Clinical trial results:
CATCH-R: A Rollover Study to Provide Continued Access to Clinical Therapy with Rucaparib

Summary

EudraCT number	2020-001538-37
Trial protocol	CZ HU PL ES IT
Global end of trial date	08 March 2023

Results information

Result version number	v1 (current)
This version publication date	09 June 2024
First version publication date	09 June 2024

Trial information

Trial identification

Sponsor protocol code	CO-338-111

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04676334
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	pharmaand GmbH
Sponsor organisation address	Taborstraße 1, Wien, Austria, 1020
Public contact	Medical Information Department pharmaand GmbH, pharmaand GmbH, +43 13560006, medinfo@pharmaand.com
Scientific contact	Medical Information Department pharmaand GmbH, pharmaand GmbH, +43 13560006, medinfo@pharmaand.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	08 March 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This protocol is designed to provide participants currently benefiting from rucaparib treatment in a Clovis-sponsored clinical study (2013-000517-20; 2013-000518-39; 2016-000816-14; 2016-003162-13) with continued access to treatment for as long as they continue to benefit. Participants in long-term follow-up (LTFU) in a parent study (2016-000816-14) may also enroll in this study for continued data collection, as applicable based on parent study objectives.

Protection of trial subjects:

The study was performed in compliance with the Declaration of Helsinki, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and regulatory requirements as applicable.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 April 2021
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	Brazil: 10
Country: Number of subjects enrolled	Czechia: 2
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Canada: 7
Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	Russian Federation: 8
Country: Number of subjects enrolled	Italy: 2
Worldwide total number of subjects	34
EEA total number of subjects	7

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)	28
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Only serious adverse event (SAE) and adverse event of special interest (AESI) safety data were collected, Other (non-serious) adverse events (AEs) were not collected.

Pre-assignment

Screening details:

Safety data were collected only for the Rucaparib arm (participants who received rucaparib during this study); safety data were not collected for the Long-term Follow-up arm (participants who did not receive rucaparib during this study).

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	Rucaparib

Arm description:

Participants received rucaparib at a dose and schedule last taken in the parent study, or per investigator decision.

Arm type	Experimental
Investigational medicinal product name	Rucaparib
Investigational medicinal product code	
Other name	CO-338, Rubraca
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Rucaparib was administered daily.

Arm title	Long-term Follow-up

Arm description:

Participants discontinued rucaparib treatment and were in long-term follow-up in the parent study.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Rucaparib	Long-term Follow-up
Started	20	14
Received at Least 1 Dose of Study Drug	20	0 [1]
Completed	20	14

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: No study drug was administered to the Long-term Follow-up arm.

Baseline characteristics

Reporting groups	
Reporting group title	Rucaparib
Reporting group description:	
Participants received rucaparib at a dose and schedule last taken in the parent study, or per investigator decision.	
Reporting group title	Long-term Follow-up
Reporting group description:	
Participants discontinued rucaparib treatment and were in long-term follow-up in the parent study.	

Reporting group values	Rucaparib	Long-term Follow-up	Total
Number of subjects	20	14	34
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	17	11	28
From 65-84 years	3	3	6
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	59.2	60.5	
standard deviation	± 8.92	± 7.04	-
Gender categorical			
Units: Subjects			
Female	19	14	33
Male	1	0	1
Ethnicity (NIH/OMB)			
NIH/OMB: National Institutes of Health/Office of Management and Budget			
Units: Subjects			
Hispanic or Latino	3	4	7
Not Hispanic or Latino	17	9	26
Unknown or Not Reported	0	1	1
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	2
White	20	12	32
More than one race	0	0	0
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Rucaparib
Reporting group description:	
Participants received rucaparib at a dose and schedule last taken in the parent study, or per investigator decision.	
Reporting group title	Long-term Follow-up
Reporting group description:	
Participants discontinued rucaparib treatment and were in long-term follow-up in the parent study.	
Subject analysis set title	Enrolled Population
Subject analysis set type	Safety analysis
Subject analysis set description:	
Enrolled Population: all participants who were enrolled in the study.	
Subject analysis set title	Safety Population
Subject analysis set type	Safety analysis
Subject analysis set description:	
Safety Population: all participants who received rucaparib during the study (Rucaparib arm), safety data were not collected for the Long-term Follow-up arm.	

Primary: Number of Participants Experiencing SAEs and AESIs

End point title	Number of Participants Experiencing SAEs and AESIs[1][2]
End point description:	
An SAE was any untoward medical occurrence that occurred at any dose, or after informed consent was given and prior to dosing if the SAE was related to a study procedure, that: resulted in death; was life-threatening; required in-patient hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability/incapacity; resulted in a congenital anomaly or birth defect; or was an important medical event that may not have resulted in death, was not life-threatening, or did not require hospitalization but may be considered an SAE, based on appropriate medical judgment. An AESI was defined as any AE of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate. A summary of all SAEs regardless of causality is located in the 'Adverse events' Section.	
End point type	Primary
End point timeframe:	
From first dose of rucaparib through 28 days after receiving last dose of rucaparib (approximately 20 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: Only the number of participants was collected for this end point.

[2] - 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: Safety data were collected only for the Rucaparib arm (participants who received rucaparib during this study); safety data were not collected for the Long-term Follow-up arm (participants who did not receive rucaparib during this study).

End point values	Rucaparib			
Subject group type	Reporting group			
Number of subjects analysed	20[3]			
Units: Participants				
SAEs	2			
AESIs	0			

Notes:
[3] - Safety Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From first dose of rucaparib through 28 days after receiving last dose of rucaparib (approximately 20 months)

Adverse event reporting additional description:

Only SAE and AESI safety data were collected, Other (non-serious) AEs were not collected. Safety data were collected only for the Rucaparib arm; safety data were not collected for the Long-term Follow-up arm. Data reported for Safety Population: all participants who received rucaparib during the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Rucaparib

Reporting group description:

Participants received rucaparib at a dose and schedule last taken in the parent study, or per investigator decision.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Only SAE and AESI safety data were collected, Other (non-serious) AEs were not collected. Safety data were collected only for the Rucaparib arm (participants who received rucaparib during this study); safety data were not collected for the Long-term Follow-up arm (participants who did not receive rucaparib during this study).

Serious adverse events	Rucaparib		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 20 (10.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			

subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Rucaparib		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

Only SAE and AESI safety data were collected, Other (non-serious) AEs were not collected. Safety data were collected only for the Rucaparib arm; safety data were not collected for the Long-term Follow-up arm.

Notes: