Clinical trial results:
An open label Phase II trial to evaluate the safety of IFX-1 in patients with moderate to severe Hidradenitis suppurativa

Summary

EudraCT number	2016-002988-33
Trial protocol	GR
Global end of trial date	04 July 2017

Results information

Result version number	v1 (current)
This version publication date	19 November 2021
First version publication date	19 November 2021

Trial information

Trial identification

Sponsor protocol code	IFX-1-P2.3

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	InflaRx GmbH
Sponsor organisation address	Winzerlaer Strasse 2, Jena, Germany, 07745
Public contact	InflaRx GmbH, InflaRx GmbH, +49 3641 508 180, info@inflarx.de
Scientific contact	InflaRx GmbH, InflaRx GmbH, +49 3641 508 180, 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	25 October 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 July 2017
Global end of trial reached?	Yes
Global end of trial date	04 July 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Explore the safety and tolerability of IFX-1 administered over 8 weeks in patients with moderate to severe hidradenitis suppurativa (HS)

Protection of trial subjects:

The study was conducted in accordance with the Good Clinical Practice (GCP) as required by the International Conference on Harmonization (ICH) E6 Guideline for GCP, 1996, in agreement with the standard operating procedures for clinical investigation and documentation. Complience with these requirements also constitutes conformity with the ethical principles of the Declaration of Helsinki (revised version, Fortaleza 2013) and any local regulations were followed appropriately. 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	13 December 2016
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	Greece: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	11
From 65 to 84 years	1

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study included male or female patients of 18 years or older, who suffered from HS lesions in at least 2 distinct anatomic areas one of which was Hurley Stage II or III, diagnosed for at least 1 year, with an AN count ≥ 3 and failure of previous antimicrobial and biological treatment.

Pre-assignment

Screening details:

Between 13-Dec-2016 and 20-Feb-2017, 12 patients were screened in one site in Greece. All 12 patients were screened for eligibility before participating in the active treatment phase of the study. Subjects were not to be entered to trial treatment if any of the eligibility criteria were violated. All of the 12 patients were randomized and treated.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Overall

Arm description:

All patients received 9 infusions of IFX-1 800 mg at the study center on Day 1 (day of first treatment) and on Days 4, 8, 15, 22, 29, 36, 43, and 50 after first treatment administration.

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:

Drug product was supplied in 10 mL glass vials at a concentration of 10 mg/mL and was administered by intravenous infusion. The drug was diluted to a volume of 250 mL with sodium chloride and administered over 60 min.

Number of subjects in period 1	Overall
Started	12
Completed	12

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial
Reporting group description:	
All patients received 9 infusions of IFX-1 800 mg at the study center on Day 1 (day of first treatment) and on Days 4, 8, 15, 22, 29, 36, 43, and 50 after first treatment administration.	

Reporting group values	Overall trial	Total	
Number of subjects	12	12	
Age categorical			
Age at screening. Full Analysis Set (FAS): All subjects who received study medication.			
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)	11	11	
From 65-84 years	1	1	
85 years and over	0	0	
Age continuous			
Age at screening, FAS			
Units: years			
arithmetic mean	48.3		
standard deviation	± 14.7	-	
Gender categorical			
FAS			
Units: Subjects			
Female	4	4	
Male	8	8	

End points

End points reporting groups

Reporting group title	Overall

Reporting group description:

All patients received 9 infusions of IFX-1 800 mg at the study center on Day 1 (day of first treatment) and on Days 4, 8, 15, 22, 29, 36, 43, and 50 after first treatment administration.

Primary: Treatment emergent adverse events

End point title	Treatment emergent adverse events[1]

End point description:

Treatment emergent adverse events (TEAEs) are adverse events which started with the administration of IFX-1 or later.
The safety analysis was performed on the FAS which was the same as the Safety Set in this study.

End point type	Primary

End point timeframe:

From first treatment administration on Day 1 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: Only descriptive analyses were defined and performed.

End point values	Overall			
Subject group type	Reporting group			
Number of subjects analysed	12[2]			
Units: Number of subjects				
TEAEs from Day 1 until Day 50	5			
TEAEs from Day 1 until Day 134	6			
Serious TEAEs	4			
Related TEAEs	0			
Related serious TEAEs	0			
Not related TEAEs (max. relationship)	5			
Unlikely related TEAEs (max. relationship)	1			

Notes:

[2] - FAS

Statistical analyses

No statistical analyses for this end point

Primary: Anti-drug antibodies

End point title	Anti-drug antibodies[3]

End point description:

The number of subjects with any detection of anti-drug antibodies (ADA) at the pre-dosing visit (i.e., Visit 1) and at any post-dosing visit (i.e., Visit 9, Visit 10, Visit 11, and Visit 12) was summarized. FAS

End point type	Primary

End point timeframe:

The subjects were examined forADA at Visit 1/Day 1, Visit 9/Day 50, Visit 10/Day 78, Visit 11/Day 106 and Visit 12/Day 134.

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: Only descriptive analyses were defined and performed.

End point values	Overall			
Subject group type	Reporting group			
Number of subjects analysed	12[4]			
Units: number of subjects				
Positive at pre-dosing visit	0			
Not detectable at pre-dosing visit	12			
Positive at any post-dosing visit	1			
Not detectable at any post-dosing visit	11			

Notes:

[4] - FAS

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first administration of IFX-1 until end of study (8 weeks treatment period and 12 weeks follow-up period).

Adverse event reporting additional description:

Reporting of TEAEs.
The safety analysis was performed on the FAS which was the same as the Safety set in this study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	Overall

Reporting group description:

All patients received 9 infusions of IFX-1 800 mg at the study center on Day 1 (day of first treatment) and on Days 4, 8, 15, 22, 29, 36, 43, and 50 after first treatment administration.

Serious adverse events	Overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 12 (33.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Soft tissue infection			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 12 (25.00%)		
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Infections and infestations			
Furuncle			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported