) [2] | -0.32 (-0.67, 0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 71.5 (22.59) | 69.1 (22.64) |
| | | Median | 75.0 | 70.8 |
| | | Q1, Q3 | 58.3, 91.7 | 58.3, 83.3 |
| | | Min, Max | 8, 100 | 17, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | -3.5 (19.62) | -7.3 (21.60) |
| | | Median | 0.0 | -4.2 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 0.0 |
| | | Min, Max | -50, 50 | -75, 42 |
| | | LS Mean (SE) | -4.7 (1.76) | -5.1 (2.15) |
| | | 95% CI | -8.2, -1.3 | -9.3, -0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (2.77) | |
| | | 95% CI | -5.1, 5.8 | |
| | | p-value | 0.8957 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.32, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 69.0 (23.54) | 73.8 (20.57) |
| | | Median | 75.0 | 75.0 |
| | | Q1, Q3 | 58.3, 83.3 | 58.3, 91.7 |
| | | Min, Max | 0, 100 | 33, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | -7.2 (21.40) | -4.9 (23.68) |
| | | Median | -8.3 | -4.2 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, 8.3 |
| | | Min, Max | -75, 58 | -58, 67 |
| | | LS Mean (SE) | -7.7 (1.67) | -3.5 (2.08) |
| | | 95% CI | -11.0, -4.4 | -7.6, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.2 (2.67) | |
| | | 95% CI | -9.4, 1.1 | |
| | | p-value | 0.1175 | |
| | | Corrected Hedges g (95% CI) [2] | -0.26 (-0.59, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 79 | 49 |
| | | Mean (StdDev) | 67.9 (23.69) | 77.0 (20.59) |
| | | Median | 75.0 | 75.0 |
| | | Q1, Q3 | 58.3, 83.3 | 66.7, 91.7 |
| | | Min, Max | 8, 100 | 33, 100 |
| | Change from BL | n | 78 | 49 |
| | | Mean (StdDev) | -8.2 (21.21) | -2.0 (20.02) |
| | | Median | -8.3 | 0.0 |
| | | Q1, Q3 | -25.0, 0.0 | -8.3, 8.3 |
| | | Min, Max | -75, 50 | -42, 42 |
| | | LS Mean (SE) | -7.7 (1.78) | -1.3 (2.25) |
| | | 95% CI | -11.2, -4.2 | -5.7, 3.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -6.4 (2.87) | |
| | | 95% CI | -12.1, -0.8 | |
| | | p-value | 0.0251 | |
| | | Corrected Hedges g (95% CI) [2] | -0.41 (-0.77, -0.05) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -3.0 (0.98) | -1.7 (1.35) |
| | | 95% CI | -4.9, -1.1 | -4.3, 1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (1.67) | |
| | | 95% CI | -4.6, 1.9 | |
| | | p-value | 0.4194 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.31, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 82.2 (19.09) | 81.6 (18.63) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 33, 100 |
| Cycle 3 Day 1 | Actual | n | 199 | 114 |
| | | Mean (StdDev) | 82.7 (18.61) | 80.7 (18.50) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 33, 100 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | -0.2 (16.58) | -1.3 (16.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 50 | -67, 33 |
| | | LS Mean (SE) | -0.6 (1.17) | -2.0 (1.55) |
| | | 95% CI | -2.9, 1.7 | -5.1, 1.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (1.95) | |
| | | 95% CI | -2.4, 5.3 | |
| | | p-value | 0.4567 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.14, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 168 | 98 |
| | | Mean (StdDev) | 83.2 (18.01) | 83.0 (17.42) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 166 | 98 |
| | | Mean (StdDev) | -1.0 (16.17) | 0.5 (14.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 16.7 |
| | | Min, Max | -50, 50 | -33, 33 |
| | | LS Mean (SE) | -0.3 (1.24) | -0.3 (1.62) |
| | | 95% CI | -2.7, 2.2 | -3.5, 2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (2.04) | |
| | | 95% CI | -3.9, 4.1 | |
| | | p-value | 0.9771 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.25, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 150 | 87 |
| | | Mean (StdDev) | 84.3 (18.44) | 83.0 (19.02) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 149 | 87 |
| | | Mean (StdDev) | -0.9 (16.87) | 0.6 (18.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 16.7 |
| | | Min, Max | -50, 50 | -50, 33 |
| | | LS Mean (SE) | -0.2 (1.29) | -0.8 (1.69) |
| | | 95% CI | -2.7, 2.3 | -4.1, 2.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (2.13) | |
| | | 95% CI | -3.6, 4.7 | |
| | | p-value | 0.7925 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.23, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 66 |
| | | Mean (StdDev) | 82.3 (18.62) | 85.1 (16.83) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 83.3, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 131 | 66 |
| | | Mean (StdDev) | -2.8 (19.41) | 3.3 (15.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 16.7 |
| | | Min, Max | -67, 50 | -33, 50 |
| | | LS Mean (SE) | -1.6 (1.35) | 1.6 (1.86) |
| | | 95% CI | -4.3, 1.0 | -2.0, 5.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.2 (2.30) | |
| | | 95% CI | -7.7, 1.3 | |
| | | p-value | 0.1618 | |
| | | Corrected Hedges g (95% CI) [2] | -0.21 (-0.51, 0.09) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 83.5 (20.09) | 79.7 (20.63) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | -2.1 (19.47) | -2.3 (19.15) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -83, 33 | -50, 33 |
| | | LS Mean (SE) | -1.4 (1.40) | -3.2 (2.04) |
| | | 95% CI | -4.2, 1.3 | -7.2, 0.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (2.48) | |
| | | 95% CI | -3.1, 6.7 | |
| | | p-value | 0.4647 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.21, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 110 | 48 |
| | | Mean (StdDev) | 84.2 (18.59) | 83.7 (18.98) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 33, 100 |
| | Change from BL | n | 109 | 48 |
| | | Mean (StdDev) | -1.4 (18.30) | 2.8 (18.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 |
| | | Min, Max | -50, 50 | -50, 67 |
| | | LS Mean (SE) | -0.6 (1.45) | 0.2 (2.11) |
| | | 95% CI | -3.4, 2.3 | -3.9, 4.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.8 (2.57) | |
| | | 95% CI | -5.8, 4.3 | |
| | | p-value | 0.7612 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.39, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 37 |
| | | Mean (StdDev) | 84.7 (17.62) | 85.6 (16.74) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 50, 100 |
| | Change from BL | n | 96 | 37 |
| | | Mean (StdDev) | -1.4 (18.84) | 2.3 (14.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 8.3 | 0.0, 16.7 |
| | | Min, Max | -67, 50 | -33, 33 |
| | | LS Mean (SE) | -1.2 (1.52) | 1.2 (2.32) |
| | | 95% CI | -4.2, 1.8 | -3.4, 5.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.4 (2.78) | |
| | | 95% CI | -7.9, 3.0 | |
| | | p-value | 0.3852 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.54, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 82.7 (15.93) | 81.8 (22.54) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 0, 100 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | -2.6 (17.94) | -2.1 (15.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -8.3, 0.0 |
| | | Min, Max | -67, 50 | -50, 33 |
| | | LS Mean (SE) | -2.5 (1.62) | -3.2 (2.49) |
| | | 95% CI | -5.7, 0.7 | -8.1, 1.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.7 (2.97) | |
| | | 95% CI | -5.1, 6.6 | |
| | | p-value | 0.8042 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.36, 0.46) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 82.8 (18.69) | 81.2 (19.01) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 33, 100 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | -2.9 (19.75) | -2.2 (16.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 0.0 |
| | | Min, Max | -67, 50 | -33, 33 |
| | | LS Mean (SE) | -1.9 (1.82) | -1.1 (2.89) |
| | | 95% CI | -5.5, 1.7 | -6.8, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.8 (3.42) | |
| | | 95% CI | -7.5, 5.9 | |
| | | p-value | 0.8190 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.53, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 84.7 (13.54) | 85.7 (20.25) |
| | | Median | 83.3 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 67, 100 | 50, 100 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 2.7 (12.44) | 0.0 (9.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 33 | -17, 17 |
| | | LS Mean (SE) | -0.7 (2.65) | -3.3 (4.89) |
| | | 95% CI | -5.9, 4.5 | -12.9, 6.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (5.57) | |
| | | 95% CI | -8.3, 13.6 | |
| | | p-value | 0.6359 | |
| | | Corrected Hedges g (95% CI) [2] | 0.19 (-0.64, 1.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 84.6 (14.37) | 75.0 (31.91) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 50.0, 100.0 |
| | | Min, Max | 67, 100 | 33, 100 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 5.1 (12.52) | -12.5 (15.96) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | 0.0, 16.7 | -25.0, 0.0 |
| | | Min, Max | -17, 33 | -33, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 79.2 (17.25) | 83.3 (NA) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 91.7 | 83.3, 83.3 |
| | | Min, Max | 50, 100 | 83, 83 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -6.3 (23.46) | -16.7 (NA) |
| | | Median | 0.0 | -16.7 |
| | | Q1, Q3 | -16.7, 8.3 | -16.7, -16.7 |
| | | Min, Max | -50, 17 | -17, -17 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 90.0 (9.13) | |
| | | Median | 83.3 | |
| | | Q1, Q3 | 83.3, 100.0 | |
| | | Min, Max | 83, 100 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 3.3 (18.26) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | -17, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 33.3 (NA) | |
| | | Median | 33.3 | |
| | | Q1, Q3 | 33.3, 33.3 | |
| | | Min, Max | 33, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 128 | 88 |
| | | Mean (StdDev) | 79.4 (22.48) | 81.1 (20.87) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 127 | 88 |
| | | Mean (StdDev) | -2.1 (22.91) | -1.3 (19.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -83, 50 | -100, 33 |
| | | LS Mean (SE) | -3.2 (1.38) | -1.5 (1.70) |
| | | 95% CI | -5.9, -0.5 | -4.8, 1.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.7 (2.19) | |
| | | 95% CI | -6.0, 2.6 | |
| | | p-value | 0.4372 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.38, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 56 |
| | | Mean (StdDev) | 81.6 (20.83) | 80.7 (22.42) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 76 | 56 |
| | | Mean (StdDev) | -0.7 (18.75) | -2.7 (18.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 50 | -67, 33 |
| | | LS Mean (SE) | -2.0 (1.65) | -3.8 (1.98) |
| | | 95% CI | -5.2, 1.3 | -7.7, 0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (2.57) | |
| | | 95% CI | -3.2, 6.9 | |
| | | p-value | 0.4792 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.22, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 78.3 (24.07) | 81.8 (20.55) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 33, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | -1.3 (17.57) | -0.3 (18.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 33 | -33, 50 |
| | | LS Mean (SE) | -3.7 (1.65) | -0.8 (2.01) |
| | | 95% CI | -7.0, -0.5 | -4.8, 3.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.9 (2.60) | |
| | | 95% CI | -8.0, 2.2 | |
| | | p-value | 0.2676 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.54, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 78.2 (23.92) | 79.4 (21.56) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | -2.6 (19.66) | -3.6 (21.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 50 | -50, 50 |
| | | LS Mean (SE) | -3.9 (1.59) | -4.3 (1.96) |
| | | 95% CI | -7.1, -0.8 | -8.1, -0.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (2.52) | |
| | | 95% CI | -4.6, 5.3 | |
| | | p-value | 0.8993 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.31, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 79 | 49 |
| | | Mean (StdDev) | 81.9 (20.36) | 81.3 (21.15) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 78 | 49 |
| | | Mean (StdDev) | 0.6 (18.89) | -3.7 (17.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 0.0 |
| | | Min, Max | -67, 50 | -50, 33 |
| | | LS Mean (SE) | -1.2 (1.68) | -3.8 (2.12) |
| | | 95% CI | -4.5, 2.1 | -8.0, 0.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.7 (2.71) | |
| | | 95% CI | -2.6, 8.0 | |
| | | p-value | 0.3226 | |
| | | Corrected Hedges g (95% CI) [2] | 0.18 (-0.18, 0.54) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -1.7 (0.90) | -1.7 (1.24) |
| | | 95% CI | -3.4, 0.1 | -4.1, 0.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (1.53) | |
| | | 95% CI | -3.0, 3.0 | |
| | | p-value | 0.9895 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.22, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 76.4 (26.56) | 76.7 (23.74) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 199 | 114 |
| | | Mean (StdDev) | 84.1 (22.62) | 84.5 (20.77) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | 6.3 (26.47) | 7.9 (22.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 100 | -33, 83 |
| | | LS Mean (SE) | 6.3 (1.49) | 7.2 (1.97) |
| | | 95% CI | 3.4, 9.2 | 3.3, 11.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.9 (2.47) | |
| | | 95% CI | -5.7, 4.0 | |
| | | p-value | 0.7228 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.27, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 98 |
| | | Mean (StdDev) | 85.7 (20.31) | 85.9 (19.20) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 165 | 98 |
| | | Mean (StdDev) | 8.2 (25.21) | 9.4 (22.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 83 | -50, 83 |
| | | LS Mean (SE) | 7.5 (1.57) | 8.2 (2.06) |
| | | 95% CI | 4.4, 10.6 | 4.1, 12.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.6 (2.59) | |
| | | 95% CI | -5.7, 4.5 | |
| | | p-value | 0.8111 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.28, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 150 | 87 |
| | | Mean (StdDev) | 85.8 (19.25) | 84.1 (24.63) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 0, 100 |
| | Change from BL | n | 149 | 87 |
| | | Mean (StdDev) | 7.0 (25.64) | 7.5 (22.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -100, 50 |
| | | LS Mean (SE) | 6.7 (1.64) | 5.2 (2.15) |
| | | 95% CI | 3.5, 9.9 | 0.9, 9.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.6 (2.71) | |
| | | 95% CI | -3.8, 6.9 | |
| | | p-value | 0.5659 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.19, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 66 |
| | | Mean (StdDev) | 88.0 (19.02) | 85.9 (19.66) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 131 | 66 |
| | | Mean (StdDev) | 9.4 (24.82) | 10.9 (20.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -33, 100 | -33, 67 |
| | | LS Mean (SE) | 8.5 (1.72) | 7.2 (2.36) |
| | | 95% CI | 5.1, 11.9 | 2.6, 11.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (2.92) | |
| | | 95% CI | -4.5, 7.0 | |
| | | p-value | 0.6624 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.23, 0.36) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 87.1 (20.09) | 85.0 (24.10) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 75.0, 100.0 | 66.7, 100.0 |
| | | Min, Max | 33, 100 | 0, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 8.1 (28.03) | 8.8 (22.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 6.7 (1.78) | 4.8 (2.61) |
| | | 95% CI | 3.2, 10.2 | -0.3, 9.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.9 (3.16) | |
| | | 95% CI | -4.3, 8.1 | |
| | | p-value | 0.5510 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.23, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 110 | 48 |
| | | Mean (StdDev) | 88.5 (20.03) | 87.2 (21.26) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 75.0, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 109 | 48 |
| | | Mean (StdDev) | 10.7 (27.36) | 10.8 (21.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -33, 67 |
| | | LS Mean (SE) | 8.6 (1.83) | 7.1 (2.68) |
| | | 95% CI | 5.1, 12.2 | 1.8, 12.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.6 (3.25) | |
| | | 95% CI | -4.8, 7.9 | |
| | | p-value | 0.6312 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.26, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 37 |
| | | Mean (StdDev) | 86.9 (20.73) | 89.6 (20.54) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 83.3, 100.0 |
| | | Min, Max | 17, 100 | 17, 100 |
| | Change from BL | n | 96 | 37 |
| | | Mean (StdDev) | 6.9 (26.34) | 12.2 (20.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 100 | -33, 67 |
| | | LS Mean (SE) | 5.6 (1.93) | 8.3 (2.97) |
| | | 95% CI | 1.8, 9.4 | 2.5, 14.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.7 (3.54) | |
| | | 95% CI | -9.6, 4.3 | |
| | | p-value | 0.4516 | |
| | | Corrected Hedges g (95% CI) [2] | -0.14 (-0.52, 0.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 31 |
| | | Mean (StdDev) | 86.5 (21.69) | 90.9 (16.58) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 83.3, 100.0 |
| | | Min, Max | 0, 100 | 33, 100 |
| | Change from BL | n | 83 | 31 |
| | | Mean (StdDev) | 7.4 (28.42) | 17.2 (23.37) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -17, 67 |
| | | LS Mean (SE) | 6.3 (2.04) | 8.7 (3.21) |
| | | 95% CI | 2.3, 10.3 | 2.4, 15.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.4 (3.81) | |
| | | 95% CI | -9.9, 5.1 | |
| | | p-value | 0.5314 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.54, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 87.3 (20.46) | 82.6 (17.75) |
| | | Median | 100.0 | 83.3 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 50, 100 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | 8.7 (29.31) | 9.4 (25.04) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | -100, 83 | -33, 67 |
| | | LS Mean (SE) | 7.4 (2.30) | 4.5 (3.70) |
| | | 95% CI | 2.9, 11.9 | -2.8, 11.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.0 (4.36) | |
| | | 95% CI | -5.5, 11.5 | |
| | | p-value | 0.4918 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.31, 0.64) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 88.7 (17.16) | 85.7 (20.25) |
| | | Median | 100.0 | 100.0 |
| | | Q1, Q3 | 83.3, 100.0 | 66.7, 100.0 |
| | | Min, Max | 50, 100 | 50, 100 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 8.7 (26.84) | 11.9 (34.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 33.3 |
| | | Min, Max | -50, 83 | -33, 67 |
| | | LS Mean (SE) | 6.0 (3.40) | 5.0 (6.28) |
| | | 95% CI | -0.6, 12.7 | -7.3, 17.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.0 (7.15) | |
| | | 95% CI | -13.0, 15.1 | |
| | | p-value | 0.8863 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.78, 0.90) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 87.2 (18.20) | 83.3 (19.25) |
| | | Median | 100.0 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 50, 100 | 67, 100 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 5.1 (32.90) | 20.8 (36.96) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 16.7 | -8.3, 50.0 |
| | | Min, Max | -50, 67 | -17, 67 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 81.3 (22.60) | 100.0 (NA) |
| | | Median | 91.7 | 100.0 |
| | | Q1, Q3 | 58.3, 100.0 | 100.0, 100.0 |
| | | Min, Max | 50, 100 | 100, 100 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -6.3 (19.80) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -8.3, 0.0 | 0.0, 0.0 |
| | | Min, Max | -50, 17 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 96.7 (7.45) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 83, 100 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 10.0 (25.28) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 16.7 | |
| | | Min, Max | -17, 50 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 100.0 (NA) | |
| | | Median | 100.0 | |
| | | Q1, Q3 | 100.0, 100.0 | |
| | | Min, Max | 100, 100 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 16.7 (NA) | |
| | | Median | 16.7 | |
| | | Q1, Q3 | 16.7, 16.7 | |
| | | Min, Max | 17, 17 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 128 | 88 |
| | | Mean (StdDev) | 74.5 (29.05) | 80.9 (22.54) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 127 | 88 |
| | | Mean (StdDev) | -0.9 (30.23) | 2.1 (22.29) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | 0.0, 16.7 |
| | | Min, Max | -100, 83 | -67, 67 |
| | | LS Mean (SE) | -0.9 (1.76) | 3.1 (2.16) |
| | | 95% CI | -4.4, 2.5 | -1.1, 7.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.0 (2.79) | |
| | | 95% CI | -9.5, 1.4 | |
| | | p-value | 0.1493 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.47, 0.07) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 56 |
| | | Mean (StdDev) | 75.7 (27.95) | 75.0 (25.62) |
| | | Median | 83.3 | 83.3 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 76 | 56 |
| | | Mean (StdDev) | -1.5 (30.93) | -7.1 (23.96) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 0.0 |
| | | Min, Max | -100, 67 | -100, 50 |
| | | LS Mean (SE) | -1.2 (2.10) | -5.1 (2.53) |
| | | 95% CI | -5.3, 2.9 | -10.1, -0.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.9 (3.29) | |
| | | 95% CI | -2.6, 10.3 | |
| | | p-value | 0.2386 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (-0.14, 0.55) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 74.1 (28.71) | 71.9 (27.63) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | -0.6 (29.96) | -6.8 (30.29) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -100, 50 |
| | | LS Mean (SE) | -2.0 (2.12) | -5.6 (2.59) |
| | | 95% CI | -6.1, 2.2 | -10.7, -0.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.6 (3.35) | |
| | | 95% CI | -2.9, 10.2 | |
| | | p-value | 0.2795 | |
| | | Corrected Hedges g (95% CI) [2] | 0.19 (-0.16, 0.54) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 72.5 (27.03) | 72.2 (26.16) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 50.0, 100.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | -3.7 (30.88) | -5.3 (29.83) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -100, 50 |
| | | LS Mean (SE) | -3.5 (2.04) | -6.1 (2.53) |
| | | 95% CI | -7.5, 0.5 | -11.1, -1.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (3.25) | |
| | | 95% CI | -3.7, 9.0 | |
| | | p-value | 0.4180 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.19, 0.46) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 79 | 49 |
| | | Mean (StdDev) | 77.2 (26.98) | 75.2 (25.03) |
| | | Median | 83.3 | 66.7 |
| | | Q1, Q3 | 66.7, 100.0 | 66.7, 100.0 |
| | | Min, Max | 0, 100 | 17, 100 |
| | Change from BL | n | 78 | 49 |
| | | Mean (StdDev) | 1.7 (25.57) | -4.1 (20.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 0.0 |
| | | Min, Max | -100, 67 | -50, 33 |
| | | LS Mean (SE) | 0.7 (2.18) | -6.2 (2.74) |
| | | 95% CI | -3.6, 5.0 | -11.6, -0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 6.9 (3.51) | |
| | | 95% CI | 0.0, 13.8 | |
| | | p-value | 0.0485 | |
| | | Corrected Hedges g (95% CI) [2] | 0.36 (0.00, 0.72) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 4.2 (1.10) | 3.1 (1.53) |
| | | 95% CI | 2.0, 6.4 | 0.1, 6.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.1 (1.88) | |
| | | 95% CI | -2.6, 4.8 | |
| | | p-value | 0.5528 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.15, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 32.2 (22.81) | 34.6 (23.29) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 11.1, 33.3 | 22.2, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 200 | 114 |
| | | Mean (StdDev) | 32.4 (20.97) | 32.8 (24.62) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 44.4 | 11.1, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 198 | 114 |
| | | Mean (StdDev) | 1.8 (20.00) | -1.6 (22.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -78, 56 | -67, 67 |
| | | LS Mean (SE) | 1.6 (1.38) | 0.1 (1.84) |
| | | 95% CI | -1.1, 4.3 | -3.5, 3.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.5 (2.30) | |
| | | 95% CI | -3.0, 6.0 | |
| | | p-value | 0.5215 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.16, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 99 |
| | | Mean (StdDev) | 30.6 (21.15) | 30.3 (21.98) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 100 | 0, 89 |
| | Change from BL | n | 165 | 99 |
| | | Mean (StdDev) | -0.1 (20.94) | -4.3 (21.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 0.0 |
| | | Min, Max | -78, 89 | -89, 44 |
| | | LS Mean (SE) | 0.3 (1.47) | -1.4 (1.92) |
| | | 95% CI | -2.5, 3.2 | -5.2, 2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (2.42) | |
| | | 95% CI | -3.0, 6.5 | |
| | | p-value | 0.4669 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.16, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 27.3 (19.90) | 28.6 (21.00) |
| | | Median | 22.2 | 33.3 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 89 | 0, 100 |
| | Change from BL | n | 147 | 87 |
| | | Mean (StdDev) | -2.9 (19.68) | -5.5 (21.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 0.0 | -22.2, 11.1 |
| | | Min, Max | -78, 56 | -89, 44 |
| | | LS Mean (SE) | -2.1 (1.54) | -1.9 (2.01) |
| | | 95% CI | -5.1, 1.0 | -5.9, 2.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.1 (2.53) | |
| | | 95% CI | -5.1, 4.8 | |
| | | p-value | 0.9589 | |
| | | Corrected Hedges g (95% CI) [2] | -0.01 (-0.27, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 131 | 68 |
| | | Mean (StdDev) | 26.8 (21.08) | 30.3 (23.73) |
| | | Median | 22.2 | 27.8 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 44.4 |
| | | Min, Max | 0, 100 | 0, 89 |
| | Change from BL | n | 129 | 68 |
| | | Mean (StdDev) | -2.9 (22.59) | -3.3 (22.04) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -22.2, 11.1 |
| | | Min, Max | -89, 67 | -44, 78 |
| | | LS Mean (SE) | -2.0 (1.61) | -0.8 (2.18) |
| | | 95% CI | -5.2, 1.2 | -5.1, 3.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.2 (2.71) | |
| | | 95% CI | -6.5, 4.1 | |
| | | p-value | 0.6606 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.36, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 23.6 (18.87) | 30.5 (23.92) |
| | | Median | 22.2 | 33.3 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 44.4 |
| | | Min, Max | 0, 100 | 0, 89 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | -5.9 (21.45) | -1.3 (24.81) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 0.0 | -11.1, 11.1 |
| | | Min, Max | -89, 44 | -67, 56 |
| | | LS Mean (SE) | -4.6 (1.65) | 1.0 (2.41) |
| | | 95% CI | -7.8, -1.3 | -3.7, 5.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -5.6 (2.92) | |
| | | 95% CI | -11.3, 0.2 | |
| | | p-value | 0.0566 | |
| | | Corrected Hedges g (95% CI) [2] | -0.31 (-0.64, 0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 23.3 (19.12) | 25.9 (23.30) |
| | | Median | 22.2 | 22.2 |
| | | Q1, Q3 | 11.1, 33.3 | 5.6, 33.3 |
| | | Min, Max | 0, 78 | 0, 78 |
| | Change from BL | n | 108 | 48 |
| | | Mean (StdDev) | -6.6 (23.14) | -6.7 (21.71) |
| | | Median | -11.1 | -5.6 |
| | | Q1, Q3 | -22.2, 0.0 | -11.1, 0.0 |
| | | Min, Max | -89, 67 | -67, 44 |
| | | LS Mean (SE) | -4.5 (1.70) | -3.5 (2.47) |
| | | 95% CI | -7.9, -1.2 | -8.4, 1.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.0 (3.00) | |
| | | 95% CI | -6.9, 4.9 | |
| | | p-value | 0.7337 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.40, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 23.5 (19.17) | 22.2 (20.67) |
| | | Median | 22.2 | 22.2 |
| | | Q1, Q3 | 11.1, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 78 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | -5.8 (20.58) | -8.2 (20.62) |
| | | Median | 0.0 | -11.1 |
| | | Q1, Q3 | -11.1, 0.0 | -22.2, 0.0 |
| | | Min, Max | -67, 44 | -67, 44 |
| | | LS Mean (SE) | -3.9 (1.77) | -5.1 (2.69) |
| | | 95% CI | -7.4, -0.5 | -10.4, 0.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (3.21) | |
| | | 95% CI | -5.1, 7.5 | |
| | | p-value | 0.7155 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.31, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 22.9 (17.81) | 25.0 (19.76) |
| | | Median | 22.2 | 22.2 |
| | | Q1, Q3 | 11.1, 33.3 | 11.1, 33.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | -6.8 (20.37) | -7.6 (21.57) |
| | | Median | 0.0 | -11.1 |
| | | Q1, Q3 | -22.2, 0.0 | -16.7, 0.0 |
| | | Min, Max | -56, 44 | -67, 44 |
| | | LS Mean (SE) | -4.8 (1.89) | -3.4 (2.91) |
| | | 95% CI | -8.5, -1.1 | -9.1, 2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.4 (3.48) | |
| | | 95% CI | -8.2, 5.4 | |
| | | p-value | 0.6853 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.49, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 24.0 (19.62) | 30.4 (29.44) |
| | | Median | 22.2 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 55.6 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | -4.4 (20.58) | -2.9 (26.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -22.2, 2.8 | -11.1, 11.1 |
| | | Min, Max | -56, 44 | -78, 44 |
| | | LS Mean (SE) | -3.2 (2.12) | -1.0 (3.39) |
| | | 95% CI | -7.4, 0.9 | -7.6, 5.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.2 (4.01) | |
| | | 95% CI | -10.1, 5.6 | |
| | | p-value | 0.5754 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.61, 0.34) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 16.4 (17.60) | 23.8 (26.00) |
| | | Median | 11.1 | 22.2 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 44.4 |
| | | Min, Max | 0, 44 | 0, 67 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -13.3 (18.98) | -11.1 (30.77) |
| | | Median | -11.1 | 0.0 |
| | | Q1, Q3 | -22.2, 0.0 | -22.2, 0.0 |
| | | Min, Max | -44, 44 | -67, 33 |
| | | LS Mean (SE) | -11.4 (3.15) | -4.8 (5.82) |
| | | 95% CI | -17.6, -5.2 | -16.3, 6.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -6.6 (6.63) | |
| | | 95% CI | -19.6, 6.4 | |
| | | p-value | 0.3224 | |
| | | Corrected Hedges g (95% CI) [2] | -0.41 (-1.25, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 21.4 (19.49) | 36.1 (26.25) |
| | | Median | 22.2 | 44.4 |
| | | Q1, Q3 | 0.0, 33.3 | 16.7, 55.6 |
| | | Min, Max | 0, 67 | 0, 56 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -3.4 (25.81) | -13.9 (37.82) |
| | | Median | 0.0 | -5.6 |
| | | Q1, Q3 | -11.1, 0.0 | -38.9, 11.1 |
| | | Min, Max | -44, 56 | -67, 22 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 22.2 (14.55) | 0.0 (NA) |
| | | Median | 27.8 | 0.0 |
| | | Q1, Q3 | 11.1, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | 5.6 (13.28) | 0.0 (NA) |
| | | Median | 5.6 | 0.0 |
| | | Q1, Q3 | -5.6, 16.7 | 0.0, 0.0 |
| | | Min, Max | -11, 22 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 15.6 (14.91) | |
| | | Median | 22.2 | |
| | | Q1, Q3 | 0.0, 22.2 | |
| | | Min, Max | 0, 33 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | -2.2 (16.48) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | -11.1, 0.0 | |
| | | Min, Max | -22, 22 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 11.1 (NA) | |
| | | Median | 11.1 | |
| | | Q1, Q3 | 11.1, 11.1 | |
| | | Min, Max | 11, 11 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -22.2 (NA) | |
| | | Median | -22.2 | |
| | | Q1, Q3 | -22.2, -22.2 | |
| | | Min, Max | -22, -22 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 127 | 89 |
| | | Mean (StdDev) | 37.4 (25.29) | 33.2 (24.99) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 44.4 | 11.1, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 126 | 89 |
| | | Mean (StdDev) | 3.2 (25.07) | -0.7 (25.39) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 11.1 | -11.1, 11.1 |
| | | Min, Max | -89, 89 | -67, 78 |
| | | LS Mean (SE) | 2.9 (1.64) | 0.5 (2.00) |
| | | 95% CI | -0.3, 6.1 | -3.4, 4.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.4 (2.58) | |
| | | 95% CI | -2.7, 7.4 | |
| | | p-value | 0.3551 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.14, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 55 |
| | | Mean (StdDev) | 35.8 (26.46) | 35.8 (22.80) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 50.0 | 22.2, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 75 | 55 |
| | | Mean (StdDev) | 3.4 (26.53) | 3.8 (22.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 22.2 | -11.1, 11.1 |
| | | Min, Max | -56, 100 | -33, 67 |
| | | LS Mean (SE) | 3.5 (1.97) | 6.3 (2.36) |
| | | 95% CI | -0.4, 7.3 | 1.7, 11.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.8 (3.07) | |
| | | 95% CI | -8.9, 3.2 | |
| | | p-value | 0.3552 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.51, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 39.5 (24.31) | 39.7 (23.70) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 55.6 | 22.2, 55.6 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | 5.6 (26.18) | 7.0 (22.97) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -11.1, 22.2 | 0.0, 22.2 |
| | | Min, Max | -56, 89 | -44, 67 |
| | | LS Mean (SE) | 6.4 (1.98) | 7.5 (2.41) |
| | | 95% CI | 2.5, 10.2 | 2.8, 12.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.2 (3.12) | |
| | | 95% CI | -7.3, 4.9 | |
| | | p-value | 0.7077 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.41, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 38.9 (25.09) | 40.0 (20.06) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 55.6 | 27.8, 55.6 |
| | | Min, Max | 0, 100 | 0, 89 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | 6.0 (24.94) | 9.3 (22.70) |
| | | Median | 0.0 | 5.6 |
| | | Q1, Q3 | -11.1, 22.2 | 0.0, 22.2 |
| | | Min, Max | -56, 78 | -33, 78 |
| | | LS Mean (SE) | 5.9 (1.90) | 9.0 (2.35) |
| | | 95% CI | 2.2, 9.7 | 4.4, 13.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.1 (3.03) | |
| | | 95% CI | -9.0, 2.9 | |
| | | p-value | 0.3106 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.50, 0.16) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 37.1 (24.78) | 34.9 (19.90) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 22.2, 55.6 | 22.2, 44.4 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 80 | 49 |
| | | Mean (StdDev) | 1.5 (22.29) | 4.3 (18.12) |
| | | Median | 0.0 | 11.1 |
| | | Q1, Q3 | -11.1, 11.1 | 0.0, 11.1 |
| | | Min, Max | -67, 67 | -44, 44 |
| | | LS Mean (SE) | 3.5 (2.00) | 7.1 (2.53) |
| | | 95% CI | -0.5, 7.4 | 2.2, 12.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.7 (3.23) | |
| | | 95% CI | -10.0, 2.7 | |
| | | p-value | 0.2562 | |
| | | Corrected Hedges g (95% CI) [2] | -0.20 (-0.56, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -0.8 (1.03) | 0.6 (1.42) |
| | | 95% CI | -2.9, 1.2 | -2.2, 3.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.5 (1.75) | |
| | | 95% CI | -4.9, 2.0 | |
| | | p-value | 0.4017 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.32, 0.13) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 4.3 (10.86) | 5.6 (14.40) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 83 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 201 | 114 |
| | | Mean (StdDev) | 10.0 (13.95) | 4.7 (10.28) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 50 |
| | Change from BL | n | 199 | 114 |
| | | Mean (StdDev) | 6.1 (15.27) | 0.0 (12.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -50, 50 |
| | | LS Mean (SE) | 6.0 (0.95) | 0.4 (1.25) |
| | | 95% CI | 4.1, 7.8 | -2.1, 2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.6 (1.57) | |
| | | 95% CI | 2.5, 8.7 | |
| | | p-value | 0.0004 | |
| | | Corrected Hedges g (95% CI) [2] | 0.42 (0.18, 0.65) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 99 |
| | | Mean (StdDev) | 8.5 (15.18) | 4.5 (12.56) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 83 | 0, 100 |
| | Change from BL | n | 165 | 99 |
| | | Mean (StdDev) | 5.1 (15.77) | -0.8 (10.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | -50, 67 | -33, 17 |
| | | LS Mean (SE) | 4.6 (1.02) | -0.5 (1.33) |
| | | 95% CI | 2.6, 6.6 | -3.1, 2.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.0 (1.68) | |
| | | 95% CI | 1.7, 8.3 | |
| | | p-value | 0.0027 | |
| | | Corrected Hedges g (95% CI) [2] | 0.38 (0.13, 0.63) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 6.8 (13.00) | 3.6 (9.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 50 |
| | Change from BL | n | 147 | 87 |
| | | Mean (StdDev) | 4.1 (11.96) | -2.3 (14.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -83, 50 |
| | | LS Mean (SE) | 2.8 (1.08) | -1.1 (1.40) |
| | | 95% CI | 0.7, 4.9 | -3.9, 1.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.9 (1.78) | |
| | | 95% CI | 0.4, 7.4 | |
| | | p-value | 0.0272 | |
| | | Corrected Hedges g (95% CI) [2] | 0.30 (0.03, 0.57) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 68 |
| | | Mean (StdDev) | 7.1 (15.29) | 5.1 (14.47) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 130 | 68 |
| | | Mean (StdDev) | 3.8 (16.01) | -0.2 (15.64) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 100 | -33, 67 |
| | | LS Mean (SE) | 3.1 (1.13) | 0.5 (1.55) |
| | | 95% CI | 0.9, 5.3 | -2.5, 3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (1.92) | |
| | | 95% CI | -1.2, 6.4 | |
| | | p-value | 0.1791 | |
| | | Corrected Hedges g (95% CI) [2] | 0.20 (-0.09, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 5.8 (11.96) | 6.2 (12.45) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 8.3 | 0.0, 16.7 |
| | | Min, Max | 0, 67 | 0, 50 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 3.4 (12.39) | 0.0 (15.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 67 | -50, 50 |
| | | LS Mean (SE) | 2.1 (1.18) | 1.3 (1.76) |
| | | 95% CI | -0.2, 4.5 | -2.1, 4.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.8 (2.13) | |
| | | 95% CI | -3.4, 5.0 | |
| | | p-value | 0.7091 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.27, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 5.4 (10.85) | 3.8 (9.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 50 | 0, 50 |
| | Change from BL | n | 108 | 48 |
| | | Mean (StdDev) | 2.9 (12.23) | -2.8 (17.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 50 | -83, 50 |
| | | LS Mean (SE) | 1.9 (1.24) | 0.0 (1.83) |
| | | 95% CI | -0.5, 4.4 | -3.6, 3.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.9 (2.22) | |
| | | 95% CI | -2.4, 6.3 | |
| | | p-value | 0.3842 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.19, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 4.1 (10.49) | 4.4 (10.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 50 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 2.1 (11.66) | -1.3 (14.17) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 50 |
| | | LS Mean (SE) | 0.9 (1.32) | 0.5 (2.02) |
| | | 95% CI | -1.7, 3.5 | -3.5, 4.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.5 (2.44) | |
| | | 95% CI | -4.3, 5.2 | |
| | | p-value | 0.8503 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.34, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 5.0 (11.56) | 4.7 (10.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 50 | 0, 50 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | 3.0 (12.79) | -1.6 (11.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 50 | -33, 17 |
| | | LS Mean (SE) | 2.0 (1.42) | 0.7 (2.21) |
| | | 95% CI | -0.8, 4.8 | -3.6, 5.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (2.67) | |
| | | 95% CI | -3.9, 6.5 | |
| | | p-value | 0.6249 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.31, 0.51) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 6.0 (11.64) | 5.1 (9.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 8.3 | 0.0, 16.7 |
| | | Min, Max | 0, 50 | 0, 33 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | 3.6 (12.05) | 0.0 (11.24) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 33 | -33, 17 |
| | | LS Mean (SE) | 3.0 (1.59) | 0.7 (2.58) |
| | | 95% CI | -0.1, 6.1 | -4.3, 5.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.3 (3.05) | |
| | | 95% CI | -3.7, 8.3 | |
| | | p-value | 0.4519 | |
| | | Corrected Hedges g (95% CI) [2] | 0.18 (-0.30, 0.66) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 3.3 (6.80) | 4.8 (12.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 17 | 0, 33 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 0.7 (7.58) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 17 | 0, 0 |
| | | LS Mean (SE) | 0.1 (2.44) | -0.3 (4.51) |
| | | 95% CI | -4.7, 4.9 | -9.2, 8.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (5.14) | |
| | | 95% CI | -9.7, 10.5 | |
| | | p-value | 0.9360 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.81, 0.87) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 5.1 (10.51) | 8.3 (16.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 16.7 |
| | | Min, Max | 0, 33 | 0, 33 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 2.6 (13.34) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -17, 33 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 6.3 (12.40) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 8.3 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | 2.1 (10.68) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 8.3 | 0.0, 0.0 |
| | | Min, Max | -17, 17 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 6.7 (14.91) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 33 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 0.0 (11.79) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | -17, 17 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -16.7 (NA) | |
| | | Median | -16.7 | |
| | | Q1, Q3 | -16.7, -16.7 | |
| | | Min, Max | -17, -17 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 127 | 89 |
| | | Mean (StdDev) | 8.3 (15.70) | 6.0 (15.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 126 | 89 |
| | | Mean (StdDev) | 3.4 (17.55) | 0.2 (20.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -50, 100 | -83, 100 |
| | | LS Mean (SE) | 3.3 (1.16) | 1.5 (1.40) |
| | | 95% CI | 1.0, 5.6 | -1.2, 4.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (1.82) | |
| | | 95% CI | -1.8, 5.3 | |
| | | p-value | 0.3350 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.14, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 55 |
| | | Mean (StdDev) | 11.4 (20.94) | 8.8 (12.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 50 |
| | Change from BL | n | 75 | 55 |
| | | Mean (StdDev) | 6.2 (22.22) | 3.9 (14.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -33, 100 | -33, 50 |
| | | LS Mean (SE) | 6.9 (1.44) | 5.3 (1.71) |
| | | 95% CI | 4.1, 9.7 | 2.0, 8.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.6 (2.23) | |
| | | 95% CI | -2.8, 5.9 | |
| | | p-value | 0.4821 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.22, 0.47) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 9.1 (15.52) | 14.8 (19.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | 0, 83 | 0, 67 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | 3.0 (17.35) | 8.6 (19.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 16.7 |
| | | Min, Max | -33, 83 | -33, 67 |
| | | LS Mean (SE) | 4.8 (1.43) | 10.6 (1.73) |
| | | 95% CI | 2.0, 7.6 | 7.2, 14.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -5.8 (2.24) | |
| | | 95% CI | -10.2, -1.4 | |
| | | p-value | 0.0094 | |
| | | Corrected Hedges g (95% CI) [2] | -0.46 (-0.81, -0.10) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 8.6 (17.10) | 9.2 (11.65) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | 0, 83 | 0, 50 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | 3.5 (15.30) | 5.3 (14.55) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 16.7 |
| | | Min, Max | -33, 50 | -33, 50 |
| | | LS Mean (SE) | 5.0 (1.35) | 5.9 (1.66) |
| | | 95% CI | 2.3, 7.6 | 2.7, 9.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.0 (2.14) | |
| | | 95% CI | -5.2, 3.2 | |
| | | p-value | 0.6454 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.40, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 8.2 (17.31) | 6.5 (11.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 50 |
| | Change from BL | n | 80 | 49 |
| | | Mean (StdDev) | 3.8 (15.68) | 1.7 (14.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 50 |
| | | LS Mean (SE) | 4.6 (1.43) | 3.6 (1.82) |
| | | 95% CI | 1.8, 7.5 | 0.1, 7.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.0 (2.32) | |
| | | 95% CI | -3.5, 5.6 | |
| | | p-value | 0.6607 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.28, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 3.4 (0.62) | 2.0 (0.88) |
| | | 95% CI | 2.2, 4.6 | 0.2, 3.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.5 (1.08) | |
| | | 95% CI | -0.7, 3.6 | |
| | | p-value | 0.1773 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.07, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 226 | 124 |
| | | Mean (StdDev) | 18.5 (22.89) | 24.7 (25.63) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 200 | 114 |
| | | Mean (StdDev) | 16.3 (21.07) | 22.8 (25.69) |
| | | Median | 8.3 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 199 | 114 |
| | | Mean (StdDev) | -1.3 (20.65) | -1.8 (22.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 16.7 |
| | | Min, Max | -100, 67 | -83, 67 |
| | | LS Mean (SE) | -1.9 (1.43) | 0.3 (1.91) |
| | | 95% CI | -4.7, 0.9 | -3.5, 4.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.2 (2.40) | |
| | | 95% CI | -6.9, 2.5 | |
| | | p-value | 0.3513 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.34, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 99 |
| | | Mean (StdDev) | 17.5 (21.71) | 23.7 (22.72) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 166 | 99 |
| | | Mean (StdDev) | -0.5 (18.11) | -0.5 (23.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 16.7 |
| | | Min, Max | -67, 50 | -83, 50 |
| | | LS Mean (SE) | -1.3 (1.52) | 2.1 (2.00) |
| | | 95% CI | -4.2, 1.7 | -1.8, 6.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.4 (2.51) | |
| | | 95% CI | -8.3, 1.6 | |
| | | p-value | 0.1789 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.42, 0.08) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 150 | 87 |
| | | Mean (StdDev) | 18.0 (21.72) | 20.3 (23.08) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 83 | 0, 83 |
| | Change from BL | n | 149 | 87 |
| | | Mean (StdDev) | 0.7 (20.86) | -2.1 (22.71) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -83, 67 |
| | | LS Mean (SE) | 0.6 (1.58) | -0.2 (2.08) |
| | | 95% CI | -2.5, 3.7 | -4.2, 3.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.7 (2.62) | |
| | | 95% CI | -4.4, 5.9 | |
| | | p-value | 0.7814 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.23, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 68 |
| | | Mean (StdDev) | 17.4 (21.97) | 22.3 (25.69) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 131 | 68 |
| | | Mean (StdDev) | 1.1 (20.80) | -2.0 (24.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 83 | -83, 67 |
| | | LS Mean (SE) | 0.8 (1.65) | 0.4 (2.25) |
| | | 95% CI | -2.5, 4.0 | -4.0, 4.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (2.80) | |
| | | 95% CI | -5.2, 5.8 | |
| | | p-value | 0.9014 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.27, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 19.4 (22.28) | 18.0 (21.82) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 2.2 (20.58) | -3.6 (22.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -83, 50 |
| | | LS Mean (SE) | 3.1 (1.71) | -1.5 (2.49) |
| | | 95% CI | -0.3, 6.4 | -6.4, 3.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.5 (3.02) | |
| | | 95% CI | -1.4, 10.5 | |
| | | p-value | 0.1340 | |
| | | Corrected Hedges g (95% CI) [2] | 0.25 (-0.08, 0.57) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 110 | 48 |
| | | Mean (StdDev) | 17.6 (23.34) | 16.0 (20.03) |
| | | Median | 8.3 | 8.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 109 | 48 |
| | | Mean (StdDev) | -0.2 (21.58) | -5.9 (21.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -8.3, 0.0 |
| | | Min, Max | -67, 83 | -83, 50 |
| | | LS Mean (SE) | 1.3 (1.76) | -3.7 (2.57) |
| | | 95% CI | -2.2, 4.7 | -8.7, 1.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.0 (3.12) | |
| | | 95% CI | -1.1, 11.1 | |
| | | p-value | 0.1110 | |
| | | Corrected Hedges g (95% CI) [2] | 0.27 (-0.07, 0.61) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 15.8 (21.02) | 17.5 (20.12) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | -1.4 (22.51) | -3.9 (22.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 67 | -83, 33 |
| | | LS Mean (SE) | 0.7 (1.85) | -0.5 (2.80) |
| | | 95% CI | -2.9, 4.3 | -6.0, 5.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (3.36) | |
| | | 95% CI | -5.4, 7.8 | |
| | | p-value | 0.7167 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.31, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 16.1 (22.91) | 14.6 (19.28) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | -0.2 (25.03) | -6.3 (21.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 0.0 |
| | | Min, Max | -67, 100 | -83, 33 |
| | | LS Mean (SE) | 0.7 (1.97) | -3.2 (3.03) |
| | | 95% CI | -3.2, 4.5 | -9.2, 2.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.9 (3.62) | |
| | | 95% CI | -3.2, 11.0 | |
| | | p-value | 0.2803 | |
| | | Corrected Hedges g (95% CI) [2] | 0.22 (-0.19, 0.63) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 13.5 (18.28) | 21.7 (23.27) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | -3.6 (19.80) | 0.0 (26.11) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | -16.7, 16.7 |
| | | Min, Max | -67, 33 | -50, 67 |
| | | LS Mean (SE) | -1.6 (2.19) | 0.1 (3.52) |
| | | 95% CI | -5.9, 2.7 | -6.8, 7.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.7 (4.16) | |
| | | 95% CI | -9.9, 6.5 | |
| | | p-value | 0.6838 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.57, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 16.7 (18.63) | 19.0 (26.23) |
| | | Median | 16.7 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 1.3 (23.03) | 0.0 (37.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -33.3, 16.7 |
| | | Min, Max | -33, 67 | -50, 67 |
| | | LS Mean (SE) | 0.2 (3.30) | 0.1 (5.99) |
| | | 95% CI | -6.3, 6.7 | -11.6, 11.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (6.83) | |
| | | 95% CI | -13.3, 13.5 | |
| | | p-value | 0.9920 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.83, 0.84) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 19.2 (24.39) | 29.2 (34.36) |
| | | Median | 0.0 | 25.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 58.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 6.4 (22.09) | 8.3 (39.67) |
| | | Median | 0.0 | -8.3 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 33.3 |
| | | Min, Max | -17, 50 | -17, 67 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 25.0 (25.20) | 0.0 (NA) |
| | | Median | 25.0 | 0.0 |
| | | Q1, Q3 | 0.0, 41.7 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 0 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | 14.6 (27.37) | 0.0 (NA) |
| | | Median | 8.3 | 0.0 |
| | | Q1, Q3 | -8.3, 41.7 | 0.0, 0.0 |
| | | Min, Max | -17, 50 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 16.7 (16.67) | |
| | | Median | 16.7 | |
| | | Q1, Q3 | 0.0, 33.3 | |
| | | Min, Max | 0, 33 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 10.0 (19.00) | |
| | | Median | 16.7 | |
| | | Q1, Q3 | 0.0, 16.7 | |
| | | Min, Max | -17, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 129 | 89 |
| | | Mean (StdDev) | 24.8 (23.21) | 26.4 (25.10) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 129 | 89 |
| | | Mean (StdDev) | 5.8 (24.53) | 2.2 (22.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 16.7 |
| | | Min, Max | -67, 83 | -83, 50 |
| | | LS Mean (SE) | 4.4 (1.68) | 4.3 (2.08) |
| | | 95% CI | 1.1, 7.7 | 0.2, 8.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.1 (2.68) | |
| | | 95% CI | -5.1, 5.4 | |
| | | p-value | 0.9647 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.26, 0.28) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 56 |
| | | Mean (StdDev) | 25.4 (28.08) | 24.4 (24.61) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 76 | 56 |
| | | Mean (StdDev) | 6.1 (32.41) | 0.9 (25.51) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 16.7 | -16.7, 16.7 |
| | | Min, Max | -67, 100 | -50, 83 |
| | | LS Mean (SE) | 6.3 (2.01) | 3.8 (2.43) |
| | | 95% CI | 2.4, 10.2 | -1.0, 8.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.5 (3.15) | |
| | | 95% CI | -3.6, 8.7 | |
| | | p-value | 0.4217 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.20, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 28.3 (26.60) | 27.2 (22.73) |
| | | Median | 33.3 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 16.7, 50.0 |
| | | Min, Max | 0, 100 | 0, 83 |
| | Change from BL | n | 79 | 54 |
| | | Mean (StdDev) | 7.6 (23.69) | 3.1 (23.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 16.7 |
| | | Min, Max | -67, 67 | -50, 50 |
| | | LS Mean (SE) | 6.2 (2.01) | 4.6 (2.49) |
| | | 95% CI | 2.2, 10.1 | -0.2, 9.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.5 (3.20) | |
| | | 95% CI | -4.7, 7.8 | |
| | | p-value | 0.6324 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.26, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 27.8 (27.45) | 26.9 (23.19) |
| | | Median | 16.7 | 25.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 50.0 |
| | | Min, Max | 0, 100 | 0, 83 |
| | Change from BL | n | 91 | 60 |
| | | Mean (StdDev) | 8.8 (28.47) | 4.7 (25.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 16.7 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 8.1 (1.93) | 6.6 (2.41) |
| | | 95% CI | 4.3, 11.8 | 1.9, 11.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.5 (3.08) | |
| | | 95% CI | -4.6, 7.5 | |
| | | p-value | 0.6331 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.25, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 27.0 (27.08) | 23.1 (23.53) |
| | | Median | 16.7 | 16.7 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 81 | 49 |
| | | Mean (StdDev) | 7.2 (27.63) | 2.0 (23.48) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -16.7, 16.7 |
| | | Min, Max | -67, 67 | -50, 50 |
| | | LS Mean (SE) | 7.7 (2.03) | 4.1 (2.60) |
| | | 95% CI | 3.7, 11.6 | -1.0, 9.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.6 (3.30) | |
| | | 95% CI | -2.9, 10.0 | |
| | | p-value | 0.2789 | |
| | | Corrected Hedges g (95% CI) [2] | 0.19 (-0.16, 0.55) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 2.3 (1.09) | 1.2 (1.51) |
| | | 95% CI | 0.2, 4.5 | -1.8, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.2 (1.87) | |
| | | 95% CI | -2.5, 4.9 | |
| | | p-value | 0.5279 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.15, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 16.3 (22.95) | 18.3 (22.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 200 | 114 |
| | | Mean (StdDev) | 19.8 (25.03) | 17.3 (24.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 198 | 114 |
| | | Mean (StdDev) | 3.9 (23.07) | 0.0 (22.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -33, 67 |
| | | LS Mean (SE) | 4.0 (1.48) | 0.7 (1.96) |
| | | 95% CI | 1.1, 7.0 | -3.1, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.3 (2.46) | |
| | | 95% CI | -1.5, 8.1 | |
| | | p-value | 0.1780 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.07, 0.39) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 165 | 99 |
| | | Mean (StdDev) | 16.4 (23.46) | 16.5 (21.49) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 163 | 99 |
| | | Mean (StdDev) | 0.2 (23.28) | 0.0 (19.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -33, 67 |
| | | LS Mean (SE) | 0.8 (1.59) | 0.6 (2.07) |
| | | 95% CI | -2.3, 4.0 | -3.5, 4.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (2.61) | |
| | | 95% CI | -4.9, 5.4 | |
| | | p-value | 0.9219 | |
| | | Corrected Hedges g (95% CI) [2] | 0.01 (-0.24, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 14.3 (22.68) | 11.9 (17.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 147 | 87 |
| | | Mean (StdDev) | -1.8 (20.56) | -4.6 (16.99) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 33 | -33, 33 |
| | | LS Mean (SE) | -0.7 (1.66) | -3.0 (2.17) |
| | | 95% CI | -3.9, 2.6 | -7.3, 1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.4 (2.73) | |
| | | 95% CI | -3.0, 7.7 | |
| | | p-value | 0.3871 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.15, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 68 |
| | | Mean (StdDev) | 12.1 (20.29) | 18.6 (23.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 130 | 68 |
| | | Mean (StdDev) | -2.3 (17.70) | 0.5 (23.39) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 67 |
| | | LS Mean (SE) | -2.1 (1.75) | 1.3 (2.38) |
| | | 95% CI | -5.5, 1.4 | -3.3, 6.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.4 (2.96) | |
| | | 95% CI | -9.2, 2.4 | |
| | | p-value | 0.2506 | |
| | | Corrected Hedges g (95% CI) [2] | -0.17 (-0.46, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 10.3 (18.73) | 15.7 (24.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | -2.5 (17.98) | 0.0 (24.04) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 67 |
| | | LS Mean (SE) | -2.2 (1.82) | 0.8 (2.67) |
| | | 95% CI | -5.7, 1.4 | -4.5, 6.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.9 (3.23) | |
| | | 95% CI | -9.2, 3.4 | |
| | | p-value | 0.3678 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.48, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 11.6 (20.48) | 14.6 (20.52) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 108 | 48 |
| | | Mean (StdDev) | -1.2 (18.75) | -2.1 (19.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 33 |
| | | LS Mean (SE) | -0.9 (1.89) | -1.7 (2.75) |
| | | 95% CI | -4.7, 2.8 | -7.1, 3.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.8 (3.34) | |
| | | 95% CI | -5.8, 7.3 | |
| | | p-value | 0.8141 | |
| | | Corrected Hedges g (95% CI) [2] | 0.04 (-0.30, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 12.7 (18.91) | 15.8 (20.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 0.0 (19.94) | 0.0 (21.92) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 33 | -33, 67 |
| | | LS Mean (SE) | 0.0 (1.98) | 2.1 (3.03) |
| | | 95% CI | -3.8, 3.9 | -3.8, 8.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.1 (3.62) | |
| | | 95% CI | -9.2, 5.0 | |
| | | p-value | 0.5703 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.48, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 10.4 (17.98) | 16.7 (20.74) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | -1.2 (21.74) | -1.0 (23.16) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -33, 67 |
| | | LS Mean (SE) | -2.3 (2.14) | 3.4 (3.30) |
| | | 95% CI | -6.5, 2.0 | -3.1, 9.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -5.6 (3.95) | |
| | | 95% CI | -13.4, 2.1 | |
| | | p-value | 0.1544 | |
| | | Corrected Hedges g (95% CI) [2] | -0.29 (-0.70, 0.12) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 12.5 (17.32) | 21.7 (25.84) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | 1.6 (19.18) | 1.4 (29.26) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 33 | -33, 100 |
| | | LS Mean (SE) | 0.4 (2.43) | 4.5 (3.88) |
| | | 95% CI | -4.3, 5.2 | -3.1, 12.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.1 (4.62) | |
| | | 95% CI | -13.2, 5.0 | |
| | | p-value | 0.3760 | |
| | | Corrected Hedges g (95% CI) [2] | -0.21 (-0.69, 0.27) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 10.7 (18.56) | 9.5 (16.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 33 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -1.3 (22.53) | 0.0 (19.25) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 33 | -33, 33 |
| | | LS Mean (SE) | -1.2 (3.68) | -0.9 (6.80) |
| | | 95% CI | -8.4, 6.0 | -14.2, 12.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.3 (7.61) | |
| | | 95% CI | -15.3, 14.6 | |
| | | p-value | 0.9645 | |
| | | Corrected Hedges g (95% CI) [2] | -0.02 (-0.86, 0.82) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 10.3 (21.01) | 16.7 (19.25) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 33 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 2.6 (25.32) | 0.0 (27.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -16.7, 16.7 |
| | | Min, Max | -33, 67 | -33, 33 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 16.7 (25.20) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 0 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | 12.5 (30.54) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 13.3 (18.26) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 33.3 | |
| | | Min, Max | 0, 33 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 6.7 (27.89) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 33.3 | |
| | | Min, Max | -33, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -33.3 (NA) | |
| | | Median | -33.3 | |
| | | Q1, Q3 | -33.3, -33.3 | |
| | | Min, Max | -33, -33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 125 | 89 |
| | | Mean (StdDev) | 25.1 (28.29) | 21.7 (24.15) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 124 | 89 |
| | | Mean (StdDev) | 7.0 (27.64) | 2.6 (22.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -33, 67 |
| | | LS Mean (SE) | 7.0 (1.81) | 4.3 (2.17) |
| | | 95% CI | 3.4, 10.5 | 0.0, 8.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.7 (2.82) | |
| | | 95% CI | -2.8, 8.2 | |
| | | p-value | 0.3392 | |
| | | Corrected Hedges g (95% CI) [2] | 0.13 (-0.14, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 55 |
| | | Mean (StdDev) | 23.2 (30.80) | 20.6 (27.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 75 | 55 |
| | | Mean (StdDev) | 3.1 (30.10) | 1.8 (27.53) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 100 |
| | | LS Mean (SE) | 5.5 (2.20) | 3.9 (2.61) |
| | | 95% CI | 1.2, 9.8 | -1.3, 9.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.6 (3.40) | |
| | | 95% CI | -5.1, 8.3 | |
| | | p-value | 0.6387 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.27, 0.43) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 20.3 (27.95) | 24.1 (27.02) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | 1.7 (30.34) | 3.1 (27.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 4.1 (2.19) | 5.1 (2.67) |
| | | 95% CI | -0.2, 8.4 | -0.2, 10.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.9 (3.44) | |
| | | 95% CI | -7.7, 5.8 | |
| | | p-value | 0.7834 | |
| | | Corrected Hedges g (95% CI) [2] | -0.05 (-0.40, 0.30) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 22.0 (26.86) | 23.9 (26.10) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | 3.7 (29.75) | 6.7 (24.39) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 5.4 (2.09) | 7.5 (2.58) |
| | | 95% CI | 1.3, 9.5 | 2.5, 12.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.2 (3.32) | |
| | | 95% CI | -8.7, 4.3 | |
| | | p-value | 0.5131 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.44, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 21.4 (28.04) | 21.1 (22.25) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 80 | 49 |
| | | Mean (StdDev) | 2.1 (29.69) | 2.0 (22.98) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 4.6 (2.22) | 4.2 (2.82) |
| | | 95% CI | 0.2, 9.0 | -1.4, 9.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.4 (3.58) | |
| | | 95% CI | -6.6, 7.5 | |
| | | p-value | 0.9001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.33, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 1.5 (1.04) | 2.2 (1.45) |
| | | 95% CI | -0.5, 3.5 | -0.7, 5.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.7 (1.78) | |
| | | 95% CI | -4.2, 2.8 | |
| | | p-value | 0.7062 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.26, 0.18) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 27.6 (29.23) | 32.5 (31.66) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 199 | 114 |
| | | Mean (StdDev) | 34.7 (30.31) | 30.4 (32.76) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | 9.8 (30.39) | -1.8 (24.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 9.4 (1.81) | 0.1 (2.40) |
| | | 95% CI | 5.8, 12.9 | -4.6, 4.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 9.2 (3.01) | |
| | | 95% CI | 3.3, 15.1 | |
| | | p-value | 0.0022 | |
| | | Corrected Hedges g (95% CI) [2] | 0.36 (0.13, 0.59) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 168 | 99 |
| | | Mean (StdDev) | 31.2 (27.81) | 27.9 (31.12) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 166 | 99 |
| | | Mean (StdDev) | 5.2 (28.65) | -2.0 (28.10) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -100, 67 |
| | | LS Mean (SE) | 4.6 (1.92) | -0.3 (2.52) |
| | | 95% CI | 0.8, 8.4 | -5.2, 4.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.9 (3.17) | |
| | | 95% CI | -1.3, 11.1 | |
| | | p-value | 0.1240 | |
| | | Corrected Hedges g (95% CI) [2] | 0.20 (-0.05, 0.44) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 150 | 87 |
| | | Mean (StdDev) | 32.7 (29.02) | 26.8 (28.68) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 148 | 87 |
| | | Mean (StdDev) | 7.4 (28.52) | -0.8 (32.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -100, 100 |
| | | LS Mean (SE) | 6.5 (2.01) | 1.2 (2.63) |
| | | 95% CI | 2.5, 10.4 | -4.0, 6.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.3 (3.31) | |
| | | 95% CI | -1.2, 11.8 | |
| | | p-value | 0.1116 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (-0.05, 0.48) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 68 |
| | | Mean (StdDev) | 32.8 (29.12) | 29.9 (32.65) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 130 | 68 |
| | | Mean (StdDev) | 9.7 (28.29) | 2.0 (30.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 8.0 (2.14) | 1.8 (2.90) |
| | | 95% CI | 3.8, 12.2 | -3.9, 7.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 6.2 (3.61) | |
| | | 95% CI | -0.9, 13.3 | |
| | | p-value | 0.0854 | |
| | | Corrected Hedges g (95% CI) [2] | 0.26 (-0.04, 0.55) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 28.6 (27.09) | 35.9 (33.89) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 5.6 (30.78) | 10.5 (33.66) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 100 |
| | | LS Mean (SE) | 4.3 (2.22) | 8.8 (3.28) |
| | | 95% CI | -0.1, 8.6 | 2.4, 15.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.6 (3.95) | |
| | | 95% CI | -12.3, 3.2 | |
| | | p-value | 0.2494 | |
| | | Corrected Hedges g (95% CI) [2] | -0.19 (-0.52, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 27.5 (23.50) | 28.5 (30.74) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 108 | 48 |
| | | Mean (StdDev) | 4.6 (30.39) | 2.8 (30.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 3.4 (2.32) | 1.6 (3.39) |
| | | 95% CI | -1.2, 7.9 | -5.0, 8.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.8 (4.10) | |
| | | 95% CI | -6.3, 9.8 | |
| | | p-value | 0.6651 | |
| | | Corrected Hedges g (95% CI) [2] | 0.07 (-0.27, 0.41) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 26.1 (23.19) | 27.2 (26.68) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 4.5 (29.66) | 4.4 (28.13) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 2.7 (2.44) | 2.6 (3.74) |
| | | 95% CI | -2.1, 7.4 | -4.7, 10.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (4.44) | |
| | | 95% CI | -8.7, 8.7 | |
| | | p-value | 0.9944 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.37, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 23.3 (21.30) | 30.2 (32.08) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | 0.8 (30.34) | 5.2 (38.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 67 | -100, 67 |
| | | LS Mean (SE) | -0.7 (2.60) | 5.5 (4.05) |
| | | 95% CI | -5.8, 4.4 | -2.4, 13.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -6.2 (4.80) | |
| | | 95% CI | -15.6, 3.2 | |
| | | p-value | 0.1954 | |
| | | Corrected Hedges g (95% CI) [2] | -0.26 (-0.67, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 28.1 (25.35) | 36.2 (34.69) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | 5.7 (30.02) | 7.2 (33.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 4.3 (2.89) | 11.0 (4.67) |
| | | 95% CI | -1.3, 10.0 | 1.9, 20.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -6.7 (5.51) | |
| | | 95% CI | -17.5, 4.1 | |
| | | p-value | 0.2227 | |
| | | Corrected Hedges g (95% CI) [2] | -0.29 (-0.77, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 24.0 (24.57) | 47.6 (32.53) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 33.3, 66.7 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -1.3 (26.32) | 4.8 (29.99) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | -33.3, 33.3 |
| | | Min, Max | -33, 67 | -33, 33 |
| | | LS Mean (SE) | -1.9 (4.37) | 16.8 (8.41) |
| | | 95% CI | -10.4, 6.7 | 0.3, 33.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -18.7 (9.52) | |
| | | 95% CI | -37.3, 0.0 | |
| | | p-value | 0.0501 | |
| | | Corrected Hedges g (95% CI) [2] | -0.83 (-1.69, 0.03) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 33.3 (33.33) | 41.7 (16.67) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 33.3, 50.0 |
| | | Min, Max | 0, 100 | 33, 67 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 17.9 (37.55) | -25.0 (31.91) |
| | | Median | 0.0 | -16.7 |
| | | Q1, Q3 | 0.0, 33.3 | -50.0, 0.0 |
| | | Min, Max | -33, 100 | -67, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 37.5 (33.03) | 33.3 (NA) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 16.7, 50.0 | 33.3, 33.3 |
| | | Min, Max | 0, 100 | 33, 33 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | 25.0 (38.83) | 0.0 (NA) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -33, 100 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 26.7 (27.89) | |
| | | Median | 33.3 | |
| | | Q1, Q3 | 0.0, 33.3 | |
| | | Min, Max | 0, 67 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 13.3 (18.26) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 33.3 | |
| | | Min, Max | 0, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 33.3 (NA) | |
| | | Median | 33.3 | |
| | | Q1, Q3 | 33.3, 33.3 | |
| | | Min, Max | 33, 33 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 33.3 (NA) | |
| | | Median | 33.3 | |
| | | Q1, Q3 | 33.3, 33.3 | |
| | | Min, Max | 33, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 127 | 89 |
| | | Mean (StdDev) | 34.4 (27.20) | 30.7 (29.82) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 126 | 89 |
| | | Mean (StdDev) | 4.8 (31.75) | 0.4 (33.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 33.3 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | 4.9 (2.17) | 3.6 (2.63) |
| | | 95% CI | 0.6, 9.2 | -1.6, 8.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.3 (3.40) | |
| | | 95% CI | -5.3, 8.0 | |
| | | p-value | 0.6929 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.22, 0.33) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 55 |
| | | Mean (StdDev) | 33.3 (28.80) | 30.3 (27.42) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 75 | 55 |
| | | Mean (StdDev) | 3.6 (30.30) | 0.0 (35.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 33.3 |
| | | Min, Max | -100, 67 | -67, 67 |
| | | LS Mean (SE) | 5.2 (2.66) | 2.9 (3.17) |
| | | 95% CI | 0.0, 10.4 | -3.3, 9.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.4 (4.13) | |
| | | 95% CI | -5.7, 10.5 | |
| | | p-value | 0.5674 | |
| | | Corrected Hedges g (95% CI) [2] | 0.10 (-0.25, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 32.1 (30.40) | 34.0 (30.02) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 66.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | 2.1 (31.02) | 1.2 (27.44) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 33.3 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | 6.1 (2.63) | 4.8 (3.22) |
| | | 95% CI | 1.0, 11.3 | -1.5, 11.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.4 (4.14) | |
| | | 95% CI | -6.7, 9.5 | |
| | | p-value | 0.7418 | |
| | | Corrected Hedges g (95% CI) [2] | 0.06 (-0.29, 0.40) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 35.5 (30.14) | 27.2 (29.75) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | 6.7 (35.05) | -3.9 (31.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 7.6 (2.49) | -1.9 (3.09) |
| | | 95% CI | 2.7, 12.5 | -8.0, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 9.5 (3.97) | |
| | | 95% CI | 1.7, 17.3 | |
| | | p-value | 0.0165 | |
| | | Corrected Hedges g (95% CI) [2] | 0.40 (0.07, 0.73) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 32.1 (28.11) | 25.9 (26.58) |
| | | Median | 33.3 | 33.3 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 80 | 49 |
| | | Mean (StdDev) | 0.4 (25.15) | -3.4 (28.26) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -33.3, 0.0 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 2.6 (2.66) | -1.4 (3.38) |
| | | 95% CI | -2.6, 7.8 | -8.1, 5.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.1 (4.30) | |
| | | 95% CI | -4.4, 12.5 | |
| | | p-value | 0.3444 | |
| | | Corrected Hedges g (95% CI) [2] | 0.17 (-0.19, 0.53) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 4.5 (1.27) | 3.8 (1.79) |
| | | 95% CI | 2.0, 7.0 | 0.3, 7.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.7 (2.20) | |
| | | 95% CI | -3.7, 5.0 | |
| | | p-value | 0.7636 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.19, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 8.6 (18.51) | 7.3 (17.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 200 | 114 |
| | | Mean (StdDev) | 14.0 (22.00) | 7.9 (17.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 198 | 114 |
| | | Mean (StdDev) | 6.6 (22.19) | 0.9 (20.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -33, 67 |
| | | LS Mean (SE) | 6.7 (1.39) | 1.1 (1.84) |
| | | 95% CI | 3.9, 9.4 | -2.5, 4.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.5 (2.31) | |
| | | 95% CI | 1.0, 10.1 | |
| | | p-value | 0.0165 | |
| | | Corrected Hedges g (95% CI) [2] | 0.28 (0.05, 0.51) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 99 |
| | | Mean (StdDev) | 10.0 (19.19) | 6.1 (18.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 165 | 99 |
| | | Mean (StdDev) | 2.2 (22.43) | -1.3 (17.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -33, 67 |
| | | LS Mean (SE) | 3.0 (1.49) | -0.7 (1.93) |
| | | 95% CI | 0.1, 5.9 | -4.5, 3.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.8 (2.44) | |
| | | 95% CI | -1.0, 8.5 | |
| | | p-value | 0.1233 | |
| | | Corrected Hedges g (95% CI) [2] | 0.20 (-0.05, 0.45) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 5.4 (13.46) | 6.5 (15.94) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 147 | 87 |
| | | Mean (StdDev) | -1.1 (18.47) | -0.4 (19.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 67 |
| | | LS Mean (SE) | -0.6 (1.56) | 0.5 (2.03) |
| | | 95% CI | -3.7, 2.5 | -3.5, 4.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.1 (2.56) | |
| | | 95% CI | -6.2, 3.9 | |
| | | p-value | 0.6567 | |
| | | Corrected Hedges g (95% CI) [2] | -0.06 (-0.33, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 68 |
| | | Mean (StdDev) | 8.3 (18.13) | 9.3 (22.19) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 130 | 68 |
| | | Mean (StdDev) | 2.1 (19.80) | 2.5 (23.97) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -33, 100 |
| | | LS Mean (SE) | 2.6 (1.65) | 3.3 (2.24) |
| | | 95% CI | -0.6, 5.9 | -1.1, 7.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.7 (2.79) | |
| | | 95% CI | -6.1, 4.8 | |
| | | p-value | 0.8138 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.33, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 50 |
| | | Mean (StdDev) | 6.9 (17.23) | 8.7 (22.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 100 |
| | Change from BL | n | 119 | 50 |
| | | Mean (StdDev) | 1.1 (20.78) | 1.3 (22.29) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 100 |
| | | LS Mean (SE) | 2.2 (1.71) | 1.8 (2.55) |
| | | 95% CI | -1.2, 5.6 | -3.2, 6.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (3.07) | |
| | | 95% CI | -5.7, 6.4 | |
| | | p-value | 0.9110 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.31, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 109 | 48 |
| | | Mean (StdDev) | 6.4 (15.37) | 6.3 (16.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 108 | 48 |
| | | Mean (StdDev) | 0.3 (18.51) | -1.4 (20.58) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -67, 67 |
| | | LS Mean (SE) | 1.5 (1.79) | 0.0 (2.63) |
| | | 95% CI | -2.0, 5.0 | -5.2, 5.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.5 (3.18) | |
| | | 95% CI | -4.8, 7.7 | |
| | | p-value | 0.6409 | |
| | | Corrected Hedges g (95% CI) [2] | 0.08 (-0.26, 0.42) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 6.5 (17.10) | 5.3 (12.32) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 33 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 1.4 (16.70) | -0.9 (16.42) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 33 |
| | | LS Mean (SE) | 2.4 (1.87) | -0.3 (2.87) |
| | | 95% CI | -1.2, 6.1 | -5.9, 5.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.7 (3.42) | |
| | | 95% CI | -4.0, 9.5 | |
| | | p-value | 0.4228 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.23, 0.53) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 4.8 (13.90) | 2.1 (8.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 33 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | -0.8 (18.75) | -5.2 (14.93) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -33, 33 |
| | | LS Mean (SE) | -0.1 (2.00) | -2.9 (3.13) |
| | | 95% CI | -4.0, 3.8 | -9.1, 3.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.8 (3.71) | |
| | | 95% CI | -4.4, 10.1 | |
| | | p-value | 0.4431 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.25, 0.56) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 11.5 (20.76) | 5.8 (21.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | 6.3 (22.91) | 0.0 (14.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -33, 33 |
| | | LS Mean (SE) | 7.1 (2.24) | 0.5 (3.64) |
| | | 95% CI | 2.7, 11.5 | -6.7, 7.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 6.6 (4.27) | |
| | | 95% CI | -1.8, 15.0 | |
| | | p-value | 0.1215 | |
| | | Corrected Hedges g (95% CI) [2] | 0.37 (-0.11, 0.85) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 6.7 (16.67) | 4.8 (12.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 33 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 4.0 (20.00) | 0.0 (19.25) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 67 | -33, 33 |
| | | LS Mean (SE) | 1.8 (3.64) | -0.8 (6.36) |
| | | 95% CI | -5.3, 9.0 | -13.3, 11.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (7.20) | |
| | | 95% CI | -11.5, 16.8 | |
| | | p-value | 0.7144 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.70, 0.98) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 10.3 (16.01) | 8.3 (16.67) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 |
| | | Min, Max | 0, 33 | 0, 33 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | 5.1 (22.96) | 0.0 (27.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -16.7, 16.7 |
| | | Min, Max | -33, 33 | -33, 33 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 12.5 (17.25) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | 8.3 (15.43) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 6.7 (14.91) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 33 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 6.7 (14.91) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 127 | 88 |
| | | Mean (StdDev) | 18.9 (28.04) | 11.7 (22.62) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 16.7 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 126 | 88 |
| | | Mean (StdDev) | 9.3 (30.00) | 4.5 (23.80) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -33, 67 |
| | | LS Mean (SE) | 10.1 (1.70) | 4.6 (2.05) |
| | | 95% CI | 6.8, 13.4 | 0.6, 8.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.5 (2.66) | |
| | | 95% CI | 0.3, 10.8 | |
| | | p-value | 0.0369 | |
| | | Corrected Hedges g (95% CI) [2] | 0.29 (0.02, 0.56) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 55 |
| | | Mean (StdDev) | 17.5 (28.01) | 9.7 (16.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 75 | 55 |
| | | Mean (StdDev) | 8.9 (28.65) | 3.6 (19.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -33, 67 |
| | | LS Mean (SE) | 10.1 (2.05) | 5.3 (2.44) |
| | | 95% CI | 6.1, 14.1 | 0.5, 10.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.8 (3.19) | |
| | | 95% CI | -1.5, 11.0 | |
| | | p-value | 0.1358 | |
| | | Corrected Hedges g (95% CI) [2] | 0.26 (-0.09, 0.61) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 13.9 (23.64) | 16.0 (22.19) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | 2.6 (25.07) | 9.3 (26.24) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | -67, 67 | -33, 67 |
| | | LS Mean (SE) | 6.5 (2.07) | 10.4 (2.49) |
| | | 95% CI | 2.5, 10.6 | 5.5, 15.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.8 (3.24) | |
| | | 95% CI | -10.2, 2.5 | |
| | | p-value | 0.2391 | |
| | | Corrected Hedges g (95% CI) [2] | -0.21 (-0.56, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 13.9 (22.26) | 13.3 (19.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | 5.6 (23.03) | 7.2 (21.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | -33, 100 | -33, 67 |
| | | LS Mean (SE) | 6.4 (1.97) | 7.7 (2.43) |
| | | 95% CI | 2.5, 10.2 | 2.9, 12.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (3.13) | |
| | | 95% CI | -7.5, 4.8 | |
| | | p-value | 0.6680 | |
| | | Corrected Hedges g (95% CI) [2] | -0.07 (-0.40, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 16.5 (30.33) | 9.5 (18.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 80 | 49 |
| | | Mean (StdDev) | 5.0 (26.57) | 4.1 (22.19) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 7.9 (2.11) | 5.3 (2.67) |
| | | 95% CI | 3.8, 12.1 | 0.1, 10.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.6 (3.41) | |
| | | 95% CI | -4.1, 9.3 | |
| | | p-value | 0.4454 | |
| | | Corrected Hedges g (95% CI) [2] | 0.14 (-0.22, 0.49) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 4.5 (0.95) | 2.4 (1.32) |
| | | 95% CI | 2.6, 6.4 | -0.2, 5.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.1 (1.62) | |
| | | 95% CI | -1.1, 5.3 | |
| | | p-value | 0.1902 | |
| | | Corrected Hedges g (95% CI) [2] | 0.15 (-0.07, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 17.2 (25.22) | 21.0 (26.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 201 | 114 |
| | | Mean (StdDev) | 28.7 (31.81) | 16.4 (24.39) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 199 | 114 |
| | | Mean (StdDev) | 11.4 (32.72) | -4.4 (23.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 11.5 (1.82) | -2.9 (2.41) |
| | | 95% CI | 8.0, 15.1 | -7.6, 1.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 14.4 (3.02) | |
| | | 95% CI | 8.5, 20.4 | |
| | | p-value | <0.0001 | |
| | | Corrected Hedges g (95% CI) [2] | 0.56 (0.33, 0.79) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 99 |
| | | Mean (StdDev) | 27.3 (29.34) | 18.2 (27.05) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 165 | 99 |
| | | Mean (StdDev) | 10.7 (28.75) | -2.7 (29.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -100, 67 |
| | | LS Mean (SE) | 10.7 (1.94) | -0.9 (2.53) |
| | | 95% CI | 6.9, 14.5 | -5.8, 4.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 11.6 (3.20) | |
| | | 95% CI | 5.3, 17.8 | |
| | | p-value | 0.0003 | |
| | | Corrected Hedges g (95% CI) [2] | 0.46 (0.21, 0.71) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 24.6 (28.58) | 16.1 (25.35) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 147 | 87 |
| | | Mean (StdDev) | 9.1 (26.04) | -4.2 (27.75) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -100, 67 |
| | | LS Mean (SE) | 9.2 (2.03) | -2.8 (2.65) |
| | | 95% CI | 5.2, 13.2 | -8.0, 2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 12.0 (3.34) | |
| | | 95% CI | 5.4, 18.6 | |
| | | p-value | 0.0003 | |
| | | Corrected Hedges g (95% CI) [2] | 0.49 (0.22, 0.75) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 68 |
| | | Mean (StdDev) | 22.0 (25.66) | 18.6 (26.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 130 | 68 |
| | | Mean (StdDev) | 6.9 (26.15) | -2.5 (25.31) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 7.5 (2.14) | -1.9 (2.91) |
| | | 95% CI | 3.4, 11.7 | -7.6, 3.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 9.5 (3.62) | |
| | | 95% CI | 2.4, 16.6 | |
| | | p-value | 0.0089 | |
| | | Corrected Hedges g (95% CI) [2] | 0.39 (0.09, 0.69) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 23.1 (27.60) | 20.9 (29.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | 7.6 (26.90) | -0.7 (20.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -33, 100 | -33, 67 |
| | | LS Mean (SE) | 8.5 (2.22) | -0.5 (3.26) |
| | | 95% CI | 4.1, 12.8 | -6.9, 5.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 9.0 (3.95) | |
| | | 95% CI | 1.2, 16.7 | |
| | | p-value | 0.0235 | |
| | | Corrected Hedges g (95% CI) [2] | 0.37 (0.04, 0.70) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 110 | 48 |
| | | Mean (StdDev) | 22.7 (27.44) | 19.4 (28.21) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 109 | 48 |
| | | Mean (StdDev) | 7.0 (26.09) | -0.7 (24.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -33, 100 |
| | | LS Mean (SE) | 7.4 (2.29) | -1.0 (3.37) |
| | | 95% CI | 2.9, 11.9 | -7.6, 5.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 8.3 (4.08) | |
| | | 95% CI | 0.3, 16.3 | |
| | | p-value | 0.0417 | |
| | | Corrected Hedges g (95% CI) [2] | 0.35 (0.01, 0.69) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 38 |
| | | Mean (StdDev) | 24.1 (27.53) | 14.9 (27.62) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 96 | 38 |
| | | Mean (StdDev) | 8.0 (27.68) | -6.1 (27.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 8.8 (2.41) | -4.9 (3.70) |
| | | 95% CI | 4.1, 13.5 | -12.2, 2.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 13.7 (4.42) | |
| | | 95% CI | 5.1, 22.4 | |
| | | p-value | 0.0019 | |
| | | Corrected Hedges g (95% CI) [2] | 0.58 (0.20, 0.97) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 20.5 (25.94) | 14.6 (26.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | 5.2 (27.78) | -6.3 (24.59) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -16.7, 0.0 |
| | | Min, Max | -67, 100 | -67, 33 |
| | | LS Mean (SE) | 6.4 (2.59) | -5.3 (4.03) |
| | | 95% CI | 1.4, 11.5 | -13.2, 2.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 11.7 (4.80) | |
| | | 95% CI | 2.3, 21.1 | |
| | | p-value | 0.0147 | |
| | | Corrected Hedges g (95% CI) [2] | 0.50 (0.09, 0.91) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 64 | 23 |
| | | Mean (StdDev) | 19.3 (25.75) | 17.4 (31.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 64 | 23 |
| | | Mean (StdDev) | 3.1 (30.70) | -8.7 (25.06) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -67, 33 |
| | | LS Mean (SE) | 4.9 (2.88) | -2.2 (4.74) |
| | | 95% CI | -0.8, 10.6 | -11.5, 7.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 7.1 (5.57) | |
| | | 95% CI | -3.8, 18.0 | |
| | | p-value | 0.2034 | |
| | | Corrected Hedges g (95% CI) [2] | 0.31 (-0.17, 0.78) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 14.7 (25.60) | 4.8 (12.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 33 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -4.0 (36.41) | -9.5 (25.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -33, 33 |
| | | LS Mean (SE) | 2.0 (4.33) | -6.8 (8.06) |
| | | 95% CI | -6.5, 10.5 | -22.6, 9.0 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 8.8 (9.16) | |
| | | 95% CI | -9.2, 26.7 | |
| | | p-value | 0.3379 | |
| | | Corrected Hedges g (95% CI) [2] | 0.40 (-0.45, 1.24) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 7.7 (14.62) | 16.7 (19.25) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 33.3 |
| | | Min, Max | 0, 33 | 0, 33 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -12.8 (25.60) | 0.0 (27.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | -16.7, 16.7 |
| | | Min, Max | -67, 33 | -33, 33 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 8.3 (15.43) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 16.7 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 0 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -8.3 (23.57) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 33 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 13.3 (18.26) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 33.3 | |
| | | Min, Max | 0, 33 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | -6.7 (27.89) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | -33.3, 0.0 | |
| | | Min, Max | -33, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | -33.3 (NA) | |
| | | Median | -33.3 | |
| | | Q1, Q3 | -33.3, -33.3 | |
| | | Min, Max | -33, -33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 126 | 89 |
| | | Mean (StdDev) | 29.4 (34.67) | 18.4 (26.60) |
| | | Median | 33.3 | 0.0 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 125 | 89 |
| | | Mean (StdDev) | 11.2 (36.40) | -1.9 (29.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | -33.3, 0.0 |
| | | Min, Max | -67, 100 | -100, 67 |
| | | LS Mean (SE) | 9.8 (2.21) | -0.3 (2.66) |
| | | 95% CI | 5.5, 14.2 | -5.5, 4.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 10.1 (3.46) | |
| | | 95% CI | 3.4, 16.9 | |
| | | p-value | 0.0034 | |
| | | Corrected Hedges g (95% CI) [2] | 0.41 (0.13, 0.68) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 55 |
| | | Mean (StdDev) | 17.5 (26.37) | 17.0 (27.12) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 75 | 55 |
| | | Mean (StdDev) | -1.8 (36.31) | 1.2 (25.63) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -67, 67 |
| | | LS Mean (SE) | -2.6 (2.66) | 1.1 (3.17) |
| | | 95% CI | -7.8, 2.6 | -5.2, 7.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.7 (4.14) | |
| | | 95% CI | -11.8, 4.4 | |
| | | p-value | 0.3729 | |
| | | Corrected Hedges g (95% CI) [2] | -0.16 (-0.51, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 53 |
| | | Mean (StdDev) | 17.3 (26.07) | 20.1 (28.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 78 | 53 |
| | | Mean (StdDev) | -1.7 (30.81) | 1.9 (28.05) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 0.0 (2.65) | 2.9 (3.24) |
| | | 95% CI | -5.2, 5.2 | -3.4, 9.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.0 (4.19) | |
| | | 95% CI | -11.2, 5.2 | |
| | | p-value | 0.4789 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.47, 0.22) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 22.0 (32.29) | 20.6 (26.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | 2.2 (35.26) | 5.0 (27.33) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 33.3 | 0.0, 33.3 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 2.6 (2.55) | 4.5 (3.15) |
| | | 95% CI | -2.4, 7.6 | -1.7, 10.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.8 (4.06) | |
| | | 95% CI | -9.8, 6.1 | |
| | | p-value | 0.6489 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.40, 0.25) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 81 | 49 |
| | | Mean (StdDev) | 16.9 (26.94) | 17.0 (23.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 80 | 49 |
| | | Mean (StdDev) | -4.2 (34.12) | 2.7 (24.38) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 67 |
| | | LS Mean (SE) | -1.6 (2.71) | 1.4 (3.45) |
| | | 95% CI | -6.9, 3.7 | -5.4, 8.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.0 (4.40) | |
| | | 95% CI | -11.6, 5.7 | |
| | | p-value | 0.4983 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.48, 0.23) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | 5.7 (1.29) | -1.3 (1.80) |
| | | 95% CI | 3.1, 8.2 | -4.8, 2.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 7.0 (2.21) | |
| | | 95% CI | 2.6, 11.3 | |
| | | p-value | 0.0017 | |
| | | Corrected Hedges g (95% CI) [2] | 0.36 (0.14, 0.58) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 225 | 124 |
| | | Mean (StdDev) | 7.6 (17.17) | 8.6 (20.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 199 | 114 |
| | | Mean (StdDev) | 3.0 (10.69) | 7.3 (17.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 197 | 114 |
| | | Mean (StdDev) | -3.4 (16.14) | -1.5 (16.23) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 33 |
| | | LS Mean (SE) | -4.0 (1.07) | -0.7 (1.41) |
| | | 95% CI | -6.1, -1.9 | -3.5, 2.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.3 (1.78) | |
| | | 95% CI | -6.8, 0.2 | |
| | | p-value | 0.0642 | |
| | | Corrected Hedges g (95% CI) [2] | -0.22 (-0.45, 0.01) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 168 | 98 |
| | | Mean (StdDev) | 5.0 (15.32) | 6.5 (16.34) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 166 | 98 |
| | | Mean (StdDev) | -3.2 (19.15) | -2.0 (20.76) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | -2.7 (1.15) | -1.1 (1.51) |
| | | 95% CI | -4.9, -0.4 | -4.0, 1.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.6 (1.90) | |
| | | 95% CI | -5.3, 2.1 | |
| | | p-value | 0.3980 | |
| | | Corrected Hedges g (95% CI) [2] | -0.11 (-0.36, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 149 | 87 |
| | | Mean (StdDev) | 5.6 (15.21) | 8.4 (20.47) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 148 | 87 |
| | | Mean (StdDev) | -2.5 (16.99) | -0.8 (20.32) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 33 | -100, 67 |
| | | LS Mean (SE) | -2.0 (1.21) | 0.3 (1.58) |
| | | 95% CI | -4.4, 0.4 | -2.8, 3.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.2 (1.99) | |
| | | 95% CI | -6.2, 1.7 | |
| | | p-value | 0.2597 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.42, 0.11) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 66 |
| | | Mean (StdDev) | 5.3 (14.75) | 7.6 (15.24) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 131 | 66 |
| | | Mean (StdDev) | -2.3 (19.48) | -2.0 (19.29) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 33 |
| | | LS Mean (SE) | -1.9 (1.28) | -0.6 (1.79) |
| | | 95% CI | -4.4, 0.6 | -4.1, 2.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -1.3 (2.20) | |
| | | 95% CI | -5.6, 3.0 | |
| | | p-value | 0.5454 | |
| | | Corrected Hedges g (95% CI) [2] | -0.09 (-0.39, 0.21) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 4.4 (12.92) | 10.5 (20.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 119 | 51 |
| | | Mean (StdDev) | -2.2 (20.23) | 0.0 (23.09) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | -2.1 (1.34) | 2.5 (2.02) |
| | | 95% CI | -4.8, 0.5 | -1.5, 6.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -4.6 (2.43) | |
| | | 95% CI | -9.4, 0.2 | |
| | | p-value | 0.0585 | |
| | | Corrected Hedges g (95% CI) [2] | -0.31 (-0.64, 0.02) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 110 | 48 |
| | | Mean (StdDev) | 3.6 (10.44) | 6.9 (16.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 67 |
| | Change from BL | n | 109 | 48 |
| | | Mean (StdDev) | -3.7 (19.43) | -1.4 (18.14) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 33 | -67, 33 |
| | | LS Mean (SE) | -3.0 (1.39) | -0.8 (2.07) |
| | | 95% CI | -5.7, -0.2 | -4.9, 3.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.2 (2.50) | |
| | | 95% CI | -7.1, 2.7 | |
| | | p-value | 0.3863 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.49, 0.19) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 37 |
| | | Mean (StdDev) | 2.7 (9.22) | 7.2 (19.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 33 | 0, 100 |
| | Change from BL | n | 96 | 37 |
| | | Mean (StdDev) | -3.8 (16.66) | 0.0 (23.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 33 | -67, 100 |
| | | LS Mean (SE) | -2.7 (1.48) | 0.4 (2.33) |
| | | 95% CI | -5.6, 0.2 | -4.2, 4.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -3.1 (2.76) | |
| | | 95% CI | -8.5, 2.4 | |
| | | p-value | 0.2685 | |
| | | Corrected Hedges g (95% CI) [2] | -0.21 (-0.59, 0.17) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 4.4 (14.51) | 6.3 (15.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 83 | 32 |
| | | Mean (StdDev) | -1.6 (17.96) | -1.0 (19.83) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -33, 67 |
| | | LS Mean (SE) | -1.8 (1.59) | 0.3 (2.52) |
| | | 95% CI | -4.9, 1.3 | -4.6, 5.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.1 (2.98) | |
| | | 95% CI | -8.0, 3.7 | |
| | | p-value | 0.4727 | |
| | | Corrected Hedges g (95% CI) [2] | -0.15 (-0.56, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 4.2 (14.03) | 2.9 (9.60) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 33 |
| | Change from BL | n | 63 | 23 |
| | | Mean (StdDev) | -2.1 (20.63) | -1.4 (6.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -33, 0 |
| | | LS Mean (SE) | -2.4 (1.80) | -3.2 (2.95) |
| | | 95% CI | -6.0, 1.1 | -9.0, 2.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.8 (3.44) | |
| | | 95% CI | -6.0, 7.5 | |
| | | p-value | 0.8229 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.42, 0.53) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | -6.7 (16.67) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 0 | 0, 0 |
| | | LS Mean (SE) | -5.7 (2.77) | -2.9 (5.33) |
| | | 95% CI | -11.1, -0.3 | -13.4, 7.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.8 (5.97) | |
| | | 95% CI | -14.5, 8.9 | |
| | | p-value | 0.6422 | |
| | | Corrected Hedges g (95% CI) [2] | -0.19 (-1.03, 0.64) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 0.0 (0.00) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 0 | 0, 0 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -5.1 (12.52) | 0.0 (0.00) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -33, 0 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 0.0 (0.00) | 33.3 (NA) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 0.0 | 33.3, 33.3 |
| | | Min, Max | 0, 0 | 33, 33 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -4.2 (11.79) | 33.3 (NA) |
| | | Median | 0.0 | 33.3 |
| | | Q1, Q3 | 0.0, 0.0 | 33.3, 33.3 |
| | | Min, Max | -33, 0 | 33, 33 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 6.7 (14.91) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 33 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 6.7 (14.91) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 33 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 126 | 88 |
| | | Mean (StdDev) | 7.4 (16.81) | 6.8 (15.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 67 |
| | Change from BL | n | 125 | 88 |
| | | Mean (StdDev) | 0.3 (21.38) | -1.9 (24.43) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | 0.1 (1.32) | -1.5 (1.59) |
| | | 95% CI | -2.5, 2.7 | -4.6, 1.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.6 (2.06) | |
| | | 95% CI | -2.4, 5.6 | |
| | | p-value | 0.4378 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.17, 0.38) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 56 |
| | | Mean (StdDev) | 7.9 (18.75) | 8.3 (15.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 76 | 56 |
| | | Mean (StdDev) | 0.0 (20.37) | 1.8 (23.29) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 67 |
| | | LS Mean (SE) | 0.3 (1.63) | 0.7 (1.92) |
| | | 95% CI | -2.9, 3.5 | -3.0, 4.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.5 (2.52) | |
| | | 95% CI | -5.4, 4.5 | |
| | | p-value | 0.8512 | |
| | | Corrected Hedges g (95% CI) [2] | -0.03 (-0.38, 0.31) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 54 |
| | | Mean (StdDev) | 11.8 (22.67) | 6.8 (16.36) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 78 | 54 |
| | | Mean (StdDev) | 1.7 (26.81) | -0.6 (26.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | 2.6 (1.63) | -1.5 (1.97) |
| | | 95% CI | -0.6, 5.8 | -5.3, 2.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.0 (2.56) | |
| | | 95% CI | -1.0, 9.1 | |
| | | p-value | 0.1149 | |
| | | Corrected Hedges g (95% CI) [2] | 0.28 (-0.07, 0.63) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 12.1 (20.80) | 6.7 (14.78) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 90 | 60 |
| | | Mean (StdDev) | 4.1 (24.39) | 1.7 (19.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 33 |
| | | LS Mean (SE) | 4.4 (1.54) | -0.5 (1.90) |
| | | 95% CI | 1.4, 7.4 | -4.2, 3.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.9 (2.45) | |
| | | 95% CI | 0.1, 9.7 | |
| | | p-value | 0.0433 | |
| | | Corrected Hedges g (95% CI) [2] | 0.34 (0.01, 0.66) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 79 | 49 |
| | | Mean (StdDev) | 9.3 (19.93) | 7.5 (15.61) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 78 | 49 |
| | | Mean (StdDev) | 0.4 (24.32) | 2.0 (20.87) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -67, 67 |
| | | LS Mean (SE) | 1.5 (1.65) | 1.2 (2.09) |
| | | 95% CI | -1.7, 4.7 | -2.9, 5.3 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.3 (2.67) | |
| | | 95% CI | -5.0, 5.5 | |
| | | p-value | 0.9251 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.34, 0.37) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -1.3 (0.68) | -0.5 (0.98) |
| | | 95% CI | -2.6, 0.1 | -2.4, 1.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.8 (1.19) | |
| | | 95% CI | -3.1, 1.5 | |
| | | p-value | 0.4999 | |
| | | Corrected Hedges g (95% CI) [2] | -0.08 (-0.30, 0.14) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Baseline | Actual | n | 223 | 124 |
| | | Mean (StdDev) | 22.7 (31.35) | 24.5 (31.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| Cycle 3 Day 1 | Actual | n | 199 | 114 |
| | | Mean (StdDev) | 20.1 (29.74) | 21.1 (29.84) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 195 | 114 |
| | | Mean (StdDev) | -2.2 (22.97) | -3.8 (24.19) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 100 |
| | | LS Mean (SE) | -2.6 (1.60) | -3.2 (2.11) |
| | | 95% CI | -5.8, 0.5 | -7.4, 0.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.6 (2.65) | |
| | | 95% CI | -4.6, 5.8 | |
| | | p-value | 0.8279 | |
| | | Corrected Hedges g (95% CI) [2] | 0.03 (-0.21, 0.26) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 5 Day 1 | Actual | n | 167 | 98 |
| | | Mean (StdDev) | 16.4 (26.10) | 21.1 (30.79) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 163 | 98 |
| | | Mean (StdDev) | -5.1 (25.28) | -4.8 (26.22) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | -6.0 (1.69) | -3.7 (2.20) |
| | | 95% CI | -9.3, -2.7 | -8.1, 0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.3 (2.78) | |
| | | 95% CI | -7.7, 3.2 | |
| | | p-value | 0.4180 | |
| | | Corrected Hedges g (95% CI) [2] | -0.10 (-0.35, 0.15) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 7 Day 1 | Actual | n | 150 | 87 |
| | | Mean (StdDev) | 17.8 (28.29) | 19.5 (27.16) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 148 | 87 |
| | | Mean (StdDev) | -4.1 (28.01) | -8.0 (23.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 33 |
| | | LS Mean (SE) | -4.6 (1.75) | -5.7 (2.29) |
| | | 95% CI | -8.0, -1.2 | -10.2, -1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.1 (2.88) | |
| | | 95% CI | -4.6, 6.7 | |
| | | p-value | 0.7081 | |
| | | Corrected Hedges g (95% CI) [2] | 0.05 (-0.21, 0.32) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 9 Day 1 | Actual | n | 132 | 66 |
| | | Mean (StdDev) | 15.9 (27.15) | 17.2 (26.95) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 130 | 66 |
| | | Mean (StdDev) | -5.9 (25.06) | -8.1 (22.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 67 | -100, 33 |
| | | LS Mean (SE) | -6.1 (1.81) | -6.0 (2.48) |
| | | 95% CI | -9.6, -2.5 | -10.9, -1.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.0 (3.07) | |
| | | 95% CI | -6.1, 6.0 | |
| | | p-value | 0.9908 | |
| | | Corrected Hedges g (95% CI) [2] | 0.00 (-0.30, 0.29) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 11 Day 1 | Actual | n | 120 | 51 |
| | | Mean (StdDev) | 16.1 (26.63) | 17.6 (27.77) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 118 | 51 |
| | | Mean (StdDev) | -5.1 (22.91) | -9.2 (22.19) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | -100, 33 |
| | | LS Mean (SE) | -5.4 (1.87) | -5.9 (2.70) |
| | | 95% CI | -9.1, -1.8 | -11.2, -0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 0.5 (3.29) | |
| | | 95% CI | -6.0, 6.9 | |
| | | p-value | 0.8877 | |
| | | Corrected Hedges g (95% CI) [2] | 0.02 (-0.31, 0.35) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 13 Day 1 | Actual | n | 110 | 48 |
| | | Mean (StdDev) | 17.0 (29.86) | 13.2 (21.46) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 108 | 48 |
| | | Mean (StdDev) | -5.6 (28.28) | -13.2 (24.54) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -100, 100 | -67, 33 |
| | | LS Mean (SE) | -5.8 (1.93) | -9.0 (2.78) |
| | | 95% CI | -9.6, -2.0 | -14.4, -3.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 3.1 (3.39) | |
| | | 95% CI | -3.5, 9.8 | |
| | | p-value | 0.3549 | |
| | | Corrected Hedges g (95% CI) [2] | 0.16 (-0.18, 0.50) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 15 Day 1 | Actual | n | 97 | 37 |
| | | Mean (StdDev) | 17.2 (28.91) | 10.8 (22.30) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 95 | 37 |
| | | Mean (StdDev) | -4.9 (25.25) | -14.4 (22.96) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -100, 67 | -67, 0 |
| | | LS Mean (SE) | -5.4 (2.02) | -10.4 (3.06) |
| | | 95% CI | -9.3, -1.4 | -16.4, -4.4 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.0 (3.67) | |
| | | 95% CI | -2.2, 12.2 | |
| | | p-value | 0.1706 | |
| | | Corrected Hedges g (95% CI) [2] | 0.26 (-0.12, 0.64) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 18 Day 1 | Actual | n | 83 | 32 |
| | | Mean (StdDev) | 17.3 (28.21) | 7.3 (20.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 82 | 32 |
| | | Mean (StdDev) | -5.3 (28.43) | -13.5 (25.20) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -33.3, 0.0 | -33.3, 0.0 |
| | | Min, Max | -100, 100 | -100, 33 |
| | | LS Mean (SE) | -5.6 (2.16) | -11.4 (3.29) |
| | | 95% CI | -9.8, -1.4 | -17.8, -4.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 5.8 (3.94) | |
| | | 95% CI | -2.0, 13.5 | |
| | | p-value | 0.1433 | |
| | | Corrected Hedges g (95% CI) [2] | 0.30 (-0.11, 0.71) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 21 Day 1 | Actual | n | 63 | 23 |
| | | Mean (StdDev) | 16.9 (29.86) | 13.0 (21.88) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 67 |
| | Change from BL | n | 62 | 23 |
| | | Mean (StdDev) | -1.6 (31.03) | -10.1 (15.68) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -100, 100 | -33, 0 |
| | | LS Mean (SE) | -4.5 (2.43) | -8.6 (3.82) |
| | | 95% CI | -9.3, 0.3 | -16.1, -1.1 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 4.1 (4.53) | |
| | | 95% CI | -4.8, 12.9 | |
| | | p-value | 0.3707 | |
| | | Corrected Hedges g (95% CI) [2] | 0.21 (-0.27, 0.69) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 24 Day 1 | Actual | n | 25 | 7 |
| | | Mean (StdDev) | 22.7 (36.92) | 14.3 (17.82) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 33 |
| | Change from BL | n | 25 | 7 |
| | | Mean (StdDev) | 1.3 (28.02) | -9.5 (16.27) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -67, 67 | -33, 0 |
| | | LS Mean (SE) | -0.4 (3.51) | -13.2 (6.43) |
| | | 95% CI | -7.3, 6.5 | -25.8, -0.6 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 12.8 (7.33) | |
| | | 95% CI | -1.6, 27.2 | |
| | | p-value | 0.0807 | |
| | | Corrected Hedges g (95% CI) [2] | 0.72 (-0.14, 1.57) | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 27 Day 1 | Actual | n | 13 | 4 |
| | | Mean (StdDev) | 23.1 (31.58) | 16.7 (19.25) |
| | | Median | 0.0 | 16.7 |
| | | Q1, Q3 | 0.0, 66.7 | 0.0, 33.3 |
| | | Min, Max | 0, 67 | 0, 33 |
| | Change from BL | n | 13 | 4 |
| | | Mean (StdDev) | -2.6 (28.74) | -16.7 (19.25) |
| | | Median | 0.0 | -16.7 |
| | | Q1, Q3 | 0.0, 0.0 | -33.3, 0.0 |
| | | Min, Max | -67, 67 | -33, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 30 Day 1 | Actual | n | 8 | 1 |
| | | Mean (StdDev) | 16.7 (25.20) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 0.0 |
| | | Min, Max | 0, 67 | 0, 0 |
| | Change from BL | n | 8 | 1 |
| | | Mean (StdDev) | -4.2 (37.53) | 0.0 (NA) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | -16.7, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 67 | 0, 0 |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 33 Day 1 | Actual | n | 5 | 0 |
| | | Mean (StdDev) | 13.3 (29.81) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 67 | |
| | Change from BL | n | 5 | 0 |
| | | Mean (StdDev) | 0.0 (0.00) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Cycle 36 Day 1 | Actual | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | Change from BL | n | 1 | 0 |
| | | Mean (StdDev) | 0.0 (NA) | |
| | | Median | 0.0 | |
| | | Q1, Q3 | 0.0, 0.0 | |
| | | Min, Max | 0, 0 | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | | |
| | | 95% CI | | |
| | | p-value | | |
| | | Corrected Hedges g (95% CI) [2] | | |

| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| End of Treatment | Actual | n | 128 | 88 |
| | | Mean (StdDev) | 20.3 (29.65) | 22.3 (29.35) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 126 | 88 |
| | | Mean (StdDev) | -3.4 (29.16) | -1.9 (23.90) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 67 |
| | | LS Mean (SE) | -2.9 (1.88) | -2.0 (2.31) |
| | | 95% CI | -6.5, 0.8 | -6.5, 2.5 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -0.9 (2.97) | |
| | | 95% CI | -6.7, 5.0 | |
| | | p-value | 0.7701 | |
| | | Corrected Hedges g (95% CI) [2] | -0.04 (-0.31, 0.23) | |

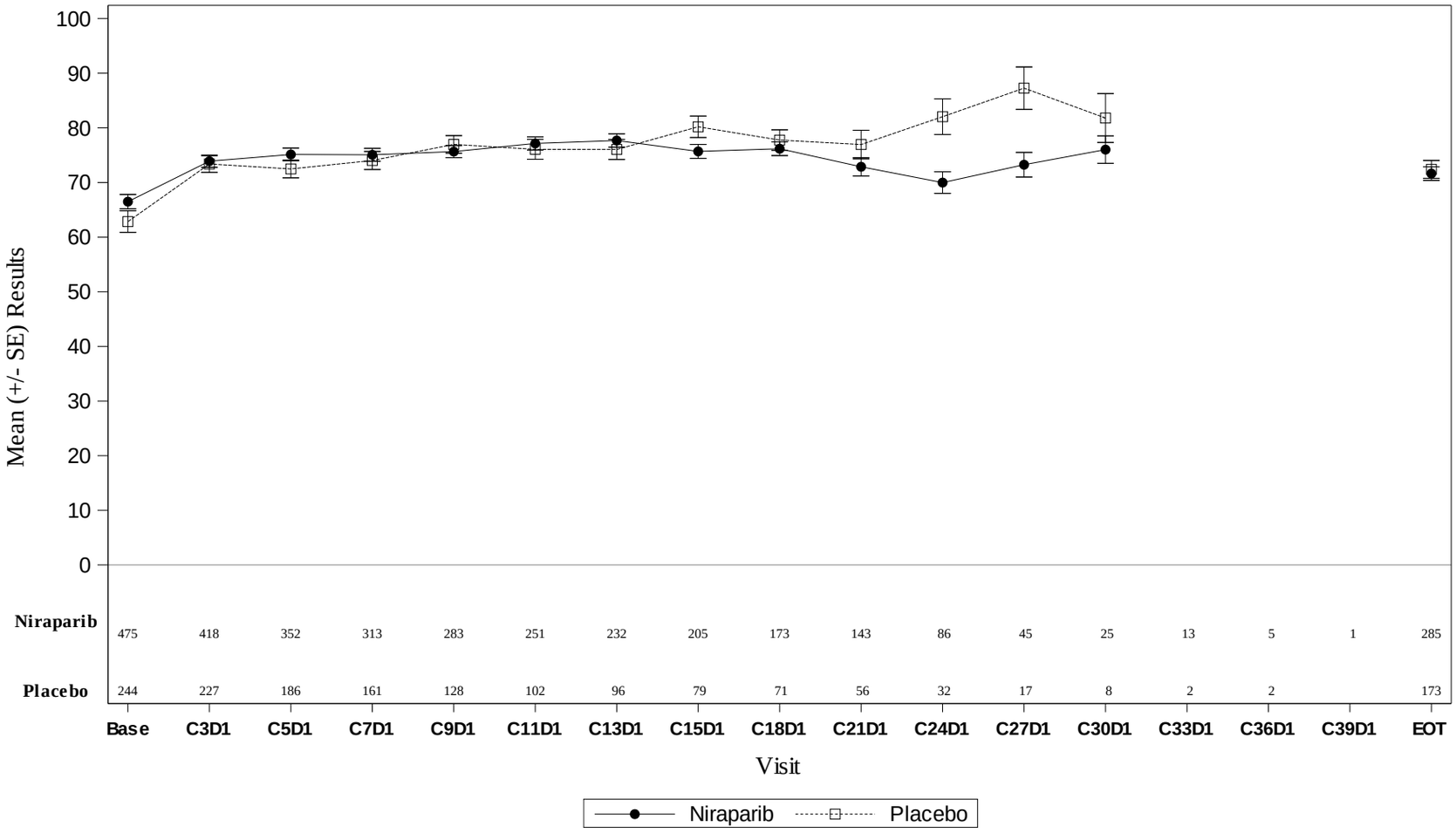
| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 4 | Actual | n | 76 | 56 |
| | | Mean (StdDev) | 20.2 (28.84) | 22.6 (33.70) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 75 | 56 |
| | | Mean (StdDev) | -1.8 (28.42) | 1.2 (22.89) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | -2.0 (2.22) | 0.5 (2.66) |
| | | 95% CI | -6.3, 2.4 | -4.7, 5.8 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.5 (3.47) | |
| | | 95% CI | -9.3, 4.3 | |
| | | p-value | 0.4714 | |
| | | Corrected Hedges g (95% CI) [2] | -0.13 (-0.47, 0.22) | |

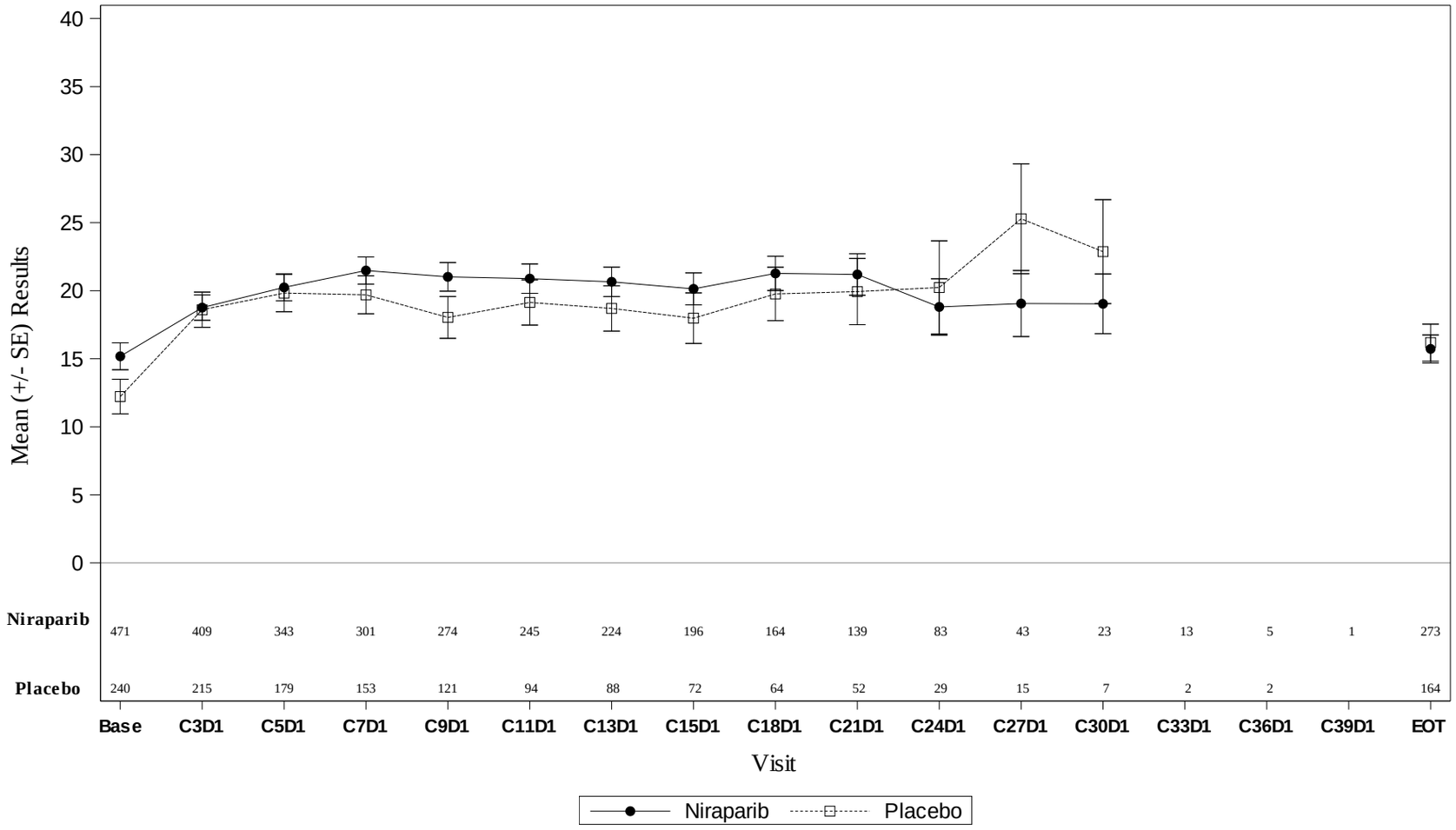
| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 8 | Actual | n | 79 | 53 |
| | | Mean (StdDev) | 22.4 (30.06) | 23.3 (33.07) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 77 | 53 |
| | | Mean (StdDev) | -1.7 (29.07) | 2.5 (22.50) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | -1.1 (2.23) | 1.3 (2.74) |
| | | 95% CI | -5.5, 3.2 | -4.0, 6.7 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | -2.5 (3.54) | |
| | | 95% CI | -9.4, 4.5 | |
| | | p-value | 0.4847 | |
| | | Corrected Hedges g (95% CI) [2] | -0.12 (-0.47, 0.23) | |

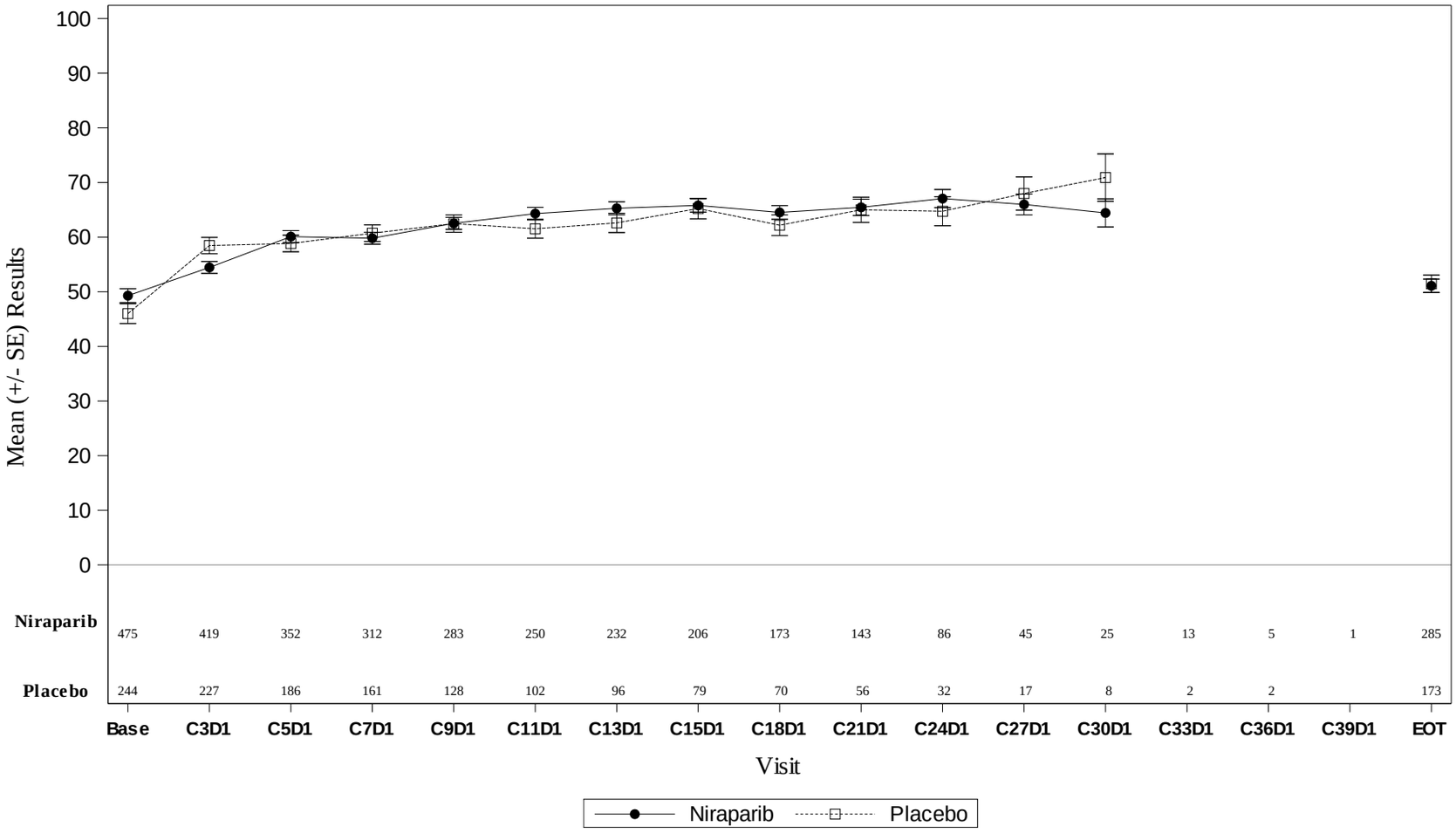
| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 12 | Actual | n | 91 | 60 |
| | | Mean (StdDev) | 24.9 (31.27) | 22.2 (31.69) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 89 | 60 |
| | | Mean (StdDev) | 3.0 (32.04) | -1.1 (26.01) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -67, 100 | -67, 67 |
| | | LS Mean (SE) | 2.4 (2.15) | 0.0 (2.65) |
| | | 95% CI | -1.8, 6.6 | -5.2, 5.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 2.4 (3.41) | |
| | | 95% CI | -4.3, 9.1 | |
| | | p-value | 0.4844 | |
| | | Corrected Hedges g (95% CI) [2] | 0.12 (-0.21, 0.44) | |

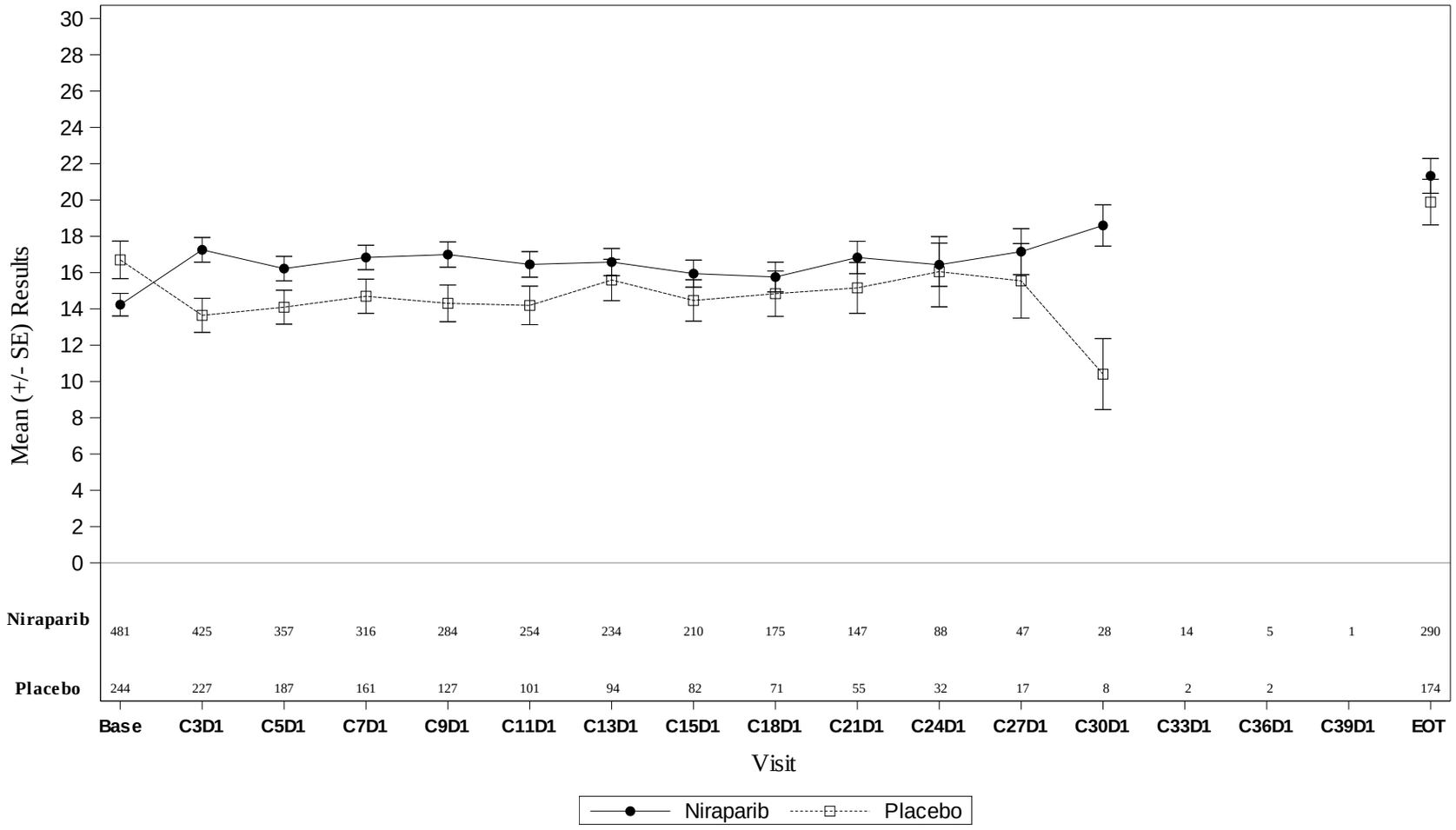
| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Follow-Up Week 24 | Actual | n | 79 | 49 |
| | | Mean (StdDev) | 23.6 (32.09) | 17.0 (25.57) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 33.3 | 0.0, 33.3 |
| | | Min, Max | 0, 100 | 0, 100 |
| | Change from BL | n | 78 | 49 |
| | | Mean (StdDev) | -1.3 (33.74) | -2.0 (23.97) |
| | | Median | 0.0 | 0.0 |
| | | Q1, Q3 | 0.0, 0.0 | 0.0, 0.0 |
| | | Min, Max | -100, 100 | -100, 33 |
| | | LS Mean (SE) | 0.5 (2.27) | -1.4 (2.86) |
| | | 95% CI | -3.9, 5.0 | -7.0, 4.2 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.9 (3.66) | |
| | | 95% CI | -5.3, 9.1 | |
| | | p-value | 0.6034 | |
| | | Corrected Hedges g (95% CI) [2] | 0.09 (-0.26, 0.45) | |

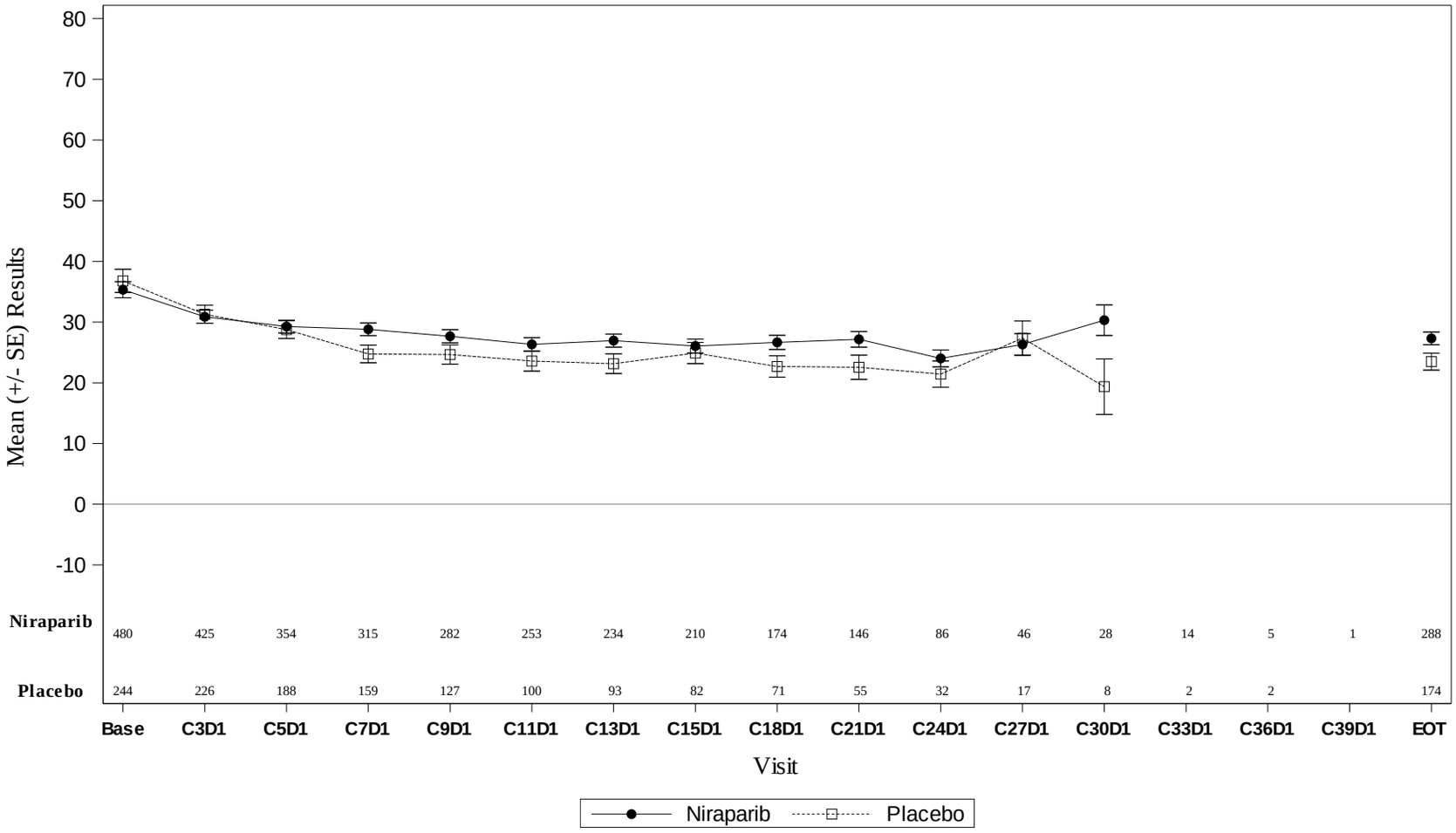
| Visit | Actual/ Change | Statistic | Niraparib (N=228) | Placebo (N=124) |
|---|---|---|---|---|
| Overall | Change from BL | LS Mean (SE) | -3.3 (1.23) | -5.2 (1.69) |
| | | 95% CI | -5.7, -0.9 | -8.6, -1.9 |
| | | Difference from placebo [1] | | |
| | | LS Mean (SE) | 1.9 (2.09) | |
| | | 95% CI | -2.2, 6.0 | |
| | | p-value | 0.3546 | |
| | | Corrected Hedges g (95% CI) [2] | 0.11 (-0.12, 0.33) | |

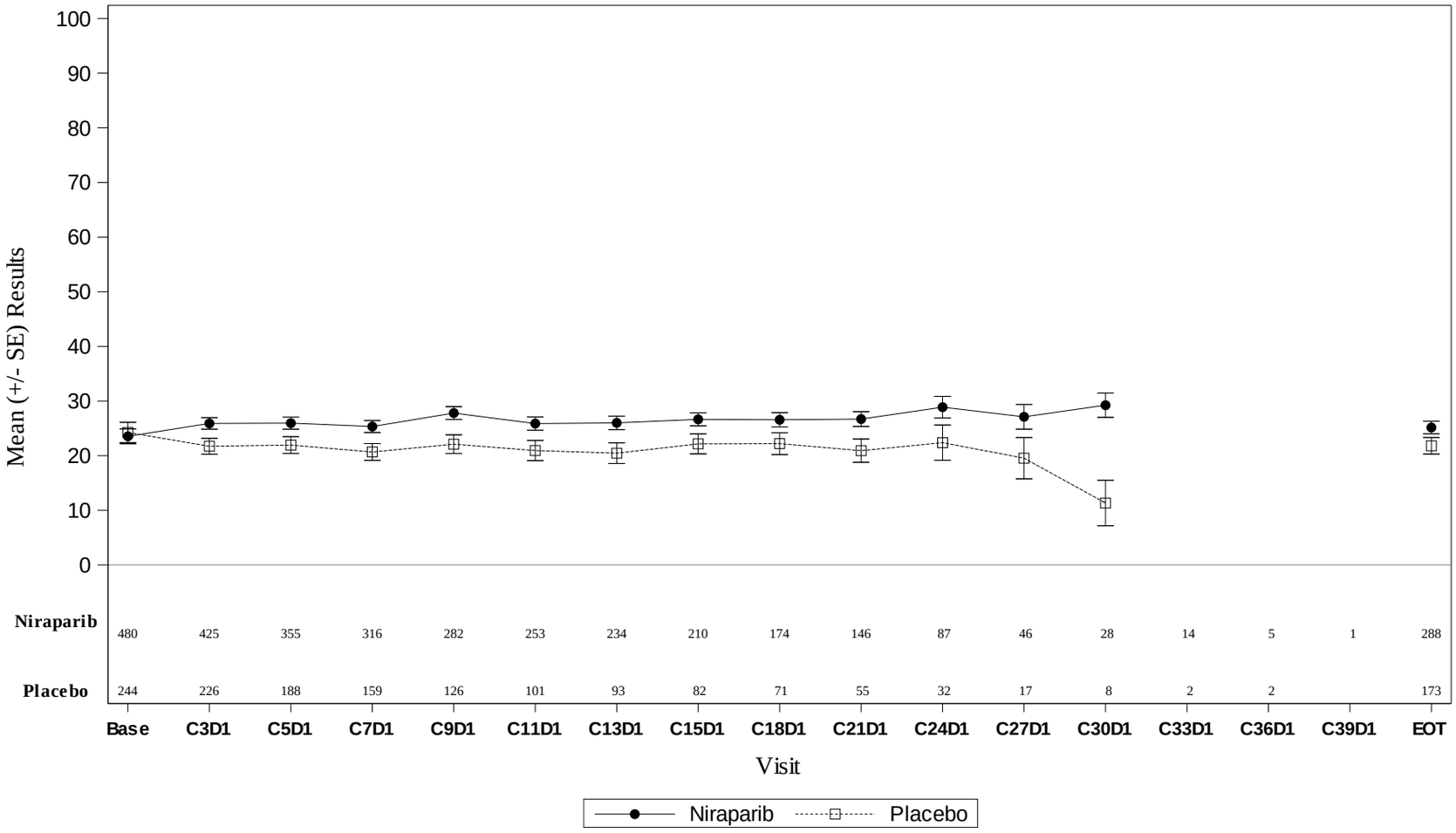

Mean (+/- SE) Results
100
90
80
70
60
50
40
30
20
10
0
Niraparib 475 418 352 313 283 251 232 205 173 143 86 45 25 13 5 1 285
Placebo 244 227 186 161 128 102 96 79 71 56 32 17 8 2 2 173
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 C39D1 EOT
Visit
Niraparib
Placebo

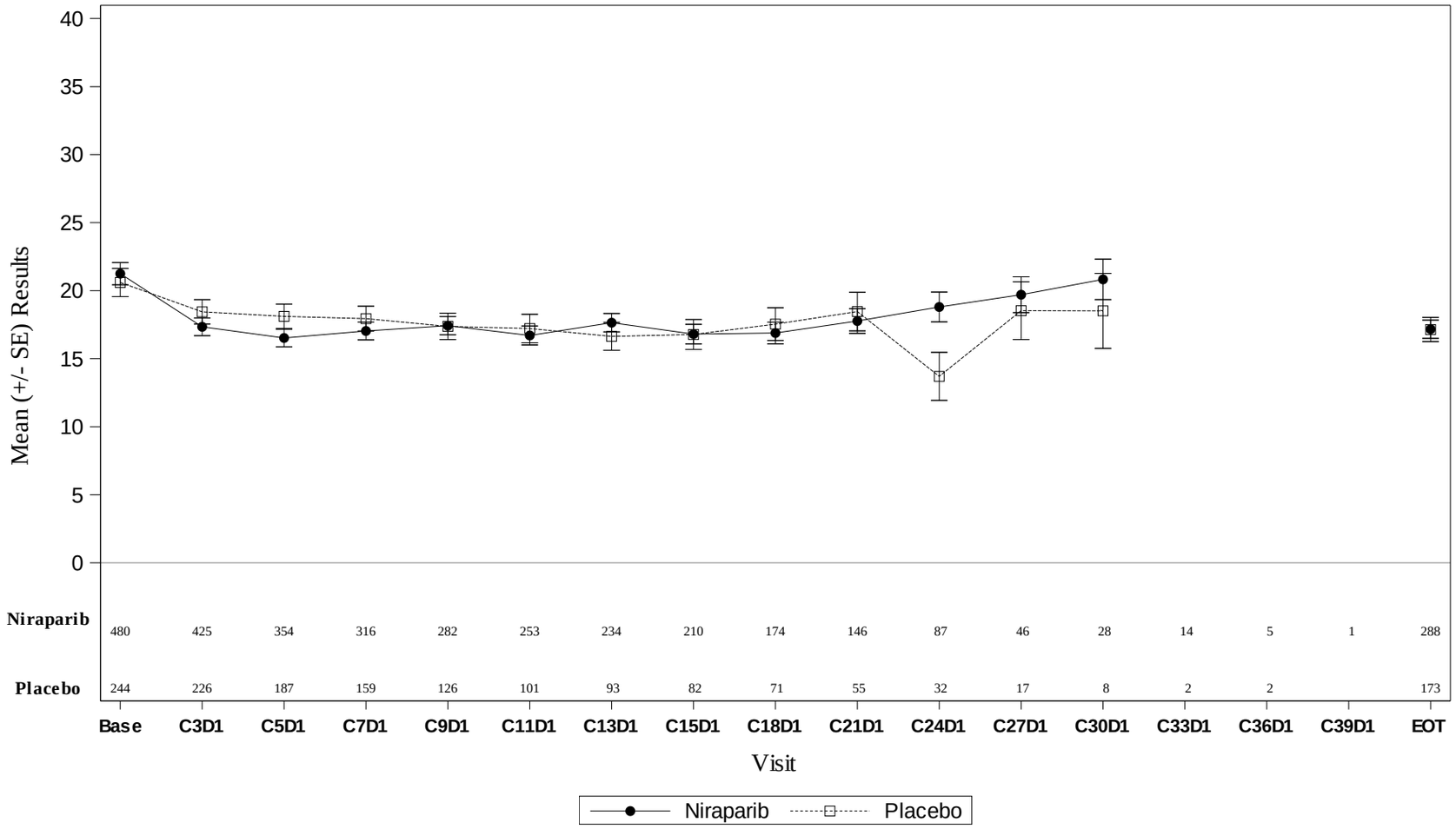

Mean (+/- SE) Results
40
35
30
25
20
15
10
5
0
Niraparib 471 409 343 301 274 245 224 196 164 139 83 43 23 13 5 1 273
Placebo 240 215 179 153 121 94 88 72 64 52 29 15 7 2 2 164
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 C39D1 EOT
Visit
Niraparib
Placebo

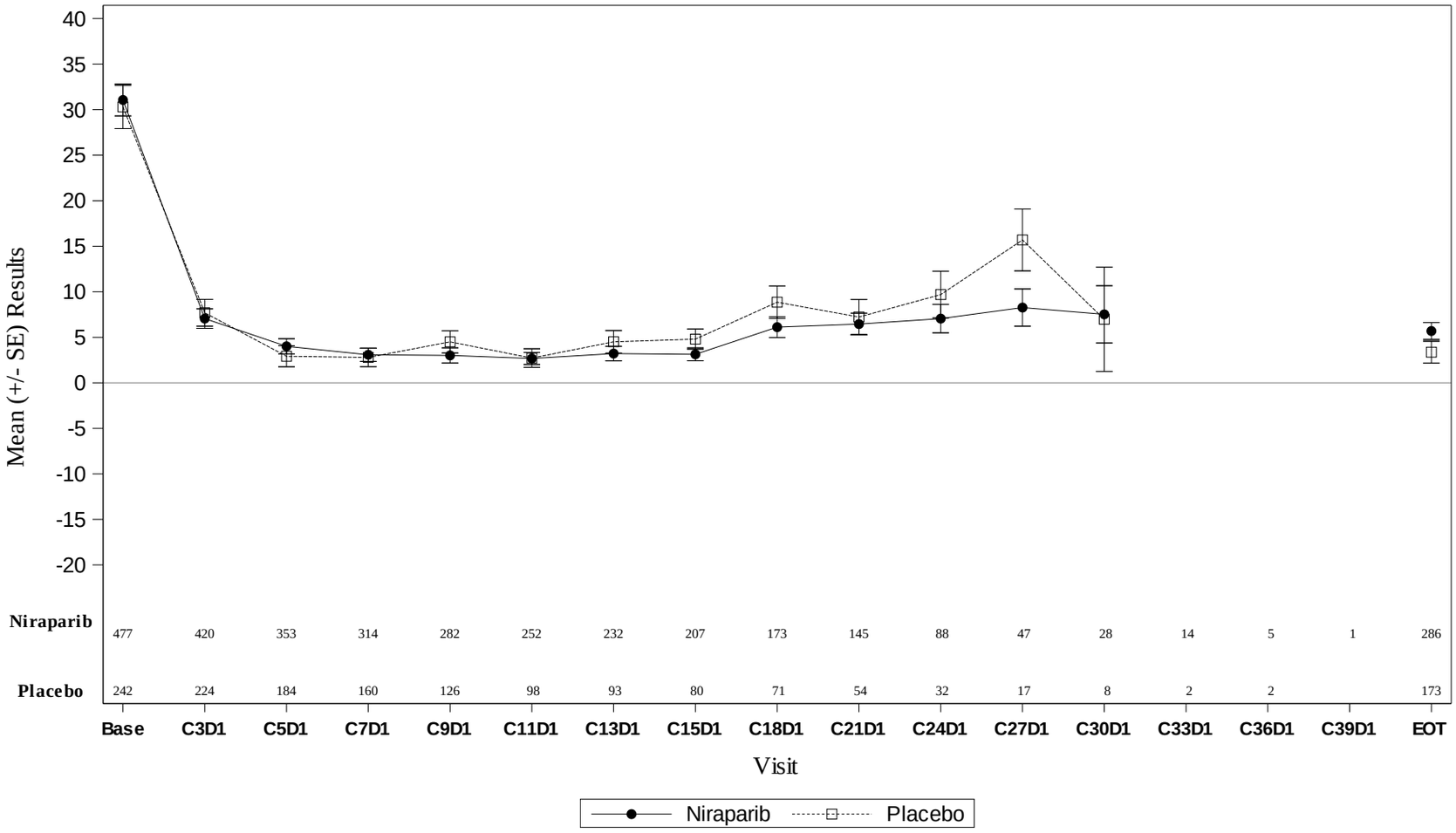

Mean (+/- SE) Results
100
90
80
70
60
50
40
30
20
10
0
Niraparib 475 419 352 312 283 250 232 206 173 143 86 45 25 13 5 1 285
Placebo 244 227 186 161 128 102 96 79 70 56 32 17 8 2 2 173
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 C39D1 EOT
Visit
Niraparib
Placebo

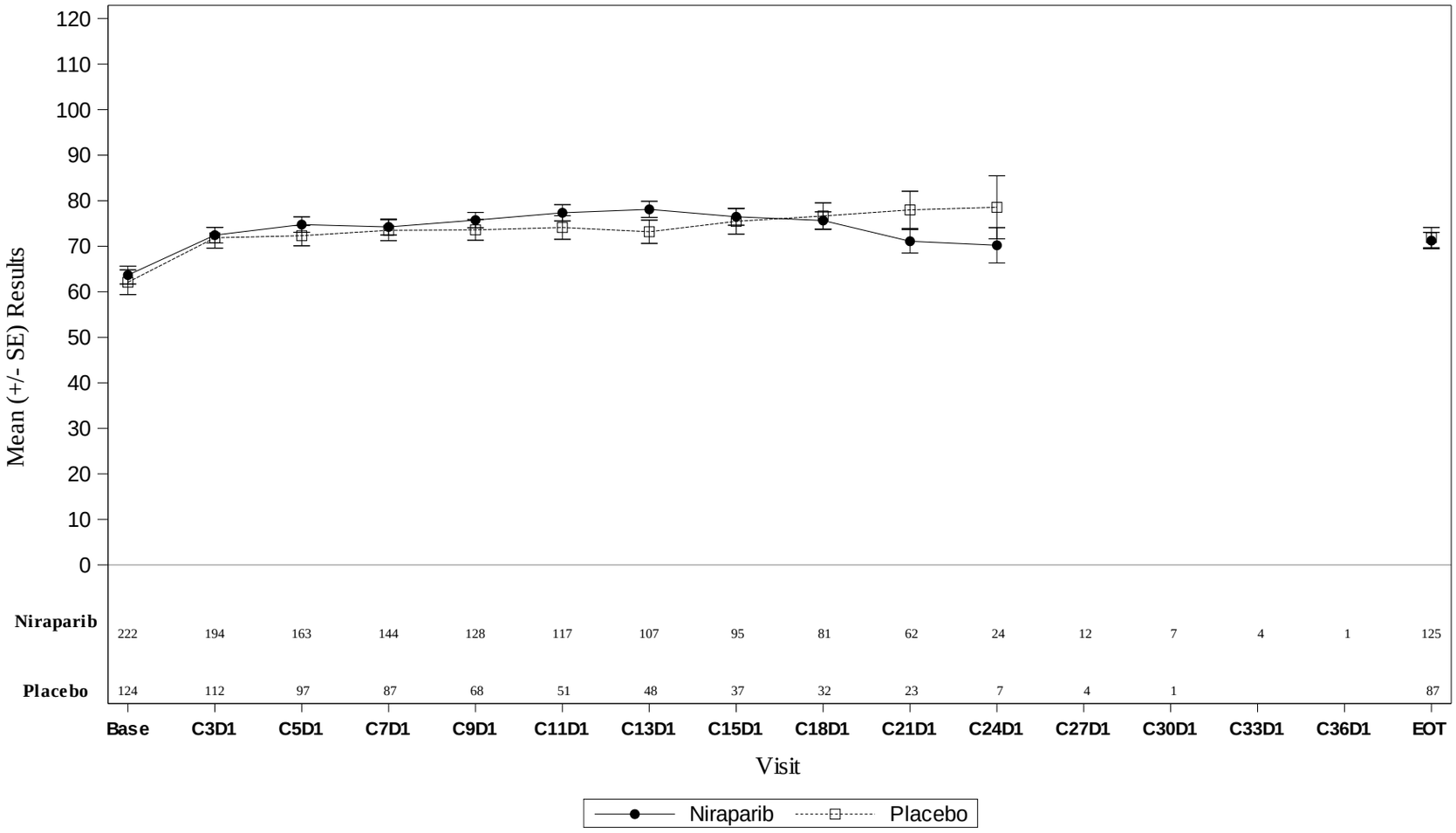

Mean (+/- SE) Results
30
28
26
24
22
20
18
16
14
12
10
8
6
4
2
0
Niraparib 481 425 357 316 284 254 234 210 175 147 88 47 28 14 5 1 290
Placebo 244 227 187 161 127 101 94 82 71 55 32 17 8 2 2 174
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 C39D1 EOT
Visit
Niraparib
Placebo

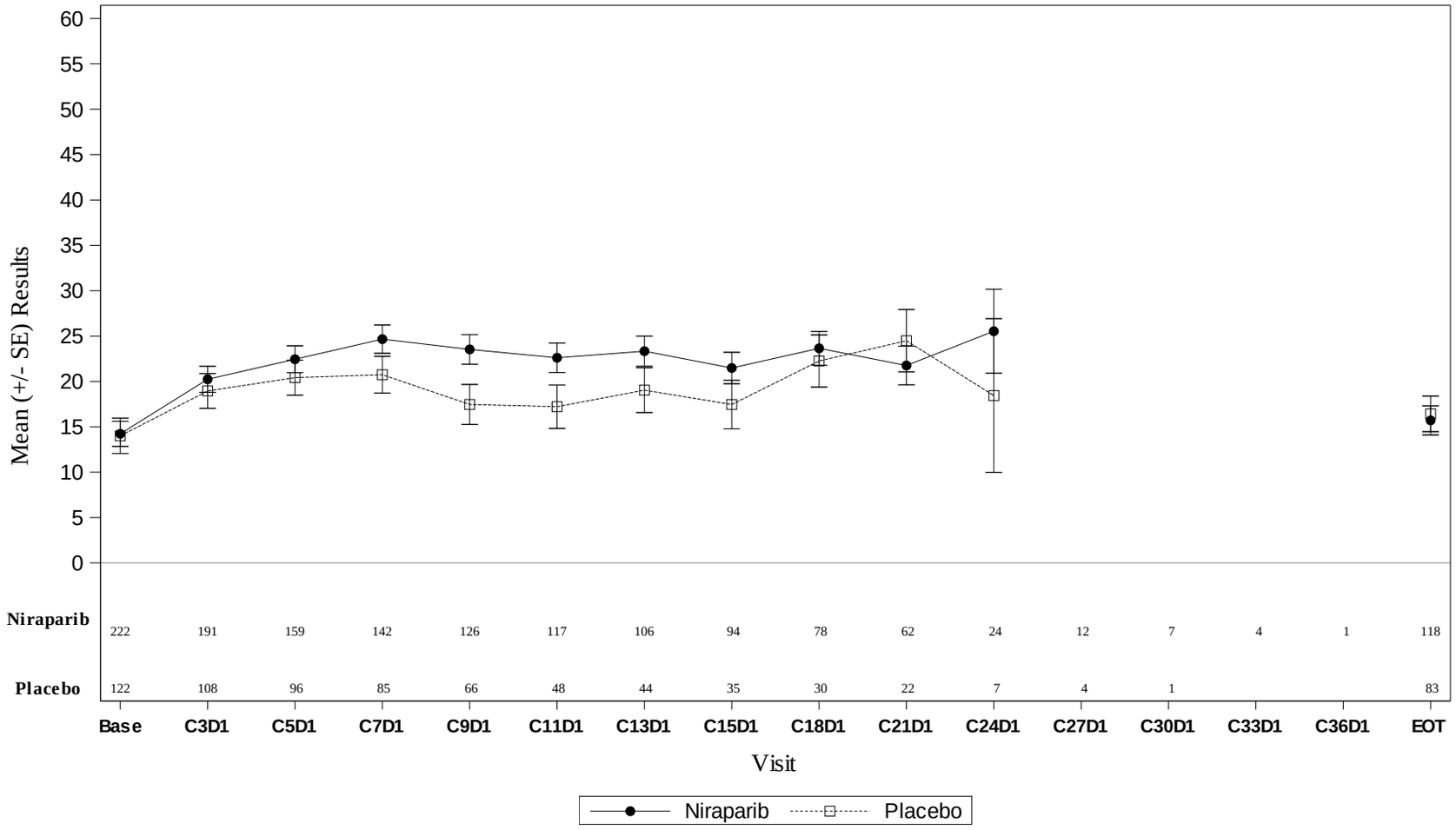

Mean (+/- SE) Results
80
70
60
50
40
30
20
10
0
-10
Niraparib
480 425 354 315 282 253 234 210 174 146 86 46 28 14 5 1 288
Placebo
244 226 188 159 127 100 93 82 71 55 32 17 8 2 2 174
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 C39D1 EOT
Visit
Niraparib
Placebo

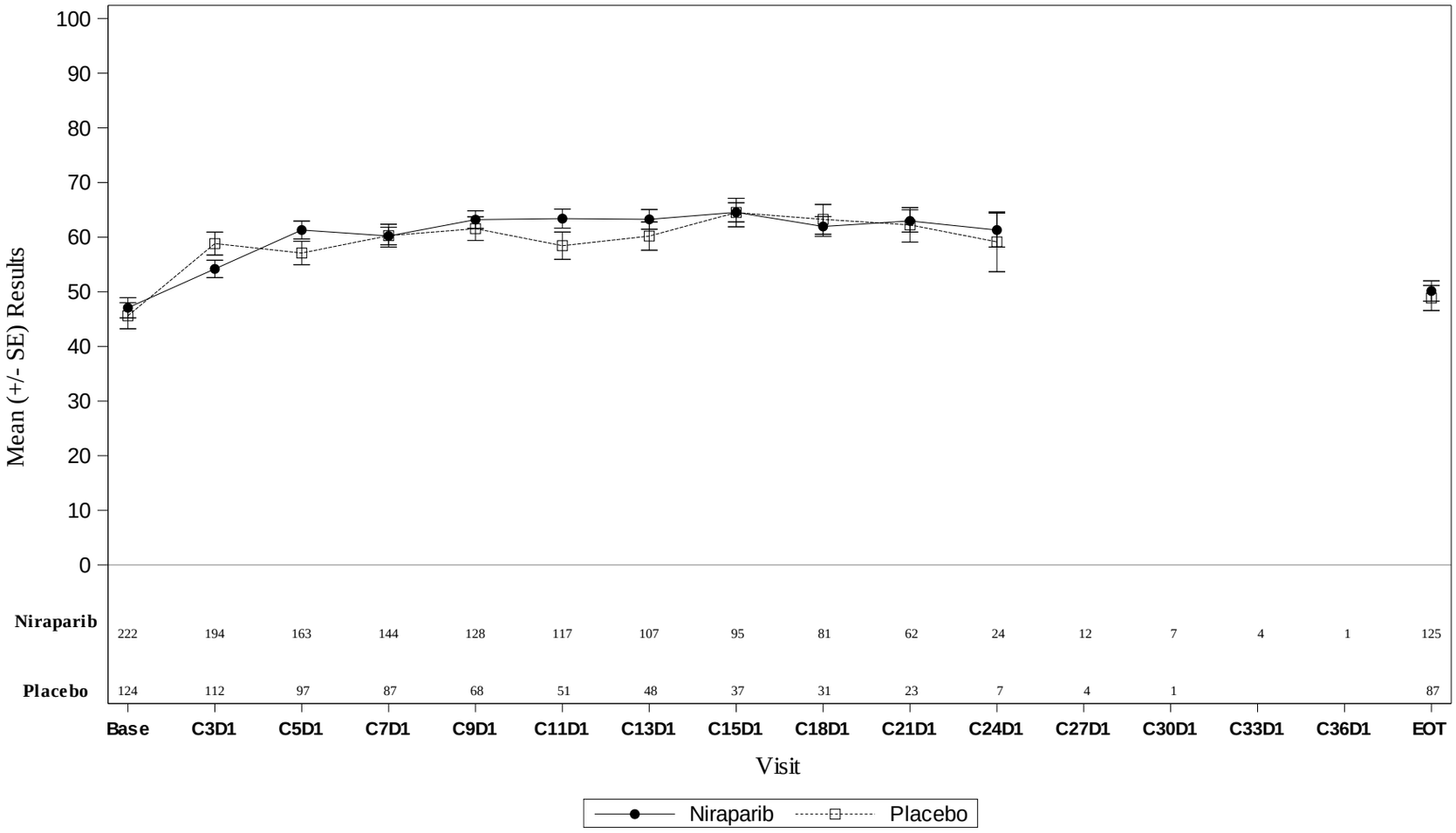

Mean (+/- SE) Results
100
90
80
70
60
50
40
30
20
10
0
Niraparib 480 425 355 316 282 253 234 210 174 146 87 46 28 14 5 1 288
Placebo 244 226 188 159 126 101 93 82 71 55 32 17 8 2 2 173
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 C39D1 EOT
Visit
Niraparib
Placebo

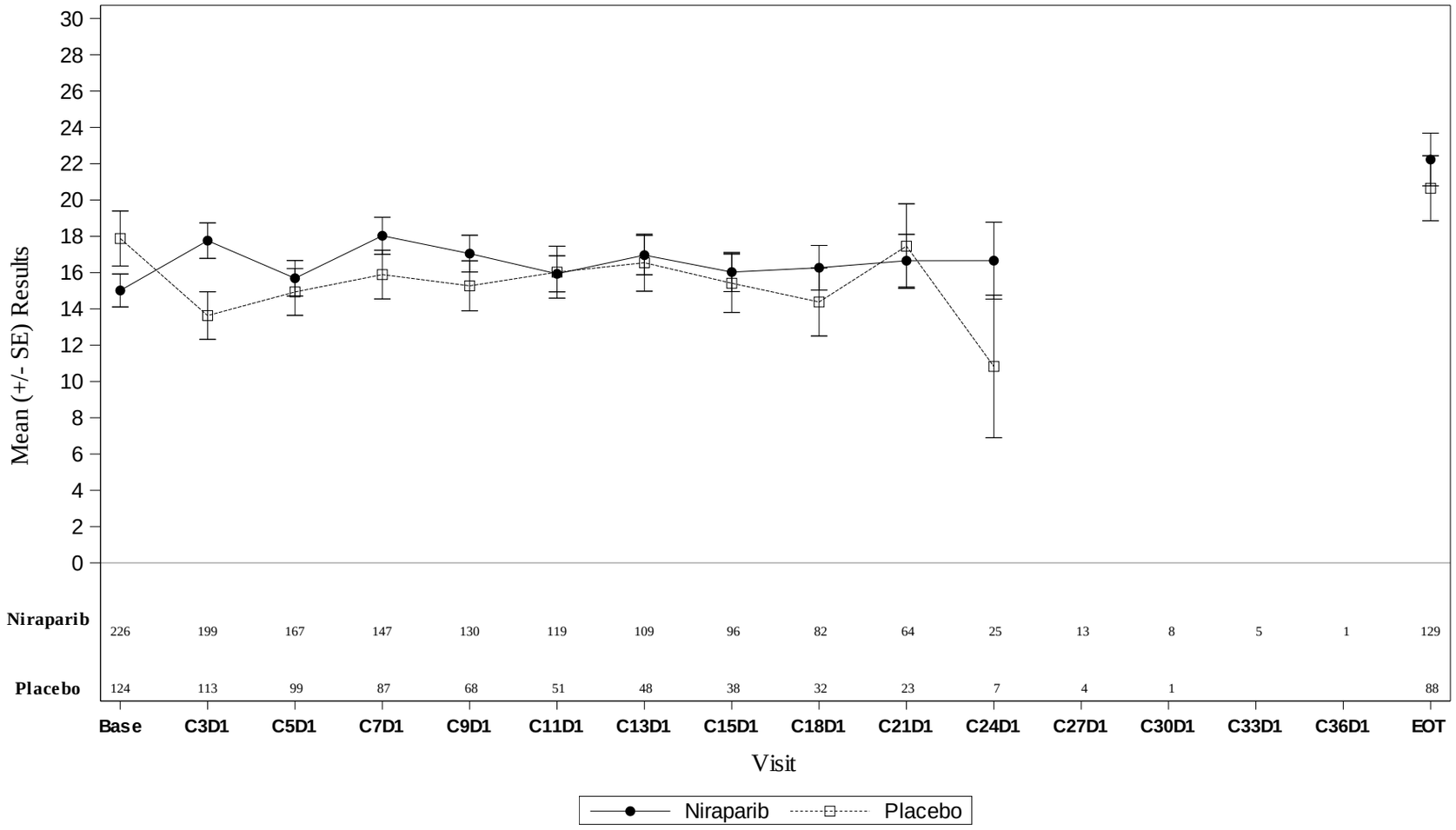

Mean (+/- SE) Results
40
35
30
25
20
15
10
5
0
Niraparib 480 425 354 316 282 253 234 210 174 146 87 46 28 14 5 1 288
Placebo 244 226 187 159 126 101 93 82 71 55 32 17 8 2 2 173
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 C39D1 EOT
Visit
Niraparib
Placebo

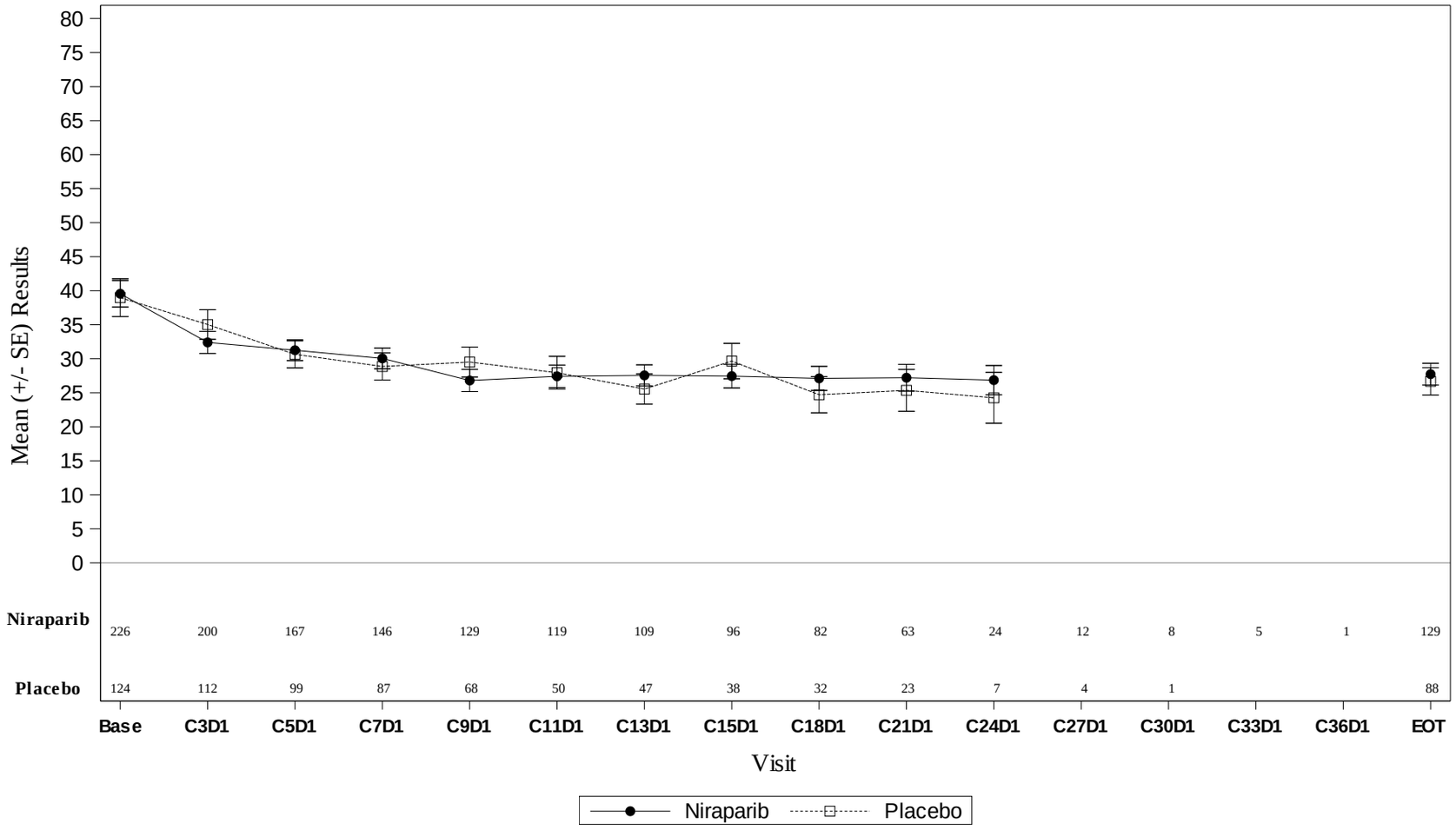

Mean (+/- SE) Results
40
35
30
25
20
15
10
5
0
-5
-10
-15
-20
Niraparib 477 420 353 314 282 252 232 207 173 145 88 47 28 14 5 1 286
Placebo 242 224 184 160 126 98 93 80 71 54 32 17 8 2 2 173
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 C39D1 EOT
Visit
Niraparib
Placebo

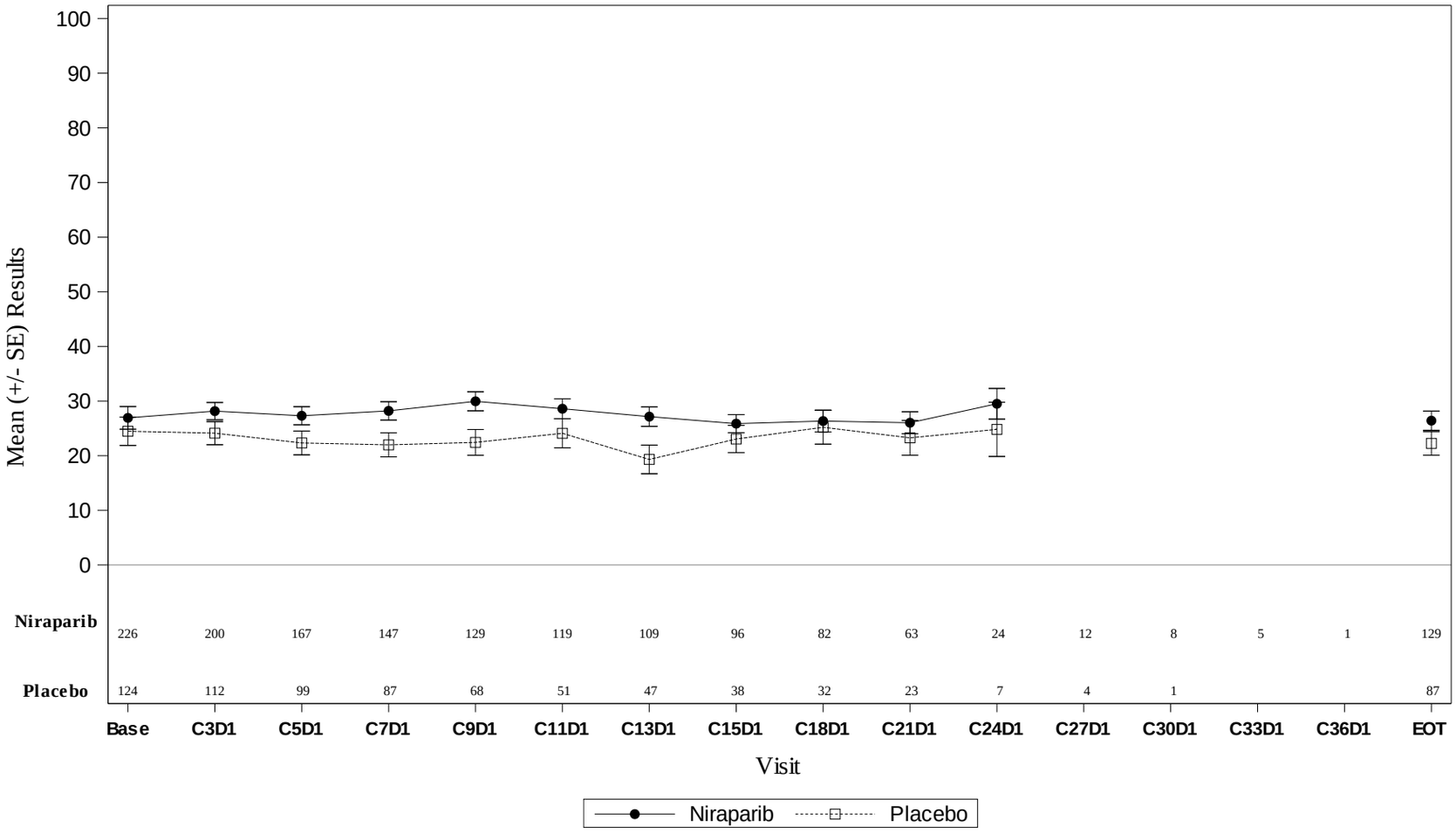

Mean (+/- SE) Results
120
110
100
90
80
70
60
50
40
30
20
10
0
Niraparib 222 194 163 144 128 117 107 95 81 62 24 12 7 4 1 125
Placebo 124 112 97 87 68 51 48 37 32 23 7 4 1 87
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 EOT
Visit
Niraparib
Placebo

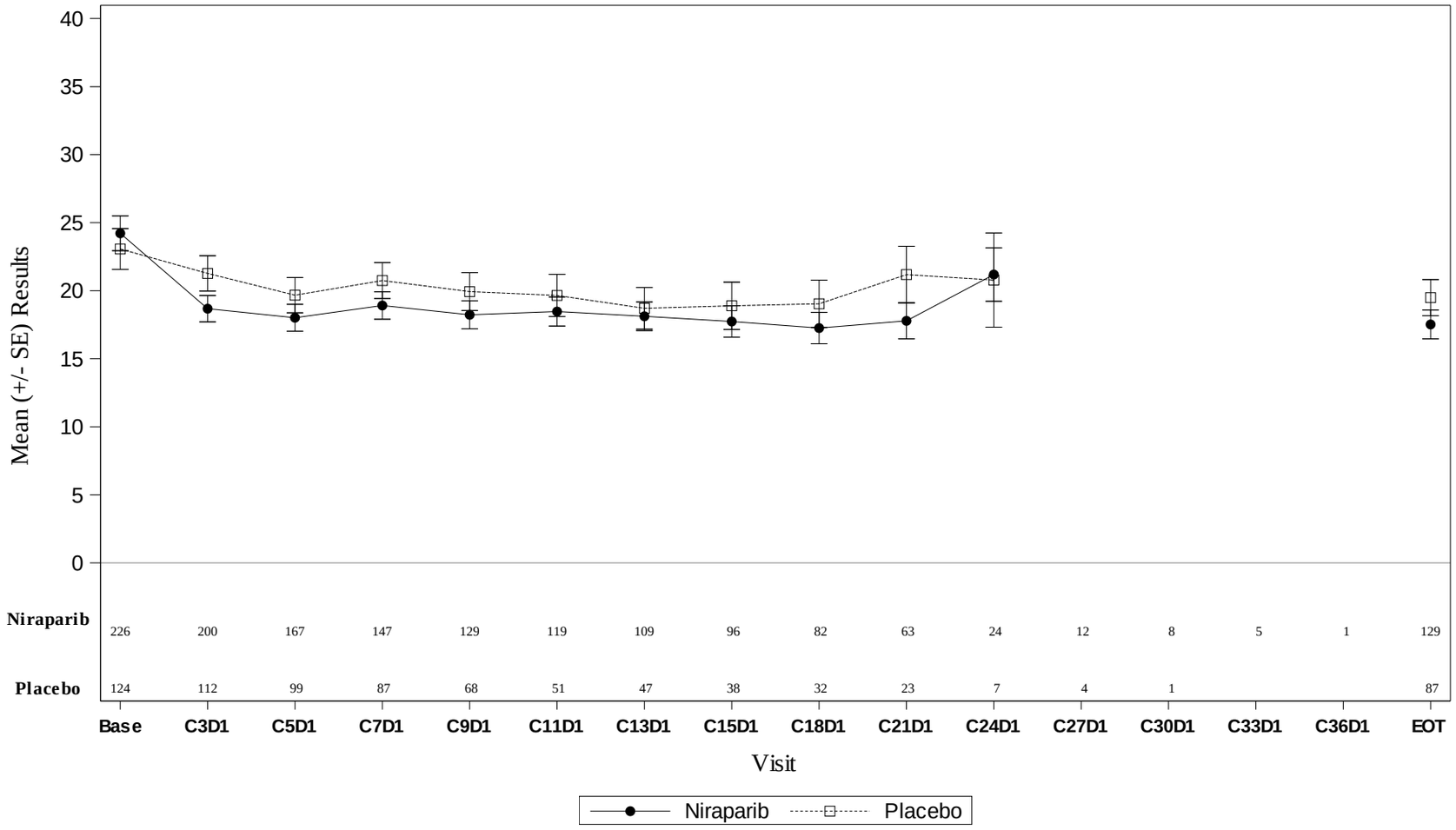

Mean (+/- SE) Results
60
55
50
45
40
35
30
25
20
15
10
5
0
Niraparib 222 191 159 142 126 117 106 94 78 62 24 12 7 4 1 118
Placebo 122 108 96 85 66 48 44 35 30 22 7 4 1 83
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 EOT
Visit
Niraparib
Placebo


Mean (+/- SE) Results
100
90
80
70
60
50
40
30
20
10
0
Niraparib 222 194 163 144 128 117 107 95 81 62 24 12 7 4 1 125
Placebo 124 112 97 87 68 51 48 37 31 23 7 4 1 87
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 EOT
Visit
Niraparib
Placebo


Mean (+/- SE) Results
30
28
26
24
22
20
18
16
14
12
10
8
6
4
2
0
Niraparib 226 199 167 147 130 119 109 96 82 64 25 13 8 5 1 129
Placebo 124 113 99 87 68 51 48 38 32 23 7 4 1 88
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 EOT
Visit
Niraparib
Placebo


Mean (+/- SE) Results
80
75
70
65
60
55
50
45
40
35
30
25
20
15
10
5
0
Niraparib 226 200 167 146 129 119 109 96 82 63 24 12 8 5 1 129
Placebo 124 112 99 87 68 50 47 38 32 23 7 4 1 88
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 EOT
Visit
Niraparib
Placebo


Mean (+/- SE) Results
100
90
80
70
60
50
40
30
20
10
0
Niraparib 226 200 167 147 129 119 109 96 82 63 24 12 8 5 1 129
Placebo 124 112 99 87 68 51 47 38 32 23 7 4 1 87
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 EOT
Visit
Niraparib
Placebo


Mean (+/- SE) Results
40
35
30
25
20
15
10
5
0
Niraparib 226 200 167 147 129 119 109 96 82 63 24 12 8 5 1 129
Placebo 124 112 99 87 68 51 47 38 32 23 7 4 1 87
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 EOT
Visit
Niraparib
Placebo

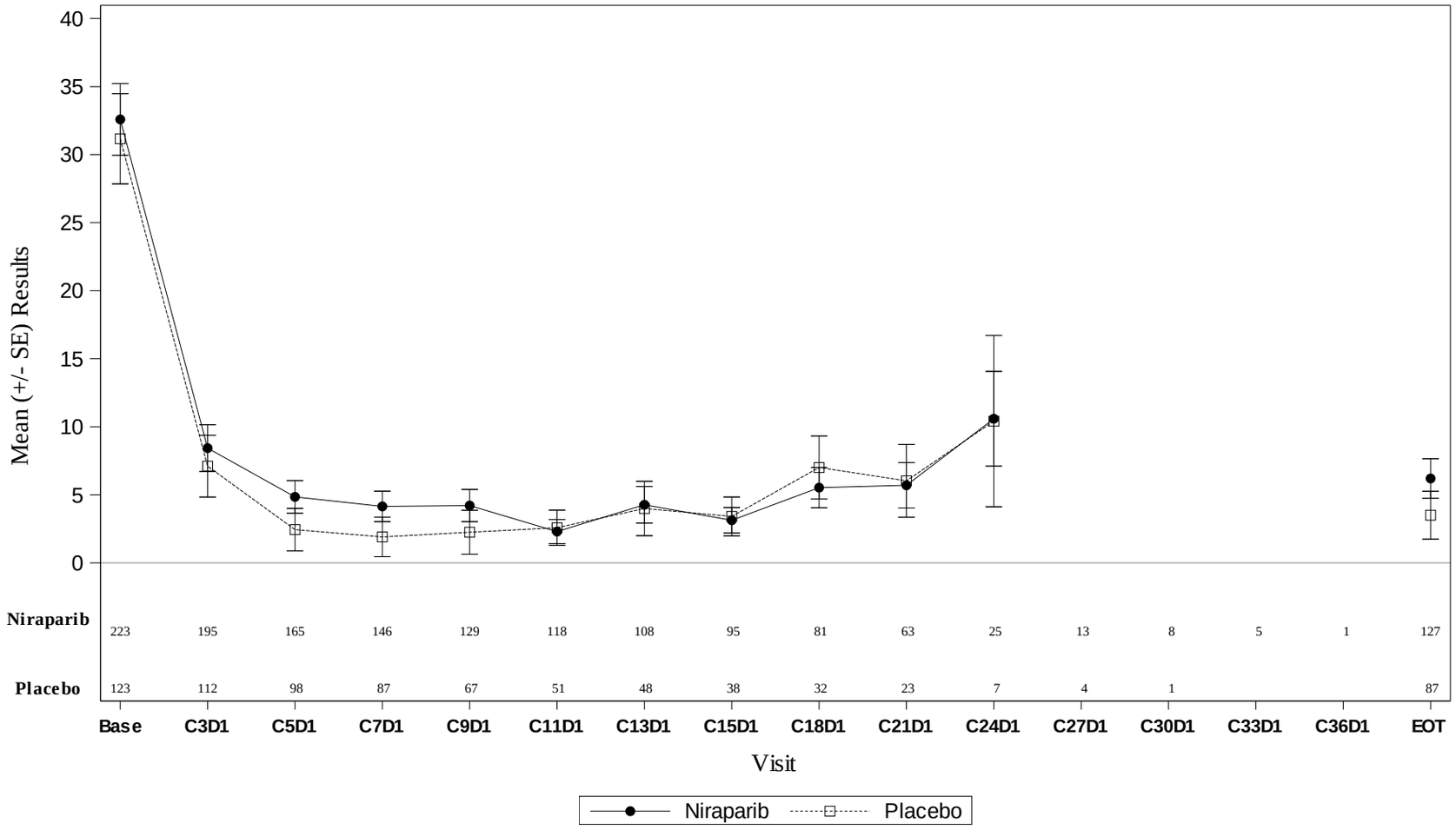
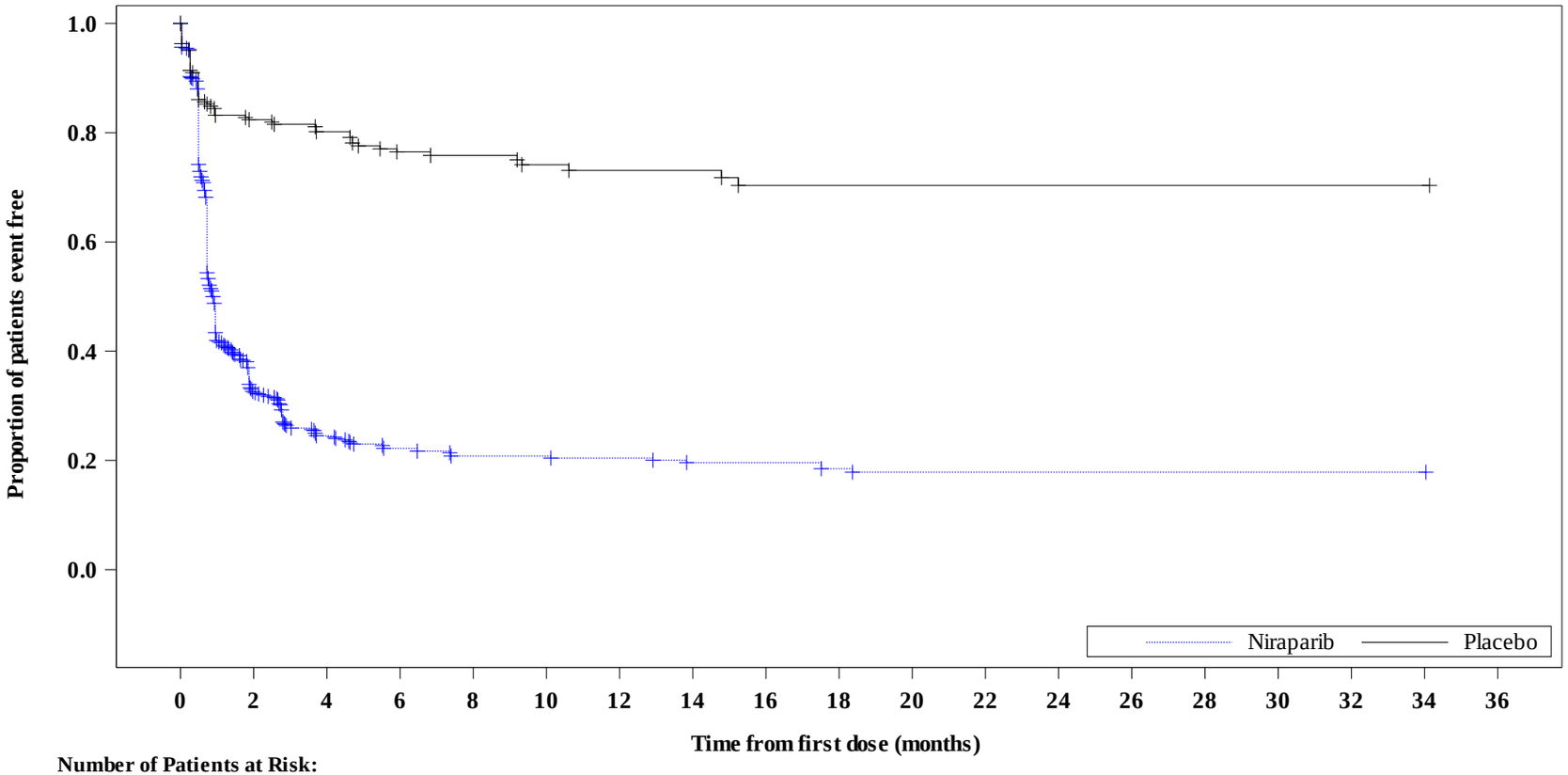

Mean (+/- SE) Results
40
35
30
25
20
15
10
5
0
Niraparib 223 195 165 146 129 118 108 95 81 63 25 13 8 5 1 127
Placebo 123 112 98 87 67 51 48 38 32 23 7 4 1 87
Base C3D1 C5D1 C7D1 C9D1 C11D1 C13D1 C15D1 C18D1 C21D1 C24D1 C27D1 C30D1 C33D1 C36D1 EOT
Visit
Niraparib
Placebo

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Blood and lymphatic system disorders

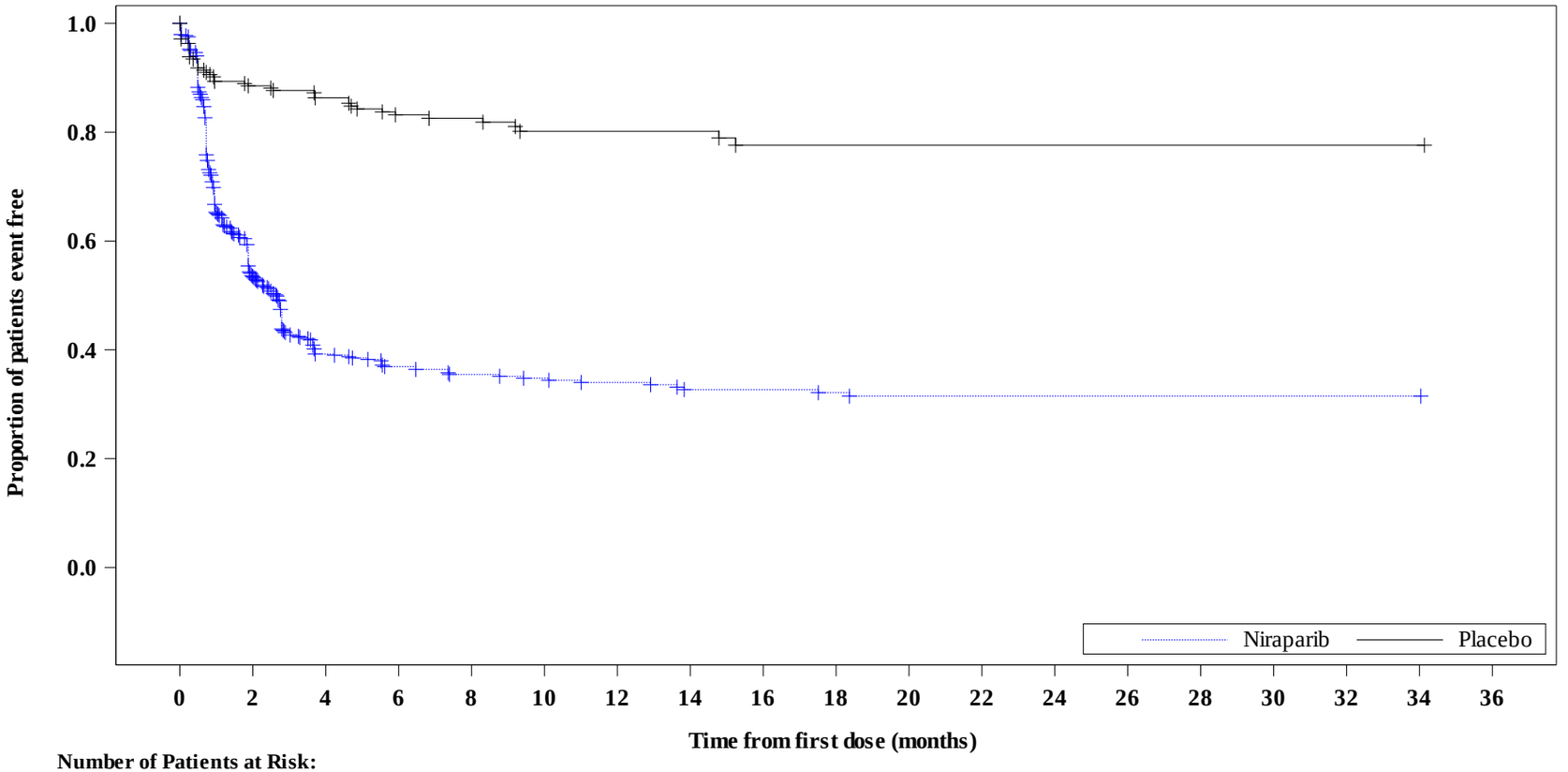



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 147 | 99 | 85 | 65 | 57 | 51 | 46 | 39 | 29 | 25 | 10 | 7 | 3 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 244 | 198 | 163 | 137 | 110 | 77 | 69 | 59 | 49 | 44 | 36 | 25 | 13 | 8 | 3 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia

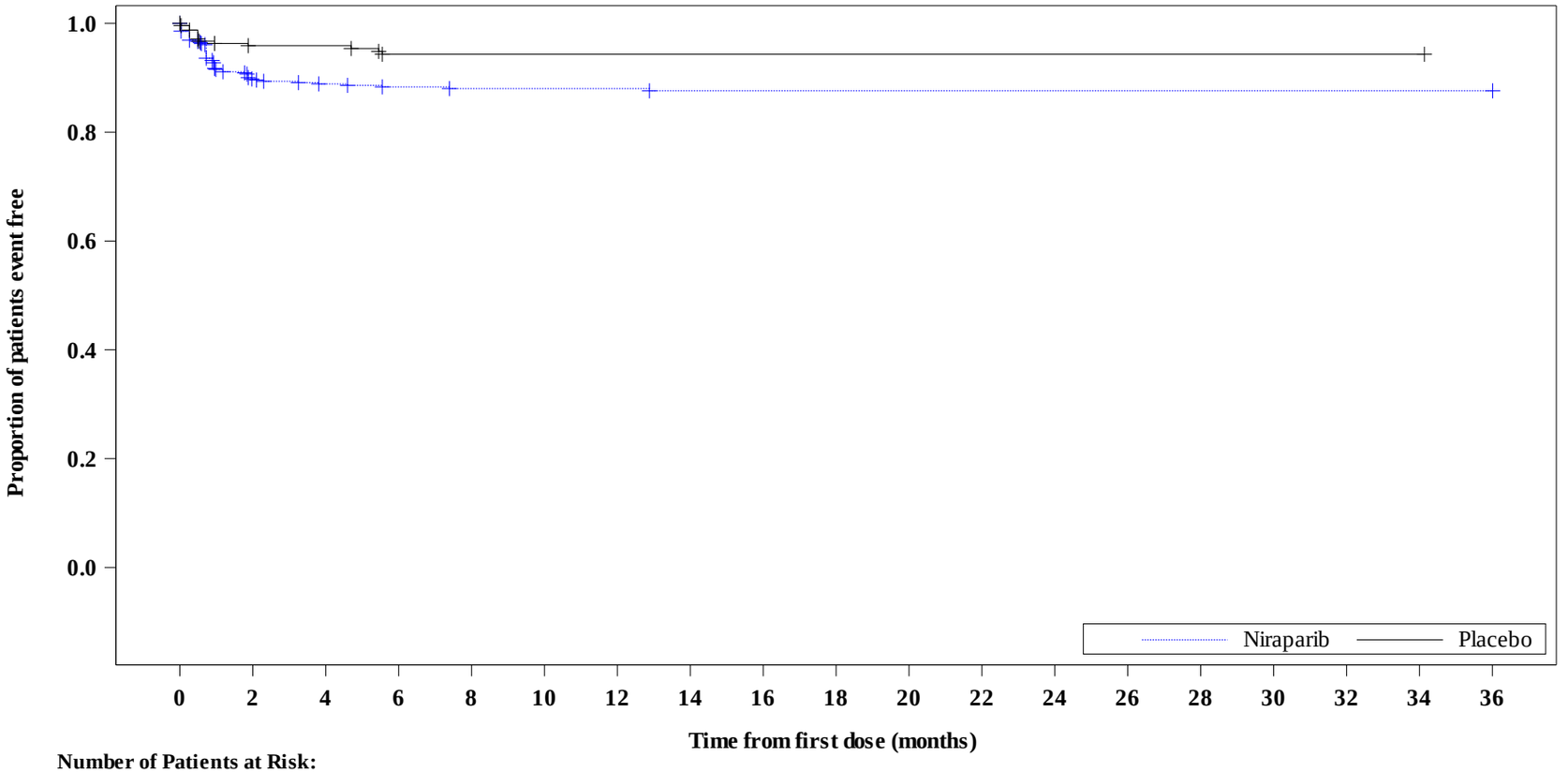



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 242 | 161 | 140 | 109 | 93 | 83 | 74 | 62 | 50 | 40 | 21 | 14 | 7 | 4 | 2 | 1 | 1 | 0 |
| Placebo | 244 | 213 | 177 | 151 | 122 | 86 | 79 | 69 | 58 | 52 | 44 | 29 | 16 | 10 | 5 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Blood and lymphatic system disorders, PT: Leukopenia

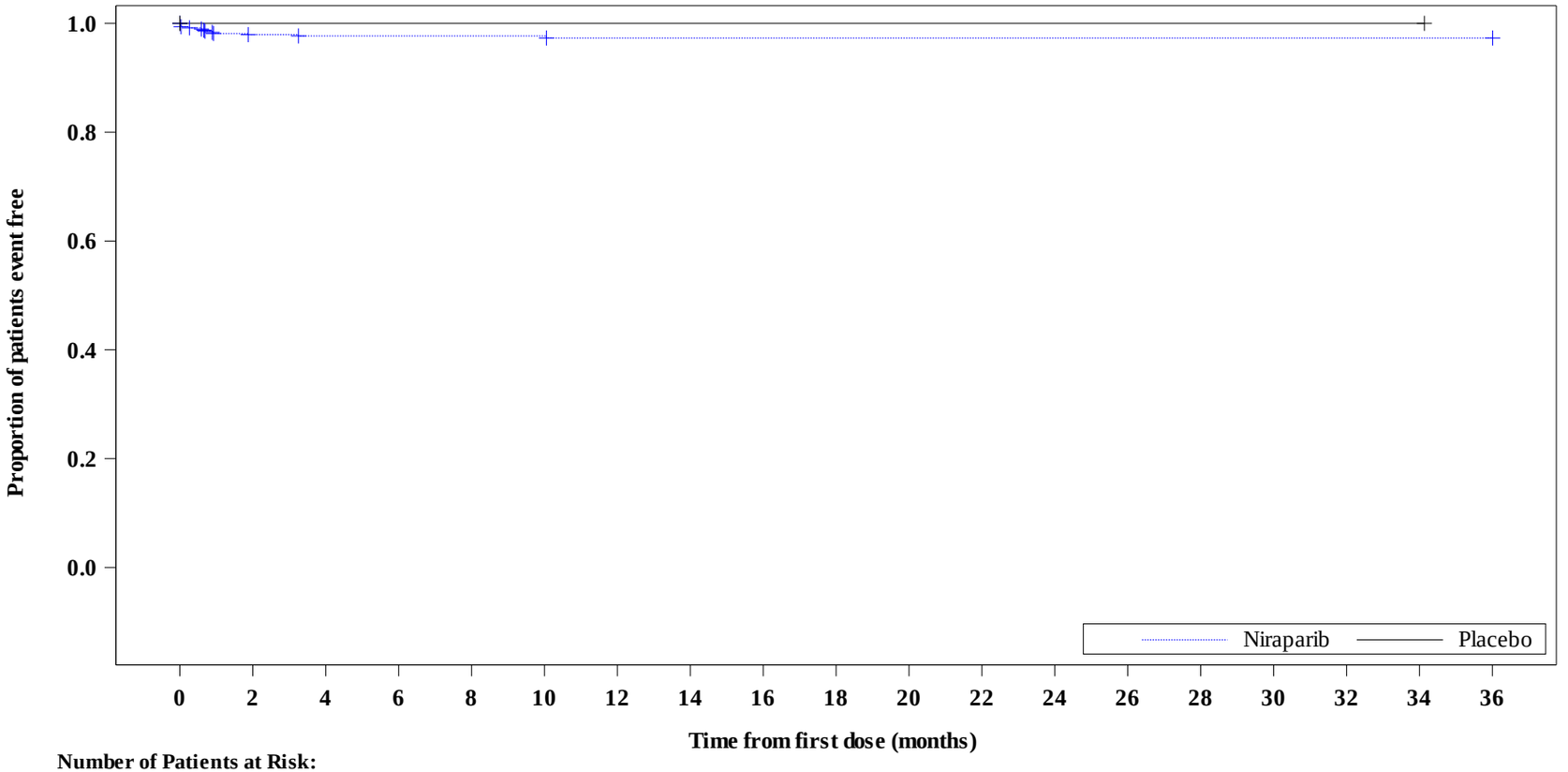



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 404 | 352 | 318 | 268 | 239 | 222 | 199 | 172 | 153 | 120 | 85 | 57 | 32 | 20 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 231 | 196 | 172 | 137 | 101 | 91 | 79 | 67 | 58 | 47 | 30 | 16 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Blood and lymphatic system disorders, PT: Lymphopenia

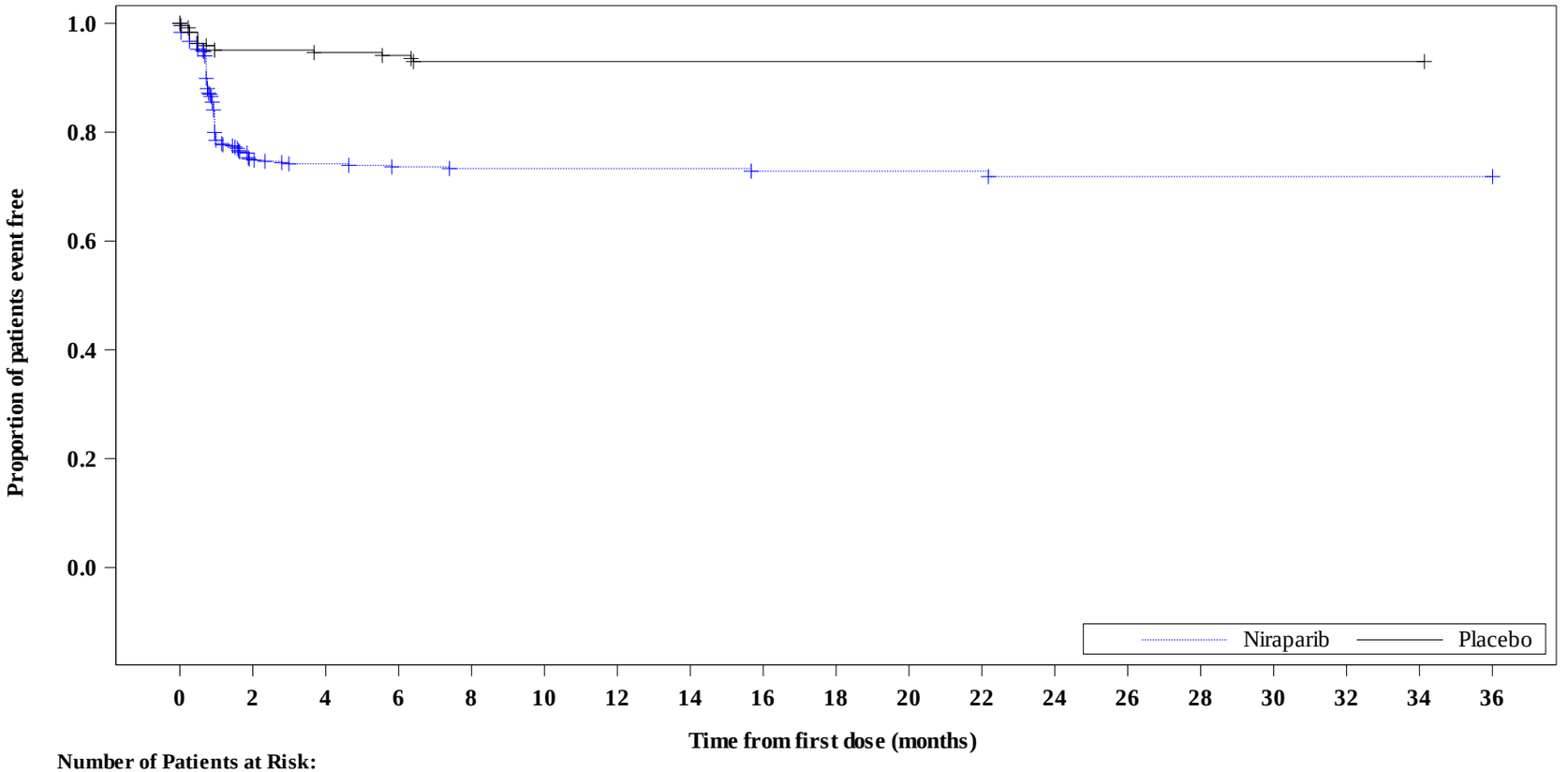



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 441 | 382 | 348 | 291 | 258 | 240 | 219 | 187 | 166 | 129 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Blood and lymphatic system disorders, PT: Neutropenia

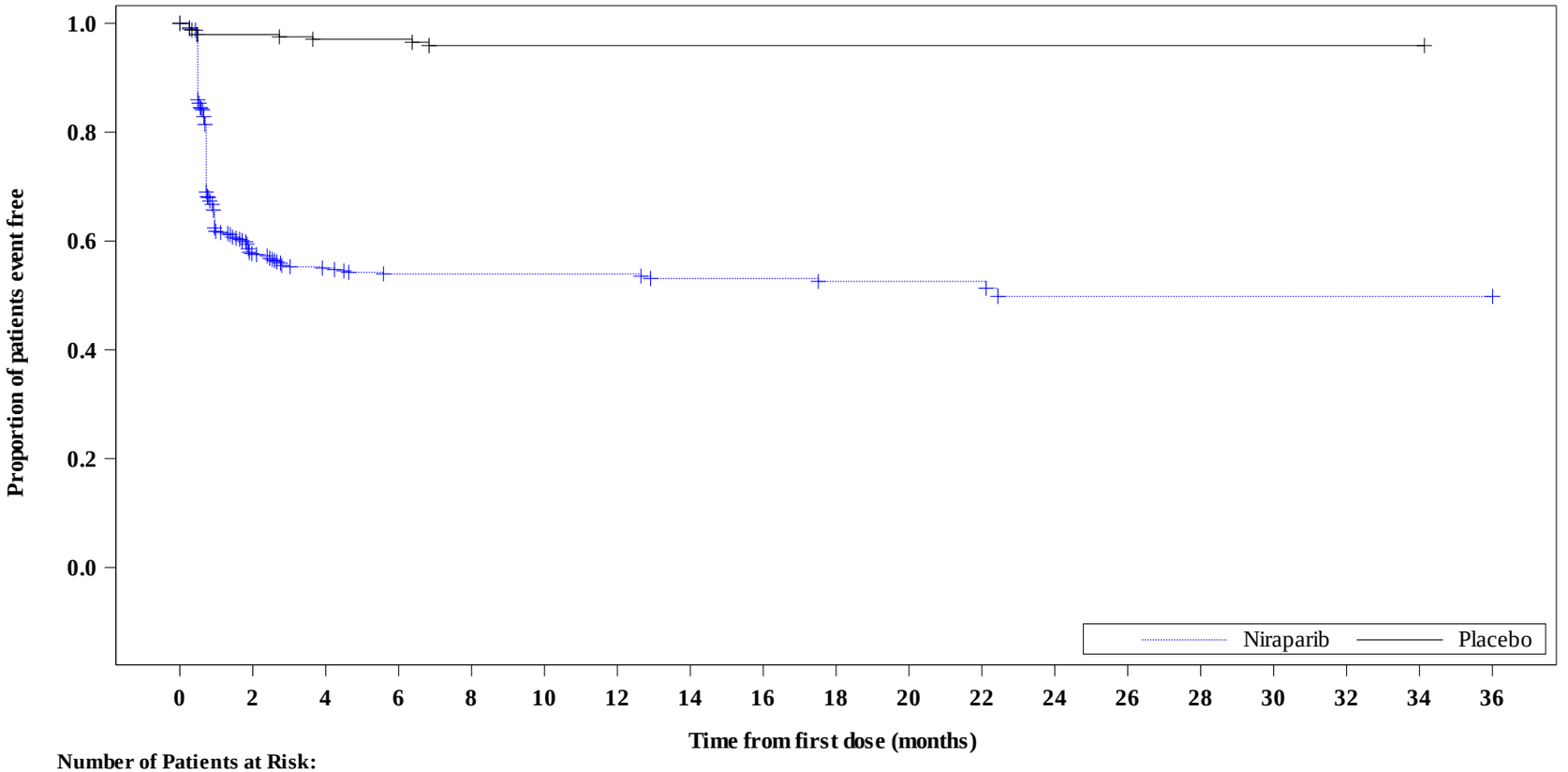



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 338 | 290 | 262 | 223 | 201 | 188 | 173 | 149 | 130 | 104 | 74 | 49 | 29 | 17 | 11 | 9 | 5 | 1 |
| Placebo | 244 | 229 | 193 | 172 | 137 | 101 | 90 | 79 | 69 | 60 | 49 | 29 | 15 | 10 | 5 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

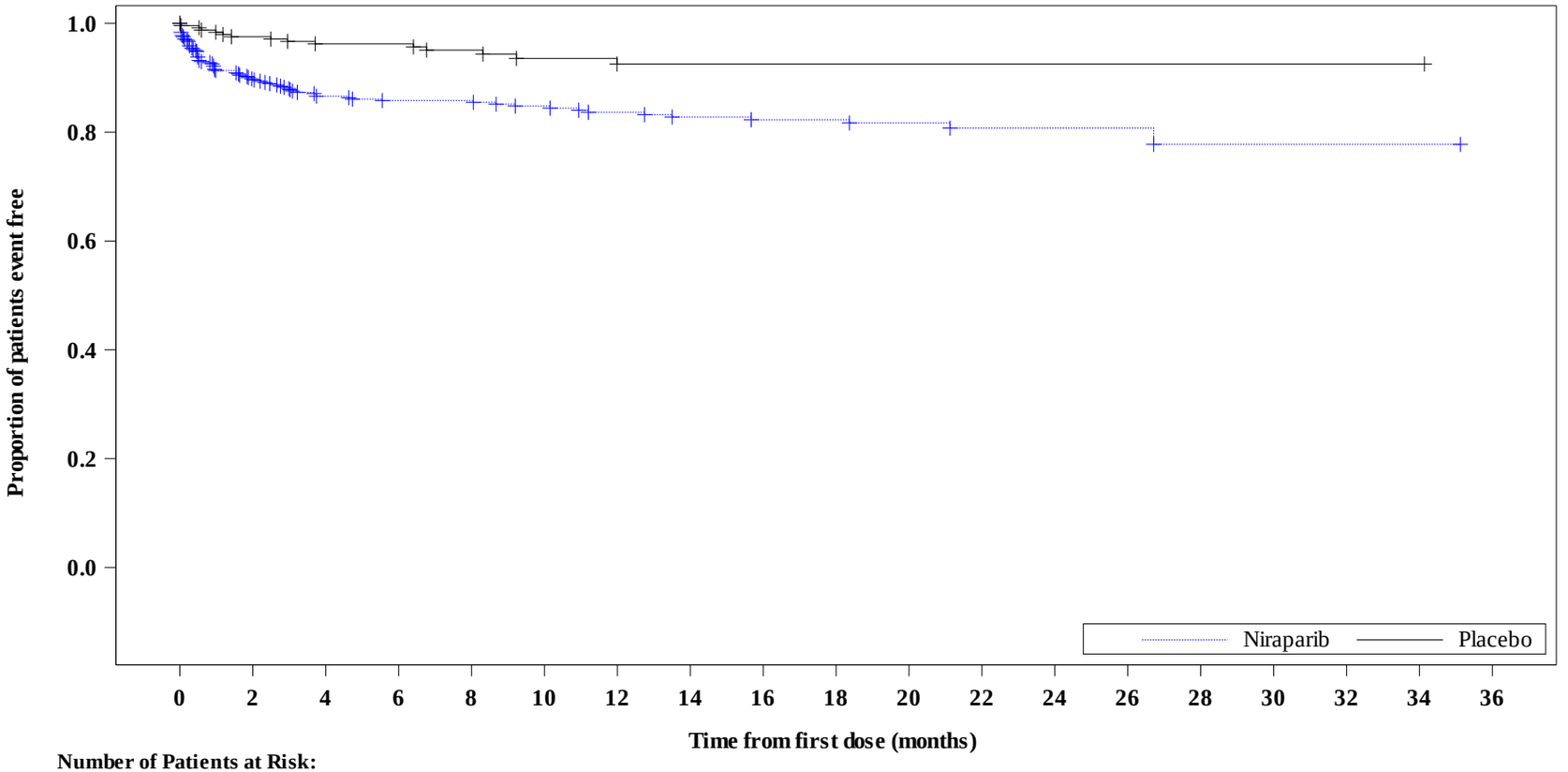



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 264 | 215 | 197 | 166 | 147 | 138 | 121 | 103 | 87 | 66 | 42 | 26 | 13 | 8 | 5 | 3 | 3 | 1 |
| Placebo | 244 | 236 | 200 | 179 | 142 | 105 | 94 | 82 | 71 | 63 | 53 | 32 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Cardiac disorders

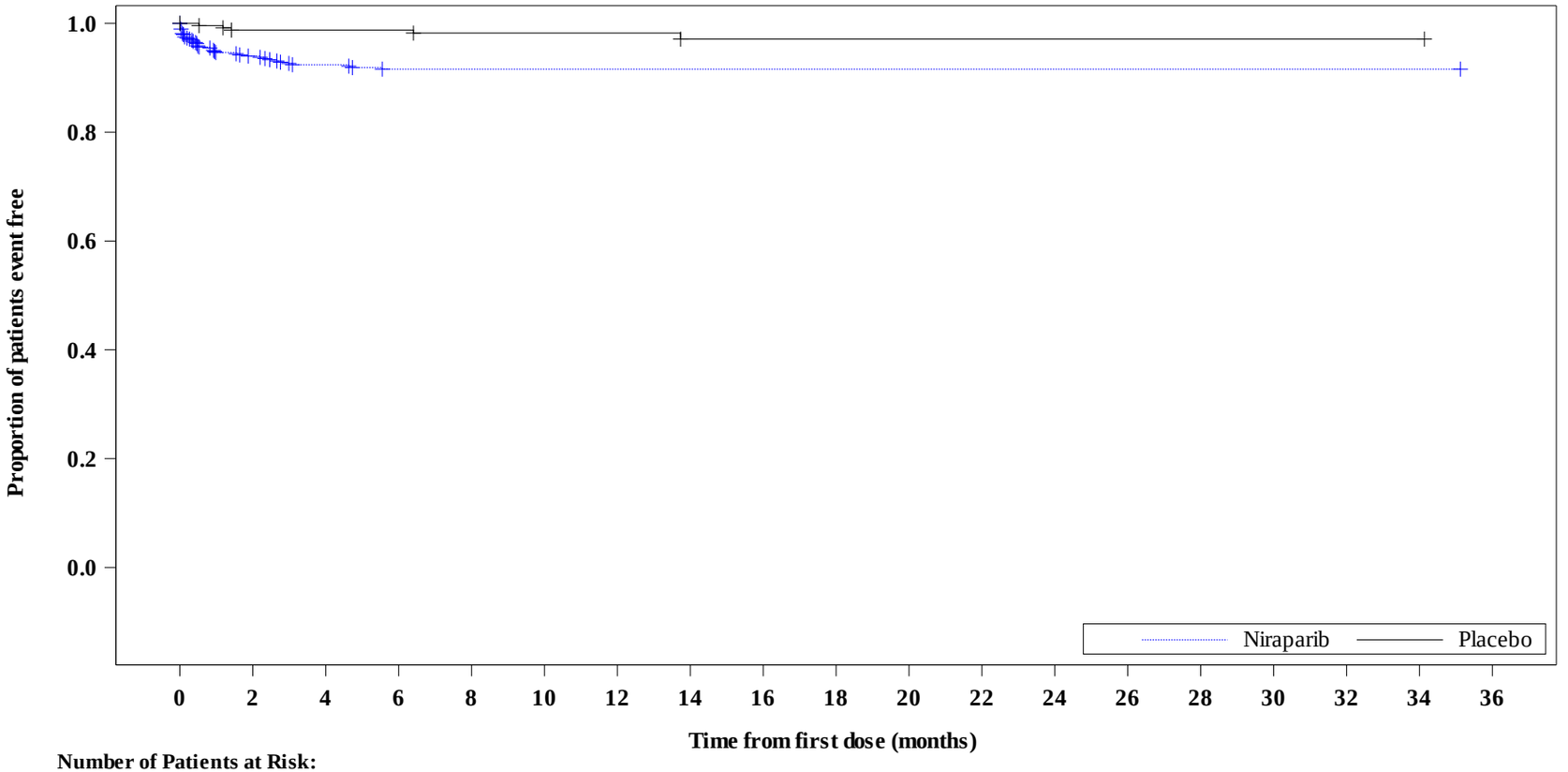



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 406 | 342 | 313 | 260 | 229 | 211 | 187 | 161 | 140 | 102 | 73 | 49 | 28 | 17 | 10 | 8 | 4 | 0 |
| Placebo | 244 | 235 | 199 | 178 | 139 | 102 | 90 | 78 | 67 | 59 | 49 | 31 | 16 | 11 | 6 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Cardiac disorders, PT: Palpitations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 425 | 363 | 330 | 275 | 245 | 229 | 207 | 176 | 154 | 117 | 84 | 57 | 33 | 21 | 12 | 8 | 4 | 0 |
| Placebo | 244 | 238 | 203 | 181 | 143 | 106 | 95 | 82 | 71 | 63 | 52 | 32 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

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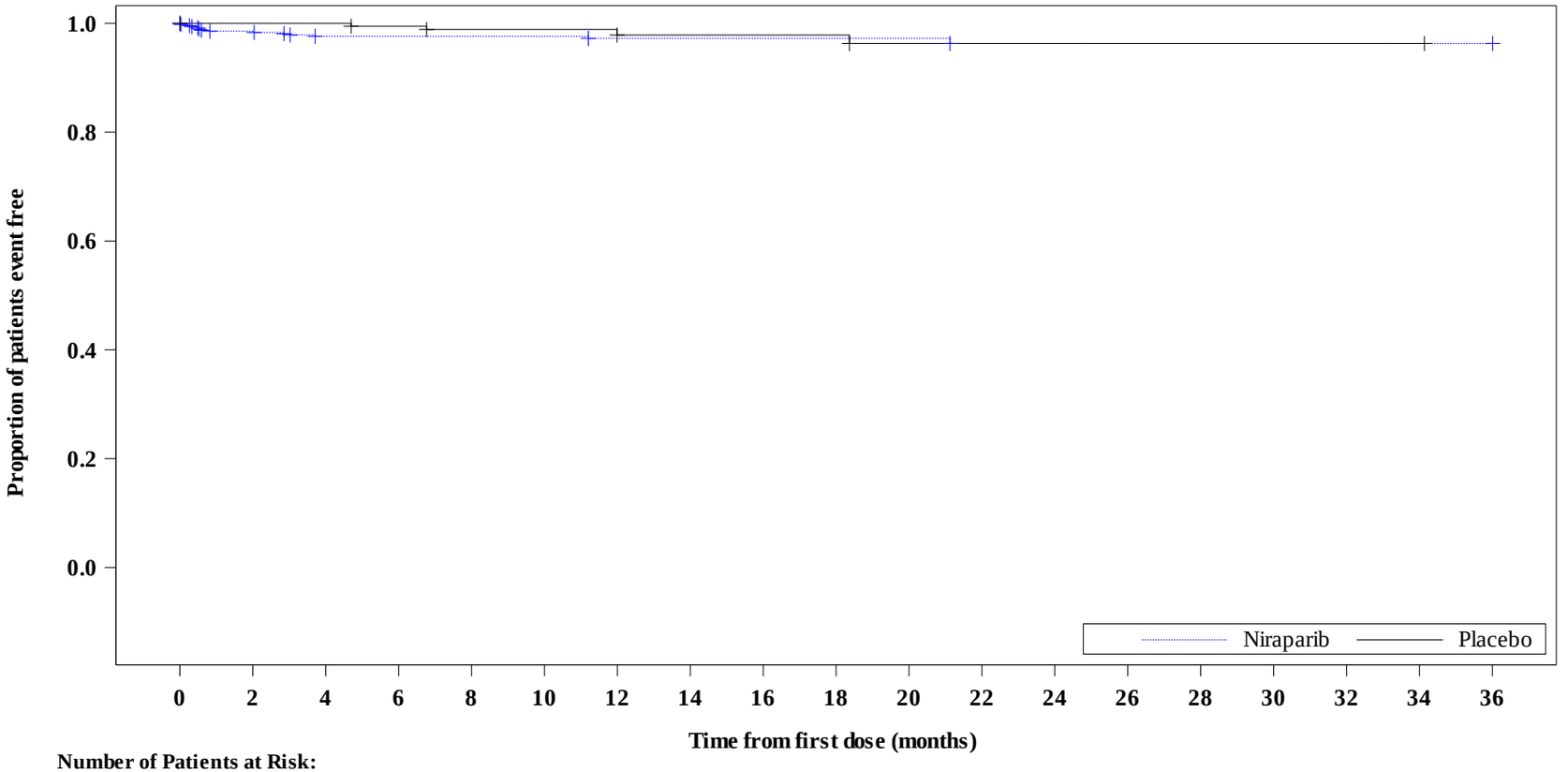
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Cardiac disorders, PT: Sinus tachycardia

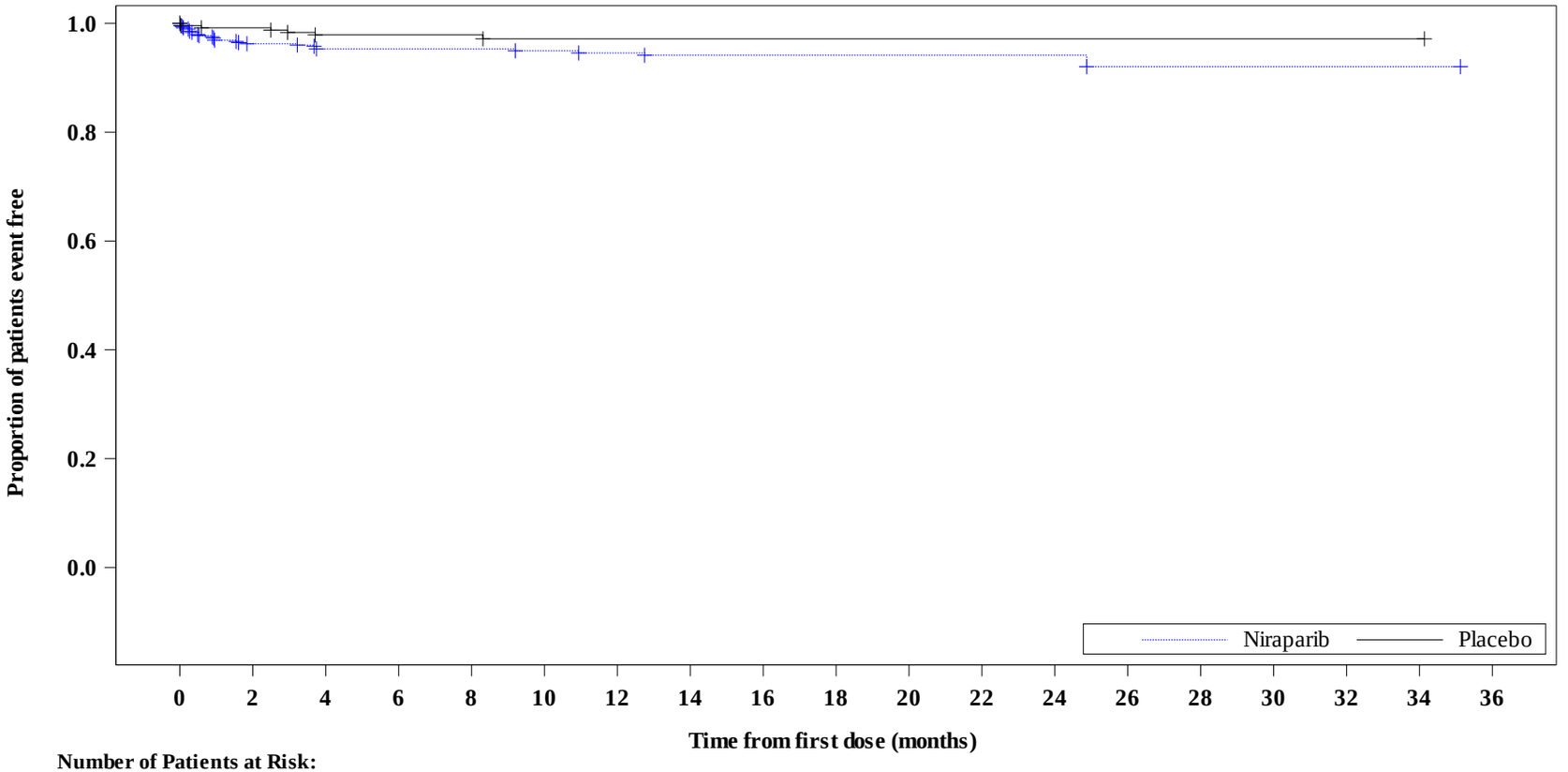



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 443 | 382 | 349 | 292 | 260 | 242 | 219 | 187 | 164 | 126 | 88 | 59 | 32 | 20 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 182 | 144 | 108 | 96 | 84 | 72 | 63 | 52 | 32 | 17 | 11 | 6 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Cardiac disorders, PT: Tachycardia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 433 | 373 | 341 | 286 | 254 | 237 | 213 | 183 | 160 | 121 | 85 | 57 | 31 | 18 | 10 | 8 | 4 | 0 |
| Placebo | 244 | 239 | 202 | 181 | 144 | 107 | 96 | 84 | 72 | 63 | 52 | 32 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

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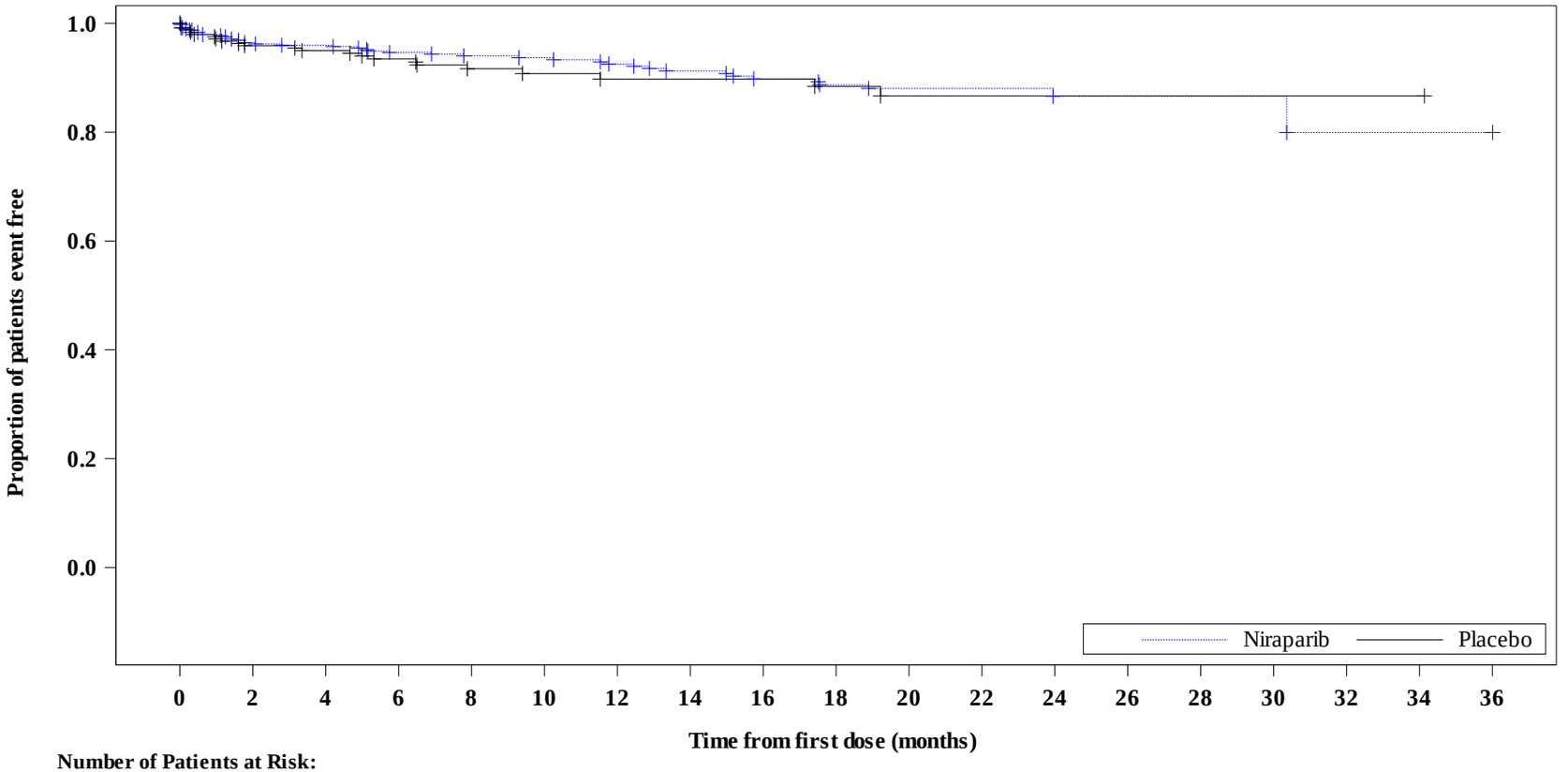
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Ear and labyrinth disorders

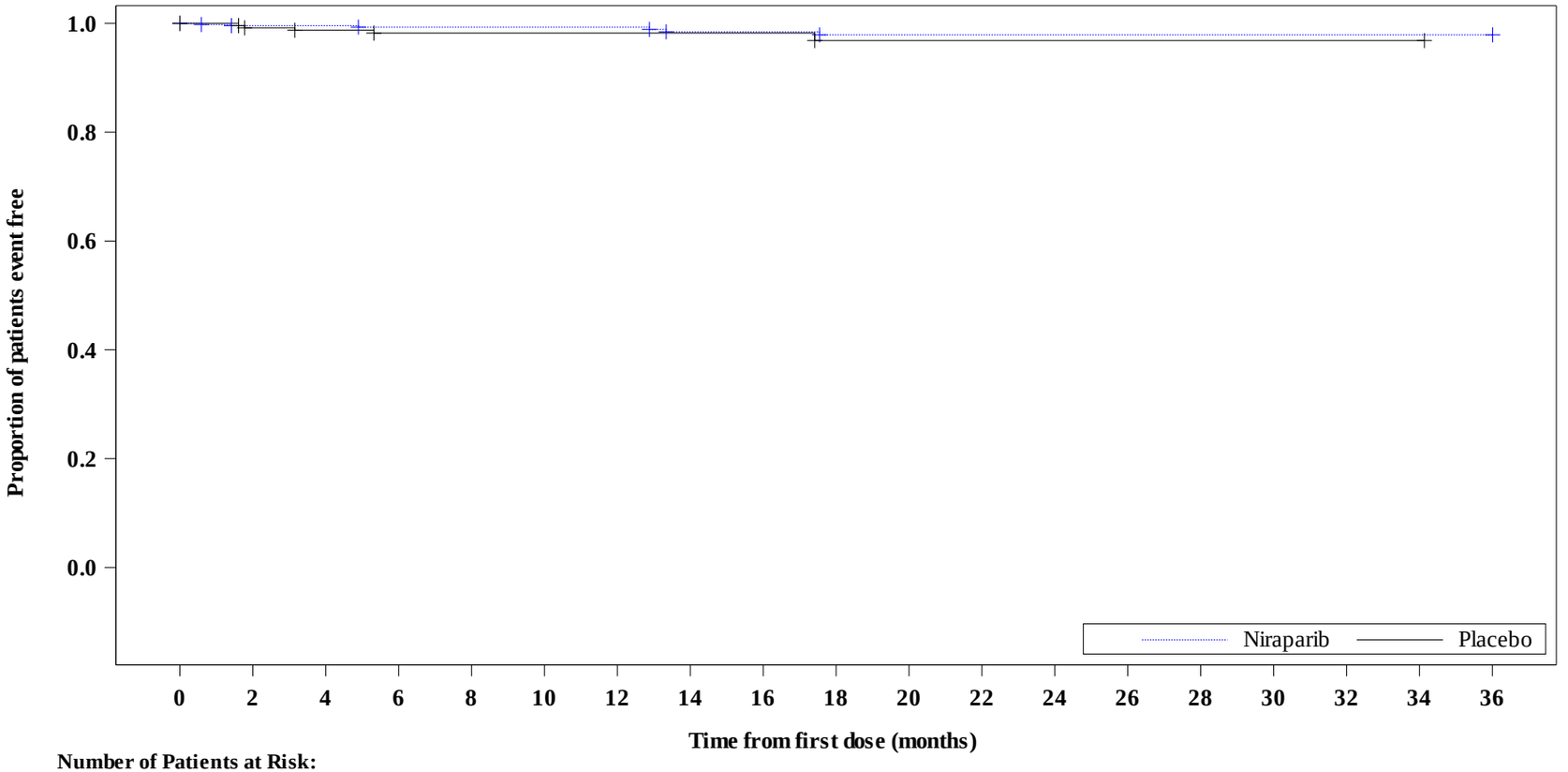



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 435 | 378 | 342 | 287 | 255 | 235 | 209 | 175 | 152 | 114 | 81 | 56 | 33 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 231 | 196 | 172 | 133 | 98 | 86 | 76 | 67 | 57 | 48 | 31 | 17 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Ear and labyrinth disorders, PT: Ear pain




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 390 | 356 | 298 | 265 | 248 | 223 | 189 | 165 | 127 | 90 | 61 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 180 | 144 | 107 | 96 | 84 | 73 | 63 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

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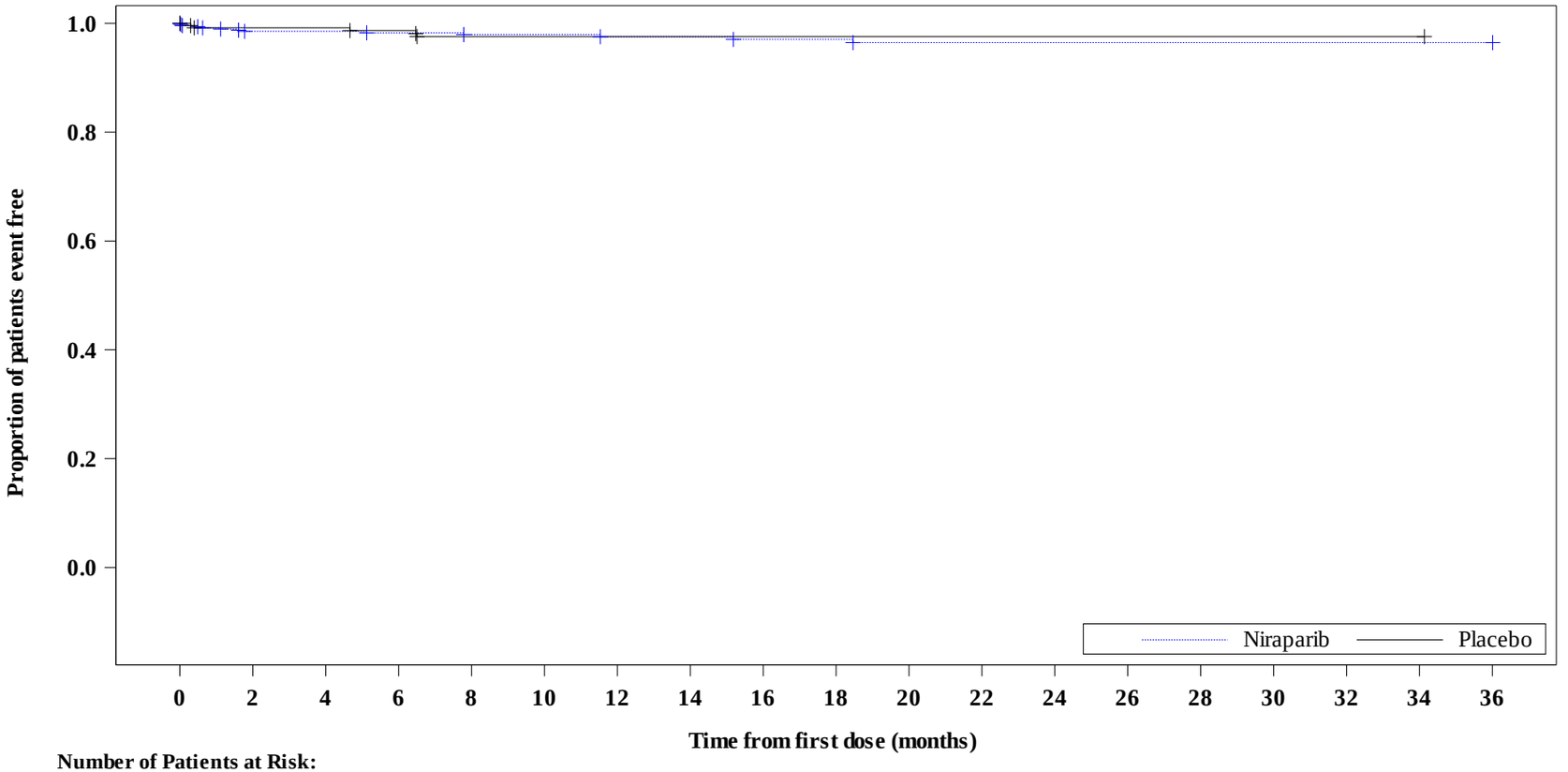
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Ear and labyrinth disorders, PT: Tinnitus

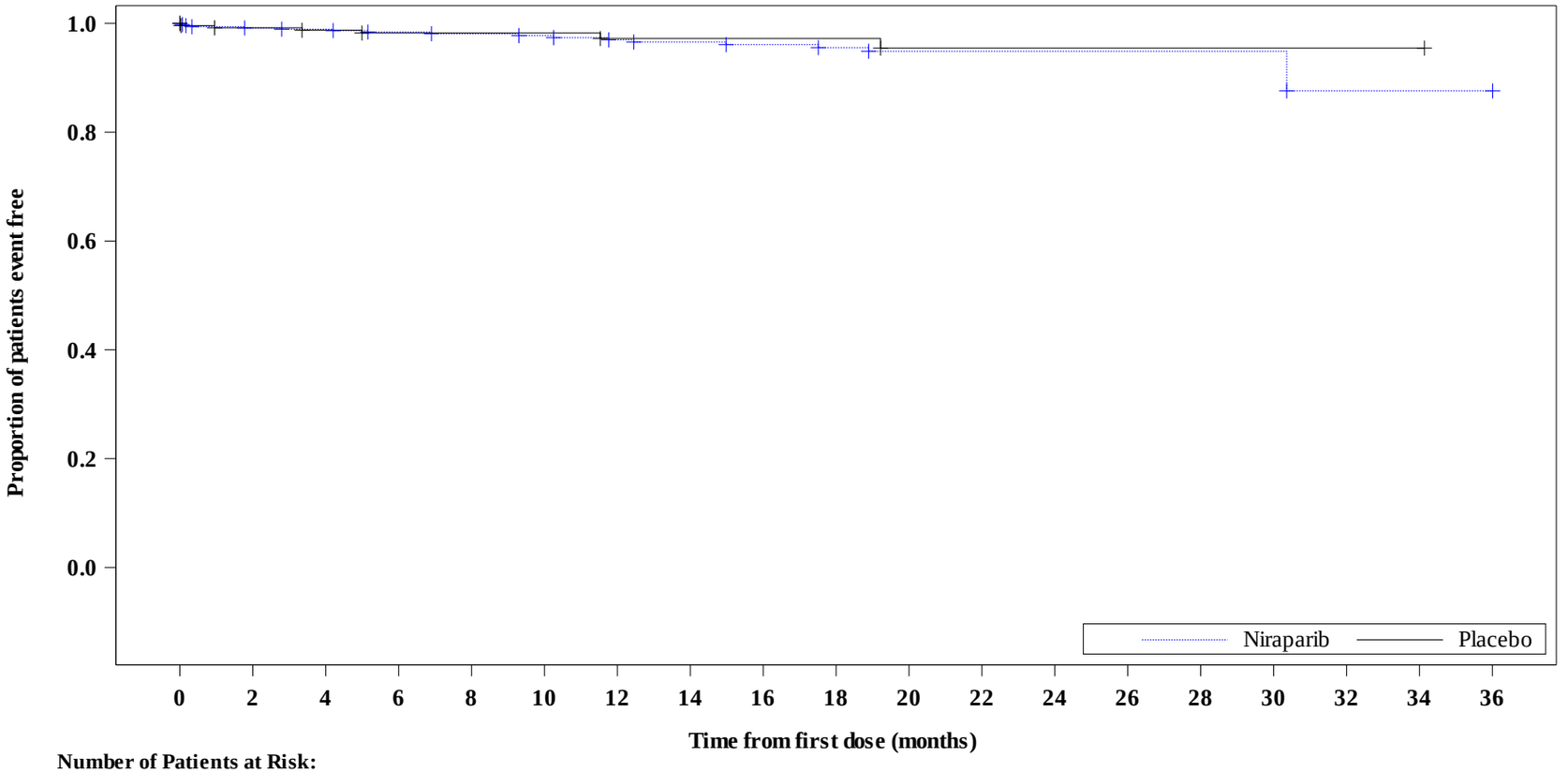



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 444 | 387 | 353 | 294 | 263 | 245 | 222 | 188 | 165 | 126 | 89 | 62 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 205 | 182 | 143 | 106 | 95 | 83 | 71 | 62 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Ear and labyrinth disorders, PT: Vertigo

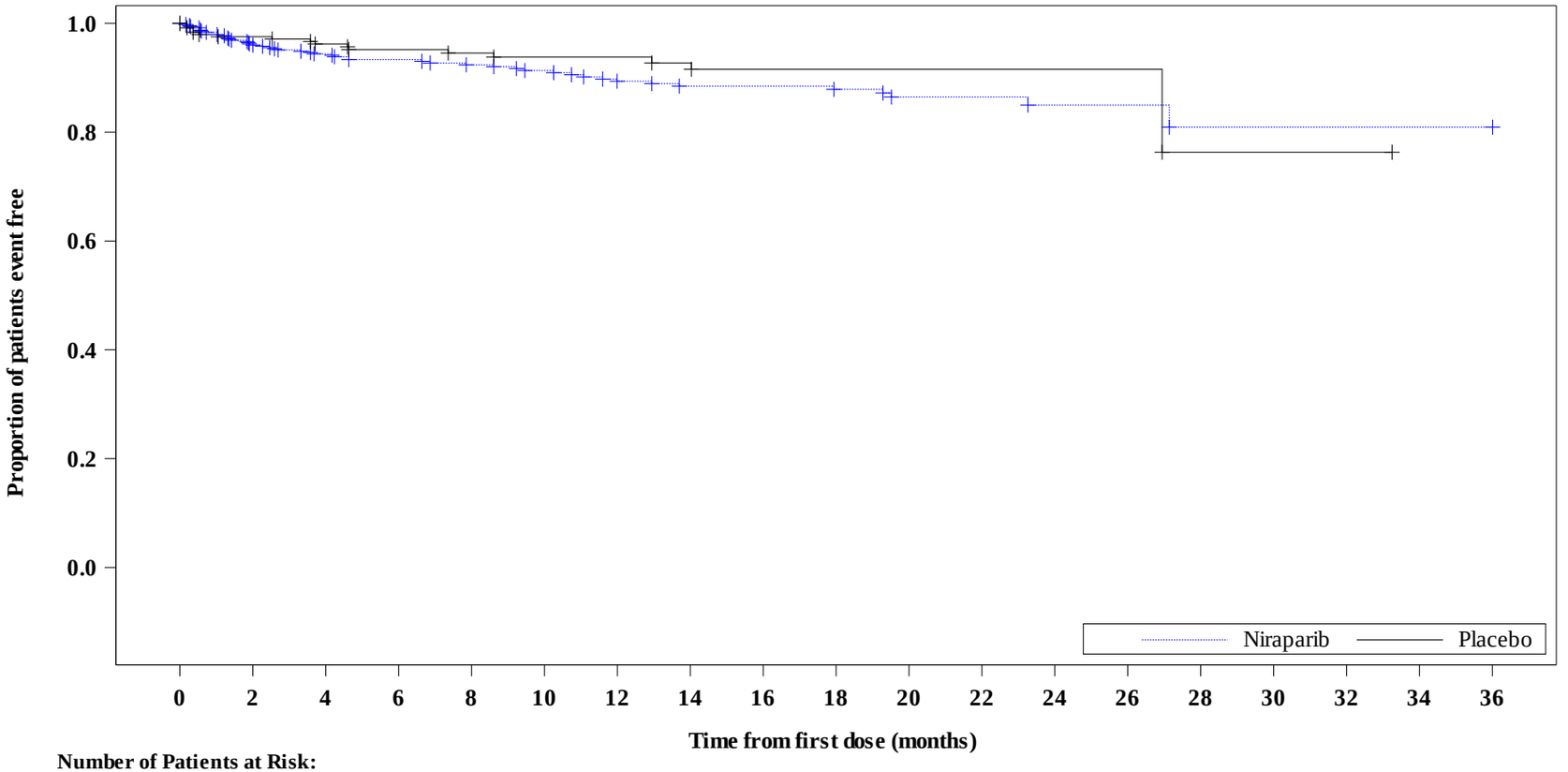



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 388 | 353 | 297 | 263 | 244 | 220 | 187 | 163 | 123 | 88 | 61 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 202 | 180 | 143 | 107 | 95 | 83 | 72 | 63 | 51 | 31 | 17 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Eye disorders

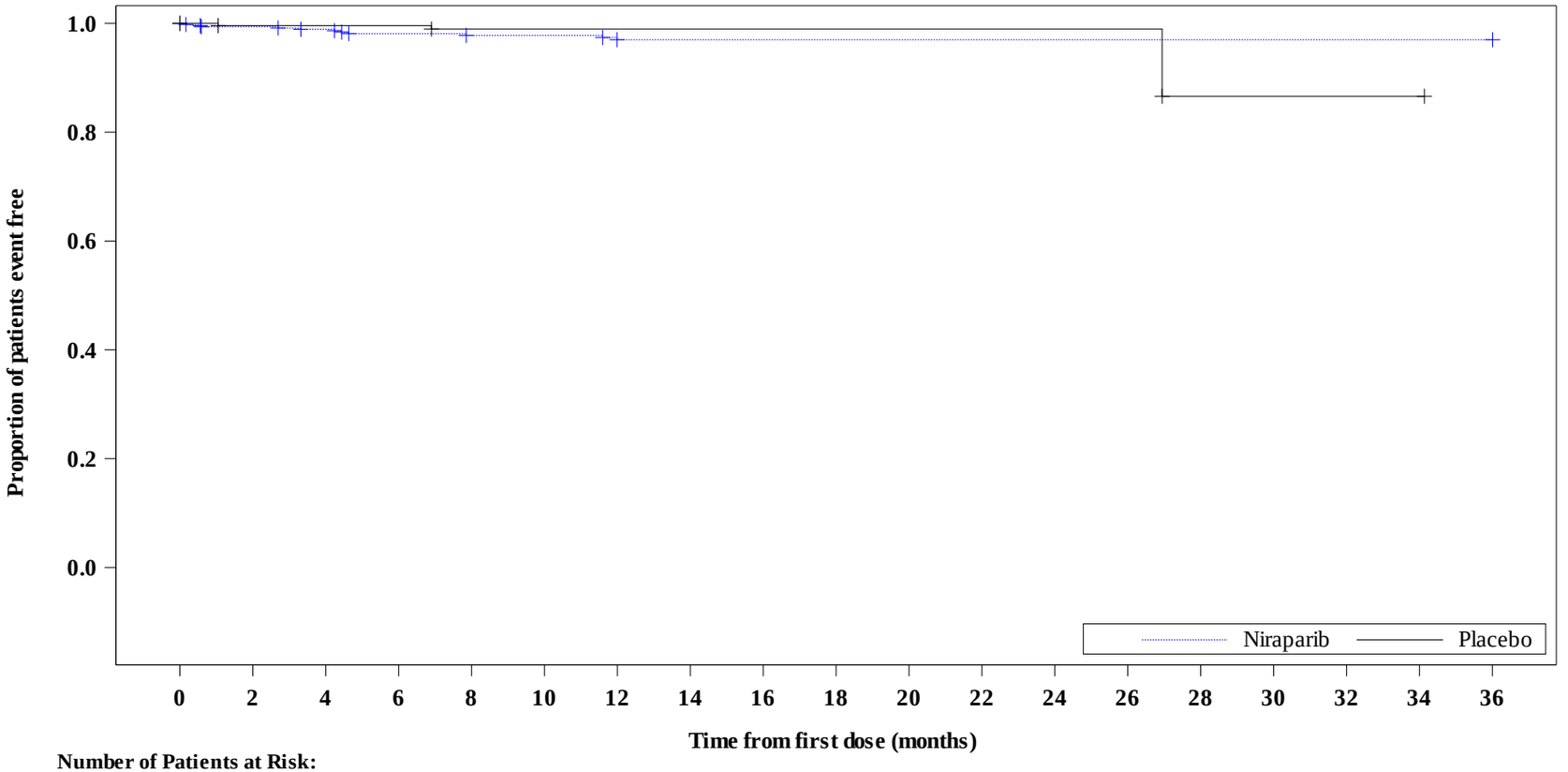



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 433 | 369 | 332 | 274 | 241 | 220 | 197 | 170 | 148 | 110 | 76 | 49 | 29 | 18 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 235 | 197 | 175 | 137 | 104 | 93 | 80 | 67 | 58 | 49 | 30 | 16 | 10 | 4 | 2 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Eye disorders, PT: Dry eye

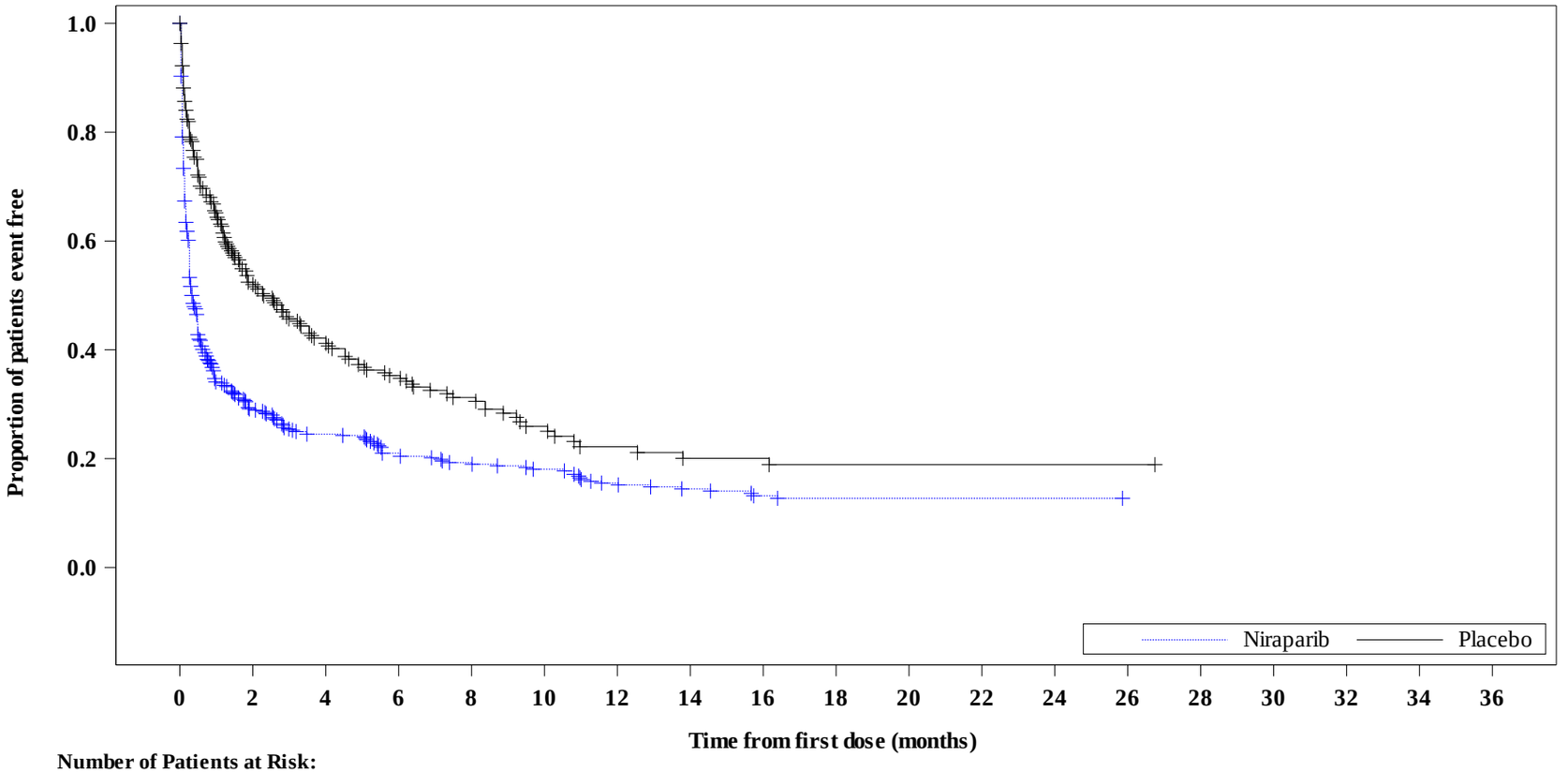



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 387 | 350 | 292 | 260 | 241 | 218 | 187 | 164 | 127 | 89 | 61 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 182 | 144 | 107 | 96 | 84 | 72 | 63 | 54 | 33 | 18 | 12 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 128 | 96 | 77 | 63 | 58 | 46 | 39 | 29 | 24 | 11 | 4 | 1 | 0 |
| Placebo | 244 | 126 | 88 | 68 | 46 | 29 | 22 | 18 | 17 | 14 | 12 | 6 | 3 | 2 | 0 |

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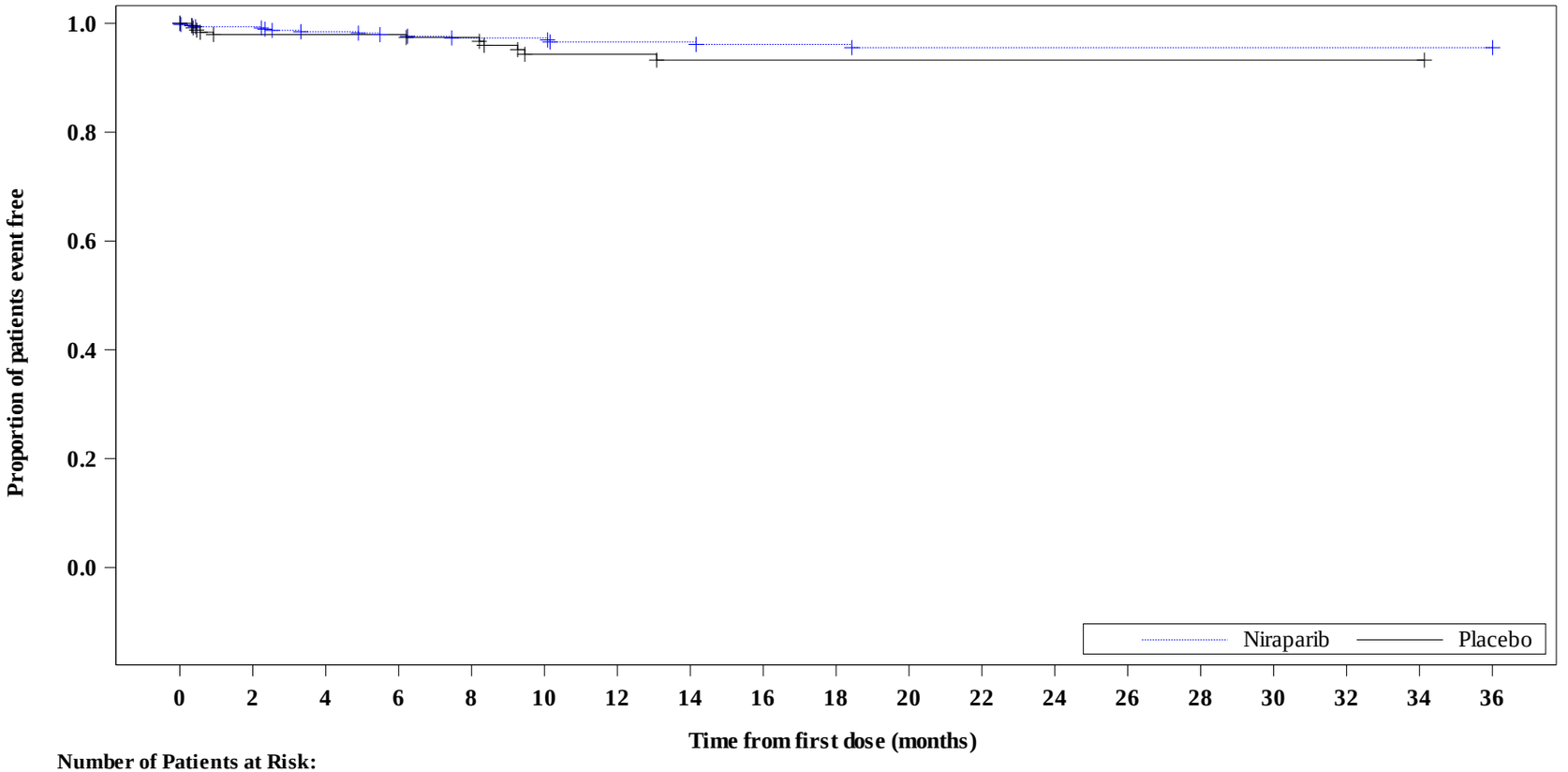
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal discomfort




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 385 | 350 | 292 | 261 | 244 | 221 | 187 | 165 | 125 | 89 | 61 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 236 | 201 | 179 | 143 | 105 | 95 | 82 | 72 | 63 | 52 | 31 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

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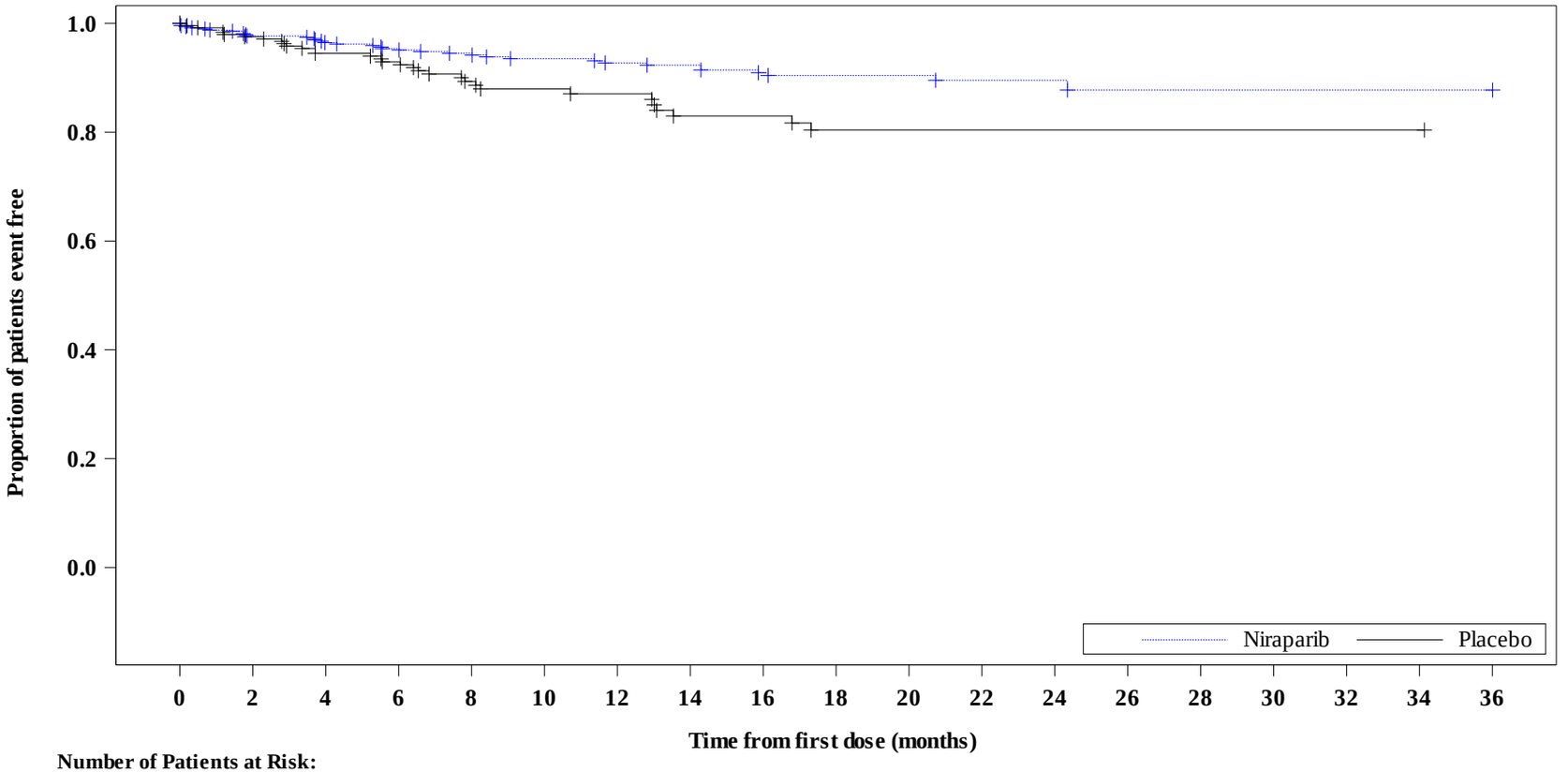
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal distension

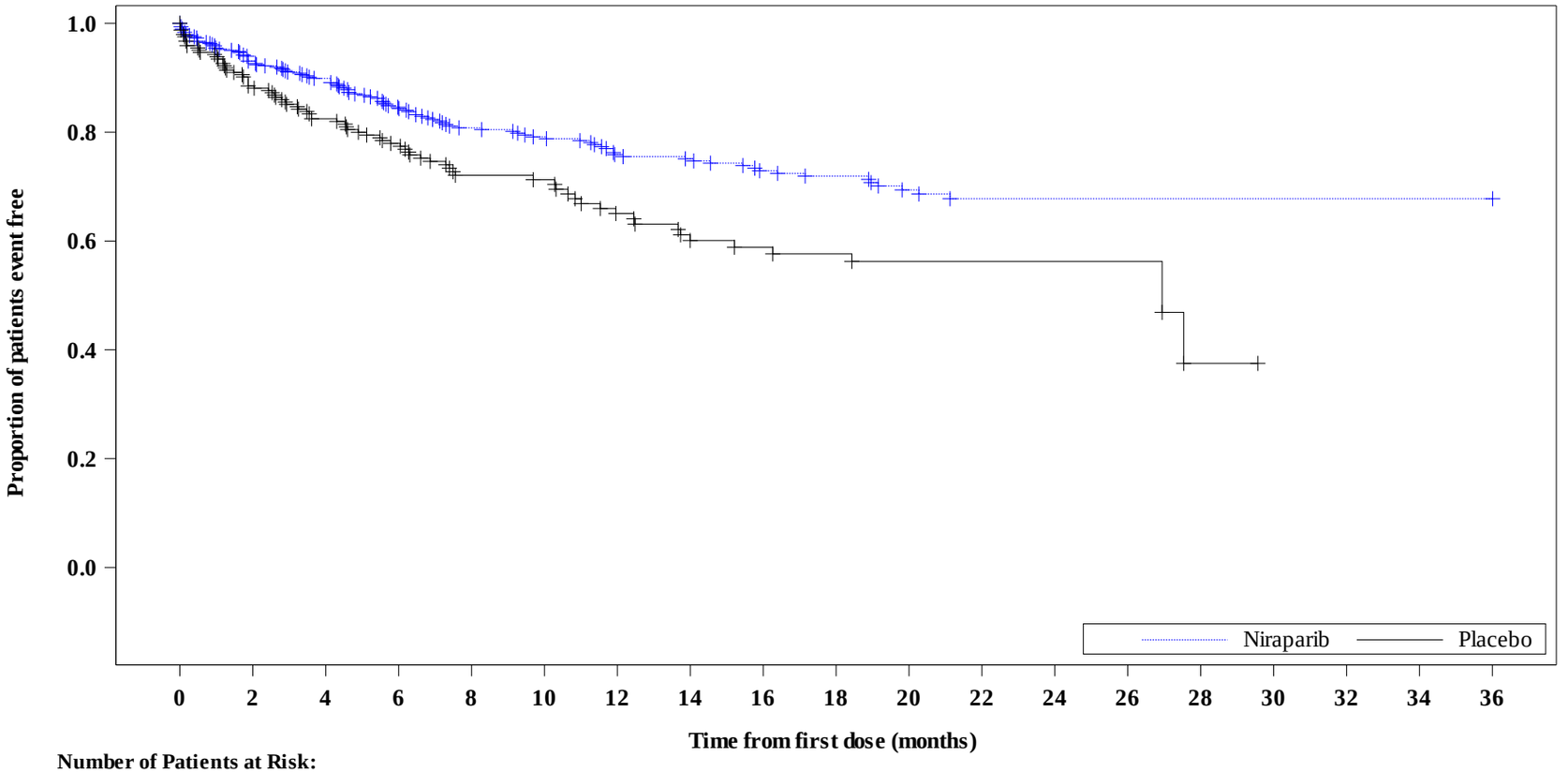



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 440 | 379 | 346 | 288 | 253 | 235 | 215 | 180 | 159 | 120 | 85 | 59 | 32 | 21 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 235 | 197 | 175 | 132 | 103 | 91 | 75 | 65 | 54 | 43 | 24 | 13 | 8 | 4 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain

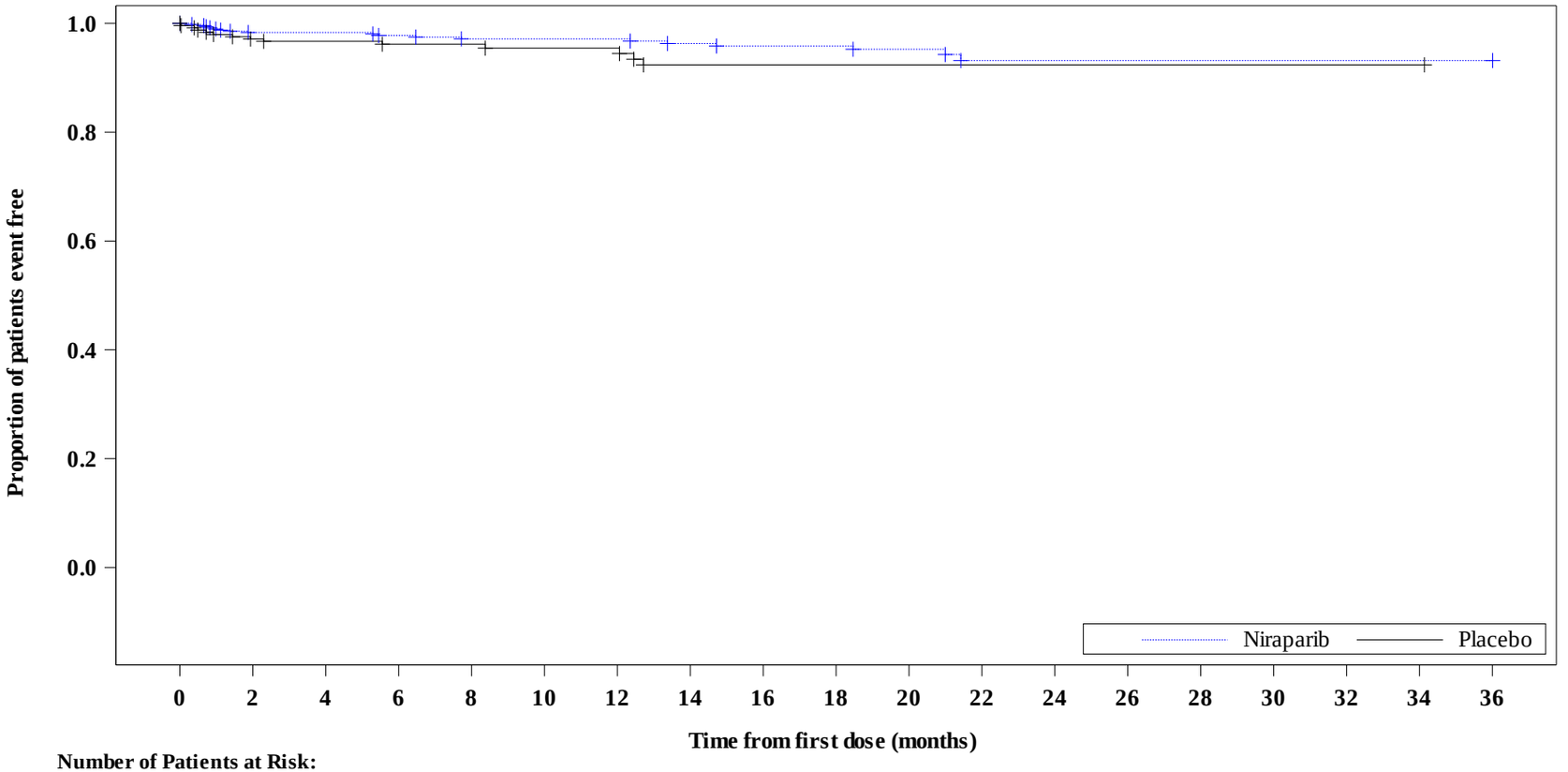



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 419 | 358 | 311 | 252 | 228 | 204 | 189 | 155 | 133 | 94 | 68 | 42 | 22 | 16 | 10 | 7 | 4 | 1 |
| Placebo | 244 | 213 | 171 | 148 | 110 | 84 | 71 | 57 | 48 | 42 | 34 | 23 | 14 | 9 | 4 | 0 | | | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain lower




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 383 | 347 | 289 | 257 | 242 | 217 | 183 | 161 | 121 | 81 | 57 | 32 | 20 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 234 | 200 | 179 | 142 | 107 | 97 | 83 | 72 | 64 | 53 | 32 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

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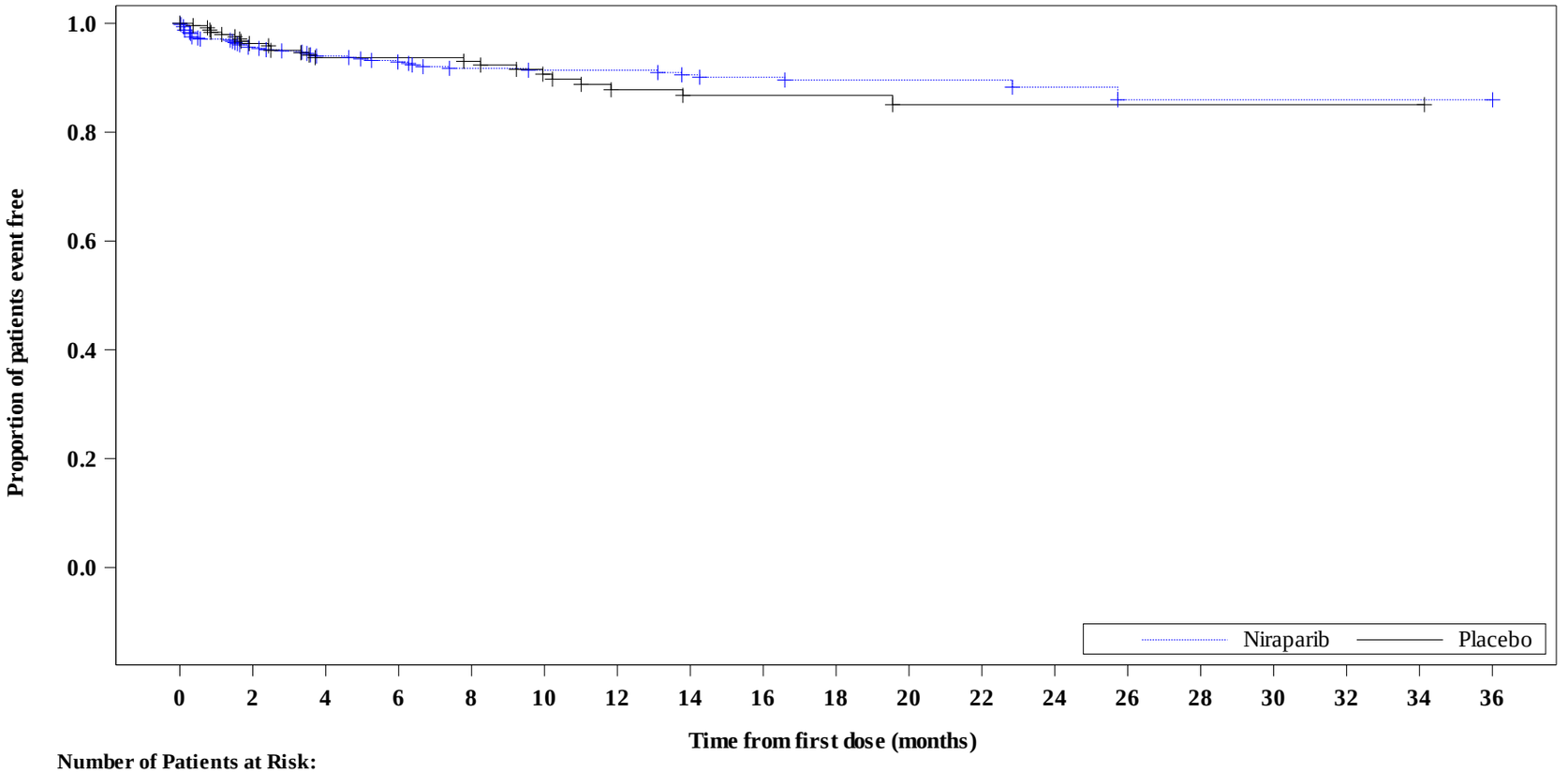
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain upper

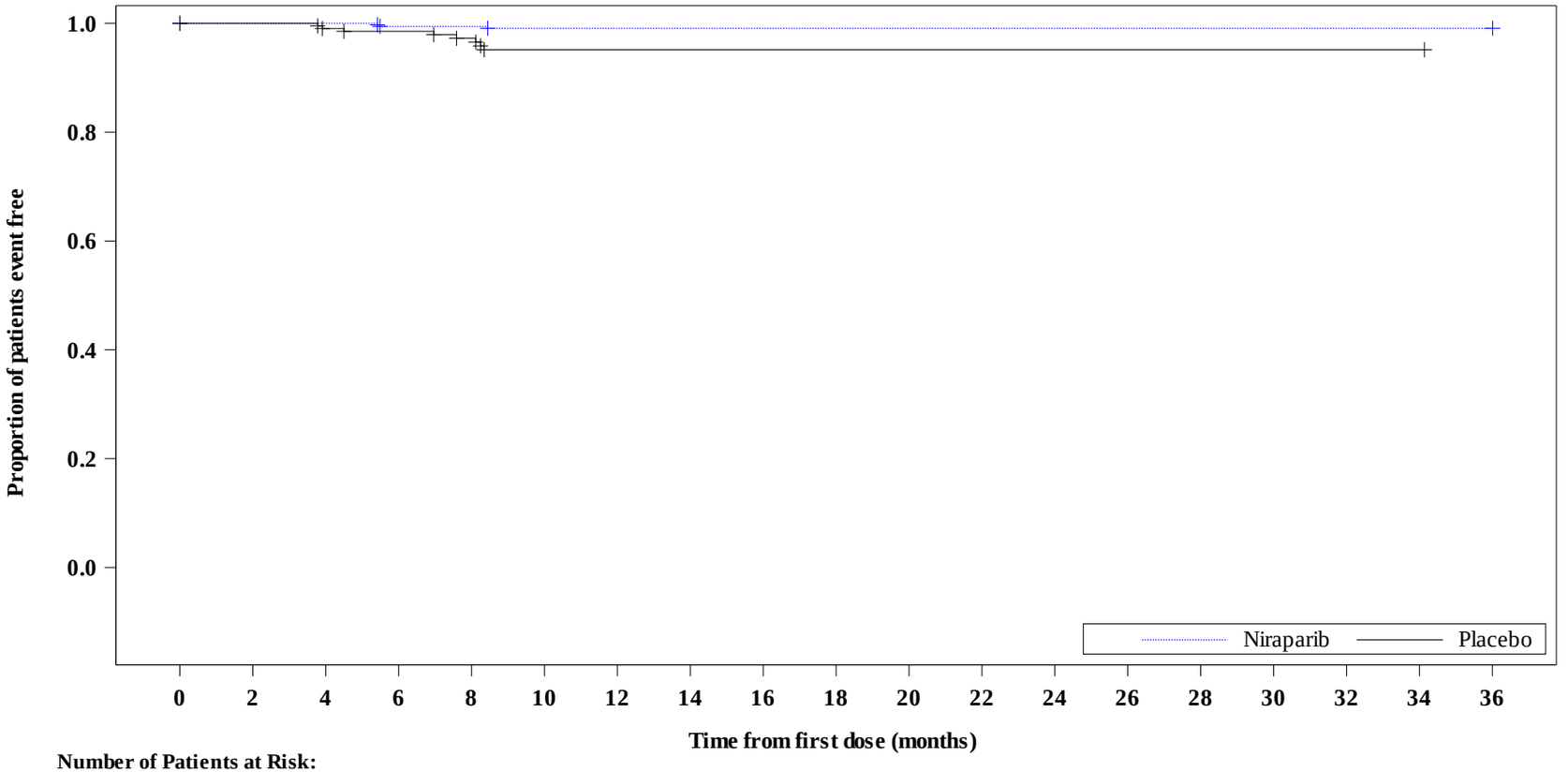



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 431 | 371 | 337 | 279 | 252 | 237 | 213 | 178 | 155 | 117 | 81 | 53 | 28 | 16 | 9 | 6 | 3 | 1 |
| Placebo | 244 | 232 | 193 | 172 | 138 | 102 | 89 | 78 | 68 | 60 | 50 | 30 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Ascites

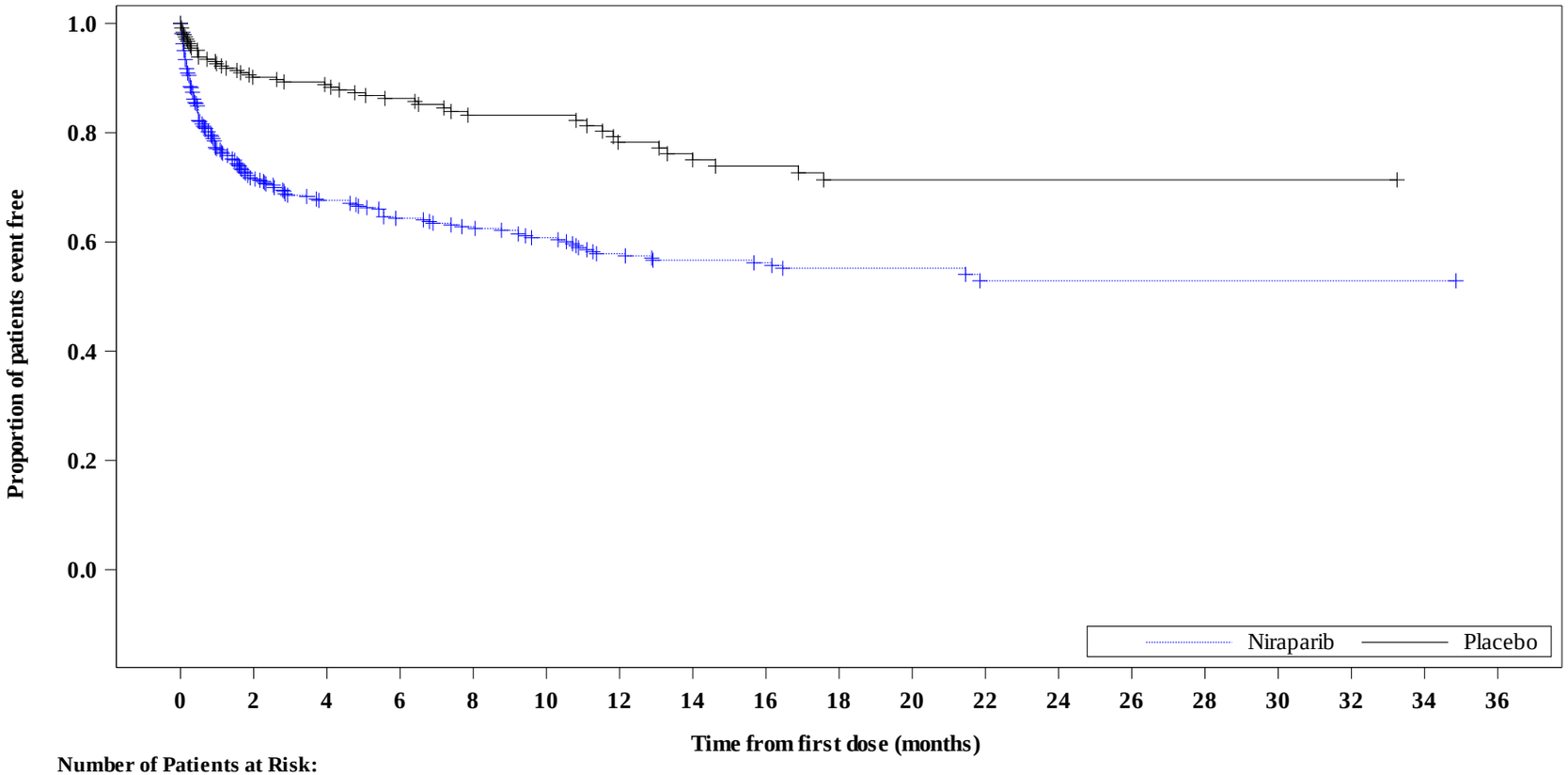



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 355 | 298 | 265 | 248 | 225 | 191 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 203 | 183 | 144 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Constipation




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 323 | 265 | 231 | 193 | 169 | 153 | 140 | 115 | 100 | 71 | 45 | 32 | 15 | 6 | 4 | 3 | 2 | 0 |
| Placebo | 244 | 218 | 182 | 161 | 122 | 91 | 77 | 67 | 60 | 51 | 42 | 26 | 14 | 10 | 5 | 2 | 1 | 0 | |

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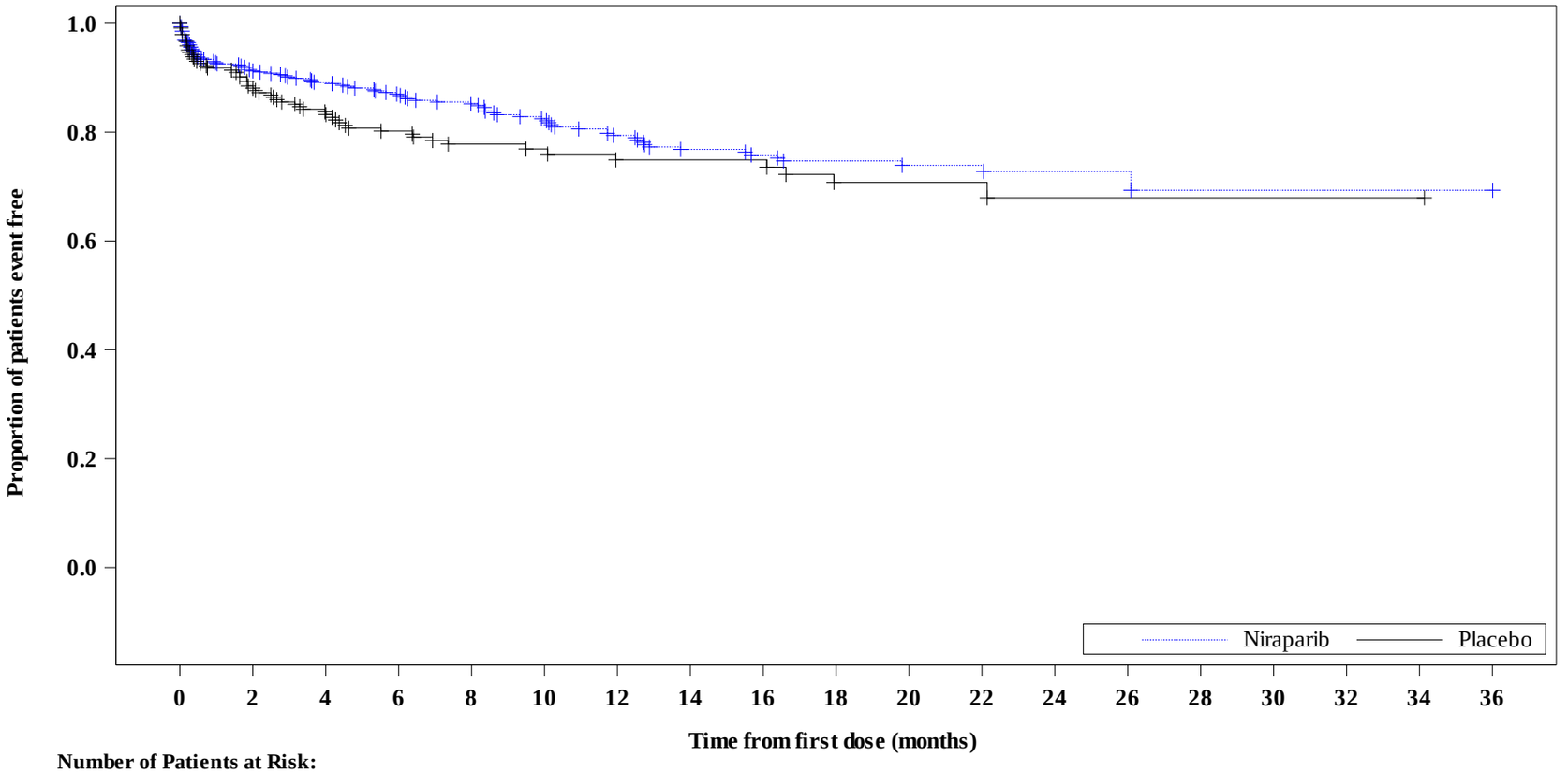
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Diarrhoea

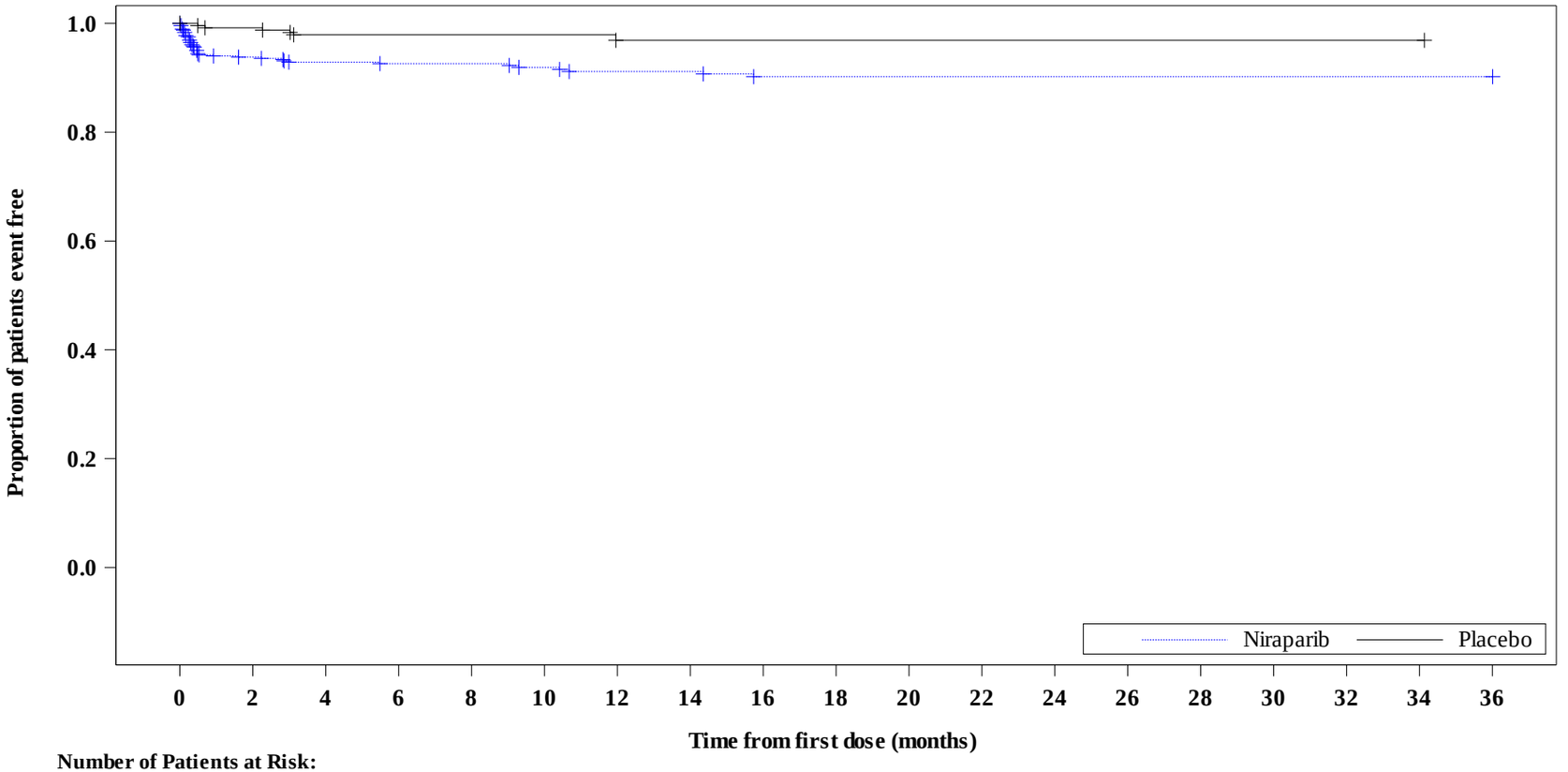



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 411 | 351 | 312 | 256 | 220 | 199 | 173 | 142 | 122 | 92 | 66 | 41 | 21 | 11 | 8 | 4 | 4 | 1 |
| Placebo | 244 | 213 | 170 | 148 | 110 | 82 | 71 | 61 | 56 | 48 | 40 | 25 | 16 | 10 | 5 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Dry mouth

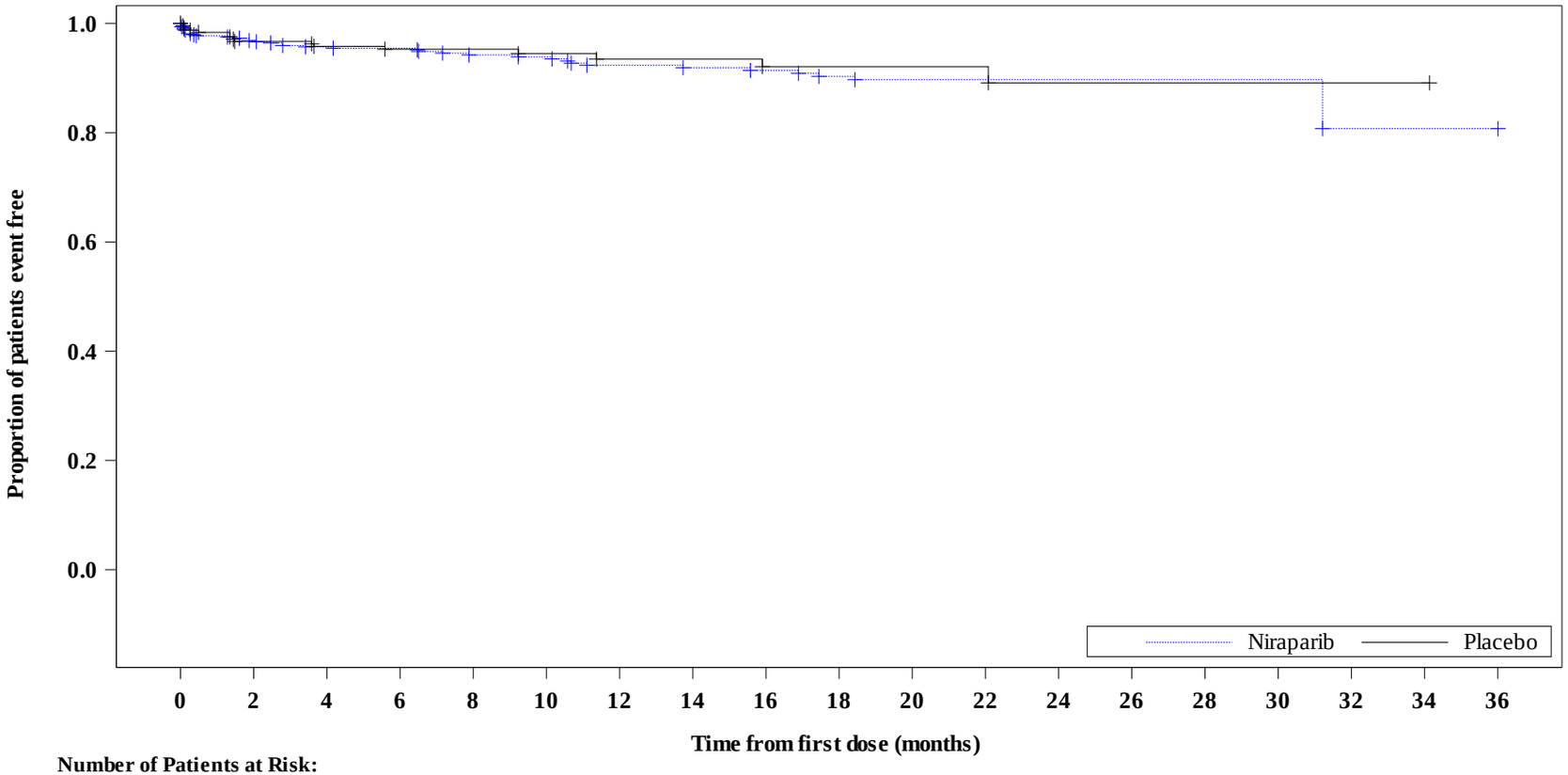



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 421 | 365 | 333 | 278 | 247 | 229 | 208 | 174 | 152 | 115 | 80 | 55 | 31 | 19 | 10 | 7 | 5 | 1 |
| Placebo | 244 | 239 | 200 | 180 | 143 | 108 | 96 | 84 | 72 | 63 | 53 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Dyspepsia

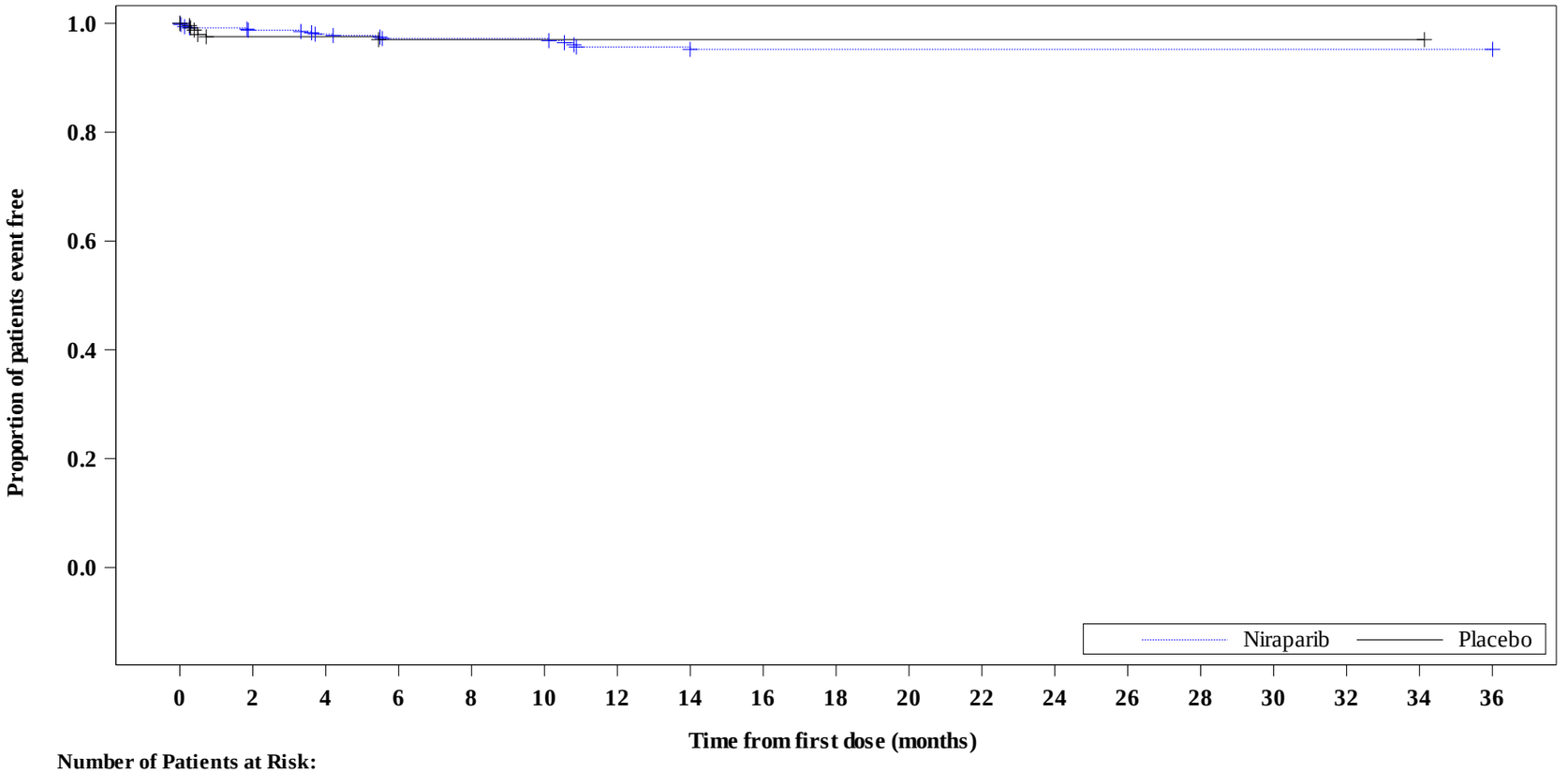



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 435 | 373 | 340 | 280 | 248 | 229 | 210 | 177 | 152 | 114 | 80 | 55 | 30 | 18 | 11 | 8 | 4 | 1 |
| Placebo | 244 | 233 | 196 | 173 | 138 | 101 | 91 | 79 | 67 | 59 | 50 | 31 | 16 | 10 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Flatulence

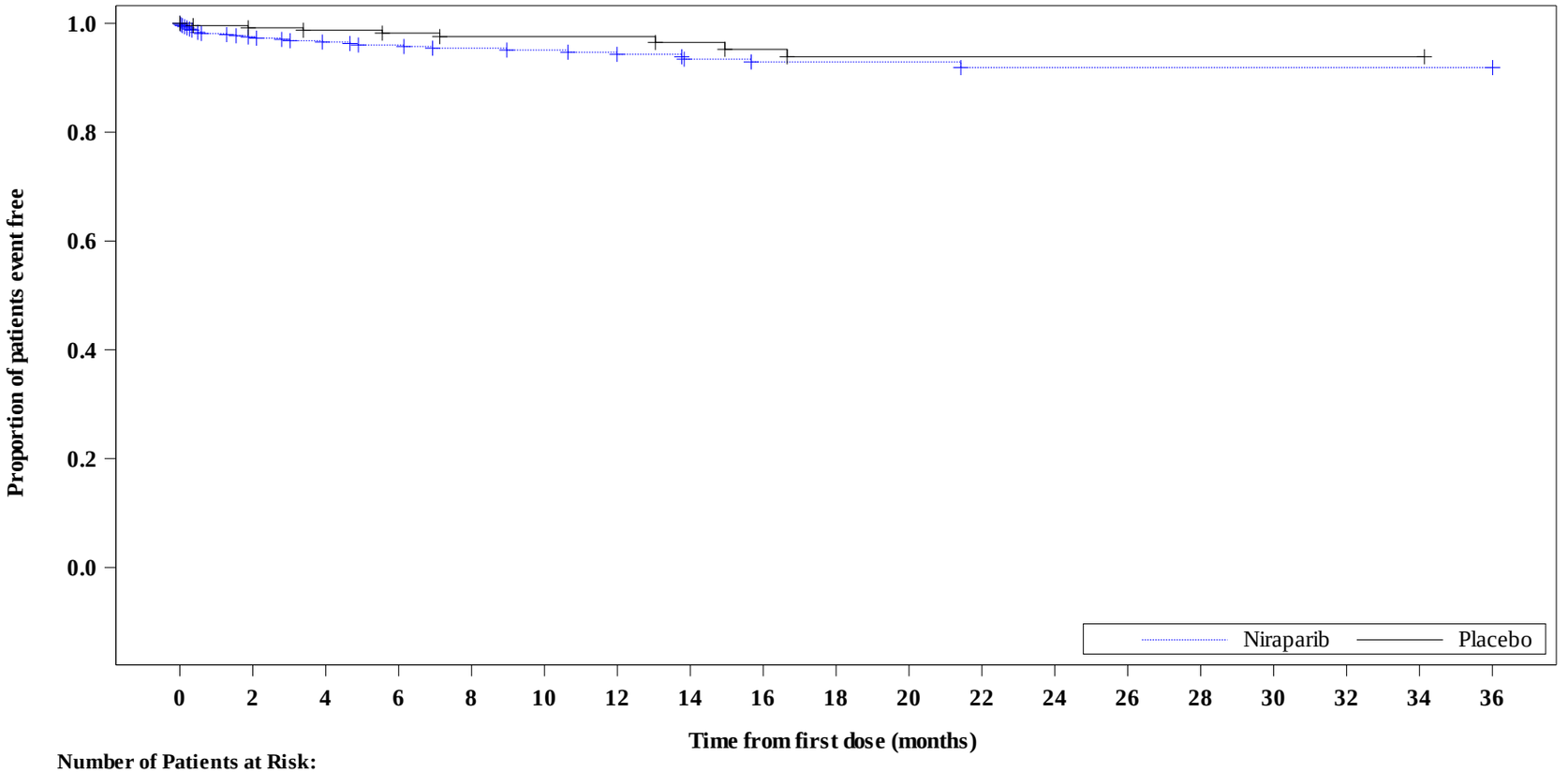



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 444 | 383 | 346 | 289 | 257 | 239 | 217 | 184 | 165 | 128 | 90 | 62 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 235 | 200 | 178 | 141 | 105 | 94 | 82 | 70 | 61 | 51 | 30 | 16 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease

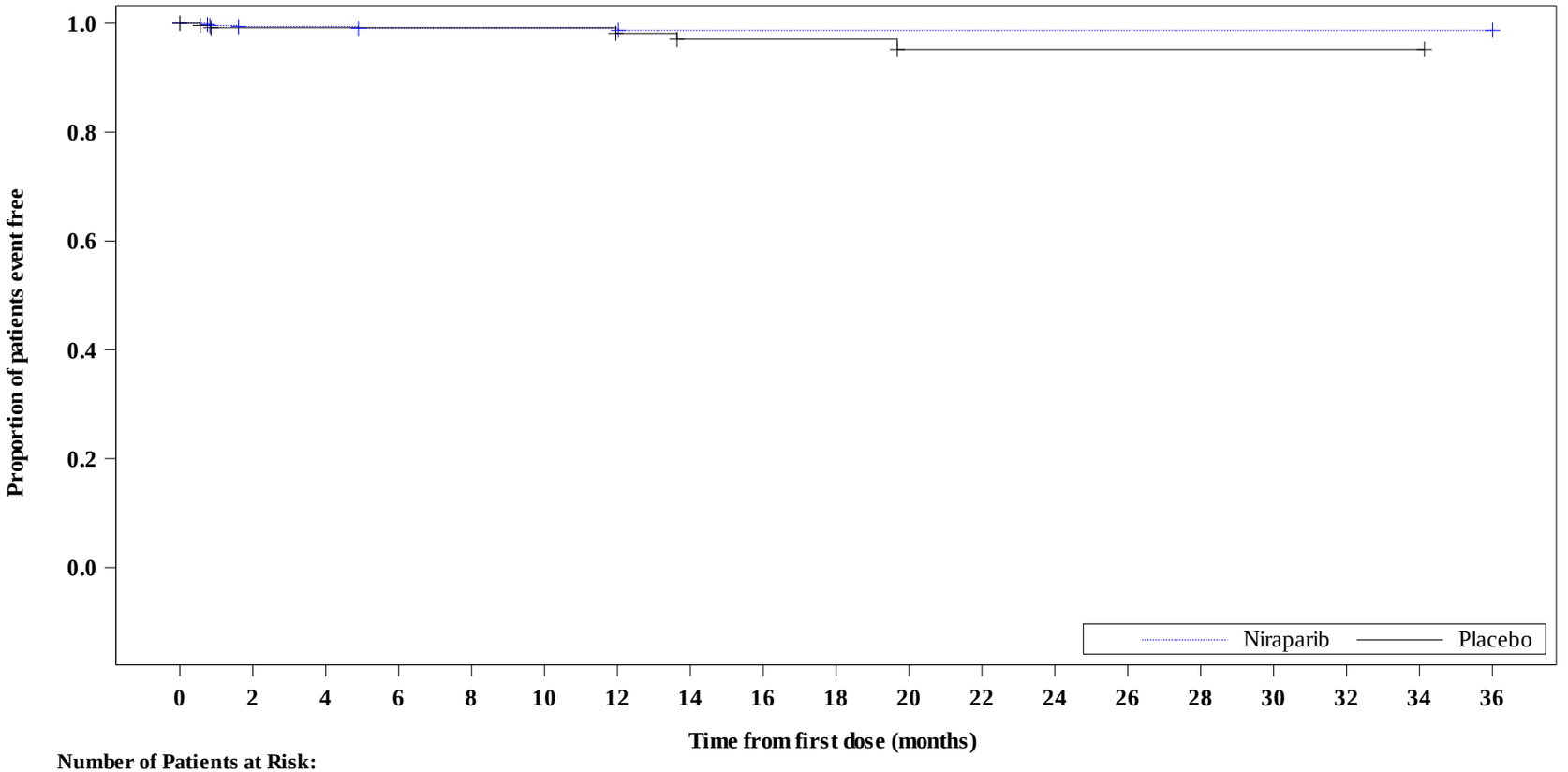



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 438 | 377 | 342 | 284 | 252 | 235 | 211 | 180 | 158 | 121 | 85 | 58 | 31 | 19 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 180 | 142 | 107 | 96 | 84 | 71 | 61 | 50 | 30 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Haemorrhoids

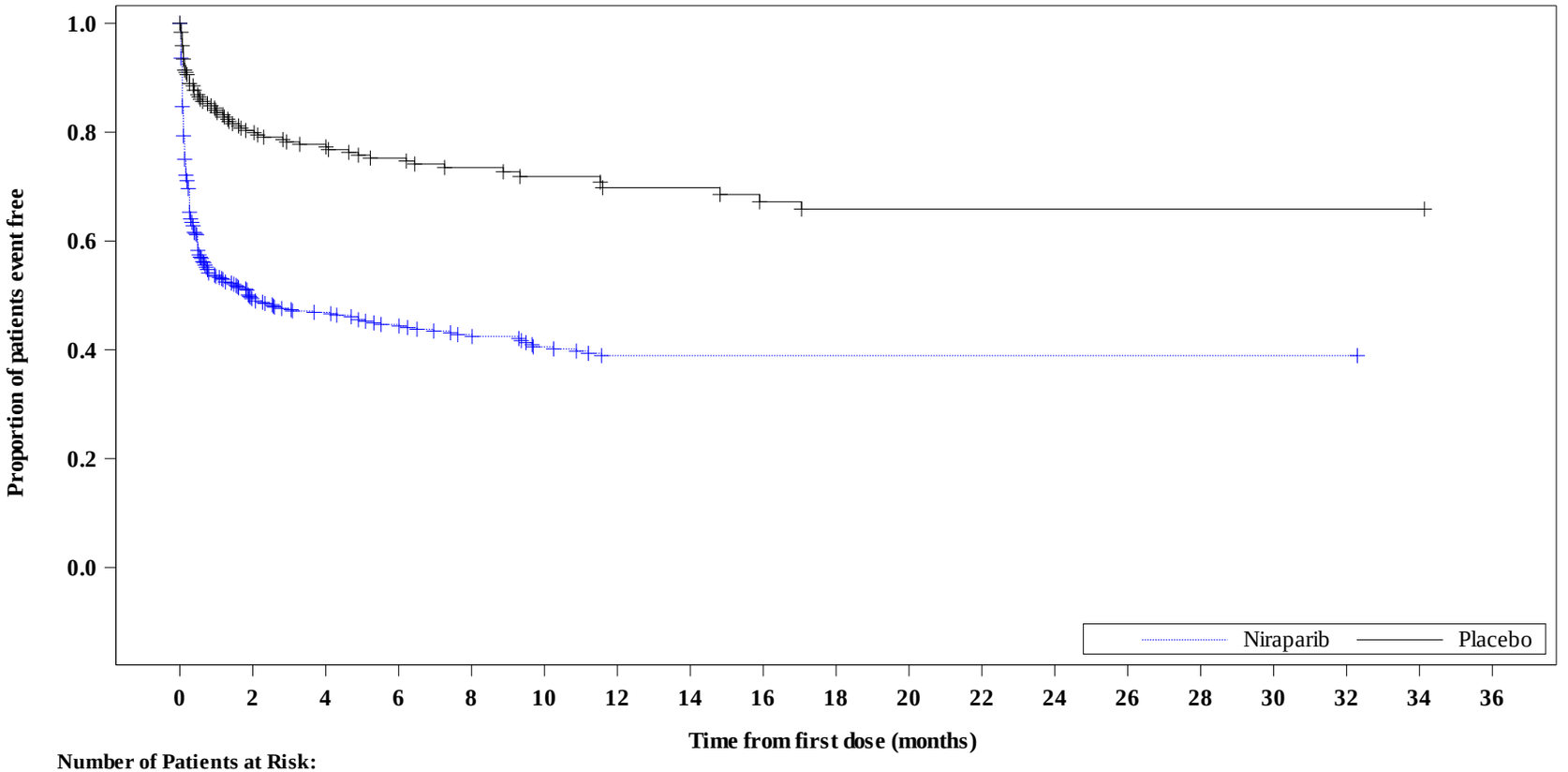



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 388 | 353 | 296 | 264 | 247 | 223 | 190 | 167 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 204 | 182 | 145 | 108 | 96 | 83 | 72 | 63 | 52 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Nausea

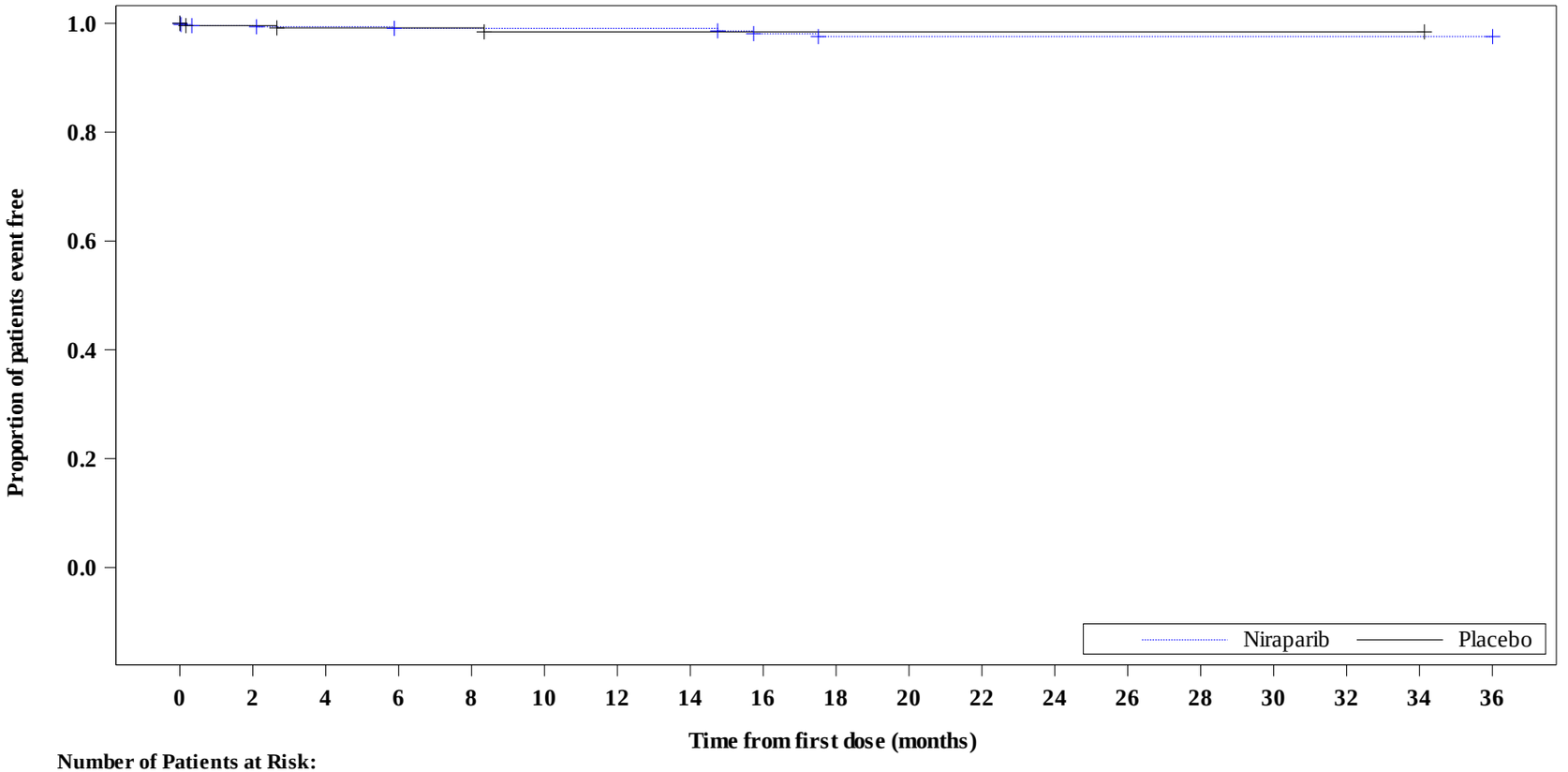



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 219 | 179 | 154 | 123 | 104 | 92 | 84 | 72 | 61 | 37 | 26 | 14 | 7 | 5 | 1 | 1 | 0 | |
| Placebo | 244 | 194 | 161 | 139 | 106 | 78 | 66 | 58 | 50 | 43 | 35 | 20 | 11 | 8 | 4 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Oral pain




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 388 | 353 | 296 | 264 | 247 | 225 | 189 | 165 | 127 | 89 | 61 | 34 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 182 | 145 | 107 | 96 | 84 | 72 | 63 | 53 | 32 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

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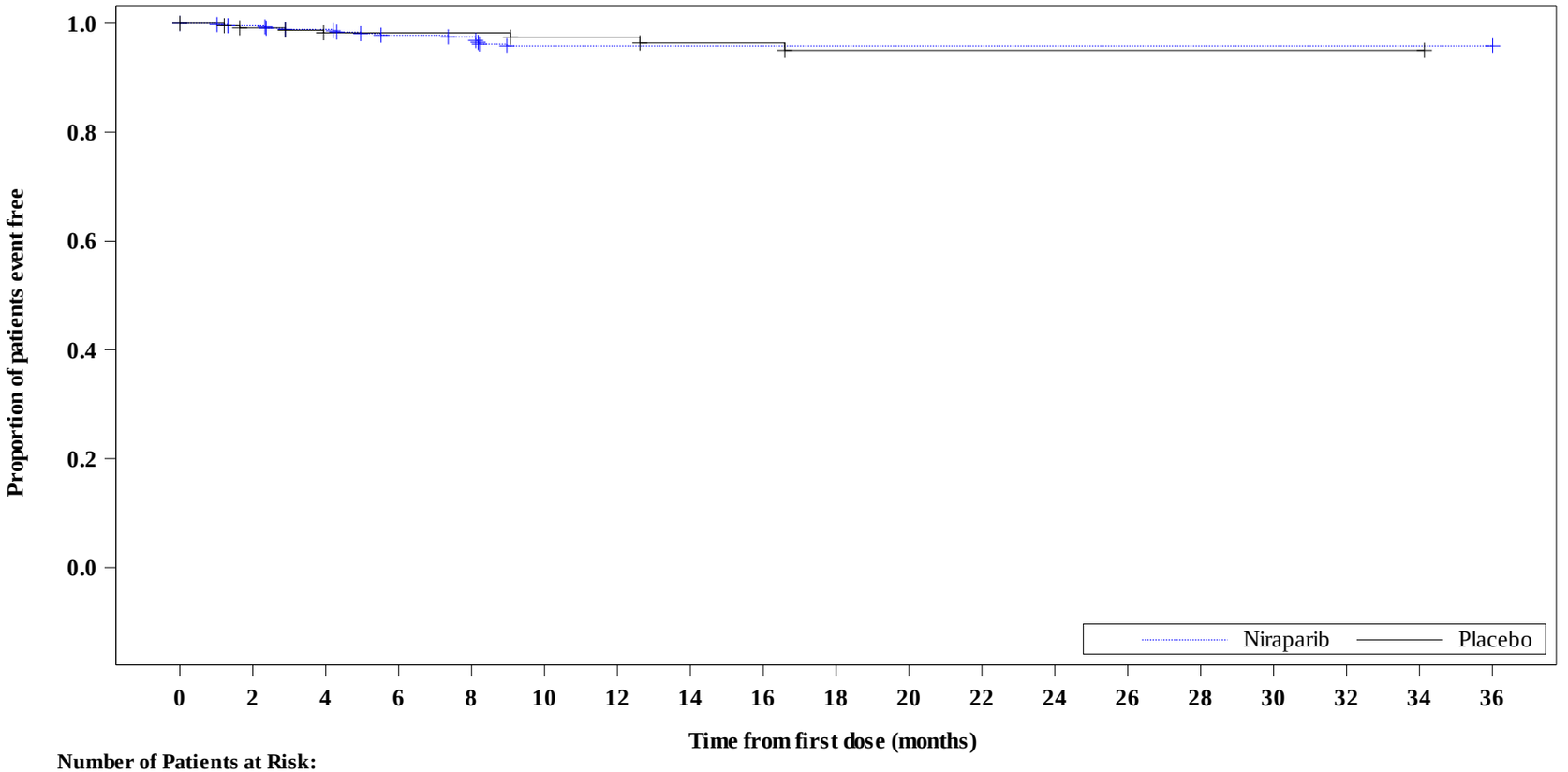
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction

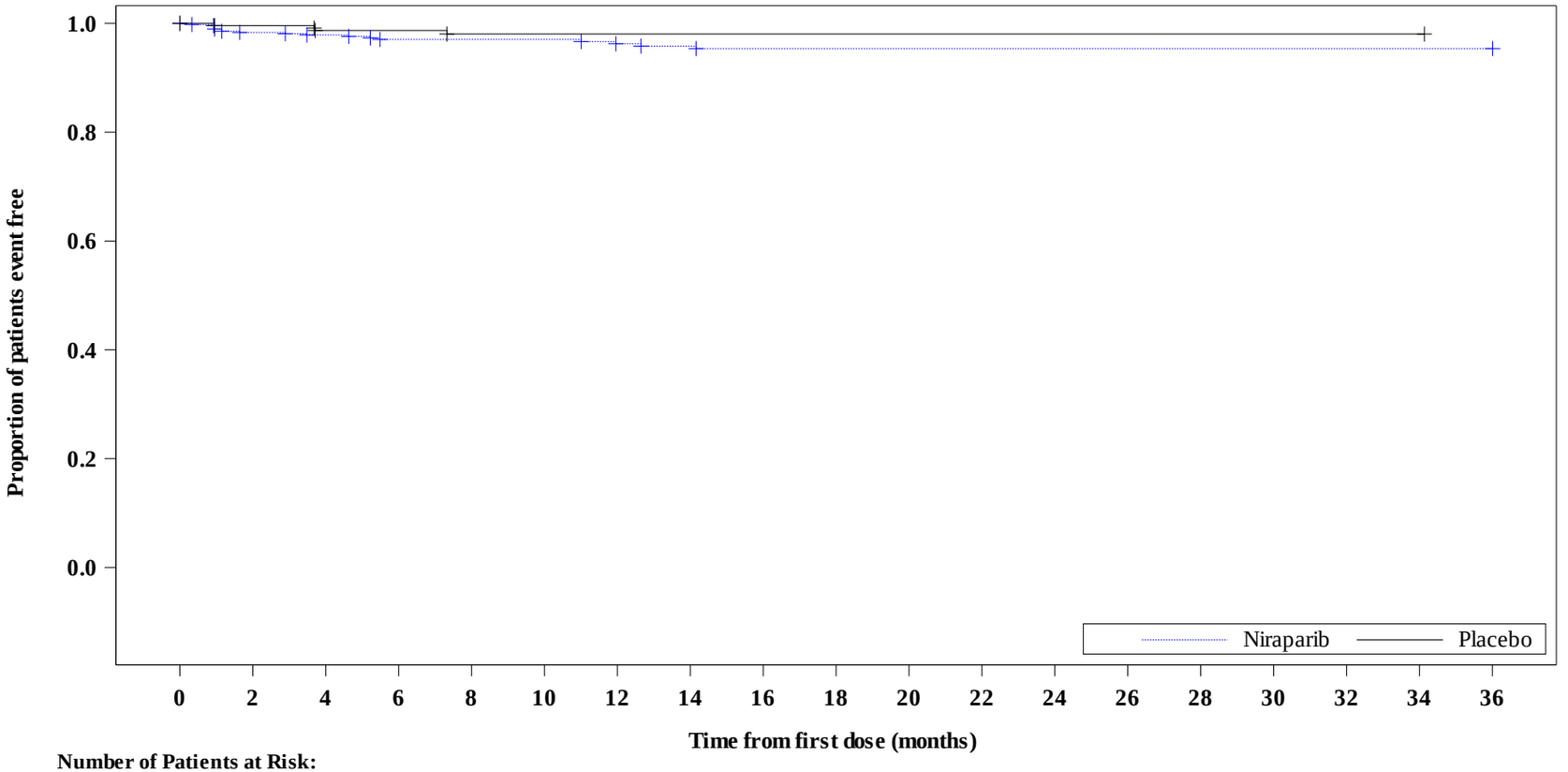



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 387 | 351 | 295 | 261 | 245 | 222 | 188 | 165 | 126 | 90 | 61 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 182 | 145 | 107 | 96 | 83 | 72 | 62 | 52 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Stomatitis

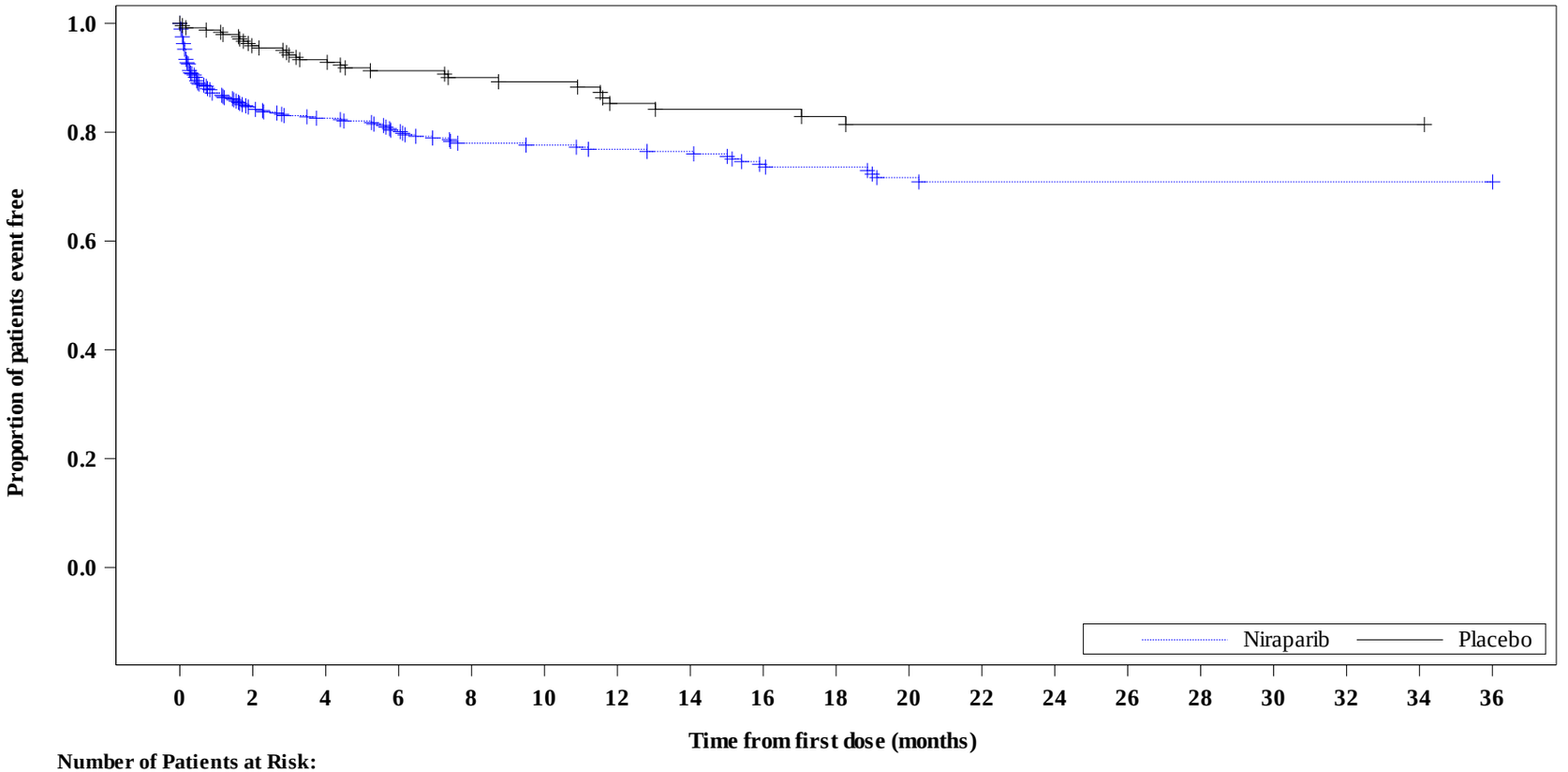



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 383 | 346 | 290 | 257 | 238 | 215 | 182 | 160 | 122 | 86 | 59 | 32 | 20 | 11 | 7 | 4 | 1 |
| Placebo | 244 | 240 | 202 | 180 | 143 | 107 | 96 | 84 | 72 | 63 | 52 | 32 | 17 | 11 | 6 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Gastrointestinal disorders, PT: Vomiting




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 379 | 323 | 286 | 234 | 214 | 197 | 178 | 148 | 130 | 92 | 66 | 43 | 28 | 18 | 11 | 7 | 5 | 1 |
| Placebo | 244 | 232 | 193 | 169 | 133 | 97 | 83 | 73 | 63 | 56 | 46 | 28 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

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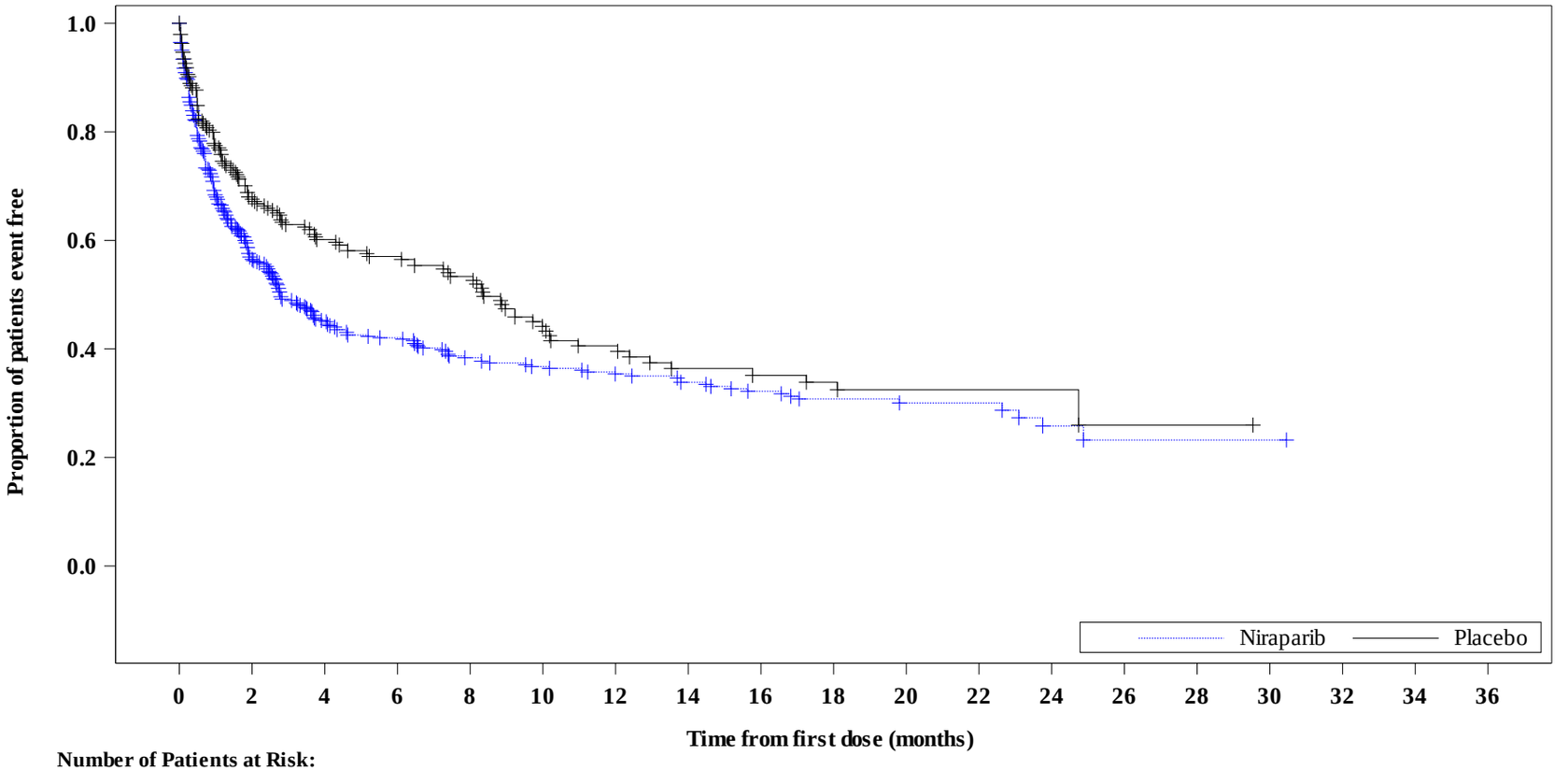
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions

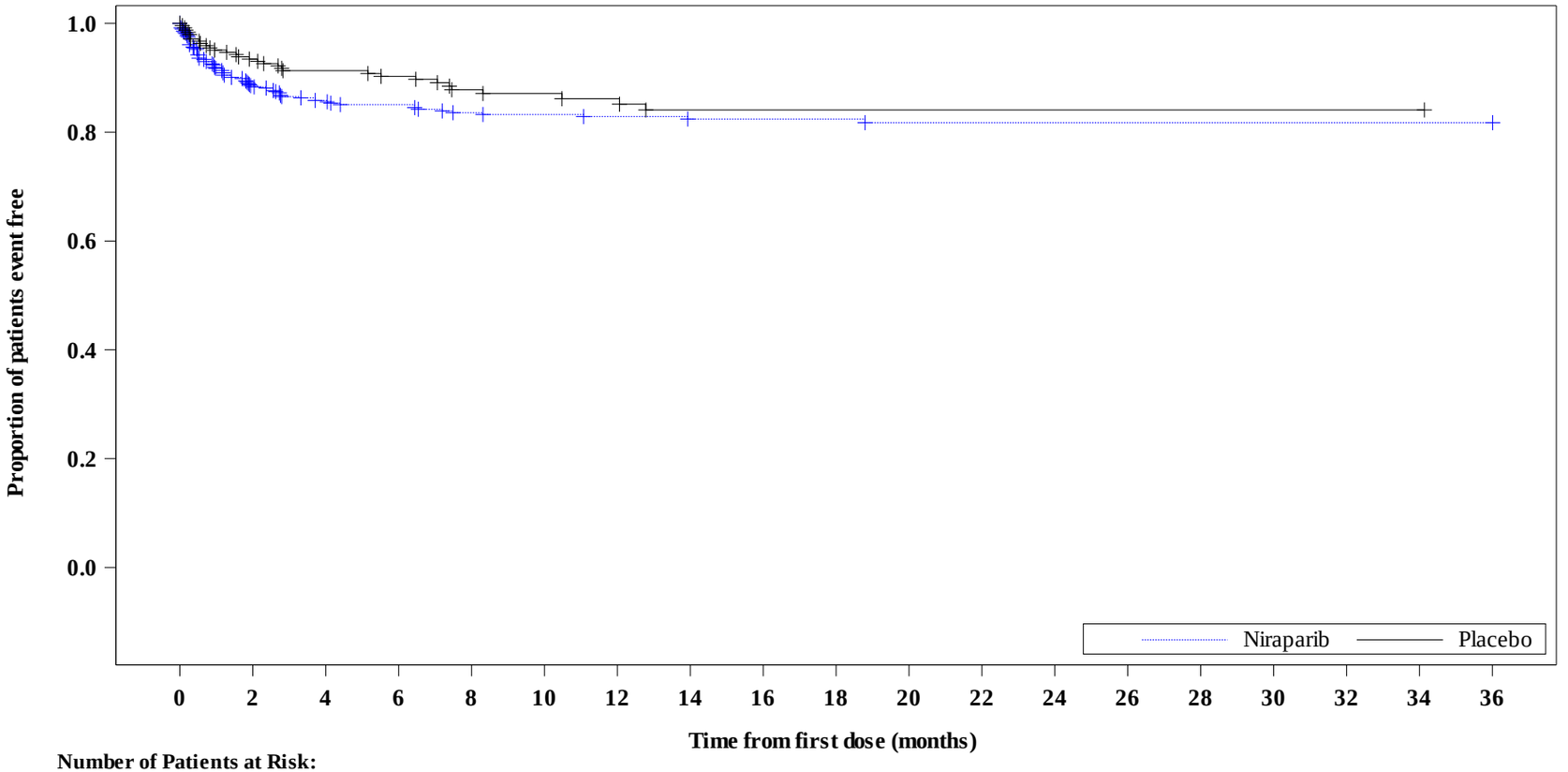



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 259 | 187 | 163 | 122 | 110 | 100 | 88 | 70 | 57 | 41 | 28 | 15 | 6 | 2 | 1 | 0 |
| Placebo | 244 | 164 | 123 | 104 | 75 | 51 | 40 | 32 | 28 | 24 | 19 | 9 | 6 | 2 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Asthenia

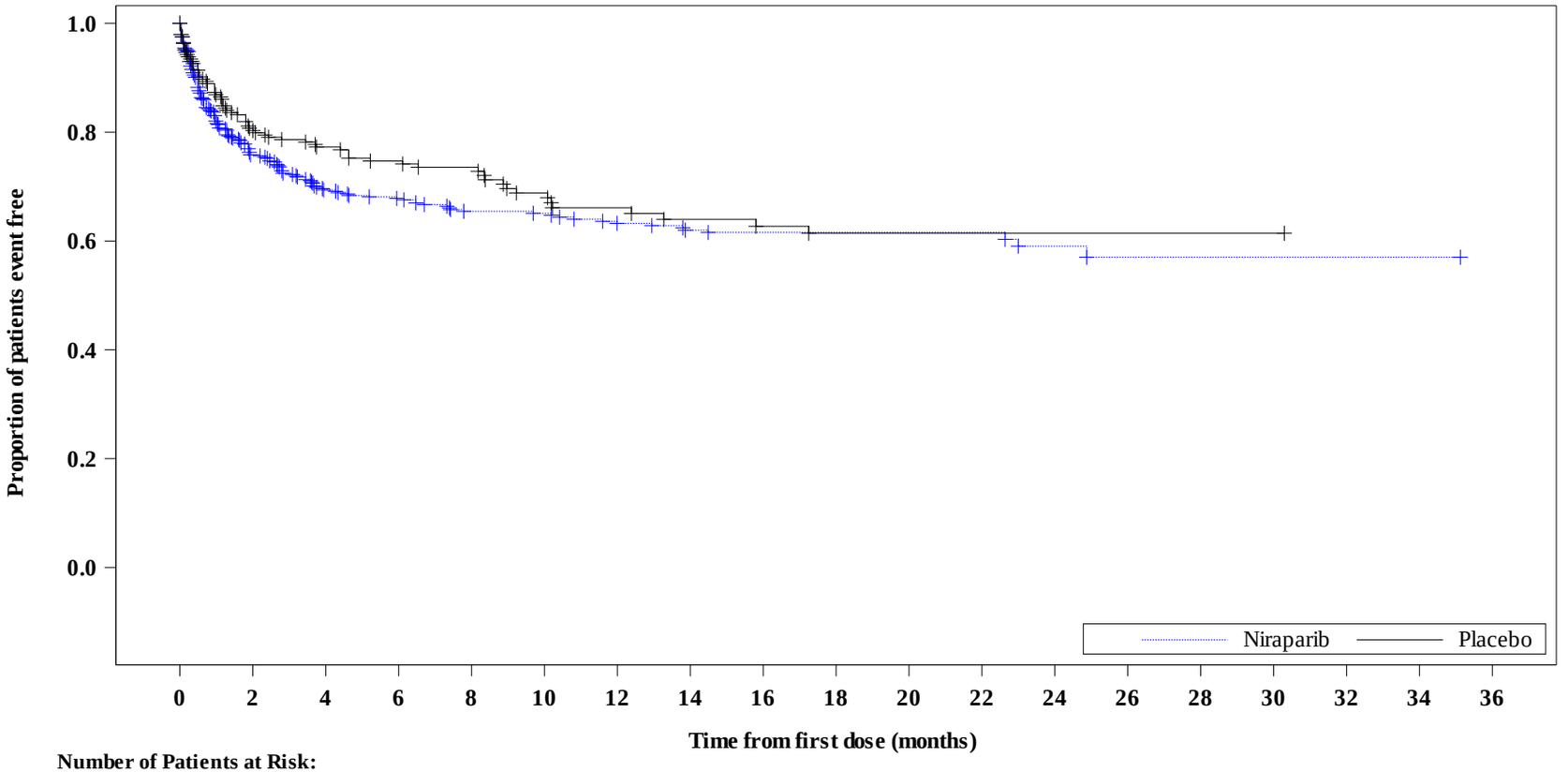



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 402 | 339 | 308 | 254 | 224 | 207 | 186 | 155 | 134 | 103 | 73 | 46 | 28 | 17 | 12 | 8 | 4 | 1 |
| Placebo | 244 | 225 | 190 | 168 | 131 | 96 | 86 | 74 | 66 | 57 | 49 | 29 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Fatigue

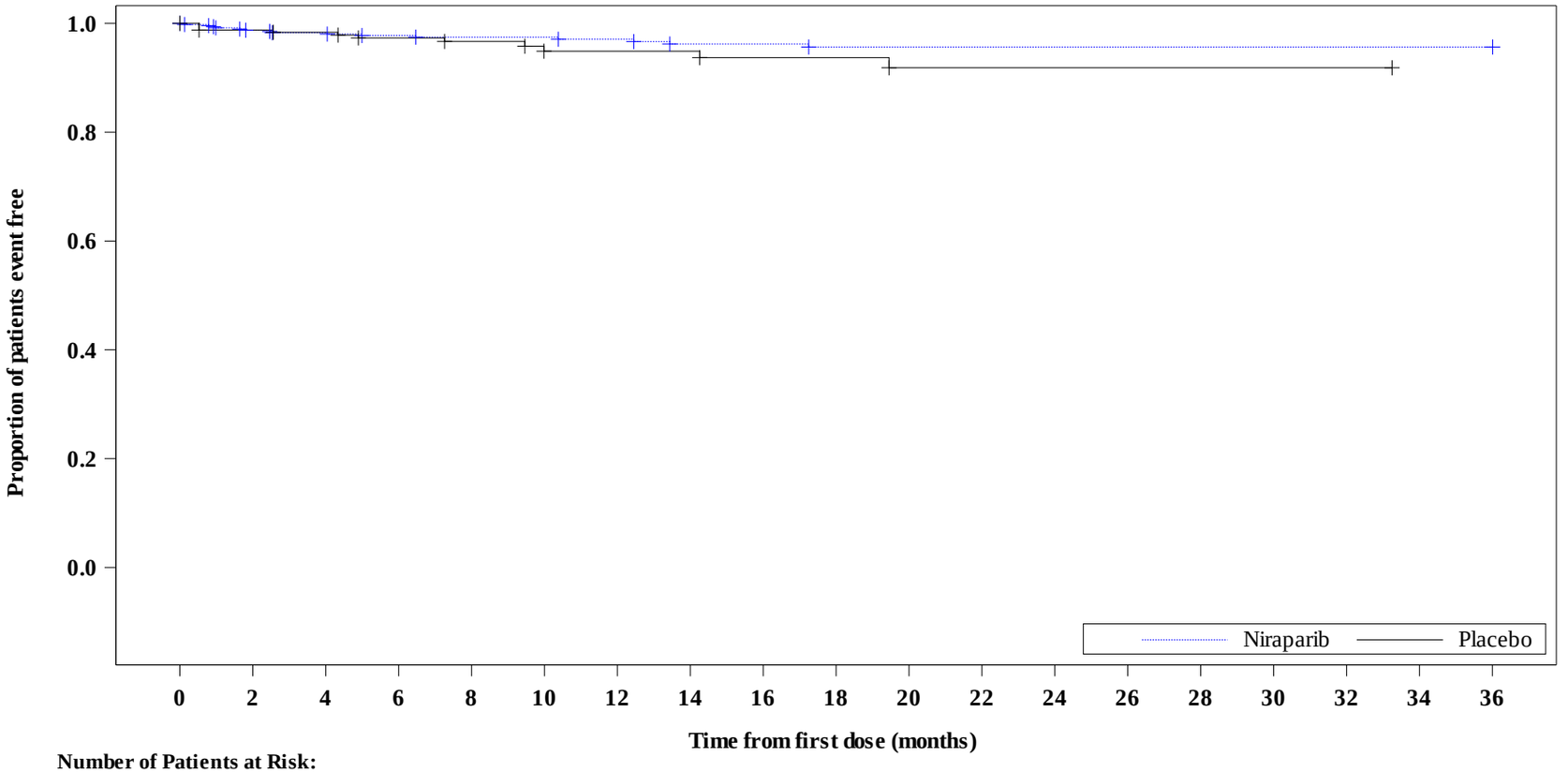



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 342 | 278 | 250 | 201 | 180 | 165 | 148 | 124 | 108 | 79 | 58 | 39 | 18 | 9 | 2 | 1 | 1 | 0 |
| Placebo | 244 | 195 | 159 | 136 | 100 | 77 | 65 | 56 | 49 | 41 | 33 | 18 | 8 | 4 | 2 | 1 | 0 | | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Influenza like illness

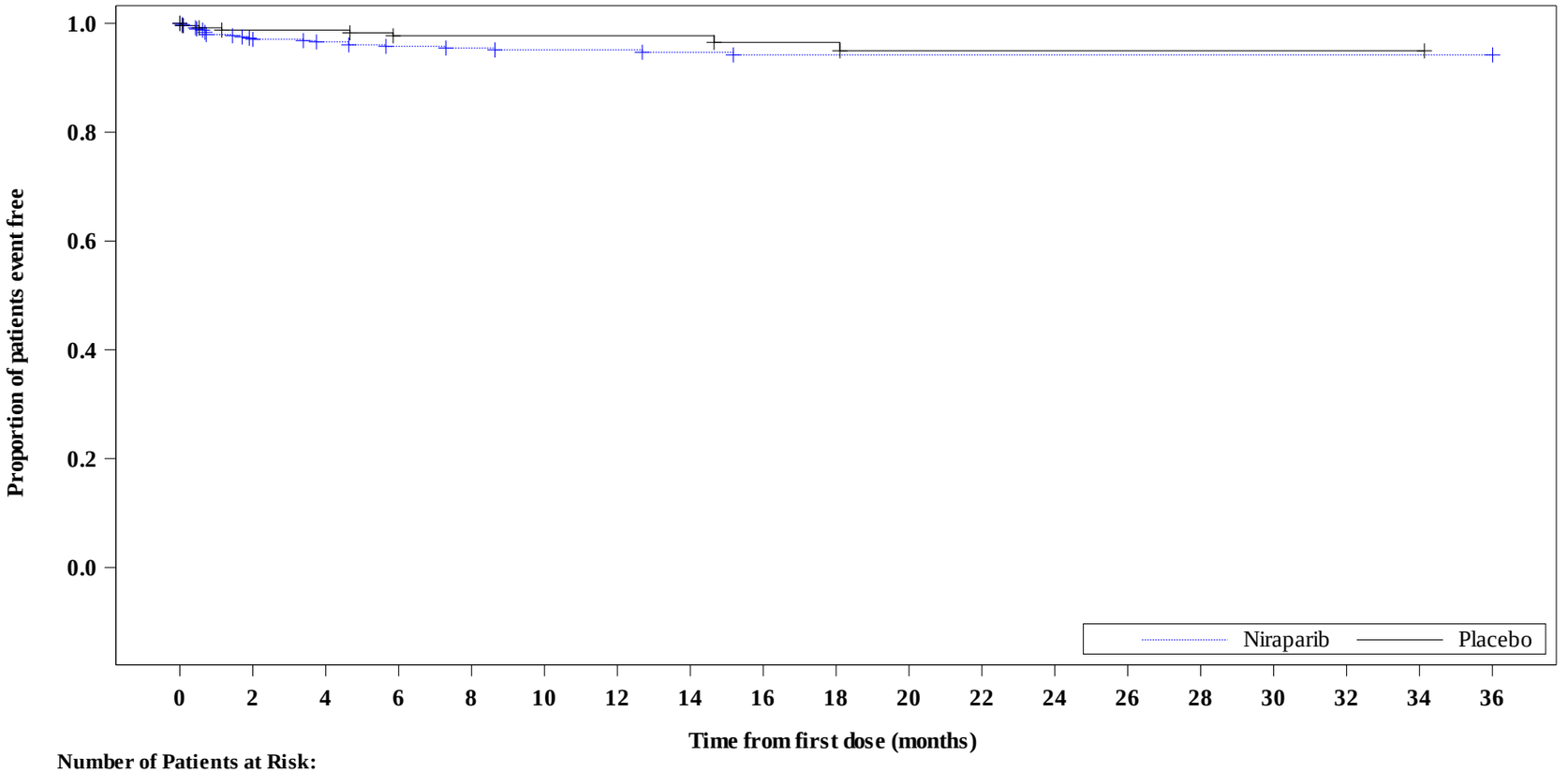



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 444 | 383 | 347 | 289 | 256 | 238 | 215 | 182 | 158 | 121 | 85 | 59 | 32 | 20 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 238 | 201 | 178 | 140 | 103 | 93 | 81 | 70 | 61 | 49 | 30 | 16 | 10 | 5 | 2 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Mucosal inflammation

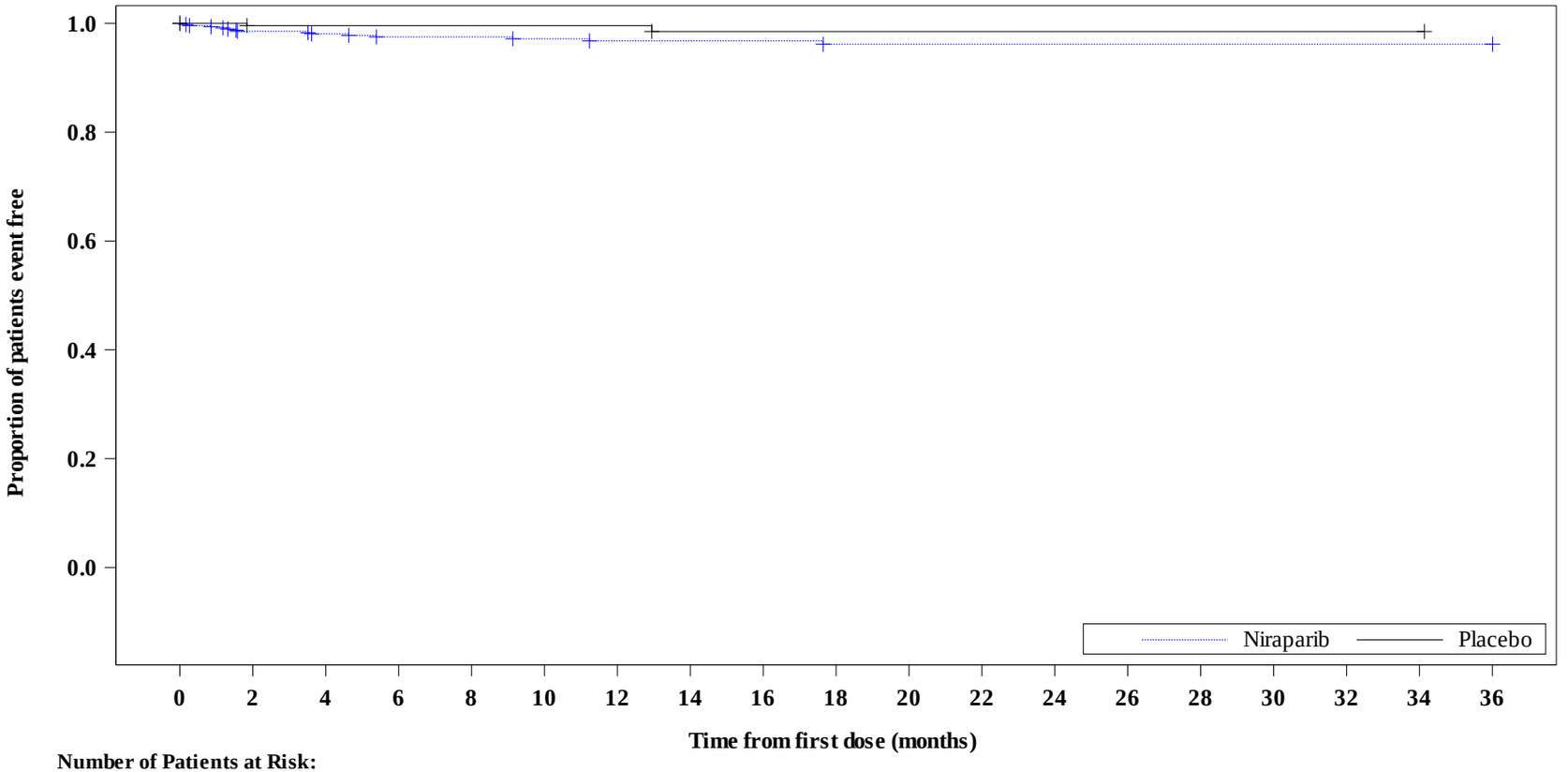



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 438 | 377 | 343 | 285 | 253 | 236 | 214 | 182 | 160 | 123 | 87 | 60 | 32 | 20 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 238 | 202 | 178 | 141 | 107 | 96 | 84 | 71 | 62 | 51 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Non-cardiac chest pain




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 443 | 383 | 348 | 291 | 258 | 240 | 217 | 183 | 159 | 121 | 84 | 58 | 32 | 21 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 182 | 145 | 108 | 97 | 84 | 73 | 64 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

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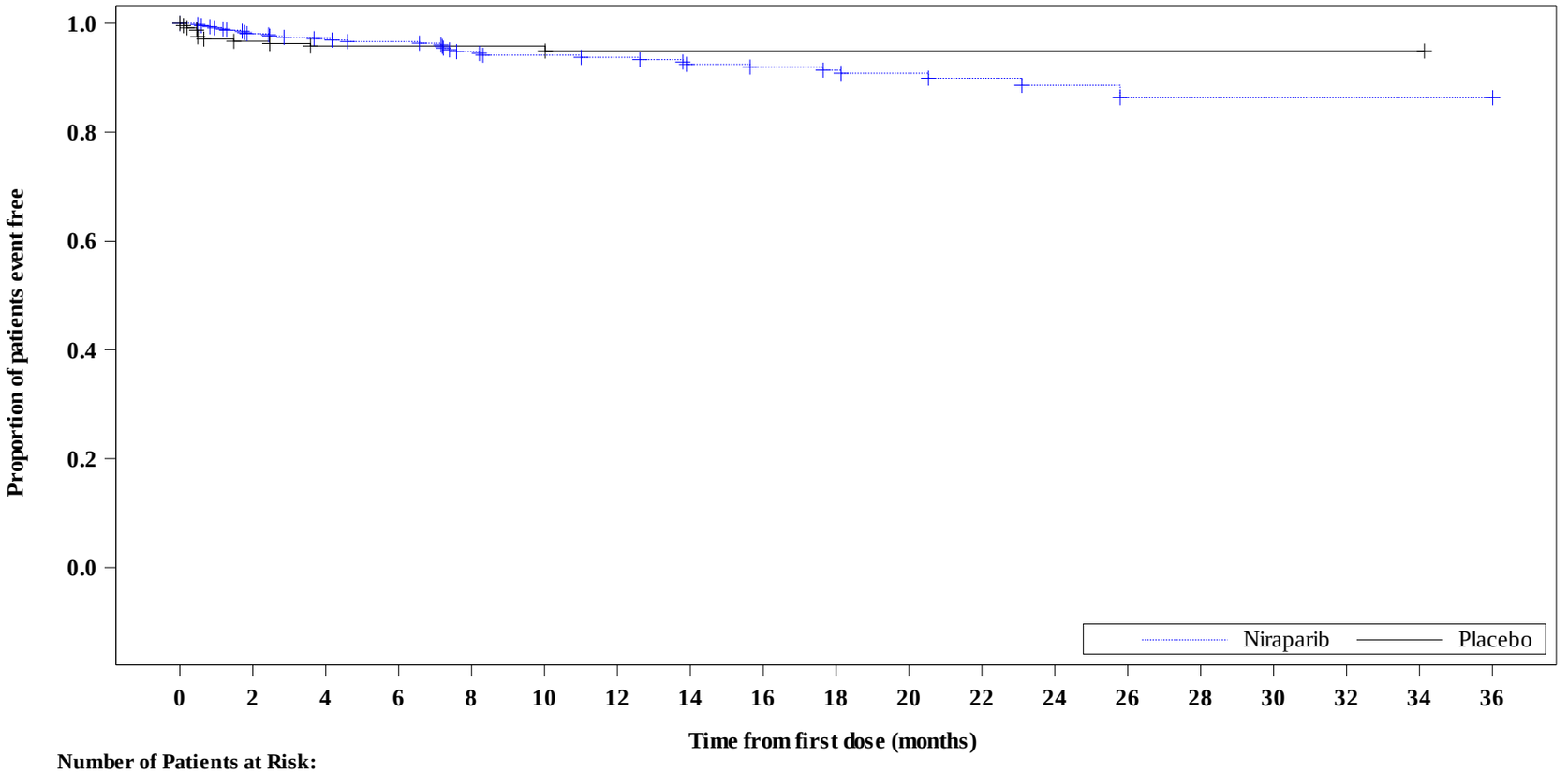
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Oedema peripheral

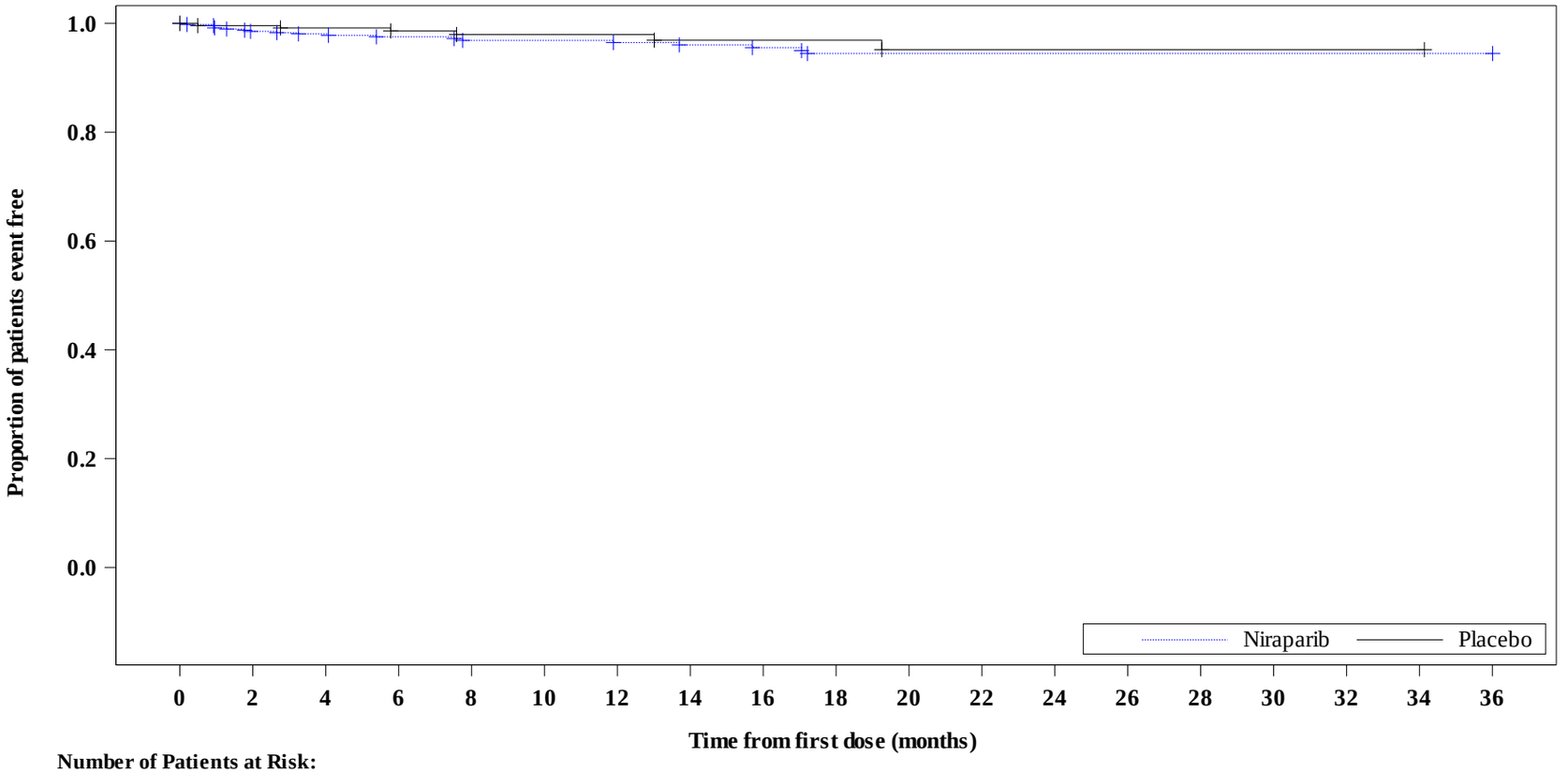



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 382 | 346 | 286 | 255 | 237 | 213 | 180 | 158 | 119 | 82 | 56 | 29 | 17 | 9 | 6 | 4 | 1 |
| Placebo | 244 | 233 | 195 | 174 | 139 | 103 | 91 | 80 | 68 | 61 | 50 | 30 | 16 | 10 | 5 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Pain

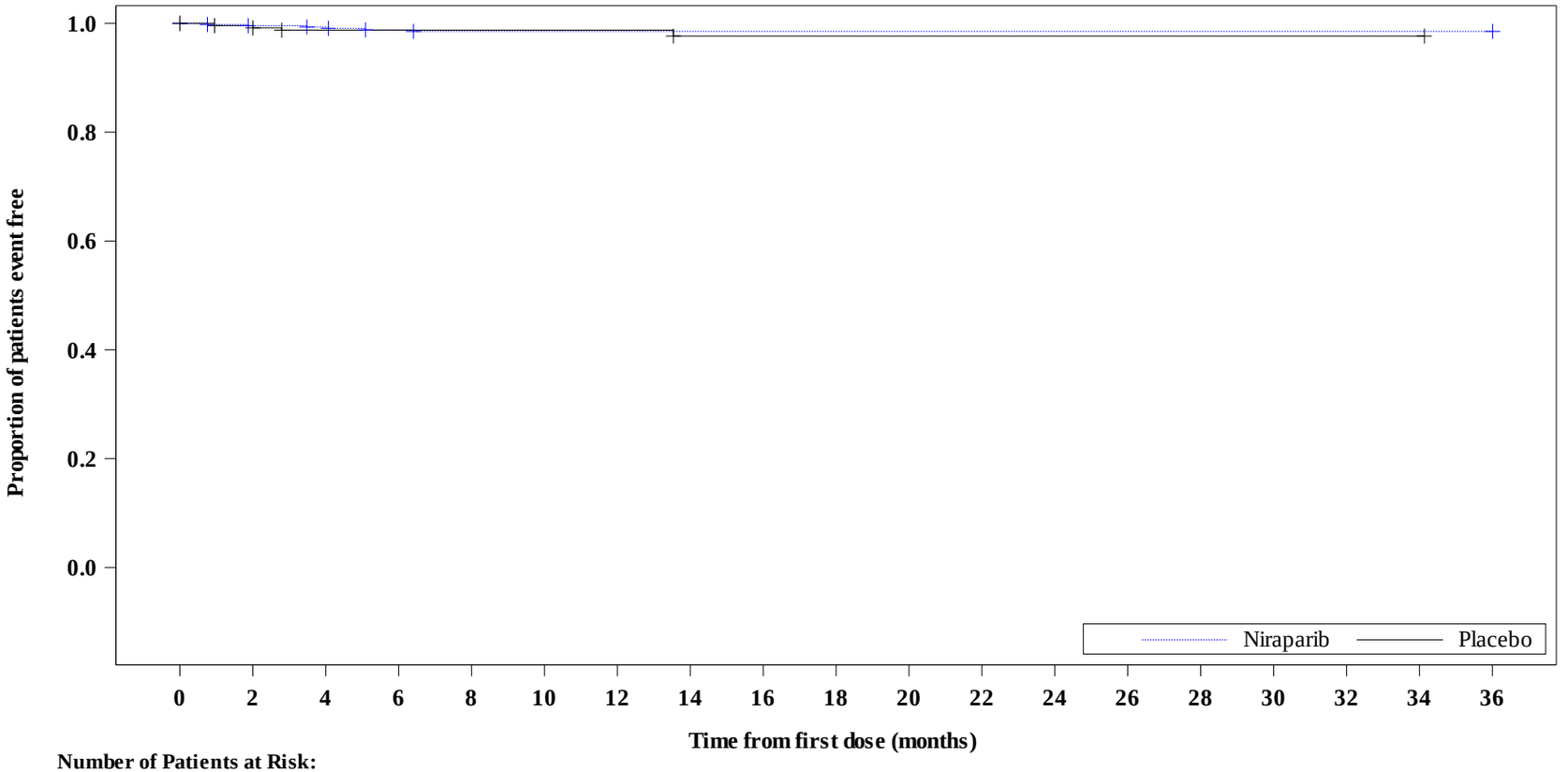



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 443 | 382 | 347 | 288 | 260 | 242 | 220 | 185 | 160 | 123 | 86 | 58 | 33 | 20 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 181 | 144 | 109 | 98 | 85 | 73 | 64 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Peripheral swelling




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 388 | 353 | 295 | 262 | 245 | 222 | 188 | 165 | 127 | 89 | 60 | 33 | 20 | 11 | 7 | 4 | 1 |
| Placebo | 244 | 240 | 202 | 181 | 145 | 109 | 98 | 85 | 73 | 64 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

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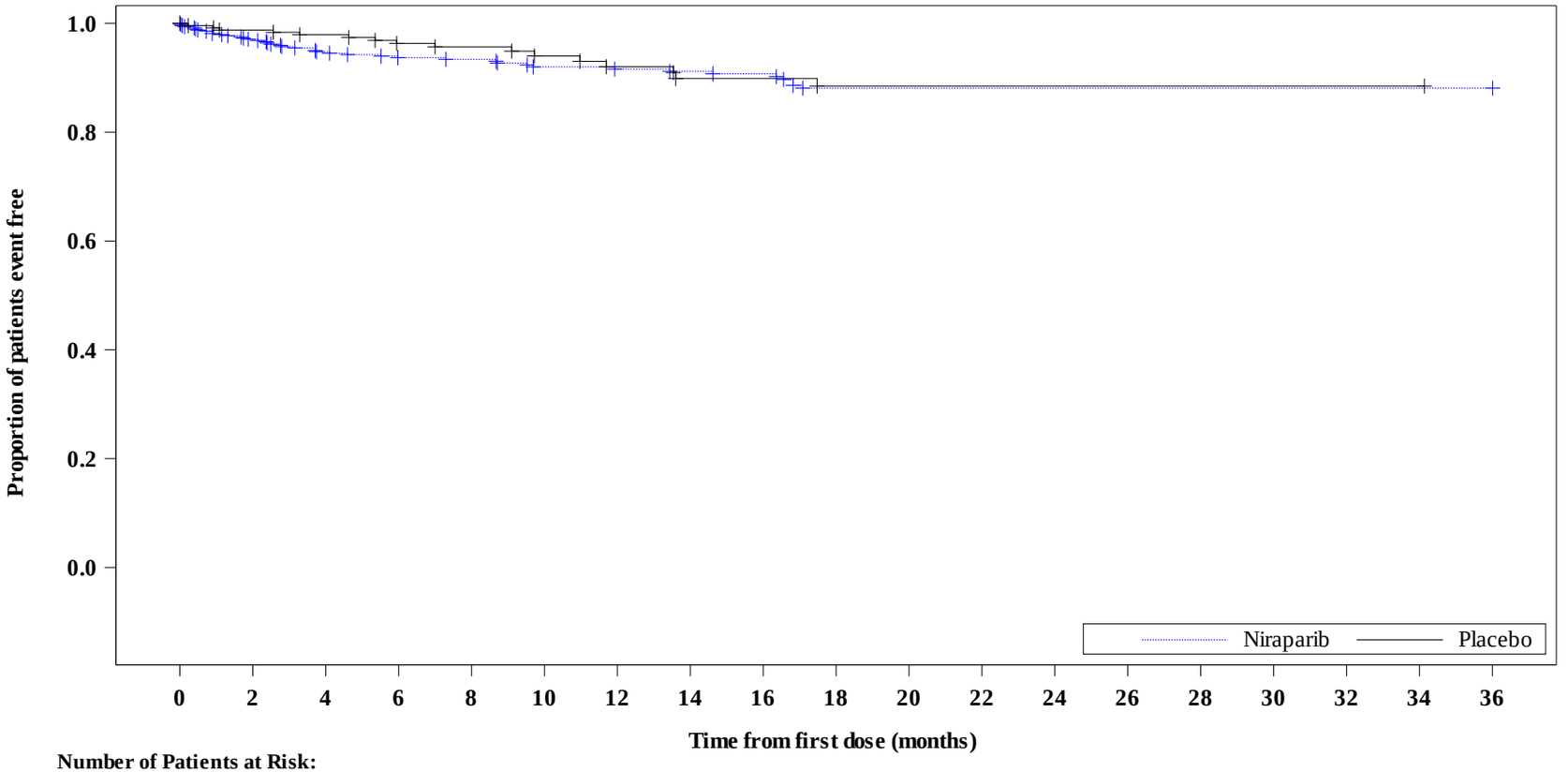
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: General disorders and administration site conditions, PT: Pyrexia

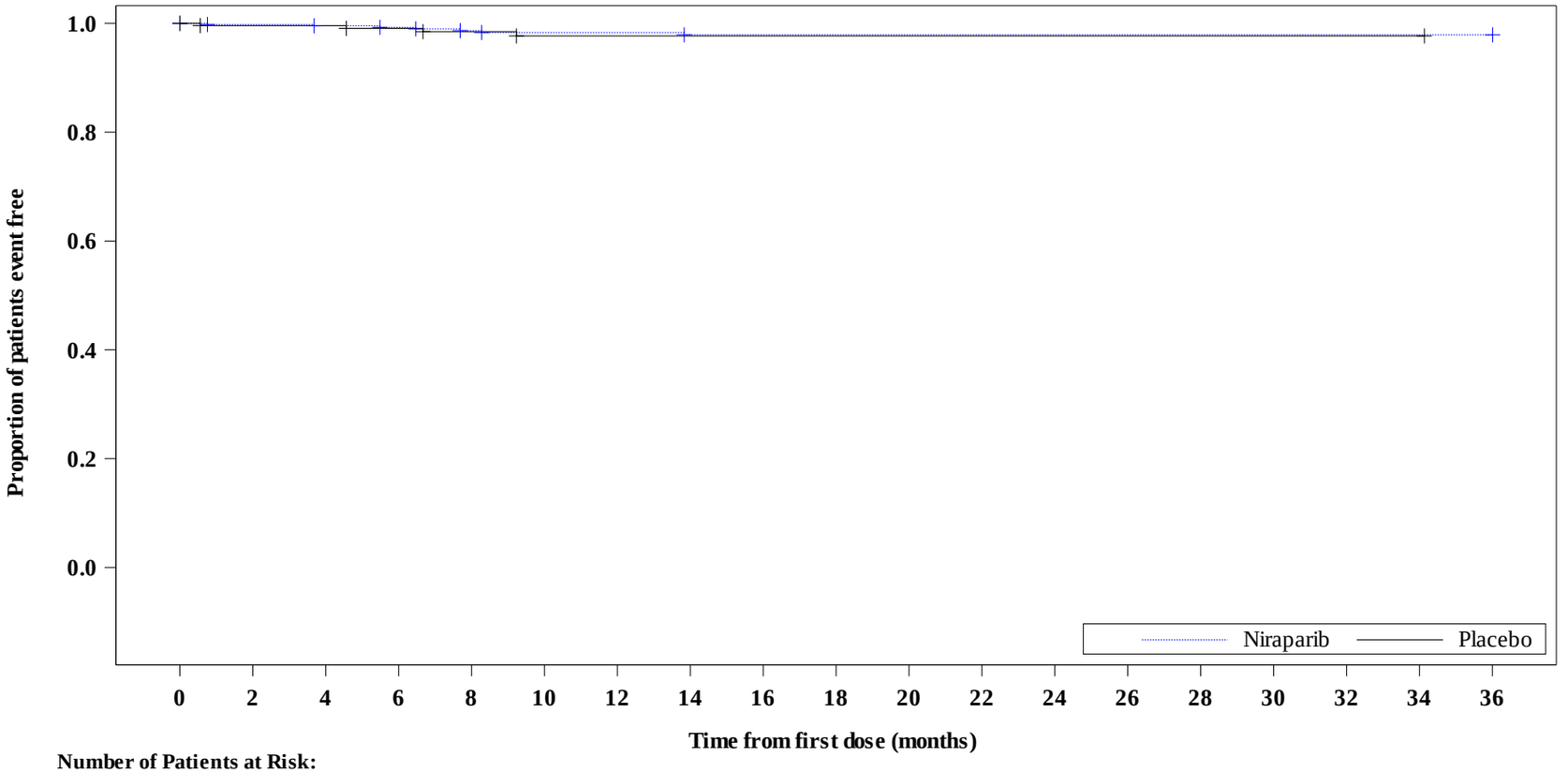



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 438 | 372 | 336 | 281 | 249 | 232 | 209 | 178 | 152 | 116 | 80 | 57 | 32 | 20 | 12 | 8 | 4 | 1 |
| Placebo | 244 | 238 | 201 | 176 | 140 | 102 | 91 | 78 | 67 | 58 | 50 | 30 | 16 | 10 | 5 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Hepatobiliary disorders

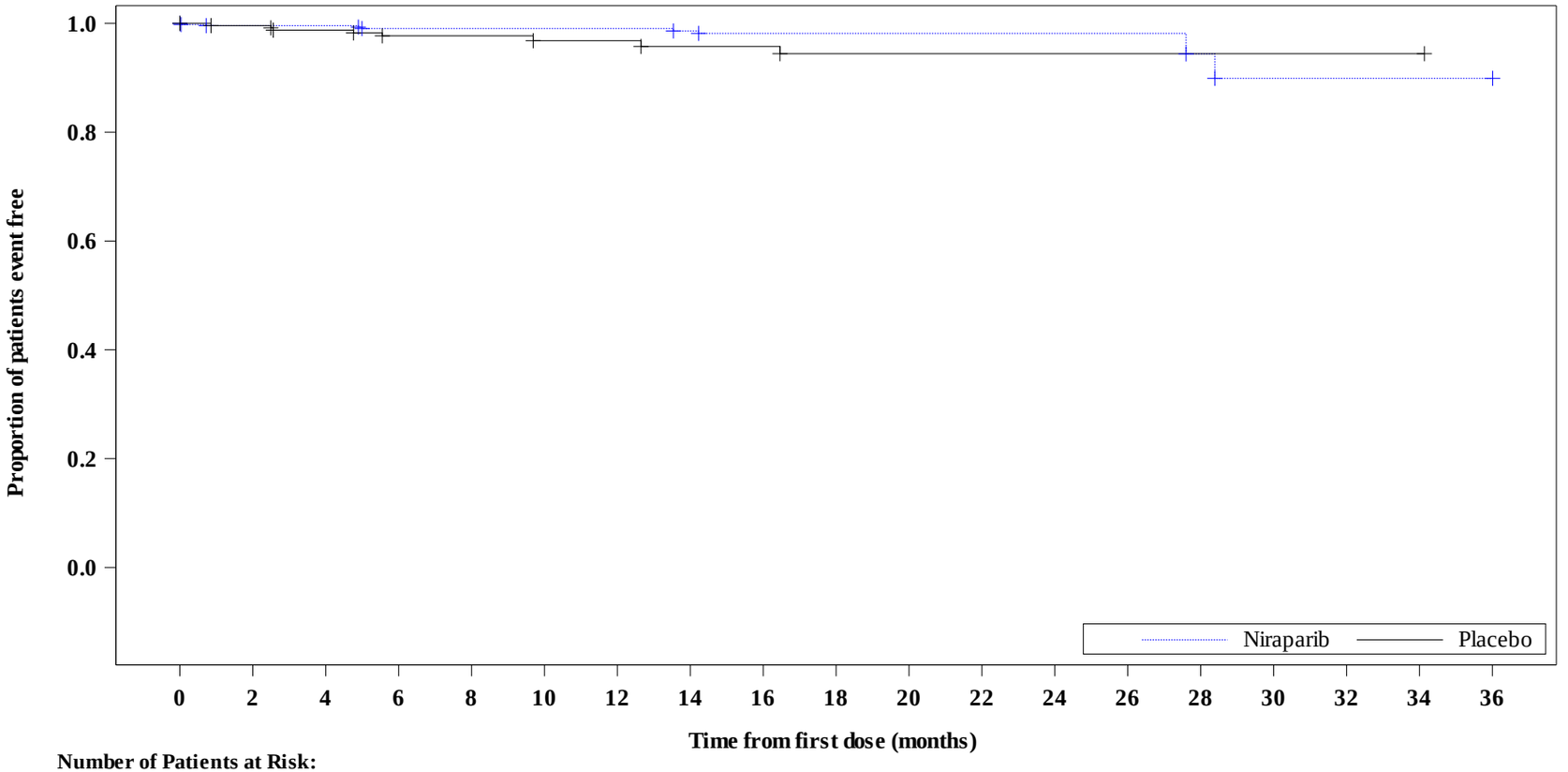



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 389 | 354 | 294 | 261 | 245 | 222 | 188 | 166 | 127 | 89 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 145 | 107 | 96 | 84 | 73 | 64 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Immune system disorders

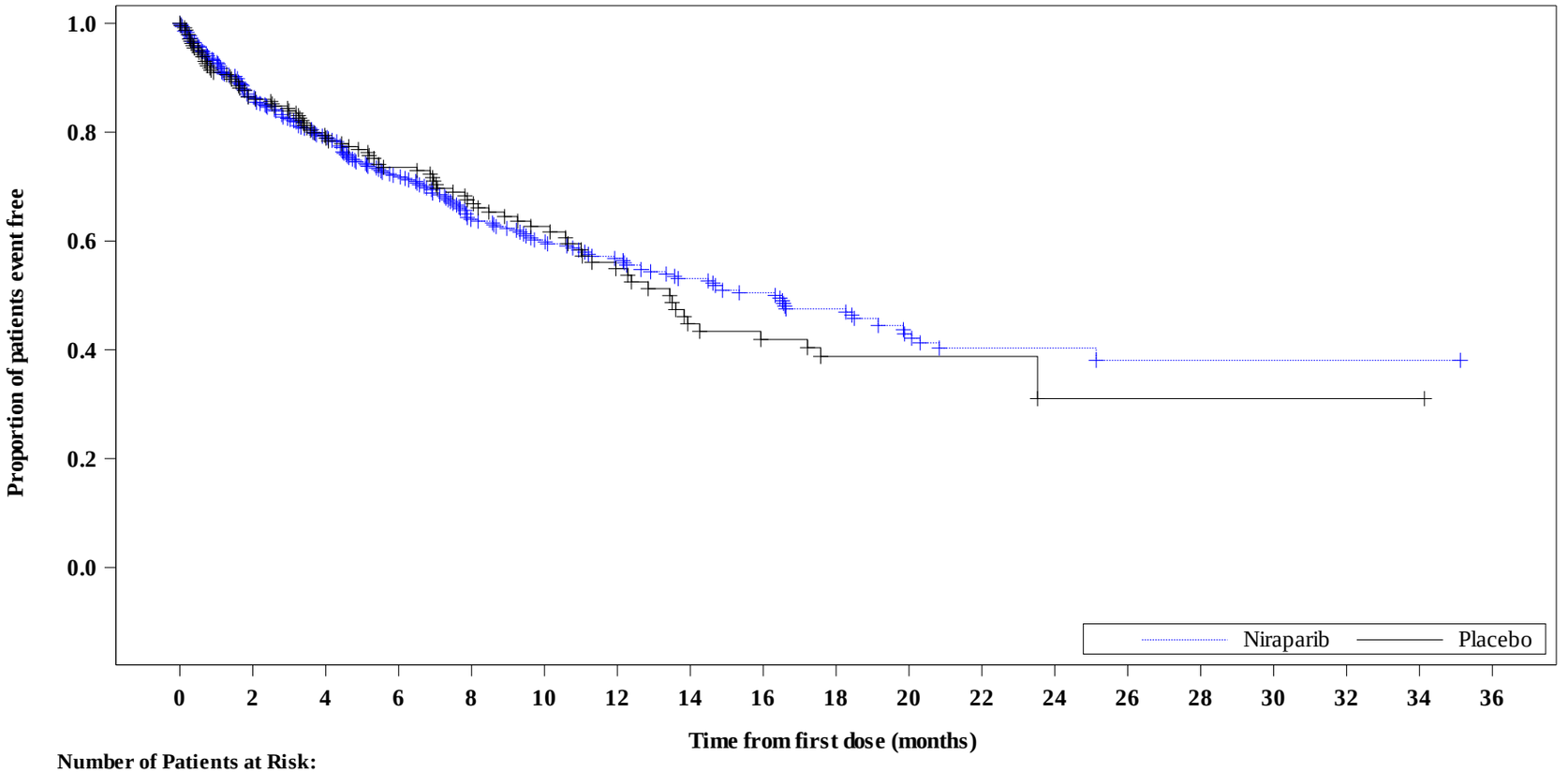



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 389 | 354 | 296 | 263 | 246 | 224 | 189 | 167 | 128 | 91 | 62 | 35 | 21 | 11 | 7 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 179 | 144 | 106 | 96 | 84 | 72 | 62 | 51 | 31 | 17 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations

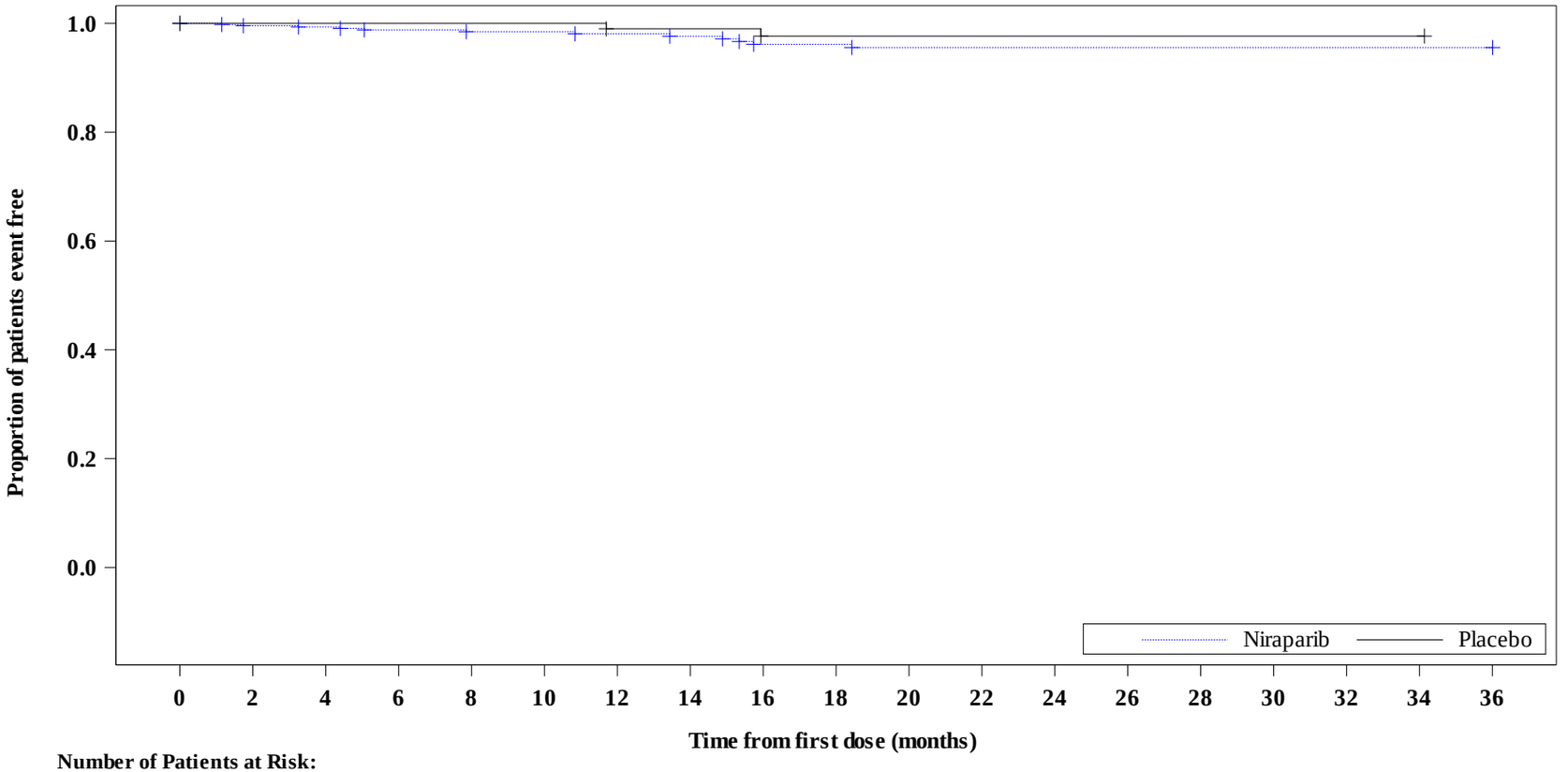



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 391 | 311 | 260 | 192 | 164 | 146 | 126 | 105 | 84 | 54 | 36 | 27 | 16 | 8 | 3 | 3 | 3 | 0 |
| Placebo | 244 | 209 | 159 | 131 | 95 | 62 | 47 | 32 | 28 | 22 | 19 | 9 | 4 | 2 | 2 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Bronchitis

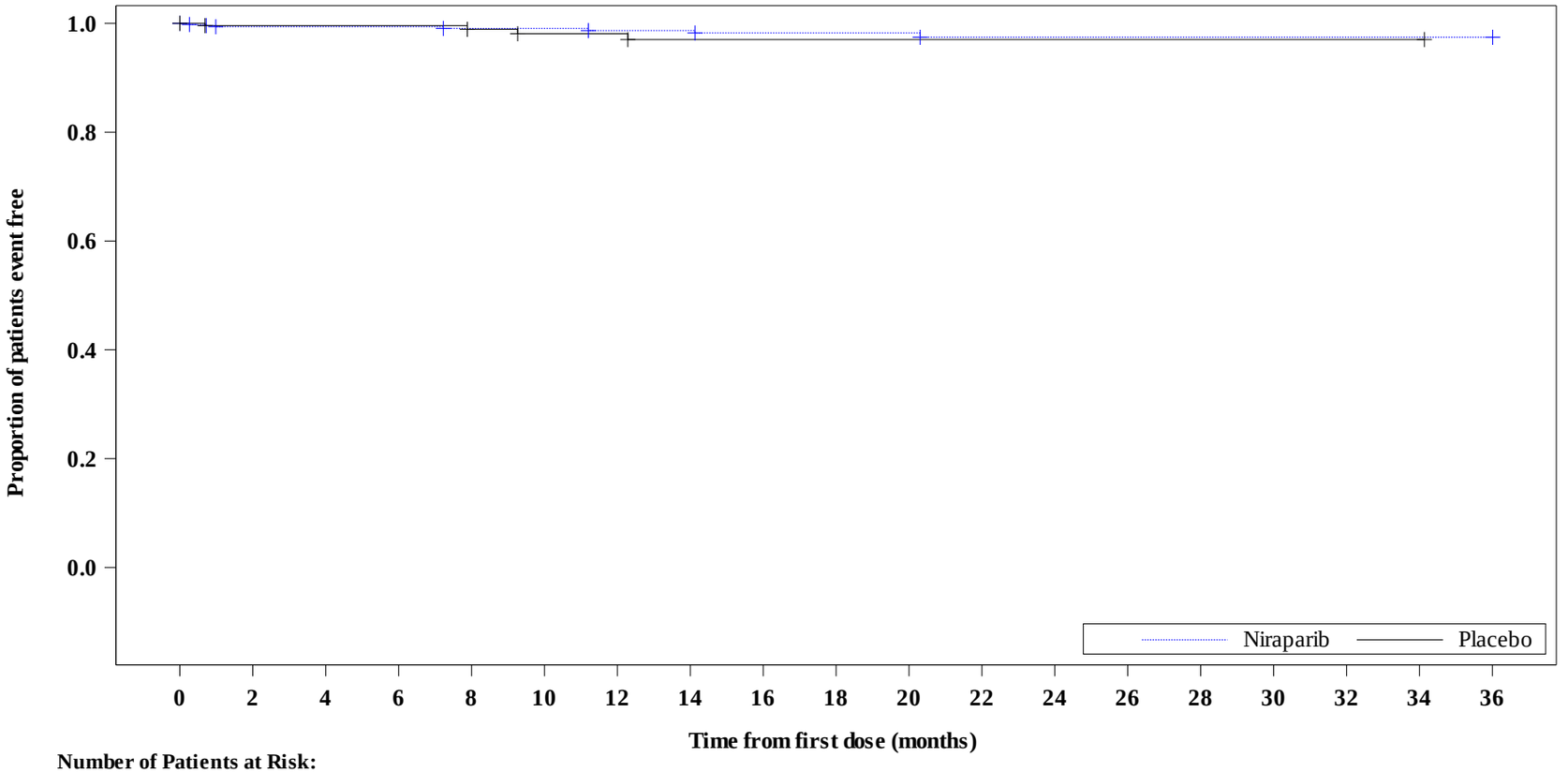



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 388 | 353 | 294 | 261 | 243 | 220 | 185 | 163 | 123 | 86 | 59 | 32 | 19 | 11 | 7 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 97 | 86 | 73 | 64 | 53 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Cystitis

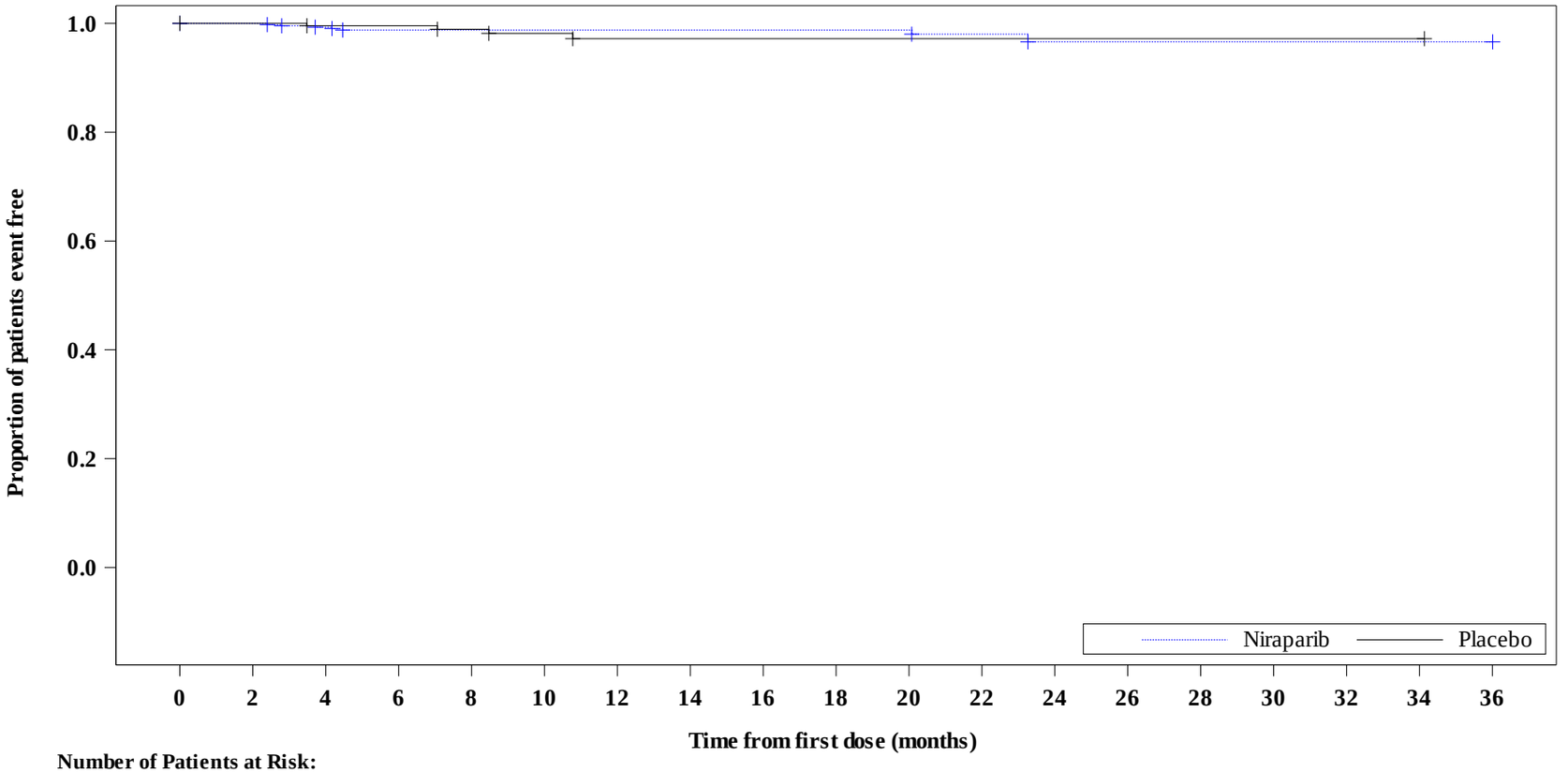



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 388 | 355 | 296 | 264 | 246 | 224 | 190 | 167 | 128 | 90 | 62 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 182 | 144 | 106 | 95 | 82 | 70 | 61 | 51 | 30 | 16 | 10 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Herpes zoster

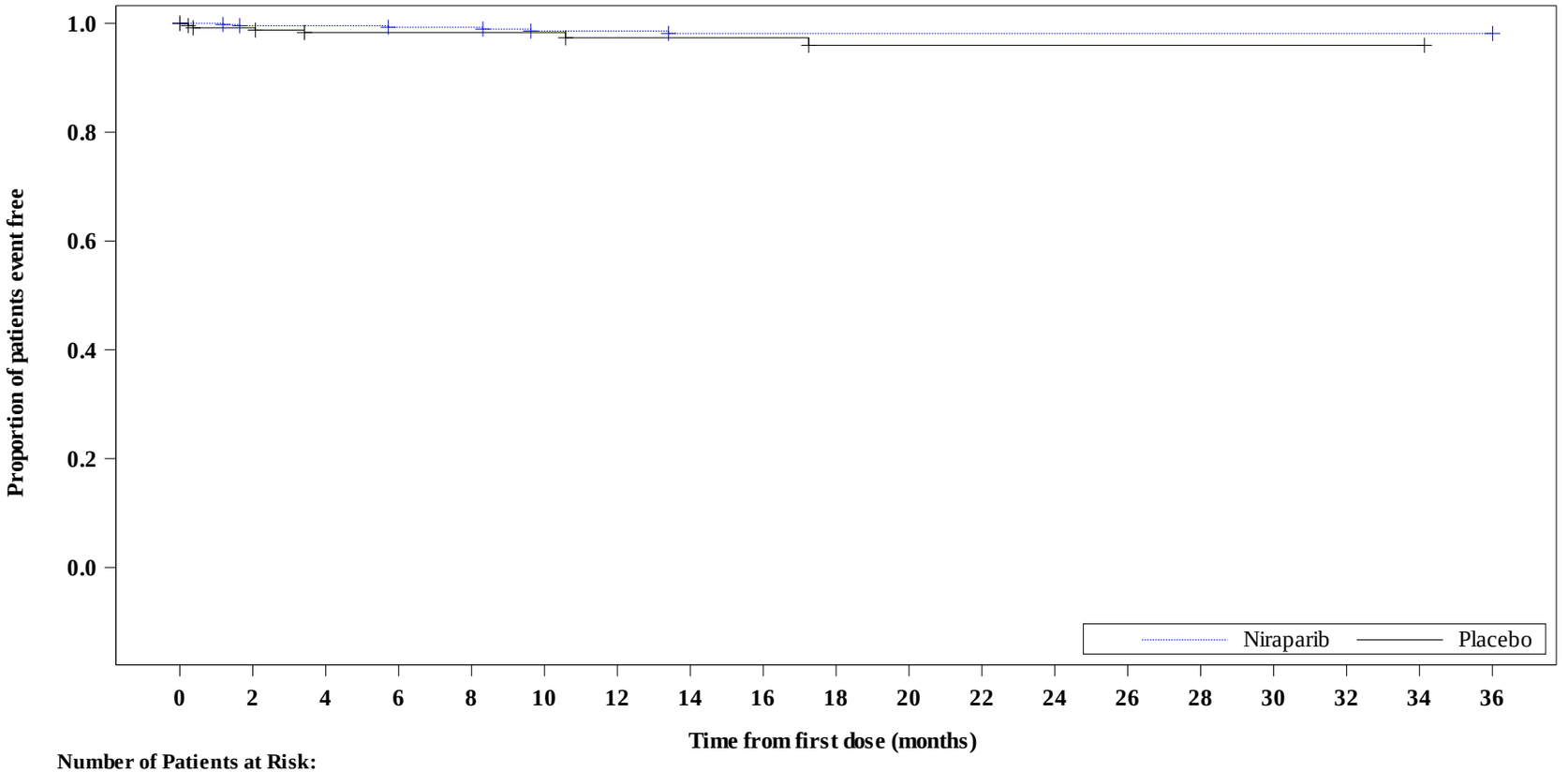



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 388 | 353 | 295 | 262 | 245 | 223 | 191 | 168 | 129 | 90 | 60 | 34 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 204 | 182 | 144 | 106 | 94 | 83 | 71 | 63 | 52 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Influenza

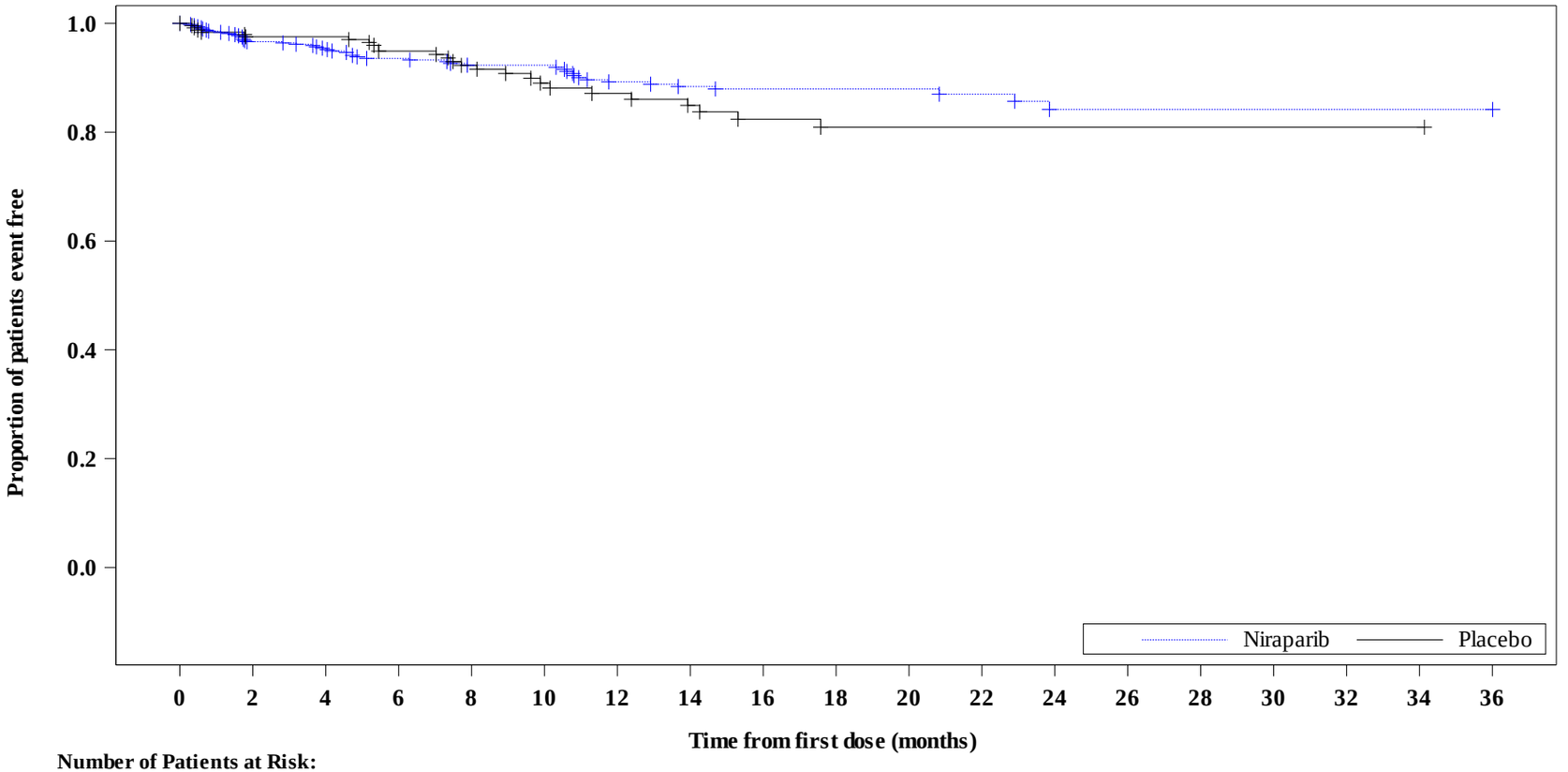



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 389 | 355 | 297 | 262 | 245 | 221 | 187 | 165 | 126 | 89 | 62 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 202 | 180 | 143 | 106 | 94 | 83 | 71 | 63 | 52 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Nasopharyngitis




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 437 | 373 | 332 | 274 | 248 | 225 | 203 | 172 | 150 | 114 | 76 | 51 | 31 | 18 | 9 | 8 | 5 | 1 |
| Placebo | 244 | 235 | 199 | 174 | 135 | 98 | 85 | 73 | 60 | 50 | 41 | 26 | 11 | 7 | 4 | 3 | 2 | 1 | 0 |

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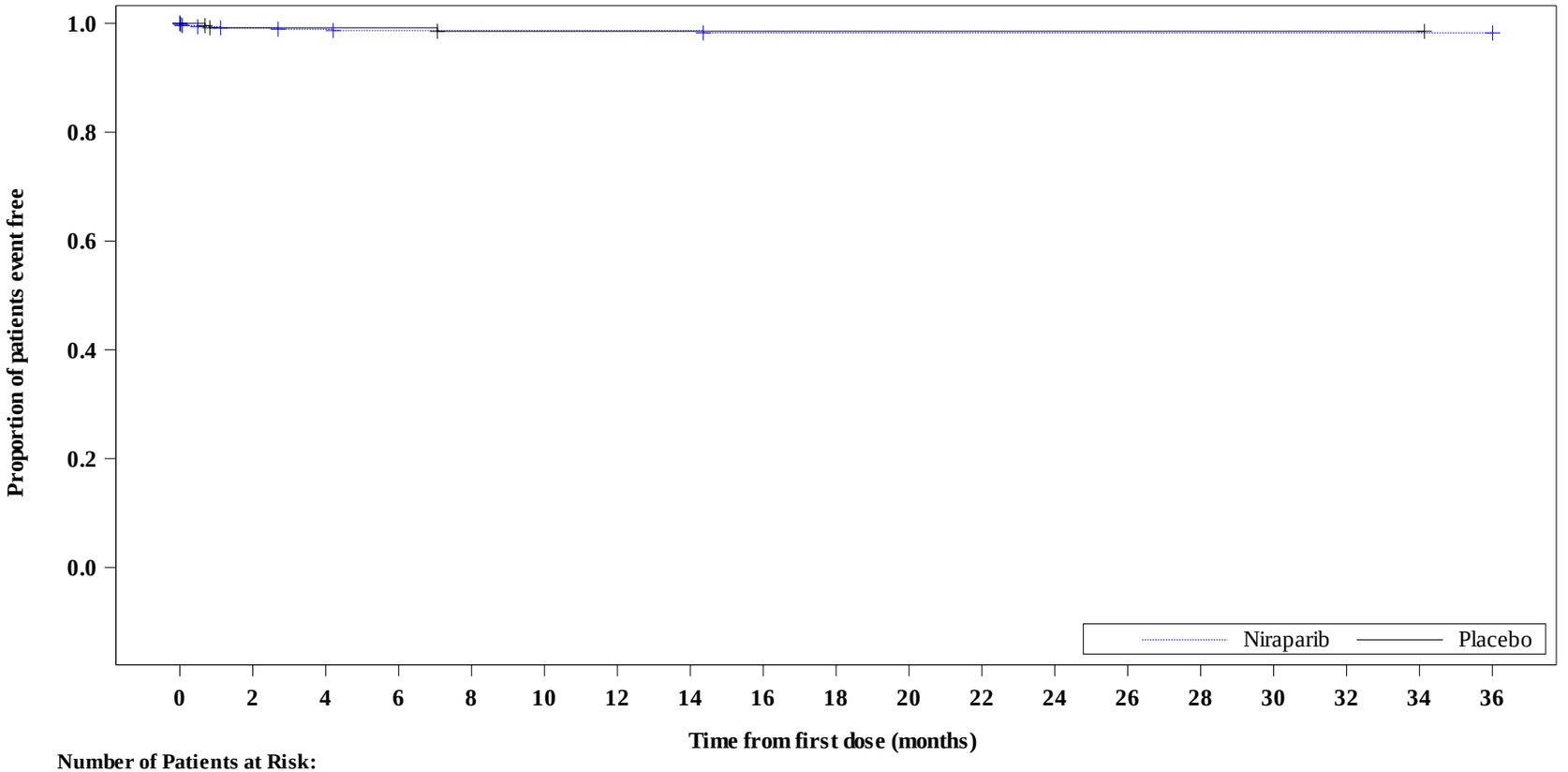
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Oral herpes

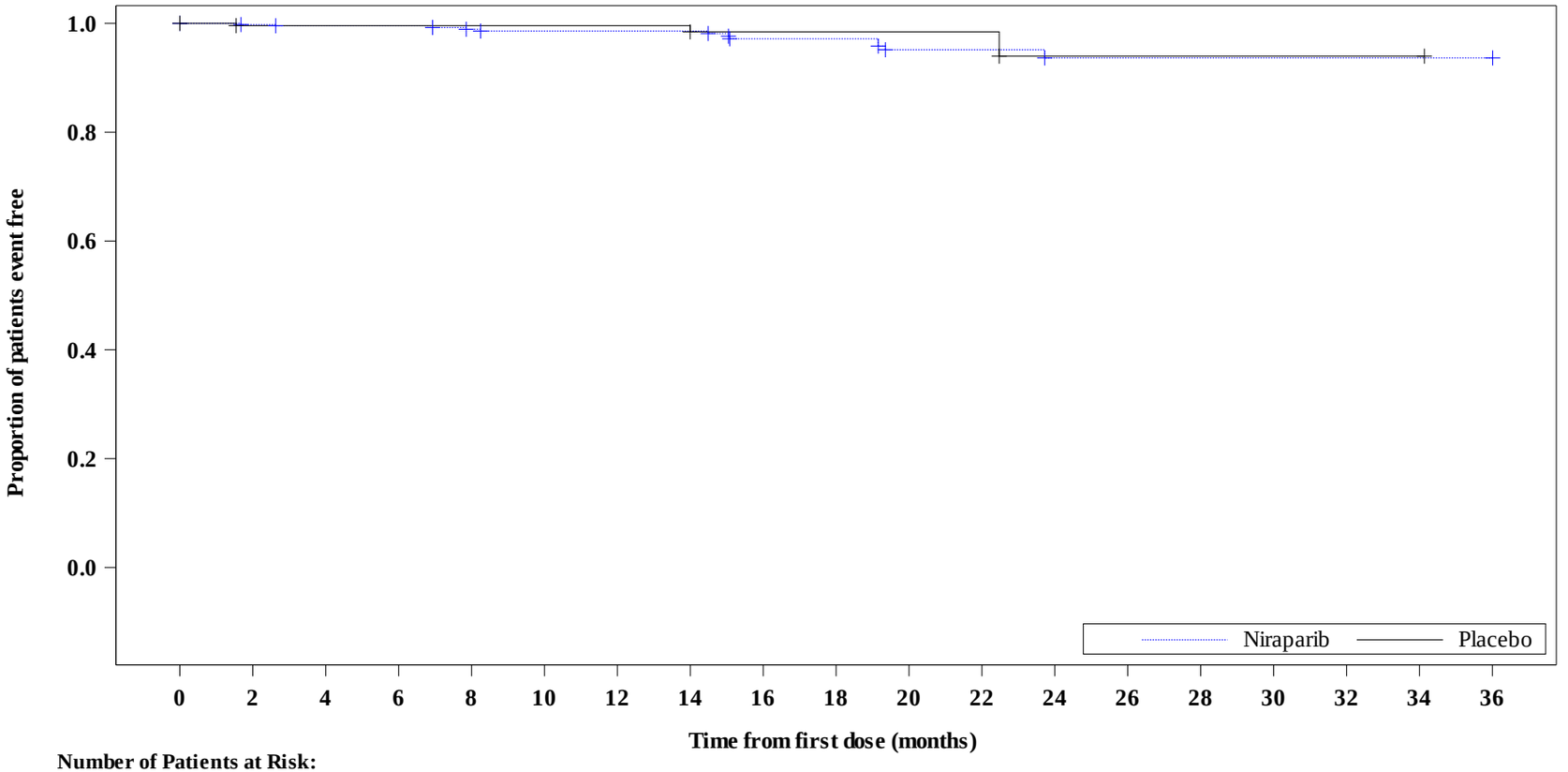



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 386 | 351 | 293 | 261 | 244 | 222 | 187 | 165 | 126 | 89 | 61 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 181 | 143 | 107 | 96 | 84 | 72 | 63 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Pneumonia

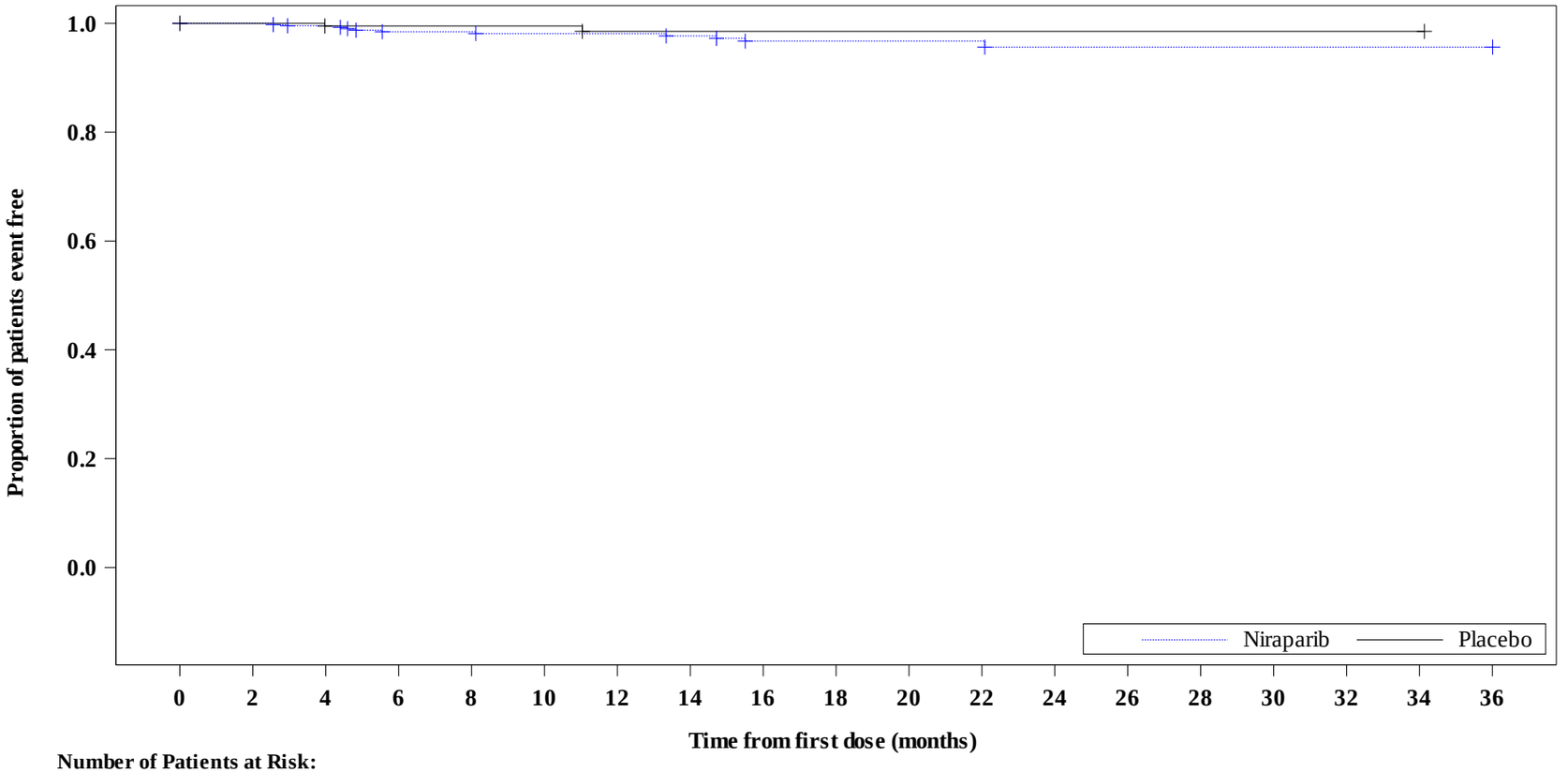



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 389 | 355 | 297 | 263 | 246 | 224 | 187 | 164 | 122 | 85 | 57 | 31 | 18 | 10 | 8 | 5 | 1 |
| Placebo | 244 | 240 | 205 | 183 | 146 | 109 | 98 | 85 | 73 | 64 | 53 | 32 | 16 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Rhinitis

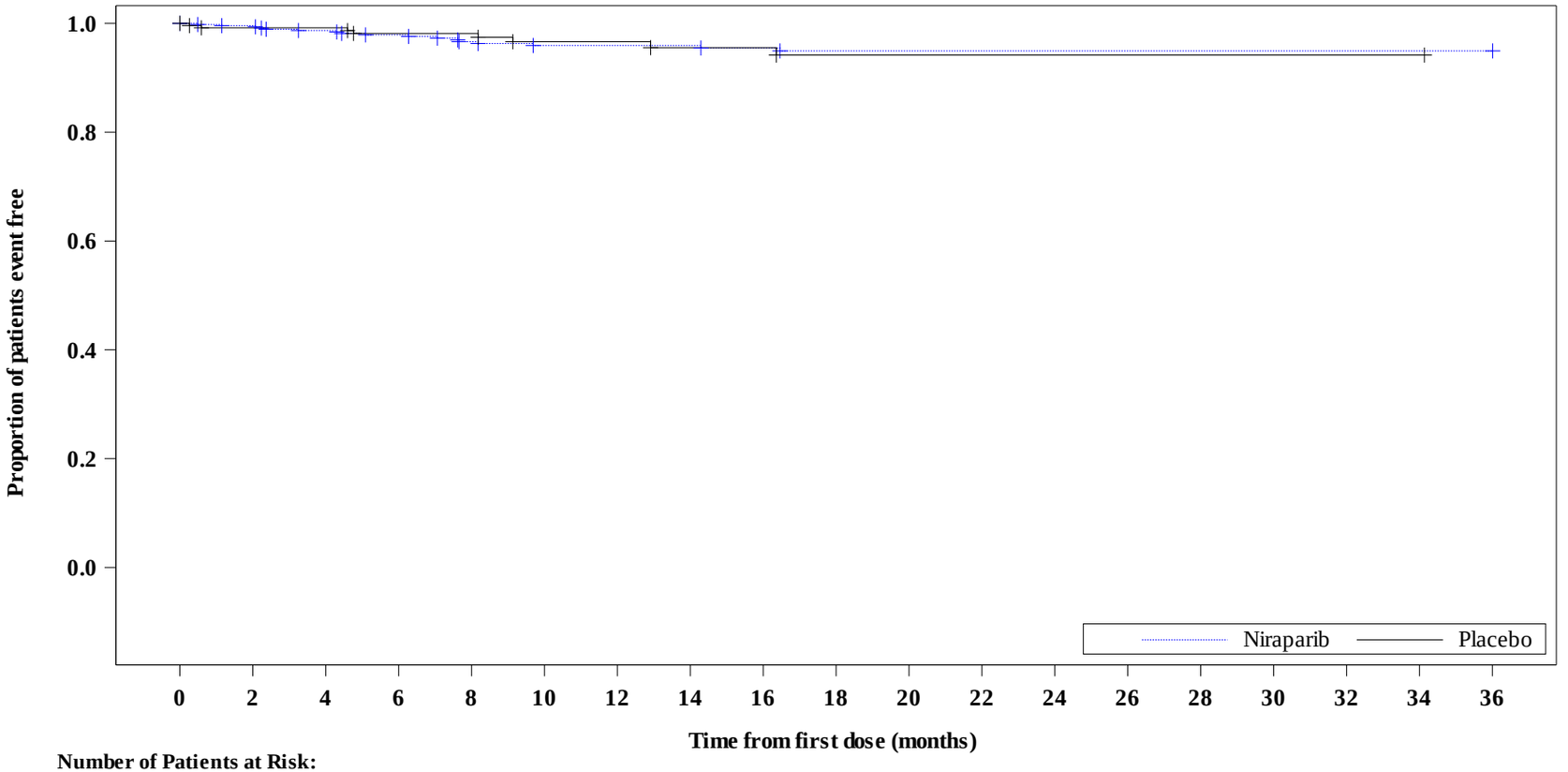



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 389 | 352 | 294 | 262 | 245 | 221 | 185 | 162 | 124 | 88 | 59 | 32 | 20 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 204 | 182 | 146 | 109 | 97 | 85 | 73 | 64 | 53 | 32 | 17 | 11 | 6 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Sinusitis

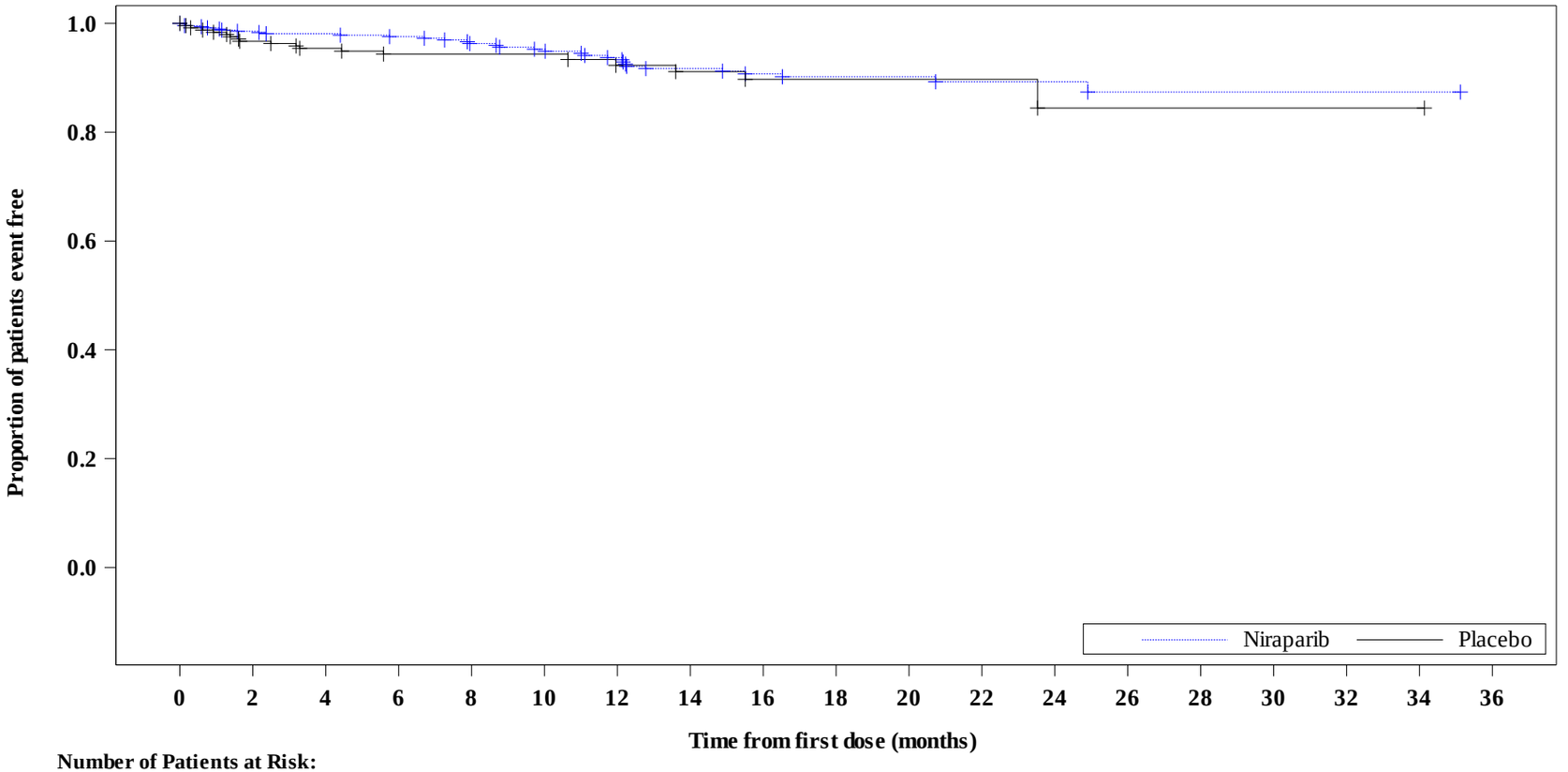



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 385 | 349 | 288 | 254 | 238 | 215 | 180 | 159 | 121 | 85 | 59 | 33 | 21 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 179 | 142 | 103 | 93 | 81 | 70 | 62 | 51 | 31 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Upper respiratory tract infection

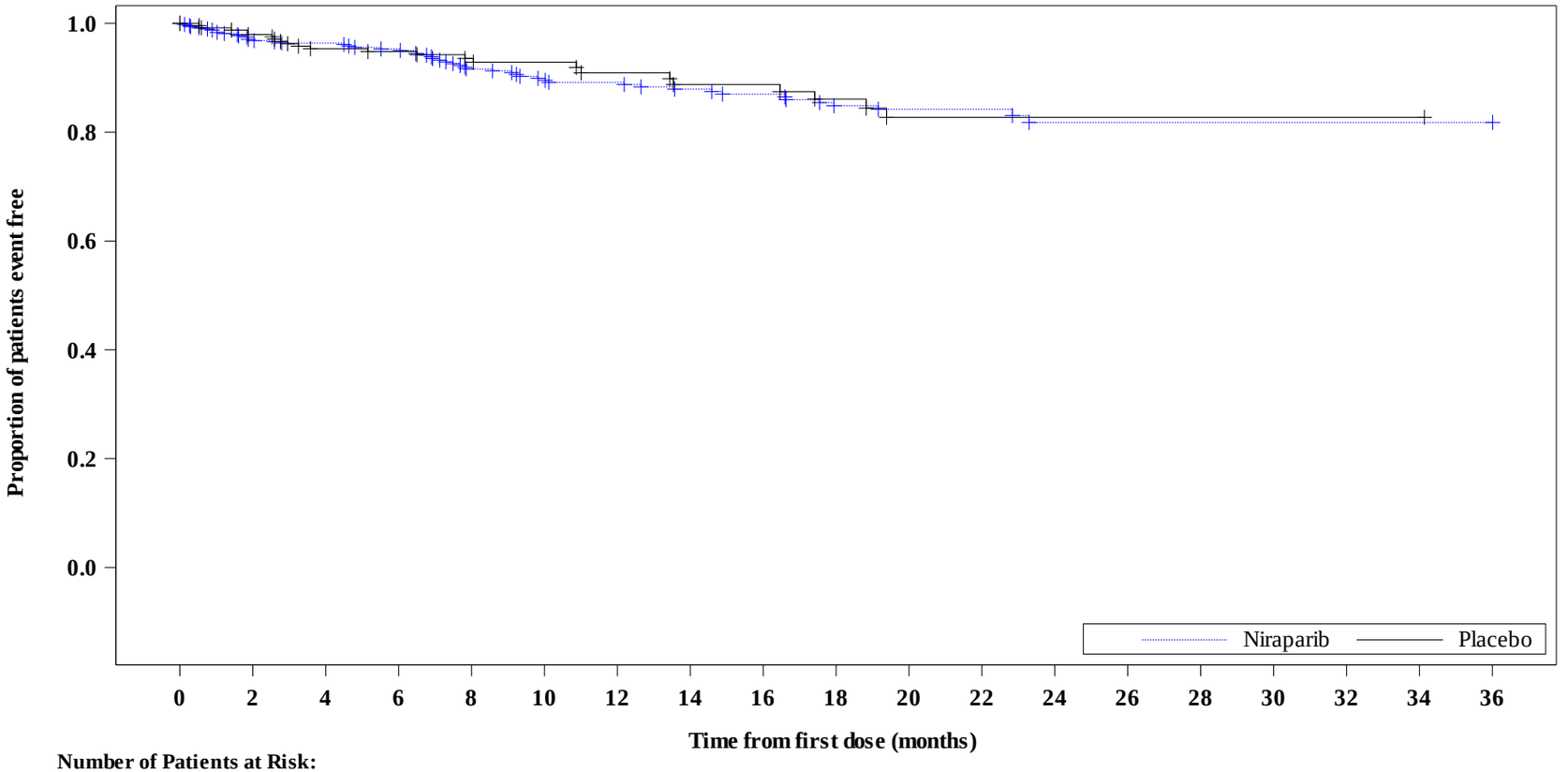



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 444 | 386 | 351 | 290 | 257 | 238 | 210 | 176 | 152 | 117 | 84 | 58 | 33 | 21 | 12 | 8 | 4 | 0 |
| Placebo | 244 | 233 | 195 | 171 | 135 | 99 | 86 | 73 | 63 | 54 | 46 | 27 | 16 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Infections and infestations, PT: Urinary tract infection

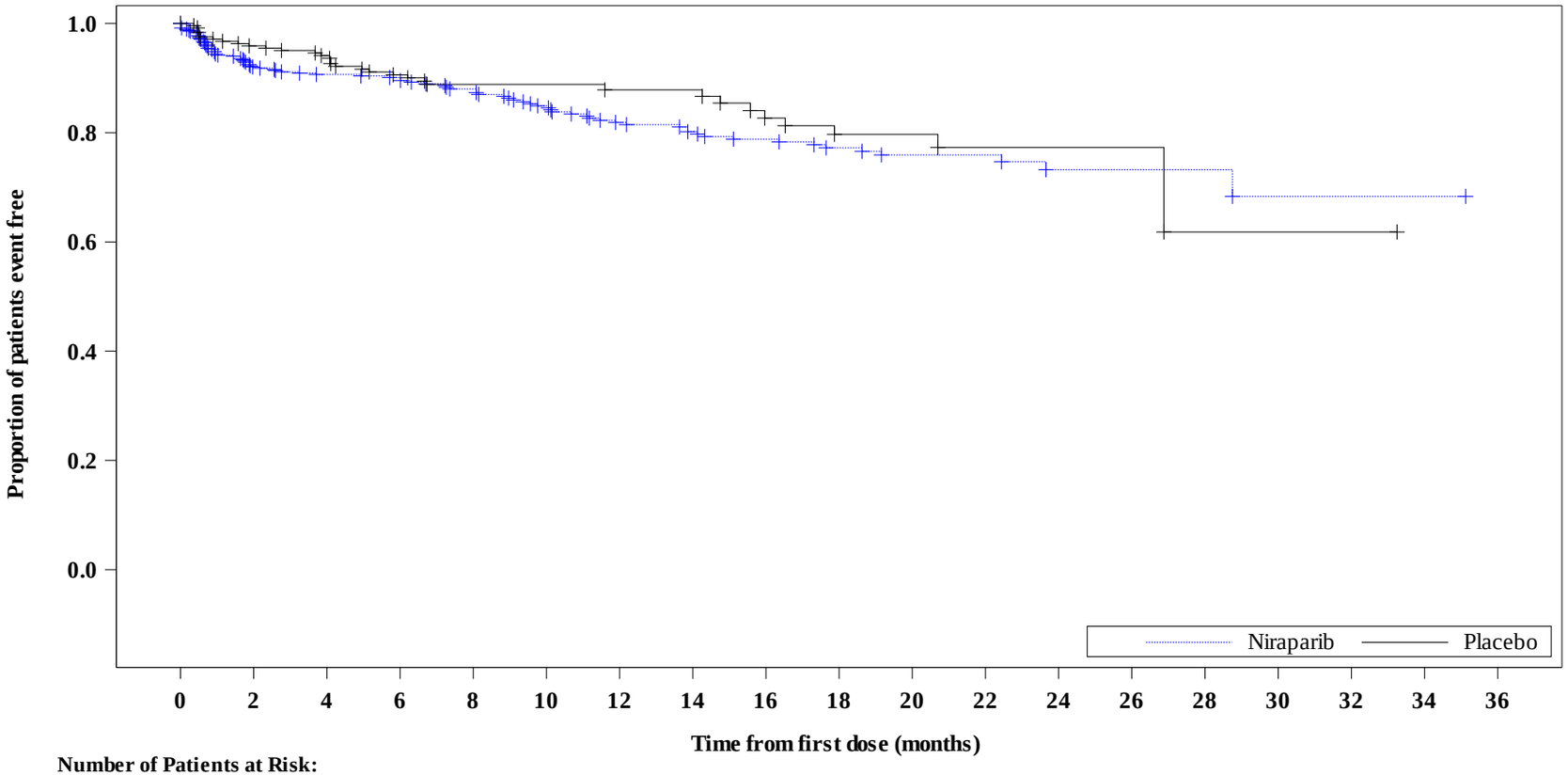



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 436 | 379 | 342 | 279 | 243 | 226 | 203 | 173 | 149 | 114 | 85 | 59 | 31 | 20 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 236 | 194 | 173 | 137 | 100 | 89 | 77 | 67 | 57 | 47 | 28 | 15 | 9 | 6 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Injury, poisoning and procedural complications

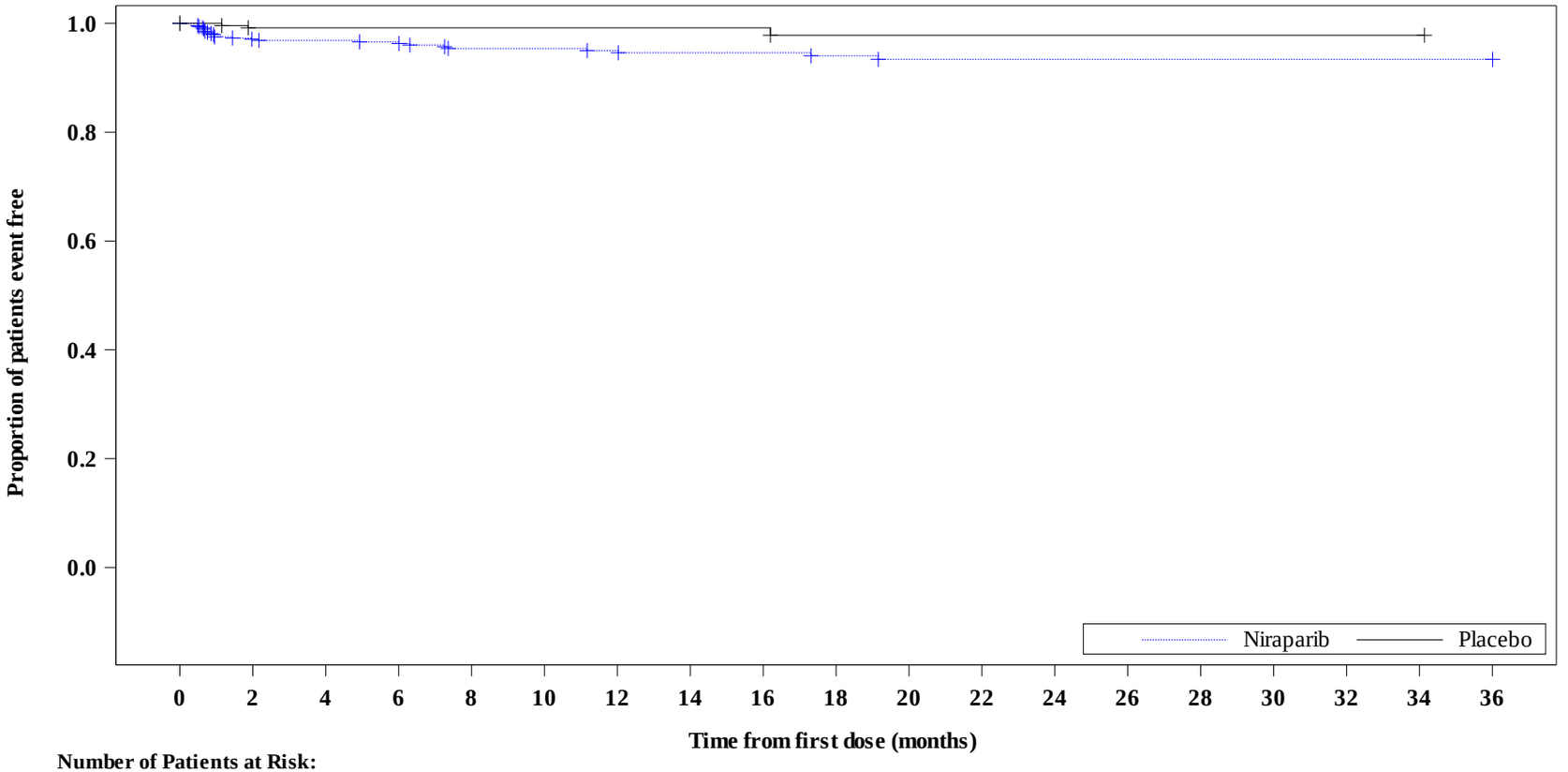



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 412 | 353 | 320 | 264 | 230 | 208 | 185 | 157 | 135 | 100 | 69 | 45 | 24 | 17 | 10 | 6 | 4 | 0 |
| Placebo | 244 | 231 | 193 | 169 | 132 | 97 | 86 | 75 | 60 | 50 | 41 | 23 | 12 | 9 | 4 | 2 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Injury, poisoning and procedural complications, PT: Contusion

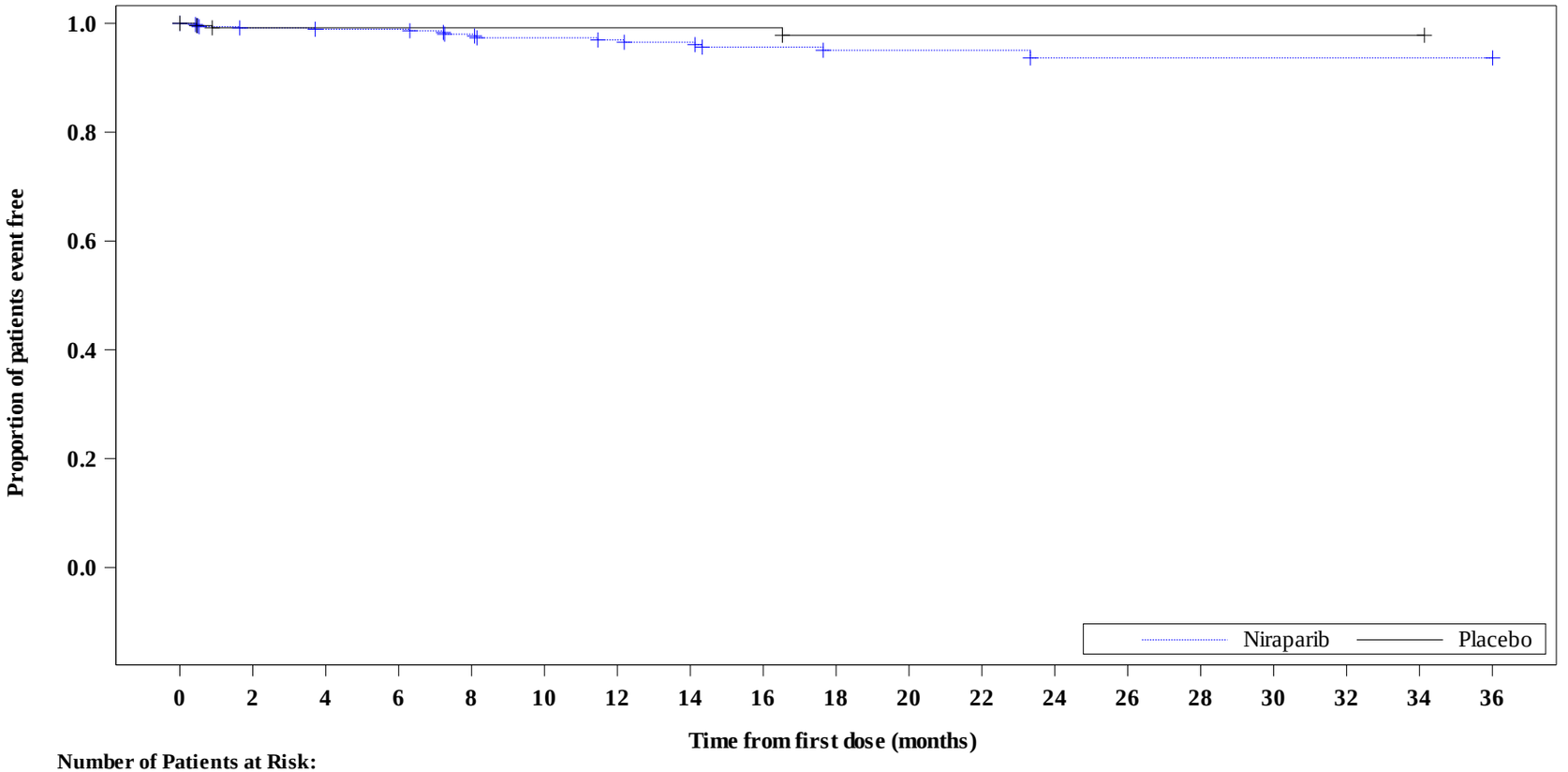



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 436 | 377 | 342 | 283 | 255 | 237 | 215 | 184 | 161 | 121 | 84 | 57 | 32 | 20 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 181 | 144 | 108 | 97 | 85 | 73 | 63 | 52 | 31 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Injury, poisoning and procedural complications, PT: Fall

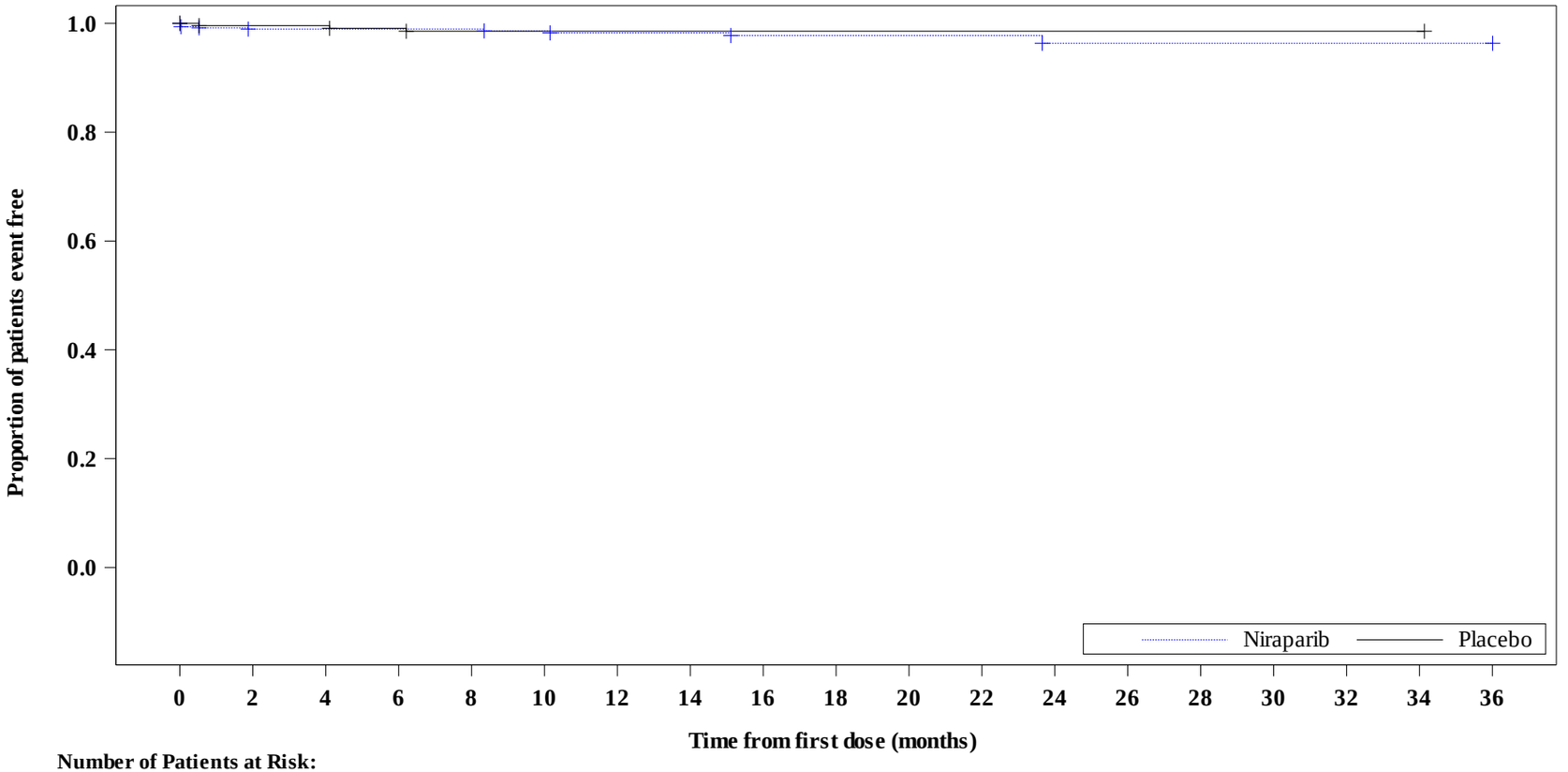



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 387 | 353 | 293 | 258 | 240 | 216 | 182 | 160 | 123 | 88 | 58 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 181 | 145 | 108 | 97 | 85 | 73 | 64 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Injury, poisoning and procedural complications, PT: Overdose

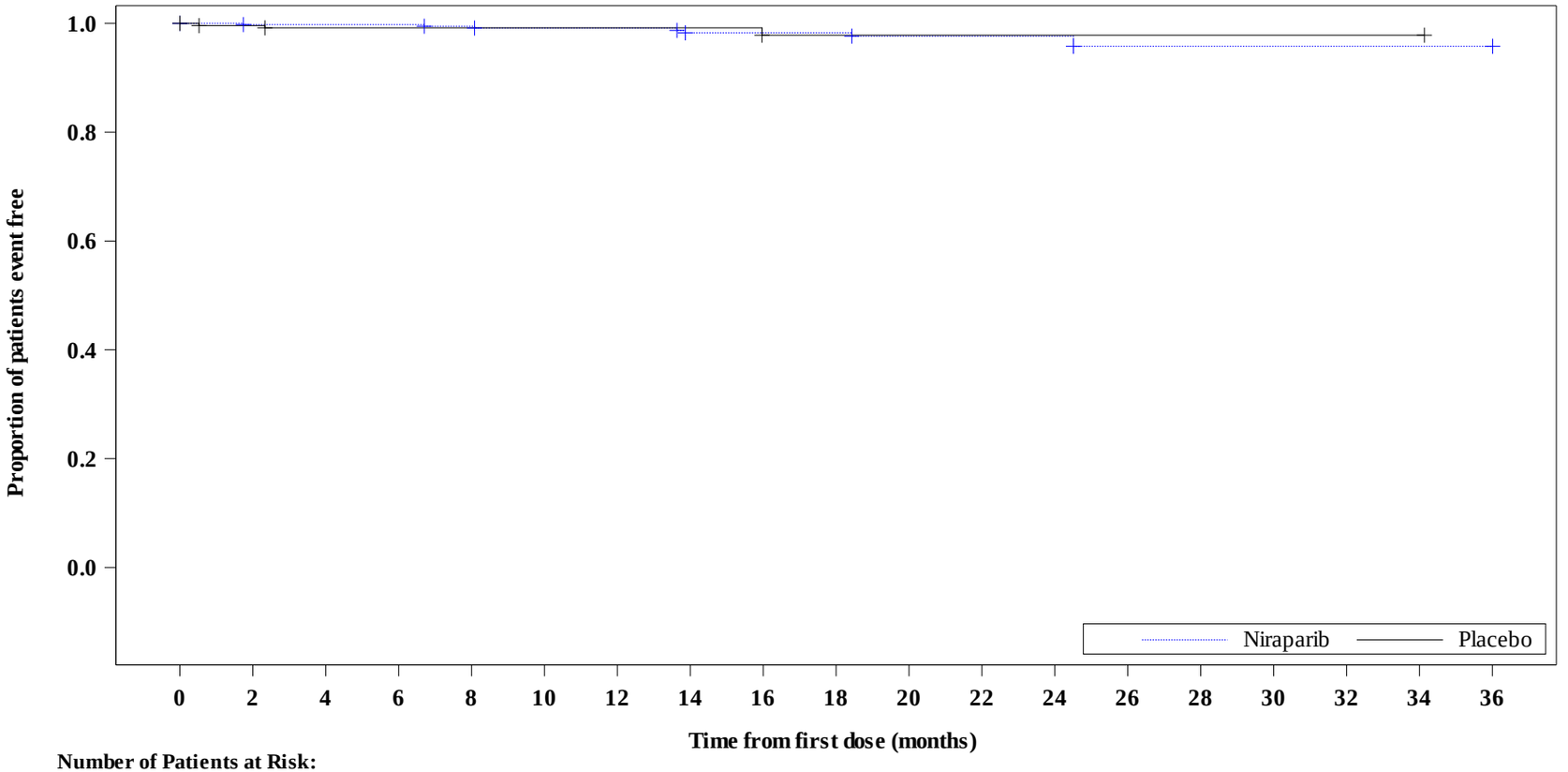



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 445 | 386 | 353 | 297 | 264 | 247 | 224 | 189 | 166 | 129 | 91 | 61 | 33 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 107 | 97 | 85 | 73 | 64 | 53 | 32 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Injury, poisoning and procedural complications, PT: Procedural pain

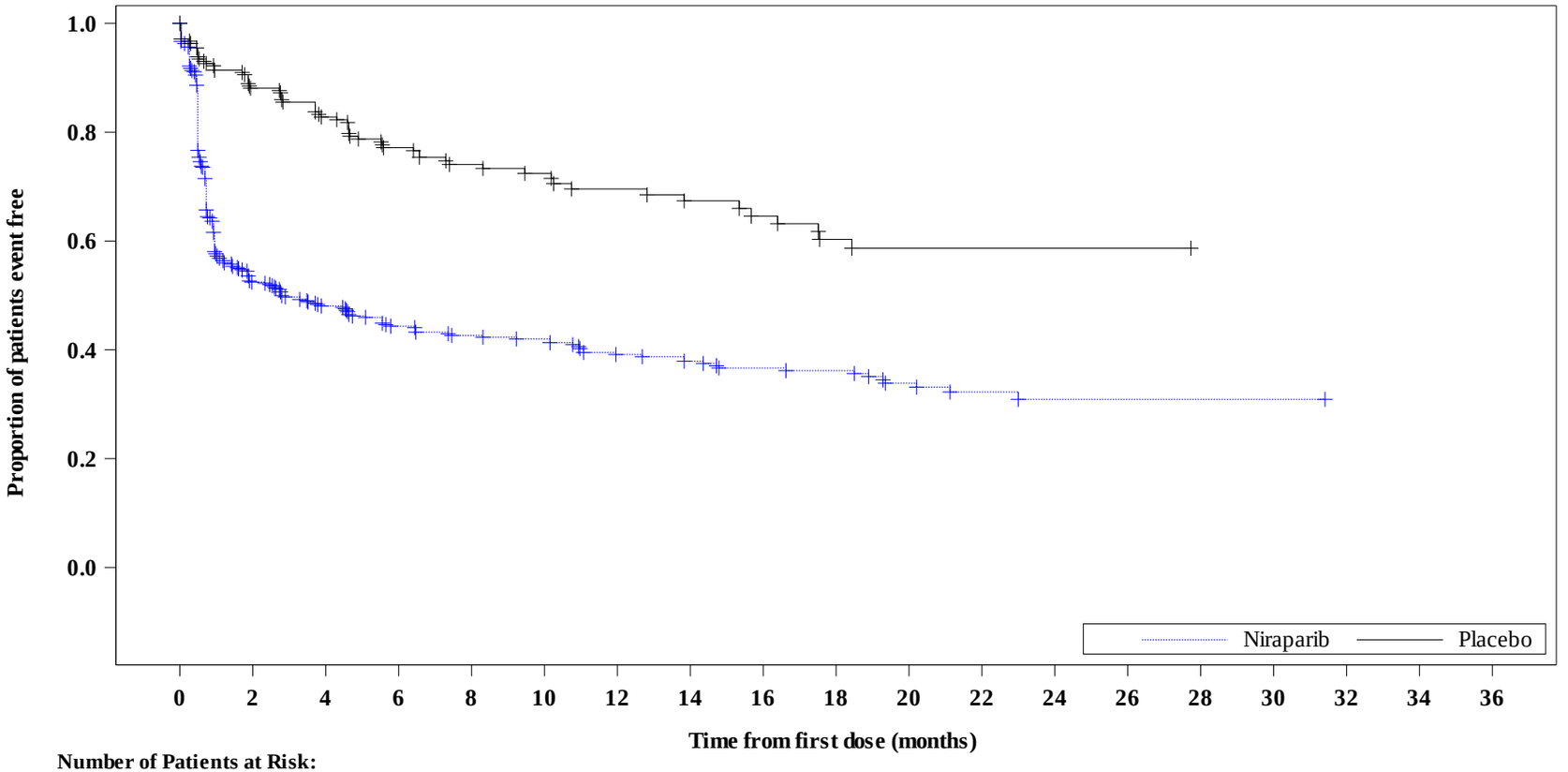



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 390 | 356 | 297 | 264 | 247 | 222 | 189 | 166 | 127 | 90 | 62 | 33 | 21 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 240 | 205 | 183 | 146 | 109 | 98 | 86 | 73 | 64 | 53 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 231 | 190 | 164 | 136 | 121 | 105 | 91 | 79 | 70 | 46 | 29 | 18 | 9 | 4 | 2 | 0 |
| Placebo | 244 | 212 | 172 | 141 | 107 | 78 | 67 | 56 | 46 | 37 | 29 | 17 | 7 | 2 | 0 | | |

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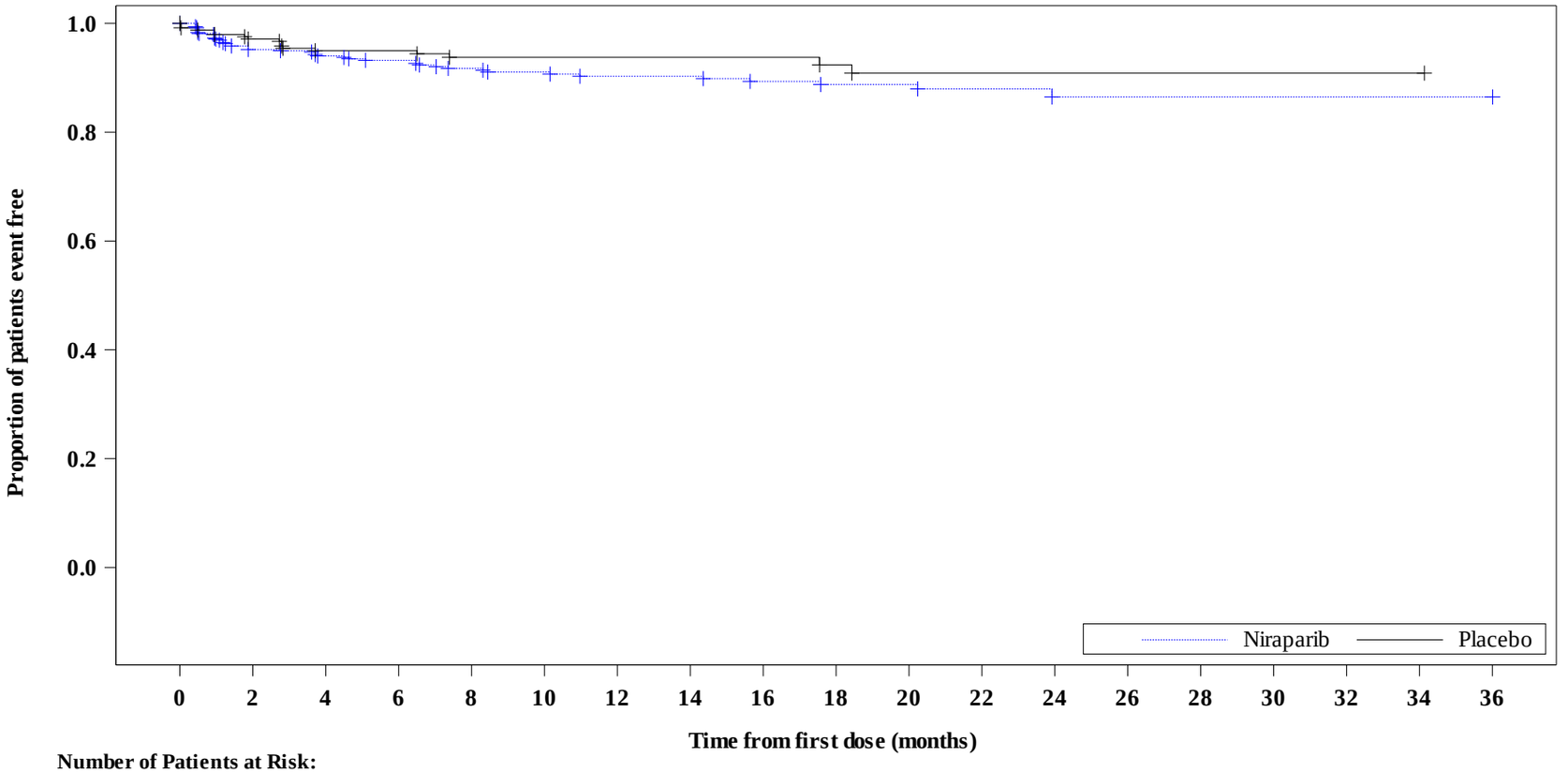
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Alanine aminotransferase increased

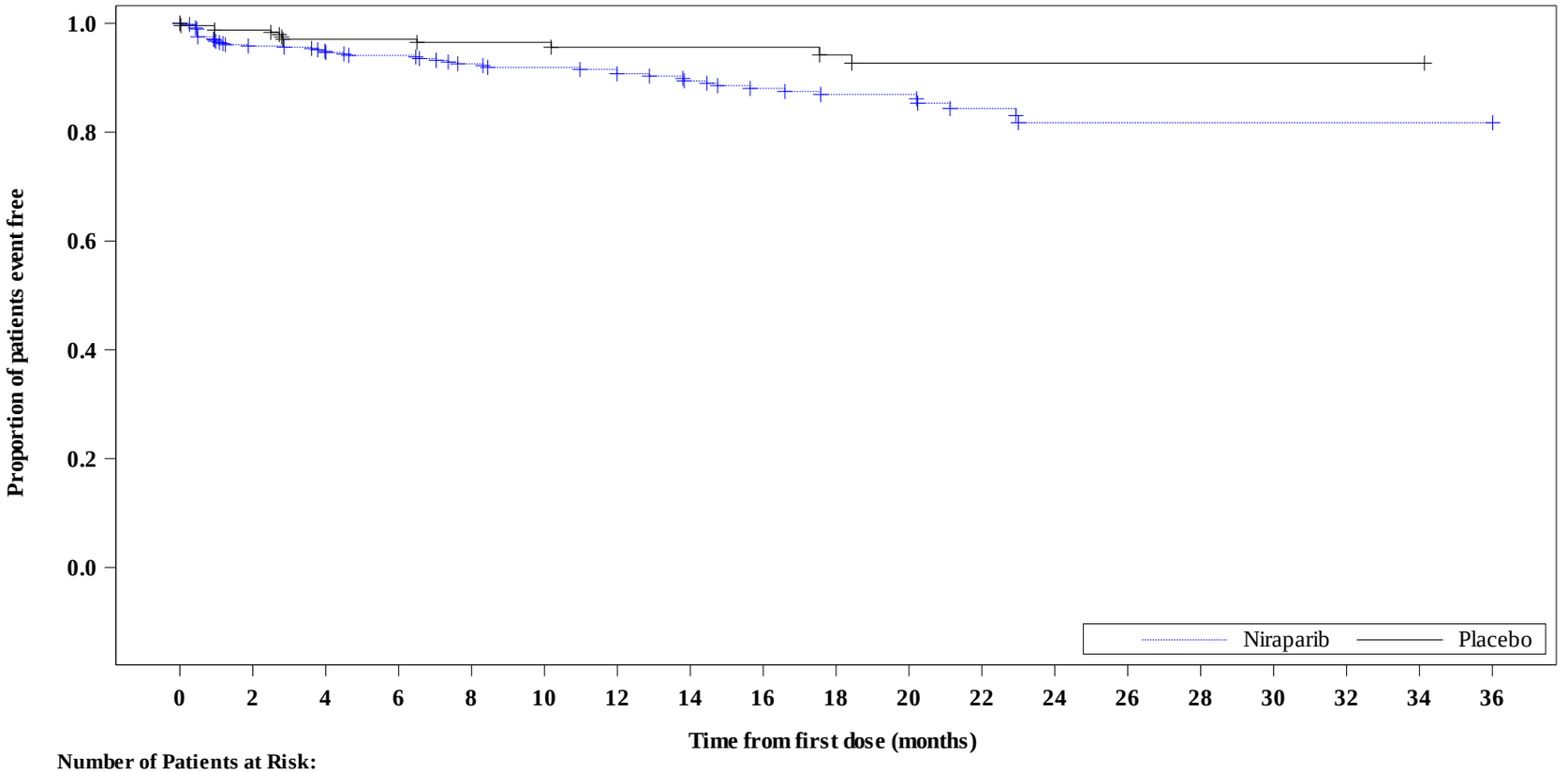



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 429 | 369 | 336 | 276 | 243 | 224 | 206 | 171 | 149 | 113 | 81 | 55 | 29 | 18 | 11 | 7 | 4 | 1 |
| Placebo | 244 | 234 | 197 | 176 | 138 | 102 | 91 | 80 | 70 | 61 | 50 | 30 | 15 | 10 | 5 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Aspartate aminotransferase increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 431 | 373 | 340 | 279 | 247 | 227 | 205 | 169 | 147 | 110 | 76 | 52 | 29 | 18 | 10 | 6 | 4 | 1 |
| Placebo | 244 | 238 | 201 | 180 | 143 | 106 | 94 | 82 | 72 | 62 | 52 | 31 | 16 | 11 | 6 | 3 | 2 | 1 | 0 |

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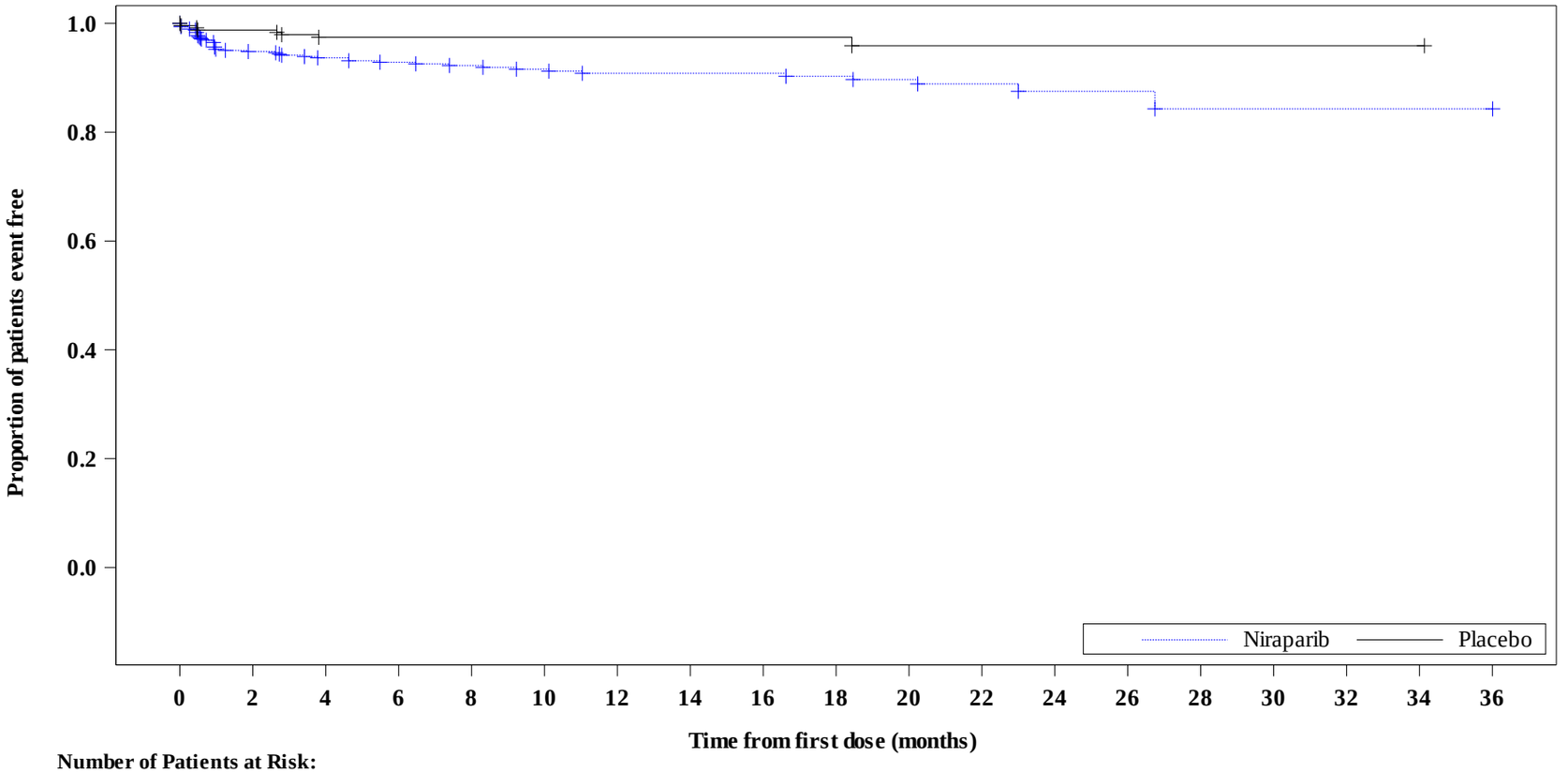
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Blood alkaline phosphatase increased

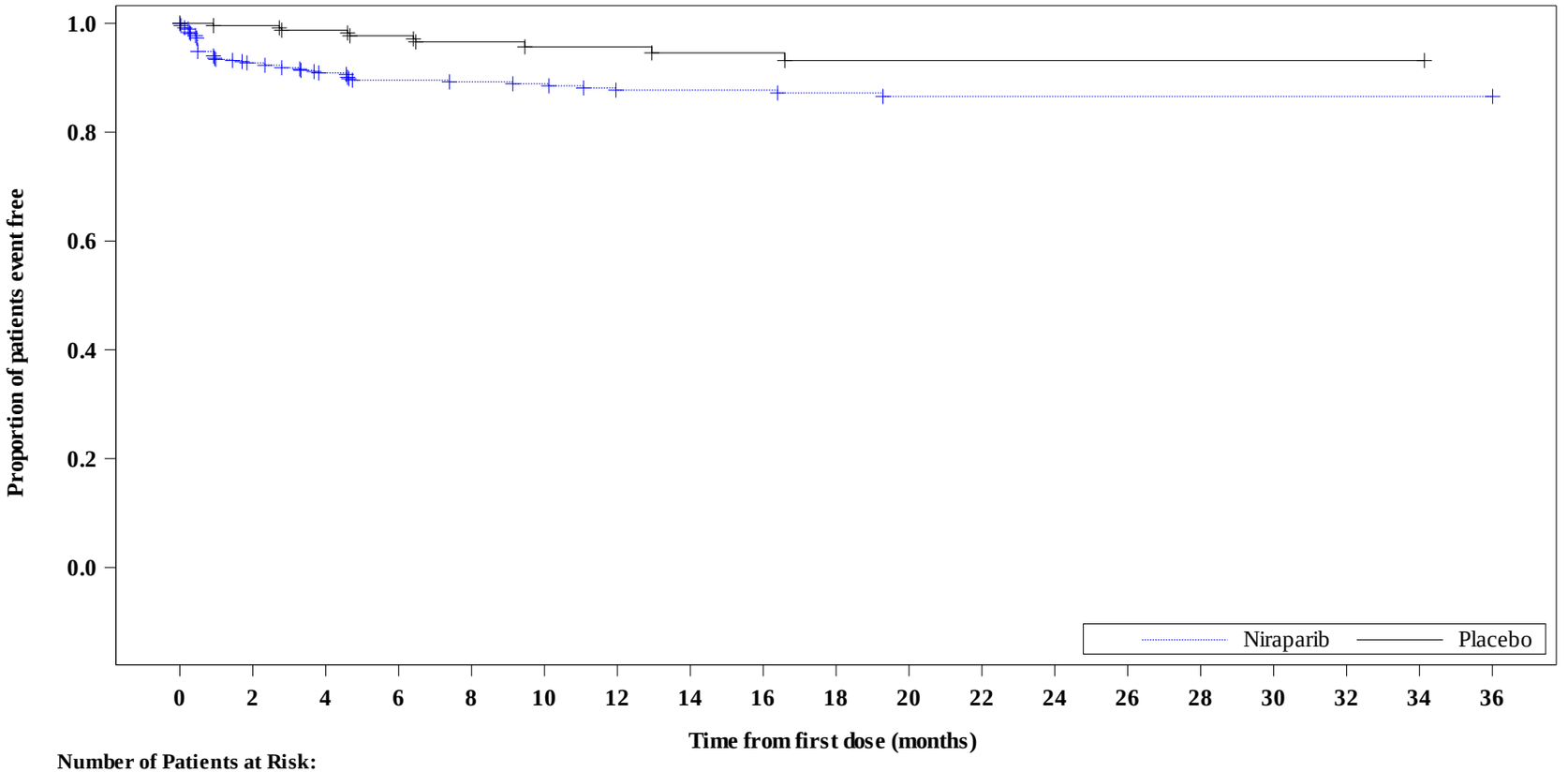



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 425 | 369 | 336 | 279 | 246 | 228 | 207 | 175 | 151 | 113 | 77 | 51 | 28 | 17 | 9 | 6 | 4 | 1 |
| Placebo | 244 | 238 | 200 | 179 | 143 | 106 | 95 | 83 | 71 | 63 | 51 | 31 | 16 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Blood creatinine increased

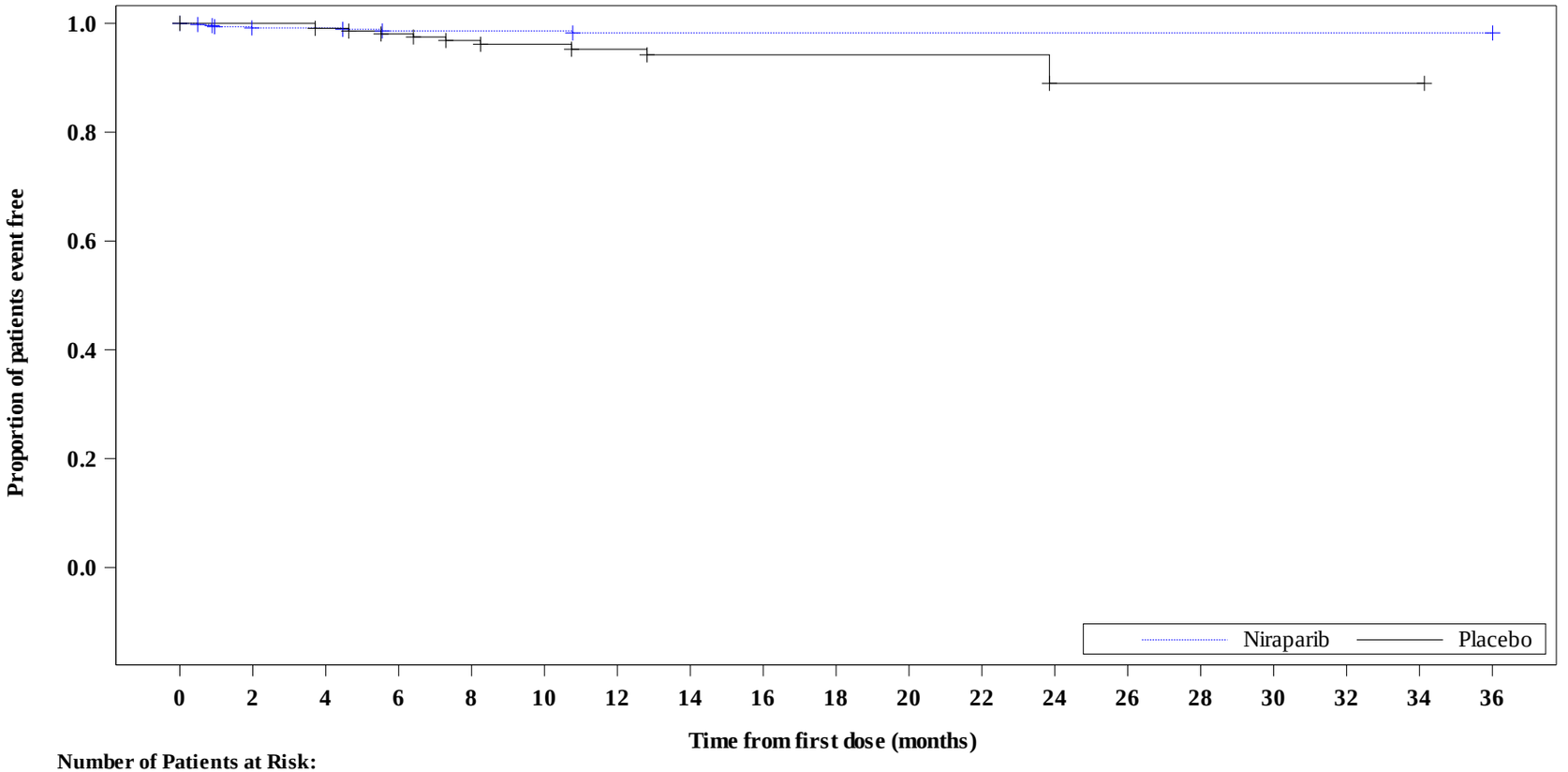



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 417 | 355 | 321 | 266 | 238 | 218 | 198 | 173 | 153 | 115 | 81 | 54 | 30 | 19 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 202 | 178 | 139 | 102 | 91 | 79 | 67 | 58 | 48 | 30 | 16 | 10 | 6 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Carbohydrate antigen 125 increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 389 | 353 | 298 | 266 | 248 | 225 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 203 | 179 | 144 | 109 | 98 | 85 | 74 | 65 | 54 | 33 | 17 | 11 | 6 | 2 | 2 | 1 | 0 |

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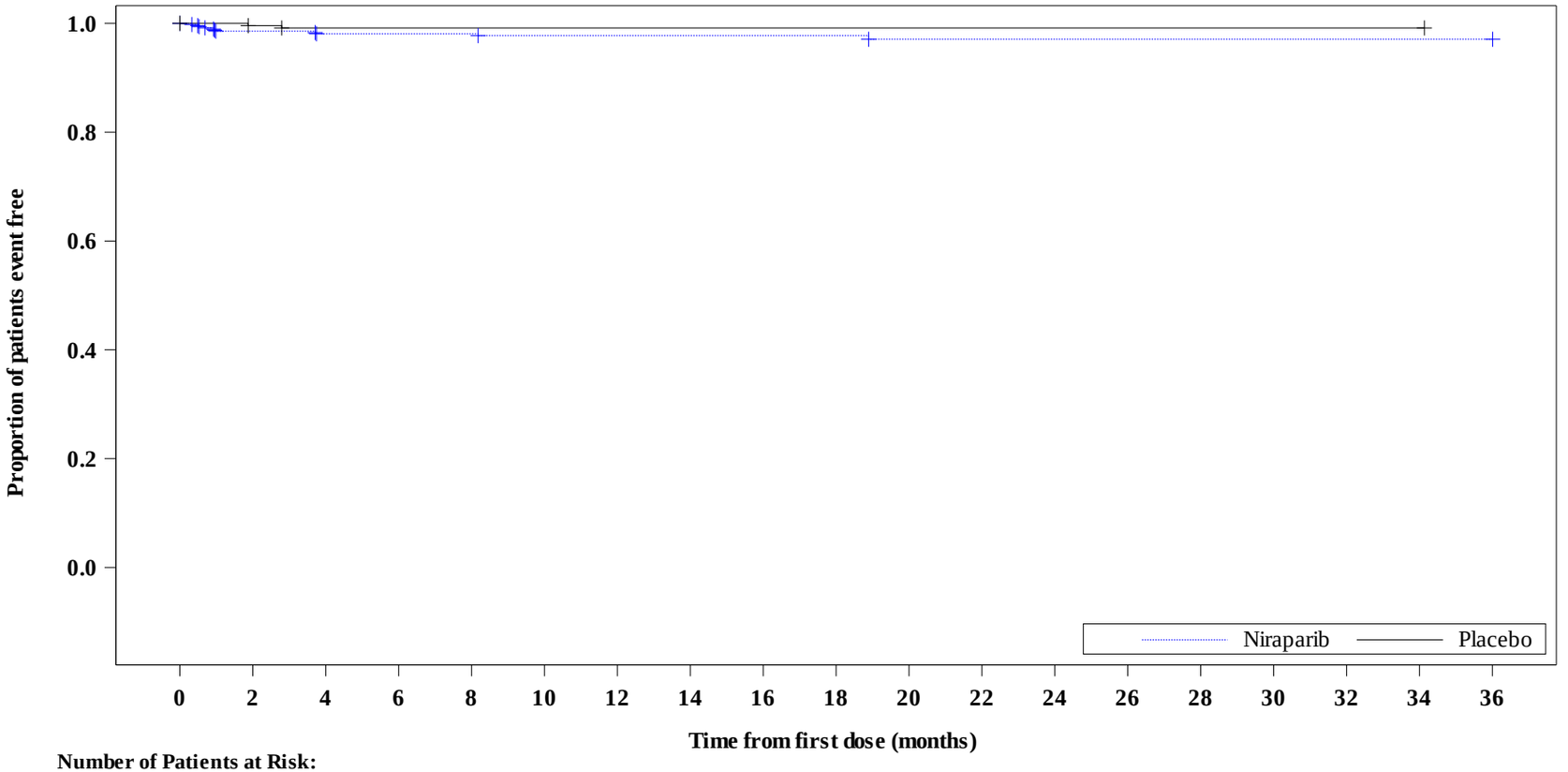
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Gamma-glutamyltransferase increased

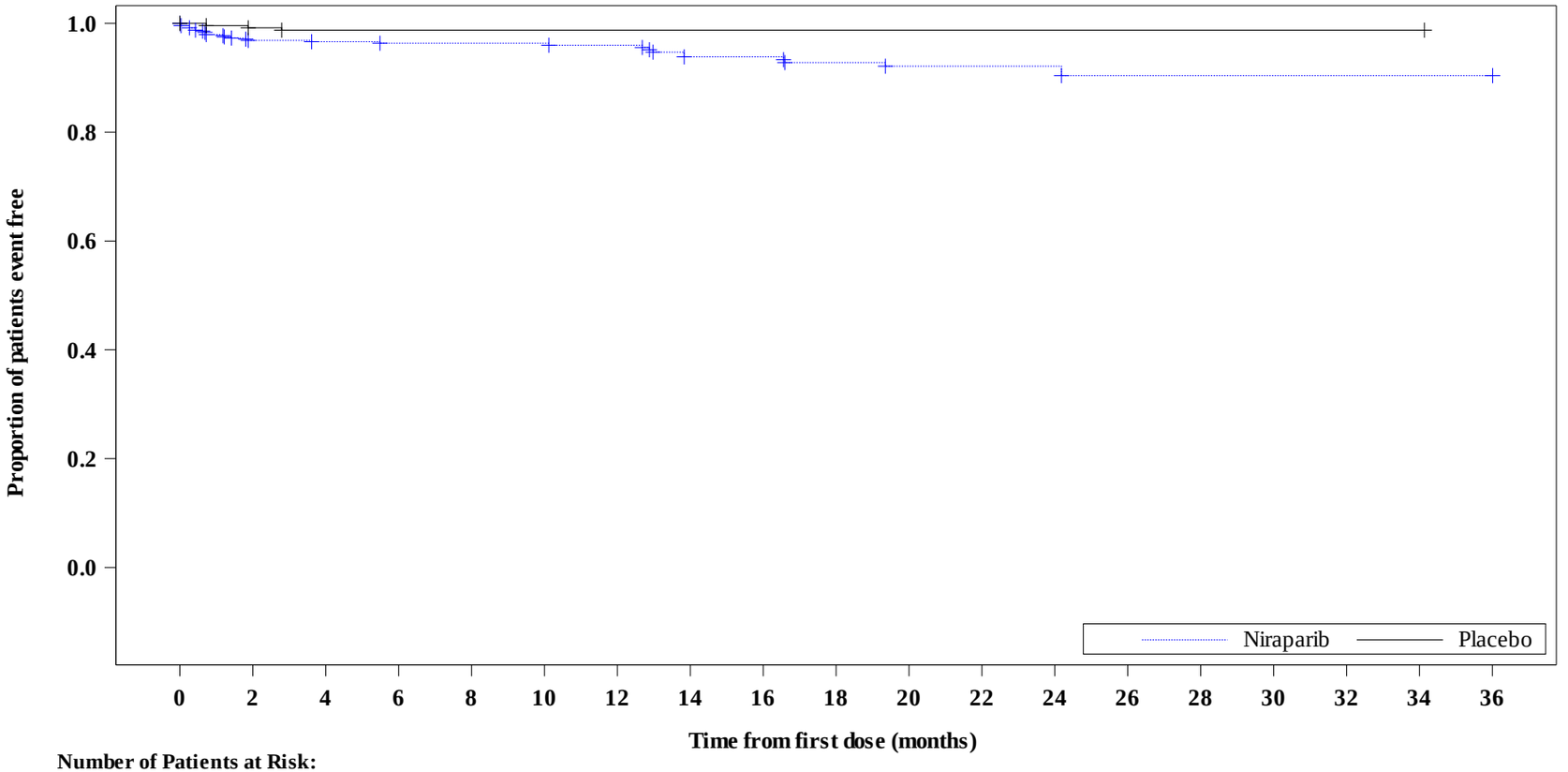



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 444 | 385 | 351 | 294 | 261 | 244 | 222 | 188 | 165 | 125 | 88 | 61 | 34 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 182 | 145 | 108 | 97 | 85 | 73 | 64 | 53 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Lymphocyte count decreased

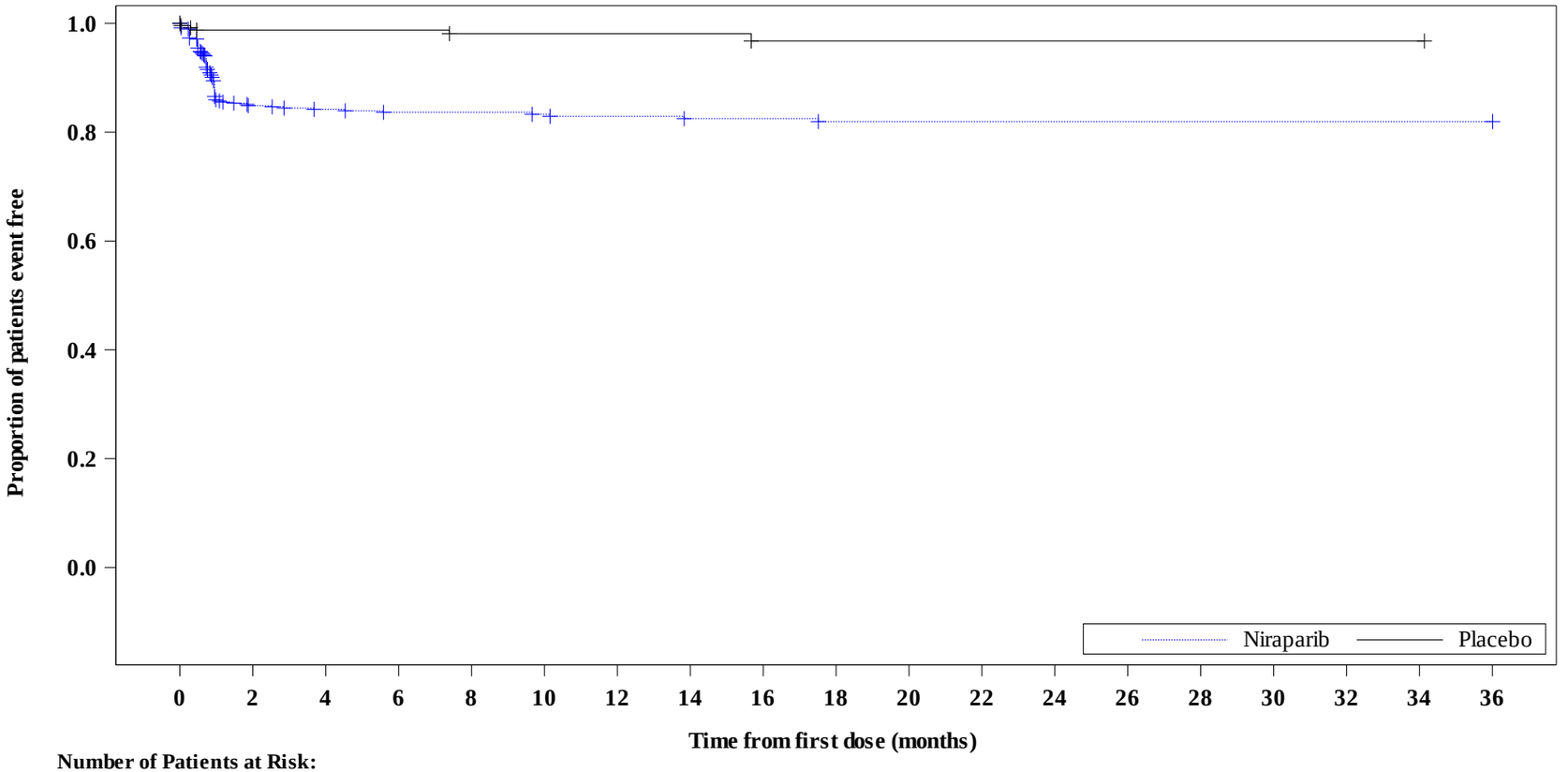



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 437 | 379 | 346 | 290 | 259 | 241 | 215 | 184 | 161 | 122 | 88 | 61 | 34 | 21 | 12 | 8 | 4 | 1 |
| Placebo | 244 | 239 | 204 | 182 | 145 | 108 | 97 | 85 | 73 | 64 | 53 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Neutrophil count decreased

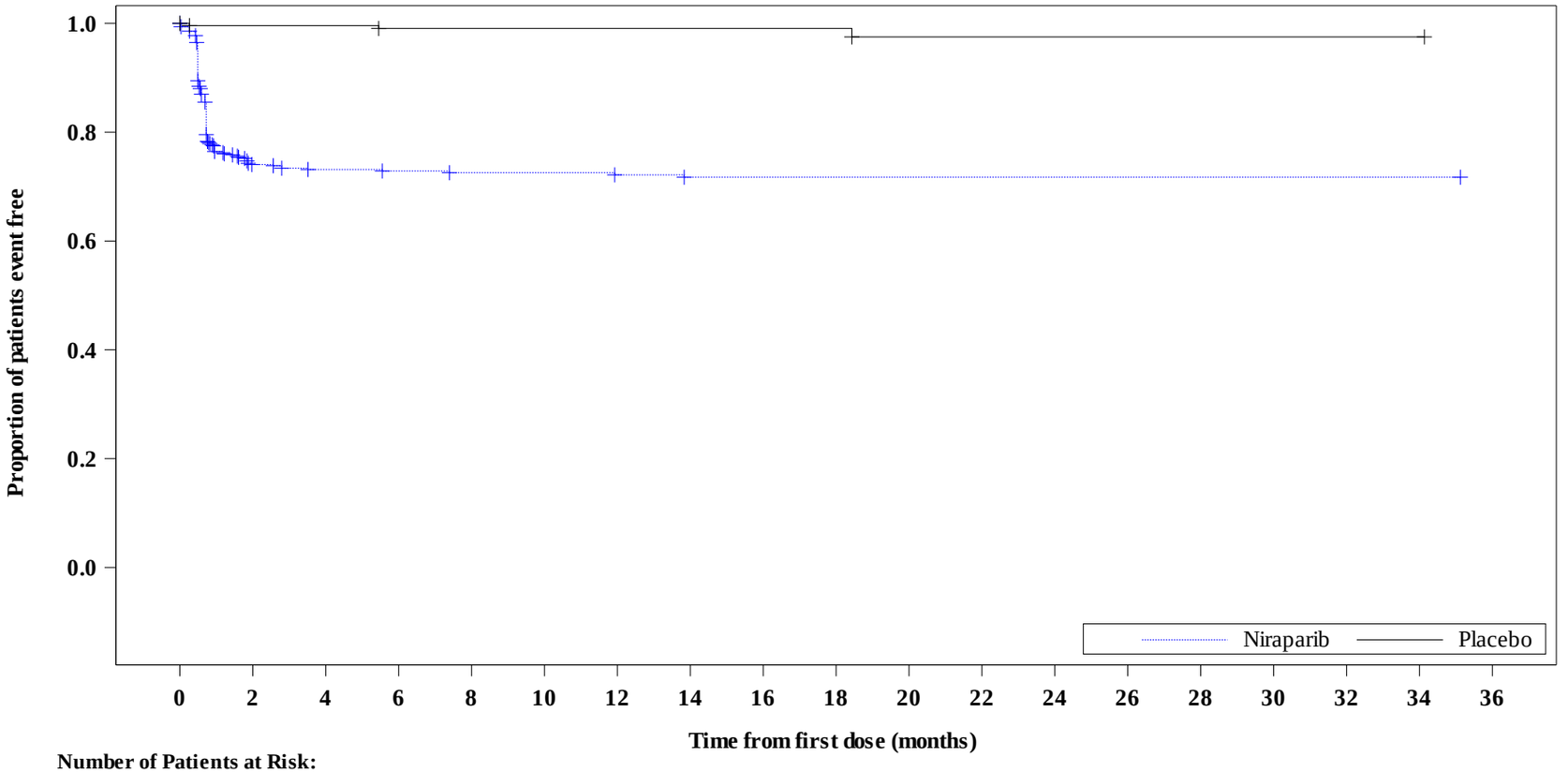



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 382 | 330 | 302 | 253 | 225 | 208 | 191 | 163 | 144 | 107 | 74 | 49 | 25 | 14 | 10 | 6 | 3 | 1 |
| Placebo | 244 | 238 | 202 | 180 | 142 | 105 | 94 | 83 | 71 | 62 | 51 | 31 | 17 | 11 | 6 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Platelet count decreased

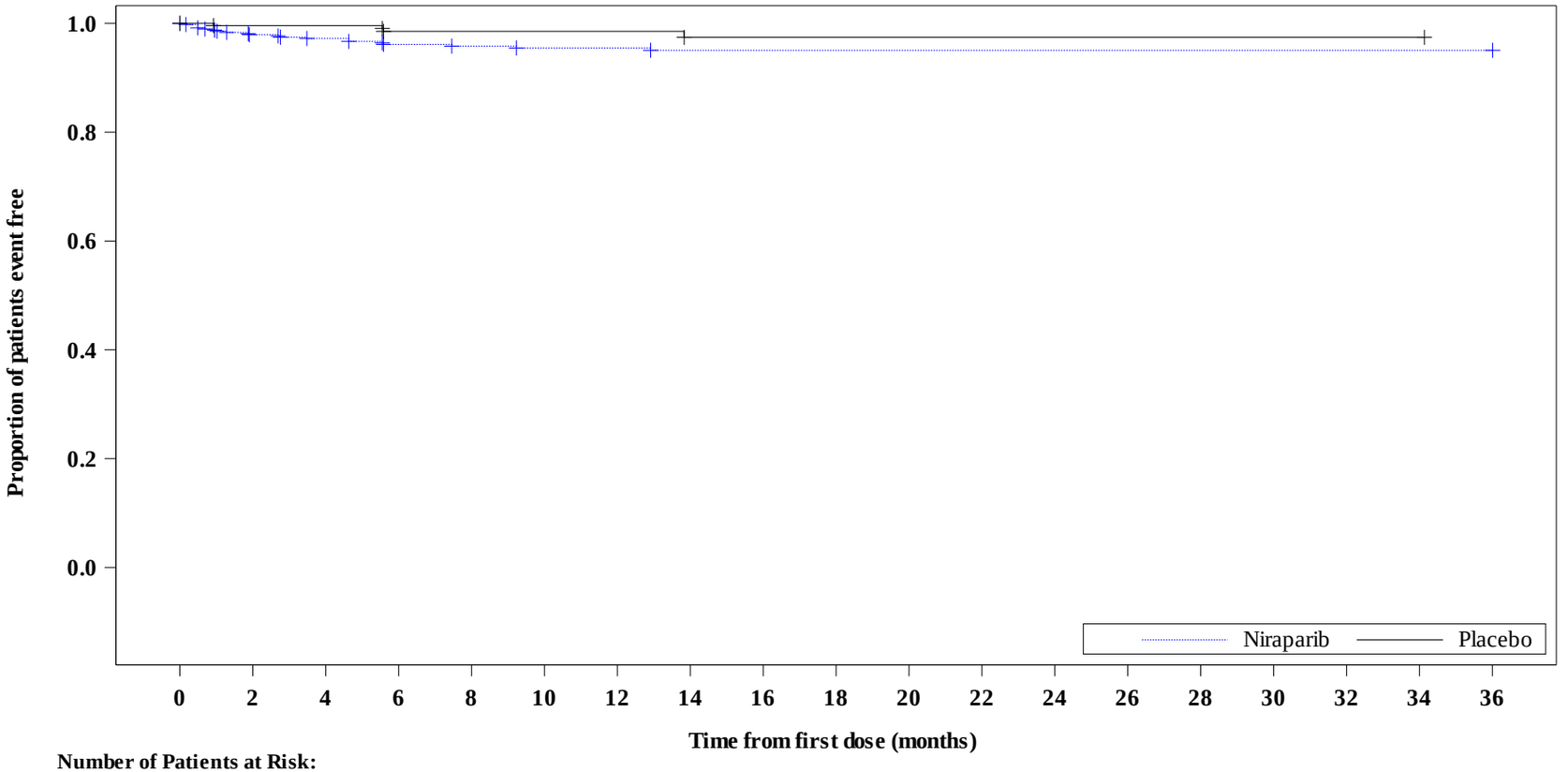



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 330 | 286 | 259 | 219 | 194 | 180 | 165 | 143 | 128 | 96 | 70 | 45 | 25 | 15 | 9 | 6 | 3 | 0 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 107 | 96 | 85 | 73 | 64 | 53 | 32 | 17 | 11 | 6 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Weight decreased

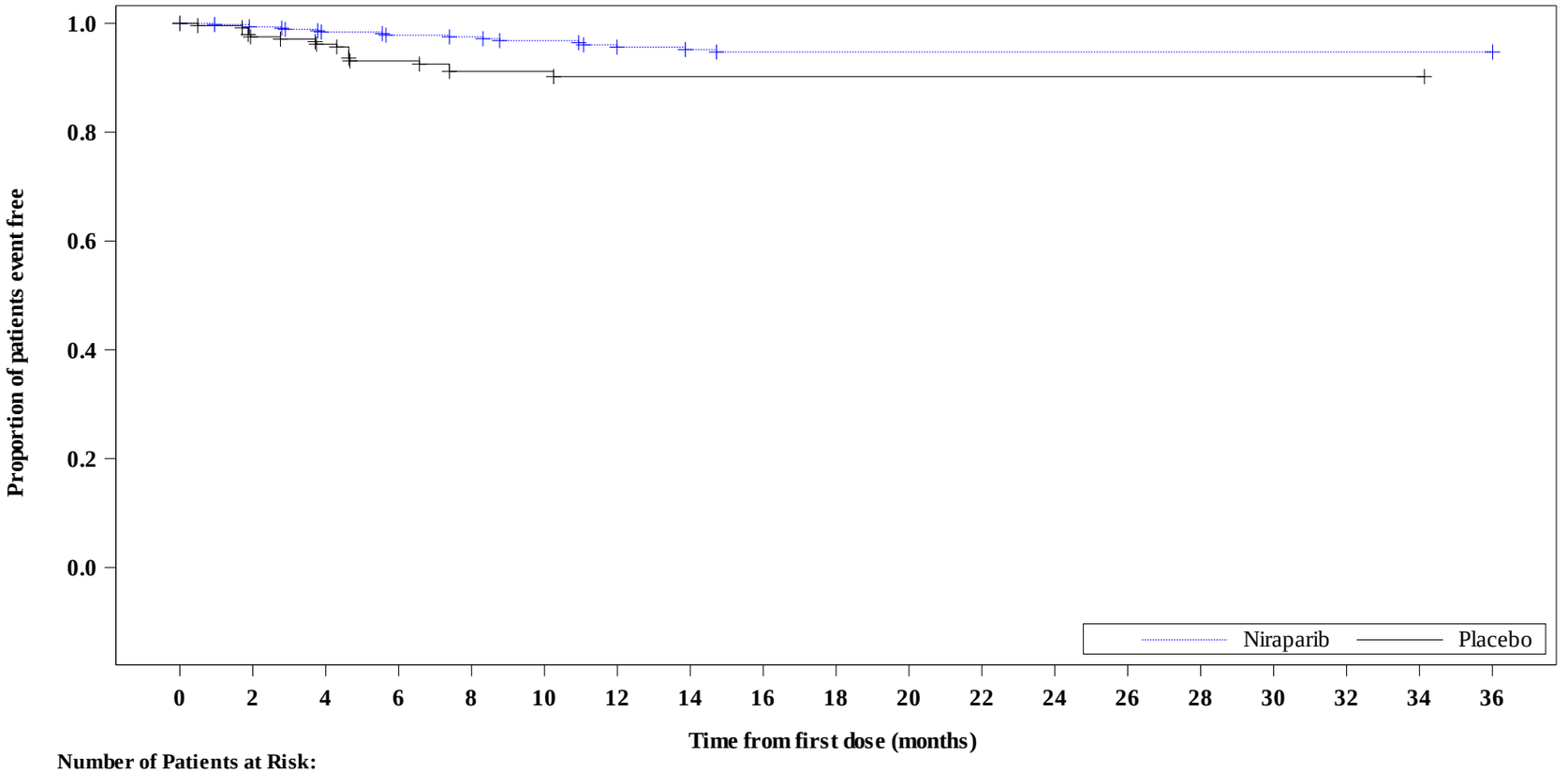



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 383 | 347 | 289 | 255 | 239 | 216 | 182 | 159 | 121 | 85 | 58 | 32 | 20 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 180 | 143 | 107 | 96 | 83 | 71 | 62 | 52 | 32 | 17 | 11 | 6 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: Weight increased

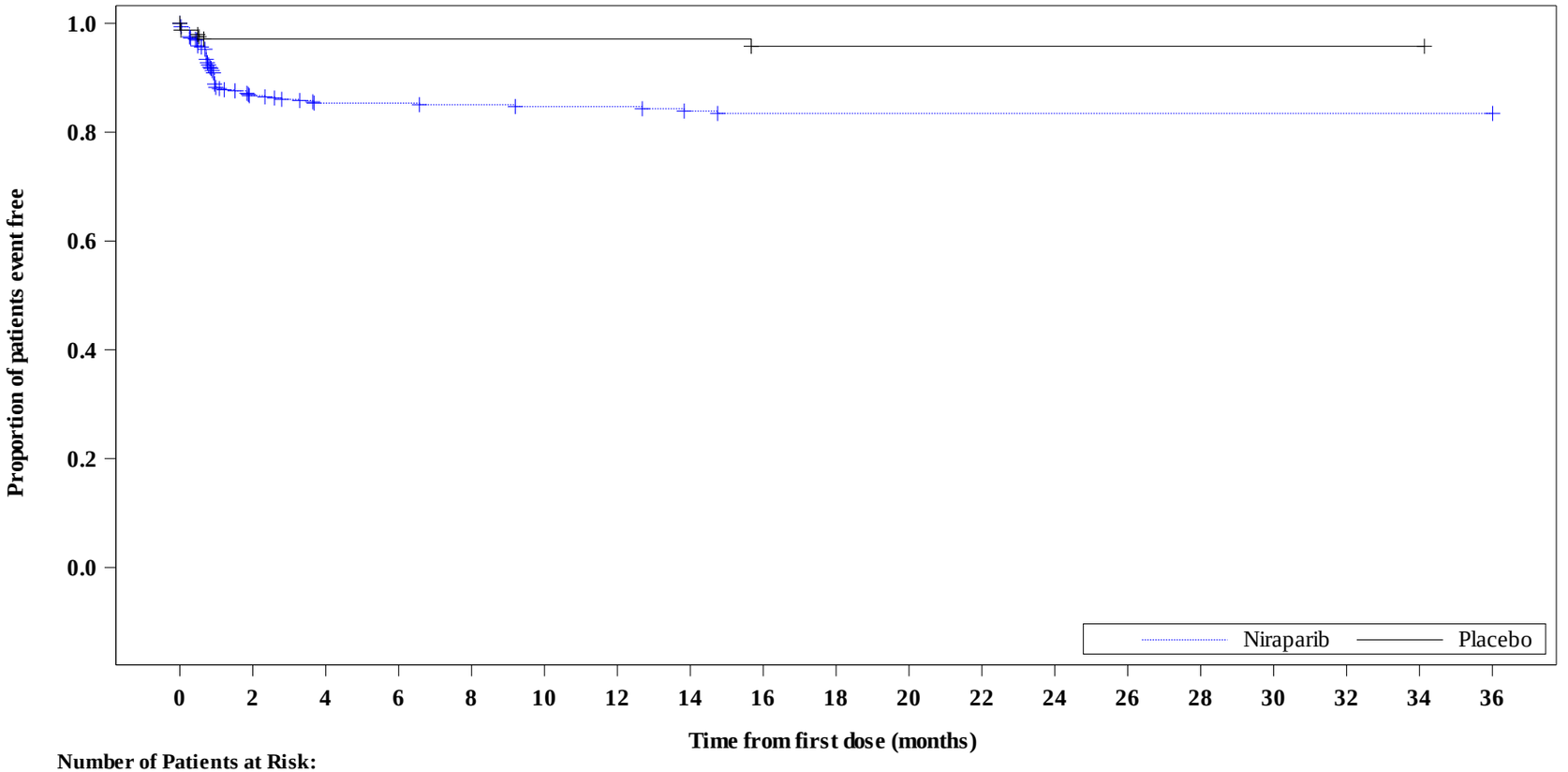



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 384 | 348 | 289 | 256 | 236 | 212 | 178 | 157 | 120 | 86 | 59 | 33 | 20 | 11 | 8 | 5 | 1 |
| Placebo | 244 | 235 | 196 | 169 | 130 | 98 | 88 | 78 | 66 | 57 | 47 | 30 | 16 | 10 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Investigations, PT: White blood cell count decreased

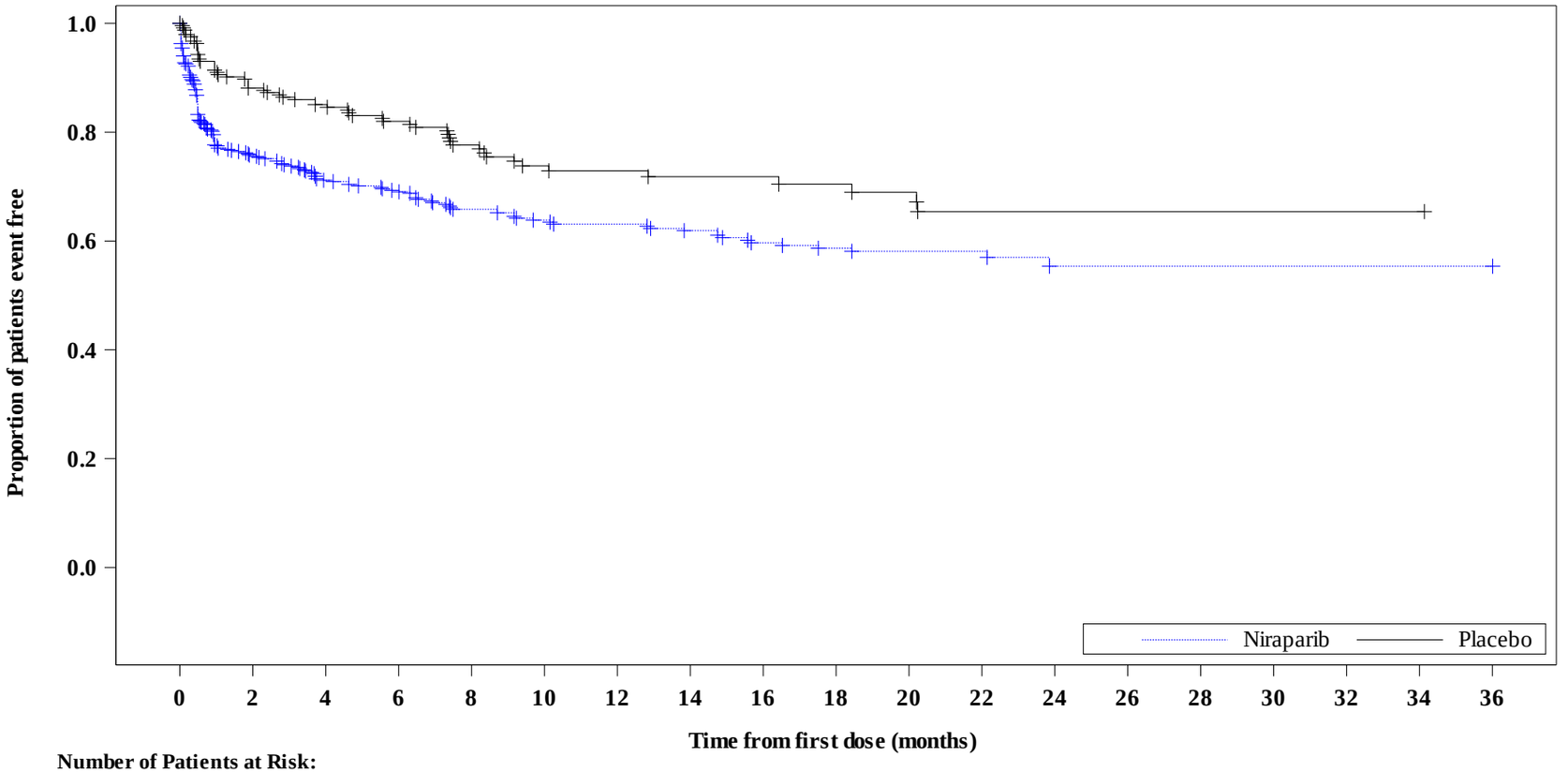



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 391 | 339 | 314 | 259 | 232 | 217 | 198 | 170 | 150 | 114 | 82 | 56 | 30 | 17 | 10 | 6 | 2 | 1 |
| Placebo | 244 | 234 | 200 | 178 | 143 | 106 | 95 | 83 | 71 | 62 | 51 | 31 | 16 | 10 | 5 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders

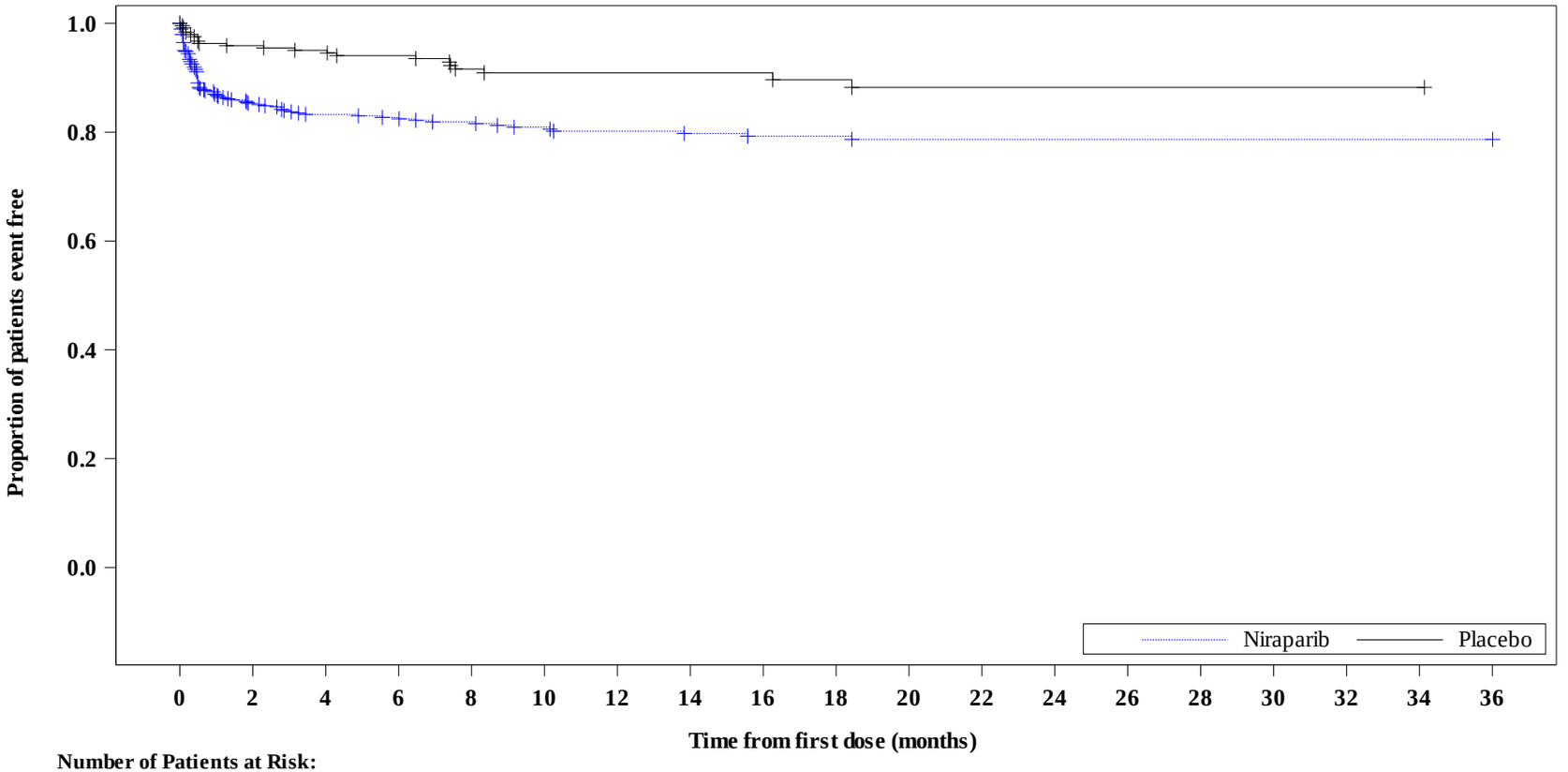



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 343 | 284 | 254 | 206 | 179 | 168 | 151 | 124 | 104 | 79 | 53 | 32 | 16 | 9 | 6 | 5 | 3 | 1 |
| Placebo | 244 | 213 | 175 | 150 | 113 | 81 | 72 | 61 | 52 | 47 | 40 | 23 | 15 | 9 | 5 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

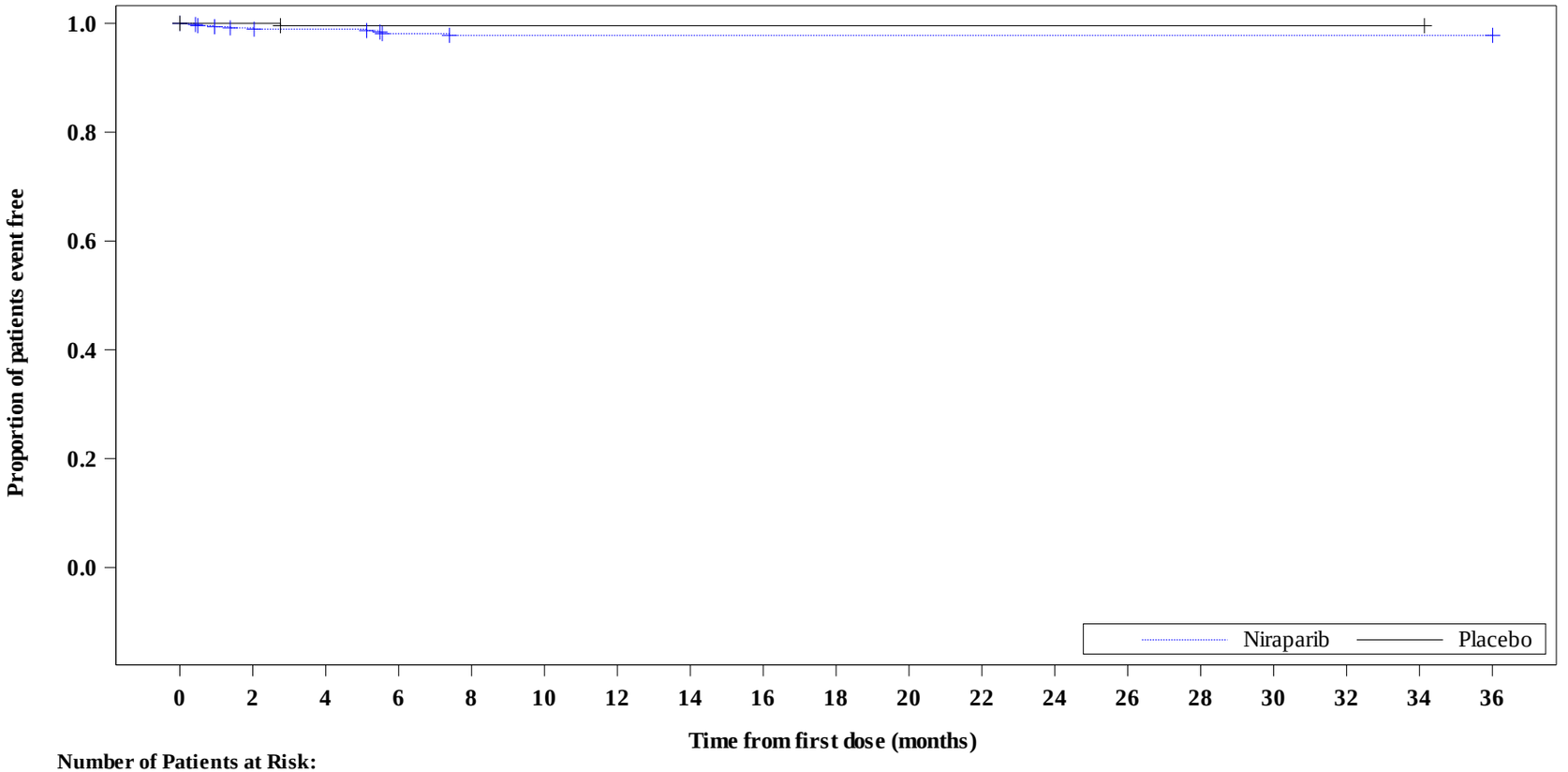



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 388 | 334 | 304 | 255 | 227 | 211 | 189 | 157 | 136 | 103 | 71 | 47 | 28 | 18 | 11 | 7 | 5 | 1 |
| Placebo | 244 | 232 | 197 | 176 | 138 | 106 | 95 | 83 | 72 | 63 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hypercalcaemia

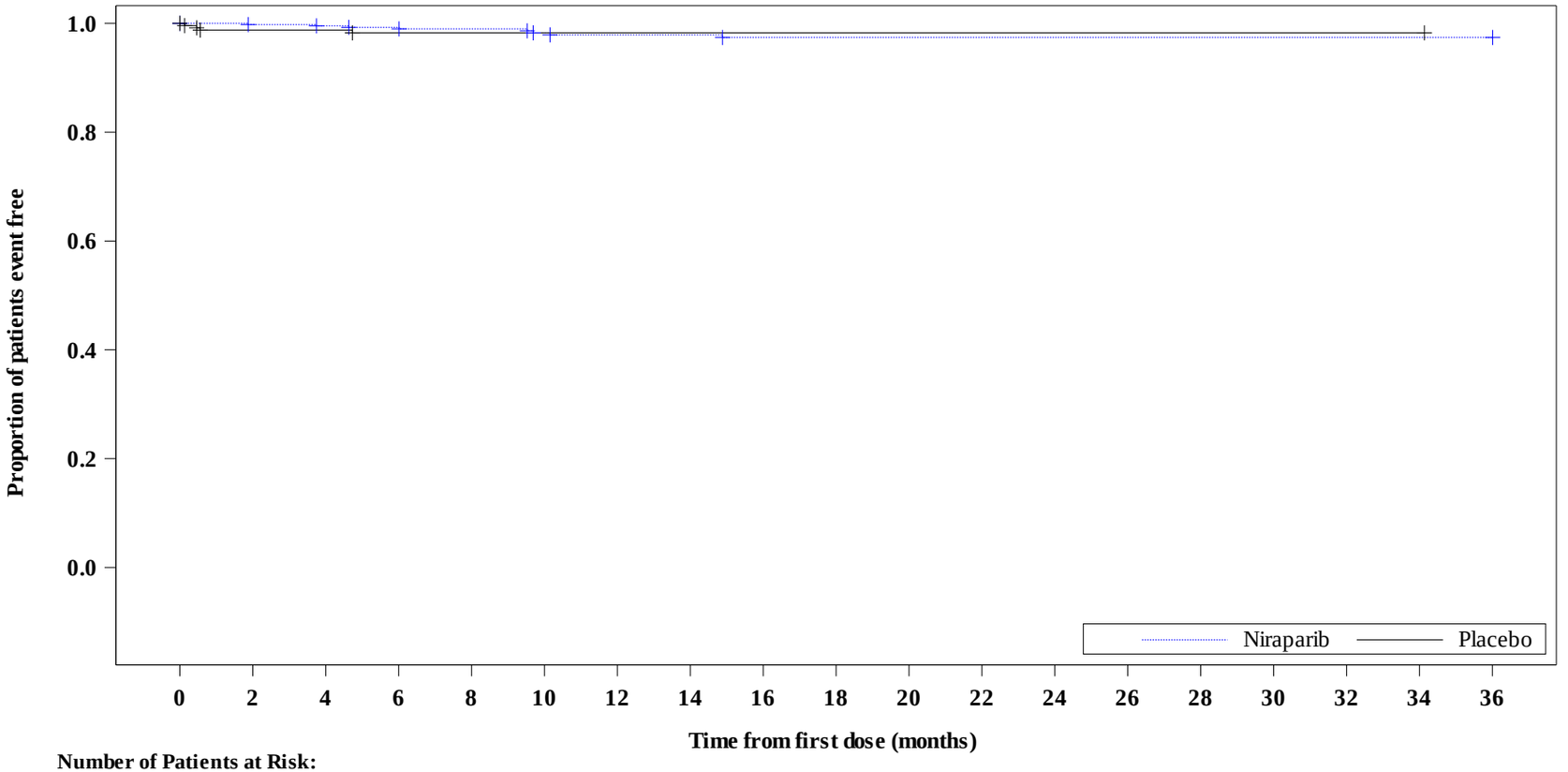



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 386 | 349 | 293 | 260 | 243 | 222 | 189 | 166 | 127 | 89 | 60 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 204 | 182 | 145 | 108 | 97 | 85 | 73 | 64 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hypercholesterolaemia

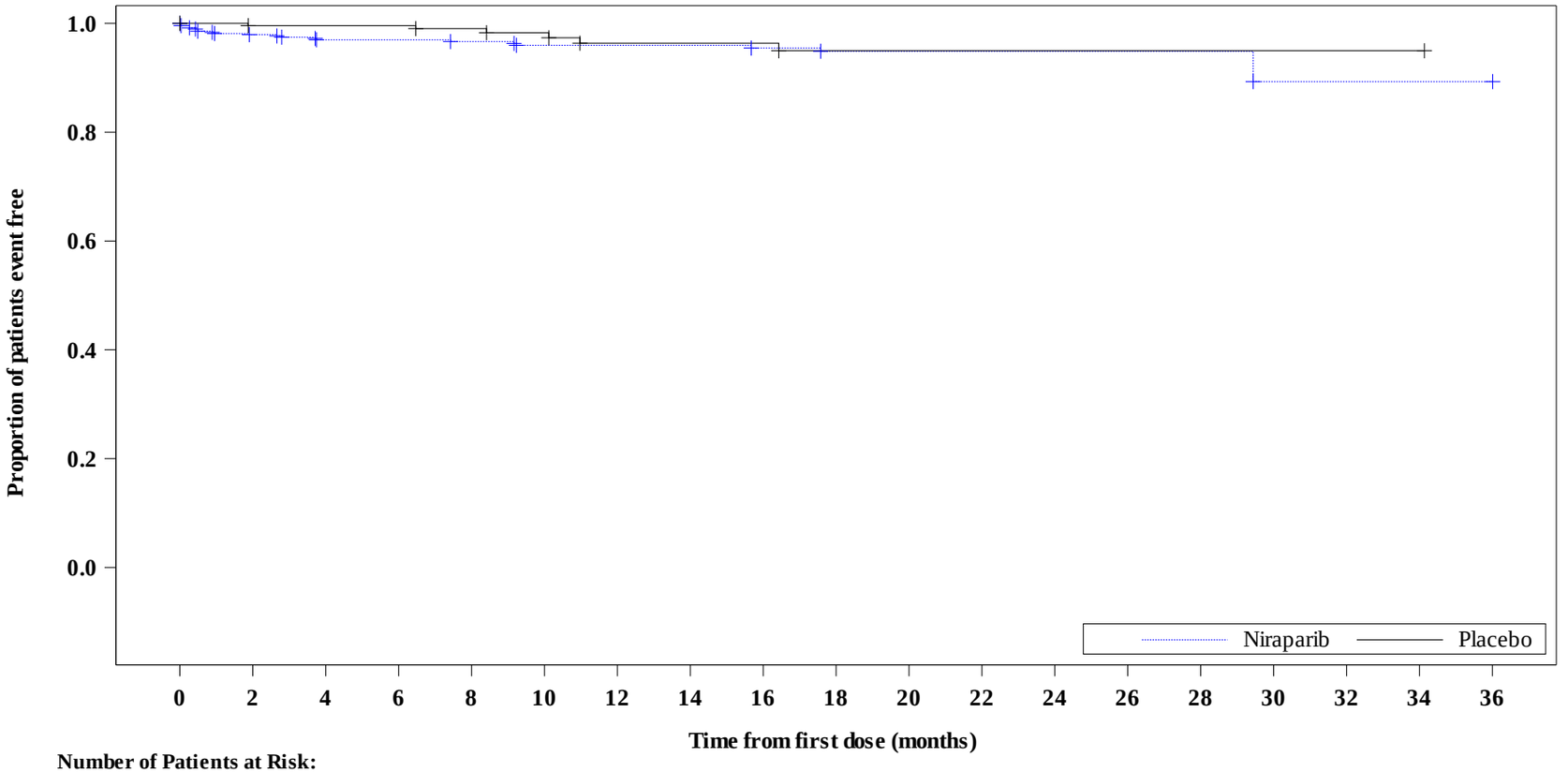



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 389 | 355 | 296 | 261 | 244 | 222 | 187 | 164 | 125 | 88 | 61 | 33 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 238 | 202 | 179 | 143 | 107 | 96 | 84 | 72 | 63 | 52 | 31 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hyperglycaemia

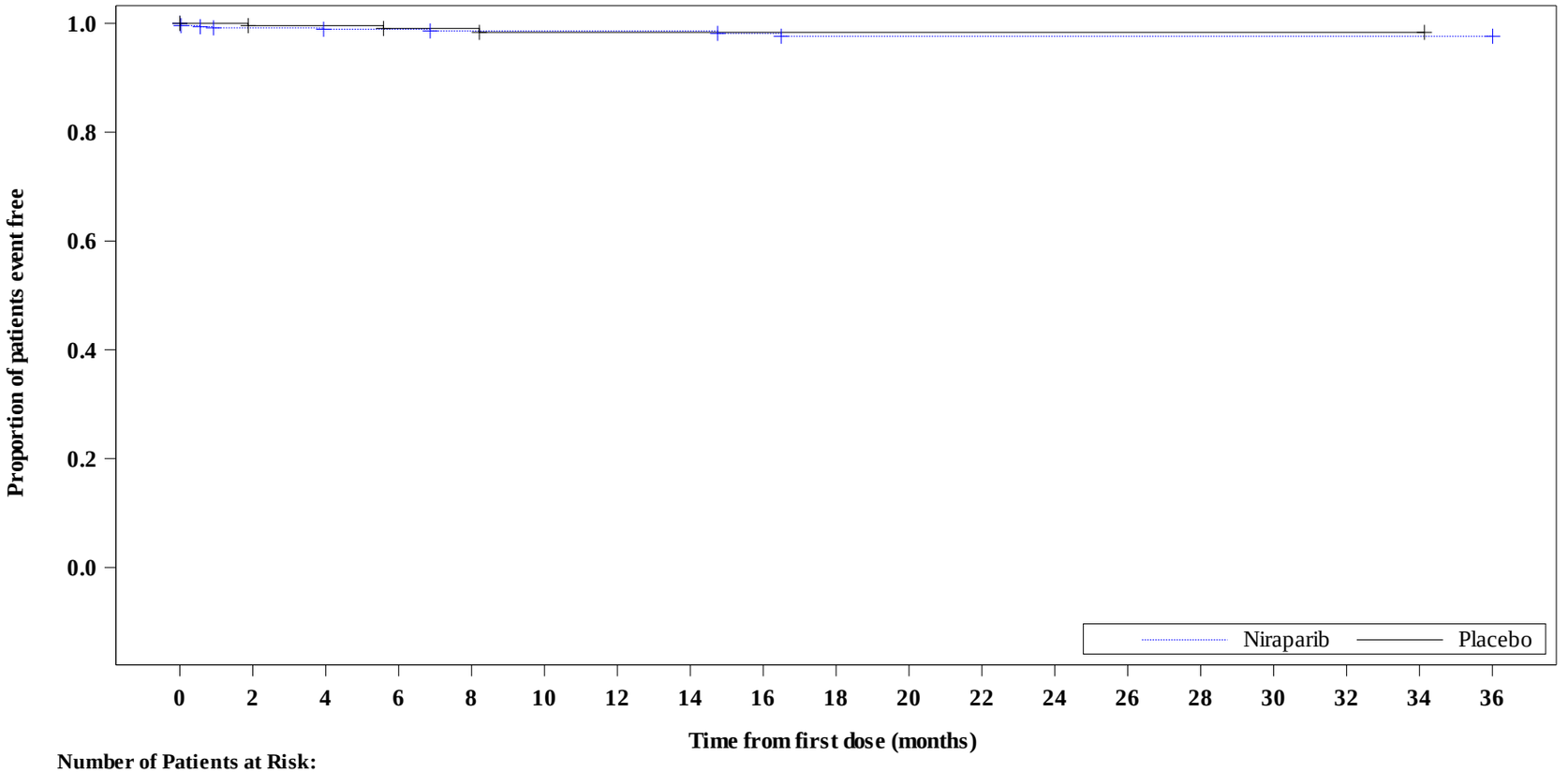



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 440 | 378 | 346 | 289 | 254 | 237 | 214 | 182 | 159 | 121 | 85 | 57 | 32 | 20 | 12 | 8 | 4 | 1 |
| Placebo | 244 | 240 | 204 | 182 | 144 | 106 | 93 | 81 | 69 | 62 | 52 | 31 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hypoalbuminaemia

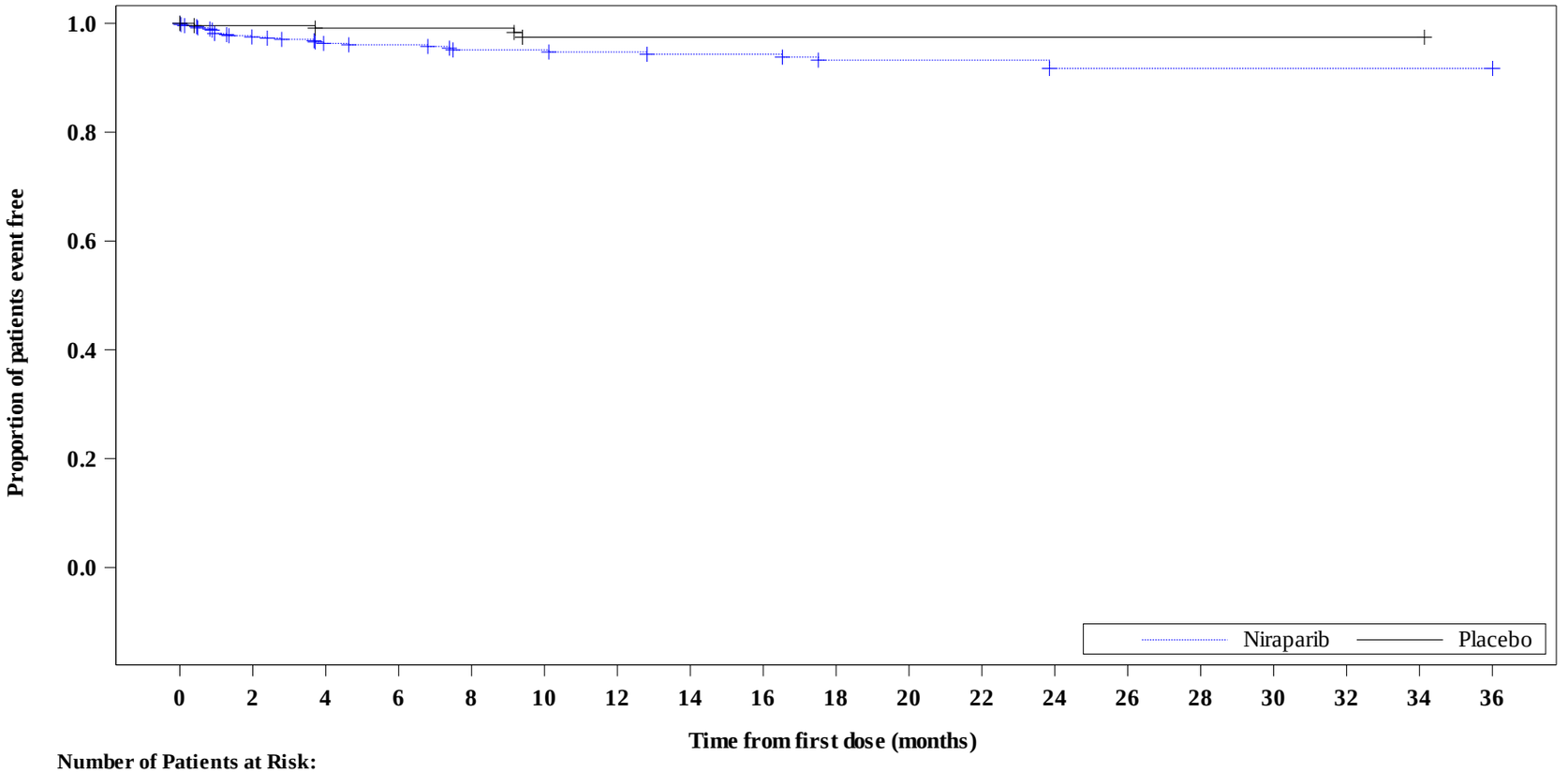



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 387 | 354 | 296 | 263 | 246 | 224 | 191 | 167 | 128 | 91 | 62 | 34 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 106 | 96 | 84 | 72 | 63 | 52 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hypokalaemia

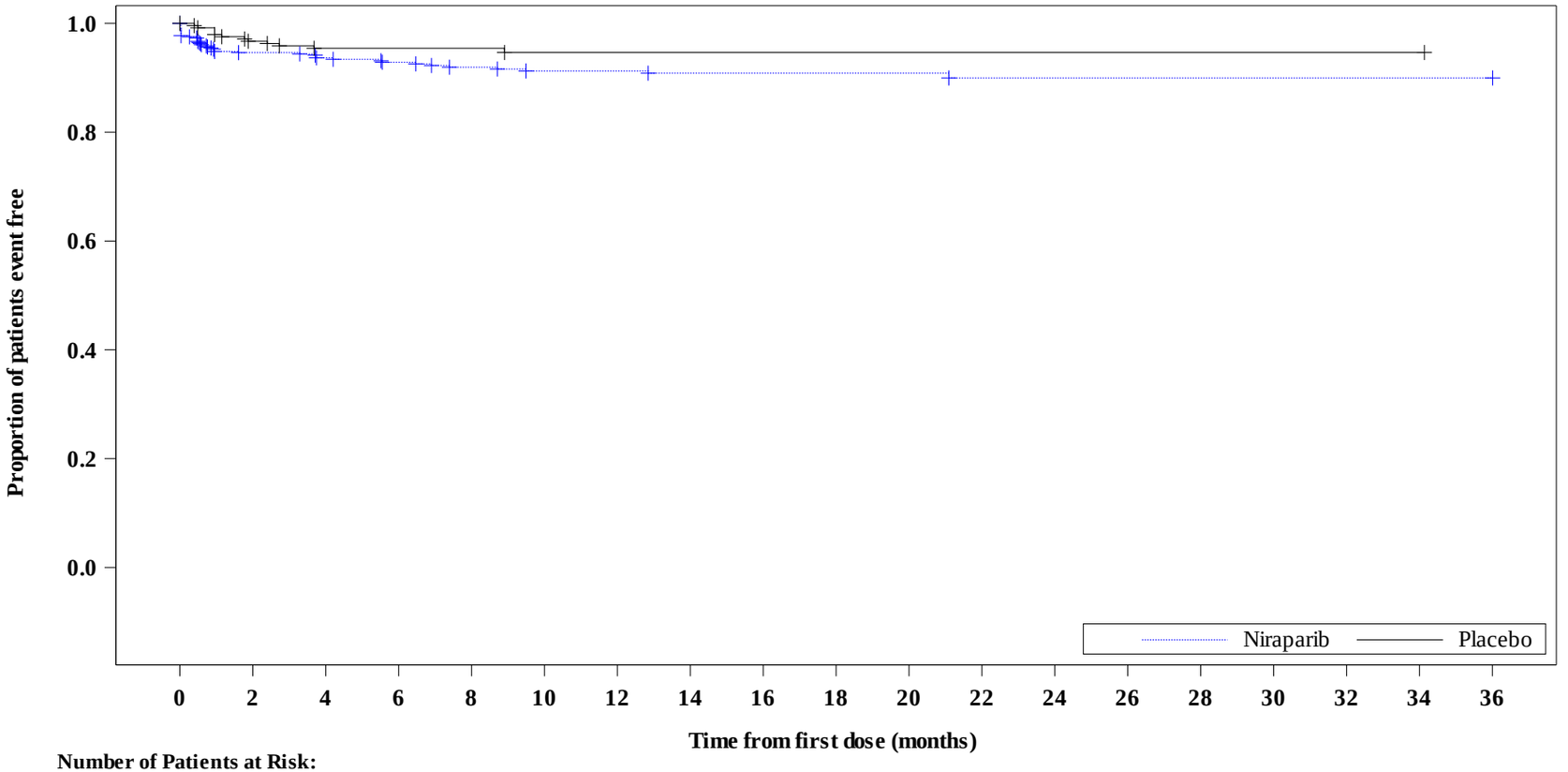



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 440 | 377 | 343 | 286 | 255 | 239 | 216 | 184 | 160 | 121 | 85 | 57 | 31 | 19 | 11 | 8 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 181 | 144 | 105 | 95 | 83 | 72 | 64 | 53 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hypomagnesaemia



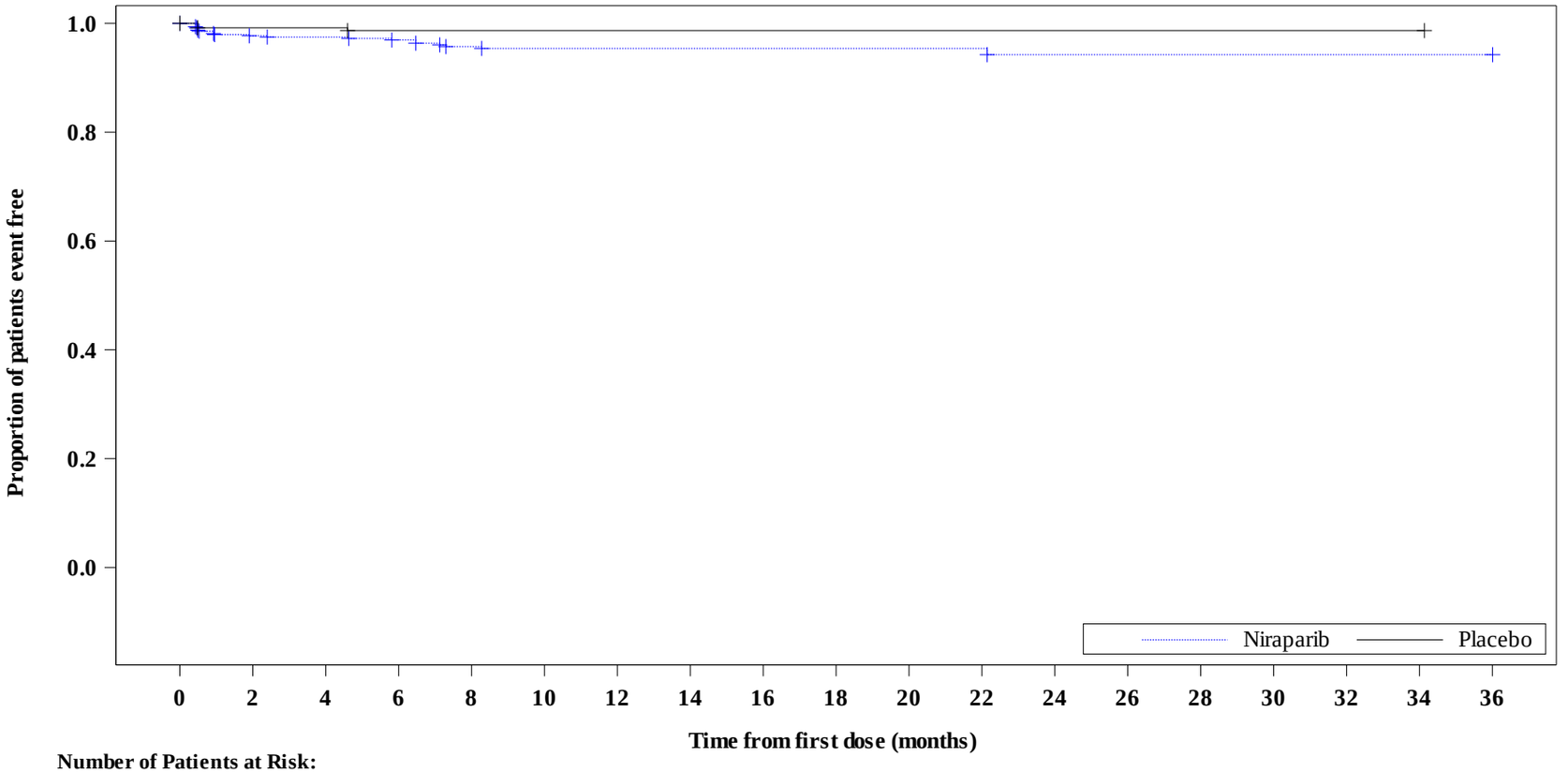

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 425 | 368 | 335 | 280 | 249 | 234 | 213 | 182 | 160 | 124 | 89 | 61 | 33 | 20 | 11 | 9 | 5 | 1 |
| Placebo | 244 | 233 | 195 | 173 | 138 | 102 | 92 | 81 | 69 | 61 | 51 | 31 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

ss737779: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-13-teaept.sas 10SEP2020 05:51

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hyponatraemia

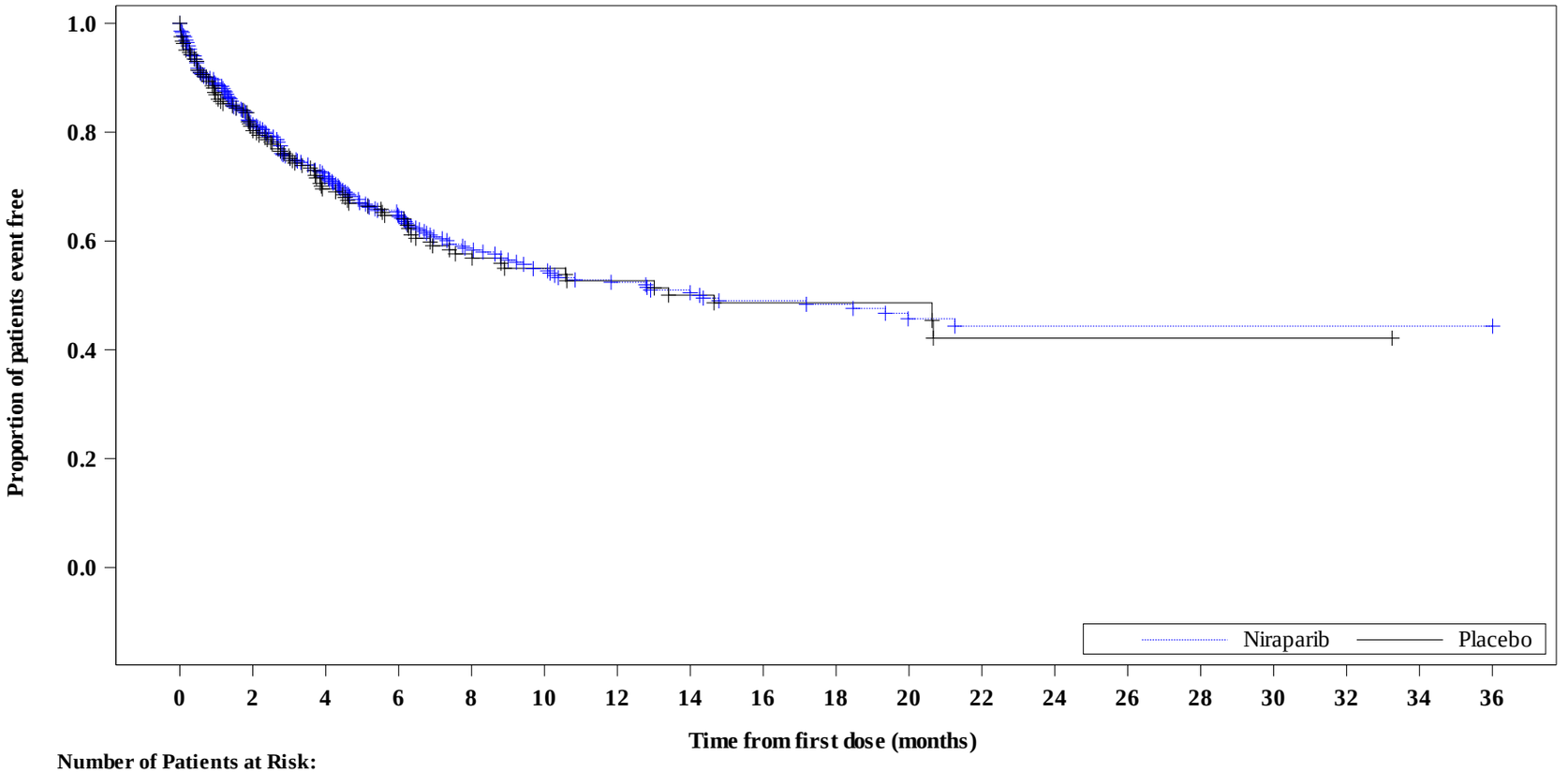



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 439 | 380 | 344 | 284 | 251 | 234 | 213 | 182 | 159 | 122 | 84 | 56 | 31 | 19 | 12 | 8 | 4 | 1 |
| Placebo | 244 | 239 | 204 | 181 | 144 | 107 | 96 | 84 | 72 | 63 | 52 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders

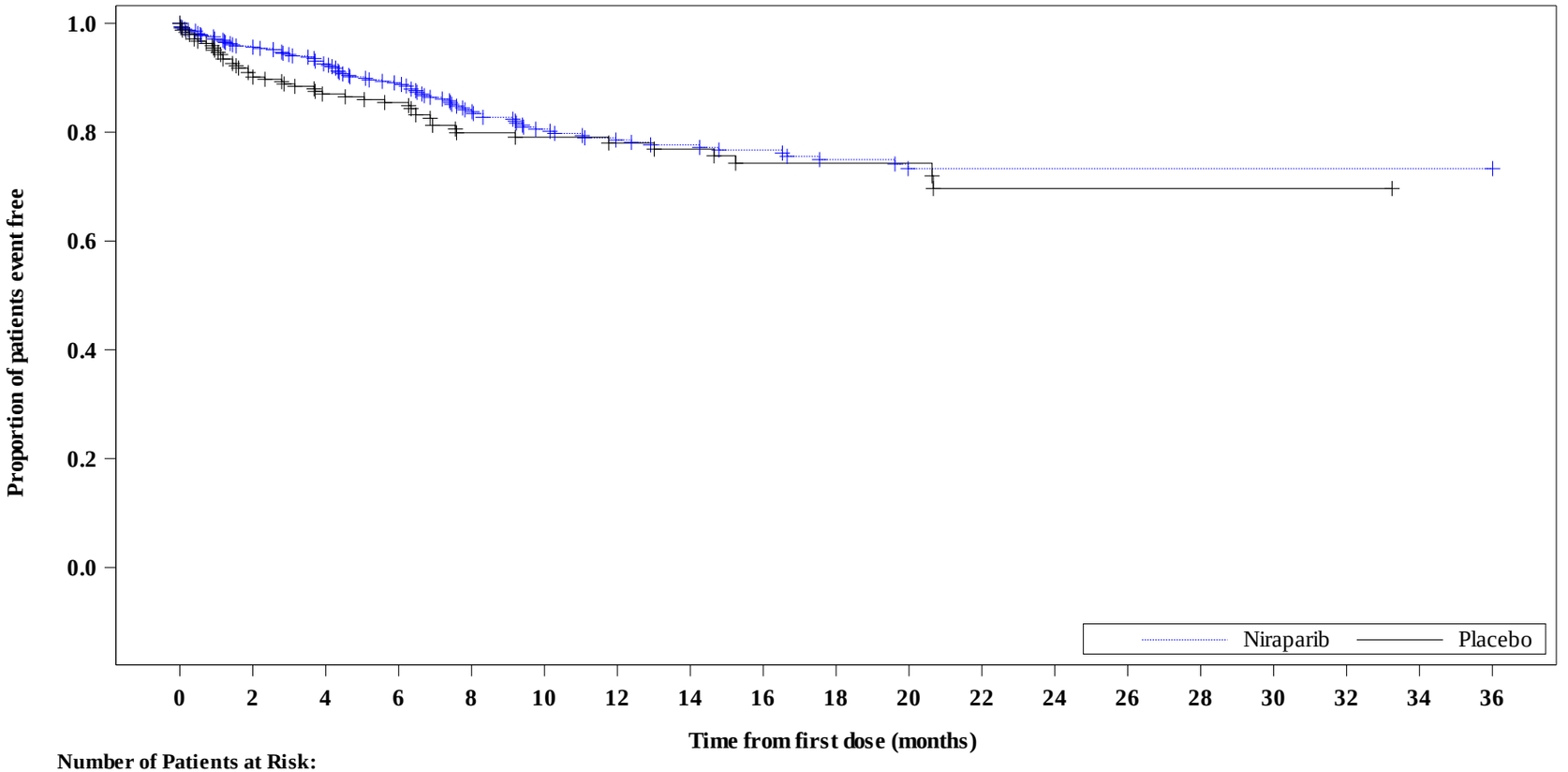



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 364 | 273 | 222 | 163 | 134 | 120 | 103 | 82 | 66 | 45 | 31 | 21 | 10 | 4 | 3 | 3 | 3 | 1 |
| Placebo | 244 | 196 | 138 | 110 | 74 | 50 | 43 | 36 | 31 | 24 | 19 | 8 | 3 | 1 | 1 | 1 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia

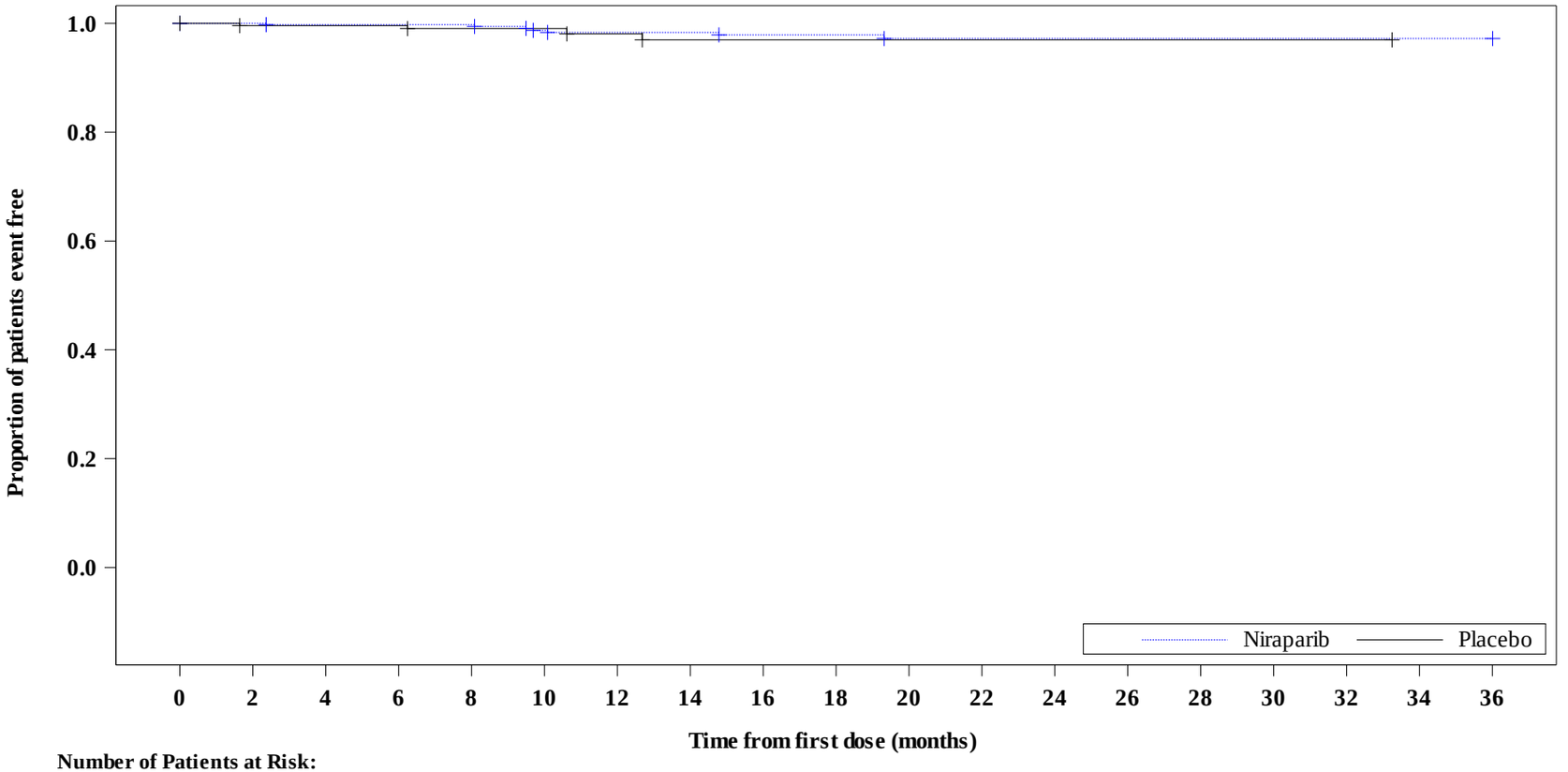



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 430 | 359 | 316 | 246 | 208 | 189 | 167 | 138 | 114 | 87 | 60 | 41 | 22 | 11 | 7 | 4 | 4 | 1 |
| Placebo | 244 | 220 | 177 | 154 | 114 | 83 | 73 | 64 | 55 | 47 | 37 | 22 | 11 | 5 | 3 | 1 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Arthritis

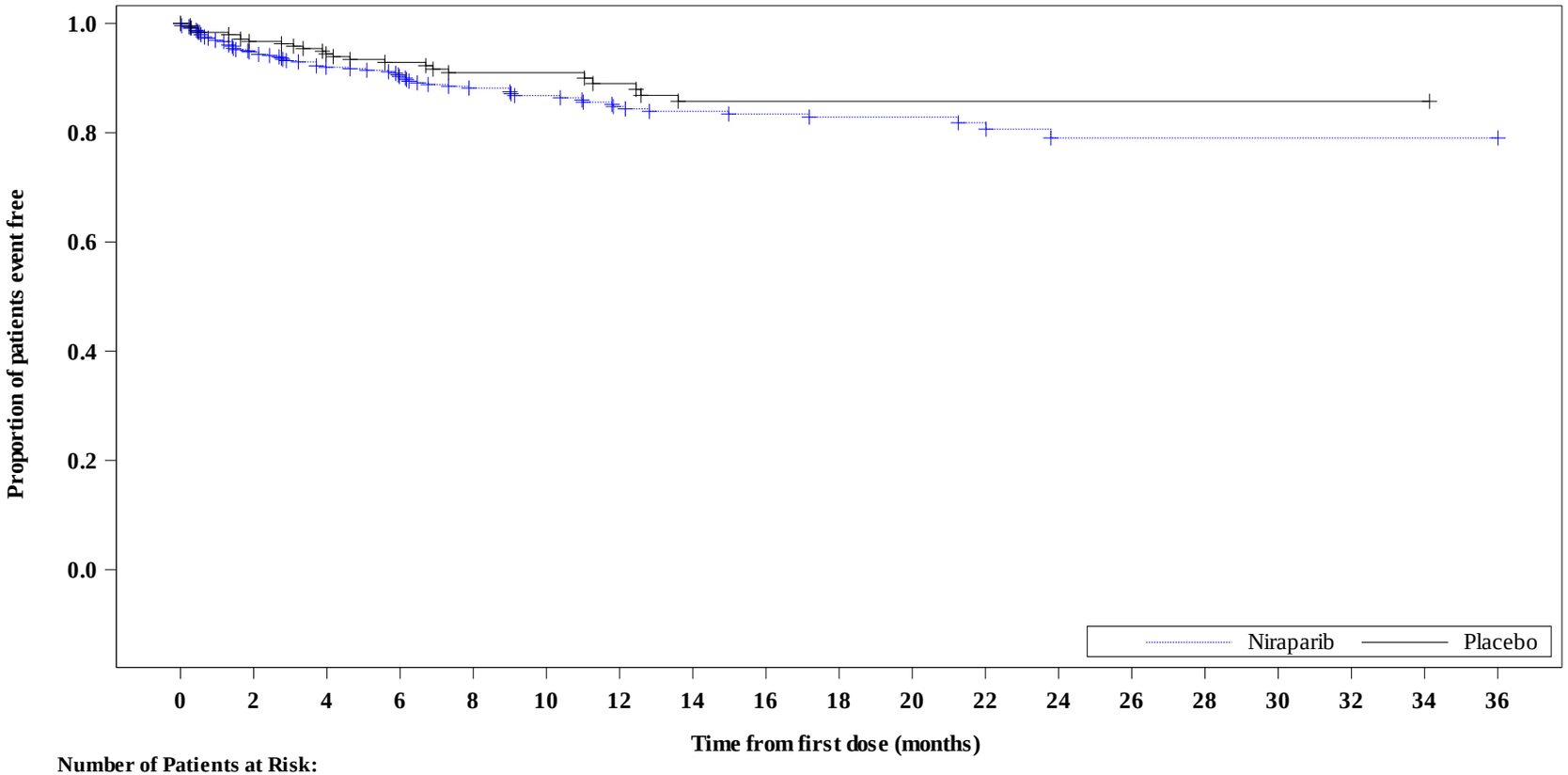



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 390 | 356 | 298 | 262 | 244 | 221 | 187 | 165 | 126 | 89 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 182 | 144 | 107 | 95 | 82 | 70 | 61 | 51 | 31 | 16 | 10 | 6 | 2 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Back pain

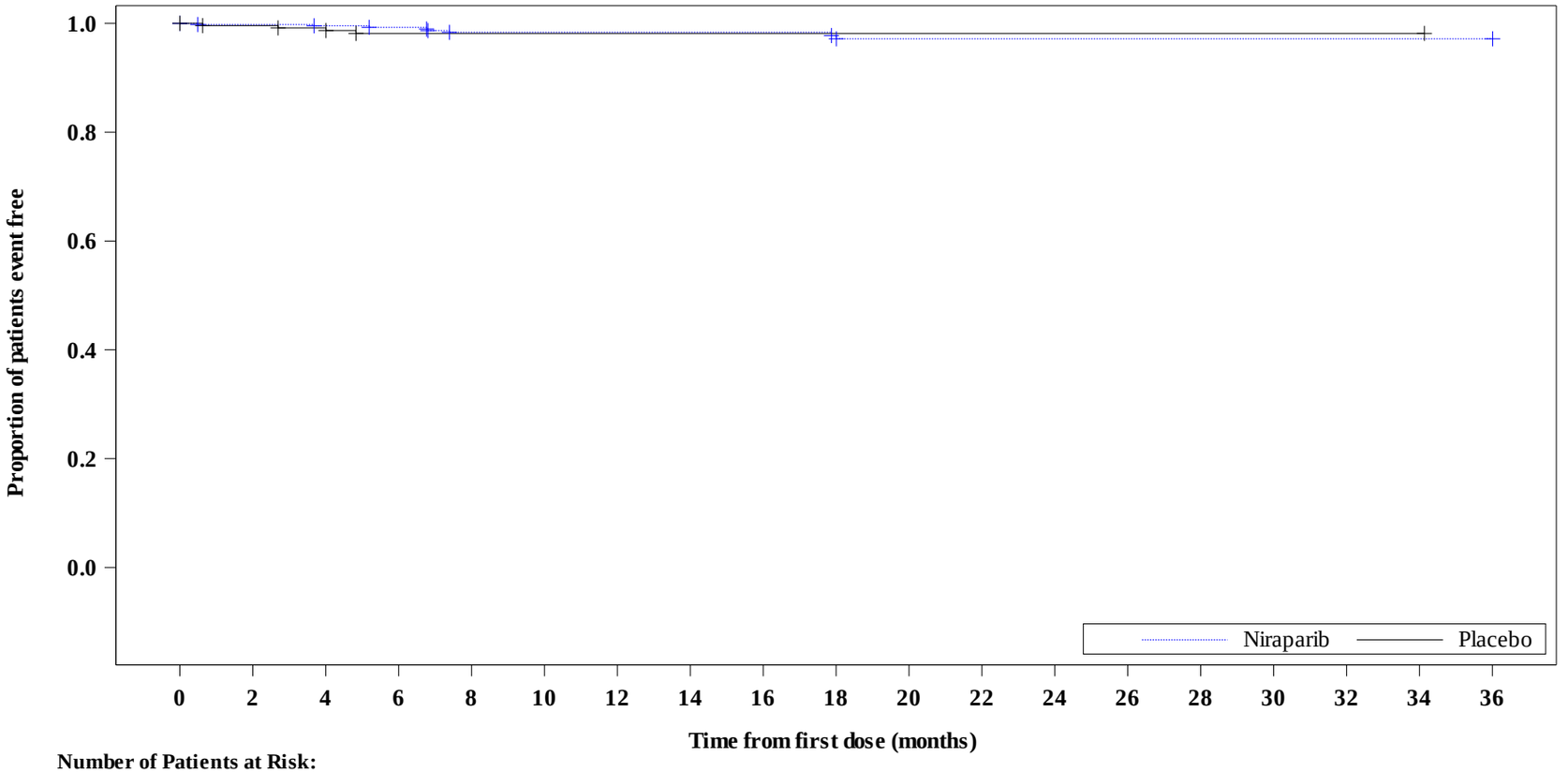



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 425 | 356 | 317 | 261 | 226 | 206 | 184 | 155 | 135 | 104 | 70 | 45 | 25 | 16 | 10 | 7 | 3 | 1 |
| Placebo | 244 | 233 | 193 | 169 | 130 | 98 | 87 | 73 | 63 | 55 | 45 | 28 | 15 | 10 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Flank pain

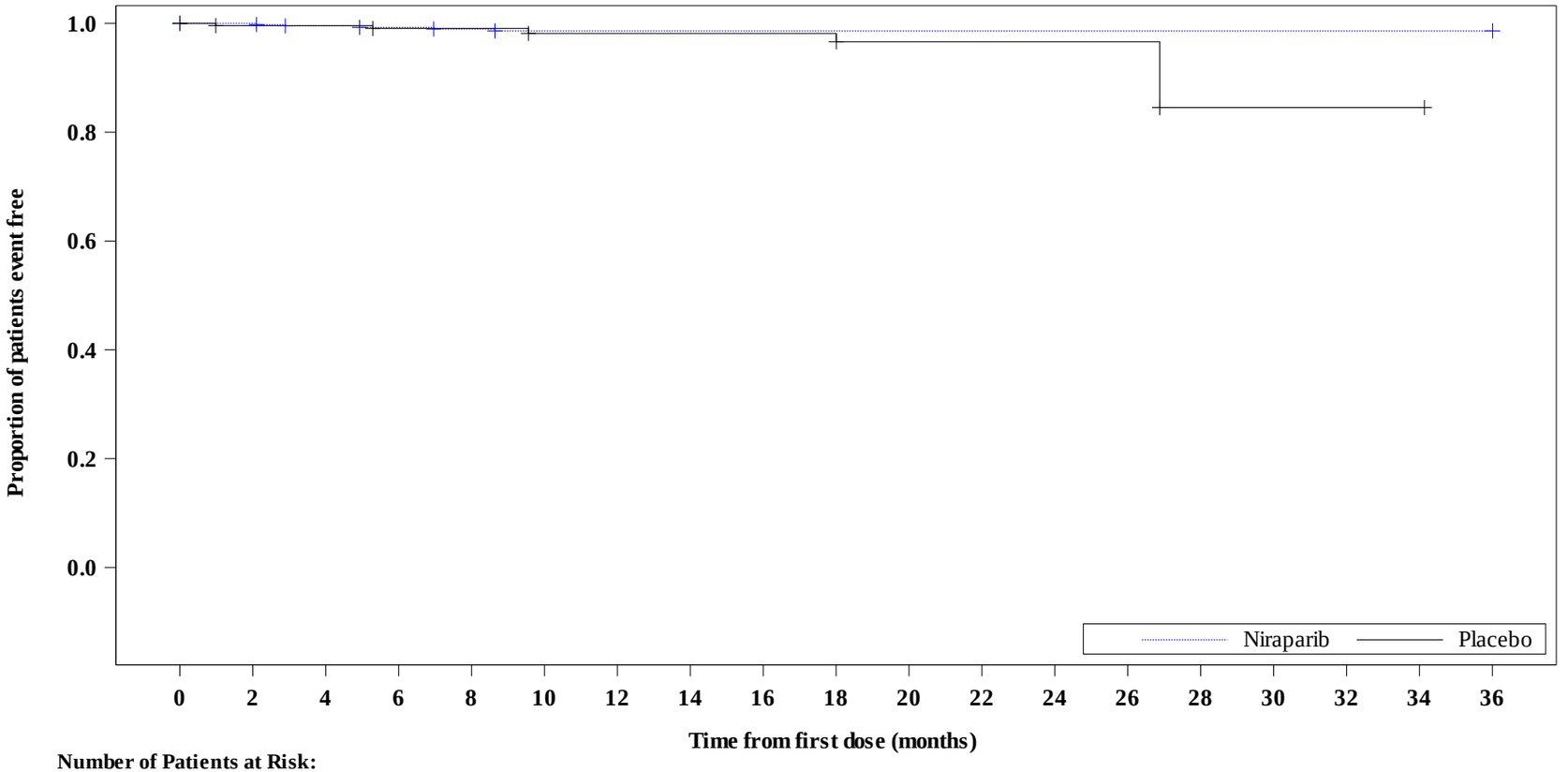



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 389 | 354 | 293 | 260 | 244 | 223 | 189 | 165 | 126 | 89 | 60 | 32 | 20 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 179 | 142 | 106 | 95 | 84 | 72 | 63 | 52 | 31 | 16 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Groin pain

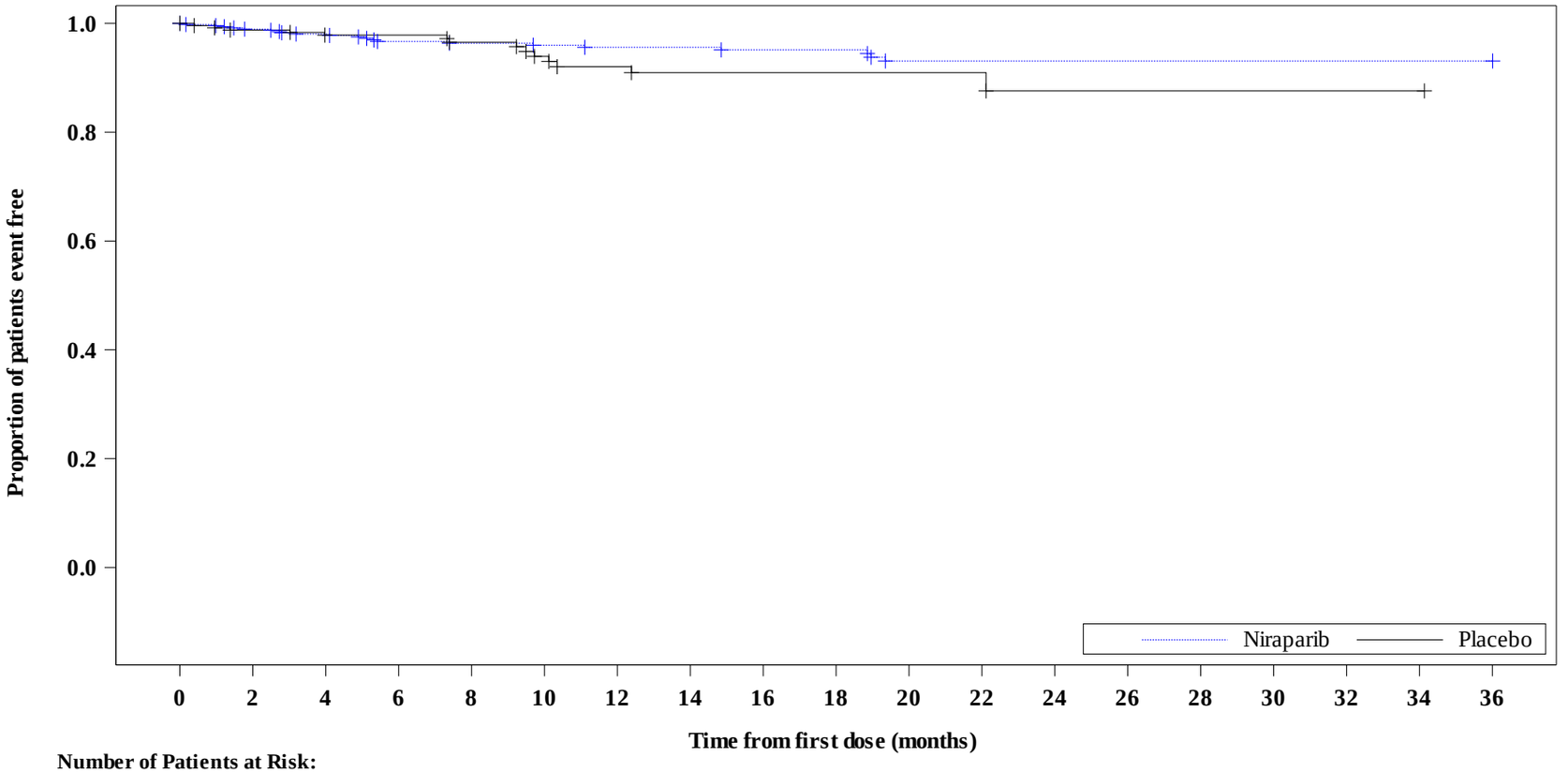



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 389 | 354 | 295 | 263 | 246 | 224 | 191 | 168 | 129 | 91 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 106 | 95 | 83 | 72 | 63 | 51 | 30 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Muscle spasms

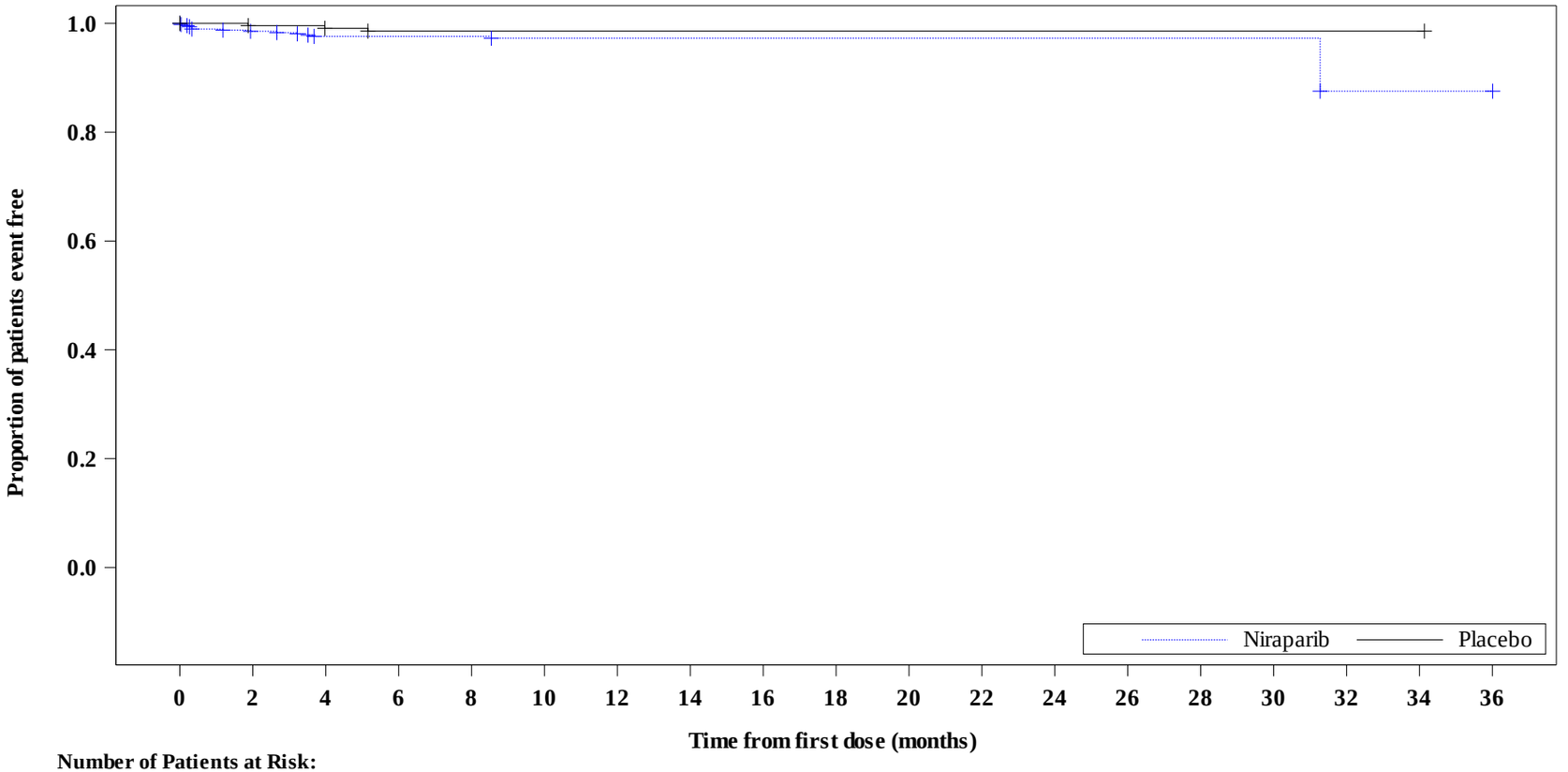



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 445 | 382 | 344 | 287 | 255 | 237 | 216 | 181 | 159 | 119 | 85 | 59 | 33 | 20 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 238 | 200 | 178 | 139 | 101 | 88 | 76 | 64 | 55 | 46 | 27 | 13 | 7 | 4 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Muscular weakness

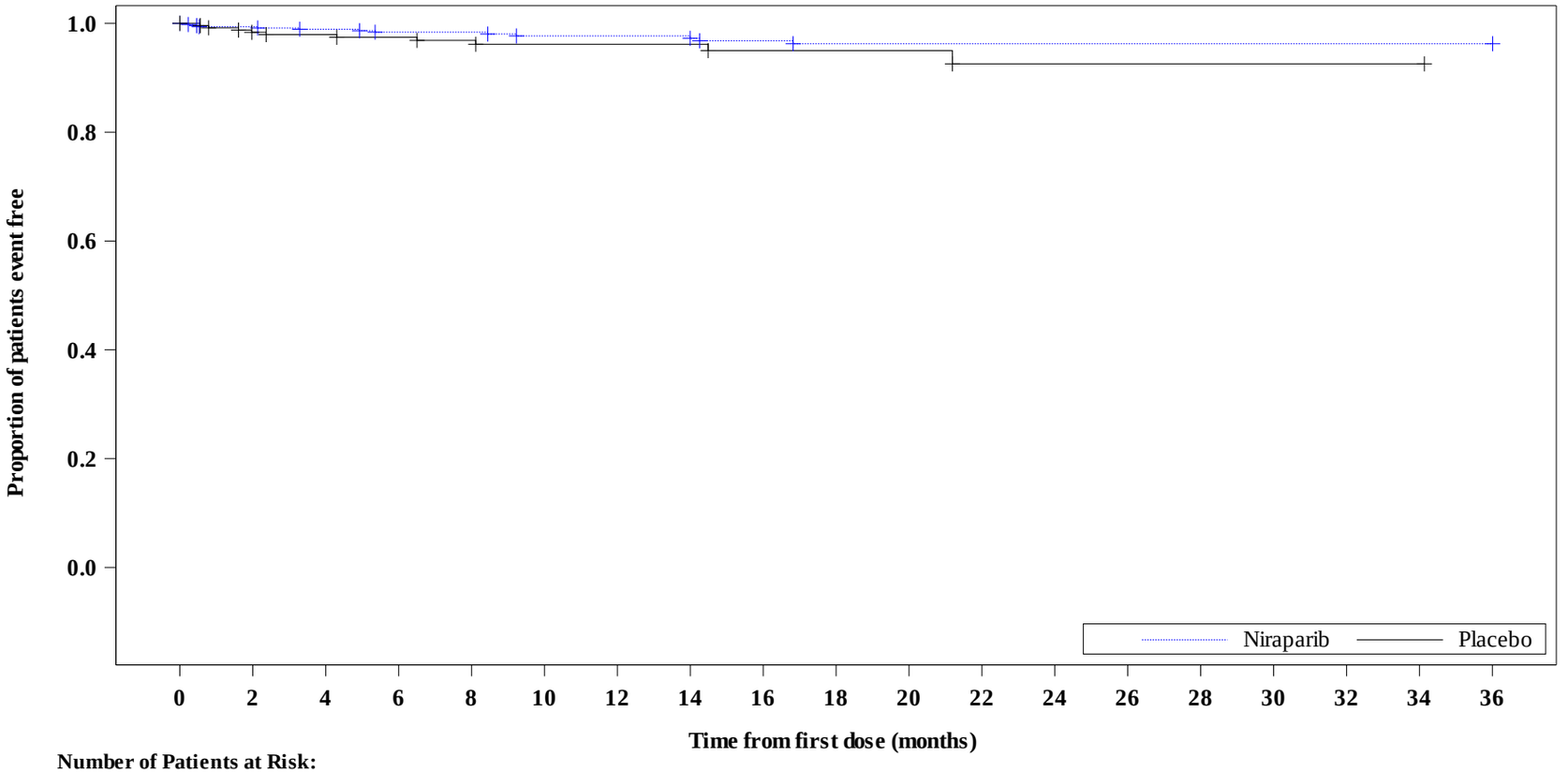



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 443 | 383 | 351 | 294 | 261 | 244 | 221 | 187 | 164 | 125 | 89 | 61 | 33 | 20 | 11 | 6 | 3 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 107 | 96 | 84 | 72 | 63 | 52 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Musculoskeletal chest pain

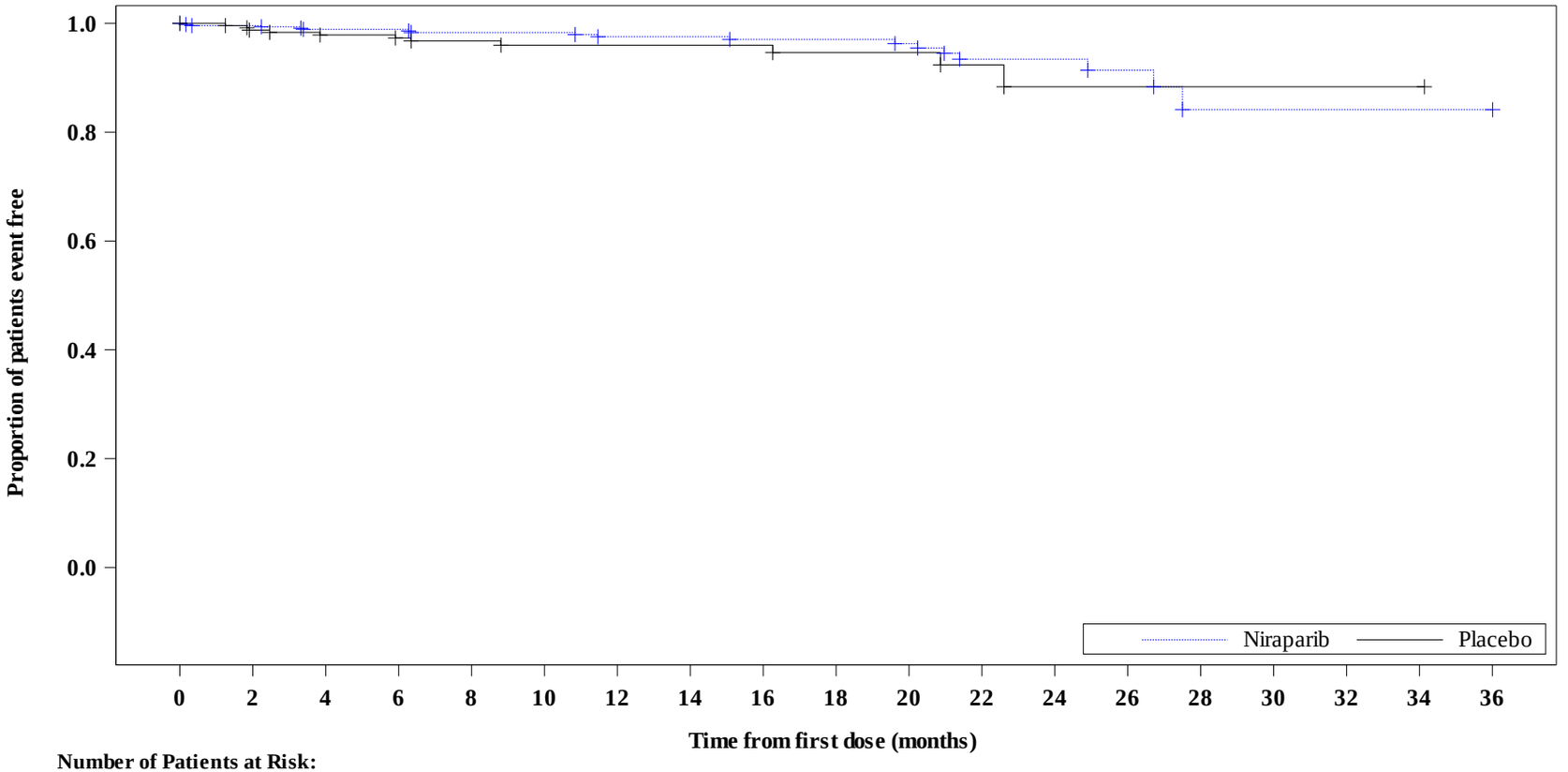



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 388 | 352 | 294 | 261 | 244 | 220 | 186 | 162 | 125 | 90 | 62 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 237 | 202 | 179 | 141 | 107 | 96 | 85 | 72 | 63 | 53 | 31 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Musculoskeletal pain

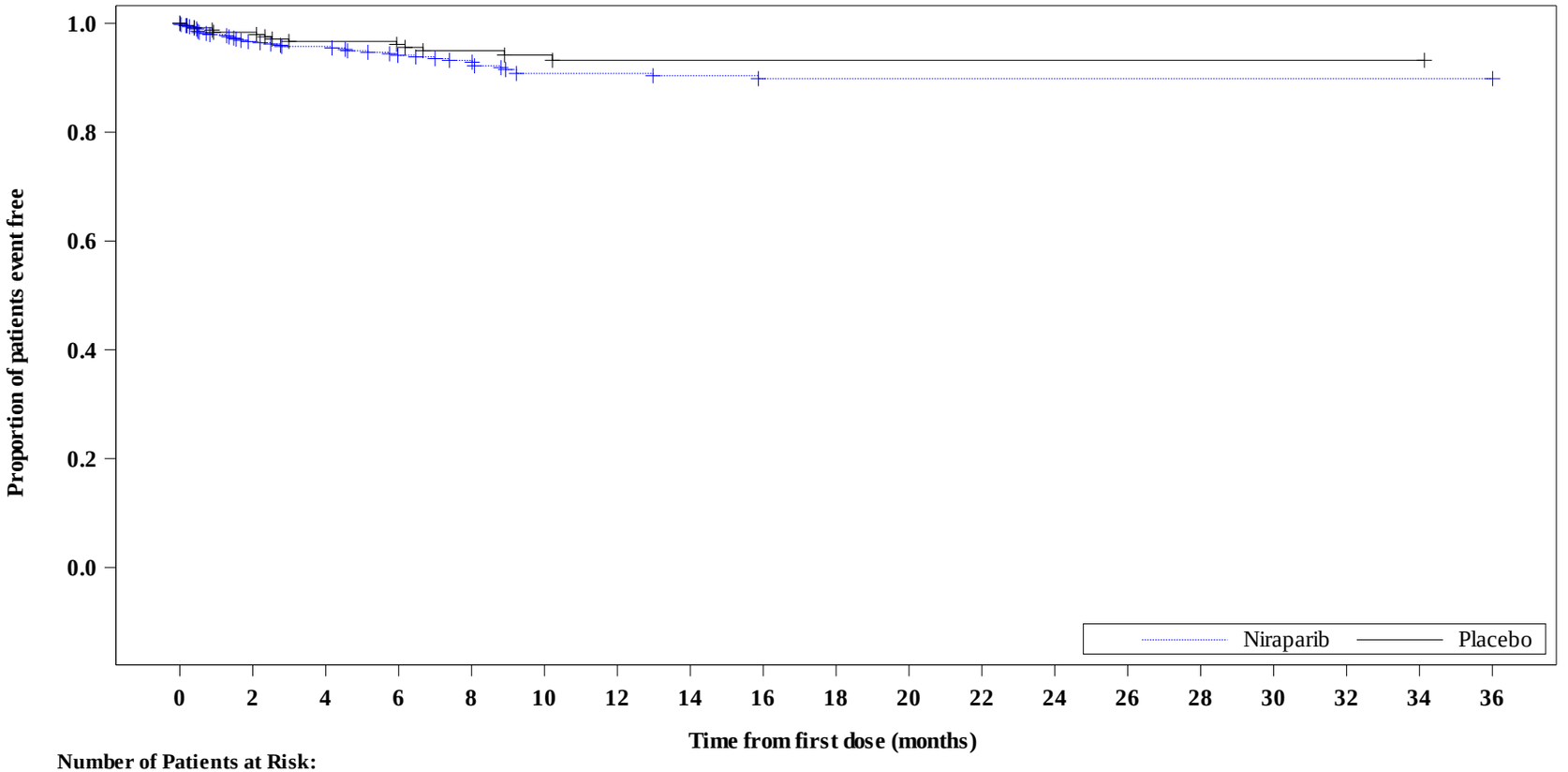



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 386 | 353 | 293 | 260 | 241 | 218 | 183 | 160 | 121 | 83 | 57 | 31 | 17 | 10 | 8 | 5 | 1 |
| Placebo | 244 | 238 | 201 | 179 | 141 | 105 | 94 | 82 | 70 | 60 | 50 | 31 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia

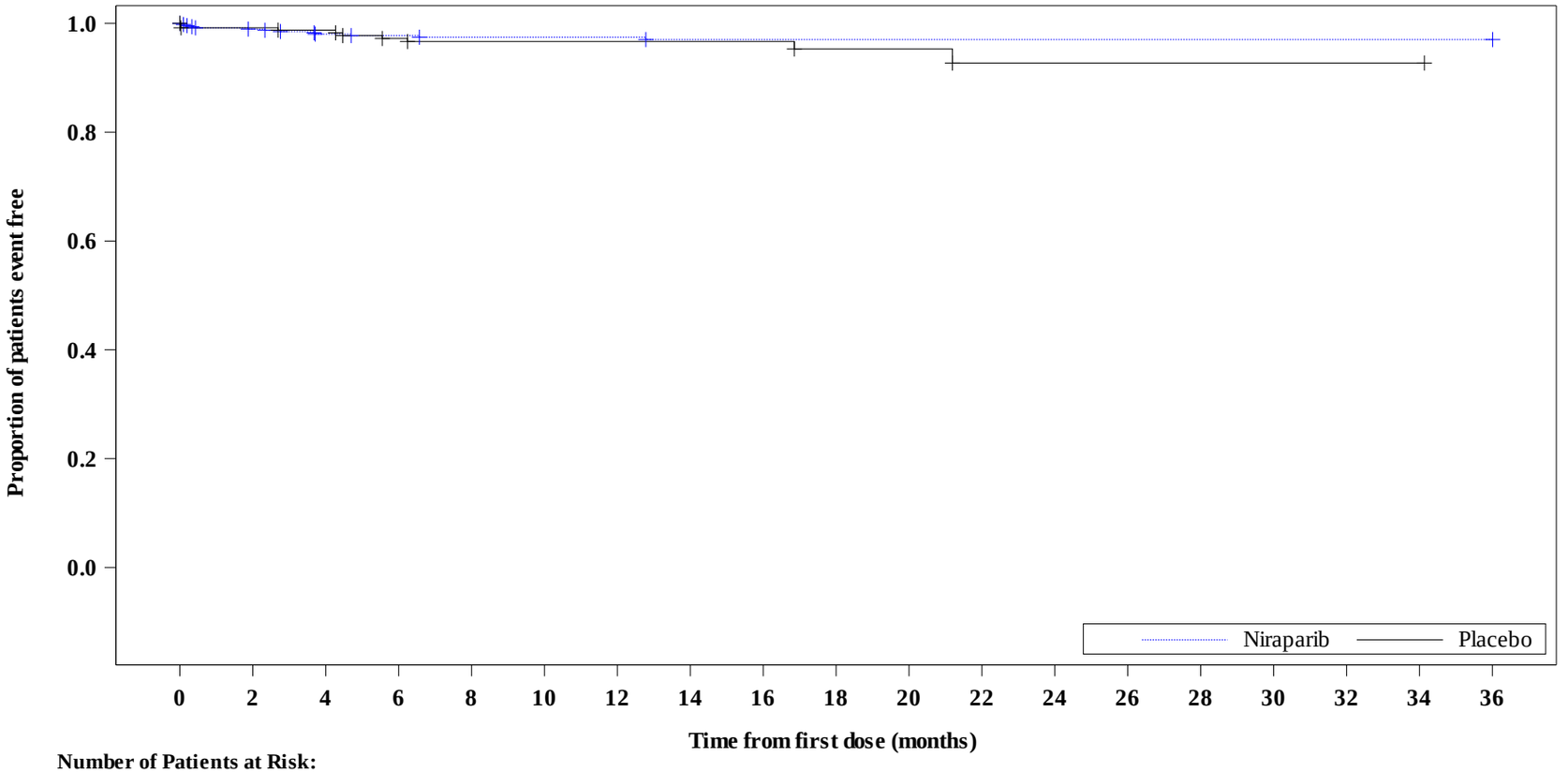



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 434 | 374 | 335 | 277 | 241 | 225 | 203 | 170 | 149 | 113 | 83 | 56 | 30 | 19 | 11 | 9 | 5 | 1 |
| Placebo | 244 | 238 | 198 | 175 | 136 | 101 | 90 | 79 | 67 | 58 | 47 | 27 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Neck pain

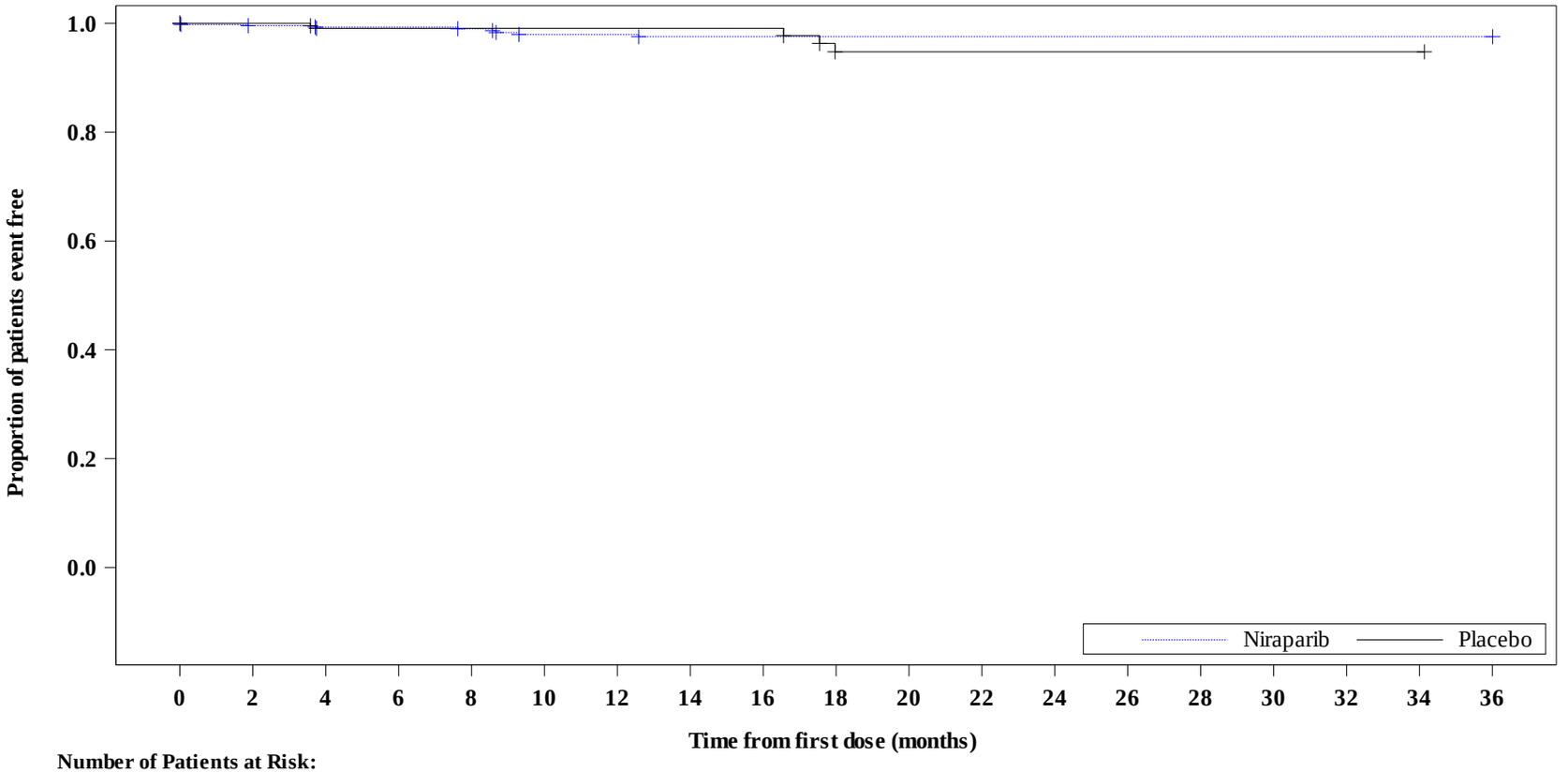



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 445 | 382 | 348 | 292 | 259 | 244 | 220 | 186 | 163 | 127 | 90 | 62 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 202 | 178 | 141 | 105 | 94 | 83 | 71 | 61 | 51 | 29 | 16 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Osteoarthritis

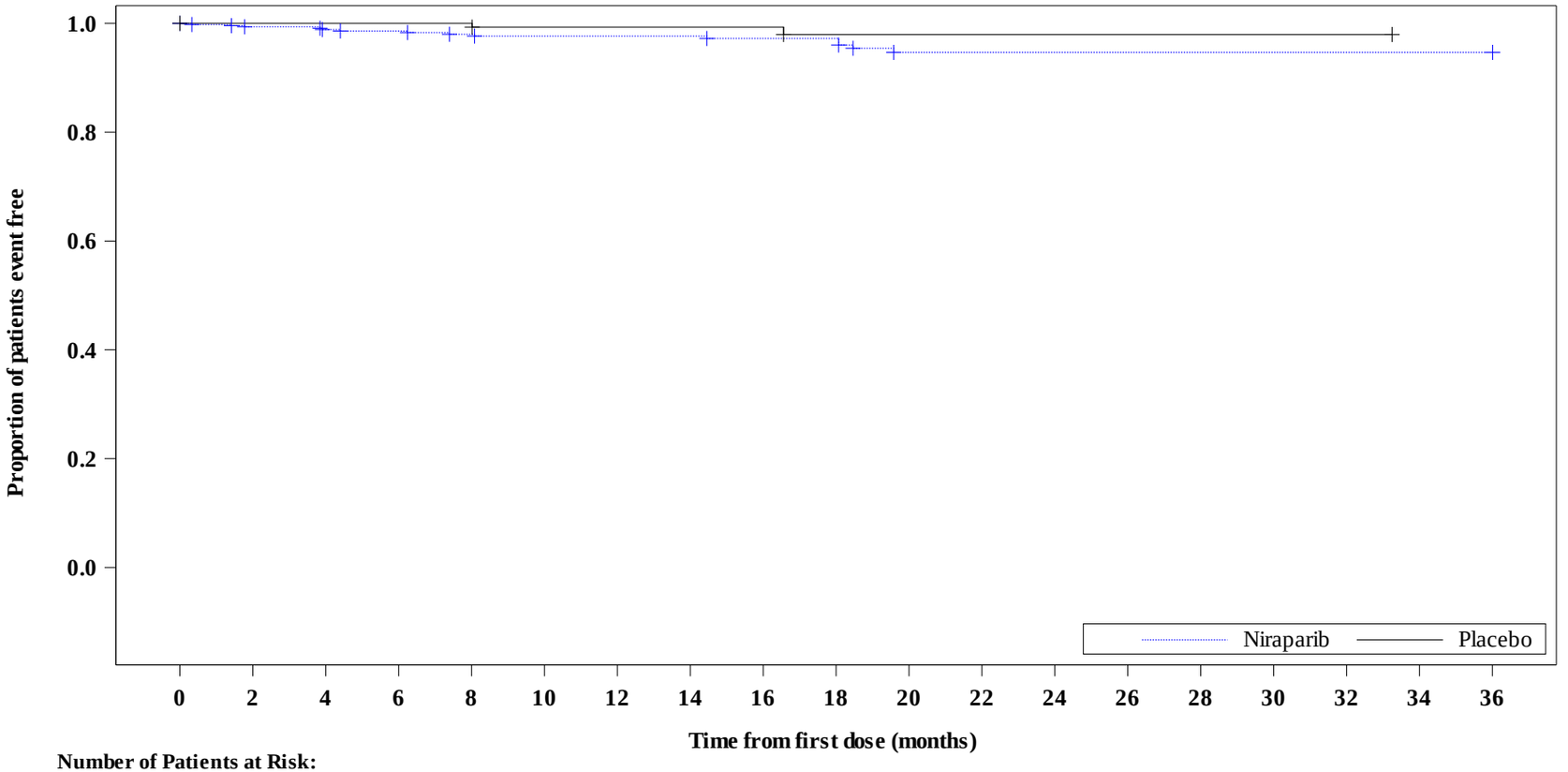



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 388 | 354 | 295 | 259 | 244 | 221 | 187 | 164 | 127 | 90 | 61 | 33 | 20 | 11 | 8 | 5 | 1 |
| Placebo | 244 | 241 | 203 | 181 | 145 | 108 | 97 | 85 | 73 | 61 | 51 | 31 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Osteoporosis

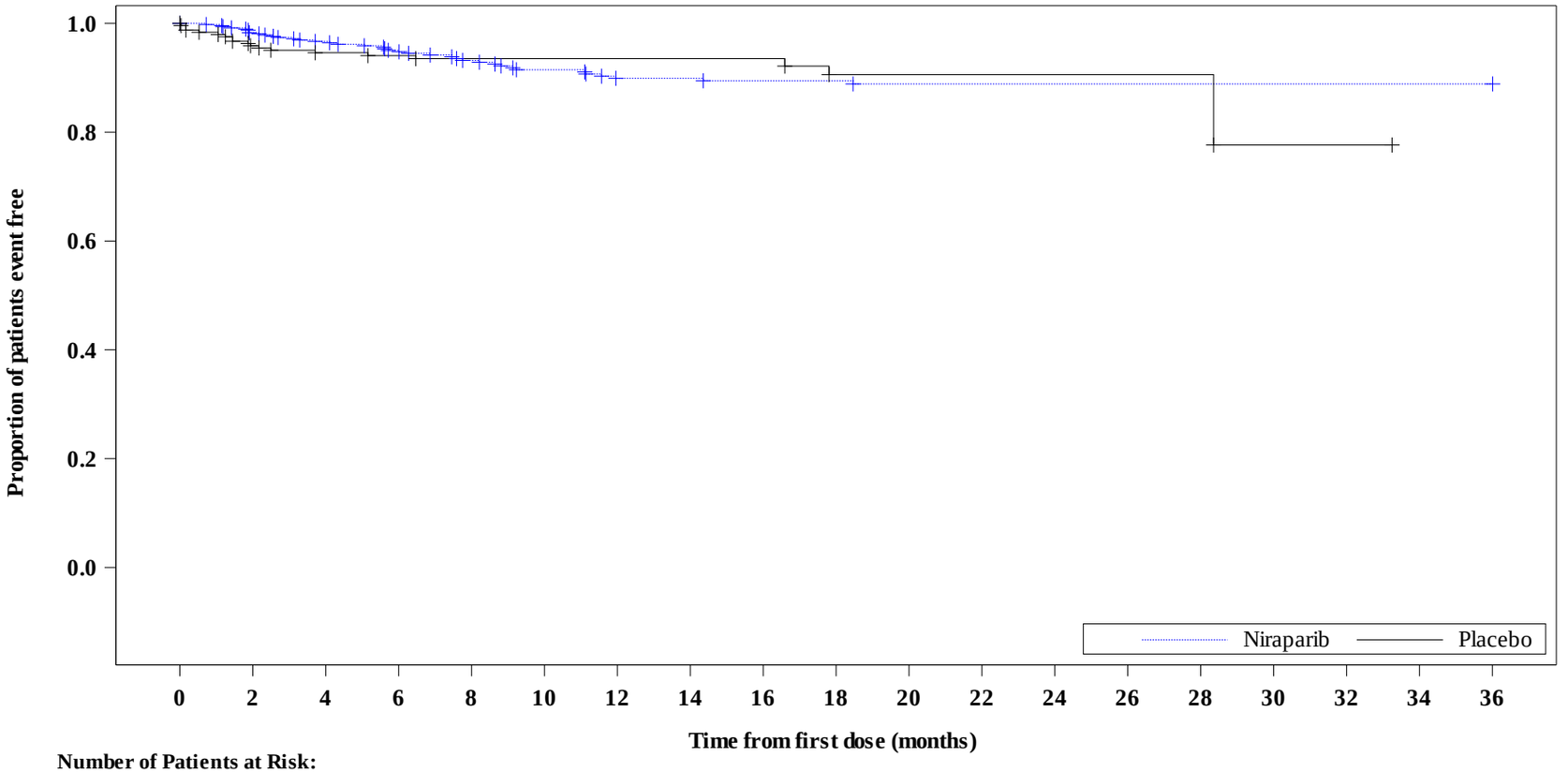



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 387 | 352 | 293 | 260 | 243 | 220 | 186 | 163 | 121 | 84 | 56 | 30 | 17 | 10 | 7 | 4 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 108 | 97 | 85 | 73 | 63 | 52 | 32 | 17 | 11 | 6 | 2 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 377 | 339 | 277 | 244 | 224 | 204 | 174 | 153 | 116 | 80 | 55 | 32 | 20 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 232 | 193 | 172 | 134 | 102 | 91 | 80 | 68 | 58 | 49 | 31 | 17 | 11 | 7 | 2 | 1 | 0 | |

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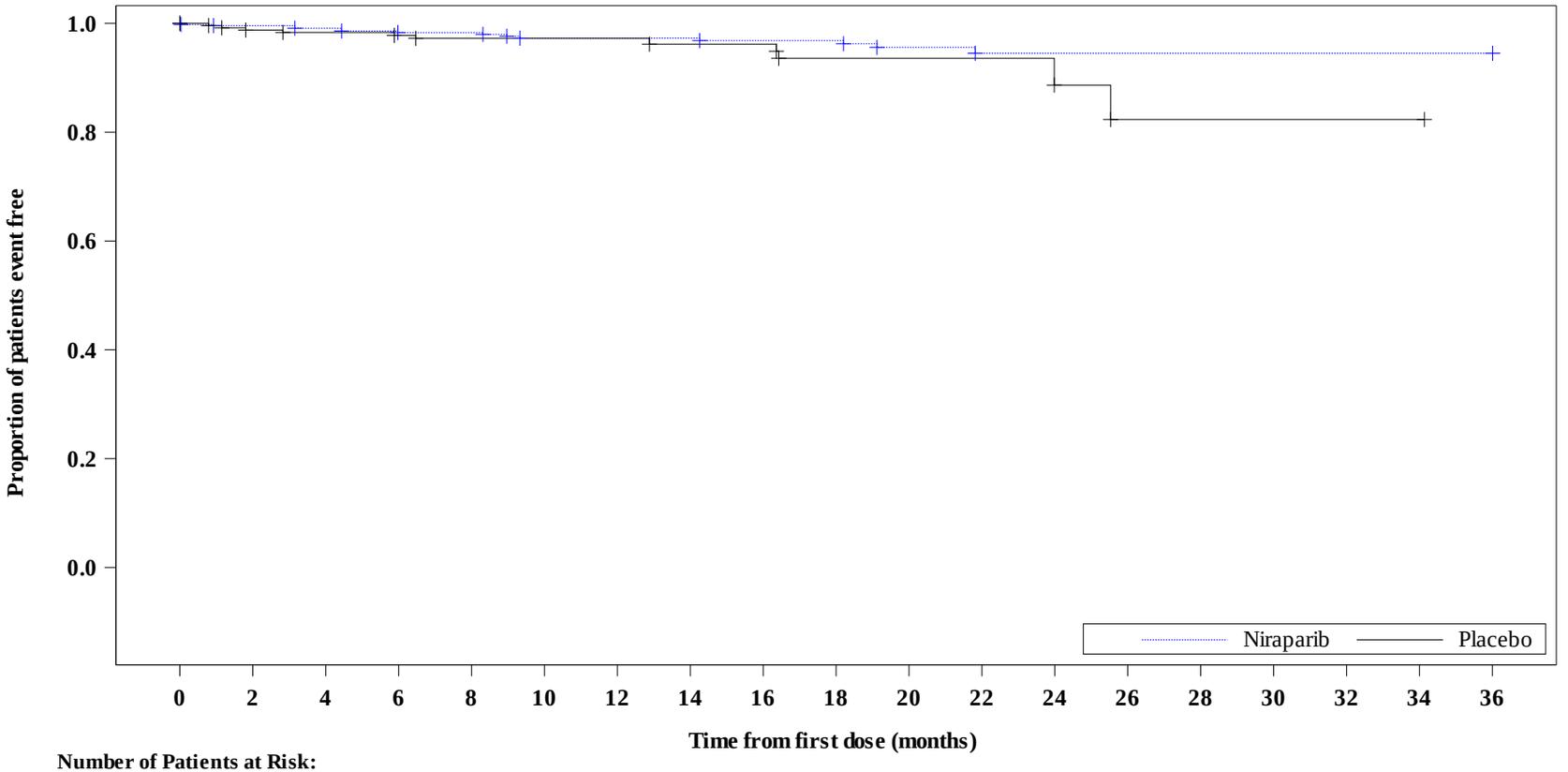
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

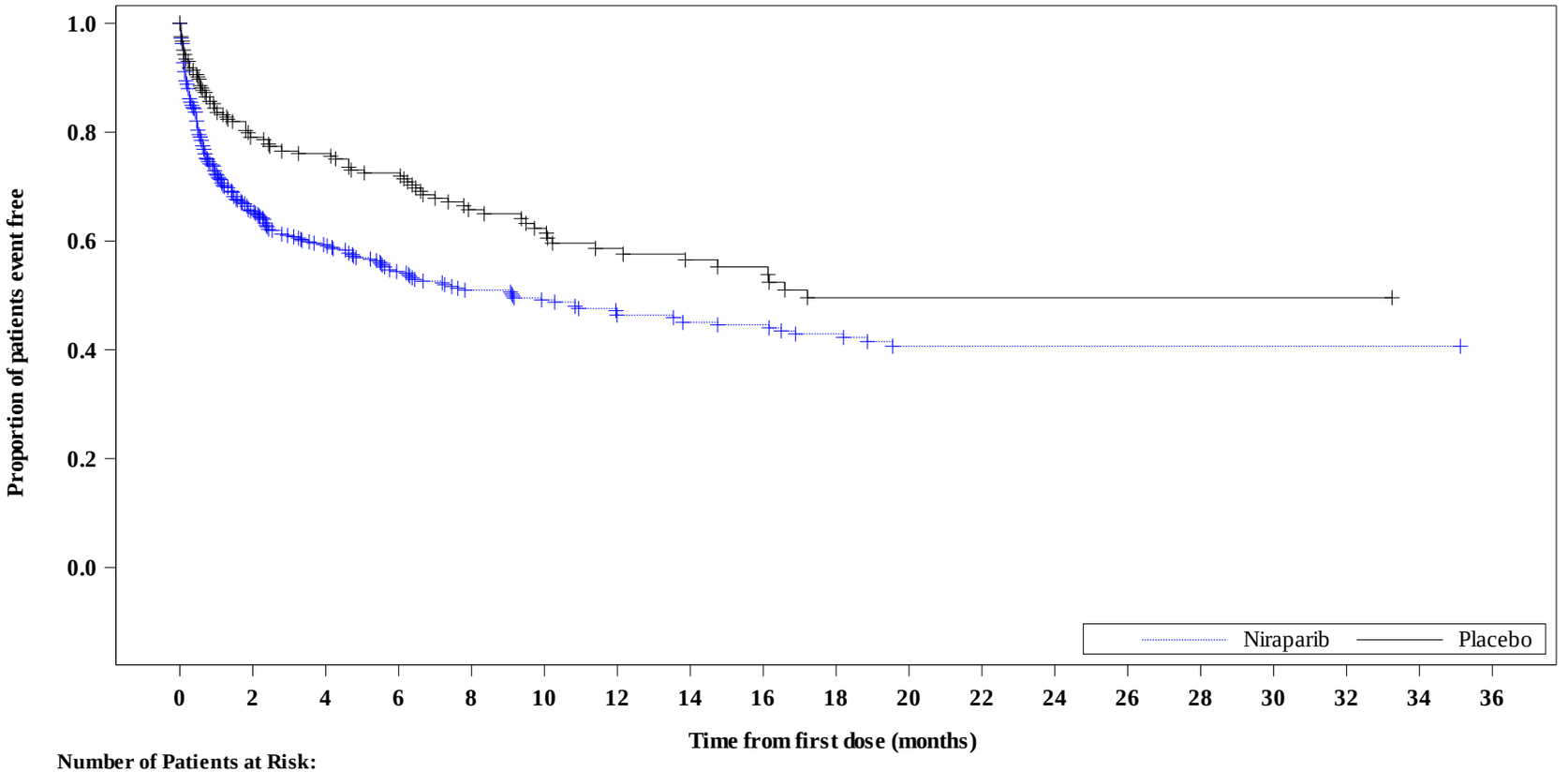



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 388 | 353 | 295 | 261 | 244 | 221 | 187 | 165 | 125 | 87 | 60 | 34 | 21 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 238 | 202 | 180 | 143 | 108 | 97 | 85 | 74 | 65 | 54 | 34 | 18 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders

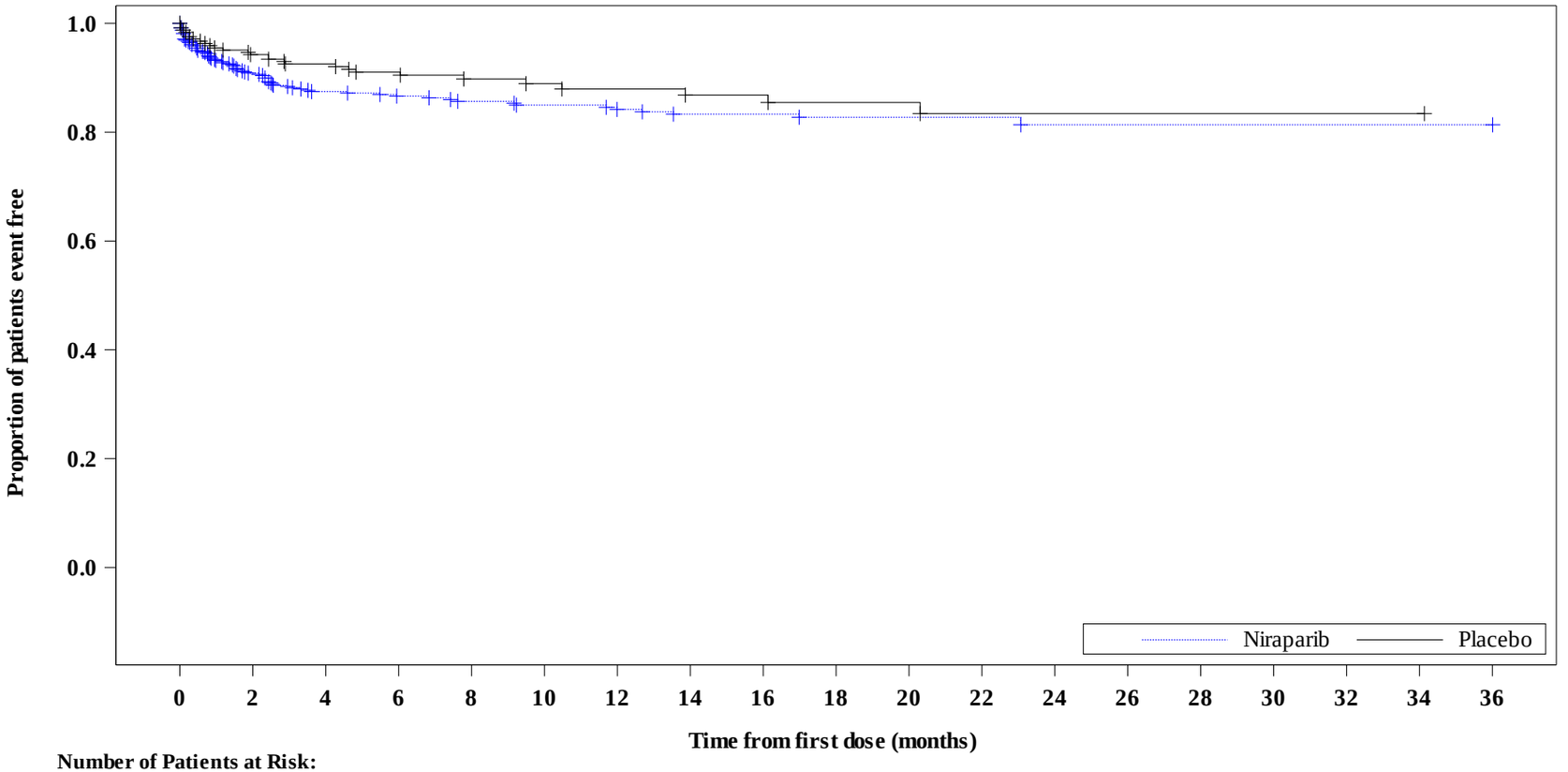



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 294 | 231 | 190 | 148 | 127 | 112 | 100 | 82 | 68 | 42 | 28 | 19 | 10 | 6 | 4 | 4 | 3 | 0 |
| Placebo | 244 | 190 | 154 | 133 | 92 | 69 | 58 | 48 | 39 | 29 | 21 | 11 | 5 | 2 | 1 | 1 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Dizziness




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 411 | 342 | 308 | 253 | 226 | 210 | 189 | 157 | 137 | 103 | 72 | 48 | 27 | 17 | 9 | 6 | 4 | 1 |
| Placebo | 244 | 227 | 189 | 168 | 129 | 96 | 85 | 72 | 63 | 53 | 43 | 26 | 15 | 10 | 6 | 3 | 2 | 1 | 0 |

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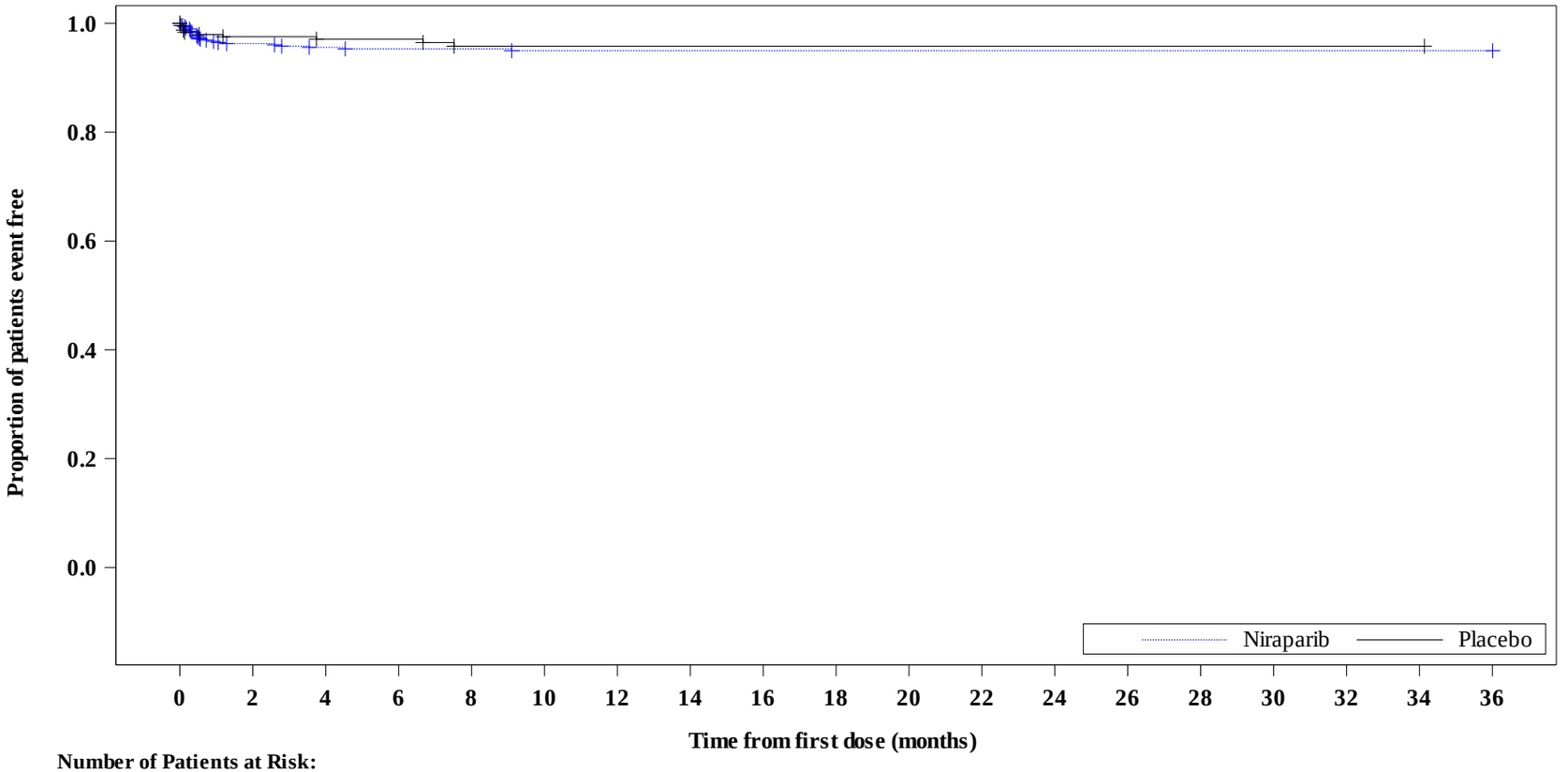
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Dysgeusia

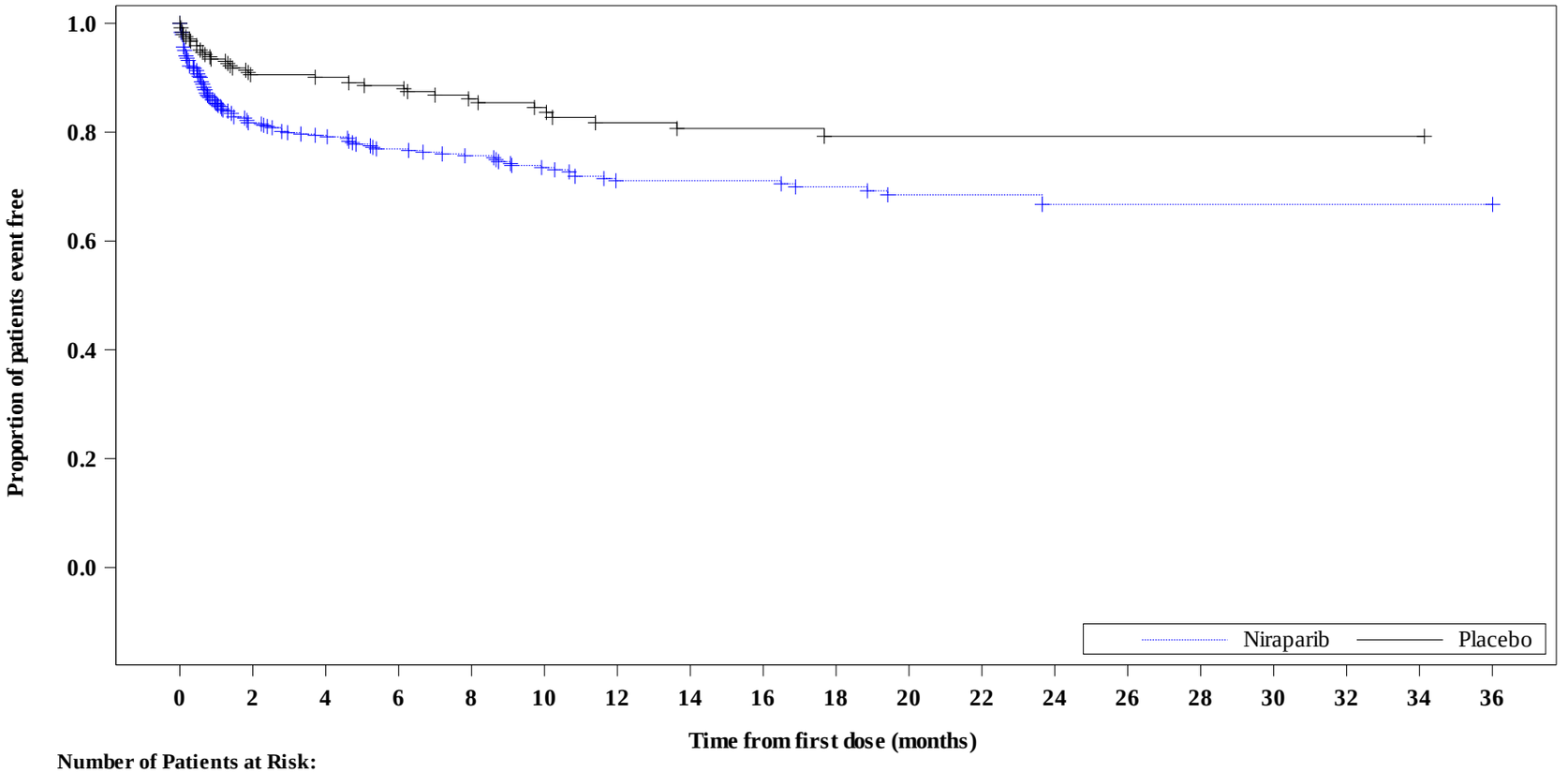



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 433 | 374 | 340 | 285 | 251 | 235 | 214 | 183 | 162 | 123 | 87 | 60 | 33 | 21 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 235 | 199 | 178 | 139 | 107 | 96 | 84 | 73 | 64 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Headache

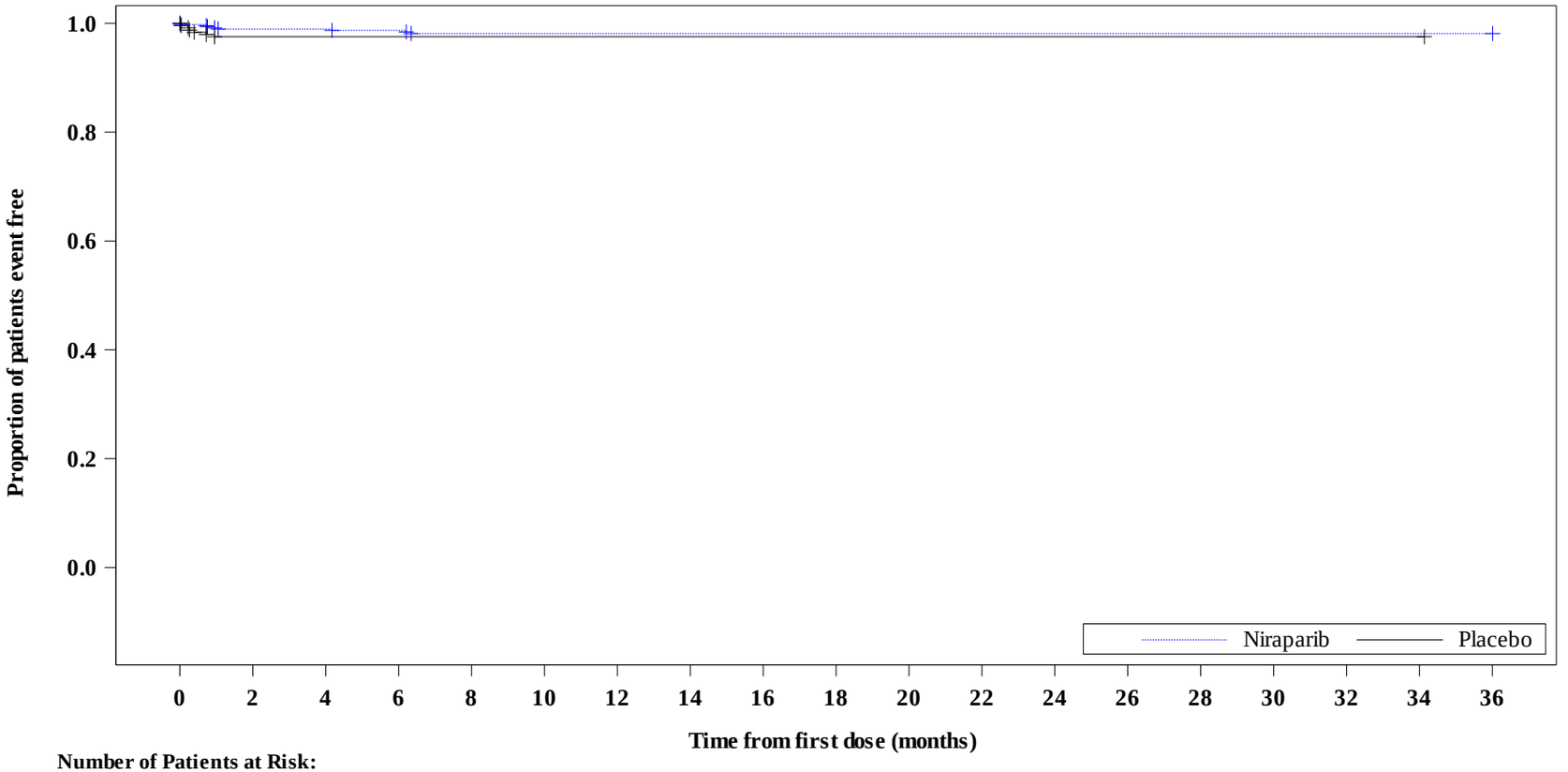



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 365 | 304 | 266 | 218 | 187 | 170 | 154 | 131 | 110 | 79 | 53 | 31 | 17 | 11 | 7 | 6 | 5 | 1 |
| Placebo | 244 | 218 | 185 | 161 | 125 | 94 | 81 | 72 | 61 | 53 | 44 | 26 | 15 | 10 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Hypoaesthesia

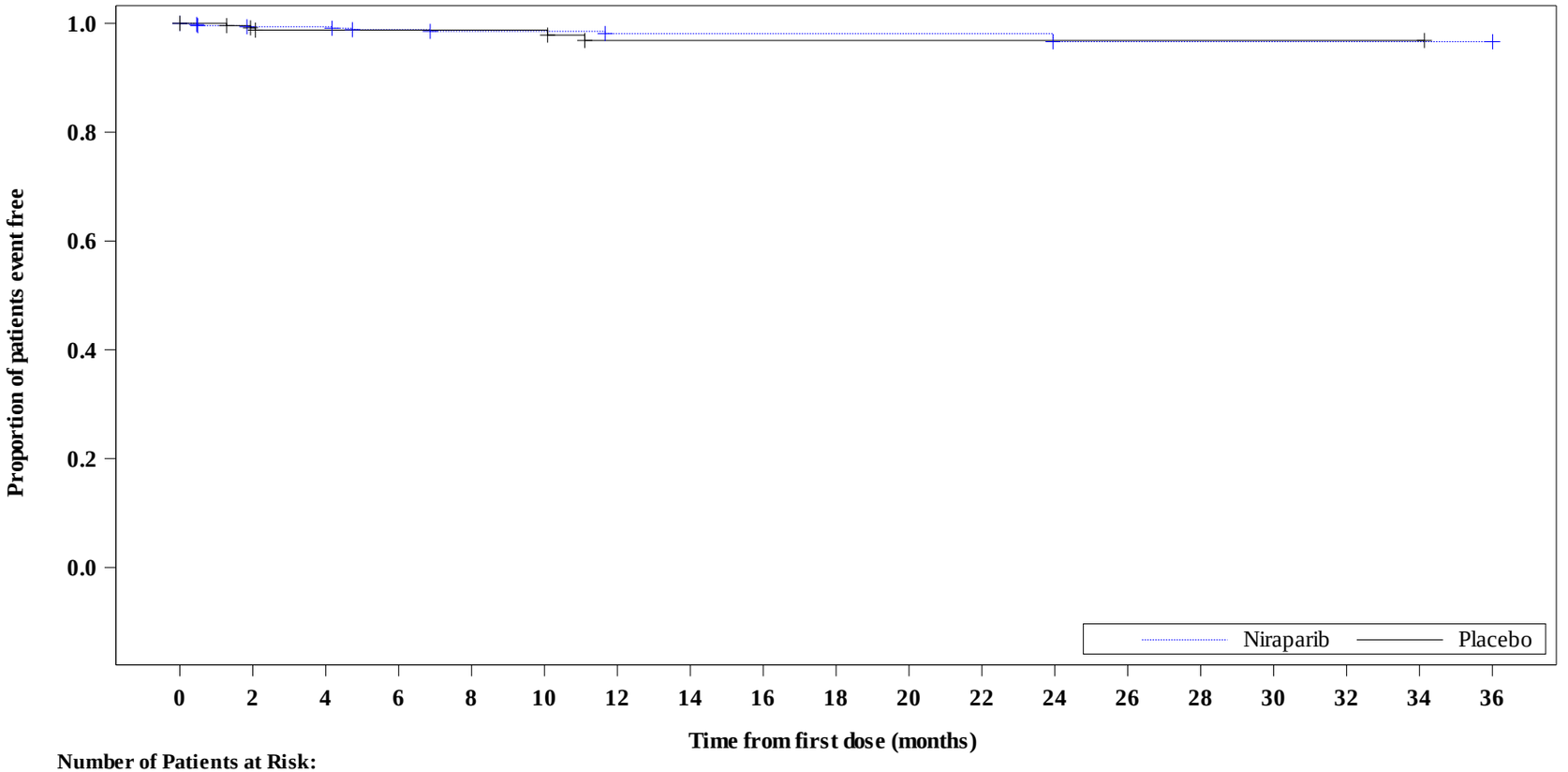



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 445 | 387 | 352 | 293 | 261 | 245 | 223 | 189 | 167 | 128 | 91 | 62 | 34 | 21 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 235 | 201 | 181 | 144 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Memory impairment

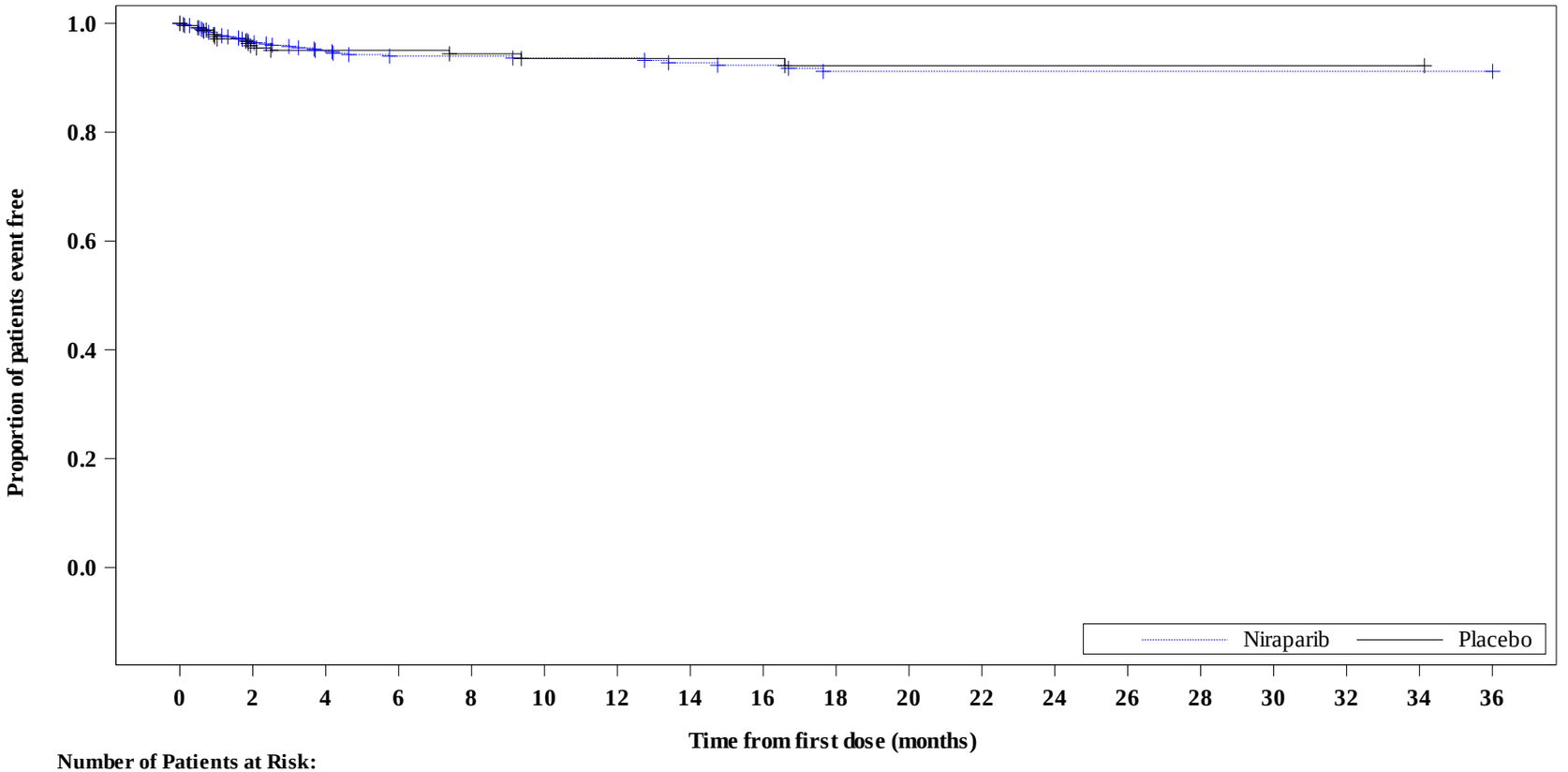



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 388 | 352 | 293 | 261 | 244 | 221 | 187 | 164 | 126 | 89 | 60 | 33 | 20 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 181 | 144 | 108 | 95 | 83 | 71 | 62 | 52 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Neuropathy peripheral




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 436 | 372 | 335 | 278 | 249 | 234 | 209 | 175 | 151 | 114 | 82 | 58 | 32 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 231 | 195 | 175 | 137 | 103 | 92 | 81 | 71 | 61 | 50 | 29 | 16 | 11 | 7 | 3 | 2 | 1 | 0 |

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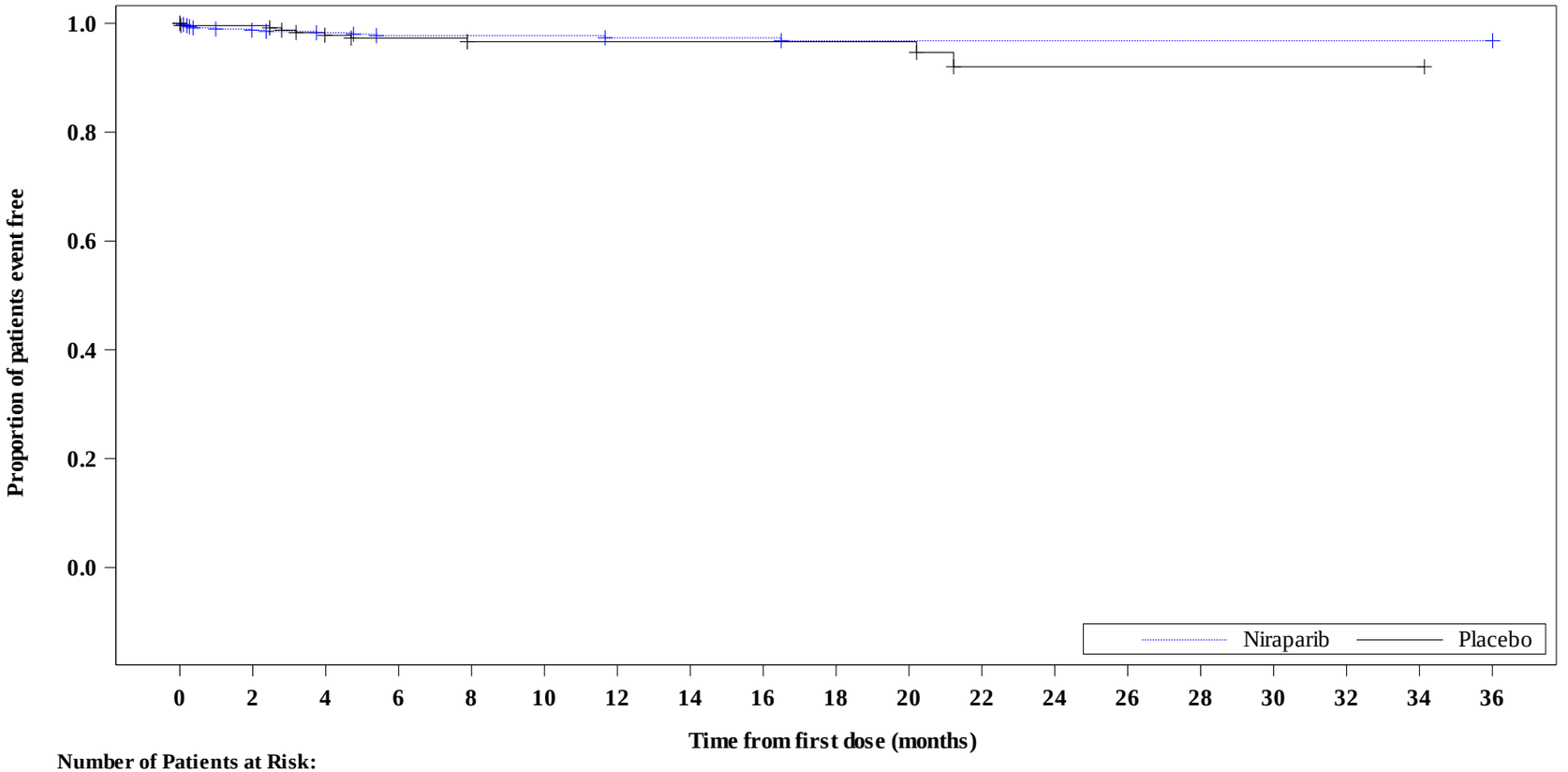
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Paraesthesia

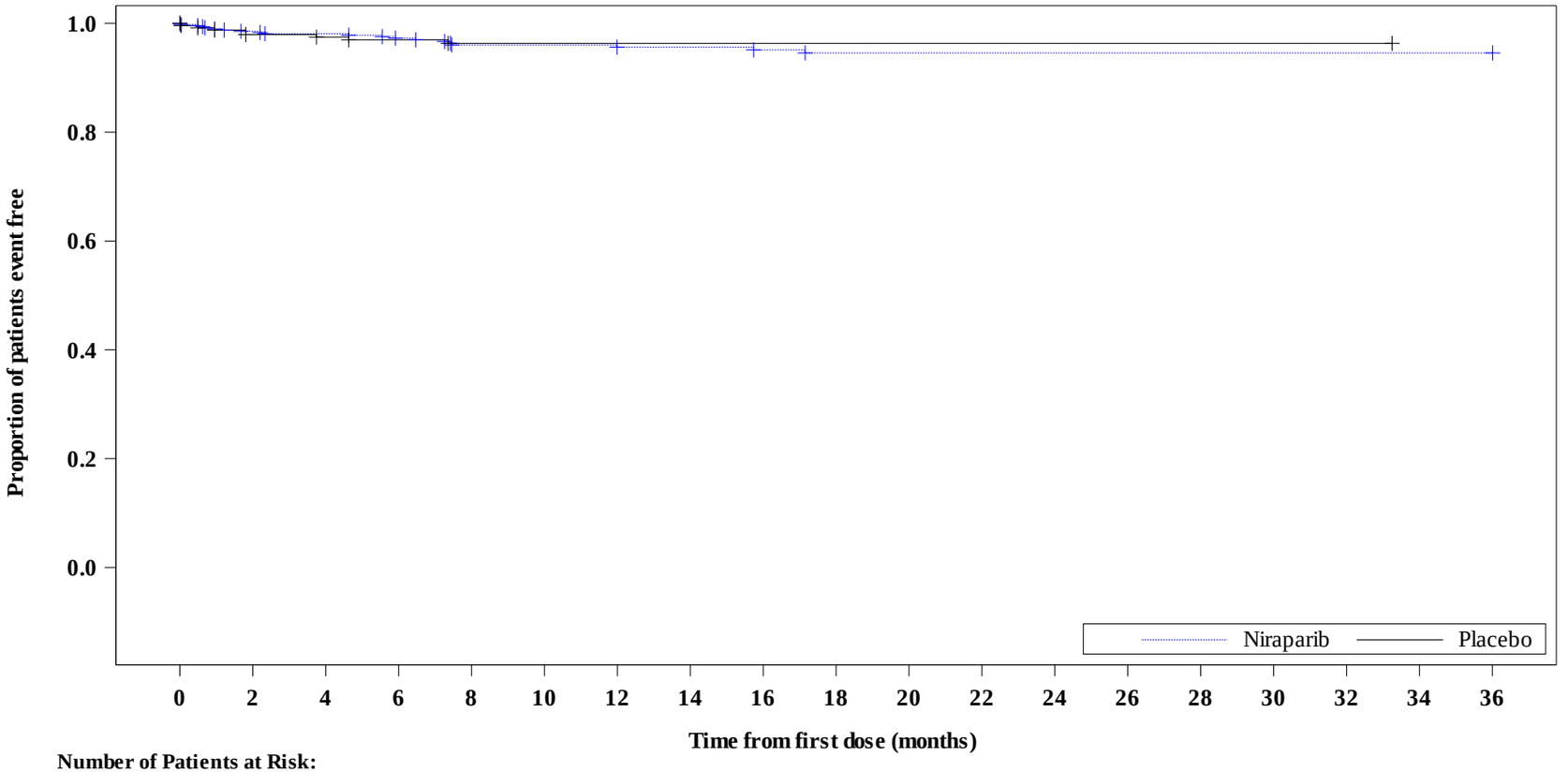



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 445 | 386 | 350 | 292 | 261 | 245 | 222 | 188 | 164 | 126 | 90 | 62 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 200 | 179 | 141 | 104 | 93 | 81 | 69 | 61 | 50 | 29 | 16 | 10 | 5 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Peripheral sensory neuropathy

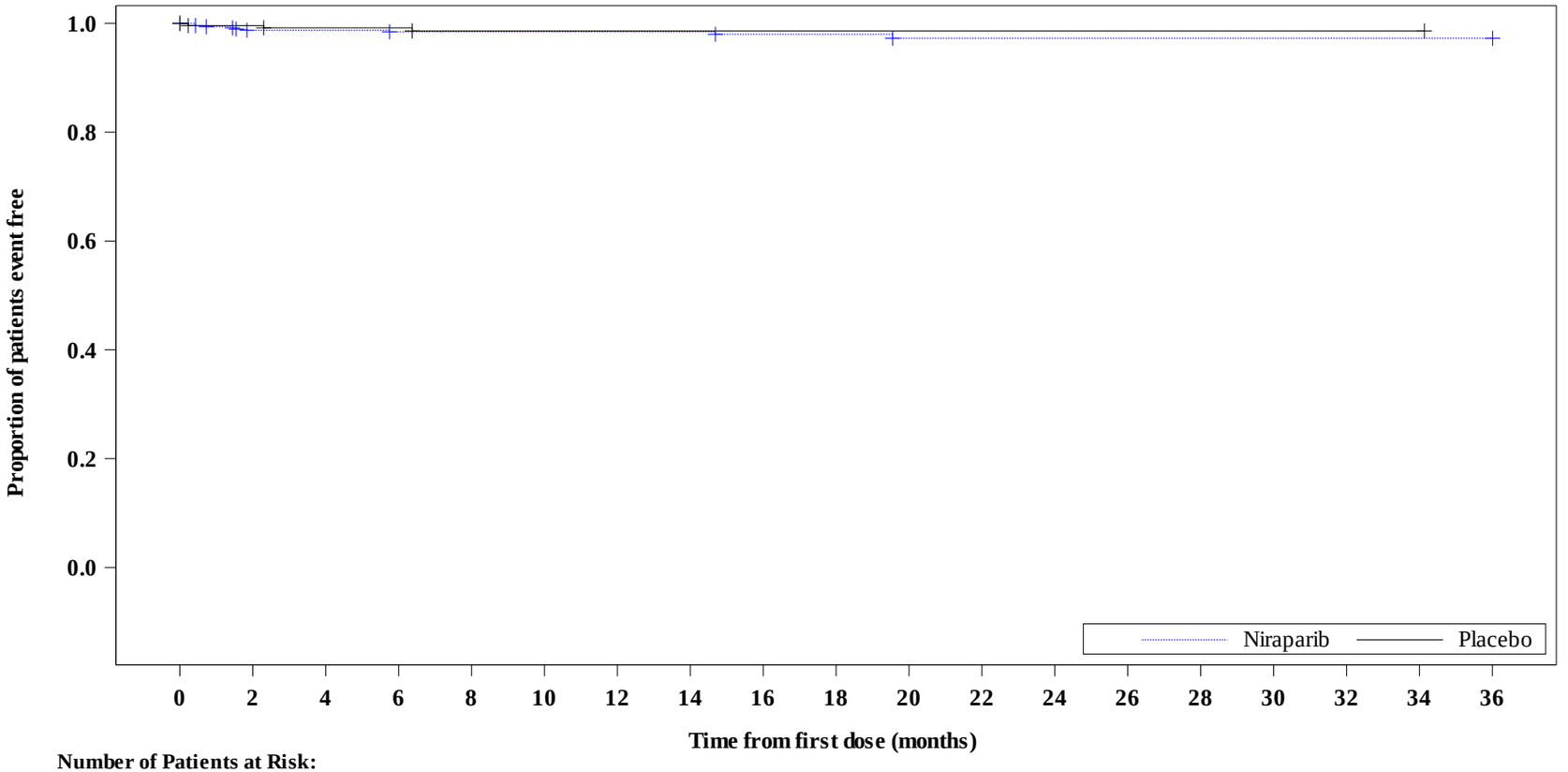



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 443 | 384 | 348 | 287 | 254 | 237 | 216 | 183 | 160 | 122 | 86 | 57 | 31 | 19 | 11 | 8 | 5 | 1 |
| Placebo | 244 | 236 | 200 | 178 | 140 | 104 | 93 | 81 | 69 | 60 | 50 | 31 | 16 | 10 | 5 | 2 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Nervous system disorders, PT: Sciatica

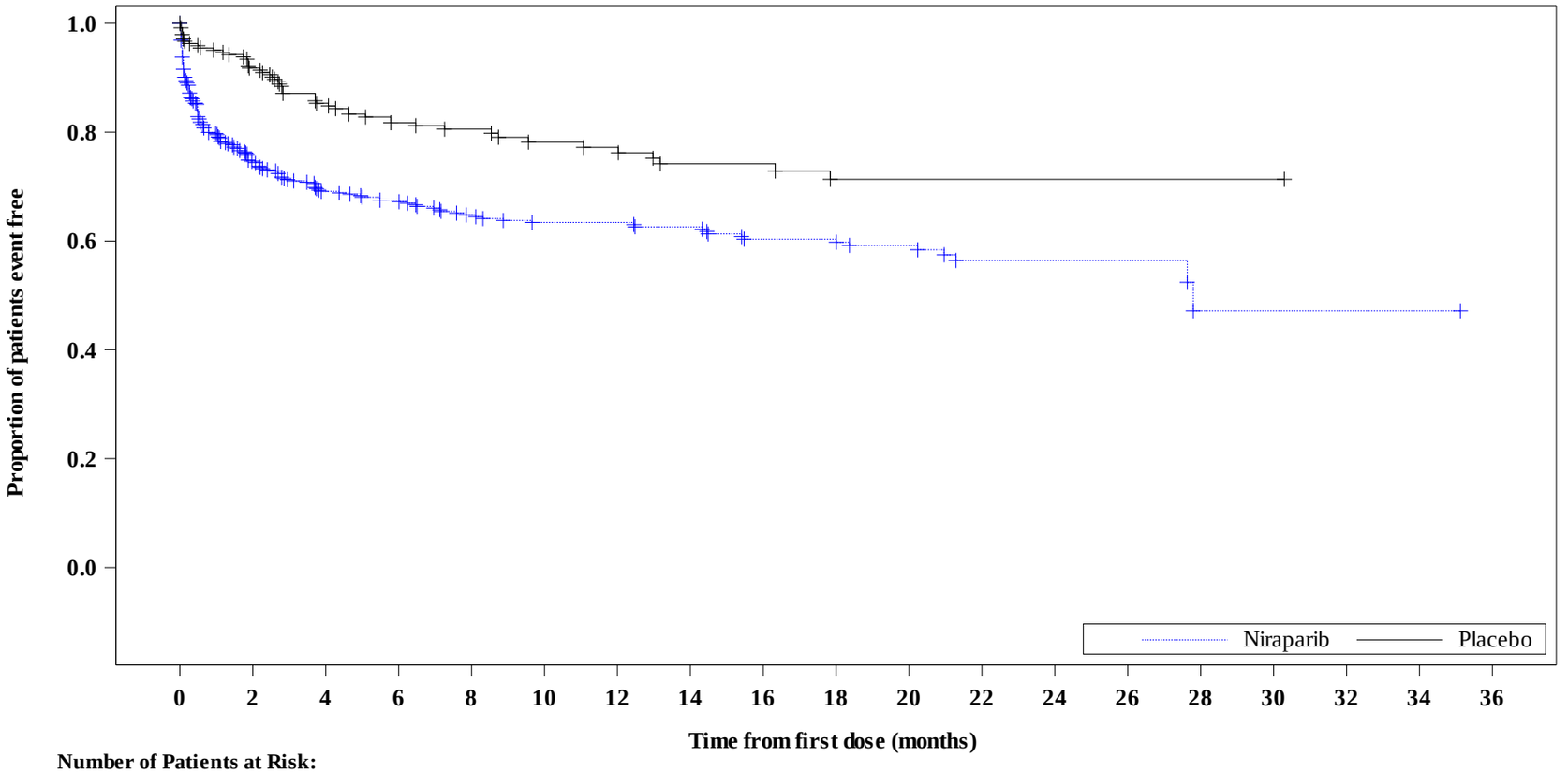



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 444 | 385 | 350 | 293 | 260 | 243 | 220 | 185 | 162 | 124 | 89 | 62 | 34 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 181 | 143 | 106 | 96 | 84 | 72 | 63 | 52 | 31 | 17 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Psychiatric disorders

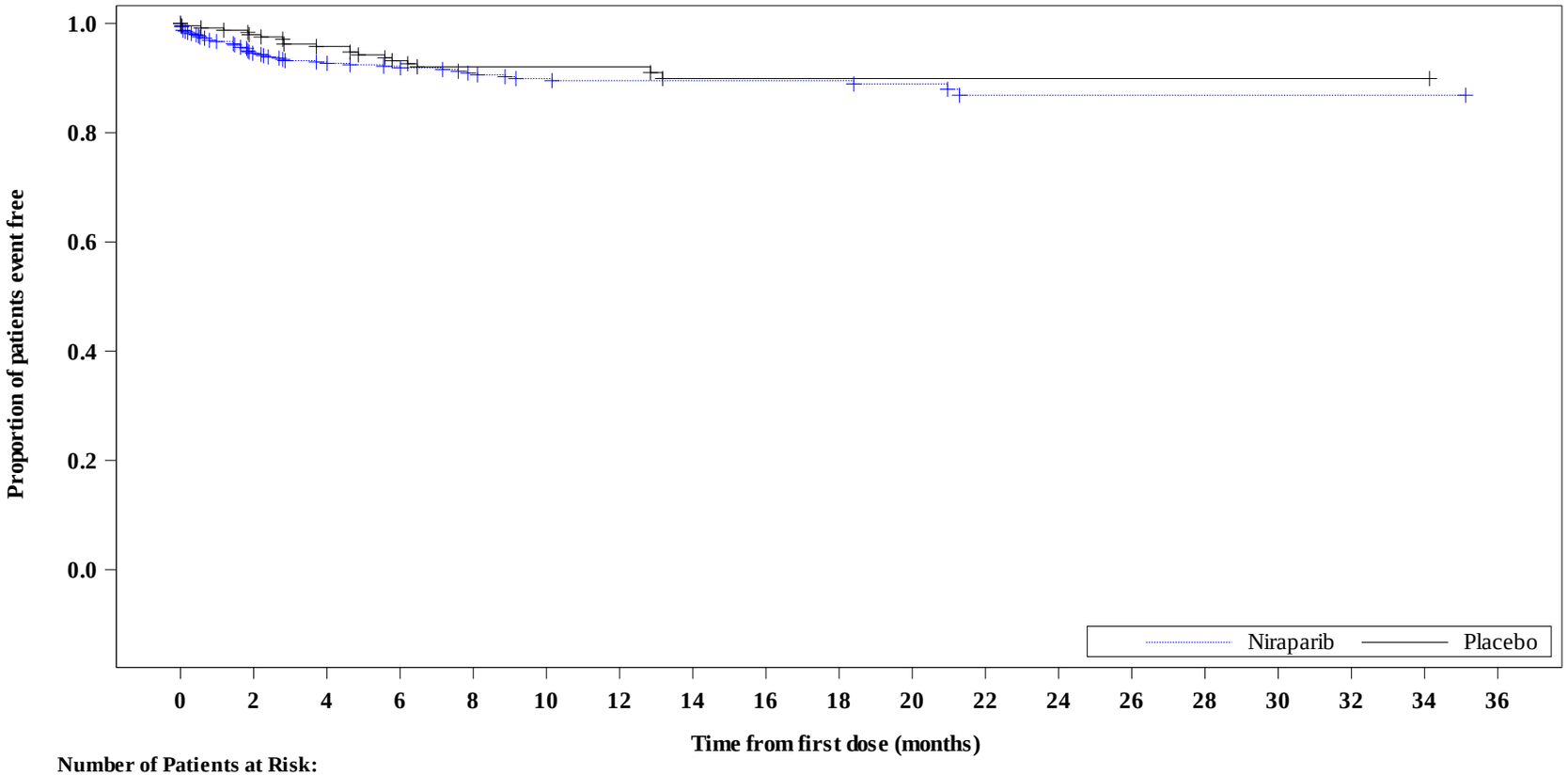



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 336 | 274 | 242 | 194 | 170 | 160 | 146 | 125 | 106 | 75 | 52 | 35 | 21 | 9 | 5 | 3 | 2 | 0 |
| Placebo | 244 | 221 | 176 | 153 | 120 | 87 | 78 | 66 | 56 | 47 | 39 | 26 | 14 | 8 | 3 | 1 | 0 | | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Psychiatric disorders, PT: Anxiety

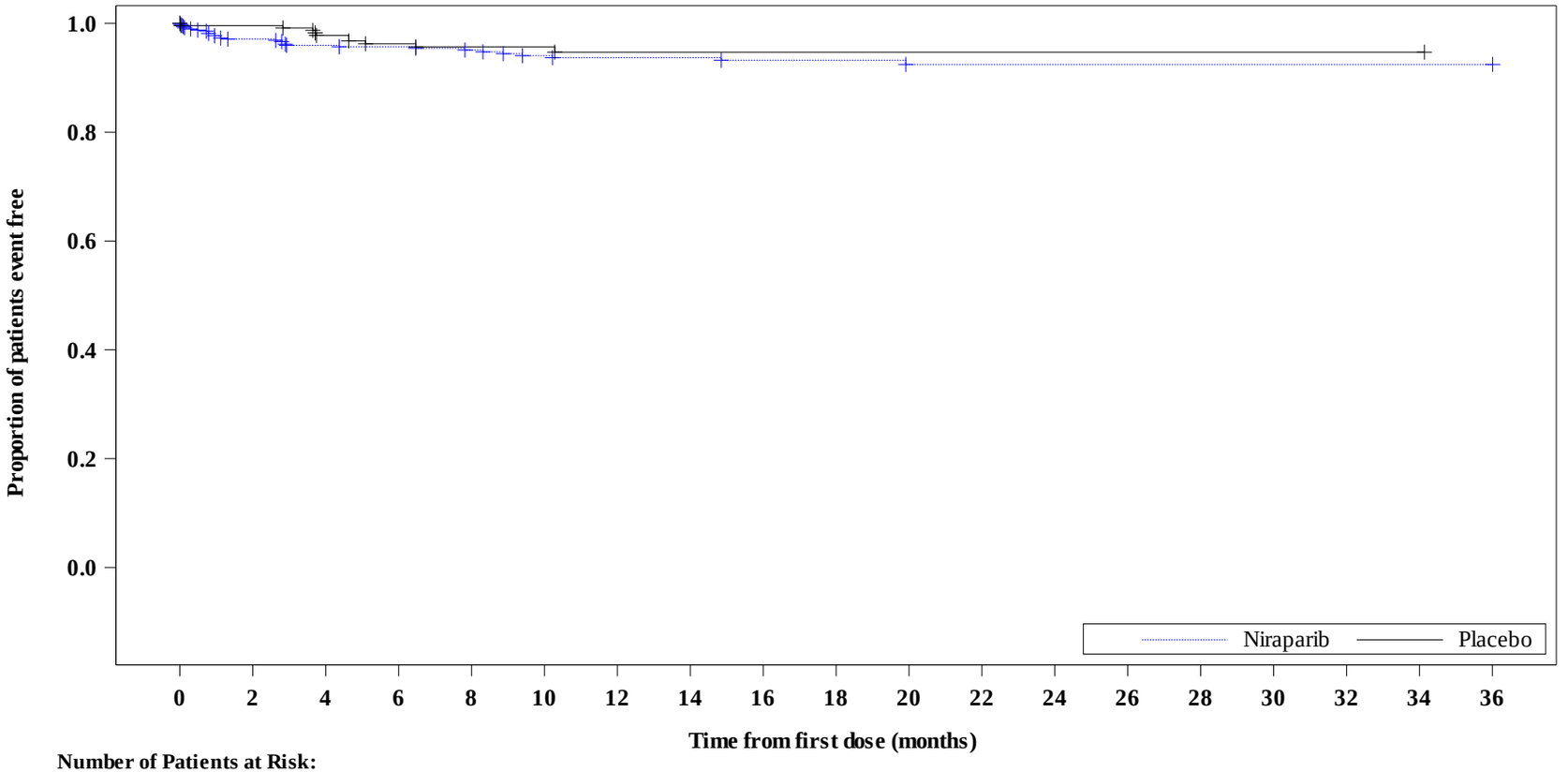



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 425 | 368 | 332 | 273 | 240 | 222 | 202 | 173 | 151 | 112 | 76 | 49 | 29 | 16 | 9 | 6 | 2 | 0 |
| Placebo | 244 | 236 | 197 | 171 | 133 | 101 | 91 | 77 | 67 | 59 | 51 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Psychiatric disorders, PT: Depression

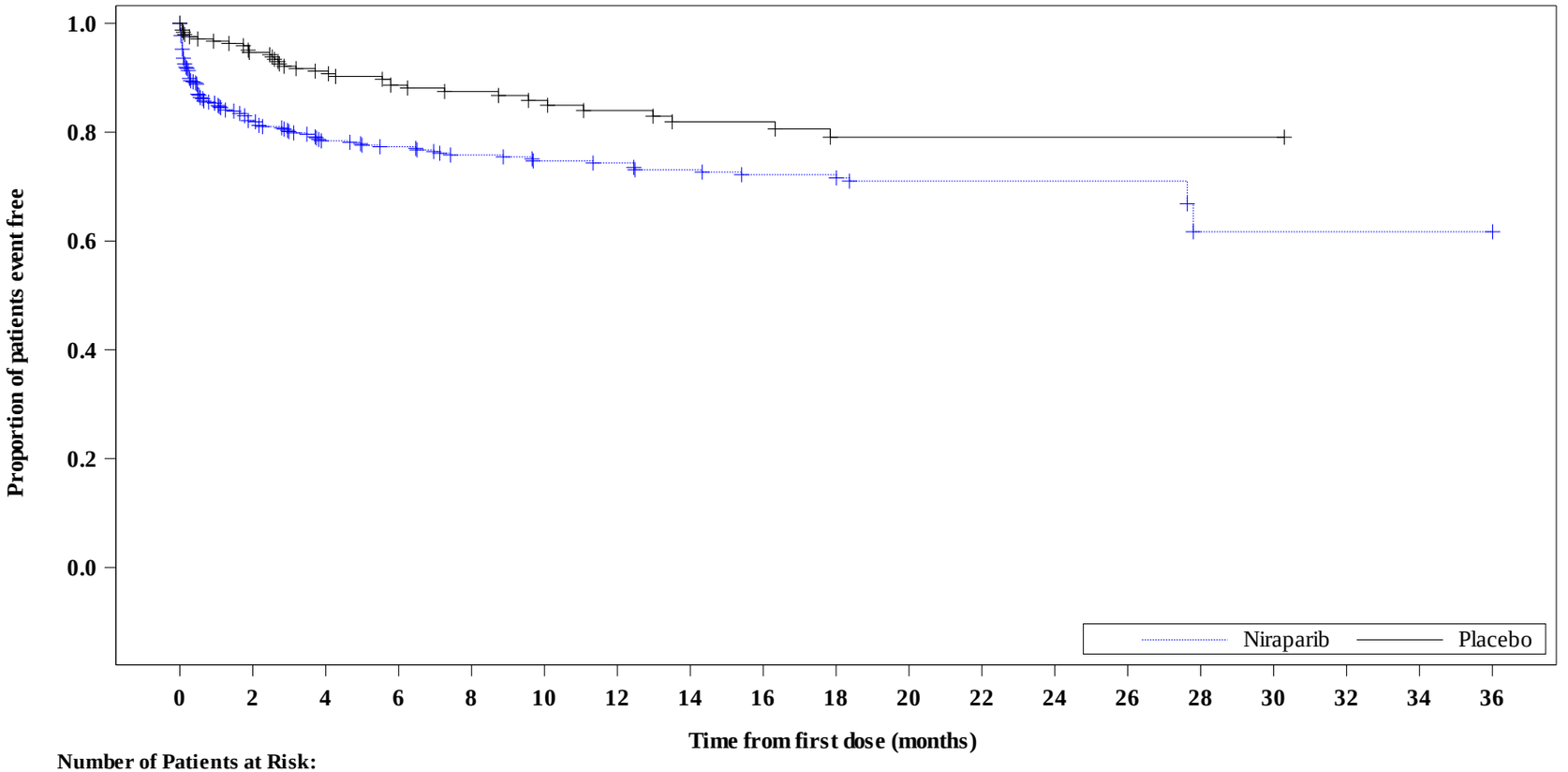



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 439 | 378 | 346 | 287 | 253 | 235 | 213 | 180 | 158 | 118 | 85 | 58 | 33 | 20 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 240 | 200 | 176 | 138 | 102 | 90 | 79 | 68 | 59 | 51 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Psychiatric disorders, PT: Insomnia

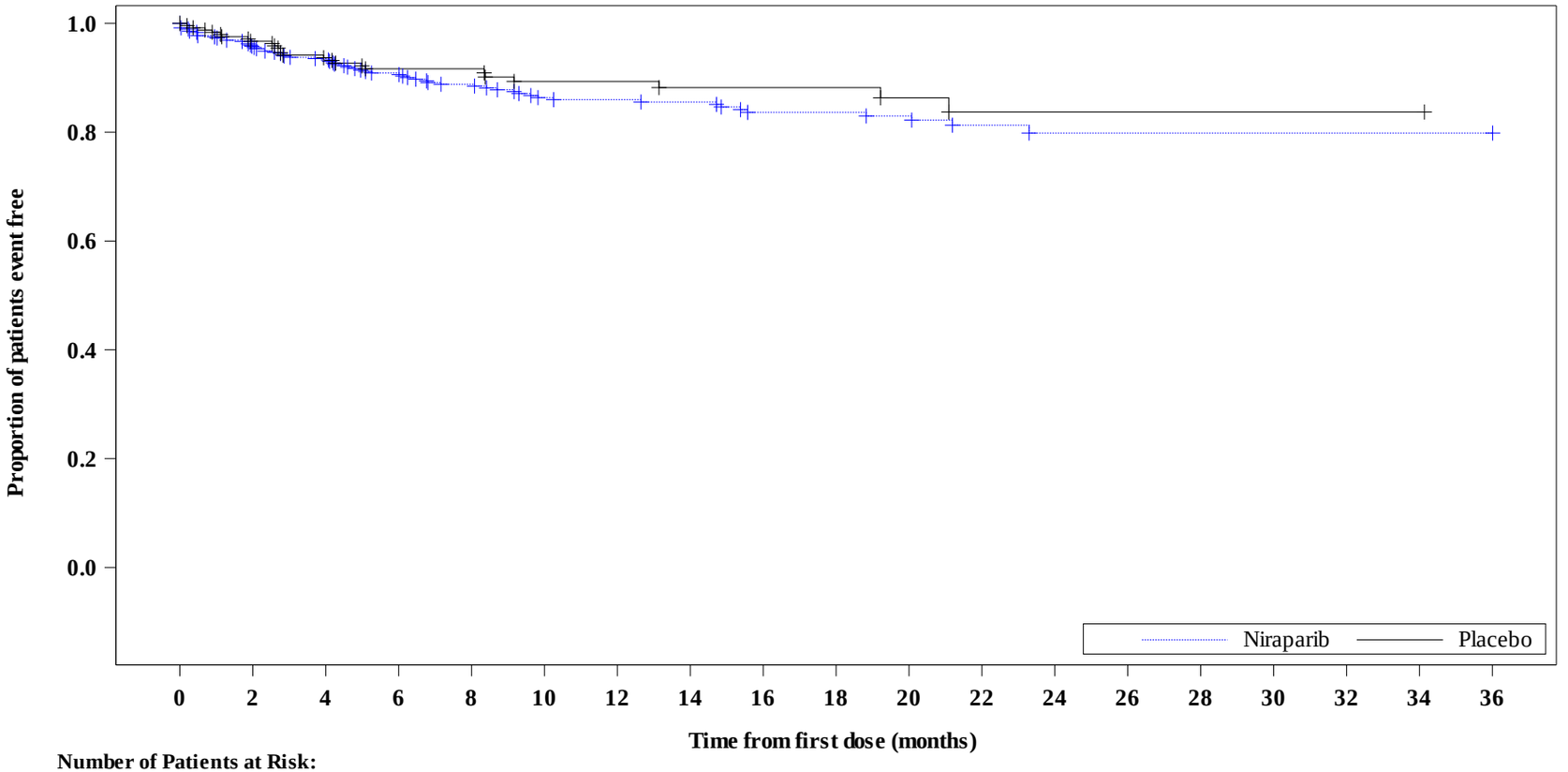



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 370 | 307 | 274 | 225 | 199 | 187 | 169 | 143 | 124 | 92 | 67 | 45 | 24 | 12 | 7 | 5 | 4 | 1 |
| Placebo | 244 | 228 | 188 | 165 | 132 | 95 | 84 | 73 | 62 | 52 | 43 | 27 | 15 | 9 | 4 | 1 | 0 | | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Renal and urinary disorders

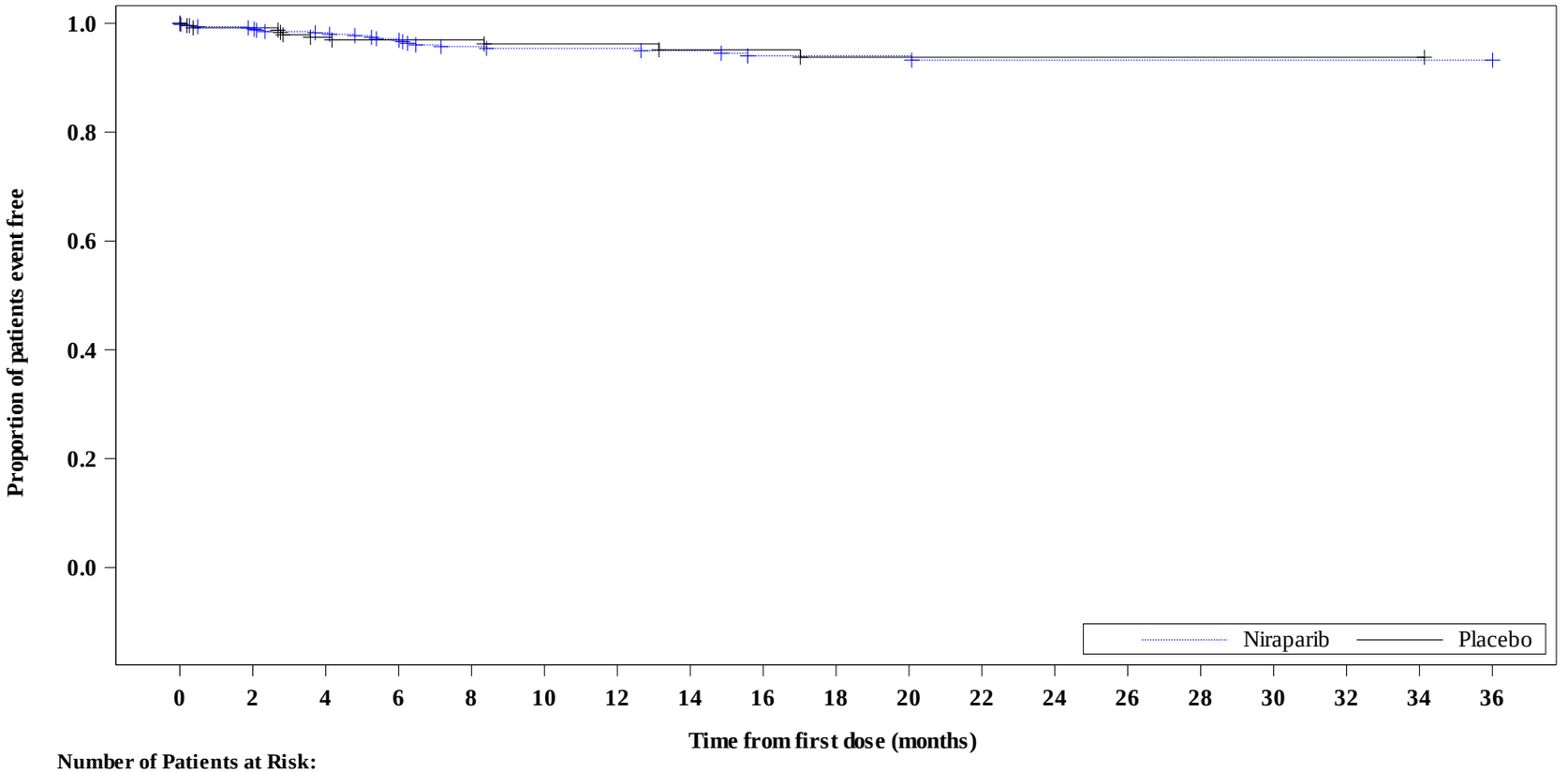



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 430 | 368 | 325 | 265 | 230 | 217 | 195 | 163 | 141 | 109 | 74 | 51 | 28 | 18 | 10 | 9 | 5 | 1 |
| Placebo | 244 | 233 | 193 | 169 | 132 | 95 | 85 | 72 | 60 | 54 | 43 | 26 | 14 | 9 | 5 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Renal and urinary disorders, PT: Dysuria

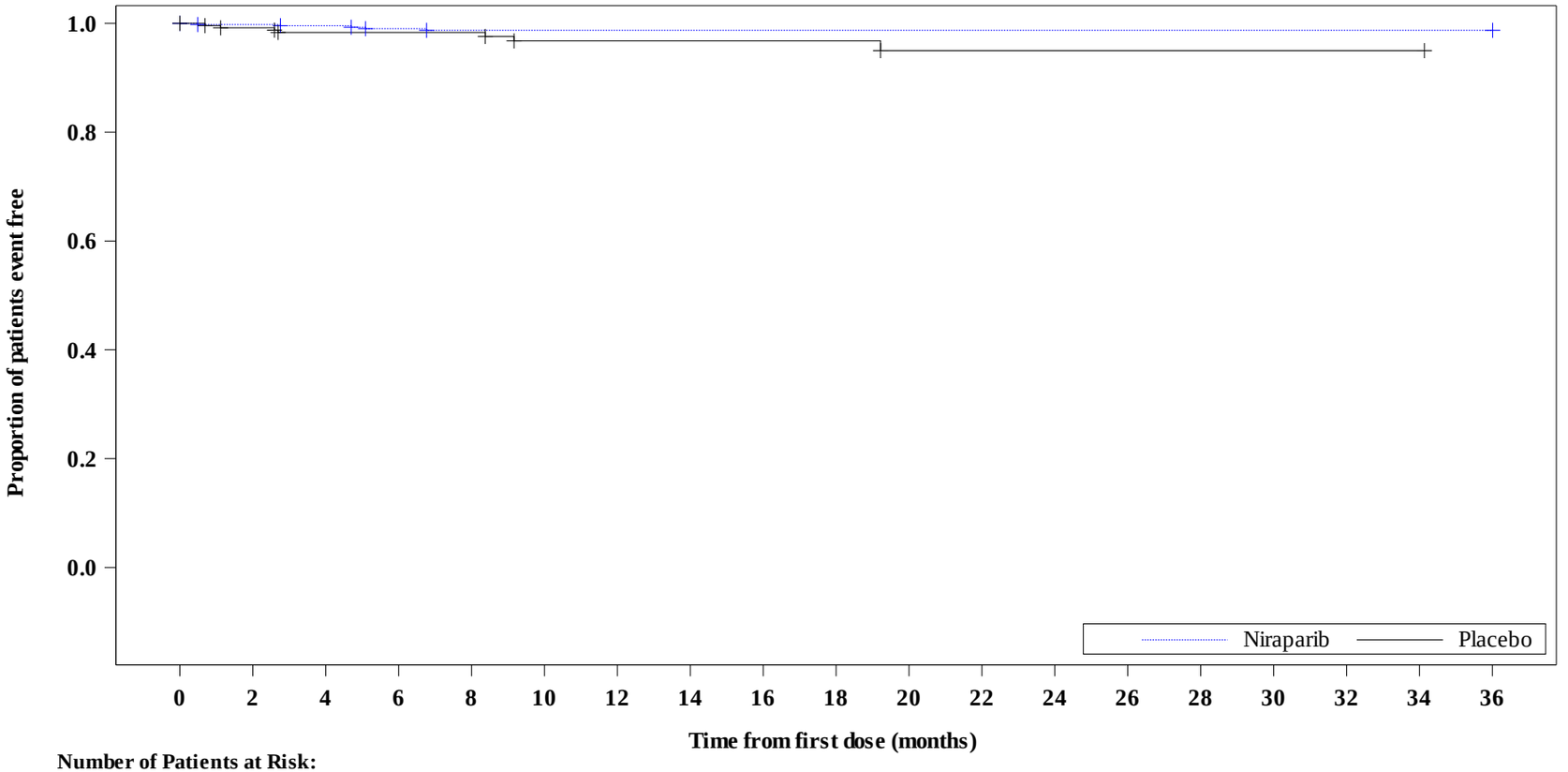



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 386 | 348 | 288 | 256 | 242 | 218 | 183 | 161 | 123 | 85 | 59 | 33 | 20 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 200 | 178 | 141 | 105 | 95 | 82 | 70 | 61 | 50 | 31 | 16 | 10 | 6 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Renal and urinary disorders, PT: Haematuria




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 389 | 353 | 294 | 261 | 245 | 222 | 188 | 165 | 126 | 89 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 202 | 180 | 143 | 104 | 93 | 81 | 69 | 61 | 50 | 31 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

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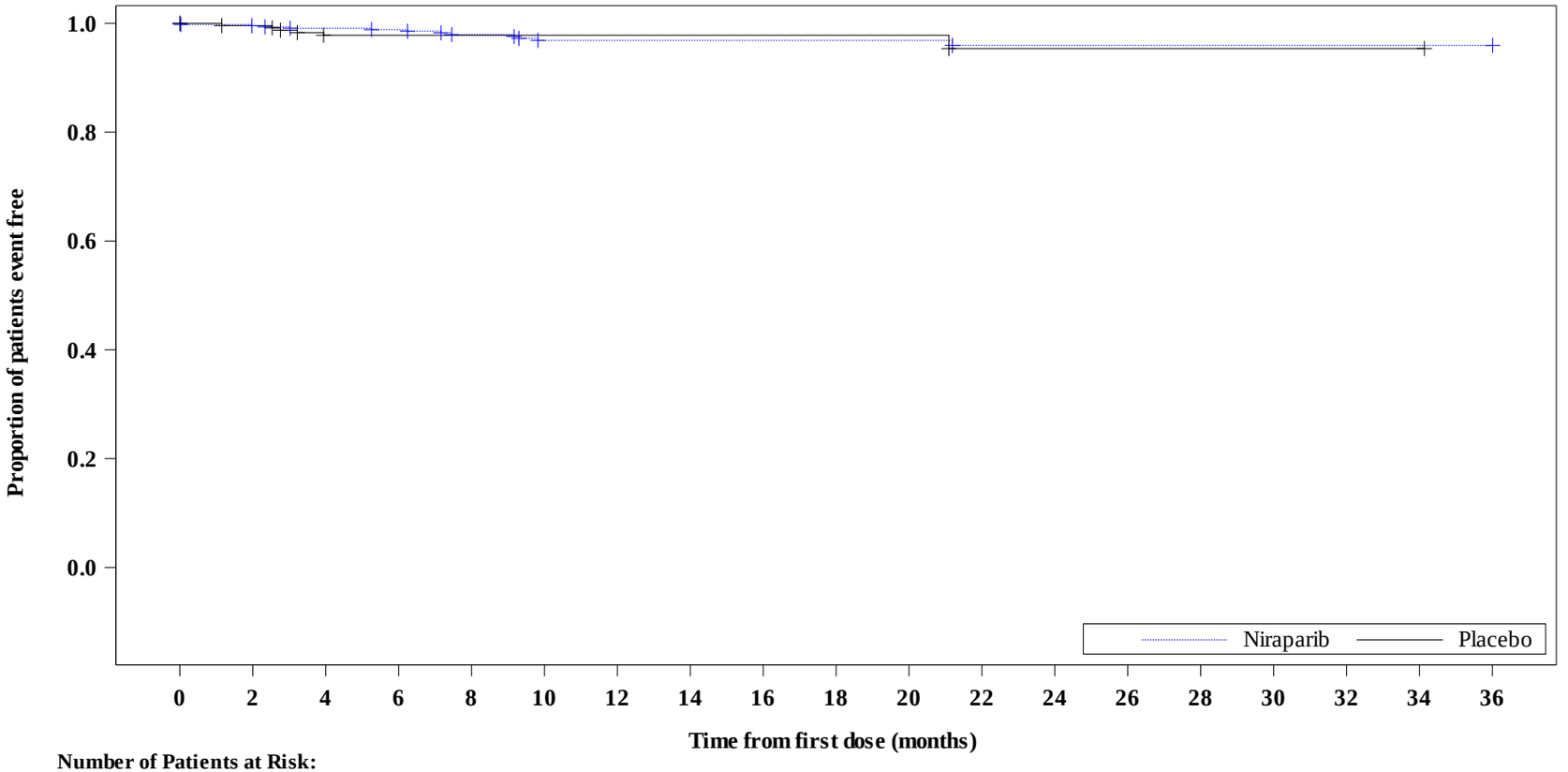
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Renal and urinary disorders, PT: Pollakiuria

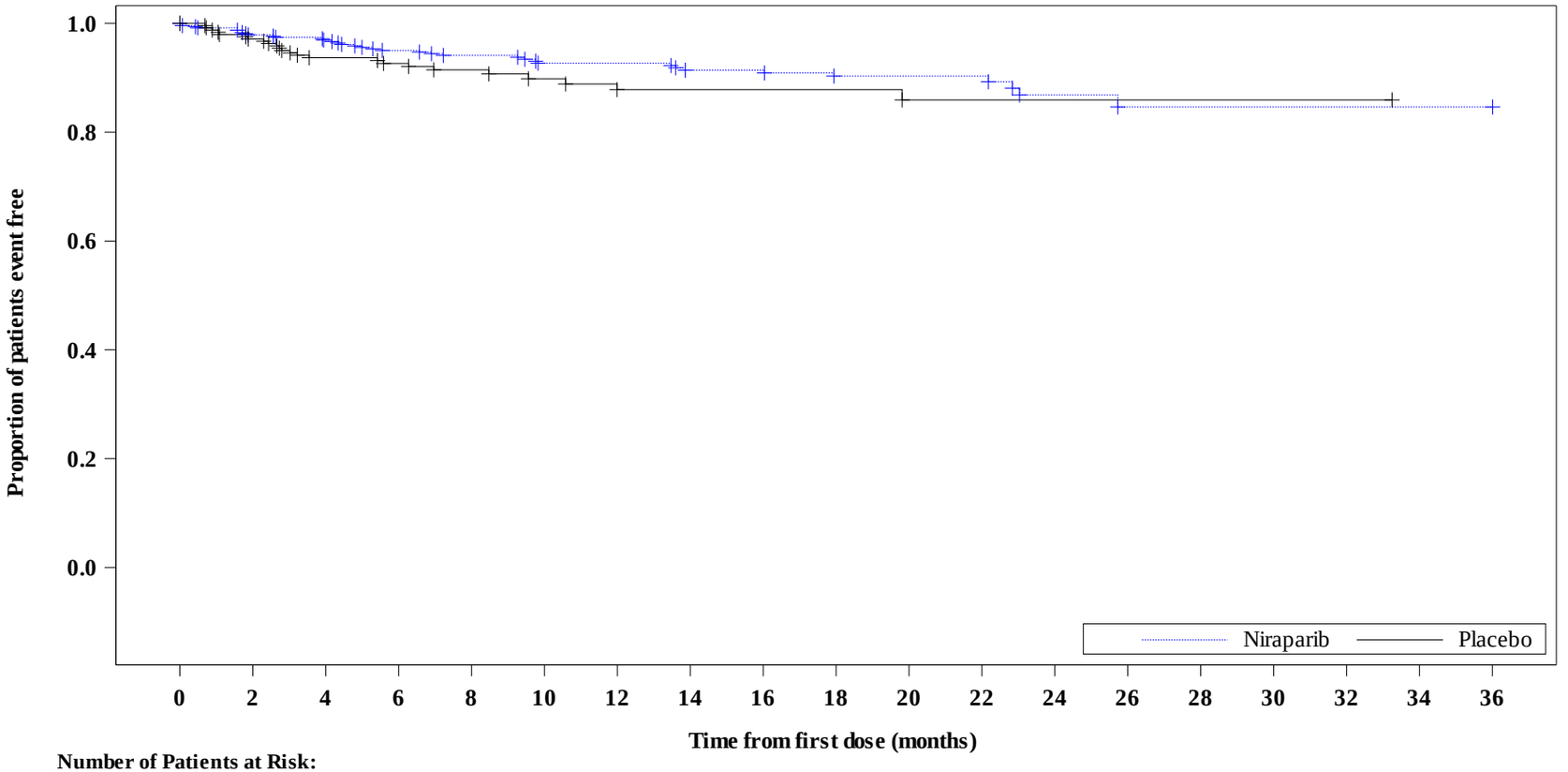



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 389 | 354 | 294 | 261 | 245 | 222 | 189 | 166 | 128 | 89 | 61 | 34 | 21 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 202 | 180 | 143 | 106 | 96 | 84 | 72 | 63 | 52 | 31 | 17 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Reproductive system and breast disorders

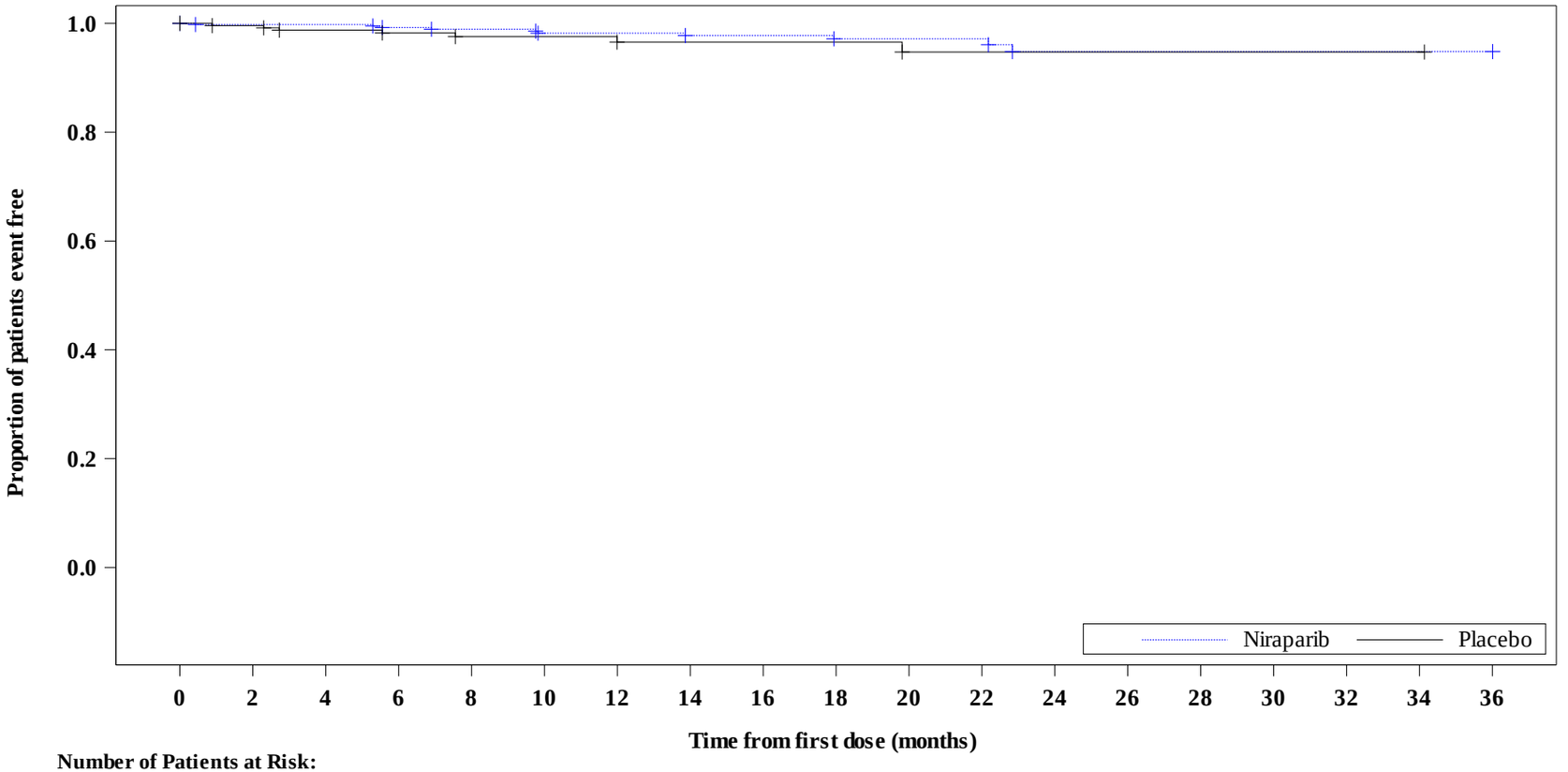



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 440 | 377 | 339 | 283 | 251 | 237 | 211 | 181 | 159 | 121 | 88 | 57 | 30 | 19 | 11 | 7 | 4 | 1 |
| Placebo | 244 | 234 | 192 | 171 | 132 | 98 | 86 | 75 | 64 | 56 | 45 | 26 | 15 | 9 | 4 | 1 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Reproductive system and breast disorders, PT: Pelvic pain

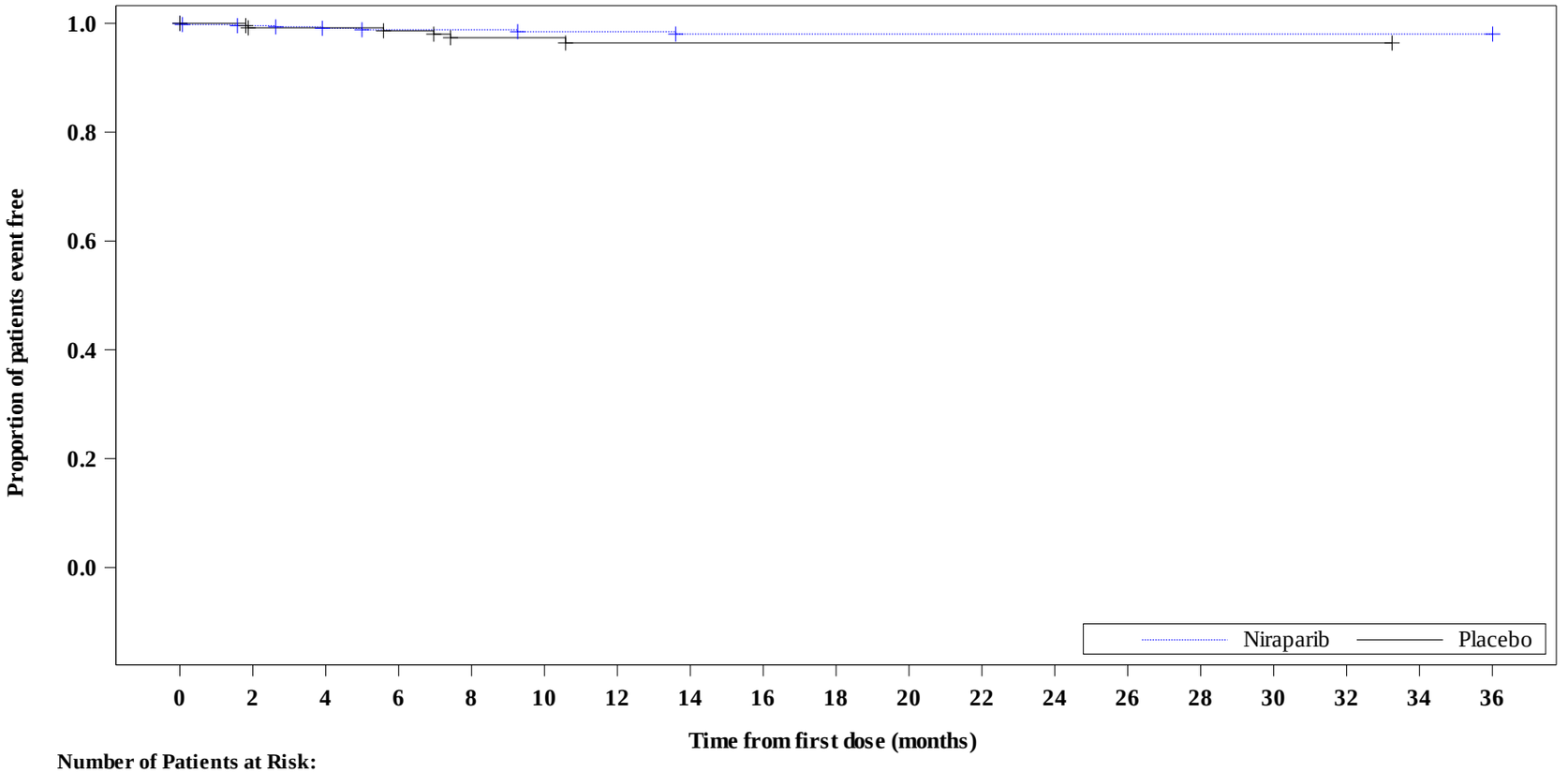



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 390 | 354 | 297 | 263 | 246 | 222 | 188 | 165 | 126 | 90 | 60 | 34 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 182 | 144 | 108 | 96 | 84 | 73 | 64 | 52 | 31 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Reproductive system and breast disorders, PT: Vulvovaginal dryness

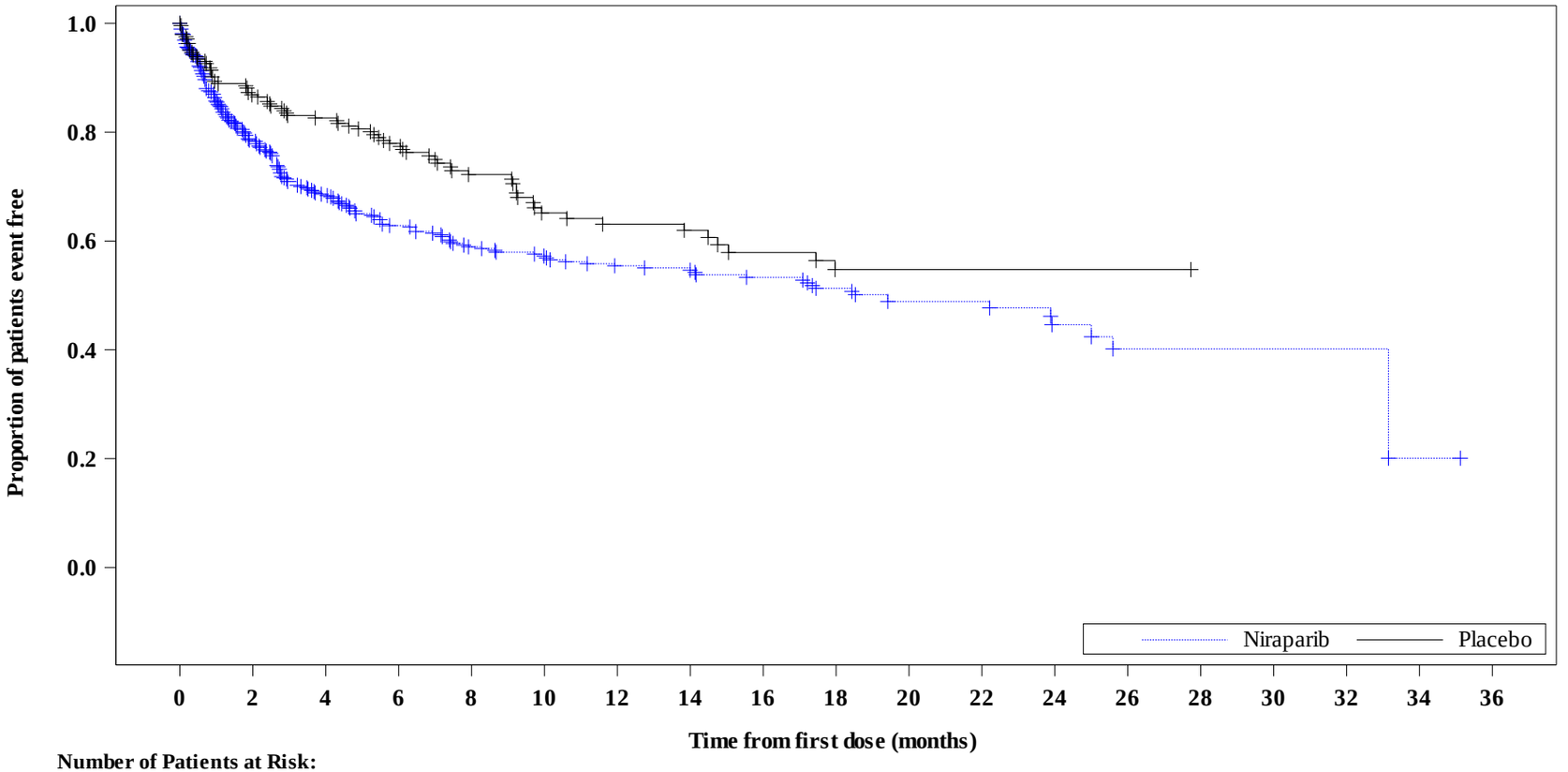



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 387 | 352 | 294 | 261 | 244 | 220 | 189 | 167 | 128 | 90 | 61 | 33 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 204 | 181 | 142 | 106 | 95 | 83 | 71 | 62 | 51 | 30 | 16 | 10 | 5 | 1 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders

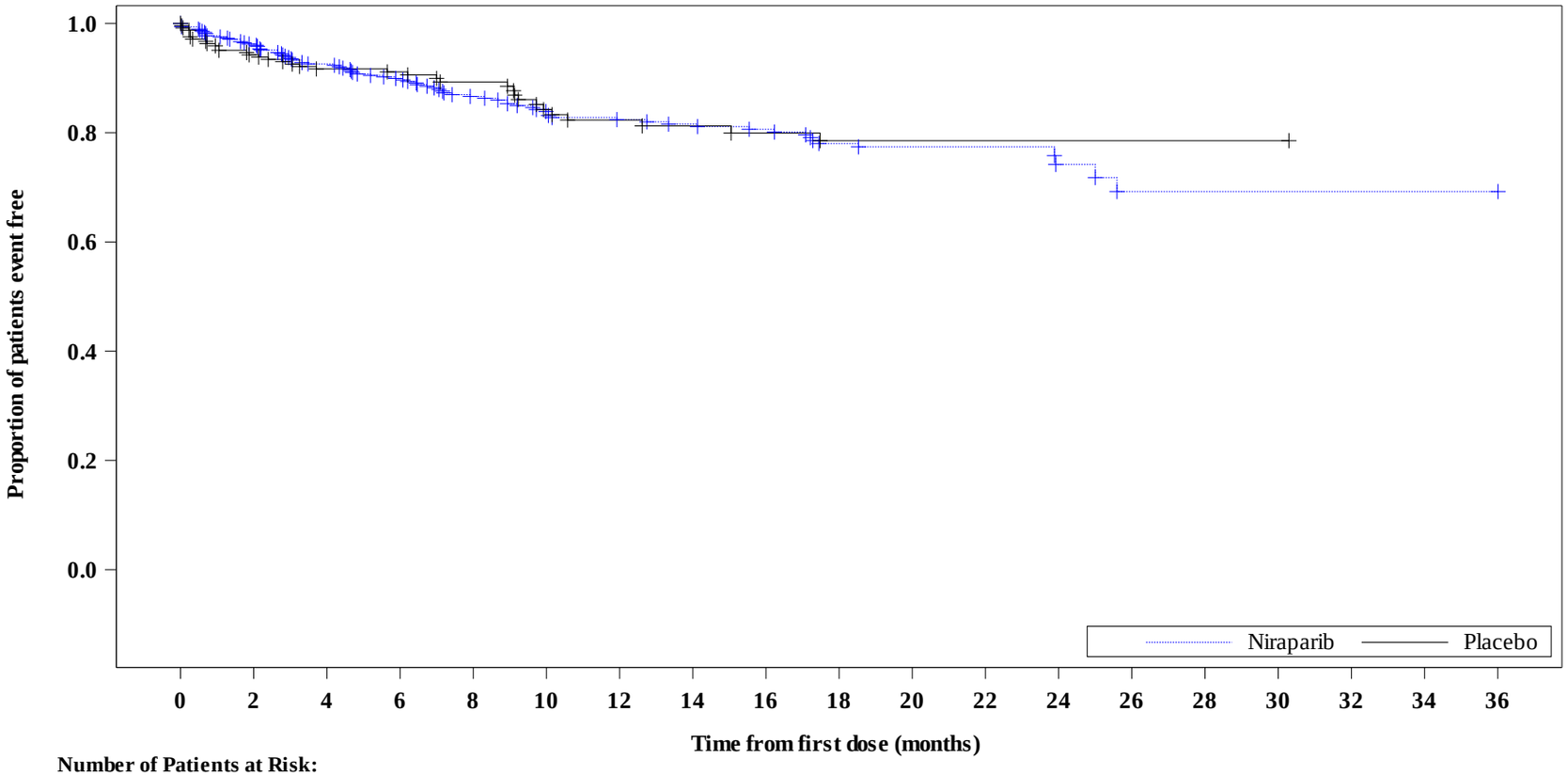



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 355 | 277 | 232 | 182 | 162 | 150 | 132 | 109 | 92 | 65 | 47 | 27 | 14 | 7 | 3 | 2 | 1 | 0 |
| Placebo | 244 | 210 | 171 | 142 | 101 | 67 | 59 | 50 | 40 | 33 | 28 | 15 | 6 | 3 | 0 | | | | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough

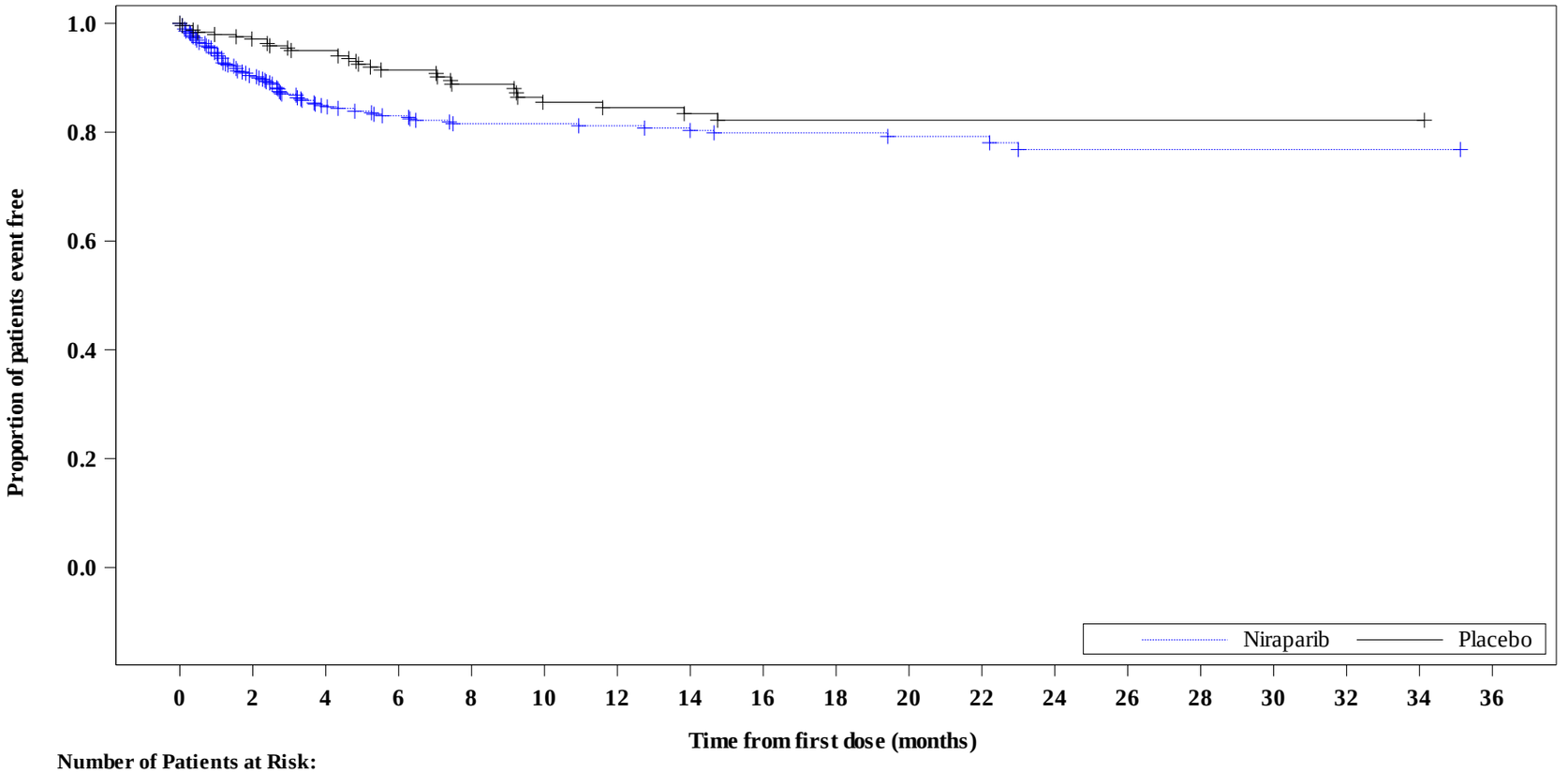



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 433 | 366 | 326 | 263 | 230 | 212 | 190 | 160 | 138 | 102 | 70 | 44 | 21 | 11 | 5 | 3 | 3 | 1 |
| Placebo | 244 | 227 | 188 | 167 | 129 | 90 | 81 | 70 | 58 | 51 | 42 | 27 | 14 | 9 | 4 | 1 | 0 | | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea

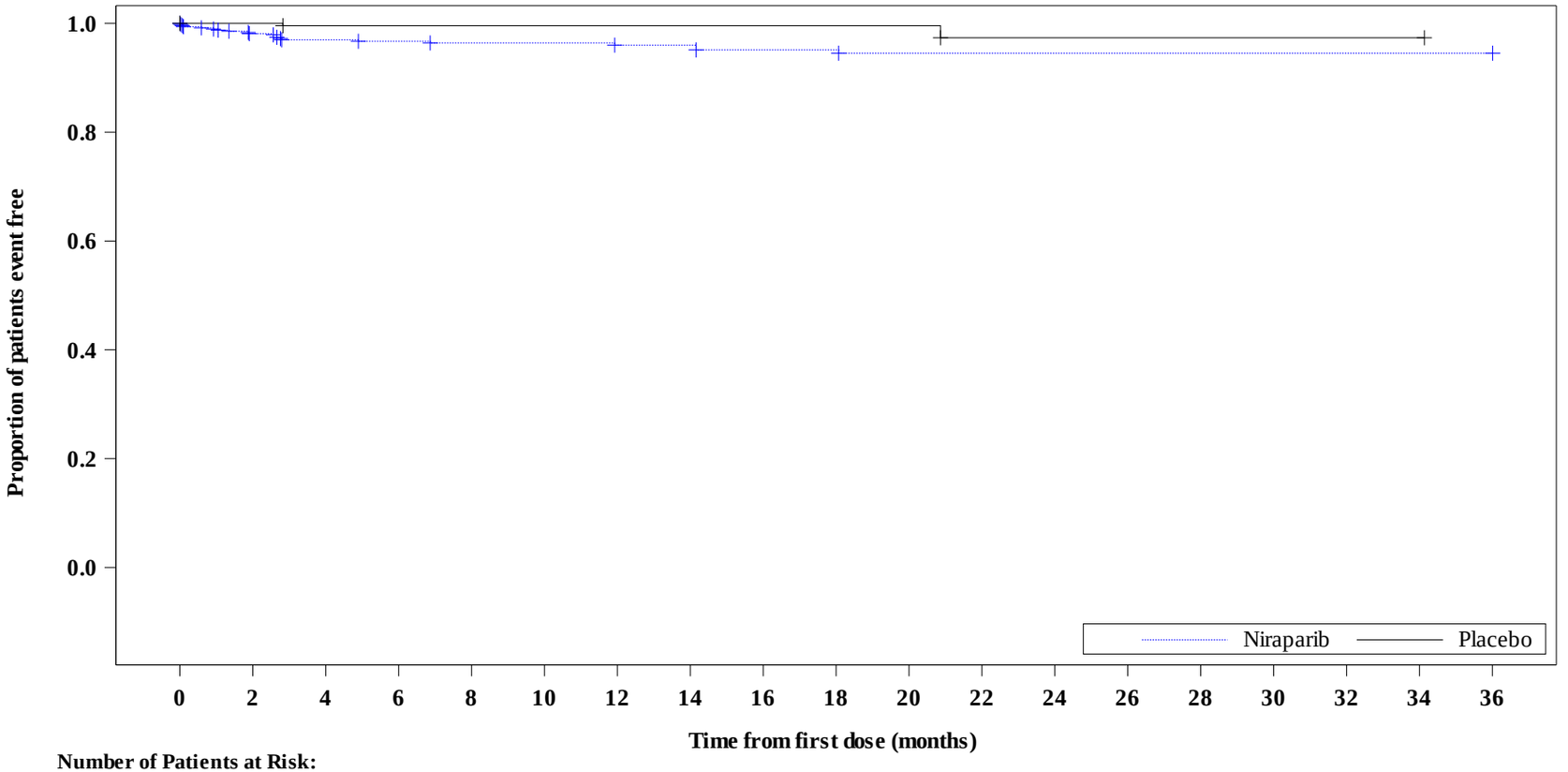



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 407 | 336 | 300 | 250 | 224 | 209 | 184 | 156 | 140 | 103 | 74 | 49 | 27 | 15 | 7 | 4 | 2 | 0 |
| Placebo | 244 | 235 | 197 | 168 | 129 | 93 | 82 | 72 | 62 | 53 | 43 | 27 | 14 | 8 | 4 | 2 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea exertional

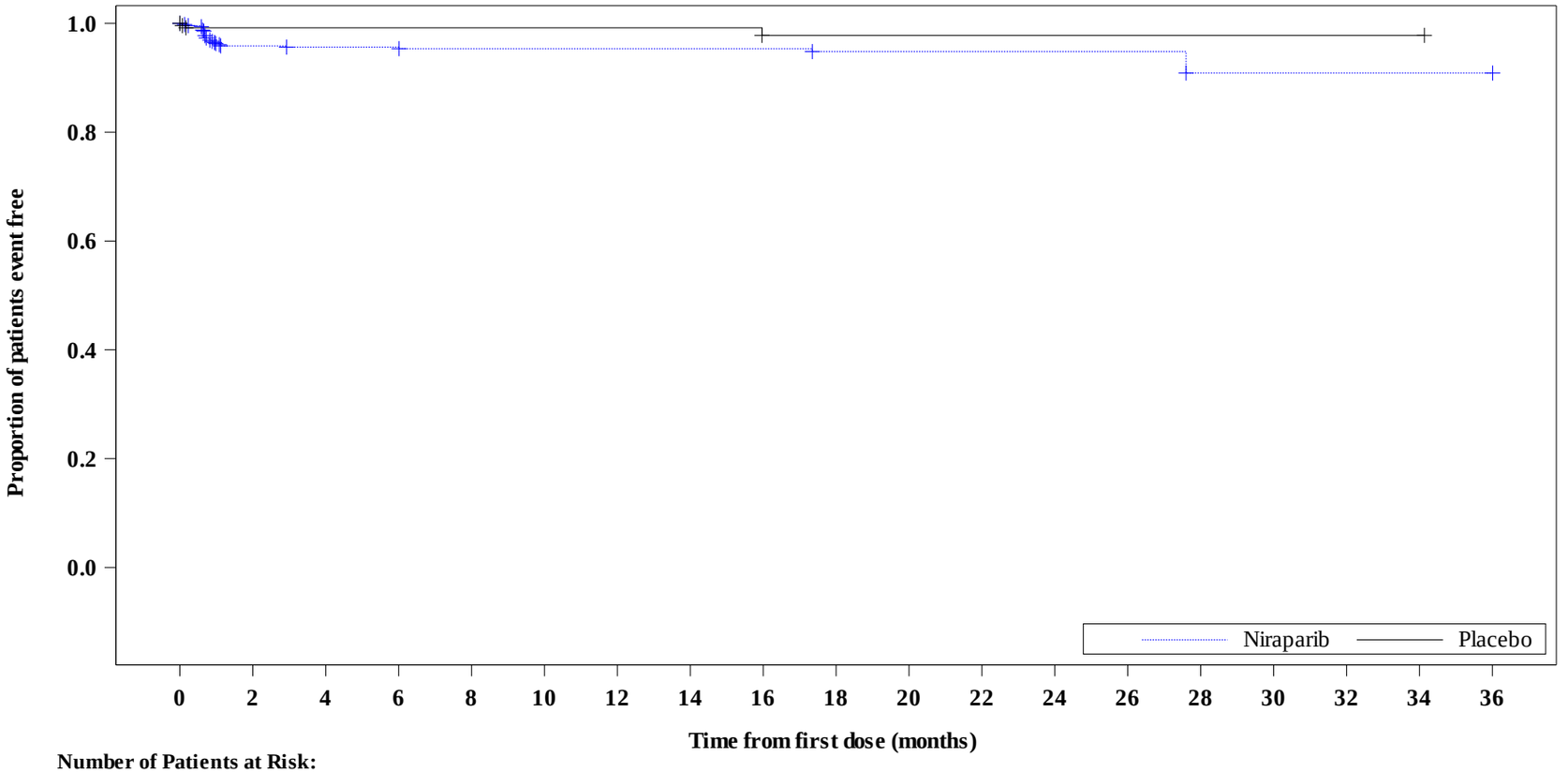



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 441 | 381 | 346 | 289 | 258 | 240 | 218 | 182 | 159 | 121 | 86 | 59 | 32 | 20 | 11 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 204 | 182 | 145 | 109 | 98 | 86 | 74 | 65 | 54 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Epistaxis

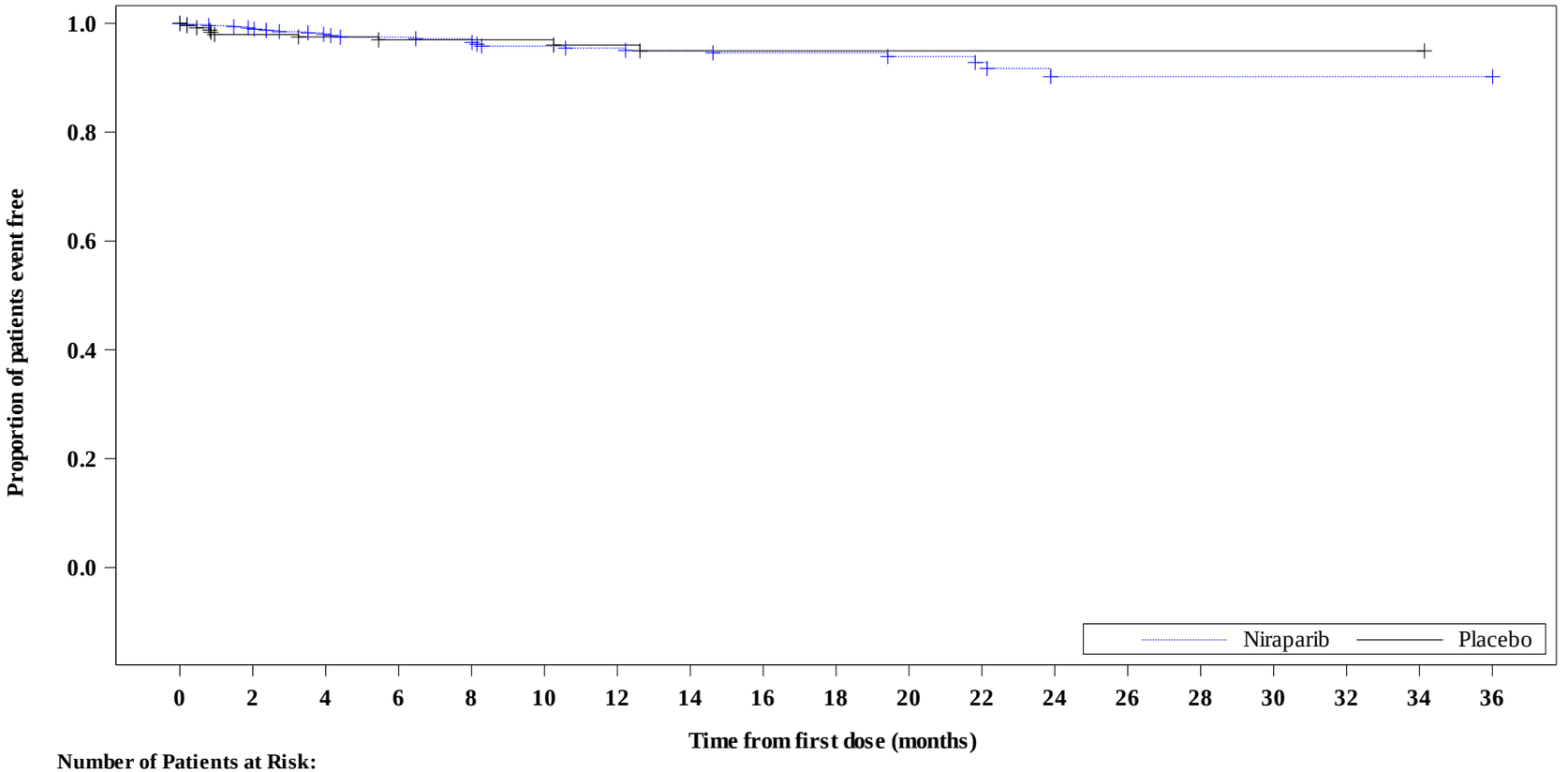



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 433 | 375 | 342 | 286 | 255 | 239 | 219 | 185 | 161 | 123 | 86 | 58 | 32 | 20 | 11 | 7 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 181 | 144 | 107 | 96 | 84 | 71 | 62 | 52 | 31 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion

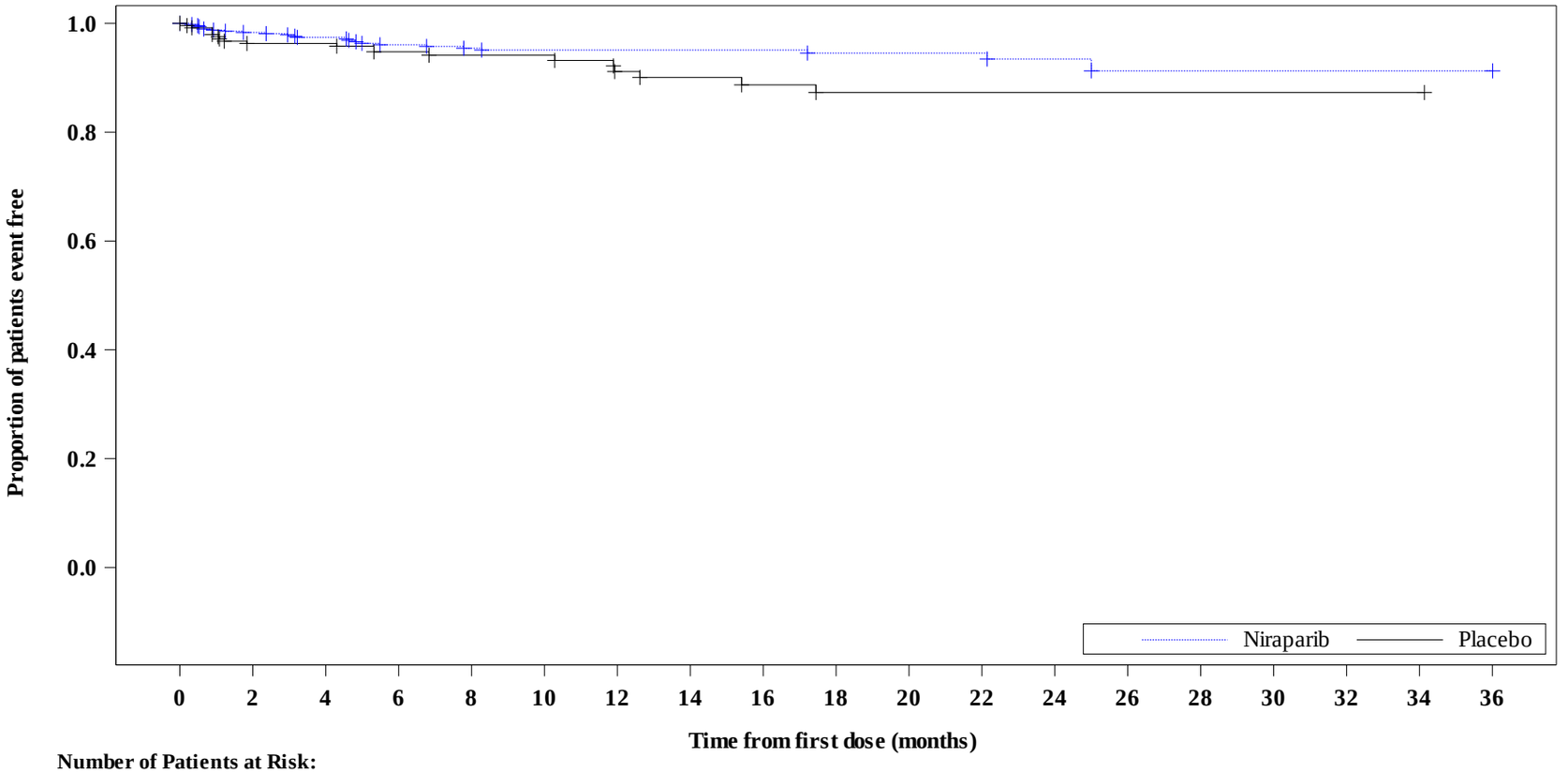



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 383 | 347 | 289 | 254 | 237 | 213 | 180 | 159 | 121 | 85 | 55 | 30 | 18 | 11 | 7 | 4 | 1 |
| Placebo | 244 | 236 | 201 | 178 | 141 | 105 | 93 | 80 | 69 | 60 | 51 | 31 | 16 | 11 | 6 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain

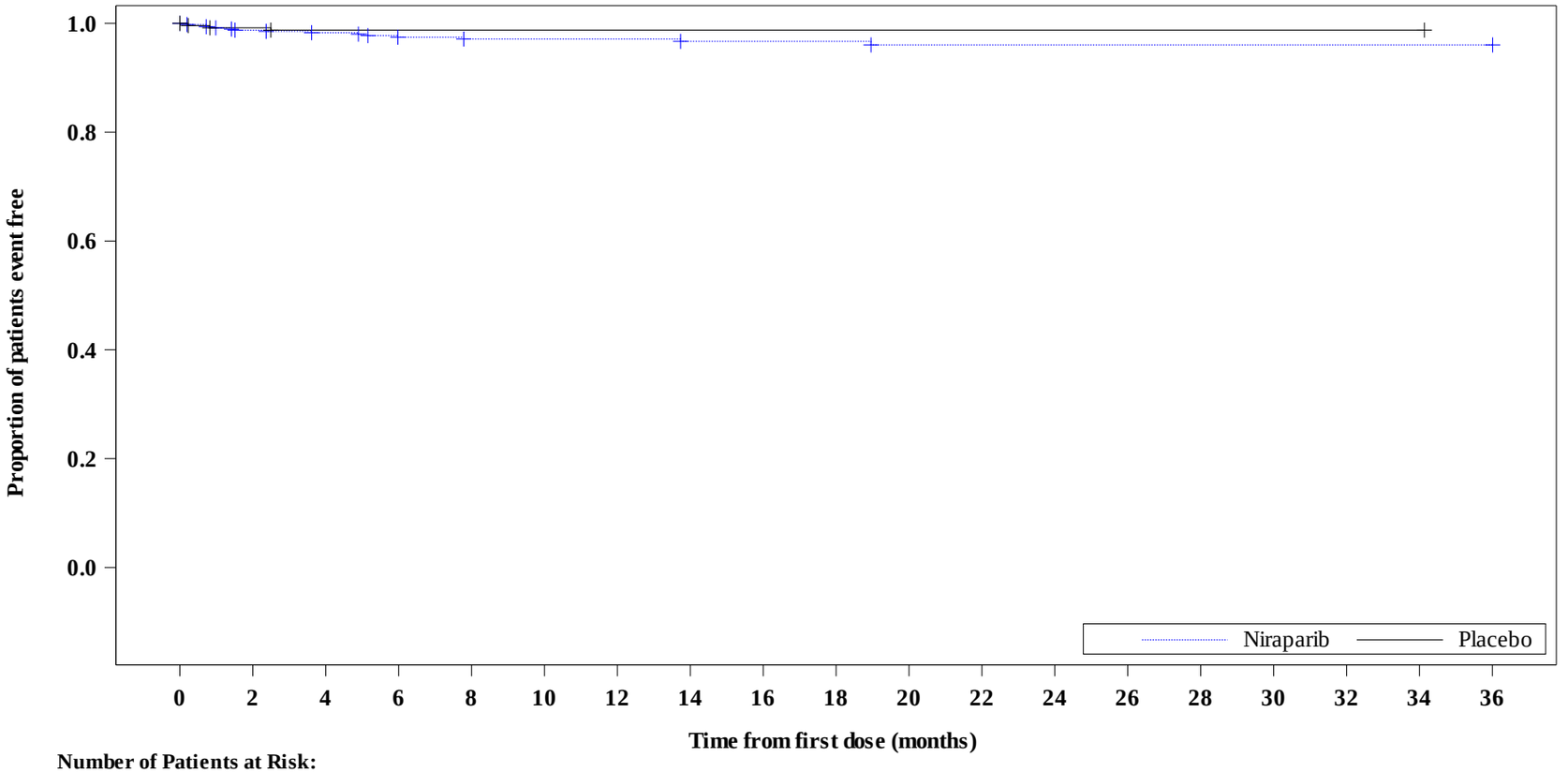



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 379 | 343 | 286 | 255 | 238 | 216 | 184 | 160 | 123 | 87 | 59 | 32 | 20 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 232 | 200 | 175 | 139 | 103 | 89 | 77 | 65 | 55 | 46 | 29 | 16 | 10 | 5 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Productive cough

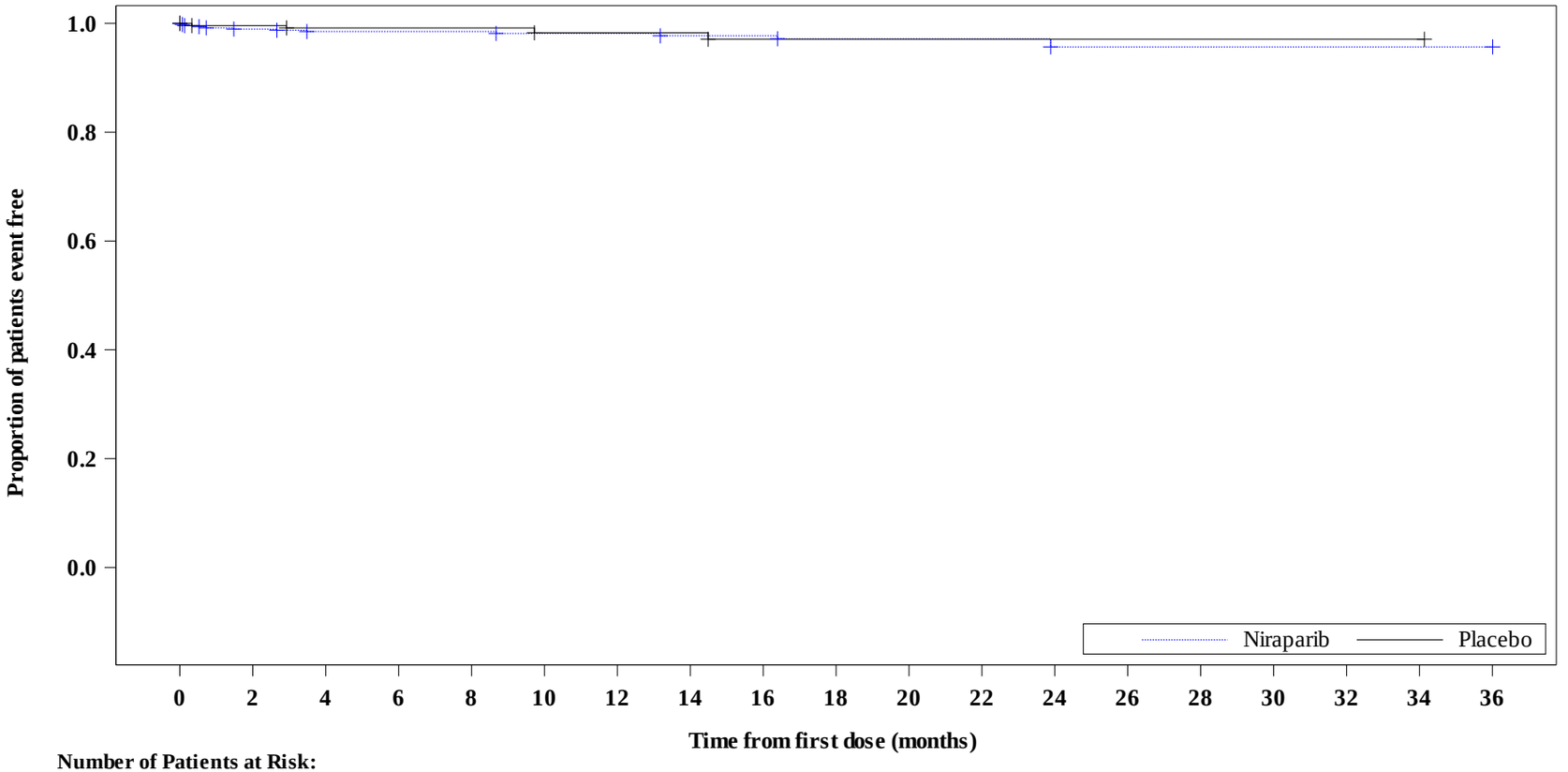



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 445 | 386 | 349 | 290 | 259 | 243 | 219 | 186 | 164 | 125 | 89 | 62 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 181 | 144 | 108 | 97 | 85 | 73 | 64 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Rhinorrhoea

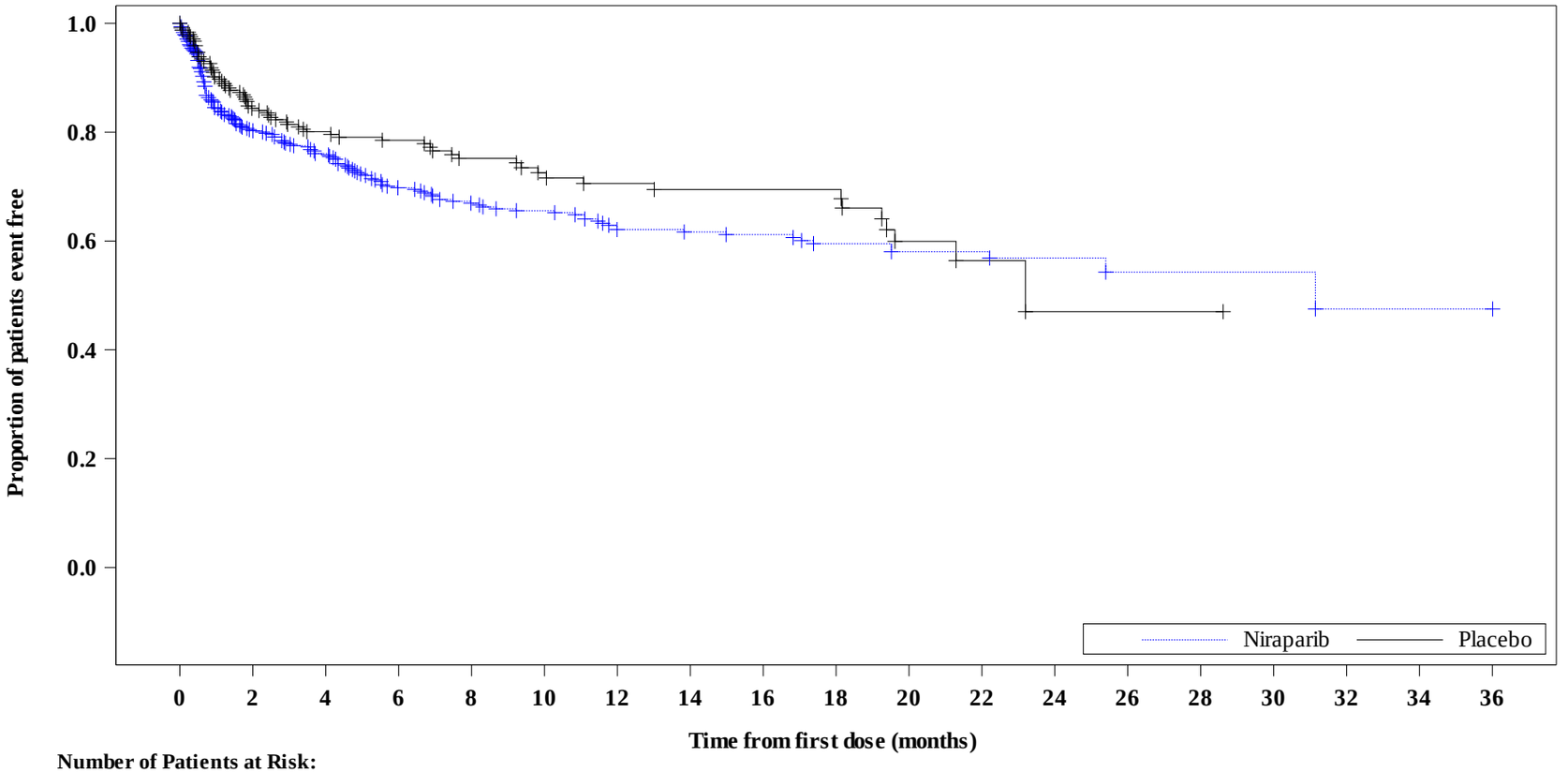



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 445 | 384 | 350 | 292 | 259 | 242 | 218 | 186 | 163 | 126 | 89 | 59 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 203 | 181 | 144 | 108 | 97 | 85 | 72 | 63 | 53 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders

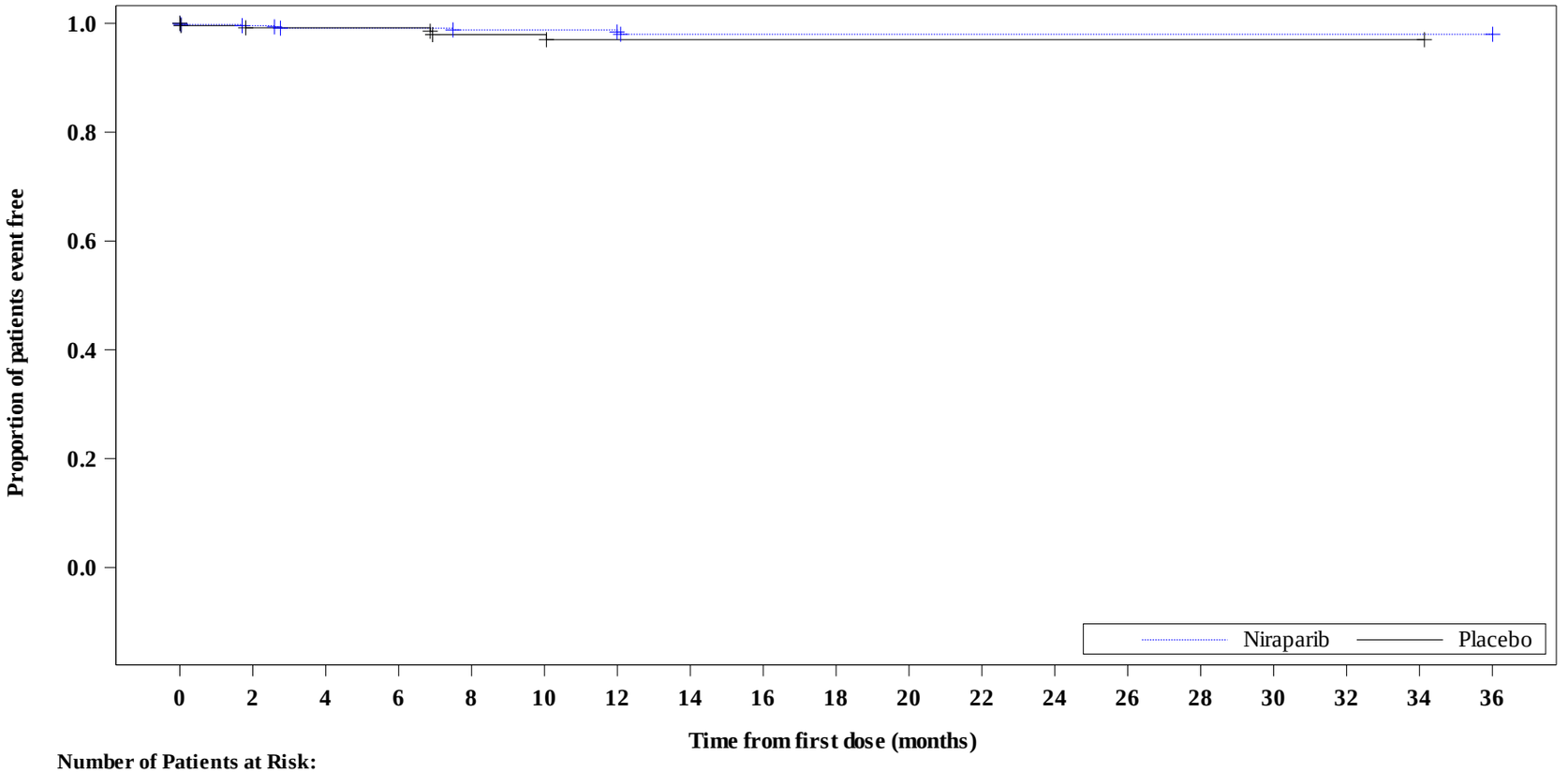



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 362 | 295 | 247 | 197 | 178 | 157 | 142 | 116 | 100 | 72 | 55 | 36 | 17 | 12 | 8 | 6 | 4 | 1 |
| Placebo | 244 | 203 | 161 | 140 | 106 | 76 | 67 | 58 | 50 | 41 | 28 | 15 | 5 | 2 | 1 | 0 | | | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Alopecia

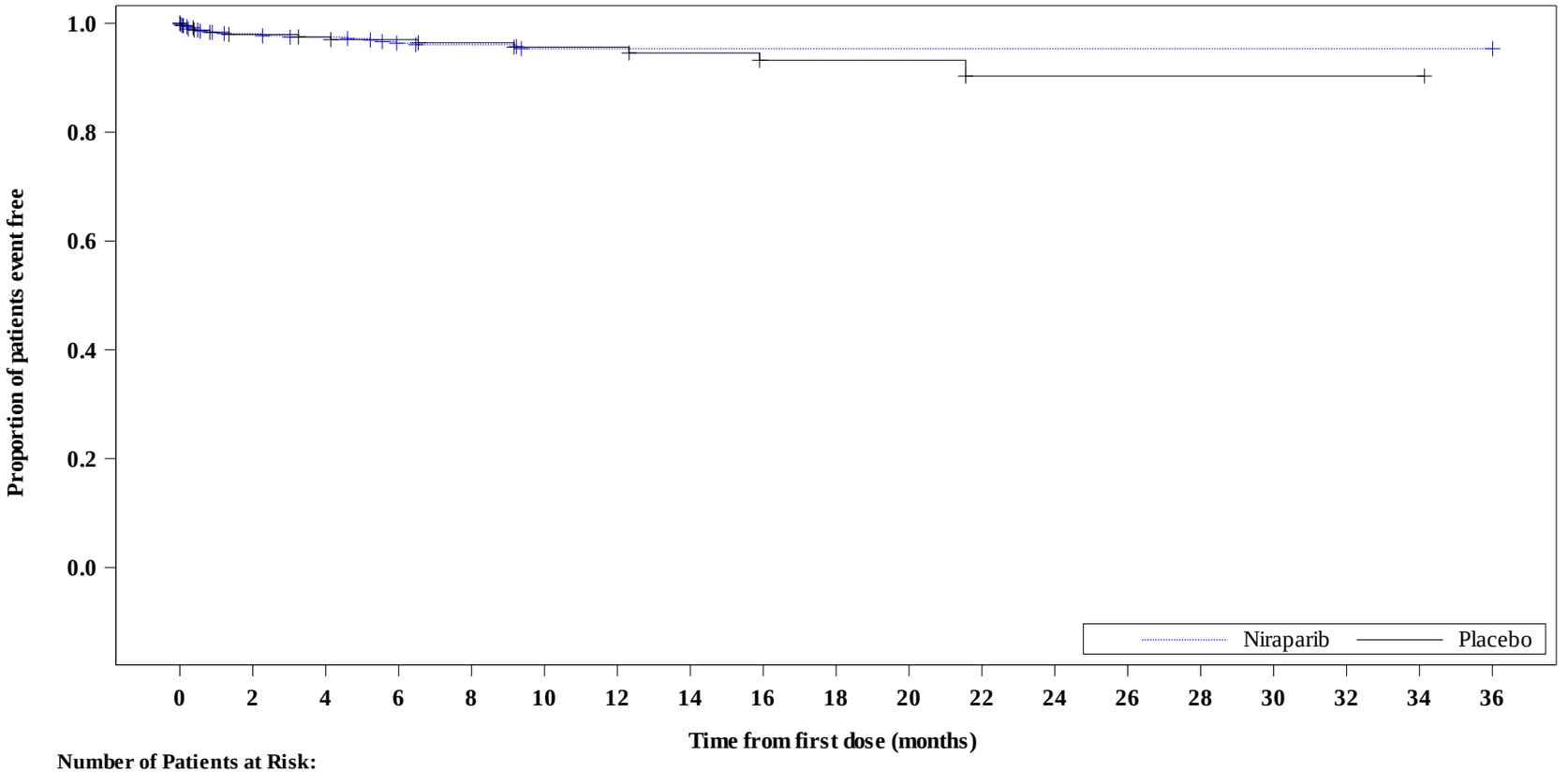



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 387 | 353 | 295 | 265 | 247 | 224 | 190 | 167 | 128 | 90 | 62 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 204 | 182 | 143 | 106 | 94 | 82 | 71 | 62 | 51 | 30 | 15 | 10 | 6 | 2 | 1 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Dry skin




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 381 | 343 | 288 | 256 | 240 | 218 | 185 | 164 | 126 | 90 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 236 | 199 | 176 | 140 | 104 | 93 | 82 | 70 | 61 | 51 | 30 | 17 | 11 | 6 | 2 | 2 | 1 | 0 |

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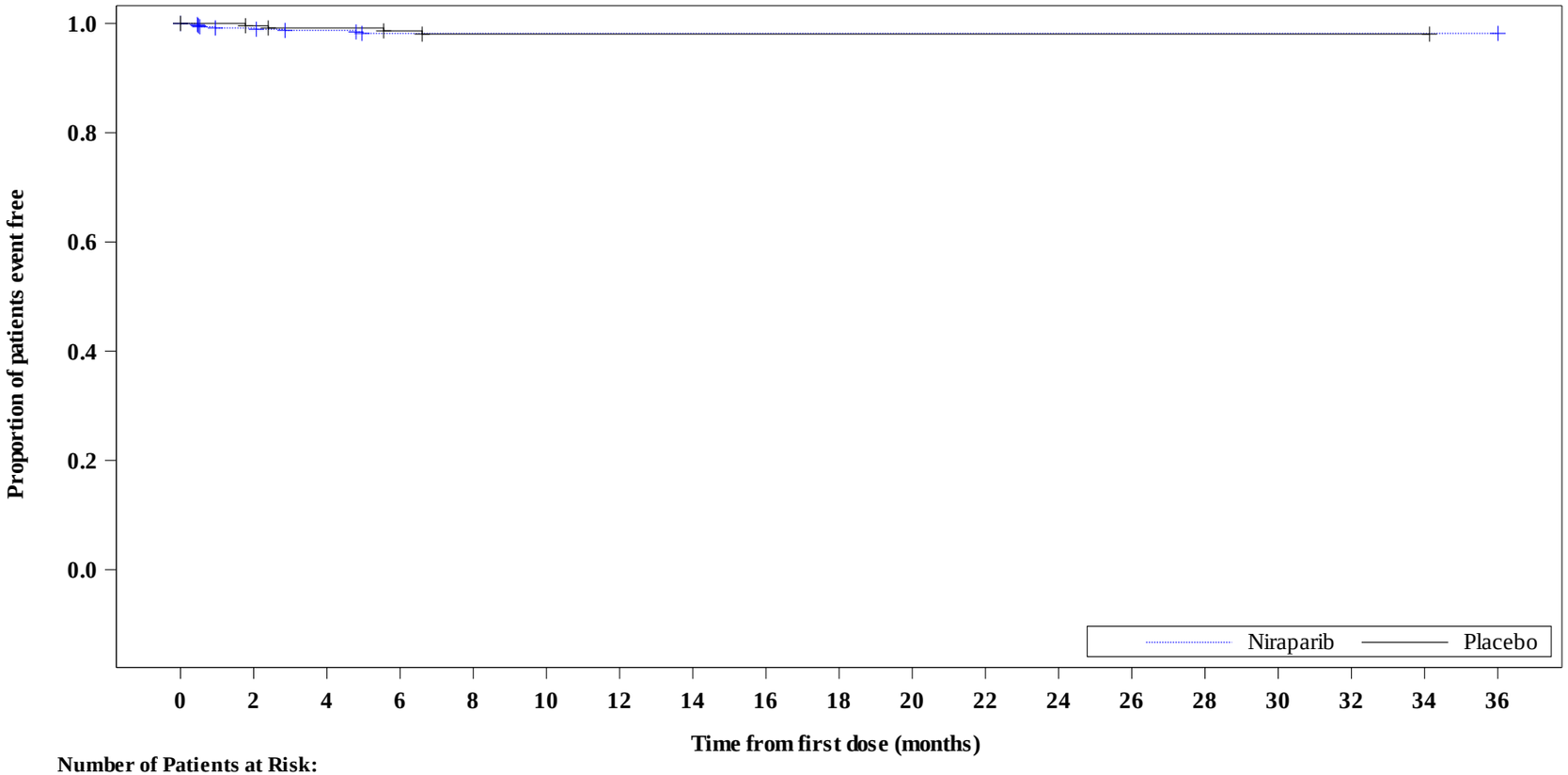
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Hyperhidrosis

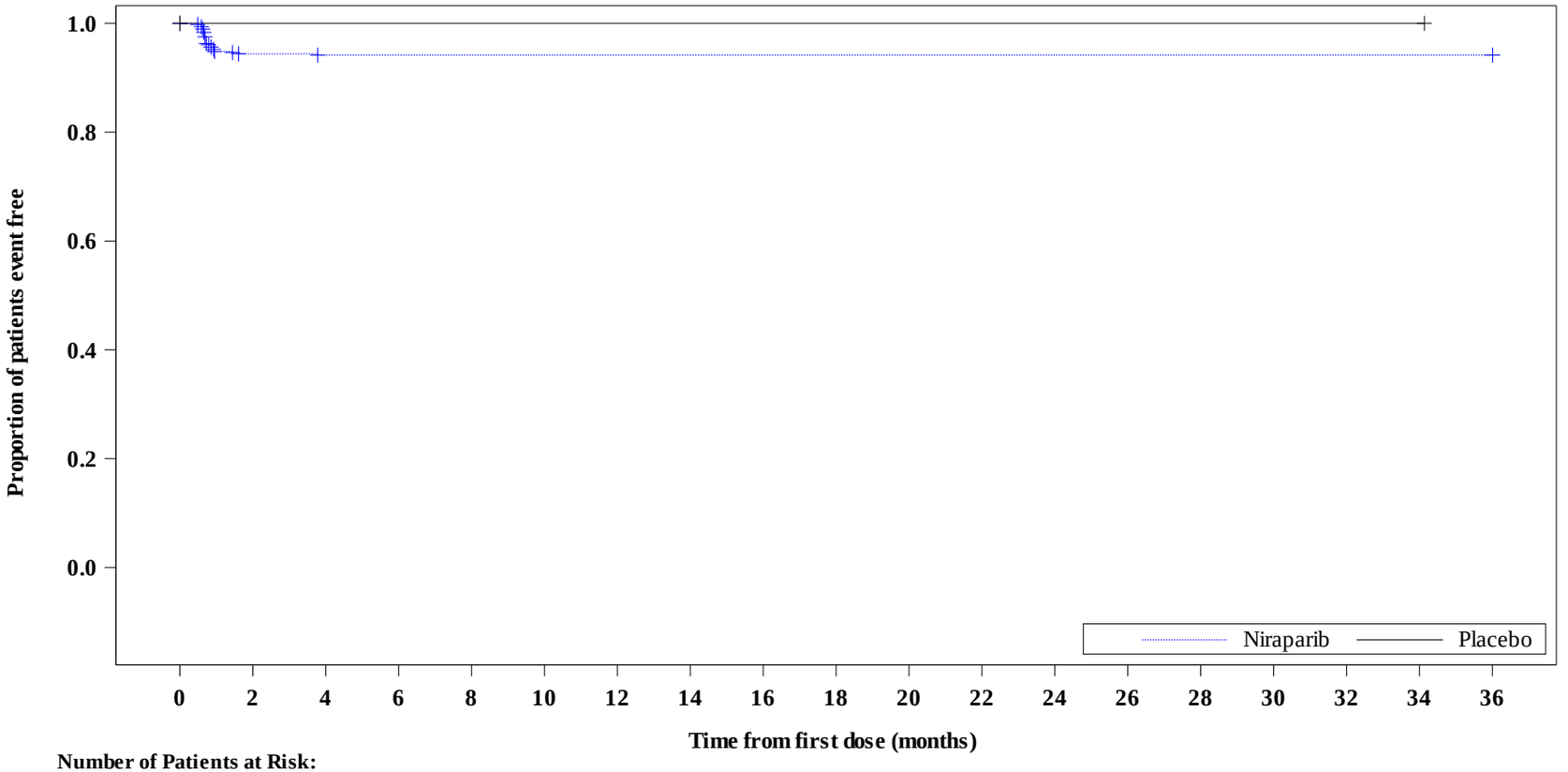



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 387 | 352 | 295 | 262 | 245 | 223 | 190 | 167 | 128 | 91 | 62 | 34 | 21 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 205 | 182 | 144 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Petechiae

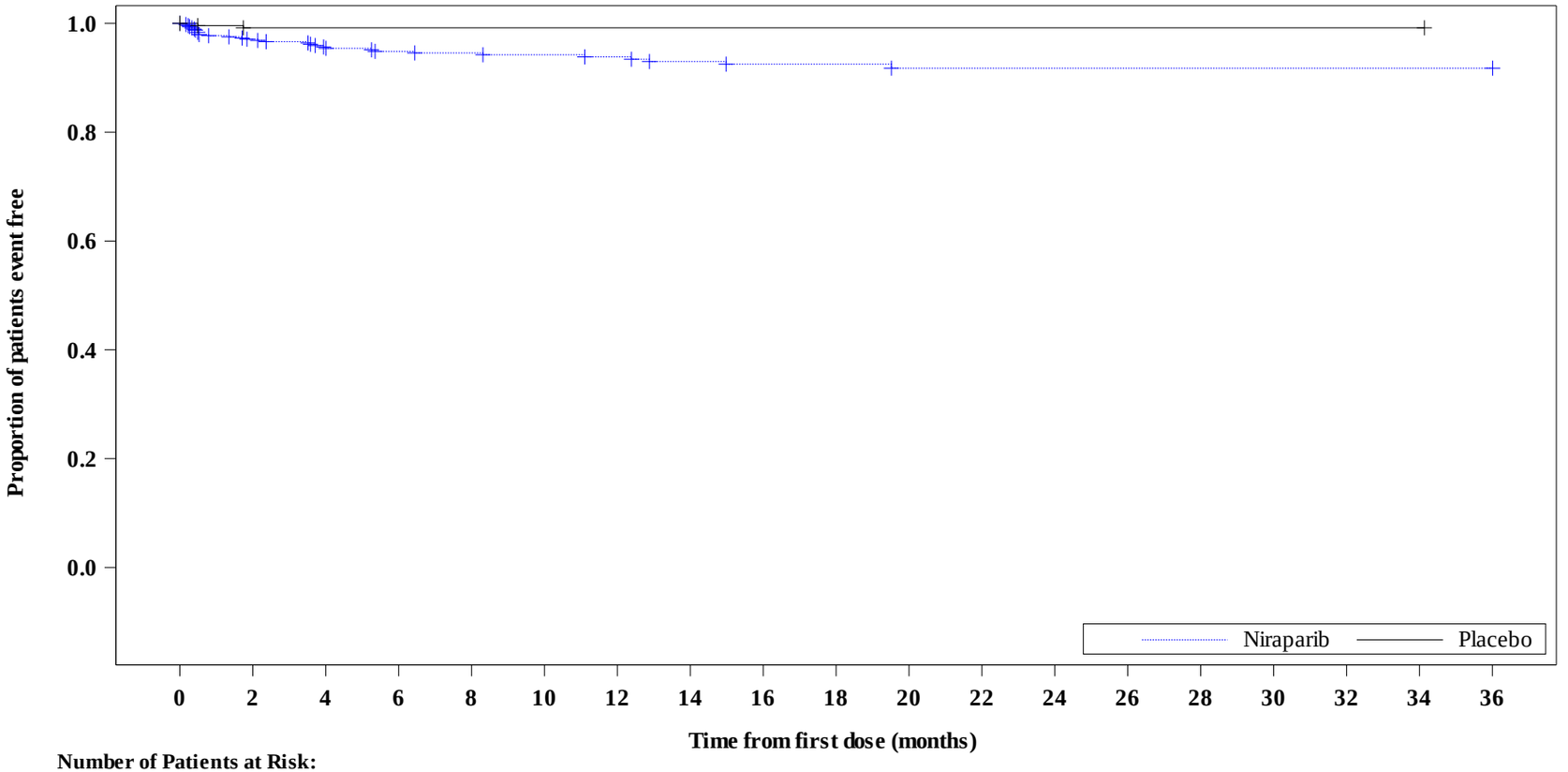



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 425 | 366 | 334 | 281 | 250 | 234 | 212 | 179 | 158 | 122 | 85 | 57 | 31 | 19 | 11 | 8 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Photosensitivity reaction

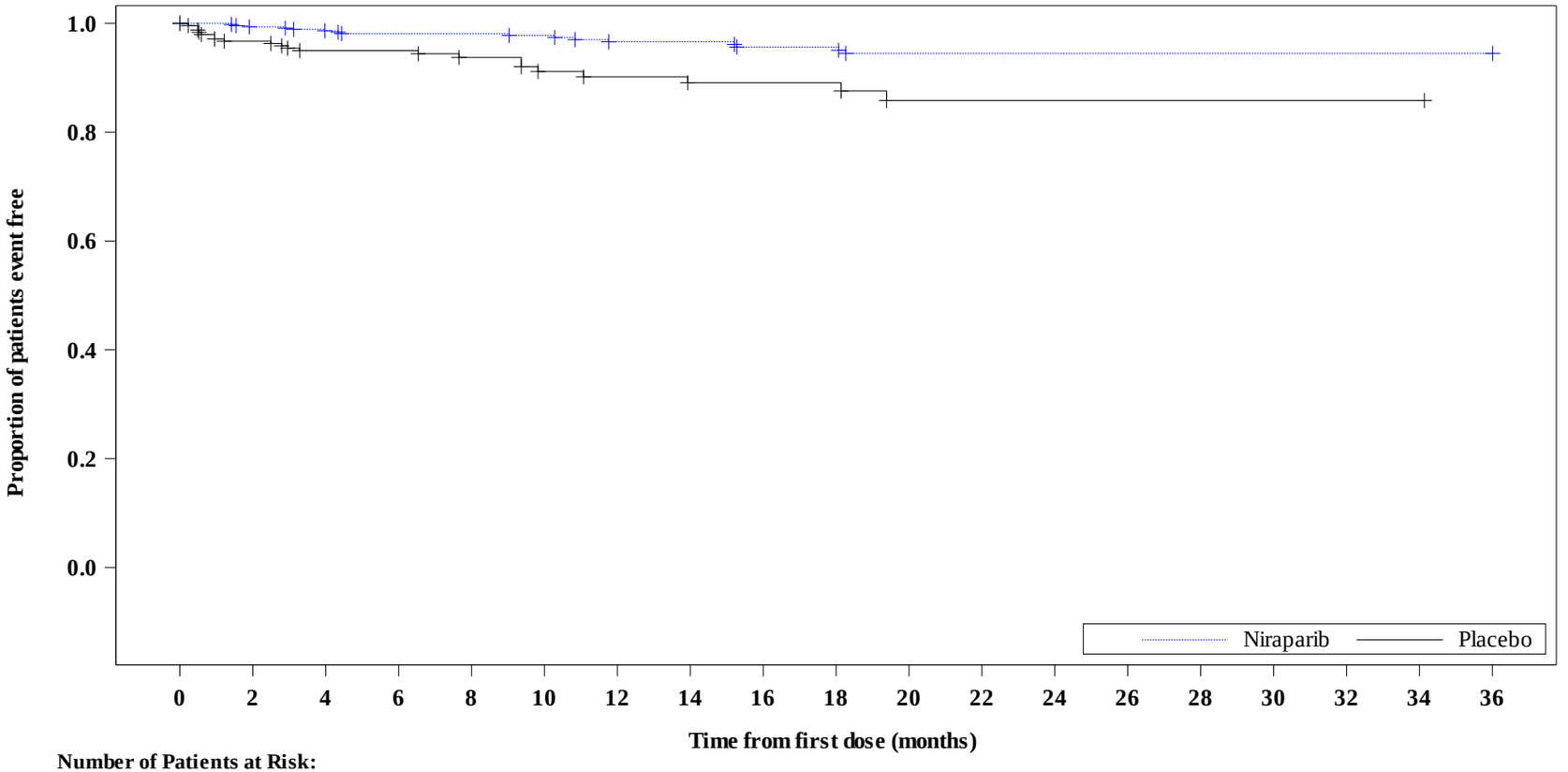



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 438 | 373 | 337 | 282 | 249 | 231 | 209 | 177 | 156 | 120 | 85 | 56 | 30 | 17 | 10 | 8 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 182 | 145 | 108 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Pruritus




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 387 | 352 | 295 | 261 | 241 | 219 | 185 | 164 | 124 | 90 | 61 | 33 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 233 | 193 | 173 | 137 | 101 | 90 | 80 | 68 | 59 | 47 | 31 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

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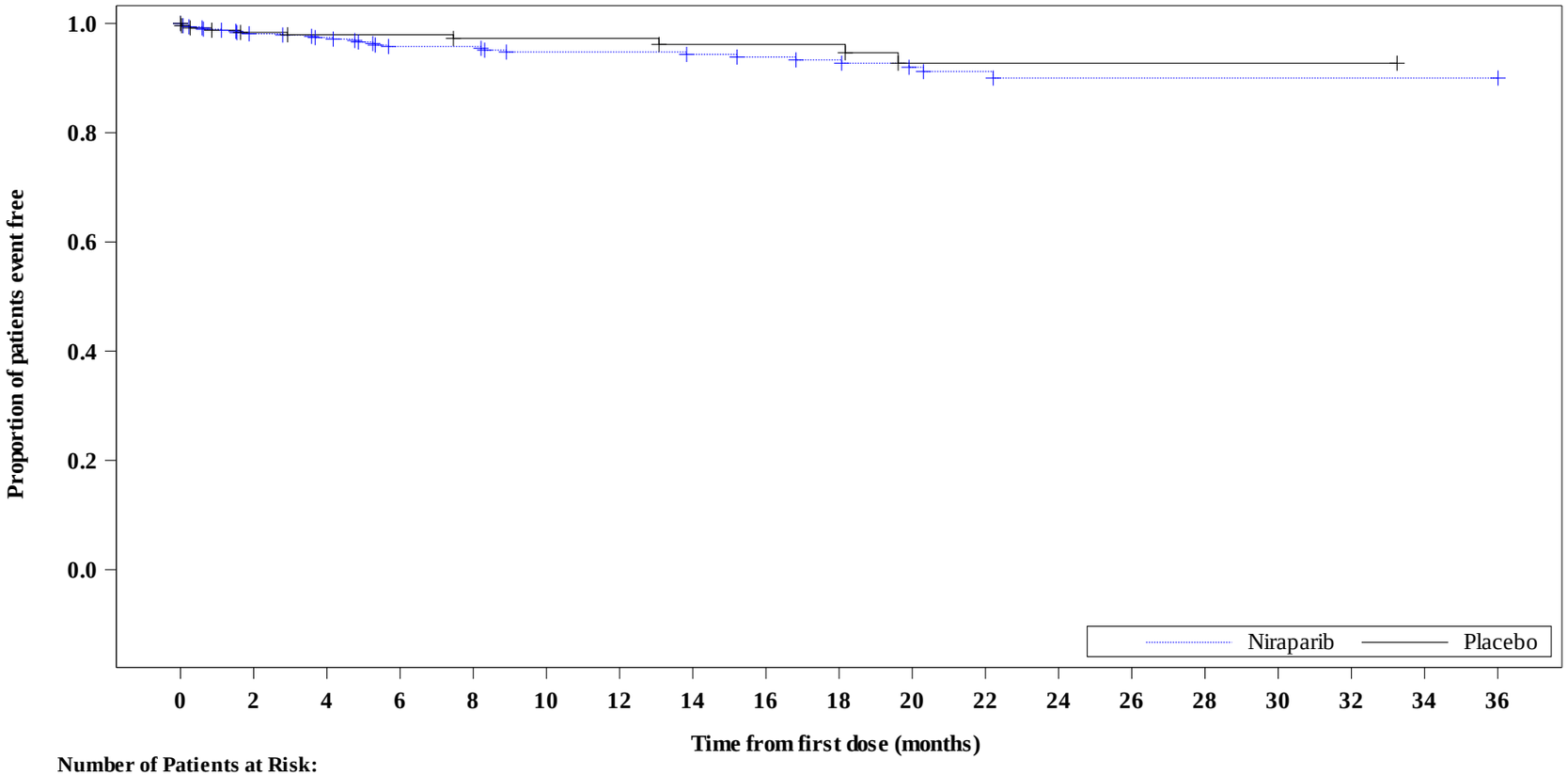
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Rash

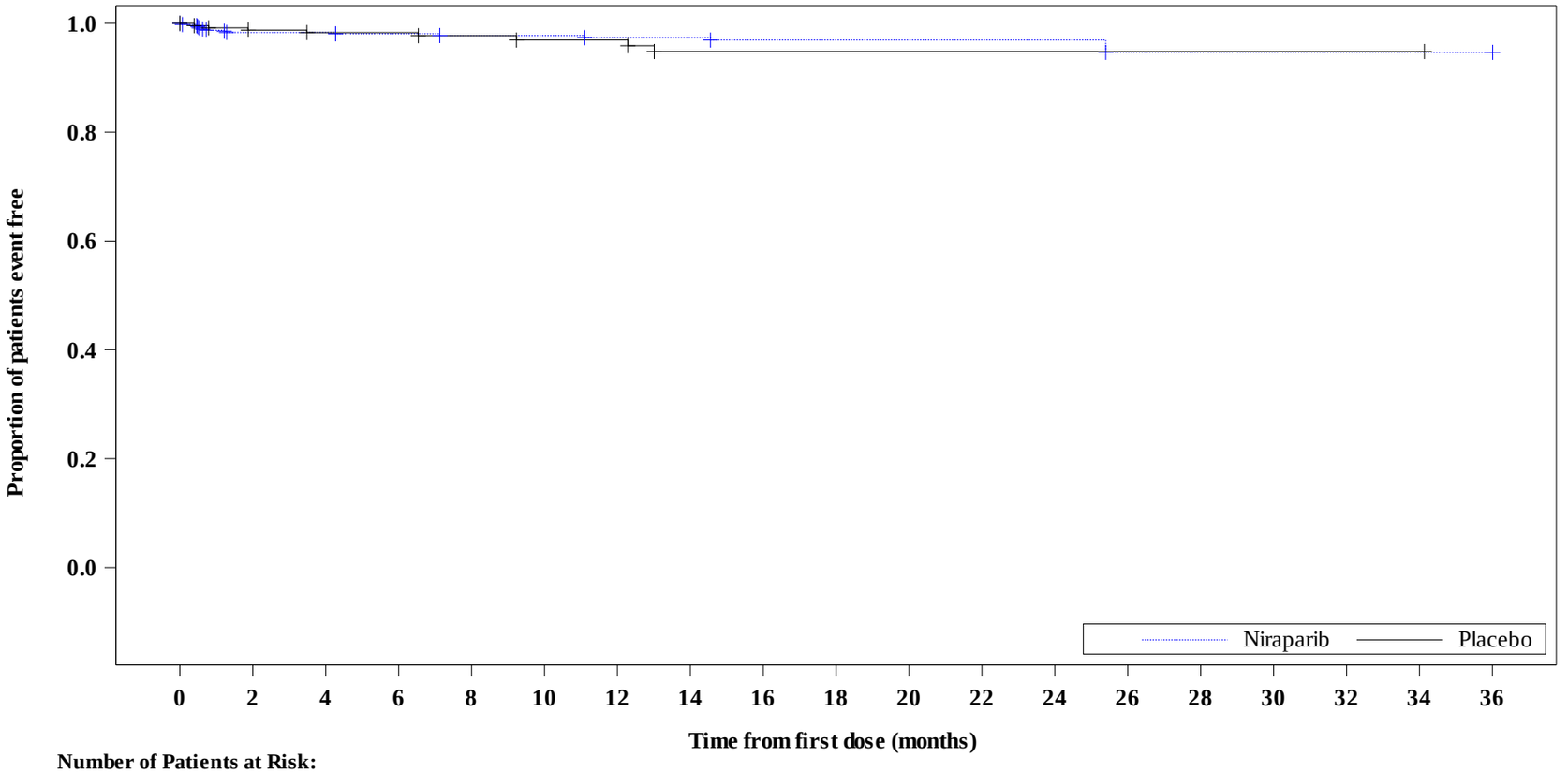



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 441 | 381 | 343 | 287 | 255 | 239 | 217 | 182 | 161 | 120 | 84 | 59 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 237 | 200 | 179 | 142 | 105 | 94 | 83 | 71 | 62 | 49 | 29 | 16 | 11 | 6 | 2 | 1 | 0 | |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Rash maculo-papular

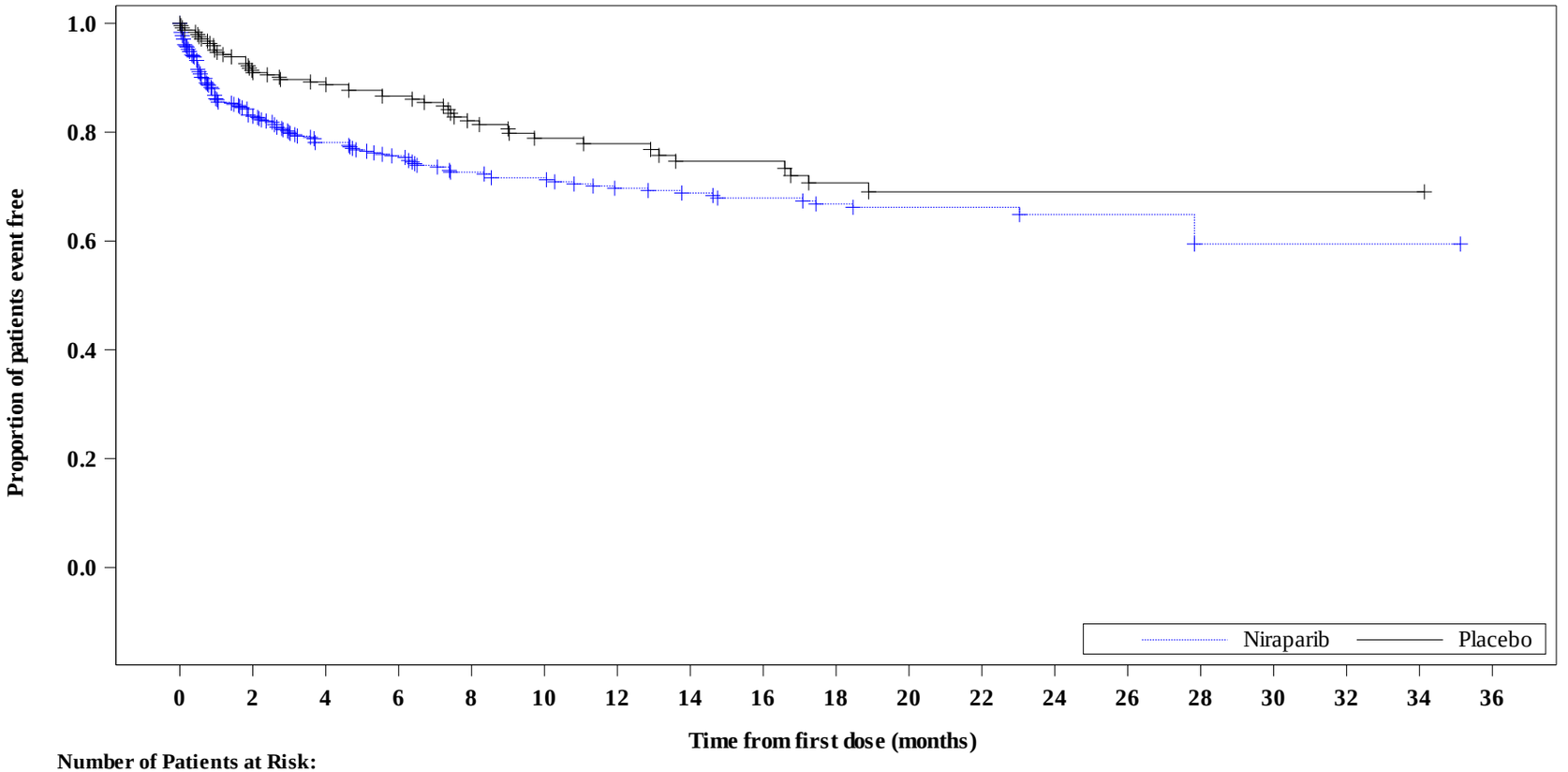



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 386 | 351 | 294 | 262 | 244 | 222 | 187 | 165 | 126 | 88 | 60 | 33 | 21 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 238 | 201 | 179 | 144 | 106 | 96 | 83 | 72 | 63 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Vascular disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 373 | 303 | 269 | 215 | 191 | 174 | 153 | 131 | 112 | 82 | 58 | 38 | 23 | 11 | 5 | 5 | 3 | 0 |
| Placebo | 244 | 220 | 181 | 157 | 119 | 84 | 76 | 66 | 57 | 46 | 40 | 24 | 13 | 10 | 6 | 3 | 2 | 1 | 0 |

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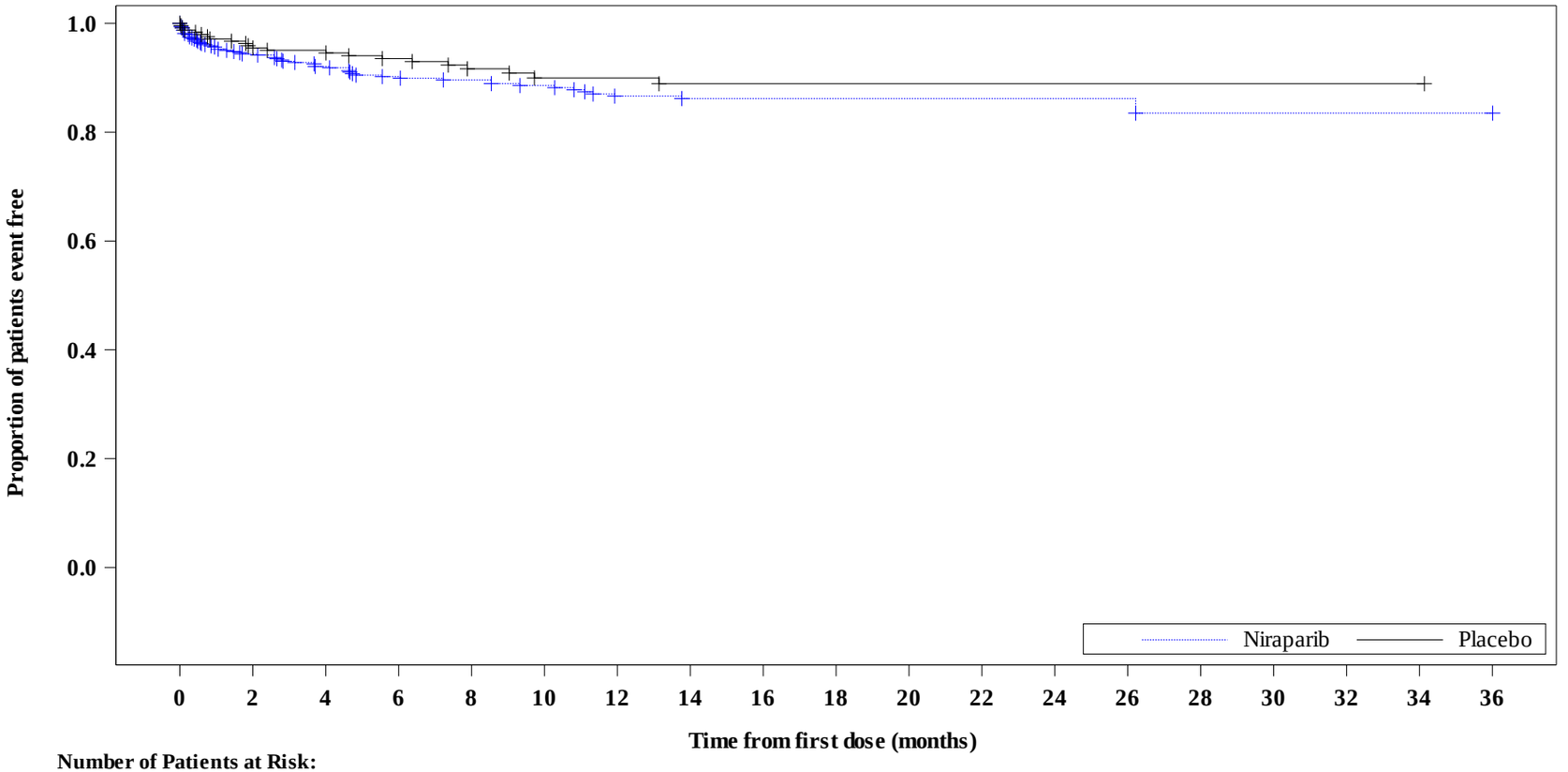
Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Vascular disorders, PT: Hot flush

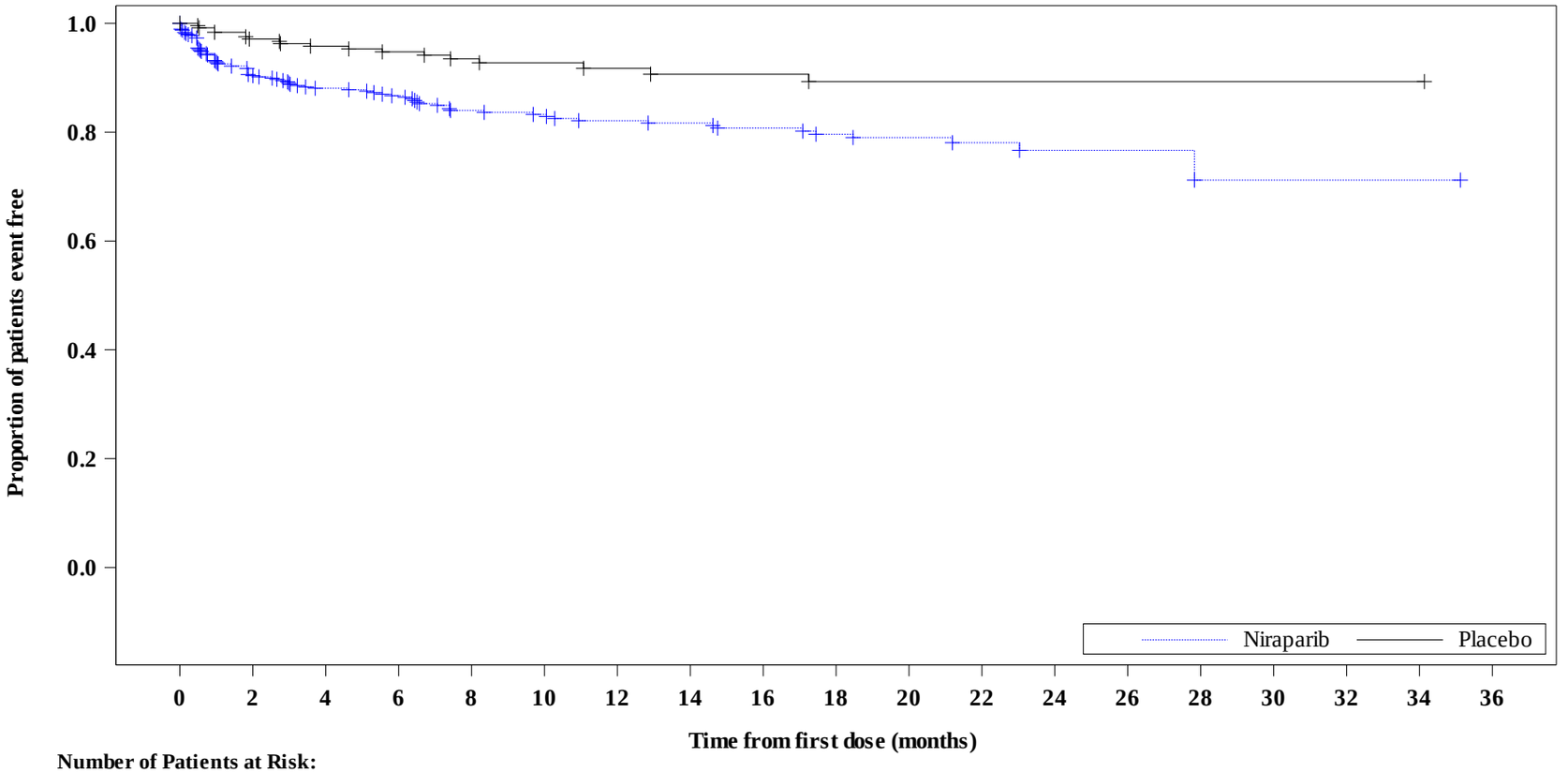



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 424 | 360 | 321 | 265 | 237 | 216 | 196 | 170 | 150 | 114 | 82 | 57 | 32 | 19 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 231 | 194 | 172 | 134 | 99 | 89 | 77 | 65 | 57 | 48 | 28 | 15 | 10 | 6 | 3 | 2 | 1 | 0 |

Figure 3.13
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)

SOC: Vascular disorders, PT: Hypertension




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 406 | 342 | 309 | 248 | 220 | 203 | 180 | 153 | 132 | 98 | 68 | 43 | 25 | 13 | 5 | 5 | 3 | 0 |
| Placebo | 244 | 234 | 195 | 171 | 135 | 99 | 89 | 78 | 68 | 58 | 49 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

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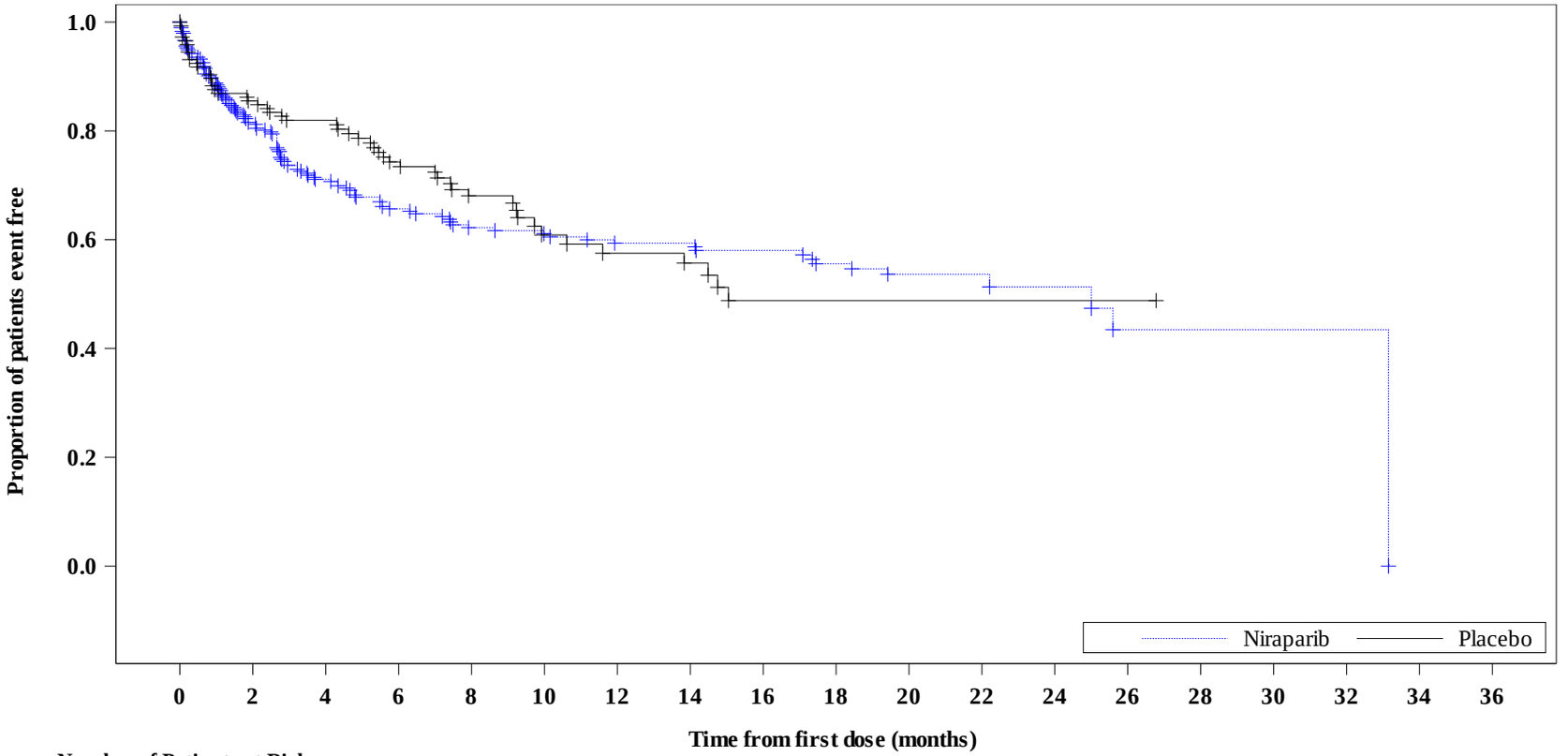
Figure 3.15
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders

Age Group (Years): <65




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 294 | 230 | 181 | 152 | 119 | 107 | 100 | 89 | 74 | 62 | 42 | 28 | 16 | 8 | 3 | 2 | 1 | 0 |
| Placebo | 145 | 123 | 101 | 85 | 61 | 37 | 34 | 27 | 19 | 17 | 14 | 9 | 4 | 1 | 0 | | | |

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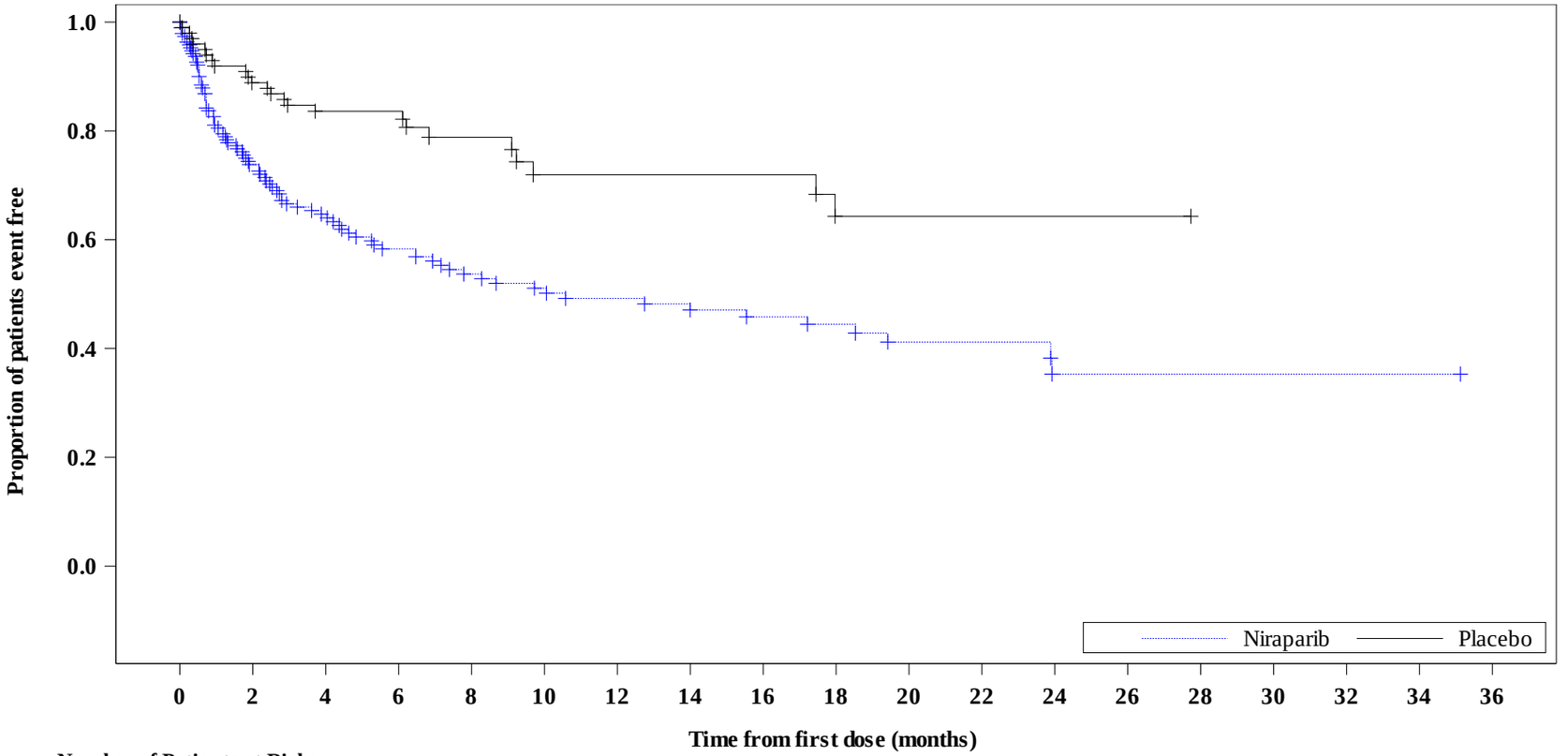
Figure 3.15
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders

Age Group (Years): >=65

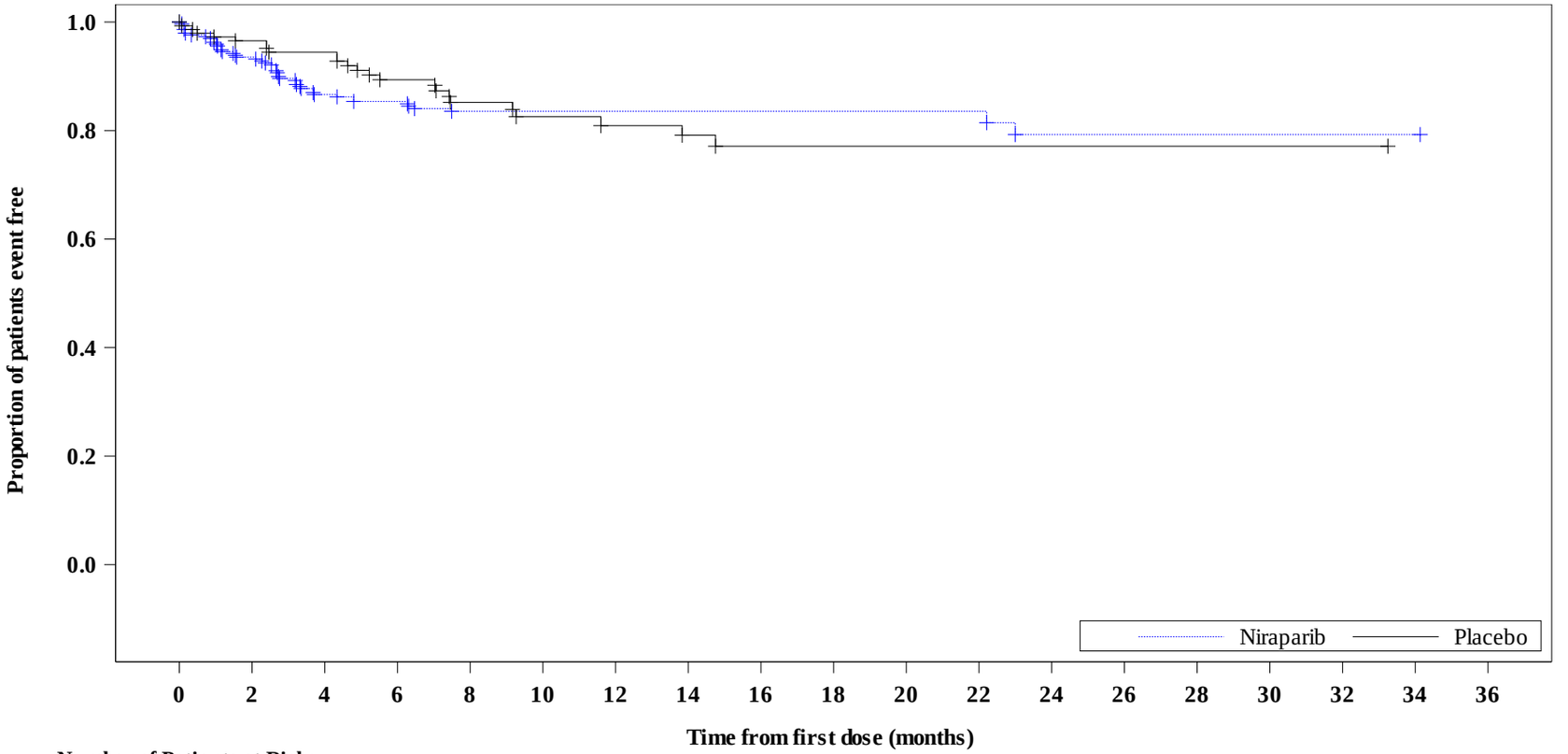



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 190 | 125 | 96 | 80 | 63 | 55 | 50 | 43 | 35 | 30 | 23 | 19 | 11 | 6 | 4 | 1 | 1 | 1 | 0 |
| Placebo | 99 | 87 | 70 | 57 | 40 | 30 | 25 | 23 | 21 | 16 | 14 | 6 | 2 | 2 | 0 | | | | |

Figure 3.15
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea
Age Group (Years): <65

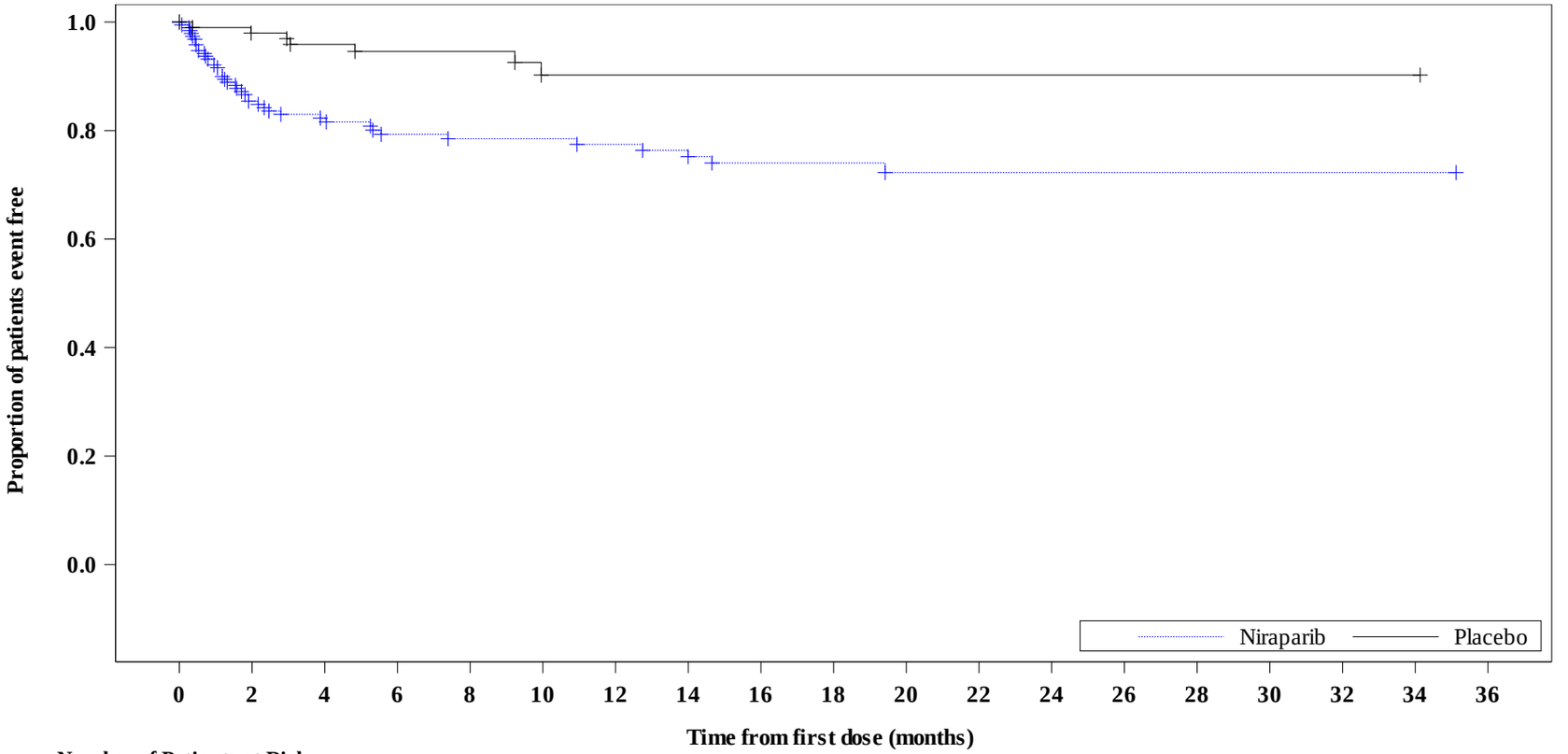



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 294 | 264 | 219 | 197 | 162 | 144 | 136 | 119 | 103 | 93 | 66 | 45 | 30 | 17 | 9 | 5 | 3 | 1 | 0 |
| Placebo | 145 | 139 | 115 | 102 | 78 | 54 | 49 | 41 | 33 | 30 | 24 | 17 | 9 | 4 | 3 | 1 | 1 | 0 | |

Figure 3.15
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea
Age Group (Years): >=65



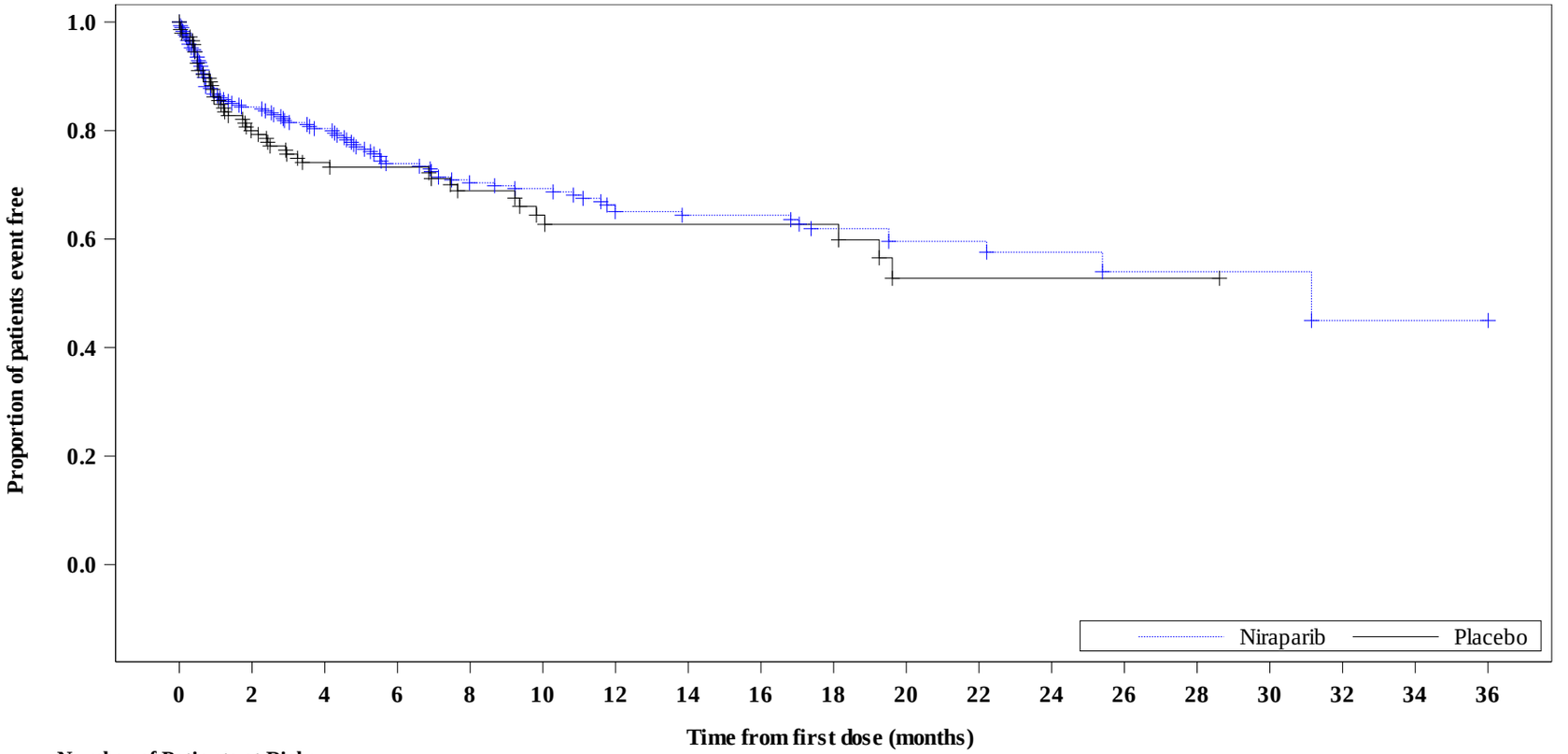

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 190 | 143 | 117 | 103 | 88 | 80 | 73 | 65 | 53 | 47 | 37 | 29 | 19 | 10 | 6 | 2 | 1 | 1 | 0 |
| Placebo | 99 | 96 | 82 | 66 | 51 | 39 | 33 | 31 | 29 | 23 | 19 | 10 | 5 | 4 | 1 | 1 | 1 | 1 | 0 |

Figure 3.15
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety Population)

SOC: Skin and subcutaneous tissue disorders

Age Group (Years): <65



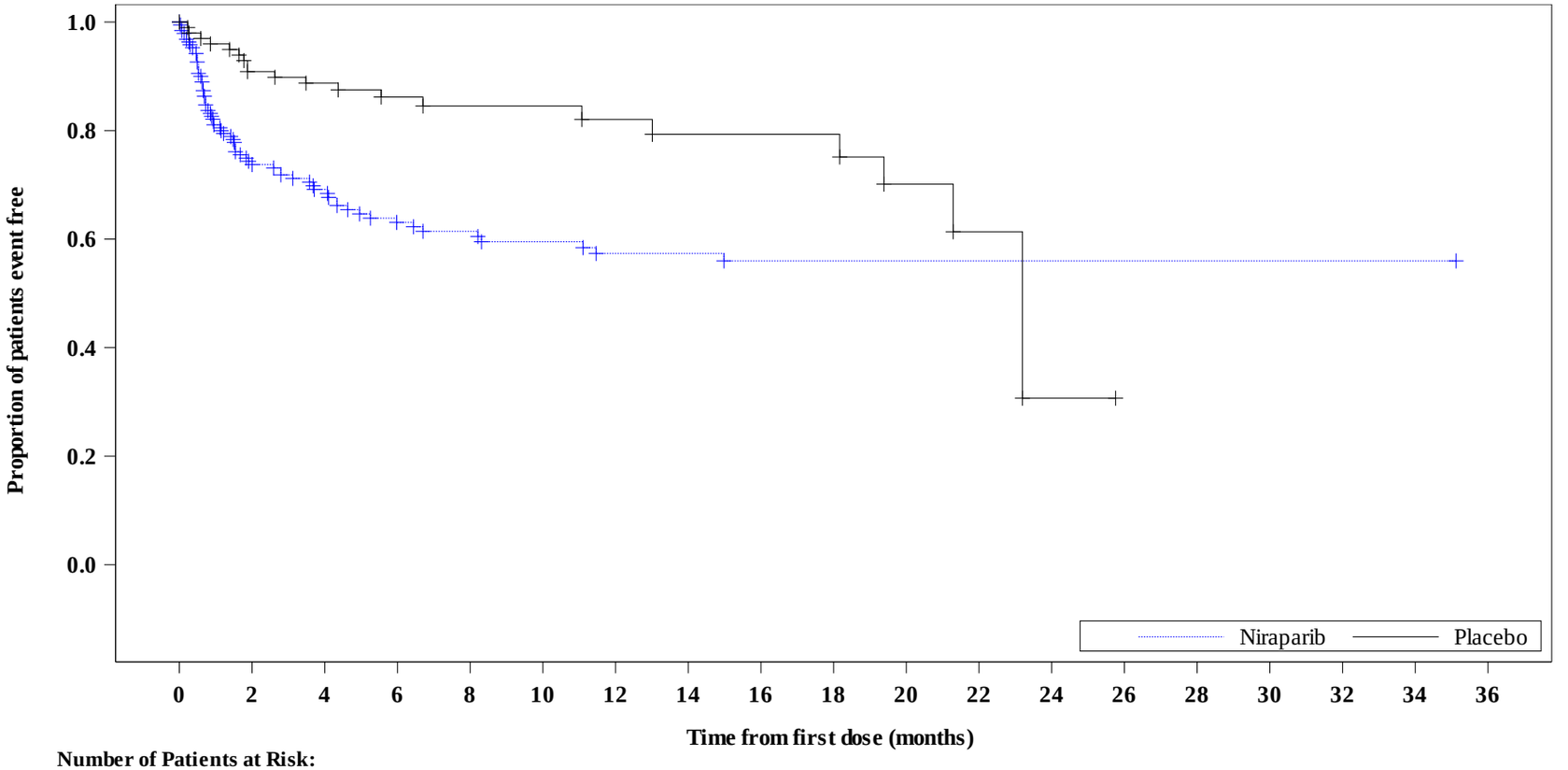

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 294 | 239 | 199 | 167 | 133 | 120 | 106 | 96 | 82 | 69 | 45 | 34 | 22 | 12 | 8 | 6 | 4 | 3 | 1 |
| Placebo | 145 | 114 | 85 | 79 | 60 | 38 | 36 | 30 | 25 | 22 | 14 | 9 | 4 | 2 | 1 | 0 | | | |

Figure 3.15
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety Population)

SOC: Skin and subcutaneous tissue disorders

Age Group (Years): >=65



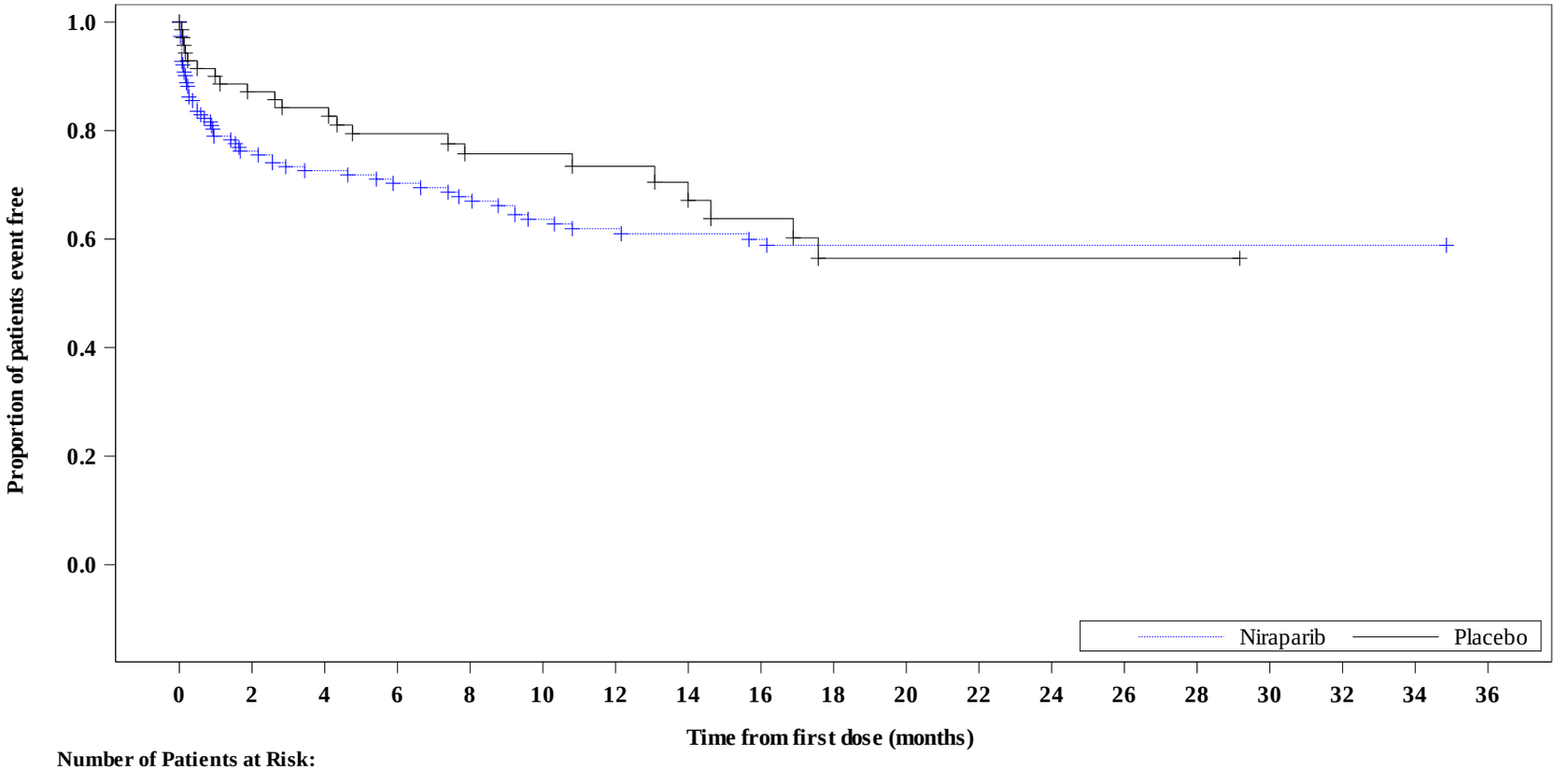

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 190 | 123 | 96 | 80 | 64 | 58 | 51 | 46 | 34 | 31 | 27 | 21 | 14 | 5 | 4 | 2 | 2 | 1 | 0 |
| Placebo | 99 | 89 | 76 | 61 | 46 | 38 | 31 | 28 | 25 | 19 | 14 | 6 | 1 | 0 | | | | | |

Figure 3.17
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety Population)

SOC: Gastrointestinal disorders, PT: Constipation

BRCA Status: BRCAmut

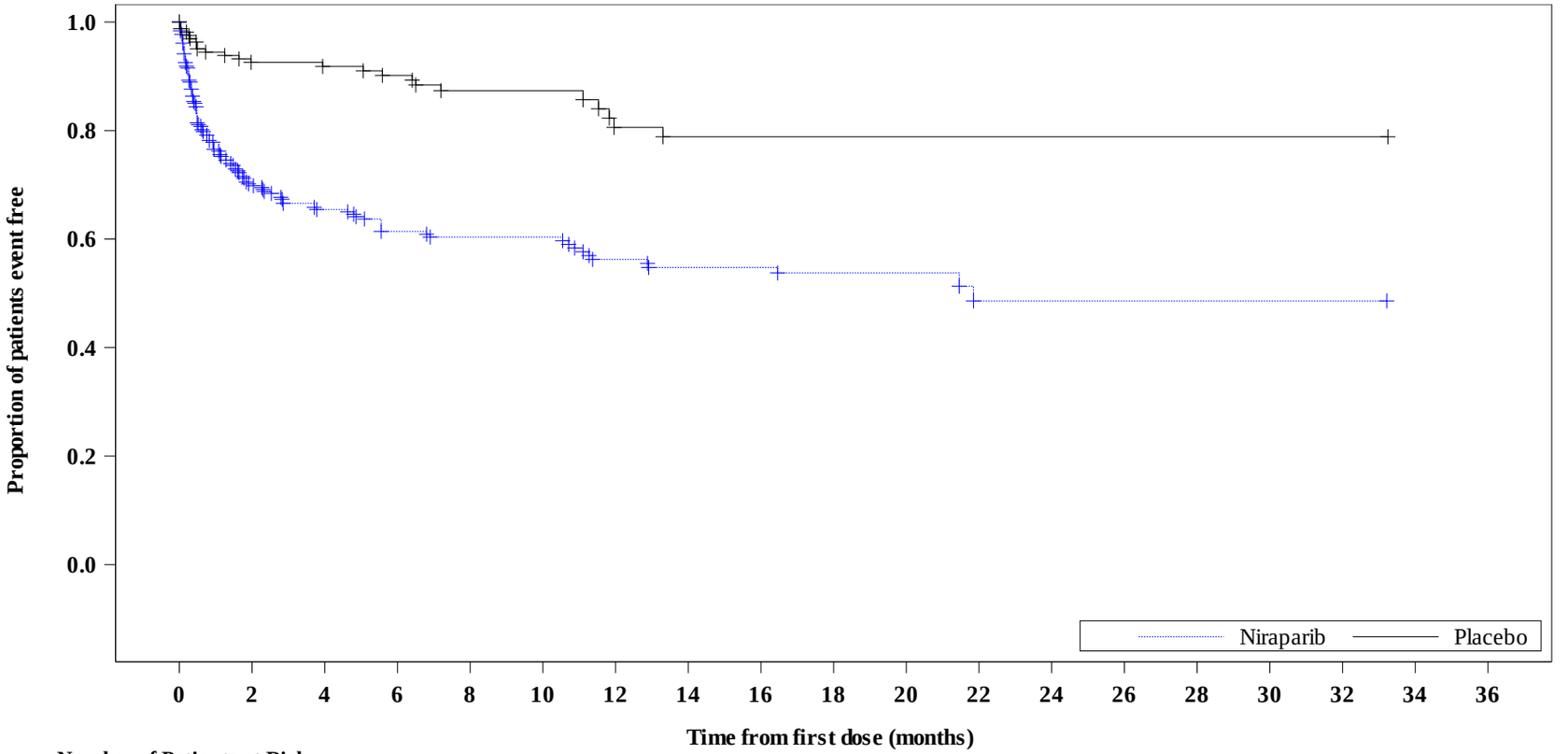



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 152 | 107 | 95 | 90 | 82 | 73 | 69 | 65 | 56 | 46 | 34 | 25 | 19 | 10 | 3 | 2 | 2 | 2 | 0 |
| Placebo | 70 | 61 | 53 | 48 | 41 | 34 | 28 | 20 | 18 | 14 | 13 | 9 | 5 | 3 | 1 | 0 | | | |

Figure 3.17
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety Population)

SOC: Gastrointestinal disorders, PT: Constipation
BRCA Status: BRCAwt



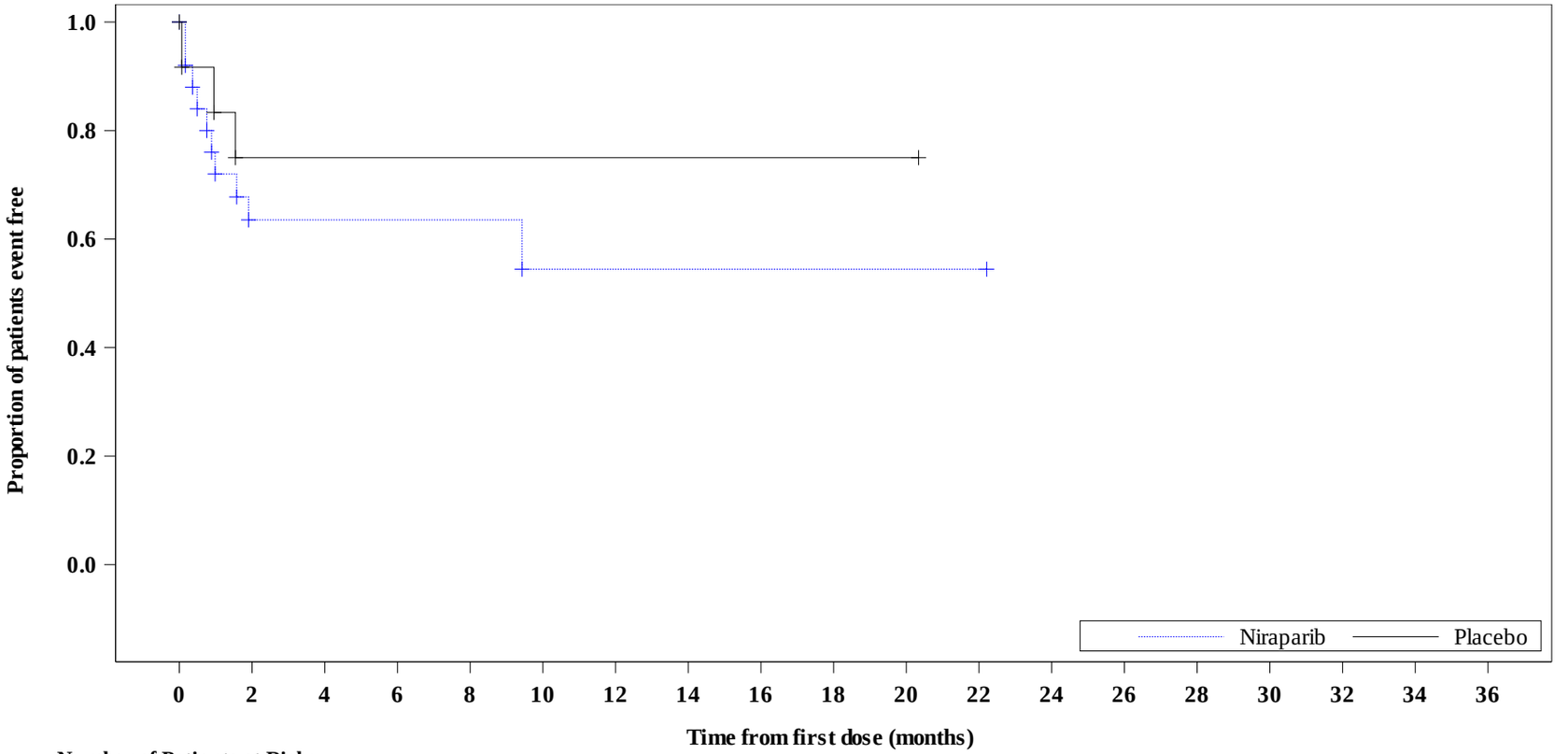

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 307 | 201 | 159 | 133 | 103 | 91 | 80 | 71 | 55 | 50 | 34 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |
| Placebo | 162 | 148 | 120 | 105 | 77 | 54 | 47 | 45 | 40 | 35 | 27 | 17 | 9 | 7 | 4 | 2 | 1 | 0 |

Figure 3.17
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety Population)

SOC: Gastrointestinal disorders, PT: Constipation

BRCA Status: BRCAnd



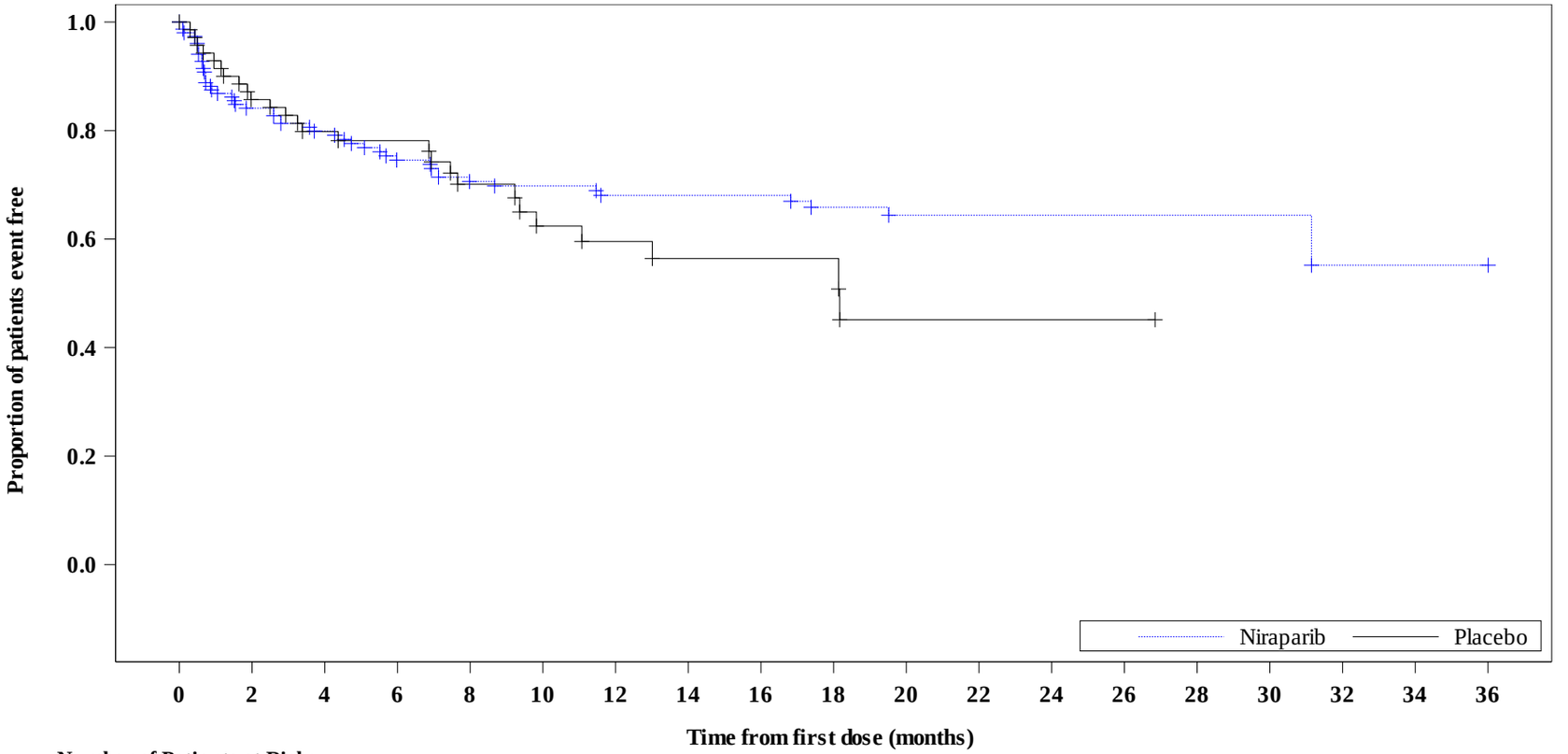

**Number of Patients at Risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 25 | 15 | 11 | 8 | 8 | 5 | 4 | 4 | 4 | 4 | 3 | 2 | 0 |
| Placebo | 12 | 9 | 9 | 8 | 4 | 3 | 2 | 2 | 2 | 2 | 2 | 0 | |

Figure 3.17
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety Population)

SOC: Skin and subcutaneous tissue disorders

BRCA Status: BRCAmut




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 152 | 120 | 107 | 98 | 87 | 84 | 78 | 74 | 66 | 54 | 40 | 33 | 24 | 14 | 9 | 7 | 5 | 4 | 1 |
| Placebo | 70 | 60 | 48 | 44 | 33 | 23 | 20 | 16 | 13 | 10 | 7 | 4 | 3 | 1 | 0 | | | | |

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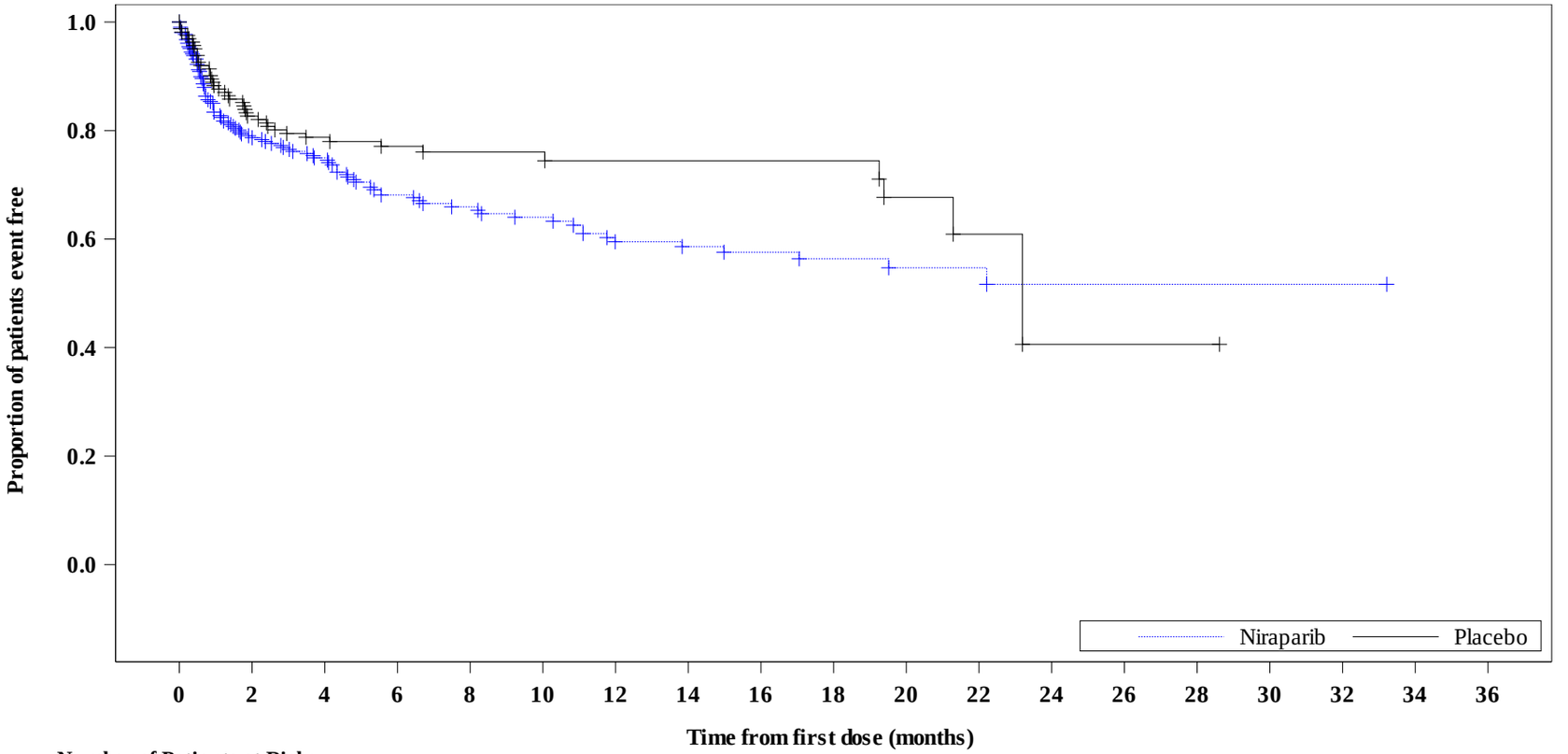
Figure 3.17
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety Population)

SOC: Skin and subcutaneous tissue disorders

BRCA Status: BRCAwt



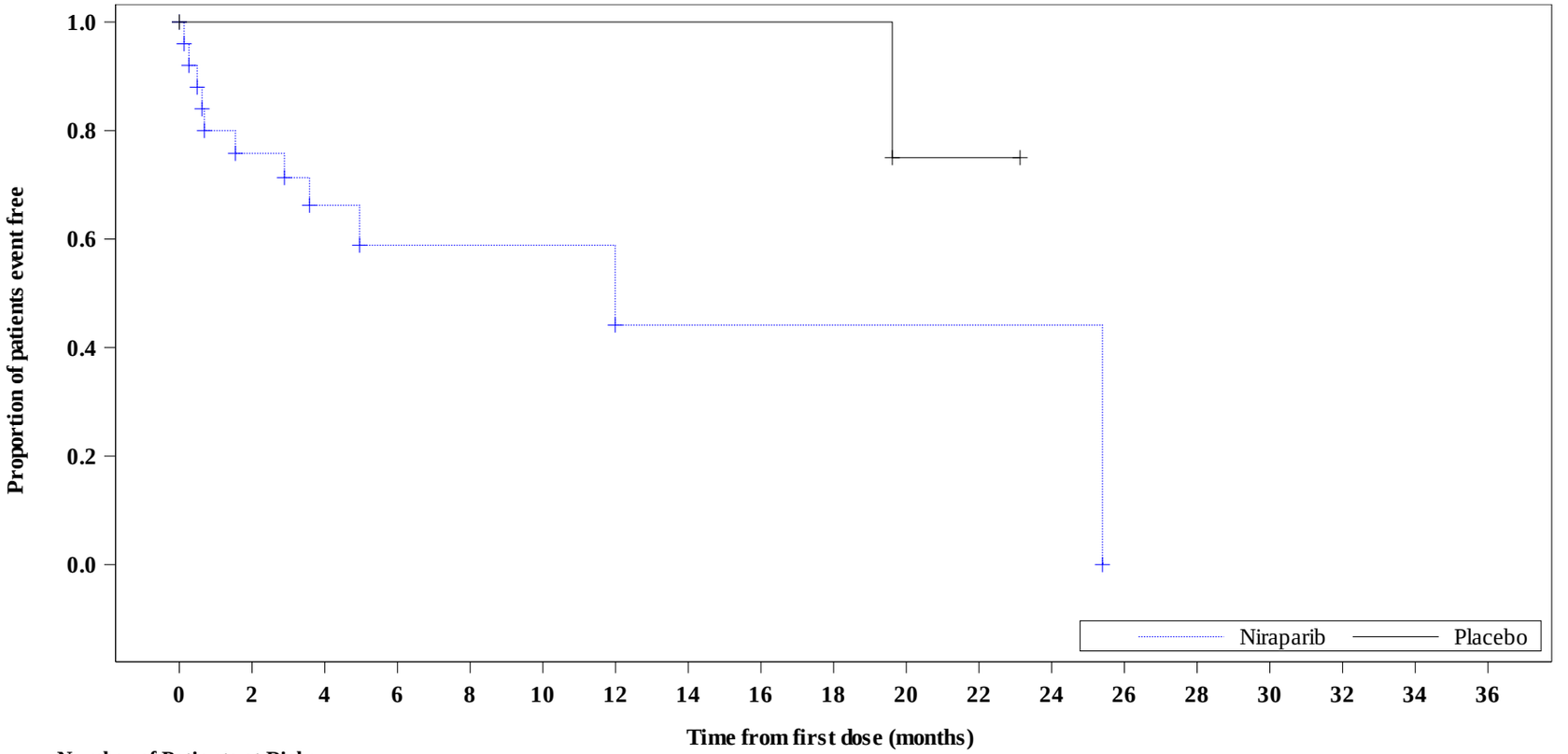

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 307 | 224 | 176 | 142 | 104 | 90 | 77 | 66 | 48 | 44 | 31 | 21 | 11 | 3 | 3 | 1 | 1 | 0 |
| Placebo | 162 | 131 | 101 | 85 | 66 | 47 | 43 | 38 | 33 | 27 | 18 | 9 | 2 | 1 | 1 | 0 | | |

Figure 3.17
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety Population)

SOC: Skin and subcutaneous tissue disorders

BRCA Status: BRCAnd

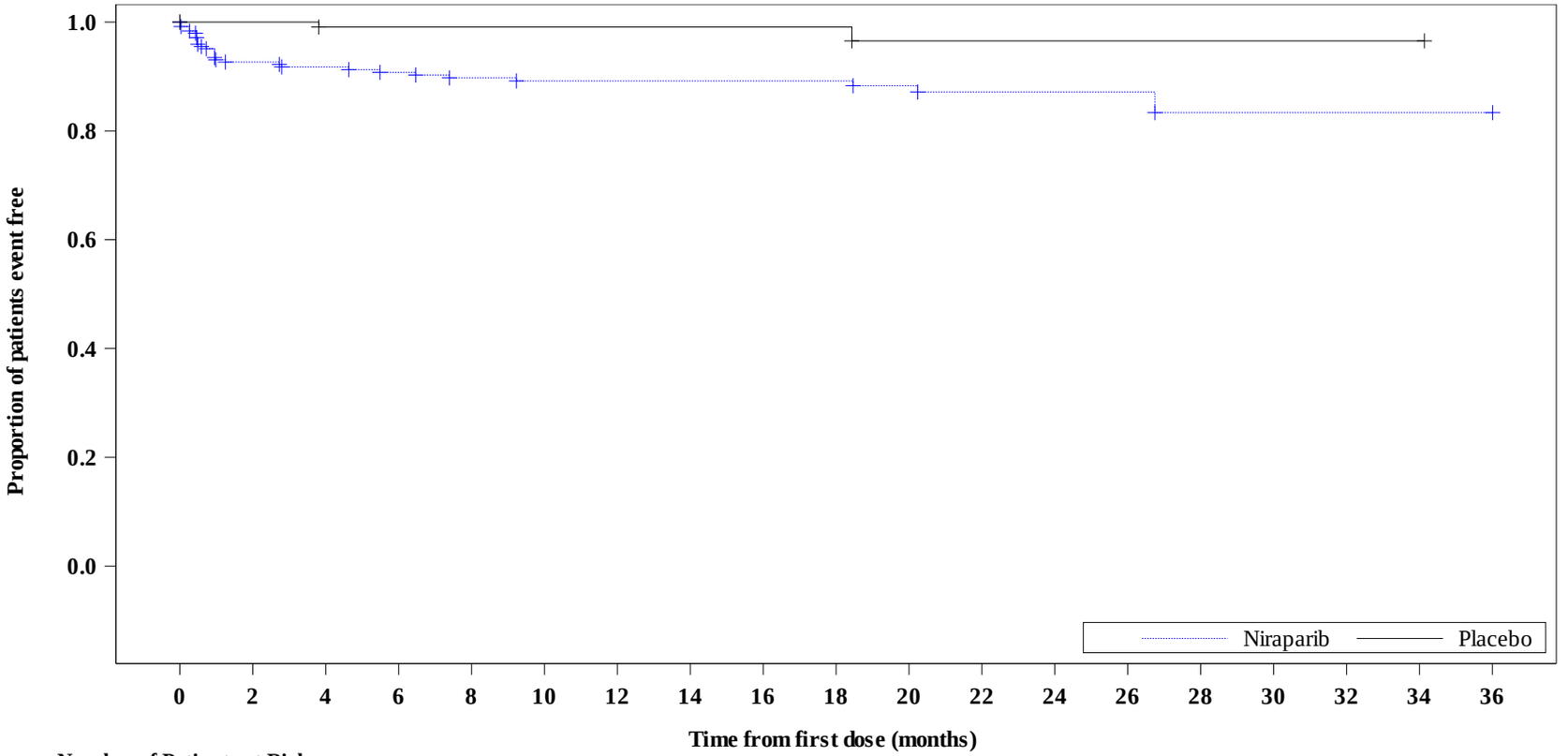



**Number of Patients at Risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 25 | 18 | 12 | 7 | 6 | 4 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 12 | 12 | 12 | 11 | 7 | 6 | 4 | 4 | 4 | 4 | 3 | 2 | 0 | |

Figure 3.19
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and HRD Status (Safety Population)

SOC: Investigations, PT: Blood alkaline phosphatase increased
HRD Status: HRd



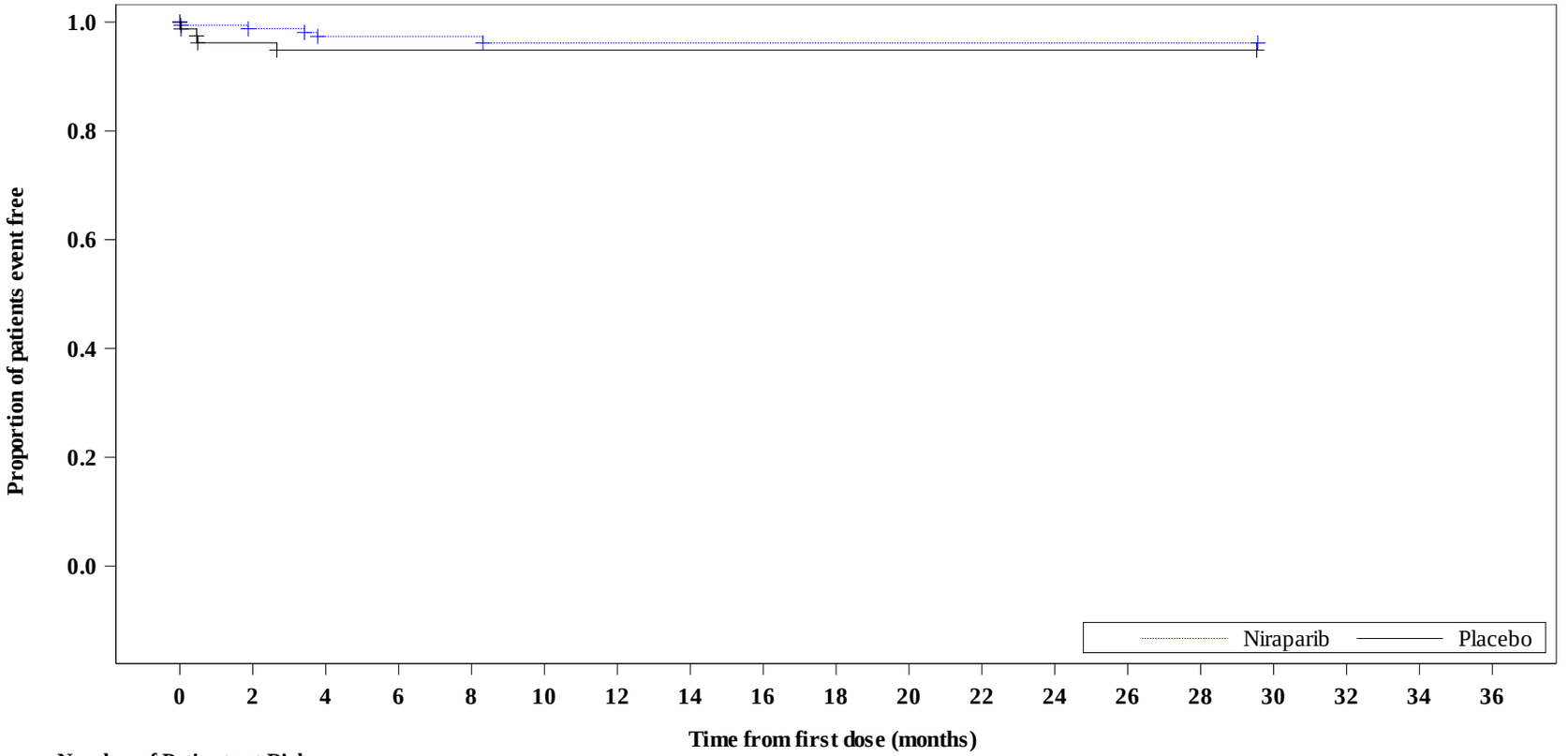

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 245 | 211 | 192 | 183 | 166 | 152 | 146 | 136 | 117 | 101 | 76 | 55 | 39 | 24 | 14 | 9 | 6 | 4 | 1 |
| Placebo | 125 | 124 | 108 | 100 | 88 | 69 | 61 | 52 | 43 | 39 | 29 | 20 | 12 | 8 | 6 | 3 | 2 | 1 | 0 |

Figure 3.19
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and HRD Status (Safety Population)

SOC: Investigations, PT: Blood alkaline phosphatase increased

HRD Status: HRp



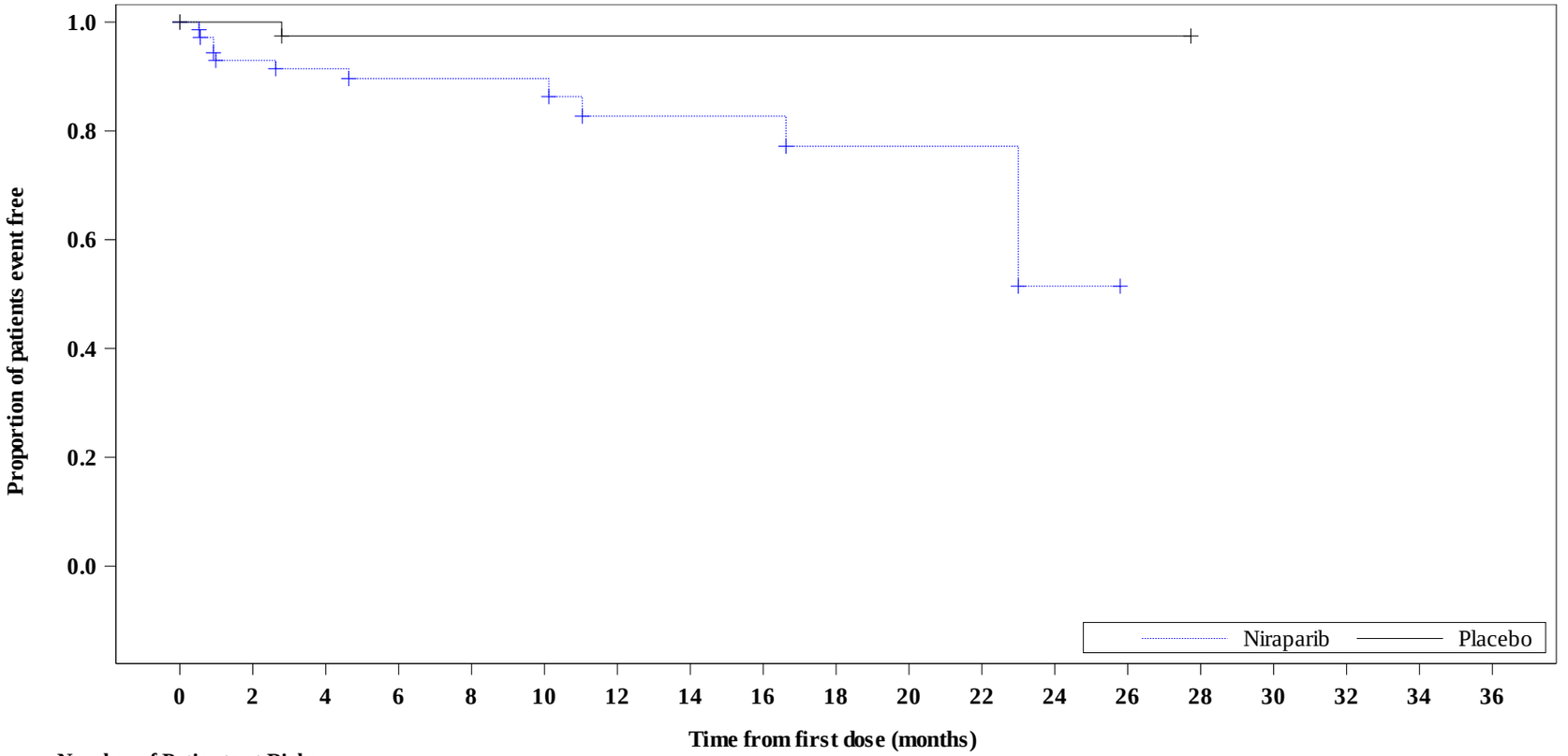

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 168 | 151 | 126 | 107 | 82 | 67 | 60 | 52 | 43 | 38 | 29 | 18 | 11 | 4 | 3 | 0 |
| Placebo | 79 | 75 | 54 | 44 | 31 | 19 | 19 | 17 | 15 | 12 | 12 | 8 | 3 | 2 | 1 | 0 |

Figure 3.19
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and HRD Status (Safety Population)

SOC: Investigations, PT: Blood alkaline phosphatase increased

HRD Status: HRnd




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 71 | 63 | 51 | 46 | 31 | 27 | 22 | 19 | 15 | 12 | 8 | 4 | 1 | 0 | |
| Placebo | 40 | 39 | 38 | 35 | 24 | 18 | 15 | 14 | 13 | 12 | 10 | 3 | 1 | 1 | 0 |

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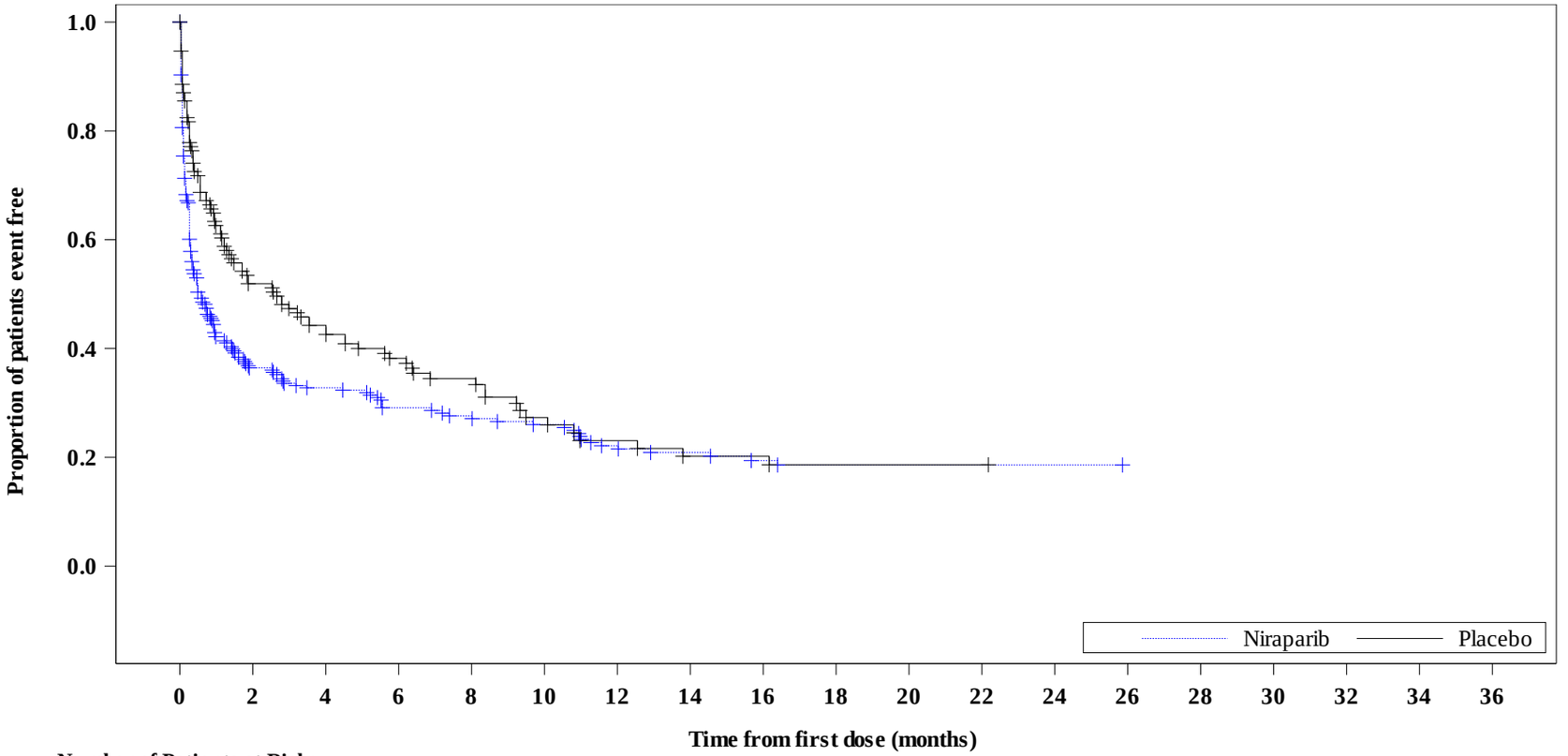
Figure 3.21
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Region (Safety Population)

SOC: Gastrointestinal disorders

Region: Europe




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 268 | 90 | 77 | 63 | 52 | 48 | 37 | 32 | 24 | 19 | 8 | 3 | 1 | 0 |
| Placebo | 131 | 68 | 53 | 42 | 32 | 20 | 16 | 14 | 13 | 10 | 8 | 2 | 0 | |

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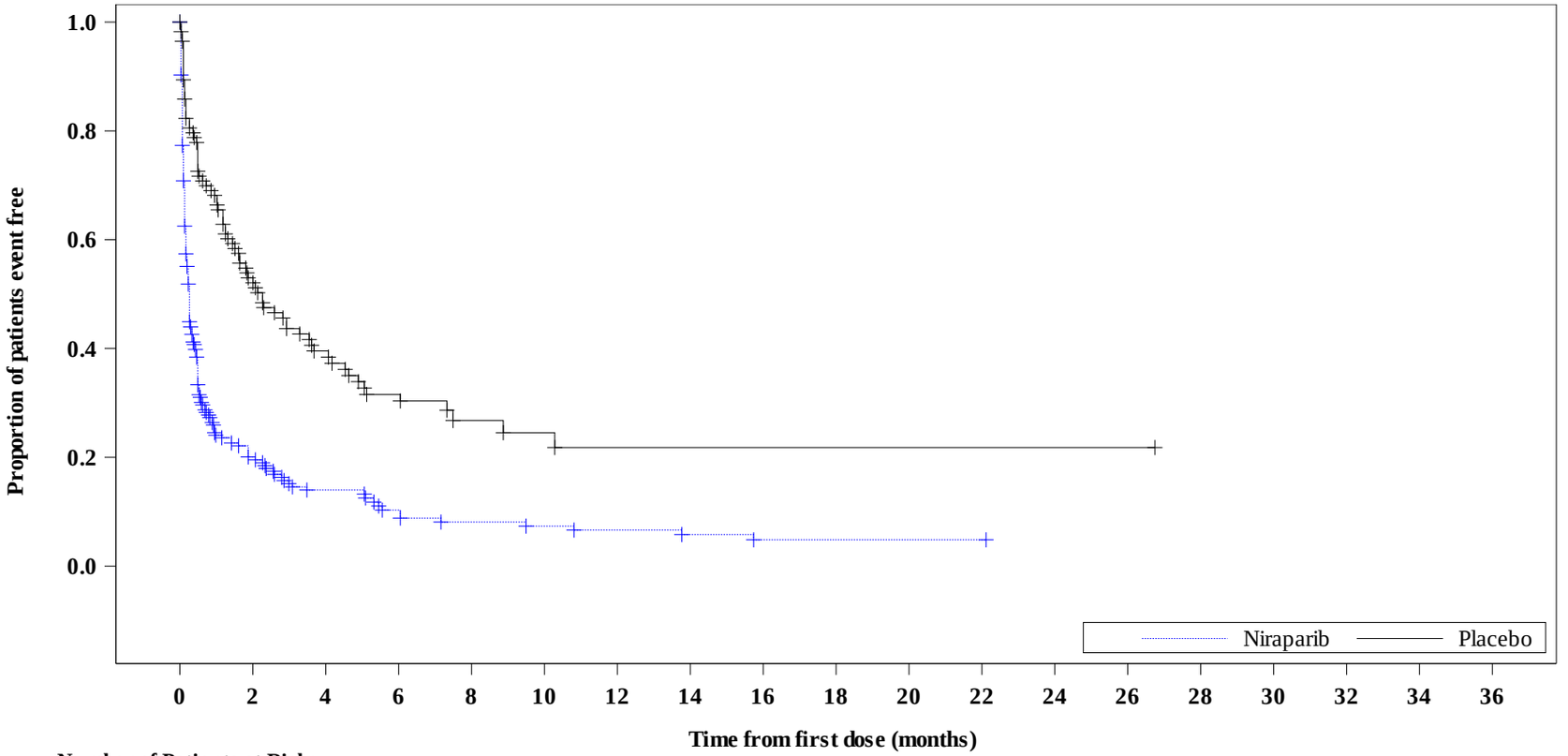
Figure 3.21
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Region (Safety Population)

SOC: Gastrointestinal disorders

Region: North America




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 216 | 38 | 19 | 14 | 11 | 10 | 9 | 7 | 5 | 5 | 3 | 1 | 0 | | |
| Placebo | 113 | 58 | 35 | 26 | 14 | 9 | 6 | 4 | 4 | 4 | 4 | 4 | 3 | 2 | 0 |

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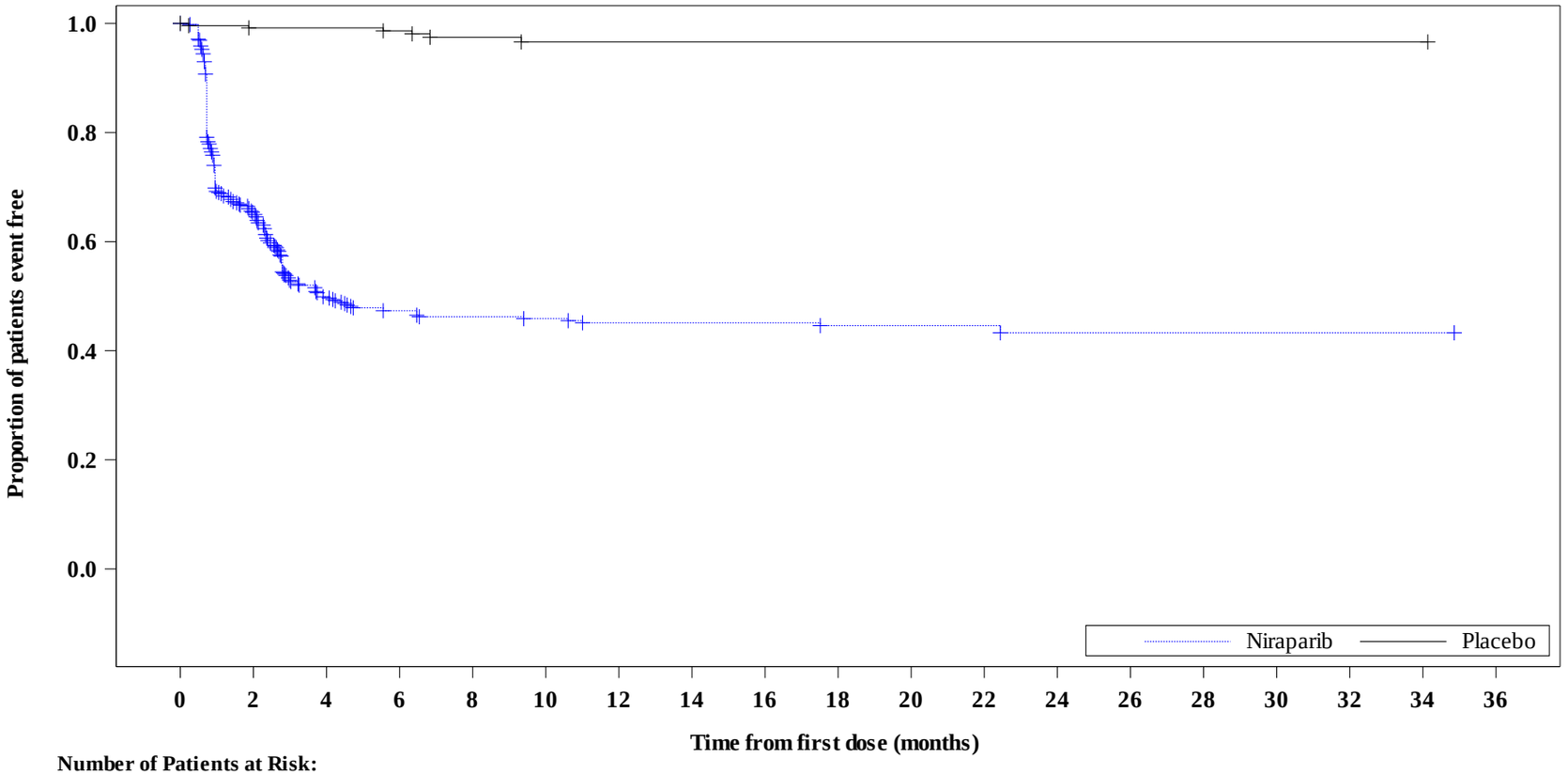
Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Blood and lymphatic system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 303 | 203 | 176 | 147 | 128 | 116 | 107 | 93 | 76 | 63 | 40 | 26 | 14 | 8 | 4 | 3 | 2 | 0 |
| Placebo | 244 | 239 | 203 | 180 | 143 | 106 | 95 | 83 | 71 | 62 | 52 | 31 | 16 | 10 | 5 | 3 | 2 | 1 | 0 |

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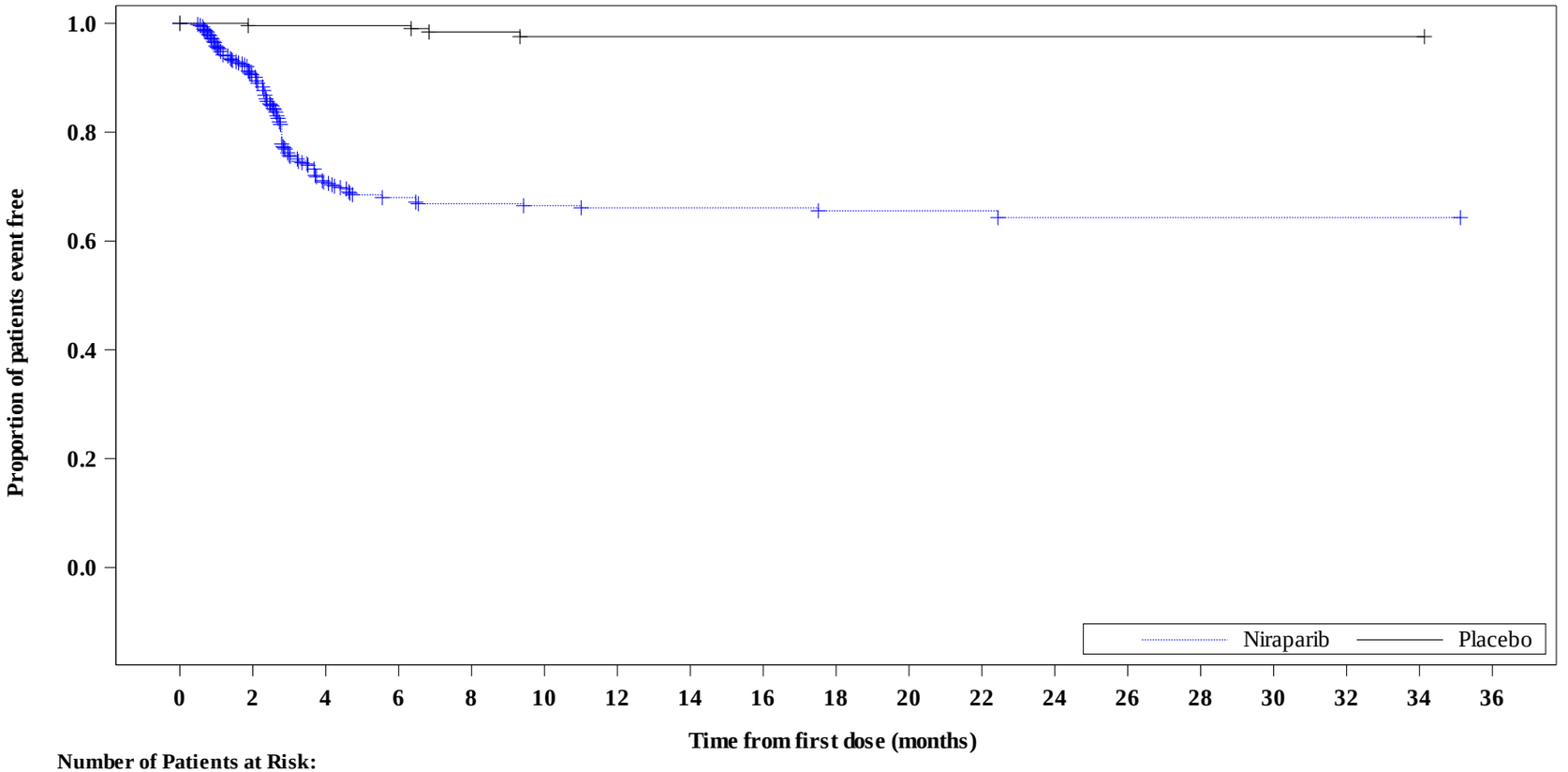
Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia

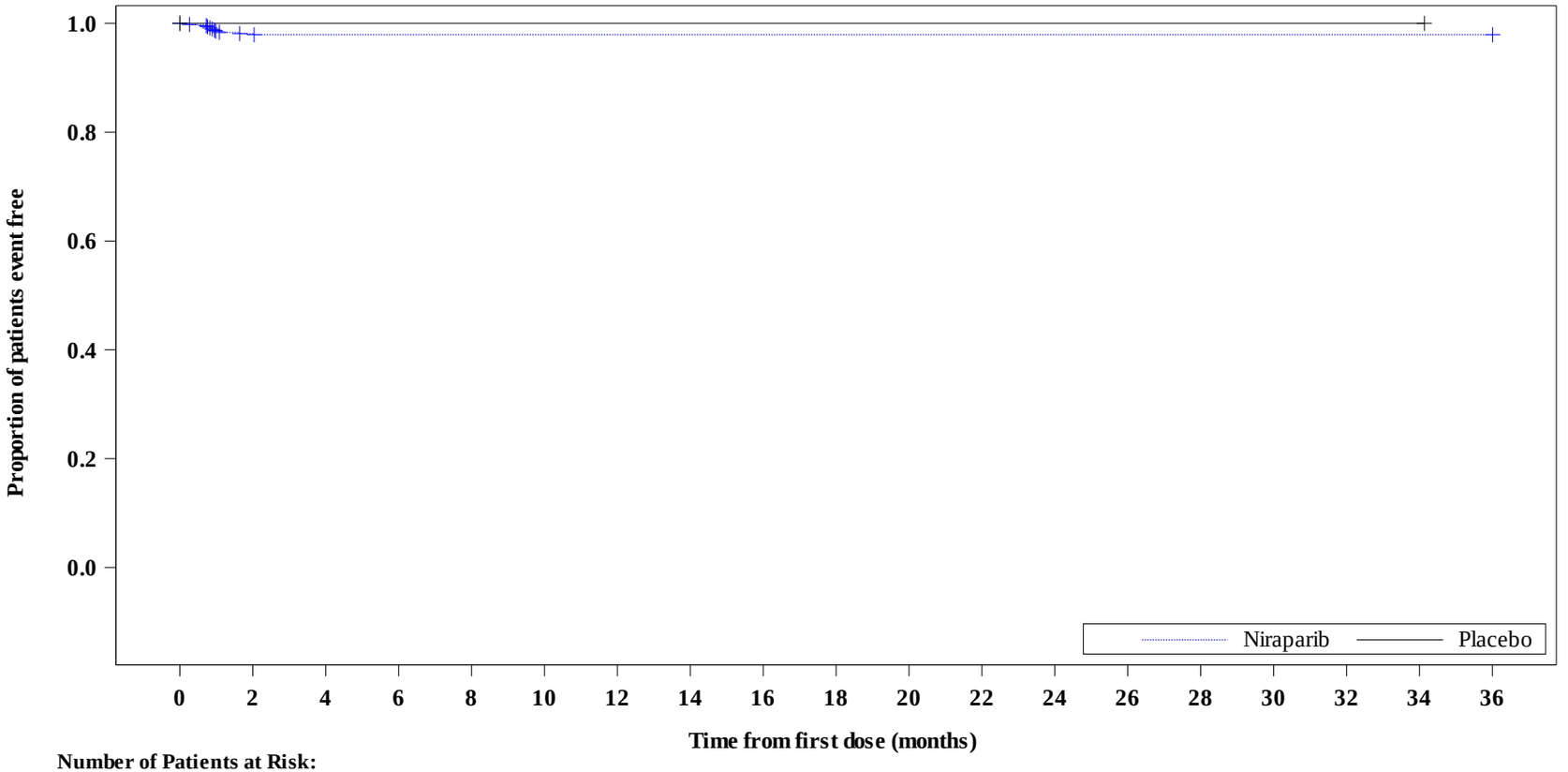



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 410 | 286 | 249 | 206 | 180 | 166 | 152 | 131 | 112 | 89 | 60 | 40 | 23 | 13 | 6 | 4 | 3 | 0 |
| Placebo | 244 | 240 | 204 | 182 | 145 | 107 | 96 | 84 | 72 | 63 | 53 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Blood and lymphatic system disorders, PT: Leukopenia

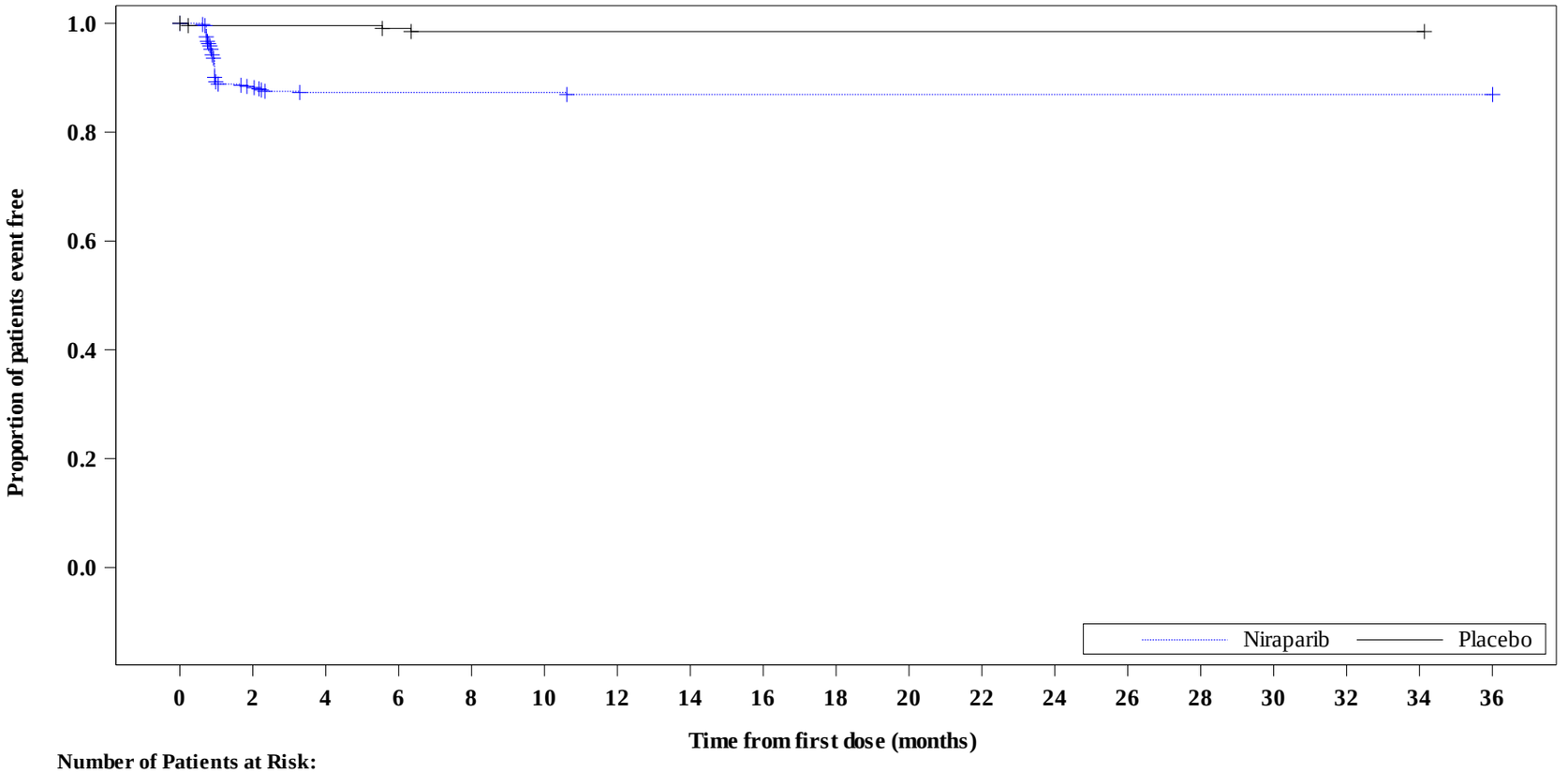



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 442 | 385 | 351 | 294 | 261 | 244 | 221 | 188 | 165 | 126 | 90 | 61 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Blood and lymphatic system disorders, PT: Neutropenia

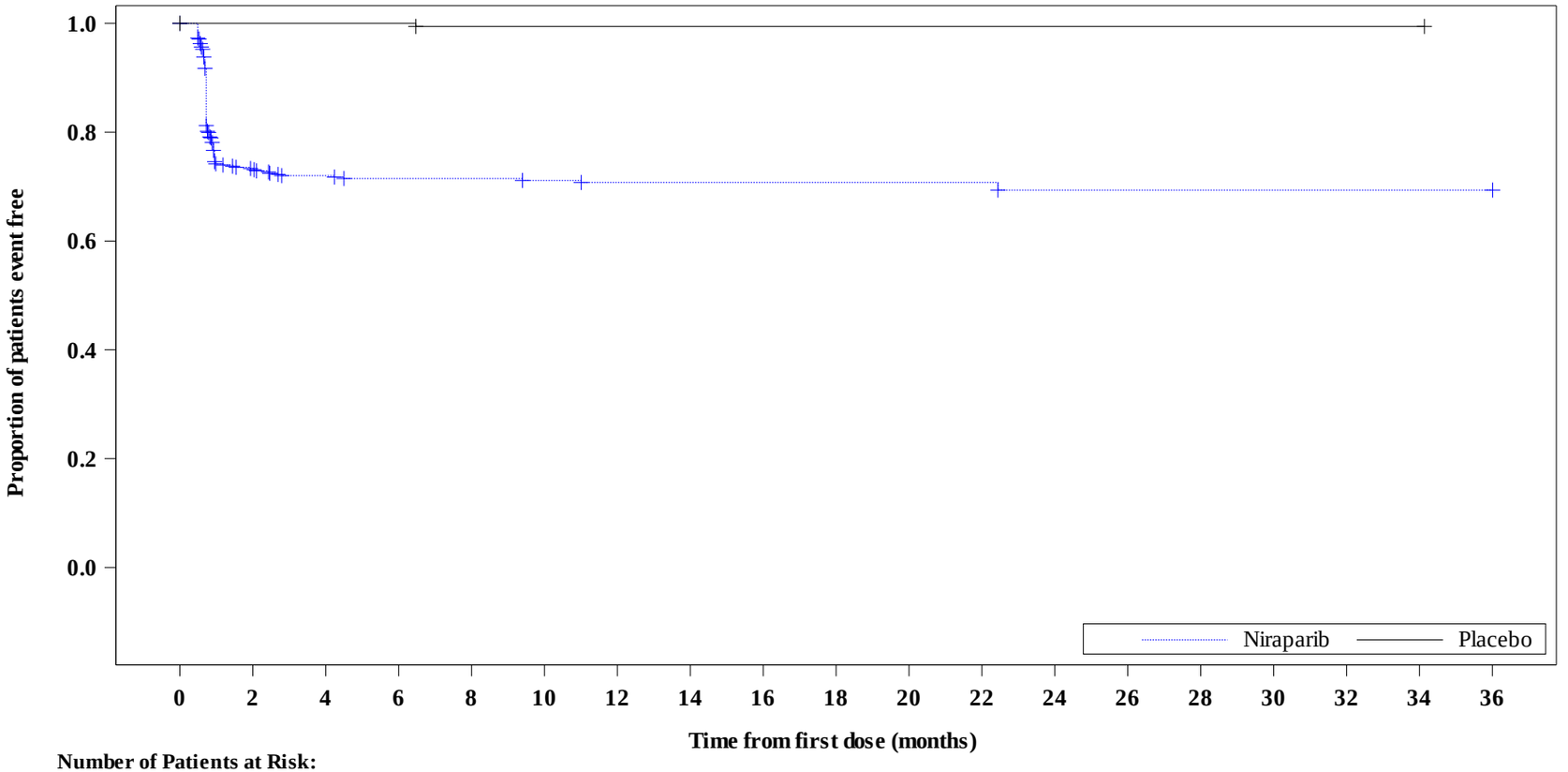



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 401 | 343 | 314 | 267 | 238 | 223 | 206 | 174 | 152 | 118 | 85 | 57 | 33 | 20 | 12 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 108 | 97 | 85 | 73 | 64 | 53 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

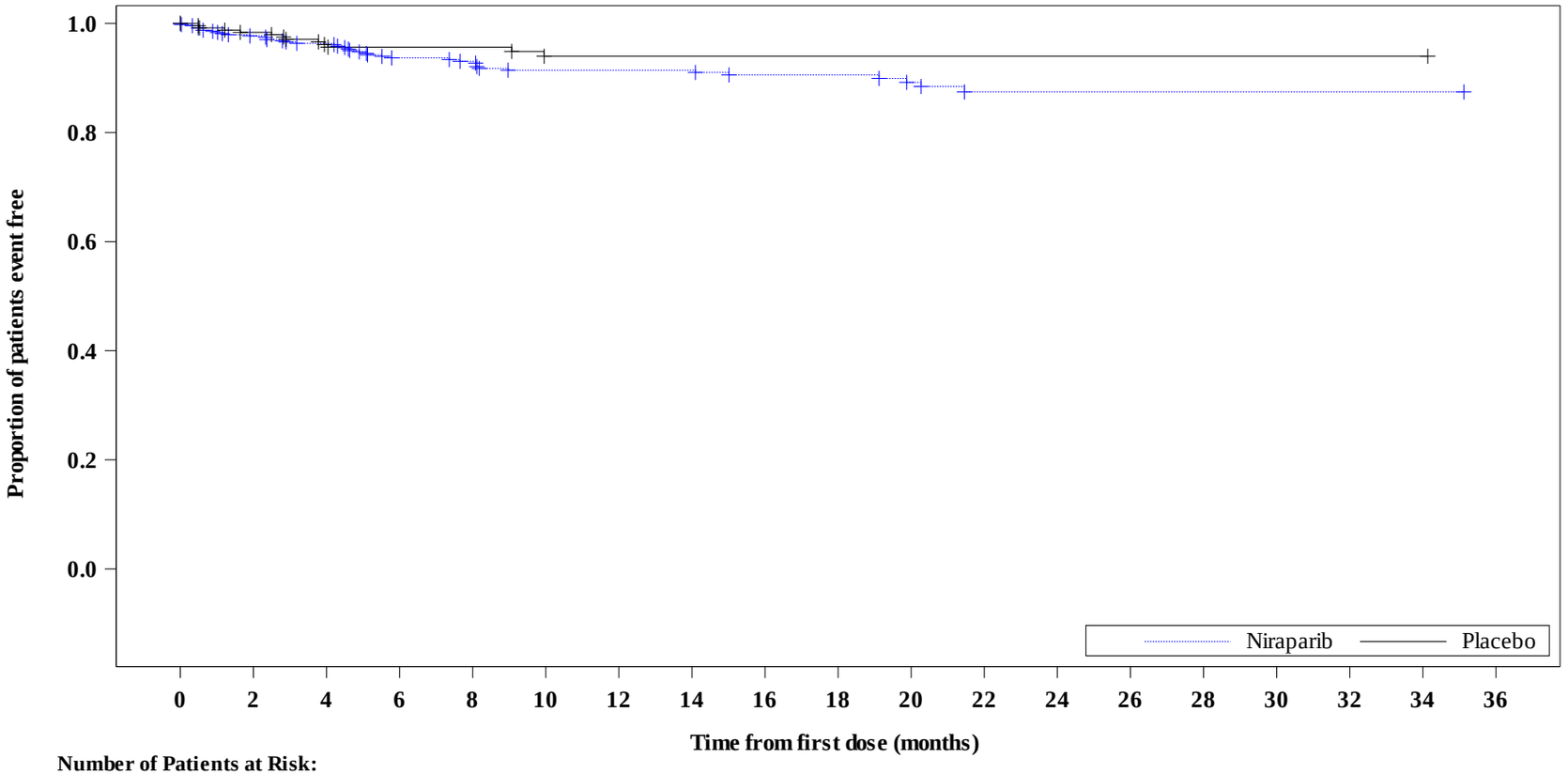



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 339 | 287 | 263 | 220 | 193 | 179 | 160 | 137 | 118 | 89 | 60 | 40 | 19 | 12 | 6 | 4 | 3 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Gastrointestinal disorders

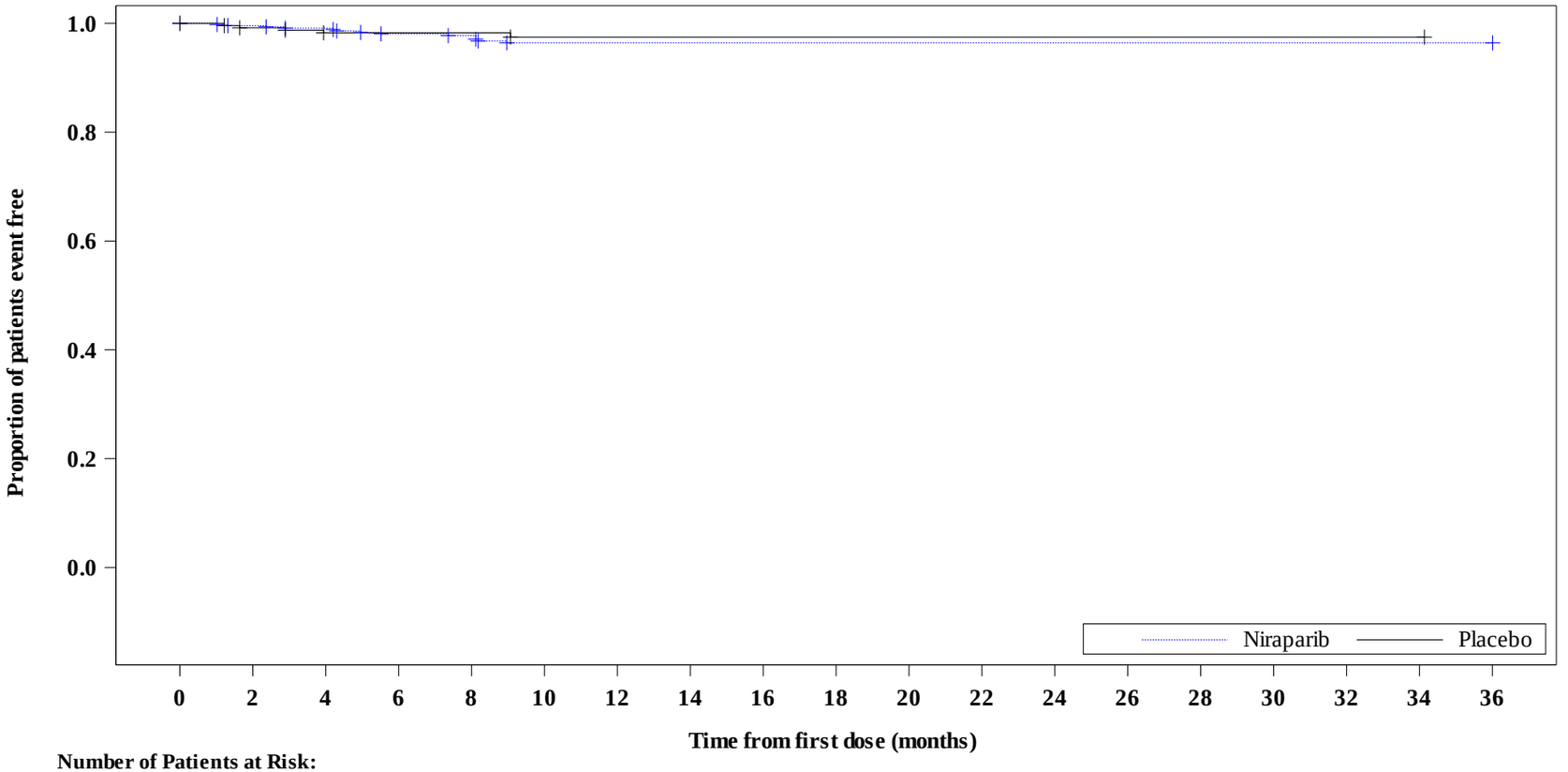



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 441 | 380 | 341 | 287 | 256 | 242 | 219 | 185 | 162 | 121 | 84 | 58 | 32 | 20 | 12 | 8 | 4 | 0 |
| Placebo | 244 | 237 | 200 | 179 | 142 | 104 | 93 | 82 | 70 | 61 | 51 | 31 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction

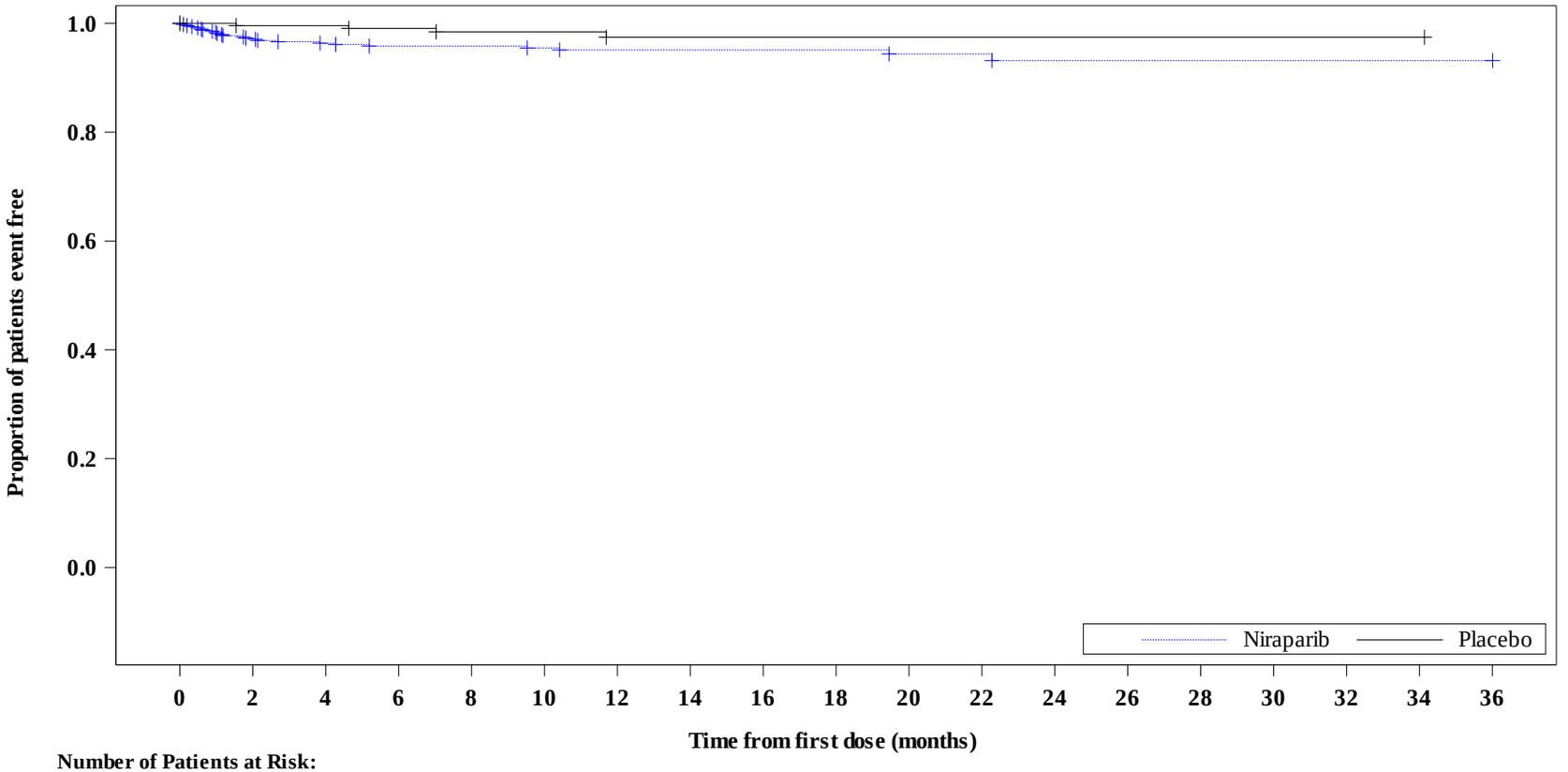



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 387 | 351 | 295 | 261 | 245 | 222 | 188 | 165 | 126 | 90 | 61 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 182 | 145 | 107 | 96 | 84 | 72 | 63 | 52 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: General disorders and administration site conditions

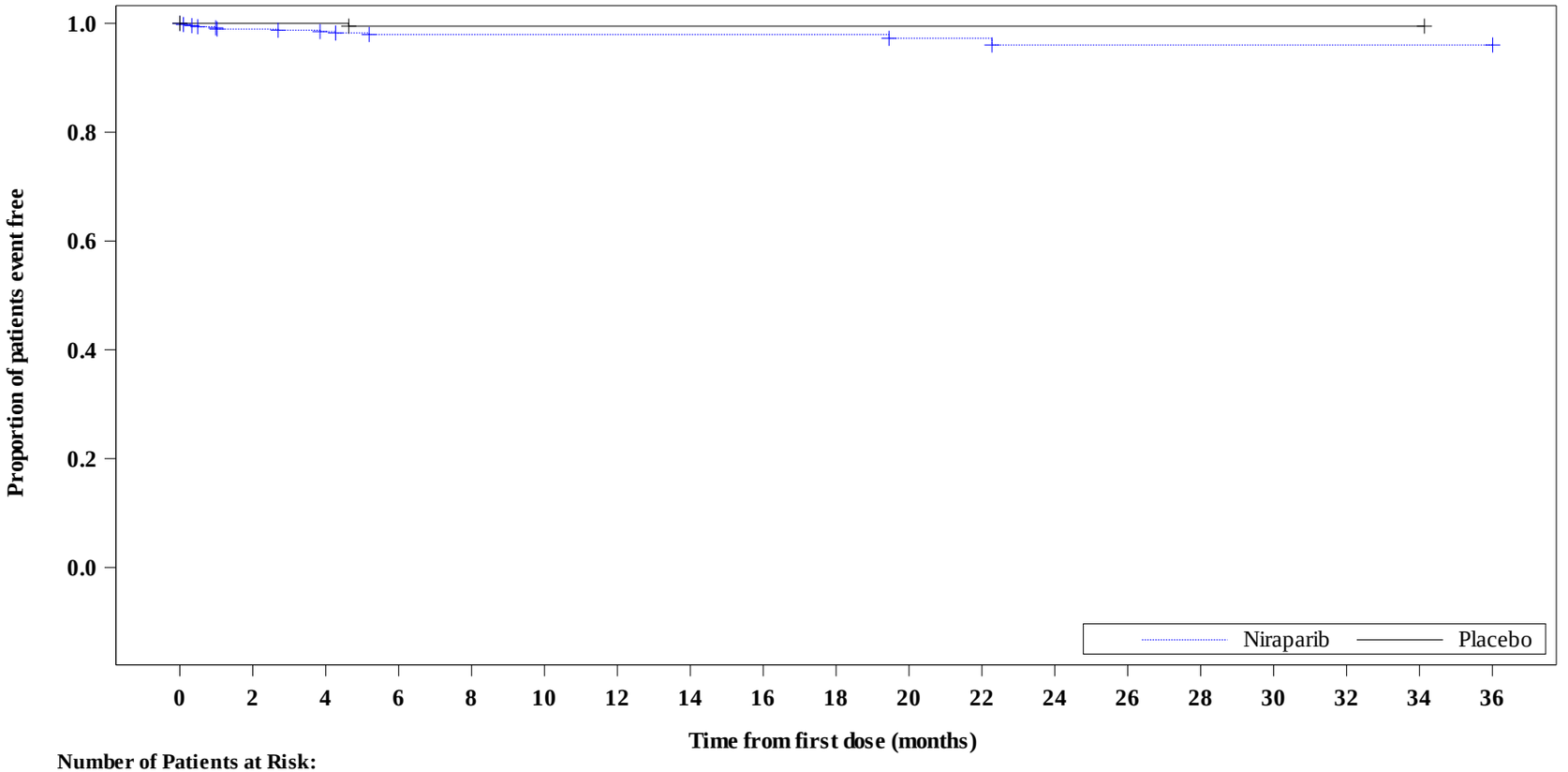



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 439 | 380 | 349 | 291 | 258 | 241 | 218 | 184 | 161 | 122 | 87 | 58 | 31 | 19 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 143 | 108 | 96 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: General disorders and administration site conditions, PT: Fatigue

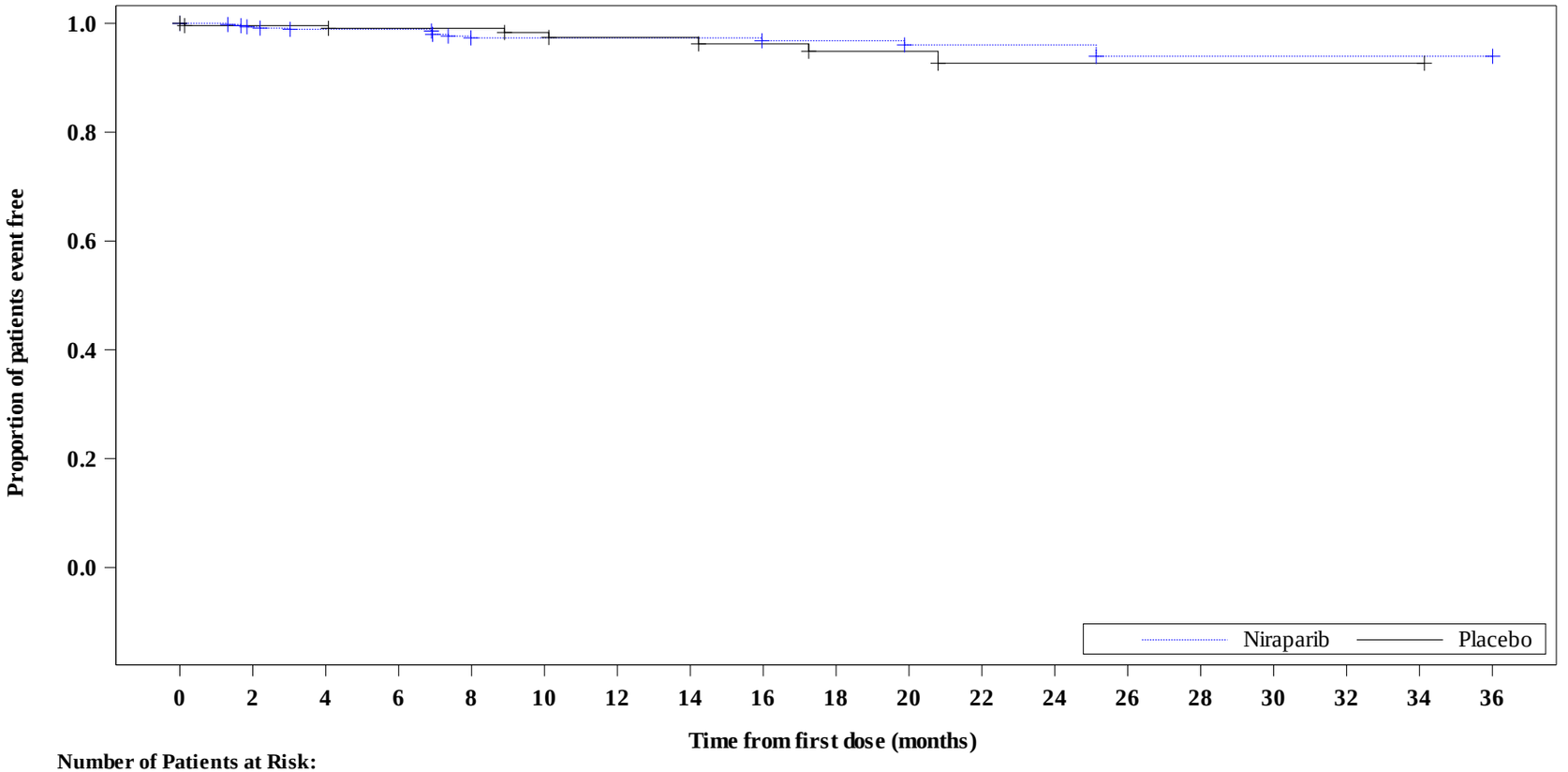



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 386 | 353 | 295 | 263 | 246 | 223 | 189 | 166 | 127 | 90 | 61 | 34 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 182 | 145 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Infections and infestations

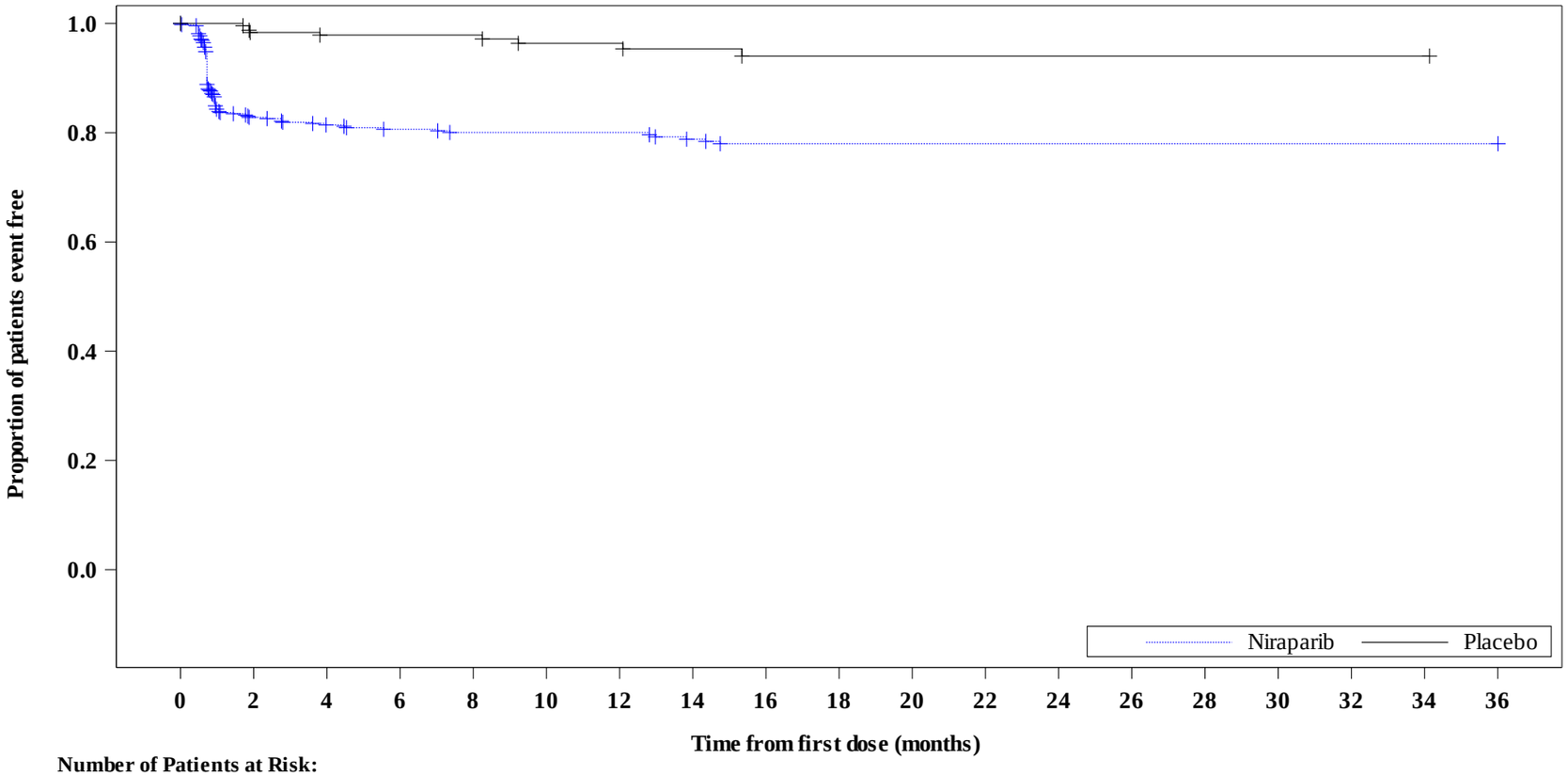



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 386 | 353 | 293 | 260 | 243 | 220 | 185 | 162 | 123 | 88 | 62 | 34 | 21 | 12 | 8 | 4 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 107 | 95 | 83 | 72 | 63 | 52 | 30 | 16 | 10 | 6 | 2 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Investigations

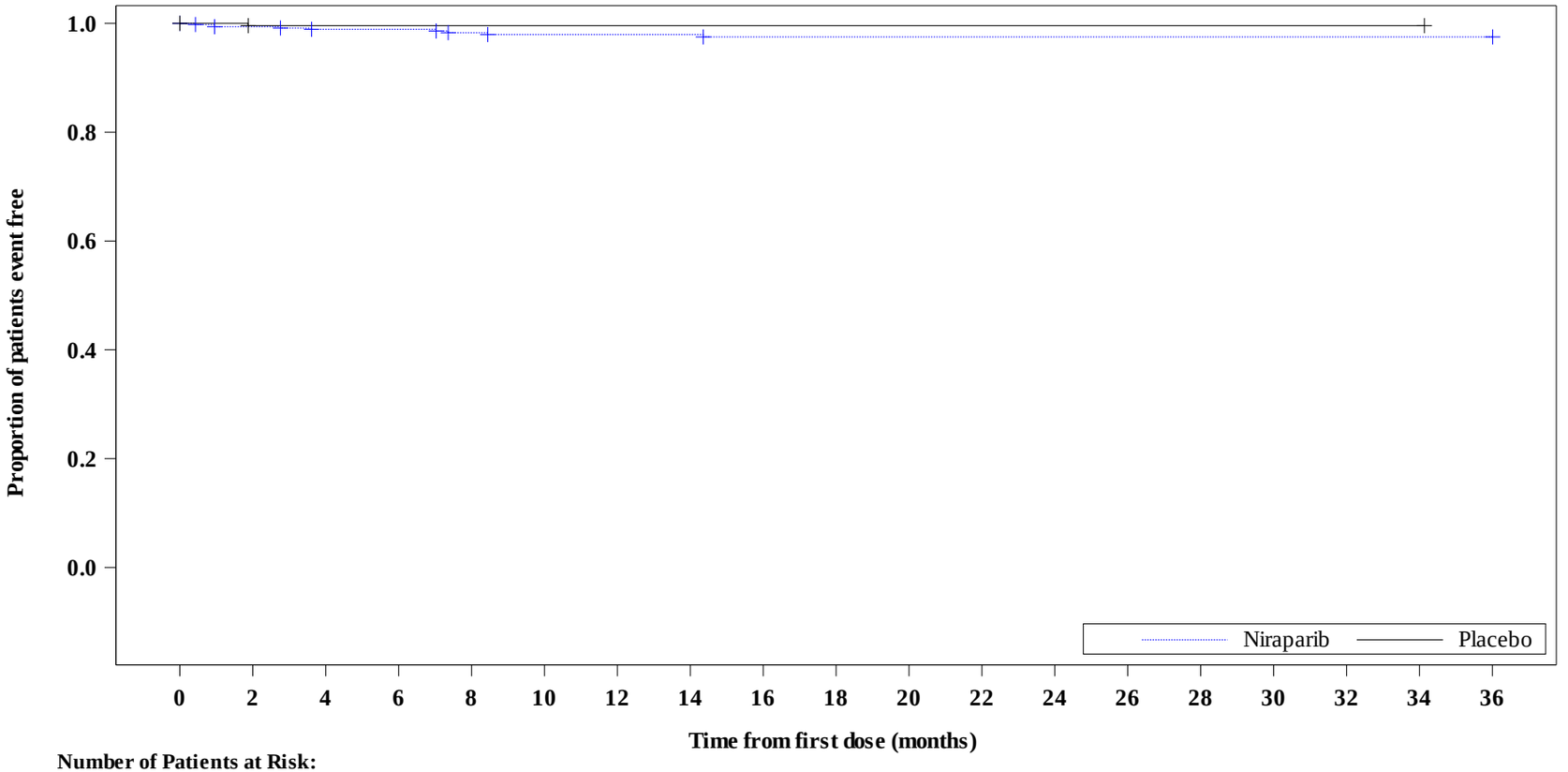



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 373 | 325 | 295 | 253 | 227 | 211 | 191 | 162 | 142 | 106 | 75 | 52 | 30 | 19 | 11 | 7 | 3 | 1 |
| Placebo | 244 | 237 | 202 | 181 | 144 | 107 | 96 | 84 | 71 | 63 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Investigations, PT: Alanine aminotransferase increased

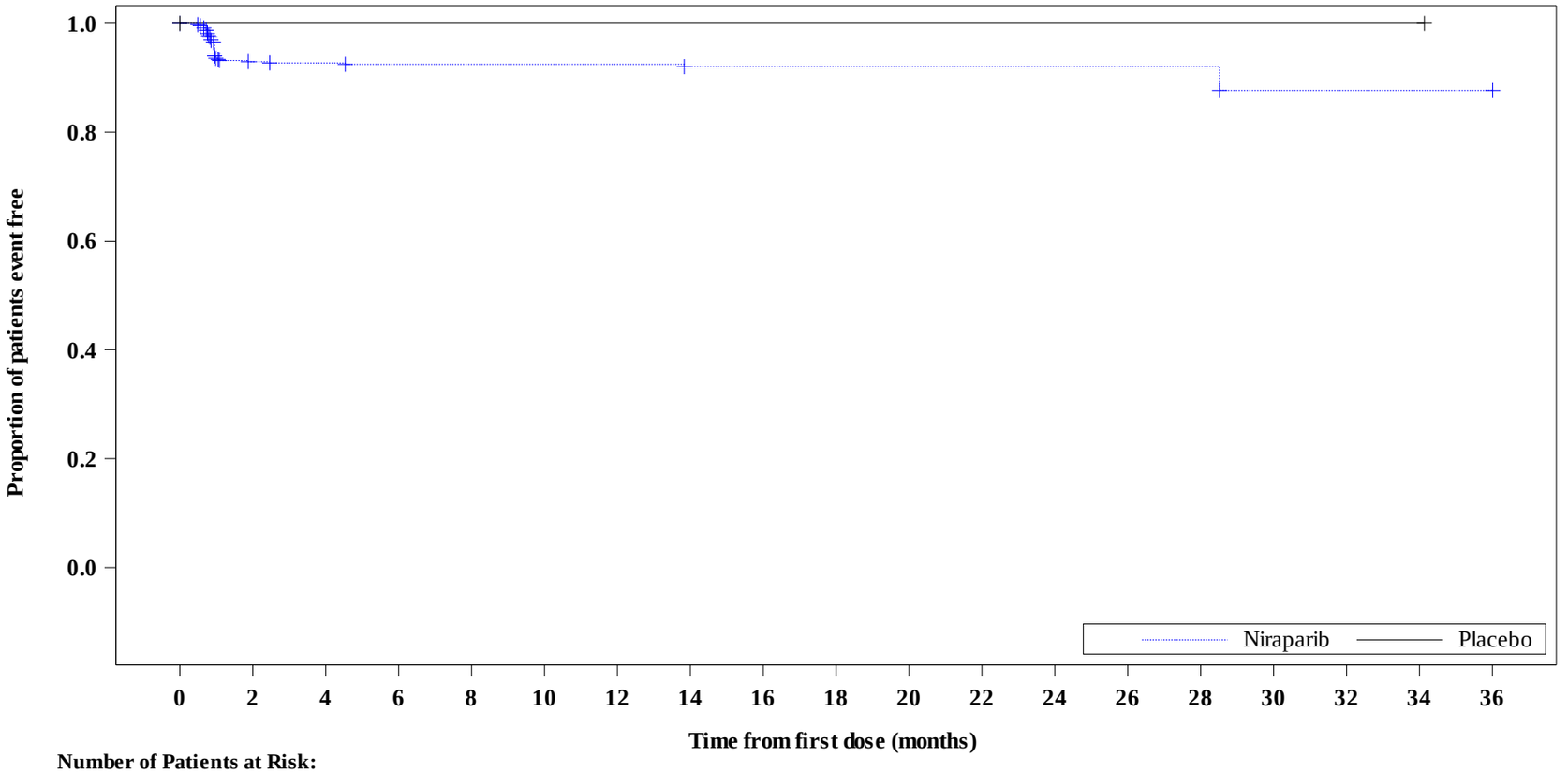



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 388 | 354 | 295 | 262 | 245 | 223 | 188 | 165 | 126 | 89 | 62 | 34 | 21 | 12 | 8 | 4 | 1 |
| Placebo | 244 | 240 | 204 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Investigations, PT: Neutrophil count decreased

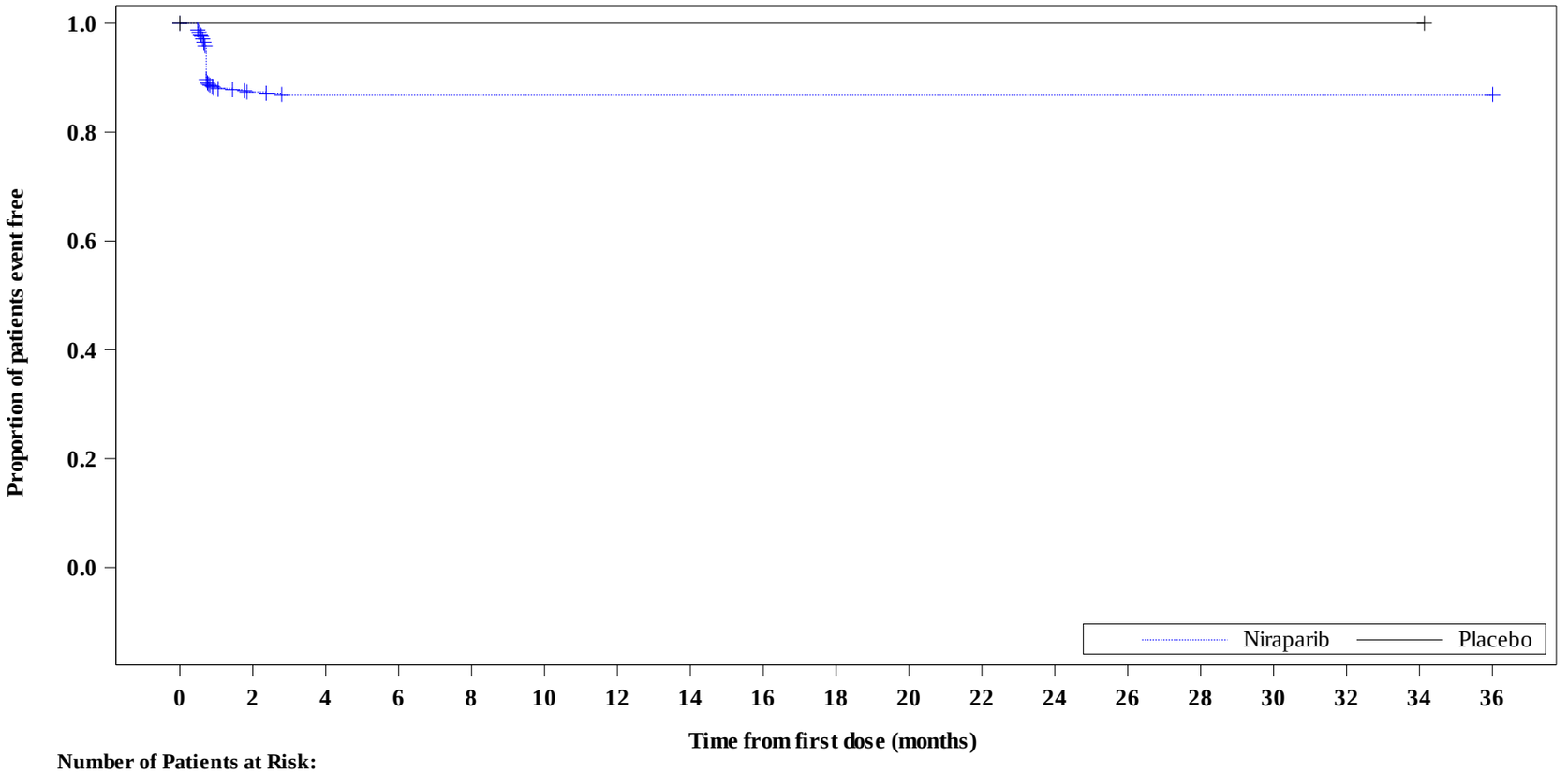



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 421 | 366 | 334 | 282 | 253 | 236 | 214 | 183 | 163 | 124 | 88 | 59 | 33 | 21 | 11 | 7 | 3 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Investigations, PT: Platelet count decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 391 | 344 | 313 | 266 | 237 | 221 | 202 | 173 | 153 | 116 | 82 | 56 | 32 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

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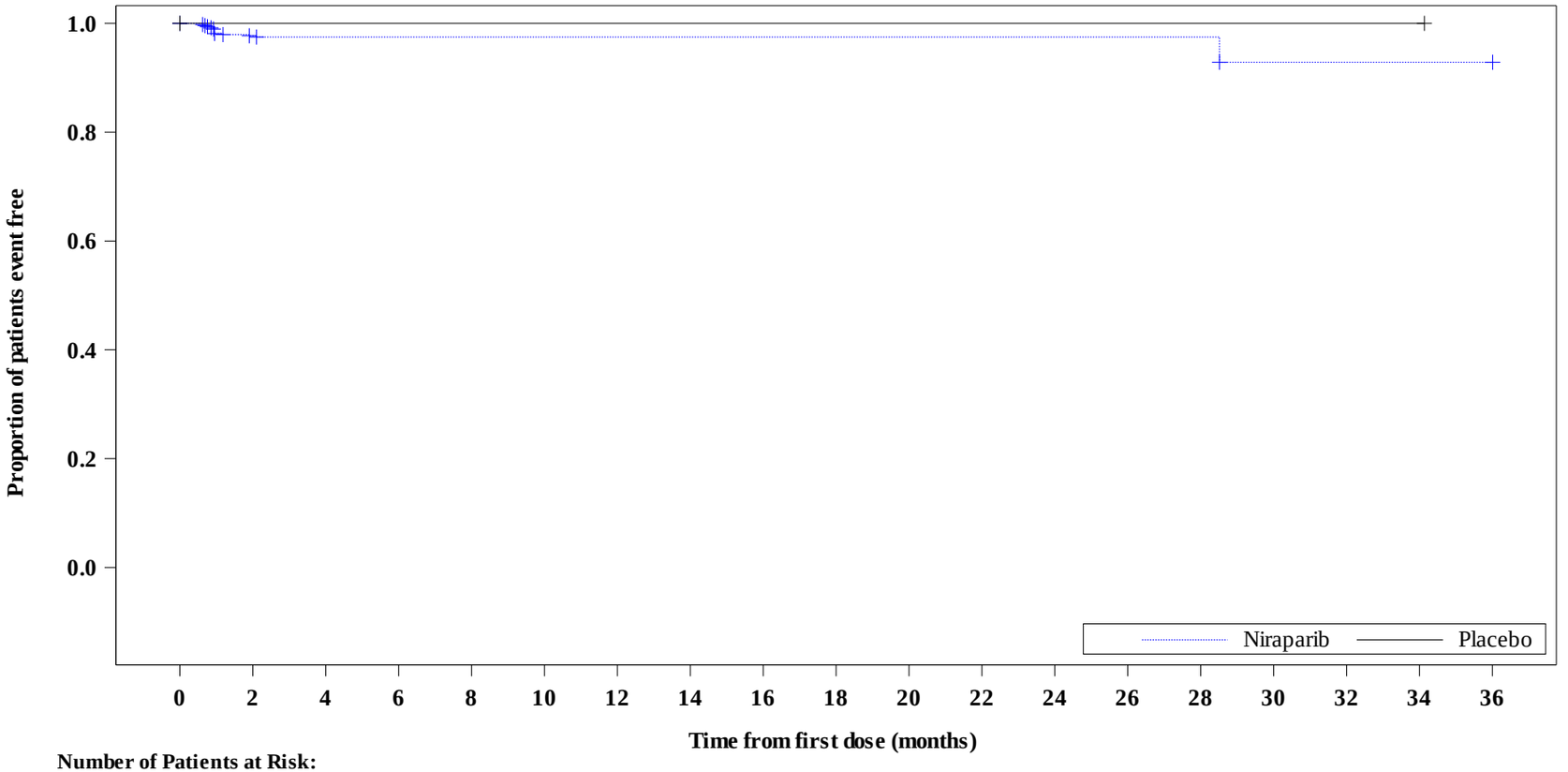
Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Investigations, PT: White blood cell count decreased

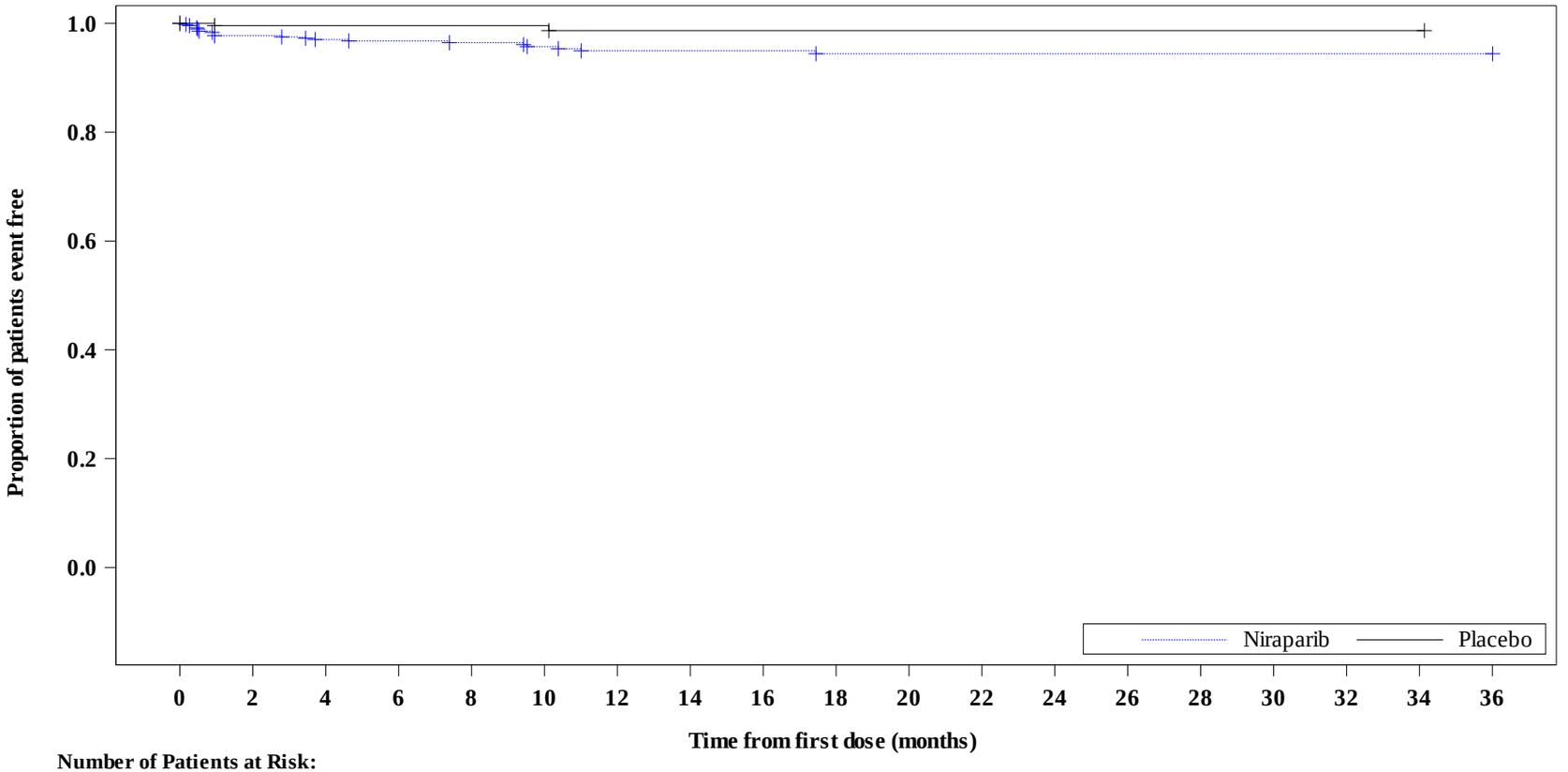



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 441 | 383 | 350 | 292 | 261 | 244 | 222 | 189 | 167 | 128 | 91 | 62 | 34 | 21 | 11 | 7 | 3 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Metabolism and nutrition disorders

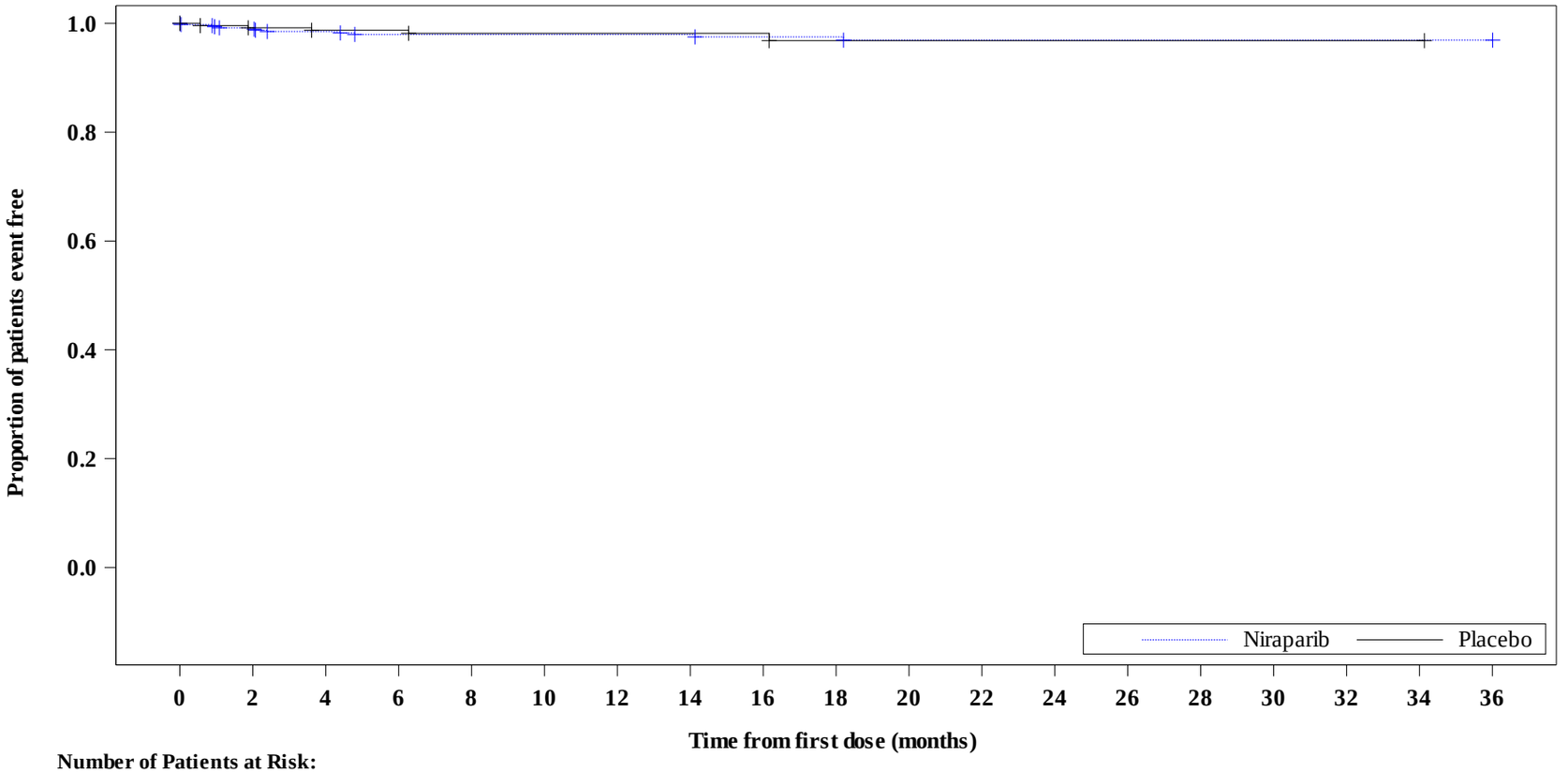



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 440 | 381 | 346 | 290 | 257 | 238 | 217 | 186 | 163 | 125 | 88 | 59 | 33 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 182 | 145 | 108 | 96 | 84 | 72 | 63 | 52 | 31 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Nervous system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 385 | 349 | 292 | 259 | 242 | 219 | 185 | 162 | 123 | 88 | 61 | 34 | 21 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 239 | 202 | 180 | 143 | 106 | 95 | 84 | 73 | 63 | 52 | 31 | 16 | 12 | 7 | 3 | 2 | 1 | 0 |

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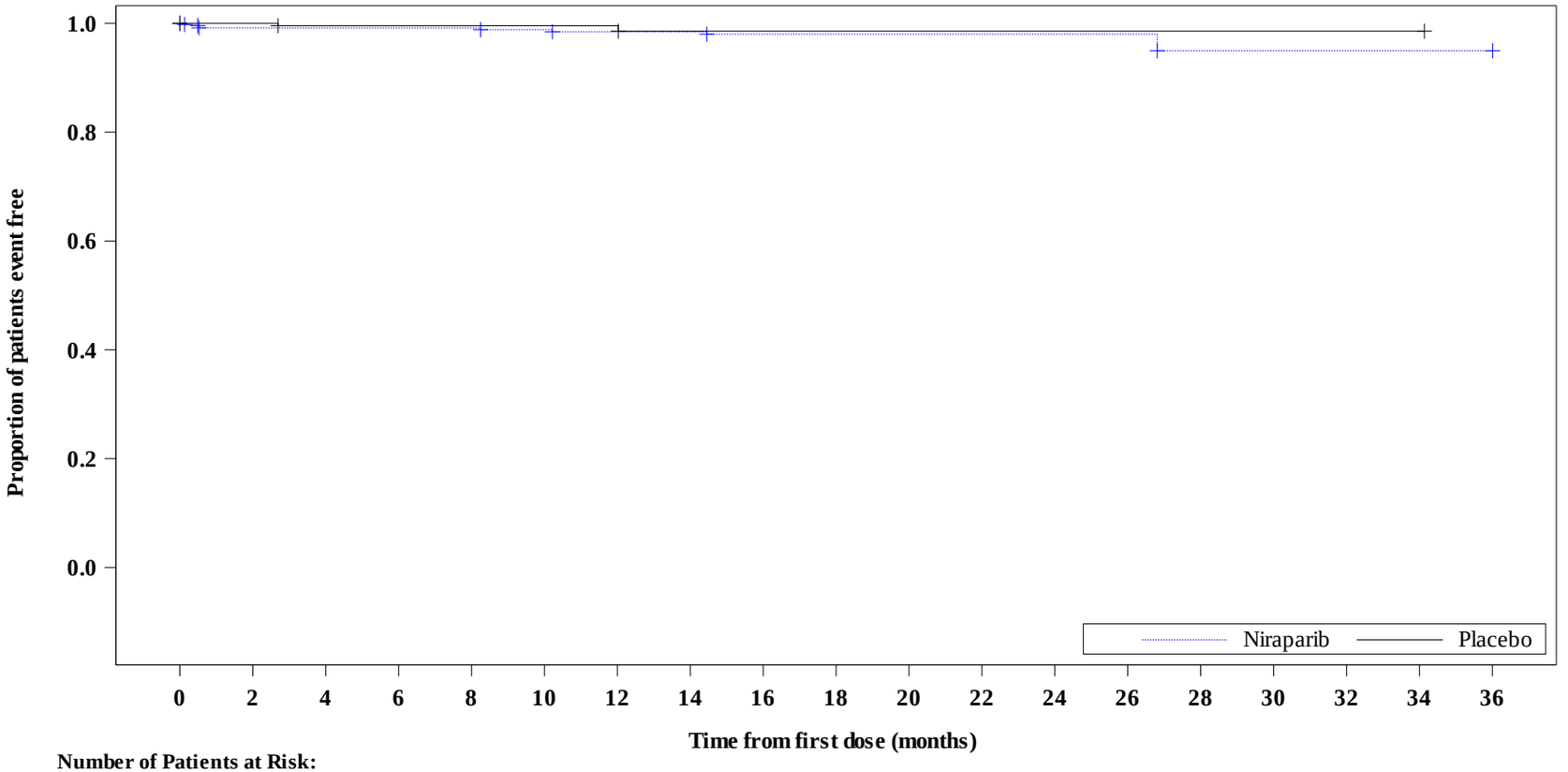
Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Psychiatric disorders

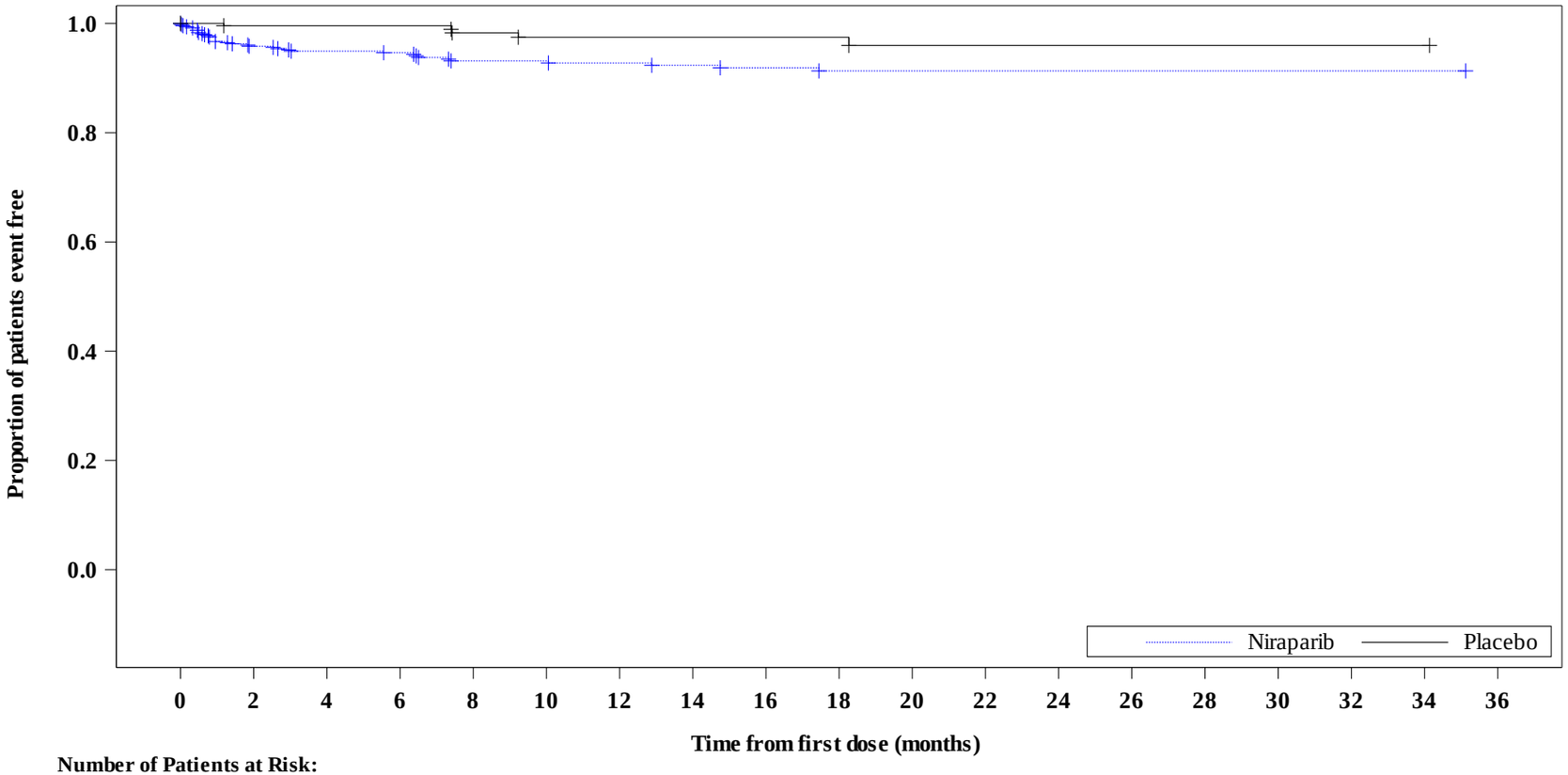



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 389 | 355 | 297 | 264 | 246 | 224 | 190 | 167 | 128 | 90 | 62 | 35 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 85 | 73 | 64 | 53 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Vascular disorders

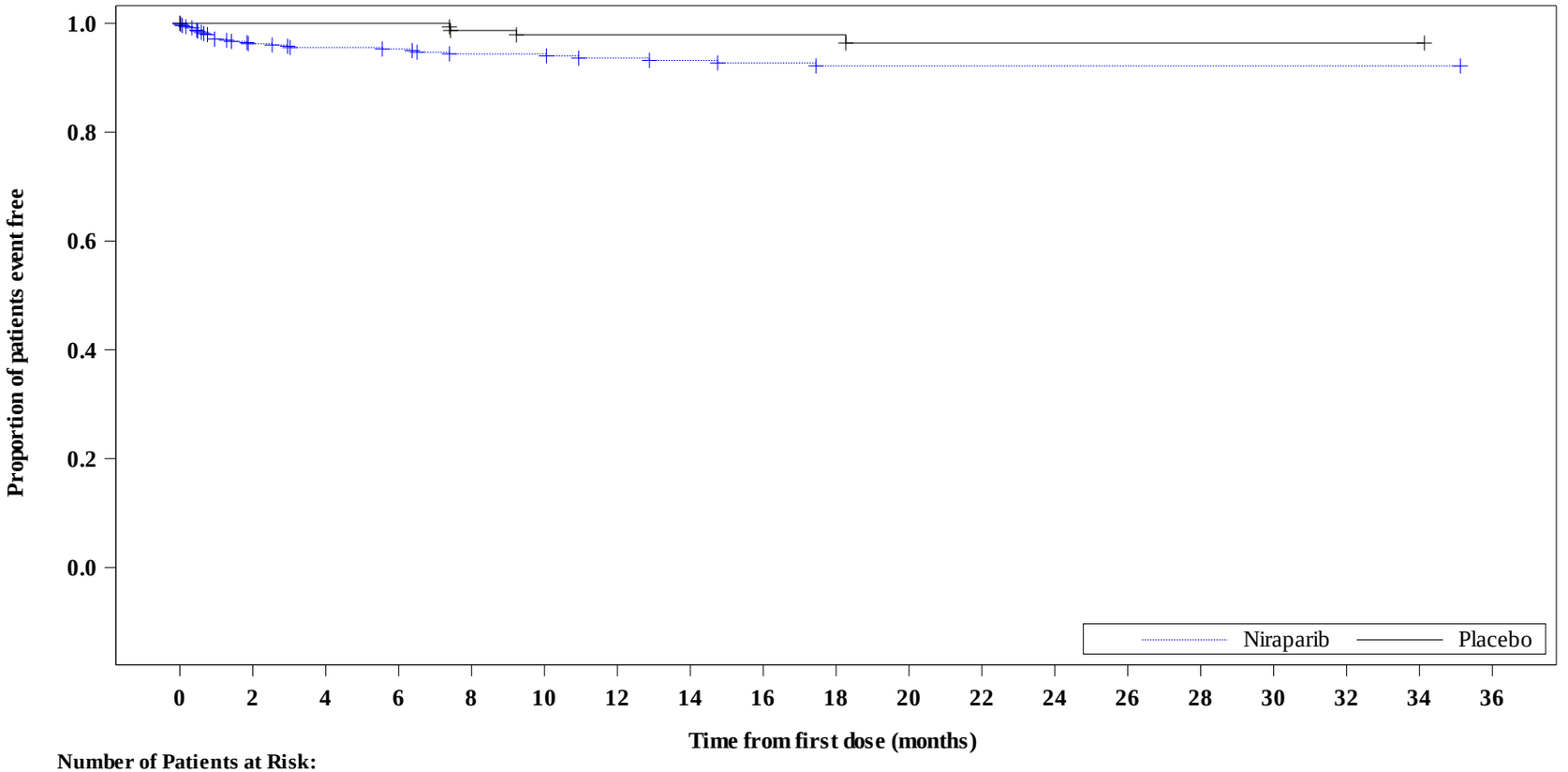



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 430 | 369 | 335 | 277 | 247 | 230 | 207 | 174 | 151 | 115 | 82 | 56 | 30 | 17 | 8 | 6 | 4 | 0 |
| Placebo | 244 | 240 | 204 | 182 | 144 | 106 | 96 | 86 | 74 | 65 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.45
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Vascular disorders, PT: Hypertension

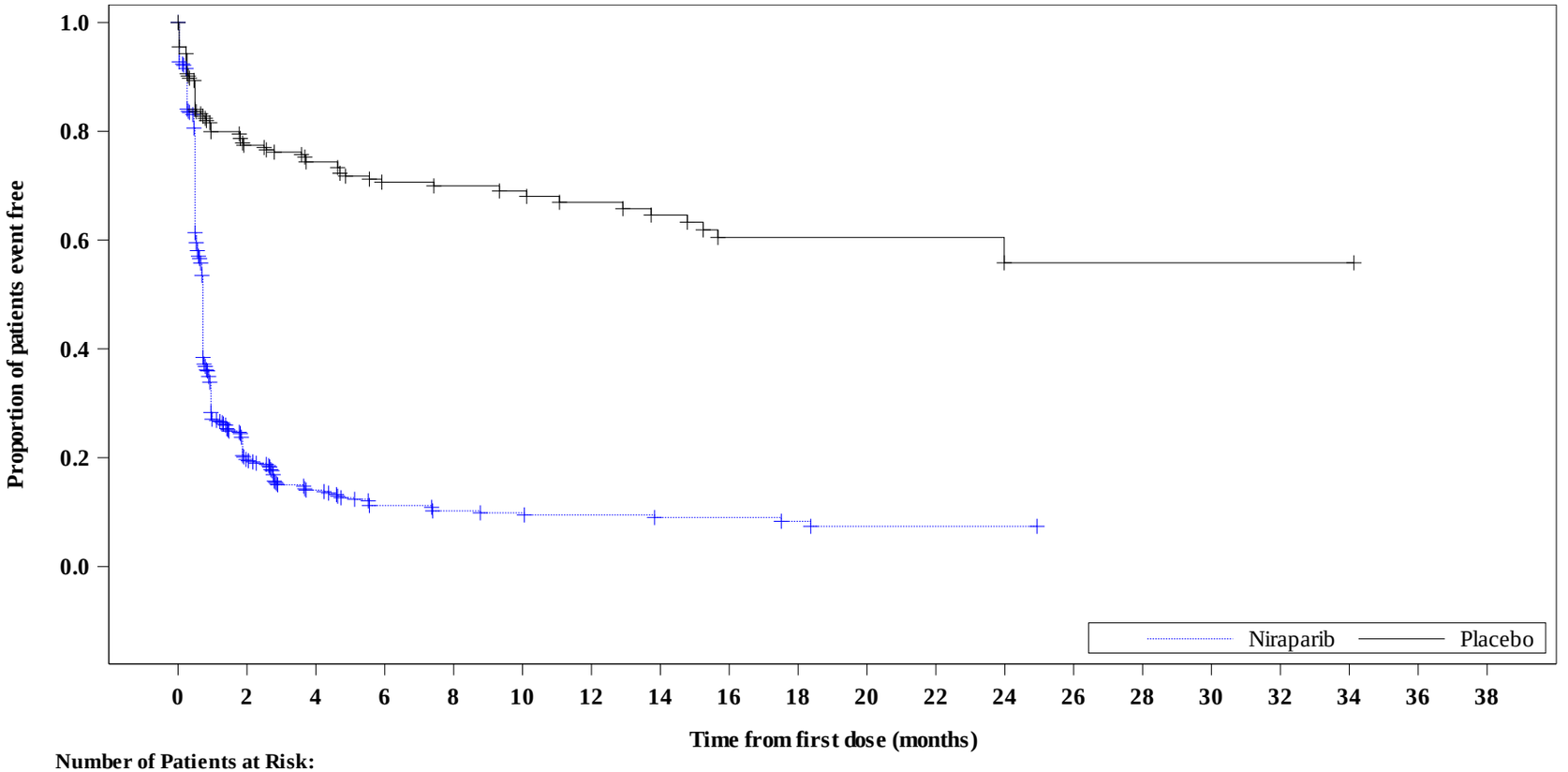



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 432 | 372 | 338 | 281 | 251 | 233 | 209 | 176 | 153 | 116 | 83 | 56 | 30 | 17 | 8 | 6 | 4 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 144 | 106 | 96 | 86 | 74 | 65 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Overall




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 85 | 52 | 39 | 30 | 26 | 20 | 19 | 15 | 9 | 7 | 3 | 2 | 0 | | | | | |
| Placebo | 244 | 186 | 151 | 126 | 99 | 69 | 61 | 51 | 43 | 38 | 31 | 22 | 12 | 7 | 2 | 2 | 1 | 1 | 0 |

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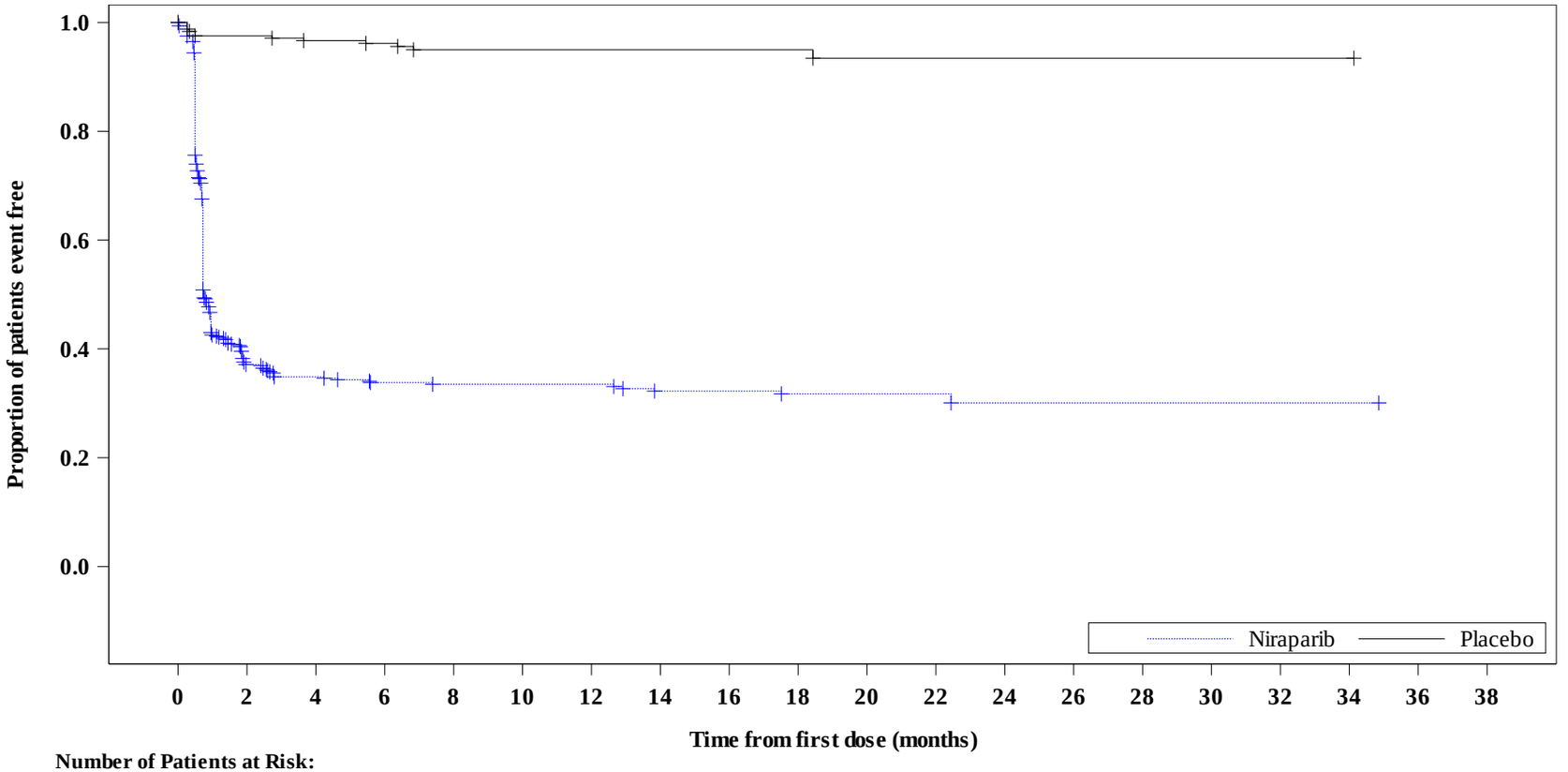
Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Thrombocytopenia

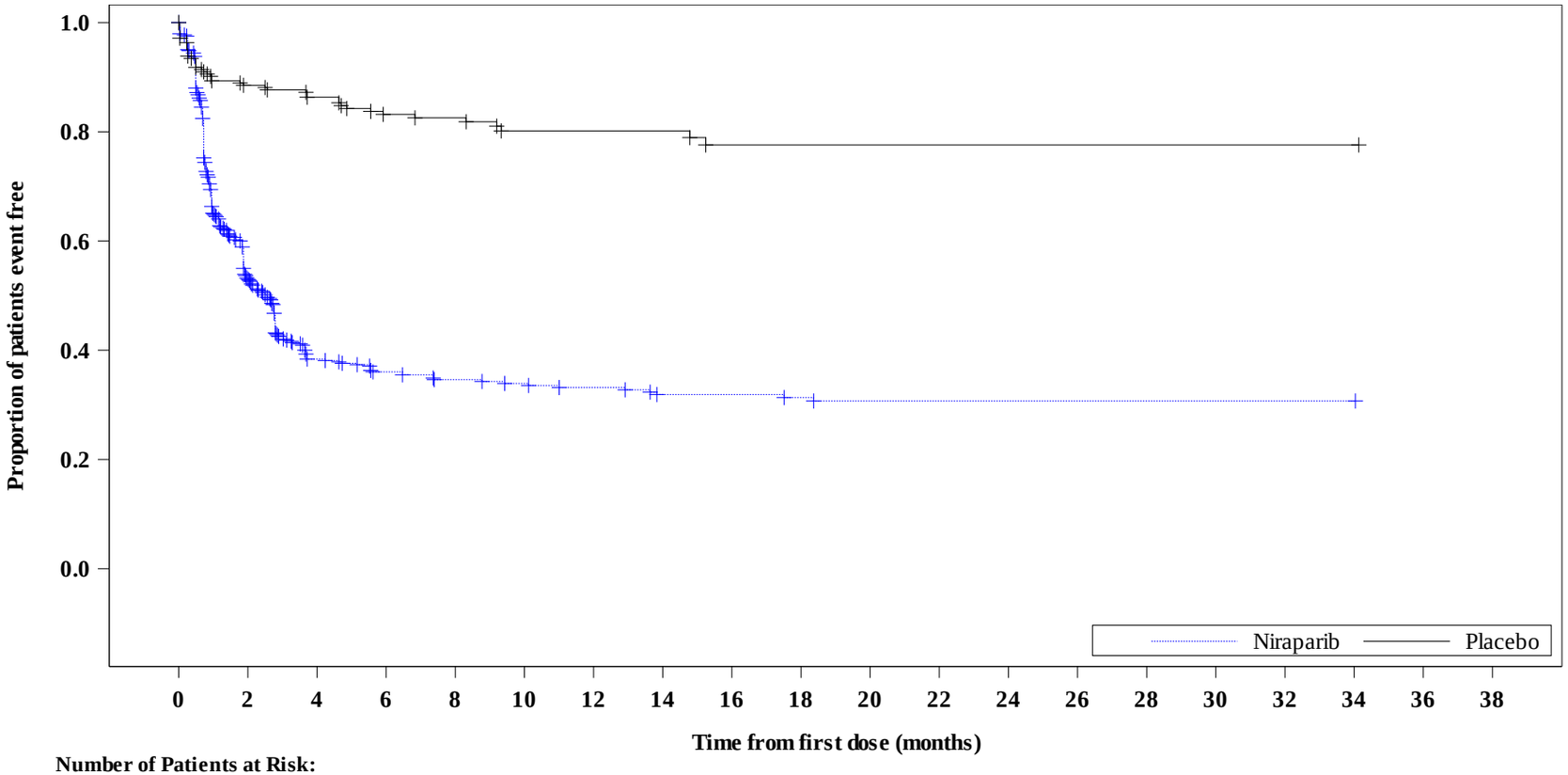



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 166 | 136 | 123 | 106 | 92 | 85 | 76 | 67 | 57 | 40 | 25 | 12 | 6 | 3 | 2 | 1 | 1 | 0 |
| Placebo | 244 | 235 | 199 | 177 | 140 | 103 | 92 | 81 | 70 | 62 | 52 | 31 | 16 | 11 | 6 | 2 | 1 | 1 | 0 |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Anemia

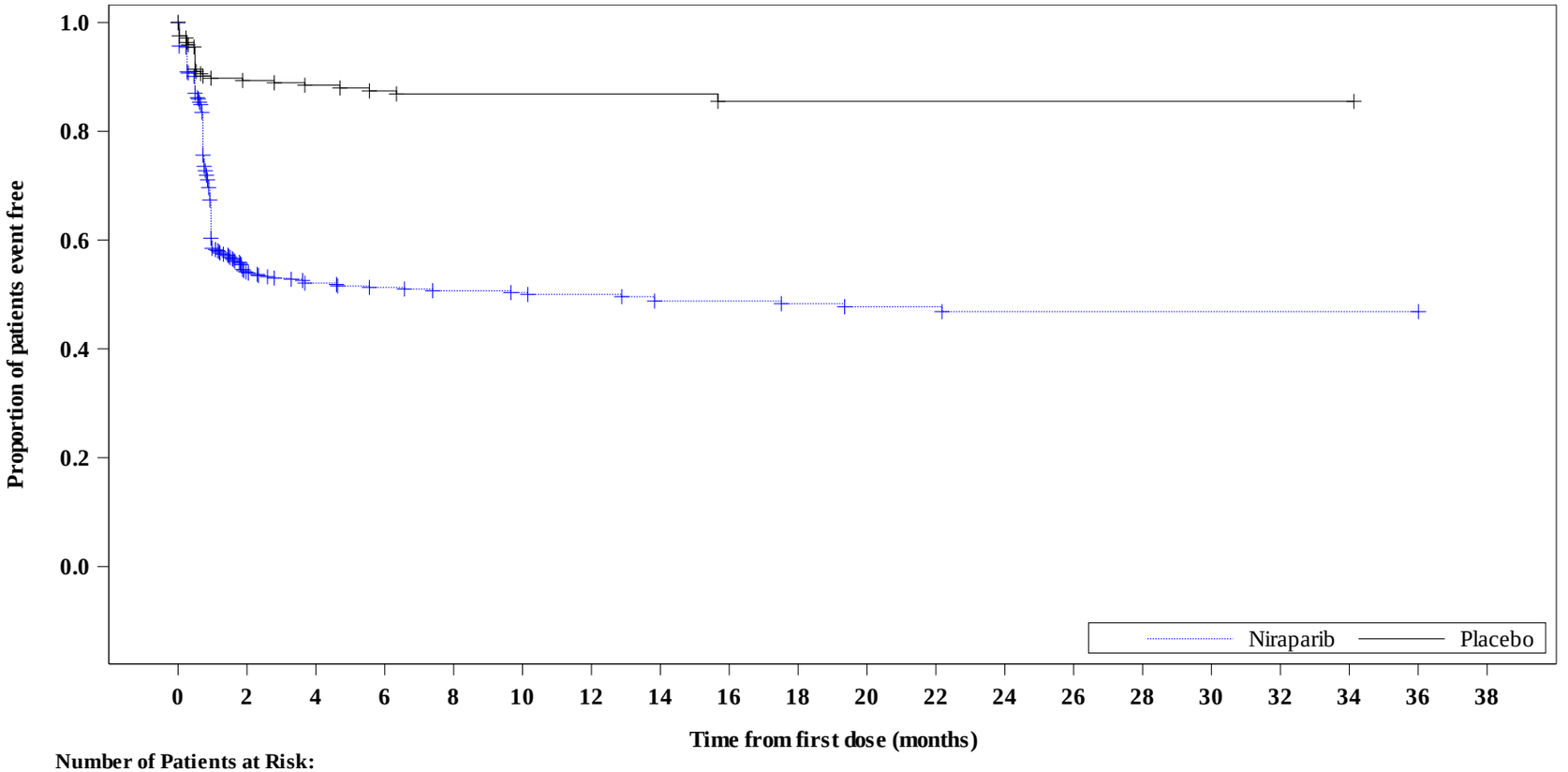



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 240 | 157 | 136 | 109 | 93 | 83 | 74 | 62 | 50 | 40 | 21 | 14 | 7 | 4 | 2 | 1 | 1 | 0 |
| Placebo | 244 | 213 | 177 | 151 | 122 | 86 | 79 | 69 | 58 | 52 | 44 | 29 | 16 | 10 | 5 | 3 | 2 | 1 | 0 |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Leukopenia

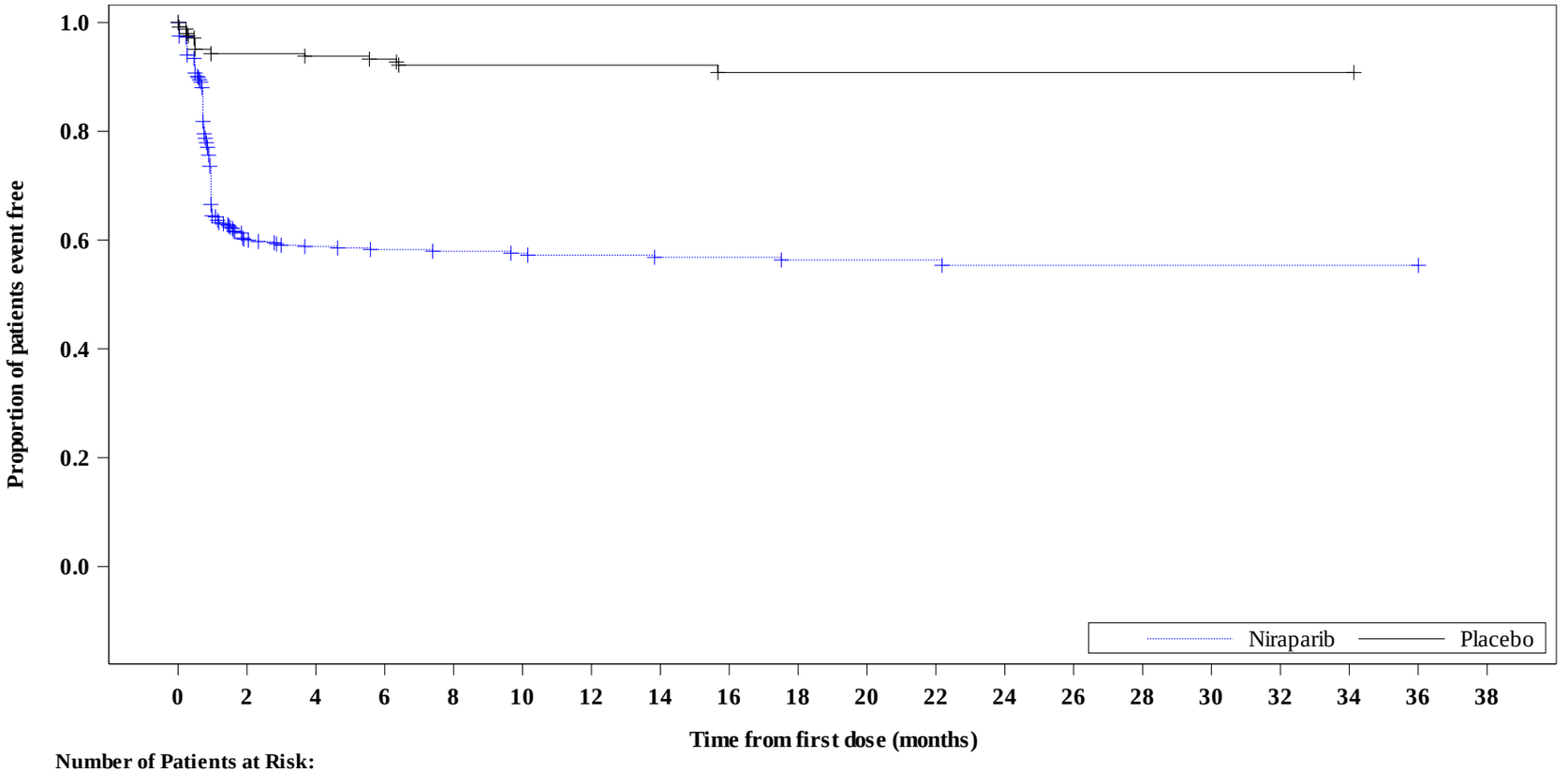



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 242 | 208 | 187 | 159 | 144 | 131 | 120 | 107 | 97 | 75 | 53 | 33 | 17 | 8 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 244 | 215 | 182 | 160 | 128 | 93 | 83 | 72 | 62 | 53 | 42 | 26 | 14 | 9 | 4 | 2 | 1 | 1 | 0 | |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Neutropenia

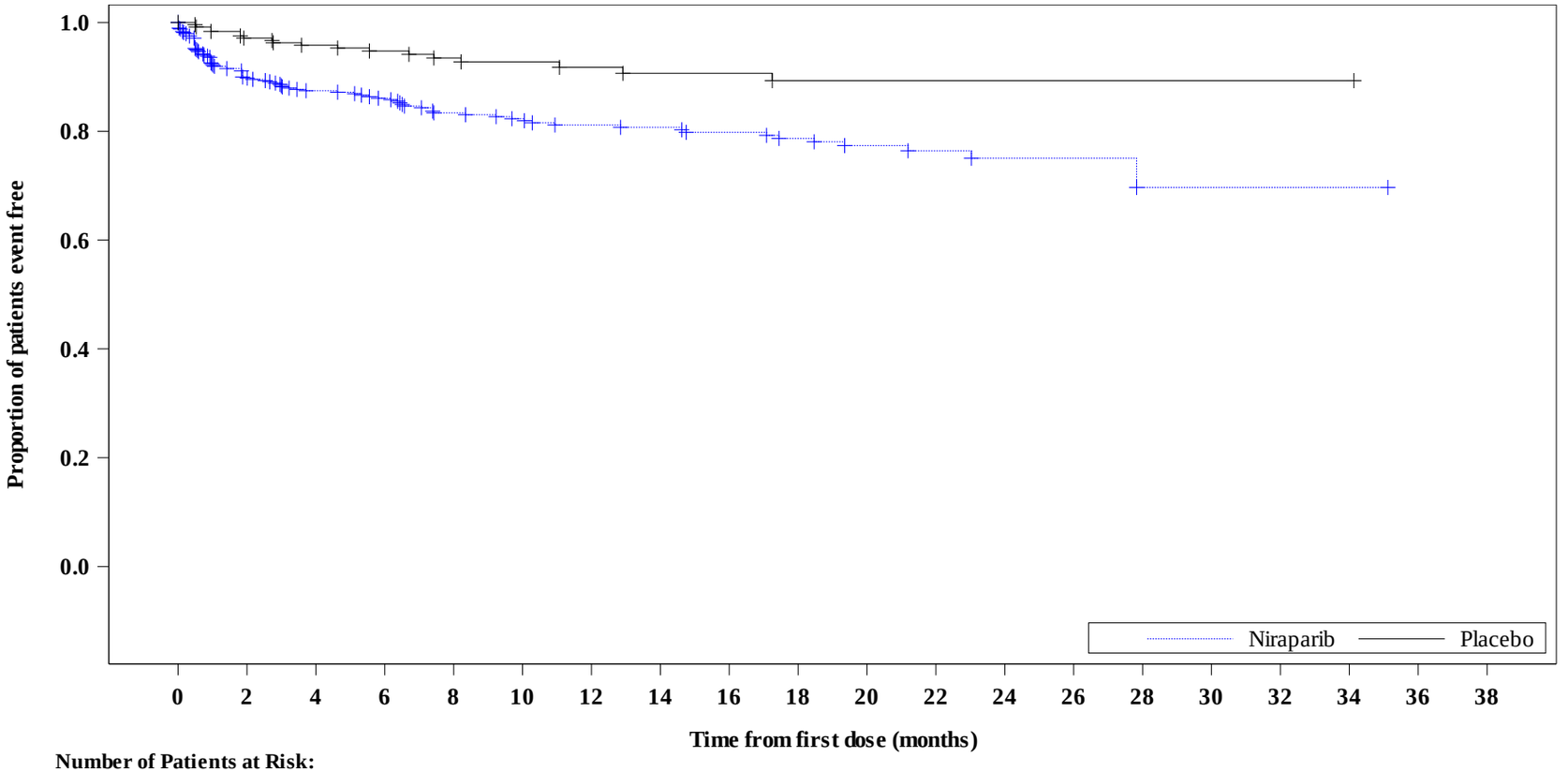



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 271 | 229 | 208 | 178 | 161 | 148 | 138 | 121 | 106 | 82 | 57 | 36 | 19 | 9 | 8 | 6 | 3 | 1 | 0 |
| Placebo | 244 | 227 | 191 | 170 | 135 | 99 | 88 | 77 | 67 | 58 | 47 | 27 | 14 | 9 | 4 | 2 | 1 | 1 | 0 | |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Hypertension

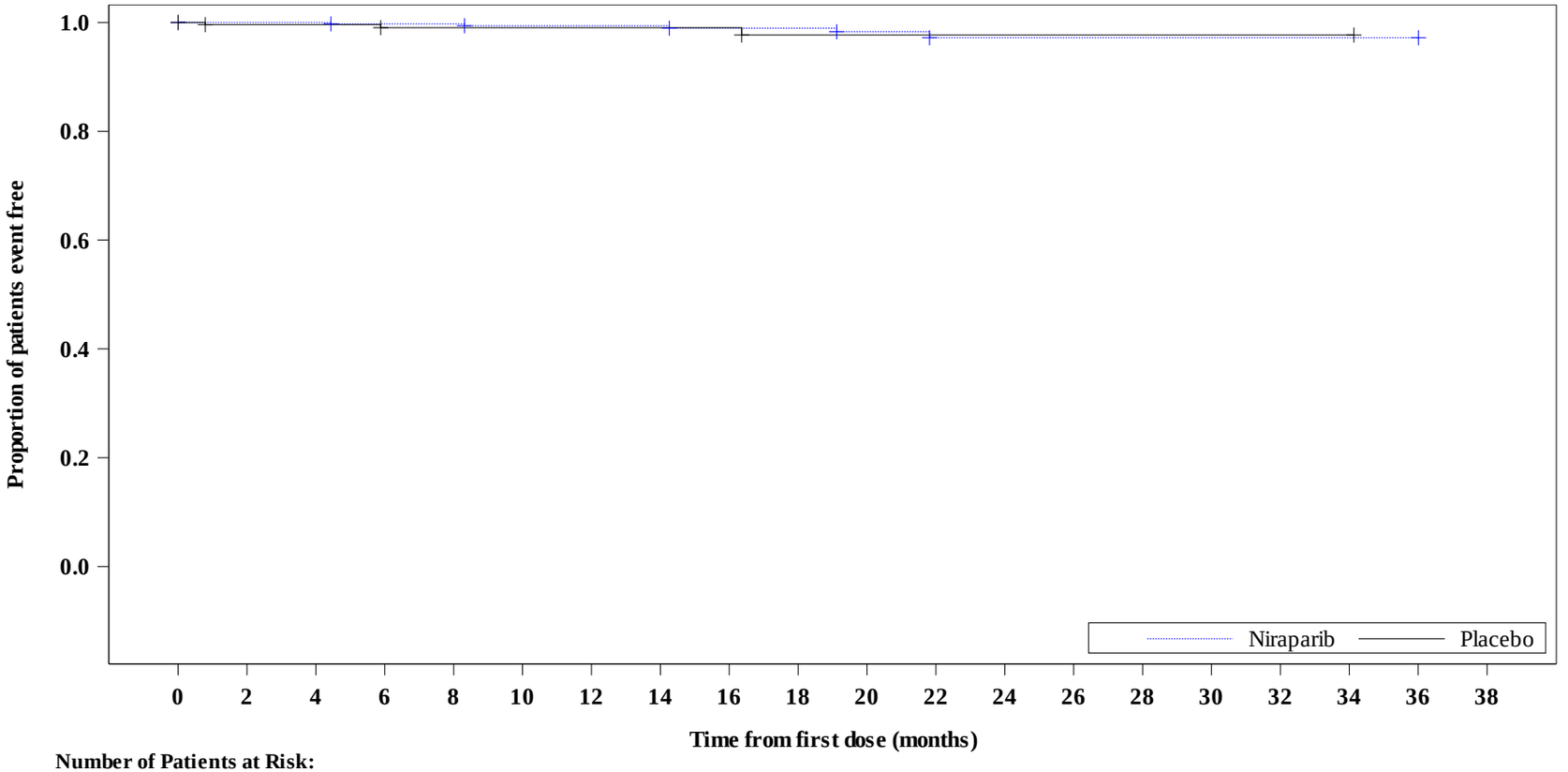



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 403 | 340 | 308 | 247 | 218 | 201 | 179 | 152 | 131 | 96 | 67 | 42 | 24 | 13 | 5 | 5 | 3 | 0 |
| Placebo | 244 | 234 | 195 | 171 | 135 | 99 | 89 | 78 | 68 | 58 | 49 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

New malignancies other than MDS/AML

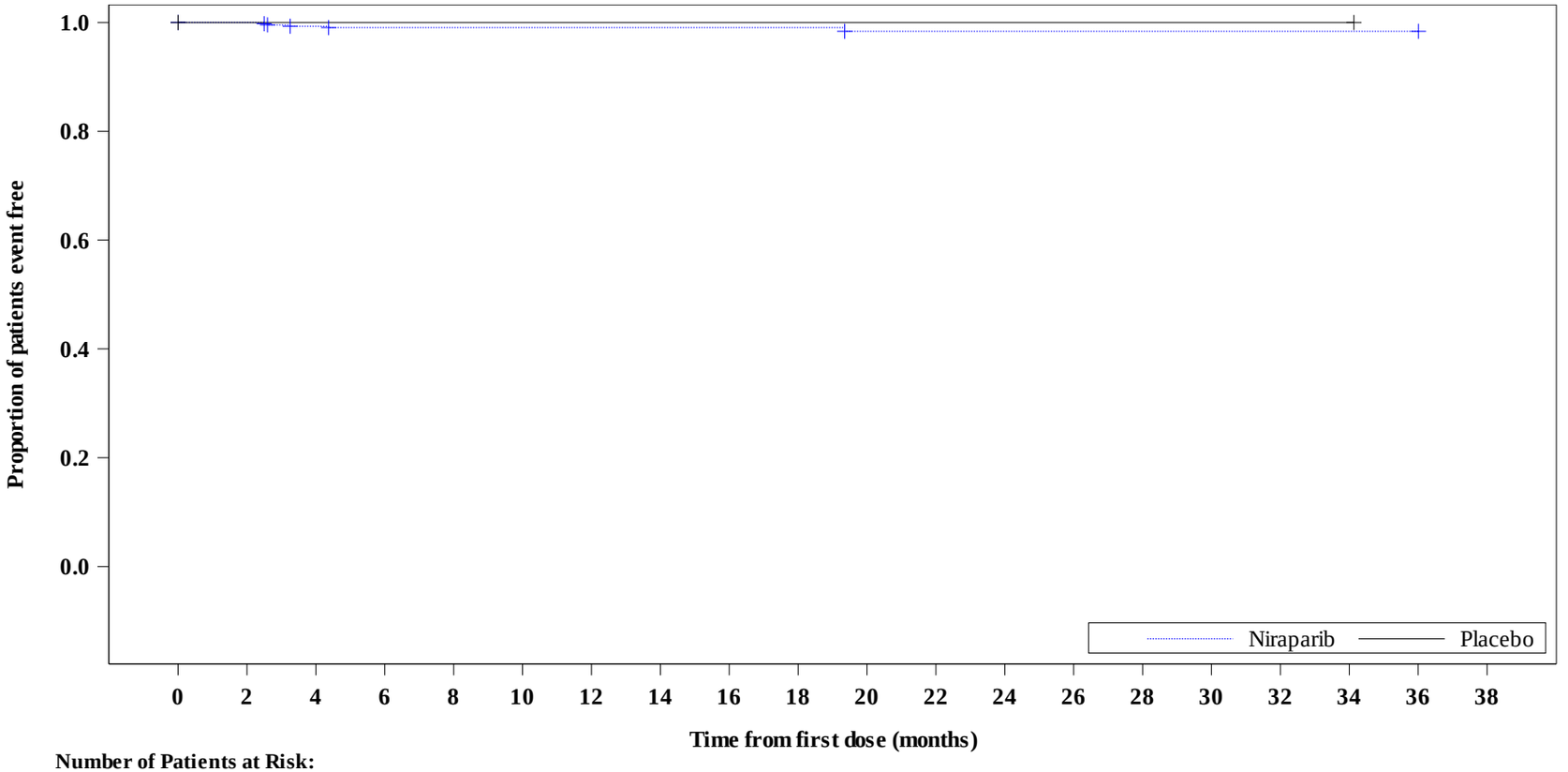



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 356 | 298 | 265 | 248 | 225 | 191 | 168 | 128 | 89 | 61 | 34 | 21 | 12 | 8 | 5 | 1 | 0 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 108 | 97 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Pneumonitis

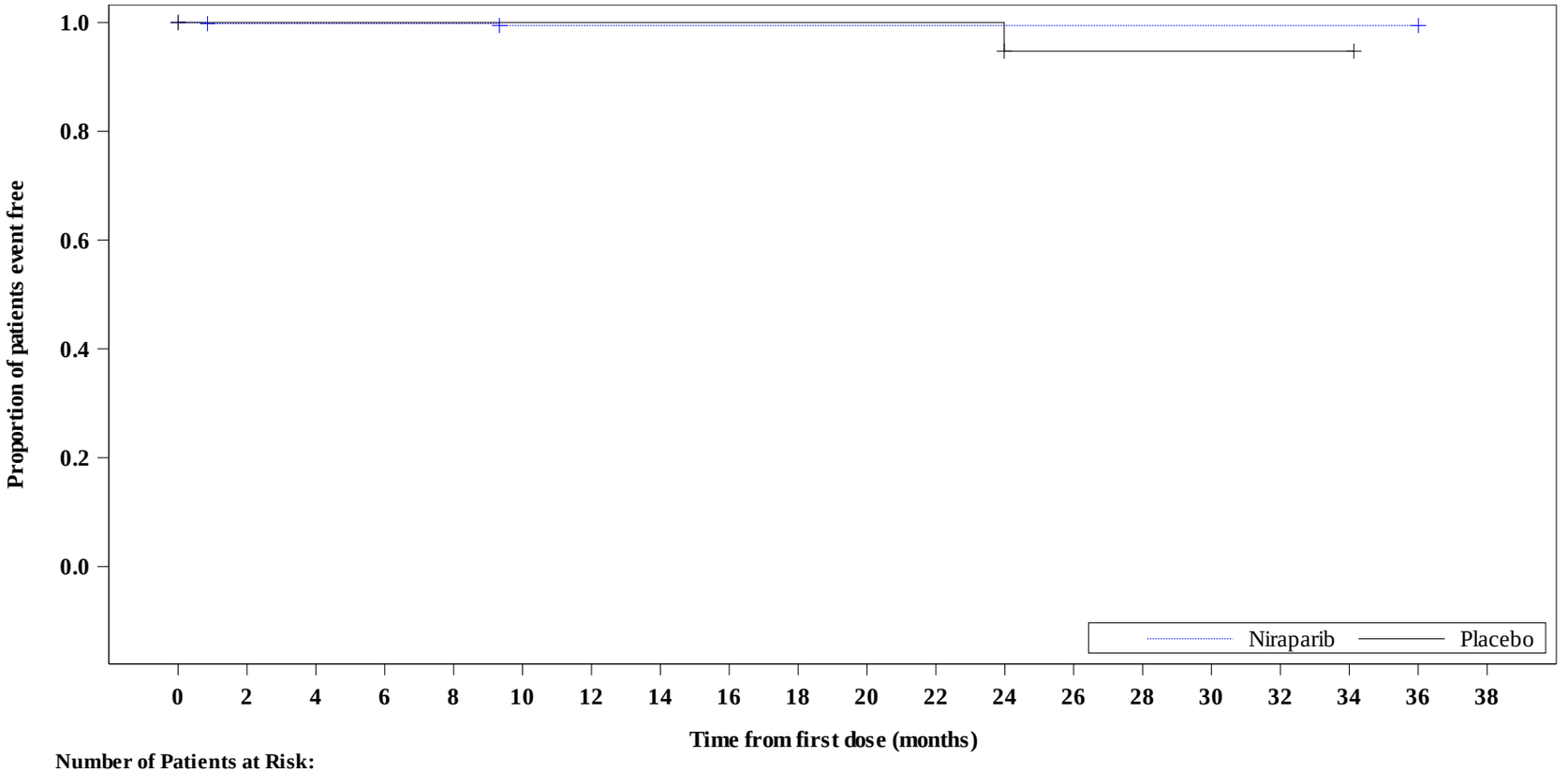



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 389 | 354 | 297 | 264 | 247 | 224 | 191 | 168 | 128 | 90 | 62 | 34 | 21 | 12 | 8 | 4 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Pancytopenia



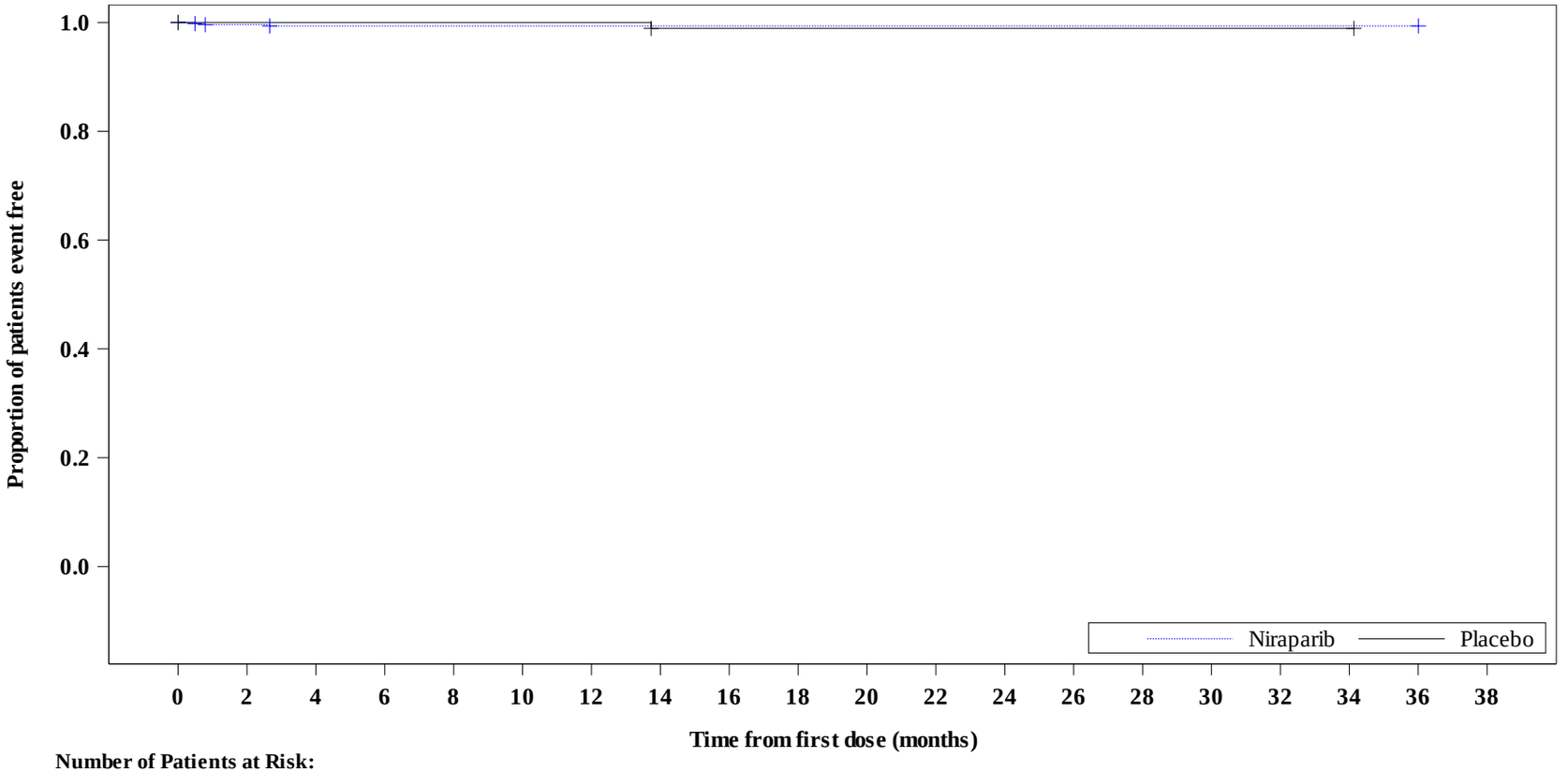

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 390 | 356 | 298 | 265 | 248 | 225 | 191 | 168 | 129 | 91 | 62 | 34 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 184 | 147 | 110 | 99 | 87 | 75 | 66 | 55 | 34 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.55

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Thromboemblic

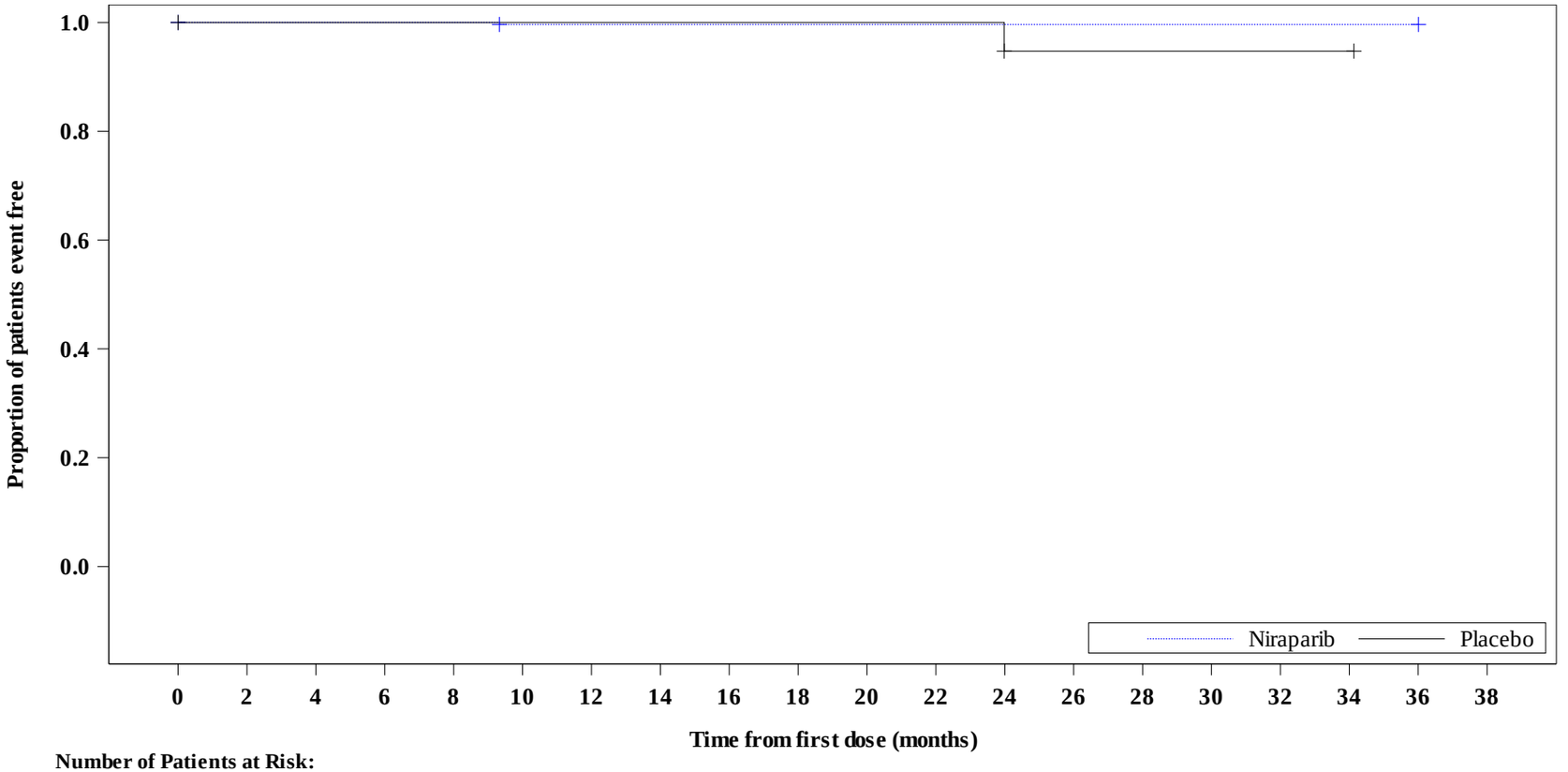



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 388 | 354 | 297 | 264 | 247 | 225 | 191 | 168 | 129 | 91 | 62 | 34 | 21 | 12 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 85 | 73 | 64 | 53 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.55
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

MDS/AML



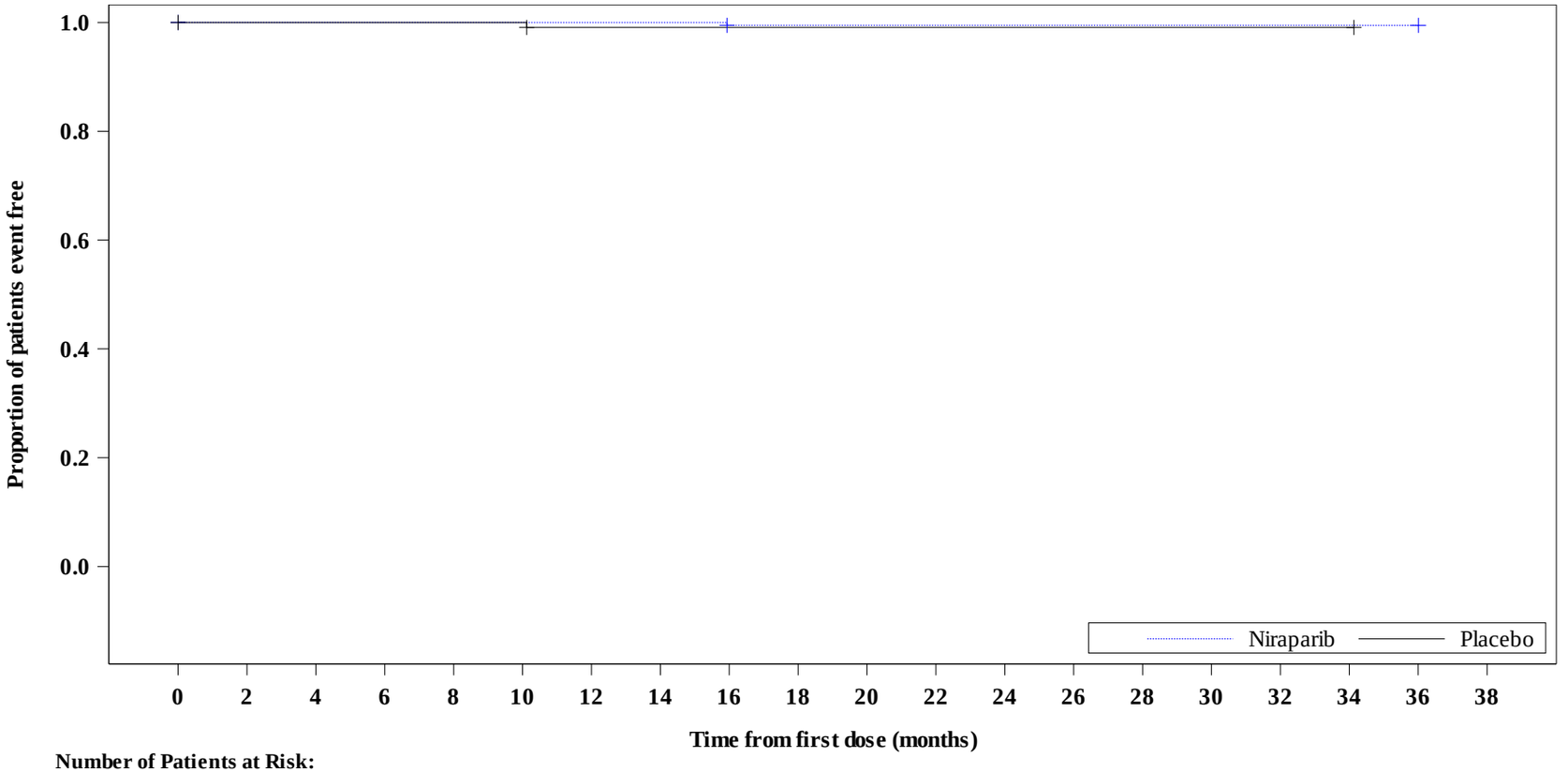

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 184 | 147 | 110 | 99 | 87 | 75 | 66 | 55 | 34 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.55

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Embryo-fetal toxicity



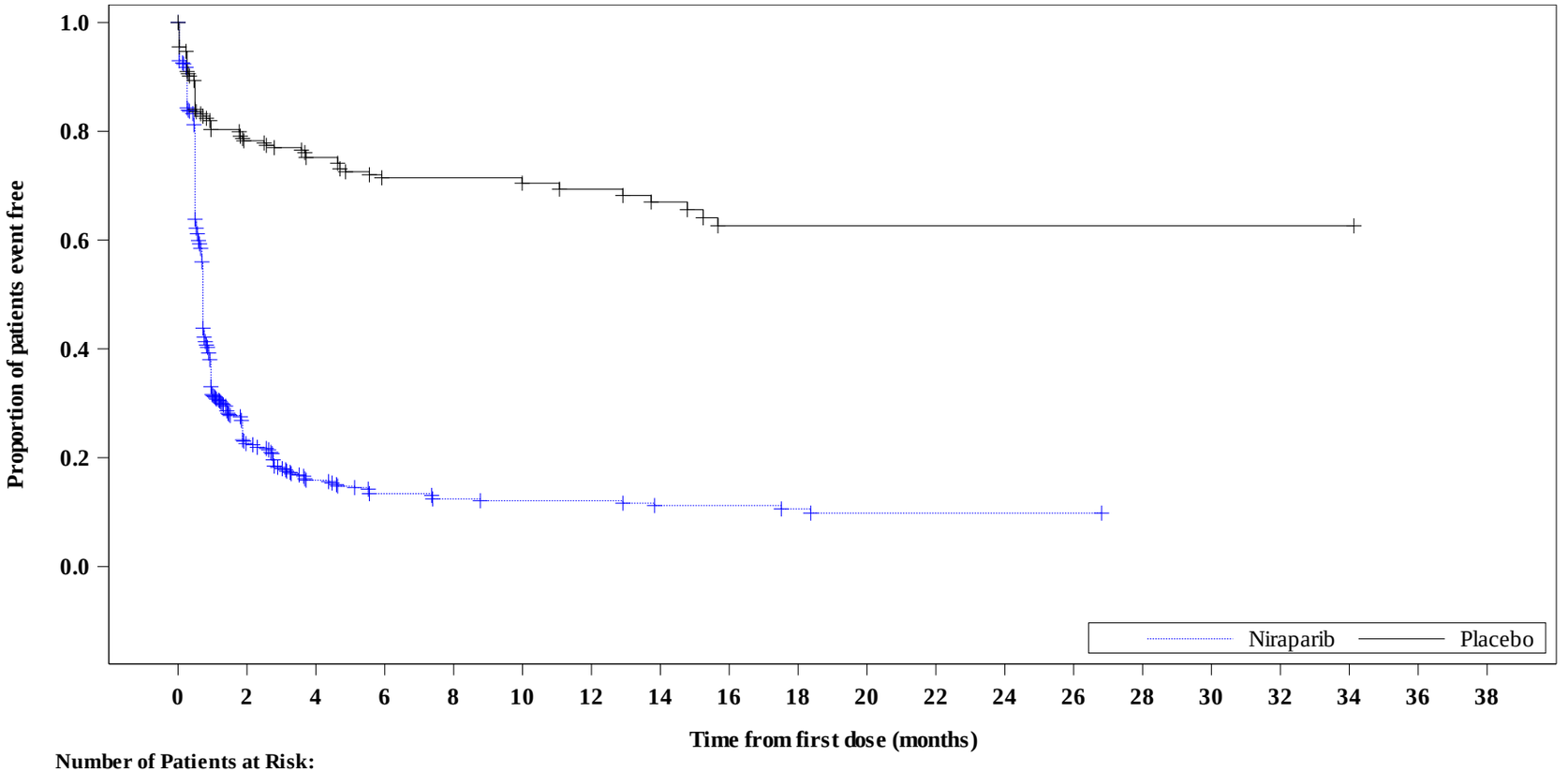

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 191 | 168 | 129 | 91 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 97 | 85 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.71

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Overall



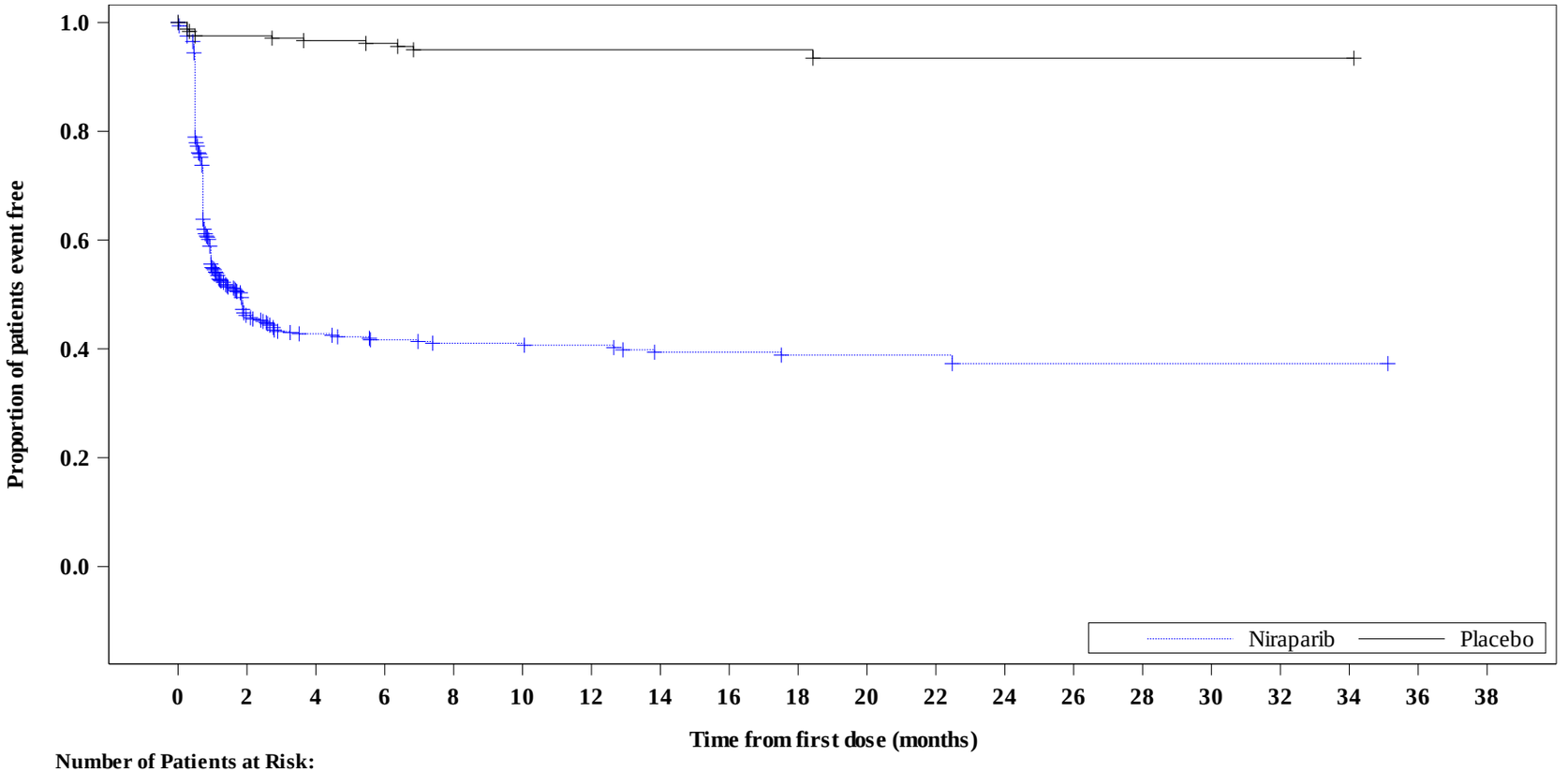

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 99 | 60 | 48 | 38 | 32 | 27 | 25 | 20 | 14 | 11 | 4 | 3 | 1 | 0 | | | | |
| Placebo | 244 | 188 | 152 | 126 | 100 | 70 | 63 | 51 | 42 | 37 | 30 | 21 | 12 | 7 | 2 | 2 | 1 | 1 | 0 |

jm734075: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-71-ttaesi.sas 04SEP2020 07:14

Figure 3.71
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Thrombocytopenia



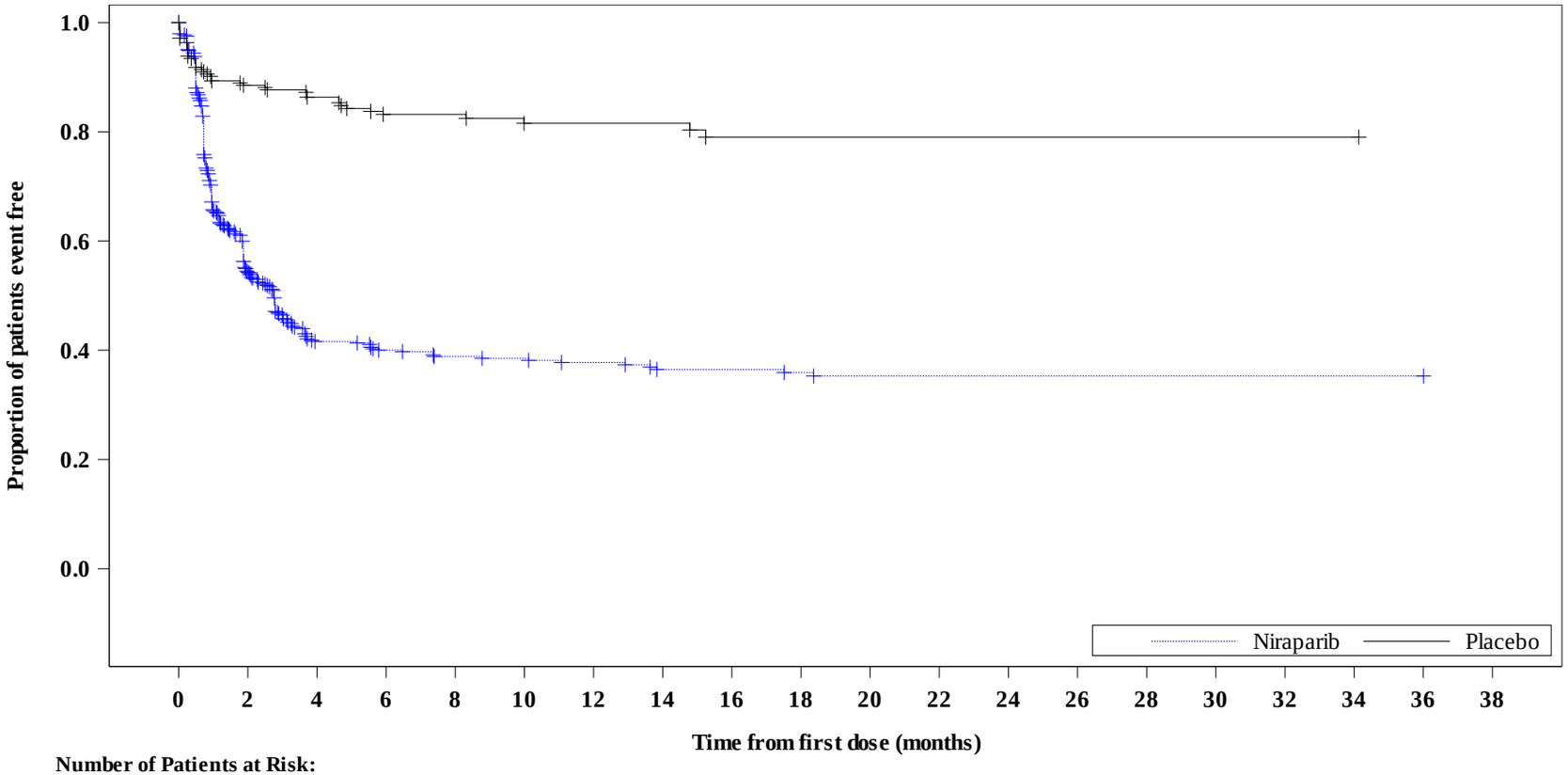

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 206 | 164 | 148 | 125 | 109 | 101 | 91 | 79 | 68 | 50 | 32 | 19 | 10 | 5 | 4 | 2 | 2 | 0 |
| Placebo | 244 | 235 | 199 | 177 | 140 | 103 | 92 | 81 | 70 | 62 | 52 | 31 | 16 | 11 | 6 | 2 | 1 | 1 | 0 |

Figure 3.71

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Anemia

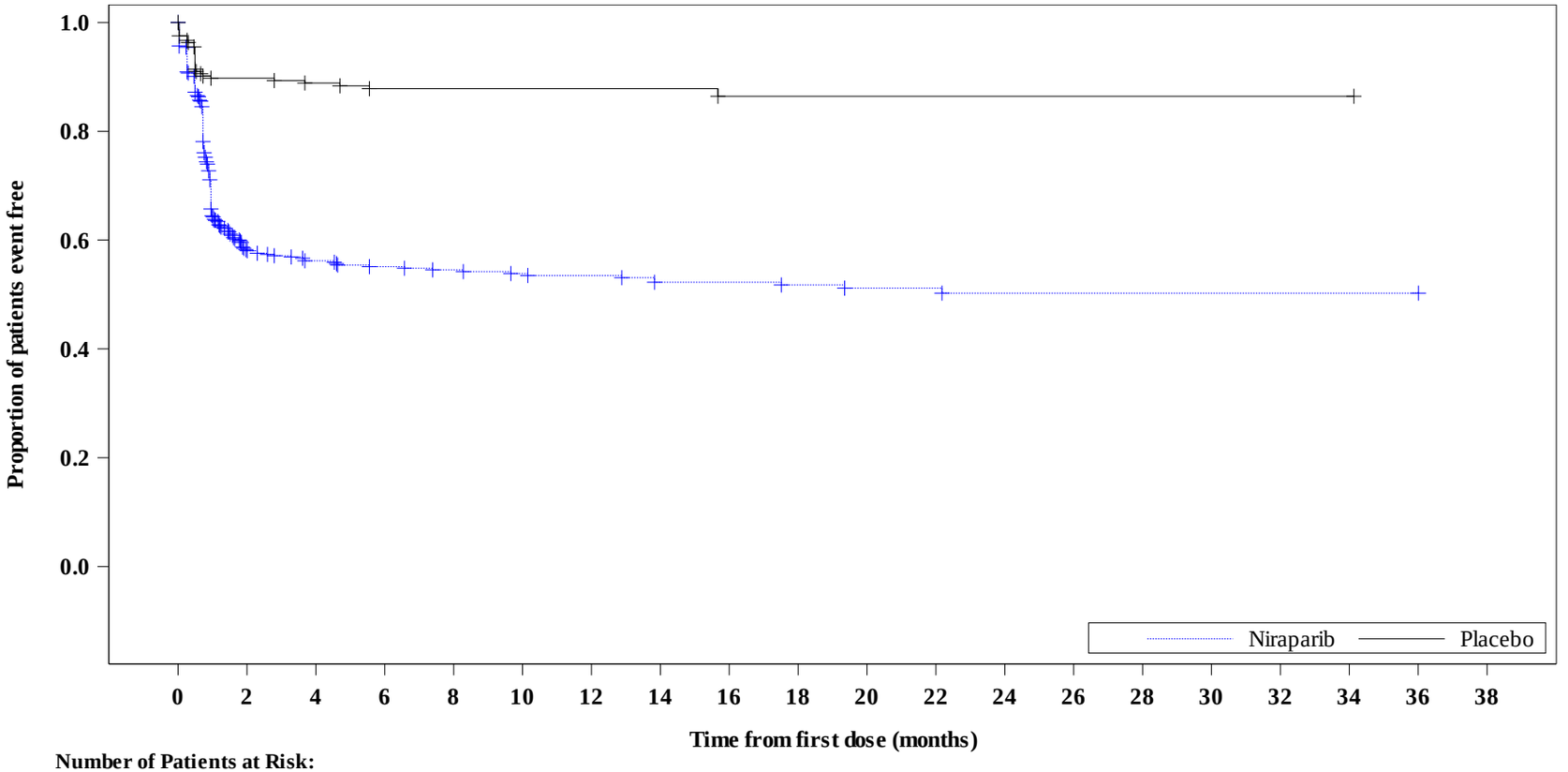



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 246 | 170 | 150 | 123 | 105 | 95 | 84 | 69 | 57 | 47 | 27 | 19 | 11 | 7 | 5 | 4 | 2 | 1 | 0 |
| Placebo | 244 | 213 | 177 | 151 | 123 | 88 | 81 | 71 | 60 | 54 | 45 | 30 | 16 | 10 | 5 | 3 | 2 | 1 | 0 | |

Figure 3.71
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Leukopenia

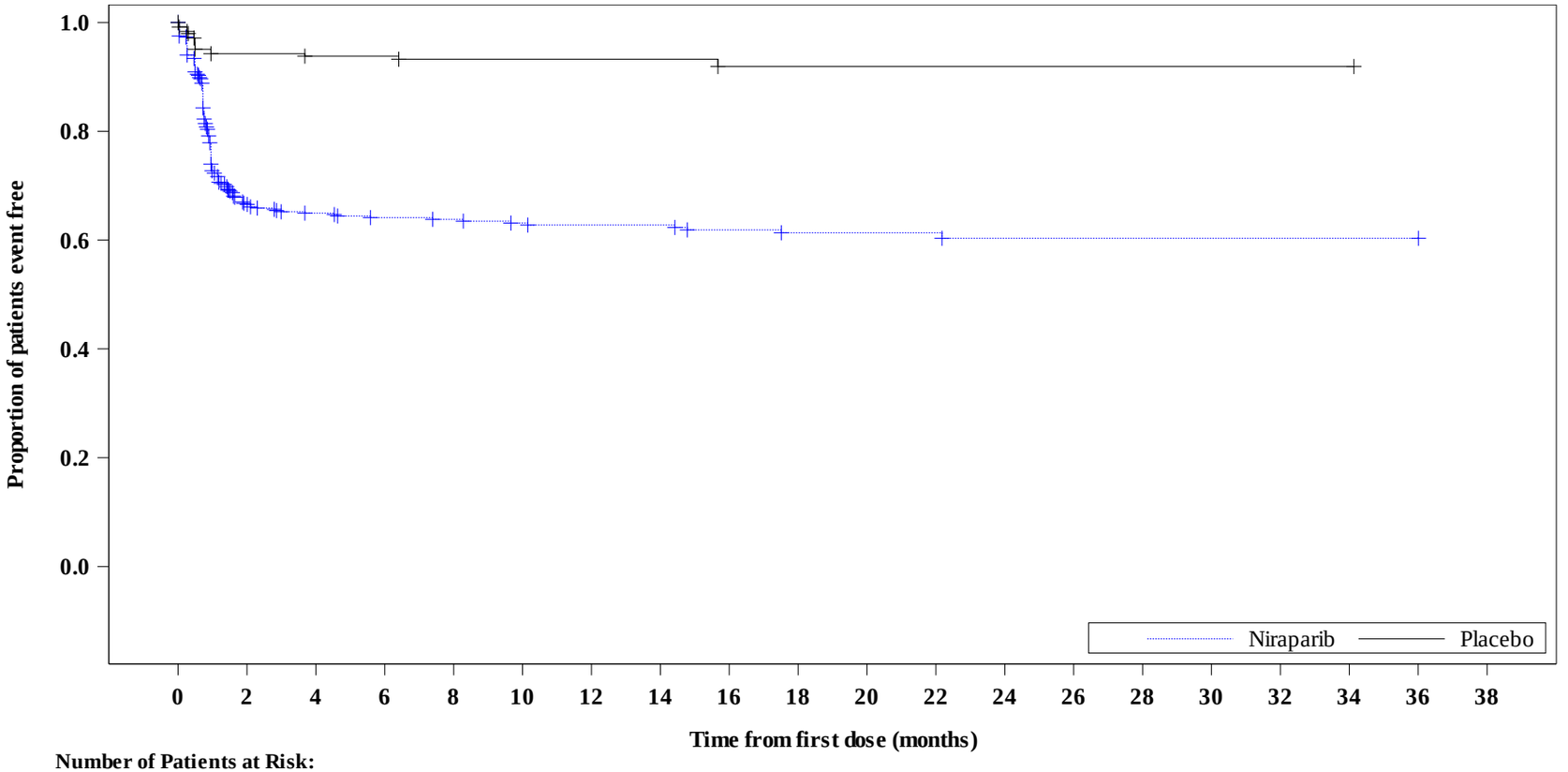



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 260 | 223 | 201 | 169 | 150 | 137 | 125 | 110 | 100 | 78 | 56 | 36 | 18 | 9 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 244 | 216 | 182 | 160 | 128 | 93 | 83 | 72 | 62 | 53 | 42 | 26 | 14 | 9 | 4 | 2 | 1 | 1 | 0 | |

Figure 3.71
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Neutropenia



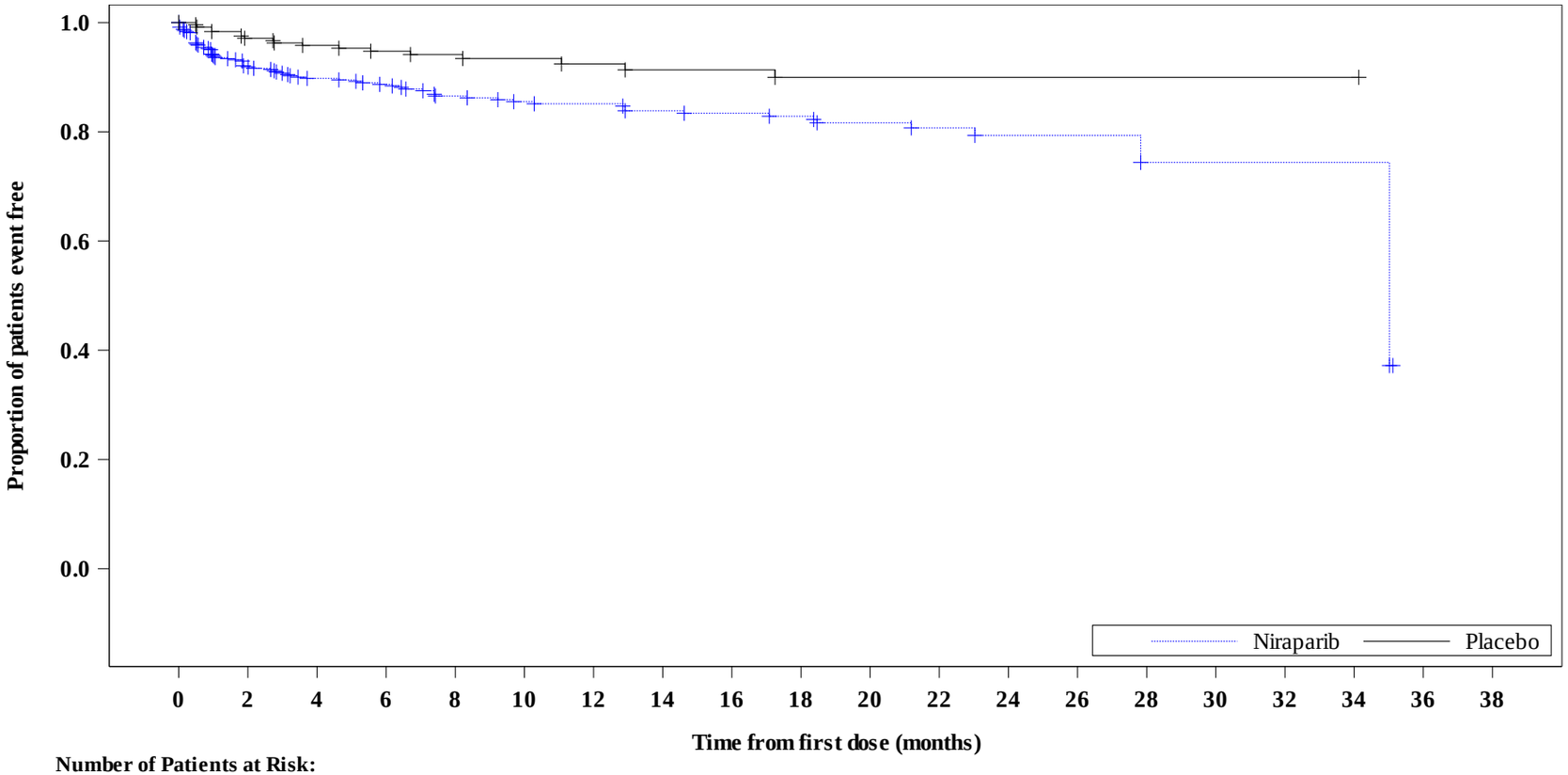

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 299 | 252 | 228 | 191 | 170 | 156 | 146 | 124 | 109 | 85 | 60 | 39 | 20 | 10 | 8 | 6 | 3 | 1 | 0 |
| Placebo | 244 | 227 | 191 | 171 | 136 | 100 | 89 | 78 | 68 | 59 | 48 | 28 | 15 | 10 | 5 | 2 | 1 | 1 | 0 | |

Figure 3.71

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Hypertension



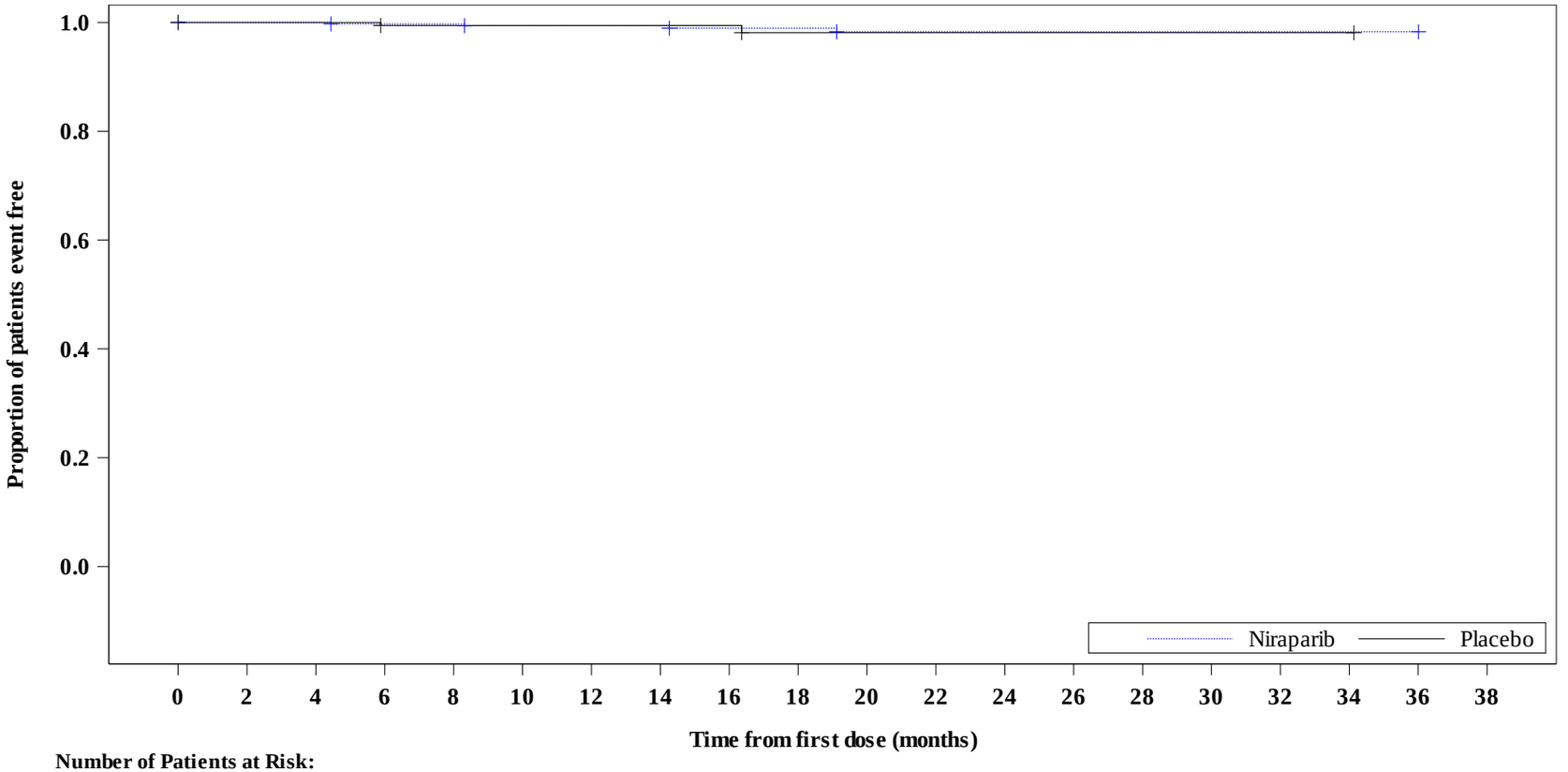

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 413 | 350 | 319 | 258 | 229 | 213 | 189 | 161 | 141 | 105 | 72 | 46 | 27 | 15 | 7 | 7 | 4 | 0 |
| Placebo | 244 | 234 | 195 | 171 | 136 | 100 | 90 | 78 | 68 | 58 | 49 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.71

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

New malignancies other than MDS/AML

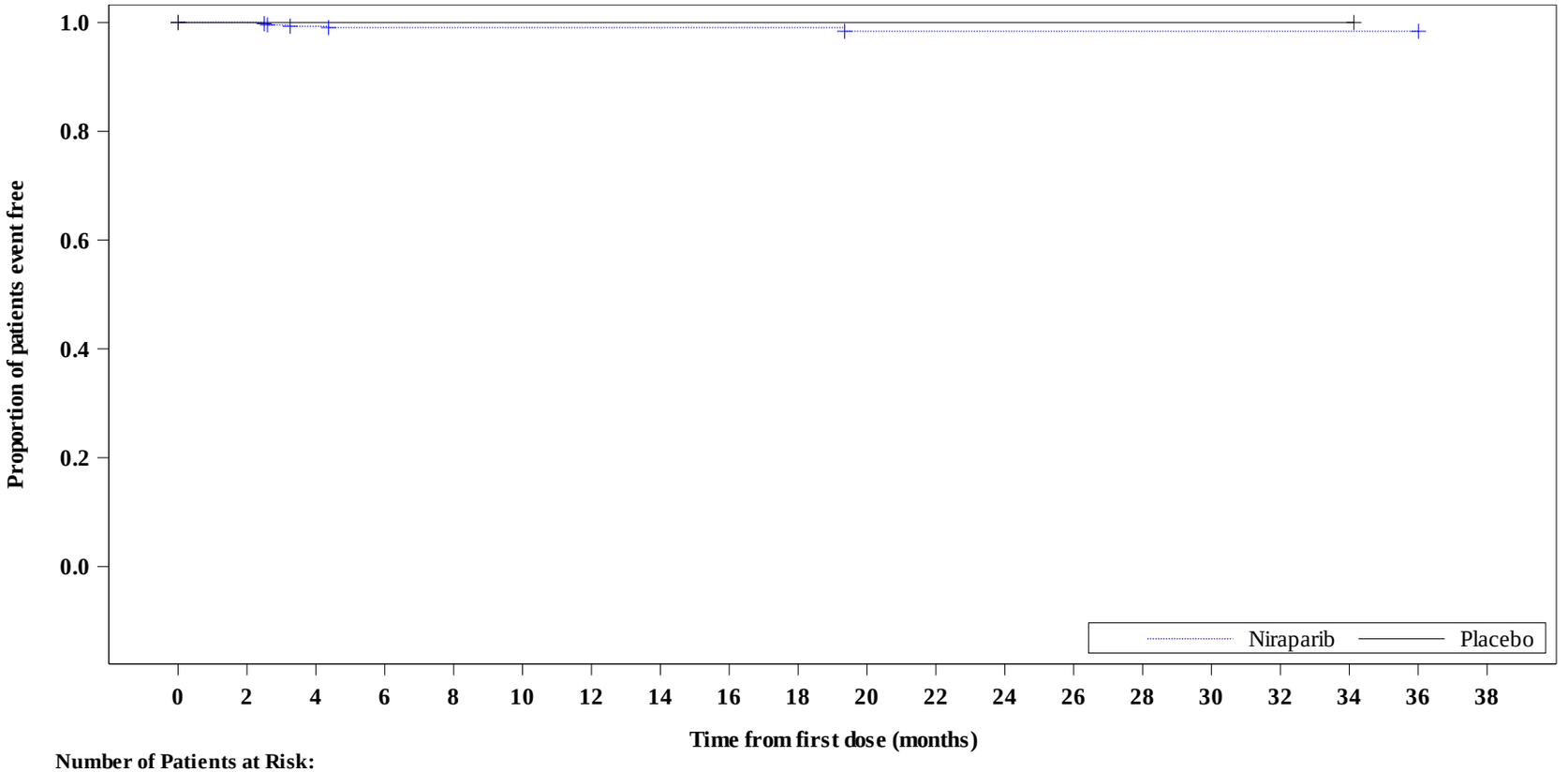



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 356 | 298 | 265 | 248 | 225 | 191 | 168 | 128 | 90 | 61 | 34 | 21 | 12 | 8 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 182 | 145 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.71
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Pneumonitis



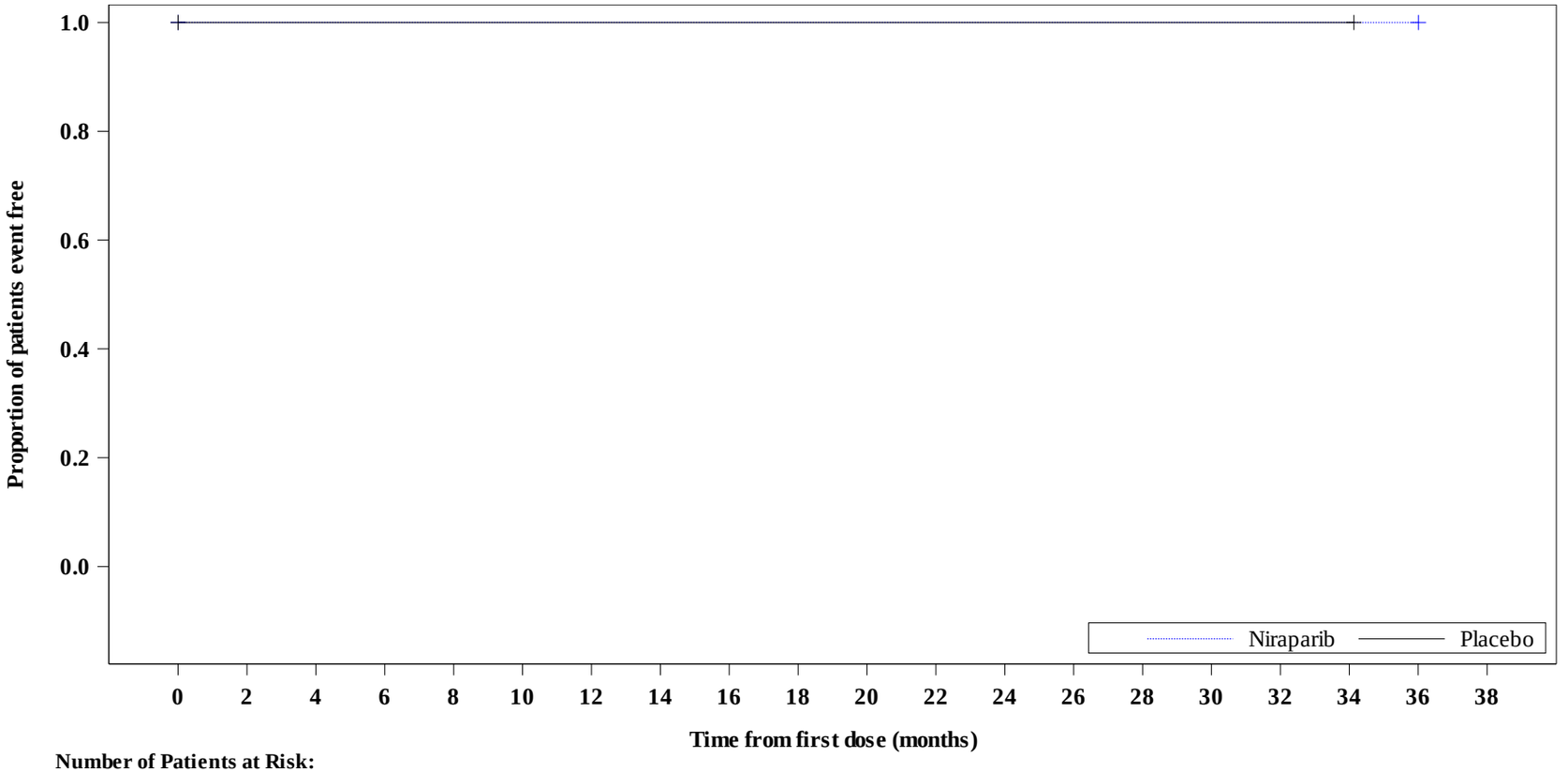

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 389 | 354 | 297 | 264 | 247 | 224 | 191 | 168 | 128 | 90 | 62 | 34 | 21 | 12 | 8 | 4 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.71

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Pancytopenia



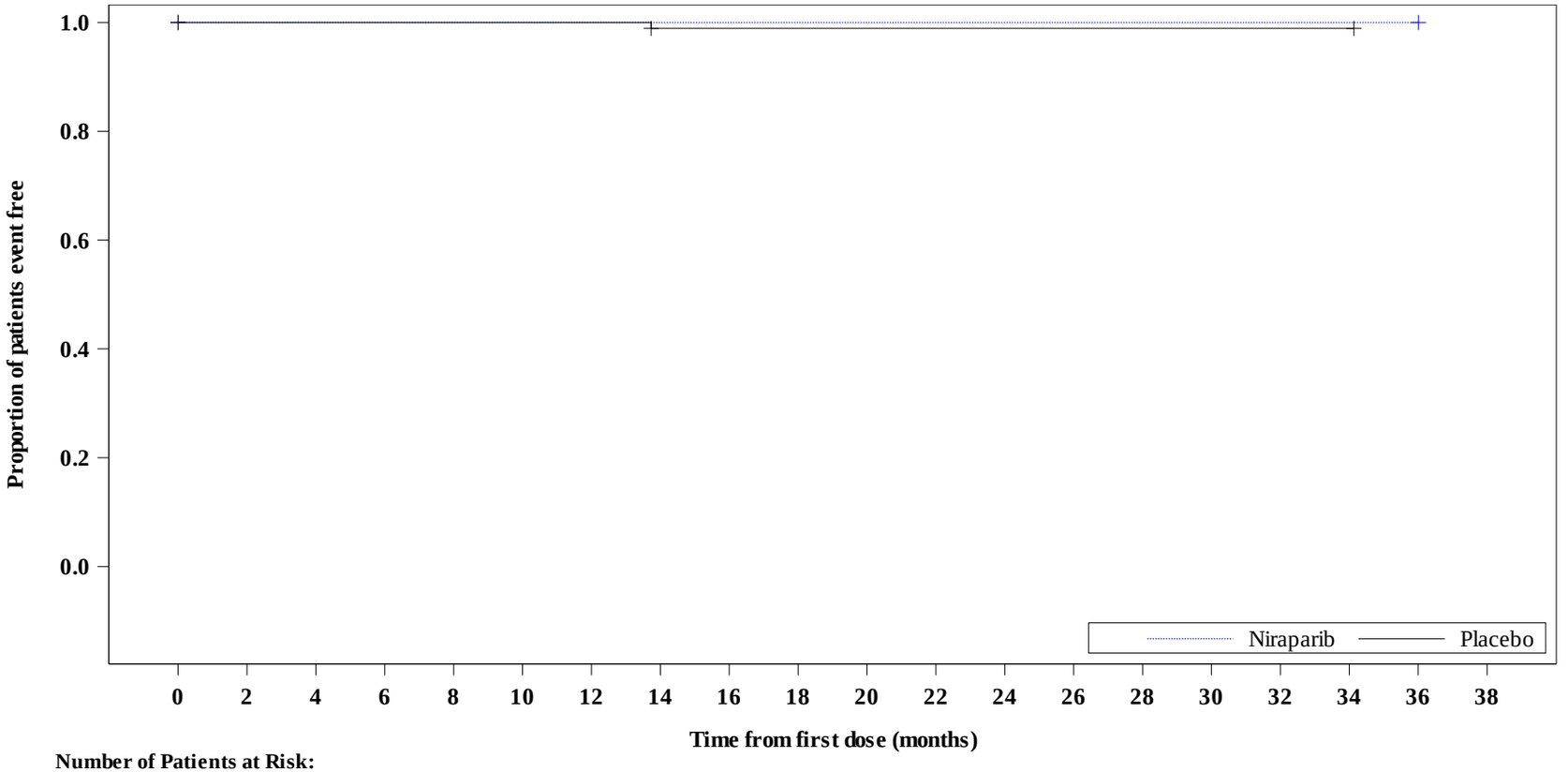

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.71

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Thromboemblic

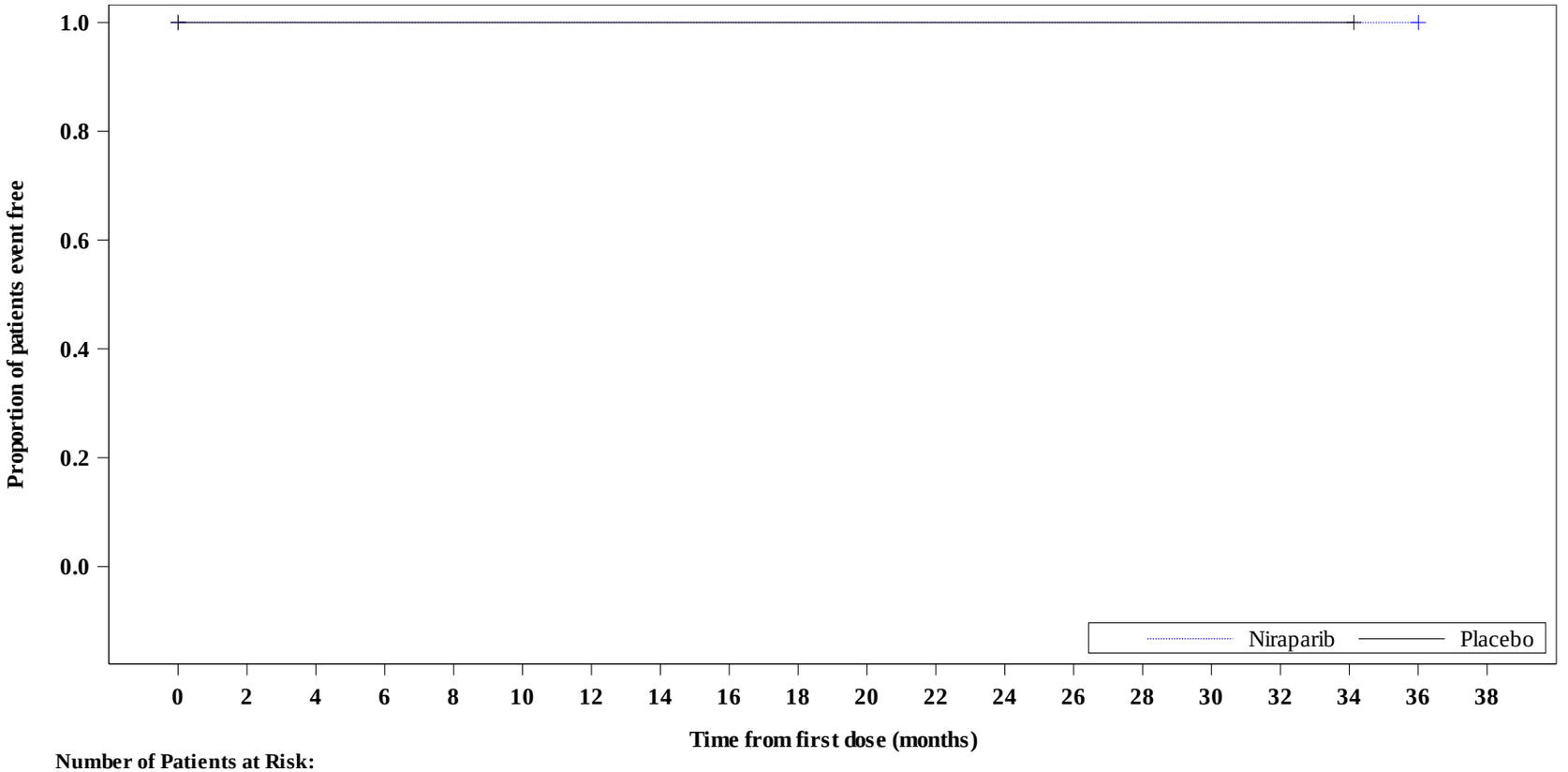



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 85 | 73 | 64 | 53 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.71
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

MDS/AML

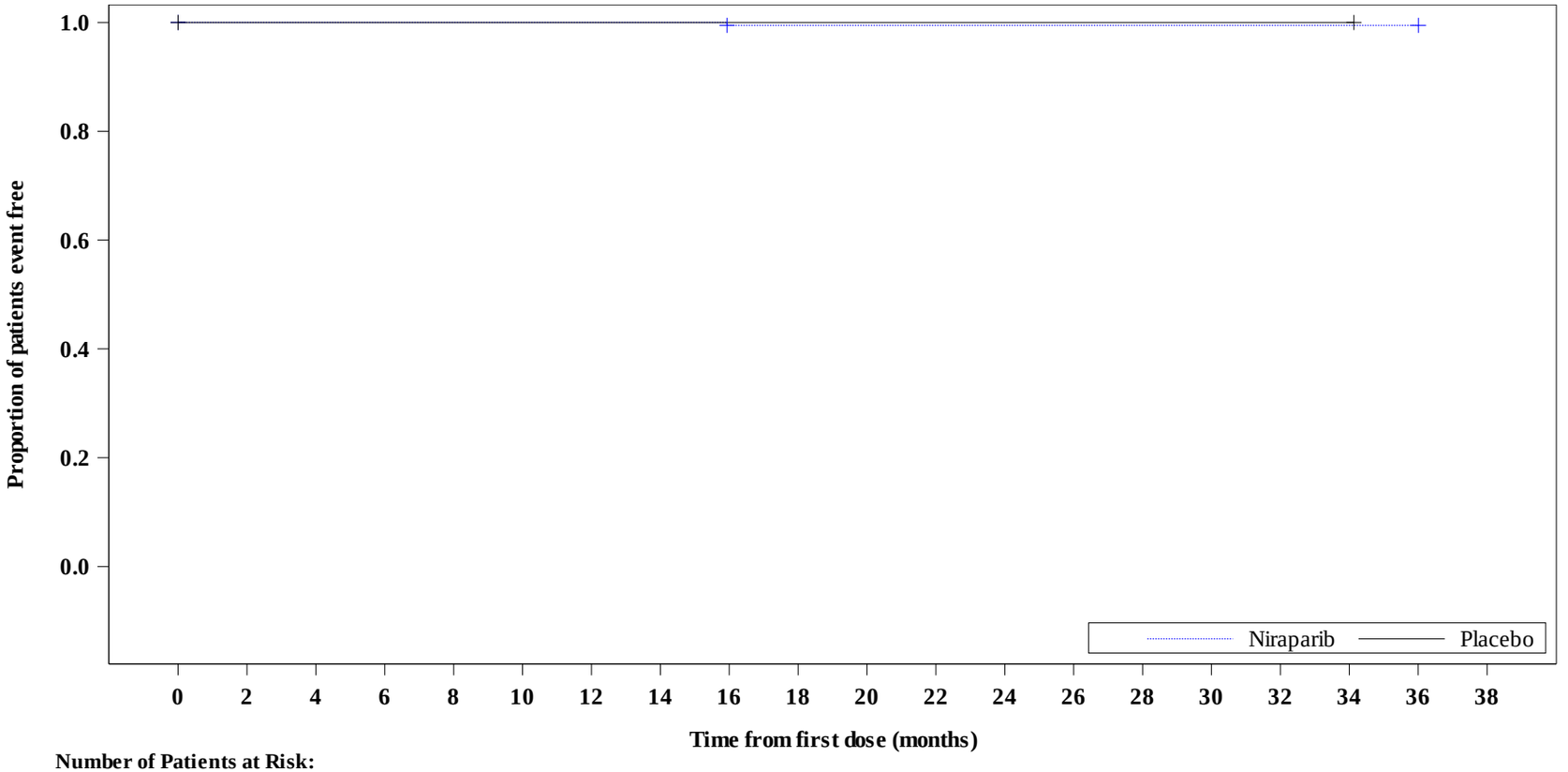



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.71
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Embryo-fetal toxicity




**Number of Patients at Risk:**

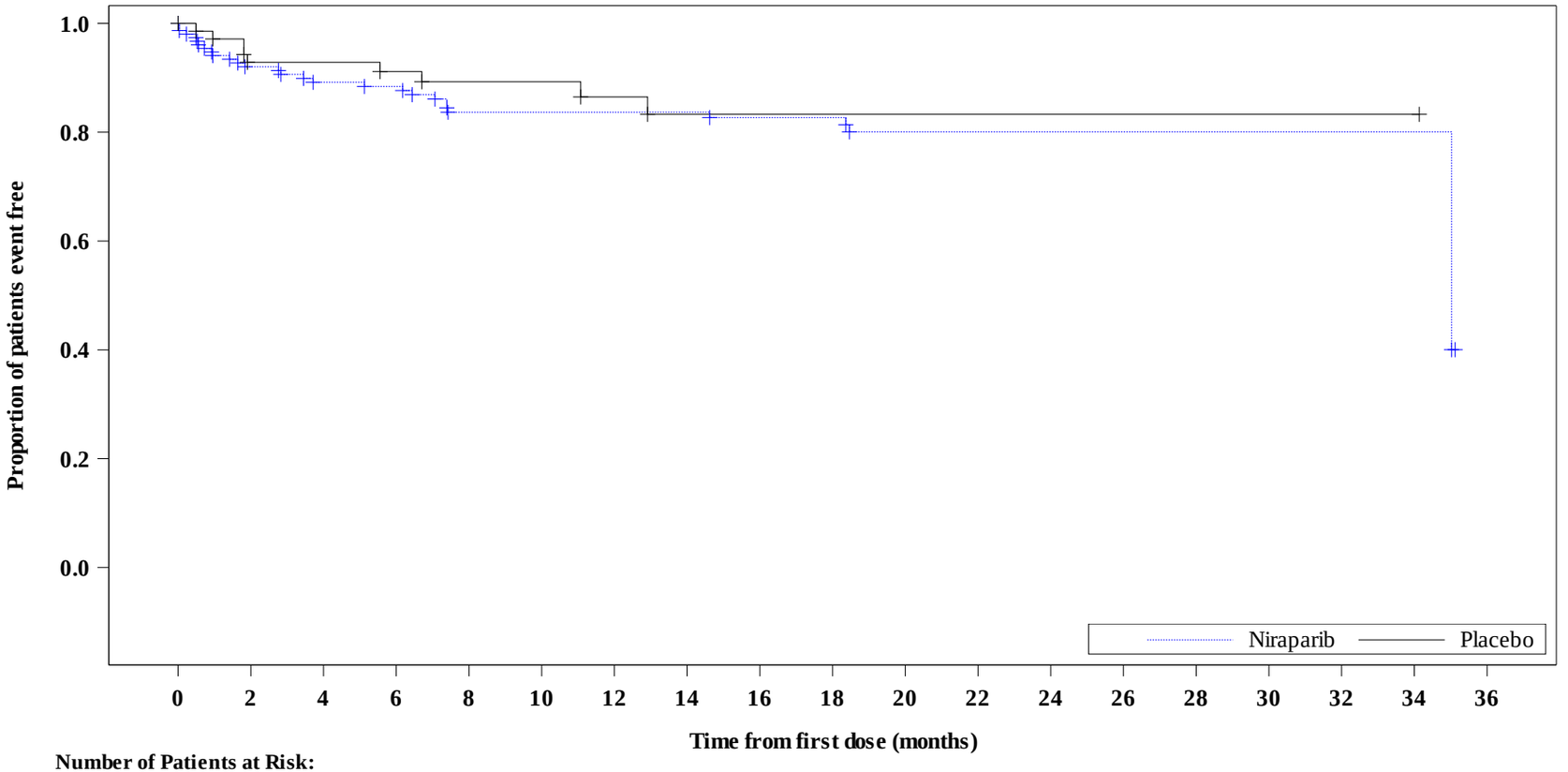
| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 191 | 168 | 129 | 91 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.65

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety Population)

Hypertension

BRCA Status: BRCAmut




**Number of Patients at Risk:**

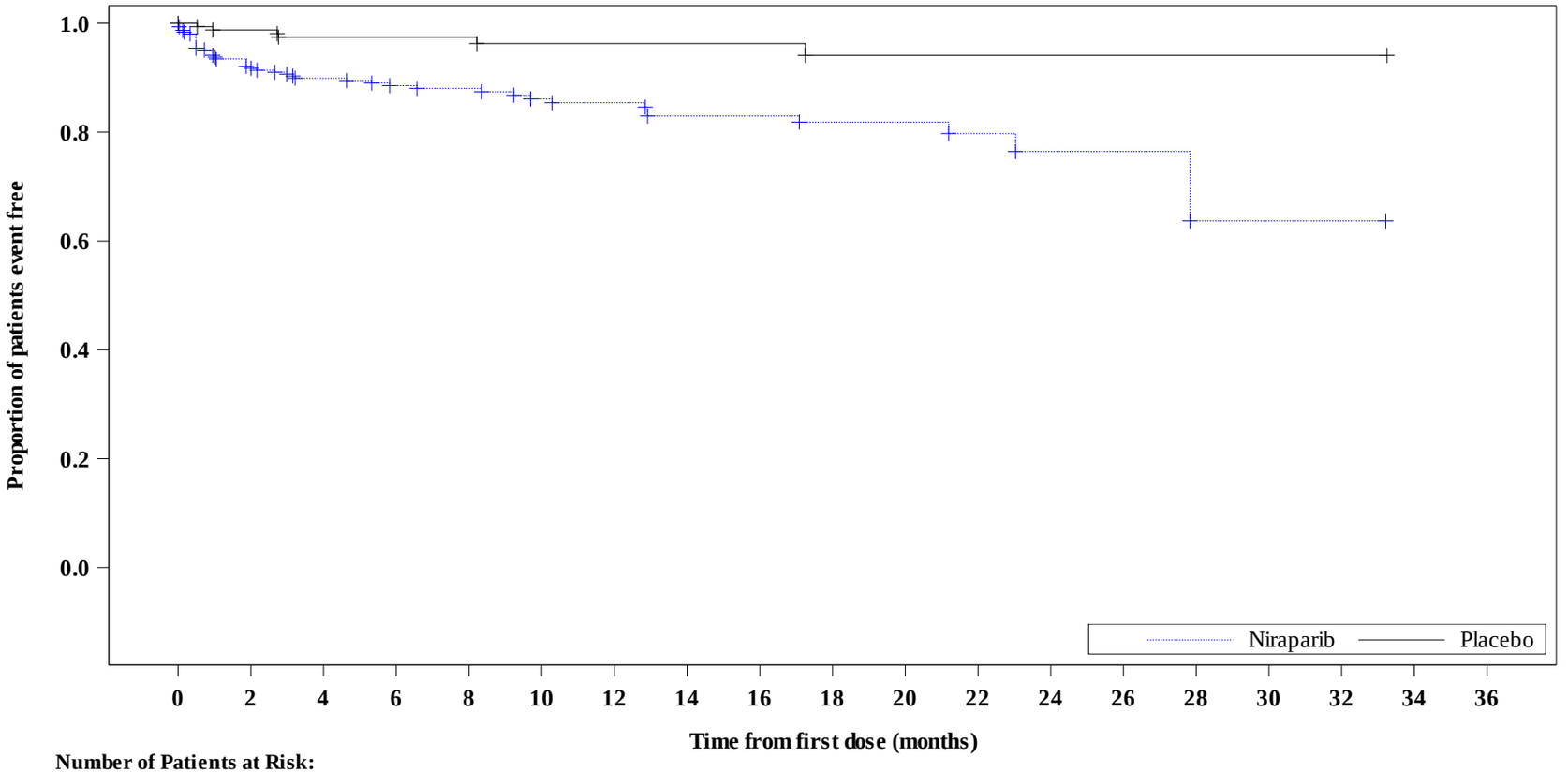
| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 152 | 131 | 119 | 117 | 101 | 96 | 92 | 85 | 76 | 63 | 48 | 37 | 25 | 18 | 10 | 6 | 6 | 4 | 0 |
| Placebo | 70 | 65 | 57 | 52 | 44 | 35 | 30 | 24 | 20 | 17 | 17 | 12 | 8 | 4 | 2 | 1 | 1 | 1 | 0 |

Figure 3.65

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety Population)

Hypertension

BRCA Status: BRCAwt




**Number of Patients at Risk:**

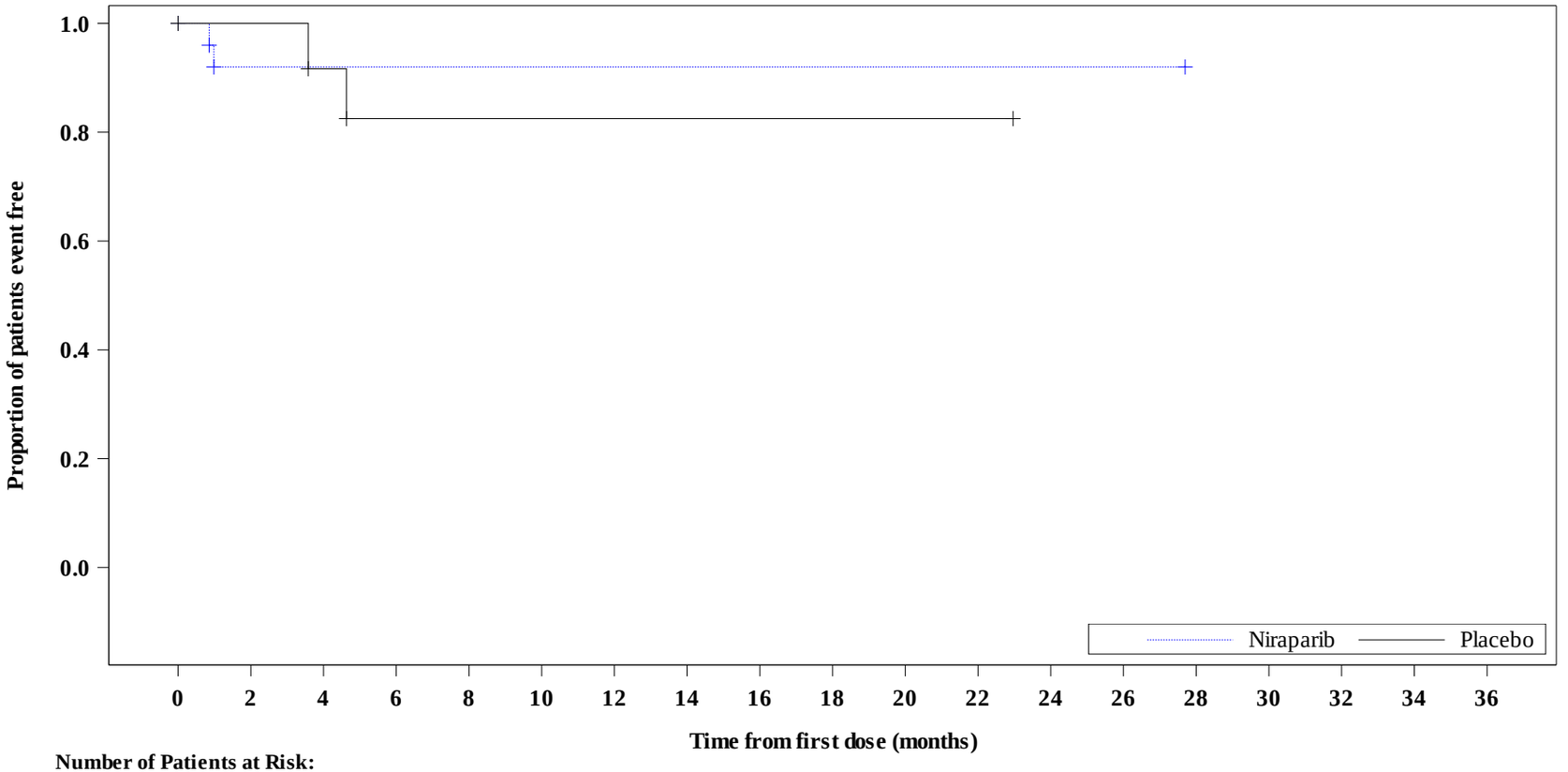
| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 307 | 261 | 213 | 189 | 146 | 125 | 114 | 97 | 78 | 71 | 52 | 31 | 19 | 8 | 5 | 1 | 1 | 0 |
| Placebo | 162 | 157 | 127 | 110 | 86 | 60 | 57 | 51 | 45 | 38 | 29 | 19 | 10 | 8 | 5 | 2 | 1 | 0 |

Figure 3.65

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety Population)

Hypertension

BRCA Status: BRCAnd



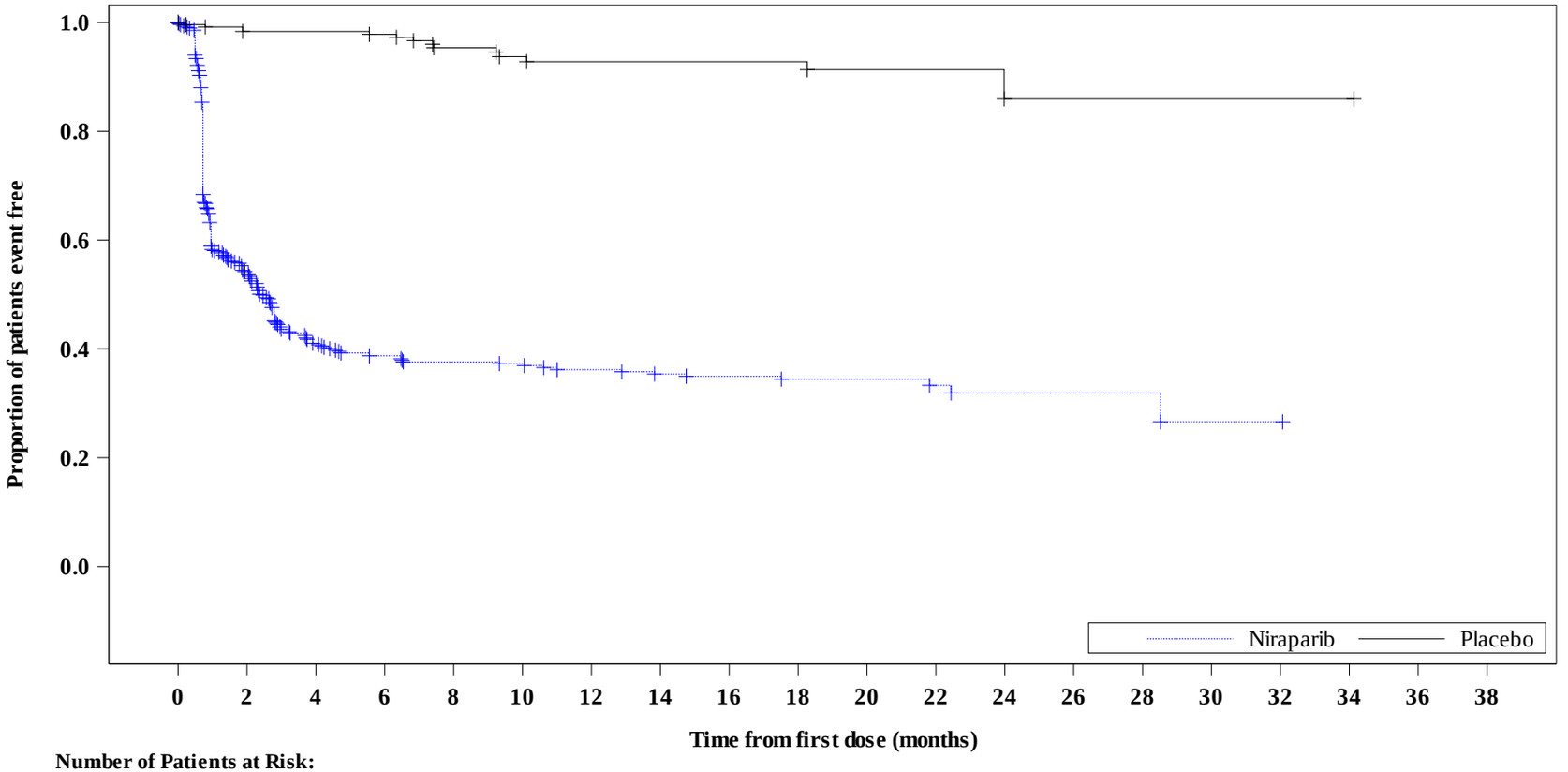

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 25 | 21 | 18 | 13 | 11 | 8 | 7 | 7 | 7 | 7 | 5 | 4 | 2 | 1 | 0 |
| Placebo | 12 | 12 | 11 | 9 | 6 | 5 | 3 | 3 | 3 | 3 | 3 | 1 | 0 | | |

Figure 3.75

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Overall

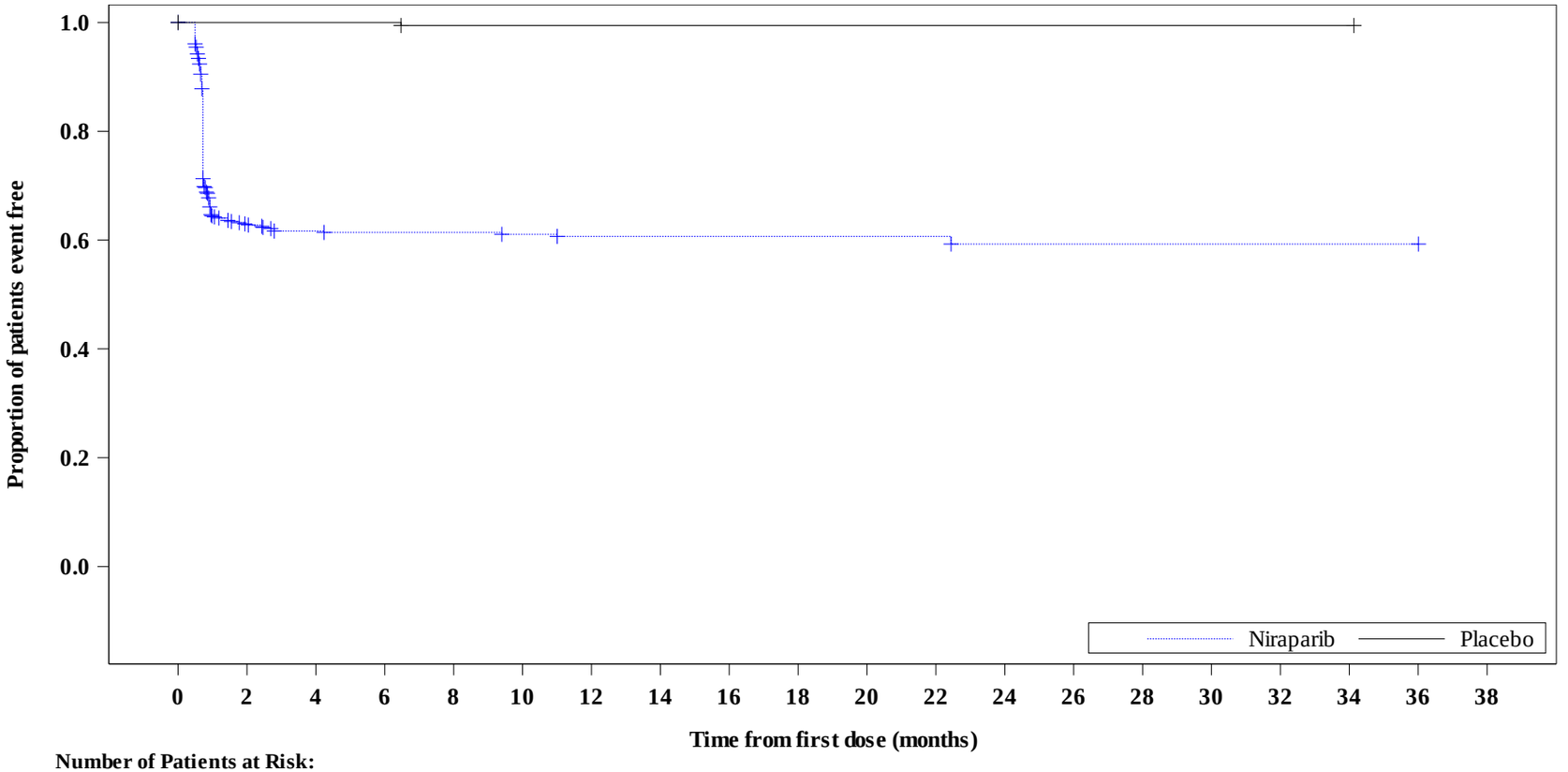



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 249 | 167 | 143 | 121 | 106 | 94 | 86 | 73 | 58 | 46 | 29 | 19 | 11 | 6 | 2 | 1 | 0 | |
| Placebo | 244 | 237 | 202 | 180 | 141 | 103 | 92 | 83 | 72 | 63 | 52 | 32 | 16 | 10 | 5 | 3 | 2 | 1 | 0 |

Figure 3.75
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Thrombocytopenia

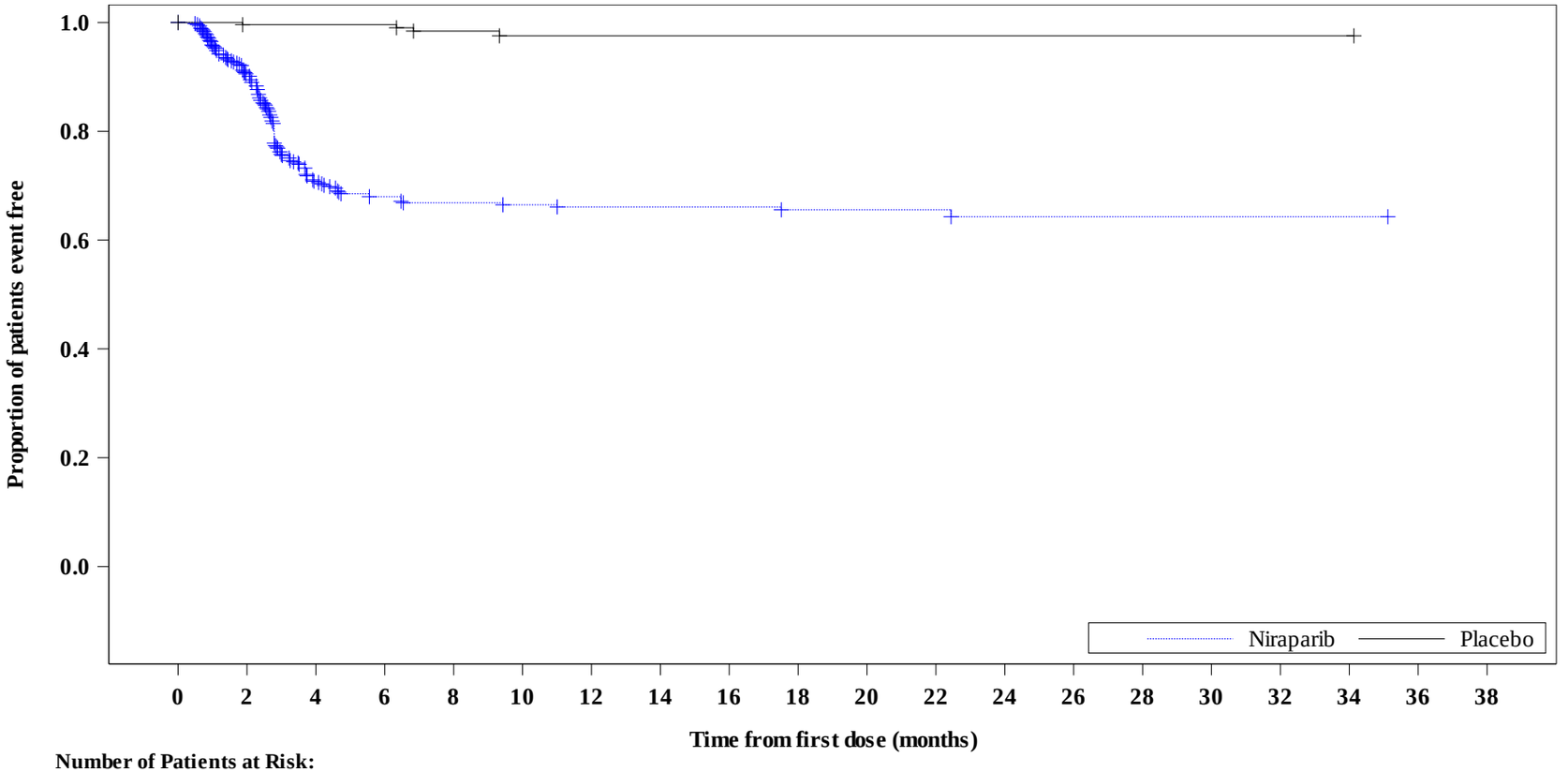



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 290 | 251 | 231 | 195 | 170 | 157 | 142 | 122 | 105 | 77 | 52 | 34 | 17 | 11 | 6 | 4 | 3 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.75
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Anemia

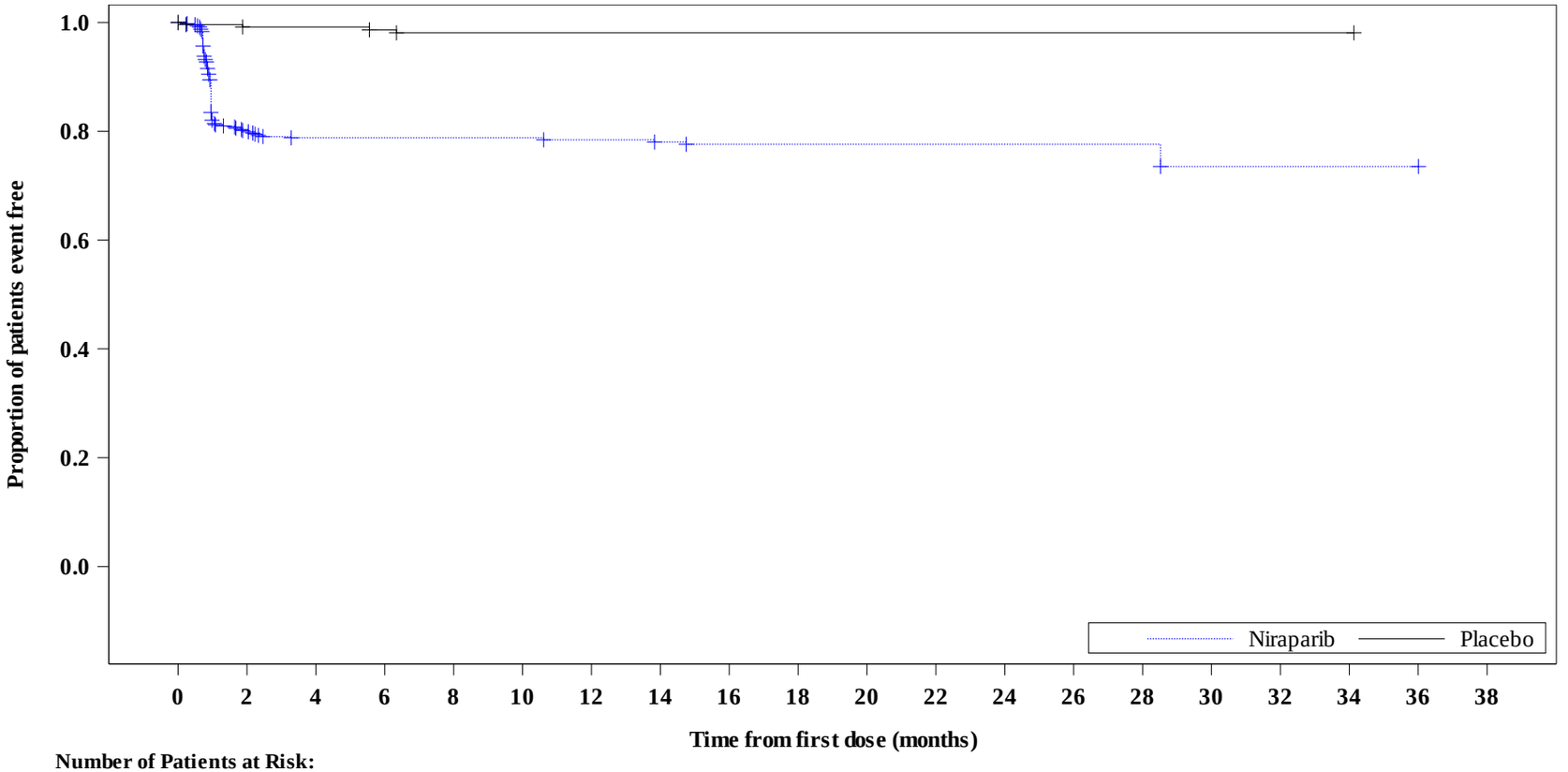



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 410 | 286 | 249 | 206 | 180 | 166 | 152 | 131 | 112 | 89 | 60 | 40 | 23 | 13 | 6 | 4 | 3 | 0 |
| Placebo | 244 | 240 | 204 | 182 | 145 | 107 | 96 | 84 | 72 | 63 | 53 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 |

Figure 3.75
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Leukopenia

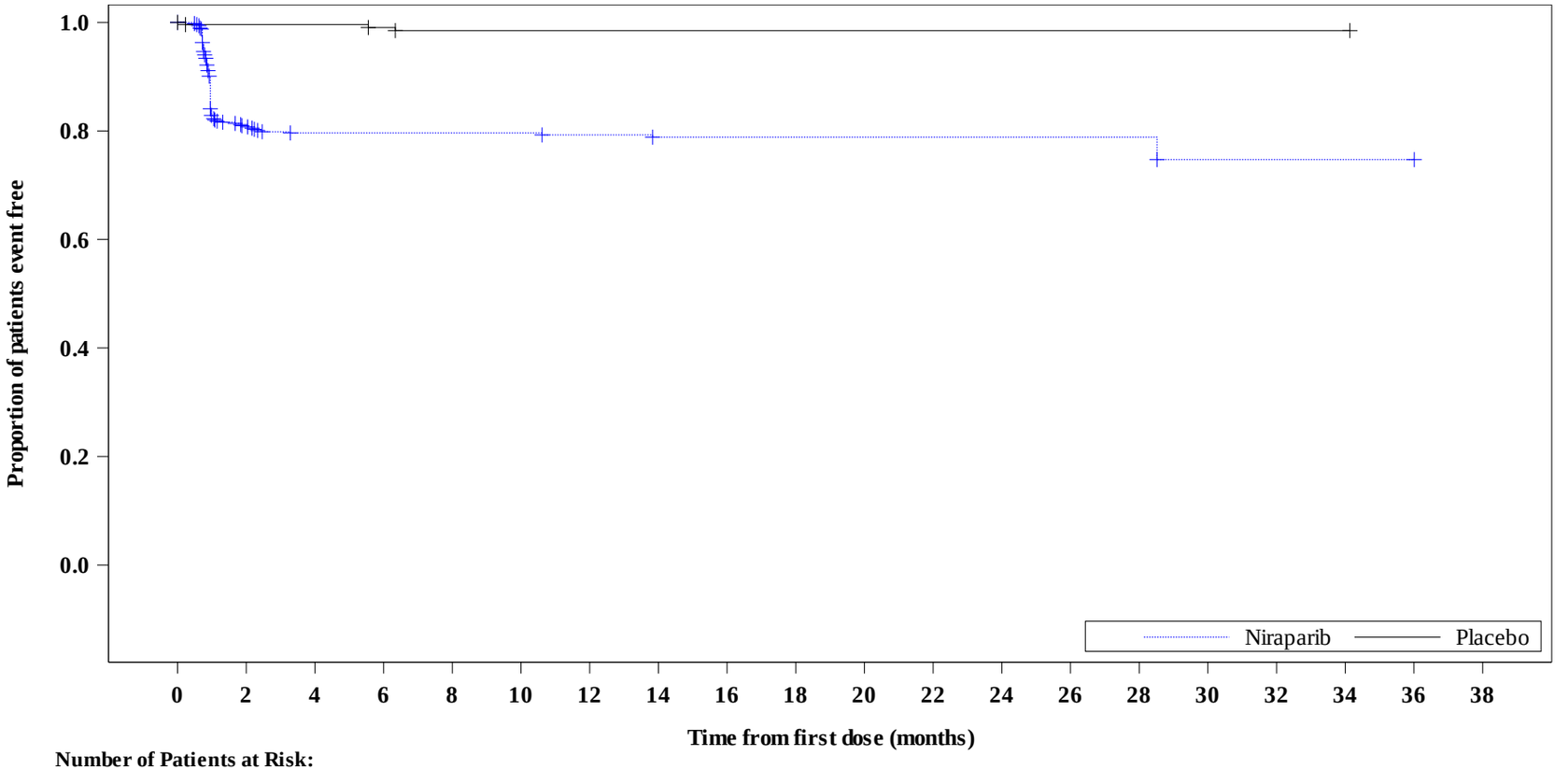



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 366 | 314 | 288 | 248 | 223 | 208 | 192 | 162 | 143 | 109 | 79 | 51 | 30 | 19 | 10 | 7 | 3 | 1 | 0 |
| Placebo | 244 | 239 | 204 | 181 | 144 | 108 | 97 | 85 | 73 | 64 | 53 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 | |

Figure 3.75
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Neutropenia



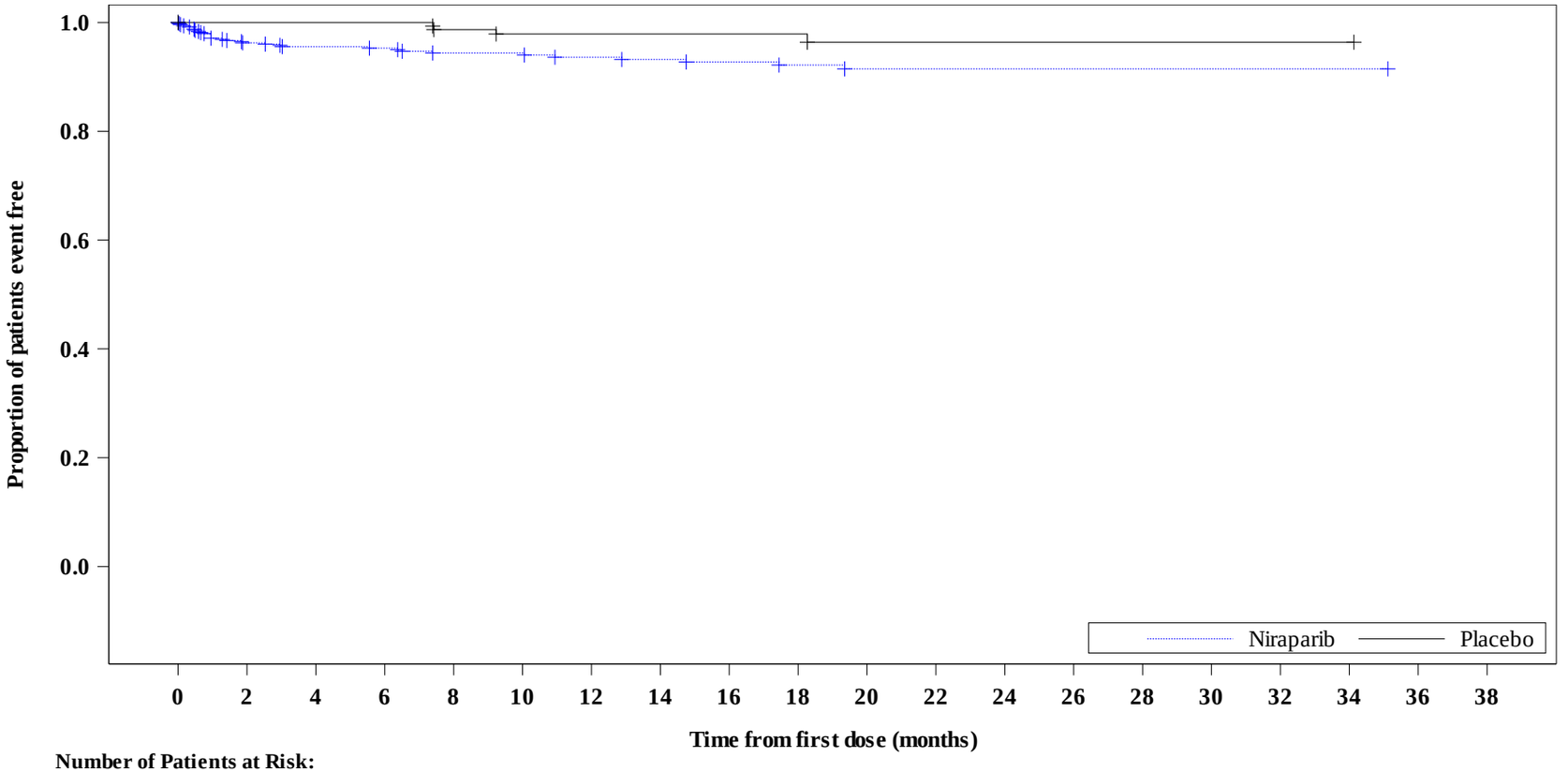

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 370 | 316 | 290 | 250 | 225 | 210 | 194 | 165 | 146 | 112 | 81 | 53 | 31 | 19 | 10 | 7 | 3 | 1 | 0 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 108 | 97 | 85 | 73 | 64 | 53 | 32 | 17 | 11 | 6 | 3 | 2 | 1 | 0 | |

Figure 3.75

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Hypertension



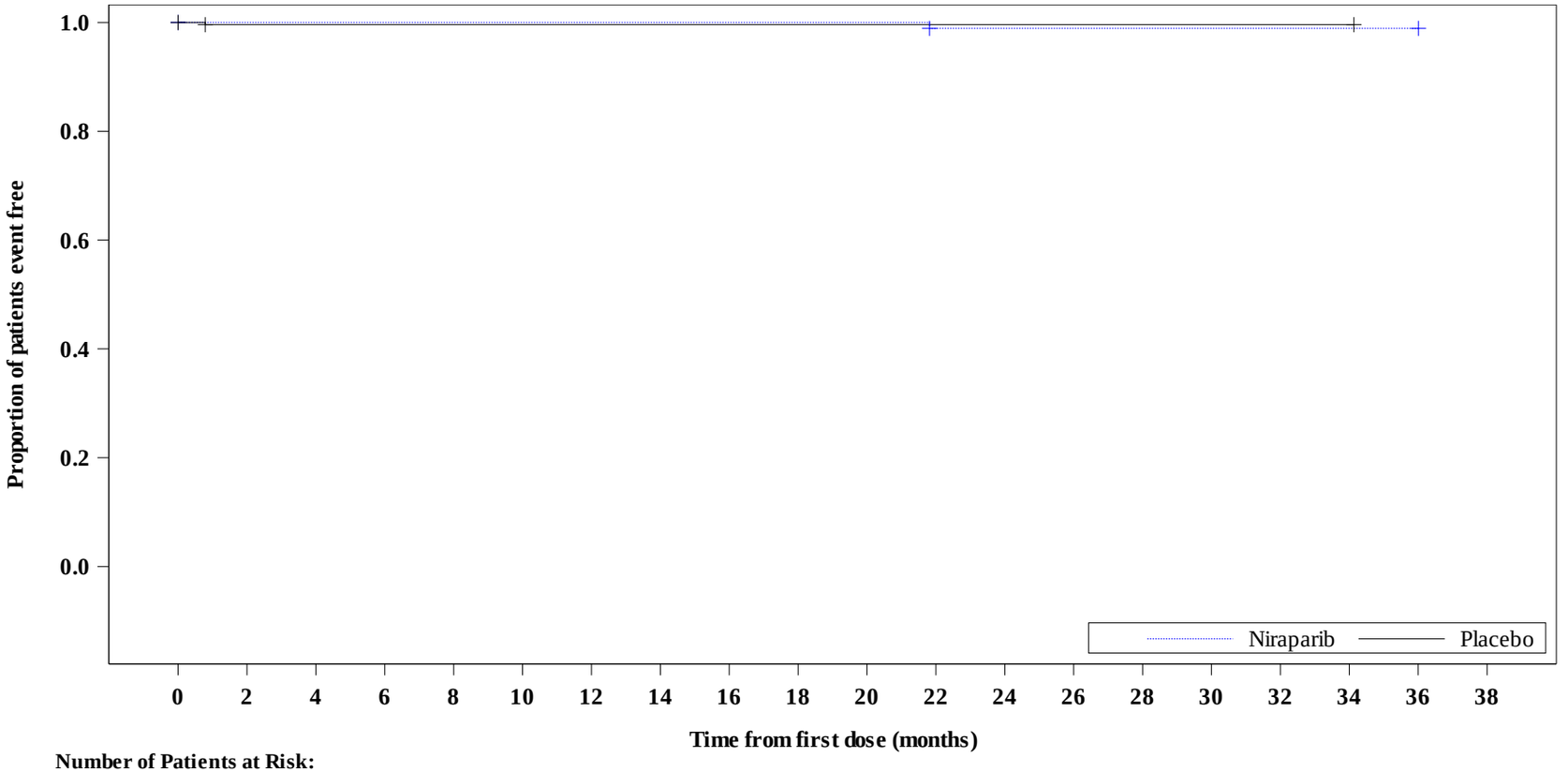

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 432 | 372 | 338 | 281 | 251 | 233 | 209 | 176 | 153 | 115 | 82 | 55 | 29 | 17 | 8 | 6 | 4 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 144 | 106 | 96 | 86 | 74 | 65 | 53 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.75

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

New malignancies other than MDS/AML



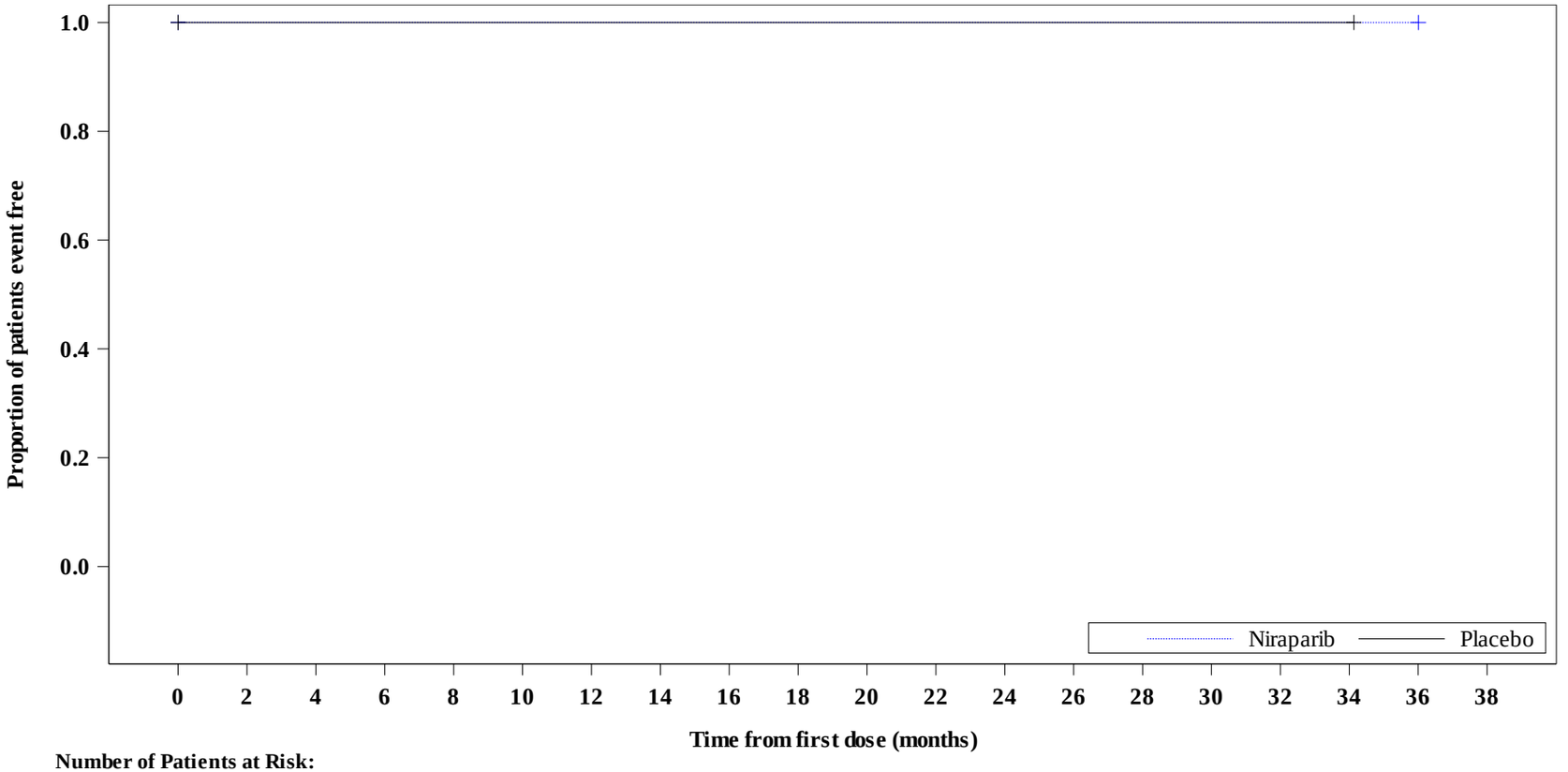

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 91 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 240 | 204 | 182 | 145 | 108 | 97 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.75

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Pneumonitis



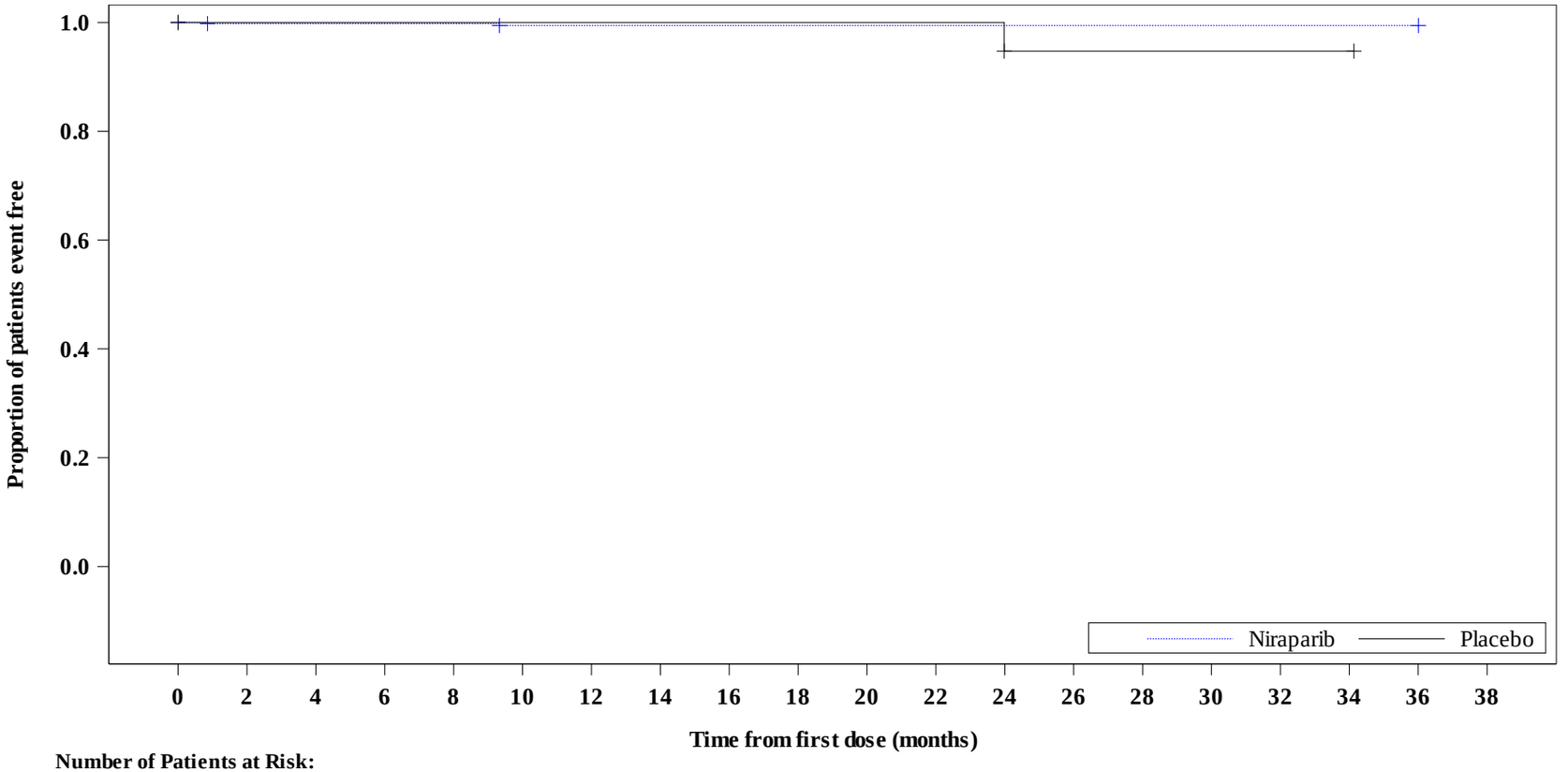

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.75

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Pancytopenia

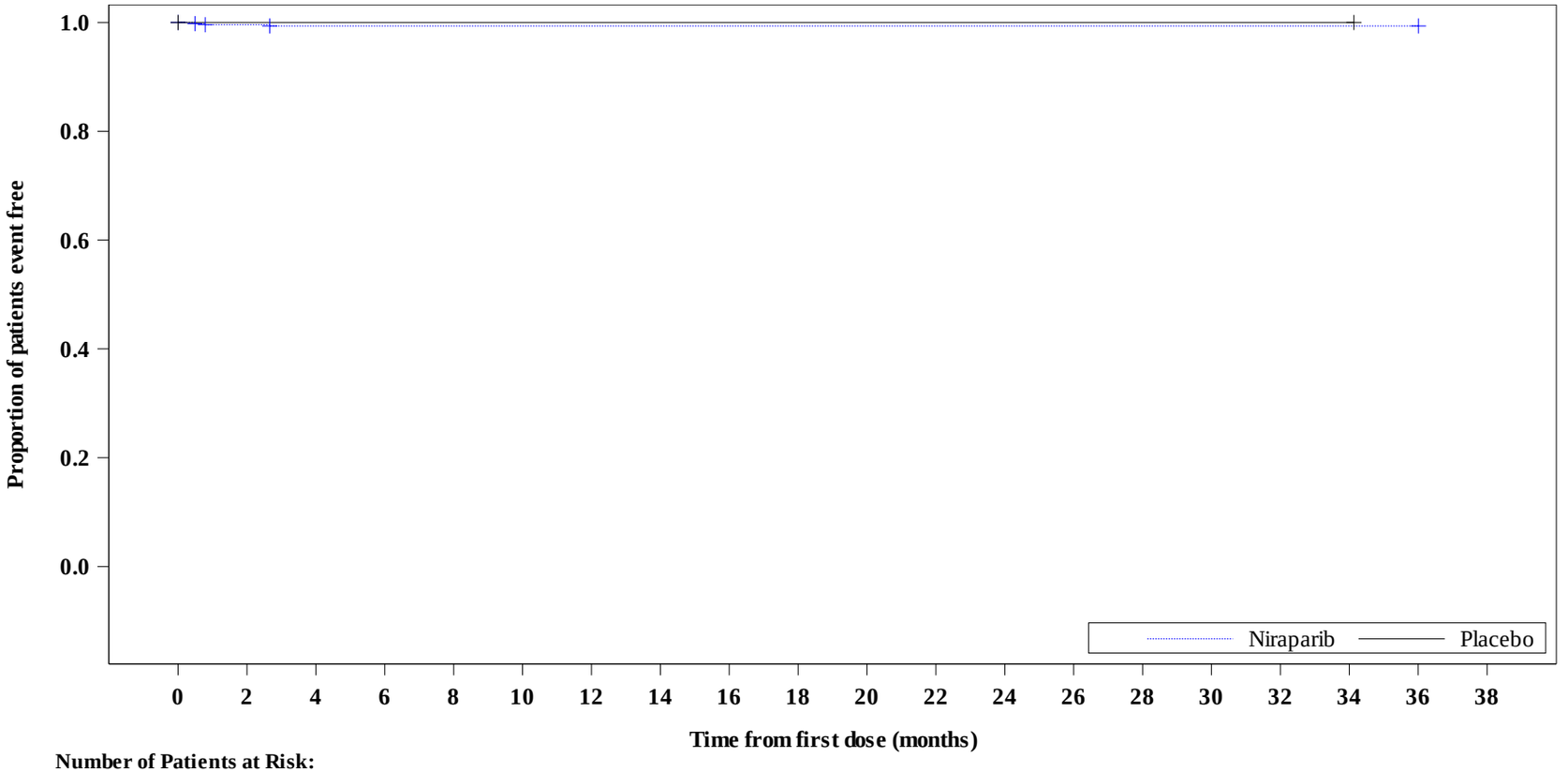



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 390 | 356 | 298 | 265 | 248 | 225 | 191 | 168 | 129 | 91 | 62 | 34 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 184 | 147 | 110 | 99 | 87 | 75 | 66 | 55 | 34 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.75
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Thromboemblic



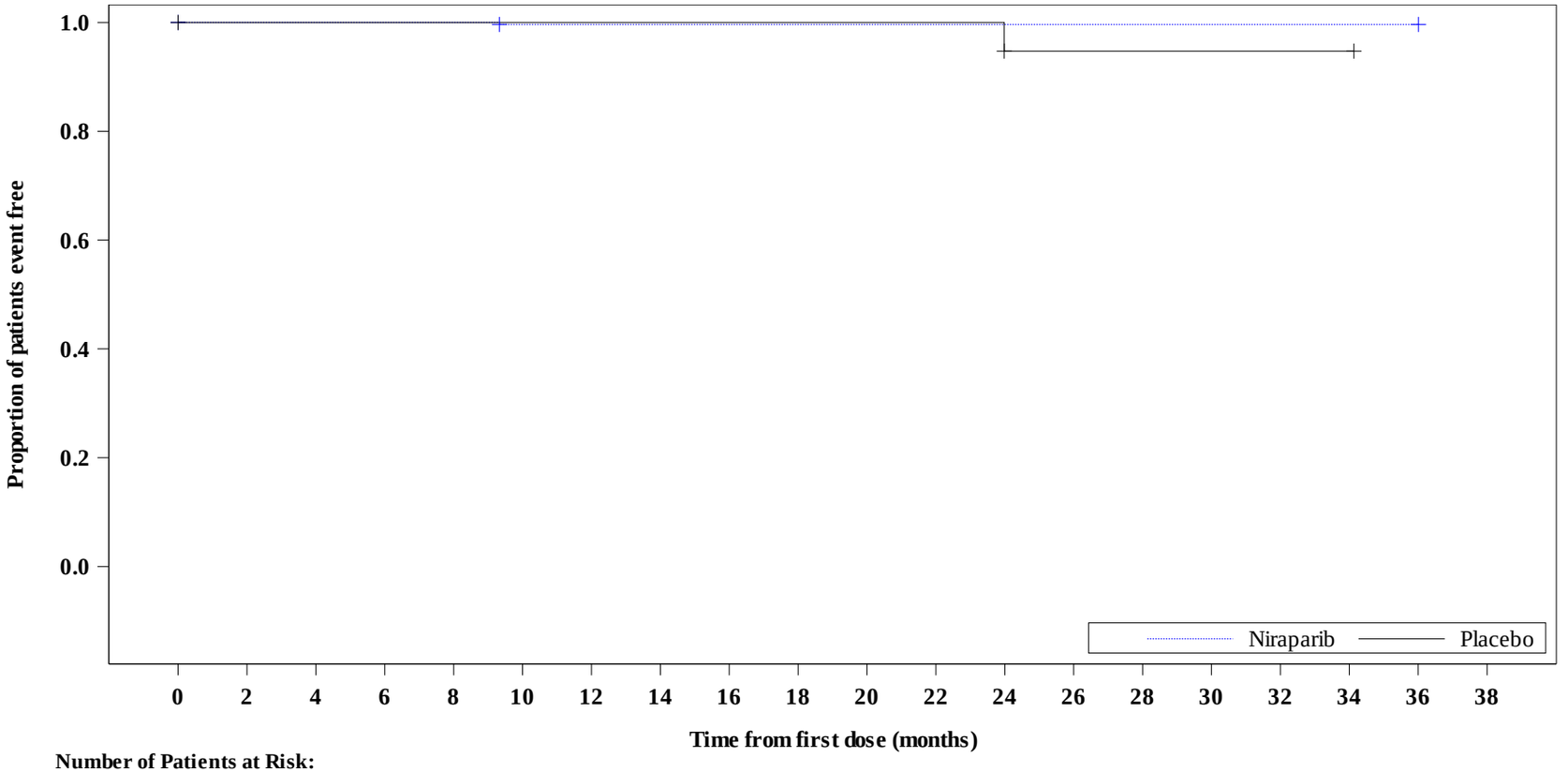

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 388 | 354 | 297 | 264 | 247 | 225 | 191 | 168 | 129 | 91 | 62 | 34 | 21 | 12 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.75

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

MDS/AML



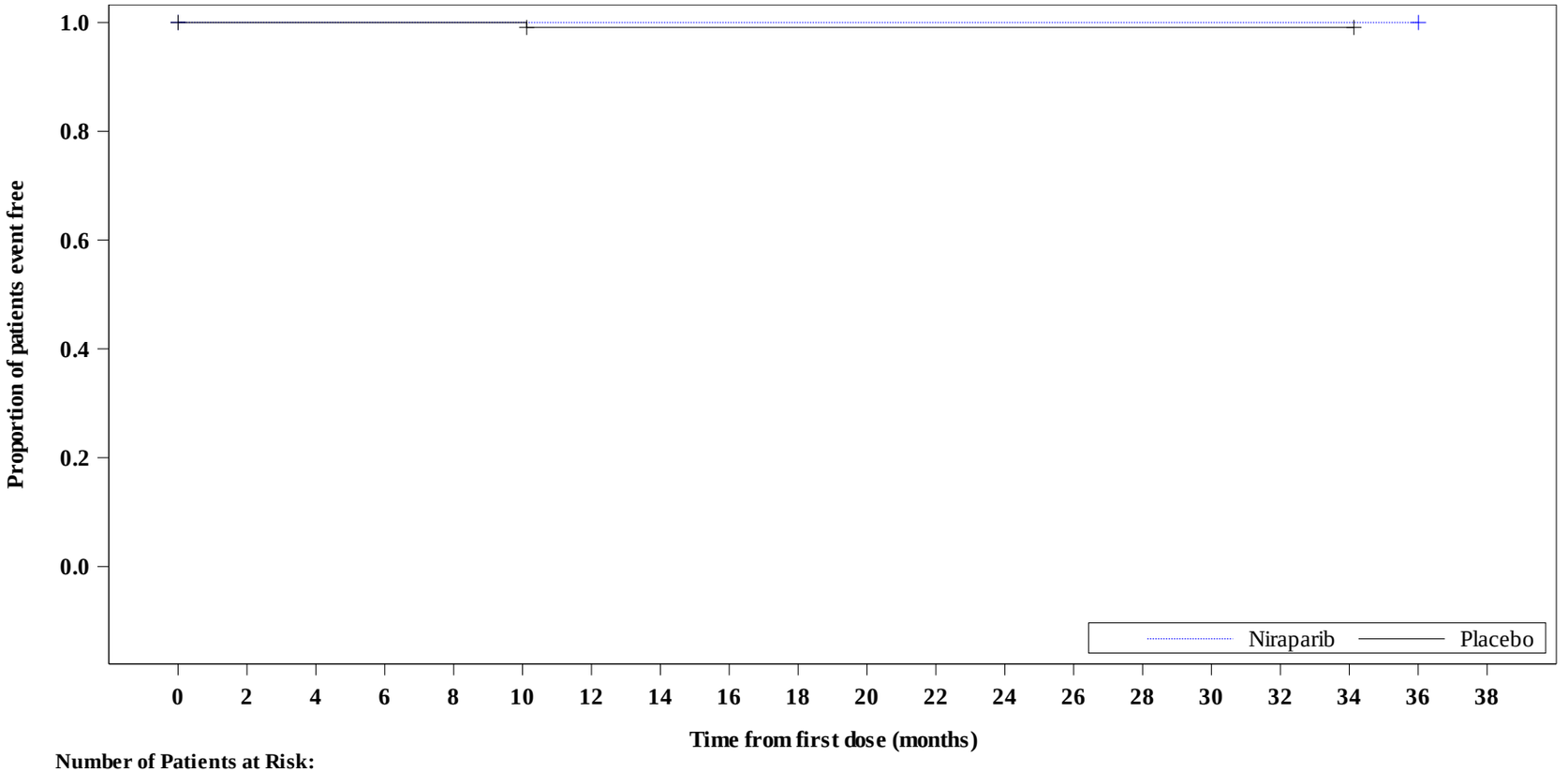

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 184 | 147 | 110 | 99 | 87 | 75 | 66 | 55 | 34 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.75

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Embryo-fetal toxicity



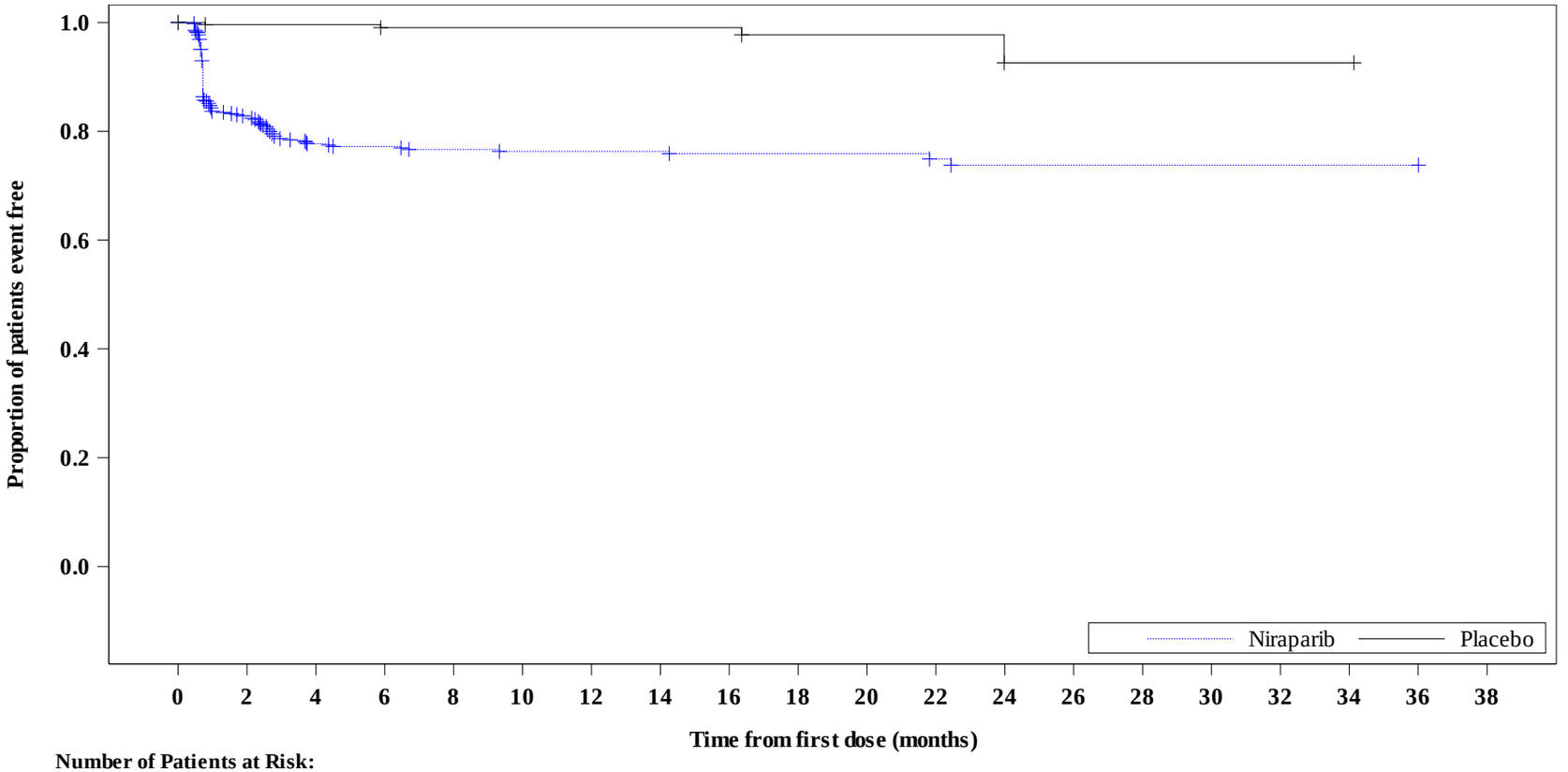

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 97 | 85 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Overall

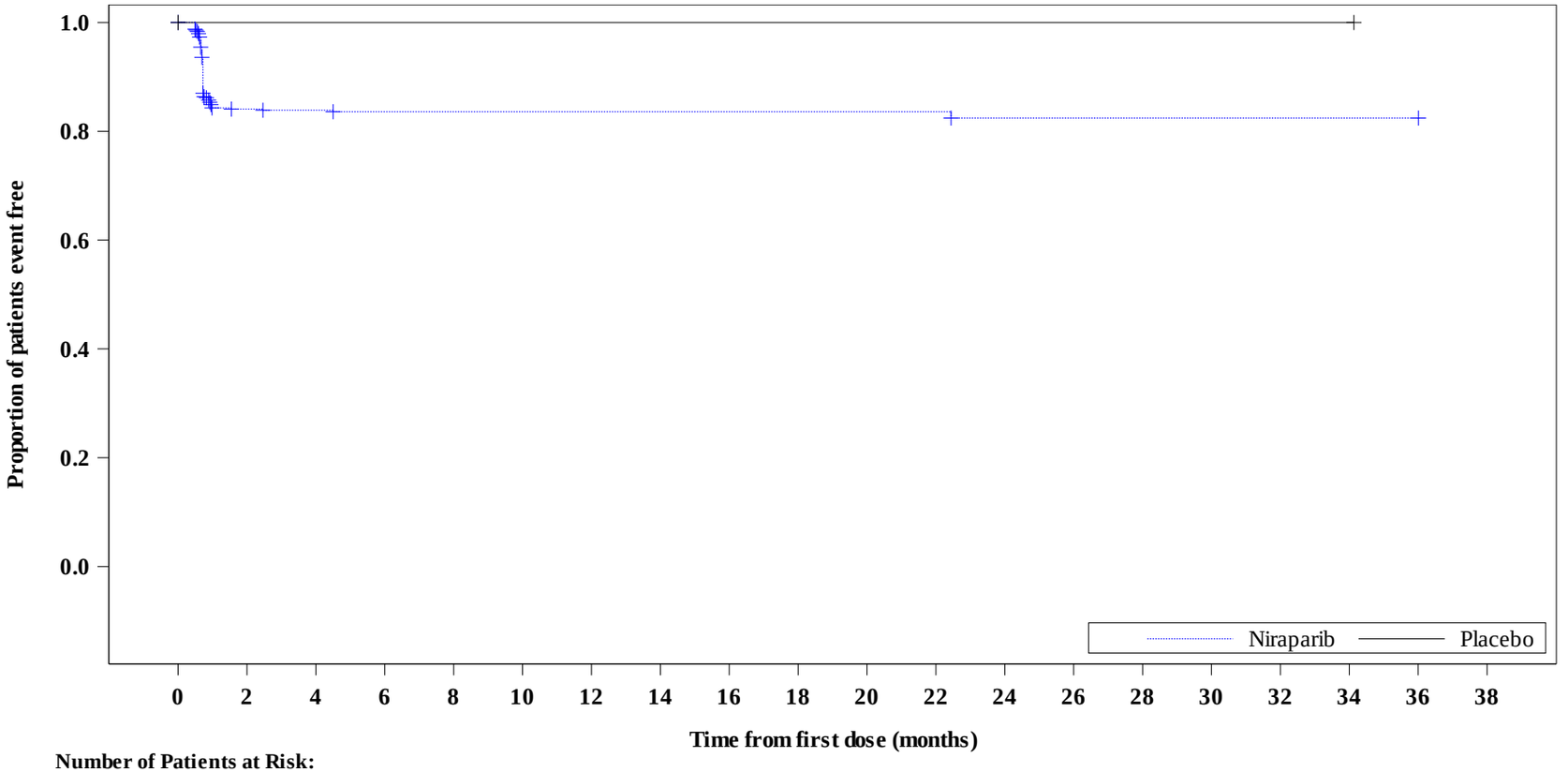



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 380 | 317 | 287 | 245 | 215 | 199 | 182 | 154 | 136 | 107 | 76 | 54 | 28 | 17 | 8 | 5 | 3 | 1 | 0 |
| Placebo | 244 | 240 | 204 | 182 | 145 | 109 | 98 | 87 | 75 | 66 | 55 | 34 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Thrombocytopenia



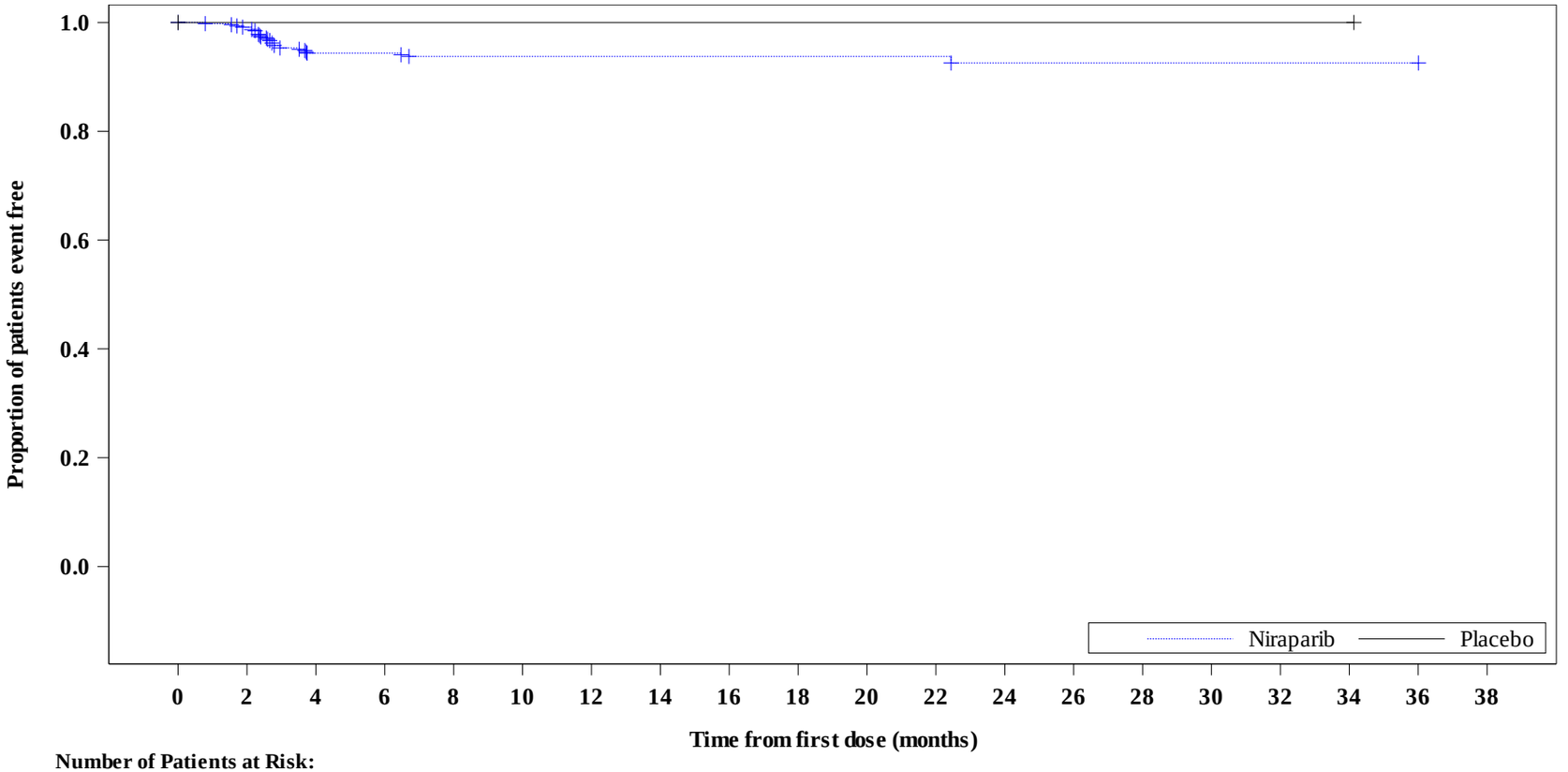

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 386 | 340 | 310 | 265 | 235 | 219 | 198 | 168 | 149 | 113 | 81 | 56 | 29 | 18 | 9 | 6 | 4 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Anemia

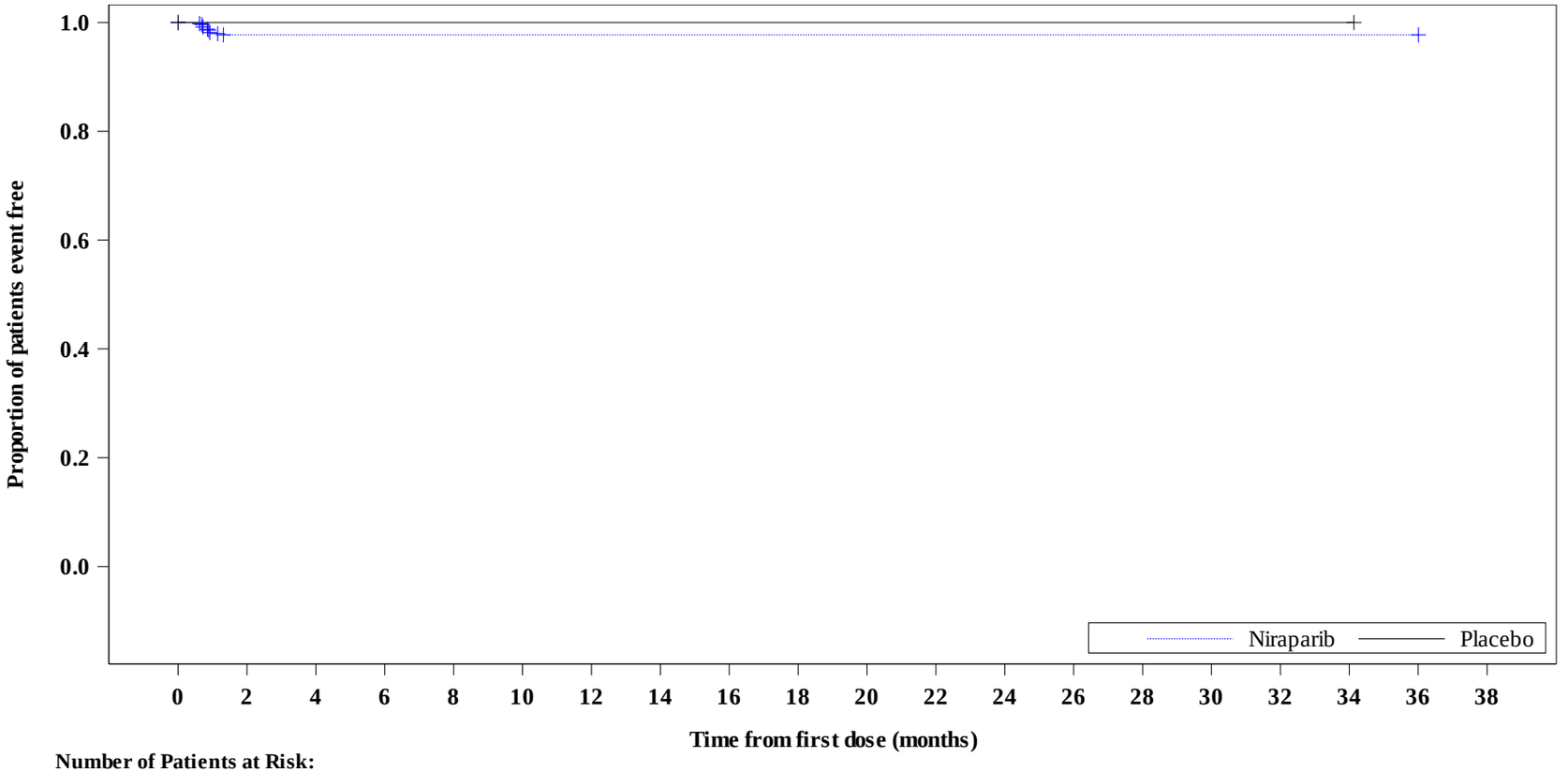



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 372 | 339 | 281 | 248 | 231 | 211 | 179 | 157 | 124 | 88 | 61 | 34 | 21 | 12 | 8 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Leukopenia

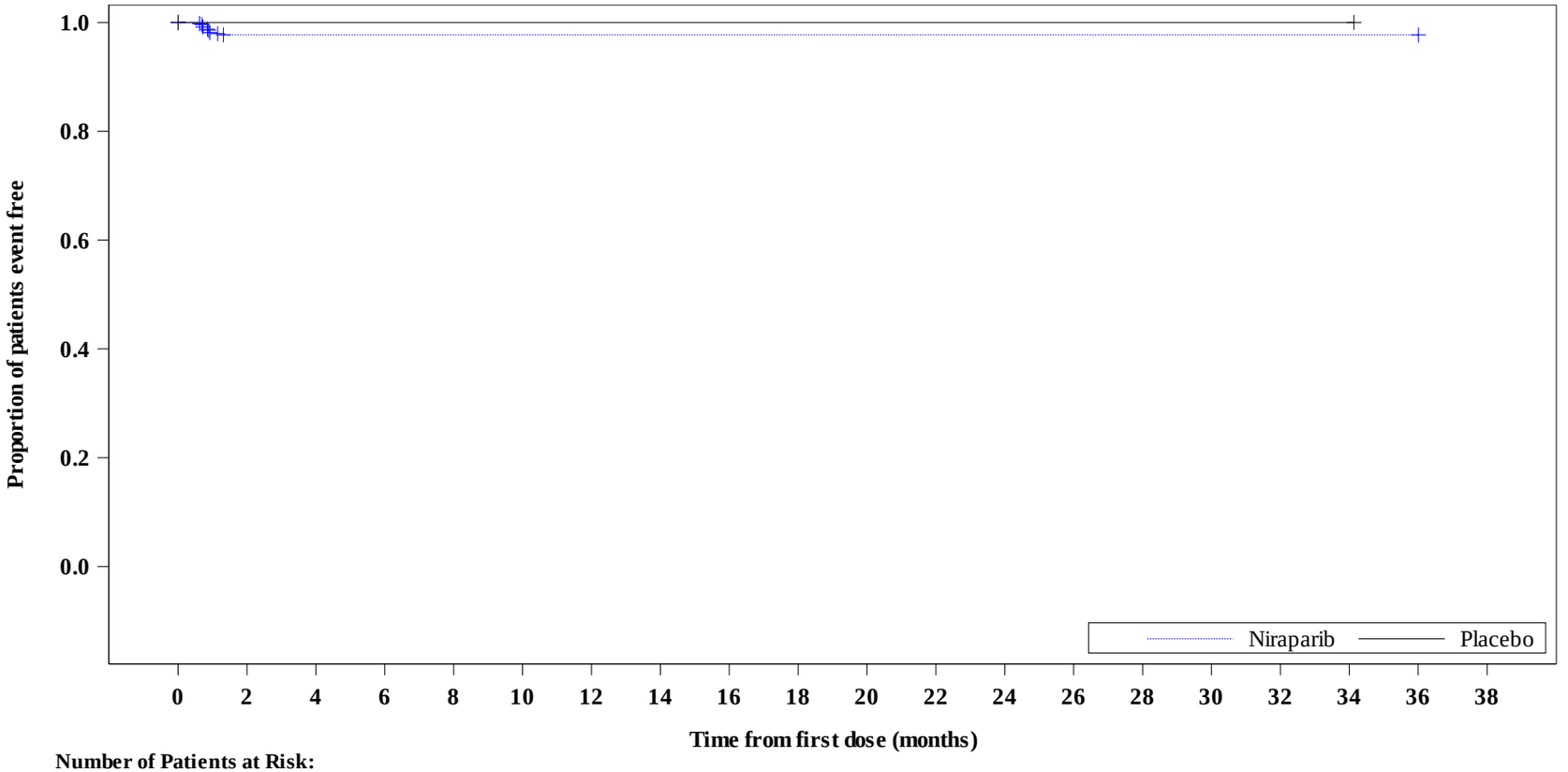



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 440 | 382 | 350 | 296 | 263 | 246 | 223 | 189 | 166 | 129 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Neutropenia

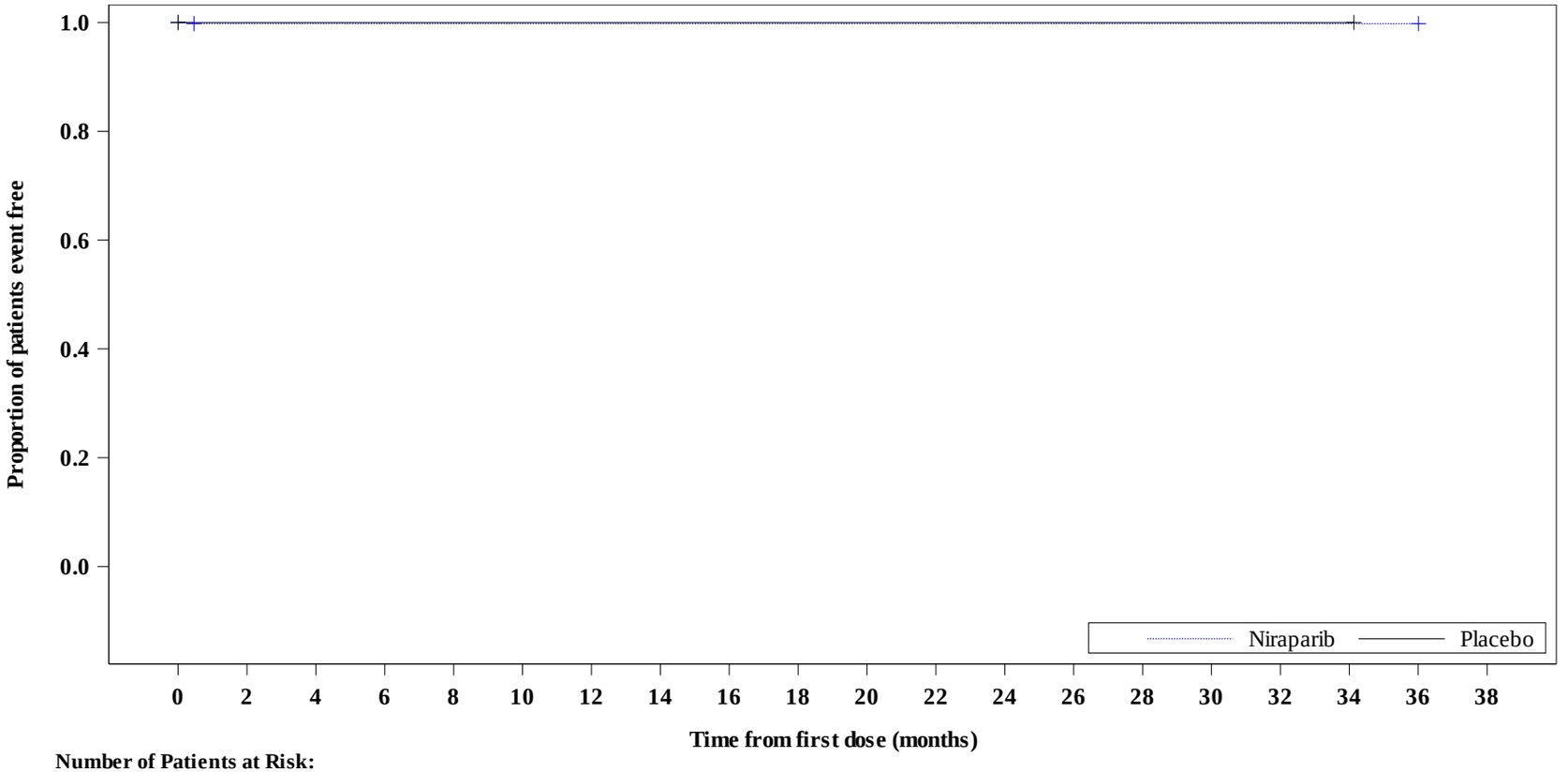



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 440 | 382 | 350 | 296 | 263 | 246 | 223 | 189 | 166 | 129 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Hypertension



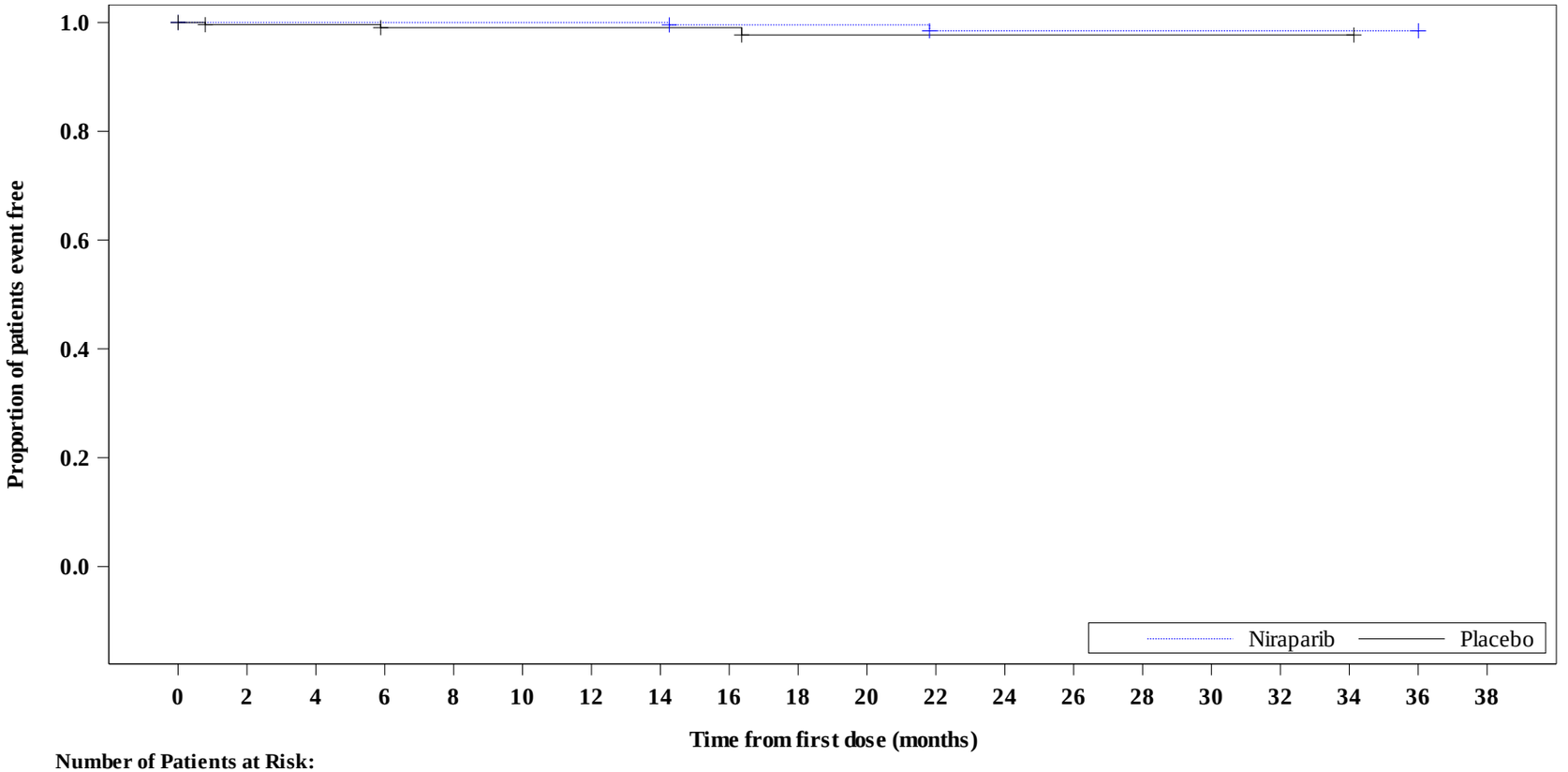

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 390 | 356 | 298 | 265 | 248 | 225 | 191 | 168 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

New malignancies other than MDS/AML



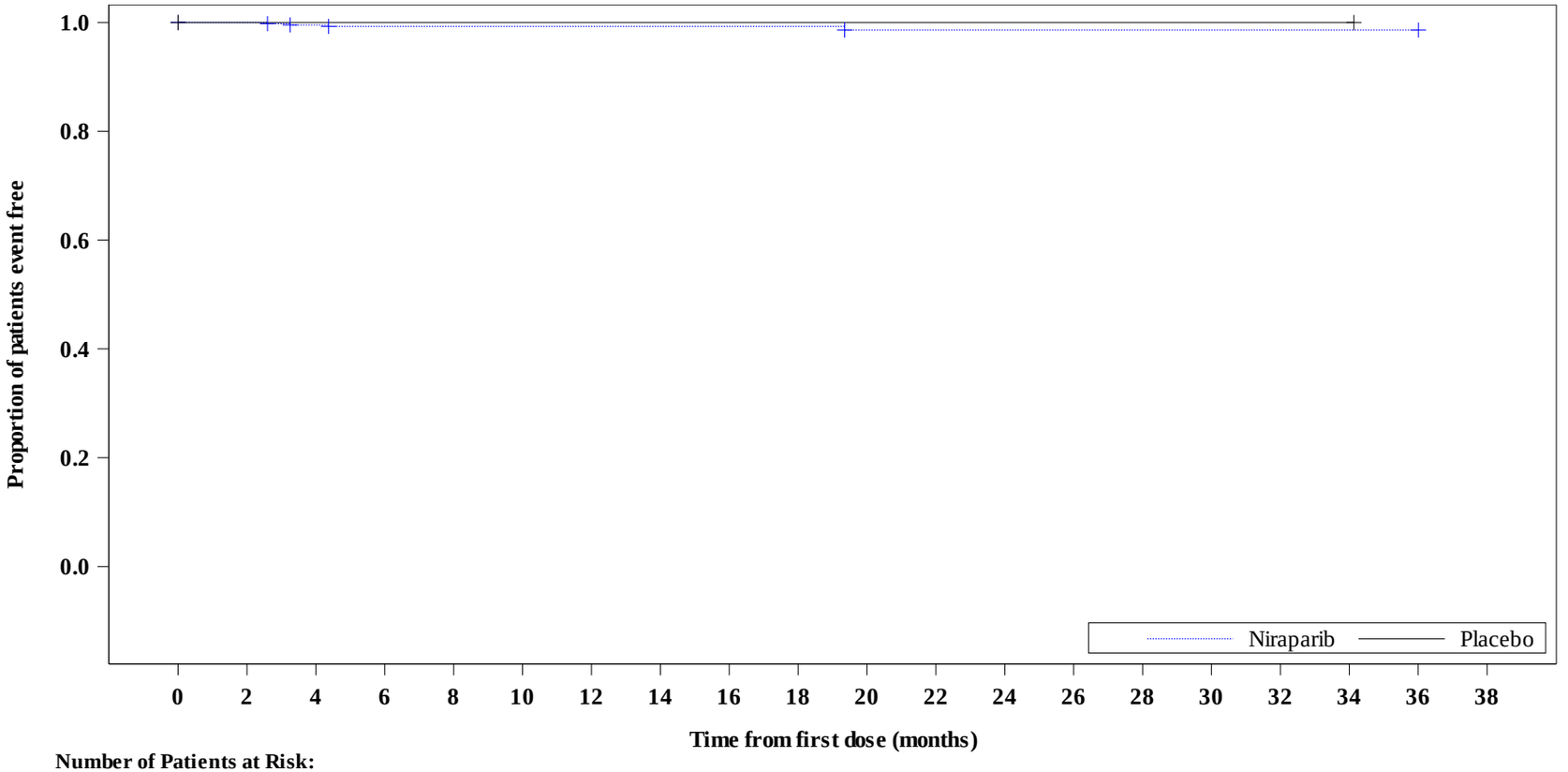

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 91 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 108 | 97 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Pneumonitis



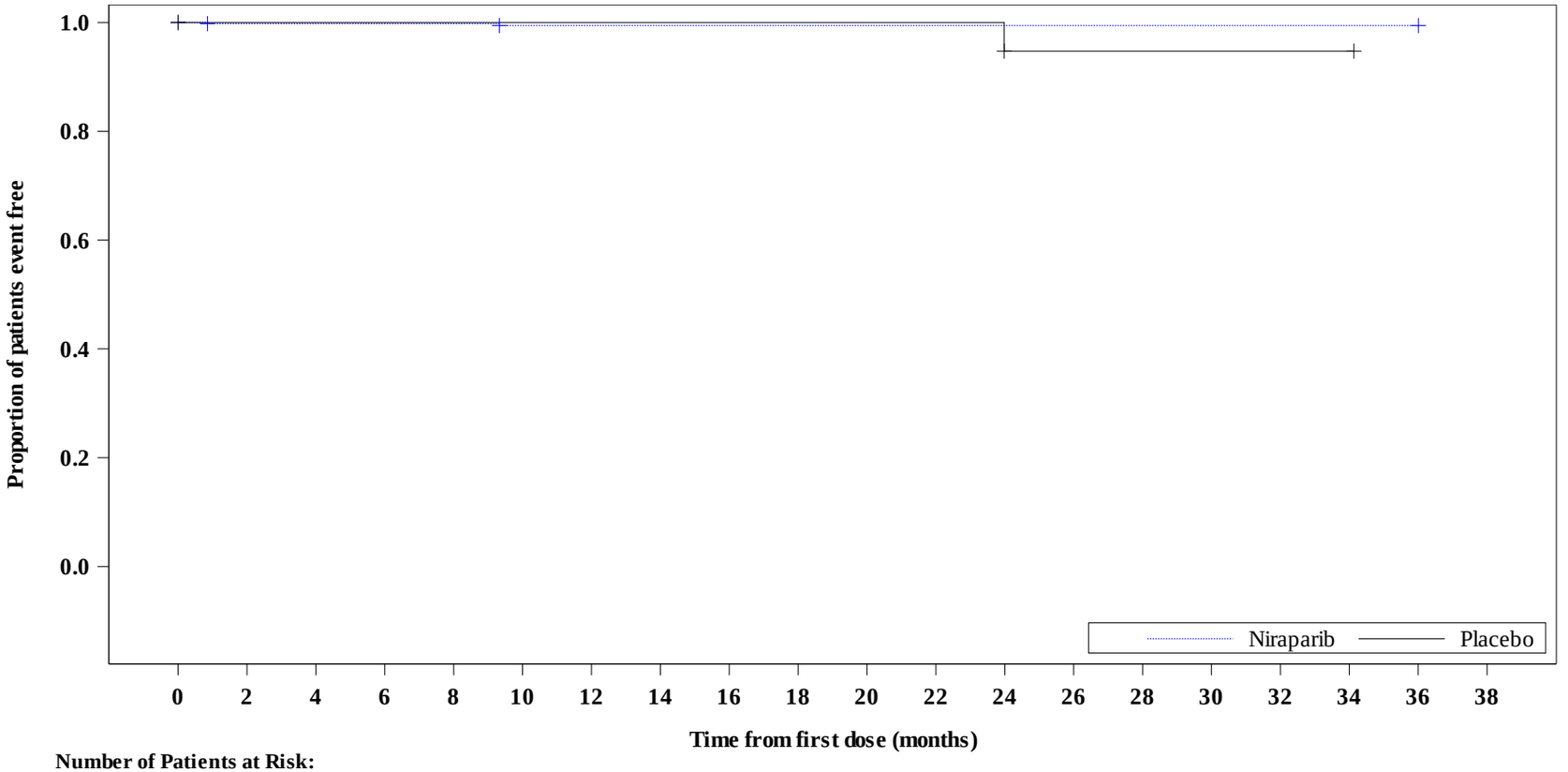

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 390 | 355 | 298 | 265 | 248 | 225 | 191 | 168 | 128 | 90 | 62 | 34 | 21 | 12 | 8 | 4 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Pancytopenia



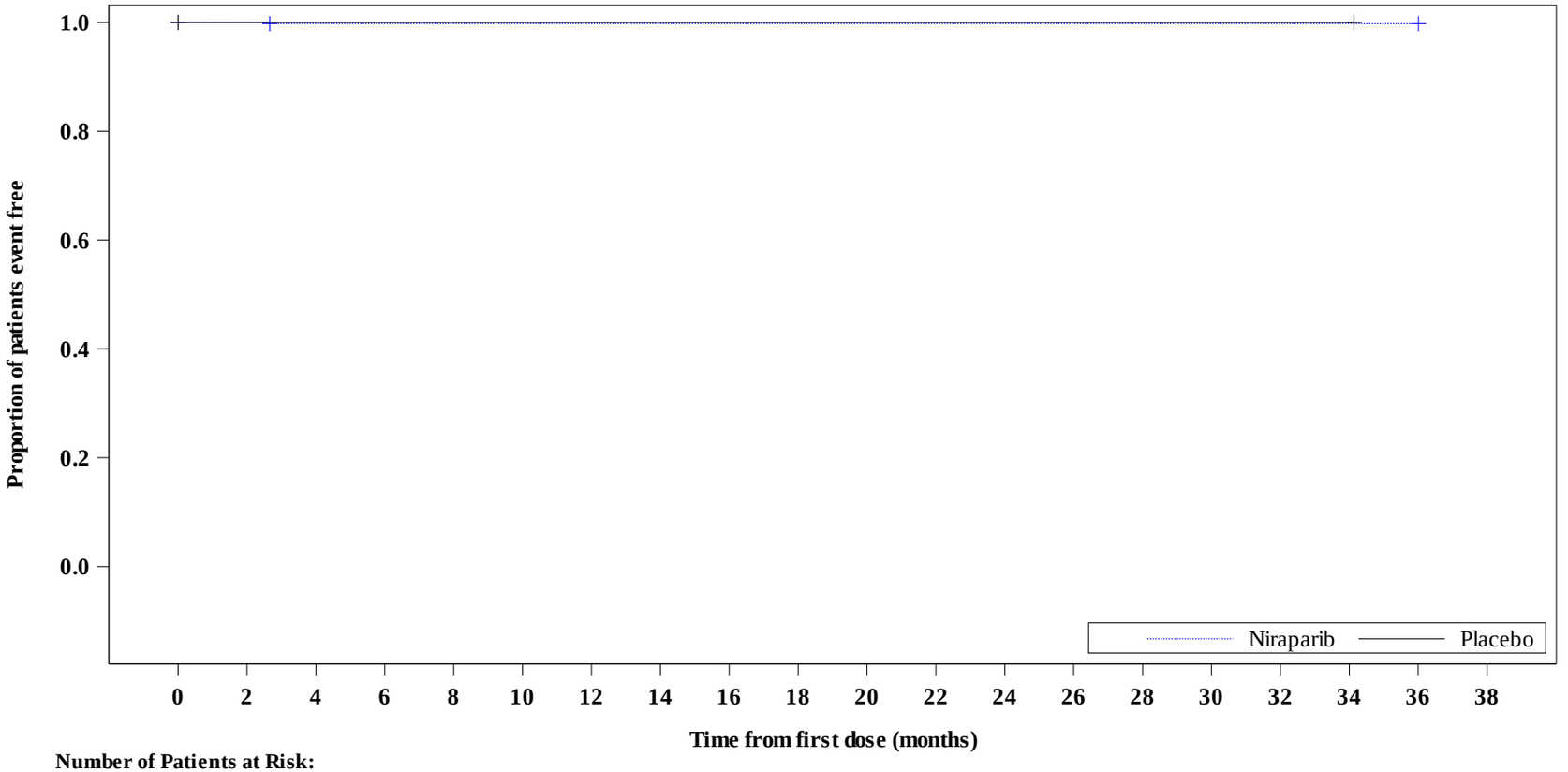

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 449 | 390 | 356 | 298 | 265 | 248 | 225 | 191 | 168 | 129 | 91 | 62 | 34 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 184 | 147 | 110 | 99 | 87 | 75 | 66 | 55 | 34 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Thromboemblic



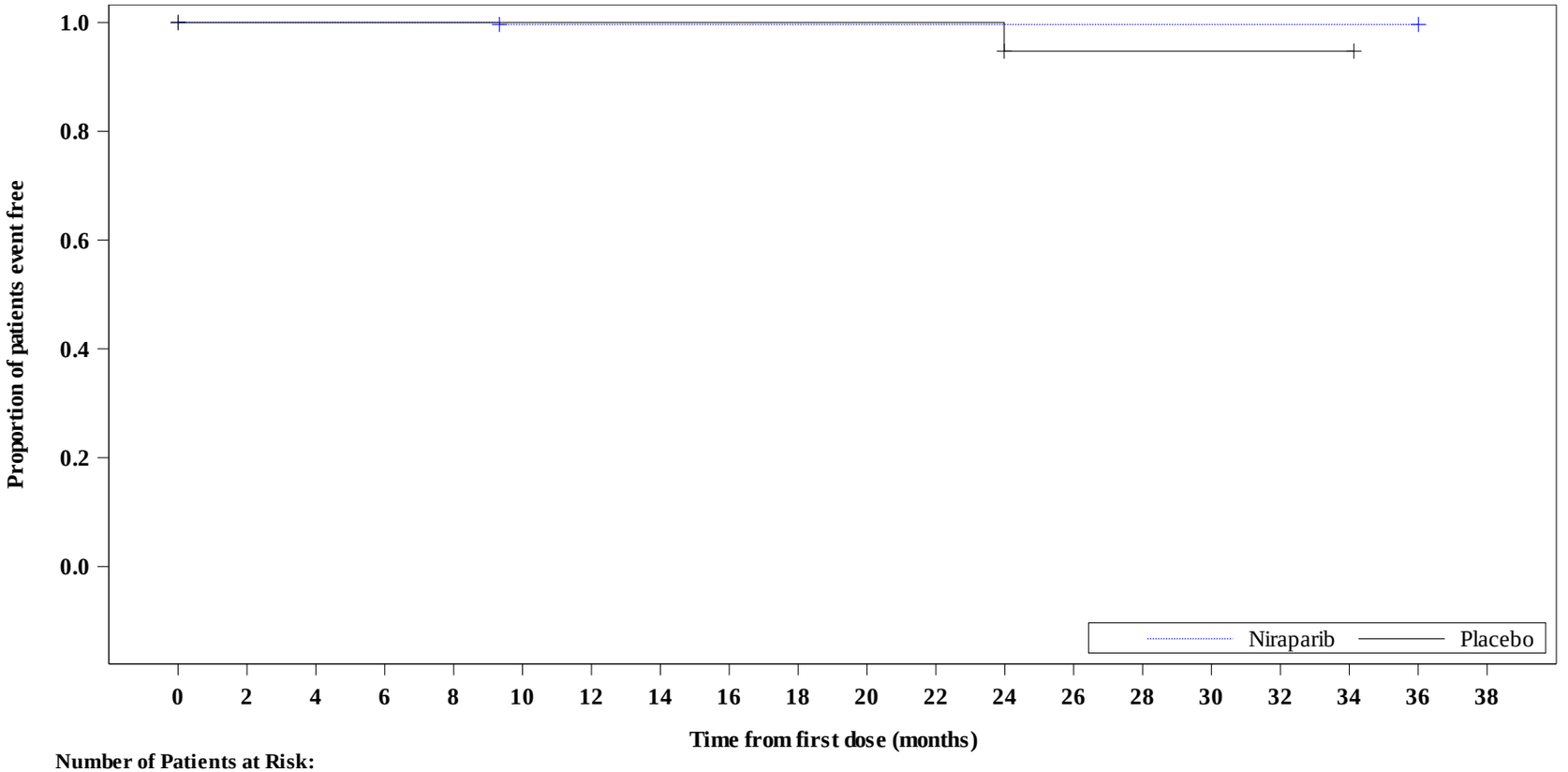

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 390 | 356 | 298 | 265 | 248 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

MDS/AML



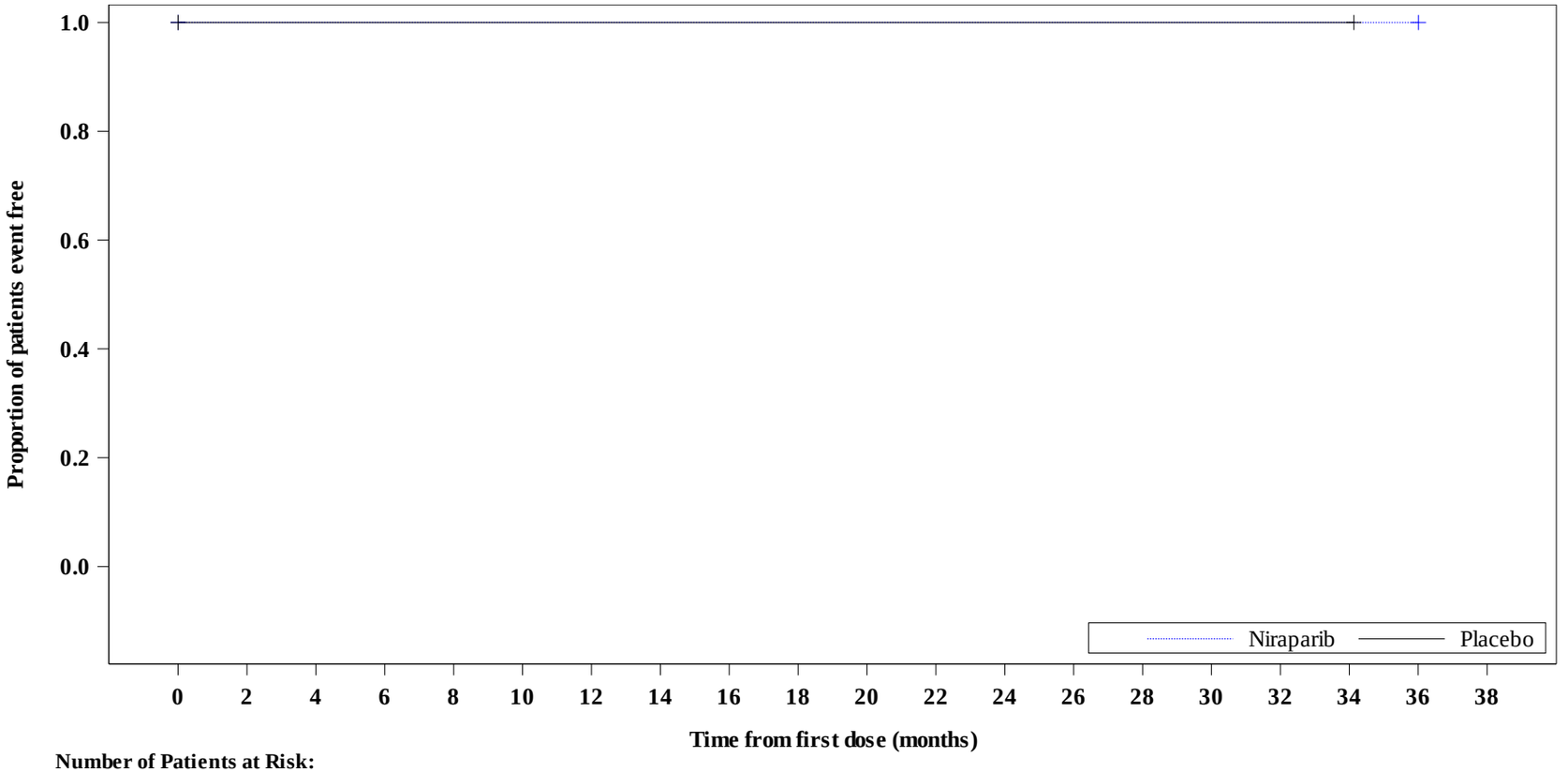

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 184 | 147 | 110 | 99 | 87 | 75 | 66 | 55 | 34 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.125

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety Population)

Embryo-fetal toxicity

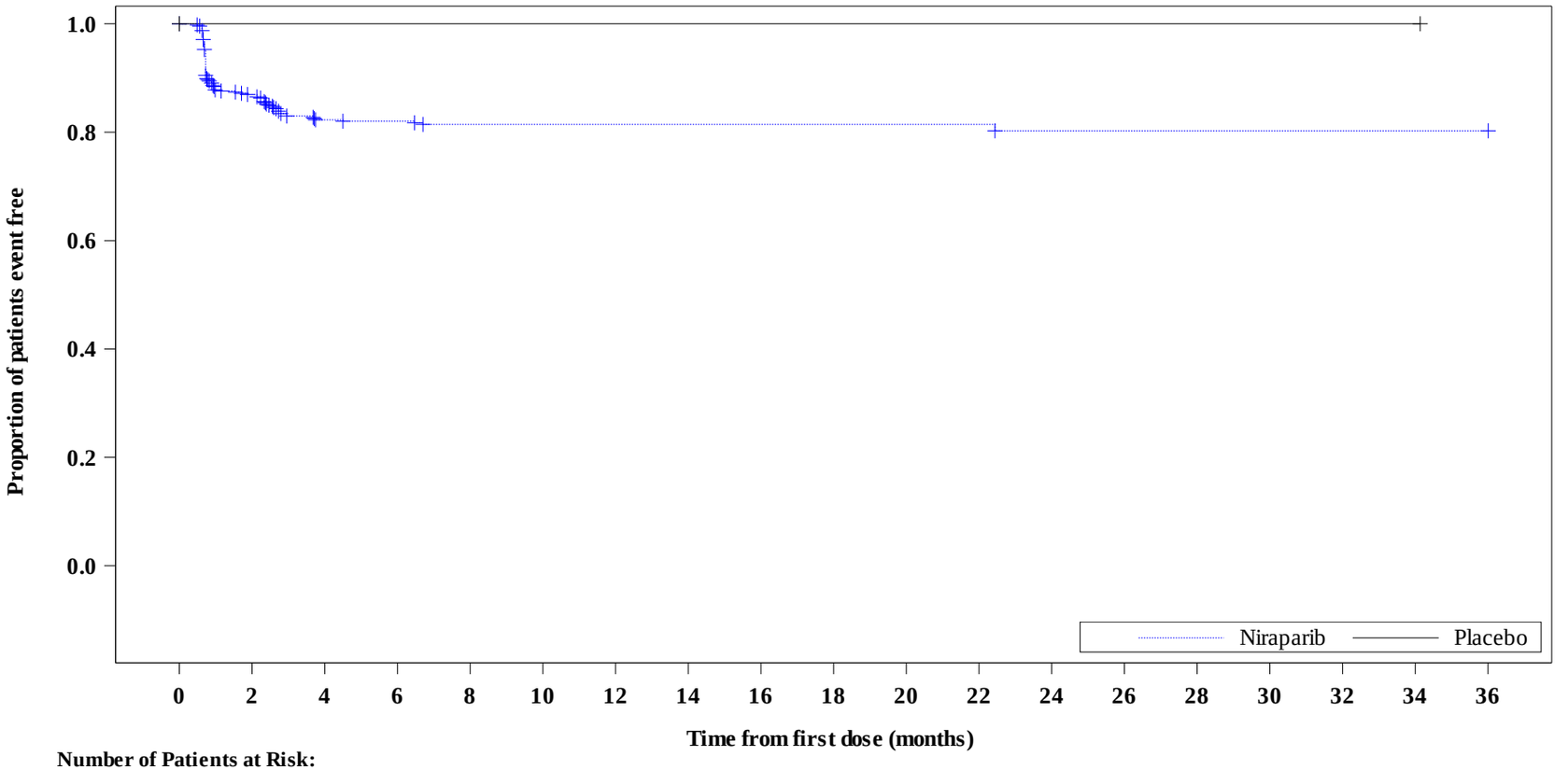



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 | 0 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 | |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)
SOC: Blood and lymphatic system disorders



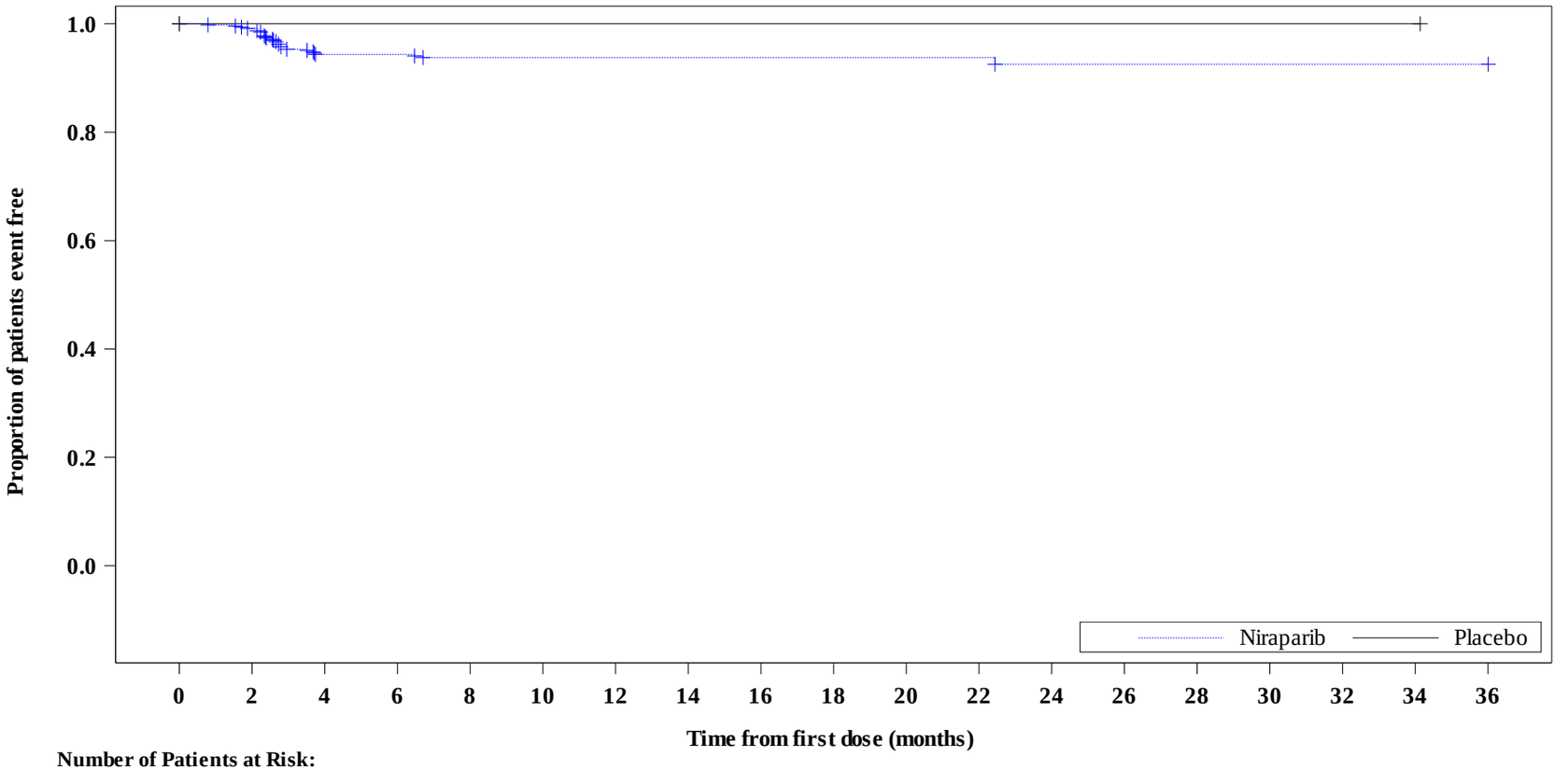

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 399 | 330 | 300 | 253 | 222 | 206 | 188 | 158 | 139 | 109 | 78 | 55 | 29 | 18 | 9 | 6 | 4 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia



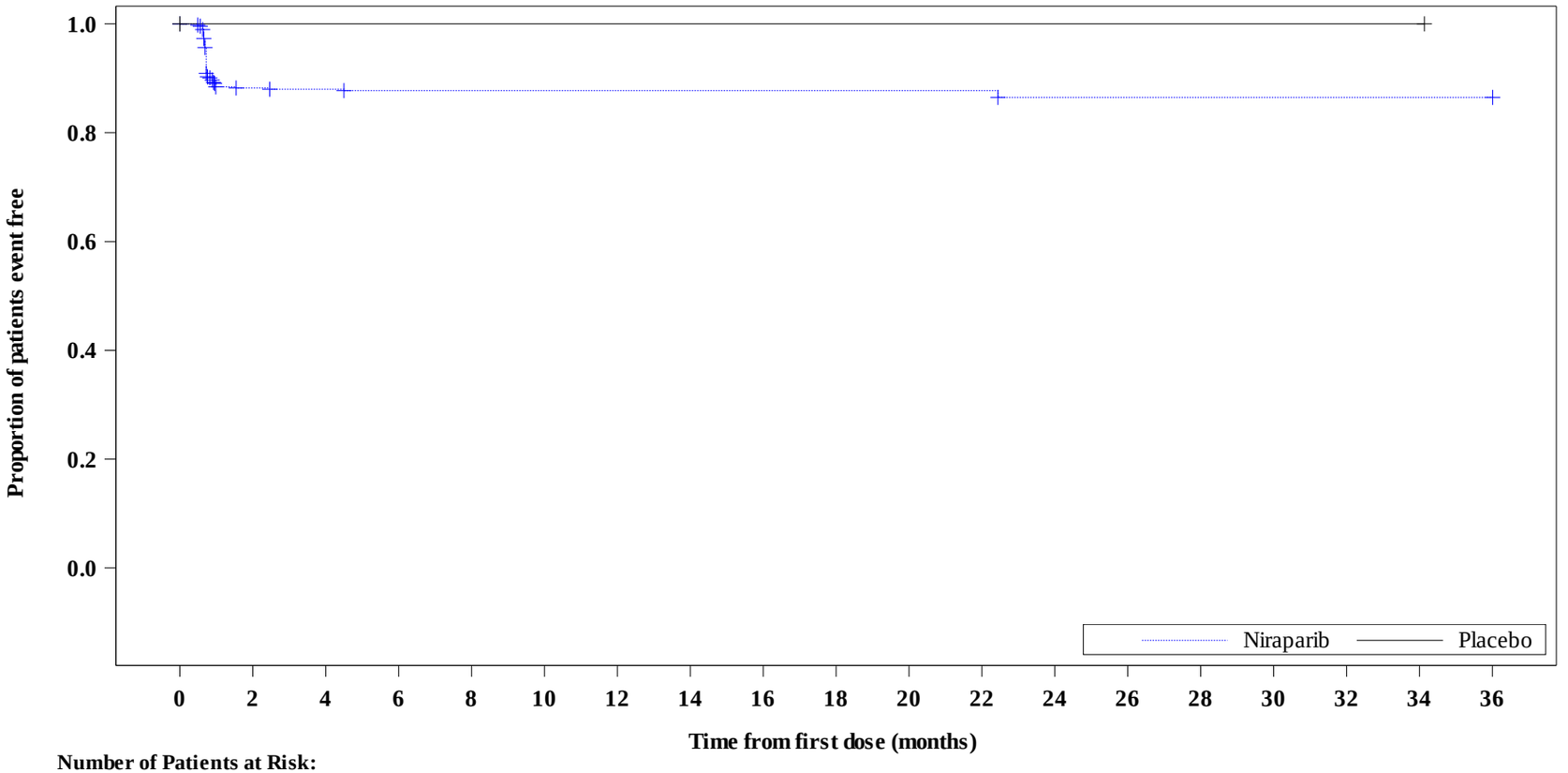

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 372 | 339 | 281 | 248 | 231 | 211 | 179 | 157 | 124 | 88 | 61 | 34 | 21 | 12 | 8 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

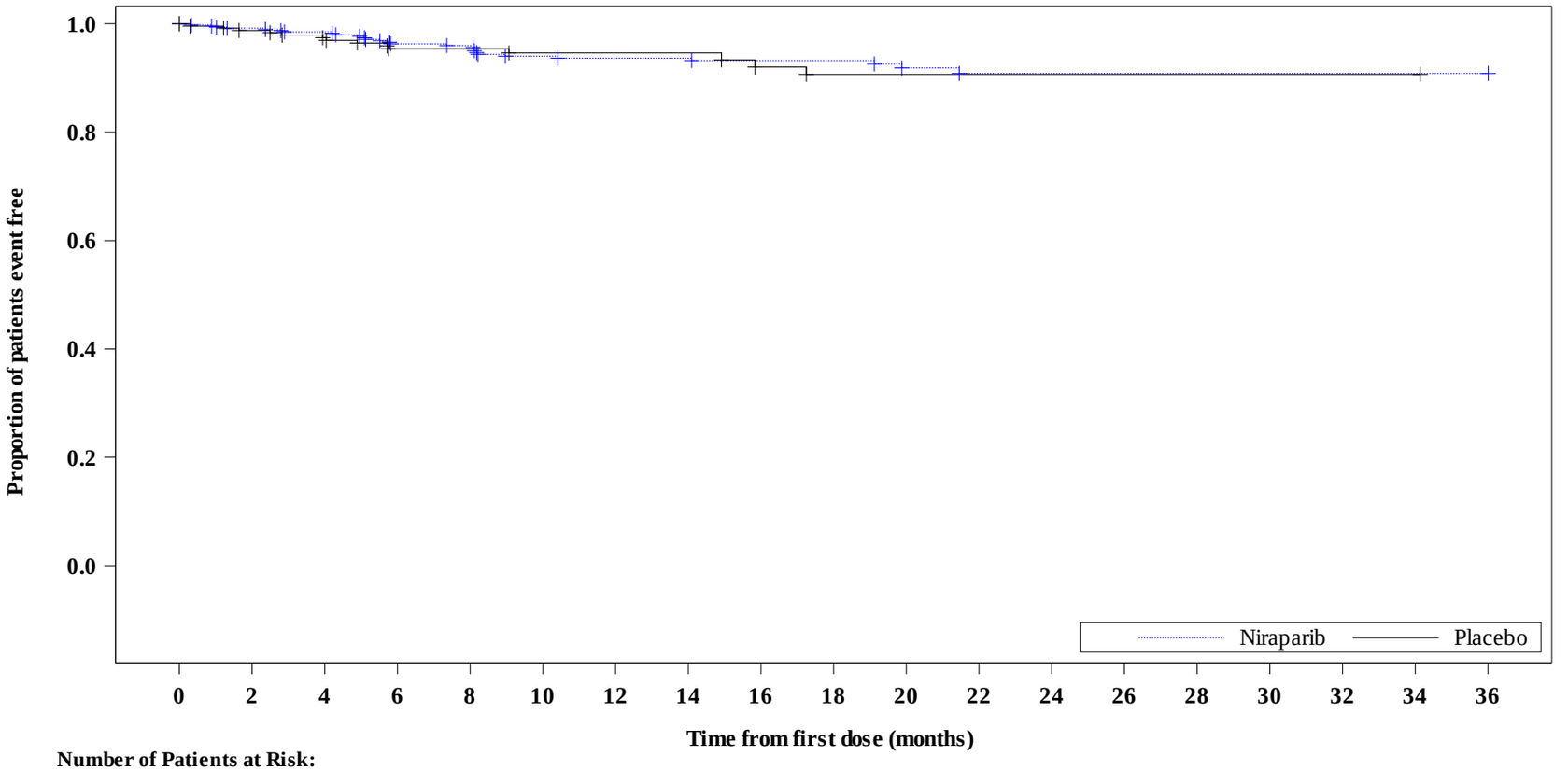



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 405 | 350 | 318 | 270 | 239 | 223 | 202 | 170 | 150 | 114 | 81 | 56 | 29 | 18 | 9 | 6 | 4 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)
SOC: Gastrointestinal disorders



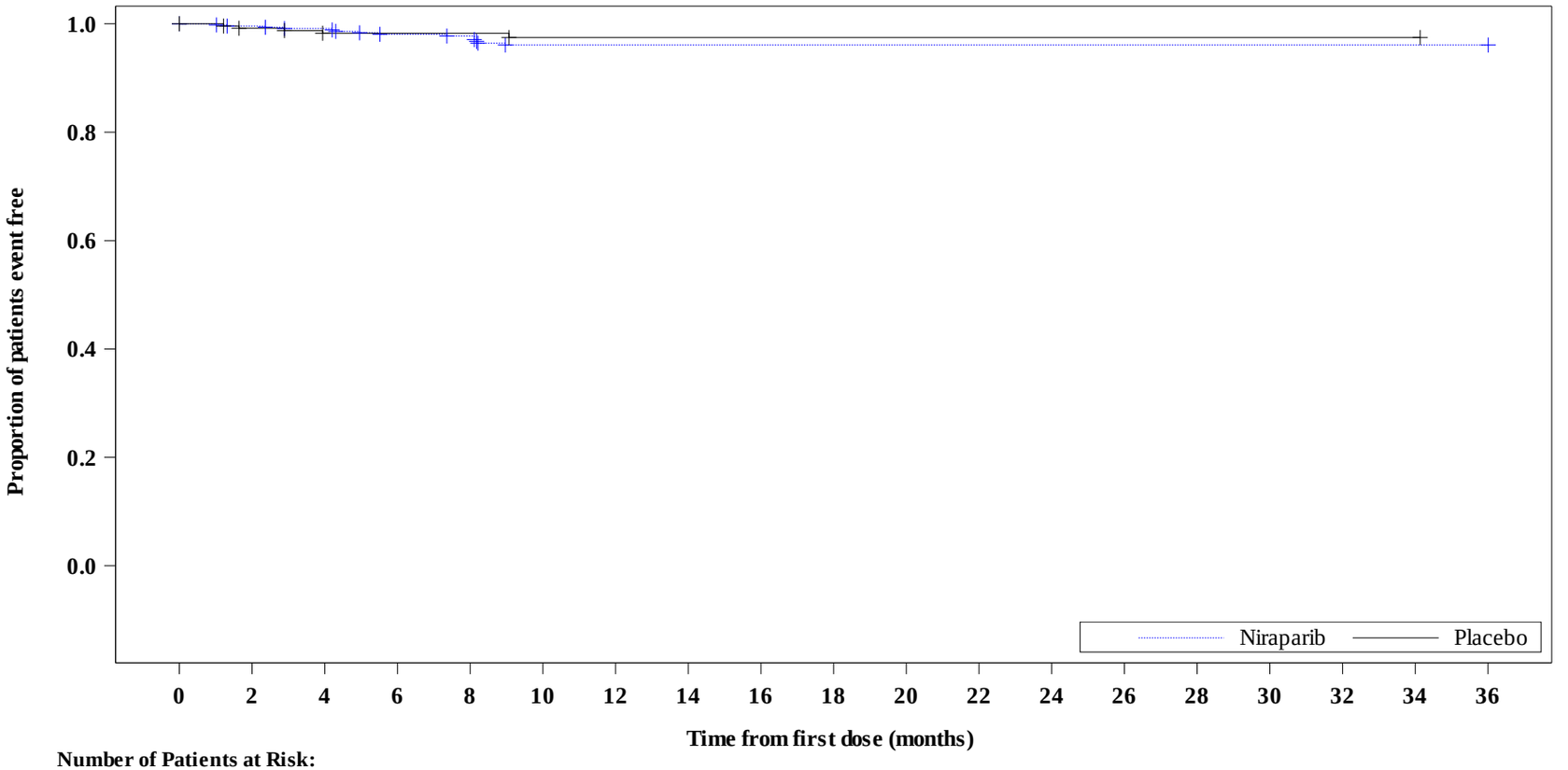

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 446 | 385 | 345 | 292 | 260 | 244 | 221 | 187 | 164 | 123 | 87 | 59 | 33 | 21 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 238 | 203 | 178 | 143 | 106 | 95 | 83 | 69 | 59 | 49 | 30 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction

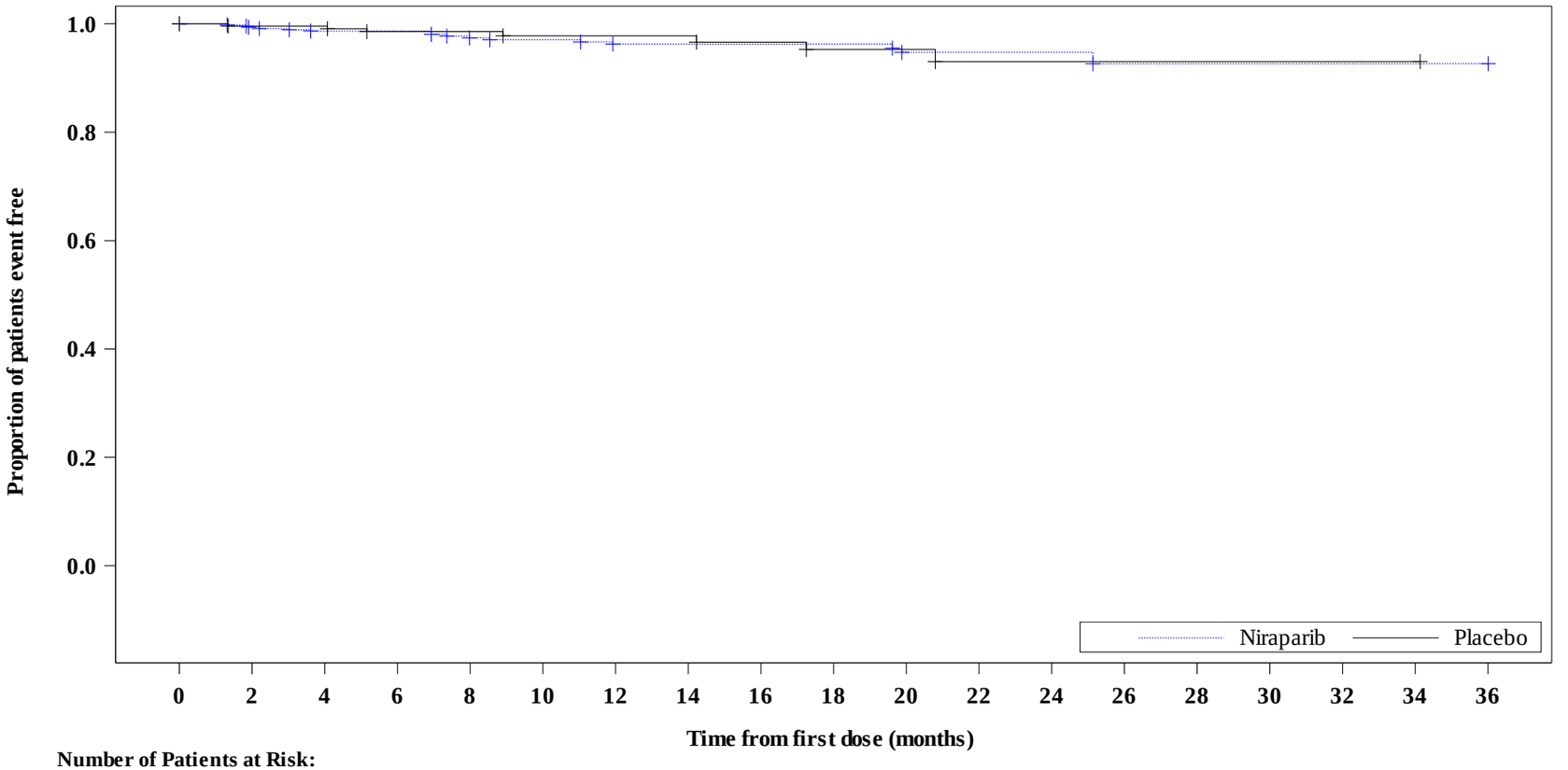



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 448 | 387 | 351 | 295 | 261 | 245 | 222 | 188 | 165 | 126 | 90 | 61 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 239 | 203 | 182 | 145 | 107 | 96 | 84 | 72 | 63 | 52 | 32 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)
SOC: Infections and infestations

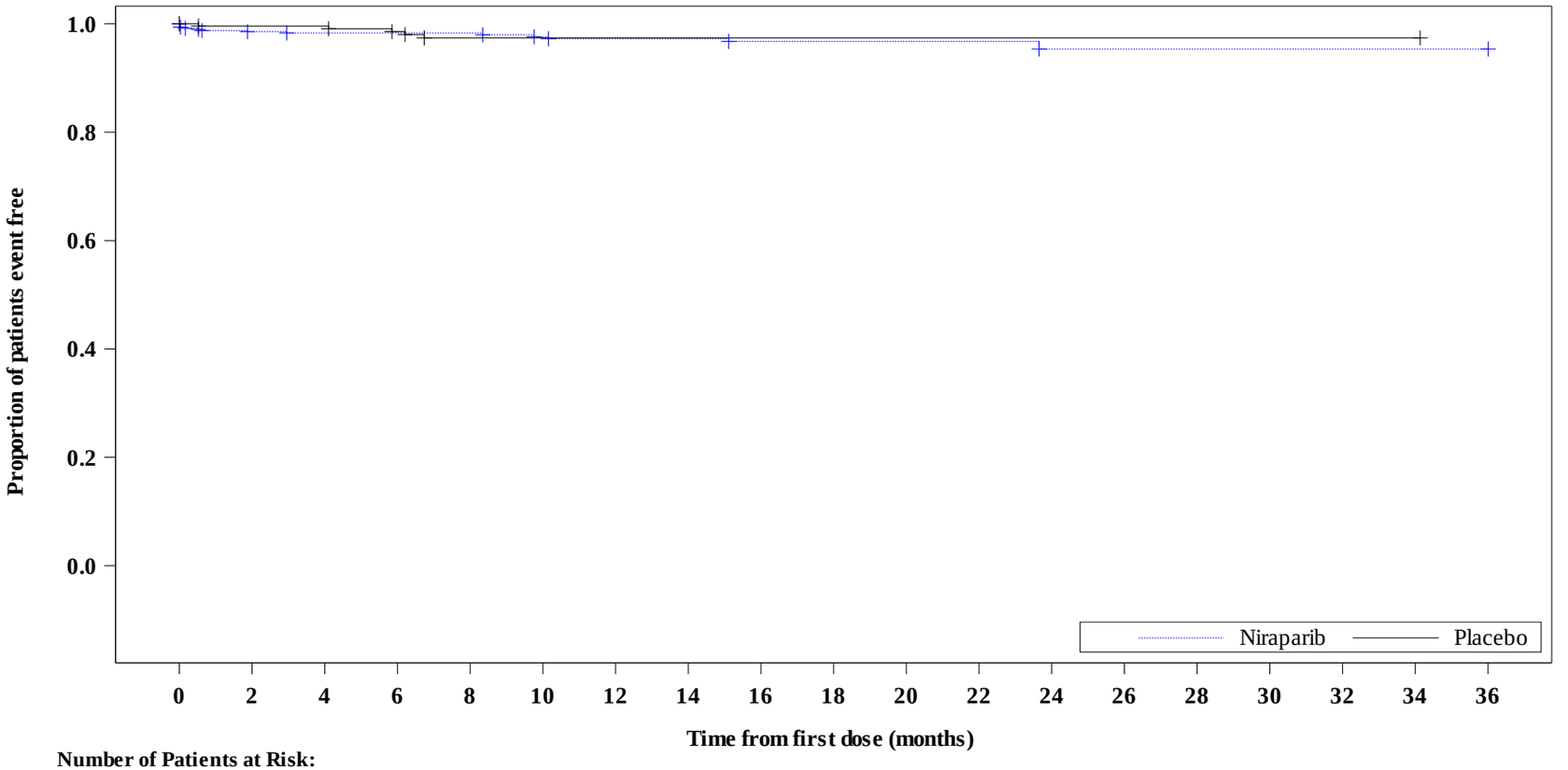



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 447 | 385 | 352 | 292 | 258 | 239 | 217 | 184 | 161 | 121 | 85 | 61 | 33 | 20 | 11 | 8 | 4 | 1 |
| Placebo | 244 | 240 | 204 | 180 | 144 | 107 | 96 | 84 | 72 | 63 | 52 | 30 | 16 | 10 | 6 | 2 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)
SOC: Injury, poisoning and procedural complications



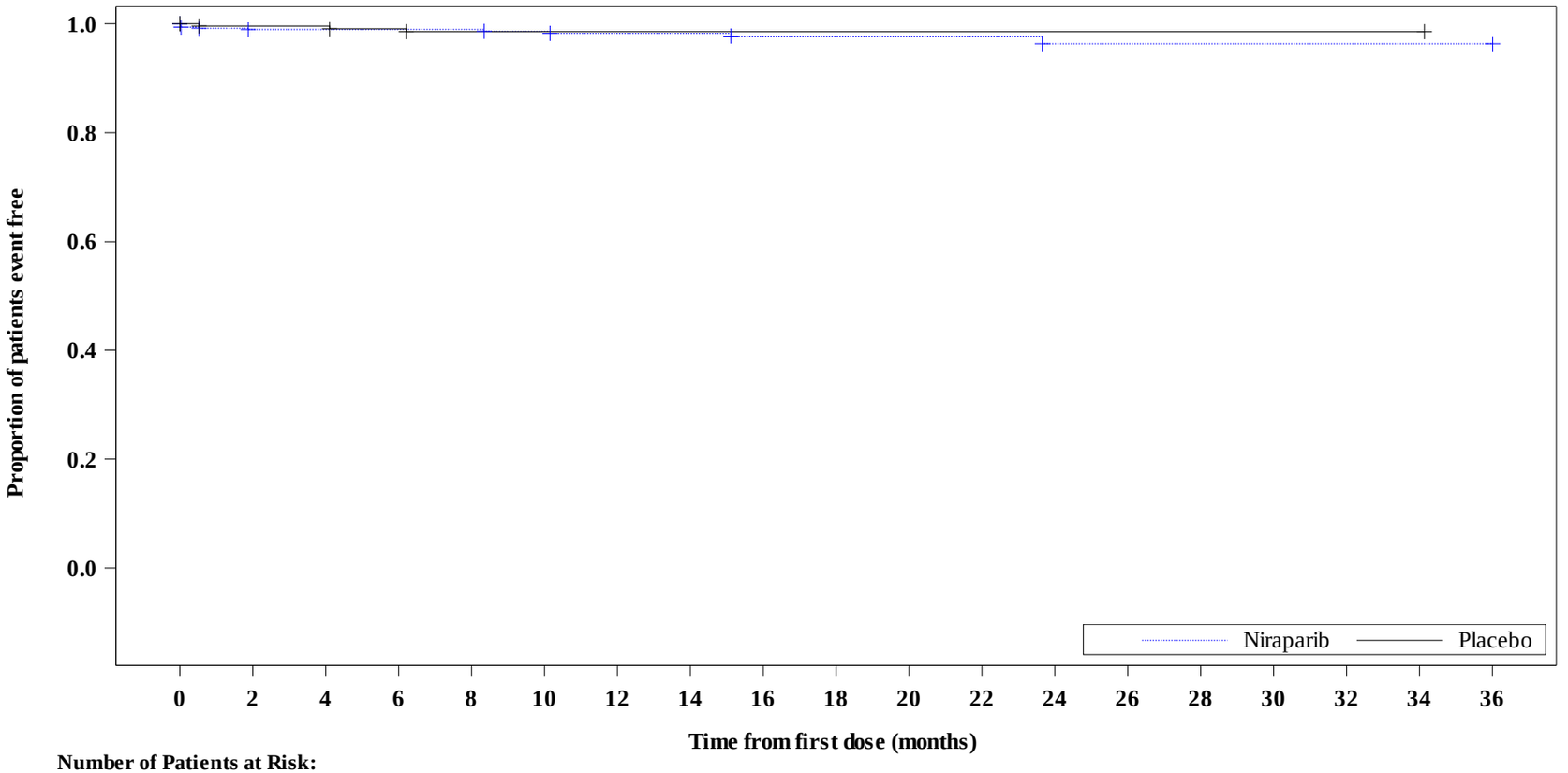

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 443 | 384 | 352 | 296 | 262 | 245 | 222 | 187 | 165 | 128 | 91 | 61 | 33 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 180 | 142 | 105 | 95 | 83 | 71 | 62 | 52 | 32 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Injury, poisoning and procedural complications, PT: Overdose

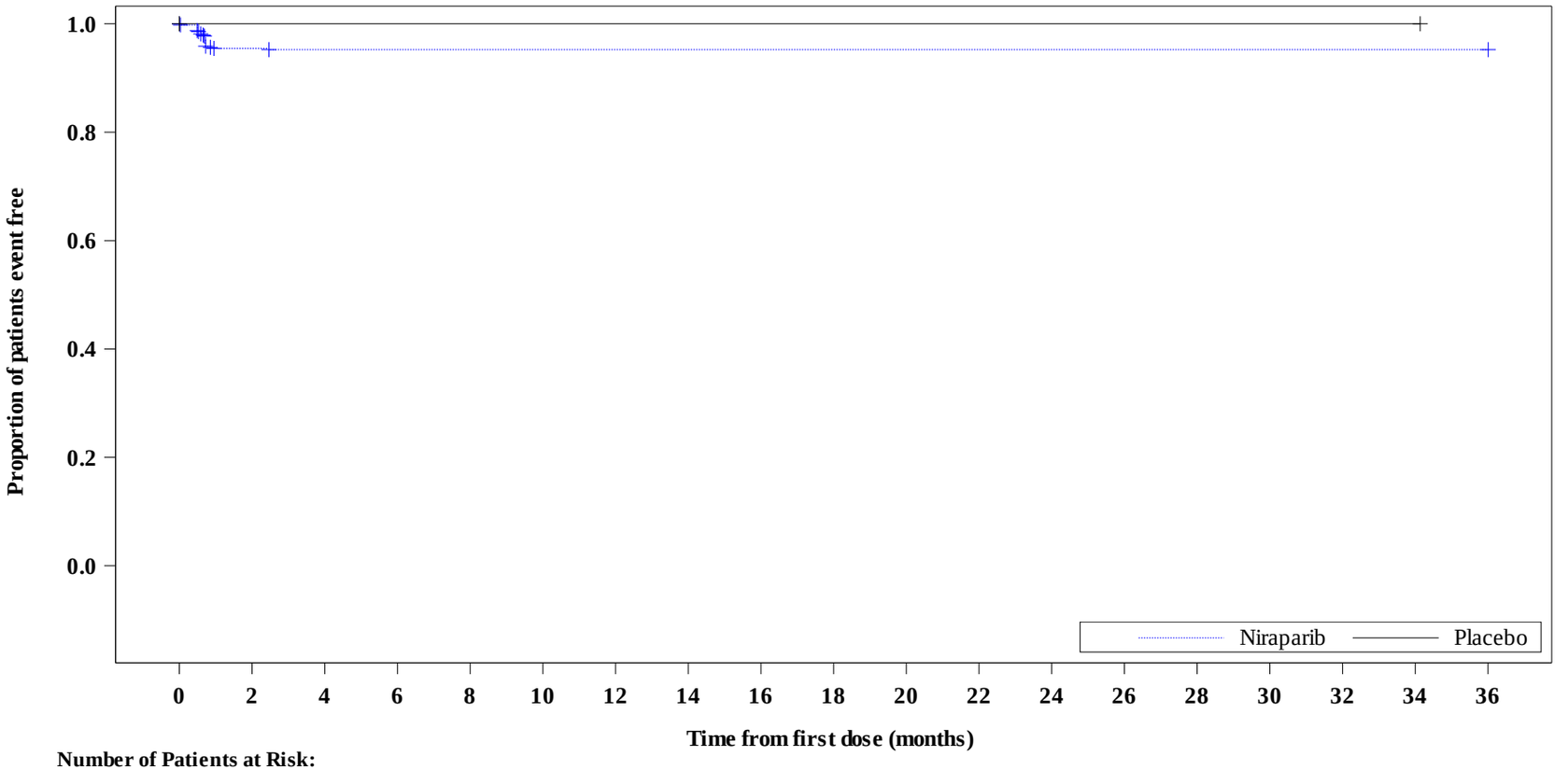



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 445 | 386 | 353 | 297 | 264 | 247 | 224 | 189 | 166 | 129 | 91 | 61 | 33 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 181 | 144 | 107 | 97 | 85 | 73 | 64 | 53 | 32 | 17 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)
SOC: Investigations



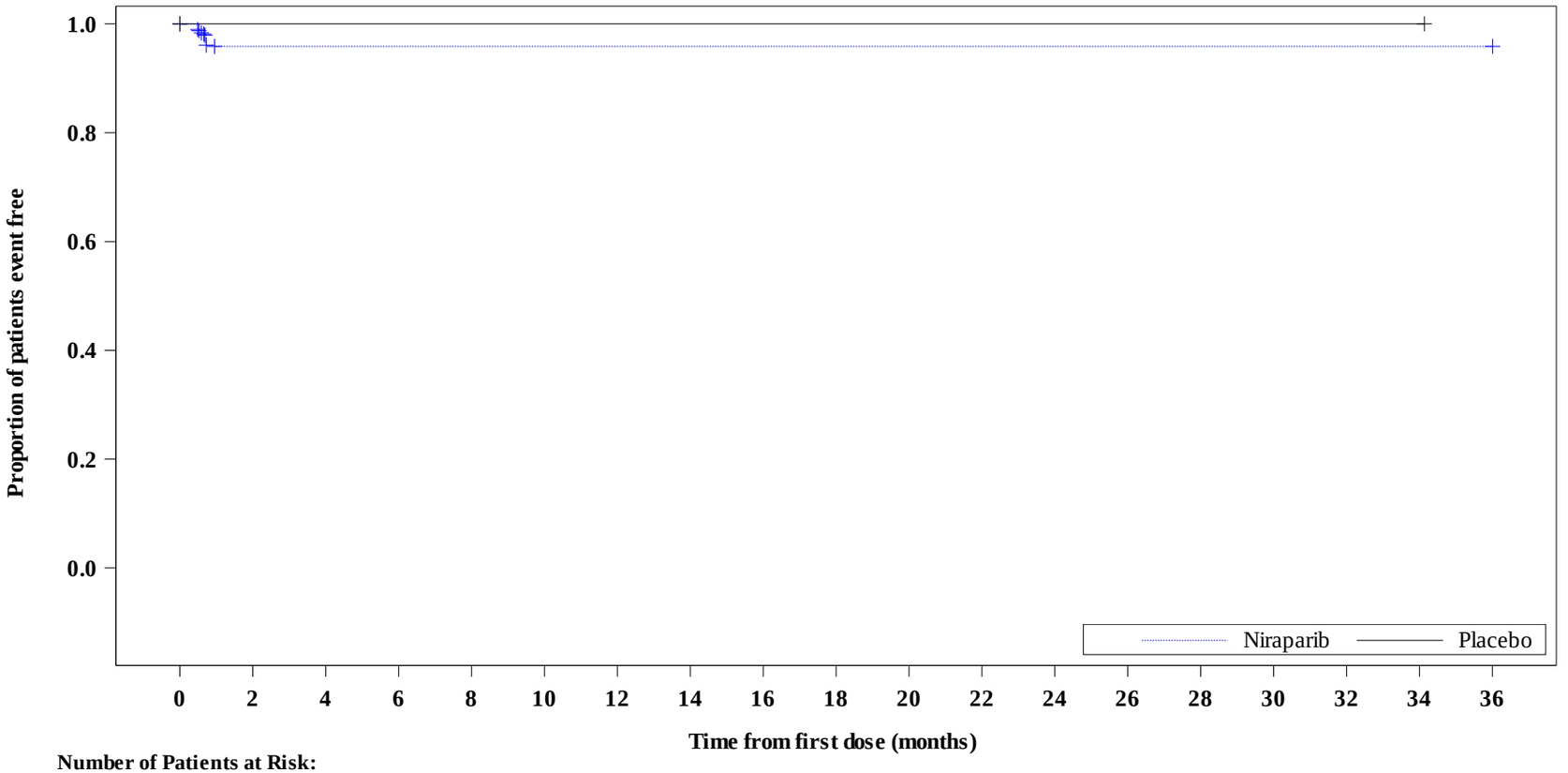

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 430 | 379 | 347 | 293 | 261 | 244 | 221 | 189 | 167 | 128 | 91 | 62 | 34 | 21 | 12 | 8 | 4 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety Population)

SOC: Investigations, PT: Platelet count decreased

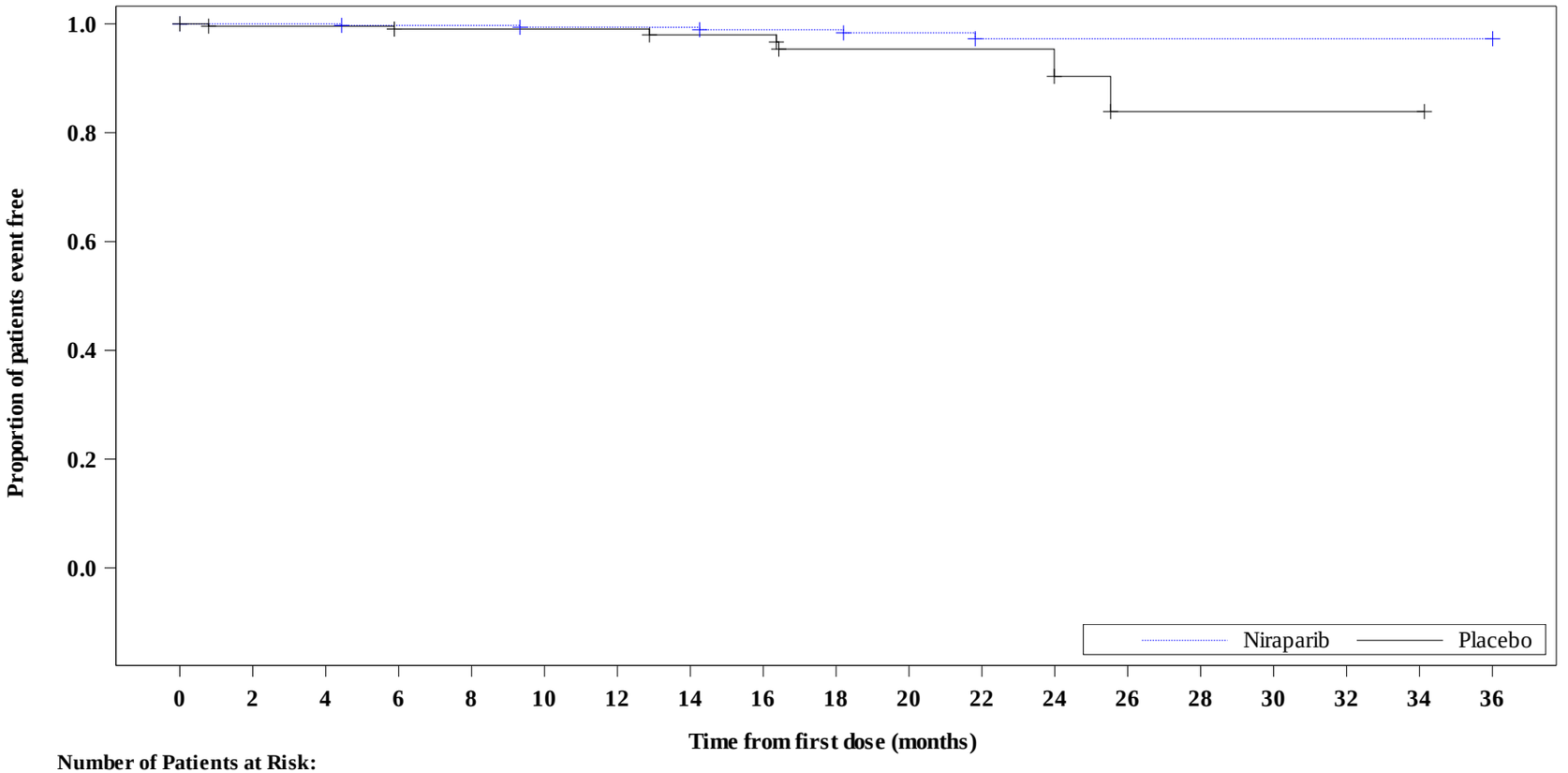



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 431 | 381 | 349 | 294 | 262 | 245 | 222 | 190 | 168 | 129 | 92 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 241 | 205 | 183 | 146 | 109 | 98 | 86 | 74 | 65 | 54 | 33 | 18 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.115

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety Population)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

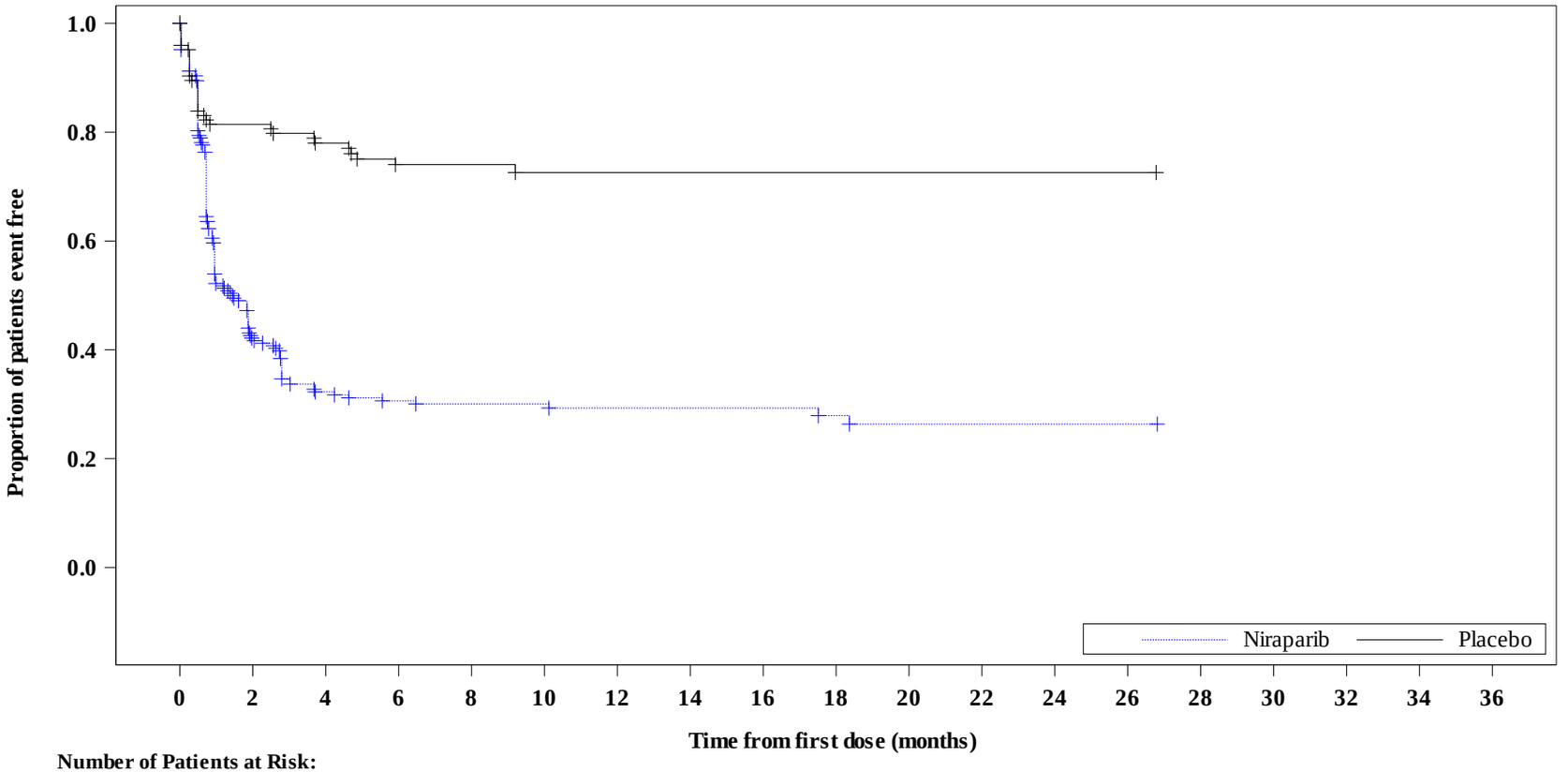



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 484 | 450 | 391 | 357 | 299 | 266 | 249 | 226 | 192 | 169 | 130 | 91 | 63 | 35 | 22 | 13 | 9 | 5 | 1 |
| Placebo | 244 | 240 | 204 | 182 | 145 | 109 | 98 | 86 | 75 | 66 | 55 | 34 | 18 | 11 | 7 | 3 | 2 | 1 | 0 |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Blood and lymphatic system disorders

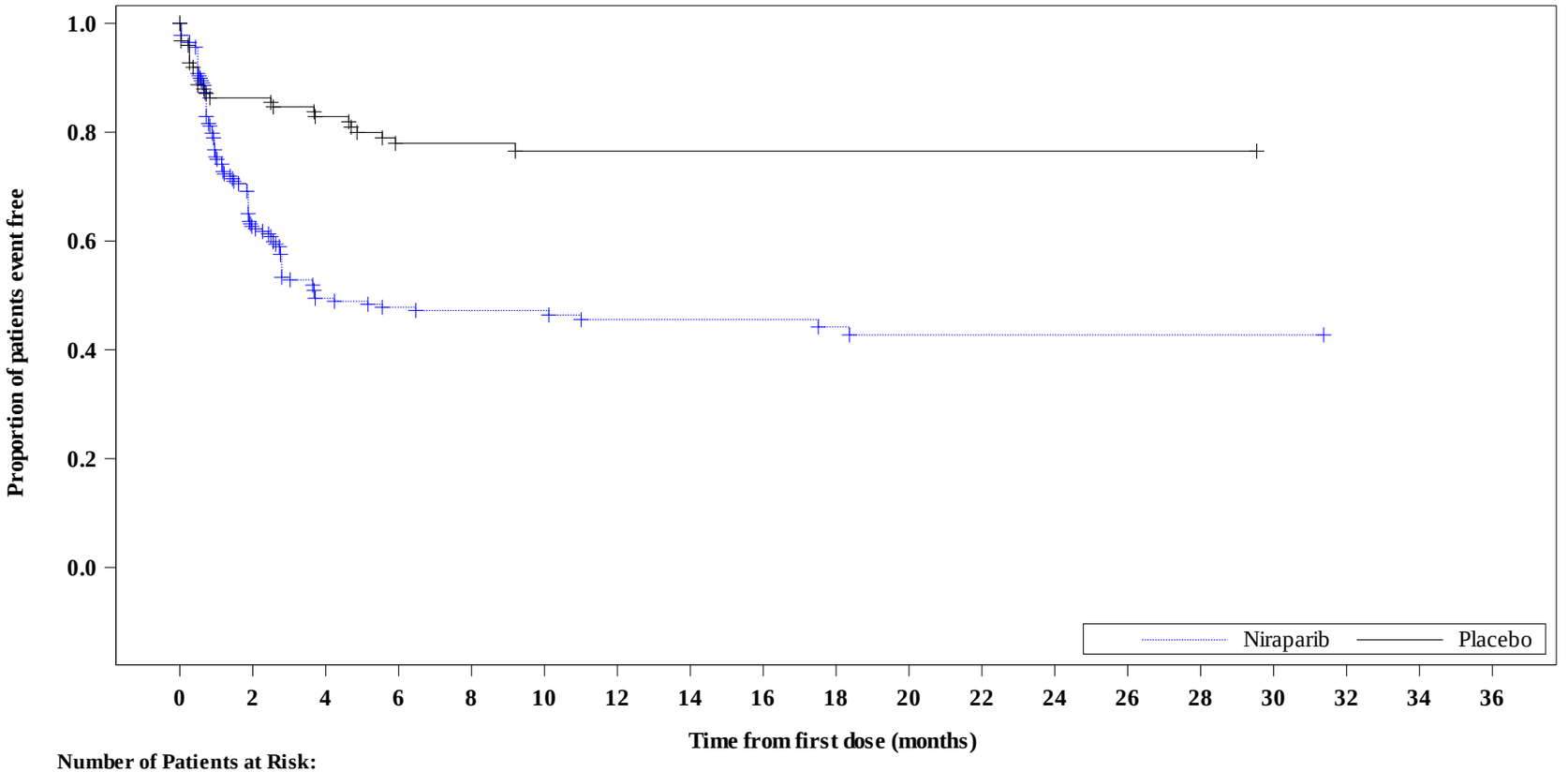



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 90 | 61 | 55 | 43 | 39 | 34 | 31 | 25 | 18 | 16 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 99 | 85 | 72 | 60 | 41 | 35 | 28 | 23 | 21 | 13 | 6 | 3 | 1 | 0 |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia

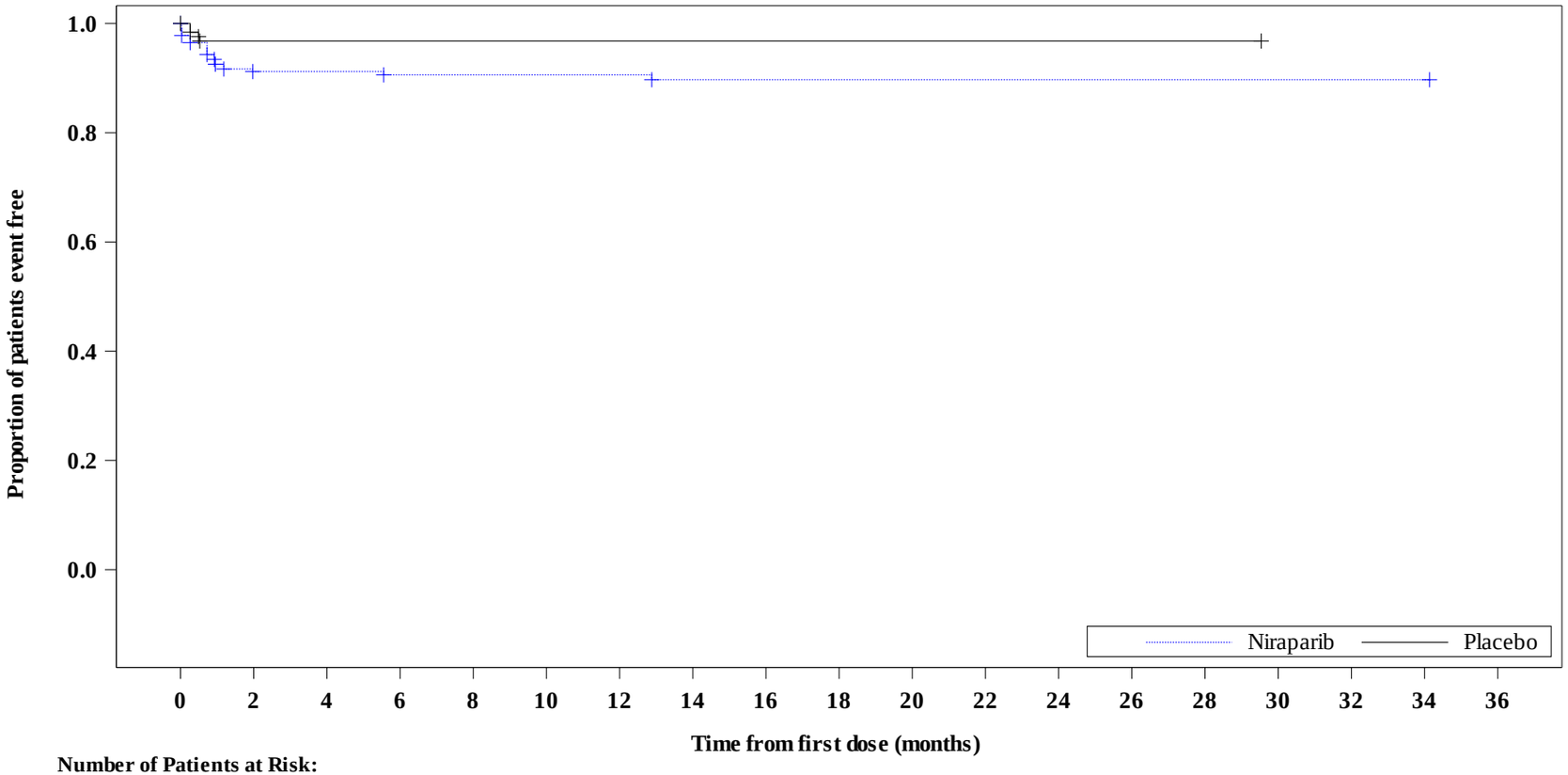



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 134 | 95 | 84 | 65 | 57 | 51 | 47 | 39 | 30 | 24 | 7 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 105 | 91 | 77 | 64 | 45 | 39 | 32 | 27 | 24 | 16 | 7 | 4 | 2 | 1 | 0 | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Leukopenia

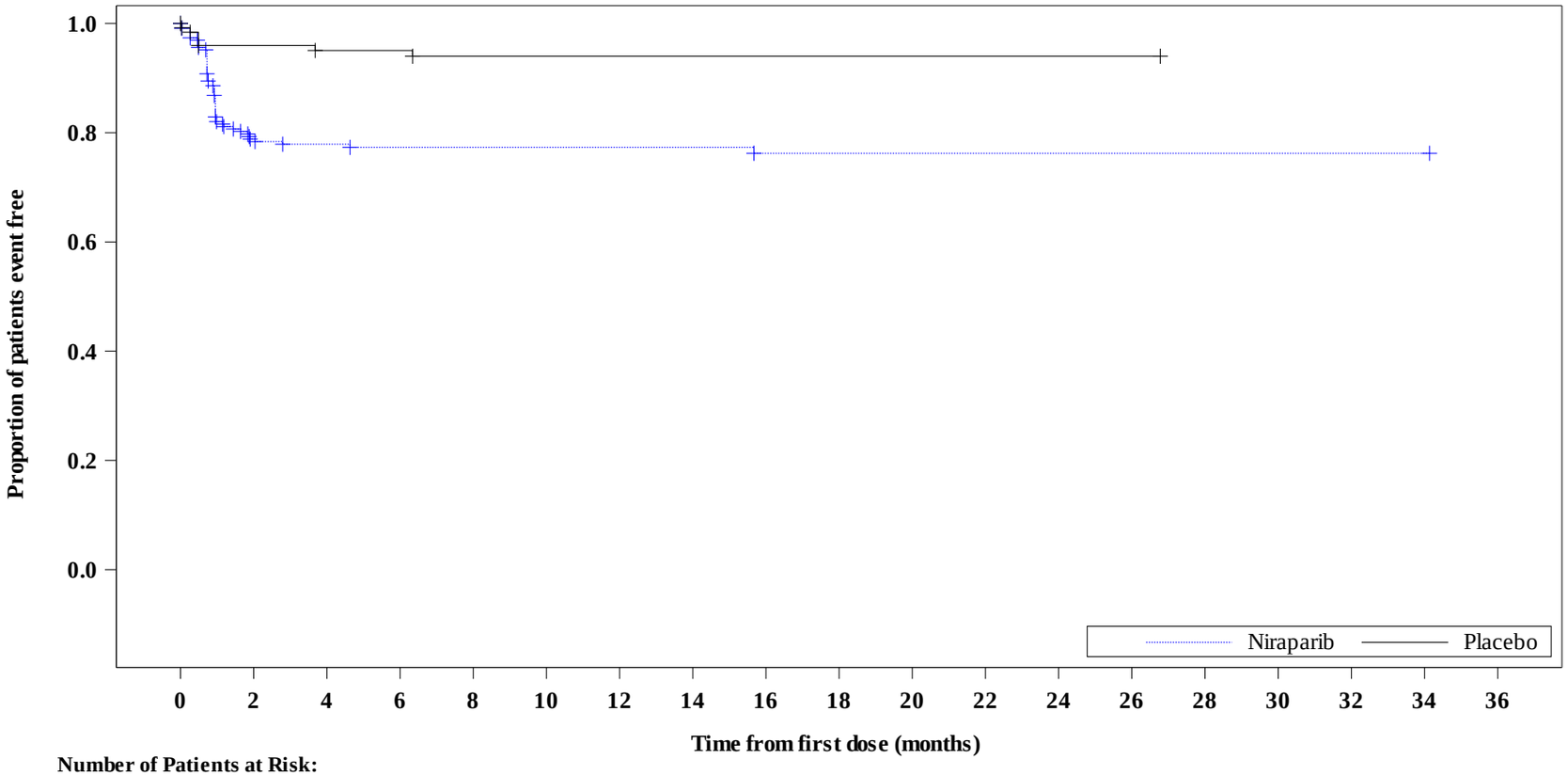



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 194 | 169 | 151 | 128 | 114 | 106 | 96 | 82 | 71 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 118 | 104 | 95 | 76 | 54 | 47 | 39 | 32 | 27 | 18 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Neutropenia

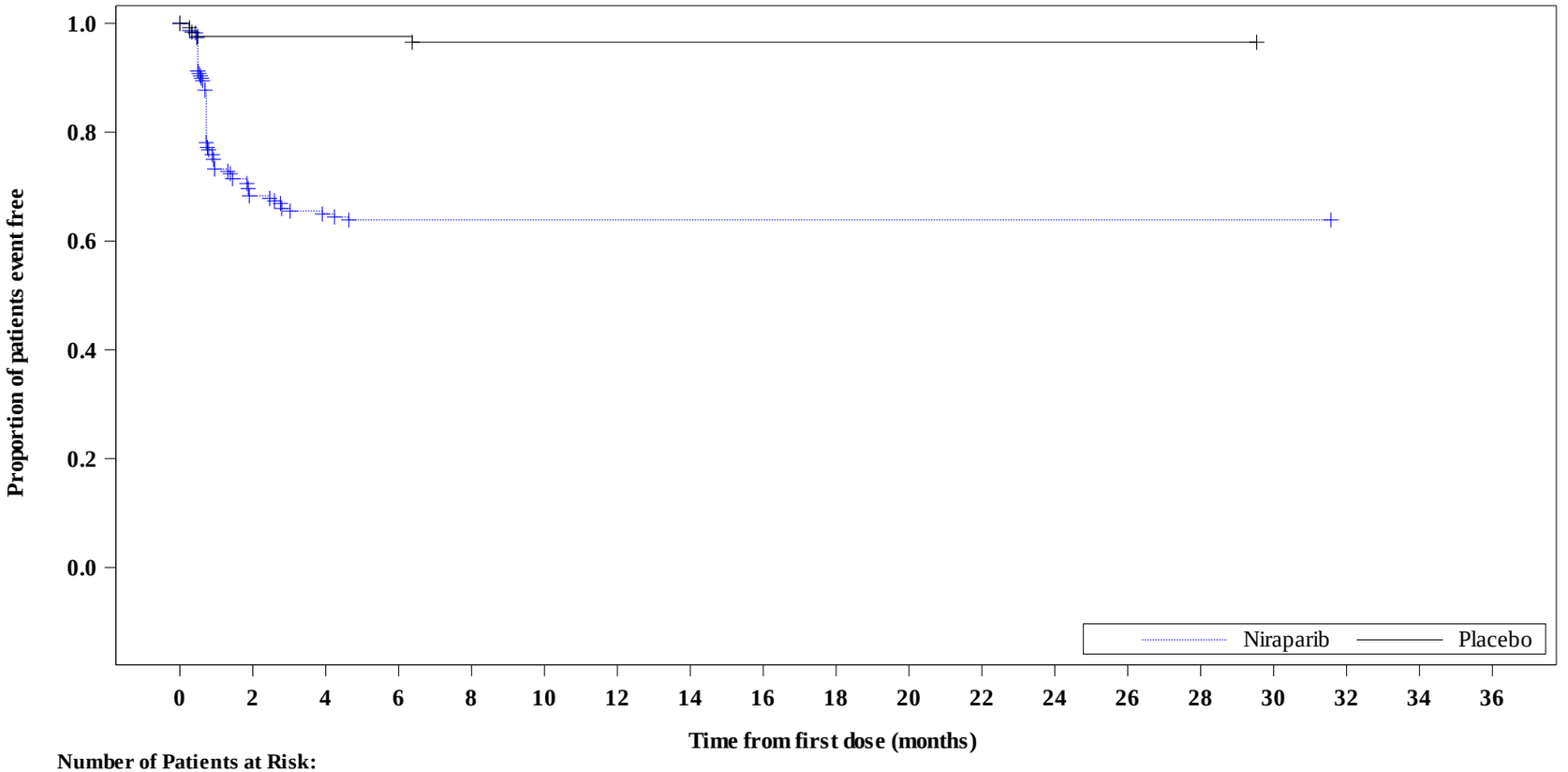



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 168 | 142 | 128 | 108 | 97 | 90 | 81 | 69 | 57 | 41 | 18 | 11 | 7 | 5 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 117 | 102 | 93 | 75 | 53 | 46 | 38 | 32 | 27 | 18 | 7 | 3 | 1 | 0 | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

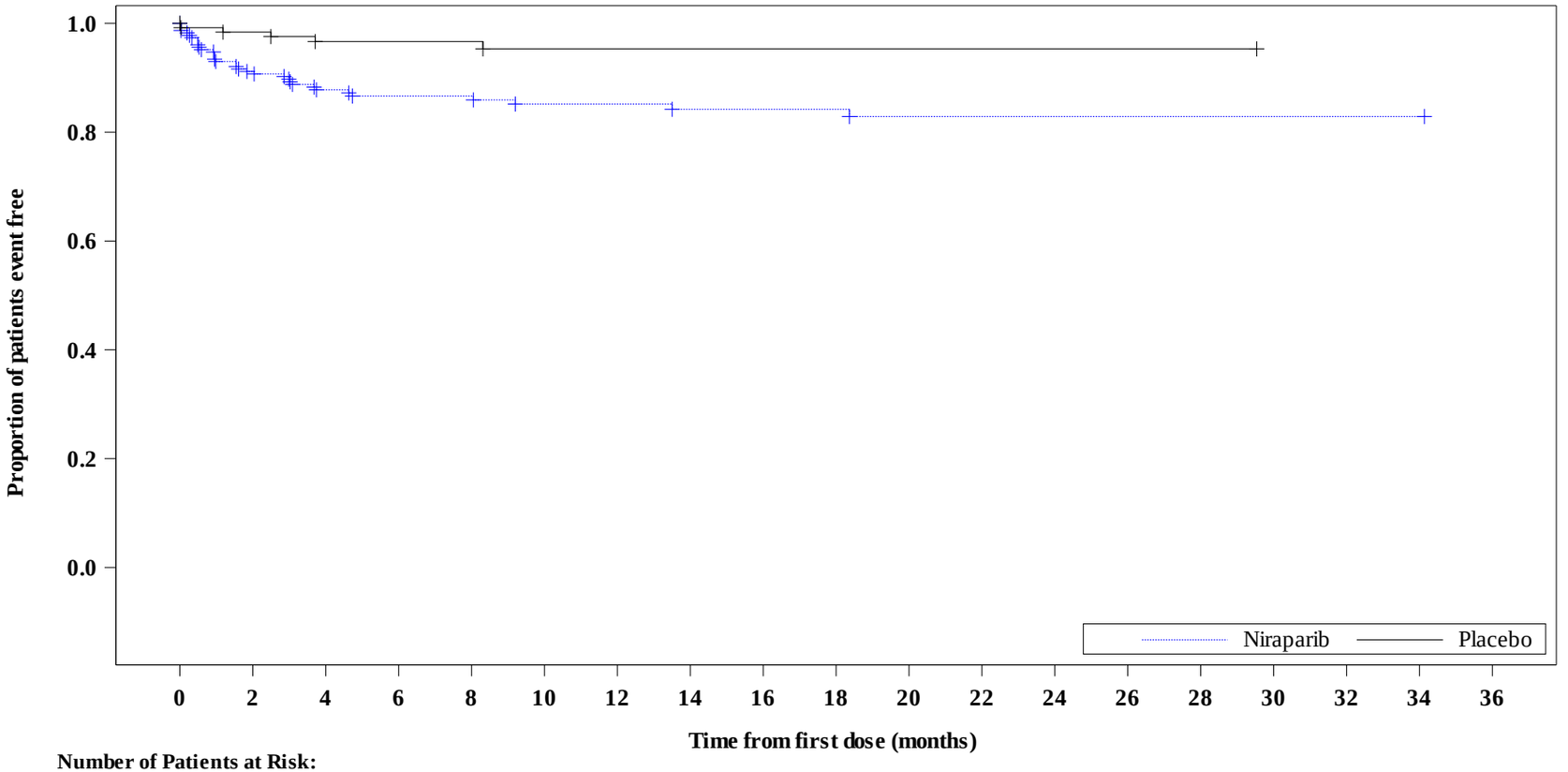



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 149 | 120 | 110 | 91 | 82 | 77 | 69 | 58 | 48 | 35 | 15 | 7 | 4 | 3 | 2 | 0 |
| Placebo | 124 | 119 | 105 | 96 | 77 | 55 | 48 | 40 | 33 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Cardiac disorders

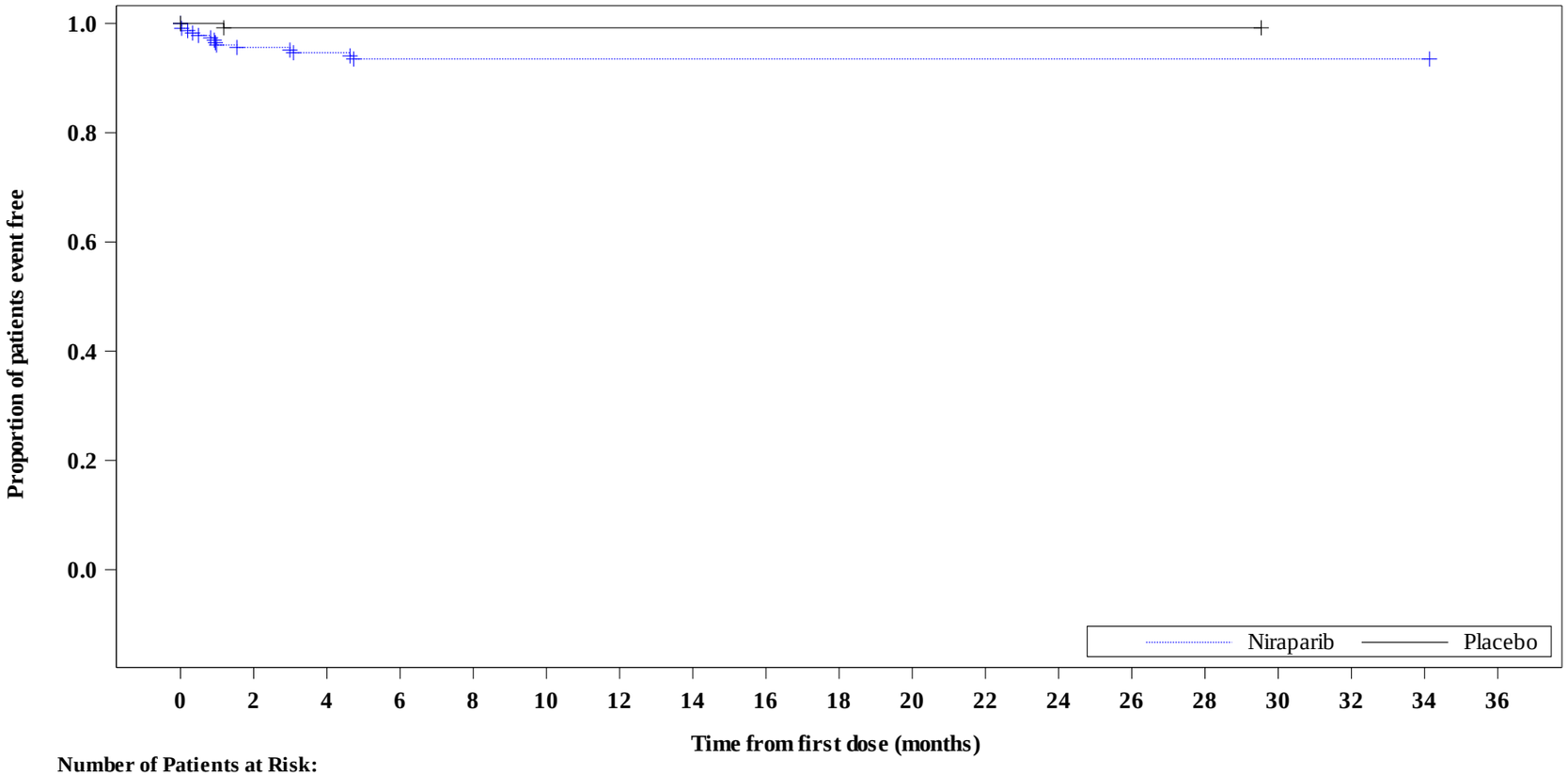



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 196 | 161 | 147 | 121 | 105 | 98 | 87 | 76 | 64 | 38 | 18 | 11 | 7 | 5 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 104 | 96 | 76 | 54 | 47 | 39 | 33 | 28 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Cardiac disorders, PT: Palpitations

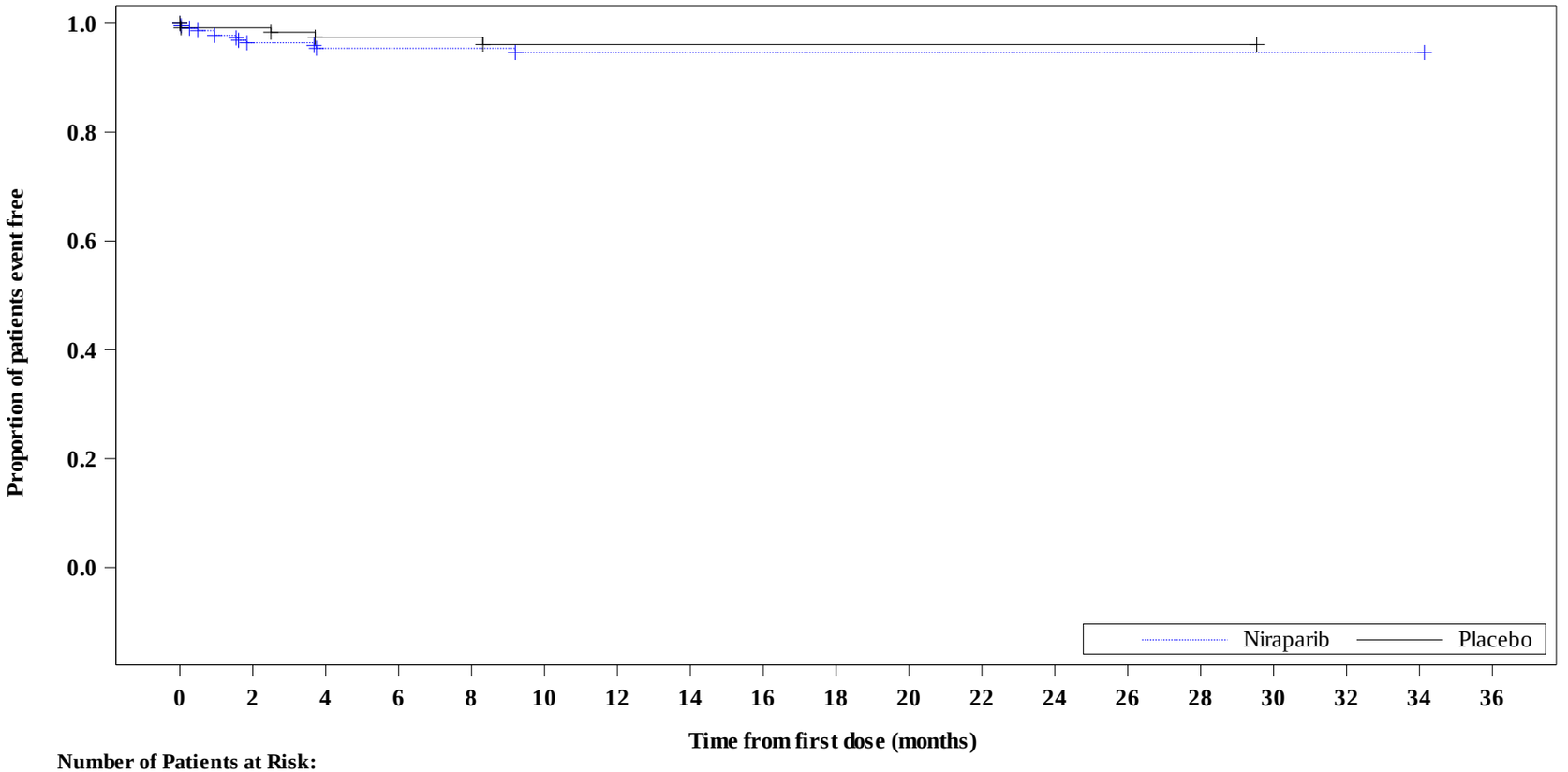



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 206 | 173 | 156 | 128 | 114 | 107 | 97 | 82 | 70 | 45 | 22 | 13 | 9 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 77 | 55 | 48 | 40 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Cardiac disorders, PT: Tachycardia

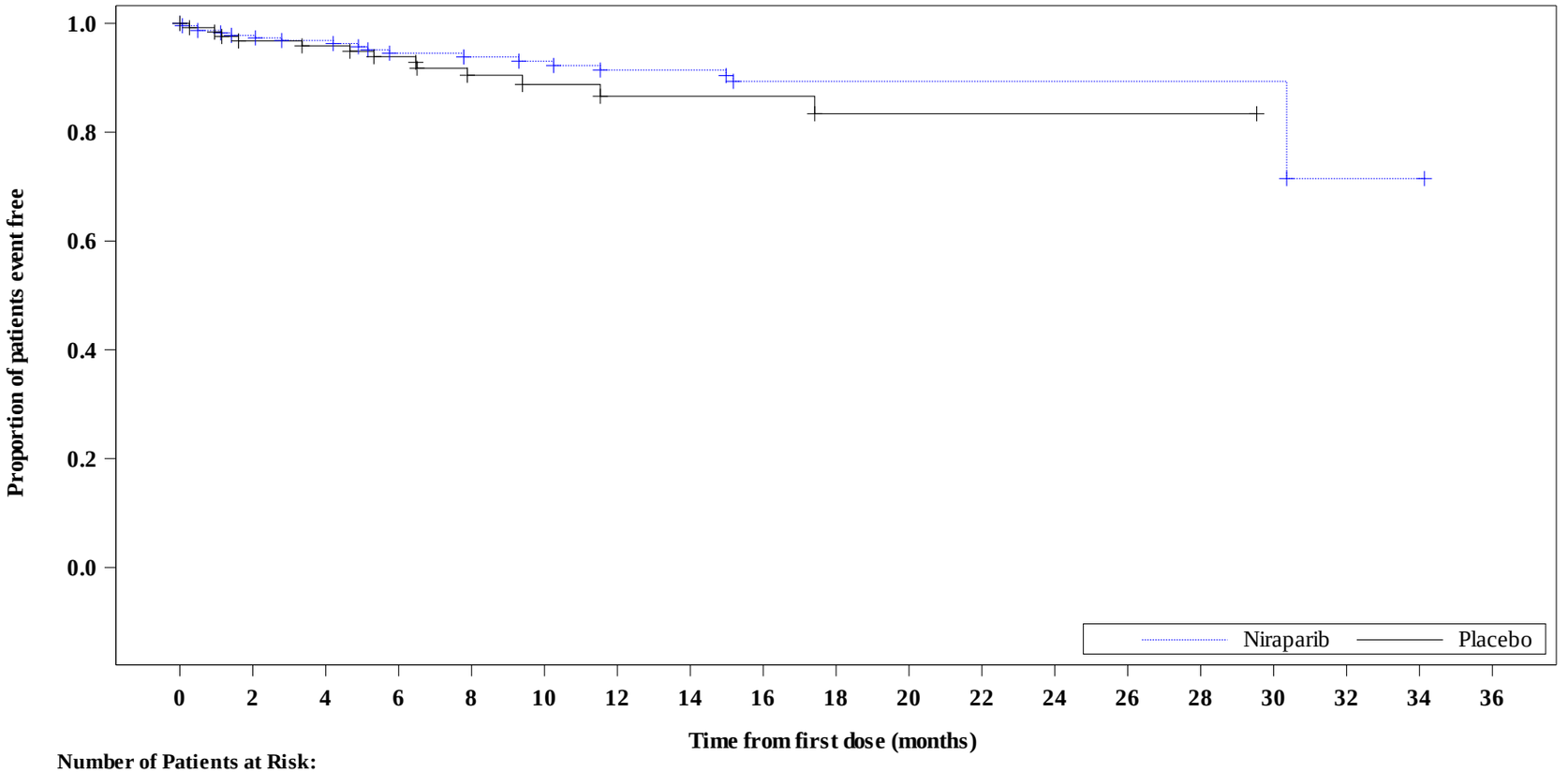



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 206 | 174 | 159 | 131 | 116 | 108 | 98 | 85 | 72 | 46 | 21 | 13 | 8 | 5 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 105 | 97 | 77 | 55 | 48 | 40 | 33 | 28 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Ear and labyrinth disorders

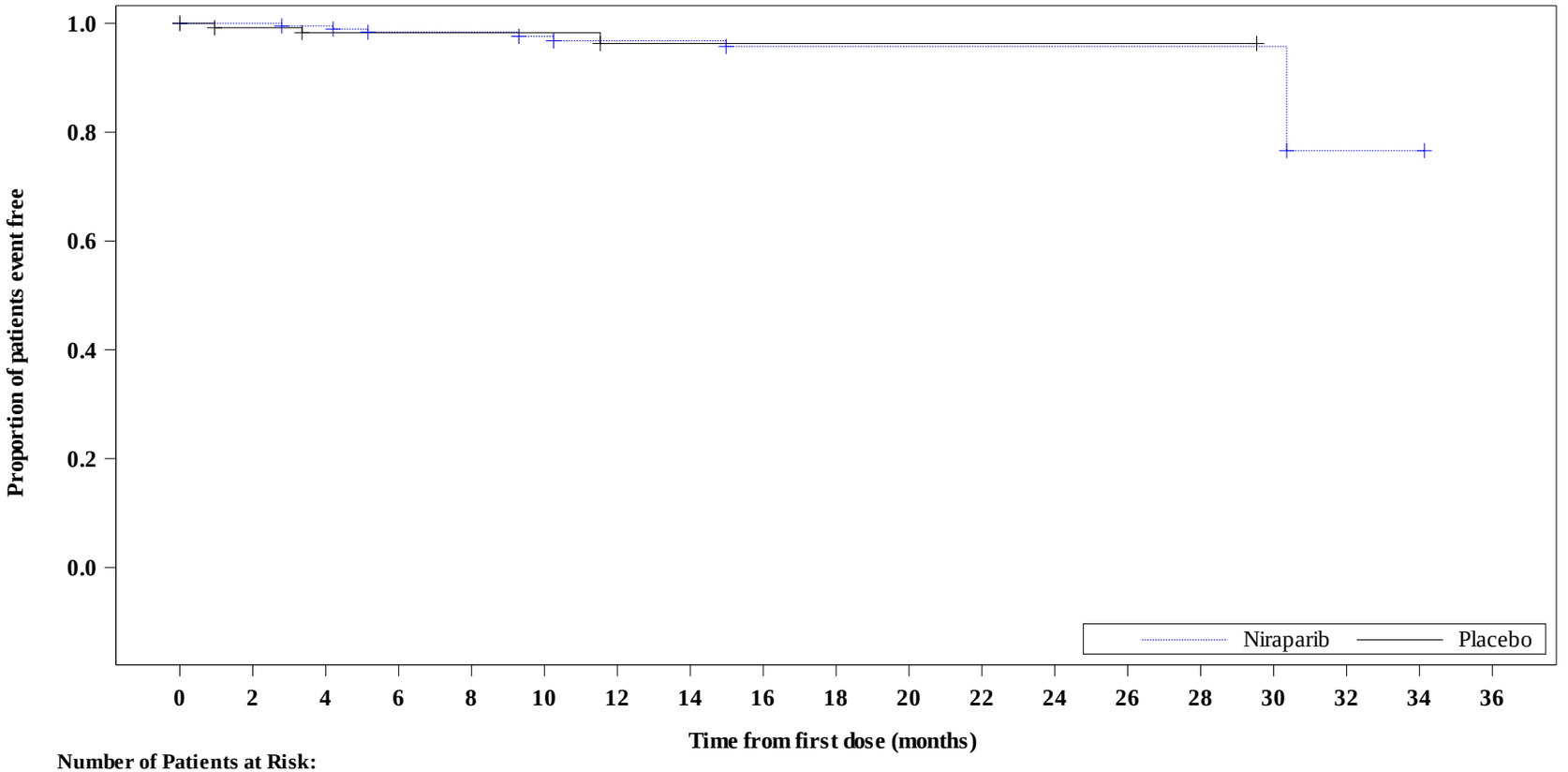



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 177 | 158 | 131 | 117 | 107 | 97 | 80 | 69 | 44 | 22 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 118 | 102 | 92 | 70 | 48 | 40 | 34 | 28 | 22 | 16 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Ear and labyrinth disorders, PT: Vertigo

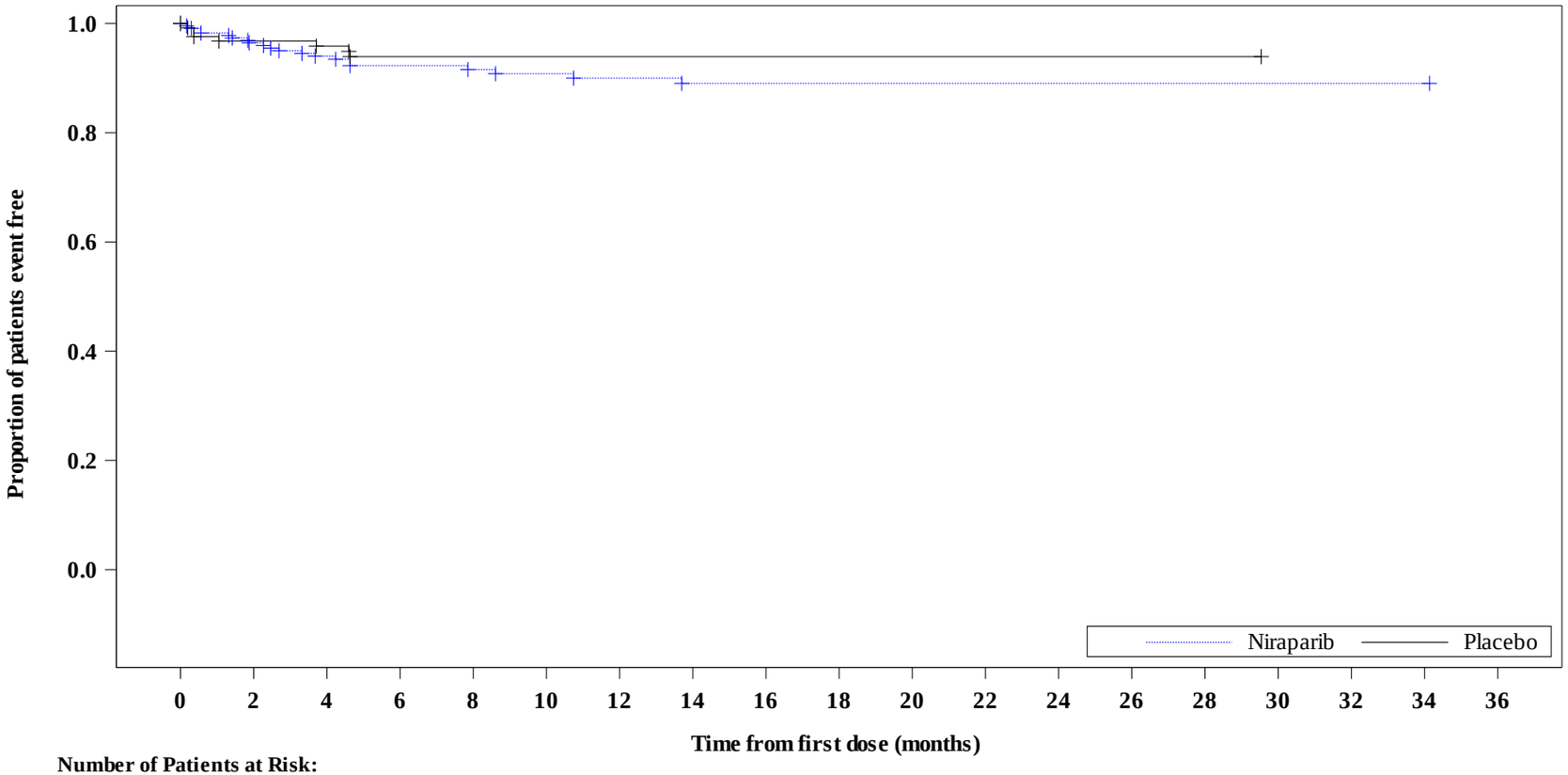



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 182 | 163 | 136 | 121 | 112 | 102 | 86 | 73 | 47 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 105 | 97 | 77 | 56 | 48 | 40 | 33 | 28 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Eye disorders

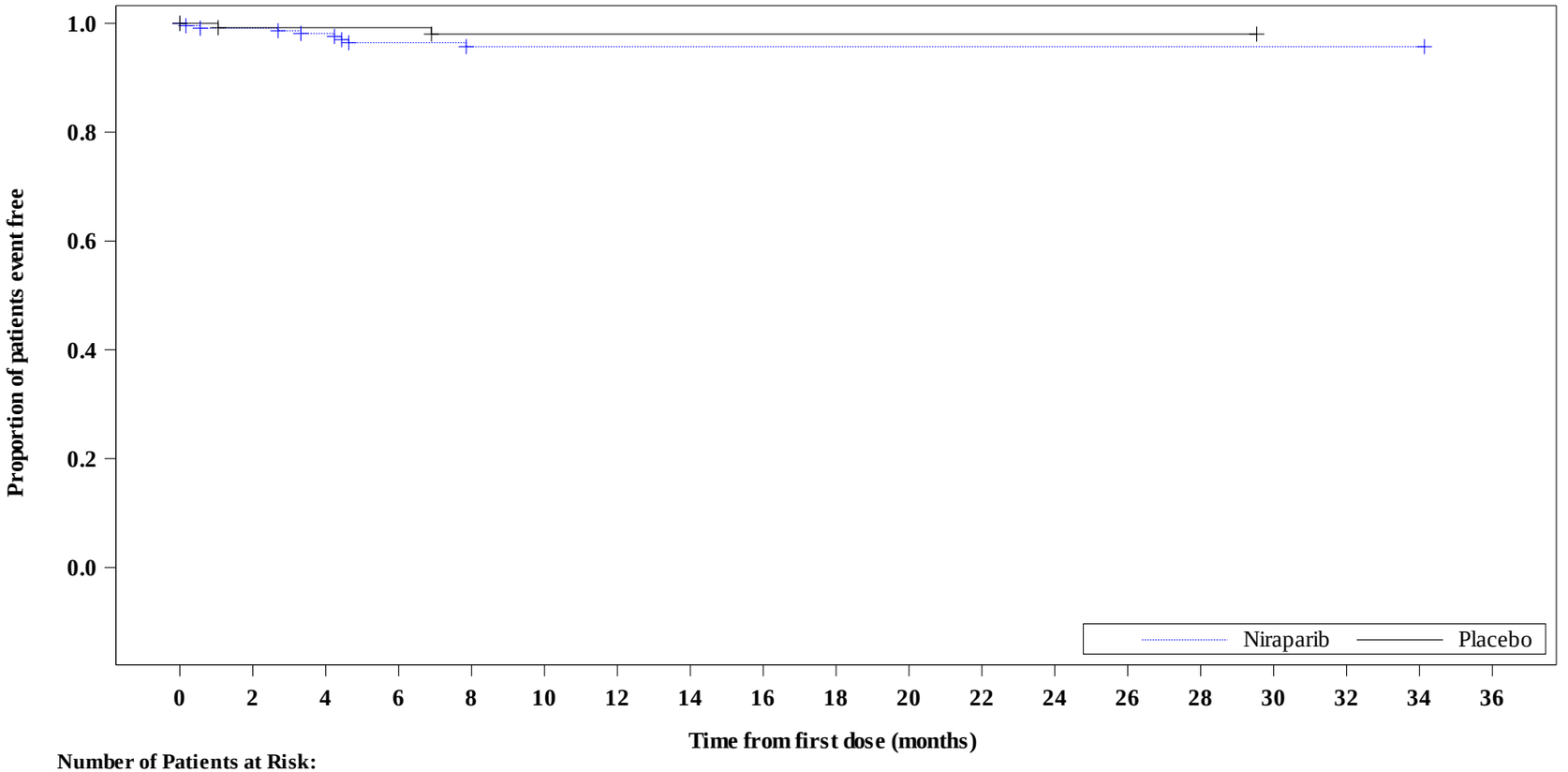



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 206 | 171 | 152 | 124 | 112 | 103 | 93 | 79 | 66 | 42 | 18 | 11 | 9 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 118 | 102 | 92 | 72 | 53 | 46 | 38 | 31 | 26 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Eye disorders, PT: Dry eye

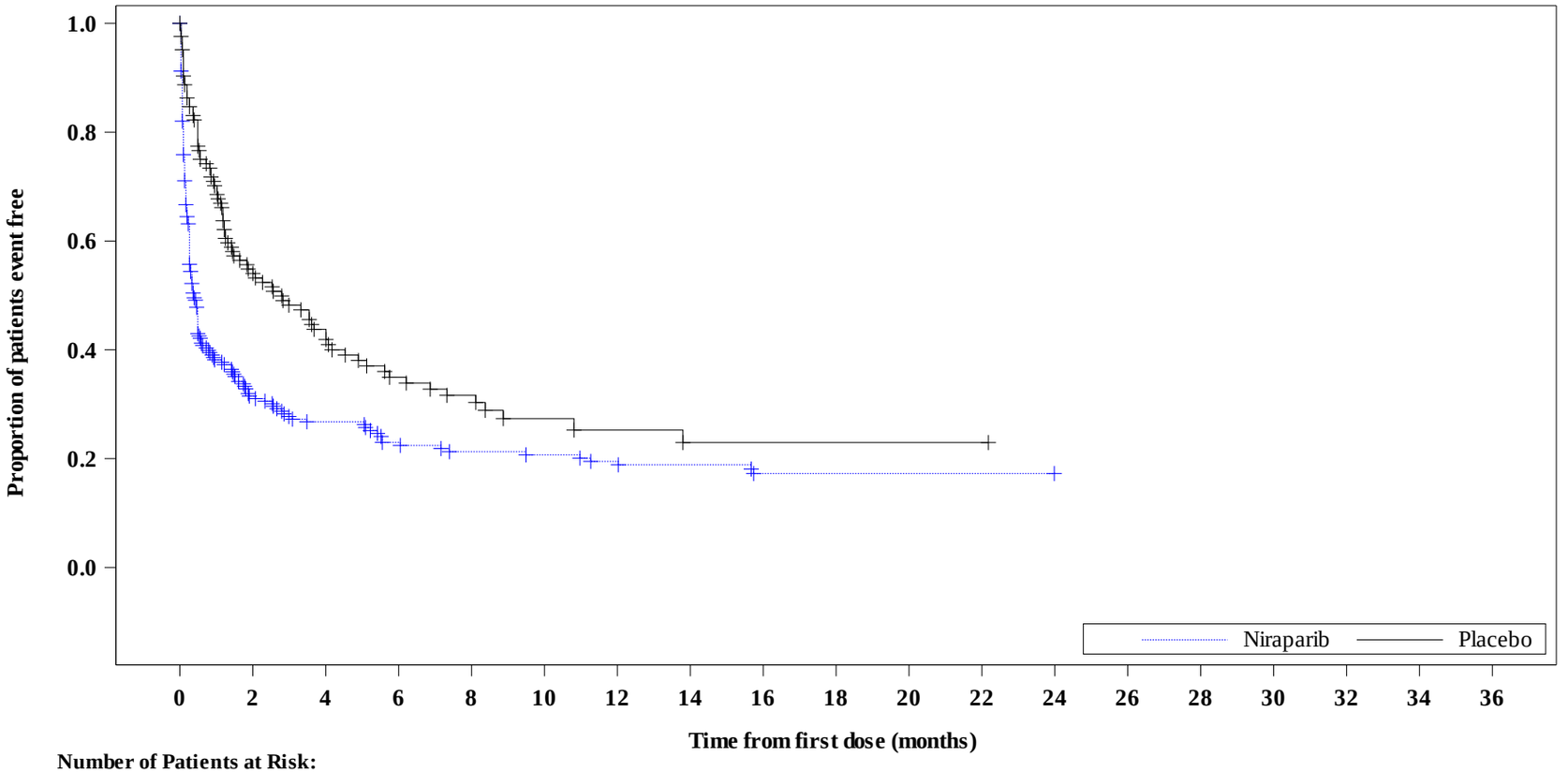



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 180 | 160 | 131 | 118 | 110 | 100 | 84 | 71 | 47 | 21 | 13 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 76 | 54 | 47 | 39 | 32 | 27 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders

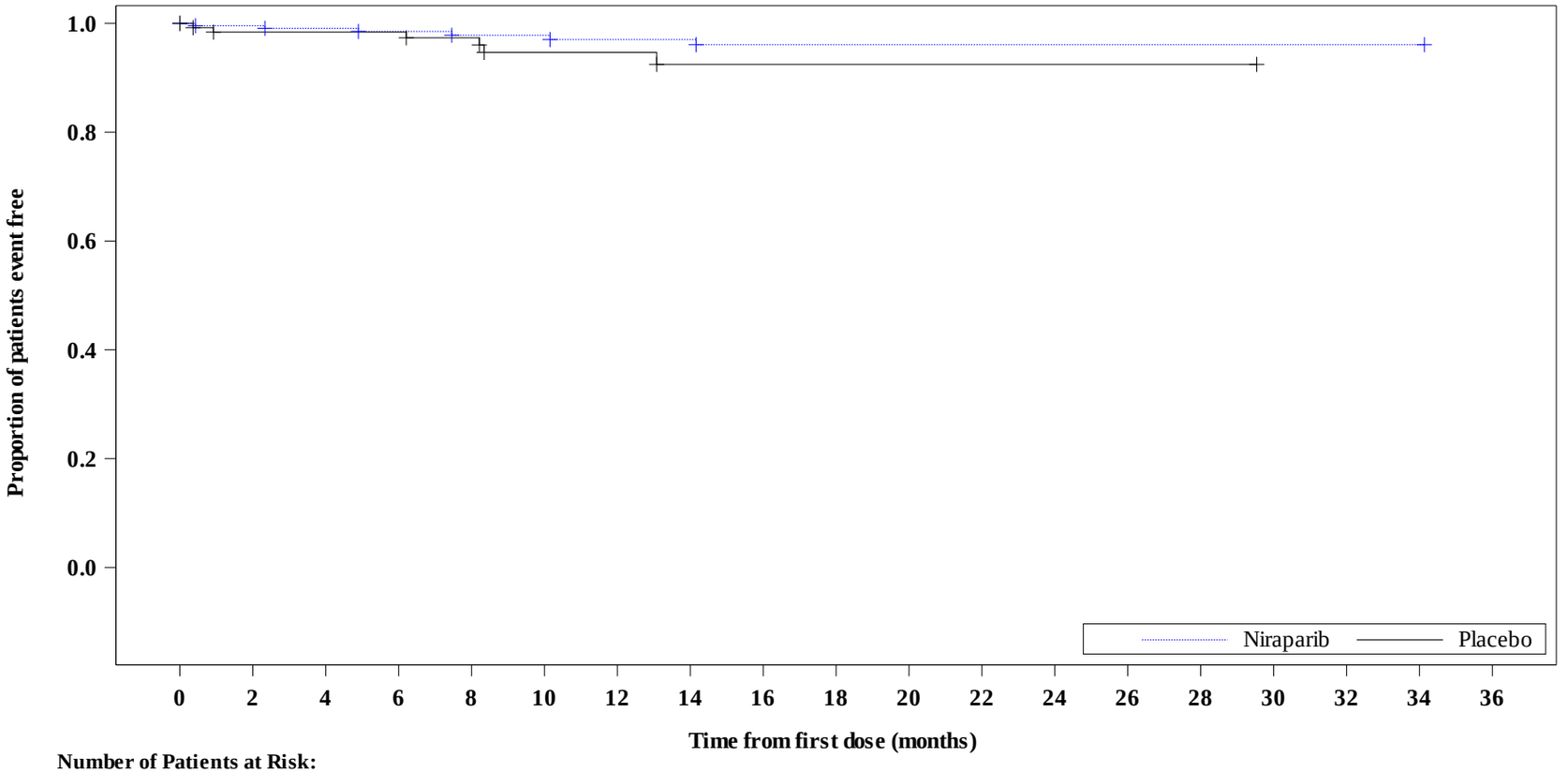



**Number of Patients at Risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 68 | 50 | 42 | 36 | 35 | 31 | 28 | 21 | 18 | 7 | 2 | 0 |
| Placebo | 124 | 67 | 47 | 33 | 25 | 15 | 12 | 9 | 8 | 6 | 4 | 1 | 0 |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Abdominal discomfort

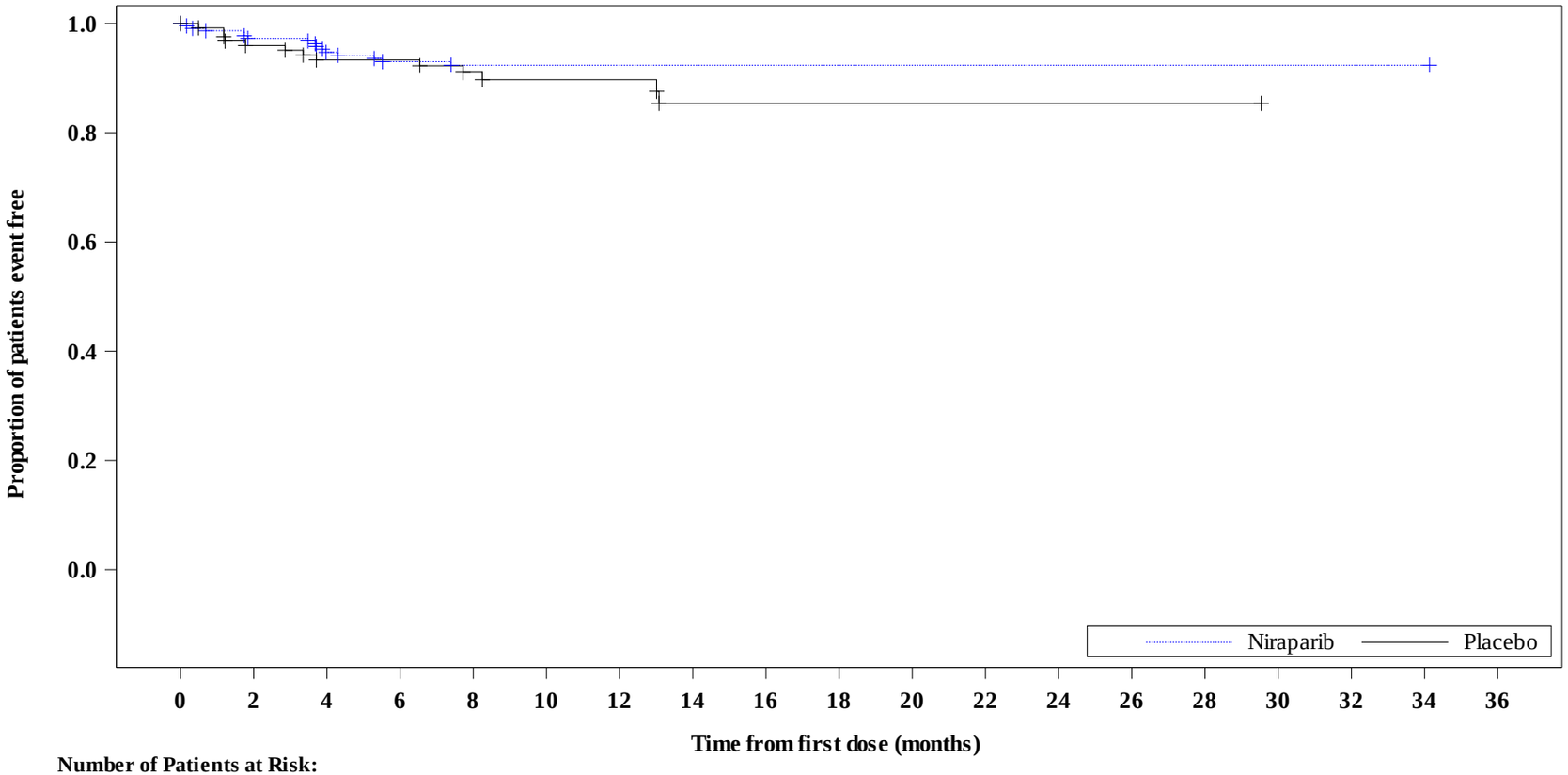



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 213 | 182 | 164 | 136 | 123 | 114 | 104 | 87 | 75 | 49 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 96 | 77 | 55 | 48 | 39 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Abdominal distension

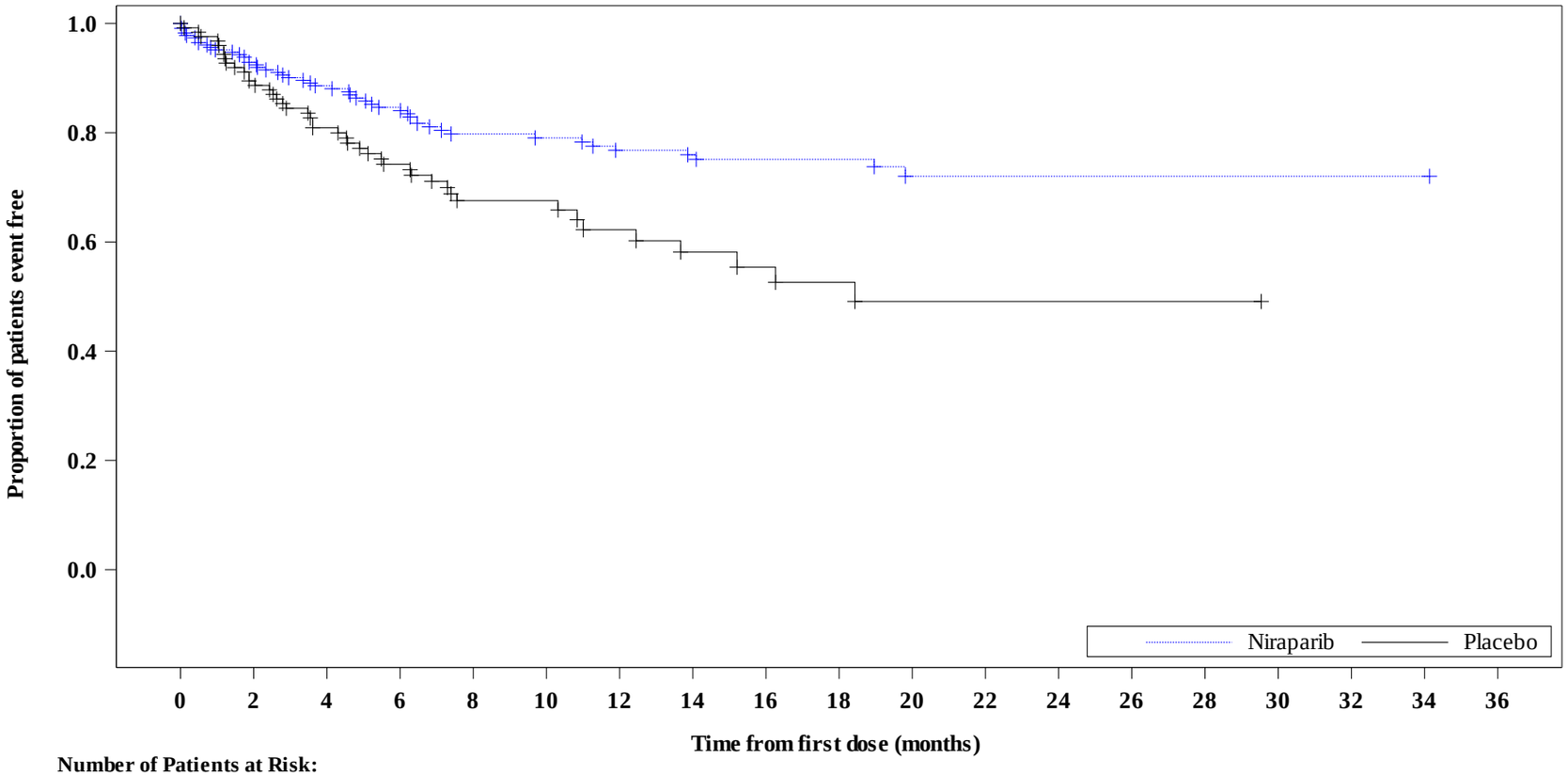



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 174 | 159 | 131 | 117 | 109 | 99 | 83 | 72 | 46 | 22 | 13 | 8 | 6 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 117 | 102 | 94 | 72 | 53 | 46 | 36 | 30 | 25 | 16 | 6 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain

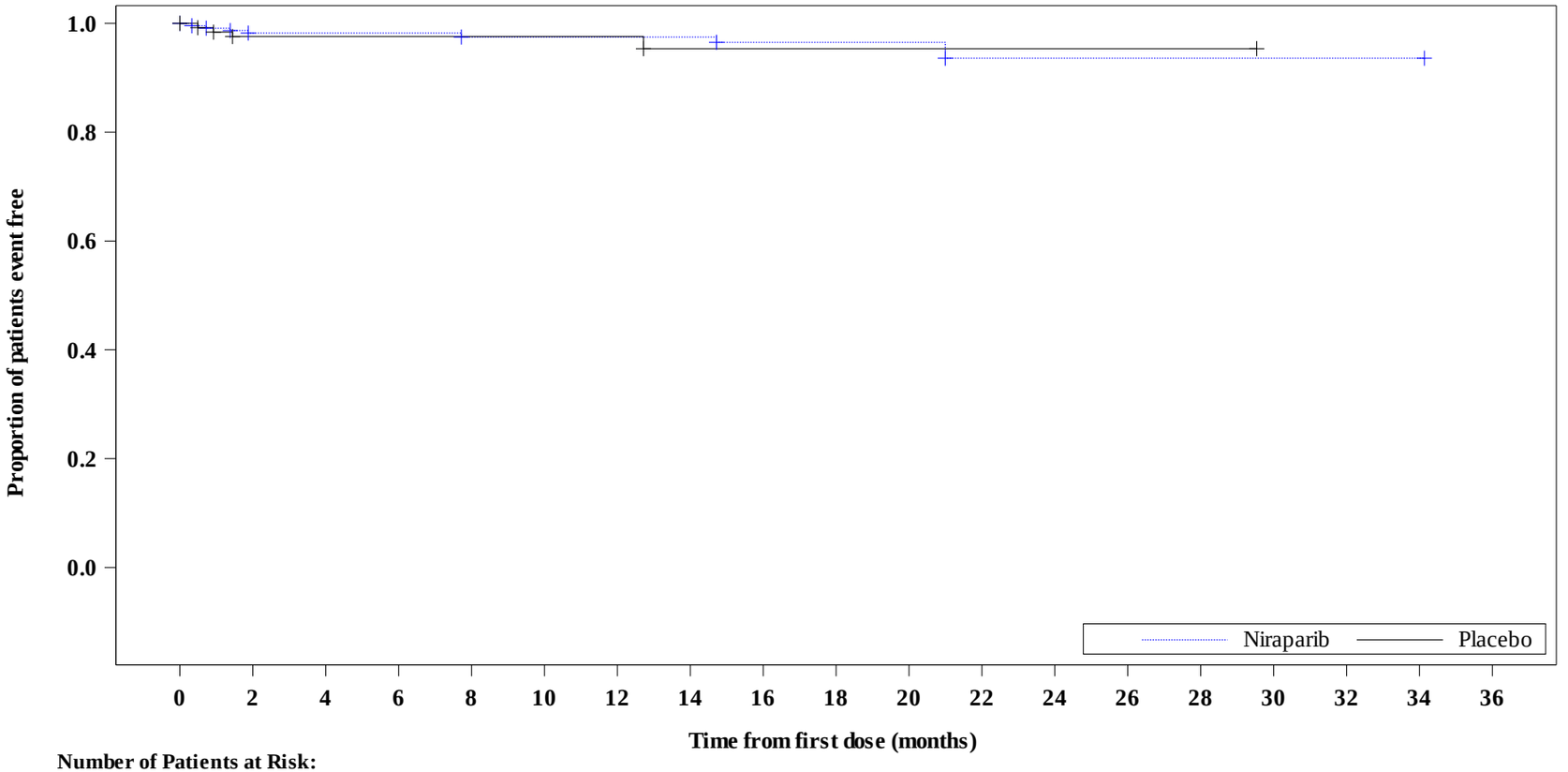



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 199 | 166 | 146 | 115 | 107 | 98 | 92 | 77 | 65 | 40 | 19 | 11 | 6 | 4 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 109 | 88 | 75 | 55 | 40 | 34 | 25 | 20 | 15 | 9 | 5 | 2 | 1 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain lower

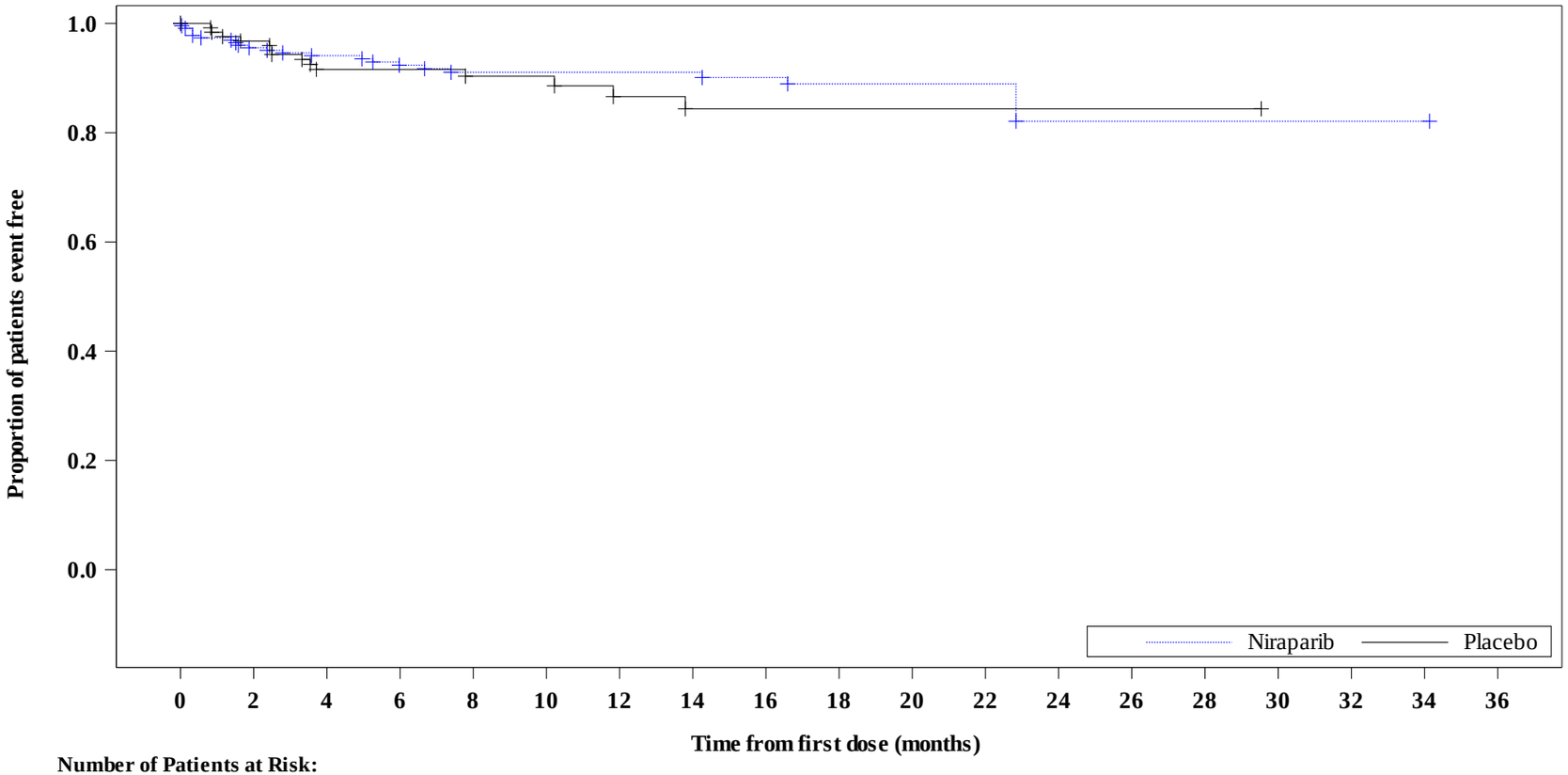



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 210 | 179 | 162 | 132 | 119 | 113 | 103 | 86 | 74 | 48 | 21 | 14 | 9 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 119 | 105 | 96 | 76 | 55 | 48 | 39 | 33 | 28 | 19 | 7 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain upper

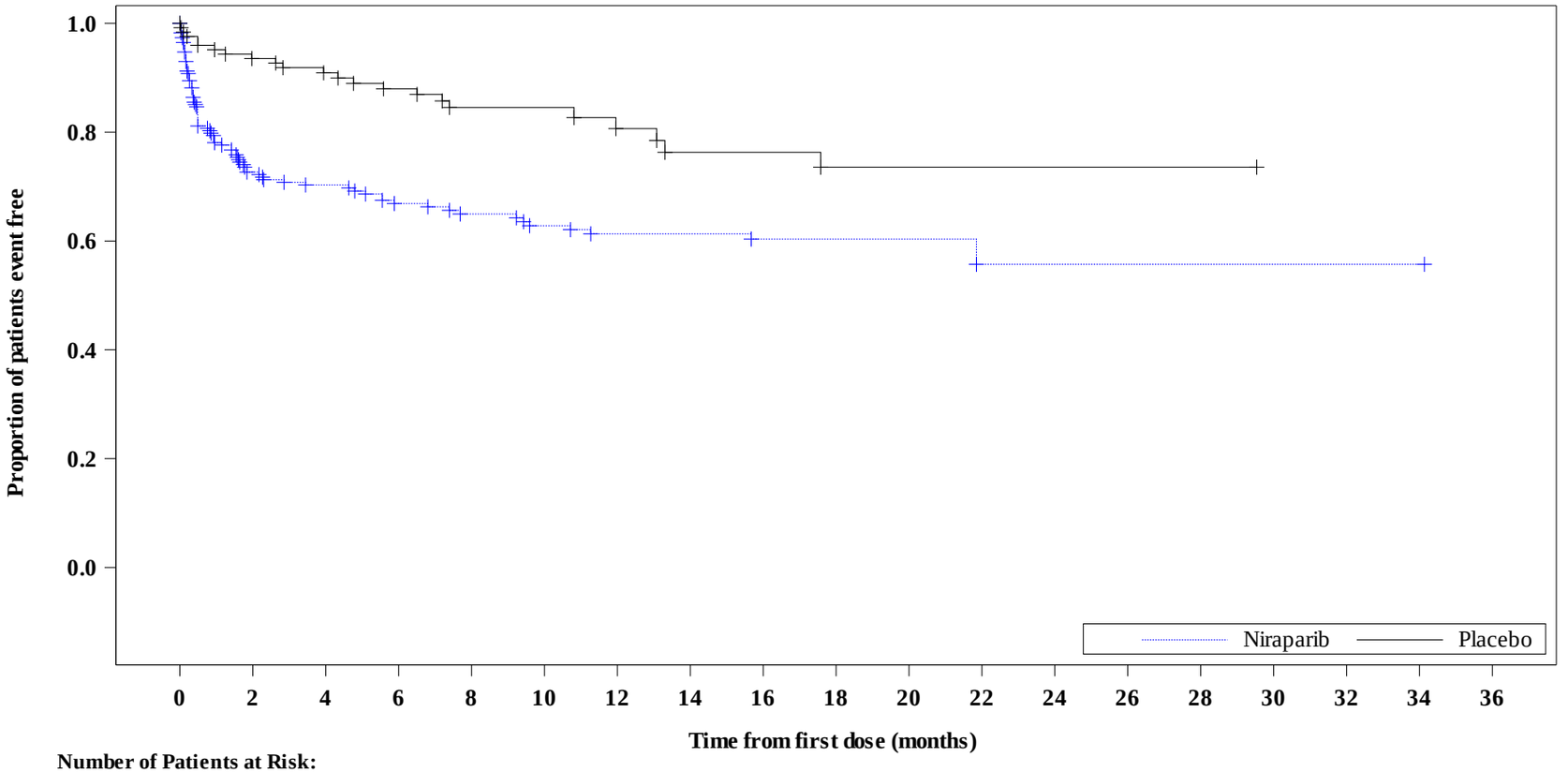



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 204 | 172 | 156 | 127 | 117 | 109 | 99 | 82 | 68 | 43 | 19 | 10 | 7 | 4 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 118 | 98 | 90 | 72 | 53 | 44 | 36 | 29 | 25 | 18 | 7 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Constipation

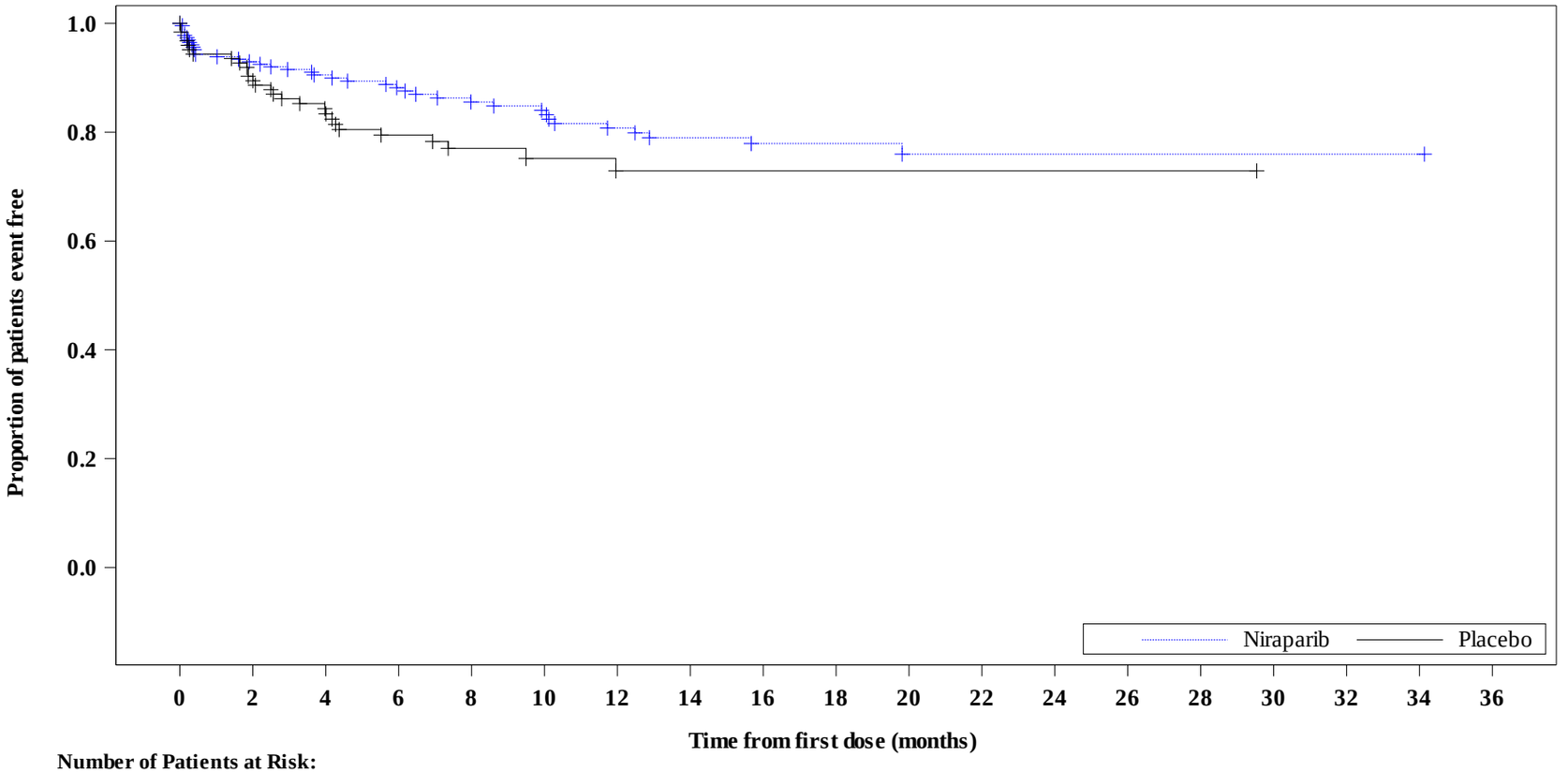



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 157 | 130 | 115 | 96 | 85 | 79 | 75 | 62 | 52 | 31 | 12 | 7 | 5 | 3 | 2 | 1 | 1 | 0 |
| Placebo | 124 | 115 | 97 | 87 | 66 | 47 | 40 | 32 | 29 | 24 | 17 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Diarrhoea

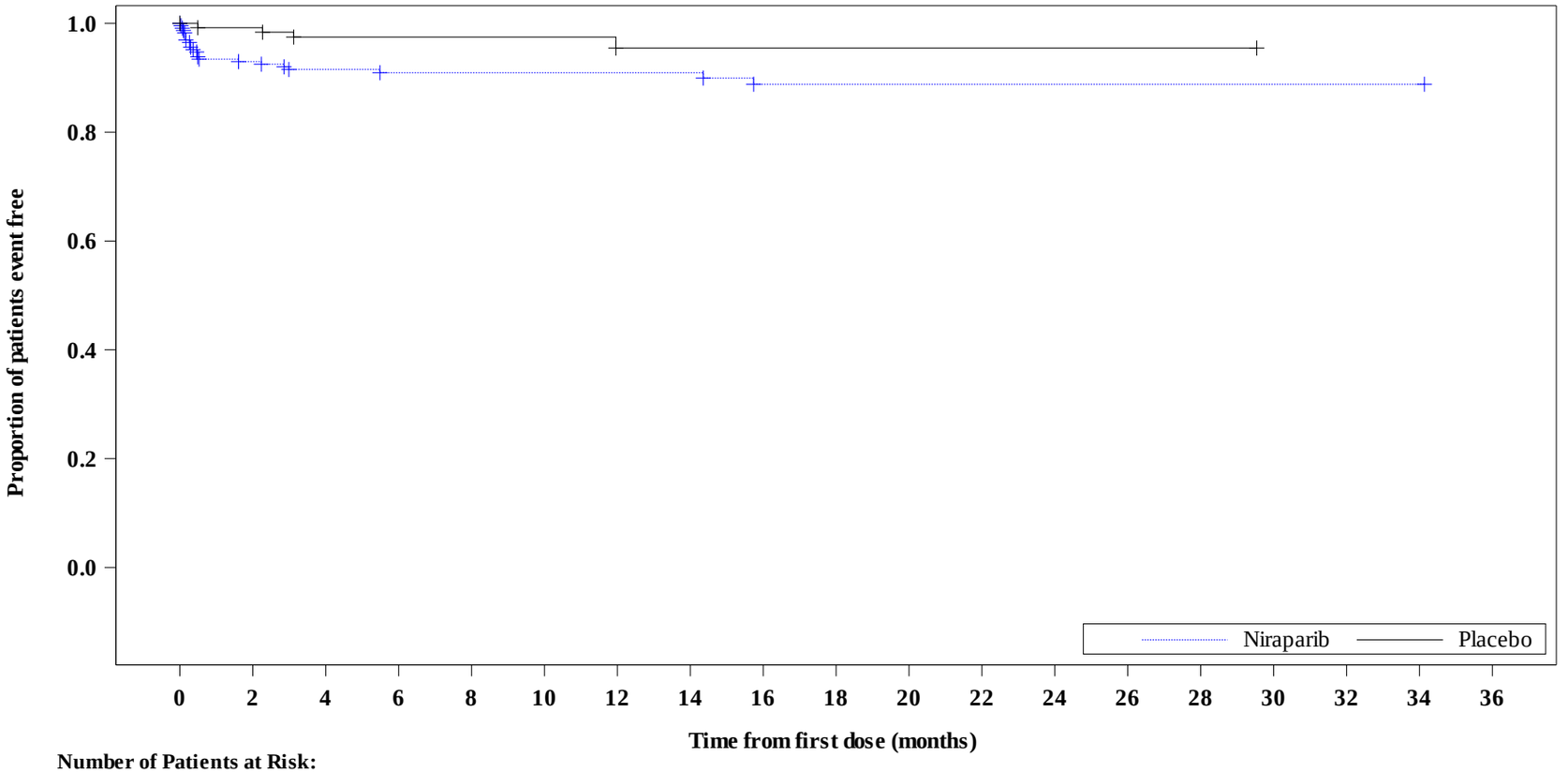



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 198 | 166 | 146 | 118 | 104 | 96 | 86 | 70 | 59 | 38 | 18 | 10 | 7 | 5 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 110 | 89 | 77 | 56 | 38 | 32 | 26 | 24 | 21 | 15 | 6 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Dry mouth

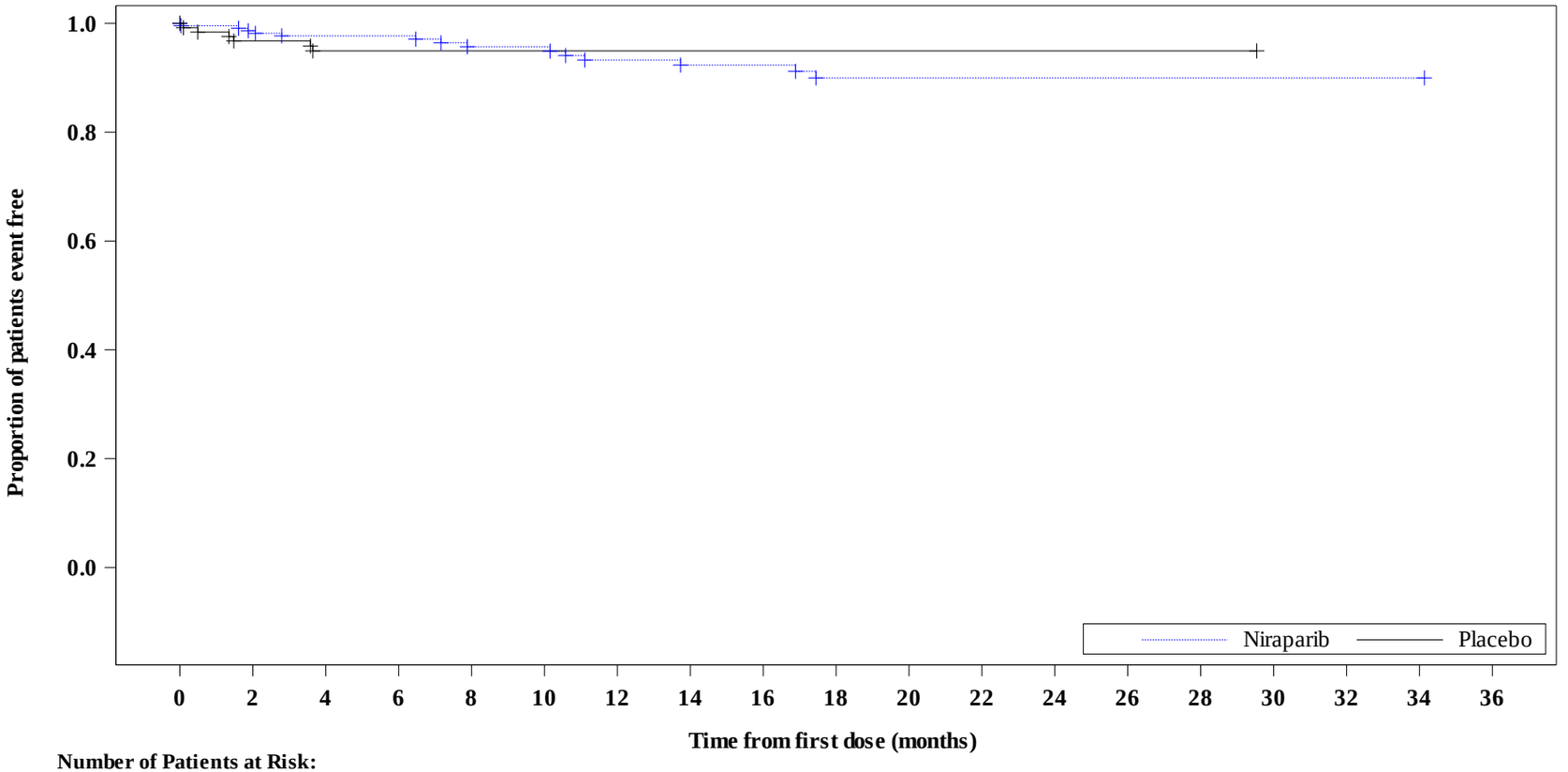



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 198 | 168 | 152 | 124 | 113 | 105 | 95 | 78 | 66 | 42 | 19 | 11 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 121 | 104 | 96 | 76 | 55 | 47 | 39 | 32 | 27 | 19 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Dyspepsia

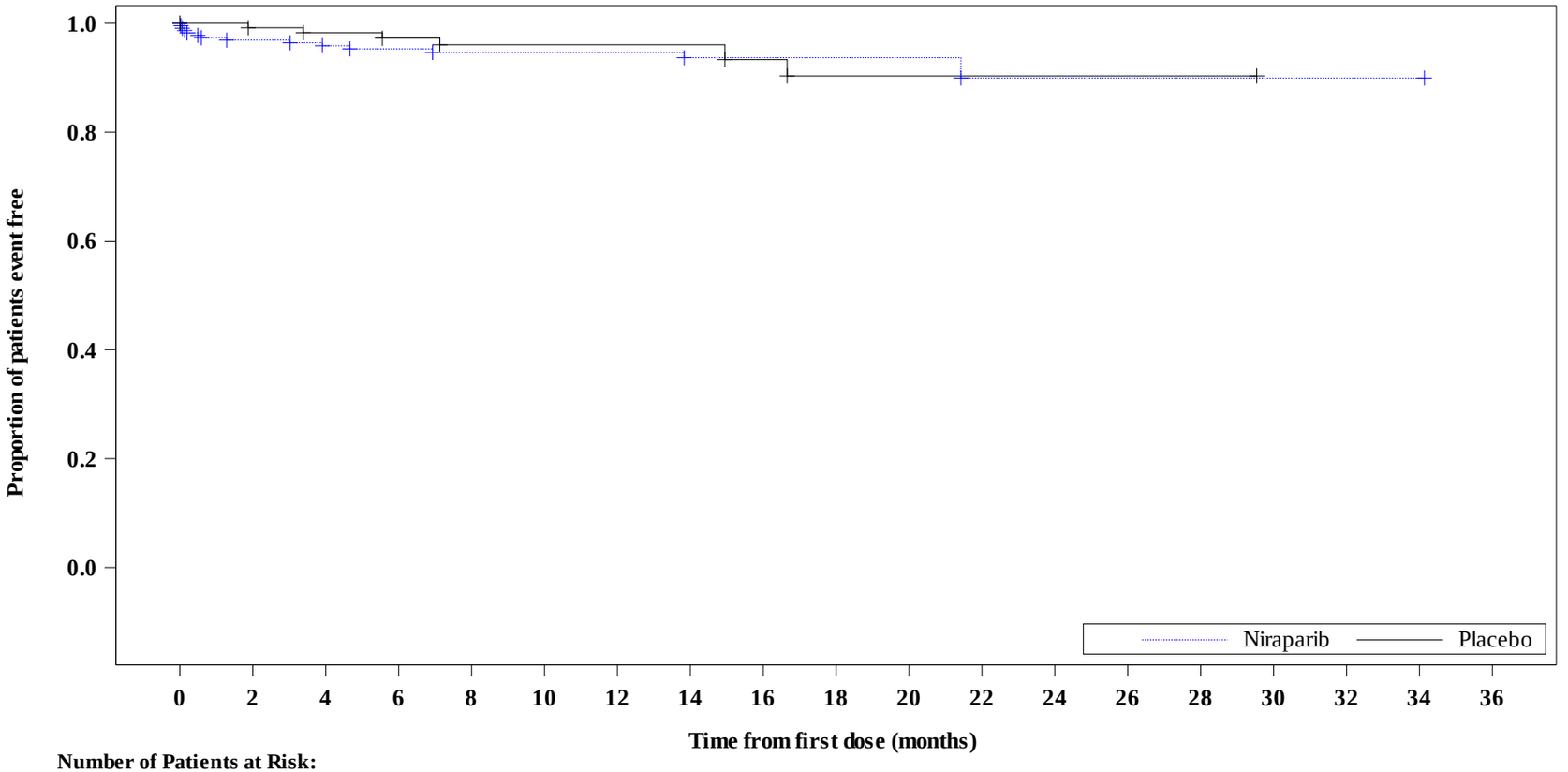



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 211 | 179 | 163 | 131 | 118 | 108 | 99 | 84 | 69 | 43 | 19 | 11 | 7 | 4 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 118 | 101 | 92 | 73 | 51 | 45 | 37 | 30 | 26 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease

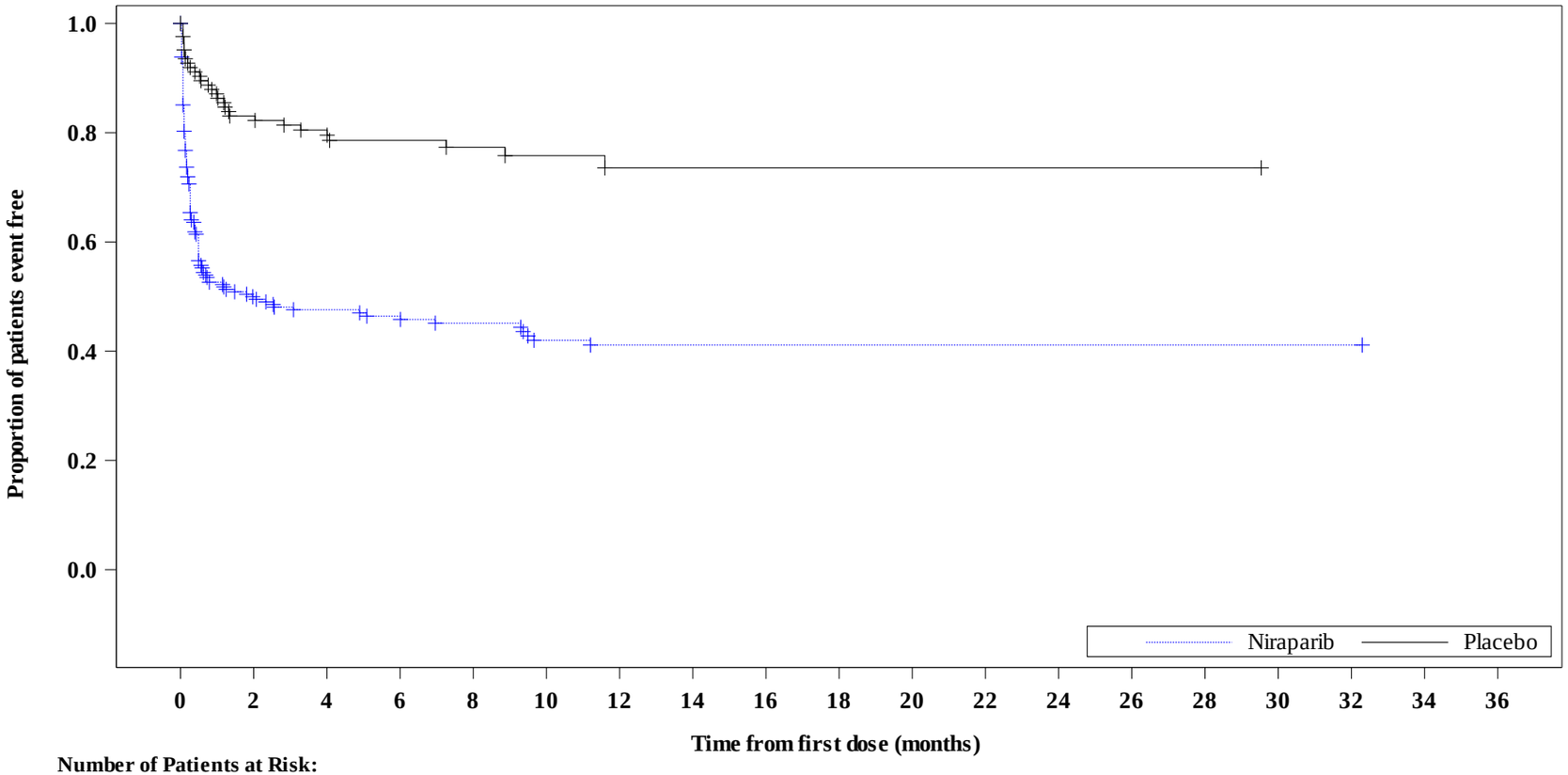



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 207 | 176 | 158 | 128 | 115 | 107 | 97 | 82 | 70 | 45 | 21 | 13 | 8 | 6 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 105 | 95 | 74 | 54 | 47 | 40 | 32 | 26 | 17 | 6 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Nausea

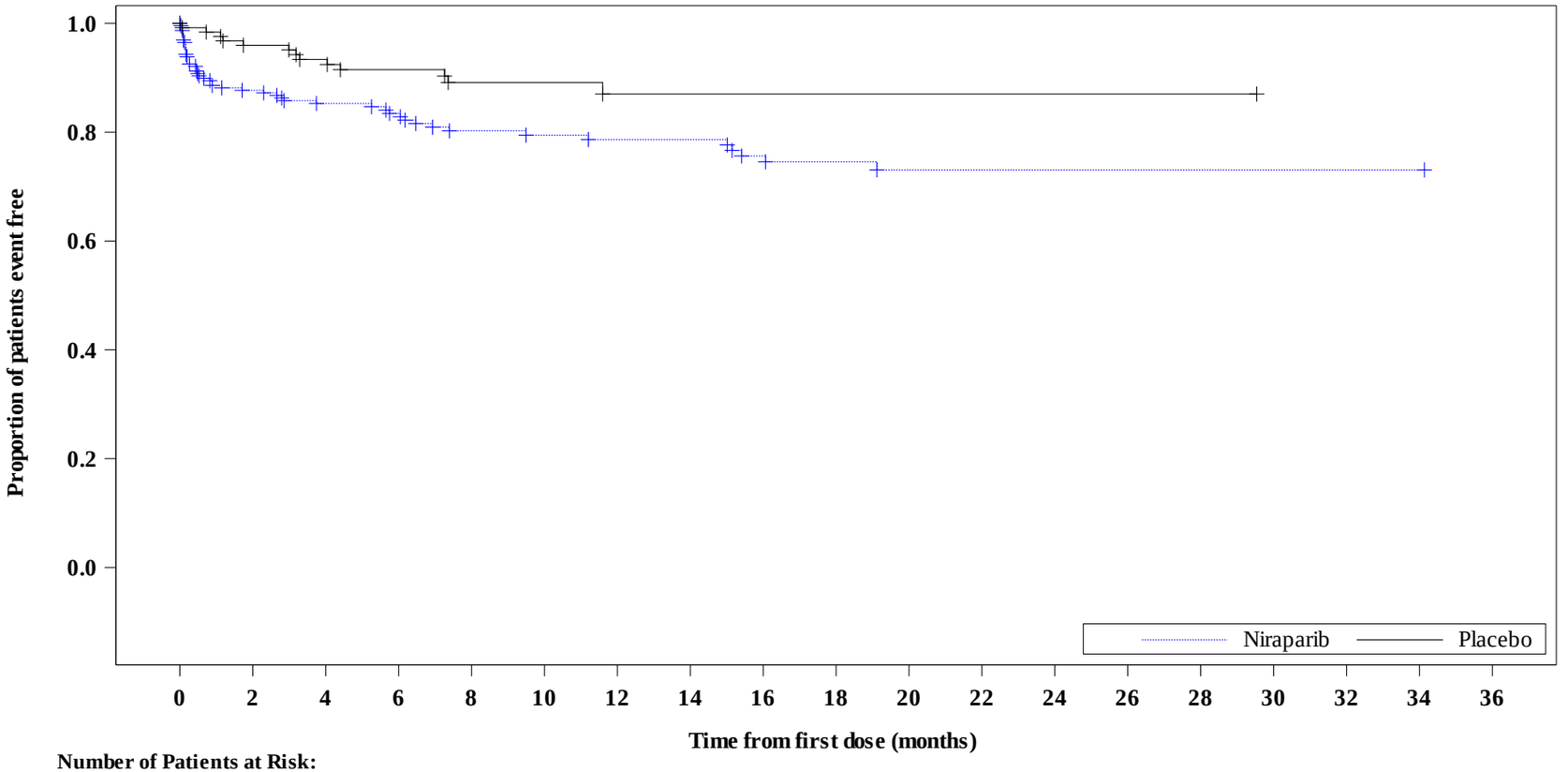



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 107 | 84 | 76 | 61 | 52 | 46 | 42 | 37 | 31 | 14 | 7 | 3 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 102 | 85 | 74 | 58 | 40 | 33 | 27 | 22 | 19 | 12 | 6 | 3 | 2 | 1 | 0 | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Vomiting

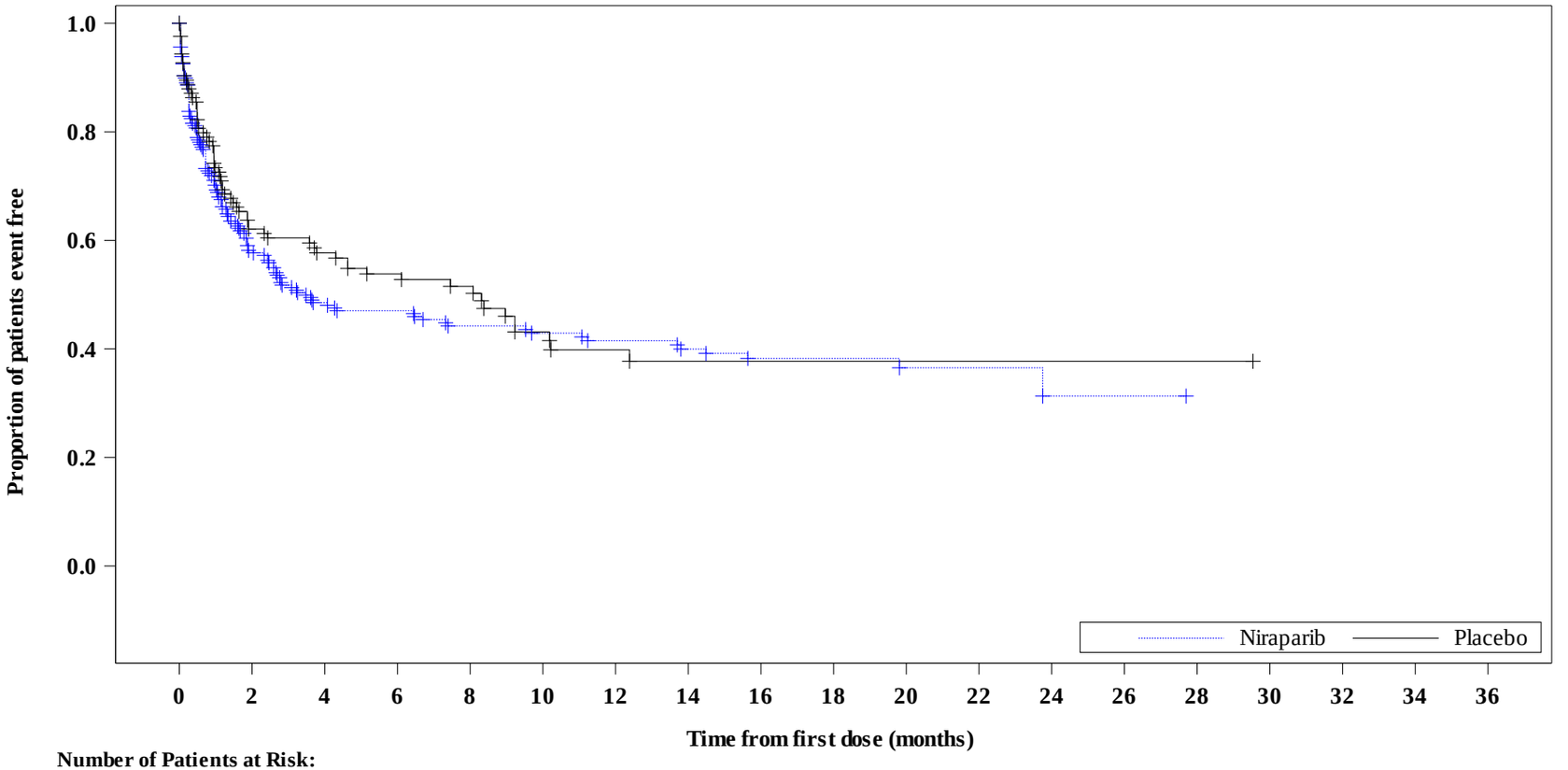



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 187 | 155 | 136 | 109 | 101 | 93 | 86 | 71 | 60 | 35 | 17 | 11 | 8 | 5 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 118 | 101 | 90 | 70 | 49 | 41 | 35 | 30 | 26 | 18 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: General disorders and administration site conditions

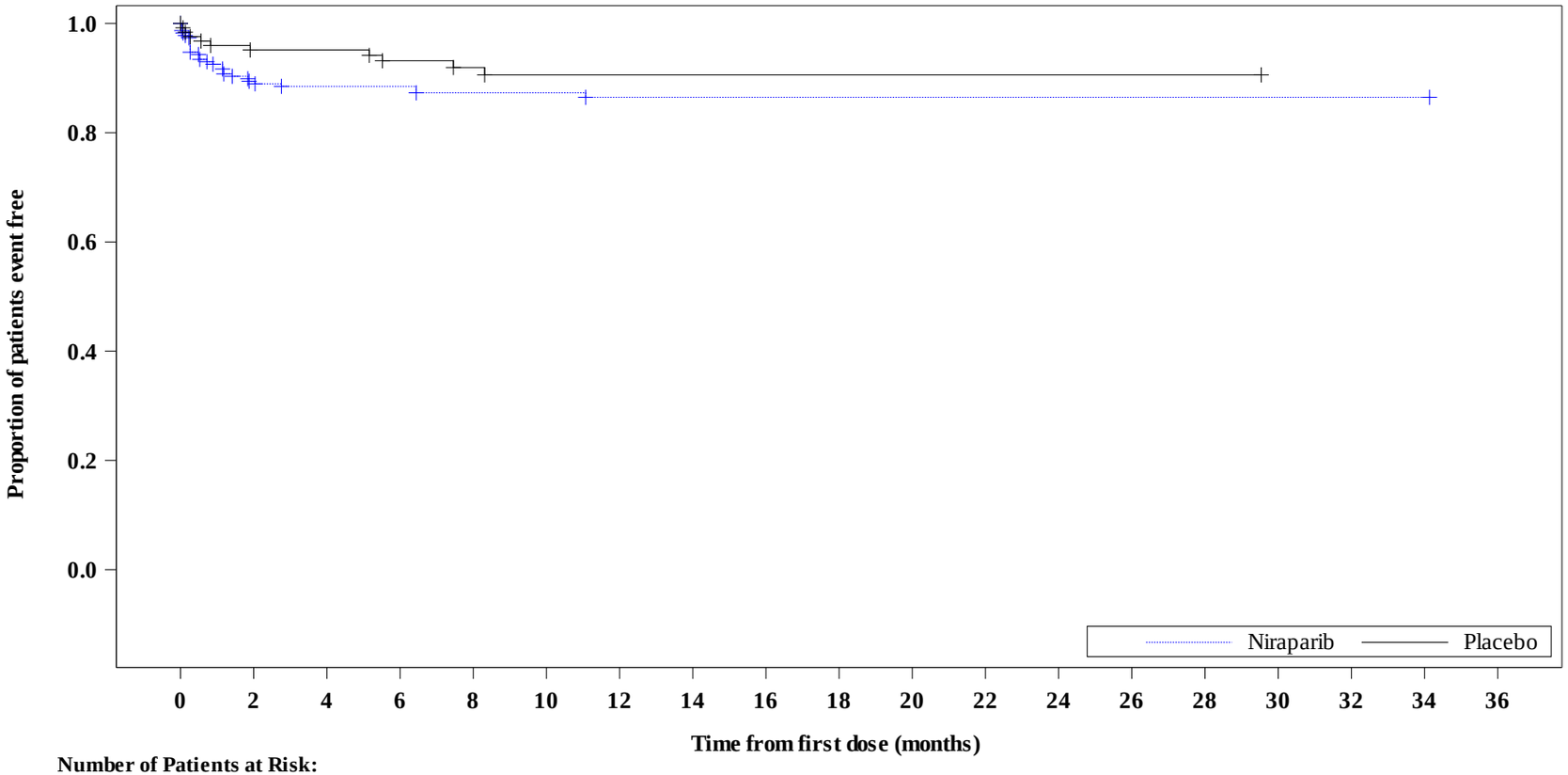



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 128 | 97 | 91 | 70 | 64 | 59 | 51 | 40 | 32 | 21 | 10 | 5 | 2 | 0 | |
| Placebo | 124 | 76 | 62 | 52 | 40 | 27 | 20 | 16 | 13 | 12 | 9 | 3 | 2 | 2 | 1 | 0 |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Asthenia

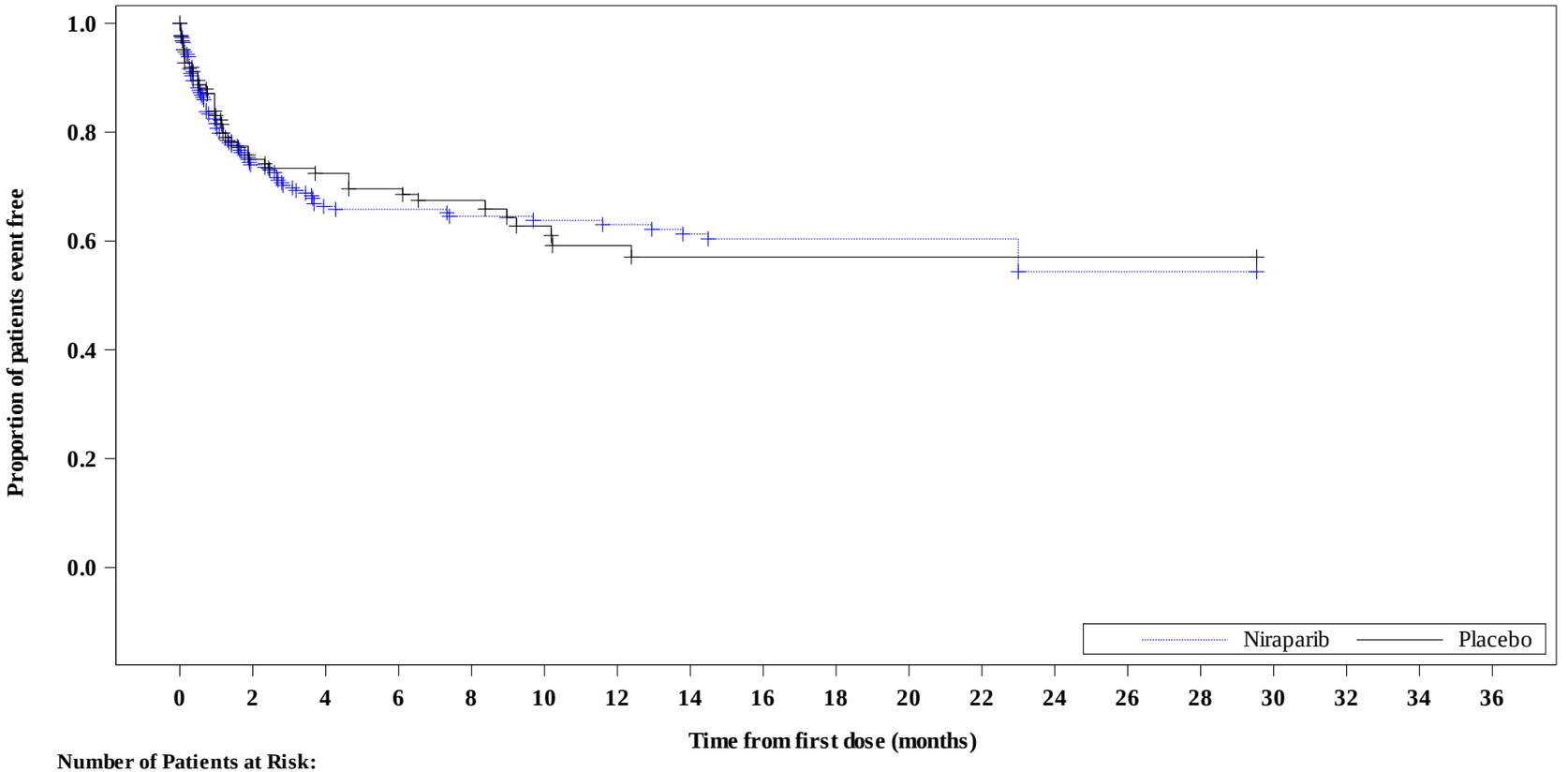



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 194 | 165 | 151 | 122 | 109 | 101 | 92 | 77 | 66 | 47 | 23 | 14 | 9 | 6 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 116 | 103 | 92 | 73 | 51 | 44 | 36 | 30 | 25 | 19 | 7 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Fatigue

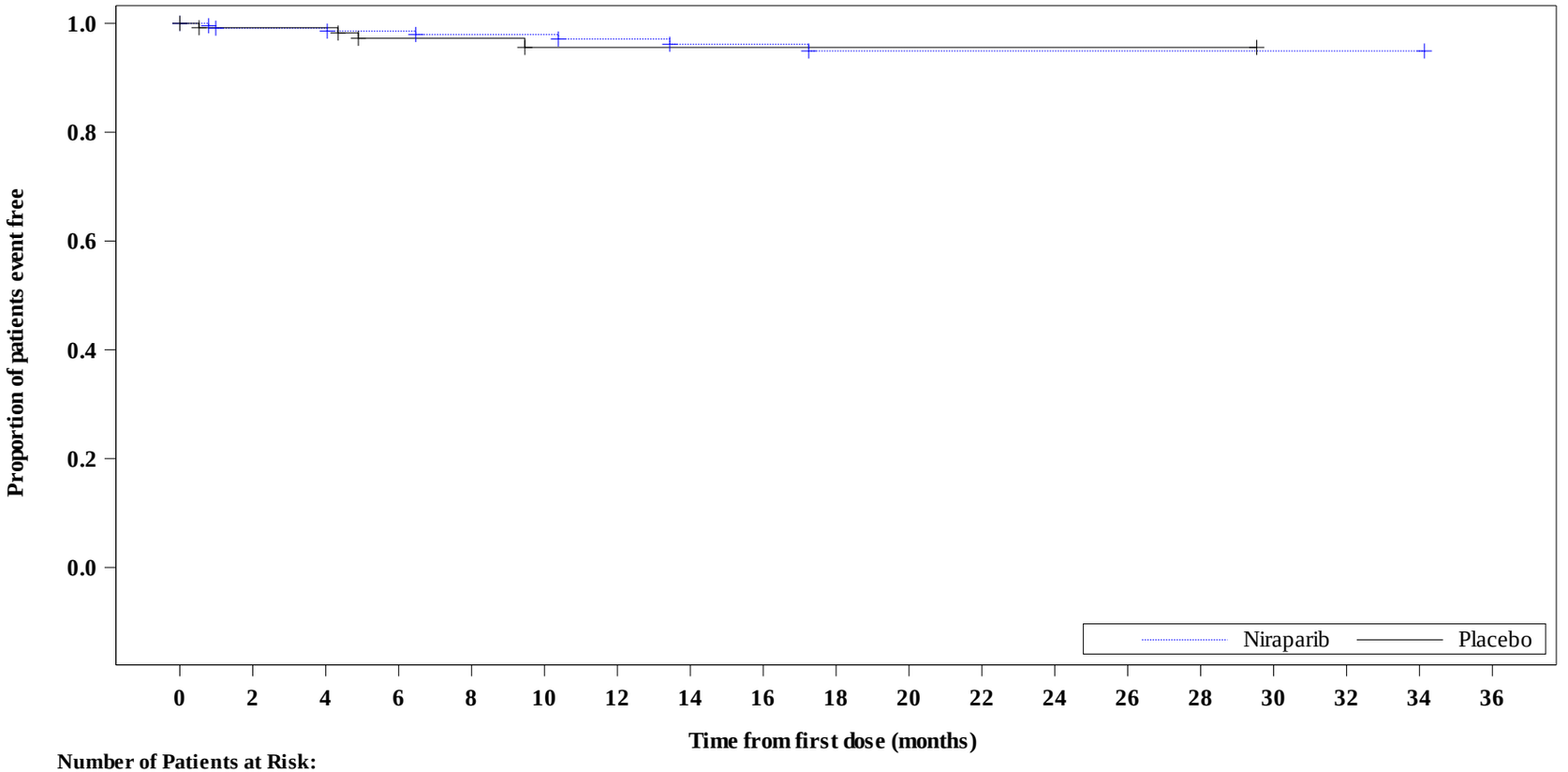



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 161 | 126 | 117 | 94 | 86 | 79 | 70 | 59 | 49 | 29 | 14 | 8 | 4 | 1 | 0 |
| Placebo | 124 | 92 | 78 | 68 | 47 | 36 | 29 | 24 | 21 | 17 | 11 | 4 | 3 | 2 | 1 | 0 |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Influenza like illness

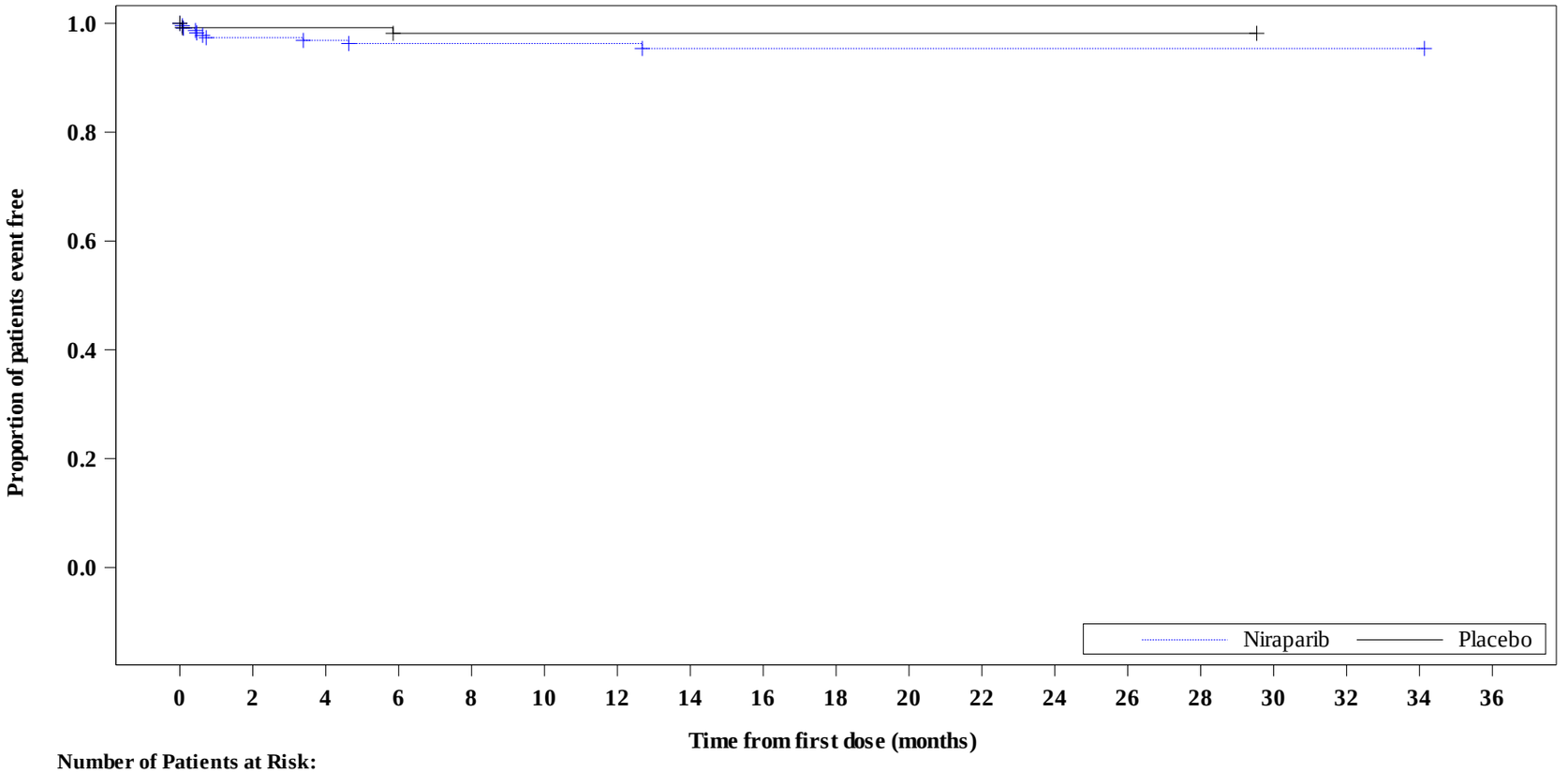



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 181 | 163 | 133 | 119 | 110 | 99 | 83 | 69 | 45 | 21 | 13 | 8 | 5 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 96 | 76 | 54 | 48 | 40 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Mucosal inflammation

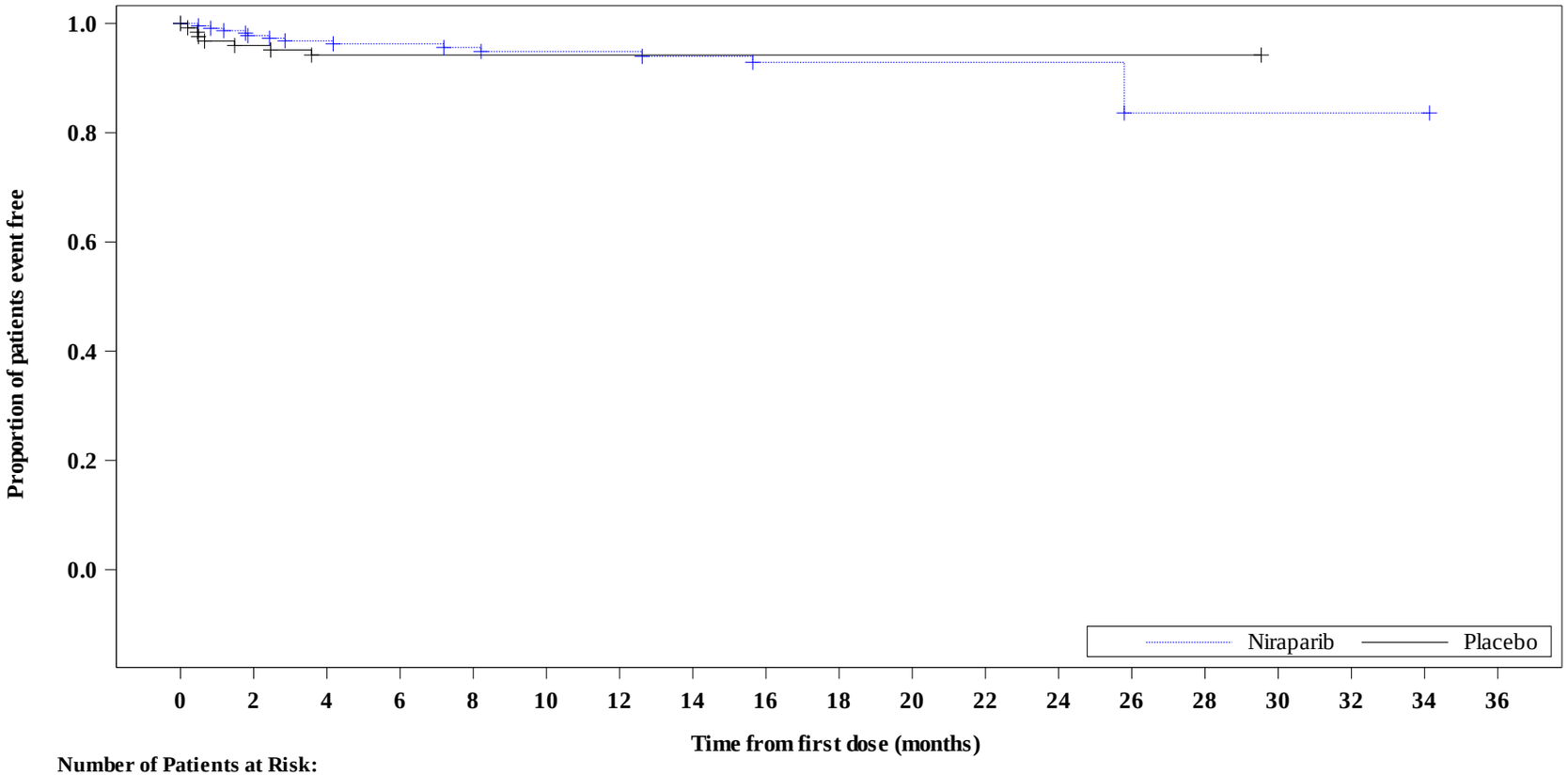



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 208 | 177 | 160 | 131 | 119 | 111 | 101 | 86 | 73 | 48 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 96 | 76 | 55 | 48 | 40 | 33 | 28 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Oedema peripheral

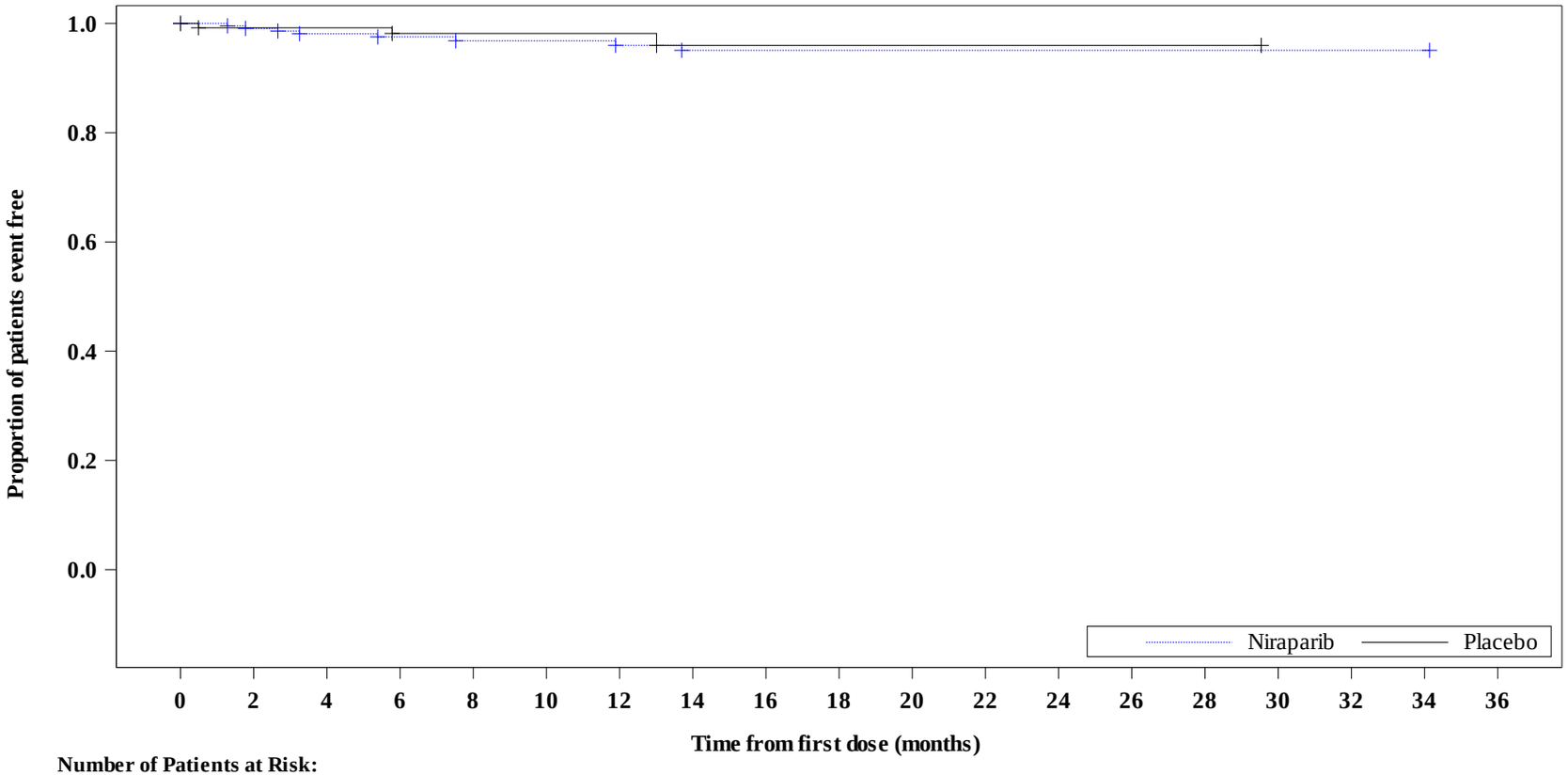



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 210 | 179 | 161 | 132 | 119 | 111 | 100 | 84 | 71 | 46 | 21 | 14 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 117 | 100 | 92 | 74 | 53 | 46 | 39 | 32 | 28 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Pain

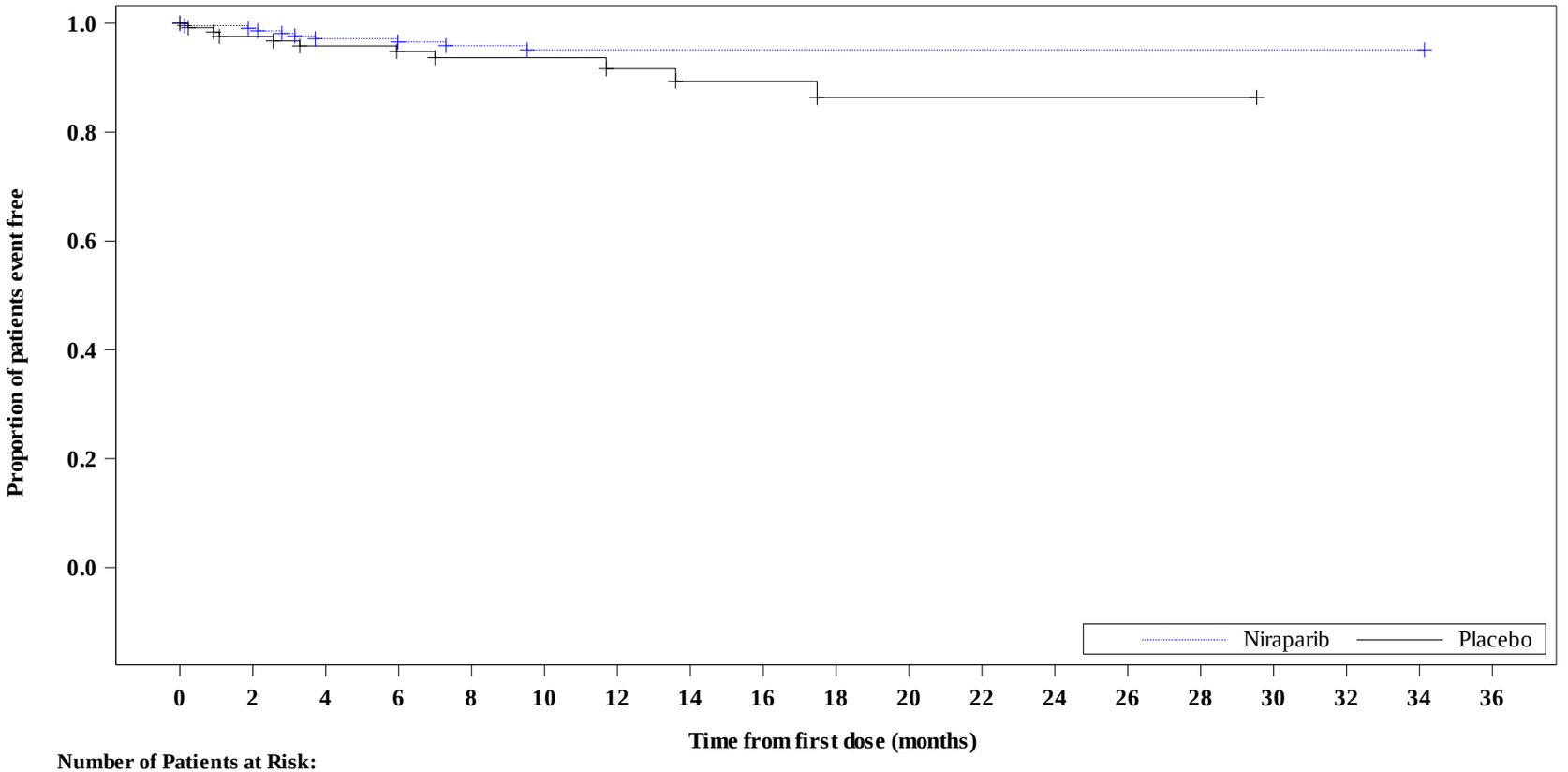



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 179 | 161 | 132 | 121 | 112 | 102 | 86 | 73 | 47 | 22 | 13 | 9 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 96 | 77 | 56 | 49 | 40 | 33 | 28 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Pyrexia

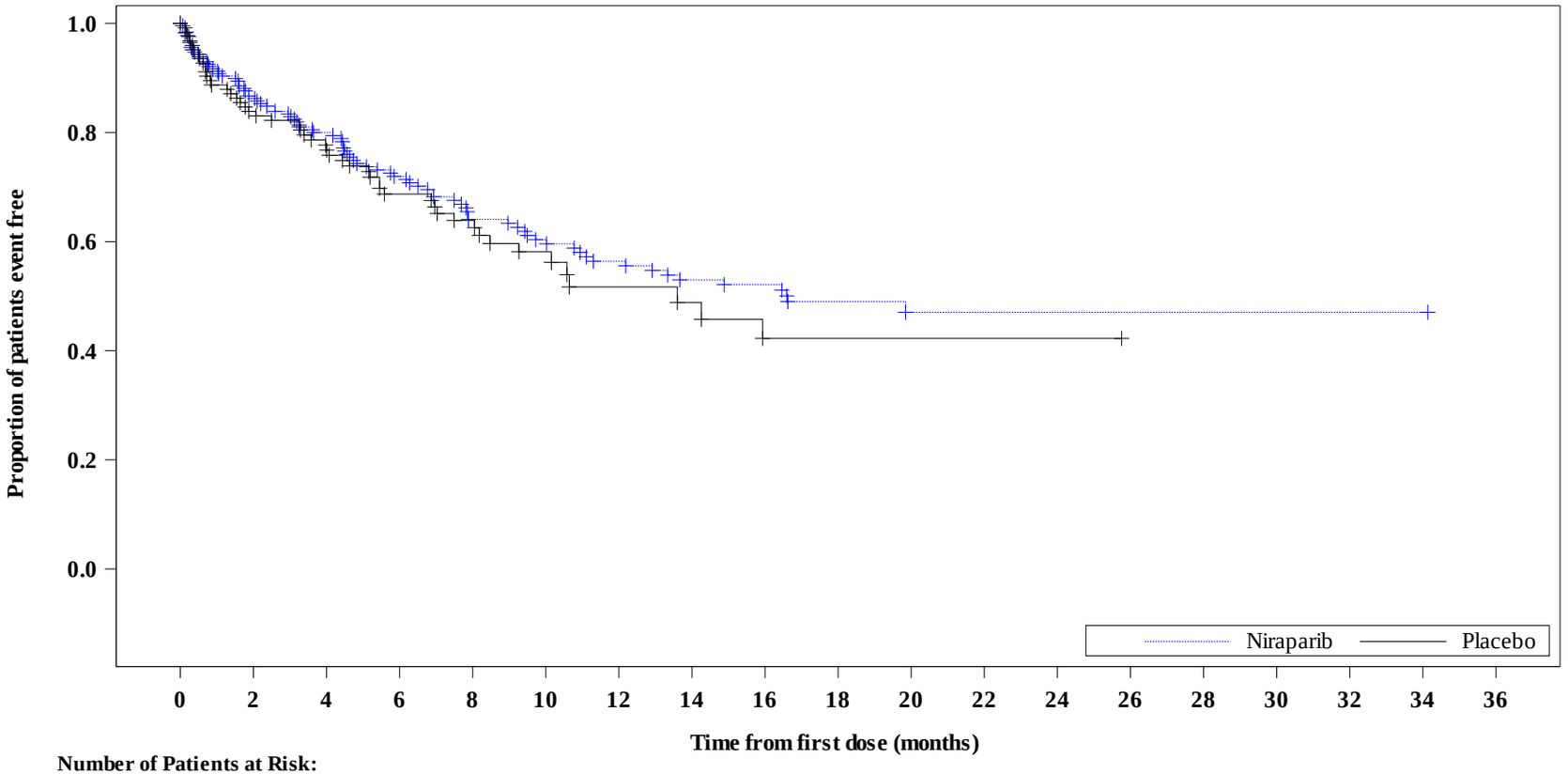



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 179 | 162 | 133 | 118 | 111 | 101 | 85 | 72 | 48 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 119 | 103 | 93 | 74 | 52 | 45 | 37 | 31 | 26 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Infections and infestations

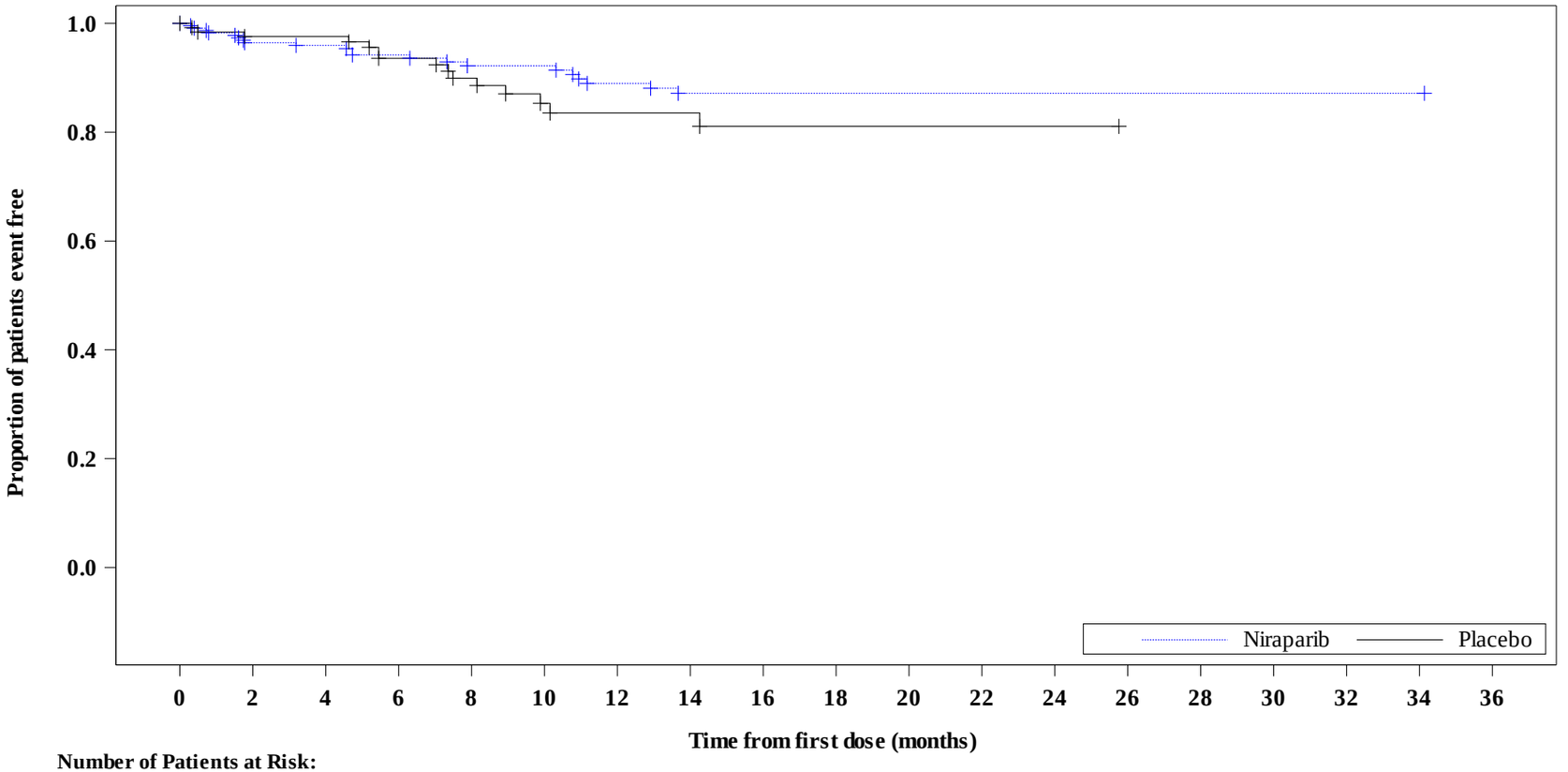



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 186 | 147 | 122 | 90 | 78 | 69 | 62 | 53 | 41 | 23 | 11 | 7 | 5 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 103 | 83 | 65 | 49 | 30 | 21 | 16 | 12 | 10 | 7 | 2 | 1 | 0 | | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Infections and infestations, PT: Nasopharyngitis

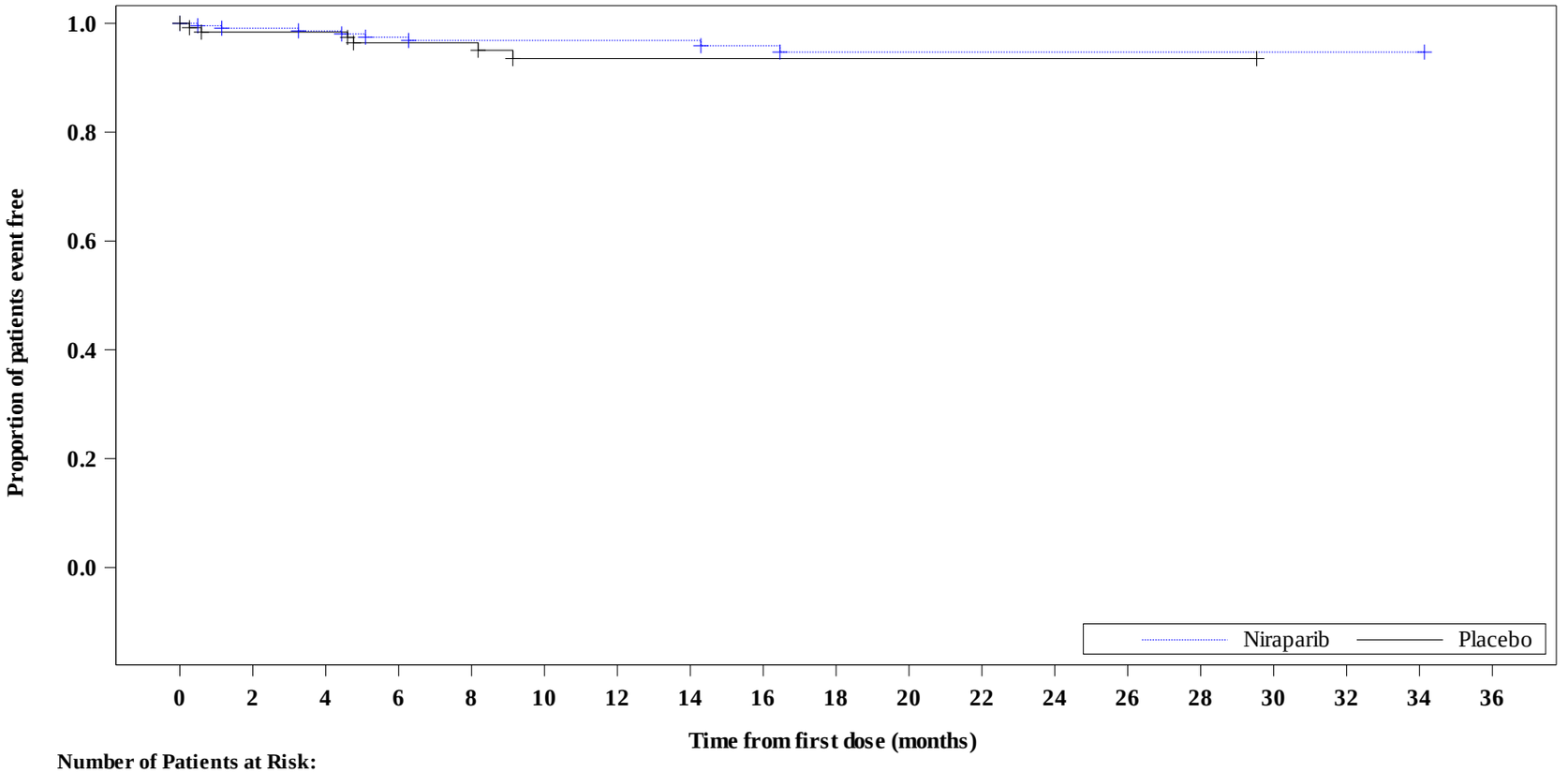



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 208 | 176 | 156 | 126 | 116 | 104 | 94 | 82 | 69 | 44 | 19 | 11 | 8 | 5 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 119 | 104 | 91 | 69 | 48 | 40 | 34 | 27 | 22 | 15 | 6 | 2 | 0 | | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Infections and infestations, PT: Sinusitis

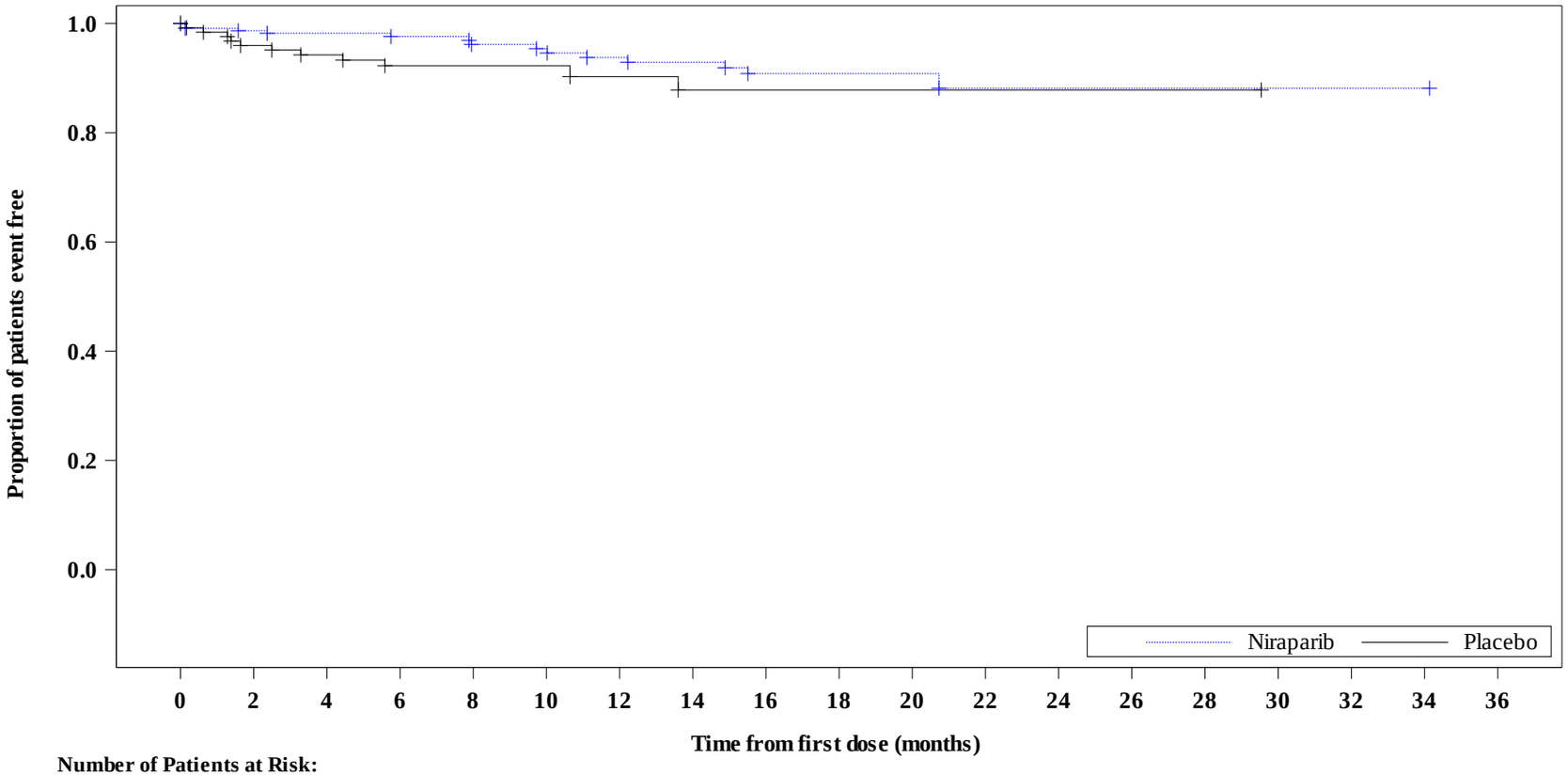



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 180 | 162 | 133 | 120 | 112 | 102 | 85 | 72 | 47 | 22 | 14 | 9 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 94 | 74 | 50 | 44 | 37 | 31 | 28 | 19 | 7 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Infections and infestations, PT: Upper respiratory tract infection

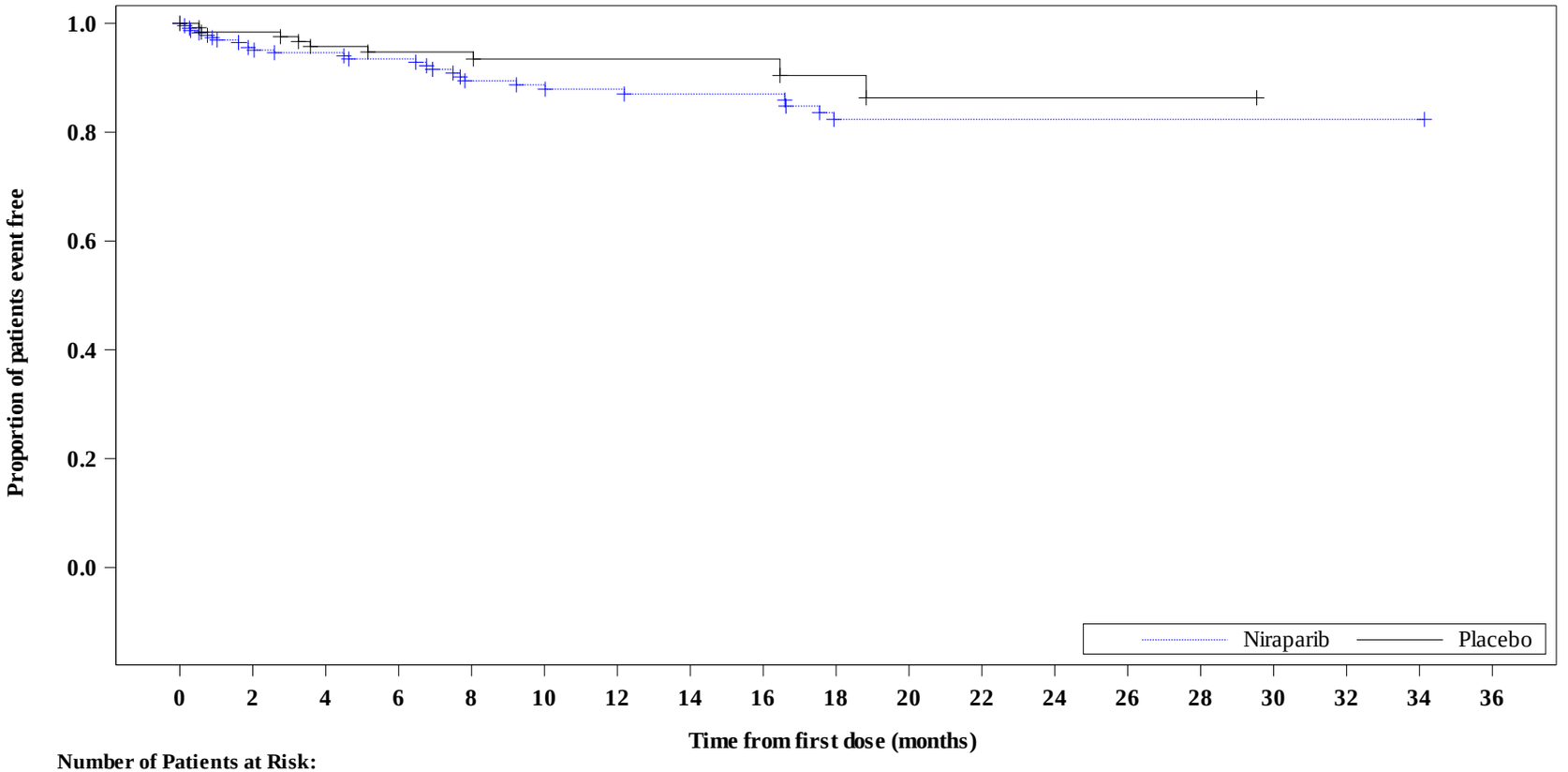



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 211 | 182 | 164 | 133 | 119 | 111 | 100 | 82 | 69 | 46 | 23 | 14 | 9 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 117 | 101 | 90 | 71 | 50 | 42 | 33 | 28 | 23 | 16 | 6 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Infections and infestations, PT: Urinary tract infection

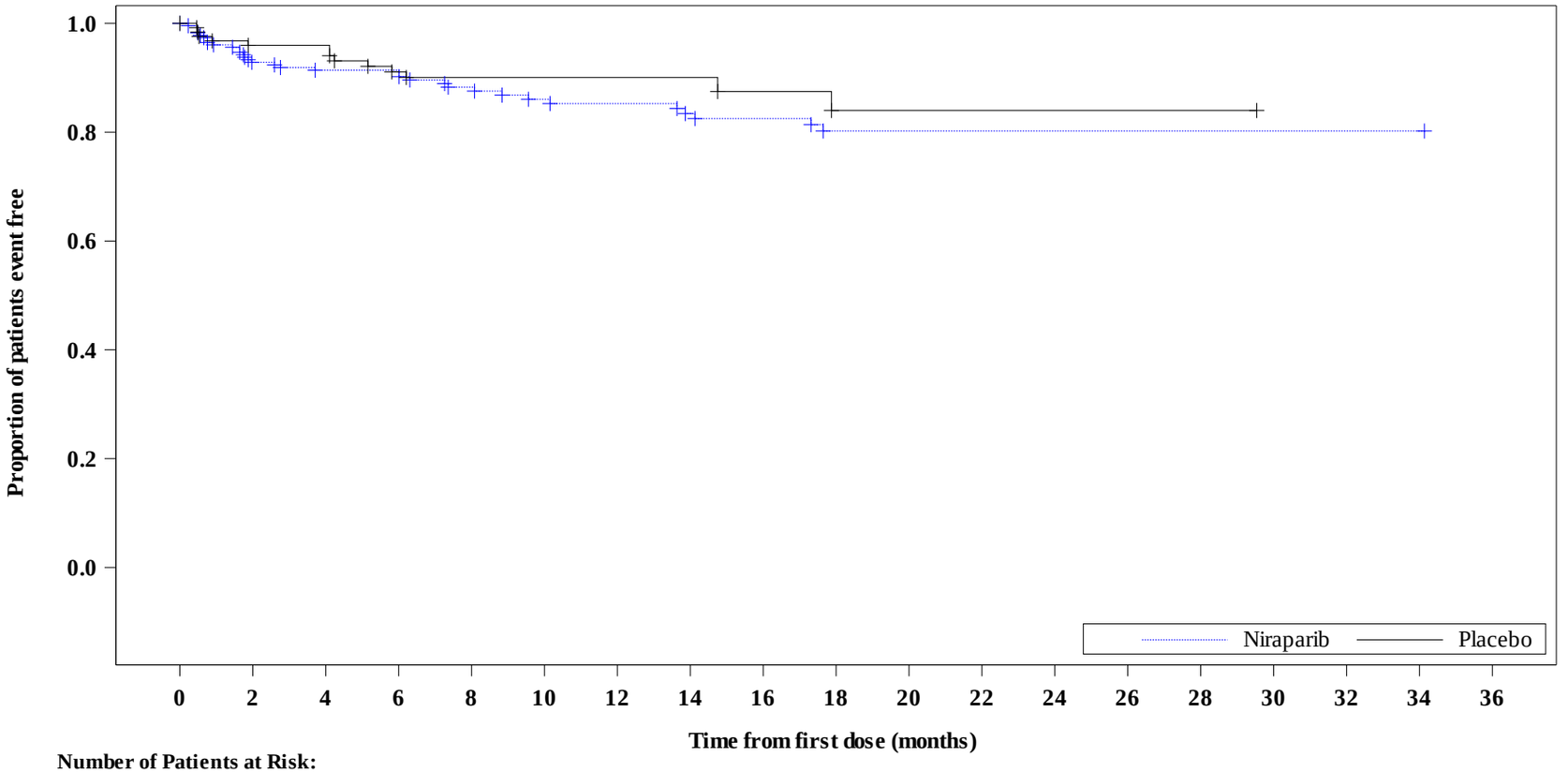



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 204 | 174 | 156 | 125 | 111 | 103 | 94 | 81 | 66 | 44 | 23 | 14 | 9 | 6 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 102 | 92 | 74 | 51 | 45 | 38 | 31 | 26 | 18 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Injury, poisoning and procedural complications

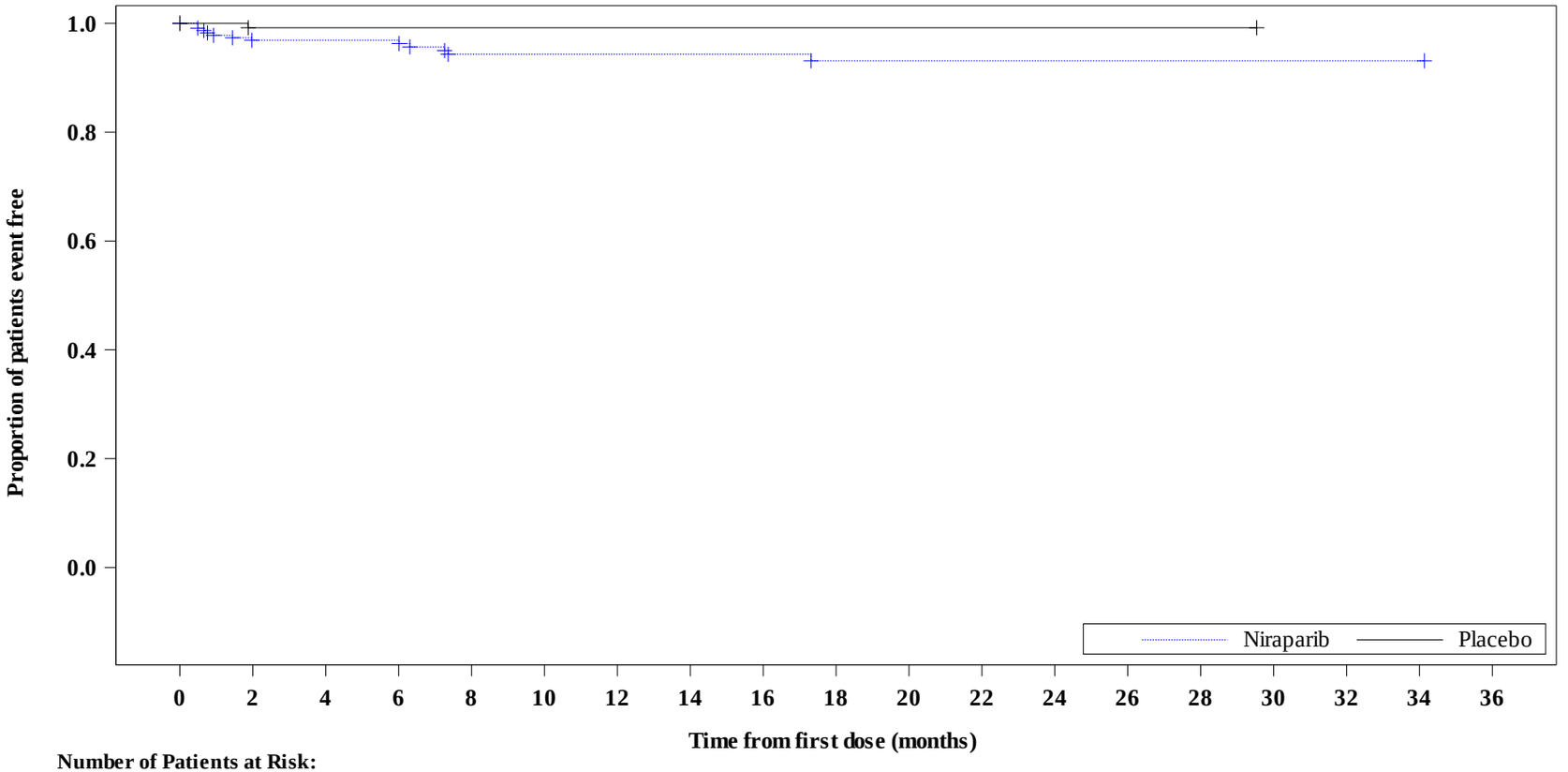



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 198 | 170 | 153 | 123 | 109 | 102 | 91 | 79 | 65 | 41 | 19 | 11 | 8 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 117 | 102 | 89 | 71 | 50 | 44 | 37 | 30 | 24 | 16 | 5 | 2 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Injury, poisoning and procedural complications, PT: Contusion



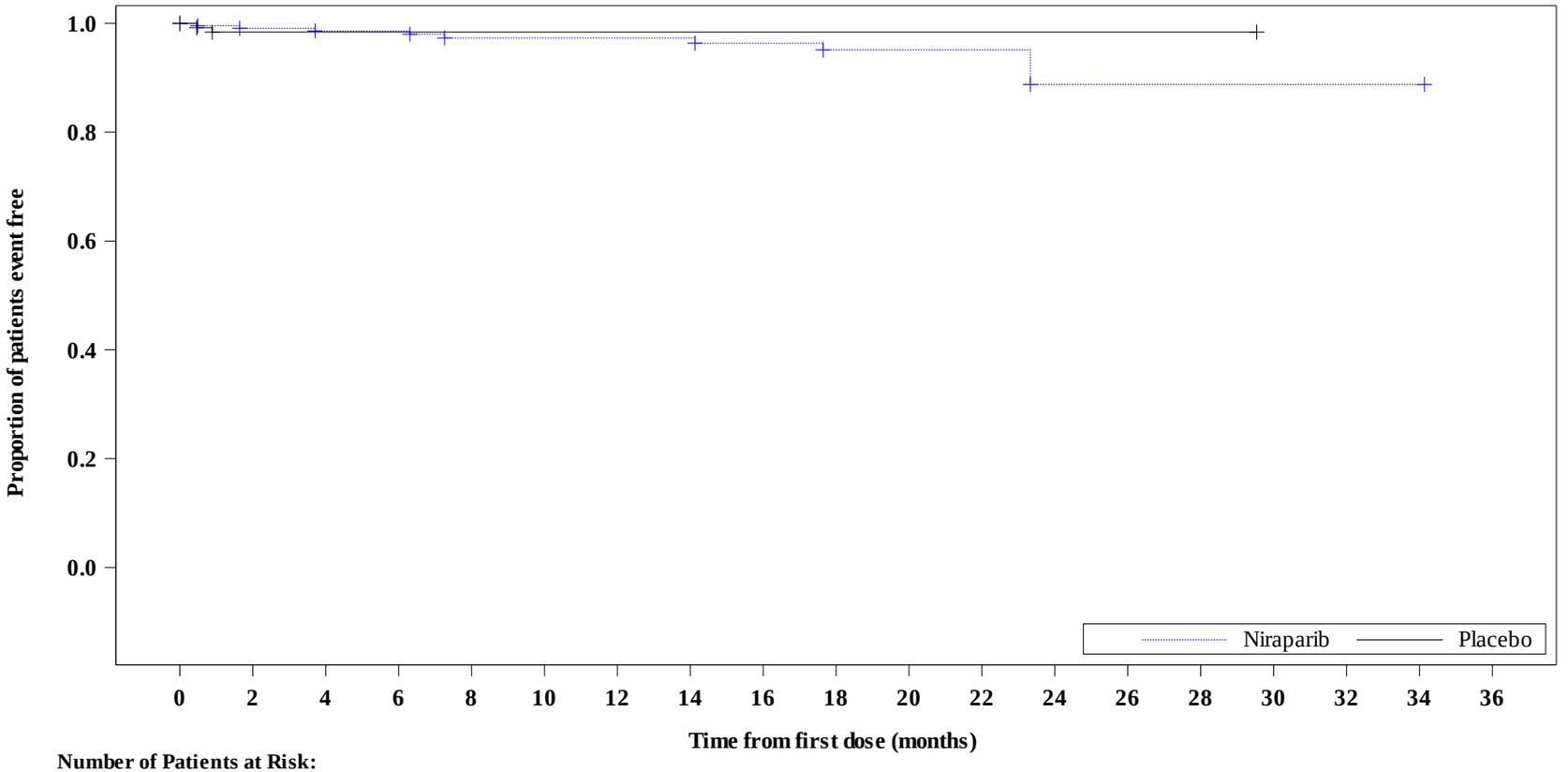

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 207 | 177 | 160 | 128 | 117 | 109 | 99 | 85 | 71 | 45 | 20 | 11 | 8 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 77 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-14-teaept-g.sas 30SEP2020 08:59

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Injury, poisoning and procedural complications, PT: Fall

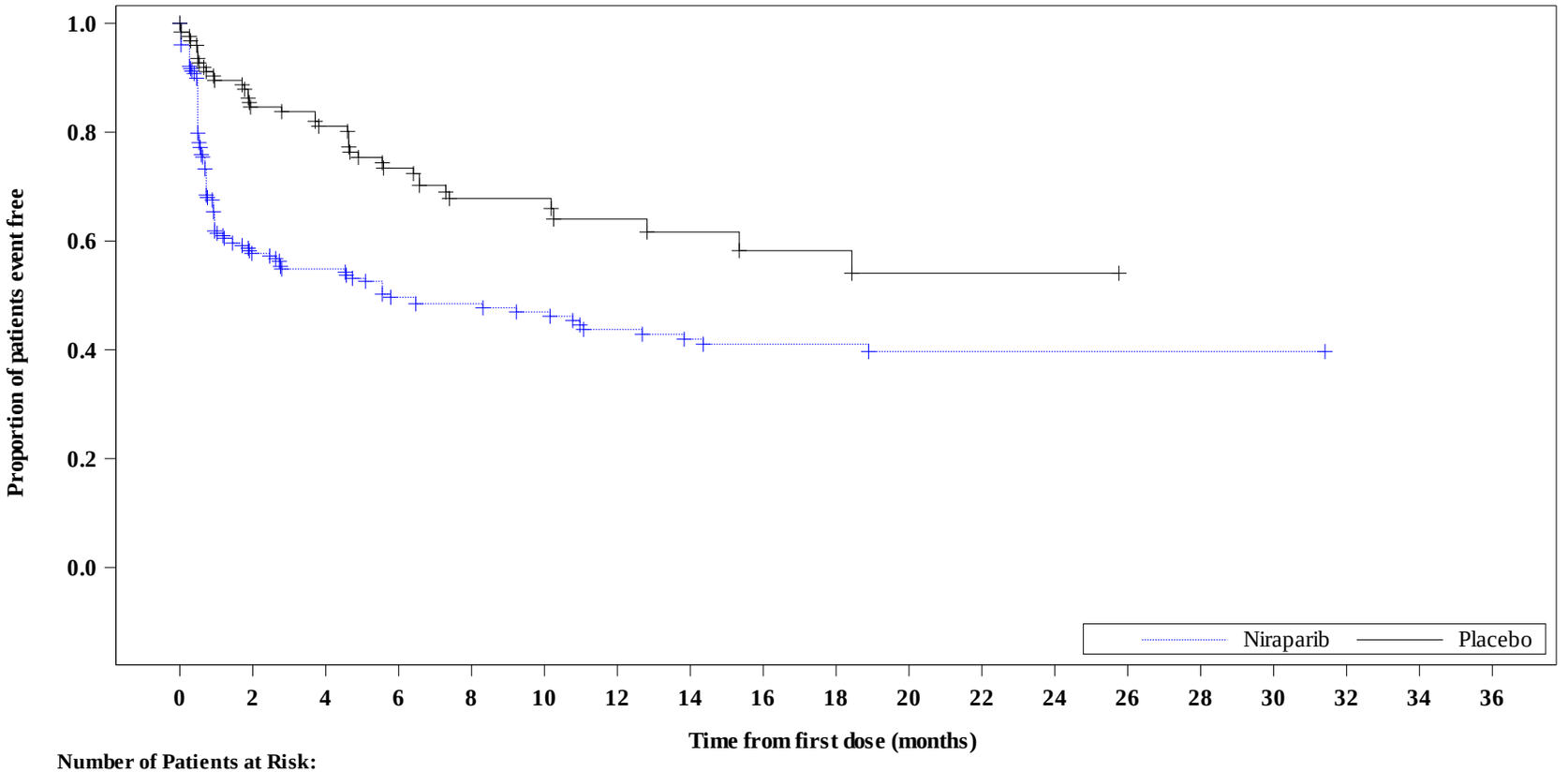



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 181 | 164 | 134 | 120 | 112 | 102 | 86 | 73 | 47 | 23 | 13 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 96 | 77 | 55 | 48 | 40 | 33 | 28 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations

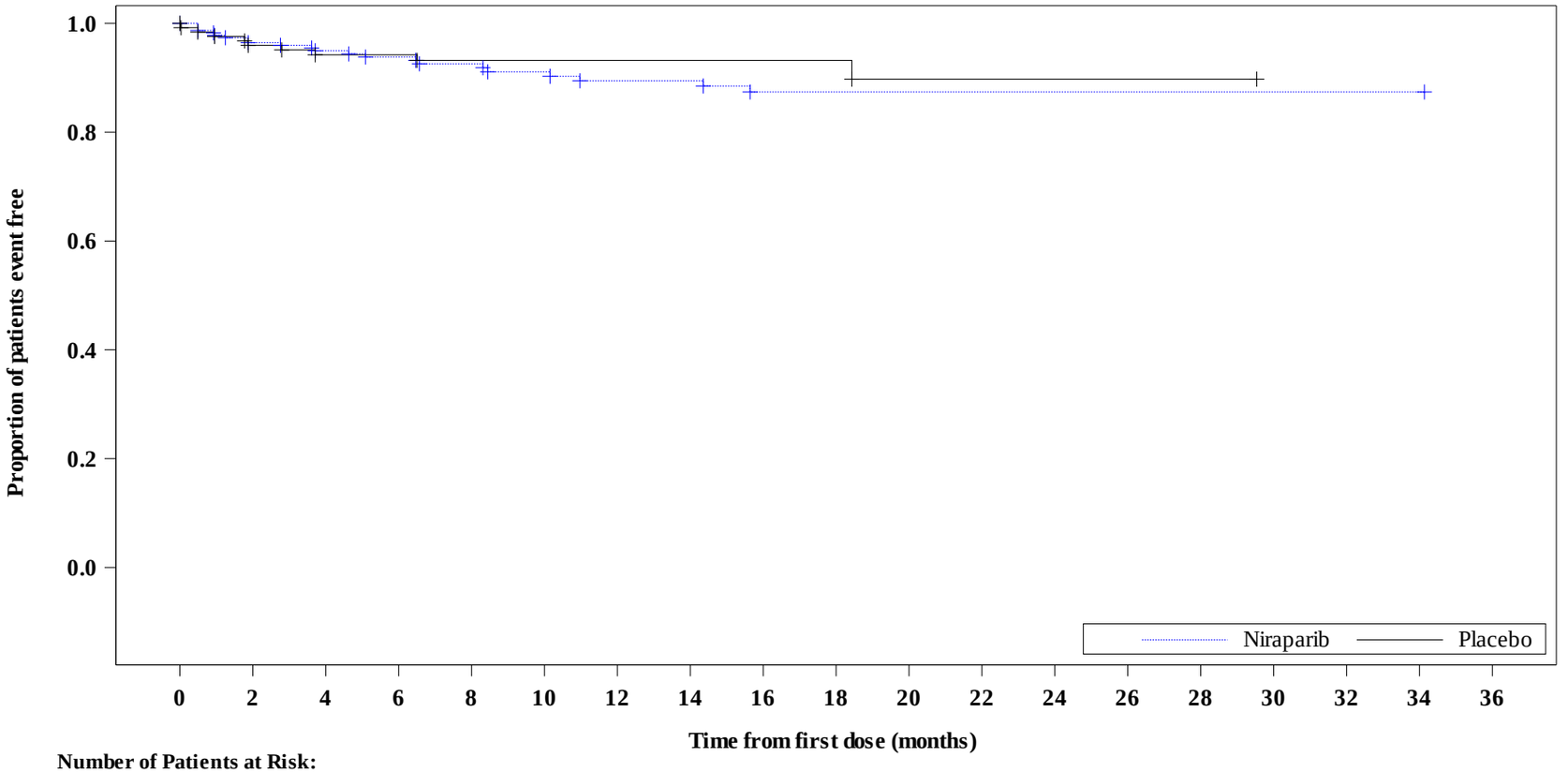



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 120 | 100 | 84 | 66 | 59 | 51 | 46 | 41 | 34 | 20 | 8 | 4 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 103 | 89 | 74 | 53 | 37 | 30 | 23 | 17 | 14 | 8 | 3 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Alanine aminotransferase increased

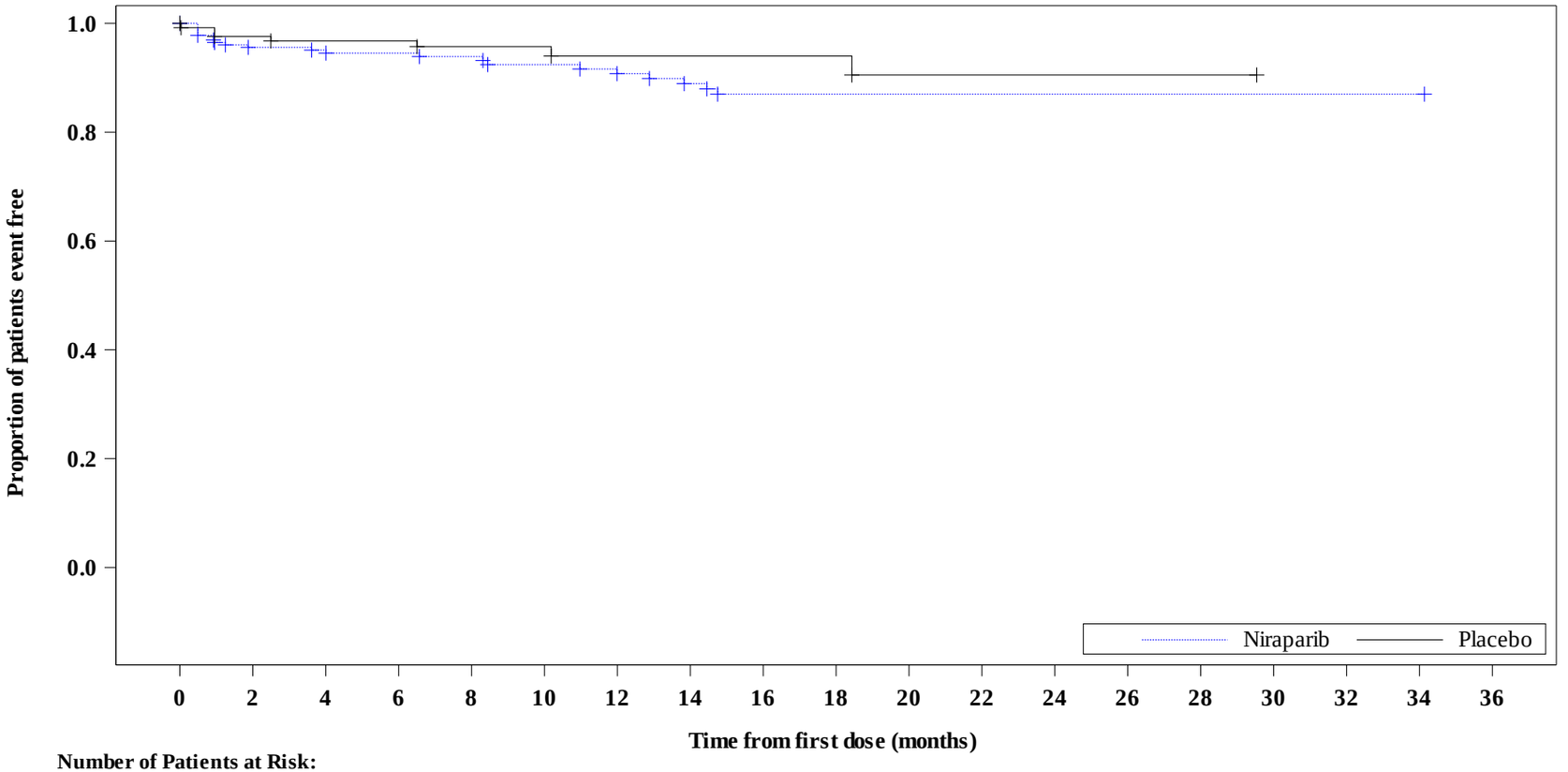



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 206 | 174 | 157 | 126 | 112 | 102 | 95 | 77 | 66 | 43 | 21 | 14 | 9 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 117 | 104 | 96 | 75 | 53 | 46 | 39 | 32 | 27 | 18 | 7 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Aspartate aminotransferase increased

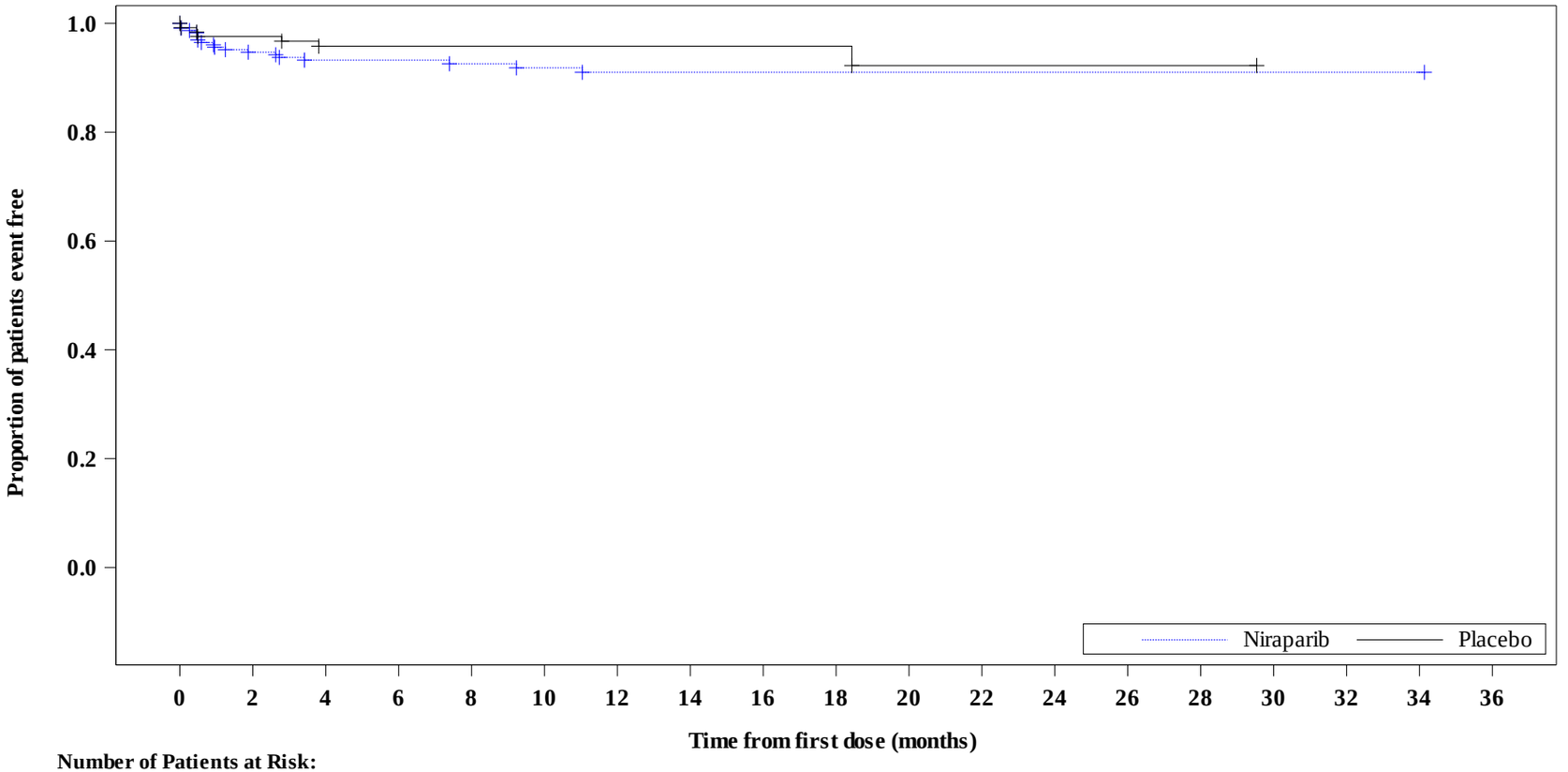



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 204 | 174 | 158 | 128 | 115 | 105 | 95 | 77 | 66 | 41 | 19 | 13 | 9 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 119 | 106 | 98 | 77 | 55 | 47 | 39 | 32 | 27 | 19 | 7 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Blood alkaline phosphatase increased

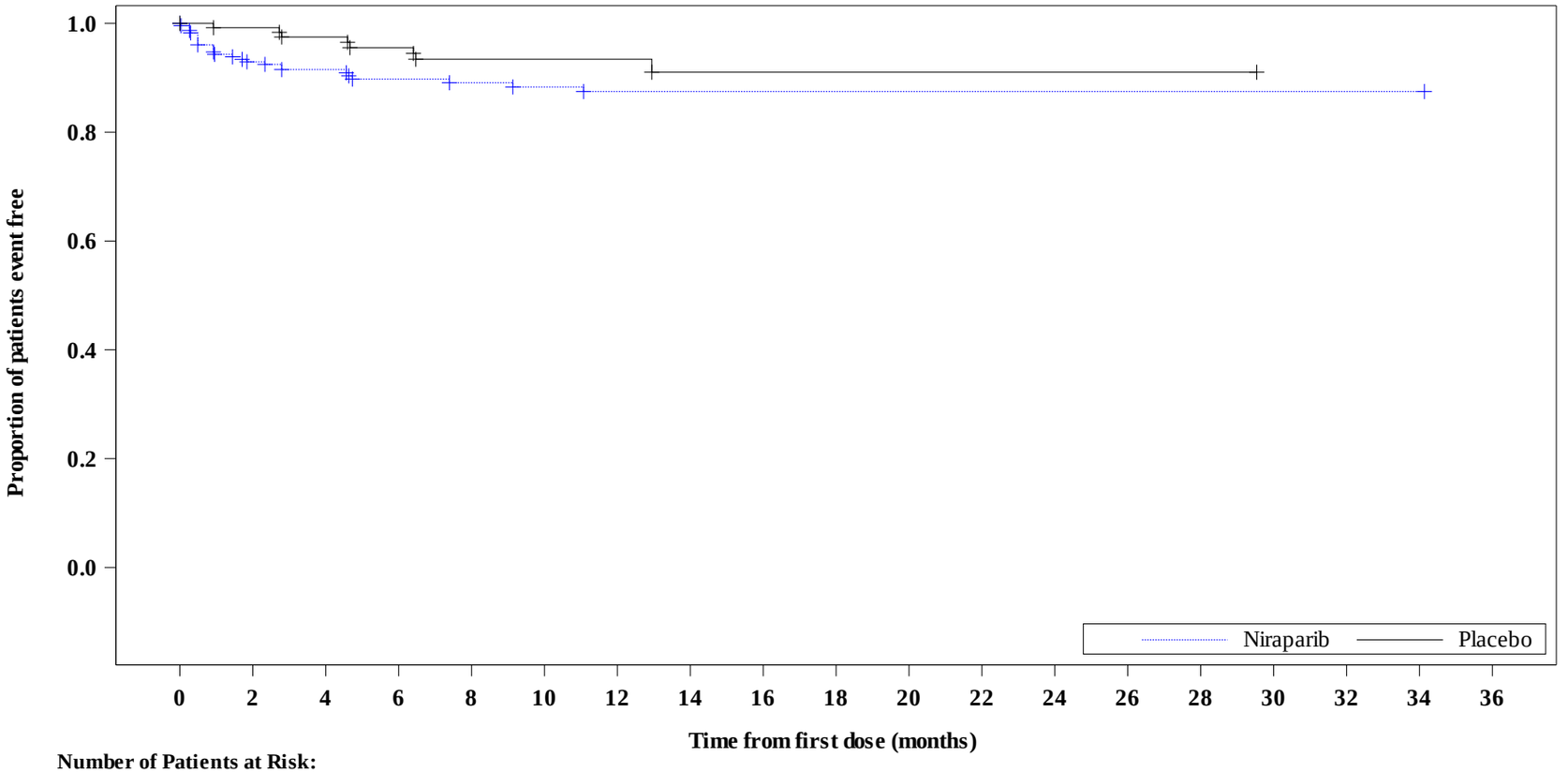



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 202 | 172 | 156 | 128 | 115 | 106 | 97 | 83 | 70 | 44 | 20 | 13 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 119 | 103 | 95 | 76 | 54 | 47 | 39 | 32 | 27 | 17 | 6 | 2 | 1 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Blood creatinine increased

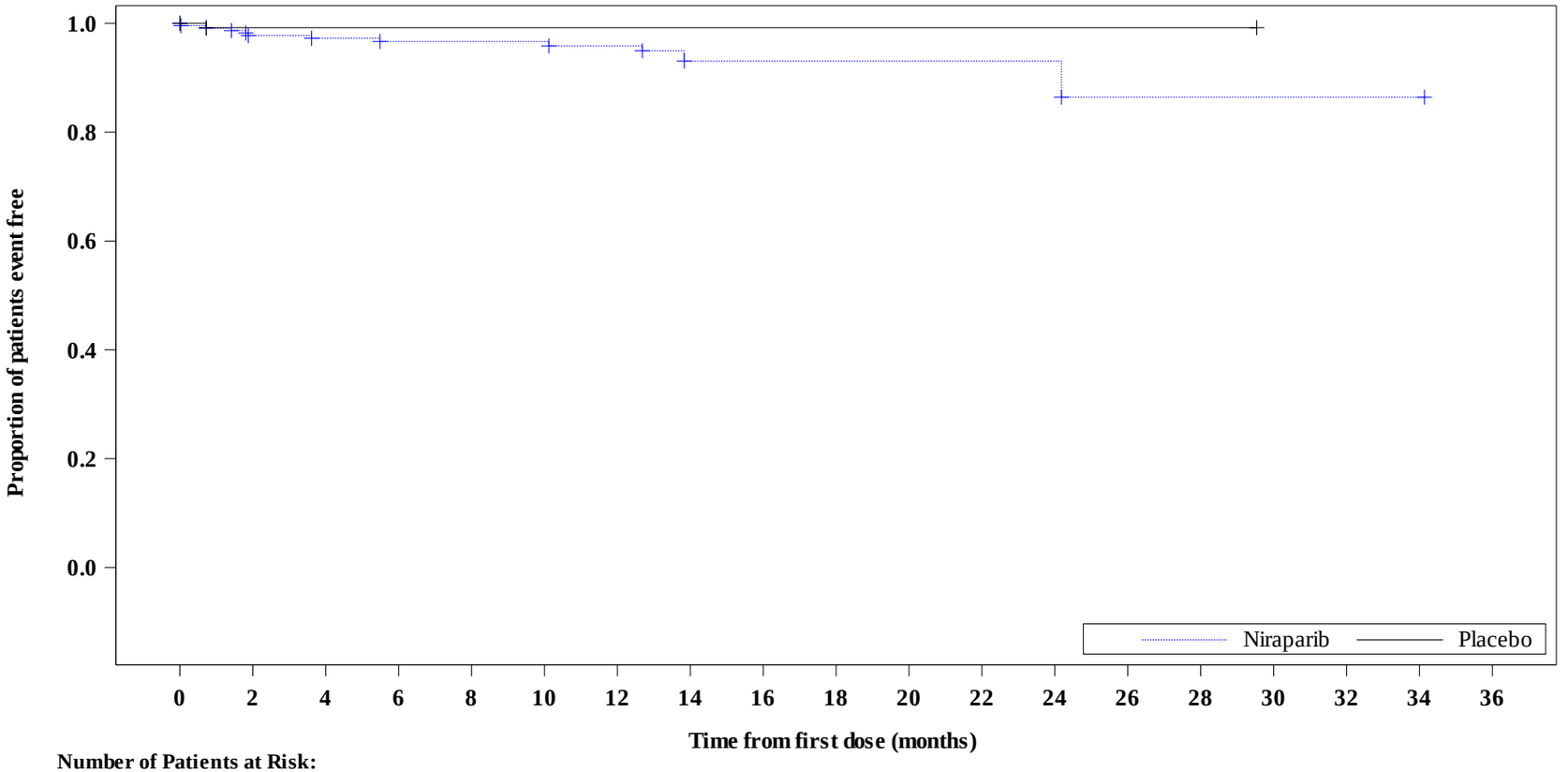



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 198 | 167 | 149 | 120 | 108 | 99 | 91 | 80 | 69 | 44 | 22 | 13 | 9 | 6 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 104 | 93 | 71 | 50 | 43 | 35 | 28 | 24 | 16 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Lymphocyte count decreased

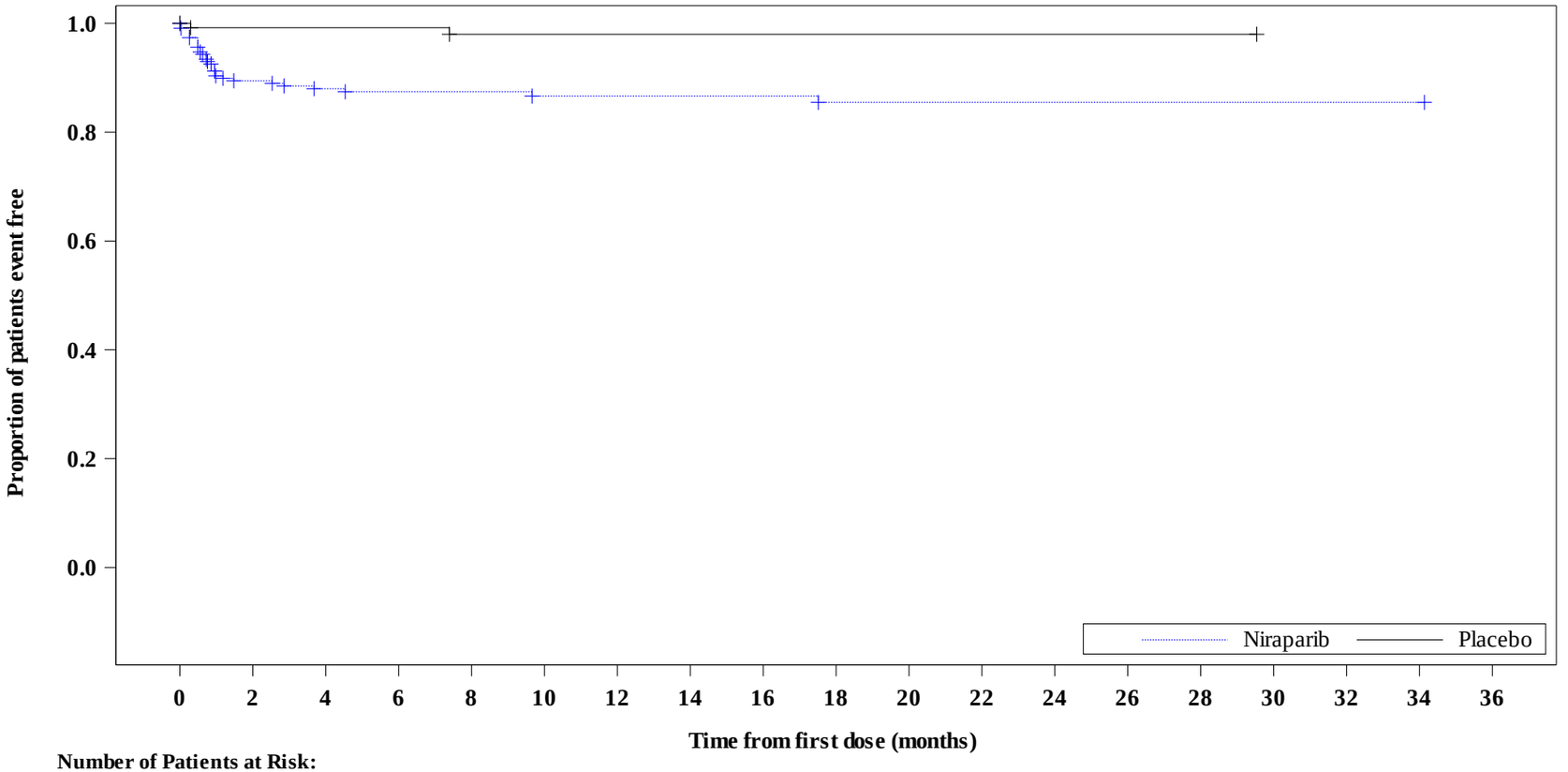



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 179 | 162 | 134 | 120 | 111 | 99 | 84 | 72 | 46 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 77 | 55 | 48 | 40 | 33 | 28 | 19 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Neutrophil count decreased

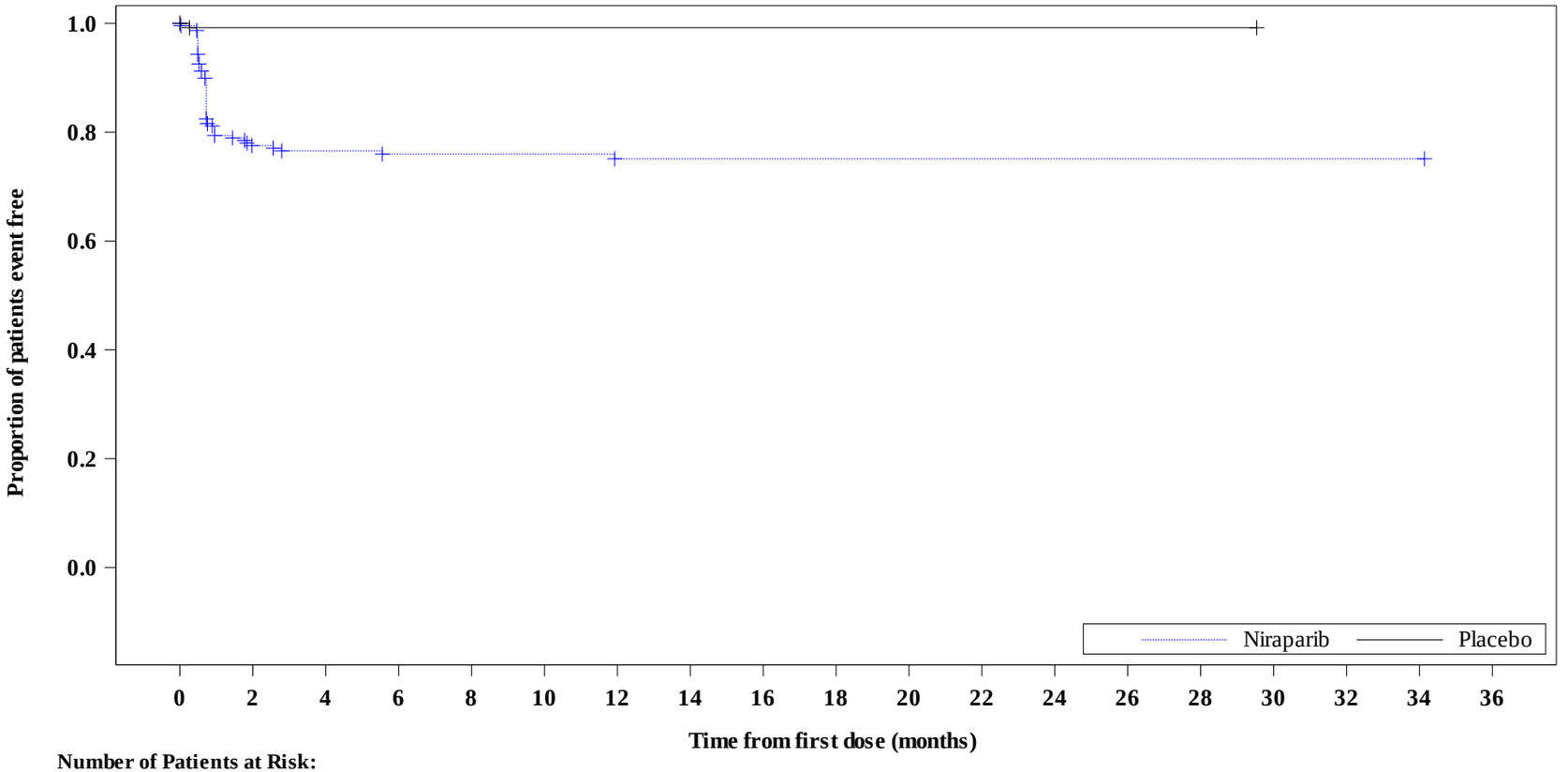



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 190 | 161 | 145 | 118 | 107 | 99 | 94 | 80 | 69 | 45 | 22 | 13 | 9 | 6 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 76 | 54 | 47 | 39 | 33 | 28 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Platelet count decreased

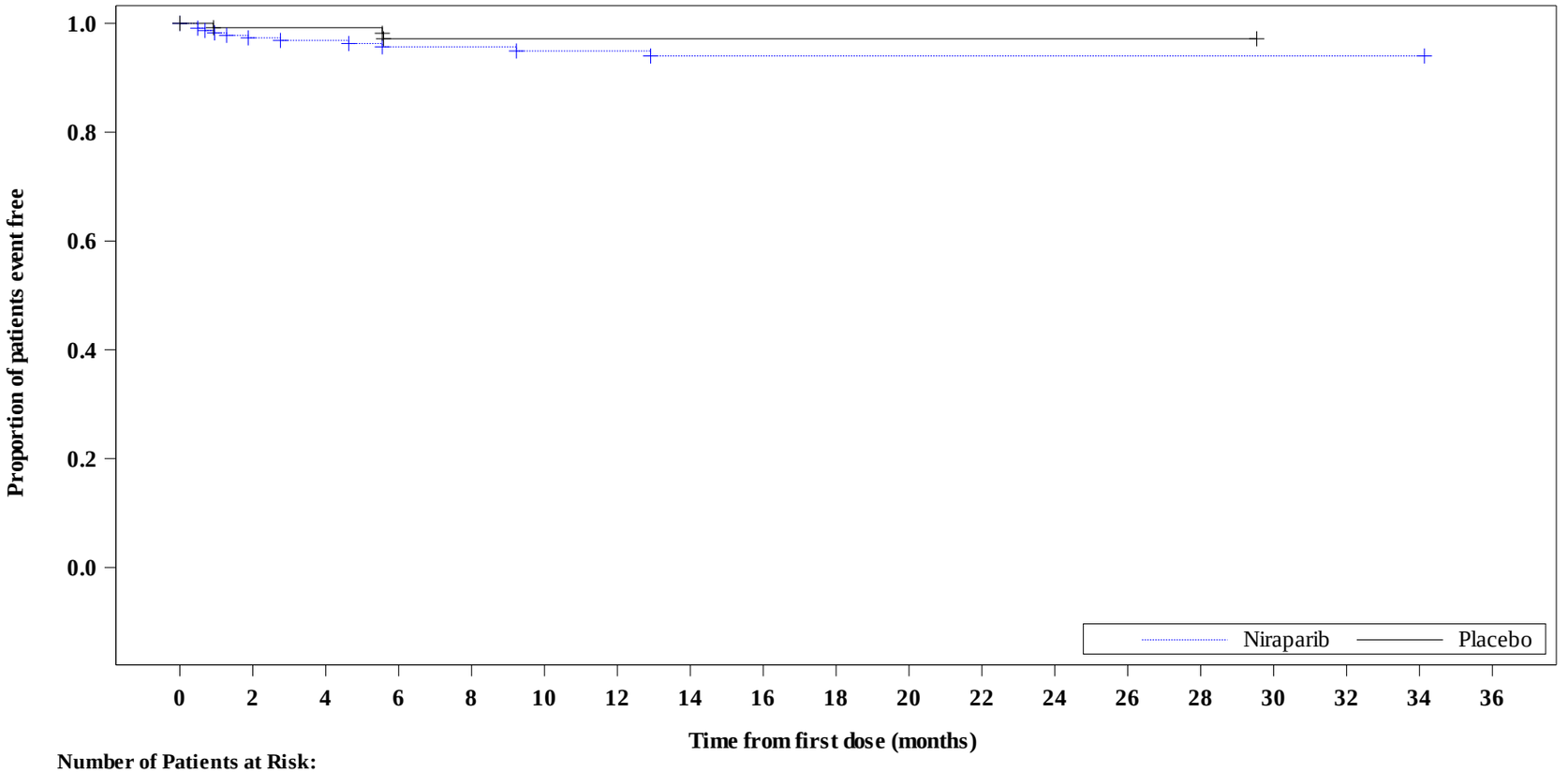



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 164 | 138 | 124 | 102 | 92 | 83 | 78 | 68 | 58 | 36 | 17 | 9 | 7 | 5 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 77 | 55 | 48 | 40 | 33 | 28 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Weight decreased

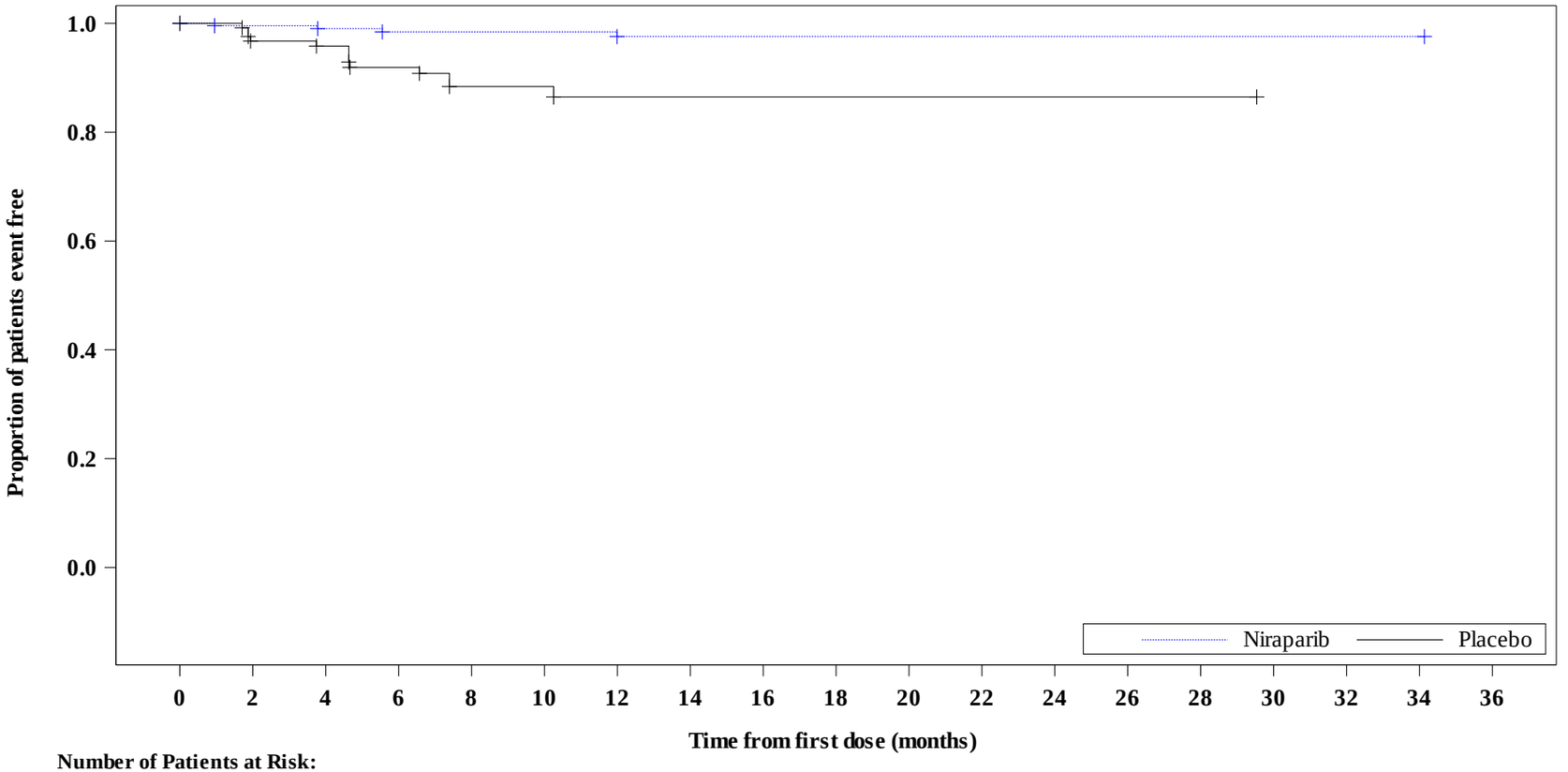



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 178 | 159 | 131 | 116 | 109 | 99 | 83 | 70 | 45 | 20 | 11 | 7 | 5 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 95 | 75 | 54 | 47 | 39 | 32 | 27 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: Weight increased

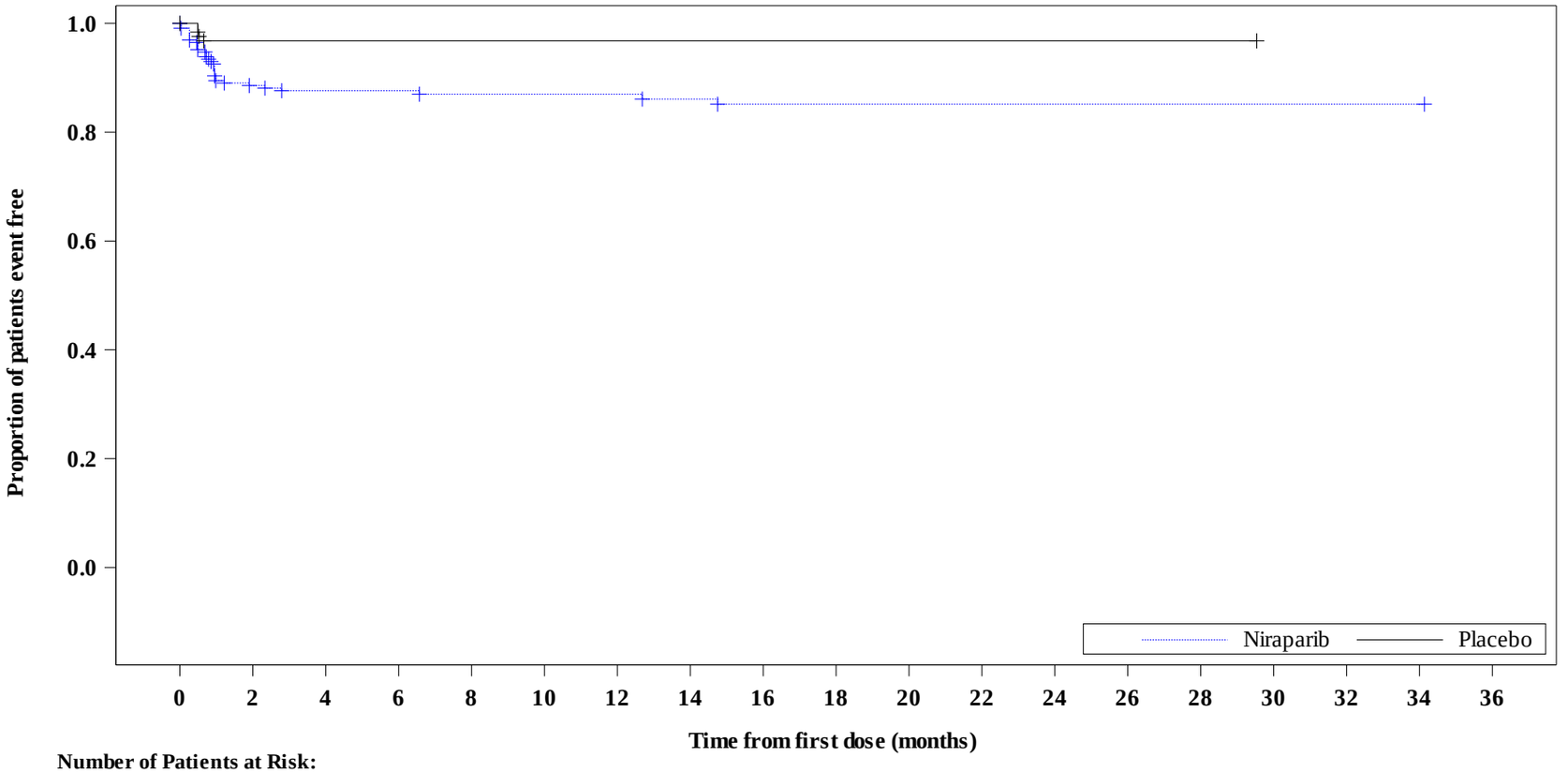



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 213 | 181 | 163 | 134 | 120 | 111 | 101 | 85 | 72 | 46 | 22 | 13 | 9 | 6 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 118 | 102 | 90 | 68 | 48 | 42 | 36 | 29 | 24 | 16 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Investigations, PT: White blood cell count decreased

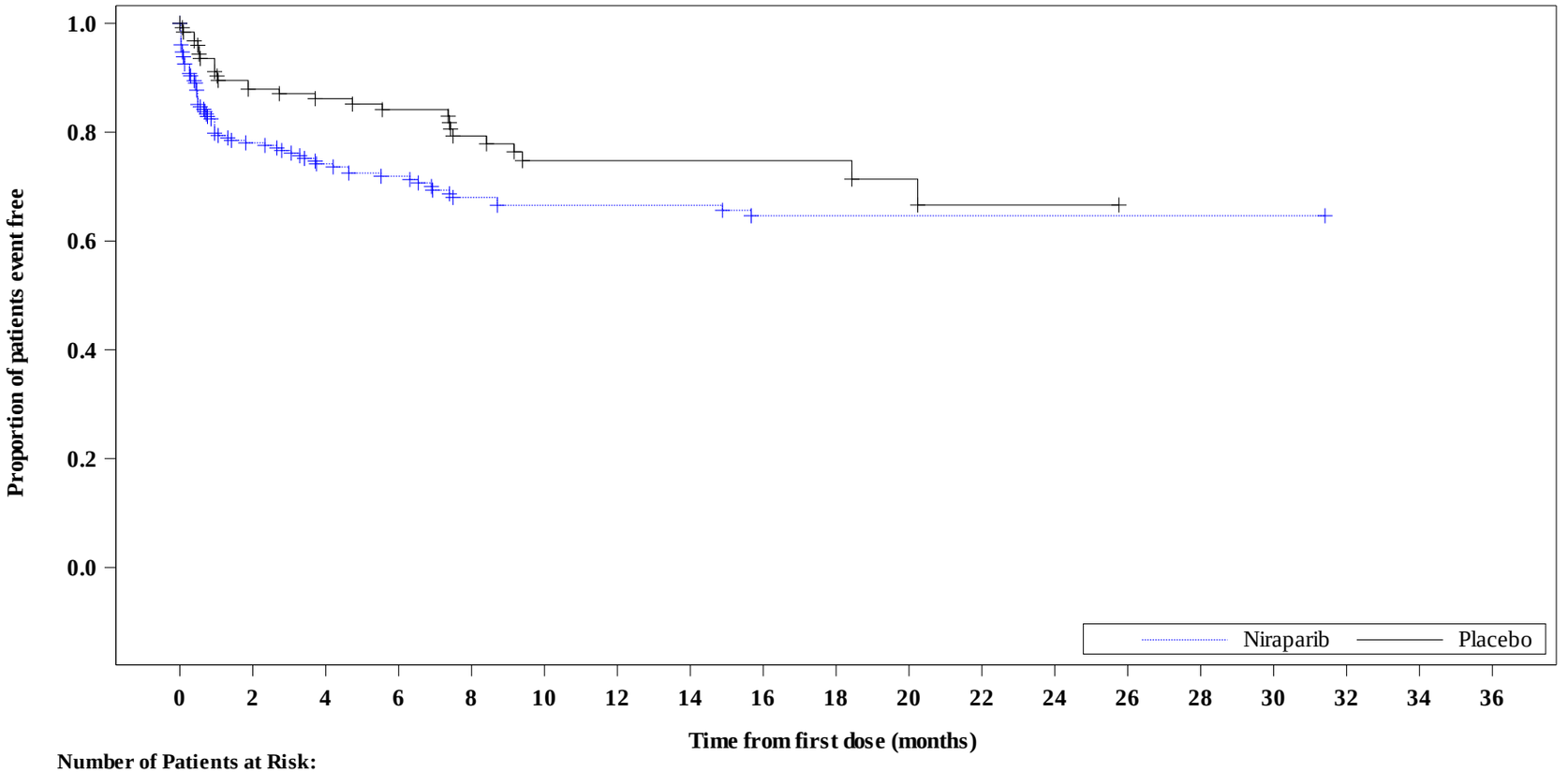



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 188 | 163 | 148 | 119 | 108 | 101 | 93 | 80 | 69 | 45 | 23 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 118 | 105 | 96 | 77 | 55 | 48 | 40 | 33 | 28 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Metabolism and nutrition disorders

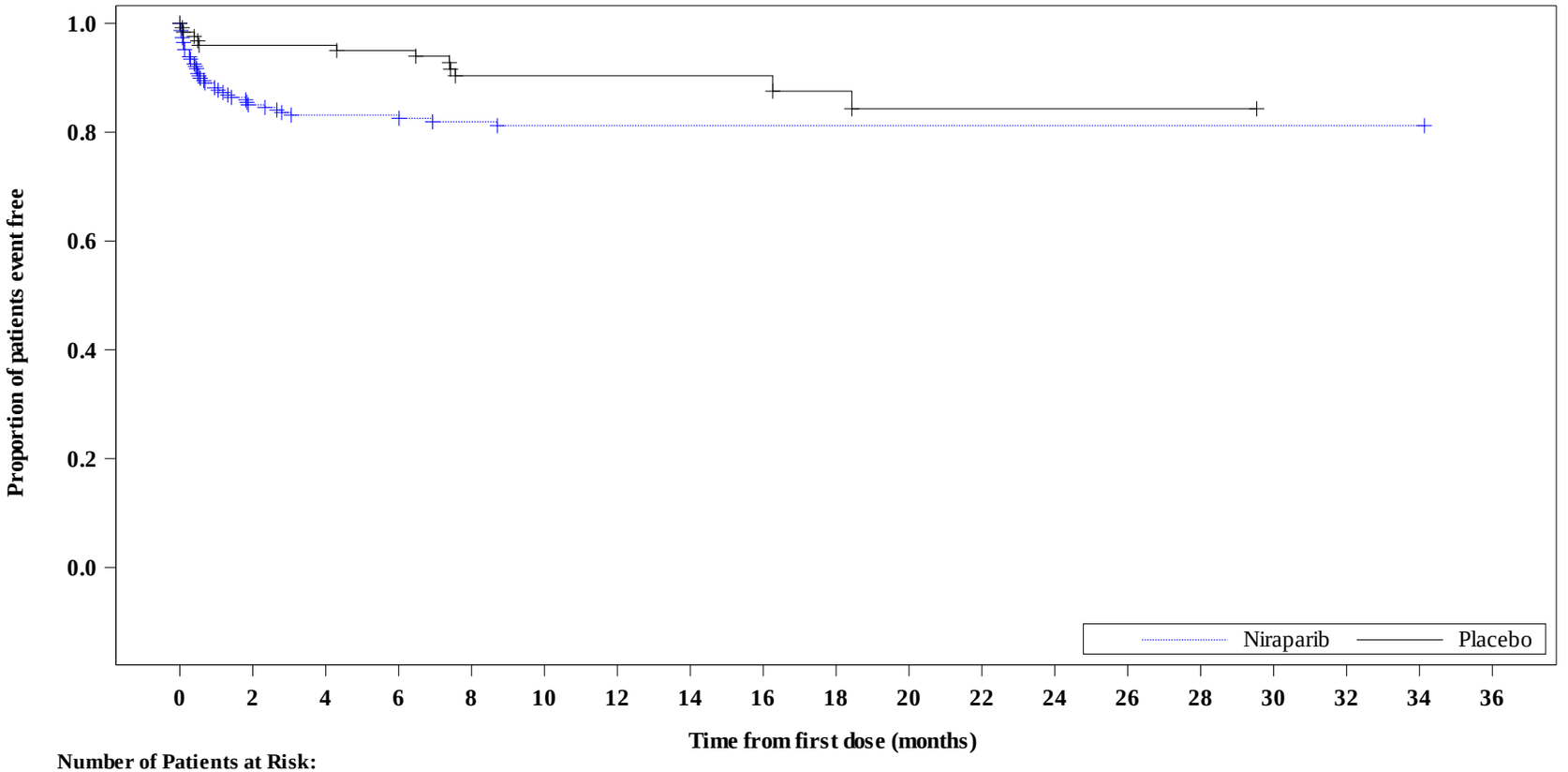



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 167 | 139 | 121 | 96 | 85 | 82 | 76 | 64 | 52 | 35 | 16 | 8 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 108 | 92 | 81 | 61 | 42 | 36 | 30 | 25 | 22 | 16 | 5 | 2 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Metabolism and nutrition disorders, PT: Decreased appetite

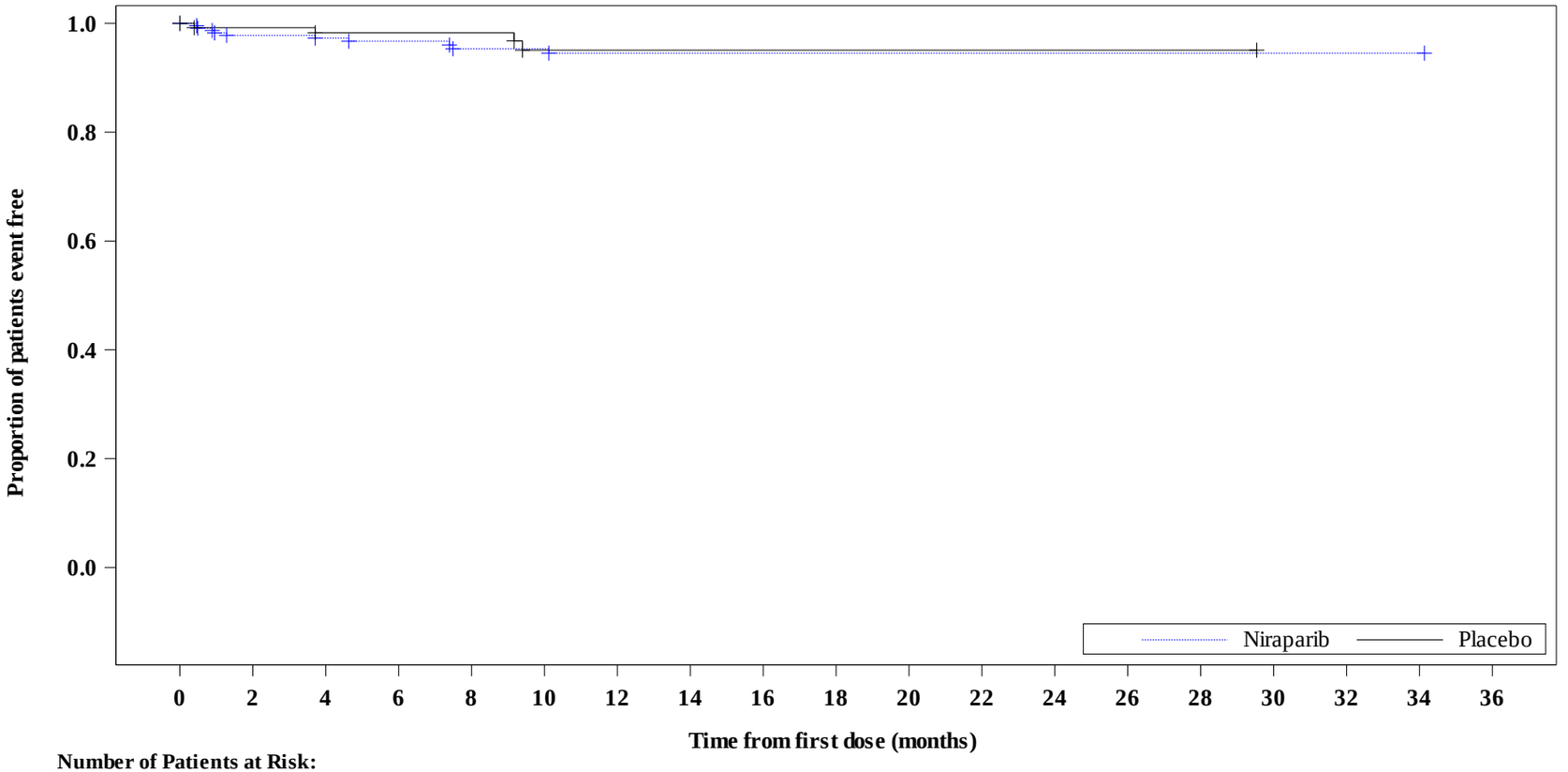



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 183 | 158 | 142 | 116 | 104 | 98 | 89 | 75 | 62 | 42 | 19 | 11 | 7 | 5 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 118 | 103 | 93 | 71 | 53 | 46 | 38 | 32 | 27 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Metabolism and nutrition disorders, PT: Hypokalaemia

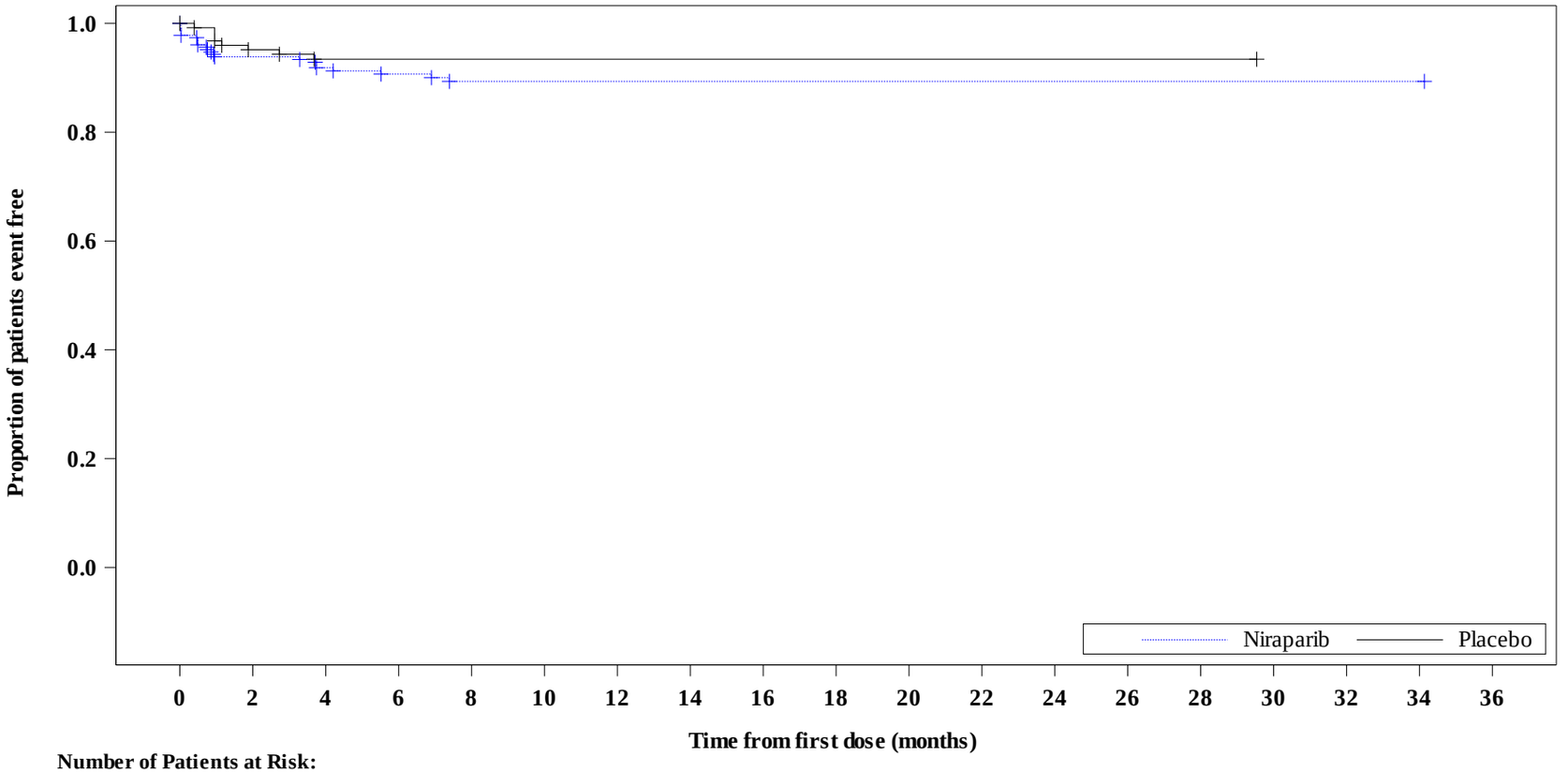



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 177 | 160 | 131 | 118 | 111 | 101 | 86 | 74 | 48 | 23 | 14 | 9 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 121 | 105 | 96 | 76 | 52 | 46 | 38 | 32 | 28 | 19 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Metabolism and nutrition disorders, PT: Hypomagnesaemia

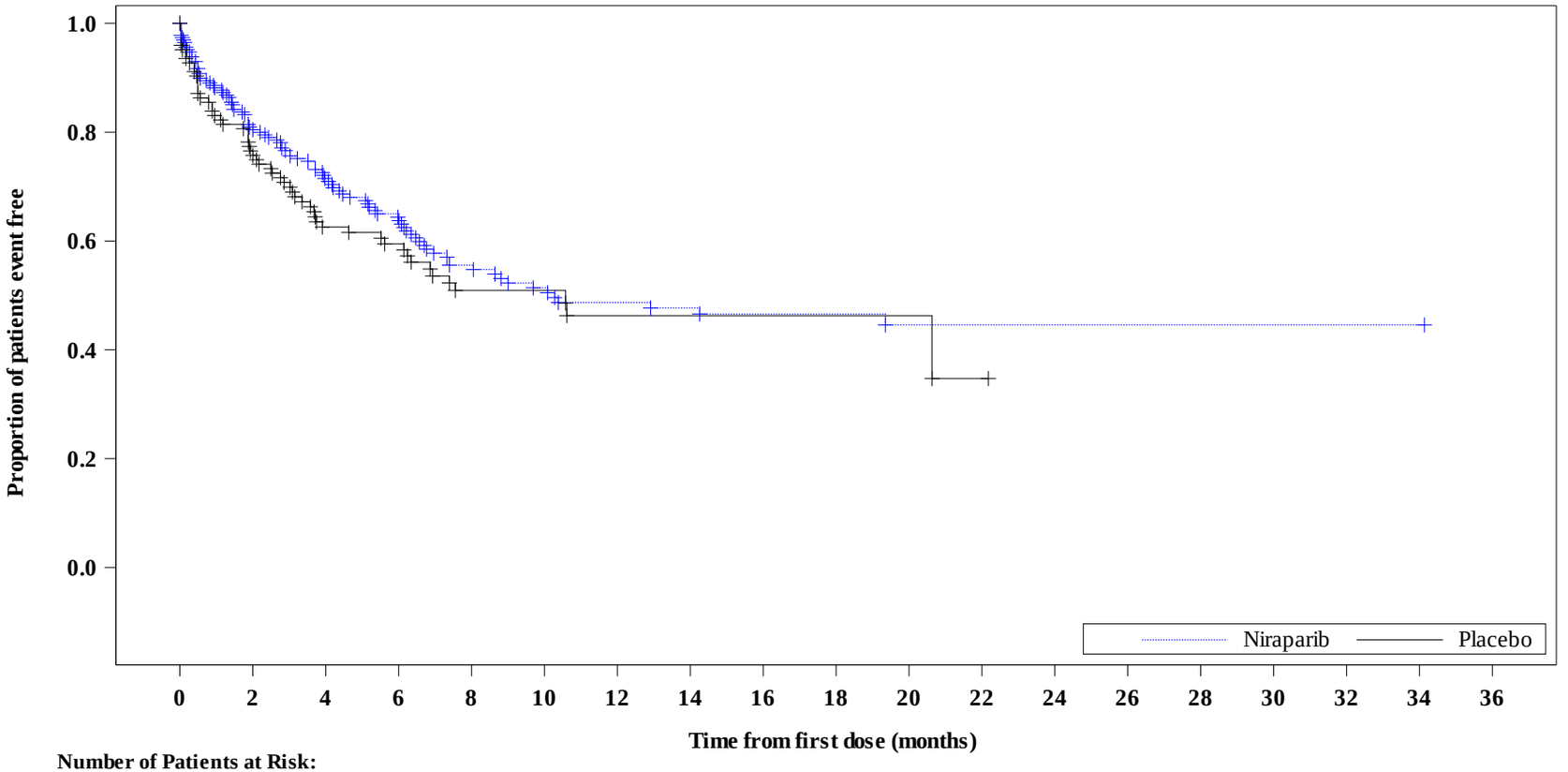



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 200 | 168 | 151 | 124 | 111 | 103 | 95 | 81 | 69 | 45 | 22 | 13 | 8 | 5 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 116 | 100 | 91 | 73 | 52 | 45 | 38 | 31 | 27 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders

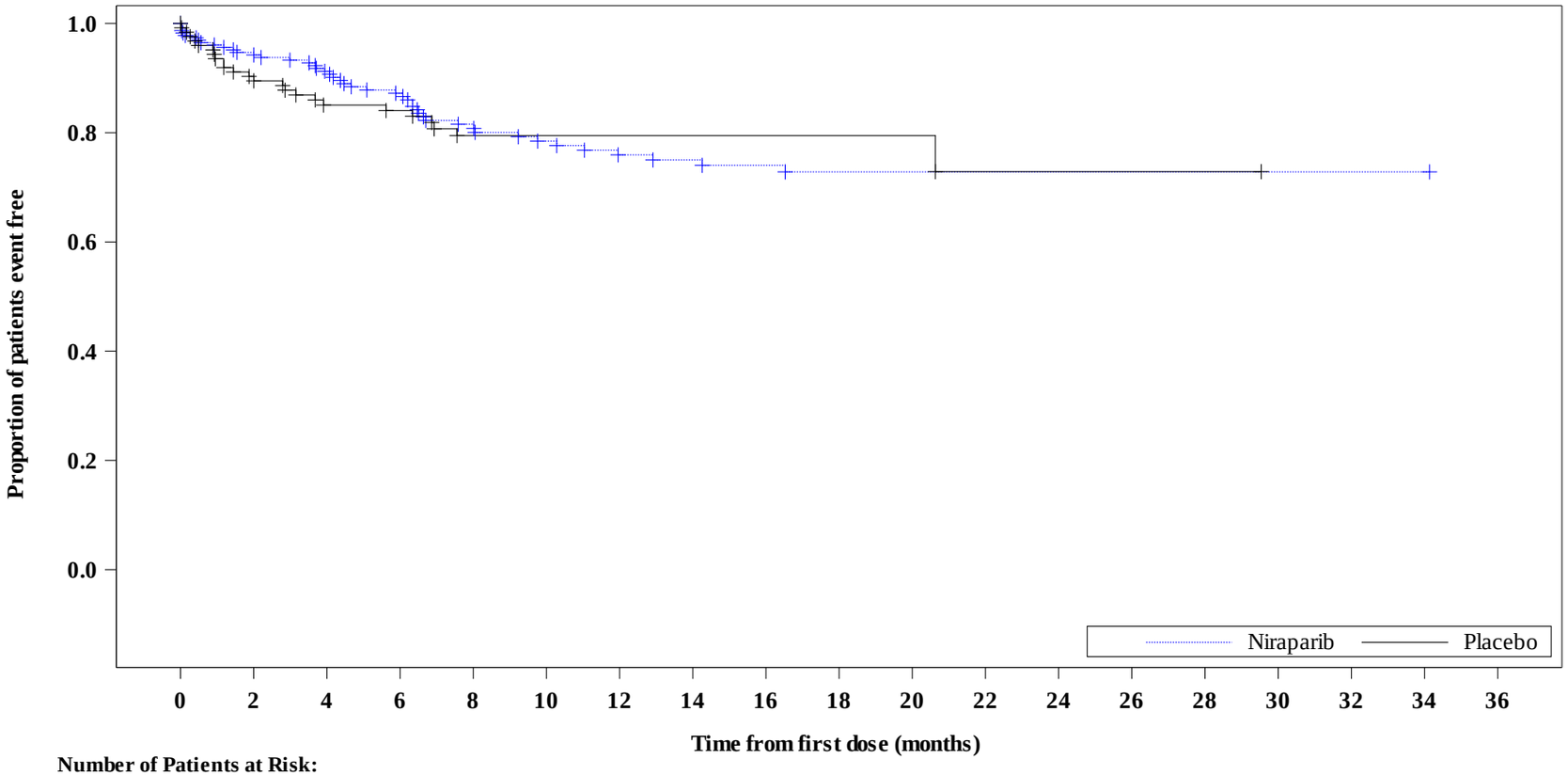



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 172 | 128 | 103 | 69 | 57 | 51 | 45 | 38 | 31 | 17 | 7 | 3 | 2 | 1 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 94 | 65 | 55 | 36 | 23 | 19 | 15 | 14 | 10 | 7 | 1 | 0 | | | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia

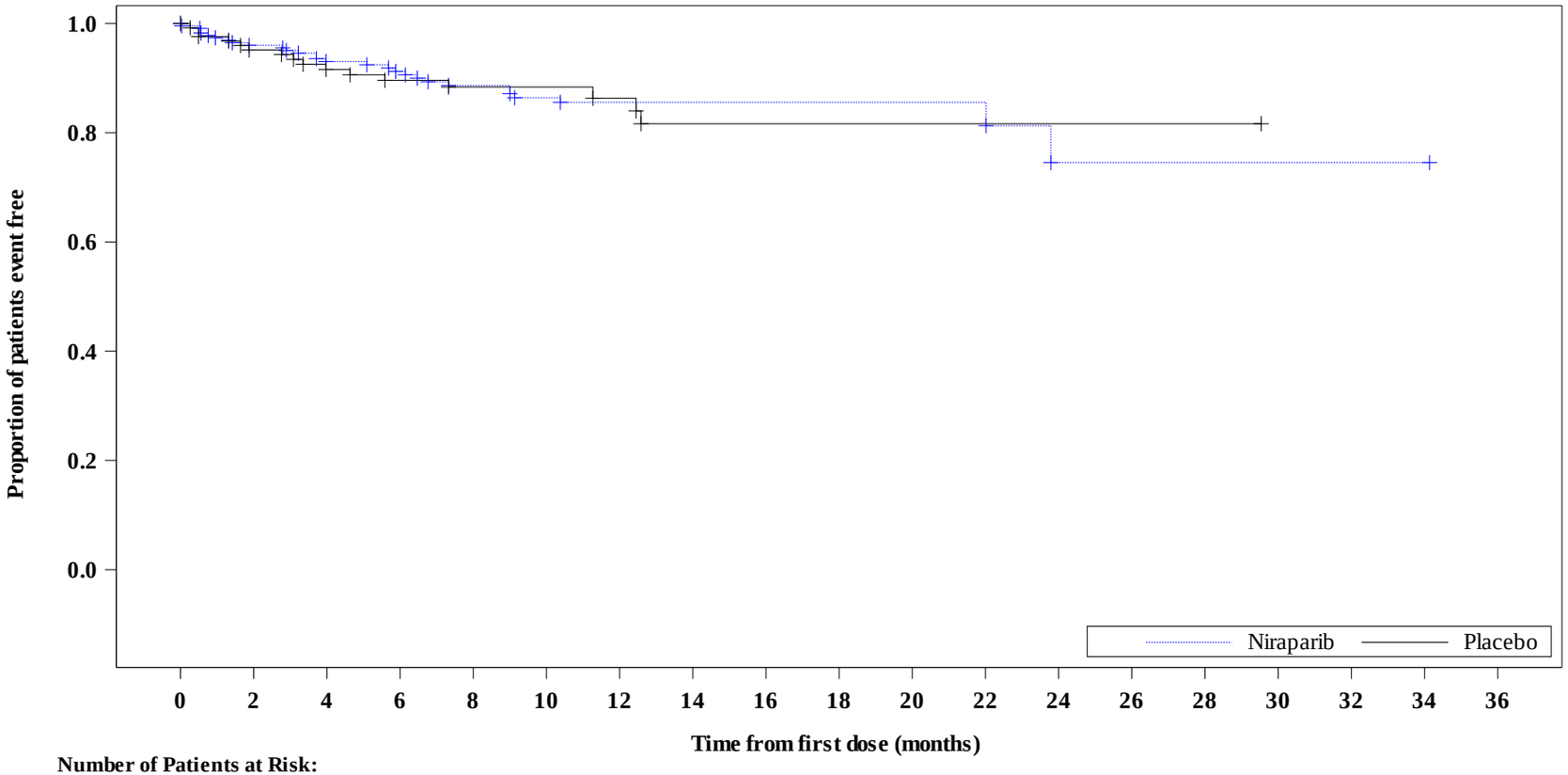



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 202 | 166 | 145 | 109 | 95 | 87 | 77 | 64 | 51 | 35 | 15 | 7 | 6 | 3 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 111 | 91 | 83 | 64 | 45 | 39 | 33 | 29 | 24 | 16 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Back pain

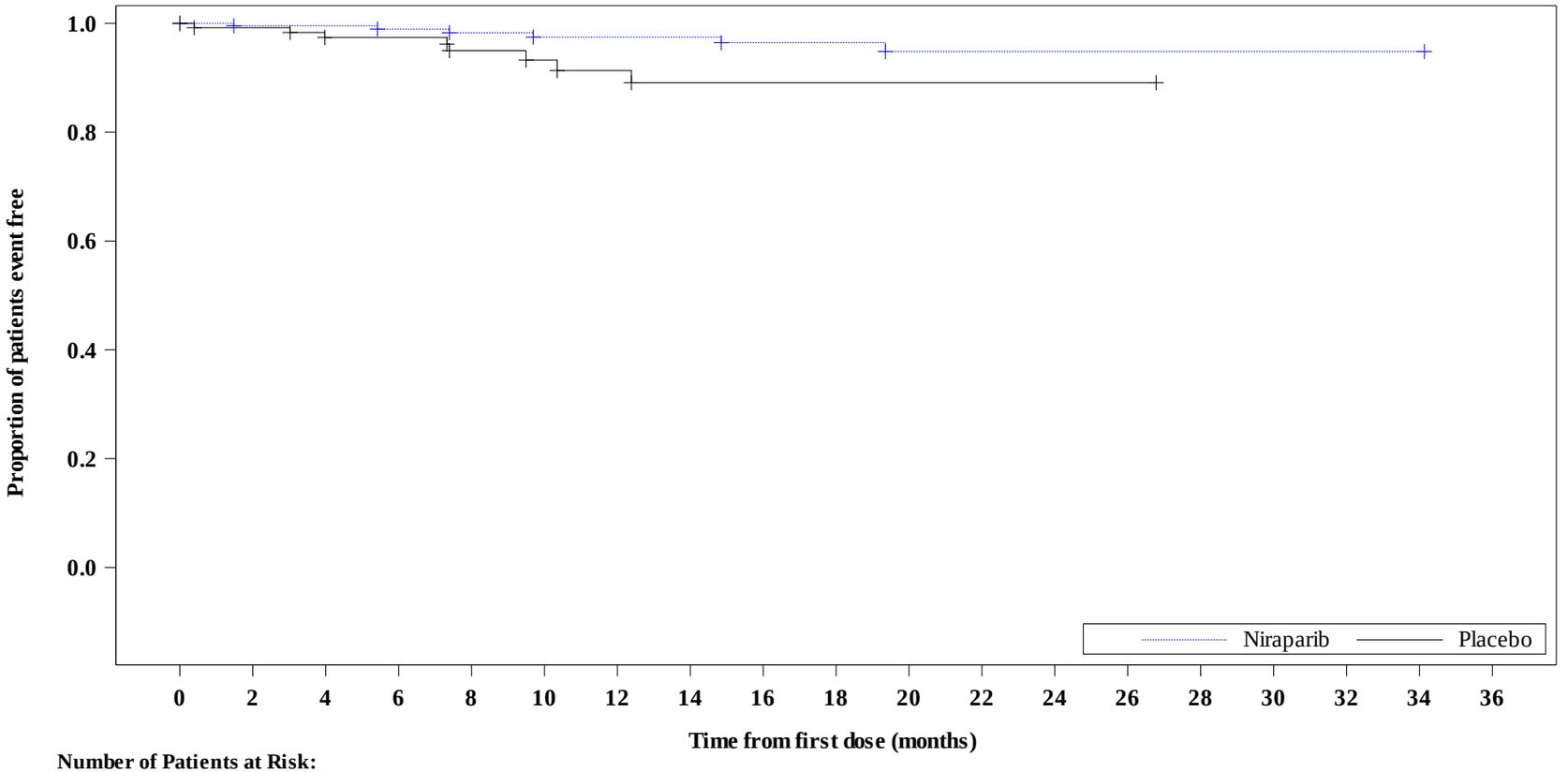



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 205 | 170 | 150 | 122 | 105 | 97 | 88 | 77 | 66 | 44 | 20 | 10 | 6 | 5 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 116 | 97 | 87 | 66 | 47 | 41 | 32 | 27 | 23 | 15 | 6 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Muscle spasms

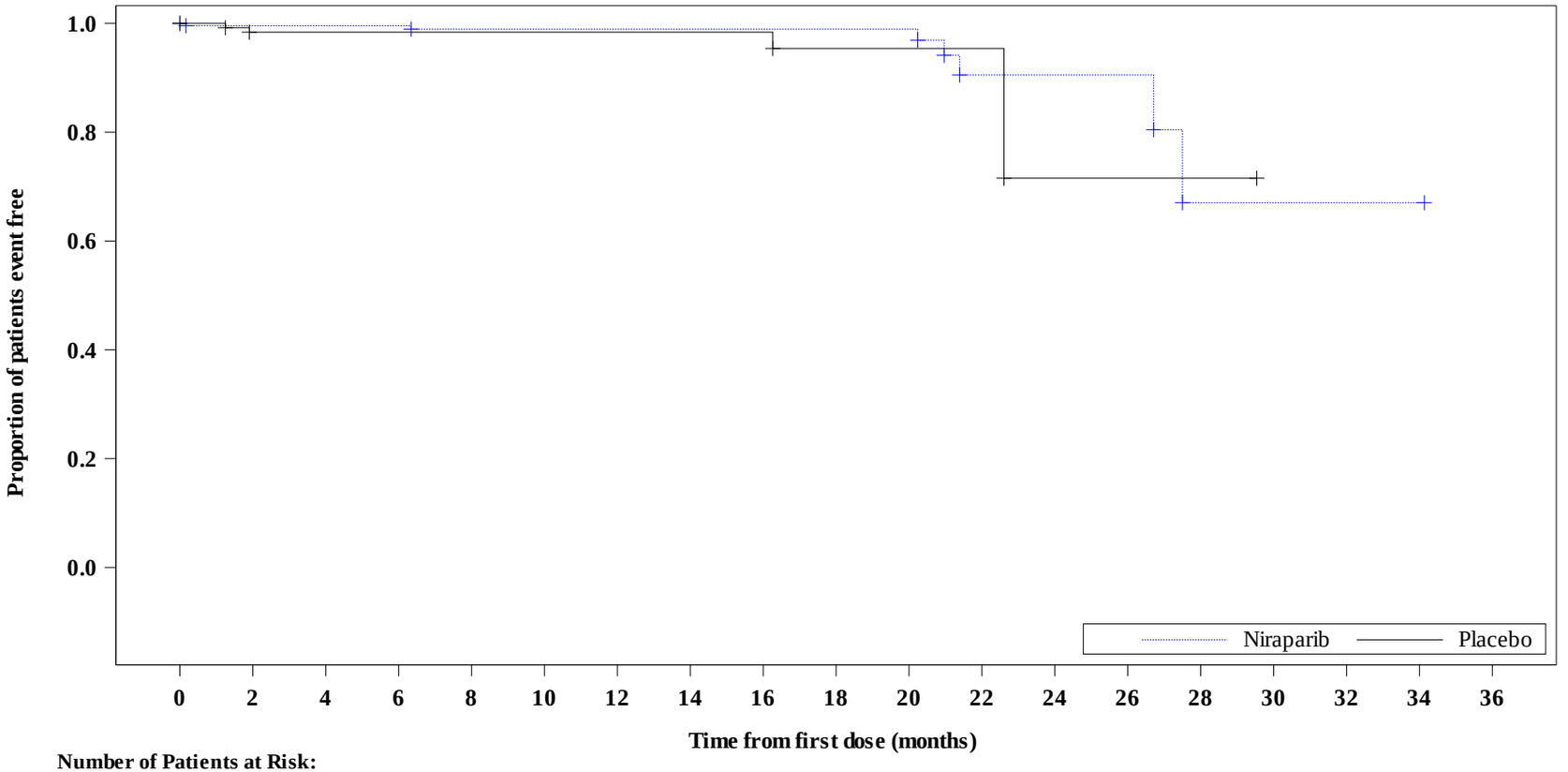



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 213 | 182 | 164 | 134 | 119 | 111 | 101 | 84 | 72 | 46 | 22 | 14 | 9 | 6 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 104 | 95 | 73 | 51 | 43 | 35 | 28 | 23 | 16 | 6 | 3 | 1 | 0 | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Musculoskeletal pain

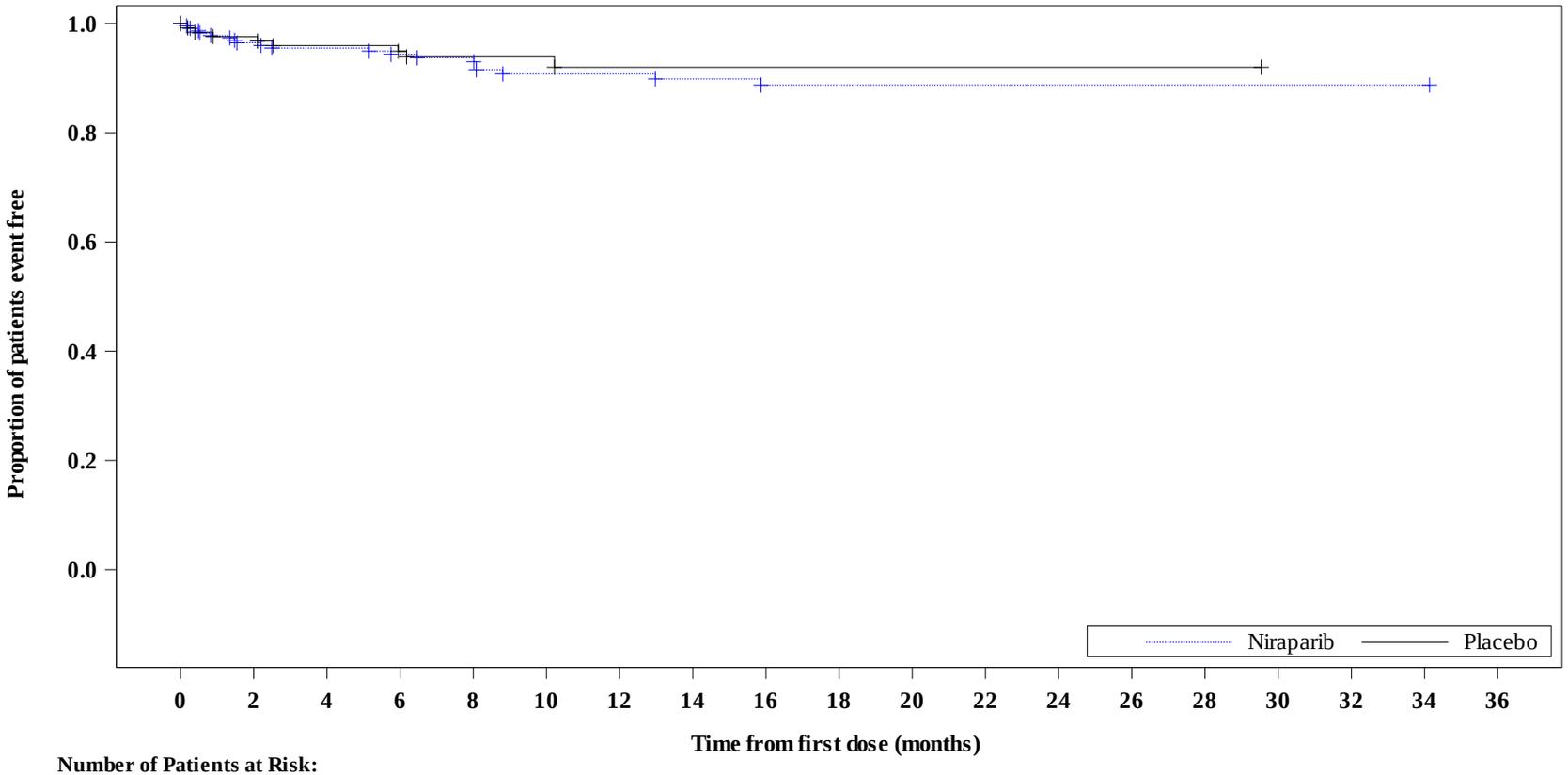



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 213 | 182 | 166 | 136 | 122 | 114 | 104 | 88 | 75 | 49 | 22 | 14 | 9 | 4 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 97 | 77 | 55 | 48 | 40 | 33 | 27 | 19 | 8 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia

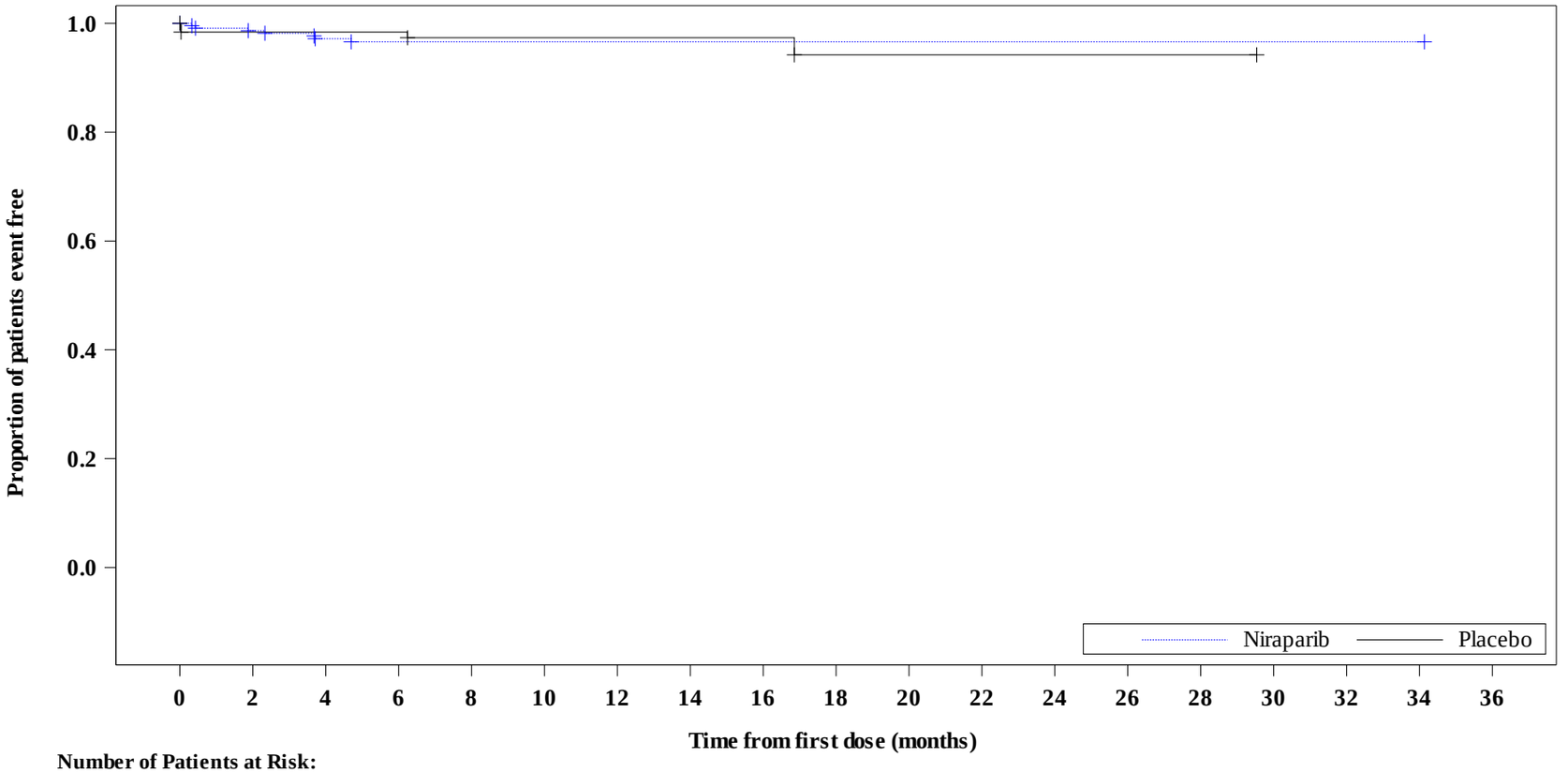



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 206 | 175 | 157 | 128 | 112 | 105 | 95 | 79 | 67 | 42 | 22 | 13 | 9 | 6 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 103 | 93 | 72 | 51 | 44 | 37 | 30 | 25 | 16 | 5 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Neck pain

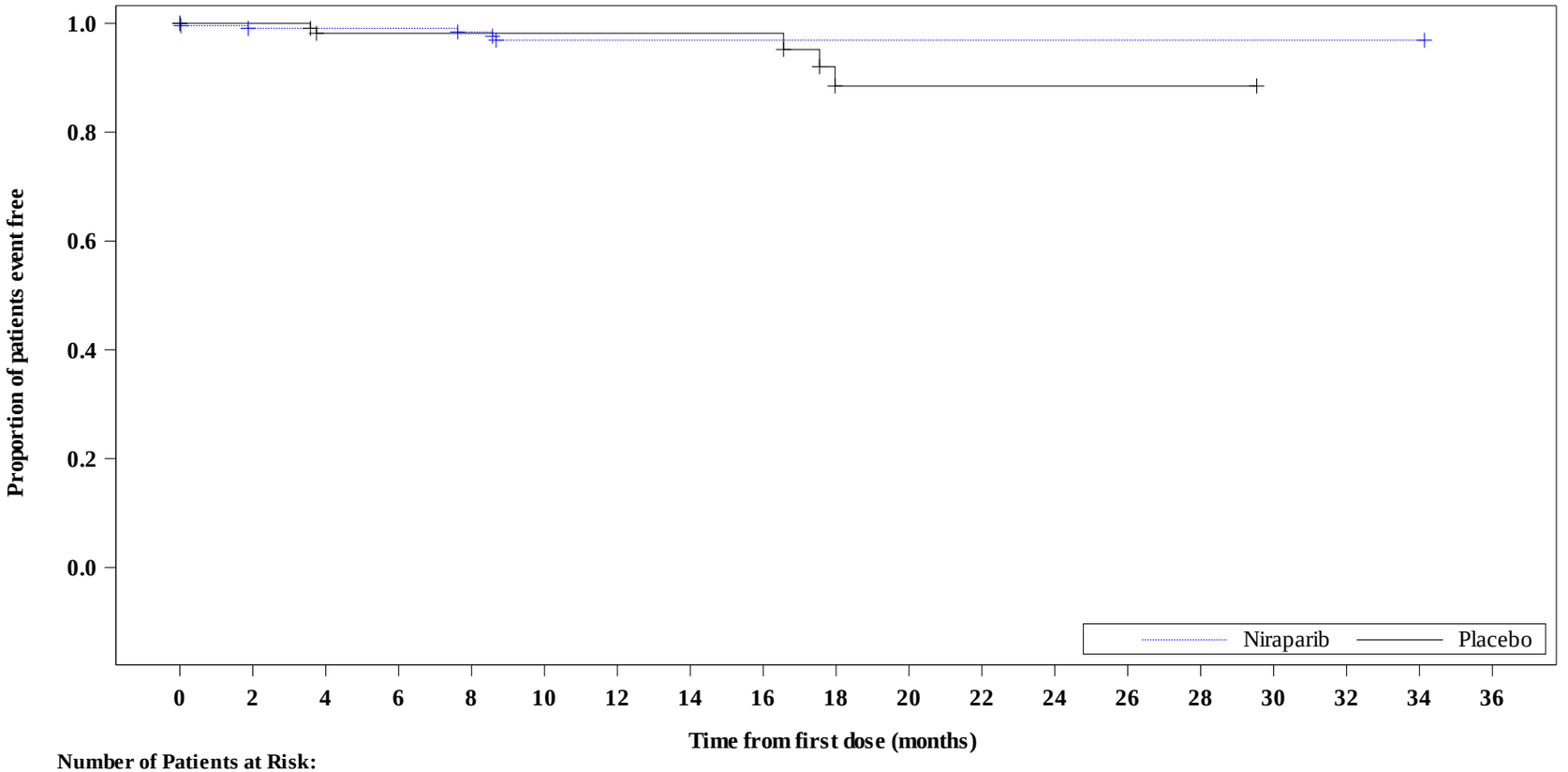



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 211 | 177 | 160 | 133 | 119 | 112 | 102 | 86 | 73 | 49 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 97 | 76 | 54 | 47 | 39 | 32 | 26 | 18 | 6 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Osteoarthritis

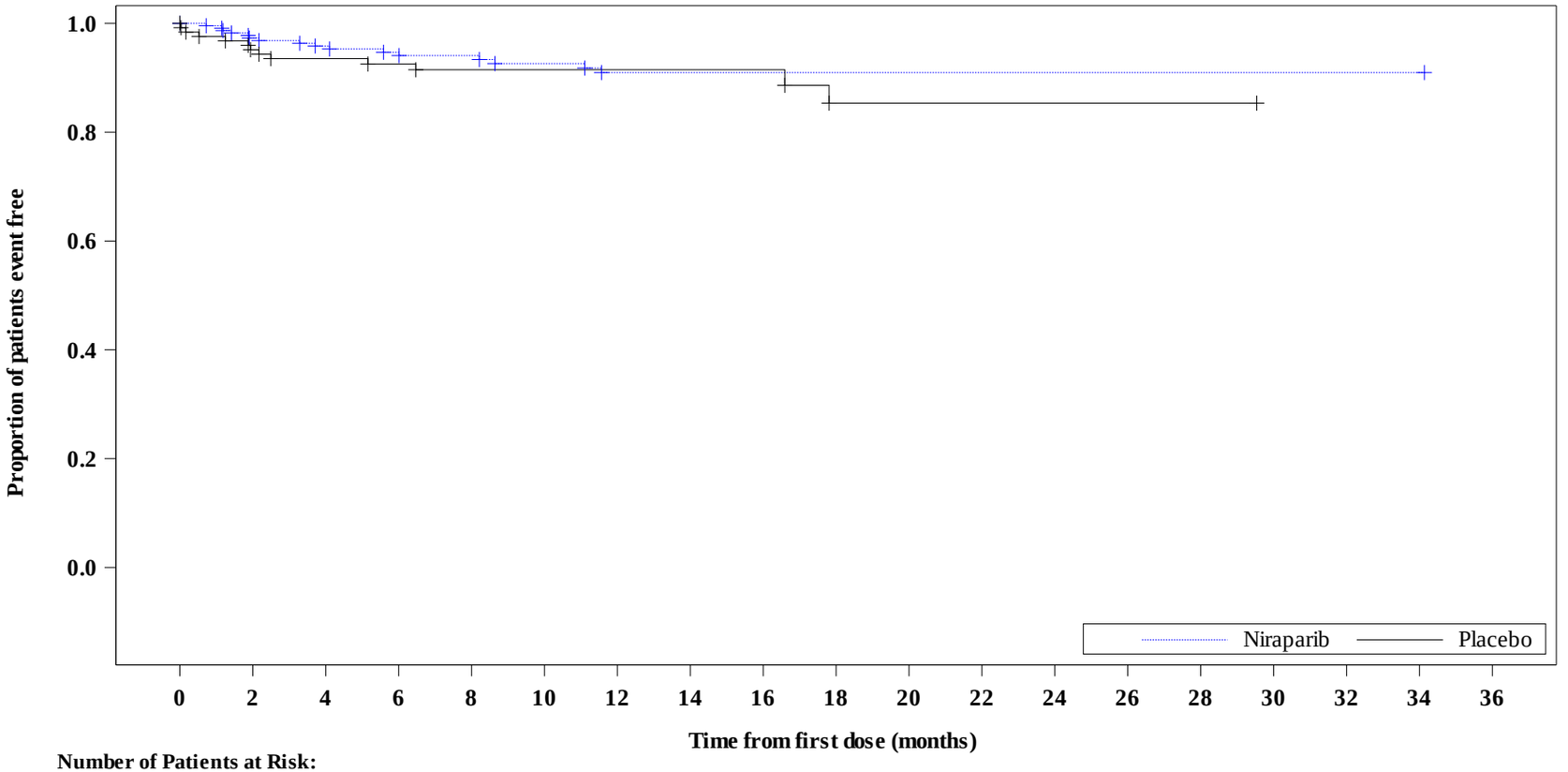



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 181 | 164 | 134 | 118 | 111 | 102 | 86 | 73 | 48 | 22 | 13 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 122 | 105 | 96 | 77 | 55 | 48 | 40 | 33 | 25 | 17 | 6 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity

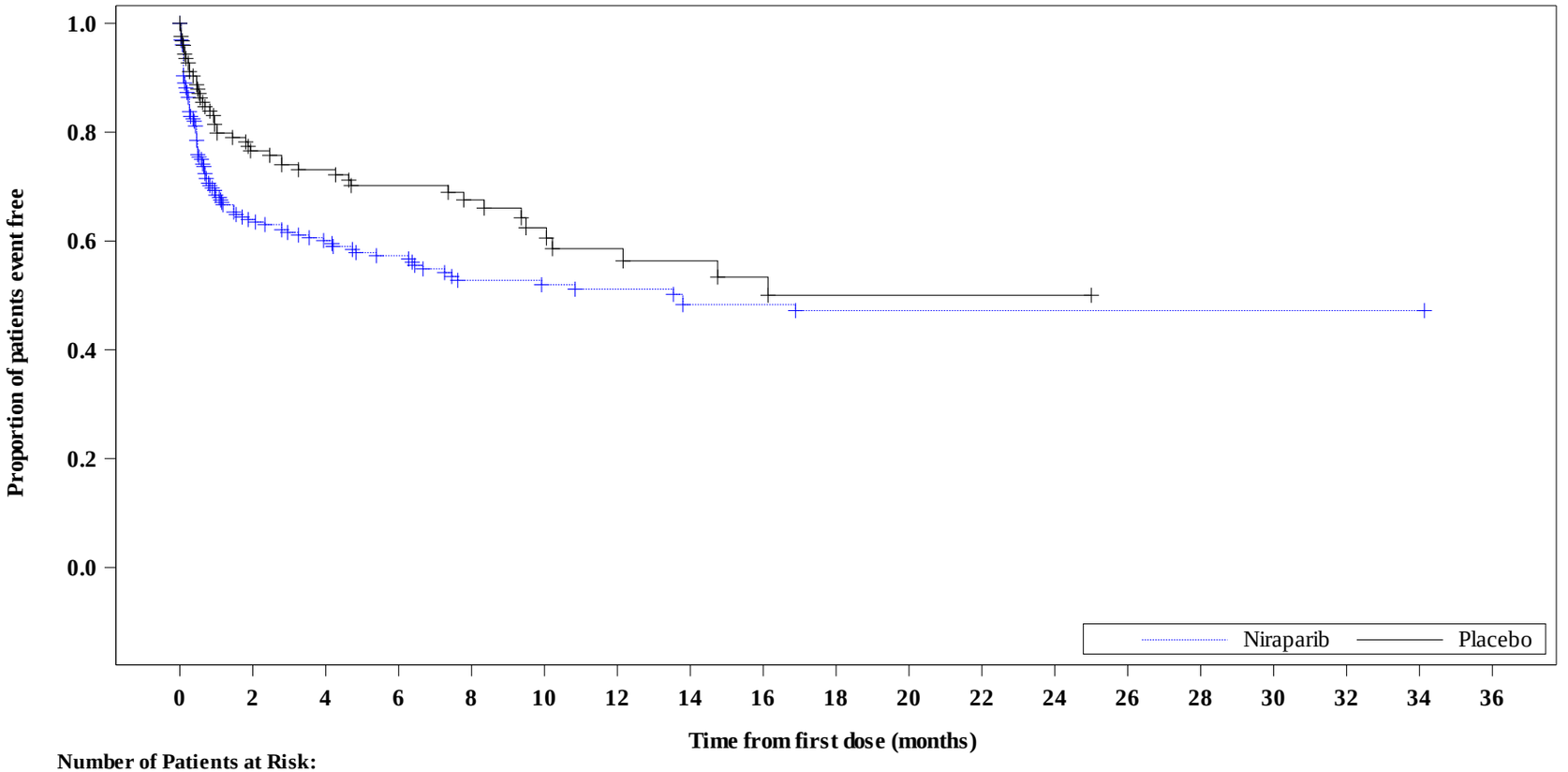



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 208 | 175 | 157 | 129 | 116 | 106 | 97 | 83 | 71 | 46 | 21 | 14 | 9 | 6 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 117 | 100 | 91 | 70 | 53 | 46 | 39 | 32 | 26 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Nervous system disorders

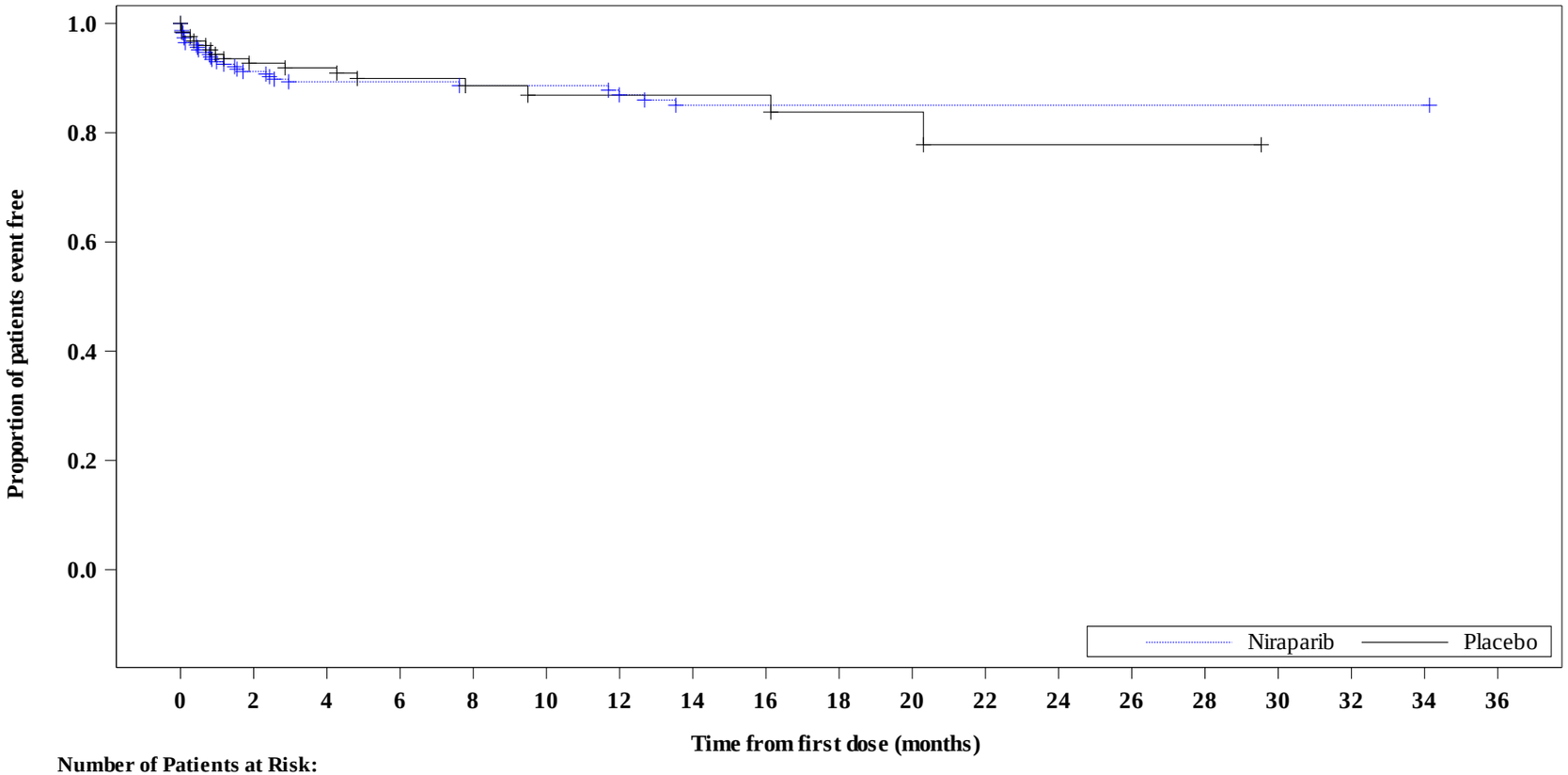



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 137 | 113 | 97 | 72 | 64 | 58 | 51 | 45 | 37 | 20 | 8 | 5 | 3 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 93 | 77 | 67 | 49 | 33 | 27 | 21 | 16 | 13 | 7 | 3 | 1 | 0 | | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Nervous system disorders, PT: Dizziness

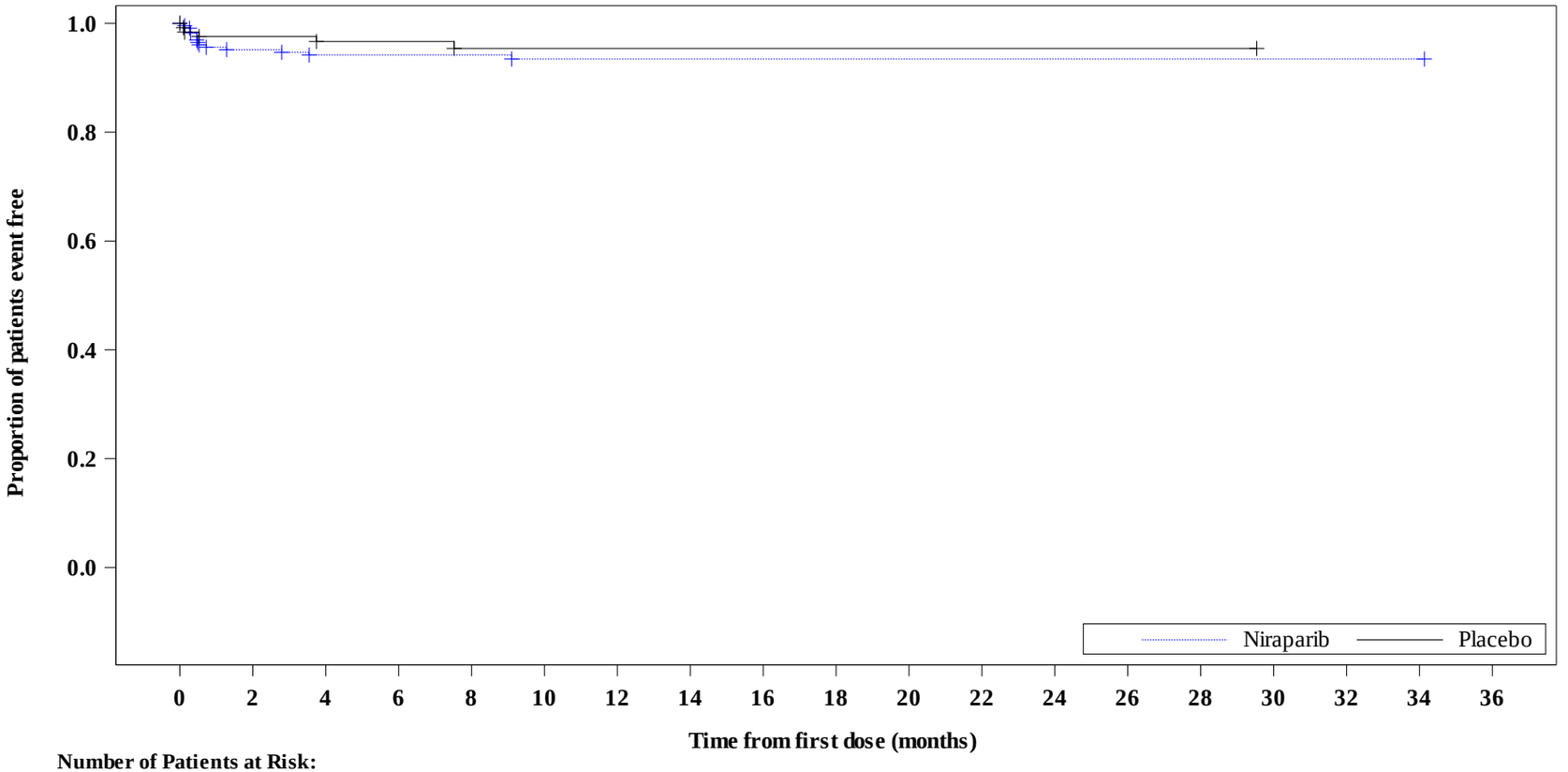



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 198 | 164 | 150 | 121 | 108 | 99 | 89 | 74 | 63 | 39 | 19 | 12 | 8 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 113 | 98 | 88 | 67 | 47 | 41 | 33 | 28 | 22 | 14 | 5 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Nervous system disorders, PT: Dysgeusia

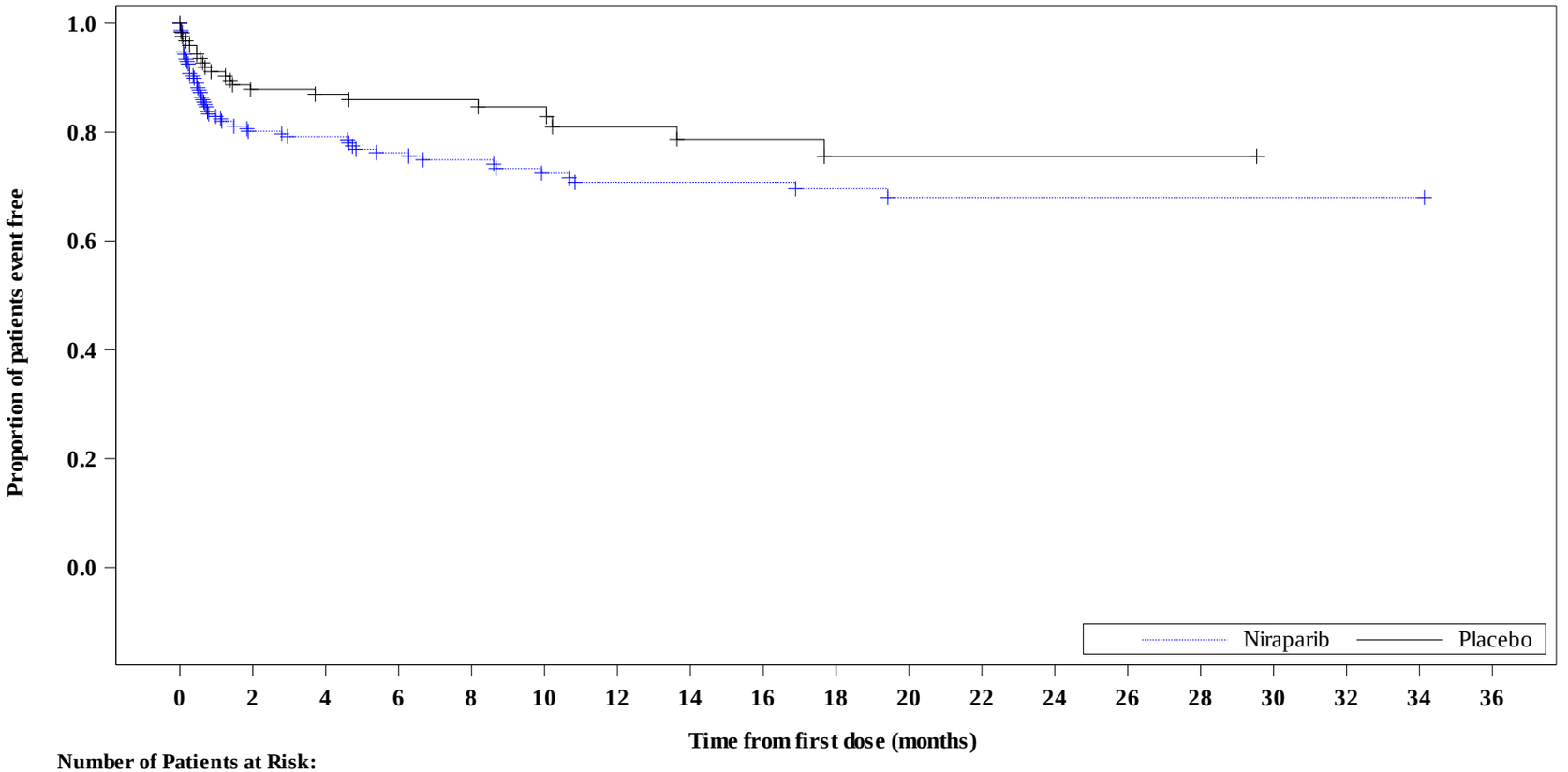



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 204 | 173 | 157 | 129 | 114 | 106 | 96 | 83 | 71 | 45 | 21 | 13 | 8 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 119 | 103 | 94 | 73 | 54 | 47 | 39 | 33 | 28 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Nervous system disorders, PT: Headache

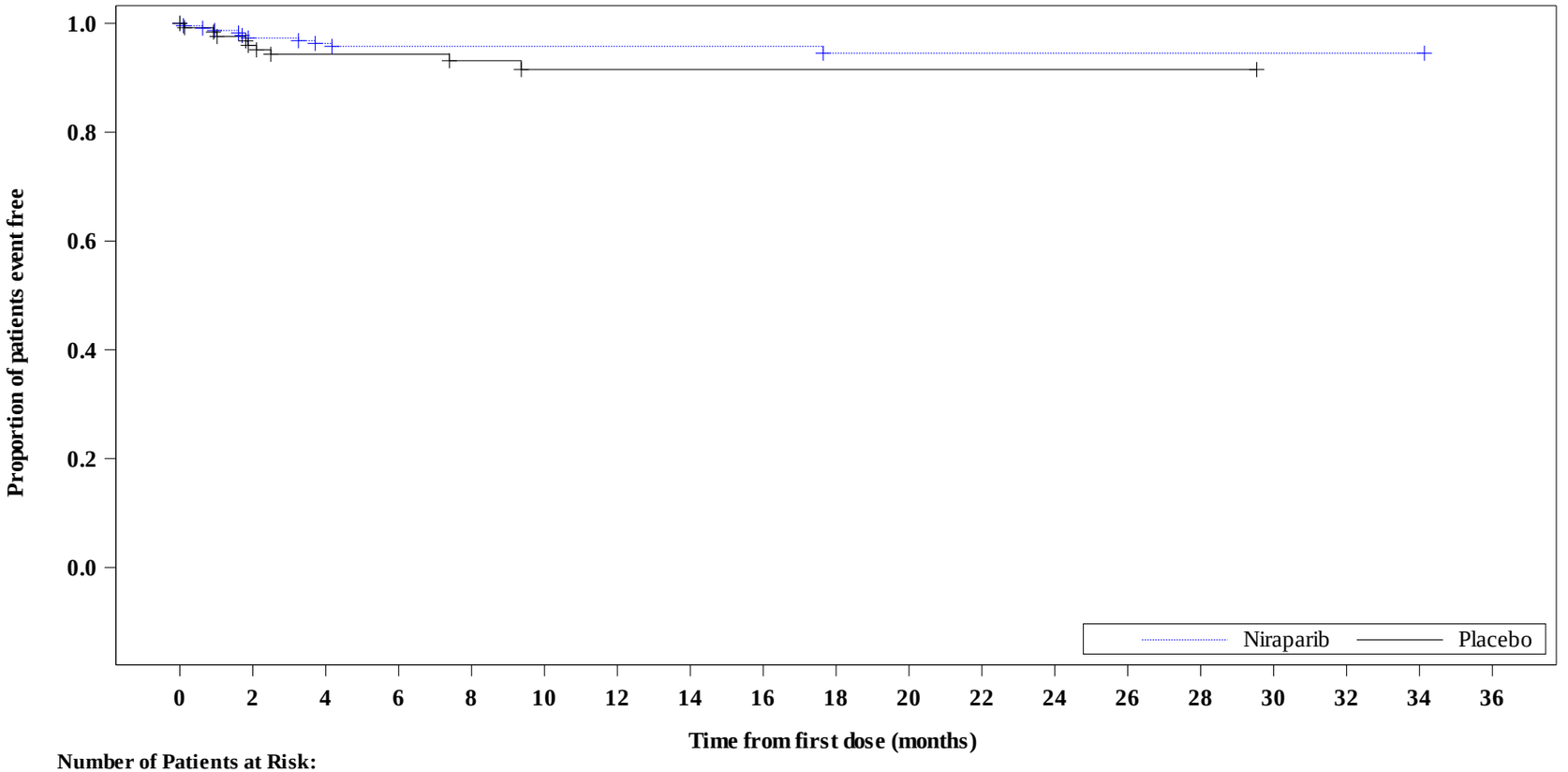



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 169 | 143 | 123 | 97 | 85 | 78 | 72 | 62 | 51 | 31 | 11 | 5 | 3 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 107 | 93 | 83 | 66 | 47 | 39 | 33 | 27 | 23 | 16 | 6 | 3 | 1 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Nervous system disorders, PT: Neuropathy peripheral

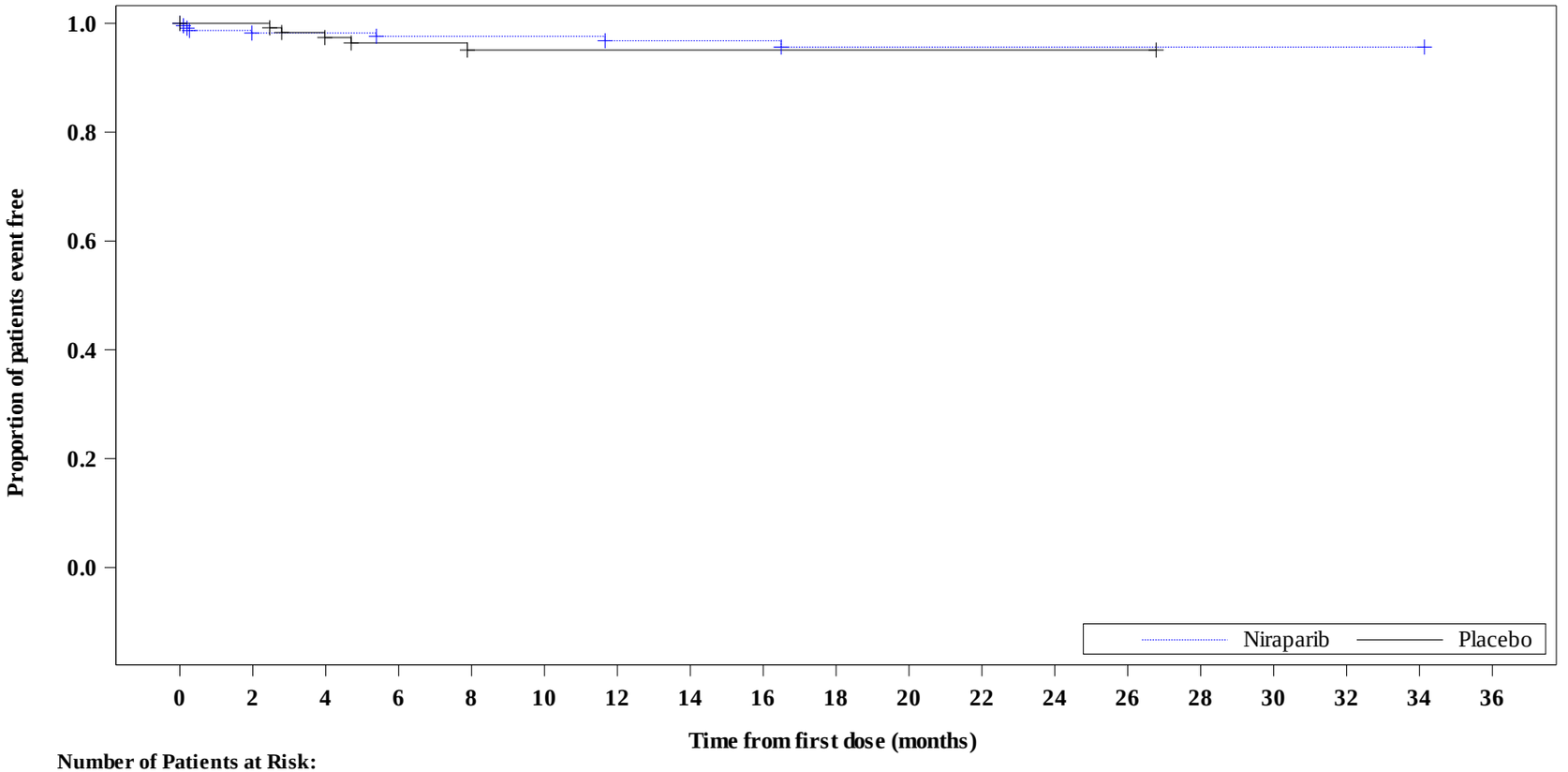



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 208 | 177 | 160 | 131 | 118 | 111 | 101 | 86 | 72 | 46 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 117 | 102 | 94 | 73 | 52 | 45 | 38 | 33 | 28 | 19 | 7 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Nervous system disorders, PT: Paraesthesia

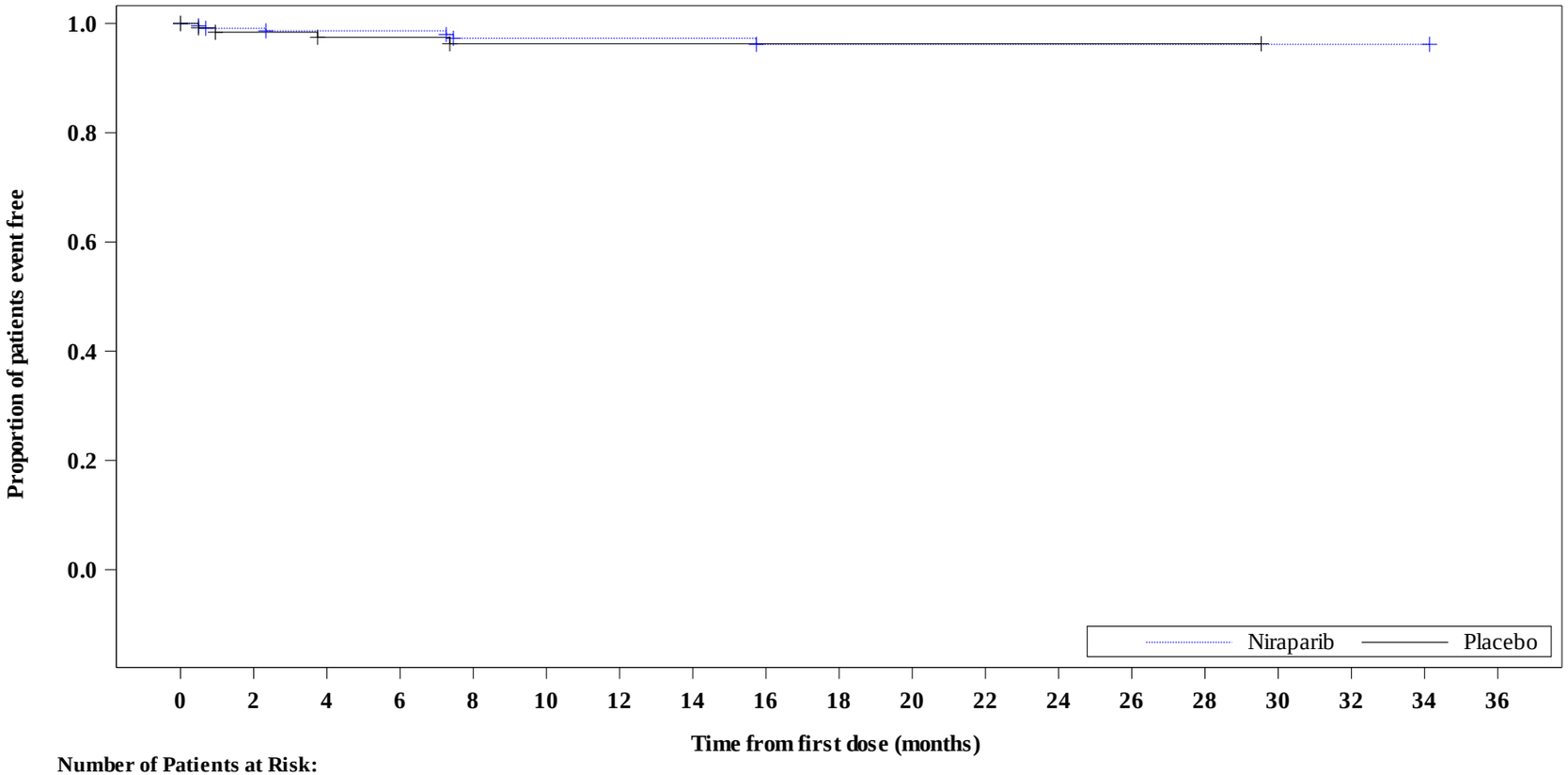



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 211 | 181 | 163 | 134 | 121 | 113 | 103 | 87 | 73 | 48 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 104 | 94 | 73 | 51 | 44 | 36 | 29 | 25 | 16 | 6 | 3 | 1 | 0 | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Nervous system disorders, PT: Peripheral sensory neuropathy

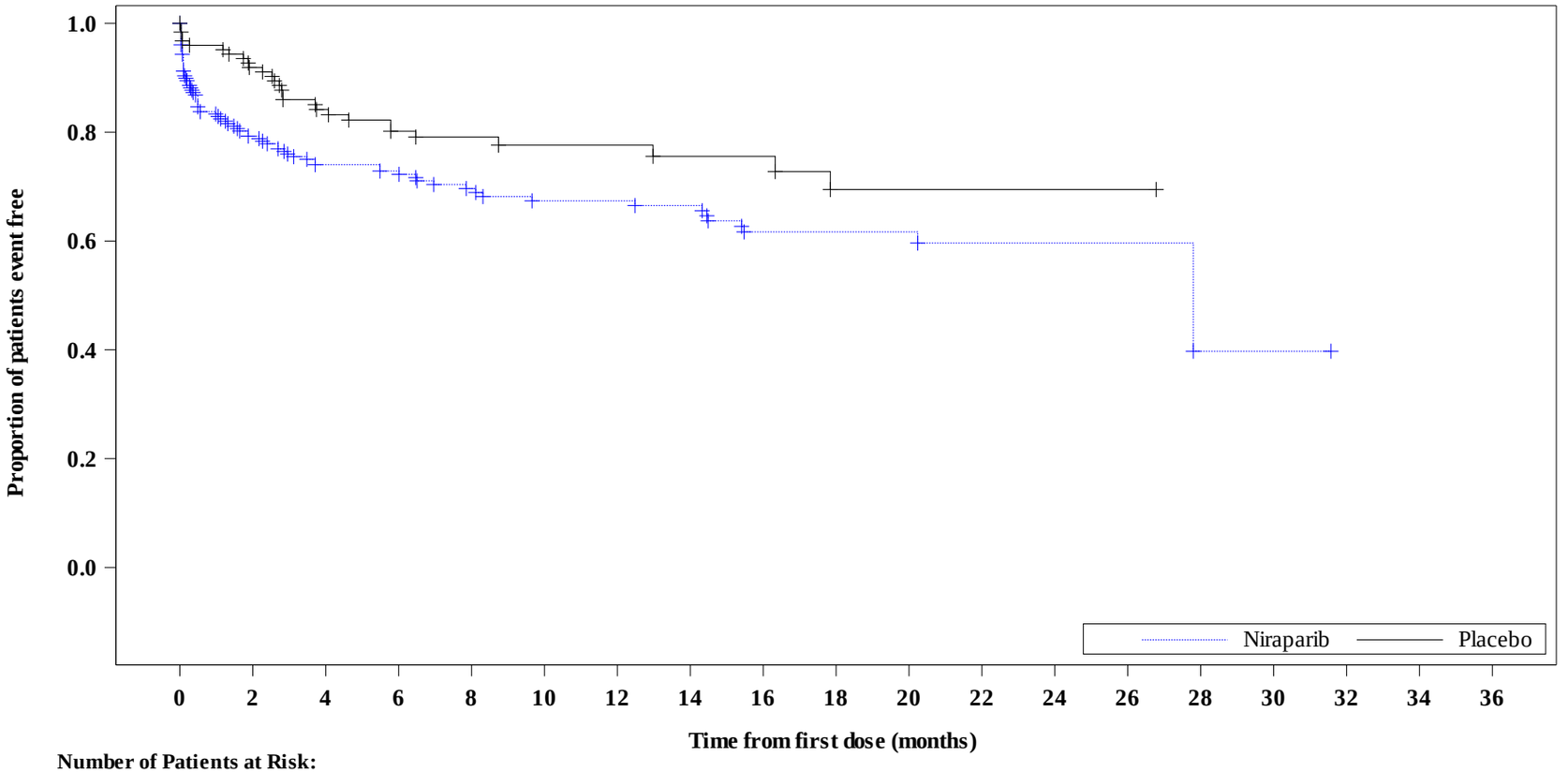



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 182 | 165 | 134 | 120 | 112 | 103 | 87 | 74 | 48 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 104 | 95 | 74 | 53 | 46 | 38 | 31 | 26 | 18 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Psychiatric disorders

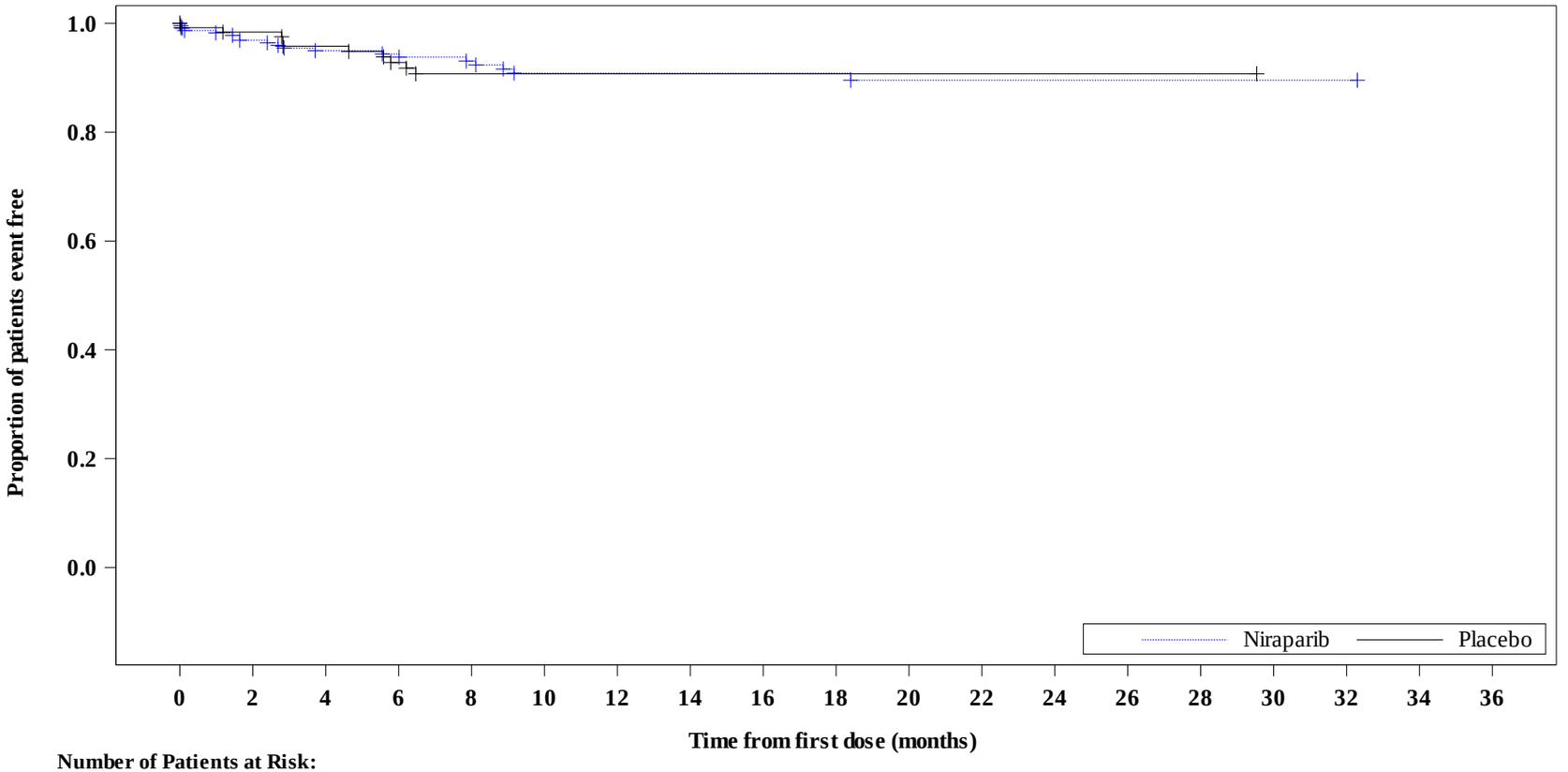



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 170 | 138 | 123 | 94 | 84 | 79 | 73 | 61 | 49 | 31 | 14 | 8 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 112 | 89 | 78 | 61 | 43 | 39 | 33 | 27 | 21 | 15 | 7 | 3 | 1 | 0 | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Psychiatric disorders, PT: Anxiety

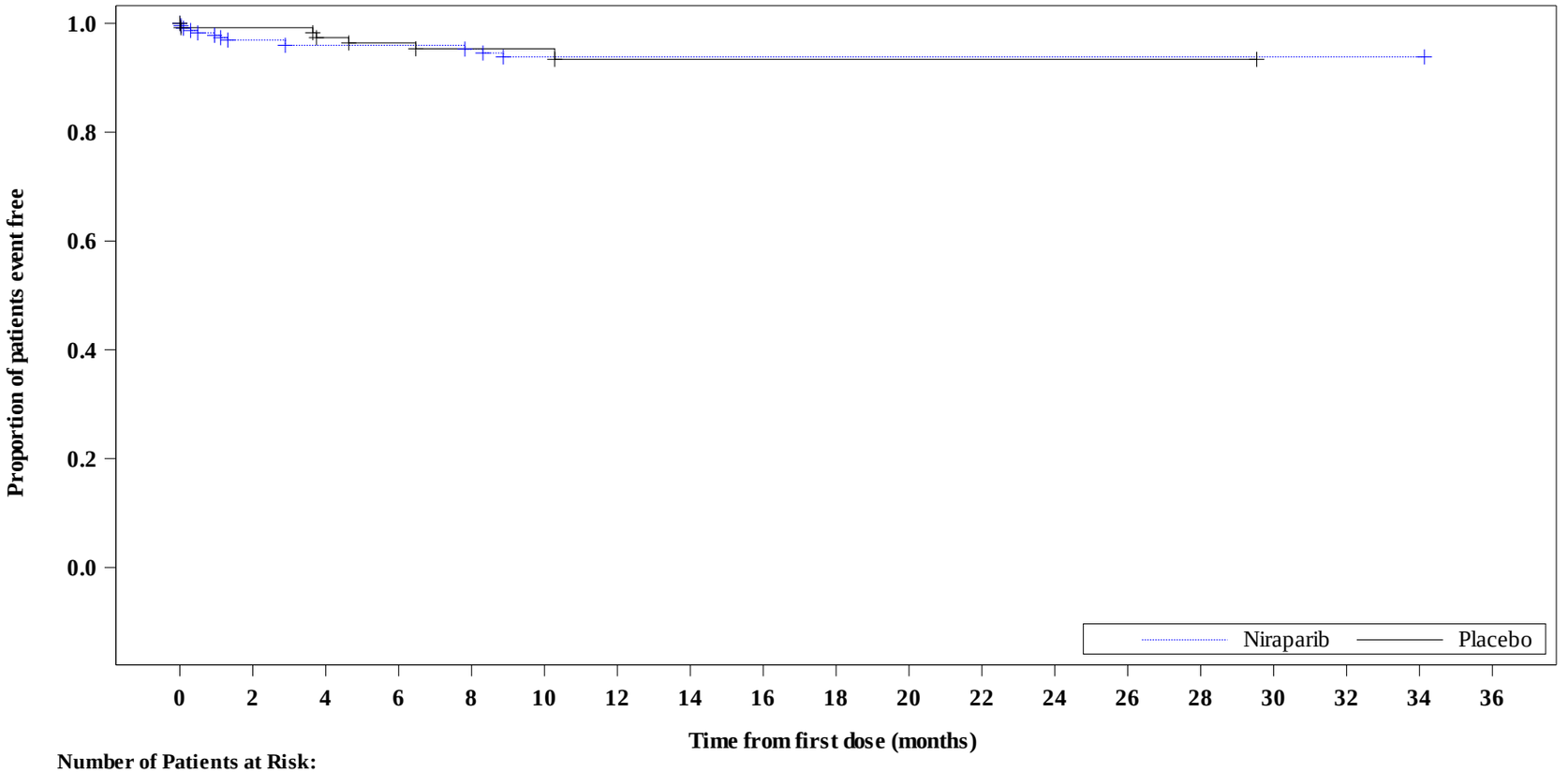



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 207 | 176 | 159 | 128 | 113 | 105 | 96 | 84 | 71 | 44 | 19 | 11 | 7 | 4 | 3 | 1 | 0 |
| Placebo | 124 | 120 | 103 | 91 | 69 | 50 | 44 | 36 | 30 | 25 | 19 | 8 | 4 | 2 | 1 | 0 | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Psychiatric disorders, PT: Depression

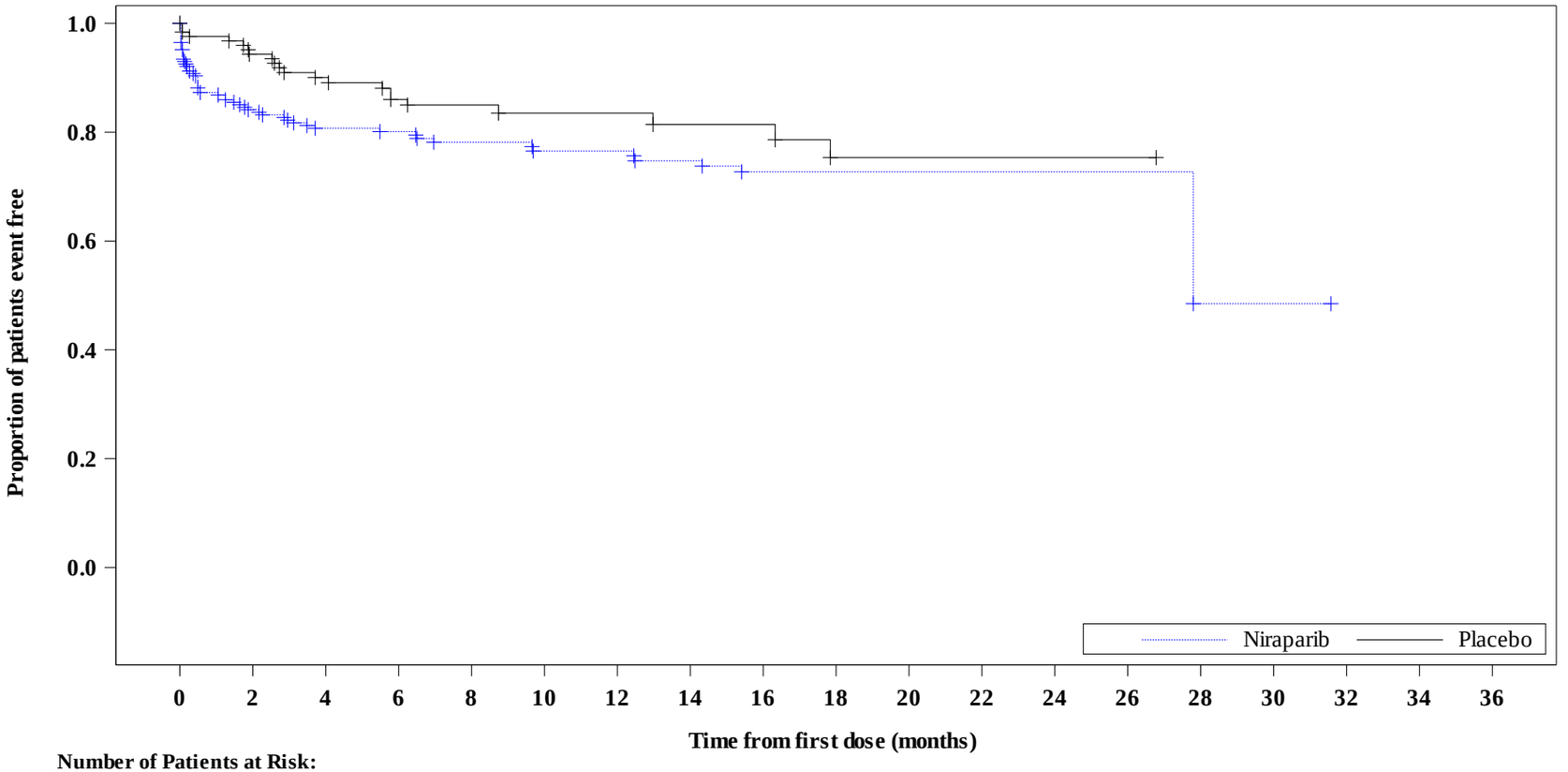



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 178 | 163 | 133 | 118 | 110 | 100 | 84 | 71 | 45 | 22 | 13 | 8 | 5 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 121 | 104 | 94 | 73 | 52 | 44 | 37 | 30 | 25 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Psychiatric disorders, PT: Insomnia

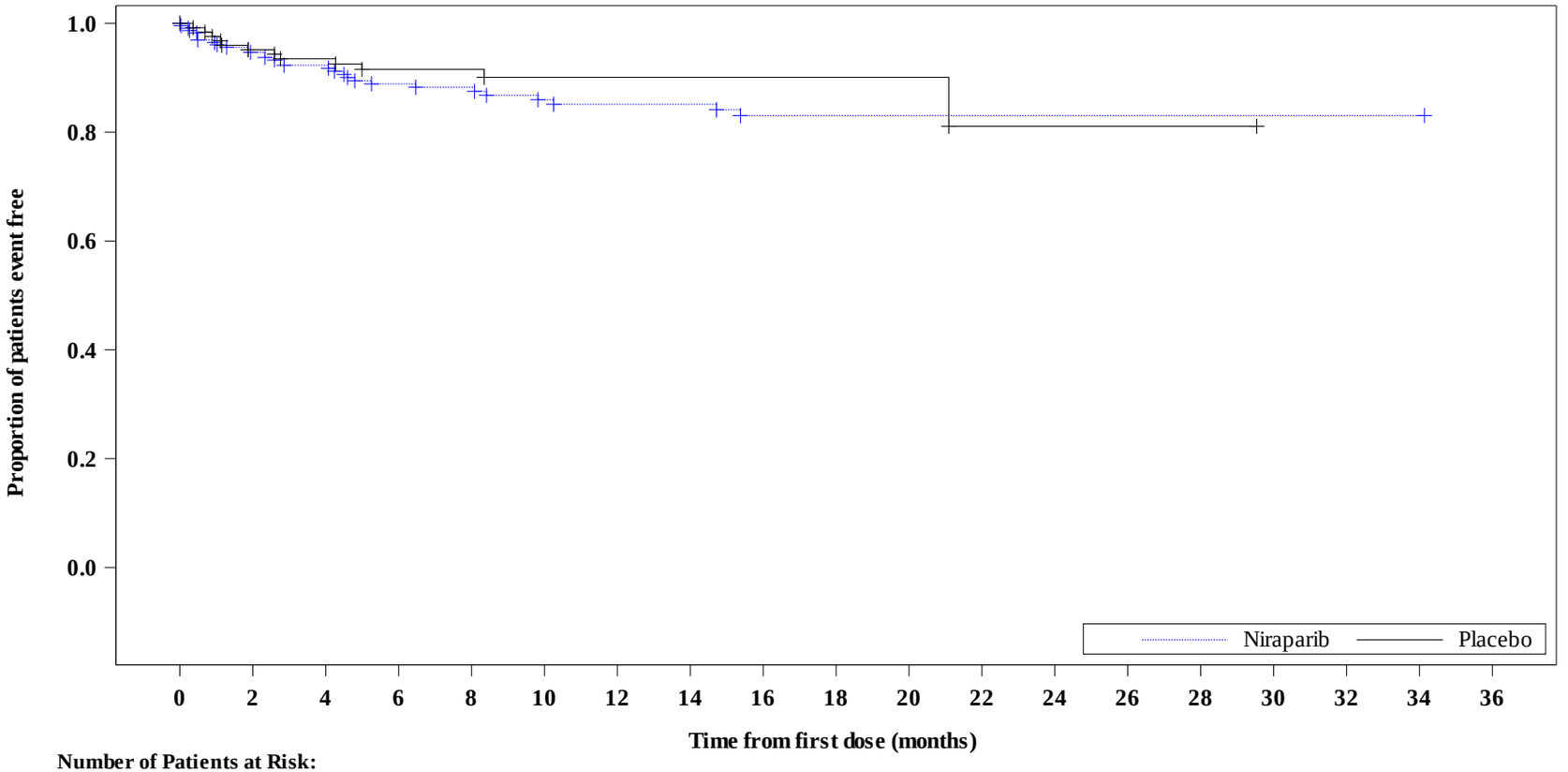



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 179 | 146 | 131 | 102 | 93 | 87 | 79 | 64 | 52 | 34 | 16 | 8 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 115 | 95 | 84 | 67 | 46 | 41 | 35 | 29 | 23 | 16 | 7 | 3 | 1 | 0 | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Renal and urinary disorders

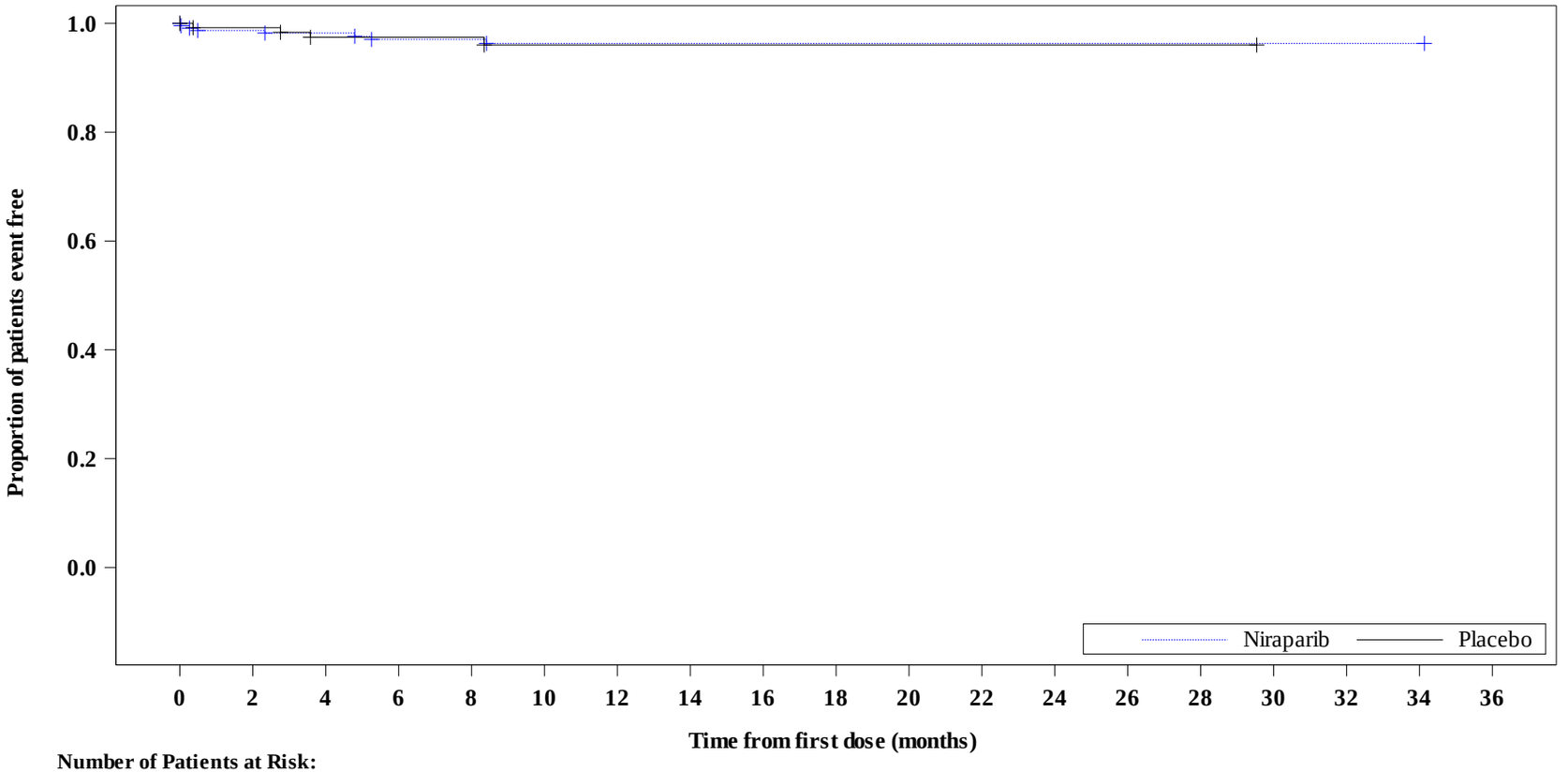



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 202 | 170 | 148 | 119 | 103 | 97 | 89 | 74 | 61 | 41 | 19 | 11 | 6 | 4 | 2 | 2 | 1 | 0 |
| Placebo | 124 | 116 | 100 | 89 | 69 | 48 | 42 | 34 | 27 | 24 | 16 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Renal and urinary disorders, PT: Dysuria

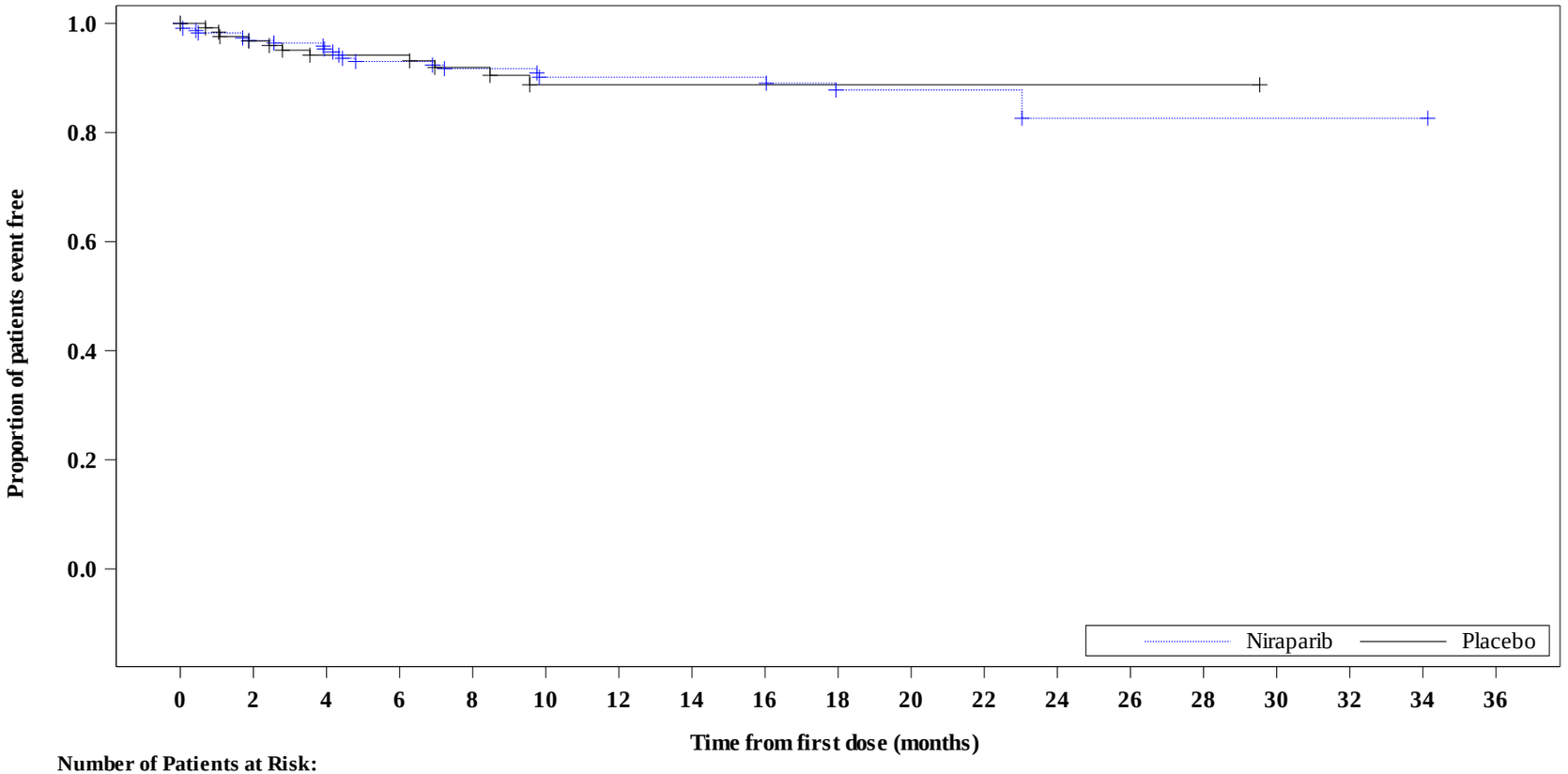



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 211 | 181 | 162 | 134 | 119 | 112 | 102 | 86 | 73 | 48 | 23 | 14 | 9 | 6 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 104 | 95 | 75 | 53 | 47 | 39 | 32 | 28 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Reproductive system and breast disorders

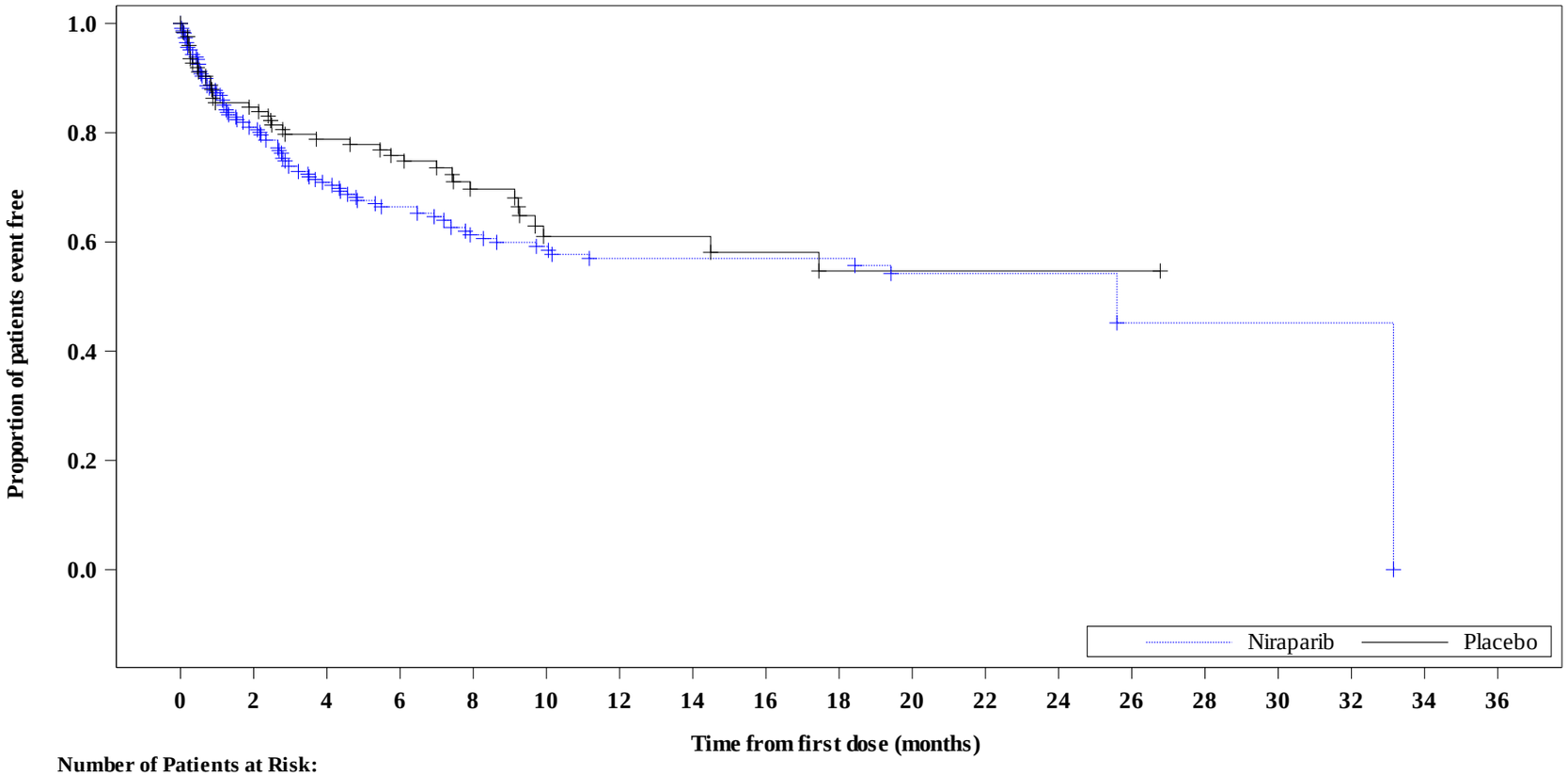



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 207 | 173 | 154 | 126 | 114 | 107 | 97 | 82 | 70 | 45 | 23 | 13 | 8 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 118 | 100 | 91 | 69 | 49 | 43 | 36 | 29 | 24 | 16 | 6 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders

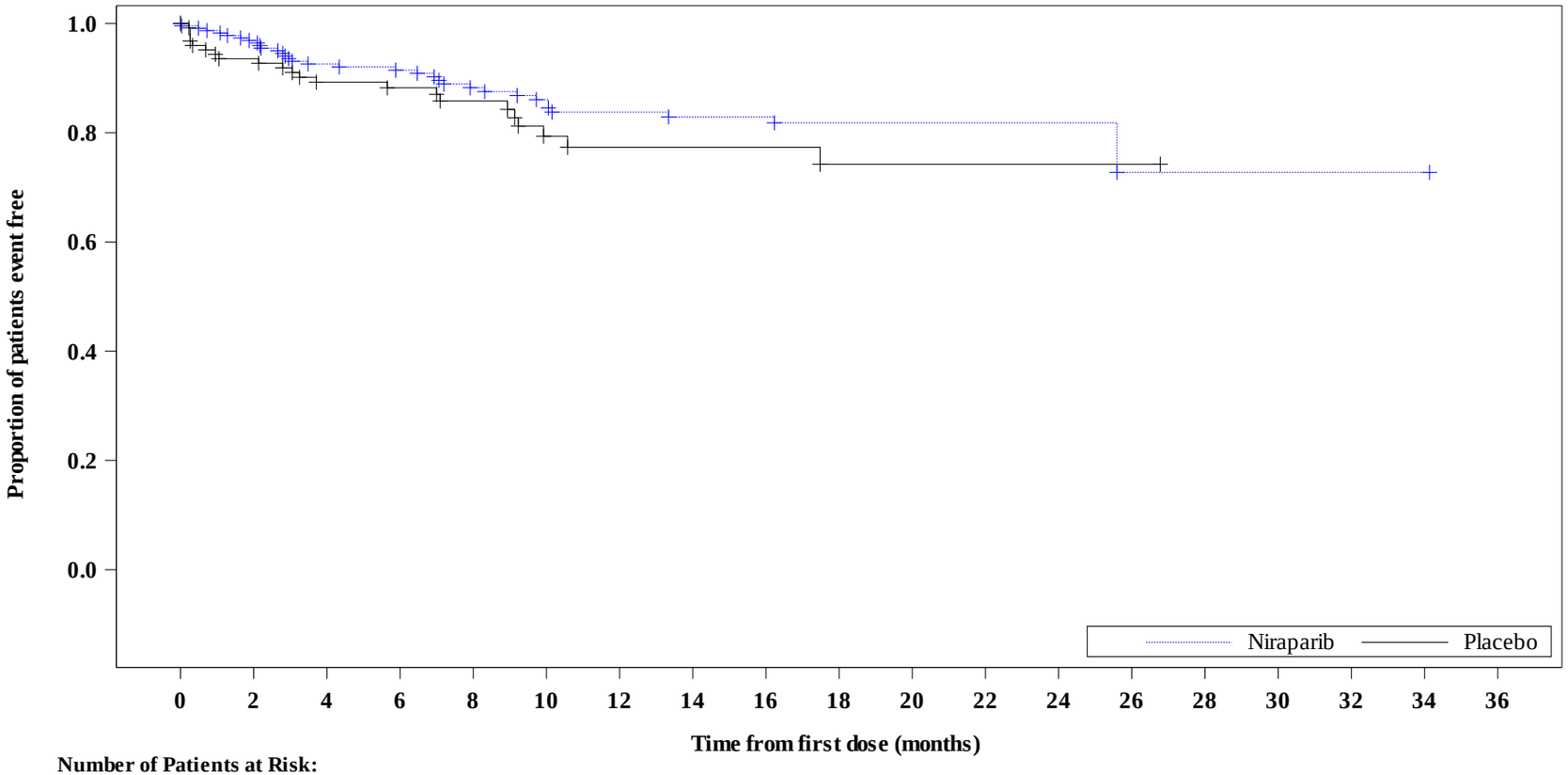



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 173 | 134 | 115 | 89 | 81 | 73 | 65 | 54 | 45 | 26 | 11 | 6 | 4 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 104 | 86 | 74 | 52 | 31 | 27 | 22 | 17 | 14 | 10 | 4 | 1 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough

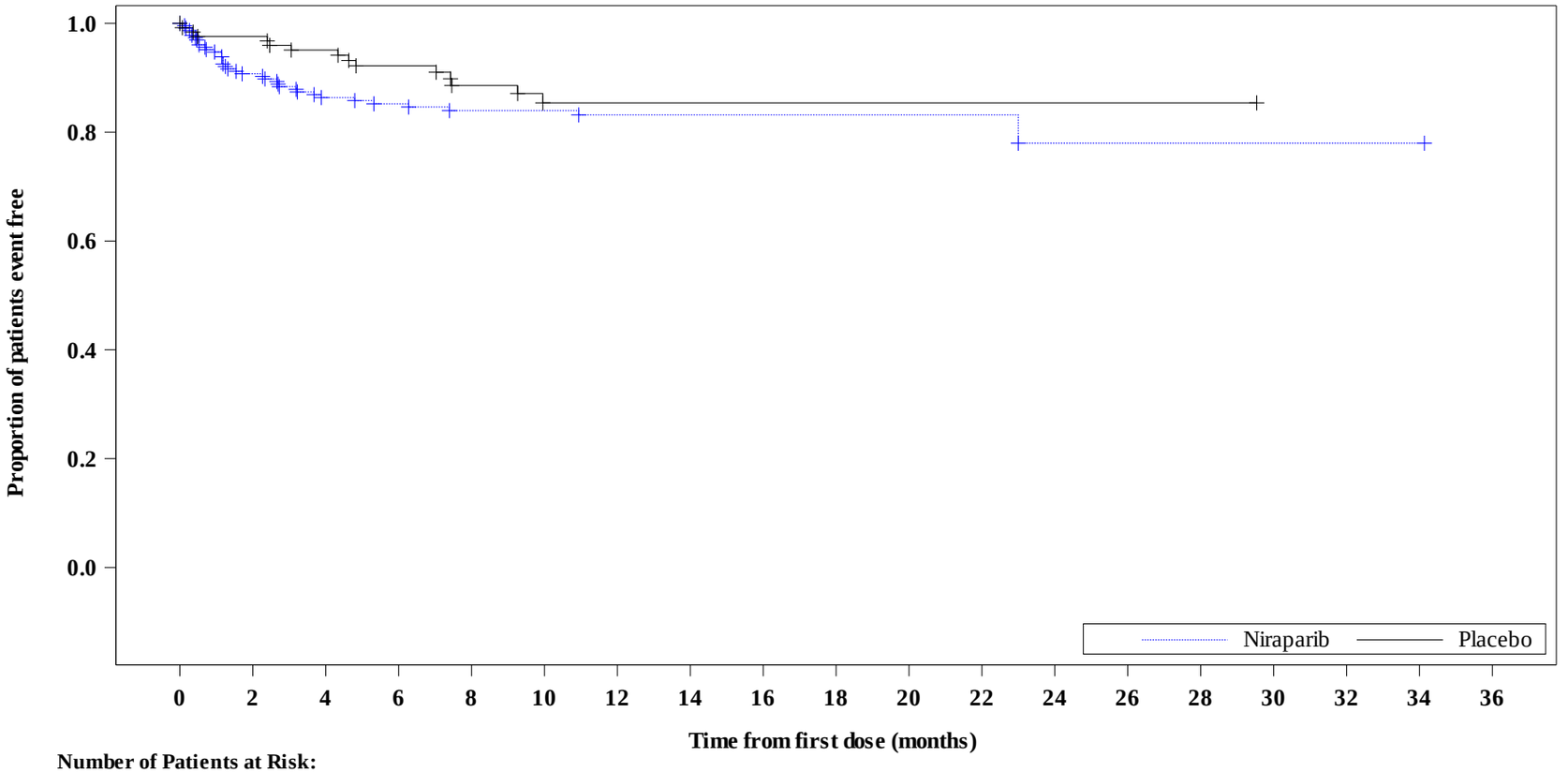



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 207 | 174 | 157 | 126 | 113 | 103 | 93 | 79 | 67 | 43 | 21 | 13 | 7 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 114 | 96 | 86 | 66 | 42 | 37 | 31 | 25 | 21 | 14 | 7 | 3 | 1 | 0 | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea

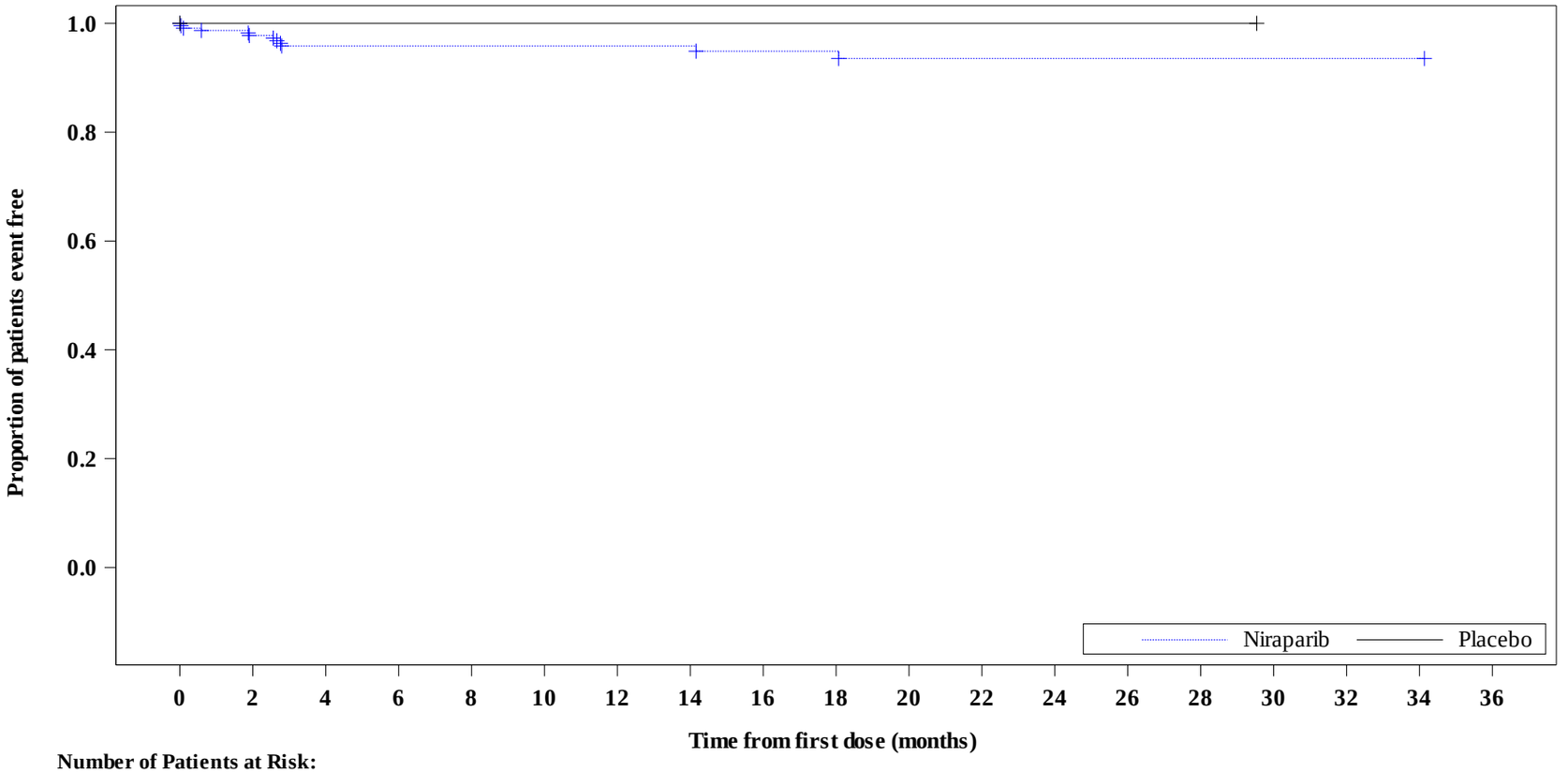



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 195 | 161 | 145 | 120 | 108 | 100 | 90 | 78 | 67 | 42 | 20 | 13 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 120 | 103 | 91 | 69 | 49 | 42 | 36 | 30 | 25 | 17 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea exertional

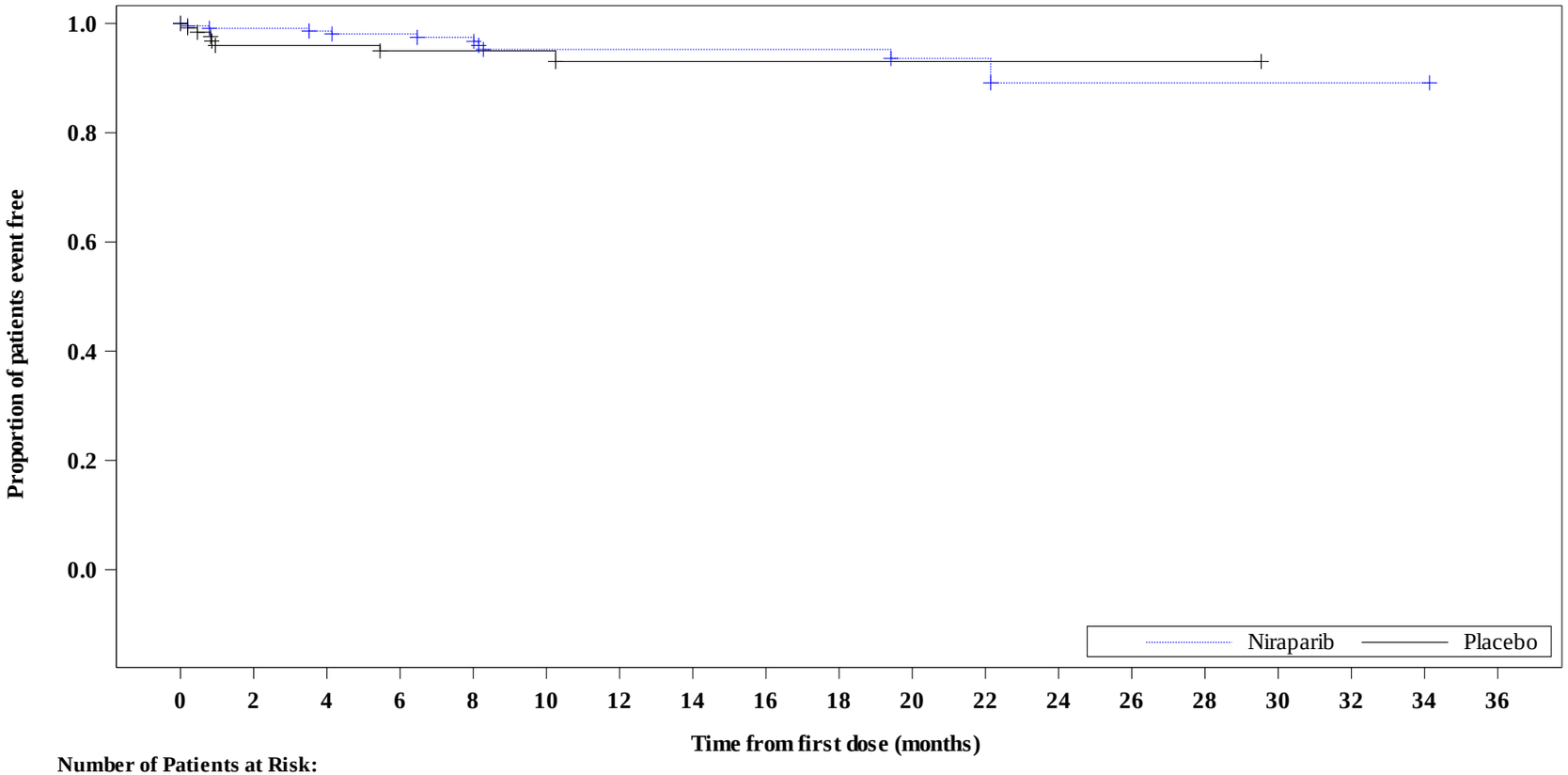



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 176 | 159 | 131 | 119 | 111 | 101 | 84 | 71 | 45 | 21 | 12 | 7 | 5 | 3 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion

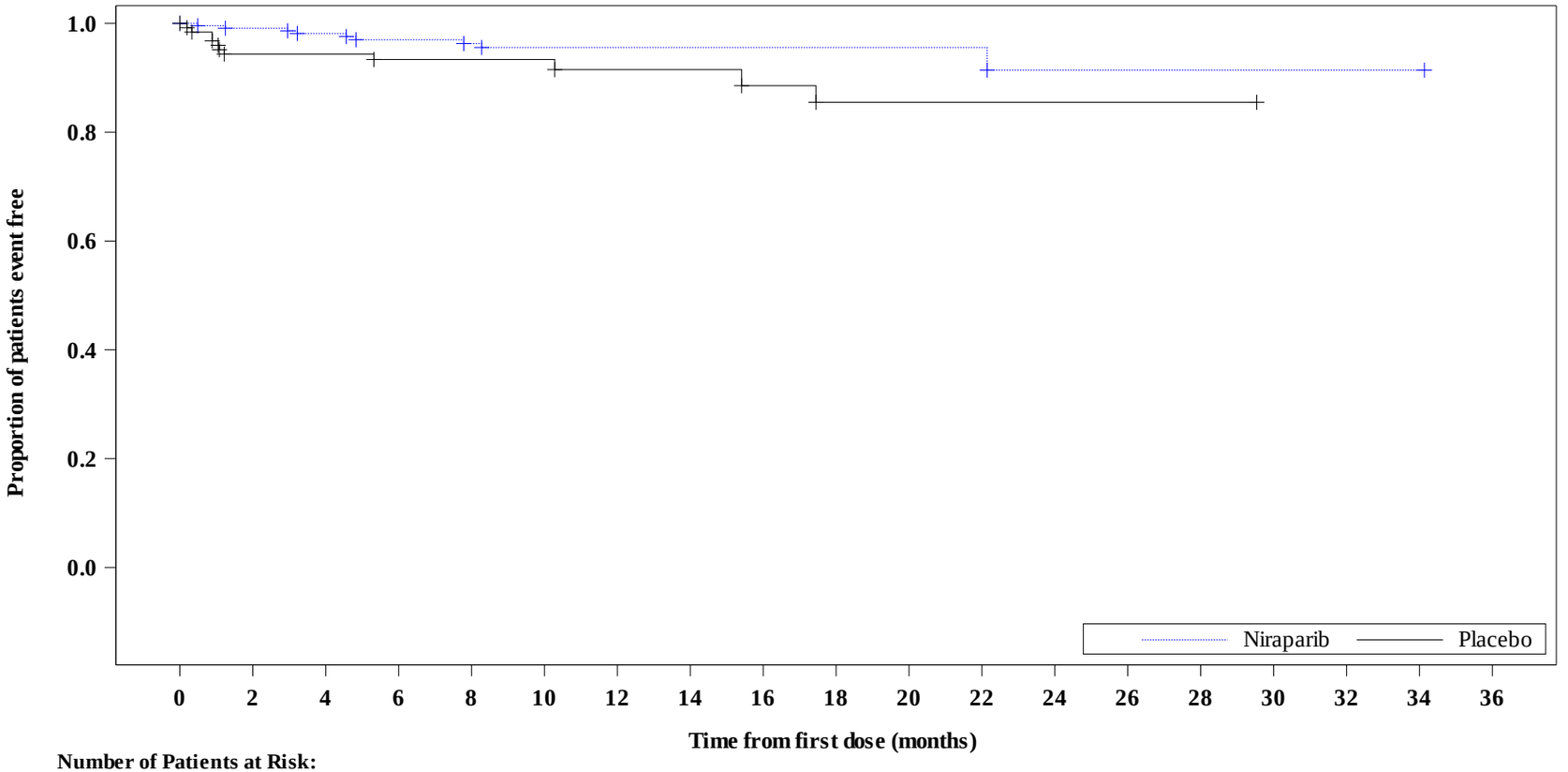



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 180 | 162 | 132 | 117 | 109 | 99 | 83 | 71 | 44 | 21 | 11 | 8 | 5 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 117 | 104 | 94 | 74 | 52 | 44 | 36 | 30 | 25 | 18 | 7 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain

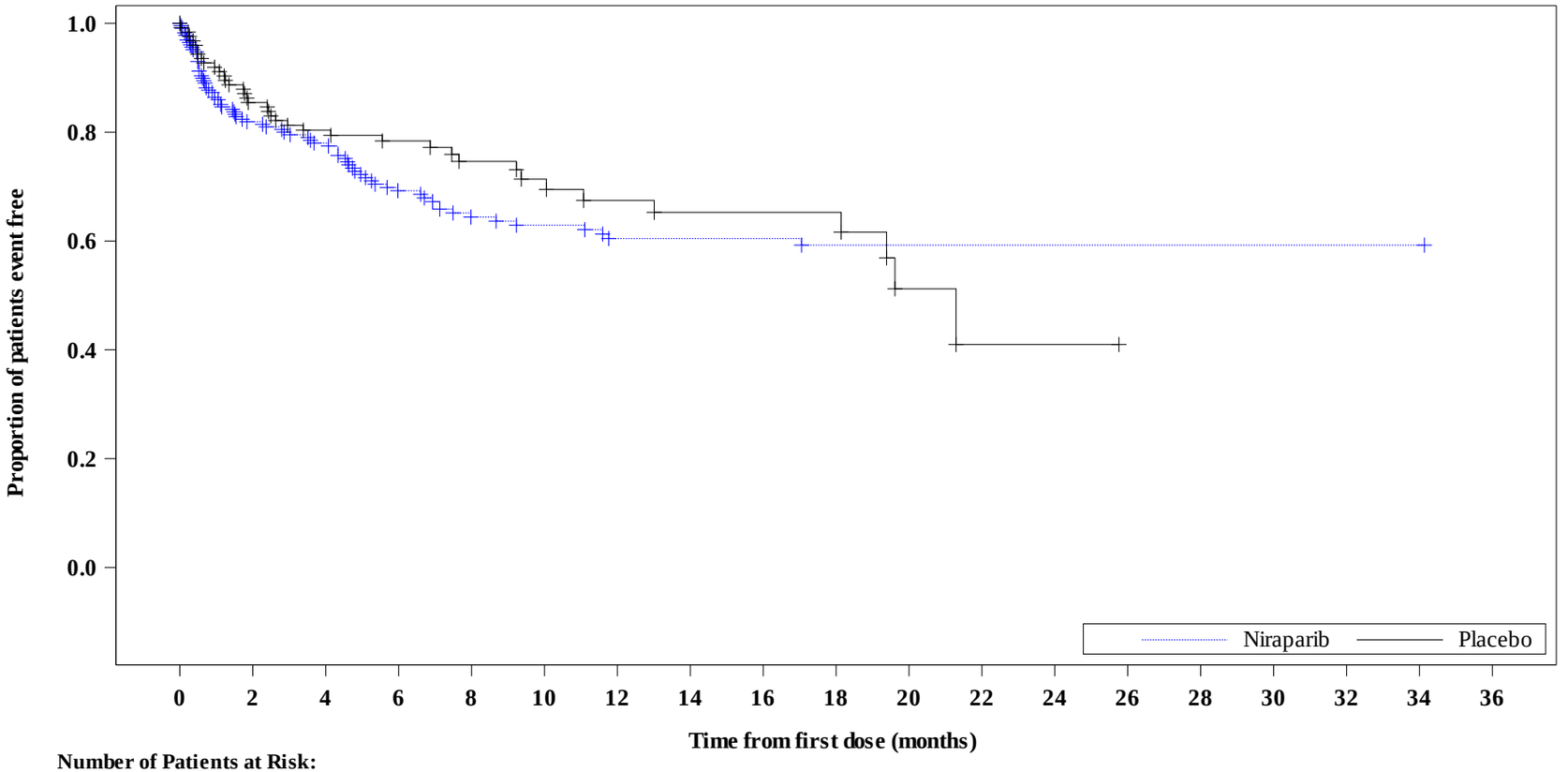



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 179 | 162 | 133 | 119 | 111 | 101 | 85 | 72 | 47 | 23 | 13 | 9 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 115 | 102 | 92 | 74 | 53 | 45 | 38 | 30 | 24 | 16 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders

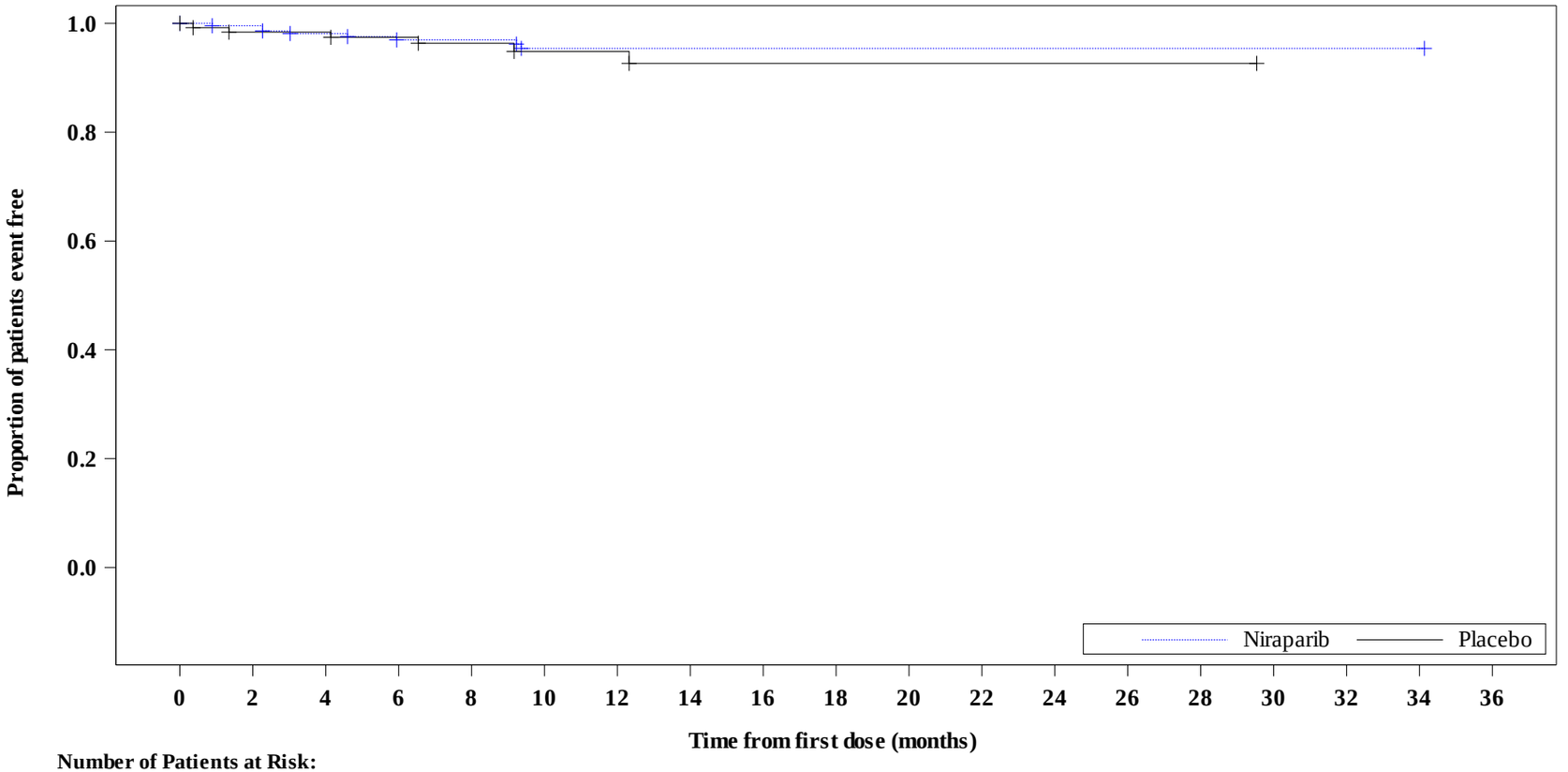



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 175 | 141 | 115 | 86 | 80 | 72 | 65 | 54 | 44 | 28 | 15 | 8 | 5 | 3 | 2 | 1 | 1 | 0 |
| Placebo | 124 | 104 | 85 | 76 | 57 | 38 | 33 | 28 | 23 | 18 | 9 | 3 | 1 | 0 | | | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Dry skin

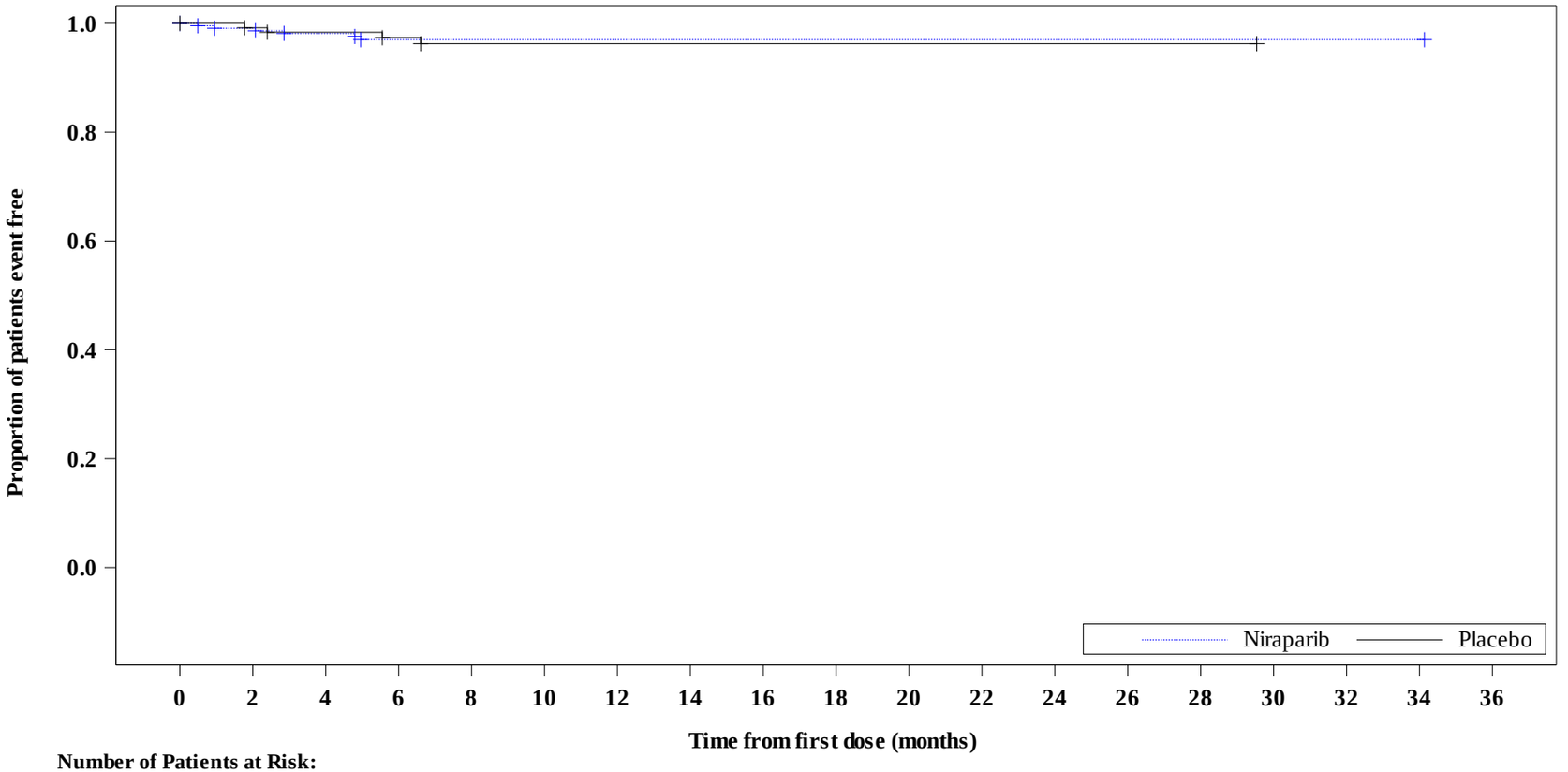



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 213 | 180 | 161 | 133 | 119 | 111 | 102 | 87 | 74 | 49 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 95 | 75 | 52 | 45 | 38 | 32 | 27 | 19 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Hyperhidrosis

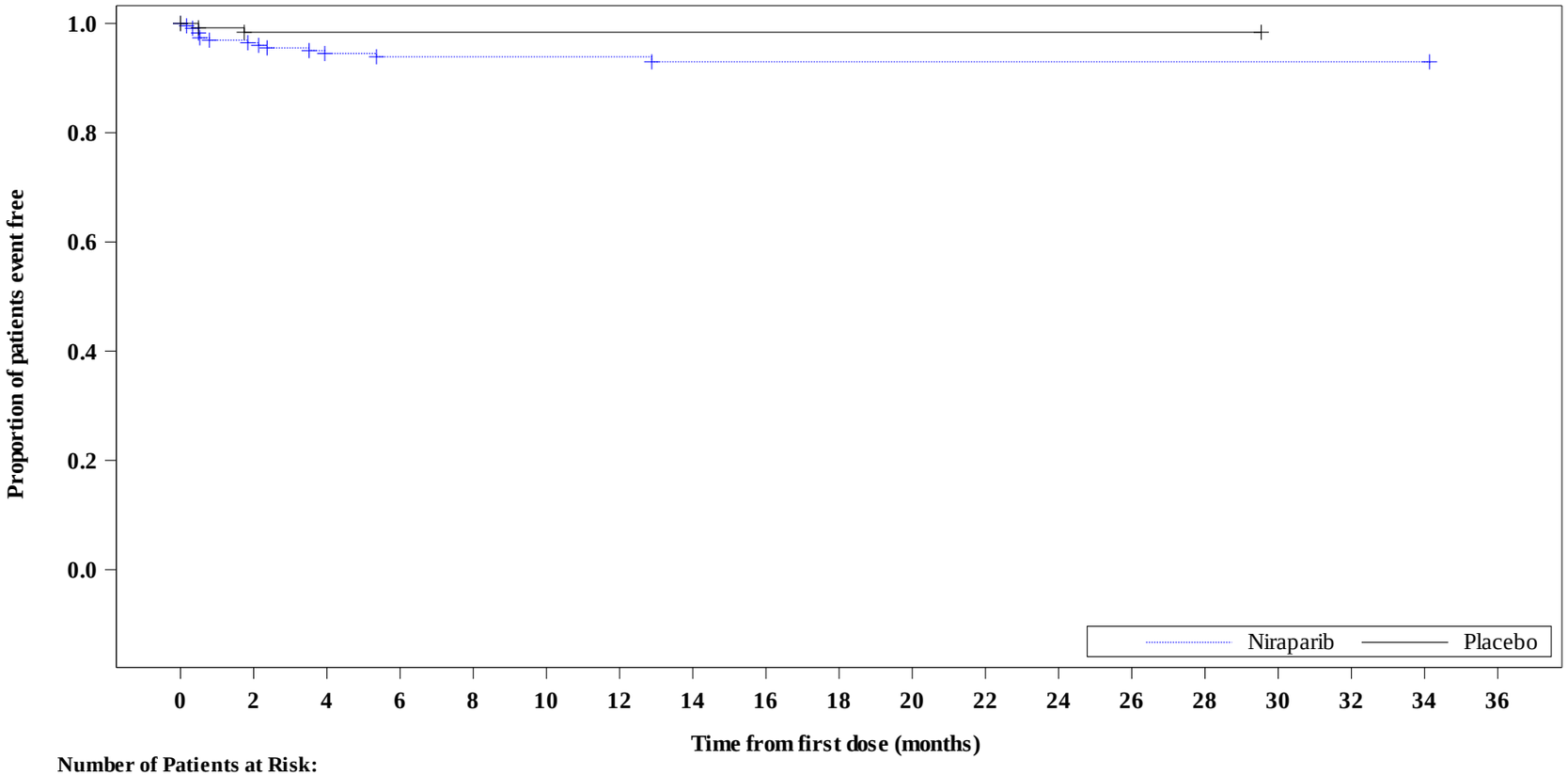



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 180 | 162 | 134 | 120 | 112 | 103 | 87 | 74 | 48 | 23 | 14 | 9 | 6 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 107 | 97 | 76 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Photosensitivity reaction

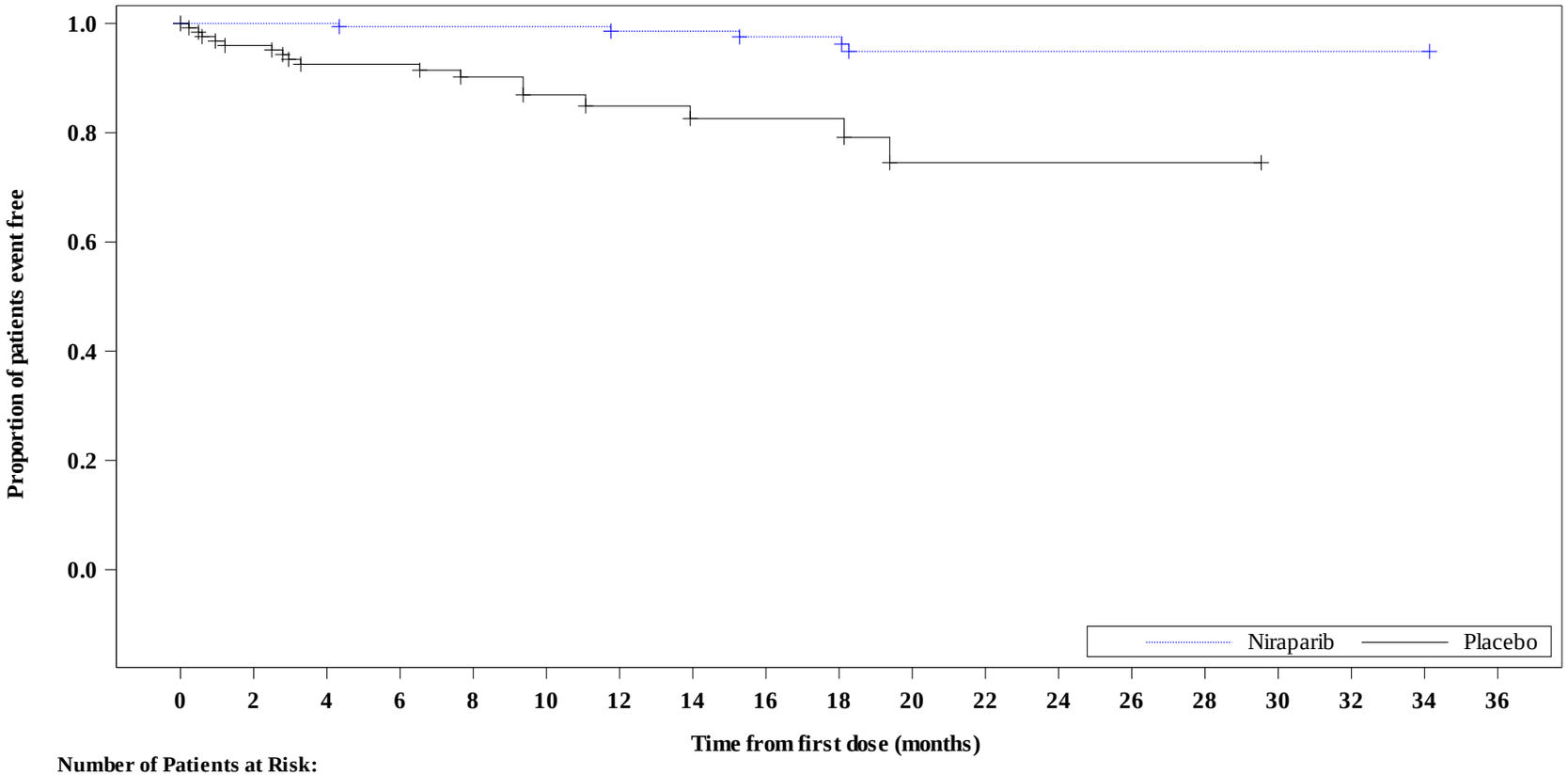



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 207 | 172 | 155 | 128 | 115 | 107 | 96 | 82 | 70 | 47 | 22 | 13 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 97 | 77 | 55 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Pruritus

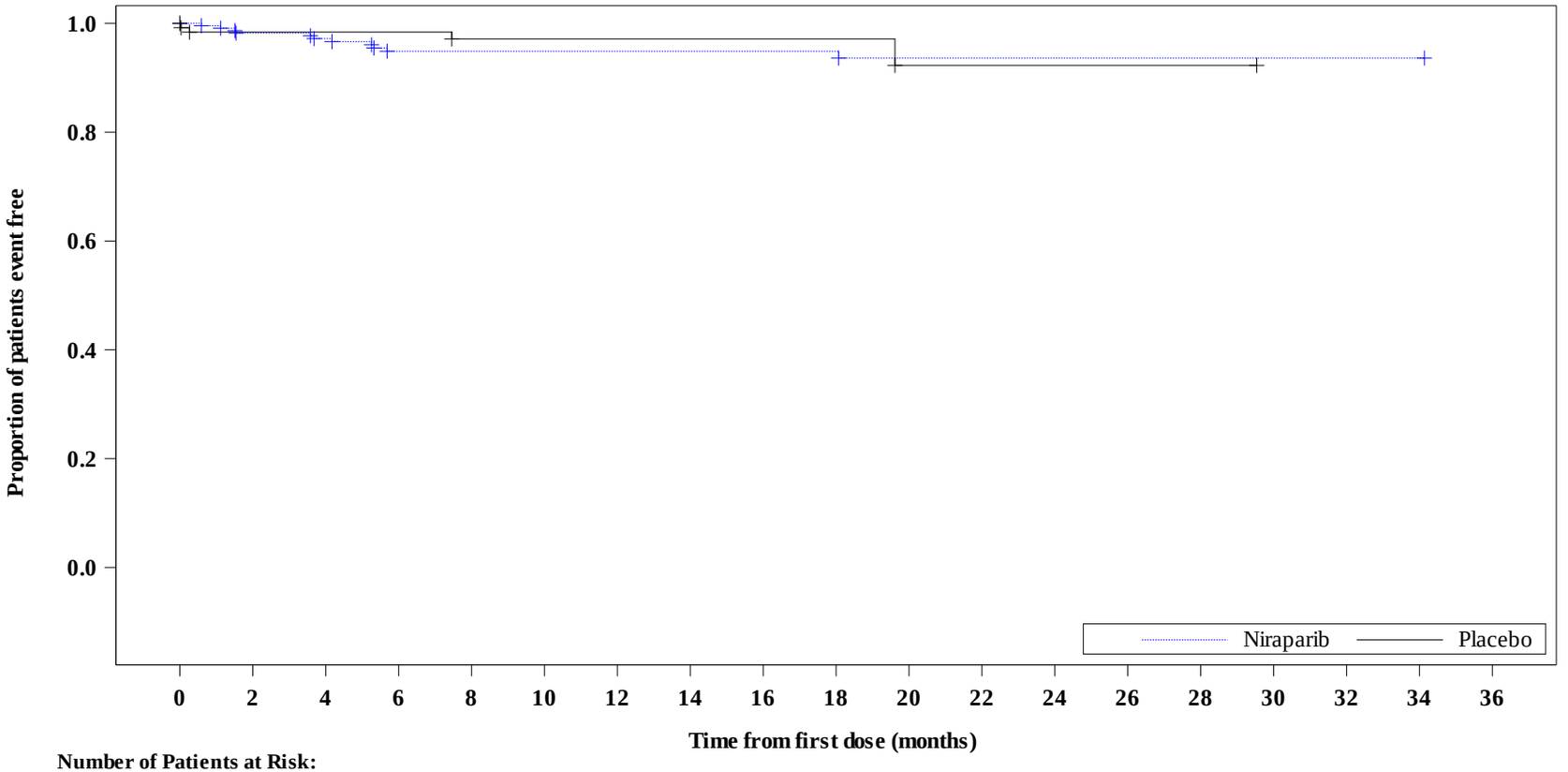



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 165 | 136 | 122 | 113 | 103 | 87 | 74 | 47 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 117 | 98 | 90 | 71 | 49 | 42 | 36 | 29 | 24 | 14 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Rash

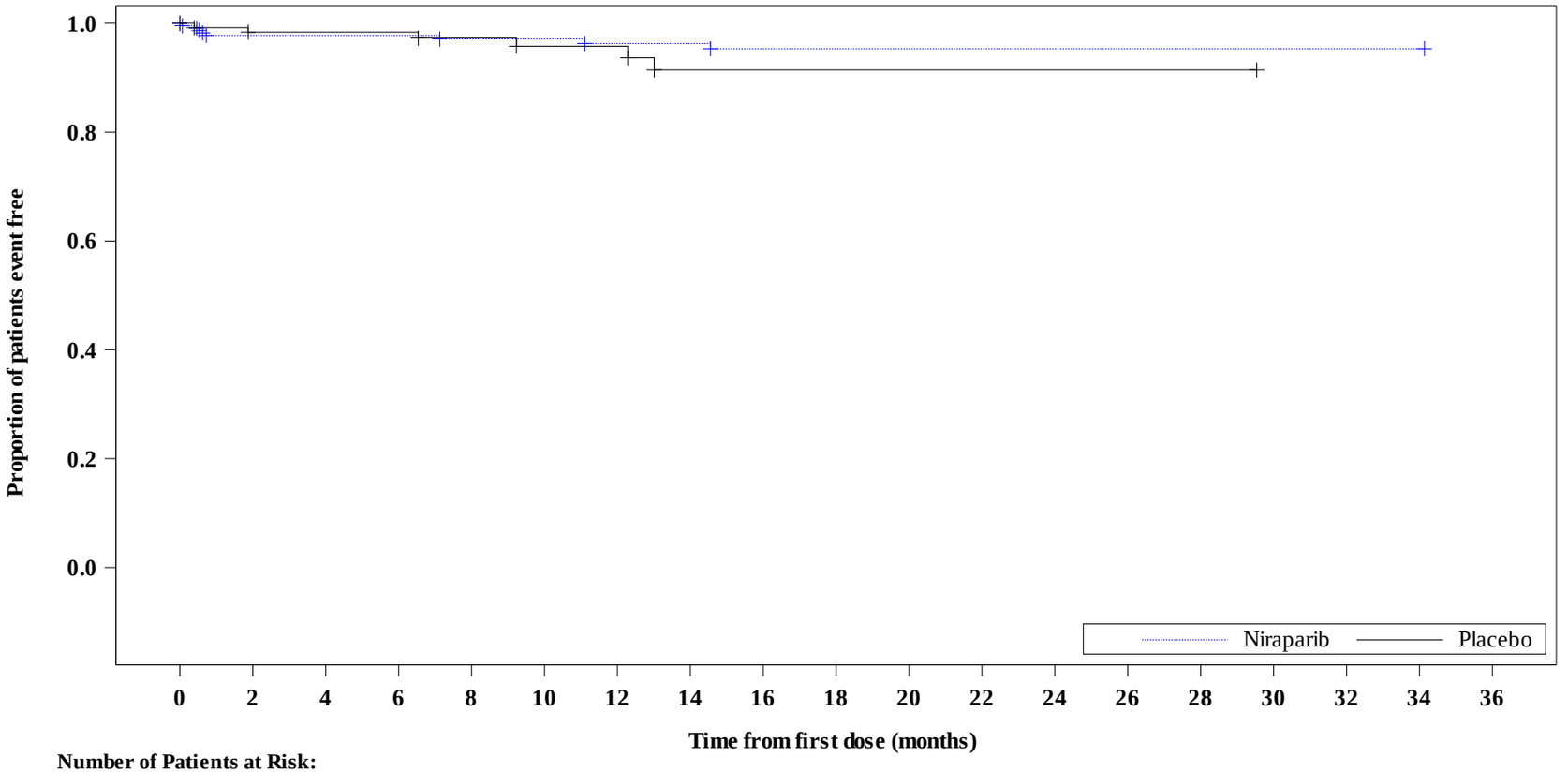



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 210 | 178 | 159 | 131 | 119 | 112 | 102 | 86 | 75 | 48 | 23 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 96 | 76 | 54 | 47 | 41 | 34 | 29 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Rash maculo-papular

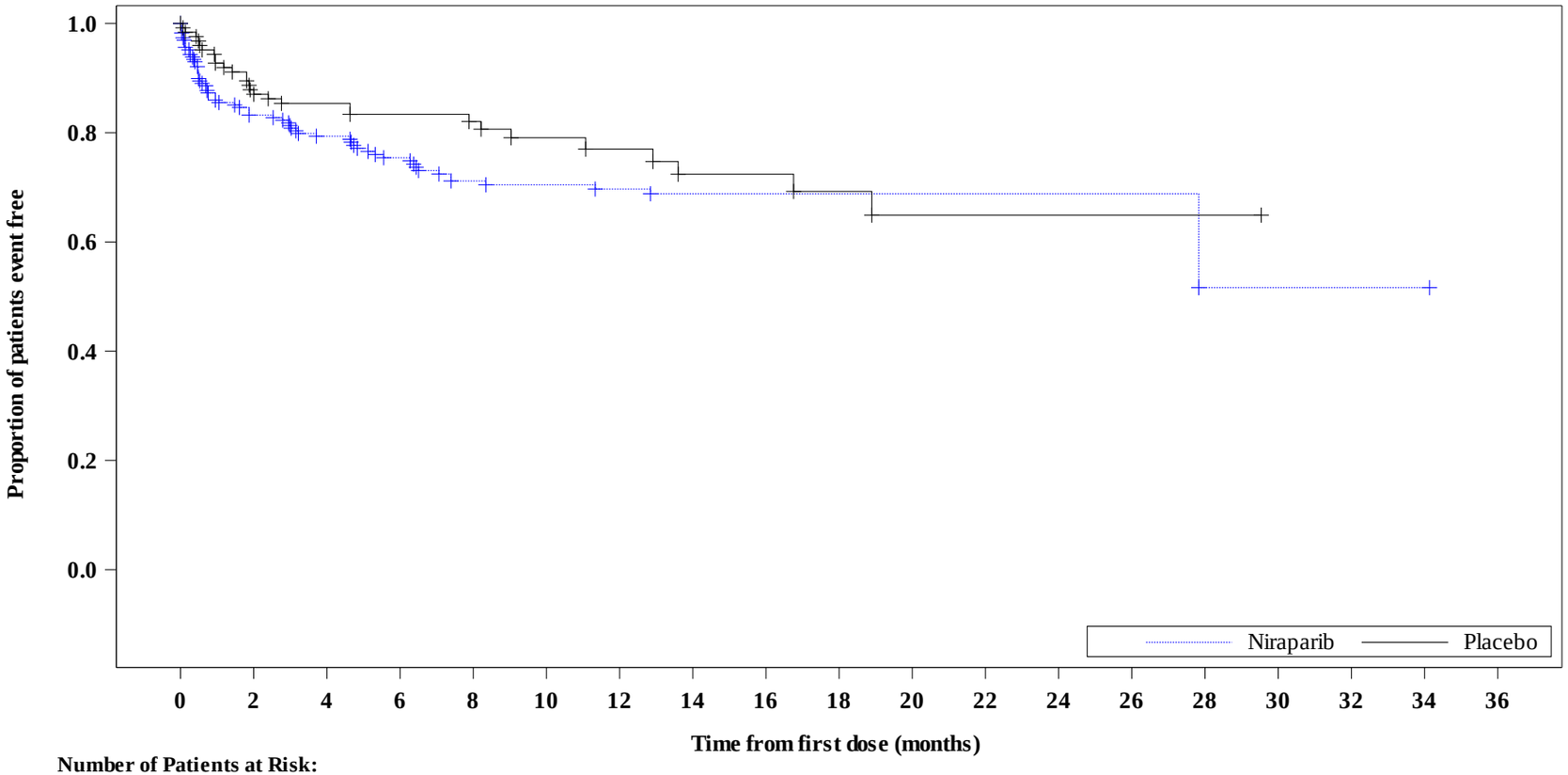



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 180 | 163 | 134 | 121 | 112 | 103 | 86 | 74 | 48 | 22 | 14 | 9 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 96 | 76 | 53 | 47 | 38 | 32 | 27 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Vascular disorders

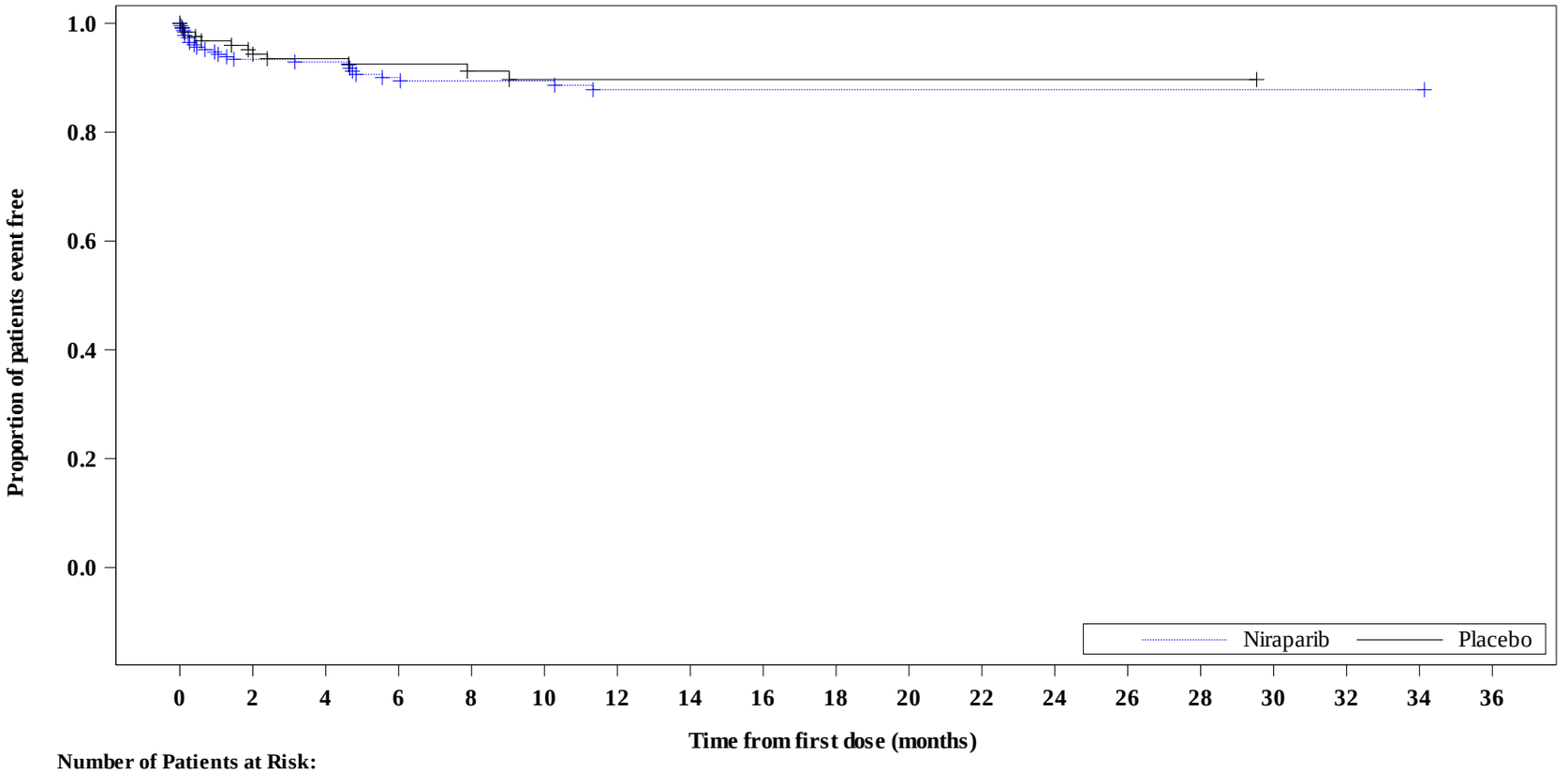



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 177 | 146 | 130 | 102 | 93 | 86 | 76 | 66 | 53 | 32 | 15 | 8 | 6 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 107 | 89 | 78 | 62 | 42 | 36 | 29 | 24 | 18 | 13 | 5 | 2 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Vascular disorders, PT: Hot flush

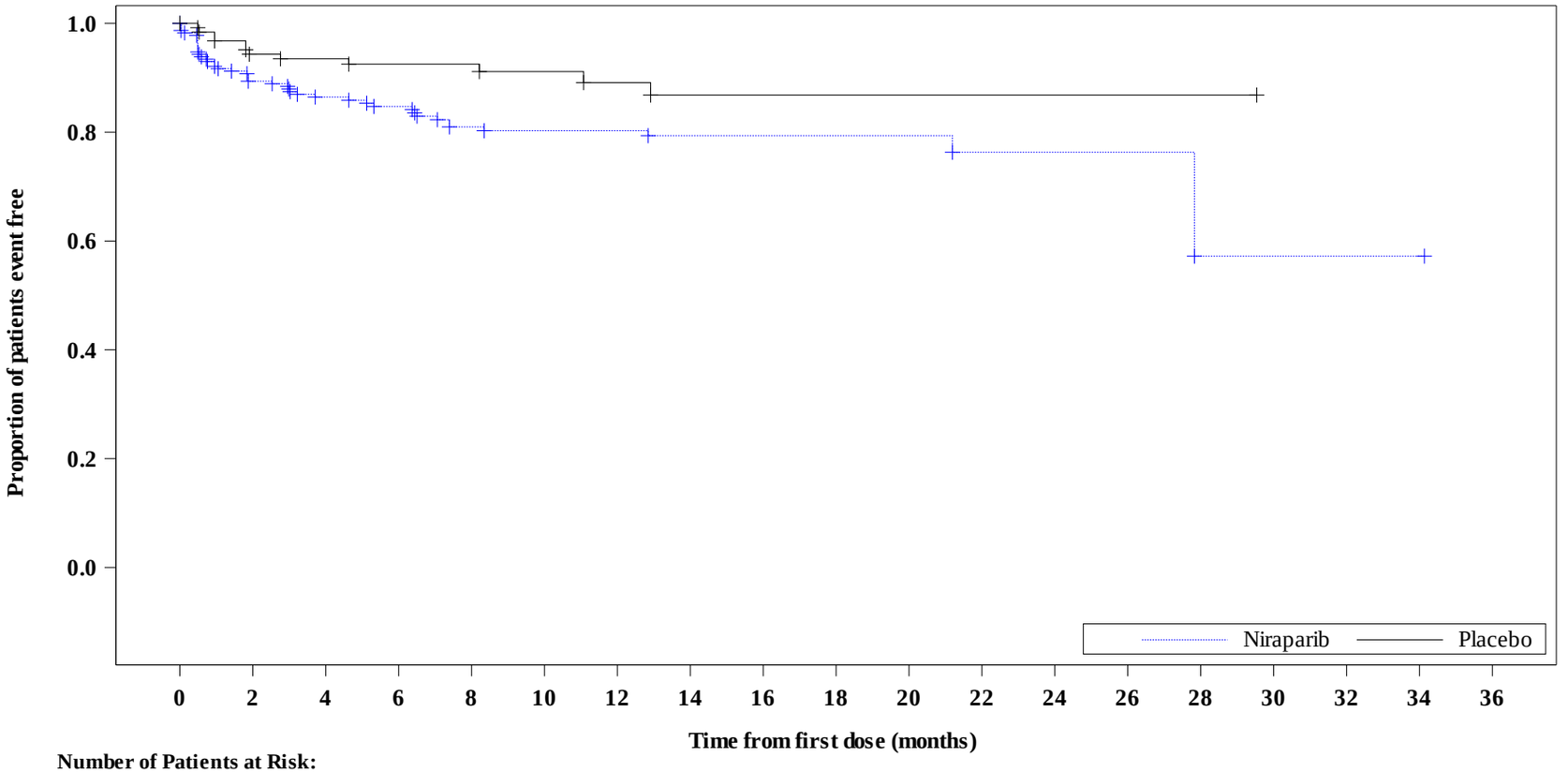



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 199 | 171 | 151 | 123 | 113 | 103 | 94 | 82 | 69 | 45 | 23 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 116 | 99 | 89 | 70 | 49 | 43 | 36 | 29 | 24 | 17 | 6 | 3 | 2 | 1 | 0 | | | |

Figure 3.14
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)

SOC: Vascular disorders, PT: Hypertension




**Number of Patients at Risk:**

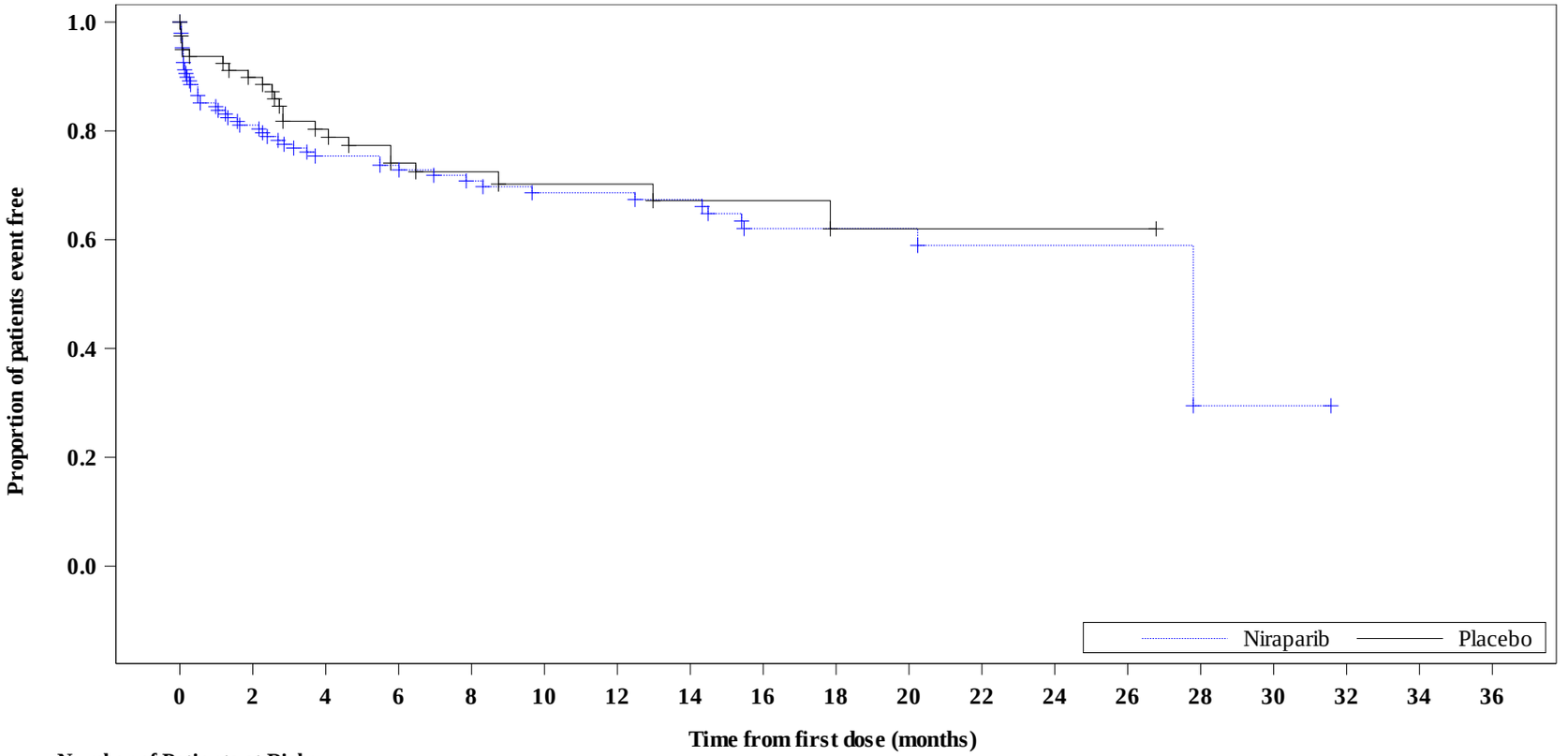
| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 190 | 158 | 144 | 113 | 102 | 95 | 84 | 72 | 59 | 36 | 15 | 8 | 6 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 115 | 99 | 89 | 71 | 50 | 43 | 35 | 30 | 25 | 17 | 8 | 4 | 2 | 1 | 0 | | | |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-14-teaept-g.sas 30SEP2020 08:59

Figure 3.16
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety-GVD Population)

SOC: Psychiatric disorders

Age Group (Years): <65



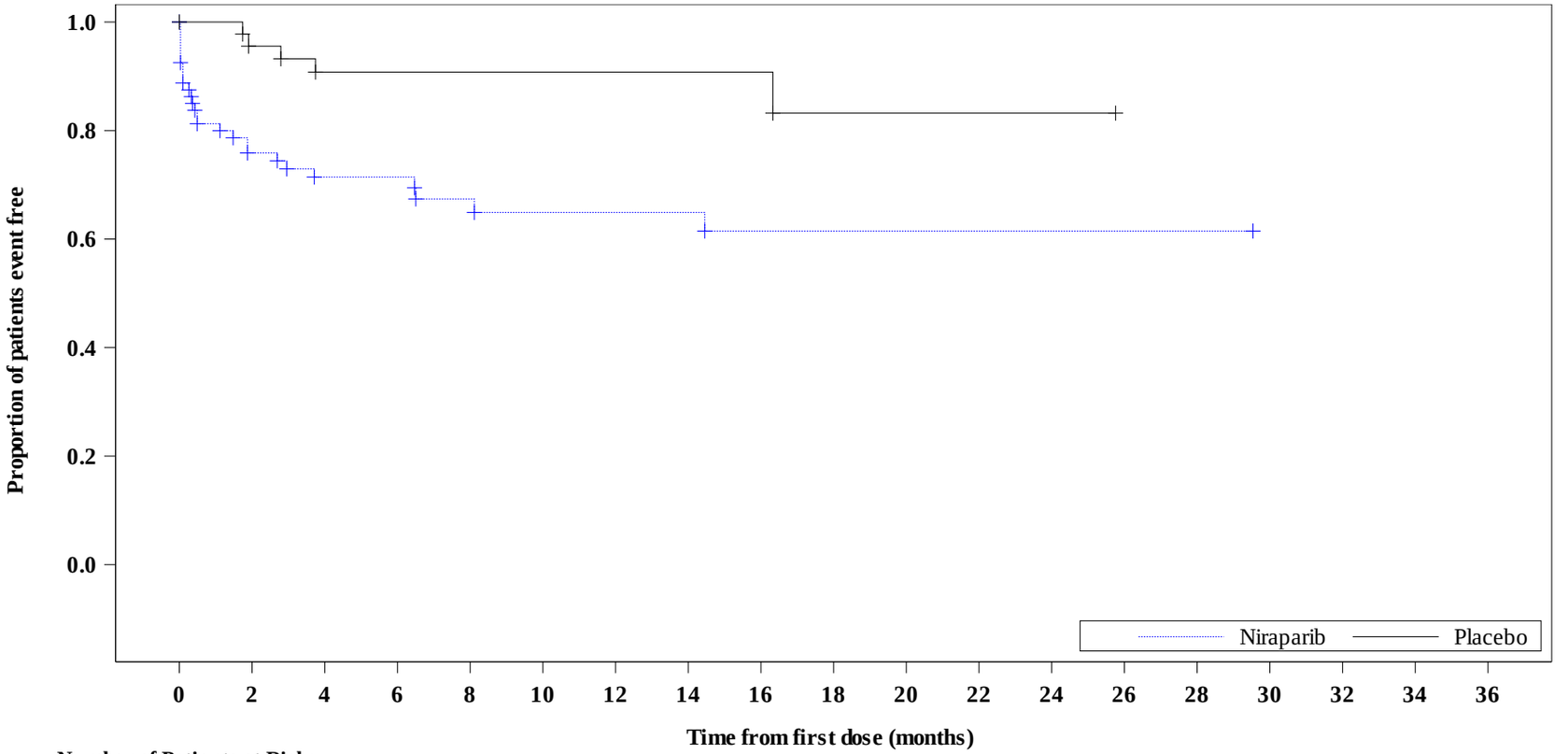

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 148 | 116 | 96 | 86 | 67 | 60 | 58 | 53 | 45 | 35 | 21 | 10 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 79 | 69 | 54 | 46 | 37 | 24 | 23 | 19 | 15 | 12 | 7 | 3 | 2 | 1 | 0 | | |

Figure 3.16
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety-GVD Population)

SOC: Psychiatric disorders

Age Group (Years): >=65



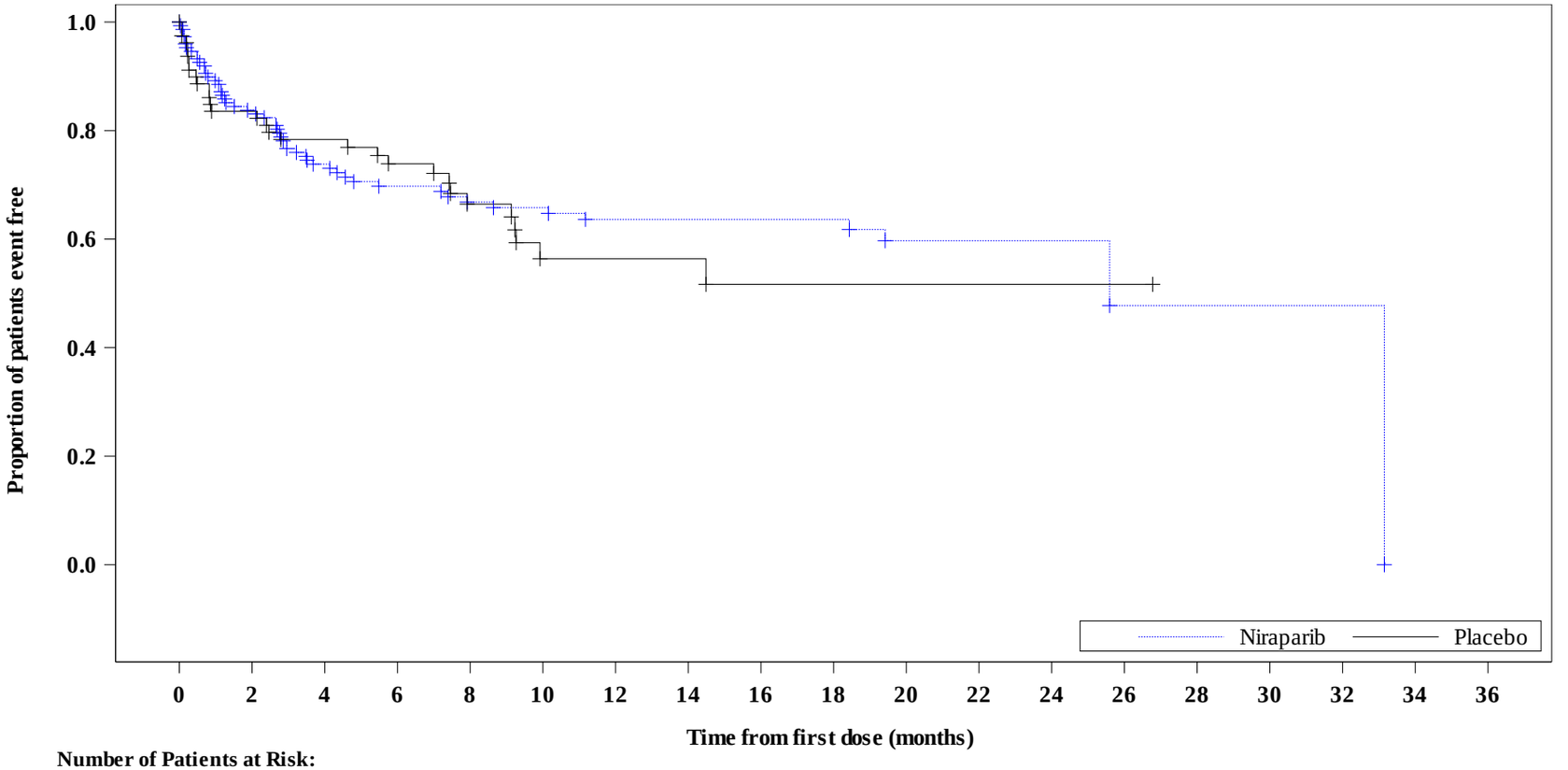

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 80 | 54 | 42 | 37 | 27 | 24 | 21 | 20 | 16 | 14 | 10 | 4 | 2 | 1 | 1 | 0 |
| Placebo | 45 | 43 | 35 | 32 | 24 | 19 | 16 | 14 | 12 | 9 | 8 | 4 | 1 | 0 | | |

Figure 3.16
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders

Age Group (Years): <65



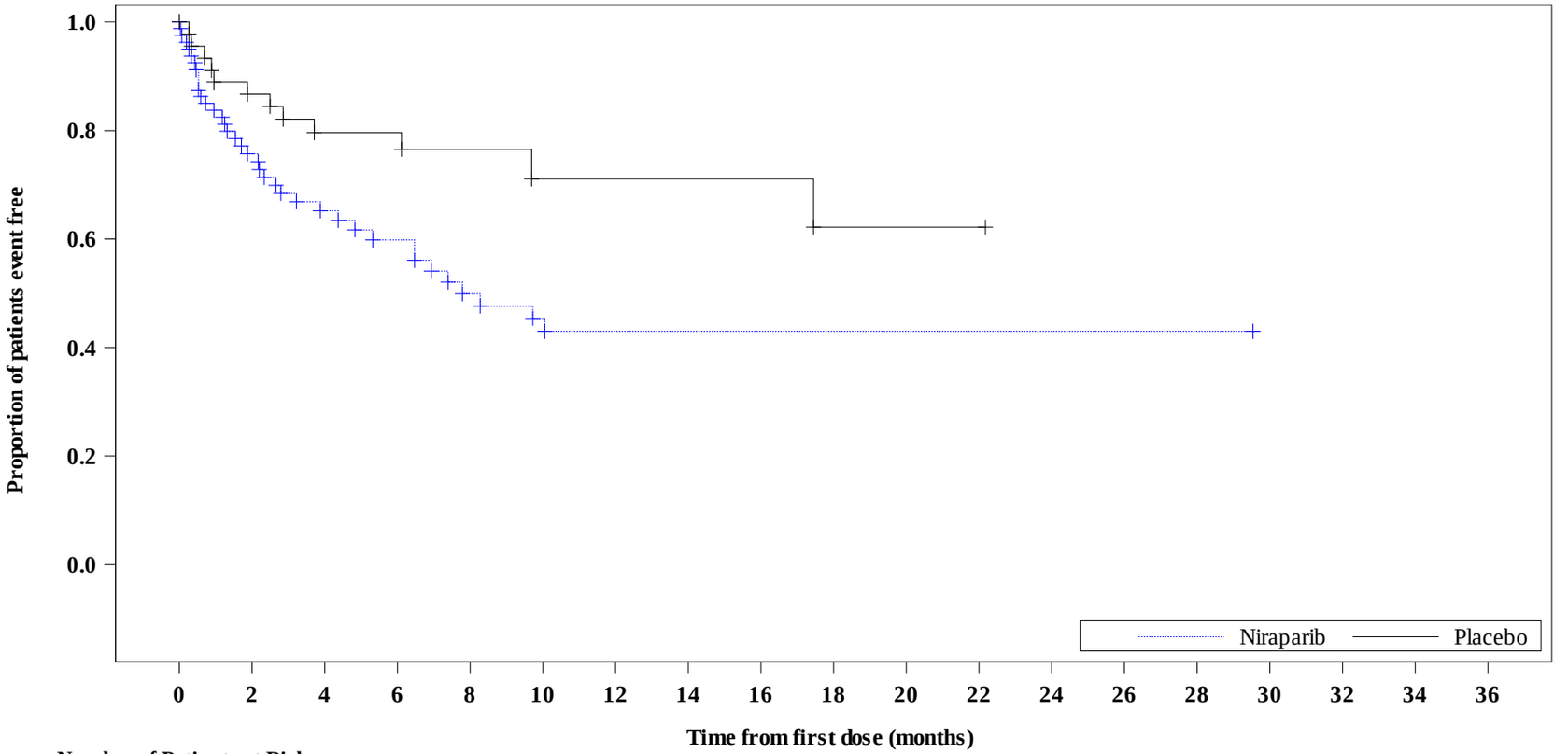

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 148 | 120 | 95 | 83 | 67 | 62 | 57 | 51 | 43 | 35 | 20 | 9 | 5 | 3 | 2 | 2 | 1 | 0 |
| Placebo | 79 | 65 | 56 | 48 | 34 | 18 | 17 | 13 | 9 | 8 | 5 | 2 | 1 | 1 | 0 | | | |

Figure 3.16
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders

Age Group (Years): >=65



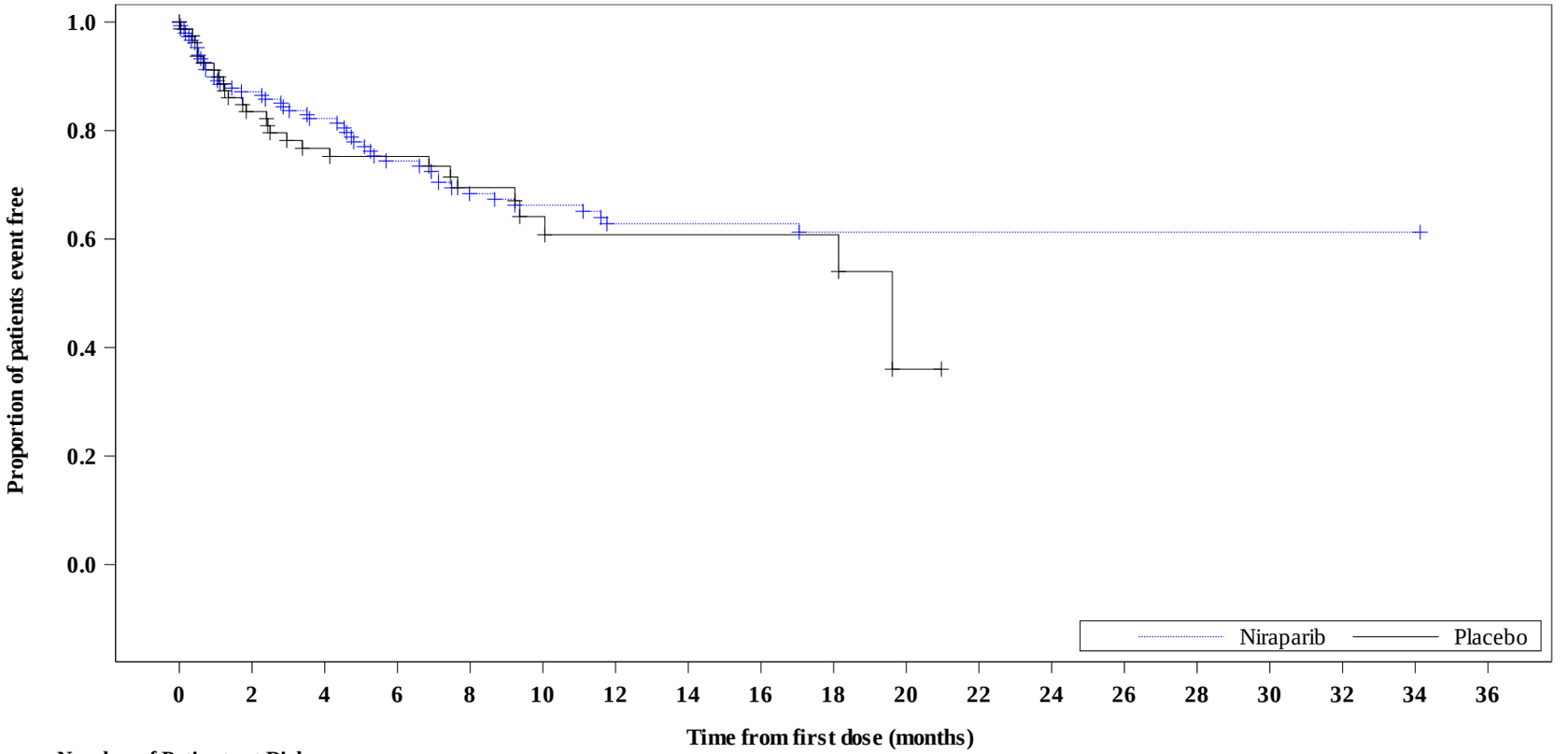

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 80 | 53 | 39 | 32 | 22 | 19 | 16 | 14 | 11 | 10 | 6 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 45 | 39 | 30 | 26 | 18 | 13 | 10 | 9 | 8 | 6 | 5 | 2 | 0 | | | |

Figure 3.16
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders

Age Group (Years): <65



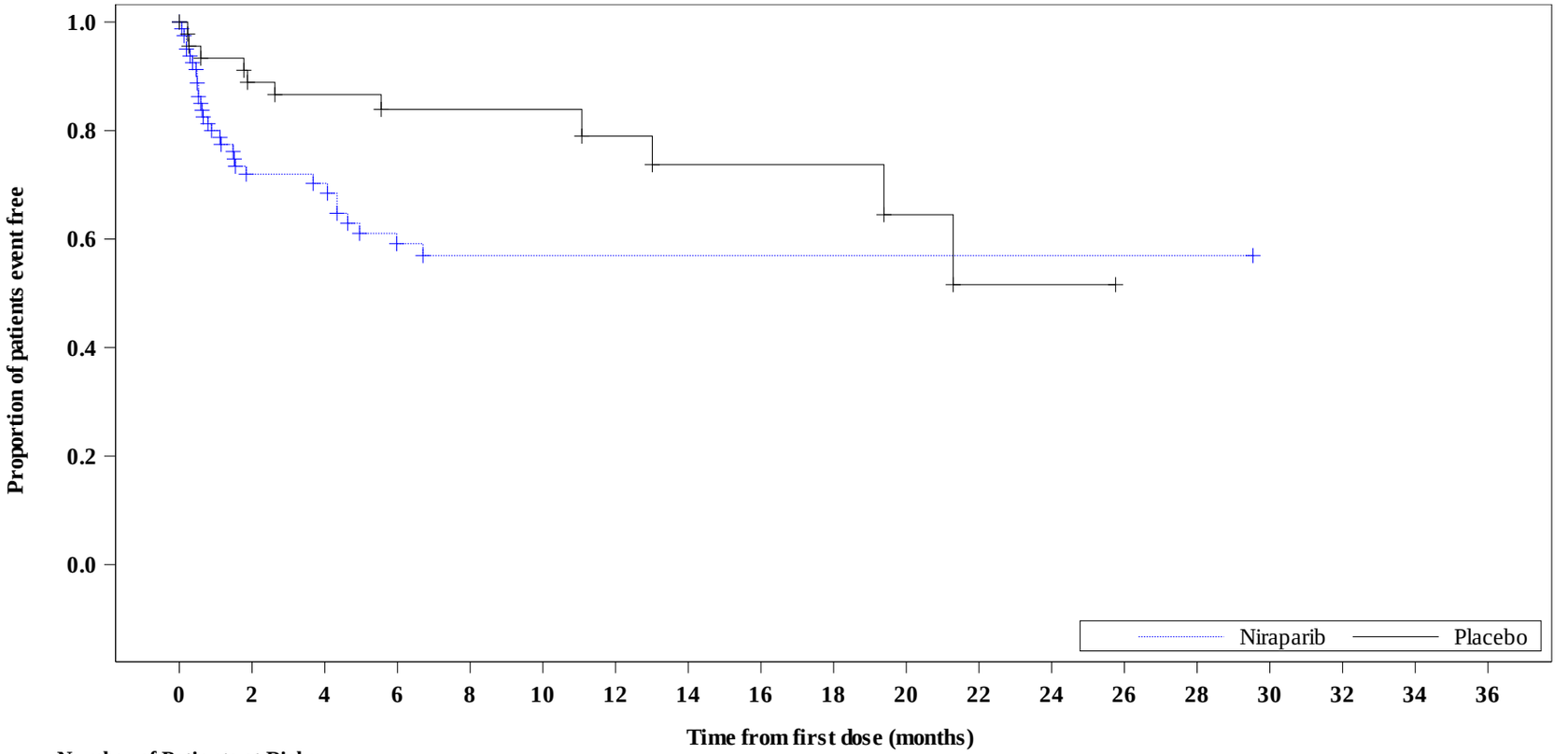

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 148 | 126 | 102 | 84 | 65 | 60 | 55 | 50 | 44 | 34 | 20 | 11 | 5 | 4 | 2 | 2 | 1 | 1 | 0 |
| Placebo | 79 | 64 | 51 | 46 | 34 | 19 | 17 | 14 | 11 | 9 | 2 | 0 | | | | | | | |

Figure 3.16
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Age Group (Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders

Age Group (Years): >=65




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 80 | 49 | 39 | 31 | 21 | 20 | 17 | 15 | 10 | 10 | 8 | 4 | 3 | 1 | 1 | 0 |
| Placebo | 45 | 40 | 34 | 30 | 23 | 19 | 16 | 14 | 12 | 9 | 7 | 3 | 1 | 0 | | |

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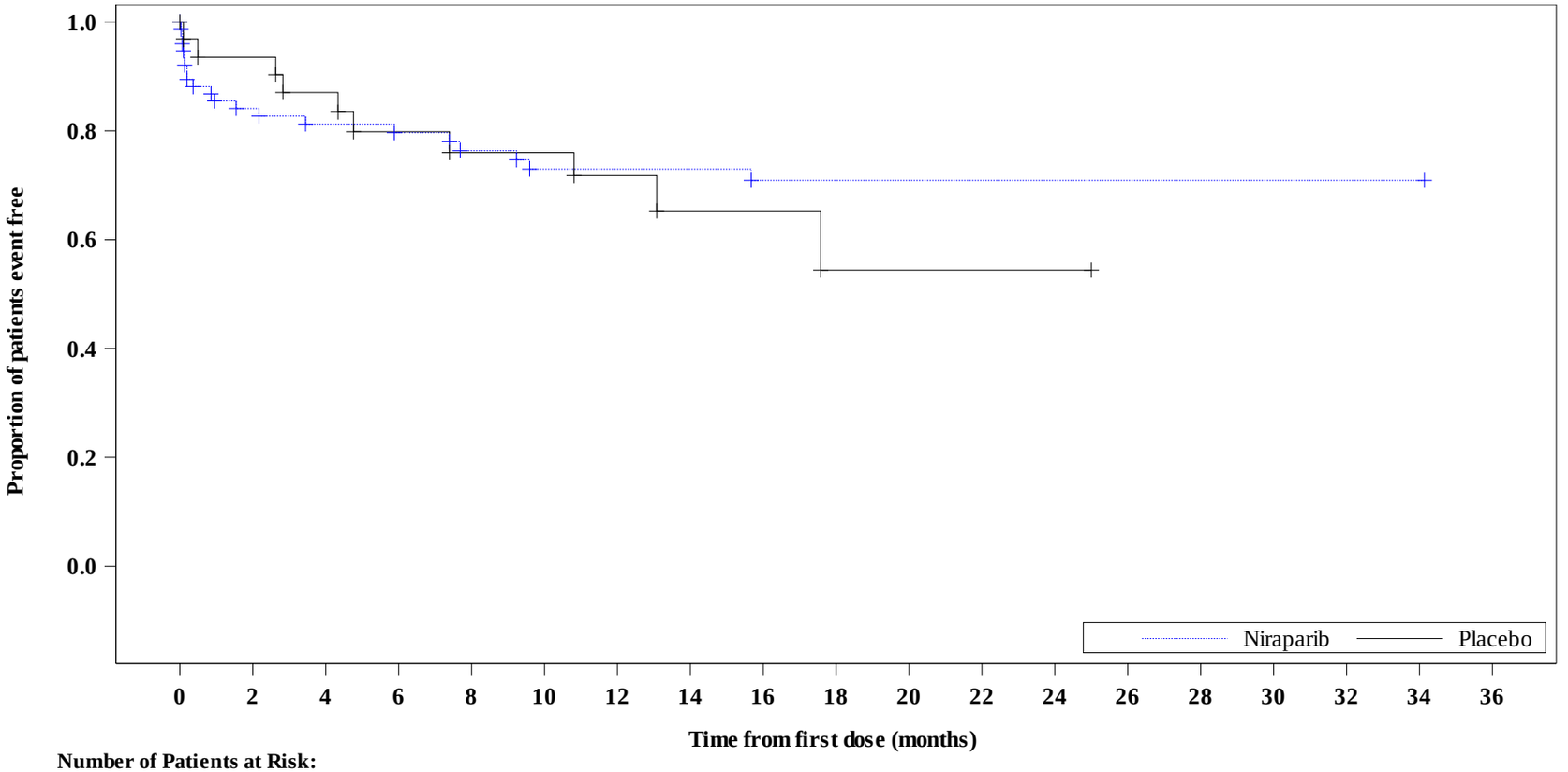
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Constipation

BRCA Status: BRCAmut




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 59 | 53 | 51 | 46 | 42 | 41 | 40 | 33 | 25 | 15 | 7 | 4 | 3 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 31 | 29 | 25 | 22 | 20 | 19 | 14 | 7 | 6 | 4 | 4 | 1 | 1 | 0 | | | | | |

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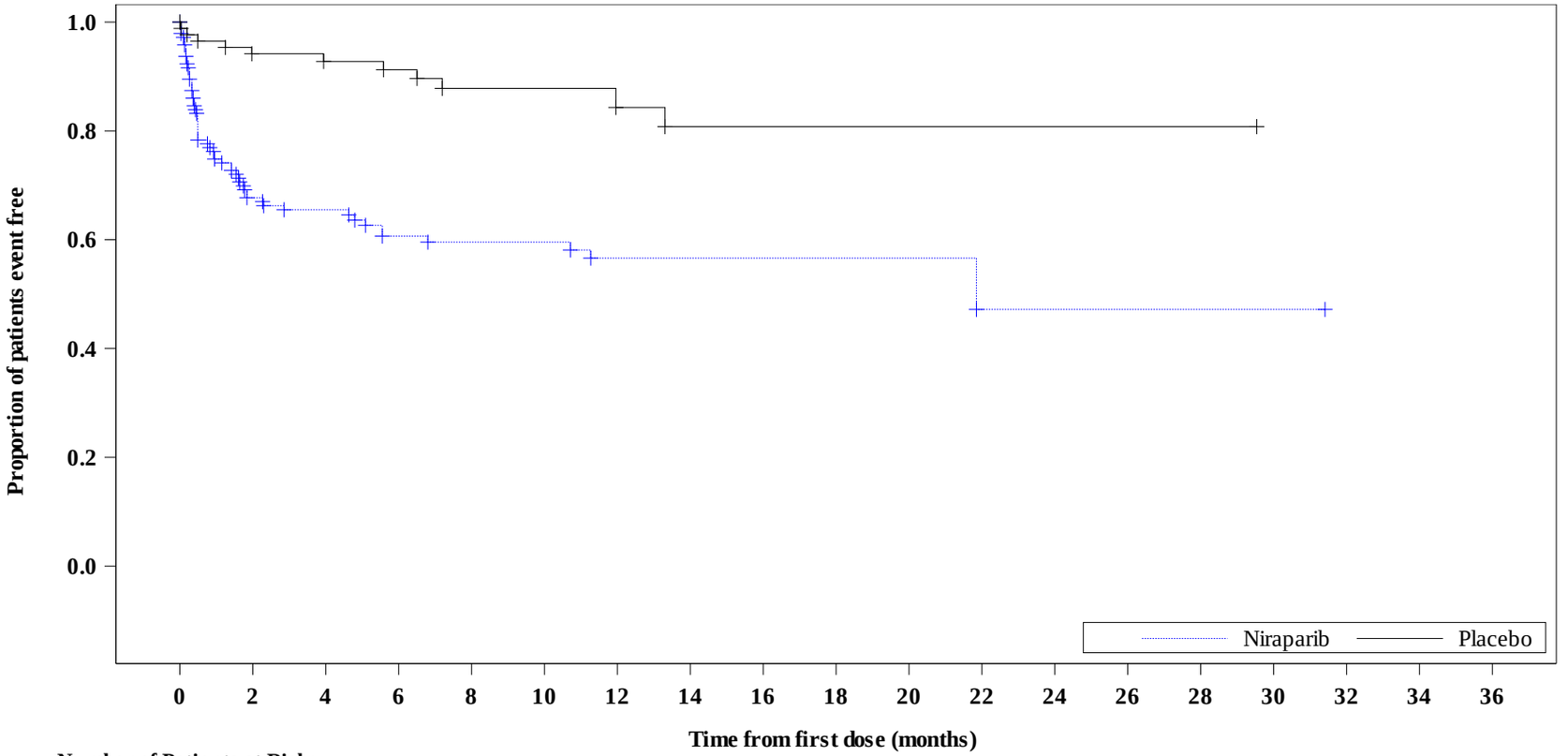
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Constipation

BRCA Status: BRCAwt



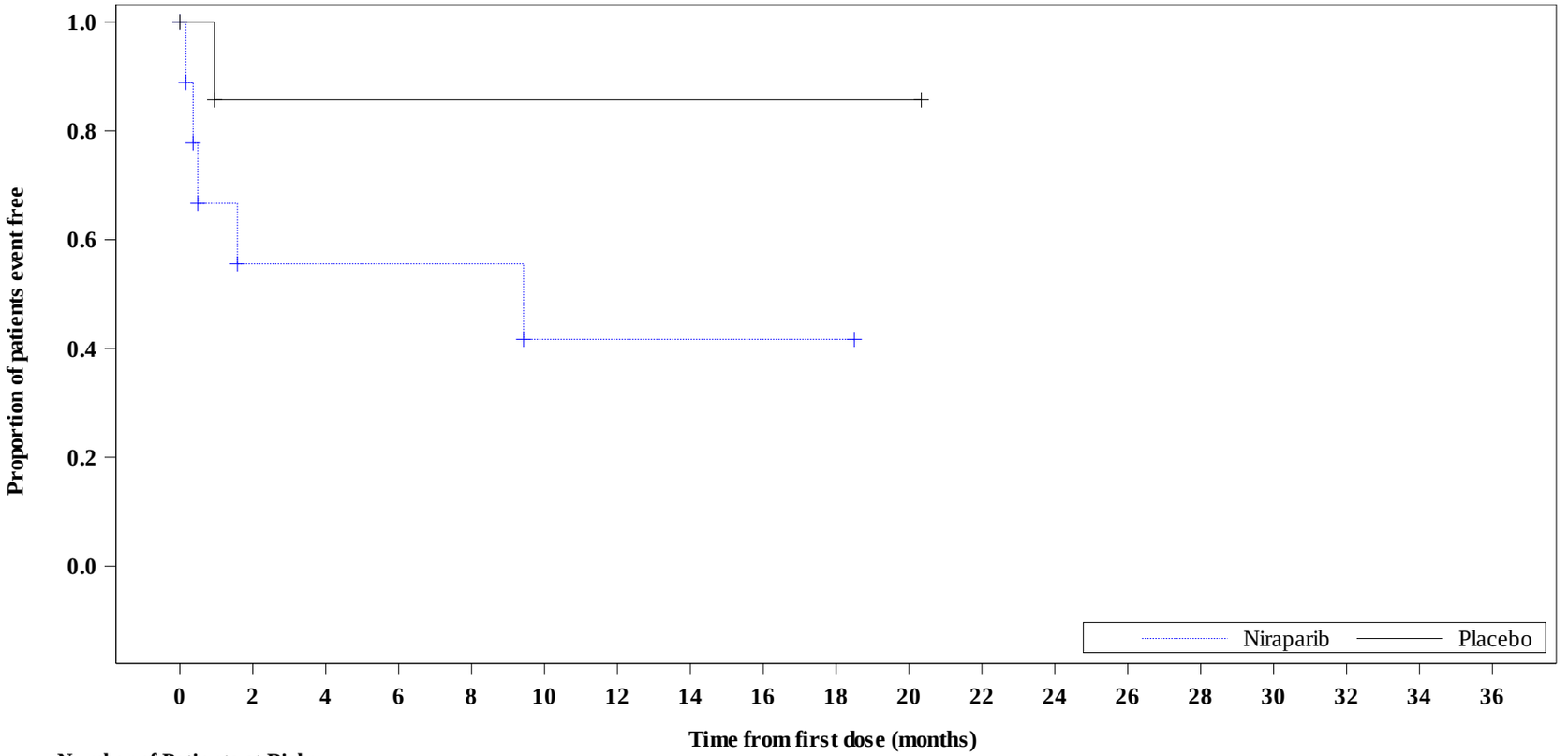

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 93 | 73 | 60 | 46 | 41 | 37 | 34 | 28 | 26 | 16 | 5 | 3 | 2 | 1 | 1 | 0 |
| Placebo | 86 | 80 | 66 | 59 | 44 | 26 | 24 | 23 | 21 | 18 | 11 | 6 | 3 | 2 | 1 | 0 | |

Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Constipation

BRCA Status: BRCAnd




**Number of Patients at Risk:**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 5 | 4 | 4 | 4 | 2 | 1 | 1 | 1 | 1 | 0 | |
| Placebo | 7 | 6 | 6 | 6 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 |

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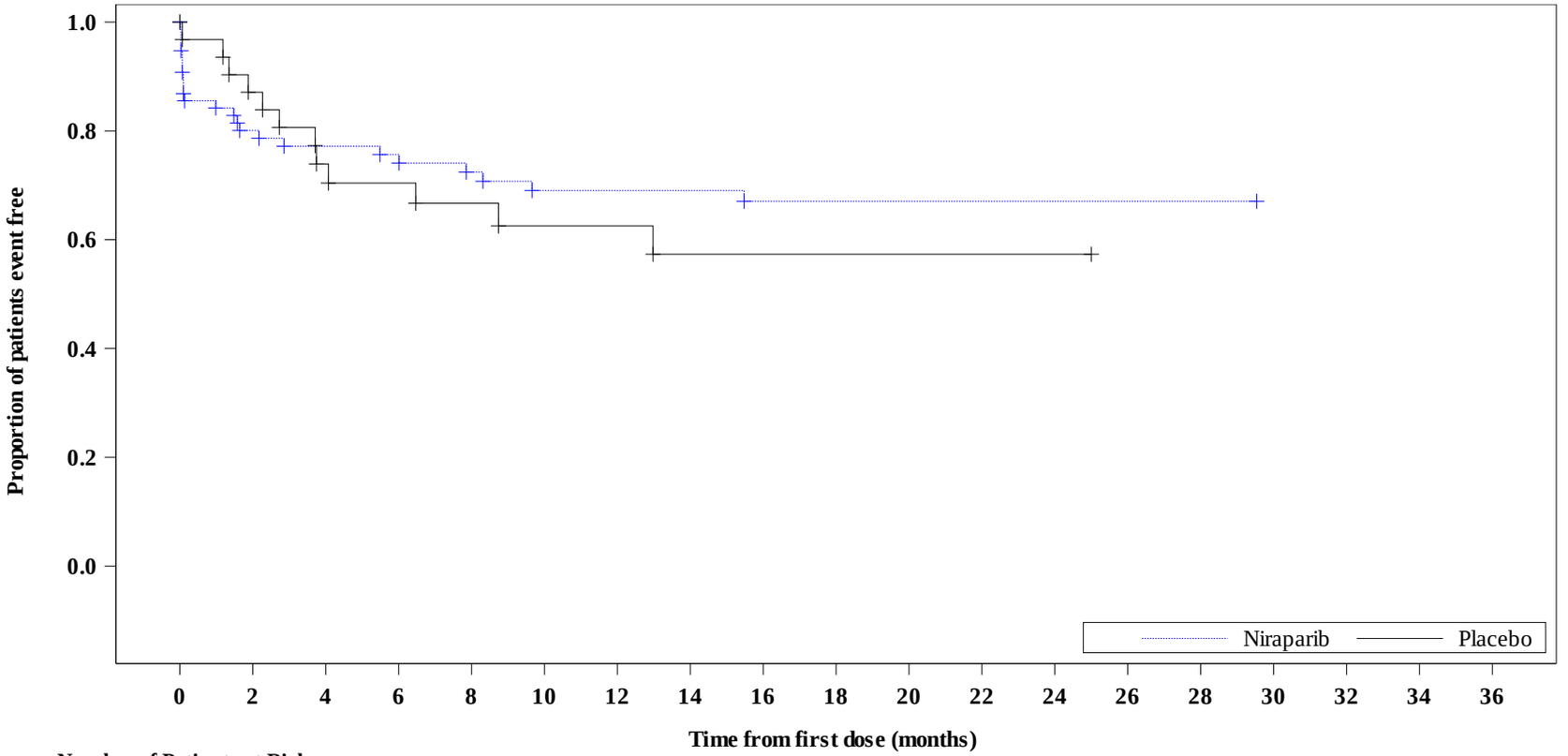
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Psychiatric disorders

BRCA Status: BRCAmut




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 56 | 52 | 49 | 43 | 41 | 40 | 38 | 34 | 24 | 15 | 9 | 5 | 3 | 1 | 0 |
| Placebo | 31 | 27 | 21 | 19 | 17 | 15 | 12 | 8 | 5 | 4 | 4 | 1 | 1 | 0 | | |

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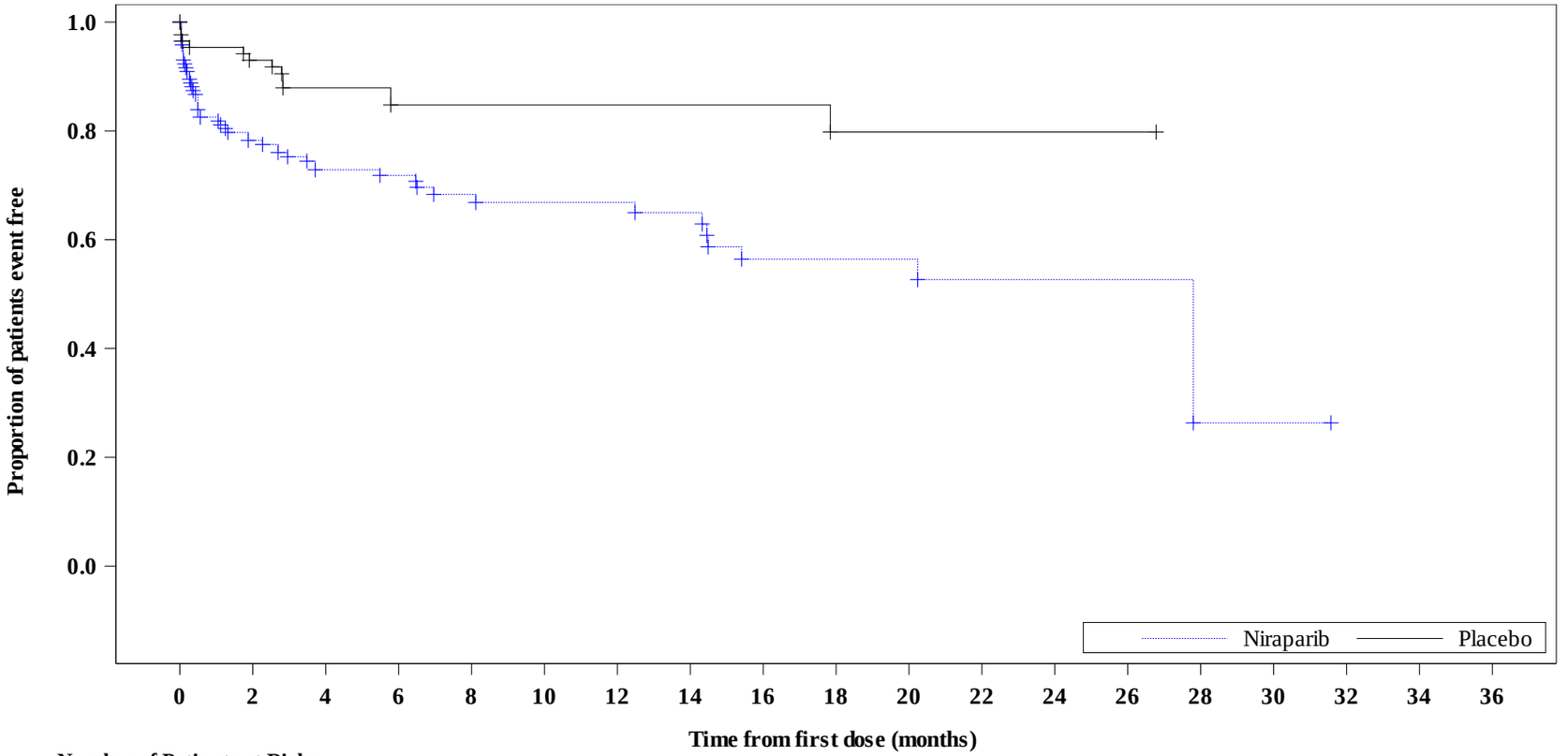
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Psychiatric disorders

BRCA Status: BRCAwt




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 106 | 80 | 68 | 46 | 40 | 37 | 33 | 25 | 23 | 16 | 5 | 3 | 2 | 1 | 1 | 0 |
| Placebo | 86 | 78 | 62 | 54 | 42 | 26 | 25 | 23 | 20 | 16 | 10 | 6 | 2 | 1 | 0 | | |

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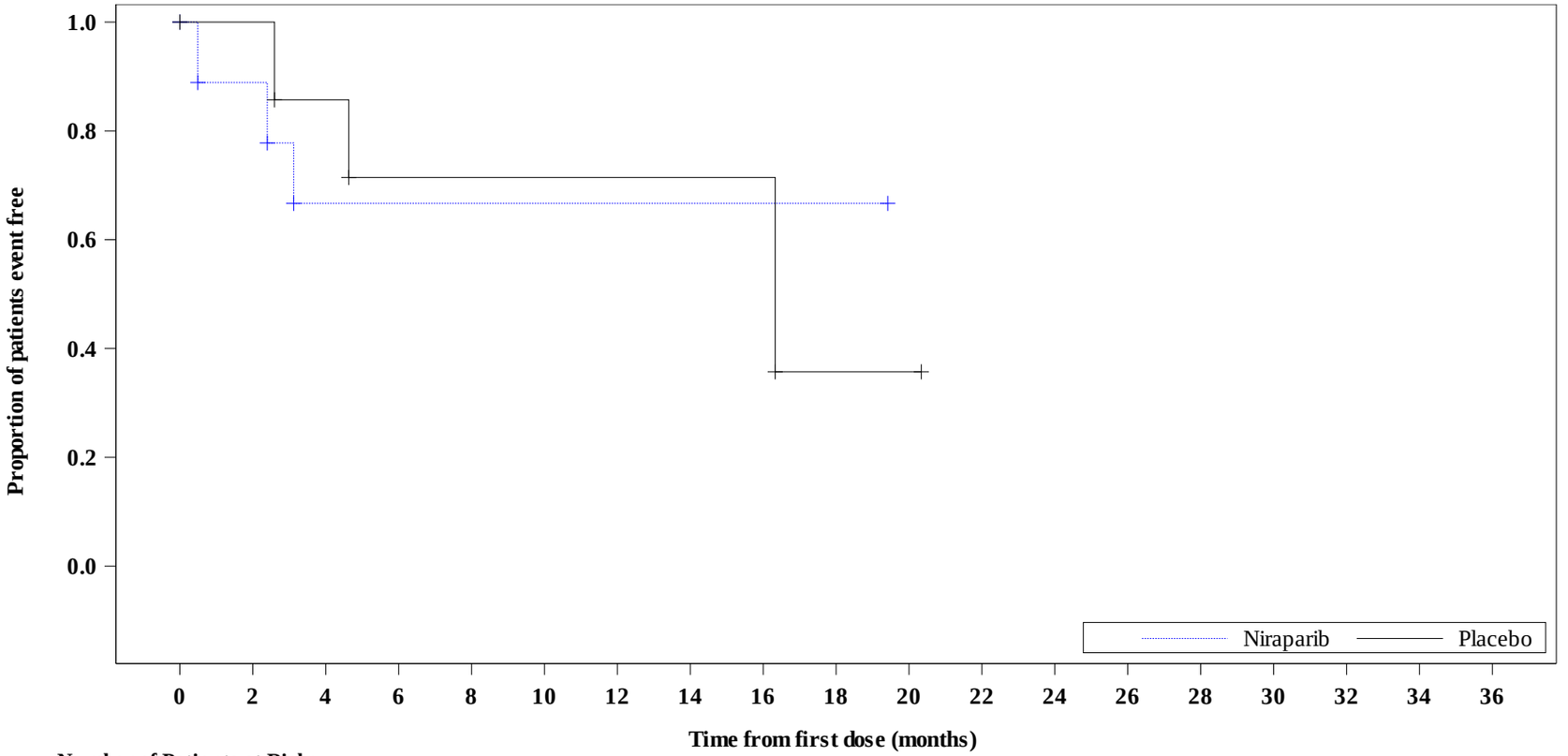
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Psychiatric disorders

BRCA Status: BRCAnd




**Number of Patients at Risk:**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 8 | 6 | 6 | 5 | 3 | 2 | 2 | 2 | 2 | 0 | |
| Placebo | 7 | 7 | 6 | 5 | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 0 |

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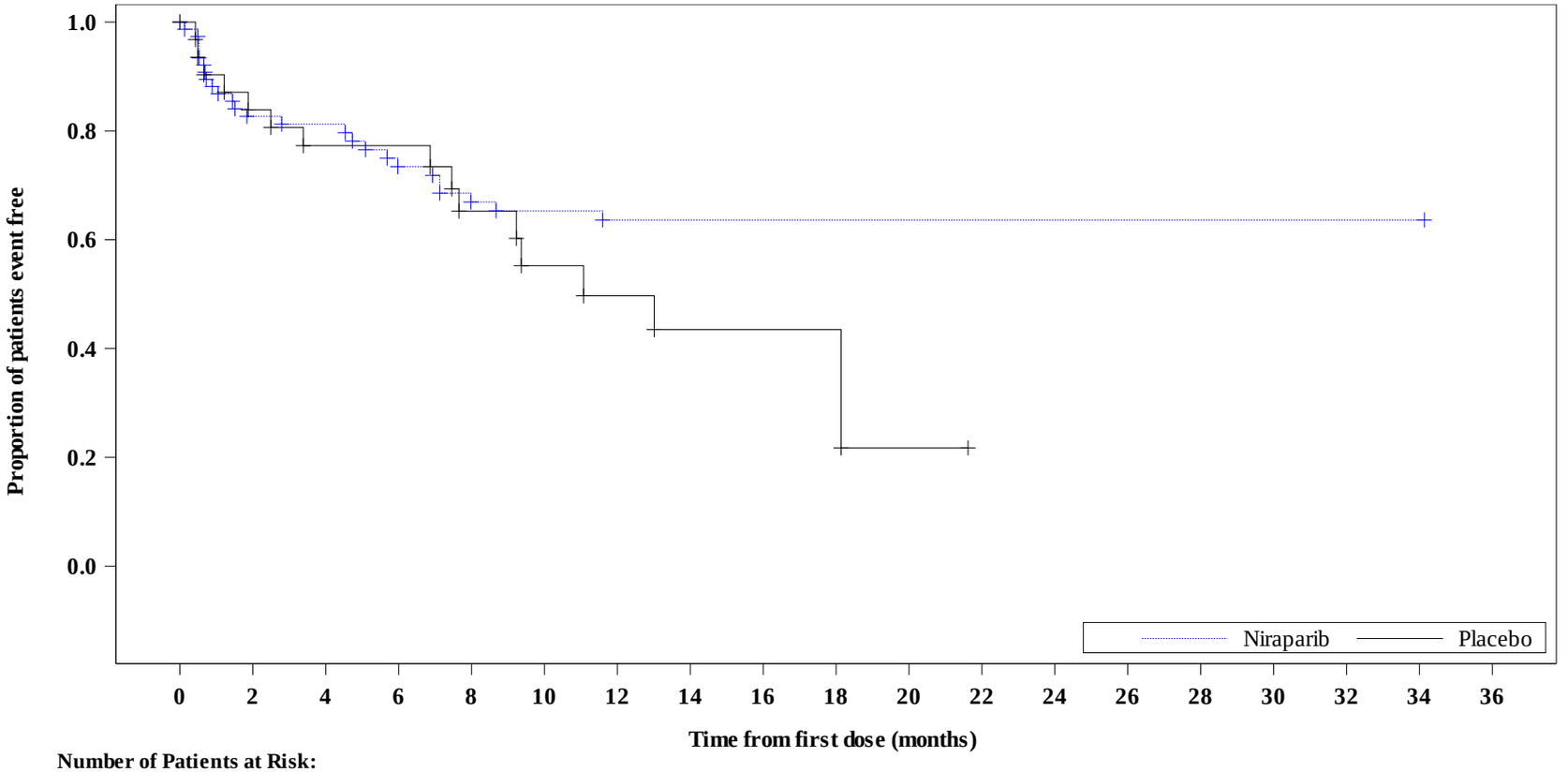
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders

BRCA Status: BRCAmut




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 58 | 53 | 47 | 41 | 40 | 38 | 36 | 32 | 24 | 15 | 10 | 6 | 5 | 3 | 2 | 1 | 1 | 0 |
| Placebo | 31 | 26 | 22 | 20 | 15 | 11 | 9 | 5 | 3 | 2 | 1 | 0 | | | | | | | |

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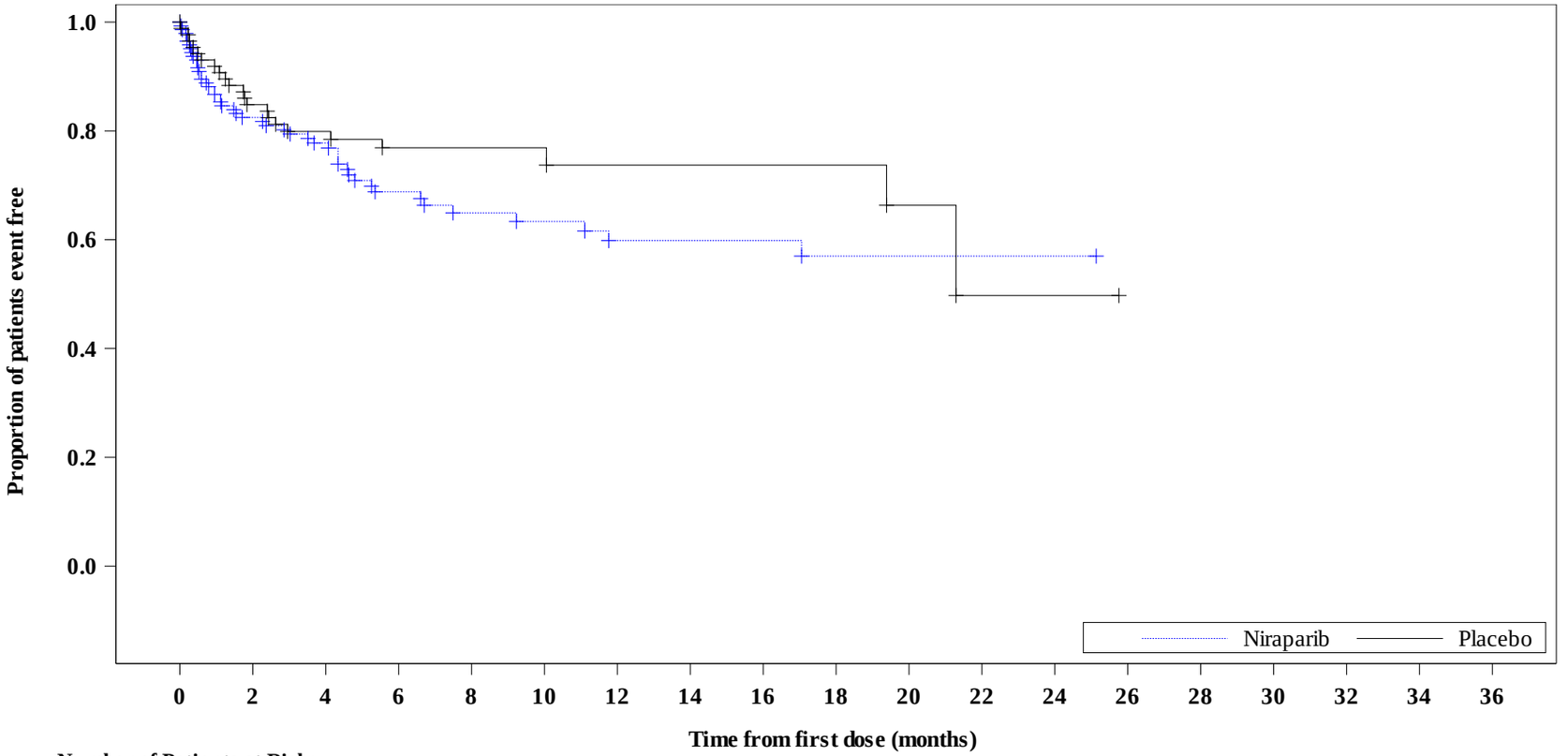
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders

BRCA Status: BRCAwt




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 111 | 84 | 65 | 42 | 38 | 33 | 28 | 21 | 19 | 13 | 5 | 2 | 0 |
| Placebo | 86 | 71 | 56 | 49 | 39 | 24 | 22 | 21 | 18 | 14 | 7 | 3 | 1 | 0 |

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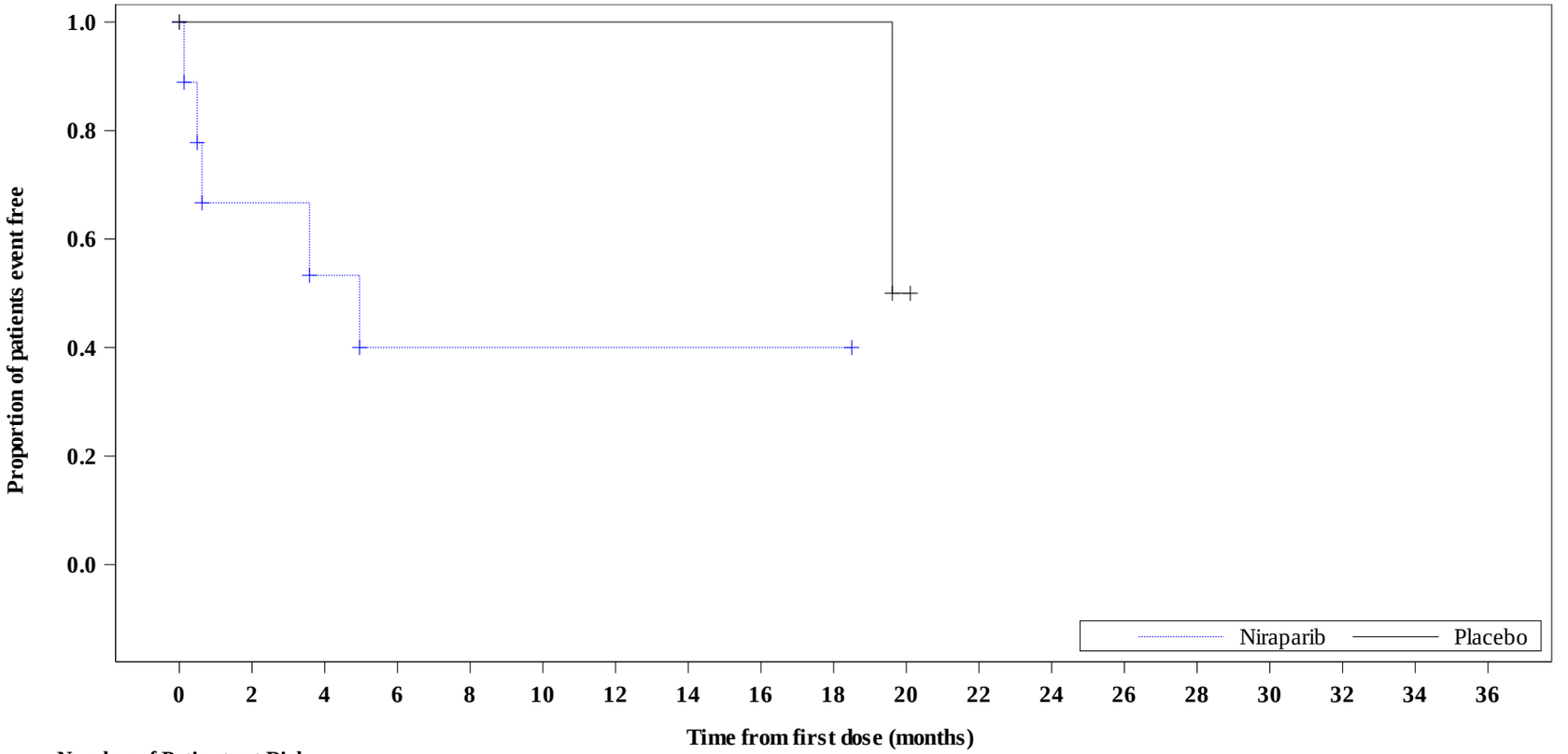
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders

BRCA Status: BRCAnd




**Number of Patients at Risk:**

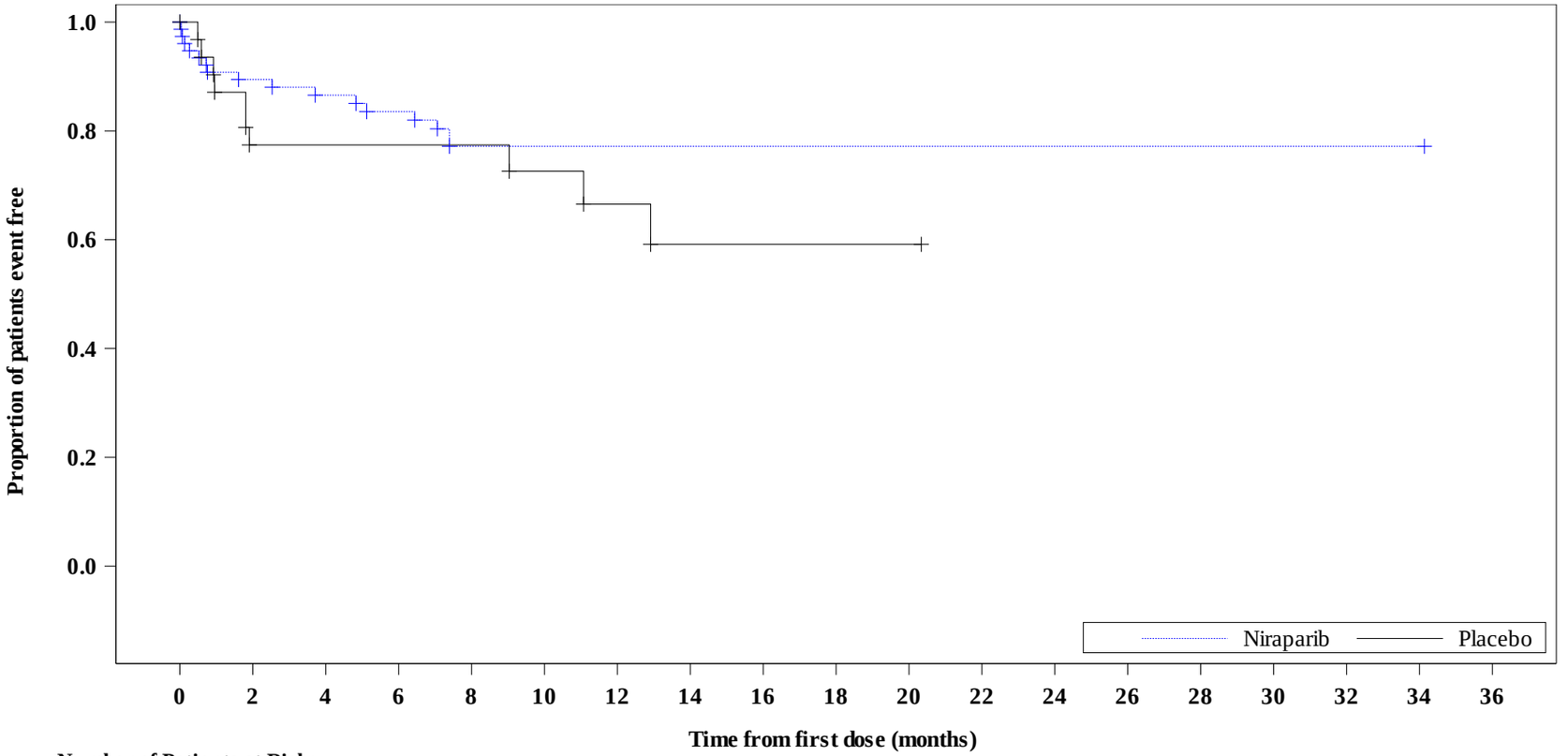
| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 6 | 4 | 3 | 3 | 2 | 1 | 1 | 1 | 1 | 0 | |
| Placebo | 7 | 7 | 7 | 7 | 3 | 3 | 2 | 2 | 2 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-18-teaeptb-g.sas 30SEP2020 08:56

Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Vascular disorders

BRCA Status: BRCAmut




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 64 | 57 | 54 | 47 | 45 | 44 | 41 | 38 | 27 | 17 | 9 | 5 | 5 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 31 | 24 | 22 | 20 | 18 | 15 | 10 | 6 | 3 | 2 | 2 | 0 | | | | | | | |

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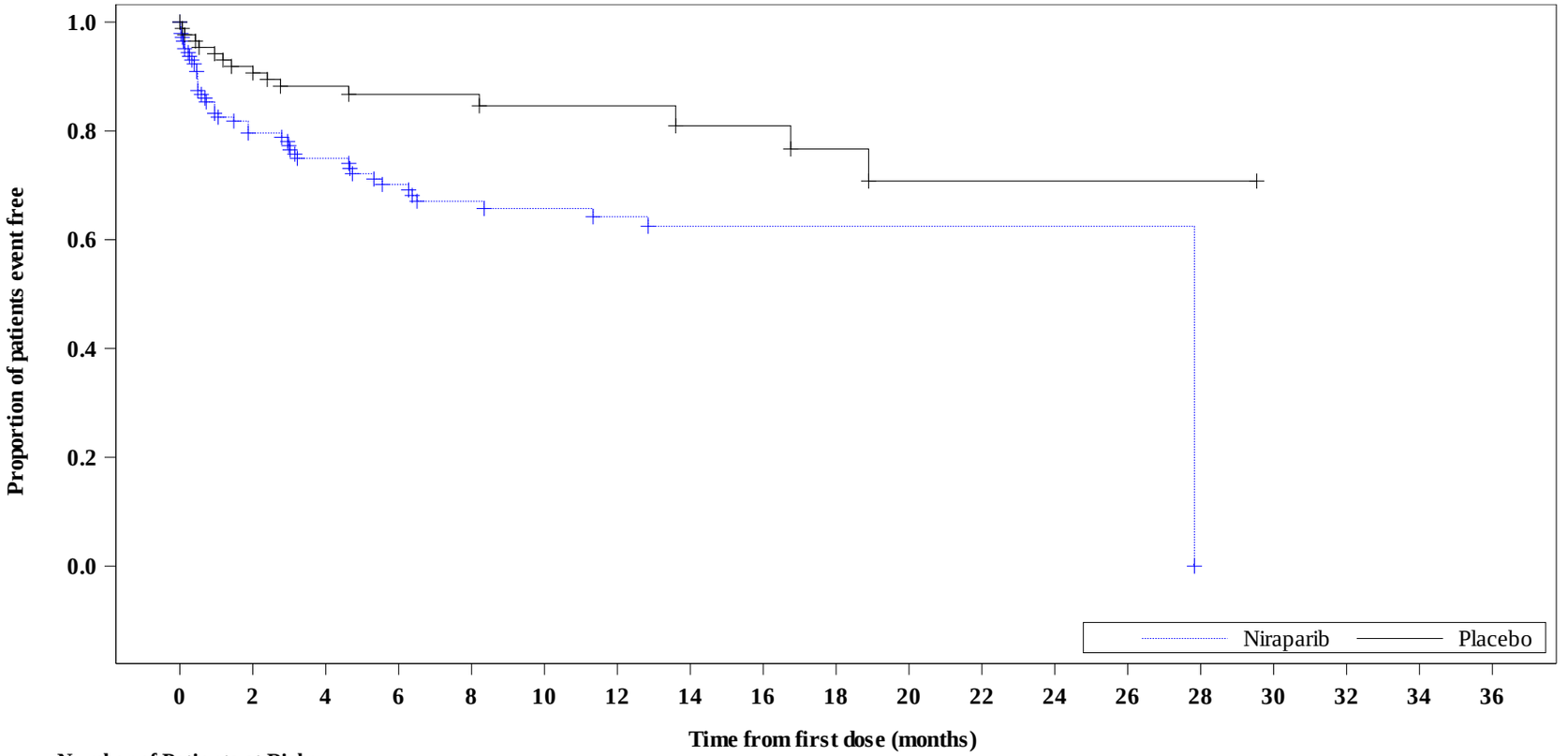
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Vascular disorders

BRCA Status: BRCAwt




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 106 | 83 | 70 | 50 | 45 | 40 | 33 | 26 | 24 | 14 | 5 | 2 | 1 | 0 | |
| Placebo | 86 | 77 | 61 | 53 | 43 | 26 | 25 | 22 | 20 | 15 | 10 | 5 | 2 | 2 | 1 | 0 |

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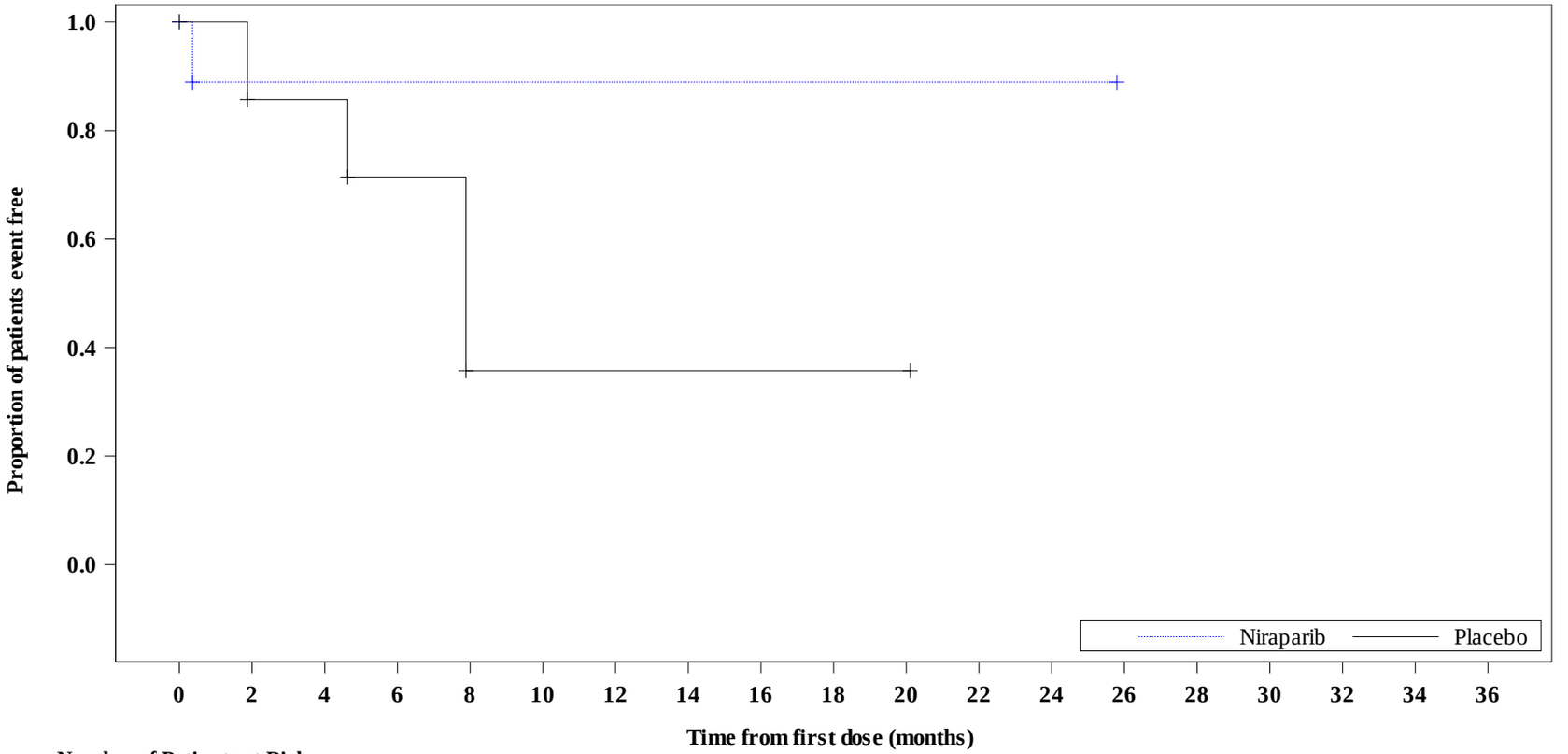
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Vascular disorders

BRCA Status: BRCAnd




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 7 | 6 | 6 | 5 | 3 | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 7 | 6 | 6 | 5 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | | |

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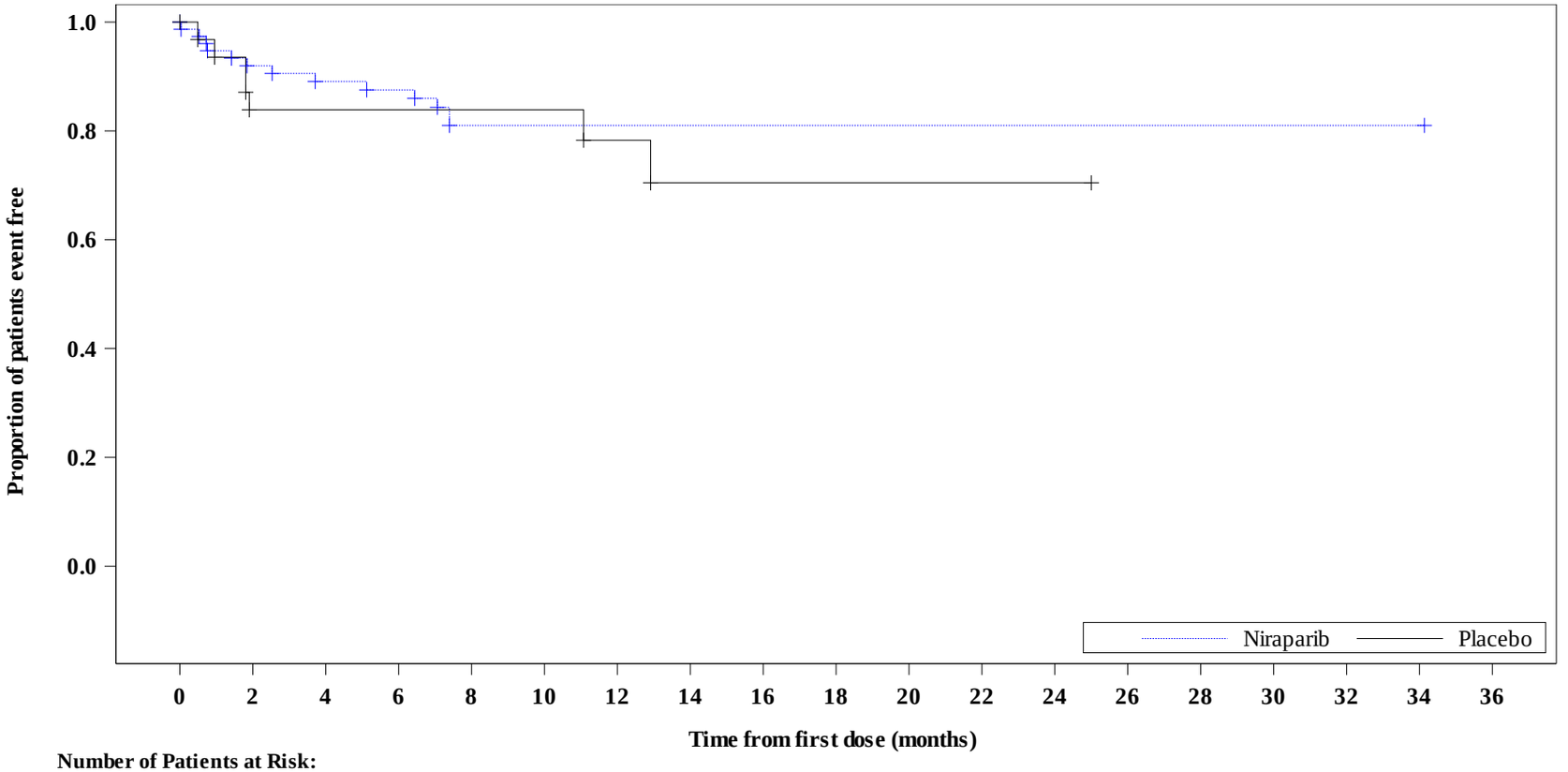
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Vascular disorders, PT: Hypertension

BRCA Status: BRCAmut




**Number of Patients at Risk:**

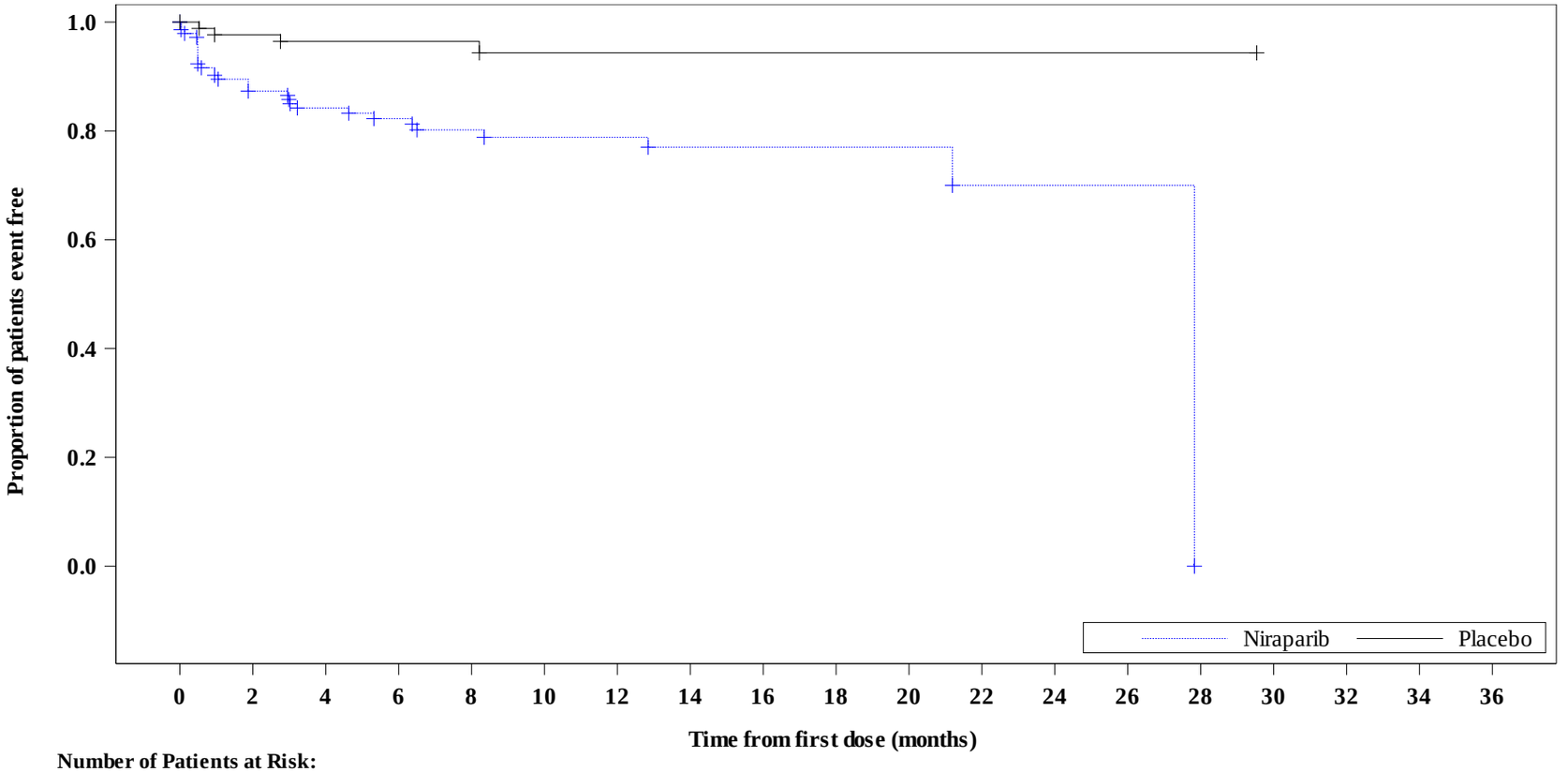
| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 65 | 58 | 56 | 48 | 46 | 45 | 42 | 38 | 27 | 17 | 9 | 5 | 5 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 31 | 26 | 24 | 22 | 20 | 18 | 13 | 7 | 4 | 3 | 3 | 1 | 1 | 0 | | | | | |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-18-teaeptb-g.sas 30SEP2020 08:56

Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Vascular disorders, PT: Hypertension

BRCA Status: BRCAwt




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 117 | 93 | 81 | 59 | 52 | 47 | 39 | 31 | 29 | 18 | 5 | 2 | 1 | 0 | |
| Placebo | 86 | 82 | 68 | 61 | 48 | 29 | 28 | 26 | 24 | 20 | 12 | 7 | 3 | 2 | 1 | 0 |

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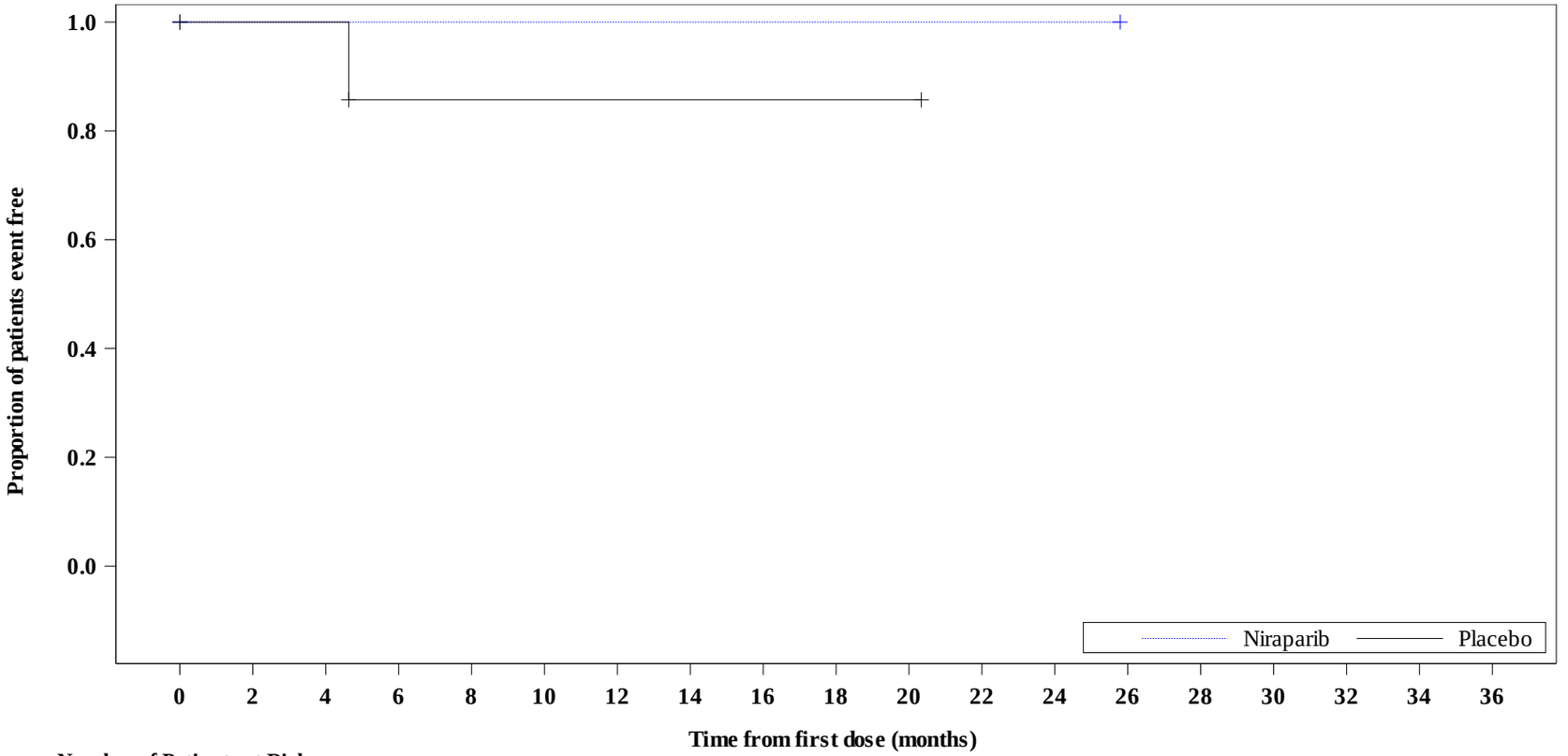
Figure 3.18
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and BRCA Status (Safety-GVD Population)

SOC: Vascular disorders, PT: Hypertension

BRCA Status: BRCAnd




**Number of Patients at Risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 8 | 7 | 7 | 6 | 4 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 7 | 7 | 7 | 6 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 0 | | |

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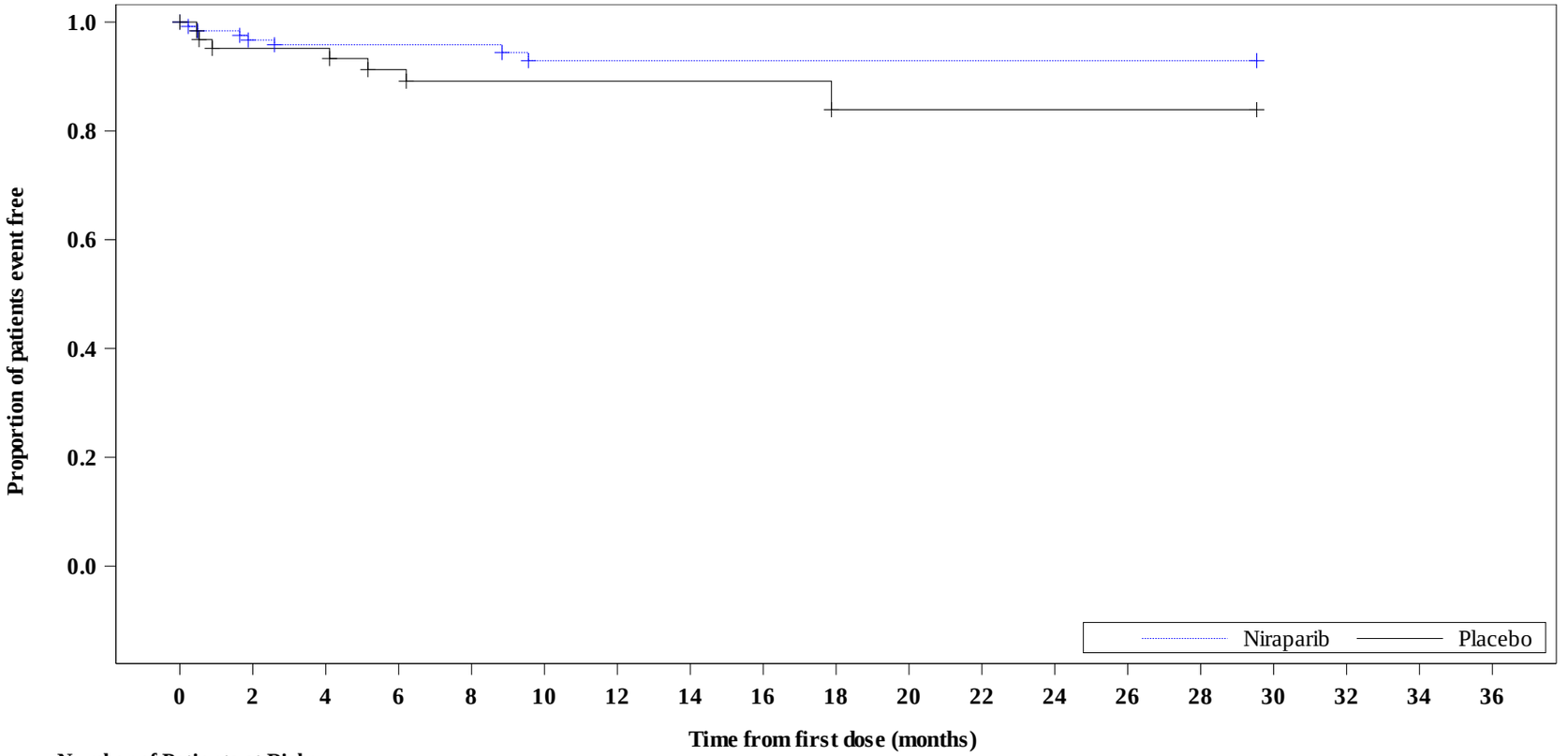
Figure 3.22
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Region (Safety-GVD Population)

SOC: Injury, poisoning and procedural complications

Region: Europe



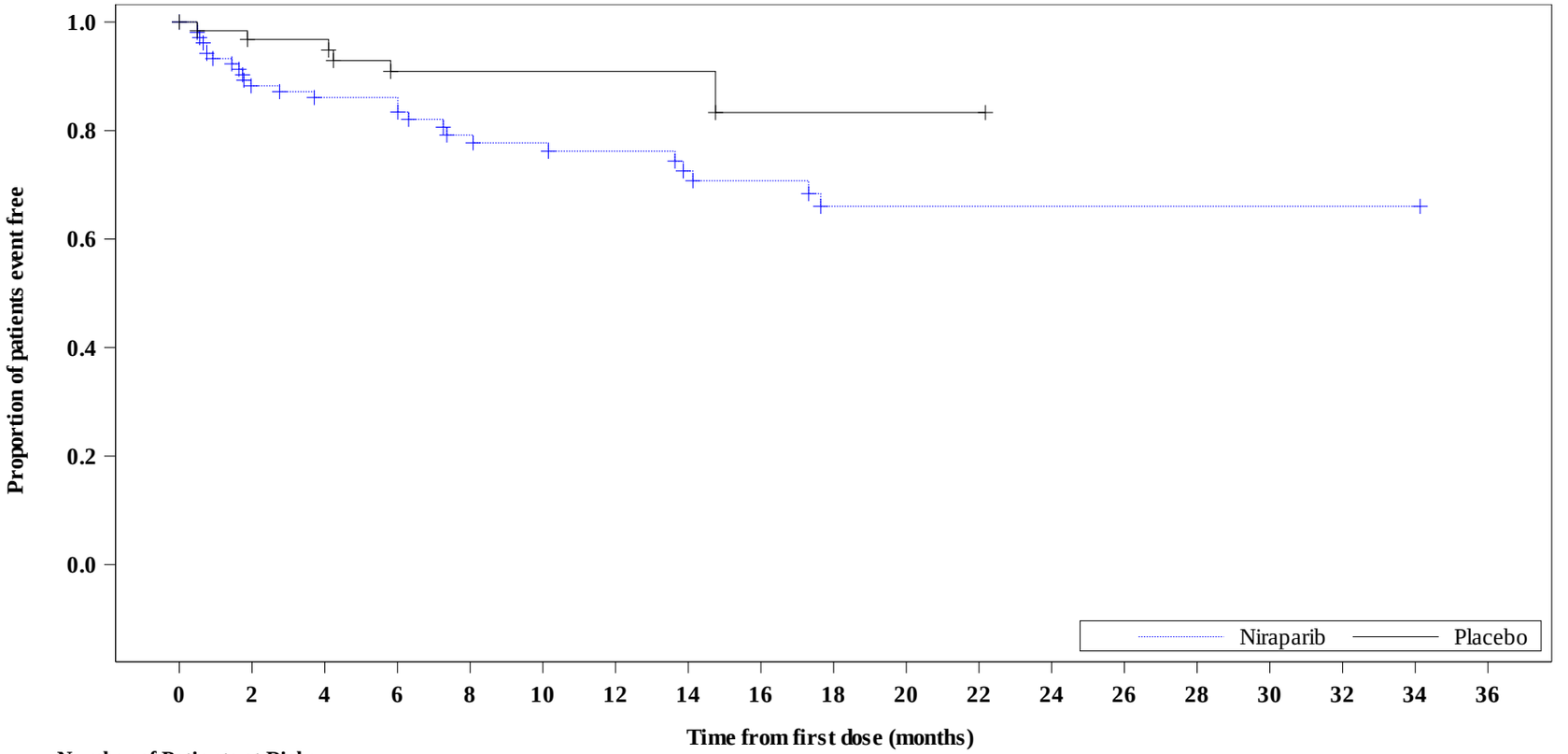

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 124 | 113 | 100 | 89 | 68 | 59 | 56 | 51 | 44 | 37 | 21 | 10 | 4 | 2 | 1 | 0 |
| Placebo | 62 | 58 | 52 | 44 | 34 | 26 | 26 | 24 | 21 | 16 | 9 | 3 | 2 | 2 | 1 | 0 |

Figure 3.22
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Region (Safety-GVD Population)

SOC: Injury, poisoning and procedural complications

Region: North America



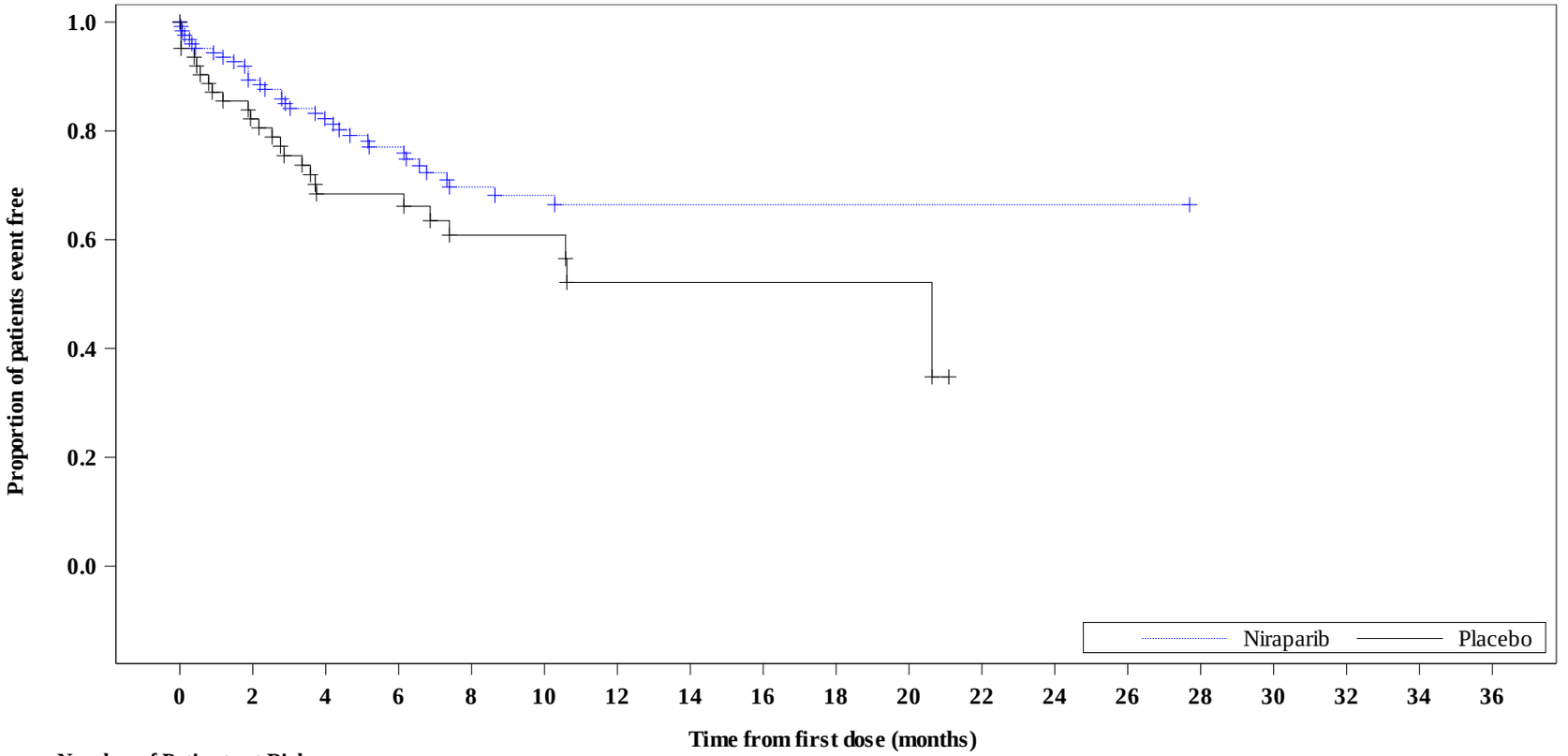

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 104 | 85 | 70 | 64 | 55 | 50 | 46 | 40 | 35 | 28 | 20 | 9 | 7 | 6 | 5 | 4 | 1 | 1 | 0 |
| Placebo | 62 | 59 | 50 | 45 | 37 | 24 | 18 | 13 | 9 | 8 | 7 | 2 | 0 | | | | | | |

Figure 3.22
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Region (Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders

Region: Europe



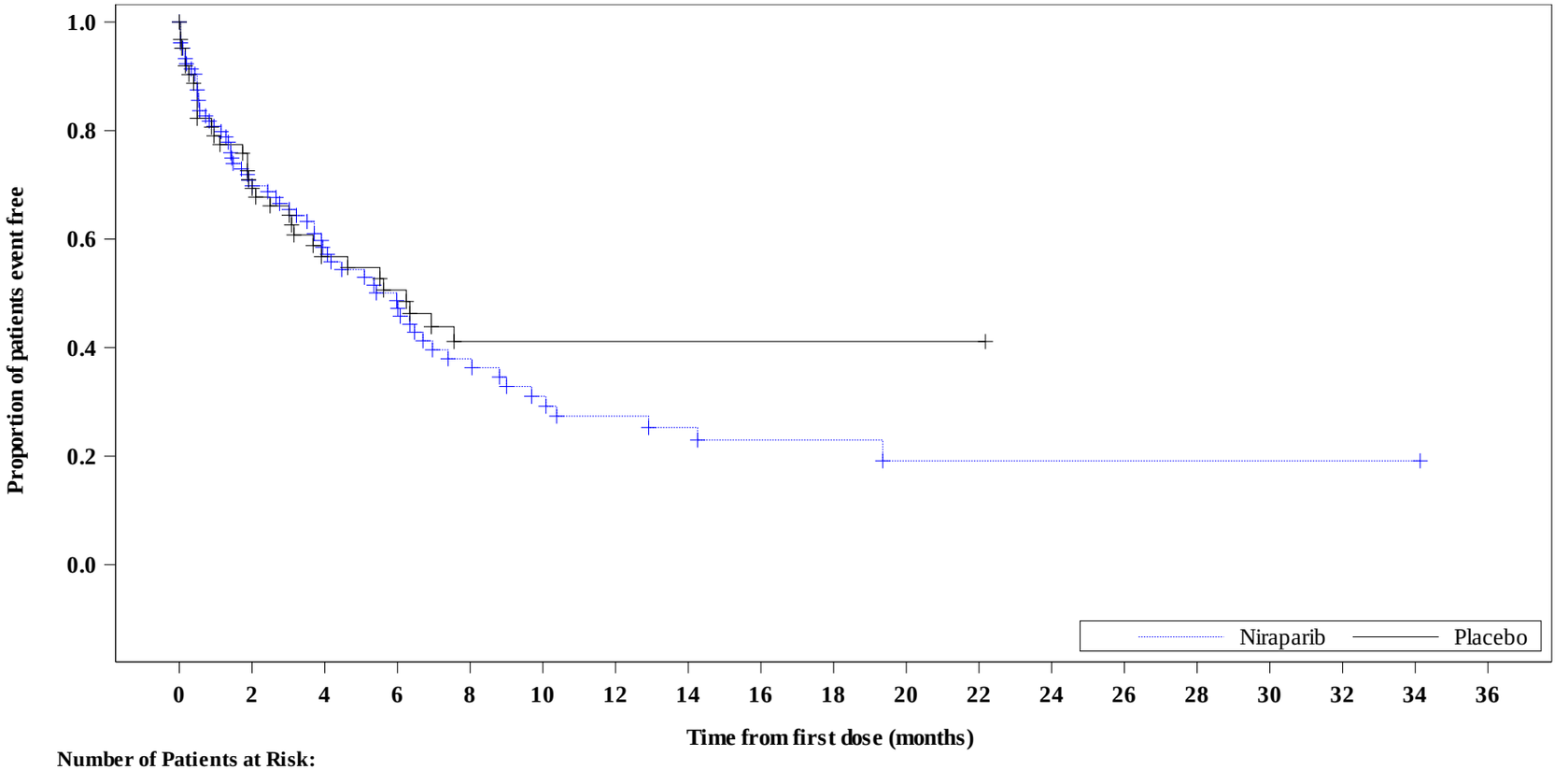

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 124 | 105 | 83 | 69 | 46 | 40 | 37 | 34 | 28 | 23 | 12 | 5 | 2 | 1 | 0 |
| Placebo | 62 | 50 | 37 | 31 | 21 | 15 | 12 | 12 | 11 | 8 | 5 | 0 | | | |

Figure 3.22
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Region (Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders

Region: North America




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 104 | 67 | 45 | 34 | 23 | 17 | 14 | 11 | 10 | 8 | 5 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 0 |
| Placebo | 62 | 44 | 28 | 24 | 15 | 8 | 7 | 3 | 3 | 2 | 2 | 1 | 0 | | | | | | |

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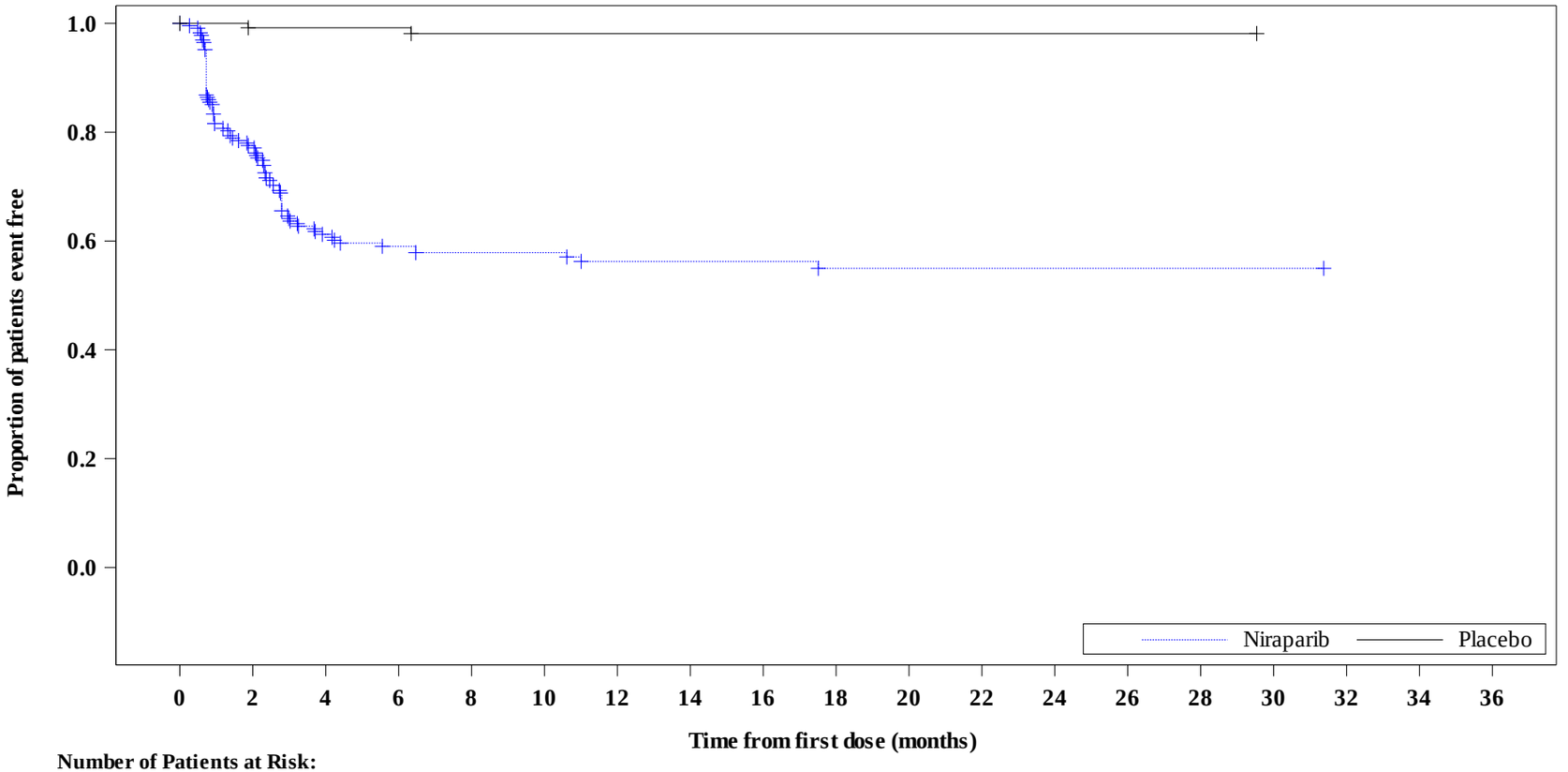
Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Blood and lymphatic system disorders

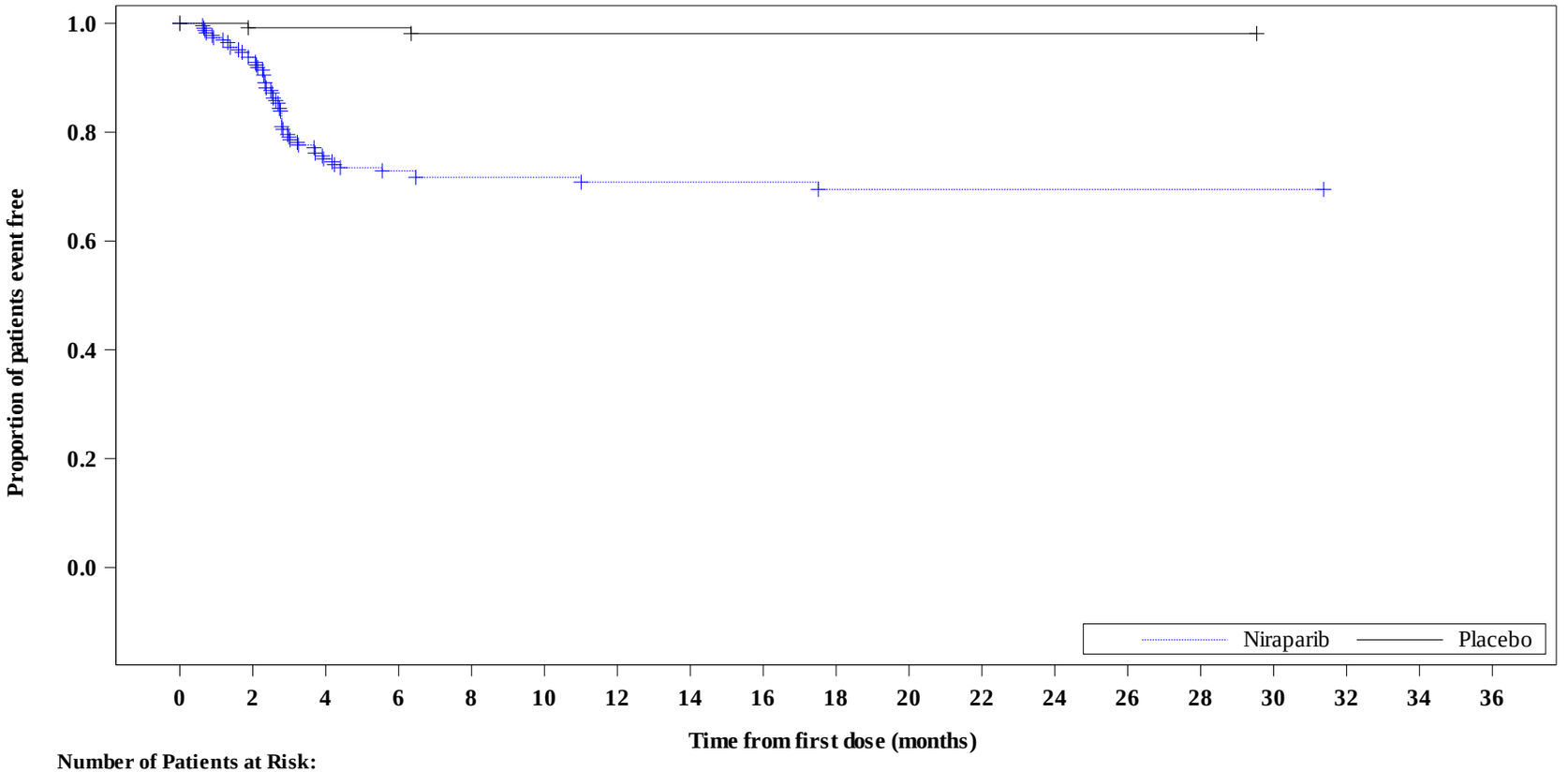



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 170 | 117 | 102 | 82 | 74 | 67 | 60 | 50 | 39 | 31 | 11 | 6 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia

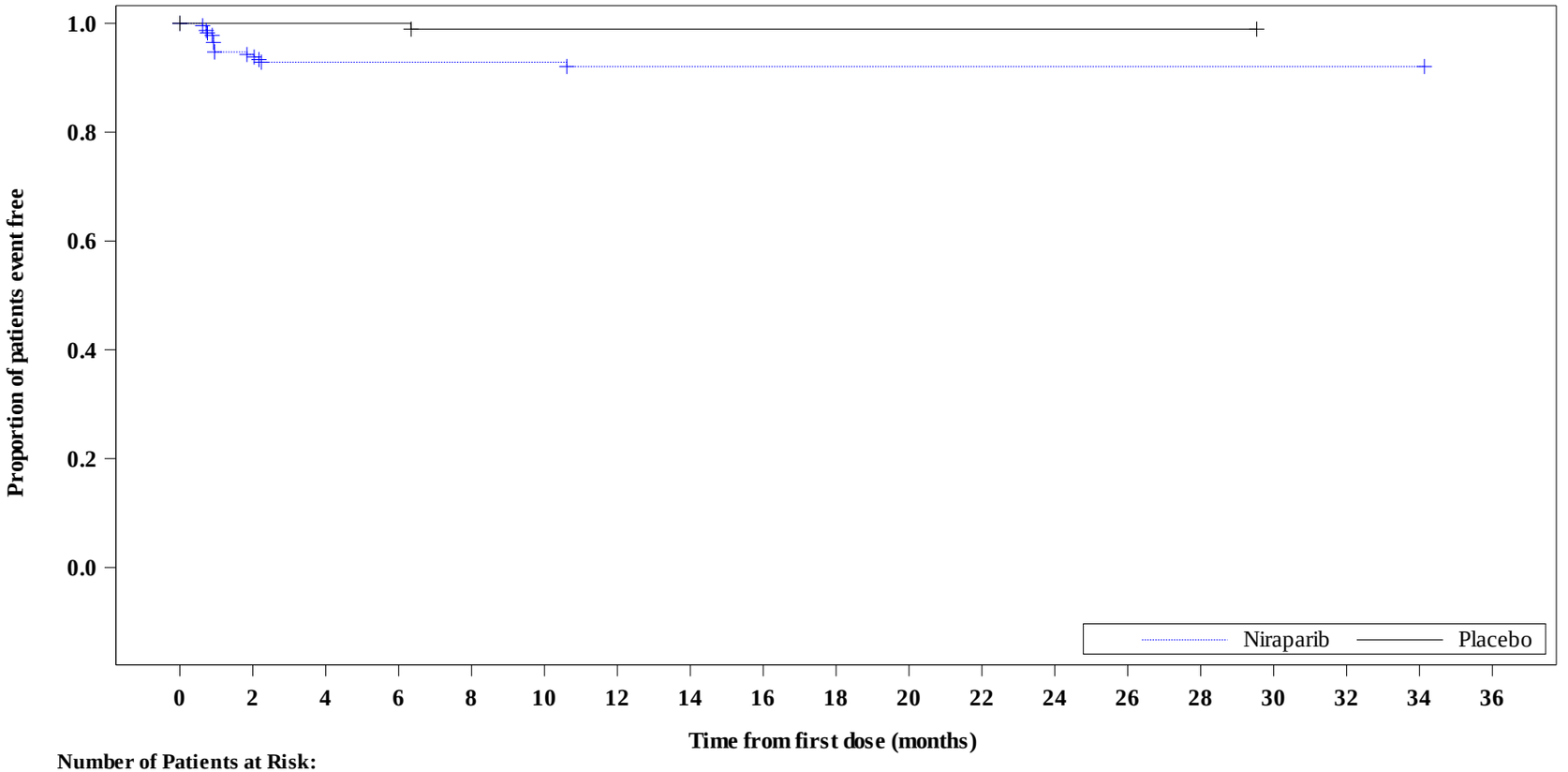



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 201 | 142 | 124 | 98 | 86 | 78 | 71 | 59 | 48 | 34 | 13 | 8 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Neutropenia

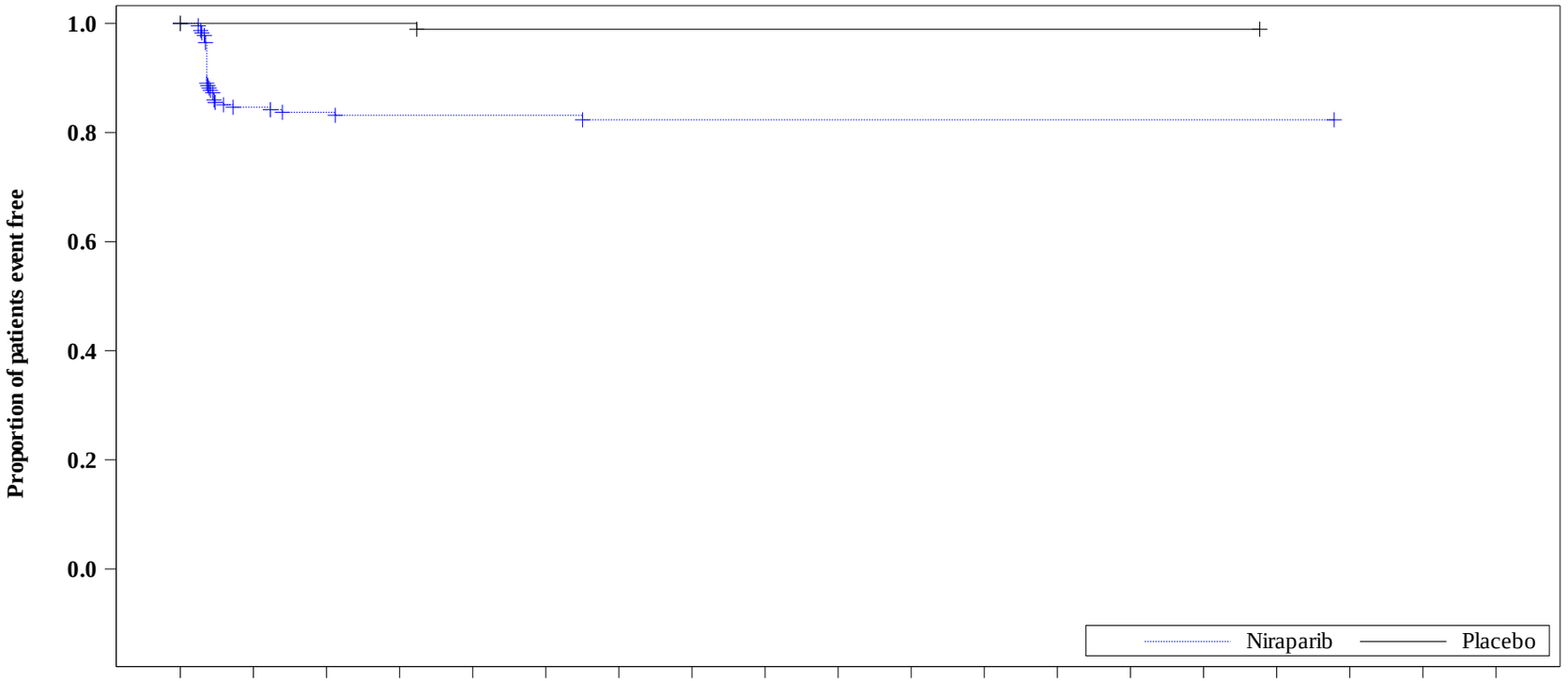



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 202 | 170 | 155 | 130 | 118 | 110 | 100 | 84 | 71 | 49 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia



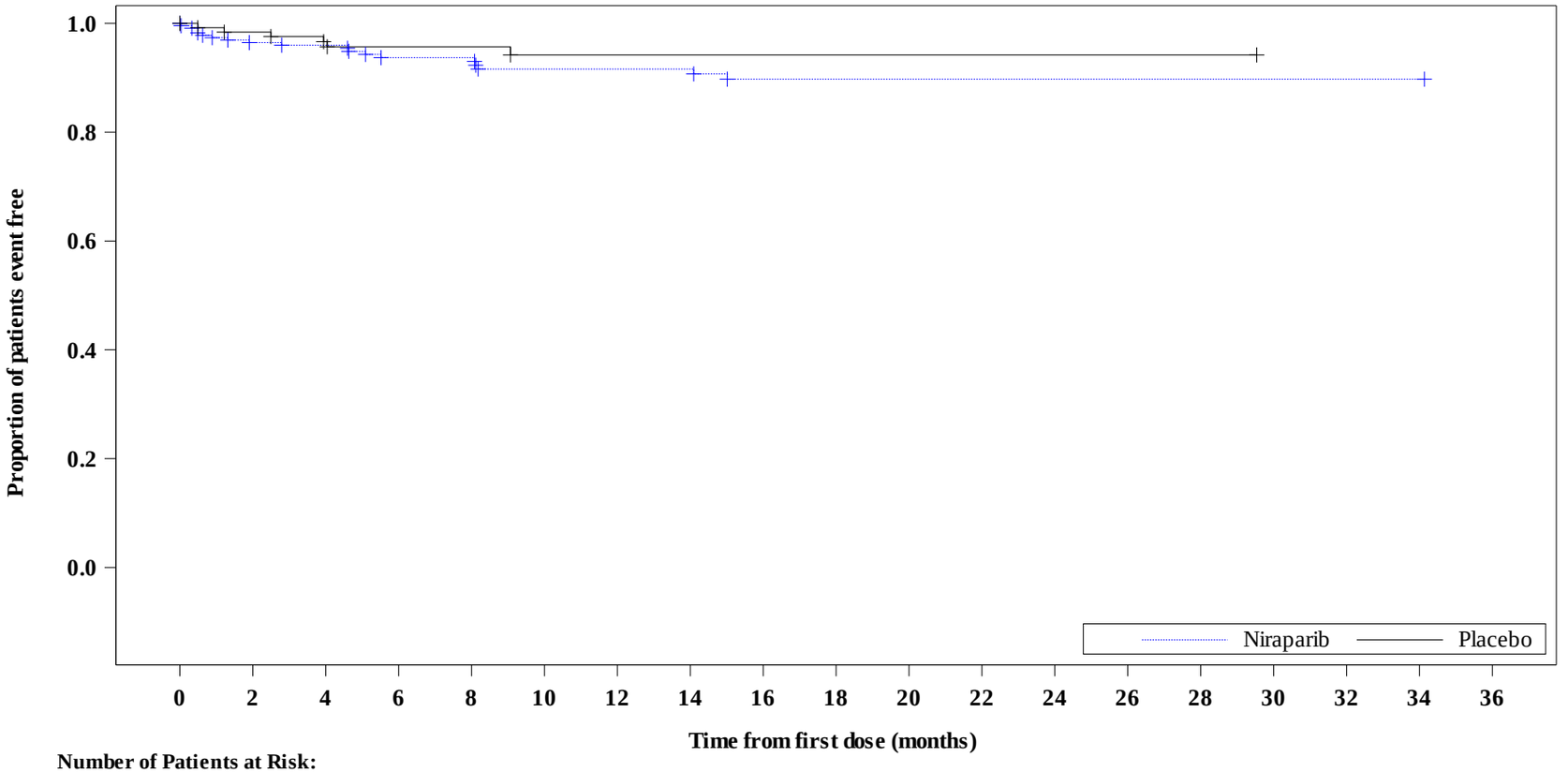

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 186 | 156 | 141 | 115 | 103 | 97 | 87 | 74 | 62 | 41 | 17 | 9 | 5 | 3 | 2 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-46-teaept-g.sas 30SEP2020 09:49

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Gastrointestinal disorders



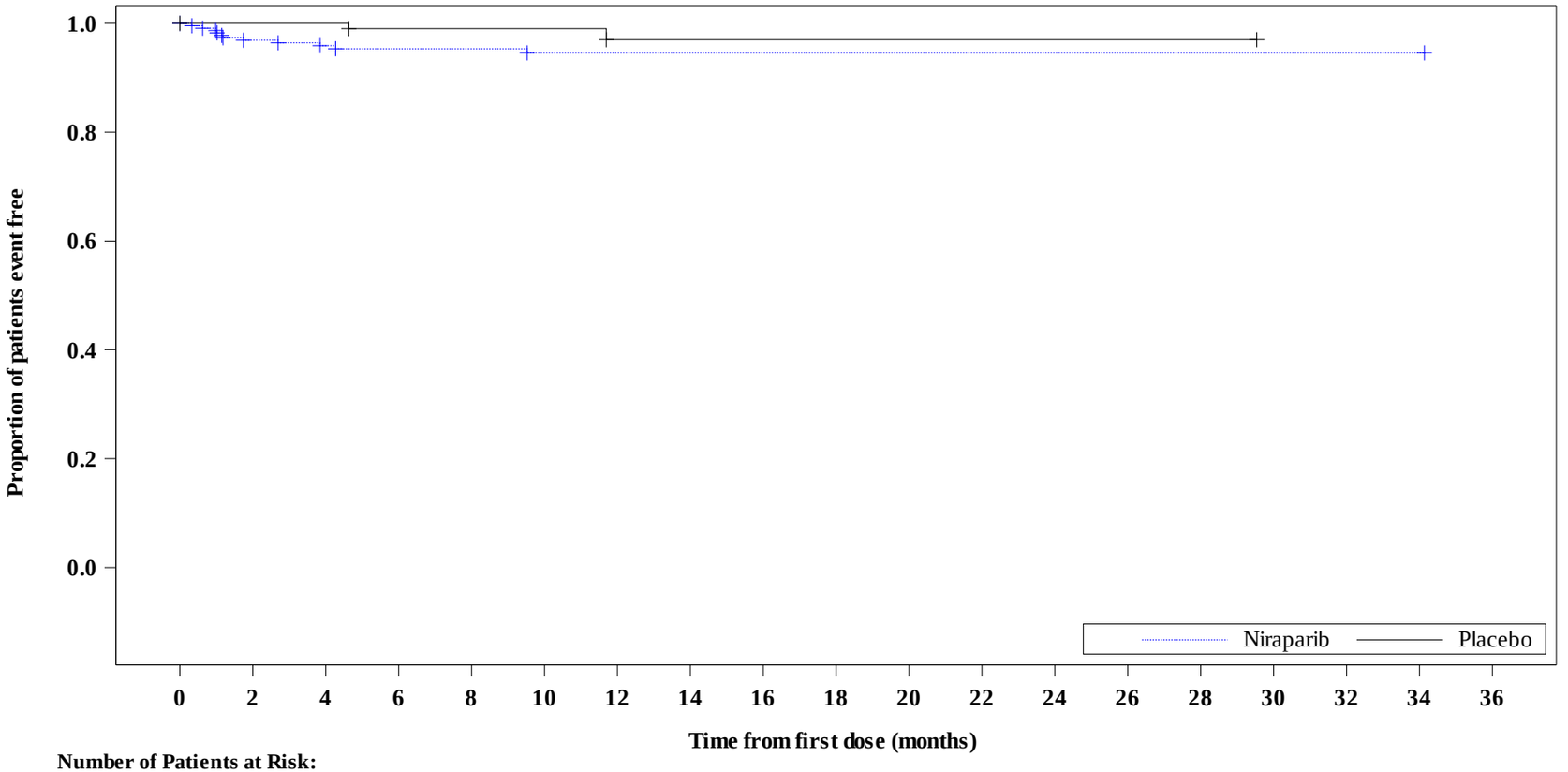

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 208 | 179 | 160 | 134 | 120 | 113 | 103 | 86 | 73 | 47 | 22 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 120 | 104 | 95 | 75 | 52 | 45 | 37 | 30 | 25 | 17 | 6 | 3 | 2 | 1 | 0 | | | |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-46-teaept-g.sas 30SEP2020 09:49

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: General disorders and administration site conditions

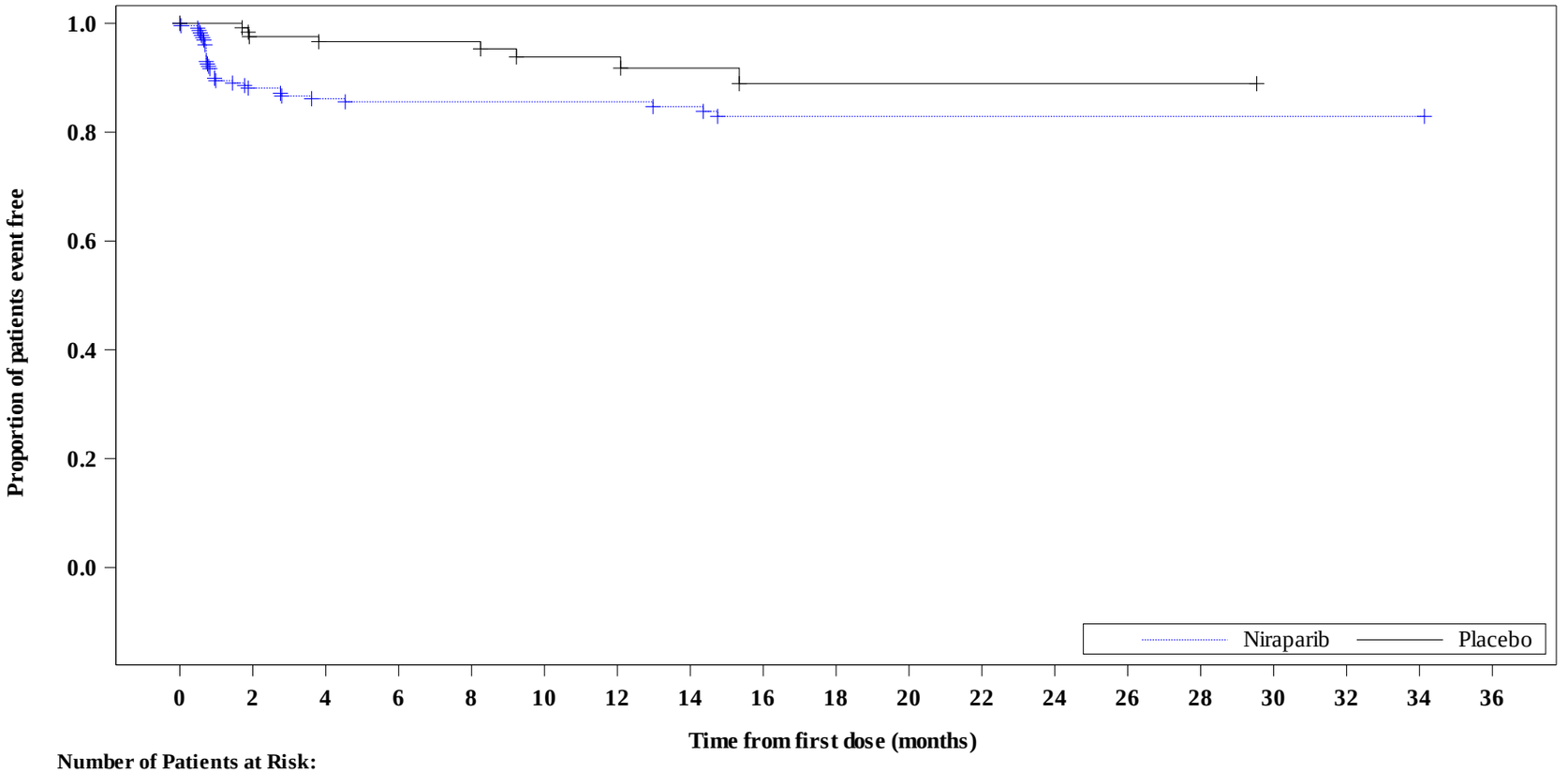



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 209 | 179 | 164 | 135 | 120 | 113 | 103 | 87 | 74 | 49 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 97 | 77 | 56 | 48 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Investigations

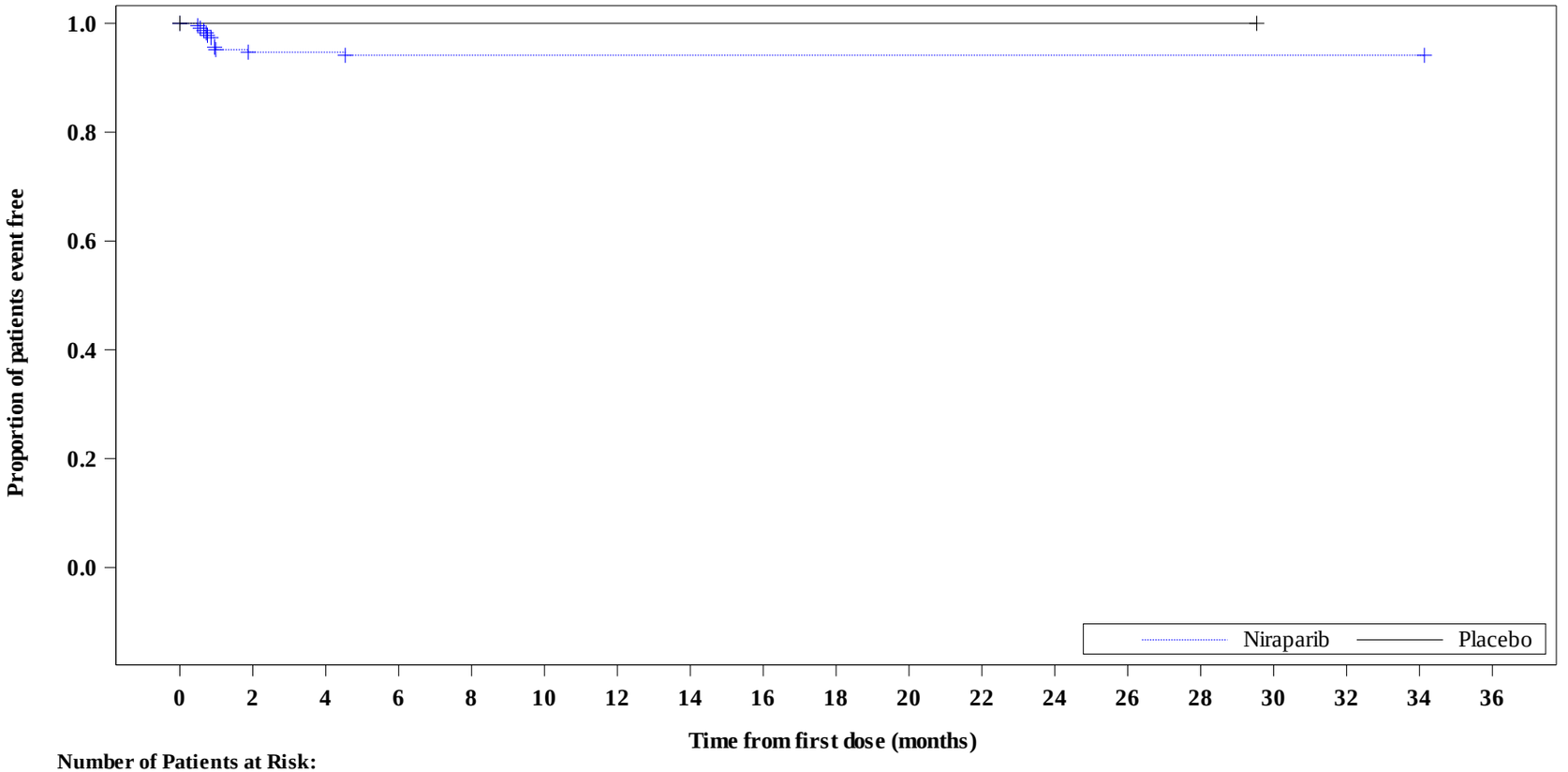



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 187 | 158 | 142 | 119 | 111 | 103 | 95 | 80 | 68 | 43 | 21 | 13 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 119 | 104 | 96 | 76 | 54 | 47 | 39 | 31 | 27 | 19 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Investigations, PT: Neutrophil count decreased

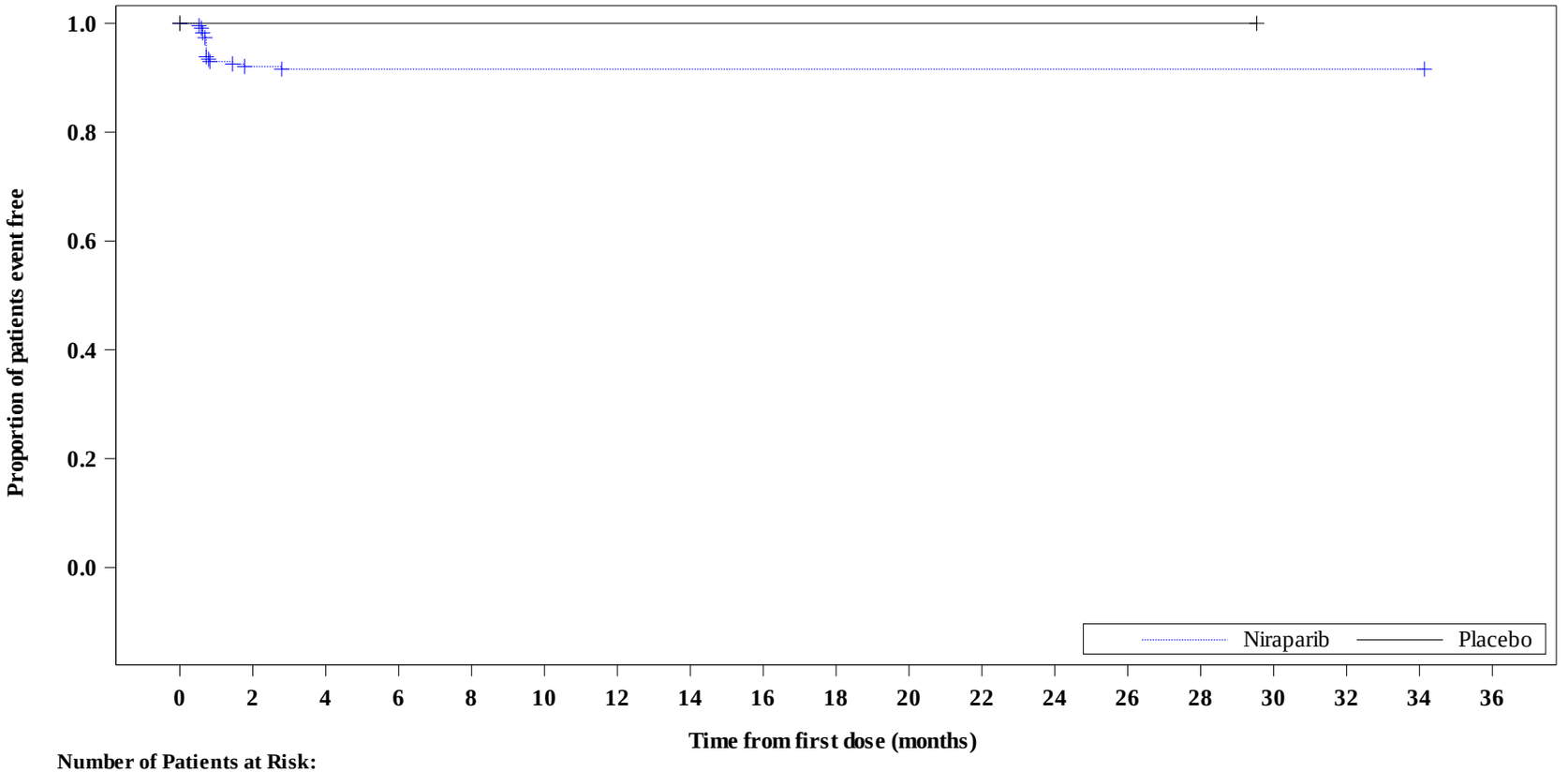



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 202 | 172 | 155 | 127 | 117 | 109 | 101 | 87 | 75 | 49 | 23 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Investigations, PT: Platelet count decreased

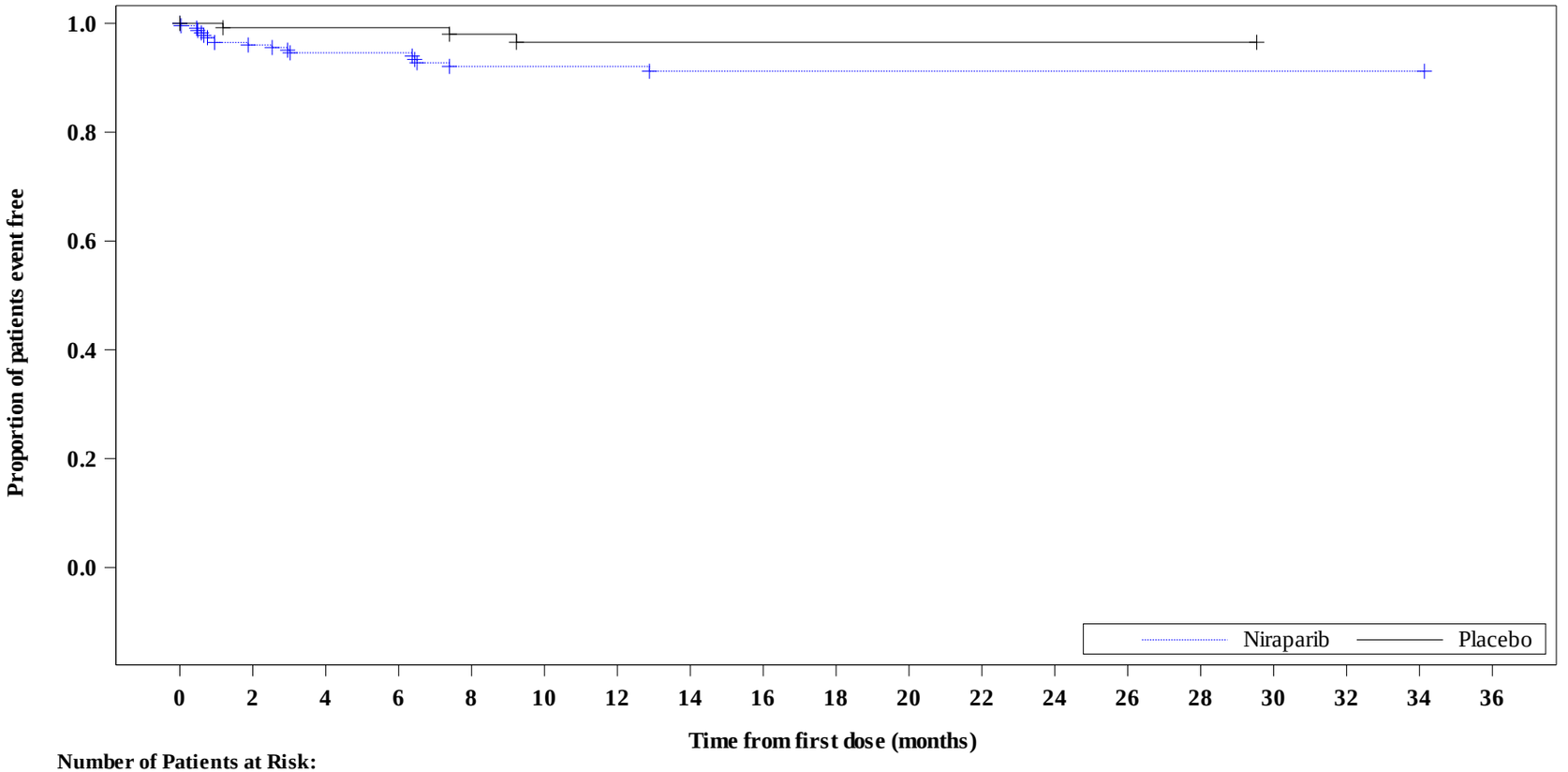



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 196 | 169 | 153 | 127 | 116 | 108 | 99 | 84 | 72 | 47 | 23 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Vascular disorders

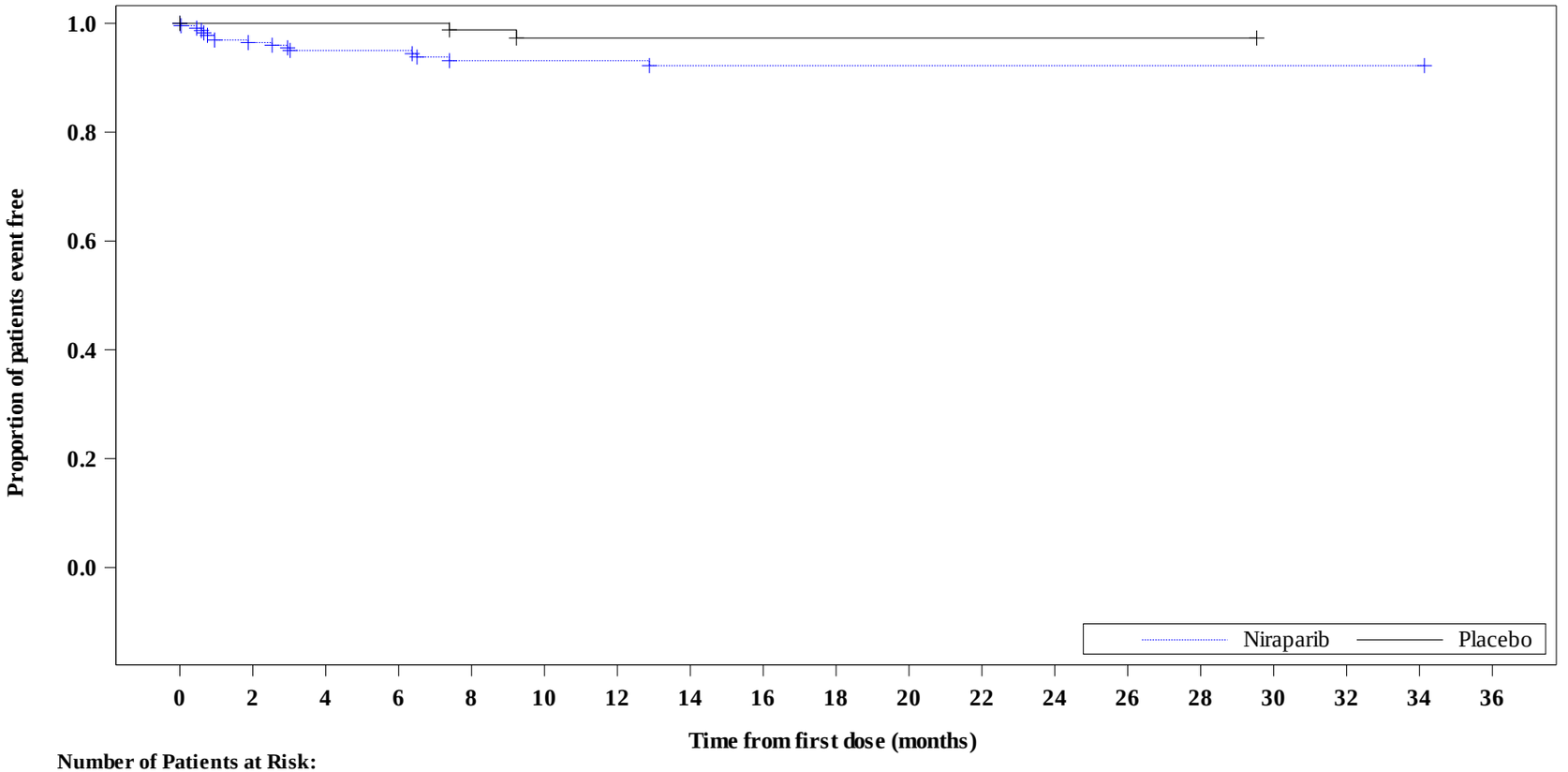



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 205 | 173 | 157 | 128 | 116 | 109 | 98 | 83 | 70 | 45 | 22 | 13 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 77 | 54 | 48 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.46
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Vascular disorders, PT: Hypertension

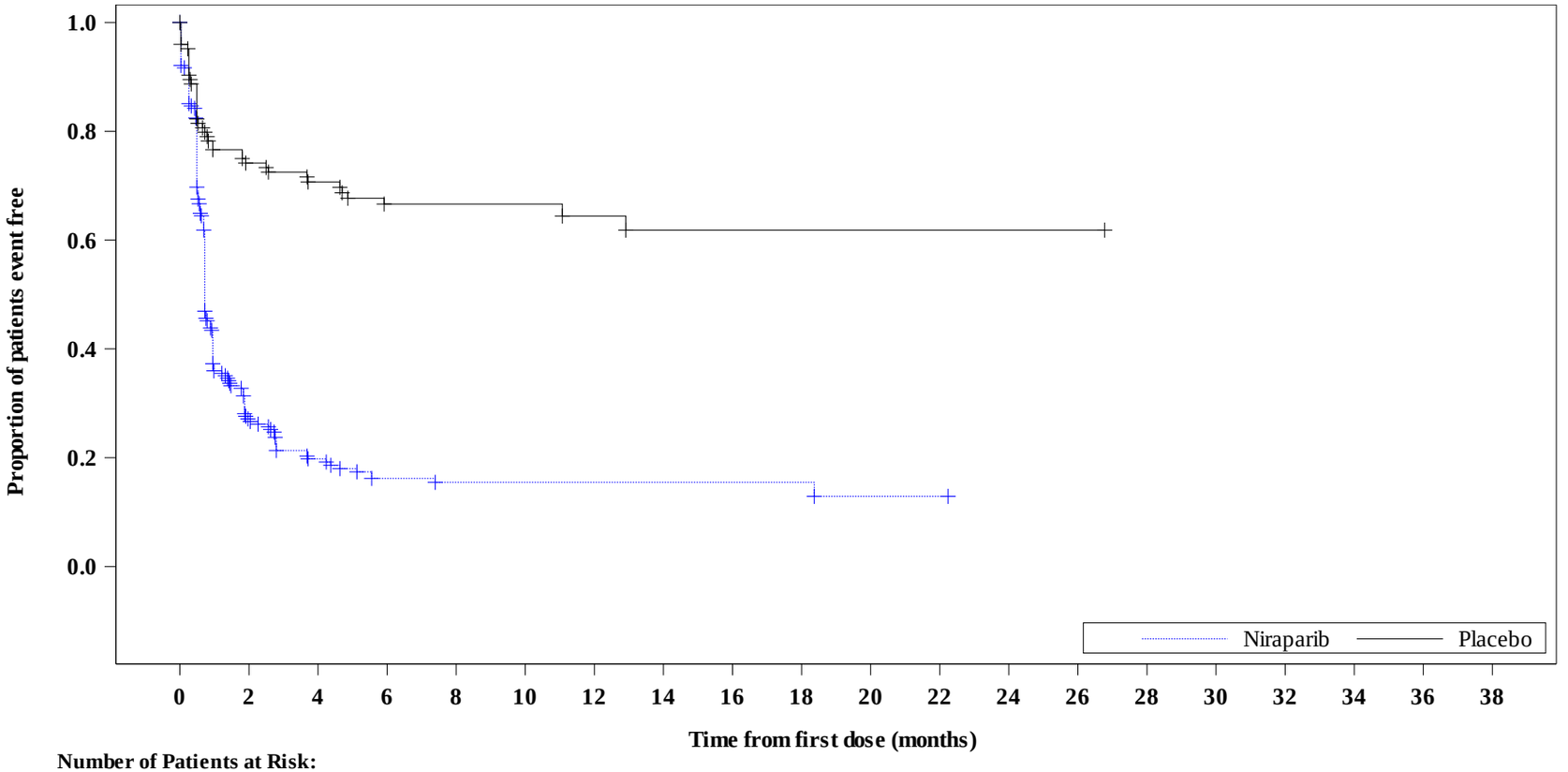



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 206 | 174 | 158 | 129 | 117 | 110 | 99 | 84 | 71 | 45 | 22 | 13 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 77 | 54 | 48 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Overall

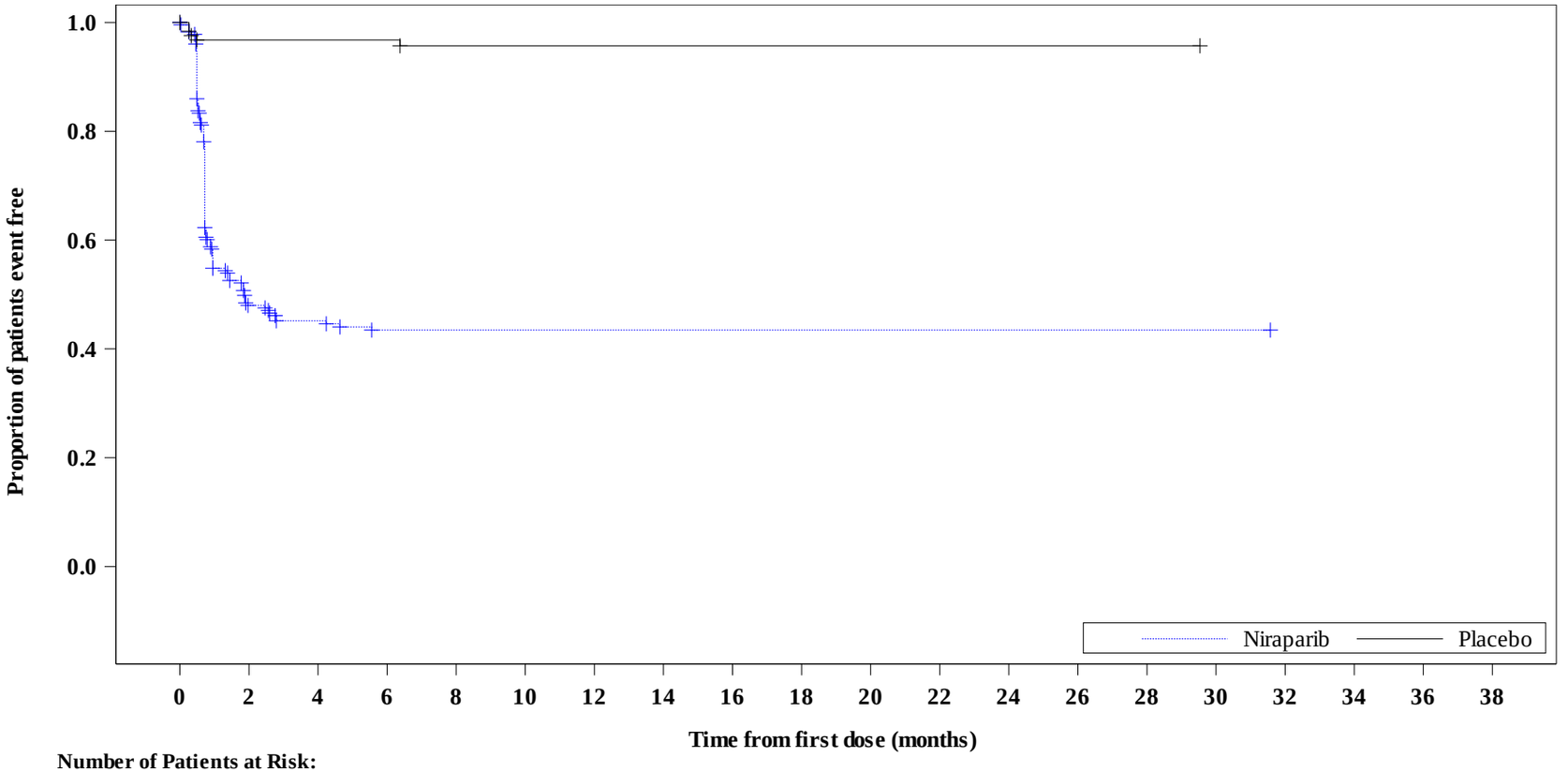



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 56 | 34 | 27 | 20 | 17 | 13 | 13 | 10 | 6 | 5 | 1 | 0 | | |
| Placebo | 124 | 90 | 76 | 63 | 51 | 35 | 29 | 22 | 19 | 17 | 10 | 6 | 3 | 1 | 0 |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Thrombocytopenia

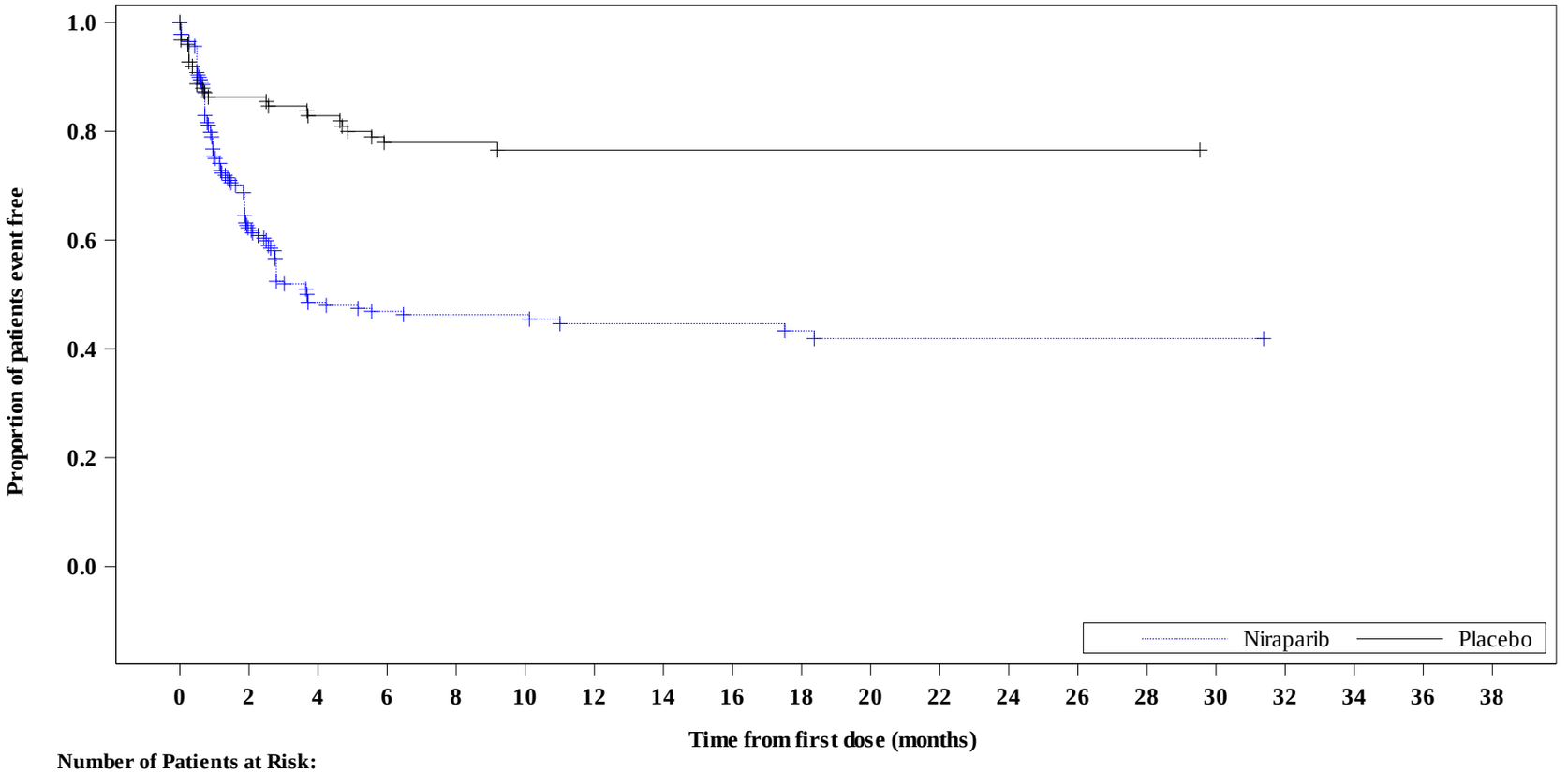



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 103 | 82 | 73 | 60 | 54 | 49 | 46 | 41 | 34 | 24 | 9 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 118 | 104 | 95 | 76 | 54 | 47 | 39 | 32 | 28 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Anemia

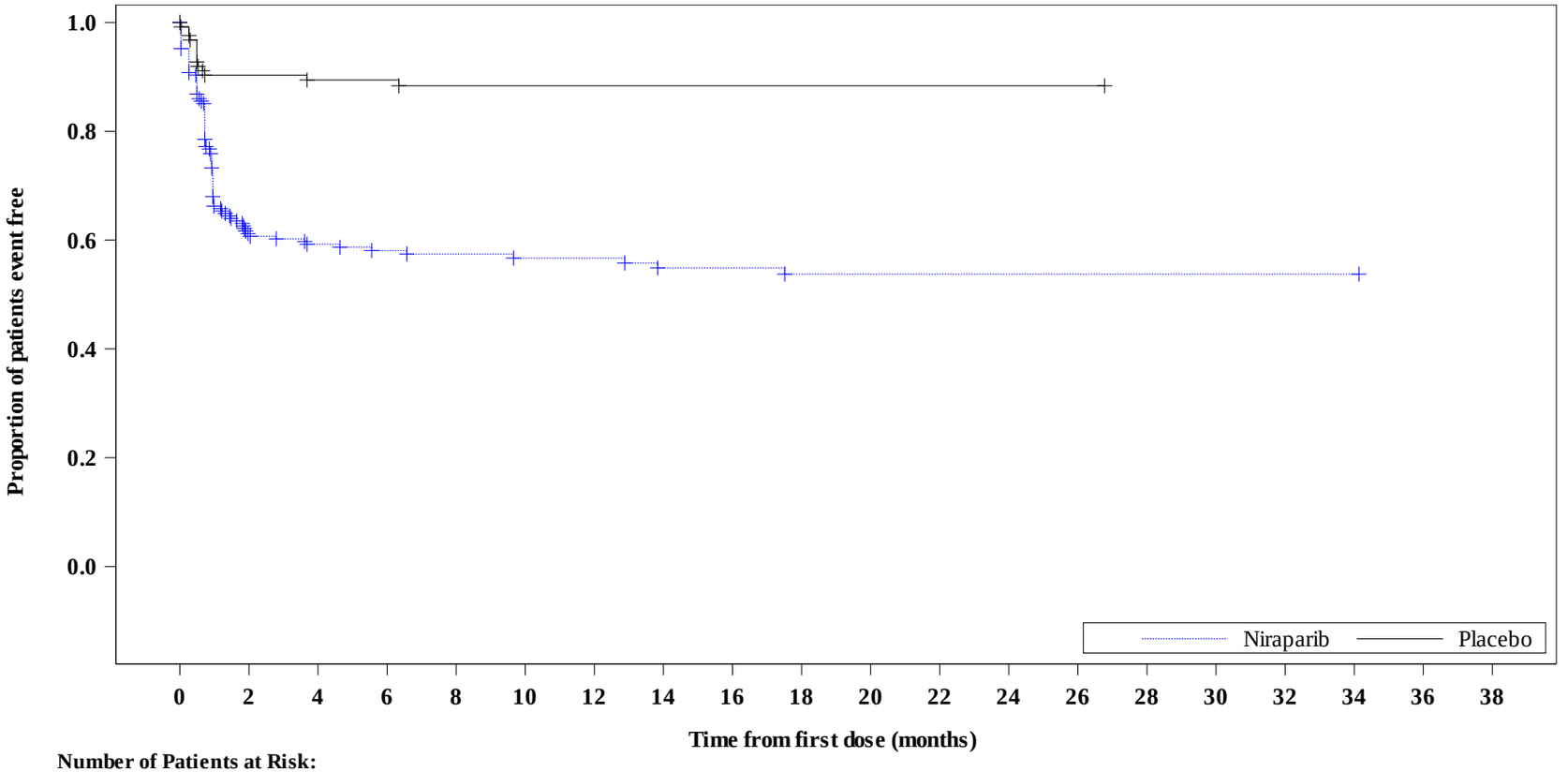



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 133 | 93 | 82 | 65 | 57 | 51 | 47 | 39 | 30 | 24 | 7 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 105 | 91 | 77 | 64 | 45 | 39 | 32 | 27 | 24 | 16 | 7 | 4 | 2 | 1 | 0 | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Leukopenia

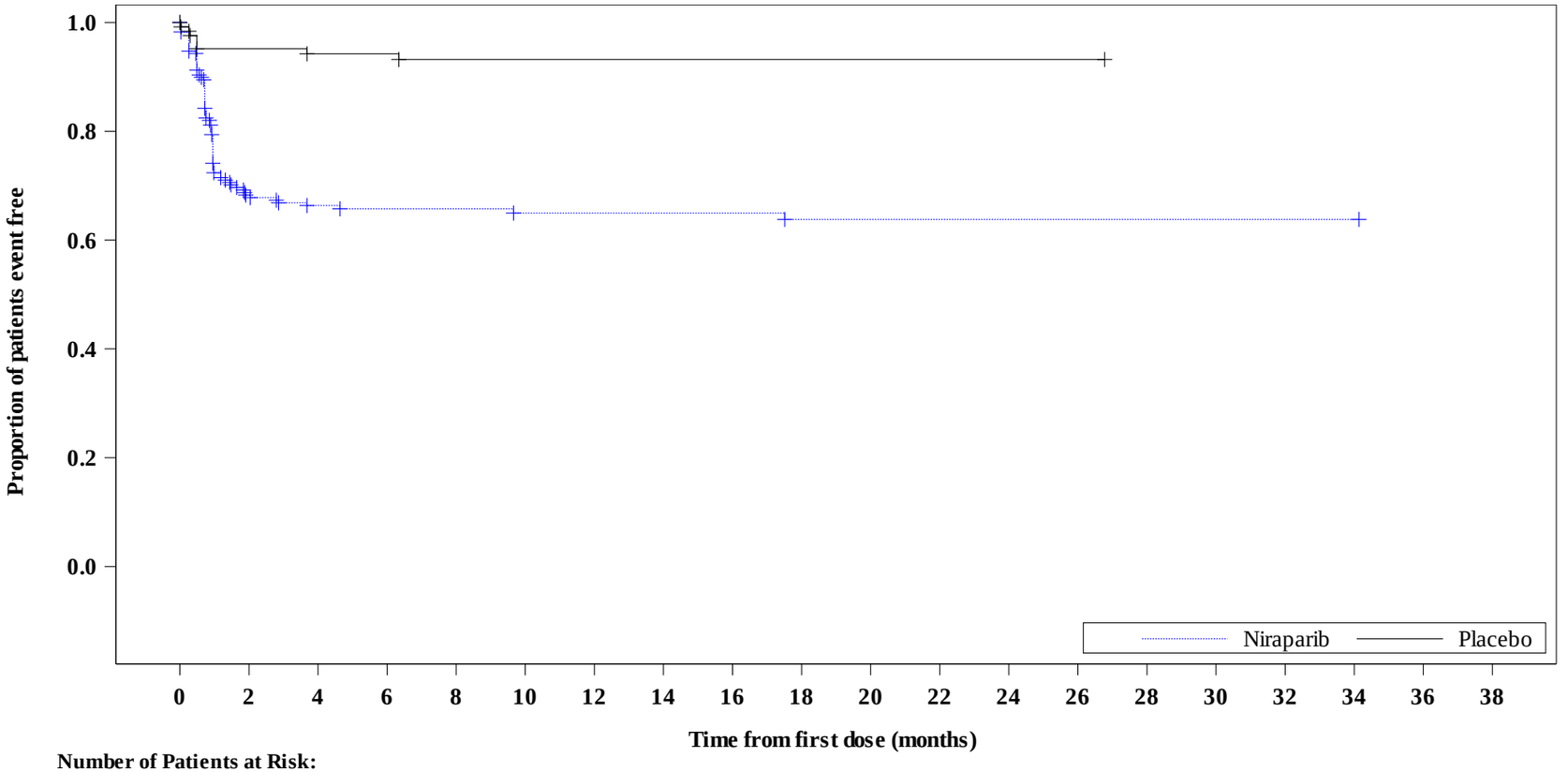



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 128 | 110 | 97 | 81 | 73 | 66 | 60 | 53 | 45 | 33 | 16 | 10 | 6 | 4 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 110 | 97 | 88 | 71 | 49 | 42 | 34 | 29 | 24 | 15 | 6 | 3 | 1 | 0 | | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Neutropenia

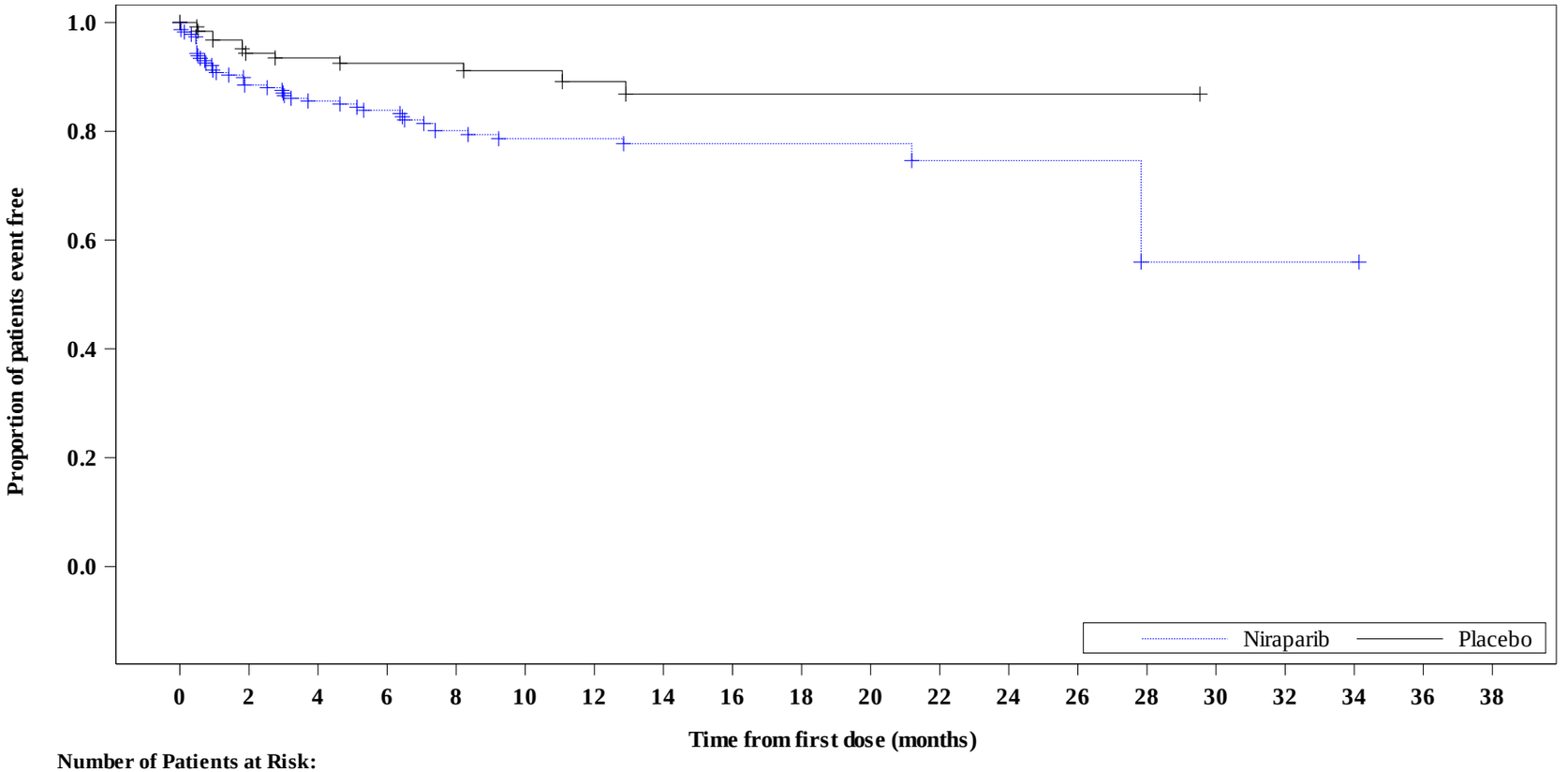



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 144 | 119 | 106 | 89 | 81 | 74 | 70 | 61 | 51 | 37 | 17 | 10 | 6 | 4 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 116 | 101 | 92 | 74 | 52 | 45 | 37 | 32 | 27 | 18 | 7 | 3 | 1 | 0 | | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Hypertension

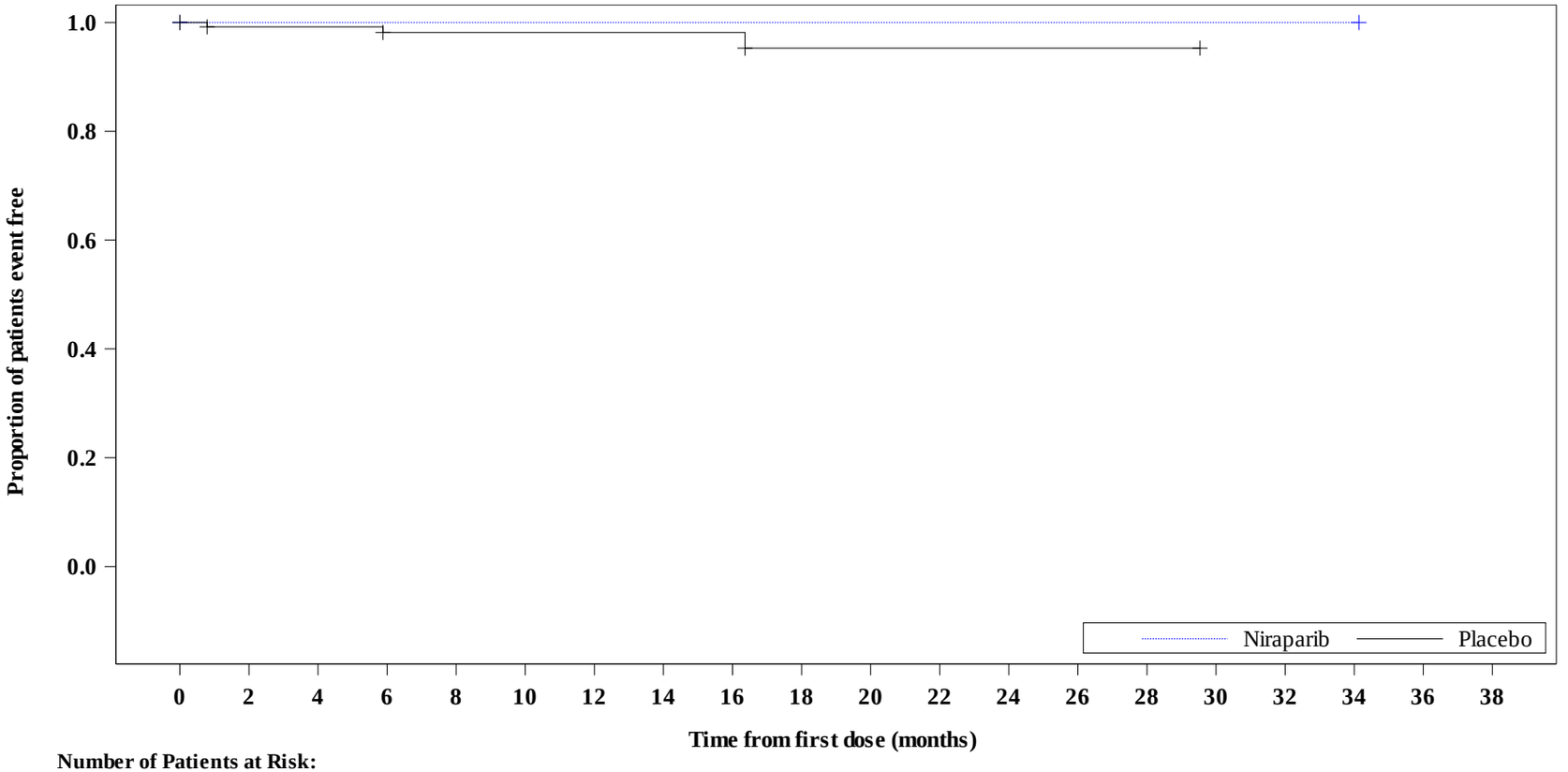



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 188 | 156 | 143 | 112 | 100 | 93 | 83 | 71 | 58 | 35 | 15 | 8 | 6 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 124 | 115 | 99 | 89 | 71 | 50 | 43 | 35 | 30 | 25 | 17 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

New malignancies other than MDS/AML

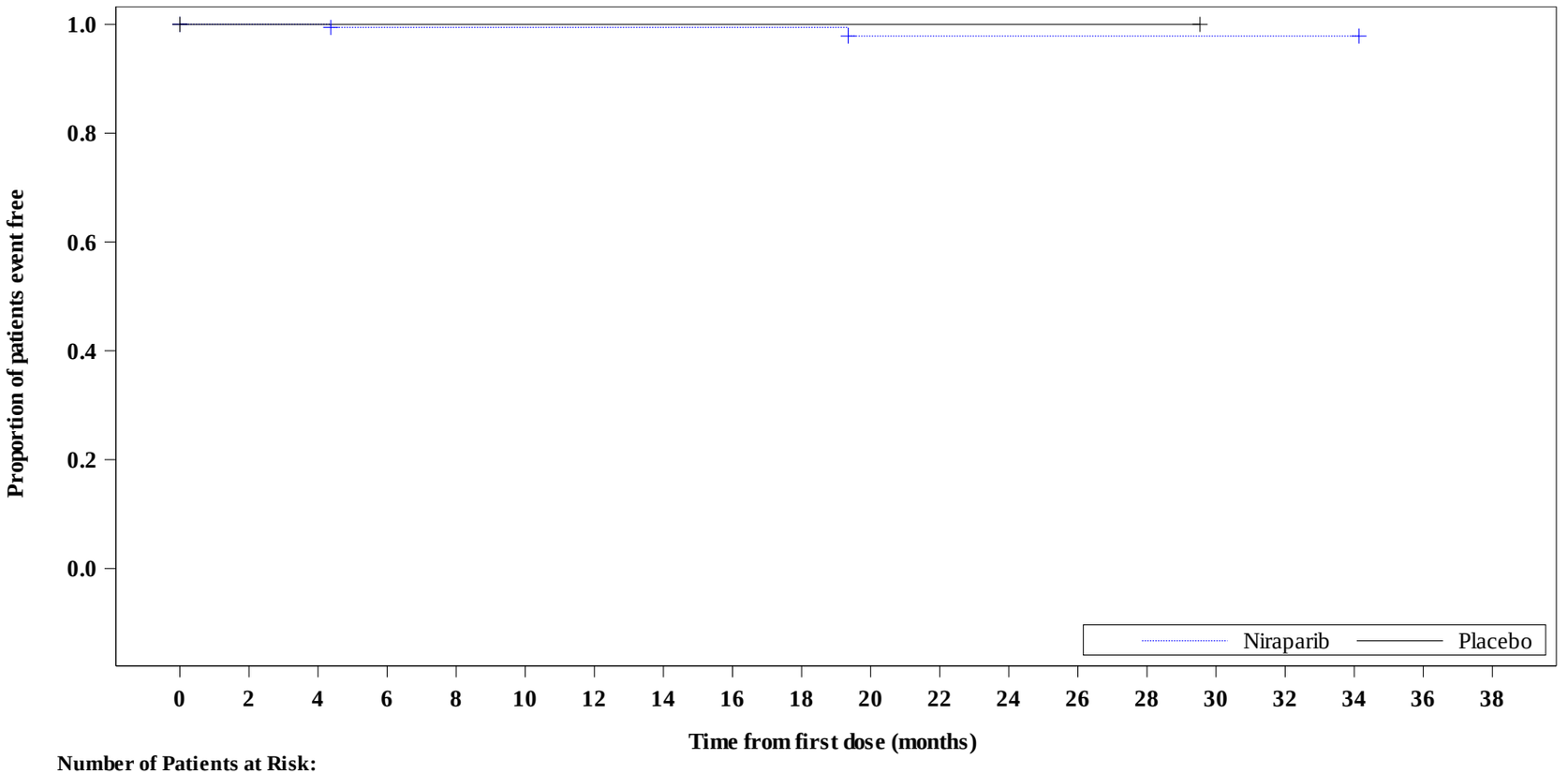



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 96 | 76 | 55 | 48 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Pneumonitis

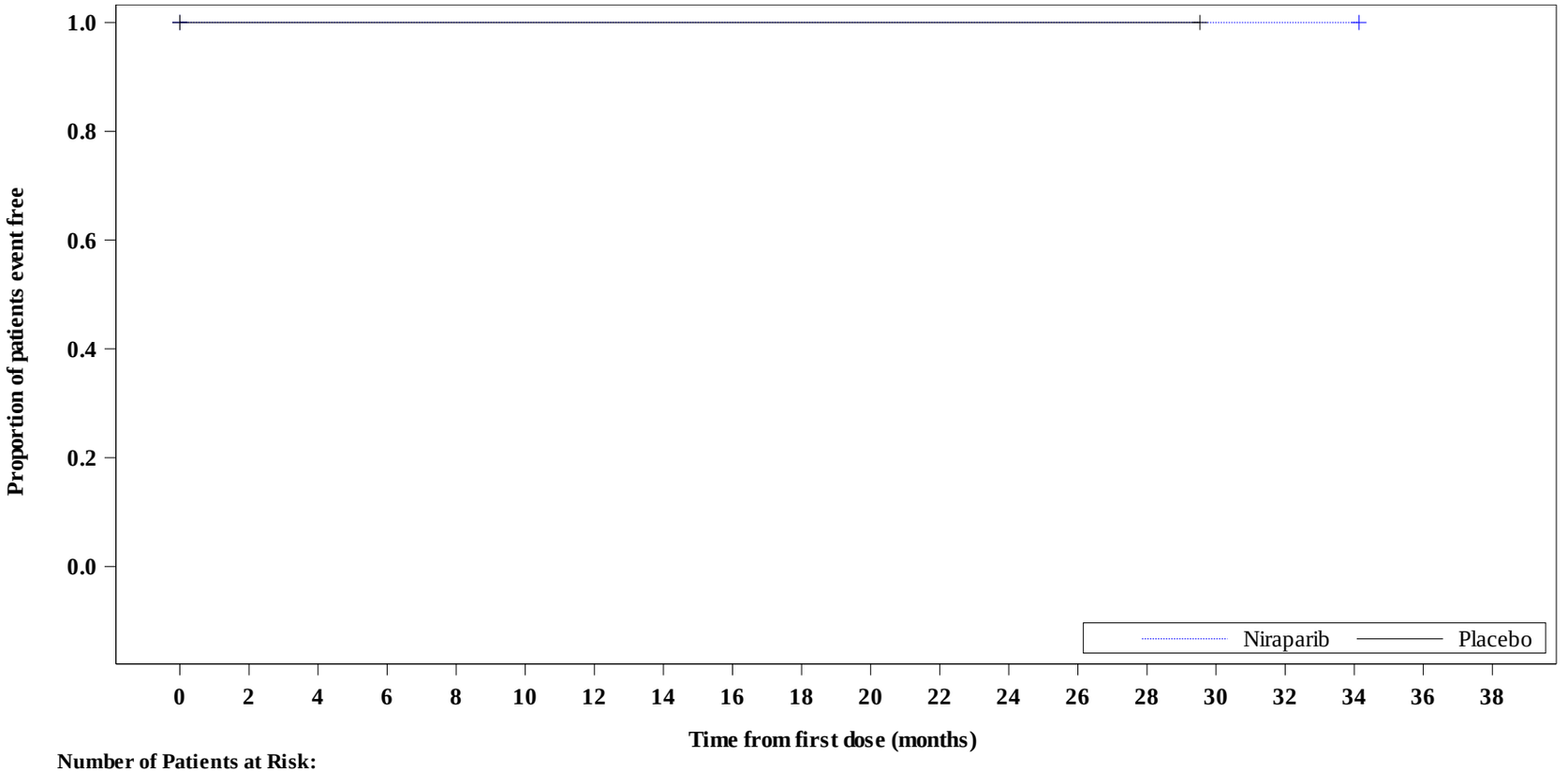



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 165 | 137 | 123 | 115 | 105 | 89 | 76 | 49 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Pancytopenia

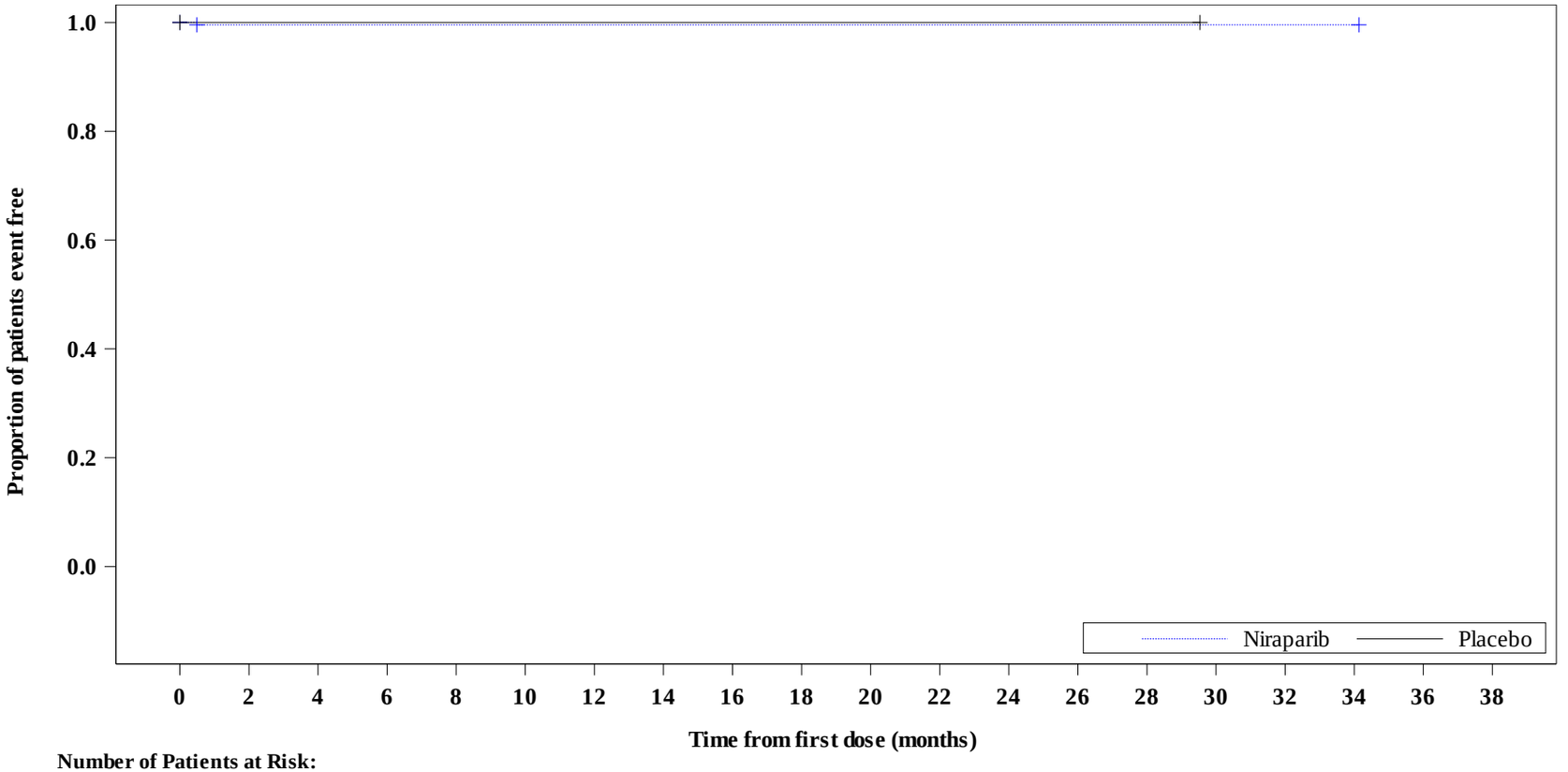



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Thromboemblic

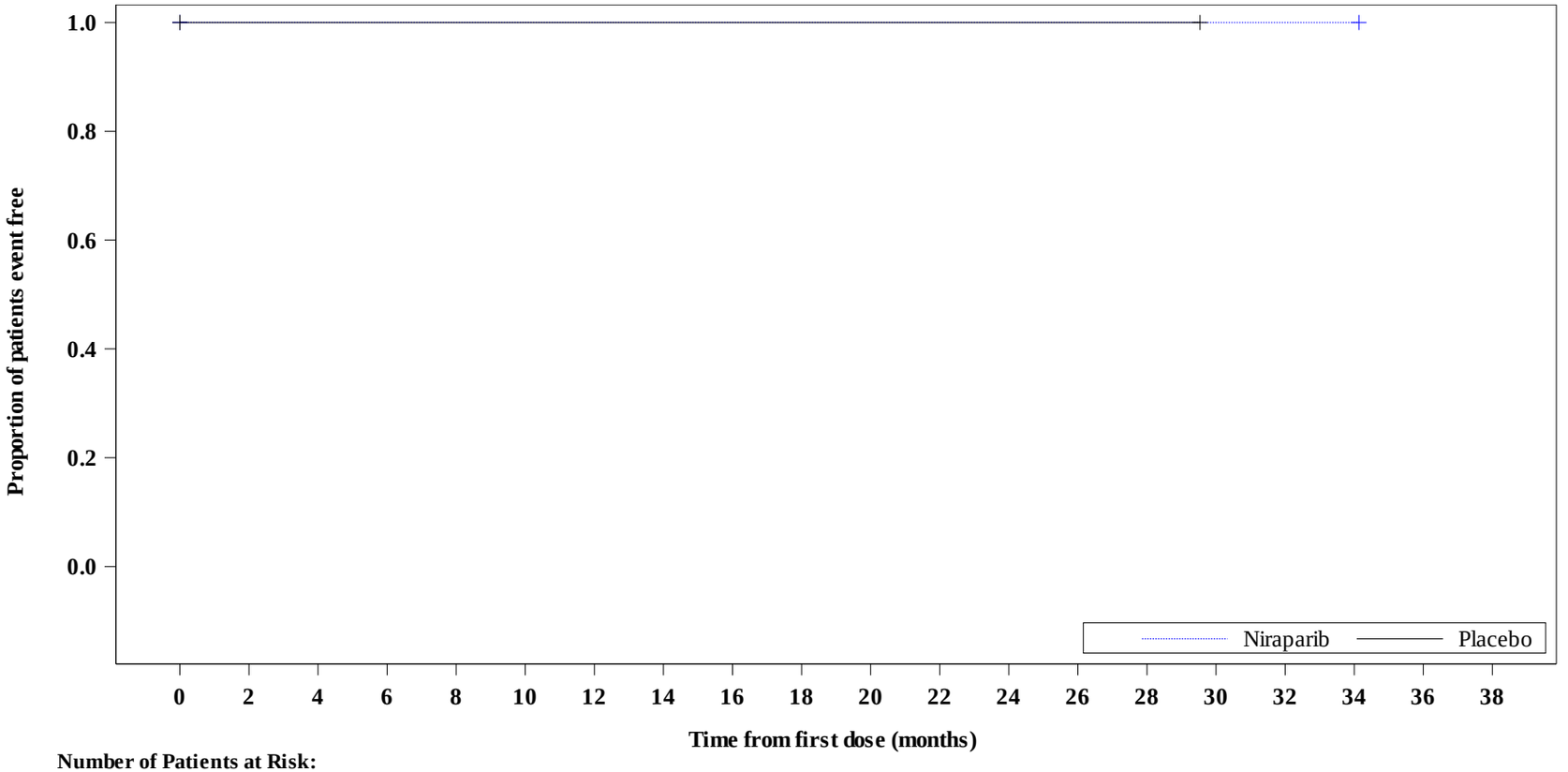



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 213 | 182 | 165 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

MDS/AML

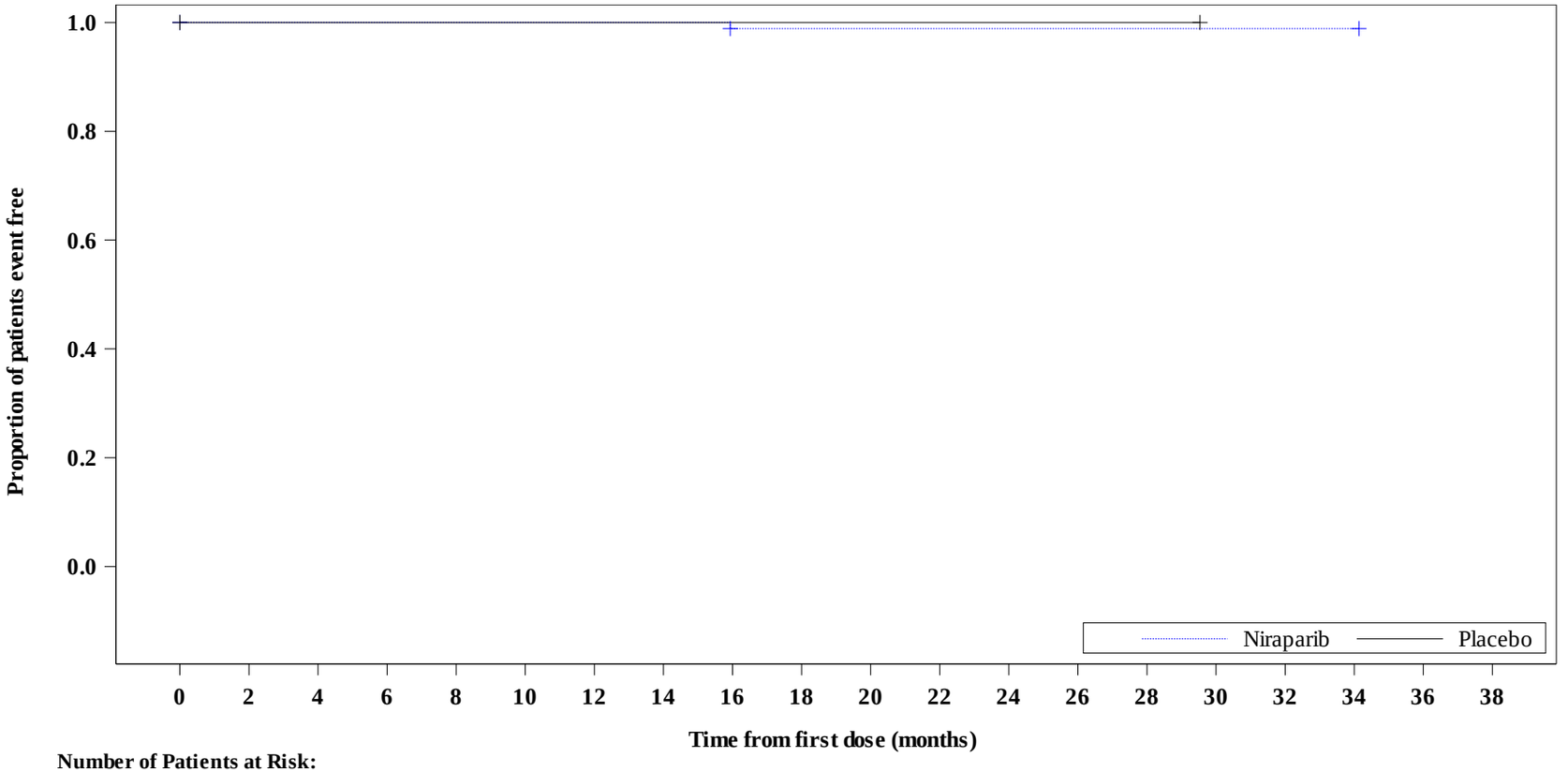



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.56
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Embryo-fetal toxicity

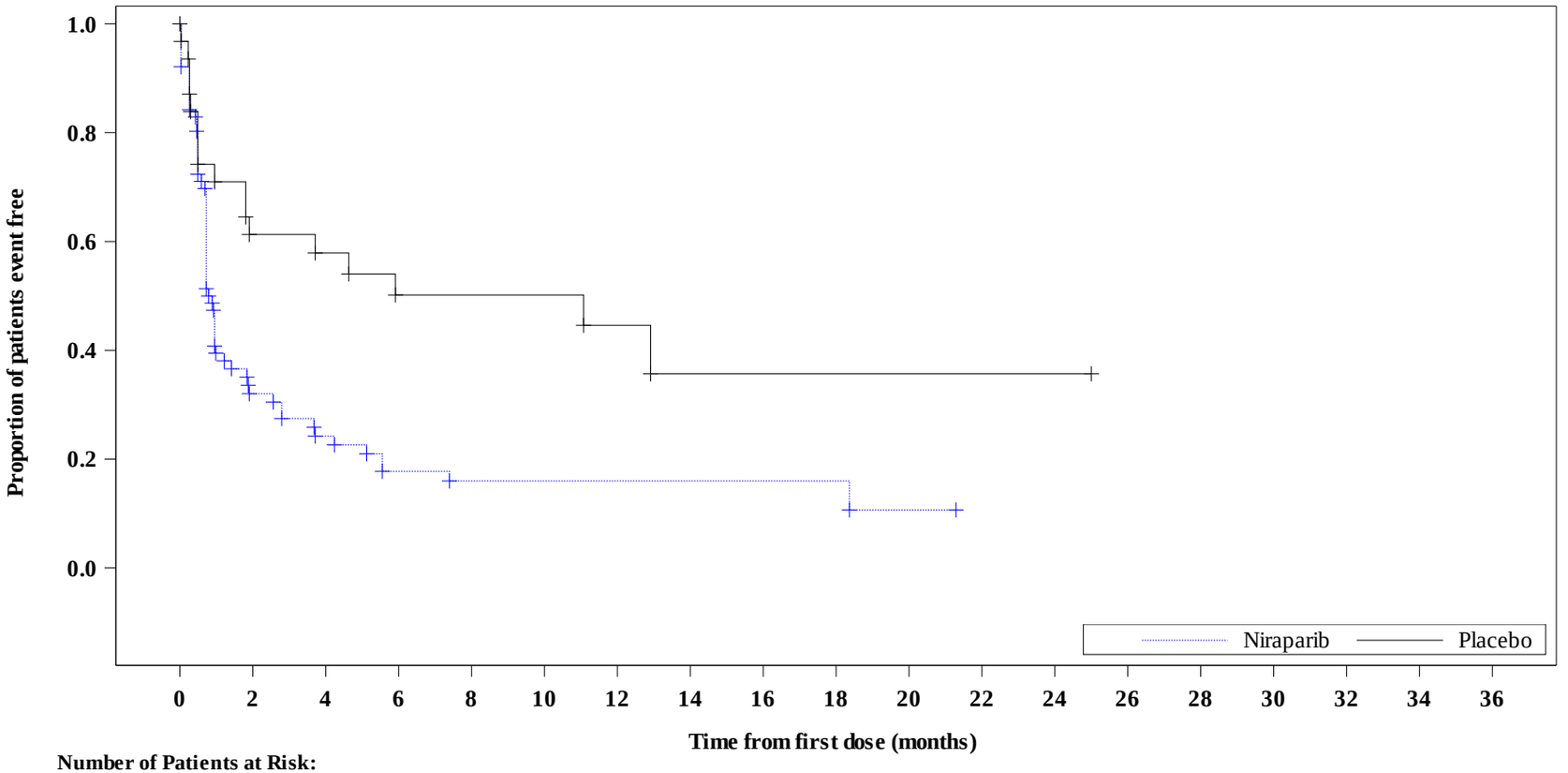



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 88 | 75 | 49 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.60
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)
Overall

BRCA Status: BRCAmut

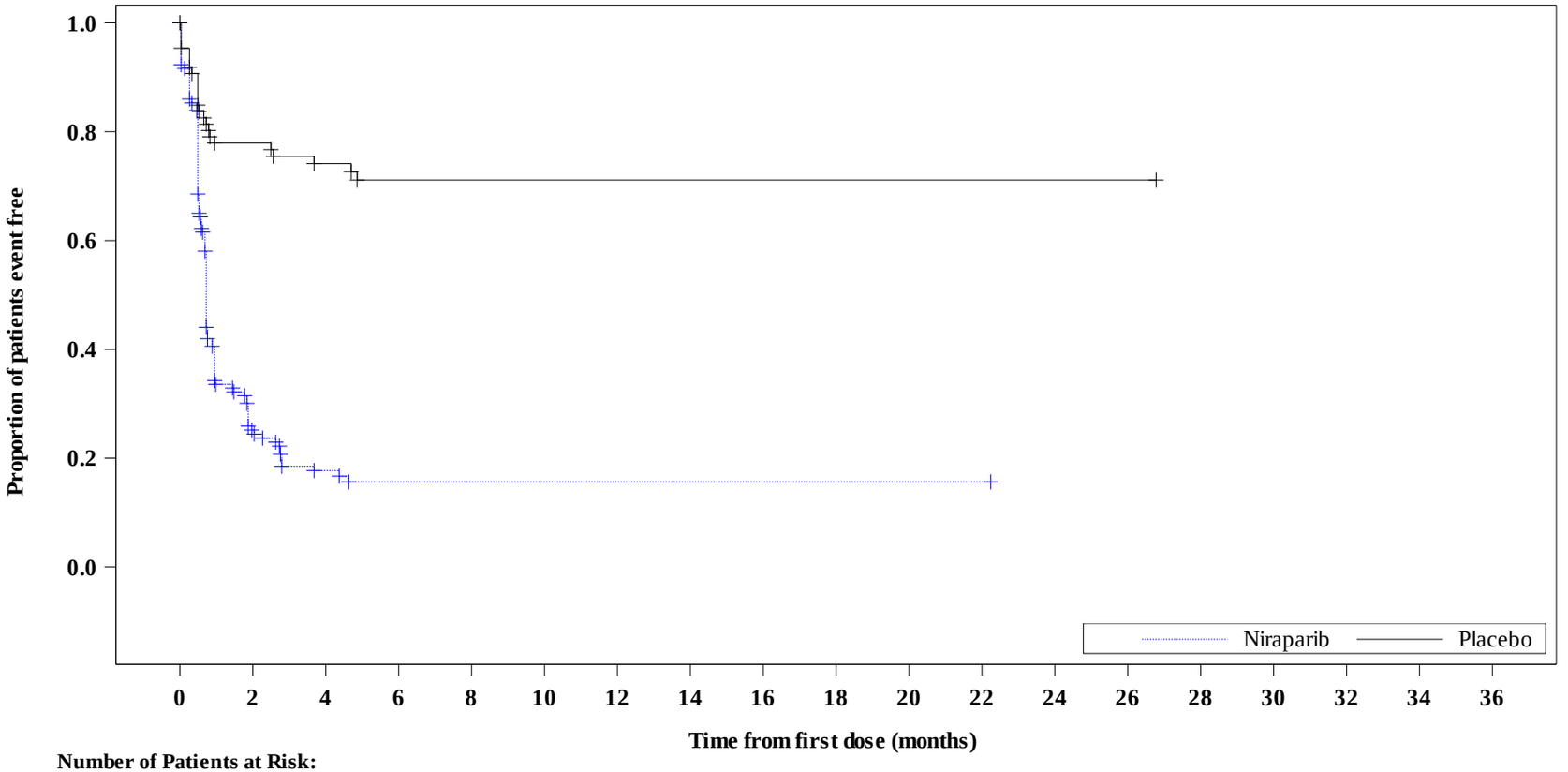



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 21 | 15 | 11 | 9 | 8 | 7 | 7 | 6 | 3 | 2 | 0 | | |
| Placebo | 31 | 19 | 17 | 13 | 13 | 12 | 8 | 2 | 1 | 1 | 1 | 1 | 1 | 0 |

Figure 3.60
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)
Overall

BRCA Status: BRCAwt

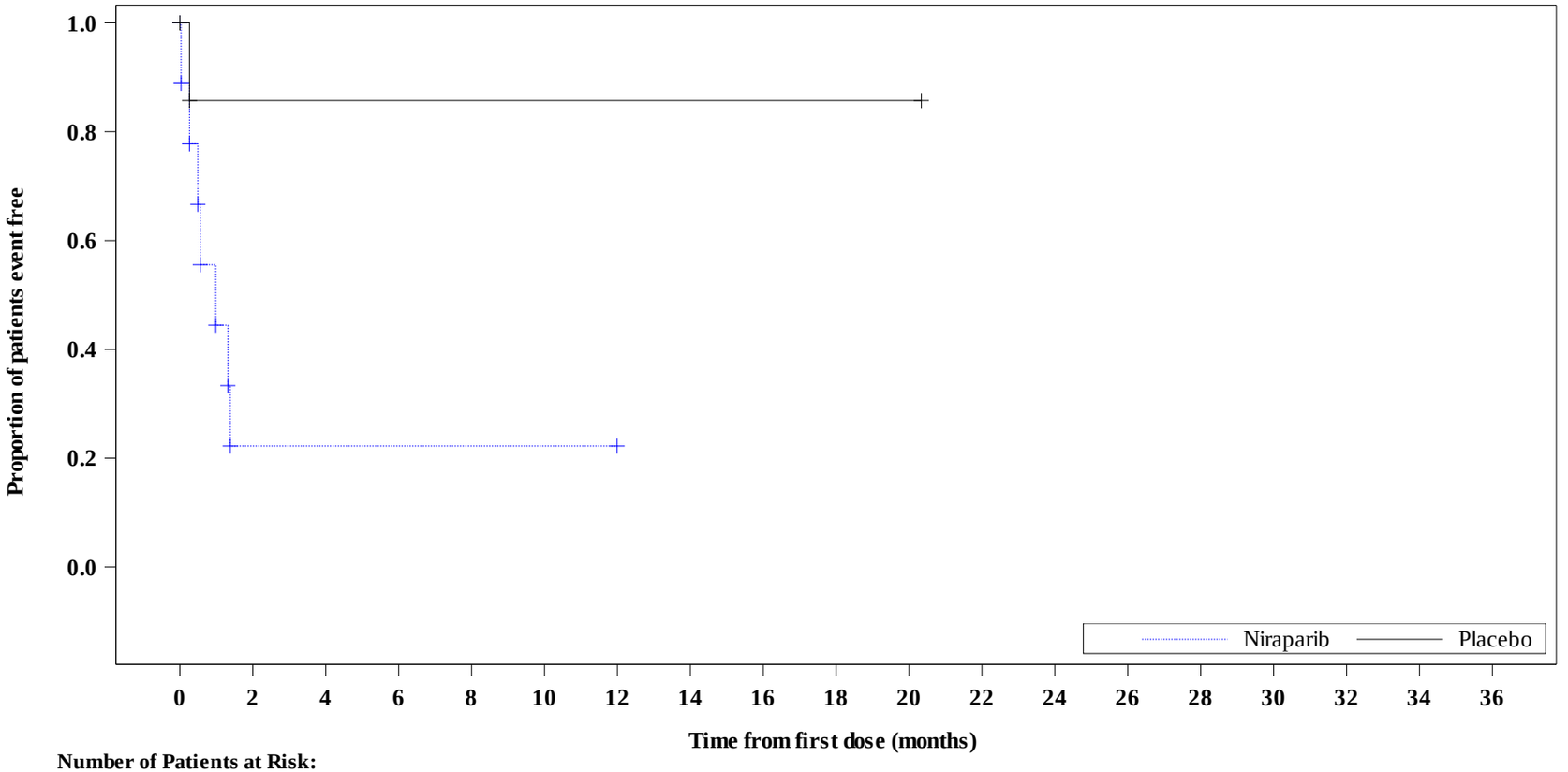



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 34 | 18 | 15 | 10 | 8 | 6 | 6 | 4 | 3 | 3 | 1 | 0 | | |
| Placebo | 86 | 65 | 53 | 44 | 35 | 20 | 19 | 18 | 16 | 14 | 7 | 5 | 2 | 1 | 0 |

Figure 3.60
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)
Overall

BRCA Status: BRCAnd




**Number of Patients at Risk:**

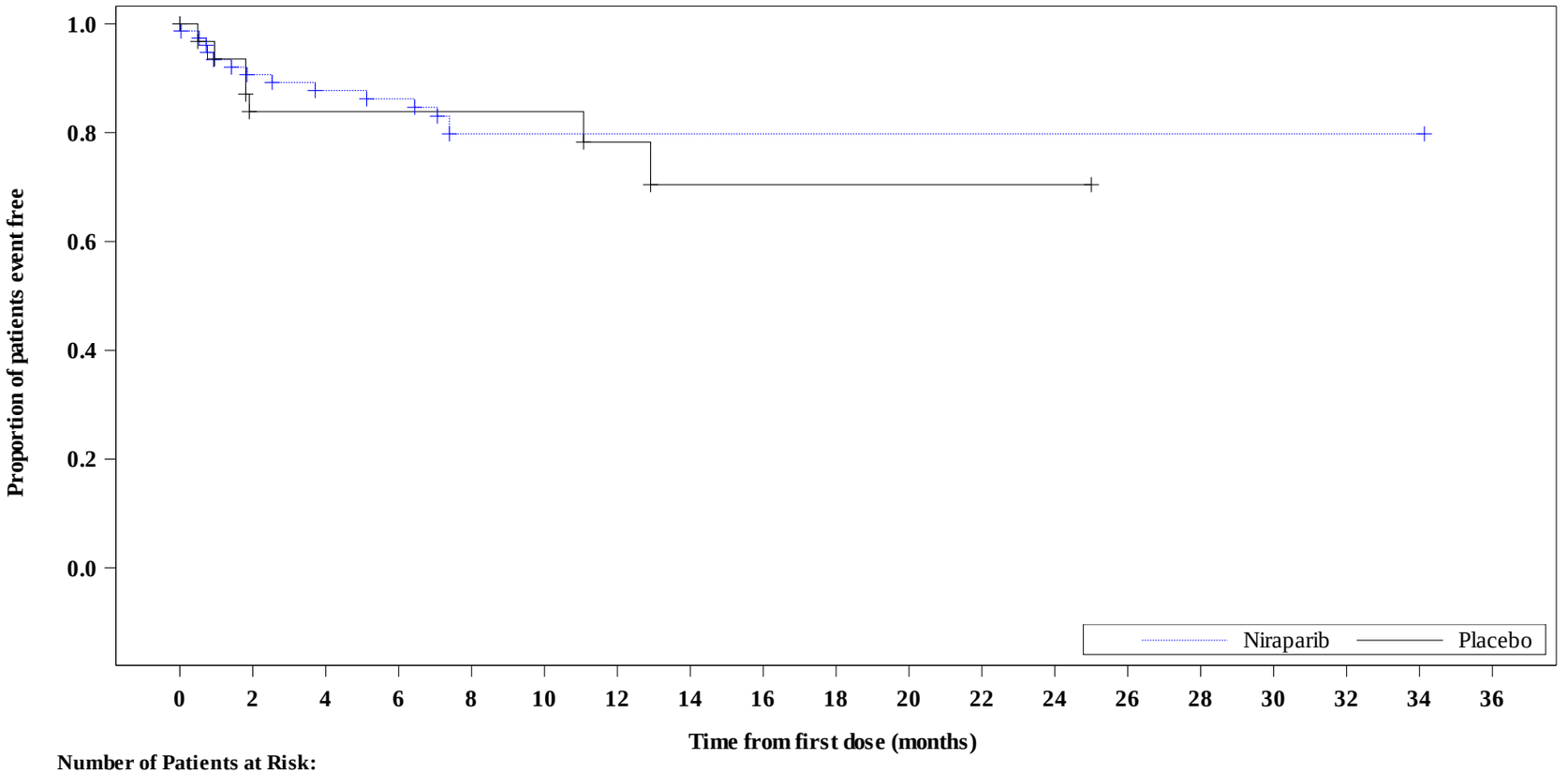
| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 1 | 1 | 1 | 1 | 1 | 0 | | | | | |
| Placebo | 7 | 6 | 6 | 6 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 0 |

Figure 3.60

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)

Hypertension

BRCA Status: BRCAmut

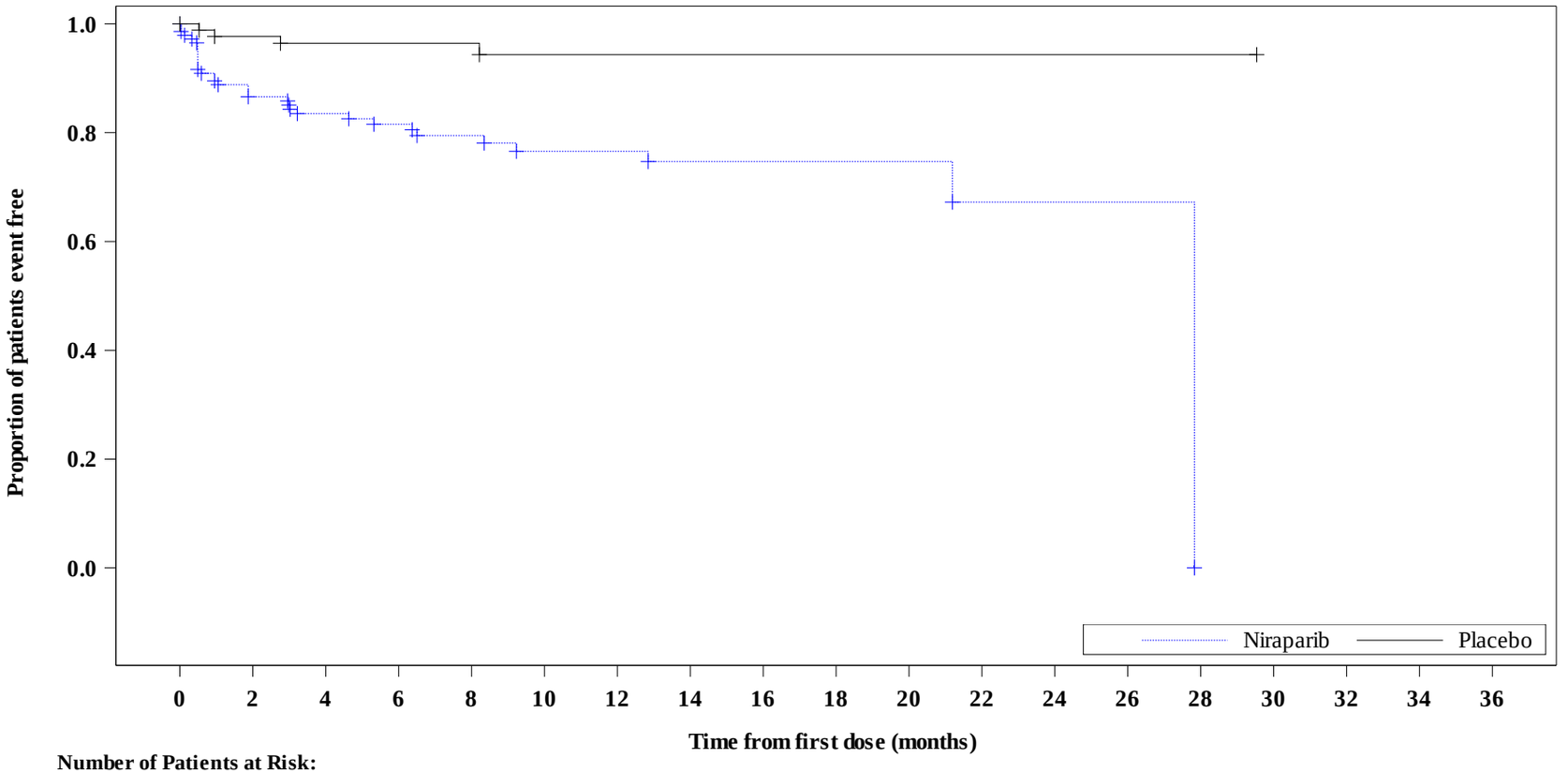



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 64 | 57 | 56 | 48 | 46 | 45 | 42 | 38 | 27 | 17 | 9 | 5 | 5 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 31 | 26 | 24 | 22 | 20 | 18 | 13 | 7 | 4 | 3 | 3 | 1 | 1 | 0 | | | | | |

Figure 3.60
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)
Hypertension

BRCA Status: BRCAwt




**Number of Patients at Risk:**

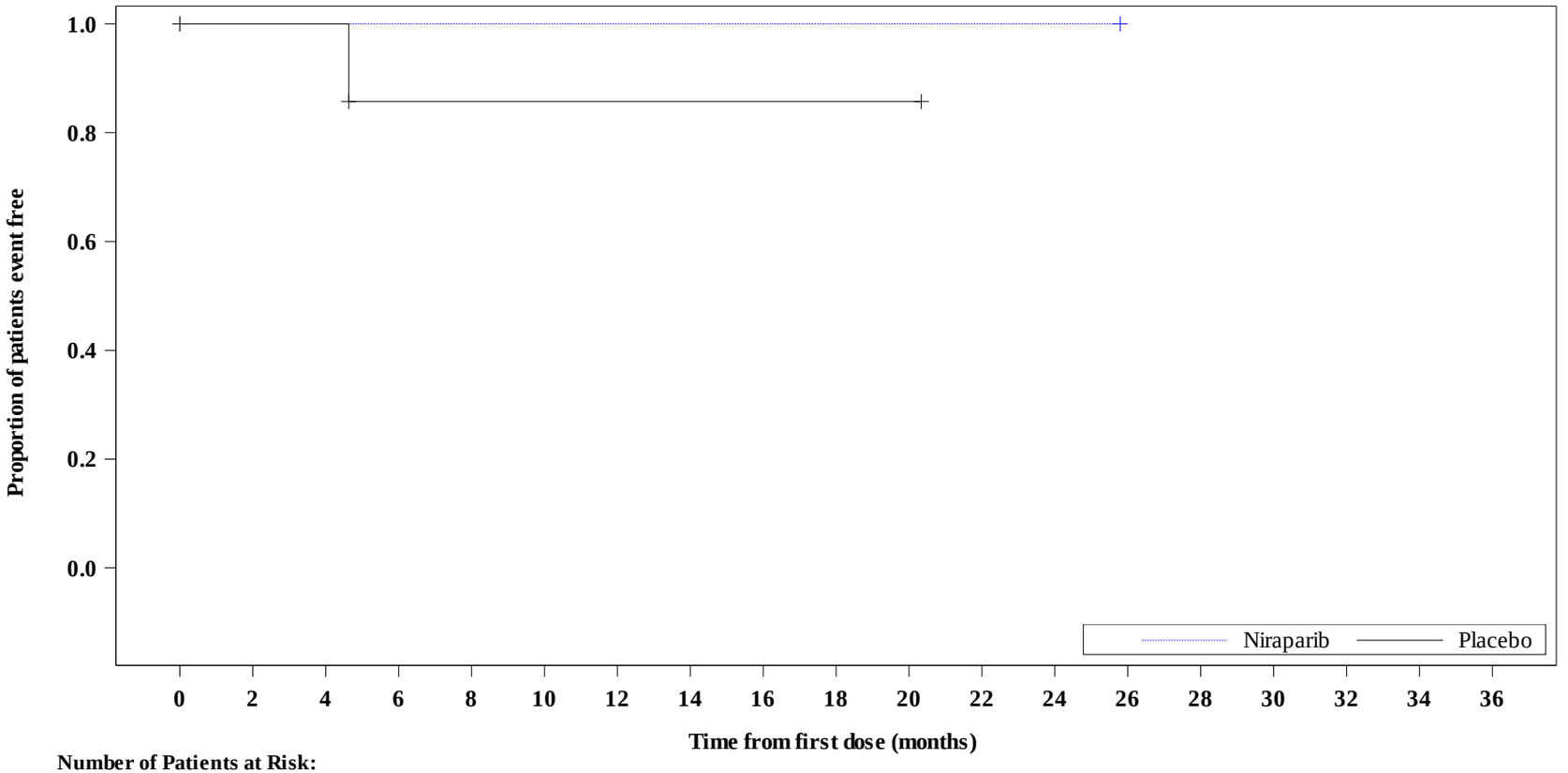
| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 116 | 92 | 80 | 58 | 50 | 45 | 38 | 30 | 28 | 17 | 5 | 2 | 1 | 0 | |
| Placebo | 86 | 82 | 68 | 61 | 48 | 29 | 28 | 26 | 24 | 20 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.60

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)

Hypertension

BRCA Status: BRCAnd



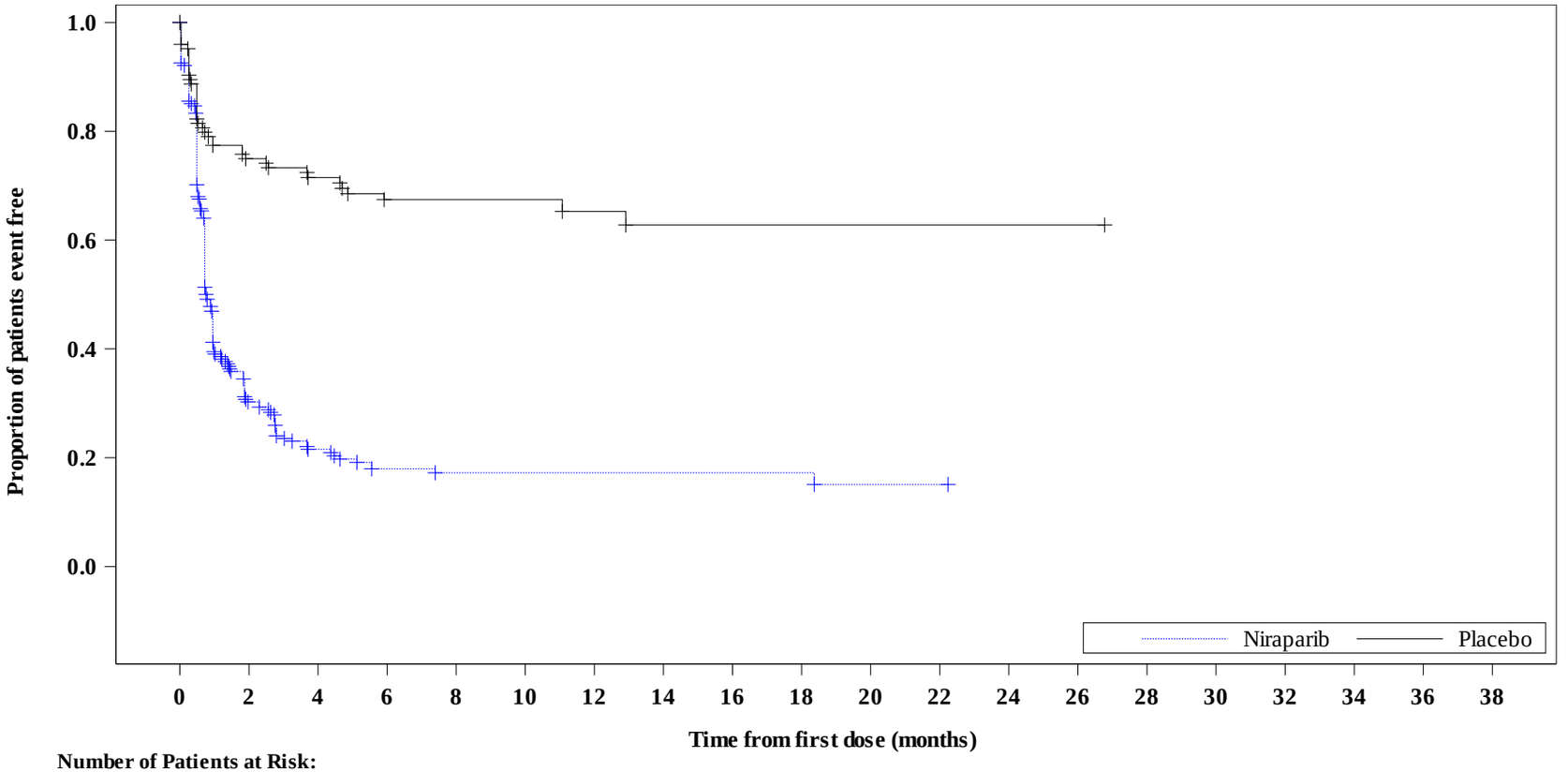

**Number of Patients at Risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 8 | 7 | 7 | 6 | 4 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 7 | 7 | 7 | 6 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 0 | | |

Figure 3.72

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Overall

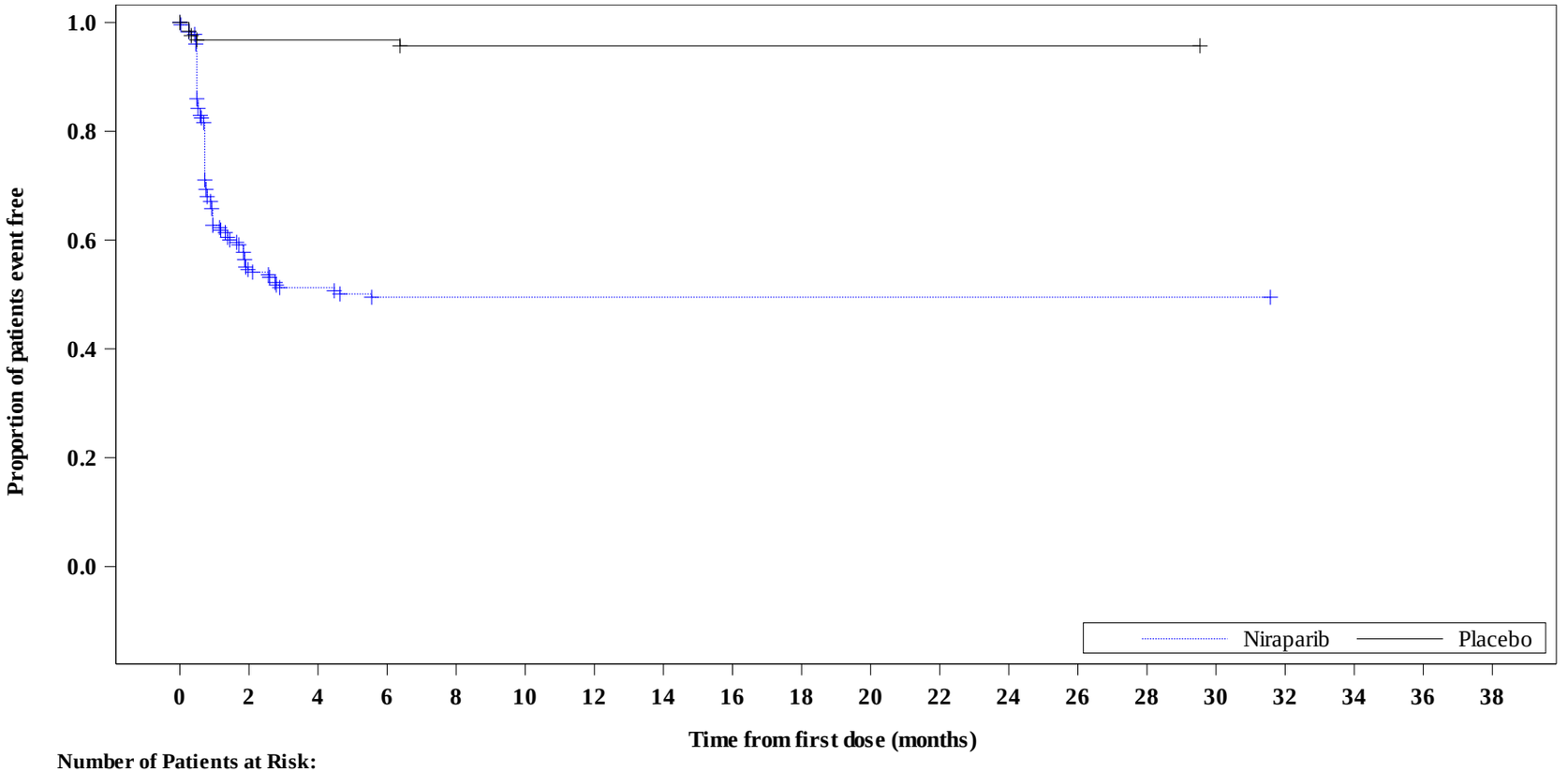



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 63 | 37 | 30 | 23 | 19 | 15 | 15 | 12 | 8 | 7 | 1 | 0 | | |
| Placebo | 124 | 91 | 77 | 64 | 52 | 36 | 30 | 22 | 19 | 17 | 10 | 6 | 3 | 1 | 0 |

Figure 3.72
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Thrombocytopenia

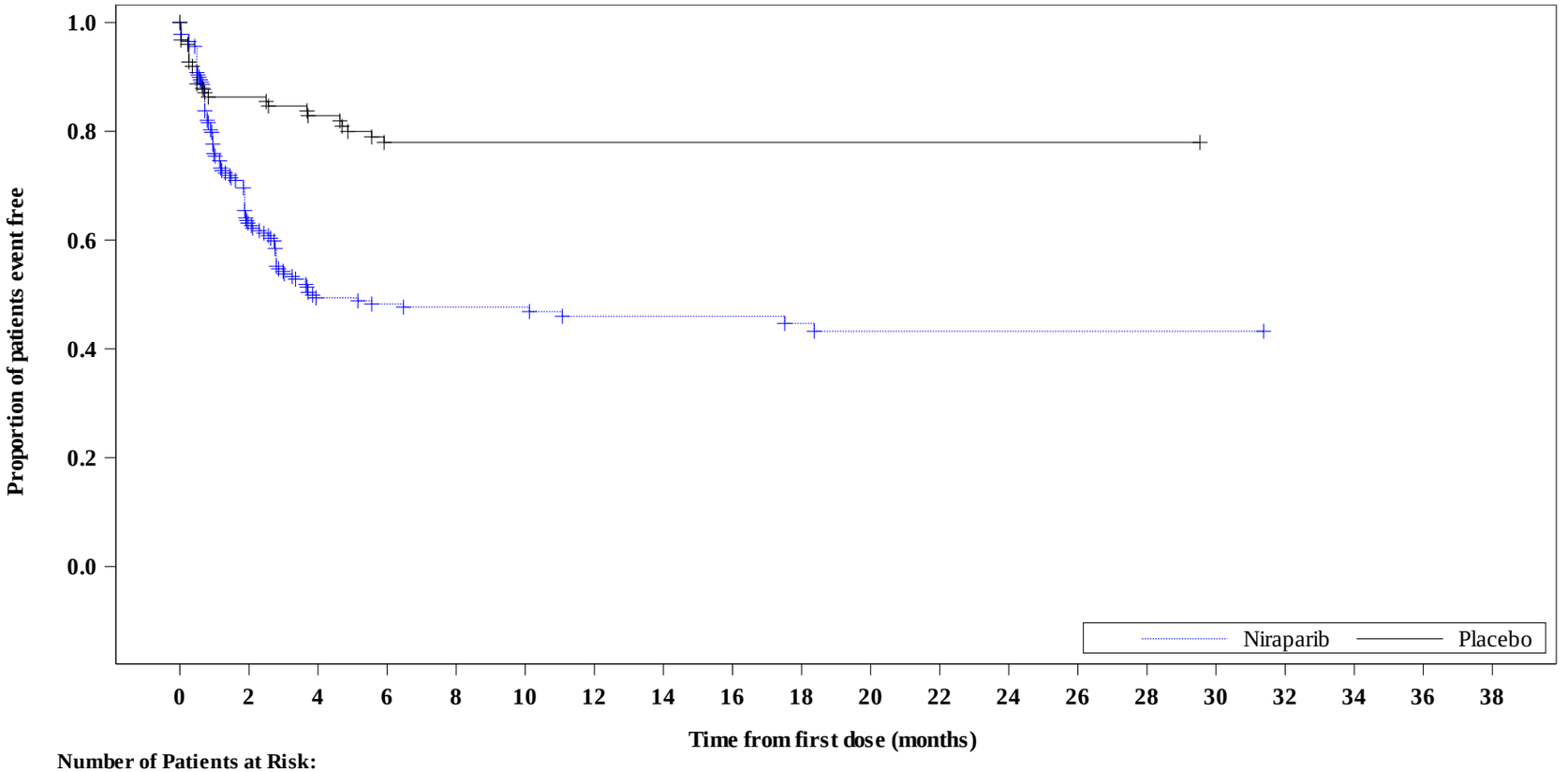



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 117 | 92 | 81 | 67 | 60 | 55 | 51 | 44 | 36 | 26 | 10 | 3 | 2 | 2 | 2 | 0 |
| Placebo | 124 | 118 | 104 | 95 | 76 | 54 | 47 | 39 | 32 | 28 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.72
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Anemia



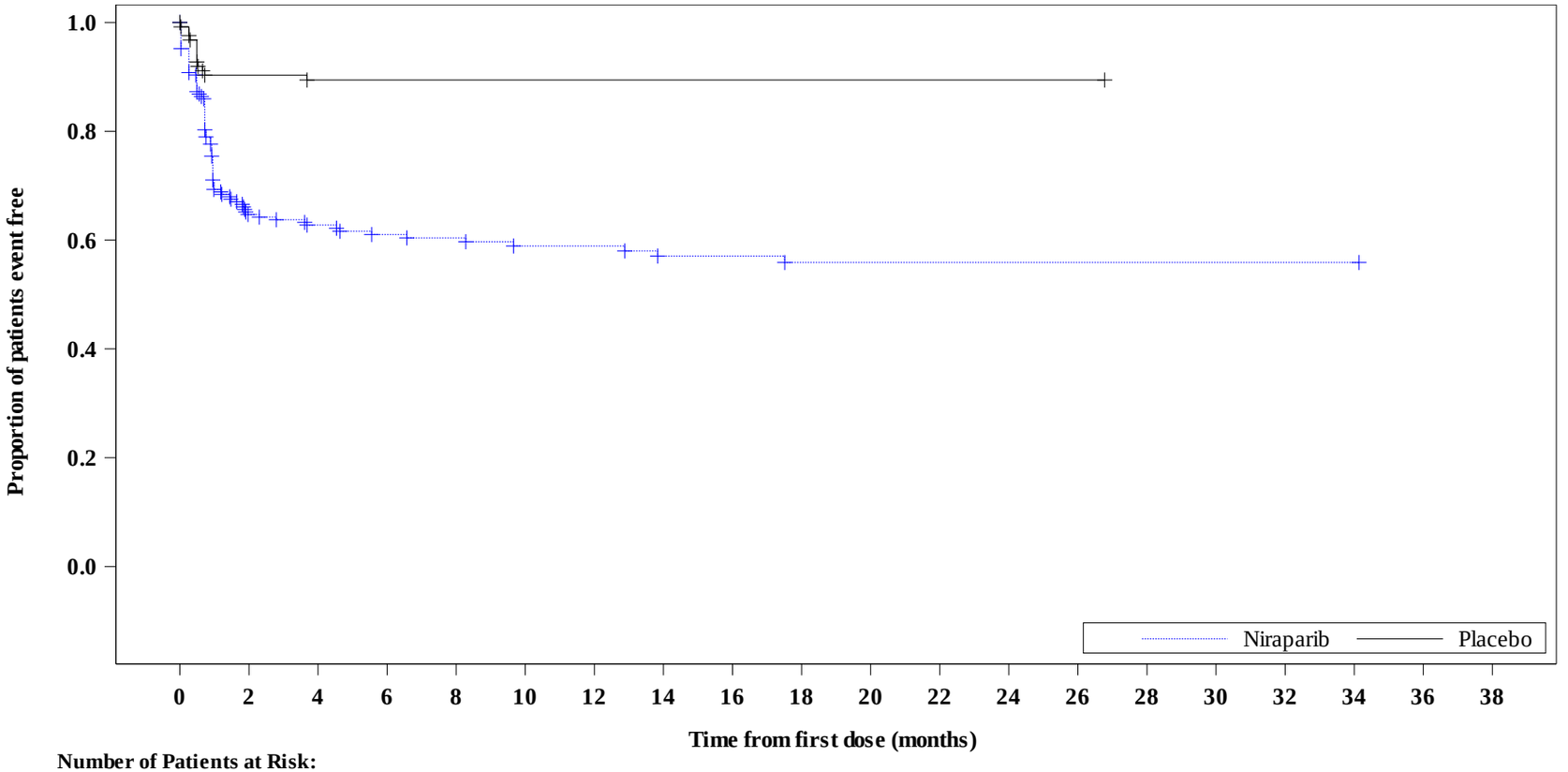

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 135 | 95 | 84 | 67 | 58 | 52 | 48 | 40 | 31 | 25 | 8 | 6 | 4 | 1 | 1 | 0 |
| Placebo | 124 | 105 | 91 | 77 | 64 | 46 | 40 | 33 | 28 | 25 | 17 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.72

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Leukopenia



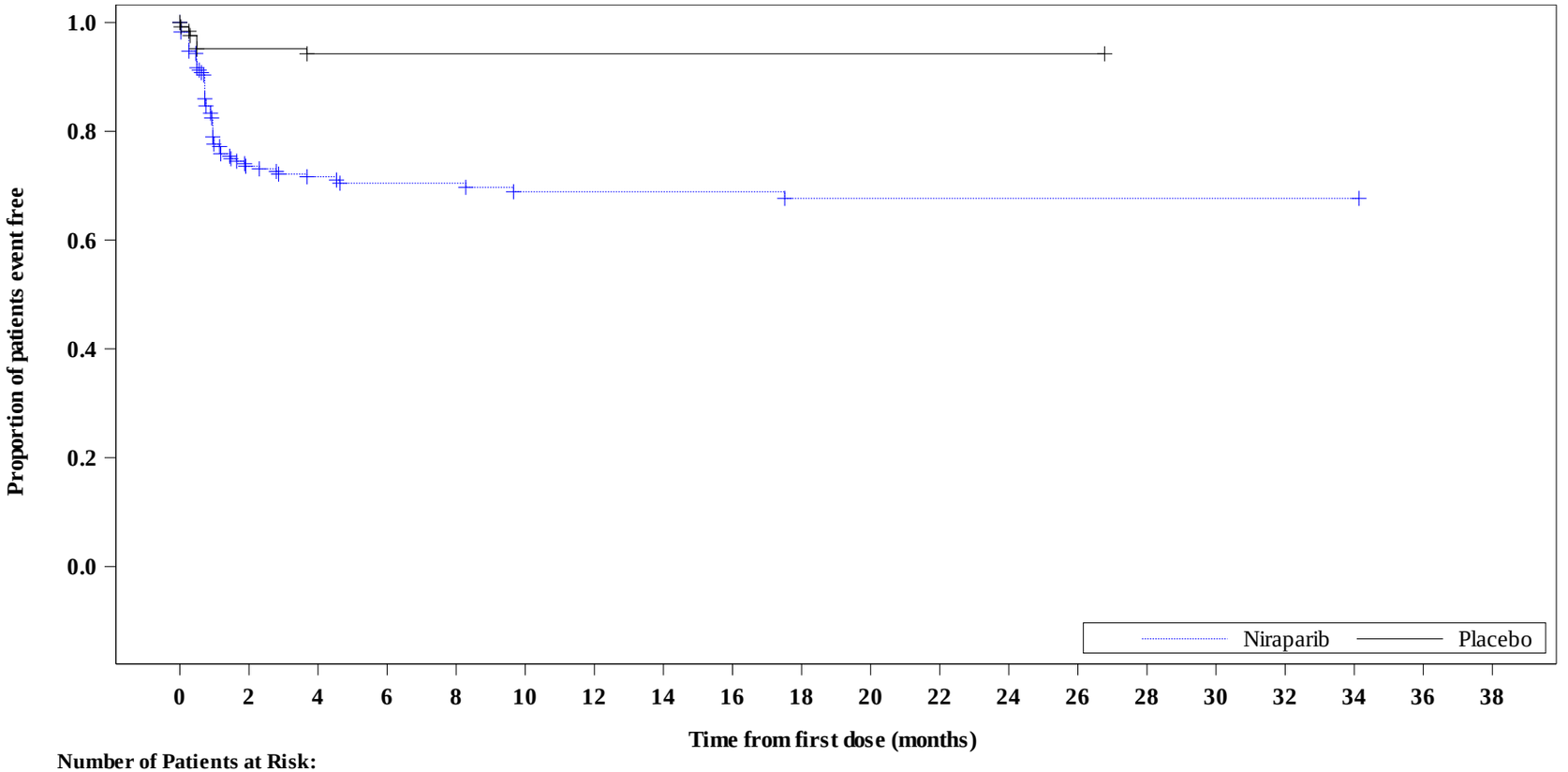

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 135 | 117 | 103 | 85 | 74 | 67 | 61 | 53 | 45 | 33 | 16 | 10 | 6 | 4 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 110 | 97 | 88 | 71 | 49 | 42 | 34 | 29 | 24 | 15 | 6 | 3 | 1 | 0 | | | | |

Figure 3.72

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Neutropenia



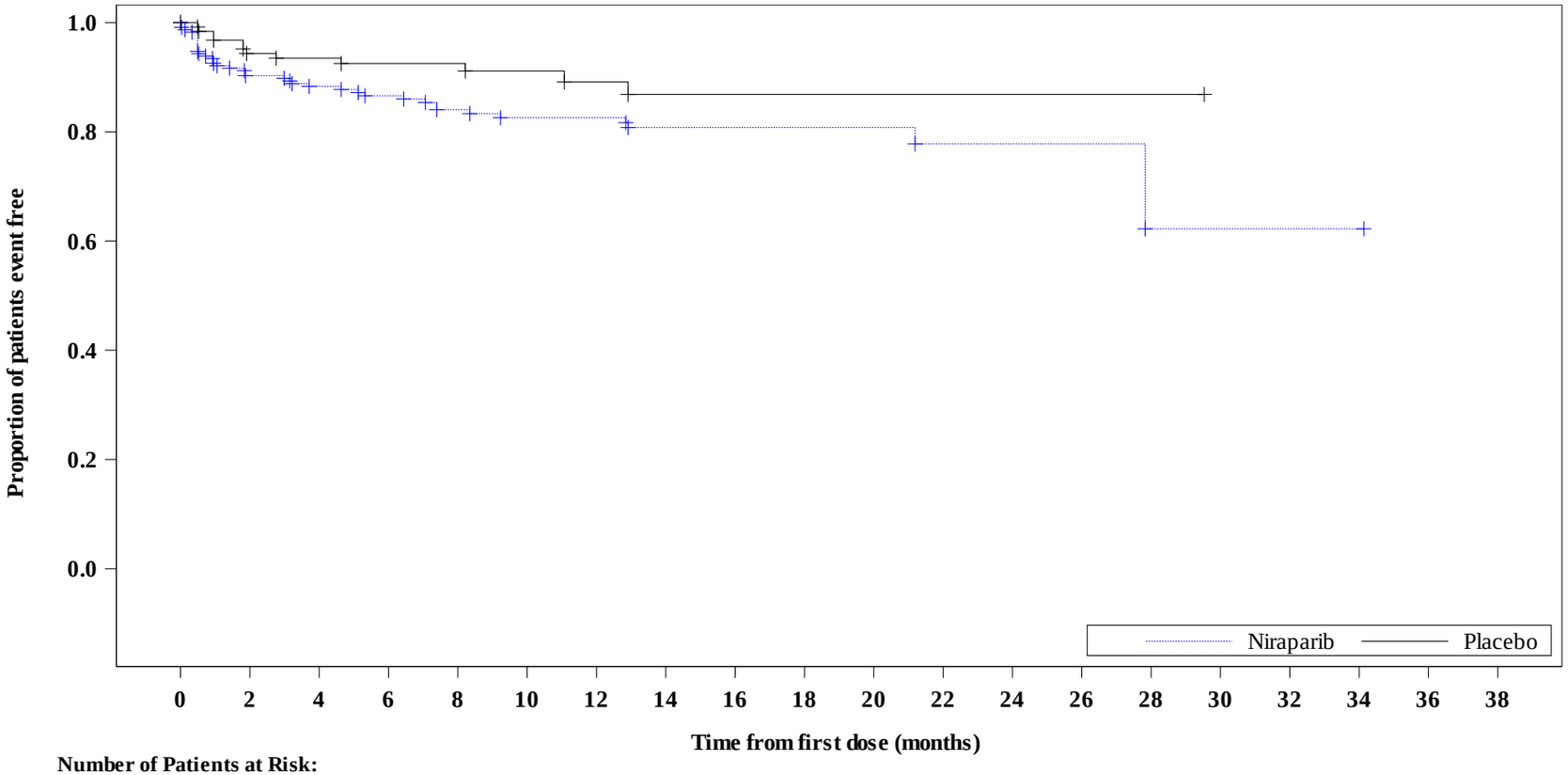

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 155 | 129 | 115 | 94 | 83 | 76 | 72 | 61 | 51 | 37 | 17 | 10 | 6 | 4 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 116 | 101 | 92 | 74 | 52 | 45 | 37 | 32 | 27 | 18 | 7 | 3 | 1 | 0 | | | | |

Figure 3.72

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Hypertension



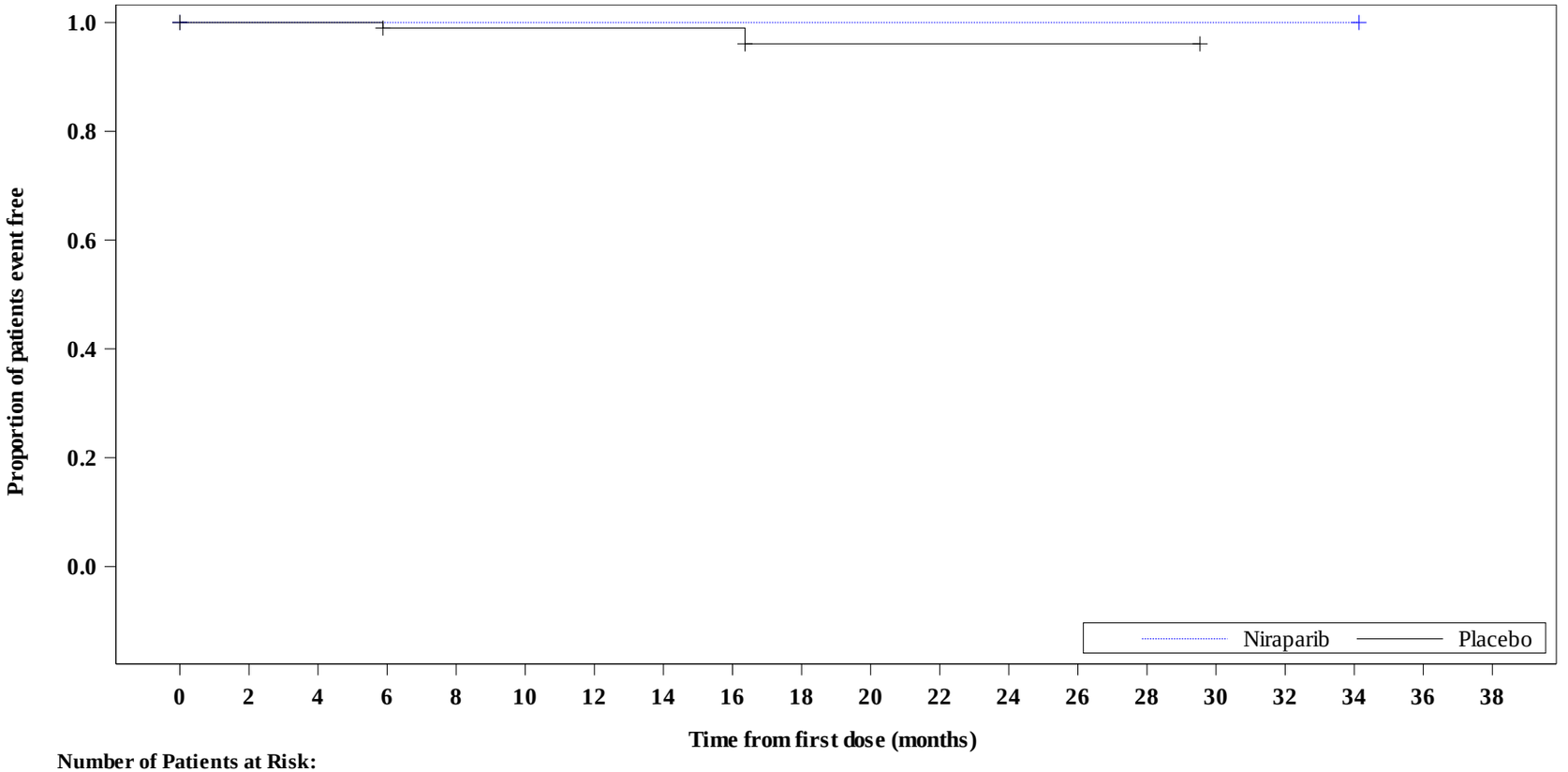

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 192 | 161 | 148 | 118 | 106 | 98 | 87 | 74 | 61 | 38 | 16 | 9 | 7 | 4 | 2 | 2 | 1 | 0 |
| Placebo | 124 | 115 | 99 | 89 | 71 | 50 | 43 | 35 | 30 | 25 | 17 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.72

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

New malignancies other than MDS/AML

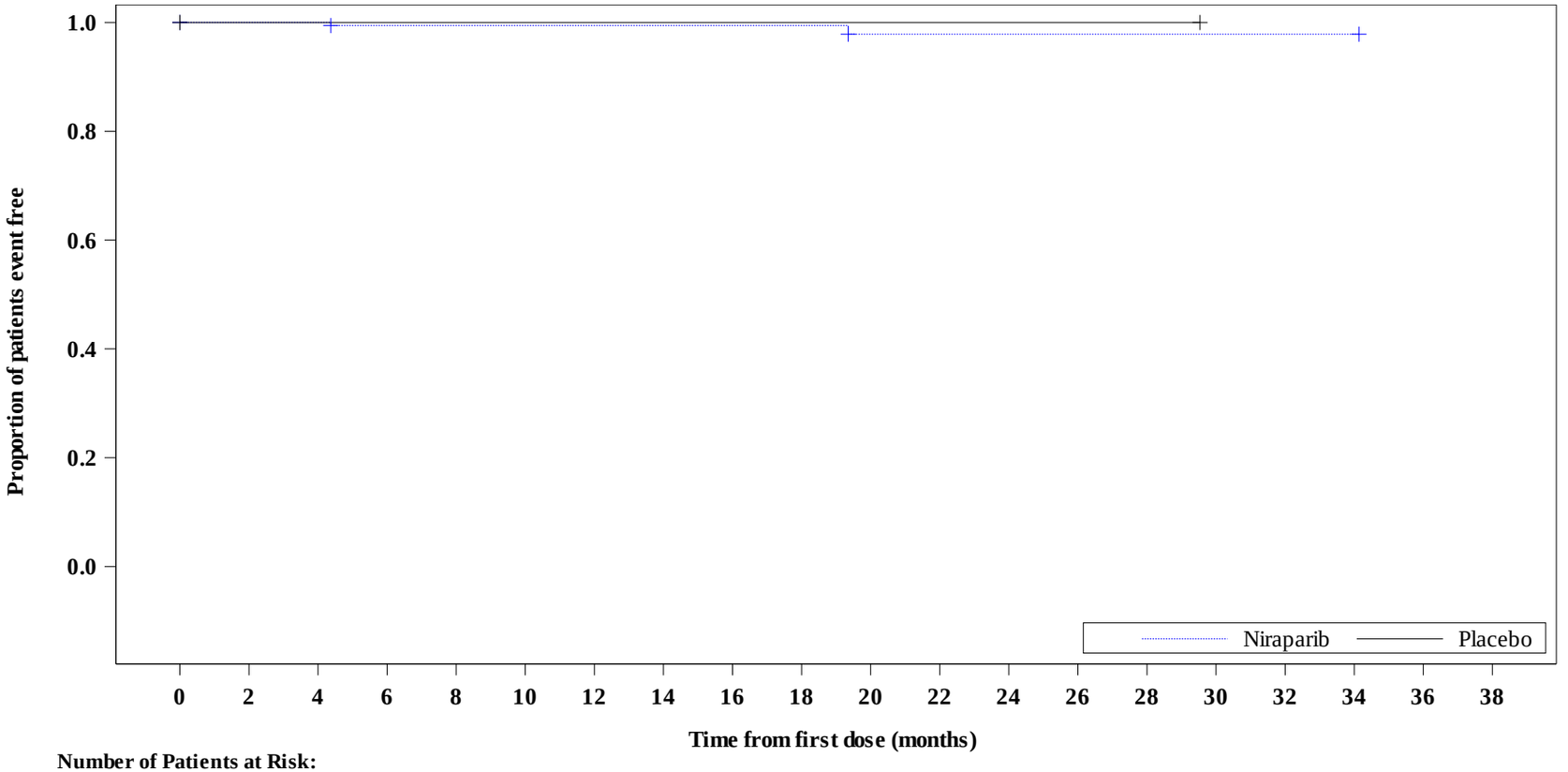



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 97 | 77 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.72
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Pneumonitis

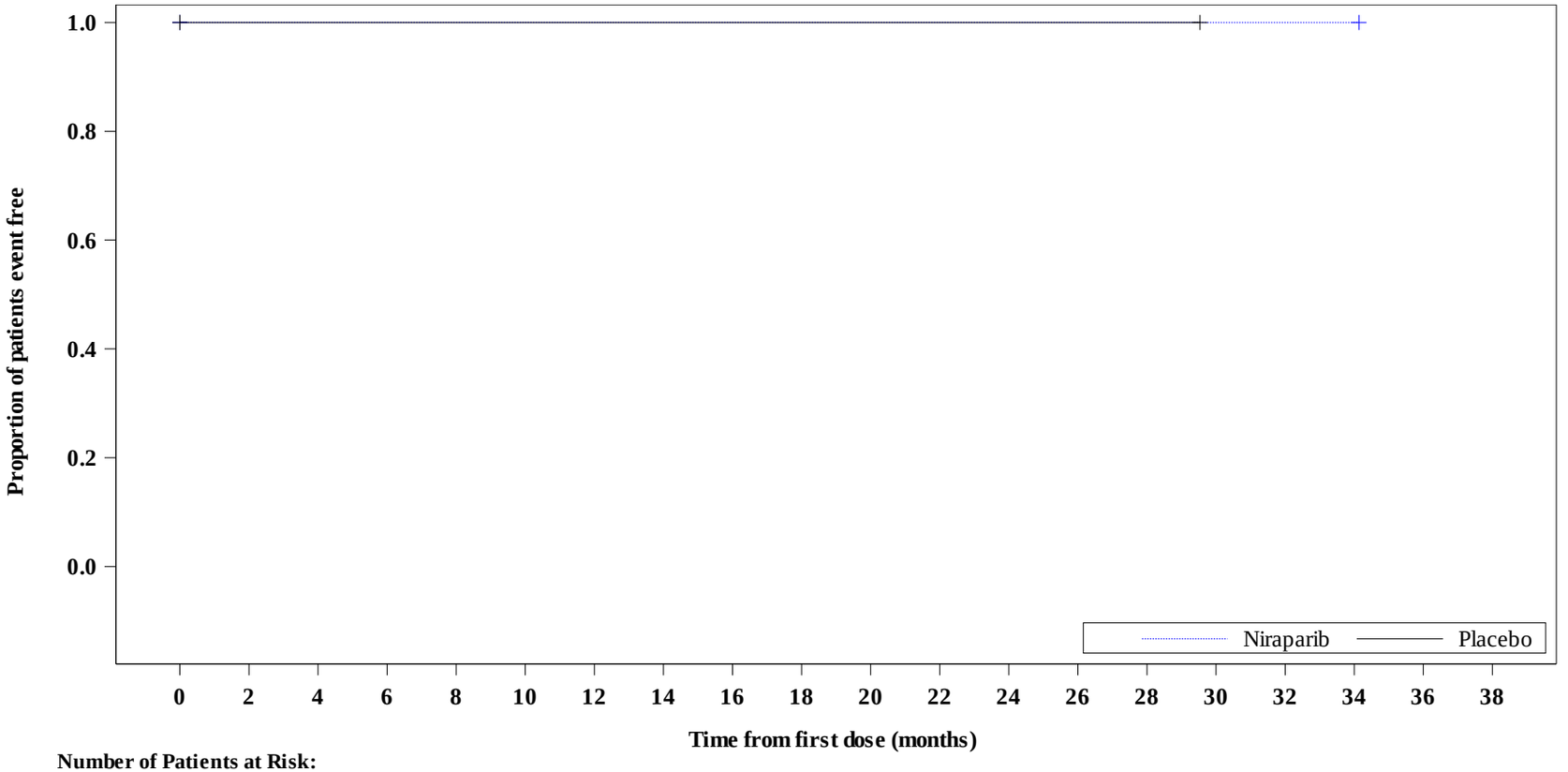



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 165 | 137 | 123 | 115 | 105 | 89 | 76 | 49 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.72
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Pancytopenia



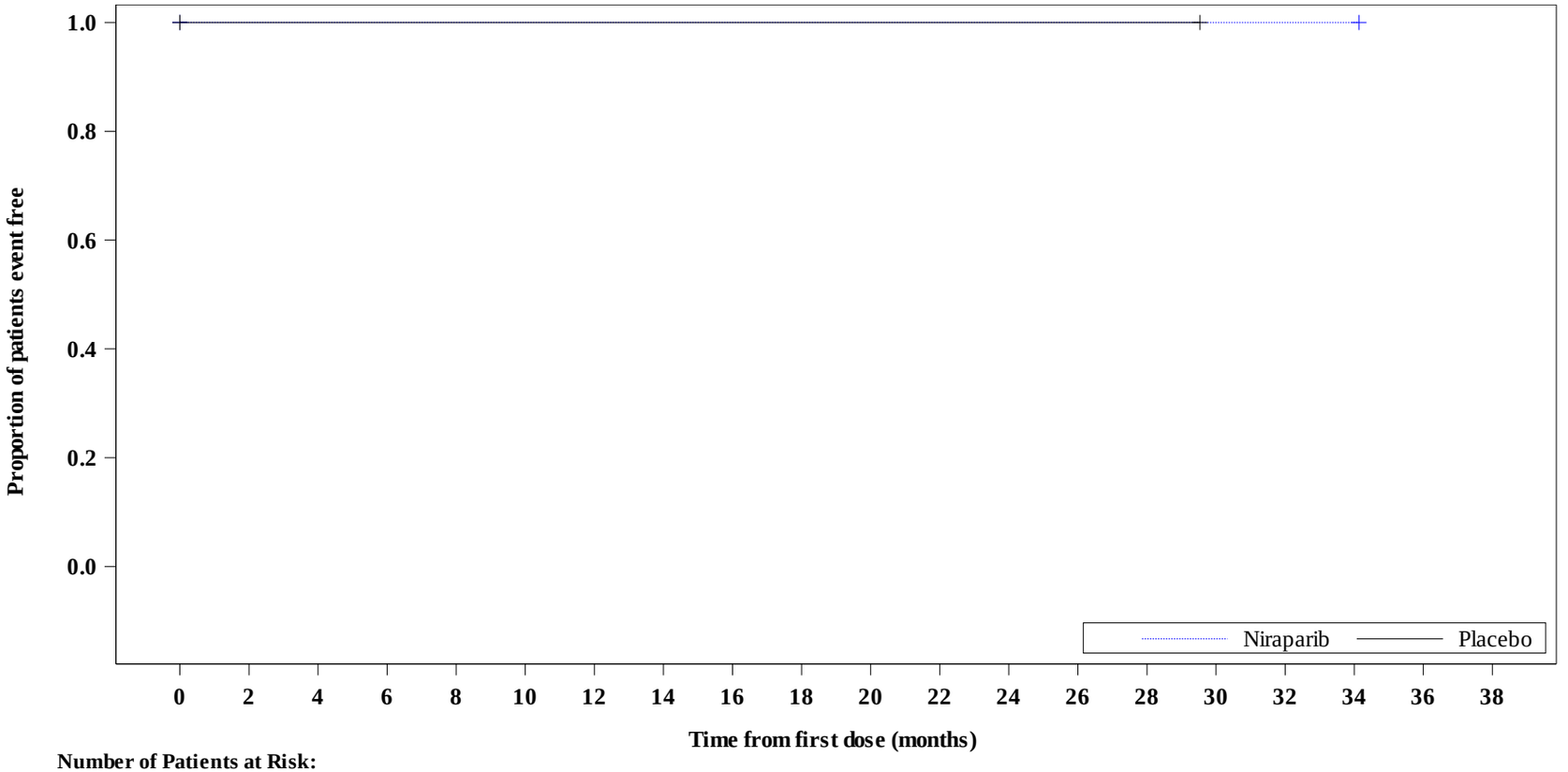

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.72

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Thromboemblic



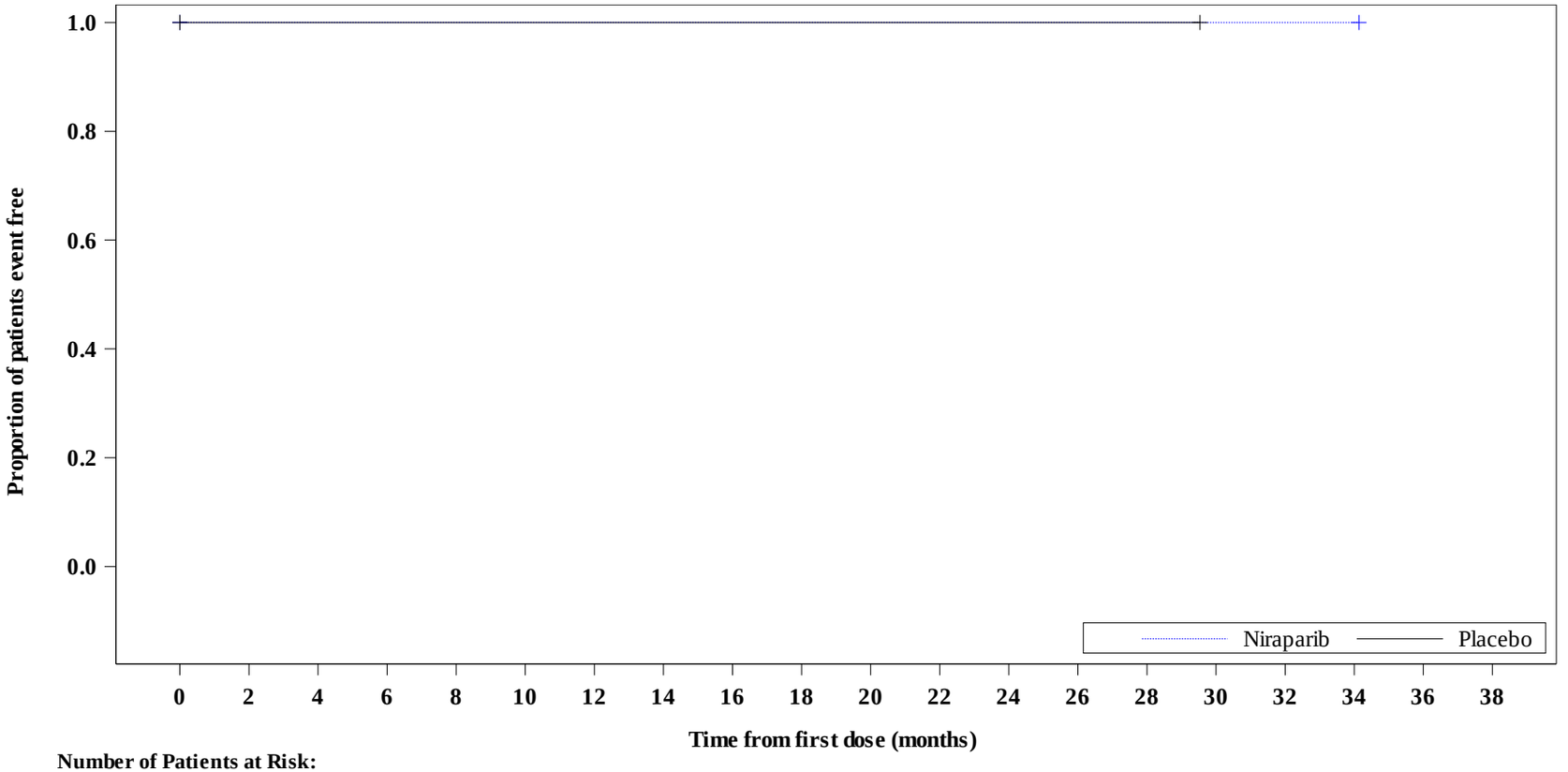

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.72

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

MDS/AML

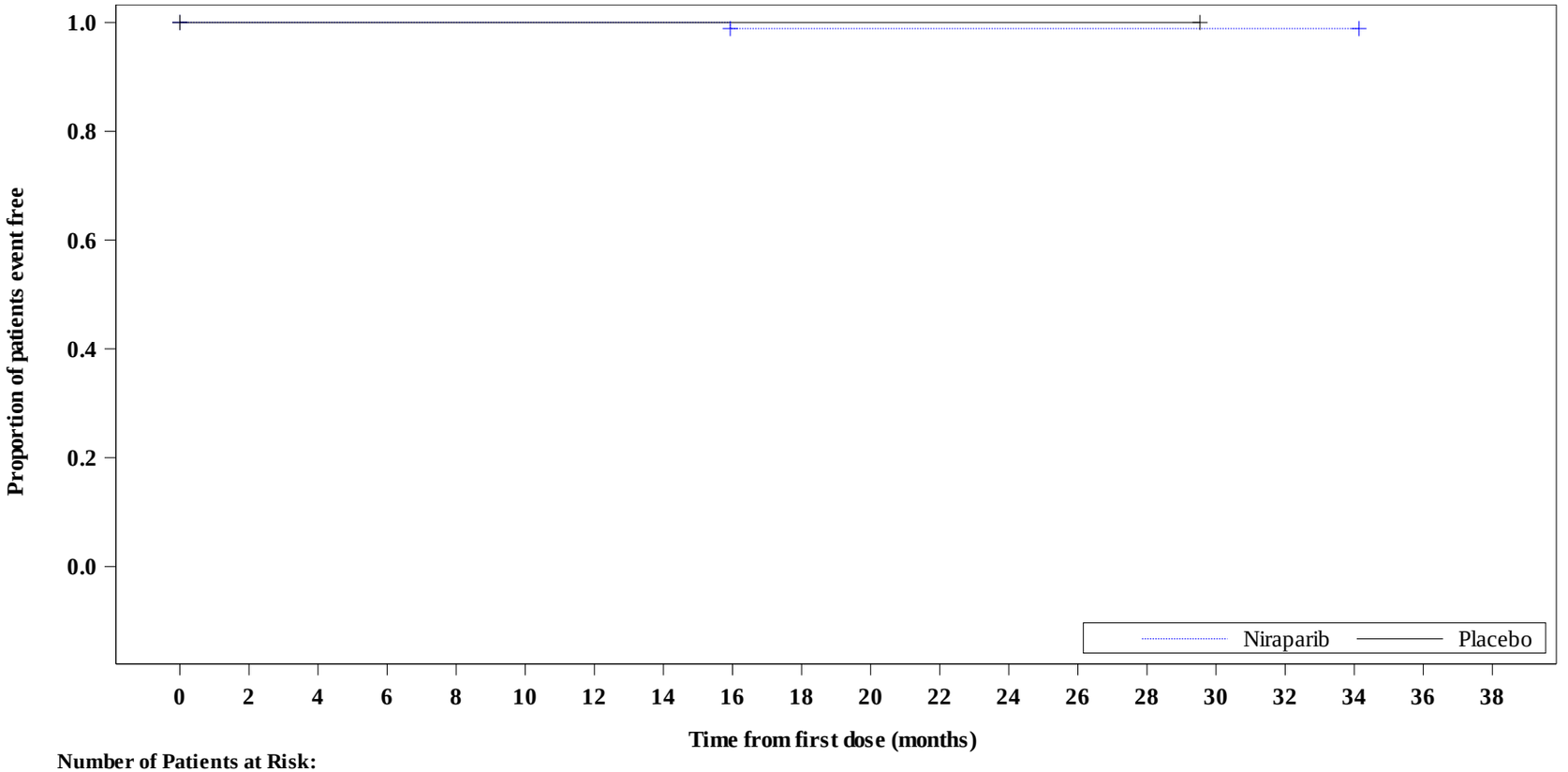



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.72
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Embryo-fetal toxicity




**Number of Patients at Risk:**

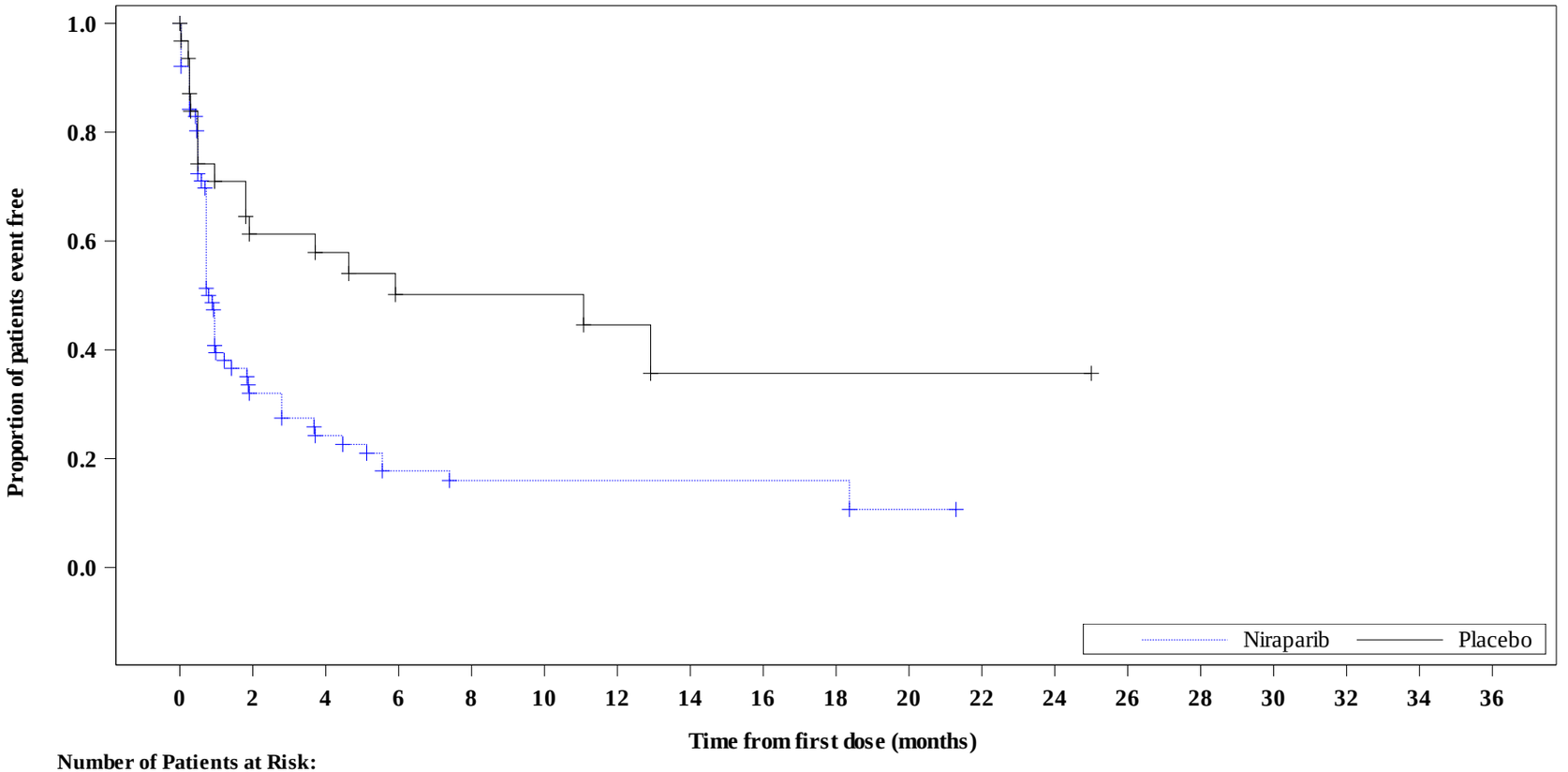
| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 88 | 75 | 49 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.66

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)

Overall

BRCA Status: BRCAmut



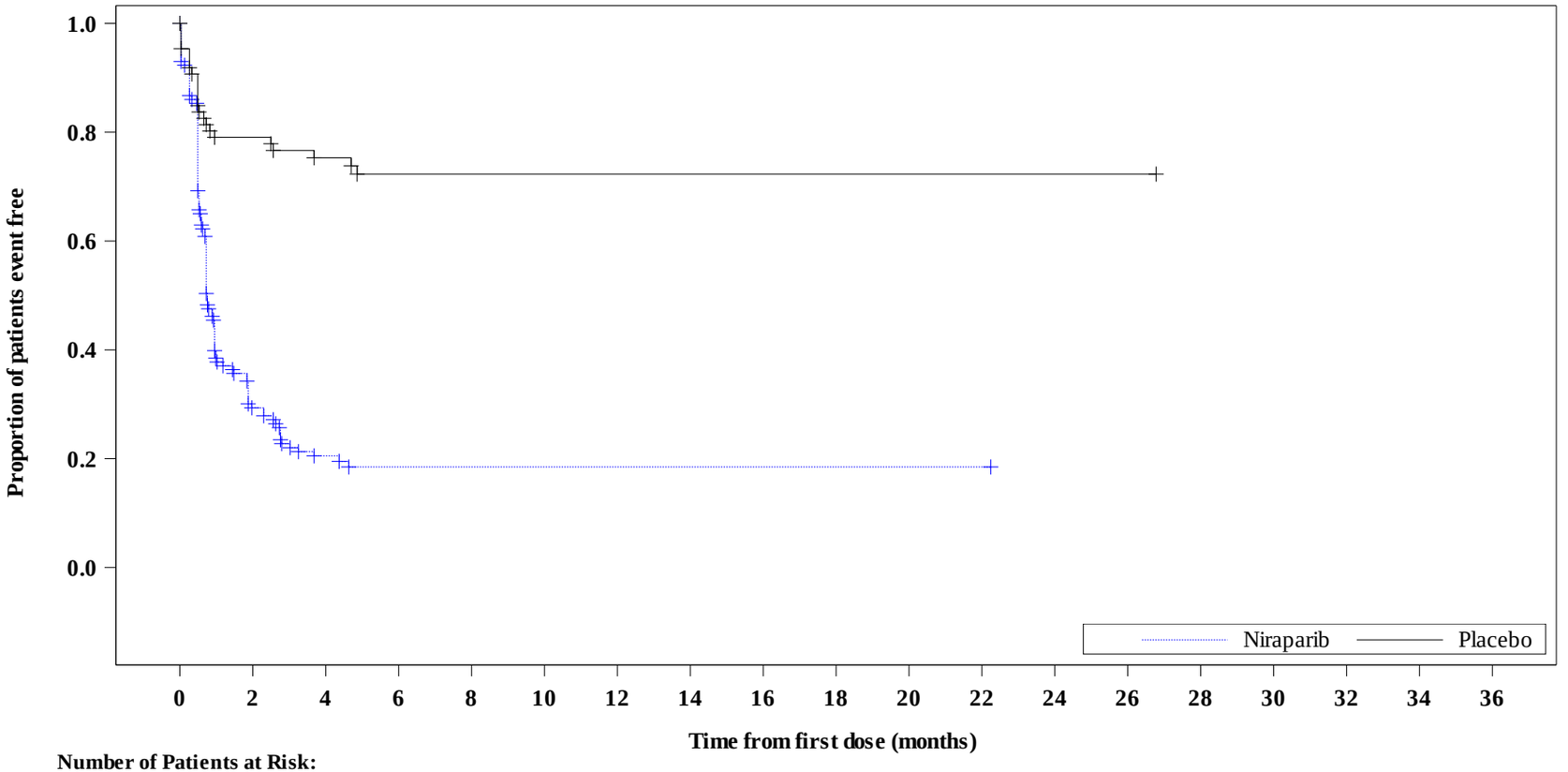

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 21 | 15 | 11 | 9 | 8 | 7 | 7 | 6 | 3 | 2 | 0 | | |
| Placebo | 31 | 19 | 17 | 13 | 13 | 12 | 8 | 2 | 1 | 1 | 1 | 1 | 1 | 0 |

Figure 3.66
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)

Overall

BRCA Status: BRCAwt



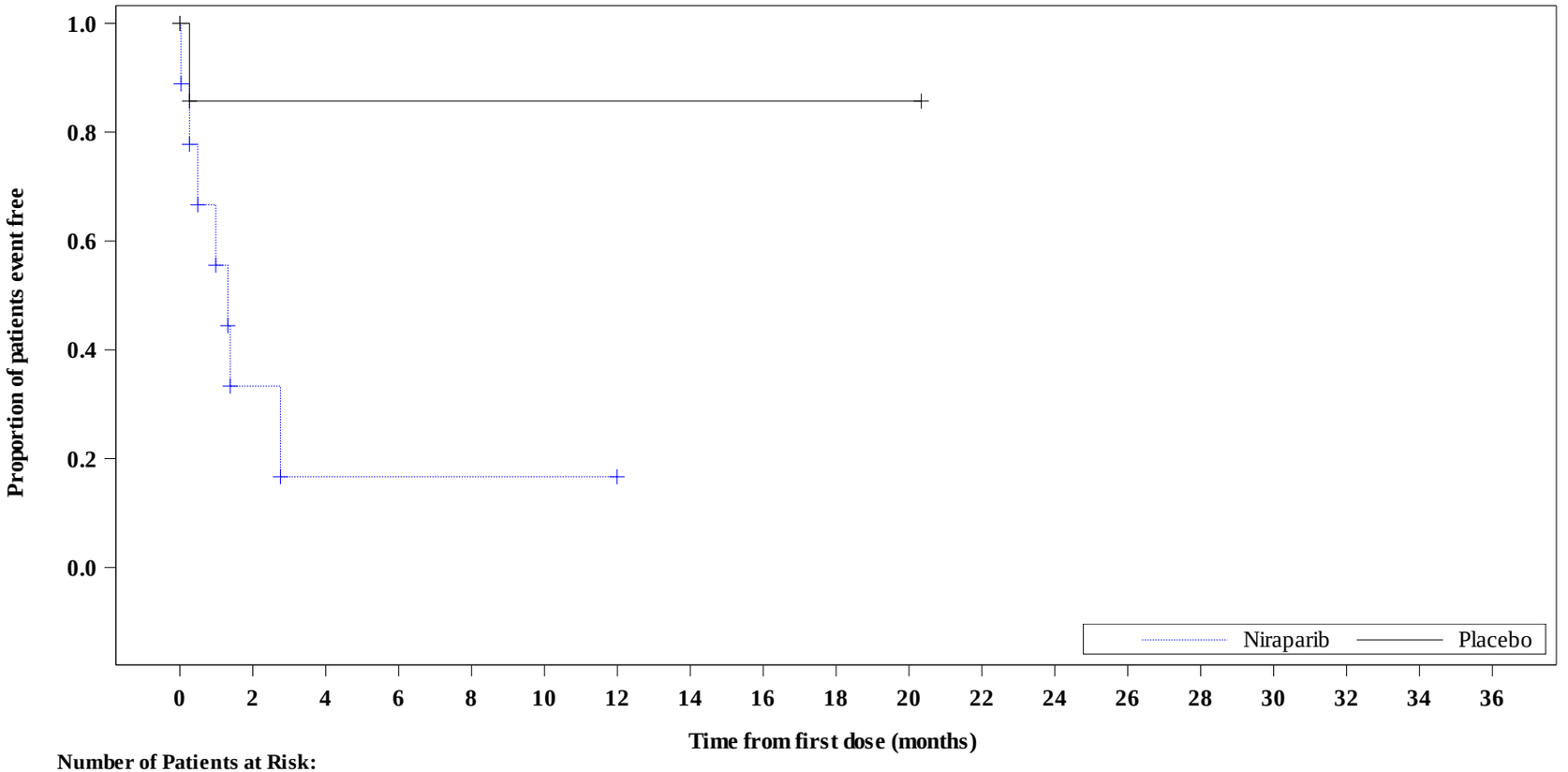

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 40 | 21 | 18 | 13 | 10 | 8 | 8 | 6 | 5 | 5 | 1 | 0 | | |
| Placebo | 86 | 66 | 54 | 45 | 36 | 21 | 20 | 18 | 16 | 14 | 7 | 5 | 2 | 1 | 0 |

Figure 3.66
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)

Overall

BRCA Status: BRCAnd




**Number of Patients at Risk:**

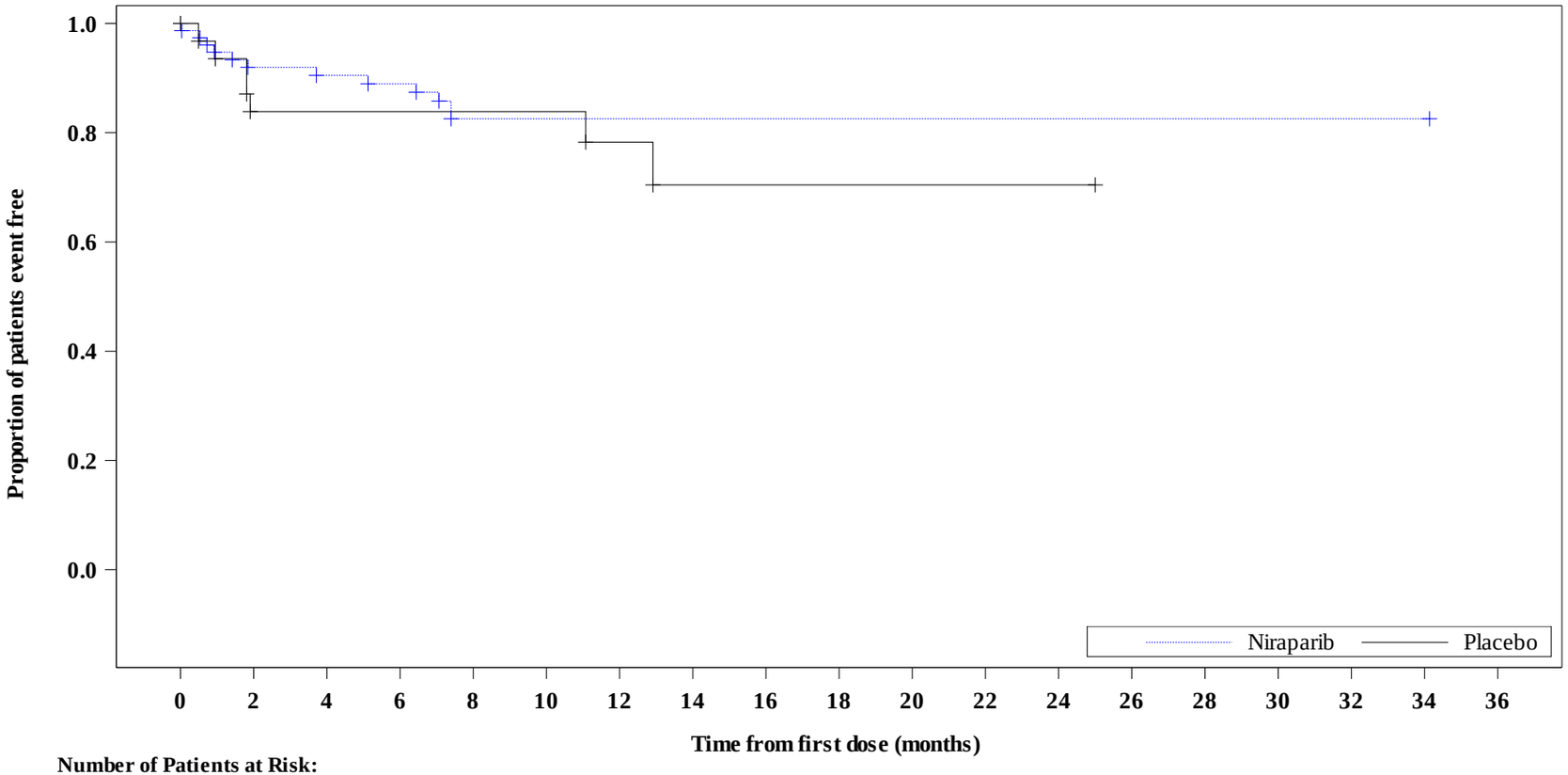
| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 2 | 1 | 1 | 1 | 1 | 0 | | | | | |
| Placebo | 7 | 6 | 6 | 6 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-66-ttaesib-g.sas 27SEP2020 17:57

Figure 3.66
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)

Hypertension

BRCA Status: BRCAmut



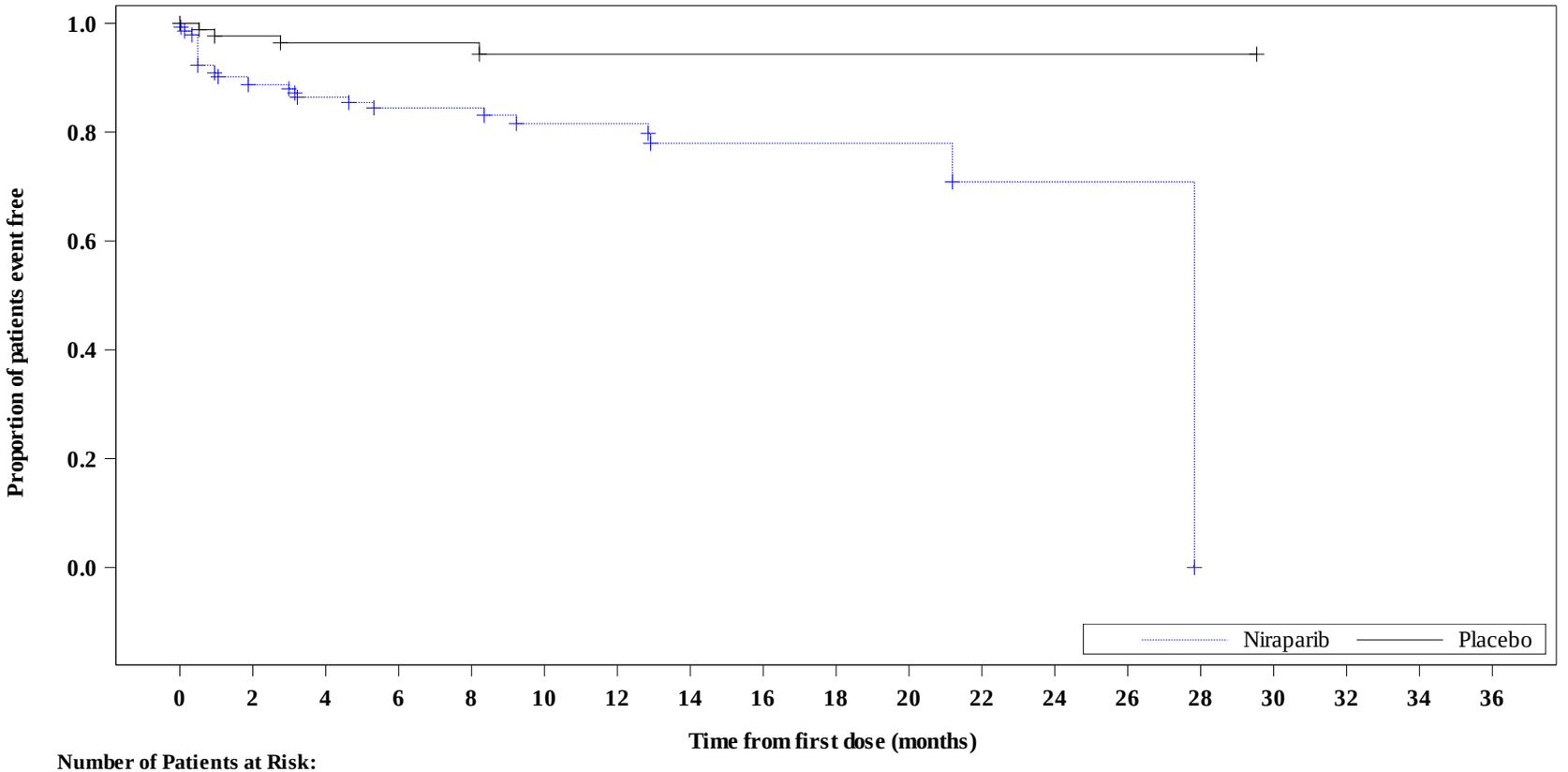

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 76 | 65 | 59 | 58 | 50 | 48 | 46 | 43 | 39 | 28 | 18 | 10 | 6 | 6 | 4 | 2 | 2 | 1 | 0 |
| Placebo | 31 | 26 | 24 | 22 | 20 | 18 | 13 | 7 | 4 | 3 | 3 | 1 | 1 | 0 | | | | | |

Figure 3.66
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)

Hypertension

BRCA Status: BRCAwt



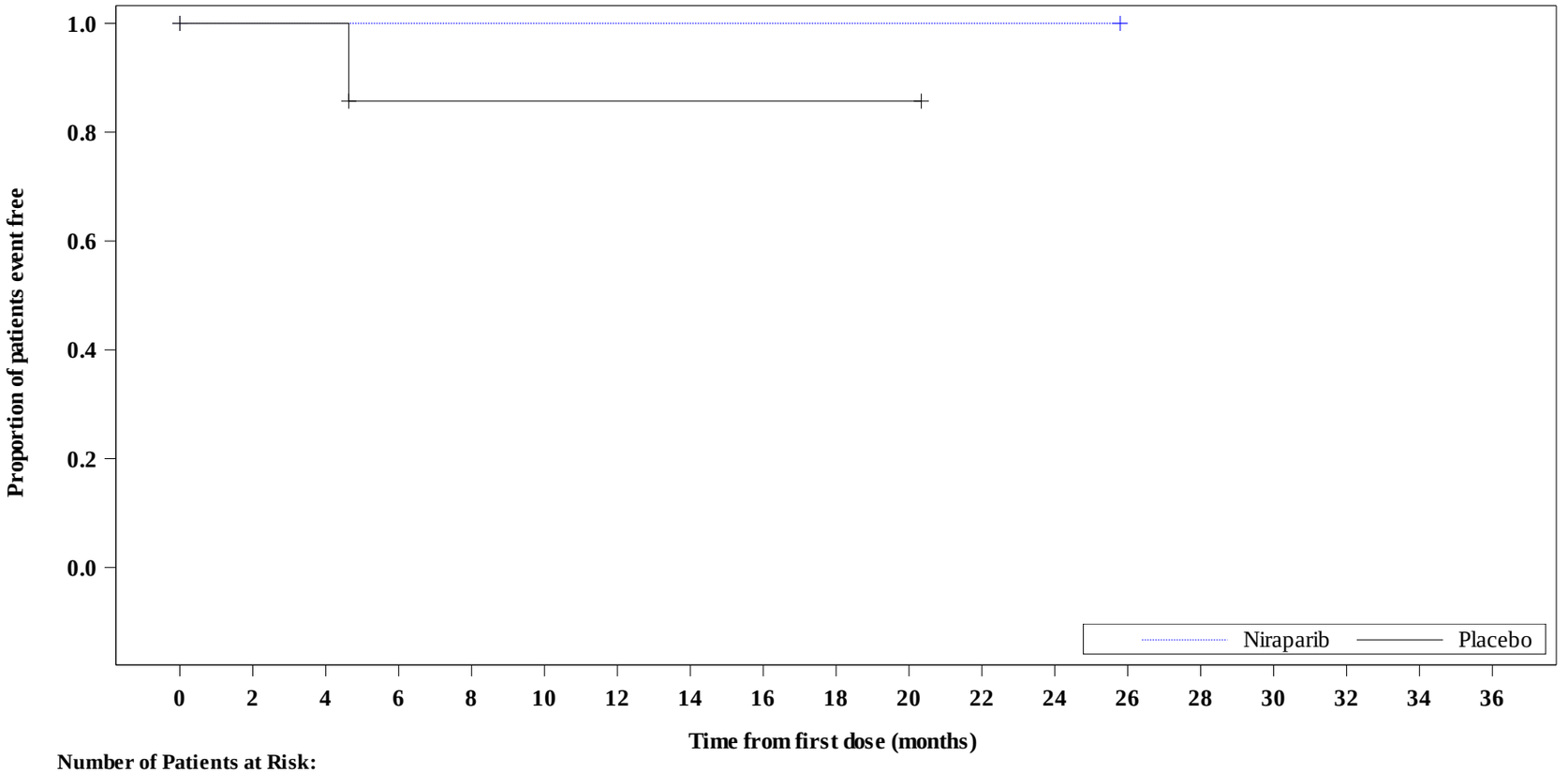

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 143 | 119 | 95 | 83 | 62 | 54 | 49 | 41 | 32 | 30 | 19 | 5 | 2 | 1 | 0 | |
| Placebo | 86 | 82 | 68 | 61 | 48 | 29 | 28 | 26 | 24 | 20 | 12 | 7 | 3 | 2 | 1 | 0 |

Figure 3.66
Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by BRCA Status (Safety-GVD Population)

Hypertension

BRCA Status: BRCAnd

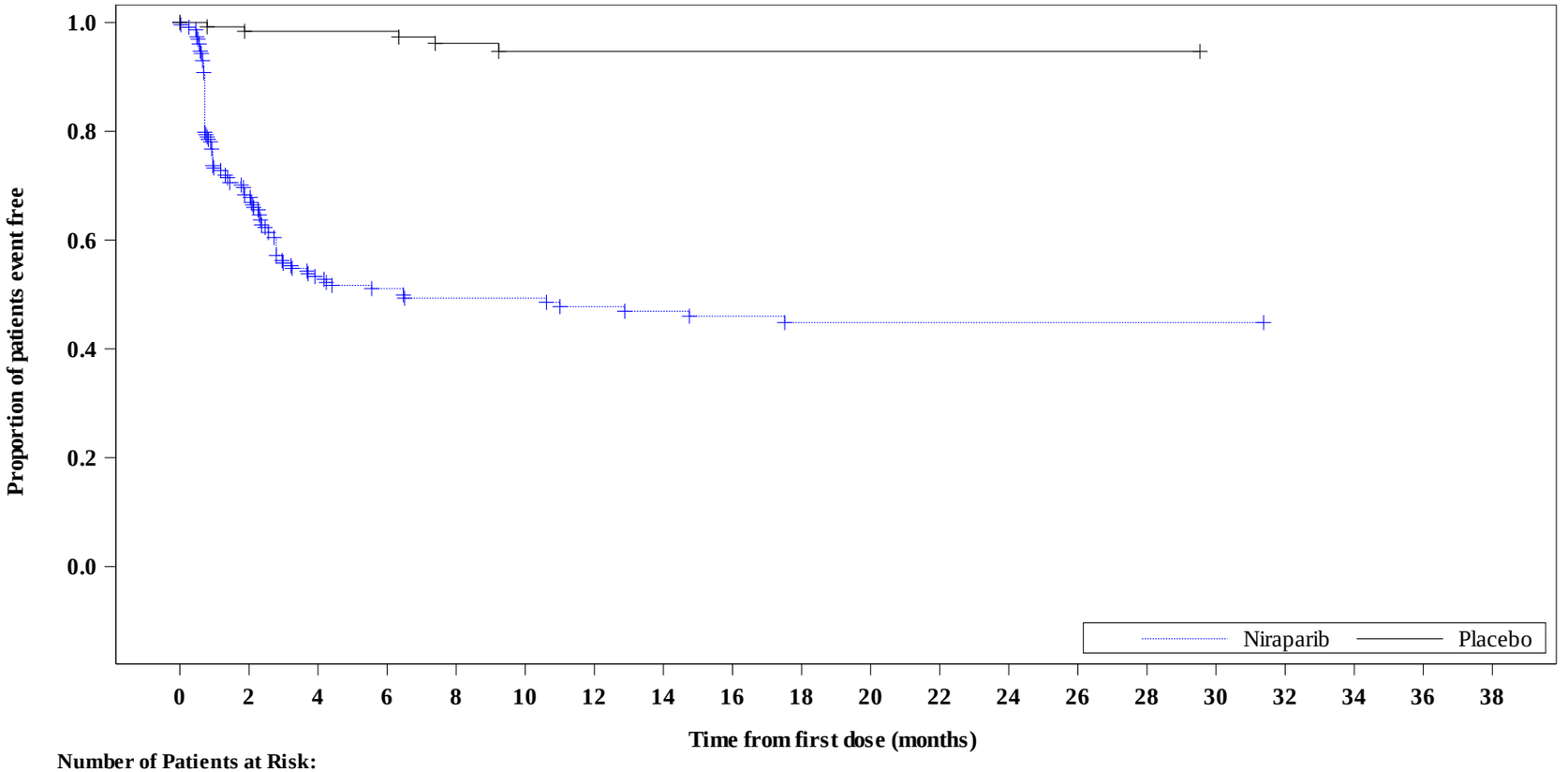



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 9 | 8 | 7 | 7 | 6 | 4 | 3 | 3 | 3 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 7 | 7 | 7 | 6 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 0 | | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Overall

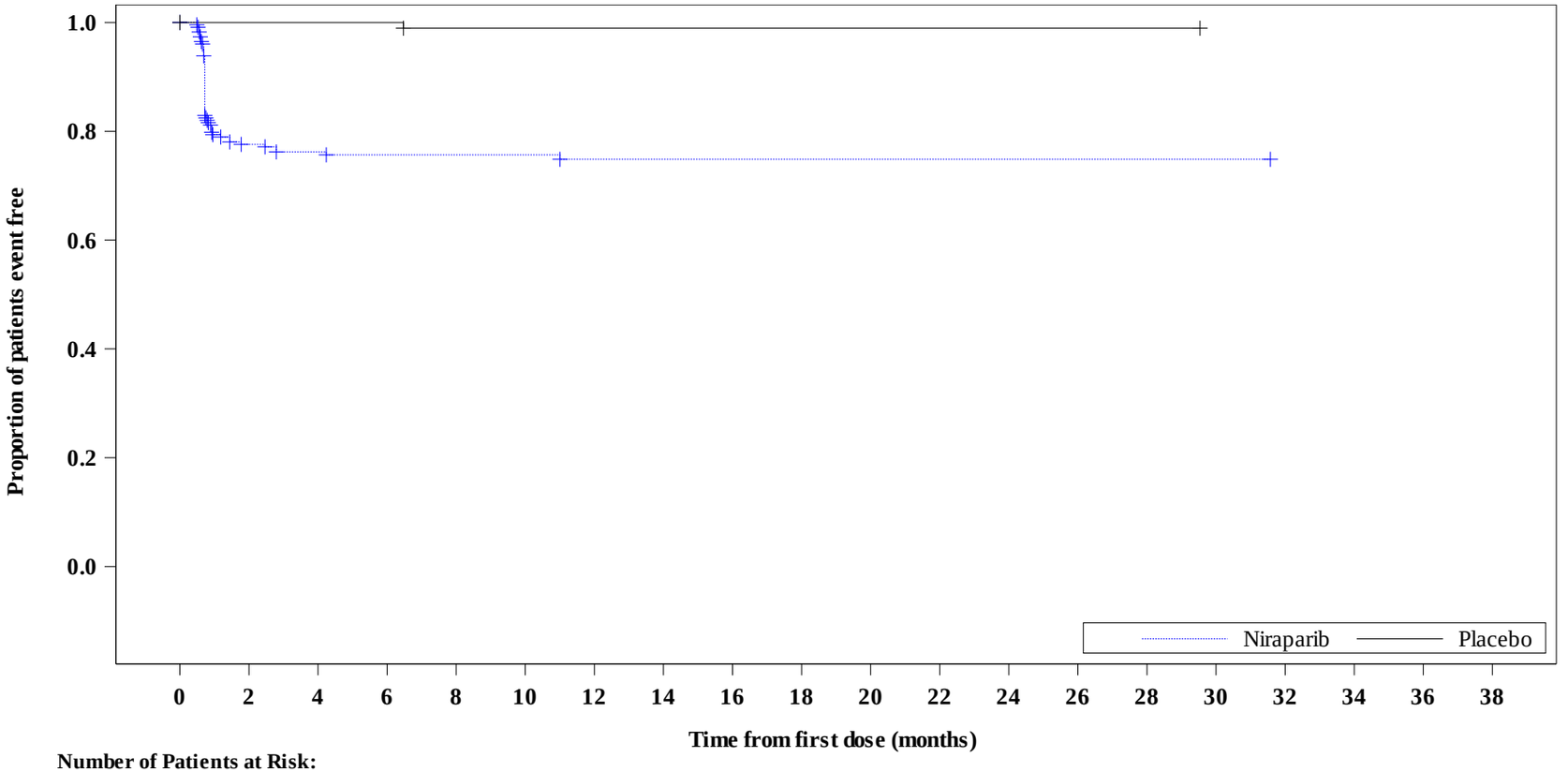



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 149 | 101 | 87 | 70 | 66 | 59 | 53 | 44 | 34 | 26 | 11 | 6 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 120 | 105 | 96 | 76 | 53 | 47 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Thrombocytopenia

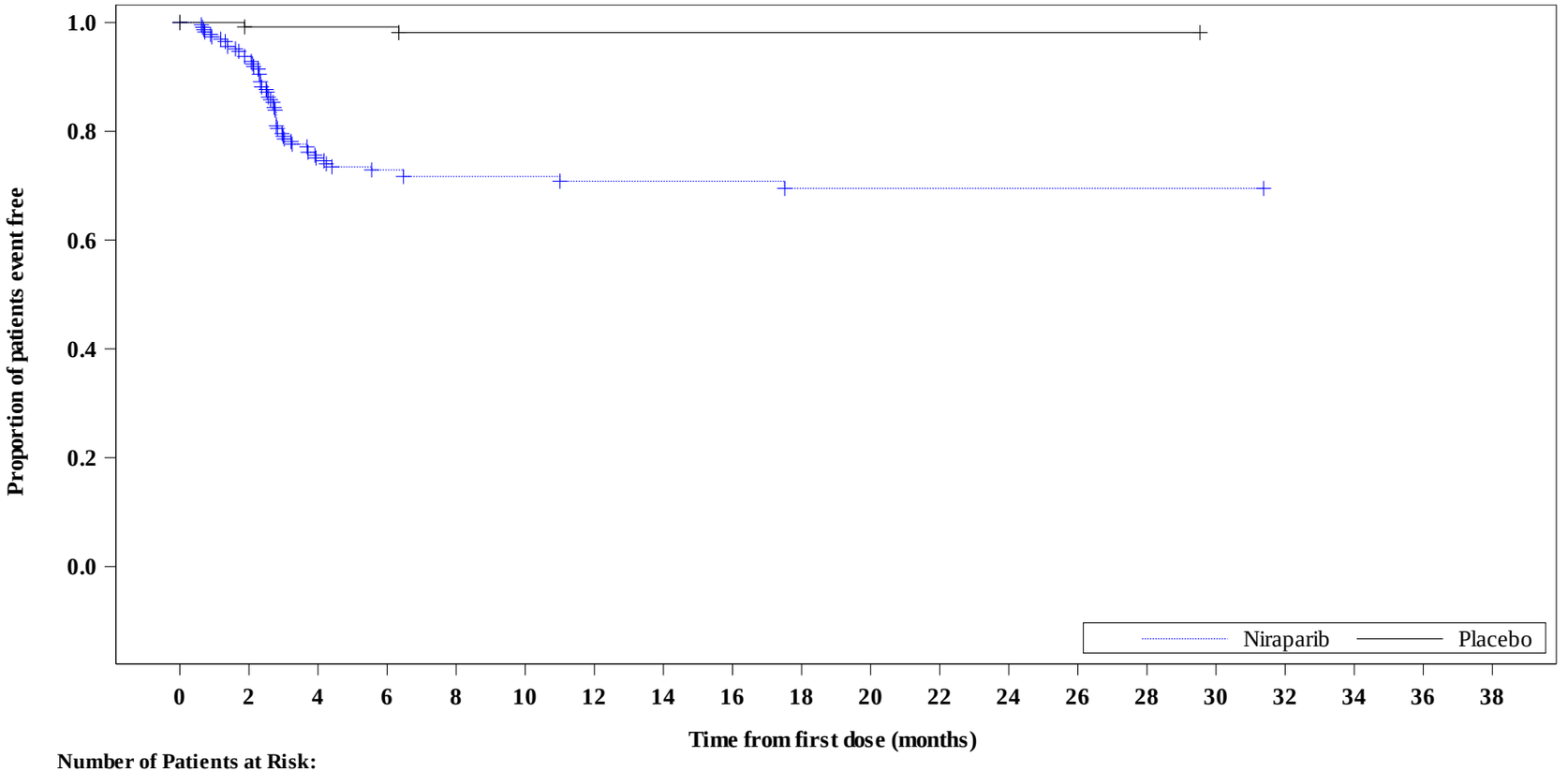



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 170 | 144 | 130 | 106 | 96 | 90 | 81 | 69 | 58 | 38 | 16 | 8 | 5 | 3 | 2 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Anemia

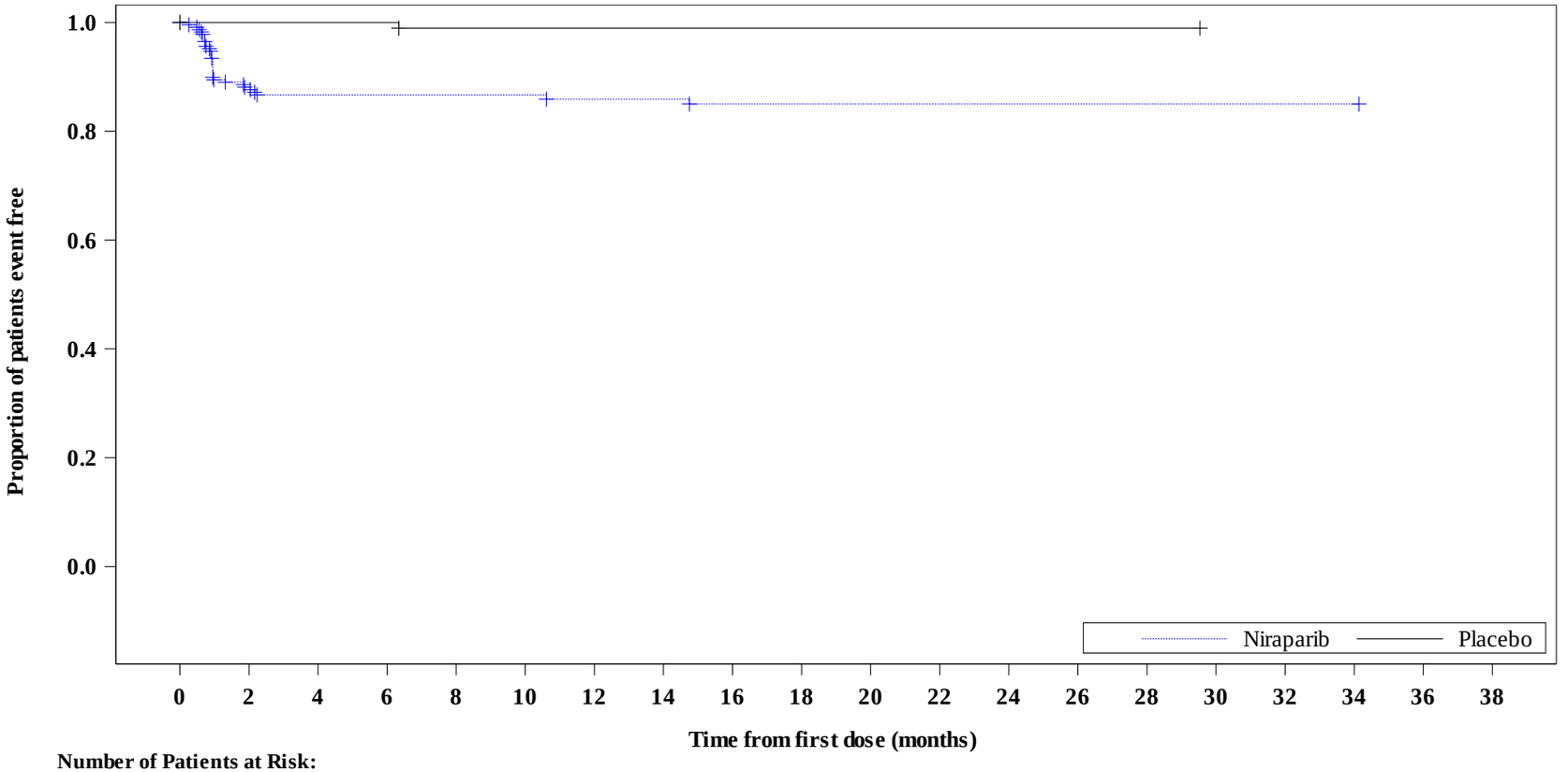



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 201 | 142 | 124 | 98 | 86 | 78 | 71 | 59 | 48 | 34 | 13 | 8 | 4 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Leukopenia

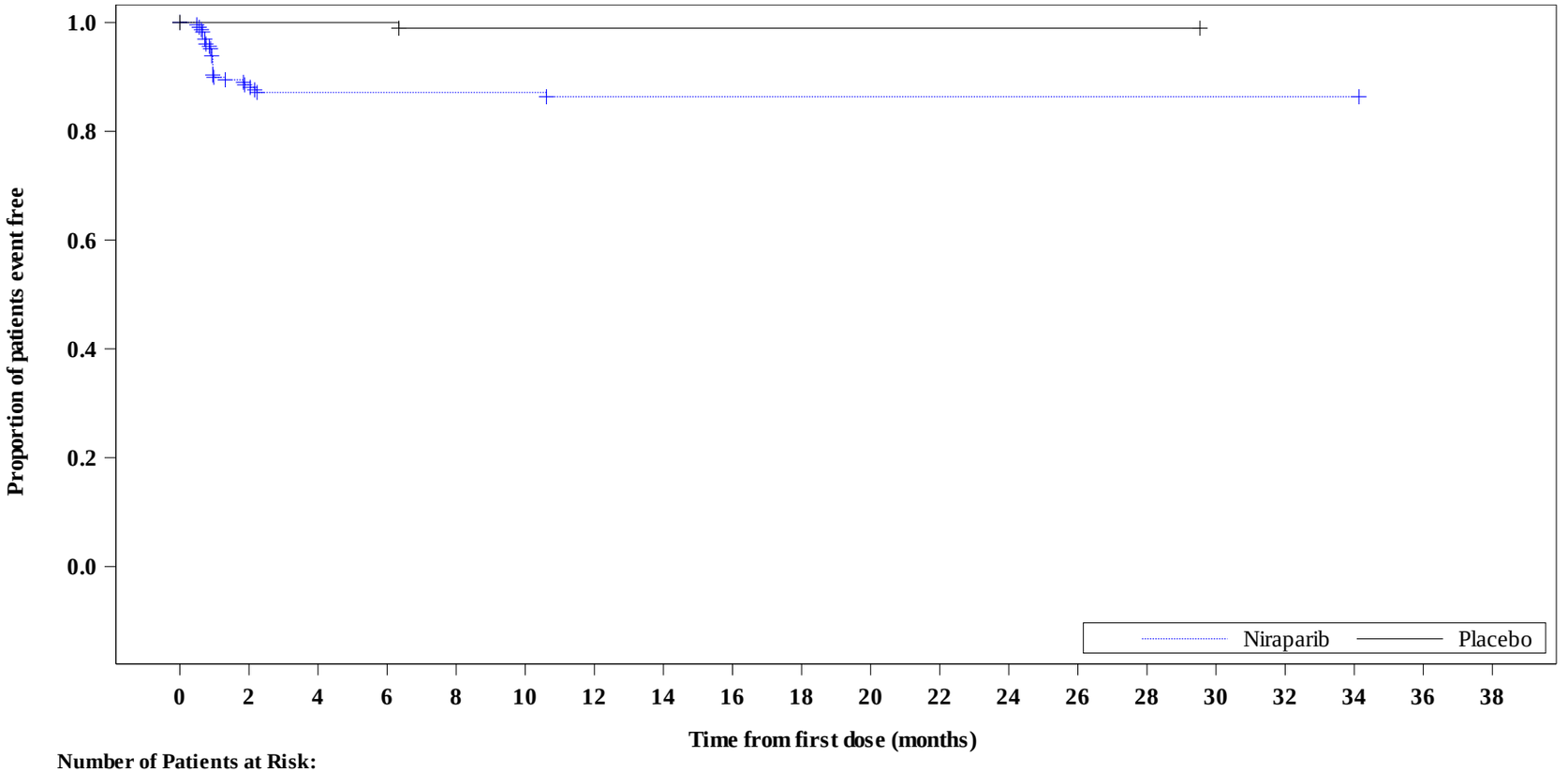



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 188 | 158 | 143 | 120 | 112 | 104 | 96 | 81 | 69 | 47 | 23 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Neutropenia

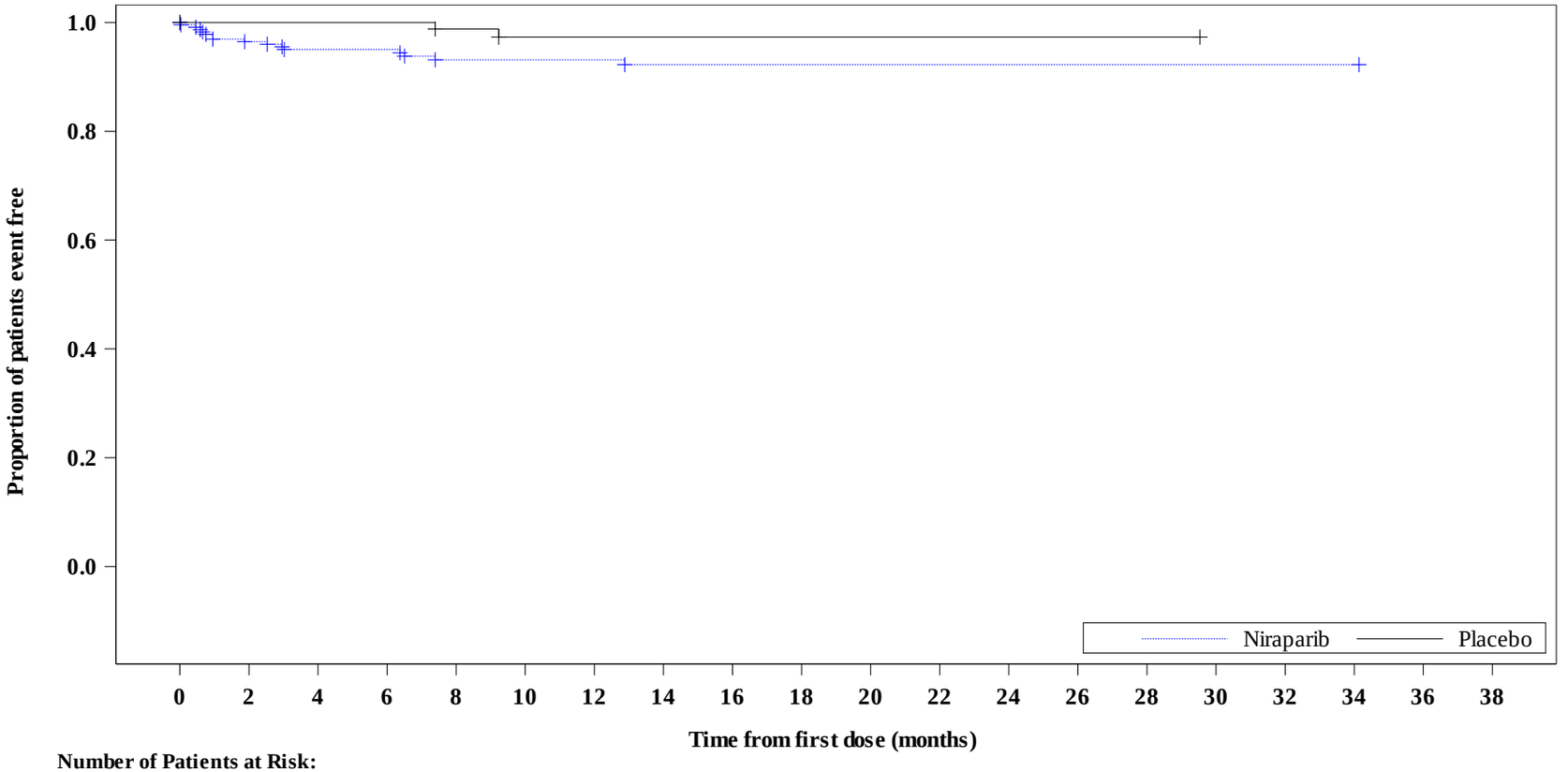



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 189 | 158 | 143 | 120 | 112 | 104 | 96 | 82 | 70 | 48 | 23 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Hypertension



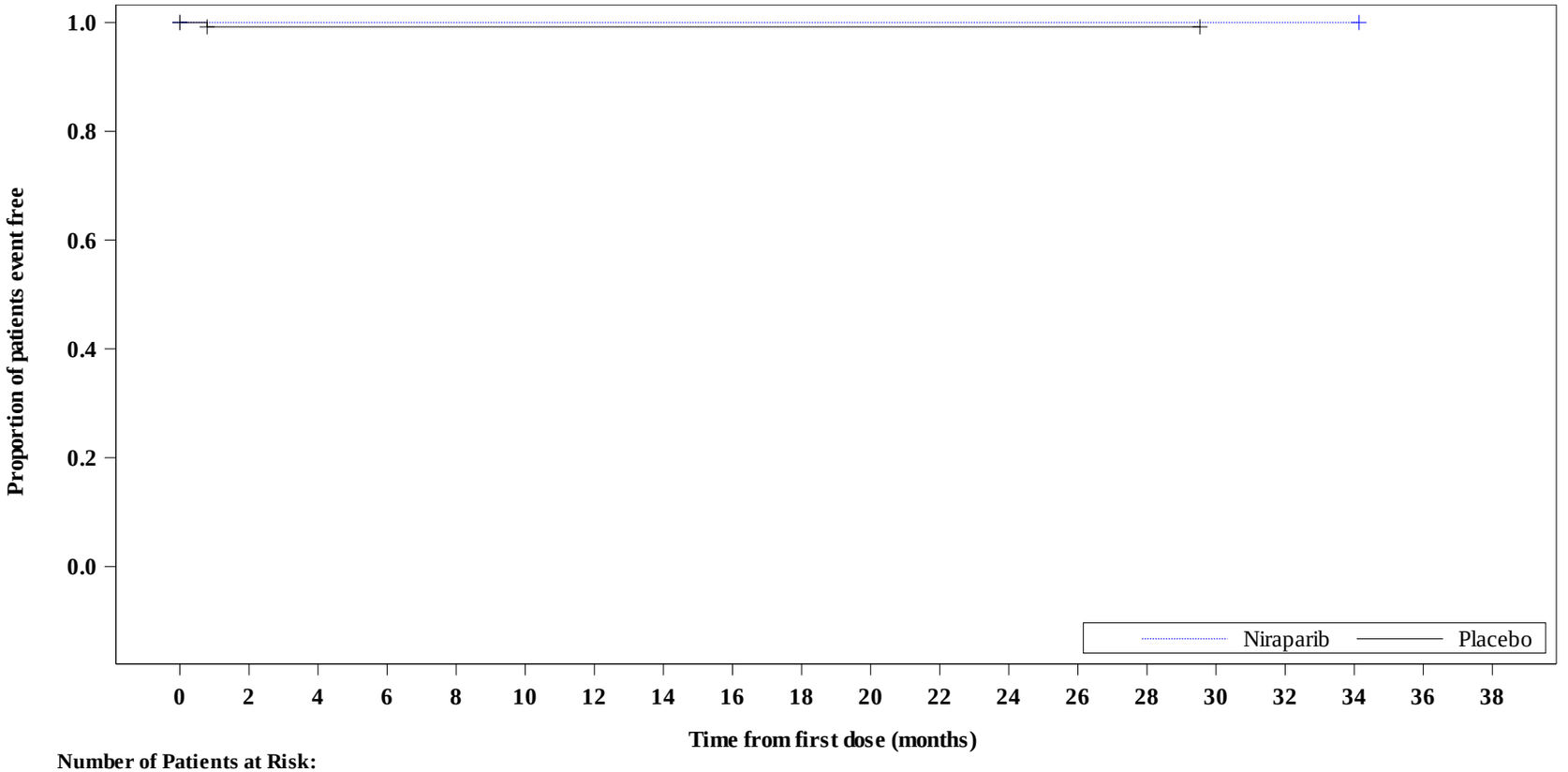

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 206 | 174 | 158 | 129 | 117 | 110 | 99 | 84 | 71 | 45 | 22 | 13 | 8 | 5 | 3 | 1 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 77 | 54 | 48 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.76

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

New malignancies other than MDS/AML

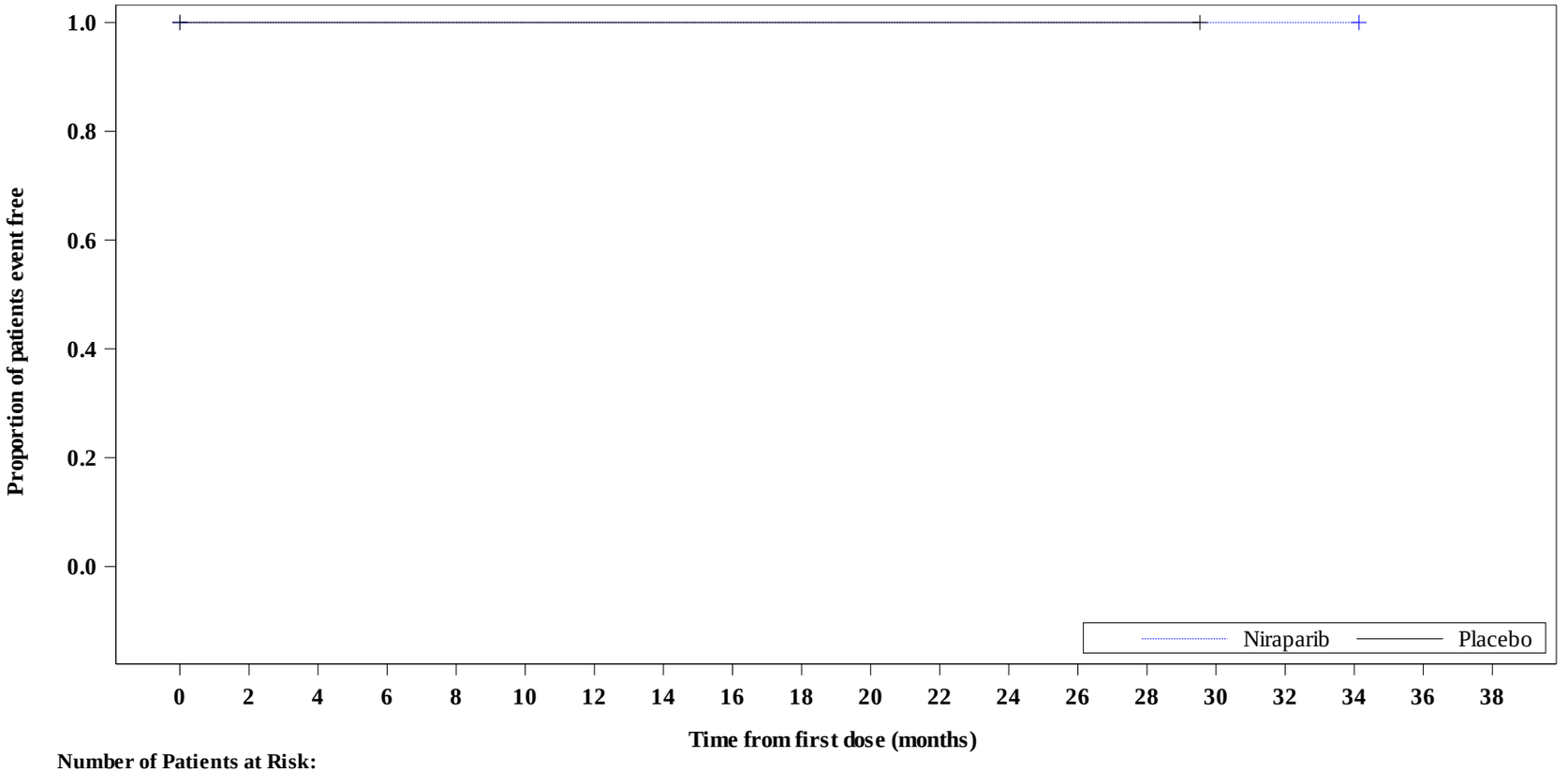



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 97 | 77 | 55 | 48 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Pneumonitis



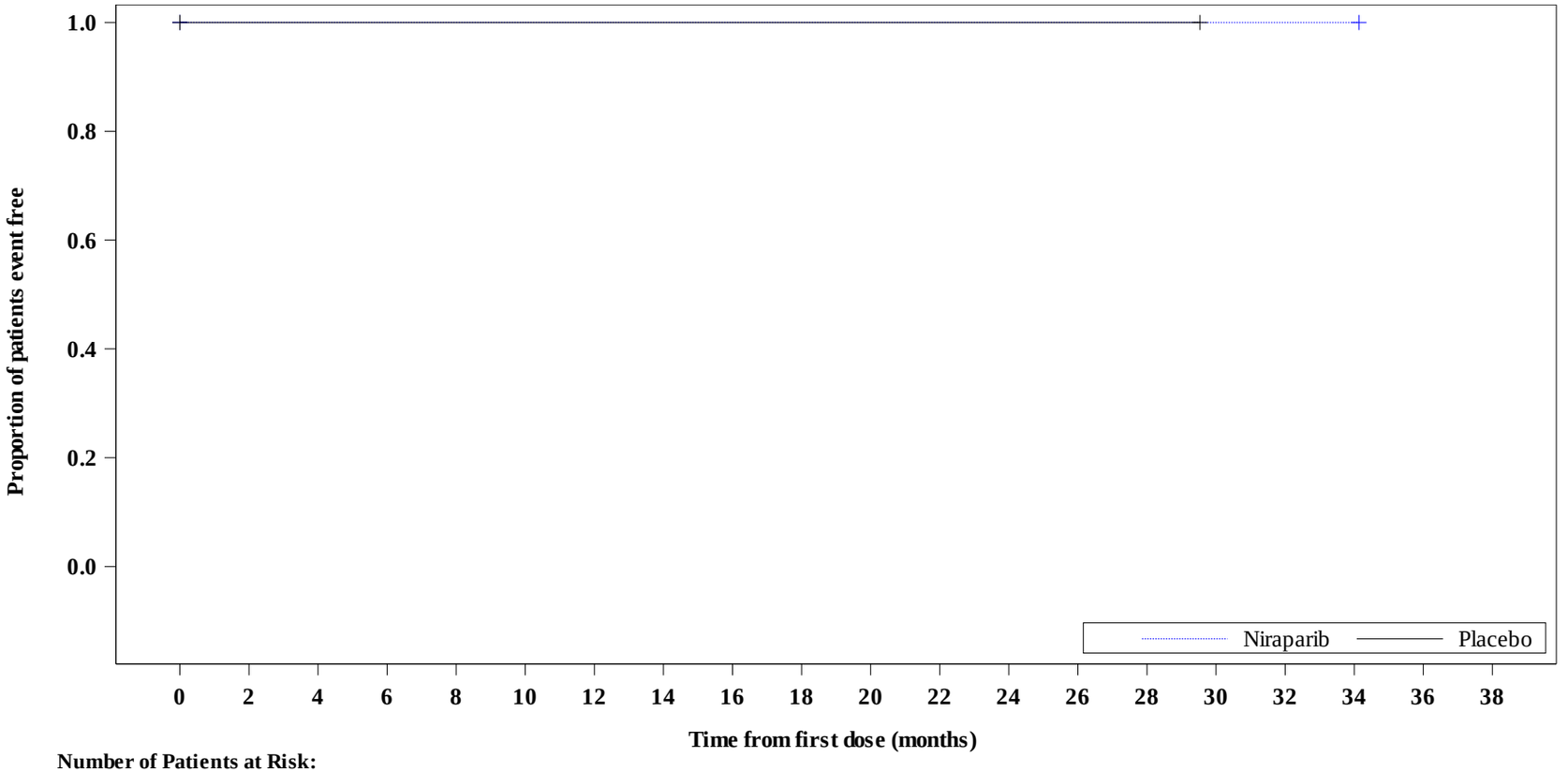

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.76

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Pancytopenia

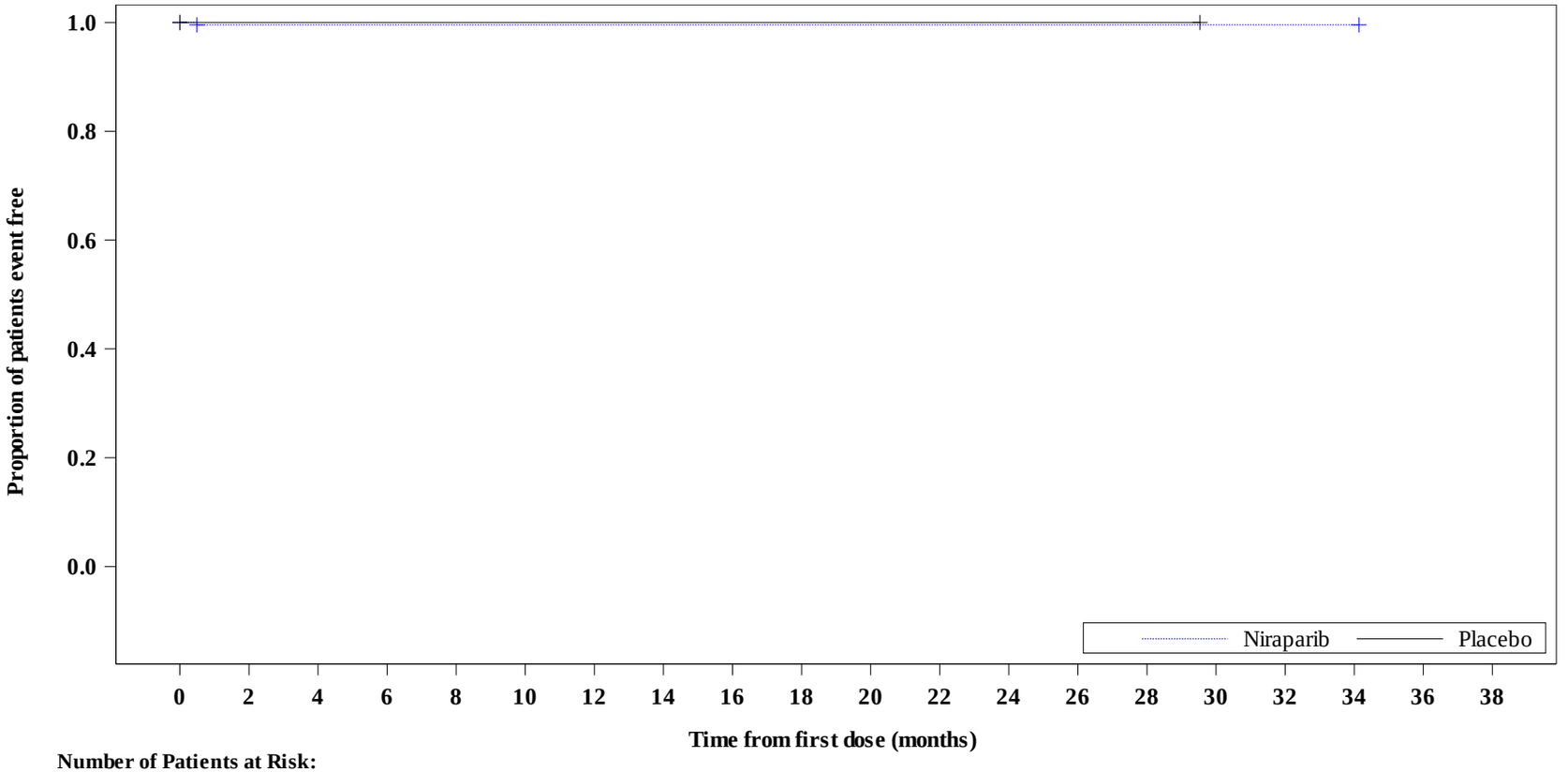



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Thromboemblic

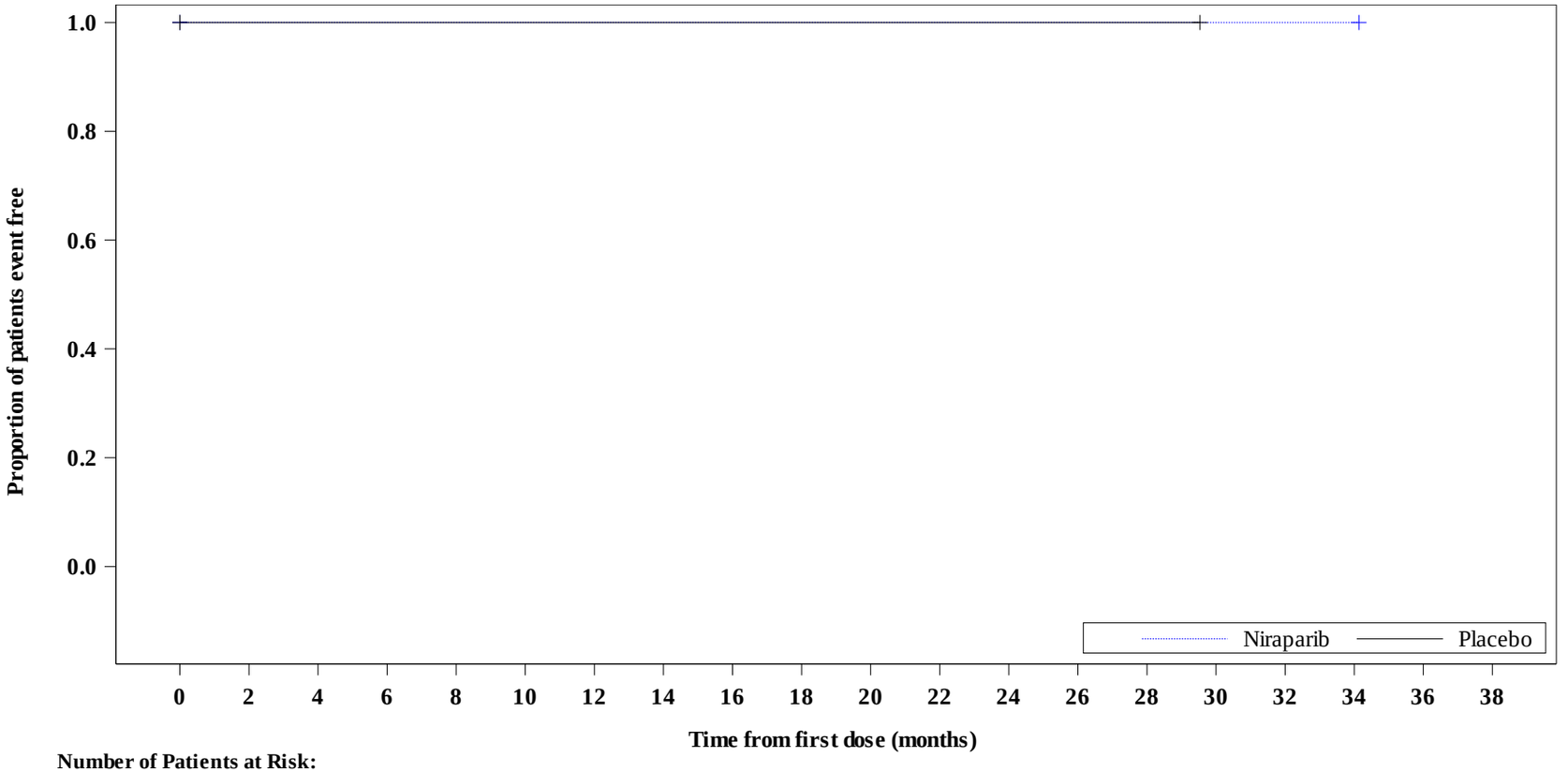



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 213 | 182 | 165 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

MDS/AML

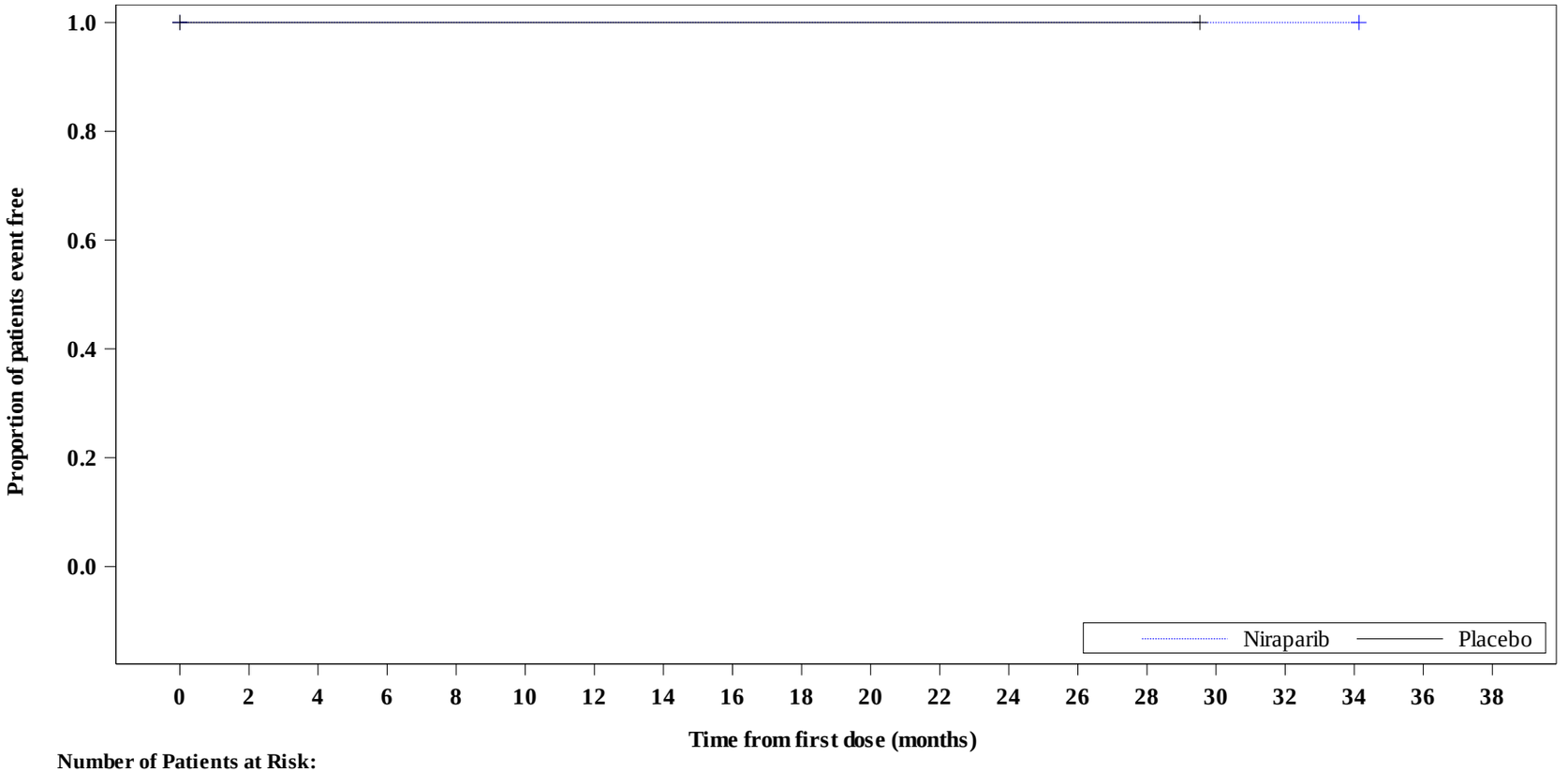



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.76
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Embryo-fetal toxicity



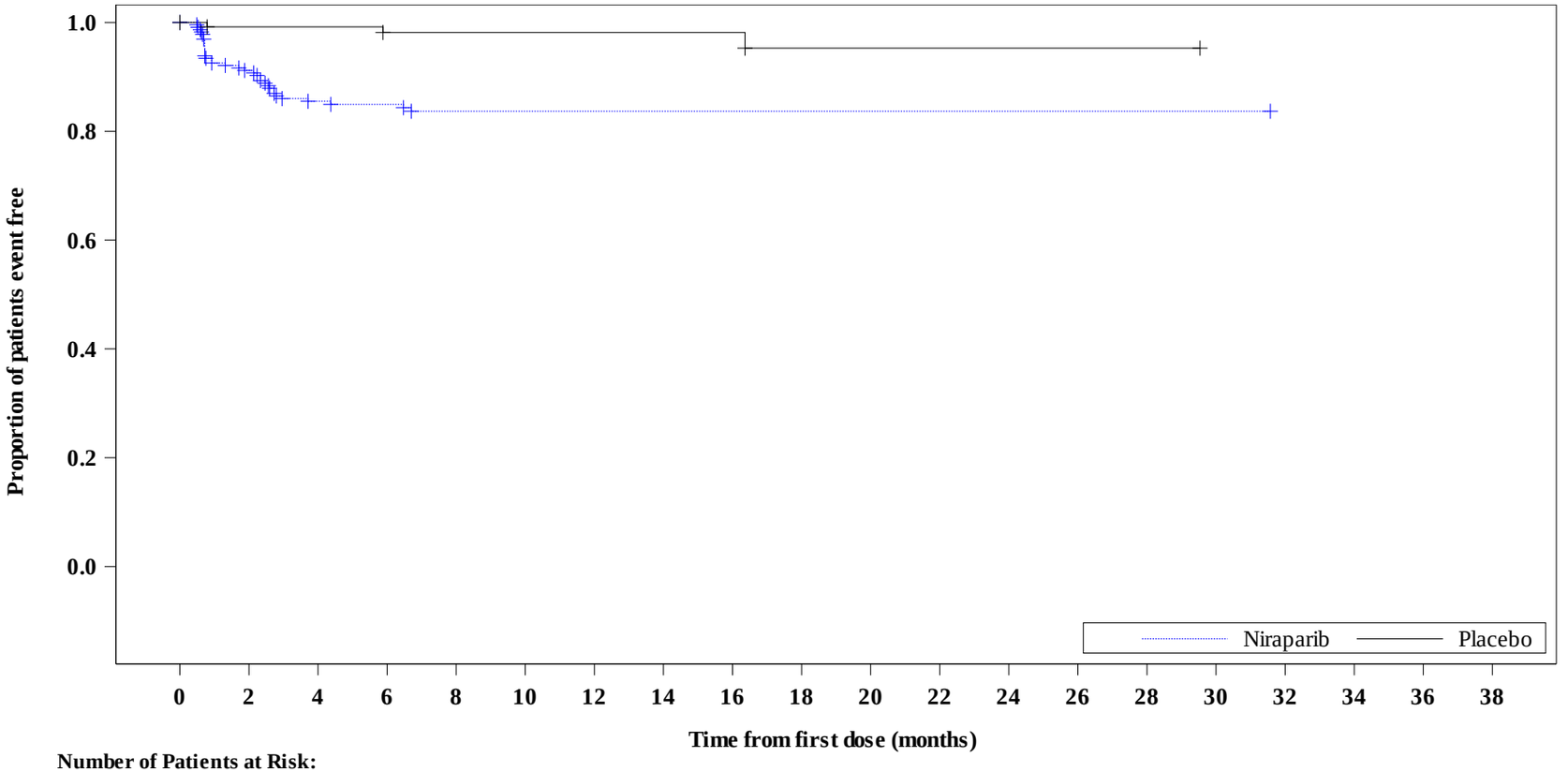

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Overall

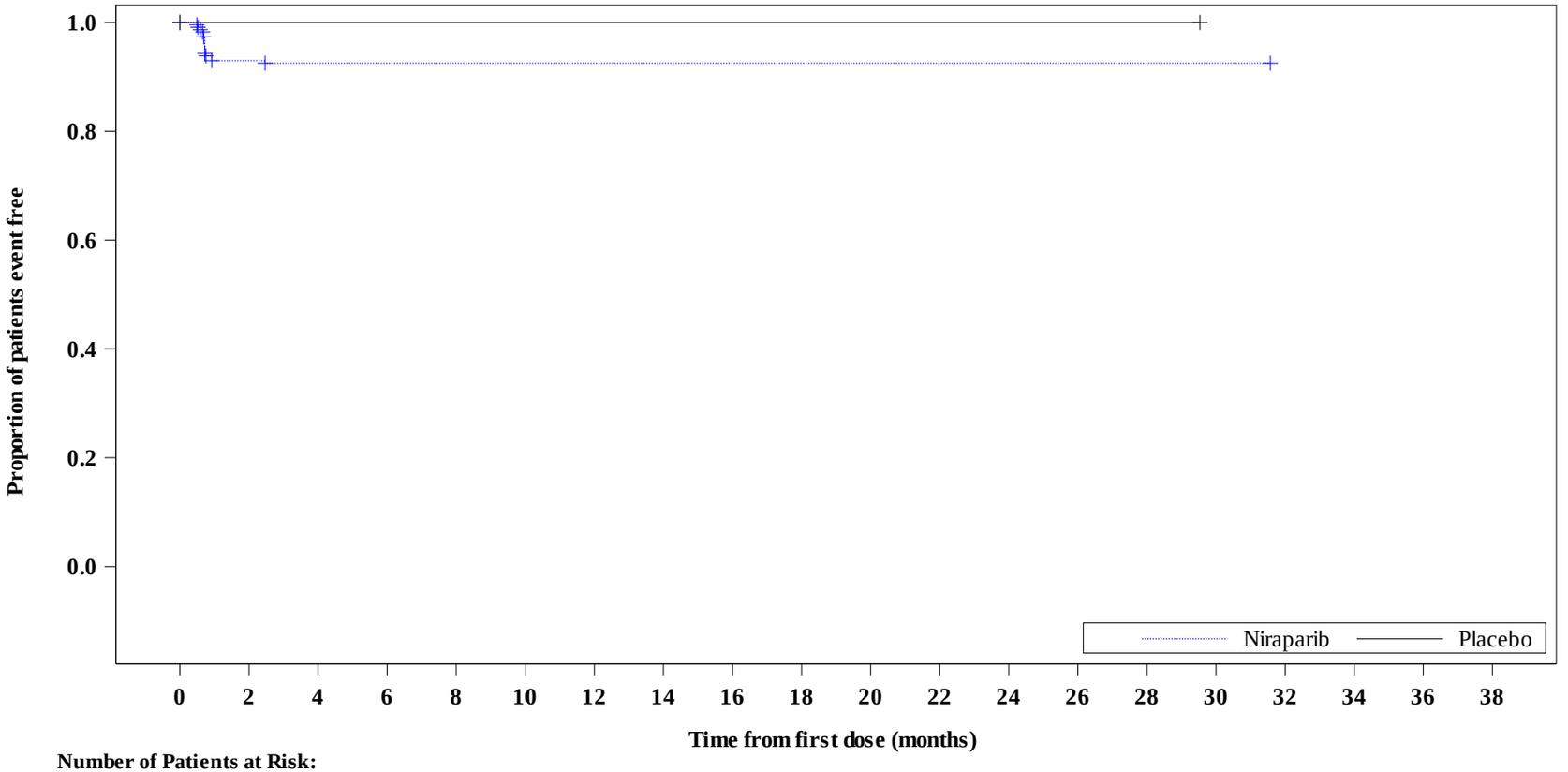



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 196 | 159 | 141 | 115 | 103 | 95 | 86 | 72 | 60 | 41 | 19 | 13 | 8 | 5 | 3 | 0 |
| Placebo | 124 | 121 | 106 | 96 | 76 | 55 | 48 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.126
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Thrombocytopenia

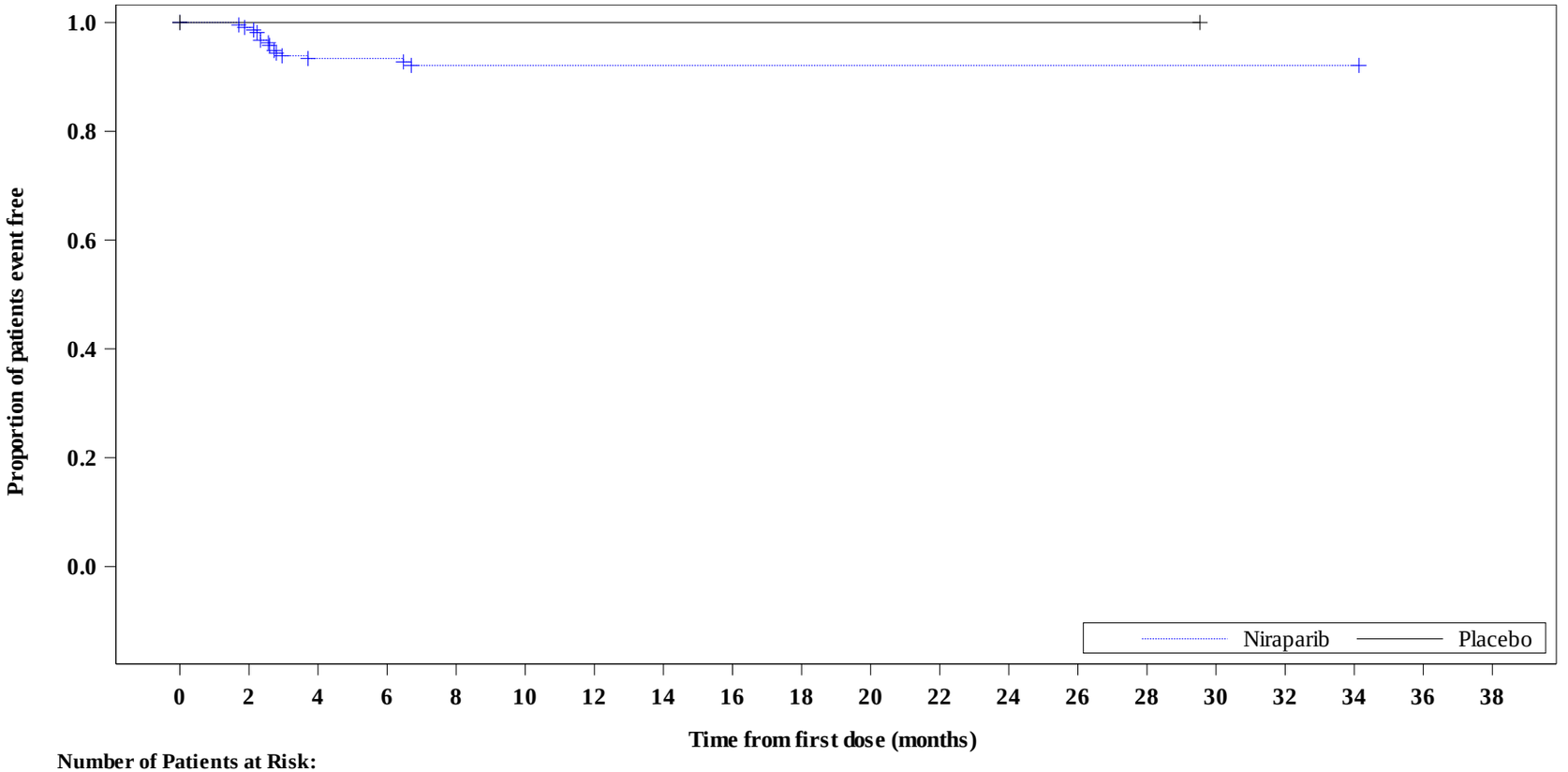



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 200 | 171 | 154 | 127 | 115 | 107 | 97 | 82 | 69 | 45 | 21 | 13 | 8 | 5 | 3 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.126
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Anemia

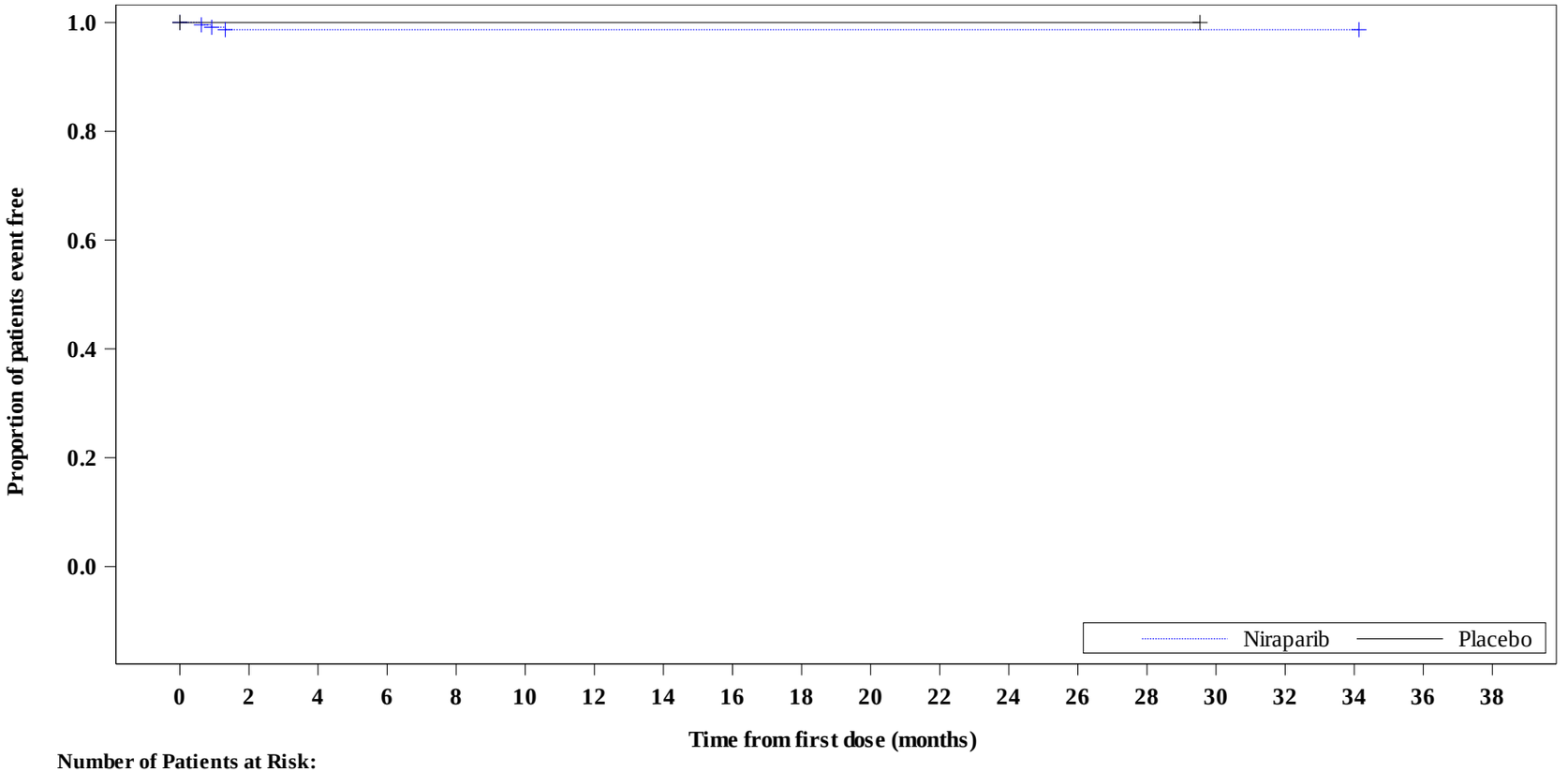



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 172 | 155 | 125 | 111 | 103 | 94 | 79 | 67 | 46 | 22 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Leukopenia

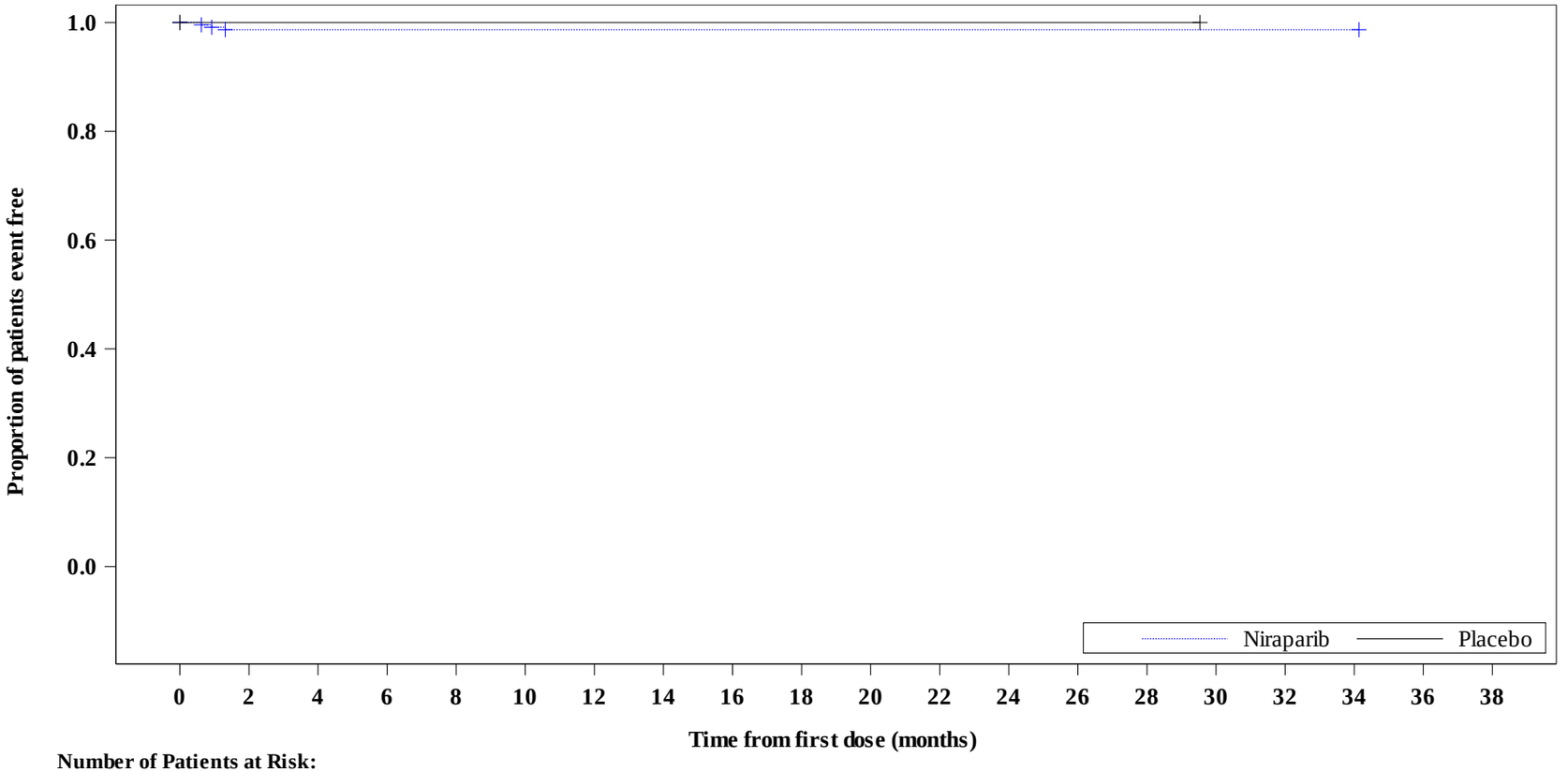



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 211 | 181 | 164 | 136 | 122 | 114 | 104 | 88 | 75 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Neutropenia

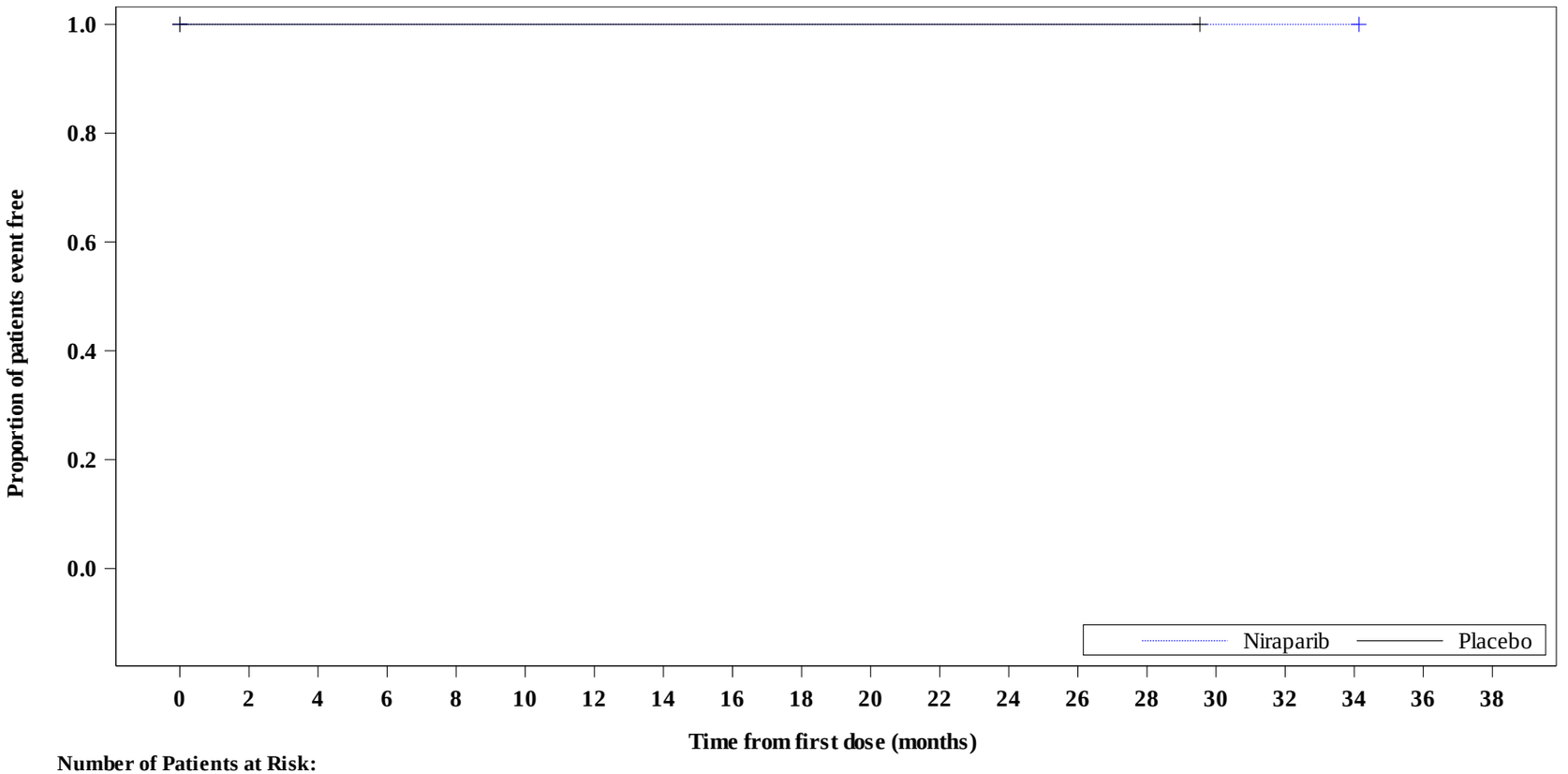



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 211 | 181 | 164 | 136 | 122 | 114 | 104 | 88 | 75 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Hypertension



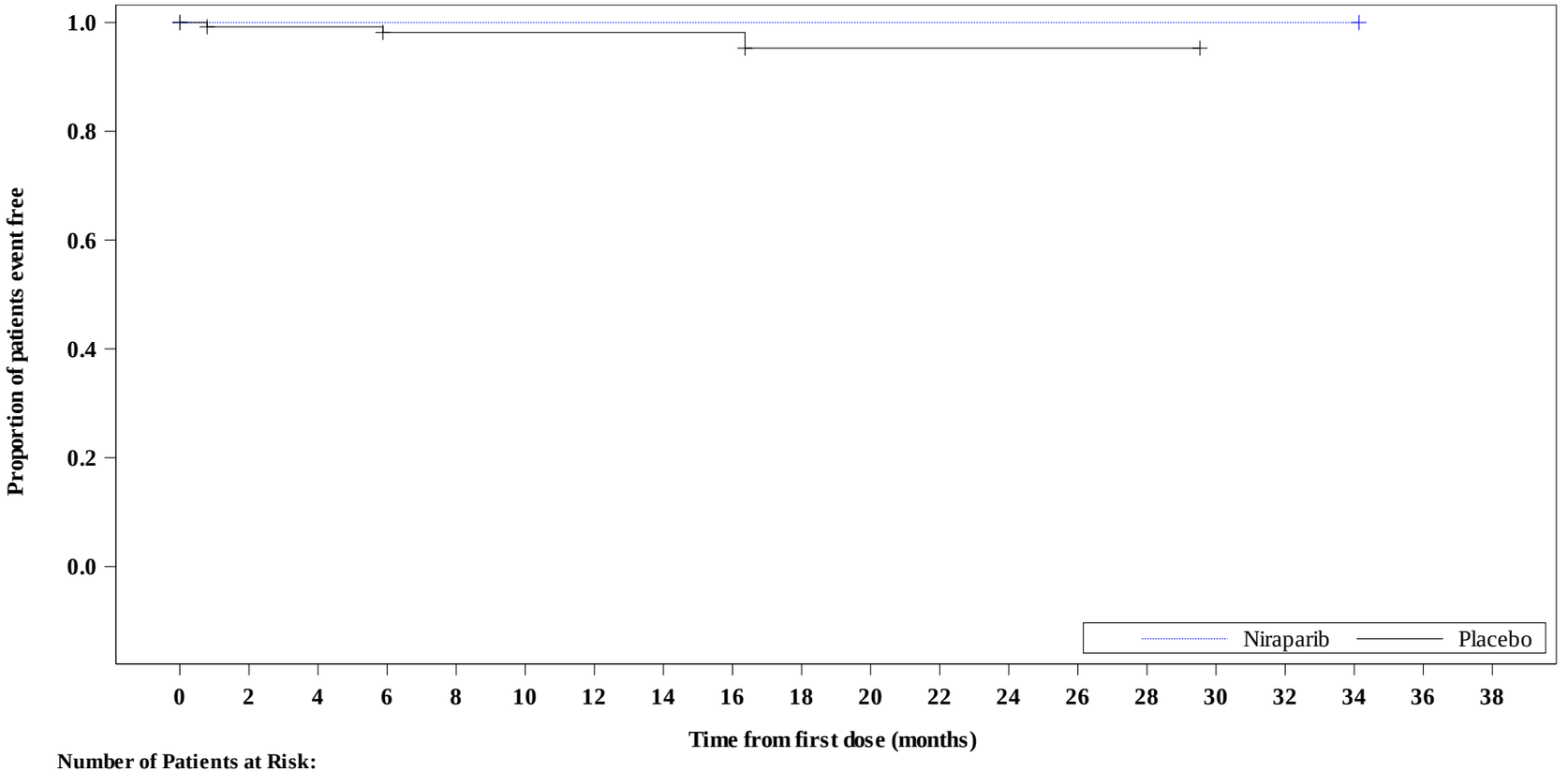

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

New malignancies other than MDS/AML

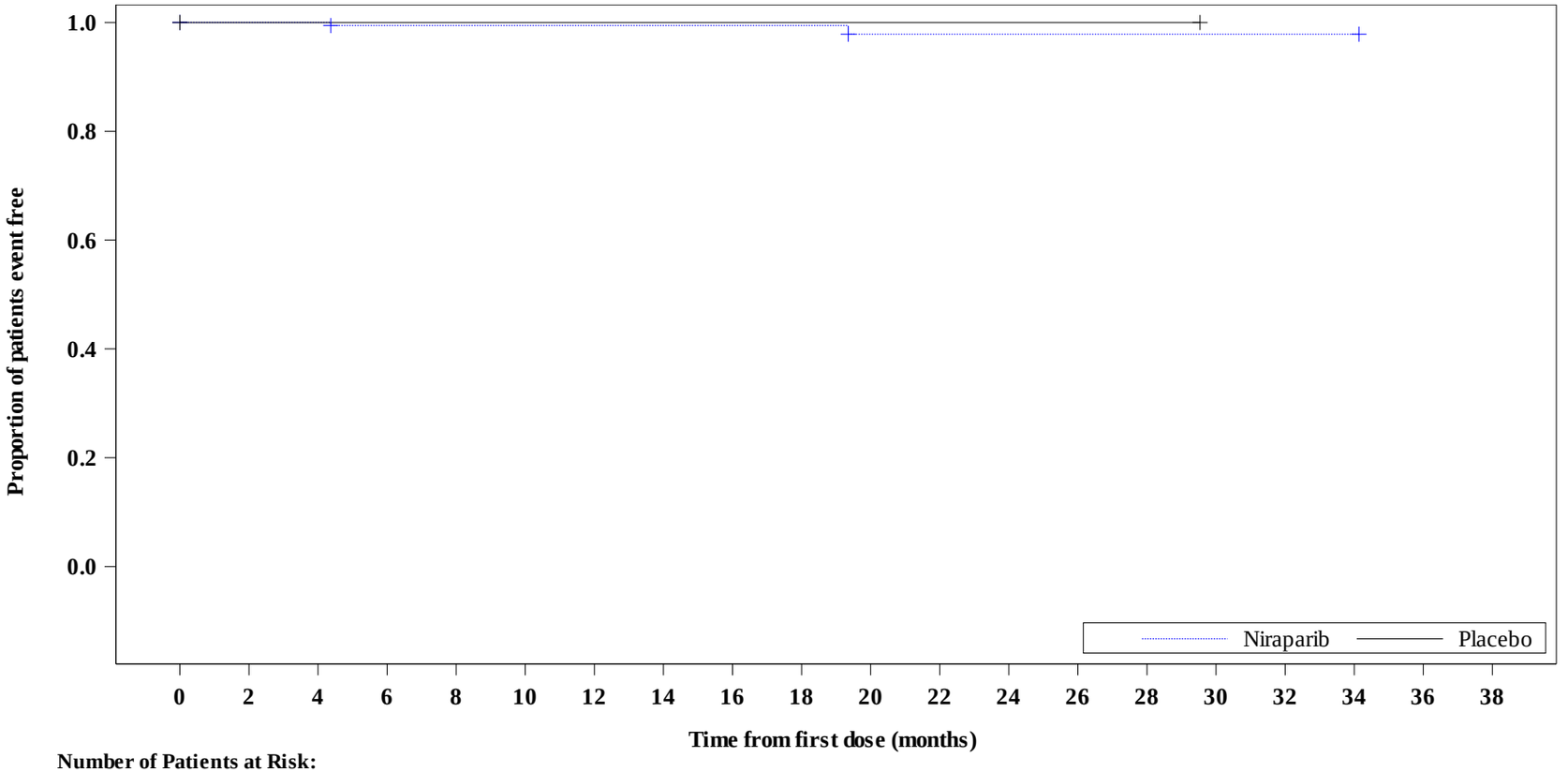



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 96 | 76 | 55 | 48 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126
Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Pneumonitis



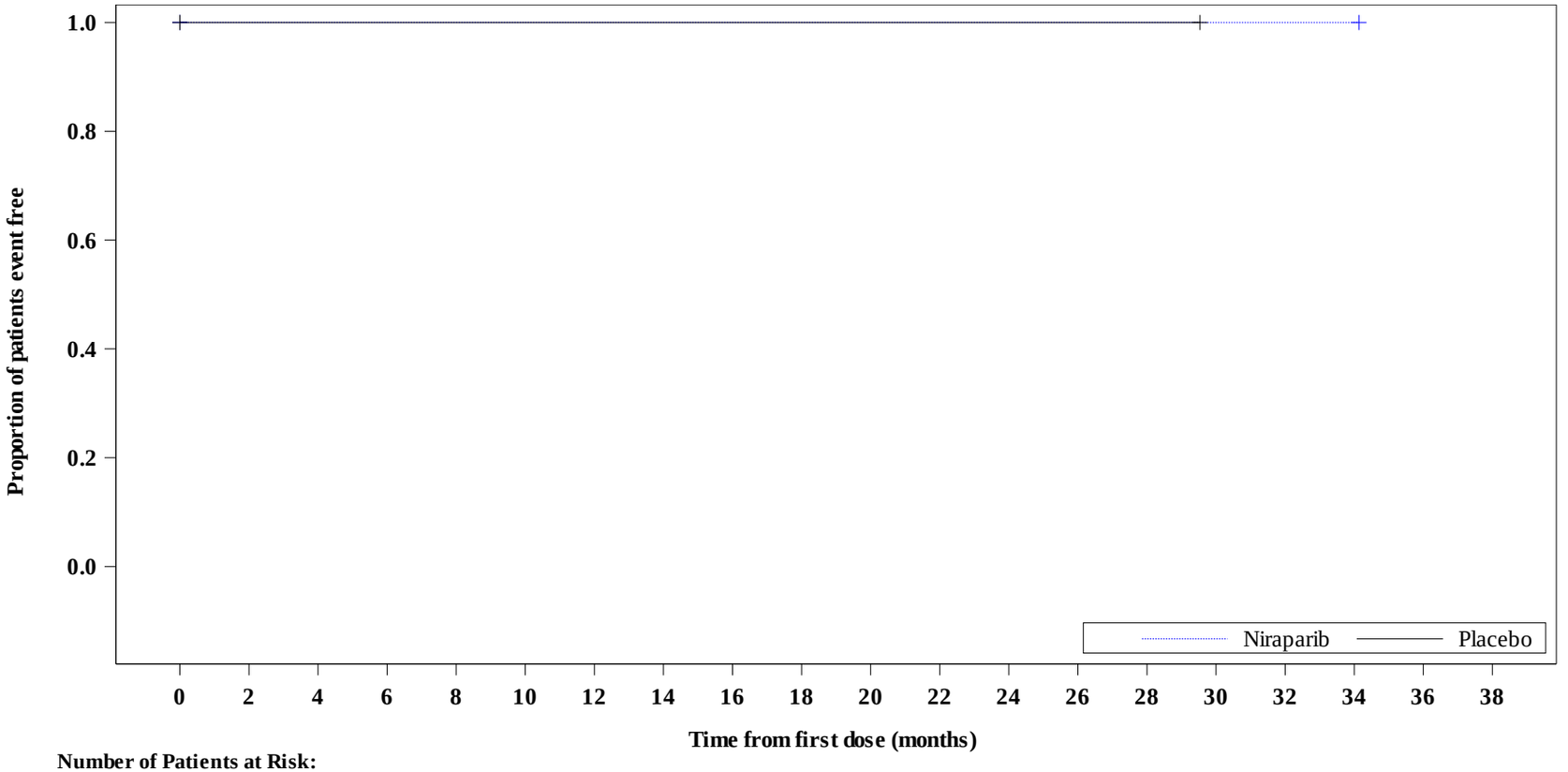

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 165 | 137 | 123 | 115 | 105 | 89 | 76 | 49 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Pancytopenia



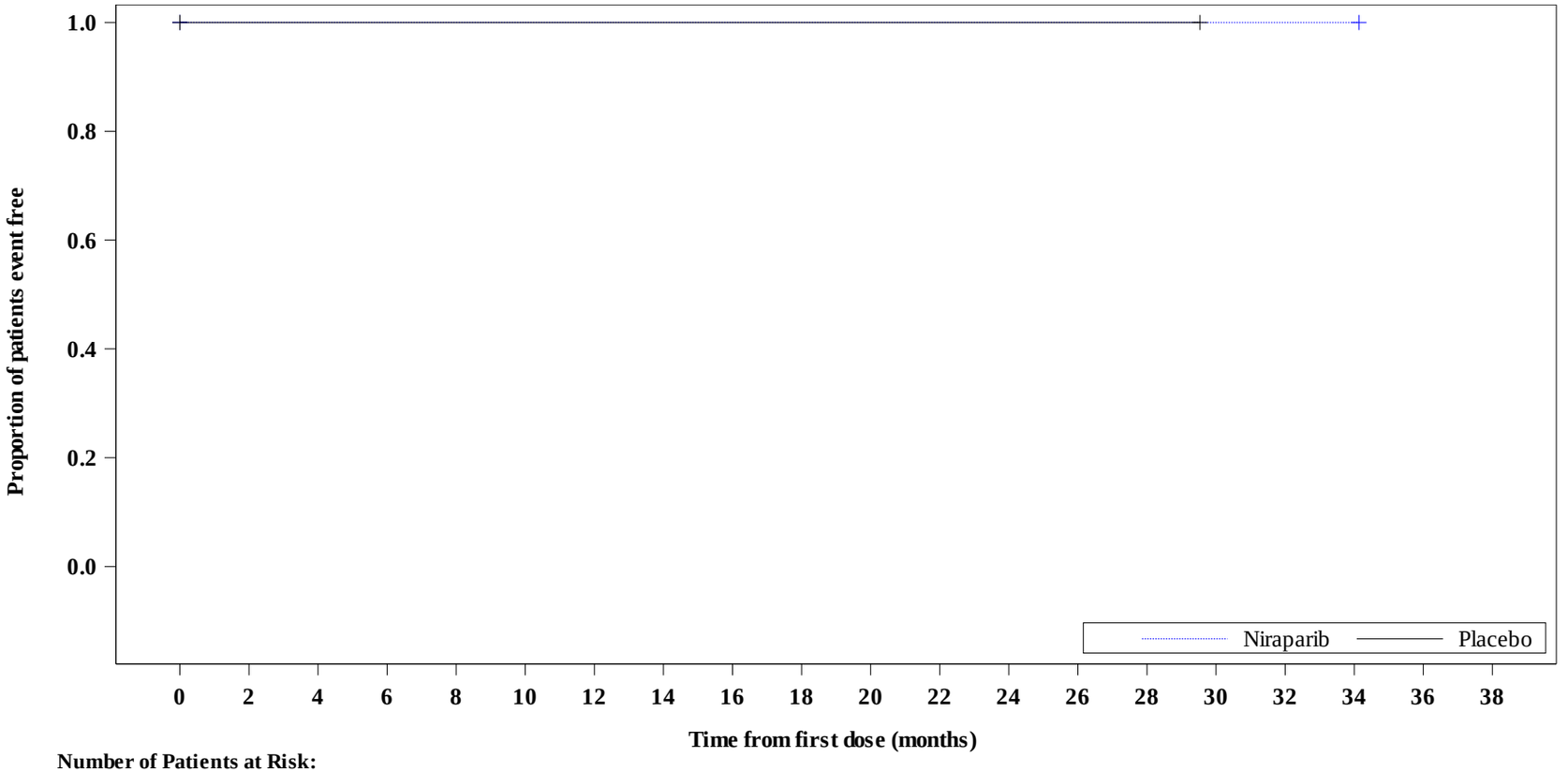

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Thromboemblic



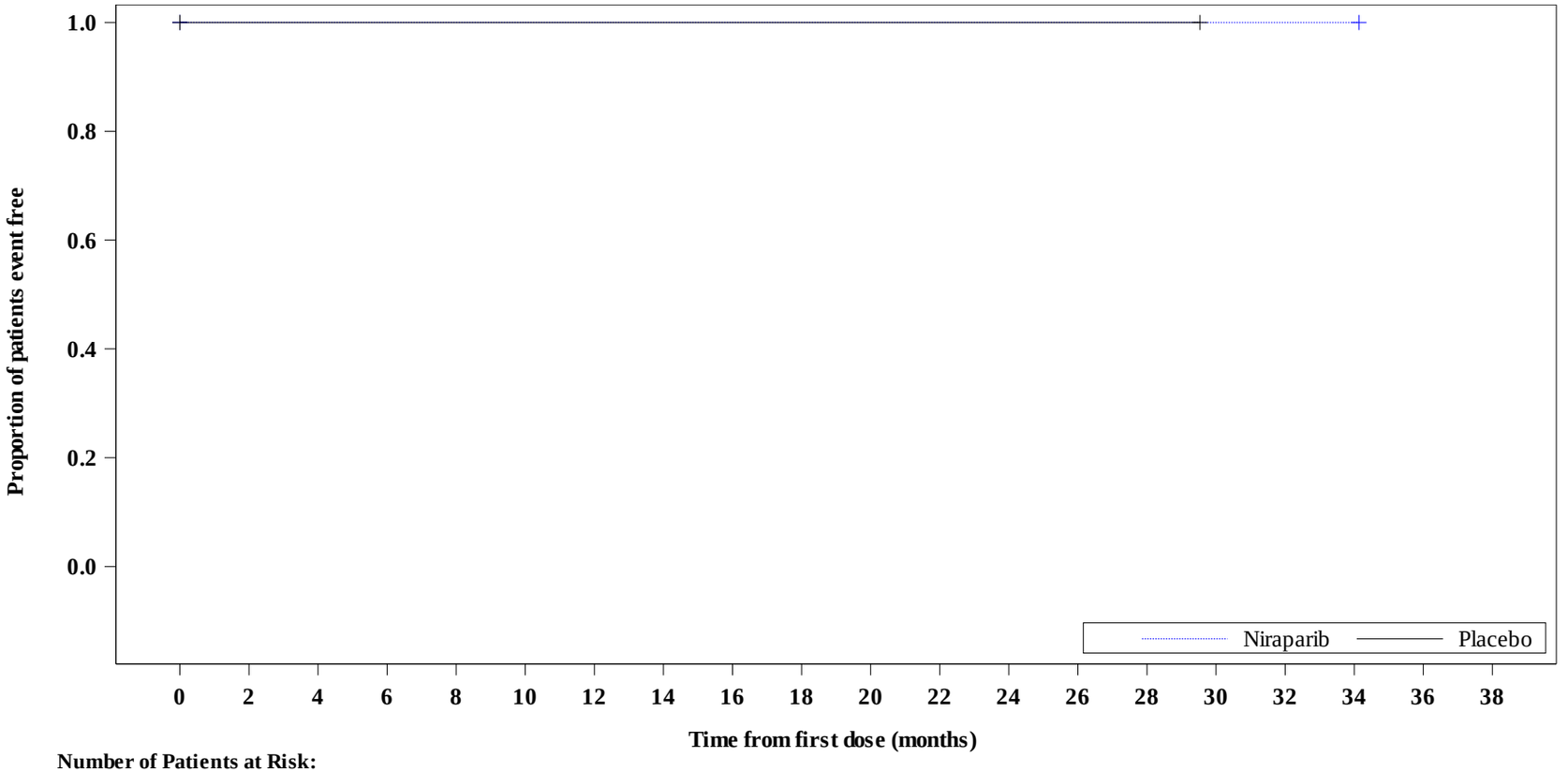

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

MDS/AML



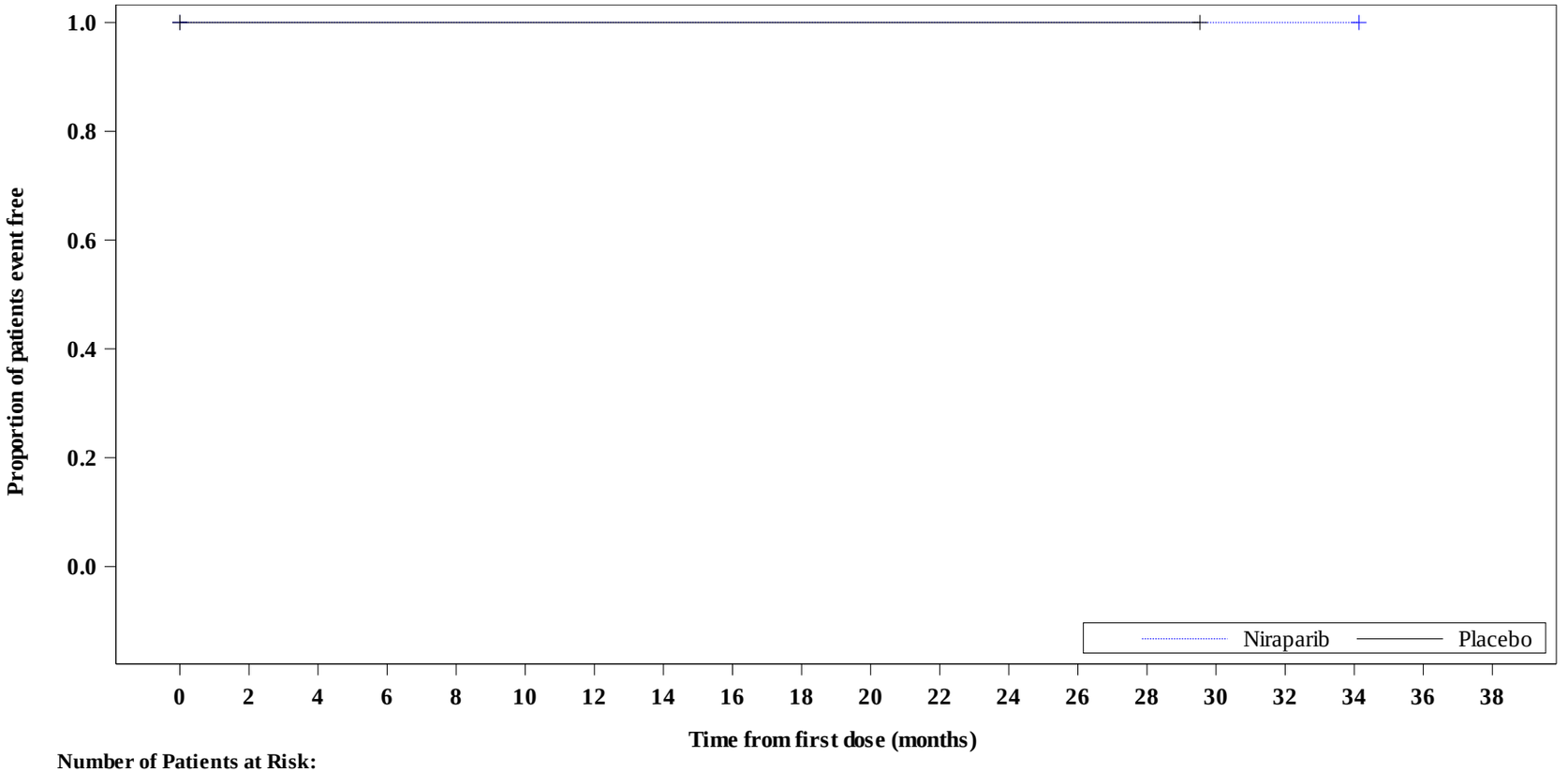

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.126

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Safety-GVD Population)

Embryo-fetal toxicity

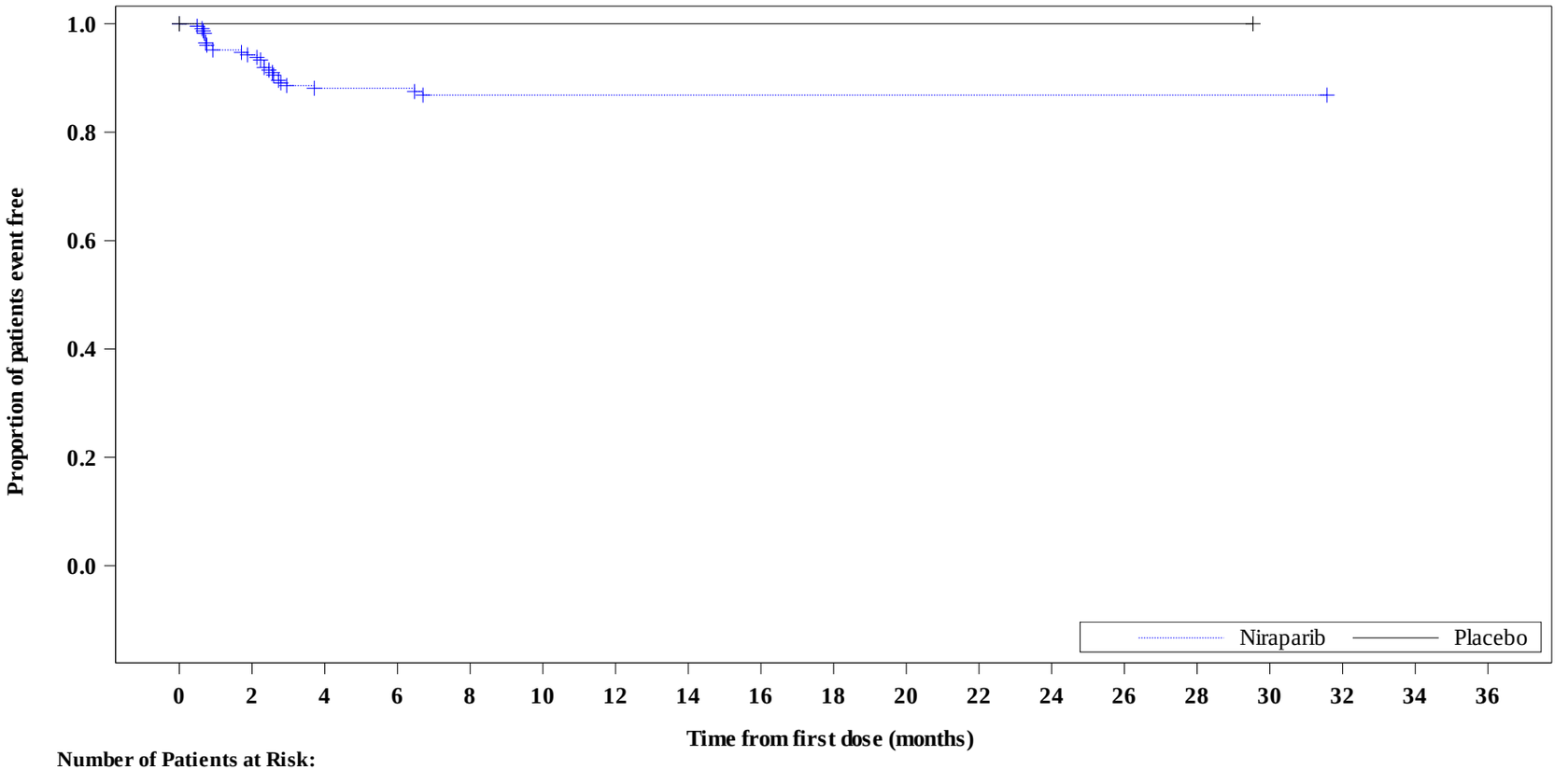



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 214 | 183 | 166 | 137 | 123 | 115 | 105 | 89 | 76 | 50 | 24 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.116

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)
SOC: Blood and lymphatic system disorders

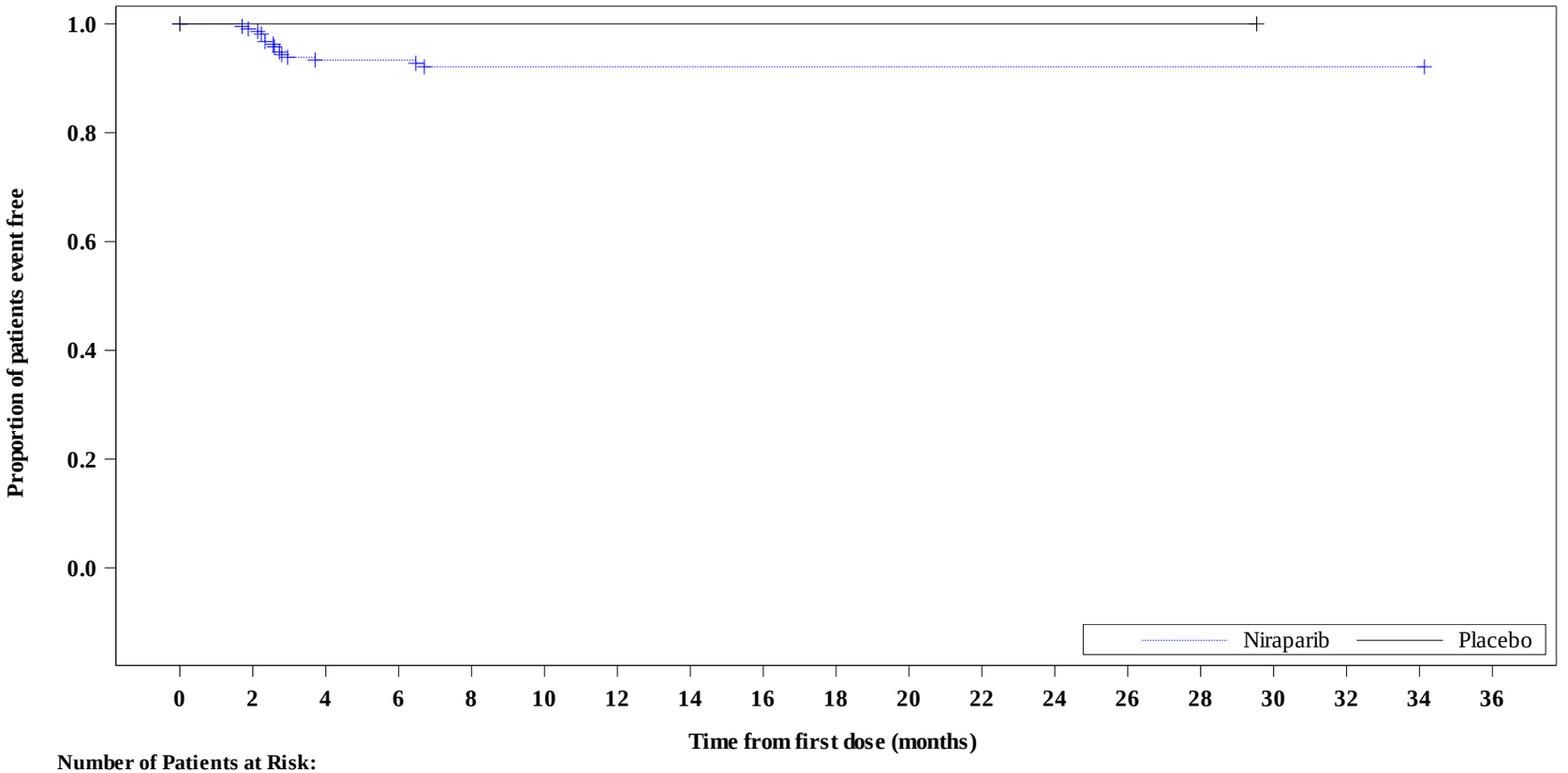



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 203 | 163 | 146 | 117 | 104 | 96 | 87 | 73 | 61 | 42 | 19 | 13 | 8 | 5 | 3 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.116

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)
SOC: Blood and lymphatic system disorders, PT: Anaemia



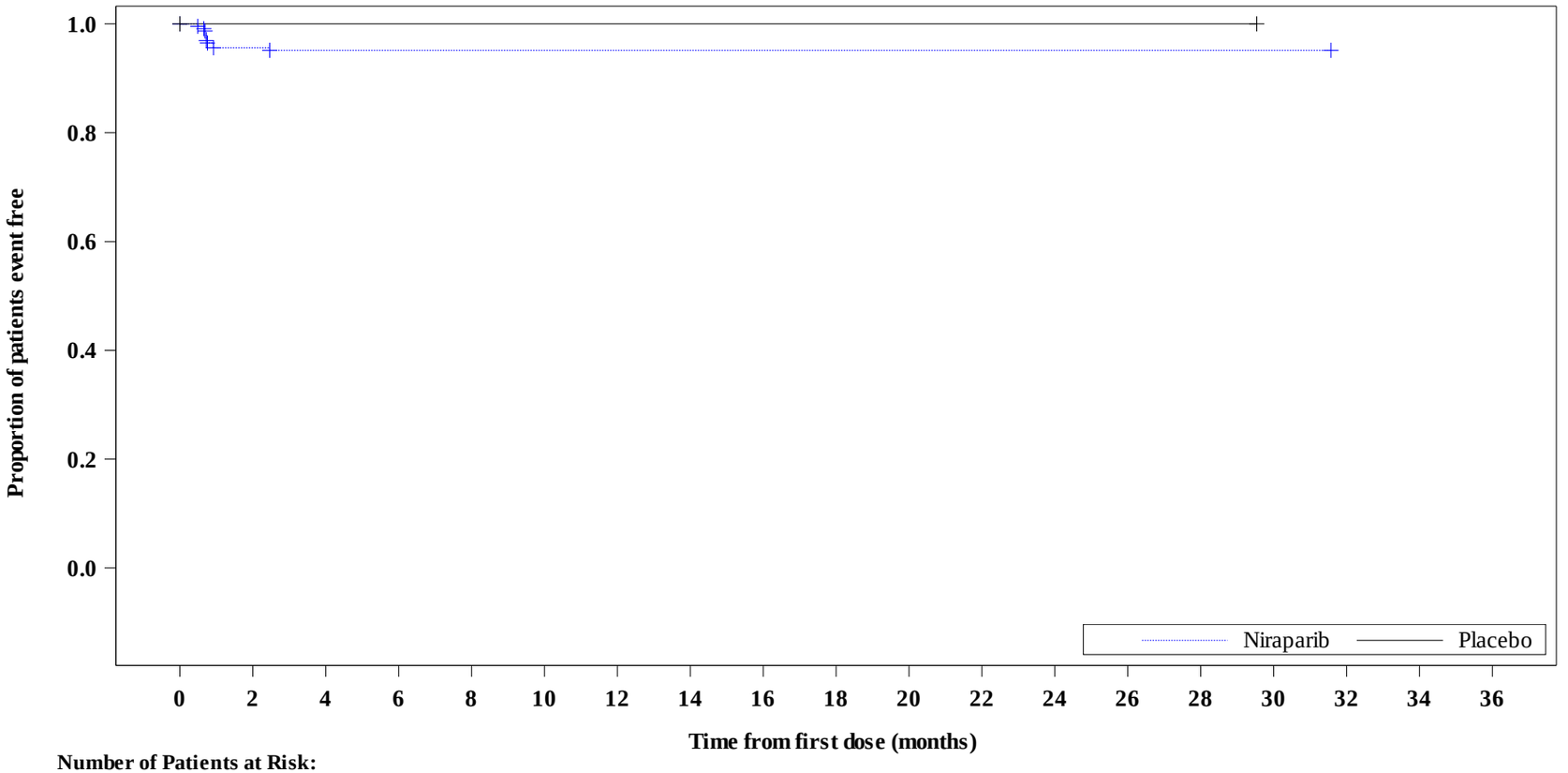

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 212 | 172 | 155 | 125 | 111 | 103 | 94 | 79 | 67 | 46 | 22 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.116

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

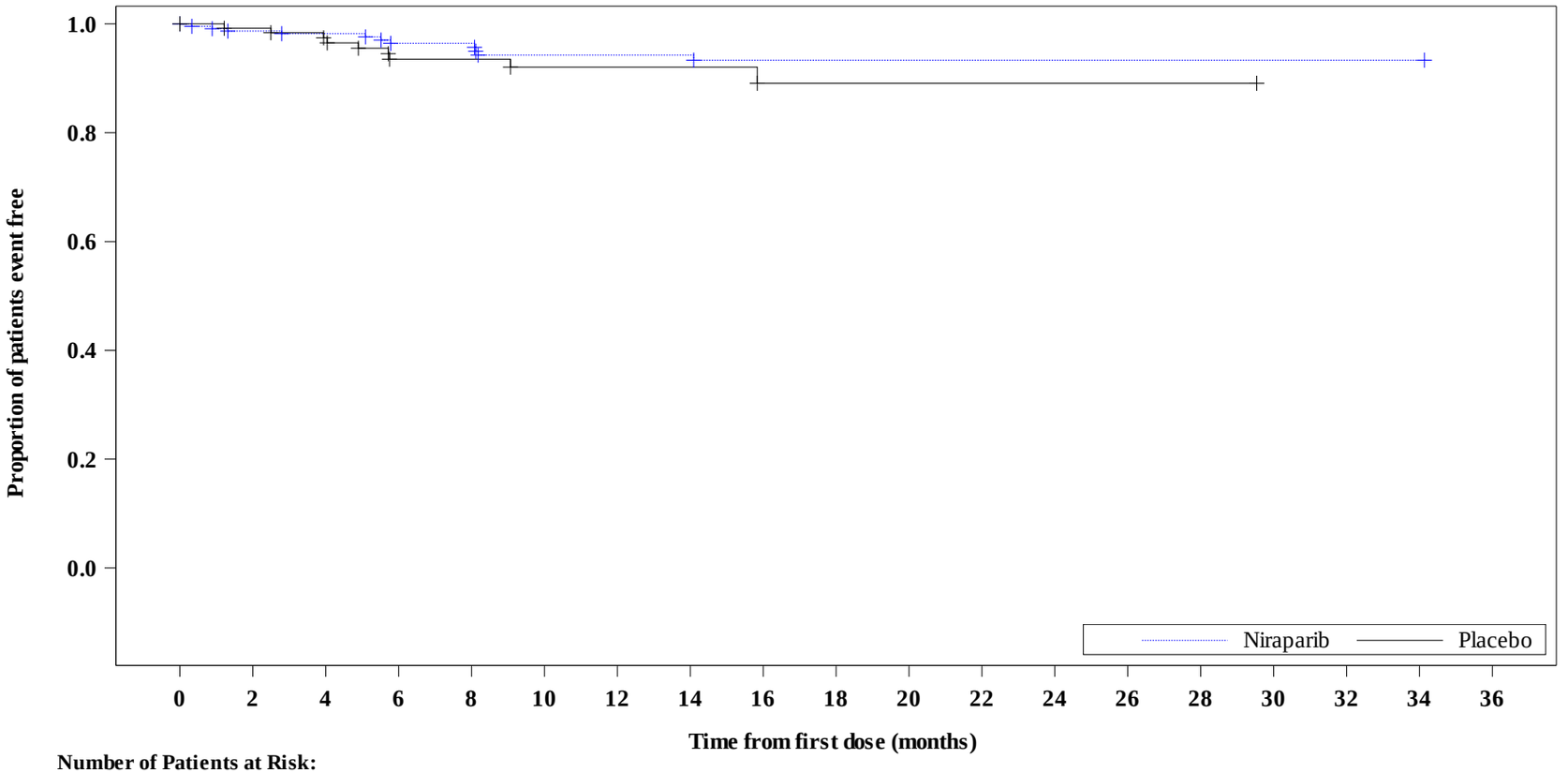



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 206 | 174 | 157 | 129 | 116 | 108 | 98 | 83 | 70 | 46 | 21 | 13 | 8 | 5 | 3 | 0 |
| Placebo | 124 | 122 | 107 | 98 | 78 | 56 | 49 | 41 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | |

Figure 3.116

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)
SOC: Gastrointestinal disorders

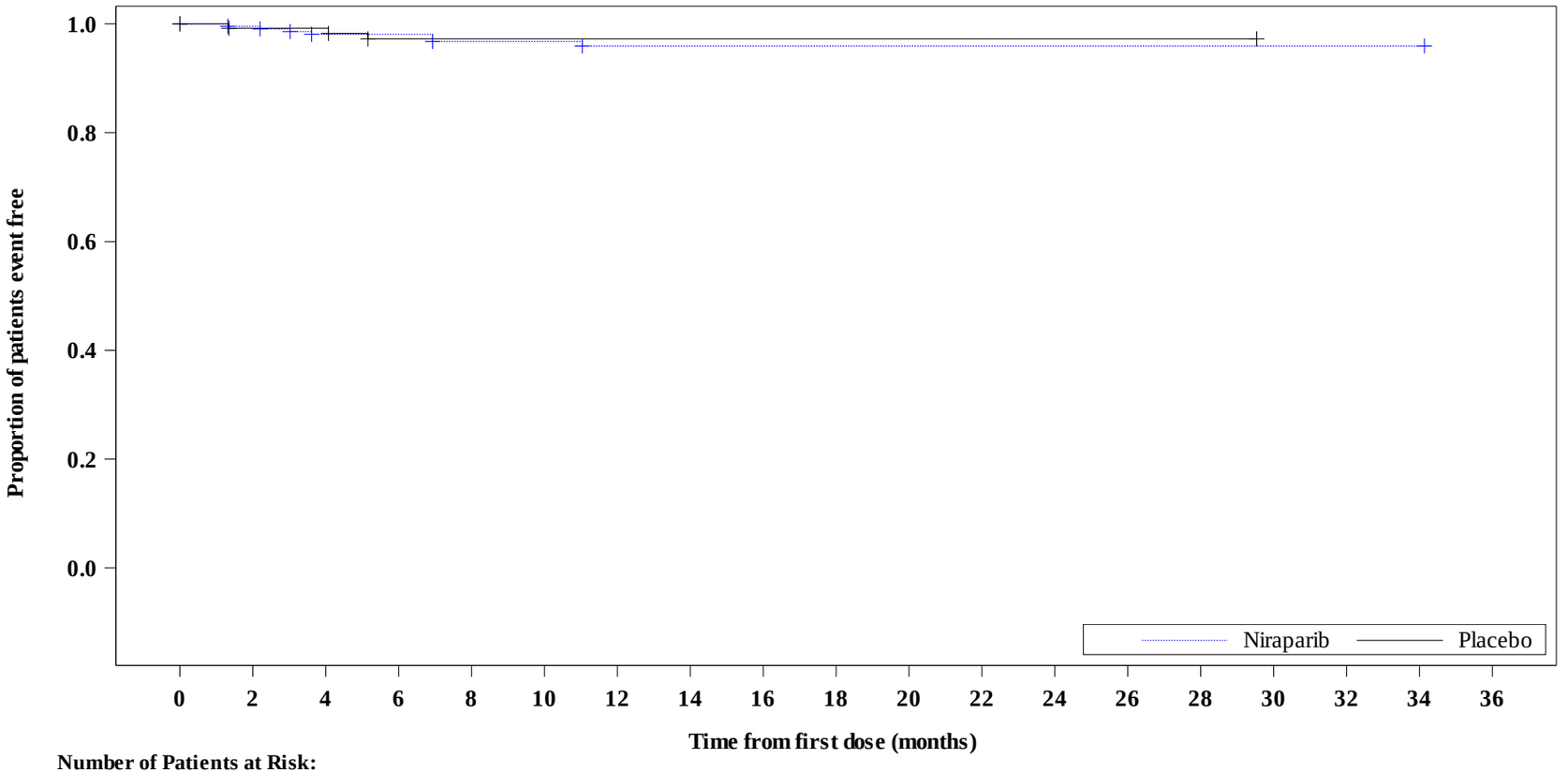



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 211 | 180 | 160 | 134 | 120 | 113 | 103 | 87 | 74 | 48 | 23 | 14 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 105 | 93 | 75 | 53 | 46 | 38 | 30 | 25 | 17 | 7 | 4 | 2 | 1 | 0 | | | |

Figure 3.116

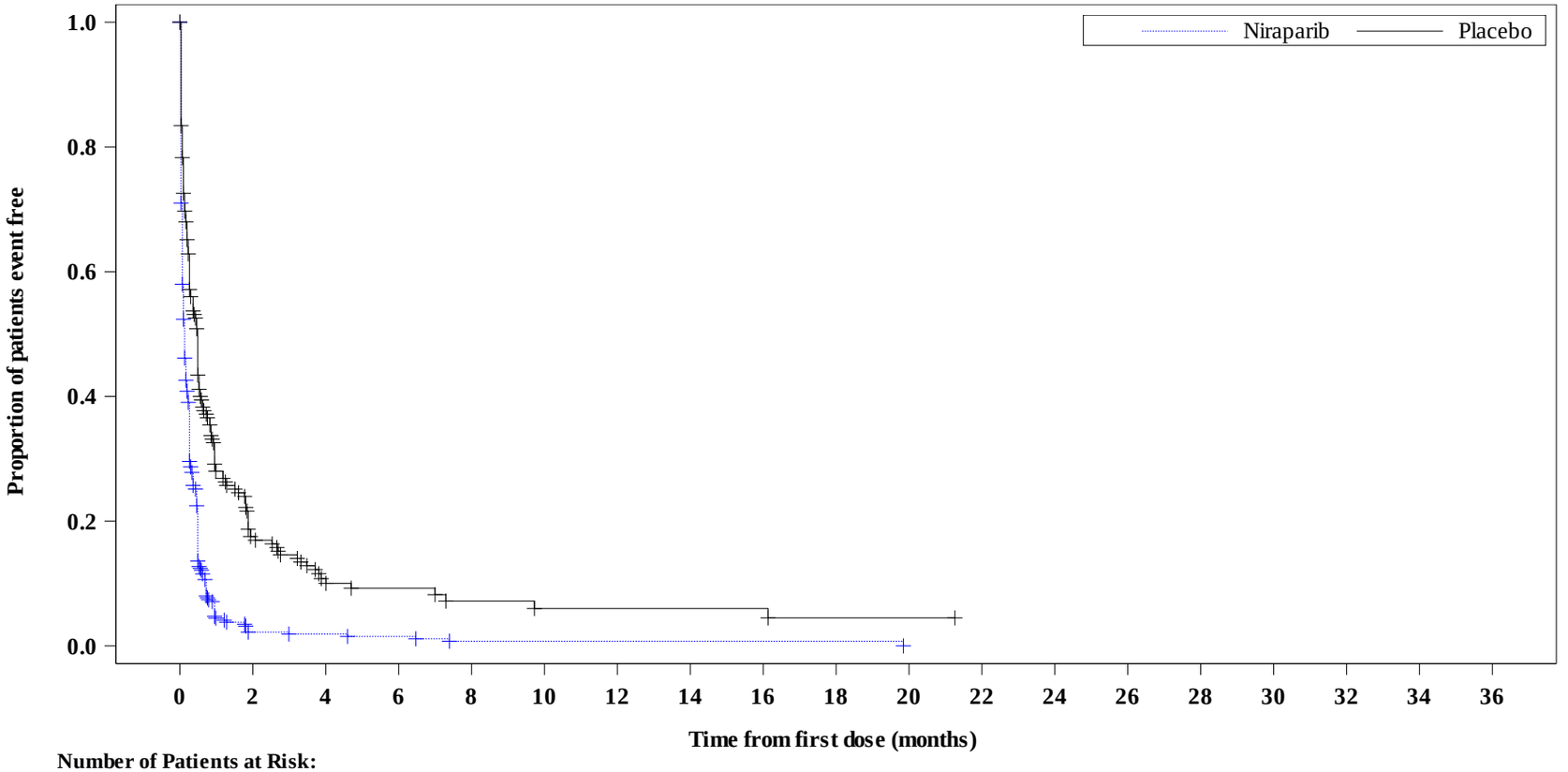
Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Safety-GVD Population)
SOC: Infections and infestations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 228 | 213 | 179 | 163 | 134 | 120 | 111 | 102 | 86 | 73 | 48 | 23 | 15 | 10 | 7 | 5 | 2 | 1 | 0 |
| Placebo | 124 | 121 | 106 | 95 | 76 | 55 | 48 | 40 | 34 | 29 | 20 | 8 | 4 | 2 | 1 | 0 | | | |

Figure 3.135a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events
(Residual Disease Safety Population)



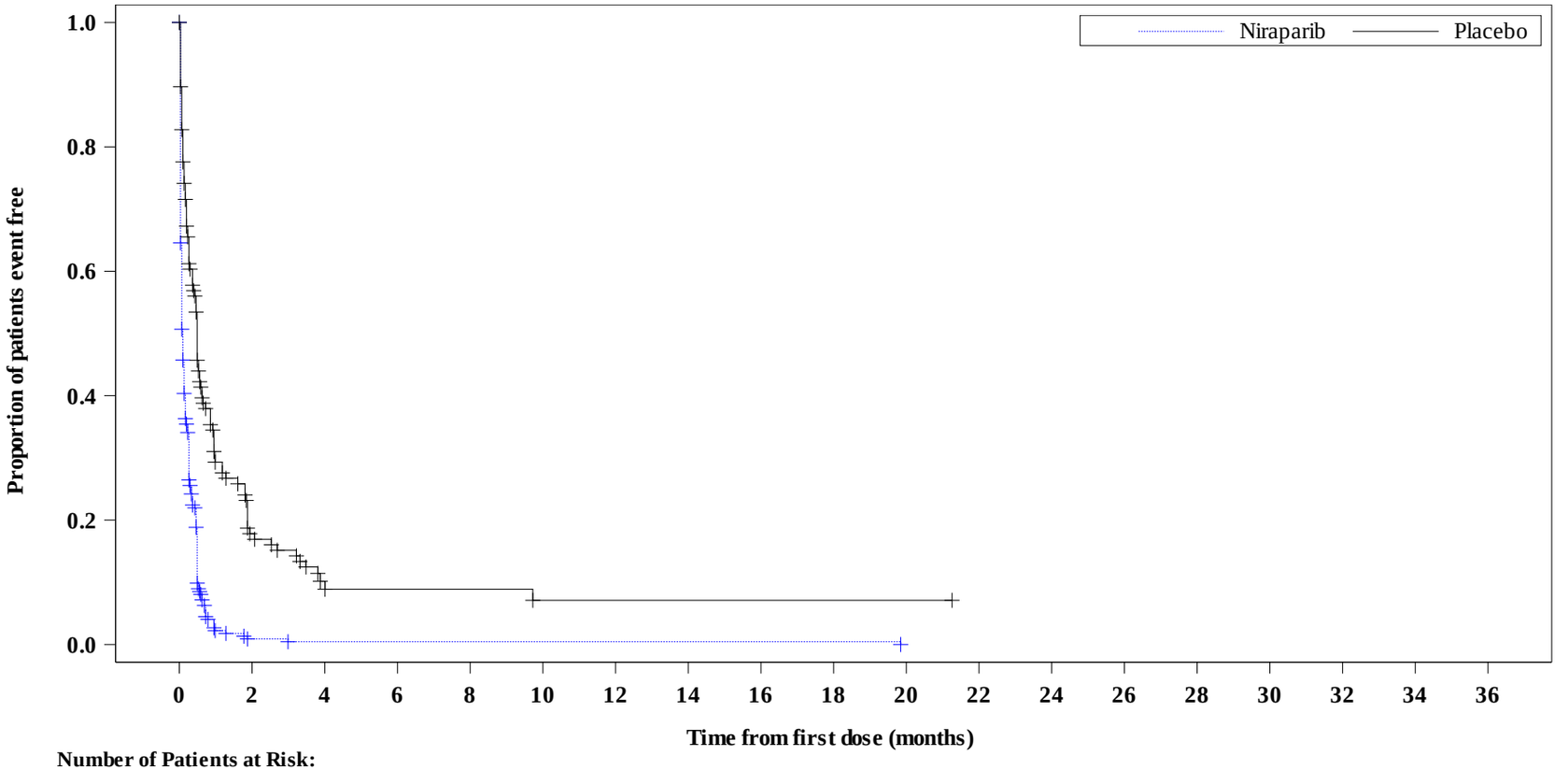

**Number of Patients at Risk:**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 7 | 5 | 4 | 2 | 2 | 1 | 1 | 1 | 1 | 0 | |
| Placebo | 175 | 30 | 14 | 12 | 7 | 5 | 5 | 4 | 4 | 3 | 2 | 0 |

Figure 3.135b

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events by Residual Disease Status
(Residual Disease Safety Population)

Residual Disease Status: R0

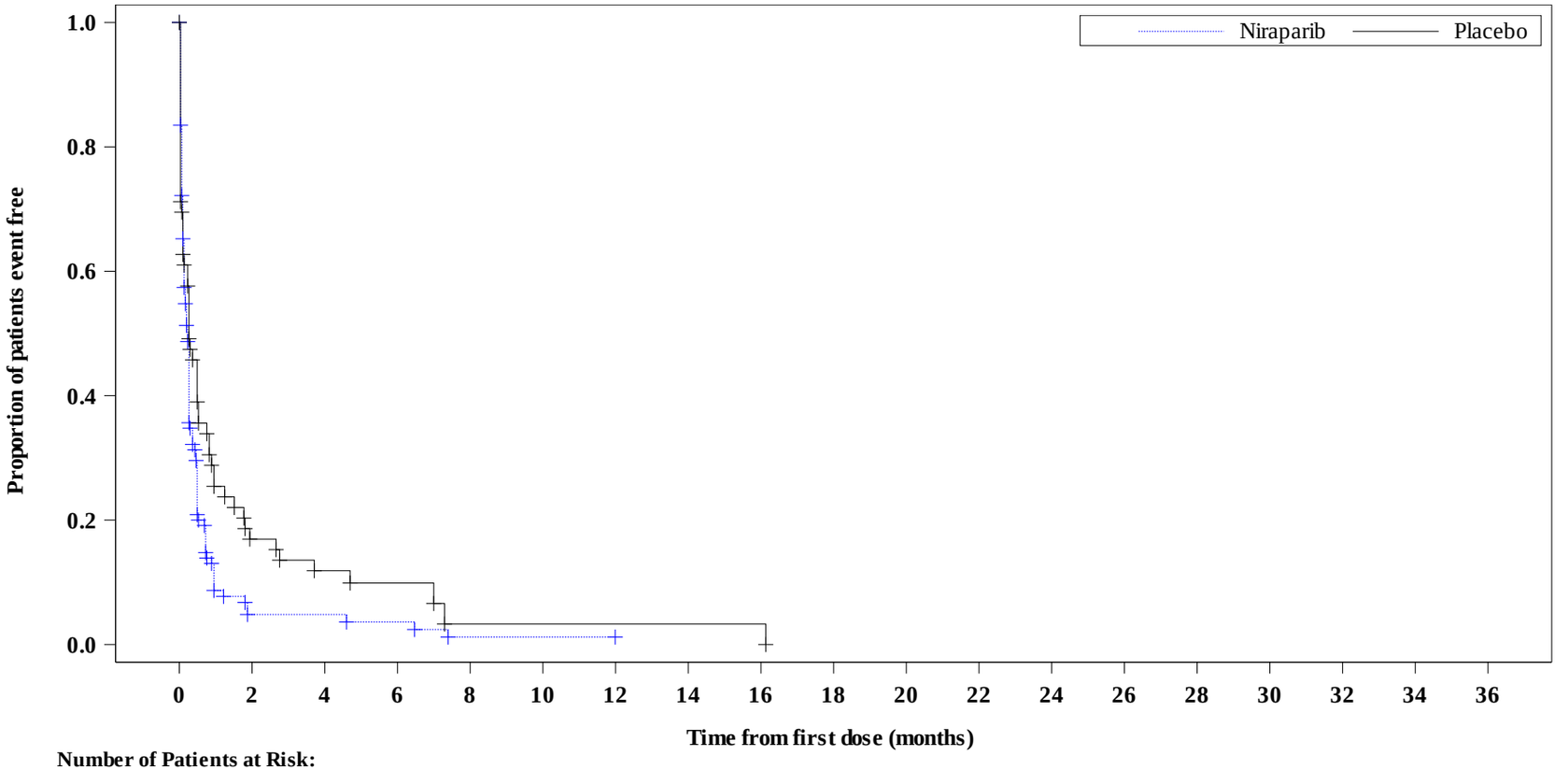



**Number of Patients at Risk:**

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 223 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | |
| Placebo | 116 | 20 | 8 | 7 | 6 | 4 | 4 | 3 | 3 | 3 | 2 | 0 |

Figure 3.135b
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events by Residual Disease Status
(Residual Disease Safety Population)

Residual Disease Status: R1/R2

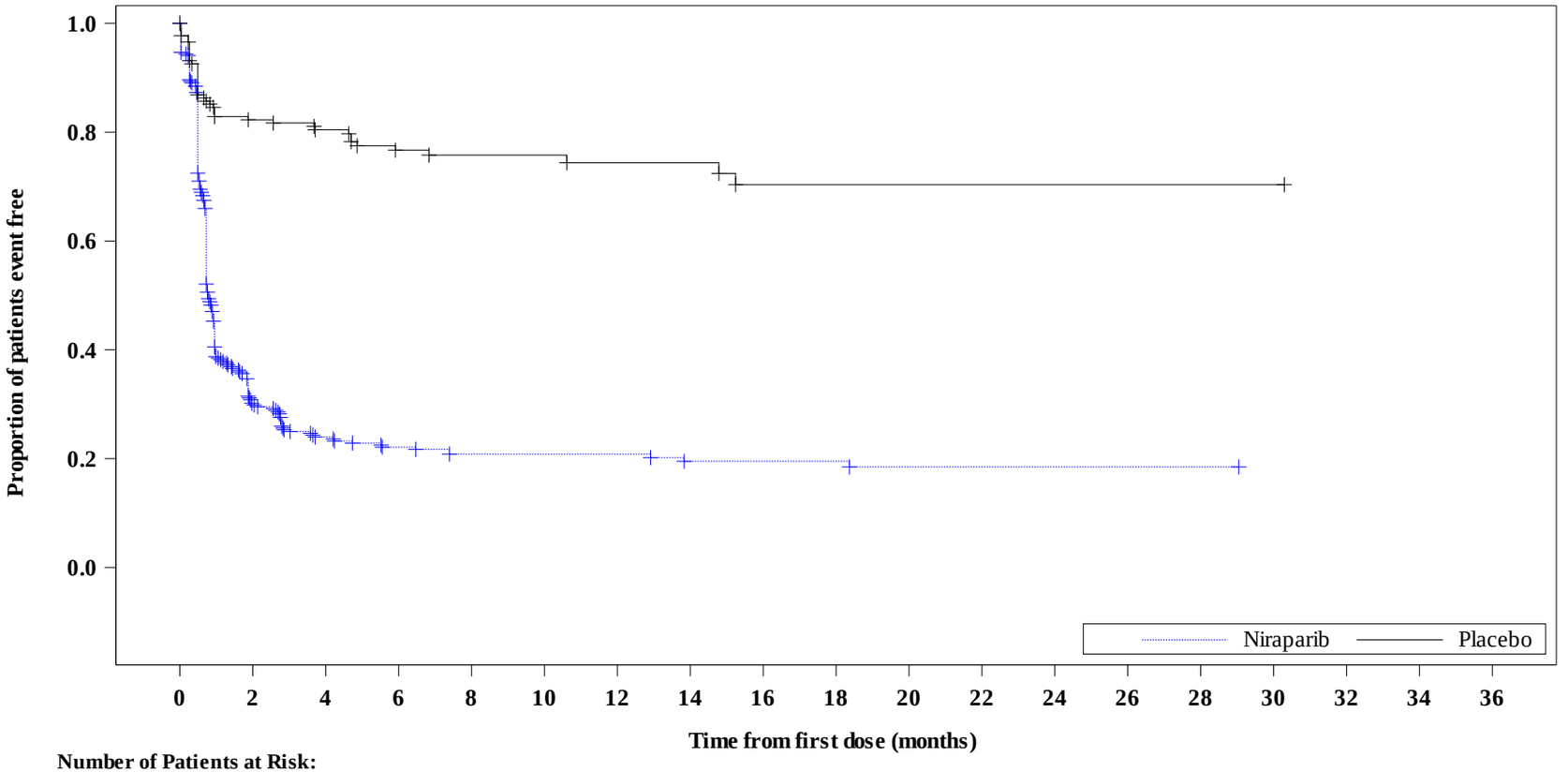



**Number of Patients at Risk:**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 115 | 5 | 4 | 3 | 1 | 1 | 0 | | | |
| Placebo | 59 | 10 | 6 | 5 | 1 | 1 | 1 | 1 | 1 | 0 |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 93 | 65 | 57 | 43 | 37 | 33 | 29 | 24 | 19 | 15 | 5 | 3 | 2 | 1 | 0 | |
| Placebo | 175 | 141 | 116 | 96 | 77 | 57 | 51 | 41 | 34 | 30 | 25 | 16 | 7 | 4 | 1 | 1 | 0 |

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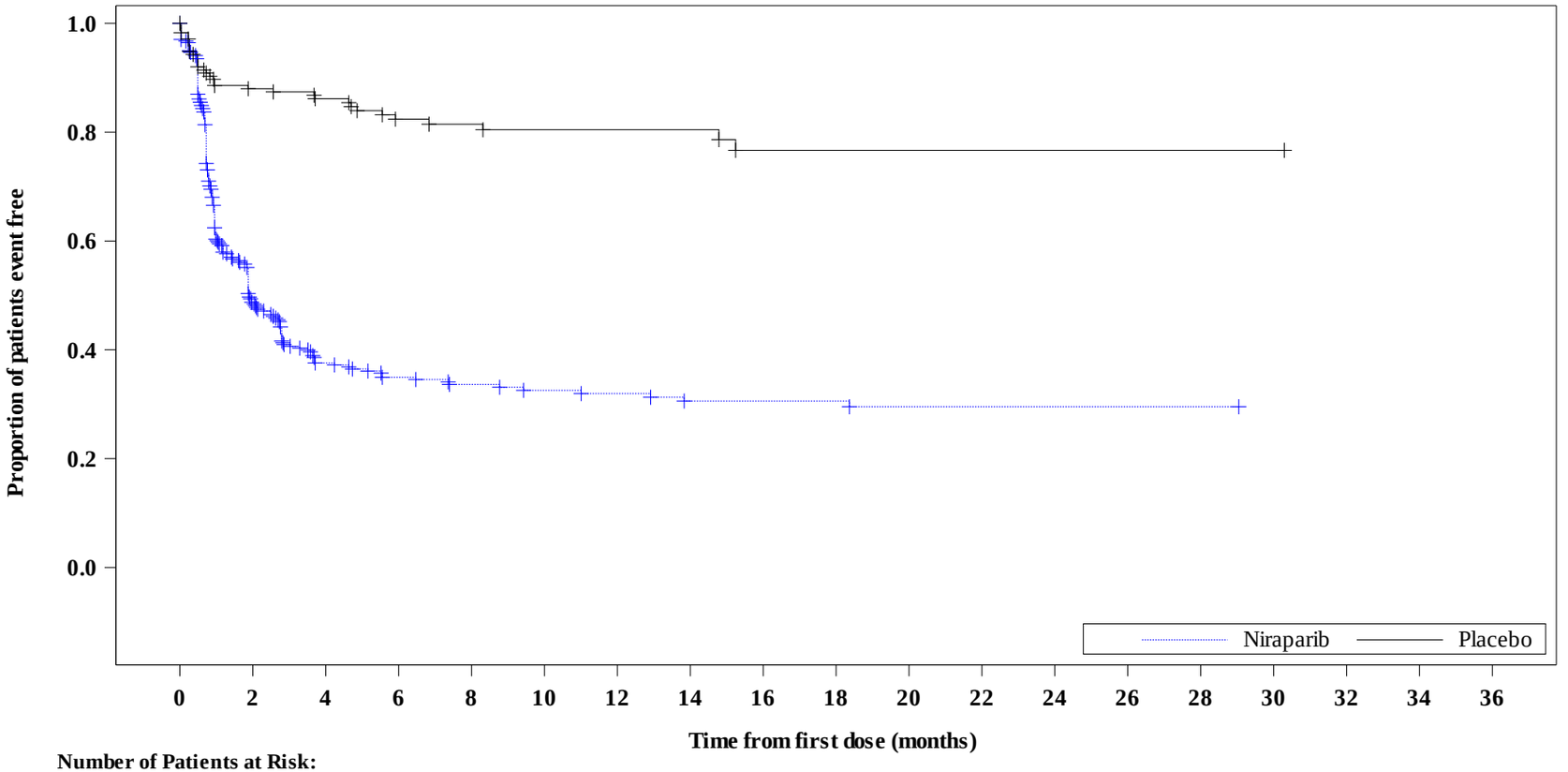
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 151 | 104 | 89 | 68 | 56 | 50 | 44 | 34 | 29 | 21 | 10 | 7 | 3 | 1 | 0 | |
| Placebo | 175 | 151 | 125 | 104 | 83 | 62 | 57 | 47 | 39 | 34 | 29 | 18 | 8 | 5 | 2 | 1 | 0 |

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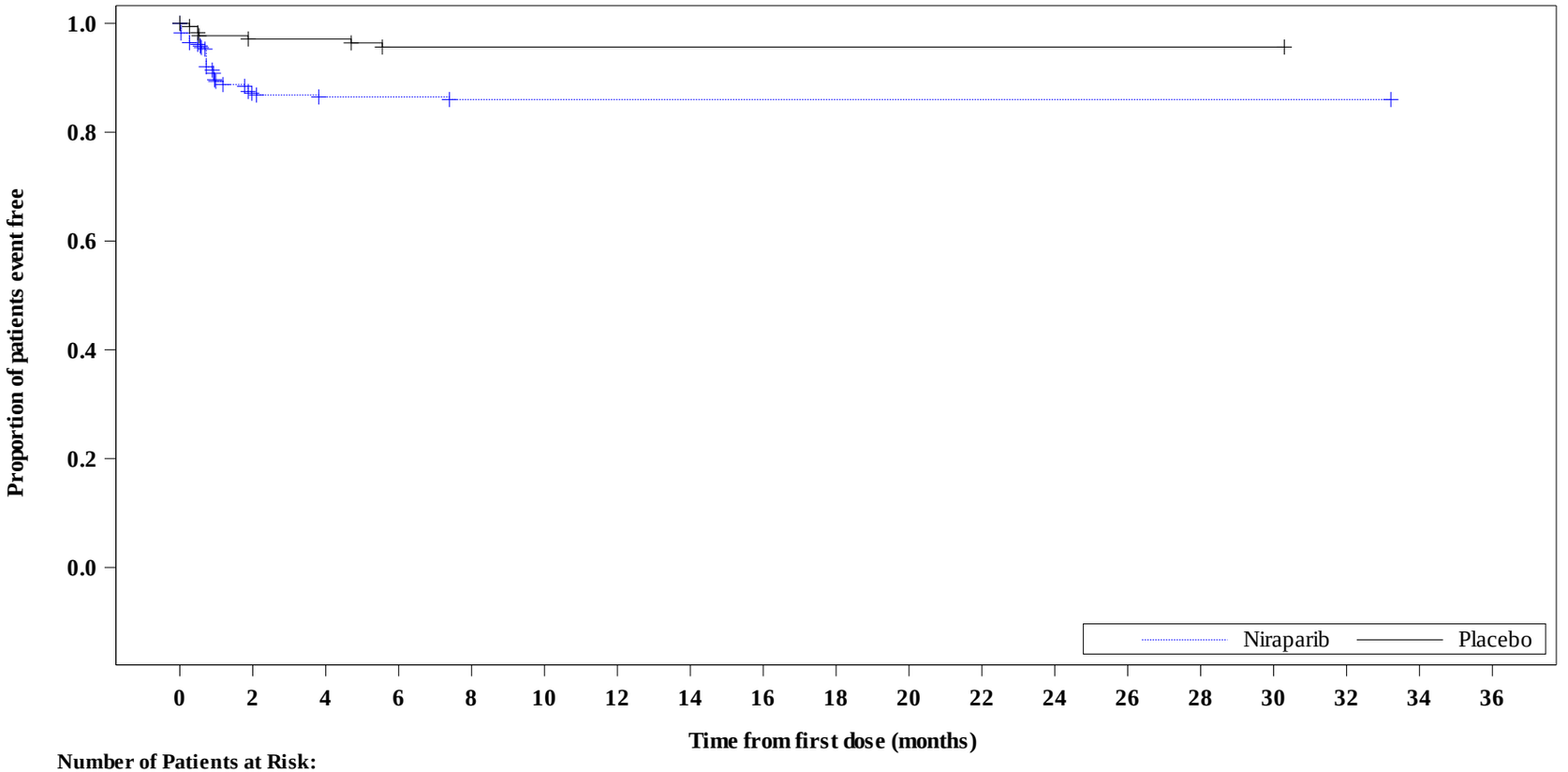
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Leukopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 271 | 232 | 208 | 171 | 151 | 143 | 131 | 111 | 101 | 76 | 53 | 35 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 141 | 122 | 98 | 74 | 67 | 56 | 47 | 40 | 33 | 18 | 8 | 5 | 2 | 1 | 0 | |

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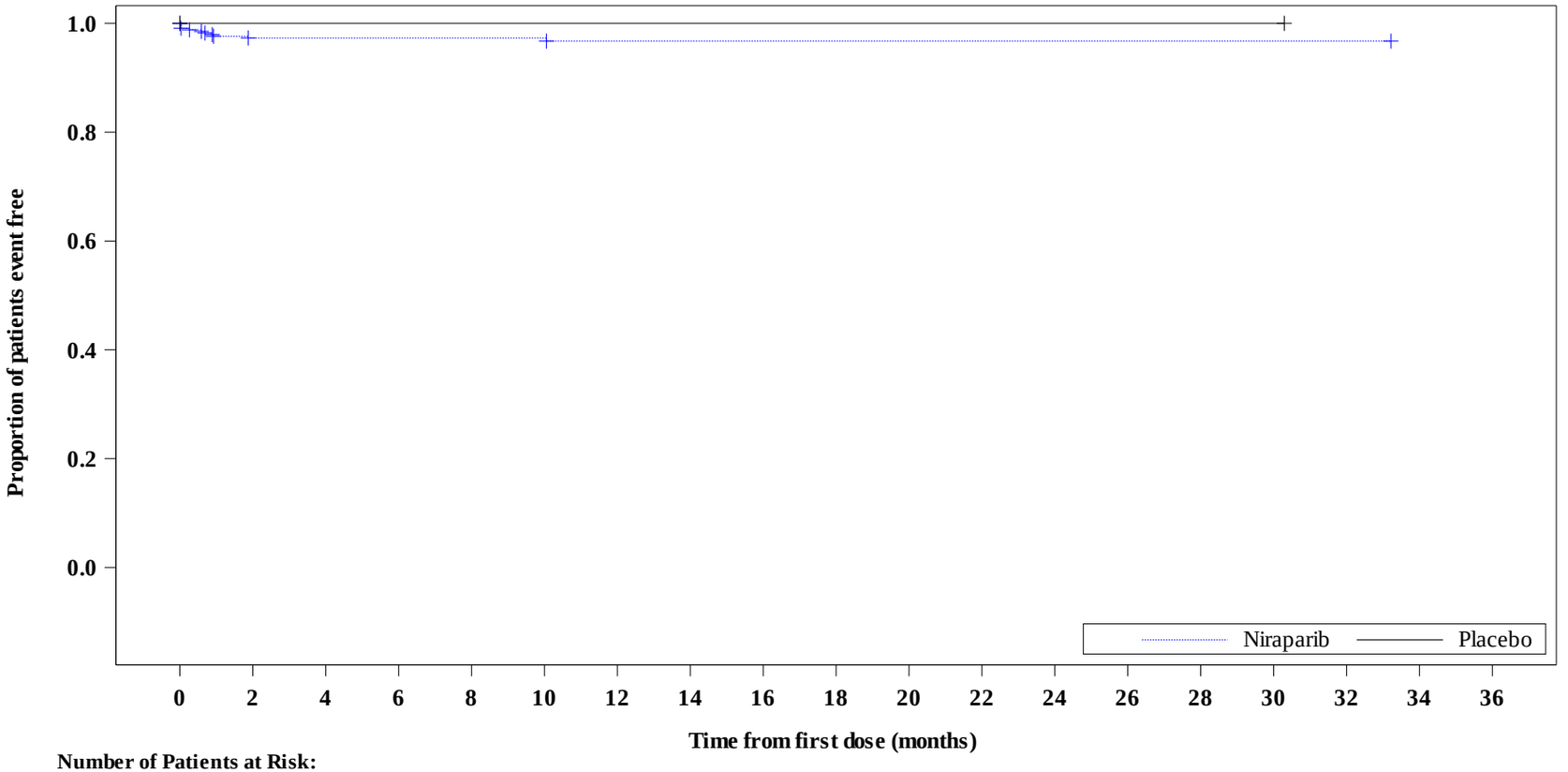
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Lymphopenia

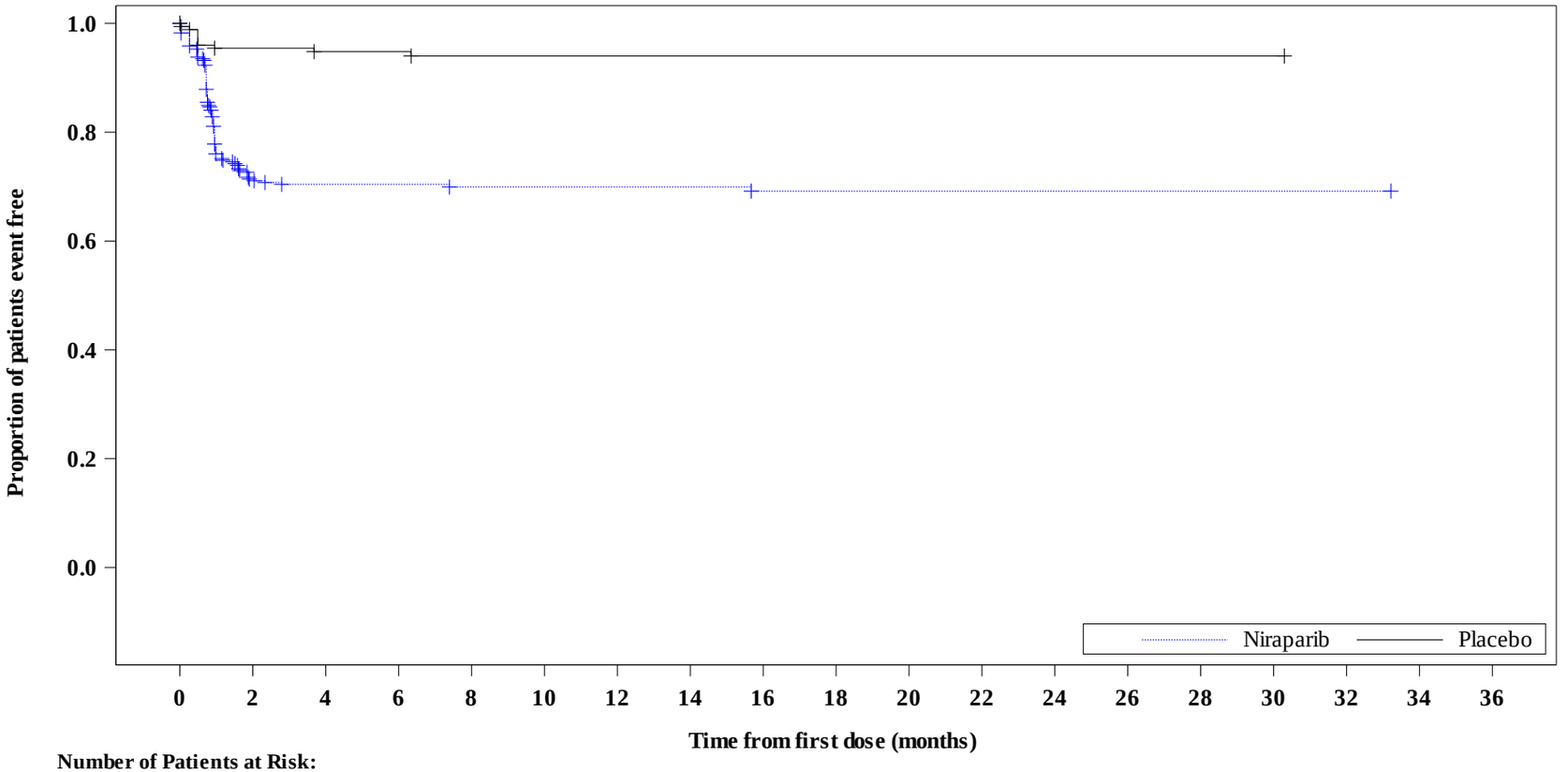



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 258 | 232 | 191 | 167 | 158 | 147 | 123 | 113 | 85 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Neutropenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 222 | 185 | 166 | 138 | 123 | 117 | 109 | 91 | 83 | 64 | 45 | 29 | 16 | 7 | 2 | 2 | 0 |
| Placebo | 175 | 164 | 137 | 121 | 97 | 73 | 65 | 54 | 47 | 40 | 33 | 17 | 7 | 4 | 1 | 1 | 0 | |

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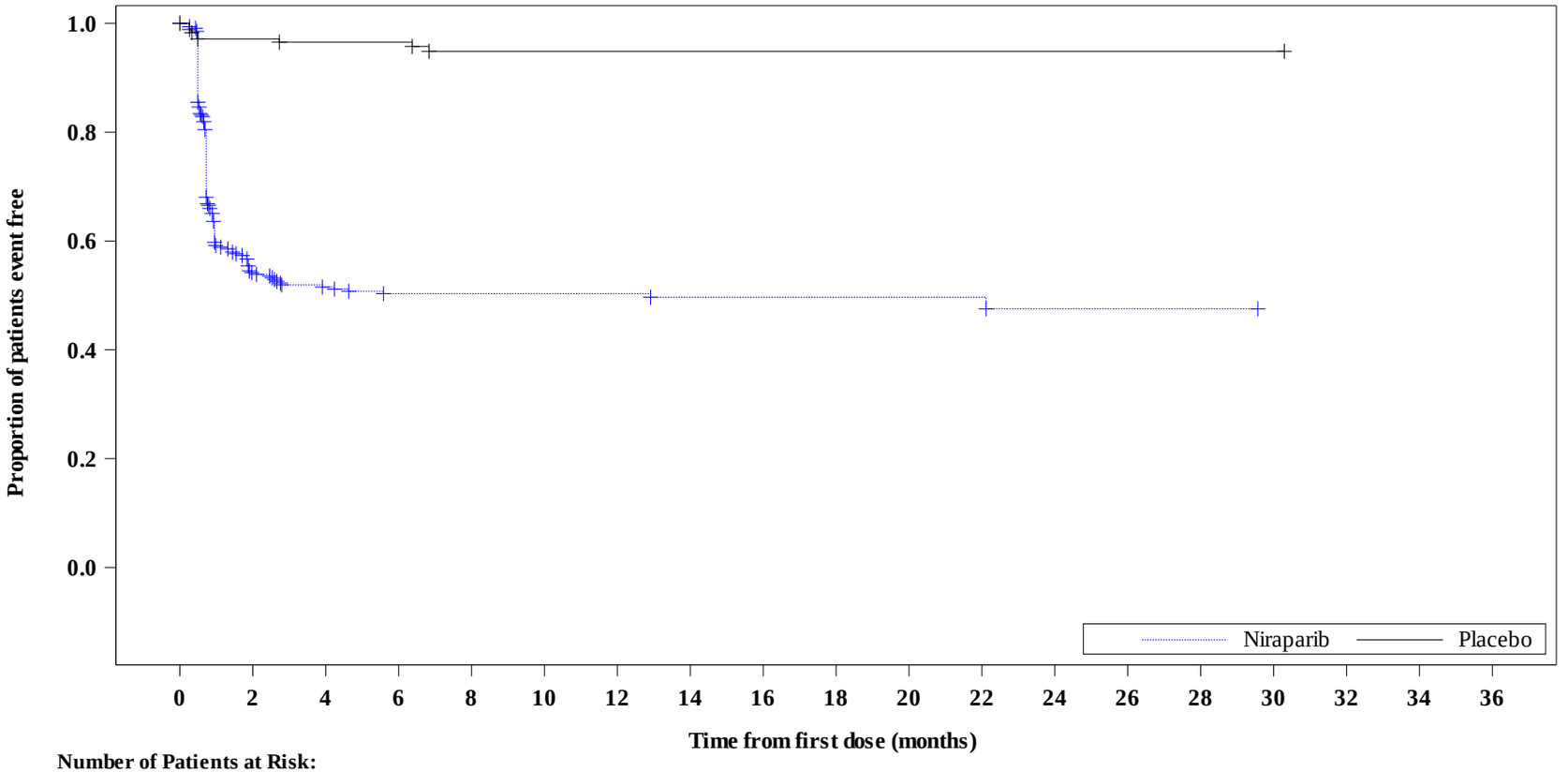
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 170 | 133 | 120 | 100 | 87 | 82 | 74 | 61 | 53 | 38 | 23 | 14 | 7 | 3 | 0 | |
| Placebo | 175 | 167 | 141 | 125 | 99 | 75 | 67 | 56 | 48 | 42 | 36 | 19 | 8 | 5 | 2 | 1 | 0 |

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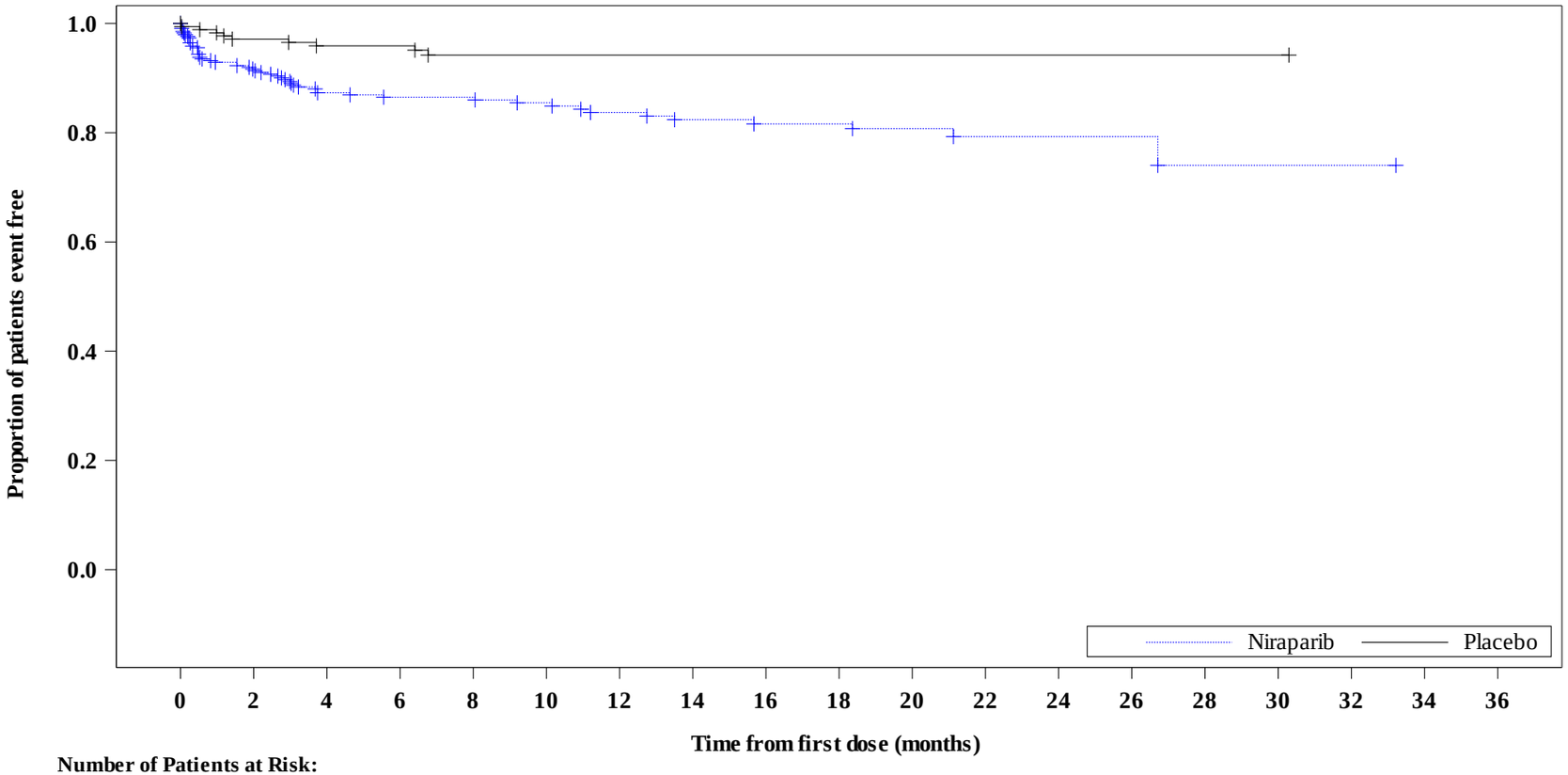
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Cardiac disorders

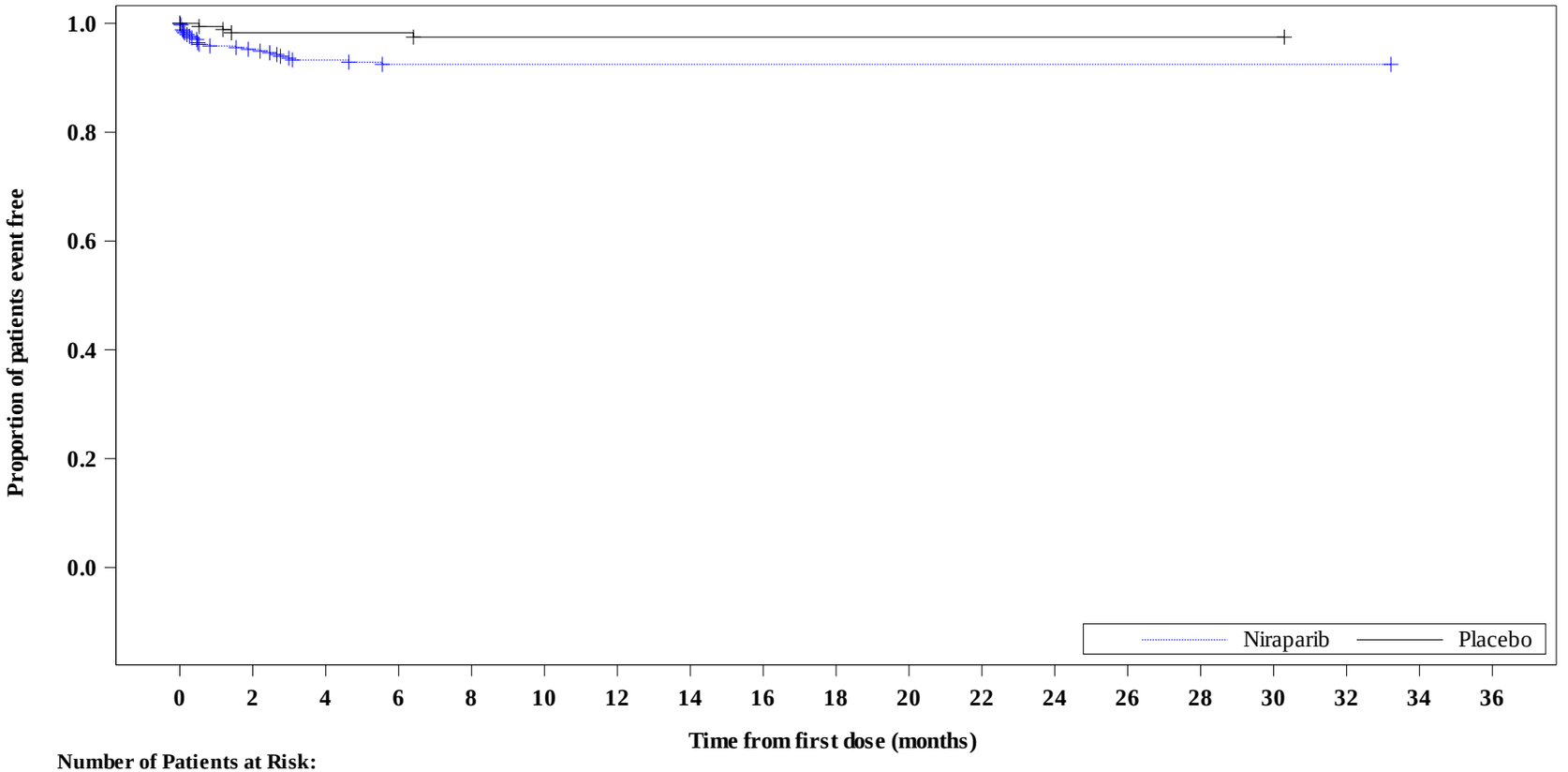



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 287 | 232 | 209 | 171 | 148 | 137 | 122 | 105 | 95 | 66 | 47 | 33 | 16 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 140 | 124 | 96 | 73 | 65 | 54 | 46 | 40 | 34 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Cardiac disorders, PT: Palpitations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 298 | 248 | 222 | 183 | 160 | 152 | 139 | 117 | 107 | 79 | 56 | 39 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 169 | 143 | 126 | 99 | 75 | 67 | 56 | 48 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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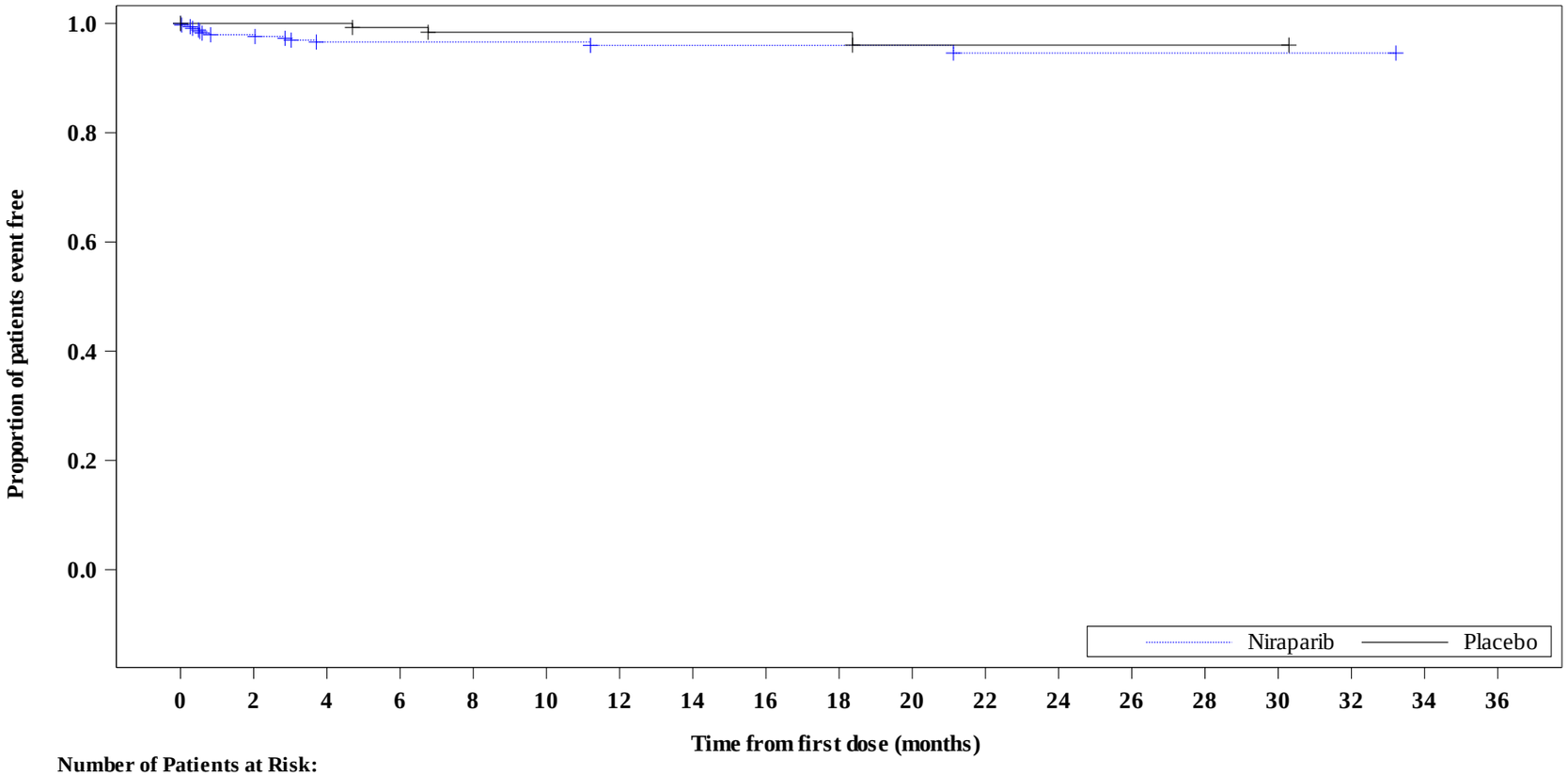
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Cardiac disorders, PT: Sinus tachycardia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 304 | 256 | 231 | 190 | 167 | 158 | 145 | 122 | 111 | 82 | 56 | 37 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 127 | 100 | 77 | 69 | 58 | 49 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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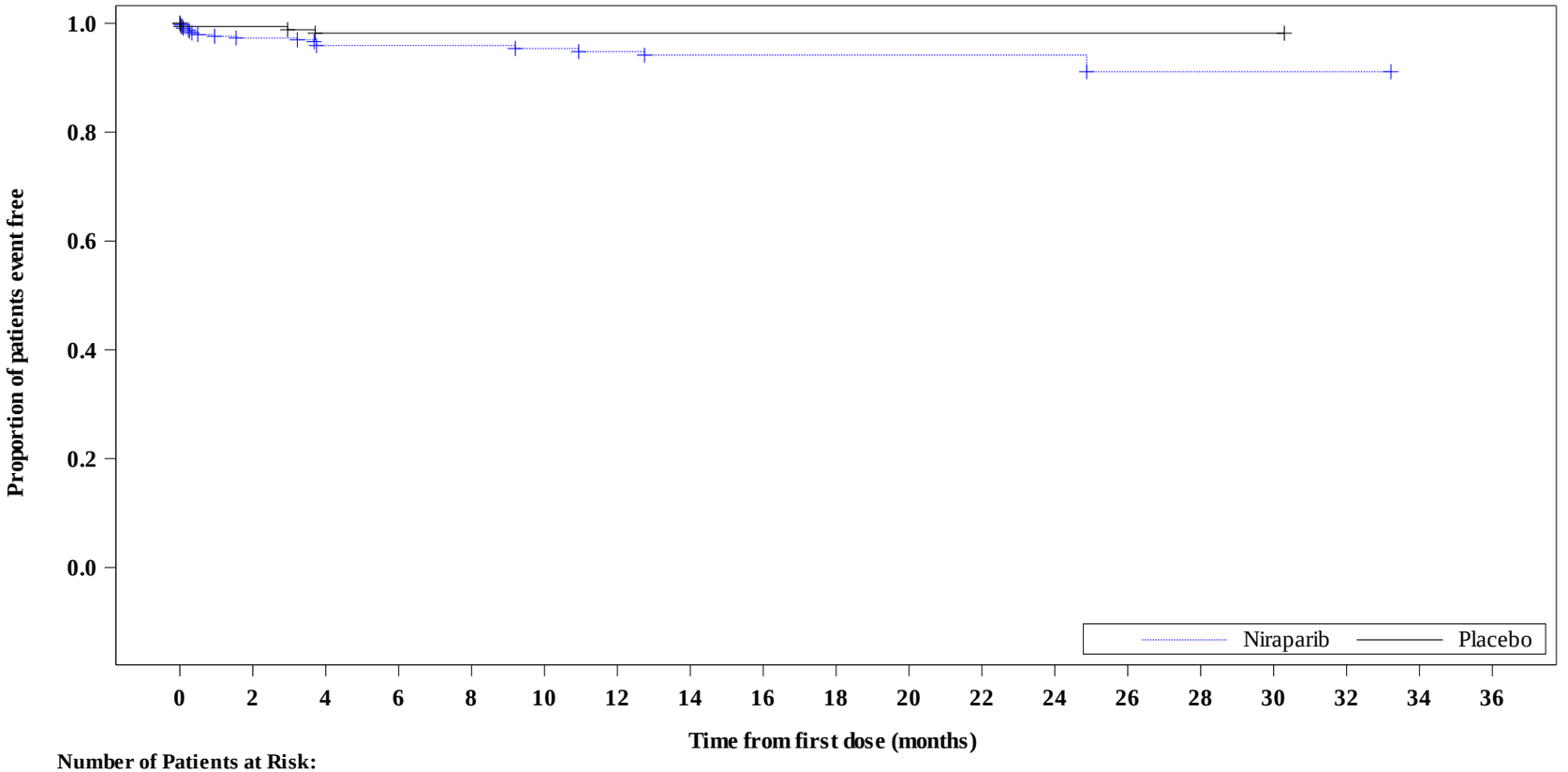
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Cardiac disorders, PT: Tachycardia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 253 | 228 | 188 | 165 | 156 | 142 | 121 | 110 | 80 | 56 | 38 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 143 | 127 | 101 | 77 | 69 | 58 | 49 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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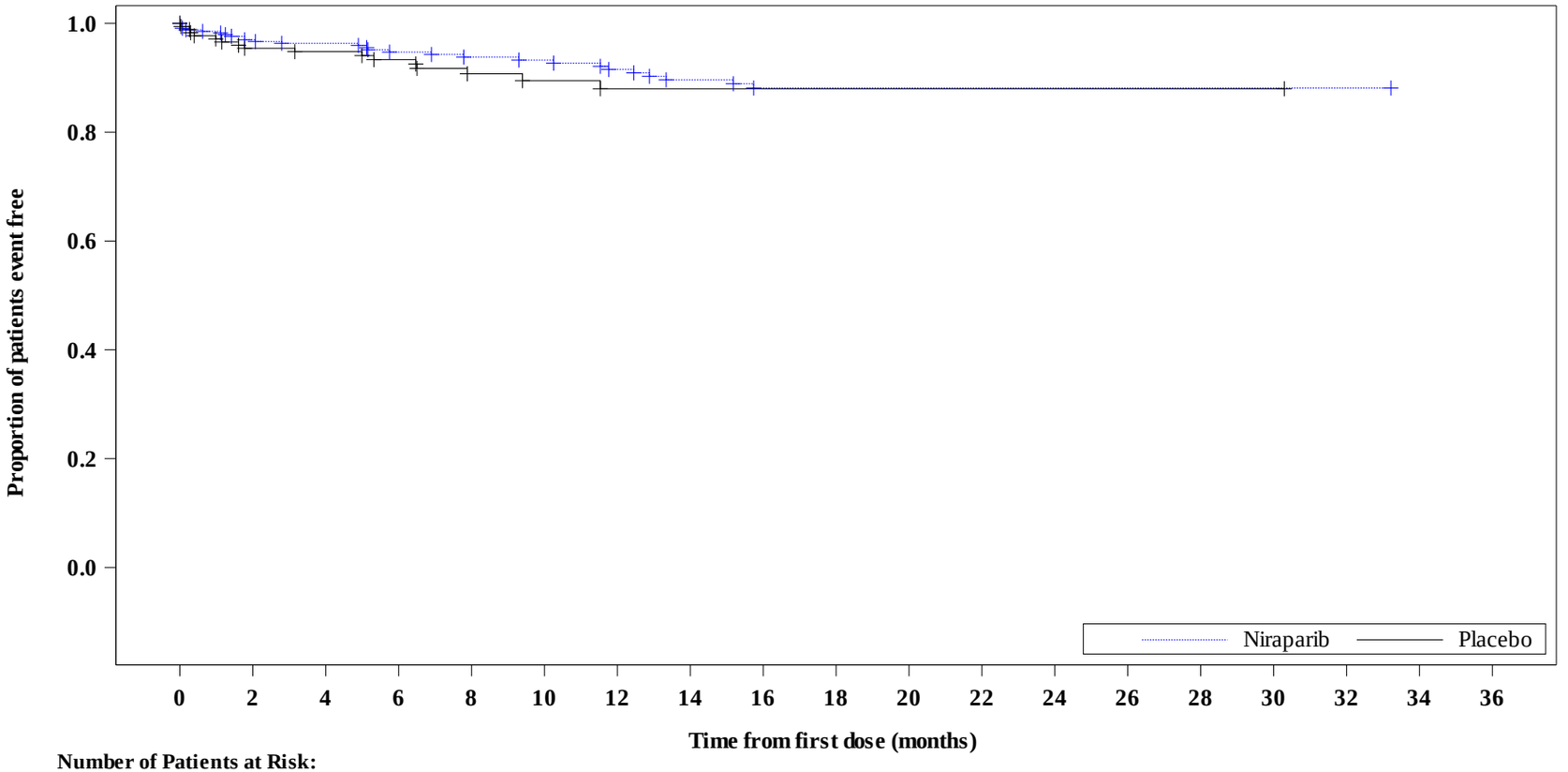
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Ear and labyrinth disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 302 | 257 | 230 | 189 | 165 | 154 | 138 | 112 | 101 | 73 | 52 | 36 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 164 | 139 | 120 | 92 | 68 | 59 | 50 | 44 | 37 | 31 | 18 | 8 | 5 | 2 | 1 | 0 | |

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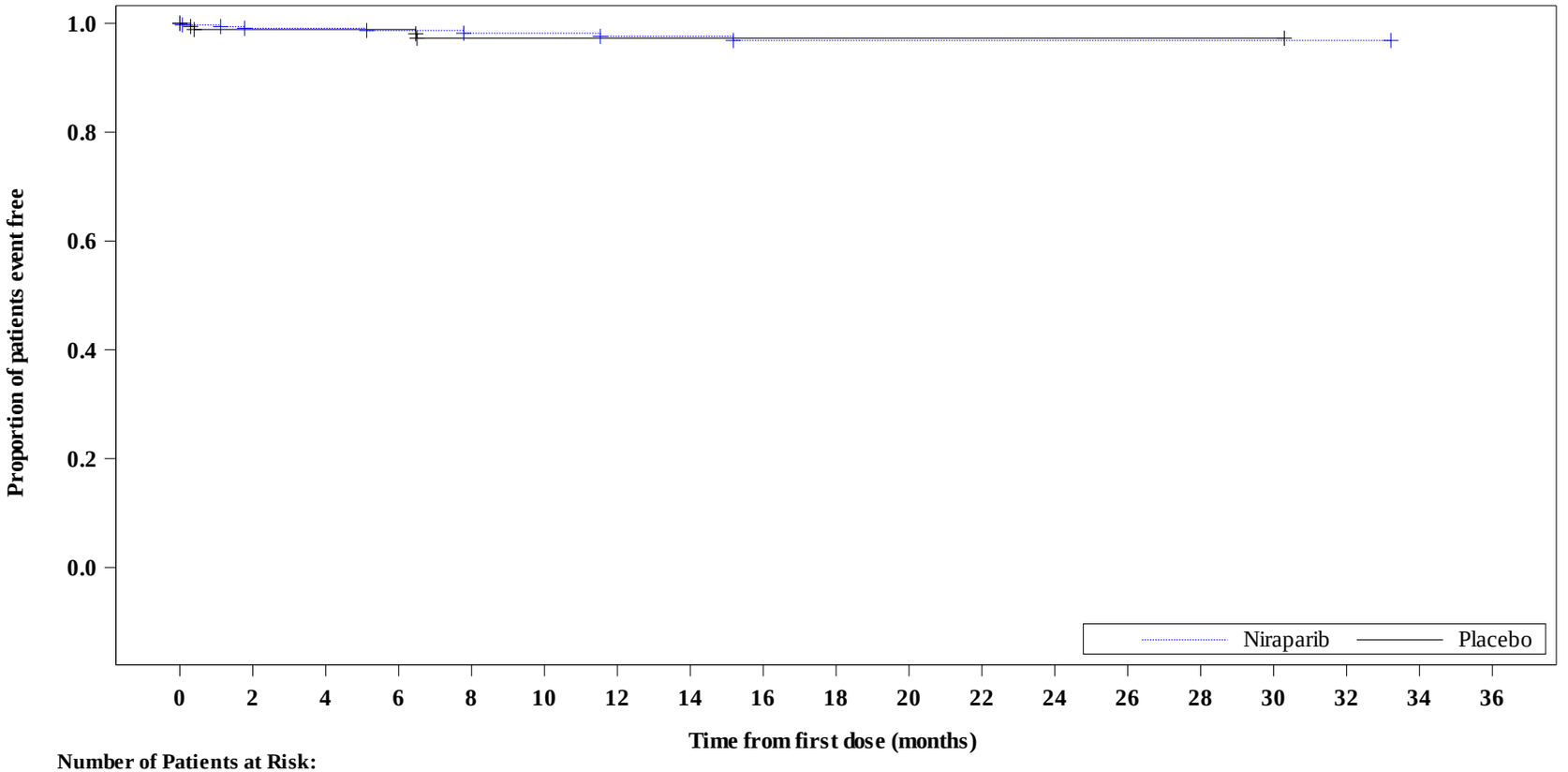
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Ear and labyrinth disorders, PT: Tinnitus




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 263 | 237 | 194 | 171 | 162 | 149 | 123 | 112 | 83 | 58 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 145 | 128 | 100 | 76 | 68 | 57 | 48 | 41 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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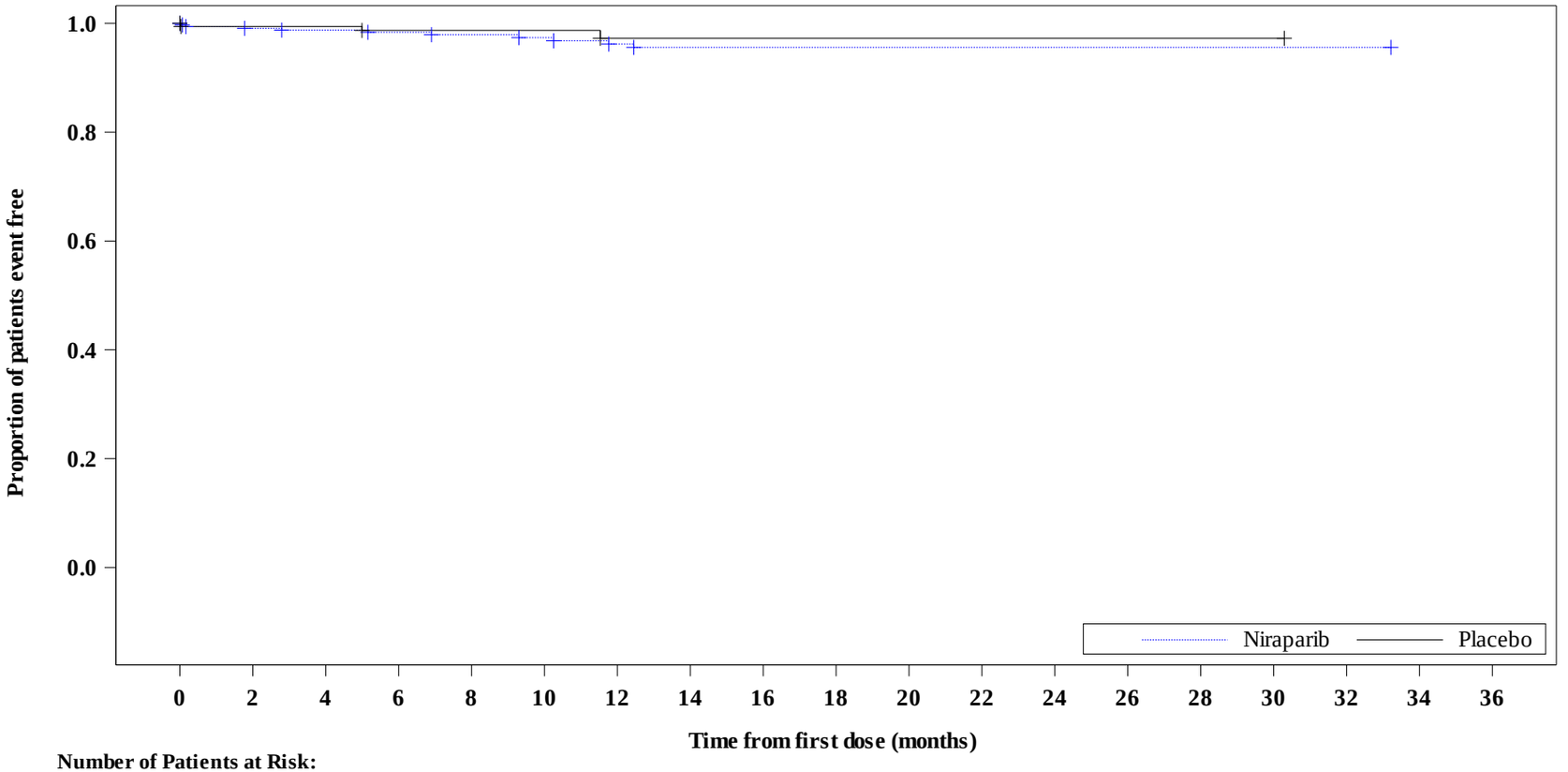
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Ear and labyrinth disorders, PT: Vertigo




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 263 | 237 | 195 | 170 | 160 | 146 | 122 | 111 | 81 | 58 | 39 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 100 | 76 | 67 | 56 | 48 | 41 | 34 | 18 | 8 | 5 | 2 | 1 | 0 | |

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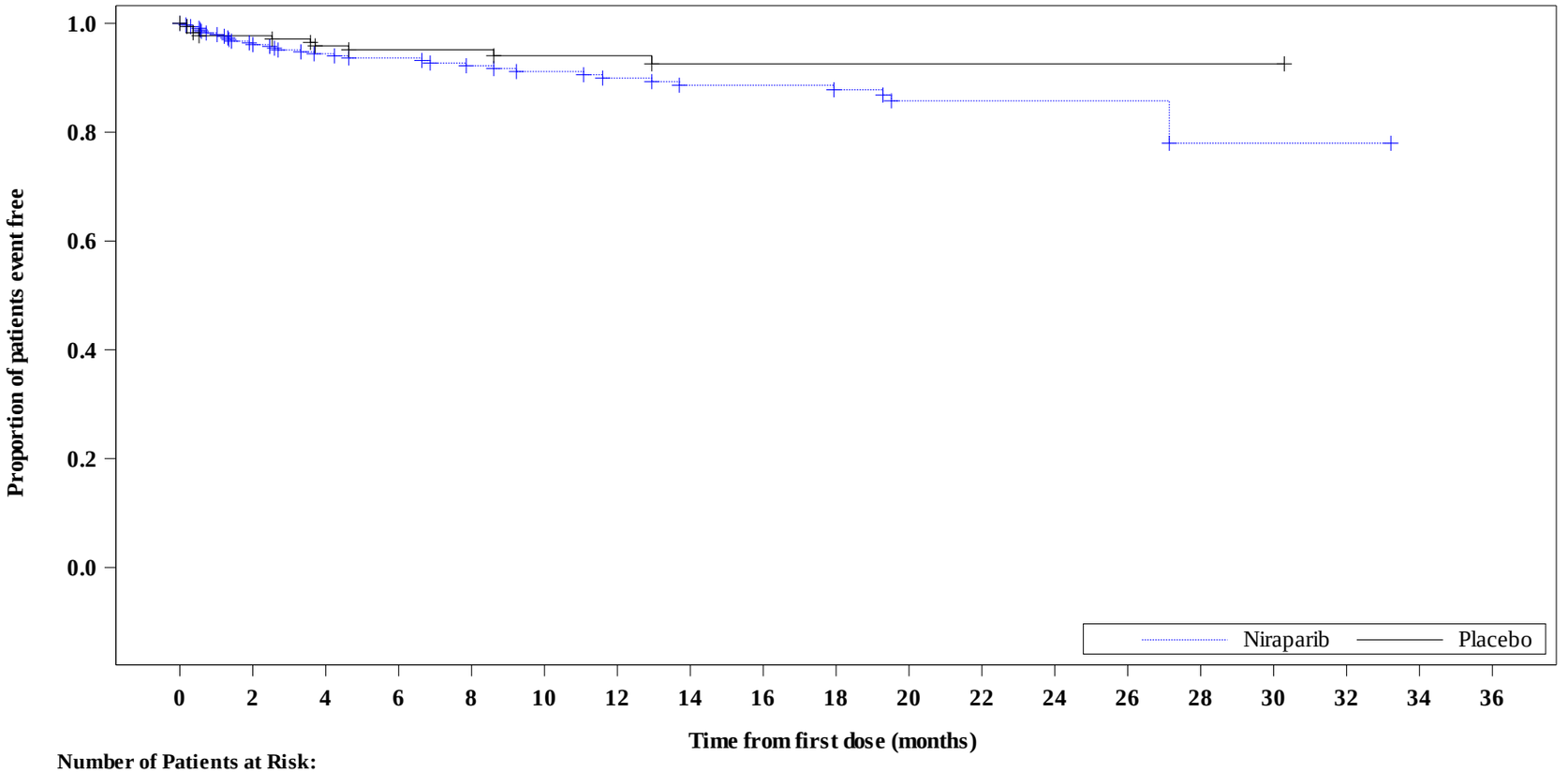
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Eye disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 300 | 251 | 223 | 180 | 156 | 147 | 134 | 114 | 104 | 75 | 50 | 33 | 16 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 168 | 138 | 122 | 96 | 75 | 67 | 55 | 46 | 39 | 33 | 18 | 8 | 5 | 2 | 1 | 0 | |

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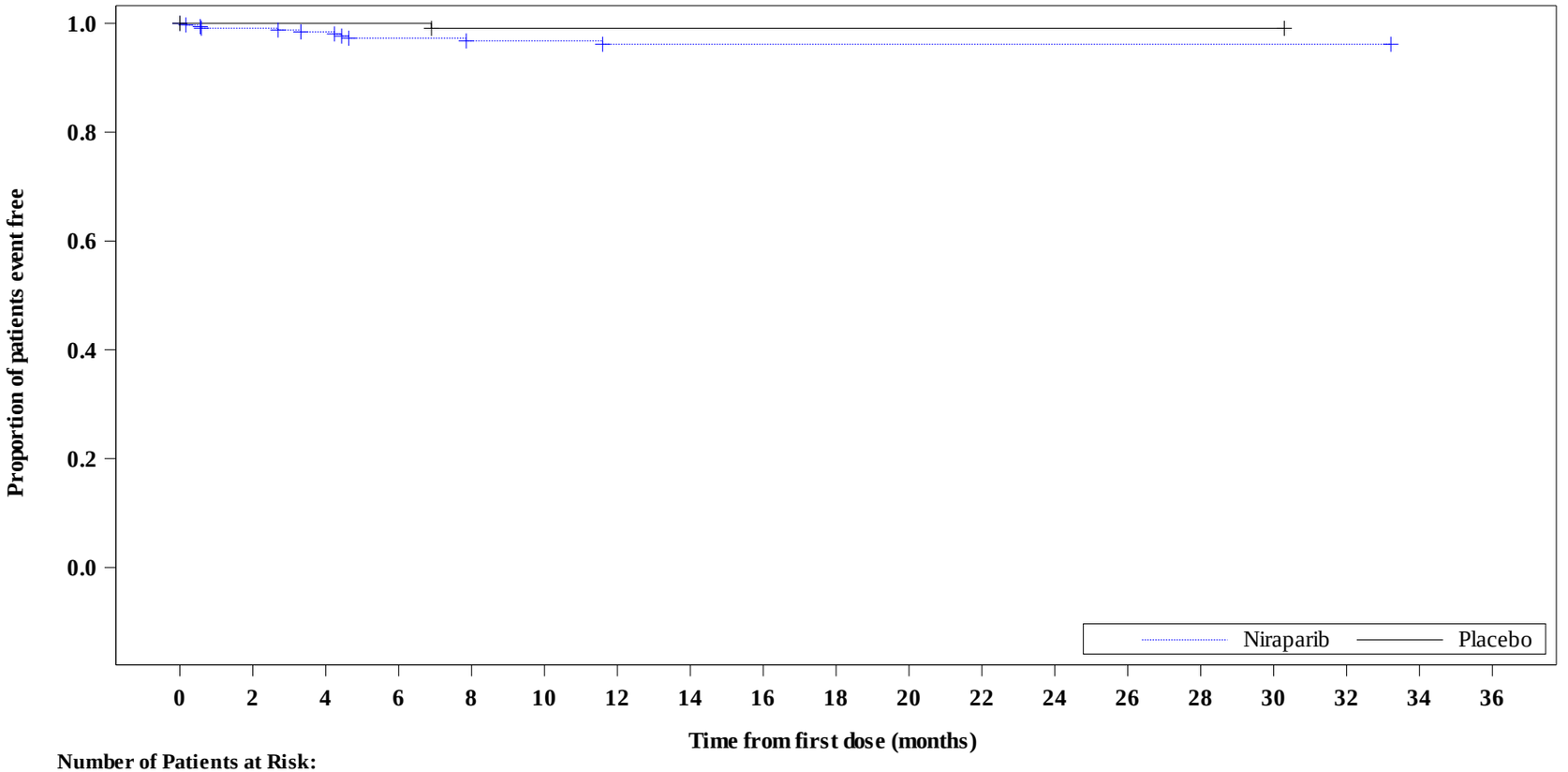
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Eye disorders, PT: Dry eye




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 261 | 232 | 190 | 167 | 158 | 145 | 122 | 111 | 83 | 57 | 39 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 101 | 77 | 69 | 58 | 49 | 42 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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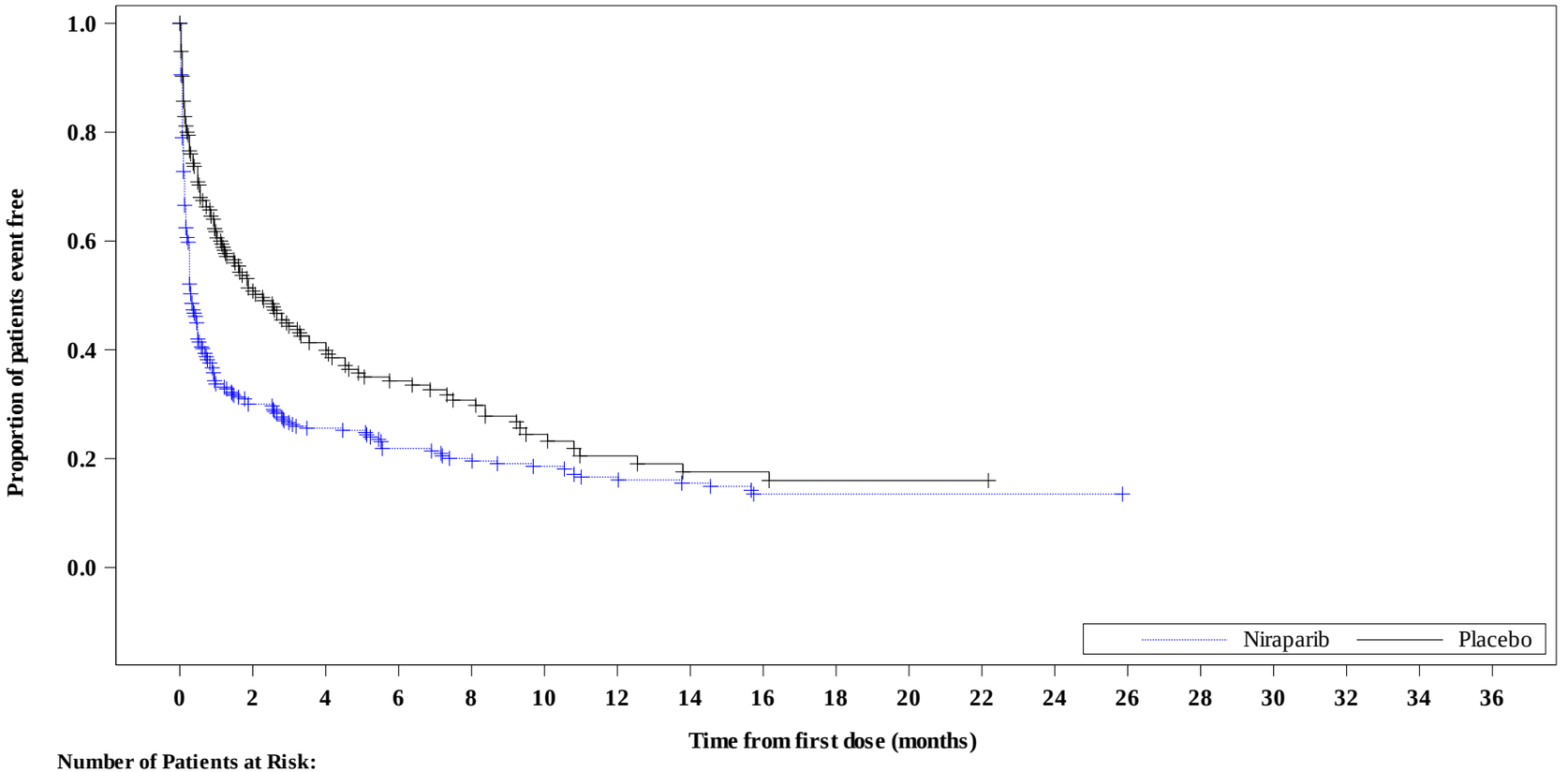
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 90 | 67 | 52 | 41 | 38 | 31 | 27 | 19 | 18 | 9 | 2 | 1 | 0 |
| Placebo | 175 | 88 | 60 | 47 | 32 | 20 | 15 | 11 | 11 | 9 | 8 | 2 | 0 | |

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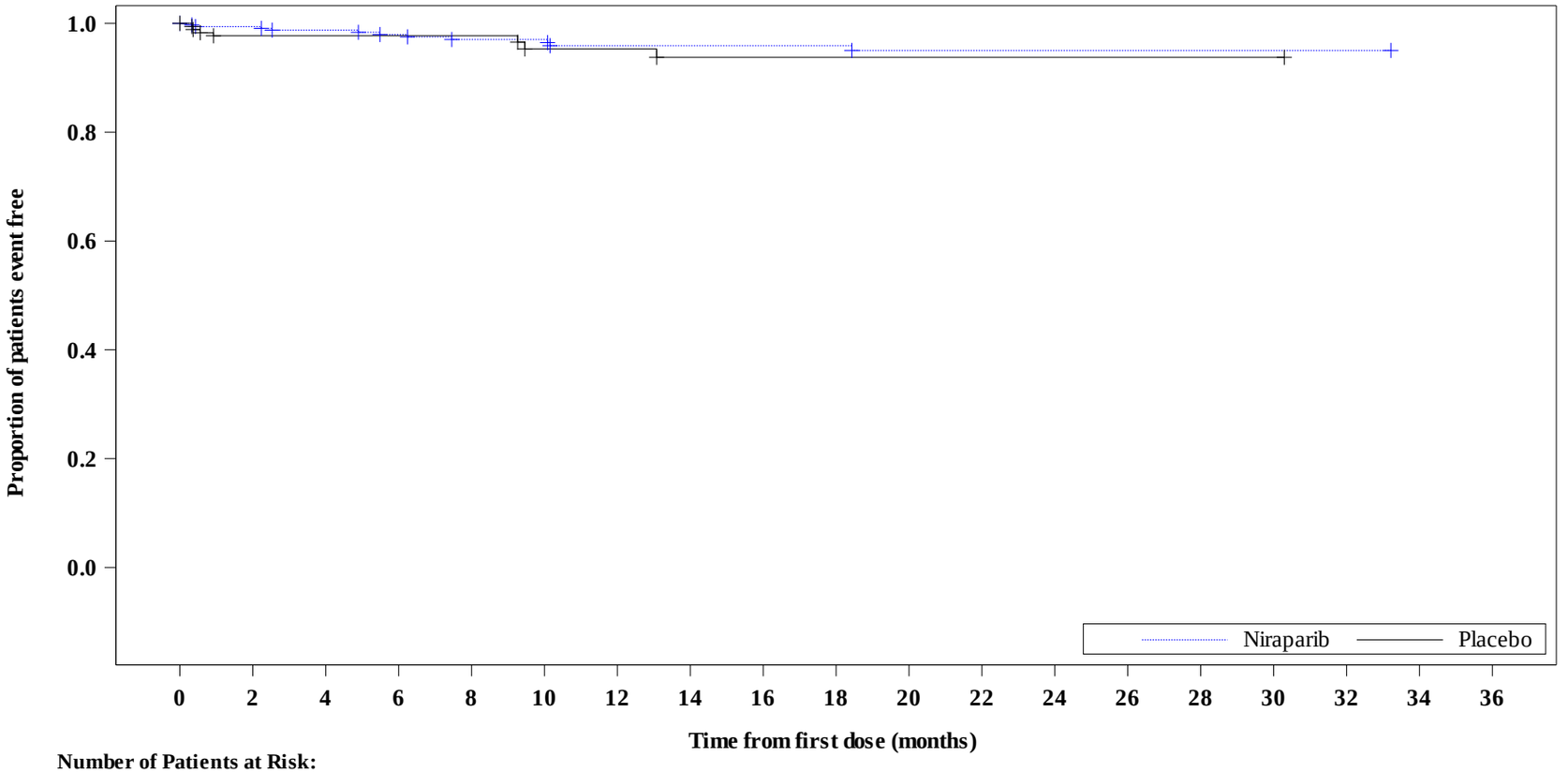
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal discomfort




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 261 | 234 | 192 | 170 | 161 | 148 | 124 | 113 | 82 | 58 | 39 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 168 | 142 | 125 | 100 | 74 | 67 | 55 | 48 | 41 | 34 | 17 | 8 | 5 | 2 | 1 | 0 | |

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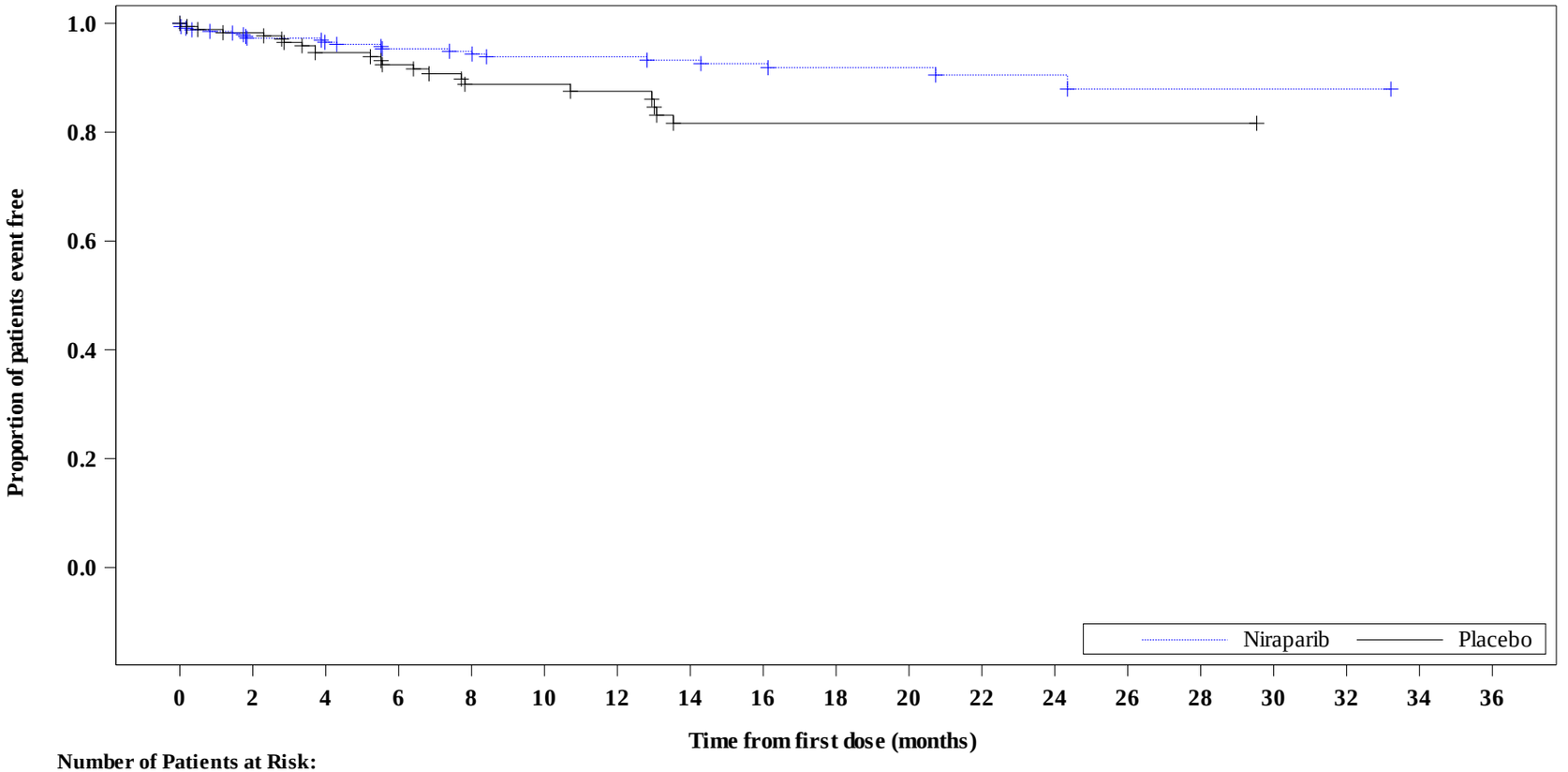
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal distension




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 258 | 232 | 191 | 166 | 159 | 147 | 123 | 113 | 83 | 58 | 40 | 18 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 169 | 139 | 122 | 92 | 73 | 64 | 49 | 42 | 35 | 28 | 13 | 5 | 3 | 1 | 0 | | |

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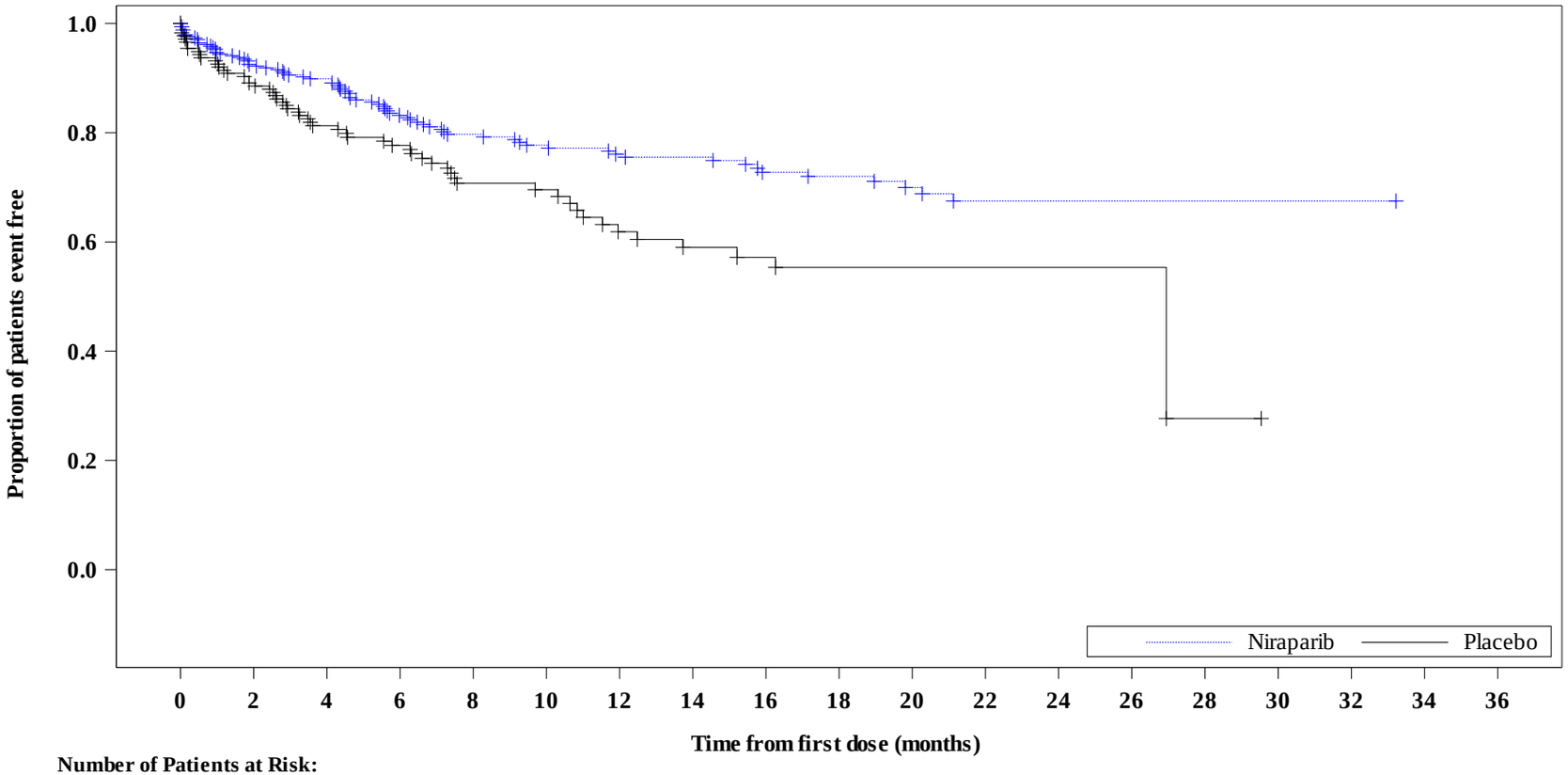
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain

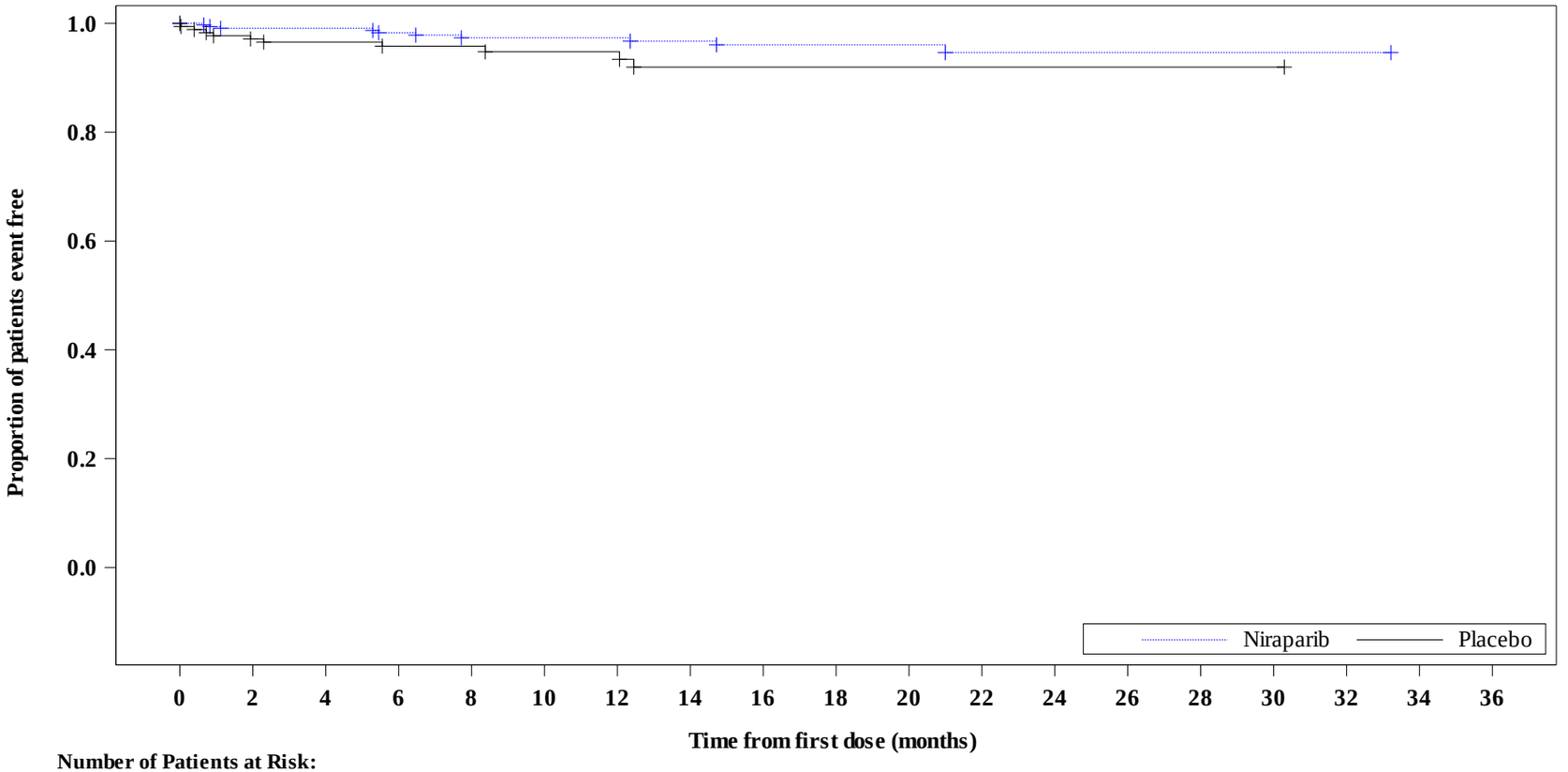



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 288 | 242 | 204 | 165 | 146 | 136 | 126 | 100 | 89 | 61 | 44 | 27 | 12 | 7 | 3 | 2 | 0 |
| Placebo | 175 | 153 | 118 | 103 | 75 | 58 | 47 | 37 | 31 | 26 | 20 | 11 | 5 | 3 | 1 | 0 | | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain lower




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 262 | 234 | 192 | 168 | 161 | 147 | 122 | 112 | 82 | 55 | 38 | 18 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 142 | 126 | 100 | 77 | 70 | 58 | 49 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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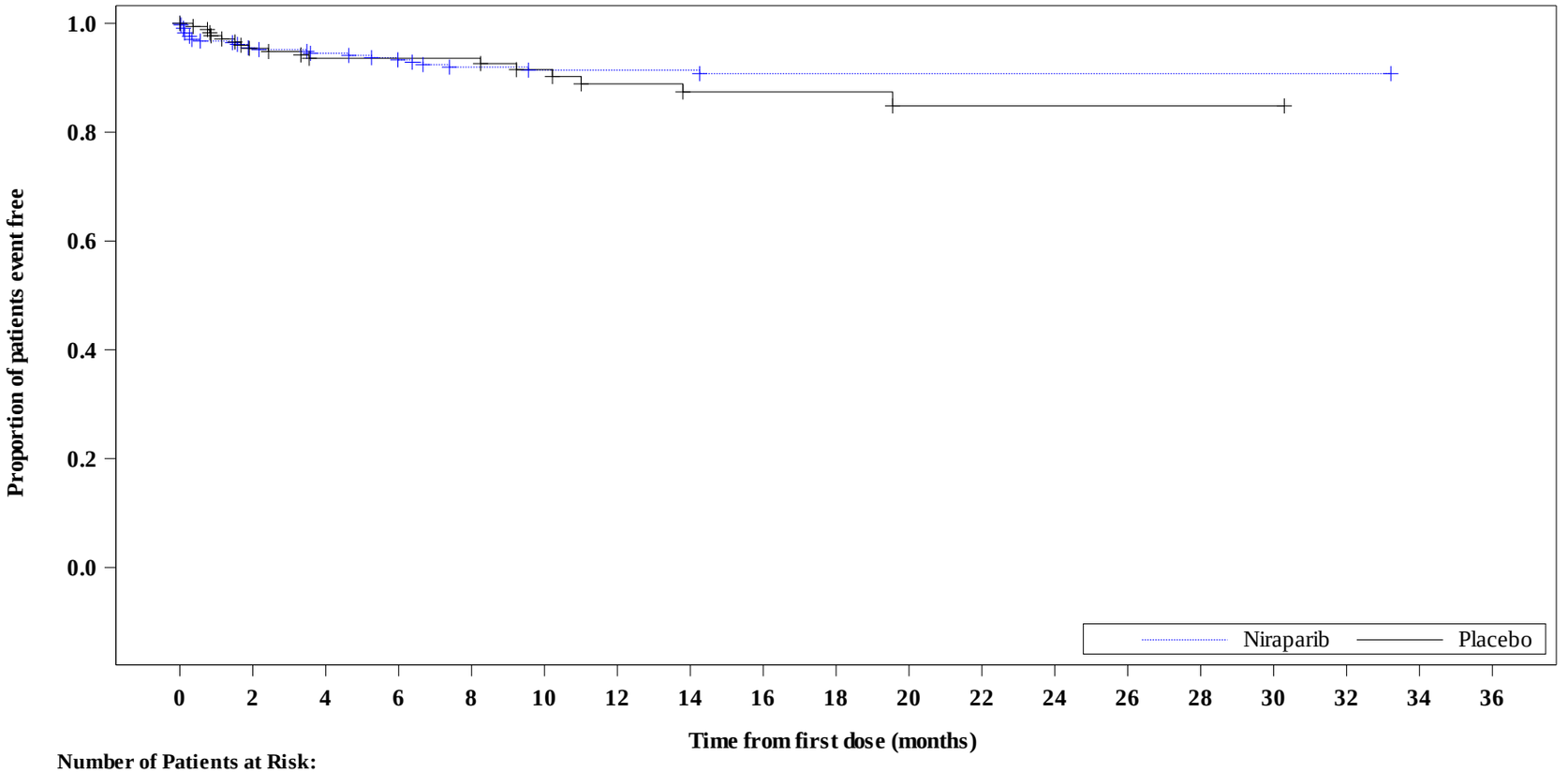
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain upper

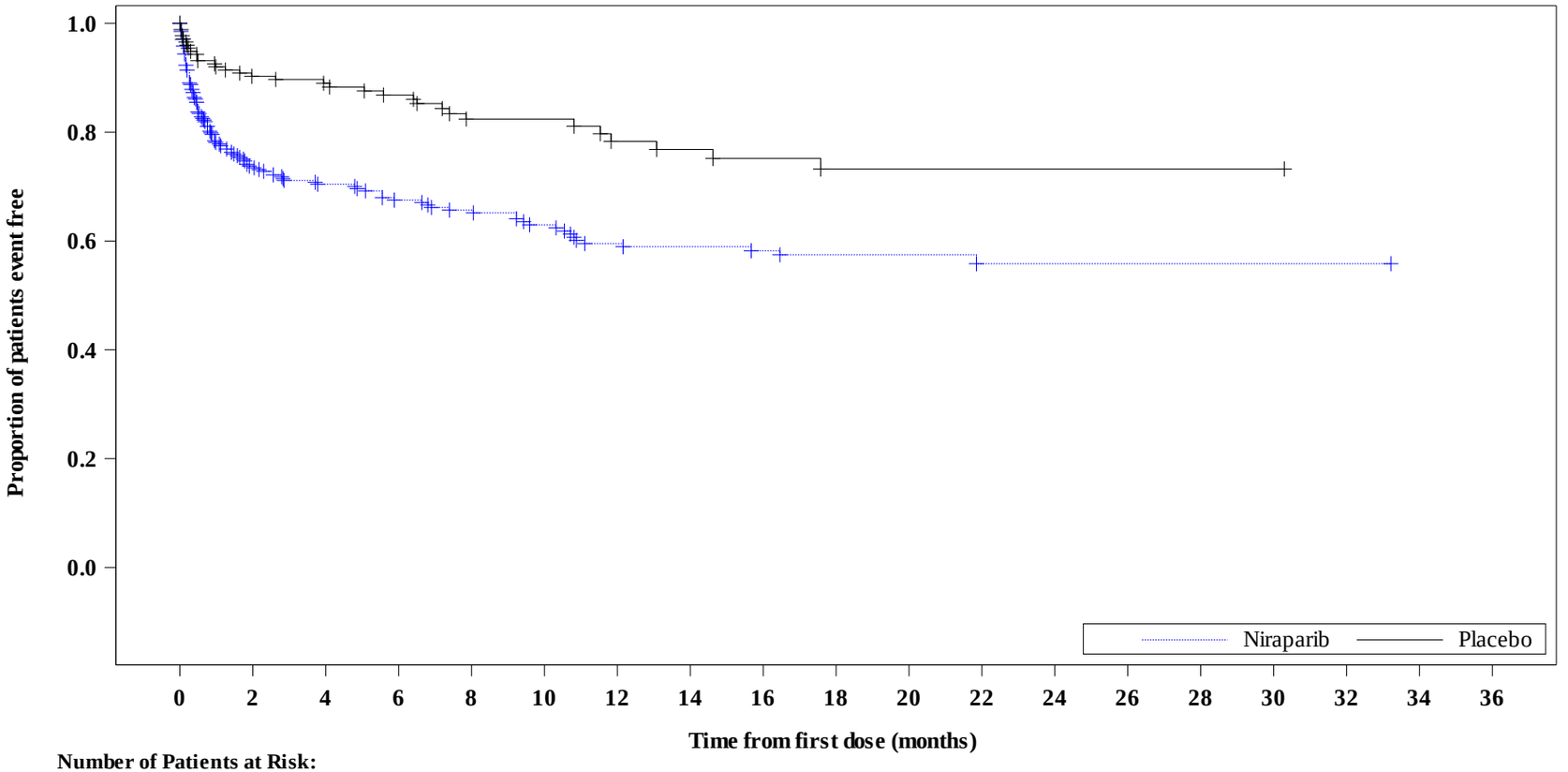



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 298 | 254 | 227 | 184 | 163 | 156 | 144 | 118 | 107 | 78 | 53 | 36 | 18 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 164 | 136 | 120 | 98 | 74 | 65 | 54 | 47 | 41 | 33 | 17 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Constipation




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 228 | 186 | 159 | 129 | 110 | 101 | 96 | 79 | 72 | 52 | 34 | 24 | 10 | 3 | 1 | 1 | 0 |
| Placebo | 175 | 156 | 129 | 114 | 84 | 66 | 56 | 48 | 42 | 35 | 29 | 17 | 7 | 5 | 2 | 1 | 0 | |

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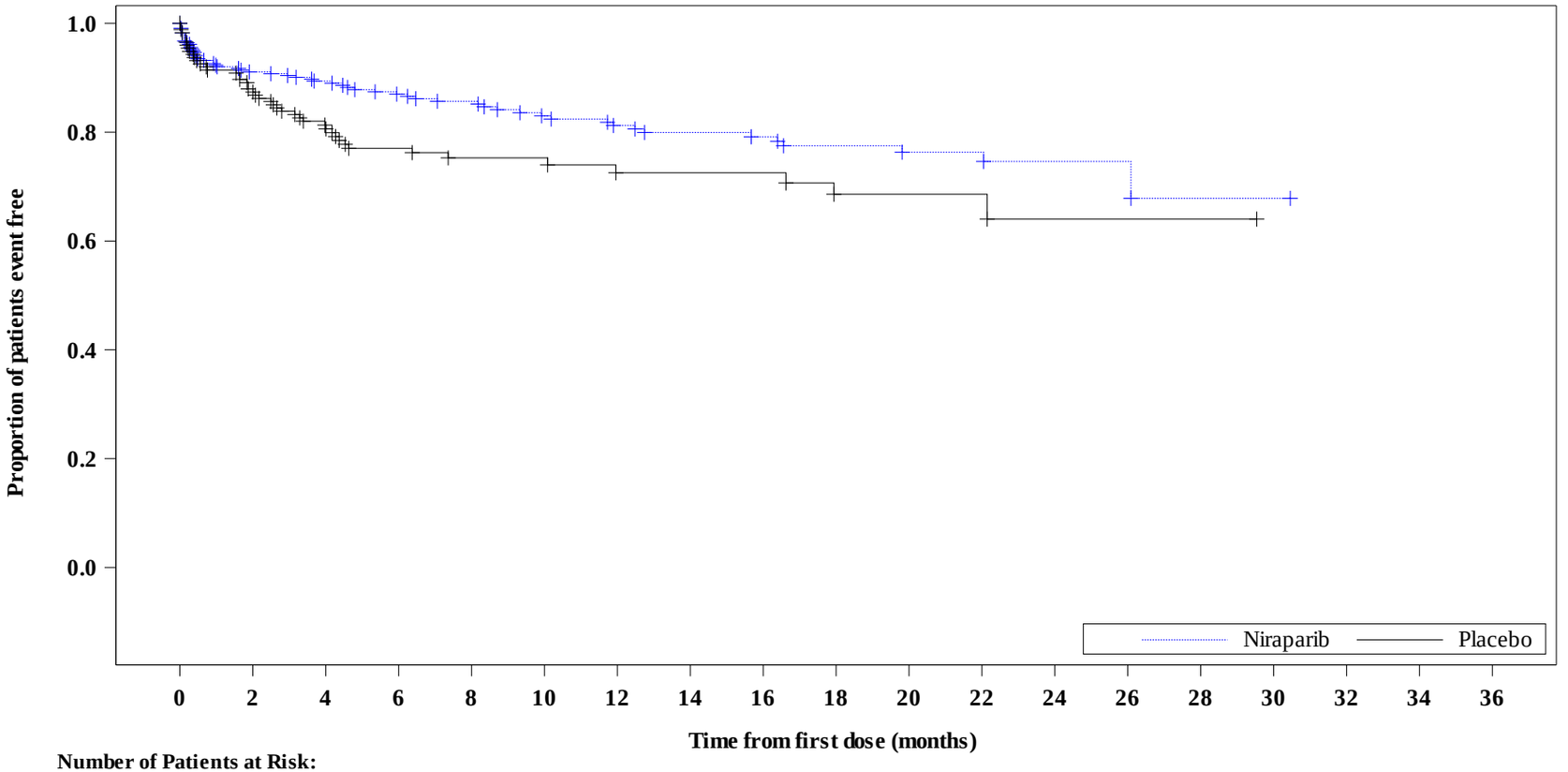
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Diarrhoea




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 283 | 239 | 210 | 167 | 143 | 134 | 121 | 98 | 86 | 63 | 45 | 27 | 11 | 3 | 1 | 0 |
| Placebo | 175 | 151 | 116 | 100 | 74 | 58 | 50 | 41 | 39 | 33 | 26 | 15 | 7 | 4 | 1 | 0 | |

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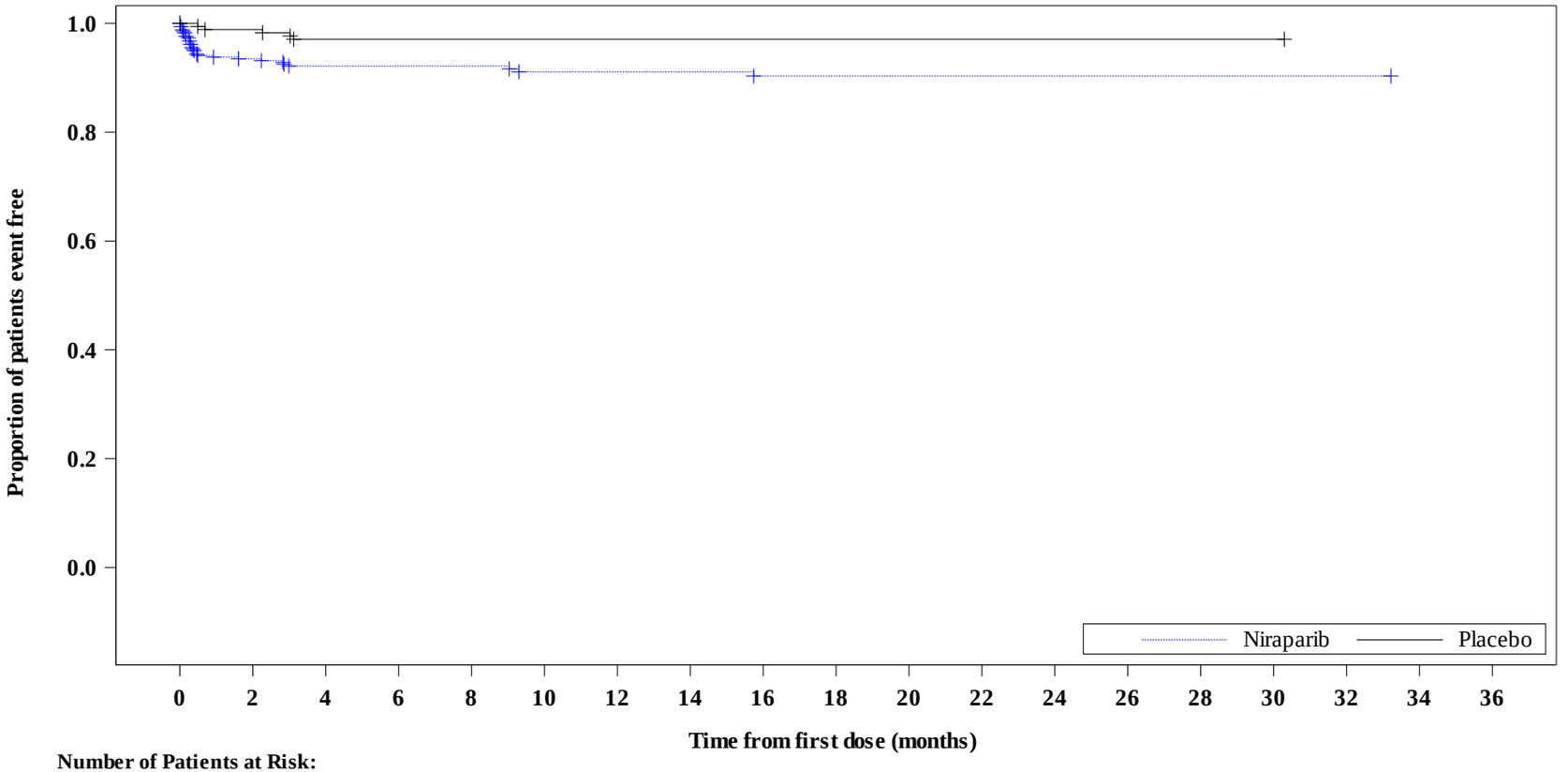
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Dry mouth




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 290 | 245 | 222 | 183 | 160 | 152 | 140 | 116 | 106 | 78 | 53 | 37 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 140 | 125 | 99 | 77 | 69 | 58 | 49 | 42 | 35 | 18 | 8 | 5 | 2 | 1 | 0 | |

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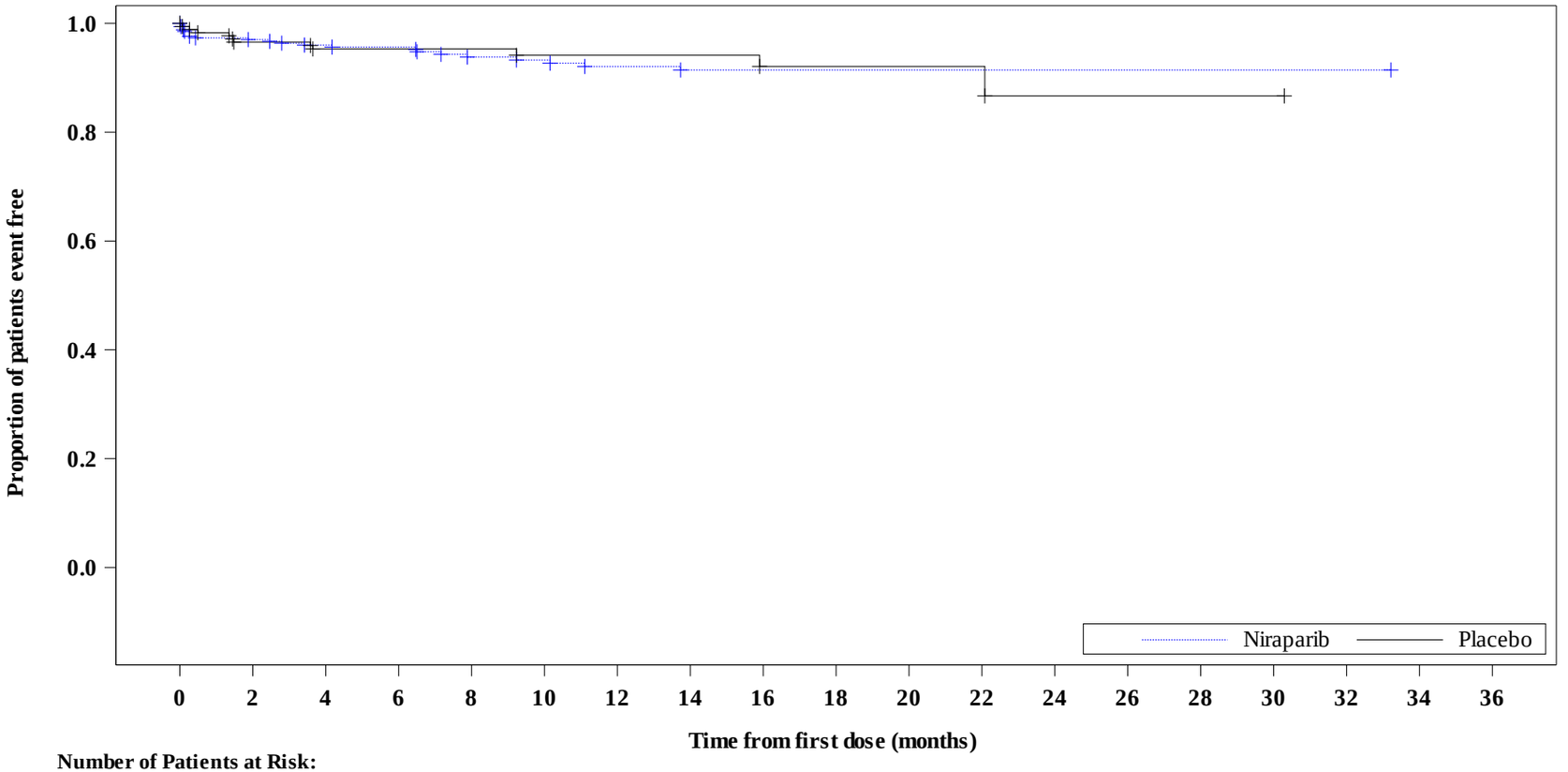
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Dyspepsia

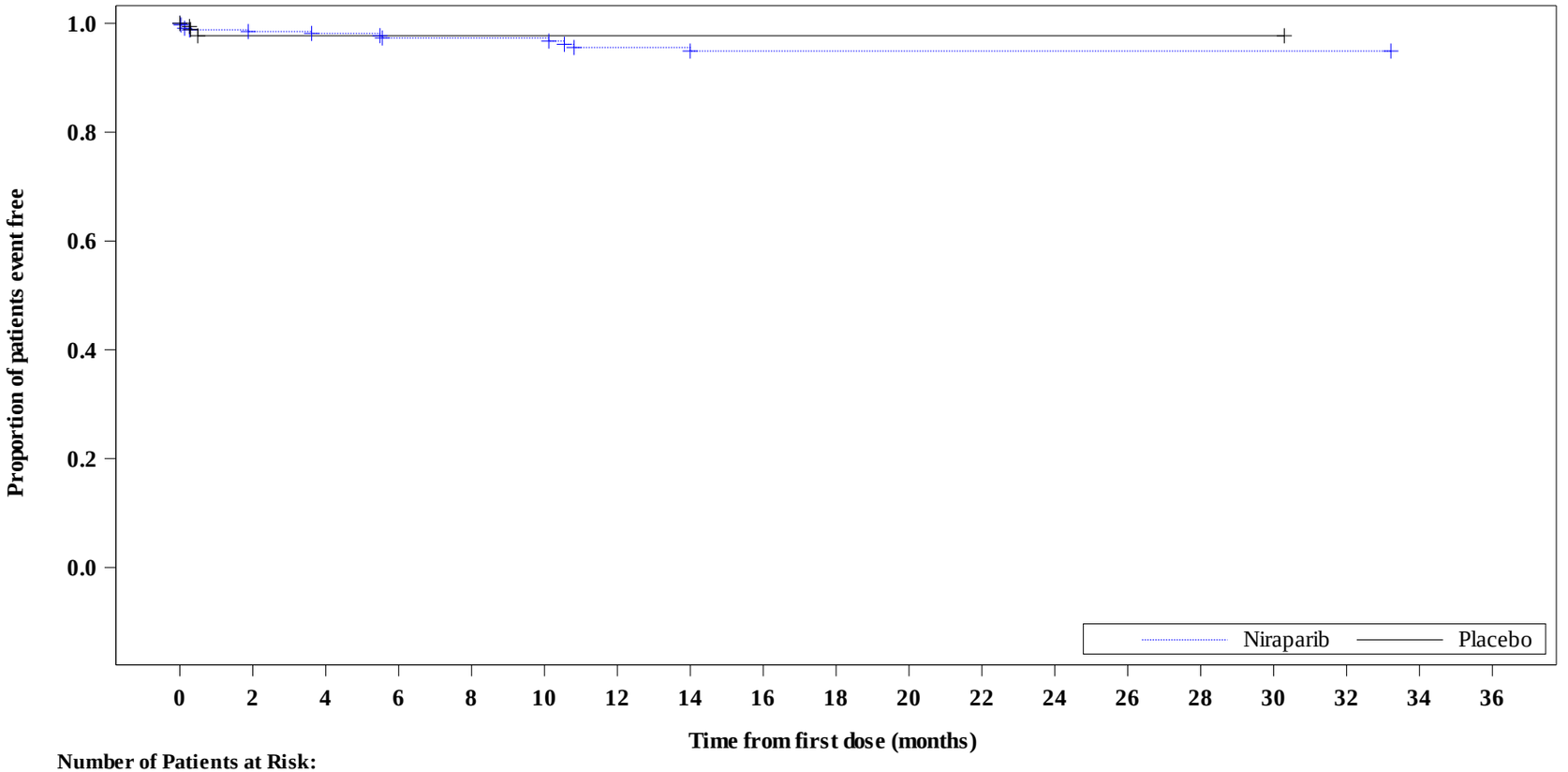



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 301 | 254 | 228 | 183 | 160 | 151 | 141 | 118 | 107 | 79 | 56 | 38 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 166 | 138 | 121 | 96 | 72 | 66 | 55 | 45 | 39 | 33 | 17 | 6 | 3 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Flatulence

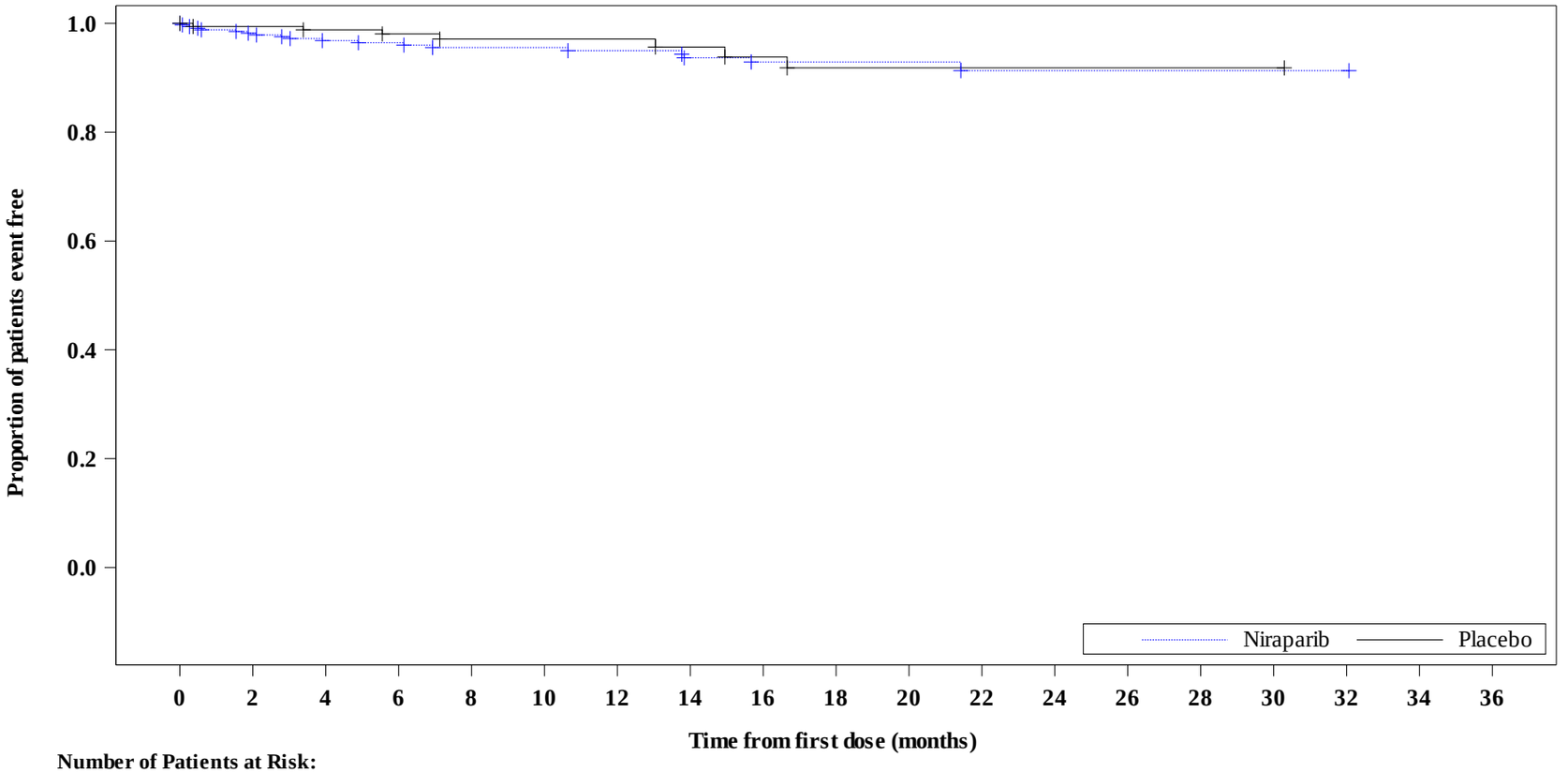



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 260 | 232 | 190 | 167 | 158 | 145 | 121 | 113 | 85 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 168 | 142 | 126 | 100 | 77 | 69 | 58 | 49 | 42 | 35 | 18 | 7 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease

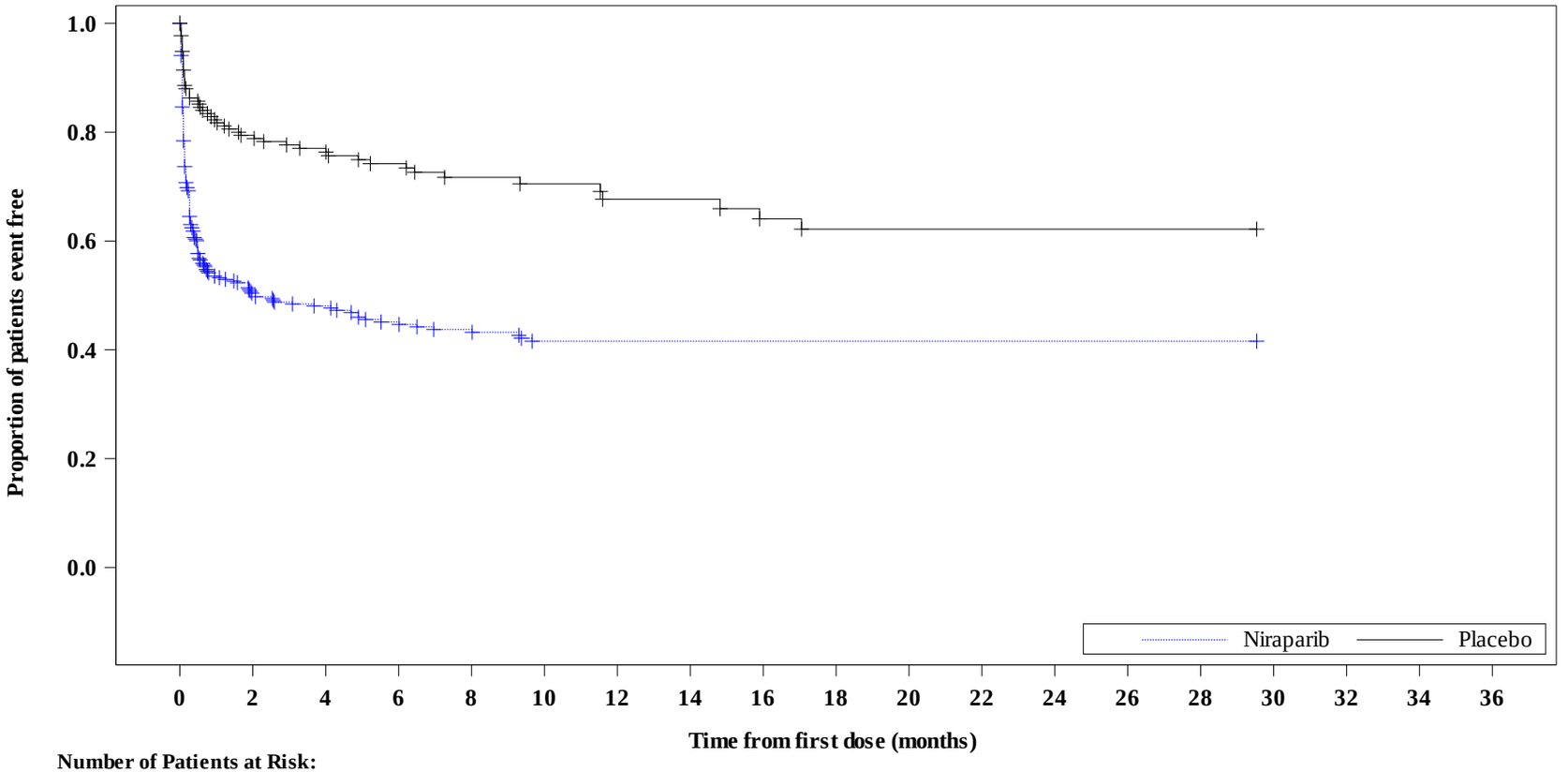



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 305 | 257 | 231 | 188 | 165 | 157 | 143 | 121 | 110 | 82 | 55 | 37 | 16 | 7 | 2 | 1 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 99 | 77 | 69 | 58 | 48 | 40 | 33 | 17 | 7 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Nausea

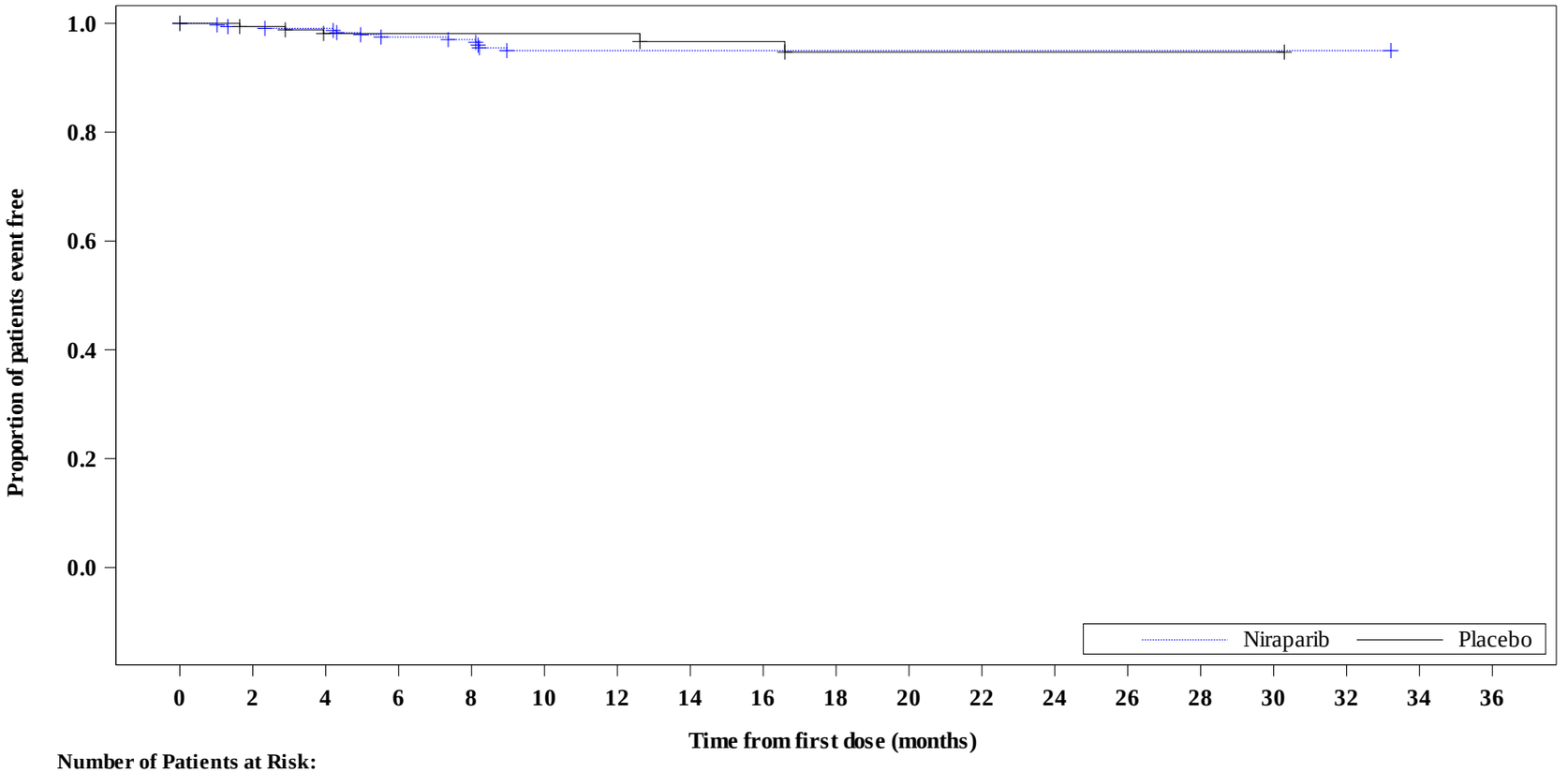



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 154 | 121 | 101 | 85 | 73 | 68 | 63 | 53 | 49 | 30 | 19 | 10 | 4 | 2 | 0 |
| Placebo | 175 | 137 | 113 | 97 | 74 | 57 | 48 | 40 | 34 | 29 | 24 | 11 | 4 | 3 | 1 | 0 |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction

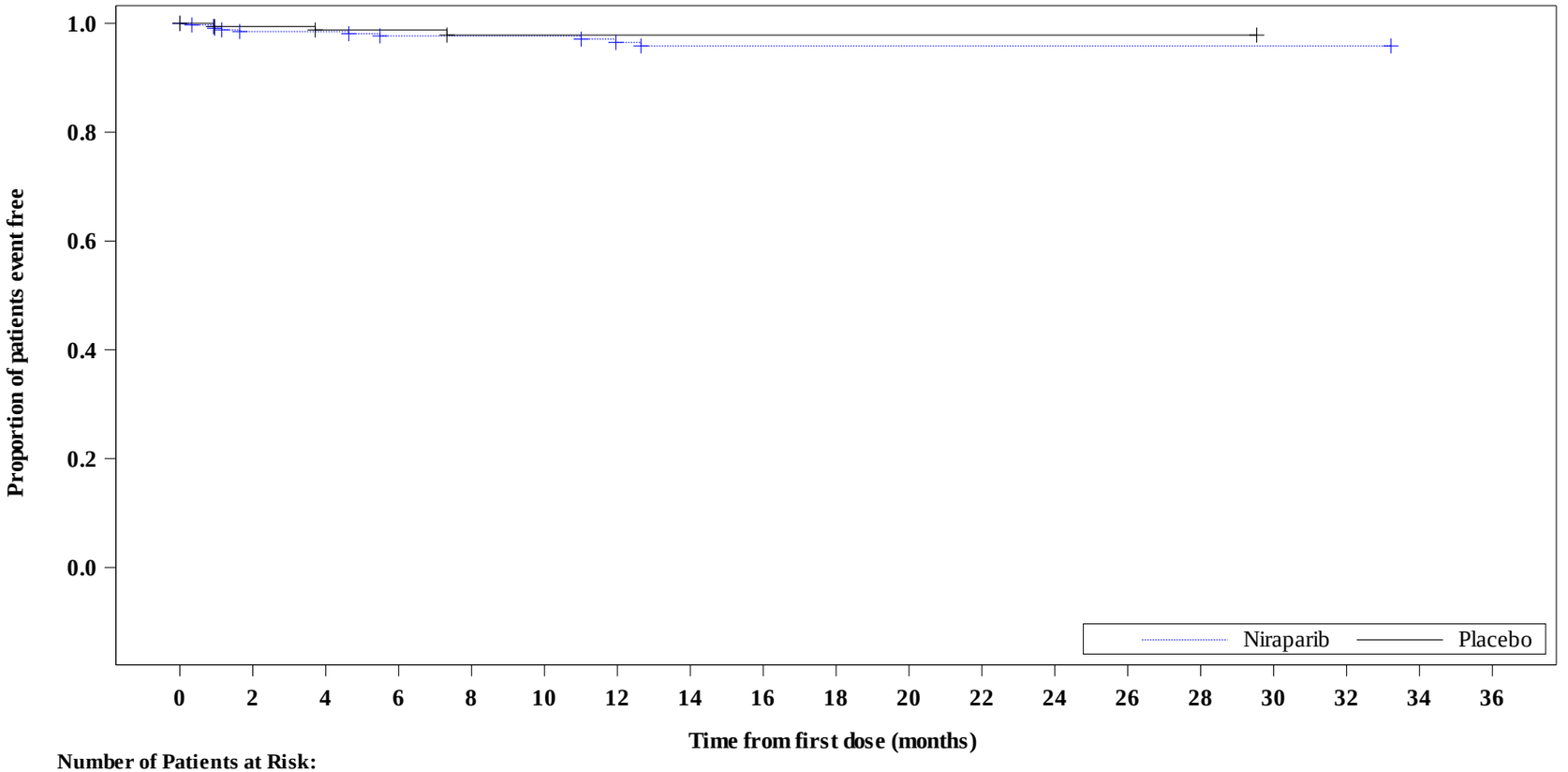



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 263 | 234 | 193 | 169 | 162 | 149 | 124 | 113 | 83 | 58 | 39 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 128 | 102 | 78 | 70 | 58 | 50 | 42 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Stomatitis

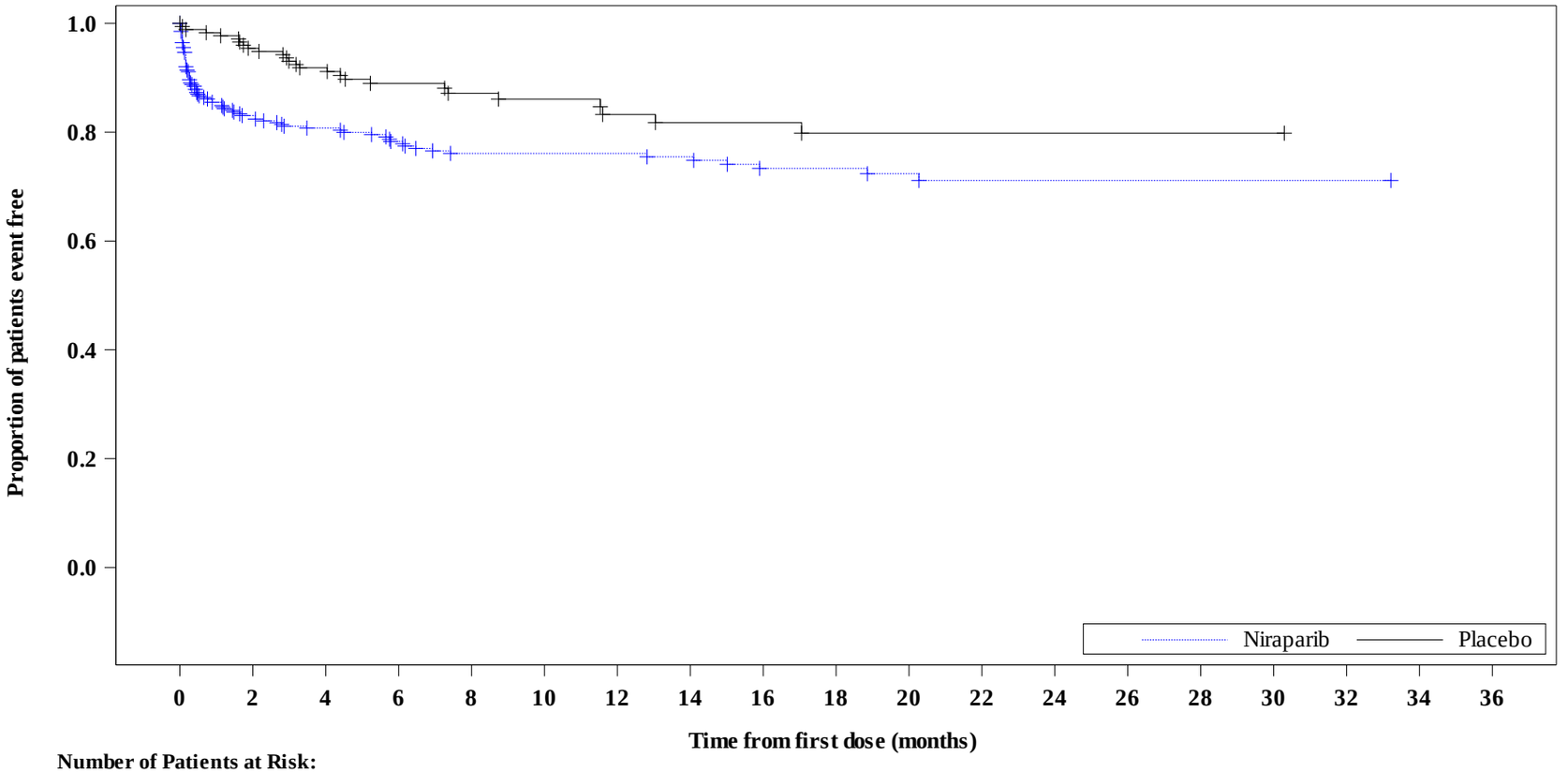



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 261 | 233 | 193 | 169 | 159 | 145 | 122 | 111 | 82 | 57 | 39 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 143 | 126 | 99 | 76 | 68 | 57 | 48 | 41 | 34 | 18 | 7 | 4 | 1 | 0 | | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Vomiting




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 256 | 213 | 186 | 150 | 137 | 129 | 117 | 96 | 88 | 59 | 41 | 25 | 16 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 165 | 135 | 116 | 91 | 68 | 59 | 49 | 42 | 36 | 31 | 16 | 8 | 5 | 2 | 1 | 0 | |

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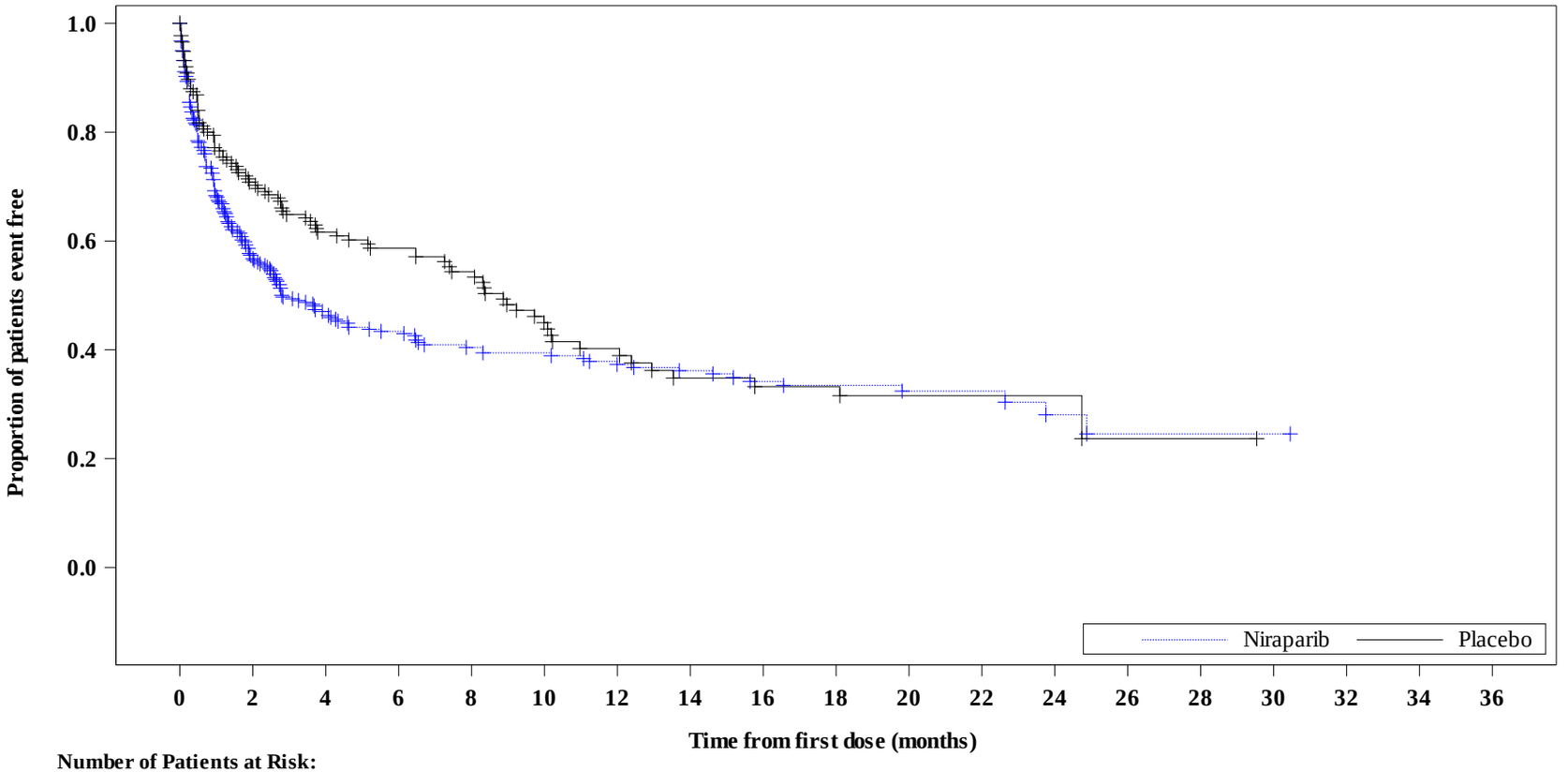
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: General disorders and administration site conditions




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 182 | 132 | 111 | 82 | 76 | 68 | 61 | 47 | 42 | 31 | 21 | 11 | 5 | 1 | 1 | 0 |
| Placebo | 175 | 122 | 89 | 76 | 56 | 39 | 31 | 23 | 21 | 20 | 16 | 7 | 4 | 2 | 1 | 0 | |

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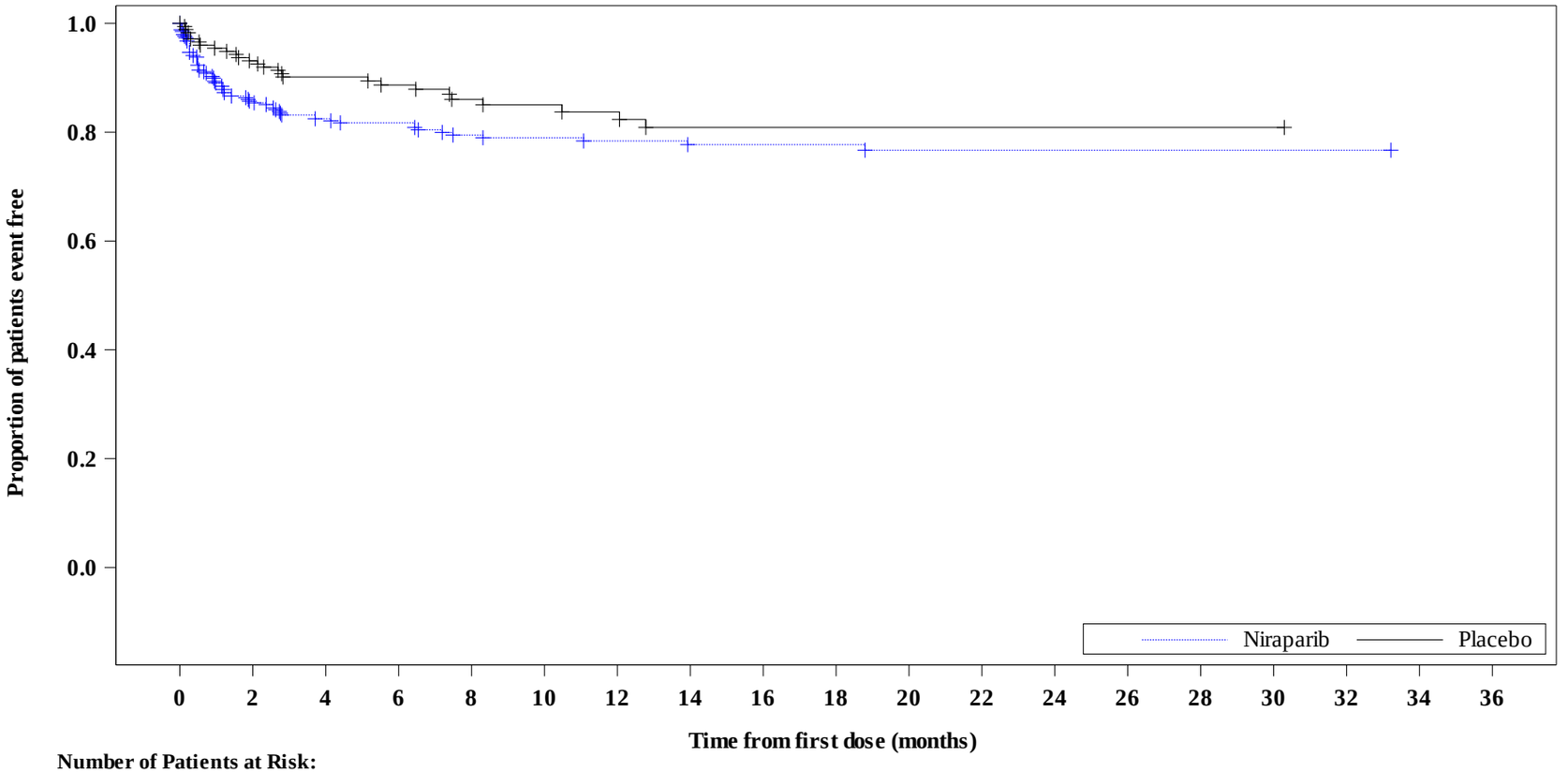
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: General disorders and administration site conditions, PT: Asthenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 270 | 221 | 198 | 159 | 137 | 129 | 116 | 93 | 84 | 62 | 43 | 26 | 15 | 6 | 3 | 2 | 0 |
| Placebo | 175 | 160 | 133 | 116 | 90 | 68 | 61 | 49 | 43 | 36 | 31 | 15 | 7 | 5 | 2 | 1 | 0 | |

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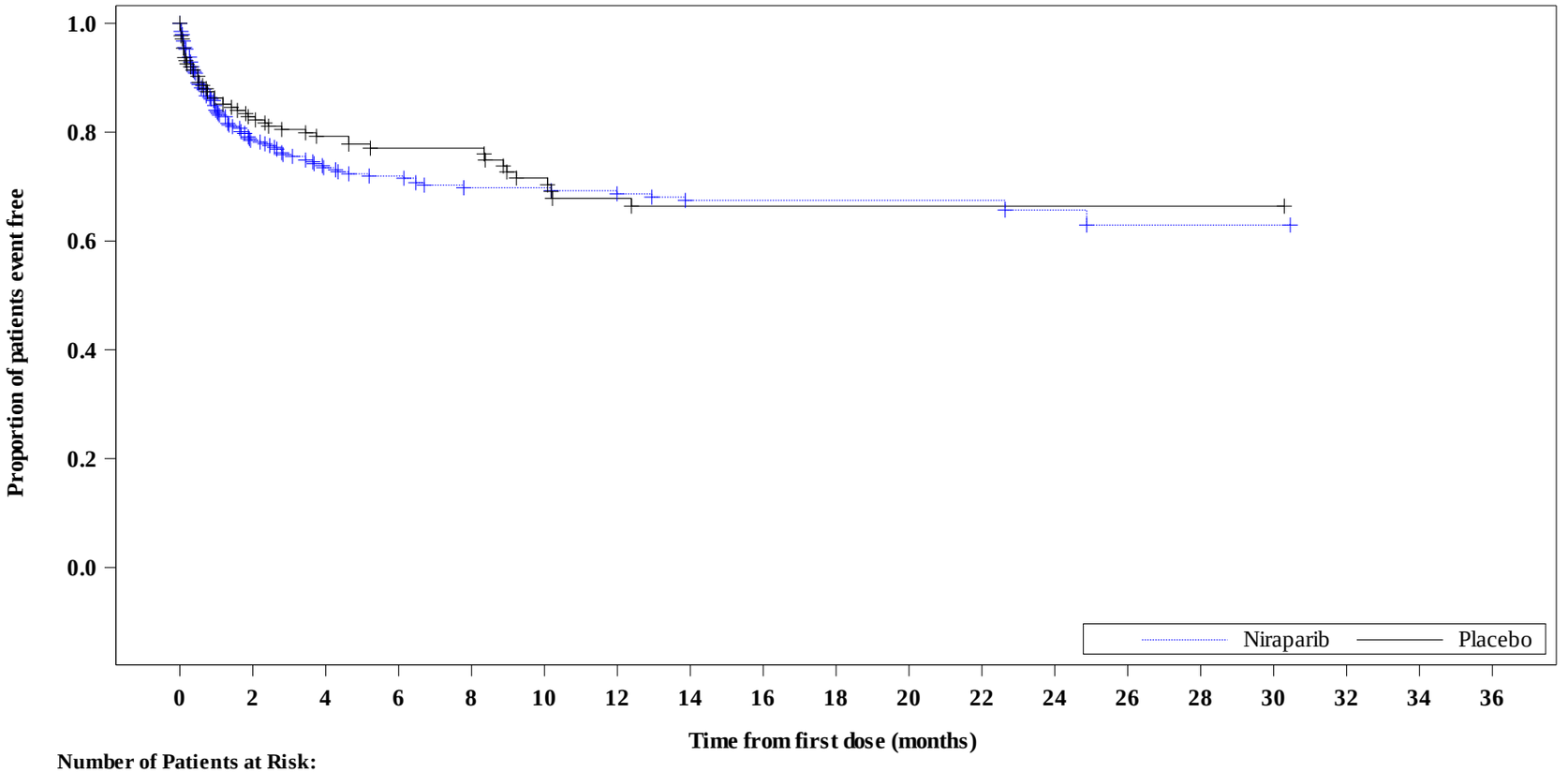
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: General disorders and administration site conditions, PT: Fatigue




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 245 | 200 | 178 | 141 | 128 | 120 | 110 | 92 | 85 | 62 | 45 | 31 | 14 | 6 | 1 | 0 |
| Placebo | 175 | 143 | 116 | 100 | 75 | 58 | 49 | 42 | 38 | 33 | 27 | 15 | 6 | 4 | 2 | 1 | 0 |

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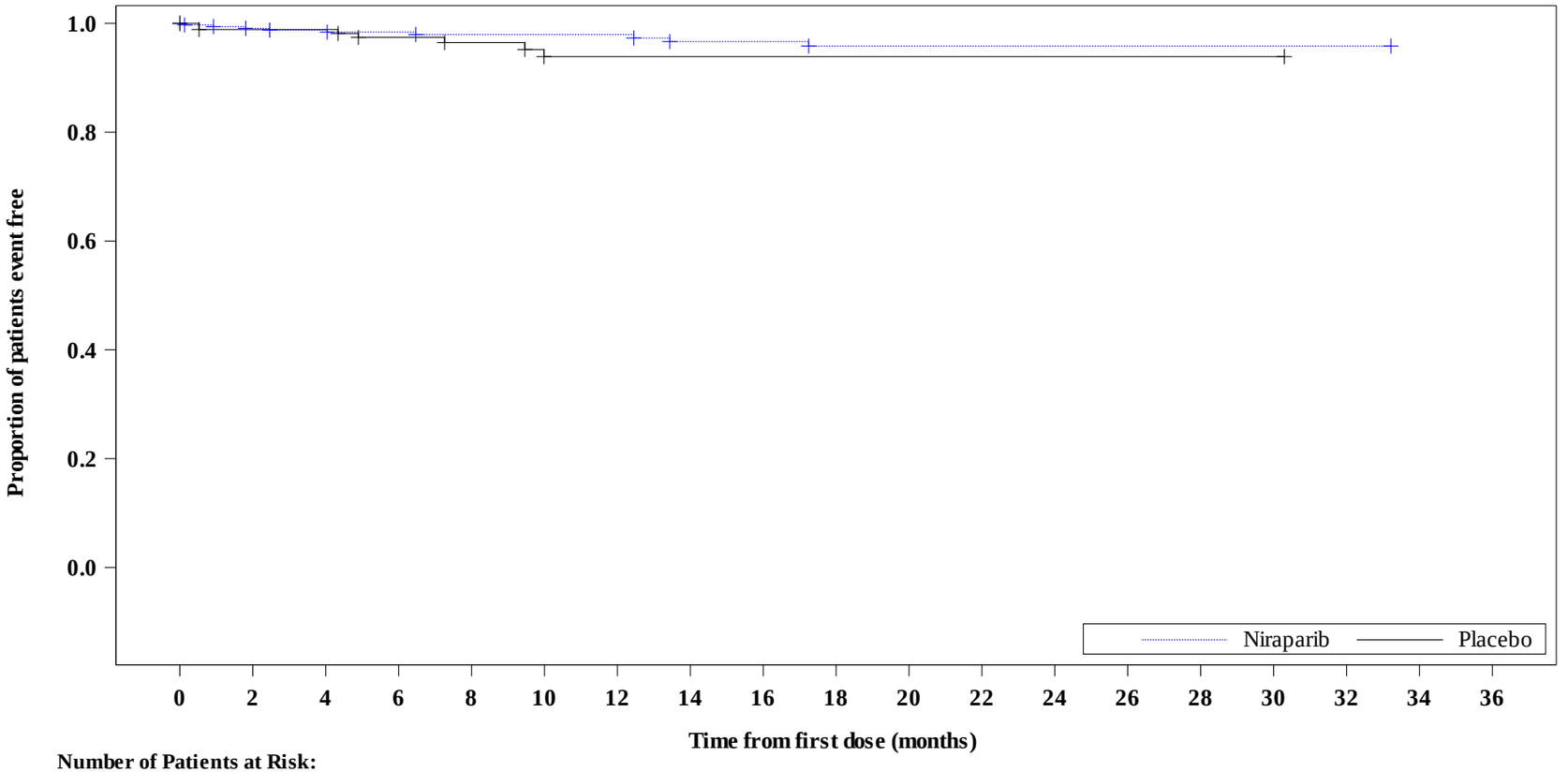
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: General disorders and administration site conditions, PT: Influenza like illness

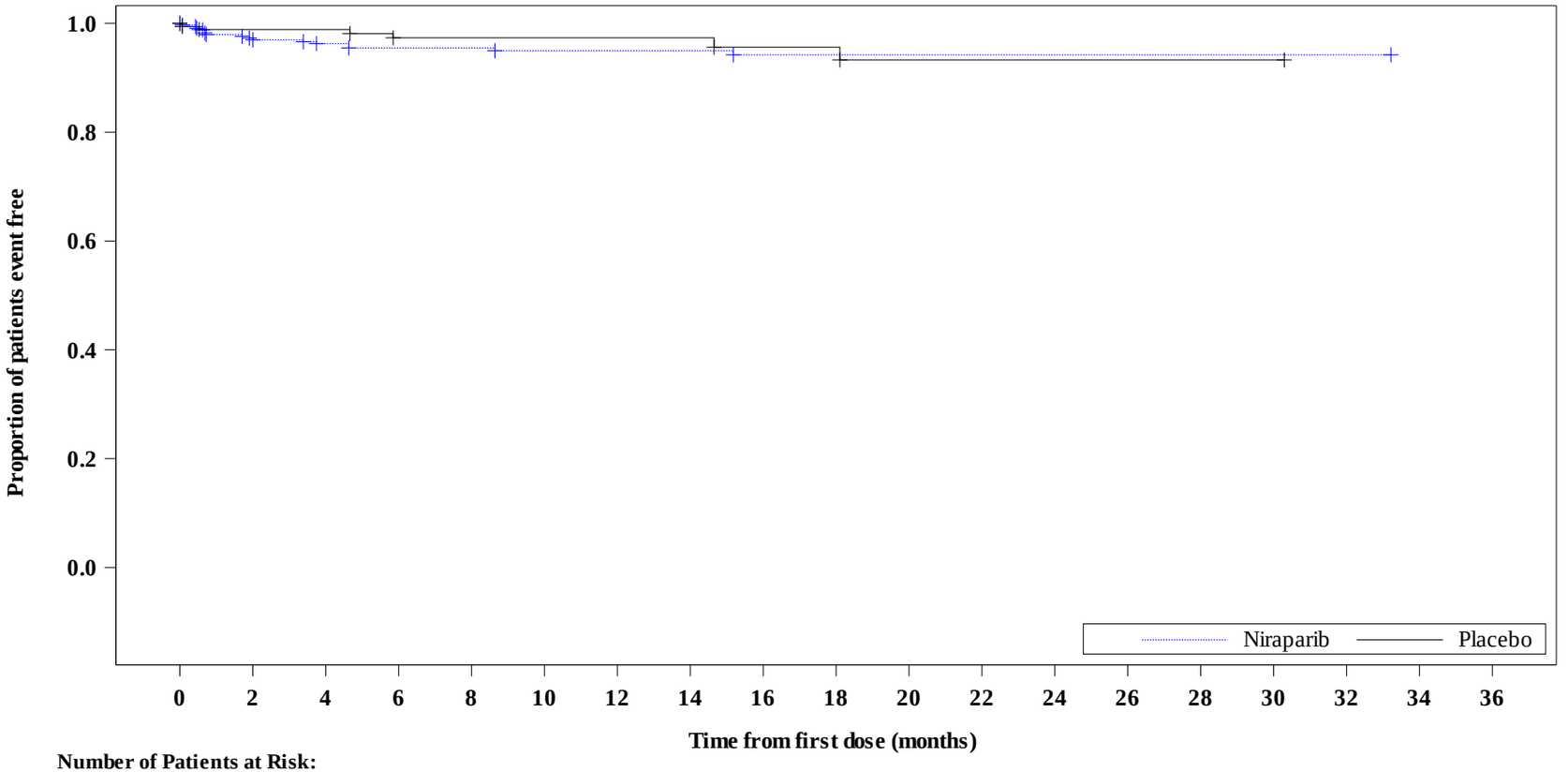



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 261 | 234 | 192 | 168 | 160 | 146 | 122 | 110 | 81 | 56 | 39 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 143 | 124 | 97 | 72 | 65 | 54 | 47 | 40 | 33 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: General disorders and administration site conditions, PT: Mucosal inflammation




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 255 | 228 | 187 | 164 | 156 | 143 | 119 | 109 | 81 | 56 | 38 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 143 | 124 | 98 | 77 | 69 | 58 | 48 | 41 | 34 | 19 | 8 | 5 | 2 | 1 | 0 | |

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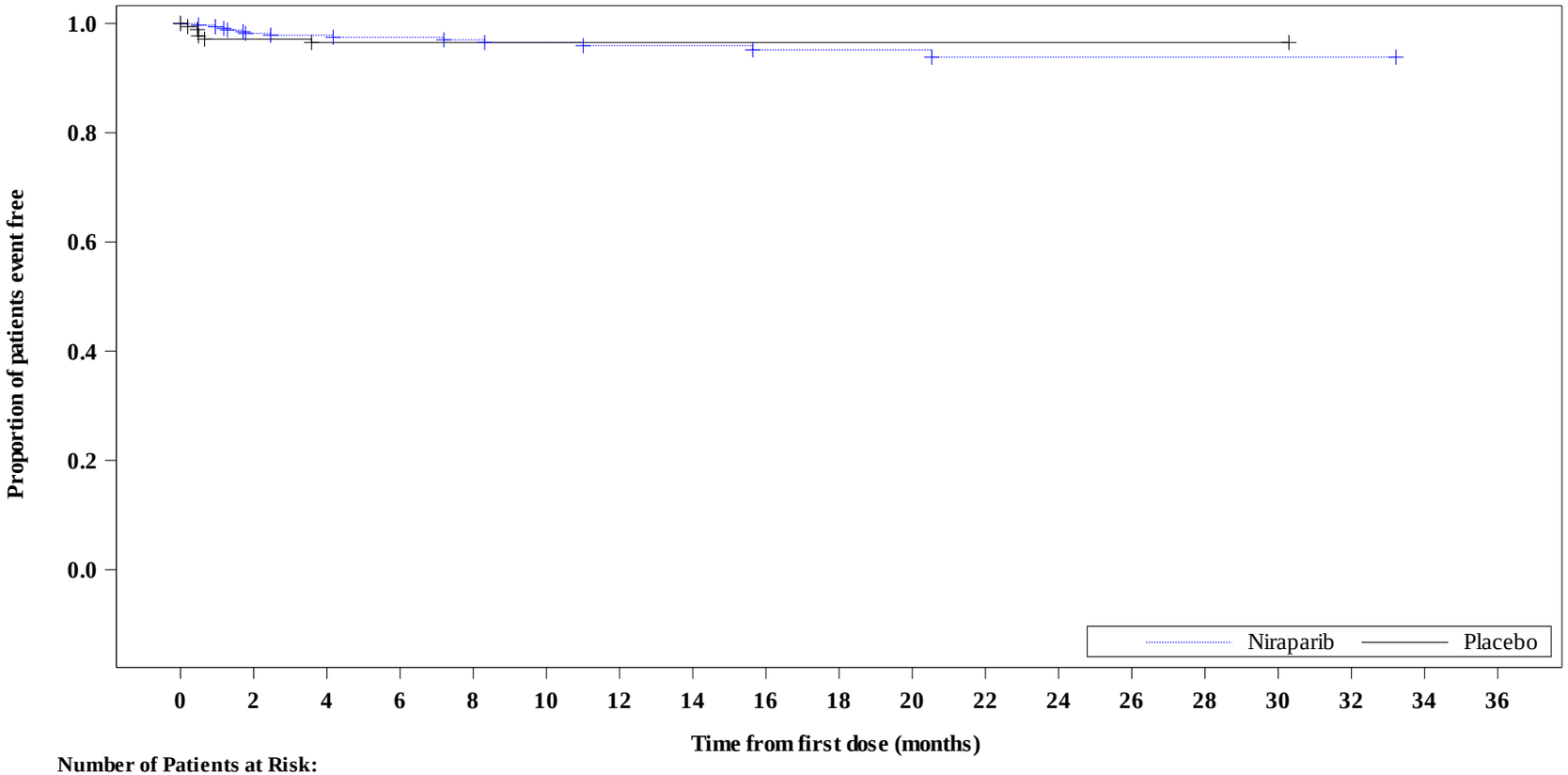
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: General disorders and administration site conditions, PT: Oedema peripheral




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 260 | 233 | 193 | 170 | 161 | 149 | 125 | 114 | 84 | 57 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 139 | 123 | 99 | 75 | 67 | 57 | 48 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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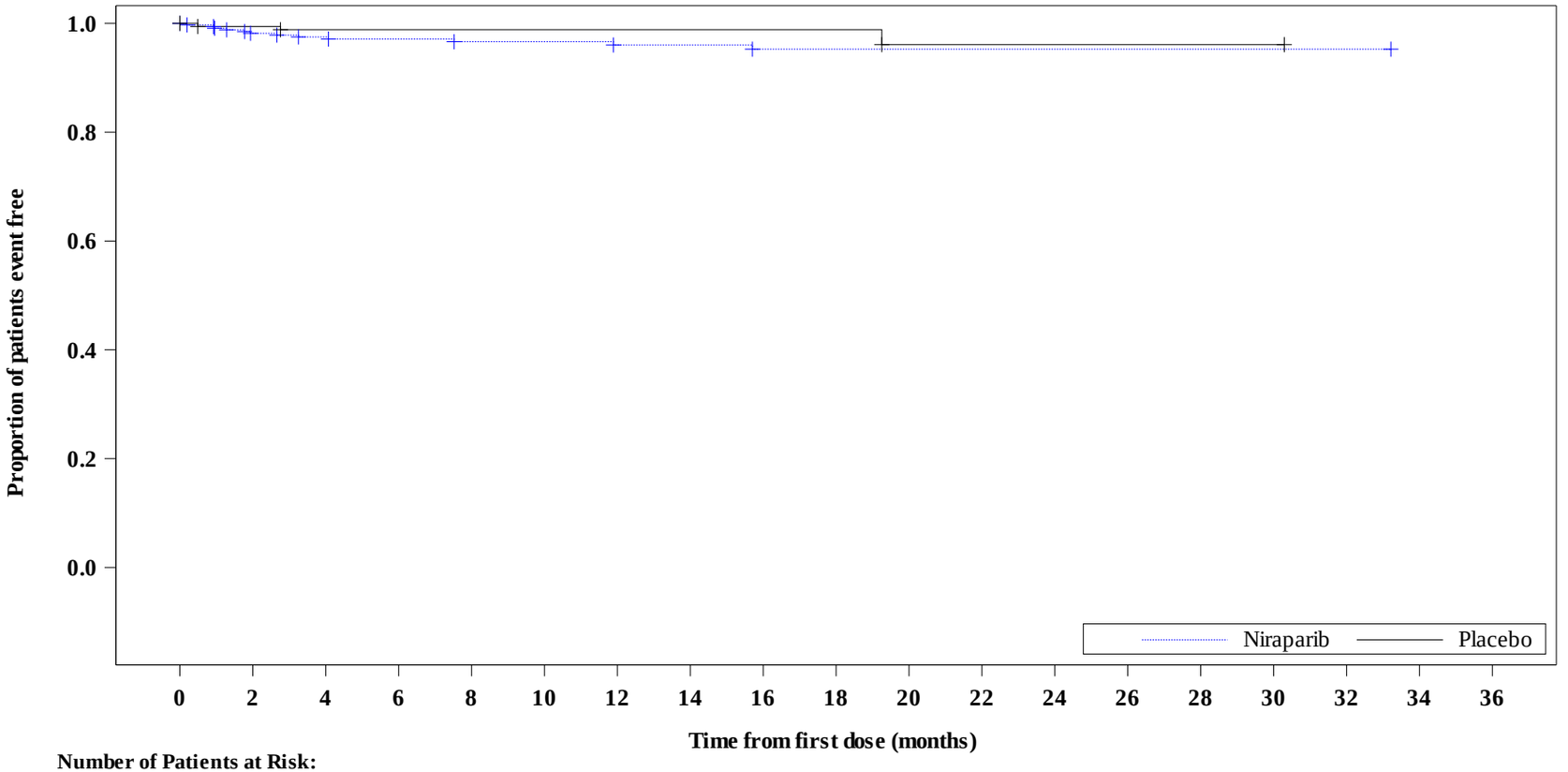
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: General disorders and administration site conditions, PT: Pain




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 305 | 257 | 230 | 188 | 167 | 158 | 147 | 121 | 110 | 81 | 56 | 37 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 143 | 127 | 102 | 78 | 70 | 59 | 50 | 43 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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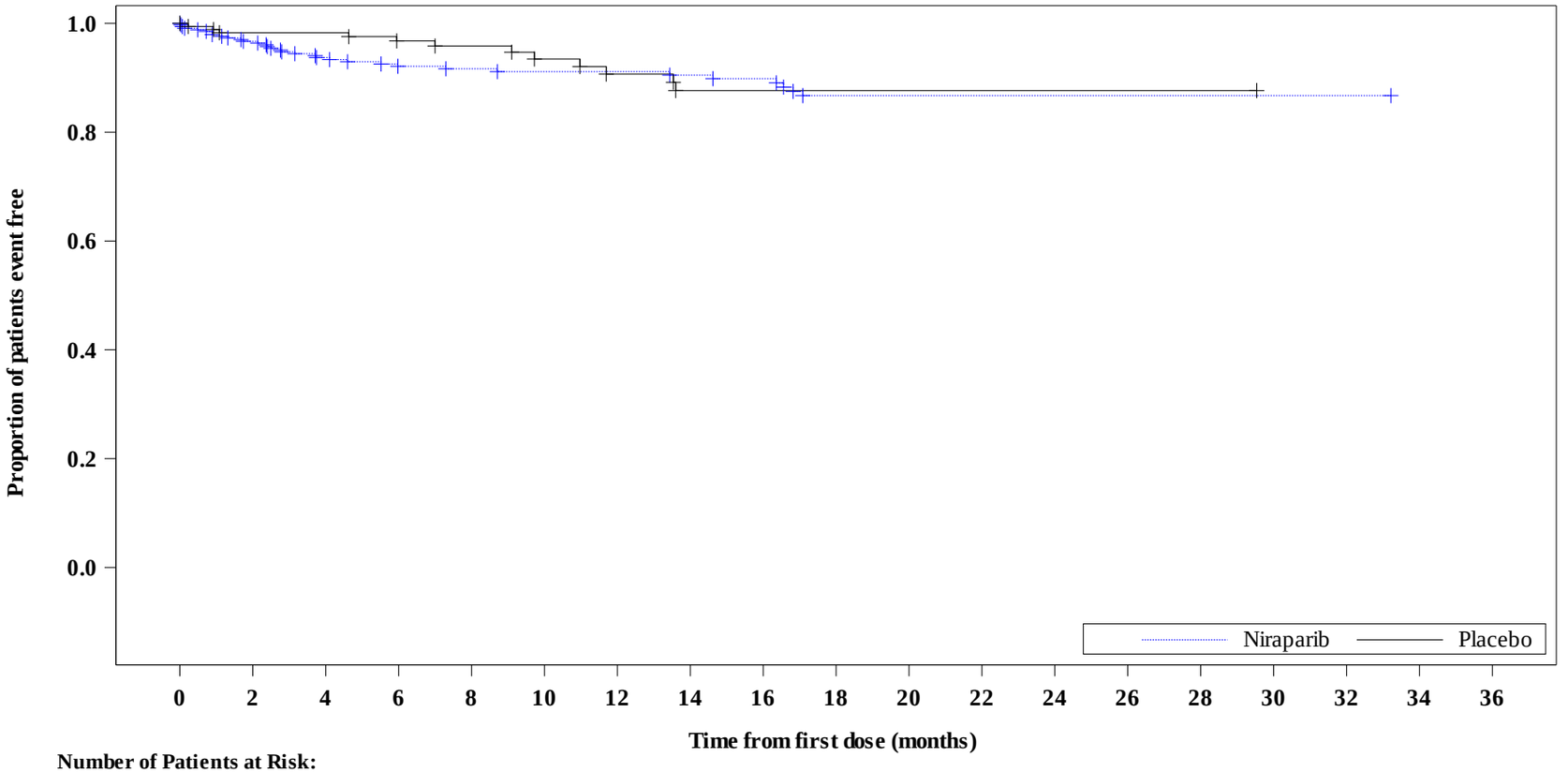
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: General disorders and administration site conditions, PT: Pyrexia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 302 | 249 | 221 | 181 | 161 | 153 | 140 | 117 | 103 | 76 | 52 | 36 | 18 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 169 | 142 | 123 | 98 | 73 | 65 | 53 | 45 | 39 | 33 | 17 | 7 | 4 | 1 | 0 | | |

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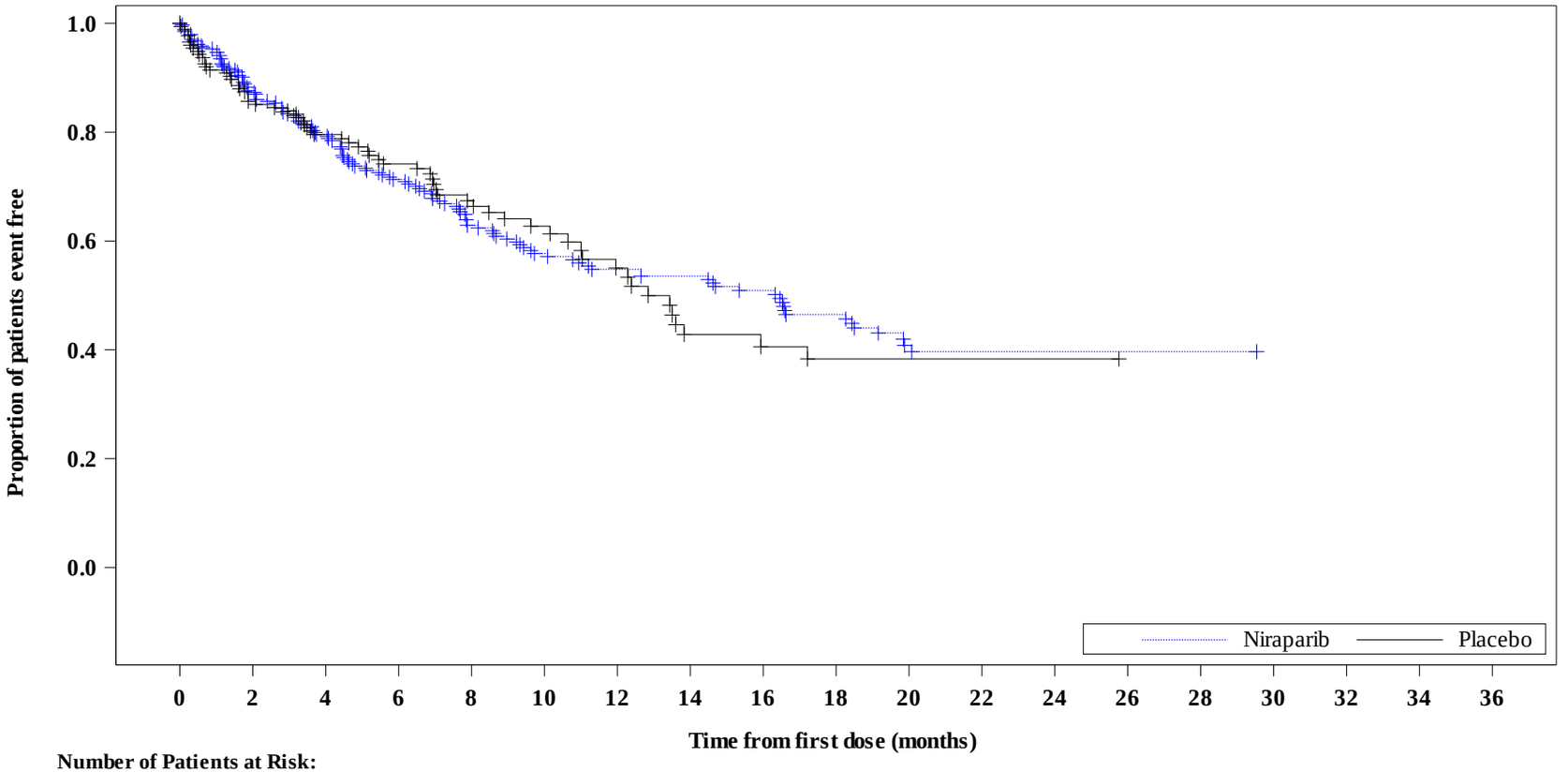
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Infections and infestations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 273 | 212 | 173 | 124 | 103 | 92 | 84 | 69 | 58 | 35 | 24 | 17 | 9 | 3 | 0 |
| Placebo | 175 | 148 | 112 | 92 | 65 | 45 | 34 | 21 | 18 | 14 | 12 | 4 | 2 | 0 | | |

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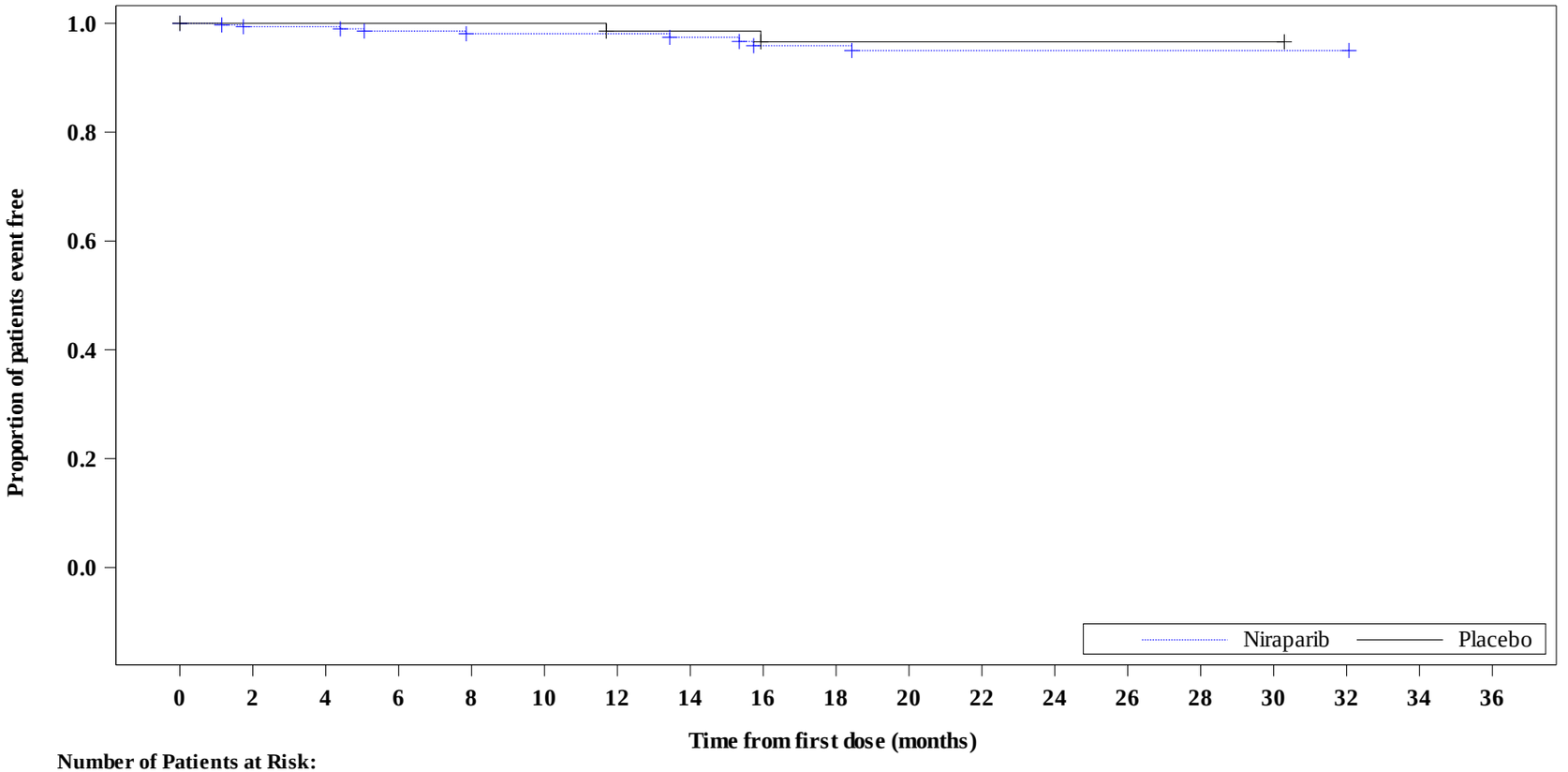
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Infections and infestations, PT: Bronchitis

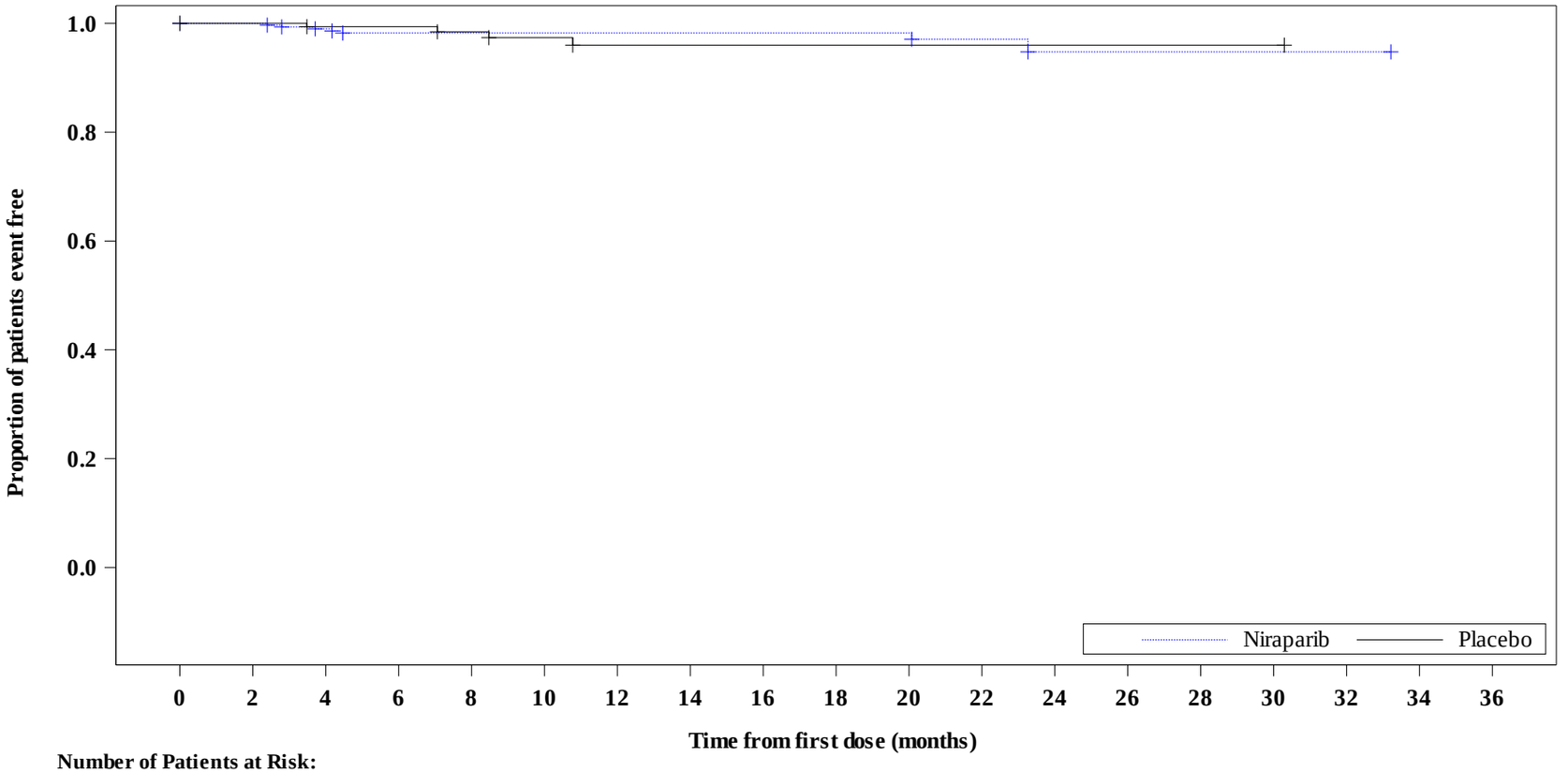



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 263 | 236 | 193 | 169 | 161 | 147 | 122 | 111 | 80 | 55 | 38 | 18 | 8 | 2 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 69 | 59 | 49 | 42 | 35 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Infections and infestations, PT: Herpes zoster

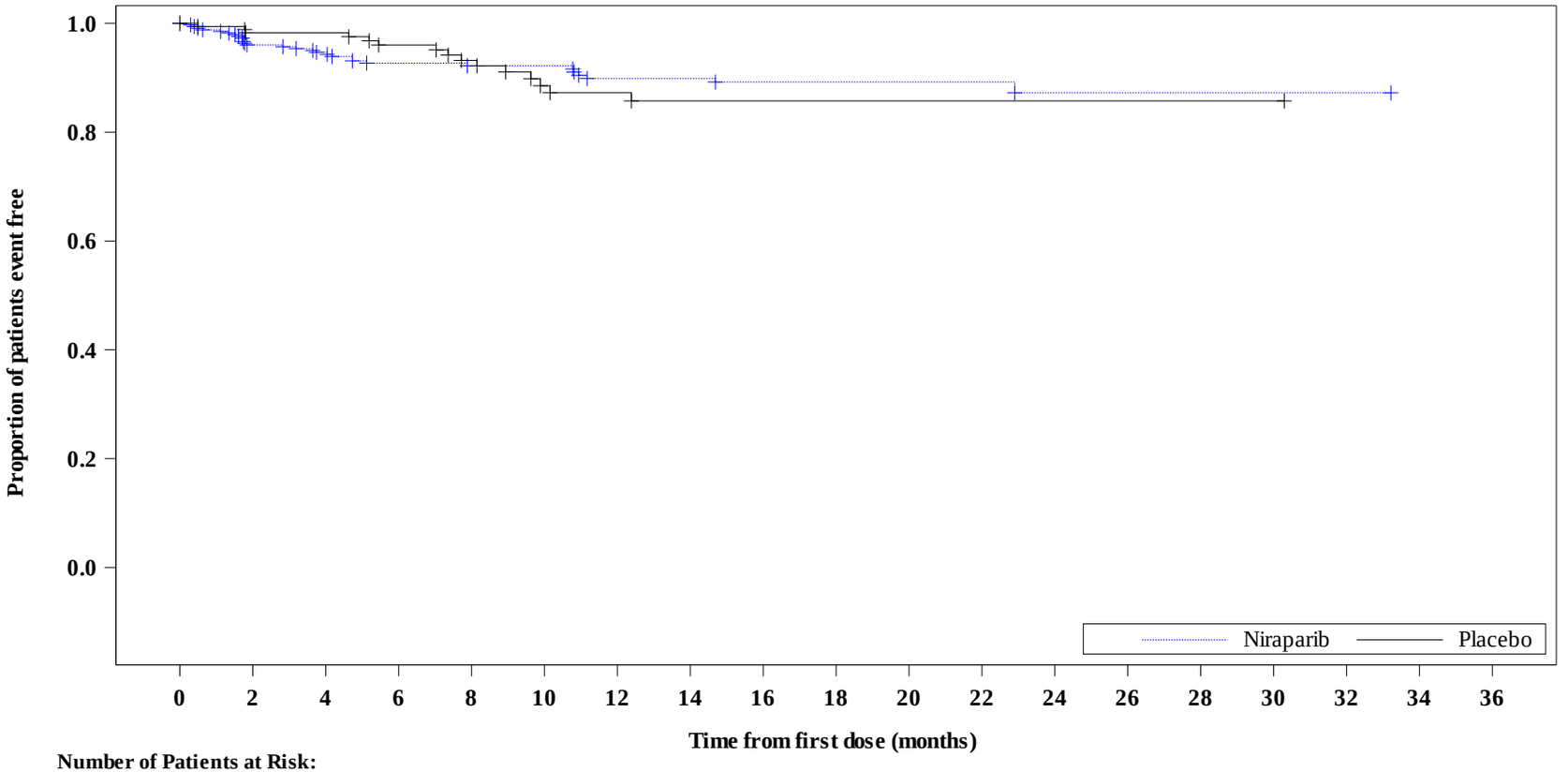



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 262 | 235 | 193 | 169 | 161 | 149 | 126 | 115 | 85 | 58 | 38 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 144 | 127 | 100 | 75 | 66 | 56 | 47 | 41 | 34 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Infections and infestations, PT: Nasopharyngitis

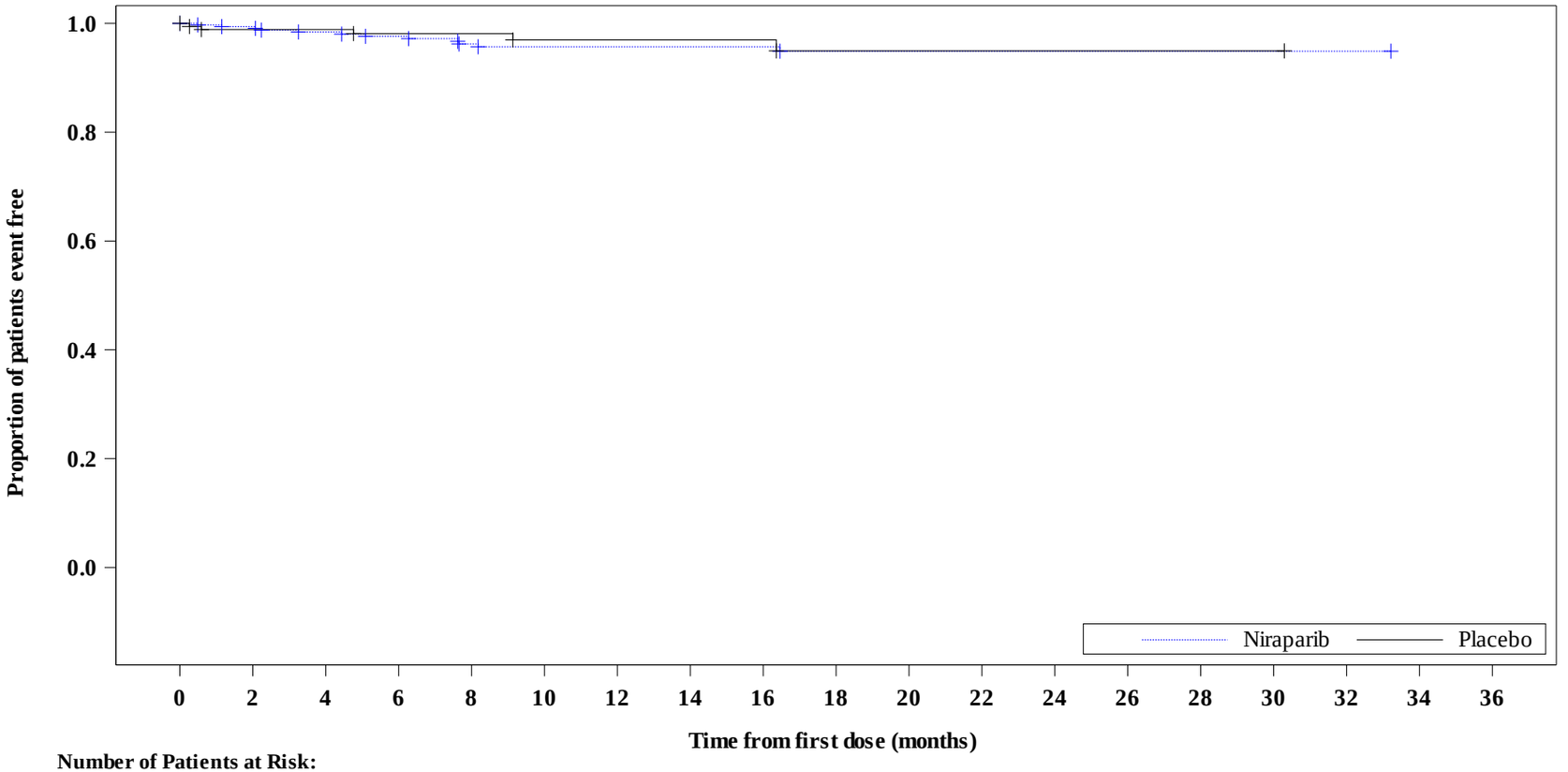



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 301 | 251 | 220 | 180 | 162 | 150 | 138 | 115 | 105 | 78 | 52 | 34 | 19 | 9 | 2 | 2 | 0 |
| Placebo | 175 | 169 | 142 | 123 | 95 | 69 | 60 | 50 | 42 | 35 | 29 | 17 | 6 | 3 | 1 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Infections and infestations, PT: Sinusitis




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 260 | 233 | 189 | 165 | 157 | 144 | 119 | 110 | 81 | 56 | 38 | 18 | 9 | 2 | 1 | 0 |
| Placebo | 175 | 170 | 143 | 125 | 99 | 74 | 67 | 57 | 48 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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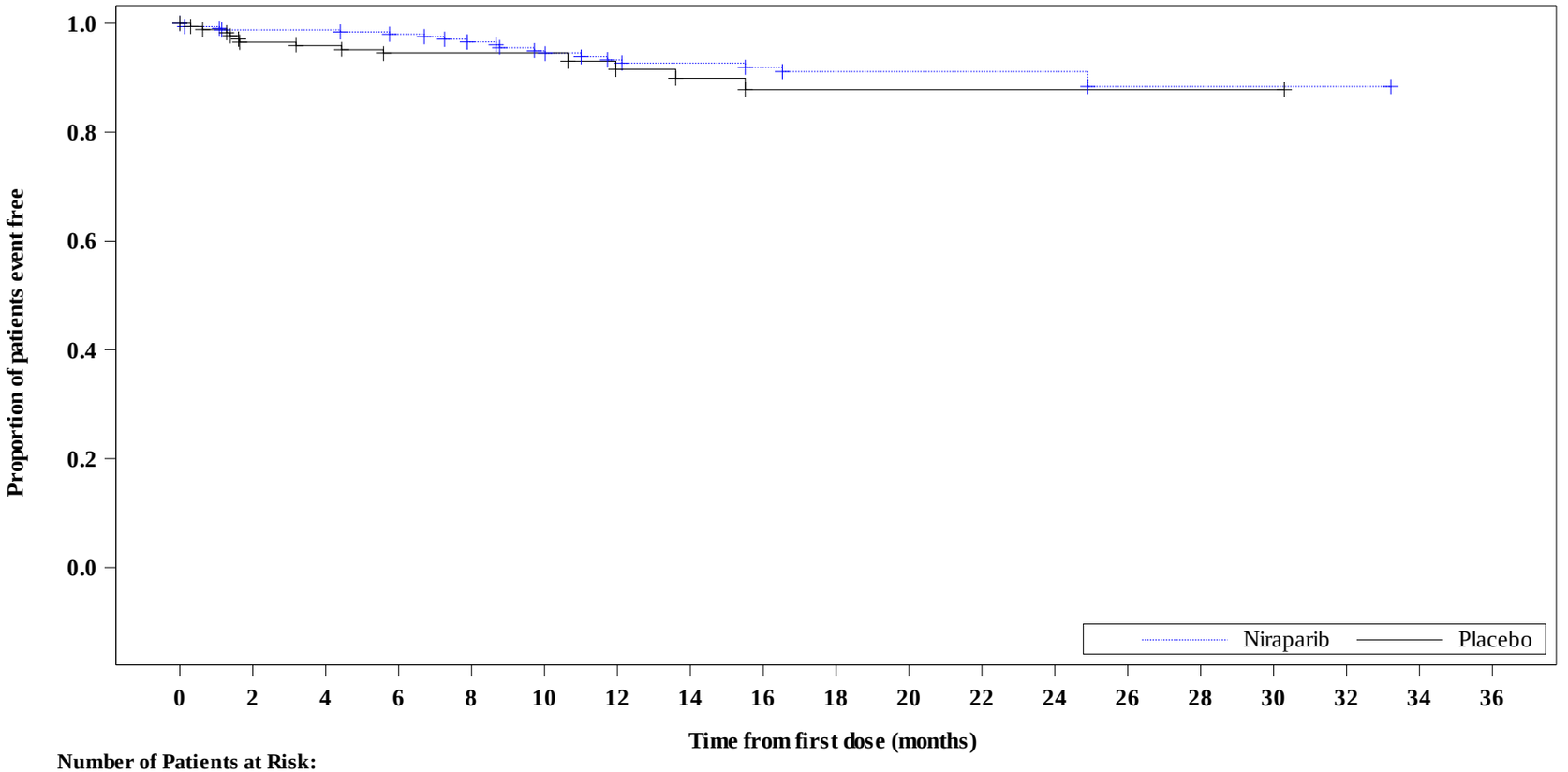
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Infections and infestations, PT: Upper respiratory tract infection

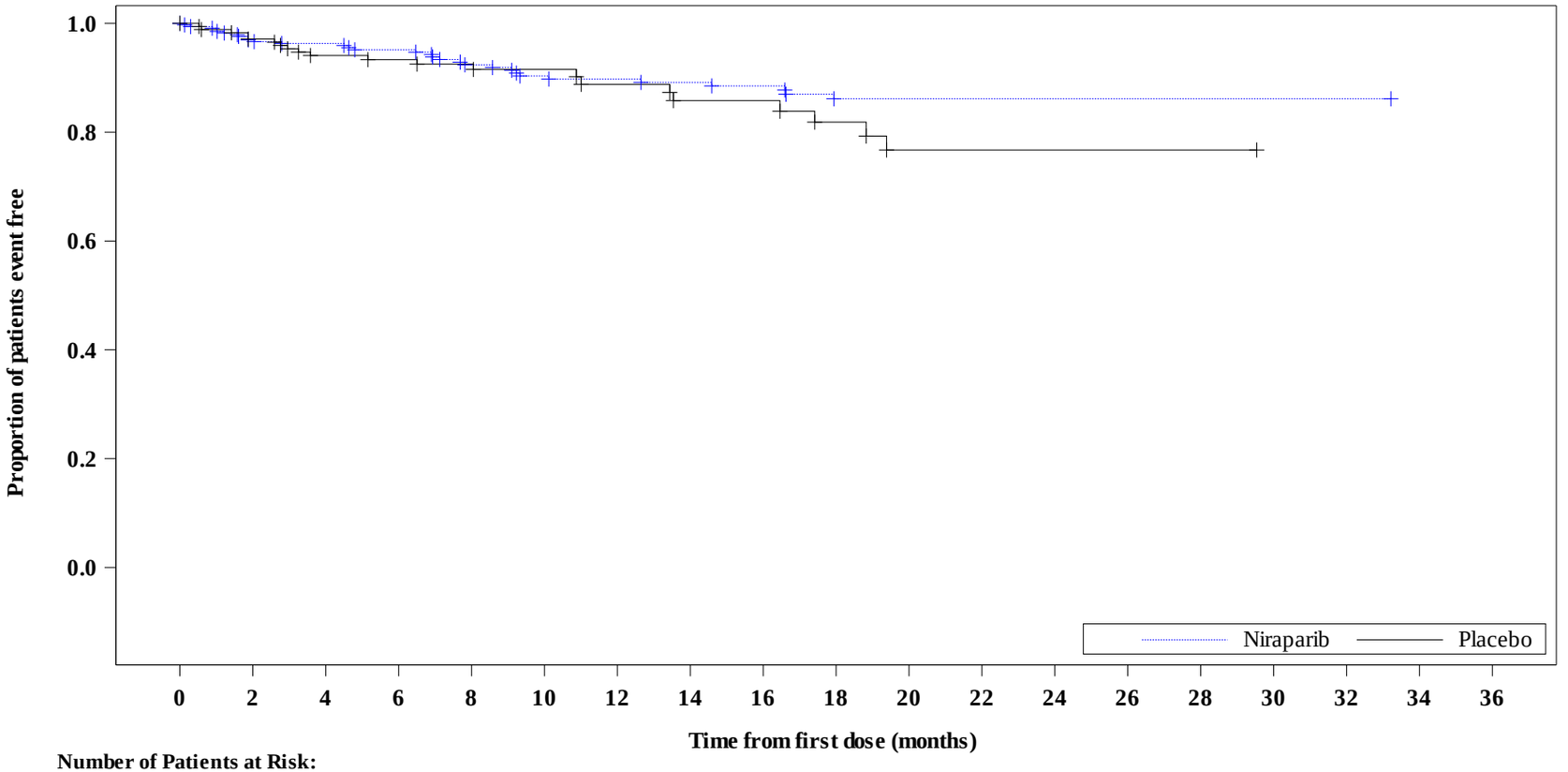



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 263 | 236 | 192 | 167 | 157 | 143 | 119 | 107 | 79 | 56 | 39 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 166 | 139 | 120 | 94 | 71 | 61 | 49 | 42 | 35 | 30 | 15 | 7 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Infections and infestations, PT: Urinary tract infection




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 301 | 258 | 230 | 187 | 161 | 152 | 139 | 116 | 103 | 77 | 57 | 39 | 18 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 135 | 119 | 95 | 71 | 63 | 52 | 44 | 36 | 30 | 15 | 6 | 3 | 1 | 0 | | |

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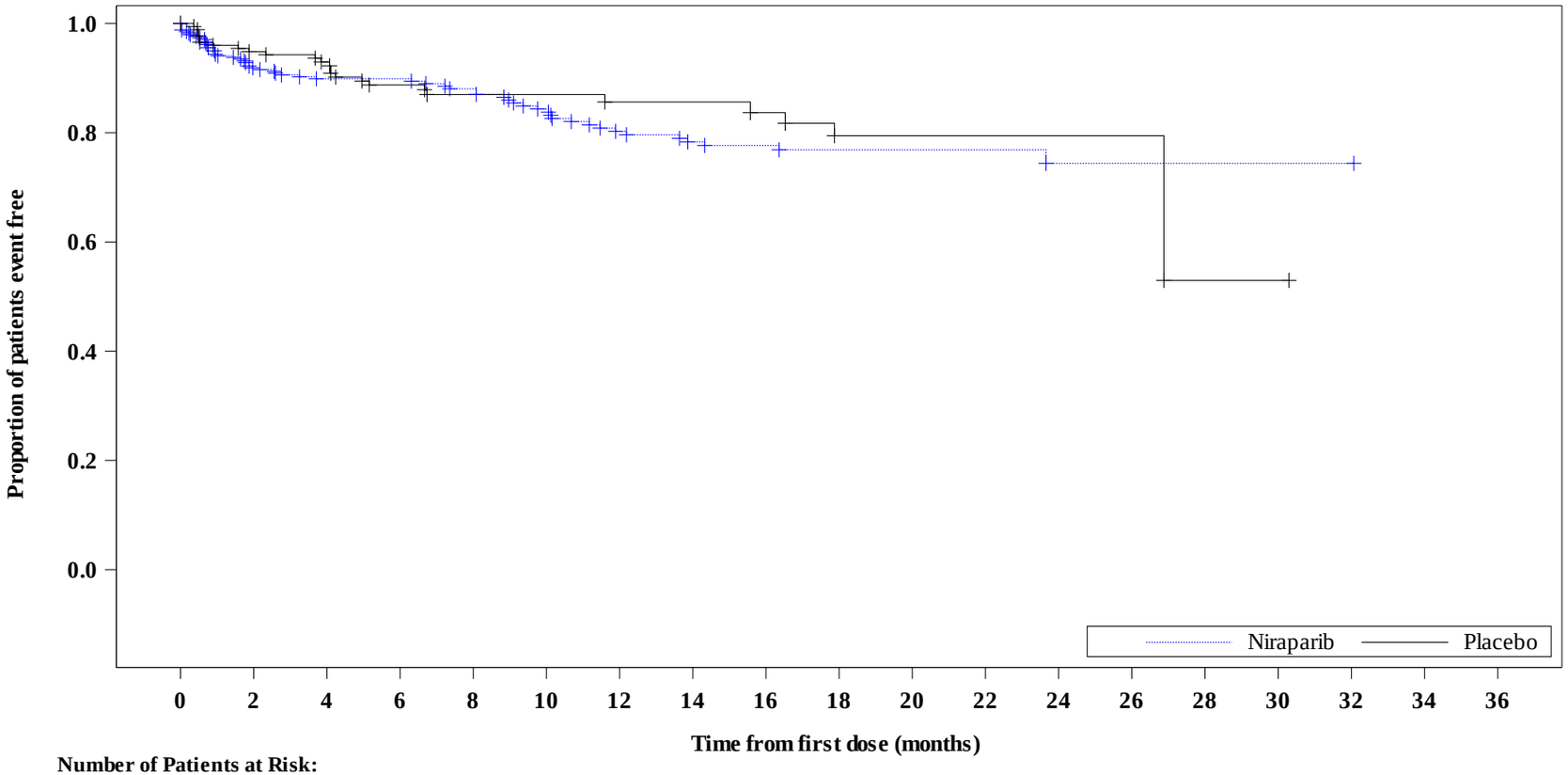
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Injury, poisoning and procedural complications




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 284 | 236 | 213 | 172 | 147 | 133 | 120 | 100 | 90 | 66 | 44 | 27 | 12 | 6 | 2 | 1 | 0 |
| Placebo | 175 | 163 | 135 | 117 | 92 | 70 | 62 | 52 | 43 | 35 | 29 | 16 | 7 | 5 | 2 | 1 | 0 | |

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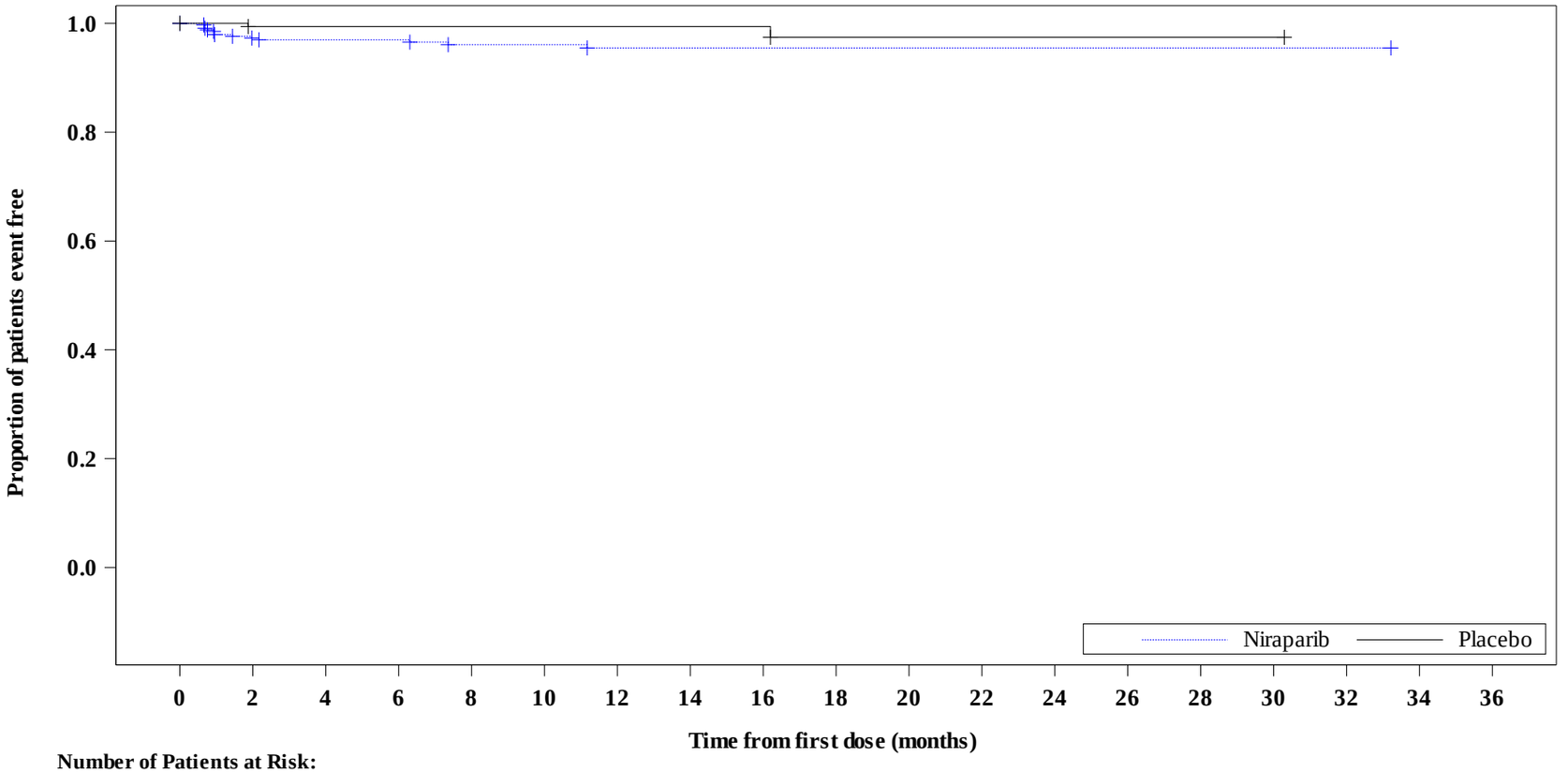
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Injury, poisoning and procedural complications, PT: Contusion

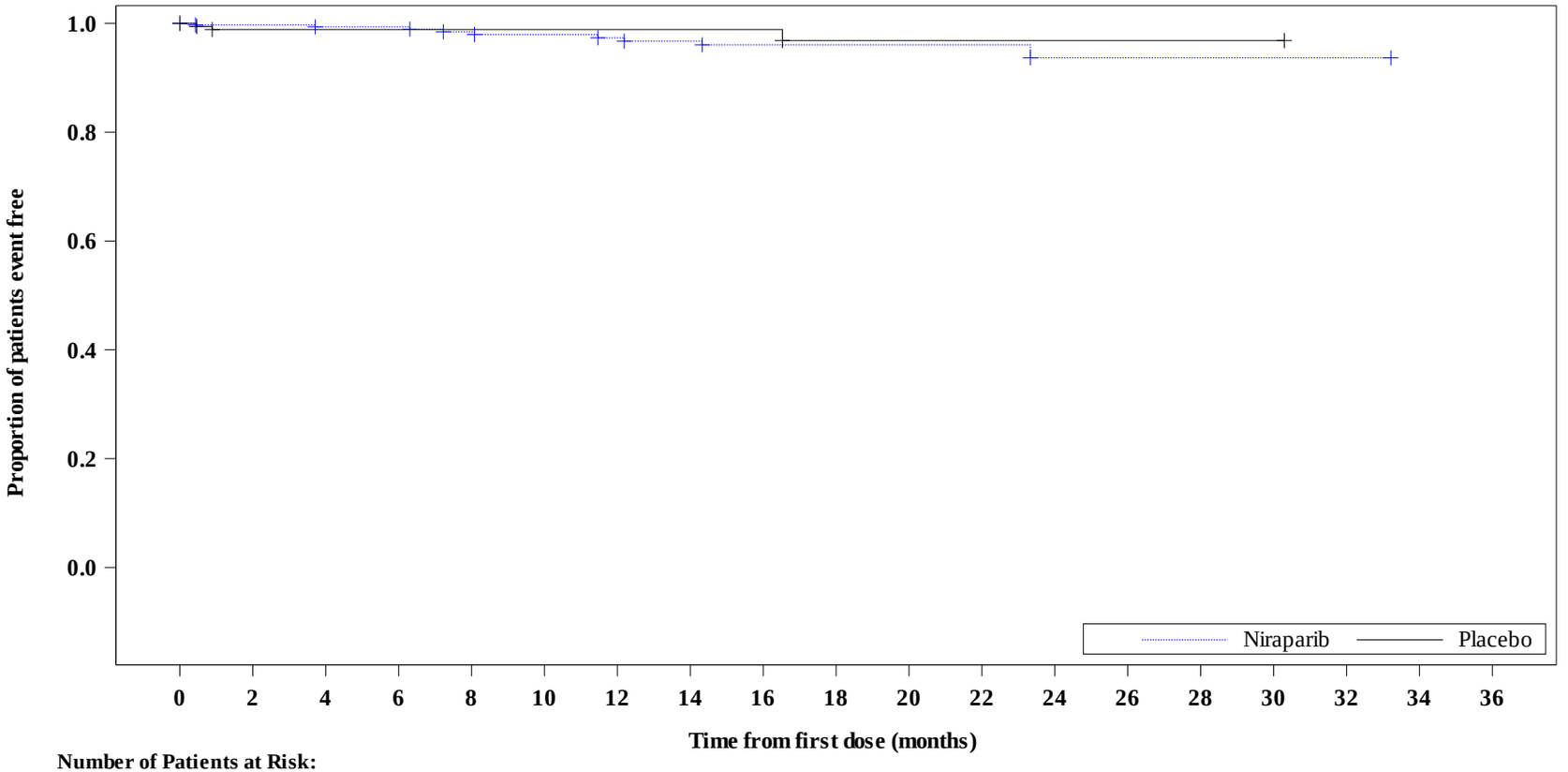



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 302 | 256 | 230 | 187 | 166 | 157 | 146 | 122 | 111 | 81 | 55 | 37 | 18 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 78 | 70 | 59 | 50 | 42 | 35 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Injury, poisoning and procedural complications, PT: Fall




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 263 | 237 | 193 | 168 | 159 | 145 | 119 | 109 | 81 | 56 | 36 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 143 | 126 | 101 | 77 | 69 | 58 | 49 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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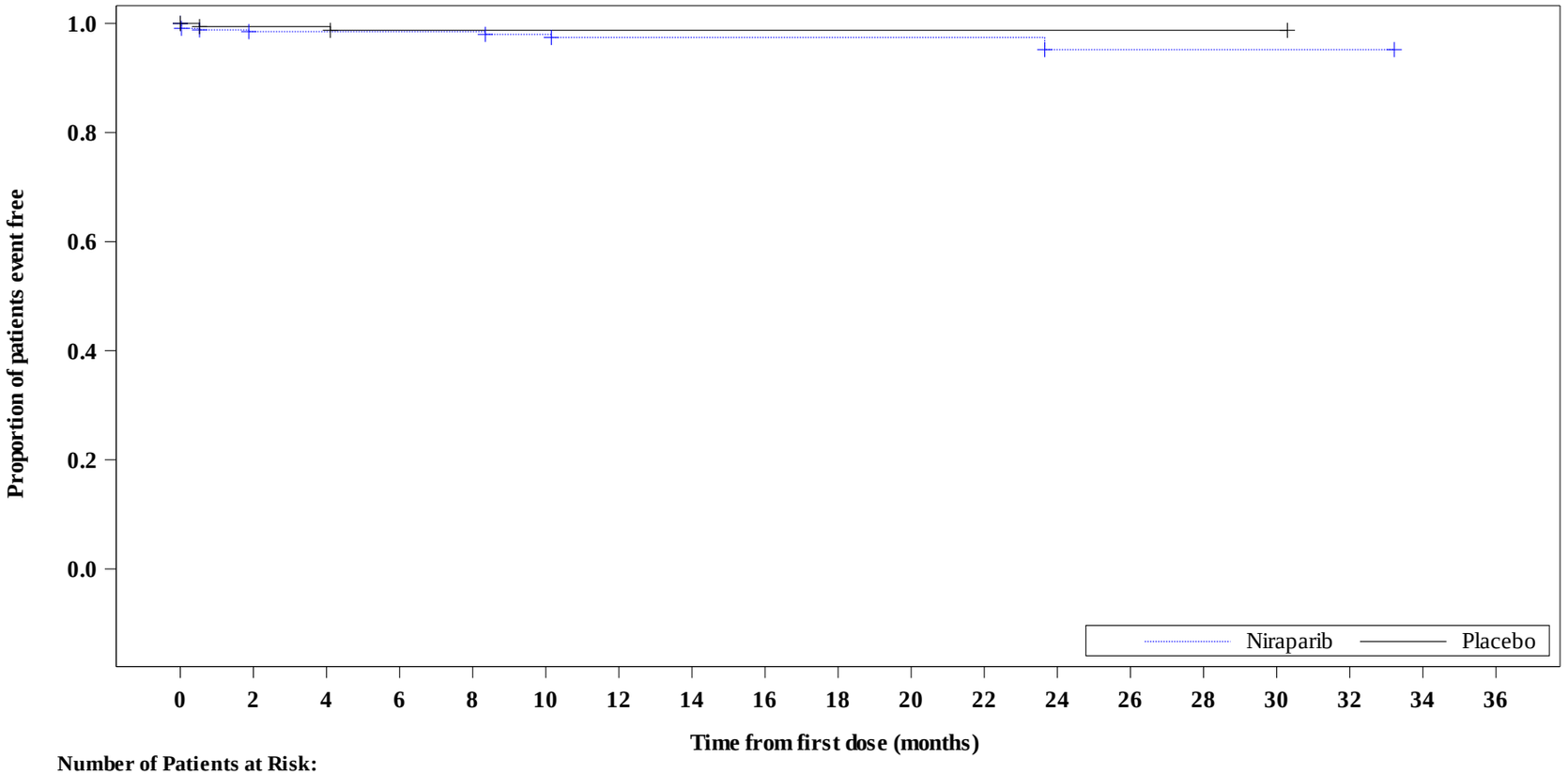
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Injury, poisoning and procedural complications, PT: Overdose

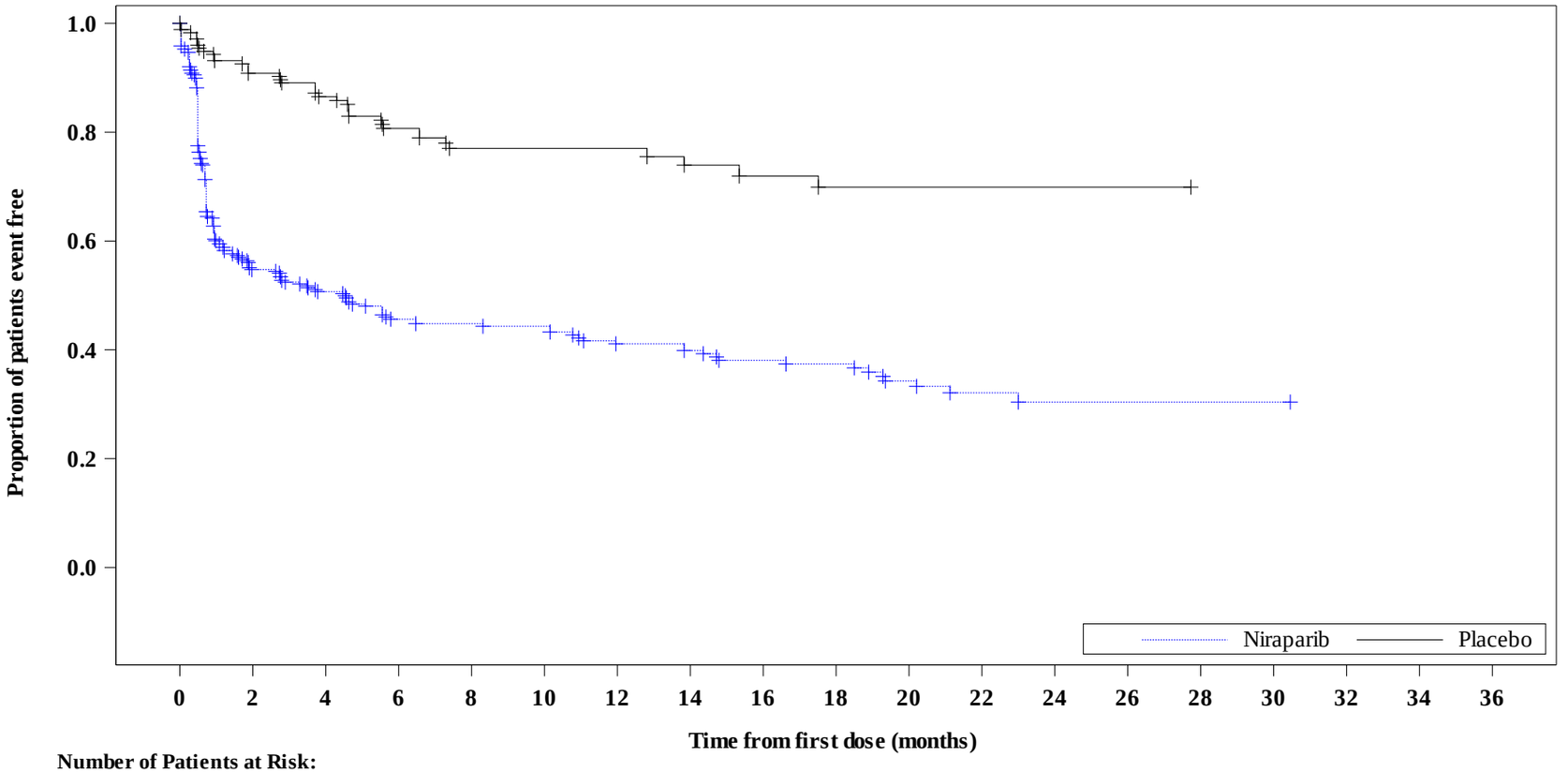



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 260 | 235 | 195 | 171 | 163 | 150 | 125 | 114 | 86 | 60 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 101 | 77 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations

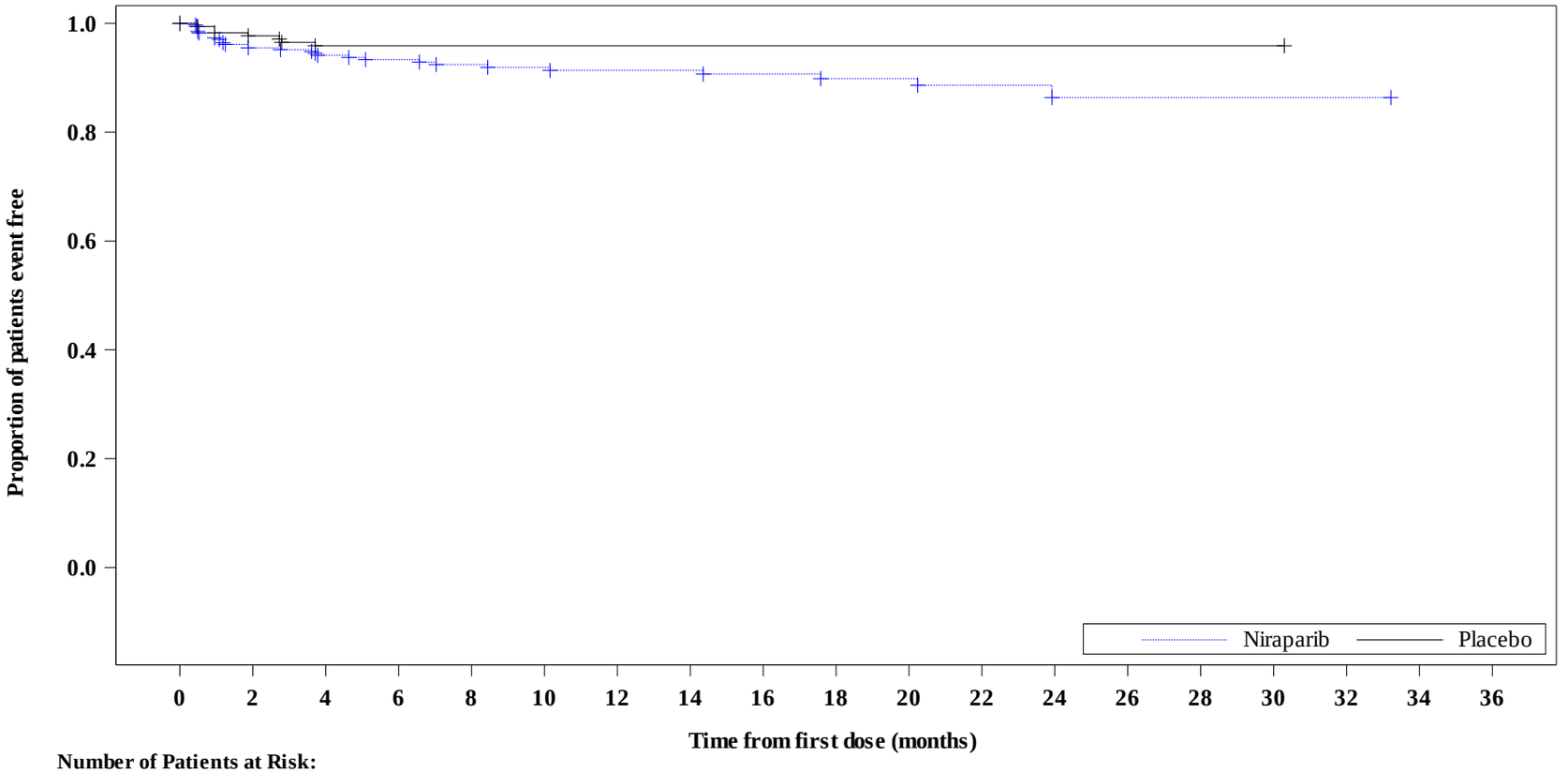



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 166 | 137 | 114 | 95 | 83 | 74 | 66 | 56 | 53 | 35 | 23 | 15 | 6 | 2 | 1 | 0 |
| Placebo | 175 | 156 | 127 | 103 | 78 | 60 | 53 | 42 | 36 | 31 | 25 | 13 | 5 | 2 | 0 | | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Alanine aminotransferase increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 298 | 251 | 226 | 183 | 159 | 150 | 139 | 114 | 103 | 75 | 55 | 36 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 168 | 140 | 124 | 98 | 74 | 66 | 56 | 49 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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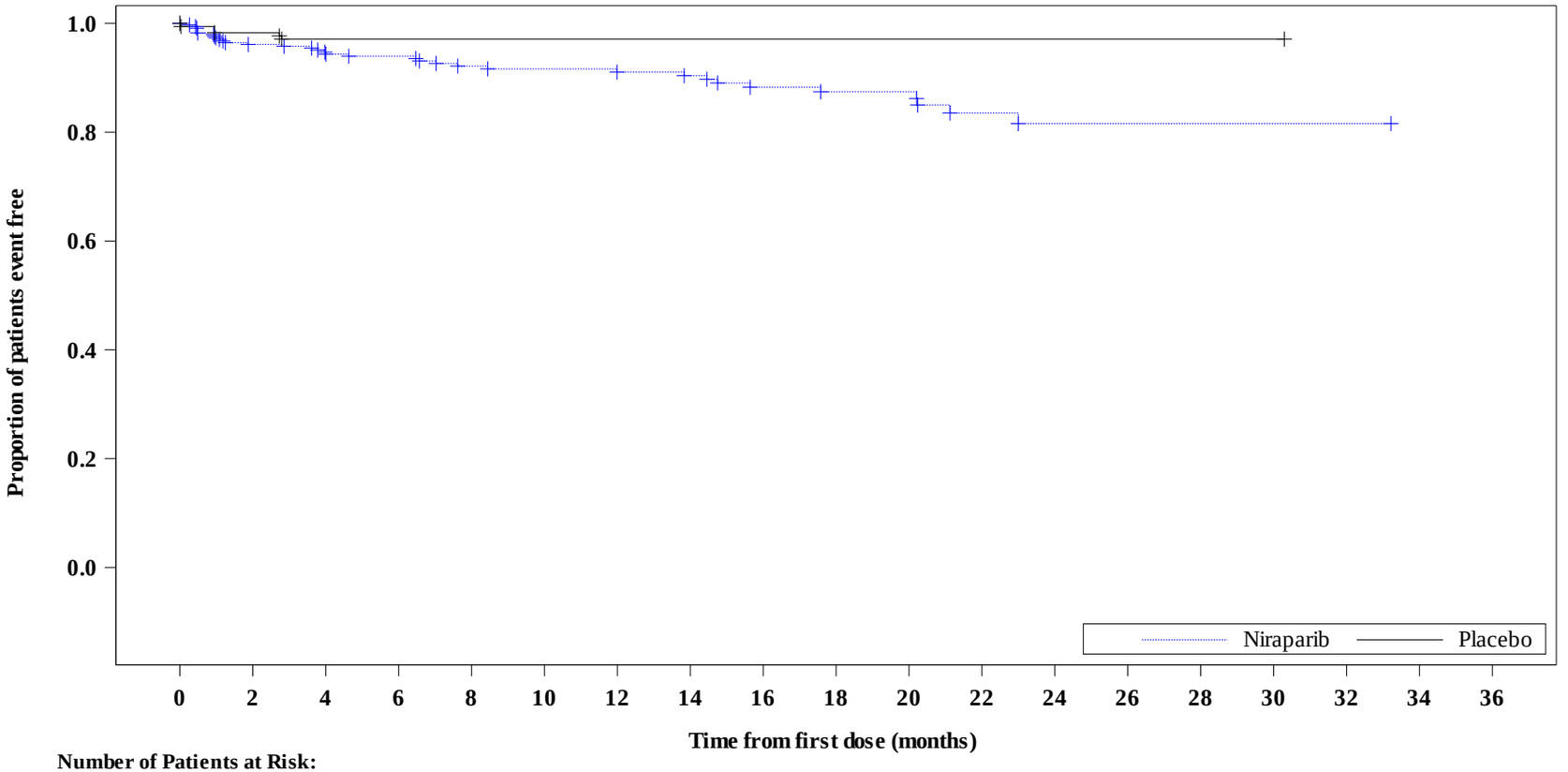
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Aspartate aminotransferase increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 299 | 253 | 228 | 183 | 159 | 150 | 138 | 111 | 100 | 72 | 50 | 34 | 16 | 8 | 2 | 1 | 0 |
| Placebo | 175 | 169 | 142 | 126 | 100 | 76 | 68 | 57 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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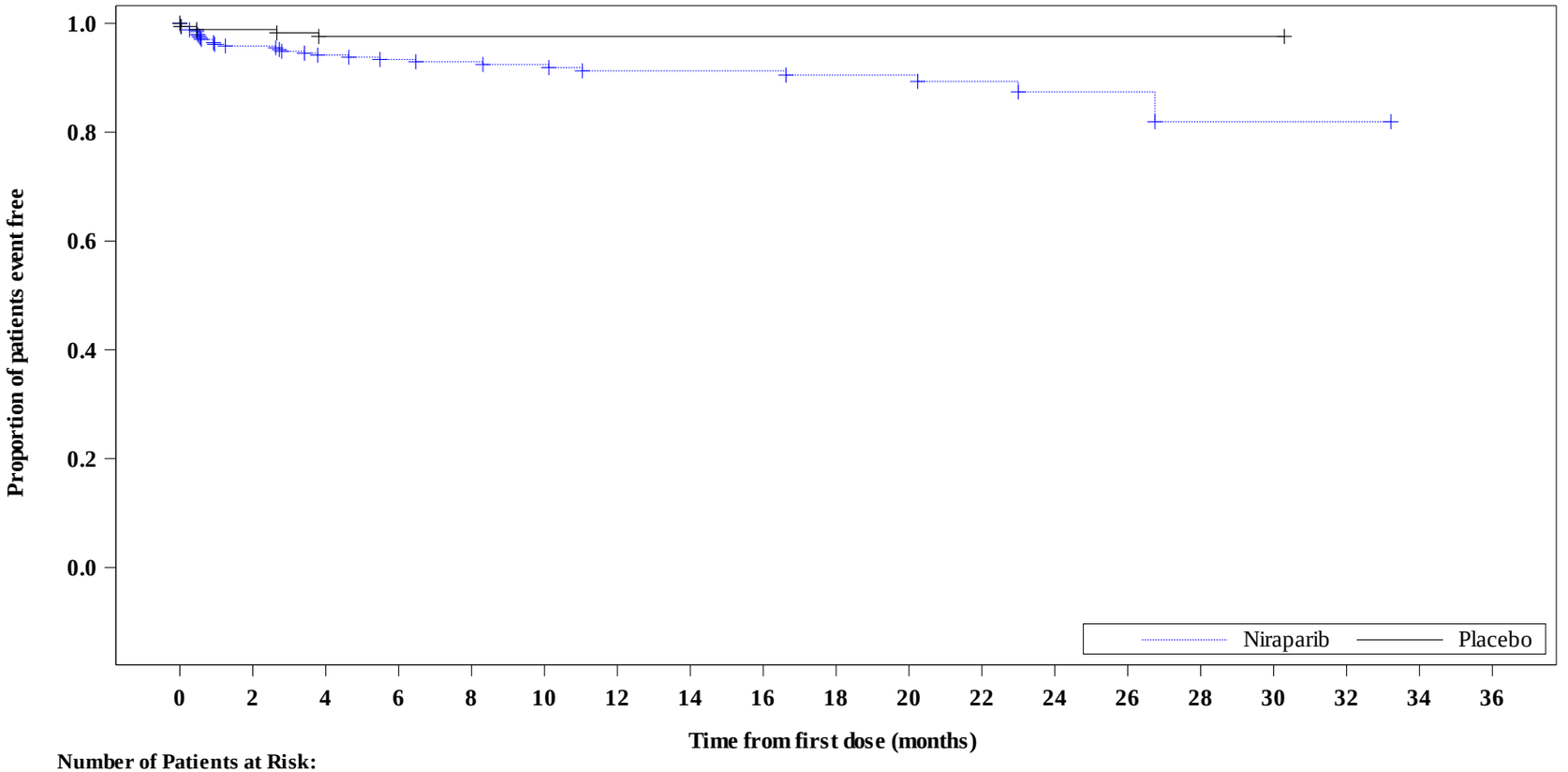
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Blood alkaline phosphatase increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 297 | 252 | 227 | 185 | 161 | 152 | 141 | 118 | 106 | 78 | 54 | 36 | 17 | 9 | 2 | 1 | 0 |
| Placebo | 175 | 170 | 141 | 125 | 99 | 75 | 67 | 56 | 47 | 41 | 34 | 18 | 7 | 4 | 2 | 1 | 0 | |

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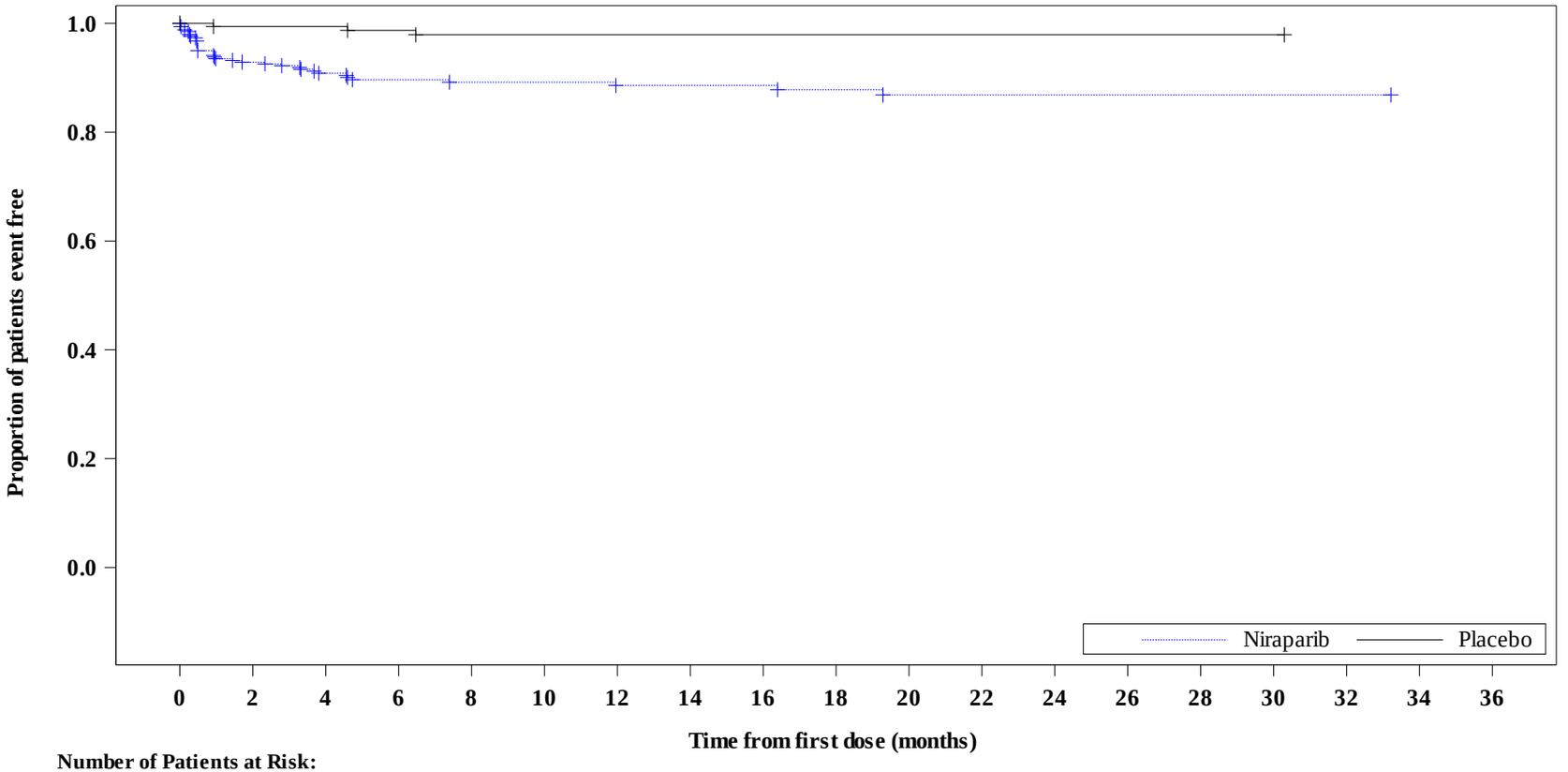
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Blood creatinine increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 289 | 241 | 215 | 176 | 156 | 147 | 135 | 117 | 106 | 77 | 53 | 35 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 99 | 75 | 67 | 57 | 48 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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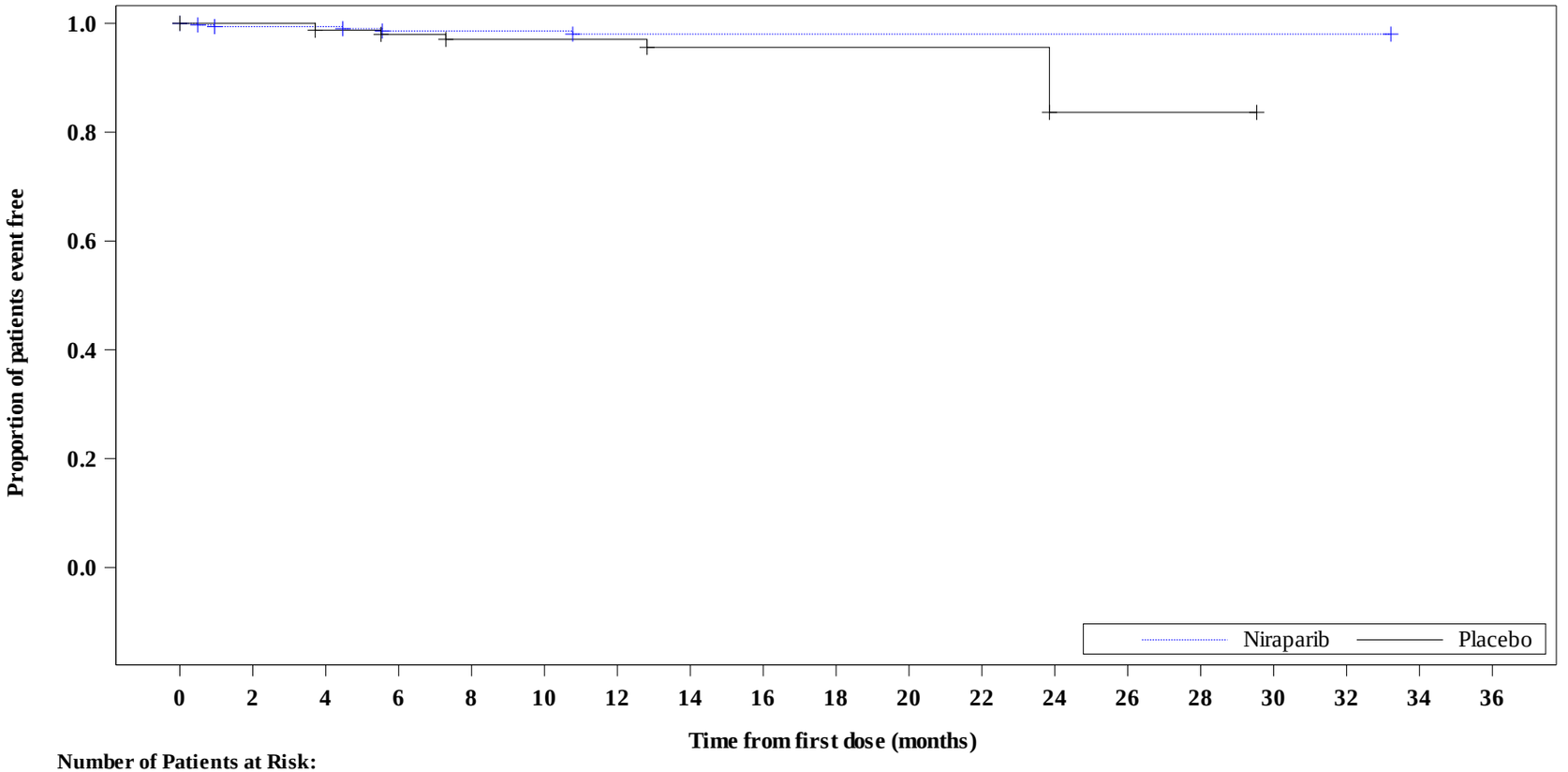
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Carbohydrate antigen 125 increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 265 | 237 | 196 | 173 | 164 | 151 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 143 | 125 | 101 | 78 | 70 | 58 | 50 | 43 | 36 | 19 | 7 | 4 | 1 | 0 | | |

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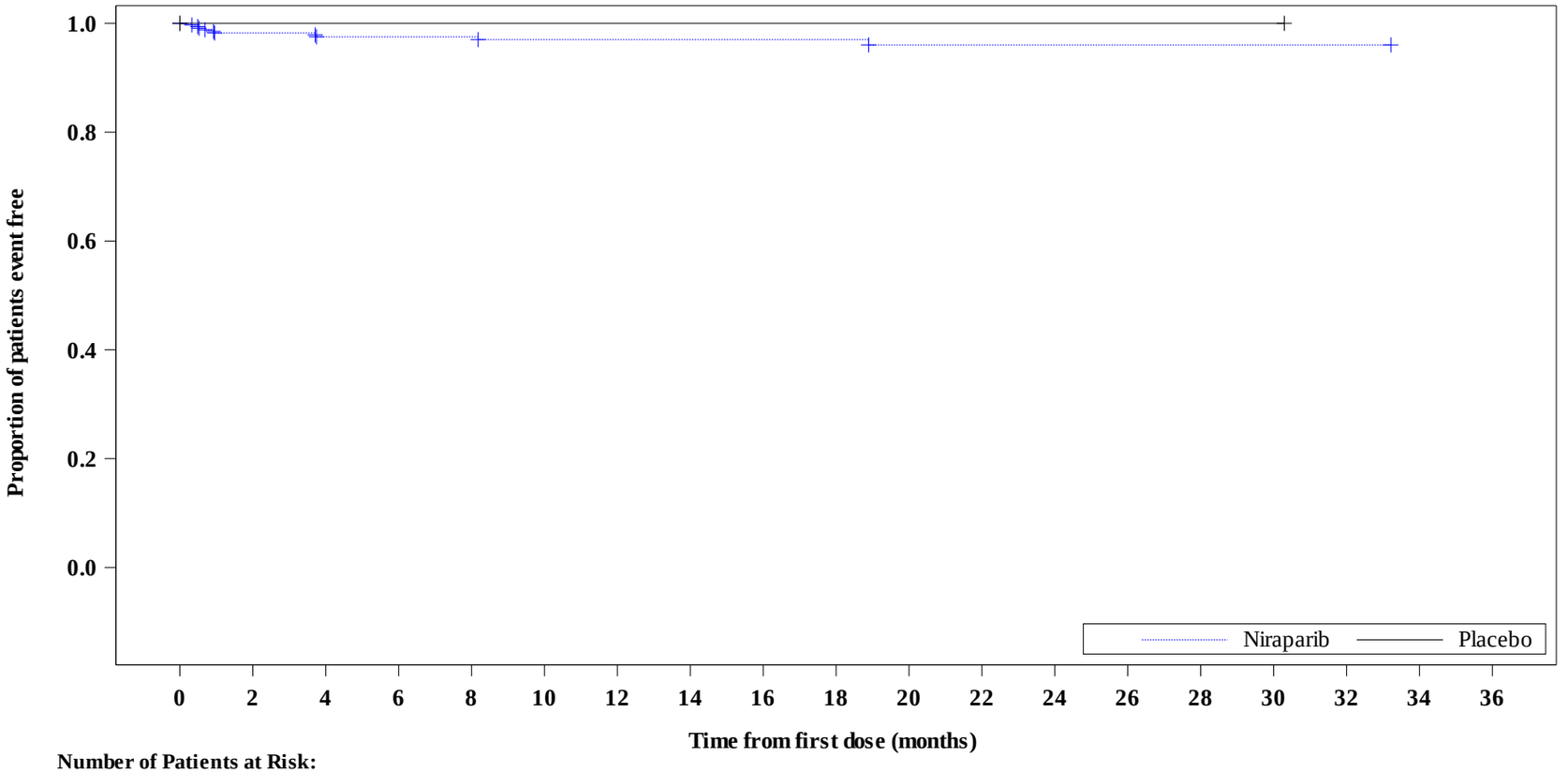
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Gamma-glutamyltransferase increased

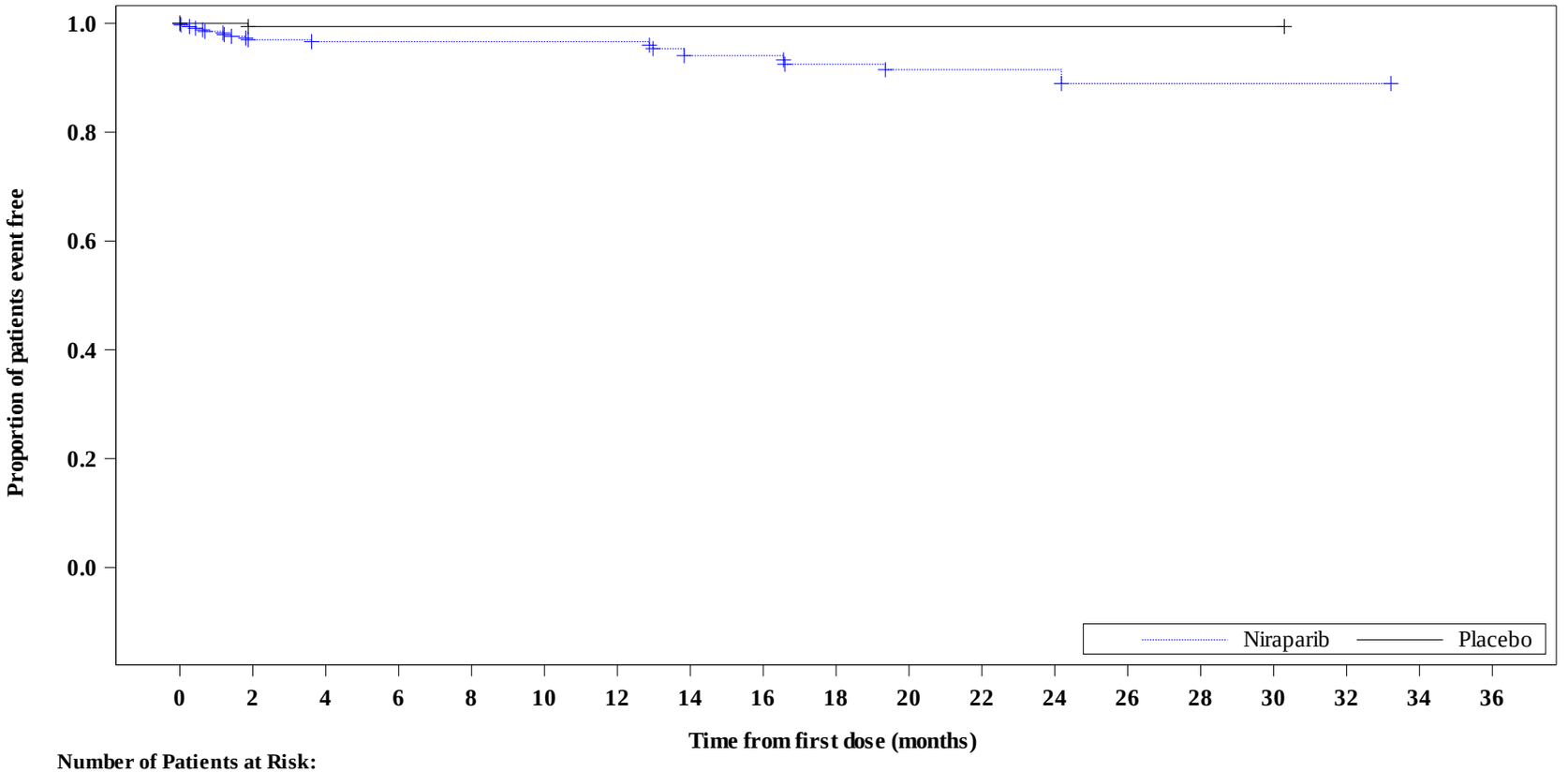



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 260 | 234 | 193 | 169 | 161 | 149 | 124 | 113 | 82 | 57 | 39 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Lymphocyte count decreased

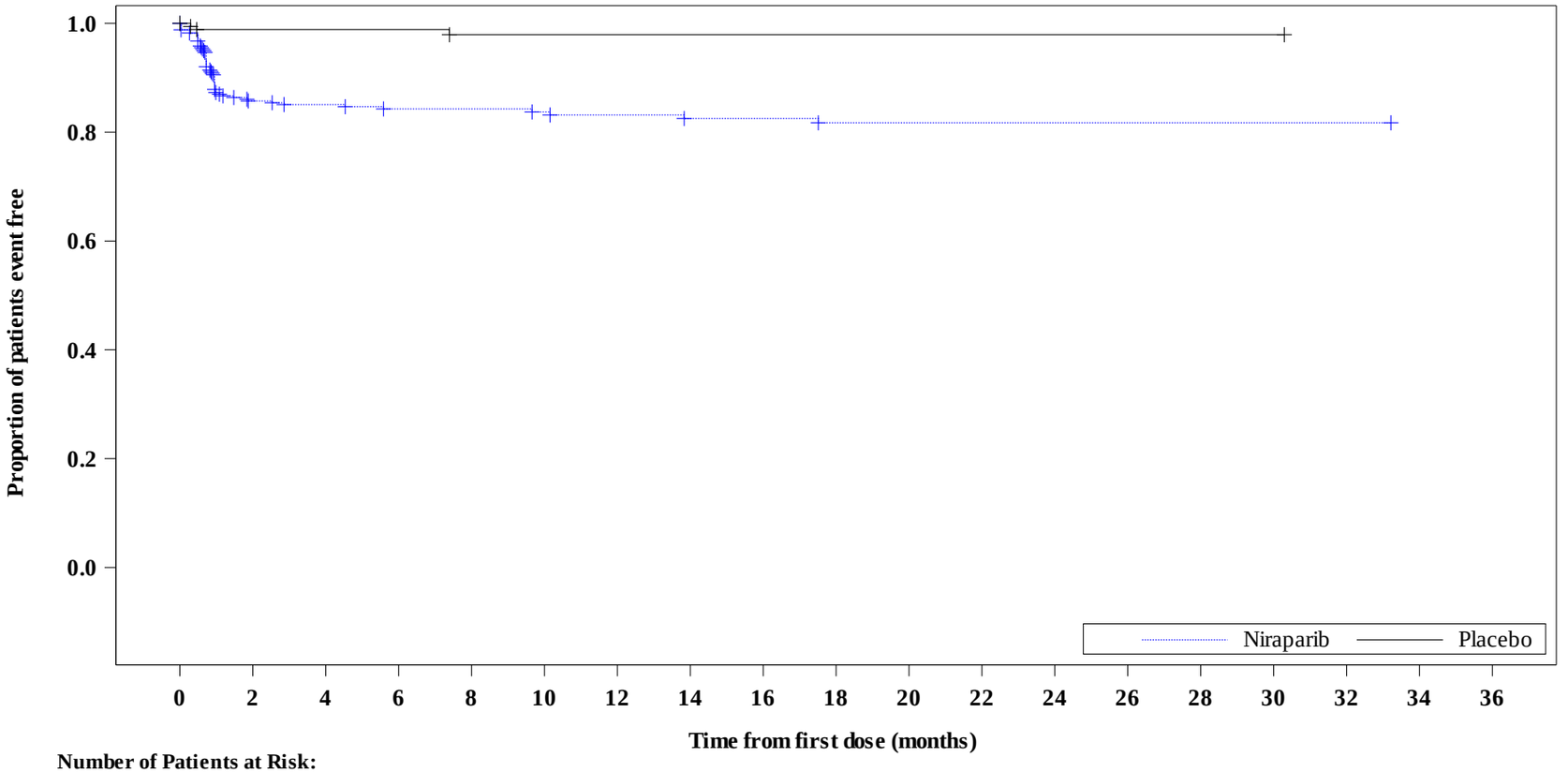



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 257 | 233 | 192 | 169 | 161 | 145 | 121 | 109 | 79 | 57 | 40 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Neutrophil count decreased

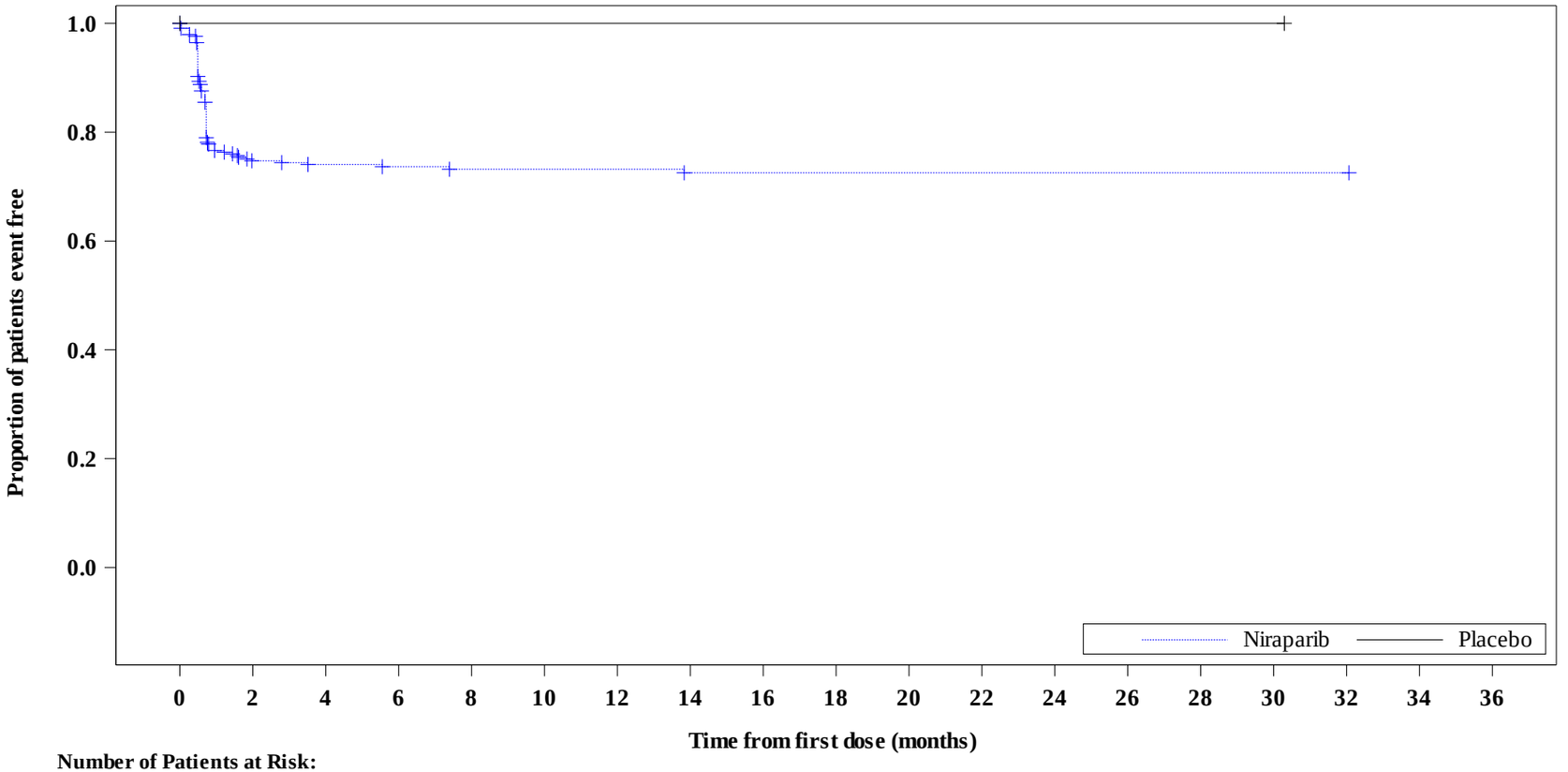



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 265 | 227 | 204 | 168 | 147 | 138 | 128 | 107 | 98 | 70 | 48 | 32 | 13 | 5 | 2 | 1 | 0 |
| Placebo | 175 | 170 | 143 | 126 | 99 | 75 | 67 | 56 | 48 | 41 | 34 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Platelet count decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 229 | 197 | 176 | 144 | 125 | 118 | 110 | 92 | 88 | 64 | 45 | 29 | 13 | 6 | 2 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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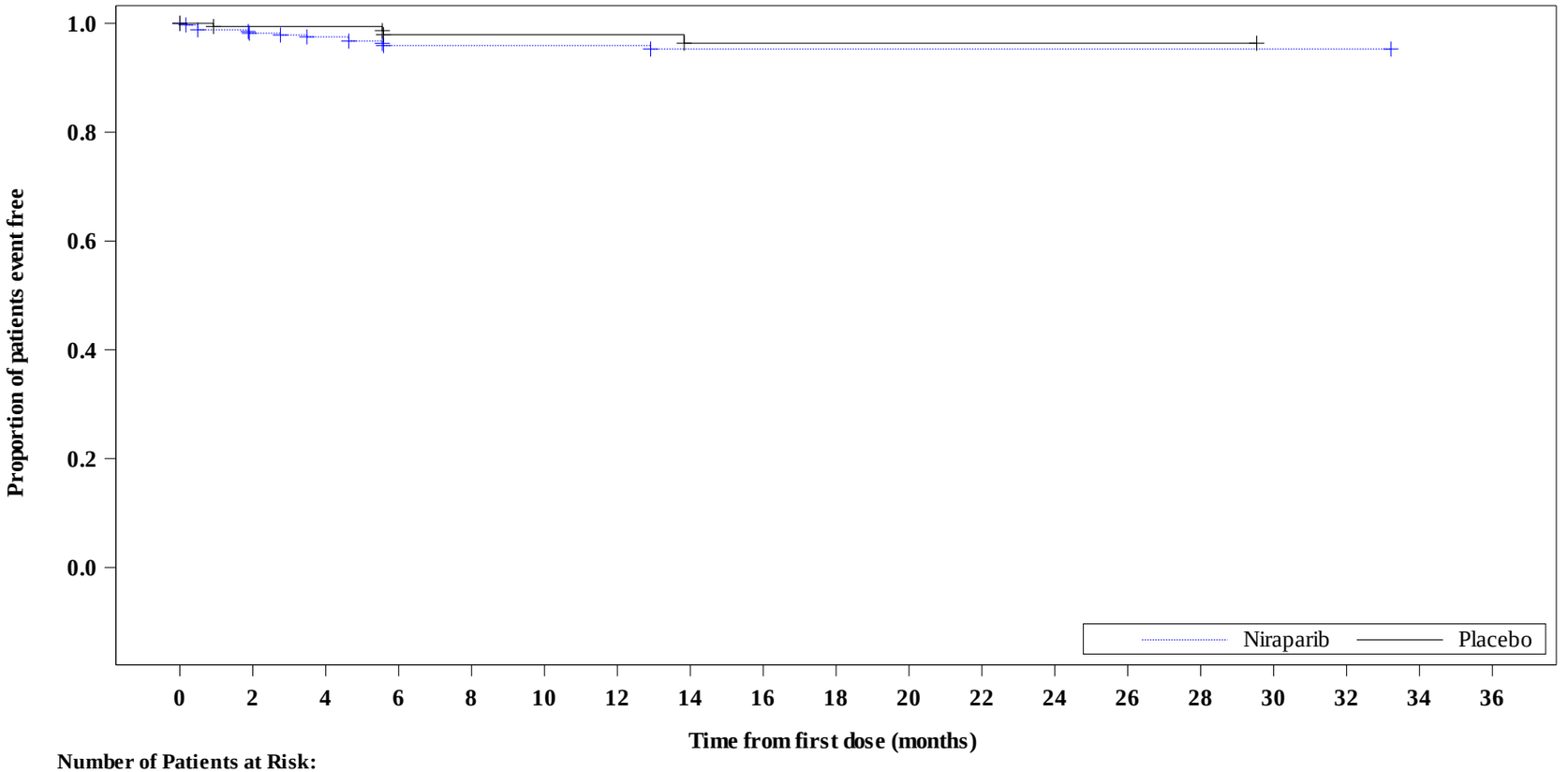
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Weight decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 261 | 232 | 190 | 166 | 159 | 145 | 120 | 109 | 80 | 56 | 38 | 18 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 125 | 99 | 76 | 68 | 56 | 47 | 40 | 34 | 18 | 7 | 4 | 1 | 0 | | |

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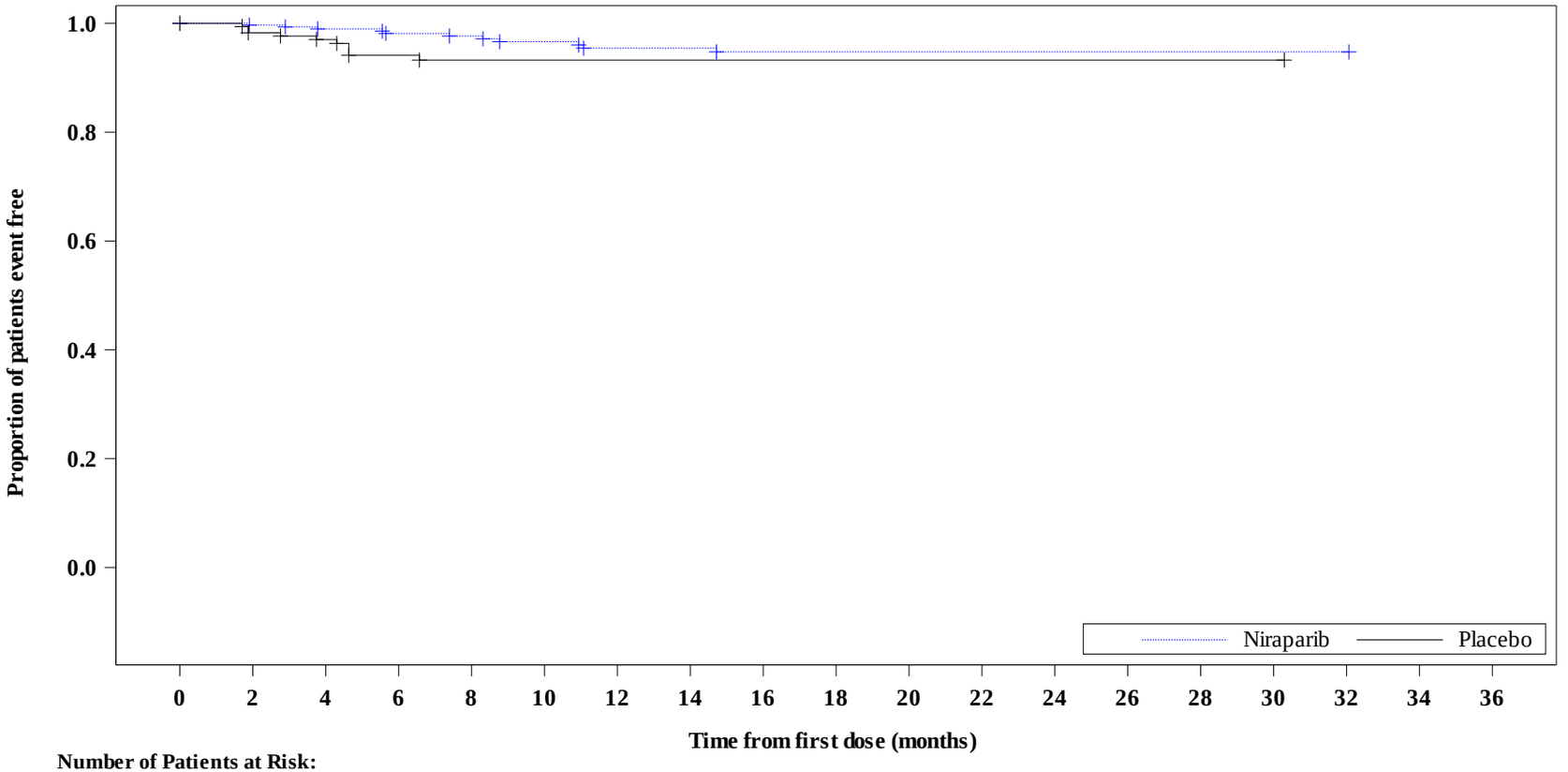
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: Weight increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 262 | 234 | 191 | 166 | 156 | 143 | 118 | 108 | 80 | 58 | 40 | 19 | 9 | 2 | 1 | 0 |
| Placebo | 175 | 169 | 140 | 119 | 93 | 73 | 66 | 57 | 48 | 41 | 34 | 18 | 8 | 5 | 2 | 1 | 0 | |

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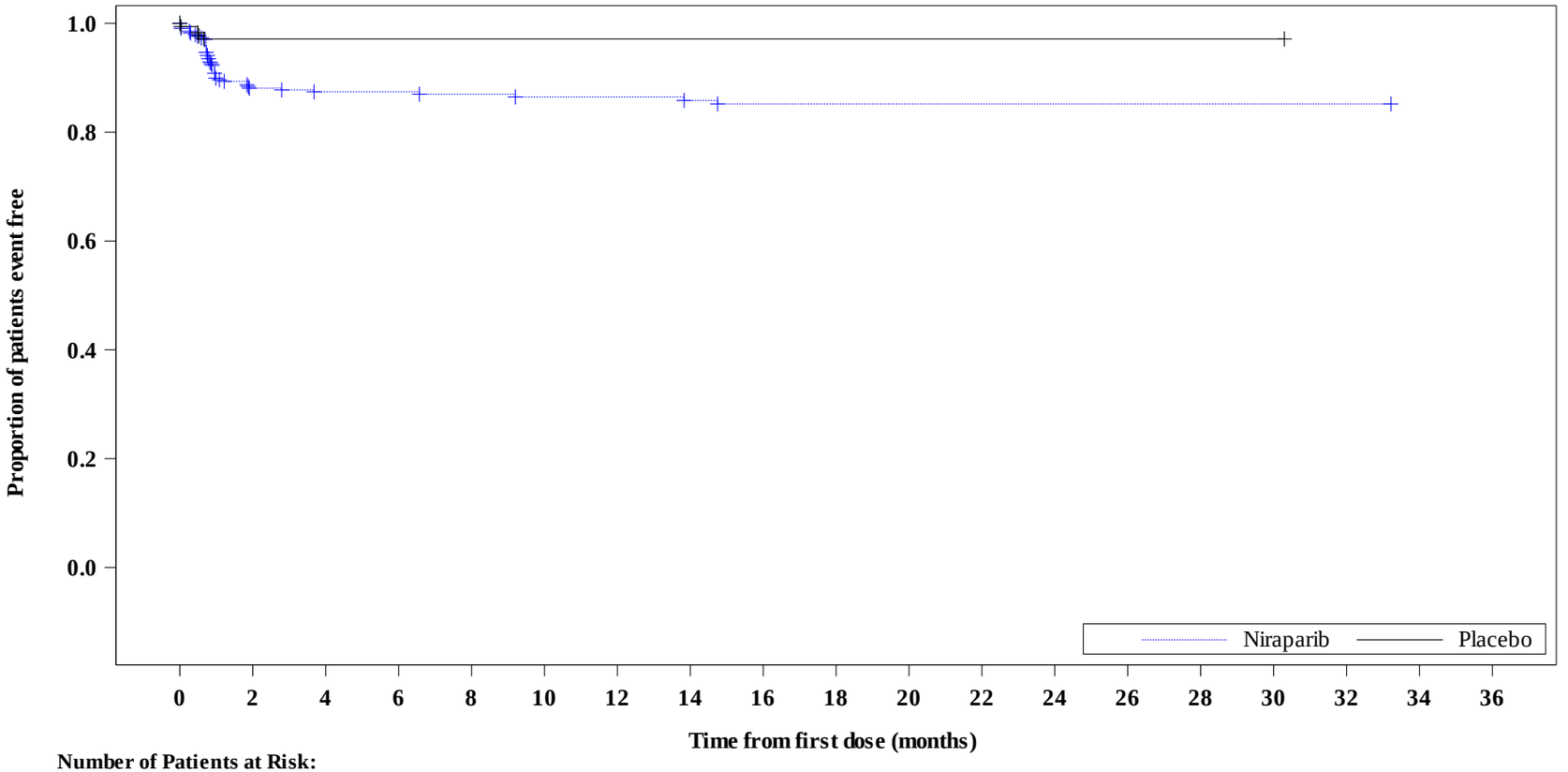
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Investigations, PT: White blood cell count decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 274 | 237 | 217 | 177 | 155 | 148 | 137 | 115 | 106 | 78 | 56 | 39 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 142 | 125 | 100 | 76 | 68 | 57 | 49 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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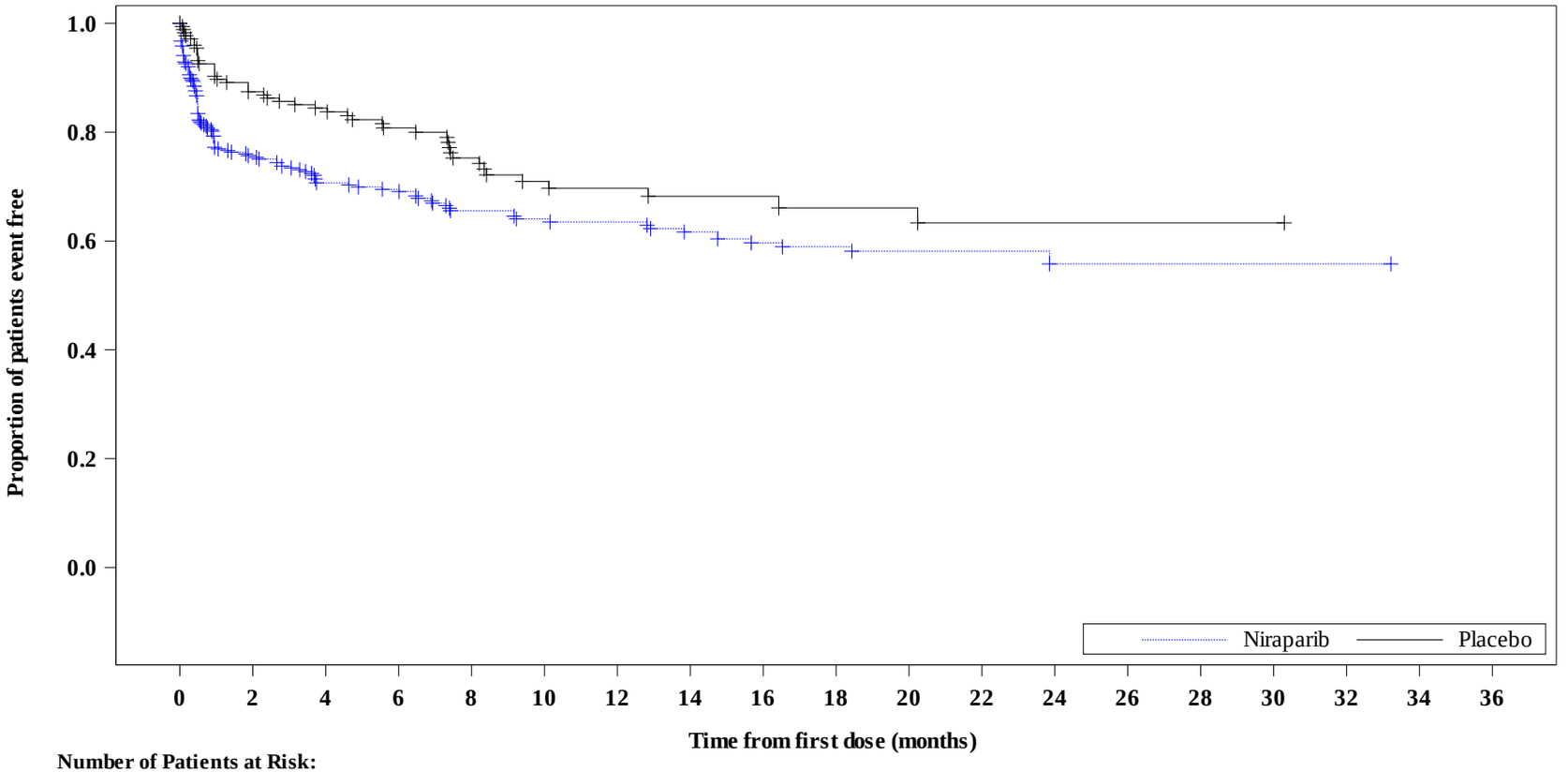
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 238 | 190 | 170 | 134 | 116 | 110 | 100 | 82 | 73 | 54 | 37 | 23 | 10 | 4 | 2 | 2 | 0 |
| Placebo | 175 | 151 | 123 | 104 | 76 | 57 | 50 | 40 | 32 | 29 | 25 | 12 | 6 | 3 | 1 | 1 | 0 | |

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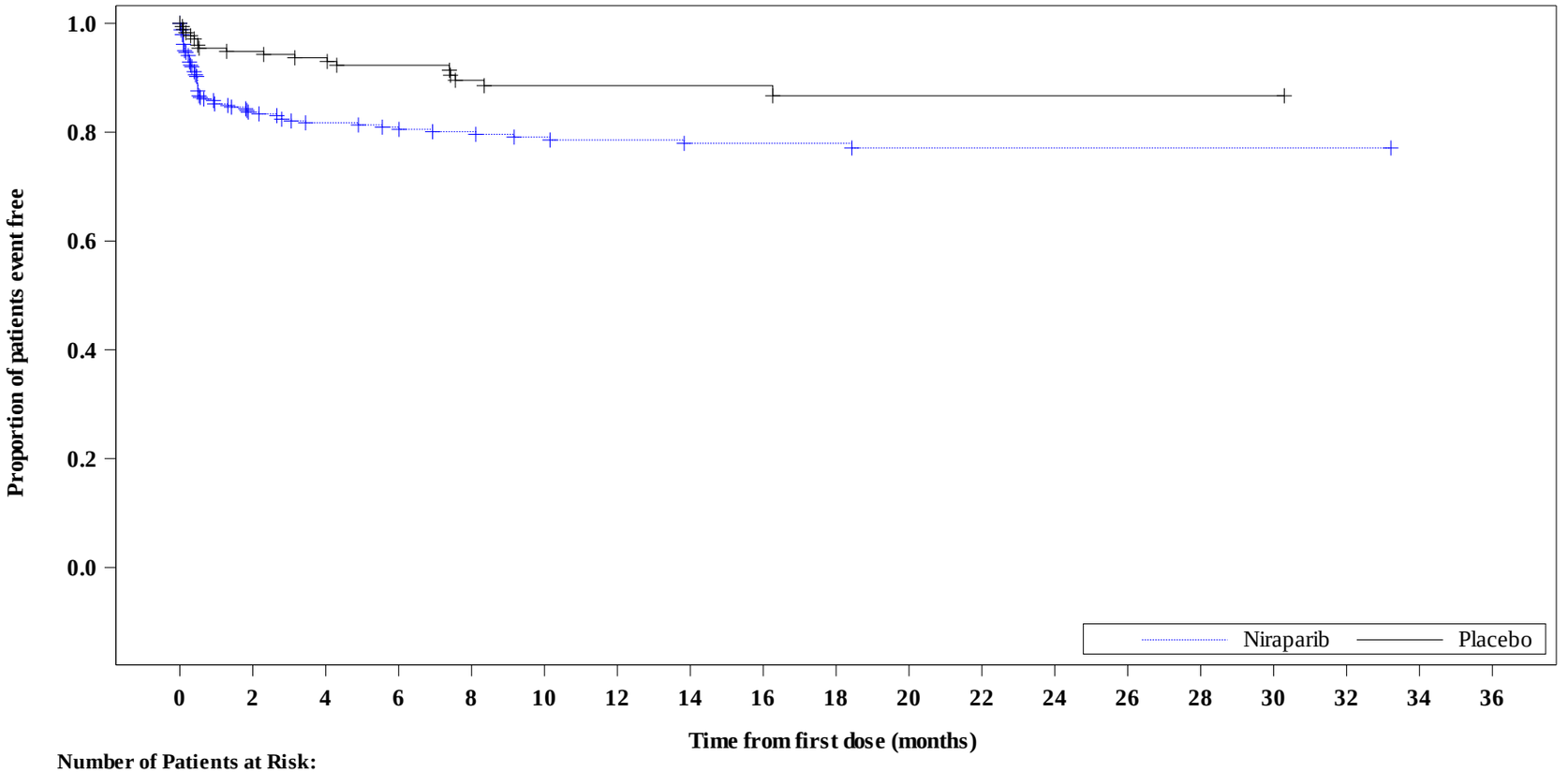
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders, PT: Decreased appetite




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 264 | 222 | 200 | 166 | 147 | 138 | 126 | 104 | 94 | 68 | 47 | 31 | 16 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 164 | 138 | 122 | 94 | 75 | 67 | 56 | 48 | 41 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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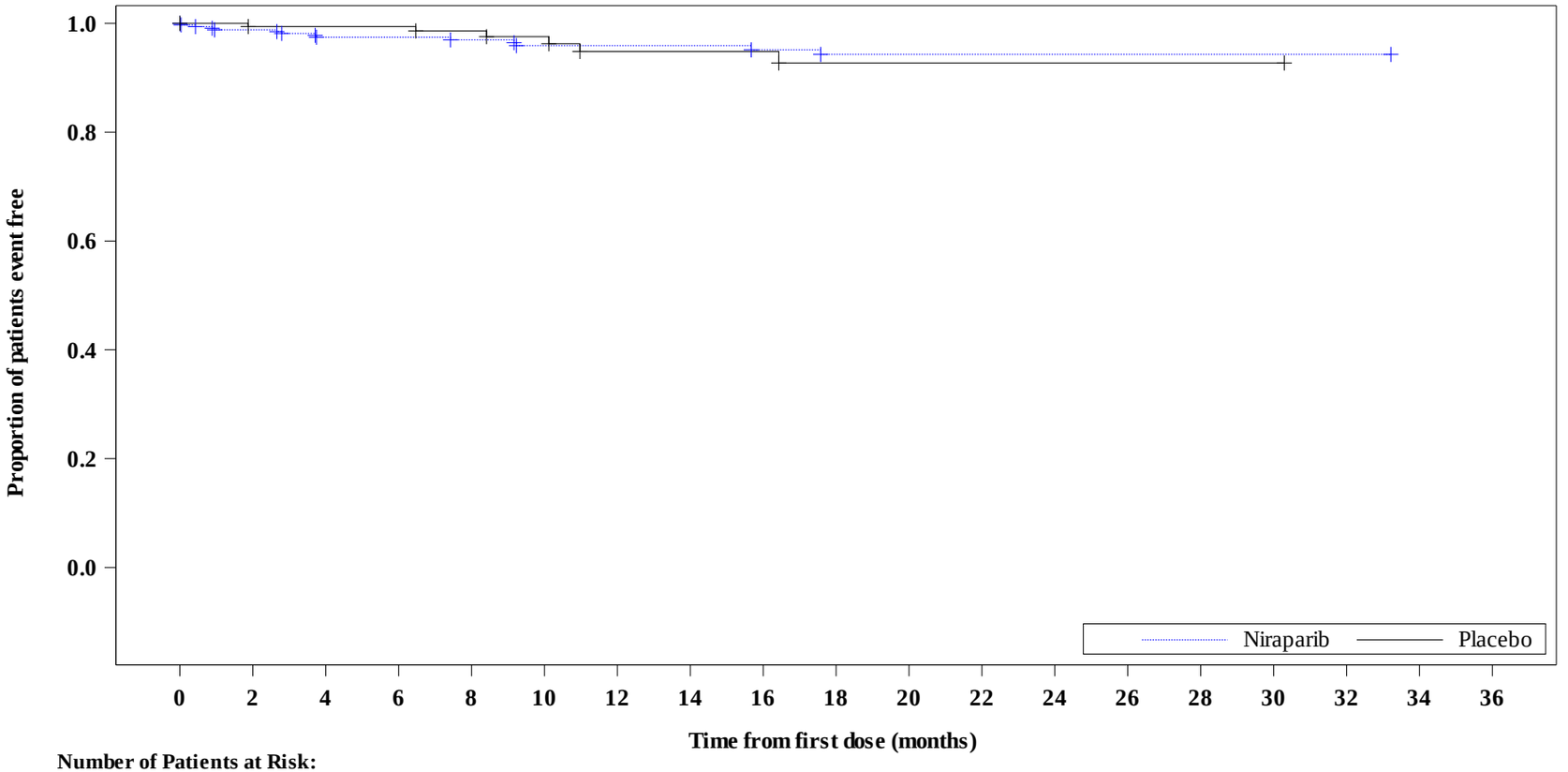
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hyperglycaemia

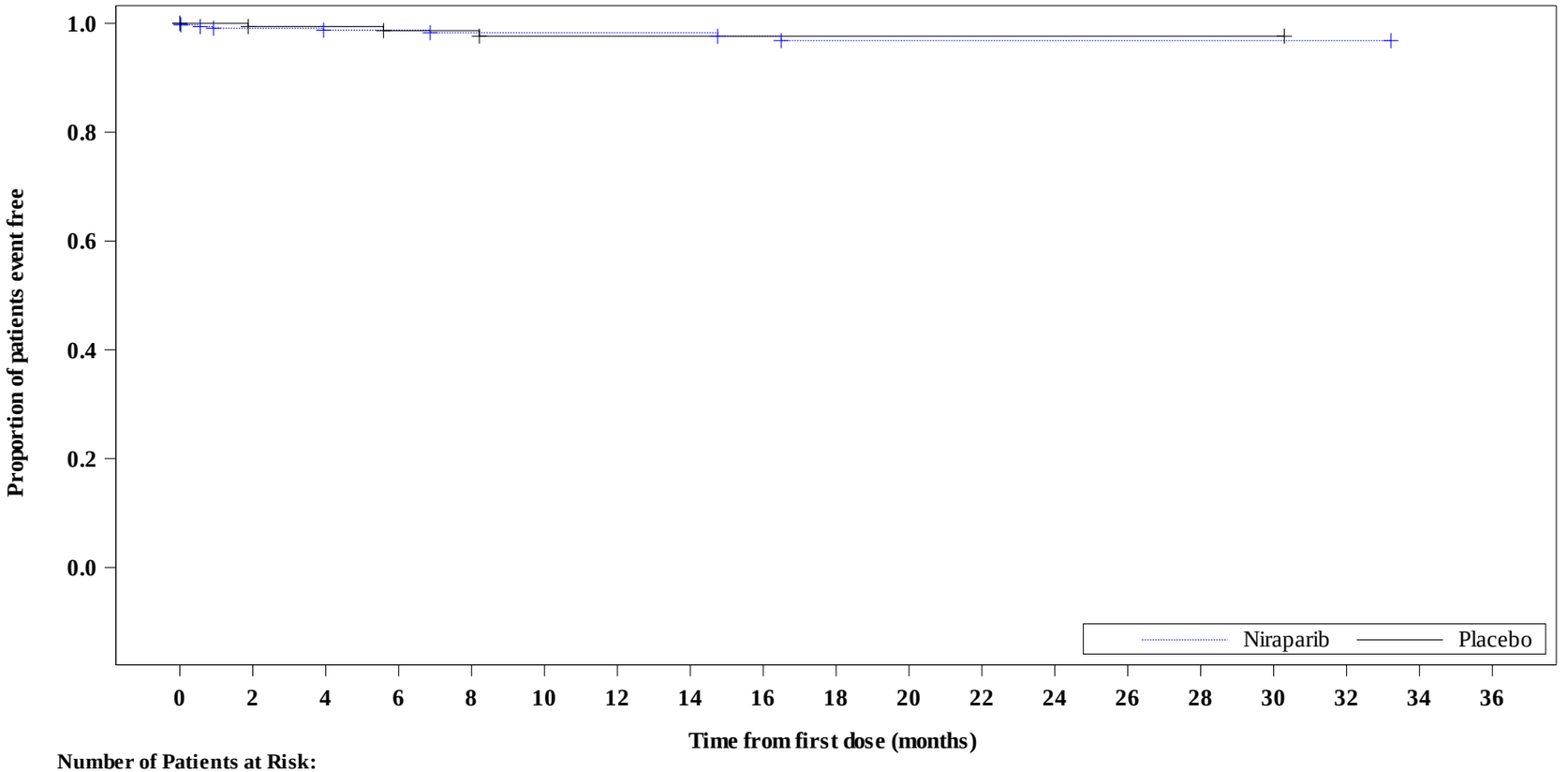



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 257 | 233 | 191 | 165 | 157 | 144 | 120 | 109 | 80 | 55 | 37 | 18 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 100 | 75 | 65 | 54 | 45 | 40 | 34 | 17 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hypoalbuminaemia

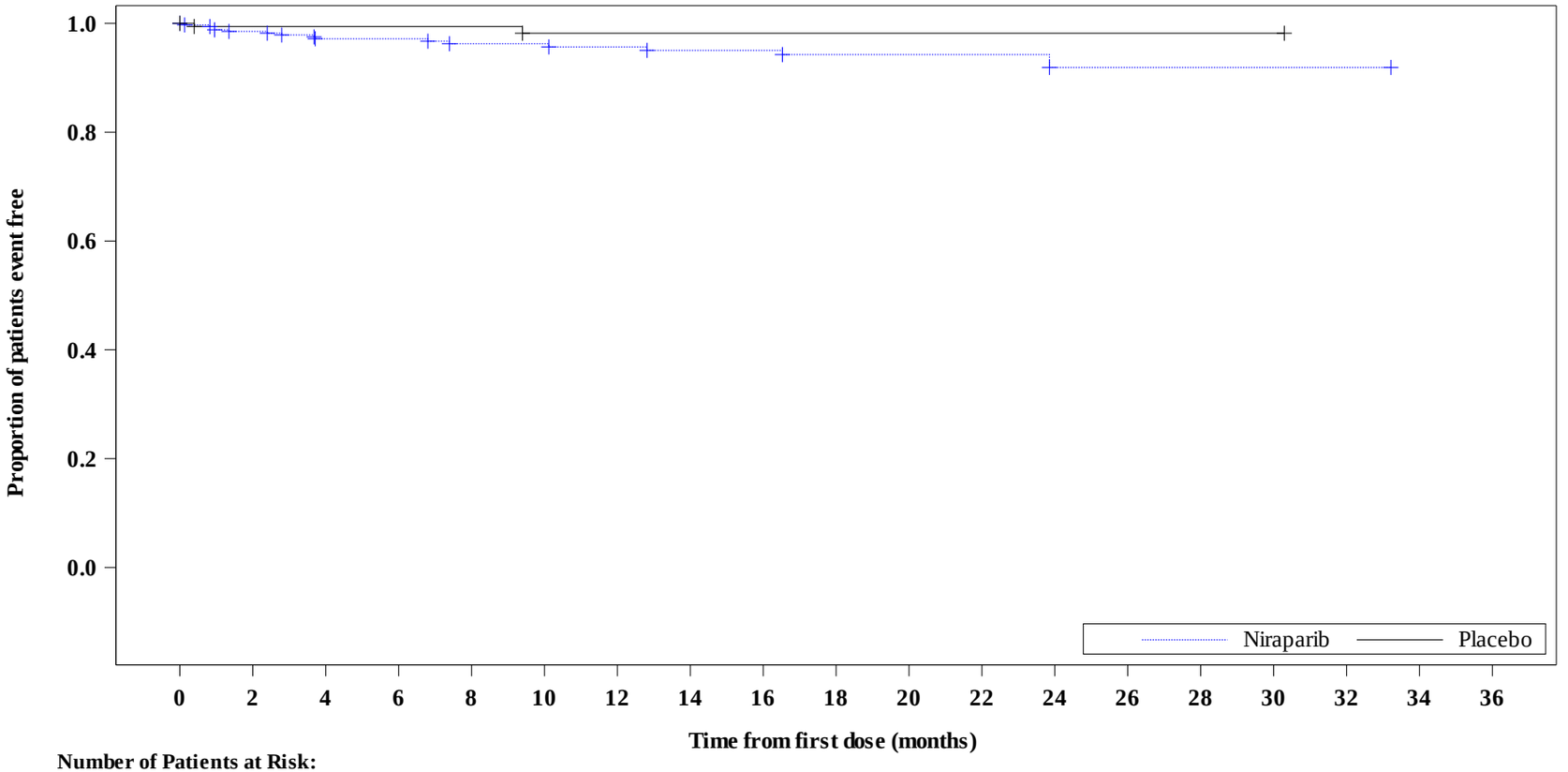



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 262 | 237 | 195 | 171 | 163 | 151 | 126 | 114 | 84 | 59 | 40 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 100 | 75 | 68 | 57 | 48 | 41 | 34 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hypokalaemia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 259 | 233 | 191 | 167 | 159 | 146 | 123 | 111 | 81 | 57 | 38 | 18 | 9 | 2 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 76 | 69 | 58 | 49 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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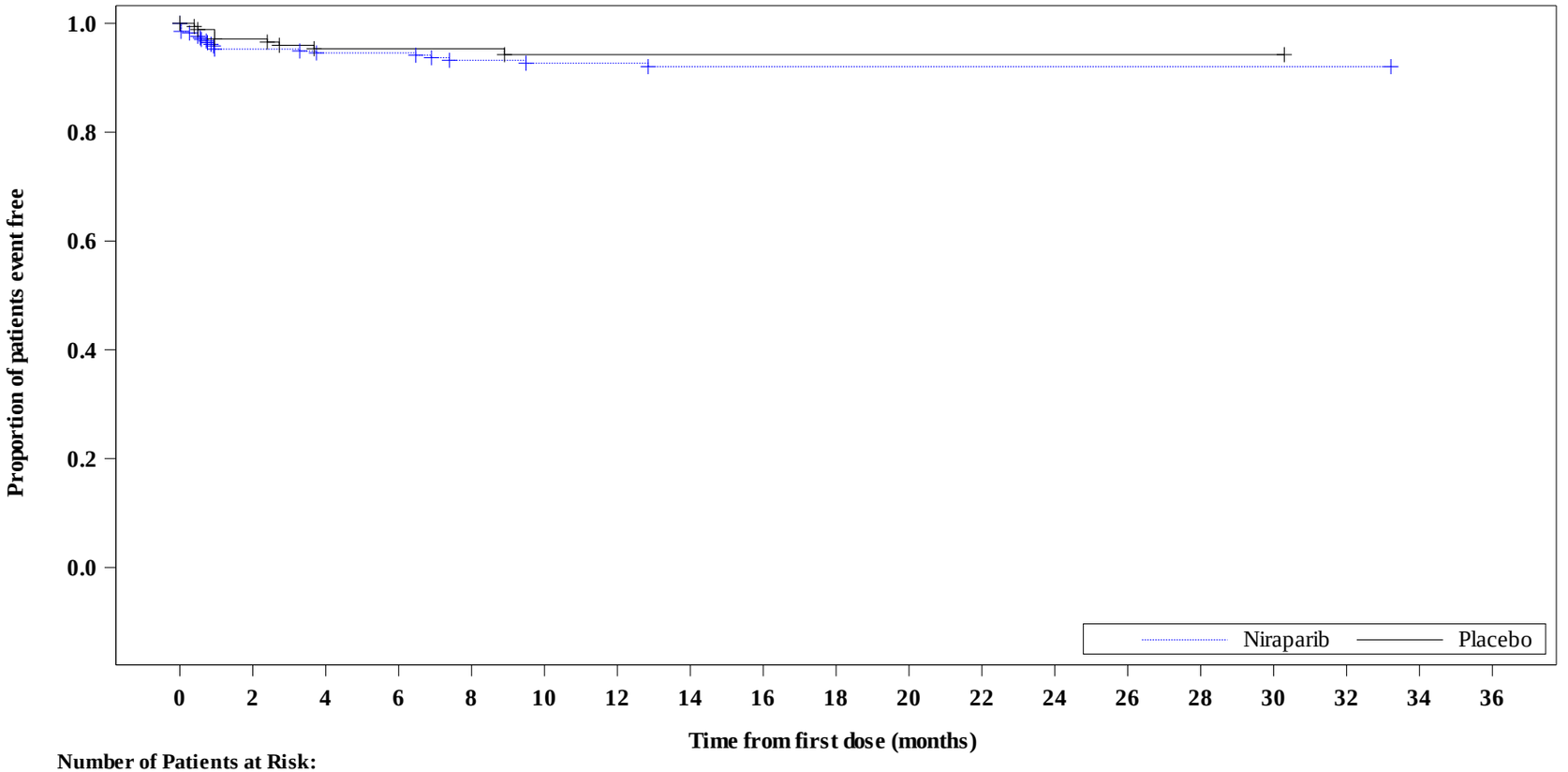
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hypomagnesaemia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 295 | 252 | 228 | 186 | 163 | 156 | 144 | 121 | 110 | 83 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 138 | 121 | 97 | 74 | 66 | 56 | 47 | 41 | 34 | 17 | 8 | 5 | 2 | 1 | 0 | |

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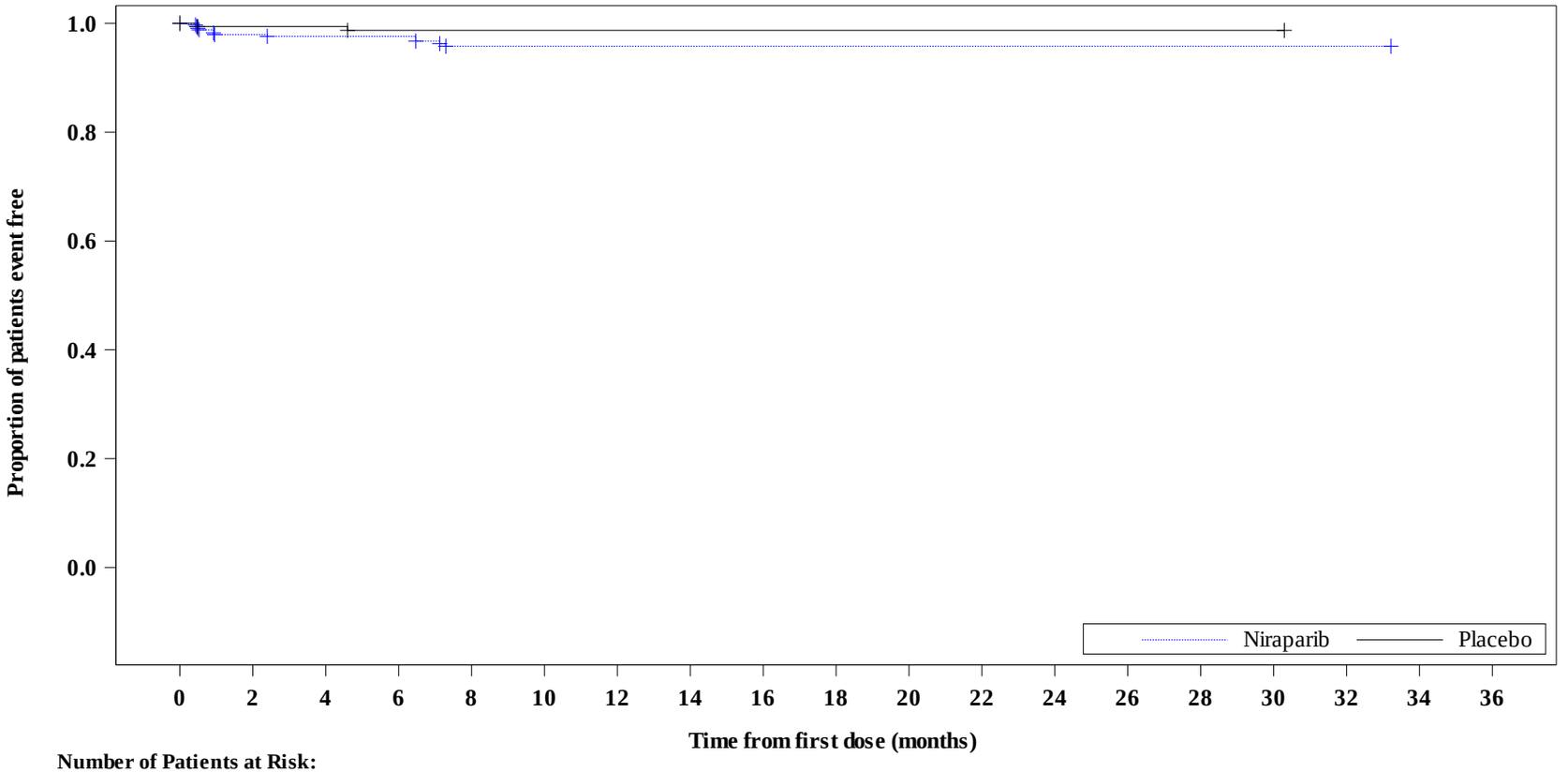
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders, PT: Hyponatraemia

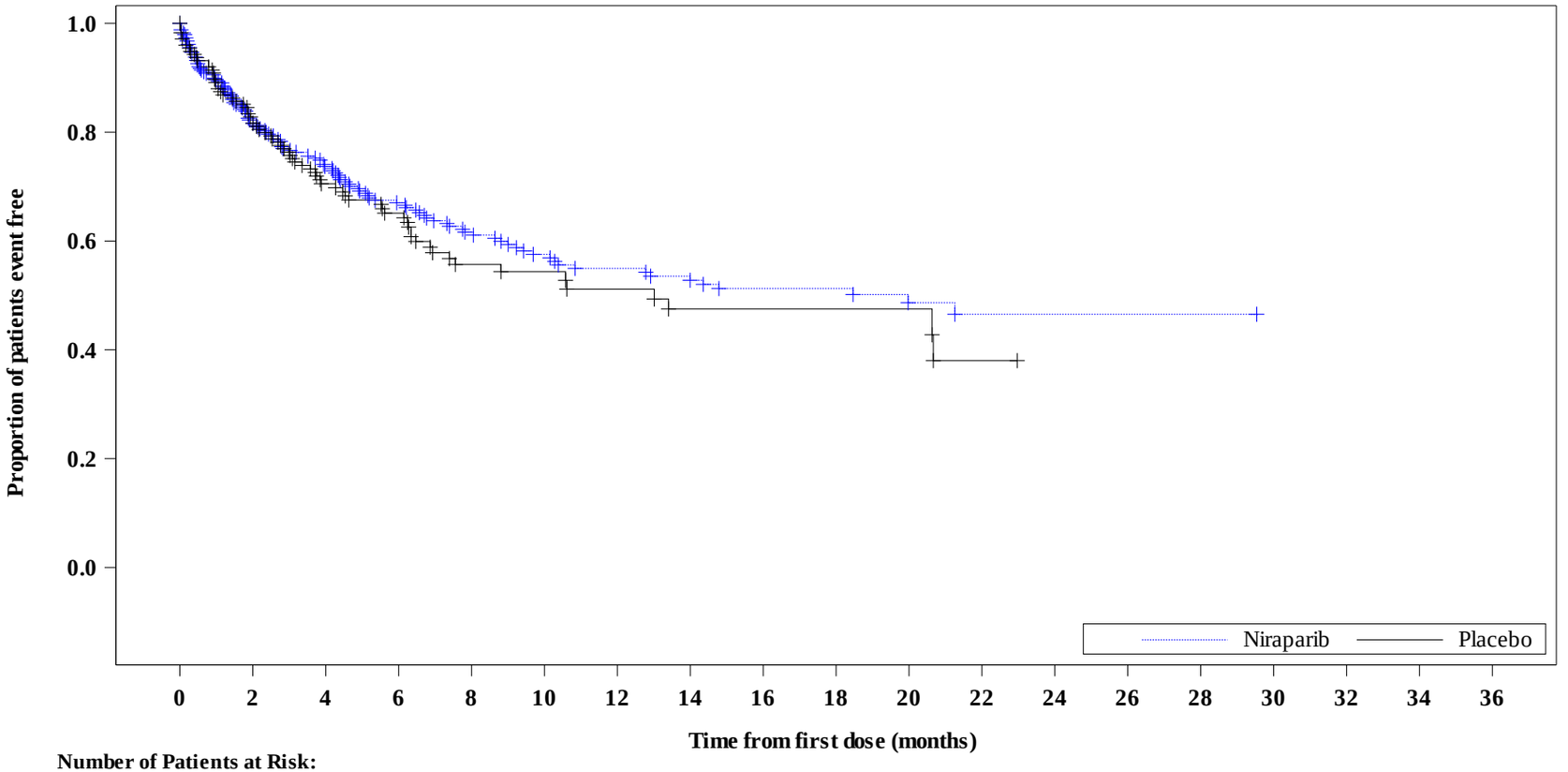



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 304 | 257 | 231 | 187 | 164 | 156 | 143 | 120 | 109 | 81 | 55 | 37 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 100 | 76 | 68 | 57 | 48 | 41 | 34 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 253 | 188 | 151 | 112 | 90 | 83 | 71 | 56 | 49 | 32 | 20 | 13 | 5 | 1 | 0 |
| Placebo | 175 | 143 | 98 | 77 | 50 | 36 | 31 | 24 | 21 | 16 | 12 | 4 | 0 | | | |

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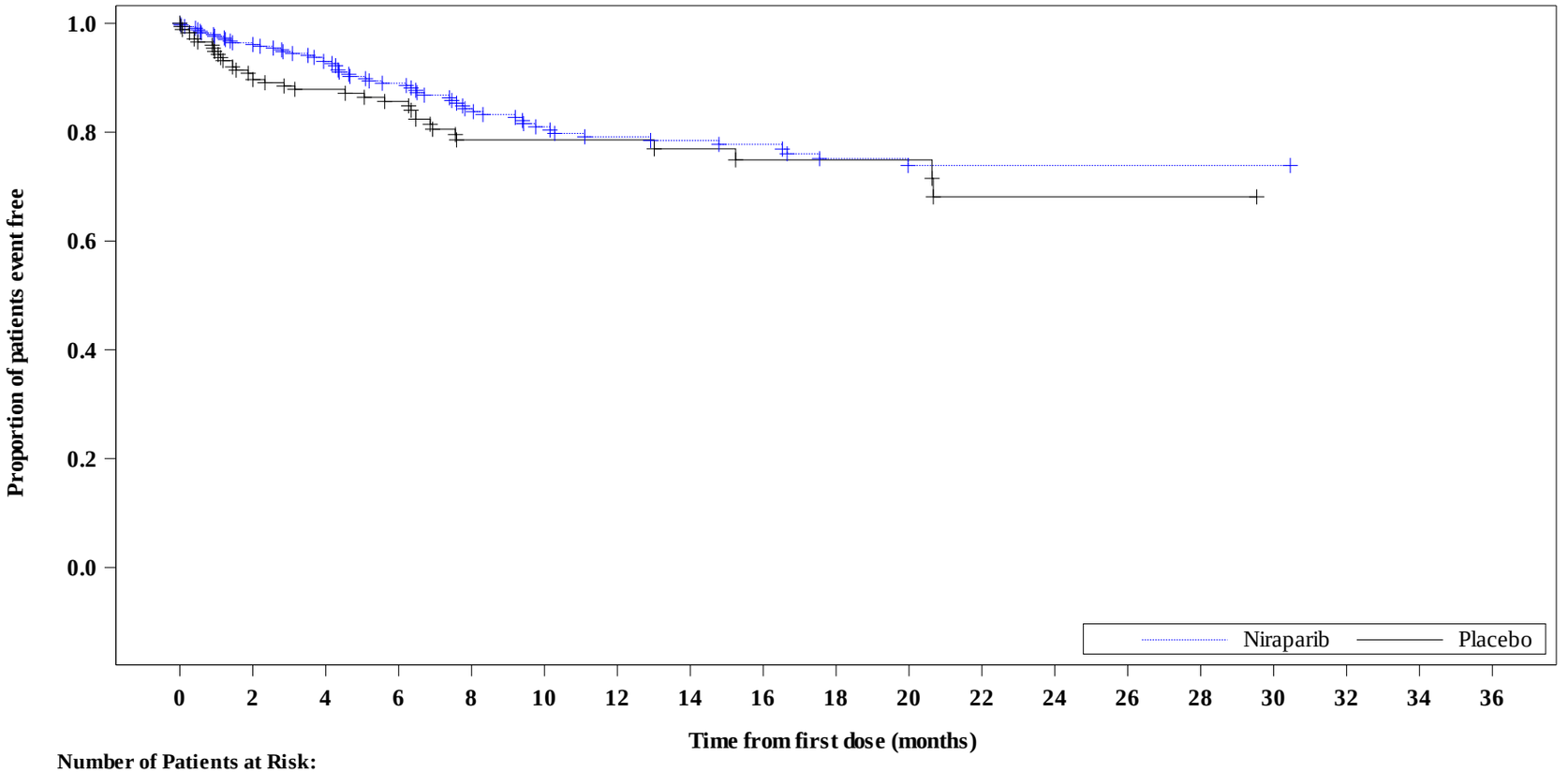
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 299 | 244 | 210 | 161 | 134 | 125 | 113 | 92 | 80 | 59 | 40 | 27 | 12 | 4 | 1 | 0 |
| Placebo | 175 | 157 | 126 | 108 | 79 | 59 | 52 | 43 | 37 | 31 | 25 | 13 | 6 | 3 | 1 | 0 | |

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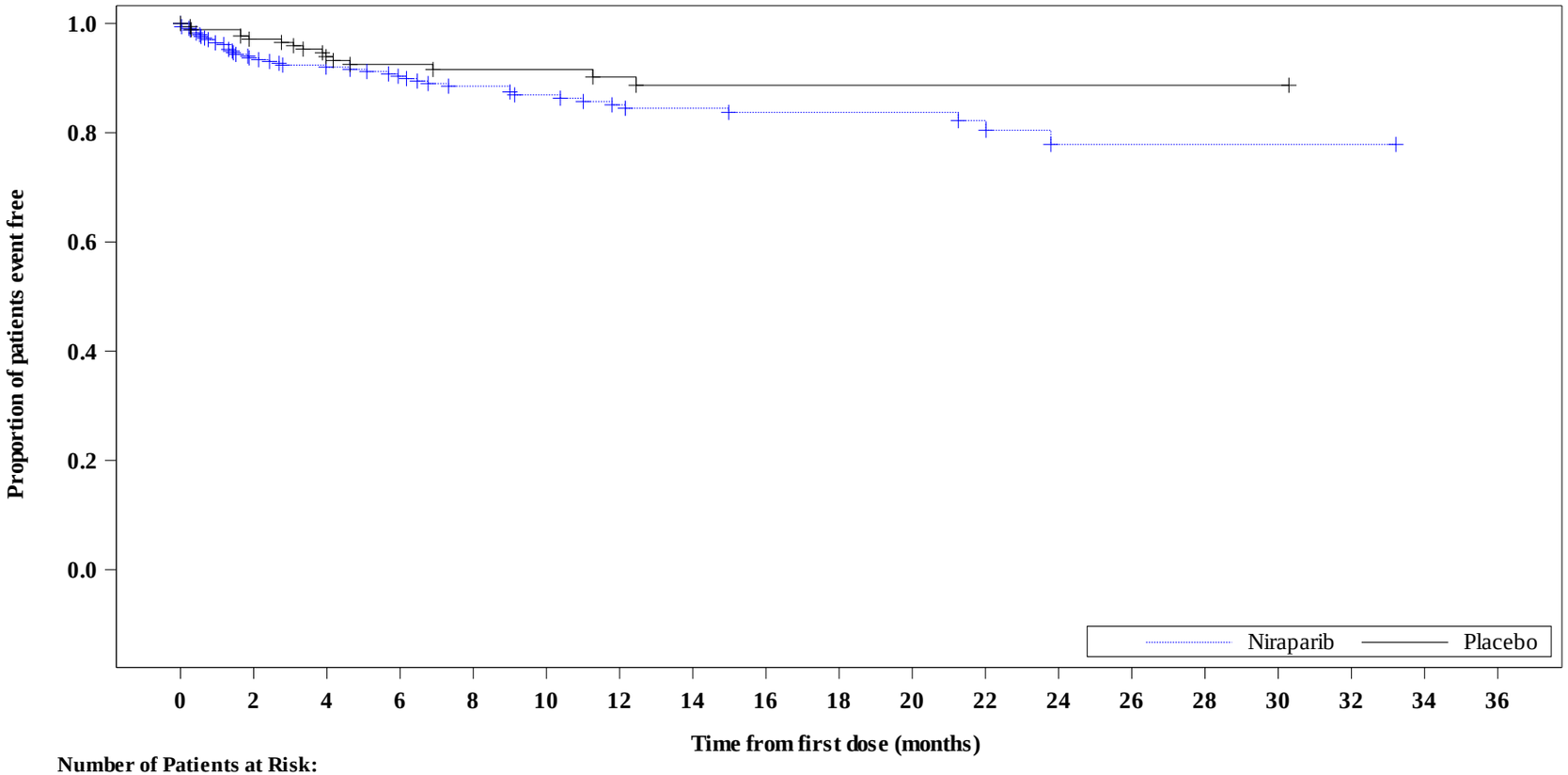
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Back pain

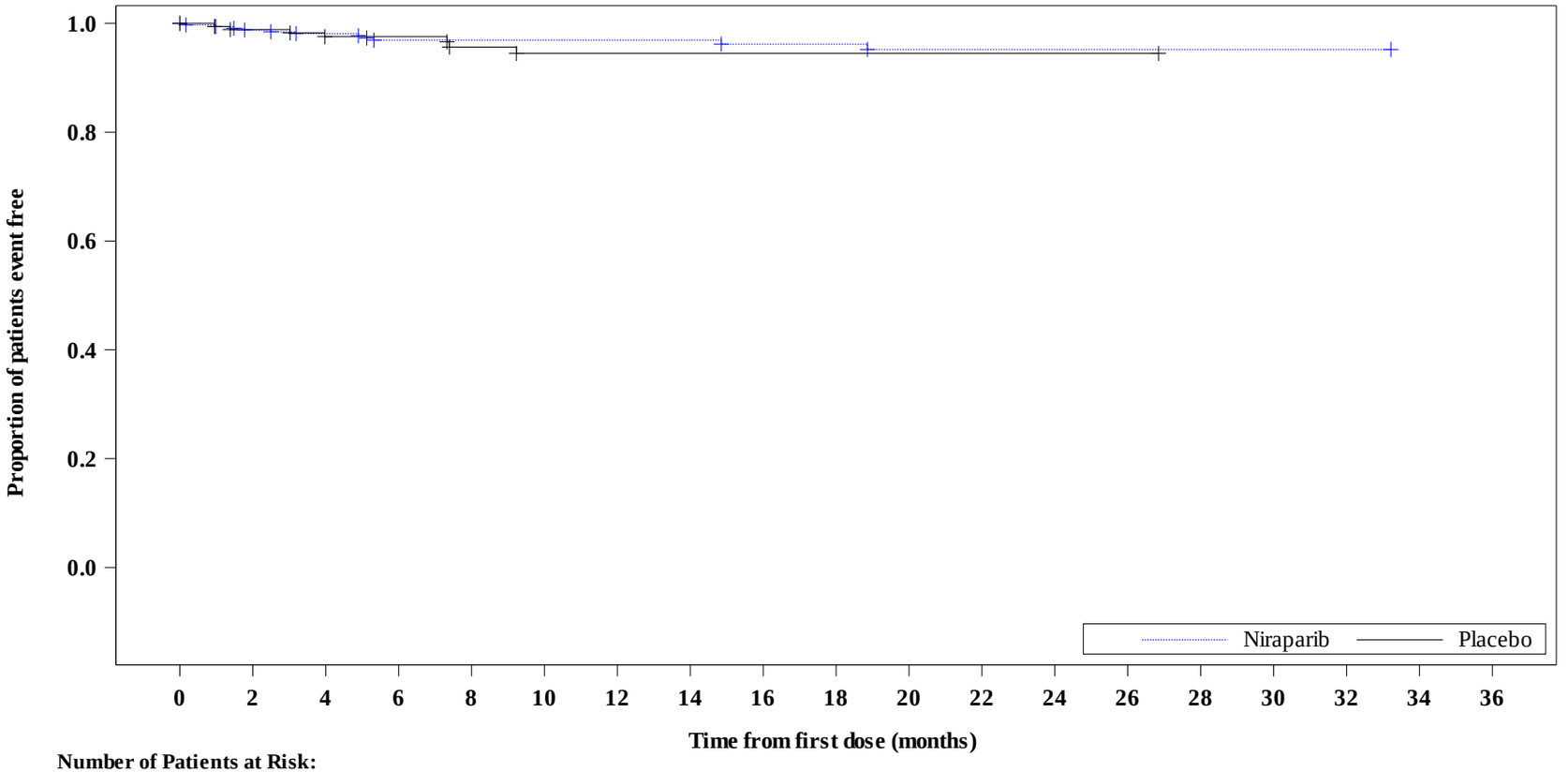



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 290 | 241 | 211 | 172 | 147 | 137 | 125 | 105 | 96 | 71 | 47 | 29 | 13 | 7 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 136 | 118 | 92 | 71 | 64 | 53 | 46 | 40 | 33 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Muscle spasms

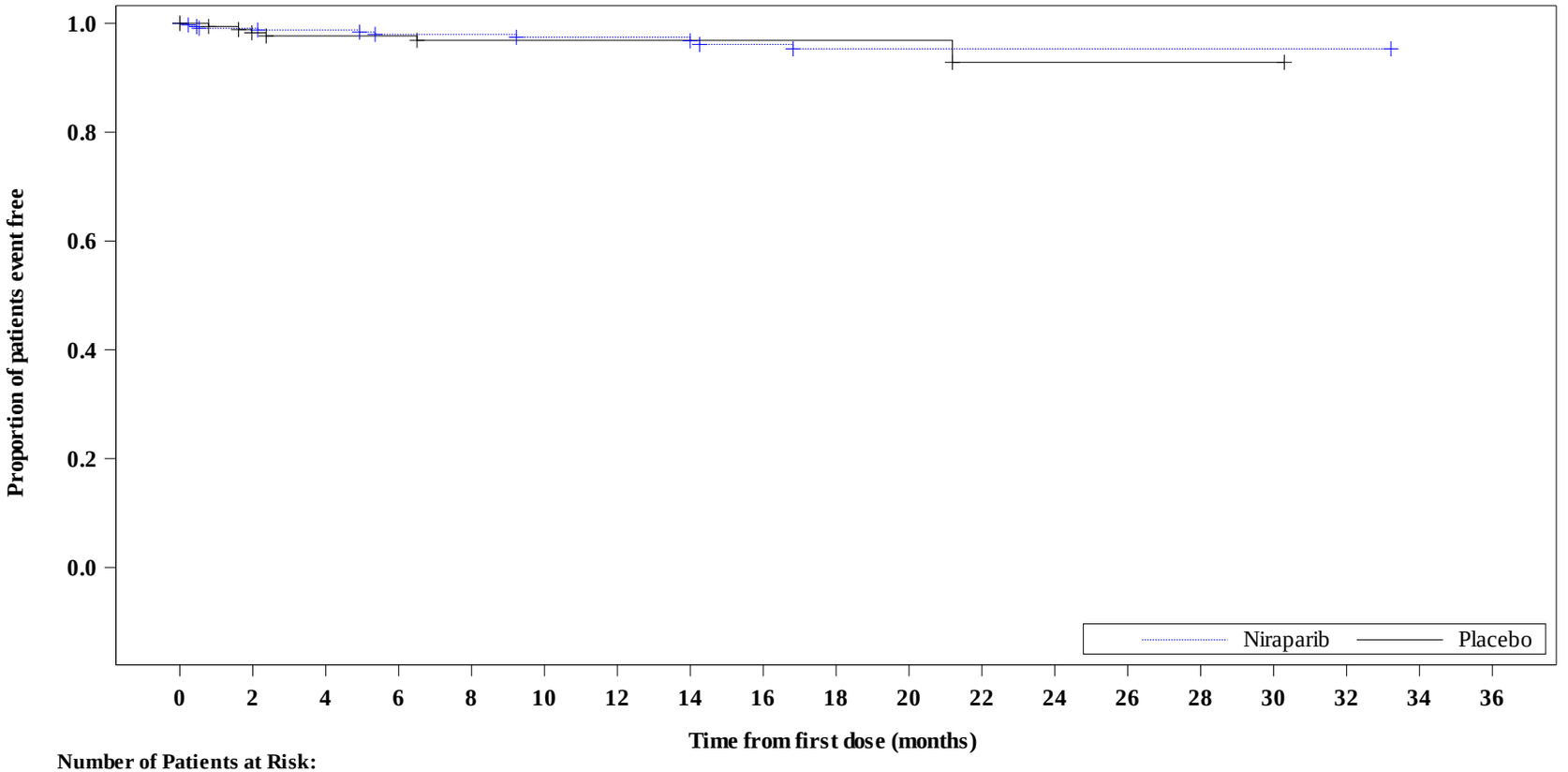



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 259 | 231 | 190 | 168 | 160 | 148 | 122 | 111 | 82 | 58 | 40 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 141 | 124 | 96 | 73 | 65 | 55 | 46 | 39 | 32 | 16 | 5 | 2 | 0 | | | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Musculoskeletal chest pain




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 263 | 235 | 193 | 169 | 161 | 147 | 122 | 110 | 82 | 59 | 40 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 169 | 142 | 125 | 98 | 77 | 69 | 58 | 49 | 42 | 35 | 17 | 8 | 5 | 2 | 1 | 0 | |

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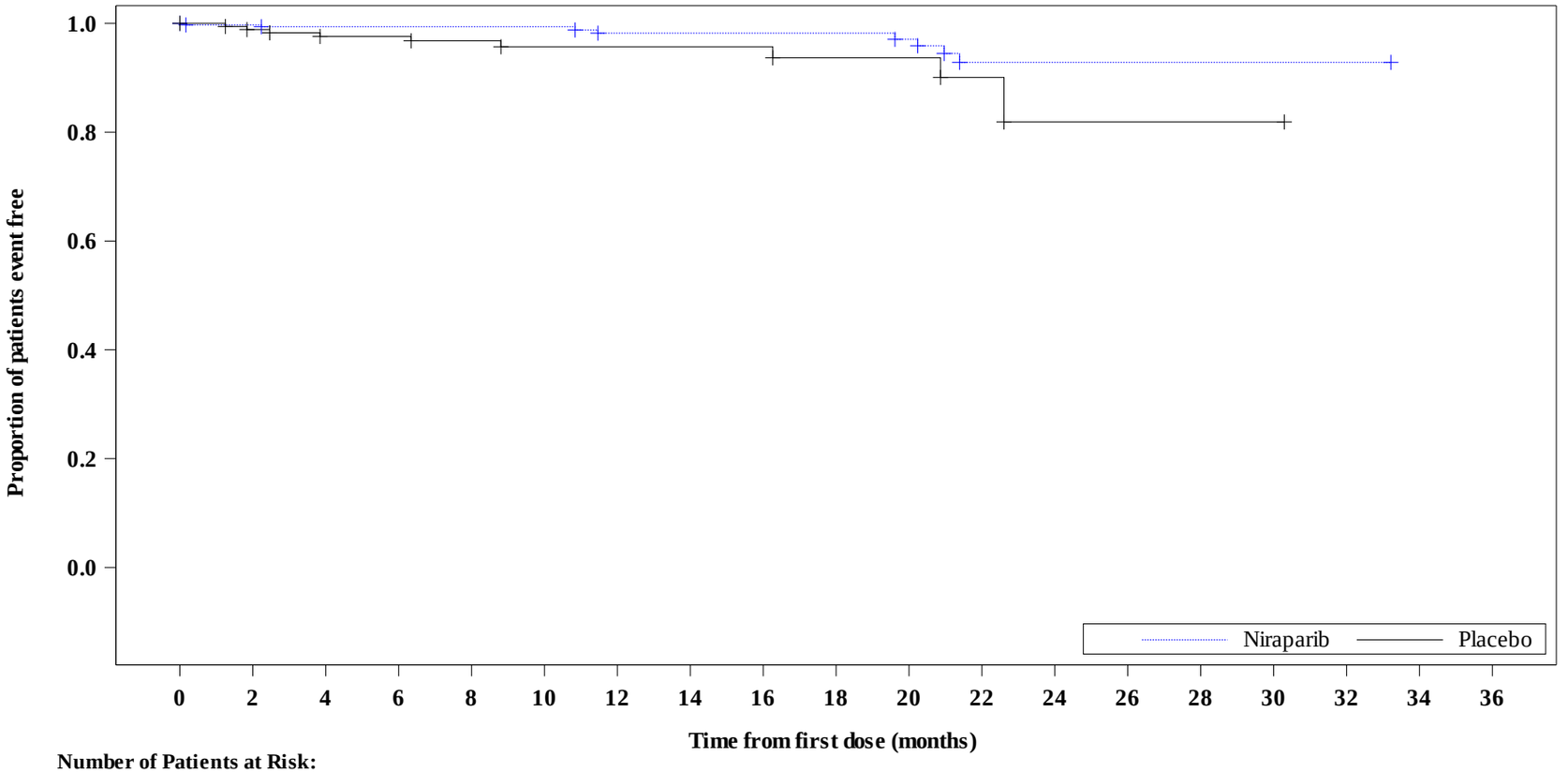
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Musculoskeletal pain




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 263 | 238 | 196 | 172 | 162 | 149 | 124 | 113 | 82 | 55 | 37 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 142 | 126 | 99 | 75 | 67 | 56 | 47 | 39 | 32 | 17 | 7 | 5 | 2 | 1 | 0 | |

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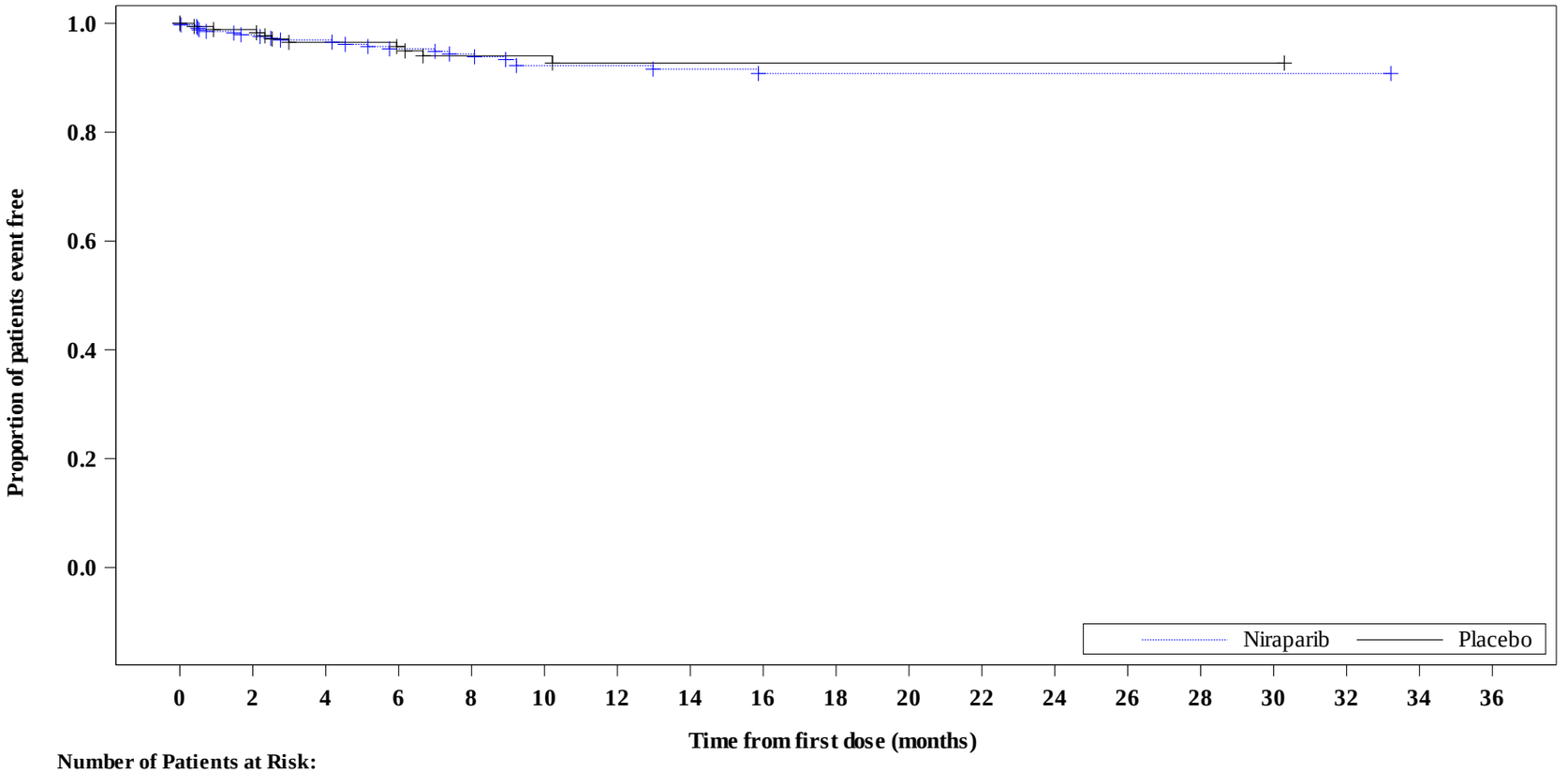
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 304 | 256 | 226 | 184 | 158 | 150 | 137 | 112 | 102 | 74 | 53 | 36 | 17 | 8 | 2 | 2 | 0 |
| Placebo | 175 | 171 | 140 | 122 | 94 | 73 | 65 | 55 | 46 | 39 | 32 | 16 | 8 | 5 | 2 | 1 | 0 | |

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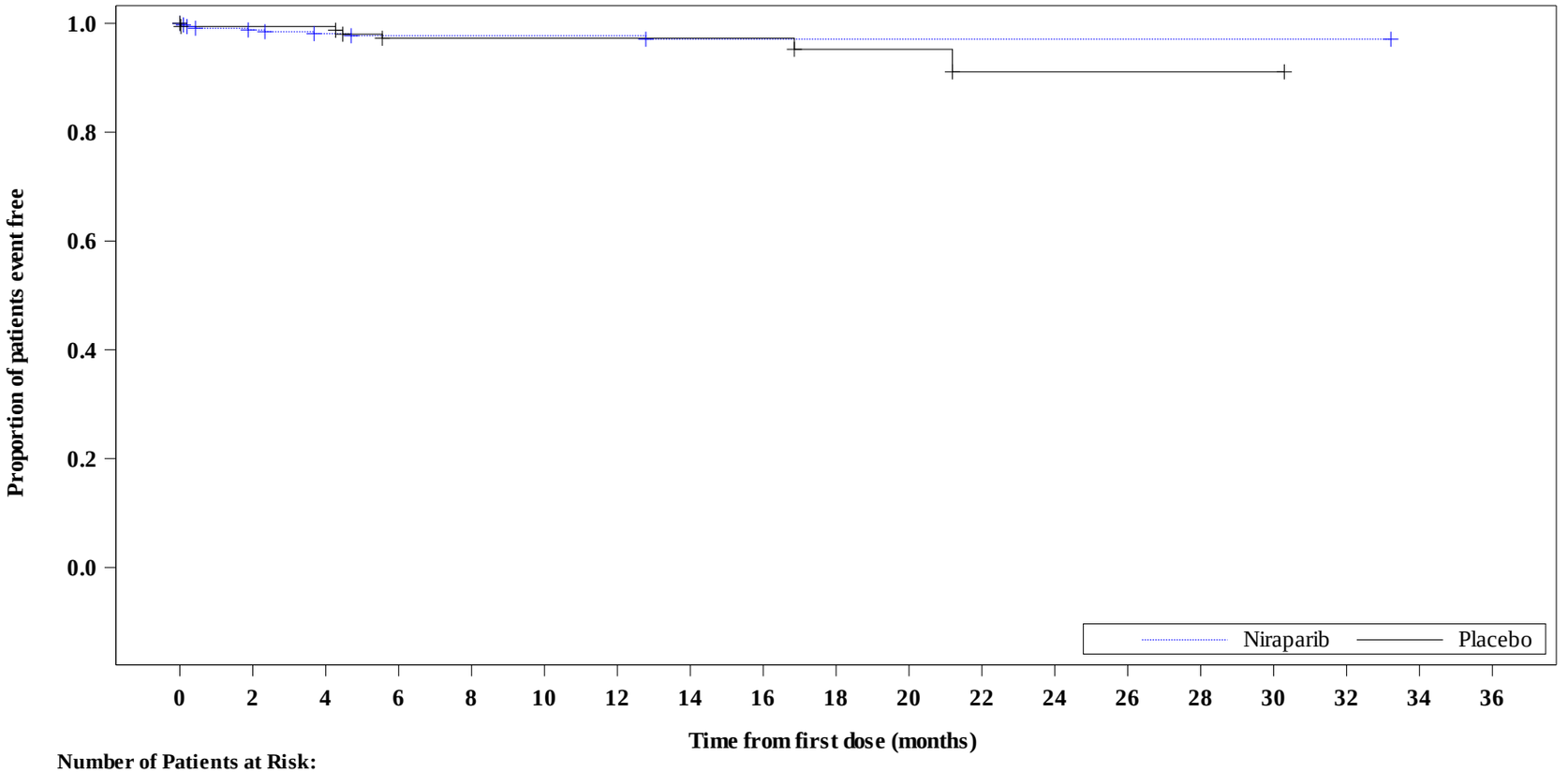
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Neck pain

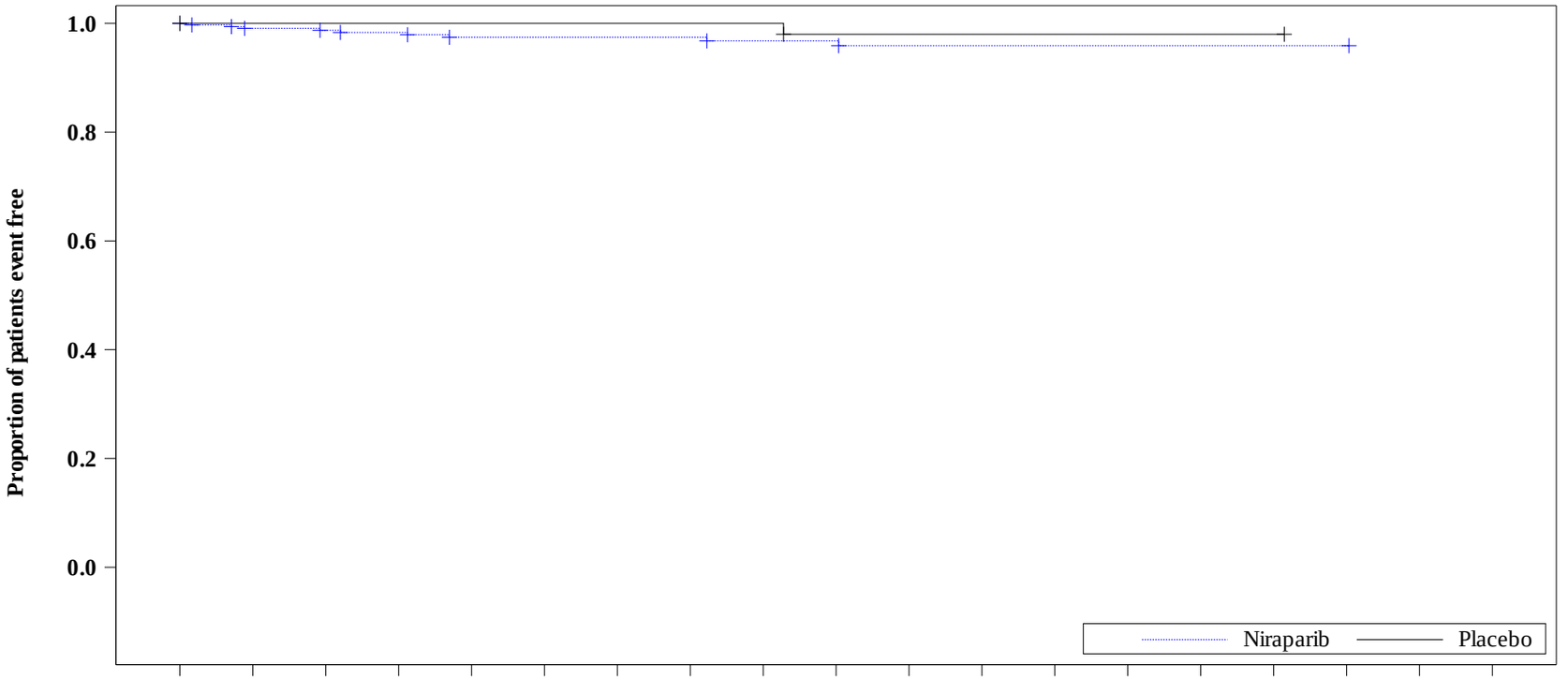



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 259 | 233 | 193 | 169 | 162 | 148 | 123 | 112 | 83 | 58 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 125 | 100 | 77 | 69 | 58 | 49 | 41 | 34 | 16 | 7 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Osteoporosis

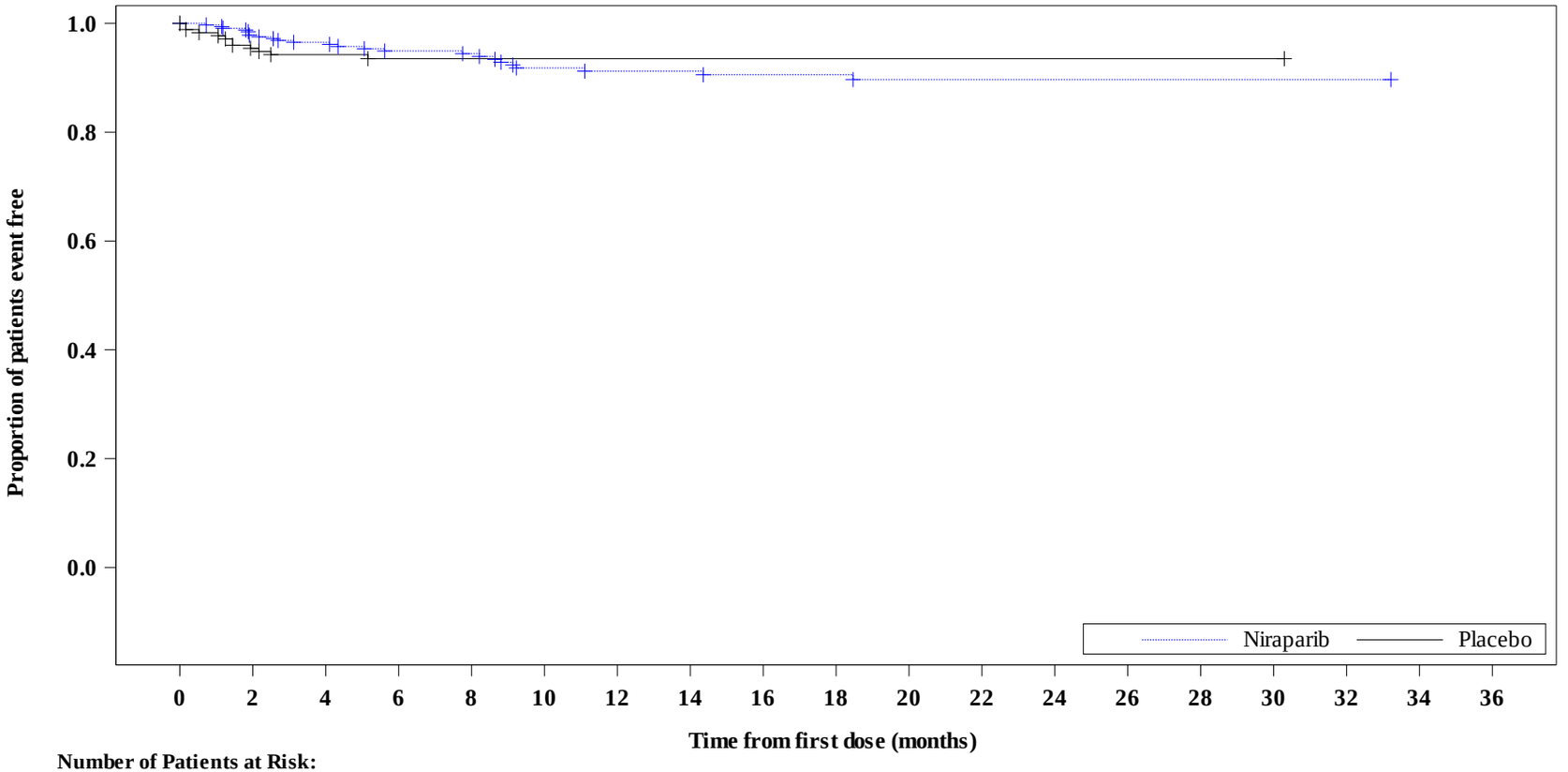



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 262 | 235 | 192 | 168 | 160 | 147 | 122 | 111 | 81 | 56 | 38 | 18 | 8 | 1 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 304 | 255 | 227 | 185 | 160 | 151 | 138 | 116 | 105 | 77 | 52 | 36 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 165 | 136 | 120 | 94 | 72 | 64 | 54 | 45 | 39 | 32 | 18 | 8 | 5 | 2 | 1 | 0 | |

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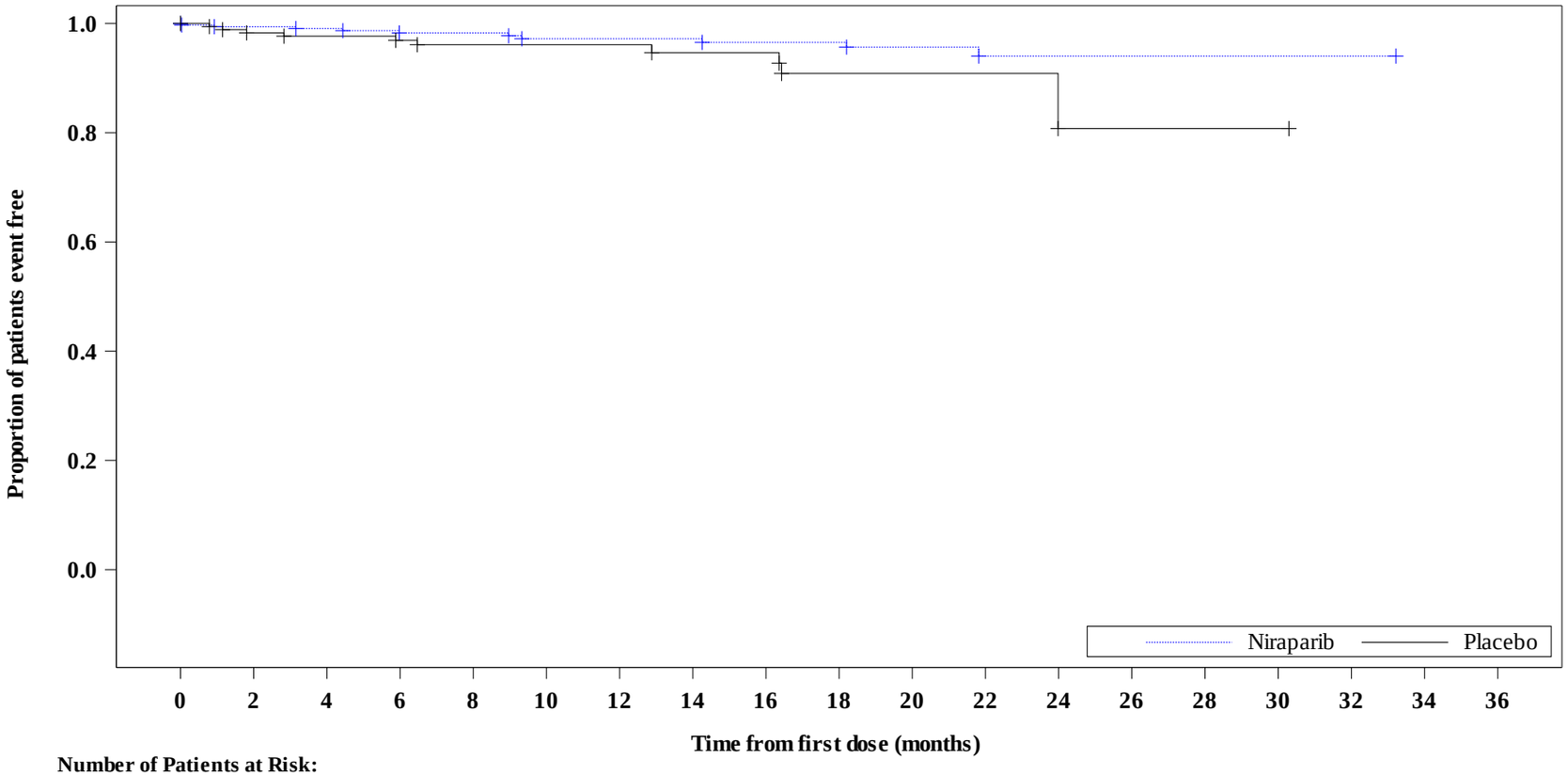
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 263 | 236 | 194 | 169 | 161 | 148 | 123 | 113 | 83 | 57 | 40 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 169 | 142 | 125 | 99 | 77 | 69 | 58 | 50 | 43 | 36 | 20 | 8 | 5 | 2 | 1 | 0 | |

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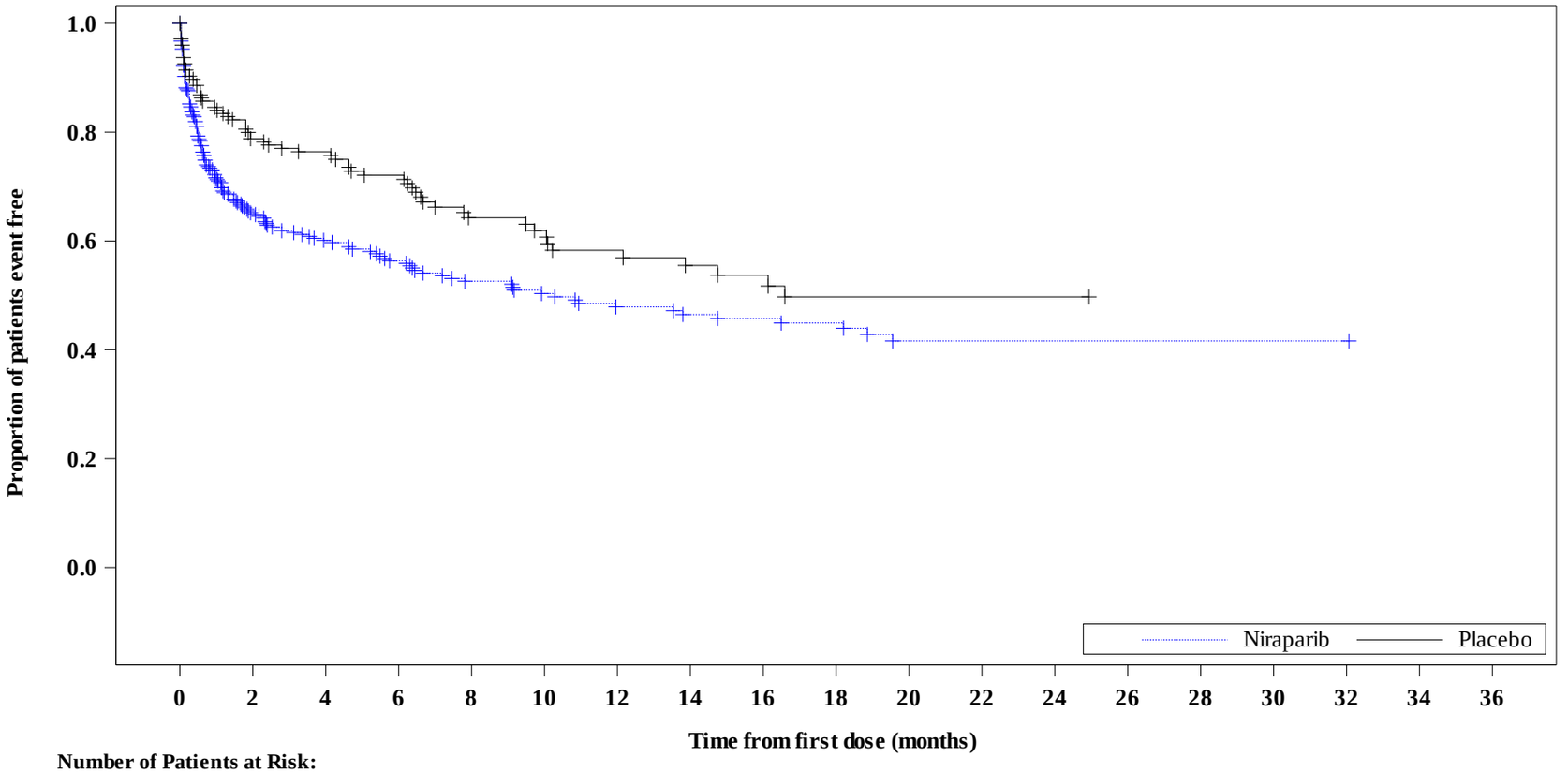
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Nervous system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 201 | 157 | 129 | 99 | 83 | 74 | 66 | 54 | 48 | 30 | 21 | 15 | 6 | 3 | 1 | 1 | 0 |
| Placebo | 175 | 135 | 109 | 94 | 66 | 52 | 44 | 34 | 27 | 21 | 15 | 6 | 1 | 0 | | | | |

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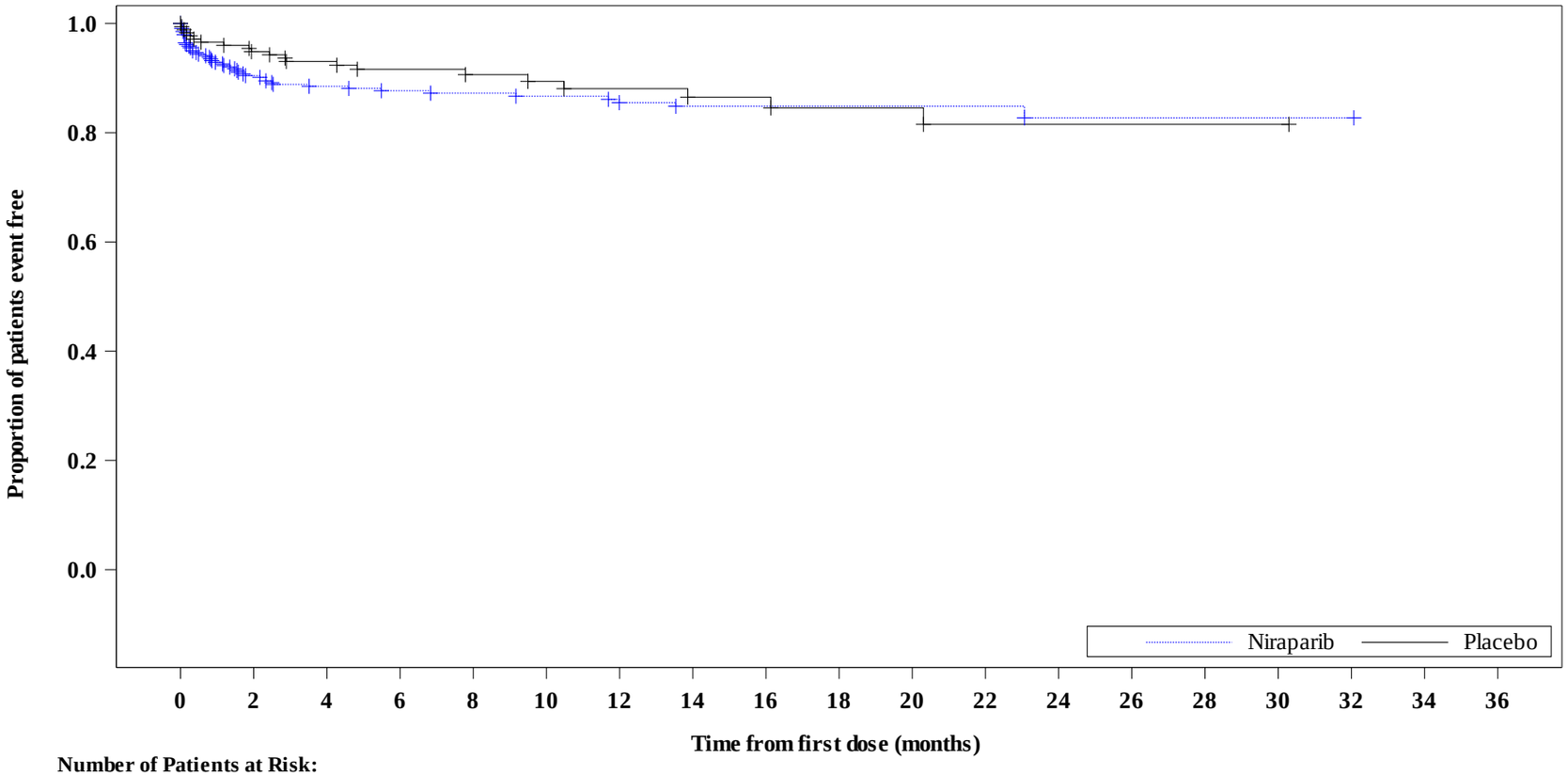
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Nervous system disorders, PT: Dizziness




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 283 | 234 | 207 | 170 | 151 | 141 | 129 | 106 | 97 | 71 | 49 | 33 | 14 | 7 | 1 | 1 | 0 |
| Placebo | 175 | 163 | 134 | 119 | 92 | 70 | 62 | 50 | 44 | 36 | 29 | 15 | 7 | 5 | 2 | 1 | 0 | |

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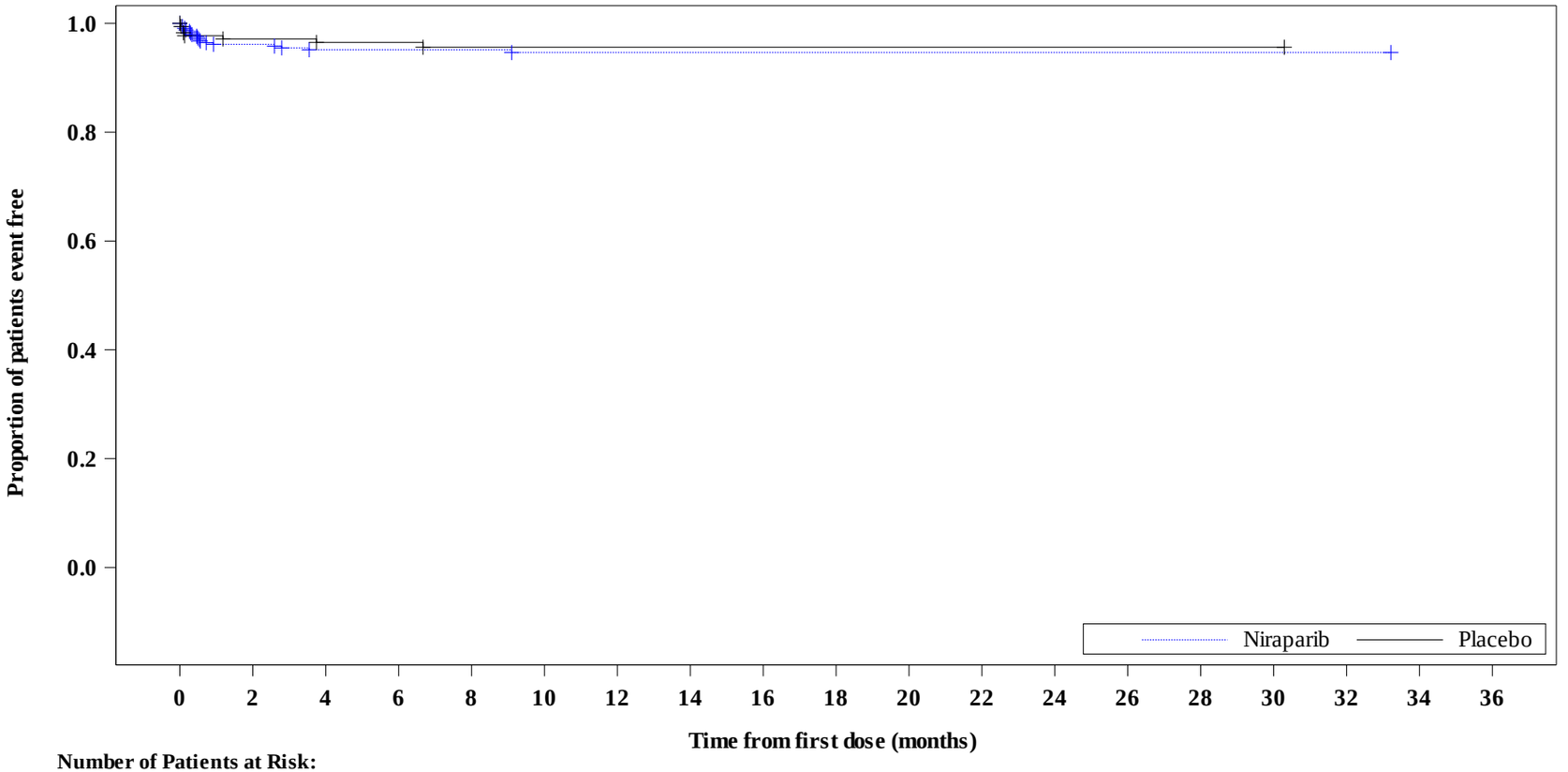
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Nervous system disorders, PT: Dysgeusia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 299 | 252 | 227 | 188 | 163 | 156 | 144 | 121 | 111 | 81 | 56 | 39 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 140 | 124 | 97 | 77 | 69 | 58 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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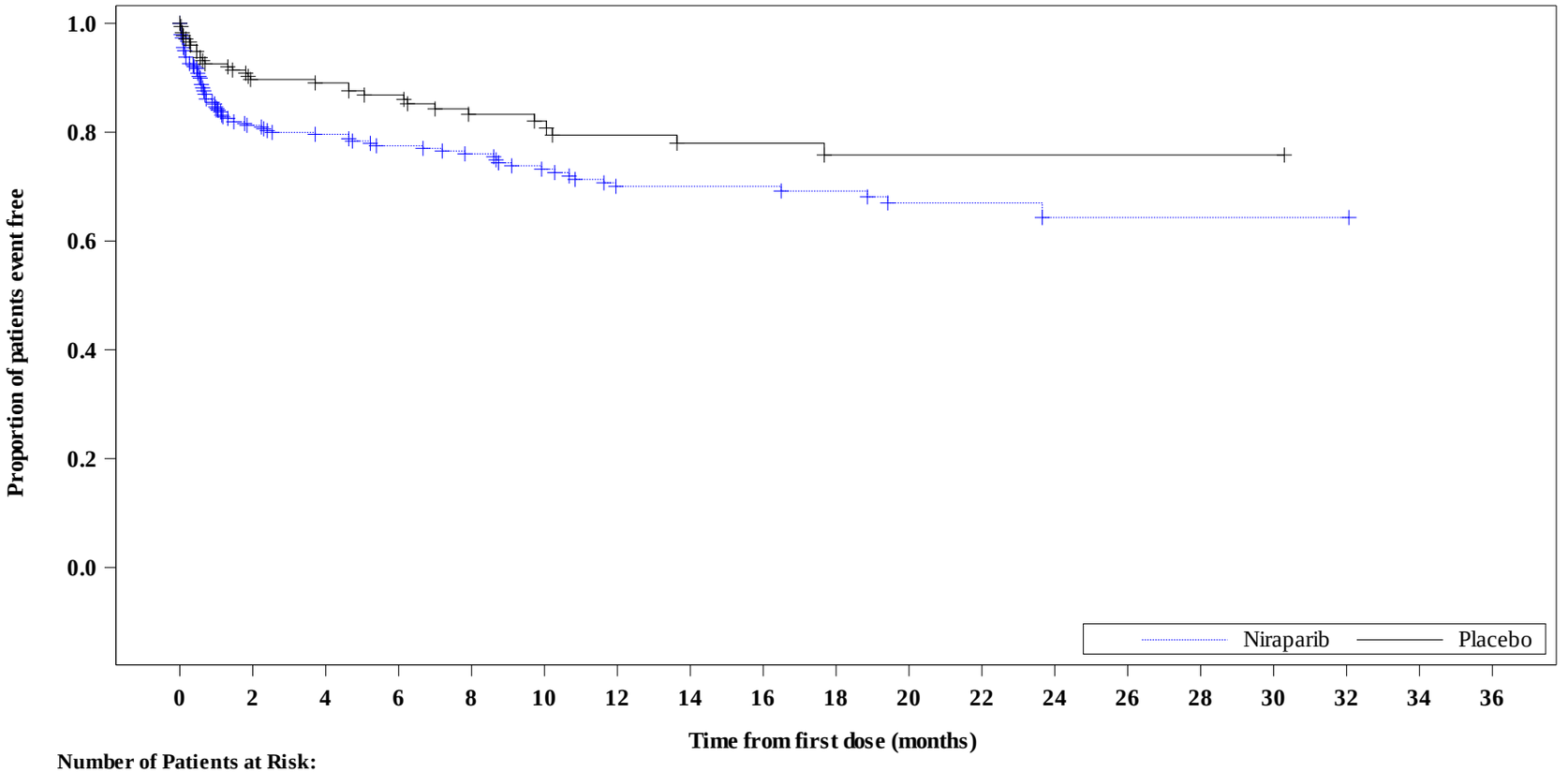
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Nervous system disorders, PT: Headache




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 250 | 205 | 176 | 142 | 118 | 107 | 99 | 83 | 73 | 51 | 34 | 21 | 9 | 5 | 2 | 1 | 0 |
| Placebo | 175 | 154 | 128 | 109 | 84 | 65 | 56 | 47 | 39 | 33 | 27 | 13 | 6 | 4 | 2 | 1 | 0 | |

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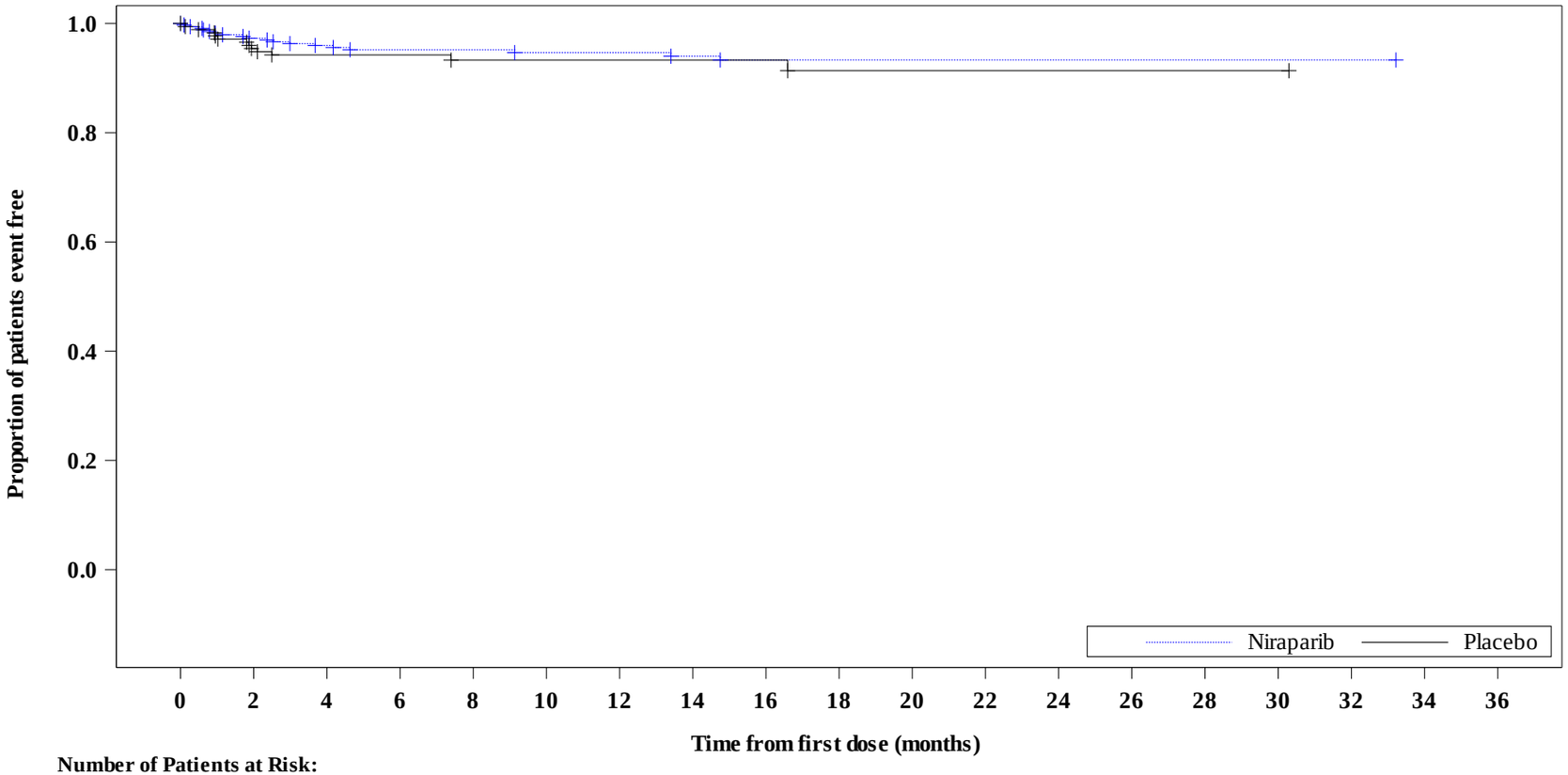
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Nervous system disorders, PT: Neuropathy peripheral

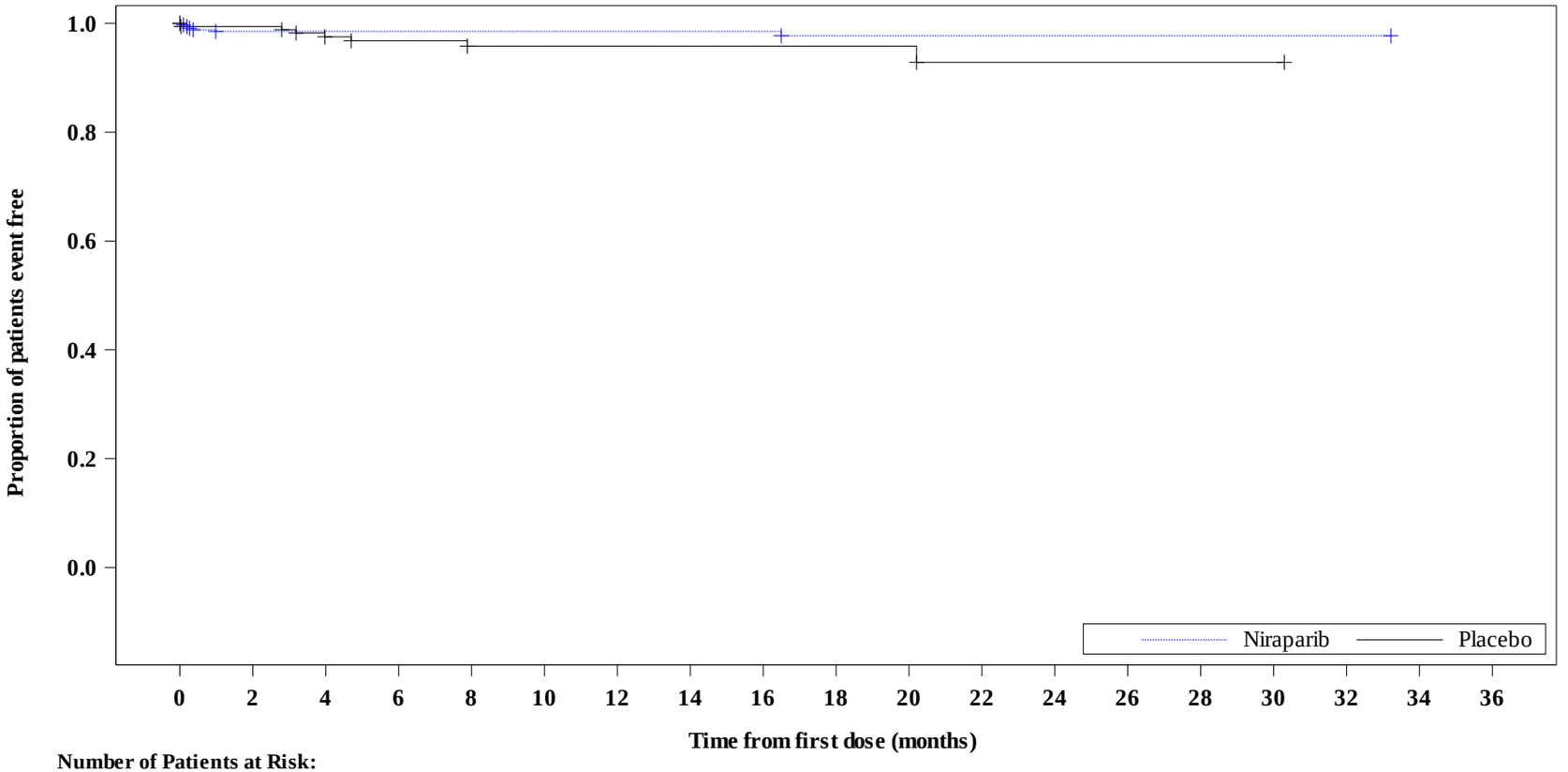



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 255 | 227 | 185 | 163 | 155 | 141 | 116 | 106 | 77 | 55 | 39 | 18 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 164 | 136 | 121 | 94 | 74 | 66 | 56 | 48 | 40 | 33 | 16 | 6 | 4 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Nervous system disorders, PT: Paraesthesia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 263 | 237 | 195 | 171 | 163 | 150 | 125 | 113 | 84 | 59 | 40 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 141 | 125 | 98 | 74 | 66 | 55 | 46 | 40 | 33 | 16 | 7 | 4 | 1 | 1 | 0 | |

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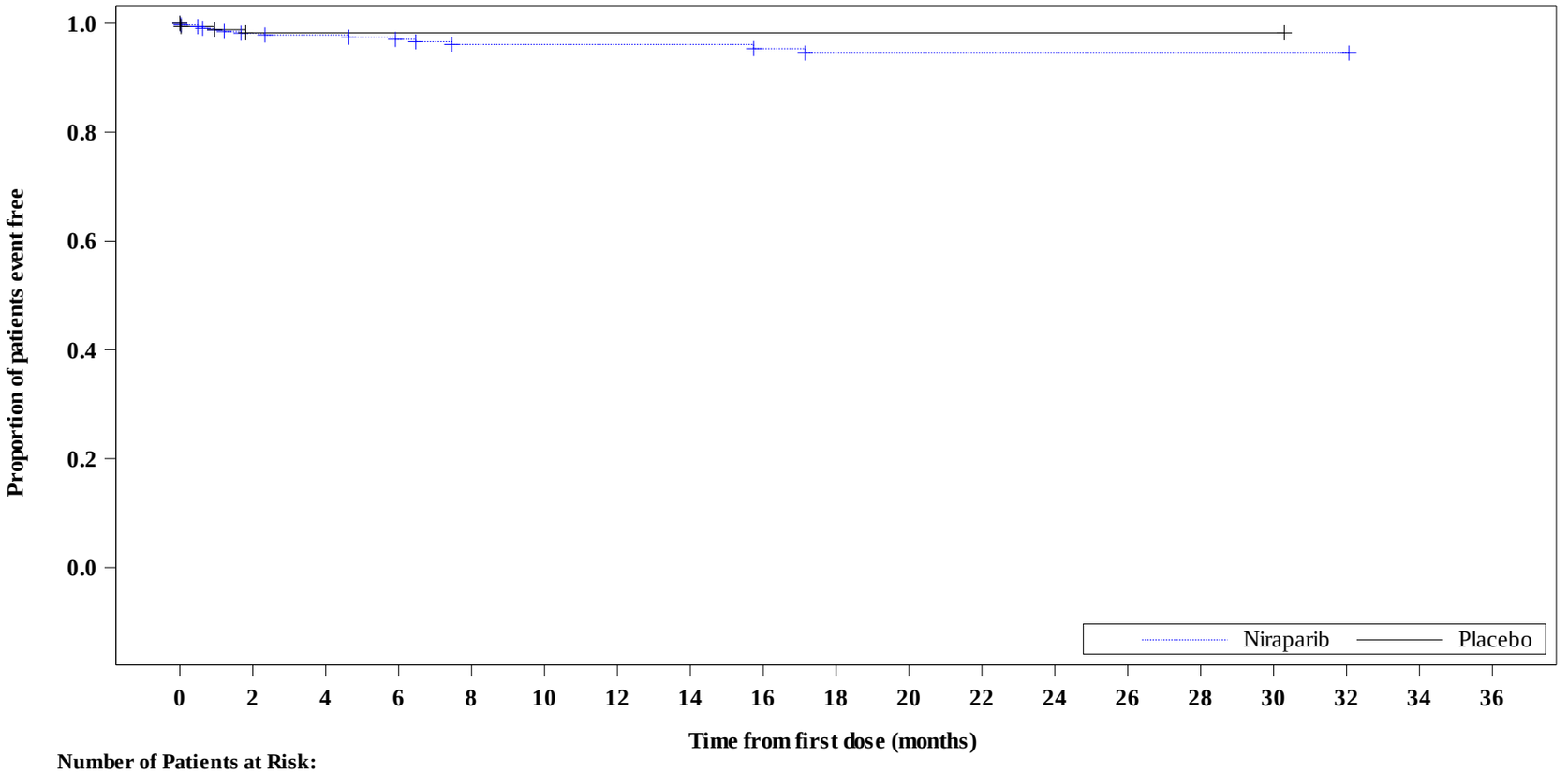
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Nervous system disorders, PT: Peripheral sensory neuropathy




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 305 | 259 | 232 | 189 | 165 | 158 | 147 | 122 | 110 | 81 | 57 | 38 | 17 | 7 | 1 | 1 | 0 |
| Placebo | 175 | 169 | 143 | 127 | 101 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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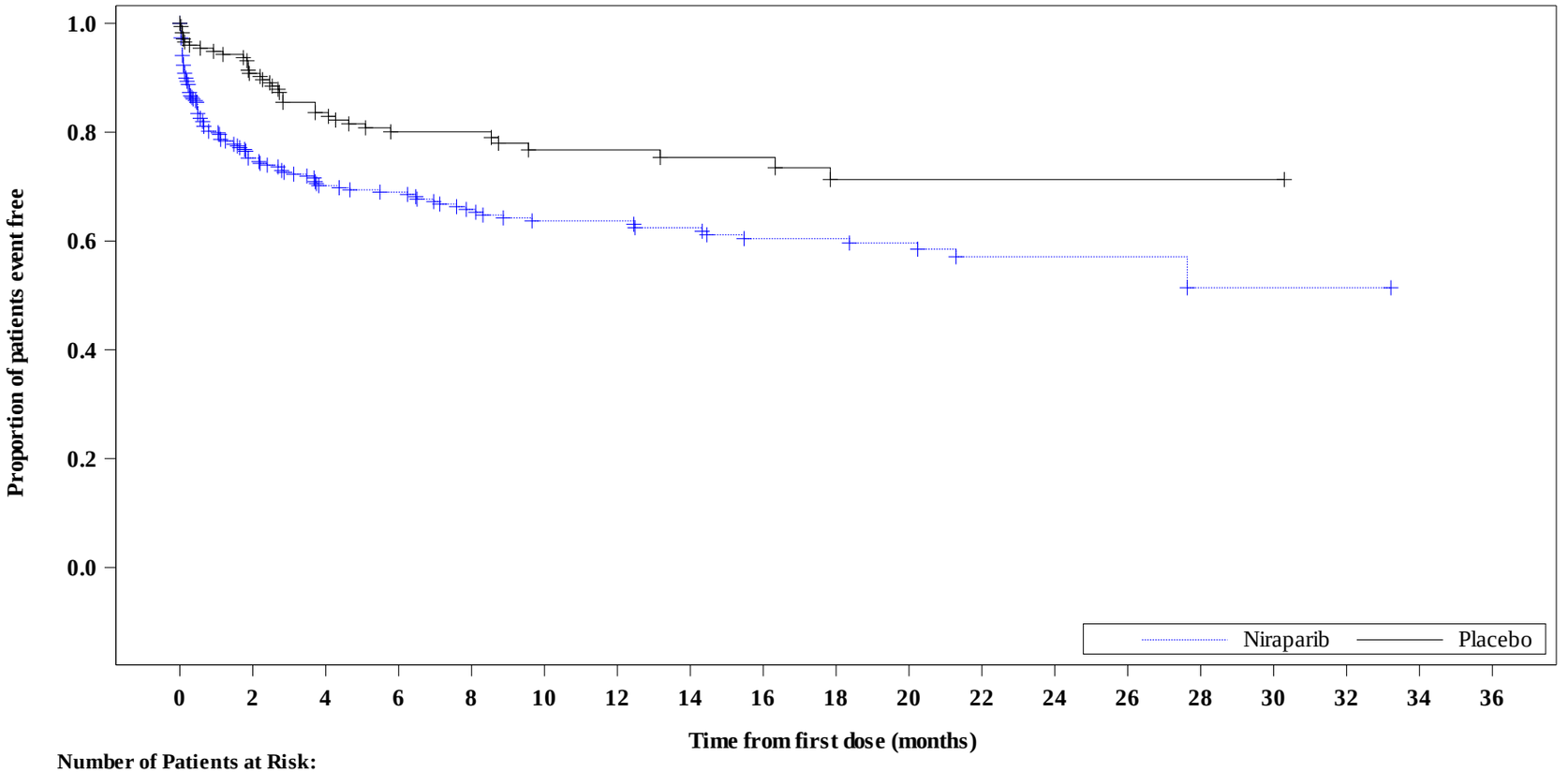
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Psychiatric disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 233 | 187 | 164 | 129 | 110 | 105 | 97 | 84 | 76 | 53 | 39 | 26 | 15 | 6 | 2 | 1 | 0 |
| Placebo | 175 | 156 | 123 | 107 | 84 | 62 | 57 | 48 | 40 | 33 | 27 | 16 | 7 | 4 | 1 | 1 | 0 | |

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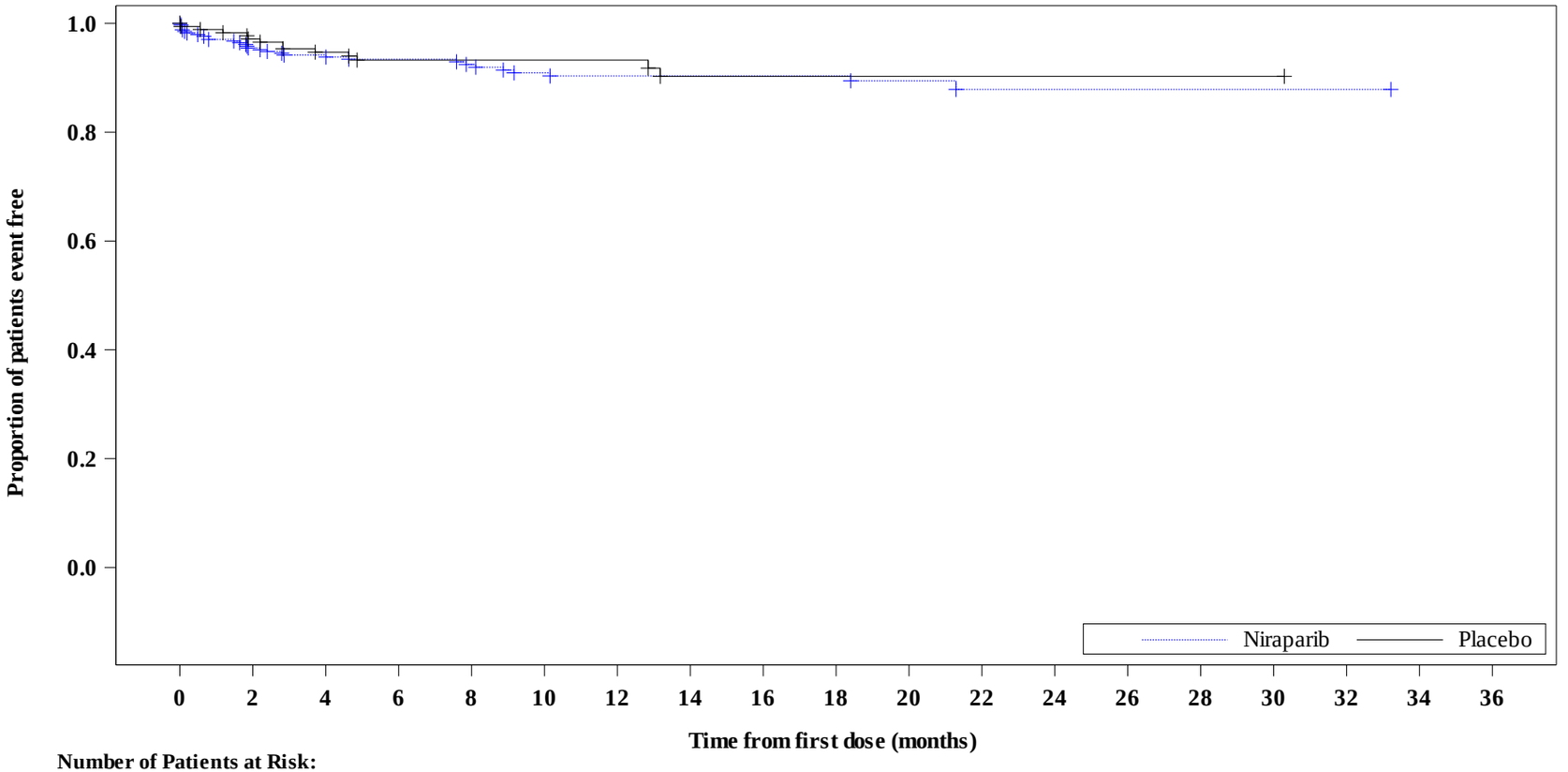
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Psychiatric disorders, PT: Anxiety

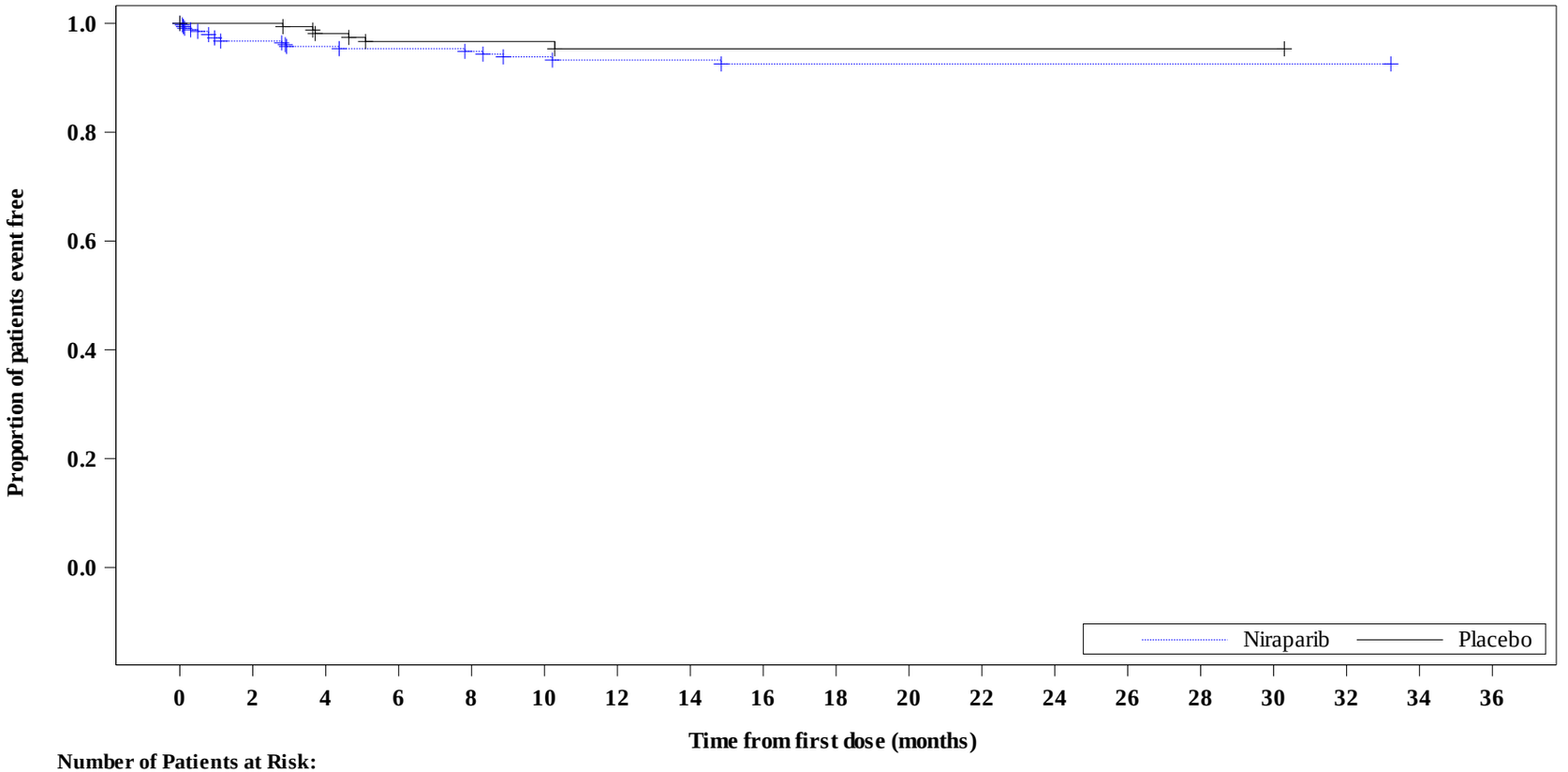



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 297 | 253 | 226 | 185 | 159 | 150 | 138 | 115 | 105 | 75 | 52 | 33 | 18 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 138 | 120 | 95 | 74 | 67 | 54 | 46 | 40 | 34 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Psychiatric disorders, PT: Depression




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 255 | 230 | 188 | 163 | 154 | 141 | 117 | 107 | 77 | 56 | 37 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 142 | 124 | 98 | 75 | 66 | 56 | 47 | 40 | 34 | 19 | 8 | 5 | 2 | 1 | 0 | |

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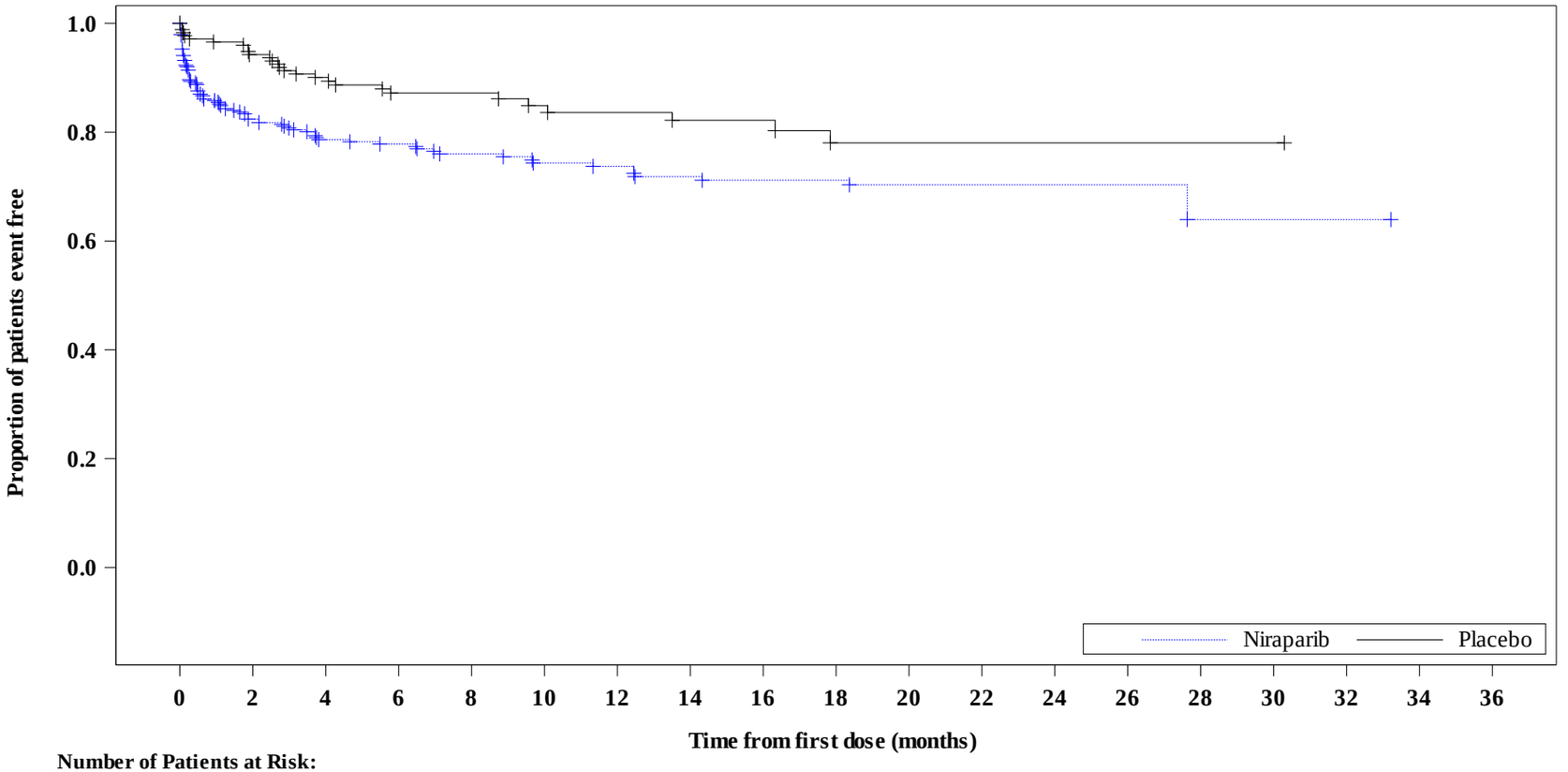
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Psychiatric disorders, PT: Insomnia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 255 | 206 | 182 | 146 | 126 | 120 | 110 | 94 | 86 | 62 | 46 | 32 | 16 | 7 | 2 | 1 | 0 |
| Placebo | 175 | 162 | 132 | 115 | 92 | 67 | 60 | 51 | 43 | 35 | 29 | 16 | 7 | 4 | 1 | 1 | 0 | |

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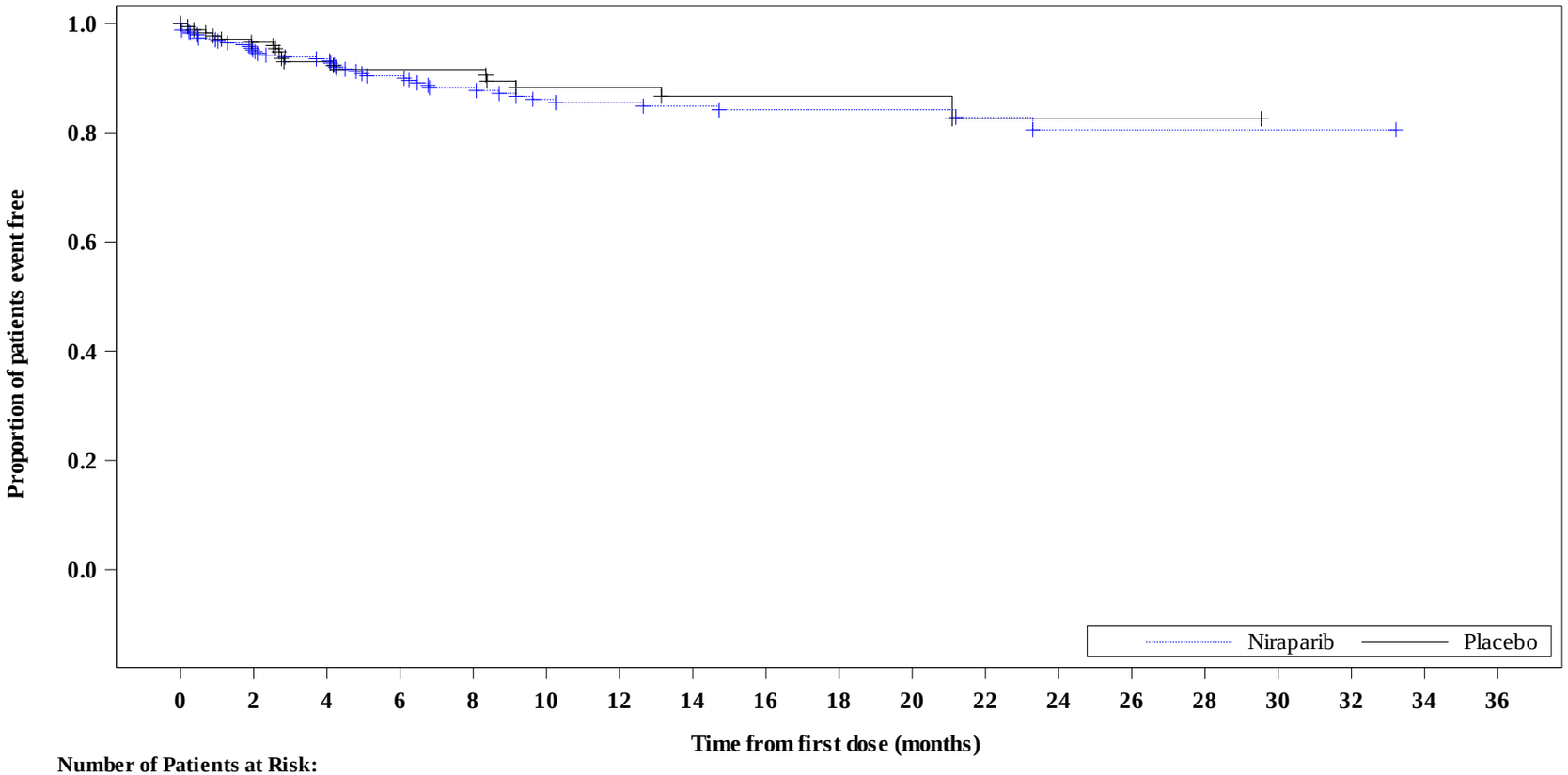
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Renal and urinary disorders



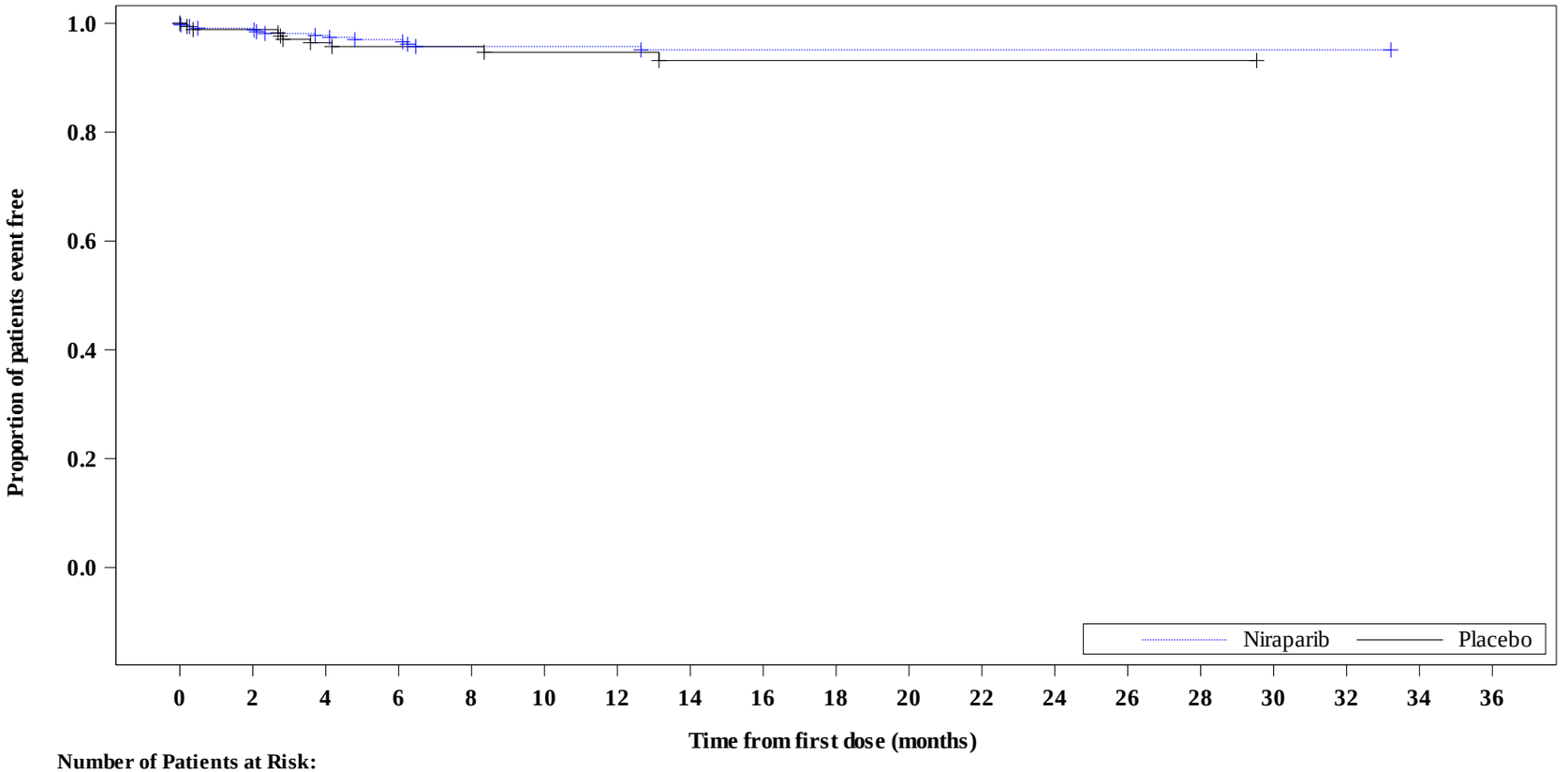

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 295 | 250 | 217 | 174 | 148 | 141 | 128 | 108 | 97 | 73 | 50 | 33 | 16 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 166 | 135 | 118 | 92 | 67 | 60 | 48 | 39 | 35 | 29 | 15 | 6 | 4 | 1 | 0 | | |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-136a-teaept-rd.sas 05OCT2020 09:19

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Renal and urinary disorders, PT: Dysuria




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 261 | 233 | 190 | 167 | 161 | 147 | 123 | 112 | 83 | 58 | 39 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 140 | 123 | 97 | 74 | 67 | 55 | 46 | 40 | 33 | 18 | 7 | 4 | 1 | 0 | | |

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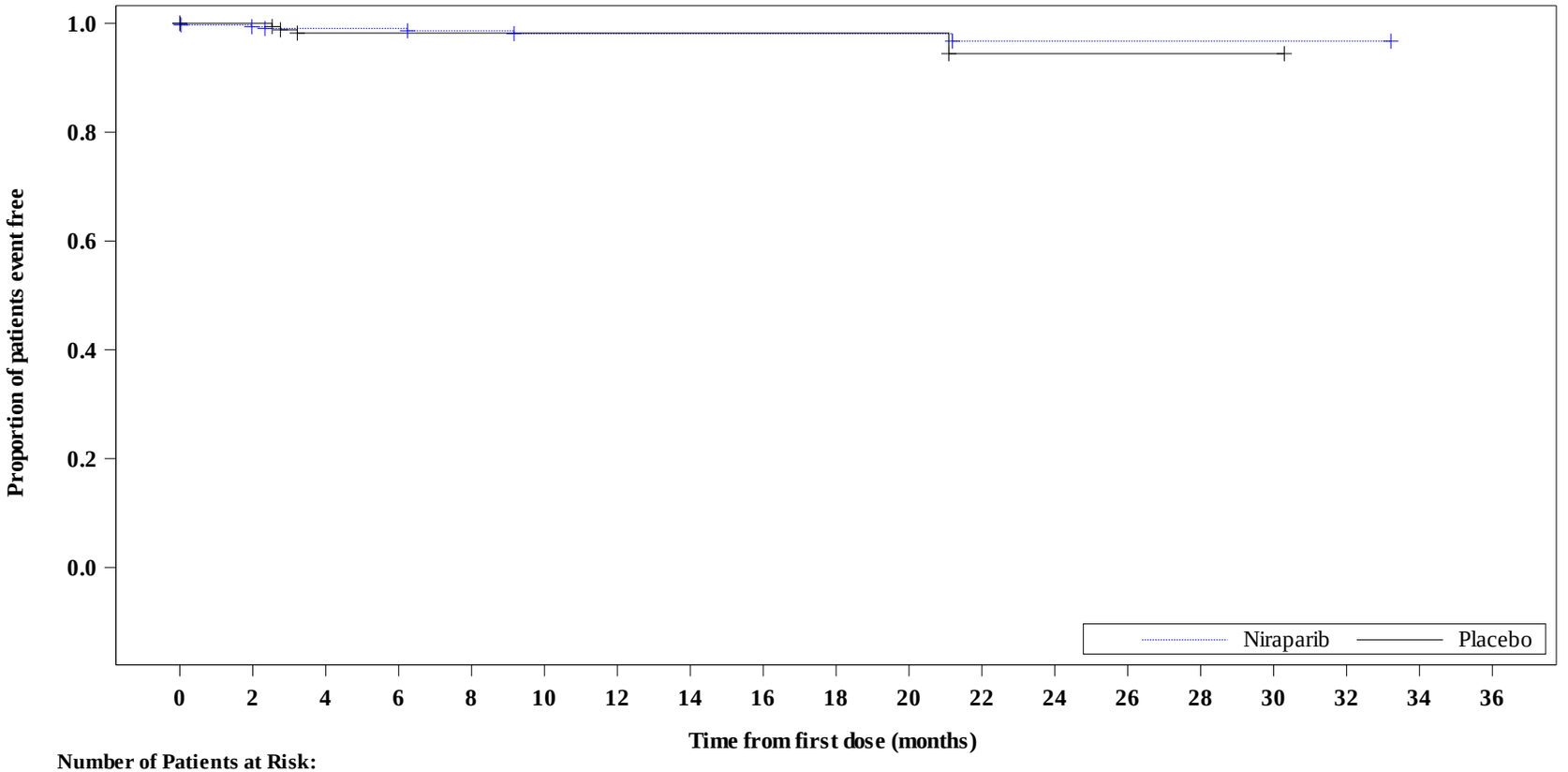
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Renal and urinary disorders, PT: Pollakiuria

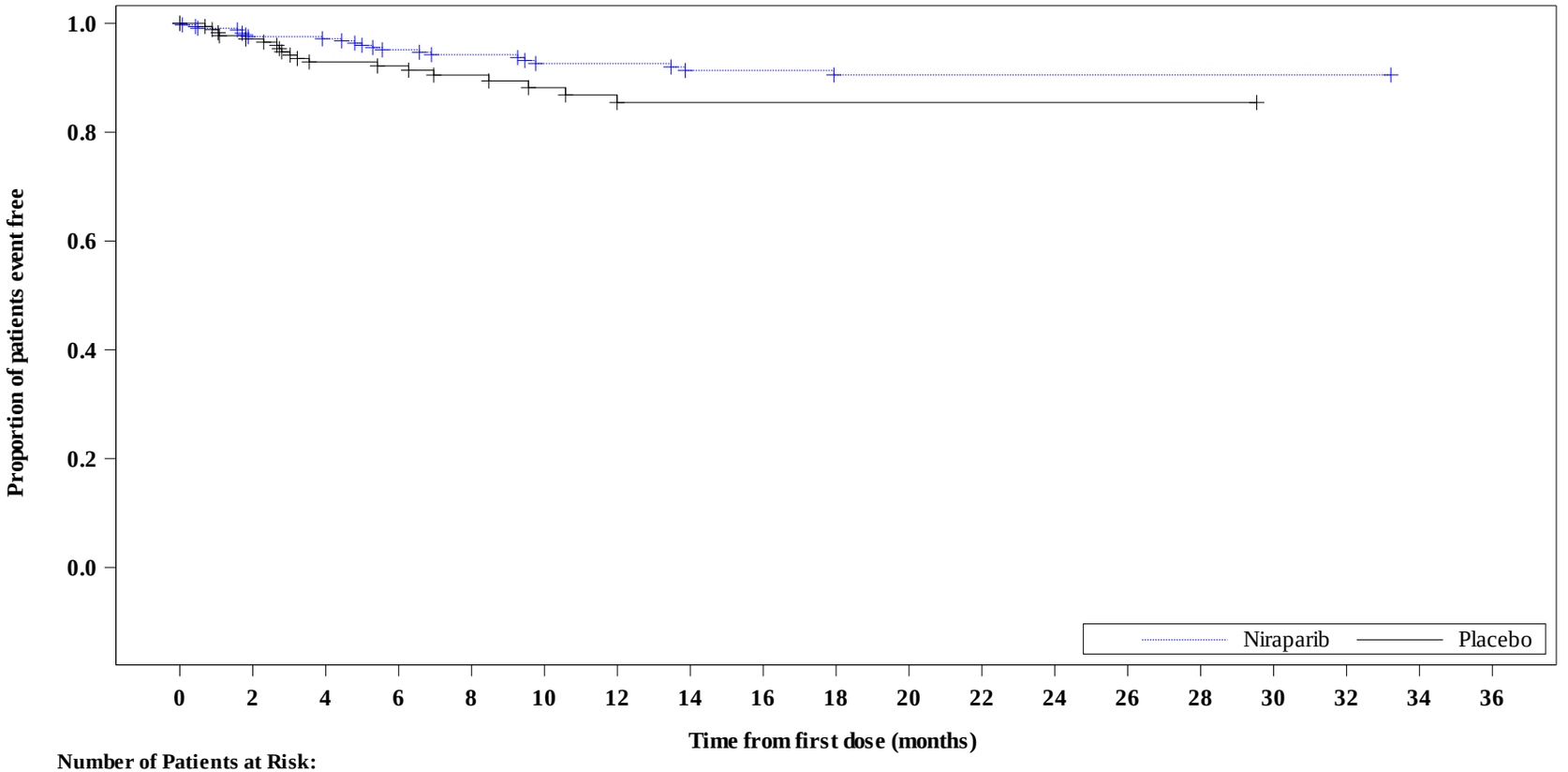



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 264 | 238 | 196 | 172 | 164 | 151 | 127 | 116 | 86 | 59 | 40 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 143 | 126 | 100 | 76 | 69 | 58 | 49 | 42 | 35 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Reproductive system and breast disorders

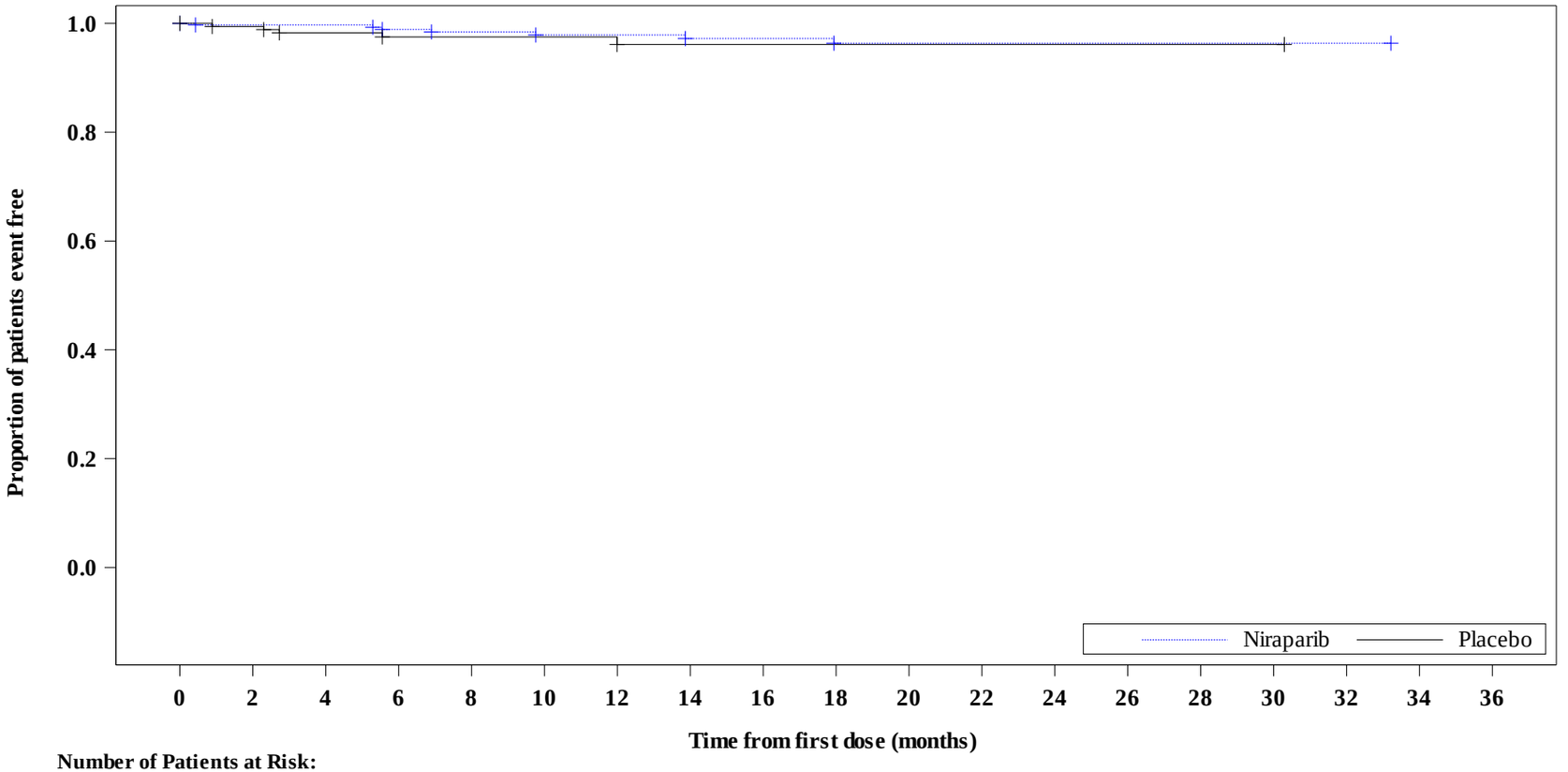



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 256 | 227 | 187 | 163 | 157 | 142 | 120 | 110 | 80 | 57 | 38 | 18 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 167 | 135 | 120 | 92 | 70 | 61 | 51 | 43 | 37 | 31 | 16 | 7 | 4 | 1 | 0 | | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Reproductive system and breast disorders, PT: Pelvic pain




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 264 | 236 | 195 | 171 | 163 | 149 | 124 | 113 | 83 | 58 | 39 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 143 | 127 | 101 | 78 | 69 | 58 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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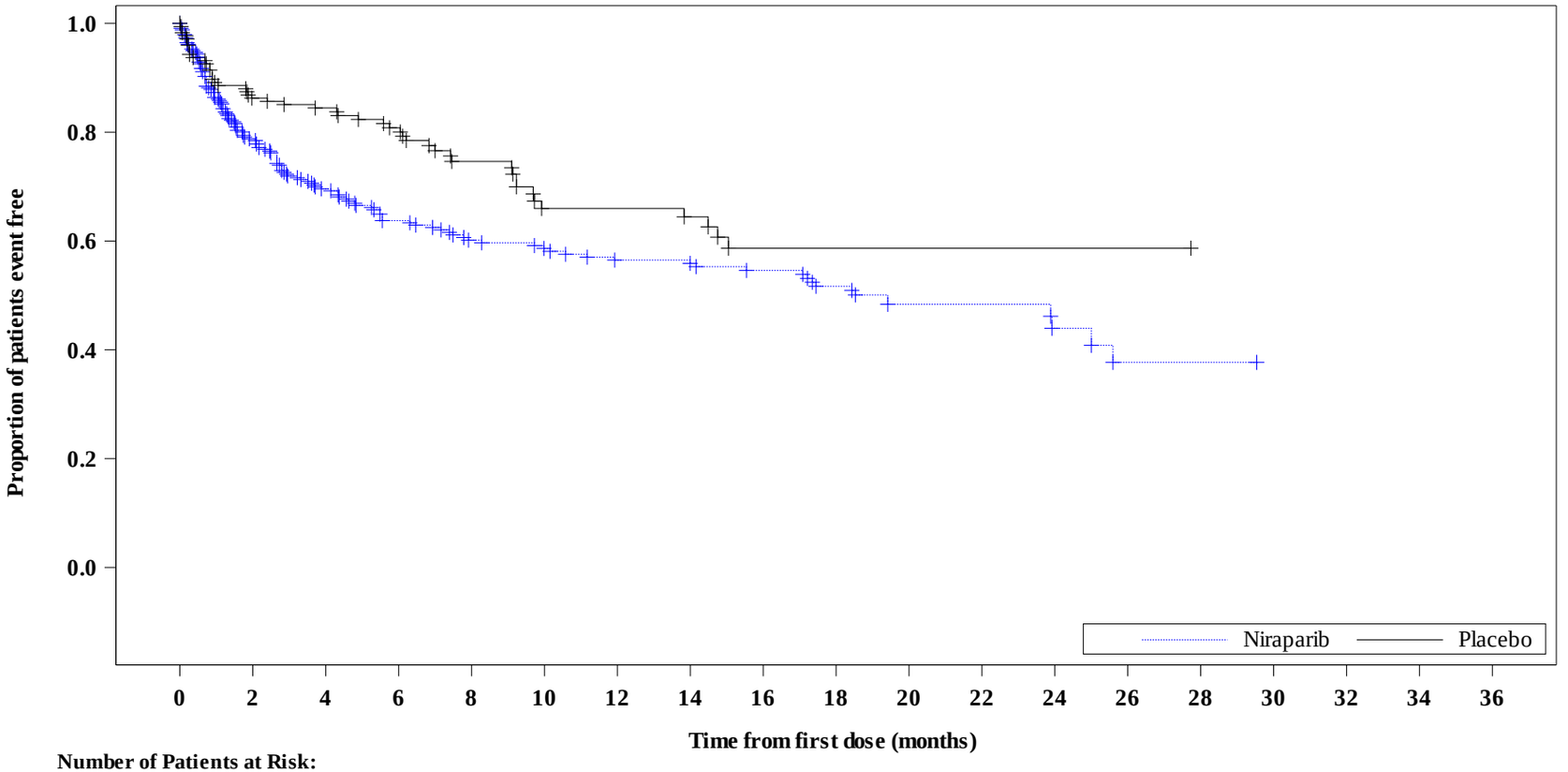
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 247 | 191 | 159 | 125 | 111 | 103 | 94 | 77 | 68 | 46 | 34 | 19 | 8 | 2 | 0 |
| Placebo | 175 | 149 | 124 | 104 | 74 | 49 | 46 | 37 | 28 | 25 | 21 | 9 | 3 | 2 | 0 | |

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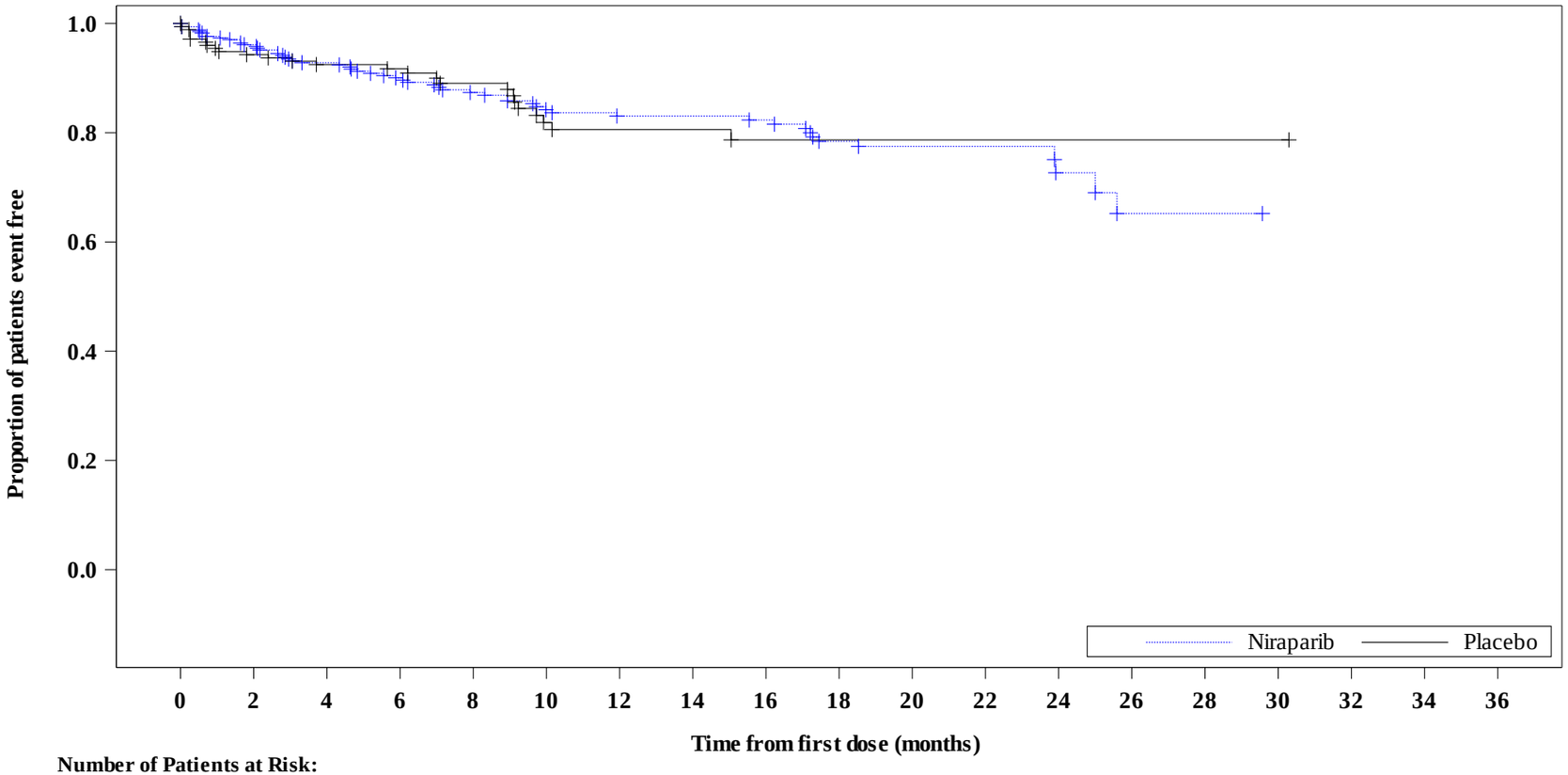
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 299 | 250 | 220 | 176 | 151 | 142 | 130 | 109 | 95 | 68 | 47 | 29 | 11 | 4 | 0 | |
| Placebo | 175 | 162 | 134 | 118 | 90 | 63 | 58 | 49 | 40 | 36 | 29 | 16 | 6 | 4 | 1 | 1 | 0 |

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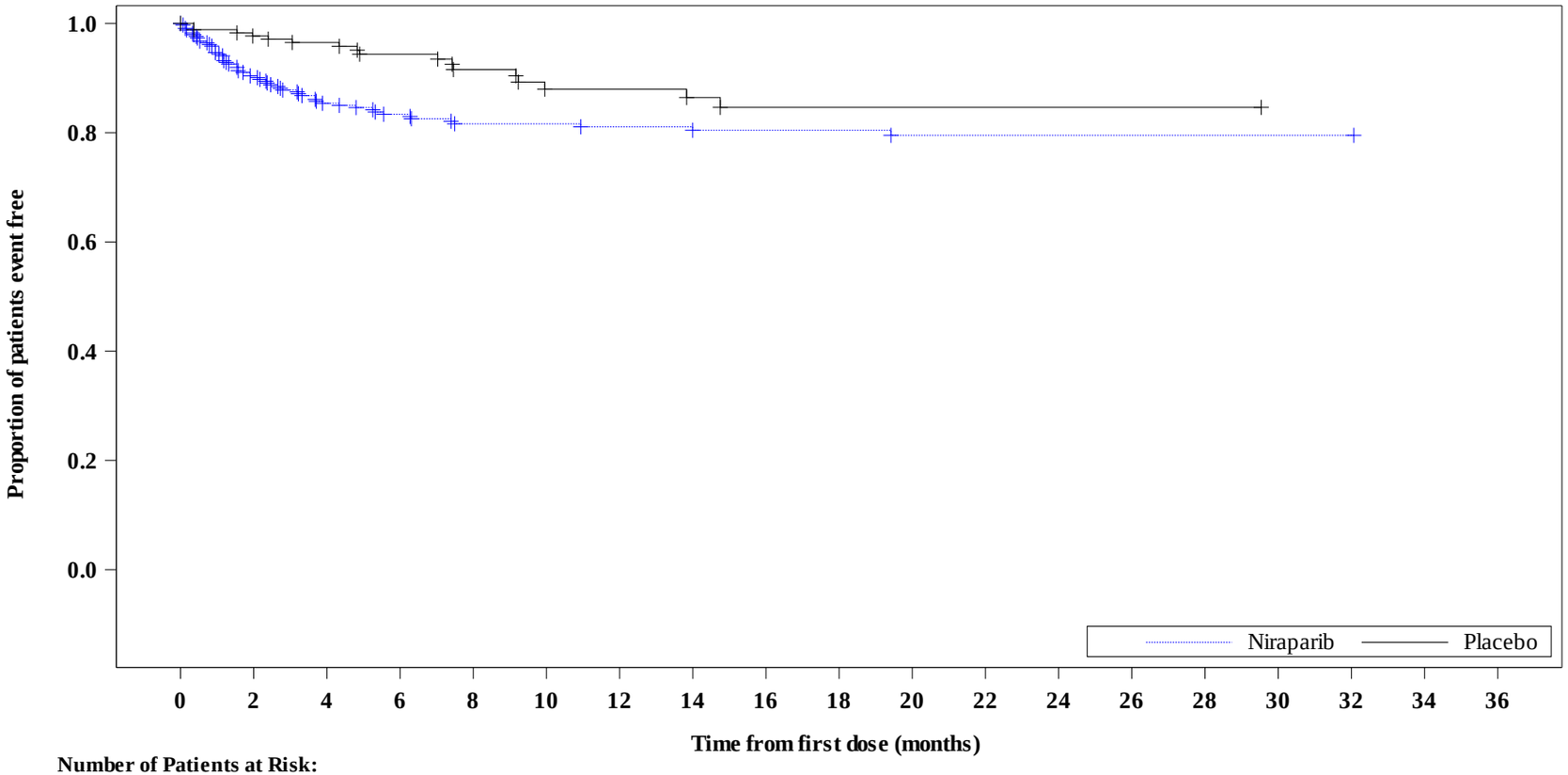
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 282 | 230 | 204 | 169 | 150 | 143 | 129 | 108 | 101 | 73 | 53 | 36 | 18 | 8 | 2 | 1 | 0 |
| Placebo | 175 | 169 | 142 | 122 | 93 | 68 | 61 | 51 | 43 | 36 | 29 | 15 | 6 | 3 | 1 | 0 | | |

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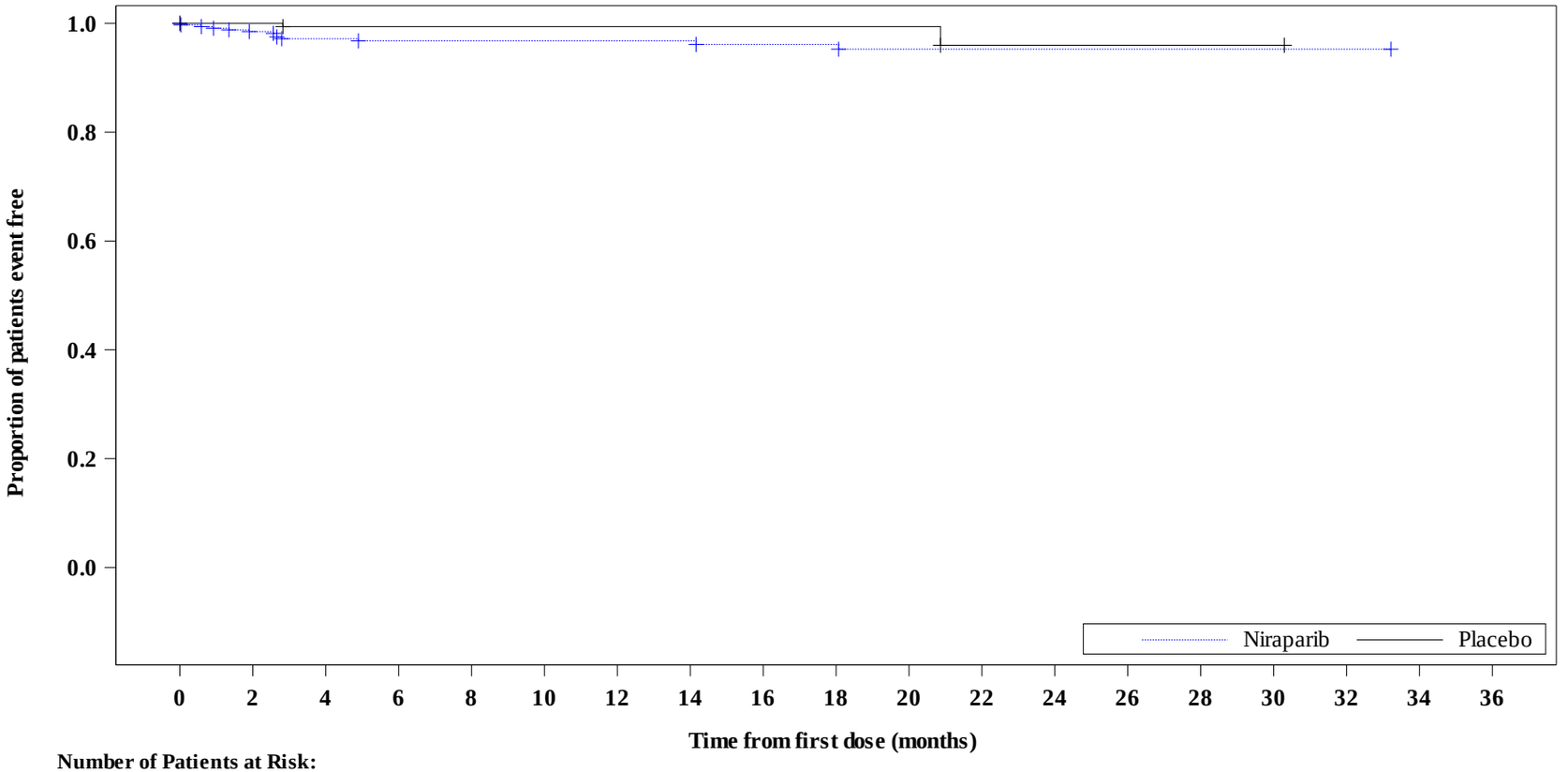
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea exertional




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 259 | 232 | 192 | 169 | 161 | 148 | 122 | 111 | 82 | 58 | 39 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 144 | 127 | 101 | 78 | 70 | 59 | 50 | 43 | 36 | 18 | 8 | 5 | 2 | 1 | 0 | |

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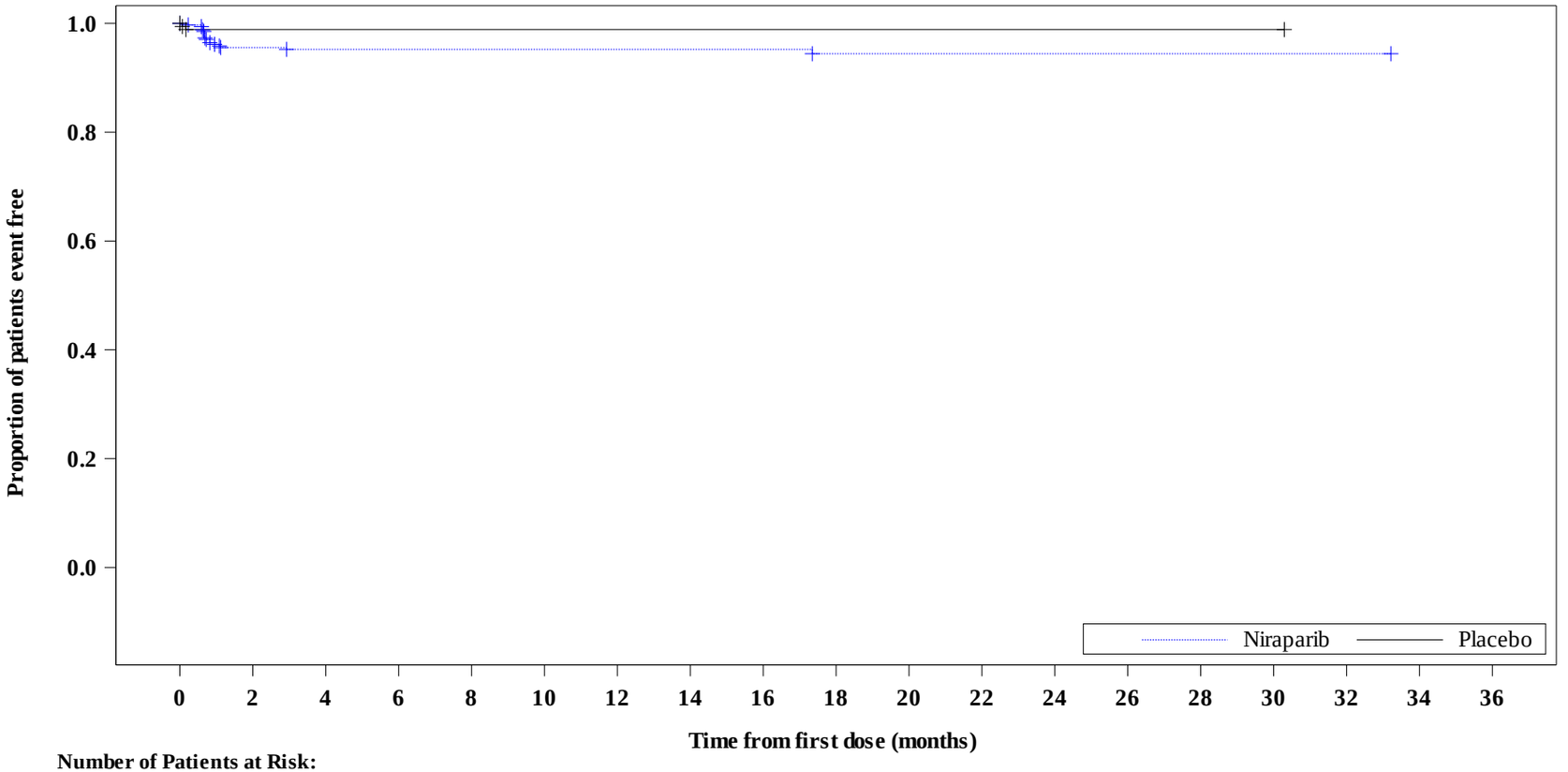
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Epistaxis




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 298 | 253 | 228 | 188 | 165 | 157 | 147 | 122 | 110 | 81 | 56 | 38 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 143 | 126 | 100 | 76 | 68 | 57 | 48 | 41 | 35 | 18 | 8 | 5 | 2 | 1 | 0 | |

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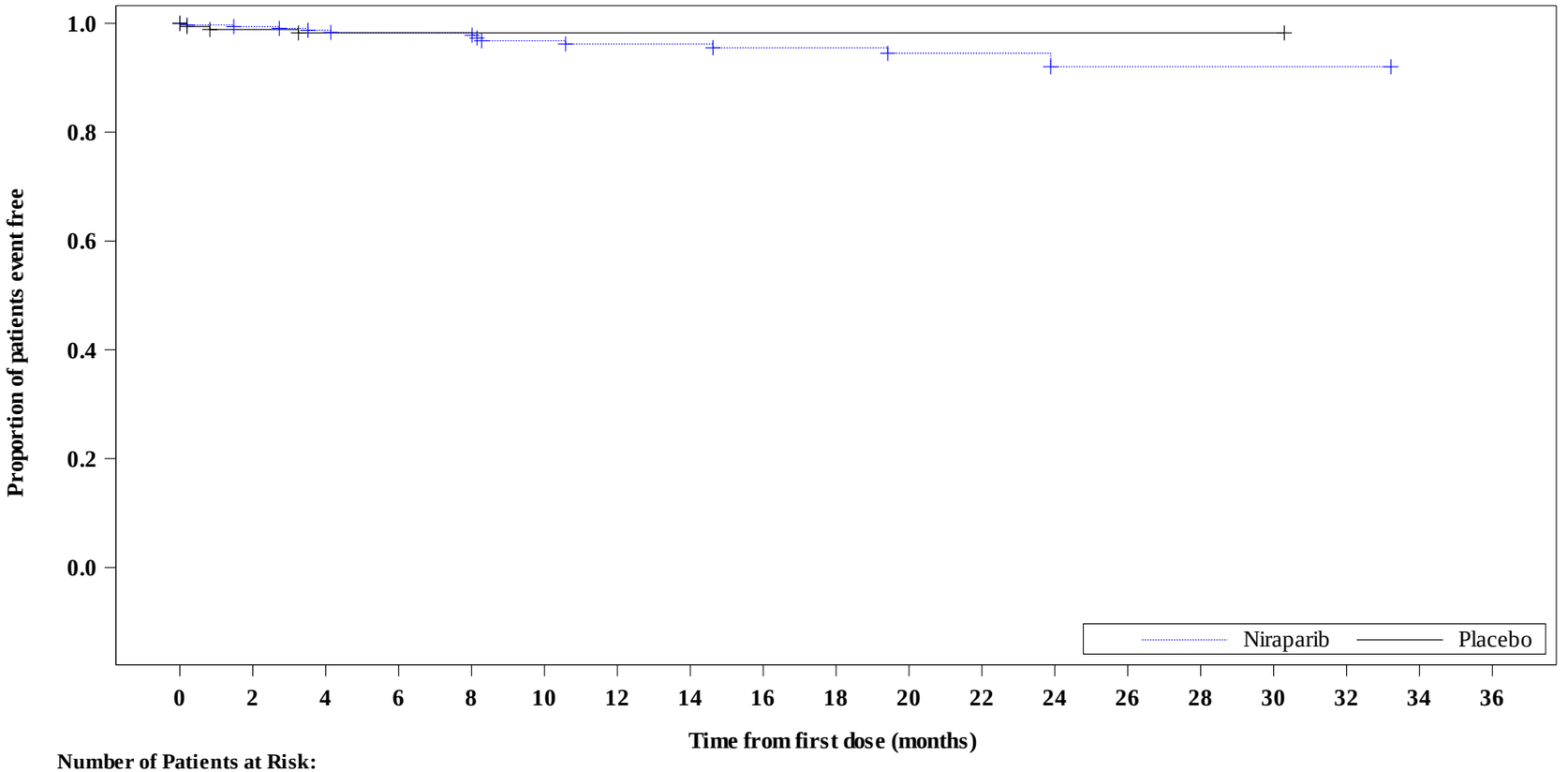
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Nasal congestion




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 261 | 234 | 192 | 166 | 157 | 144 | 118 | 109 | 80 | 55 | 35 | 17 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 143 | 126 | 100 | 77 | 69 | 58 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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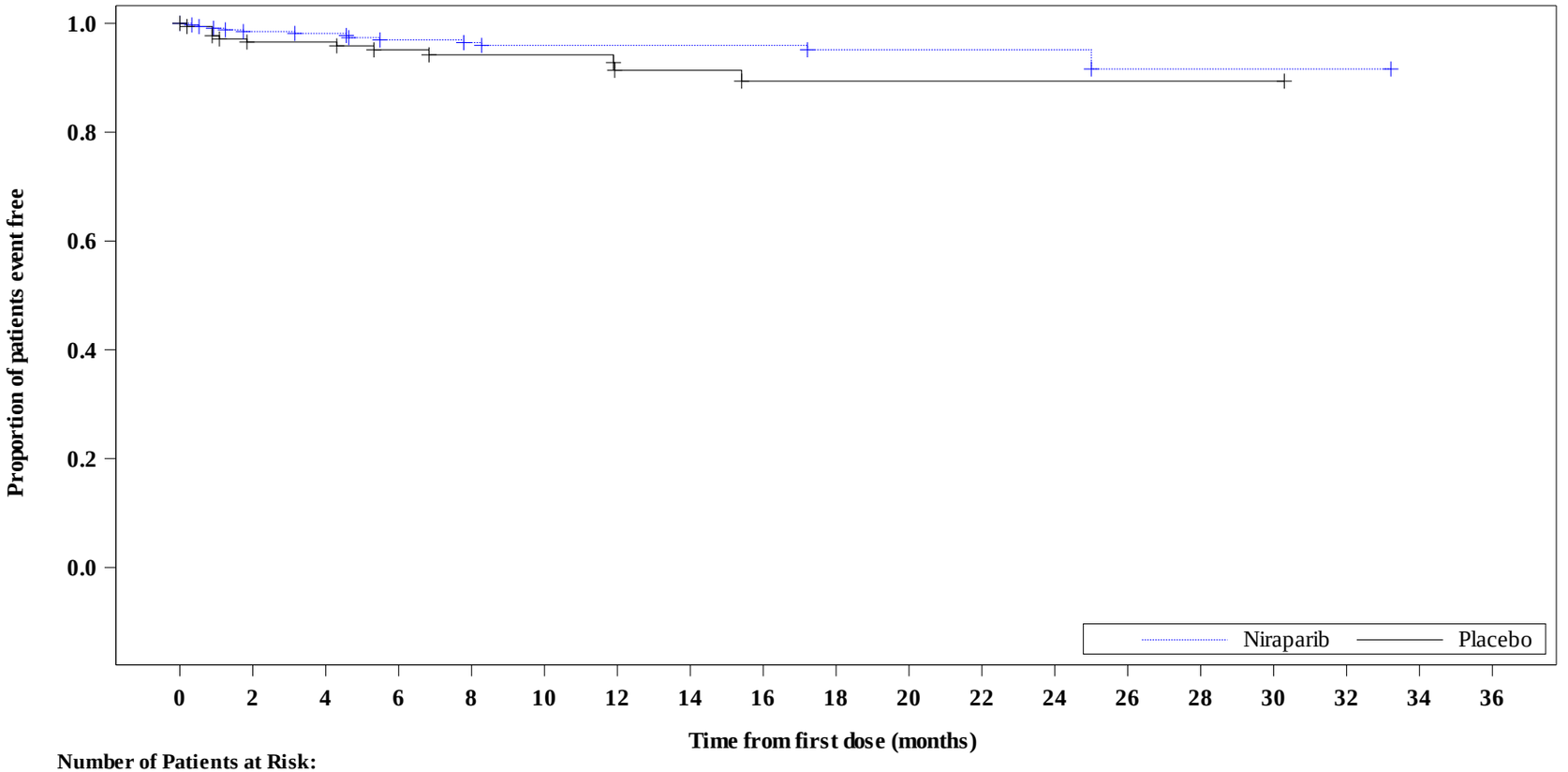
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain

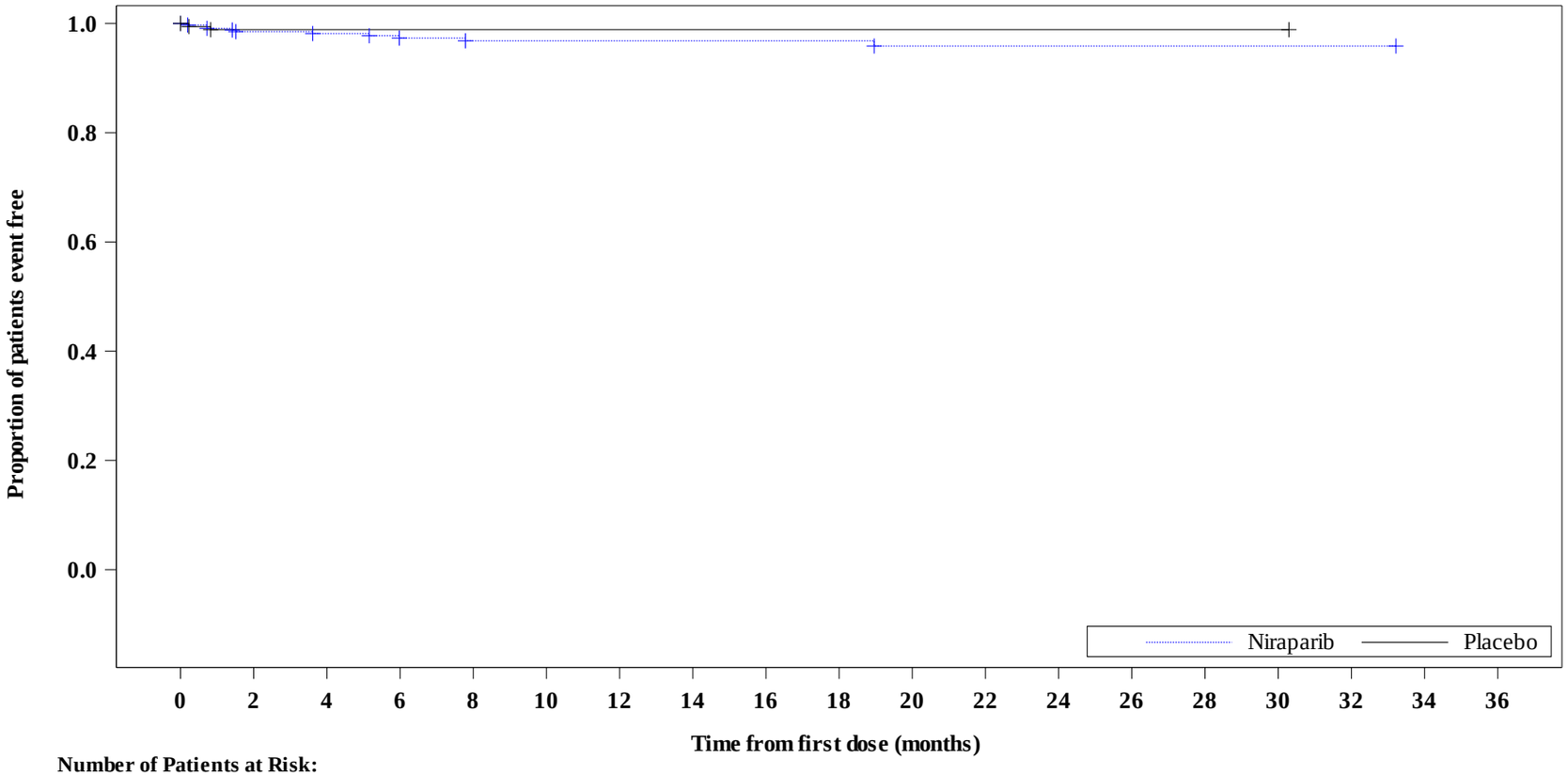



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 259 | 231 | 190 | 167 | 159 | 146 | 123 | 111 | 82 | 57 | 38 | 18 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 166 | 142 | 123 | 98 | 74 | 64 | 54 | 45 | 38 | 32 | 17 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Productive cough




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 261 | 233 | 190 | 168 | 161 | 148 | 124 | 114 | 84 | 59 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 77 | 69 | 58 | 49 | 42 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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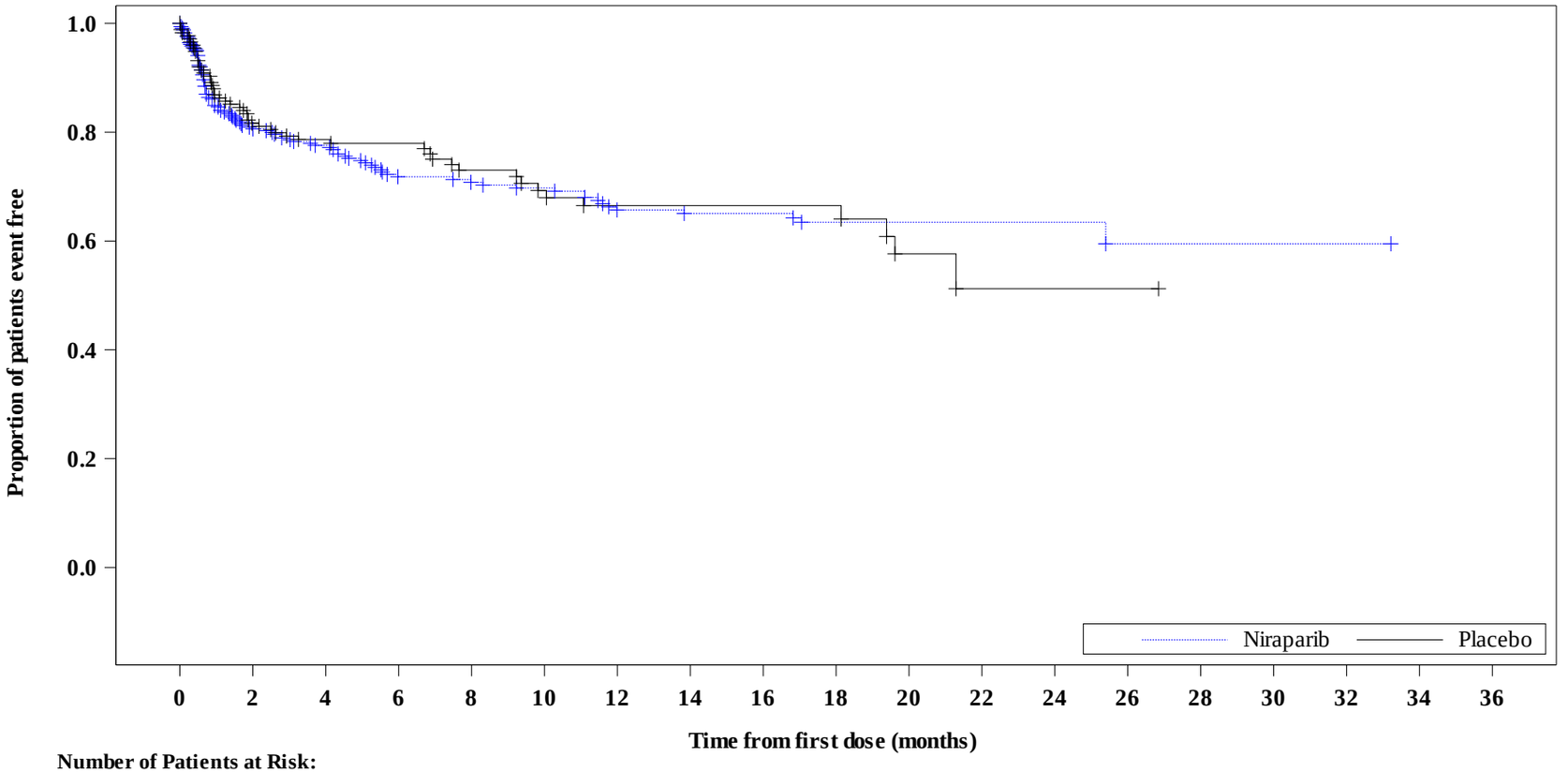
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Skin and subcutaneous tissue disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 250 | 202 | 168 | 136 | 124 | 111 | 101 | 83 | 75 | 54 | 43 | 29 | 11 | 6 | 2 | 2 | 0 |
| Placebo | 175 | 140 | 110 | 96 | 71 | 52 | 46 | 39 | 34 | 27 | 18 | 7 | 2 | 1 | 0 | | | |

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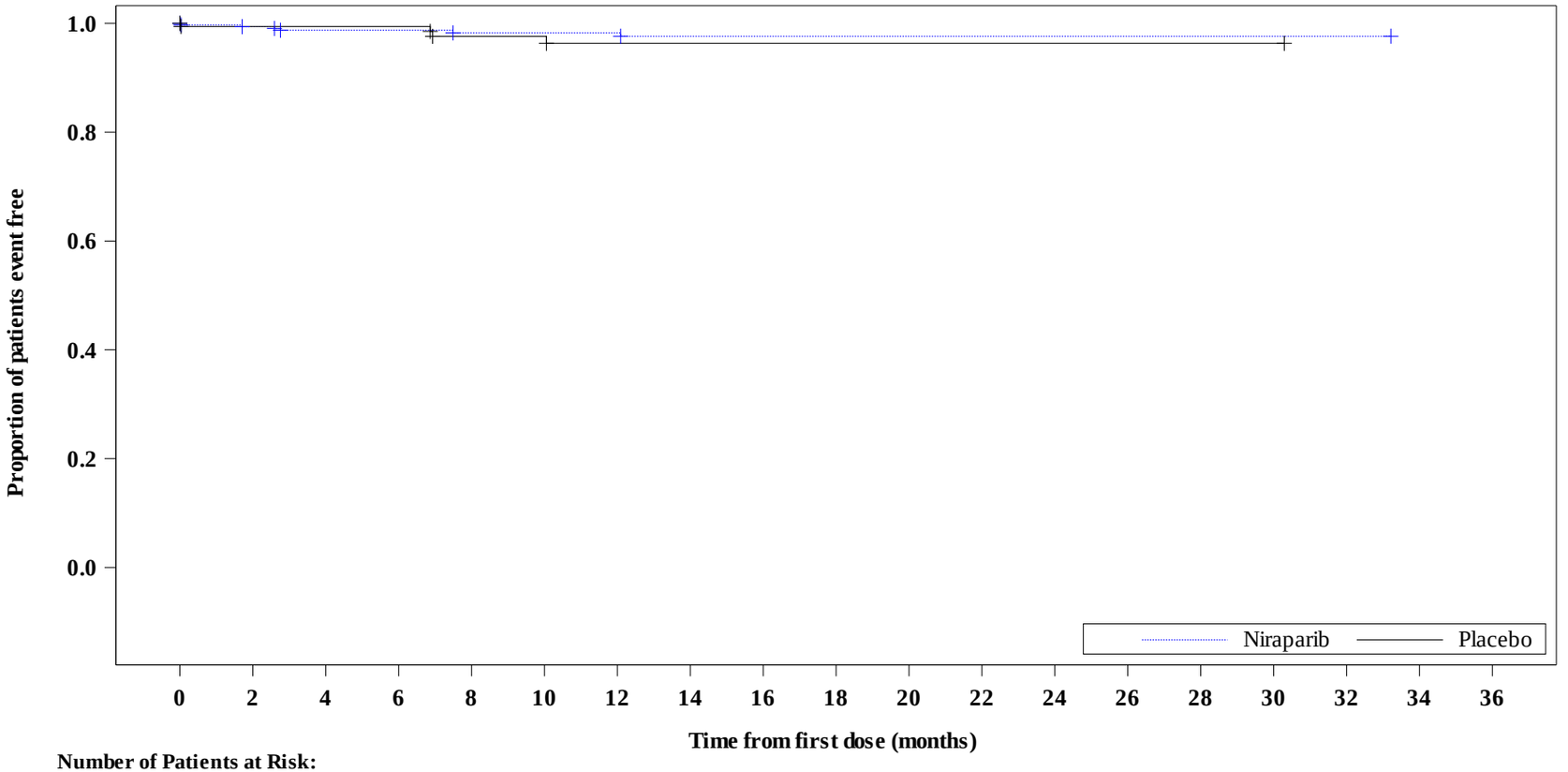
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Alopecia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 261 | 235 | 193 | 172 | 164 | 151 | 126 | 115 | 85 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 145 | 128 | 100 | 76 | 67 | 56 | 48 | 41 | 34 | 17 | 6 | 4 | 2 | 1 | 0 | |

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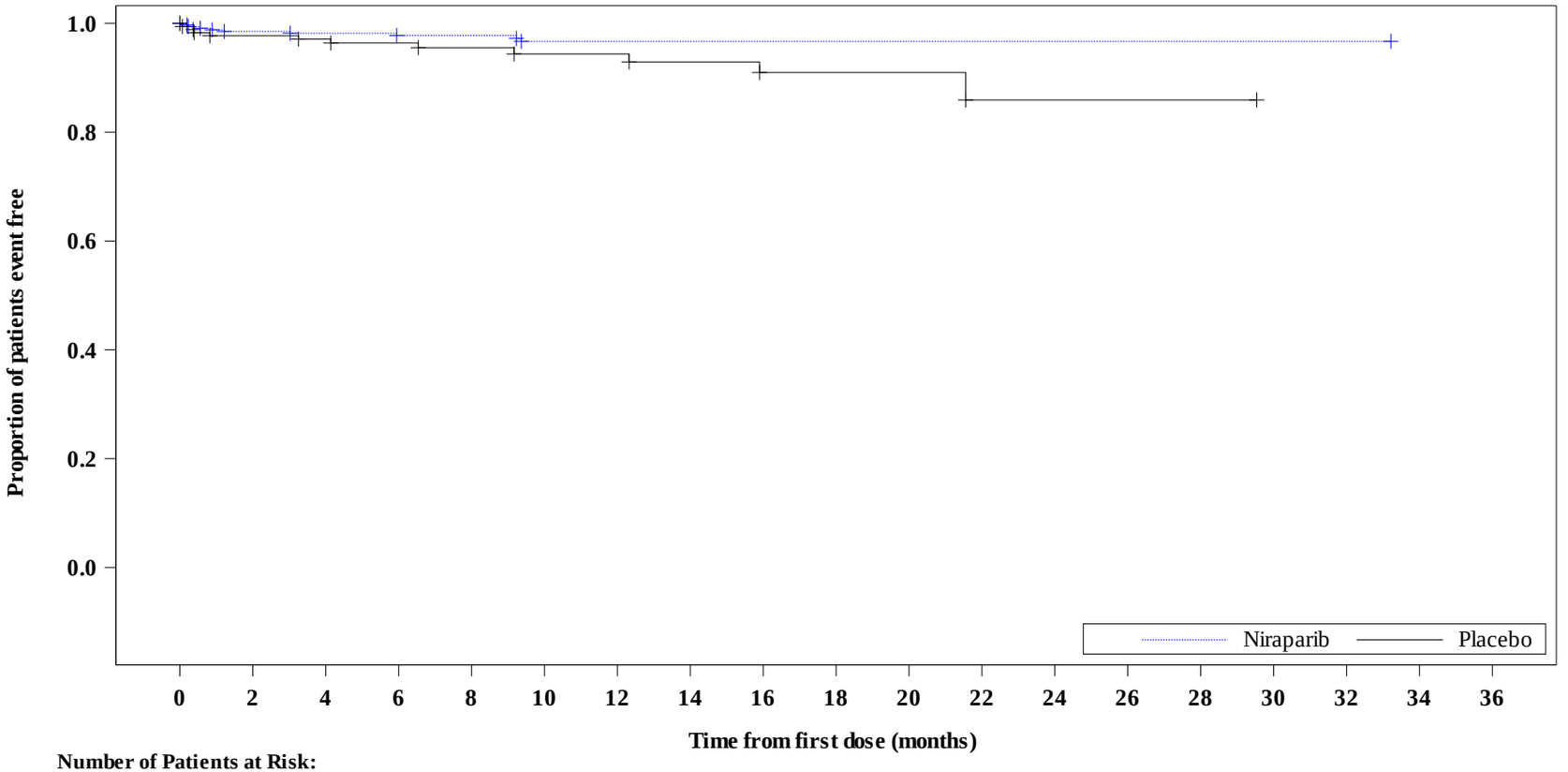
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Dry skin

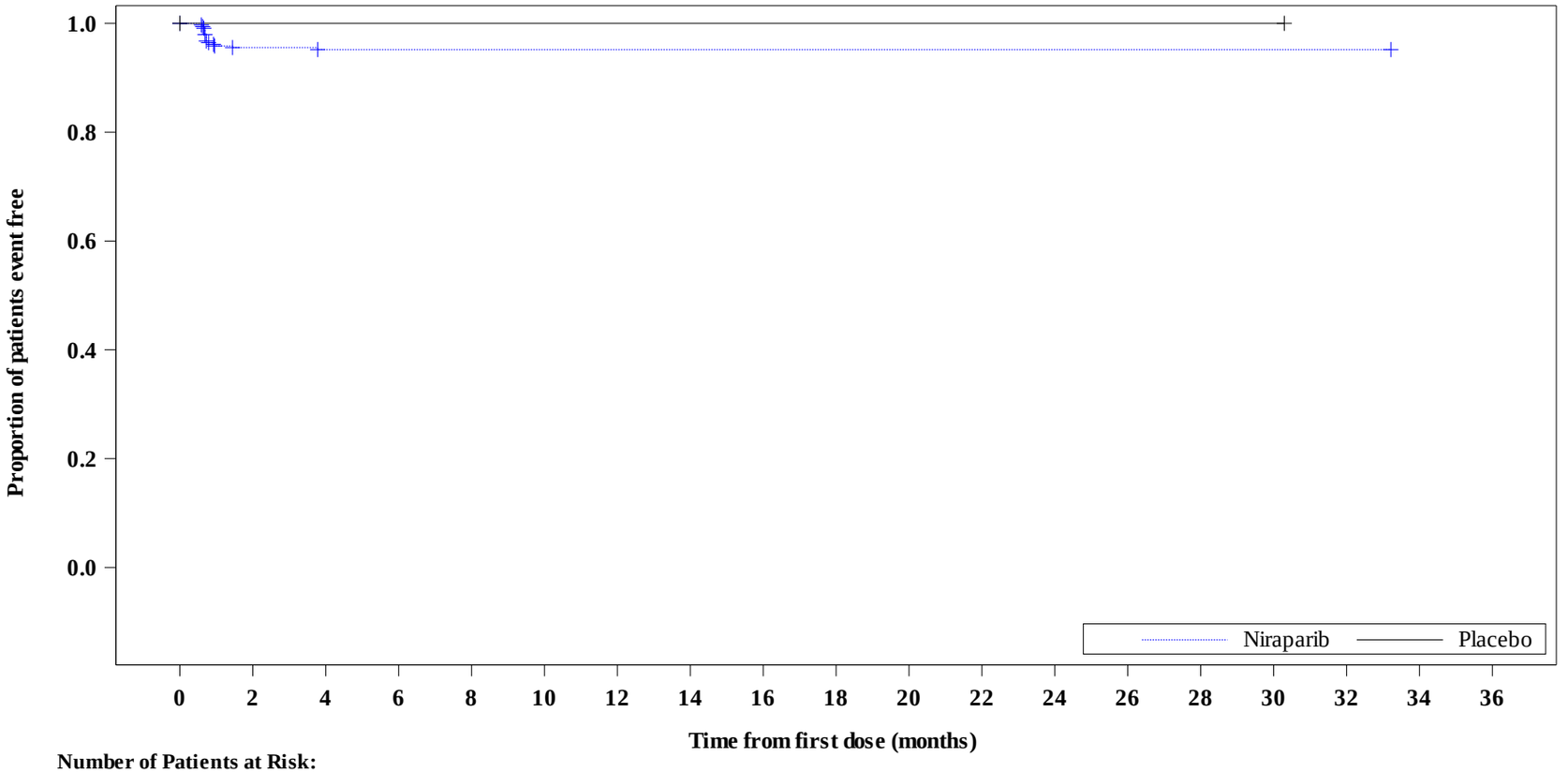



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 260 | 233 | 194 | 169 | 161 | 149 | 124 | 113 | 84 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 168 | 140 | 122 | 97 | 74 | 66 | 56 | 47 | 40 | 33 | 16 | 7 | 4 | 1 | 0 | | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Petechiae




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 297 | 251 | 226 | 187 | 164 | 157 | 145 | 121 | 110 | 82 | 57 | 39 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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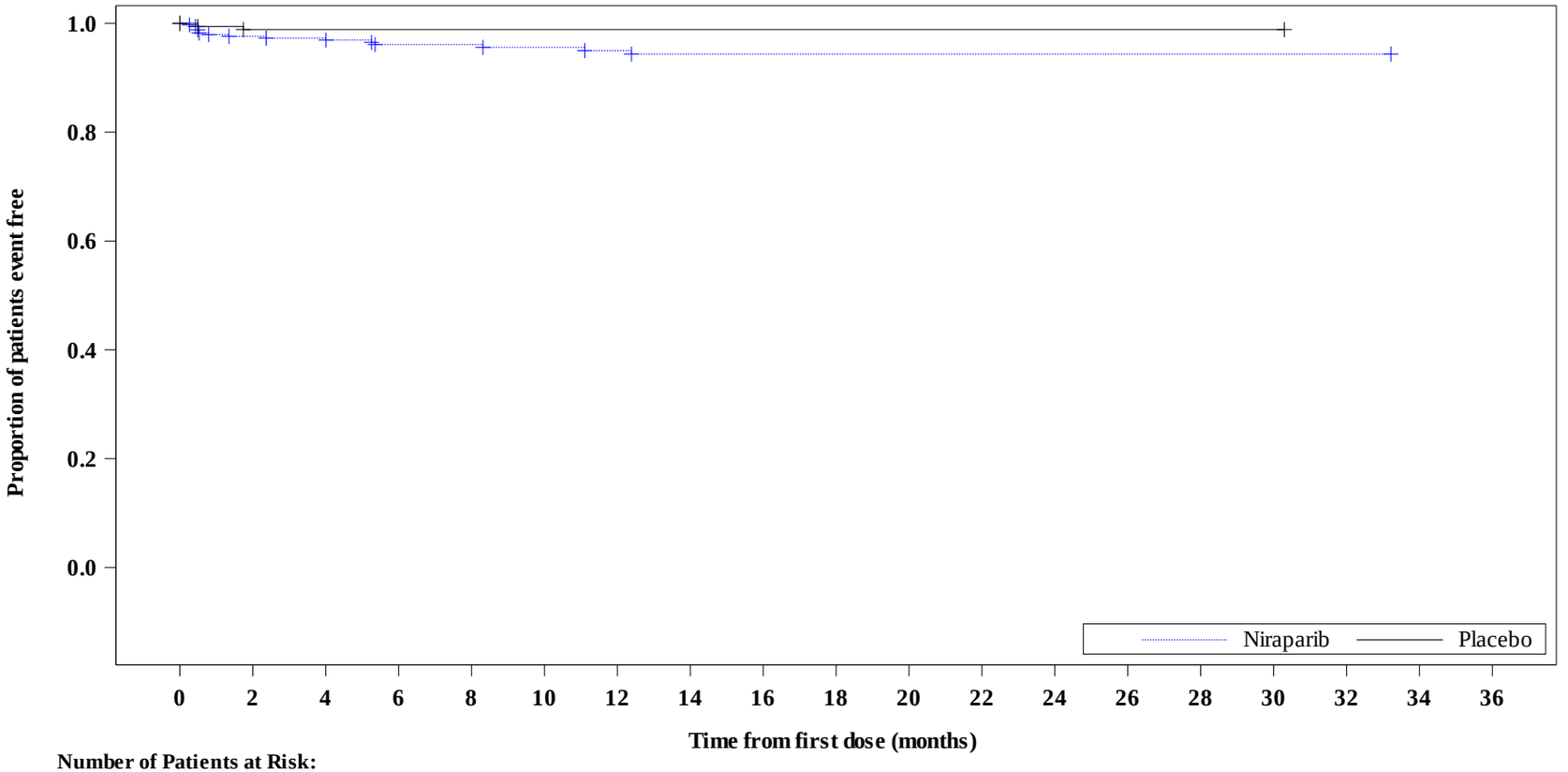
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Photosensitivity reaction

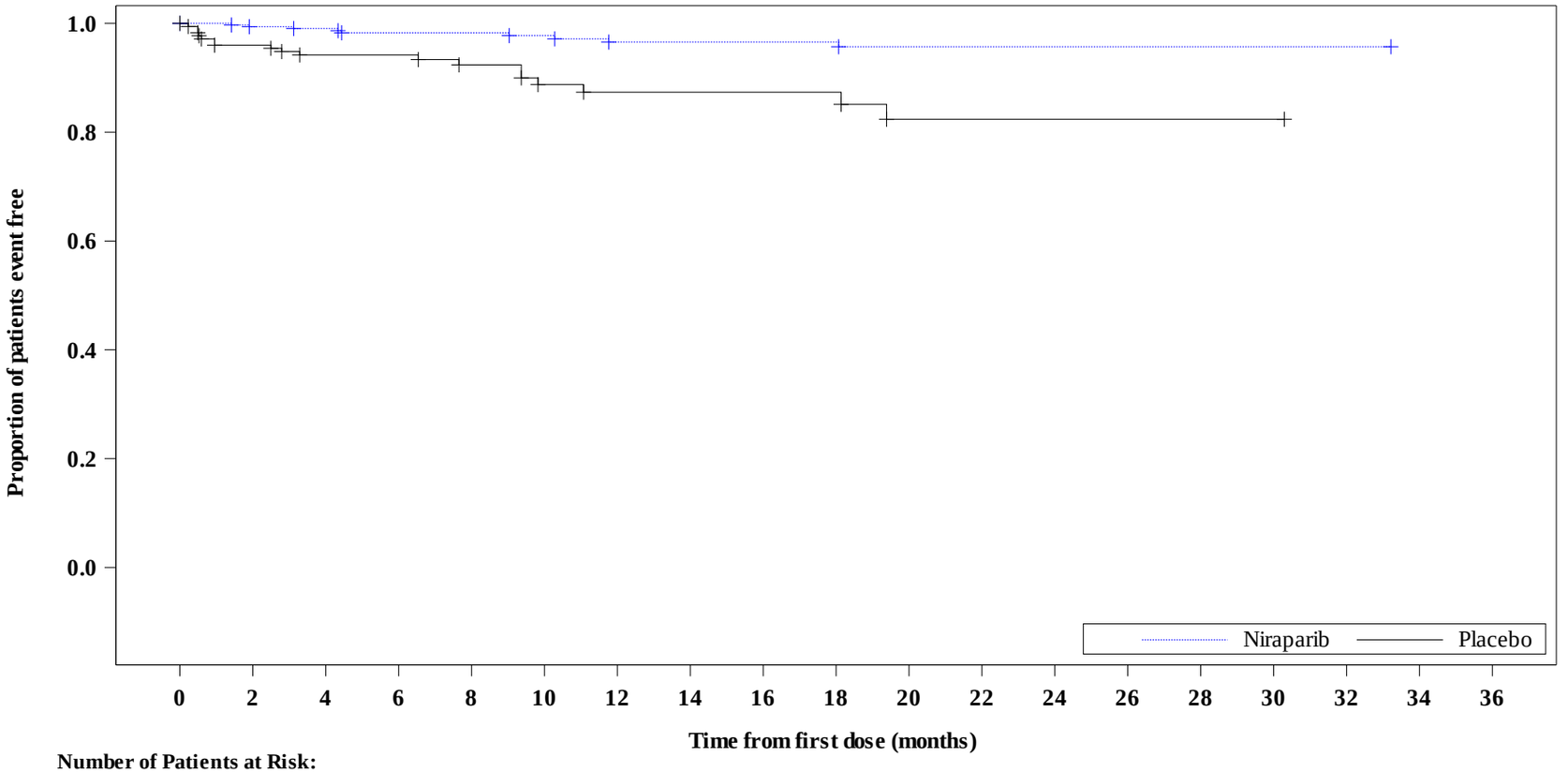



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 304 | 257 | 229 | 189 | 165 | 156 | 143 | 120 | 109 | 82 | 58 | 39 | 18 | 8 | 2 | 2 | 0 |
| Placebo | 175 | 170 | 143 | 127 | 101 | 77 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Pruritus

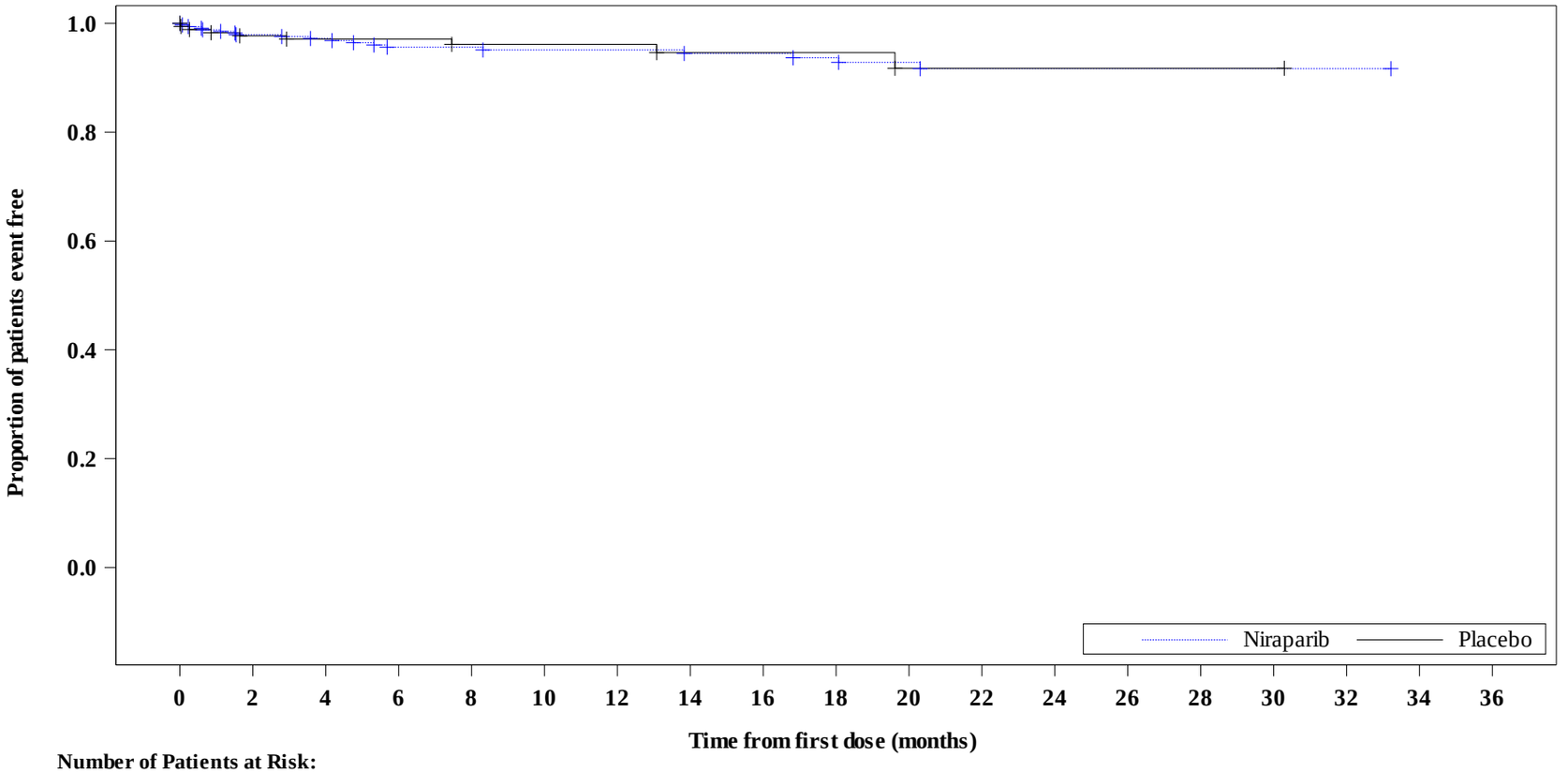



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 263 | 235 | 194 | 169 | 159 | 147 | 124 | 113 | 83 | 59 | 40 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 165 | 135 | 120 | 94 | 71 | 63 | 55 | 46 | 39 | 30 | 17 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Rash




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 304 | 258 | 230 | 190 | 167 | 159 | 147 | 122 | 111 | 80 | 56 | 38 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 168 | 140 | 124 | 98 | 74 | 66 | 56 | 47 | 40 | 32 | 16 | 7 | 5 | 2 | 1 | 0 | |

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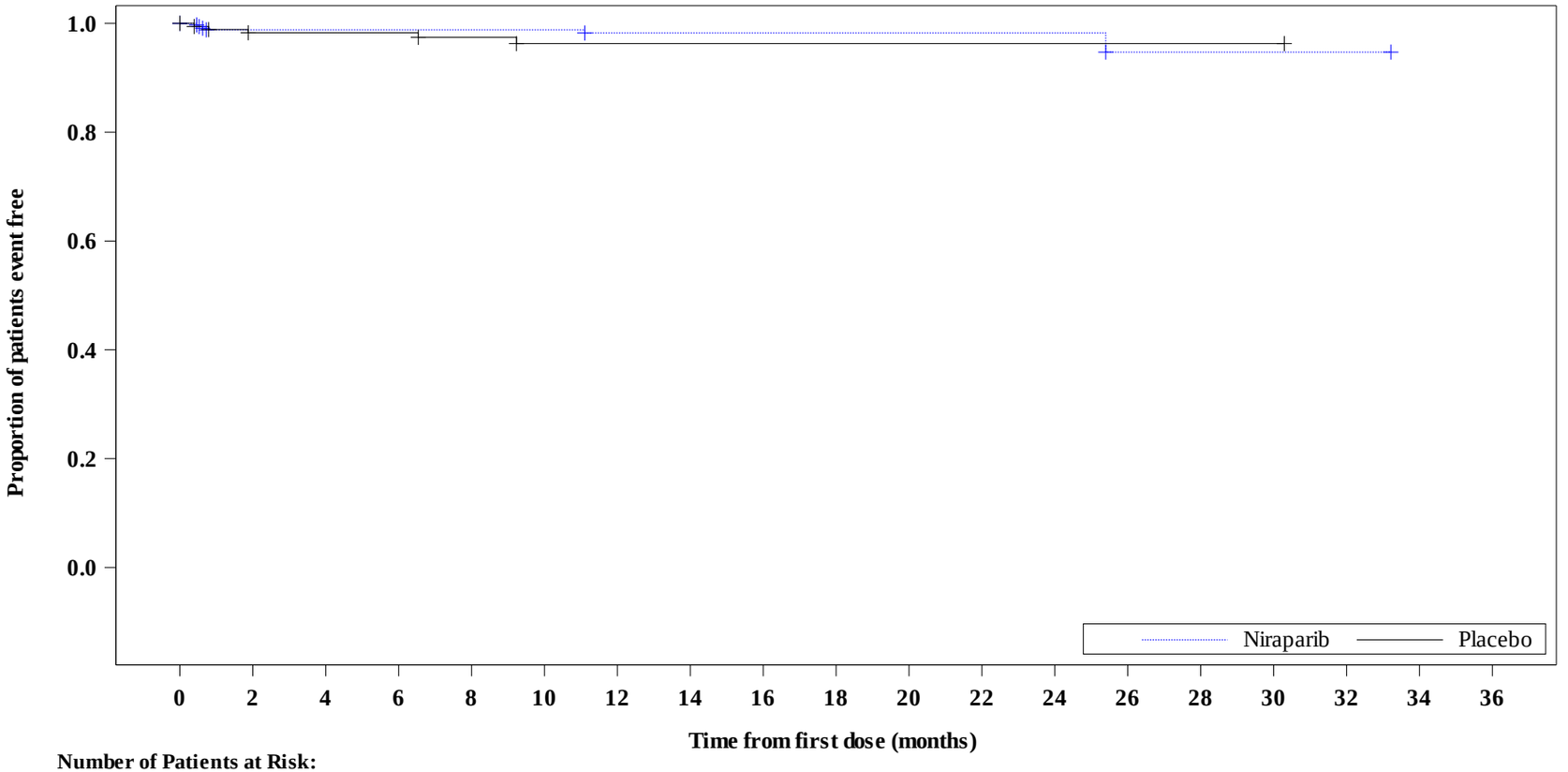
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Skin and subcutaneous tissue disorders, PT: Rash maculo-papular




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 262 | 236 | 195 | 172 | 163 | 150 | 125 | 115 | 85 | 59 | 41 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 169 | 142 | 125 | 100 | 75 | 68 | 58 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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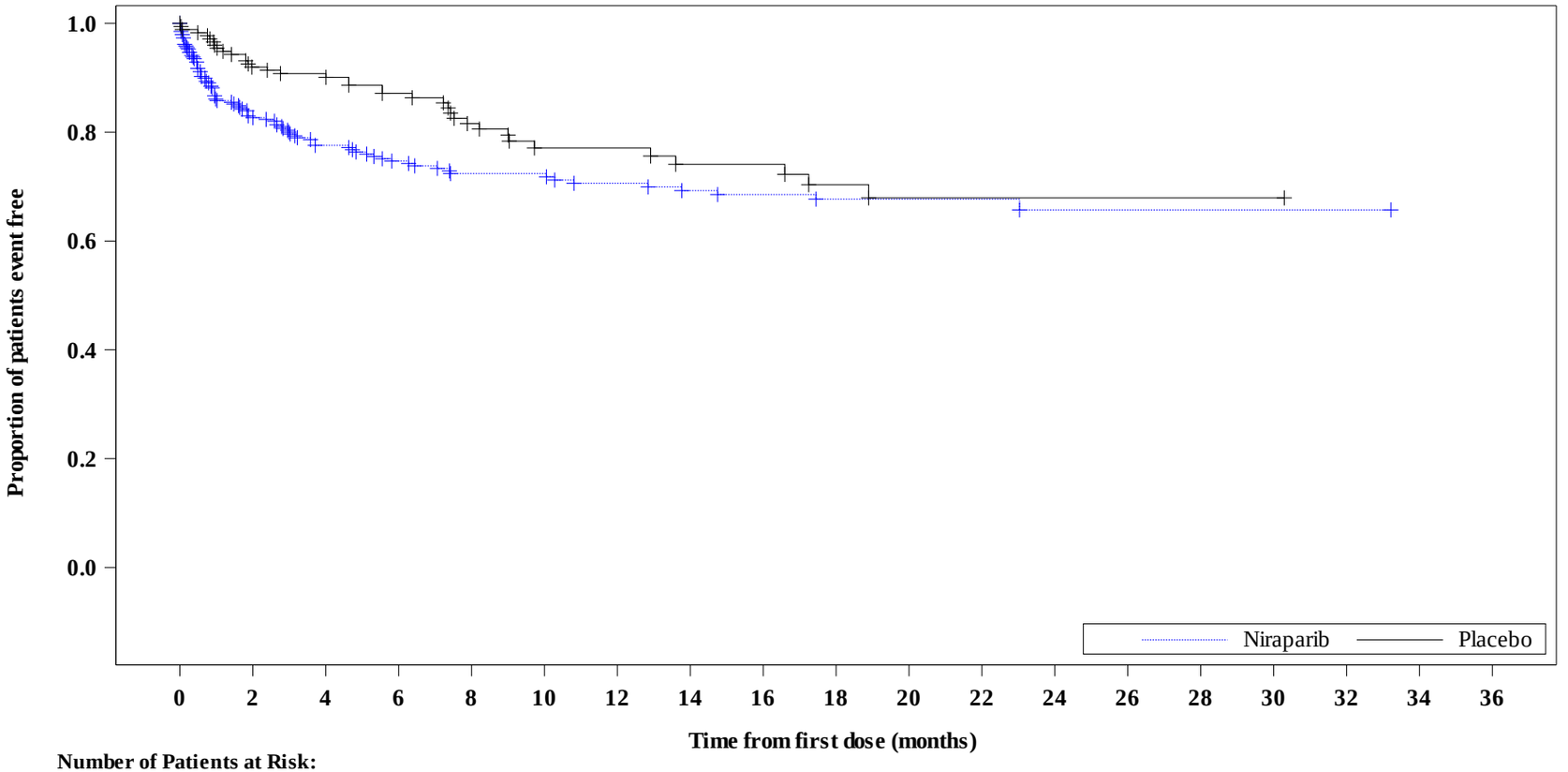
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Vascular disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 257 | 202 | 175 | 140 | 123 | 114 | 101 | 86 | 78 | 57 | 40 | 27 | 14 | 6 | 2 | 2 | 0 |
| Placebo | 175 | 158 | 131 | 112 | 84 | 60 | 54 | 46 | 40 | 32 | 28 | 14 | 5 | 4 | 2 | 1 | 0 | |

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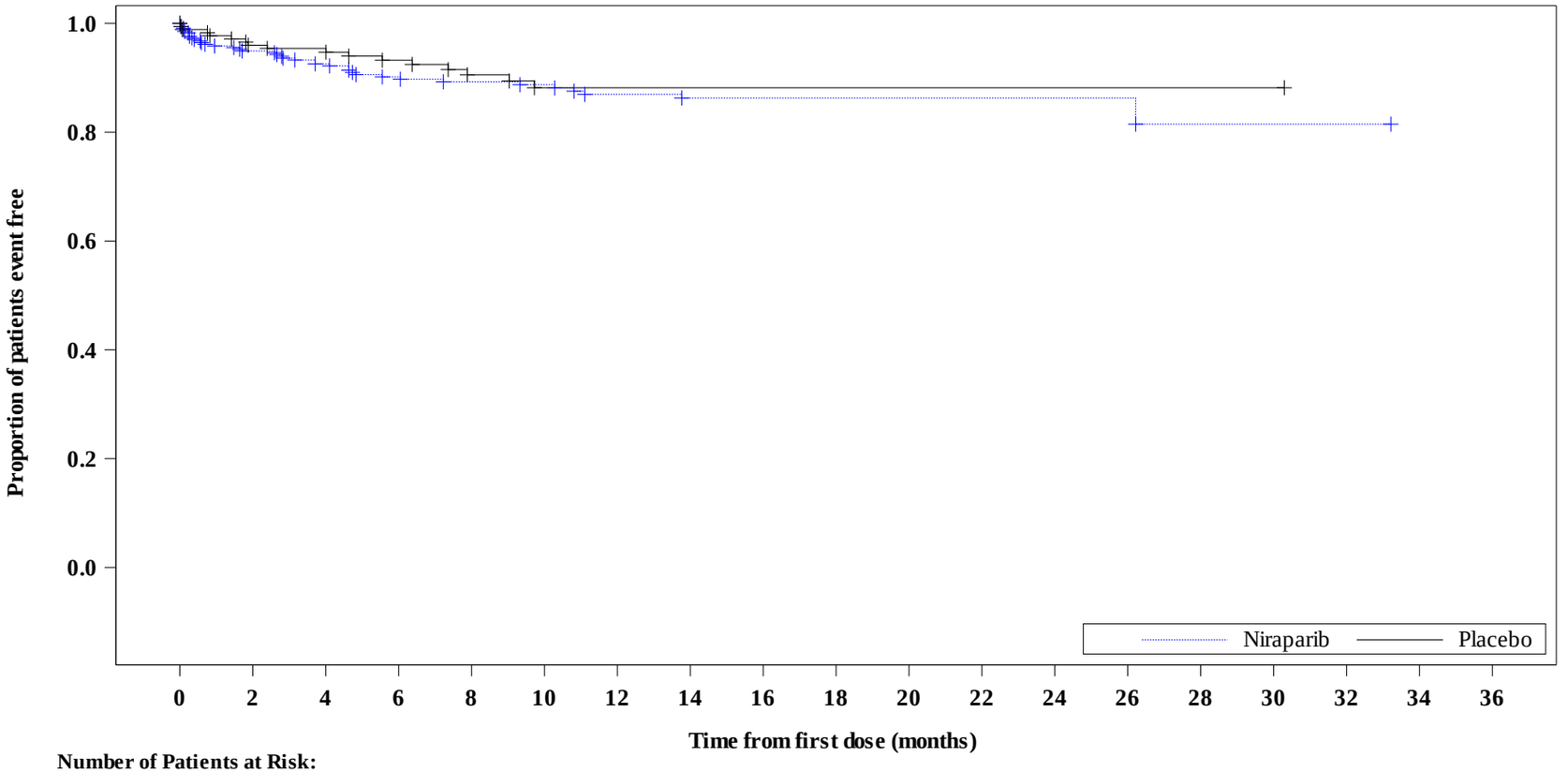
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Vascular disorders, PT: Hot flush




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 294 | 244 | 213 | 173 | 153 | 142 | 130 | 111 | 102 | 74 | 52 | 37 | 18 | 8 | 3 | 2 | 0 |
| Placebo | 175 | 165 | 138 | 121 | 93 | 70 | 63 | 53 | 44 | 38 | 33 | 17 | 7 | 4 | 2 | 1 | 0 | |

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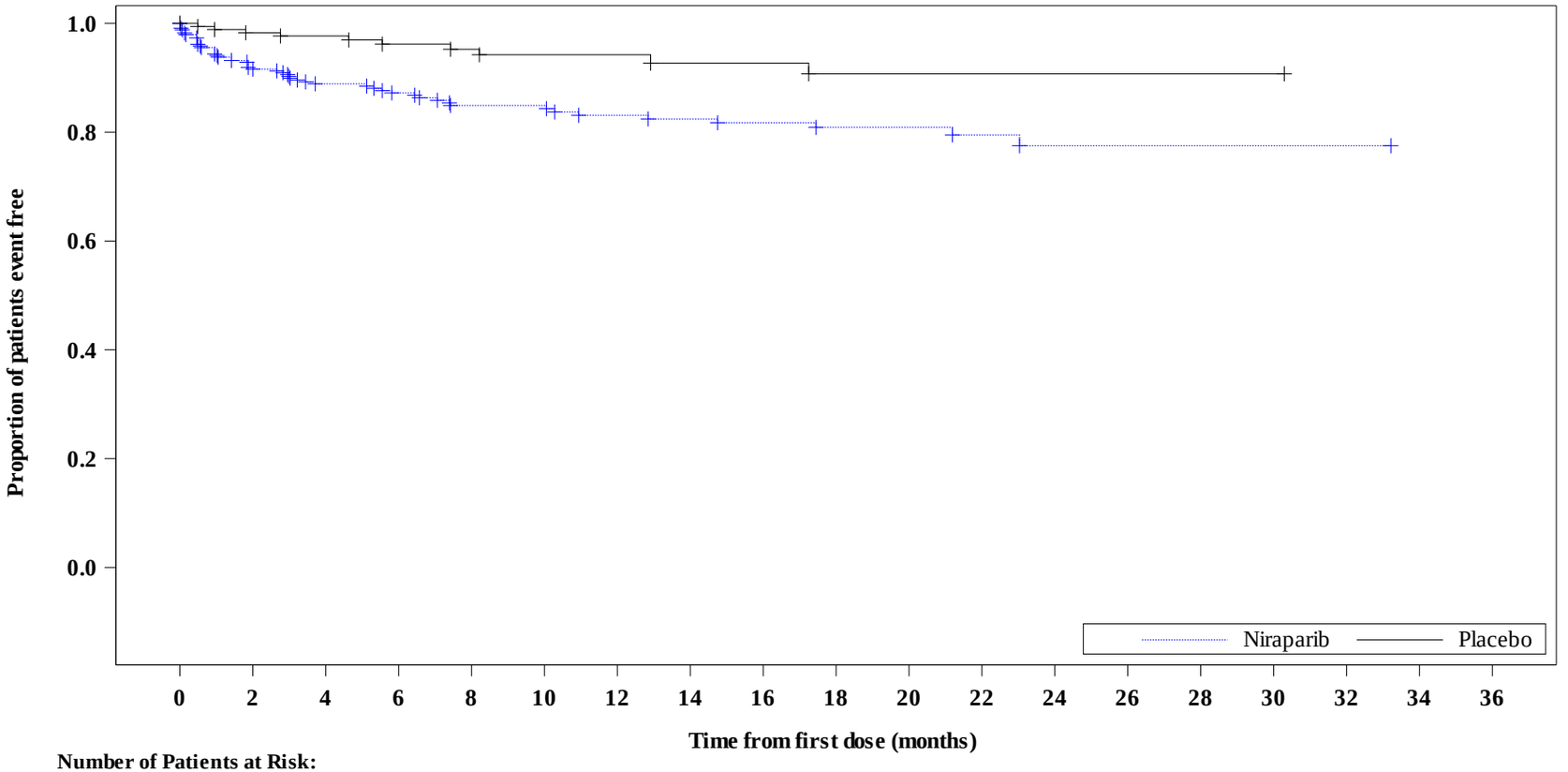
Figure 3.136a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)

SOC: Vascular disorders, PT: Hypertension




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 285 | 233 | 207 | 164 | 143 | 133 | 120 | 101 | 92 | 68 | 48 | 31 | 16 | 8 | 2 | 2 | 0 |
| Placebo | 175 | 169 | 141 | 122 | 97 | 73 | 65 | 55 | 48 | 40 | 34 | 19 | 8 | 5 | 2 | 1 | 0 | |

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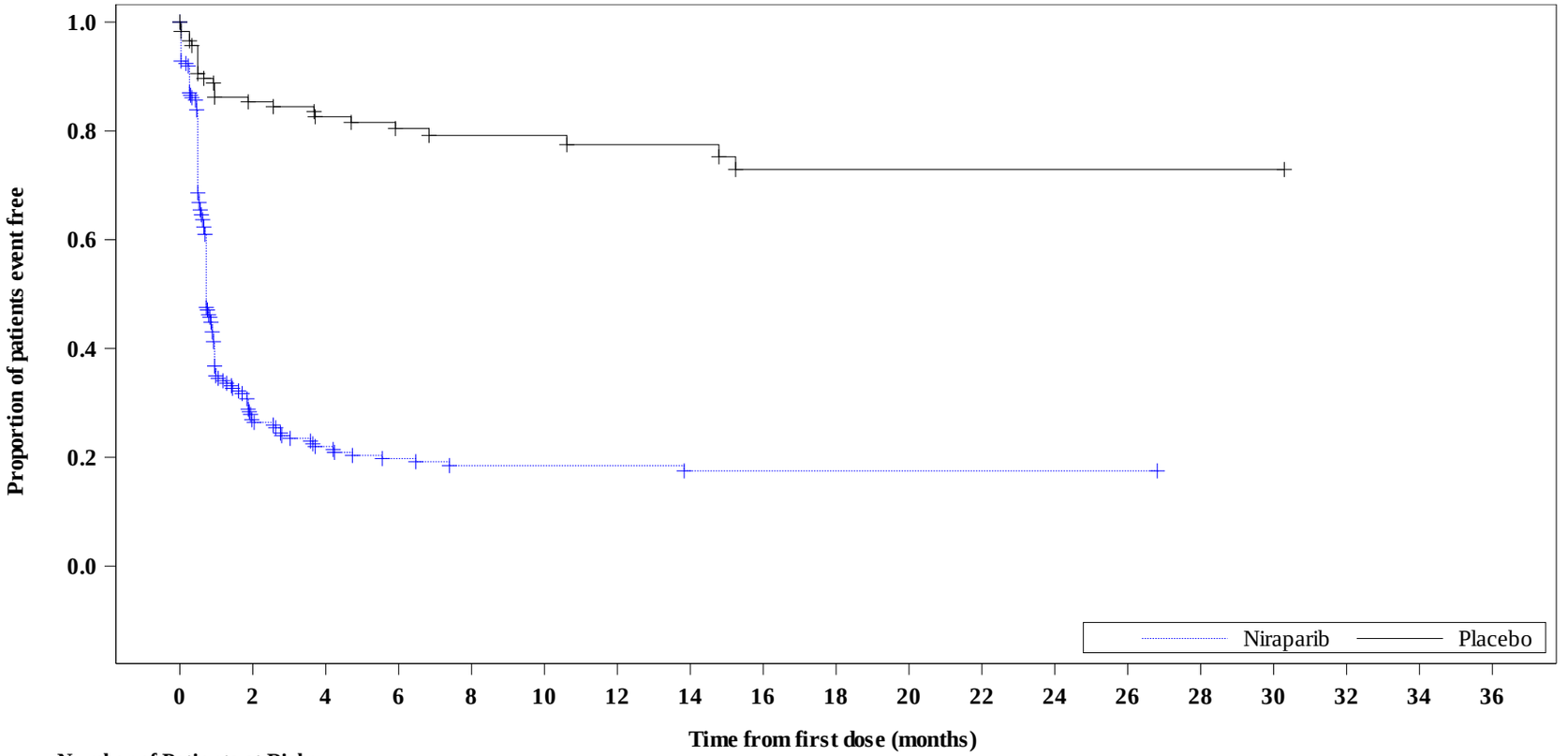
Figure 3.136b
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Residual Disease Status (Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders

Residual Disease Status: R0




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 223 | 55 | 41 | 34 | 24 | 21 | 21 | 18 | 16 | 12 | 11 | 3 | 2 | 1 | 0 | | |
| Placebo | 116 | 98 | 81 | 72 | 59 | 47 | 43 | 37 | 31 | 28 | 23 | 15 | 7 | 4 | 1 | 1 | 0 |

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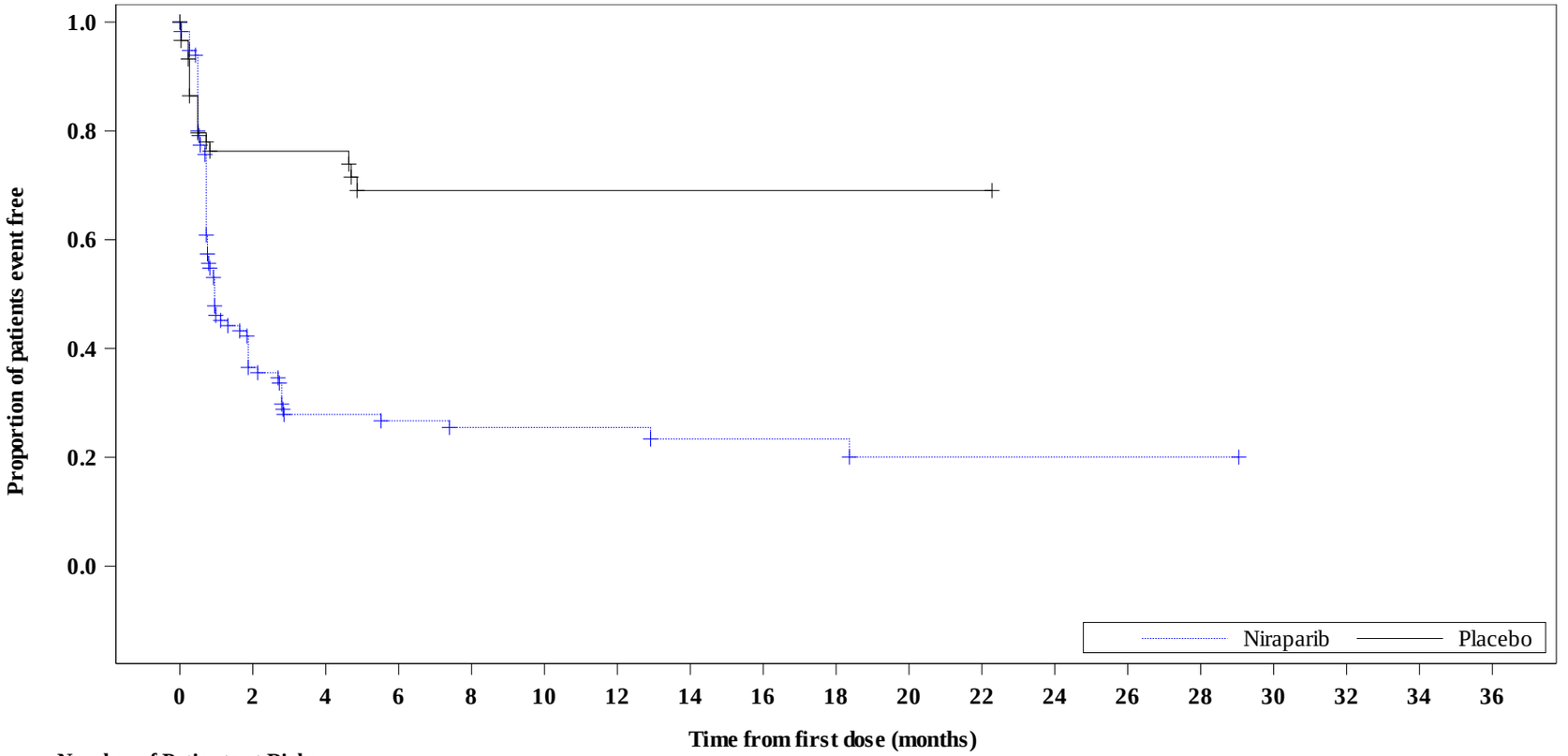
Figure 3.136b
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Residual Disease Status (Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders

Residual Disease Status: R1/R2




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 115 | 38 | 24 | 23 | 19 | 16 | 12 | 11 | 8 | 7 | 4 | 2 | 1 | 1 | 1 | 0 |
| Placebo | 59 | 43 | 35 | 24 | 18 | 10 | 8 | 4 | 3 | 2 | 2 | 1 | 0 | | | |

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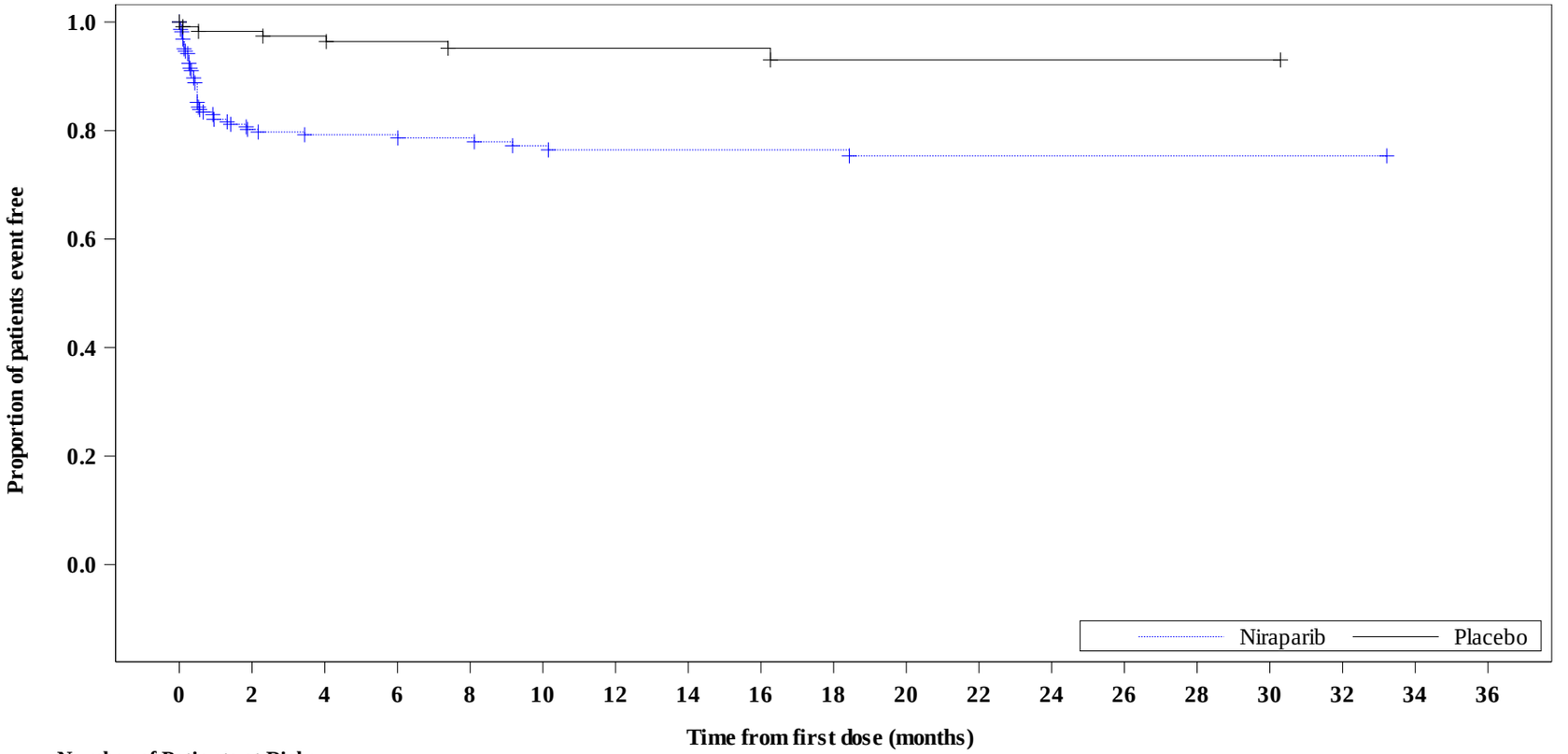
Figure 3.136b
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Residual Disease Status (Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders, PT: Decreased appetite
Residual Disease Status: R0



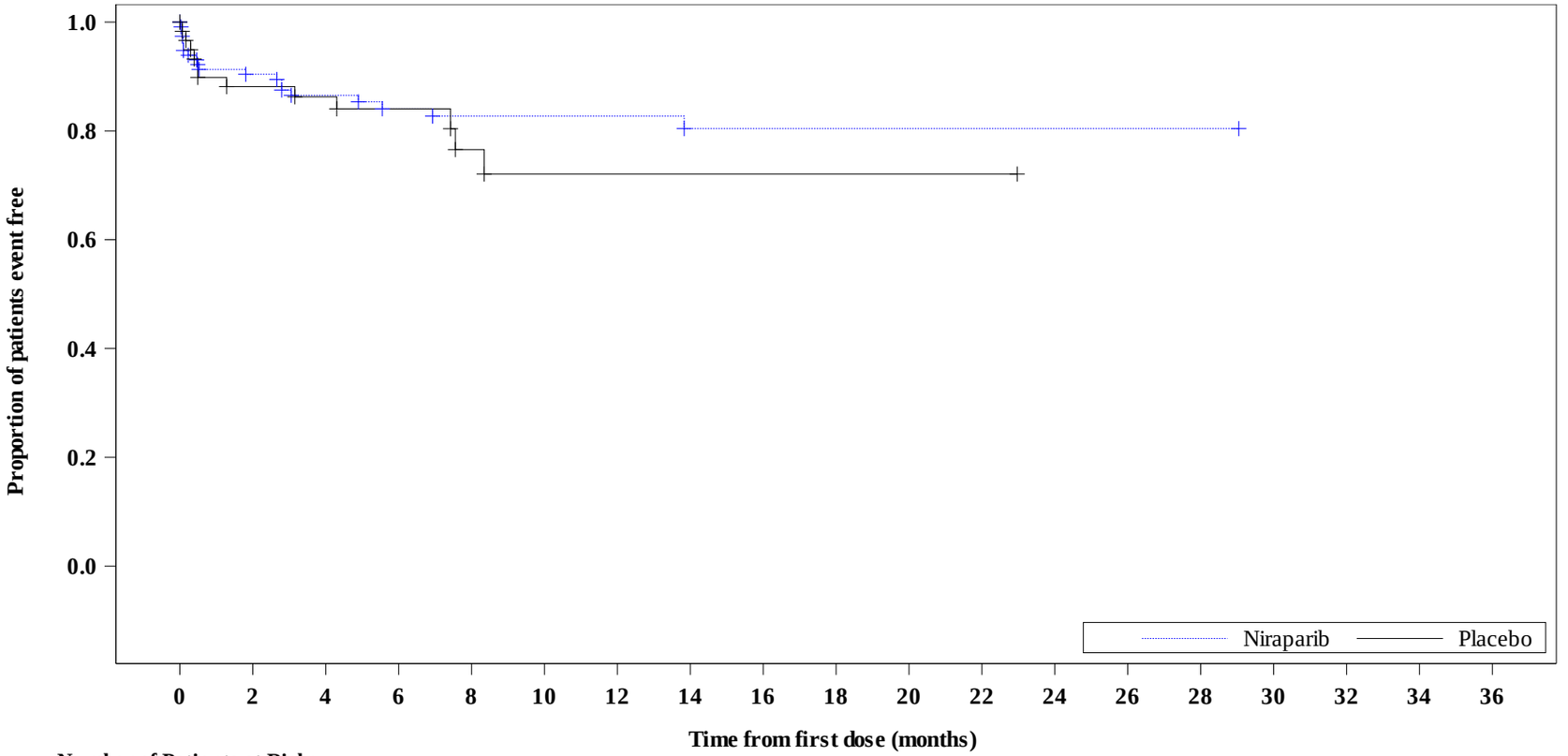

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 223 | 168 | 147 | 134 | 111 | 100 | 97 | 91 | 79 | 71 | 52 | 36 | 26 | 15 | 7 | 3 | 2 | 0 |
| Placebo | 116 | 113 | 98 | 90 | 75 | 62 | 57 | 50 | 44 | 38 | 32 | 17 | 8 | 5 | 2 | 1 | 0 | |

jg247770: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-136b-teaept-rd.sas 07OCT2020 08:41

Figure 3.136b
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Residual Disease Status (Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders, PT: Decreased appetite
Residual Disease Status: R1/R2




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 115 | 96 | 75 | 66 | 55 | 47 | 41 | 35 | 25 | 23 | 16 | 11 | 5 | 1 | 1 | 0 |
| Placebo | 59 | 51 | 40 | 32 | 19 | 13 | 10 | 6 | 4 | 3 | 3 | 2 | 0 | | | |

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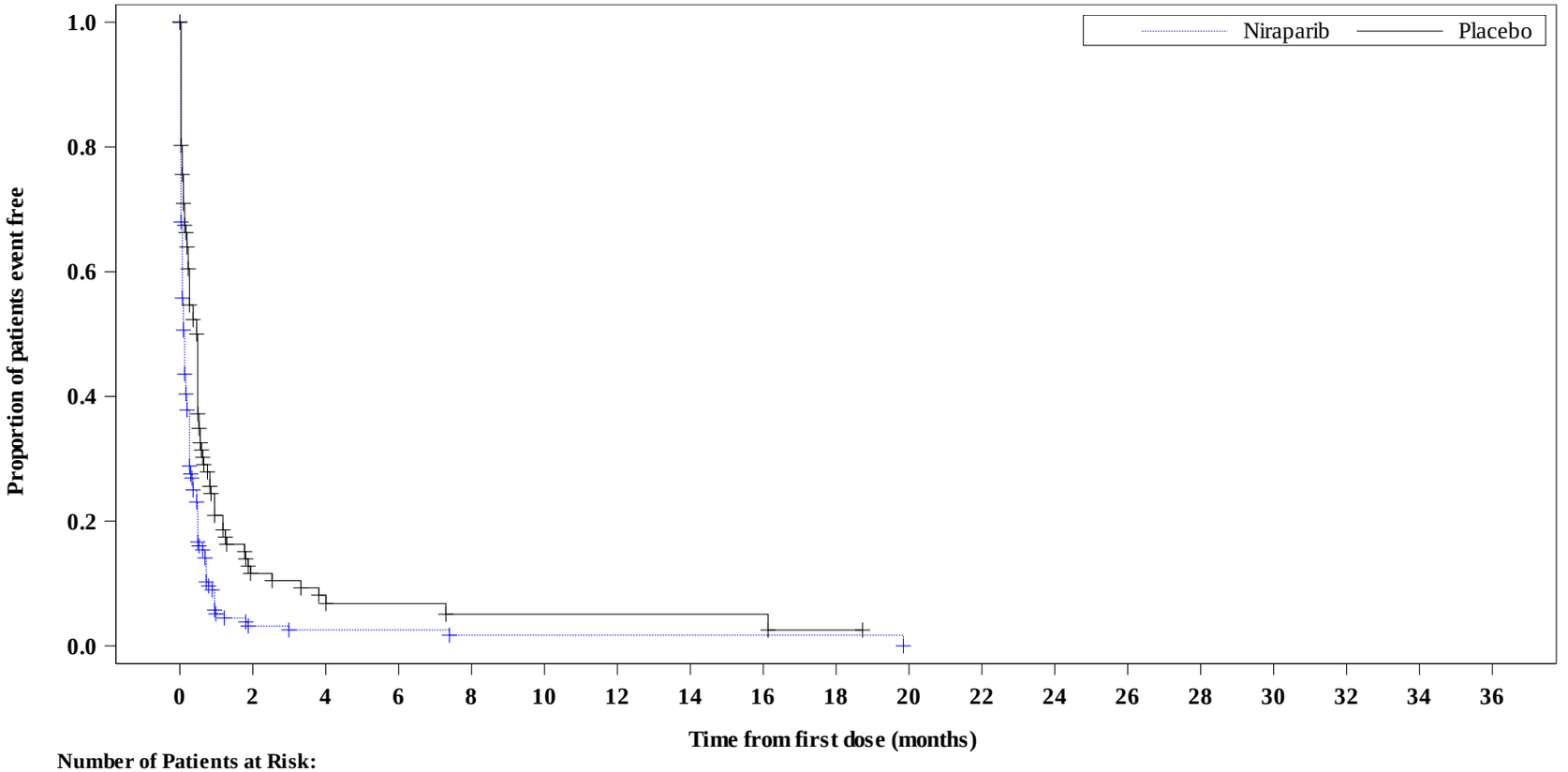
Figure 3.137a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events
(Residual Disease Safety-GVD Population)




**Number of Patients at Risk:**

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 5 | 3 | 3 | 2 | 2 | 1 | 1 | 1 | 1 | 0 |
| Placebo | 86 | 10 | 6 | 5 | 3 | 3 | 3 | 2 | 2 | 1 | 0 |

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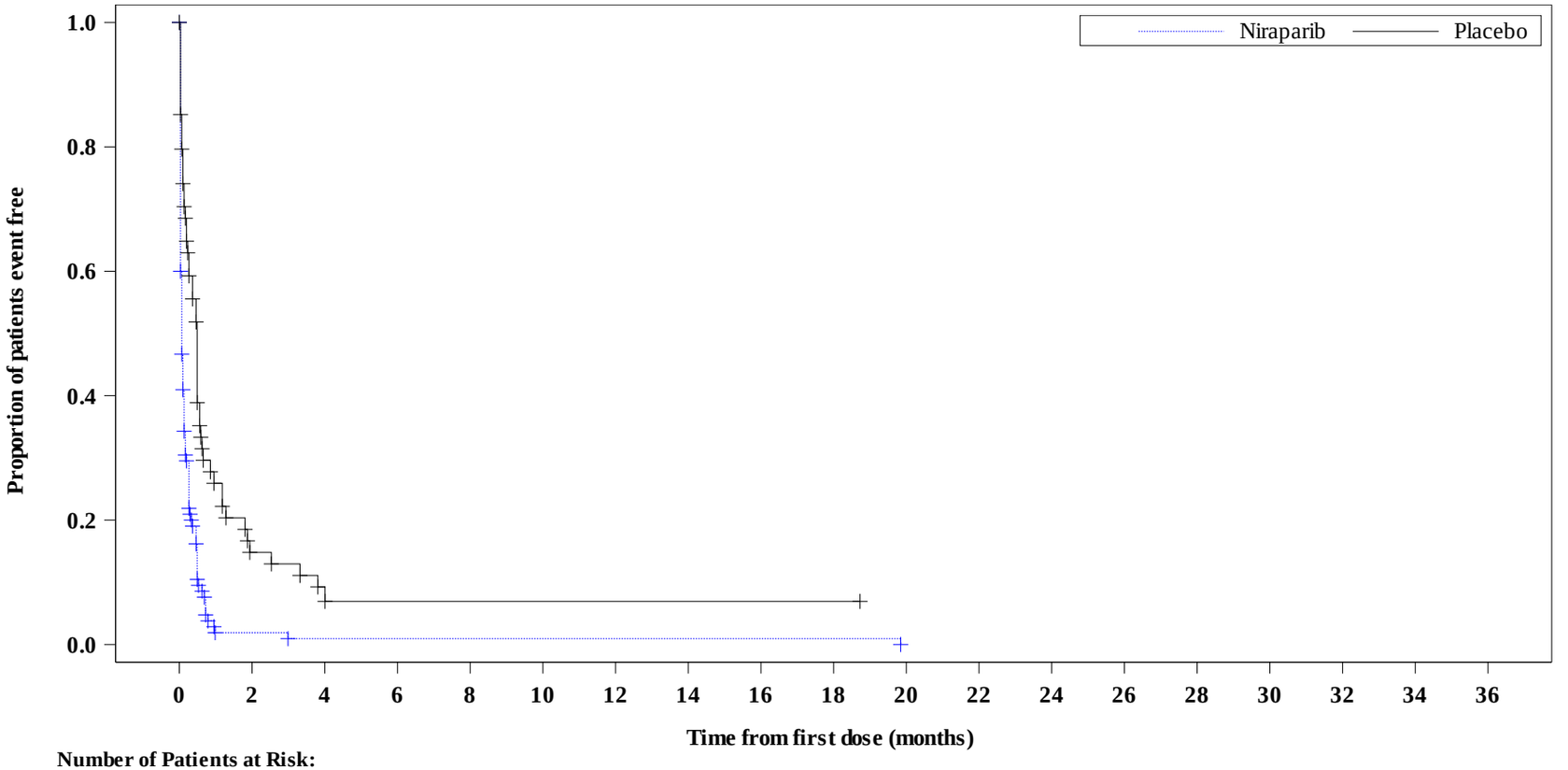
08:25

Figure 3.137b

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events by Residual Disease Status
(Residual Disease Safety-GVD Population)

Residual Disease Status: R0



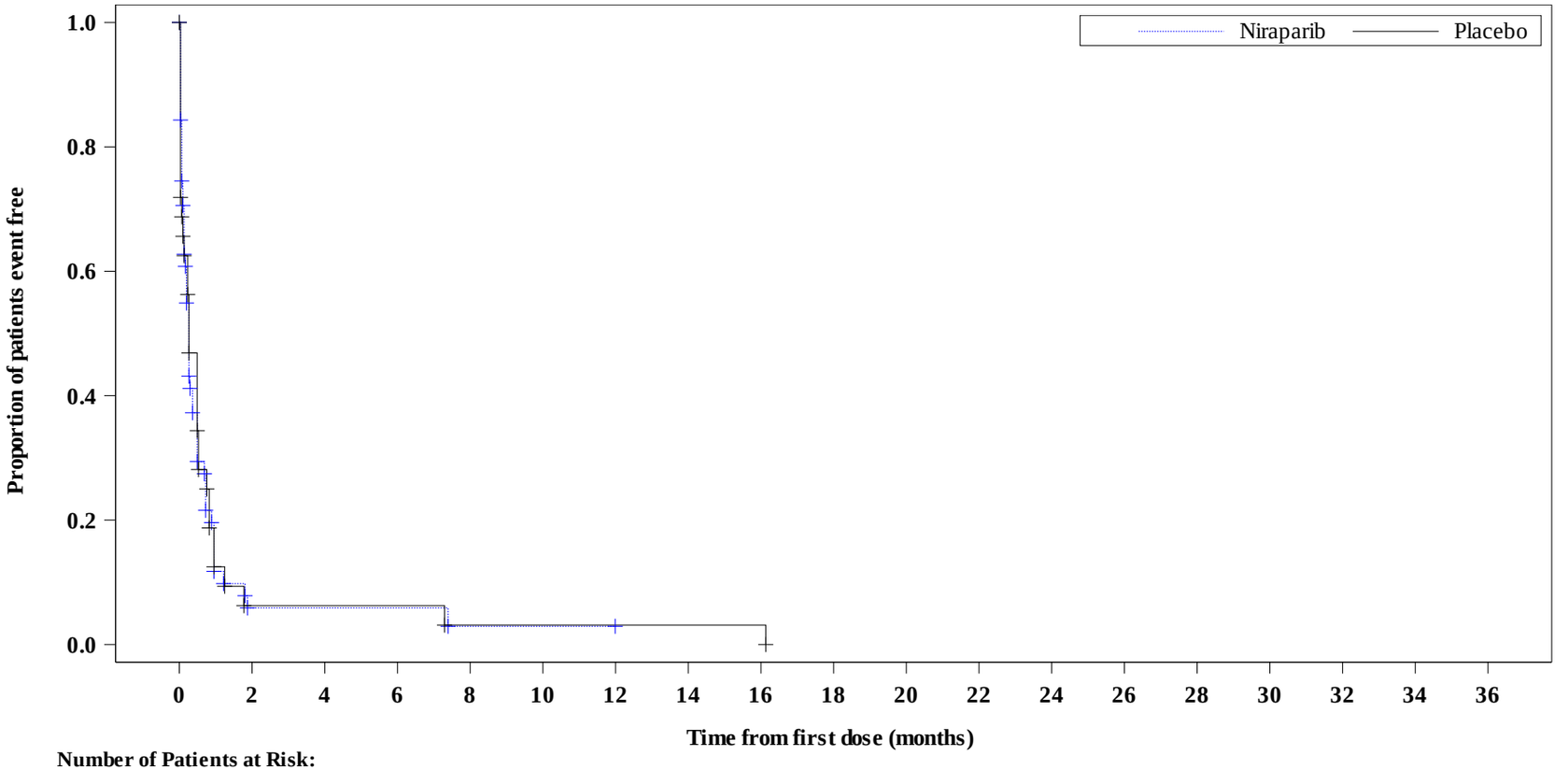

**Number of Patients at Risk:**

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 105 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 |
| Placebo | 54 | 8 | 4 | 3 | 2 | 2 | 2 | 1 | 1 | 1 | 0 |

Figure 3.137b

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events by Residual Disease Status
(Residual Disease Safety-GVD Population)

Residual Disease Status: R1/R2

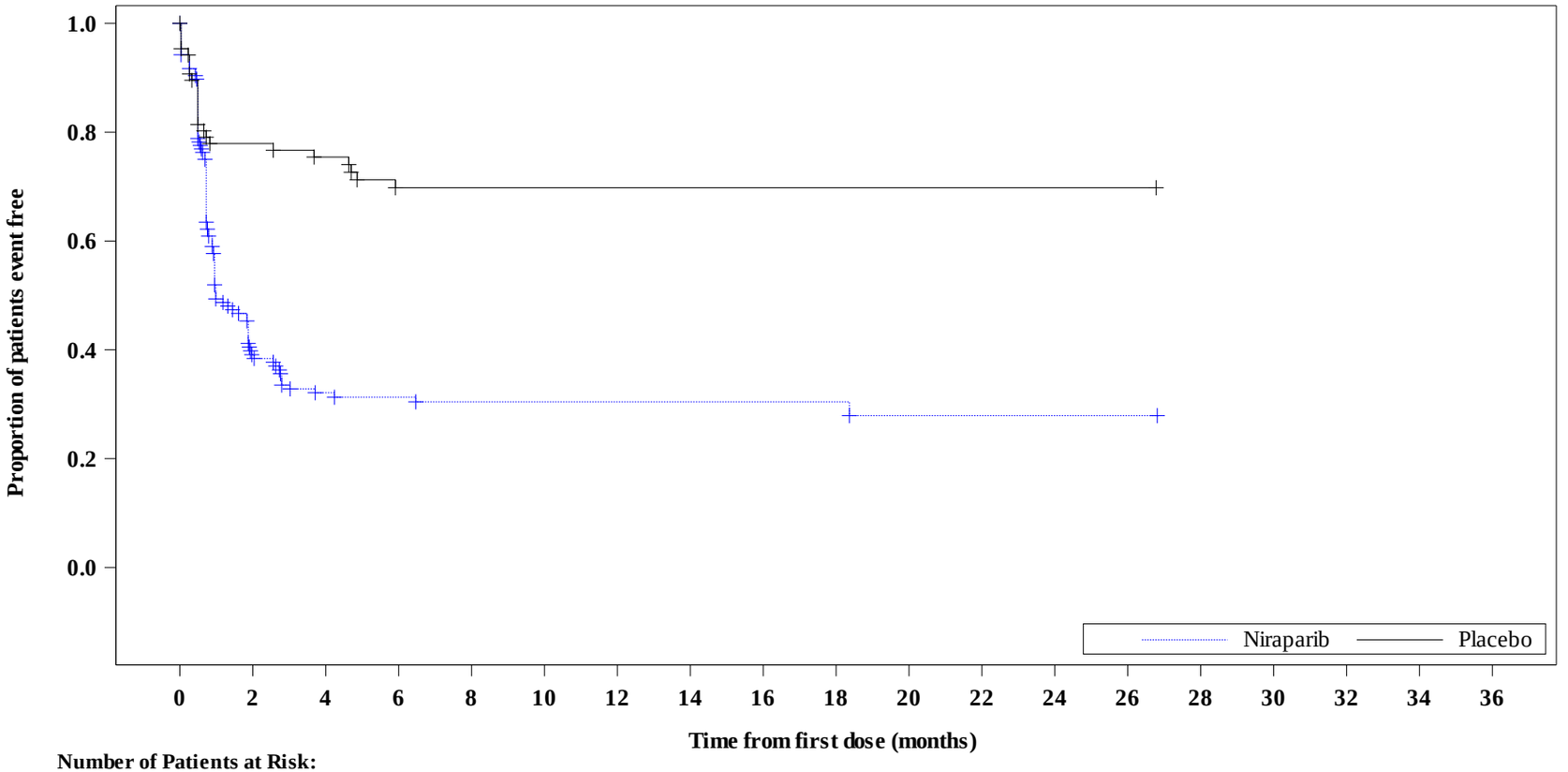



**Number of Patients at Risk:**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 51 | 3 | 2 | 2 | 1 | 1 | 0 | | | |
| Placebo | 32 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 56 | 39 | 37 | 29 | 25 | 22 | 20 | 16 | 12 | 10 | 2 | 1 | 1 | 0 |
| Placebo | 86 | 65 | 58 | 48 | 41 | 31 | 26 | 19 | 16 | 14 | 9 | 4 | 2 | 1 | 0 |

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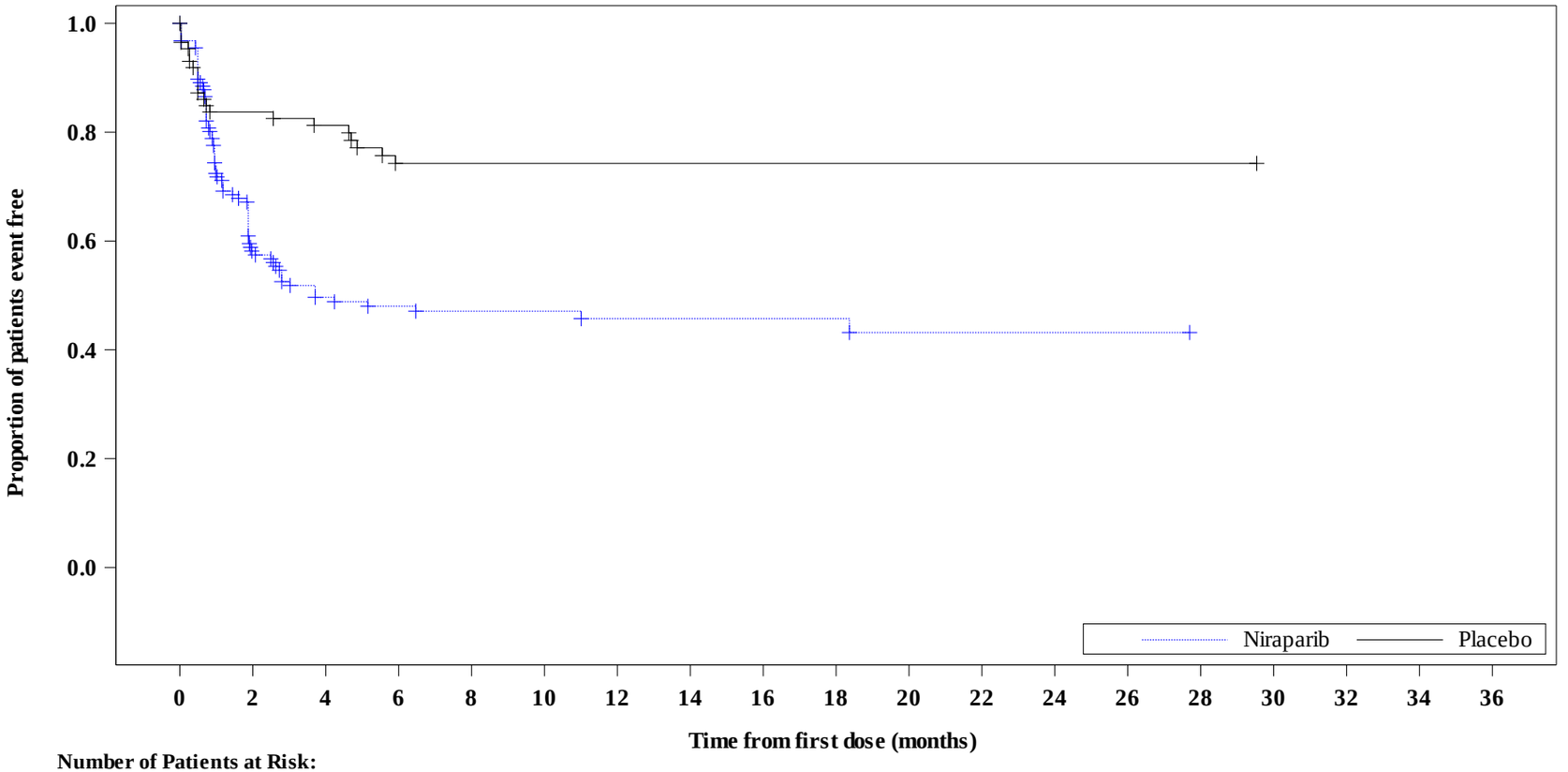
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia

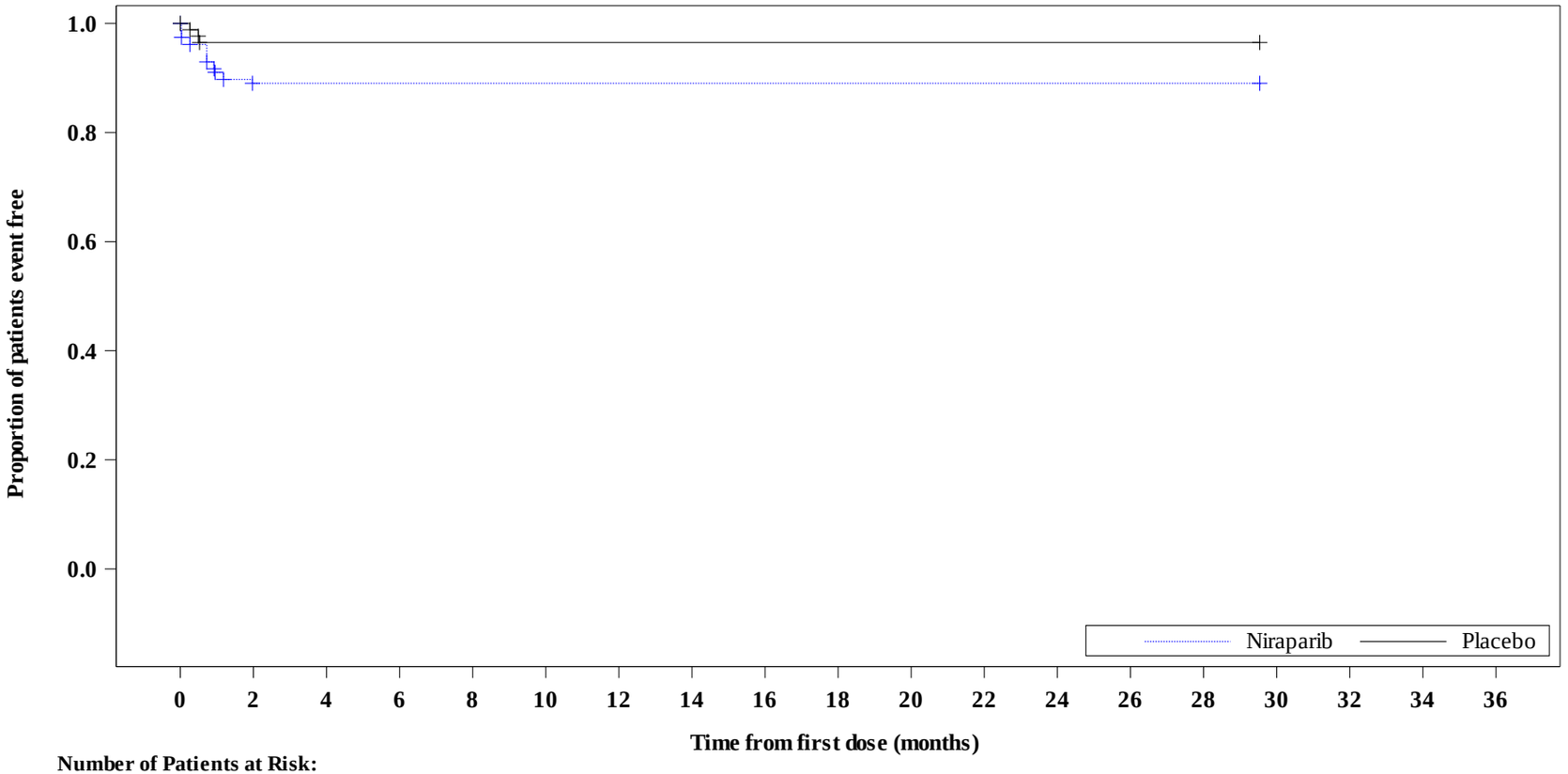



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 83 | 62 | 55 | 42 | 35 | 31 | 28 | 22 | 18 | 13 | 4 | 3 | 2 | 0 | |
| Placebo | 86 | 70 | 63 | 52 | 44 | 34 | 29 | 22 | 19 | 16 | 11 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Leukopenia

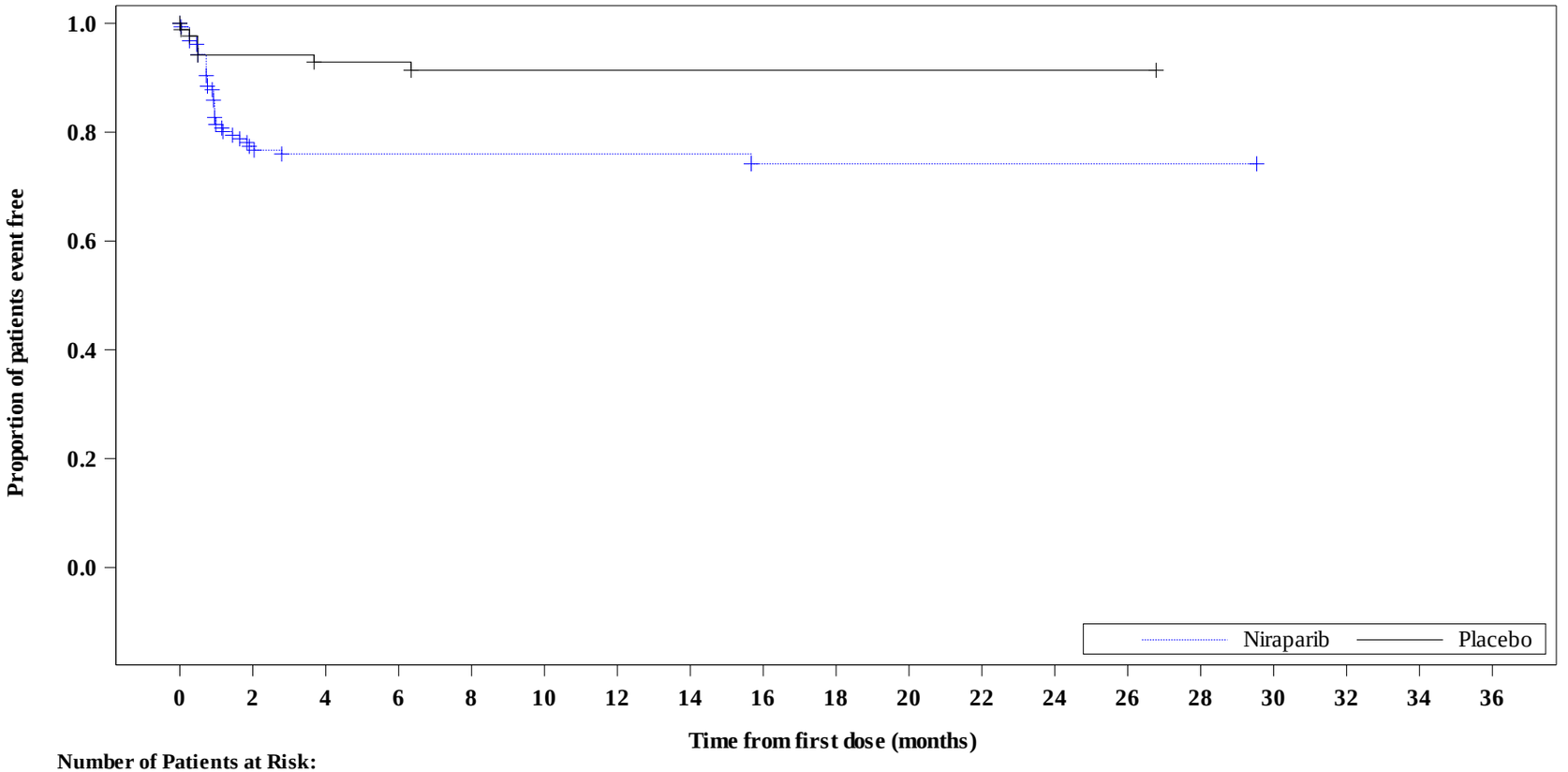



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 127 | 107 | 96 | 80 | 71 | 67 | 61 | 51 | 45 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 81 | 73 | 67 | 55 | 41 | 35 | 27 | 22 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Neutropenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 111 | 89 | 81 | 67 | 59 | 55 | 49 | 40 | 35 | 24 | 11 | 6 | 3 | 1 | 0 |
| Placebo | 86 | 79 | 70 | 64 | 53 | 39 | 33 | 25 | 21 | 17 | 12 | 4 | 2 | 1 | 0 | |

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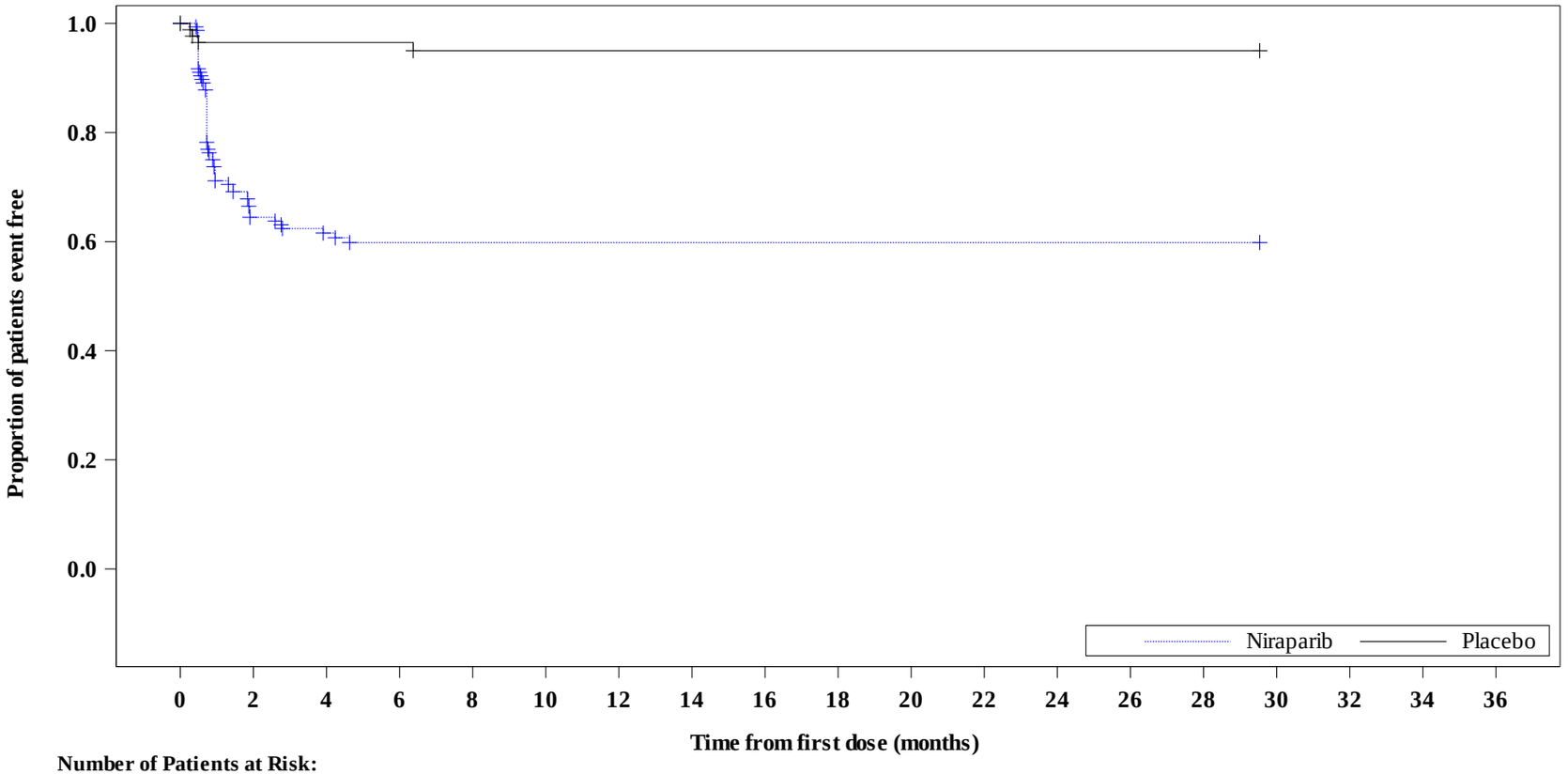
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

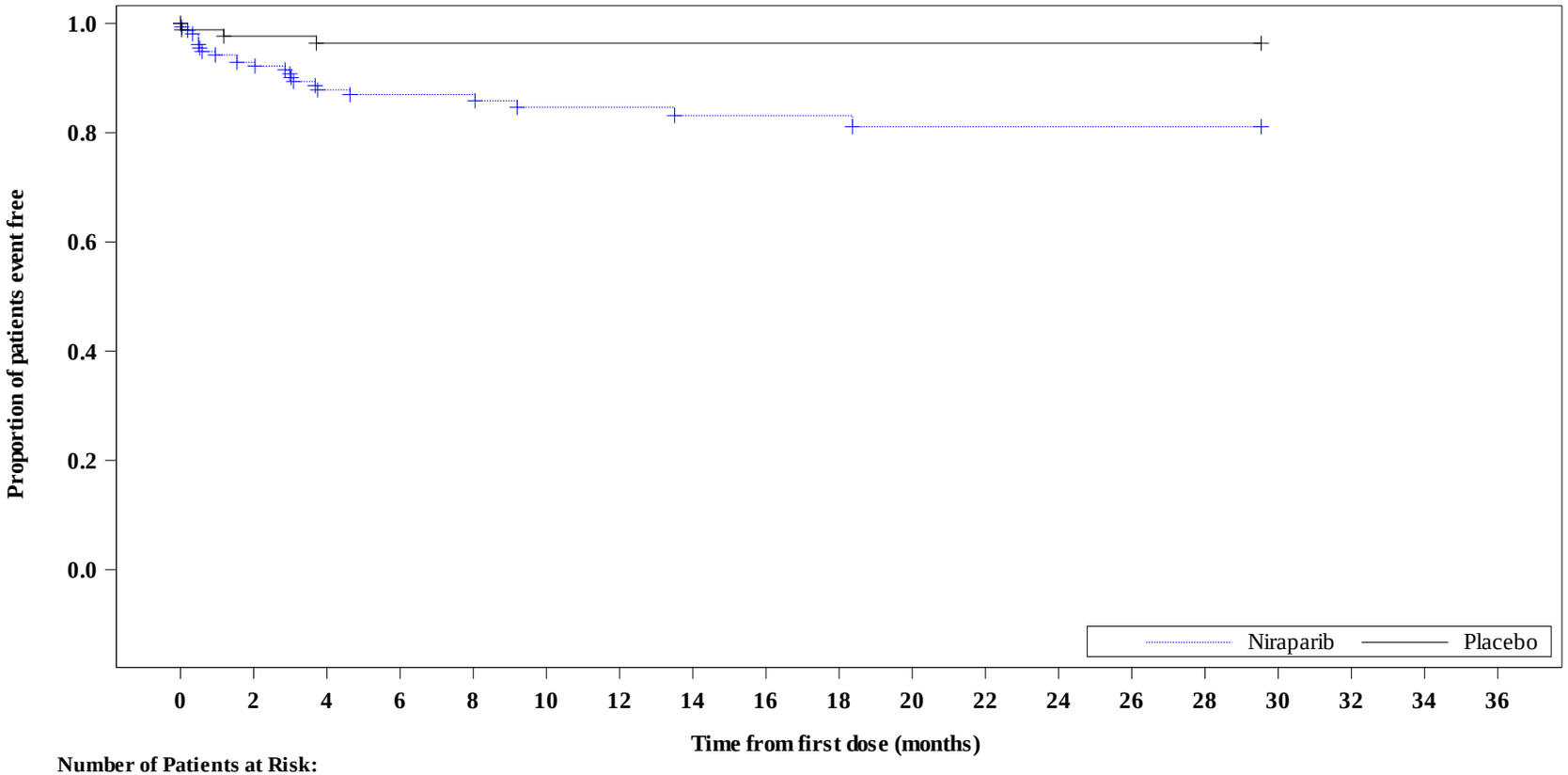



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 95 | 72 | 66 | 55 | 50 | 47 | 42 | 34 | 29 | 21 | 9 | 4 | 2 | 1 | 0 |
| Placebo | 86 | 81 | 73 | 67 | 55 | 41 | 35 | 27 | 22 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Cardiac disorders

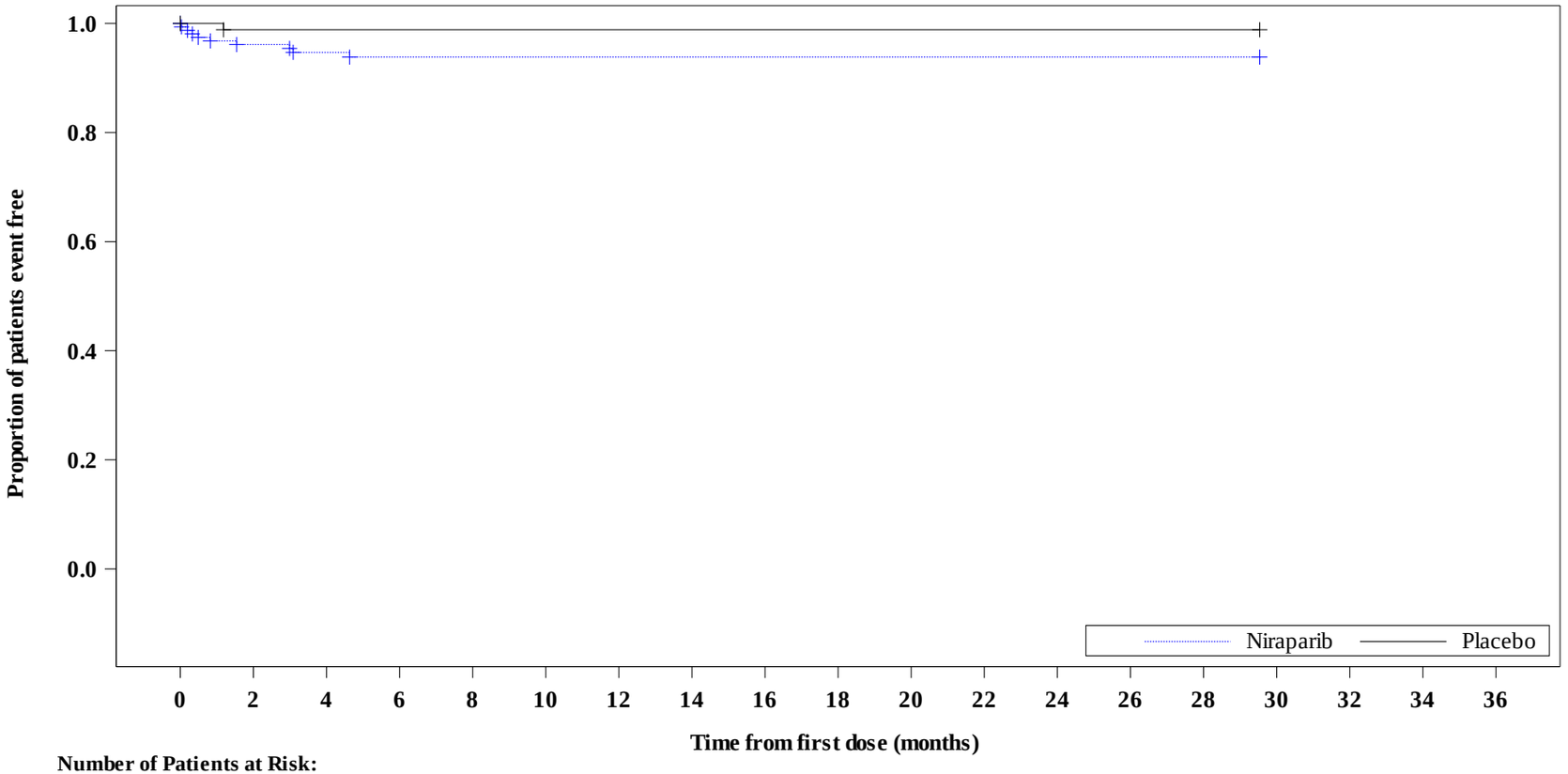



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 135 | 104 | 95 | 77 | 66 | 62 | 54 | 47 | 42 | 23 | 12 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 82 | 72 | 67 | 54 | 40 | 34 | 26 | 22 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Cardiac disorders, PT: Palpitations

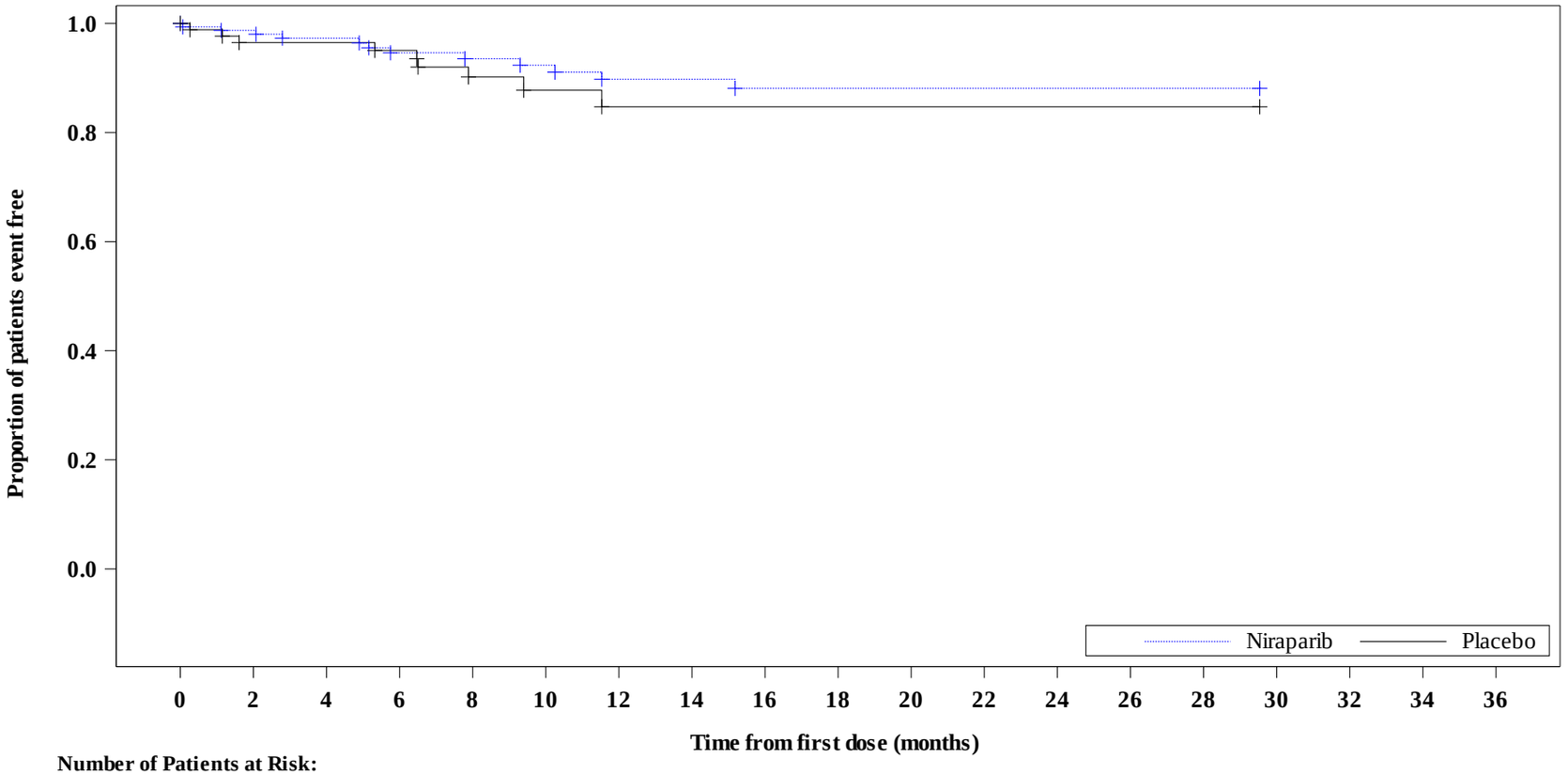



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 140 | 112 | 101 | 82 | 73 | 69 | 62 | 51 | 46 | 28 | 14 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 83 | 74 | 68 | 55 | 41 | 35 | 27 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Ear and labyrinth disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 115 | 103 | 84 | 74 | 68 | 61 | 48 | 42 | 24 | 13 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 81 | 72 | 65 | 50 | 35 | 28 | 22 | 18 | 14 | 10 | 5 | 3 | 2 | 1 | 0 |

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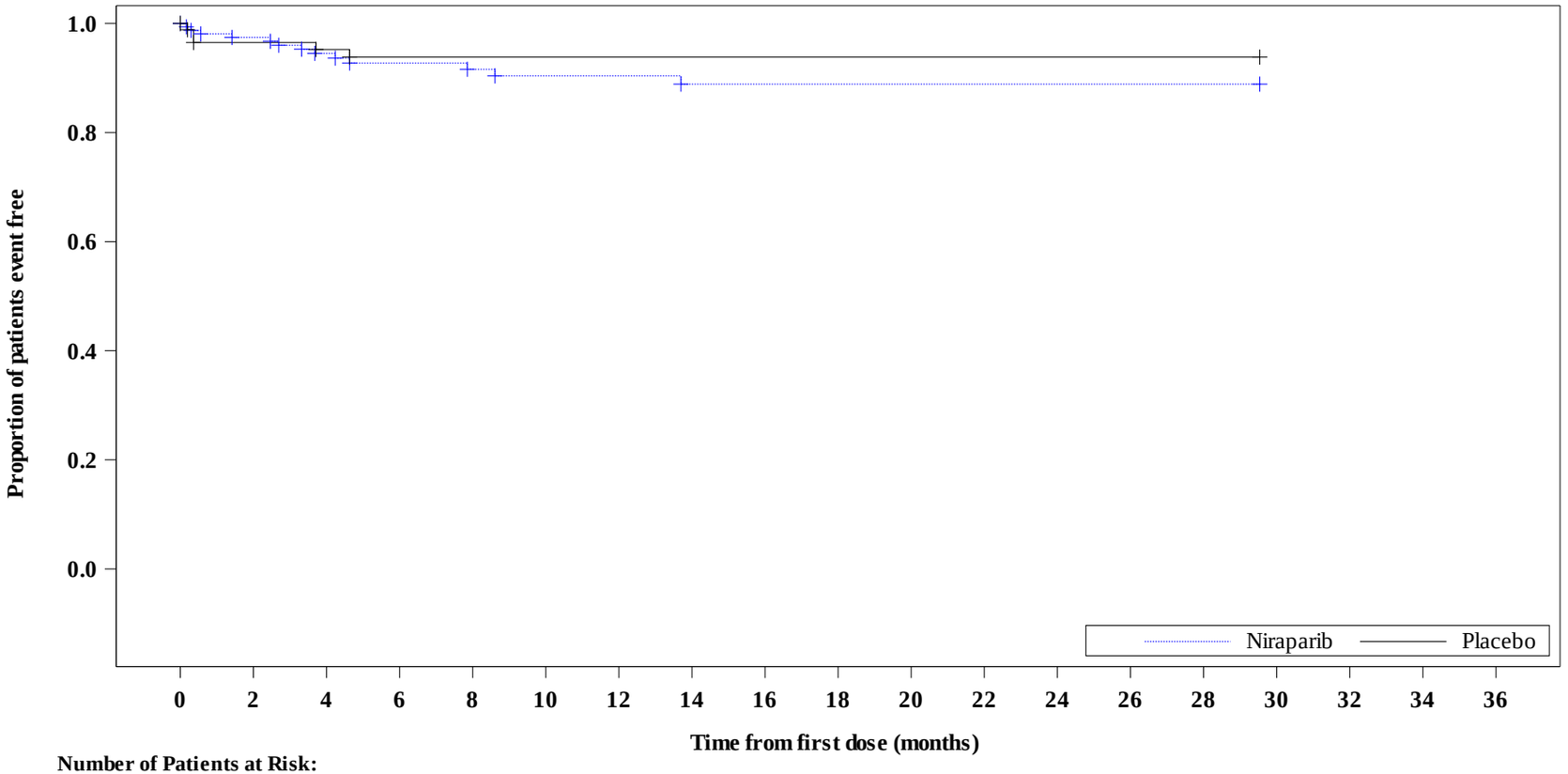
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Eye disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 140 | 111 | 98 | 78 | 70 | 66 | 59 | 49 | 43 | 26 | 11 | 7 | 5 | 2 | 0 |
| Placebo | 86 | 81 | 71 | 65 | 52 | 40 | 34 | 26 | 21 | 17 | 13 | 5 | 3 | 2 | 1 | 0 |

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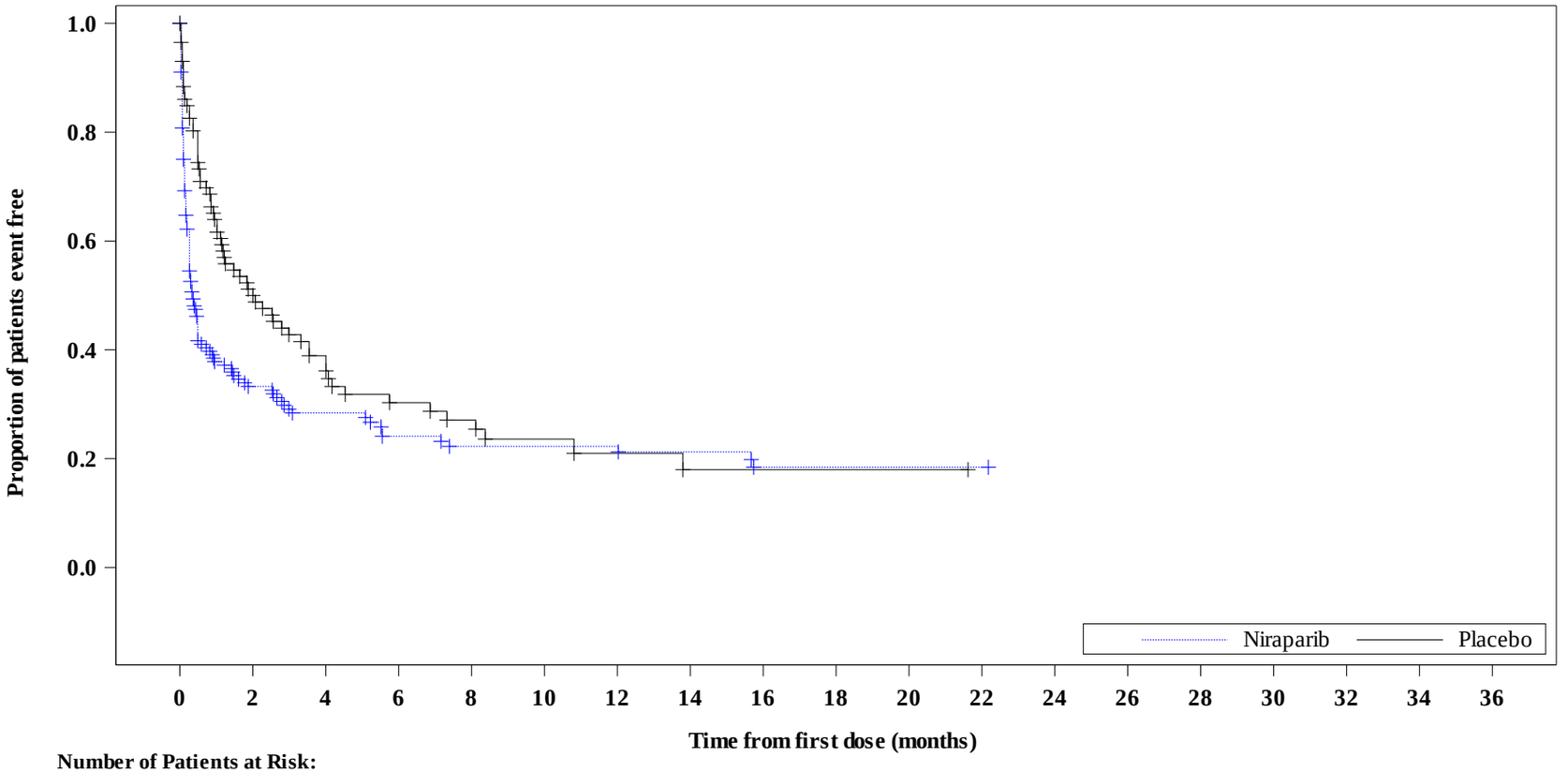
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders



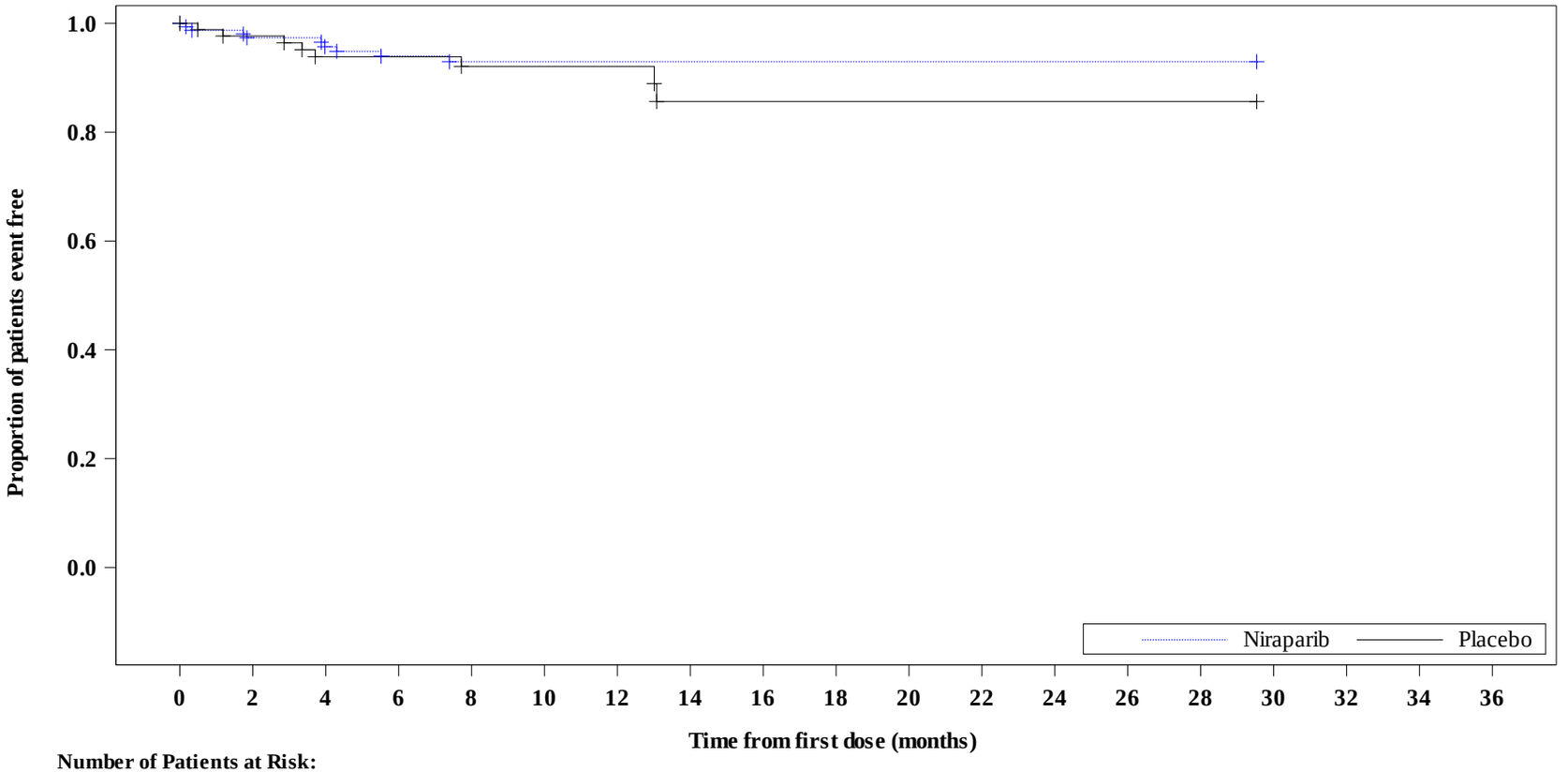

**Number of Patients at Risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 49 | 34 | 28 | 23 | 23 | 22 | 19 | 13 | 13 | 6 | 1 | 0 |
| Placebo | 86 | 43 | 28 | 20 | 16 | 11 | 8 | 5 | 5 | 4 | 3 | 0 | |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Abdominal distension



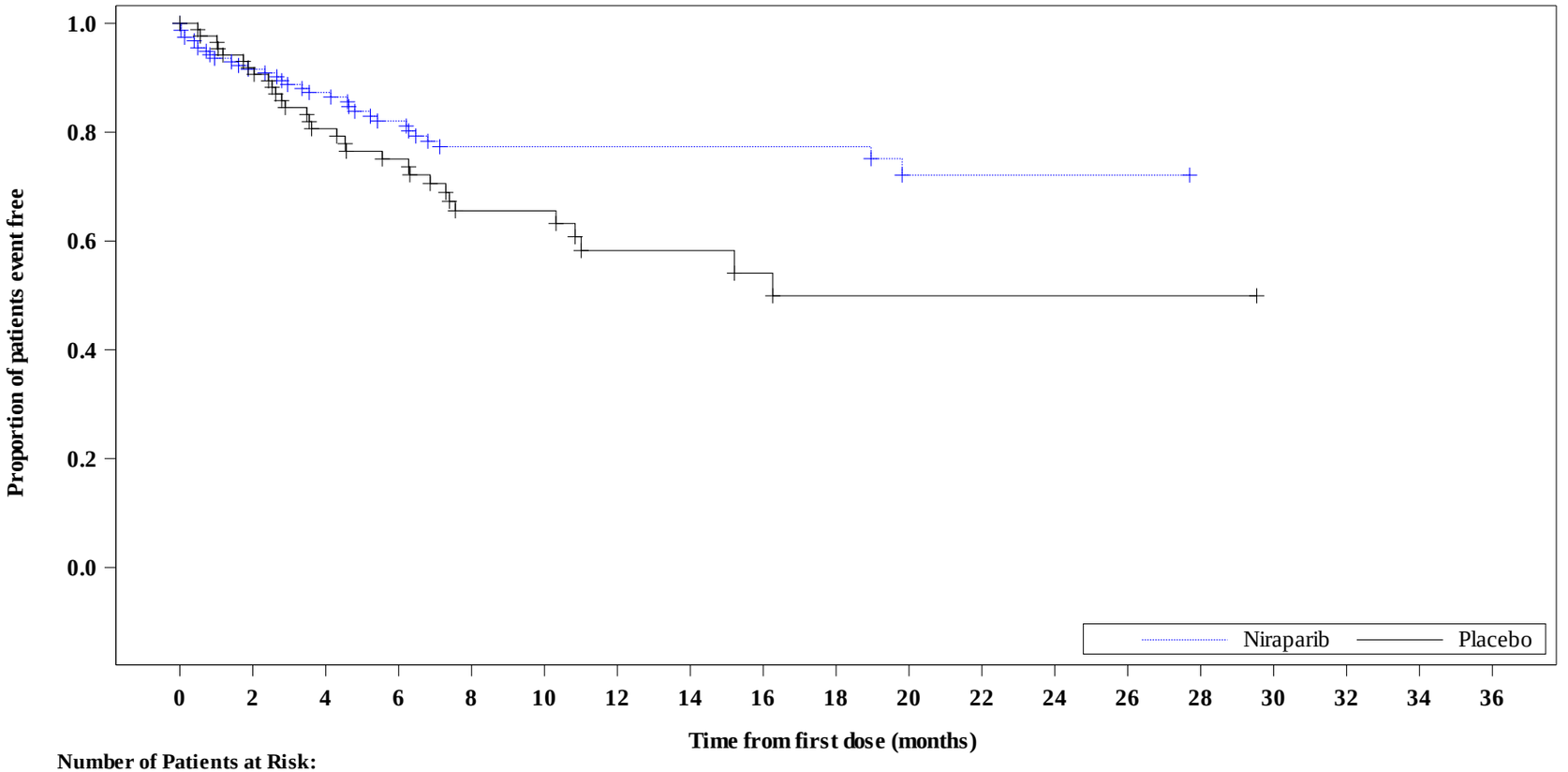

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 141 | 114 | 104 | 84 | 75 | 71 | 64 | 52 | 47 | 28 | 14 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 82 | 71 | 66 | 52 | 39 | 33 | 23 | 19 | 15 | 10 | 3 | 2 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain



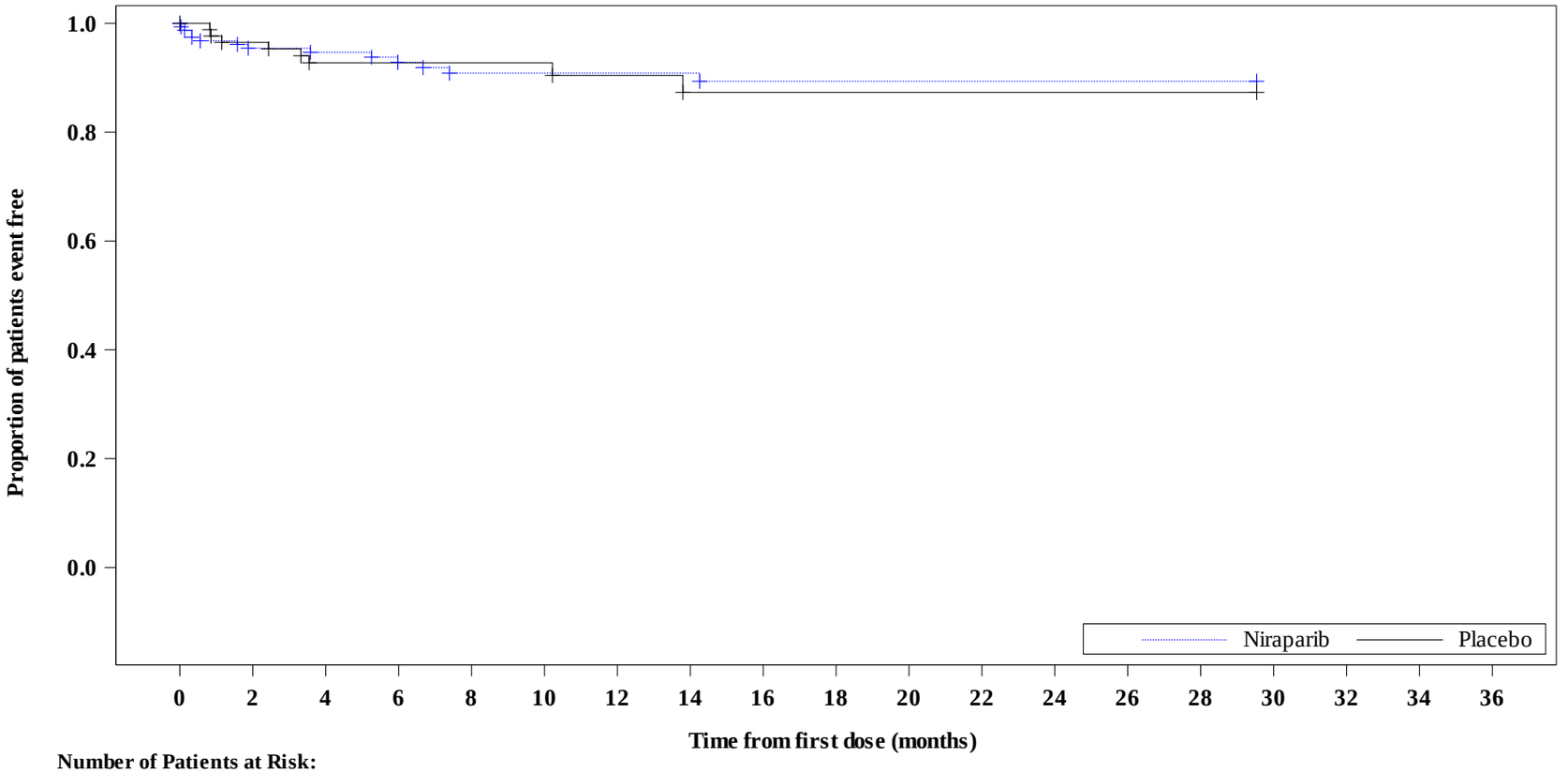

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 132 | 105 | 91 | 71 | 66 | 63 | 58 | 47 | 41 | 23 | 11 | 6 | 2 | 0 | |
| Placebo | 86 | 77 | 60 | 53 | 38 | 29 | 23 | 16 | 13 | 9 | 5 | 2 | 1 | 1 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Abdominal pain upper




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 137 | 112 | 101 | 80 | 73 | 69 | 62 | 49 | 43 | 25 | 11 | 6 | 4 | 1 | 0 |
| Placebo | 86 | 81 | 69 | 64 | 54 | 41 | 34 | 26 | 21 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

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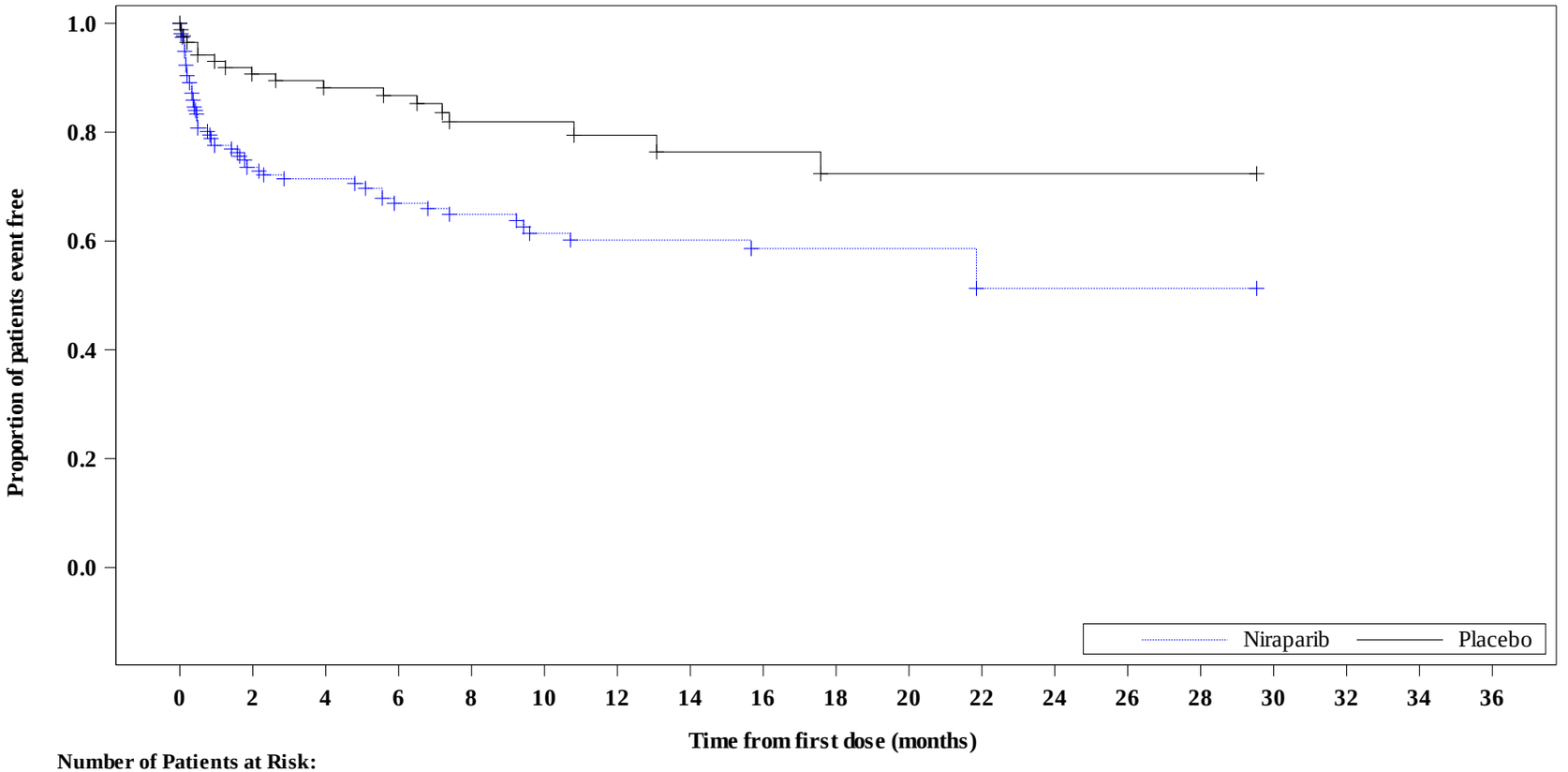
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Constipation




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 107 | 85 | 72 | 59 | 51 | 49 | 46 | 37 | 33 | 19 | 7 | 4 | 3 | 1 | 0 |
| Placebo | 86 | 77 | 66 | 61 | 46 | 35 | 29 | 22 | 20 | 16 | 12 | 5 | 3 | 2 | 1 | 0 |

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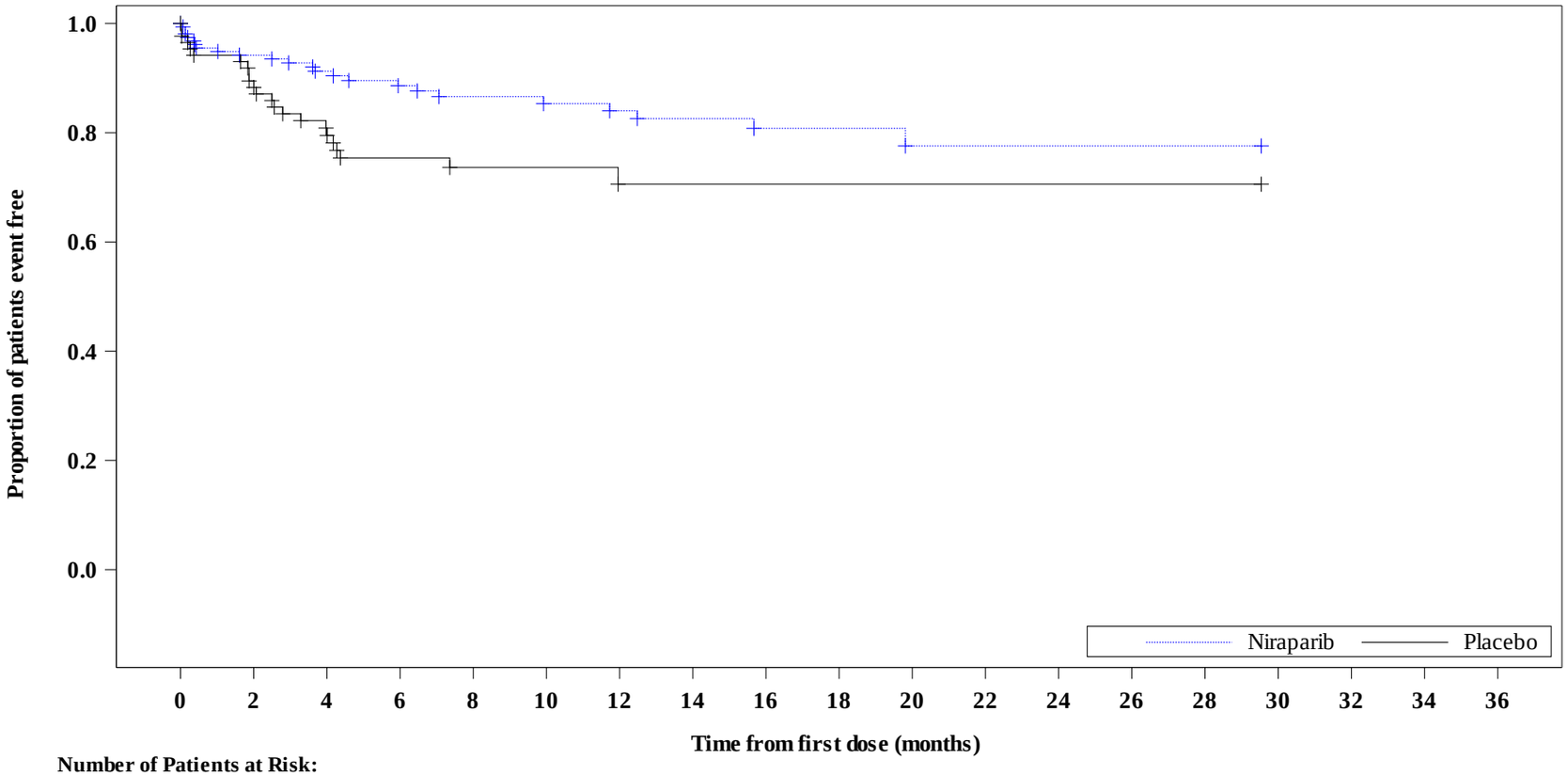
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Diarrhoea

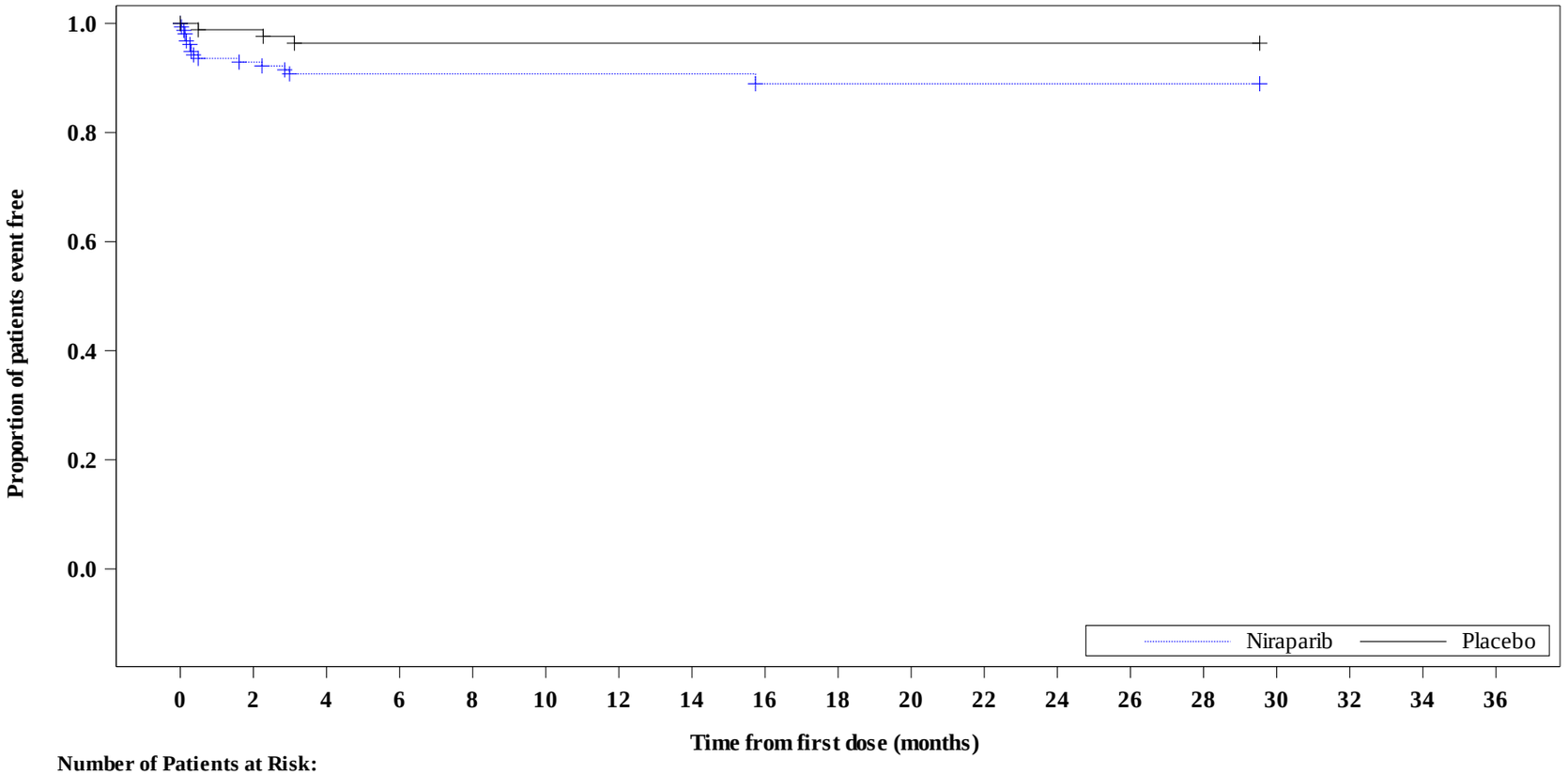



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 135 | 108 | 95 | 74 | 66 | 63 | 57 | 44 | 38 | 23 | 10 | 5 | 3 | 1 | 0 |
| Placebo | 86 | 75 | 60 | 52 | 39 | 28 | 23 | 17 | 17 | 15 | 10 | 4 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Dry mouth




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 133 | 107 | 98 | 79 | 72 | 68 | 61 | 49 | 44 | 27 | 13 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 72 | 67 | 54 | 41 | 35 | 27 | 22 | 18 | 13 | 4 | 3 | 2 | 1 | 0 |

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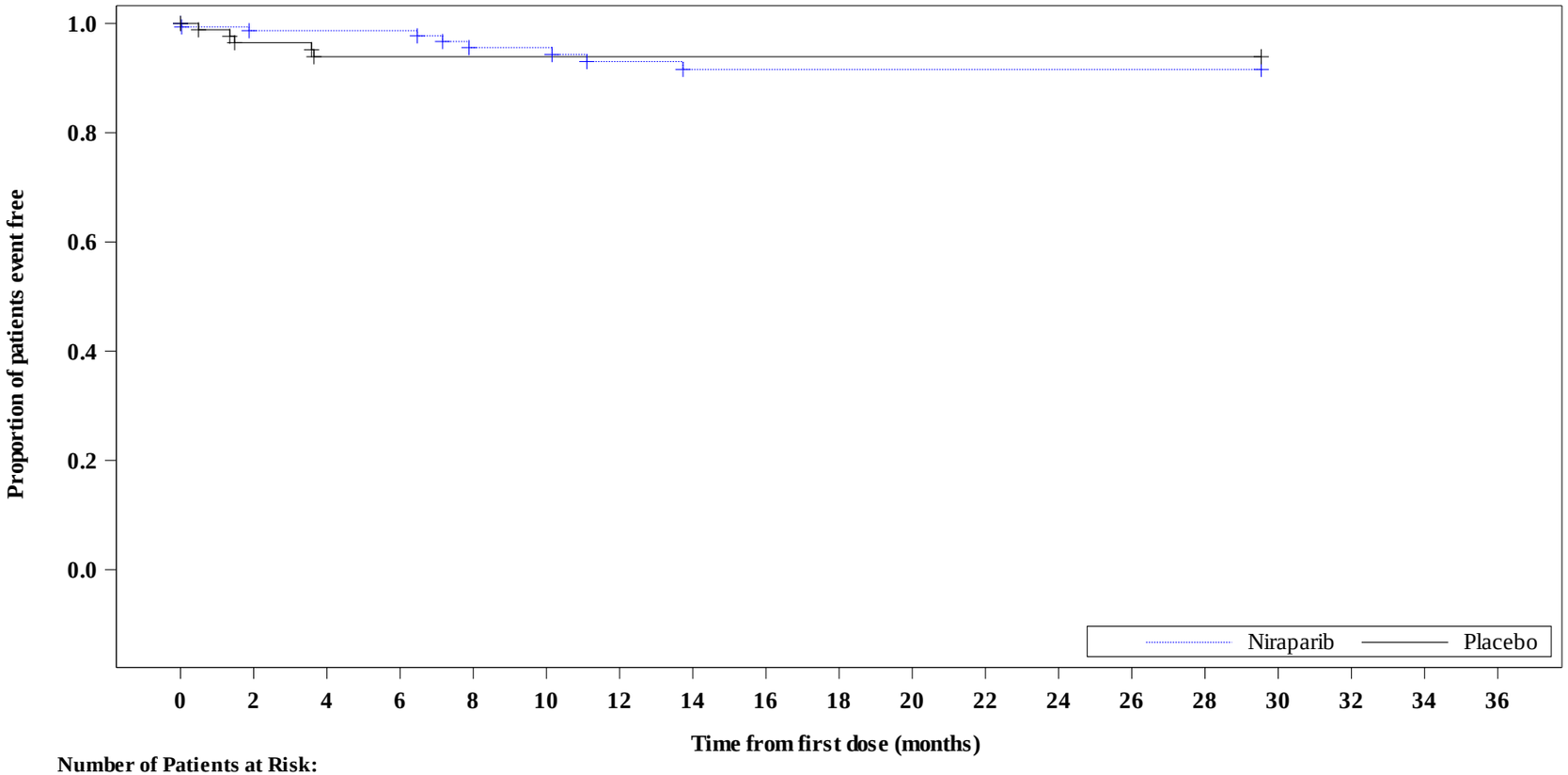
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Dyspepsia

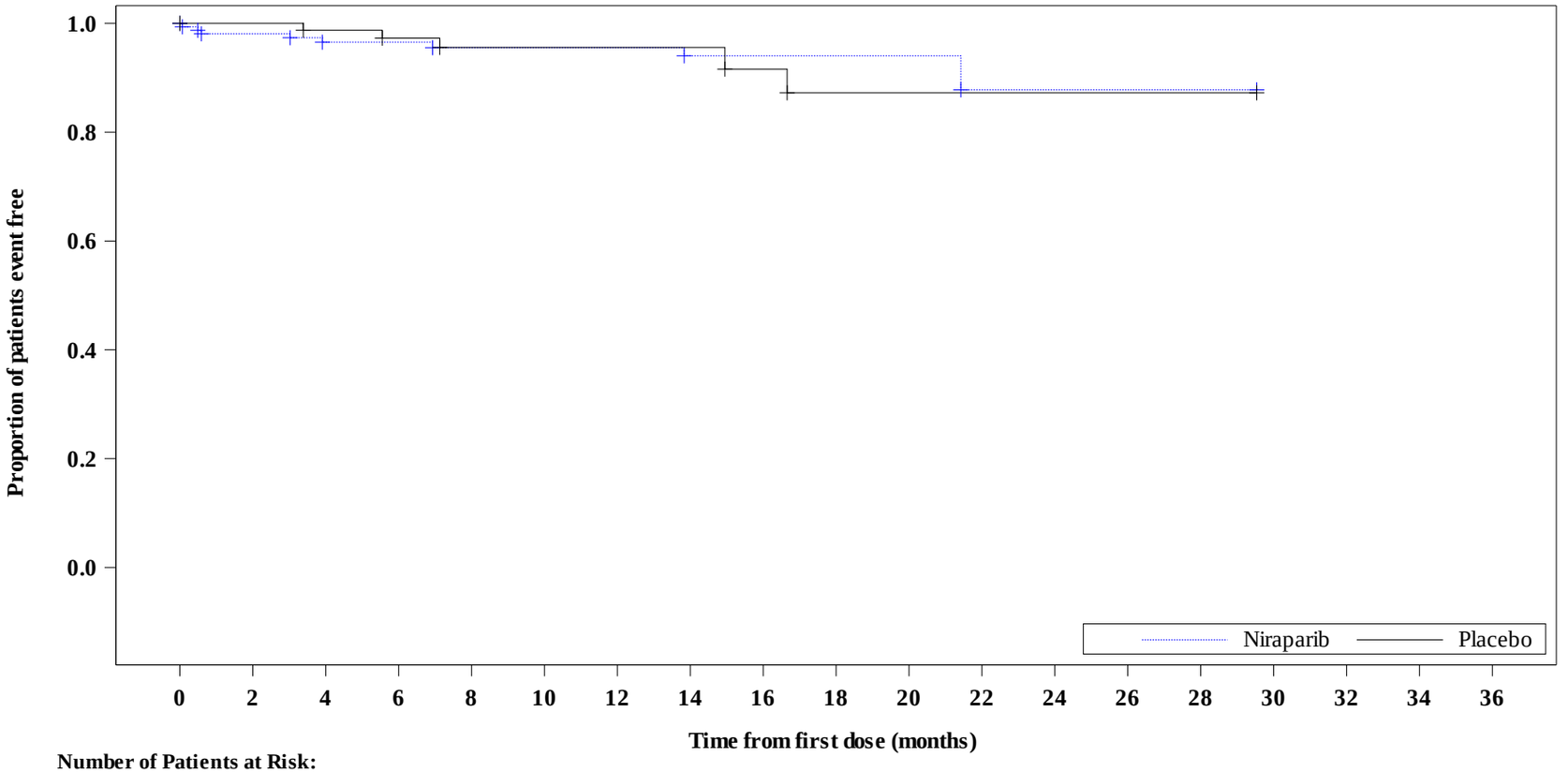



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 117 | 106 | 83 | 75 | 70 | 64 | 53 | 47 | 28 | 14 | 8 | 4 | 1 | 0 |
| Placebo | 86 | 81 | 70 | 64 | 52 | 38 | 33 | 25 | 20 | 17 | 13 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease

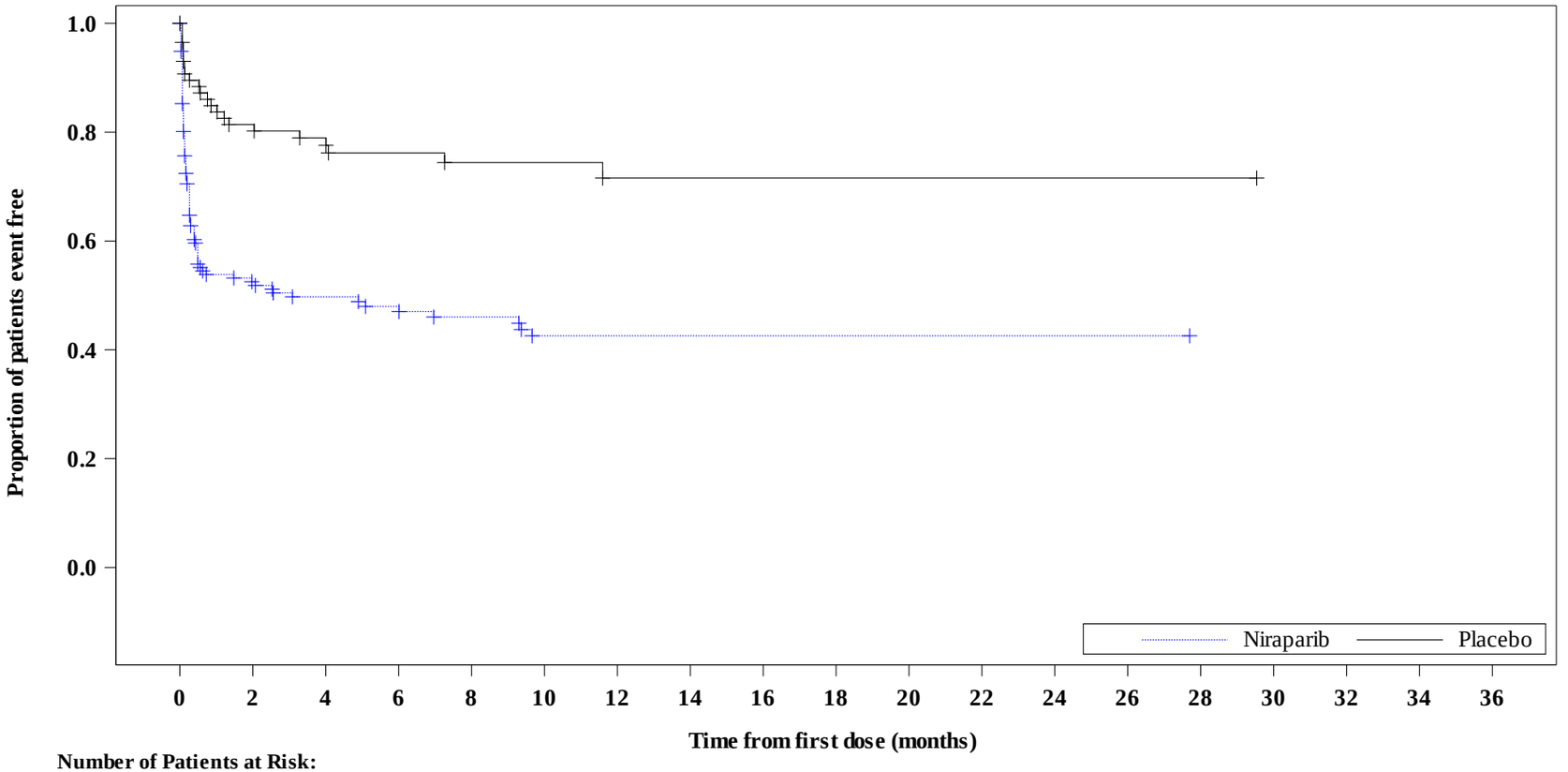



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 141 | 115 | 104 | 83 | 74 | 70 | 63 | 52 | 46 | 28 | 12 | 7 | 3 | 1 | 0 |
| Placebo | 86 | 84 | 74 | 67 | 53 | 41 | 35 | 28 | 22 | 17 | 12 | 4 | 2 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Nausea




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 77 | 56 | 51 | 42 | 36 | 33 | 30 | 26 | 25 | 12 | 5 | 2 | 1 | 0 | |
| Placebo | 86 | 69 | 58 | 50 | 41 | 31 | 25 | 19 | 16 | 14 | 10 | 5 | 3 | 2 | 1 | 0 |

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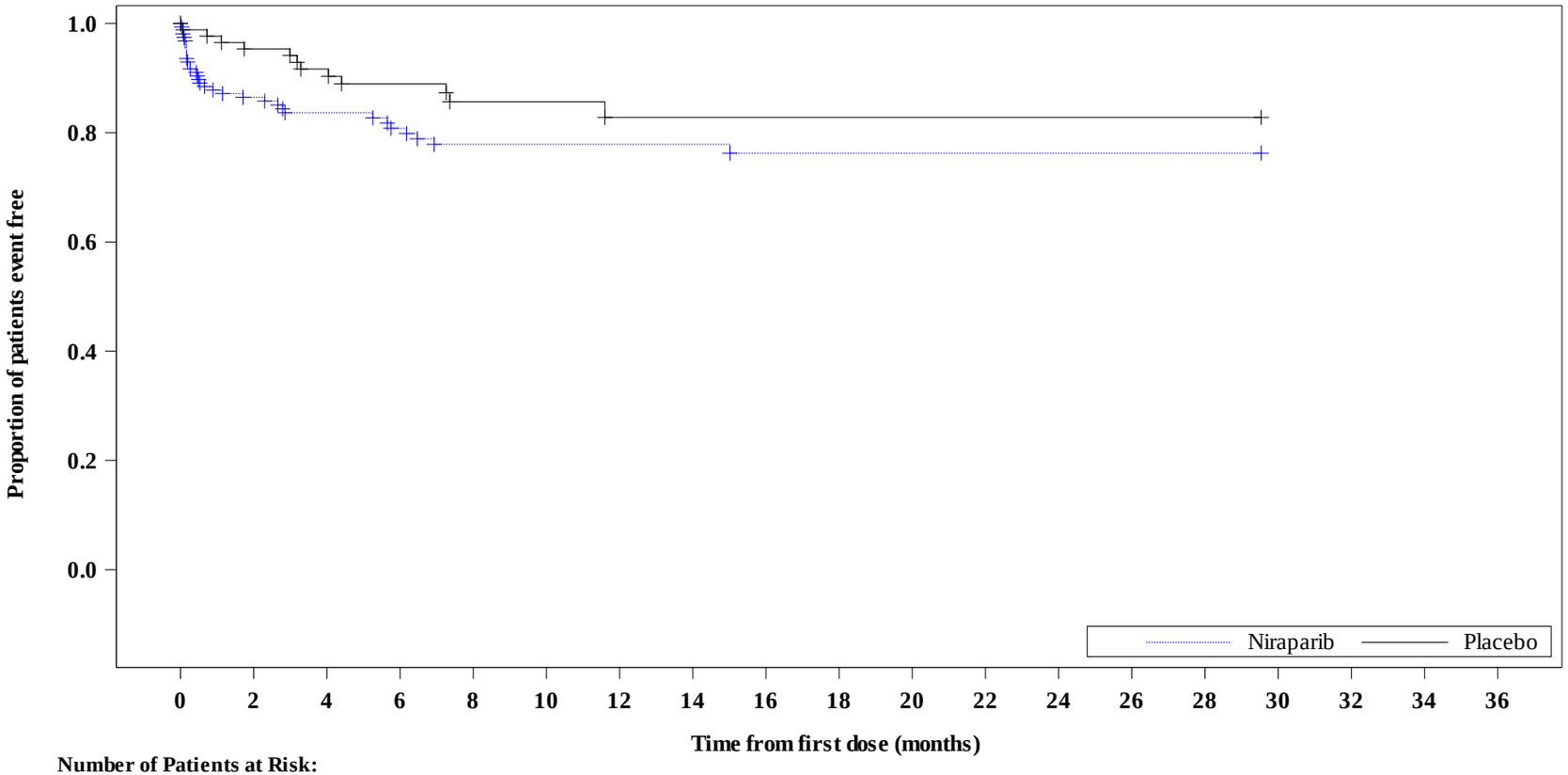
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders, PT: Vomiting




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 124 | 98 | 85 | 66 | 62 | 58 | 53 | 44 | 39 | 21 | 10 | 6 | 4 | 1 | 0 |
| Placebo | 86 | 81 | 70 | 62 | 49 | 36 | 29 | 23 | 20 | 17 | 13 | 5 | 3 | 2 | 1 | 0 |

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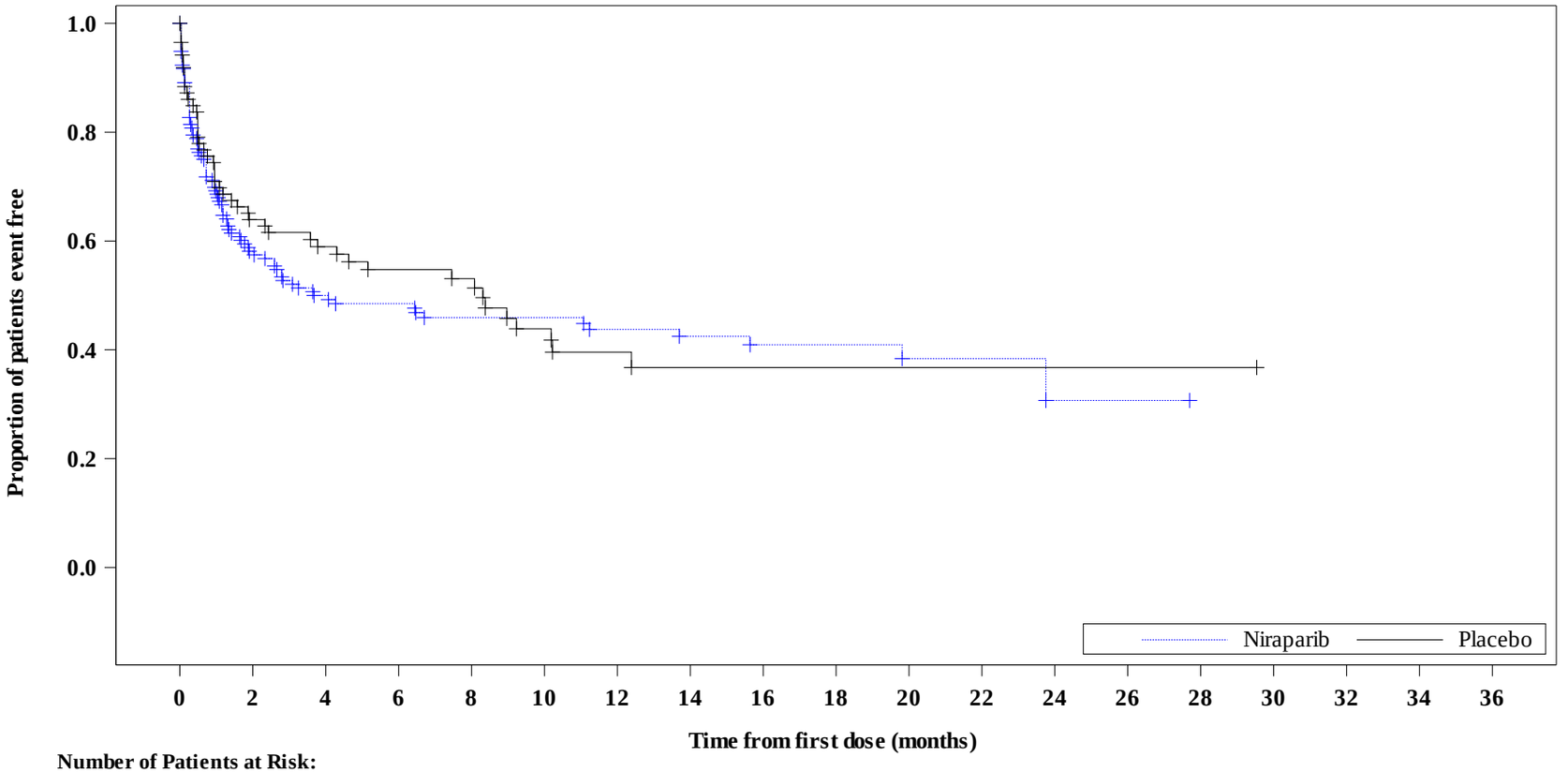
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: General disorders and administration site conditions




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 87 | 66 | 61 | 45 | 43 | 39 | 33 | 25 | 22 | 15 | 7 | 4 | 2 | 0 | |
| Placebo | 86 | 54 | 44 | 37 | 31 | 21 | 15 | 11 | 10 | 10 | 8 | 3 | 2 | 2 | 1 | 0 |

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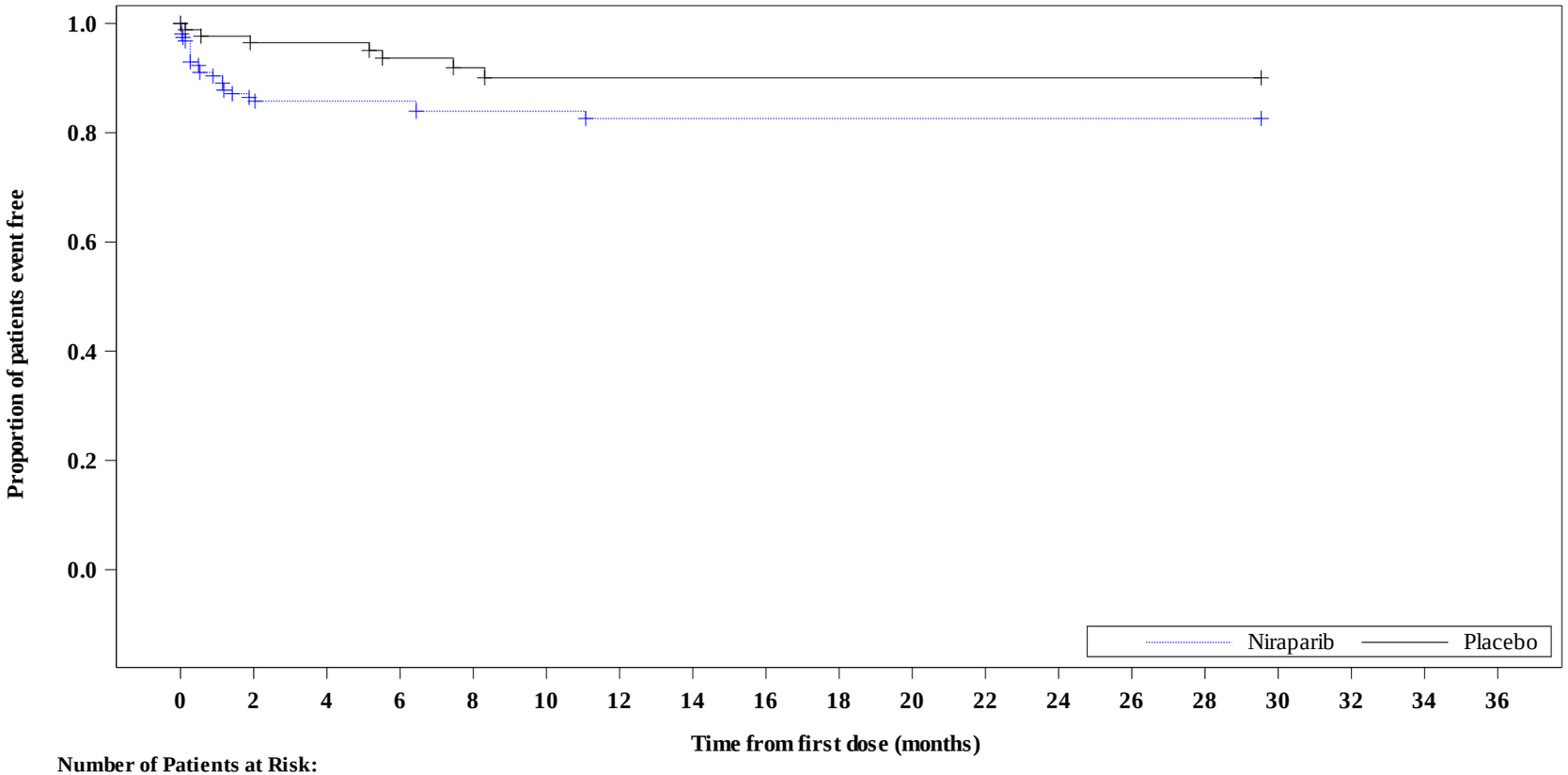
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Asthenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 127 | 104 | 95 | 74 | 65 | 61 | 54 | 43 | 39 | 27 | 14 | 8 | 4 | 1 | 0 |
| Placebo | 86 | 81 | 73 | 65 | 52 | 38 | 32 | 24 | 20 | 16 | 13 | 4 | 2 | 2 | 1 | 0 |

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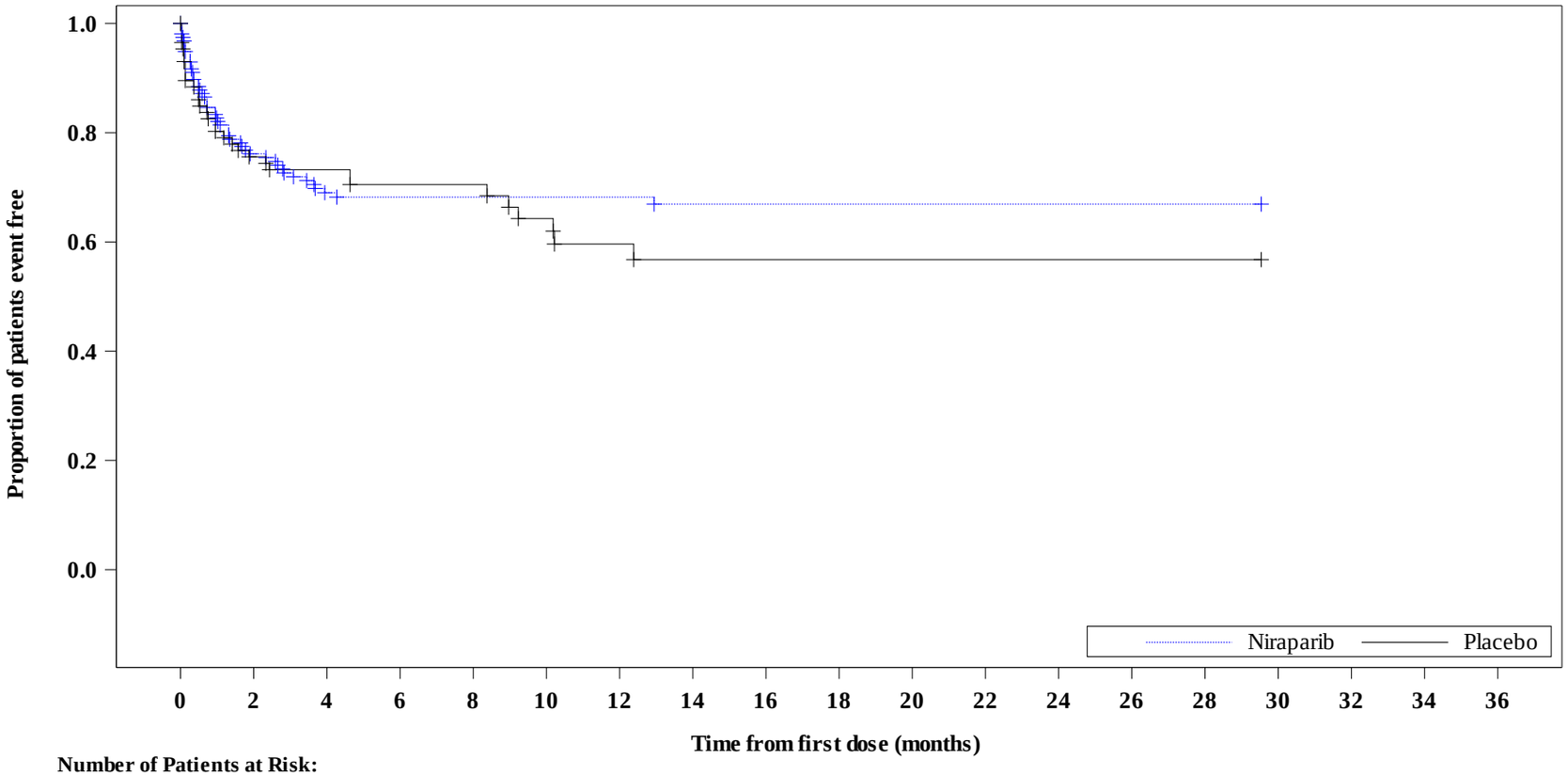
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Fatigue




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 112 | 87 | 81 | 65 | 61 | 57 | 51 | 43 | 38 | 22 | 10 | 7 | 4 | 1 | 0 |
| Placebo | 86 | 64 | 56 | 50 | 37 | 28 | 22 | 17 | 16 | 13 | 9 | 4 | 3 | 2 | 1 | 0 |

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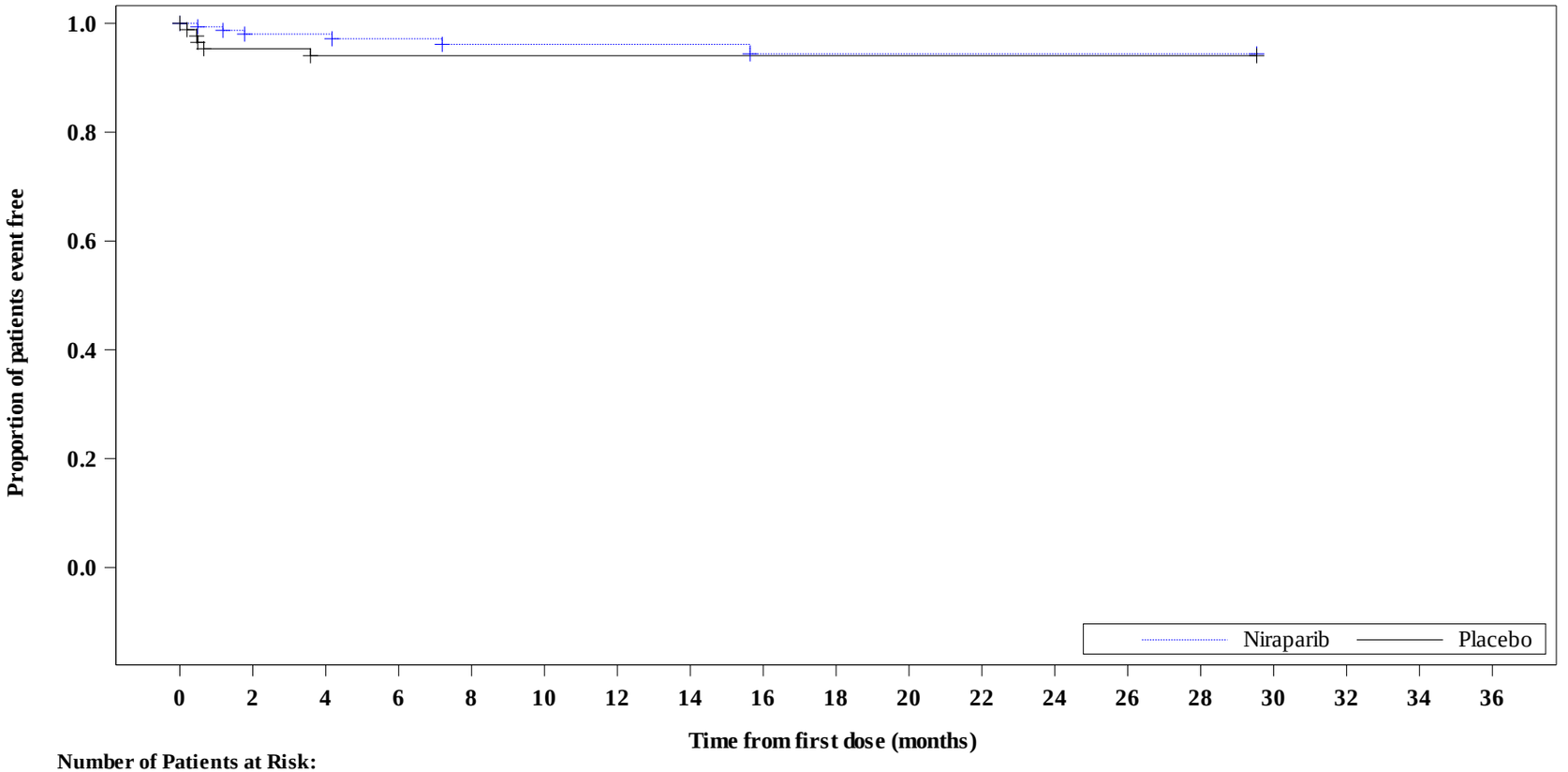
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Oedema peripheral

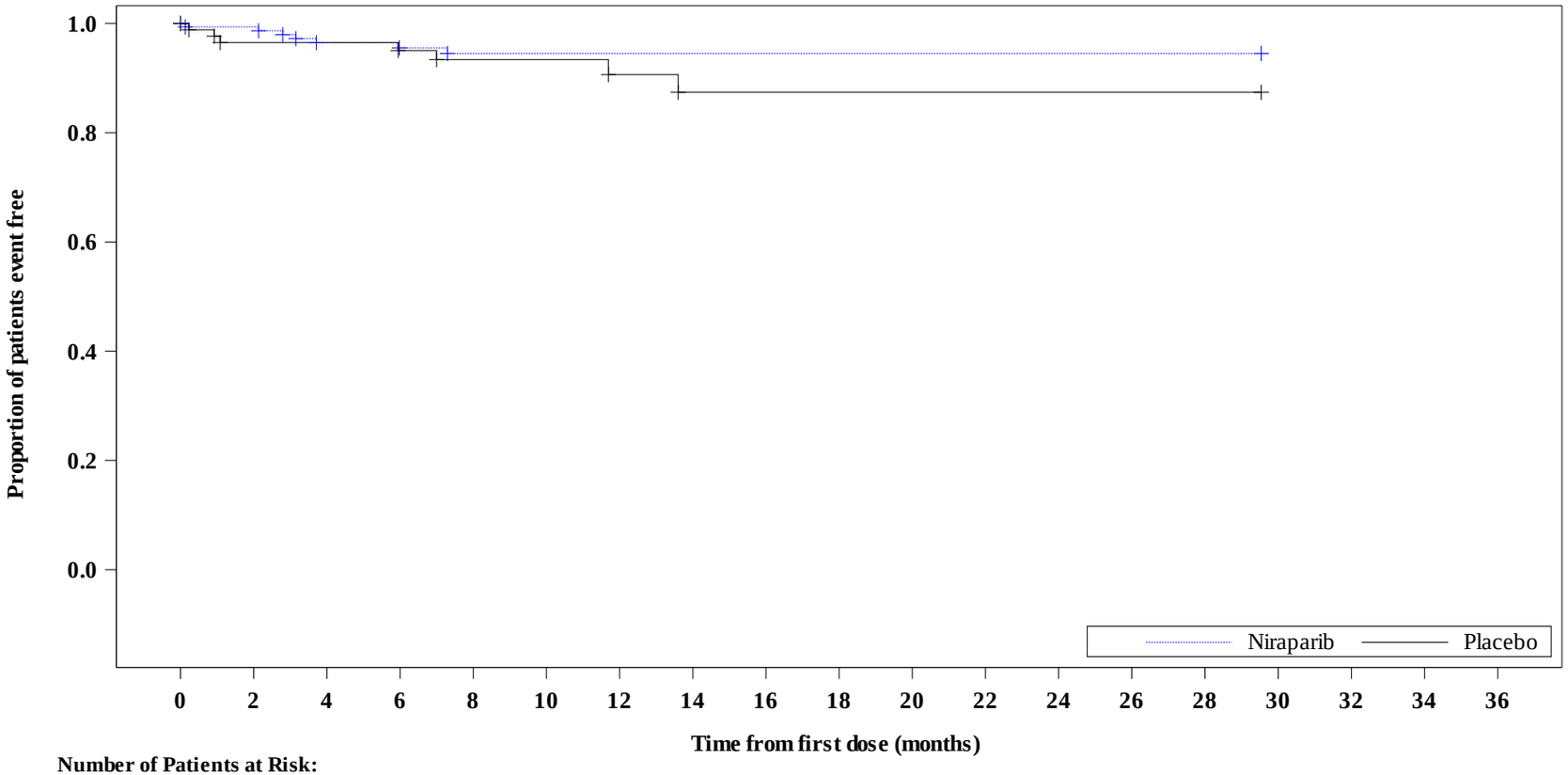



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 116 | 104 | 84 | 76 | 72 | 65 | 53 | 47 | 28 | 13 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 80 | 70 | 65 | 54 | 40 | 34 | 27 | 22 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: General disorders and administration site conditions, PT: Pyrexia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 143 | 114 | 103 | 83 | 74 | 70 | 63 | 51 | 45 | 28 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 81 | 72 | 65 | 53 | 39 | 33 | 25 | 21 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

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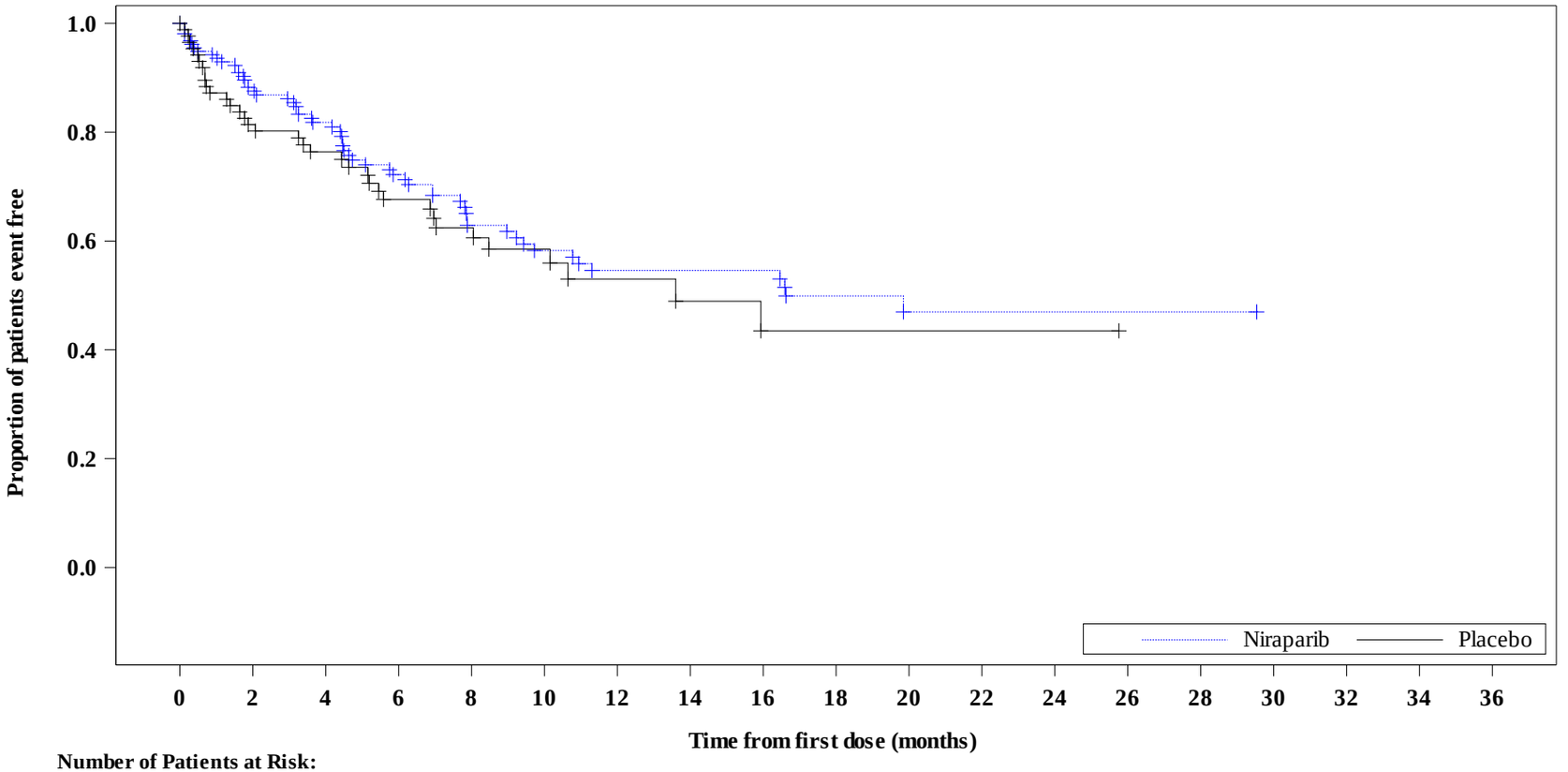
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Infections and infestations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 128 | 98 | 80 | 56 | 49 | 43 | 41 | 35 | 29 | 15 | 8 | 6 | 4 | 2 | 0 |
| Placebo | 86 | 69 | 57 | 45 | 34 | 23 | 16 | 11 | 8 | 7 | 5 | 1 | 1 | 0 | | |

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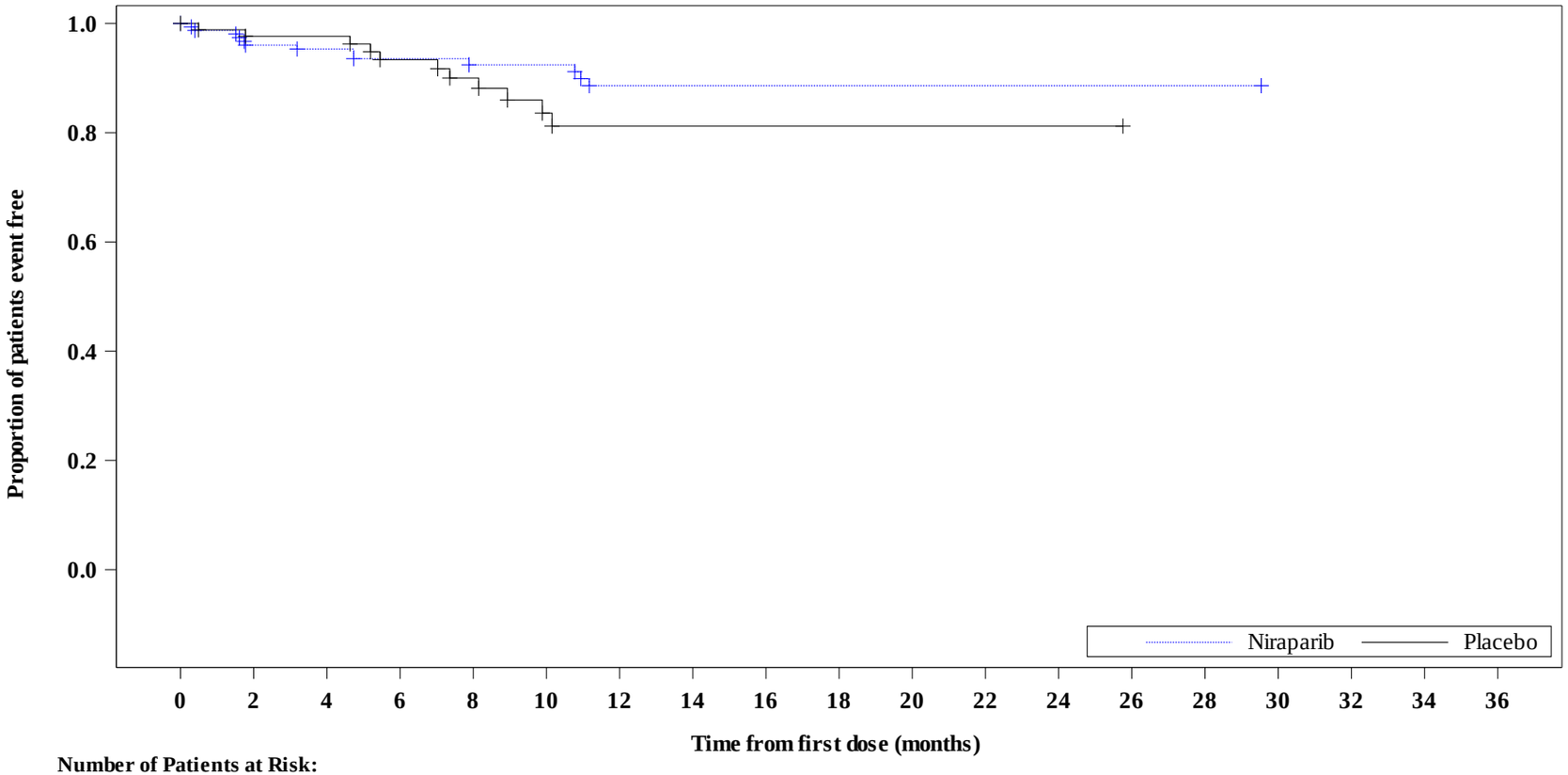
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Infections and infestations, PT: Nasopharyngitis




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 140 | 113 | 100 | 80 | 74 | 67 | 61 | 52 | 46 | 28 | 13 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 82 | 73 | 64 | 50 | 35 | 28 | 22 | 18 | 14 | 10 | 3 | 1 | 0 | | |

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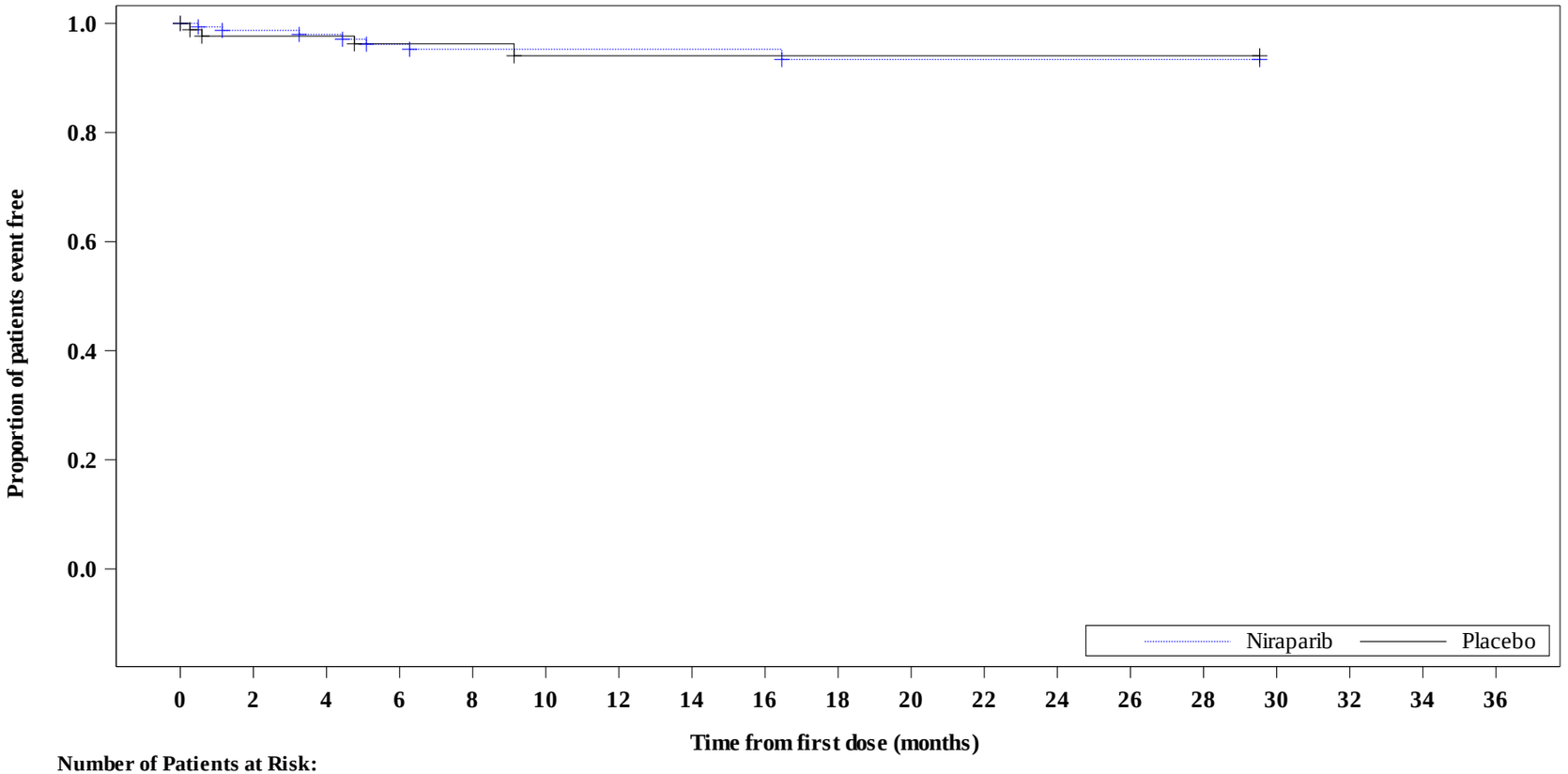
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Infections and infestations, PT: Sinusitis




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 115 | 103 | 83 | 75 | 71 | 64 | 52 | 46 | 28 | 13 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 82 | 73 | 66 | 53 | 38 | 33 | 26 | 21 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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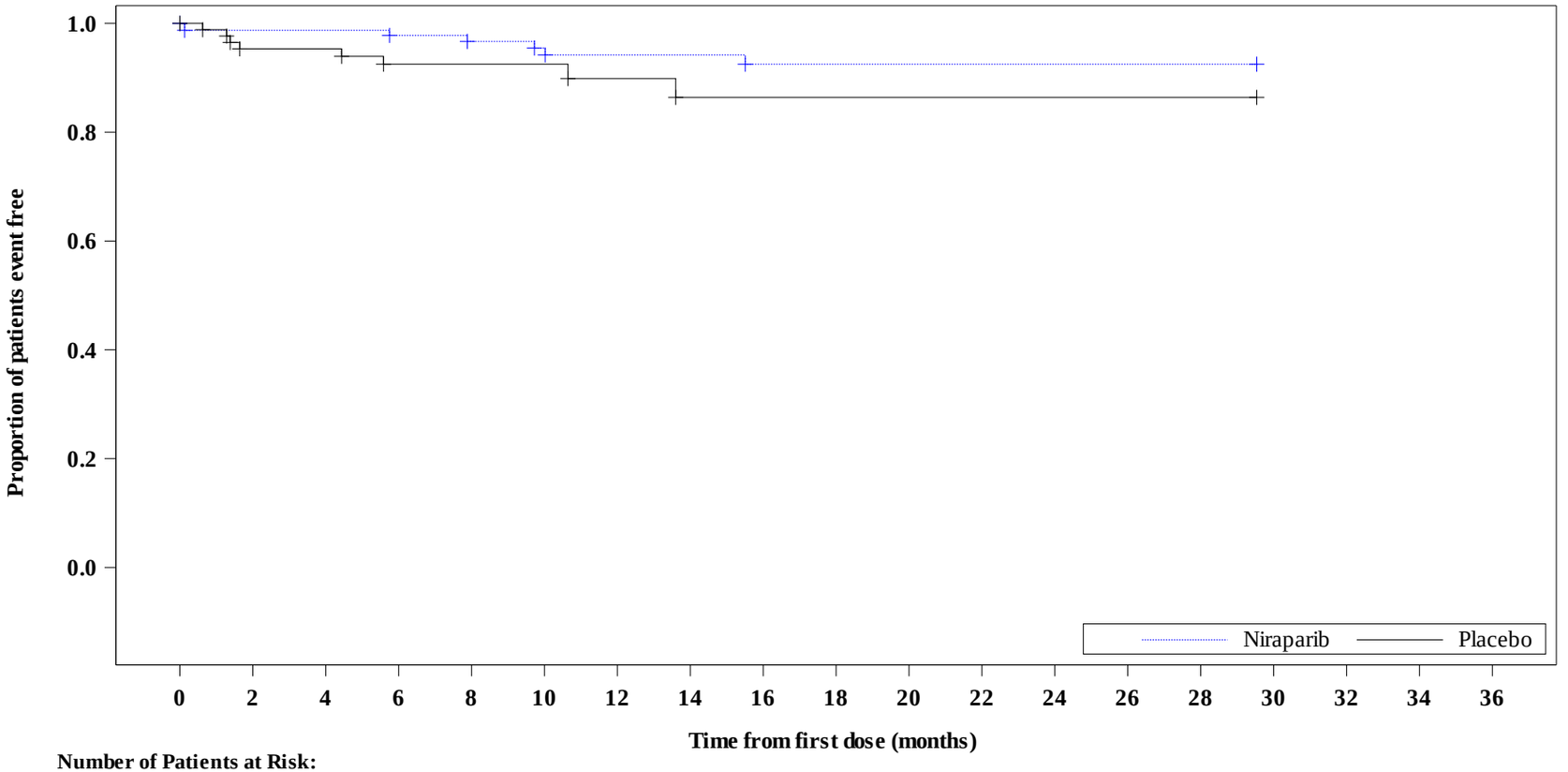
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Infections and infestations, PT: Upper respiratory tract infection

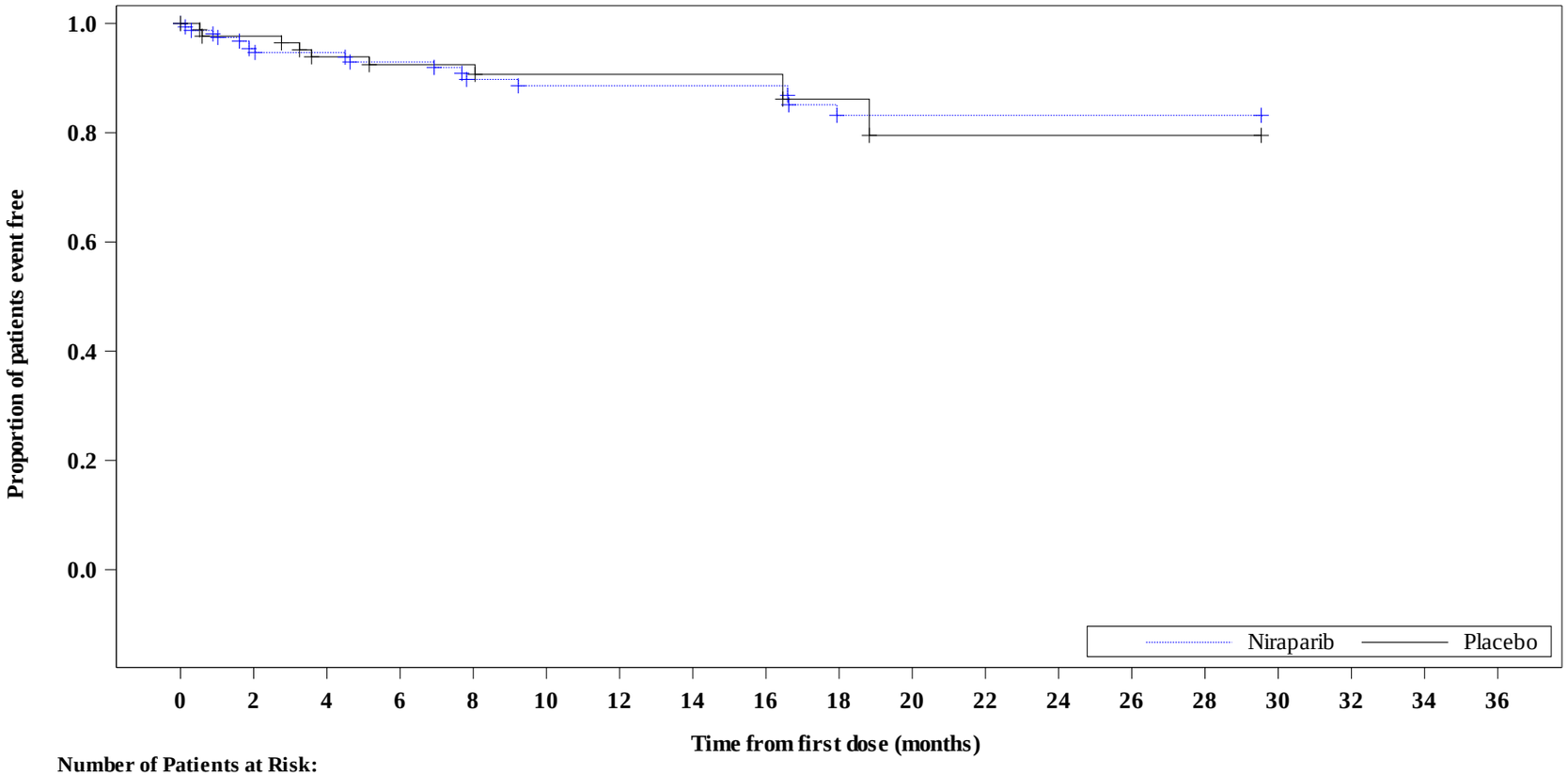



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 118 | 106 | 85 | 76 | 72 | 65 | 52 | 46 | 28 | 14 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 80 | 72 | 64 | 51 | 38 | 31 | 22 | 19 | 15 | 11 | 4 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Infections and infestations, PT: Urinary tract infection

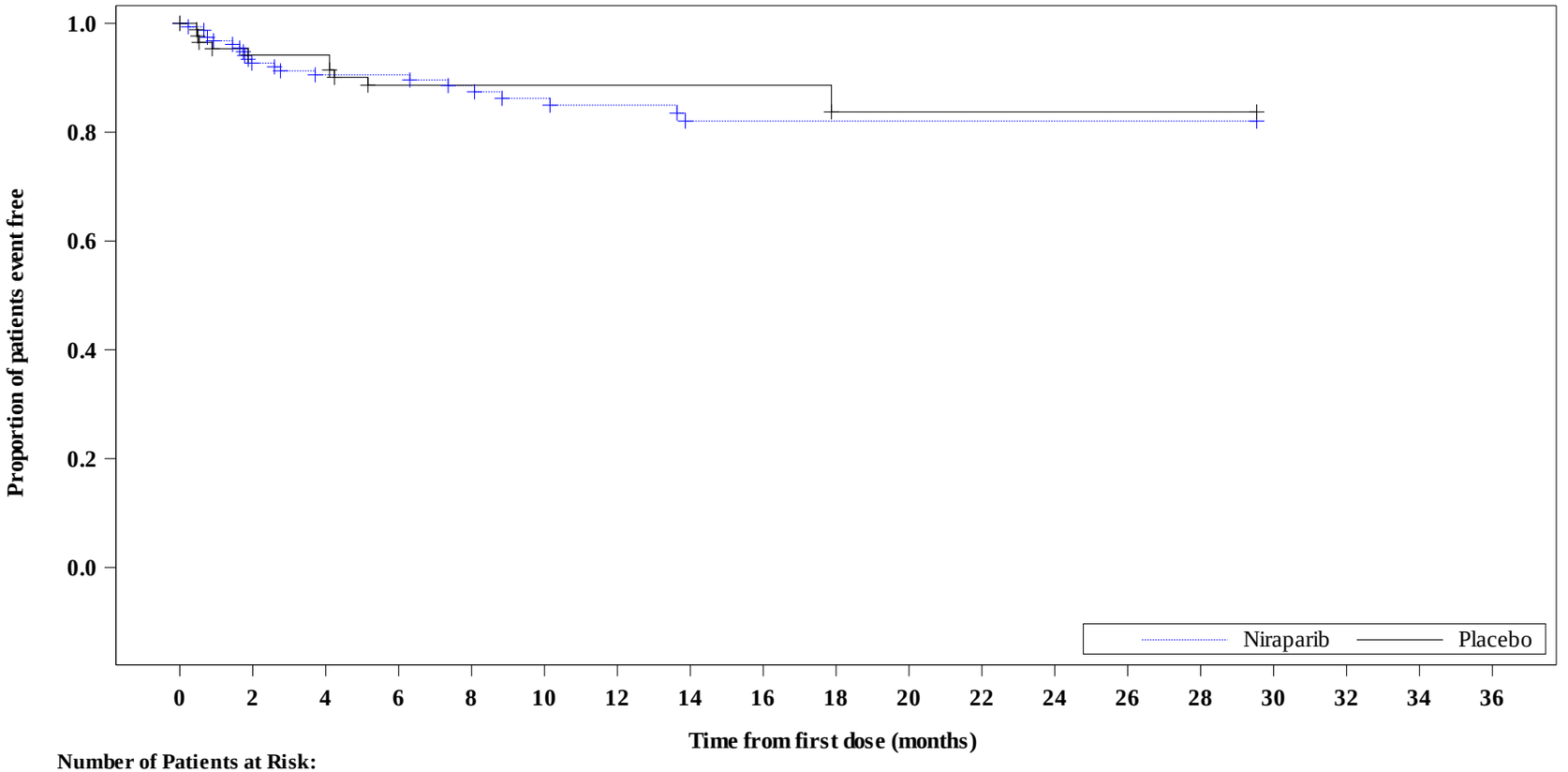



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 137 | 113 | 101 | 81 | 72 | 68 | 62 | 51 | 43 | 27 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 82 | 70 | 63 | 52 | 37 | 32 | 25 | 20 | 16 | 12 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Injury, poisoning and procedural complications




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 133 | 108 | 97 | 77 | 68 | 64 | 56 | 47 | 42 | 25 | 11 | 6 | 4 | 2 | 0 |
| Placebo | 86 | 79 | 70 | 61 | 51 | 38 | 33 | 26 | 22 | 17 | 12 | 4 | 2 | 2 | 1 | 0 |

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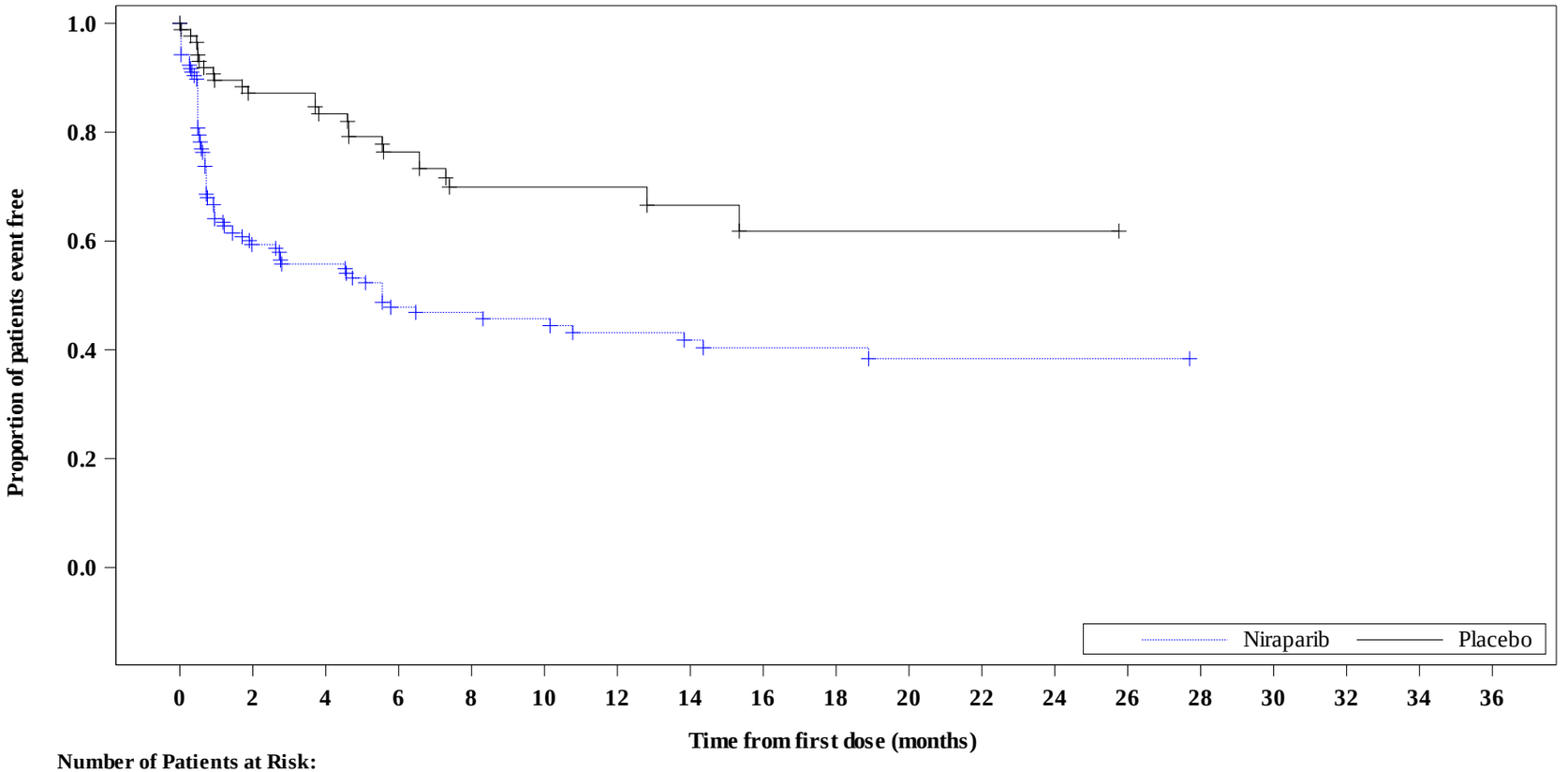
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 83 | 66 | 52 | 40 | 36 | 33 | 30 | 25 | 23 | 13 | 6 | 3 | 2 | 0 |
| Placebo | 86 | 73 | 64 | 54 | 40 | 29 | 24 | 17 | 13 | 11 | 7 | 2 | 1 | 0 | |

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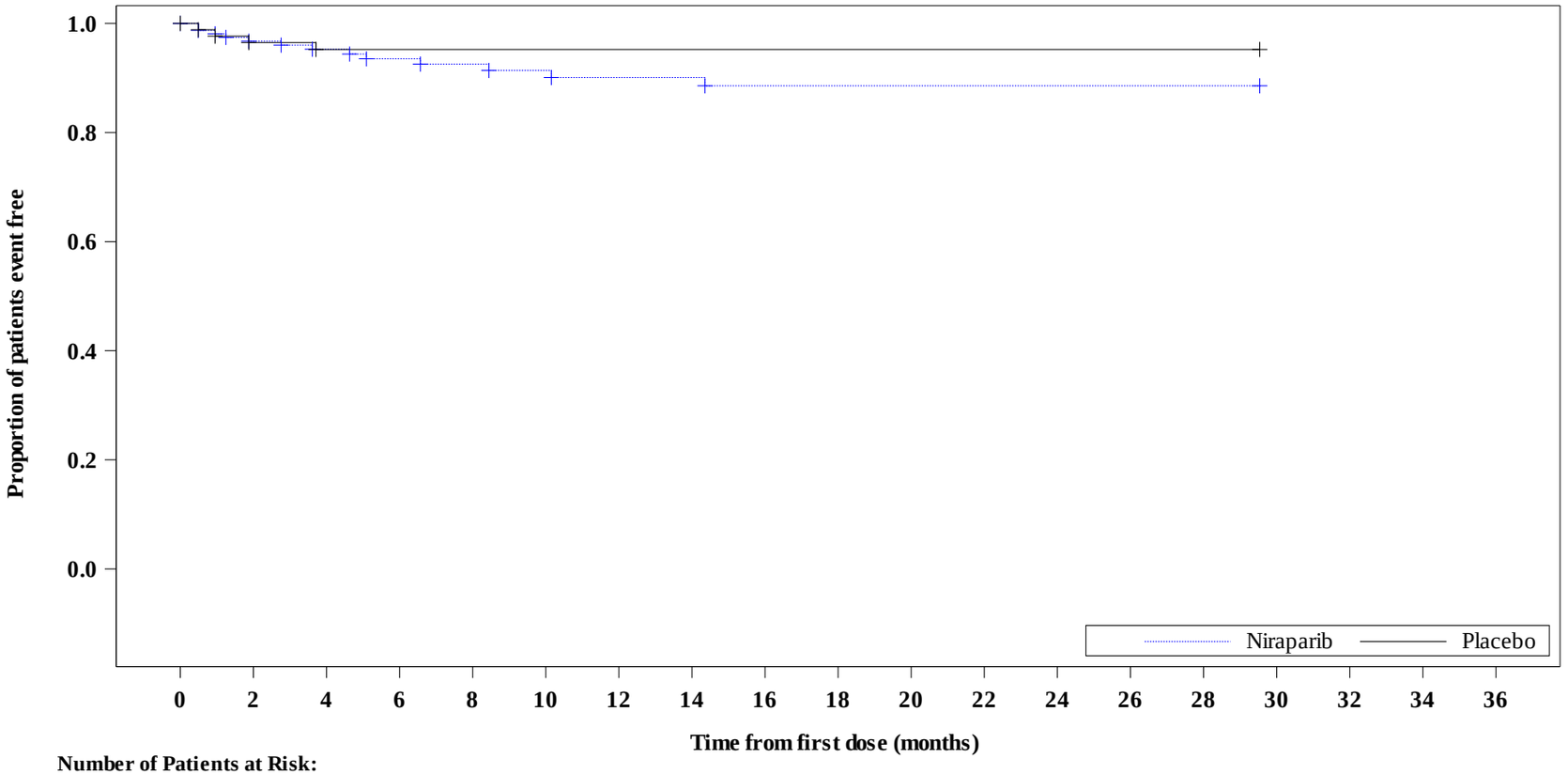
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Alanine aminotransferase increased

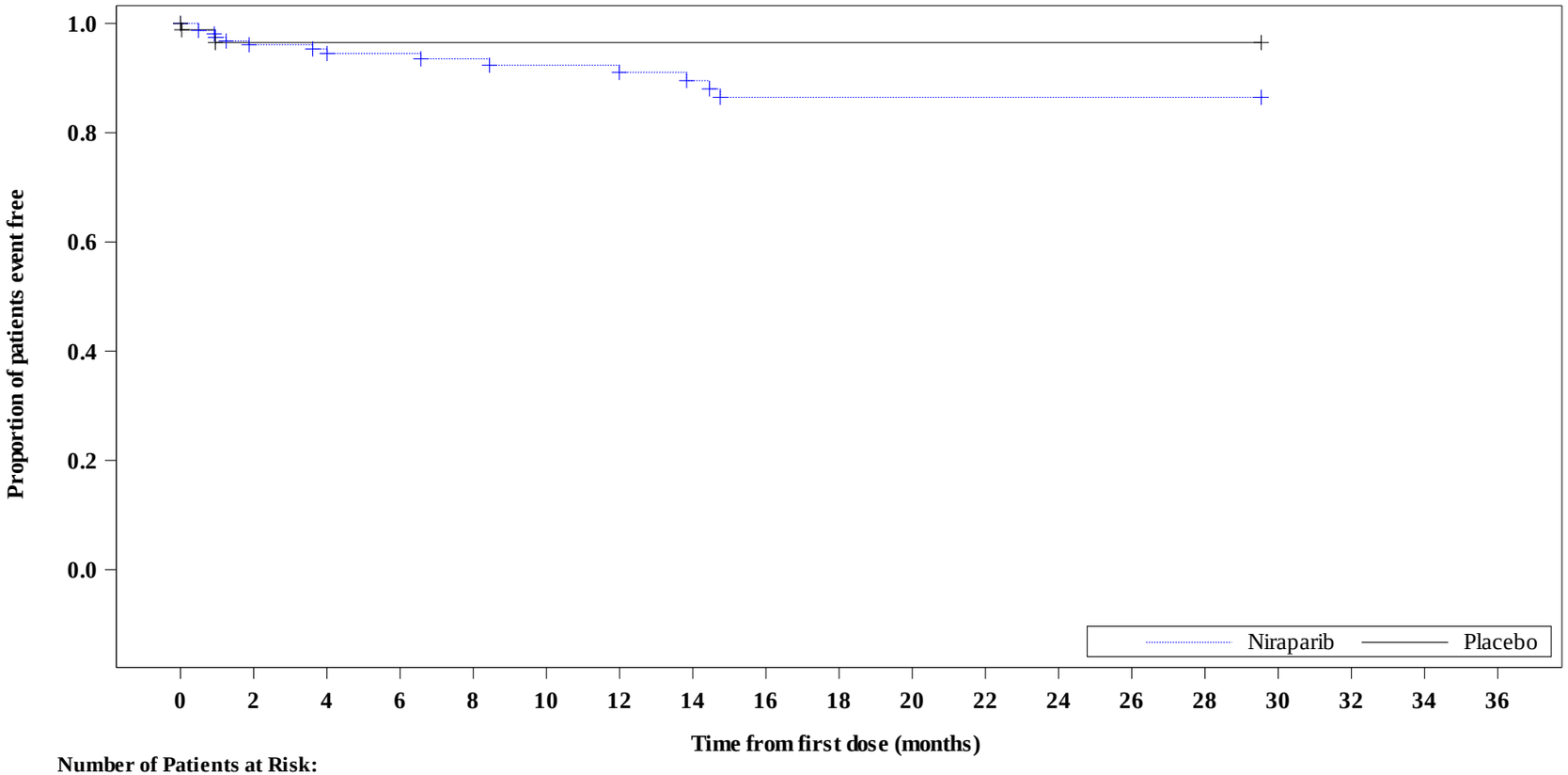



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 139 | 112 | 101 | 80 | 71 | 66 | 60 | 47 | 42 | 25 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 81 | 73 | 68 | 55 | 41 | 35 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Aspartate aminotransferase increased

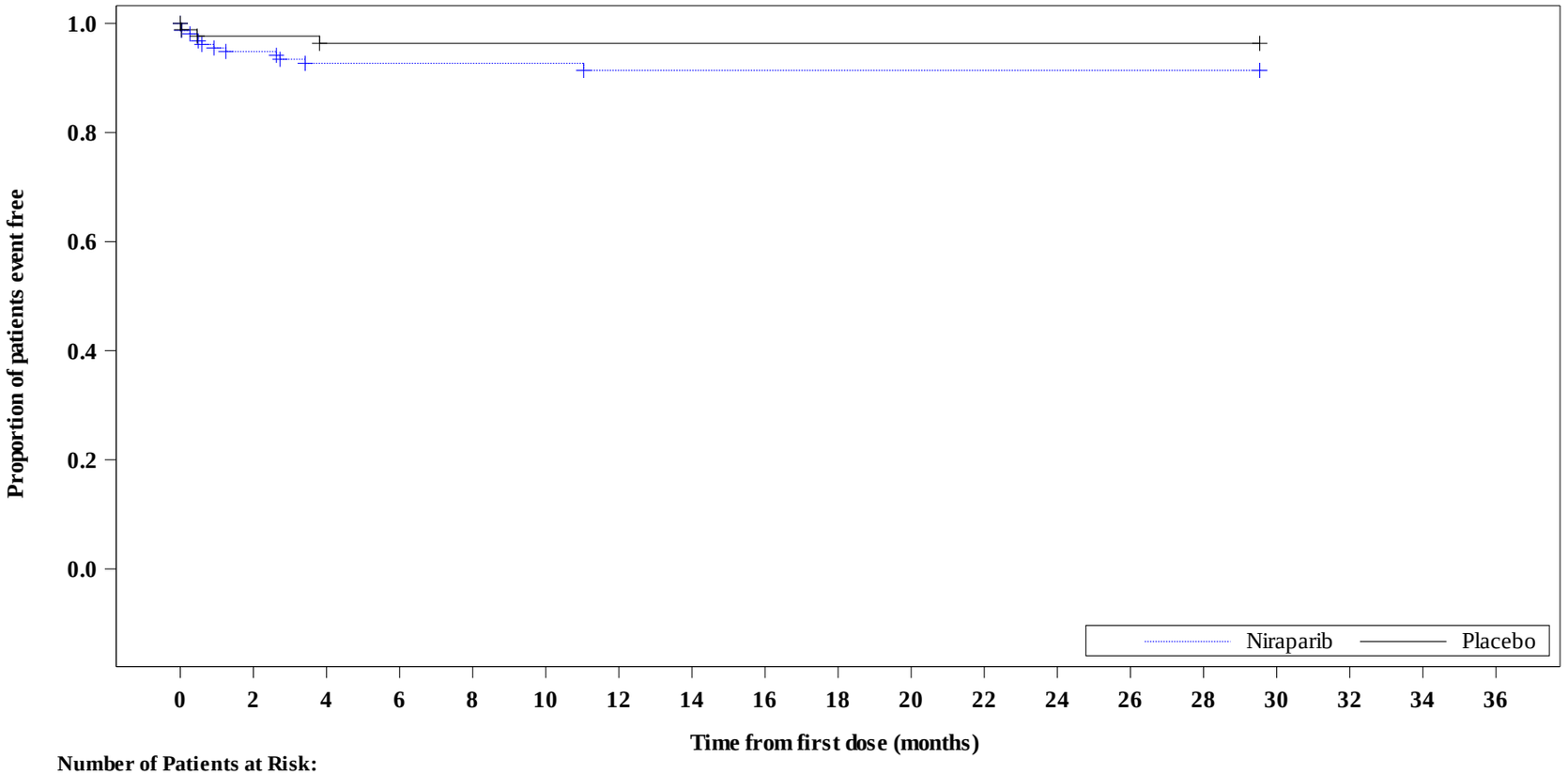



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 138 | 112 | 102 | 81 | 72 | 67 | 60 | 46 | 41 | 23 | 12 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 81 | 74 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Blood alkaline phosphatase increased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 136 | 110 | 100 | 81 | 73 | 68 | 62 | 52 | 46 | 27 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 82 | 72 | 67 | 54 | 40 | 34 | 26 | 21 | 17 | 12 | 4 | 2 | 1 | 1 | 0 |

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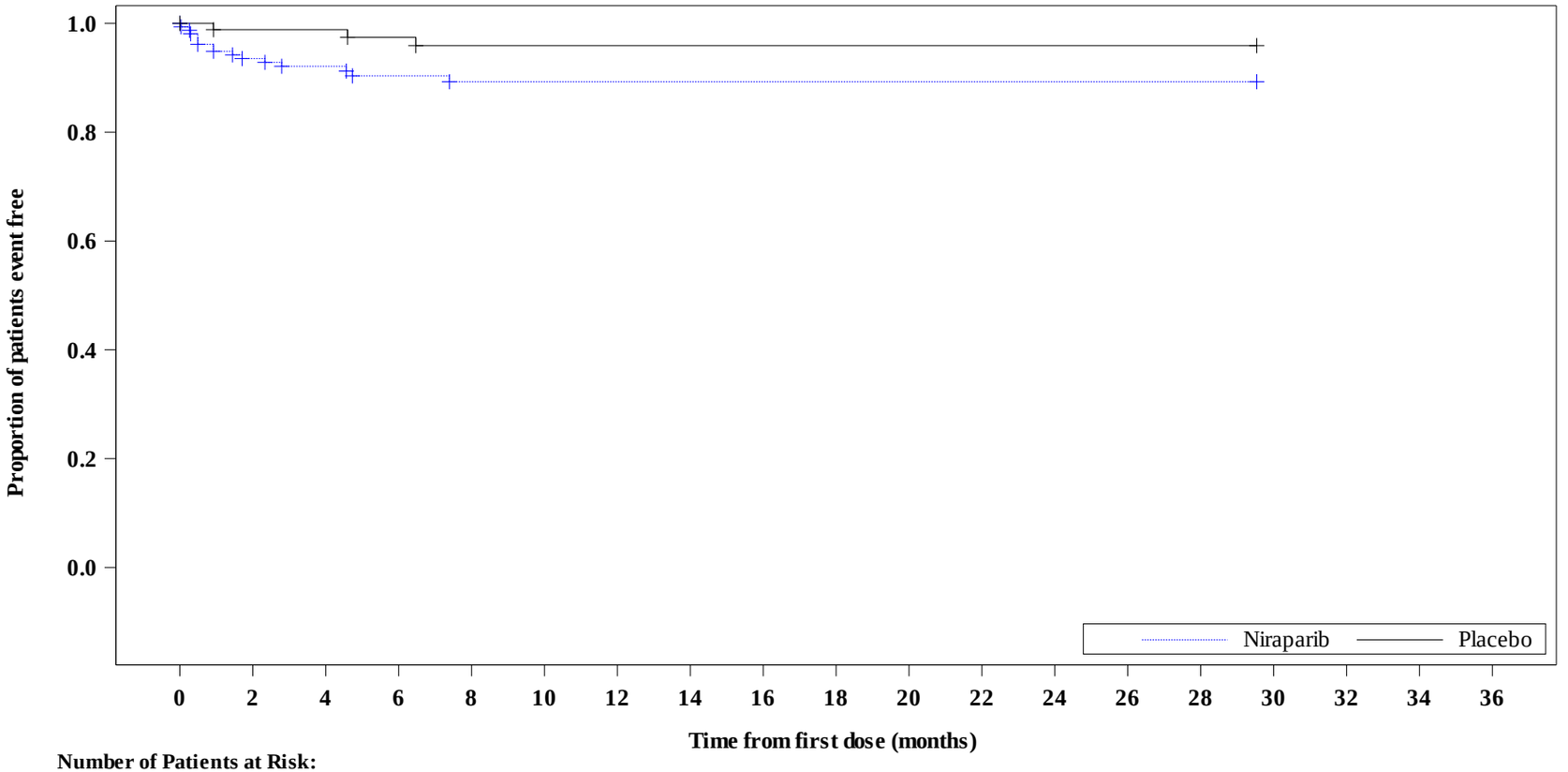
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Blood creatinine increased

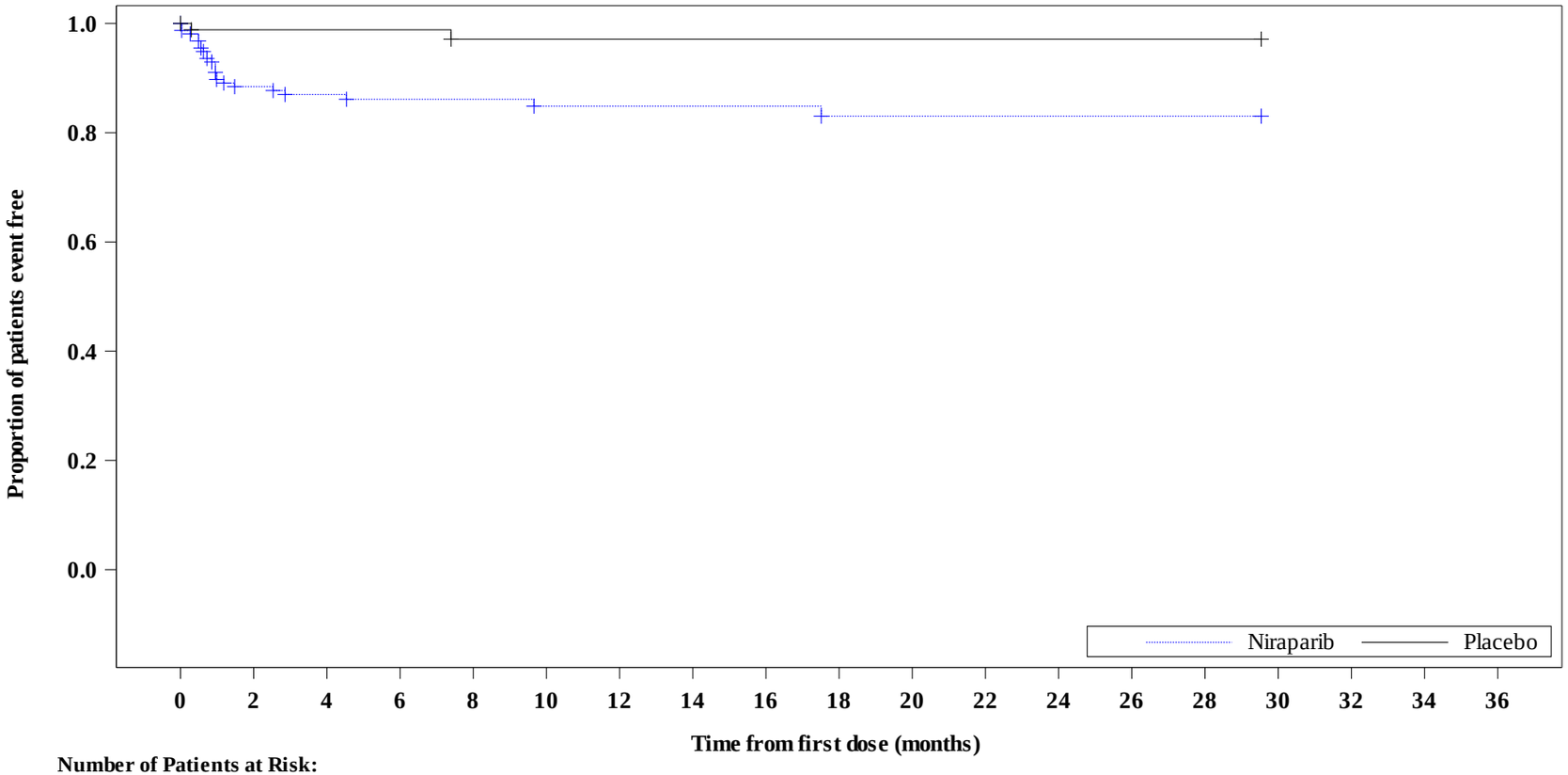



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 134 | 108 | 96 | 76 | 68 | 64 | 58 | 50 | 45 | 27 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 74 | 67 | 53 | 39 | 33 | 26 | 21 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Neutrophil count decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 126 | 103 | 92 | 74 | 67 | 63 | 60 | 48 | 43 | 26 | 13 | 7 | 4 | 1 | 0 |
| Placebo | 86 | 83 | 74 | 68 | 54 | 40 | 34 | 26 | 22 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

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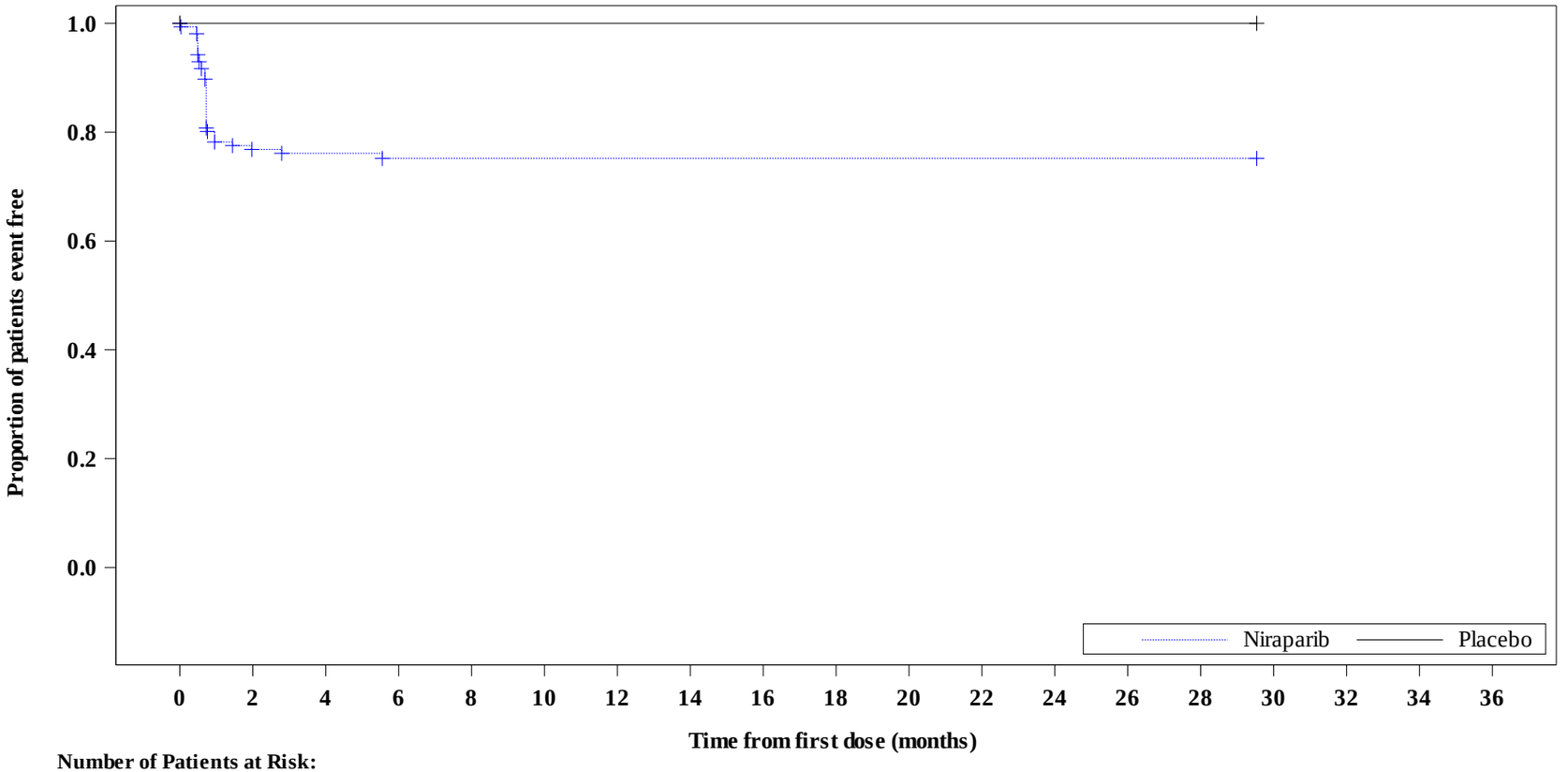
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Platelet count decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 109 | 89 | 79 | 62 | 56 | 52 | 49 | 40 | 37 | 21 | 9 | 4 | 3 | 1 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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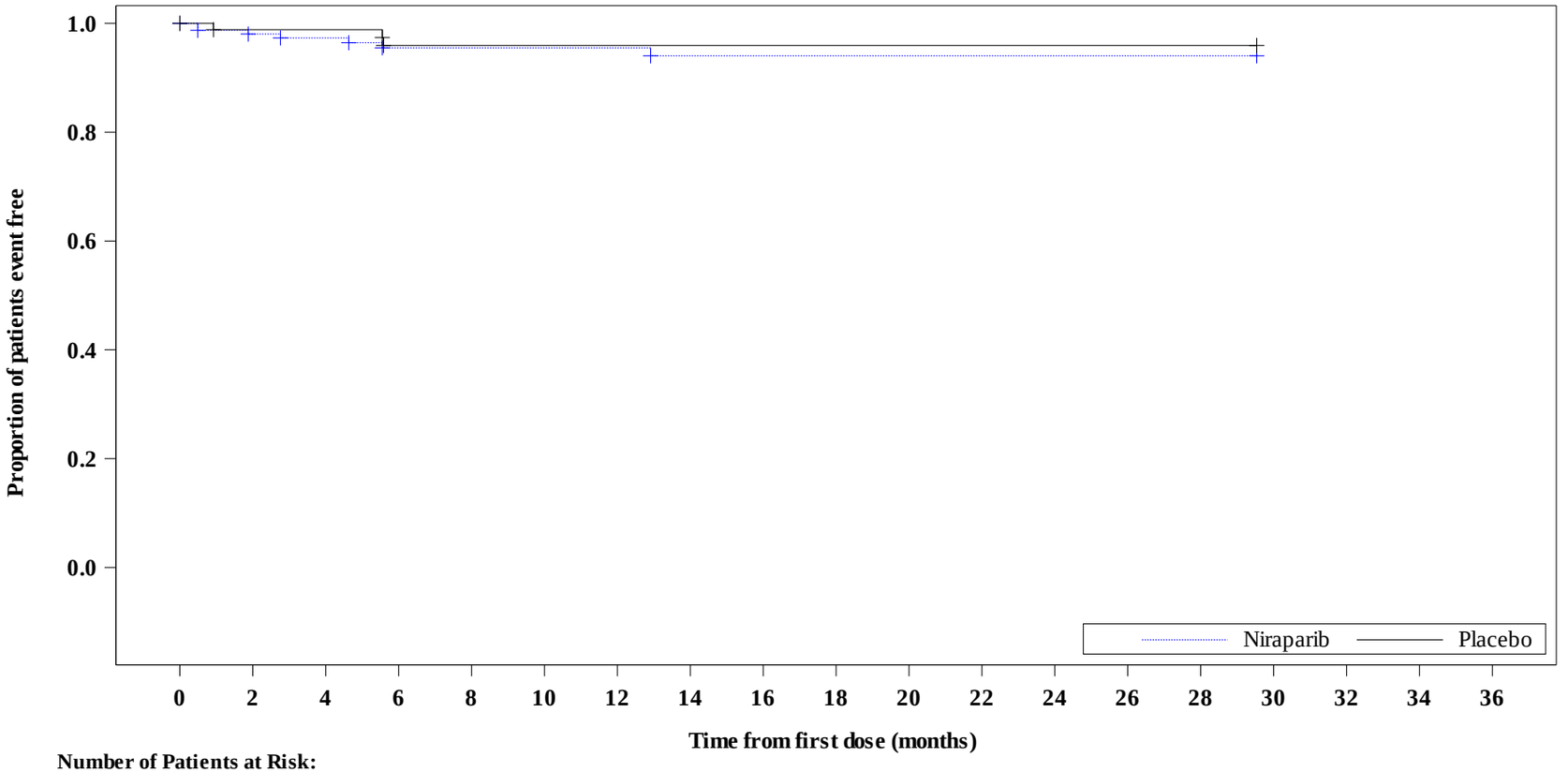
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Weight decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 115 | 102 | 82 | 73 | 70 | 62 | 50 | 44 | 26 | 12 | 6 | 3 | 1 | 0 |
| Placebo | 86 | 83 | 74 | 66 | 53 | 40 | 34 | 26 | 21 | 17 | 13 | 5 | 3 | 2 | 1 | 0 |

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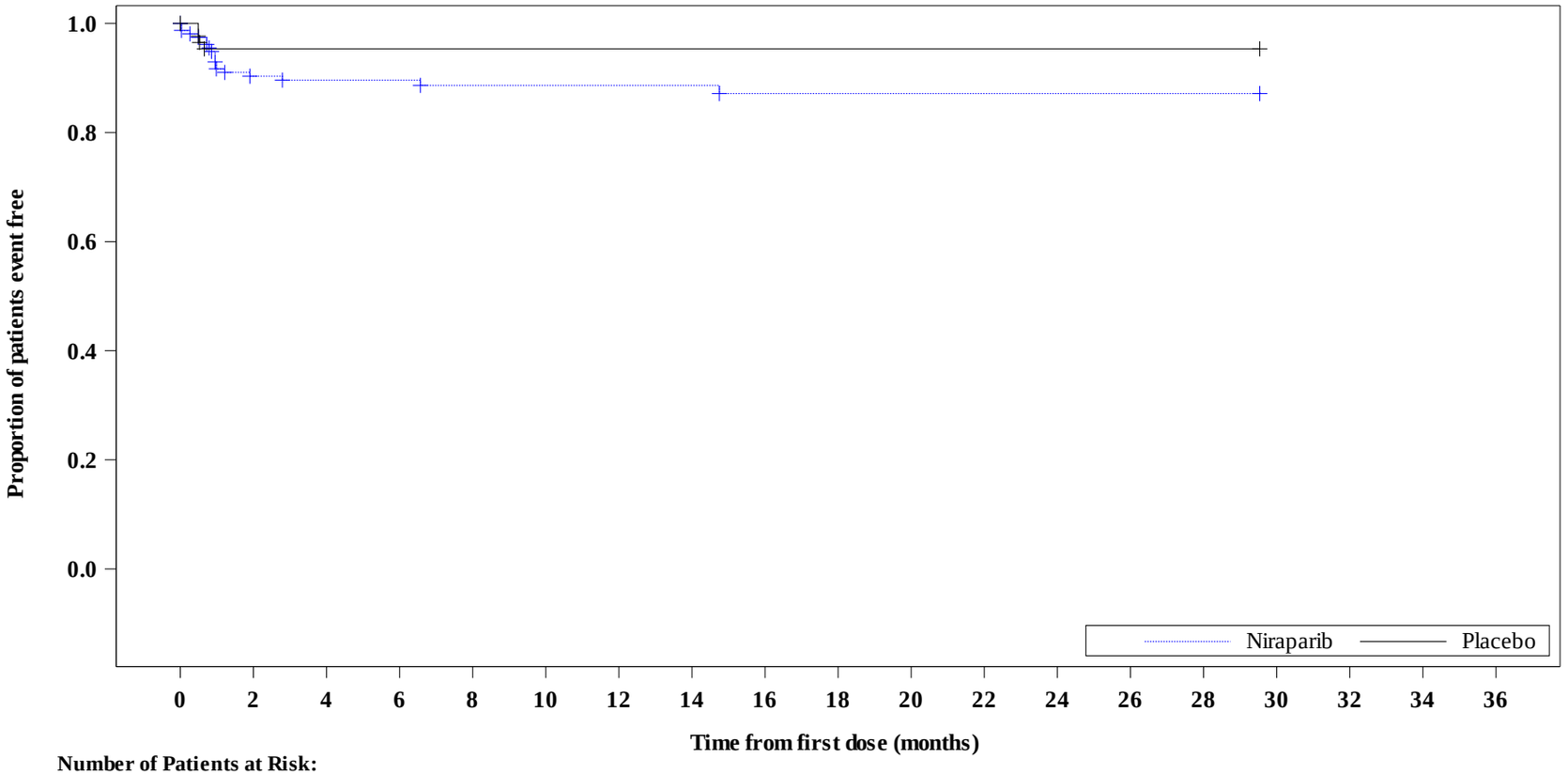
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Investigations, PT: White blood cell count decreased

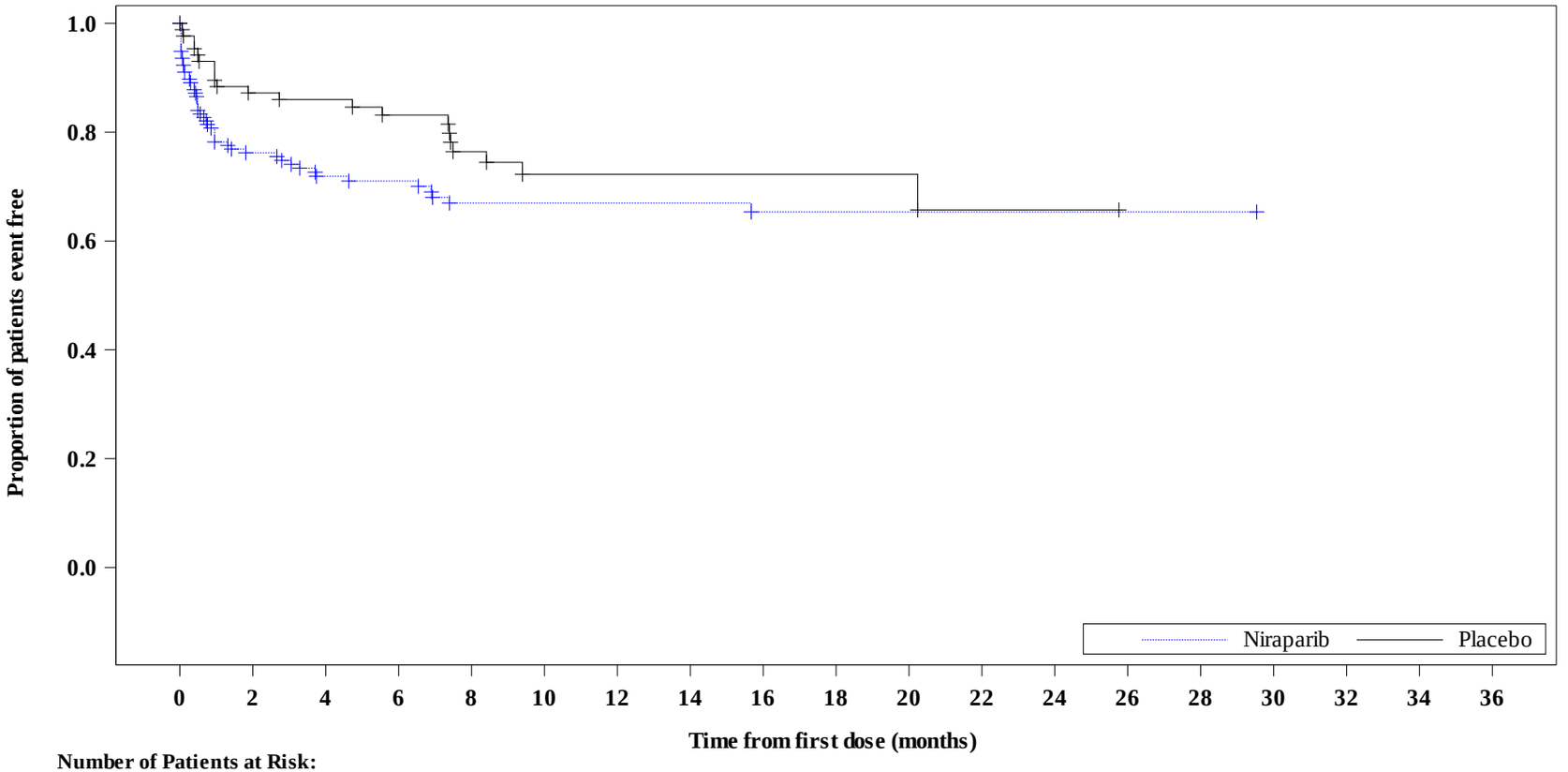



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 129 | 108 | 98 | 78 | 70 | 66 | 61 | 50 | 45 | 27 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 80 | 73 | 67 | 55 | 41 | 35 | 27 | 22 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Metabolism and nutrition disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 110 | 87 | 77 | 59 | 54 | 52 | 48 | 40 | 34 | 21 | 11 | 6 | 3 | 1 | 0 |
| Placebo | 86 | 74 | 65 | 57 | 43 | 32 | 27 | 21 | 17 | 15 | 12 | 3 | 1 | 0 | | |

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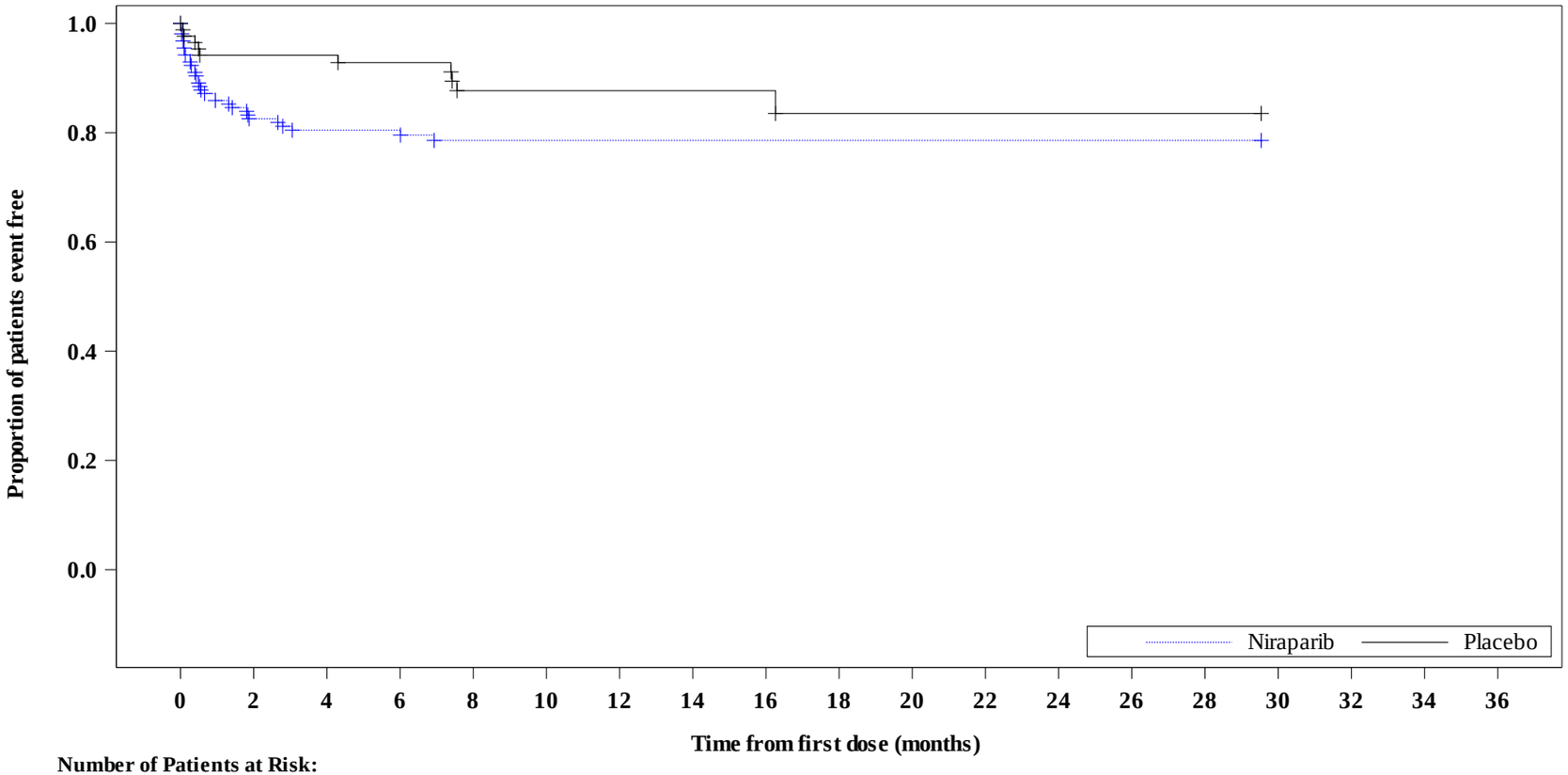
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Metabolism and nutrition disorders, PT: Decreased appetite




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 120 | 99 | 89 | 71 | 65 | 61 | 55 | 45 | 39 | 24 | 11 | 6 | 3 | 1 | 0 |
| Placebo | 86 | 80 | 71 | 64 | 49 | 39 | 33 | 25 | 21 | 17 | 13 | 5 | 3 | 2 | 1 | 0 |

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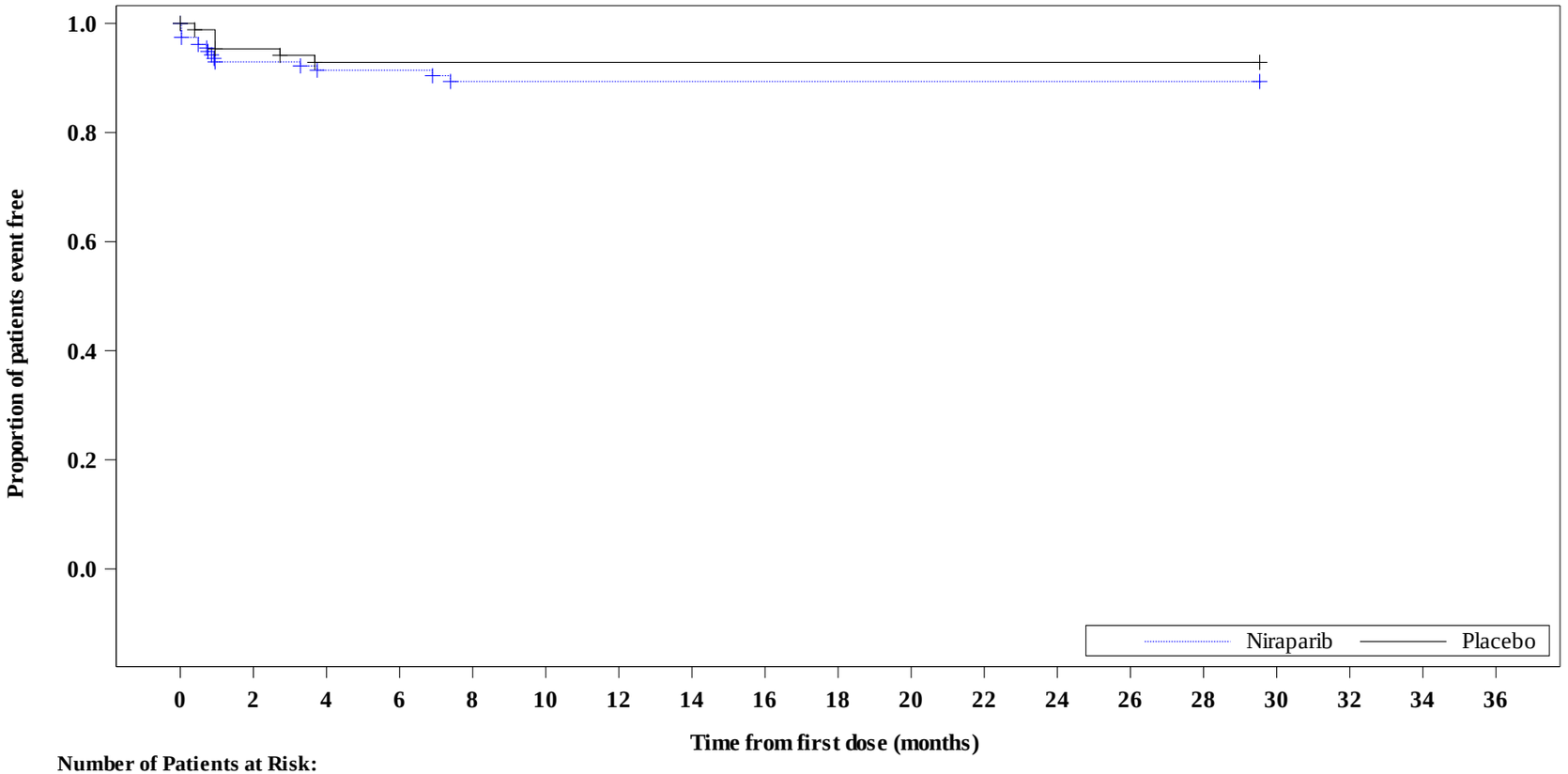
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Metabolism and nutrition disorders, PT: Hypomagnesaemia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 133 | 108 | 98 | 78 | 69 | 65 | 60 | 50 | 44 | 27 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 80 | 70 | 64 | 53 | 40 | 34 | 27 | 22 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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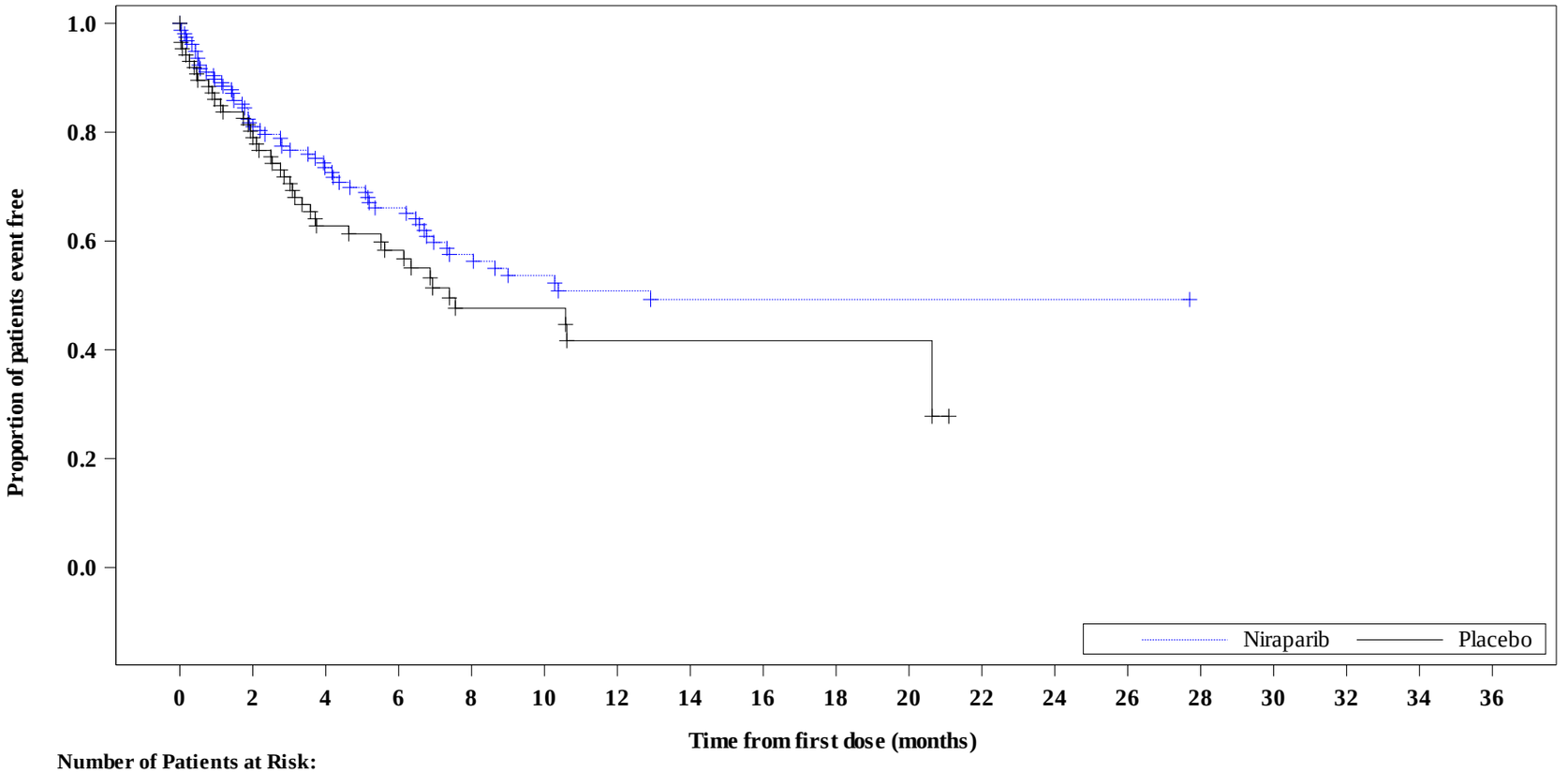
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 117 | 84 | 67 | 46 | 38 | 35 | 30 | 25 | 22 | 12 | 4 | 2 | 1 | 0 |
| Placebo | 86 | 68 | 45 | 38 | 25 | 17 | 13 | 9 | 9 | 6 | 4 | 0 | | | |

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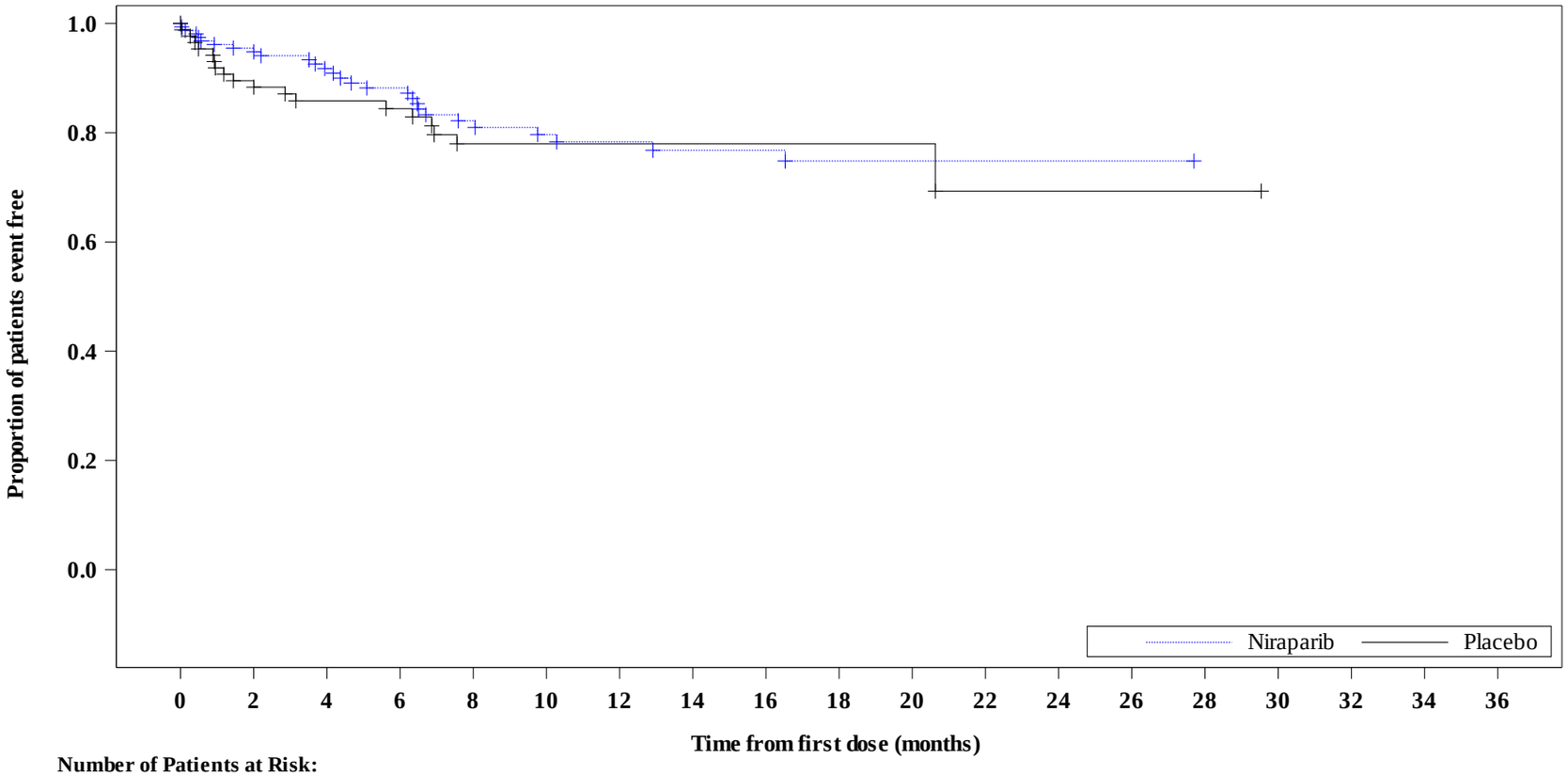
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Arthralgia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 137 | 107 | 93 | 68 | 59 | 56 | 49 | 39 | 33 | 21 | 9 | 4 | 3 | 0 | |
| Placebo | 86 | 76 | 64 | 59 | 46 | 33 | 27 | 21 | 19 | 15 | 11 | 4 | 3 | 2 | 1 | 0 |

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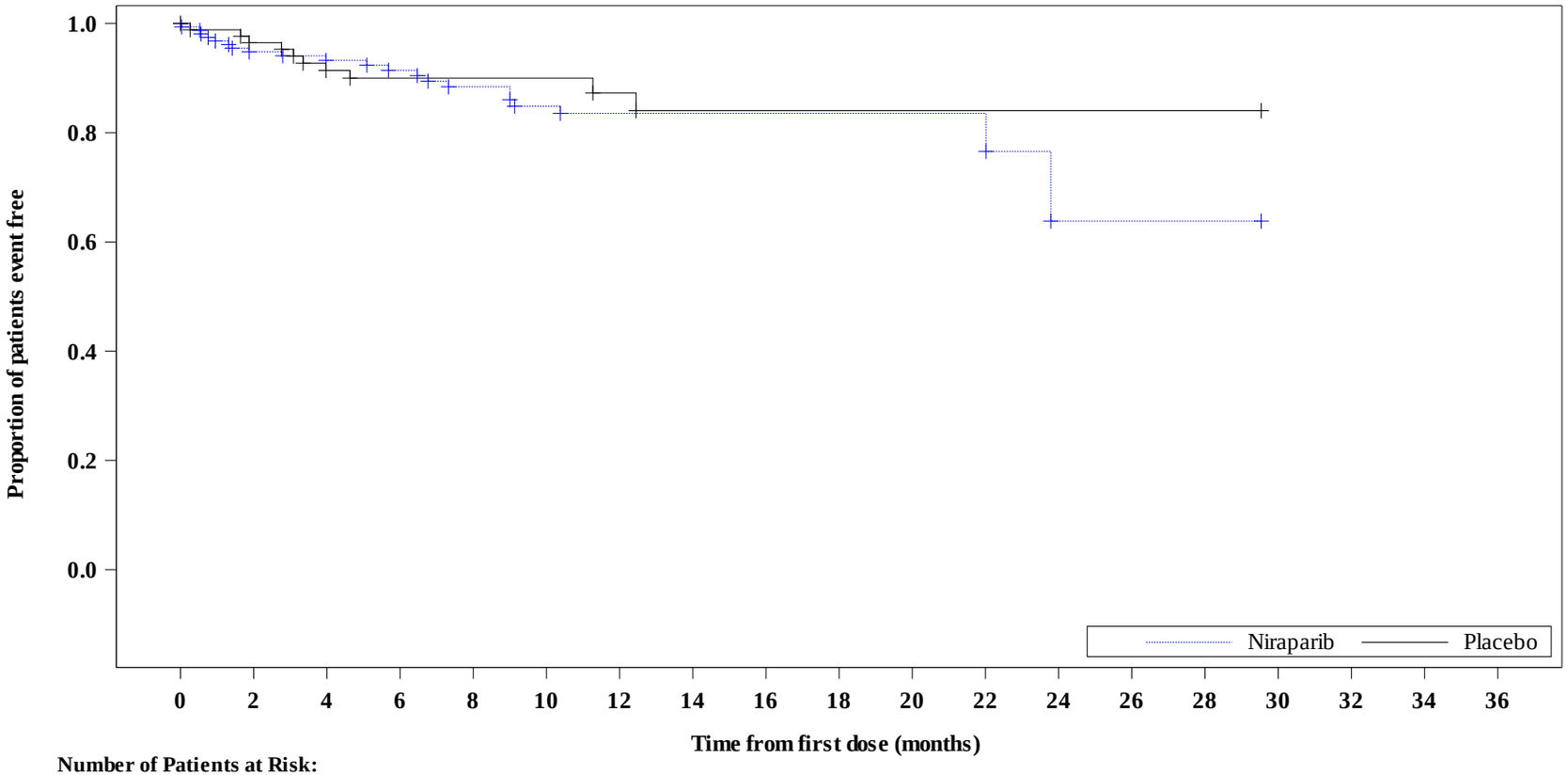
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Back pain



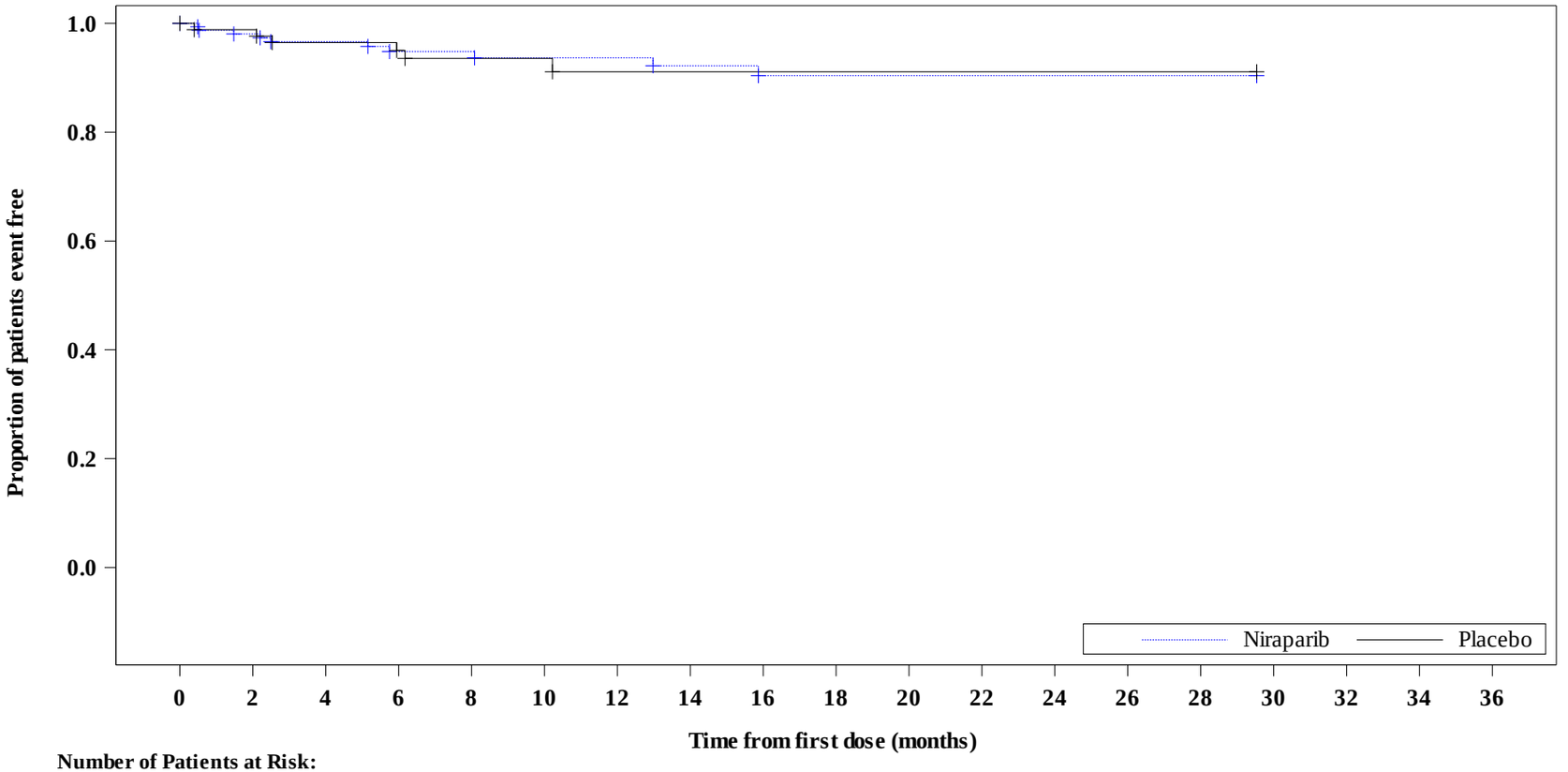

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 136 | 110 | 97 | 78 | 66 | 62 | 56 | 49 | 44 | 27 | 12 | 5 | 2 | 1 | 0 |
| Placebo | 86 | 81 | 68 | 62 | 49 | 36 | 31 | 23 | 20 | 17 | 12 | 5 | 3 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Myalgia



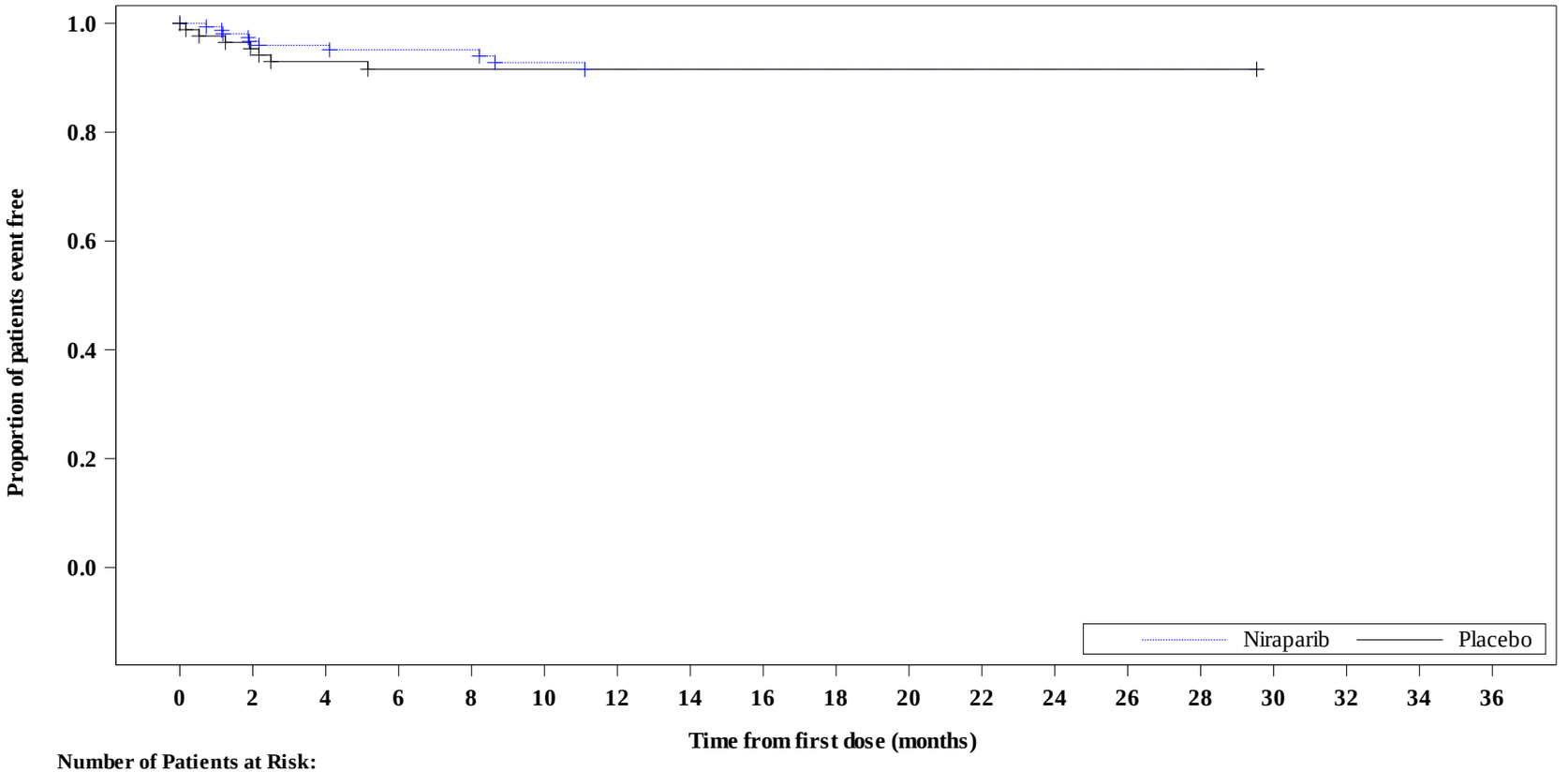

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 141 | 114 | 101 | 82 | 73 | 69 | 62 | 50 | 45 | 26 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 73 | 66 | 52 | 39 | 33 | 26 | 21 | 17 | 12 | 4 | 3 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Musculoskeletal and connective tissue disorders, PT: Pain in extremity

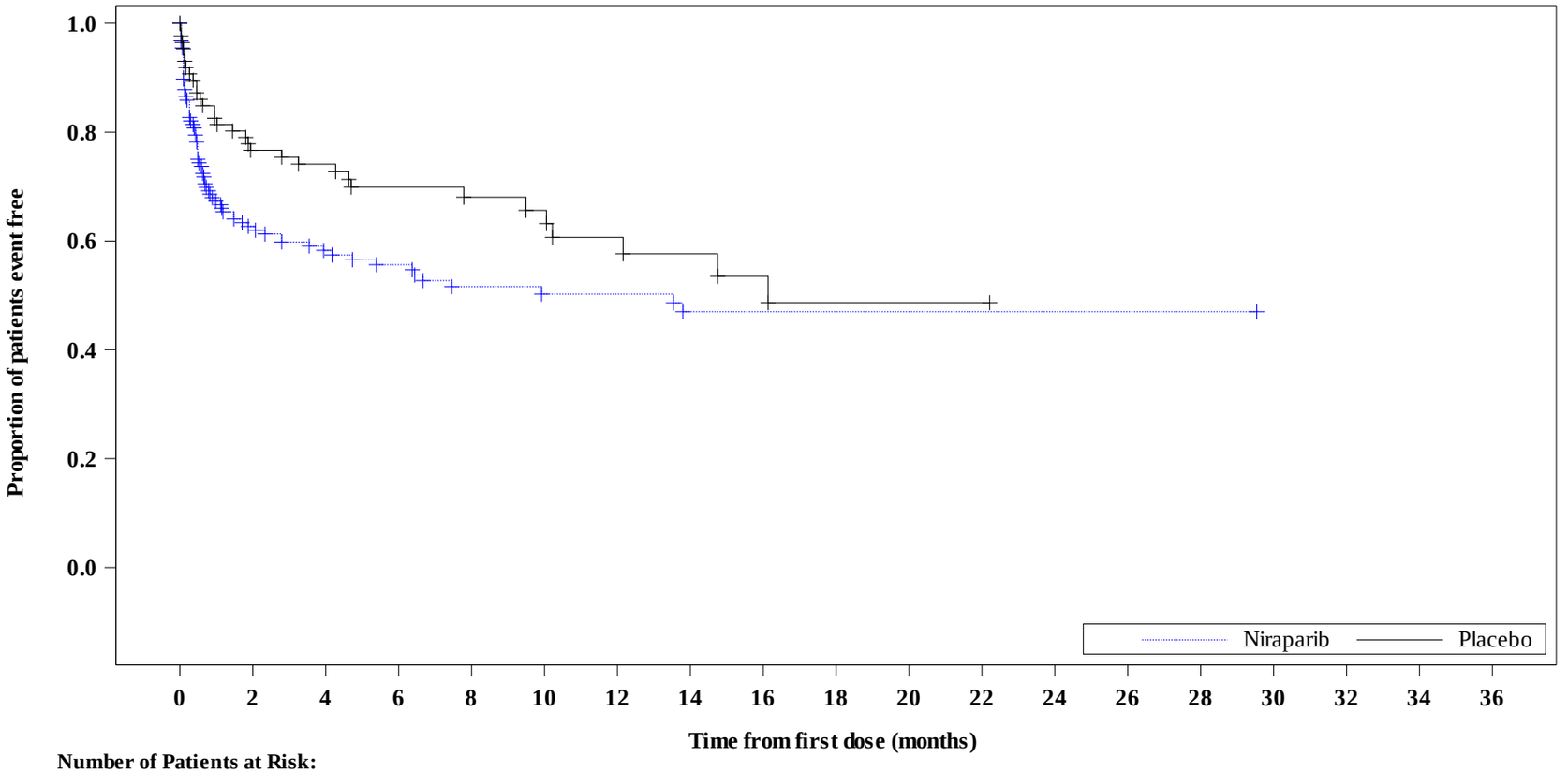



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 139 | 113 | 102 | 83 | 74 | 69 | 62 | 51 | 45 | 27 | 12 | 8 | 4 | 1 | 0 |
| Placebo | 86 | 81 | 70 | 64 | 51 | 39 | 33 | 26 | 21 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Nervous system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 90 | 70 | 59 | 43 | 37 | 34 | 29 | 25 | 22 | 12 | 5 | 4 | 2 | 1 | 0 |
| Placebo | 86 | 64 | 54 | 47 | 37 | 27 | 21 | 15 | 11 | 9 | 5 | 1 | 0 | | | |

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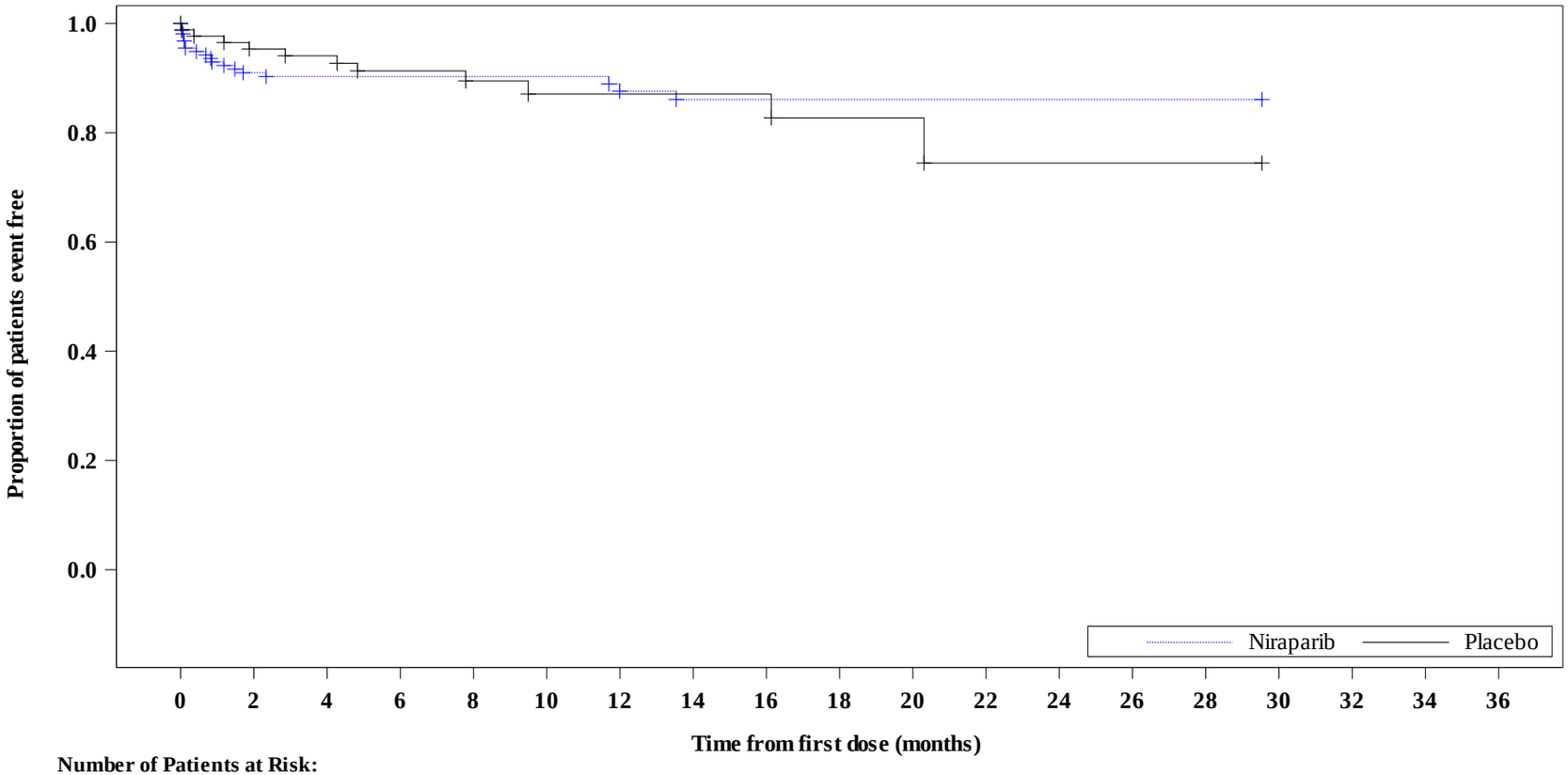
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Nervous system disorders, PT: Dizziness

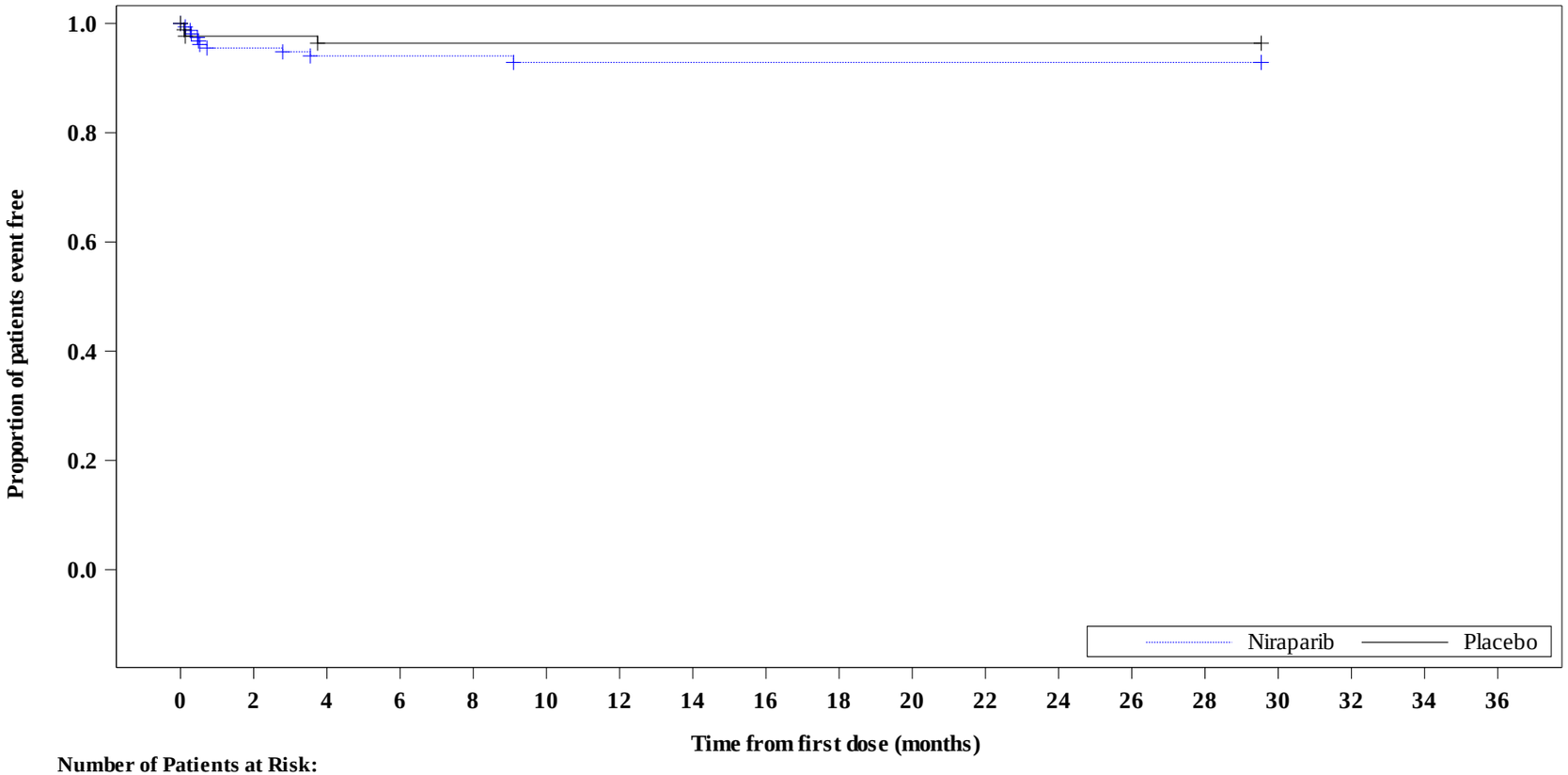



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 133 | 107 | 97 | 78 | 69 | 63 | 57 | 46 | 41 | 24 | 12 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 80 | 70 | 63 | 49 | 36 | 31 | 23 | 20 | 15 | 10 | 3 | 2 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Nervous system disorders, PT: Dysgeusia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 138 | 111 | 101 | 82 | 72 | 68 | 61 | 51 | 46 | 27 | 13 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 82 | 72 | 66 | 53 | 41 | 35 | 27 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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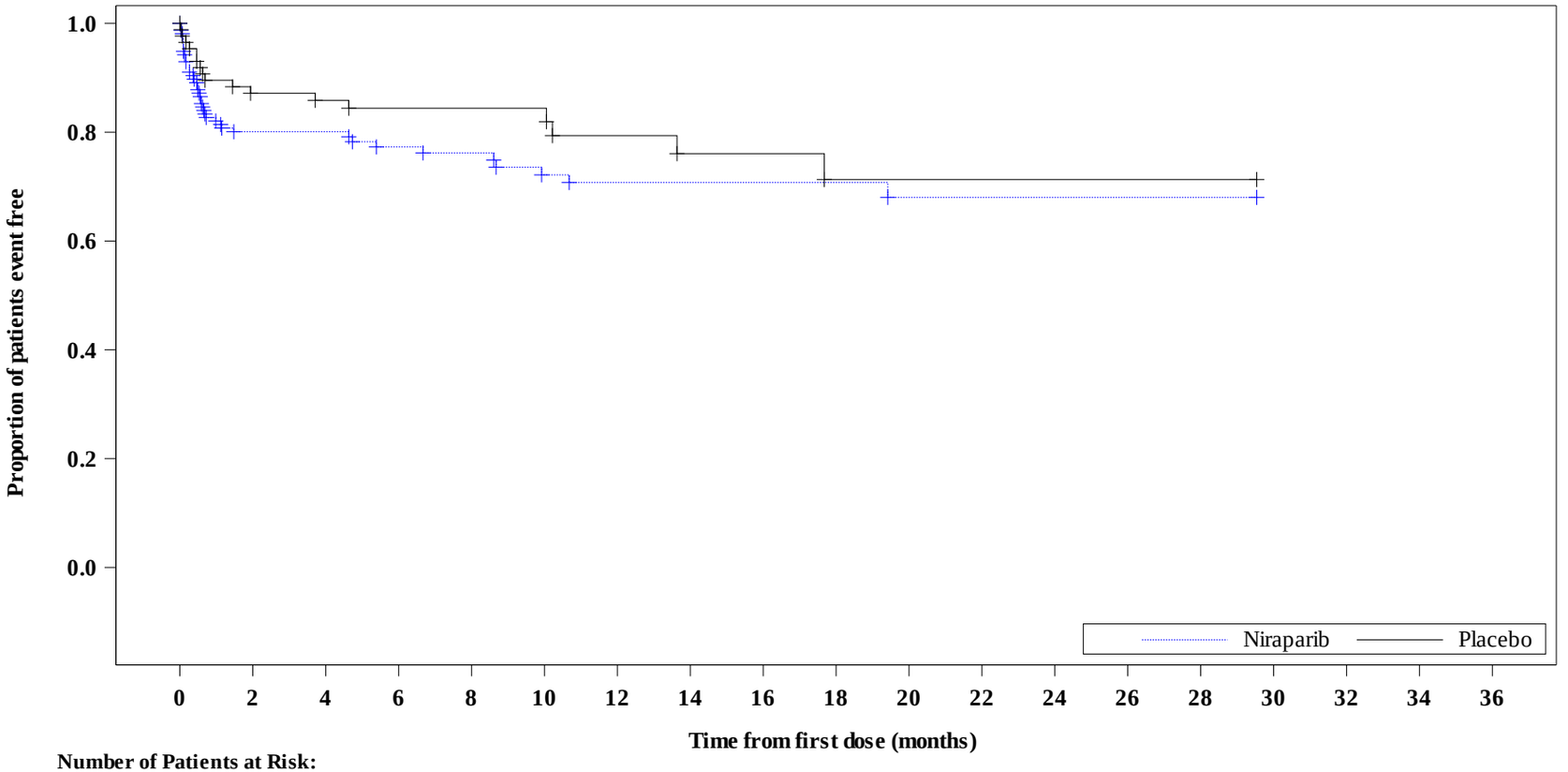
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Nervous system disorders, PT: Headache



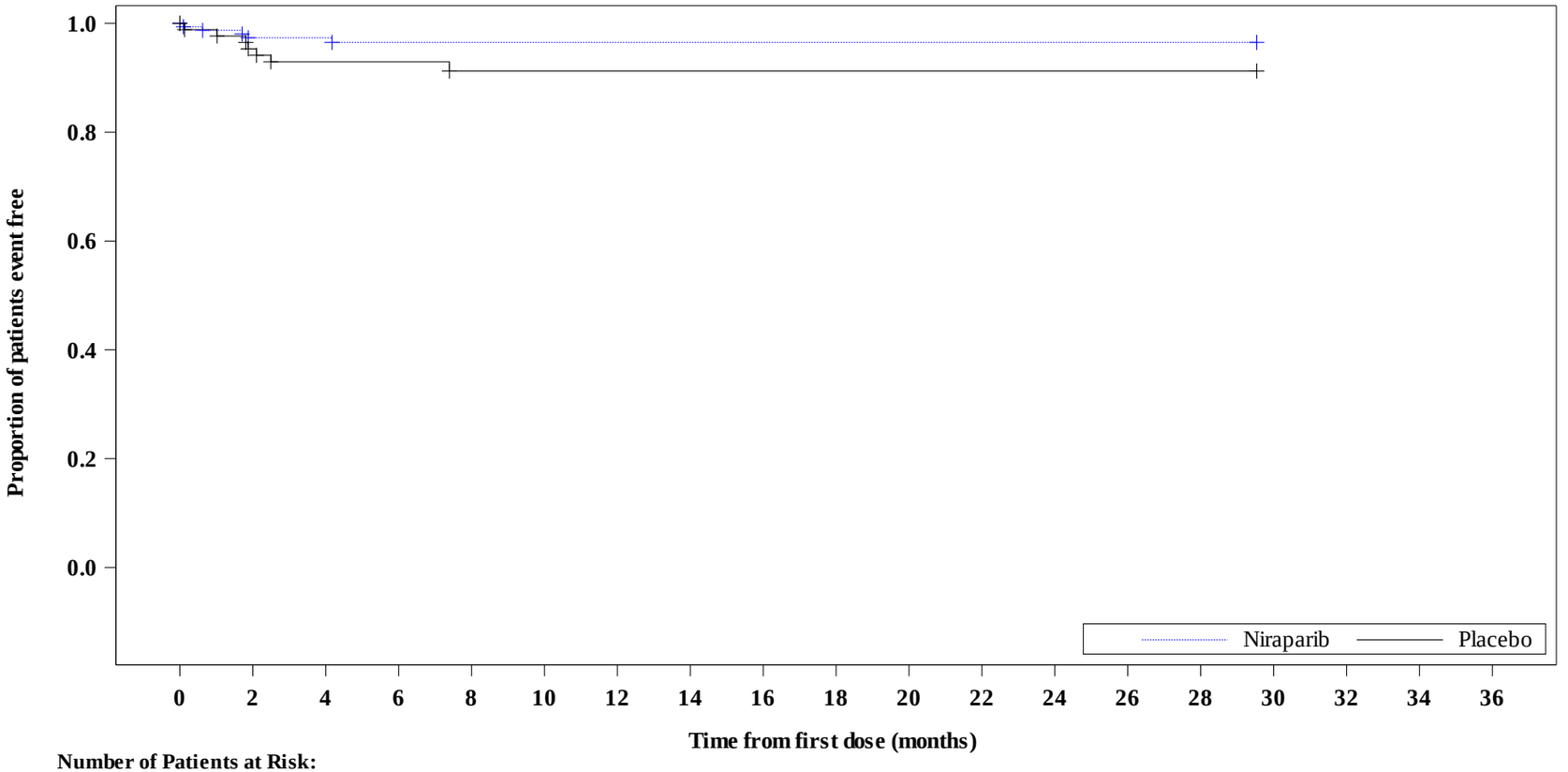

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 113 | 92 | 78 | 61 | 51 | 47 | 43 | 36 | 31 | 18 | 7 | 4 | 2 | 1 | 0 |
| Placebo | 86 | 73 | 63 | 56 | 46 | 34 | 27 | 21 | 17 | 14 | 10 | 3 | 2 | 1 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Nervous system disorders, PT: Neuropathy peripheral



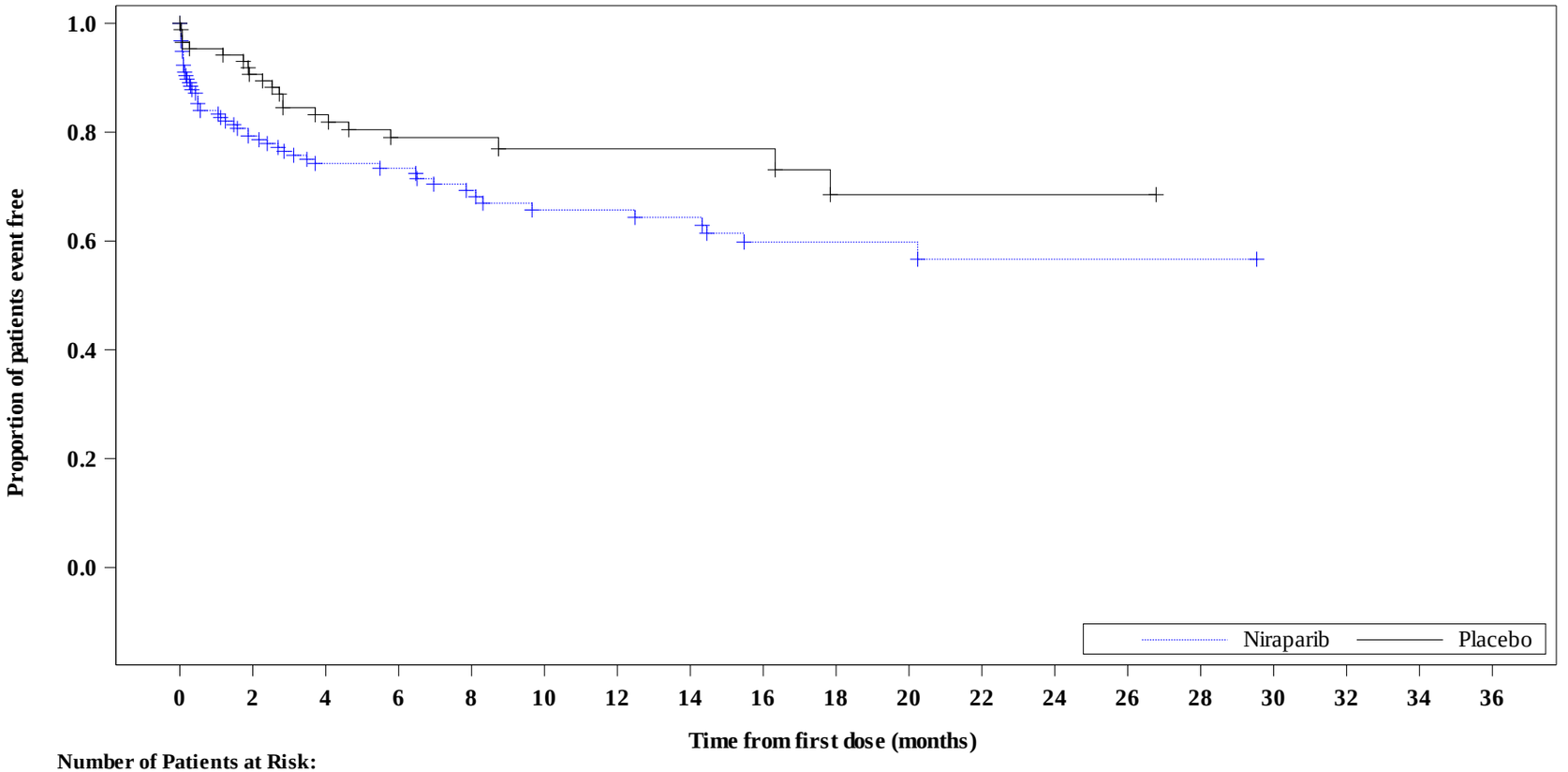

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 140 | 116 | 104 | 84 | 75 | 71 | 64 | 53 | 47 | 28 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 80 | 70 | 65 | 51 | 39 | 33 | 26 | 22 | 18 | 13 | 4 | 2 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Psychiatric disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 114 | 89 | 80 | 59 | 52 | 49 | 45 | 37 | 32 | 19 | 9 | 5 | 3 | 1 | 0 |
| Placebo | 86 | 76 | 62 | 55 | 44 | 32 | 29 | 24 | 20 | 15 | 11 | 4 | 2 | 1 | 0 | |

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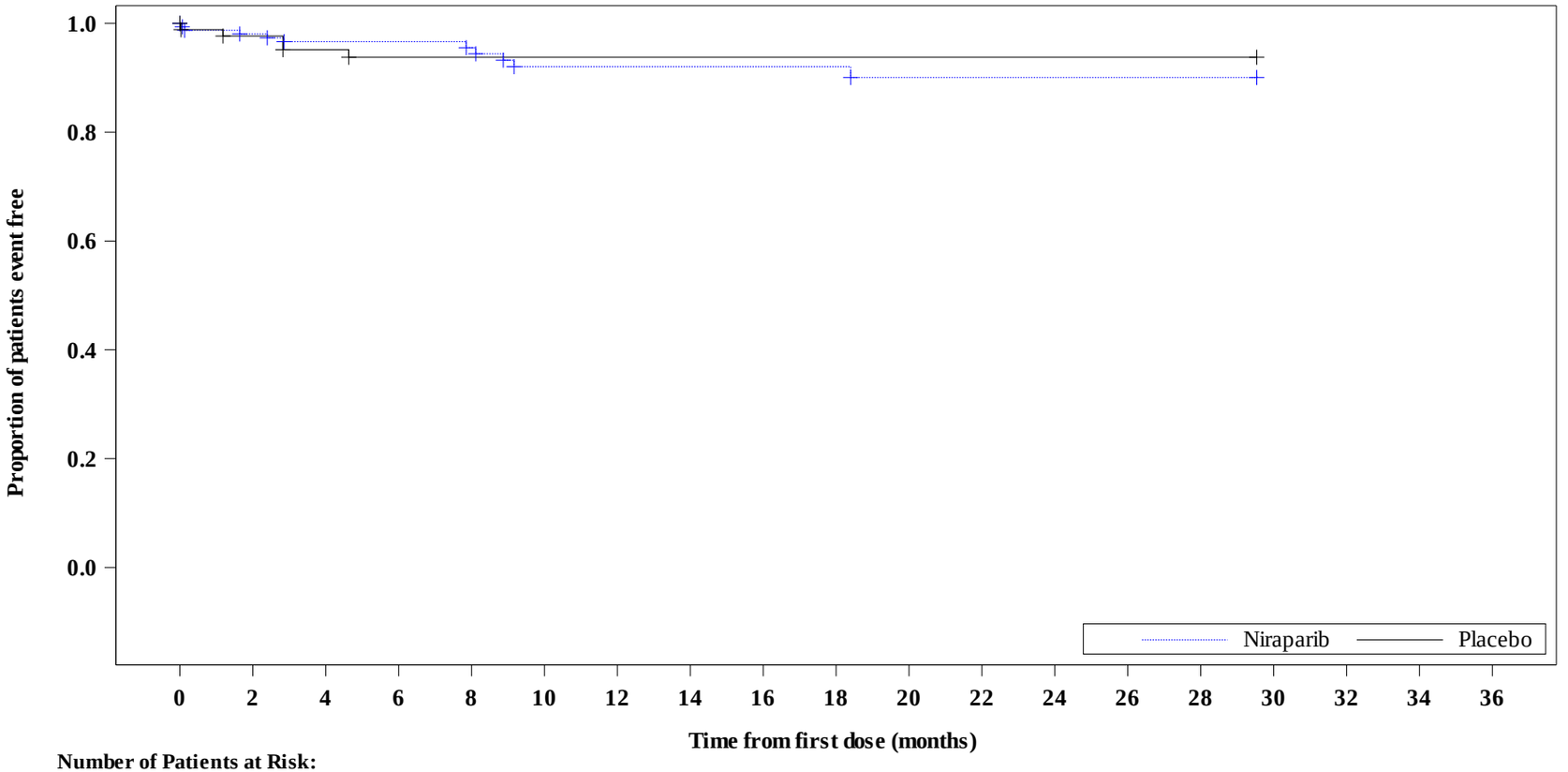
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Psychiatric disorders, PT: Anxiety

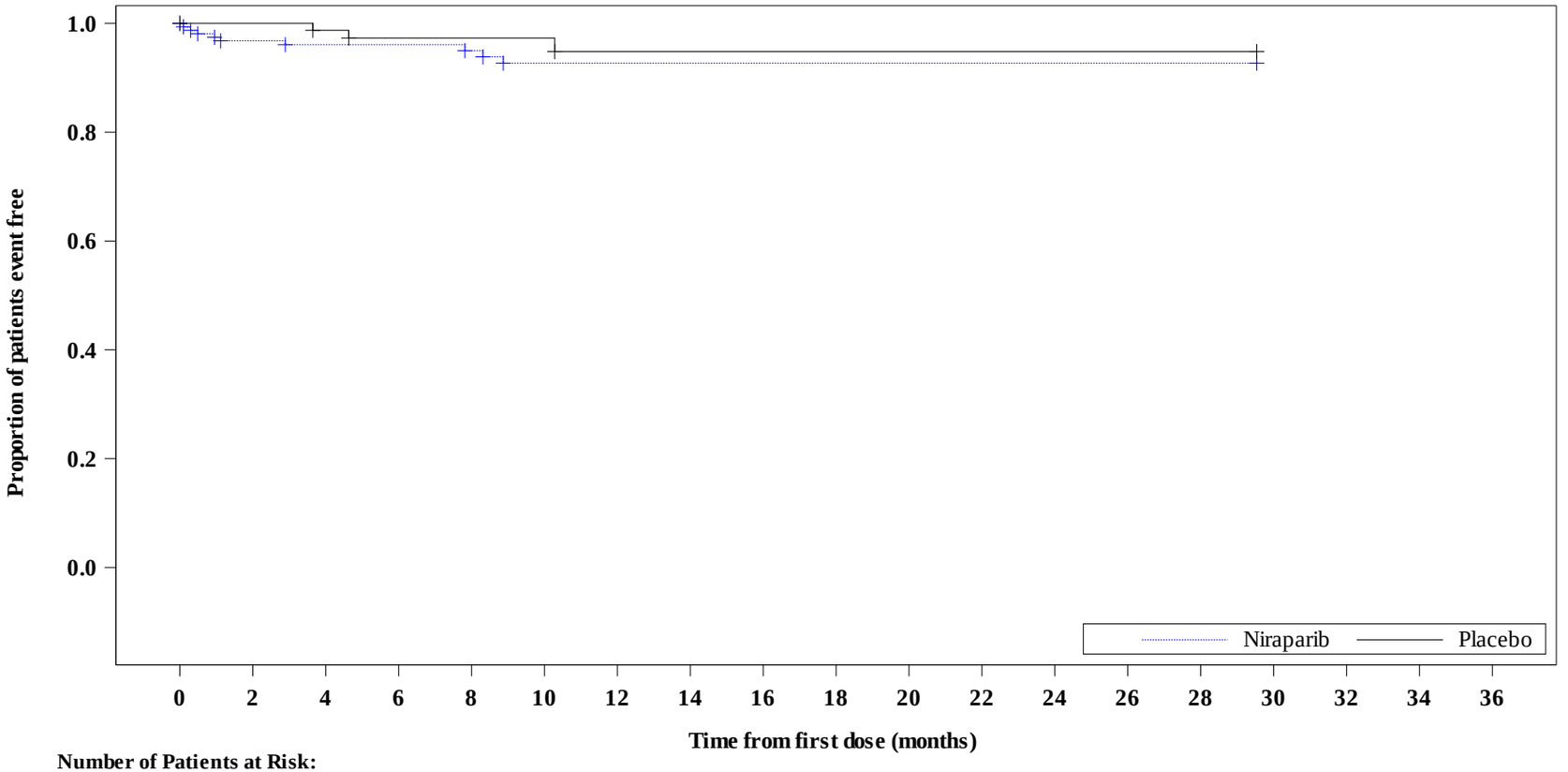



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 141 | 116 | 106 | 85 | 74 | 70 | 63 | 53 | 47 | 27 | 13 | 7 | 4 | 1 | 0 |
| Placebo | 86 | 82 | 72 | 65 | 52 | 39 | 34 | 26 | 22 | 18 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Psychiatric disorders, PT: Depression

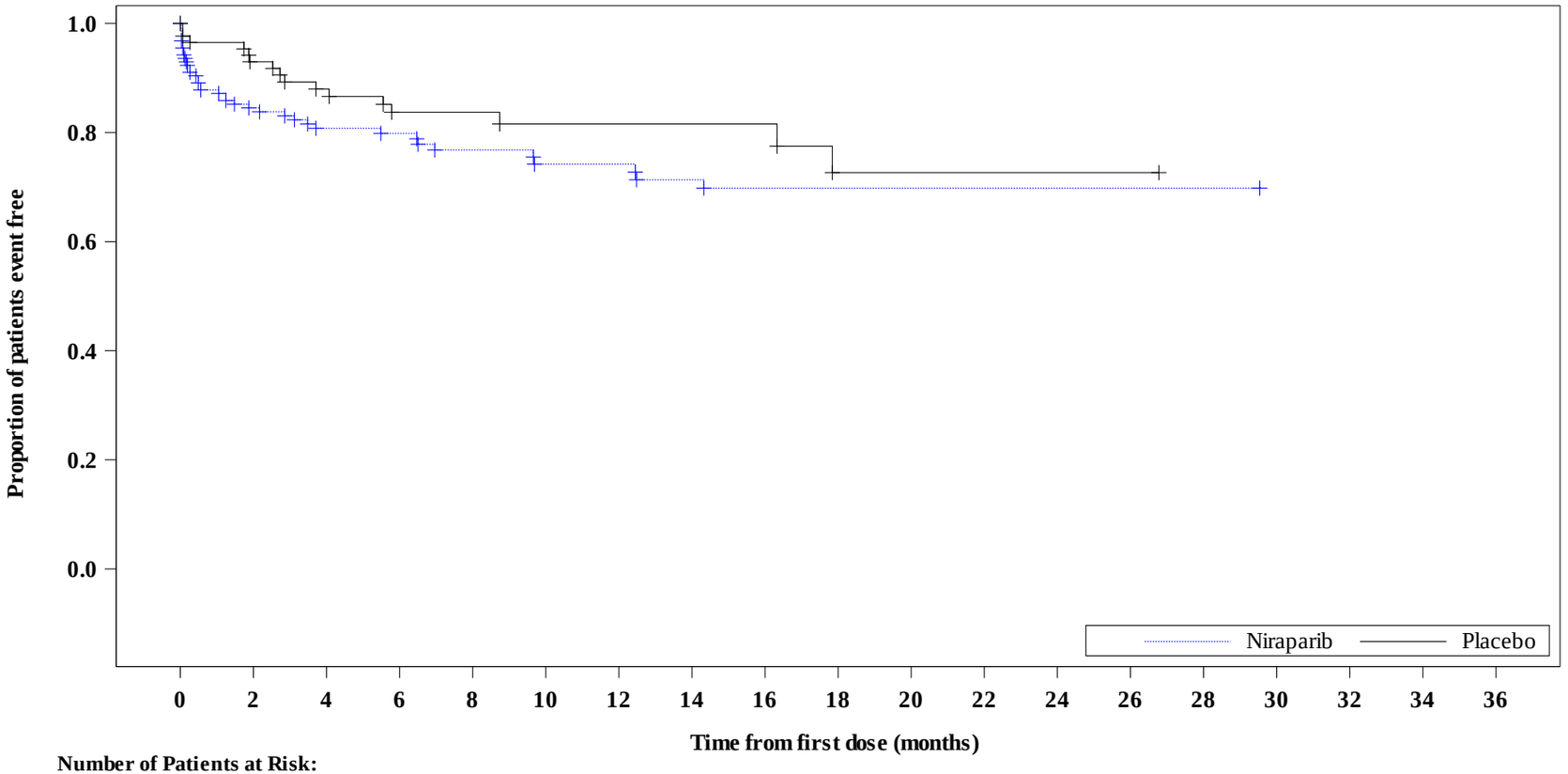



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 141 | 115 | 105 | 84 | 74 | 70 | 63 | 51 | 45 | 26 | 14 | 8 | 4 | 1 | 0 |
| Placebo | 86 | 84 | 74 | 67 | 54 | 41 | 34 | 27 | 22 | 18 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Psychiatric disorders, PT: Insomnia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 120 | 93 | 83 | 62 | 56 | 53 | 48 | 38 | 33 | 20 | 10 | 5 | 3 | 1 | 0 |
| Placebo | 86 | 78 | 65 | 58 | 47 | 33 | 29 | 24 | 20 | 15 | 11 | 4 | 2 | 1 | 0 | |

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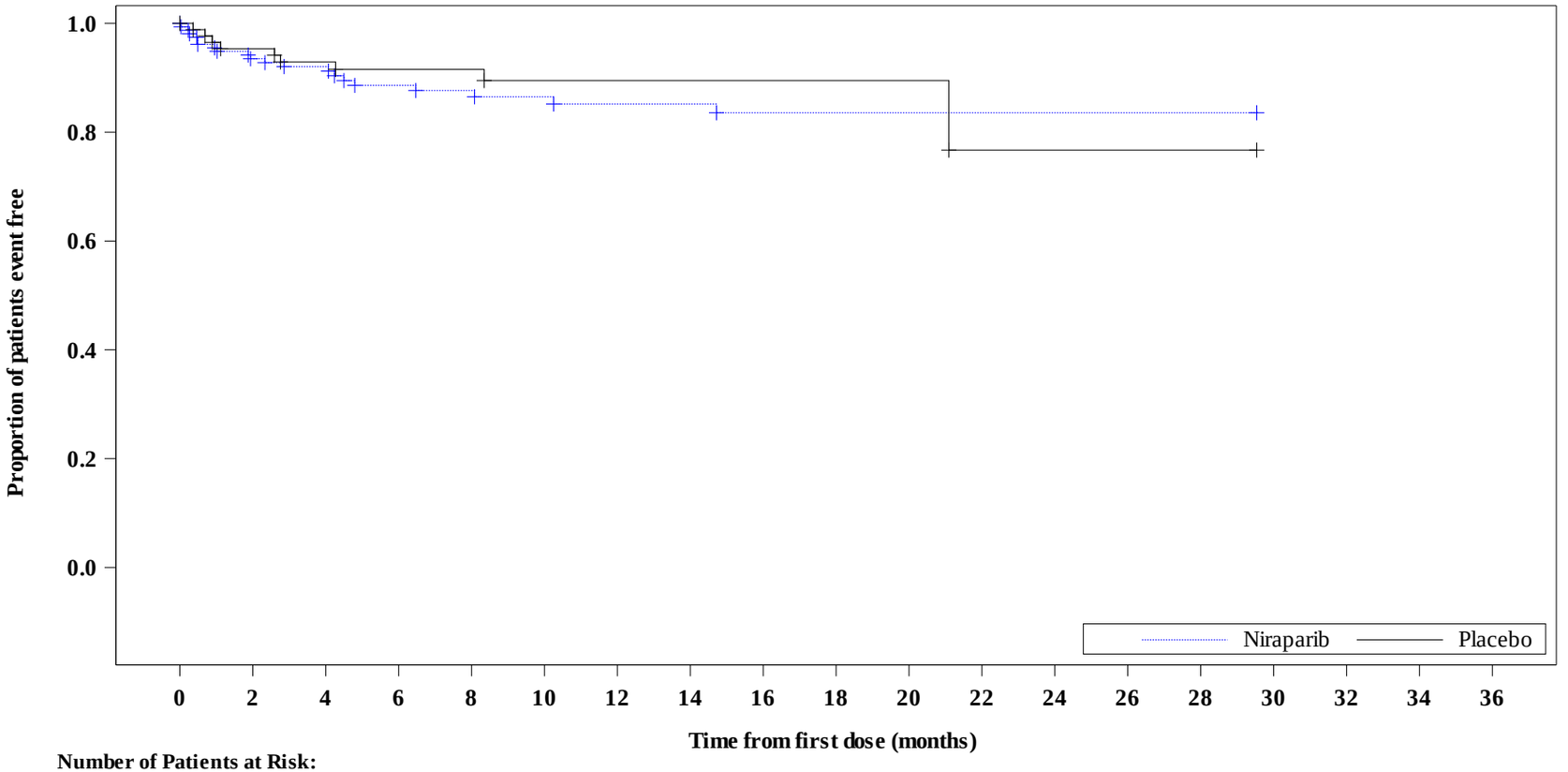
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Renal and urinary disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 134 | 110 | 96 | 76 | 66 | 61 | 55 | 45 | 39 | 25 | 14 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 80 | 69 | 62 | 49 | 35 | 30 | 22 | 17 | 15 | 11 | 4 | 3 | 2 | 1 | 0 |

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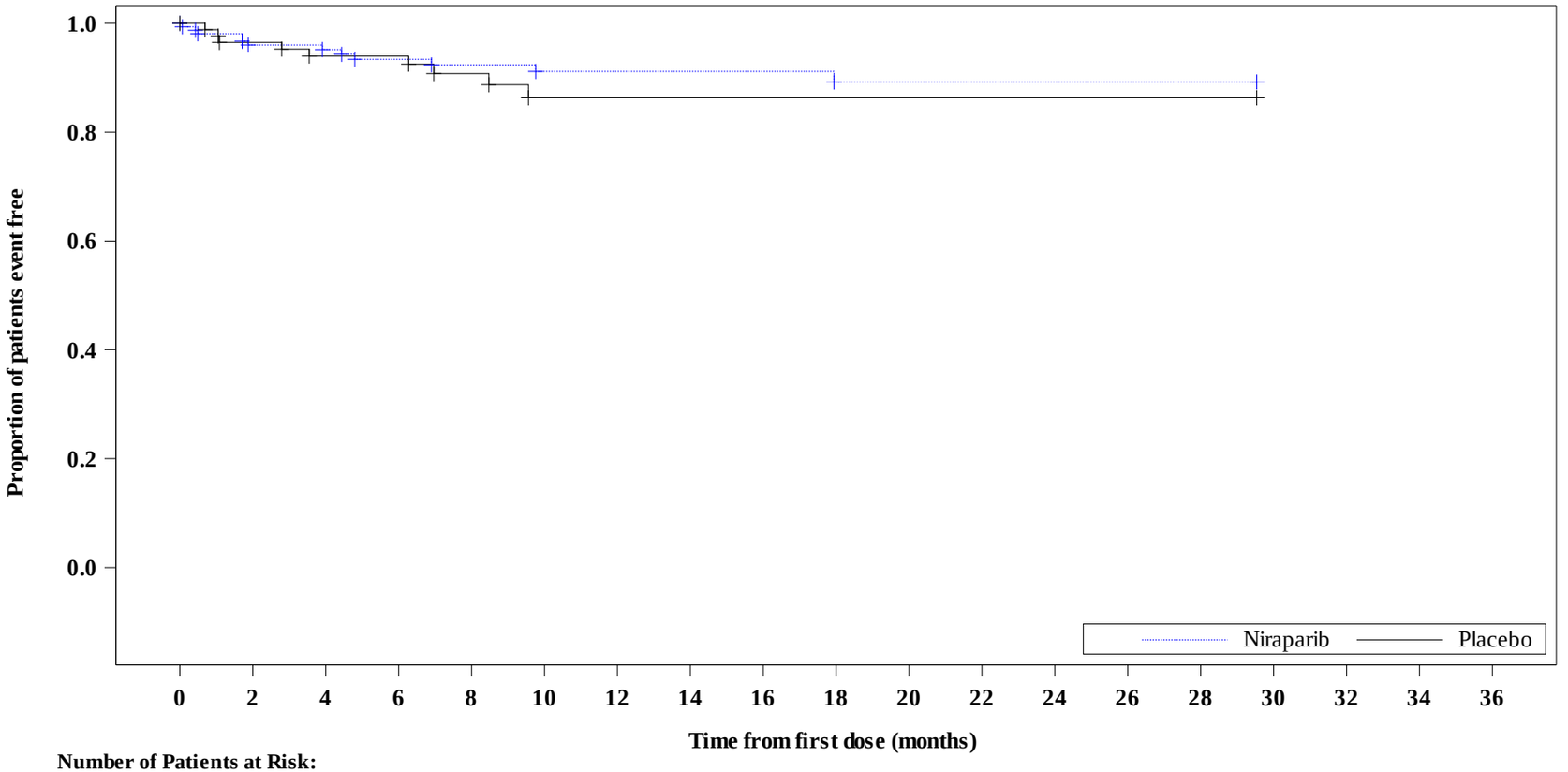
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Reproductive system and breast disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 138 | 111 | 99 | 80 | 73 | 69 | 62 | 51 | 46 | 27 | 14 | 8 | 4 | 2 | 0 |
| Placebo | 86 | 81 | 70 | 64 | 49 | 36 | 31 | 24 | 19 | 15 | 11 | 4 | 3 | 2 | 1 | 0 |

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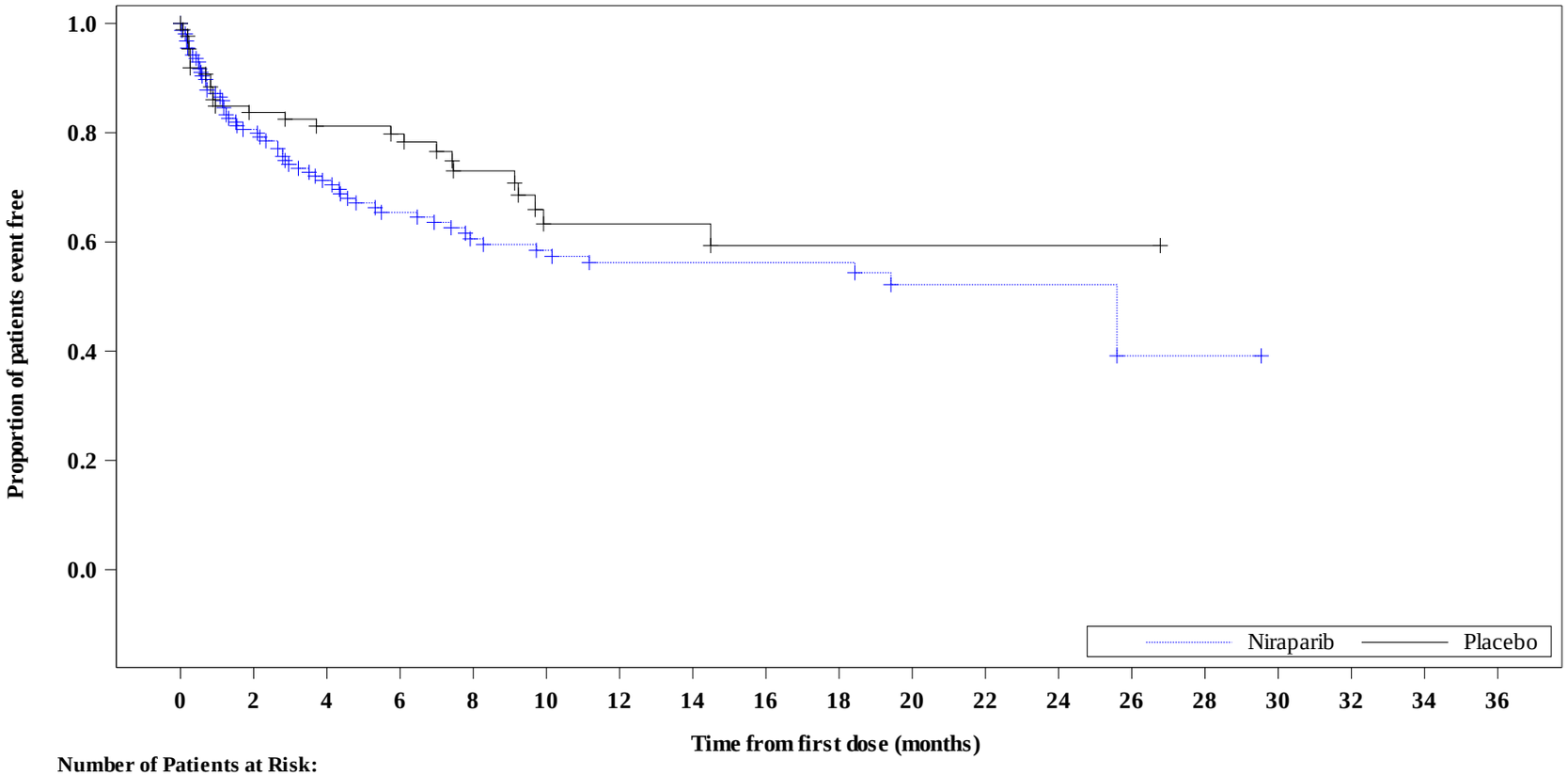
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 116 | 89 | 76 | 59 | 53 | 49 | 43 | 35 | 31 | 16 | 7 | 4 | 2 | 1 | 0 |
| Placebo | 86 | 71 | 62 | 55 | 40 | 24 | 21 | 16 | 12 | 11 | 8 | 2 | 1 | 1 | 0 | |

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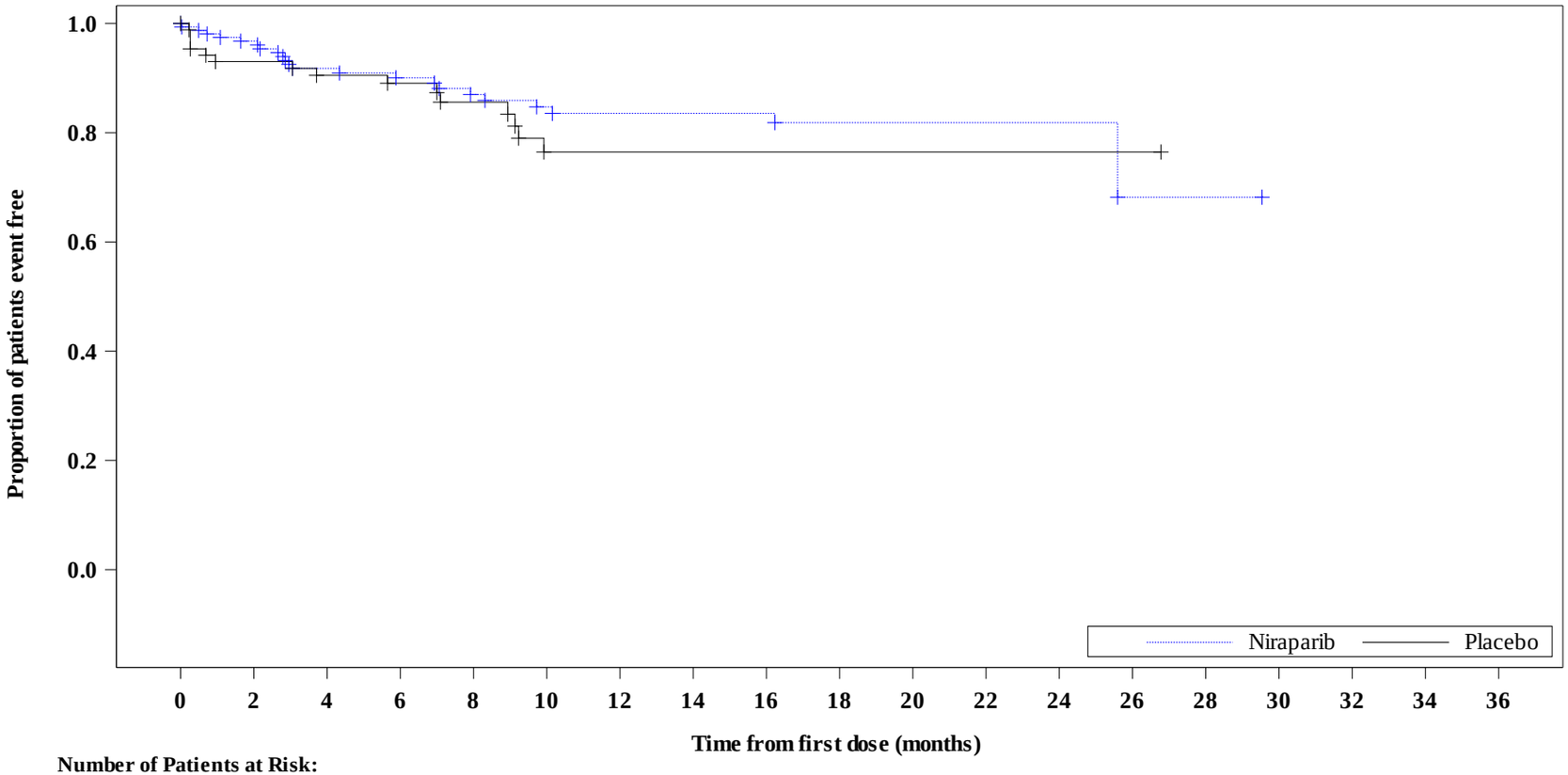
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 139 | 112 | 101 | 80 | 71 | 67 | 60 | 50 | 43 | 26 | 14 | 9 | 4 | 2 | 0 |
| Placebo | 86 | 78 | 68 | 61 | 47 | 30 | 27 | 21 | 17 | 15 | 10 | 4 | 2 | 1 | 0 | |

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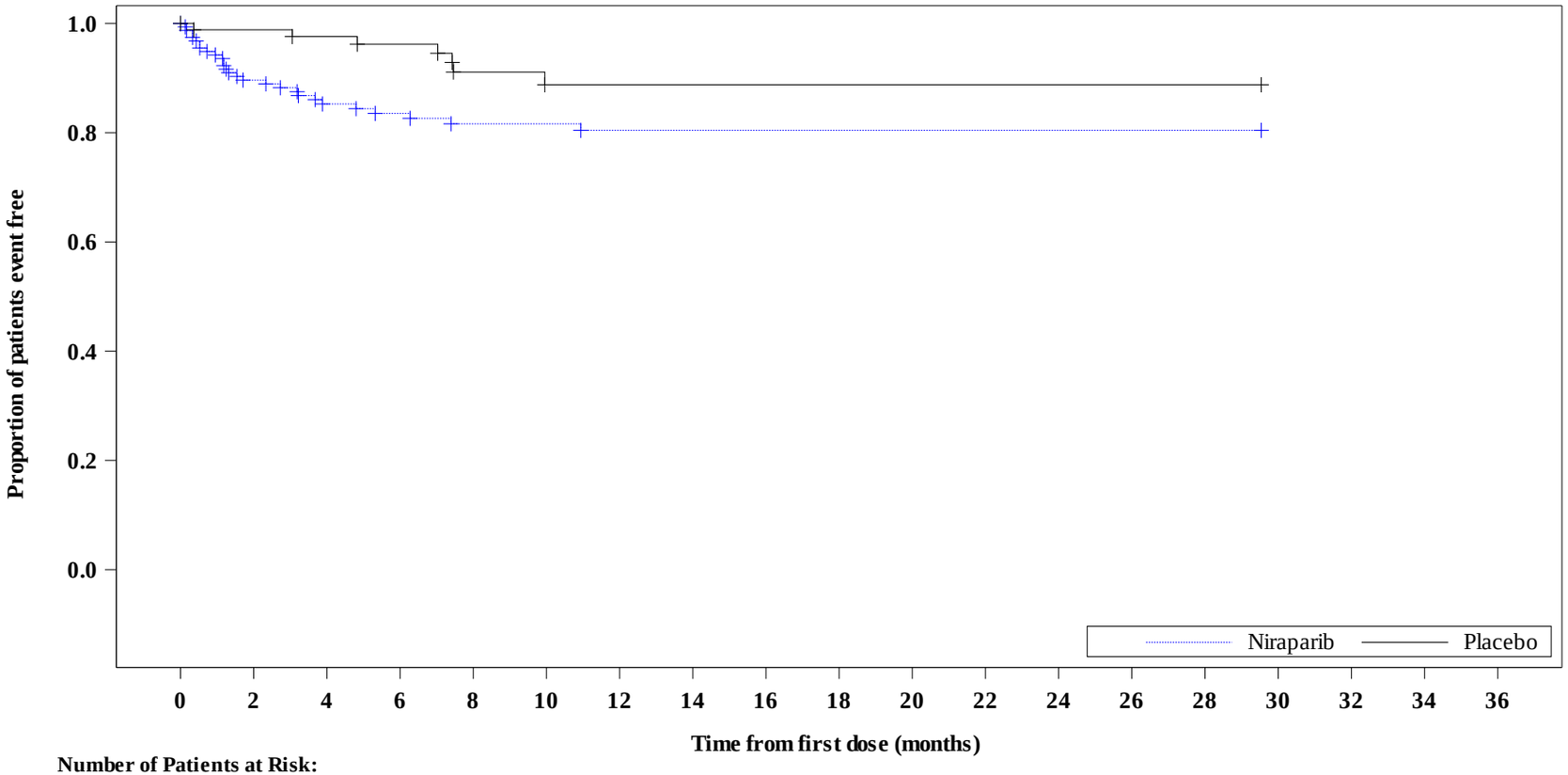
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Dyspnoea




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 130 | 104 | 94 | 77 | 69 | 65 | 58 | 49 | 44 | 26 | 13 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 74 | 67 | 51 | 38 | 32 | 26 | 22 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

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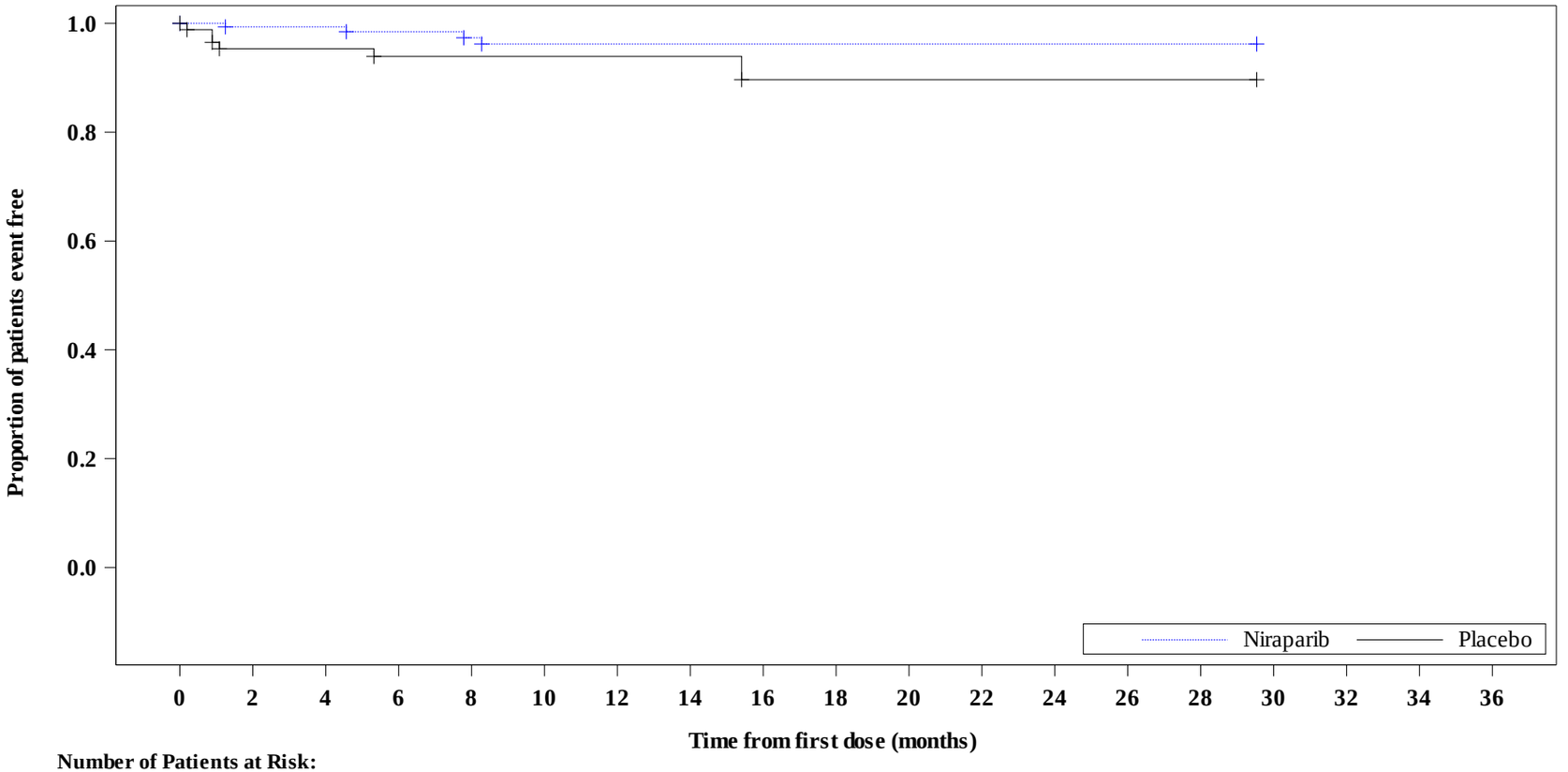
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Respiratory, thoracic and mediastinal disorders, PT: Oropharyngeal pain

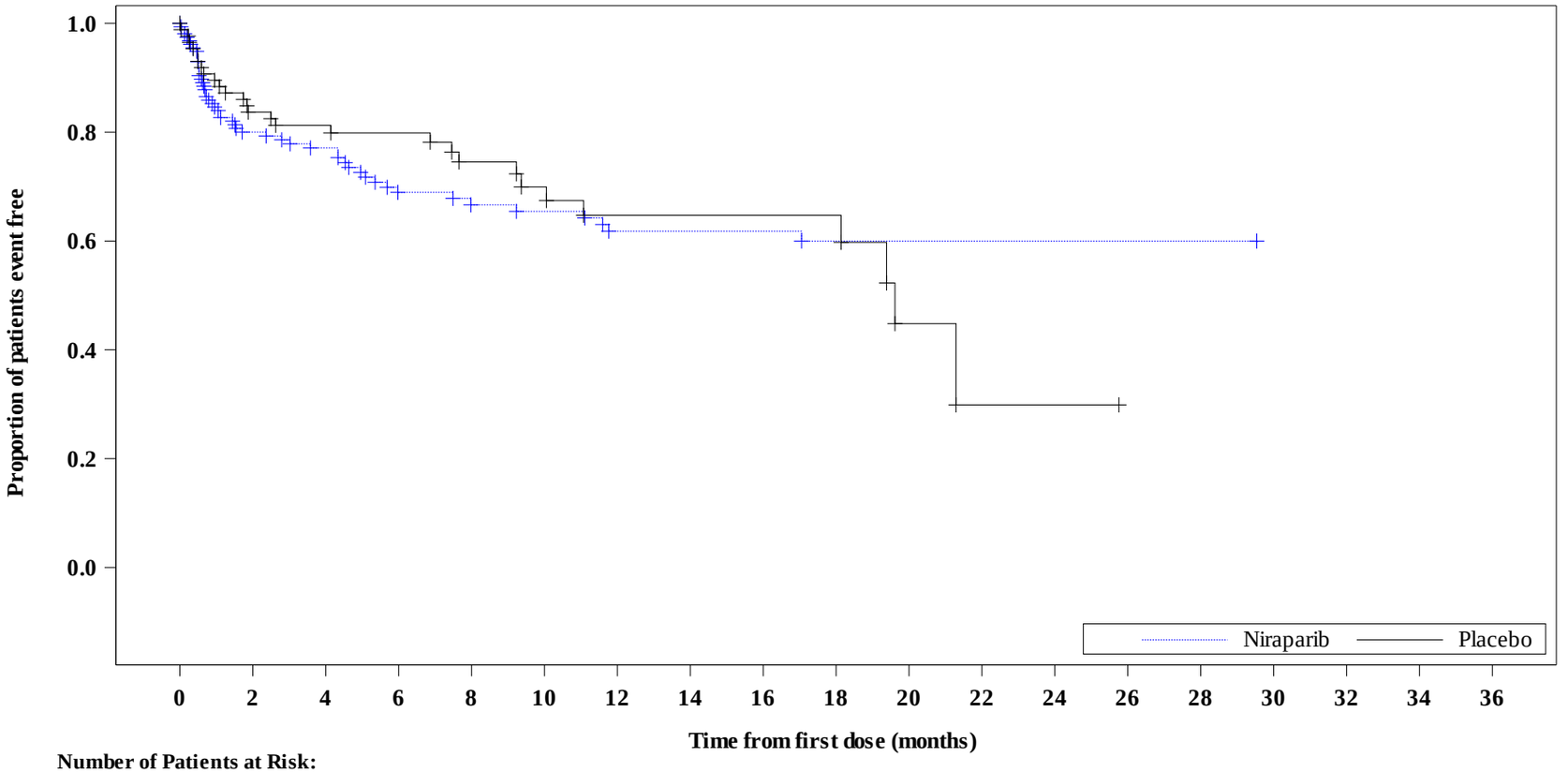



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 143 | 117 | 106 | 85 | 76 | 72 | 65 | 53 | 47 | 28 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 80 | 72 | 65 | 54 | 40 | 34 | 27 | 21 | 17 | 12 | 4 | 3 | 2 | 1 | 0 |

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 115 | 89 | 74 | 56 | 55 | 49 | 44 | 35 | 30 | 18 | 10 | 6 | 3 | 1 | 0 |
| Placebo | 86 | 70 | 59 | 54 | 41 | 28 | 24 | 20 | 17 | 13 | 6 | 1 | 1 | 0 | | |

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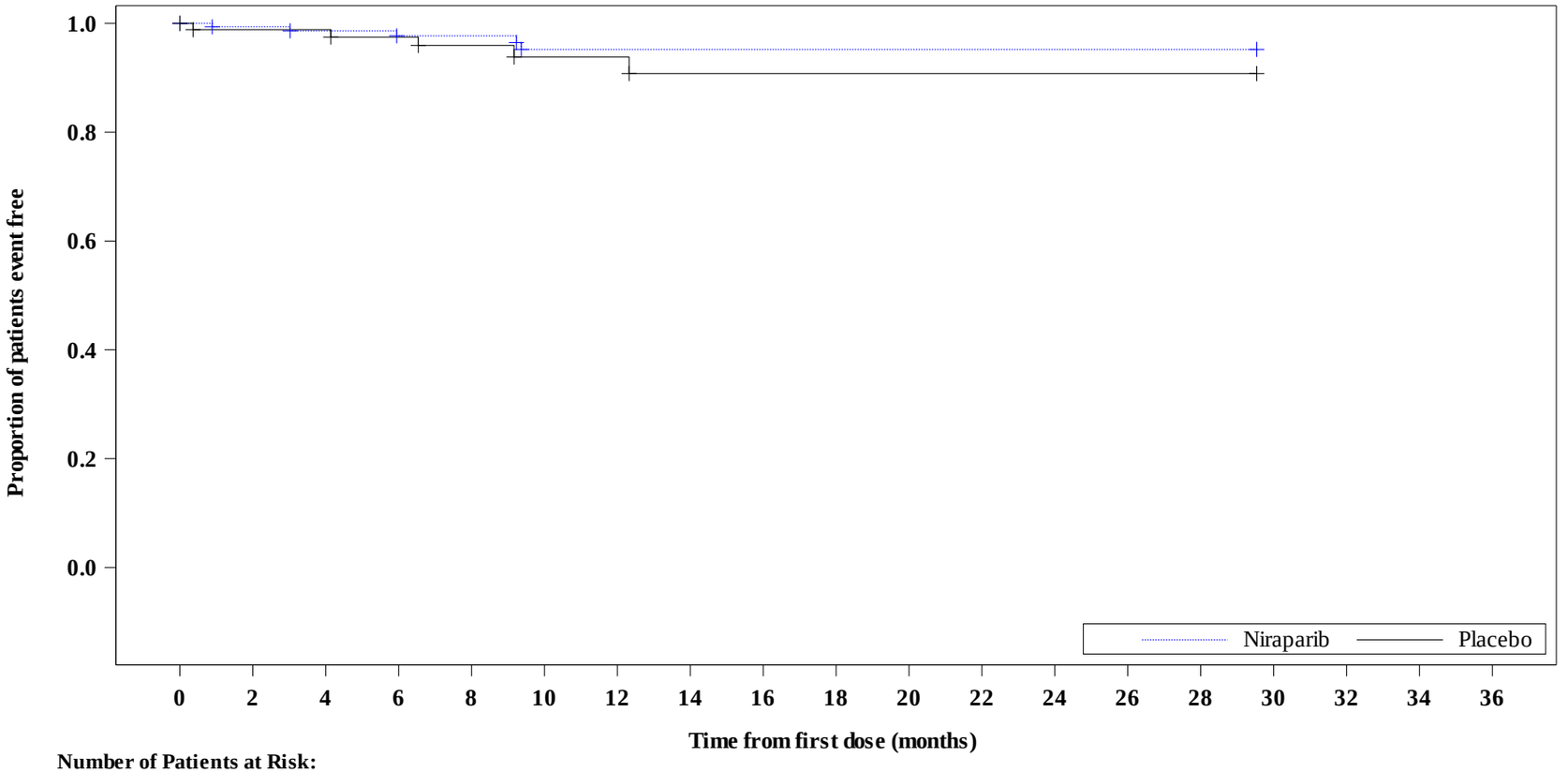
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Dry skin



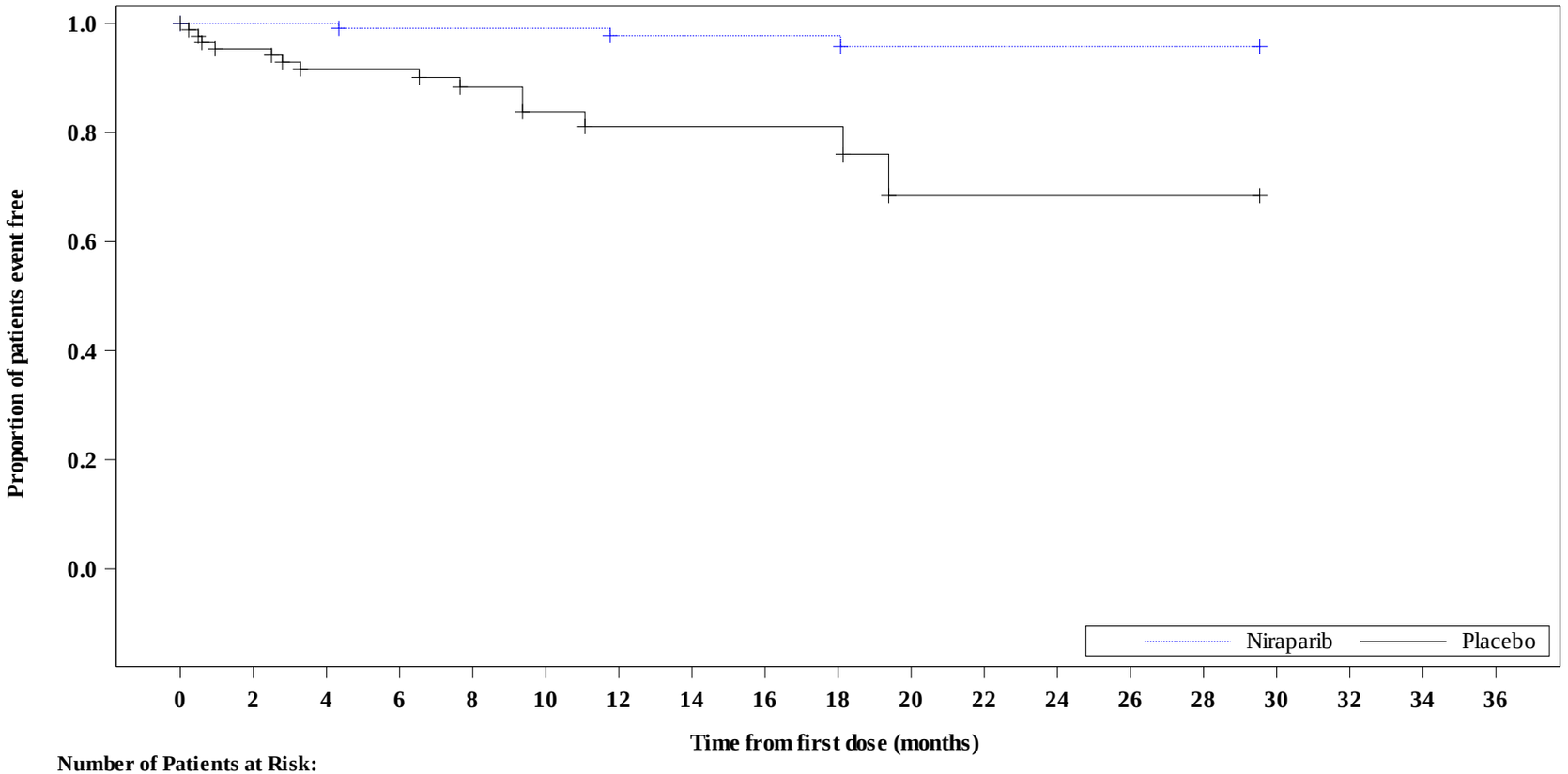

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 143 | 117 | 105 | 85 | 75 | 71 | 65 | 53 | 47 | 29 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 74 | 67 | 54 | 39 | 33 | 26 | 22 | 18 | 13 | 4 | 3 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Pruritus




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 106 | 86 | 77 | 72 | 65 | 54 | 48 | 29 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 80 | 68 | 63 | 50 | 36 | 30 | 25 | 20 | 16 | 9 | 4 | 3 | 2 | 1 | 0 |

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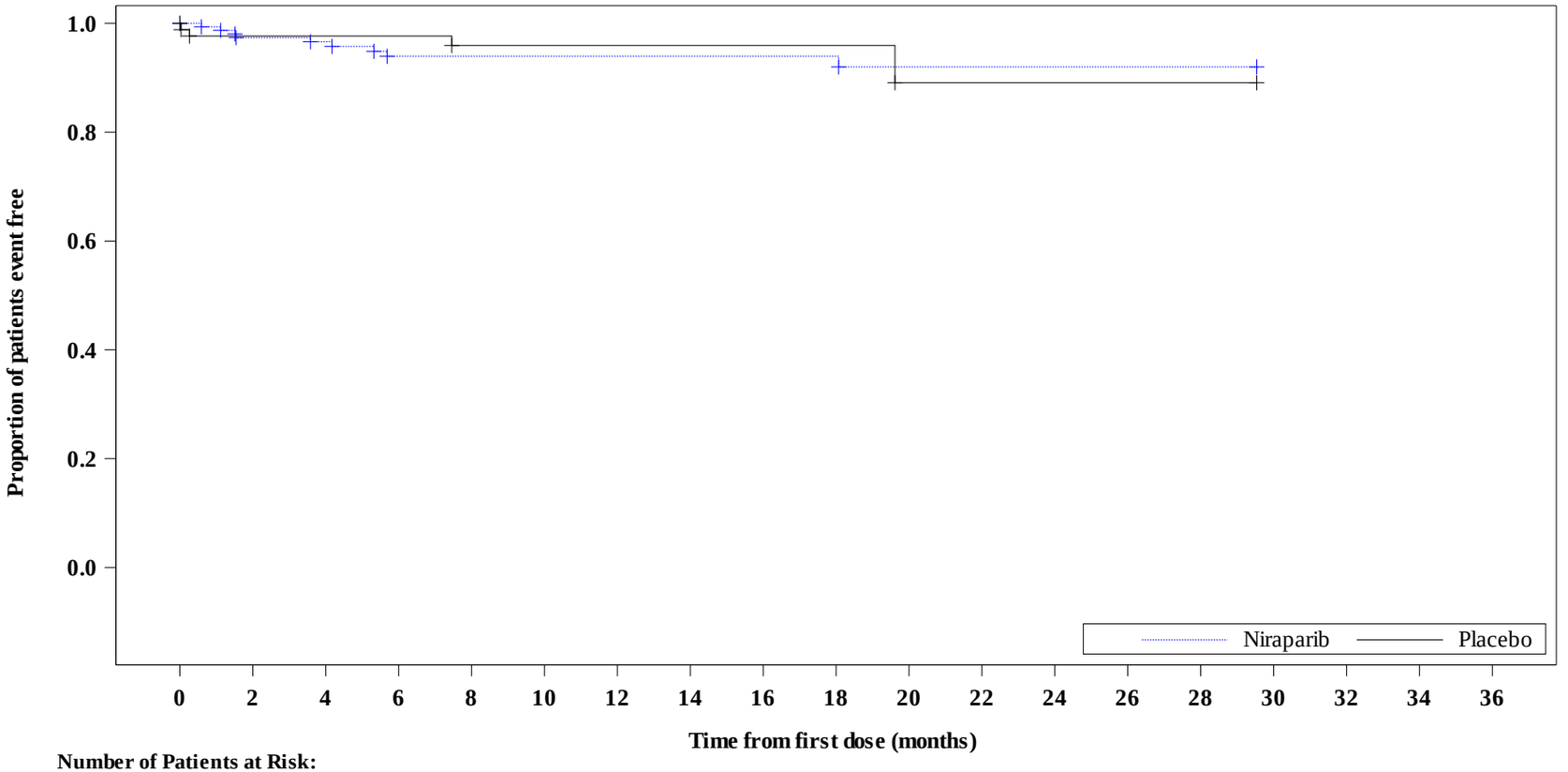
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Skin and subcutaneous tissue disorders, PT: Rash




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 140 | 114 | 102 | 83 | 76 | 72 | 65 | 53 | 48 | 28 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 82 | 73 | 67 | 54 | 40 | 34 | 28 | 23 | 19 | 13 | 5 | 3 | 2 | 1 | 0 |

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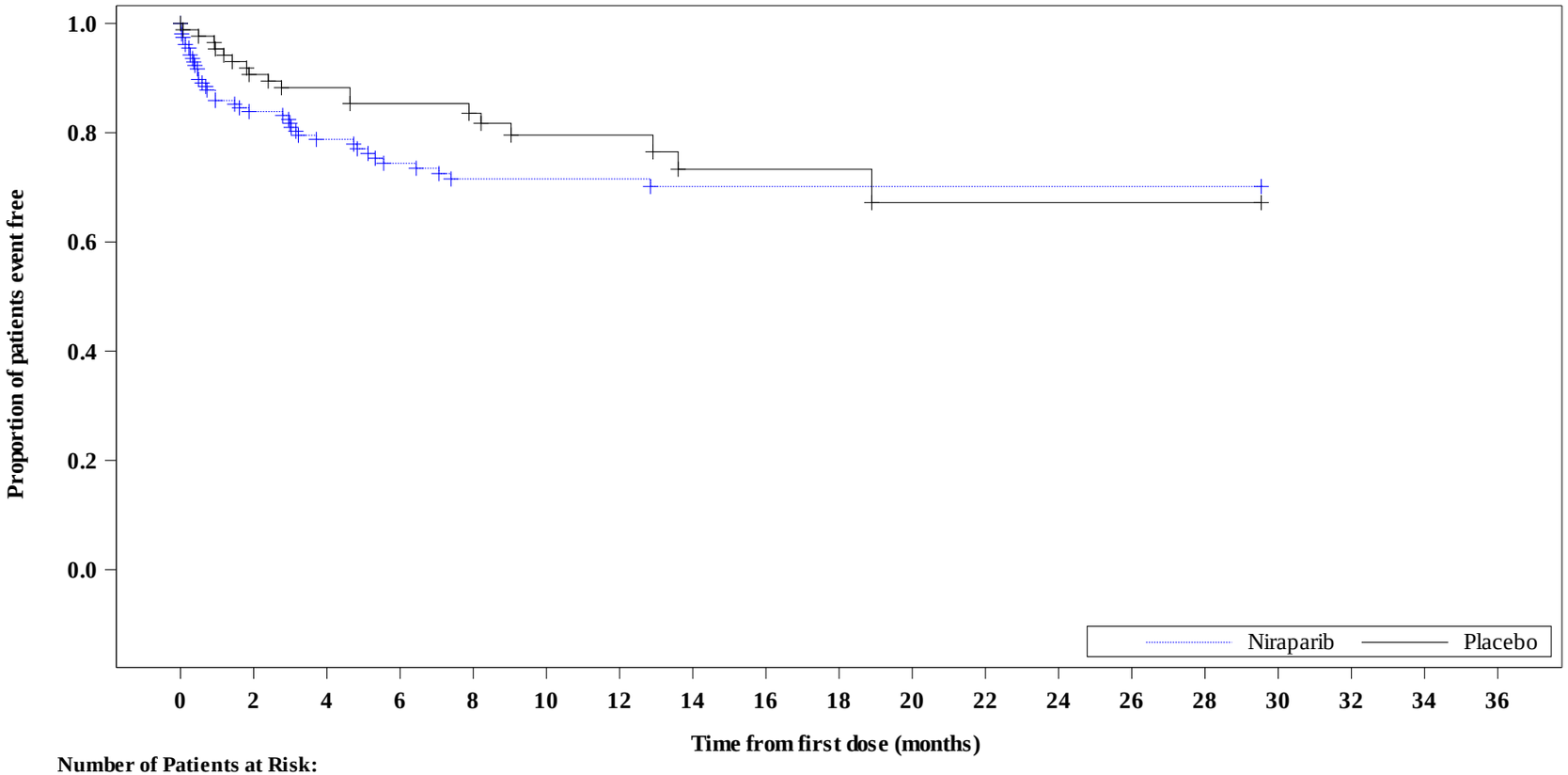
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Vascular disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 120 | 93 | 82 | 65 | 59 | 56 | 49 | 42 | 36 | 21 | 10 | 6 | 4 | 2 | 0 |
| Placebo | 86 | 76 | 65 | 57 | 47 | 33 | 28 | 21 | 18 | 14 | 11 | 4 | 2 | 2 | 1 | 0 |

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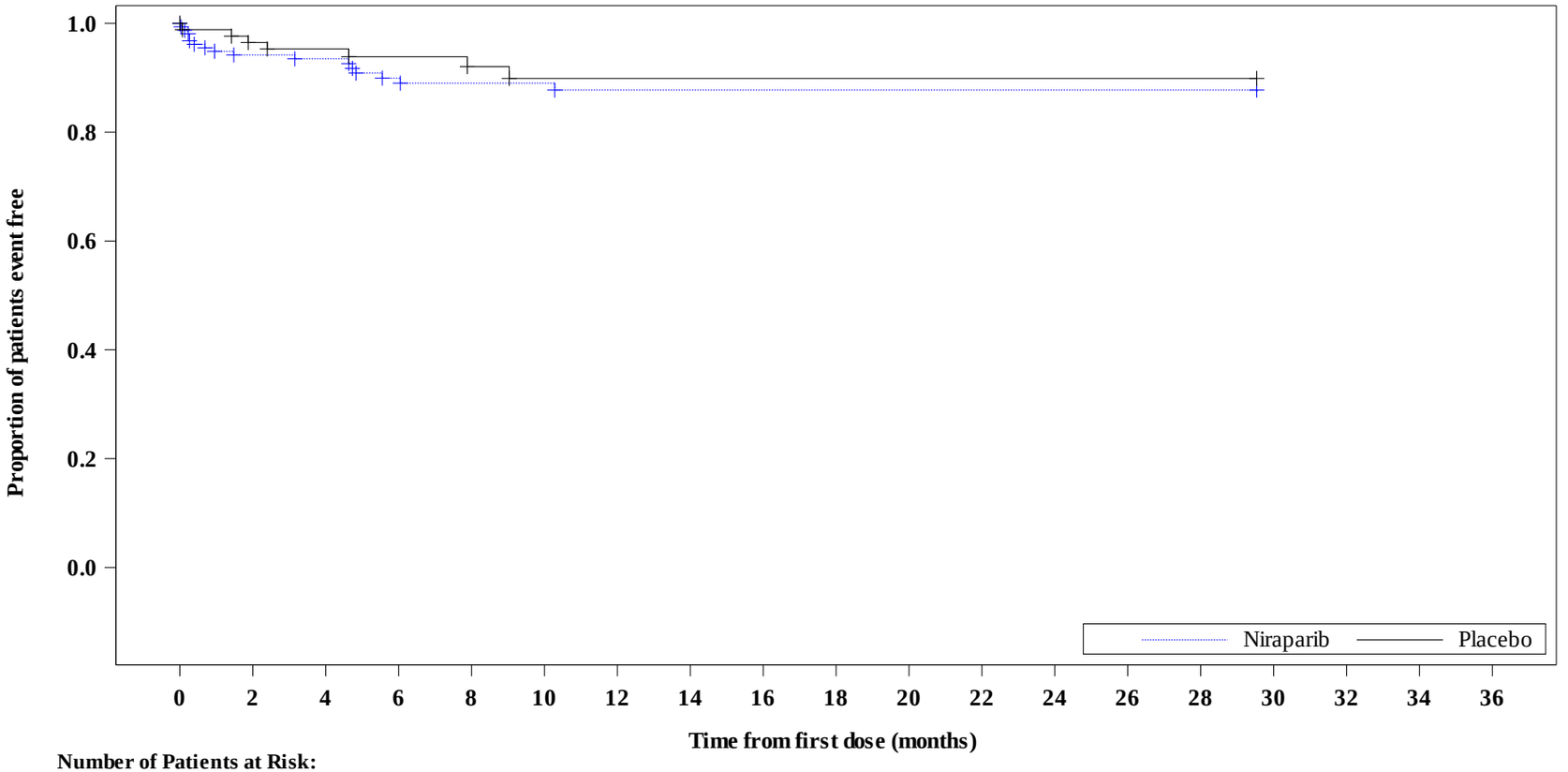
Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Vascular disorders, PT: Hot flush



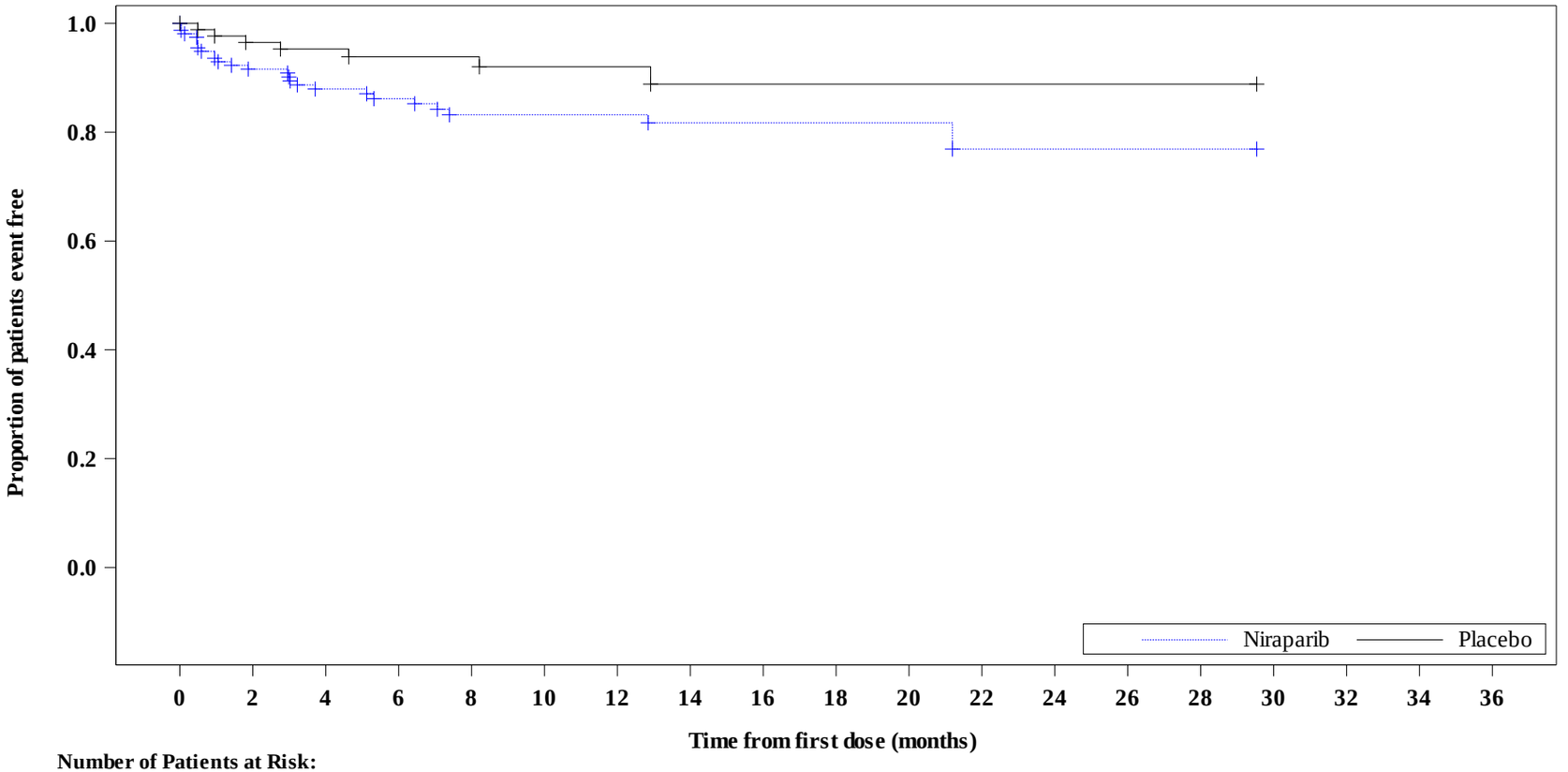

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 135 | 111 | 97 | 78 | 71 | 66 | 60 | 51 | 45 | 27 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 81 | 71 | 64 | 51 | 37 | 32 | 25 | 20 | 16 | 13 | 5 | 3 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-138a-teaept-rdg.sas 06OCT2020 07:06

Figure 3.138a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)

SOC: Vascular disorders, PT: Hypertension




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 131 | 103 | 94 | 73 | 65 | 61 | 53 | 44 | 38 | 22 | 10 | 6 | 4 | 2 | 0 |
| Placebo | 86 | 81 | 71 | 64 | 53 | 39 | 33 | 25 | 22 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

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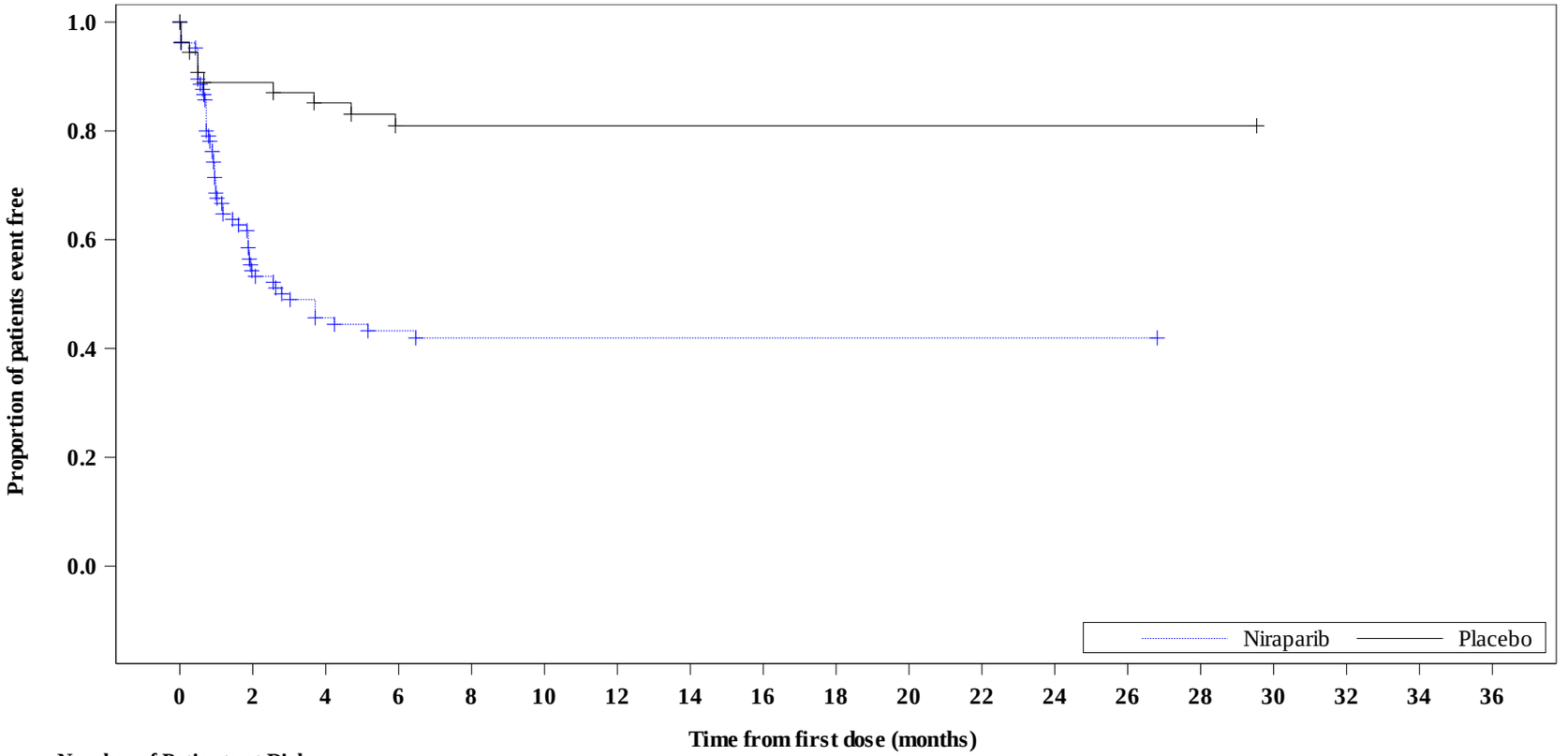
Figure 3.138b
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Residual Disease Status (Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia
Residual Disease Status: R0




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 105 | 51 | 39 | 34 | 24 | 20 | 20 | 18 | 14 | 11 | 9 | 2 | 1 | 1 | 0 | |
| Placebo | 54 | 48 | 43 | 38 | 32 | 28 | 25 | 21 | 18 | 15 | 10 | 5 | 3 | 2 | 1 | 0 |

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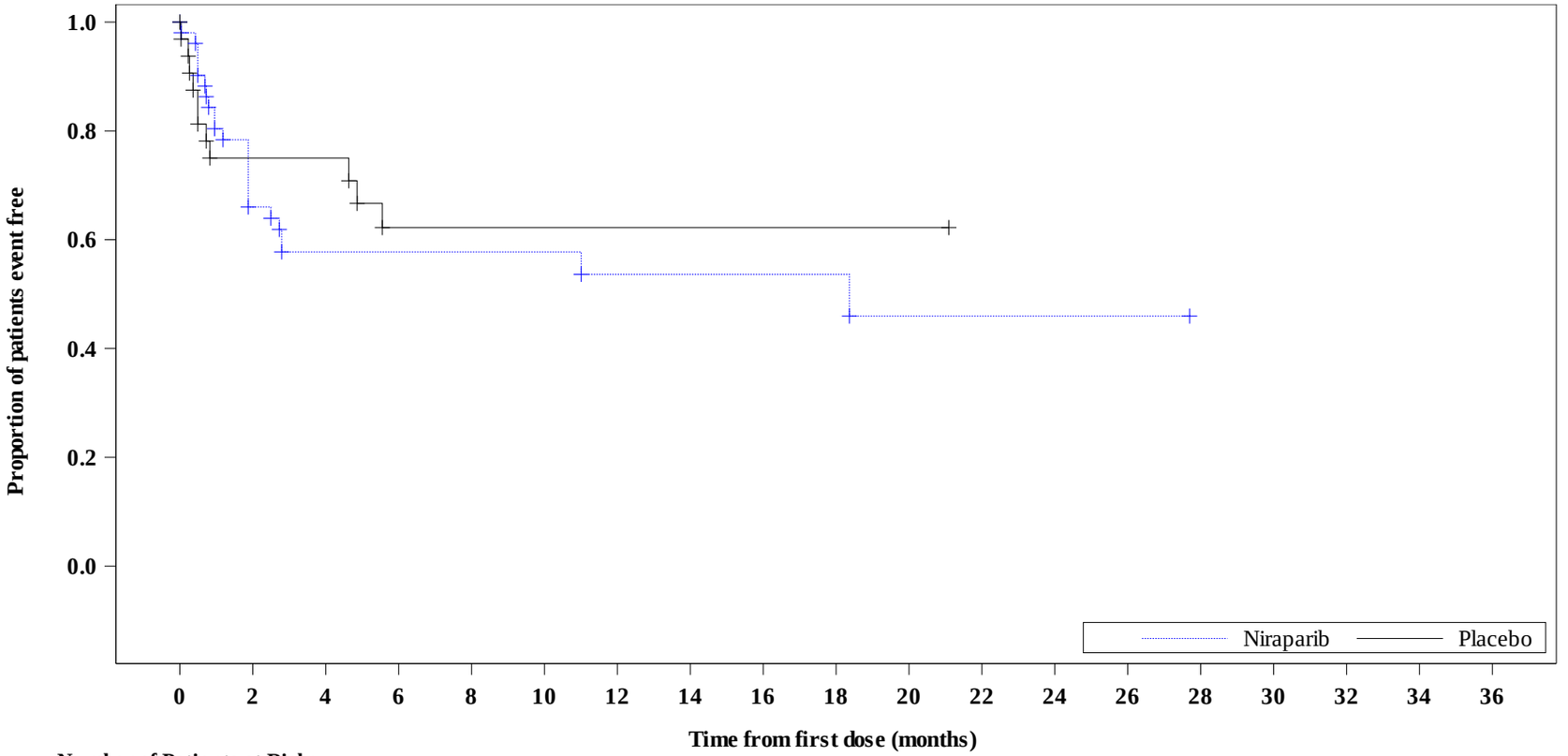
Figure 3.138b
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events Experienced by (>= 10% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT and Residual Disease Status (Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia
Residual Disease Status: R1/R2




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 51 | 32 | 23 | 21 | 18 | 15 | 11 | 10 | 8 | 7 | 4 | 2 | 2 | 1 | 0 |
| Placebo | 32 | 22 | 20 | 14 | 12 | 6 | 4 | 1 | 1 | 1 | 1 | 0 | | | |

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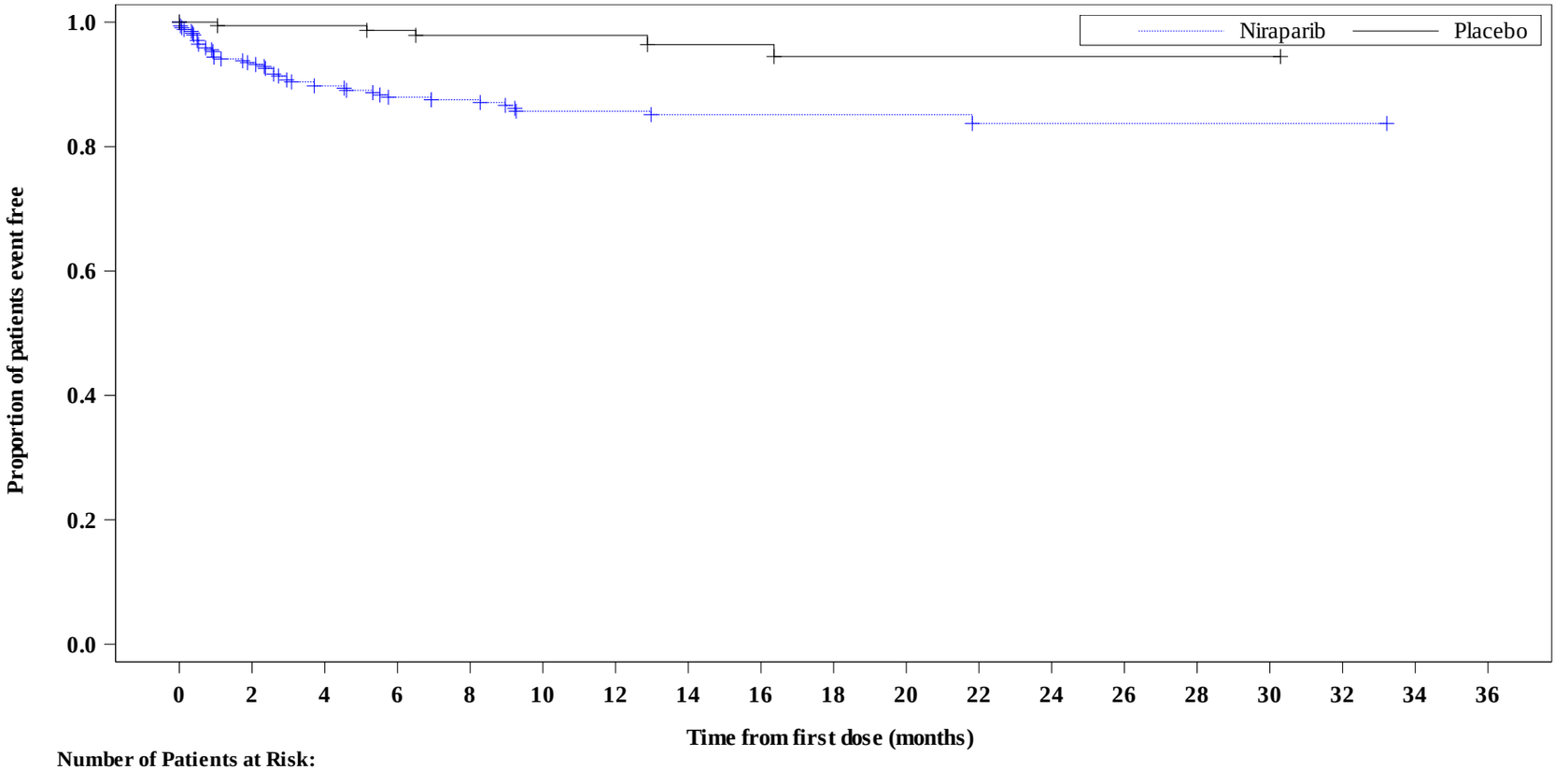
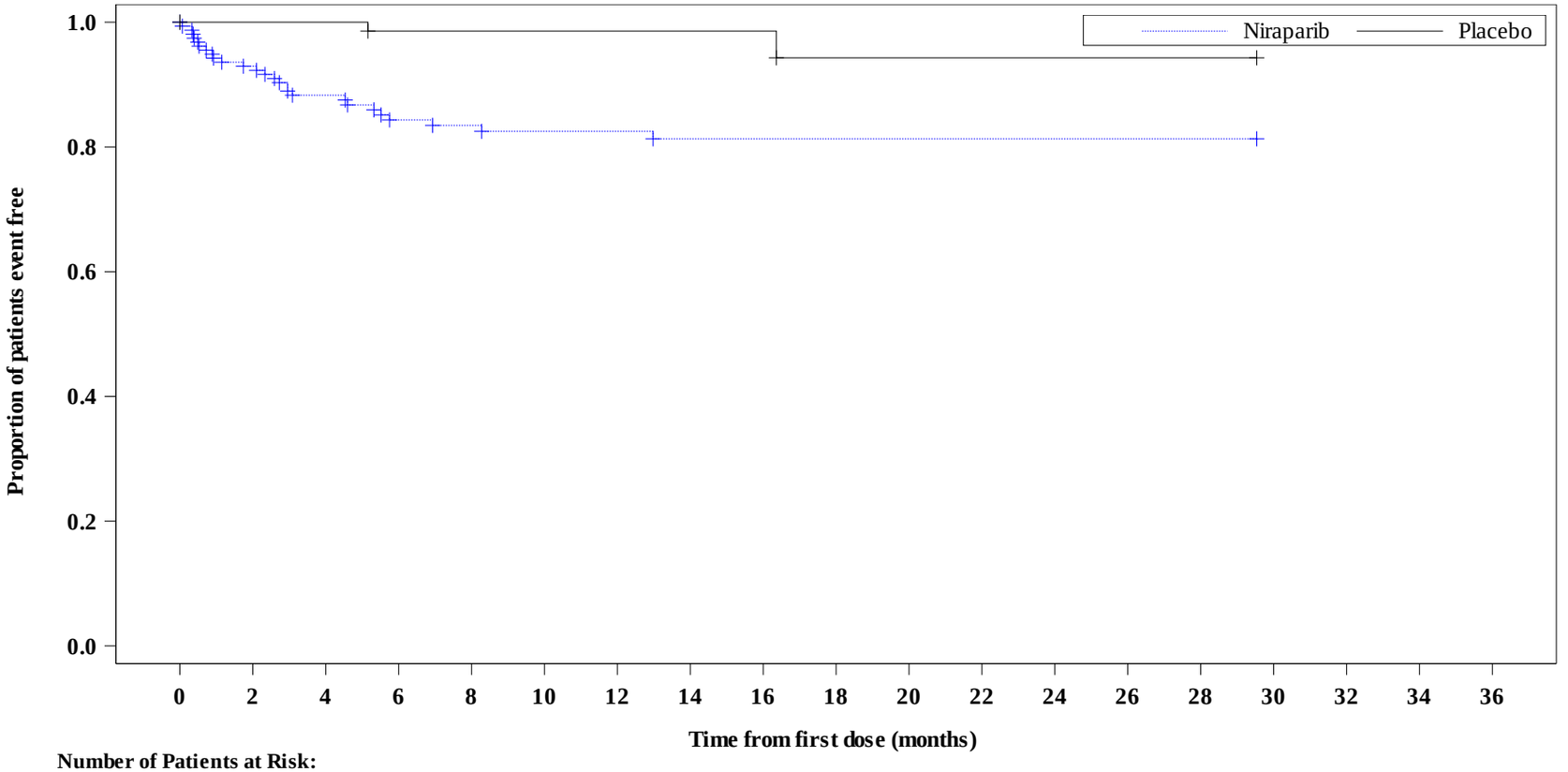
Figure 3.139a
Time to Onset of First Occurrence of TEAE Leading to Study Drug Withdrawal
(Residual Disease Safety Population)




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 307 | 259 | 236 | 197 | 172 | 165 | 151 | 127 | 116 | 86 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 78 | 70 | 58 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

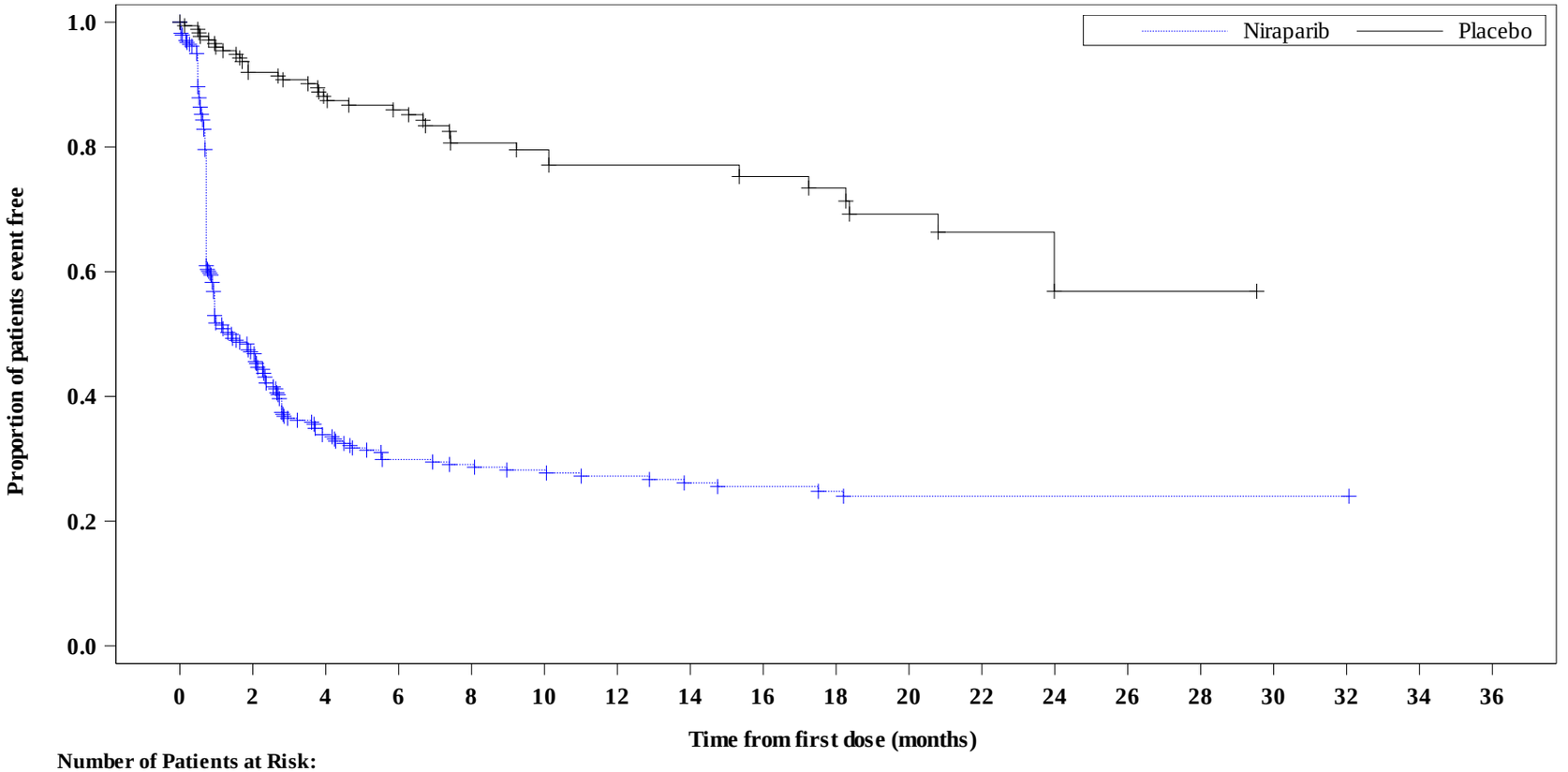
Figure 3.140a
Time to Onset of First Occurrence of TEAE Leading to Study Drug Withdrawal
(Residual Disease Safety-GVD Population)




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 116 | 104 | 87 | 78 | 74 | 66 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 68 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.141a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events
(Residual Disease Safety Population)

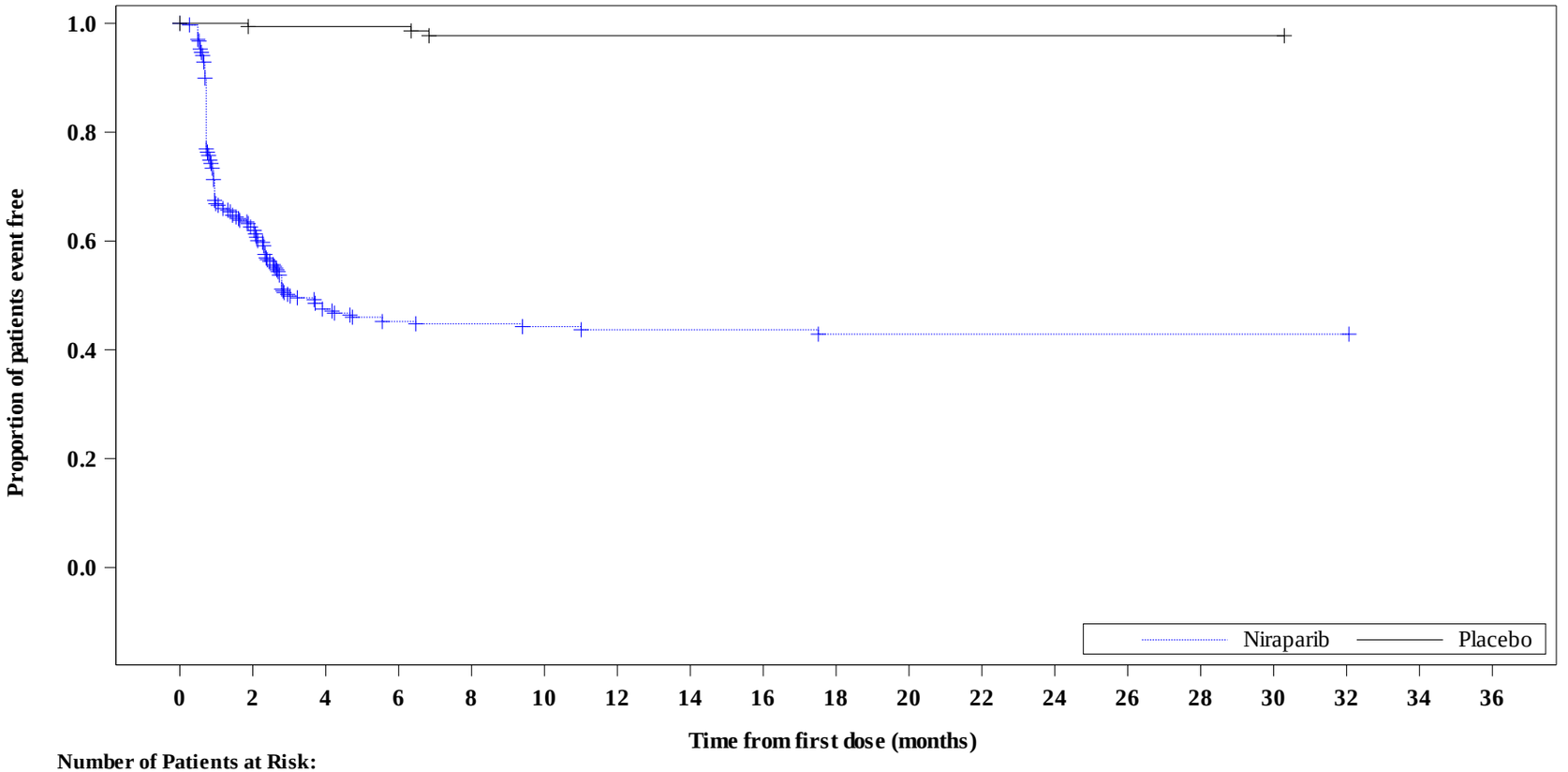



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 151 | 98 | 80 | 68 | 58 | 52 | 47 | 36 | 31 | 22 | 14 | 10 | 6 | 2 | 1 | 1 | 0 |
| Placebo | 175 | 158 | 128 | 112 | 83 | 65 | 57 | 49 | 41 | 35 | 29 | 16 | 6 | 4 | 1 | 0 | | |

Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 200 | 131 | 112 | 95 | 80 | 74 | 68 | 57 | 49 | 37 | 23 | 15 | 9 | 4 | 1 | 1 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 77 | 69 | 58 | 49 | 42 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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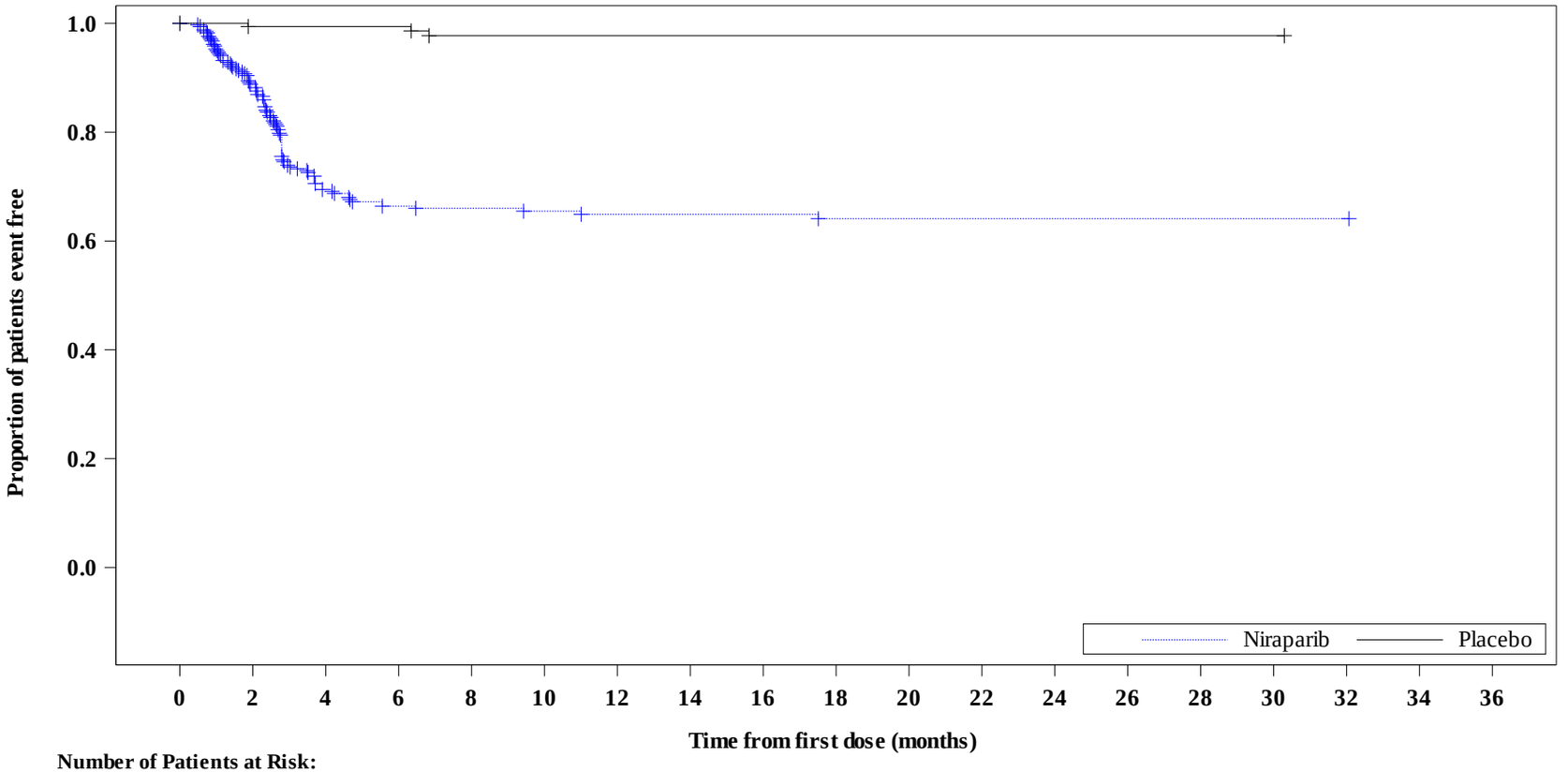
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 278 | 192 | 165 | 137 | 118 | 111 | 102 | 85 | 76 | 57 | 38 | 25 | 14 | 7 | 2 | 1 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 77 | 69 | 58 | 49 | 42 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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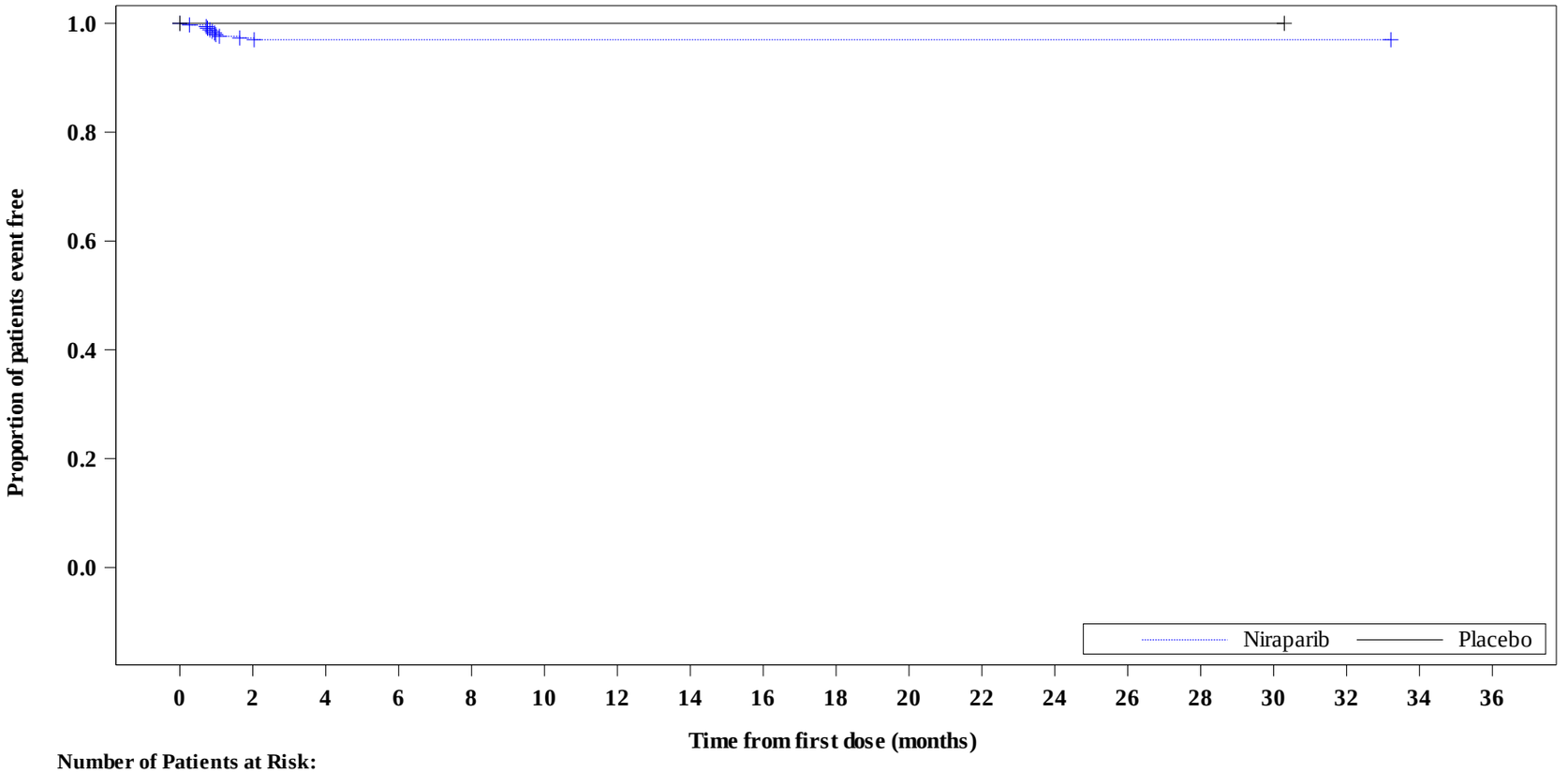
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Leukopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 303 | 259 | 233 | 192 | 168 | 160 | 147 | 123 | 112 | 82 | 58 | 39 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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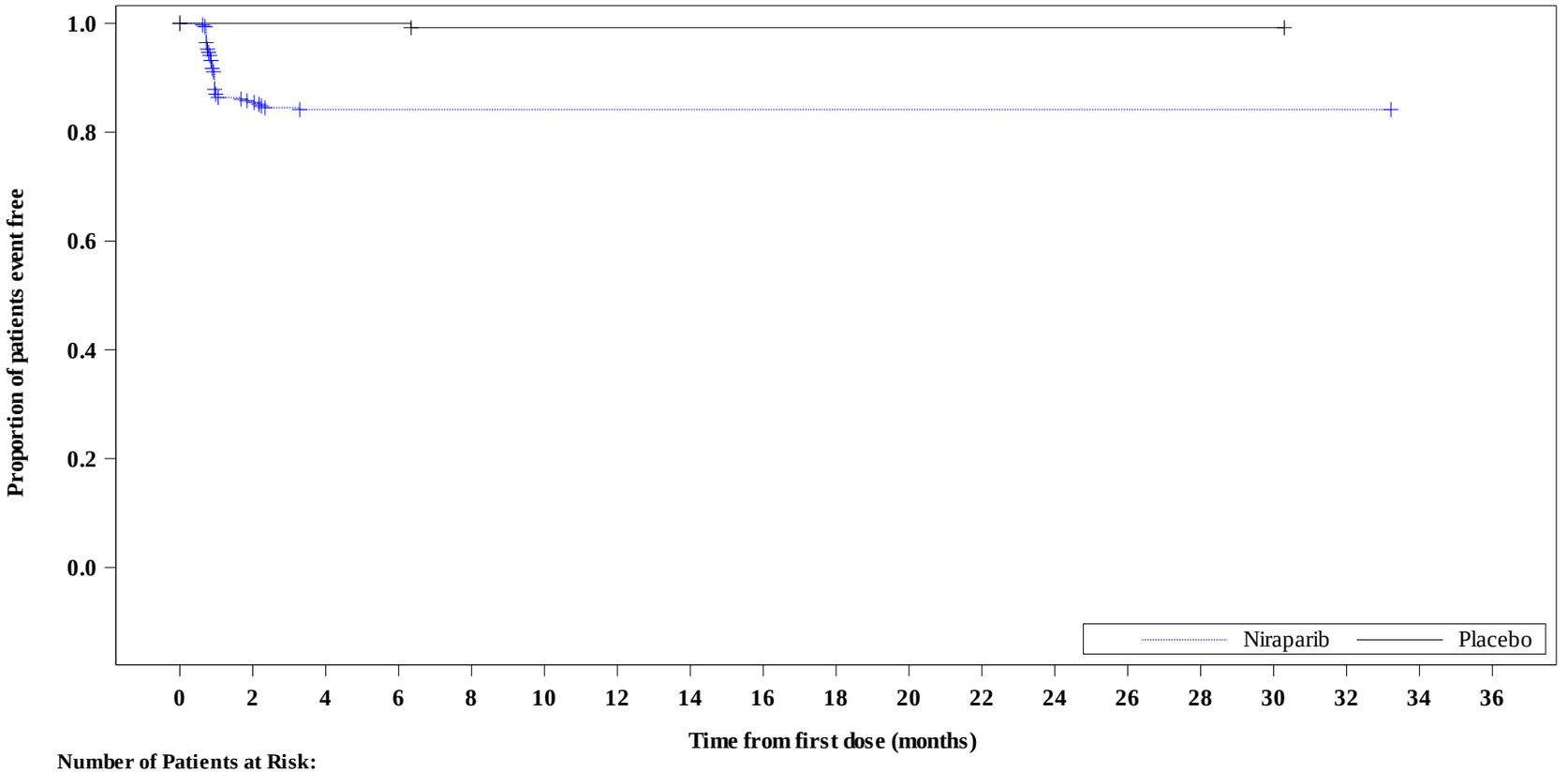
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Neutropenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 269 | 224 | 202 | 170 | 148 | 142 | 133 | 110 | 100 | 74 | 53 | 35 | 18 | 8 | 2 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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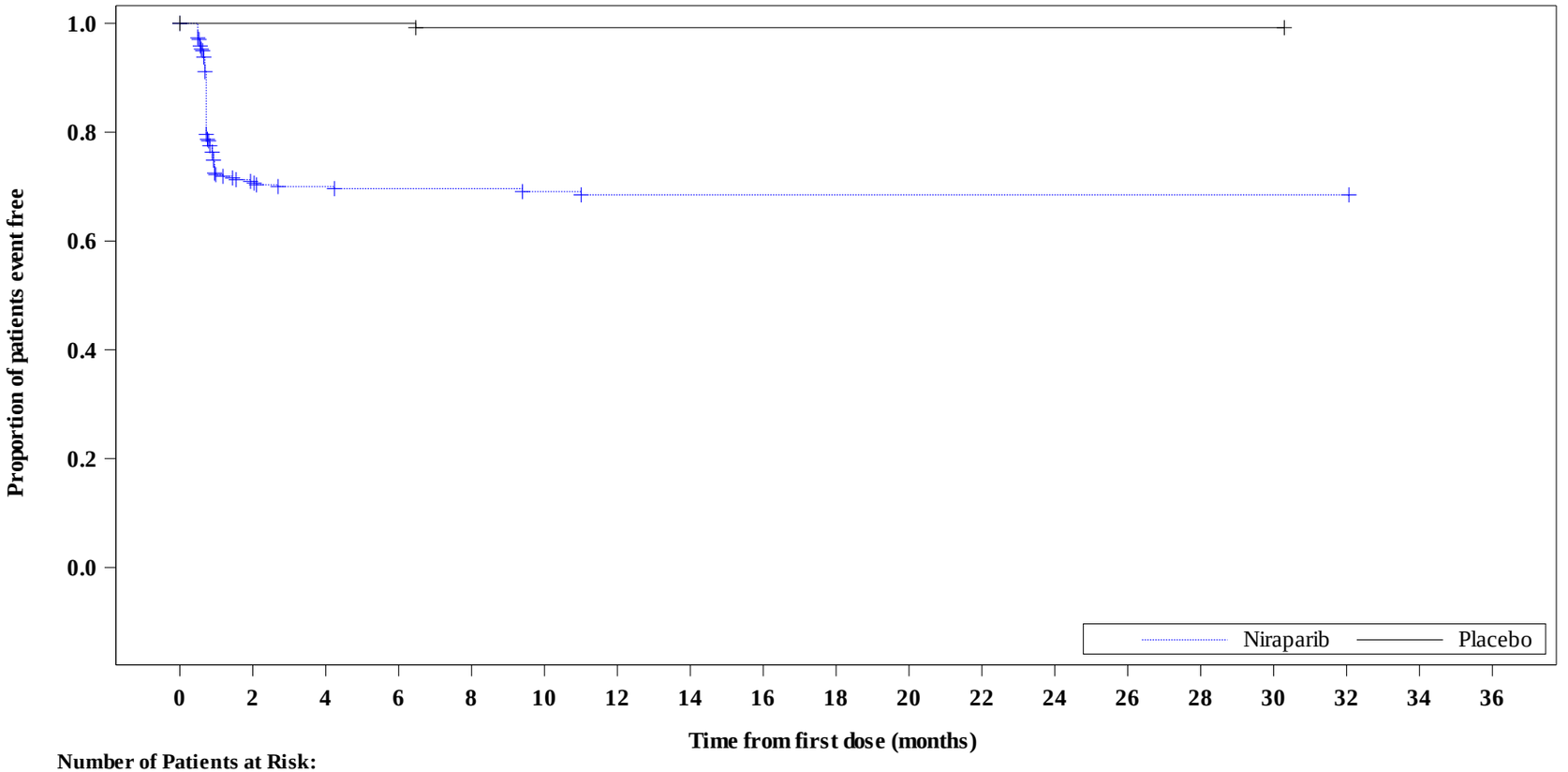
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

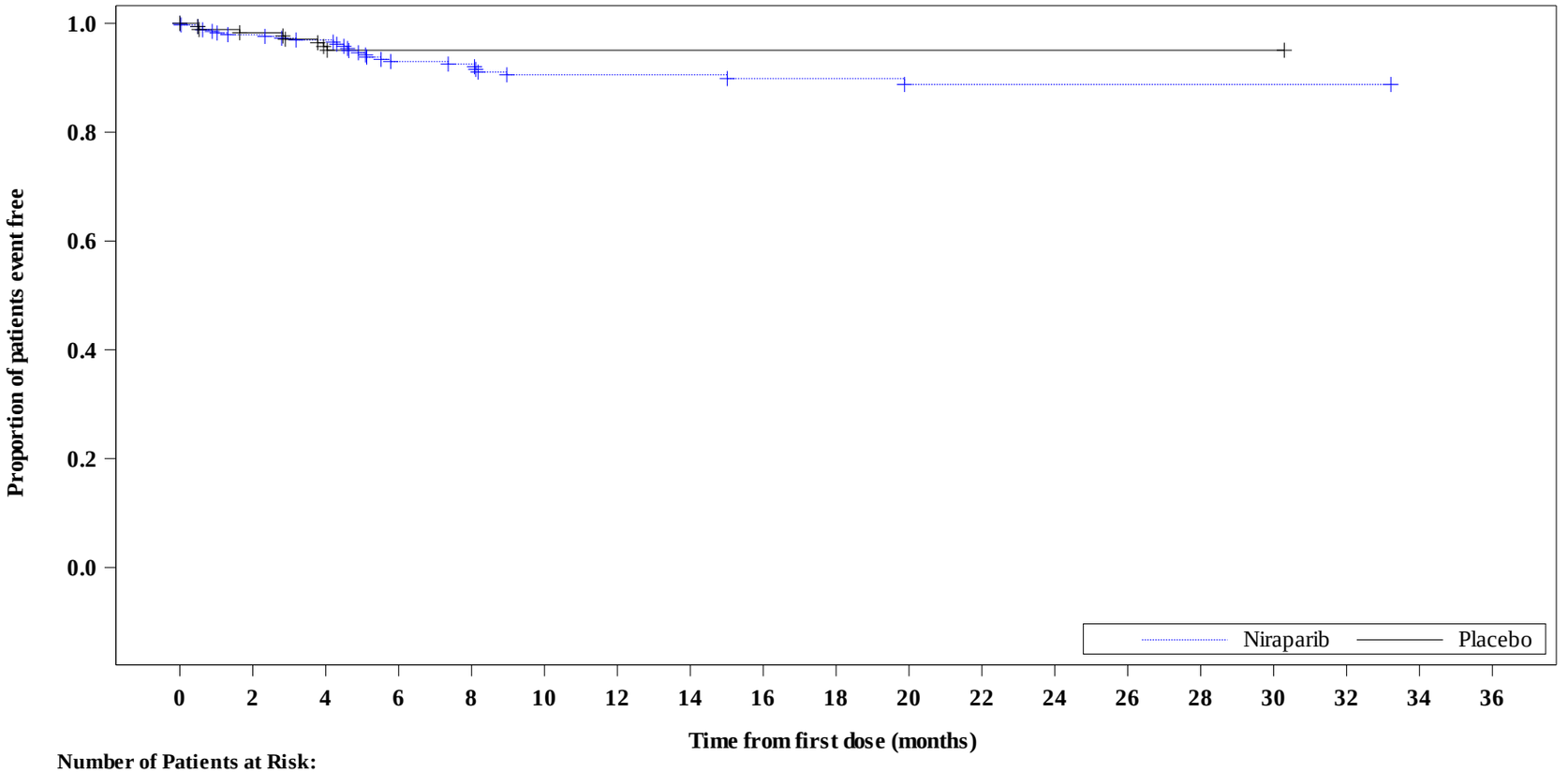



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 226 | 186 | 168 | 138 | 119 | 112 | 102 | 86 | 77 | 55 | 37 | 26 | 12 | 6 | 1 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Gastrointestinal disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 259 | 227 | 188 | 166 | 160 | 147 | 122 | 111 | 80 | 55 | 38 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 169 | 141 | 125 | 99 | 76 | 68 | 57 | 48 | 41 | 35 | 18 | 7 | 5 | 2 | 1 | 0 | |

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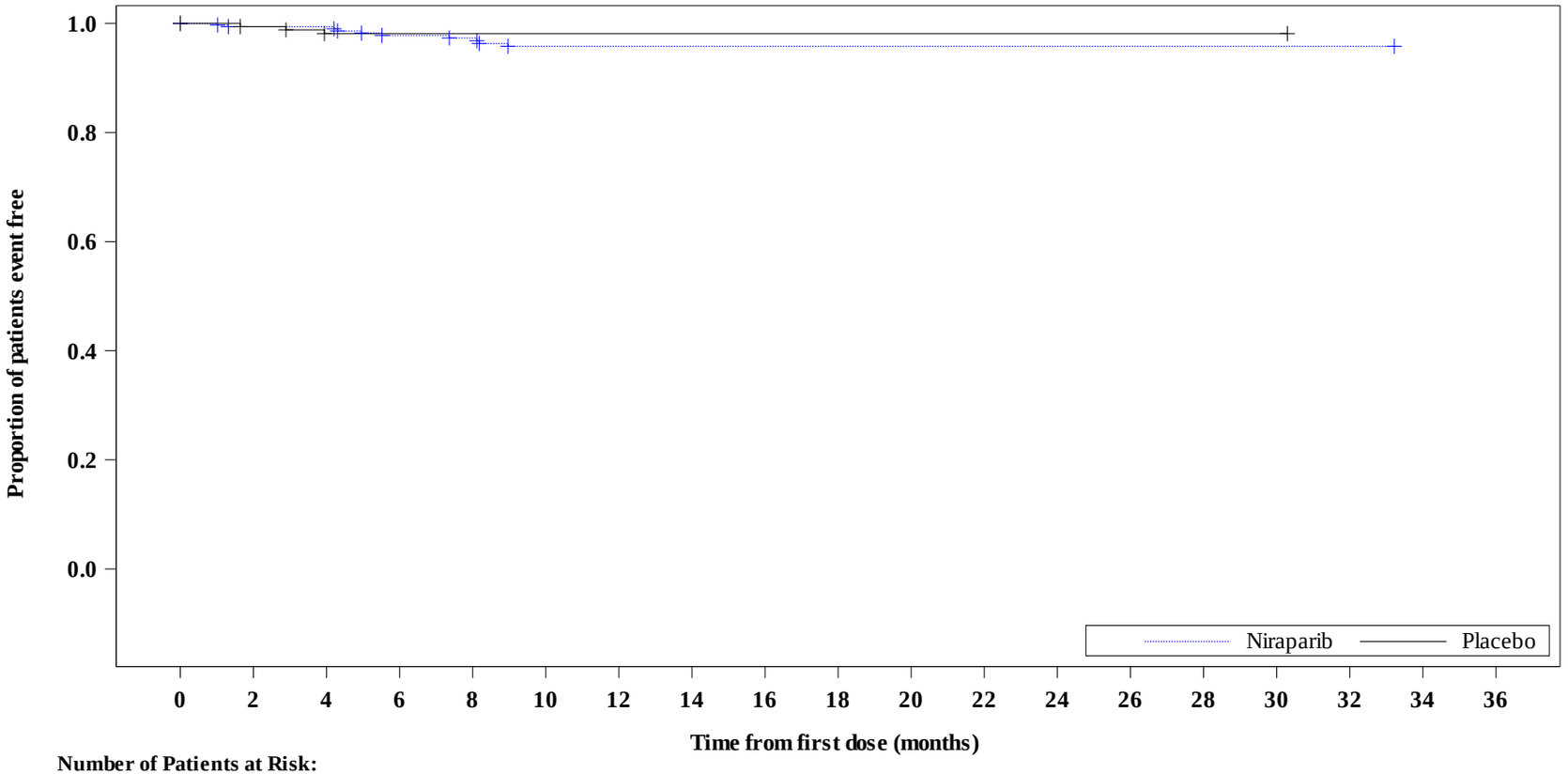
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Gastrointestinal disorders, PT: Small intestinal obstruction




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 263 | 234 | 193 | 169 | 162 | 149 | 124 | 113 | 83 | 58 | 39 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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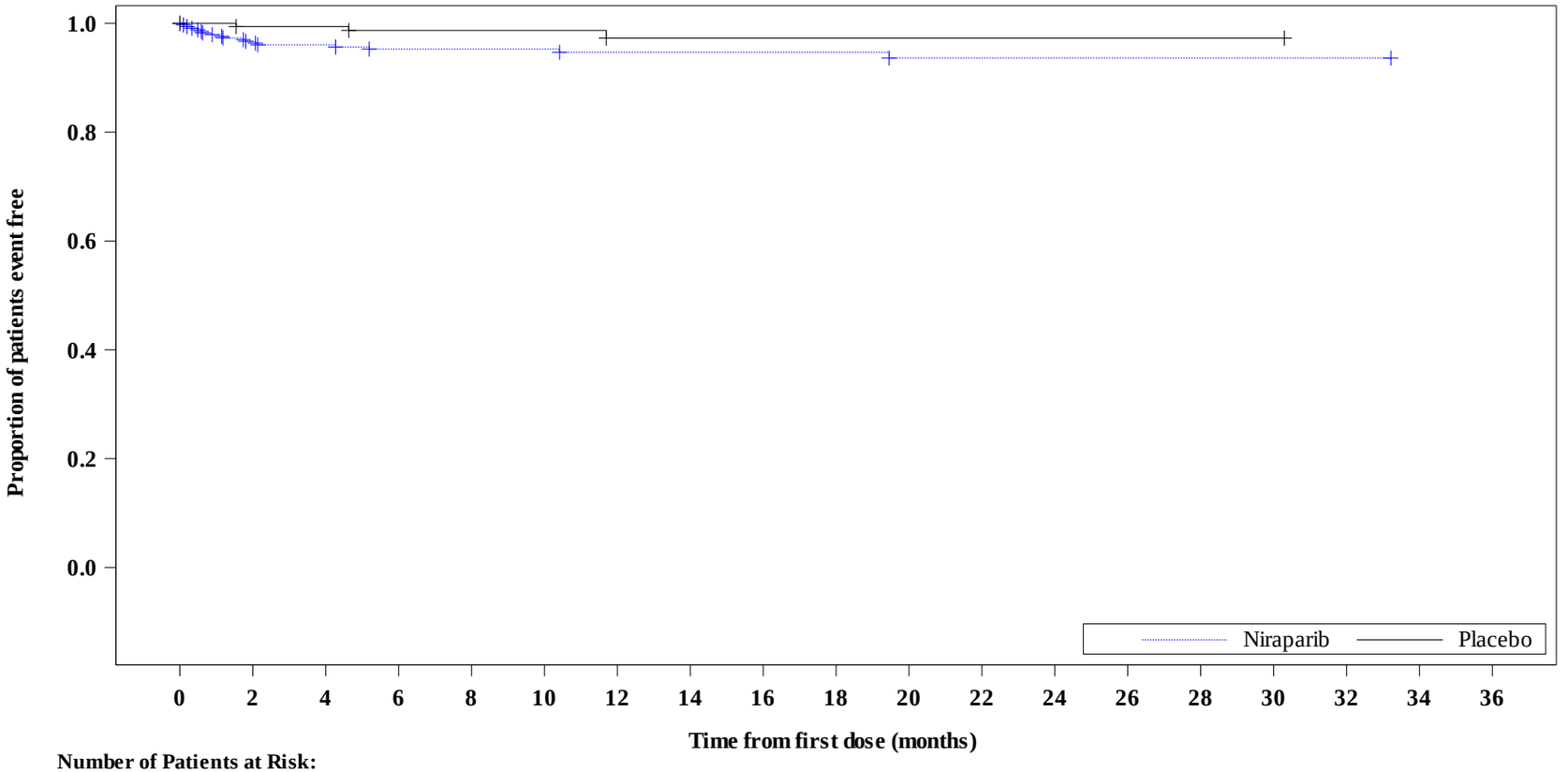
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: General disorders and administration site conditions




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 301 | 257 | 233 | 191 | 168 | 159 | 146 | 121 | 110 | 79 | 56 | 37 | 17 | 7 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 100 | 78 | 69 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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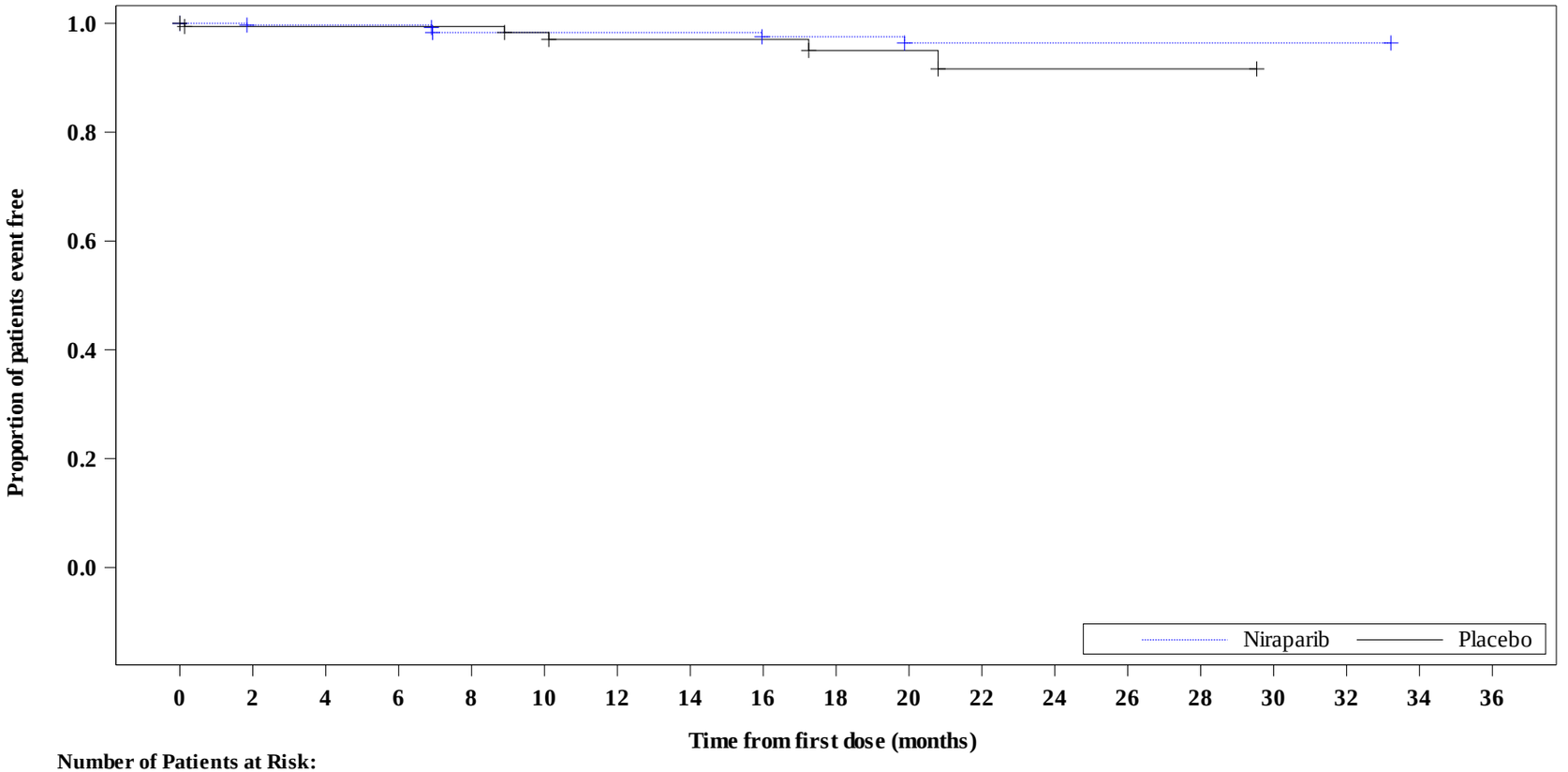
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Infections and infestations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 264 | 238 | 195 | 171 | 163 | 150 | 124 | 113 | 83 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 77 | 68 | 57 | 49 | 42 | 35 | 17 | 7 | 4 | 1 | 0 | | |

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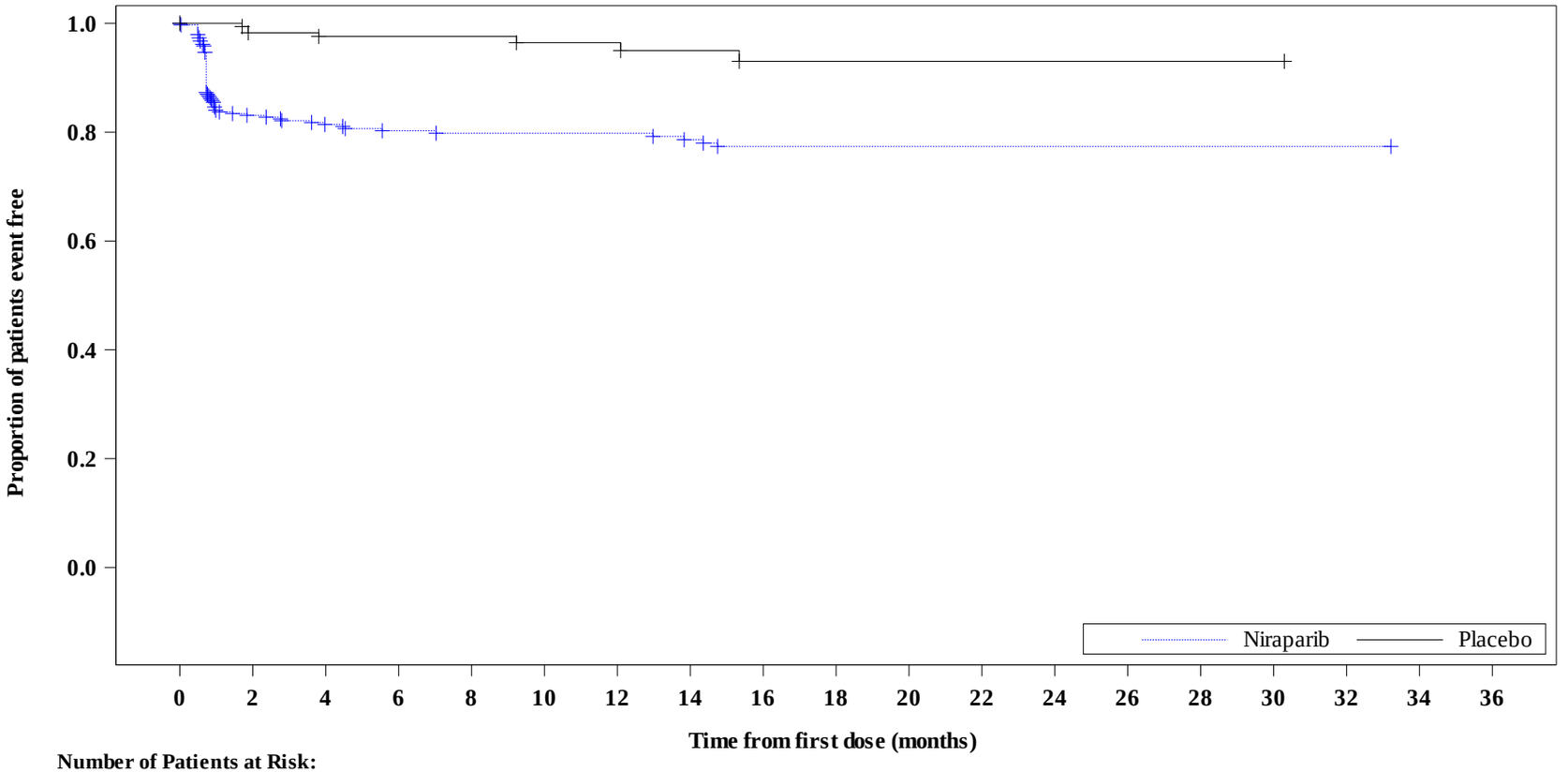
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Investigations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 257 | 222 | 198 | 167 | 148 | 141 | 129 | 106 | 97 | 70 | 50 | 34 | 17 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 169 | 142 | 126 | 100 | 76 | 68 | 57 | 47 | 41 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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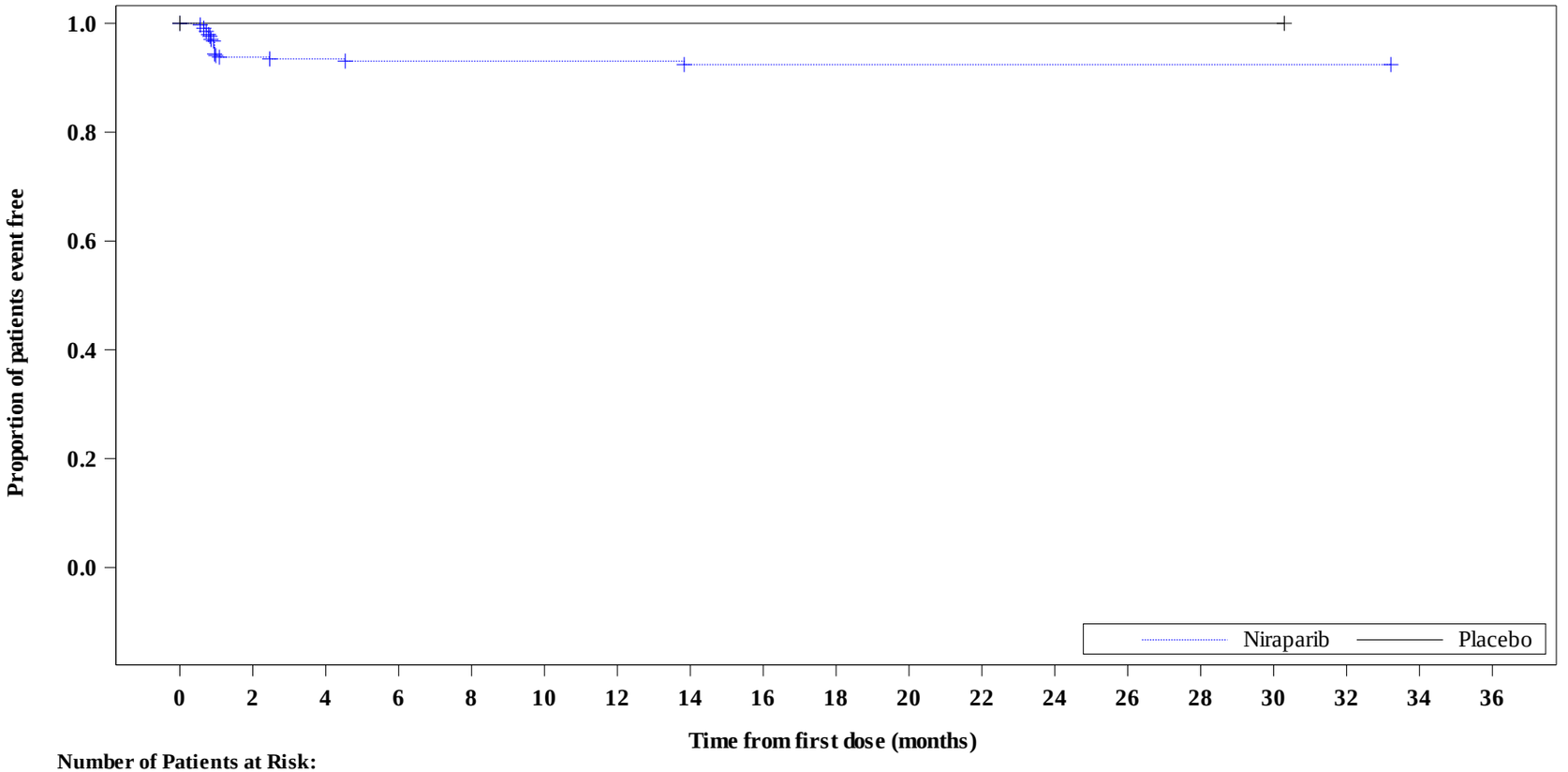
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Investigations, PT: Neutrophil count decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 292 | 250 | 224 | 186 | 165 | 157 | 145 | 121 | 112 | 82 | 58 | 39 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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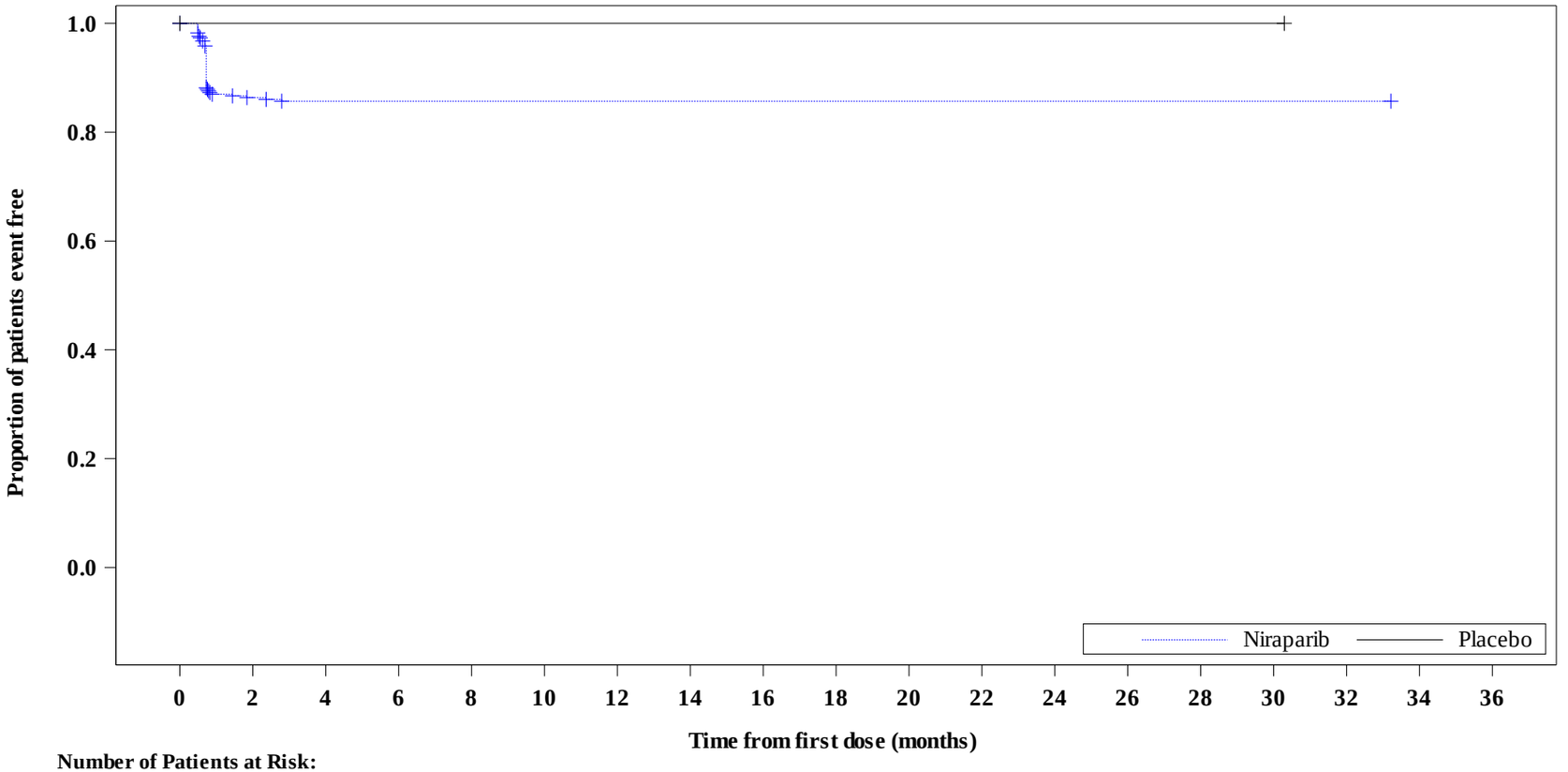
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Investigations, PT: Platelet count decreased




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 266 | 231 | 208 | 172 | 152 | 145 | 134 | 112 | 103 | 75 | 52 | 35 | 17 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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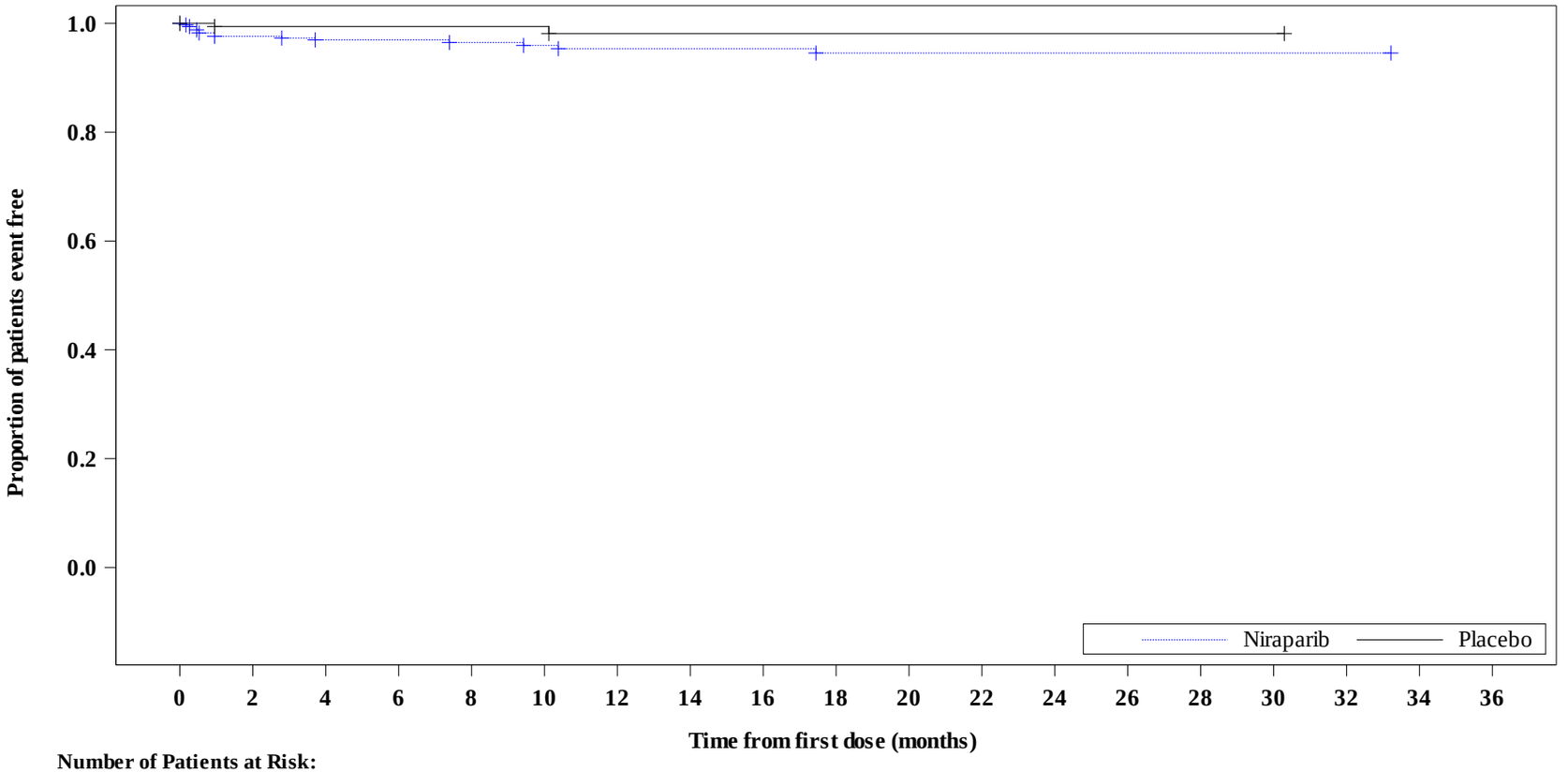
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Metabolism and nutrition disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 304 | 258 | 232 | 191 | 167 | 158 | 146 | 123 | 112 | 83 | 58 | 39 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 77 | 68 | 57 | 48 | 41 | 34 | 17 | 8 | 5 | 2 | 1 | 0 | |

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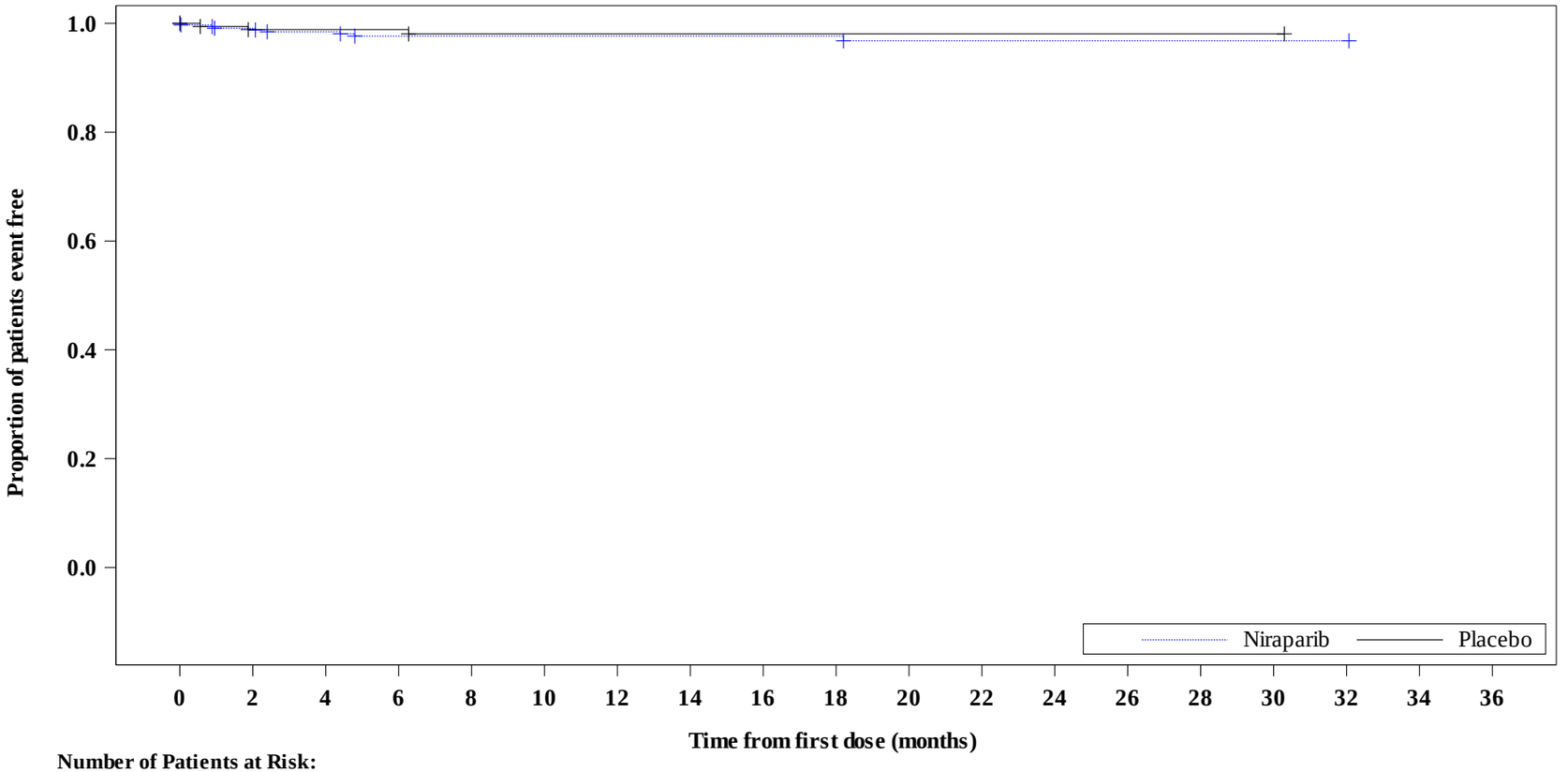
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Nervous system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 261 | 233 | 192 | 168 | 160 | 147 | 123 | 112 | 82 | 57 | 39 | 19 | 9 | 2 | 1 | 0 |
| Placebo | 175 | 170 | 143 | 126 | 100 | 76 | 68 | 57 | 49 | 42 | 35 | 18 | 7 | 5 | 2 | 1 | 0 | |

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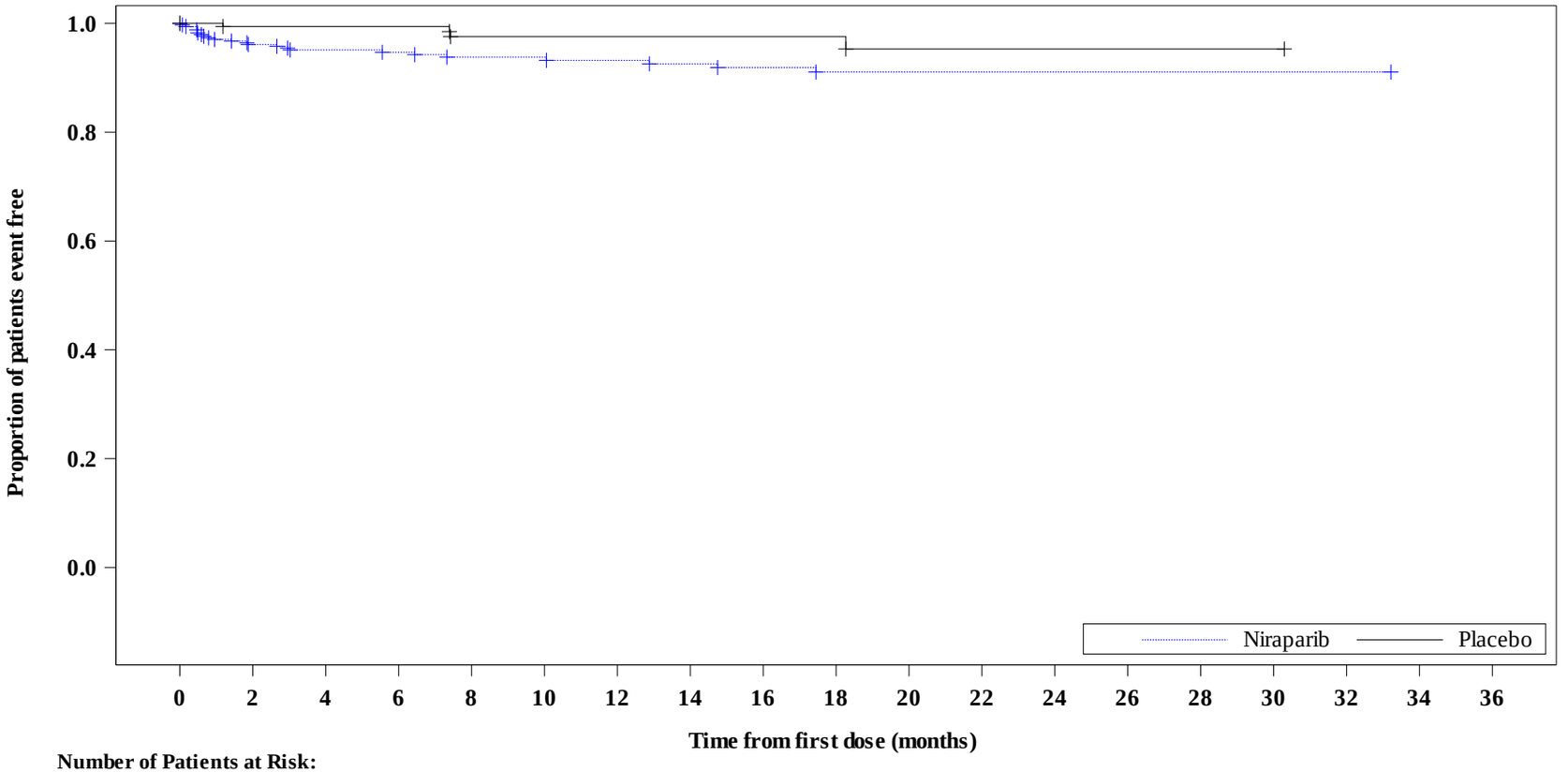
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Vascular disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 298 | 251 | 225 | 185 | 162 | 153 | 140 | 116 | 105 | 78 | 56 | 39 | 19 | 9 | 2 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 100 | 76 | 68 | 59 | 50 | 43 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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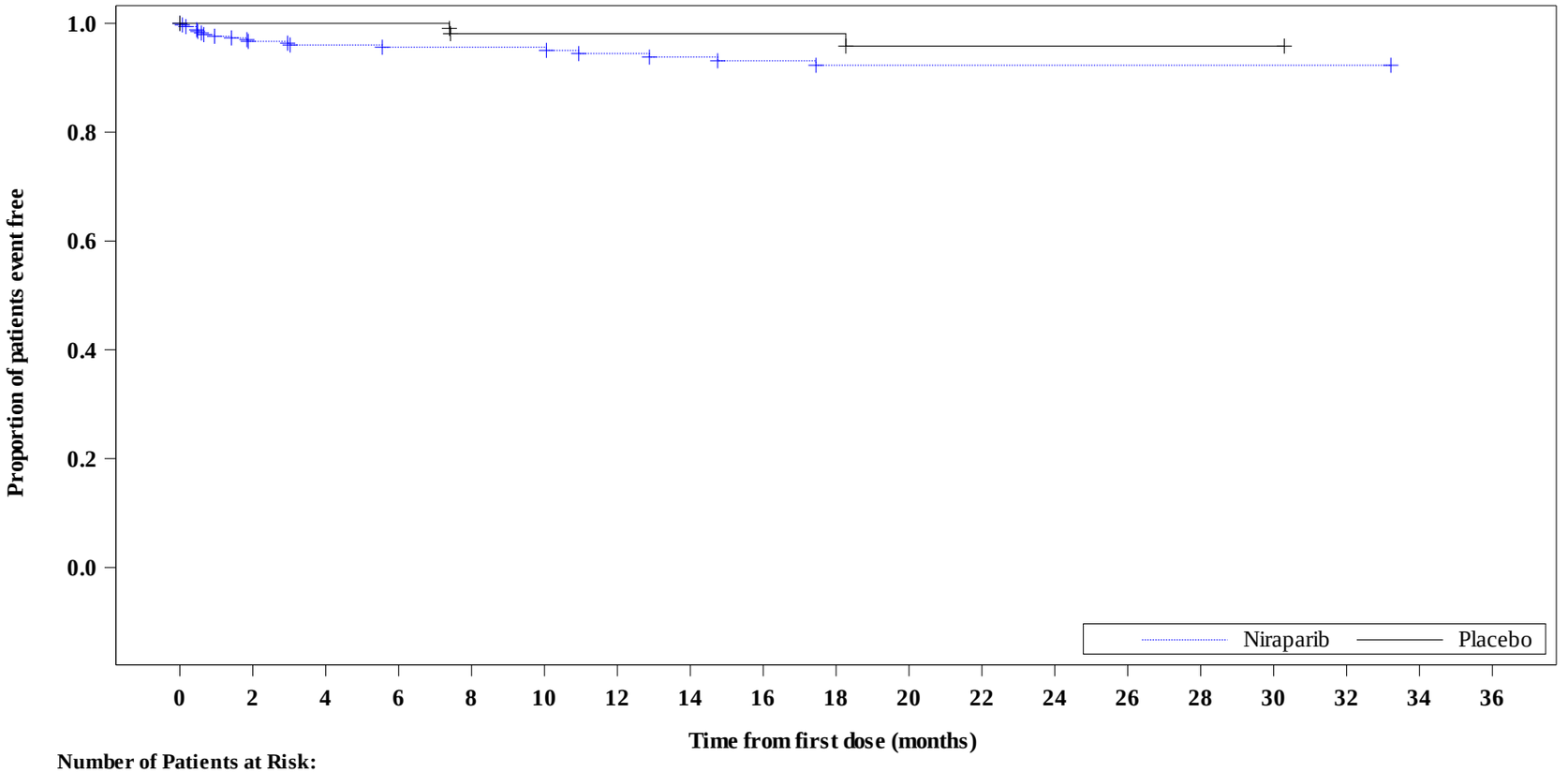
Figure 3.142a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety Population)

SOC: Vascular disorders, PT: Hypertension




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 300 | 254 | 228 | 189 | 166 | 156 | 142 | 118 | 107 | 79 | 57 | 39 | 19 | 9 | 2 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 100 | 76 | 68 | 59 | 50 | 43 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

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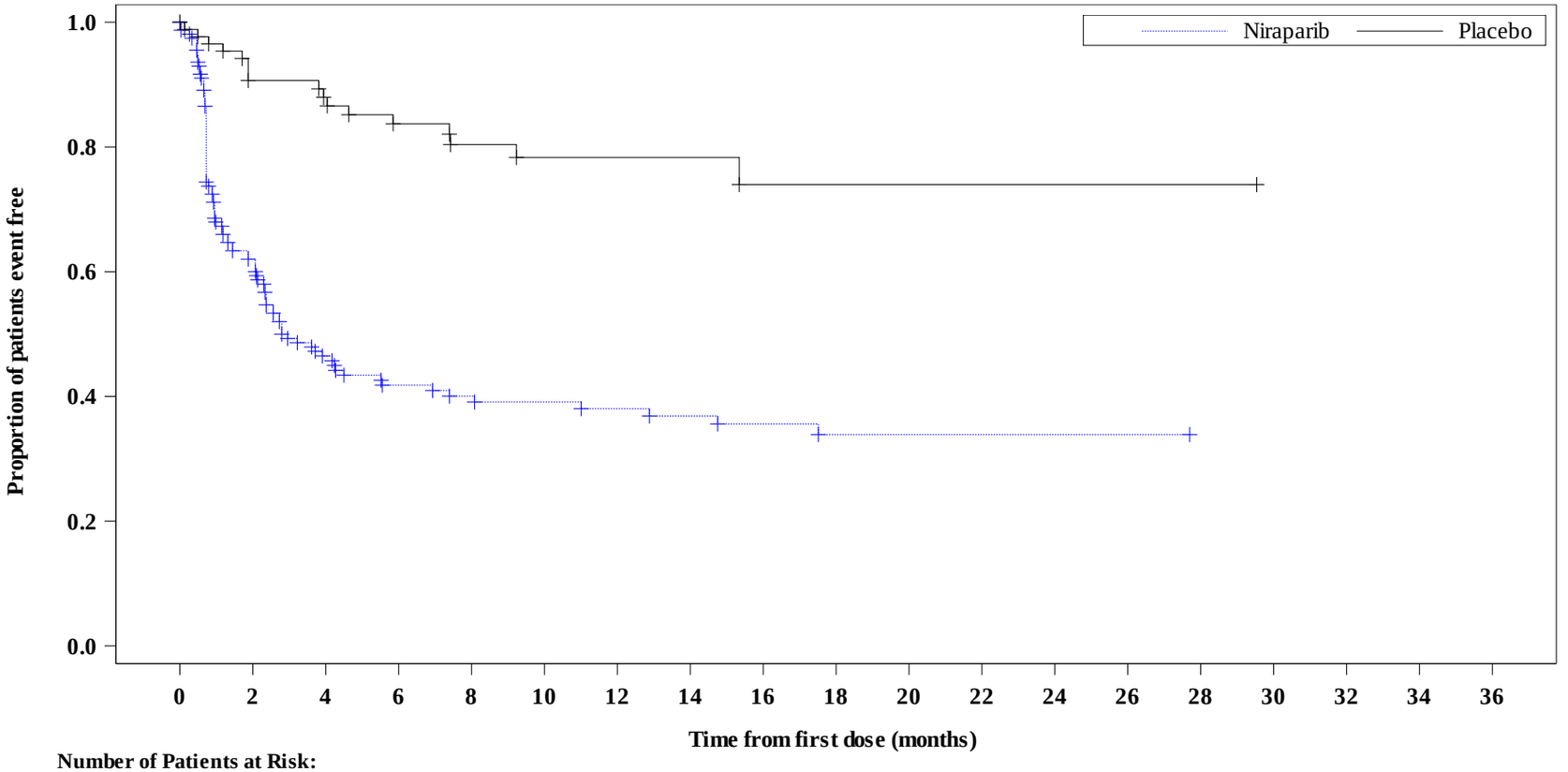
Figure 3.143a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events
(Residual Disease Safety-GVD Population)

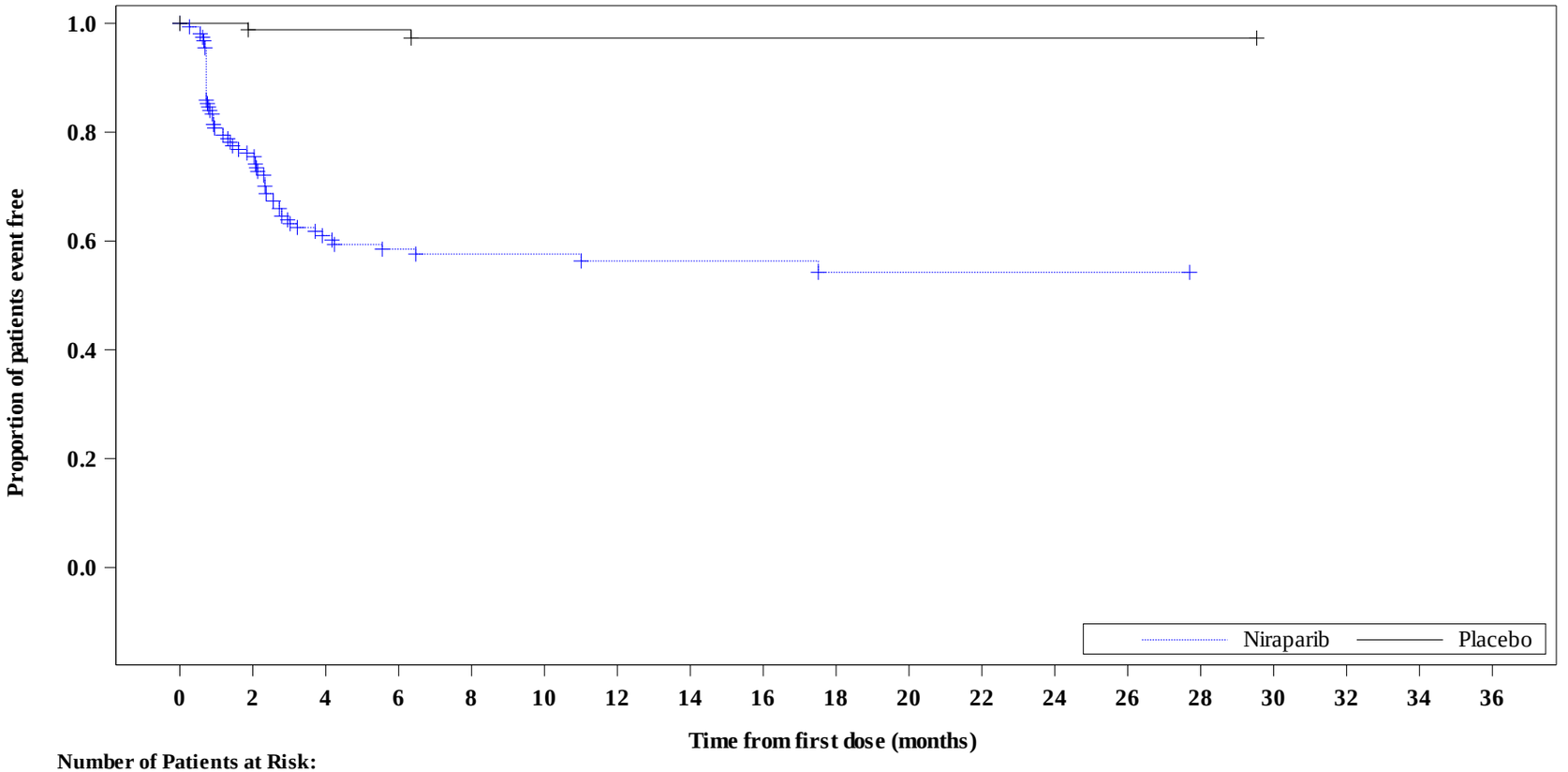



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 93 | 61 | 52 | 42 | 38 | 34 | 30 | 23 | 19 | 12 | 5 | 3 | 2 | 0 | |
| Placebo | 86 | 76 | 65 | 58 | 45 | 34 | 29 | 23 | 17 | 14 | 11 | 4 | 2 | 2 | 1 | 0 |

Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 113 | 76 | 66 | 53 | 46 | 42 | 37 | 30 | 25 | 18 | 7 | 4 | 2 | 0 | |
| Placebo | 86 | 83 | 74 | 68 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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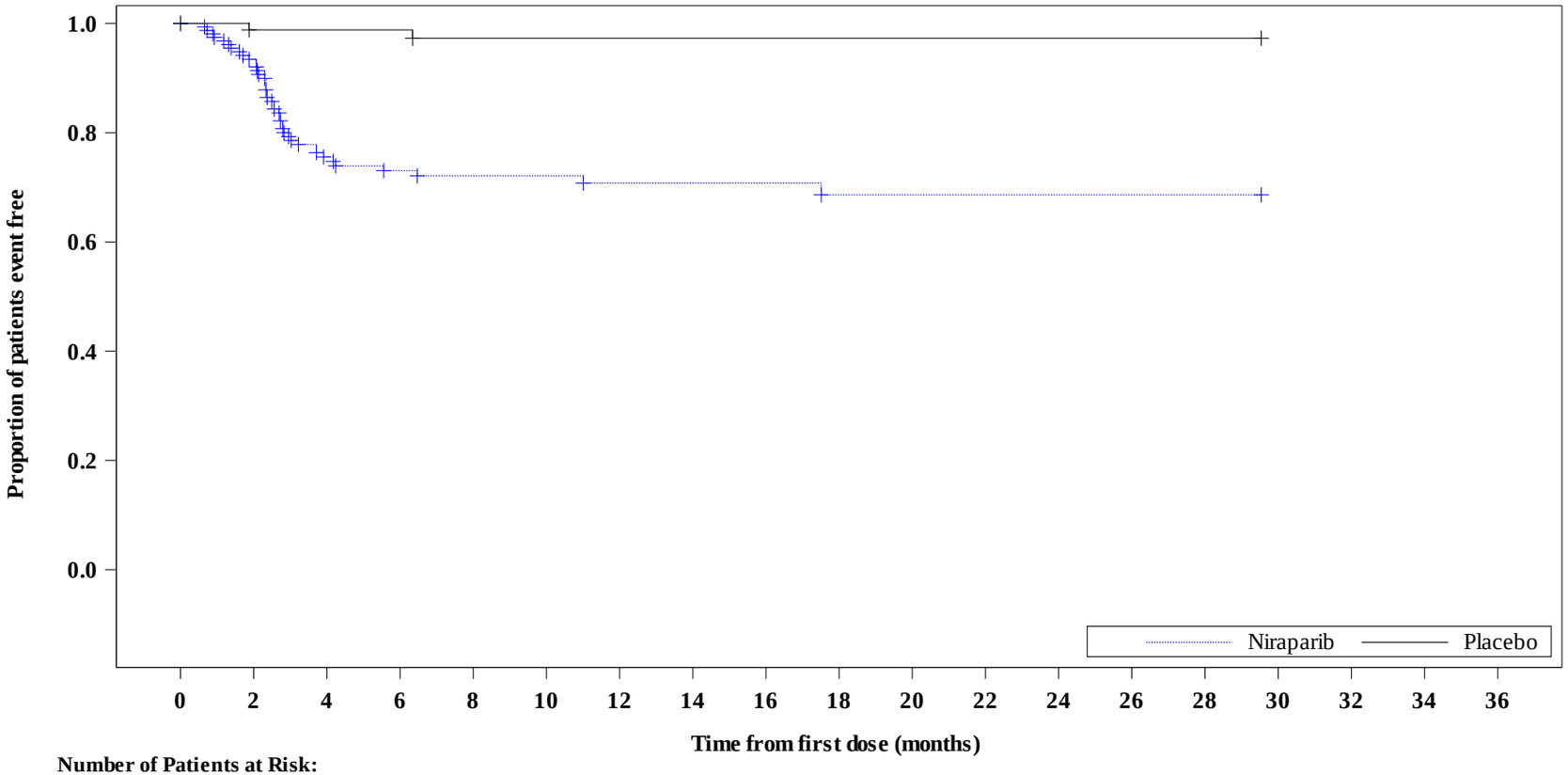
Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Anaemia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 134 | 93 | 81 | 63 | 54 | 50 | 45 | 36 | 31 | 20 | 9 | 6 | 3 | 1 | 0 |
| Placebo | 86 | 83 | 74 | 68 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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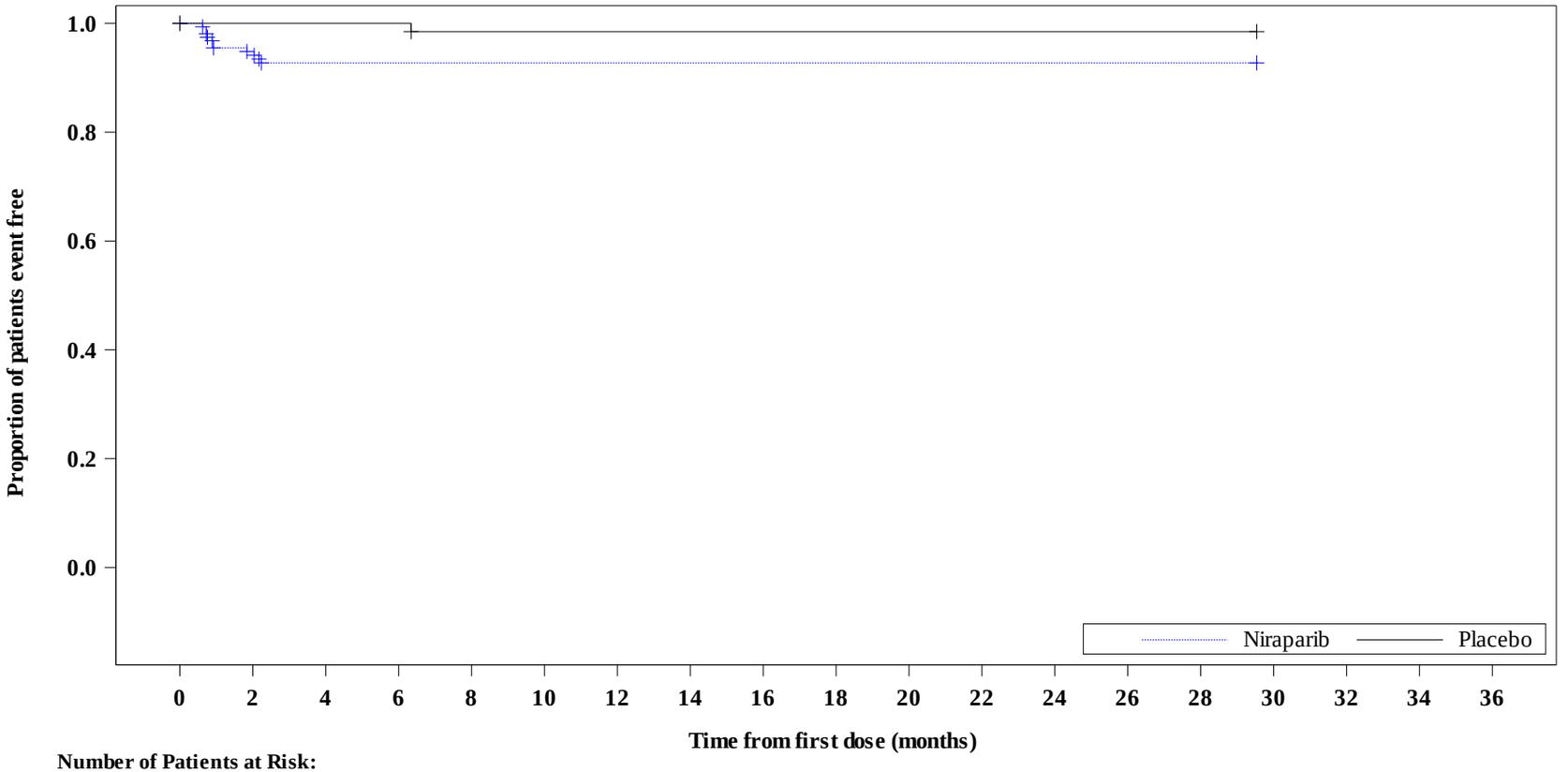
Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Neutropenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 137 | 110 | 100 | 83 | 74 | 70 | 63 | 51 | 45 | 29 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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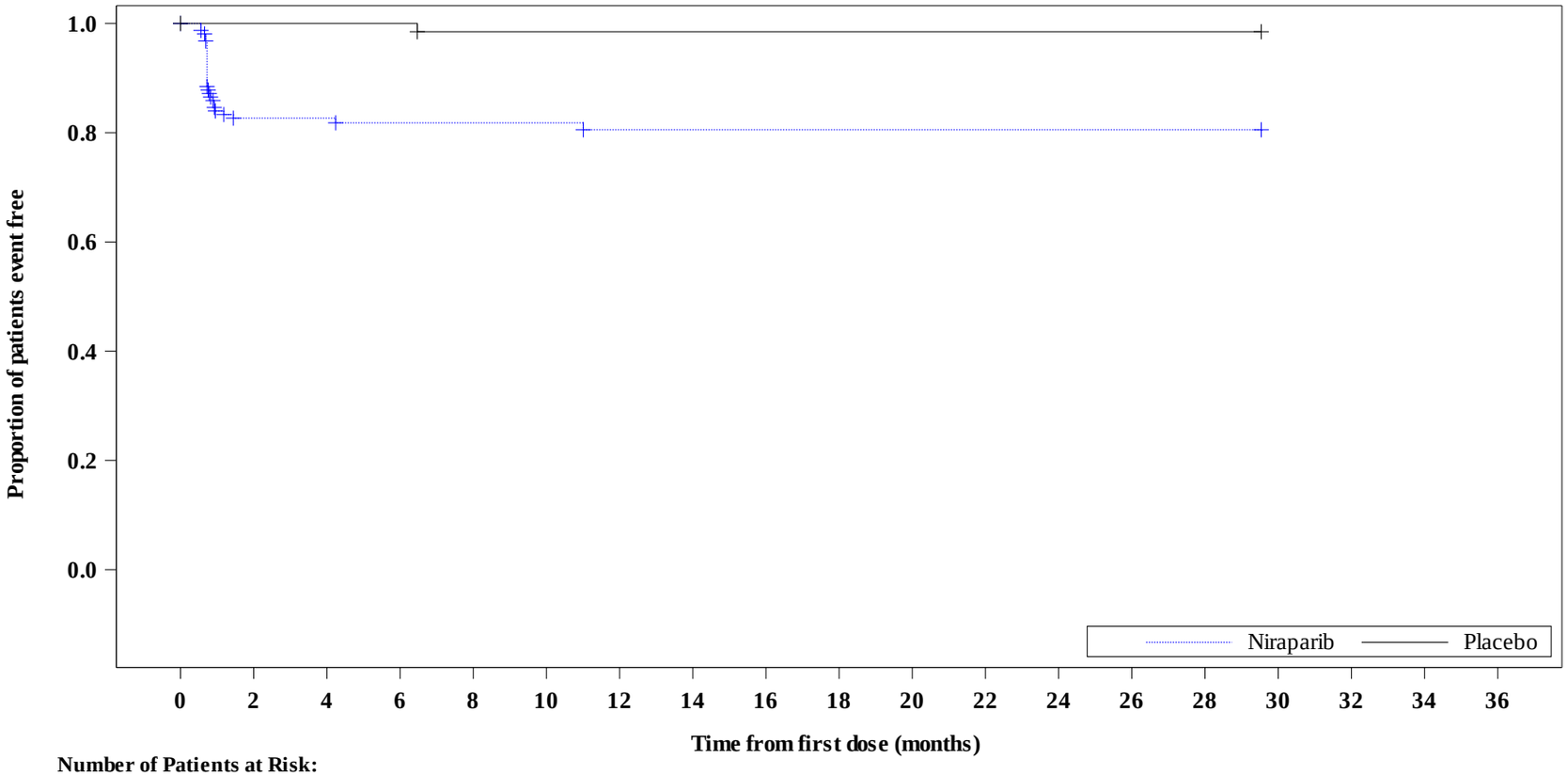
Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 123 | 99 | 89 | 72 | 65 | 61 | 54 | 45 | 40 | 25 | 11 | 6 | 3 | 1 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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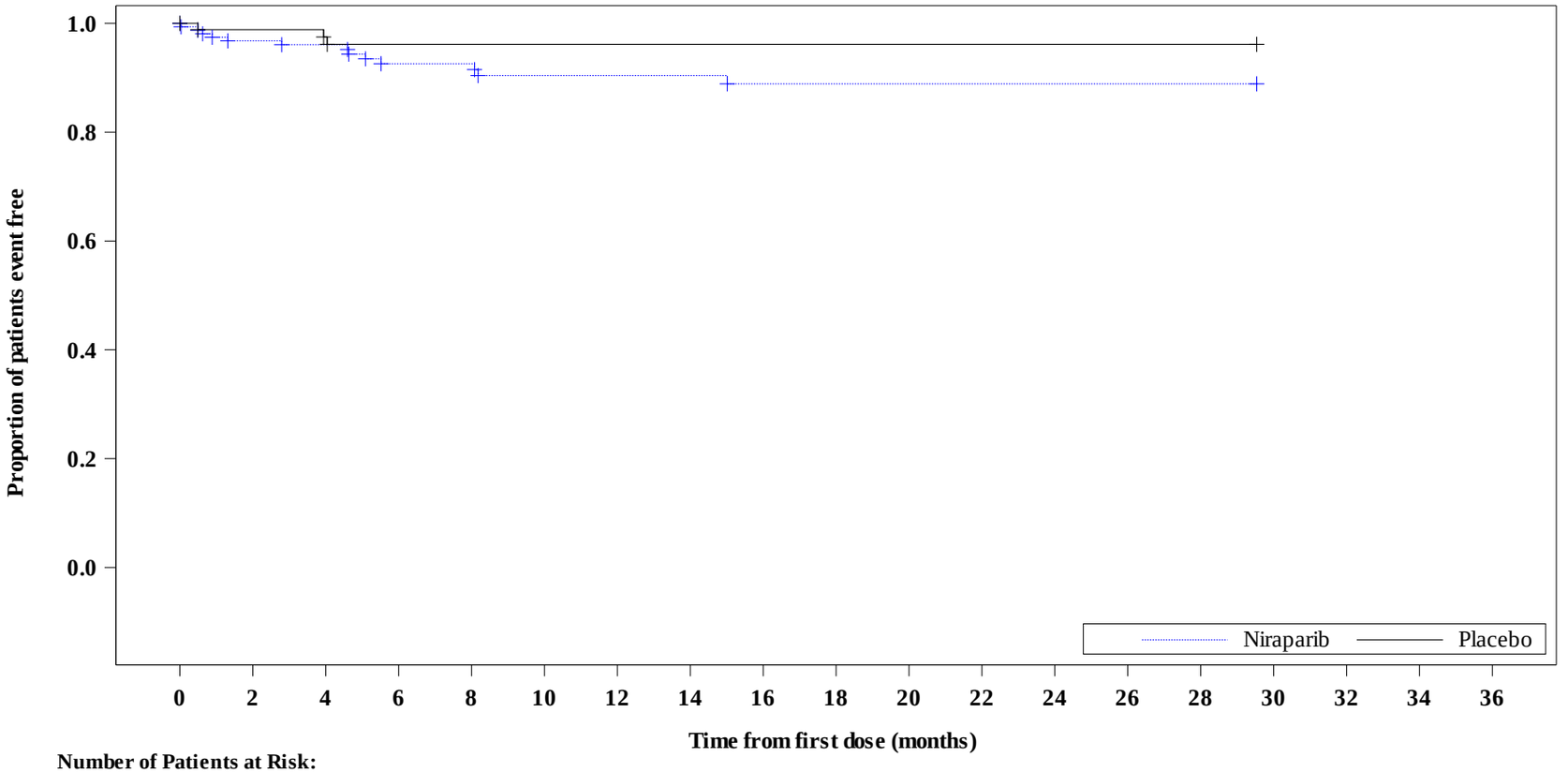
Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Gastrointestinal disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 141 | 116 | 103 | 85 | 77 | 73 | 66 | 53 | 47 | 28 | 13 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 73 | 67 | 54 | 40 | 34 | 26 | 21 | 17 | 13 | 4 | 2 | 2 | 1 | 0 |

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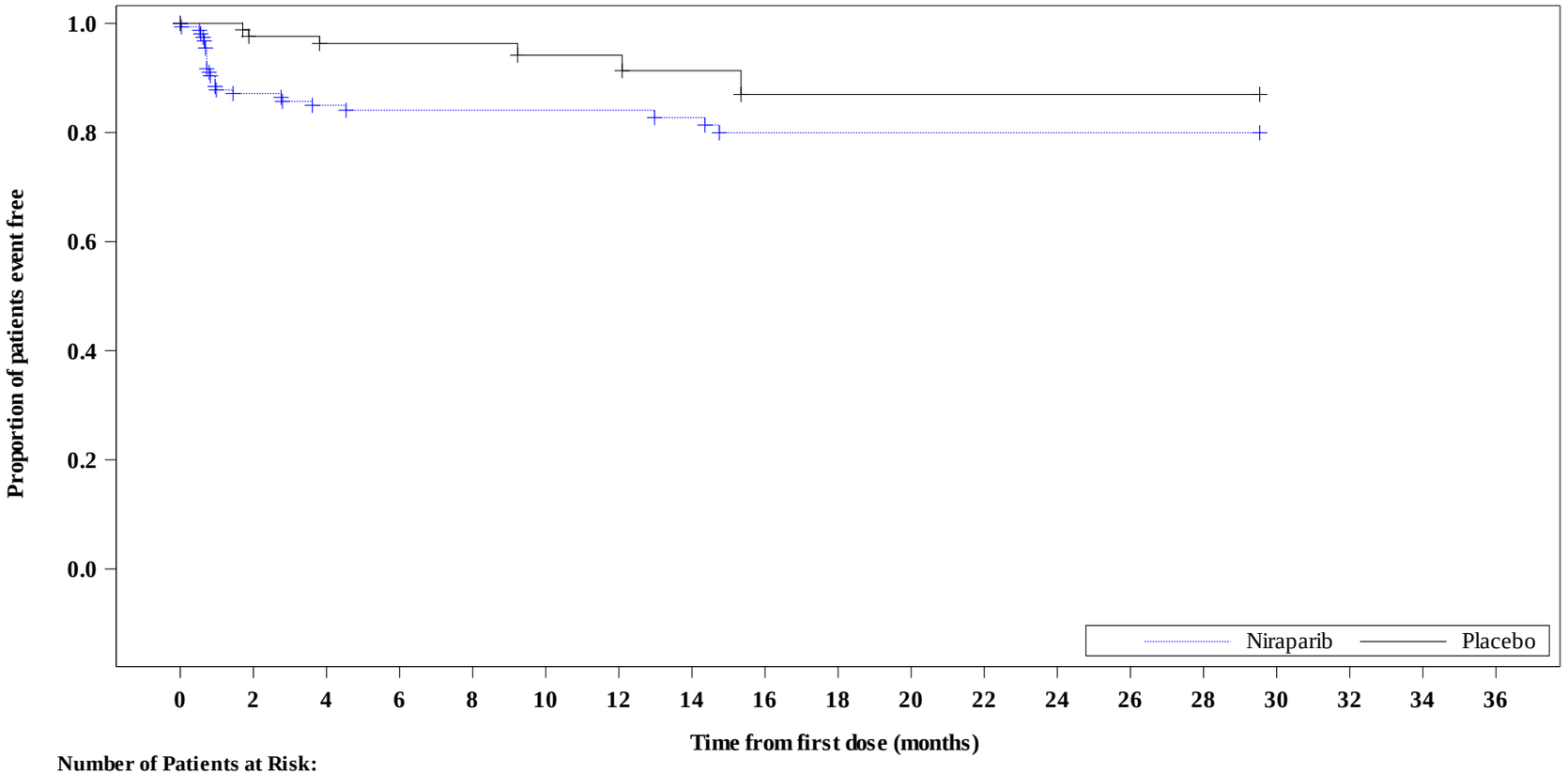
Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Investigations




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 124 | 101 | 91 | 75 | 70 | 66 | 60 | 47 | 42 | 24 | 12 | 7 | 5 | 2 | 0 |
| Placebo | 86 | 82 | 72 | 67 | 54 | 40 | 34 | 26 | 20 | 17 | 13 | 5 | 3 | 2 | 1 | 0 |

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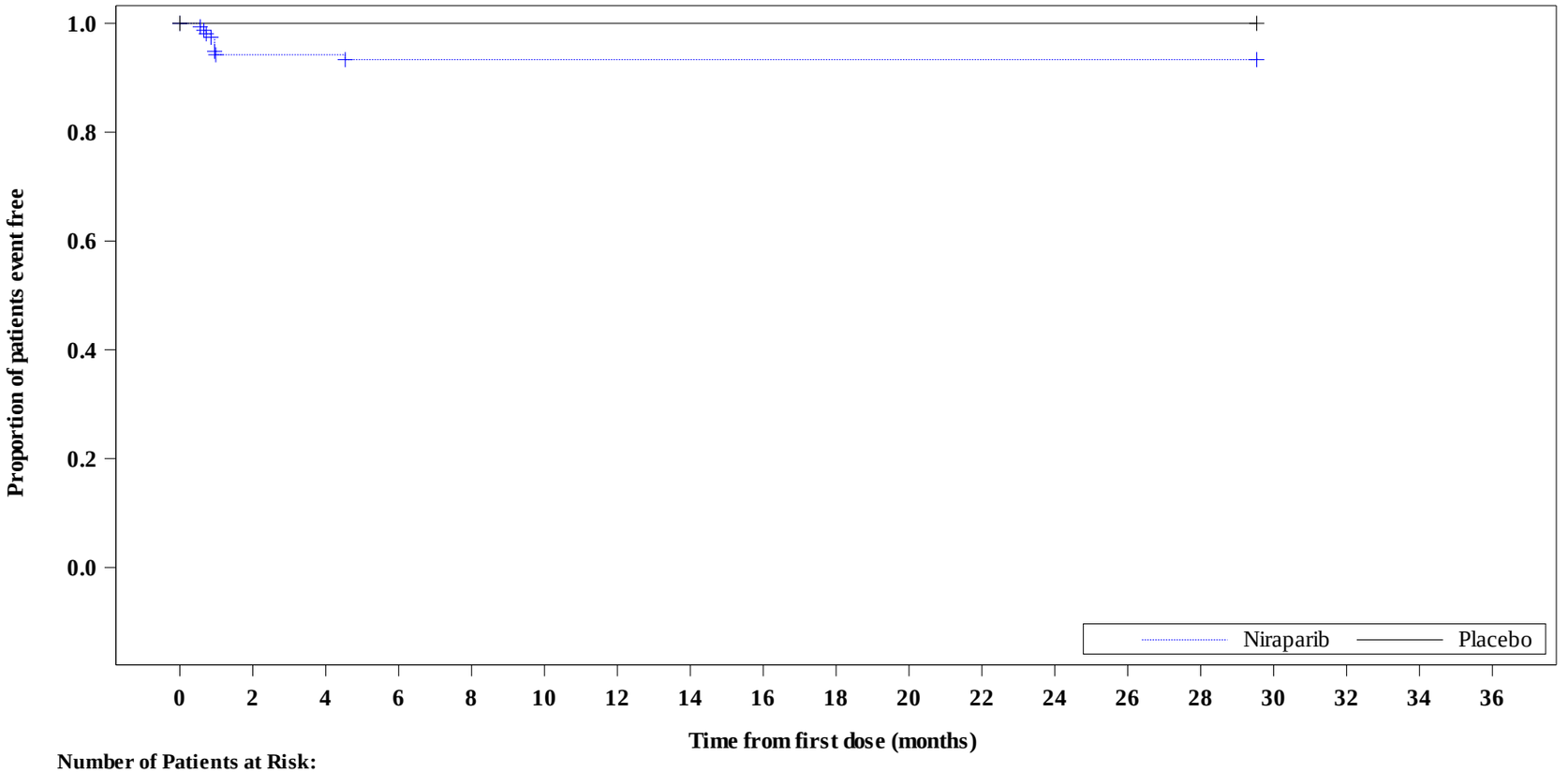
Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Neutrophil count decreased

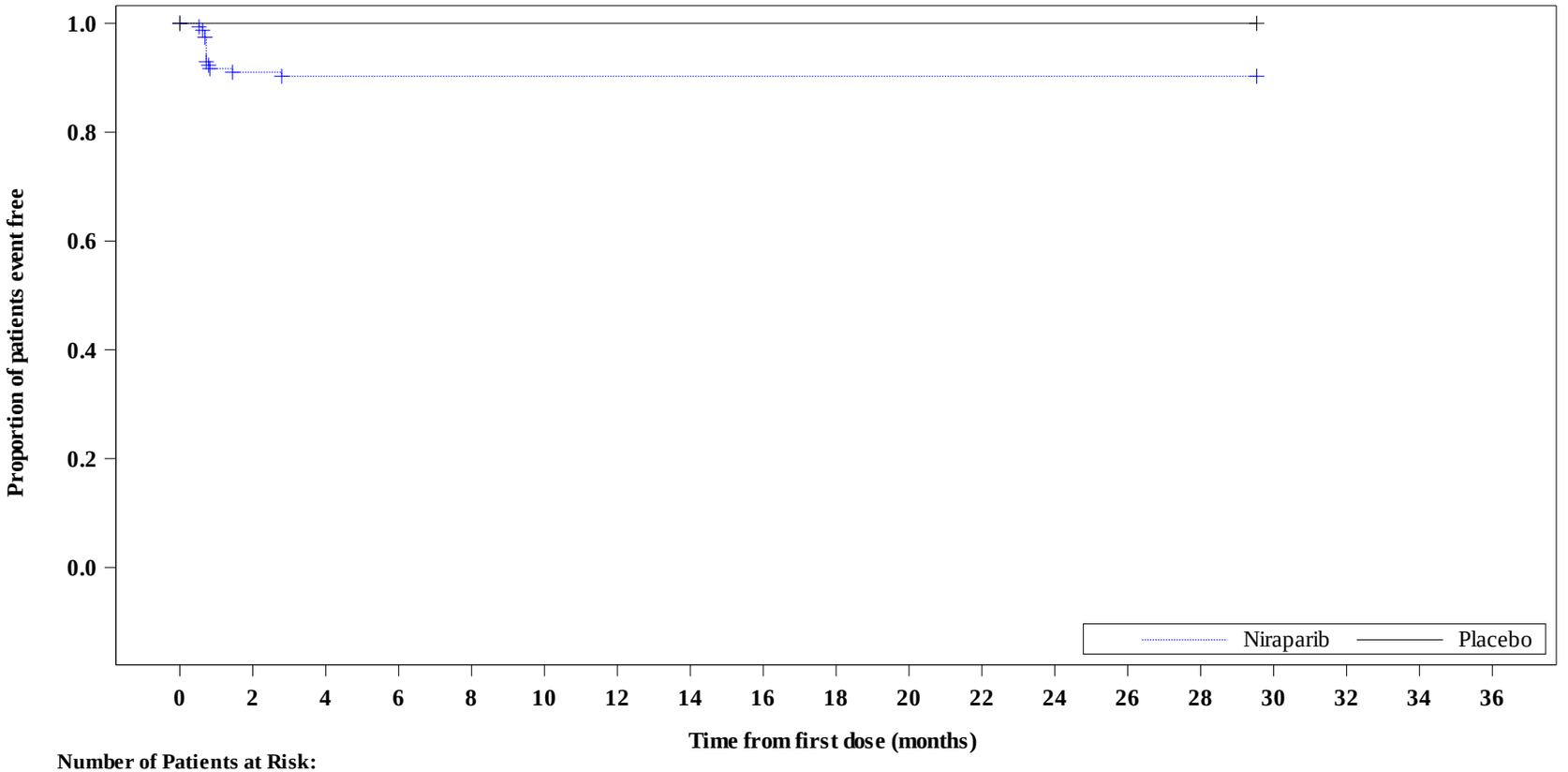



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 135 | 110 | 99 | 80 | 74 | 70 | 65 | 53 | 48 | 29 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Investigations, PT: Platelet count decreased

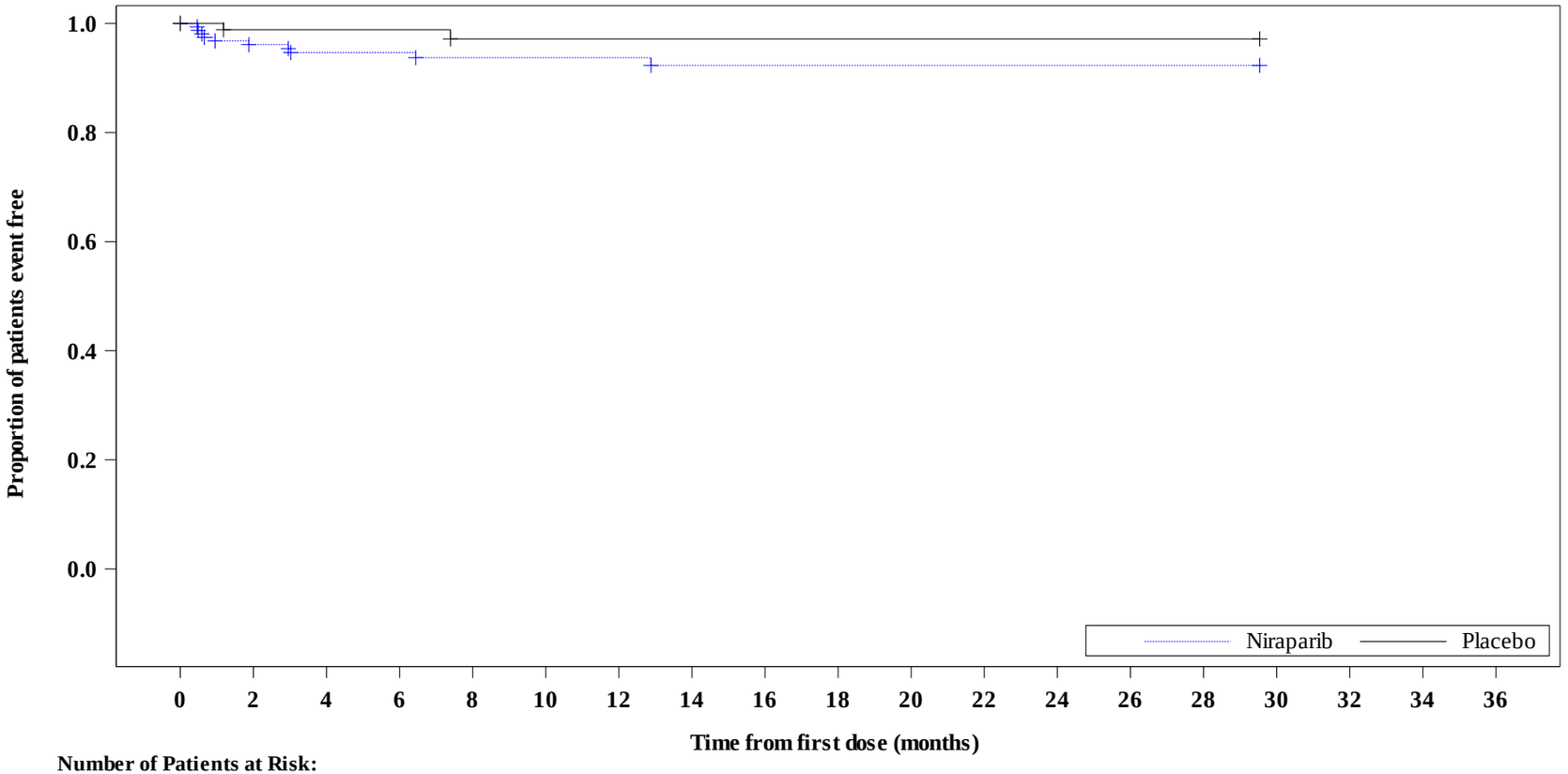



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 130 | 108 | 98 | 79 | 73 | 69 | 63 | 51 | 46 | 28 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Vascular disorders




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 138 | 112 | 102 | 84 | 75 | 71 | 63 | 52 | 46 | 28 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 74 | 68 | 55 | 41 | 35 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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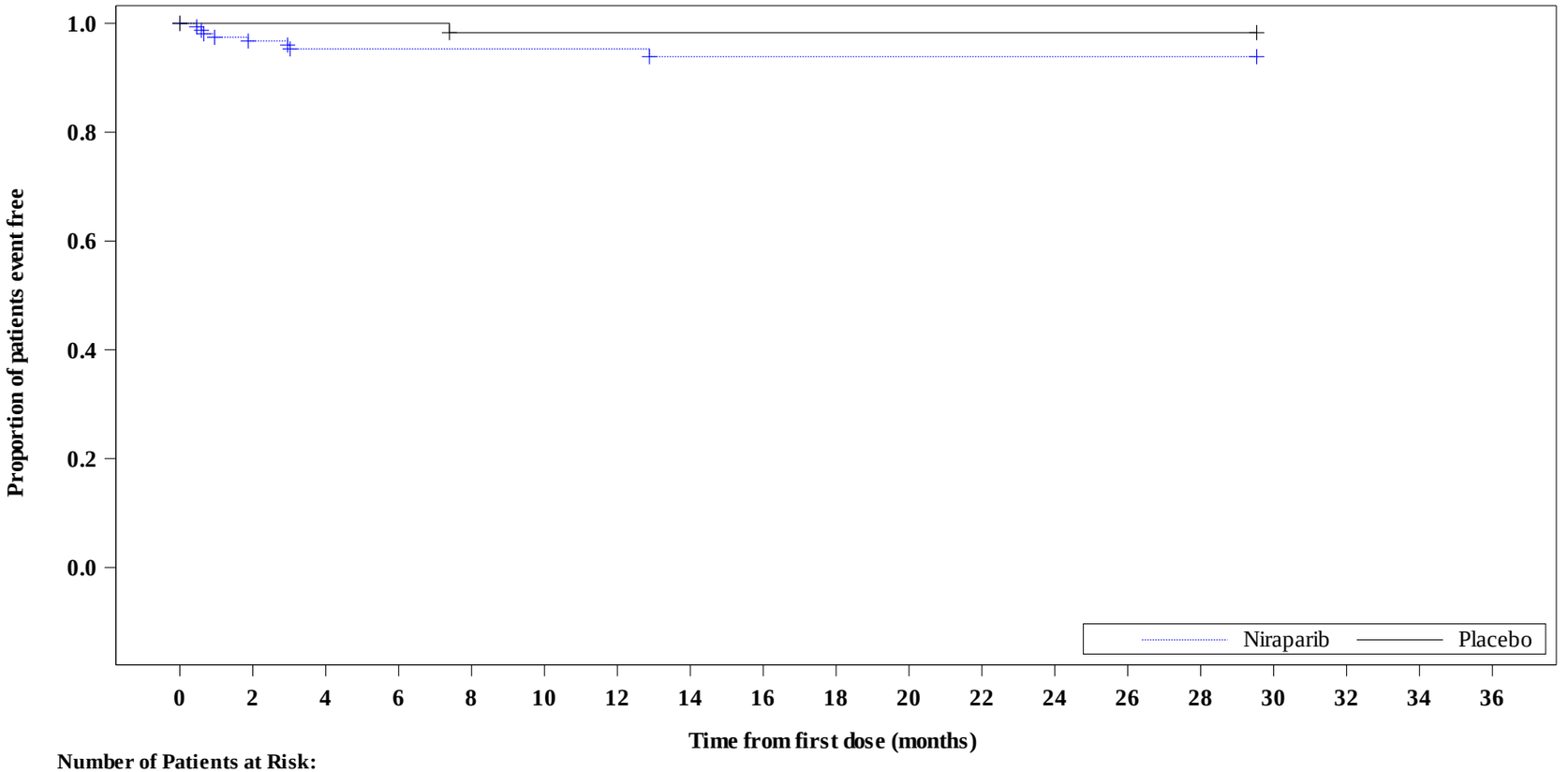
Figure 3.144a
Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT (Residual Disease Safety-GVD Population)

SOC: Vascular disorders, PT: Hypertension




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 139 | 113 | 103 | 85 | 76 | 72 | 64 | 53 | 47 | 28 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 55 | 41 | 35 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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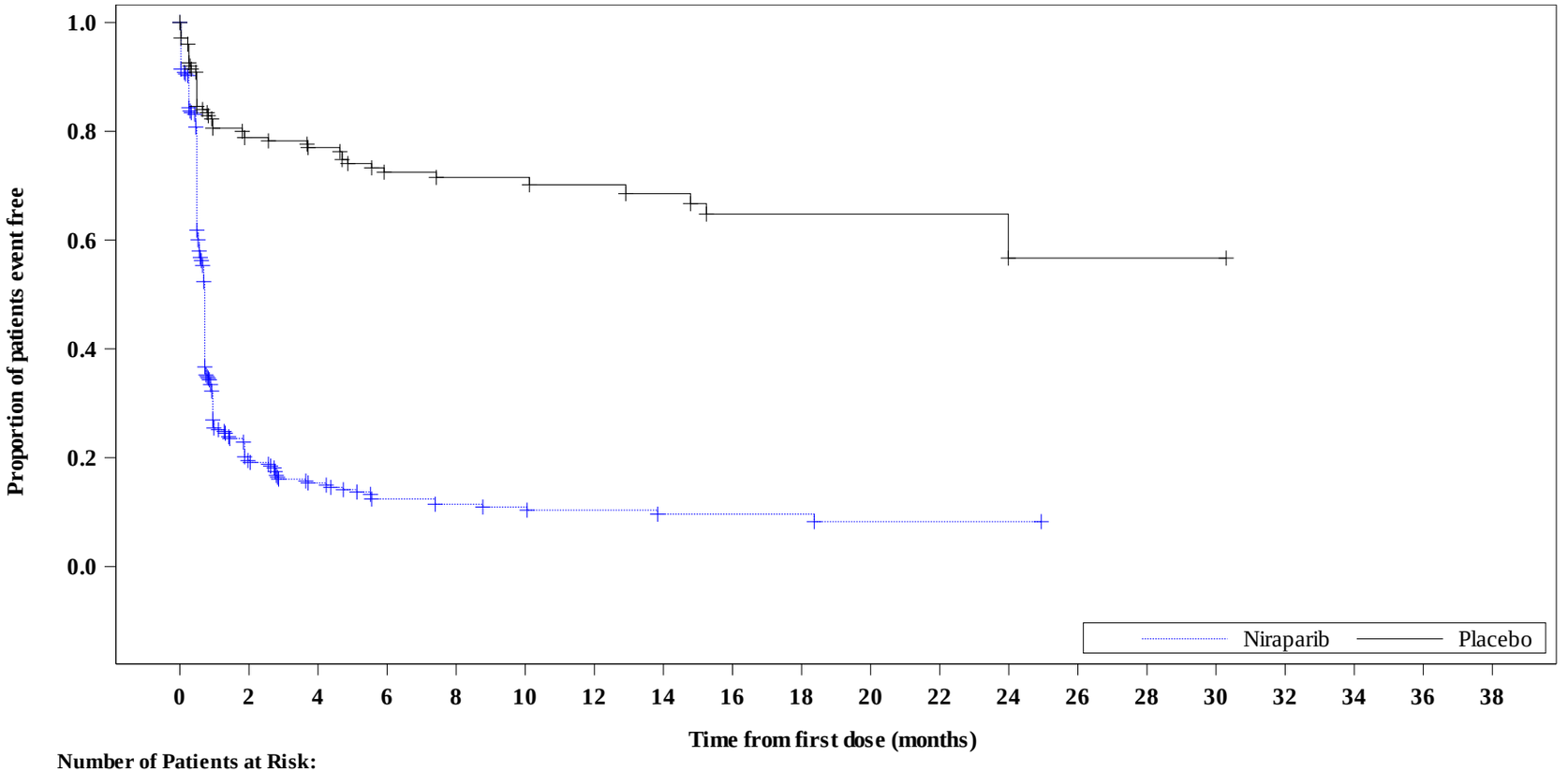
Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Overall



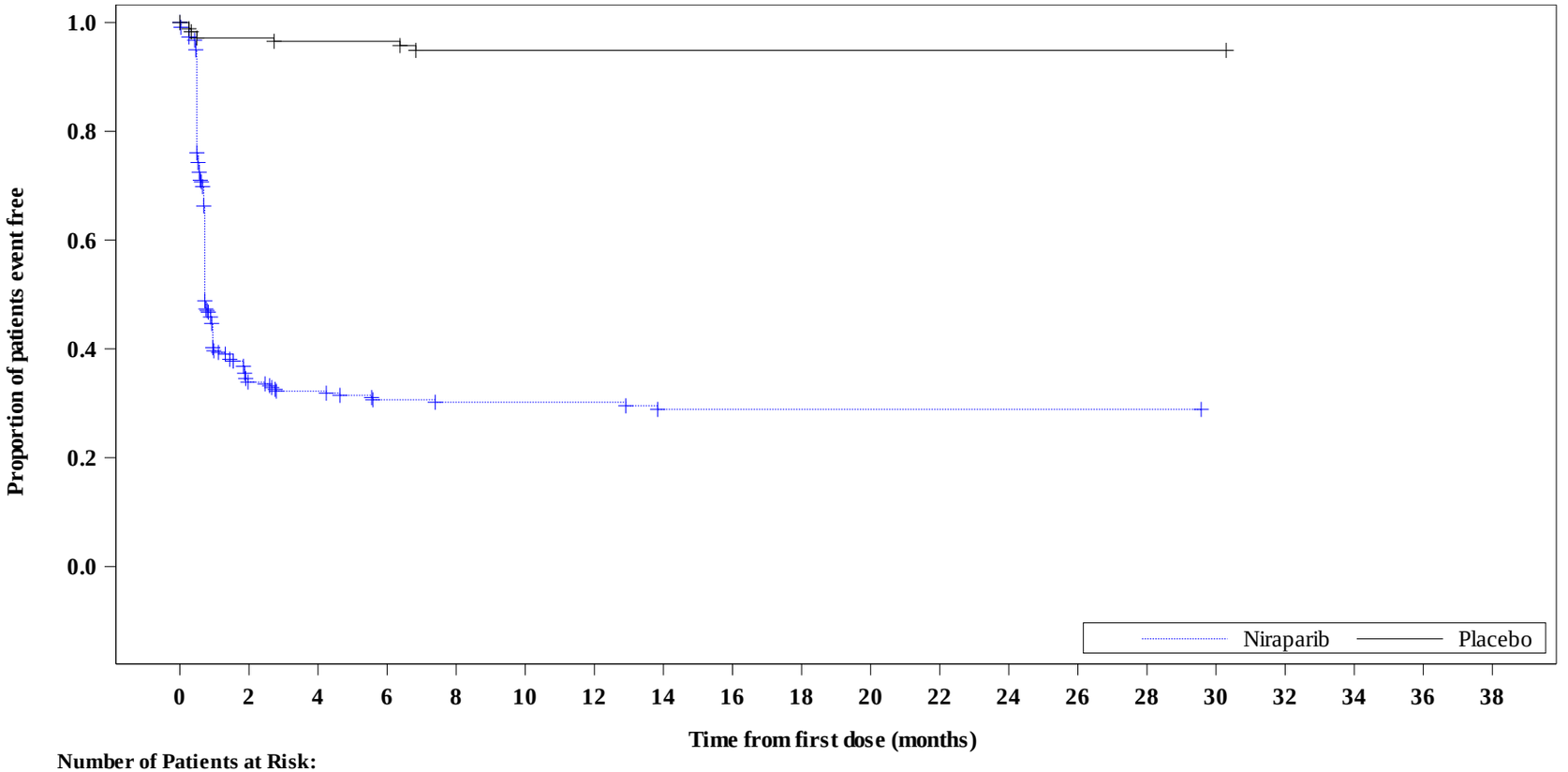

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 57 | 38 | 29 | 23 | 19 | 14 | 13 | 9 | 7 | 5 | 2 | 1 | 0 | | | |
| Placebo | 175 | 135 | 111 | 91 | 72 | 53 | 47 | 38 | 34 | 30 | 25 | 16 | 7 | 4 | 1 | 1 | 0 |

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Thrombocytopenia



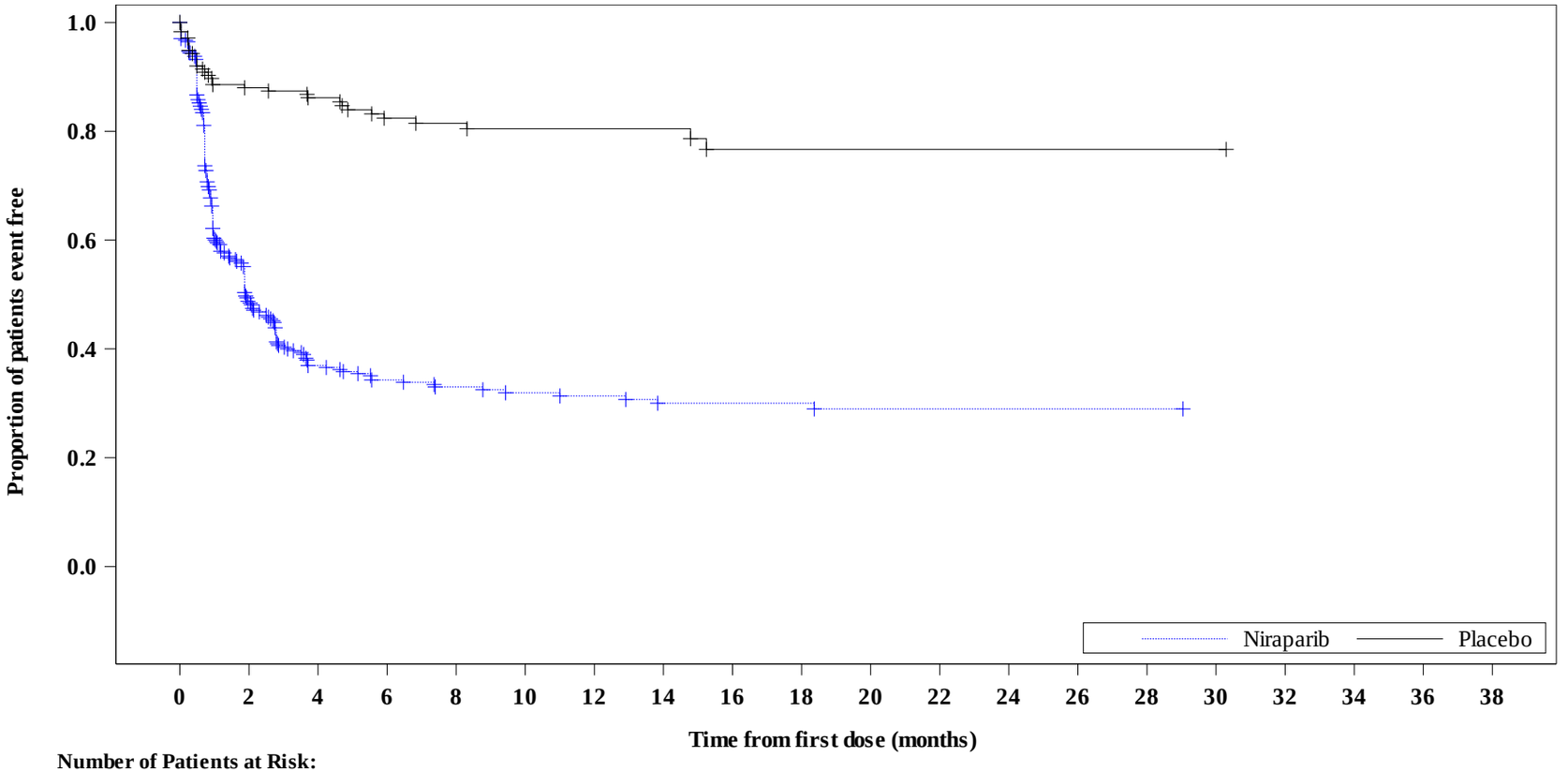

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 103 | 84 | 74 | 61 | 51 | 47 | 44 | 36 | 34 | 22 | 12 | 6 | 3 | 1 | 0 | |
| Placebo | 175 | 167 | 141 | 125 | 99 | 75 | 67 | 56 | 48 | 42 | 36 | 19 | 8 | 5 | 2 | 1 | 0 |

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Anemia



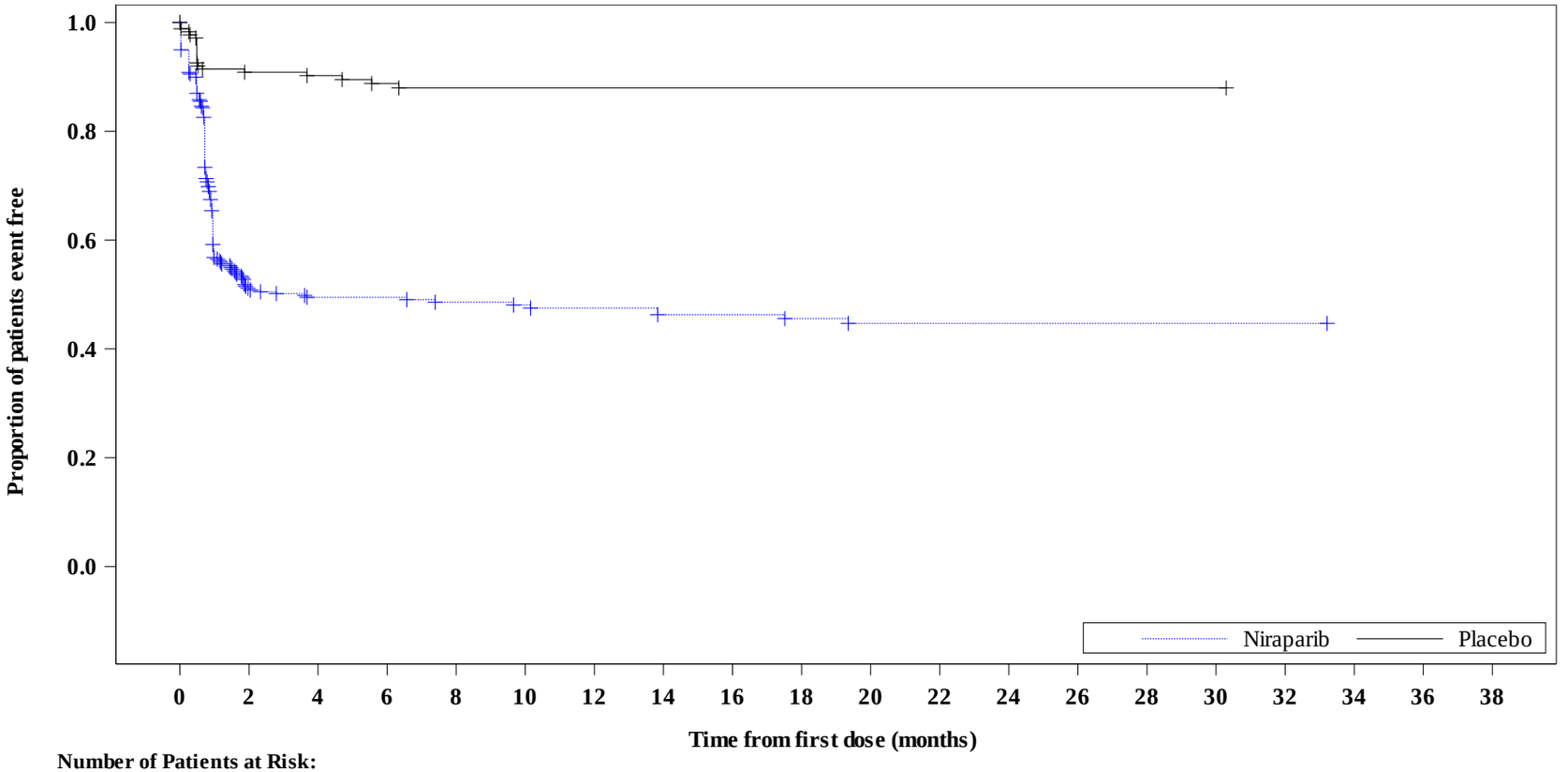

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 151 | 102 | 87 | 68 | 56 | 50 | 44 | 34 | 29 | 21 | 10 | 7 | 3 | 1 | 0 | |
| Placebo | 175 | 151 | 125 | 104 | 83 | 62 | 57 | 47 | 39 | 34 | 29 | 18 | 8 | 5 | 2 | 1 | 0 |

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Leukopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 156 | 134 | 120 | 99 | 88 | 81 | 76 | 66 | 61 | 45 | 31 | 19 | 8 | 2 | 1 | 1 | 0 |
| Placebo | 175 | 156 | 132 | 114 | 92 | 68 | 61 | 50 | 44 | 37 | 30 | 16 | 7 | 4 | 1 | 1 | 0 | |

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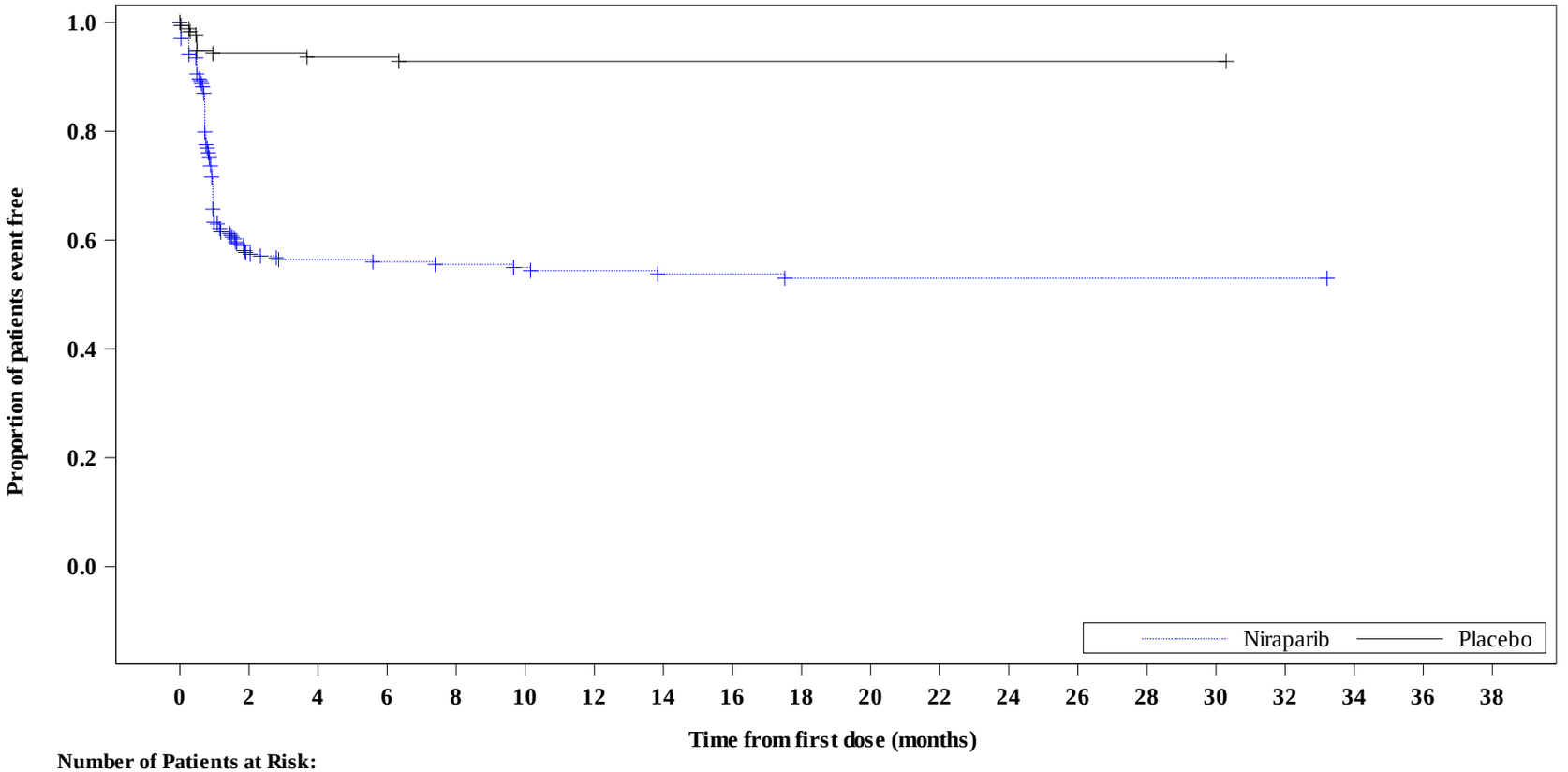
Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Neutropenia



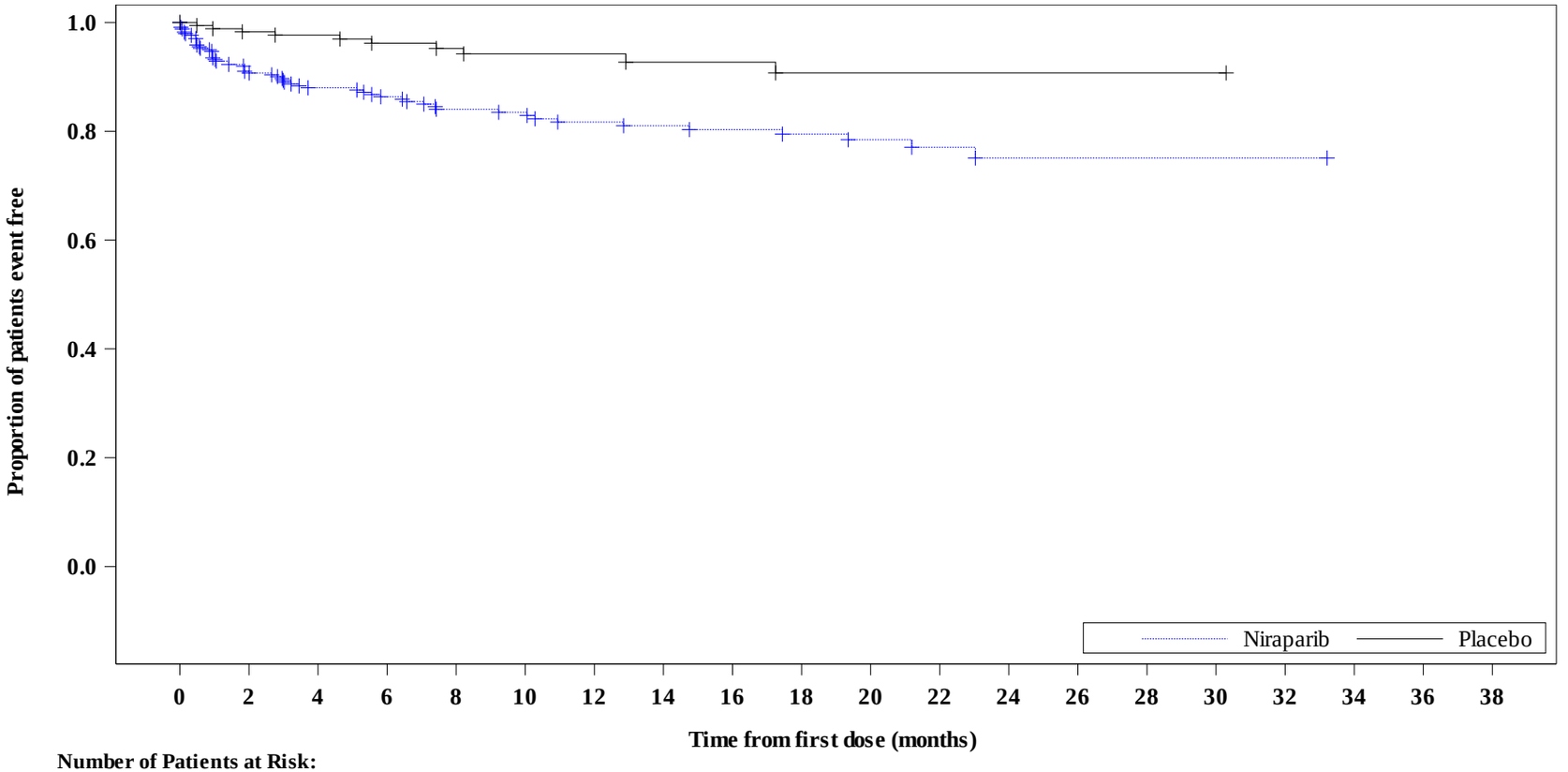

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 178 | 148 | 132 | 109 | 97 | 90 | 85 | 72 | 66 | 49 | 34 | 21 | 9 | 2 | 1 | 1 | 0 |
| Placebo | 175 | 162 | 135 | 119 | 95 | 71 | 63 | 52 | 46 | 39 | 32 | 16 | 7 | 4 | 1 | 1 | 0 | |

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Hypertension



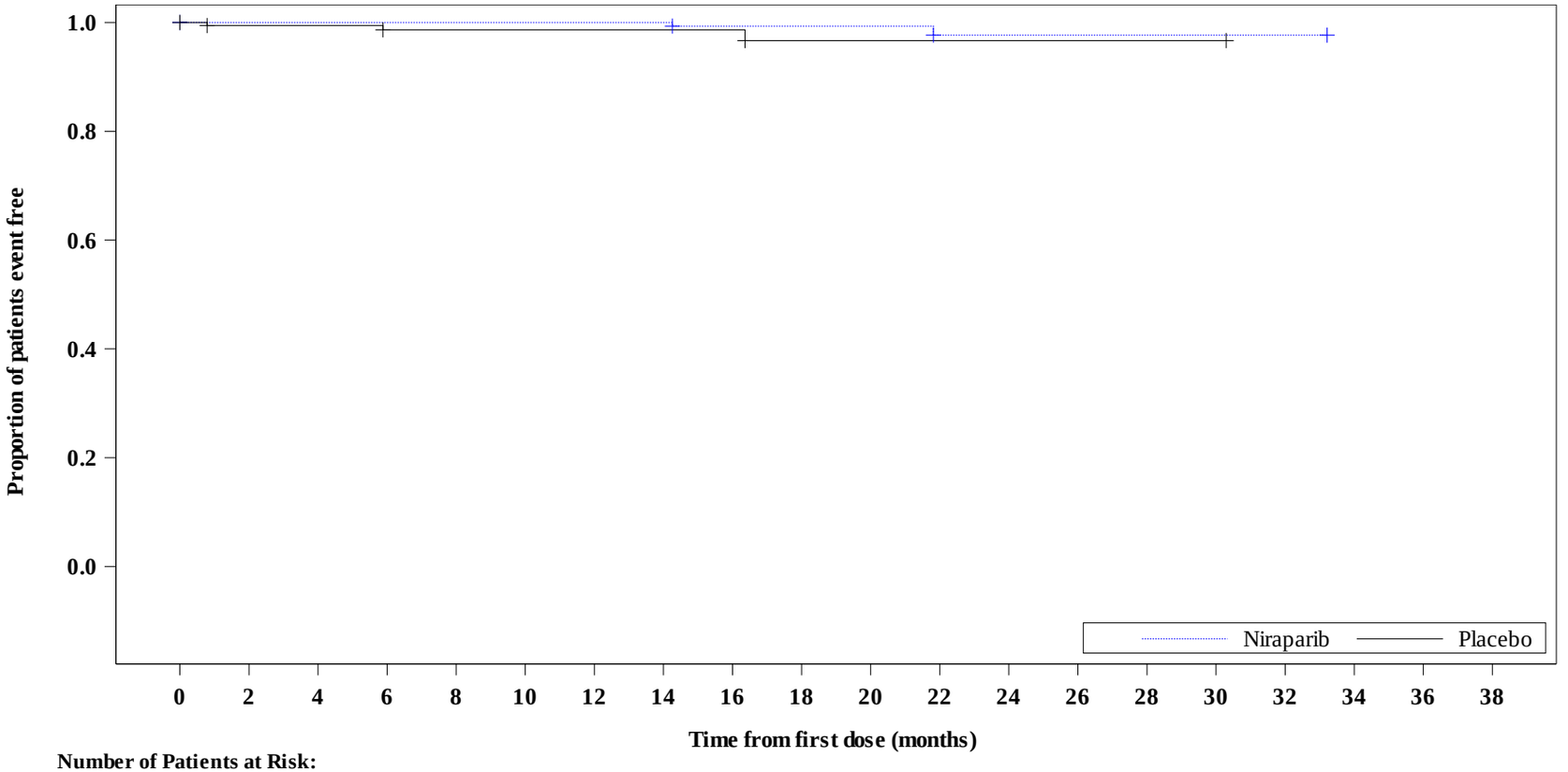

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 282 | 231 | 206 | 163 | 141 | 131 | 119 | 100 | 91 | 66 | 47 | 30 | 15 | 8 | 2 | 2 | 0 |
| Placebo | 175 | 169 | 141 | 122 | 97 | 73 | 65 | 55 | 48 | 40 | 34 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

New malignancies other than MDS/AML



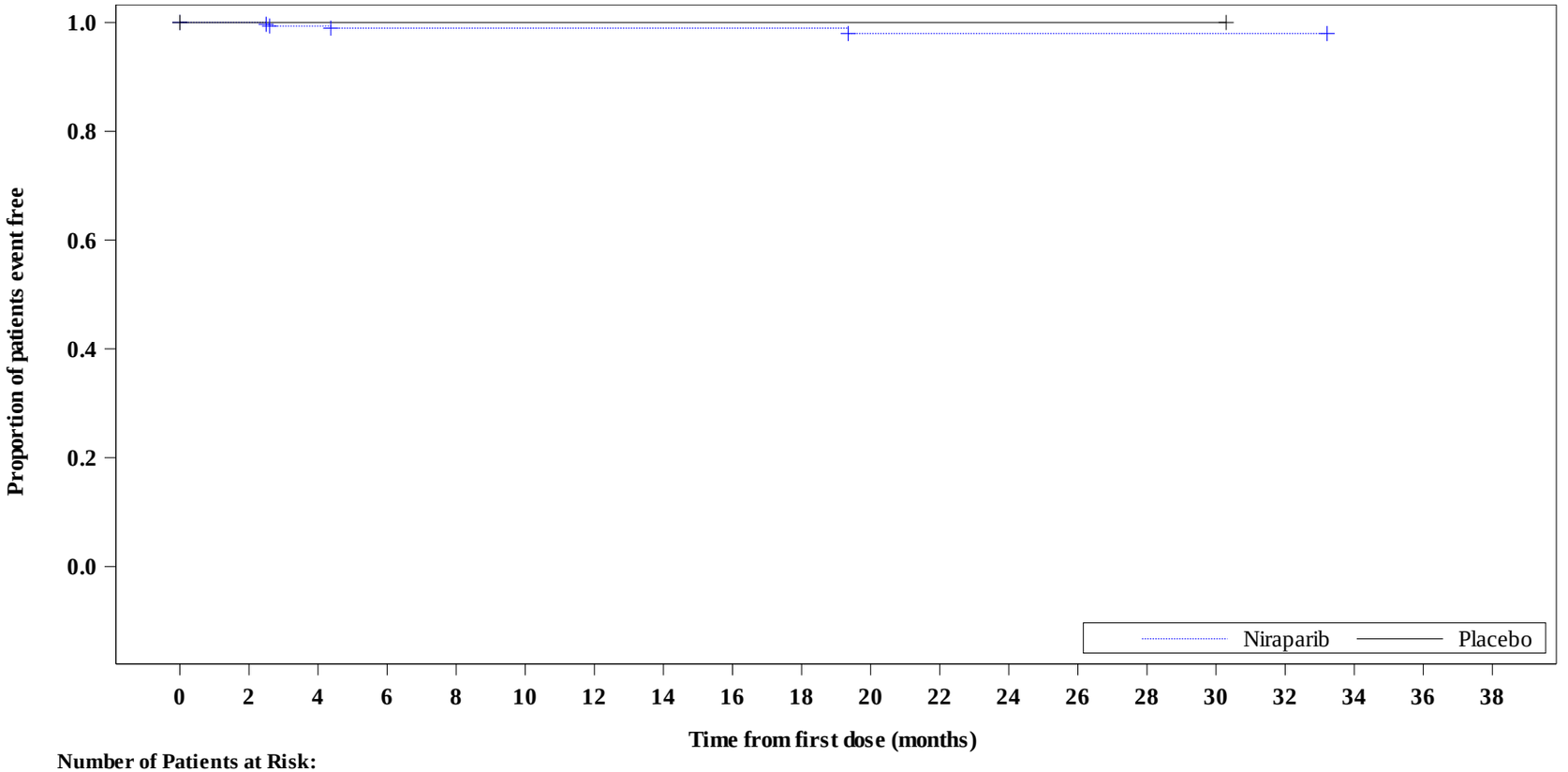

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 100 | 77 | 69 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Pneumonitis



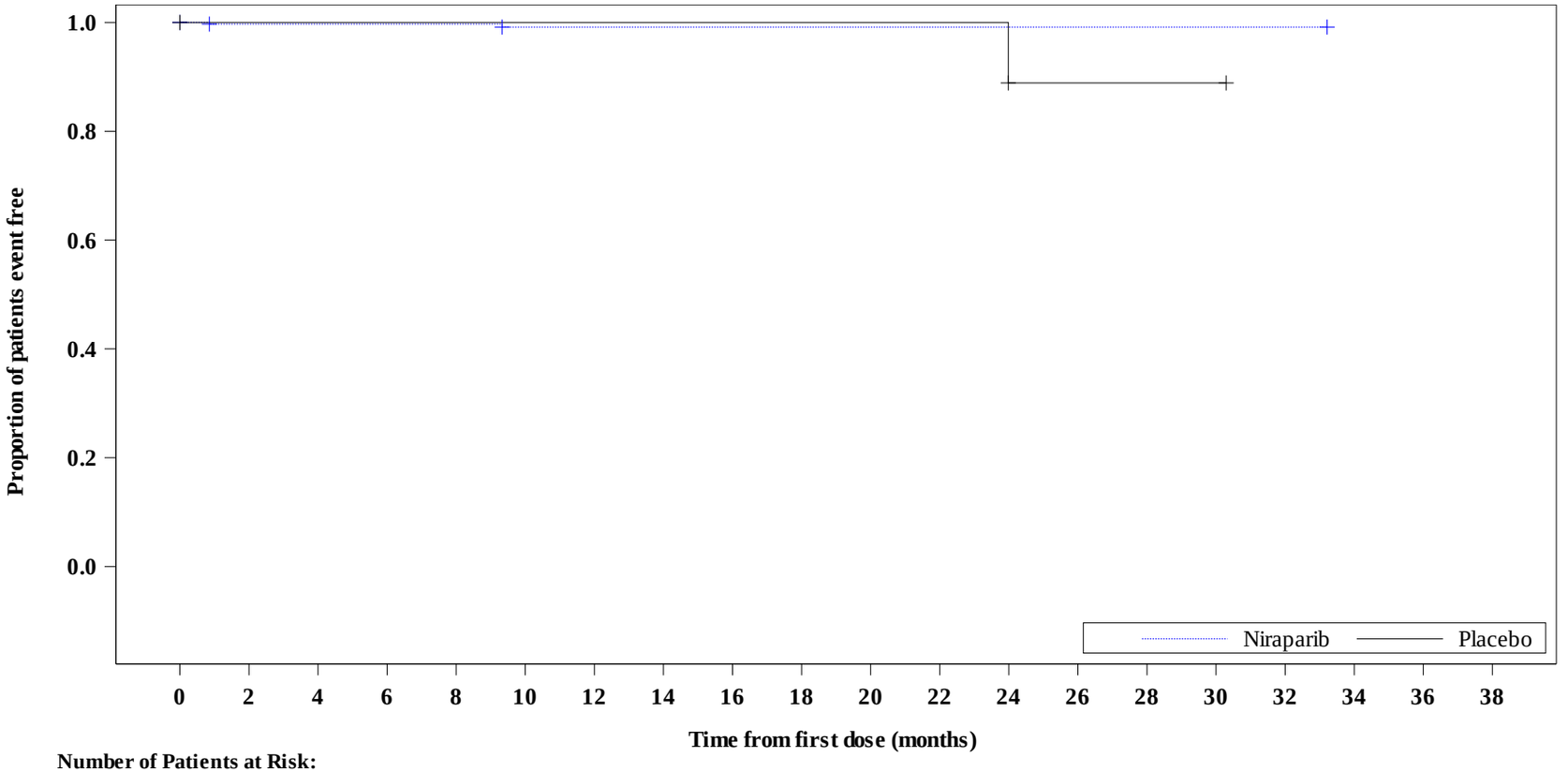

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 264 | 237 | 196 | 172 | 164 | 151 | 127 | 116 | 85 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Pancytopenia



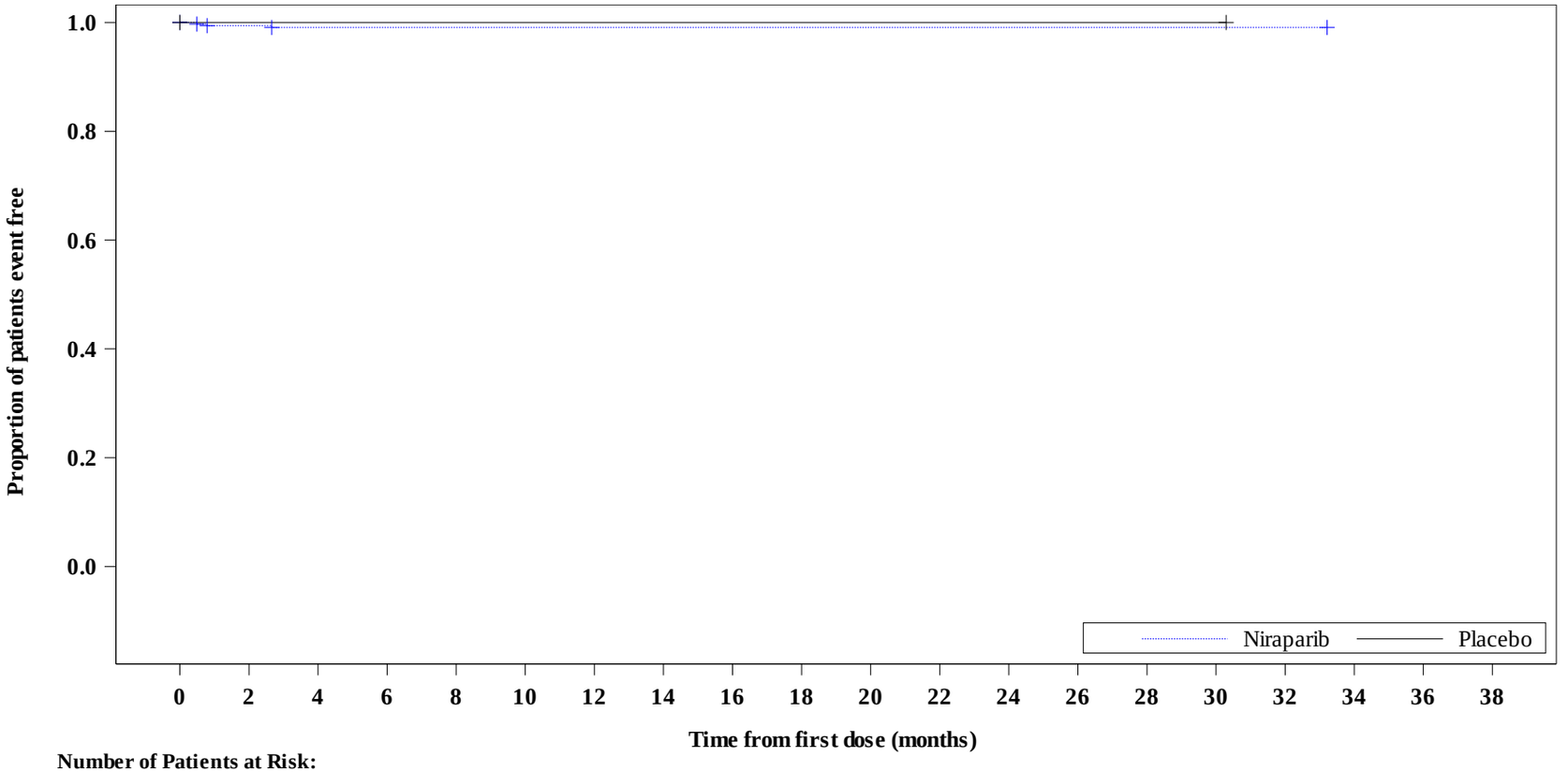

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 264 | 238 | 196 | 172 | 164 | 151 | 126 | 115 | 85 | 59 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 129 | 103 | 79 | 71 | 60 | 51 | 44 | 37 | 20 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Thromboemblic




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 262 | 236 | 195 | 171 | 163 | 151 | 126 | 115 | 85 | 59 | 40 | 19 | 9 | 2 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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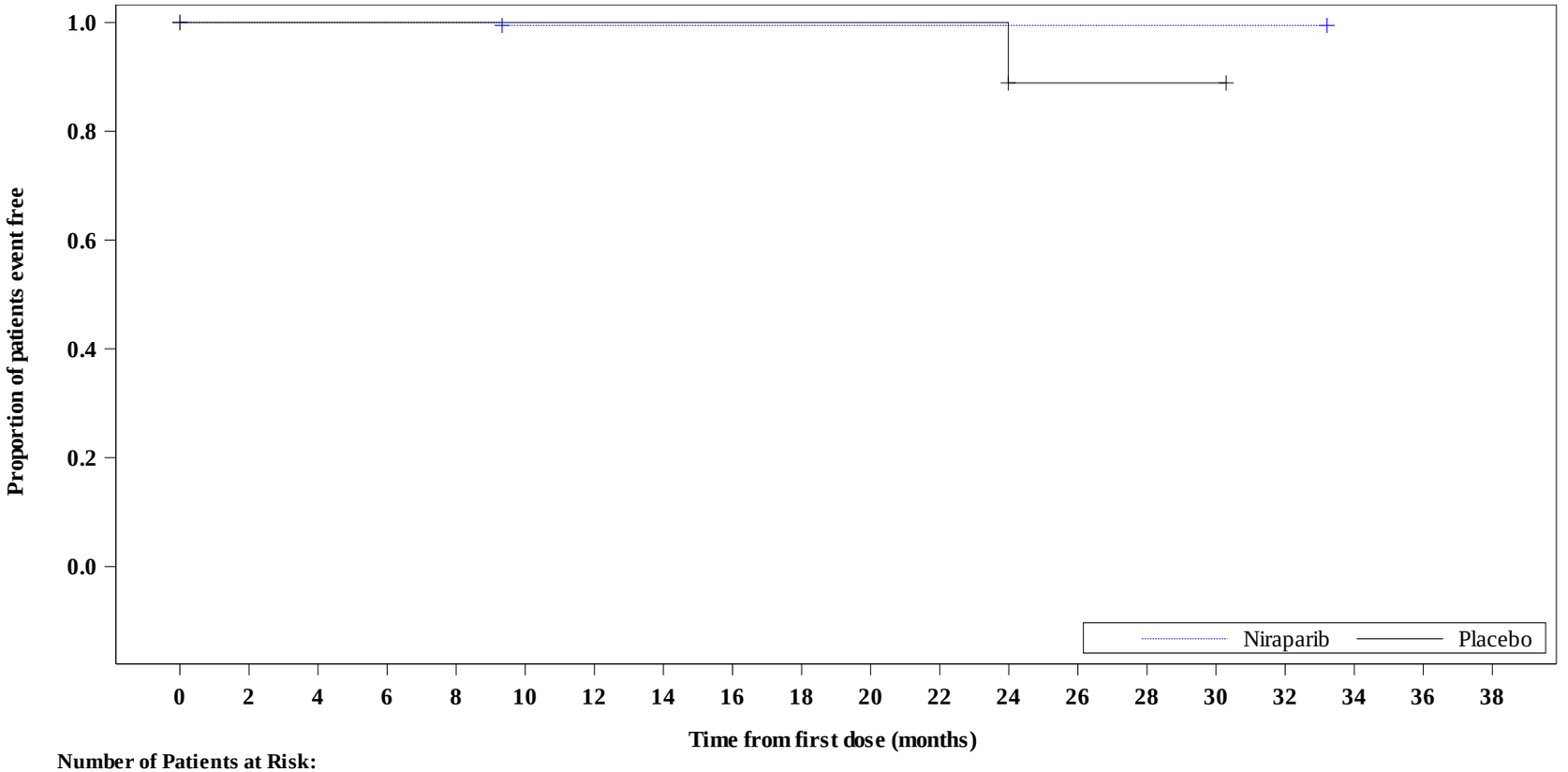
Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

MDS/AML




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 129 | 103 | 79 | 71 | 60 | 51 | 44 | 37 | 20 | 8 | 5 | 2 | 1 | 0 | |

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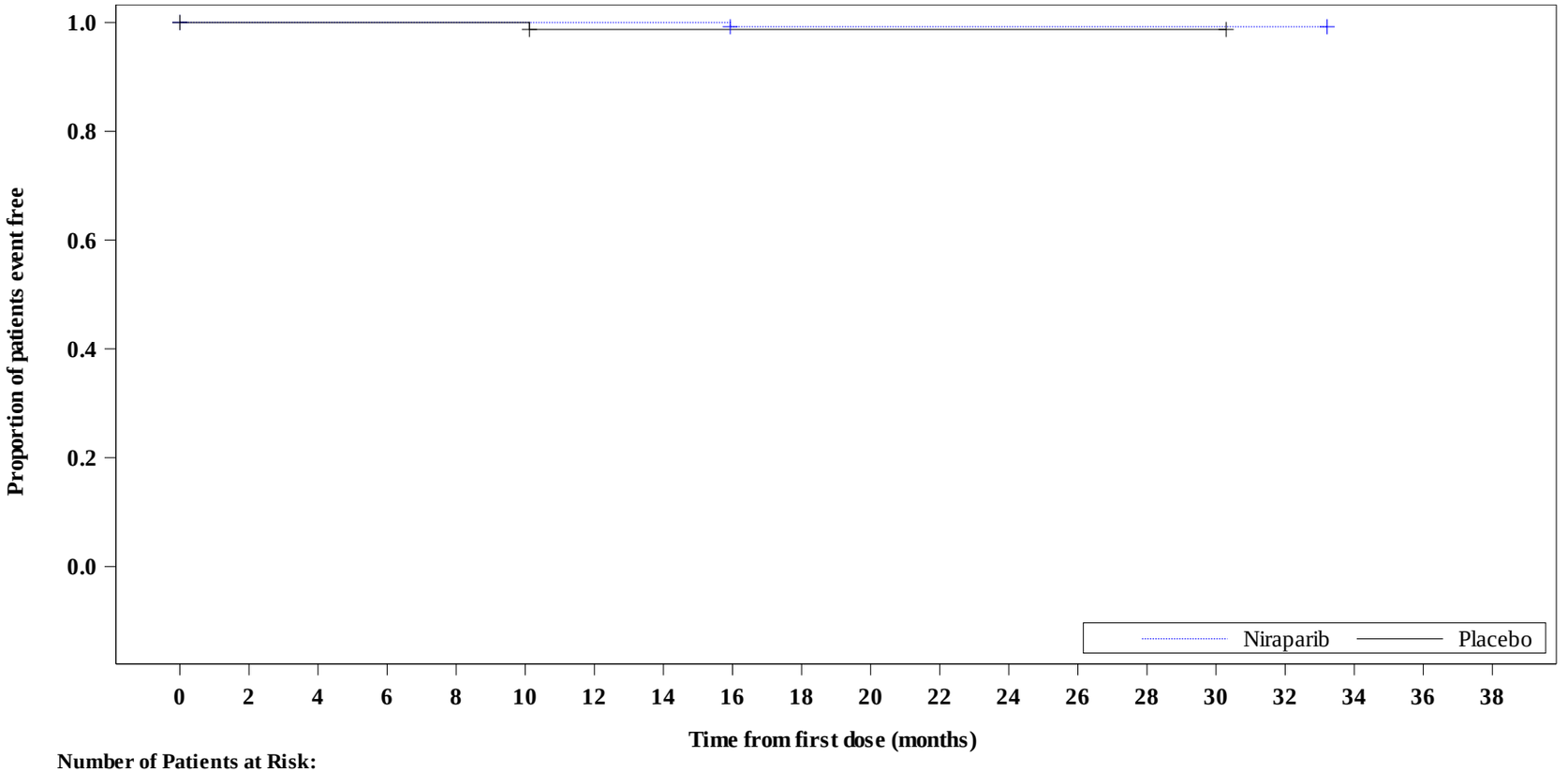
11:29

Figure 3.145a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Embryo-fetal toxicity




**Number of Patients at Risk:**

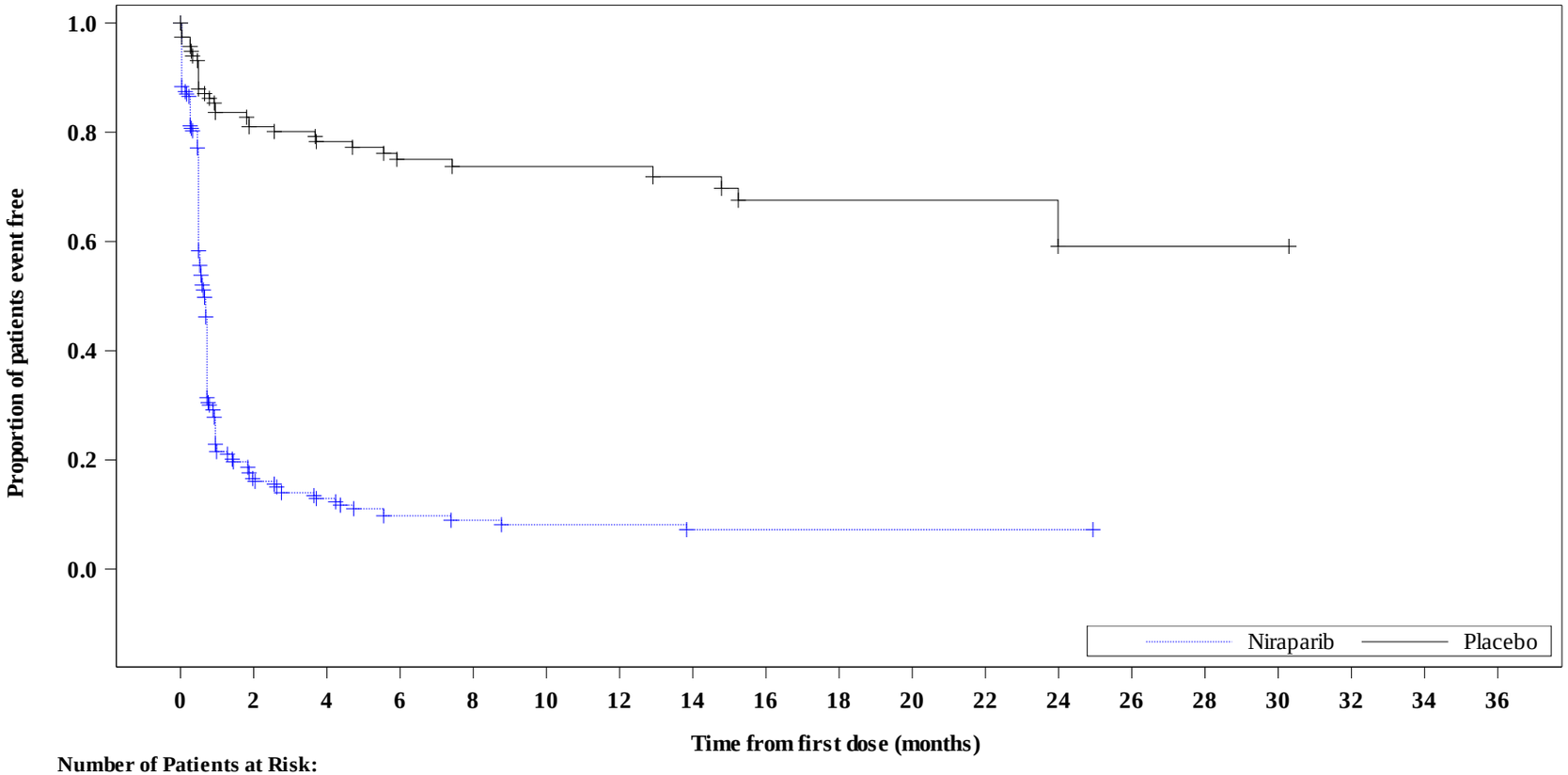
| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 126 | 115 | 85 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 69 | 58 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.145b

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety Population)

Overall

Residual Disease Status: R0




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 223 | 32 | 22 | 15 | 11 | 9 | 9 | 8 | 6 | 5 | 5 | 2 | 1 | 0 | | | |
| Placebo | 116 | 93 | 77 | 68 | 55 | 43 | 40 | 35 | 31 | 28 | 23 | 15 | 7 | 4 | 1 | 1 | 0 |

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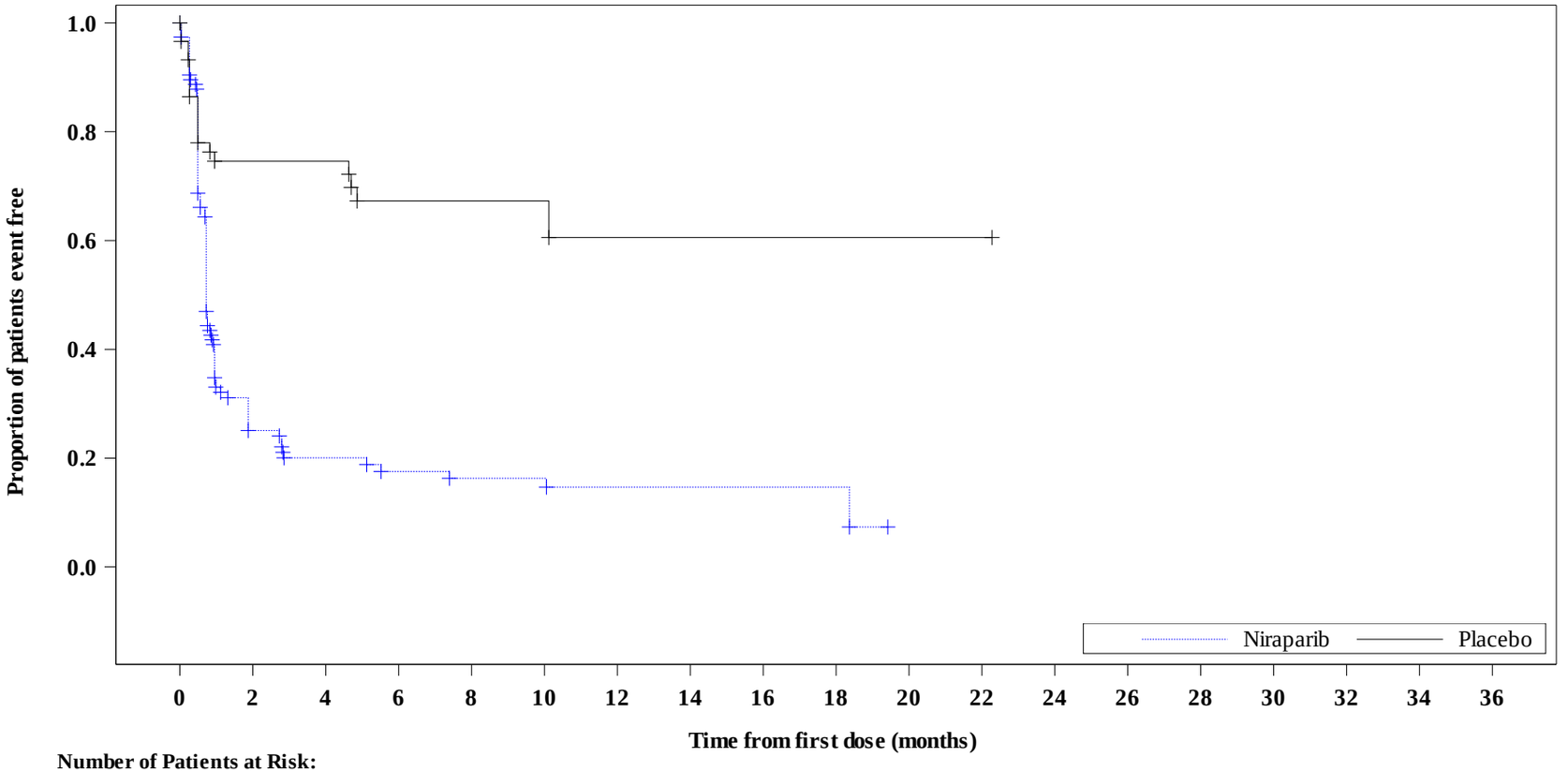
Figure 3.145b

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety Population)

Overall

Residual Disease Status: R1/R2



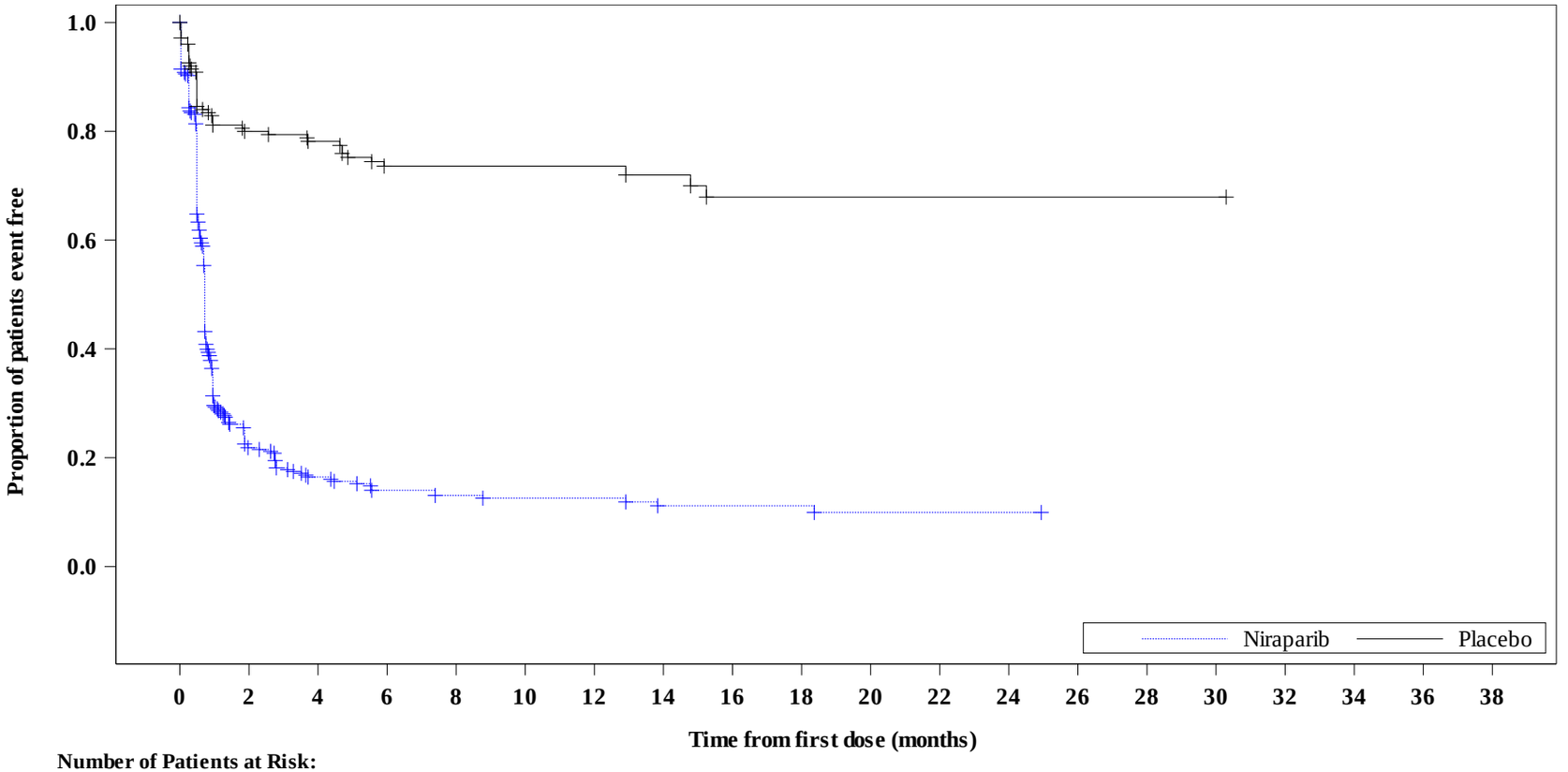

**Number of Patients at Risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 115 | 25 | 16 | 14 | 12 | 10 | 5 | 5 | 3 | 2 | 0 | | |
| Placebo | 59 | 42 | 34 | 23 | 17 | 10 | 7 | 3 | 3 | 2 | 2 | 1 | 0 |

Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Overall




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 65 | 42 | 34 | 27 | 22 | 18 | 16 | 11 | 9 | 7 | 2 | 1 | 0 | | | |
| Placebo | 175 | 137 | 112 | 91 | 73 | 54 | 49 | 38 | 33 | 29 | 24 | 15 | 7 | 4 | 1 | 1 | 0 |

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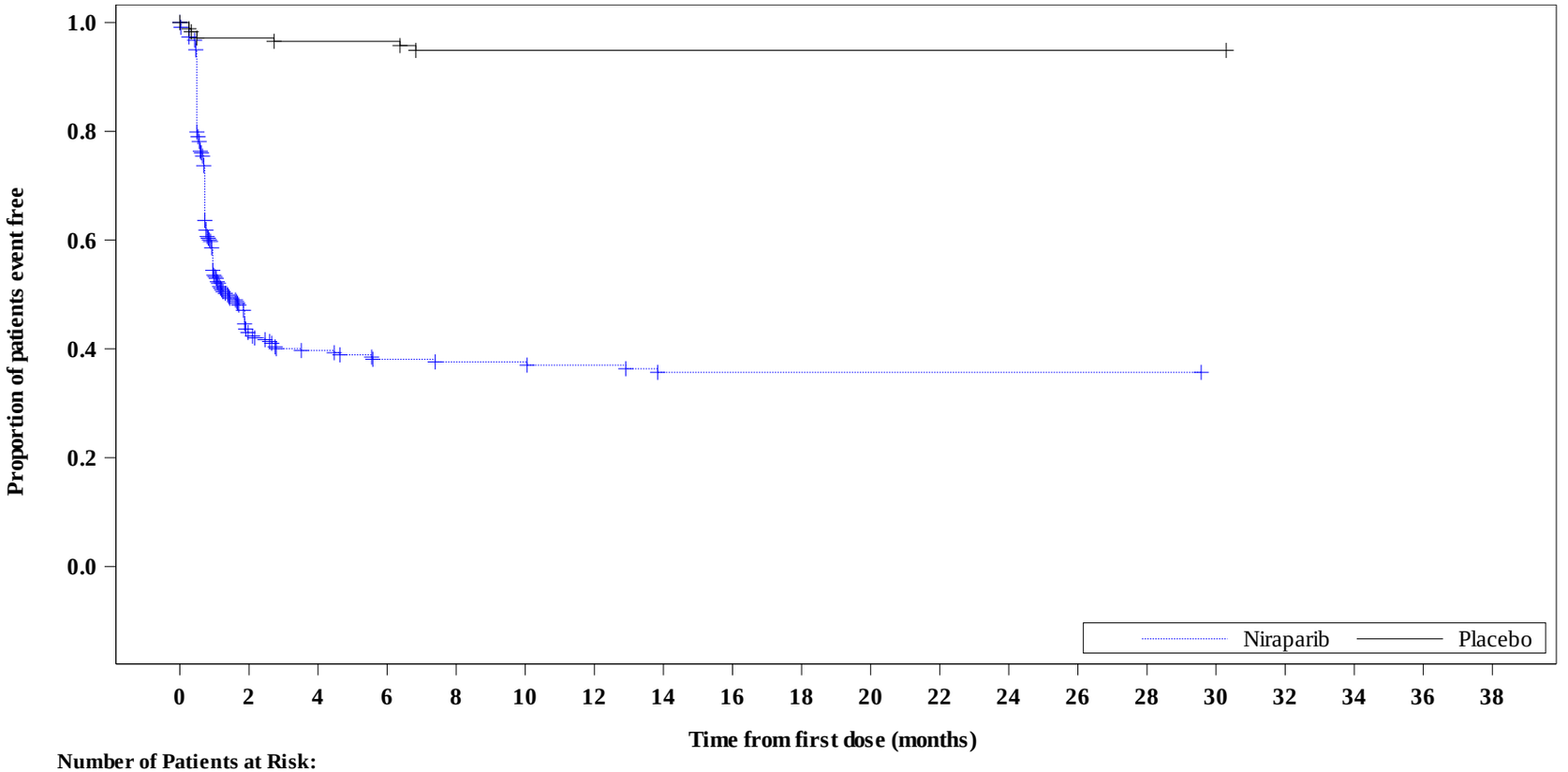
Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Thrombocytopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 132 | 104 | 92 | 75 | 63 | 58 | 54 | 43 | 40 | 28 | 16 | 10 | 4 | 1 | 0 | |
| Placebo | 175 | 167 | 141 | 125 | 99 | 75 | 67 | 56 | 48 | 42 | 36 | 19 | 8 | 5 | 2 | 1 | 0 |

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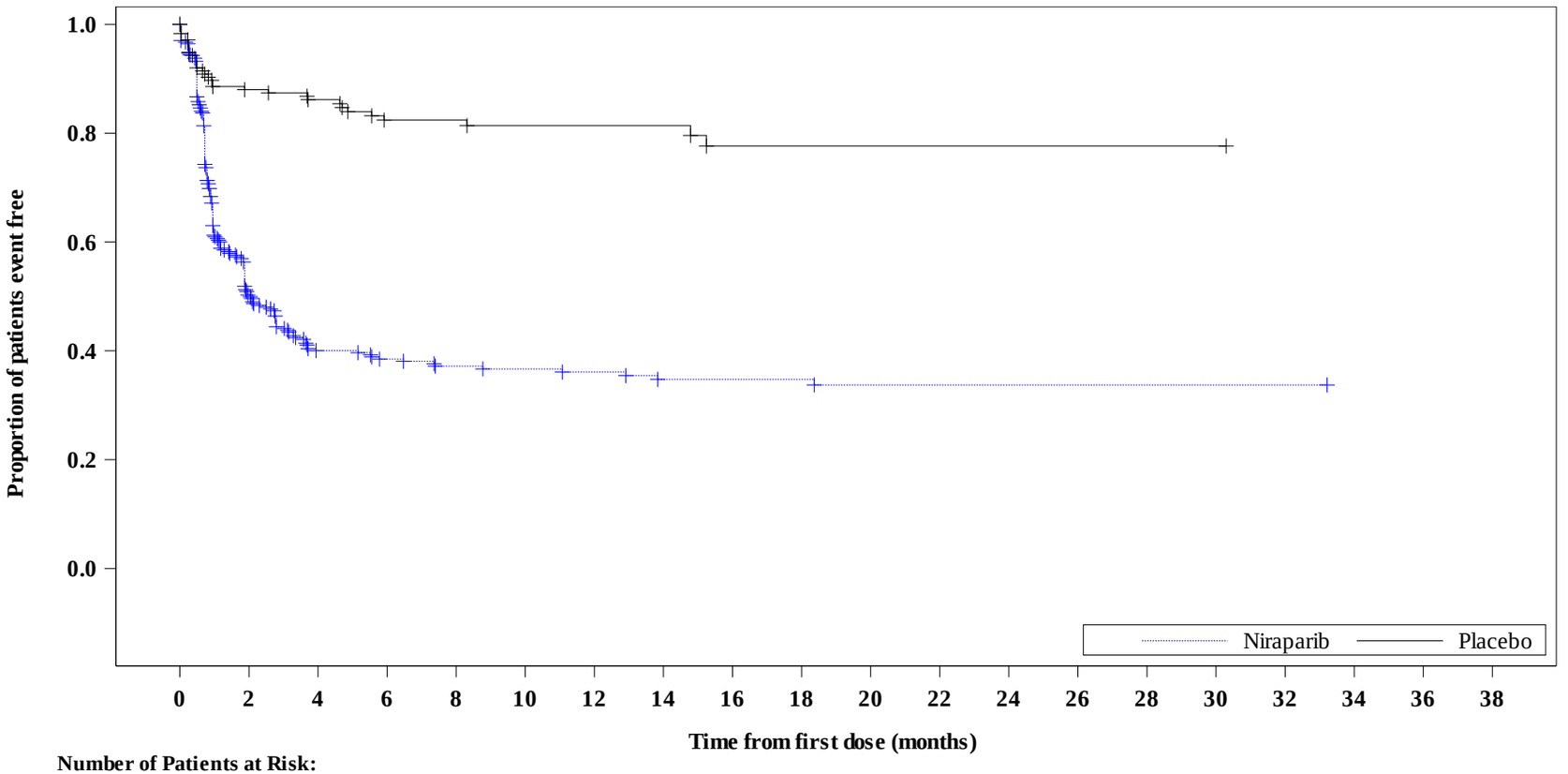
Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Anemia



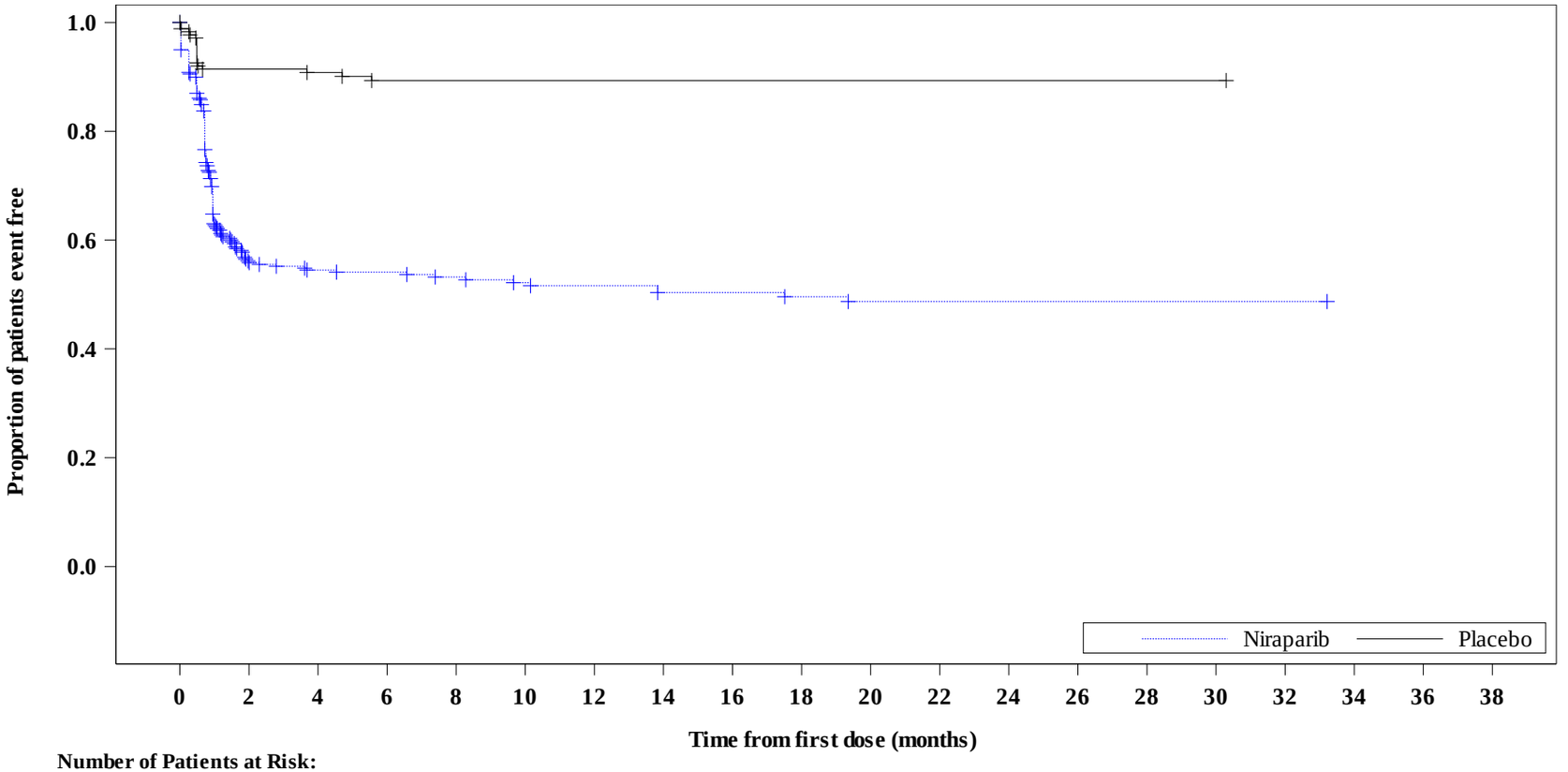

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 156 | 111 | 97 | 77 | 64 | 58 | 51 | 39 | 34 | 26 | 14 | 10 | 5 | 2 | 1 | 1 | 0 |
| Placebo | 175 | 151 | 125 | 104 | 84 | 63 | 58 | 48 | 40 | 35 | 29 | 18 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Leukopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 171 | 146 | 131 | 106 | 93 | 86 | 80 | 69 | 64 | 48 | 34 | 22 | 9 | 3 | 1 | 1 | 0 |
| Placebo | 175 | 157 | 132 | 114 | 92 | 68 | 61 | 50 | 44 | 37 | 30 | 16 | 7 | 4 | 1 | 1 | 0 | |

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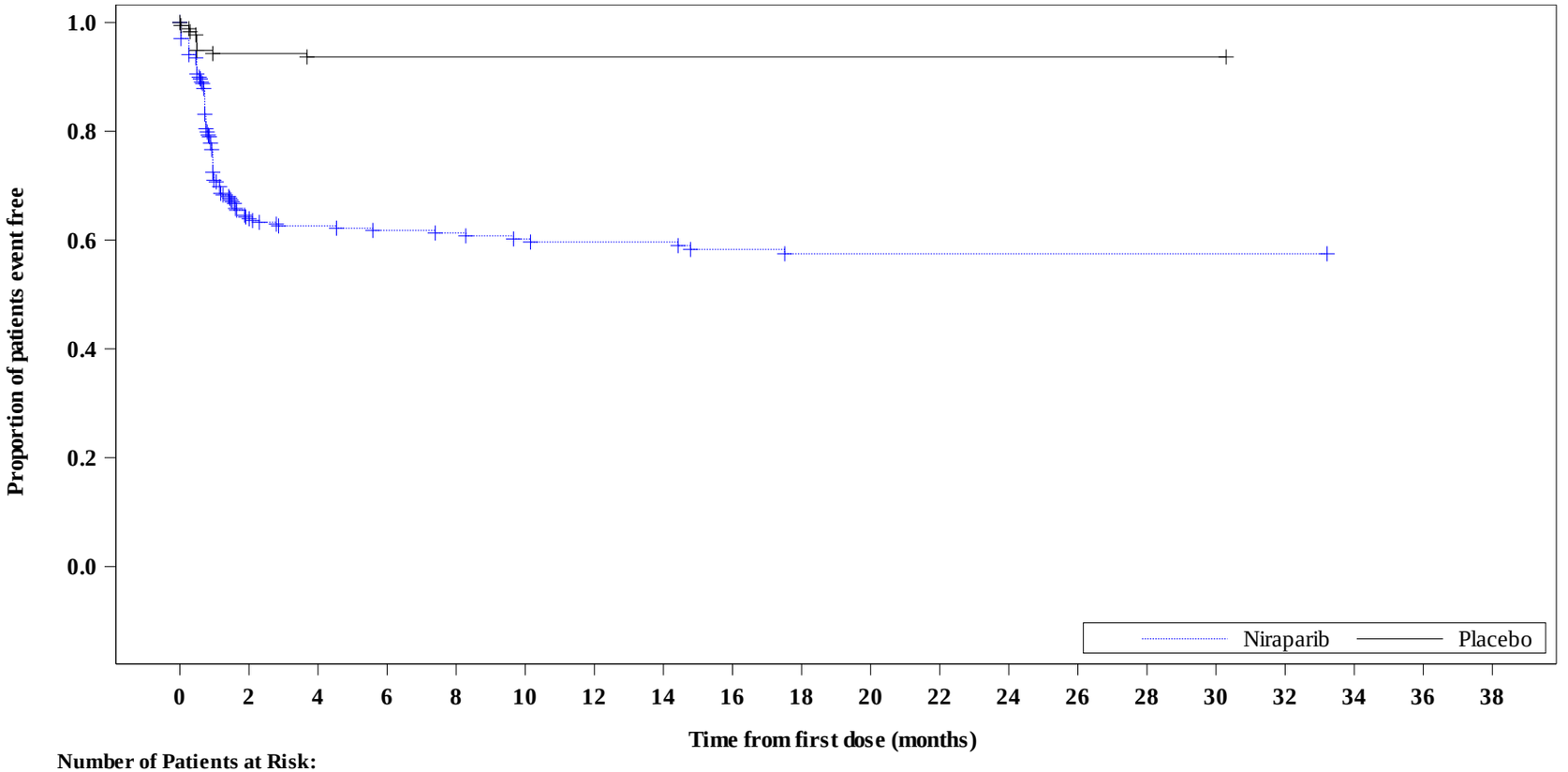
11:47

Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Neutropenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 198 | 164 | 146 | 118 | 104 | 96 | 91 | 75 | 69 | 52 | 37 | 24 | 10 | 3 | 1 | 1 | 0 |
| Placebo | 175 | 162 | 135 | 119 | 95 | 71 | 63 | 52 | 46 | 39 | 32 | 16 | 7 | 4 | 1 | 1 | 0 | |

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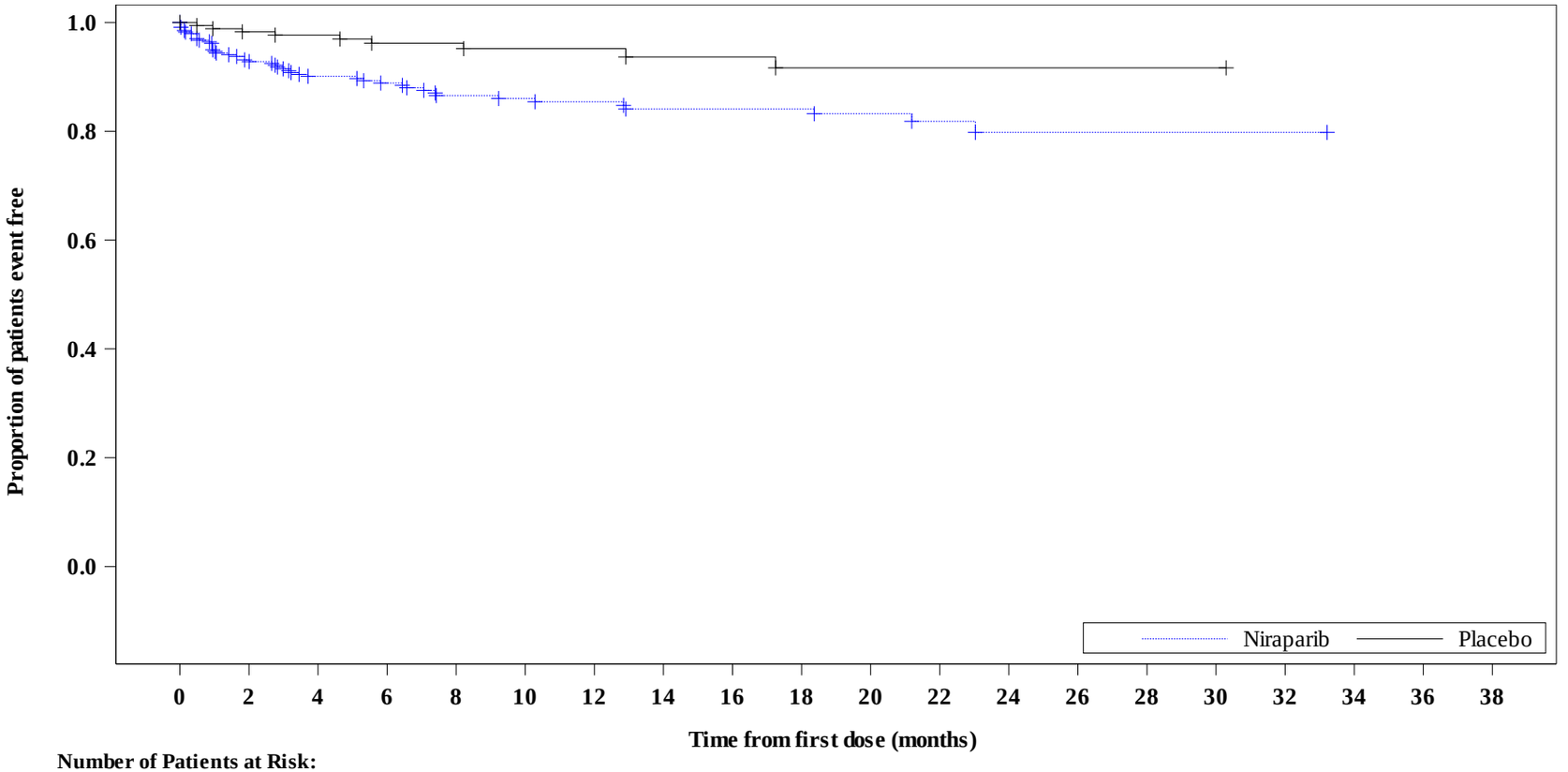
Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Hypertension




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 289 | 237 | 213 | 168 | 146 | 138 | 125 | 105 | 97 | 71 | 49 | 31 | 16 | 8 | 2 | 2 | 0 |
| Placebo | 175 | 169 | 141 | 122 | 98 | 74 | 66 | 55 | 48 | 40 | 34 | 19 | 8 | 5 | 2 | 1 | 0 | |

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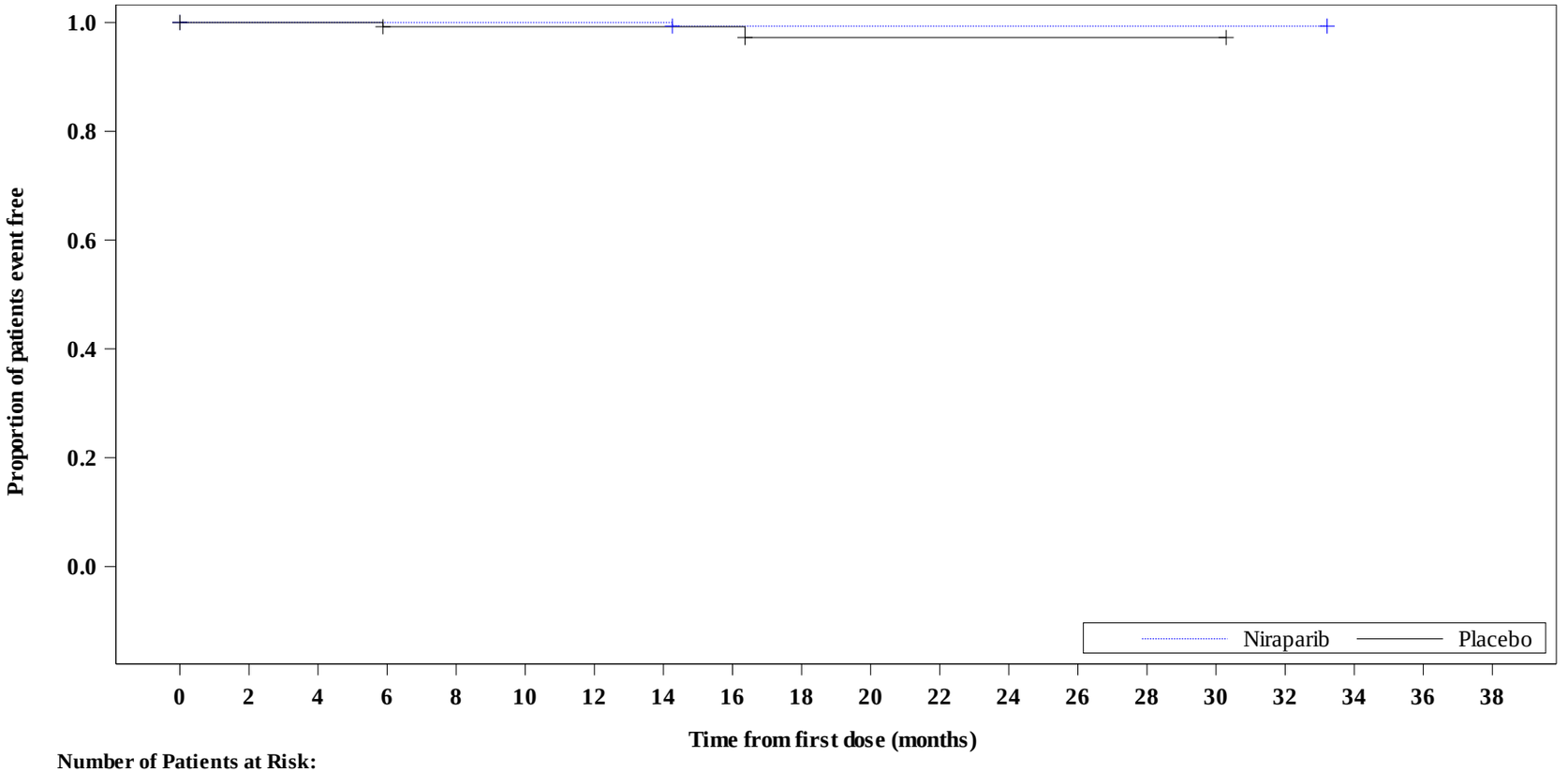
Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

New malignancies other than MDS/AML



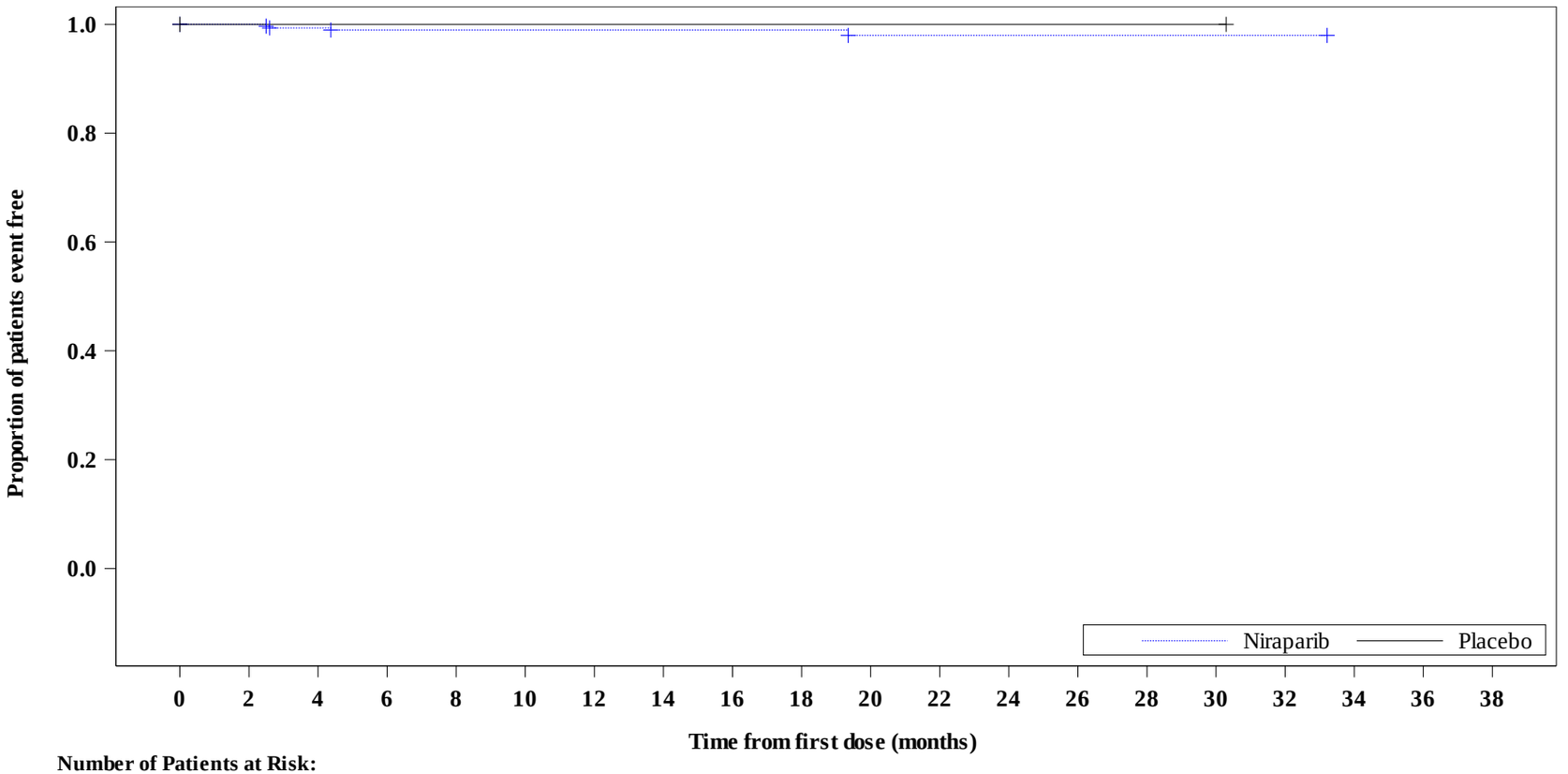

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 127 | 101 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Pneumonitis




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 264 | 237 | 196 | 172 | 164 | 151 | 127 | 116 | 85 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

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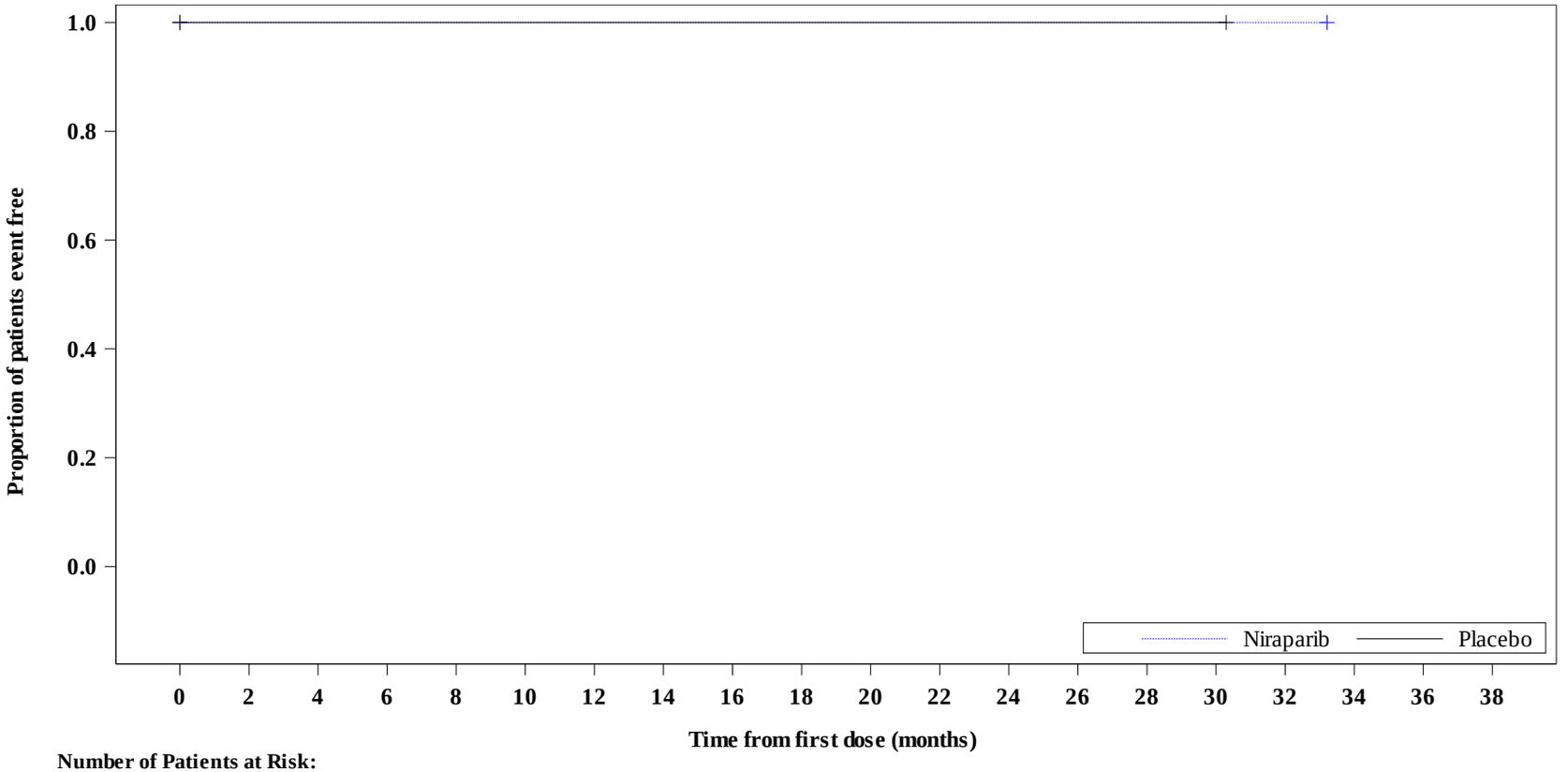
11:47

Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Pancytopenia



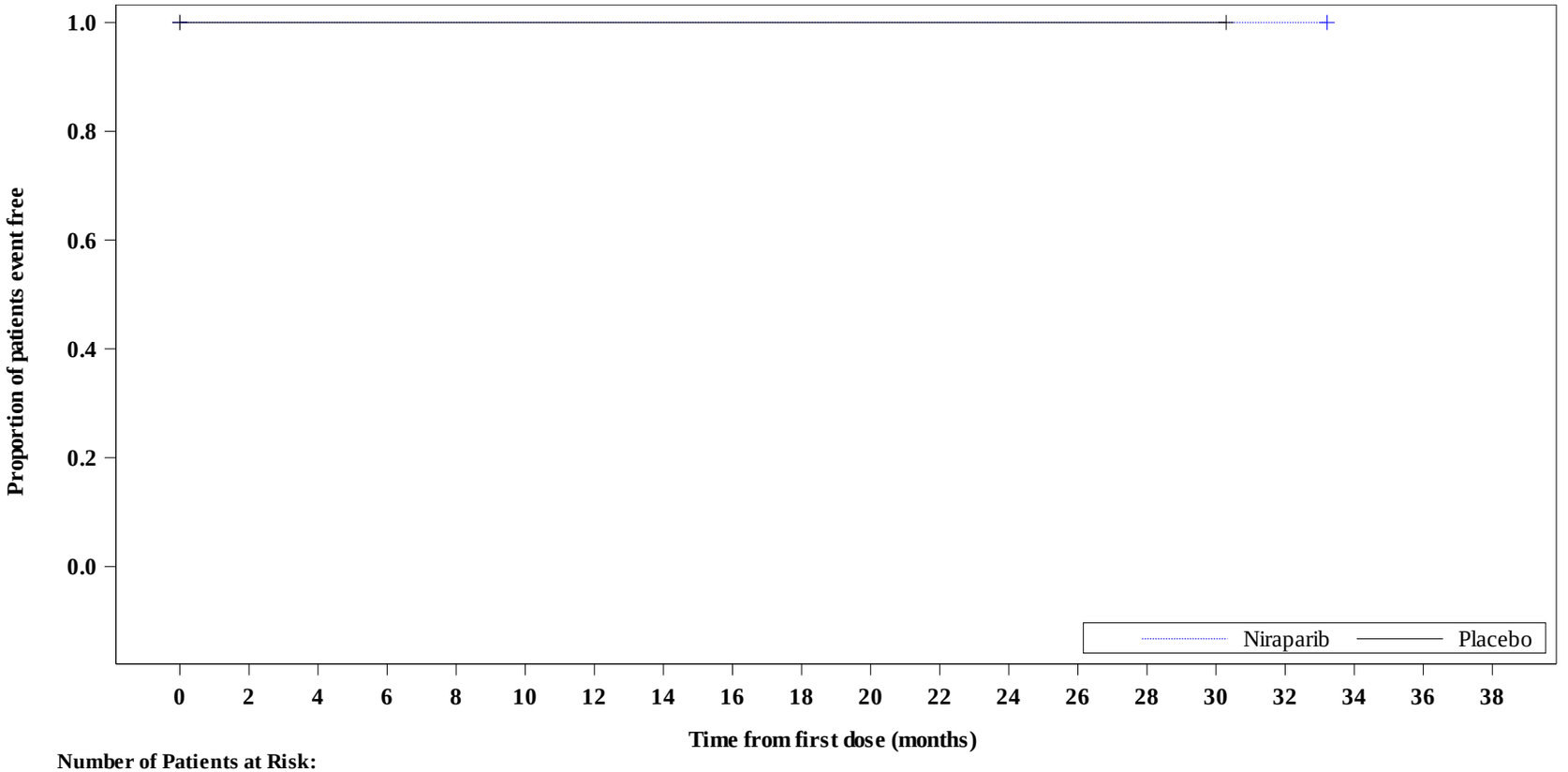

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Thromboemblic



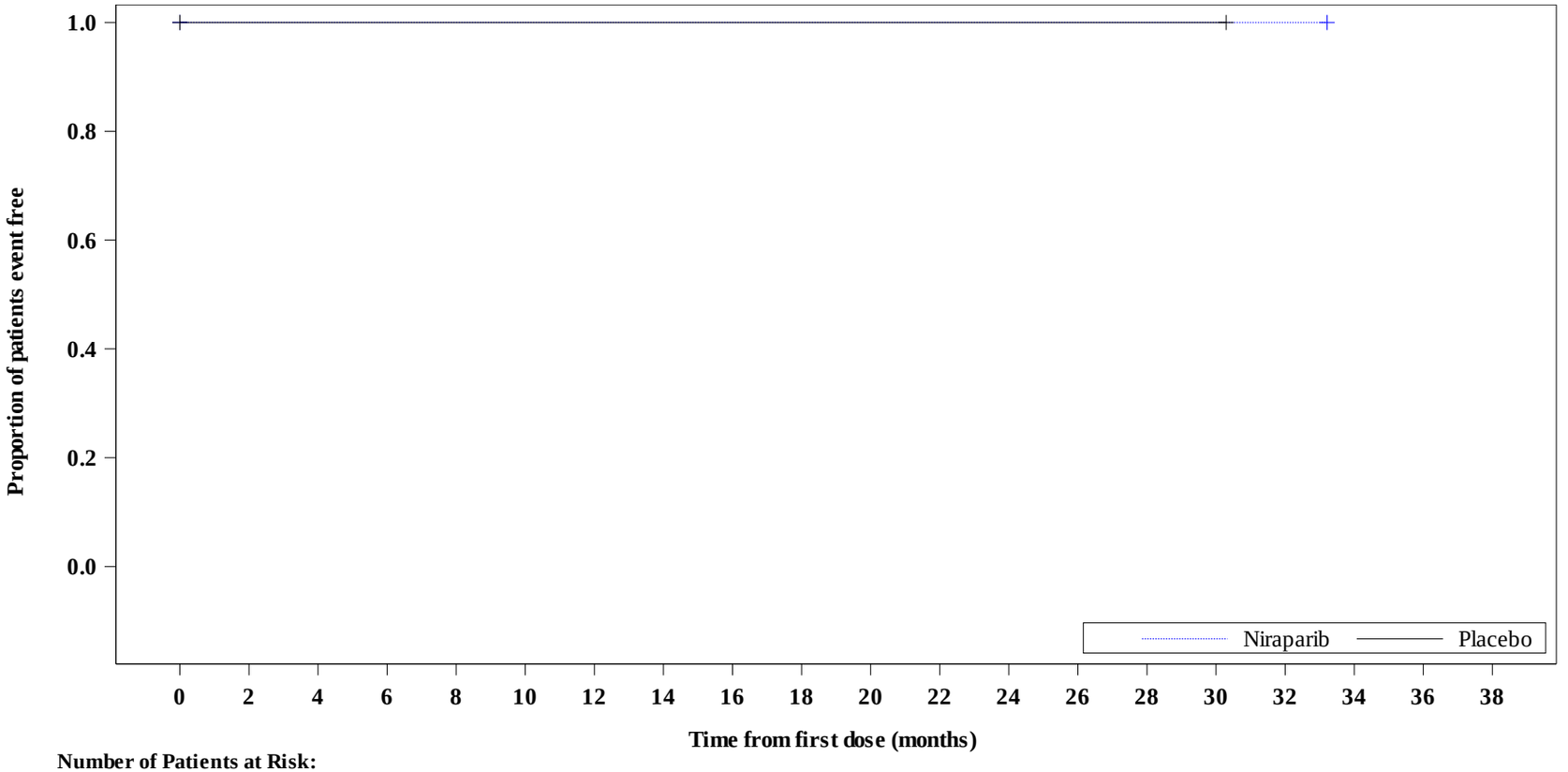

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

MDS/AML



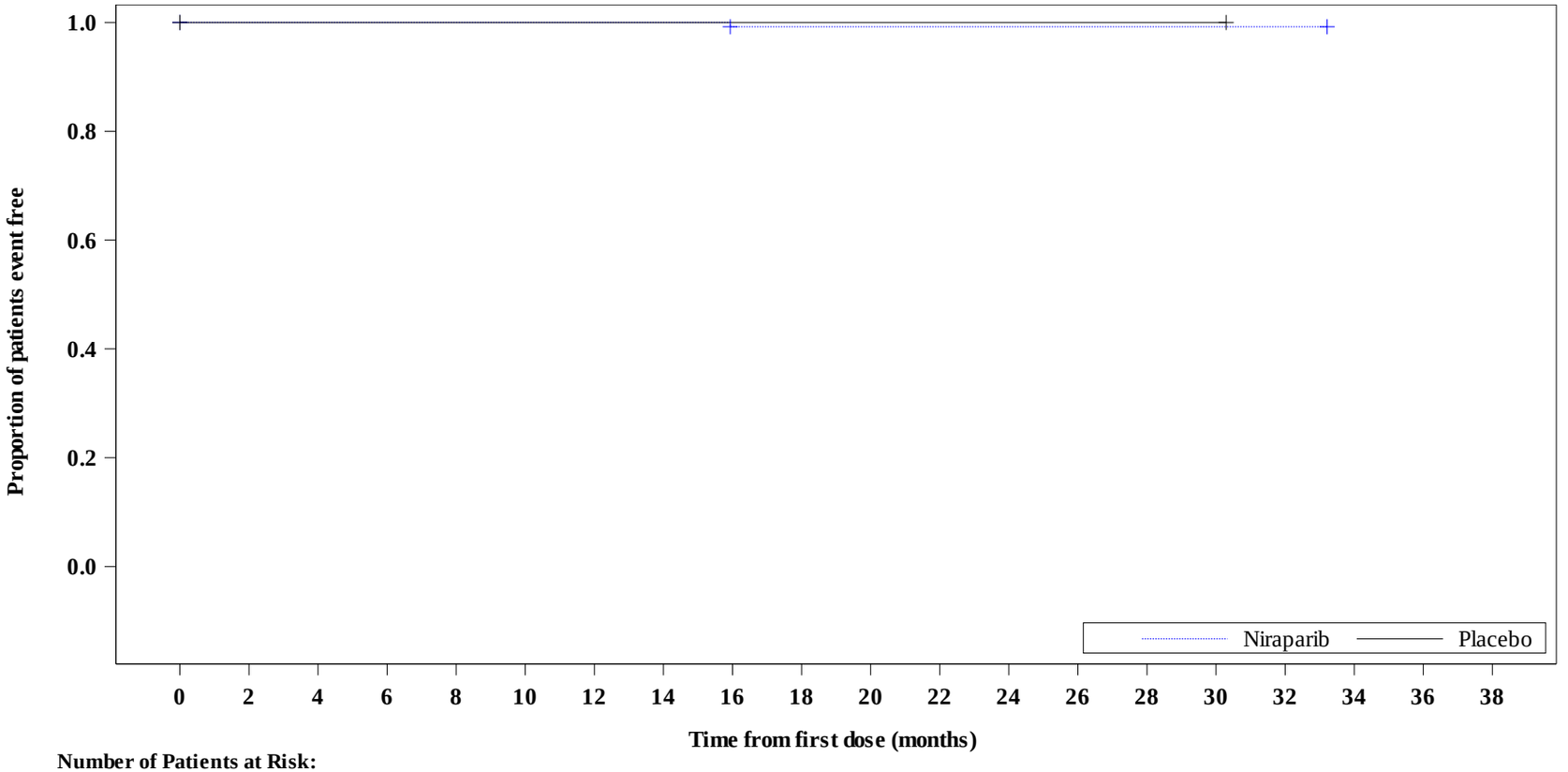

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.146a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Embryo-fetal toxicity




**Number of Patients at Risk:**

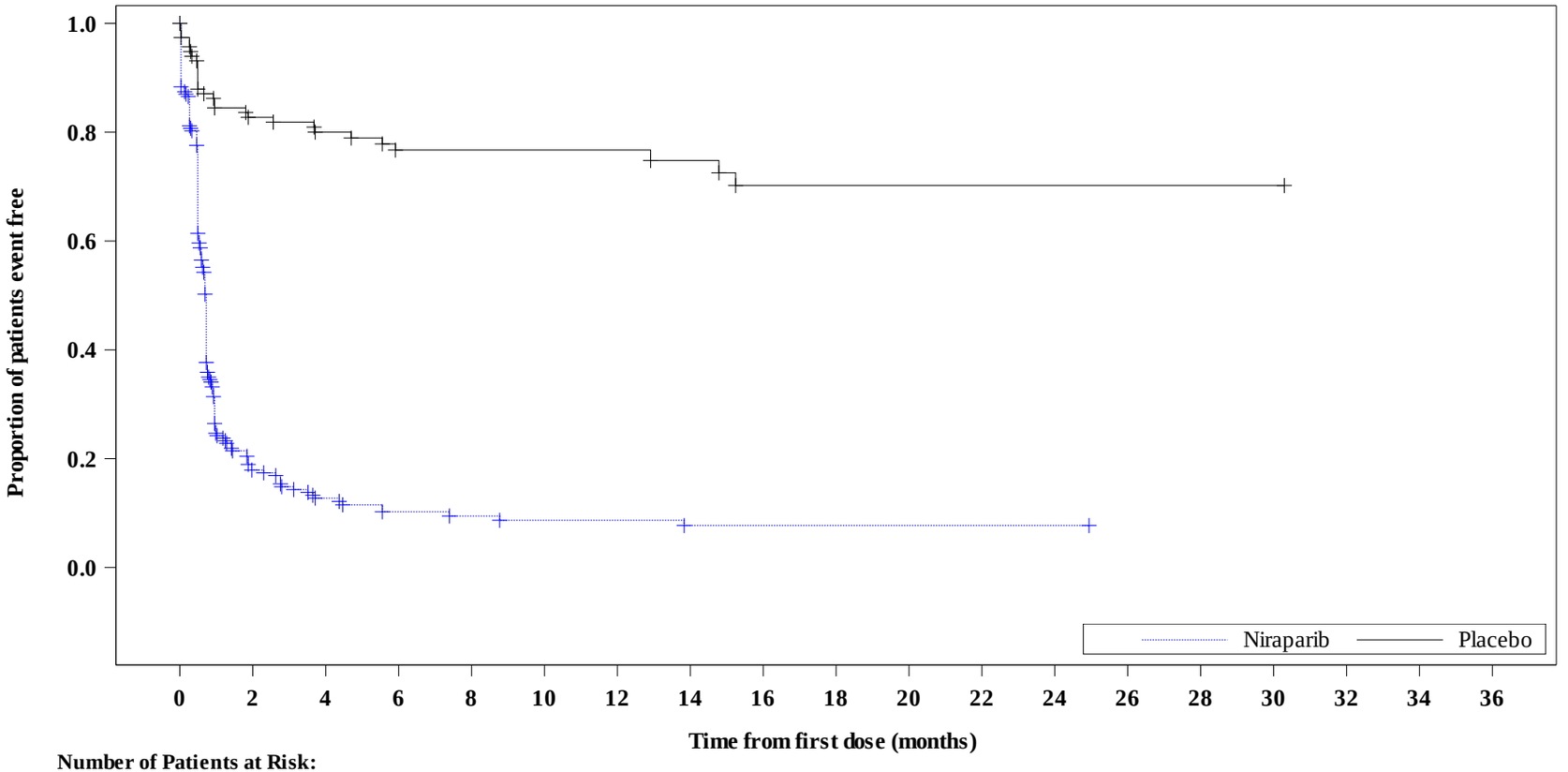
| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 126 | 115 | 85 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.146b

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety Population)

Overall

Residual Disease Status: R0




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 223 | 35 | 22 | 16 | 12 | 9 | 9 | 8 | 6 | 5 | 5 | 2 | 1 | 0 | | | |
| Placebo | 116 | 95 | 78 | 68 | 56 | 44 | 41 | 34 | 30 | 27 | 22 | 14 | 7 | 4 | 1 | 1 | 0 |

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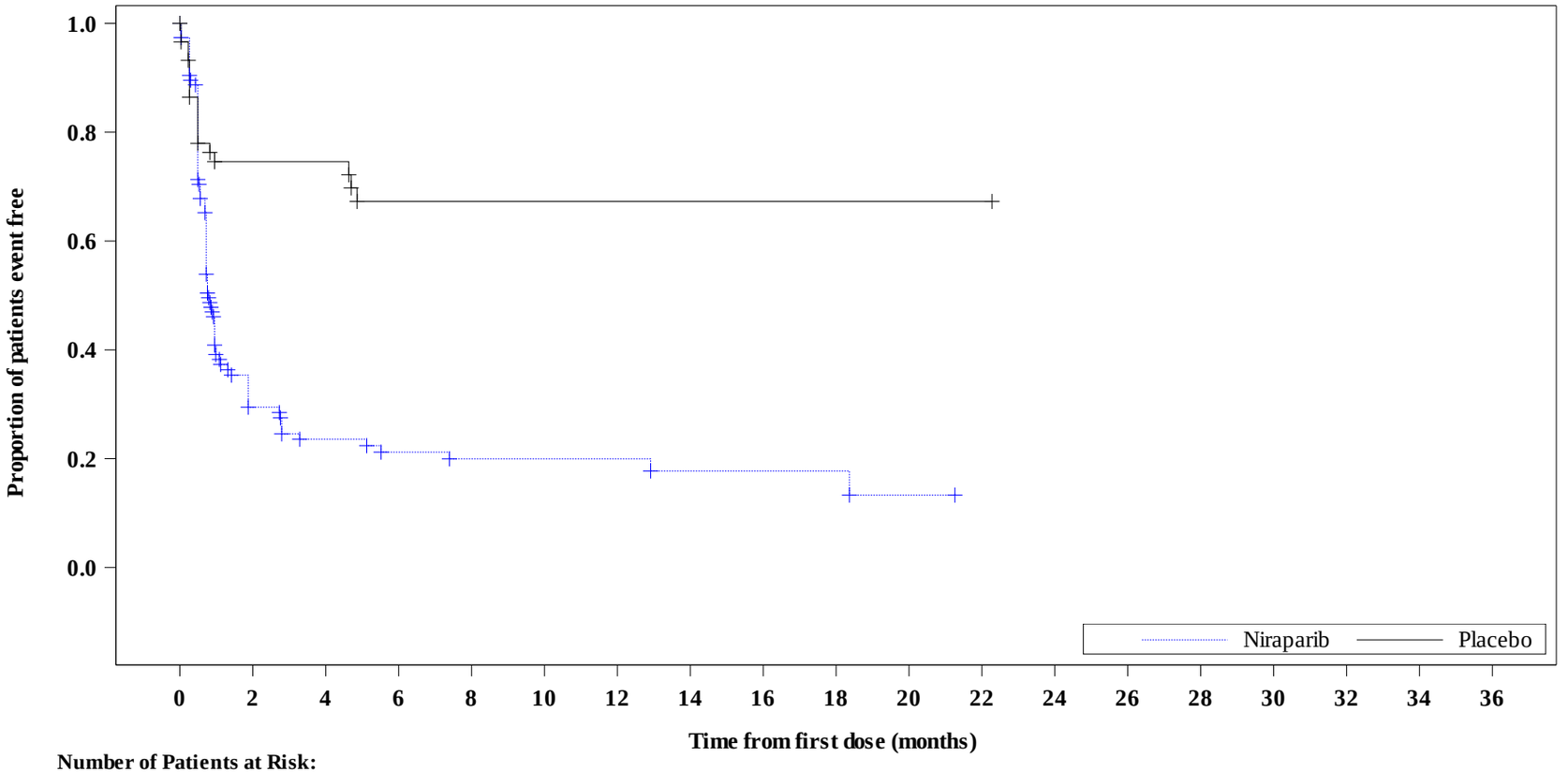
Figure 3.146b

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety Population)

Overall

Residual Disease Status: R1/R2




**Number of Patients at Risk:**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 115 | 30 | 20 | 18 | 15 | 13 | 9 | 8 | 5 | 4 | 2 | 0 | |
| Placebo | 59 | 42 | 34 | 23 | 17 | 10 | 8 | 4 | 3 | 2 | 2 | 1 | 0 |

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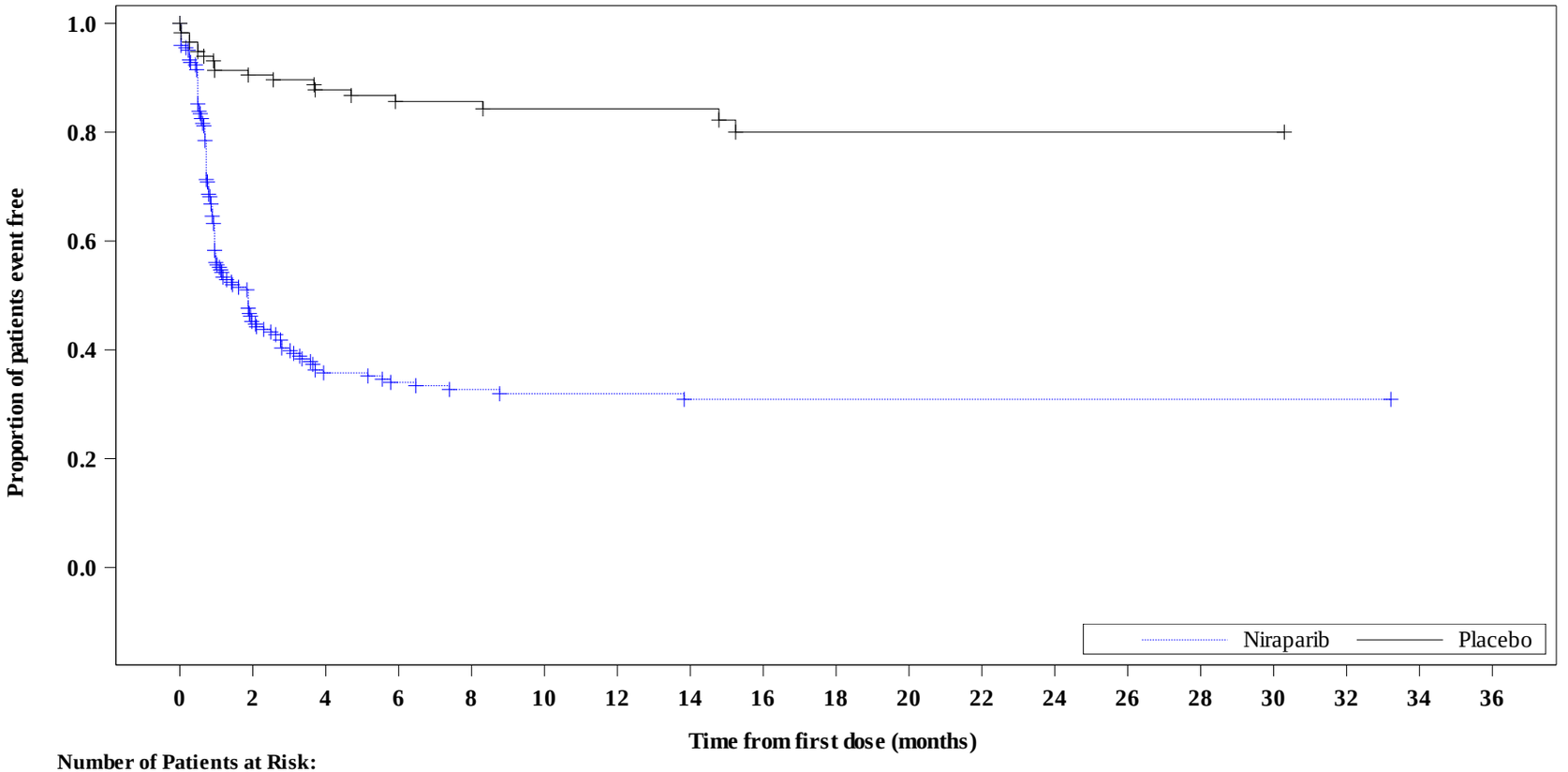
Figure 3.146b

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety Population)

Anemia

Residual Disease Status: R0




**Number of Patients at Risk:**

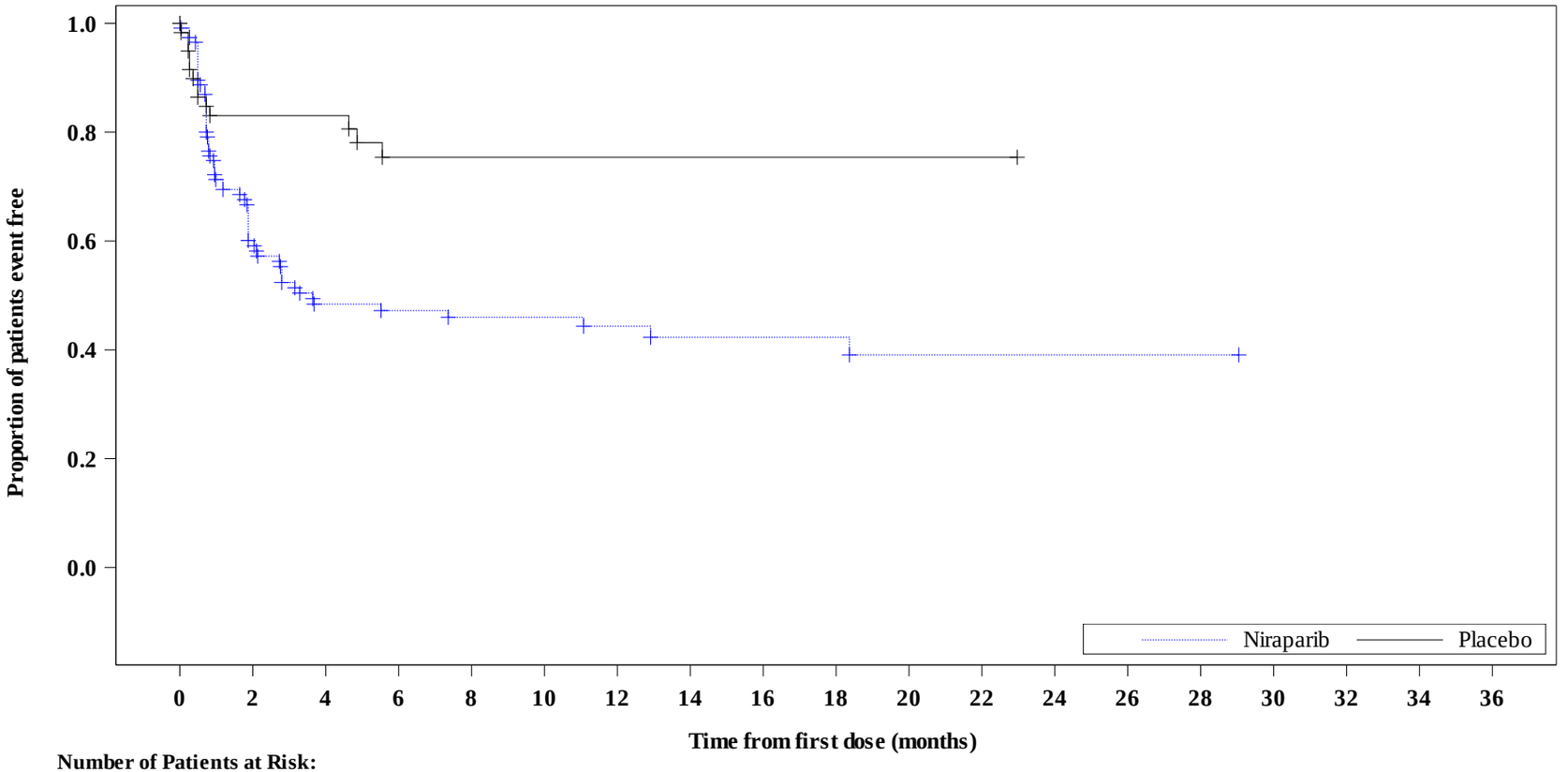
| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 223 | 93 | 67 | 57 | 43 | 35 | 34 | 30 | 25 | 21 | 17 | 8 | 7 | 3 | 1 | 1 | 1 | 0 |
| Placebo | 116 | 104 | 87 | 78 | 65 | 52 | 49 | 43 | 36 | 32 | 26 | 16 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.146b

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety Population)

Anemia

Residual Disease Status: R1/R2




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 115 | 63 | 44 | 40 | 34 | 29 | 24 | 21 | 14 | 13 | 9 | 6 | 3 | 2 | 1 | 0 |
| Placebo | 59 | 47 | 38 | 26 | 19 | 11 | 9 | 5 | 4 | 3 | 3 | 2 | 0 | | | |

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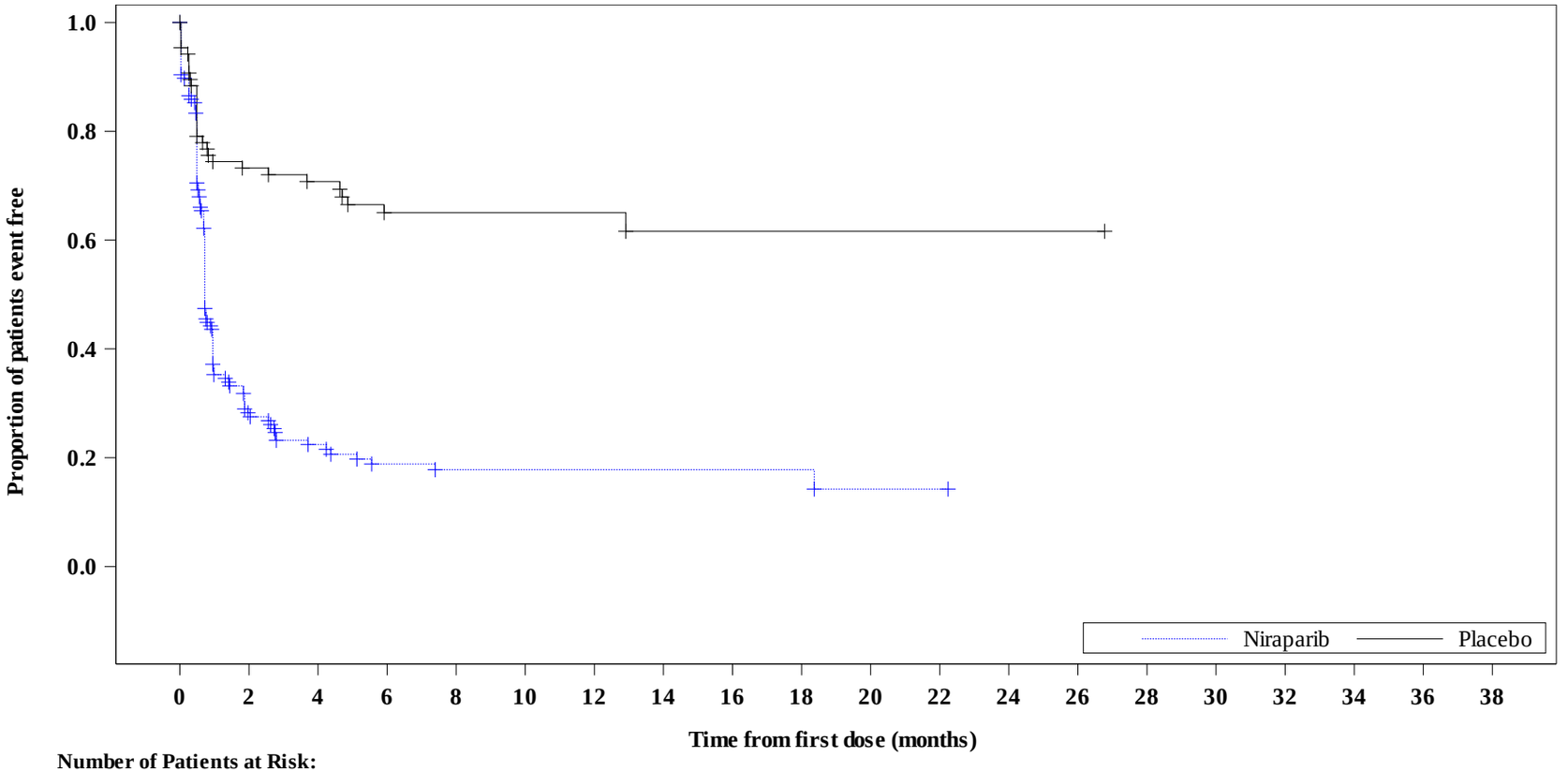
Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Overall




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 39 | 25 | 21 | 16 | 13 | 10 | 10 | 7 | 5 | 4 | 1 | 0 | | |
| Placebo | 86 | 61 | 54 | 44 | 37 | 28 | 23 | 16 | 15 | 13 | 8 | 4 | 2 | 1 | 0 |

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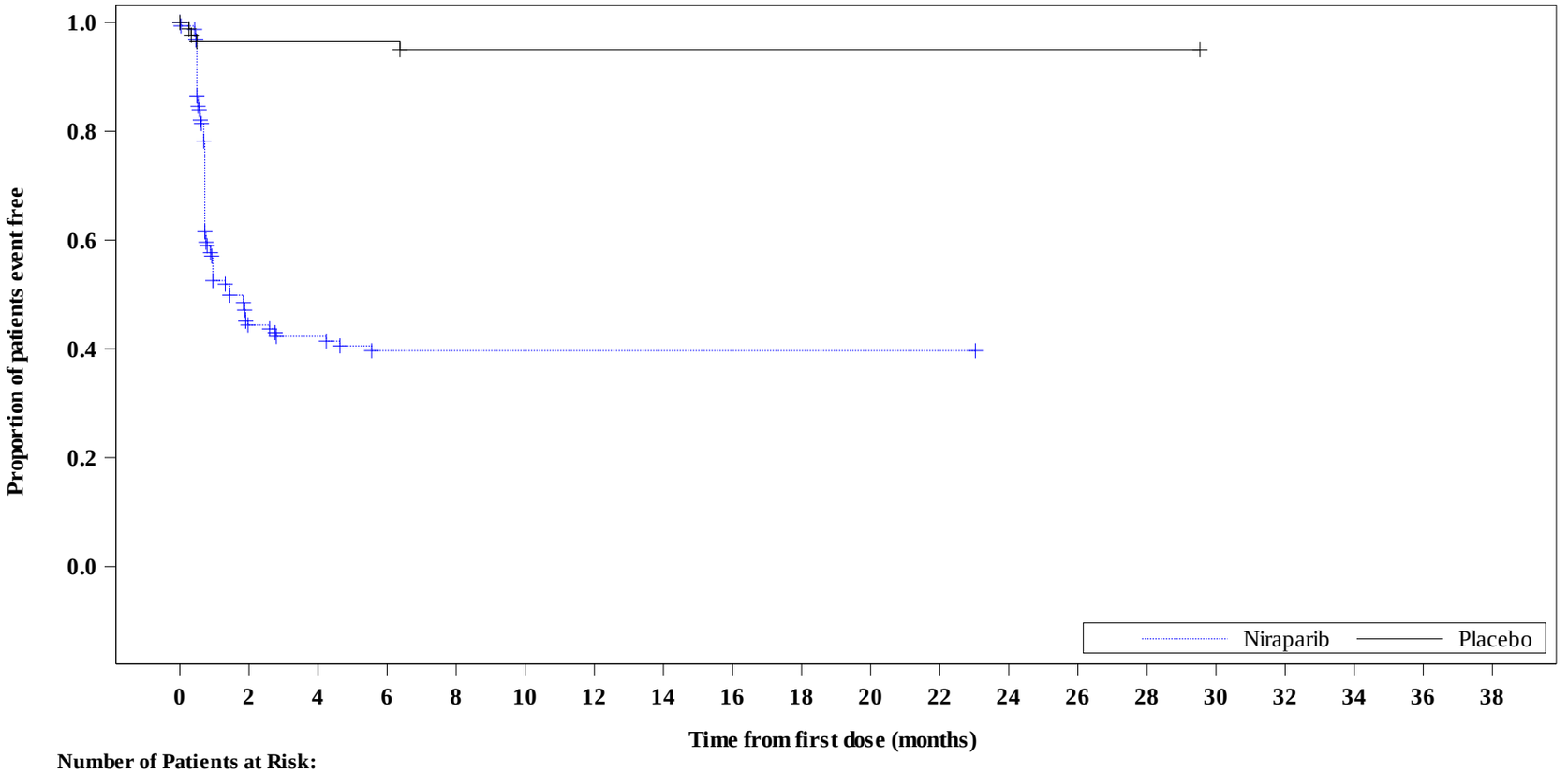
Figure 3.147a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Thrombocytopenia



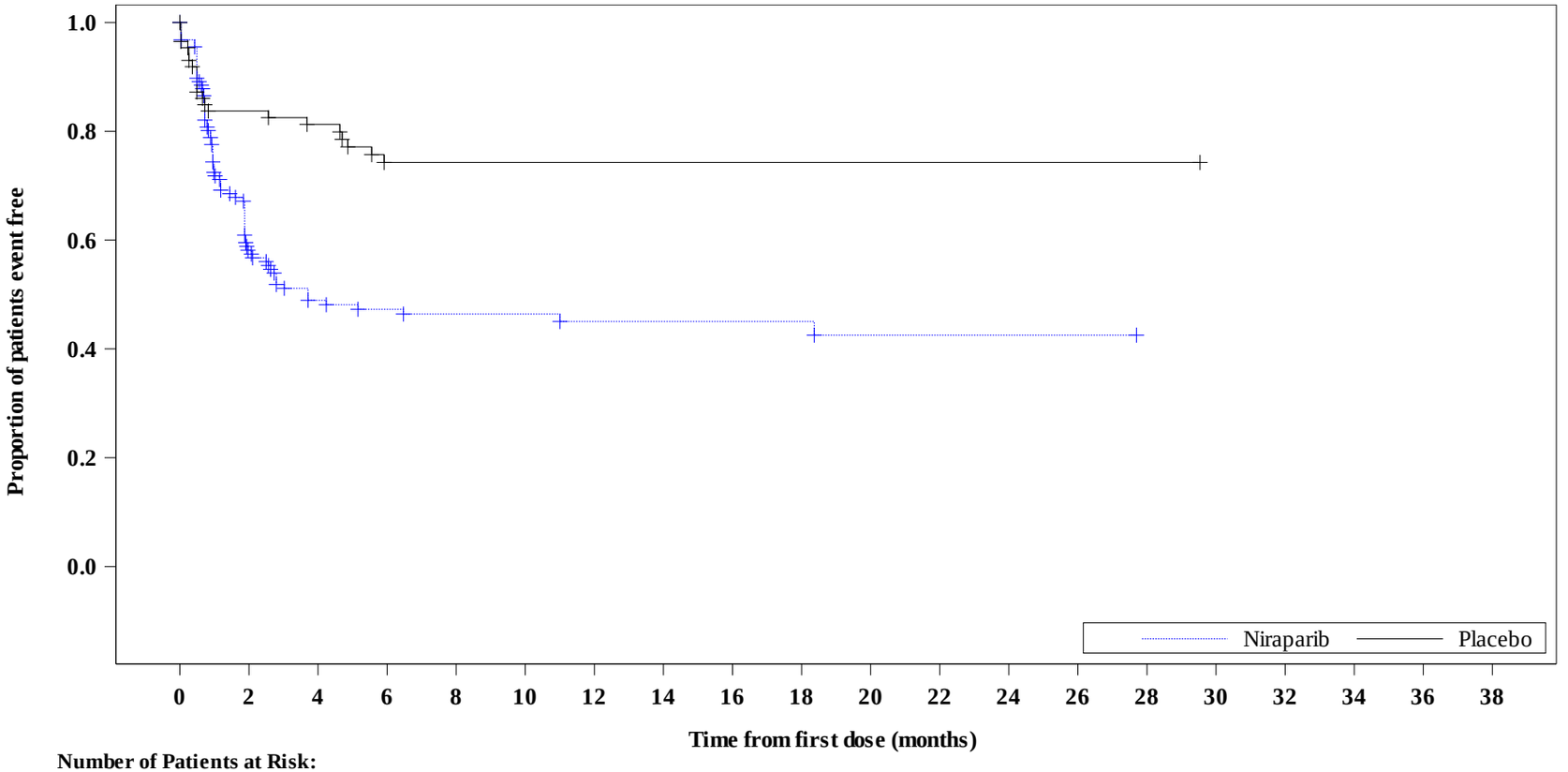

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 64 | 49 | 43 | 34 | 31 | 28 | 27 | 22 | 20 | 14 | 4 | 0 | | | |
| Placebo | 86 | 81 | 73 | 67 | 55 | 41 | 35 | 27 | 22 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Anemia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 83 | 61 | 54 | 42 | 35 | 31 | 28 | 22 | 18 | 13 | 4 | 3 | 2 | 0 | |
| Placebo | 86 | 70 | 63 | 52 | 44 | 34 | 29 | 22 | 19 | 16 | 11 | 5 | 3 | 2 | 1 | 0 |

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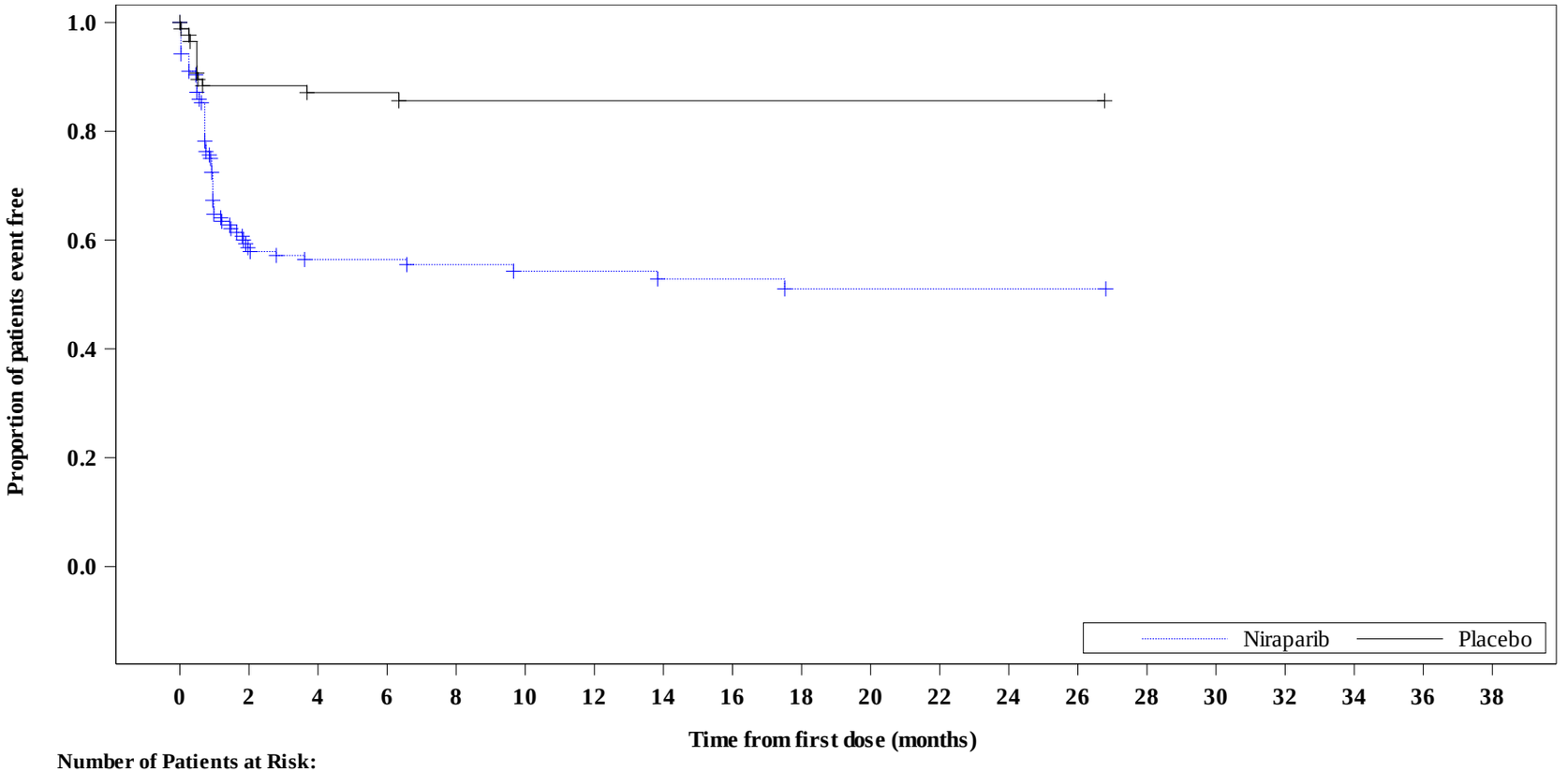
Figure 3.147a
Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Leukopenia



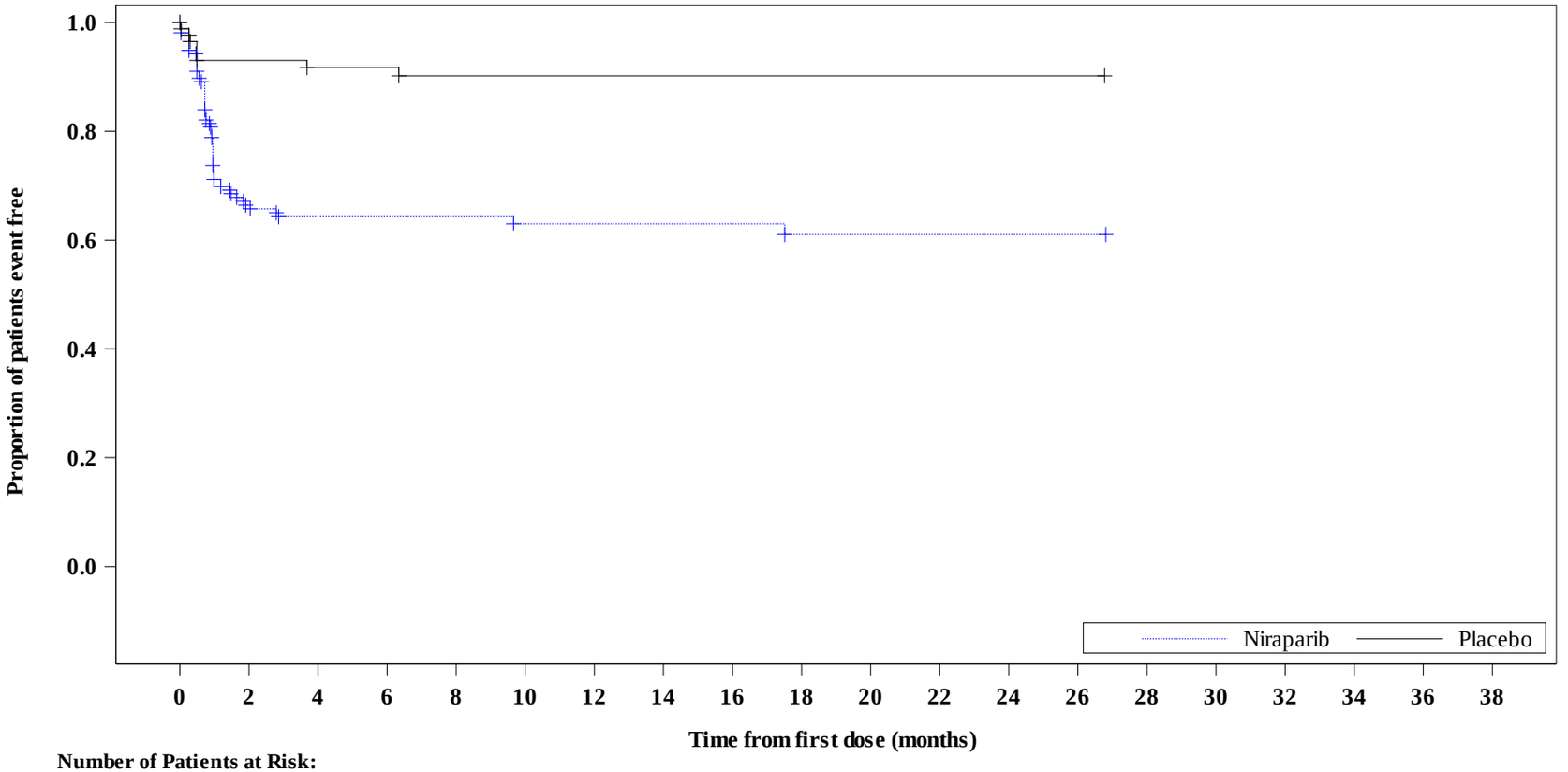

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 82 | 68 | 61 | 50 | 44 | 40 | 37 | 31 | 27 | 19 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 74 | 67 | 61 | 51 | 37 | 31 | 23 | 20 | 16 | 11 | 4 | 2 | 1 | 0 |

Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Neutropenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 94 | 74 | 66 | 54 | 48 | 44 | 42 | 34 | 30 | 21 | 10 | 5 | 2 | 0 |
| Placebo | 86 | 78 | 69 | 63 | 52 | 38 | 32 | 24 | 21 | 17 | 12 | 4 | 2 | 1 | 0 |

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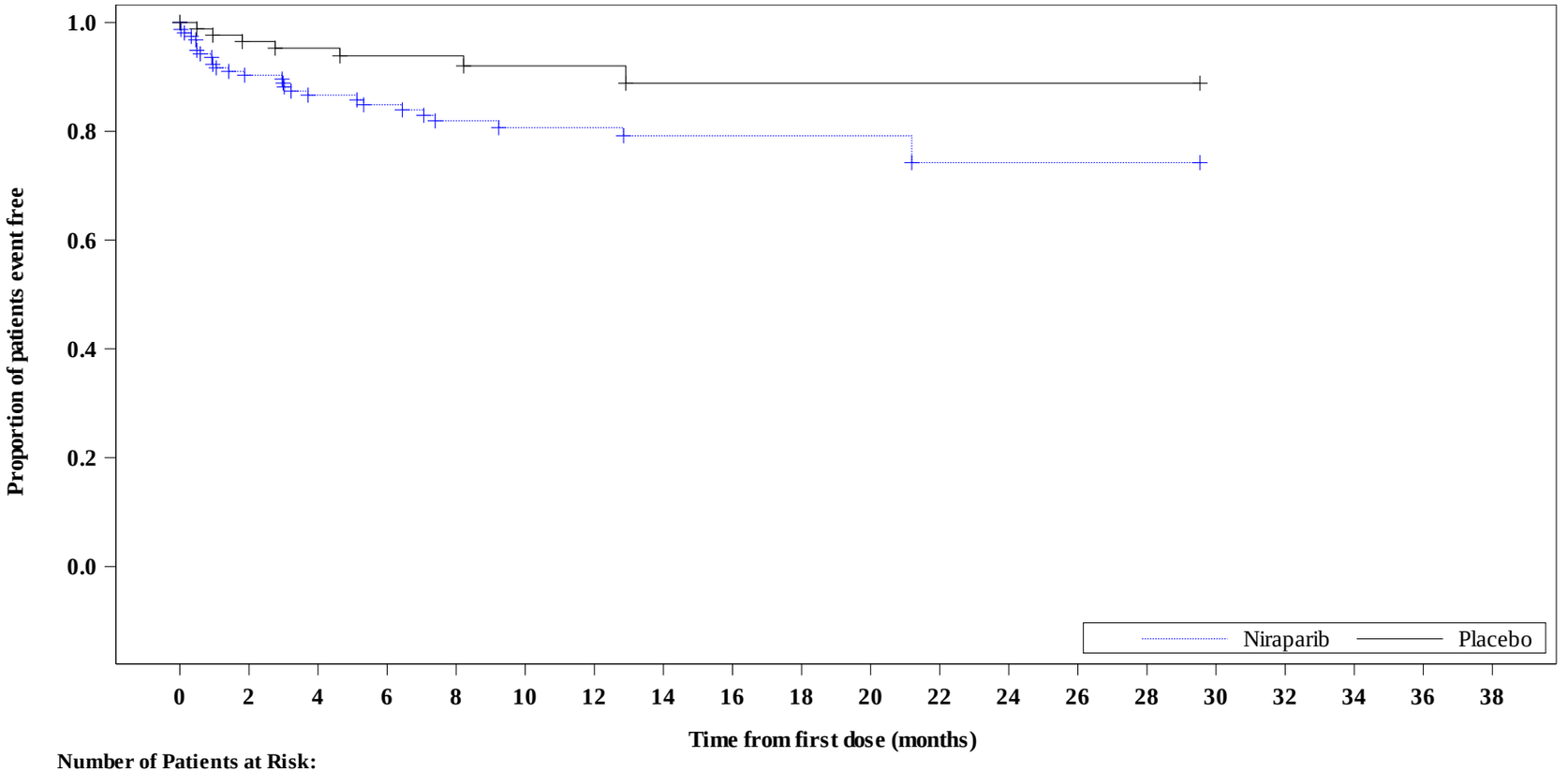
Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Hypertension



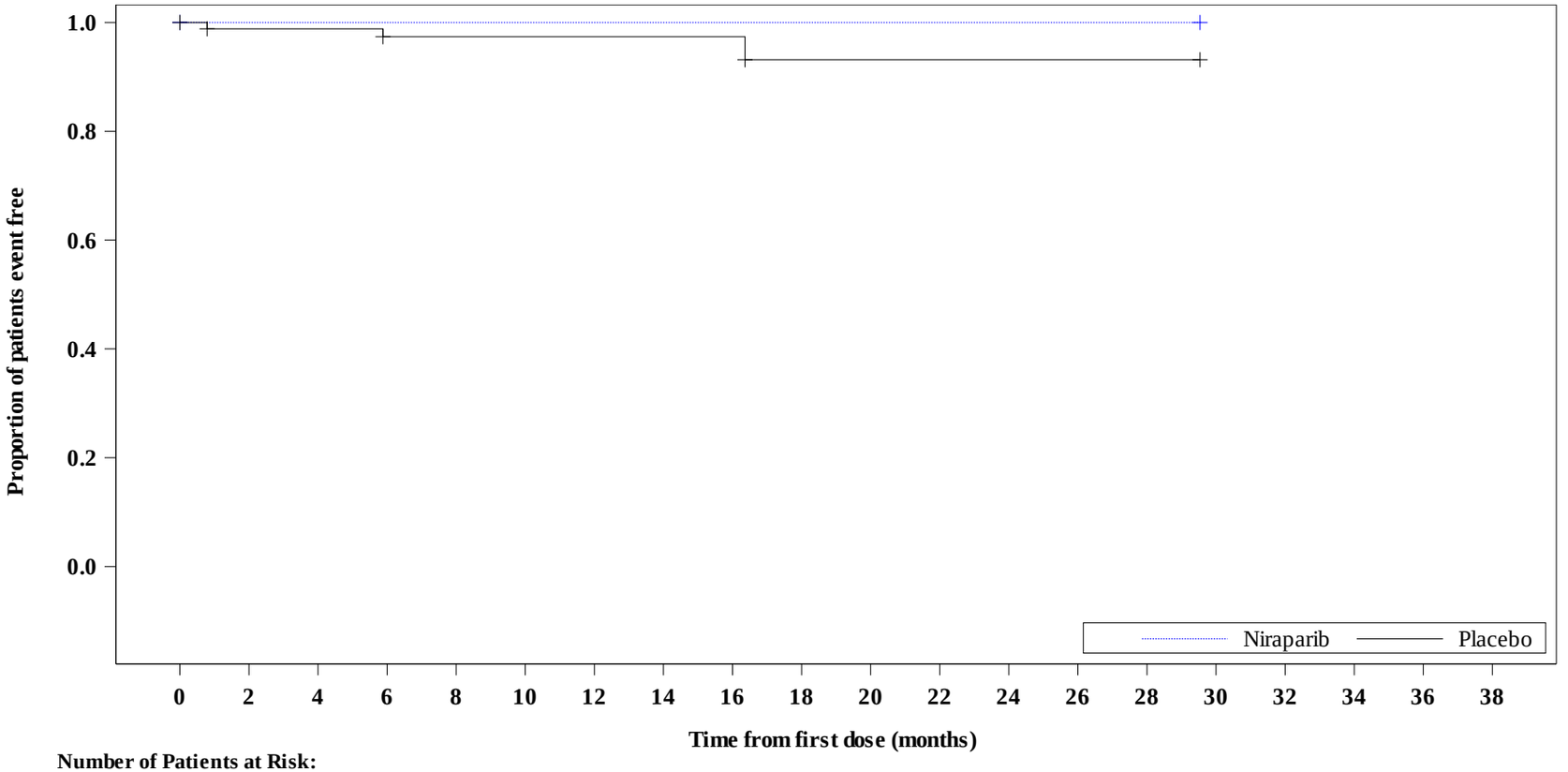

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 129 | 101 | 93 | 72 | 63 | 59 | 52 | 43 | 37 | 21 | 10 | 6 | 4 | 2 | 0 |
| Placebo | 86 | 81 | 71 | 64 | 53 | 39 | 33 | 25 | 22 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

New malignancies other than MDS/AML



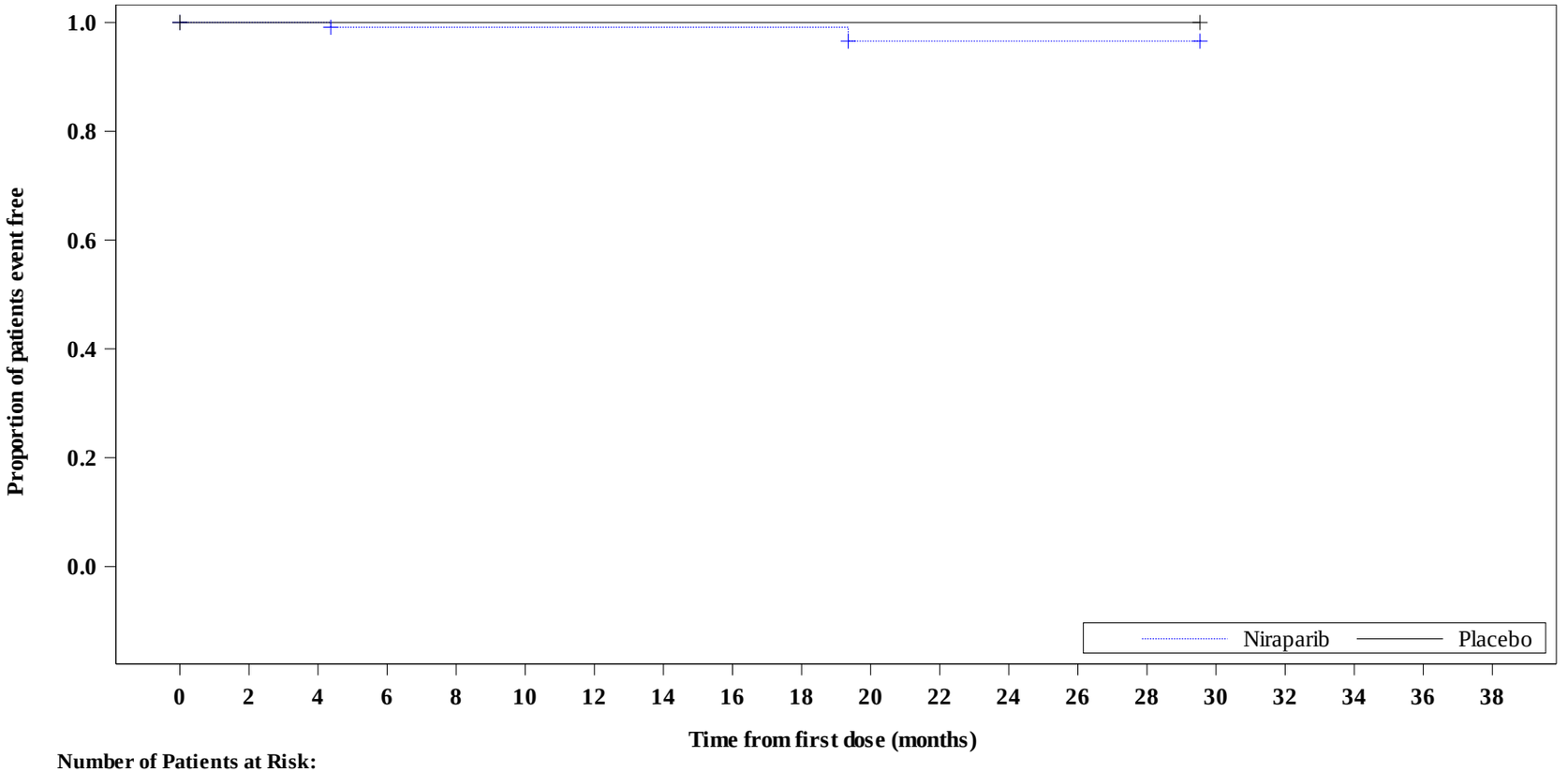

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 74 | 67 | 54 | 41 | 35 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Pneumonitis




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 106 | 87 | 78 | 74 | 67 | 55 | 49 | 29 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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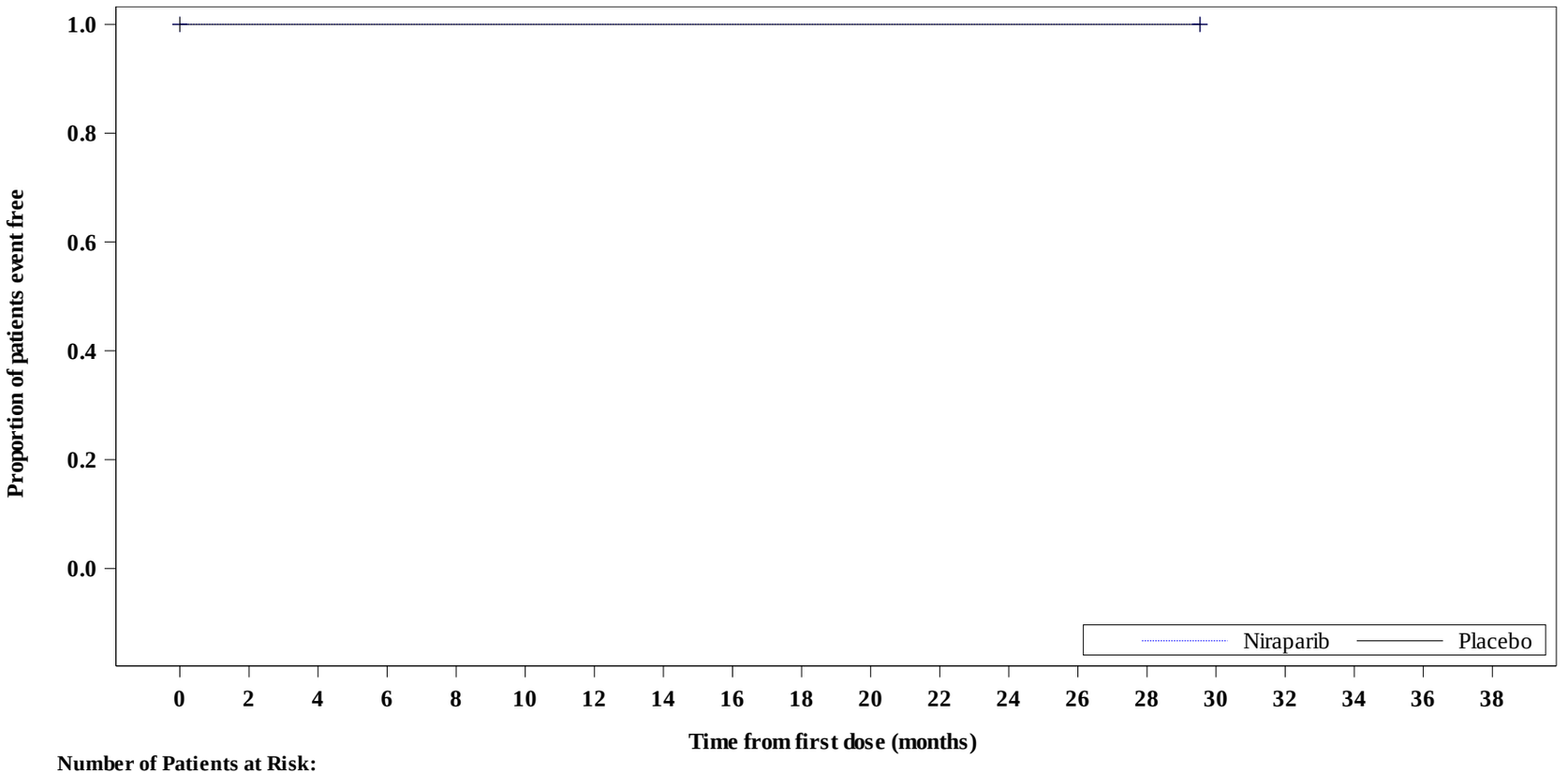
Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Pancytopenia



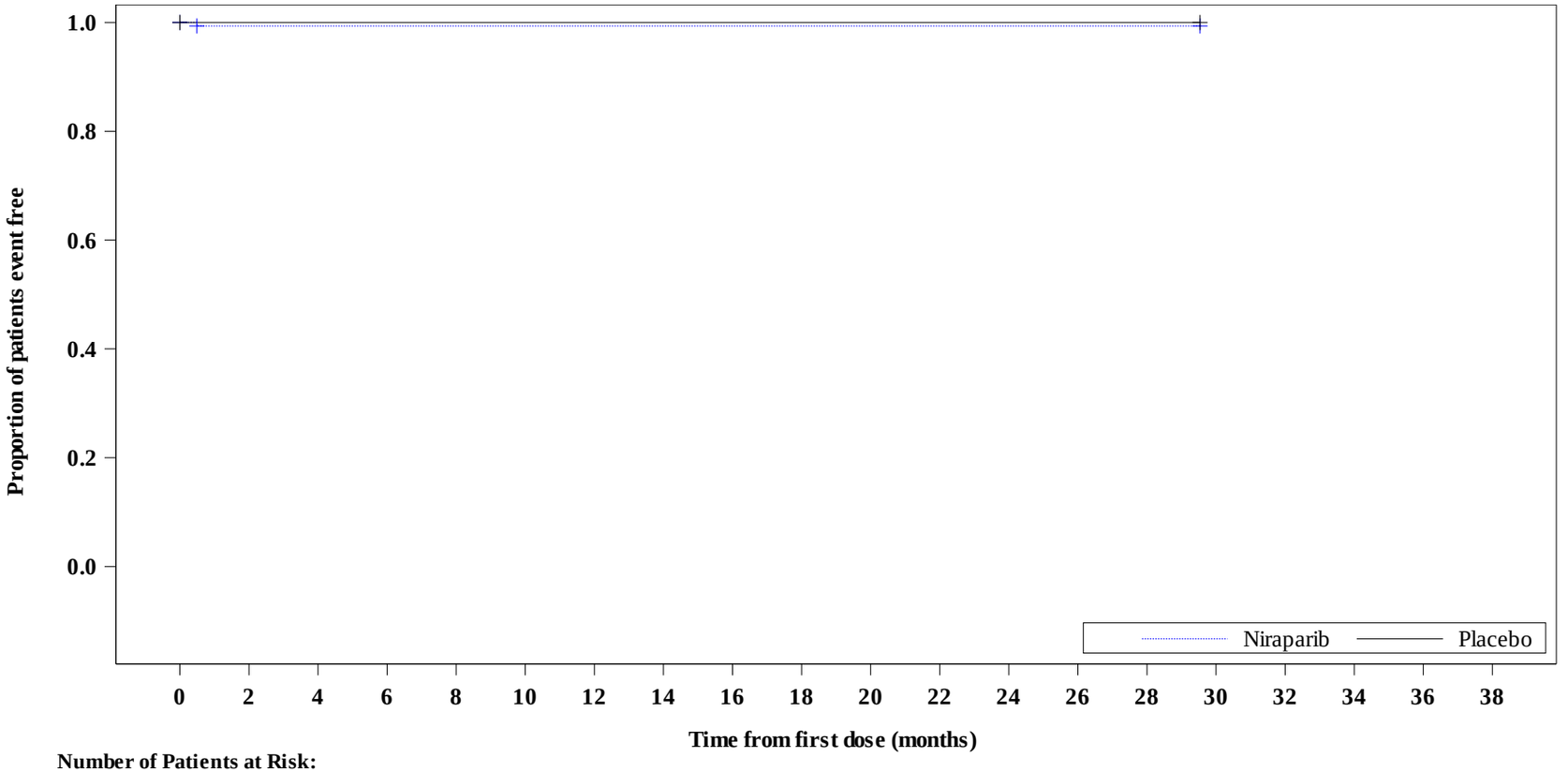

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Thromboemblic




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 143 | 117 | 106 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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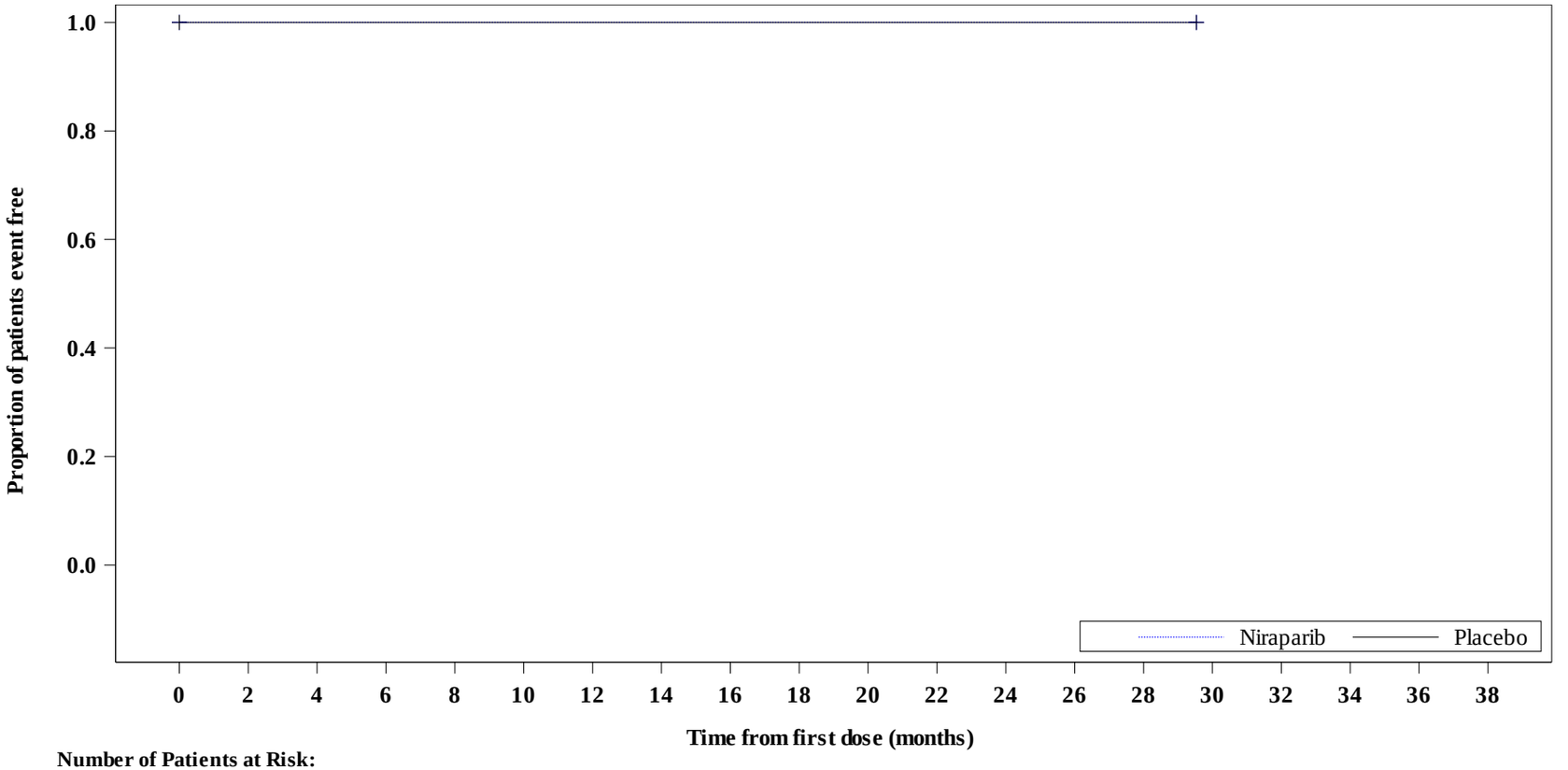
Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

MDS/AML




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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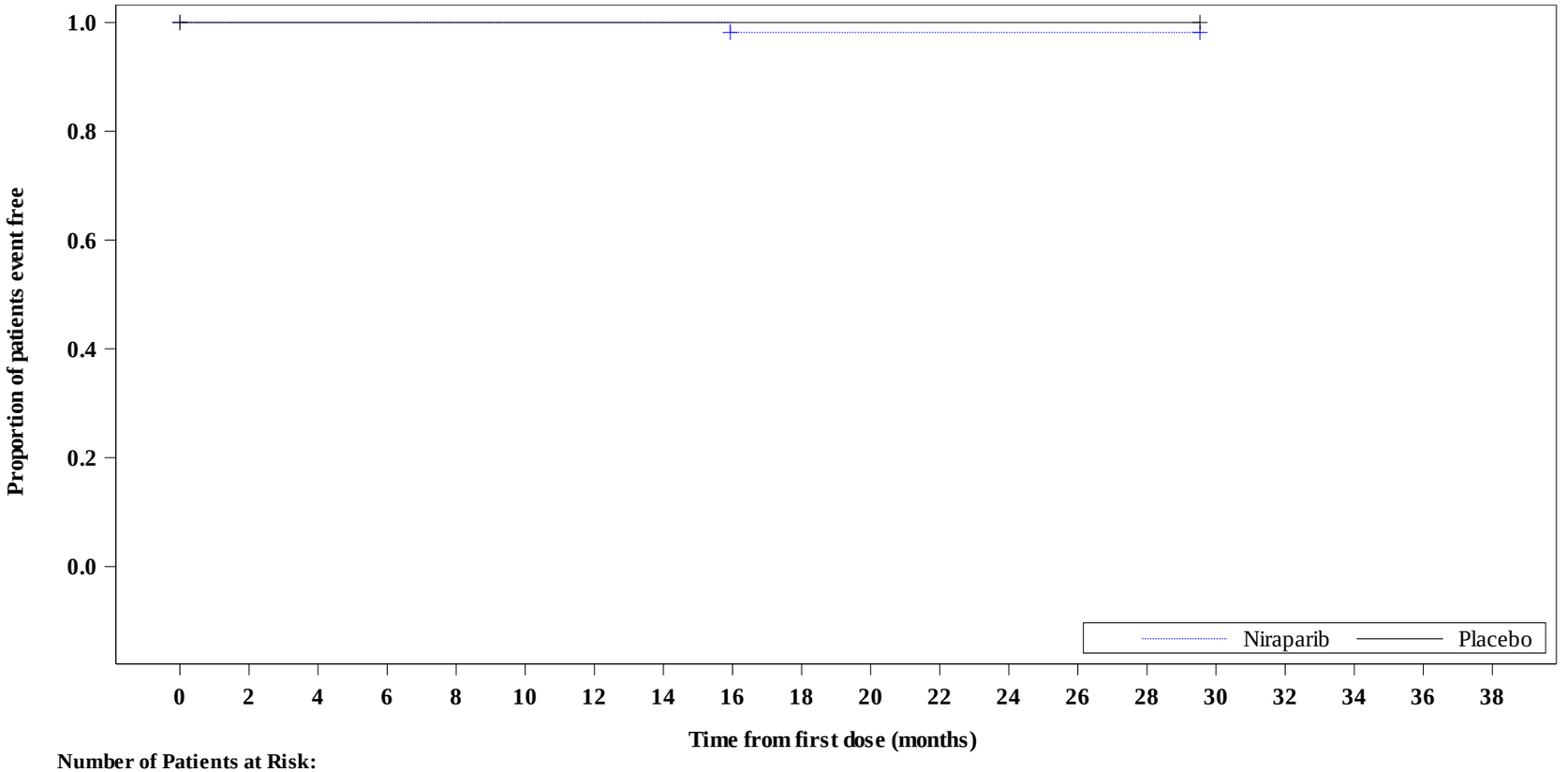
Figure 3.147a

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Embryo-fetal toxicity




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 54 | 48 | 29 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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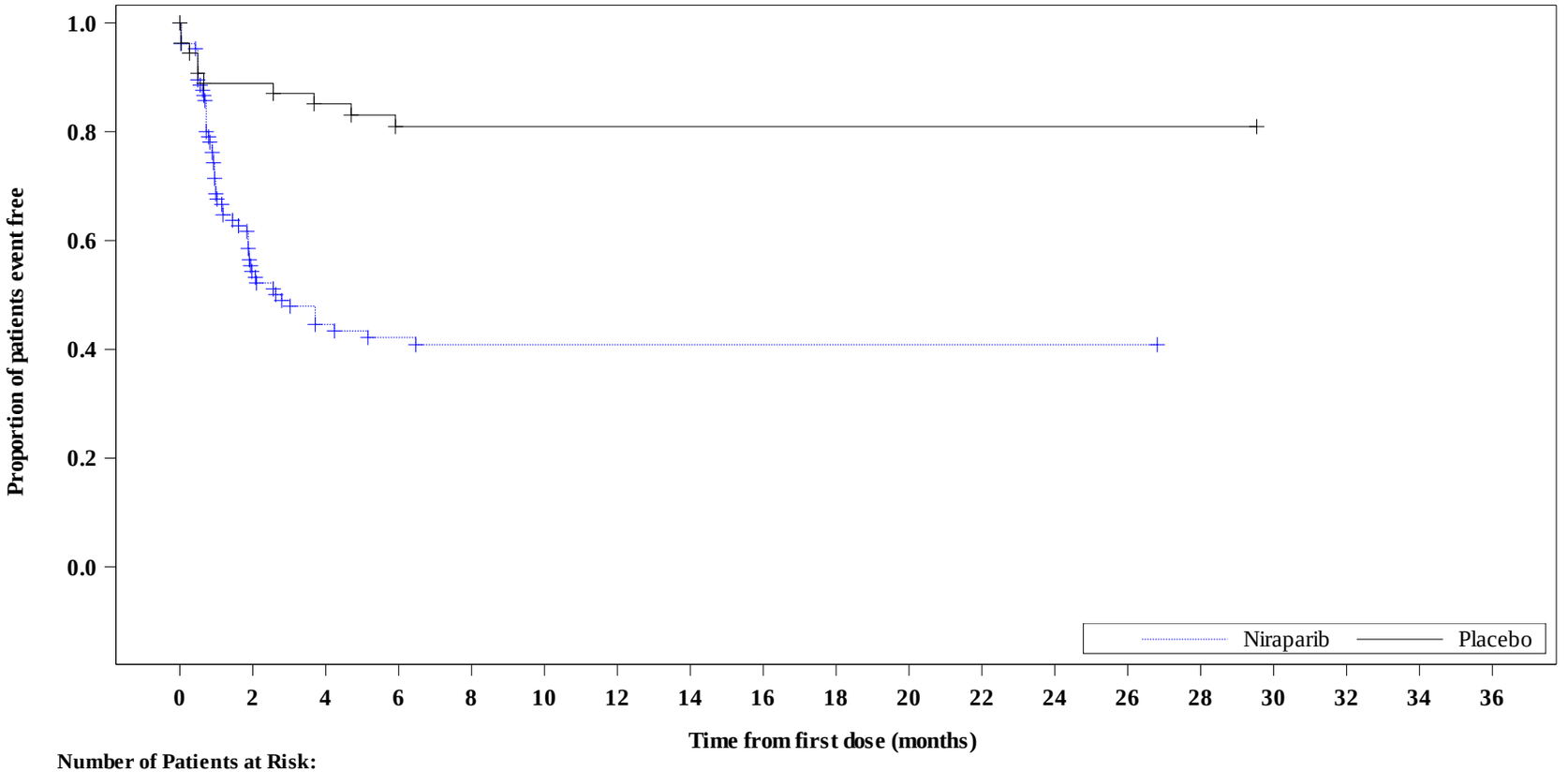
Figure 3.147b

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety-GVD Population)

Anemia

Residual Disease Status: R0




**Number of Patients at Risk:**

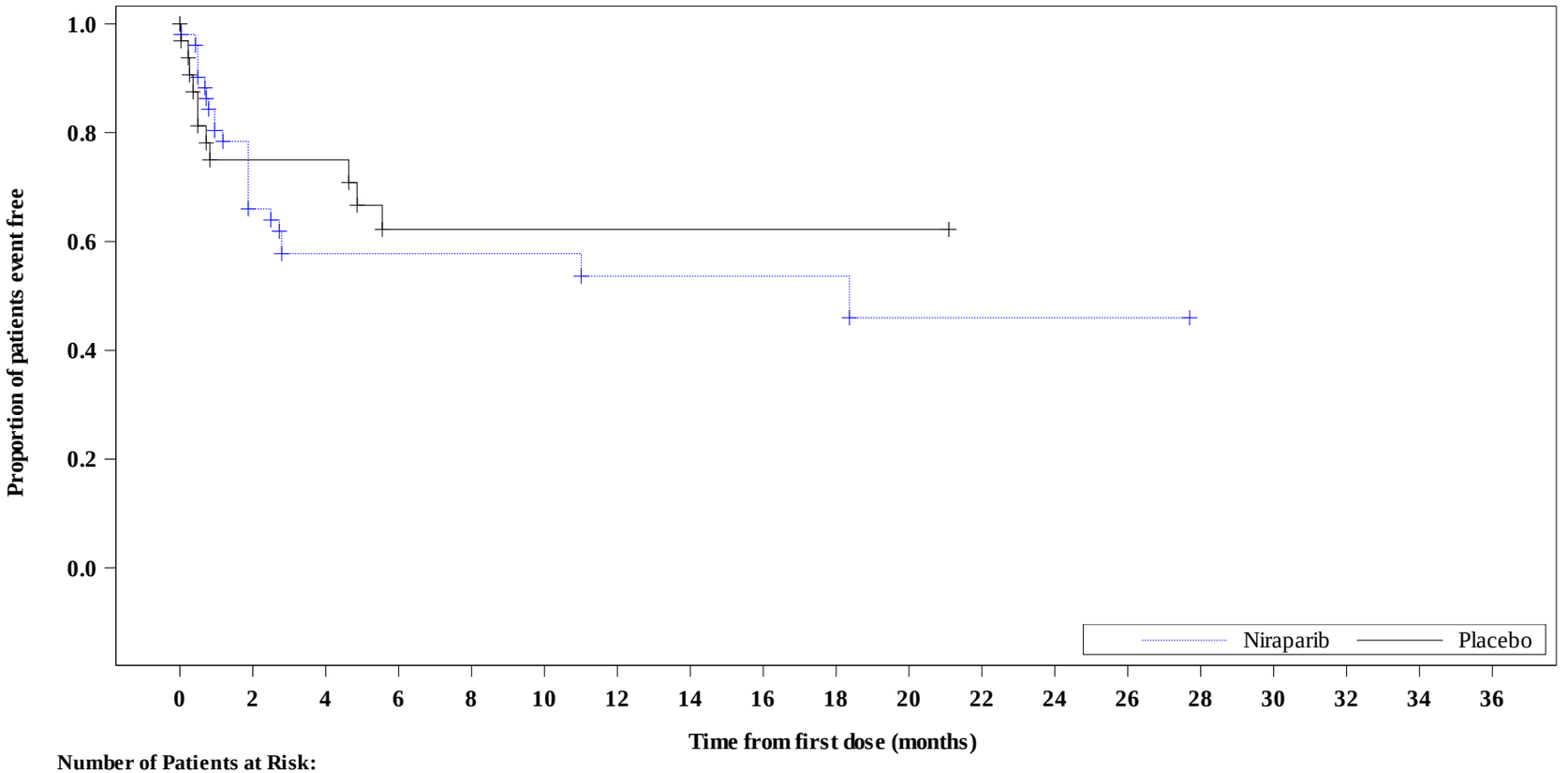
| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 105 | 51 | 38 | 33 | 24 | 20 | 20 | 18 | 14 | 11 | 9 | 2 | 1 | 1 | 0 | |
| Placebo | 54 | 48 | 43 | 38 | 32 | 28 | 25 | 21 | 18 | 15 | 10 | 5 | 3 | 2 | 1 | 0 |

Figure 3.147b

Time to Onset of First Occurrence of Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety-GVD Population)

Anemia

Residual Disease Status: R1/R2




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 51 | 32 | 23 | 21 | 18 | 15 | 11 | 10 | 8 | 7 | 4 | 2 | 2 | 1 | 0 |
| Placebo | 32 | 22 | 20 | 14 | 12 | 6 | 4 | 1 | 1 | 1 | 1 | 0 | | | |

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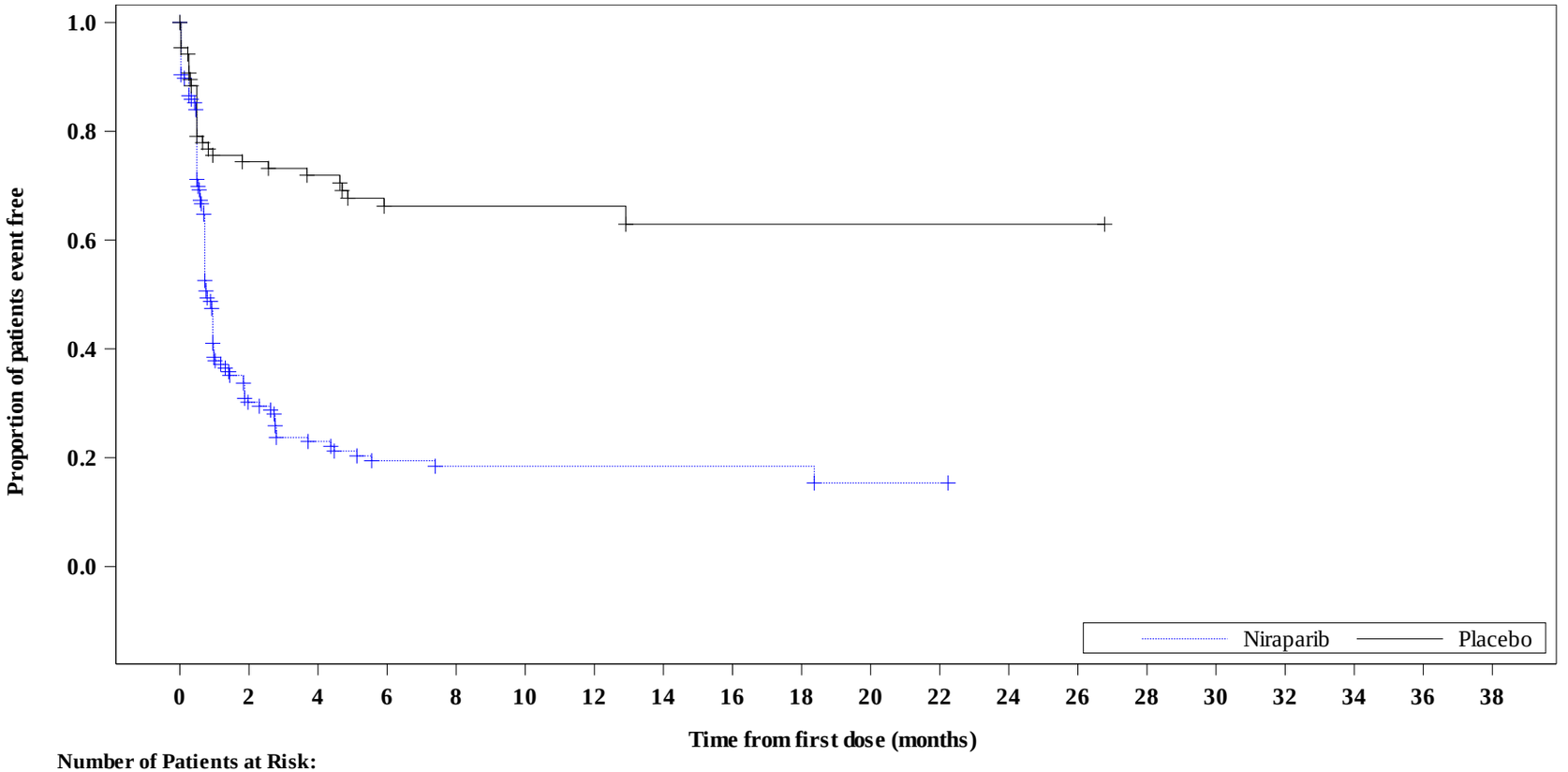
Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Overall



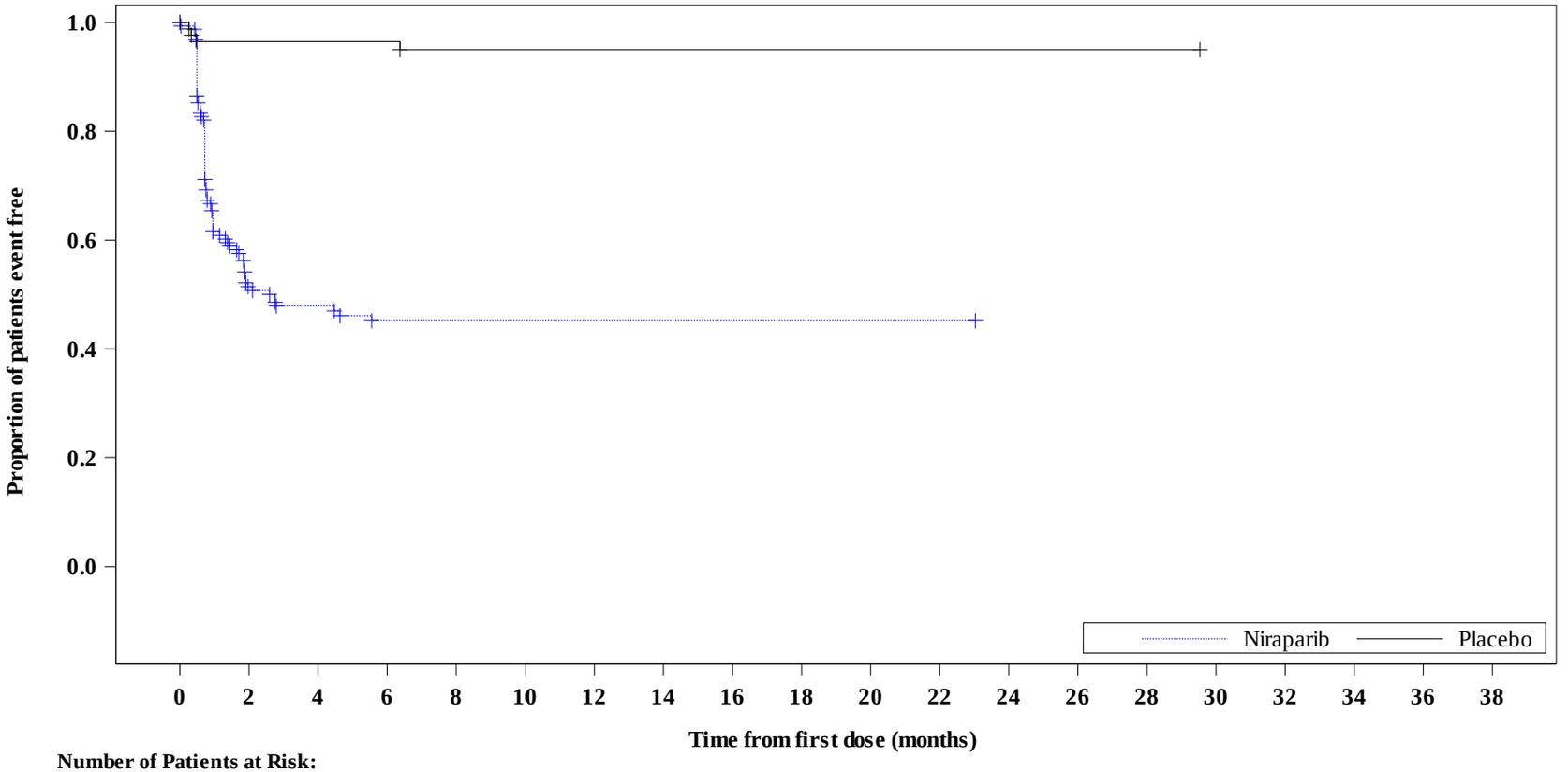

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 42 | 26 | 22 | 17 | 14 | 11 | 11 | 8 | 6 | 5 | 1 | 0 | | |
| Placebo | 86 | 62 | 55 | 45 | 38 | 29 | 24 | 16 | 15 | 13 | 8 | 4 | 2 | 1 | 0 |

Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Thrombocytopenia



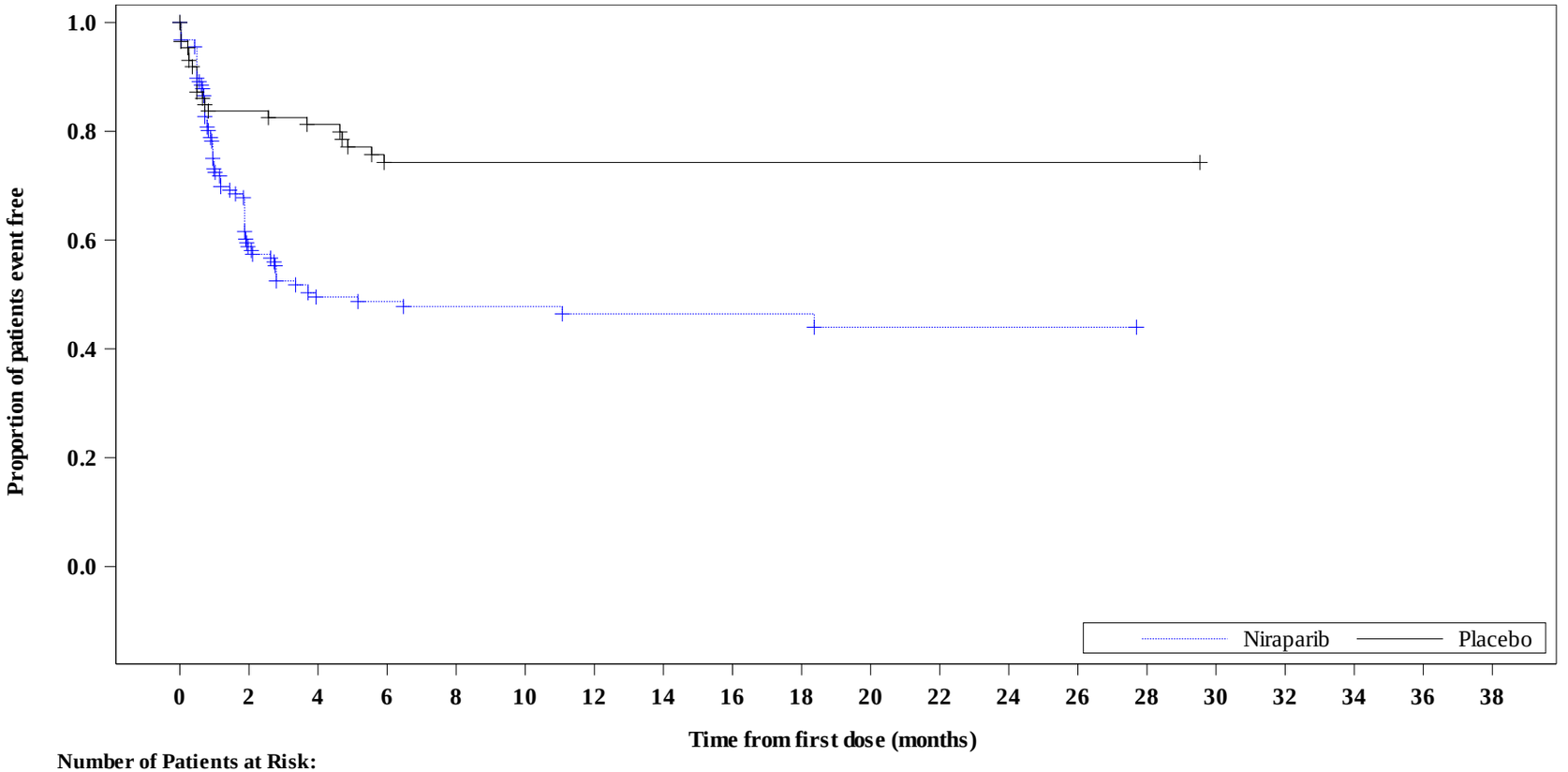

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 74 | 55 | 48 | 39 | 35 | 32 | 30 | 23 | 20 | 14 | 4 | 0 | | | |
| Placebo | 86 | 81 | 73 | 67 | 55 | 41 | 35 | 27 | 22 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Anemia



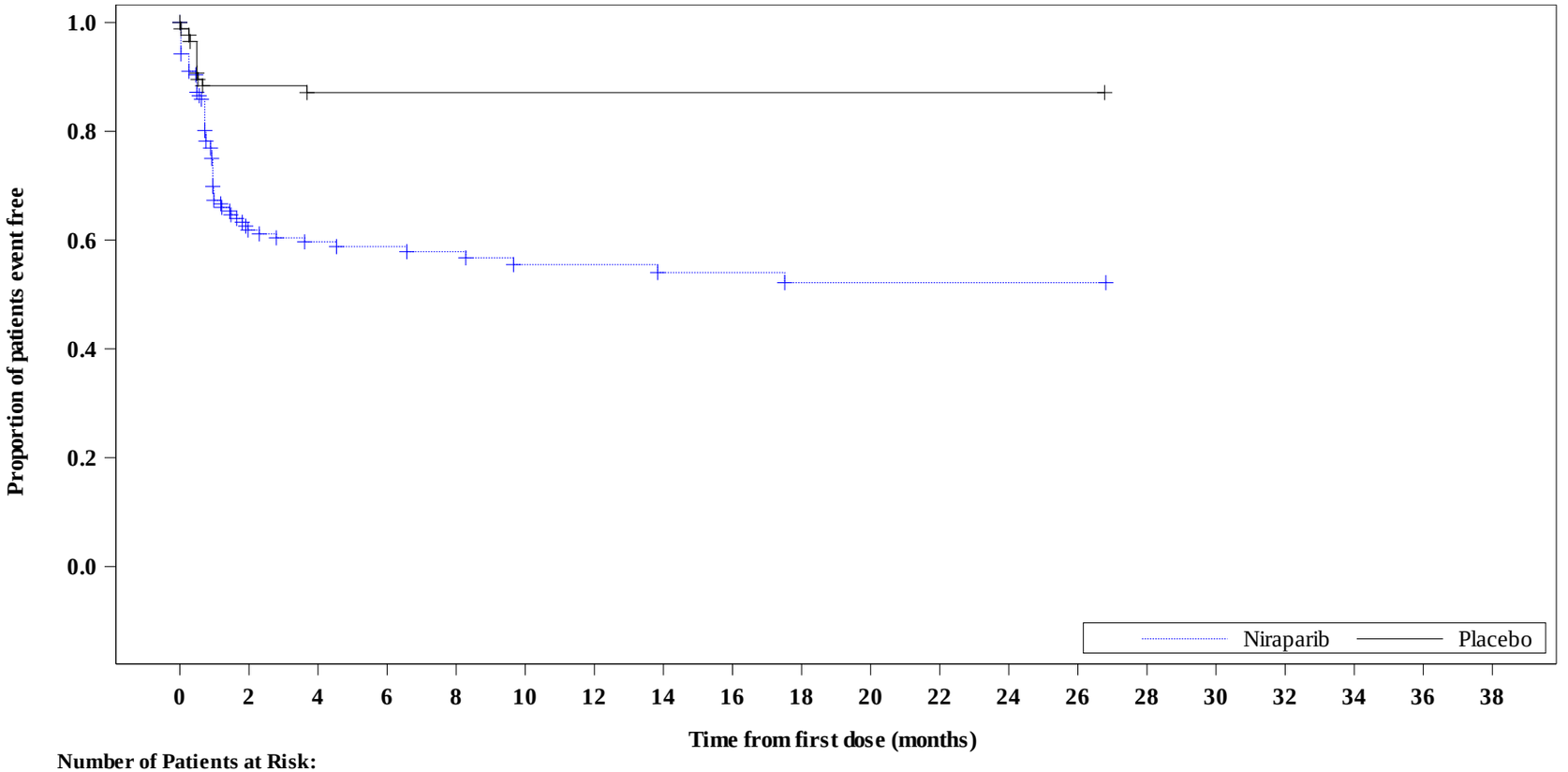

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 84 | 62 | 55 | 43 | 36 | 32 | 29 | 23 | 19 | 14 | 5 | 4 | 3 | 0 | |
| Placebo | 86 | 70 | 63 | 52 | 44 | 34 | 29 | 22 | 19 | 16 | 11 | 5 | 3 | 2 | 1 | 0 |

Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Leukopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 86 | 72 | 64 | 51 | 44 | 40 | 37 | 31 | 27 | 19 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 74 | 67 | 61 | 51 | 37 | 31 | 23 | 20 | 16 | 11 | 4 | 2 | 1 | 0 |

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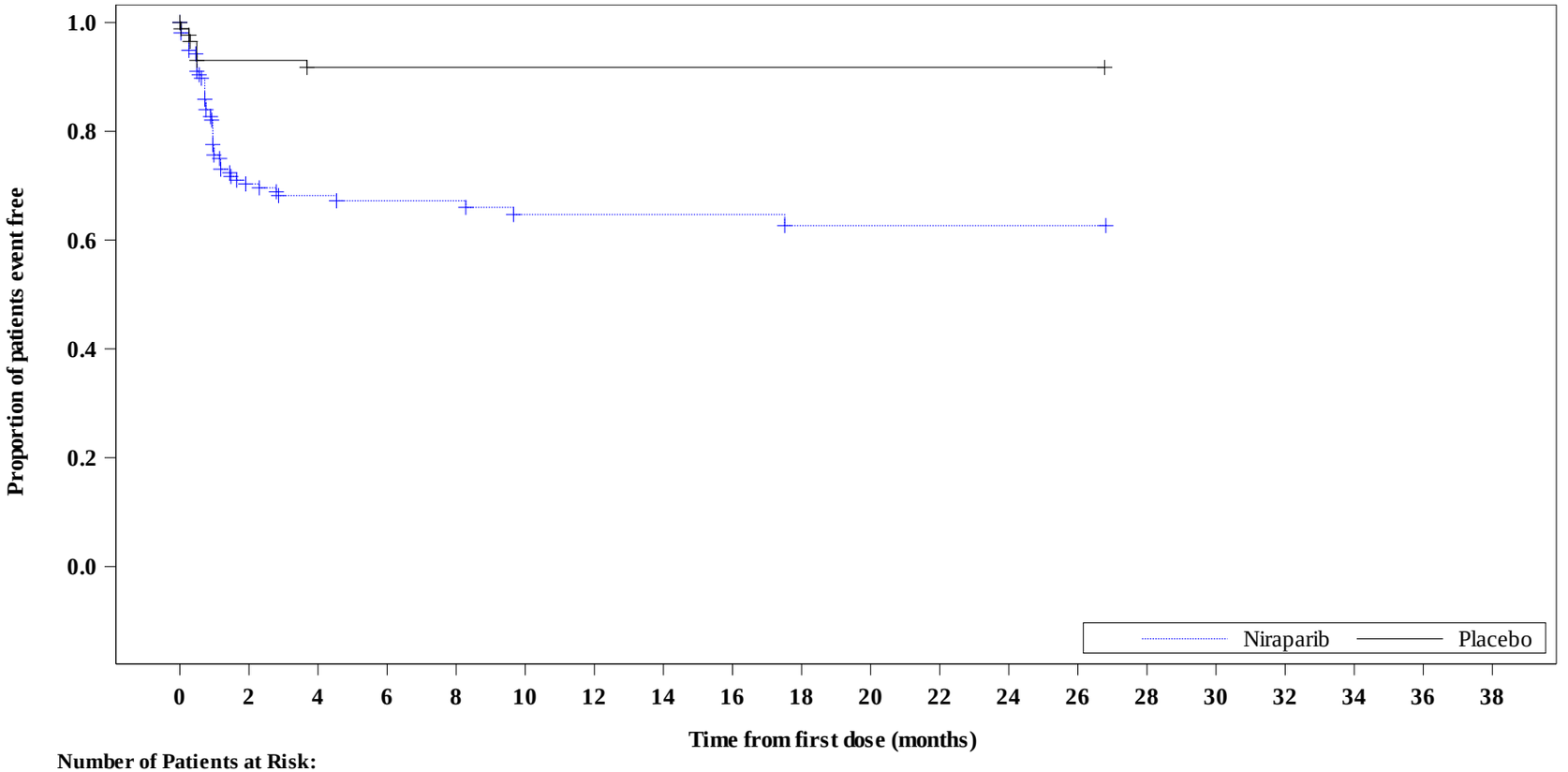
Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Neutropenia




**Number of Patients at Risk:**

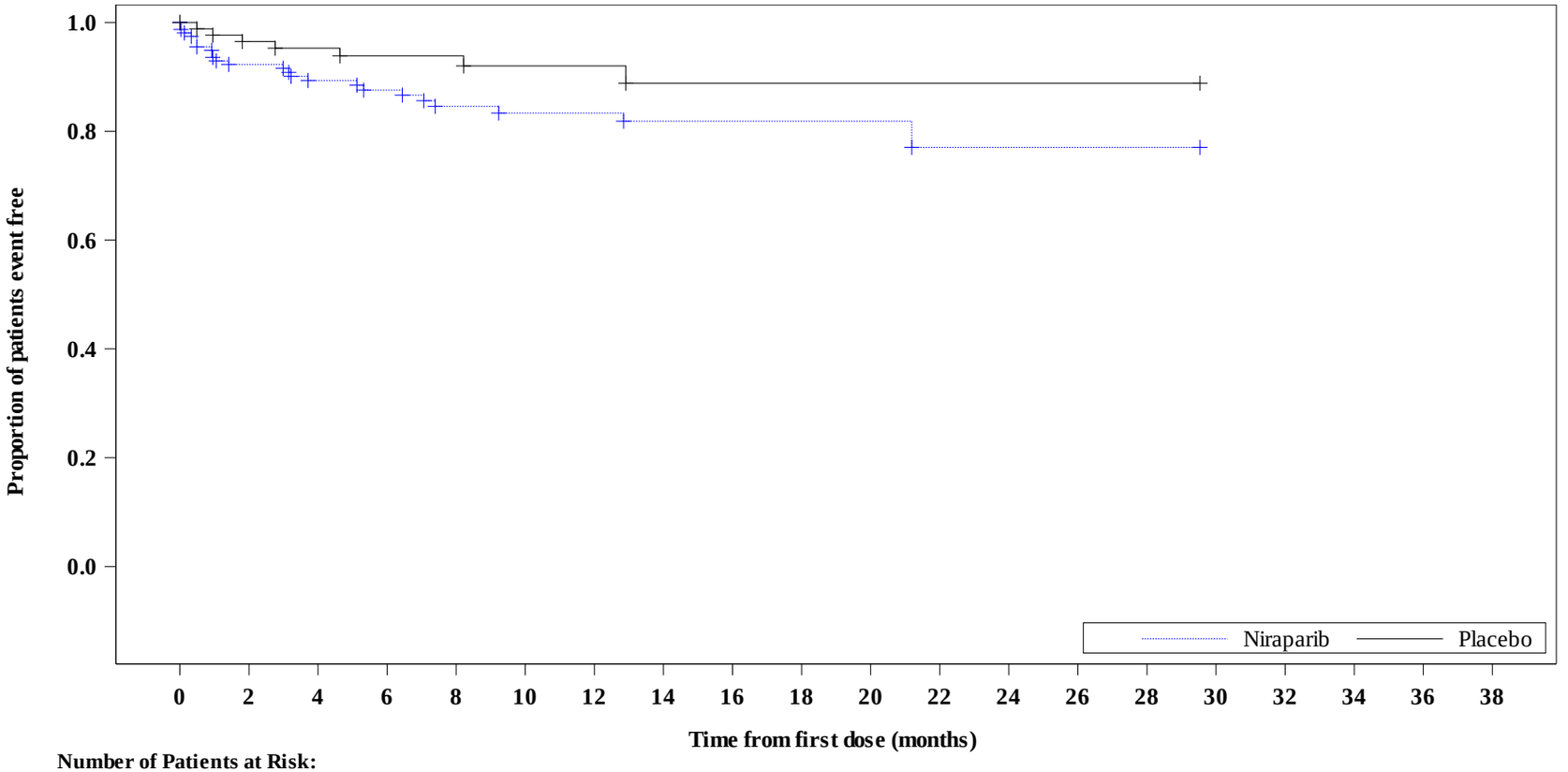
| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 99 | 78 | 69 | 55 | 48 | 44 | 42 | 34 | 30 | 21 | 10 | 5 | 2 | 0 |
| Placebo | 86 | 78 | 69 | 63 | 52 | 38 | 32 | 24 | 21 | 17 | 12 | 4 | 2 | 1 | 0 |

jg247770: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-148a-tteaesi-rdg.sas 06OCT2020
11:58

Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Hypertension



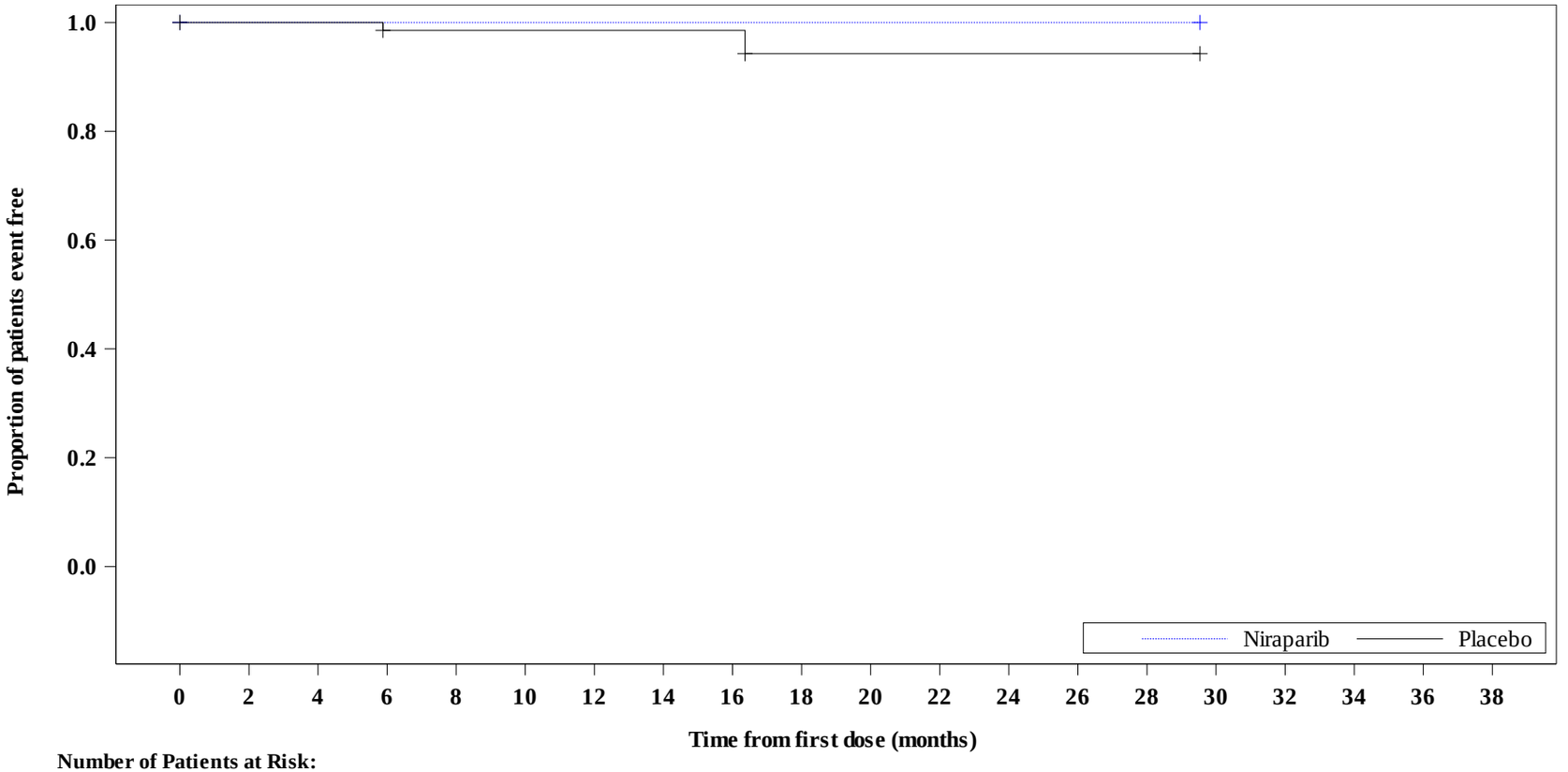

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 132 | 104 | 96 | 74 | 65 | 61 | 54 | 44 | 38 | 22 | 10 | 6 | 4 | 2 | 0 |
| Placebo | 86 | 81 | 71 | 64 | 53 | 39 | 33 | 25 | 22 | 18 | 13 | 5 | 3 | 2 | 1 | 0 |

Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

New malignancies other than MDS/AML




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 68 | 55 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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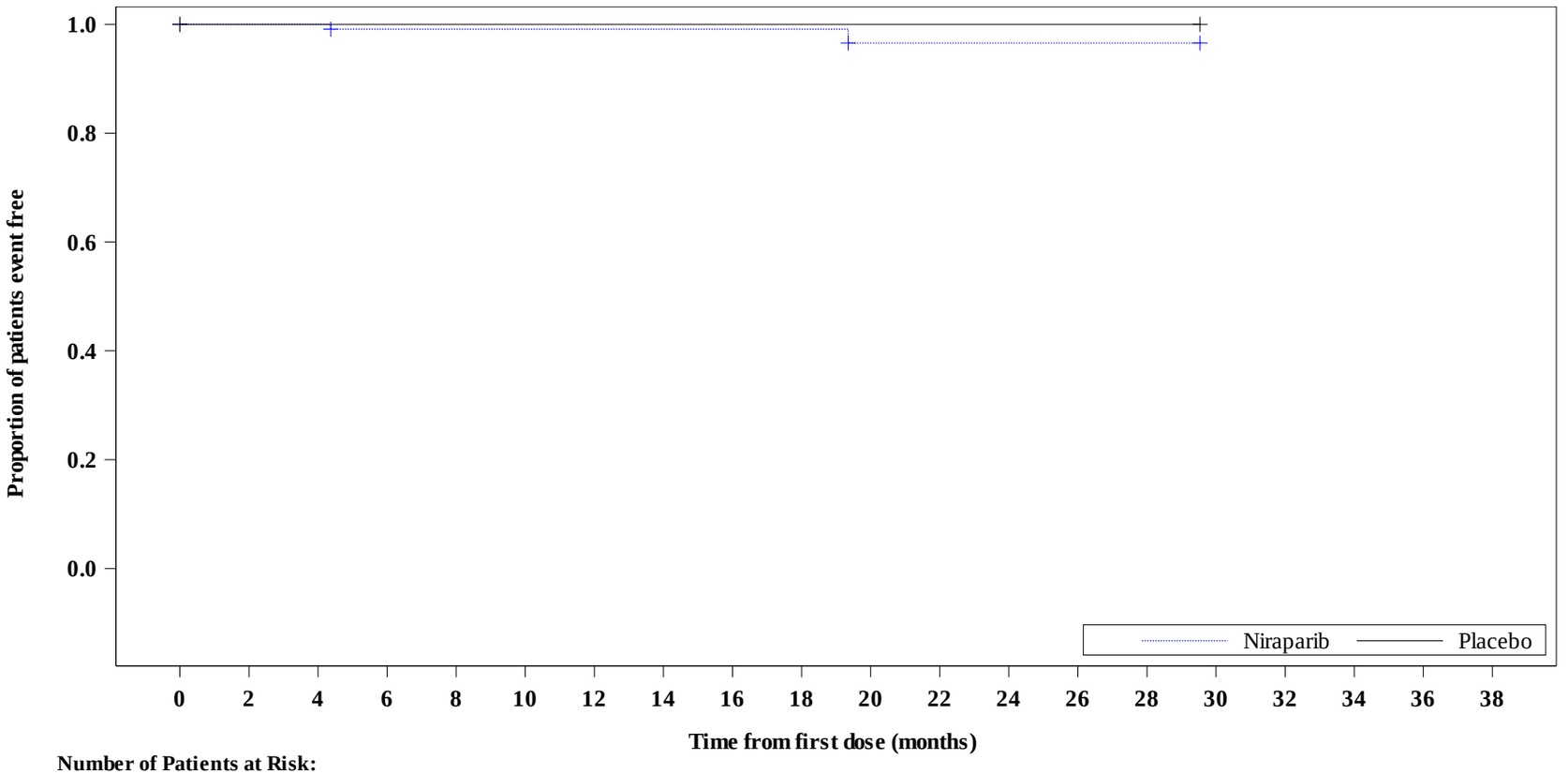
Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Pneumonitis




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 106 | 87 | 78 | 74 | 67 | 55 | 49 | 29 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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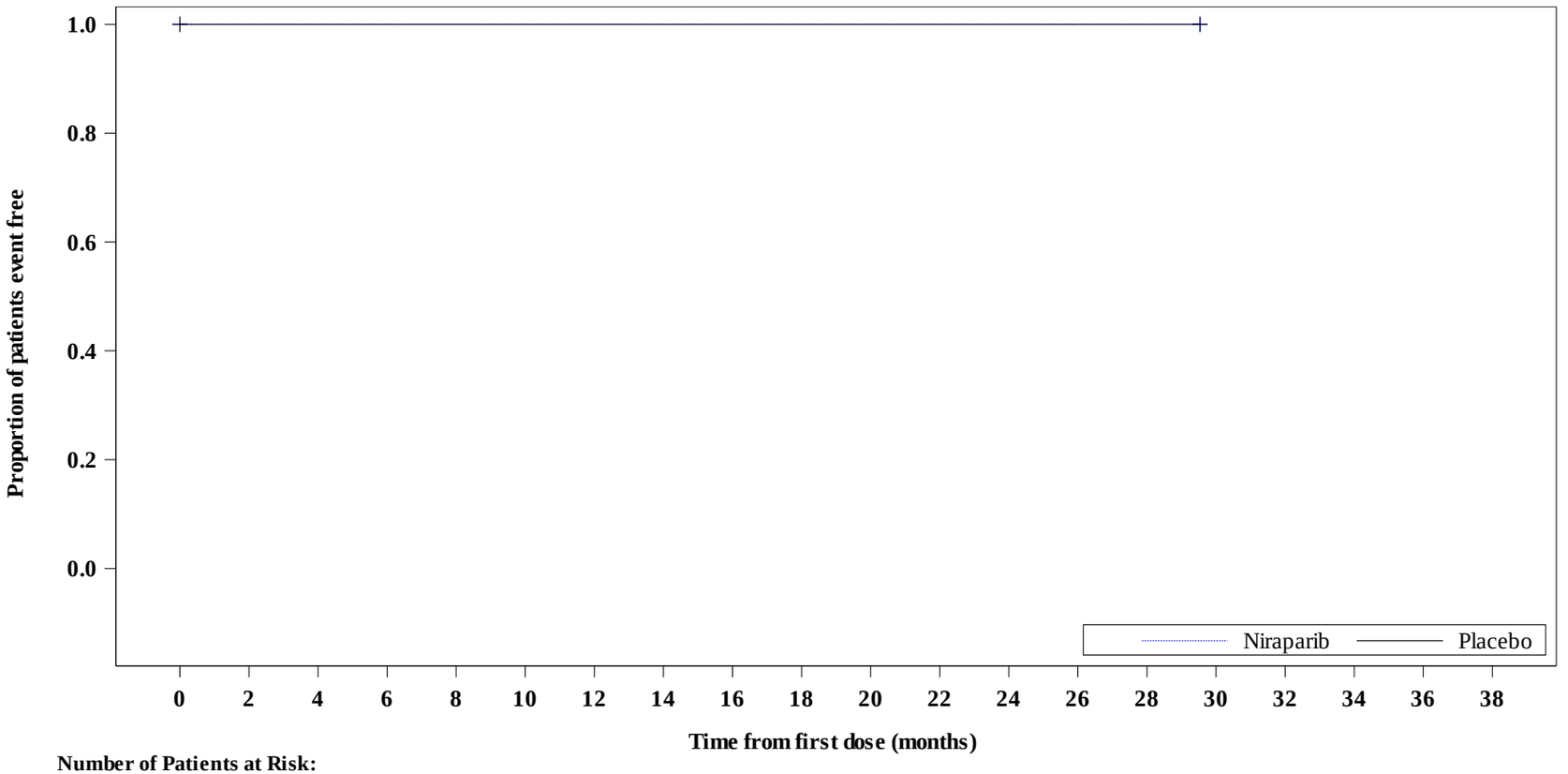
Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Pancytopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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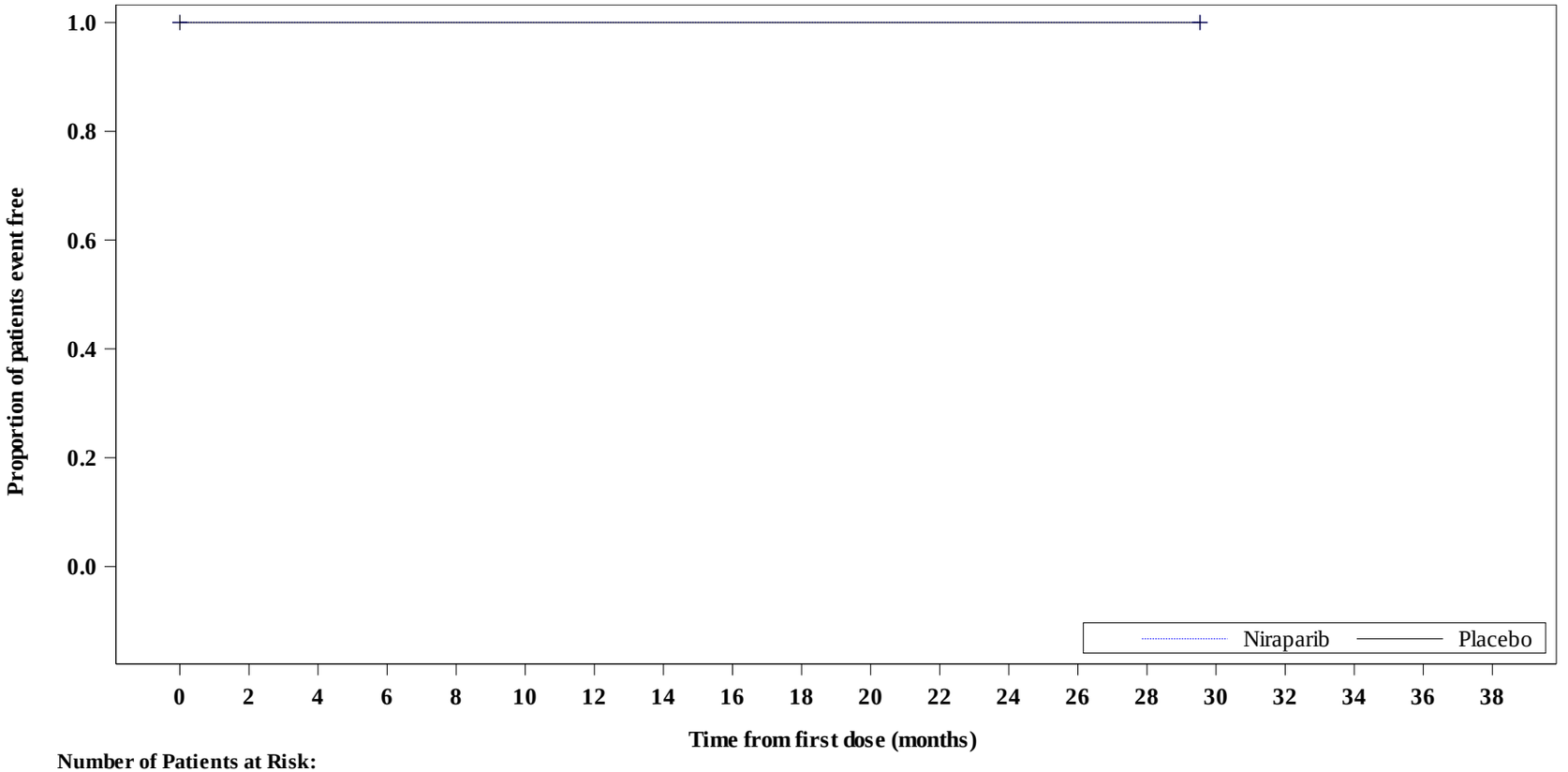
Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Thromboemblic



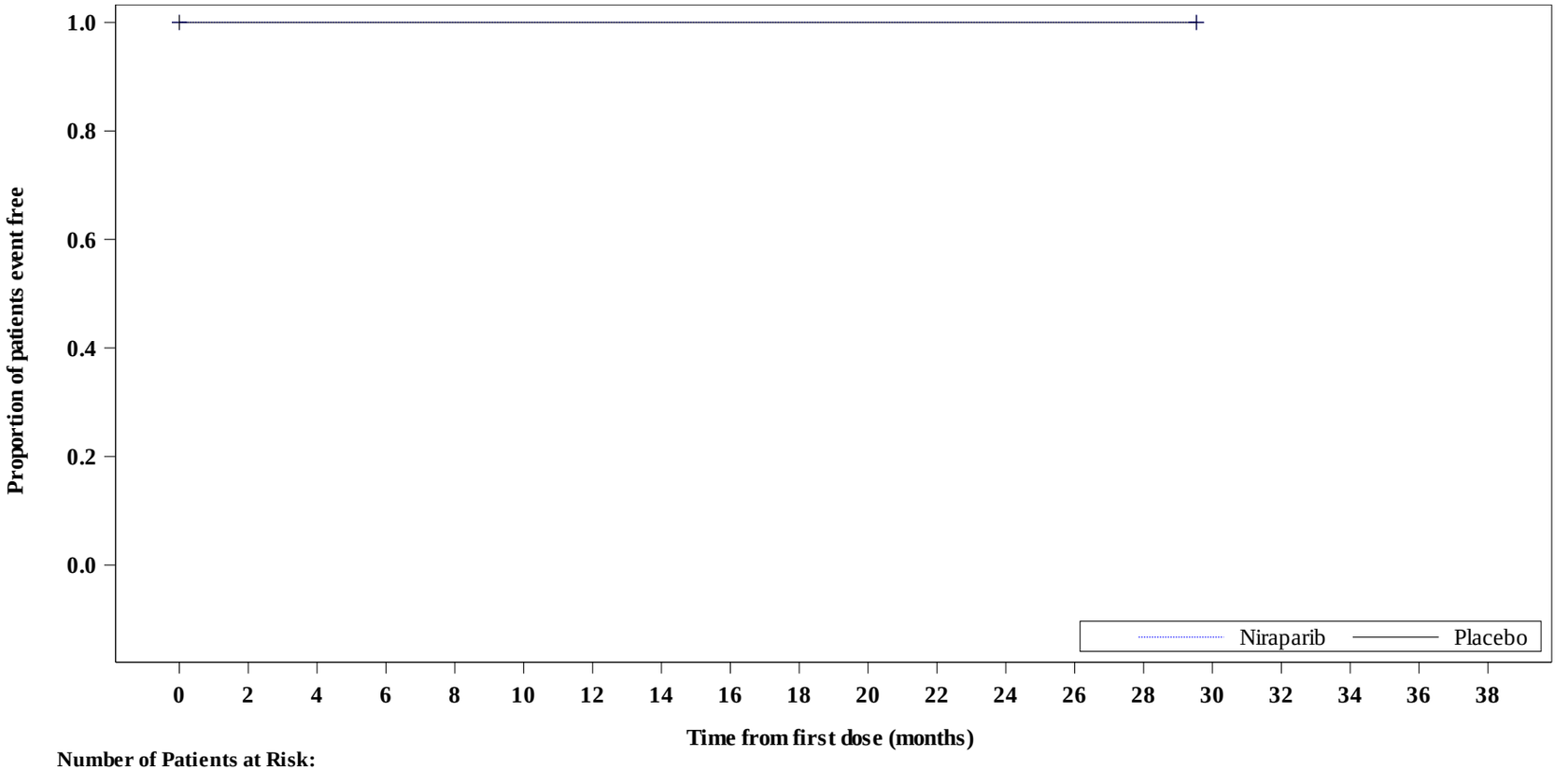

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

MDS/AML



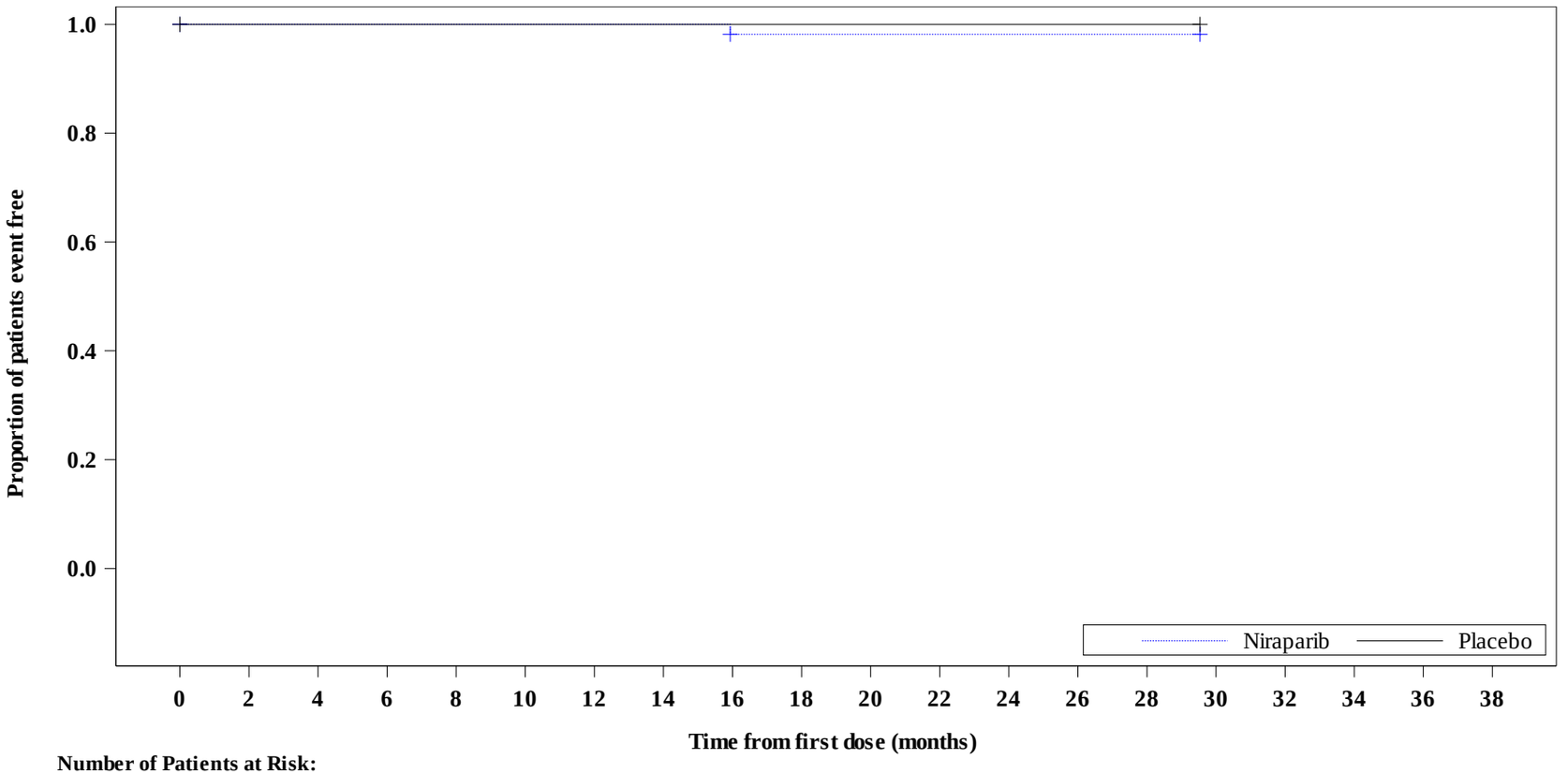

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.148a

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Embryo-fetal toxicity




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 54 | 48 | 29 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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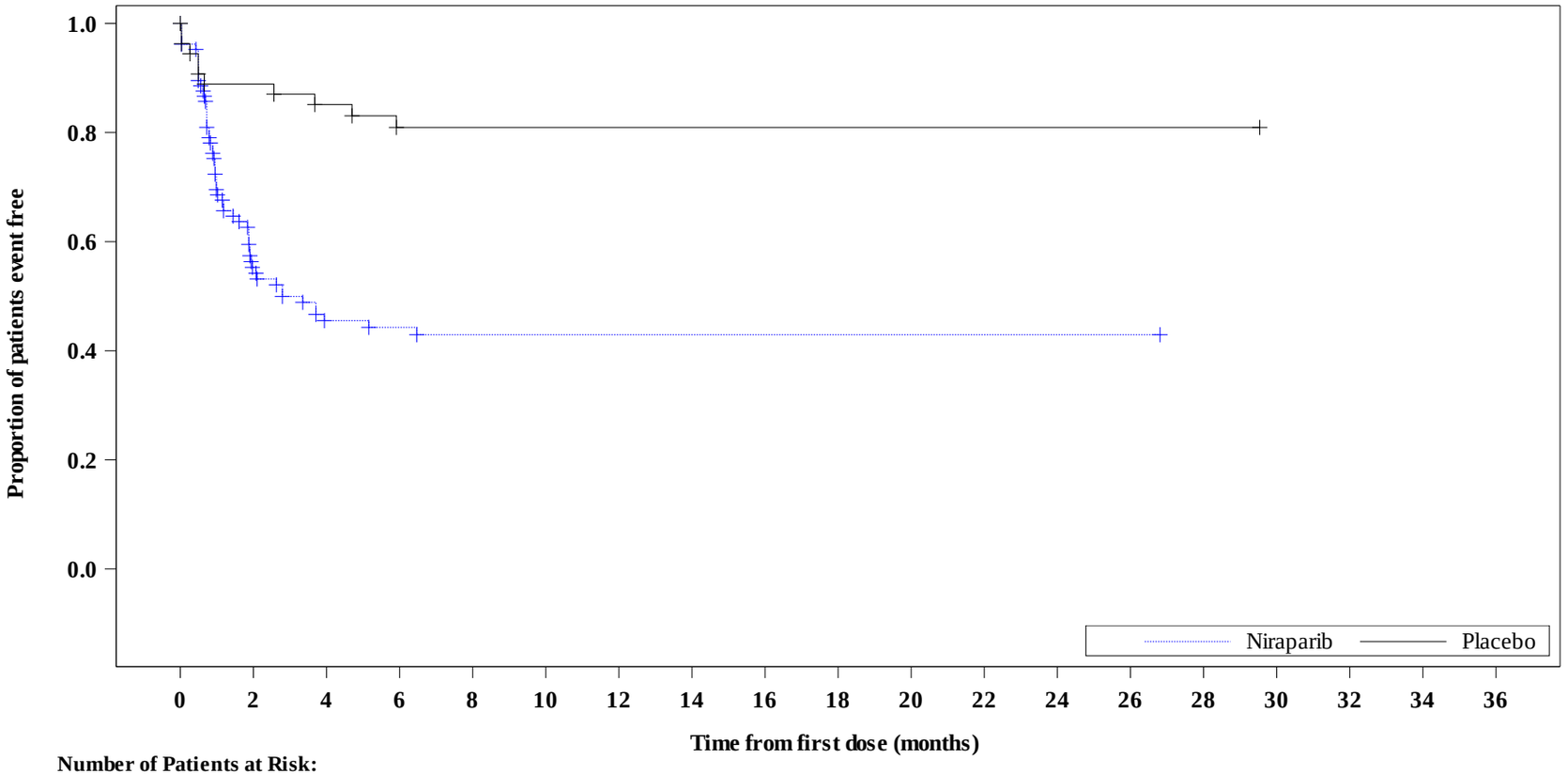
Figure 3.148b

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety-GVD Population)

Anemia

Residual Disease Status: R0




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 105 | 52 | 39 | 34 | 25 | 21 | 21 | 19 | 15 | 12 | 10 | 3 | 2 | 2 | 0 | |
| Placebo | 54 | 48 | 43 | 38 | 32 | 28 | 25 | 21 | 18 | 15 | 10 | 5 | 3 | 2 | 1 | 0 |

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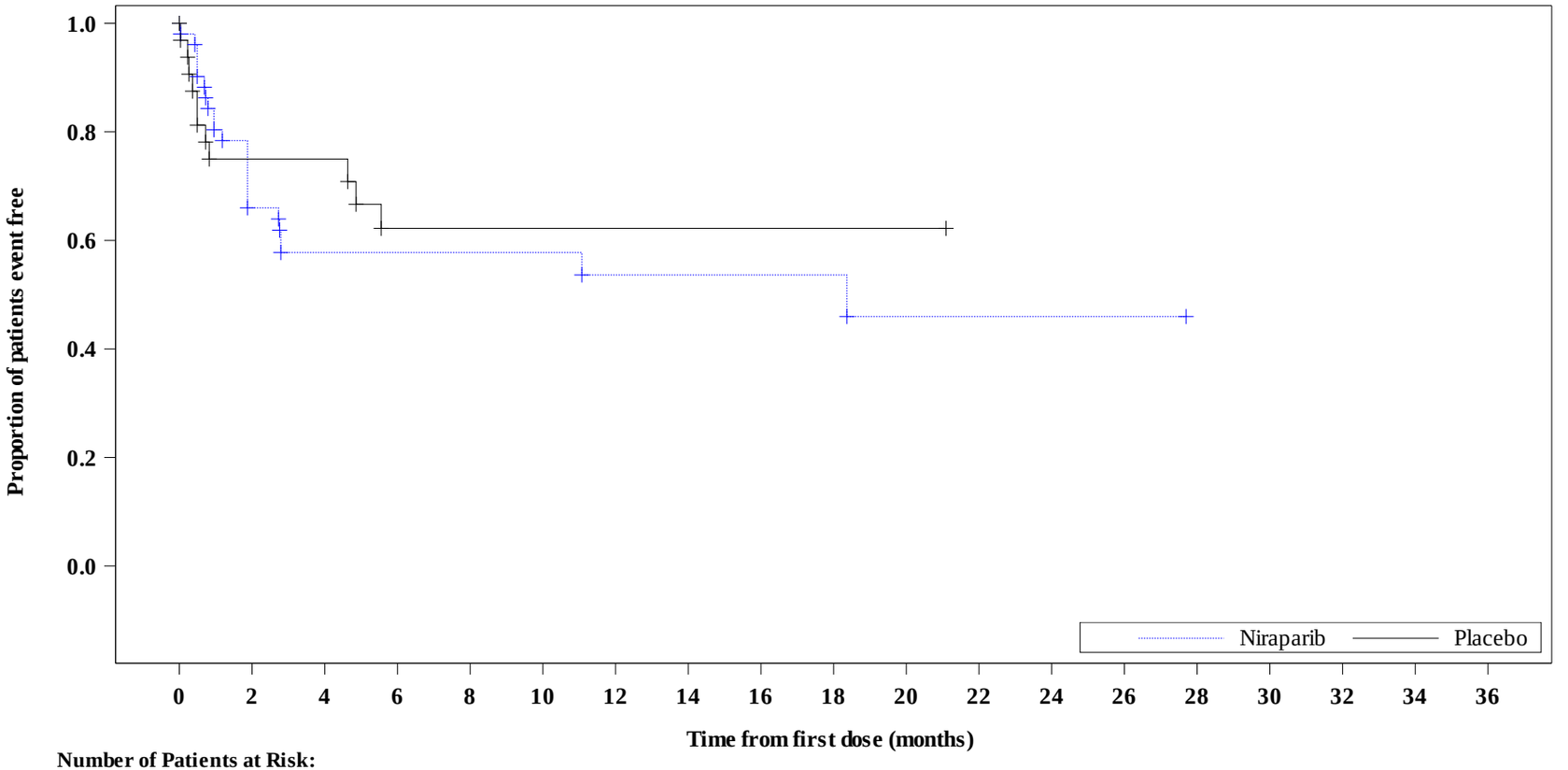
Figure 3.148b

Time to Onset of First Occurrence of CTCAE grade 1, 2 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events by Residual Disease Status (Residual Disease Safety-GVD Population)

Anemia

Residual Disease Status: R1/R2




**Number of Patients at Risk:**

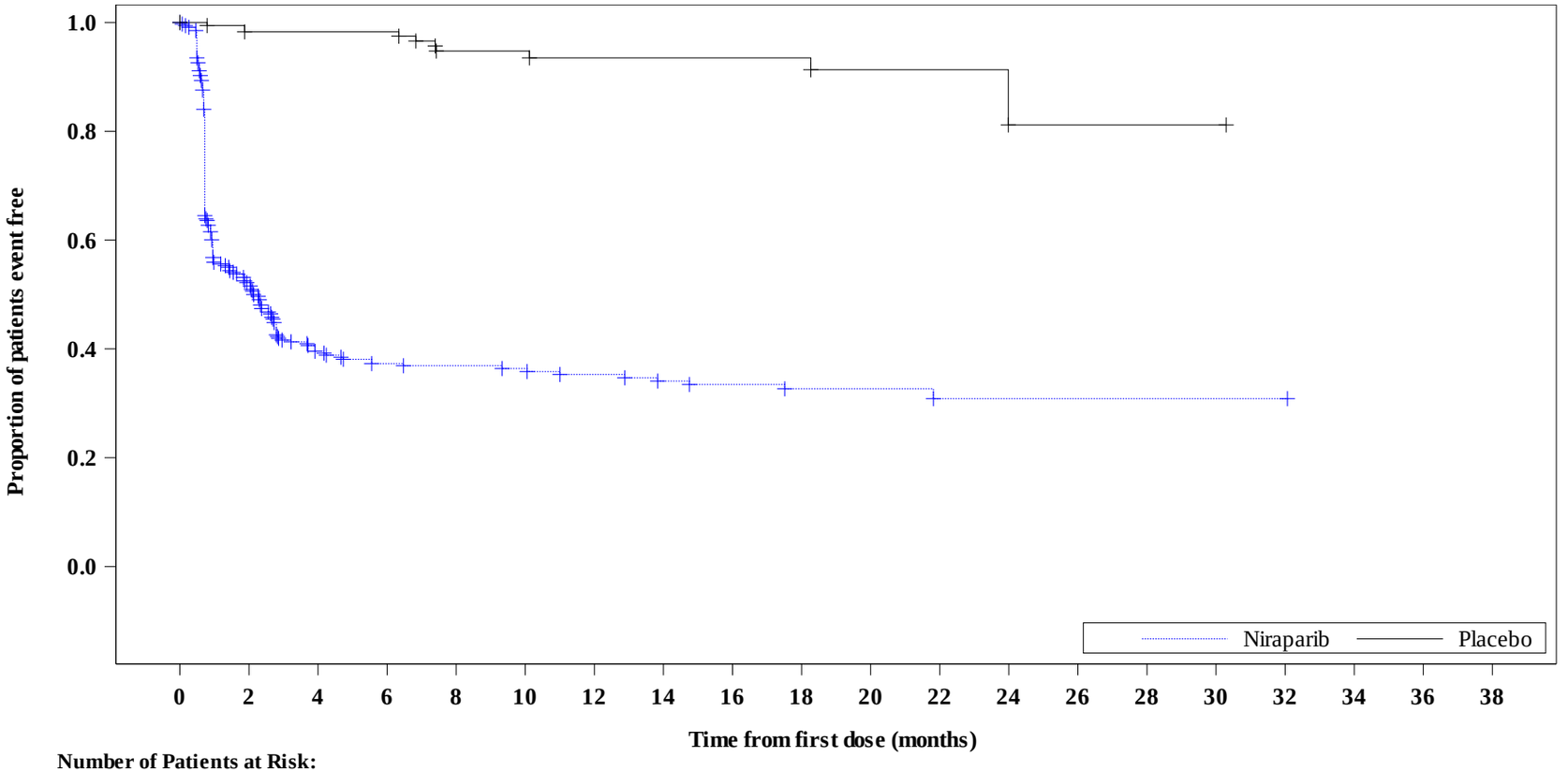
| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 51 | 32 | 23 | 21 | 18 | 15 | 11 | 10 | 8 | 7 | 4 | 2 | 2 | 1 | 0 |
| Placebo | 32 | 22 | 20 | 14 | 12 | 6 | 4 | 1 | 1 | 1 | 1 | 0 | | | |

jg247770: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-148b-tteaesi-rdg.sas 07OCT2020 05:09

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Overall



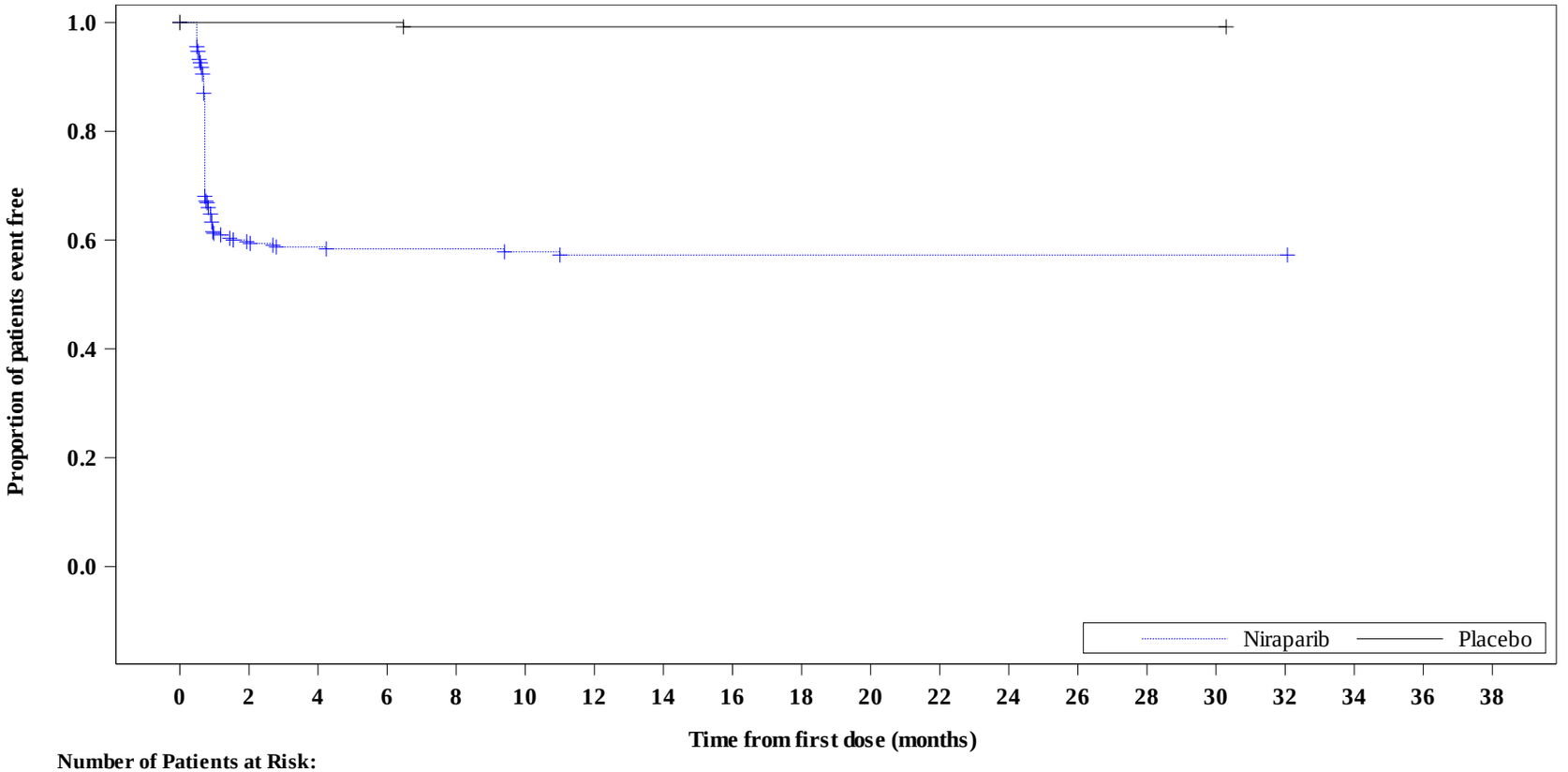

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 165 | 110 | 93 | 79 | 67 | 61 | 56 | 44 | 38 | 27 | 17 | 12 | 7 | 3 | 1 | 1 | 0 |
| Placebo | 175 | 169 | 143 | 127 | 99 | 75 | 66 | 58 | 50 | 43 | 36 | 20 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Thrombocytopenia



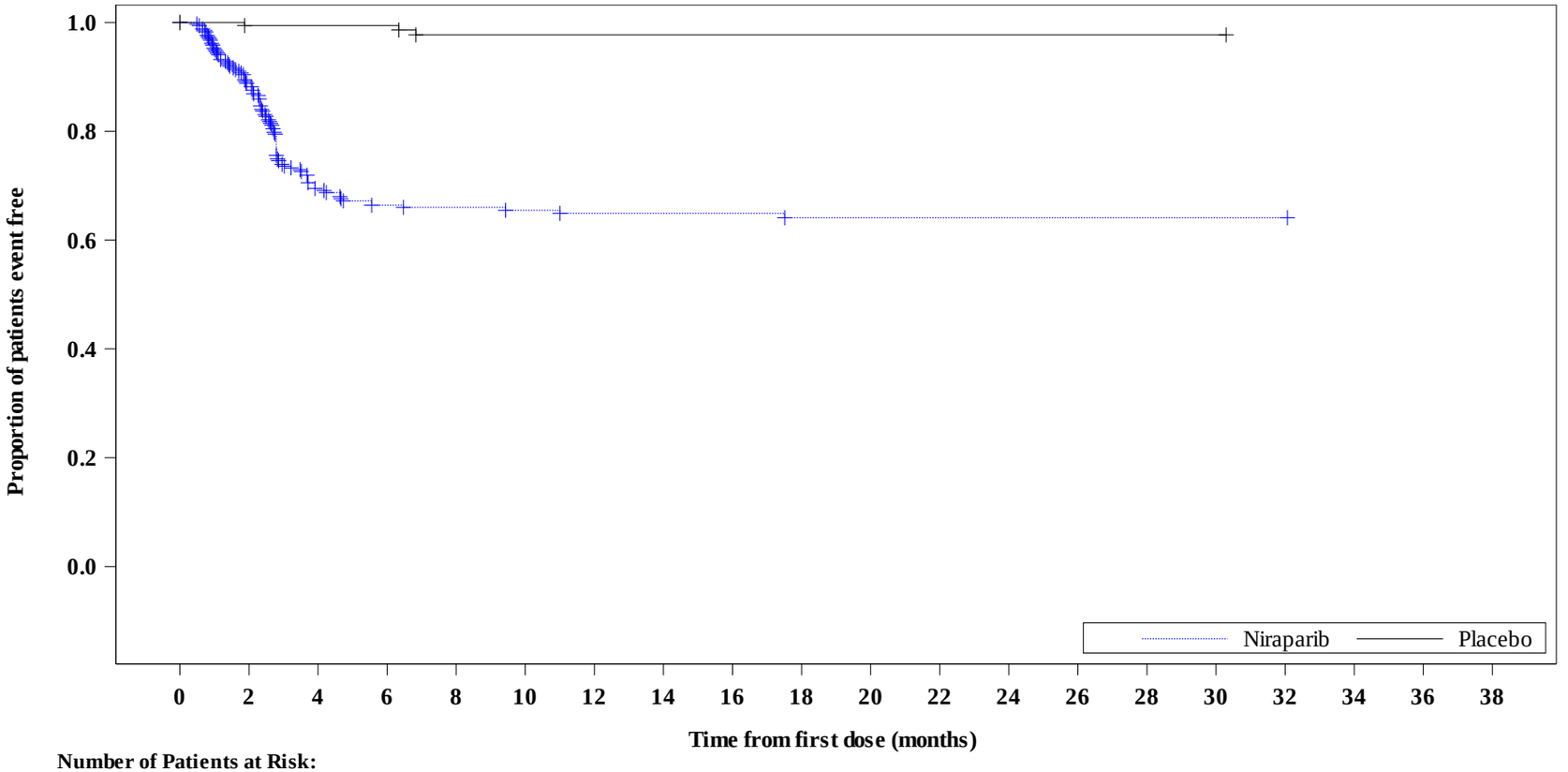

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 189 | 161 | 146 | 119 | 102 | 96 | 88 | 74 | 67 | 46 | 31 | 21 | 10 | 5 | 1 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Anemia



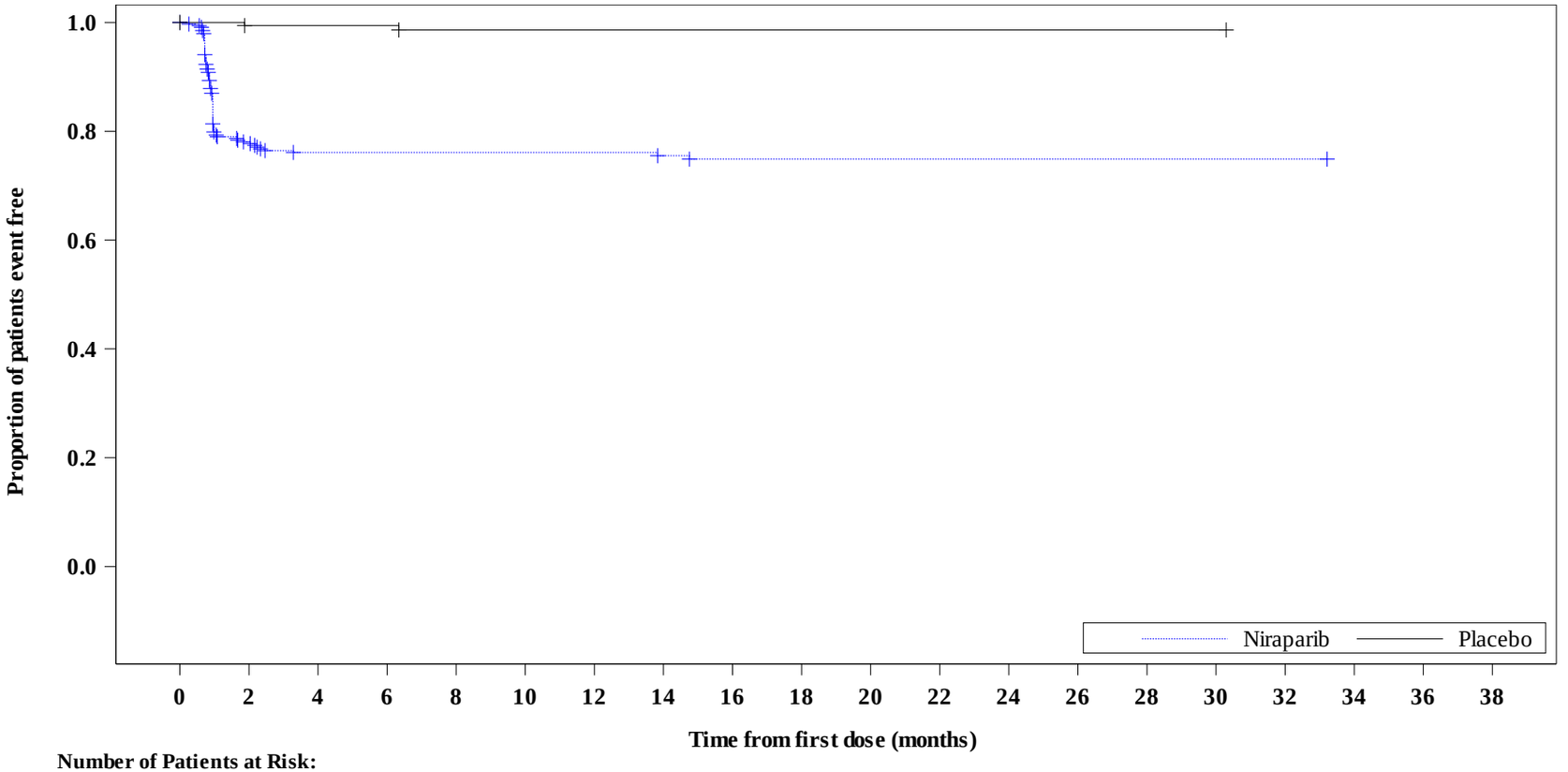

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 278 | 192 | 165 | 137 | 118 | 111 | 102 | 85 | 76 | 57 | 38 | 25 | 14 | 7 | 2 | 1 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 77 | 69 | 58 | 49 | 42 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Leukopenia



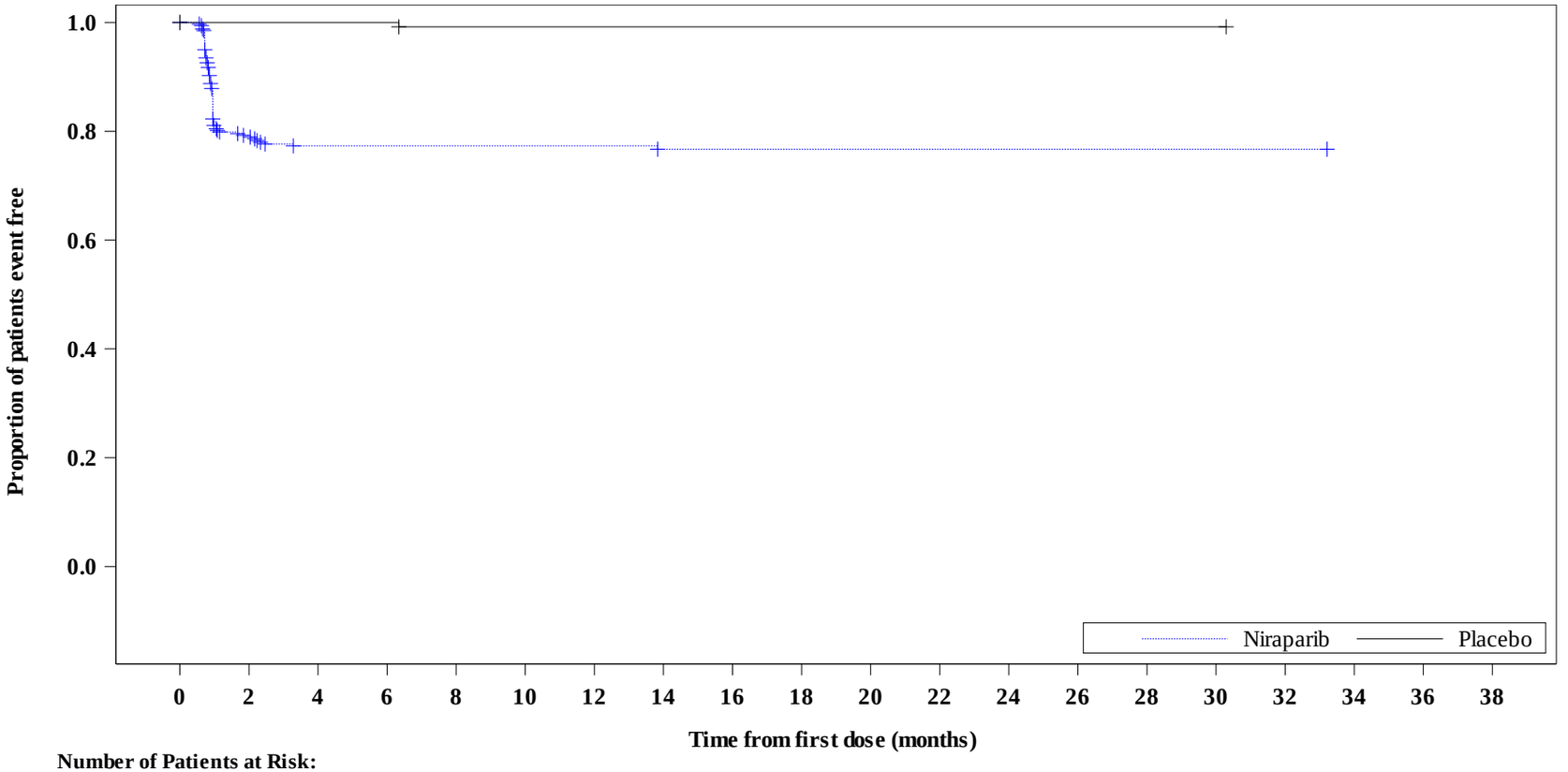

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 245 | 206 | 185 | 157 | 138 | 132 | 124 | 101 | 93 | 67 | 49 | 31 | 16 | 8 | 2 | 2 | 0 |
| Placebo | 175 | 171 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Neutropenia



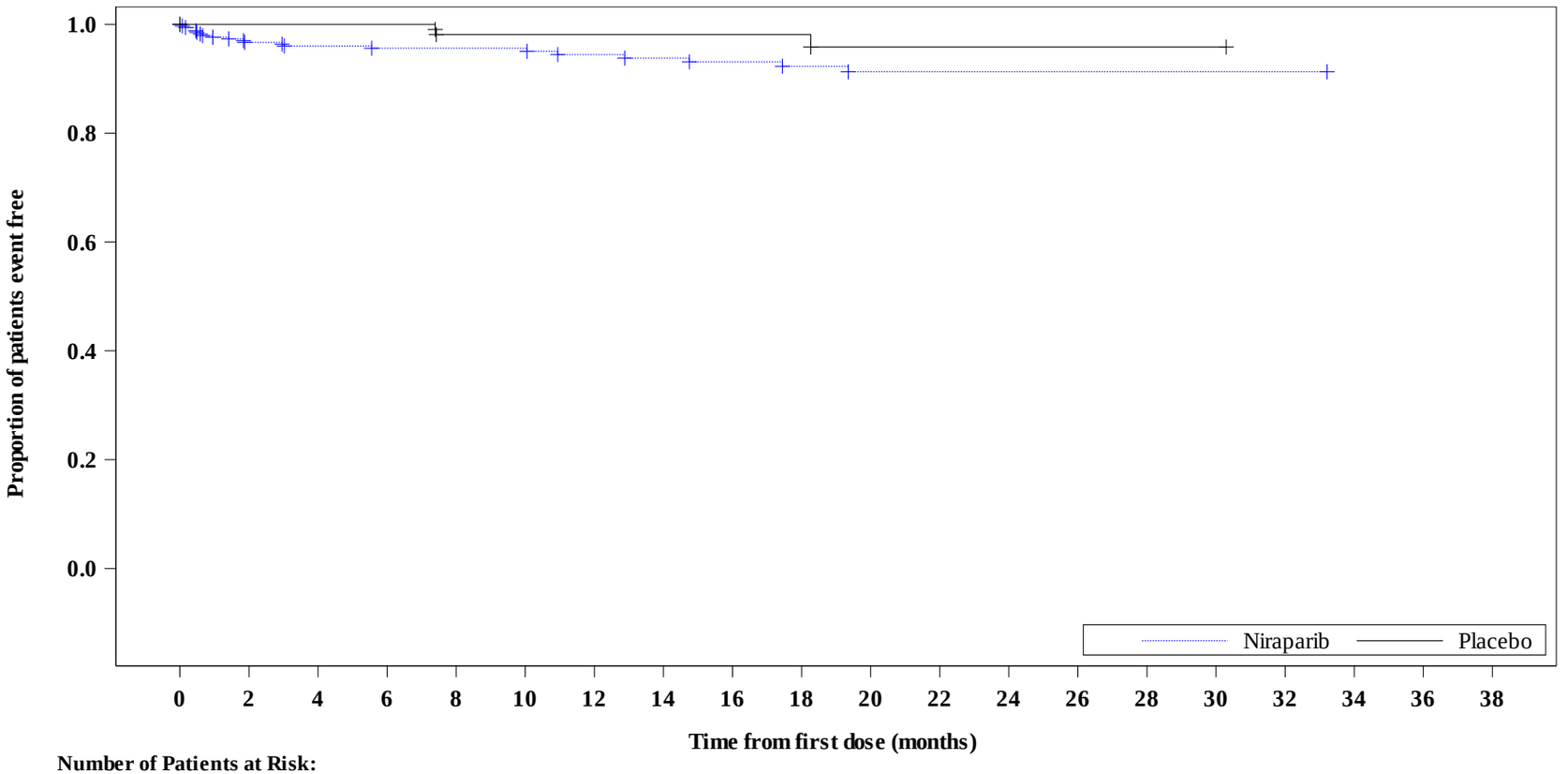

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 249 | 208 | 187 | 159 | 140 | 134 | 126 | 104 | 96 | 70 | 51 | 33 | 17 | 8 | 2 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Hypertension



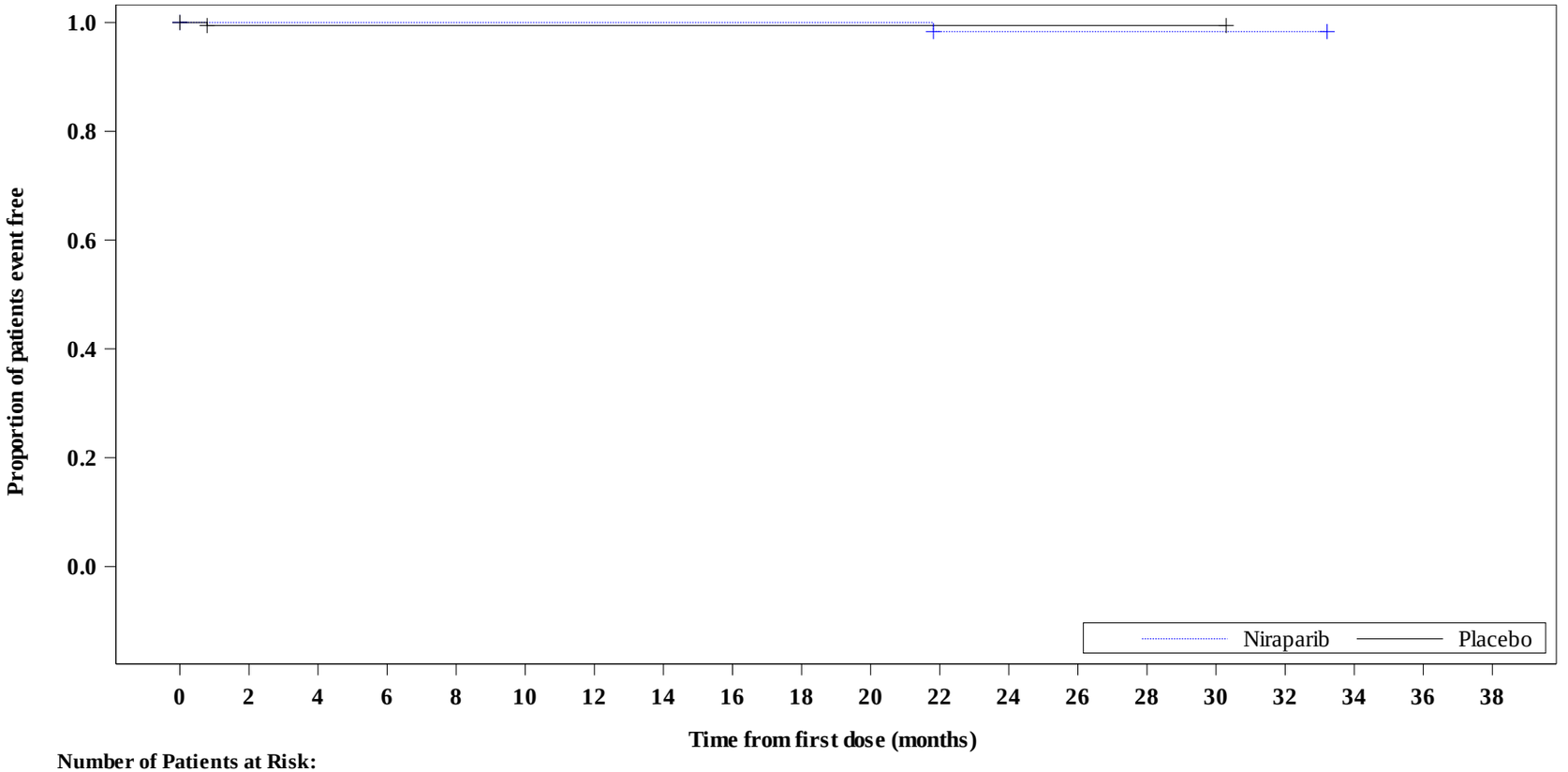

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 300 | 254 | 228 | 189 | 166 | 156 | 142 | 118 | 107 | 78 | 56 | 38 | 18 | 9 | 2 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 100 | 76 | 68 | 59 | 50 | 43 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

New malignancies other than MDS/AML



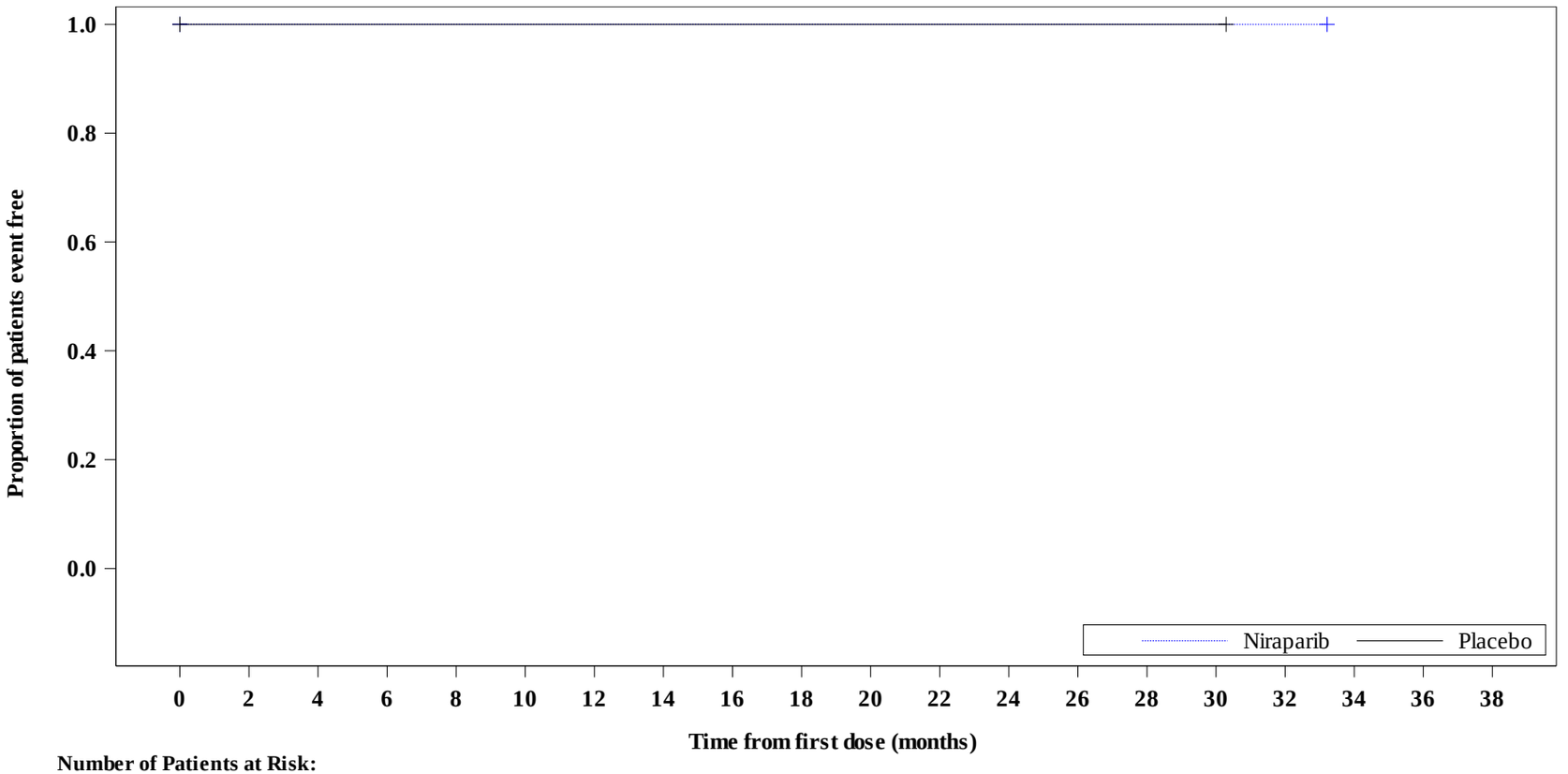

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 77 | 69 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Pneumonitis



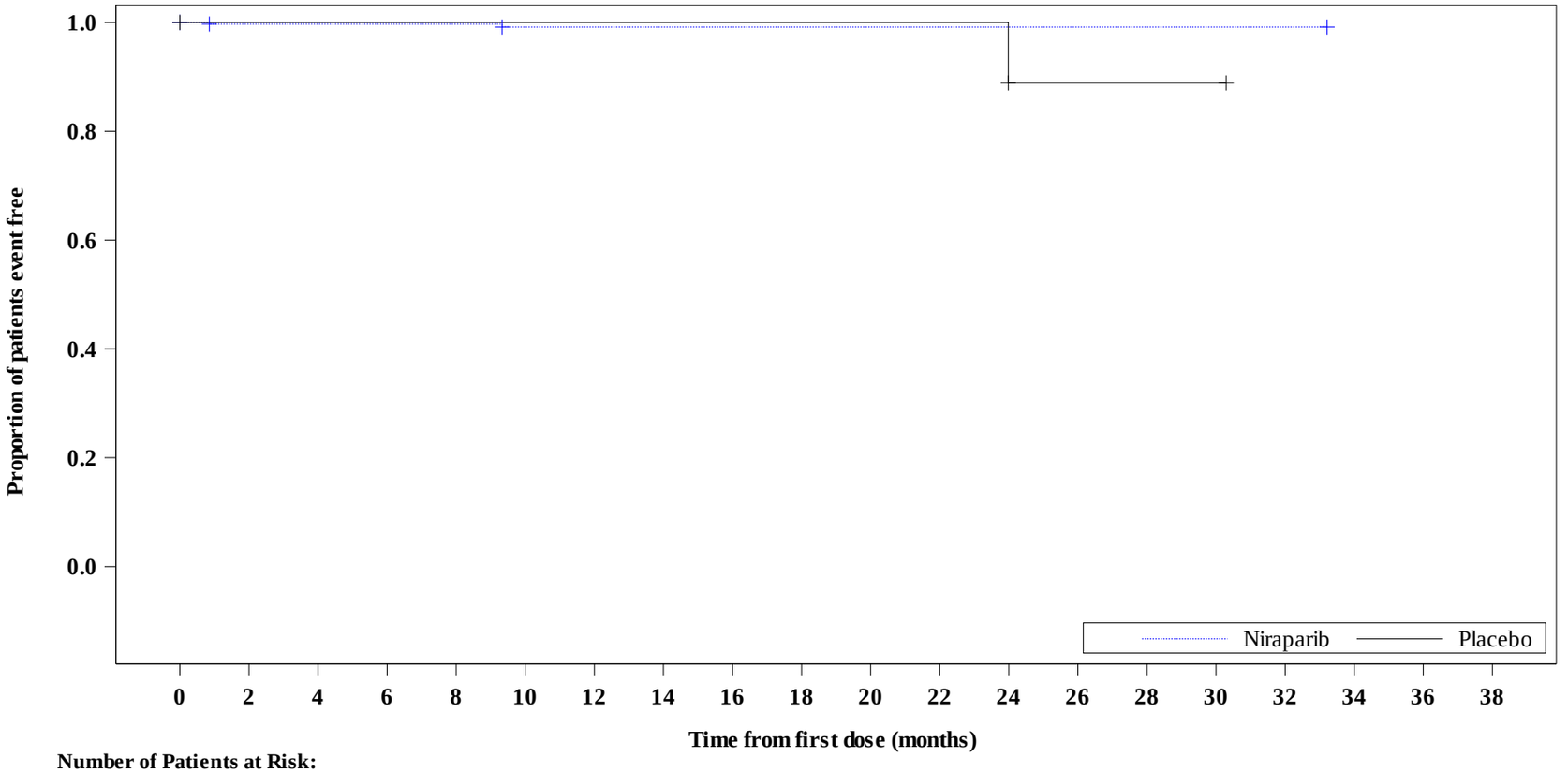

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Pancytopenia



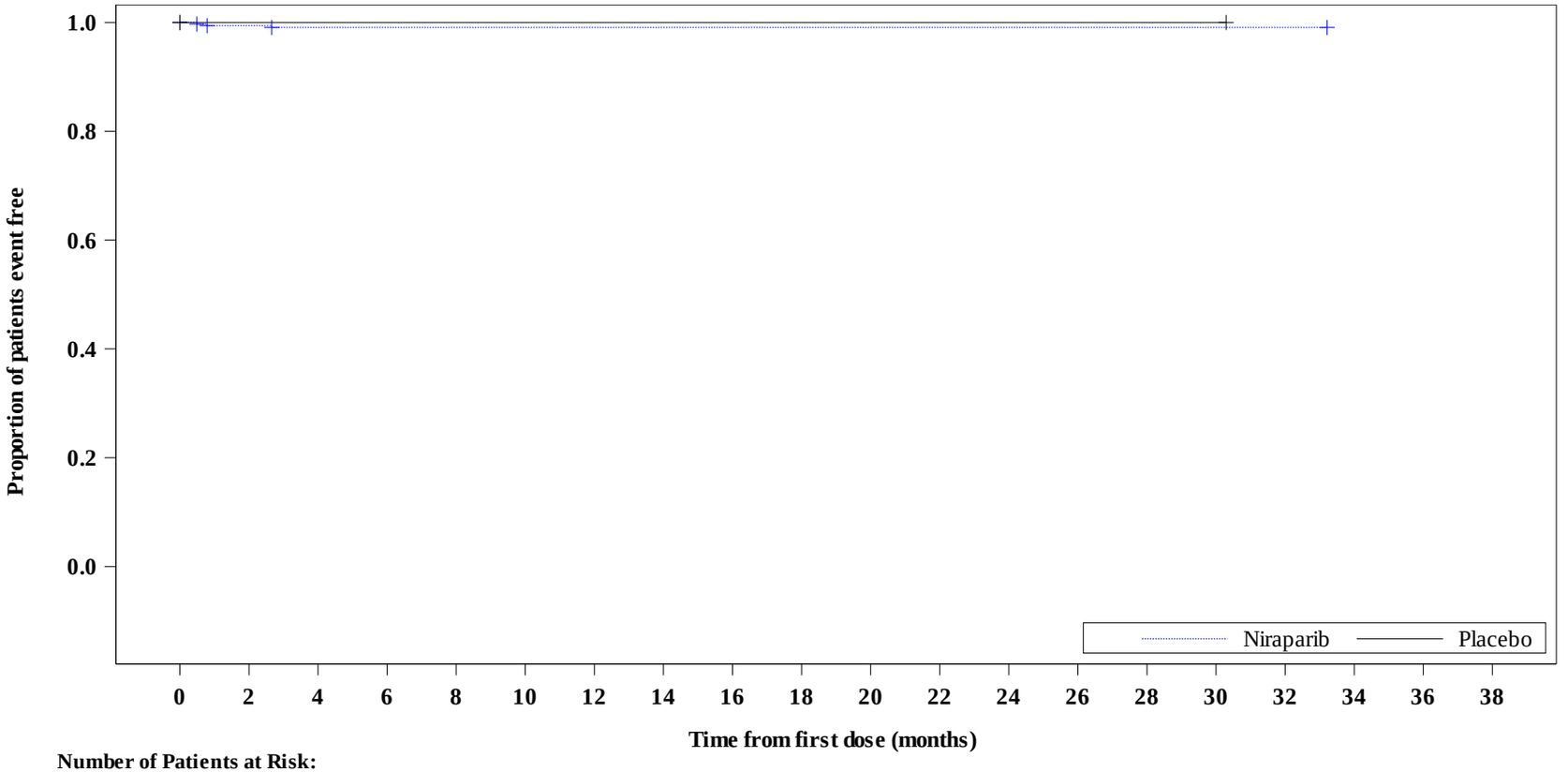

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 264 | 238 | 196 | 172 | 164 | 151 | 126 | 115 | 85 | 59 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 129 | 103 | 79 | 71 | 60 | 51 | 44 | 37 | 20 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Thromboemblic



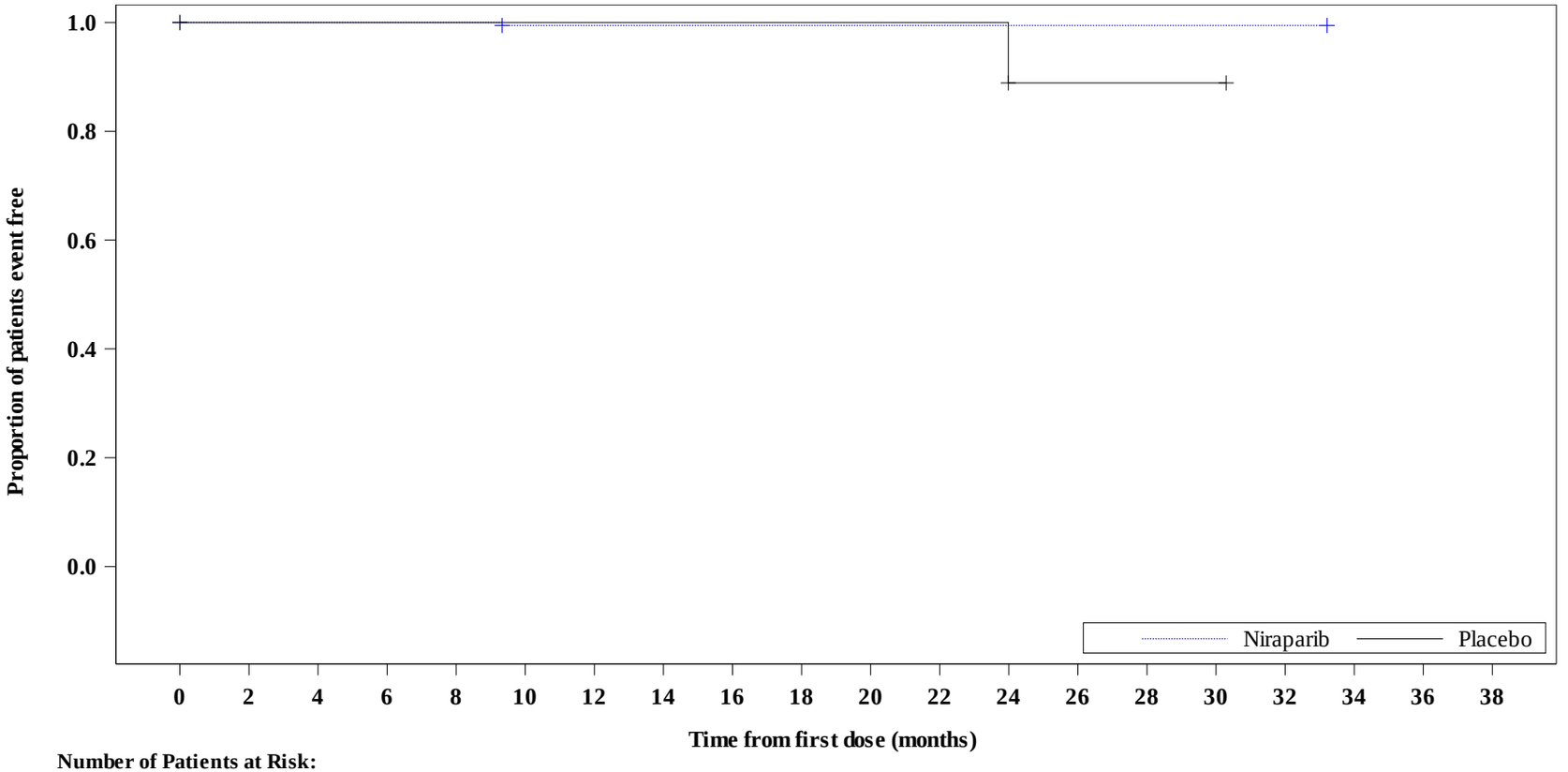

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 262 | 236 | 195 | 171 | 163 | 151 | 126 | 115 | 85 | 59 | 40 | 19 | 9 | 2 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

MDS/AML



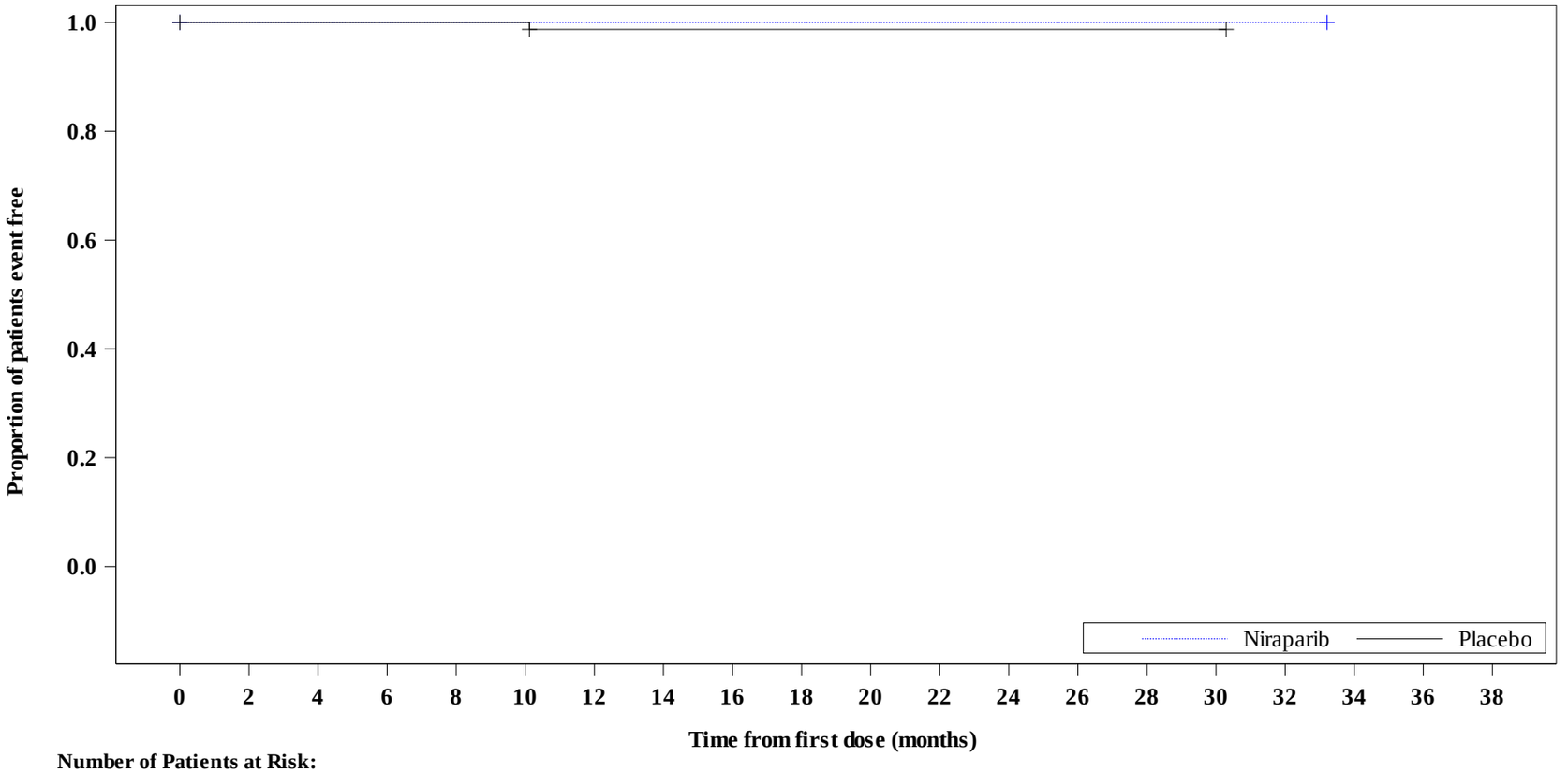

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 129 | 103 | 79 | 71 | 60 | 51 | 44 | 37 | 20 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.149a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Embryo-fetal toxicity



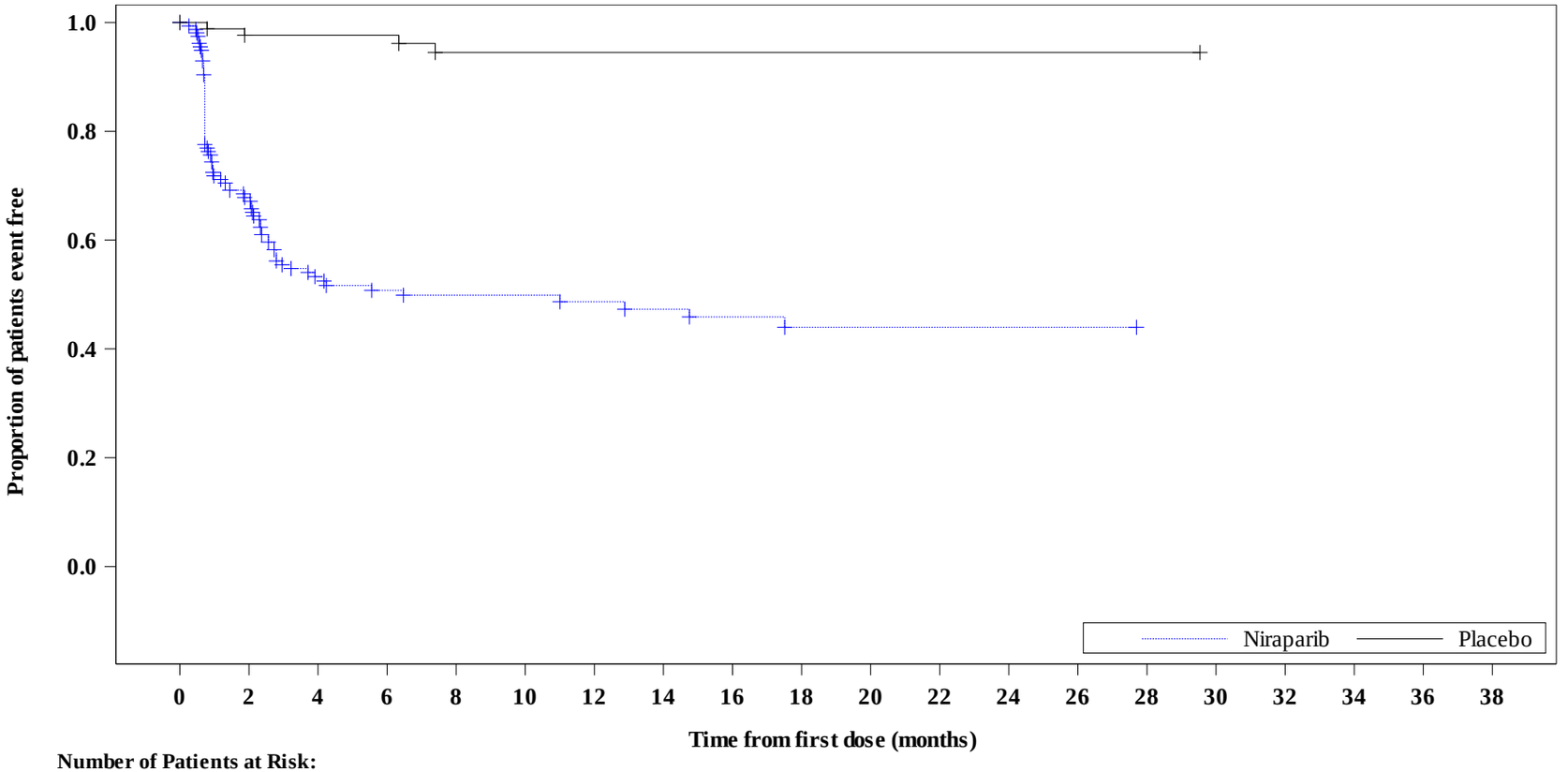

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 69 | 58 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Overall



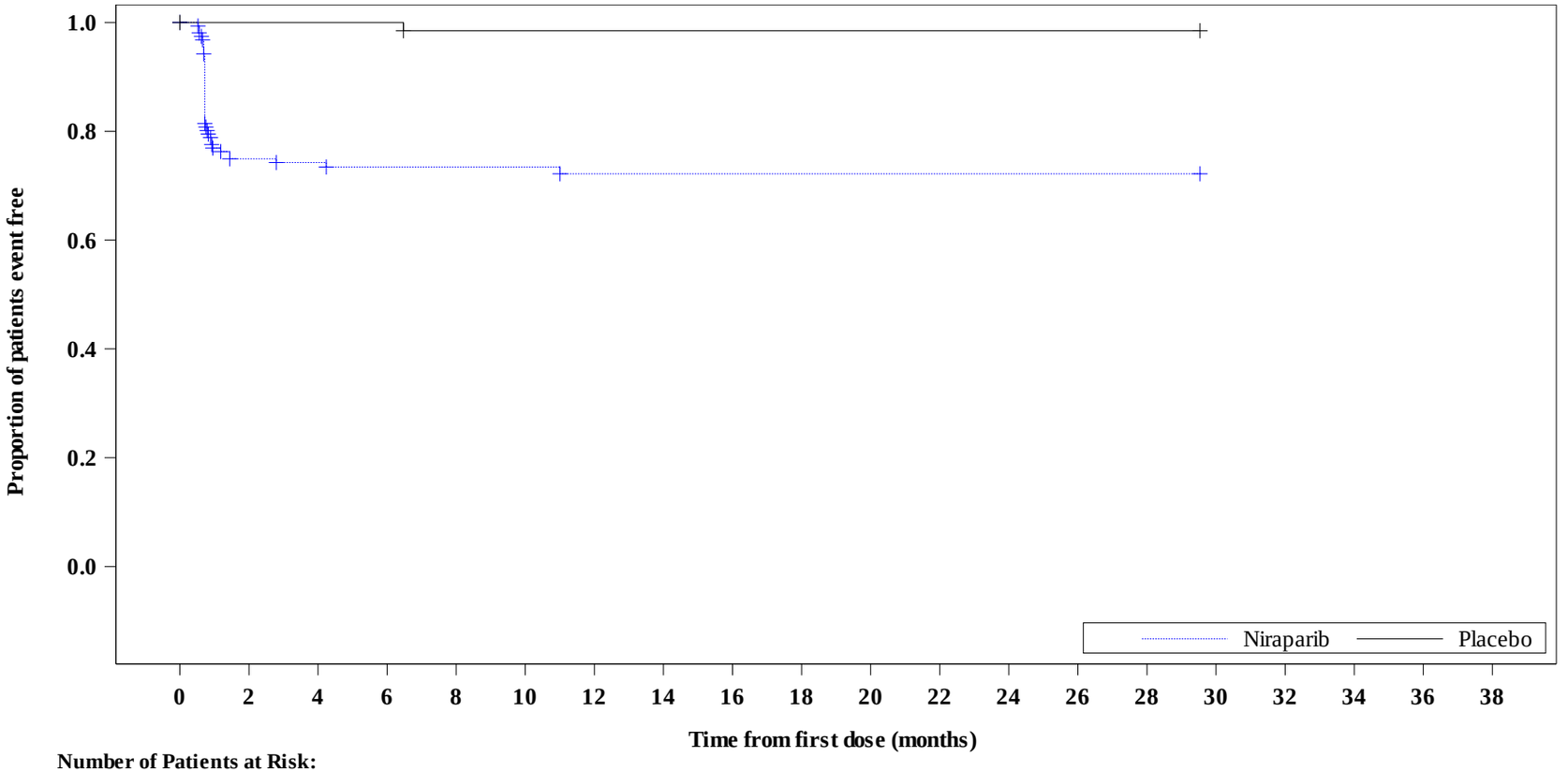

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 100 | 66 | 57 | 46 | 42 | 38 | 34 | 26 | 22 | 15 | 7 | 4 | 2 | 0 | |
| Placebo | 86 | 82 | 73 | 67 | 54 | 40 | 34 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Thrombocytopenia



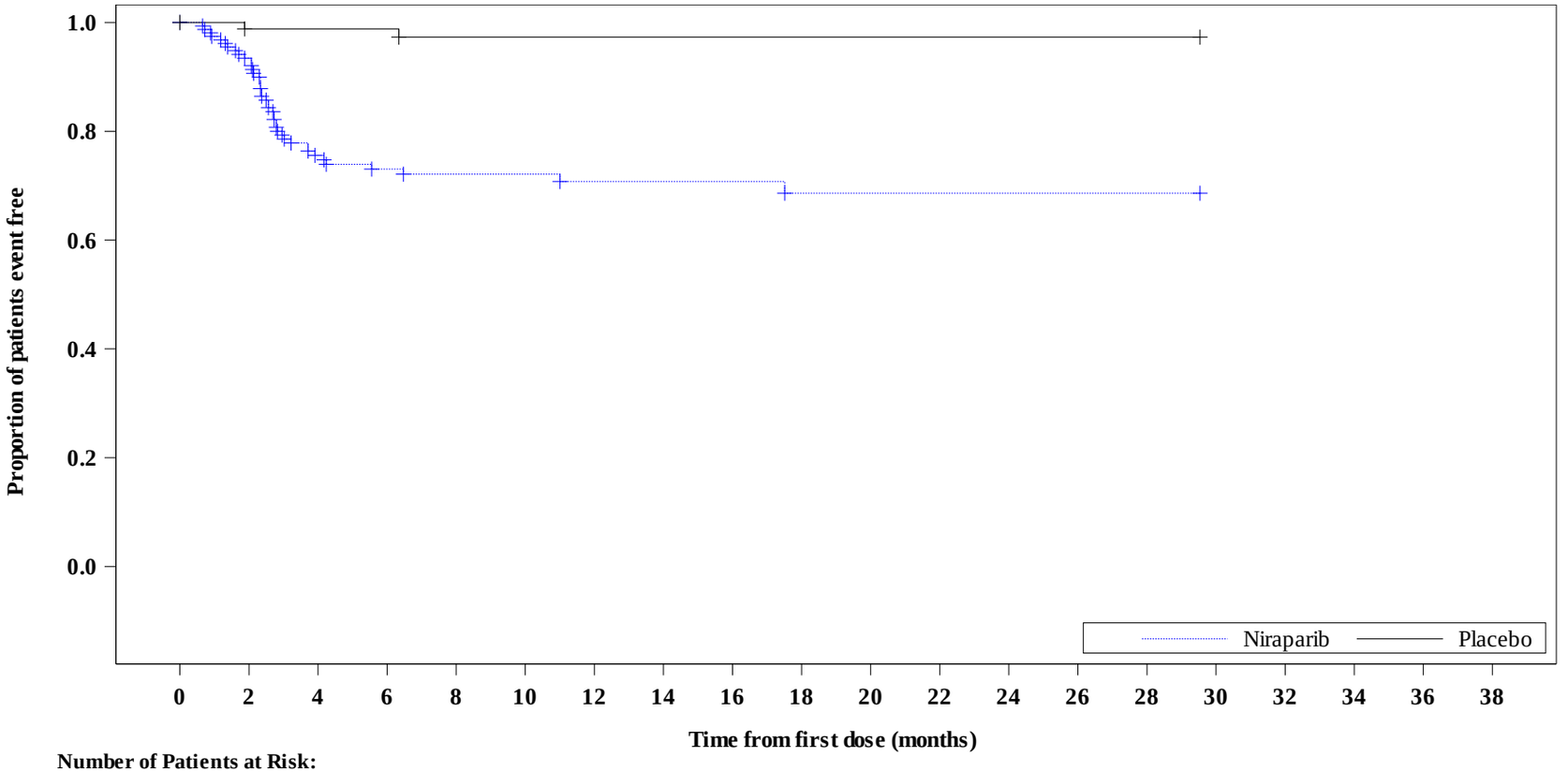

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 111 | 91 | 82 | 65 | 60 | 56 | 50 | 41 | 37 | 23 | 10 | 5 | 3 | 1 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Anemia



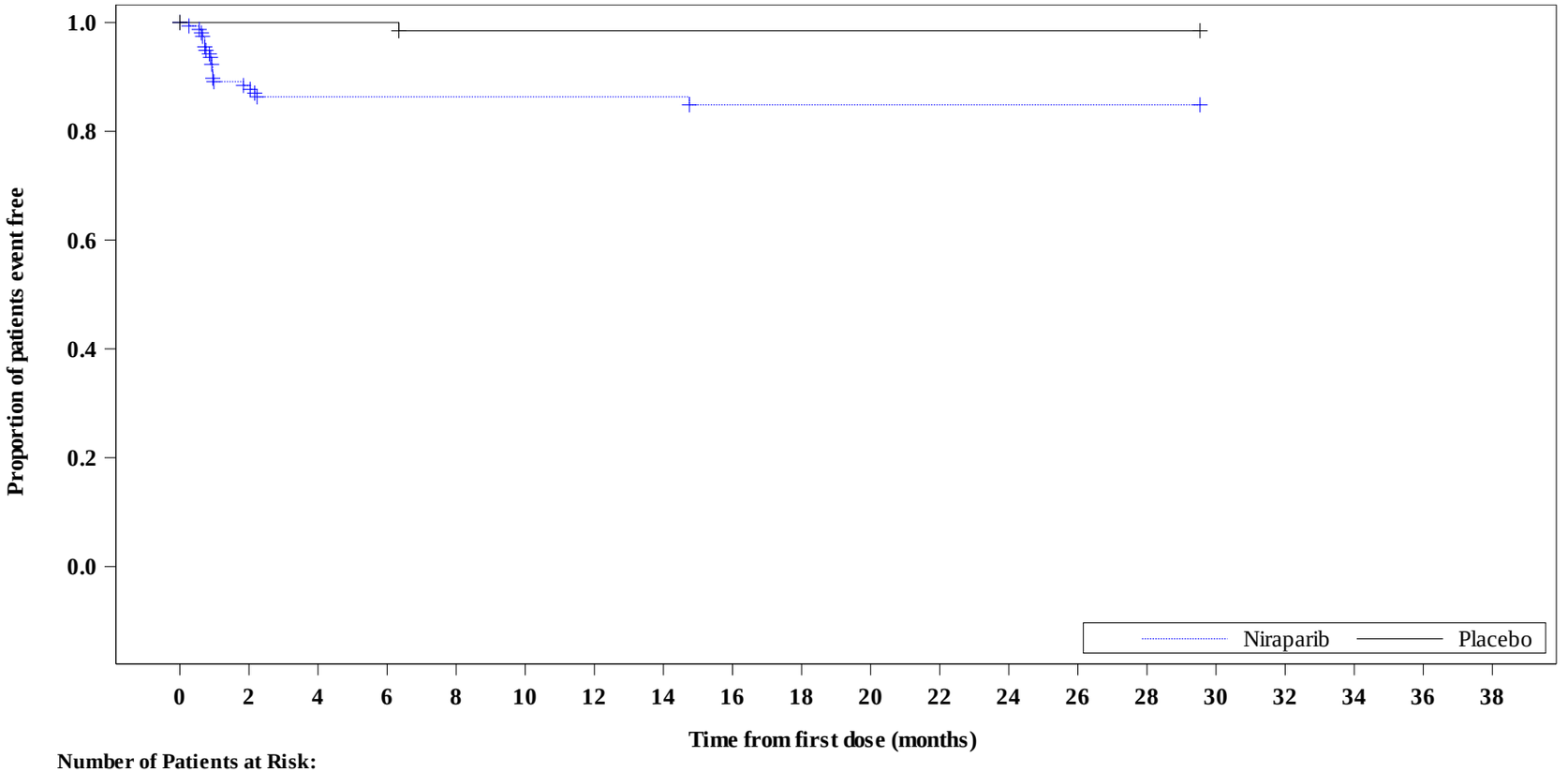

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 134 | 93 | 81 | 63 | 54 | 50 | 45 | 36 | 31 | 20 | 9 | 6 | 3 | 1 | 0 |
| Placebo | 86 | 83 | 74 | 68 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Leukopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 127 | 102 | 92 | 76 | 70 | 66 | 61 | 48 | 43 | 27 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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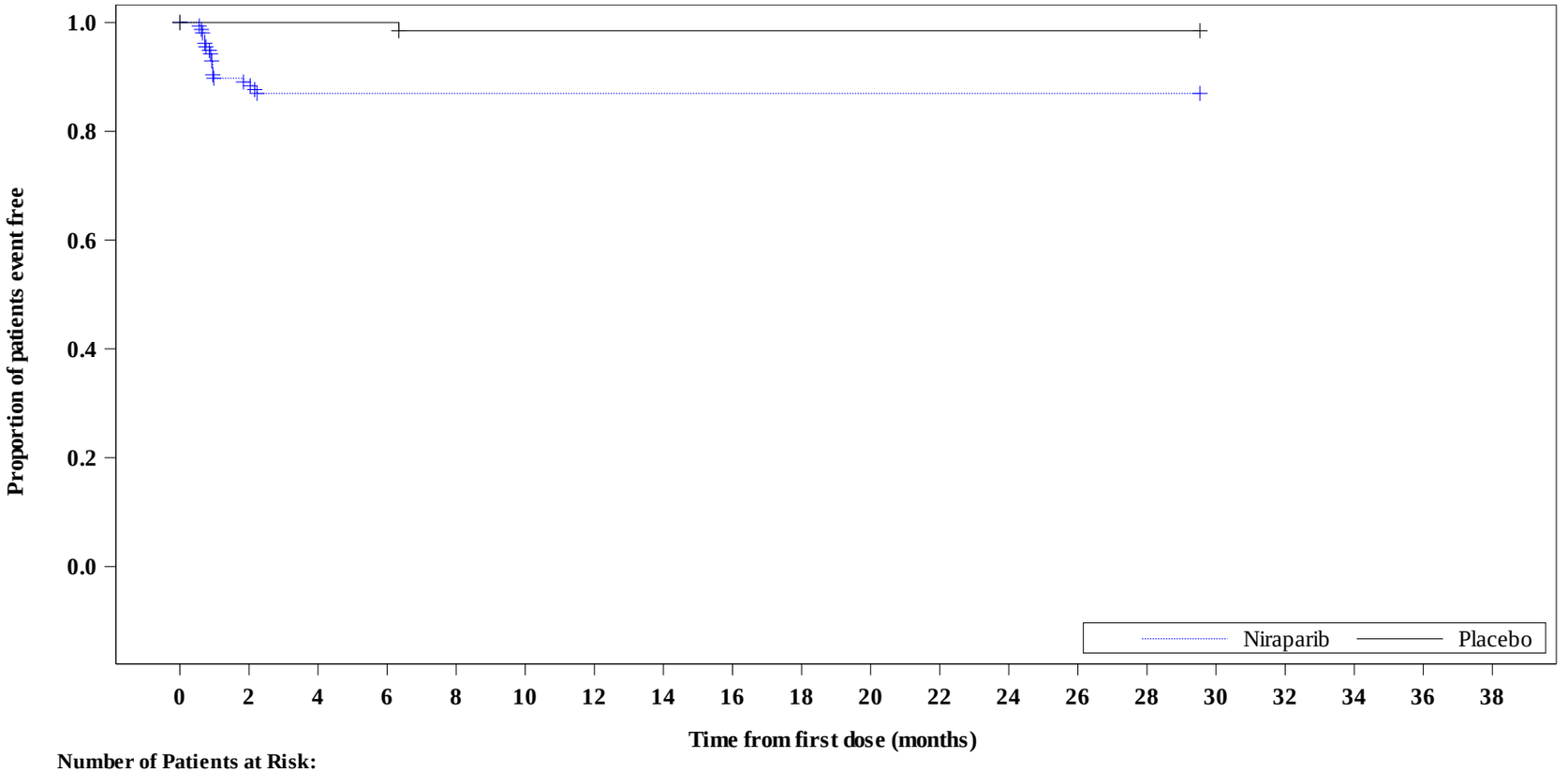
Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Neutropenia



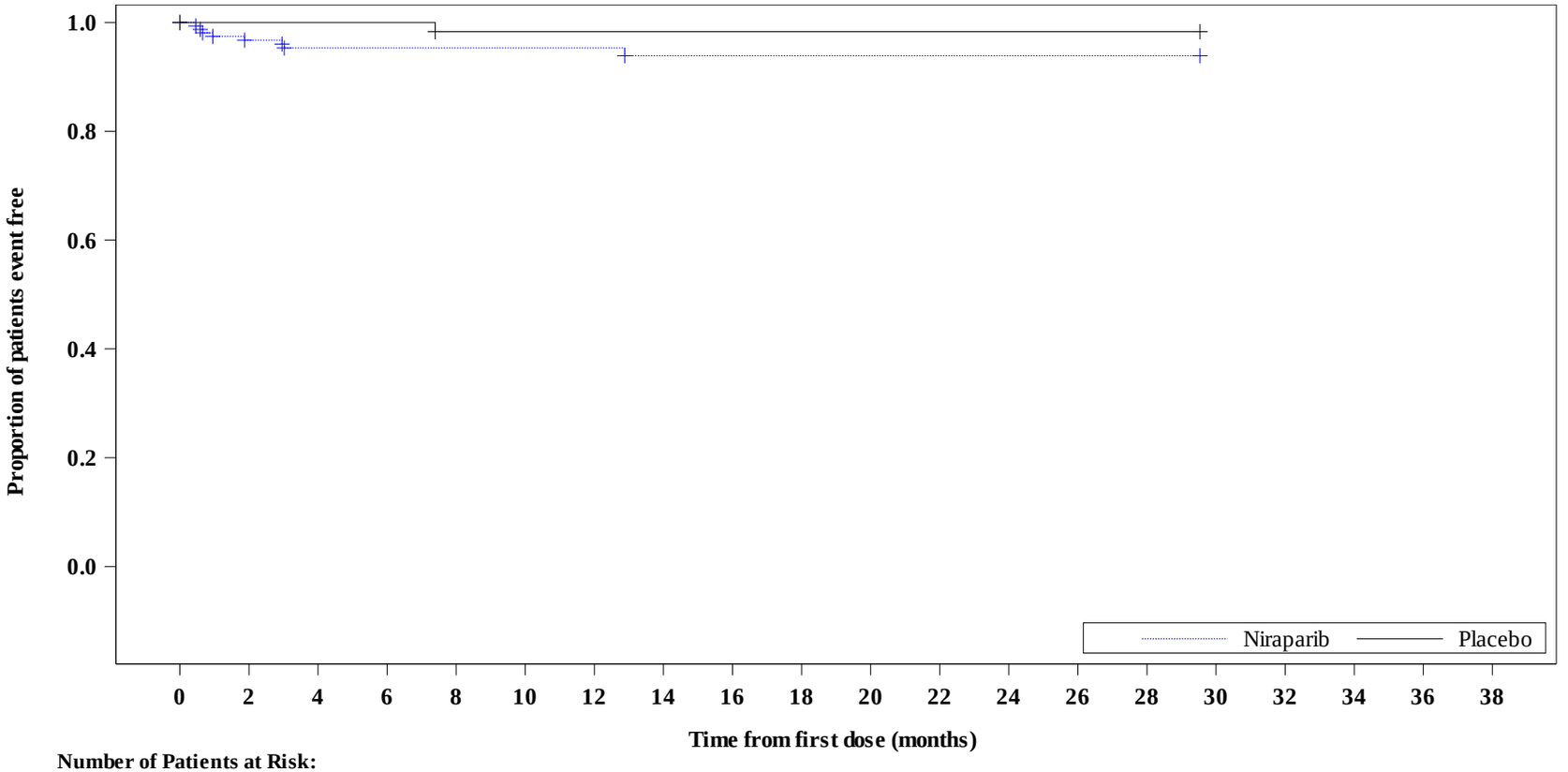

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 128 | 102 | 92 | 76 | 70 | 66 | 61 | 49 | 44 | 28 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Hypertension



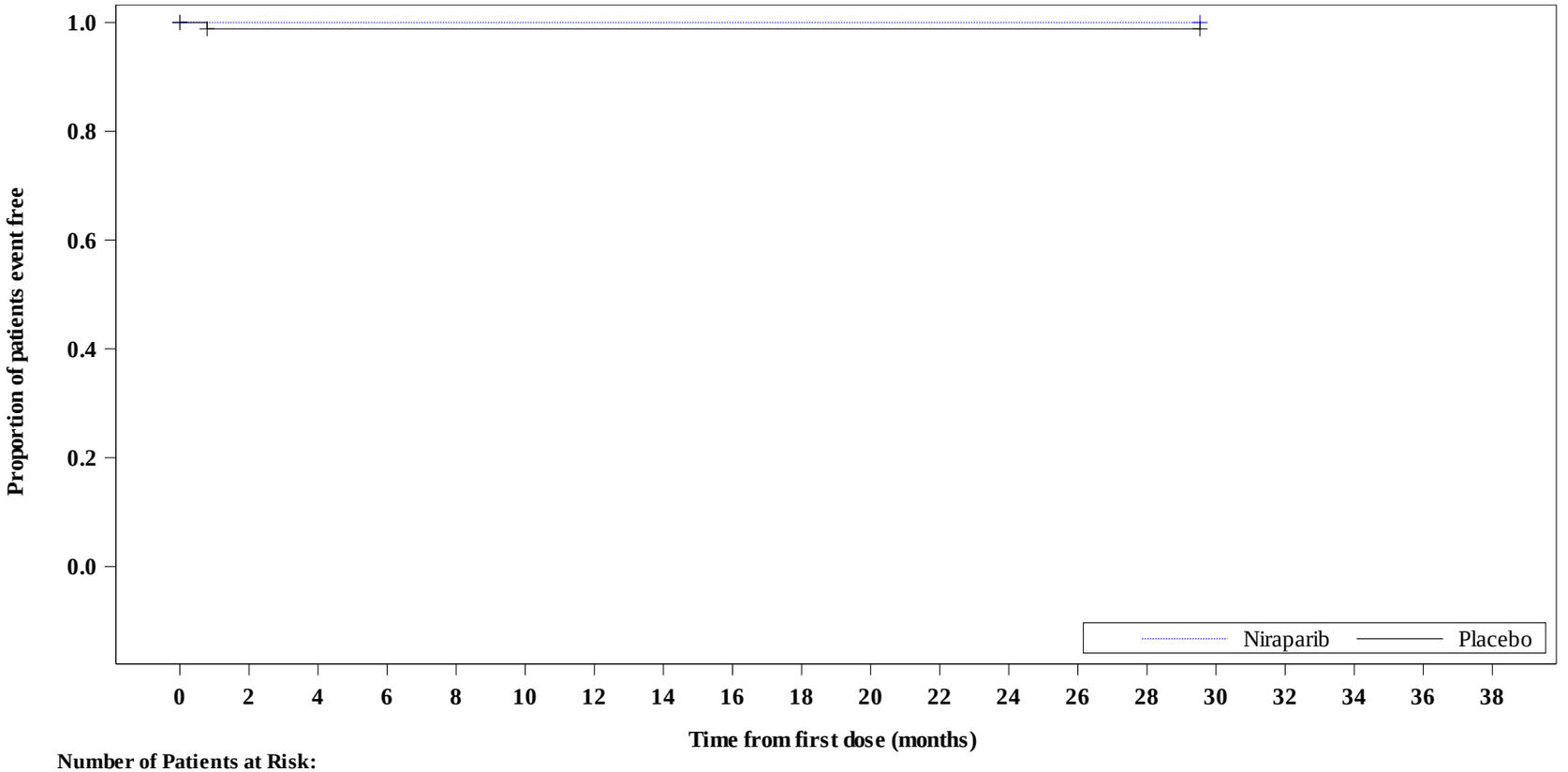

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 139 | 113 | 103 | 85 | 76 | 72 | 64 | 53 | 47 | 28 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 55 | 41 | 35 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

New malignancies other than MDS/AML




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 74 | 68 | 55 | 41 | 35 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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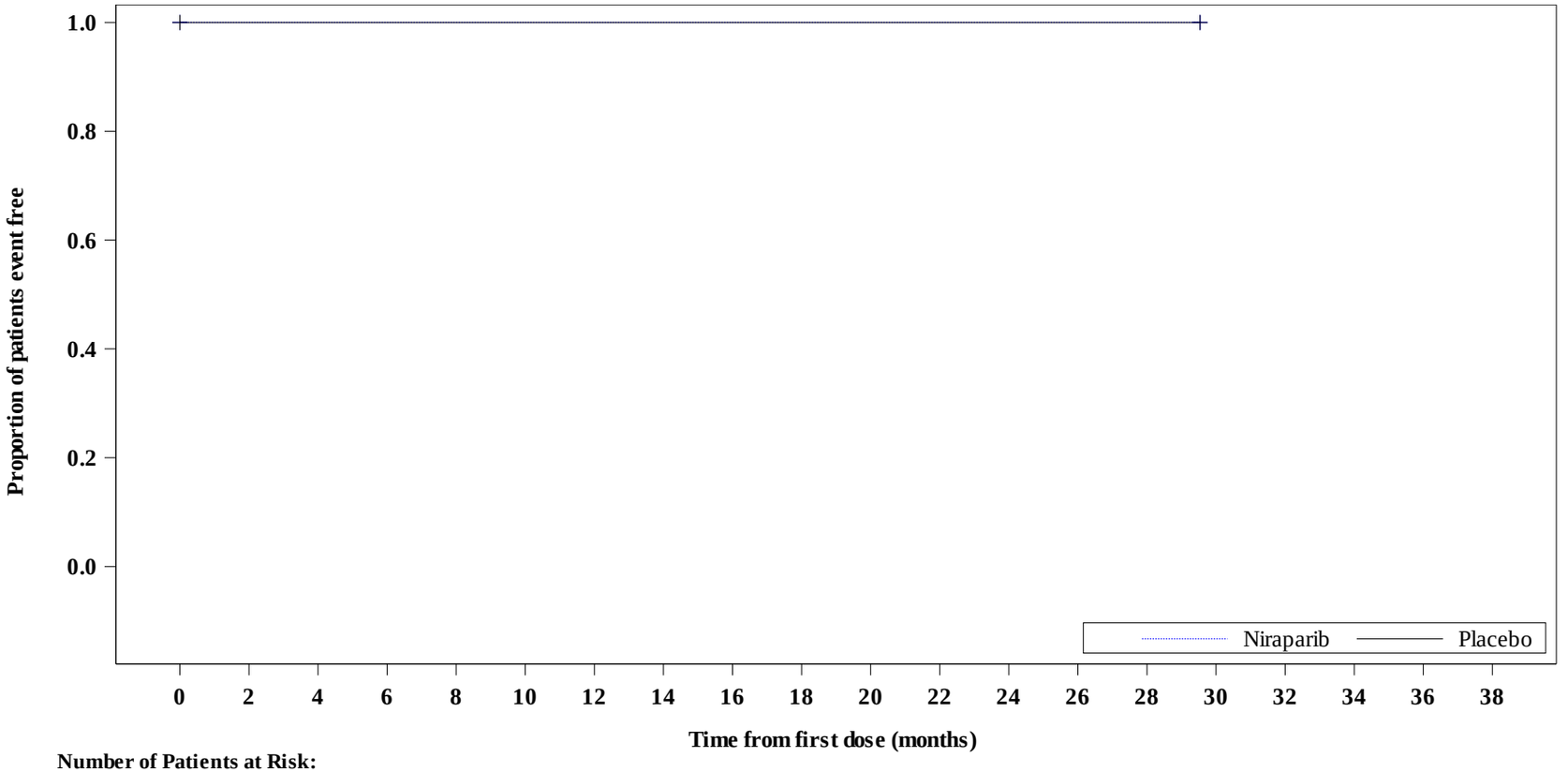
Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Pneumonitis



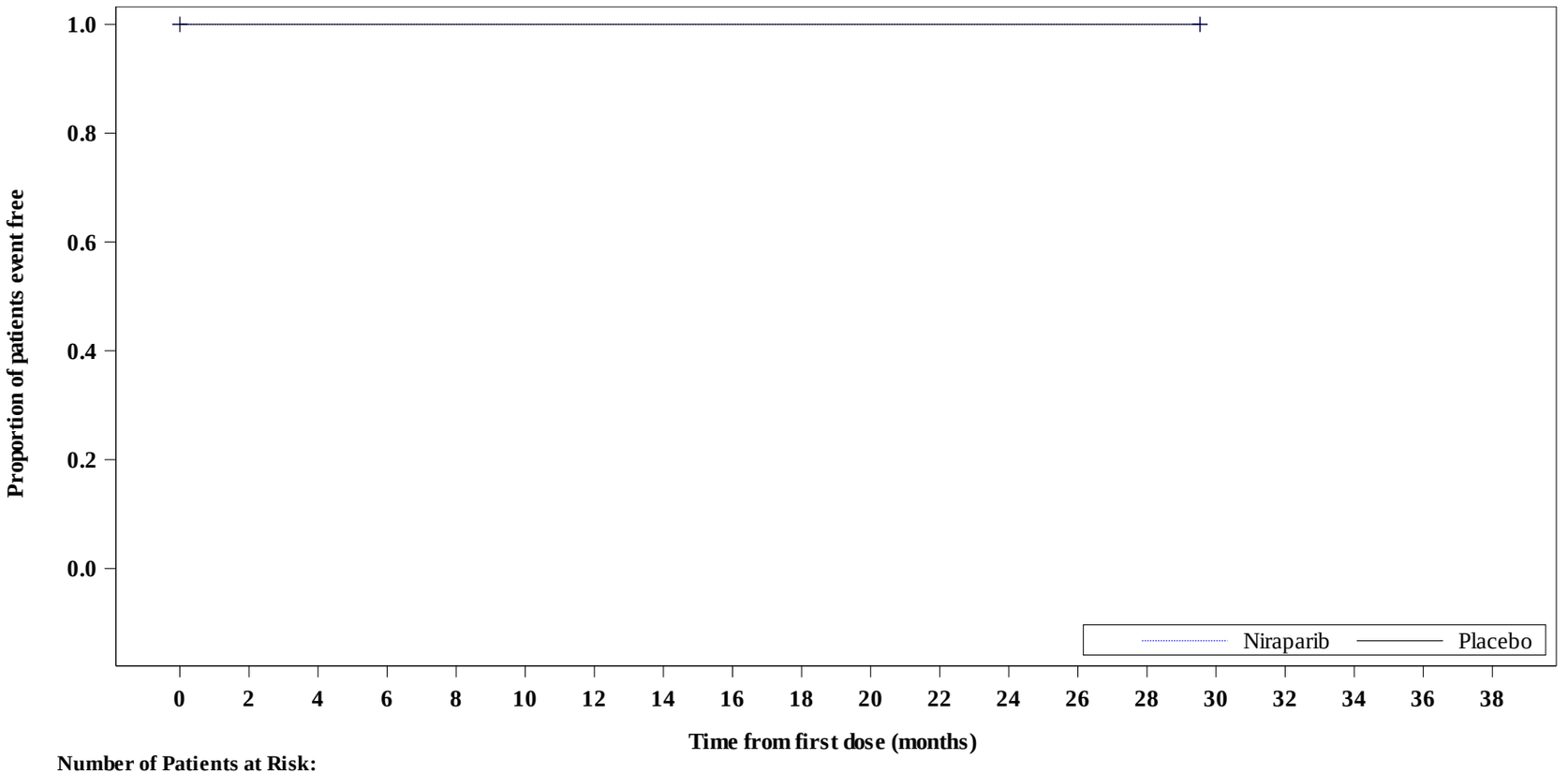

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Pancytopenia




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

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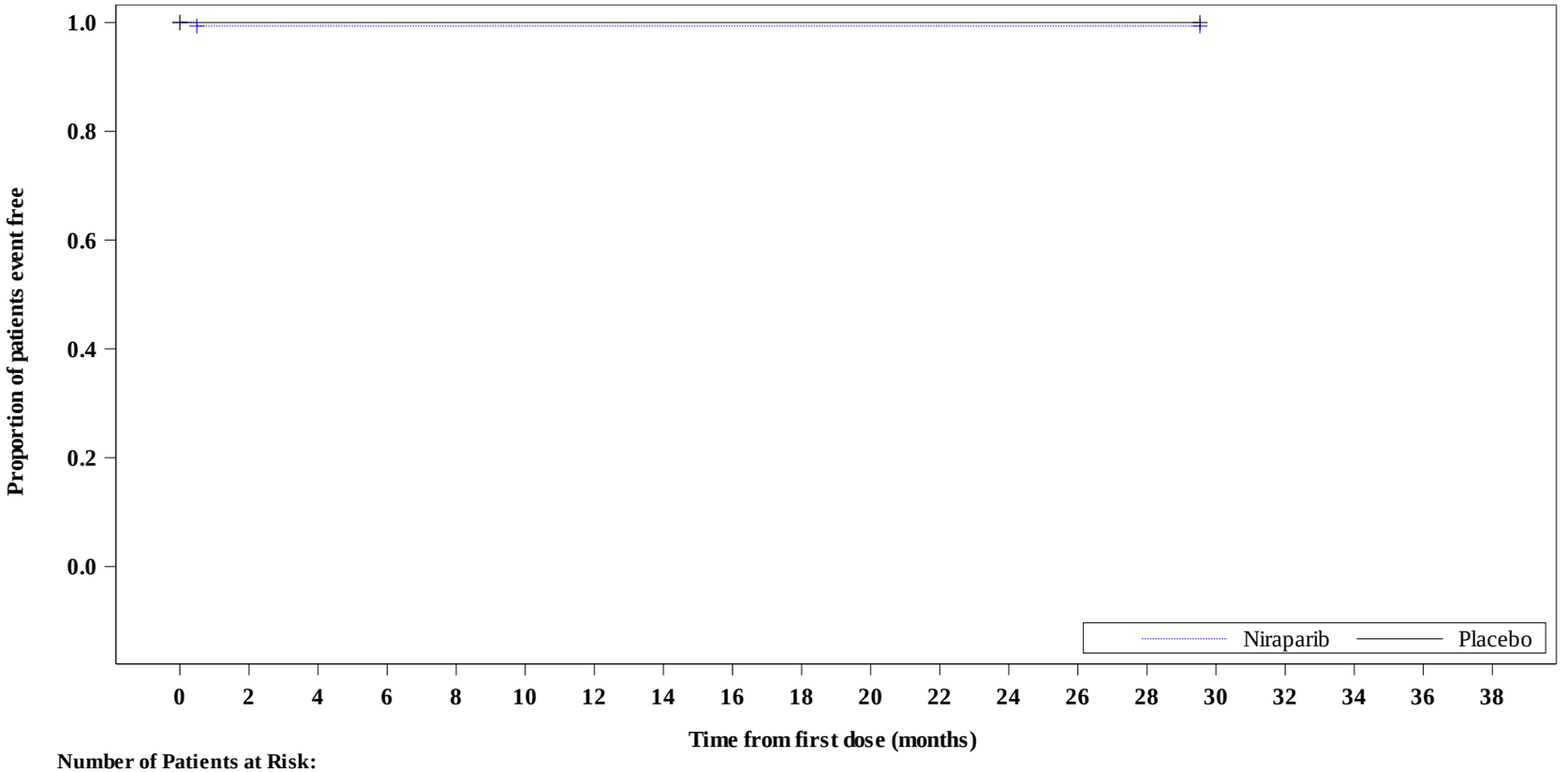
Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Thromboemblic



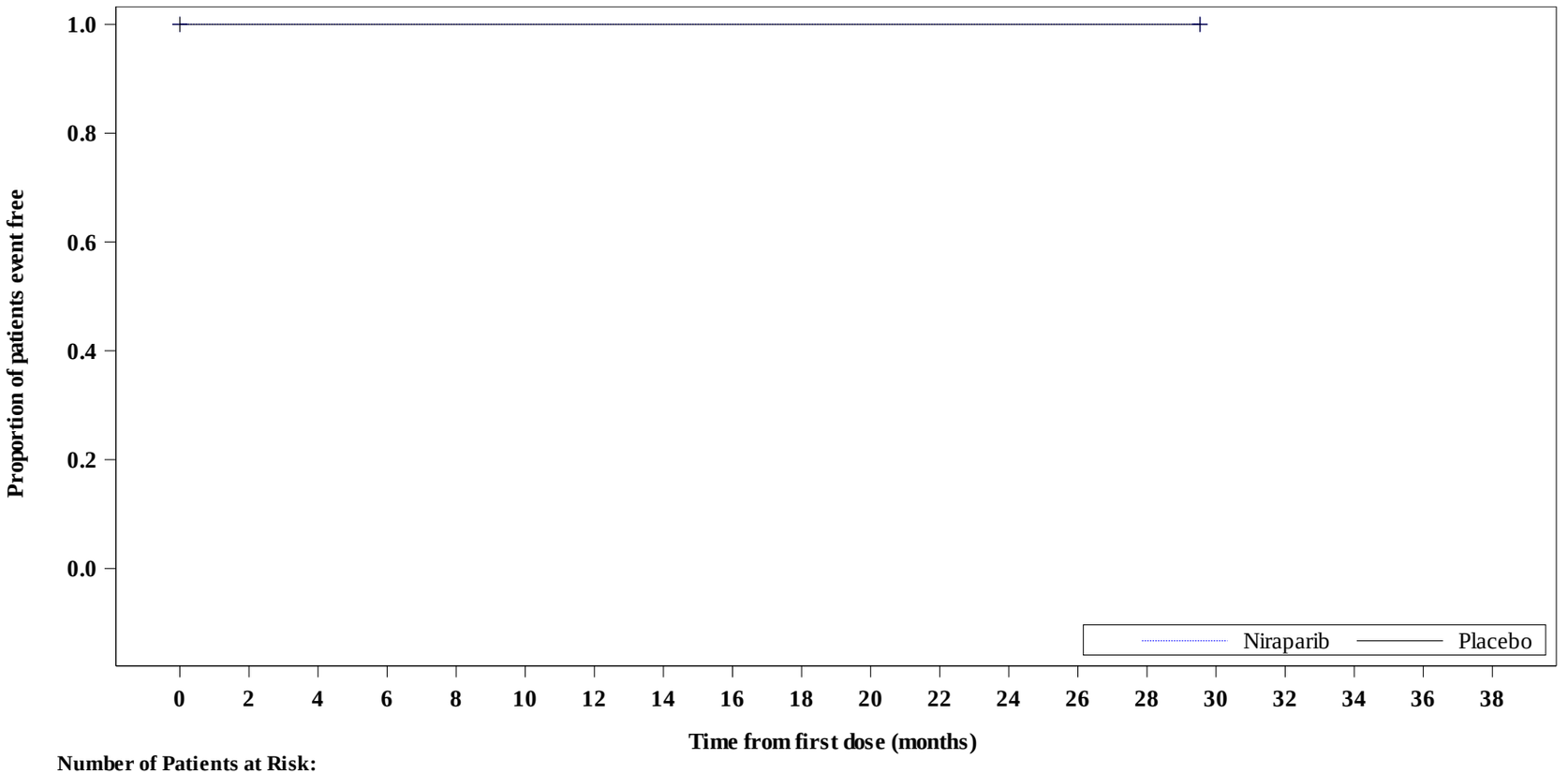

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 143 | 117 | 106 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

MDS/AML



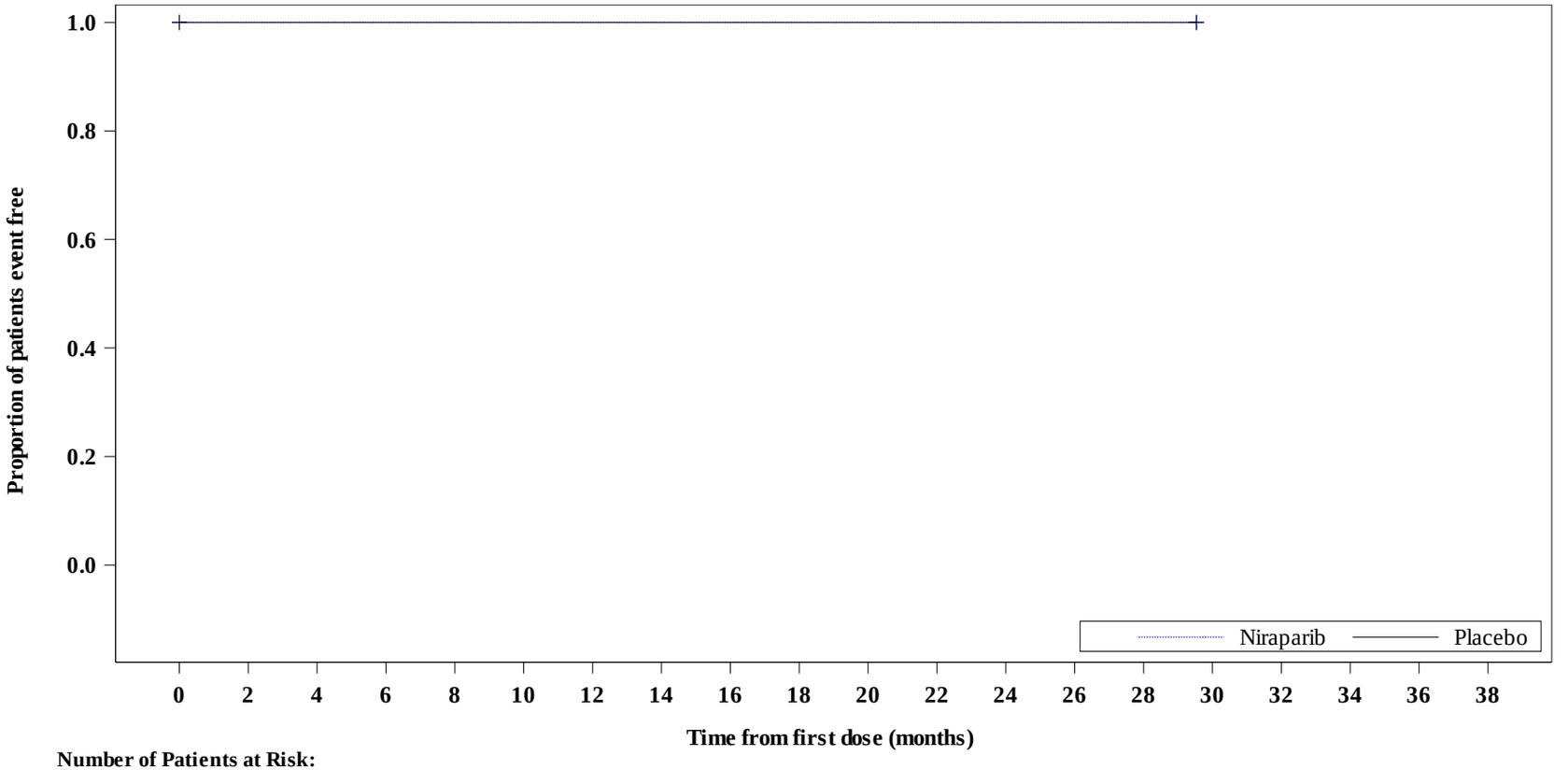

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.150a

Time to Onset of First Occurrence of CTCAE grade > = 3 Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

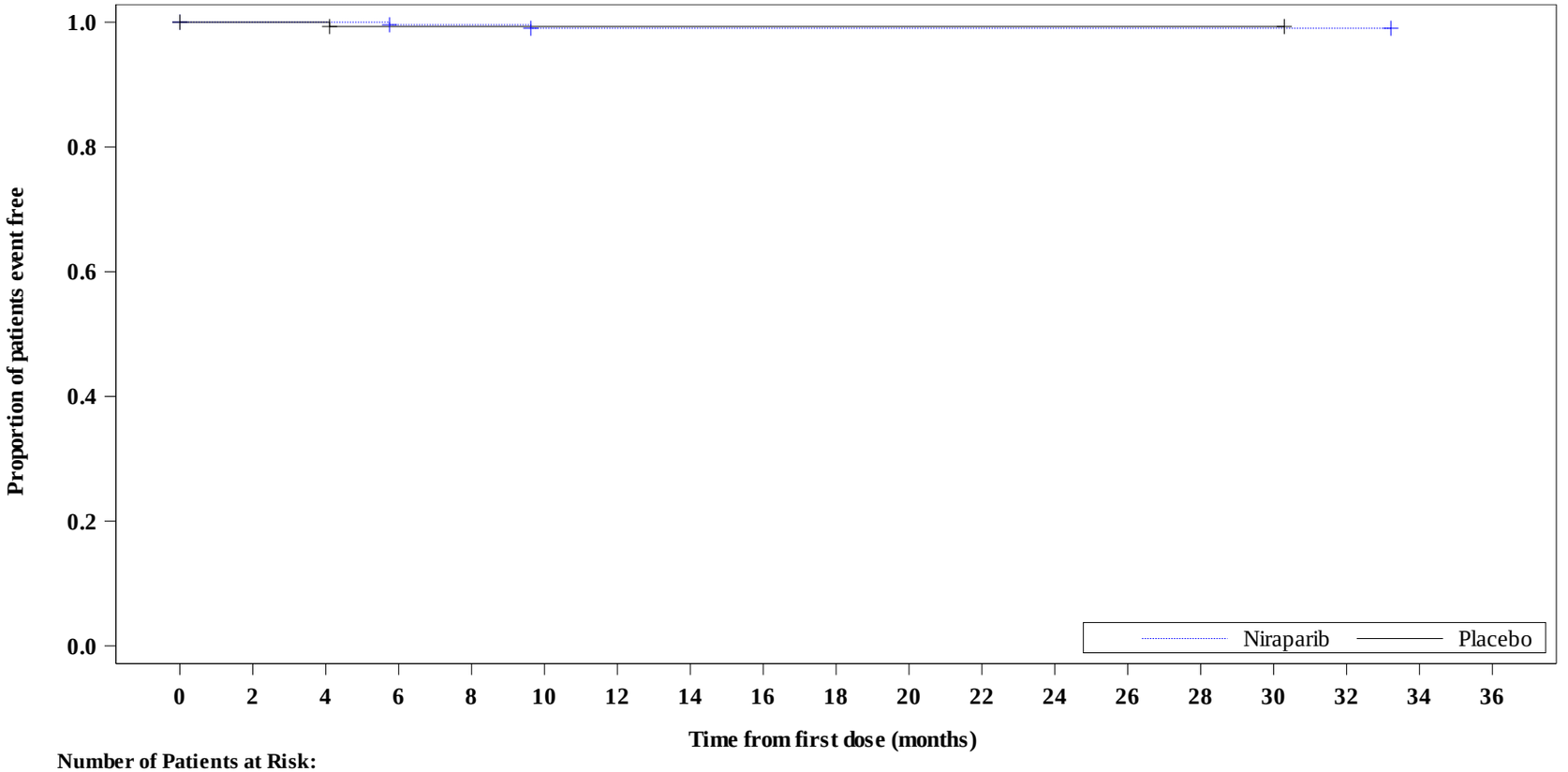
Embryo-fetal toxicity




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

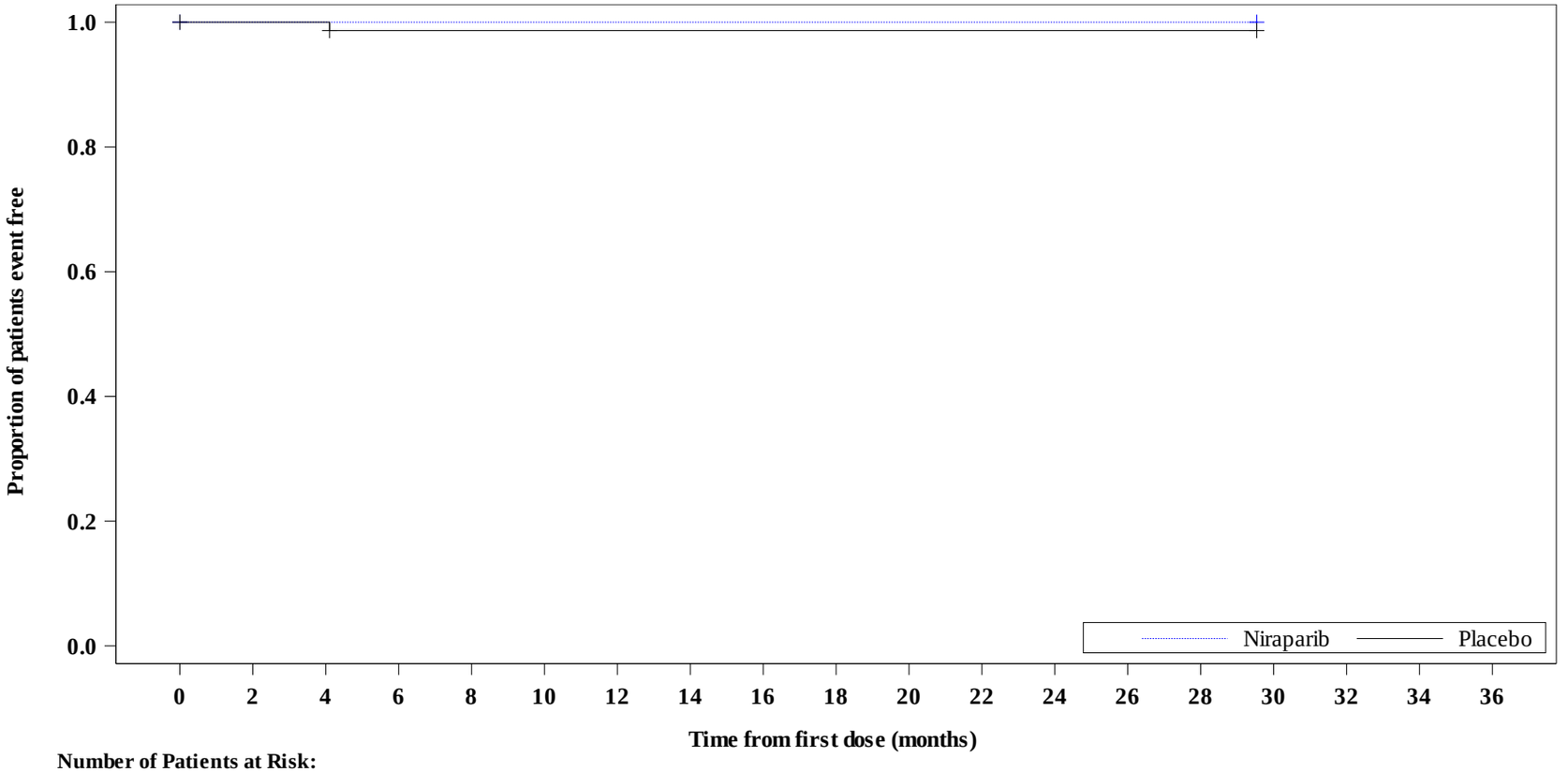
Figure 3.151
Time to Onset of First Occurrence of Fatal Serious Treatment-Emergent Adverse Events
(Residual Disease Safety Population)




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 238 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

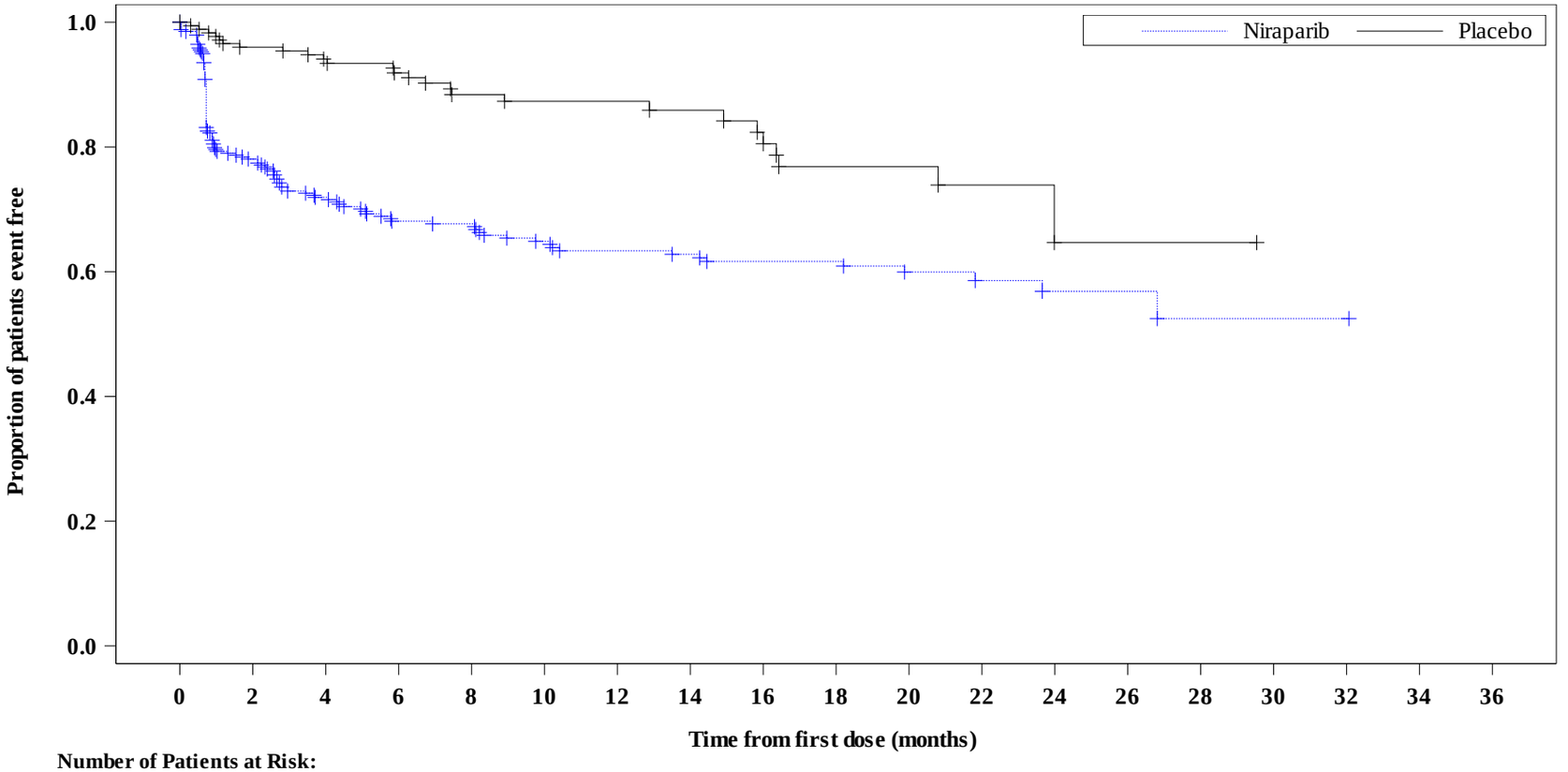
Figure 3.152
Time to Onset of First Occurrence of Fatal Serious Treatment-Emergent Adverse Events
(Residual Disease Safety-GVD Population)




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.153a
Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events
(Residual Disease Safety Population)

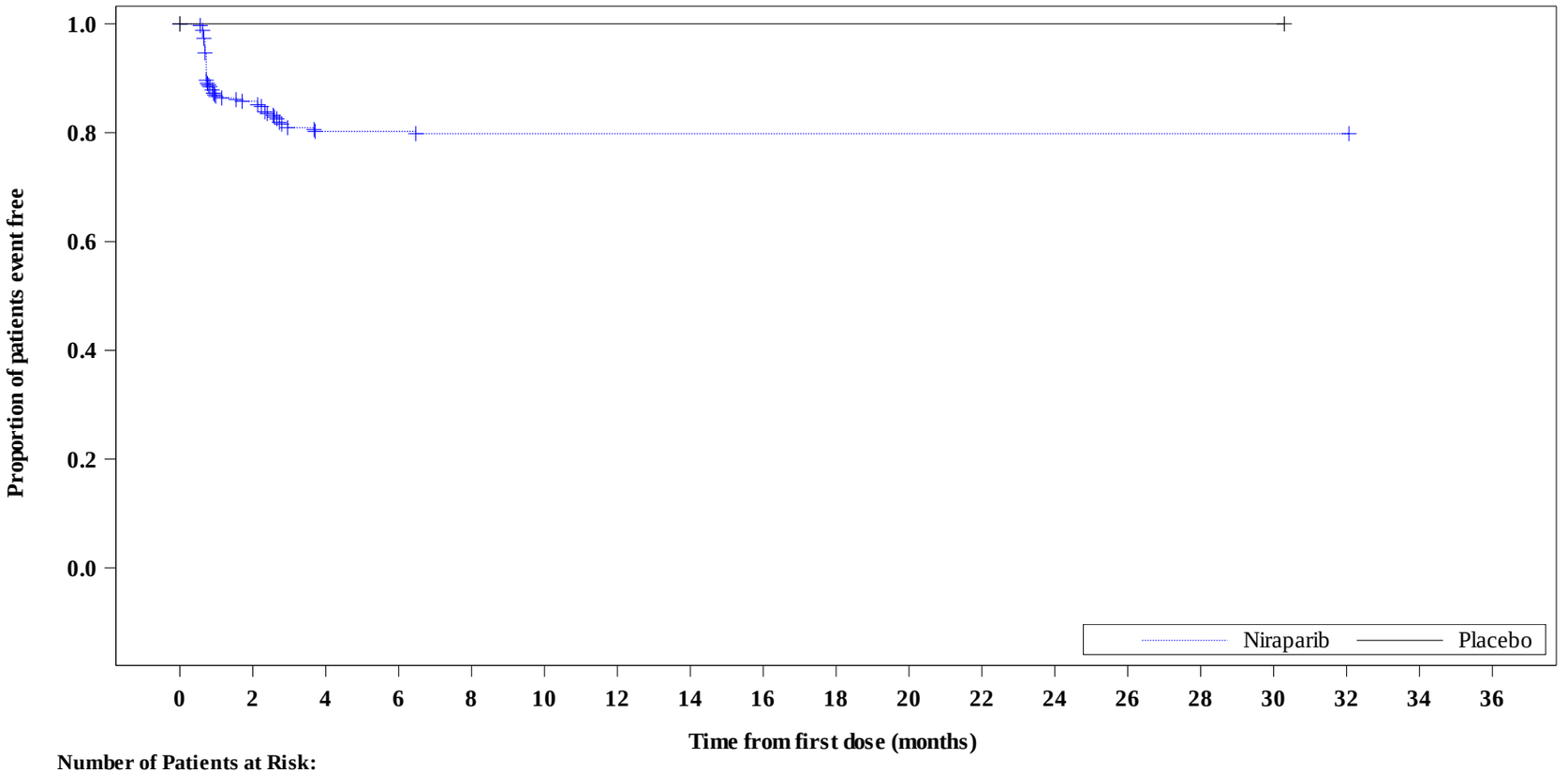



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 246 | 200 | 171 | 149 | 128 | 119 | 110 | 92 | 84 | 61 | 43 | 31 | 15 | 6 | 1 | 1 | 0 |
| Placebo | 175 | 165 | 138 | 120 | 93 | 71 | 65 | 55 | 45 | 37 | 32 | 17 | 7 | 4 | 1 | 0 | | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Blood and lymphatic system disorders

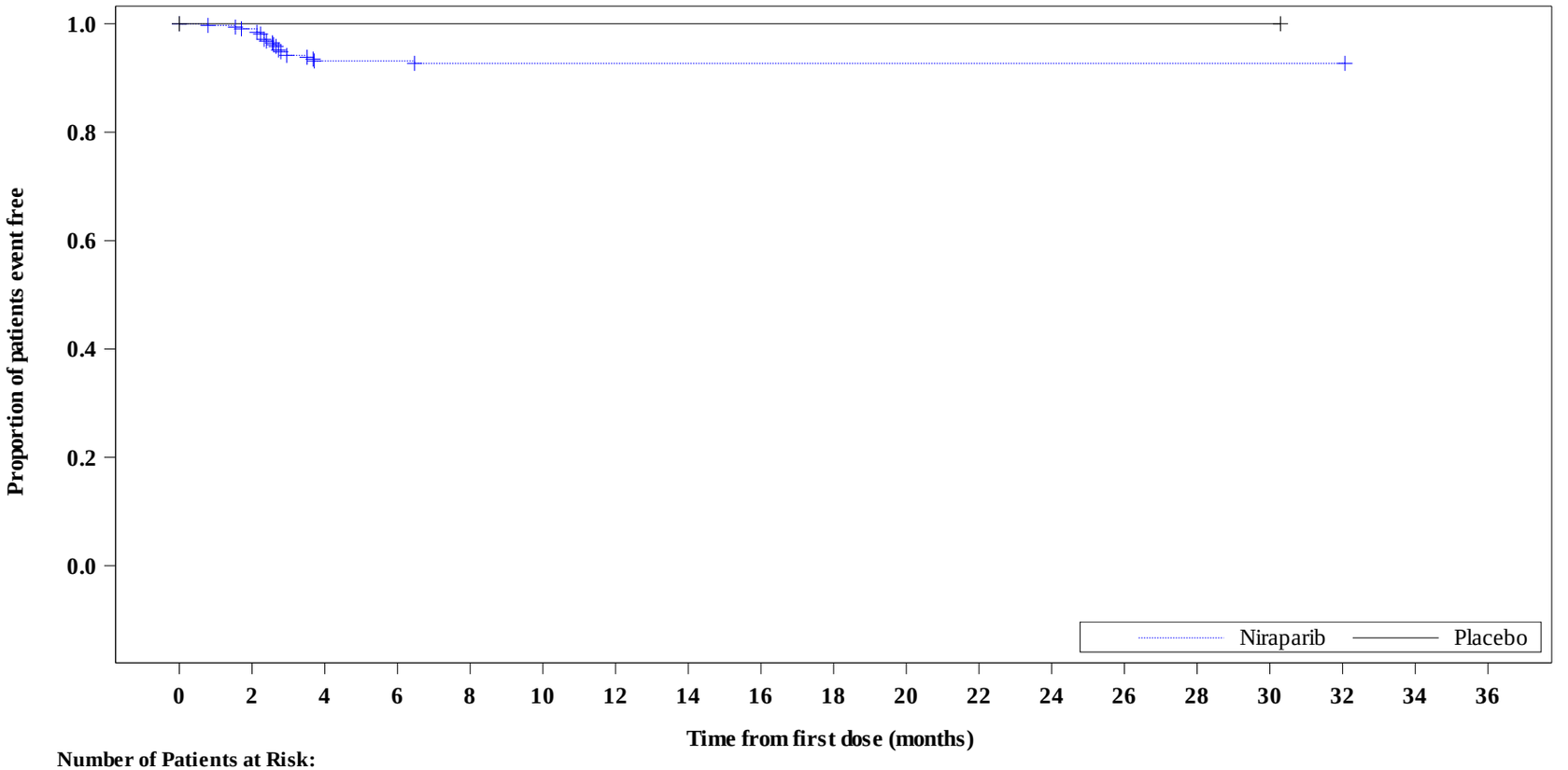



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 270 | 217 | 195 | 162 | 139 | 132 | 123 | 102 | 93 | 69 | 49 | 36 | 17 | 8 | 1 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Blood and lymphatic system disorders, PT: Anaemia

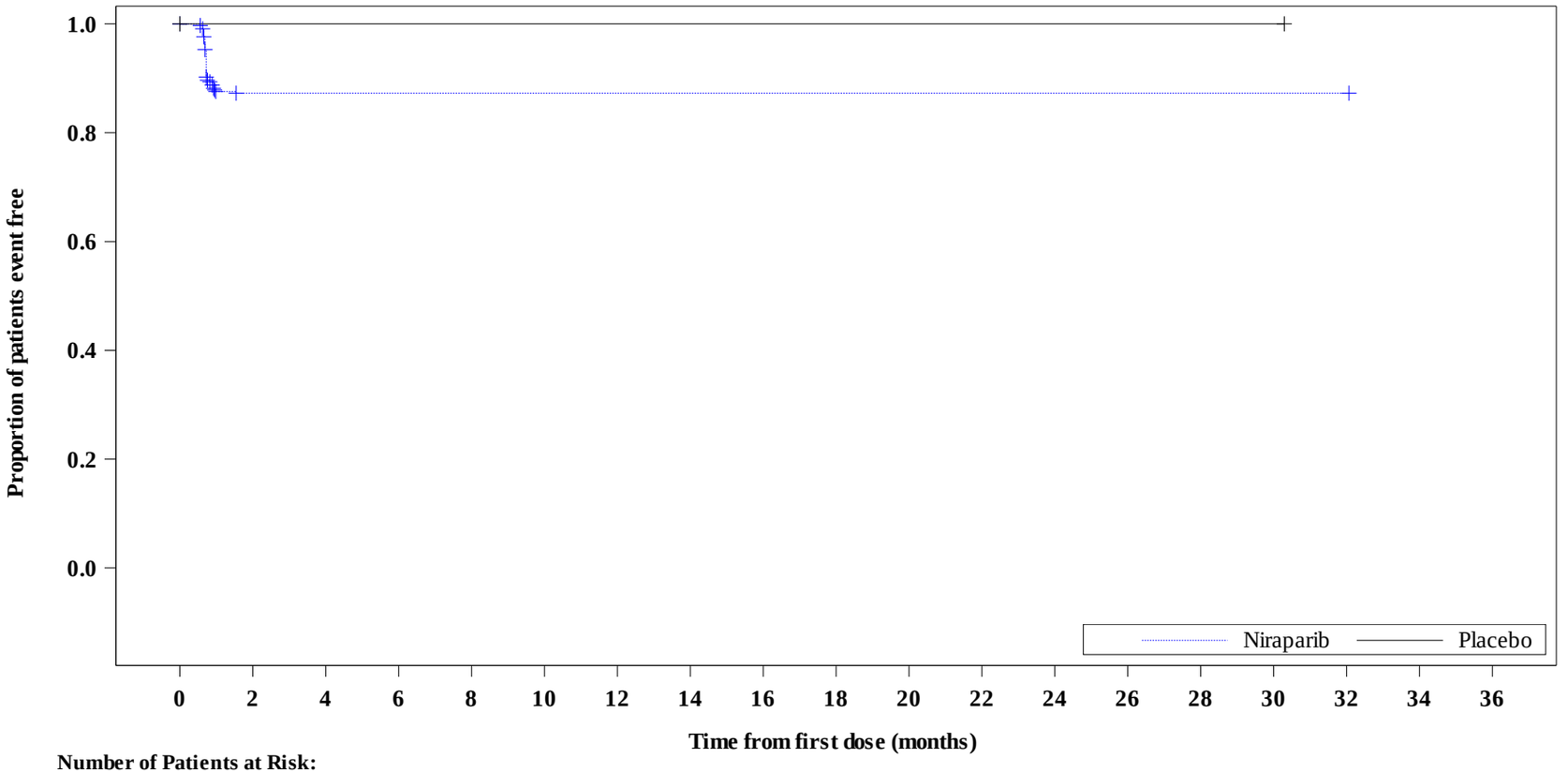



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 250 | 225 | 184 | 160 | 152 | 141 | 118 | 108 | 81 | 56 | 39 | 19 | 9 | 2 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

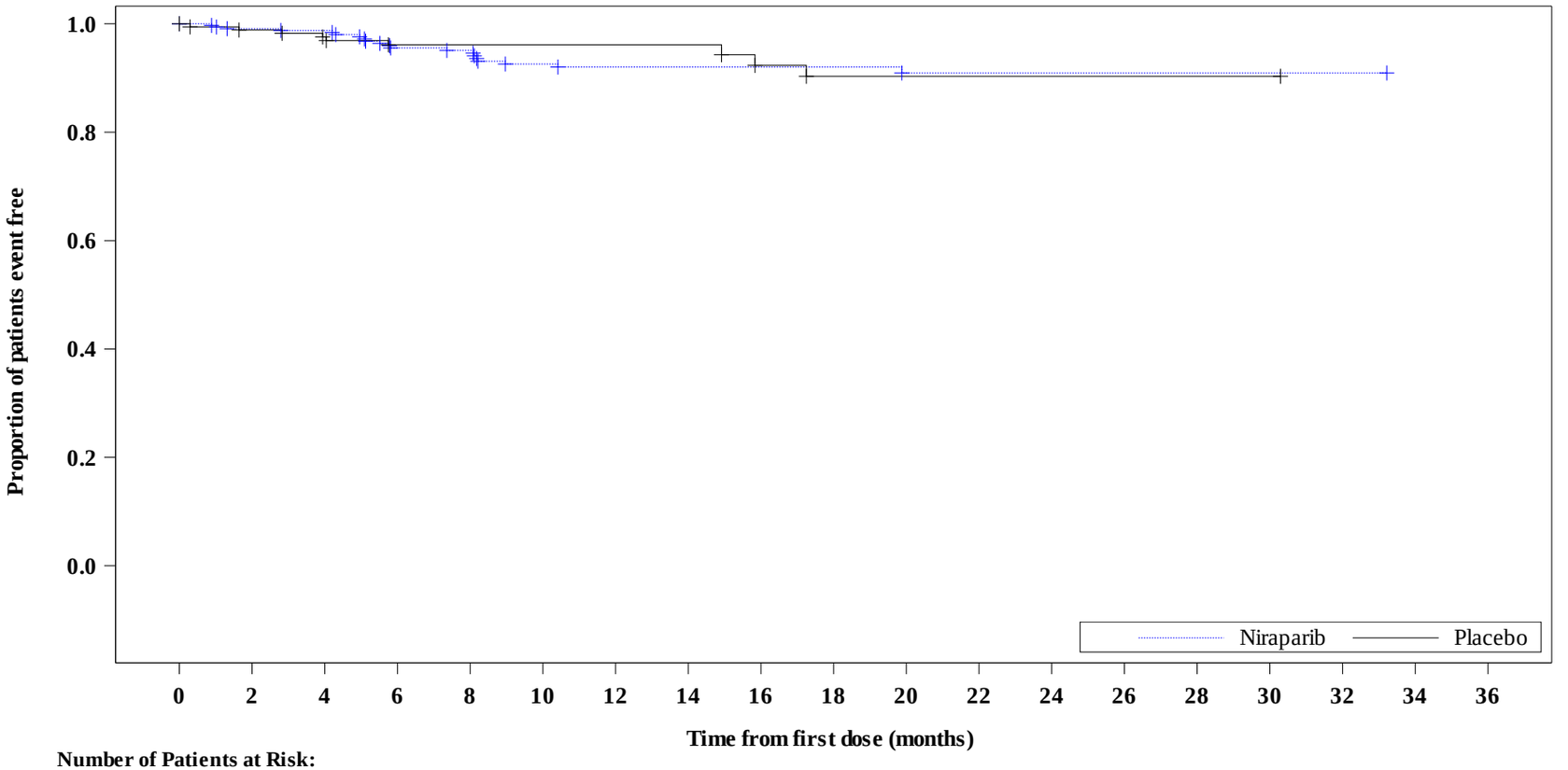



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 275 | 233 | 209 | 174 | 151 | 144 | 133 | 110 | 100 | 73 | 52 | 37 | 17 | 8 | 1 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Gastrointestinal disorders

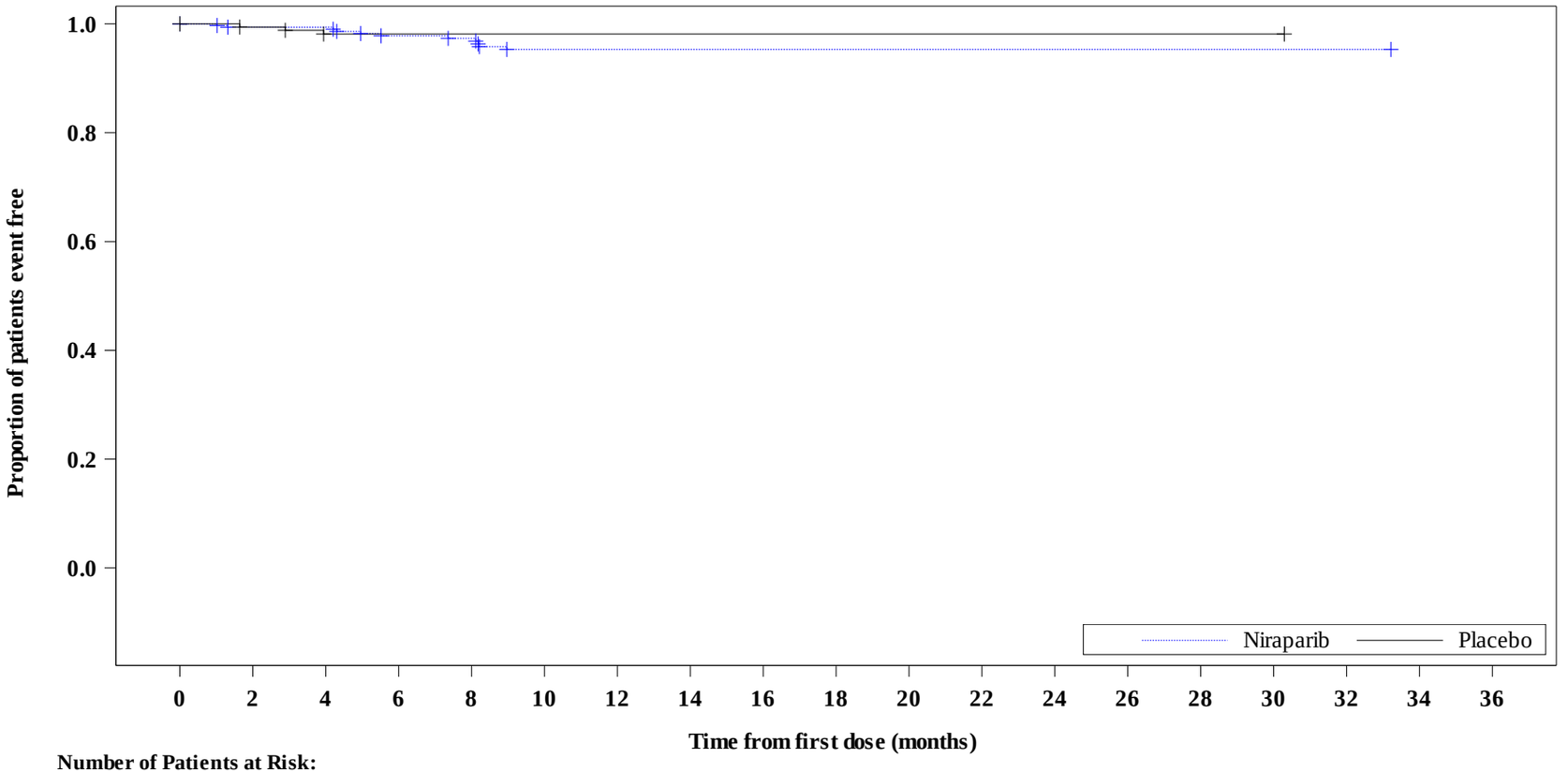



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 262 | 229 | 191 | 169 | 161 | 148 | 123 | 112 | 81 | 56 | 38 | 19 | 9 | 3 | 2 | 0 |
| Placebo | 175 | 170 | 144 | 126 | 101 | 77 | 69 | 58 | 47 | 39 | 33 | 17 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Gastrointestinal disorders, PT: Small intestinal obstruction

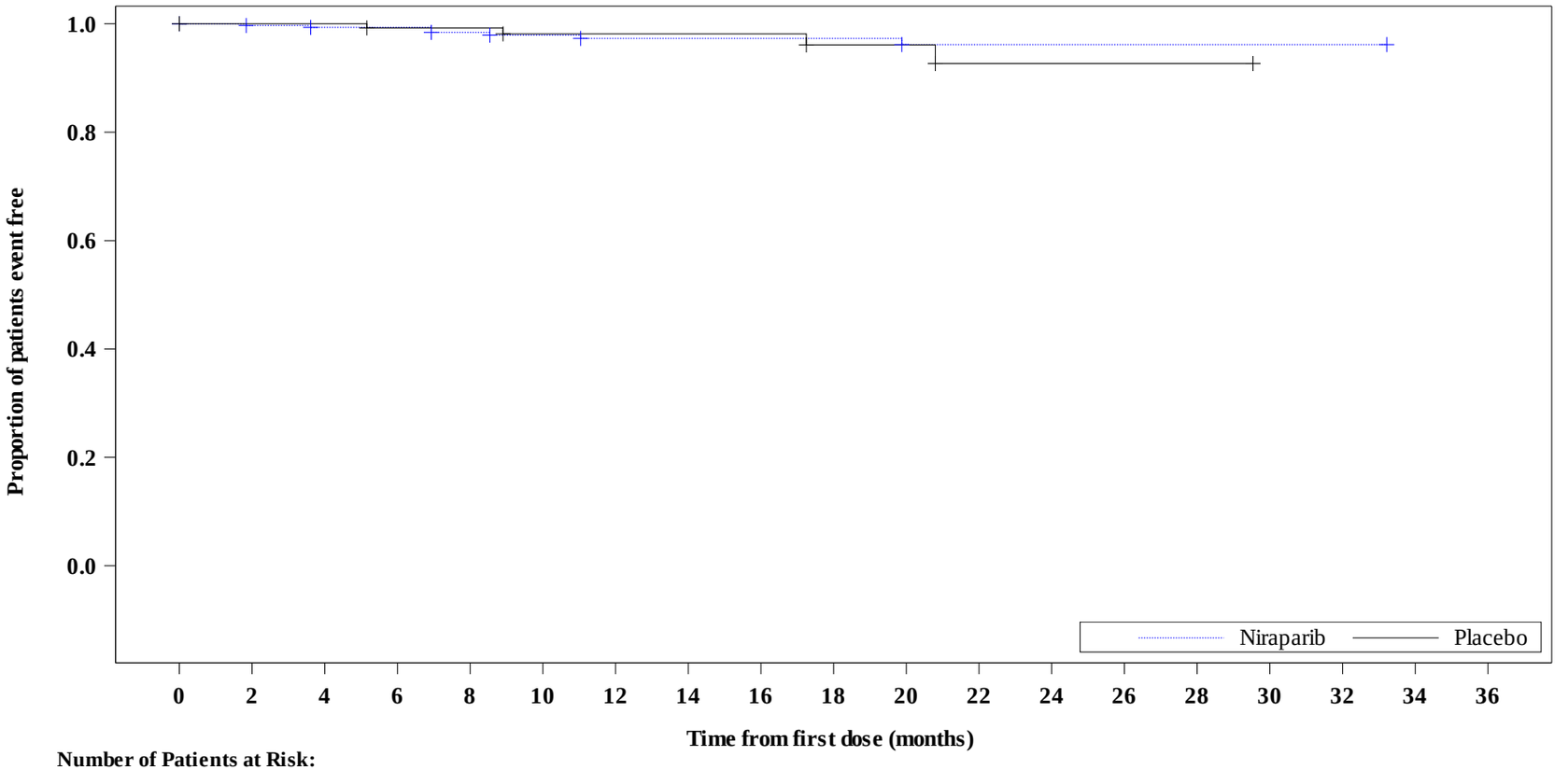



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 309 | 263 | 234 | 193 | 169 | 162 | 149 | 124 | 113 | 83 | 58 | 39 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Infections and infestations

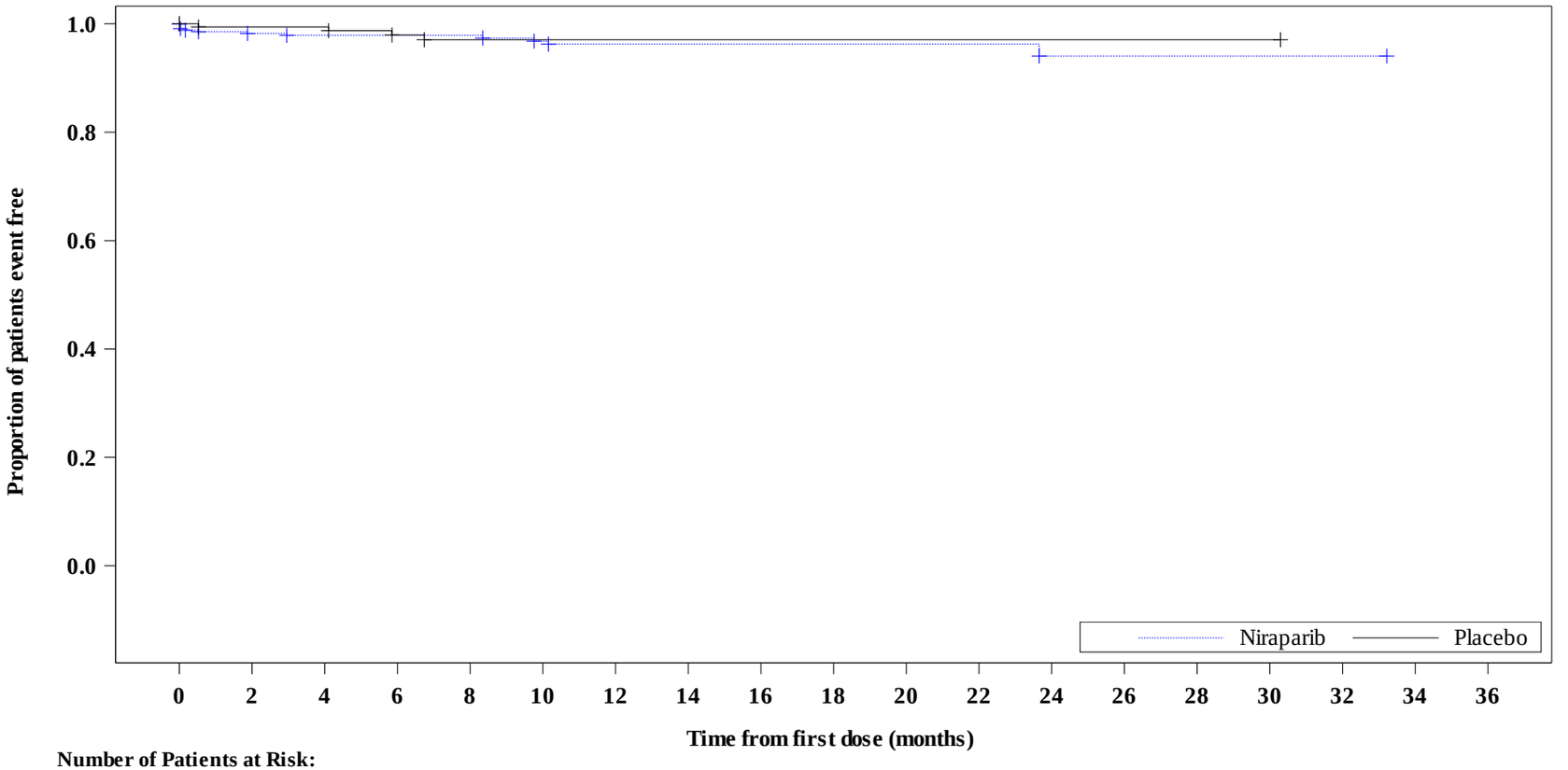



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 263 | 237 | 194 | 169 | 160 | 148 | 123 | 112 | 82 | 57 | 40 | 19 | 9 | 2 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 127 | 102 | 77 | 69 | 58 | 49 | 42 | 35 | 17 | 7 | 4 | 1 | 0 | | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Injury, poisoning and procedural complications

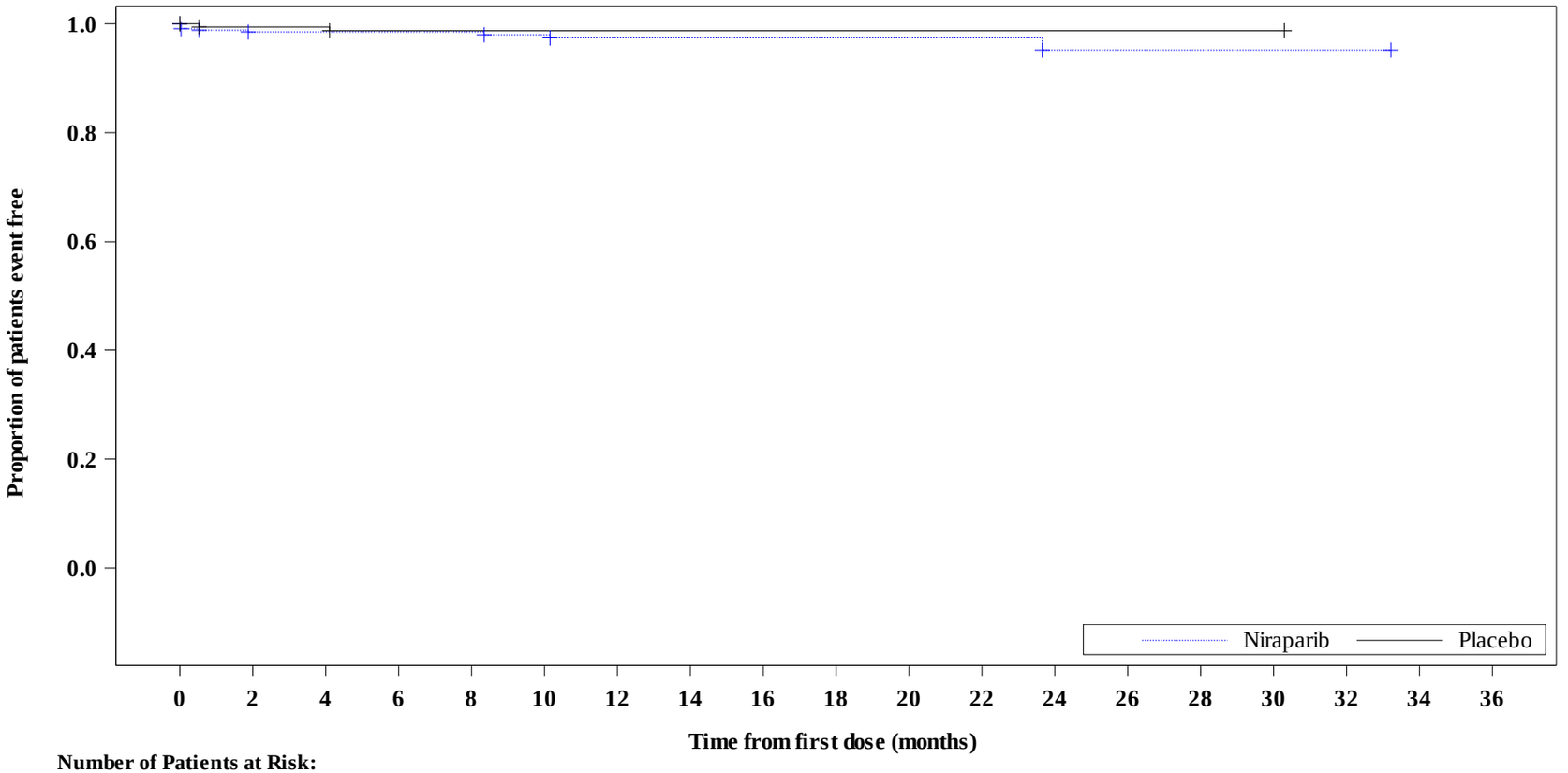



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 305 | 259 | 235 | 195 | 170 | 162 | 149 | 124 | 113 | 85 | 60 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 125 | 99 | 75 | 68 | 57 | 48 | 41 | 35 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Injury, poisoning and procedural complications, PT: Overdose

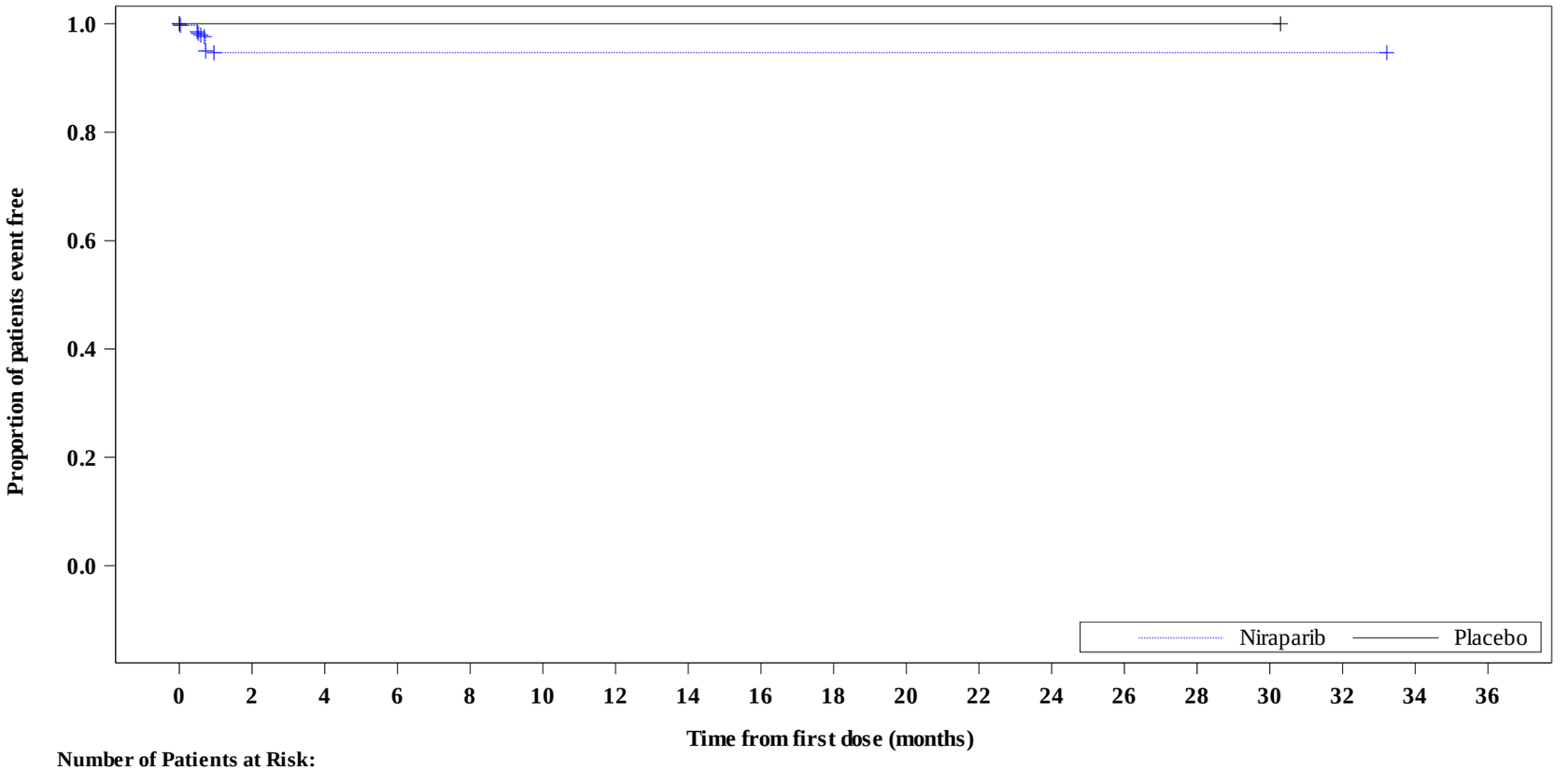



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 306 | 260 | 235 | 195 | 171 | 163 | 150 | 125 | 114 | 86 | 60 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 101 | 77 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Investigations

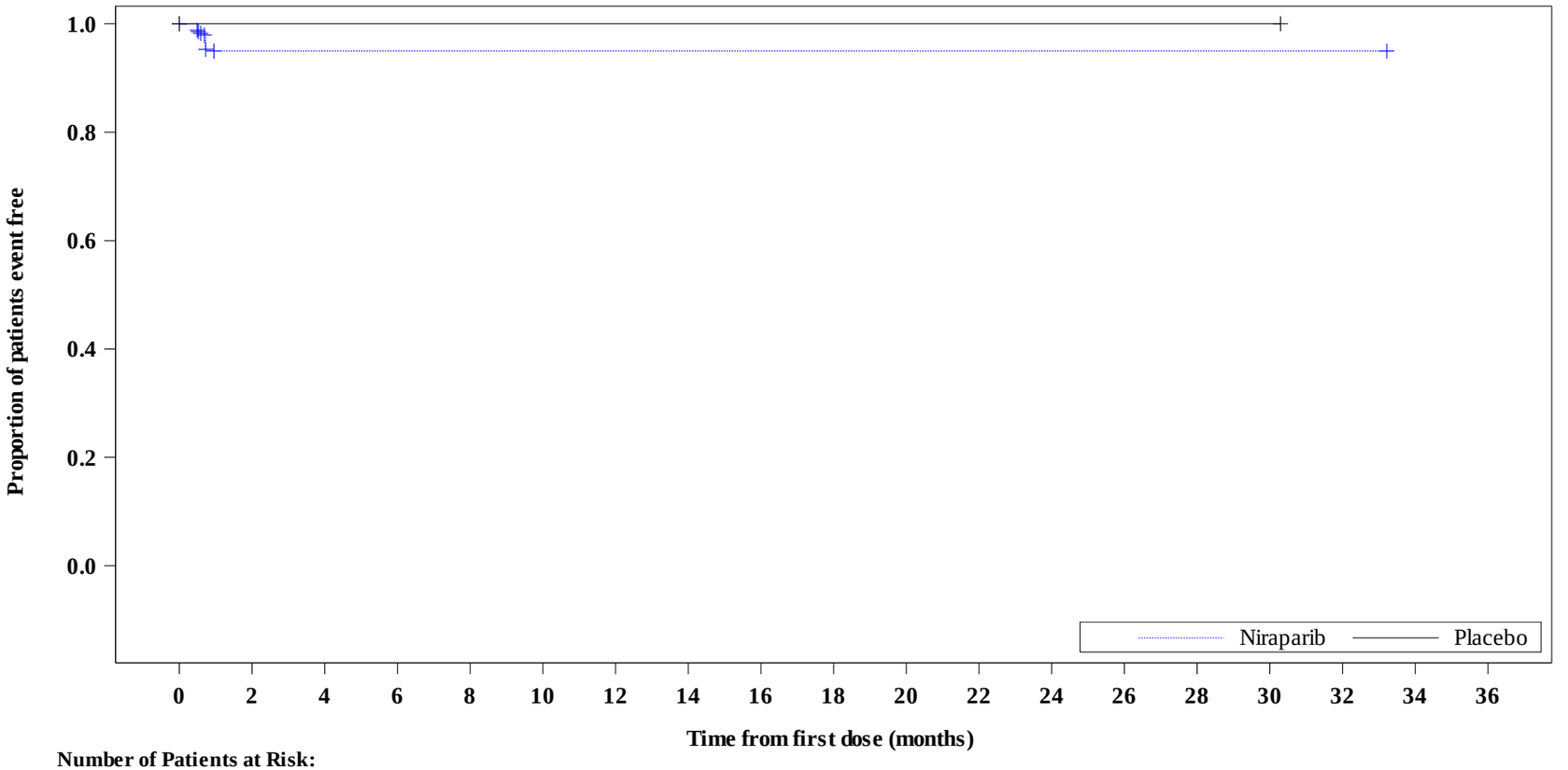



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 294 | 256 | 232 | 192 | 169 | 161 | 148 | 125 | 115 | 85 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Investigations, PT: Platelet count decreased

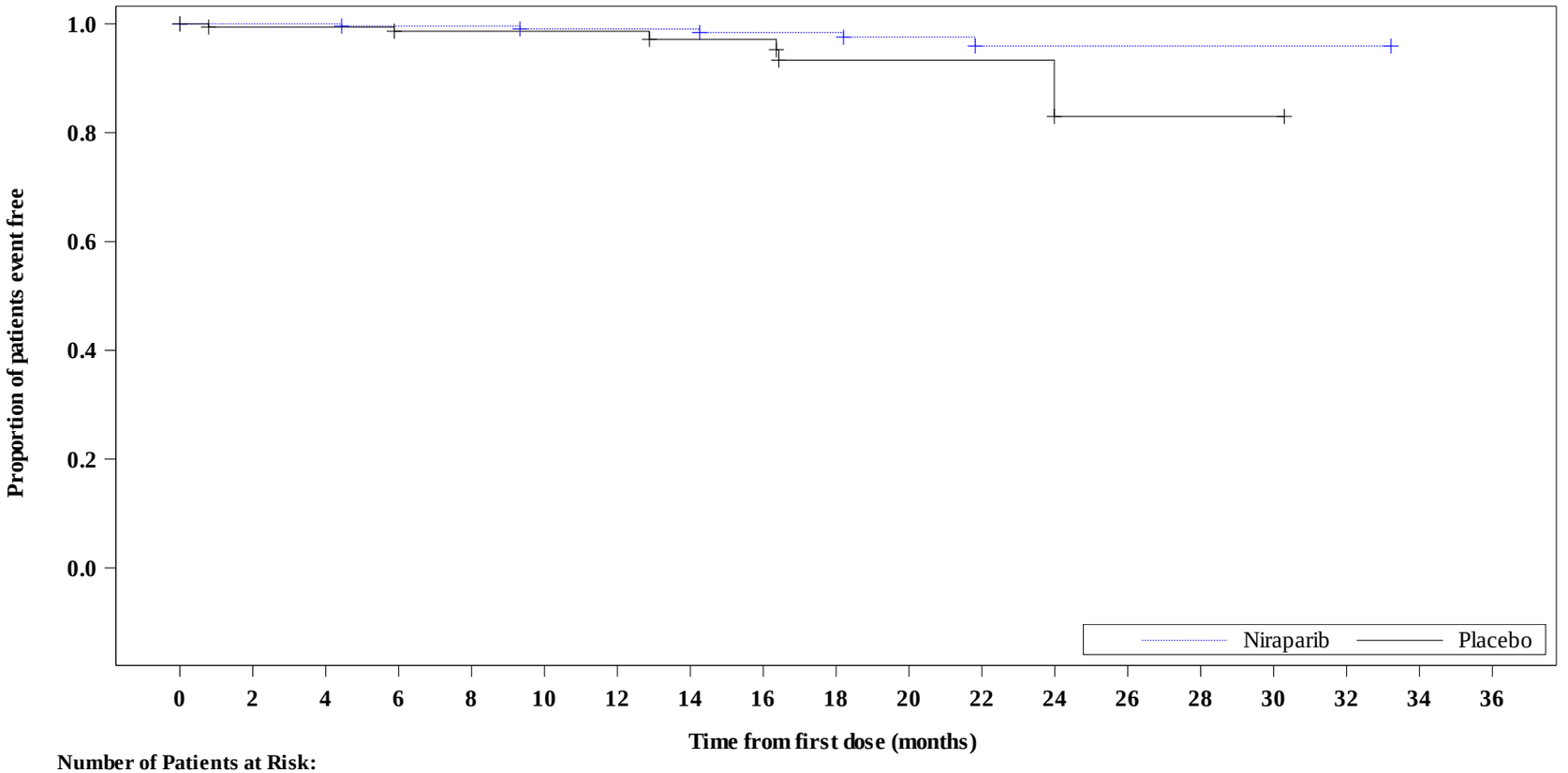



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 295 | 257 | 233 | 192 | 169 | 161 | 148 | 125 | 115 | 85 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.154a

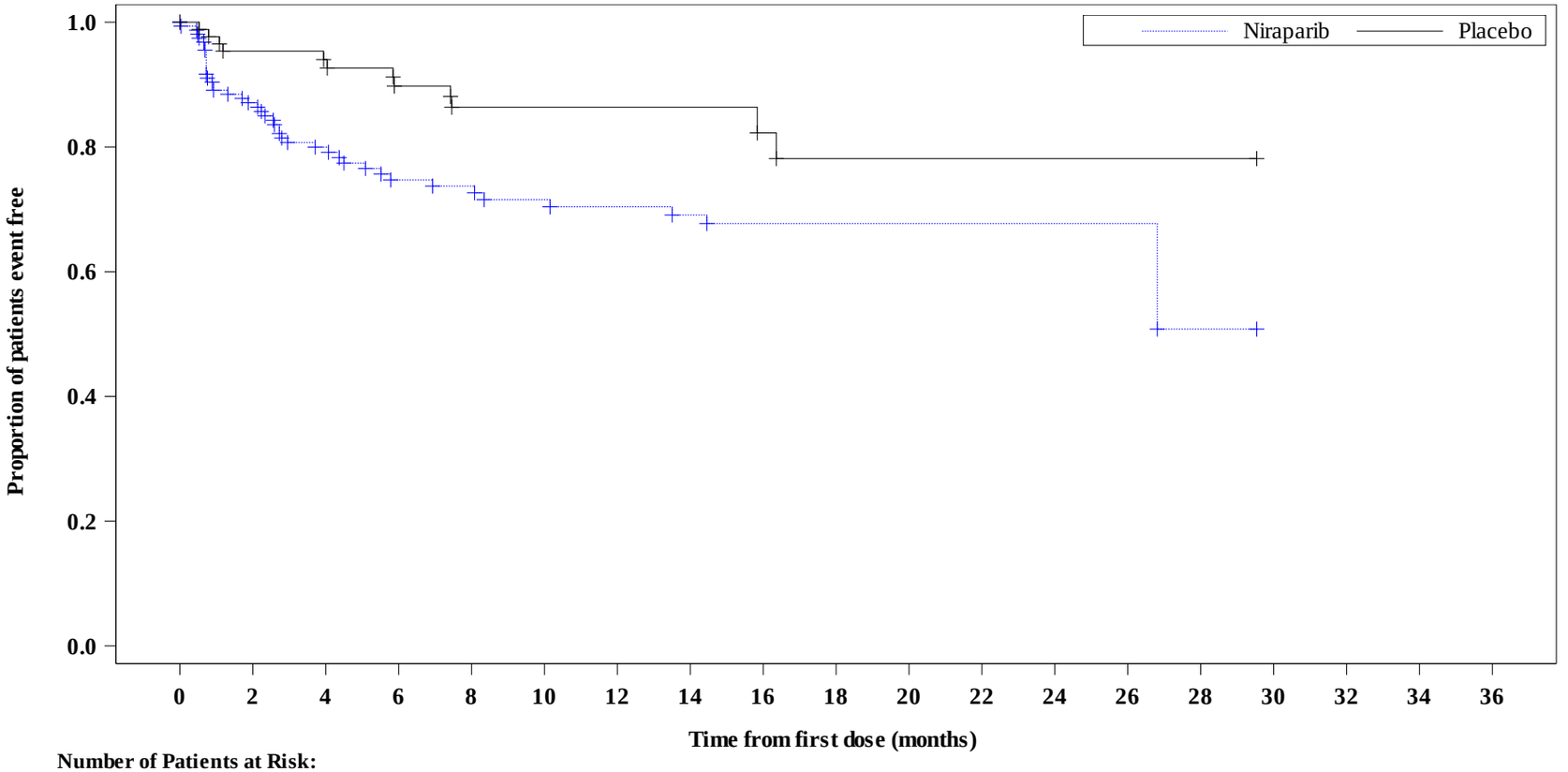
Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety Population)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 78 | 70 | 59 | 51 | 44 | 37 | 20 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.155a
Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events
(Residual Disease Safety-GVD Population)

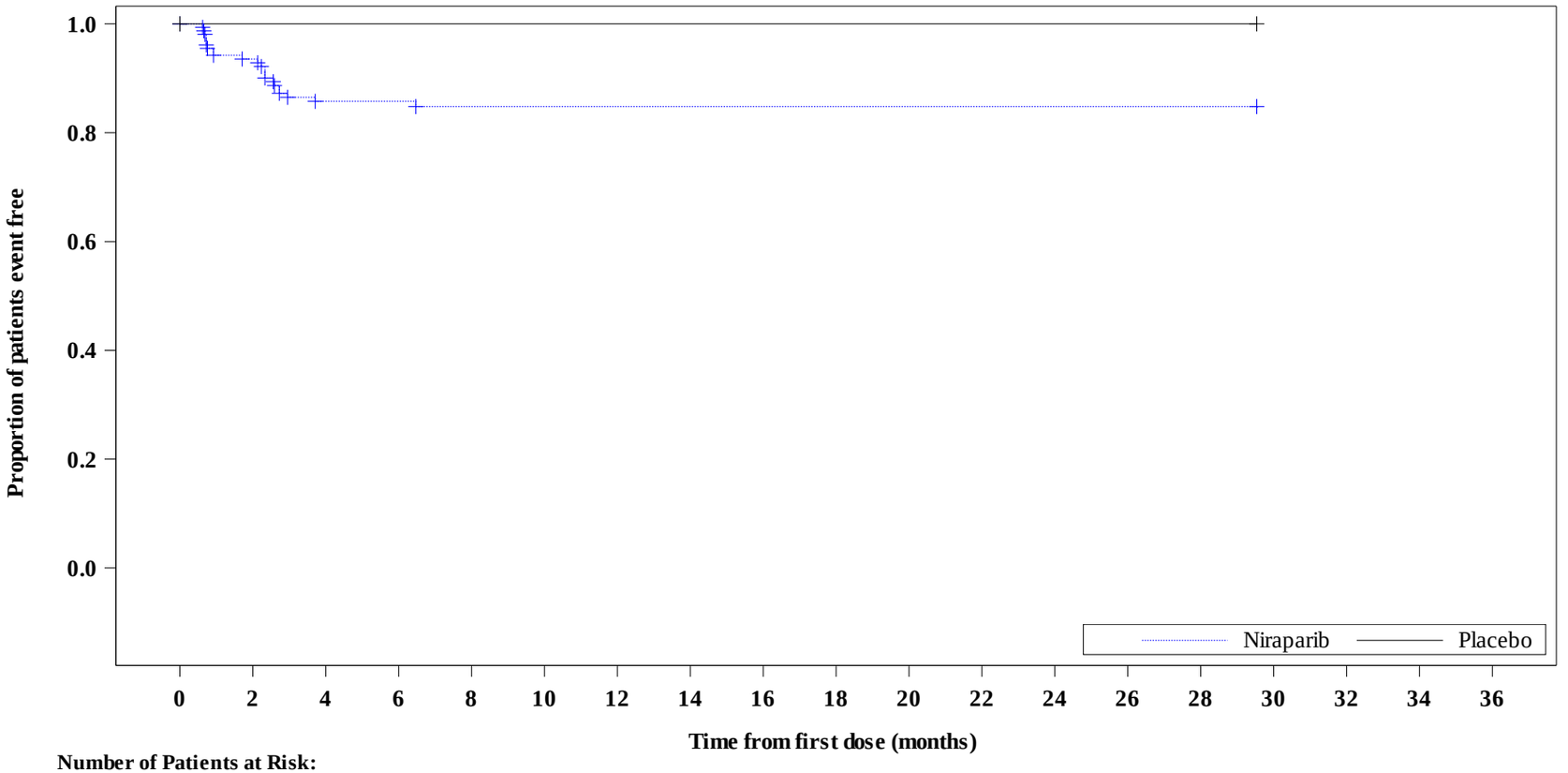



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 125 | 97 | 81 | 68 | 62 | 58 | 51 | 42 | 37 | 23 | 11 | 8 | 5 | 1 | 0 |
| Placebo | 86 | 80 | 70 | 62 | 49 | 37 | 32 | 26 | 20 | 16 | 12 | 5 | 3 | 2 | 1 | 0 |

Figure 3.156a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)
SOC: Blood and lymphatic system disorders

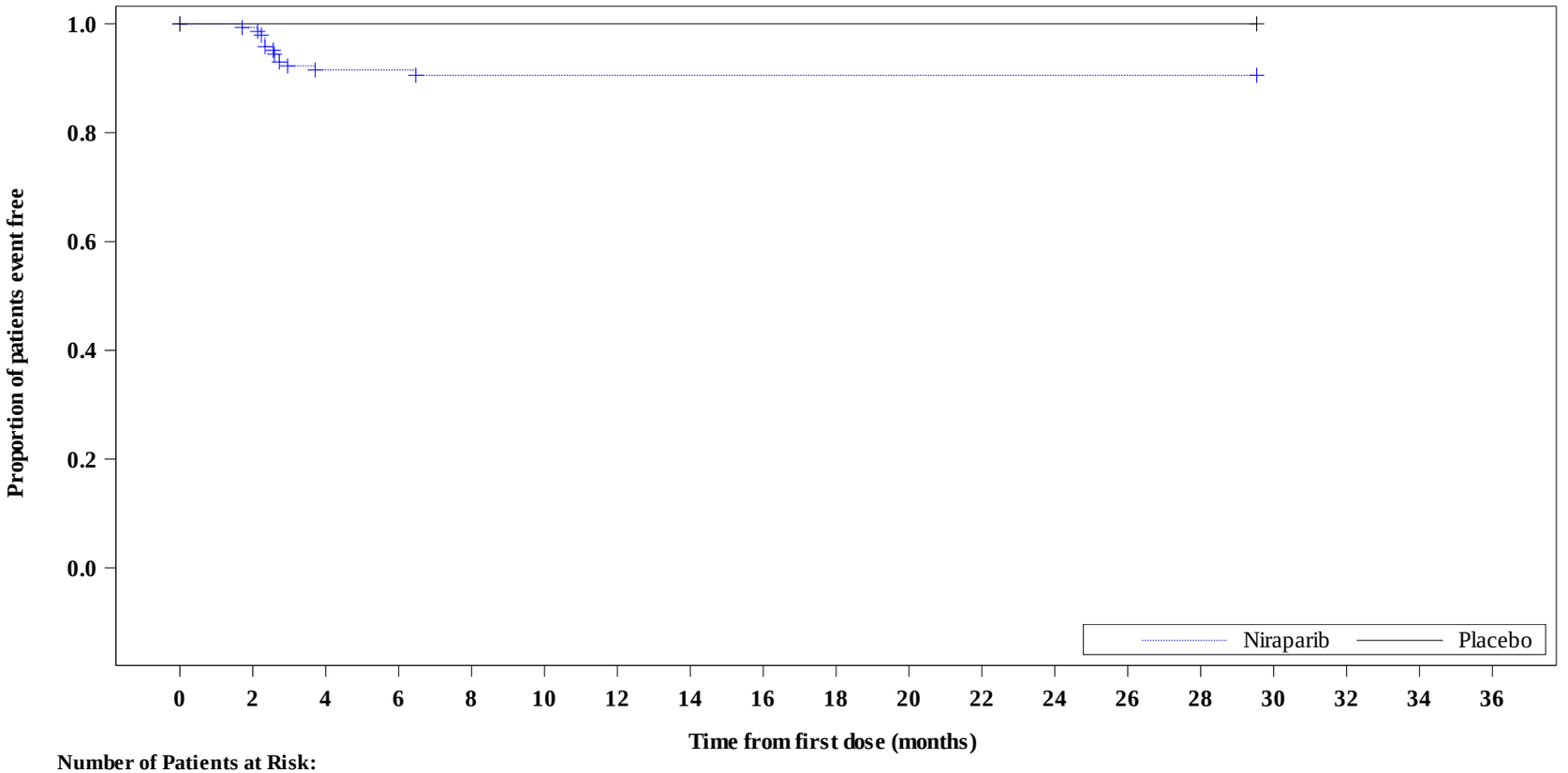



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 135 | 102 | 91 | 72 | 64 | 60 | 54 | 44 | 39 | 25 | 12 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.156a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)
SOC: Blood and lymphatic system disorders, PT: Anaemia



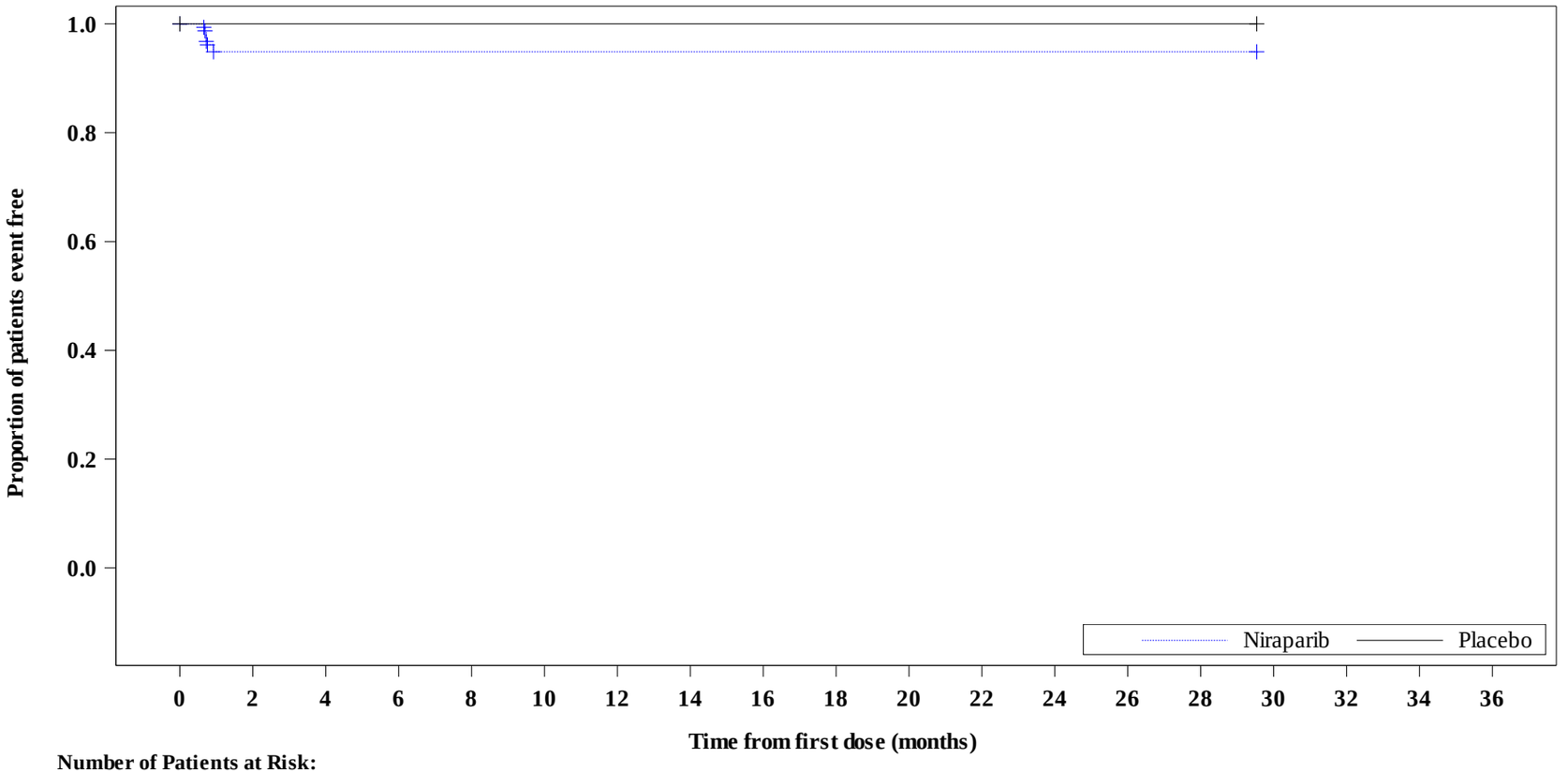

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 143 | 109 | 98 | 78 | 69 | 65 | 59 | 48 | 43 | 27 | 13 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-156a-teaept-rdg.sas 06OCT2020 11:40

Figure 3.156a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)
SOC: Blood and lymphatic system disorders, PT: Thrombocytopenia

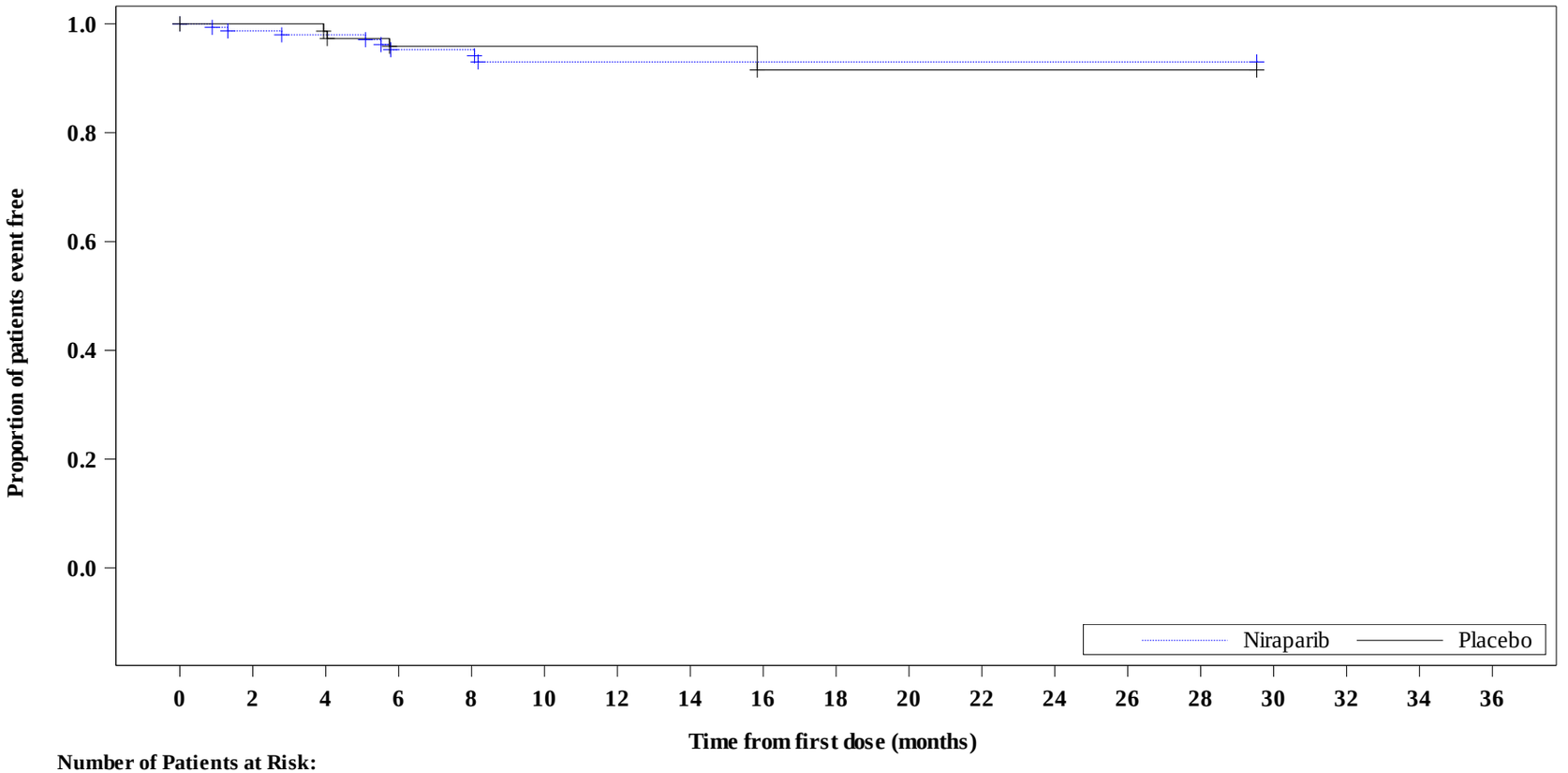



**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 137 | 111 | 100 | 81 | 73 | 69 | 62 | 51 | 45 | 28 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.156a

Time to Onset of First Occurrence of Non-Fatal Serious Treatment-Emergent Adverse Events Experienced by (>= 5% of Patients in any study arm) or (in at least 10 patients overall AND in at least 1% of patients in any study arm) by SOC/PT
(Residual Disease Safety-GVD Population)
SOC: Gastrointestinal disorders




**Number of Patients at Risk:**

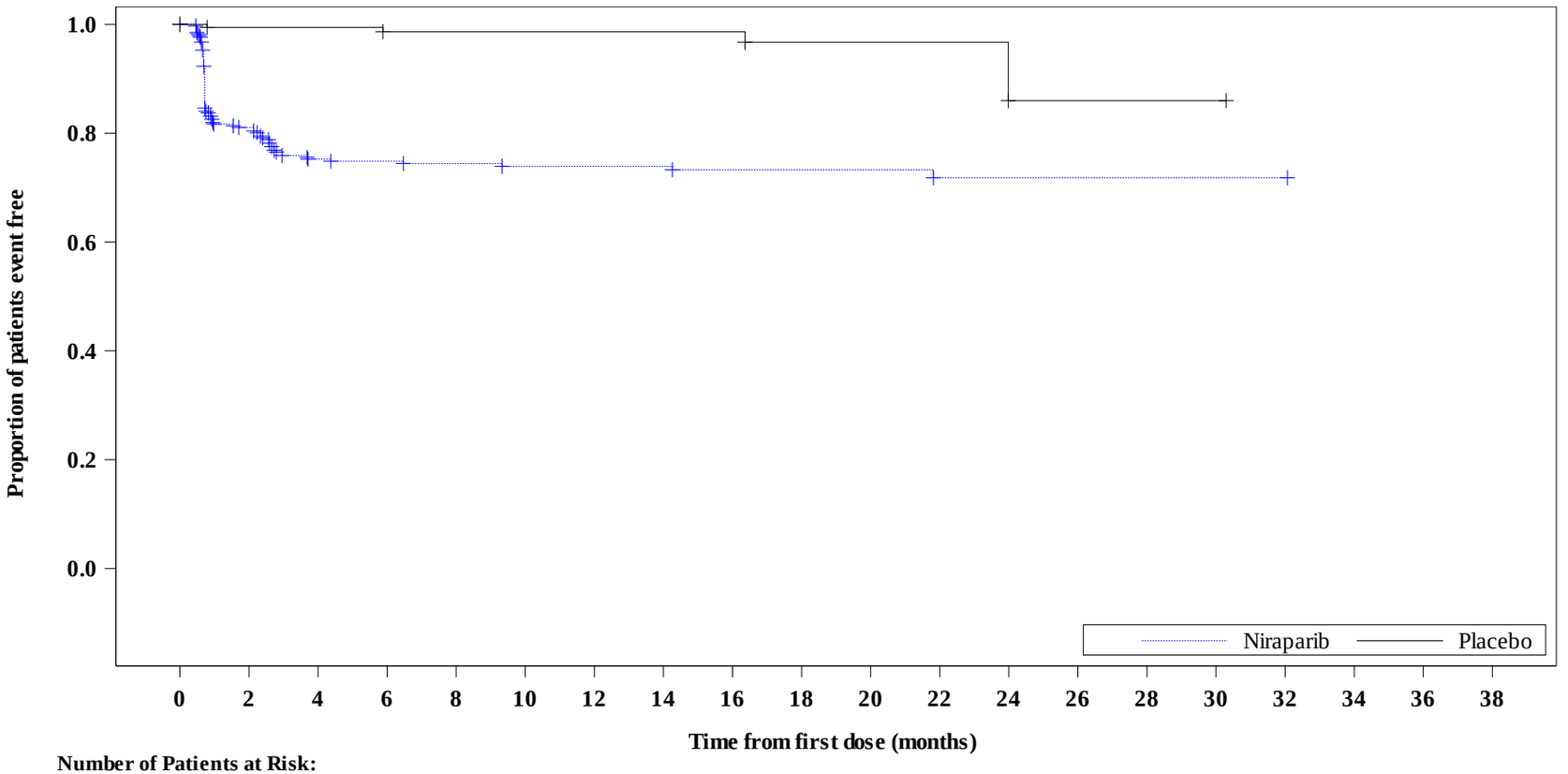
| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 116 | 102 | 85 | 77 | 73 | 66 | 54 | 48 | 29 | 14 | 8 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 74 | 67 | 55 | 41 | 35 | 27 | 21 | 17 | 13 | 5 | 3 | 2 | 1 | 0 |

fz255471: T:\Common\Clinical Operations\Programming\Niraparib\5017 (PRIMA)\GVD\Program\Figures\f-3-156a-teaept-rdg.sas 06OCT2020
11:40

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Overall



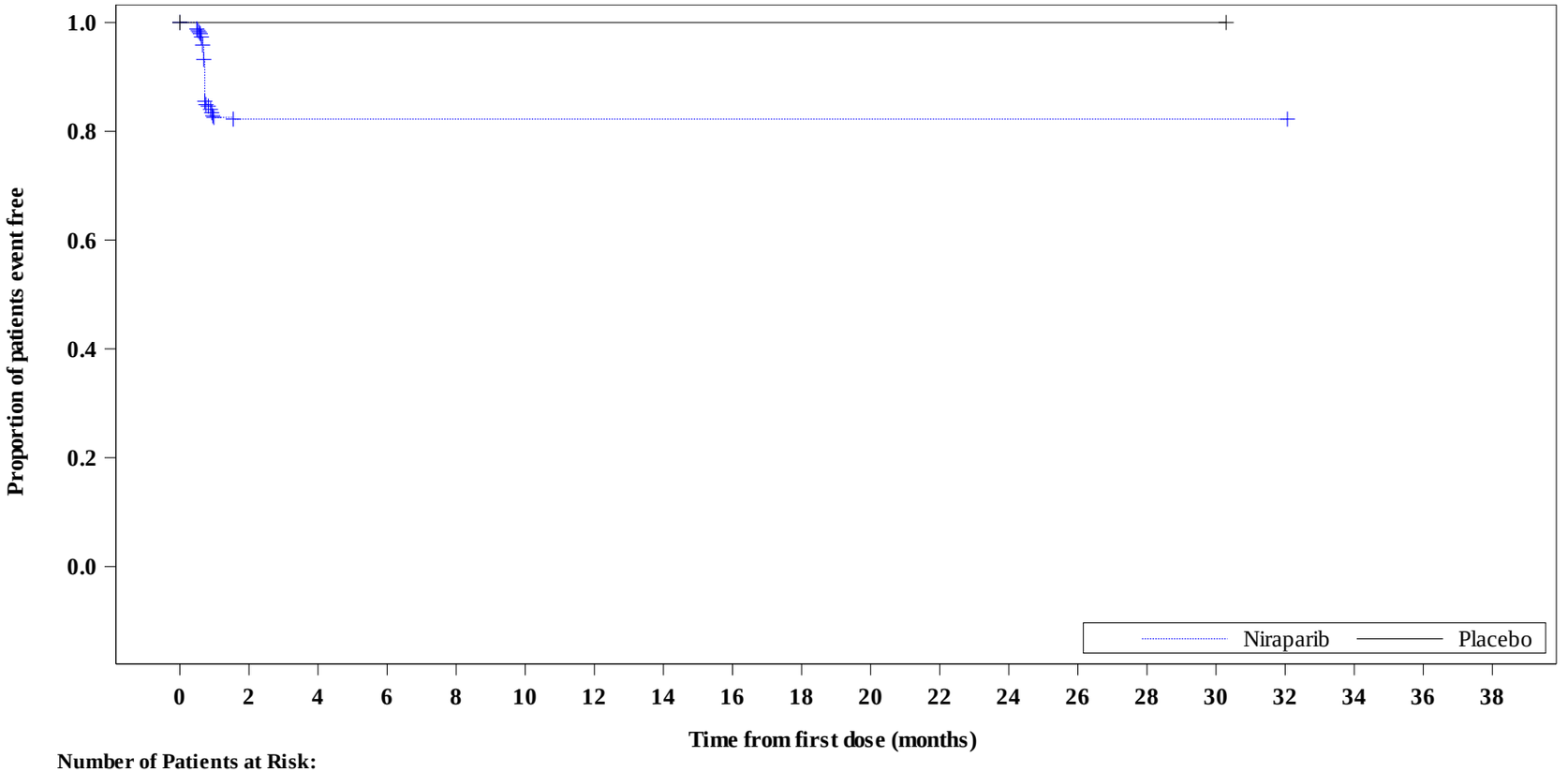

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 255 | 208 | 186 | 155 | 133 | 126 | 118 | 99 | 91 | 68 | 48 | 36 | 17 | 8 | 1 | 1 | 0 |
| Placebo | 175 | 171 | 144 | 127 | 101 | 78 | 70 | 60 | 51 | 44 | 37 | 20 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Thrombocytopenia



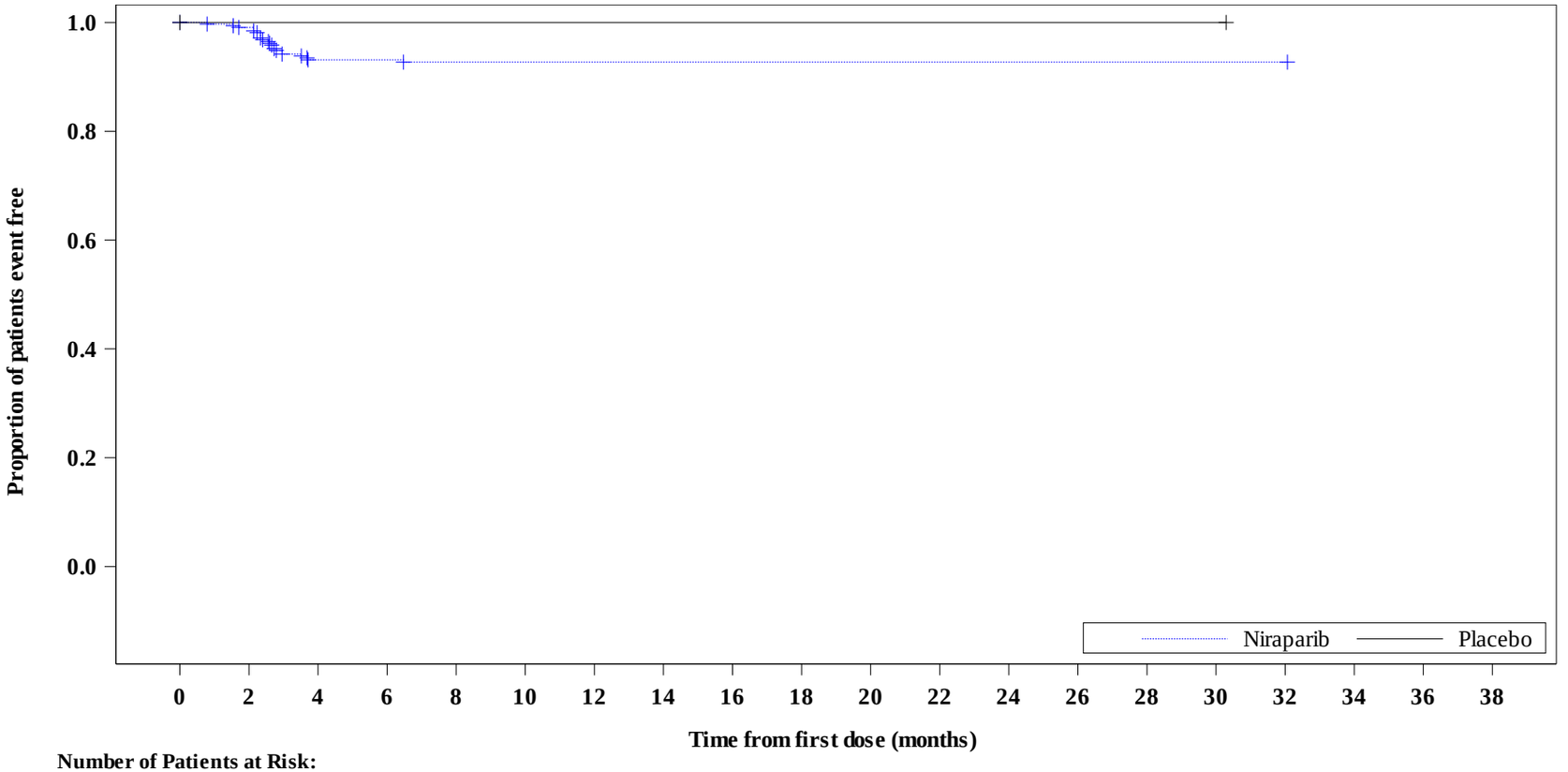

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 259 | 225 | 203 | 169 | 147 | 140 | 129 | 108 | 99 | 72 | 52 | 37 | 17 | 8 | 1 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Anemia



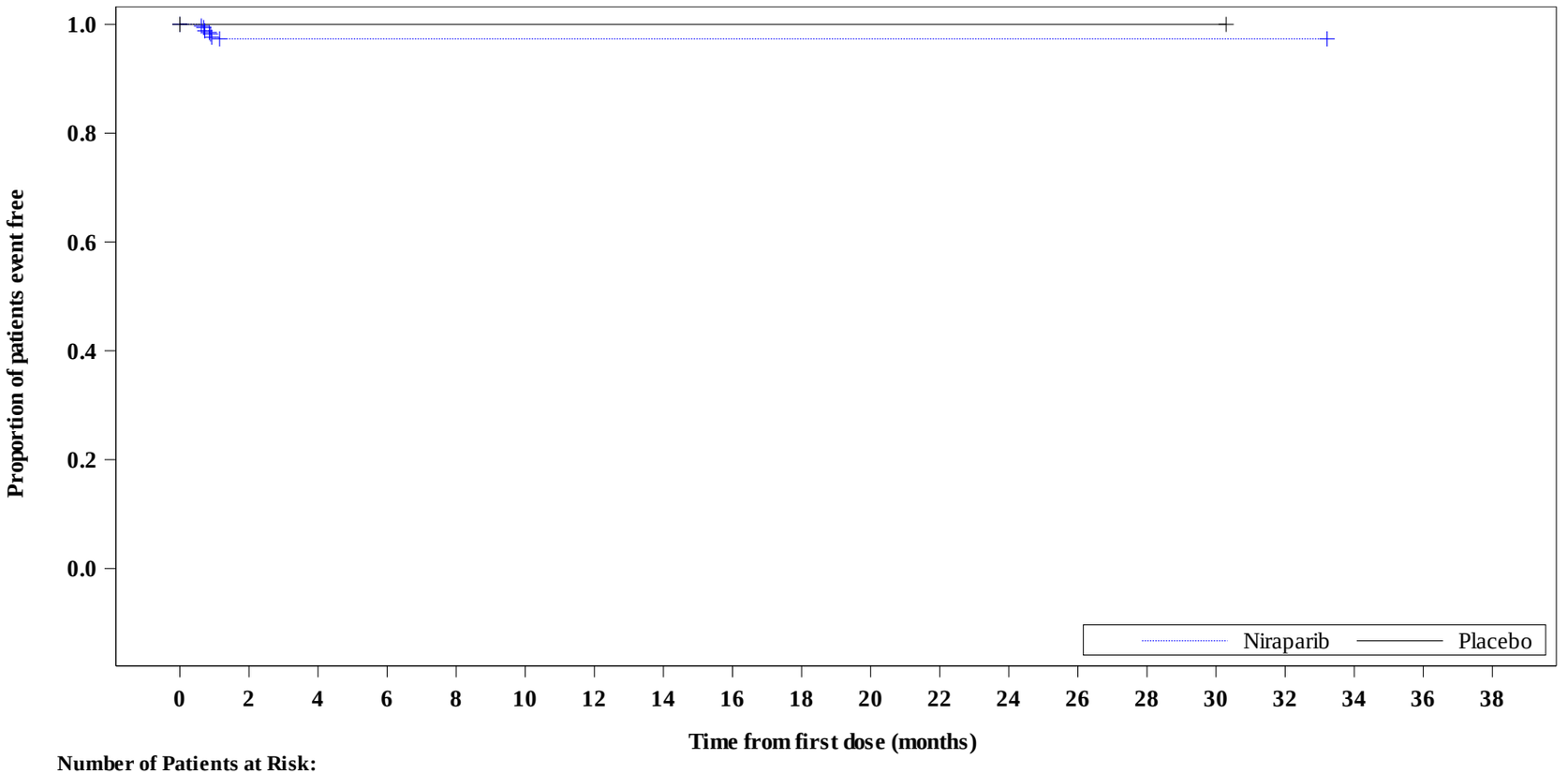

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 308 | 250 | 225 | 184 | 160 | 152 | 141 | 118 | 108 | 81 | 56 | 39 | 19 | 9 | 2 | 1 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Leukopenia



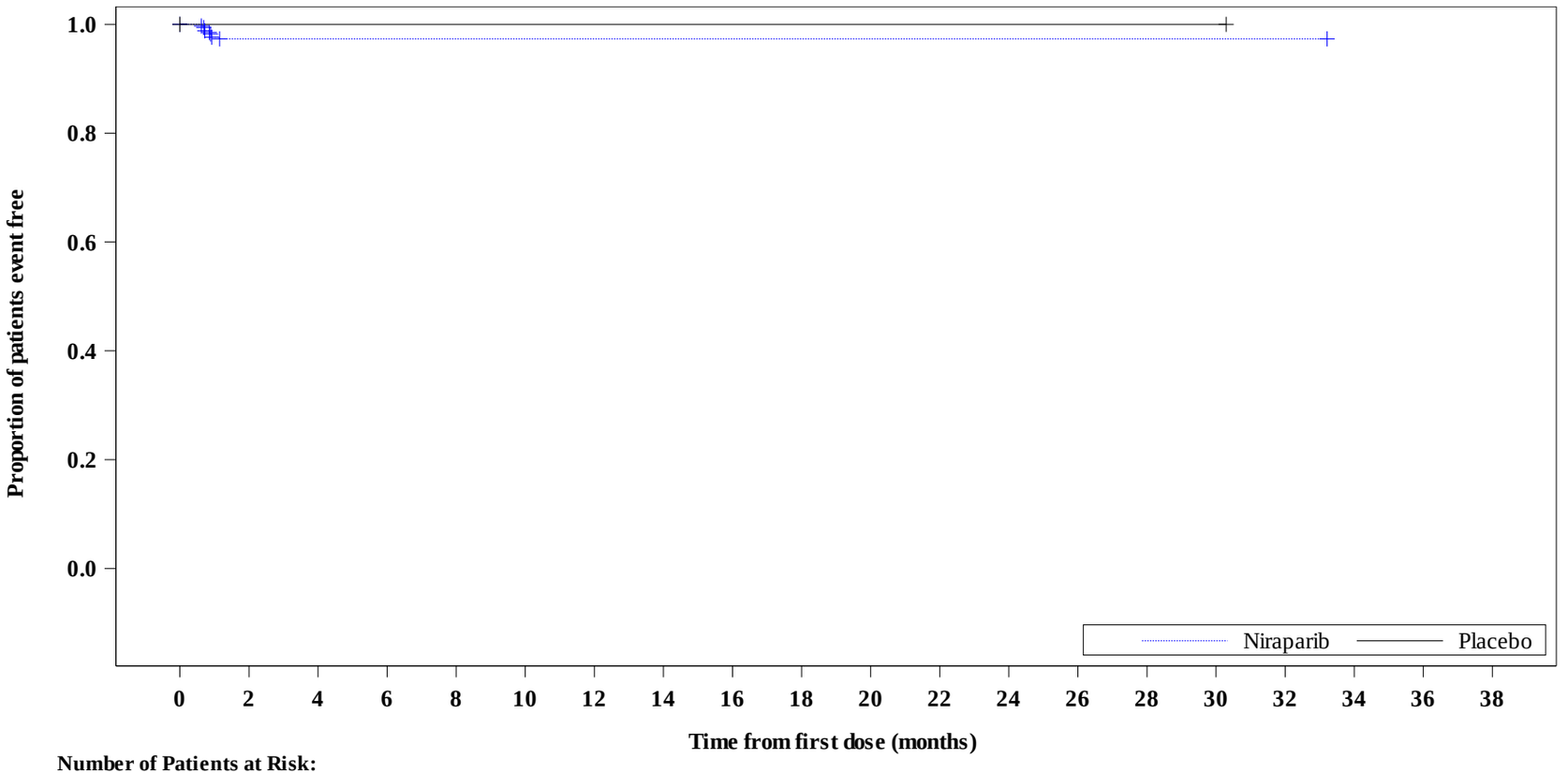

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 302 | 257 | 233 | 194 | 170 | 162 | 149 | 124 | 113 | 85 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Neutropenia



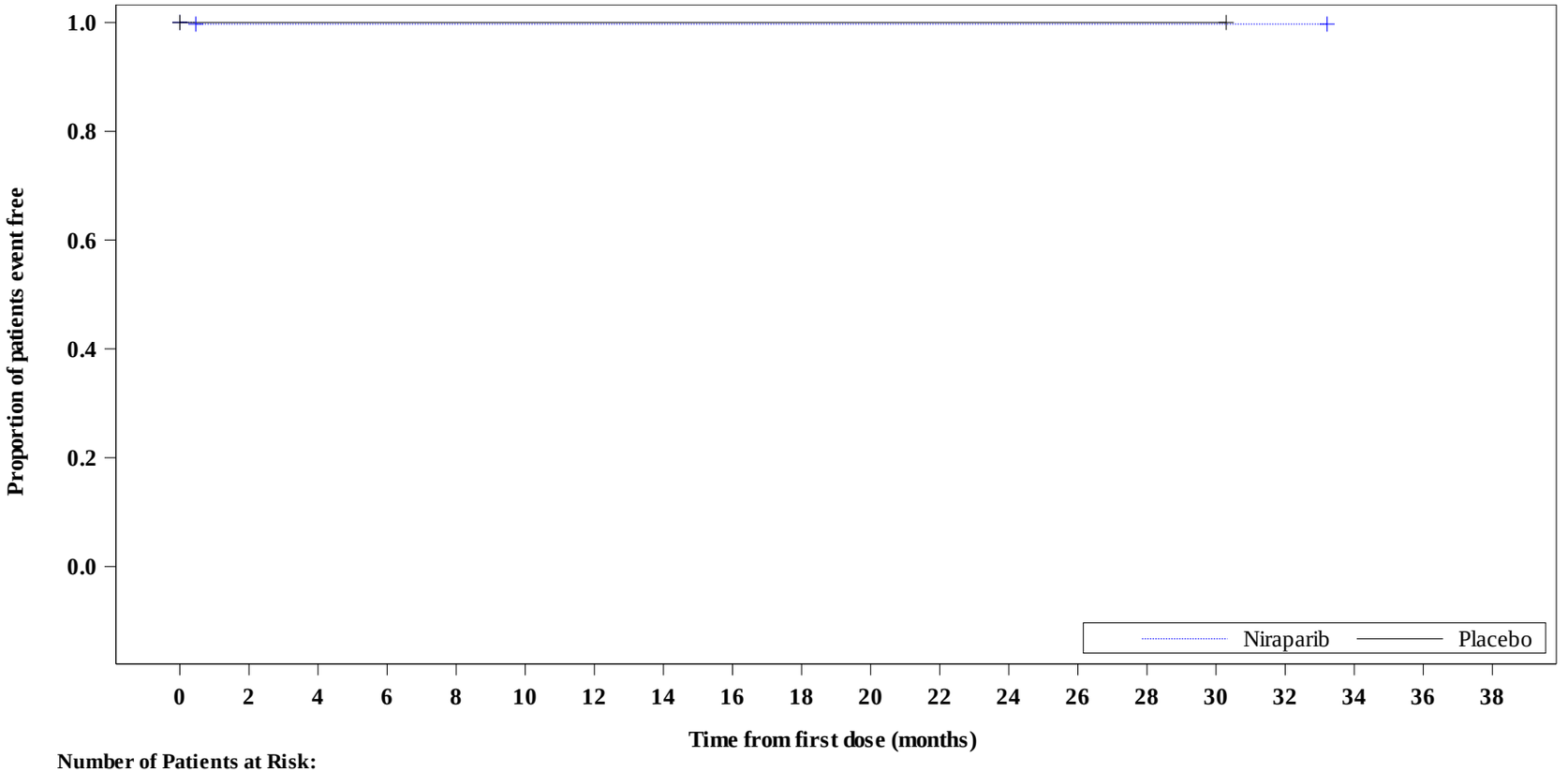

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 302 | 257 | 233 | 194 | 170 | 162 | 149 | 124 | 113 | 85 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Hypertension



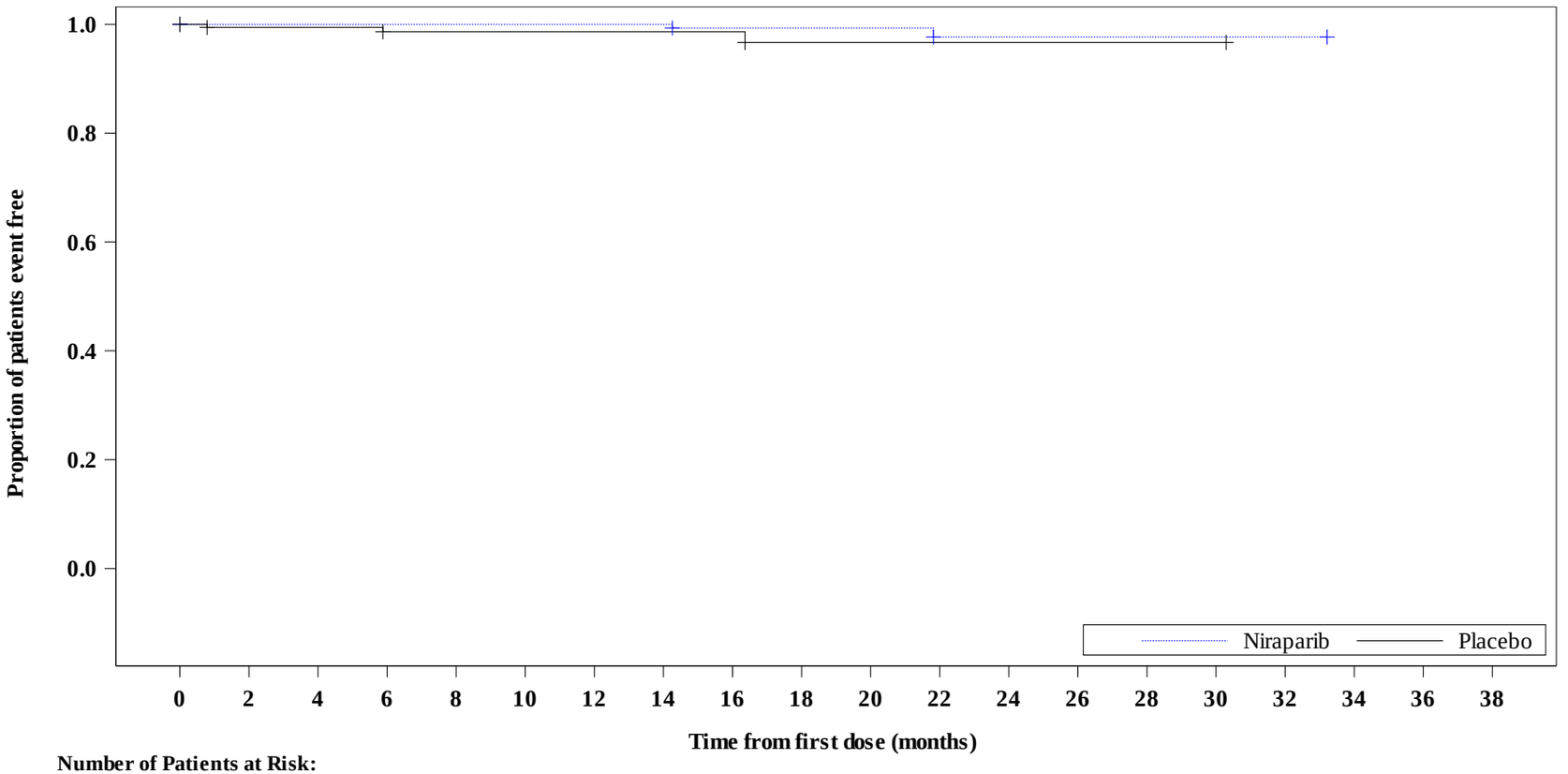

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 264 | 238 | 196 | 172 | 164 | 151 | 126 | 115 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

New malignancies other than MDS/AML



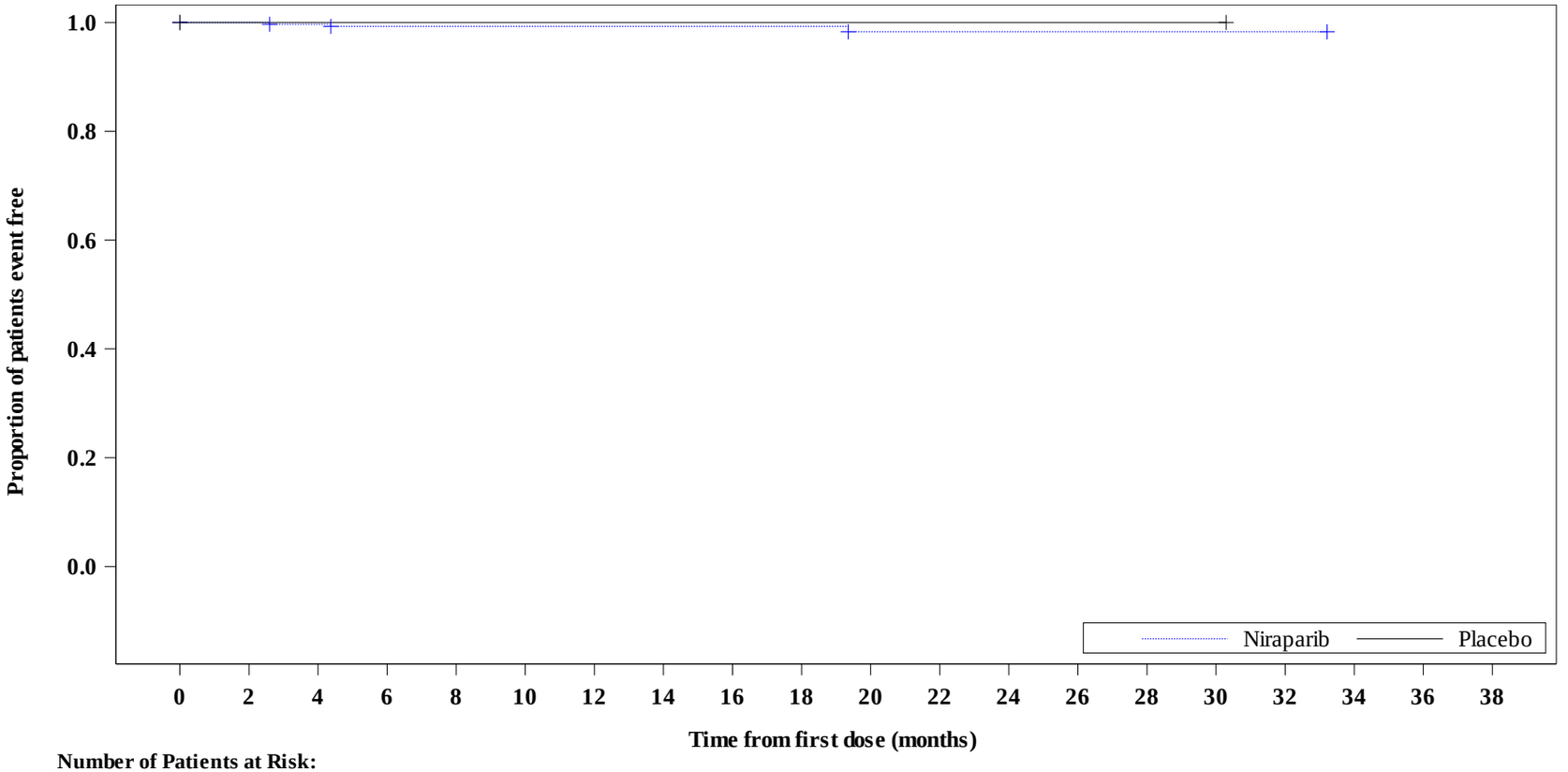

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 171 | 144 | 126 | 100 | 77 | 69 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Pneumonitis



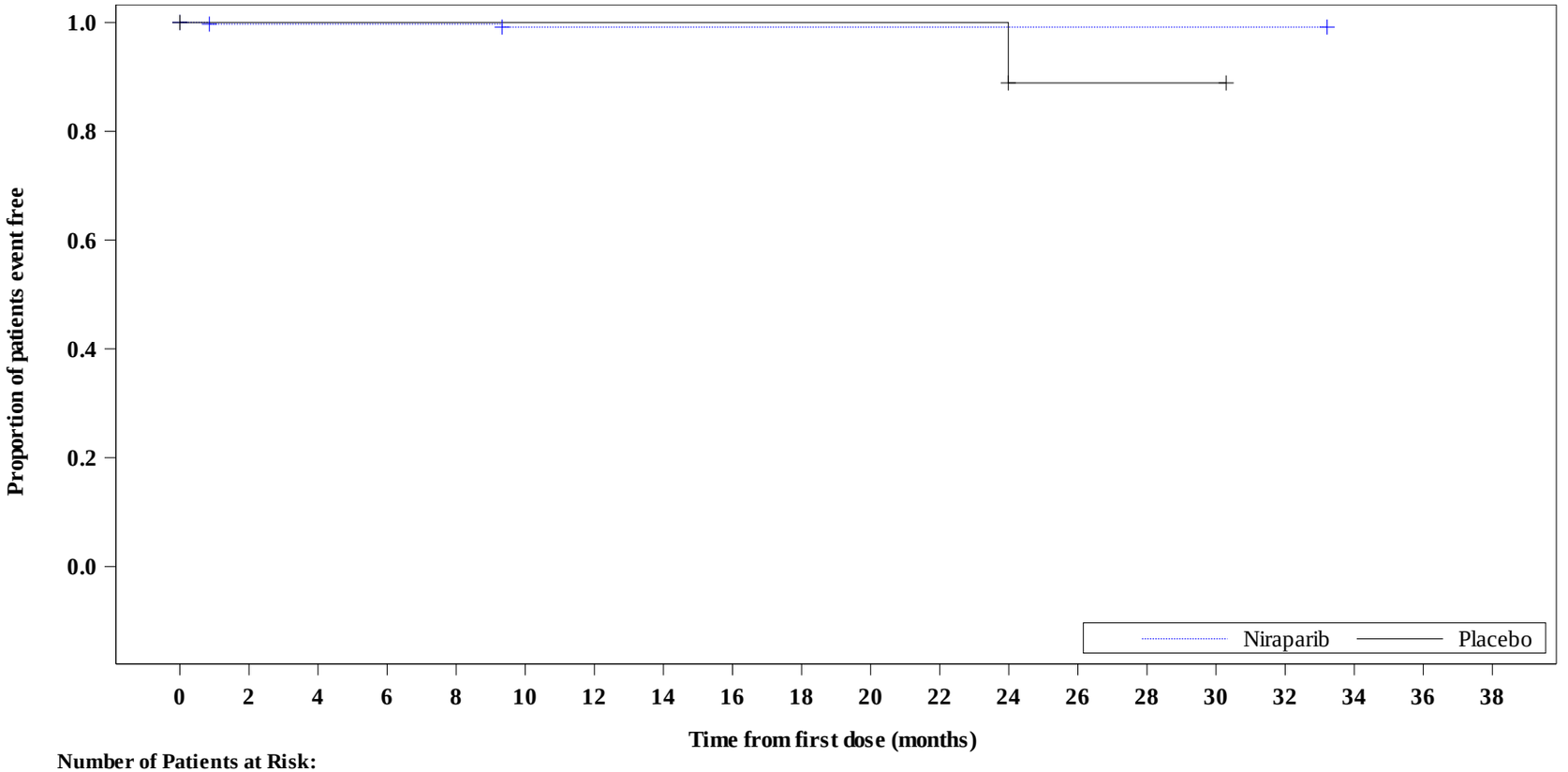

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 238 | 197 | 173 | 165 | 152 | 127 | 116 | 85 | 59 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Pancytopenia



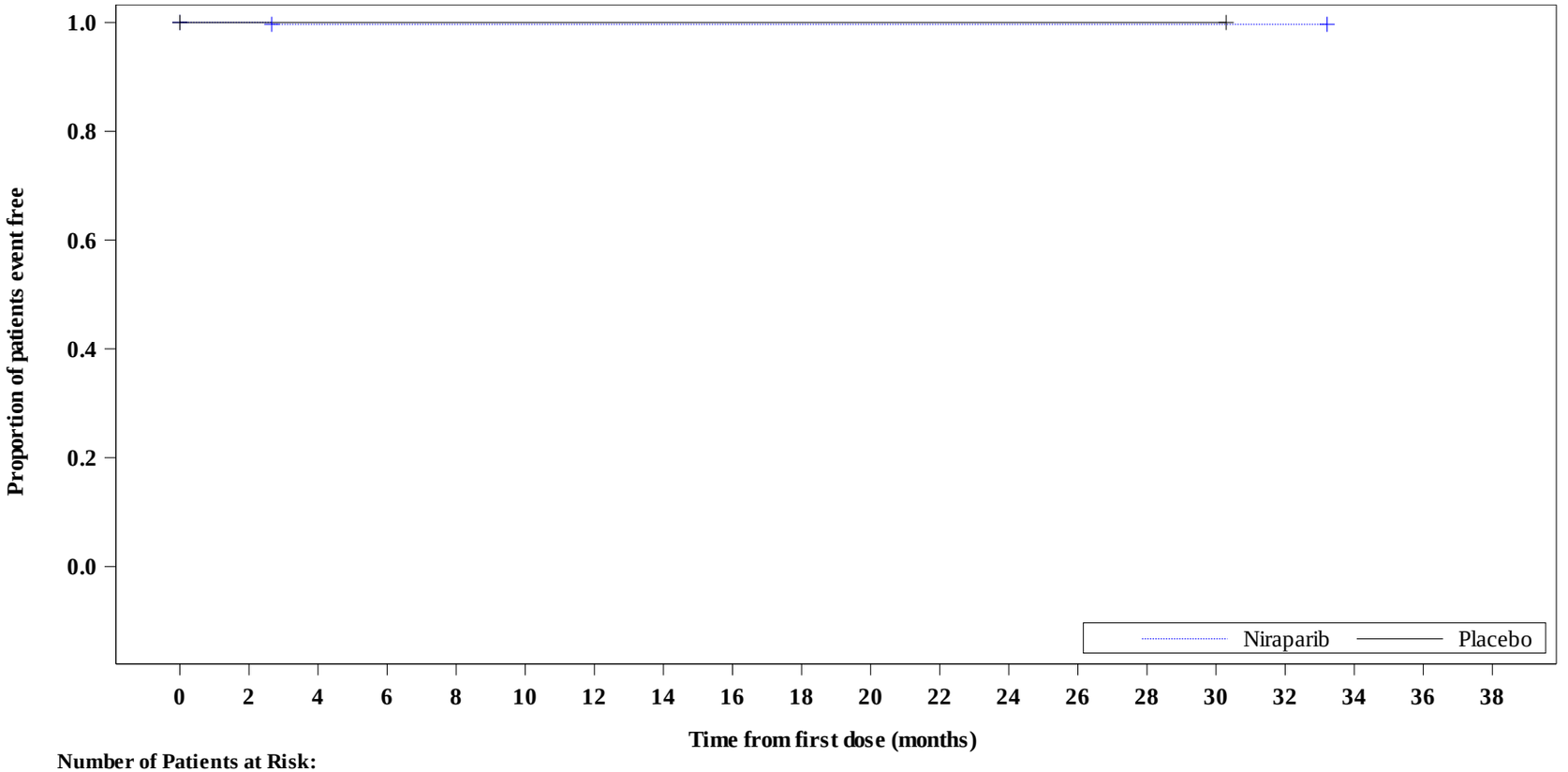

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 310 | 264 | 238 | 196 | 172 | 164 | 151 | 126 | 115 | 85 | 59 | 40 | 19 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 129 | 103 | 79 | 71 | 60 | 51 | 44 | 37 | 20 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Thromboemblic



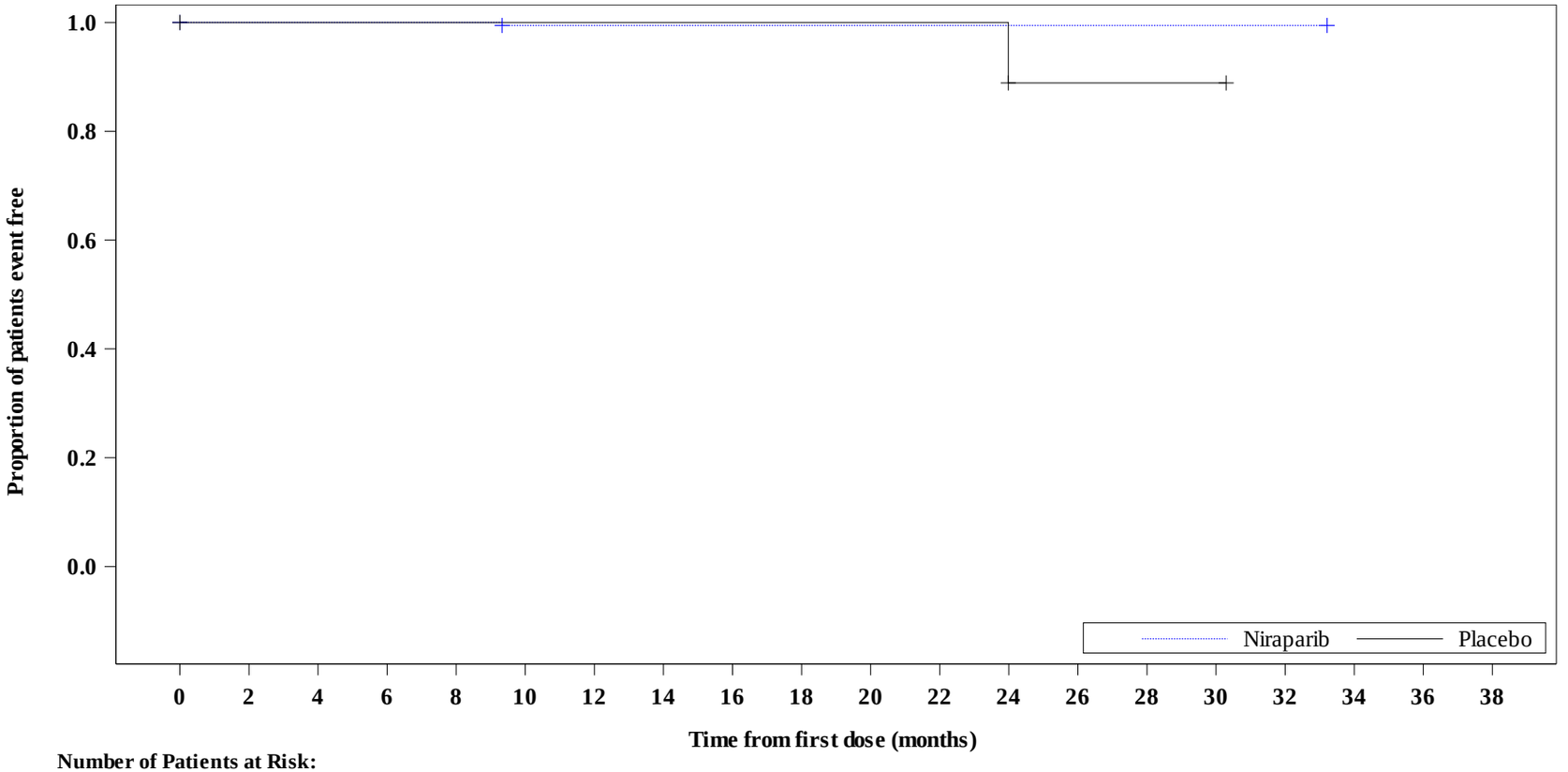

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 264 | 238 | 196 | 172 | 164 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

MDS/AML



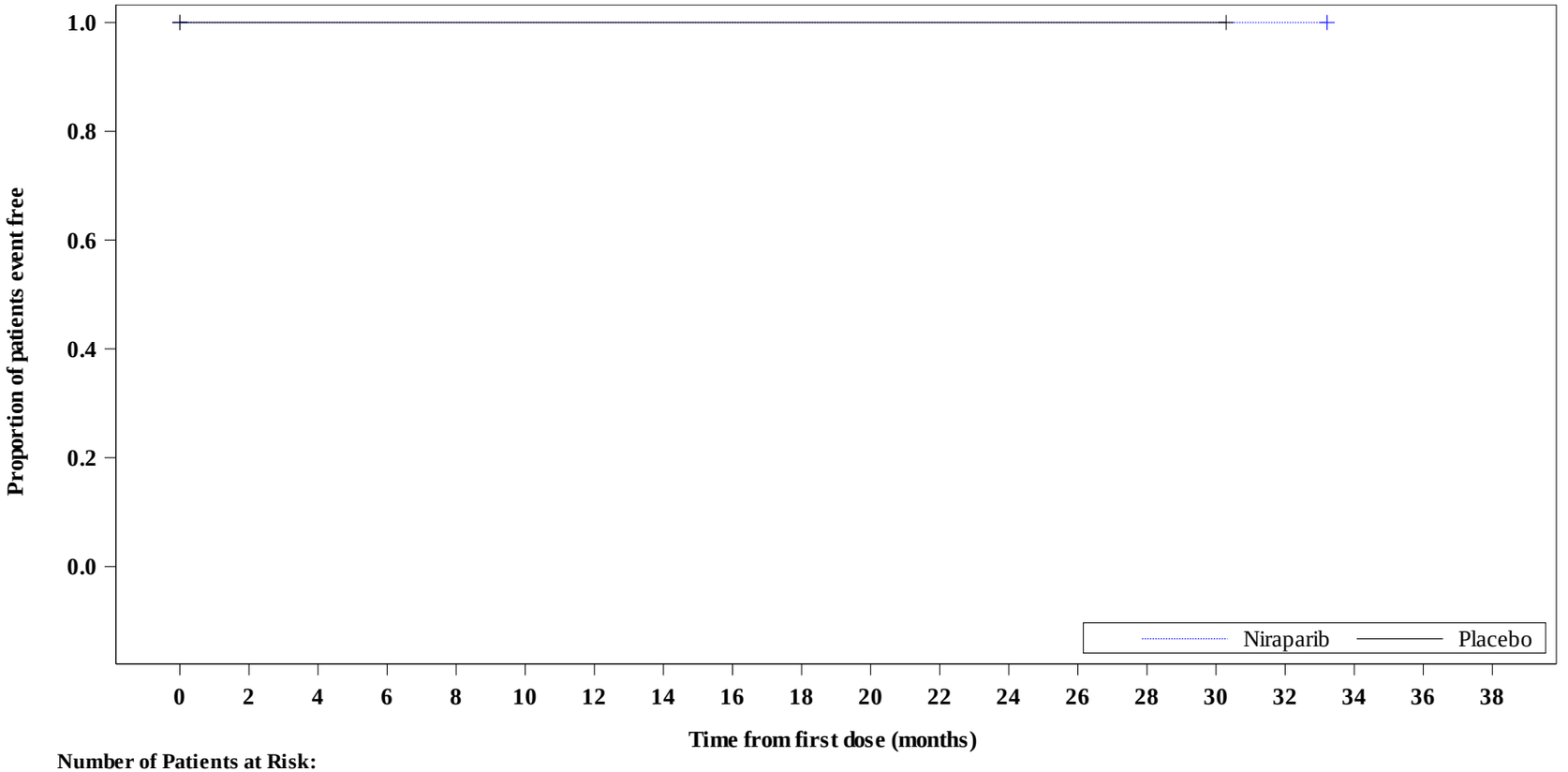

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 129 | 103 | 79 | 71 | 60 | 51 | 44 | 37 | 20 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.157a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety Population)

Embryo-fetal toxicity



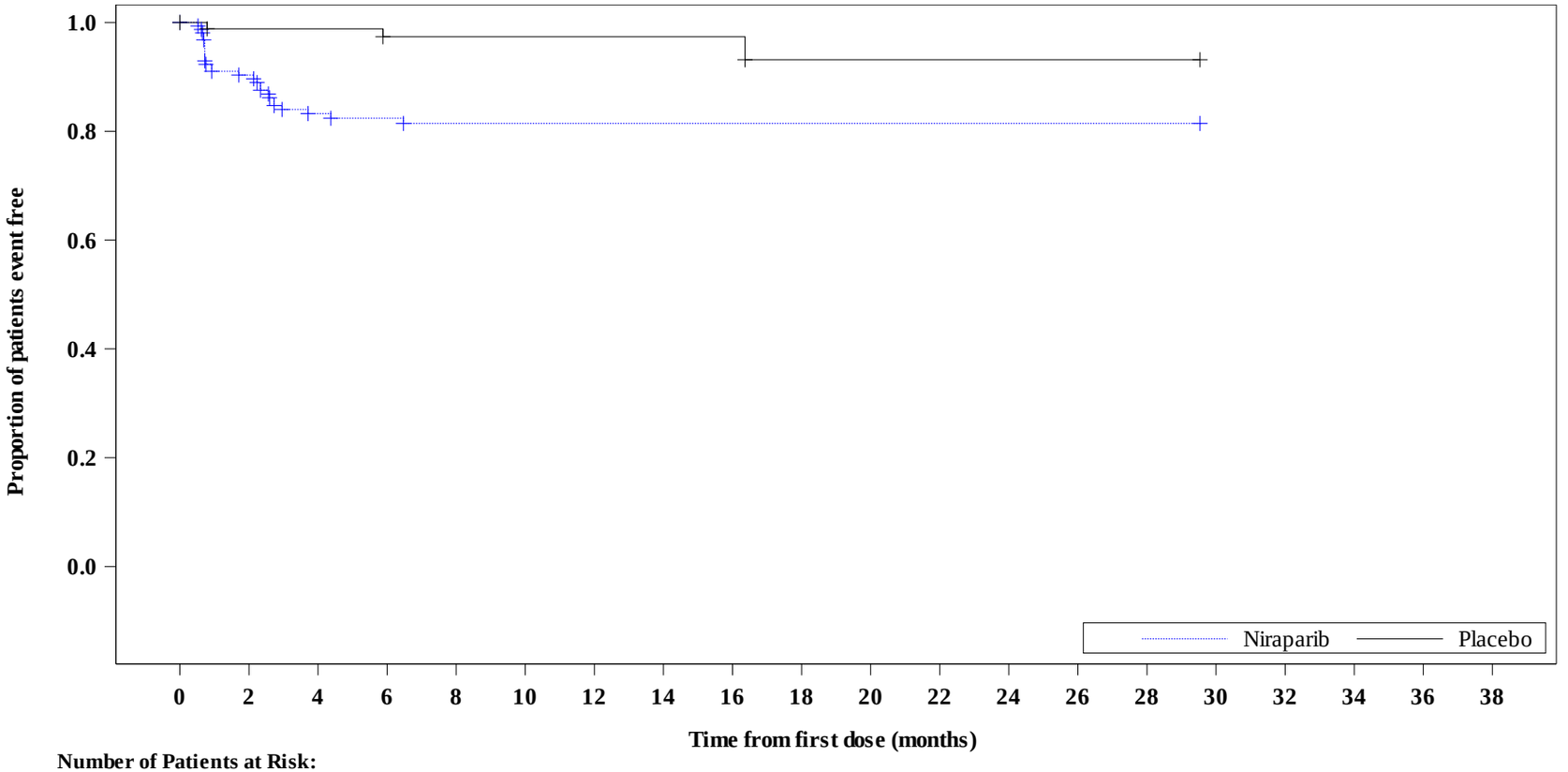

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 338 | 311 | 265 | 239 | 197 | 173 | 165 | 152 | 127 | 116 | 86 | 60 | 41 | 20 | 10 | 3 | 2 | 0 |
| Placebo | 175 | 172 | 145 | 128 | 102 | 78 | 70 | 59 | 50 | 43 | 36 | 19 | 8 | 5 | 2 | 1 | 0 | |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Overall



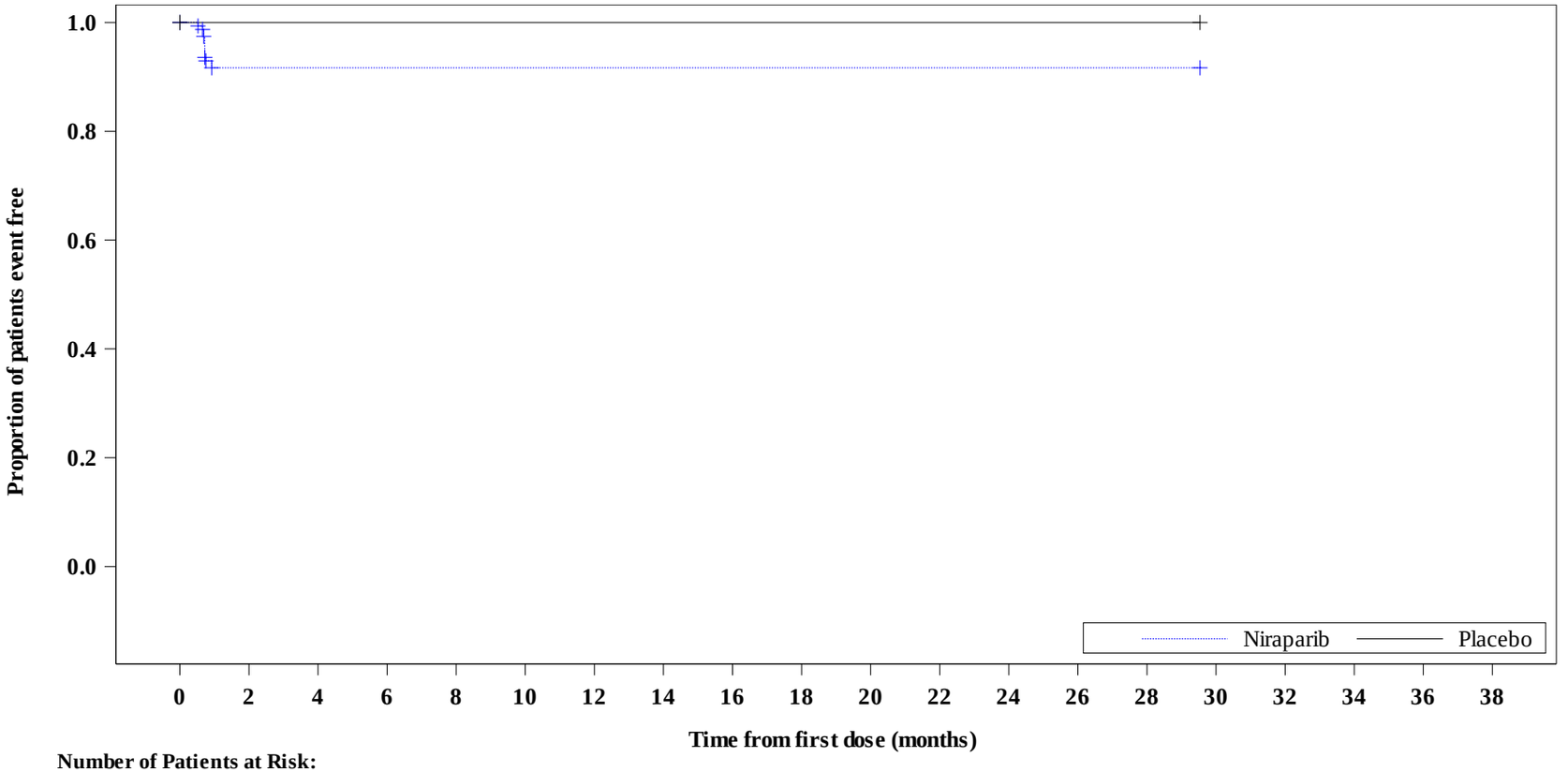

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 130 | 100 | 88 | 70 | 63 | 59 | 53 | 43 | 38 | 24 | 12 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 74 | 67 | 54 | 41 | 35 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Thrombocytopenia



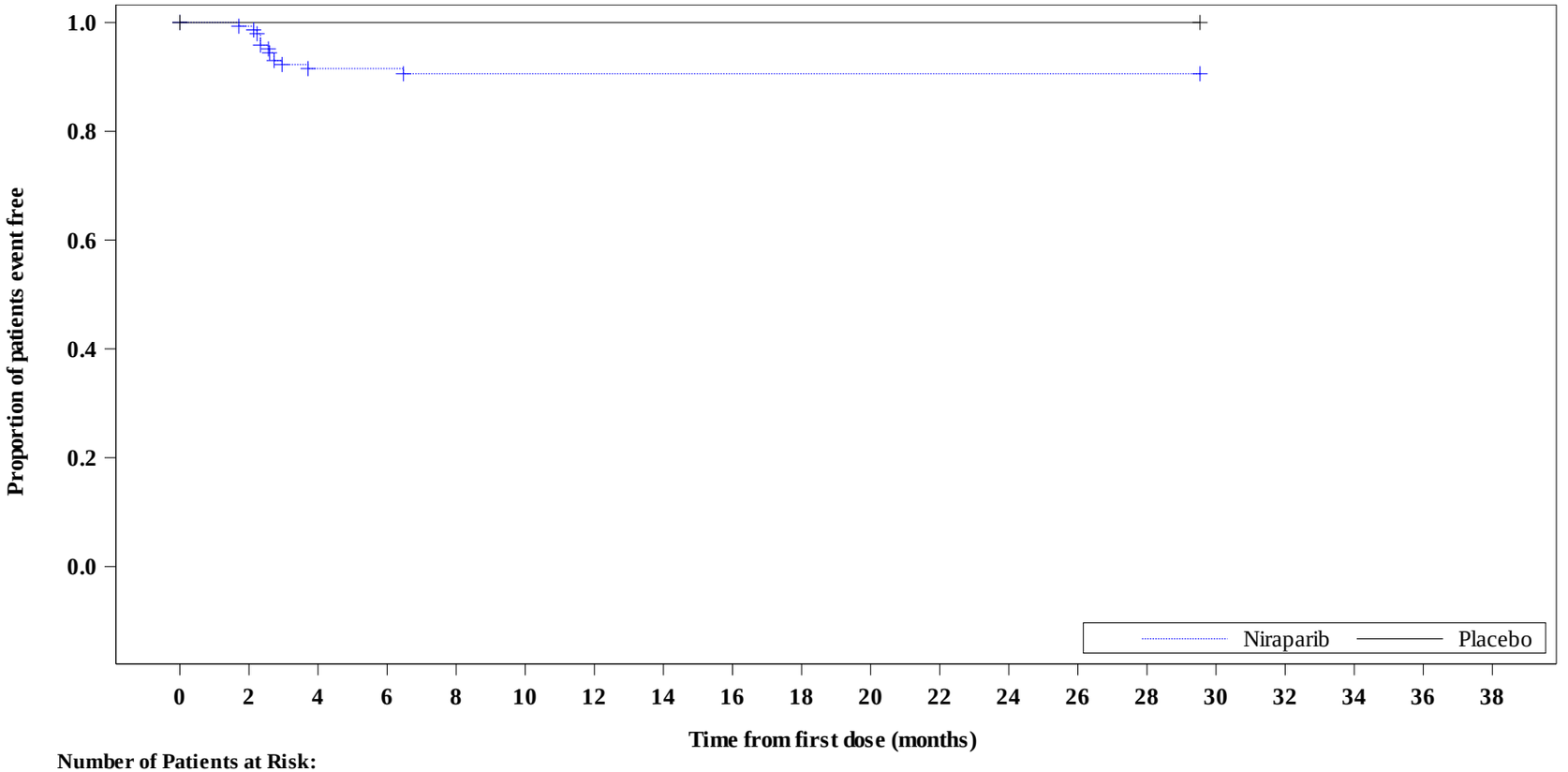

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 132 | 109 | 98 | 79 | 72 | 68 | 61 | 50 | 44 | 27 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Anemia



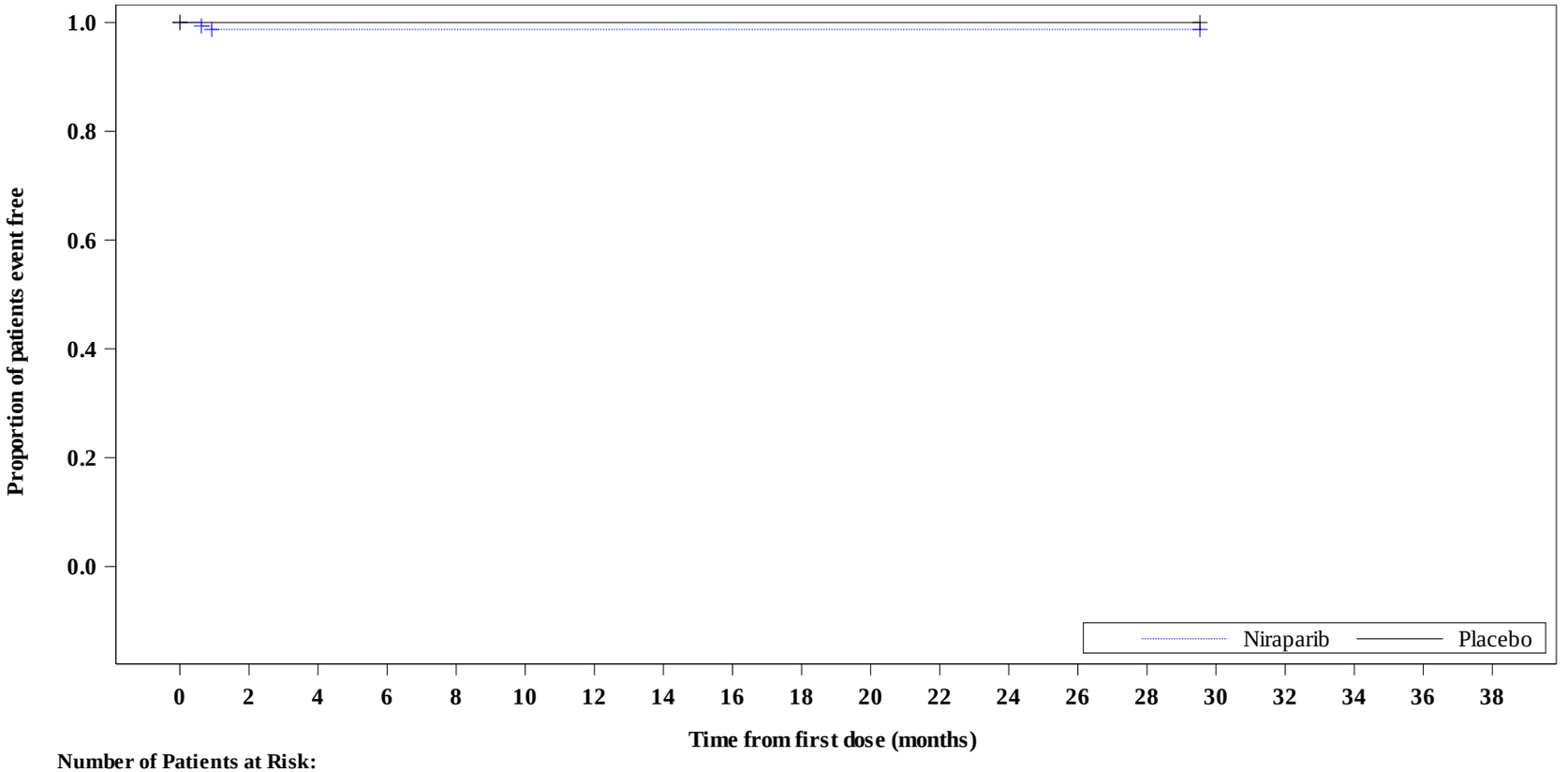

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 143 | 109 | 98 | 78 | 69 | 65 | 59 | 48 | 43 | 27 | 13 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Leukopenia



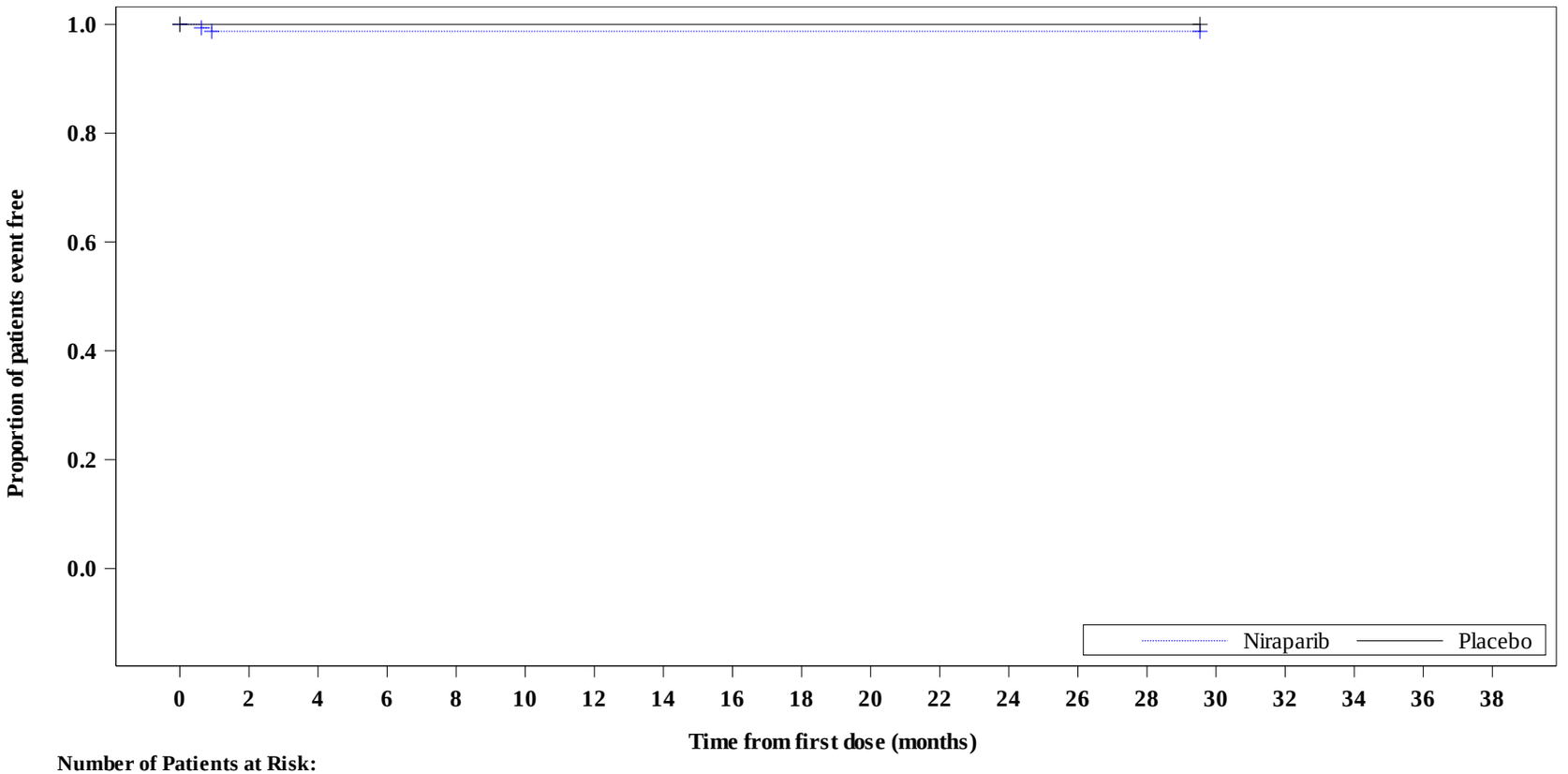

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 117 | 106 | 86 | 77 | 73 | 66 | 54 | 48 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Neutropenia



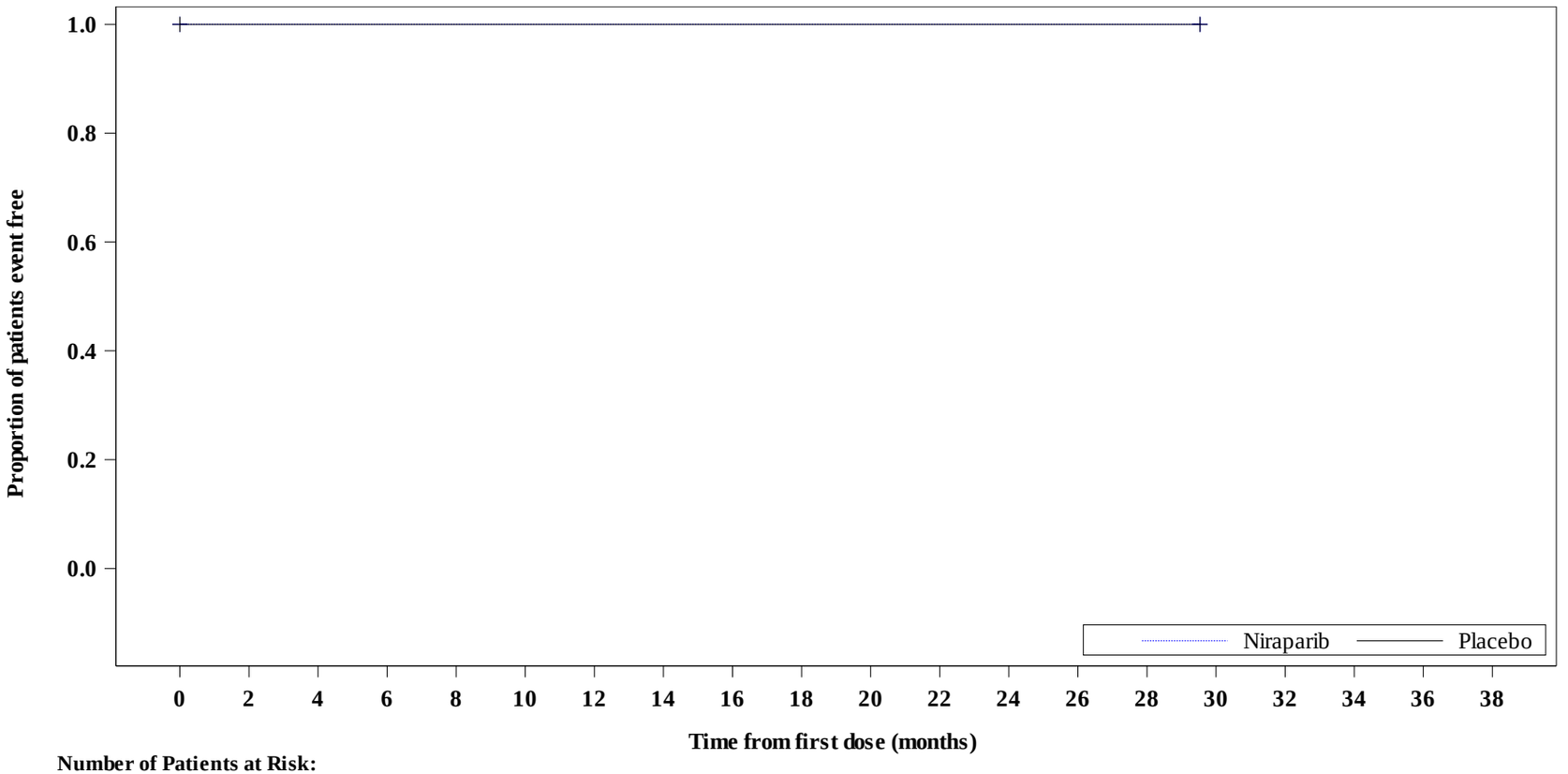

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 142 | 117 | 106 | 86 | 77 | 73 | 66 | 54 | 48 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Hypertension



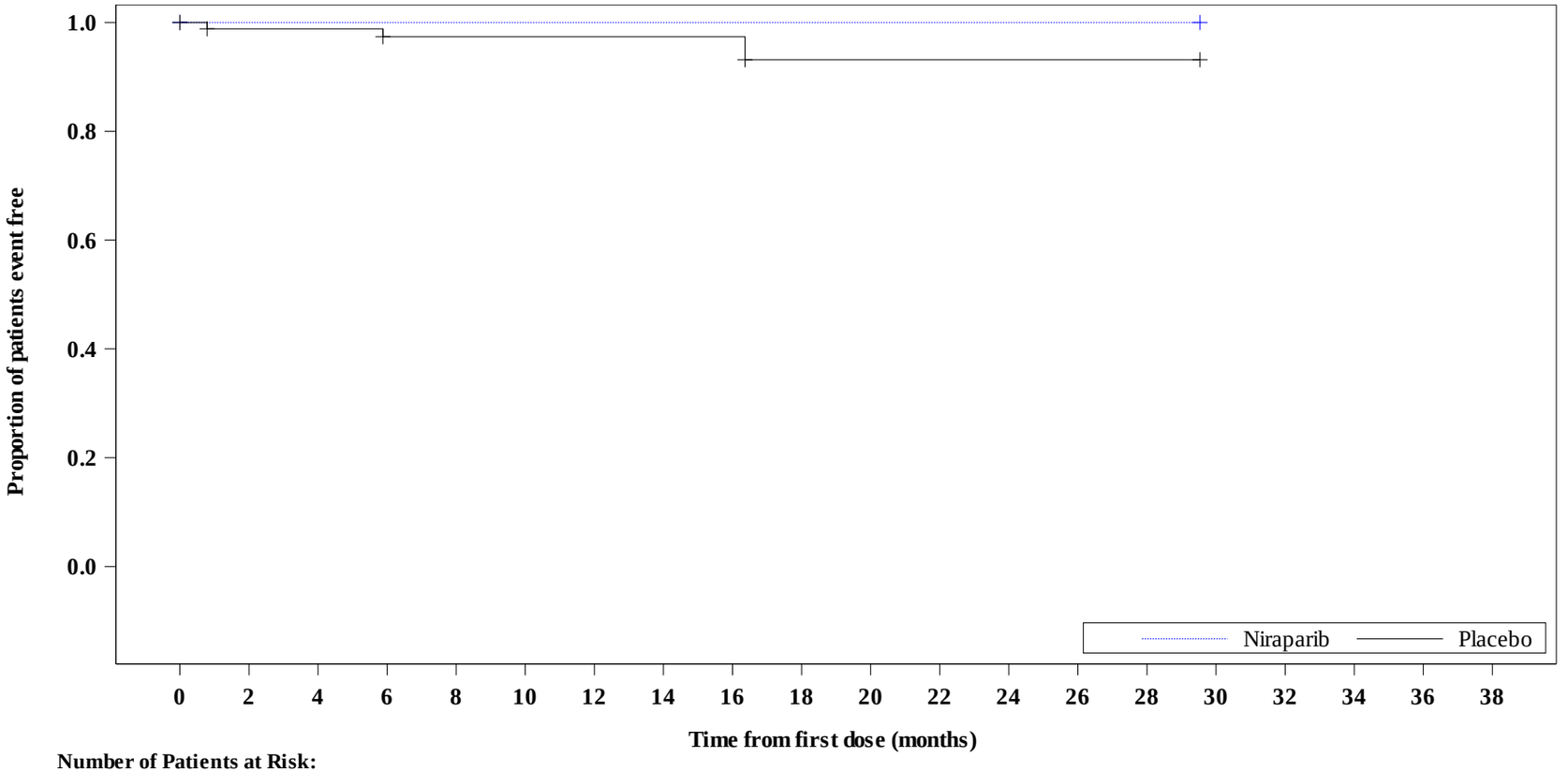

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

New malignancies other than MDS/AML



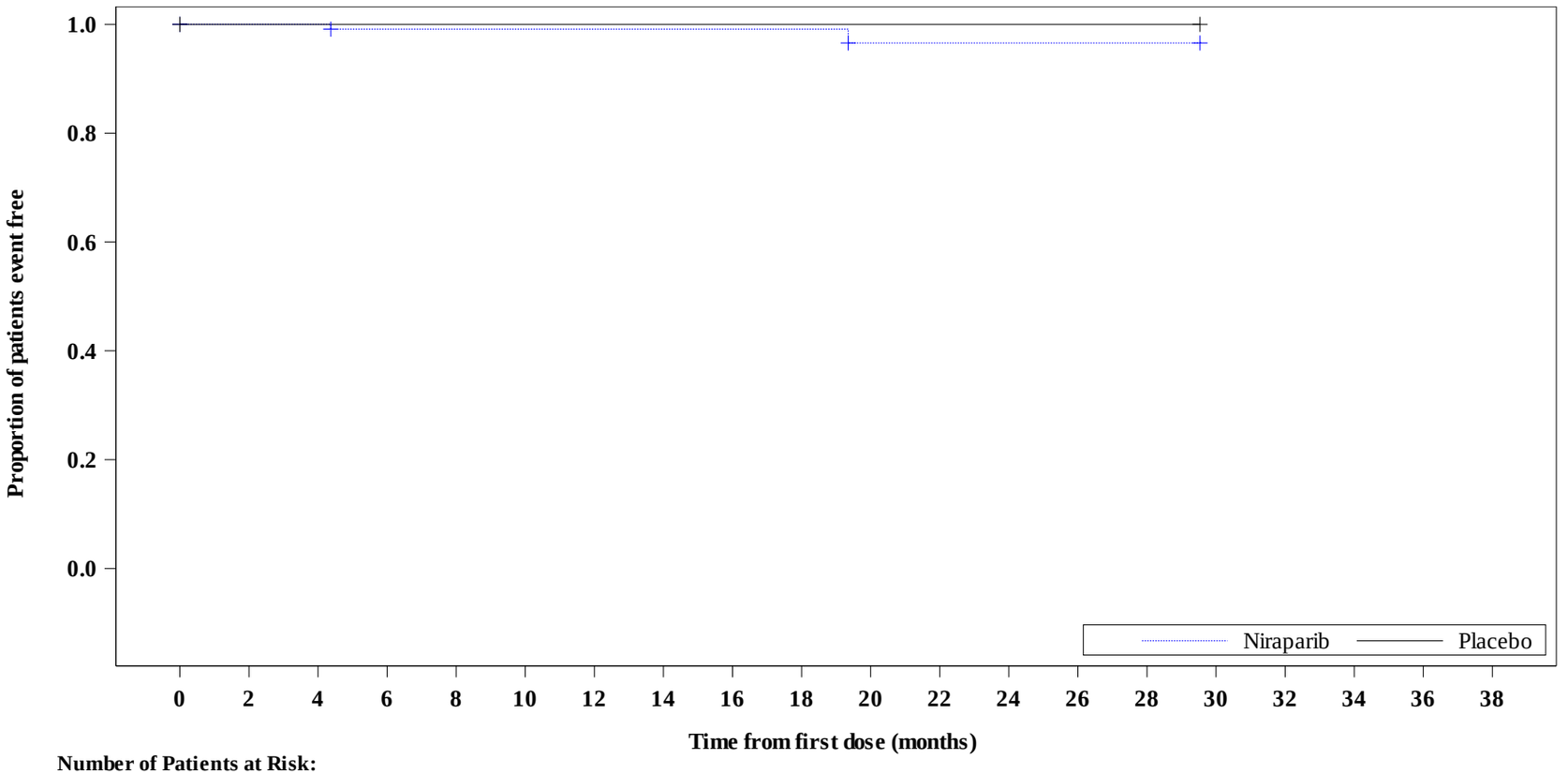

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 83 | 74 | 67 | 54 | 41 | 35 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Pneumonitis



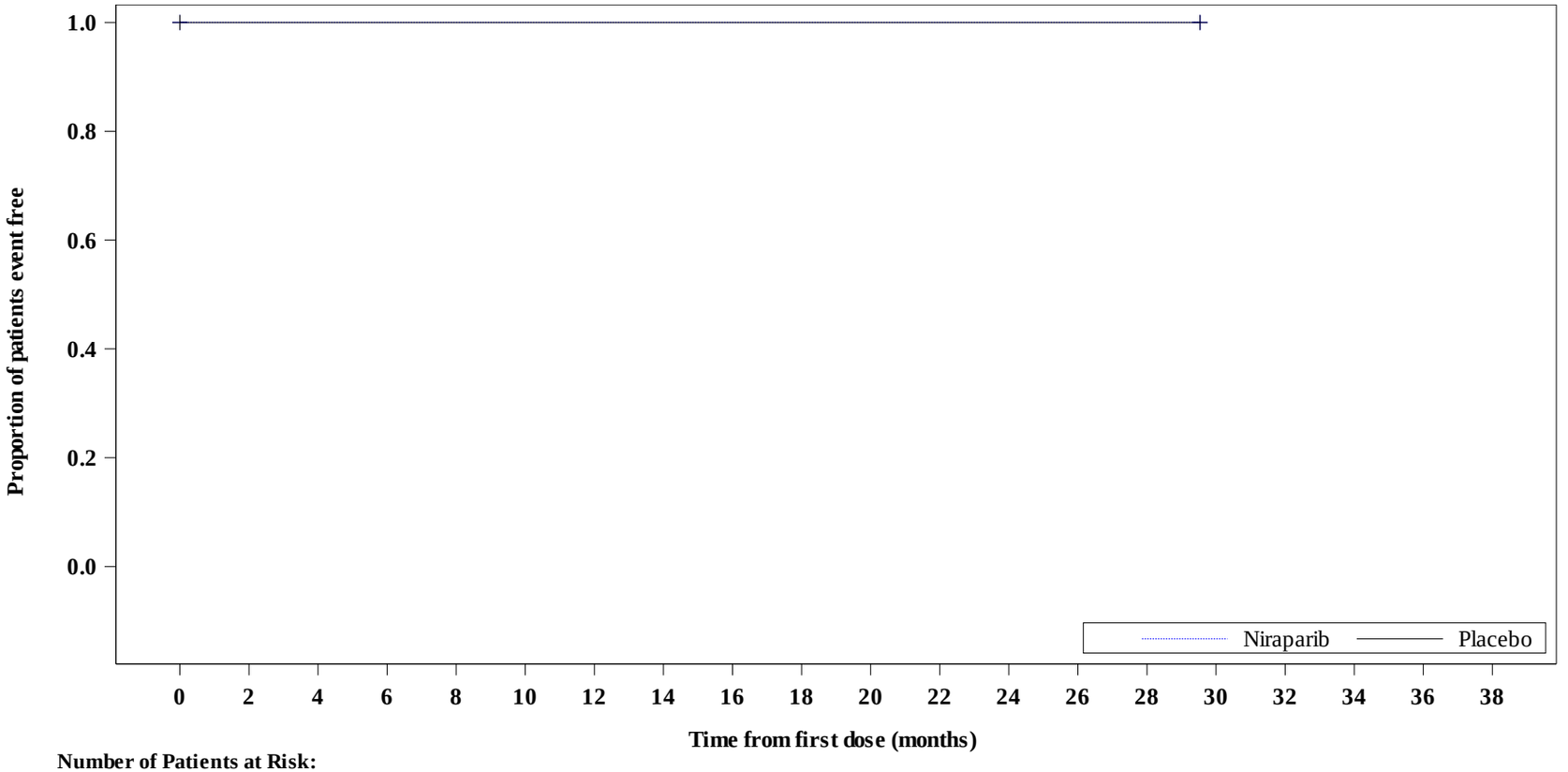

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 106 | 87 | 78 | 74 | 67 | 55 | 49 | 29 | 14 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Pancytopenia



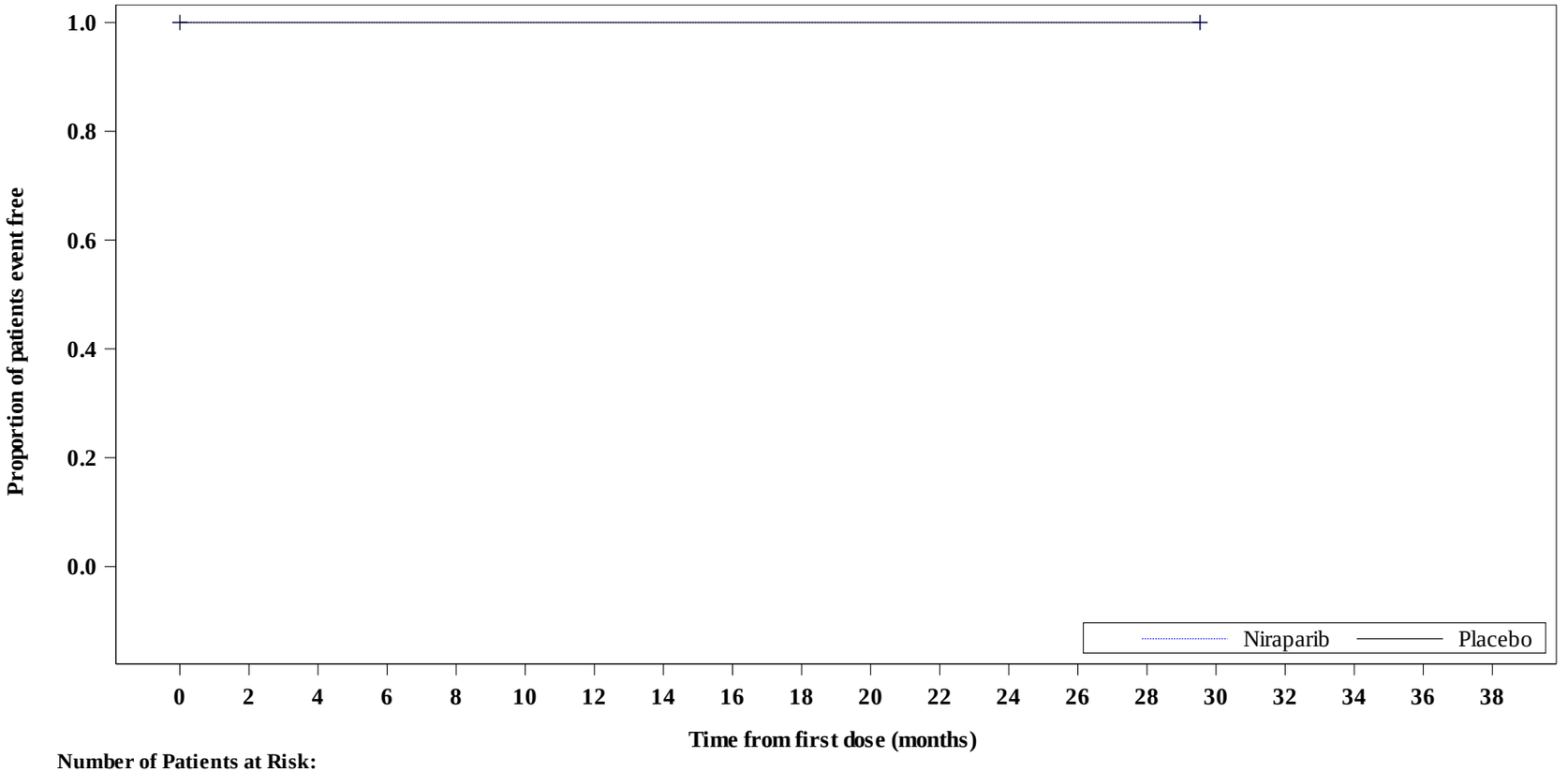

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Thromboemblic



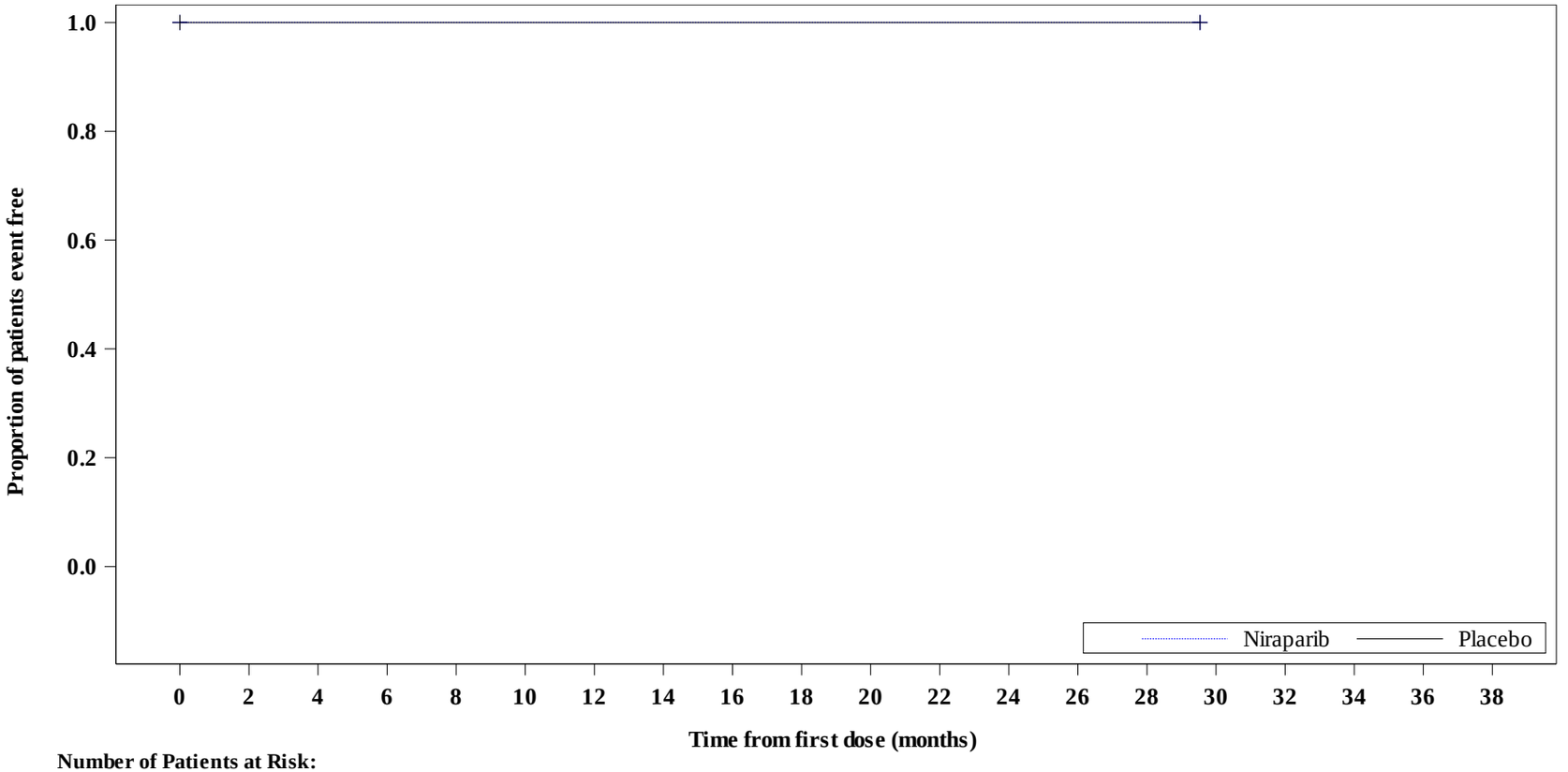

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

MDS/AML



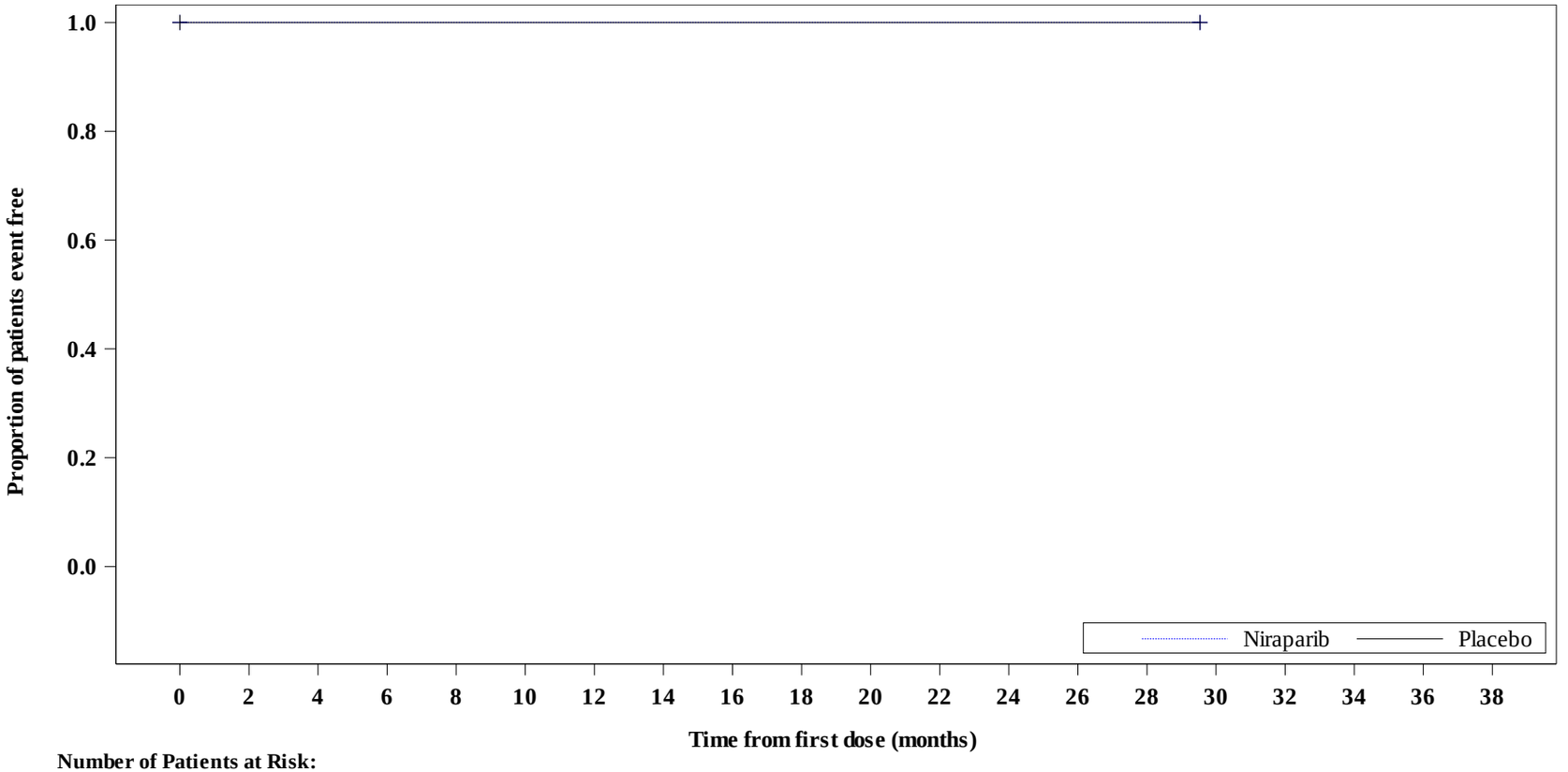

**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |

Figure 3.158a

Time to Onset of First Occurrence of Serious Treatment-Emergent Adverse Events of Special Interest and Other Grouped Events (Residual Disease Safety-GVD Population)

Embryo-fetal toxicity




**Number of Patients at Risk:**

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Niraparib | 156 | 144 | 118 | 107 | 87 | 78 | 74 | 67 | 55 | 49 | 30 | 15 | 9 | 5 | 2 | 0 |
| Placebo | 86 | 84 | 75 | 69 | 56 | 42 | 36 | 28 | 23 | 19 | 14 | 5 | 3 | 2 | 1 | 0 |