



Clinical trial results: An Observational Long-Term Safety Surveillance of Participants from Corbus Sponsored Lenabasum Pivotal Clinical Trials

Summary

EudraCT number	2020-001762-11
Trial protocol	HU SE GB AT DE
Global end of trial date	30 September 2020

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	00JBT101-LTS-001
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Corbus Pharmaceuticals, Inc.
Sponsor organisation address	500 River Ridge Drive,, Norwood, Massachusetts, United States, 02062
Public contact	Rachael Brake, Corbus Pharmaceuticals, Inc., rachael.brake@corbuspharma.com
Scientific contact	Brian Walsh, Corbus Pharmaceuticals, Inc., brian.walsh@corbuspharma.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	28 February 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 September 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the long-term safety of subjects who received at least one dose of study treatment (lenabasum or placebo) in a Corbus sponsored lenabasum pivotal clinical trial and do not enroll in an open-label extension (OLE) phase of a qualifying trial

Protection of trial subjects:

This was an observational safety trial without any intervention.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 August 2020
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	United States: 7
Worldwide total number of subjects	7
EEA total number of subjects	0

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)	1
Adults (18-64 years)	6
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study population comprised consented subjects who completed or discontinued from a Corbus-sponsored pivotal clinical study and did not enter an OLE phase of a Corbus-sponsored pivotal clinical study.

Pre-assignment

Screening details:

A total of 9 subjects were screened, and 7 subjects were enrolled into the study with 2 screen failures.

Period 1

Period 1 title	Safety follow-up (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Safety
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Arm description:

Enrolled patients were followed-up every 6 months for the duration of 2 years.

Arm type	Long term observation
Investigational medicinal product name	Lenabasum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were only treated during Study JBT101-CF-002.

Number of subjects in period 1	Safety
Started	7
Completed	0
Not completed	7
Trial terminated	7

Baseline characteristics

Reporting groups

Reporting group title	Safety follow-up
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Reporting group description: -

Reporting group values	Safety follow-up	Total	
Number of subjects	7	7	
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	28.4		
full range (min-max)	14 to 37	-	
Gender categorical			
Units: Subjects			
Female	1	1	
Male	6	6	

End points

End points reporting groups

Reporting group title	Safety
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Reporting group description:

Enrolled patients were followed-up every 6 months for the duration of 2 years.

Primary: Adverse event incidence

End point title	Adverse event incidence ^[1]
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End point description:

End point type	Primary
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End point timeframe:

Study duration

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: It is an observational study, with the objective of collecting long-term safety data. Adverse events were counted and listed.

End point values	Safety			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: event	3			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From screening until the end of the study.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24
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Reporting groups

Reporting group title	All enrolled patients
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Reporting group description: -

Serious adverse events	All enrolled patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All enrolled patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 7 (28.57%)		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Distal intestinal obstruction syndrome			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 March 2020	Protocol amendment 1.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
30 September 2020	Study was early terminated due to Sponsor termination of the lenabasum development program	-

Notes:

Limitations and caveats

None reported