



Clinical trial results:

A randomized, double-blind, placebo-controlled, multicenter Phase II study to determine efficacy and safety of IFX-1 in subjects with moderate to severe hidradenitis suppurativa

Summary

EudraCT number	2017-004501-40
Trial protocol	NL DE GR BG DK PL
Global end of trial date	14 November 2019

Results information

Result version number	v1 (current)
This version publication date	09 December 2020
First version publication date	09 December 2020

Trial information

Trial identification

Sponsor protocol code	IFX-1-P2.4
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03487276
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	InflaRx GmbH
Sponsor organisation address	Winzerlaer Str. 2, Jena, Germany, 07745
Public contact	InflaRx GmbH, InflaRx GmbH, +49 3641508 180, info@inflarx.de
Scientific contact	InflaRx GmbH, InflaRx GmbH, +49 3641508 180, info@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	16 April 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	14 November 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluate a dose-response signal of IFX-1 in subjects with moderate to severe hidradenitis suppurativa according to the Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 16.

Protection of trial subjects:

The study was conducted in accordance with Good Clinical Practice (GCP). All persons participating in the conduct of the study (Sponsor, Investigators, and other personnel) committed themselves to observe the Declaration of Helsinki (Version Fortaleza 2013) as well as all pertinent national laws and the ICH guidelines for GCP issued in June 1996 and CPMP/ICH/135/95 from September 1997.

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	01 February 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	Netherlands: 6
Country: Number of subjects enrolled	Poland: 38
Country: Number of subjects enrolled	Bulgaria: 9
Country: Number of subjects enrolled	Denmark: 5
Country: Number of subjects enrolled	France: 19
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Greece: 47
Country: Number of subjects enrolled	Canada: 8
Country: Number of subjects enrolled	United States: 33
Worldwide total number of subjects	177
EEA total number of subjects	136

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	174
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study included patients of 18 years or older with moderate to severe HS. The study was conducted at 38 study sites in 9 countries (Bulgaria 3, Canada 2, Denmark 2, France 6, Germany 4, Greece 3, the Netherlands 1, Poland 5, USA 12). 177 subjects were enrolled between and treated out of 225 subjects screened between 28-Feb-2018 and 02-Nov-2018.

Pre-assignment

Screening details:

225 patients were screened for eligibility before participating in the active treatment phase of the study. Subjects were not to be entered to the trial treatment if any of the eligibility criteria were violated. Of the 225 patients, 179 patients were randomized and of these, 177 were treated.

Period 1

Period 1 title	Main Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

The identity of the treatments was concealed by the use of IMP that was identical in packaging, labeling, administration schedule, appearance, taste, and odor.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo (Cohort 1)

Arm description:

Subjects in this cohort received intravenous infusions of Placebo every other week starting at Week 0.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Placebo is provided in 10 mL vials containing sodium chloride, sodium phosphate, and Polysorbate 80. The placebo vials and content have the same appearance as the IFX-1 vials and additives. Placebo was administered via an intravenous (iv) line over a period of 30 to 60 minutes.

Arm title	IFX-1 400 mg Q4W (Cohort 2)
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Arm description:

Subjects in this cohort received alternating intravenous infusions of IFX-1 400mg every 4 weeks starting at Week 0, and Placebo starting at Week 2, following a fractionated loading dosing during the first treatment interval.

Arm type	Experimental
Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

IFX-1 is provided in 10 mL vials containing 100 mg IFX-1 and will be infused over a period of 30 to 60 minutes (min) via an intravenous (iv) line.

Arm title	IFX-1 800 mg Q4W (Cohort 3)
Arm description: Subjects in this cohort received alternating intravenous infusions of IFX-1 800mg every 4 weeks starting at Week 0, and Placebo starting at Week 2, following a fractionated loading dosing during the first treatment interval.	
Arm type	Experimental
Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

IFX-1 is provided in 10 mL vials containing 100 mg IFX-1 and will be infused over a period of 30 to 60 minutes (min) via an intravenous (iv) line.

Arm title	IFX-1 800 mg Q2W (Cohort 4)
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Arm description:

Subjects in this cohort received intravenous infusions of IFX-1 800mg every other week starting at Week 0, following a fractionated loading dosing during the first treatment interval.

Arm type	Experimental
Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

IFX-1 is provided in 10 mL vials containing 100 mg IFX-1 and will be infused over a period of 30 to 60 minutes (min) via an intravenous (iv) line.

Arm title	IFX-1 1200 mg Q2W (Cohort 5)
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Arm description:

Subjects in this cohort received intravenous infusions of IFX-1 1200mg every other week starting at Week 0, following a fractionated loading dosing during the first treatment interval.

Arm type	Experimental
Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

IFX-1 is provided in 10 mL vials containing 100 mg IFX-1 and will be infused over a period of 30 to 60 minutes (min) via an intravenous (iv) line.

Number of subjects in period 1	Placebo (Cohort 1)	IFX-1 400 mg Q4W (Cohort 2)	IFX-1 800 mg Q4W (Cohort 3)
Started	36	34	35
Completed	34	30	32
Not completed	2	4	3
Consent withdrawn by subject	1	-	1
Adverse event, non-fatal	-	2	1
Other	-	-	-

Non-compliance with study drug	-	-	-
Lost to follow-up	1	2	-
Progressive disease	-	-	-
Lack of efficacy	-	-	1

Number of subjects in period 1	IFX-1 800 mg Q2W (Cohort 4)	IFX-1 1200 mg Q2W (Cohort 5)
Started	36	36
Completed	30	31
Not completed	6	5
Consent withdrawn by subject	1	-
Adverse event, non-fatal	2	1
Other	1	1
Non-compliance with study drug	-	1
Lost to follow-up	1	-
Progressive disease	1	-
Lack of efficacy	-	2

Period 2

Period 2 title	Extension Period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	IFX-1 800mg Q4W (HiSCR responders)

Arm description:

Subjects from all main period cohorts who were HiSCR responders at Week 16 received IFX-1 at a dose of 800mg every 4 weeks, starting at Week 20 through Week 40.

Arm type	Experimental
Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

IFX-1 is provided in 10 mL vials containing 100 mg IFX-1 and will be infused over a period of 30 to 60 minutes (min) via an intravenous (iv) line.

Arm title	IFX-1 800mg Q2W (HiSCR nonresponders)
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Arm description:

Subjects from all main period cohorts who were HiSCR non-responders at Week 16 received IMP during an Induction Phase, followed by IFX-1 at a dose of 800 mg every two Weeks up to Week 40. IMP administration during the induction phase depended on the main period cohort of the subject.

Arm type	Experimental
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Investigational medicinal product name	IFX-1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

IFX-1 is provided in 10 mL vials containing 100 mg IFX-1 and will be infused over a period of 30 to 60 minutes (min) via an intravenous (iv) line.

Number of subjects in period 2 ^[1]	IFX-1 800mg Q4W (HiSCR responders)	IFX-1 800mg Q2W (HiSCR nonresponders)
	Started	72
Completed	67	54
Not completed	5	30
Consent withdrawn by subject	-	12
Adverse event, non-fatal	1	-
Protocol-specified withdrawal criterion met	-	1
Other	-	2
Disease relapse	1	1
Progressive disease	1	3
Lack of efficacy	2	11

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: One patient completed the main period but was not treated in the extension period, thus this patient is not counted as having started the extension period

Baseline characteristics

Reporting groups

Reporting group title	Placebo (Cohort 1)
Reporting group description: Subjects in this cohort received intravenous infusions of Placebo every other week starting at Week 0.	
Reporting group title	IFX-1 400 mg Q4W (Cohort 2)
Reporting group description: Subjects in this cohort received alternating intravenous infusions of IFX-1 400mg every 4 weeks starting at Week 0, and Placebo starting at Week 2, following a fractionated loading dosing during the first treatment interval.	
Reporting group title	IFX-1 800 mg Q4W (Cohort 3)
Reporting group description: Subjects in this cohort received alternating intravenous infusions of IFX-1 800mg every 4 weeks starting at Week 0, and Placebo starting at Week 2, following a fractionated loading dosing during the first treatment interval.	
Reporting group title	IFX-1 800 mg Q2W (Cohort 4)
Reporting group description: Subjects in this cohort received intravenous infusions of IFX-1 800mg every other week starting at Week 0, following a fractionated loading dosing during the first treatment interval.	
Reporting group title	IFX-1 1200 mg Q2W (Cohort 5)
Reporting group description: Subjects in this cohort received intravenous infusions of IFX-1 1200mg every other week starting at Week 0, following a fractionated loading dosing during the first treatment interval.	

Reporting group values	Placebo (Cohort 1)	IFX-1 400 mg Q4W (Cohort 2)	IFX-1 800 mg Q4W (Cohort 3)
Number of subjects	36	34	35
Age categorical			
Analysis of baseline characteristics is based on the Safety Analysis Set (SAS): all subjects who received at least 1 infusion of IMP. Subjects will be analyzed according to the treatment they actually received.			
Units: Subjects			
Adults (18-64 years)	35	33	35
From 65-84 years	1	1	0
Age continuous			
Analysis of baseline characteristics is based on the Safety Analysis Set (SAS): all subjects who received at least 1 infusion of IMP. Subjects will be analyzed according to the treatment they actually received.			
Units: years			
arithmetic mean	35.4	39.6	37.3
standard deviation	± 11.25	± 10.03	± 12.52
Gender categorical			
Analysis of baseline characteristics is based on the Safety Analysis Set (SAS): all subjects who received at least 1 infusion of IMP. Subjects will be analyzed according to the treatment they actually received.			
Units: Subjects			
Female	21	16	18
Male	15	18	17

Reporting group values	IFX-1 800 mg Q2W (Cohort 4)	IFX-1 1200 mg Q2W (Cohort 5)	Total
Number of subjects	36	36	177
Age categorical			
Analysis of baseline characteristics is based on the Safety Analysis Set (SAS): all subjects who received at least 1 infusion of IMP. Subjects will be analyzed according to the treatment they actually received.			

Units: Subjects			
Adults (18-64 years)	36	35	174
From 65-84 years	0	1	3
Age continuous			
Analysis of baseline characteristics is based on the Safety Analysis Set (SAS): all subjects who received at least 1 infusion of IMP. Subjects will be analyzed according to the treatment they actually received.			
Units: years			
arithmetic mean	38.3	35.8	
standard deviation	± 11.05	± 12.33	-
Gender categorical			
Analysis of baseline characteristics is based on the Safety Analysis Set (SAS): all subjects who received at least 1 infusion of IMP. Subjects will be analyzed according to the treatment they actually received.			
Units: Subjects			
Female	20	23	98
Male	16	13	79

End points

End points reporting groups

Reporting group title	Placebo (Cohort 1)
Reporting group description:	Subjects in this cohort received intravenous infusions of Placebo every other week starting at Week 0.
Reporting group title	IFX-1 400 mg Q4W (Cohort 2)
Reporting group description:	Subjects in this cohort received alternating intravenous infusions of IFX-1 400mg every 4 weeks starting at Week 0, and Placebo starting at Week 2, following a fractionated loading dosing during the first treatment interval.
Reporting group title	IFX-1 800 mg Q4W (Cohort 3)
Reporting group description:	Subjects in this cohort received alternating intravenous infusions of IFX-1 800mg every 4 weeks starting at Week 0, and Placebo starting at Week 2, following a fractionated loading dosing during the first treatment interval.
Reporting group title	IFX-1 800 mg Q2W (Cohort 4)
Reporting group description:	Subjects in this cohort received intravenous infusions of IFX-1 800mg every other week starting at Week 0, following a fractionated loading dosing during the first treatment interval.
Reporting group title	IFX-1 1200 mg Q2W (Cohort 5)
Reporting group description:	Subjects in this cohort received intravenous infusions of IFX-1 1200mg every other week starting at Week 0, following a fractionated loading dosing during the first treatment interval.
Reporting group title	IFX-1 800mg Q4W (HiSCR responders)
Reporting group description:	Subjects from all main period cohorts who were HiSCR responders at Week 16 received IFX-1 at a dose of 800mg every 4 weeks, starting at Week 20 through Week 40.
Reporting group title	IFX-1 800mg Q2W (HiSCR nonresponders)
Reporting group description:	Subjects from all main period cohorts who were HiSCR non-responders at Week 16 received IMP during an Induction Phase, followed by IFX-1 at a dose of 800 mg every two Weeks up to Week 40. IMP administration during the induction phase depended on the main period cohort of the subject.

Primary: Percentage of subjects with a response on the basis of the HiSCR.

End point title	Percentage of subjects with a response on the basis of the HiSCR.
End point description:	Analysis of the primary efficacy endpoint is based on the Full analysis set (FAS): the FAS consists of all subjects who received at least 1 infusion of IMP. The analysis will be based on the cohort the subjects were randomized to (intention-to-treat principle).
End point type	Primary
End point timeframe:	Response on the basis of the HiSCR is determined at Week 16 before IMP administration.

End point values	Placebo (Cohort 1)	IFX-1 400 mg Q4W (Cohort 2)	IFX-1 800 mg Q4W (Cohort 3)	IFX-1 800 mg Q2W (Cohort 4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	30	33	31
Units: Subjects				
Responder	16	12	17	12
Non-responder	18	18	16	19

End point values	IFX-1 1200 mg Q2W (Cohort 5)			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Subjects				
Responder	15			
Non-responder	18			

Statistical analyses

Statistical analysis title	Dose-response analysis by MCP-Mod
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Statistical analysis description:

Primary analysis of primary efficacy endpoint: Dose-response analysis by MCP-Mod for HiSCR at Week 16.

Analysis of the primary efficacy endpoint is based on the Full analysis set (FAS): the FAS consists of all subjects who received at least 1 infusion of IMP. The analysis will be based on the cohort the subjects were randomized to (intention-to-treat principle).

Comparison groups	Placebo (Cohort 1) v IFX-1 400 mg Q4W (Cohort 2) v IFX-1 800 mg Q4W (Cohort 3) v IFX-1 800 mg Q2W (Cohort 4) v IFX-1 1200 mg Q2W (Cohort 5)
Number of subjects included in analysis	161
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	= 0.5955 ^[2]
Method	MCP-Mod (Logistic model)

Notes:

[1] - Dose-response analysis by MCP-Mod.

[2] - P-value based on MCP-Mod with Emax model: 0.6519

Post-hoc: IHS4 percentage change from baseline

End point title	IHS4 percentage change from baseline
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End point description:

IHS4 count (total number of inflammatory nodules + 2 x total number of abscesses + 4 x total number of draining fistulas) percentage change from baseline at Week 16.

Analysis is based on the Full analysis set (FAS): the FAS will consist of all subjects who will receive at least 1 infusion of IMP. The analysis will be based on the cohort the subjects are randomized to (intention-to-treat principle).

End point type	Post-hoc
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End point timeframe:

Week 16

End point values	Placebo (Cohort 1)	IFX-1 400 mg Q4W (Cohort 2)	IFX-1 800 mg Q4W (Cohort 3)	IFX-1 800 mg Q2W (Cohort 4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	30	32	30
Units: percent				
arithmetic mean (standard deviation)	-21.40 (± 63.327)	-25.14 (± 70.589)	-42.57 (± 49.216)	-40.19 (± 36.356)

End point values	IFX-1 1200 mg Q2W (Cohort 5)			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: percent				
arithmetic mean (standard deviation)	-51.27 (± 47.066)			

Statistical analyses

No statistical analyses for this end point

Post-hoc: IHS4 percentage change from baseline ANCOVA

End point title	IHS4 percentage change from baseline ANCOVA
End point description:	ANCOVA results of IHS4 count (total number of inflammatory nodules + 2 x total number of abscesses + 4 x total number of draining fistulas) percentage change from baseline at Week 16. Analysis is based on the Full analysis set (FAS): the FAS will consist of all subjects who will receive at least 1 infusion of IMP. The analysis will be based on the cohort the subjects are randomized to (intention-to-treat principle).
End point type	Post-hoc
End point timeframe:	Week 16

End point values	Placebo (Cohort 1)	IFX-1 400 mg Q4W (Cohort 2)	IFX-1 800 mg Q4W (Cohort 3)	IFX-1 800 mg Q2W (Cohort 4)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	30	32	30
Units: percent				
least squares mean (confidence interval 95%)	-19.82 (-38.39 to -1.24)	-24.61 (-44.34 to -4.88)	-41.08 (-60.18 to -21.98)	-38.40 (-58.19 to -18.60)

End point values	IFX-1 1200 mg Q2W (Cohort 5)			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: percent				
least squares mean (confidence interval 95%)	-51.45 (-70.49 to -32.42)			

Statistical analyses

Statistical analysis title	ANCOVA of IHS4 relative change at Week 16
Statistical analysis description:	
Ancova results of IHS4 relative change from baseline at Week 16. P-values of the contrast for each treatment cohort versus Placebo are reported. Analysis is based on the Full analysis set (FAS): the FAS consists of all subjects who received at least 1 infusion of IMP. The analysis will be based on the cohort the subjects were randomized to (intention-to-treat principle).	
Comparison groups	Placebo (Cohort 1) v IFX-1 400 mg Q4W (Cohort 2) v IFX-1 800 mg Q4W (Cohort 3) v IFX-1 800 mg Q2W (Cohort 4) v IFX-1 1200 mg Q2W (Cohort 5)
Number of subjects included in analysis	158
Analysis specification	Post-hoc
Analysis type	other
P-value	= 0.0202 ^[3]
Method	ANCOVA

Notes:

[3] - P-value for the contrast 1200 mg IFX-1 Q2W versus Placebo. P-values for the other treatment cohorts versus Placebo are:

800 mg IFX-1 Q2W versus Placebo: 0.1754

800 mg IFX-1 Q4W versus Placebo: 0.1159

400 mg IFX-1 Q4W versus Placebo: 0.7276

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment emergent adverse events are reported separately for the main period (start of study treatment until Week 16, Cohort 1.X) and the extension period (Week 16 until Week 44, Cohort 2.X).

Adverse event reporting additional description:

Adverse events analysis is based on the Safety analysis set (SAS): the SAS consists of all subjects who received at least 1 infusion of IMP. Subjects will be analyzed according to the treatment they actually received.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Cohort 1.1 Placebo (Main Period Data)
Reporting group description:	-
Reporting group title	Cohort 1.2 IFX-1 400 mg Q4W (Main Period Data)
Reporting group description:	-
Reporting group title	Cohort 1.3 IFX-1 800 mg Q4W (Main Period Data)
Reporting group description:	-
Reporting group title	Cohort 1.4 IFX-1 800 mg Q2W (Main Period Data)
Reporting group description:	-
Reporting group title	Cohort 1.5 IFX-1 1200 mg Q2W (Main Period Data)
Reporting group description:	-
Reporting group title	Cohort 2.1 IFX-1 800 mg Q4W (Extension Period Data)
Reporting group description:	-
Reporting group title	Cohort 2.2 IFX-1 800 mg Q2W (Extension Period Data)
Reporting group description:	-

Serious adverse events	Cohort 1.1 Placebo (Main Period Data)	Cohort 1.2 IFX-1 400 mg Q4W (Main Period Data)	Cohort 1.3 IFX-1 800 mg Q4W (Main Period Data)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Nervous system disorders			

Sciatica	Additional description: Sciatica		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Hepatobiliary disorders	Additional description: Bile duct stone		
Bile duct stone	Additional description: Bile duct stone		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Respiratory, thoracic and mediastinal disorders	Additional description: Asthma		
Asthma	Additional description: Asthma		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Dyspnoea	Additional description: Dyspnoea		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	1 / 35 (2.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders	Additional description: Hidradenitis		
Hidradenitis	Additional description: Hidradenitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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

Musculoskeletal and connective tissue disorders			
Bursitis	Additional description: Bursitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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			
Abscess bacterial	Additional description: Abscess bacterial		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Cholangitis infective	Additional description: Cholangitis infective		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Influenza	Additional description: Influenza		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Pneumonia	Additional description: Pneumonia		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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
Sepsis	Additional description: Sepsis		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (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	Cohort 1.4 IFX-1 800 mg Q2W (Main Period Data)	Cohort 1.5 IFX-1 1200 mg Q2W (Main Period Data)	Cohort 2.1 IFX-1 800 mg Q4W (Extension Period Data)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 36 (5.56%)	3 / 36 (8.33%)	2 / 72 (2.78%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Sciatica	Additional description: Sciatica		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone	Additional description: Bile duct stone		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Asthma		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 36 (0.00%)	1 / 36 (2.78%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea	Additional description: Dyspnoea		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 72 (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
Skin and subcutaneous tissue disorders			
Hidradenitis	Additional description: Hidradenitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	1 / 36 (2.78%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bursitis	Additional description: Bursitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 72 (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			
Abscess bacterial	Additional description: Abscess bacterial		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	0 / 36 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis infective	Additional description: Cholangitis infective		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza	Additional description: Influenza		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 72 (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
Pneumonia	Additional description: Pneumonia		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	1 / 36 (2.78%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	0 / 36 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 2.2 IFX-1 800 mg Q2W (Extension Period Data)		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 84 (3.57%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Femoral neck fracture	Additional description: Femoral neck fracture		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Sciatica	Additional description: Sciatica		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stone	Additional description: Bile duct stone		
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Asthma		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea	Additional description: Dyspnoea		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Hidradenitis	Additional description: Hidradenitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 84 (2.38%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Bursitis	Additional description: Bursitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 84 (1.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			

Abscess bacterial	Additional description: Abscess bacterial		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis infective	Additional description: Cholangitis infective		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza	Additional description: Influenza		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 84 (1.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia	Additional description: Pneumonia		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis	Additional description: Sepsis		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 84 (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	Cohort 1.1 Placebo (Main Period Data)	Cohort 1.2 IFX-1 400 mg Q4W (Main Period Data)	Cohort 1.3 IFX-1 800 mg Q4W (Main Period Data)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 36 (58.33%)	20 / 34 (58.82%)	16 / 35 (45.71%)
Investigations			

International normalised ratio increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: International normalised ratio increased		
	2 / 36 (5.56%) 2	0 / 34 (0.00%) 0	0 / 35 (0.00%) 0
Injury, poisoning and procedural complications Foot fracture alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Foot fracture		
	0 / 36 (0.00%) 0	2 / 34 (5.88%) 3	0 / 35 (0.00%) 0
Vascular disorders Hypertension alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Hypertension		
	0 / 36 (0.00%) 0	0 / 34 (0.00%) 0	0 / 35 (0.00%) 0
Nervous system disorders Headache alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Headache		
	6 / 36 (16.67%) 10	4 / 34 (11.76%) 12	0 / 35 (0.00%) 0
Presyncope alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Presyncope		
	0 / 36 (0.00%) 0	0 / 34 (0.00%) 0	2 / 35 (5.71%) 2
Syncope alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Syncope		
	0 / 36 (0.00%) 0	0 / 34 (0.00%) 0	0 / 35 (0.00%) 0
General disorders and administration site conditions Fatigue alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Fatigue		
	2 / 36 (5.56%) 2	0 / 34 (0.00%) 0	3 / 35 (8.57%) 3
Pain alternative assessment type: Non-systematic	Additional description: Pain		

subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Pyrexia	Additional description: Pyrexia		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	1	2	0
Gastrointestinal disorders			
Diarrhoea	Additional description: Diarrhoea		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	4 / 34 (11.76%)	2 / 35 (5.71%)
occurrences (all)	0	5	2
Dyspepsia	Additional description: Dyspepsia		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	0	3	0
Gastroesophageal reflux disease	Additional description: Gastroesophageal reflux disease		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 36 (5.56%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	2	1	0
Nausea	Additional description: Nausea		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 36 (5.56%)	2 / 34 (5.88%)	1 / 35 (2.86%)
occurrences (all)	4	2	1
Vomiting	Additional description: Vomiting		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Hidradenitis	Additional description: Hidradenitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 36 (13.89%)	4 / 34 (11.76%)	2 / 35 (5.71%)
occurrences (all)	5	8	4
Pain of skin	Additional description: Pain of skin		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 36 (0.00%)	3 / 34 (8.82%)	1 / 35 (2.86%)
occurrences (all)	0	4	3
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Back pain	Additional description: Back pain		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	1 / 34 (2.94%)	0 / 35 (0.00%)
occurrences (all)	1	1	0
Pain in extremity	Additional description: Pain in extremity		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	2 / 34 (5.88%)	0 / 35 (0.00%)
occurrences (all)	2	2	0
Infections and infestations			
Abscess	Additional description: Abscess		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	1 / 34 (2.94%)	2 / 35 (5.71%)
occurrences (all)	0	1	2
Bronchitis	Additional description: Bronchitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 36 (5.56%)	1 / 34 (2.94%)	1 / 35 (2.86%)
occurrences (all)	2	1	1
Cellulitis	Additional description: Cellulitis		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Gastroenteritis		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	0 / 34 (0.00%)	0 / 35 (0.00%)
occurrences (all)	1	0	0
Influenza	Additional description: Influenza		
alternative assessment type: Non-systematic			

subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 3	0 / 34 (0.00%) 0	0 / 35 (0.00%) 0
Nasopharyngitis	Additional description: Nasopharyngitis		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	6 / 36 (16.67%) 6	4 / 34 (11.76%) 5	6 / 35 (17.14%) 8
Pharyngitis	Additional description: Pharyngitis		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 2	1 / 34 (2.94%) 1	1 / 35 (2.86%) 1
Sinusitis	Additional description: Sinusitis		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 34 (0.00%) 0	2 / 35 (5.71%) 2
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	2 / 34 (5.88%) 2	0 / 35 (0.00%) 0
Vulvovaginal candidiasis	Additional description: Vulvovaginal candidiasis		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 36 (5.56%) 2	0 / 34 (0.00%) 0	0 / 35 (0.00%) 0

Non-serious adverse events	Cohort 1.4 IFX-1 800 mg Q2W (Main Period Data)	Cohort 1.5 IFX-1 1200 mg Q2W (Main Period Data)	Cohort 2.1 IFX-1 800 mg Q4W (Extension Period Data)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 36 (50.00%)	17 / 36 (47.22%)	25 / 72 (34.72%)
Investigations	Additional description: International normalised ratio increased		
International normalised ratio increased	Additional description: International normalised ratio increased		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	2 / 36 (5.56%) 2	1 / 72 (1.39%) 1
Injury, poisoning and procedural complications			

Foot fracture alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Foot fracture		
	0 / 36 (0.00%) 0	0 / 36 (0.00%) 0	0 / 72 (0.00%) 0
Vascular disorders Hypertension alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Hypertension		
	2 / 36 (5.56%) 2	1 / 36 (2.78%) 1	2 / 72 (2.78%) 2
Nervous system disorders Headache alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Presyncope alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Syncope alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Headache		
	4 / 36 (11.11%) 12	5 / 36 (13.89%) 12	4 / 72 (5.56%) 9
	Additional description: Presyncope		
	0 / 36 (0.00%) 0	1 / 36 (2.78%) 1	0 / 72 (0.00%) 0
	Additional description: Syncope		
	2 / 36 (5.56%) 5	1 / 36 (2.78%) 1	1 / 72 (1.39%) 1
General disorders and administration site conditions Fatigue alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Pyrexia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Fatigue		
	2 / 36 (5.56%) 3	3 / 36 (8.33%) 5	0 / 72 (0.00%) 0
	Additional description: Pain		
	1 / 36 (2.78%) 1	2 / 36 (5.56%) 2	0 / 72 (0.00%) 0
	Additional description: Pyrexia		
0 / 36 (0.00%) 0	2 / 36 (5.56%) 2	2 / 72 (2.78%) 3	

Gastrointestinal disorders			
Diarrhoea			
Additional description: Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 36 (8.33%)	1 / 36 (2.78%)	2 / 72 (2.78%)
occurrences (all)	3	1	2
Dyspepsia			
Additional description: Dyspepsia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
Additional description: Gastrooesophageal reflux disease			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Nausea			
Additional description: Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 36 (2.78%)	2 / 36 (5.56%)	0 / 72 (0.00%)
occurrences (all)	1	2	0
Vomiting			
Additional description: Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Hidradenitis			
Additional description: Hidradenitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 36 (16.67%)	5 / 36 (13.89%)	8 / 72 (11.11%)
occurrences (all)	8	8	9
Pain of skin			
Additional description: Pain of skin			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
Additional description: Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 36 (5.56%)	0 / 36 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0

Back pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Back pain		
	2 / 36 (5.56%) 2	0 / 36 (0.00%) 0	0 / 72 (0.00%) 0
Pain in extremity alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Pain in extremity		
	0 / 36 (0.00%) 0	1 / 36 (2.78%) 1	0 / 72 (0.00%) 0
Infections and infestations Abscess alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Abscess		
	0 / 36 (0.00%) 0	0 / 36 (0.00%) 0	0 / 72 (0.00%) 0
Bronchitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Bronchitis		
	0 / 36 (0.00%) 0	0 / 36 (0.00%) 0	0 / 72 (0.00%) 0
Cellulitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Cellulitis		
	2 / 36 (5.56%) 2	0 / 36 (0.00%) 0	0 / 72 (0.00%) 0
Gastroenteritis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Gastroenteritis		
	2 / 36 (5.56%) 3	0 / 36 (0.00%) 0	0 / 72 (0.00%) 0
Influenza alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Influenza		
	0 / 36 (0.00%) 0	3 / 36 (8.33%) 3	2 / 72 (2.78%) 2
Nasopharyngitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Nasopharyngitis		
	4 / 36 (11.11%) 5	3 / 36 (8.33%) 3	4 / 72 (5.56%) 5
Pharyngitis alternative assessment type: Non-systematic	Additional description: Pharyngitis		

subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	1 / 36 (2.78%) 1	2 / 72 (2.78%) 2
Sinusitis	Additional description: Sinusitis		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 36 (2.78%) 1	1 / 36 (2.78%) 1	1 / 72 (1.39%) 2
Viral upper respiratory tract infection	Additional description: Viral upper respiratory tract infection		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 36 (0.00%) 0	0 / 72 (0.00%) 0
Vulvovaginal candidiasis	Additional description: Vulvovaginal candidiasis		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 36 (0.00%) 0	0 / 36 (0.00%) 0	0 / 72 (0.00%) 0

Non-serious adverse events	Cohort 2.2 IFX-1 800 mg Q2W (Extension Period Data)		
Total subjects affected by non-serious adverse events subjects affected / exposed	31 / 84 (36.90%)		
Investigations	Additional description: International normalised ratio increased		
International normalised ratio increased alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	3 / 84 (3.57%) 3		
Injury, poisoning and procedural complications	Additional description: Foot fracture		
Foot fracture alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 84 (0.00%) 0		
Vascular disorders	Additional description: Hypertension		
Hypertension alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 84 (1.19%) 1		
Nervous system disorders			

Headache alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Headache		
	6 / 84 (7.14%)		
	7		
Presyncope alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Presyncope		
	0 / 84 (0.00%)		
	0		
Syncope alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Syncope		
	0 / 84 (0.00%)		
	0		
General disorders and administration site conditions Fatigue alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Fatigue		
	1 / 84 (1.19%)		
	1		
Pain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Pain		
	0 / 84 (0.00%)		
	0		
Pyrexia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Pyrexia		
	0 / 84 (0.00%)		
	0		
Gastrointestinal disorders Diarrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Diarrhoea		
	2 / 84 (2.38%)		
	2		
Dyspepsia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Dyspepsia		
	1 / 84 (1.19%)		
	1		
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		

alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 84 (1.19%) 1		
Nausea	Additional description: Nausea		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 84 (2.38%) 2		
Vomiting	Additional description: Vomiting		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 84 (0.00%) 0		
Skin and subcutaneous tissue disorders			
Hidradenitis	Additional description: Hidradenitis		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	10 / 84 (11.90%) 12		
Pain of skin	Additional description: Pain of skin		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 84 (1.19%) 1		
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 84 (1.19%) 1		
Back pain	Additional description: Back pain		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 84 (1.19%) 1		
Pain in extremity	Additional description: Pain in extremity		
alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 84 (0.00%) 0		
Infections and infestations			

Abscess alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Abscess	
	0 / 84 (0.00%) 0	
Bronchitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Bronchitis	
	0 / 84 (0.00%) 0	
Cellulitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Cellulitis	
	0 / 84 (0.00%) 0	
Gastroenteritis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Gastroenteritis	
	1 / 84 (1.19%) 1	
Influenza alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Influenza	
	2 / 84 (2.38%) 2	
Nasopharyngitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Nasopharyngitis	
	8 / 84 (9.52%) 8	
Pharyngitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Pharyngitis	
	2 / 84 (2.38%) 2	
Sinusitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	Additional description: Sinusitis	
	0 / 84 (0.00%) 0	
Viral upper respiratory tract infection alternative assessment type: Non-systematic	Additional description: Viral upper respiratory tract infection	

subjects affected / exposed	0 / 84 (0.00%)		
occurrences (all)	0		
Vulvovaginal candidiasis	Additional description: Vulvovaginal candidiasis		
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 84 (3.57%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 November 2018	Global Protocol Amendment 1.1 leading to protocol version 2.0, dated 16-Nov-2018. There were 33 changes to the original protocol (Version 1.0 dated: 30-Nov-2017).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported