



Clinical trial results:

A Phase II, Multicentre, Open-Label Study to Assess the Efficacy and Safety of Olaparib Monotherapy and Olaparib Plus Durvalumab Combination as Neoadjuvant Therapy in Patients with BRCA Mutations and Early Stage HER2-Negative Breast Cancer (OlympiaN)

Summary

EudraCT number	2021-005231-22
Trial protocol	ES DE AT IT
Global end of trial date	16 September 2025

Results information

Result version number	v1 (current)
This version publication date	27 September 2026
First version publication date	27 September 2026

Trial information

Trial identification

Sponsor protocol code	D931CC00001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	EudraCT Number: 2021-005231-22, EU CT Number: 2023-503529-20

Notes:

Sponsors

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	151 85, Södertälje, Sweden,
Public contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.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	16 September 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	16 September 2025
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This study was to determine the efficacy and safety of neoadjuvant olaparib monotherapy and olaparib plus durvalumab combination therapy in participants with primary, operable, oestrogen receptor (ER)-negative or ER-low, human epidermal growth factor receptor 2 (HER2)-negative breast cancer with documented breast cancer susceptibility gene mutation (BRCAm) who are candidates for neoadjuvant therapy.

Protection of trial subjects:

Based upon the available clinical efficacy and safety data for olaparib monotherapy and olaparib and durvalumab combination, and the mitigations designed for this study through participant selection and close clinical monitoring during treatment, the investigation of the potential therapeutic efficacy of neoadjuvant olaparib and of the combination of olaparib plus durvalumab in participants with BRCAm ER-negative or ER-low, HER2-negative breast cancer is acceptable, and the overall benefit/risk assessment supports the proposed study design.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 November 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 22
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	United States: 4
Country: Number of subjects enrolled	Australia: 3
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Austria: 2
Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	United Kingdom: 1
Worldwide total number of subjects	50
EEA total number of subjects	40

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)	45
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 114 participants were screened from 28 study sites across 9 countries. Of these, 50 participants were enrolled.

Pre-assignment

Screening details:

Approximately 50 participants were planned to be enrolled in 2 cohorts, Cohort A (lower risk) and Cohort B (higher risk), with approximately 25 participants each.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	AZD2281

Arm description:

Cohort A: AZD2281 monotherapy 300 mg BID continuously to lower-risk participants

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

Dosage and administration details:

300 mg twice daily

Arm title	AZD2281+MEDI4736
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Arm description:

Cohort B: AZD2281 300 mg BID plus MEDI4736 1500 mg Q4W combination therapy to higher-risk participants

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1500 mg every 4 weeks or 20 mg/kg every 4 weeks in participants who weighed ≤ 30 kg

Investigational medicinal product name	Olaparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

300 mg twice daily

Number of subjects in period 1	AZD2281	AZD2281+MEDI473 6
Started	25	25
Completed	0	0
Not completed	25	25
Consent withdrawn by subject	-	1
Site terminated by sponsor	2	2
Study terminated by sponsor	23	22

Baseline characteristics

Reporting groups

Reporting group title	AZD2281
Reporting group description:	
Cohort A: AZD2281 monotherapy 300 mg BID continuously to lower-risk participants	
Reporting group title	AZD2281+MEDI4736
Reporting group description:	
Cohort B: AZD2281 300 mg BID plus MEDI4736 1500 mg Q4W combination therapy to higher-risk participants	

Reporting group values	AZD2281	AZD2281+MEDI4736	Total
Number of subjects	25	25	50
Age Categorical			
Age at Screening			
Units: Participants			
< 30	0	1	1
30 - 39	6	8	14
40 - 49	11	8	19
50 - 59	3	3	6
60 - 69	5	3	8
>= 70	0	2	2
Age Continuous			
Age at Screening			
Units: Years			
arithmetic mean	47.8	47.2	-
standard deviation	± 10.32	± 14.24	-
Sex: Female, Male			
Units: Participants			
Female	25	25	50
Male	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	0	2
Not Hispanic or Latino	23	25	48
Race (NIH/OMB)			
Units: Subjects			
Black or African American	1	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
American Indian or Alaska Native	0	0	0
Asian	0	1	1
White	24	20	44
Other	0	3	3
Not reported	0	0	0
Region of Enrollment			
Units: Subjects			
Spain	13	9	22
Germany	5	5	10

United States	2	2	4
Australia	1	2	3
Belgium	1	2	3
Italy	1	2	3
Austria	1	1	2
Israel	1	1	2
United Kingdom	0	1	1
Weight group			
Units: Subjects			
< 50	1	0	1
50 - 90	21	24	45
>= 90	3	1	4
Height			
Units: cm			
arithmetic mean	162.3	162.3	
standard deviation	± 6.55	± 6.67	-
Weight			
Units: kg			
arithmetic mean	68.29	69.38	
standard deviation	± 15.767	± 12.380	-

End points

End points reporting groups

Reporting group title	AZD2281
Reporting group description:	
Cohort A: AZD2281 monotherapy 300 mg BID continuously to lower-risk participants	
Reporting group title	AZD2281+MEDI4736
Reporting group description:	
Cohort B: AZD2281 300 mg BID plus MEDI4736 1500 mg Q4W combination therapy to higher-risk participants	

Primary: pCR rate of olaparib monotherapy and olaparib plus durvalumab combination therapy, assessed by central pathology review

End point title	pCR rate of olaparib monotherapy and olaparib plus durvalumab combination therapy, assessed by central pathology review ^[1]
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End point description:

pCR = pathological complete response

pCR was defined as ypT0/Tis ypN0 (ie, no invasive residual in breast and the axillary lymph nodes on evaluation of the complete resected breast specimen and all sampled regional lymph nodes) following completion of neoadjuvant systemic therapy.

Results of this outcome measure are from DCO1 (20 November 2024). The Clopper Pearson method is for the computation of the 95% confidence interval (CI).

End point type	Primary
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End point timeframe:

Approx. 4 to 6 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical testing was performed for this study.

End point values	AZD2281	AZD2281+MED I4736		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Percentage				
arithmetic mean (confidence interval 95%)				
Responder - Achieved pCR	68.0 (46.50 to 85.05)	80.0 (59.30 to 93.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: pCR rate of olaparib monotherapy and olaparib plus durvalumab combination therapy, assessed by local pathology review

End point title	pCR rate of olaparib monotherapy and olaparib plus durvalumab combination therapy, assessed by local pathology review
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End point description:

pCR was defined as ypT0/Tis ypN0 (ie, no invasive residual in breast and the axillary lymph nodes on evaluation of the complete resected breast specimen and all sampled regional lymph nodes) following completion of neoadjuvant systemic therapy.

Results of this outcome measure are from DCO1 (20 November 2024). The Clopper Pearson method is for the computation of the 95% CI.

End point type	Secondary
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End point timeframe:

Approx. 4 to 6 months

End point values	AZD2281	AZD2281+MED I4736		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Percentage				
arithmetic mean (confidence interval 95%)				
Responder - Achieved pCR	68.0 (46.50 to 85.05)	76.0 (54.87 to 90.64)		

Statistical analyses

No statistical analyses for this end point

Secondary: RCB of olaparib monotherapy and olaparib plus durvalumab combination therapy as assessed by central pathology review

End point title	RCB of olaparib monotherapy and olaparib plus durvalumab combination therapy as assessed by central pathology review
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End point description:

RCB = residual cancer burden

RCB index value using 6 variables to categorize response in 1 of 4 classes: RCB 0 (pCR), I (minimal RCB), II (moderate RCB), and III (extensive RCB). RCB III included patients who had clinical progression before surgery, and there was no central pCR performed. Results of this outcome measure are from DCO1 (20 November 2024).

End point type	Secondary
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End point timeframe:

Approx. 4 to 6 months

End point values	AZD2281	AZD2281+MED I4736		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Participants				
RCB-0	17	20		
RCB-I	1	1		
RCB-II	6	1		
RCB-III	1	2		
Missing	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: RCB of olaparib monotherapy and olaparib plus durvalumab combination therapy as assessed by local pathology review

End point title	RCB of olaparib monotherapy and olaparib plus durvalumab combination therapy as assessed by local pathology review
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End point description:

RCB index value using 6 variables to categorize response in 1 of 4 classes: RCB 0 (pCR), I (minimal RCB), II (moderate RCB), and III (extensive RCB). RCB III included patients who had clinical progression before surgery, and there was no central pCR performed. Results of this outcome measure are from DCO1 (20 November 2024).

End point type	Secondary
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End point timeframe:

Approx. 4 to 6 months

End point values	AZD2281	AZD2281+MED I4736		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Participants				
RCB-0	17	19		
RCB-I	2	2		
RCB-II	5	0		
RCB-III	1	2		
Missing	0	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage change in tumour volume at Week 12 and Week 24 from baseline

End point title	Percentage change in tumour volume at Week 12 and Week 24 from baseline
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End point description:

Percentage change in tumour volume at Week 12 and Week 24 from baseline was measured using magnetic resonance imaging (MRI). Baseline was defined as the most recent measurement prior to the first administration of study intervention. Percent change from baseline was defined as: (Difference in value between post-baseline volume and baseline volume) divided by baseline volume and multiplied by 100.

Results of this outcome measure are from DCO1 (20 November 2024).

End point type	Secondary
End point timeframe:	
Week 12 and Week 24	

End point values	AZD2281	AZD2281+MED I4736		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Percentage in tumour volume				
arithmetic mean (standard deviation)				
Percentage change from baseline at week 12	-87.86 ($\pm$ 17.527)	-84.49 ($\pm$ 29.998)		
Percentage change from baseline at week 24	-42.32 ($\pm$ 227.333)	-89.87 ($\pm$ 34.726)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with EFS (event-free survival)

End point title	Number of Participants with EFS (event-free survival)
End point description:	
EFS was defined as time from the first dose of study intervention administration to any of the following events: progression of disease that precluded surgery, local or distant recurrence after surgery, second primary malignancy (breast or other invasive cancers), or death due to any cause. Results of this outcome measure are from final DCO (16 September 2025). One of 3 subjects in AZD2281 + MEDI4736 group had a disease progression recorded in error; 2 (8.0%) participants had an EFS event of progression of disease reported in the neoadjuvant period.	
End point type	Secondary
End point timeframe:	
Approx. 3 years	

End point values	AZD2281	AZD2281+MED I4736		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Participants	3	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with AEs

End point title	Number of participants with AEs
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End point description:

AE = adverse event; ECG = electrocardiogram

Data included clinical observations, ECG parameters, haematology/clinical chemistry, vital signs assessed as the number of participants with AEs.

Results of participants with AEs are from final DCO (16 September 2025).

End point type	Secondary
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End point timeframe:

Through study completion, approximately 34 months

End point values	AZD2281	AZD2281+MED I4736		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Participants	24	24		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with SAEs

End point title	Number of participants with SAEs
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End point description:

SAE = serious adverse event

Data included clinical observations, ECG parameters, haematology/clinical chemistry, vital signs assessed as the number of participants with AEs.

Results of participants with SAEs are from final DCO (16 September 2025).

End point type	Secondary
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End point timeframe:

Through study completion, approximately 34 months

End point values	AZD2281	AZD2281+MED I4736		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: Participants	4	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were collected from the time of informed consent form signature through study completion, approximately 34 months (final DCO: 16 September 2025).

Adverse event reporting additional description:

Graded according to the Common Terminology Criteria for Adverse Event (CTCAE) grade and changes in CTCAE grade

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.0
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Reporting groups

Reporting group title	AZD2281+MEDI4736
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Reporting group description:

Cohort B: AZD2281 300 mg BID plus MEDI4736 1500 mg Q4W combination therapy to higher-risk participants

Reporting group title	AZD2281
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Reporting group description:

Cohort A: AZD2281 monotherapy 300 mg BID continuously to lower-risk participants

Serious adverse events	AZD2281+MEDI4736	AZD2281	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 25 (20.00%)	4 / 25 (16.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Transient ischaemic attack			

subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pelvic mass			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 25 (0.00%)	2 / 25 (8.00%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Internal device exposed			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus			

subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	1 / 1	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	AZD2281+MEDI4736	AZD2281	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 25 (92.00%)	23 / 25 (92.00%)	
Vascular disorders			
Hot flush			
subjects affected / exposed	3 / 25 (12.00%)	4 / 25 (16.00%)	
occurrences (all)	4	4	
Hypertension			
subjects affected / exposed	2 / 25 (8.00%)	0 / 25 (0.00%)	
occurrences (all)	3	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	13 / 25 (52.00%)	9 / 25 (36.00%)	
occurrences (all)	13	10	
Asthenia			
subjects affected / exposed	8 / 25 (32.00%)	10 / 25 (40.00%)	
occurrences (all)	11	14	
Pyrexia			
subjects affected / exposed	5 / 25 (20.00%)	2 / 25 (8.00%)	
occurrences (all)	7	2	
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	3 / 25 (12.00%)	4 / 25 (16.00%)	
occurrences (all)	4	4	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 25 (20.00%)	1 / 25 (4.00%)	
occurrences (all)	7	1	
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3	1 / 25 (4.00%) 1	
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3	3 / 25 (12.00%) 3	
Amylase increased subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 25 (4.00%) 1	
Blood creatinine increased subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	2 / 25 (8.00%) 2	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	2 / 25 (8.00%) 4	
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 3	2 / 25 (8.00%) 2	
Weight increased subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 25 (0.00%) 0	
Injury, poisoning and procedural complications			
Procedural pain subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 25 (4.00%) 1	
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 4	4 / 25 (16.00%) 4	
Dysgeusia subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 5	8 / 25 (32.00%) 9	
Headache			

subjects affected / exposed occurrences (all)	8 / 25 (32.00%) 9	8 / 25 (32.00%) 9	
Taste disorder subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 25 (4.00%) 1	
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	9 / 25 (36.00%) 13	10 / 25 (40.00%) 16	
Neutropenia subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 7	3 / 25 (12.00%) 4	
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 25 (0.00%) 0	
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	9 / 25 (36.00%) 11	10 / 25 (40.00%) 16	
Dyspepsia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	3 / 25 (12.00%) 3	
Dry mouth subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 25 (0.00%) 0	
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 25 (4.00%) 2	
Nausea subjects affected / exposed occurrences (all)	19 / 25 (76.00%) 33	15 / 25 (60.00%) 22	
Stomatitis subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 2	2 / 25 (8.00%) 4	
Vomiting			

subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 11	3 / 25 (12.00%) 4	
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	3 / 25 (12.00%) 4	
Abdominal pain subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3	4 / 25 (16.00%) 5	
Constipation subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 5	1 / 25 (4.00%) 2	
Skin and subcutaneous tissue disorders			
Pruritus subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 4	2 / 25 (8.00%) 2	
Rash subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	2 / 25 (8.00%) 3	
Endocrine disorders			
Hyperthyroidism subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3	0 / 25 (0.00%) 0	
Hypothyroidism subjects affected / exposed occurrences (all)	7 / 25 (28.00%) 7	0 / 25 (0.00%) 0	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3	2 / 25 (8.00%) 2	
Myalgia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	2 / 25 (8.00%) 2	
Back pain subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 25 (4.00%) 1	
Infections and infestations			

COVID-19			
subjects affected / exposed	1 / 25 (4.00%)	2 / 25 (8.00%)	
occurrences (all)	1	2	
Nasopharyngitis			
subjects affected / exposed	3 / 25 (12.00%)	5 / 25 (20.00%)	
occurrences (all)	3	8	
Tonsillitis			
subjects affected / exposed	0 / 25 (0.00%)	3 / 25 (12.00%)	
occurrences (all)	0	3	
Urinary tract infection			
subjects affected / exposed	2 / 25 (8.00%)	4 / 25 (16.00%)	
occurrences (all)	2	4	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 25 (8.00%)	4 / 25 (16.00%)	
occurrences (all)	2	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 March 2022	The amendment is made to expand the eligible participant population based on current literature supporting the use of neoadjuvant immuno-oncology therapy in participants with smaller volume, high-risk breast cancer.
10 June 2022	The primary purpose of this amendment is to modify inclusion criteria related to reproduction and fertility in alignment with olaparib safety guidelines.
01 June 2023	The primary purpose of this amendment is to modify safety monitoring for patients in Cohort B who experience anaemia or prolonged haematological toxicity in alignment with the updated olaparib Investigator's Brochure and to incorporate recent changes for contraception requirements for patients being treated with olaparib.
22 March 2024	The primary purpose of this amendment is to clarify details regarding the schedule of assessments and study procedures that resulted from many questions from investigative sites when they attempted to conduct the study and to add missing procedures and tests into the End of Treatment Visit and the mandatory collection of tumour samples at definitive surgery.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was closed earlier than originally planned in alignment with the scientific and ethical standards. All participants were off study treatment and had completed post-treatment safety follow-up on 17 July 2025.

Notes: