Clinical trial results:
Open label exploratory phase IIa trial to investigate the safety and efficacy of IFX-1 in treating patients with Pyoderma Gangrenosum (OPTIMA).

Summary

EudraCT number	2020-003273-21
Trial protocol	PL
Global end of trial date	03 January 2022

Results information

Result version number	v1 (current)
This version publication date	20 July 2023
First version publication date	20 July 2023

Trial information

Trial identification

Sponsor protocol code	IFX-1-P2.7

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03971643
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	InflaRx GmbH
Sponsor organisation address	Winzerlaer Strasse 2, Jena, Germany, 07745
Public contact	Prof. Niels C. Riedemann, M.D., Ph.D., InflaRx GmbH, +49 3641508180, niels.Riedemann@inflarx.de
Scientific contact	Prof. Niels C. Riedemann, M.D., Ph.D., InflaRx GmbH, +49 3641508180, niels.Riedemann@inflarx.de

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	30 September 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 January 2022
Global end of trial reached?	Yes
Global end of trial date	03 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Explore the safety of Vilobelimab (development name: IFX-1) for the treatment of subjects with pyoderma gangrenosum (PG)

Protection of trial subjects:

The study was conducted according to the ethical principles of the Declaration of Helsinki and in compliance with International Council for Harmonization (ICH) guideline on good clinical practice (GCP). All persons participating in the conduct of the study (e.g., Sponsor, Investigators) committed themselves to observe the Declaration of Helsinki and CIOMS guidelines, as well as all the requirements of 21 CFR, ICH guidelines, the IEC, European regulation 536/2014 for clinical studies, and all other applicable local regulations. Only subjects that met all inclusion criteria and no exclusion criteria were to enter the study. All patients were free to discontinue their participation in the study at any time.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 May 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	Canada: 5
Country: Number of subjects enrolled	United States: 7
Country: Number of subjects enrolled	Poland: 7
Worldwide total number of subjects	19
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)	12
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

First Subject First Visit: 16-May-2019; Last Subject Last Visit: 03-Jan-2022;
This study was conducted at 8 sites in 3 countries: Canada (1 site), the USA (5 sites) and in Poland (2 sites)

Pre-assignment

Screening details:

A total of 29 patients were screened (of whom one patient was re-screened, i.e. 30 Screenings took place), 19 patients were treated with vilobelimab. Reasons for screen failure included failure to meet inclusion/exclusion criteria (n=9, including the one patient that was successfully treated after re-screening) and adverse event (n=2).

Period 1

Period 1 title	Treatment & observational visits (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	vilobelimab 800 mg (Q2W)

Arm description:

Group 1 (N=6) received vilobelimab 800 mg every 2 weeks (Q2W).

Arm type	Experimental
Investigational medicinal product name	vilobelimab
Investigational medicinal product code	IFX-1
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Proof of Concept with a total of 15 doses of vilobelimab.

vilobelimab: IV infusions of vilobelimab diluted in sodium chloride.

All patients received vilobelimab 800 mg three times during the first week (Days 1, 4, and 8).

Starting at Day 15:
Group 1 (N=6) continued to receive vilobelimab 800 mg every 2 weeks (Q2W). With option to increase dose from Day 57 to 1600 mg every two week (Q2W).

Arm title	vilobelimab 1600 mg (Q2W)

Arm description:

Group 2 (N=6) received vilobelimab 1600 mg every 2 weeks (Q2W).

Arm type	Experimental
Investigational medicinal product name	vilobelimab
Investigational medicinal product code	IFX-1
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Proof of Concept with a total of 15 doses of vilobelimab.

vilobelimab: IV infusions of vilobelimab diluted in sodium chloride.

All patients received vilobelimab 800 mg three times during the first week (Days 1, 4, and 8).

Starting at Day 15:
Group 2 (N=6) received vilobelimab 1600 mg every 2 weeks (Q2W). With option to increase dose from Day 57 to 2400 mg every two week (Q2W).

Arm title	vilobelimab 2400 mg (Q2W)
Arm description:	
Group 3 (N=7) received vilobelimab 2400 mg every 2 weeks (Q2W).	
Arm type	Experimental
Investigational medicinal product name	vilobelimab
Investigational medicinal product code	IFX-1
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Proof of Concept with a total of 15 doses of vilobelimab.

vilobelimab: IV infusions of vilobelimab diluted in sodium chloride.

All patients received vilobelimab 800 mg three times during the first week (Days 1, 4, and 8).

Starting at Day 15:
Group 3 (N=7) received vilobelimab 2400 mg every 2 weeks (Q2W).

Number of subjects in period 1	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)
Started	6	6	7
Completed until Day 99 (evaluable)	6	4	7
Completed	1	3	6
Not completed	5	3	1
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	2	1	-
Met exclusion criterion	-	-	1
Missed visits due to COVID-19	1	-	-
Progressive disease	-	1	-
Site closure	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	vilobelimab 800 mg (Q2W)
Reporting group description:	
Group 1 (N=6) received vilobelimab 800 mg every 2 weeks (Q2W).	
Reporting group title	vilobelimab 1600 mg (Q2W)
Reporting group description:	
Group 2 (N=6) received vilobelimab 1600 mg every 2 weeks (Q2W).	
Reporting group title	vilobelimab 2400 mg (Q2W)
Reporting group description:	
Group 3 (N=7) received vilobelimab 2400 mg every 2 weeks (Q2W).	

Reporting group values	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)
Number of subjects	6	6	7
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)	3	3	6
From 65-84 years	3	3	1
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	60	61	43
standard deviation	± 11.4	± 12.4	± 15.0
Gender categorical Units: Subjects			
Female	4	3	3
Male	2	3	4

Reporting group values	Total		
Number of subjects	19		
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)	12		

From 65-84 years	7		
85 years and over	0		

Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	10		
Male	9		

End points

End points reporting groups

Reporting group title	vilobelimab 800 mg (Q2W)
Reporting group description: Group 1 (N=6) received vilobelimab 800 mg every 2 weeks (Q2W).	
Reporting group title	vilobelimab 1600 mg (Q2W)
Reporting group description: Group 2 (N=6) received vilobelimab 1600 mg every 2 weeks (Q2W).	
Reporting group title	vilobelimab 2400 mg (Q2W)
Reporting group description: Group 3 (N=7) received vilobelimab 2400 mg every 2 weeks (Q2W).	
Subject analysis set title	Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All subjects who received at least 1 dose of Investigational Medicinal Product (IMP).	

Primary: Occurrence, nature and intensity of treatment-emergent adverse events (TEAEs)

End point title	Occurrence, nature and intensity of treatment-emergent adverse events (TEAEs)[1]
End point description: Number of patients with TEAEs	
End point type	Primary
End point timeframe: First administration of vilobelimab until end of study	

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: The primary objective of the study was to explore the safety by observing the occurrence, nature and intensity of the adverse events. No explicit statistical analysis was done.
Adverse events is also reported in the 'Adverse events' section. No separate reporting on SOC/PT level is performed here.

End point values	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	7	
Units: Patient number	6	4	5	

Statistical analyses

No statistical analyses for this end point

Primary: Occurrence, nature and intensity of related TEAEs

End point title	Occurrence, nature and intensity of related TEAEs[2]
End point description: Number of patients with related TEAEs	
End point type	Primary

End point timeframe:

First administration of vilobelimab until end of study

Notes:

[2] - 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: The primary objective of the study was to explore the safety by observing the occurrence, nature and intensity of the adverse events. No explicit statistical analysis was done.
Adverse events is also reported in the 'Adverse events' section. No separate reporting on SOC/PT level is performed here.

End point values	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	7	
Units: Patient number, occurrences	0	2	2	

Statistical analyses

No statistical analyses for this end point

Primary: Occurrence, nature and intensity of serious TEAEs

End point title	Occurrence, nature and intensity of serious TEAEs[3]

End point description:

Number of patients with serious TEAEs

End point type	Primary

End point timeframe:

First administration of vilobelimab until end of study

Notes:

[3] - 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: The primary objective of the study was to explore the safety by observing the occurrence, nature and intensity of the adverse events. No explicit statistical analysis was done.
Adverse events is also reported in the 'Adverse events' section. No separate reporting on SOC/PT level is performed here.

End point values	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	7	
Units: Patient number	1	1	2	

Statistical analyses

No statistical analyses for this end point

Primary: Occurrence, nature and intensity of adverse events of special interest (AESIs) by investigator

End point title	Occurrence, nature and intensity of adverse events of special interest (AESIs) by investigator[4]

End point description:

Number of patients with AESIs by investigator

End point type	Primary

End point timeframe:

First administration of vilobelimab until end of study

Notes:

[4] - 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: The primary objective of the study was to explore the safety by observing the occurrence, nature and intensity of the adverse events. No explicit statistical analysis was done.
Adverse events is also reported in the 'Adverse events' section. No separate reporting on SOC/PT level is performed here.

End point values	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	7	
Units: Patient number	0	1	1	

Statistical analyses

No statistical analyses for this end point

Primary: Occurrence, nature and intensity of adverse events of special interest (AESIs) by sponsor

End point title	Occurrence, nature and intensity of adverse events of special interest (AESIs) by sponsor[5]

End point description:

Number of patients with AESIs by sponsor

End point type	Primary

End point timeframe:

First administration of vilobelimab until end of study

Notes:

[5] - 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: The primary objective of the study was to explore the safety by observing the occurrence, nature and intensity of the adverse events. No explicit statistical analysis was done.
Adverse events is also reported in the 'Adverse events' section. No separate reporting on SOC/PT level is performed here.

End point values	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	7	
Units: Patient number	2	1	2	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
First administration of vilobelimab until end of study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups	
Reporting group title	vilobelimab 800 mg (Q2W)
Reporting group description: -	
Reporting group title	vilobelimab 1600 mg (Q2W)
Reporting group description: -	
Reporting group title	vilobelimab 2400 mg (Q2W)
Reporting group description: -	

Serious adverse events	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	2 / 7 (28.57%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Skin and subcutaneous tissue disorders			
Pyoderma gangrenosum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (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
Infections and infestations			
Endocarditis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection bacterial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	vilobelimab 800 mg (Q2W)	vilobelimab 1600 mg (Q2W)	vilobelimab 2400 mg (Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	3 / 6 (50.00%)	5 / 7 (71.43%)
Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Haemoglobin decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			

Traumatic haematoma			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Burns second degree			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Head injury			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin laceration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Superficial vein thrombosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Glossitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Peptic ulcer			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Pyoderma gangrenosum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Actinic keratosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Lichen planus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Urticaria			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Wound infection			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Wound infection pseudomonas			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Abscess limb			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oral herpes			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 November 2019	Version 3.0 including Amendment 01 on vilobelimab dosing in dermatological diseases. The summary of changes is detailed in appendix 7 of the protocol (Appendix 16.1.1).
14 May 2020	Version 4.0 including Amendment 02 on trial enrollment and pain medication. The summary of changes is detailed in appendix 8 of the protocol (Appendix 16.1.1).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None

Notes: