Clinical trial results:
eMonarcHER: A Randomized, Double Blind, Placebo-Controlled Phase 3 Study of Abemaciclib plus Standard Adjuvant Endocrine Therapy in Participants with High-Risk, Node-Positive, HR+, HER2+ Early Breast Cancer Who Have Completed Adjuvant HER2-Targeted Therapy

Summary

EudraCT number	2020-004035-24
Trial protocol	FR BE DE FI AT HU GR IT ES
Global end of trial date	26 June 2024

Results information

Result version number	v1 (current)
This version publication date	12 July 2025
First version publication date	12 July 2025

Trial information

Trial identification

Sponsor protocol code	I3Y-MC-JPCW

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04752332
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Clinical Trial Registry Office, Eli Lilly, 1 08772854559,, EU_Lilly_Clinical_Trials@lilly.com
Scientific contact	Clinical Trial Registry Office, Eli Lilly, 1 877CTLilly, EU_Lilly_Clinical_Trials@lilly.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	26 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 June 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of abemaciclib plus physician’s choice ET versus placebo plus physician’s choice ET in the study population.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	10 May 2021
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	Spain: 8
Country: Number of subjects enrolled	Austria: 1
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Greece: 8
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Argentina: 9
Country: Number of subjects enrolled	Australia: 2
Country: Number of subjects enrolled	Brazil: 6
Country: Number of subjects enrolled	China: 27
Country: Number of subjects enrolled	Israel: 1
Country: Number of subjects enrolled	Japan: 10
Country: Number of subjects enrolled	Mexico: 2
Country: Number of subjects enrolled	Korea, Republic of: 6
Country: Number of subjects enrolled	Switzerland: 2
Country: Number of subjects enrolled	Taiwan: 4
Country: Number of subjects enrolled	United Kingdom: 5

Country: Number of subjects enrolled	United States: 8
Worldwide total number of subjects	111
EEA total number of subjects	29

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)	98
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was terminated early due to inability to enroll study participants. Data was not collected after termination and outcome measures were not assessed.

Pre-assignment

Screening details:

Completers were defined as participants who received abemaciclib and were allowed to stay on treatment in the study. Participants receiving placebo discontinued after the study was terminated.

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	150 mg Abemaciclib + Endocrine Therapy (ET)

Arm description:

Participants received 150 milligrams (mg) of abemaciclib administered twice daily (BID) orally along with standard adjuvant endocrine therapy (ET).

Arm type	Experimental
Investigational medicinal product name	Abemaciclib
Investigational medicinal product code	
Other name	LY2835219
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally.

Arm title	Placebo + ET

Arm description:

Participants received placebo administered BID orally along with standard adjuvant ET.

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

Dosage and administration details:

Administered orally.

Number of subjects in period 1	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET
Started	55	56
Received At Least One Dose of Study Drug	55	56
Completed	25	0
Not completed	30	56
Disease Relapse	1	-
Physician decision	2	1
Consent withdrawn by subject	11	3
Adverse event, non-fatal	3	1
Non-compliance With Study Drug	2	-
Study Terminated by IRB/ERB	-	2
Study Terminated by Sponsor	10	48
Protocol deviation	1	1

Baseline characteristics

Reporting groups	
Reporting group title	150 mg Abemaciclib + Endocrine Therapy (ET)
Reporting group description:	
Participants received 150 milligrams (mg) of abemaciclib administered twice daily (BID) orally along with standard adjuvant endocrine therapy (ET).	
Reporting group title	Placebo + ET
Reporting group description:	
Participants received placebo administered BID orally along with standard adjuvant ET.	

Reporting group values	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET	Total
Number of subjects	55	56	111
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	48.60	49.70	
standard deviation	± 11.76	± 11.17	-
Gender categorical Units: Subjects			
Female	54	56	110
Male	1	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	9	12	21
Not Hispanic or Latino	44	41	85
Unknown or Not Reported	2	3	5
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	1
Asian	26	23	49
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	2	3
White	27	29	56
More than one race	0	0	0
Unknown or Not Reported	1	1	2

Region of Enrollment Units: Subjects			
Argentina	4	5	9
Australia	1	1	2
Austria	0	1	1
Belgium	2	2	4
Brazil	3	3	6
China	12	15	27
France	2	0	2
Germany	2	1	3
Greece	4	4	8
Hungary	1	0	1
Israel	1	0	1
Italy	1	1	2
Japan	7	3	10
Mexico	1	1	2
South Korea	4	2	6
Spain	3	5	8
Switzerland	0	2	2
Taiwan	1	3	4
United Kingdom	1	4	5
United States	5	3	8

End points

End points reporting groups

Reporting group title	150 mg Abemaciclib + Endocrine Therapy (ET)

Reporting group description:

Participants received 150 milligrams (mg) of abemaciclib administered twice daily (BID) orally along with standard adjuvant endocrine therapy (ET).

Reporting group title	Placebo + ET

Reporting group description:

Participants received placebo administered BID orally along with standard adjuvant ET.

Primary: Invasive Disease Free Survival (IDFS)

End point title	Invasive Disease Free Survival (IDFS)[1]

End point description:

IDFS, as defined by the STEEP System, is measured from the date of randomization to the date of first occurrence of one of the following events: ipsilateral invasive breast tumor recurrence, regional invasive breast cancer recurrence, distant recurrence, contralateral invasive breast cancer, second primary non-breast invasive cancer, death attributable to any cause. Study was terminated early. Data was not collected for this outcome and outcome measures were not assessed.

End point type	Primary

End point timeframe:

Randomization to Recurrence or Death from Any Cause (up to 890 days)

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: Study was terminated early. Data was not collected after termination and outcome measures were not assessed.

End point values	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: Months				
arithmetic mean (standard deviation)	()	()		

Notes:

[2] - Study was terminated early, and no outcome measures were assessed.

[3] - Study was terminated early, and no outcome measures were assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS is defined as the time from randomization until death from any cause. Study was terminated early. Data was not collected for this outcome and outcome measures were not assessed.

End point type	Secondary

End point timeframe:

Randomization to Death from Any Cause (up to 890 days)

End point values	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[4]	0[5]		
Units: Months				
arithmetic mean (standard deviation)	()	()		

Notes:

[4] - Study was terminated early, and no outcome measures were assessed.

[5] - Study was terminated early, and no outcome measures were assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Distant Relapse-Free Survival (DRFS)

End point title	Distant Relapse-Free Survival (DRFS)

End point description:

DRFS is defined as the time from randomization to distant recurrence or death from any cause, whichever occurs first.
Study was terminated early. Data was not collected for this outcome and outcome measures were not assessed.

End point type	Secondary

End point timeframe:

Randomization to Distant Recurrence or Death from Any Cause (up to 890 days)

End point values	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[6]	0[7]		
Units: Months				
arithmetic mean (standard deviation)	()	()		

Notes:

[6] - Study was terminated early, and no outcome measures were assessed.

[7] - Study was terminated early, and no outcome measures were assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Central Nervous System (CNS) Metastases as First Site of Disease Recurrence

End point title	Percentage of Participants With Central Nervous System (CNS) Metastases as First Site of Disease Recurrence

End point description:

Study was terminated early. Data was not collected for this outcome and outcome measures were not assessed.

End point type	Secondary

End point timeframe:

Randomization to Distant Recurrence or Death from Any Cause (up to 10 Years)

End point values	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[8]	0[9]		
Units: Percentage of Participants				
number (not applicable)				

Notes:

[8] - Study was terminated early, and no outcome measures were assessed.

[9] - Study was terminated early, and no outcome measures were assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) Scale Score

End point title	Change From Baseline in the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) Scale Score

End point description:

The EORTC QLQ-C30 (v. 3.0) is a self-administered, cancer-specific questionnaire with multidimensional scales assessing 15 domains (5 functional domains, 9 symptoms, and global health status). A linear transformation will be applied to standardize the raw scores to range between 0 and 100 per developer guidelines. For the functional domains and global health status scale, higher scores represent a better level of functioning. For symptom scales, higher scores represent a greater degree of symptoms. Study was terminated early. Data was not collected for this outcome and outcome measures were not assessed.

End point type	Secondary

End point timeframe:

Cycle 1 up to 390 days

End point values	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[10]	0[11]		
Units: Score on a scale				
arithmetic mean (standard error)	()	()		

Notes:

[10] - Study was terminated early, and no outcome measures were assessed.

[11] - Study was terminated early, and no outcome measures were assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the EuroQOL 5 Dimension 5 Level (EQ-5D 5L) Index Score

End point title	Change From Baseline in the EuroQOL 5 Dimension 5 Level (EQ-5D 5L) Index Score

End point description:

The EQ-5D-5L is a standardized instrument for use as a measure of self-reported health status. Participants completed the 5-level (no problem, slight problem, moderate problem, severe problem, and inability or extreme problem), 5-dimension (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) questionnaire concerning their current health state. Five dimensions of health status are each assessed with 5 response options and scored as a composite index which are anchored on a scale of 0 to 1 with a higher score representing better health status. Study was terminated early. Data was not collected for this outcome and outcome measures were not assessed.

End point type	Secondary

End point timeframe:

Cycle 1 up to 390 days

End point values	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[12]	0[13]		
Units: Score on a scale				
arithmetic mean (standard error)	()	()		

Notes:

[12] - Study was terminated early, and no outcome measures were assessed.

[13] - Study was terminated early, and no outcome measures were assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Mean Steady State Concentrations of Abemaciclib

End point title	Pharmacokinetics (PK): Mean Steady State Concentrations of Abemaciclib

End point description:

Study was terminated early. Data was not collected for this outcome and outcome measures were not assessed.

End point type	Secondary

End point timeframe:

Day 1 of Cycles 1-3 (Cycle = 28 days)

End point values	150 mg Abemaciclib + Endocrine Therapy (ET)	Placebo + ET		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[14]	0[15]		
Units: microgram(s)/millilitre				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[14] - Study was terminated early, and no outcome measures were assessed.

[15] - Study was terminated early, and no outcome measures were assessed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up To 890 Days

Adverse event reporting additional description:

All participants who received at least one dose of study drug. Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly. Based on the planned safety analysis, adverse event analysis was planned as per the cohorts corresponding regimen received.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	150 mg Abemaciclib + ET

Reporting group description:

Participants received 150 mg of abemaciclib administered BID orally along with standard adjuvant ET.

Reporting group title	Placebo + ET

Reporting group description:

Participants received placebo administered BID orally along with standard adjuvant ET.

Serious adverse events	150 mg Abemaciclib + ET	Placebo + ET	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 55 (10.91%)	2 / 56 (3.57%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 56 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
uterine leiomyoma			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed[1]	0 / 54 (0.00%)	1 / 56 (1.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural			

complications			
radius fracture			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 55 (1.82%)	1 / 56 (1.79%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
neutropenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 56 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
pulmonary embolism			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 56 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 56 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal abscess			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 55 (1.82%)	0 / 56 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

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

Non-serious adverse events	150 mg Abemaciclib + ET	Placebo + ET	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 55 (96.36%)	40 / 56 (71.43%)	
Investigations			
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 55 (5.45%)	1 / 56 (1.79%)	
occurrences (all)	3	1	
alanine aminotransferase increased			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 55 (5.45%)	0 / 56 (0.00%)	
occurrences (all)	3	0	
blood creatinine increased			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	10 / 55 (18.18%)	0 / 56 (0.00%)	
occurrences (all)	13	0	
Vascular disorders			
hot flush			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	0 / 55 (0.00%)	8 / 56 (14.29%)	
occurrences (all)	0	8	
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 55 (5.45%)	1 / 56 (1.79%)	
occurrences (all)	3	1	
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	5 / 55 (9.09%)	6 / 56 (10.71%)	
occurrences (all)	7	6	
dizziness			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	7 / 55 (12.73%)	5 / 56 (8.93%)	
occurrences (all)	8	8	
Blood and lymphatic system disorders			

anaemia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	13 / 55 (23.64%)	1 / 56 (1.79%)	
occurrences (all)	24	1	
lymphopenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	5 / 55 (9.09%)	0 / 56 (0.00%)	
occurrences (all)	8	0	
leukopenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	17 / 55 (30.91%)	3 / 56 (5.36%)	
occurrences (all)	31	3	
neutropenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	28 / 55 (50.91%)	4 / 56 (7.14%)	
occurrences (all)	63	5	
thrombocytopenia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	12 / 55 (21.82%)	0 / 56 (0.00%)	
occurrences (all)	14	0	
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	16 / 55 (29.09%)	6 / 56 (10.71%)	
occurrences (all)	24	7	
oedema peripheral			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 55 (5.45%)	3 / 56 (5.36%)	
occurrences (all)	3	3	
pyrexia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	4 / 55 (7.27%)	0 / 56 (0.00%)	
occurrences (all)	4	0	
Gastrointestinal disorders			

abdominal pain alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	12 / 55 (21.82%) 18	6 / 56 (10.71%) 11	
abdominal distension alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	1 / 55 (1.82%) 1	3 / 56 (5.36%) 3	
diarrhoea alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	44 / 55 (80.00%) 97	5 / 56 (8.93%) 7	
constipation alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	3 / 55 (5.45%) 4	6 / 56 (10.71%) 9	
nausea alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	17 / 55 (30.91%) 24	8 / 56 (14.29%) 8	
stomatitis alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	5 / 55 (9.09%) 5	0 / 56 (0.00%) 0	
vomiting alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	11 / 55 (20.00%) 12	1 / 56 (1.79%) 1	
Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 27.0 subjects affected / exposed occurrences (all)	4 / 55 (7.27%) 4	2 / 56 (3.57%) 2	
Skin and subcutaneous tissue disorders			

pruritus			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	6 / 55 (10.91%)	2 / 56 (3.57%)	
occurrences (all)	9	2	
rash			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 55 (5.45%)	0 / 56 (0.00%)	
occurrences (all)	7	0	
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	4 / 55 (7.27%)	1 / 56 (1.79%)	
occurrences (all)	4	1	
arthralgia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	6 / 55 (10.91%)	11 / 56 (19.64%)	
occurrences (all)	7	13	
myalgia			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 55 (5.45%)	1 / 56 (1.79%)	
occurrences (all)	3	1	
pain in extremity			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	1 / 55 (1.82%)	4 / 56 (7.14%)	
occurrences (all)	2	4	
Infections and infestations			
covid-19			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	13 / 55 (23.64%)	8 / 56 (14.29%)	
occurrences (all)	13	9	
nasopharyngitis			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	4 / 55 (7.27%)	1 / 56 (1.79%)	
occurrences (all)	4	2	
upper respiratory tract infection			

alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 55 (5.45%)	1 / 56 (1.79%)	
occurrences (all)	3	2	
urinary tract infection			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	3 / 55 (5.45%)	2 / 56 (3.57%)	
occurrences (all)	4	2	
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 27.0			
subjects affected / exposed	4 / 55 (7.27%)	0 / 56 (0.00%)	
occurrences (all)	7	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 April 2021	- Updated inclusion and exclusion criteria for clarity; - Corrections made in Risk Assessment table and CYP3A guidance text.
20 May 2021	- Modified definition of high risk with regard to histologic grade, restricting it to participants with histologic Grade 3 disease; - Updated inclusion criteria to provide more clarity on related treatment discontinuation.
14 February 2022	- Added details about participant enrolment and unblinding; - Updated objectives section for this amendment; - Updated end of study and study completion definitions; - Specified that study will not evaluate compliance/PK assessments and safety data capture instructions.

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 terminated early due to inability to enroll study participants.

Notes: