Clinical trial results:
A Phase II Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of UTTR1147A in Patients with Moderate to Severe Ulcerative Colitis or Crohn's Disease

Summary

EudraCT number	2017-004997-32
Trial protocol	ES GB NL IE DE HU IT
Global end of trial date	12 June 2022

Results information

Result version number	v1 (current)
This version publication date	28 July 2023
First version publication date	28 July 2023

Trial information

Trial identification

Sponsor protocol code	GA40209

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche, Ltd.
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche, Ltd., F. Hoffmann-La Roche, Ltd., +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche, Ltd., F. Hoffmann-La Roche, Ltd., +41 616878333, global.trial_information@roche.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	12 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study evaluated the long-term safety and tolerability of UTTR1147A in participants with moderate to severe ulcerative colitis (UC) or Crohn's disease (CD).

Protection of trial subjects:

This study is conducted in full conformance with the ICH E6 guideline for Good Clinical Practice and the principles of the Declaration of Helsinki, or the laws and regulations of the country in which the research is conducted, whichever affords the greater protection to the individual. All participants are required to read and sign an informed consent form prior to participation in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 January 2019
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	Bulgaria: 2
Country: Number of subjects enrolled	Georgia: 2
Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	Greece: 3
Country: Number of subjects enrolled	Ireland: 2
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Moldova, Republic of: 4
Country: Number of subjects enrolled	Poland: 33
Country: Number of subjects enrolled	Russian Federation: 8
Country: Number of subjects enrolled	Serbia: 15
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Ukraine: 56
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 1
Worldwide total number of subjects	143
EEA total number of subjects	56

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)	135
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All 143 patients were included in the intent-to-treat (ITT) population, with 128 patients allocated to study treatment and 15 patients that were not treated.

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

Arm title	UTTR1147A

Arm description:

Participants received treatment with UTTR1147A until clinical remission was achieved.

Arm type	Experimental
Investigational medicinal product name	UTTR1147A
Investigational medicinal product code	
Other name	Efmarodocokin alfa RO7021610 RG7880 IL-22Fc
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

UTTR1147A was administered based on disease status, as described in the protocol.

Number of subjects in period 1	UTTR1147A
Started	143
Completed	82
Not completed	61
Consent withdrawn by subject	16
Physician decision	2
Adverse event, non-fatal	1
Study Terminated By Sponsor	16
Not Specified	9
Lack of efficacy	17

Baseline characteristics

Reporting groups	
Reporting group title	UTTR1147A
Reporting group description:	
Participants received treatment with UTTR1147A until clinical remission was achieved.	

Reporting group values	UTTR1147A	Total	
Number of subjects	143	143	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	135	135	
From 65-84 years	8	8	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	41.5		
standard deviation	± 12.4	-	
Gender categorical Units: Subjects			
Female	39	39	
Male	104	104	
Race Units: Subjects			
American Indian or Alaska Native	1	1	
White	142	142	
Race/Ethnicity Units: Subjects			
Not Hispanic or Latino	142	142	
Not Stated	1	1	

End points

End points reporting groups

Reporting group title	UTTR1147A

Reporting group description:

Participants received treatment with UTTR1147A until clinical remission was achieved.

Primary: Number of Participants with Adverse Events

End point title	Number of Participants with Adverse Events[1]

End point description:

Severity Determined According to National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0 Scale (NCI CTCAE v4.0).

The safety-evaluable population comprised 128 patients who received at least one dose of the study drug.

End point type	Primary

End point timeframe:

Up to 2 years

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 analysis provided

End point values	UTTR1147A			
Subject group type	Reporting group			
Number of subjects analysed	128			
Units: Participants				
Serious Adverse Events	9			
Non-Serious Adverse Events Reported	52			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From baseline up to 2 years	
Adverse event reporting additional description:	
The safety-evaluable population comprised 128 patients who received at least one dose of the study drug.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups	
Reporting group title	UTTR1147A 60
Reporting group description:	
Participants received treatment with UTTR1147A until clinical remission was achieved.	

Serious adverse events	UTTR1147A 60		
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 128 (7.03%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Lipase increased			
subjects affected / exposed	3 / 128 (2.34%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Amylase increased			
subjects affected / exposed	2 / 128 (1.56%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Venous thrombosis limb			
subjects affected / exposed	1 / 128 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Arteriosclerosis coronary artery			

subjects affected / exposed	1 / 128 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 128 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	1 / 128 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	2 / 128 (1.56%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	1 / 128 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			
subjects affected / exposed	1 / 128 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	UTTR1147A 60		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 128 (40.63%)		
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	8 / 128 (6.25%) 10		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	15 / 128 (11.72%) 16		
Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all)	30 / 128 (23.44%) 45 8 / 128 (6.25%) 13		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	10 / 128 (7.81%) 11		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 December 2020	Changes to study duration, eligibility

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported