Clinical trial results:
A Phase 3 Randomized Double-Blind Trial of Maintenance with Niraparib Versus Placebo in Patients with Platinum Sensitive Ovarian Cancer

Summary

EudraCT number	2013-000685-11
Trial protocol	SE DE AT GB DK IT HU ES BE PL
Global end of trial date	26 December 2021

Results information

Result version number	v2
This version publication date	16 April 2023
First version publication date	01 January 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	213356

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GSK
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GSK, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GSK, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 March 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate efficacy of niraparib as maintenance therapy in participants who have platinum sensitive ovarian cancer as assessed by the prolongation of progression-free survival (PFS)

Protection of trial subjects:

Protocol Amendment 7 introduced less visits burden to participants, as so called "Extended Cycle Visit":
– Required in-clinic visit every cycle (28 days) optional; participants may visit the clinic every three cycles (84 days).
– Option for in-home nursing visit or site local clinic/hospital except for visit every three cycles which must be performed at the site
– Study assessments which can be performed by study coordinator through telephone contact include Adverse event, ConMed and Eastern Cooperative Oncology Group.
– Study assessments which can be performed at the in home nursing visits, local clinic or hospital include vitals, blood draw (complete blood count, chemistry, CA-125) and dispensation of study drug
Protective measures were also taken temporarily during Coronavirus disease-19 pandemic 2020/2021 by allowing most assessments done remotely, or locally; and providing study drug supply by courier to participants.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 June 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 198
Country: Number of subjects enrolled	Austria: 6
Country: Number of subjects enrolled	Belgium: 18
Country: Number of subjects enrolled	Canada: 66
Country: Number of subjects enrolled	Germany: 52
Country: Number of subjects enrolled	Denmark: 48
Country: Number of subjects enrolled	Spain: 48
Country: Number of subjects enrolled	France: 47
Country: Number of subjects enrolled	United Kingdom: 32
Country: Number of subjects enrolled	Hungary: 3
Country: Number of subjects enrolled	Israel: 18
Country: Number of subjects enrolled	Italy: 19
Country: Number of subjects enrolled	Norway: 12

Country: Number of subjects enrolled	Poland: 15
Country: Number of subjects enrolled	Sweden: 14
Worldwide total number of subjects	596
EEA total number of subjects	282

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	384
From 65 to 84 years	212
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a randomized, double-blind study conducted to analyze maintenance with niraparib versus placebo in participants with ovarian cancer.

Pre-assignment

Screening details:

A total of 596 participants were enrolled in the study. The results presented are based on the data cut-off date of 31 March 2021 (which aligns with the time of the study unblinding) and the post-unblinding safety data until the end of study (01-April-2021 to 26-December-2021).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	gBRCA Niraparib

Arm description:

Participants with germline breast cancer gene (gBRCA) mutation received oral dose of niraparib 300 milligrams (mg) once daily in 28-day cycles until disease progression.

Arm type	Experimental
Investigational medicinal product name	Niraparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 3x100 milligrams of niraparib as oral dose.

Arm title	gBRCA Placebo

Arm description:

Participants with germline BRCA mutation received oral dose of placebo matching niraparib once daily in 28-day cycles until disease progression.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received placebo matching 3x capsules as oral dose.

Arm title	Non-gBRCA Niraparib

Arm description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Arm type	Experimental

Investigational medicinal product name	Niraparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 3x100 milligrams of niraparib as oral dose.

Arm title	Non-gBRCA Placebo

Arm description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received placebo matching 3x capsules as oral dose.

Arm title	FE sub-study: Fasted/fed

Arm description:

Participants received a single dose of 3x100 mg capsules of niraparib administered orally following a minimum 10-hour overnight fast in Period 1 followed by 300 mg capsules of niraparib administered orally as single dose in fed condition (high-fat meal) in Period 2. There was a washout period of 7 days between treatment periods.

Arm type	Experimental
Investigational medicinal product name	Niraparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 3x100 milligrams of niraparib as oral dose.

Arm title	FE sub-study: Fed/fasted

Arm description:

Participants received single dose of 3x100 mg capsules of niraparib administered orally following a high-fat meal in Period 1 followed by 3x100 mg capsules of niraparib administered orally as single dose in fasted condition in Period 2. There was a washout period of 7 days between treatment periods.

Arm type	Experimental
Investigational medicinal product name	Niraparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 3x100 milligrams of niraparib as oral dose.

Arm title	QTc sub-study: Niraparib

Arm description:

Participants received Niraparib 300 mg once daily orally.

Arm type	Experimental

Investigational medicinal product name	Niraparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received 3x100 milligrams of niraparib as oral dose.

Number of subjects in period 1[1]	gBRCA Niraparib	gBRCA Placebo	Non-gBRCA Niraparib
Started	138	65	234
Completed	0	0	0
Not completed	138	65	234
Consent withdrawn by subject	20	11	30
Disease progression	-	-	-
Subject Moved to Rollover Study	6	-	9
Adverse event, non-fatal	-	-	-
Death	72	29	146
Transferred to other arm/group	-	-	-
Subject unblinded by sponsor	27	20	33
Other reasons	6	3	11
Lost to follow-up	7	2	5

Number of subjects in period 1[1]	Non-gBRCA Placebo	FE sub-study: Fasted/fed	FE sub-study: Fed/fasted
Started	116	8	9
Completed	0	7	8
Not completed	116	1	1
Consent withdrawn by subject	14	-	-
Disease progression	2	-	-
Subject Moved to Rollover Study	-	-	-
Adverse event, non-fatal	-	-	1
Death	68	-	-
Transferred to other arm/group	-	1	-
Subject unblinded by sponsor	26	-	-
Other reasons	5	-	-
Lost to follow-up	1	-	-

Number of subjects in period 1[1]	QTc sub-study: Niraparib
Started	26

Completed	0
Not completed	26
Consent withdrawn by subject	4
Disease progression	-
Subject Moved to Rollover Study	-
Adverse event, non-fatal	-
Death	5
Transferred to other arm/group	-
Subject unblinded by sponsor	-
Other reasons	17
Lost to follow-up	-

Notes:

[1] - The number of subjects transferring in and out of the arms in the period are not the same. It is expected the net number of transfers in and out of the arms in a period, will be zero.
Justification: Subject is transferred to another treatment group

Baseline characteristics

Reporting groups	
Reporting group title	gBRCA Niraparib
Reporting group description:	
Participants with germline breast cancer gene (gBRCA) mutation received oral dose of niraparib 300 milligrams (mg) once daily in 28-day cycles until disease progression.	
Reporting group title	gBRCA Placebo
Reporting group description:	
Participants with germline BRCA mutation received oral dose of placebo matching niraparib once daily in 28-day cycles until disease progression.	
Reporting group title	Non-gBRCA Niraparib
Reporting group description:	
Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.	
Reporting group title	Non-gBRCA Placebo
Reporting group description:	
Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression	
Reporting group title	FE sub-study: Fasted/fed
Reporting group description:	
Participants received a single dose of 3x100 mg capsules of niraparib administered orally following a minimum 10-hour overnight fast in Period 1 followed by 300 mg capsules of niraparib administered orally as single dose in fed condition (high-fat meal) in Period 2. There was a washout period of 7 days between treatment periods.	
Reporting group title	FE sub-study: Fed/fasted
Reporting group description:	
Participants received single dose of 3x100 mg capsules of niraparib administered orally following a high-fat meal in Period 1 followed by 3x100 mg capsules of niraparib administered orally as single dose in fasted condition in Period 2. There was a washout period of 7 days between treatment periods.	
Reporting group title	QTc sub-study: Niraparib
Reporting group description:	
Participants received Niraparib 300 mg once daily orally.	

Reporting group values	gBRCA Niraparib	gBRCA Placebo	Non-gBRCA Niraparib
Number of subjects	138	65	234
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 64 years	110	49	130
>=65 years	28	16	104
Sex: Female, Male Units: Participants			
Female	138	65	234
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	2	3	10
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	1	4

White	123	55	201
Unknown or Not Reported	11	6	19

Reporting group values	Non-gBRCA Placebo	FE sub-study: Fasted/fed	FE sub-study: Fed/fasted
Number of subjects	116	8	9
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 64 years	69	5	5
>=65 years	47	3	4
Sex: Female, Male Units: Participants			
Female	116	8	9
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	4	0	0
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	1	1	0
White	101	6	9
Unknown or Not Reported	10	0	0

Reporting group values	QTc sub-study: Niraparib	Total	
Number of subjects	26	596	
Age Categorical Units: Participants			
<=18 years	0	0	
Between 18 and 64 years	16	384	
>=65 years	10	212	
Sex: Female, Male Units: Participants			
Female	26	596	
Male	0	0	
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1	2	
Asian	1	20	
Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	3	11	
White	21	516	
Unknown or Not Reported	0	46	

End points

End points reporting groups

Reporting group title	gBRCA Niraparib
Reporting group description:	
Participants with germline breast cancer gene (gBRCA) mutation received oral dose of niraparib 300 milligrams (mg) once daily in 28-day cycles until disease progression.	
Reporting group title	gBRCA Placebo
Reporting group description:	
Participants with germline BRCA mutation received oral dose of placebo matching niraparib once daily in 28-day cycles until disease progression.	
Reporting group title	Non-gBRCA Niraparib
Reporting group description:	
Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.	
Reporting group title	Non-gBRCA Placebo
Reporting group description:	
Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression	
Reporting group title	FE sub-study: Fasted/fed
Reporting group description:	
Participants received a single dose of 3x100 mg capsules of niraparib administered orally following a minimum 10-hour overnight fast in Period 1 followed by 300 mg capsules of niraparib administered orally as single dose in fed condition (high-fat meal) in Period 2. There was a washout period of 7 days between treatment periods.	
Reporting group title	FE sub-study: Fed/fasted
Reporting group description:	
Participants received single dose of 3x100 mg capsules of niraparib administered orally following a high-fat meal in Period 1 followed by 3x100 mg capsules of niraparib administered orally as single dose in fasted condition in Period 2. There was a washout period of 7 days between treatment periods.	
Reporting group title	QTc sub-study: Niraparib
Reporting group description:	
Participants received Niraparib 300 mg once daily orally.	
Subject analysis set title	non-gBRCAmut HRD+ Niraparib
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Niraparib (300 mg) once daily in 28-day cycles until disease progression in participants with homologous recombination deficiency-positive (HRD+) tumors Niraparib vs. Placebo 2:1 ratio	
Subject analysis set title	non-gBRCAmut HRD+ Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Placebo once daily in 28-day cycles until disease progression patients with homologous recombination deficiency-positive (HRD+) tumors Niraparib vs. Placebo 2:1 ratio	
Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Niraparib (300 mg) once daily in 28-day cycles until disease progression in patients without germline BRCA mutation Niraparib vs. Placebo 2:1 ratio	
Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Placebo once daily in 28-day cycles until disease progression in patients without germline BRCA mutation Niraparib vs. Placebo 2:1 ratio	
Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Niraparib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	non-gBRCA Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	FE Niraparib Fasted
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received Niraparib 300 mg in fasted condition

Subject analysis set title	FE Niraparib Fed
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received Niraparib 300 mg in fed condition

Subject analysis set title	FE Niraparib Fasted
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received Niraparib 300 mg in fasted condition

Subject analysis set title	FE Niraparib Fed
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received Niraparib 300 mg in fed condition

Subject analysis set title	gBRCA Niraparib (PSU)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression

Subject analysis set title	gBRCA Placebo (PSU)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Subject analysis set title	Non-gBRCA Niraparib (PSU)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression

Subject analysis set title	Non-gBRCA Placebo (PSU)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Primary: Progression-Free Survival (PFS) in Cohort With Germline BReast CAncer gene (BRCA) Mutation (gBRCA)

End point title	Progression-Free Survival (PFS) in Cohort With Germline BReast CAncer gene (BRCA) Mutation (gBRCA)[1]

End point description:

PFS was defined as the time between randomization and disease progression or death from any cause. Computed tomography or magnetic resonance imaging to assess disease progression was performed at baseline, every 8 weeks through cycle 14, and then every 12 weeks until treatment discontinuation. The objective assessment of disease progression was determined by means of central radiologic and clinical review, according to Response Evaluation Criteria in Solid Tumors (RECIST),version 1.1, which was performed in a blinded fashion. Intent-to-treat population was defined as all randomized participants with participants analyzed according to the study drug assigned via randomization. 99999 indicates Upper limit of confidence interval (CI) was not estimable as upper limits of CI for survivor function were above 0.5 (SAS PROC LIFETEST).

End point type	Primary

End point timeframe:

From date of randomization to the earliest date of disease progression or death from any cause, up to 7 years 7 months and 4 days

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138[2]	65[3]		
Units: months				
median (confidence interval 95%)	21 (12.9 to 99999)	5.5 (3.8 to 7.2)		

Notes:

[2] - Intent-to-treat population

[3] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [4]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.173
upper limit	0.41

Notes:

[4] - Two-sided P-value. PFS was independently evaluated in gBRCAmut cohort and non-gBRCAmut cohort.

Primary: Progression-Free Survival (PFS) in Cohort with No Germline BCRA with homologous recombination deficiency-positive (HRD+) tumors (non-gBRCAmut HRD+)

End point title	Progression-Free Survival (PFS) in Cohort with No Germline BCRA with homologous recombination deficiency-positive (HRD+) tumors (non-gBRCAmut HRD+)

End point description:

PFS was defined as the time between randomization and disease progression or death from any cause. Computed tomography or magnetic resonance imaging to assess disease progression was performed at baseline, every 8 weeks through cycle 14, and then every 12 weeks until treatment discontinuation. The objective assessment of disease progression was determined by means of central radiologic and clinical review, according to Response Evaluation Criteria in Solid Tumors (RECIST),version 1.1, which was performed in a blinded fashion. PD was defined as at least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study.

End point type	Primary

End point timeframe:

From date of randomization to the earliest date of disease progression or death from any cause, up to 7

End point values	non-gBRCAmut HRD+ Niraparib	non-gBRCAmut HRD+ Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	106[5]	56[6]		
Units: months				
median (confidence interval 95%)	12.9 (8.1 to 15.9)	3.8 (3.5 to 5.7)		

Notes:

[5] - Intent-to-treat population

[6] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCAmut HRD+ Niraparib v non-gBRCAmut HRD+ Placebo
Number of subjects included in analysis	162
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [7]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.243
upper limit	0.586

Notes:

[7] - Two-sided P-value. PFS was independently evaluated in gBRCAmut cohort and non-gBRCAmut cohort. Hierarchical testing: HRD+ subset tested first. If HRD+ subset demonstrated statistical significance, overall non-gBRCA cohort was then tested

Primary: Progression-Free Survival (PFS) in Cohort with No Germline BRCA Mutation (non-gBRCA)

End point title	Progression-Free Survival (PFS) in Cohort with No Germline BRCA Mutation (non-gBRCA)

End point description:

PFS was defined as the time between randomization and disease progression or death from any cause. Computed tomography or magnetic resonance imaging to assess disease progression was performed at baseline, every 8 weeks through cycle 14, and then every 12 weeks until treatment discontinuation. The objective assessment of disease progression was determined by means of central radiologic and clinical review, according to Response Evaluation Criteria in Solid Tumors (RECIST),version 1.1, which was performed in a blinded fashion.

End point type	Primary

End point timeframe:

From date of randomization to the earliest date of disease progression or death from any cause, up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	234[8]	116[9]		
Units: Months				
median (confidence interval 95%)	9.3 (7.2 to 11.2)	3.9 (3.7 to 5.5)		

Notes:

[8] - Intent-to-treat population

[9] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [10]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.338
upper limit	0.607

Notes:

[10] - Two-sided P-value. PFS was independently evaluated in gBRCAmut cohort and non-gBRCAmut cohort. Hierarchical testing: HRD+ subset tested first. If HRD+ subset demonstrated statistical significance, overall non-gBRCA cohort was then tested.

Secondary: Time to First Subsequent Therapy in Cohort With Germline BRCA Mutation (gBRCA)

End point title	Time to First Subsequent Therapy in Cohort With Germline BRCA Mutation (gBRCA)[11]

End point description:

The TFST was defined as the time from the date of randomization to the start date of the first subsequent anti-cancer therapy or death.

End point type	Secondary

End point timeframe:

From date of randomization to the earliest date of first subsequent therapy or death, up to 7 years, 7 months and 4 days

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138[12]	65[13]		
Units: Months				
median (confidence interval 95%)	19.1 (14.6 to 21.9)	8.6 (6.9 to 12.2)		

Notes:

[12] - Intent-to-treat population

[13] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0005 [14]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.412
upper limit	0.783

Notes:

[14] - Two-sided P-value.

Secondary: Time to First Subsequent Therapy in Cohort With No Germline BRCA Mutation

End point title	Time to First Subsequent Therapy in Cohort With No Germline BRCA Mutation

End point description:

The TFST was defined as the time from the date of randomization to the start date of the first subsequent anti-cancer therapy or death

End point type	Secondary

End point timeframe:

From date of randomization to the earliest date of first subsequent therapy or death, up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	234[15]	116[16]		
Units: Months				
median (confidence interval 95%)	12.4 (10.9 to 14.5)	7.4 (5.9 to 8.7)		

Notes:

[15] - Intent-to-treat population

[16] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [17]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.454
upper limit	0.74

Notes:

[17] - Two-sided P-value.

Secondary: Chemotherapy-Free Interval in Cohort With Germline BRCA Mutation (gBRCA)

End point title	Chemotherapy-Free Interval in Cohort With Germline BRCA Mutation (gBRCA)[18]

End point description:

Chemotherapy-Free Interval was defined as the time from the last platinum therapy prior to randomization to the initiation of the next anti-cancer therapy after maintenance treatment

End point type	Secondary

End point timeframe:

From date of last platinum therapy prior to randomization to the initiation of the next anti-cancer therapy after maintenance treatment, up to 7 years, 7 months and 4 days

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138[19]	65[20]		
Units: Months				
median (confidence interval 95%)	20.0 (16.2 to 23.3)	9.4 (7.9 to 10.4)		

Notes:

[19] - Intent-to-treat population

[20] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [21]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.268
upper limit	0.561

Notes:

[21] - Two-sided P-value.

Secondary: Progression-Free Survival 2 in Cohort With Germline BRCA Mutation (gBRCA)

End point title	Progression-Free Survival 2 in Cohort With Germline BRCA Mutation (gBRCA)[22]

End point description:

Progression-Free Survival 2 was 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 due to any cause. Progression was determined by the investigator via clinical and radiographic assessment using the same criteria as used in the current study.

End point type	Secondary

End point timeframe:

From treatment randomization to the earlier of the date of disease progression on the next anti-cancer therapy following study treatment or death due to any cause, up to 7 years, 7 months and 4 days

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138[23]	65[24]		
Units: Months				
median (confidence interval 95%)	29.9 (24.8 to 33.4)	22.7 (19.5 to 25.9)		

Notes:

[23] - Intent-to-treat population

[24] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	gBRCA Niraparib v gBRCA Placebo

Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0302 [25]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.968

Notes:

[25] - Two-sided P-value.

Secondary: Chemotherapy-Free Interval in Cohort With No Germline BRCA Mutation

End point title	Chemotherapy-Free Interval in Cohort With No Germline BRCA Mutation

End point description:

Chemotherapy-Free Interval was defined as the time from the last platinum therapy prior to randomization to the initiation of the next anti-cancer therapy after maintenance treatment

End point type	Secondary

End point timeframe:

From date of last platinum therapy prior to randomization to the initiation of the next anti-cancer therapy after maintenance treatment, up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	234[26]	116[27]		
Units: Months				
median (confidence interval 95%)	13.4 (11.3 to 14.8)	8.7 (6.9 to 10.0)		

Notes:

[26] - Intent-to-treat population

[27] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [28]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.56

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.428
upper limit	0.727

Notes:

[28] - Two-sided P-value.

Secondary: Progression-Free Survival 2 in Cohort With No Germline BRCA Mutation

End point title	Progression-Free Survival 2 in Cohort With No Germline BRCA Mutation

End point description:

Progression-Free Survival 2 was 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 due to any cause. Progression was determined by the investigator via clinical and radiographic assessment using the same criteria as used in the current study.

End point type	Secondary

End point timeframe:

From treatment randomization to the earlier of the date of disease progression on the next anti-cancer therapy following study treatment or death due to any cause, up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	234[29]	116[30]		
Units: Months				
median (confidence interval 95%)	19.5 (17.1 to 22.3)	16.1 (13.6 to 22.8)		

Notes:

[29] - Intent-to-treat population

[30] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0748 [31]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.627
upper limit	1.022

Notes:

[31] - Two-sided P-value.

Secondary: Overall Survival in Cohort With Germline BRCA Mutation (gBRCA)

End point title	Overall Survival in Cohort With Germline BRCA Mutation (gBRCA)[32]

End point description:

Overall survival was defined as the date of randomization to the date of death by any cause.

End point type	Secondary

End point timeframe:

From treatment randomization to date of death by any cause, up to 7 years, 7 months and 4 days

Notes:

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138[33]	65[34]		
Units: Months				
median (confidence interval 95%)	40.9 (34.9 to 52.9)	38.1 (27.6 to 47.3)		

Notes:

[33] - Intent-to-treat population

[34] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.358 [35]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.606
upper limit	1.198

Notes:

[35] - Two-sided P-value.

Secondary: Overall Survival in Cohort With No Germline BRCA Mutation

End point title	Overall Survival in Cohort With No Germline BRCA Mutation

End point description:

Overall survival was defined as the date of randomization to the date of death by any cause.

End point type	Secondary

End point timeframe:

From treatment randomization to date of death by any cause, up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	234[36]	116[37]		
Units: Months				
median (confidence interval 95%)	31.0 (27.8 to 35.6)	34.8 (27.9 to 41.4)		

Notes:

[36] - Intent-to-treat population

[37] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6868 [38]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.813
upper limit	1.369

Notes:

[38] - Two-sided P-value.

Secondary: Time to Second Subsequent Therapy in Cohort With Germline BRCA Mutation (gBRCA)

End point title	Time to Second Subsequent Therapy in Cohort With Germline BRCA Mutation (gBRCA)[39]

End point description:

TSST was defined as the date of randomization to the earlier of the start date of second follow-up anti-cancer treatment or death.

End point type	Secondary

End point timeframe:

From the date of randomization to the start date of the second subsequent anti-cancer therapy, up to 7 years, 7 months and 4 days

Notes:

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138[40]	65[41]		
Units: Months				
median (confidence interval 95%)	29.7 (23.3 to 33.4)	19.6 (14.4 to 25.5)		

Notes:

[40] - Intent-to-treat population

[41] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0061 [42]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.451
upper limit	0.878

Notes:

[42] - Two-sided P-value.

Secondary: Time to Second Subsequent Therapy in Cohort With No Germline BRCA Mutation

End point title	Time to Second Subsequent Therapy in Cohort With No Germline BRCA Mutation

End point description:

TSST was defined as the date of randomization to the earlier of the start date of second follow-up anti-cancer treatment or death.

End point type	Secondary

End point timeframe:

From the date of randomization to the start date of the second subsequent anti-cancer therapy, up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	234[43]	116[44]		
Units: Months				
median (confidence interval 95%)	20.3 (18.0 to 23.4)	16.7 (14.9 to 21.3)		

Notes:

[43] - Intent-to-treat population

[44] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1674 [45]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.654
upper limit	1.077

Notes:

[45] - Two-sided P-value.

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With Germline BRCA at Cycle 2

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With Germline BRCA at Cycle 2[46]

End point description:

Functional Assessment of Cancer Therapy-Ovarian Symptom Index is a validated, 8-item measure of symptom response to treatment for ovarian cancer. Participants respond to their symptom experience over the past 7 days using a 5-point Likert scale score from “not at all” (0) to “very much” (4). The total score was calculated by multiplying the sum of all items scored by 8 and dividing the result by the number of responses. The total symptom index was calculated as the total of the 8 scores, ranging from 0 ("severely symptomatic") to 32 ("asymptomatic"). A positive change from Baseline indicates improvement. Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (pre-dose on Day 1) and at Cycle 2 (Each cycle was of 28 days)

Notes:

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114[47]	55[48]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.8 (± 4.58)	-0.3 (± 3.19)		

Notes:

[47] - Intent-to-treat population

[48] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With Germline BRCA at post-progression

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With Germline BRCA at post-progression[49]

End point description:

Functional Assessment of Cancer Therapy-Ovarian Symptom Index is a validated, 8-item measure of symptom response to treatment for ovarian cancer. Participants respond to their symptom experience over the past 7 days using a 5-point Likert scale score from "not at all" (0) to "very much" (4). The total score was calculated by multiplying the sum of all items scored by 8 and dividing the result by the number of responses. The total symptom index was calculated as the total of the 8 scores, ranging from 0 ("severely symptomatic") to 32 ("asymptomatic"). A positive change from Baseline indicates improvement. Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Cycle 1 Day 1, Each cycle was of 28 days) and up to 7 years, 7 months and 4 days

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80[50]	37[51]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.751 (± 4.4342)	-1.324 (± 4.5034)		

Notes:

[50] - Intent-to-treat population

[51] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With Germline BRCA at Cycle 4

End point title	Change From Baseline in Functional Assessment of Cancer

	Therapy-Ovarian Symptom Index in Cohort With Germline BRCA at Cycle 4[52]

End point description:

Functional Assessment of Cancer Therapy-Ovarian Symptom Index is a validated, 8-item measure of symptom response to treatment for ovarian cancer. Participantsrespond to their symptom experience over the past 7 days using a 5-point Likert scale score from "not at all" (0) to "very much" (4). The total score was calculated by multiplying the sum of all items scored by 8 and dividing the result by the number of responses. The total symptom index was calculated as the total of the 8 scores, ranging from 0 ("severely symptomatic") to 32 ("asymptomatic"). A positive change from Baseline indicates improvement. Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 4 (Each cycle was of 28 days)

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109[53]	43[54]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.1 (± 4.07)	-0.3 (± 3.88)		

Notes:

[53] - Intent-to-treat population

[54] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With Germline BRCA at Cycle 6

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With Germline BRCA at Cycle 6[55]

End point description:

Functional Assessment of Cancer Therapy-Ovarian Symptom Index is a validated, 8-item measure of symptom response to treatment for ovarian cancer. Participantsrespond to their symptom experience over the past 7 days using a 5-point Likert scale score from "not at all" (0) to "very much" (4). The total score was calculated by multiplying the sum of all items scored by 8 and dividing the result by the number of responses. The total symptom index was calculated as the total of the 8 scores, ranging from 0 ("severely symptomatic") to 32 ("asymptomatic"). A positive change from Baseline indicates improvement. Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (pre-dose on Day 1) and at Cycle 6 (Each cycle was of 28 days)

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95[56]	36[57]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	0.5 (± 3.77)	-0.5 (± 4.27)		

Notes:

[56] - Intent-to-treat population

[57] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With no Germline BRCA at Cycle 4

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With no Germline BRCA at Cycle 4

End point description:

Functional Assessment of Cancer Therapy-Ovarian Symptom Index is a validated, 8-item measure of symptom response to treatment for ovarian cancer. Participants respond to their symptom experience over the past 7 days using a 5-point Likert scale score from "not at all" (0) to "very much" (4). The total score was calculated by multiplying the sum of all items scored by 8 and dividing the result by the number of responses. The total symptom index was calculated as the total of the 8 scores, ranging from 0 ("severely symptomatic") to 32 ("asymptomatic"). A positive change from Baseline indicates improvement. Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 4 (Each cycle was of 28 days)

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	150[58]	77[59]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.7 (± 4.16)	-0.9 (± 4.23)		

Notes:

[58] - Intent-to-treat population

[59] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With no Germline BRCA at Cycle 2

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With no Germline BRCA at Cycle 2

End point description:

Functional Assessment of Cancer Therapy-Ovarian Symptom Index is a validated, 8-item measure of

symptom response to treatment for ovarian cancer. Participants respond to their symptom experience over the past 7 days using a 5-point Likert scale score from “not at all” (0) to “very much” (4). The total score was calculated by multiplying the sum of all items scored by 8 and dividing the result by the number of responses. The total symptom index was calculated as the total of the 8 scores, ranging from 0 ("severely symptomatic") to 32 ("asymptomatic"). A positive change from Baseline indicates improvement. Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 2 (Each cycle was of 28 days)

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	181[60]	97[61]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-1.0 (± 3.79)	-0.3 (± 2.84)		

Notes:

[60] - Intent-to-treat population

[61] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With no Germline BRCA at Cycle 6

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With no Germline BRCA at Cycle 6

End point description:

Functional Assessment of Cancer Therapy-Ovarian Symptom Index is a validated, 8-item measure of symptom response to treatment for ovarian cancer. Participants respond to their symptom experience over the past 7 days using a 5-point Likert scale score from “not at all” (0) to “very much” (4). The total score was calculated by multiplying the sum of all items scored by 8 and dividing the result by the number of responses. The total symptom index was calculated as the total of the 8 scores, ranging from 0 ("severely symptomatic") to 32 ("asymptomatic"). A positive change from Baseline indicates improvement. Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 6 (Each cycle was of 28 days)

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	124[62]	50[63]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.2 (± 3.76)	-0.9 (± 3.43)		

Notes:

[62] - Intent-to-treat population

[63] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life Scale, 5-Dimensions (EQ-5D-5L) in Cohort With Germline BRCA at Cycle 2

End point title	Change From Baseline in European Quality of Life Scale, 5-Dimensions (EQ-5D-5L) in Cohort With Germline BRCA at Cycle 2[64]

End point description:

EQ-5D-5L is a well-validated, general preference-based, health-related Quality of Life (QoL) instrument. The EQ-5D-5L encompasses 5 domains, asking participants to rate their perceived health state today on the following dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has 5 possible levels: "no problems" (Level 1), "slight problems" (Level 2), "moderate problems" (Level 3), "severe problems" (Level 4), and "extreme problems" (Level 5). Responses for 5 dimensions together formed a 5-figure description of health state (e.g.11111 indicates no problems in all 5 dimensions). Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 2 (Each cycle was of 28 days)

Notes:

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118[65]	59[66]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.008 (± 0.1092)	-0.008 (± 0.1354)		

Notes:

[65] - Intent-to-treat population

[66] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With no Germline BRCA at post-progression

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Ovarian Symptom Index in Cohort With no Germline BRCA at post-progression

End point description:

Functional Assessment of Cancer Therapy-Ovarian Symptom Index is a validated, 8-item measure of

symptom response to treatment for ovarian cancer. Participants respond to their symptom experience over the past 7 days using a 5-point Likert scale score from "not at all" (0) to "very much" (4). The total score was calculated by multiplying the sum of all items scored by 8 and dividing the result by the number of responses. The total symptom index was calculated as the total of the 8 scores, ranging from 0 ("severely symptomatic") to 32 ("asymptomatic"). A positive change from Baseline indicates improvement. Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	146[67]	82[68]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-2.595 (± 5.5700)	-1.801 (± 4.0290)		

Notes:

[67] - Intent-to-treat population

[68] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L in Cohort With Germline BRCA at Cycle 4

End point title	Change From Baseline in EQ-5D-5L in Cohort With Germline BRCA at Cycle 4[69]

End point description:

EQ-5D-5L is a well-validated, general preference-based, health-related Quality of Life (QoL) instrument. The EQ-5D-5L encompasses 5 domains, asking participants to rate their perceived health state today on the following dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has 5 possible levels: "no problems" (Level 1), "slight problems" (Level 2), "moderate problems" (Level 3), "severe problems" (Level 4), and "extreme problems" (Level 5). Responses for 5 dimensions together formed a 5-figure description of health state (e.g.11111 indicates no problems in all 5 dimensions). Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 4 (Each cycle was of 28 days)

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113[70]	44[71]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.010 (± 0.1225)	-0.035 (± 0.1156)		

Notes:

[70] - Intent-to-treat population

[71] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L in Cohort With Germline BRCA at post-progression

End point title	Change From Baseline in EQ-5D-5L in Cohort With Germline BRCA at post-progression[72]

End point description:

EQ-5D-5L is a well-validated, general preference-based, health-related Quality of Life (QoL) instrument. The EQ-5D-5L encompasses 5 domains, asking participants to rate their perceived health state today on the following dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has 5 possible levels: "no problems" (Level 1), "slight problems" (Level 2), "moderate problems" (Level 3), "severe problems" (Level 4), and "extreme problems" (Level 5). Responses for 5 dimensions together formed a 5-figure description of health state (e.g.11111 indicates no problems in all 5 dimensions). Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and up to 7 years, 7 months and 4 days

Notes:

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	81[73]	38[74]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.041 (± 0.1192)	-0.013 (± 0.1580)		

Notes:

[73] - Intent-to-treat population

[74] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L in Cohort With Germline BRCA at Cycle 6

End point title	Change From Baseline in EQ-5D-5L in Cohort With Germline BRCA at Cycle 6[75]

End point description:

EQ-5D-5L is a well-validated, general preference-based, health-related Quality of Life (QoL) instrument. The EQ-5D-5L encompasses 5 domains, asking participants to rate their perceived health state today on the following dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has 5 possible levels: "no problems" (Level 1), "slight problems" (Level 2), "moderate problems" (Level 3), "severe problems" (Level 4), and "extreme problems" (Level 5). Responses for 5 dimensions together formed a 5-figure description of health state (e.g.11111 indicates no problems in all 5 dimensions). Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 6 (Each cycle was of 28 days)

Notes:

[75] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	99[76]	36[77]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	0.002 (± 0.1116)	-0.004 (± 0.1463)		

Notes:

[76] - Intent-to-treat population

[77] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L in Cohort With no Germline BRCA at Cycle 2

End point title	Change From Baseline in EQ-5D-5L in Cohort With no Germline BRCA at Cycle 2

End point description:

EQ-5D-5L is a well-validated, general preference-based, health-related Quality of Life (QoL) instrument. The EQ-5D-5L encompasses 5 domains, asking participants to rate their perceived health state today on the following dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has 5 possible levels: "no problems" (Level 1), "slight problems" (Level 2), "moderate problems" (Level 3), "severe problems" (Level 4), and "extreme problems" (Level 5). Responses for 5 dimensions together formed a 5-figure description of health state (e.g.11111 indicates no problems in all 5 dimensions). Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 2 (Each cycle was of 28 days)

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185[78]	96[79]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.007 (± 0.1013)	-0.011 (± 0.1015)		

Notes:

[78] - Intent-to-treat population

[79] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L in Cohort With no Germline BRCA at Cycle 4

End point title	Change From Baseline in EQ-5D-5L in Cohort With no Germline BRCA at Cycle 4

End point description:

EQ-5D-5L is a well-validated, general preference-based, health-related Quality of Life (QoL) instrument. The EQ-5D-5L encompasses 5 domains, asking participants to rate their perceived health state today on the following dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has 5 possible levels: "no problems" (Level 1), "slight problems" (Level 2), "moderate problems" (Level 3), "severe problems" (Level 4), and "extreme problems" (Level 5). Responses for 5 dimensions together formed a 5-figure description of health state (e.g.11111 indicates no problems in all 5 dimensions). Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 4 (Each cycle was of 28 days)

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	155[80]	80[81]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.004 (± 0.1077)	-0.014 (± 0.0870)		

Notes:

[80] - Intent-to-treat population

[81] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L in Cohort With no Germline BRCA at Cycle 6

End point title	Change From Baseline in EQ-5D-5L in Cohort With no Germline BRCA at Cycle 6

End point description:

EQ-5D-5L is a well-validated, general preference-based, health-related Quality of Life (QoL) instrument.

The EQ-5D-5L encompasses 5 domains, asking participants to rate their perceived health state today on the following dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has 5 possible levels: "no problems" (Level 1), "slight problems" (Level 2), "moderate problems" (Level 3), "severe problems" (Level 4), and "extreme problems" (Level 5). Responses for 5 dimensions together formed a 5-figure description of health state (e.g.11111 indicates no problems in all 5 dimensions). Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and at Cycle 6 (Each cycle was of 28 days)

End point values	non-gBRCA Placebo	non-gBRCA Niraparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	50[82]	127[83]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.011 (± 0.0949)	0.005 (± 0.1097)		

Notes:

[82] - Intent-to-treat population

[83] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EQ-5D-5L in Cohort With no Germline BRCA at post-progression

End point title	Change From Baseline in EQ-5D-5L in Cohort With no Germline BRCA at post-progression

End point description:

EQ-5D-5L is a well-validated, general preference-based, health-related Quality of Life (QoL) instrument. The EQ-5D-5L encompasses 5 domains, asking participants to rate their perceived health state today on the following dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has 5 possible levels: "no problems" (Level 1), "slight problems" (Level 2), "moderate problems" (Level 3), "severe problems" (Level 4), and "extreme problems" (Level 5). Responses for 5 dimensions together formed a 5-figure description of health state (e.g.11111 indicates no problems in all 5 dimensions). Baseline was latest non-missing pre-dose assessment on or before randomization date. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) and up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	149[84]	84[85]		
Units: Scores on a scale				
arithmetic mean (standard deviation)	-0.047 (± 0.1355)	-0.050 (± 0.1351)		

Notes:

[84] - Intent-to-treat population

[85] - Intent-to-treat population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at Baseline

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at Baseline[86]

End point description:

A Neuropathy Questionnaire measures the participant's symptom experience over the past 7 days using a 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if the participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. The Neuropathy Questionnaire was used to determine the chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For the first, a participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For the second, CIPN was assigned if a participant recorded a score greater than 1 ("a little bit"). Baseline was latest non-missing pre-dose assessment on or before randomization date.

End point type	Secondary

End point timeframe:

At Baseline

Notes:

[86] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138[87]	65[88]		
Units: Participants				
Feet, 0-Not at all	47	26		
Feet, 1-A little bit	32	12		
Feet, 2-Somewhat	24	9		
Feet, 3-Quite a bit	21	10		
Feet, 4-Very much	9	6		
Hands, 0-Not at all	80	37		
Hands, 1-A little bit	28	13		
Hands, 2-Somewhat	8	6		
Hands, 3-Quite a bit	14	5		
Hands, 4-Very much	3	2		

Notes:

[87] - Intent-to-treat population

[88] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands	
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8794
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet	
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7969
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at Cycle 2

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at Cycle 2[89]

End point description:

A Neuropathy Questionnaire measures participant's symptom experience over past 7 days using 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. Neuropathy Questionnaire was used to determine chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For first, participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For second, CIPN was assigned if participant recorded a score greater than 1 ("a little bit"). Only those participants with data available at indicated time points were analyzed

End point type	Secondary

End point timeframe:

At Cycle 2 (Each cycle was of 28 days)

Notes:

[89] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132[90]	64[91]		
Units: Participants				
Feet, 0-Not at all	48	25		
Feet, 1-A little bit	22	5		

Feet, 2-Somewhat	17	15		
Feet, 3-Quite a bit	20	10		
Feet, 4-Very much	8	3		
Hands, 0-Not at all	73	31		
Hands, 1-A little bit	19	16		
Hands, 2-Somewhat	13	6		
Hands, 3-Quite a bit	7	2		
Hands, 4-Very much	3	2		

Notes:

[90] - Intent-to-treat population

[91] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet

Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2399
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands

Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4584
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at Cycle 4

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at Cycle 4[92]

End point description:

A Neuropathy Questionnaire measures participant's symptom experience over past 7 days using 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. Neuropathy Questionnaire was used to determine chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For first, participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For second, CIPN was assigned if participant recorded a score greater than 1 ("a little bit"). Only those participants with data available at indicated time points were analyzed.

End point type	Secondary

End point timeframe:

At Cycle 4 (Each cycle was of 28 days)

Notes:

[92] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120[93]	54[94]		
Units: Participants				
Feet, 0-Not at all	47	20		
Feet, 1-A little bit	22	6		
Feet, 2-Somewhat	20	7		
Feet, 3-Quite a bit	15	8		
Feet, 4-Very much	6	2		
Hands, 0-Not at all	70	29		
Hands, 1-A little bit	18	6		
Hands, 2-Somewhat	16	3		
Hands, 3-Quite a bit	4	4		
Hands, 4-Very much	2	1		

Notes:

[93] - Intent-to-treat population

[94] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet	
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8566
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands	
Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4705
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at Cycle 6

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at Cycle 6[95]

End point description:

A Neuropathy Questionnaire measures participant's symptom experience over past 7 days using 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. Neuropathy Questionnaire was used to determine chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For first, participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For second, CIPN was assigned if participant recorded a score greater than 1 ("a little bit"). Only those participants with data available at indicated time points were analyzed.

End point type	Secondary

End point timeframe:

At Cycle 6 (Each cycle was of 28 days)

Notes:

[95] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105[96]	41[97]		
Units: Participants				
Feet, 0-Not at all	44	17		
Feet, 1-A little bit	17	5		
Feet, 2-Somewhat	13	7		
Feet, 3-Quite a bit	15	5		
Feet, 4-Very much	9	2		
Hands, 0-Not at all	54	21		
Hands, 1-A little bit	25	8		
Hands, 2-Somewhat	10	4		
Hands, 3-Quite a bit	6	2		
Hands, 4-Very much	2	1		

Notes:

[96] - Intent-to-treat population

[97] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands

Comparison groups	gBRCA Niraparib v gBRCA Placebo

Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9923
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet

Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8521
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at post-progression

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With Germline BRCA at post-progression[98]

End point description:

A Neuropathy Questionnaire measures participant's symptom experience over past 7 days using 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. Neuropathy Questionnaire was used to determine chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For first, participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For second, CIPN was assigned if participant recorded a score greater than 1 ("a little bit"). Only those participants with data available at indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Up to 7 years, 7 months and 4 days

Notes:

[98] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	104[99]	49[100]		
Units: Participants				
Feet, 0-Not at all	31	15		
Feet, 1-A little bit	20	9		
Feet, 2-Somewhat	7	3		
Feet, 3-Quite a bit	15	7		
Feet, 4-Very much	7	3		

Hands, 0-Not at all	44	26		
Hands, 1-A little bit	18	4		
Hands, 2-Somewhat	8	3		
Hands, 3-Quite a bit	7	4		
Hands, 4-Very much	3	0		

Notes:

[99] - Intent-to-treat population

[100] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands

Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3518
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet

Comparison groups	gBRCA Niraparib v gBRCA Placebo
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9997
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at Baseline

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at Baseline

End point description:

A Neuropathy Questionnaire measures the participant's symptom experience over the past 7 days using a 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if the participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. The Neuropathy Questionnaire was used to determine the chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For the first, a participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For the second, CIPN was assigned if a participant recorded a score greater than 1 ("a little bit"). Baseline was latest non-missing pre-dose assessment on or before randomization date.

End point type	Secondary

End point timeframe:

At Baseline

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	234[101]	116[102]		
Units: Participants				
Feet, 0-Not at all	71	40		
Feet, 1-A little bit	58	26		
Feet, 2-Somewhat	37	16		
Feet, 3-Quite a bit	43	21		
Feet, 4-Very much	18	9		
Hands, 0-Not at all	120	48		
Hands, 1-A little bit	56	37		
Hands, 2-Somewhat	28	12		
Hands, 3-Quite a bit	15	11		
Hands, 4-Very much	8	2		

Notes:

[101] - Intent-to-treat population

[102] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands	
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2502
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet	
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9367
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at Cycle 2

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at Cycle 2

End point description:

A Neuropathy Questionnaire measures participant's symptom experience over past 7 days using 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. Neuropathy Questionnaire was used to determine chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For first, participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For second, CIPN was assigned if participant recorded a score greater than 1 ("a little bit"). Only those participants with data available at indicated time points were analyzed

End point type	Secondary

End point timeframe:

At Cycle 2 (Each cycle was of 28 days)

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	212[103]	113[104]		
Units: Participants				
Feet, 0-Not at all	69	32		
Feet, 1-A little bit	39	17		
Feet, 2-Somewhat	30	22		
Feet, 3-Quite a bit	34	18		
Feet, 4-Very much	9	8		
Hands, 0-Not at all	100	44		
Hands, 1-A little bit	38	24		
Hands, 2-Somewhat	20	19		
Hands, 3-Quite a bit	17	5		
Hands, 4-Very much	4	3		

Notes:

[103] - Intent-to-treat population

[104] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands

Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.164
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet

Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5037
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at Cycle 4

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at Cycle 4

End point description:

A Neuropathy Questionnaire measures participant's symptom experience over past 7 days using 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. Neuropathy Questionnaire was used to determine chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For first, participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For second, CIPN was assigned if participant recorded a score greater than 1 ("a little bit"). Change from Baseline was calculated as on-treatment visit value minus Baseline value. Baseline was latest non-missing pre-dose assessment on or before randomization date.Only those participants with data available at indicated time points were analyzed.

End point type	Secondary

End point timeframe:

At Cycle 4 (Each cycle was of 28 days)

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	181[105]	95[106]		
Units: Participants				
Feet, 0-Not at all	54	31		
Feet, 1-A little bit	37	16		
Feet, 2-Somewhat	34	17		
Feet, 3-Quite a bit	20	11		
Feet, 4-Very much	9	5		
Hands, 0-Not at all	89	43		
Hands, 1-A little bit	29	21		
Hands, 2-Somewhat	14	10		
Hands, 3-Quite a bit	14	3		
Hands, 4-Very much	6	1		

Notes:

[105] - Intent-to-treat population

[106] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands

Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	276
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.247
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet	
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	276
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9599
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at Cycle 6

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at Cycle 6

End point description:

A Neuropathy Questionnaire measures participant's symptom experience over past 7 days using 5-point Likert scale of "not at all" (0) to "very much" (4). There are 2 items that ask if participant's feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. Neuropathy Questionnaire was used to determine chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant's QoL. Two thresholds were used. For first, participant was determined to have CIPN if a score greater than 0 ("not at all") was recorded for either item. For second, CIPN was assigned if participant recorded a score greater than 1 ("a little bit"). Only those participants with data available at indicated time points were analyzed

End point type	Secondary

End point timeframe:

At Cycle 6 (Each cycle was of 28 days)

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	144[107]	56[108]		
Units: Participants				
Feet, 0-Not at all	43	16		
Feet, 1-A little bit	29	10		
Feet, 2-Somewhat	30	11		
Feet, 3-Quite a bit	18	9		
Feet, 4-Very much	5	5		
Hands, 0-Not at all	68	29		
Hands, 1-A little bit	30	10		

Hands, 2-Somewhat	13	6		
Hands, 3-Quite a bit	9	5		
Hands, 4-Very much	3	0		

Notes:

[107] - Intent-to-treat population

[108] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Analysis for gBRCA Niraparib vs gBRCA Placebo-Hands	
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7459
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Analysis for gBRCA Niraparib vs gBRCA Placebo-Feet	
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	200
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5921
Method	Pearson's Chi-squared test

Secondary: Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at post-progression

End point title	Number of participants with response to Neuropathy questionnaire in Cohort With no Germline BRCA at post-progression

End point description:

A Neuropathy Questionnaire measures participant's symptom experience over past 7 days using 5-point Likert scale of “not at all” (0) to “very much” (4). There are 2 items that ask if participant’s feet (item 1) or hands (item 2) feel numb or have prickling/tingling feelings. Neuropathy Questionnaire was used to determine chemotherapy-induced peripheral neuropathy (CIPN) status of each participant as well as provide an anchor for interpreting the impact of CIPN on participant’s QoL. Two thresholds were used. For first, participant was determined to have CIPN if a score greater than 0 (“not at all”) was recorded for either item. For second, CIPN was assigned if participant recorded a score greater than 1 (“a little bit”). Only those participants with data available at indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Up to 7 years, 7 months and 4 days

End point values	non-gBRCA Niraparib	non-gBRCA Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185[109]	105[110]		
Units: Participants				
Feet, 0-Not at all	57	32		
Feet, 1-A little bit	45	12		
Feet, 2-Somewhat	23	16		
Feet, 3-Quite a bit	19	16		
Feet, 4-Very much	5	8		
Hands, 0-Not at all	88	48		
Hands, 1-A little bit	35	15		
Hands, 2-Somewhat	13	9		
Hands, 3-Quite a bit	7	10		
Hands, 4-Very much	3	1		

Notes:

[109] - Intent-to-treat population

[110] - Intent-to-treat population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	290
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2798
Method	Pearson's Chi-squared test

Statistical analysis title	Statistical Analysis 1
Comparison groups	non-gBRCA Niraparib v non-gBRCA Placebo
Number of subjects included in analysis	290
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0259
Method	Pearson's Chi-squared test

Secondary: Number of participants with non-serious adverse events (AEs) and serious AEs (SAEs)

End point title	Number of participants with non-serious adverse events (AEs) and serious AEs (SAEs)[111]

End point description:

An AE is any untoward medical occurrence that occurs in a participants or clinical investigation participant administered a pharmaceutical product, and which does not necessarily have to have a causal relationship with this treatment. A SAE is defined as any untoward medical occurrence that at any dose which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, is an important medical event(s) as per medical and scientific judgment. Adverse events which were not serious adverse events were considered as non serious adverse events.

Data presented for this outcome measure is based on the data cut-off date of 31-March-2021, which aligns with the time of the study unblinding. Safety Population consisted of all participants who ingested any amount of study drug.

End point type	Secondary

End point timeframe:

Up to 7 years, 7 months and 6 days

Notes:

[111] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	gBRCA Niraparib	gBRCA Placebo	Non-gBRCA Niraparib	Non-gBRCA Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136[112]	65[113]	231[114]	114[115]
Units: Participants				
Non-serious AEs	136	62	231	110
SAEs	51	9	76	20

Notes:

[112] - Safety Population

[113] - Safety Population

[114] - Safety Population

[115] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with non-serious AEs and SAEs (Post-study unblinding)

End point title	Number of participants with non-serious AEs and SAEs (Post-study unblinding)

End point description:

An AE is any untoward medical occurrence that occurs in a participants or clinical investigation participant administered a pharmaceutical product, and which does not necessarily have to have a causal relationship with this treatment. A SAE is defined as any untoward medical occurrence that at any dose which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, is an important medical event(s) as per medical and scientific judgment. Adverse events which were not serious adverse events were considered as non serious adverse events. The data is presented for post-study unblinding duration 01-Apr-2021 to 26-Dec-2021

End point type	Secondary

End point timeframe:

Up to 8 months, 26 days

End point values	gBRCA Niraparib (PSU)	gBRCA Placebo (PSU)	Non-gBRCA Niraparib (PSU)	Non-gBRCA Placebo (PSU)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22[116]	8[117]	31[118]	13[119]
Units: Participants				
Non-serious AEs	0	0	0	0
SAEs	0	0	0	0

Notes:

[116] - Safety Population

[117] - Safety Population

[118] - Safety Population

[119] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with non-serious AEs and SAEs in FE sub-study

End point title	Number of participants with non-serious AEs and SAEs in FE sub-study

End point description:

An AE is any untoward medical occurrence that occurs in a participants or clinical investigation participant administered a pharmaceutical product, and which does not necessarily have to have a causal relationship with this treatment. A SAE is defined as any untoward medical occurrence that at any dose which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, is an important medical event(s) as per medical and scientific judgment. Adverse events which were not serious adverse events were considered as non serious adverse events.

End point type	Secondary

End point timeframe:

Up to 2 years 3 months and 11 days

End point values	FE Niraparib Fasted	FE Niraparib Fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16[120]	16[121]		
Units: Participants				
Non-serious AEs	4	6		
SAEs	1	0		

Notes:

[120] - Safety Population

[121] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the plasma concentration-time curve from time 0 extrapolated to infinity (AUC[0-infinity]) following administration of Niraparib (FE sub-study)

End point title	Area under the plasma concentration-time curve from time 0 extrapolated to infinity (AUC[0-infinity]) following administration of Niraparib (FE sub-study)

End point description:

Blood samples were collected at indicated time points to analyze AUC(0-infinity) of niraparib. Pharmacokinetic population consisted of all participants who received at least one dose of study drug, with sufficient data available to calculate parameters. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose and at 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96, 120 hours post dose

End point values	FE Niraparib Fasted	FE Niraparib Fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15[122]	14[123]		
Units: Nanograms*hour per milliliter				
arithmetic mean (standard deviation)	29016.1 (± 18405.23)	31194 (± 16894.88)		

Notes:

[122] - Pharmacokinetic population

[123] - Pharmacokinetic population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	FE Niraparib Fasted v FE Niraparib Fed
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Ratio of Least square mean
Point estimate	1.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.997
upper limit	1.216

Secondary: Number of participants with non-serious AEs and SAEs in QTc sub-study

End point title	Number of participants with non-serious AEs and SAEs in QTc sub-study[124]

End point description:

An AE is any untoward medical occurrence that occurs in a participants or clinical investigation participant administered a pharmaceutical product, and which does not necessarily have to have a causal relationship with this treatment. A SAE is defined as any untoward medical occurrence that at any dose which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, is an important medical event(s) as per medical and scientific judgment. Adverse events which were not serious adverse events were considered as non serious adverse events.

End point type	Secondary

End point timeframe:

Up to 5 years 10 months and 22 days

Notes:

[124] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	QTc sub-study: Niraparib			
Subject group type	Reporting group			
Number of subjects analysed	26[125]			
Units: Participants				
Non-serious AEs	24			
SAEs	12			

Notes:

[125] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the plasma concentration-time curve from time 0 to the last quantifiable concentration (AUC[0-last]) following administration of Niraparib (FE sub-study)

End point title	Area under the plasma concentration-time curve from time 0 to the last quantifiable concentration (AUC[0-last]) following administration of Niraparib (FE sub-study)

End point description:

Blood samples were collected at indicated time points to analyze the AUC(0-last) of niraparib. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose (Day -1) and at 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96, 120 hours post dose

End point values	FE Niraparib Fasted	FE Niraparib Fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16[126]	15		
Units: Nanograms*hour per milliliter				
arithmetic mean (standard deviation)	28638.1 (± 17911.86)	27186.4 (± 14111.37)		

Notes:

[126] - Pharmacokinetic population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	FE Niraparib Fasted v FE Niraparib Fed
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Ratio of Least square mean
Point estimate	1.068

Confidence interval	
level	90 %
sides	2-sided
lower limit	0.978
upper limit	1.166

Secondary: Maximum observed plasma concentration (Cmax) following administration of Niraparib (FE sub-study)

End point title	Maximum observed plasma concentration (Cmax) following administration of Niraparib (FE sub-study)

End point description:

Blood samples were collected at indicated time points to analyze the maximum observed plasma concentration of niraparib. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose (Day -1) and at 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96, 120 hours post dose

End point values	FE Niraparib Fasted	FE Niraparib Fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16[127]	15		
Units: Nanograms per milliliter				
arithmetic mean (standard deviation)	803.7 (± 403.35)	582.1 (± 228.57)		

Notes:

[127] - Pharmacokinetic population

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	FE Niraparib Fasted v FE Niraparib Fed
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Ratio of Least square mean
Point estimate	0.785
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.695
upper limit	0.886

Secondary: Time to reach maximum (tmax) following administration of Niraparib (FE sub-study)

End point title	Time to reach maximum (tmax) following administration of Niraparib (FE sub-study)

End point description:

Blood samples were collected at indicated time points to analyze the tmax of niraparib. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose (Day -1) and at 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96, 120 hours post dose

End point values	FE Niraparib Fasted	FE Niraparib Fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16[128]	15		
Units: Hour				
median (full range (min-max))	3.1 (1.7 to 6.1)	6.1 (1.2 to 23)		

Notes:

[128] - Pharmacokinetic population

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal elimination half-life (t1/2) following administration of Niraparib (FE sub-study)

End point title	Terminal elimination half-life (t1/2) following administration of Niraparib (FE sub-study)

End point description:

Blood samples were collected at indicated time points to analyze the t1/2 of niraparib. Only those participants with data available at the indicated time points were analyzed.

End point type	Secondary

End point timeframe:

Pre-dose (Day -1) and at 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96, 120 hours post dose

End point values	FE Niraparib Fasted	FE Niraparib Fed		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	16[129]	14[130]		
Units: Hour				
arithmetic mean (standard deviation)	50.5 (± 17.87)	47.9 (± 17.54)		

Notes:

[129] - Pharmacokinetic population

[130] - Pharmacokinetic population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with maximum post-Baseline QT Interval

Corrected by Fridericia's Formula (QTcF) greater than pre-specified thresholds

End point title	Number of participants with maximum post-Baseline QT Interval Corrected by Fridericia's Formula (QTcF) greater than pre-specified thresholds[131]

End point description:

12-lead electrocardiogram was obtained at indicated time points using an automated electrocardiogram machine that measured QTcF interval. The number of participants with maximum post-Baseline ECG value exceeding the following limits have been reported: QTcF interval >450 and <= 480 milliseconds (msec) and >500 msec.

End point type	Secondary

End point timeframe:

At Baseline (Cycle 1 Day 1, each cycle was of 28 days)

Notes:

[131] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	QTc sub-study: Niraparib			
Subject group type	Reporting group			
Number of subjects analysed	26[132]			
Units: Participants				
>450 msec	2			
>480 msec	0			
>500 msec	0			

Notes:

[132] - Safety Population

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, non-serious AEs (non-SAEs) and SAEs were collected up to 7 years, 7 months and 6 days

Adverse event reporting additional description:

Safety Population was used to assess SAEs and non-SAEs, which comprised of all participants who ingested any amount of study drug. The data is presented in separate arms for adverse events before unblinding (data cut-off date of 31-March-2021) and post-study unblinding until the end of study (01-April-2021 to 26-December-2021).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	gBRCA Placebo

Reporting group description:

Participants with germline BRCA mutation received oral dose of placebo matching niraparib once daily in 28-day cycles until disease progression

Reporting group title	gBRCA Niraparib

Reporting group description:

Participants with germline breast cancer gene (gBRCA) mutation received oral dose of niraparib 300 milligrams (mg) once daily in 28-day cycles until disease progression.

Reporting group title	Non-gBRCA Niraparib

Reporting group description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in 28-day cycles until disease progression.

Reporting group title	FE Niraparib Fasted

Reporting group description:

Participants received Niraparib 300 mg in fasted condition

Reporting group title	Non-gBRCA Placebo

Reporting group description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression

Reporting group title	FE Niraparib Fed

Reporting group description:

Participants received Niraparib 300 mg in fed condition

Reporting group title	gBRCA Placebo (PSU)

Reporting group description:

Participants with germline BRCA mutation received oral dose of placebo matching niraparib once daily in 28-day cycles until disease progression. This arm presents data for post-study unblinding duration 1-Apr-2021 to 26-Dec-2021.

Reporting group title	QTc sub-study: Niraparib

Reporting group description:

Participants received Niraparib 300 mg once daily orally.

Reporting group title	gBRCA Niraparib (PSU)

Reporting group description:

Participants with germline breast cancer gene (gBRCA) mutation received oral dose of niraparib 300 milligrams (mg) once daily in 28-day cycles until disease progression. This arm presents data for post-study unblinding duration 1-Apr-2021 to 26-Dec-2021

Reporting group title	Non-gBRCA Niraparib (PSU)

Reporting group description:

Participants without germline BRCA mutation received oral dose of niraparib 300 mg once daily orally in

28-day cycles until disease progression. This arm presents data for post-study unblinding duration 1-Apr-2021 to 26-Dec-2021.

Reporting group title	Non-gBRCA Placebo (PSU)

Reporting group description:

Participants without germline BRCA mutation received matching placebo once daily orally in 28-day cycles until disease progression. This arm presents data for post-study unblinding duration 1-Apr-2021 to 26-Dec-2021.

Serious adverse events	gBRCA Placebo	gBRCA Niraparib	Non-gBRCA Niraparib
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 65 (13.85%)	51 / 136 (37.50%)	76 / 231 (32.90%)
number of deaths (all causes)	29	72	146
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 65 (1.54%)	6 / 136 (4.41%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 1	6 / 6	0 / 0
deaths causally related to treatment / all	0 / 1	2 / 2	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	1 / 65 (1.54%)	5 / 136 (3.68%)	2 / 231 (0.87%)
occurrences causally related to treatment / all	0 / 1	5 / 5	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	2 / 2
Metastases to central nervous system			
subjects affected / exposed	1 / 65 (1.54%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute erythroid leukaemia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Intraductal proliferative breast lesion			

subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Undifferentiated sarcoma			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer recurrent			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 65 (0.00%)	2 / 136 (1.47%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mucosal inflammation			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	2 / 231 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactoid reaction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast disorder			
subjects affected / exposed	1 / 65 (1.54%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			

subjects affected / exposed	1 / 65 (1.54%)	1 / 136 (0.74%)	2 / 231 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute pulmonary oedema			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Behaviour disorder			

subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 65 (1.54%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Thrombosis in device			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	1 / 65 (1.54%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			

subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	2 / 231 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural discomfort			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product use complaint			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Cardiac failure			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 65 (0.00%)	18 / 136 (13.24%)	23 / 231 (9.96%)
occurrences causally related to treatment / all	0 / 0	38 / 38	36 / 36
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 65 (0.00%)	4 / 136 (2.94%)	13 / 231 (5.63%)
occurrences causally related to treatment / all	0 / 0	6 / 6	15 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	2 / 231 (0.87%)
occurrences causally related to treatment / all	0 / 0	1 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 65 (0.00%)	3 / 136 (2.21%)	6 / 231 (2.60%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	2 / 65 (3.08%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	0 / 65 (0.00%)	2 / 136 (1.47%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	3 / 231 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	2 / 231 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			

subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			

subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			

subjects affected / exposed	1 / 65 (1.54%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 65 (1.54%)	1 / 136 (0.74%)	2 / 231 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	3 / 231 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Infection			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pyelonephritis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	1 / 231 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 136 (0.74%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	FE Niraparib Fasted	Non-gBRCA Placebo	FE Niraparib Fed
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	20 / 114 (17.54%)	0 / 16 (0.00%)
number of deaths (all causes)	0	68	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			

subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute erythroid leukaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Undifferentiated sarcoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer recurrent			

subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical health deterioration			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactoid reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute pulmonary oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			

subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Behaviour disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			

subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Thrombosis in device			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Post procedural discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product use complaint			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	4 / 114 (3.51%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			

subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 16 (6.25%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			

subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	gBRCA Placebo (PSU)	QTc sub-study: Niraparib	gBRCA Niraparib (PSU)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	12 / 26 (46.15%)	0 / 22 (0.00%)
number of deaths (all causes)	0	5	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute erythroid leukaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Undifferentiated sarcoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer recurrent			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactoid reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Behaviour disorder			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Thrombosis in device			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural complication			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product use complaint			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 26 (11.54%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	9 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant gastrointestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 26 (3.85%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Non-gBRCA Niraparib (PSU)	Non-gBRCA Placebo (PSU)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to peritoneum			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute erythroid leukaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Undifferentiated sarcoma			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer recurrent			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

General physical health deterioration			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactoid reaction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Breast disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory disorder			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Behaviour disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Thrombosis in device			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Post procedural discomfort			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transfusion reaction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product use complaint			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Small intestinal obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant gastrointestinal obstruction			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	gBRCA Placebo	gBRCA Niraparib	Non-gBRCA Niraparib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	62 / 65 (95.38%)	136 / 136 (100.00%)	231 / 231 (100.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	5 / 65 (7.69%)	38 / 136 (27.94%)	46 / 231 (19.91%)
occurrences (all)	6	123	207
Deep vein thrombosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	3 / 65 (4.62%)	10 / 136 (7.35%)	24 / 231 (10.39%)
occurrences (all)	3	11	43
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	19 / 65 (29.23%)	66 / 136 (48.53%)	110 / 231 (47.62%)
occurrences (all)	37	134	189
Catheter site pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	3 / 65 (4.62%)	27 / 136 (19.85%)	36 / 231 (15.58%)
occurrences (all)	3	75	81
Pyrexia			
subjects affected / exposed	4 / 65 (6.15%)	11 / 136 (8.09%)	16 / 231 (6.93%)
occurrences (all)	5	17	23

Oedema peripheral			
subjects affected / exposed	2 / 65 (3.08%)	12 / 136 (8.82%)	15 / 231 (6.49%)
occurrences (all)	3	15	23
Influenza like illness			
subjects affected / exposed	1 / 65 (1.54%)	8 / 136 (5.88%)	0 / 231 (0.00%)
occurrences (all)	1	11	0
Mucosal inflammation			
subjects affected / exposed	1 / 65 (1.54%)	7 / 136 (5.15%)	19 / 231 (8.23%)
occurrences (all)	1	9	23
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 65 (4.62%)	23 / 136 (16.91%)	49 / 231 (21.21%)
occurrences (all)	4	34	62
Cough			
subjects affected / exposed	2 / 65 (3.08%)	26 / 136 (19.12%)	42 / 231 (18.18%)
occurrences (all)	4	36	60
Dysphonia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 65 (3.08%)	11 / 136 (8.09%)	16 / 231 (6.93%)
occurrences (all)	2	19	21
Epistaxis			
subjects affected / exposed	0 / 65 (0.00%)	7 / 136 (5.15%)	12 / 231 (5.19%)
occurrences (all)	0	9	15
Psychiatric disorders			
Insomnia			
subjects affected / exposed	6 / 65 (9.23%)	26 / 136 (19.12%)	67 / 231 (29.00%)
occurrences (all)	7	36	88
Anxiety			
subjects affected / exposed	7 / 65 (10.77%)	12 / 136 (8.82%)	21 / 231 (9.09%)
occurrences (all)	11	27	27
Depression			

subjects affected / exposed	2 / 65 (3.08%)	9 / 136 (6.62%)	14 / 231 (6.06%)
occurrences (all)	3	14	21
Investigations			
Platelet count decreased			
subjects affected / exposed	1 / 65 (1.54%)	34 / 136 (25.00%)	45 / 231 (19.48%)
occurrences (all)	1	85	132
Neutrophil count decreased			
subjects affected / exposed	3 / 65 (4.62%)	23 / 136 (16.91%)	31 / 231 (13.42%)
occurrences (all)	5	64	79
Blood creatinine increased			
subjects affected / exposed	3 / 65 (4.62%)	11 / 136 (8.09%)	15 / 231 (6.49%)
occurrences (all)	4	29	32
White blood cell count decreased			
subjects affected / exposed	5 / 65 (7.69%)	20 / 136 (14.71%)	22 / 231 (9.52%)
occurrences (all)	14	42	64
Alanine aminotransferase increased			
subjects affected / exposed	0 / 65 (0.00%)	7 / 136 (5.15%)	13 / 231 (5.63%)
occurrences (all)	0	10	21
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 65 (4.62%)	7 / 136 (5.15%)	20 / 231 (8.66%)
occurrences (all)	3	17	48
Weight decreased			
subjects affected / exposed	0 / 65 (0.00%)	9 / 136 (6.62%)	0 / 231 (0.00%)
occurrences (all)	0	15	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 65 (0.00%)	7 / 136 (5.15%)	15 / 231 (6.49%)
occurrences (all)	0	15	27
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	13 / 231 (5.63%)
occurrences (all)	0	0	19
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 65 (0.00%)	10 / 136 (7.35%)	0 / 231 (0.00%)
occurrences (all)	0	12	0
Fall			

subjects affected / exposed	0 / 65 (0.00%)	7 / 136 (5.15%)	0 / 231 (0.00%)
occurrences (all)	0	10	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 65 (1.54%)	14 / 136 (10.29%)	27 / 231 (11.69%)
occurrences (all)	1	19	35
Tachycardia			
subjects affected / exposed	1 / 65 (1.54%)	11 / 136 (8.09%)	14 / 231 (6.06%)
occurrences (all)	1	13	20
Nervous system disorders			
Dizziness			
subjects affected / exposed	7 / 65 (10.77%)	26 / 136 (19.12%)	43 / 231 (18.61%)
occurrences (all)	14	39	53
Amnesia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	4 / 65 (6.15%)	13 / 136 (9.56%)	14 / 231 (6.06%)
occurrences (all)	4	17	19
Headache			
subjects affected / exposed	7 / 65 (10.77%)	52 / 136 (38.24%)	52 / 231 (22.51%)
occurrences (all)	12	76	97
Dysgeusia			
subjects affected / exposed	1 / 65 (1.54%)	12 / 136 (8.82%)	14 / 231 (6.06%)
occurrences (all)	1	13	18
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 65 (0.00%)	7 / 136 (5.15%)	0 / 231 (0.00%)
occurrences (all)	0	7	0
Paraesthesia			
subjects affected / exposed	1 / 65 (1.54%)	11 / 136 (8.09%)	0 / 231 (0.00%)
occurrences (all)	1	31	0
Blood and lymphatic system disorders			

Thrombocytopenia			
subjects affected / exposed	2 / 65 (3.08%)	73 / 136 (53.68%)	93 / 231 (40.26%)
occurrences (all)	3	226	256
Anaemia			
subjects affected / exposed	5 / 65 (7.69%)	74 / 136 (54.41%)	111 / 231 (48.05%)
occurrences (all)	5	259	328
Neutropenia			
subjects affected / exposed	3 / 65 (4.62%)	24 / 136 (17.65%)	42 / 231 (18.18%)
occurrences (all)	7	77	128
Leukopenia			
subjects affected / exposed	4 / 65 (6.15%)	11 / 136 (8.09%)	17 / 231 (7.36%)
occurrences (all)	6	38	52
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	12 / 65 (18.46%)	56 / 136 (41.18%)	96 / 231 (41.56%)
occurrences (all)	14	105	163
Diarrhoea			
subjects affected / exposed	15 / 65 (23.08%)	40 / 136 (29.41%)	44 / 231 (19.05%)
occurrences (all)	28	71	76
Ascites			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	3 / 65 (4.62%)	7 / 136 (5.15%)	12 / 231 (5.19%)
occurrences (all)	3	9	17
Abdominal pain			
subjects affected / exposed	17 / 65 (26.15%)	34 / 136 (25.00%)	63 / 231 (27.27%)
occurrences (all)	24	50	93
Abdominal pain lower			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	23 / 65 (35.38%)	106 / 136 (77.94%)	168 / 231 (72.73%)
occurrences (all)	46	205	304
Vomiting			
subjects affected / exposed	10 / 65 (15.38%)	57 / 136 (41.91%)	74 / 231 (32.03%)
occurrences (all)	13	96	126
Stomatitis			
subjects affected / exposed	4 / 65 (6.15%)	5 / 136 (3.68%)	11 / 231 (4.76%)
occurrences (all)	4	5	18
Abdominal pain upper			
subjects affected / exposed	9 / 65 (13.85%)	17 / 136 (12.50%)	24 / 231 (10.39%)
occurrences (all)	12	26	36
Abdominal distension			
subjects affected / exposed	6 / 65 (9.23%)	4 / 136 (2.94%)	23 / 231 (9.96%)
occurrences (all)	7	6	29
Dyspepsia			
subjects affected / exposed	10 / 65 (15.38%)	23 / 136 (16.91%)	22 / 231 (9.52%)
occurrences (all)	11	37	25
Dry mouth			
subjects affected / exposed	2 / 65 (3.08%)	19 / 136 (13.97%)	19 / 231 (8.23%)
occurrences (all)	5	38	27
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	22 / 231 (9.52%)
occurrences (all)	0	0	25
Haemorrhoids			
subjects affected / exposed	2 / 65 (3.08%)	7 / 136 (5.15%)	0 / 231 (0.00%)
occurrences (all)	2	7	0
Skin and subcutaneous tissue disorders			
Photosensitivity reaction			
subjects affected / exposed	0 / 65 (0.00%)	11 / 136 (8.09%)	25 / 231 (10.82%)
occurrences (all)	0	13	37
Rash			
subjects affected / exposed	1 / 65 (1.54%)	14 / 136 (10.29%)	16 / 231 (6.93%)
occurrences (all)	1	16	20
Alopecia			
subjects affected / exposed	6 / 65 (9.23%)	15 / 136 (11.03%)	20 / 231 (8.66%)
occurrences (all)	6	17	21

Pruritus			
subjects affected / exposed	3 / 65 (4.62%)	12 / 136 (8.82%)	5 / 231 (2.16%)
occurrences (all)	3	13	5
Petechiae			
subjects affected / exposed	0 / 65 (0.00%)	9 / 136 (6.62%)	0 / 231 (0.00%)
occurrences (all)	0	10	0
Dry skin			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	18 / 231 (7.79%)
occurrences (all)	0	0	30
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 65 (1.54%)	7 / 136 (5.15%)	0 / 231 (0.00%)
occurrences (all)	1	11	0
Musculoskeletal and connective tissue disorders			
Joint swelling			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	10 / 65 (15.38%)	29 / 136 (21.32%)	27 / 231 (11.69%)
occurrences (all)	11	44	40
Back pain			
subjects affected / exposed	9 / 65 (13.85%)	29 / 136 (21.32%)	33 / 231 (14.29%)
occurrences (all)	9	40	38
Pain in extremity			
subjects affected / exposed	4 / 65 (6.15%)	19 / 136 (13.97%)	16 / 231 (6.93%)
occurrences (all)	4	27	19
Muscle spasms			
subjects affected / exposed	2 / 65 (3.08%)	16 / 136 (11.76%)	14 / 231 (6.06%)
occurrences (all)	2	24	15
Myalgia			
subjects affected / exposed	6 / 65 (9.23%)	15 / 136 (11.03%)	21 / 231 (9.09%)
occurrences (all)	7	18	24
Musculoskeletal pain			
subjects affected / exposed	2 / 65 (3.08%)	11 / 136 (8.09%)	12 / 231 (5.19%)
occurrences (all)	2	14	23
Musculoskeletal chest pain			

subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	8 / 231 (3.46%)
occurrences (all)	0	0	9
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	6 / 65 (9.23%)	20 / 136 (14.71%)	26 / 231 (11.26%)
occurrences (all)	11	25	40
Nasopharyngitis			
subjects affected / exposed	4 / 65 (6.15%)	21 / 136 (15.44%)	29 / 231 (12.55%)
occurrences (all)	7	33	40
Upper respiratory tract infection			
subjects affected / exposed	3 / 65 (4.62%)	15 / 136 (11.03%)	14 / 231 (6.06%)
occurrences (all)	5	18	18
Bronchitis			
subjects affected / exposed	4 / 65 (6.15%)	6 / 136 (4.41%)	15 / 231 (6.49%)
occurrences (all)	4	8	19
Sinusitis			
subjects affected / exposed	1 / 65 (1.54%)	10 / 136 (7.35%)	15 / 231 (6.49%)
occurrences (all)	1	13	19
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	9 / 65 (13.85%)	30 / 136 (22.06%)	67 / 231 (29.00%)
occurrences (all)	12	49	94
Hypomagnesaemia			
subjects affected / exposed	8 / 65 (12.31%)	15 / 136 (11.03%)	18 / 231 (7.79%)
occurrences (all)	18	40	28
Hypokalaemia			
subjects affected / exposed	5 / 65 (7.69%)	11 / 136 (8.09%)	15 / 231 (6.49%)
occurrences (all)	10	14	26
Hyperglycaemia			
subjects affected / exposed	5 / 65 (7.69%)	7 / 136 (5.15%)	0 / 231 (0.00%)
occurrences (all)	10	8	0
Dehydration			
subjects affected / exposed	0 / 65 (0.00%)	0 / 136 (0.00%)	0 / 231 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	FE Niraparib Fasted	Non-gBRCA Placebo	FE Niraparib Fed
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	4 / 16 (25.00%)	110 / 114 (96.49%)	6 / 16 (37.50%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 16 (0.00%)	4 / 114 (3.51%)	0 / 16 (0.00%)
occurrences (all)	0	5	0
Deep vein thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 16 (0.00%)	6 / 114 (5.26%)	0 / 16 (0.00%)
occurrences (all)	0	8	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 16 (0.00%)	38 / 114 (33.33%)	1 / 16 (6.25%)
occurrences (all)	0	53	1
Catheter site pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	0 / 16 (0.00%)	13 / 114 (11.40%)	0 / 16 (0.00%)
occurrences (all)	0	17	0
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	7 / 114 (6.14%)	1 / 16 (6.25%)
occurrences (all)	0	8	1
Oedema peripheral			
subjects affected / exposed	0 / 16 (0.00%)	6 / 114 (5.26%)	0 / 16 (0.00%)
occurrences (all)	0	10	0
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			

subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	12 / 114 (10.53%)	0 / 16 (0.00%)
occurrences (all)	0	14	0
Cough			
subjects affected / exposed	1 / 16 (6.25%)	8 / 114 (7.02%)	0 / 16 (0.00%)
occurrences (all)	1	9	0
Dysphonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	3 / 114 (2.63%)	0 / 16 (0.00%)
occurrences (all)	0	4	0
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	4 / 114 (3.51%)	0 / 16 (0.00%)
occurrences (all)	0	4	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 16 (0.00%)	10 / 114 (8.77%)	0 / 16 (0.00%)
occurrences (all)	0	11	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	5 / 114 (4.39%)	0 / 16 (0.00%)
occurrences (all)	0	5	0
Depression			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Neutrophil count decreased			

subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased			
subjects affected / exposed	1 / 16 (6.25%)	3 / 114 (2.63%)	0 / 16 (0.00%)
occurrences (all)	1	3	0
White blood cell count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences (all)	0	4	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	5 / 114 (4.39%)	0 / 16 (0.00%)
occurrences (all)	0	9	0
Weight decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Palpitations			

subjects affected / exposed	0 / 16 (0.00%)	4 / 114 (3.51%)	0 / 16 (0.00%)
occurrences (all)	0	4	0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 16 (0.00%)	9 / 114 (7.89%)	0 / 16 (0.00%)
occurrences (all)	0	12	0
Amnesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 16 (0.00%)	8 / 114 (7.02%)	0 / 16 (0.00%)
occurrences (all)	0	9	0
Headache			
subjects affected / exposed	0 / 16 (0.00%)	14 / 114 (12.28%)	0 / 16 (0.00%)
occurrences (all)	0	21	0
Dysgeusia			
subjects affected / exposed	0 / 16 (0.00%)	3 / 114 (2.63%)	1 / 16 (6.25%)
occurrences (all)	0	3	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 16 (0.00%)	4 / 114 (3.51%)	0 / 16 (0.00%)
occurrences (all)	0	4	0
Anaemia			
subjects affected / exposed	1 / 16 (6.25%)	7 / 114 (6.14%)	0 / 16 (0.00%)
occurrences (all)	1	11	0
Neutropenia			

subjects affected / exposed	0 / 16 (0.00%)	3 / 114 (2.63%)	0 / 16 (0.00%)
occurrences (all)	0	14	0
Leukopenia			
subjects affected / exposed	0 / 16 (0.00%)	5 / 114 (4.39%)	0 / 16 (0.00%)
occurrences (all)	0	17	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 16 (6.25%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	23 / 114 (20.18%)	1 / 16 (6.25%)
occurrences (all)	0	30	1
Diarrhoea			
subjects affected / exposed	1 / 16 (6.25%)	23 / 114 (20.18%)	0 / 16 (0.00%)
occurrences (all)	2	34	0
Ascites			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 16 (0.00%)	9 / 114 (7.89%)	0 / 16 (0.00%)
occurrences (all)	0	10	0
Abdominal pain			
subjects affected / exposed	0 / 16 (0.00%)	39 / 114 (34.21%)	0 / 16 (0.00%)
occurrences (all)	0	50	0
Abdominal pain lower			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 16 (0.00%)	41 / 114 (35.96%)	0 / 16 (0.00%)
occurrences (all)	0	59	0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	21 / 114 (18.42%)	1 / 16 (6.25%)
occurrences (all)	0	31	1
Stomatitis			

subjects affected / exposed	0 / 16 (0.00%)	7 / 114 (6.14%)	0 / 16 (0.00%)
occurrences (all)	0	11	0
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	9 / 114 (7.89%)	0 / 16 (0.00%)
occurrences (all)	0	17	0
Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	15 / 114 (13.16%)	0 / 16 (0.00%)
occurrences (all)	0	17	0
Dyspepsia			
subjects affected / exposed	0 / 16 (0.00%)	9 / 114 (7.89%)	0 / 16 (0.00%)
occurrences (all)	0	10	0
Dry mouth			
subjects affected / exposed	0 / 16 (0.00%)	5 / 114 (4.39%)	0 / 16 (0.00%)
occurrences (all)	0	6	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 16 (0.00%)	4 / 114 (3.51%)	0 / 16 (0.00%)
occurrences (all)	0	4	0
Haemorrhoids			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Photosensitivity reaction			
subjects affected / exposed	0 / 16 (0.00%)	1 / 114 (0.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 16 (0.00%)	5 / 114 (4.39%)	0 / 16 (0.00%)
occurrences (all)	0	5	0
Alopecia			
subjects affected / exposed	0 / 16 (0.00%)	8 / 114 (7.02%)	0 / 16 (0.00%)
occurrences (all)	0	9	0
Pruritus			
subjects affected / exposed	0 / 16 (0.00%)	8 / 114 (7.02%)	0 / 16 (0.00%)
occurrences (all)	0	8	0
Petechiae			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 16 (0.00%)	5 / 114 (4.39%)	0 / 16 (0.00%)
occurrences (all)	0	7	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Joint swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 16 (0.00%)	14 / 114 (12.28%)	0 / 16 (0.00%)
occurrences (all)	0	20	0
Back pain			
subjects affected / exposed	0 / 16 (0.00%)	16 / 114 (14.04%)	0 / 16 (0.00%)
occurrences (all)	0	38	0
Pain in extremity			
subjects affected / exposed	0 / 16 (0.00%)	13 / 114 (11.40%)	0 / 16 (0.00%)
occurrences (all)	0	14	0
Muscle spasms			
subjects affected / exposed	0 / 16 (0.00%)	5 / 114 (4.39%)	0 / 16 (0.00%)
occurrences (all)	0	5	0
Myalgia			
subjects affected / exposed	0 / 16 (0.00%)	12 / 114 (10.53%)	0 / 16 (0.00%)
occurrences (all)	0	13	0
Musculoskeletal pain			
subjects affected / exposed	0 / 16 (0.00%)	3 / 114 (2.63%)	0 / 16 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 16 (0.00%)	7 / 114 (6.14%)	0 / 16 (0.00%)
occurrences (all)	0	11	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	5 / 114 (4.39%)	0 / 16 (0.00%)
occurrences (all)	0	5	0

Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	11 / 114 (9.65%)	0 / 16 (0.00%)
occurrences (all)	0	17	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	4 / 114 (3.51%)	0 / 16 (0.00%)
occurrences (all)	0	5	0
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	2 / 114 (1.75%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 16 (6.25%)	18 / 114 (15.79%)	0 / 16 (0.00%)
occurrences (all)	1	22	0
Hypomagnesaemia			
subjects affected / exposed	1 / 16 (6.25%)	6 / 114 (5.26%)	0 / 16 (0.00%)
occurrences (all)	1	14	0
Hypokalaemia			
subjects affected / exposed	1 / 16 (6.25%)	4 / 114 (3.51%)	1 / 16 (6.25%)
occurrences (all)	1	5	1
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 114 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	gBRCA Placebo (PSU)	QTc sub-study: Niraparib	gBRCA Niraparib (PSU)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	24 / 26 (92.31%)	0 / 22 (0.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	4 / 26 (15.38%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
Deep vein thrombosis			

subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Hot flush			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	13 / 26 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	20	0
Catheter site pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	5 / 26 (19.23%)	0 / 22 (0.00%)
occurrences (all)	0	5	0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	4 / 26 (15.38%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
Cough			

subjects affected / exposed	0 / 8 (0.00%)	4 / 26 (15.38%)	0 / 22 (0.00%)
occurrences (all)	0	6	0
Dysphonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 26 (11.54%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	3 / 26 (11.54%)	0 / 22 (0.00%)
occurrences (all)	0	8	0
Neutrophil count decreased			
subjects affected / exposed	0 / 8 (0.00%)	4 / 26 (15.38%)	0 / 22 (0.00%)
occurrences (all)	0	6	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	4 / 26 (15.38%)	0 / 22 (0.00%)
occurrences (all)	0	6	0
White blood cell count decreased			

subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	5	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	4 / 26 (15.38%)	0 / 22 (0.00%)
occurrences (all)	0	5	0
Amnesia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 26 (11.54%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
Neuropathy peripheral			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Headache			
subjects affected / exposed	0 / 8 (0.00%)	5 / 26 (19.23%)	0 / 22 (0.00%)
occurrences (all)	0	7	0
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	13 / 26 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	36	0
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	12 / 26 (46.15%)	0 / 22 (0.00%)
occurrences (all)	0	23	0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	10 / 26 (38.46%)	0 / 22 (0.00%)
occurrences (all)	0	19	0
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	9 / 26 (34.62%)	0 / 22 (0.00%)
occurrences (all)	0	12	0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Flatulence			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	7 / 26 (26.92%)	0 / 22 (0.00%)
occurrences (all)	0	8	0
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	13 / 26 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	16	0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	10 / 26 (38.46%)	0 / 22 (0.00%)
occurrences (all)	0	11	0
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Photosensitivity reaction			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Joint swelling			
subjects affected / exposed	0 / 8 (0.00%)	3 / 26 (11.54%)	0 / 22 (0.00%)
occurrences (all)	0	3	0
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 26 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	6 / 26 (23.08%)	0 / 22 (0.00%)
occurrences (all)	0	6	0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	4 / 26 (15.38%)	0 / 22 (0.00%)
occurrences (all)	0	5	0
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	2 / 26 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Non-gBRCA Niraparib (PSU)	Non-gBRCA Placebo (PSU)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Deep vein thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Hot flush			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Catheter site pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Mucosal inflammation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Dysphonia			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
White blood cell count decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	

Amnesia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Anaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			

Constipation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Abdominal pain lower			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	

Dry mouth			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Photosensitivity reaction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Petechiae			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Joint swelling			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	

Arthralgia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Sinusitis			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 May 2013	Protocol amendment 01: Addition of defined clinical criteria for disease progression, clarification of definition of platinum sensitivity.
09 April 2014	Protocol amendment 03: Clarified the following: -assignment of participants to cohort based on Myriad Breast Cancer gene (BRCA) test, -exclusion for immunocompromised participants, -approach to dose modification and discontinuation due to hematologic events. Added Cycle 1 visit for complete blood count (CBC) to allow early detection of hematologic abnormalities
04 December 2014	Protocol amendment 04: Addition of centralized homologous recombination deficiency (HRD) testing and associated end points and sample size changes. Clarifying that dose modifications could be made at any time for intolerable toxicity
11 September 2015	Protocol amendment 05: Clarification of exclusion criteria of corrected QT interval (QTc)-prolonging medications. Updated guidance on monitoring and following participants for potential risk for myelodysplastic syndrome (MDS)/ acute myeloid leukemia (AML). Clarifying that progression is not considered an adverse event (AE).
09 March 2016	Protocol amendment 06: Clarification of HRD+ definition and primary endpoint, addition of secondary objectives, and removal of an interim analysis.
31 May 2017	Protocol amendment 07: Alignment with unblinding standard operating procedure (SOP) and updated standard niraparib safety language for AEs, serious AEs (SAEs), and adverse events of specific interests (AESIs) reporting. Addition of primary analysis data to replace Phase 1 data. Additional guidance for blood pressure monitoring. Introduction of Extended Visit Cycle to minimize participant burden.
29 January 2019	Protocol amendment 08: Clarifying survival assessment and decreasing data collection burden in follow-up. Alignment of safety language with updated niraparib risk management plan and General Data Protection Regulation

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported