Clinical trial results:
A Phase II, Randomized, Parallel-Group, Double-Blind, Double-Dummy, Placebo-Controlled, Multicenter Study To Evaluate the Efficacy, Safety, and Pharmacokinetics of UTTR1147A Compared with Placebo and Compared with Vedolizumab in Patients with Moderate to Severe Ulcerative Colitis

Summary

EudraCT number	2017-002350-36
Trial protocol	DE GB IE HU NL BG ES GR IT
Global end of trial date	15 December 2021

Results information

Result version number	v1 (current)
This version publication date	30 December 2022
First version publication date	30 December 2022

Trial information

Trial identification

Sponsor protocol code	GA39925

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03558152
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com
Scientific contact	Medical Communications, F. Hoffmann-La Roche AG, 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	22 October 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study is designed to evaluate the efficacy, safety, and pharmacokinetics of UTTR1147A compared with vedolizumab and with placebo in the treatment of participants with moderate to severe UC. This study consist of two parts, Part A and Part B. Part A will test the induction of clinical remission and Part B will test the durability of clinical remission.

Protection of trial subjects:

This study was conducted in accordance with the protocol and with the following:
. Consensus ethical principles derived from international guidelines, including the Declaration of Helsinki
. Applicable International Committee on Harmonisation (ICH) Good Clinical Practice Guidelines
. Applicable laws and regulations

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 October 2018
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	Bulgaria: 2
Country: Number of subjects enrolled	Germany: 13
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	Georgia: 4
Country: Number of subjects enrolled	Greece: 4
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Ireland: 2
Country: Number of subjects enrolled	Israel: 1
Country: Number of subjects enrolled	Italy: 9
Country: Number of subjects enrolled	Moldova, Republic of: 7
Country: Number of subjects enrolled	Poland: 52
Country: Number of subjects enrolled	Russian Federation: 11
Country: Number of subjects enrolled	Serbia: 17
Country: Number of subjects enrolled	Ukraine: 64
Country: Number of subjects enrolled	United States: 4
Worldwide total number of subjects	195
EEA total number of subjects	86

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)	183
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients were assigned in a 1:1:1:1:1:1:2:1 ratio to one of eight treatment arms. Following completion of the screening period and after all patient eligibility requirements were confirmed, patients were assigned a patient number and randomly assigned to a treatment arm through an interactive voice or Web-based response system (IxRS).

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	Investigator, Subject, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)

Arm description:

Part A: UTTR1147A dose level 1 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.

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

Dosage and administration details:

UTTR1147A will be administered intravenously (IV) Part A, and at the maintenance dose level in Part B, per the respective arm descriptions.

Investigational medicinal product name	Vedolizumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The matching placebo to vedolizumab (Vedolizumab Placebo) will be administered IV.

Investigational medicinal product name	UTTR1147A Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

The matching placebo to UTTR1147A (UTTR1147A Placebo) will be administered IV.

Arm title	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)

Arm description:

Part A: UTTR1147A dose level 1 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab Placebo.

Arm type	Experimental

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

Dosage and administration details:

UTTR1147A will be administered intravenously (IV) Part A, and at the maintenance dose level in Part B, per the respective arm descriptions.

Investigational medicinal product name	Vedolizumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The matching placebo to vedolizumab (Vedolizumab Placebo) will be administered IV.

Investigational medicinal product name	UTTR1147A Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

The matching placebo to UTTR1147A (UTTR1147A Placebo) will be administered IV.

Arm title	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)

Arm description:

Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.

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

Dosage and administration details:

UTTR1147A will be administered intravenously (IV) Part A, and at the maintenance dose level in Part B, per the respective arm descriptions.

Investigational medicinal product name	UTTR1147A Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

The matching placebo to UTTR1147A (UTTR1147A Placebo) will be administered IV.

Investigational medicinal product name	Vedolizumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The matching placebo to vedolizumab (Vedolizumab Placebo) will be administered IV.

Arm title	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)

Arm description:

Part A: UTTR1147A dose level 2 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab

Placebo.

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

Dosage and administration details:

UTTR1147A will be administered intravenously (IV) Part A, and at the maintenance dose level in Part B, per the respective arm descriptions.

Investigational medicinal product name	UTTR1147A Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

The matching placebo to UTTR1147A (UTTR1147A Placebo) will be administered IV.

Investigational medicinal product name	Vedolizumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The matching placebo to vedolizumab (Vedolizumab Placebo) will be administered IV.

Arm title	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)

Arm description:

Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.

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

Dosage and administration details:

UTTR1147A will be administered intravenously (IV) Part A, and at the maintenance dose level in Part B, per the respective arm descriptions.

Investigational medicinal product name	UTTR1147A Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

The matching placebo to UTTR1147A (UTTR1147A Placebo) will be administered IV.

Investigational medicinal product name	Vedolizumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The matching placebo to vedolizumab (Vedolizumab Placebo) will be administered IV.

Arm title	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)

Arm description:

Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab Placebo.

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

Dosage and administration details:

UTTR1147A will be administered intravenously (IV) Part A, and at the maintenance dose level in Part B, per the respective arm descriptions.

Investigational medicinal product name	Vedolizumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The matching placebo to vedolizumab (Vedolizumab Placebo) will be administered IV.

Investigational medicinal product name	UTTR1147A Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

The matching placebo to UTTR1147A (UTTR1147A Placebo) will be administered IV.

Arm title	Arm 4: Vedolizumab

Arm description:

Parts A and B: Vedolizumab and UTTR1147A Placebo.

Arm type	Active comparator
Investigational medicinal product name	UTTR1147A Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

The matching placebo to UTTR1147A (UTTR1147A Placebo) will be administered IV.

Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	Entyvio
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab will be administered IV, as specified in the prescribing information.

Arm title	Arm 5: Placebo

Arm description:

Parts A and B: UTTR1147A Placebo and Vedolizumab Placebo.

Arm type	Placebo

Investigational medicinal product name	Vedolizumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

The matching placebo to vedolizumab (Vedolizumab Placebo) will be administered IV.

Investigational medicinal product name	UTTR1147A Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

The matching placebo to UTTR1147A (UTTR1147A Placebo) will be administered IV.

Number of subjects in period 1	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)
Started	22	21	21
Completed	7	6	8
Not completed	15	15	13
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	3	2
Mistake in calculation	-	-	-
Physician decision	-	-	-
Miscalculation in mmcs	-	-	-
Adverse event, non-fatal	-	-	1
Rolled over in GA40209 due to worsening of disease	1	-	-
Mistake in evaluation of disease status	-	-	-
Lack of efficacy	11	11	10
Protocol deviation	1	1	-

Number of subjects in period 1	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)
Started	23	22	21
Completed	8	3	7
Not completed	15	19	14
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	1	1	1
Mistake in calculation	1	-	-
Physician decision	-	-	-
Miscalculation in mmcs	-	-	-

Adverse event, non-fatal	1	2	1
Rolled over in GA40209 due to worsening of disease	-	-	-
Mistake in evaluation of disease status	-	-	-
Lack of efficacy	11	14	12
Protocol deviation	1	1	-

Number of subjects in period 1	Arm 4: Vedolizumab	Arm 5: Placebo
Started	43	22
Completed	21	6
Not completed	22	16
Adverse event, serious fatal	-	-
Consent withdrawn by subject	3	2
Mistake in calculation	-	-
Physician decision	1	-
Miscalculation in mmcs	1	-
Adverse event, non-fatal	1	-
Rolled over in GA40209 due to worsening of disease	-	-
Mistake in evaluation of disease status	-	1
Lack of efficacy	14	13
Protocol deviation	2	-

Baseline characteristics

Reporting groups

Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	195	195	
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)	183	183	
From 65-84 years	12	12	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	40.8		
standard deviation	± 13.2	-	
Sex: Female, Male Units: Participants			
Female	60	60	
Male	135	135	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	1	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	194	194	
More than one race	0	0	
Unknown or Not Reported	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	195	195	
Unknown or Not Reported	0	0	

Subject analysis sets

Subject analysis set title	Arm 1
Subject analysis set type	Intention-to-treat

Subject analysis set description:	
Participants received UTTR1147A at a dose of 30 ug/kg	
Subject analysis set title	Arm 2
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received UTTR1147A at a dose of 60 ug/kg	
Subject analysis set title	Arm 3
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received UTTR1147A at a dose of 90 ug/kg	
Subject analysis set title	Arm 4
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received Vedolizumab and UTTR1147A Placebo.	
Subject analysis set title	Arm 5
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received UTTR1147A Placebo and Vedolizumab Placebo.	

Reporting group values	Arm 1	Arm 2	Arm 3
Number of subjects	43	44	43
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)	40	42	42
From 65-84 years	3	1	4
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	40.6	39.4	39.5
standard deviation	± 13.2	± 12.1	± 12.3
Sex: Female, Male Units: Participants			
Female	15	15	11
Male	28	29	32
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	43	43	43
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	43	44	43
Unknown or Not Reported	0	0	0

Reporting group values	Arm 4	Arm 5	
Number of subjects	43	22	
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)	39	20	
From 65-84 years	2		
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	43.4	41.9	
standard deviation	± 14.8	± 14.0	
Sex: Female, Male Units: Participants			
Female	13	6	
Male	30	16	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	43	22	
More than one race	0	0	
Unknown or Not Reported	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	43	22	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)
Reporting group description: Part A: UTTR1147A dose level 1 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.	
Reporting group title	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)
Reporting group description: Part A: UTTR1147A dose level 1 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab Placebo.	
Reporting group title	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)
Reporting group description: Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.	
Reporting group title	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)
Reporting group description: Part A: UTTR1147A dose level 2 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab Placebo.	
Reporting group title	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)
Reporting group description: Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.	
Reporting group title	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)
Reporting group description: Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab Placebo.	
Reporting group title	Arm 4: Vedolizumab
Reporting group description: Parts A and B: Vedolizumab and UTTR1147A Placebo.	
Reporting group title	Arm 5: Placebo
Reporting group description: Parts A and B: UTTR1147A Placebo and Vedolizumab Placebo.	
Subject analysis set title	Arm 1
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants received UTTR1147A at a dose of 30 ug/kg	
Subject analysis set title	Arm 2
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants received UTTR1147A at a dose of 60 ug/kg	
Subject analysis set title	Arm 3
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants received UTTR1147A at a dose of 90 ug/kg	
Subject analysis set title	Arm 4
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants received Vedolizumab and UTTR1147A Placebo.	
Subject analysis set title	Arm 5

Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received UTTR1147A Placebo and Vedolizumab Placebo.

Primary: Percentage of Participants with Clinical Remission at Week 8

End point title	Percentage of Participants with Clinical Remission at Week

End point description:

Clinical remission is defined as modified Mayo Clinic Score (mMCS) <= 2 with Mayo rectal bleeding subscore = 0, Mayo stool frequency subscore <=1 and Centrally read endoscopic score <= 1. Patients were classified as Non-Remitters if Week 8 assessments were missing or patient received permitted/ prohibited Rescue Therapy prior to assessment.

End point type	Primary

End point timeframe:

8 weeks

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 statistical analyses provided

[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: No statistical analyses provided

End point values	Arm 4: Vedolizumab	Arm 5: Placebo	Arm 1	Arm 2
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	43	22	43	44
Units: Participants				
Yes	11	2	5	4
No	32	20	38	40

End point values	Arm 3			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Participants				
Yes	5			
No	38			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Sustained Remission

End point title	Percentage of Participants with Sustained Remission

End point description:

The evaluation of the secondary endpoints was affected by the proportion of patients in Part A who elected to enroll in the OLE study versus those who elected
to participate in Part B. Meaningful conclusions could not be made due to low enrollment in Part B and therefore secondary endpoints were not discussed.

End point type	Secondary

End point timeframe:

At Weeks 8 and 30

End point values	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[3]	0[4]	0[5]	0[6]
Units: Percentage of Participants				

Notes:

[3] - Meaningful conclusions could not be made due to low enrollment

[4] - Meaningful conclusions could not be made due to low enrollment

[5] - Meaningful conclusions could not be made due to low enrollment

[6] - Meaningful conclusions could not be made due to low enrollment

End point values	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)	Arm 4: Vedolizumab	Arm 5: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	0[8]	0[9]	0[10]
Units: Percentage of Participants				

Notes:

[7] - Meaningful conclusions could not be made due to low enrollment

[8] - Meaningful conclusions could not be made due to low enrollment

[9] - Meaningful conclusions could not be made due to low enrollment

[10] - Meaningful conclusions could not be made due to low enrollment

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Serum Concentration (Cmax) of UTTR1147A

End point title	Maximum Serum Concentration (Cmax) of UTTR1147A

End point description:

Due to low enrollment in Part B of the study, the PK data from pooled Arms 1-3 (1A + 1B; 2A + 2B; 3A + 3B) are summarized based on data up through Week 8 which is the primary efficacy assessment for Part A (Induction phase). A total of 130 patients who received at least one dose of efmarodocokin alfa and had measurable PK concentrations are included in the analysis.

End point type	Secondary

End point timeframe:

Postdose at Baseline and Week 8

End point values	Arm 1	Arm 2	Arm 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	43	44	43	
Units: ng/mL				
arithmetic mean (standard deviation)				
Visit: Days 1 - 29	449 (± 658)	590 (± 265)	837 (± 560)	
Visit: Day 57	426 (± 344)	693 (± 348)	1340 (± 883)	

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Serum Concentration (Cmin) of UTTR1147A

End point title	Minimum Serum Concentration (Cmin) of UTTR1147A

End point description:

Due to low enrollment in Part B of the study, the PK data from pooled Arms 1-3 (1A + 1B; 2A + 2B; 3A + 3B) are summarized based on data up through Week 8 which is the primary efficacy assessment for Part A (Induction phase). A total of 130 patients who received at least one dose of efmarodocokin alfa and had measurable PK concentrations are included in the analysis.

End point type	Secondary

End point timeframe:

Postdose at Baseline and Week 8

End point values	Arm 1	Arm 2	Arm 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	39	40	42	
Units: ng/mL				
arithmetic mean (standard deviation)				
Days 1 - 29	12.6 (± 9.55)	28.3 (± 17.1)	40.6 (± 27.7)	
Visit: Day 57	15.8 (± 11.7)	37.2 (± 35.2)	44.5 (± 28.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Clinical Response at Weeks 8 and 30

End point title	Percentage of Participants with Clinical Response at Weeks 8 and 30

End point description:

The evaluation of the secondary endpoints was affected by the proportion of patients in Part A who elected to enroll in the OLE study versus those who elected to participate in Part B. Meaningful conclusions could not be made due to low enrollment in Part B and therefore secondary endpoints were not discussed.

End point type	Secondary

End point timeframe:

At Weeks 8 and 30

End point values	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[11]	0[12]	0[13]	0[14]
Units: Percentage of Participants				

Notes:

[11] - Meaningful conclusions could not be made due to low enrollment

[12] - Meaningful conclusions could not be made due to low enrollment

[13] - Meaningful conclusions could not be made due to low enrollment

[14] - Meaningful conclusions could not be made due to low enrollment

End point values	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)	Arm 4: Vedolizumab	Arm 5: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[15]	0[16]	0[17]	0[18]
Units: Percentage of Participants				

Notes:

[15] - Meaningful conclusions could not be made due to low enrollment

[16] - Meaningful conclusions could not be made due to low enrollment

[17] - Meaningful conclusions could not be made due to low enrollment

[18] - Meaningful conclusions could not be made due to low enrollment

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Endoscopic Healing at Weeks 8 and 30

End point title	Percentage of Participants with Endoscopic Healing at Weeks 8 and 30

End point description:

The evaluation of the secondary endpoints was affected by the proportion of patients in Part A who elected to enroll in the OLE study versus those who elected
to participate in Part B. Meaningful conclusions could not be made due to low enrollment in Part B and therefore secondary endpoints were not discussed.

End point type	Secondary

End point timeframe:

At Weeks 8 and 30

End point values	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[19]	0[20]	0[21]	0[22]
Units: Percentage of Participants				

Notes:

[19] - Meaningful conclusions could not be made due to low enrollment

[20] - Meaningful conclusions could not be made due to low enrollment

[21] - Meaningful conclusions could not be made due to low enrollment

[22] - Meaningful conclusions could not be made due to low enrollment

End point values	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)	Arm 4: Vedolizumab	Arm 5: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[23]	0[24]	0[25]	0[26]
Units: Percentage of Participants				

Notes:

[23] - Meaningful conclusions could not be made due to low enrollment

[24] - Meaningful conclusions could not be made due to low enrollment

[25] - Meaningful conclusions could not be made due to low enrollment

[26] - Meaningful conclusions could not be made due to low enrollment

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Endoscopic Remission at Weeks 8 and 30

End point title	Percentage of Participants with Endoscopic Remission at Weeks 8 and 30

End point description:

The evaluation of the secondary endpoints was affected by the proportion of patients in Part A who elected to enroll in the OLE study versus those who elected
to participate in Part B. Meaningful conclusions could not be made due to low enrollment in Part B and therefore secondary endpoints were not discussed.

End point type	Secondary

End point timeframe:

At Weeks 8 and 30

End point values	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[27]	0[28]	0[29]	0[30]

Units: Percentage of Participants				

Notes:

[27] - Meaningful conclusions could not be made due to low enrollment

[28] - Meaningful conclusions could not be made due to low enrollment

[29] - Meaningful conclusions could not be made due to low enrollment

[30] - Meaningful conclusions could not be made due to low enrollment

End point values	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)	Arm 4: Vedolizumab	Arm 5: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[31]	0[32]	0[33]	0[34]
Units: Percentage of Participants				

Notes:

[31] - Meaningful conclusions could not be made due to low enrollment

[32] - Meaningful conclusions could not be made due to low enrollment

[33] - Meaningful conclusions could not be made due to low enrollment

[34] - Meaningful conclusions could not be made due to low enrollment

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in UC Bowel Movement Signs and Symptoms at Weeks 8 and 30, as Assessed by Ulcerative Colitis Patient-Reported Outcome Signs and Symptoms (UC-PRO/SS) Score

End point title	Change From Baseline in UC Bowel Movement Signs and Symptoms at Weeks 8 and 30, as Assessed by Ulcerative Colitis Patient-Reported Outcome Signs and Symptoms (UC-PRO/SS) Score

End point description:

The evaluation of the secondary endpoints was affected by the proportion of patients in Part A who elected to enroll in the OLE study versus those who elected
to participate in Part B. Meaningful conclusions could not be made due to low enrollment in Part B and therefore secondary endpoints were not discussed.

End point type	Secondary

End point timeframe:

At Weeks 8 and 30

End point values	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[35]	0[36]	0[37]	0[38]
Units: Points on scale				

Notes:

[35] - Meaningful conclusions could not be made due to low enrollment

[36] - Meaningful conclusions could not be made due to low enrollment

[37] - Meaningful conclusions could not be made due to low enrollment

[38] - Meaningful conclusions could not be made due to low enrollment

End point values	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)	Arm 4: Vedolizumab	Arm 5: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[39]	0[40]	0[41]	0[42]
Units: Points on scale				

Notes:

[39] - Meaningful conclusions could not be made due to low enrollment

[40] - Meaningful conclusions could not be made due to low enrollment

[41] - Meaningful conclusions could not be made due to low enrollment

[42] - Meaningful conclusions could not be made due to low enrollment

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in UC Abdominal Signs and Symptoms at Weeks 8 and 30, as Assessed by Ulcerative Colitis Patient-Reported Outcome Signs and Symptoms (UC-PRO/SS) Score

End point title	Change From Baseline in UC Abdominal Signs and Symptoms at Weeks 8 and 30, as Assessed by Ulcerative Colitis Patient-Reported Outcome Signs and Symptoms (UC-PRO/SS) Score

End point description:

The evaluation of the secondary endpoints was affected by the proportion of patients in Part A who elected to enroll in the OLE study versus those who elected
to participate in Part B. Meaningful conclusions could not be made due to low enrollment in Part B and therefore secondary endpoints were not discussed.

End point type	Secondary

End point timeframe:

At Weeks 8 and 30

End point values	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[43]	0[44]	0[45]	0[46]
Units: Points on scale				

Notes:

[43] - Meaningful conclusions could not be made due to low enrollment

[44] - Meaningful conclusions could not be made due to low enrollment

[45] - Meaningful conclusions could not be made due to low enrollment

[46] - Meaningful conclusions could not be made due to low enrollment

End point values	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)	Arm 4: Vedolizumab	Arm 5: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[47]	0[48]	0[49]	0[50]
Units: Points on scale				

Notes:

[47] - Meaningful conclusions could not be made due to low enrollment

[48] - Meaningful conclusions could not be made due to low enrollment

[49] - Meaningful conclusions could not be made due to low enrollment

[50] - Meaningful conclusions could not be made due to low enrollment

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Patient-Reported Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Weeks 8 and 30

End point title	Change From Baseline in Patient-Reported Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Weeks 8 and 30[51]

End point description:

The evaluation of the secondary endpoints was affected by the proportion of patients in Part A who elected to enroll in the OLE study versus those who elected
to participate in Part B. Meaningful conclusions could not be made due to low enrollment in Part B and therefore secondary endpoints were not discussed.

End point type	Secondary

End point timeframe:

At Weeks 8 and 30

Notes:

[51] - 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: No statistical analyses provided

End point values	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[52]	0[53]	0[54]	0[55]
Units: Points on scale				

Notes:

[52] - Meaningful conclusions could not be made due to low enrollment

[53] - Meaningful conclusions could not be made due to low enrollment

[54] - Meaningful conclusions could not be made due to low enrollment

[55] - Meaningful conclusions could not be made due to low enrollment

End point values	Arm 4:	Arm 5: Placebo		

	Vedolizumab			
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[56]	0[57]		
Units: Points on scale				

Notes:

[56] - Meaningful conclusions could not be made due to low enrollment

[57] - Meaningful conclusions could not be made due to low enrollment

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Adverse Events

End point title	Percentage of Participants with Adverse Events[58]

End point description:

End point type	Secondary

End point timeframe:

Up to 30 weeks

Notes:

[58] - 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: No statistical analyses provided

End point values	Arm 4: Vedolizumab	Arm 5: Placebo	Arm 1	Arm 2
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	43	22	43	44
Units: Participants				
Non-Serious Adverse Events	6	4	12	11
Serious Adverse Events	0	0	1	1

End point values	Arm 3			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Participants				
Non-Serious Adverse Events	15			
Serious Adverse Events	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Presence of Anti-Drug Antibodies (ADA) at Baseline and After Drug Administration

End point title	Percentage of Participants with Presence of Anti-Drug

	Antibodies (ADA) at Baseline and After Drug Administration[59]

End point description:

Participants in placebo group were not analysed for post-baseline Anti-Drug Antibodies (ADA)

End point type	Secondary

End point timeframe:

Baseline up to 30 weeks

Notes:

[59] - 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: No statistical analyses provided

End point values	Arm 1a: UTTR1147A Dose Level 1 (Part A) + UTTR1147A (Part B)	Arm 1b: UTTR1147A Dose Level 1 (Part A) + Placebo (Part B)	Arm 2a: UTTR1147A Dose Level 2 (Part A) + UTTR1147A (Part B)	Arm 2b: UTTR1147A Dose Level 2 (Part A) + Placebo (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	21	21	23
Units: Partcipants				
number (not applicable)				
Patients with a positive sample at baseline	14.55	9.52	4.76	4.35
Patients with no positive samples at baseline	95.45	100	94.24	95.65
Patients positive for Treatment Emergent ADA	0	9.52	4.76	4.35
Treatment-induced ADA	0	9.52	4.76	4.35
Treatment-enhanced ADA	0	0	0	0
Treatment unaffected	4.55	9.52	4.76	4.35

End point values	Arm 3a: UTTR1147A Dose Level 3 (Part A) + UTTR1147A (Part B)	Arm 3b: UTTR1147A Dose Level 3 (Part A) + Placebo (Part B)	Arm 5: Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	22	21	22	
Units: Partcipants				
number (not applicable)				
Patients with a positive sample at baseline	4.55	0	4.62	
Patients with no positive samples at baseline	95.45	92.24	95.38	
Patients positive for Treatment Emergent ADA	9.09	4.76	0000	
Treatment-induced ADA	9.09	4.76	0000	
Treatment-enhanced ADA	0	0	0000	
Treatment unaffected	14.55	4.76	0000	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 30 weeks

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Arm 1: UTTR1147A 30 ug/kgInduction

Reporting group description:

Participants received UTTR1147A at a dose of 30 ug/kg

Reporting group title	Arm 2: UTTR1147A 60 ug/kgInduction

Reporting group description:

Participants received UTTR1147A at a dose of 60 ug/kg

Reporting group title	Arm 3: UTTR1147A 90 ug/kg Induction

Reporting group description:

Participants received UTTR1147A at a dose of 90 ug/kg

Reporting group title	Arm 4: VEDOLIZUMAB 300 mg Induction

Reporting group description:

Participants received Vedolizumab and UTTR1147A Placebo.

Reporting group title	1A: UTTR1147A 30 + UTTR1147A 60Maintenance

Reporting group description:

Part A: UTTR1147A dose level 1 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.

Reporting group title	Arm 5: PLACEBOInduction

Reporting group description:

Parts A and B: UTTR1147A Placebo and Vedolizumab Placebo.

Reporting group title	1B: UTTR1147A 30 + PLACEBOMaintenance

Reporting group description:

Part A: UTTR1147A dose level 1 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab Placebo.

Reporting group title	2A: UTTR1147A 60 + UTTR1147A 60Maintenance

Reporting group description:

Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.

Reporting group title	2B: UTTR1147A 60 + PLACEBOMaintenance

Reporting group description:

Part A: UTTR1147A dose level 2 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab Placebo.

Reporting group title	3A: UTTR1147A 90 + UTTR1147A 60Maintenance

Reporting group description:

Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A maintenance dose and Vedolizumab Placebo.

Reporting group title	3B: UTTR1147A 90 + PLACEBO Maintenance

Reporting group description:

Part A: UTTR1147A dose level 3 and Vedolizumab Placebo. Part B: UTTR1147A Placebo and Vedolizumab Placebo.

Reporting group title	ARM4: VEDOLIZUMAB 300 + VEDOLIZUMAB 300 Maintenance

Reporting group description:

Parts A and B: Vedolizumab and UTTR1147A Placebo.

Reporting group title	ARM5: PLACEBO + PLACEBO Maintenance

Reporting group description:

Parts A and B: UTTR1147A Placebo and Vedolizumab Placebo.

Serious adverse events	Arm 1: UTTR1147A 30 ug/kgInduction	Arm 2: UTTR1147A 60 ug/kgInduction	Arm 3: UTTR1147A 90 ug/kg Induction
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 43 (2.33%)	1 / 44 (2.27%)	5 / 43 (11.63%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 43 (0.00%)	1 / 44 (2.27%)	0 / 43 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	1 / 43 (2.33%)	1 / 44 (2.27%)	4 / 43 (9.30%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm 4: VEDOLIZUMAB 300 mg Induction	1A: UTTR1147A 30 + UTTR1147A 60Maintenance	Arm 5: PLACEBOInduction
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	1B: UTTR1147A 30 + PLACEBOMaintenance	2A: UTTR1147A 60 + UTTR1147A 60Maintenance	2B: UTTR1147A 60 + PLACEBOMaintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphopenia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	3A: UTTR1147A 90 + UTTR1147A 60Maintenance	3B: UTTR1147A 90 + PLACEBO Maintenance	ARM4: VEDOLIZUMAB 300 + VEDOLIZUMAB 300 Maintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ARM5: PLACEBO + PLACEBO Maintenance		
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		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Arm 1: UTTR1147A 30 ug/kgInduction	Arm 2: UTTR1147A 60 ug/kgInduction	Arm 3: UTTR1147A 90 ug/kg Induction
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 43 (27.91%)	11 / 44 (25.00%)	15 / 43 (34.88%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 43 (4.65%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	6	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 43 (6.98%)	0 / 44 (0.00%)	1 / 43 (2.33%)
occurrences (all)	8	0	2
Blood glucose increased			
subjects affected / exposed	2 / 43 (4.65%)	1 / 44 (2.27%)	0 / 43 (0.00%)
occurrences (all)	4	2	0
Blood uric acid increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	4
Electrocardiogram abnormal			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 43 (0.00%)	1 / 44 (2.27%)	1 / 43 (2.33%)
occurrences (all)	0	2	2
Headache			
subjects affected / exposed	1 / 43 (2.33%)	1 / 44 (2.27%)	2 / 43 (4.65%)
occurrences (all)	2	2	6
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	3 / 43 (6.98%)	1 / 44 (2.27%)	0 / 43 (0.00%)
occurrences (all)	6	2	0
Eosinophilia			
subjects affected / exposed	1 / 43 (2.33%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	2	0	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 43 (2.33%)	0 / 44 (0.00%)	1 / 43 (2.33%)
occurrences (all)	2	0	2
Reproductive system and breast disorders			
Epididymal cyst			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	3 / 43 (6.98%)	5 / 44 (11.36%)	9 / 43 (20.93%)
occurrences (all)	6	14	28
Hand dermatitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	2
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 43 (2.33%)	1 / 44 (2.27%)	0 / 43 (0.00%)
occurrences (all)	2	2	0
Conjunctivitis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 44 (2.27%)	0 / 43 (0.00%)
occurrences (all)	0	2	0
Herpes zoster			

subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Herpes zoster infection neurological			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 43 (4.65%)	3 / 44 (6.82%)	1 / 43 (2.33%)
occurrences (all)	4	6	2
Urinary tract infection			
subjects affected / exposed	1 / 43 (2.33%)	1 / 44 (2.27%)	1 / 43 (2.33%)
occurrences (all)	2	2	2
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 43 (0.00%)	0 / 44 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Arm 4: VEDOLIZUMAB 300 mg Induction	1A: UTTR1147A 30 + UTTR1147A 60Maintenance	Arm 5: PLACEBOInduction
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 43 (13.95%)	2 / 10 (20.00%)	4 / 22 (18.18%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 43 (0.00%)	1 / 10 (10.00%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Blood uric acid increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram abnormal			

subjects affected / exposed	0 / 43 (0.00%)	1 / 10 (10.00%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 43 (2.33%)	0 / 10 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 43 (4.65%)	0 / 10 (0.00%)	1 / 22 (4.55%)
occurrences (all)	4	0	2
Eosinophilia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Epididymal cyst			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Dry skin			
subjects affected / exposed	1 / 43 (2.33%)	0 / 10 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	2
Hand dermatitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 43 (2.33%)	0 / 10 (0.00%)	2 / 22 (9.09%)
occurrences (all)	2	0	4
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes zoster infection neurological			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	1 / 43 (2.33%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	4	0	0
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 43 (0.00%)	0 / 10 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	1B: UTTR1147A 30 + PLACEBOMaintenance	2A: UTTR1147A 60 + UTTR1147A 60Maintenance	2B: UTTR1147A 60 + PLACEBOMaintenance
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 7 (28.57%)	6 / 10 (60.00%)	3 / 9 (33.33%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Blood glucose increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 10 (10.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Blood uric acid increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 10 (10.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Epididymal cyst			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	2 / 10 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Hand dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 10 (10.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 7 (0.00%)	1 / 10 (10.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Herpes zoster			

subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes zoster infection neurological			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 10 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 10 (10.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	3A: UTTR1147A 90 + UTTR1147A 60Maintenance	3B: UTTR1147A 90 + PLACEBO Maintenance	ARM4: VEDOLIZUMAB 300 + VEDOLIZUMAB 300 Maintenance
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	3 / 8 (37.50%)	2 / 22 (9.09%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Electrocardiogram abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	2	0	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Epididymal cyst			
subjects affected / exposed	0 / 6 (0.00%)	1 / 8 (12.50%)	0 / 22 (0.00%)
occurrences (all)	0	2	0

Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 8 (25.00%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	1 / 8 (12.50%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Herpes zoster infection neurological			
subjects affected / exposed	0 / 6 (0.00%)	1 / 8 (12.50%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 6 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	ARM5: PLACEBO + PLACEBO Maintenance		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 7 (28.57%)		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood glucose increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood uric acid increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Electrocardiogram abnormal			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	2		
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Headache			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Eosinophilia subjects affected / exposed occurrences (all)	 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0		
Eye disorders Lacrimation increased subjects affected / exposed occurrences (all)	 0 / 7 (0.00%) 0		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	 0 / 7 (0.00%) 0		
Reproductive system and breast disorders Epididymal cyst subjects affected / exposed occurrences (all)	 0 / 7 (0.00%) 0		
Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all) Hand dermatitis subjects affected / exposed occurrences (all)	 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	 0 / 7 (0.00%) 0		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Conjunctivitis	 0 / 7 (0.00%) 0		

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Herpes zoster infection neurological			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 November 2017	A placebo control arm was added to the study and the primary endpoint was updated accordingly.
26 January 2018	The purpose of this update was based on feedback from the FDA. Additional guidance on the management of patients with evidence of hepatotoxicity was added and randomization stratification factors were updated.
28 February 2020	The amendment represents a harmonization of v4 and v4 VHP. The protocol was amended to clarify that the randomization scheme within the IxRS was set up to enroll Clinical Study Report GA39925 Number 1116106 18 patients in the placebo arm for the entire duration of the study and not just within the first 150 patients.
08 April 2021	The purpose of this update was to address an urgent safety measure for COVID-19 infection. Guidance for the management of suspected or confirmed COVID-19 infections was added and suspected or confirmed COVID-19 infection was added to the list of AESIs.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported