IFX-1 IN MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA Baseline characteristics of a double-blinded, randomized phase 2b dose-finding study (SHINE)

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Conflicts of interest

Evangelos Giamarellos-Bourboulis has received honoraria (paid to the University of Athens) from AbbVie, Biotest, Brahms GmbH, and The Medicines Company; has received compensation as a consultant for Astellas Greece, InflaRx GmbH, Germany and for XBiotech (paid to the University of Athens); and has received independent educational grants (paid to the University of Athens) from AbbVie and Sanofi. He is funded by the FrameWork 7 program HemoSpec (granted to the University of Athens) and by the Horizon2020 Marie-Curie Grant European Academy (granted to the University of Athens).
Othmar Zenker is an employee of InflaRx GmbH

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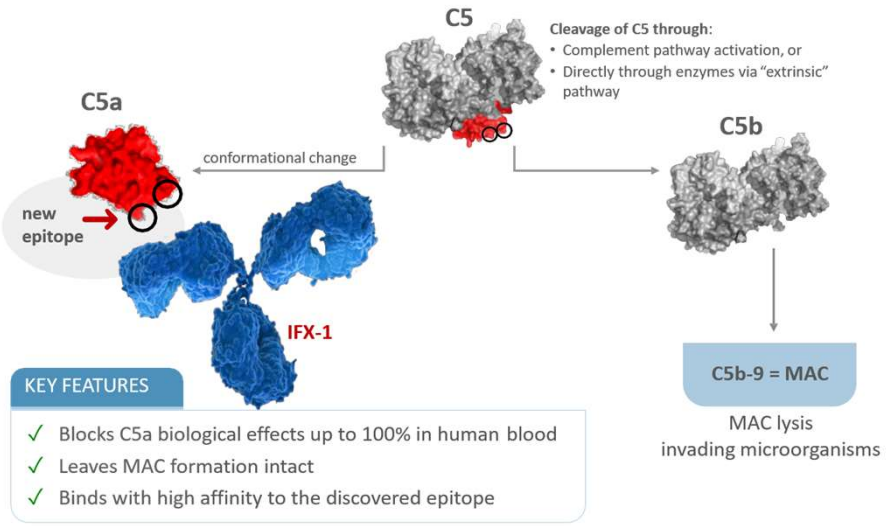
Background Information on IFX-1

- IFX-1 is a monoclonal antibody which specifically binds to the soluble human complement split product C5a.
- Nonclinical studies have demonstrated that IFX-1 binds to its target rapidly and is capable of a nearly complete blockade of C5a-induced biological effects while not affecting cleavage of C5 and formation of the complement membrane attack complex (MAC)



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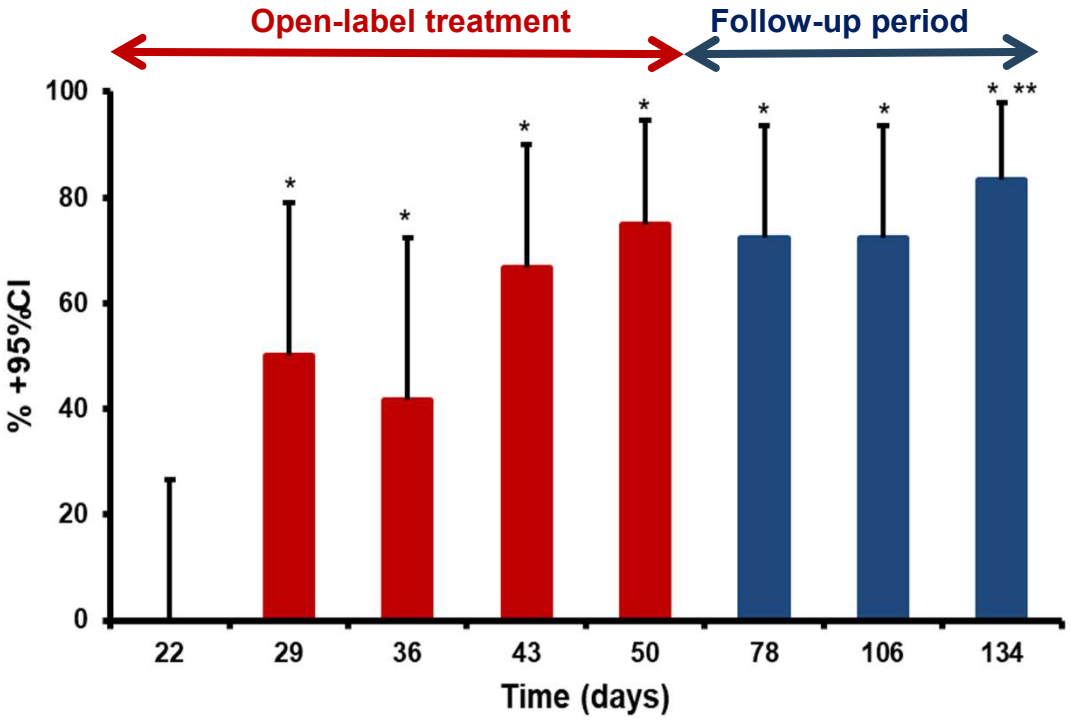
SMALL-SCALE PHASE IIa STUDY
(Giamarellos-Bourboulis EJ, et al. 7th EHSF 2018)



- 12 patients
- Refractory or not eligible for adalimumab
- 800mg of IFX-1
- Once weekly
- Nine doses in total
- HiSCR

*p<0.05 compared to day 22
**p: 0.089 compared to day 50

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Aim of the study

Here we present the demographics and baseline characteristics of a phase IIb study with the objective to establish a dose response relationship

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 (SHINE)

EudraCT 2017-004501-40
ClinicalTrials.gov NCT03487276

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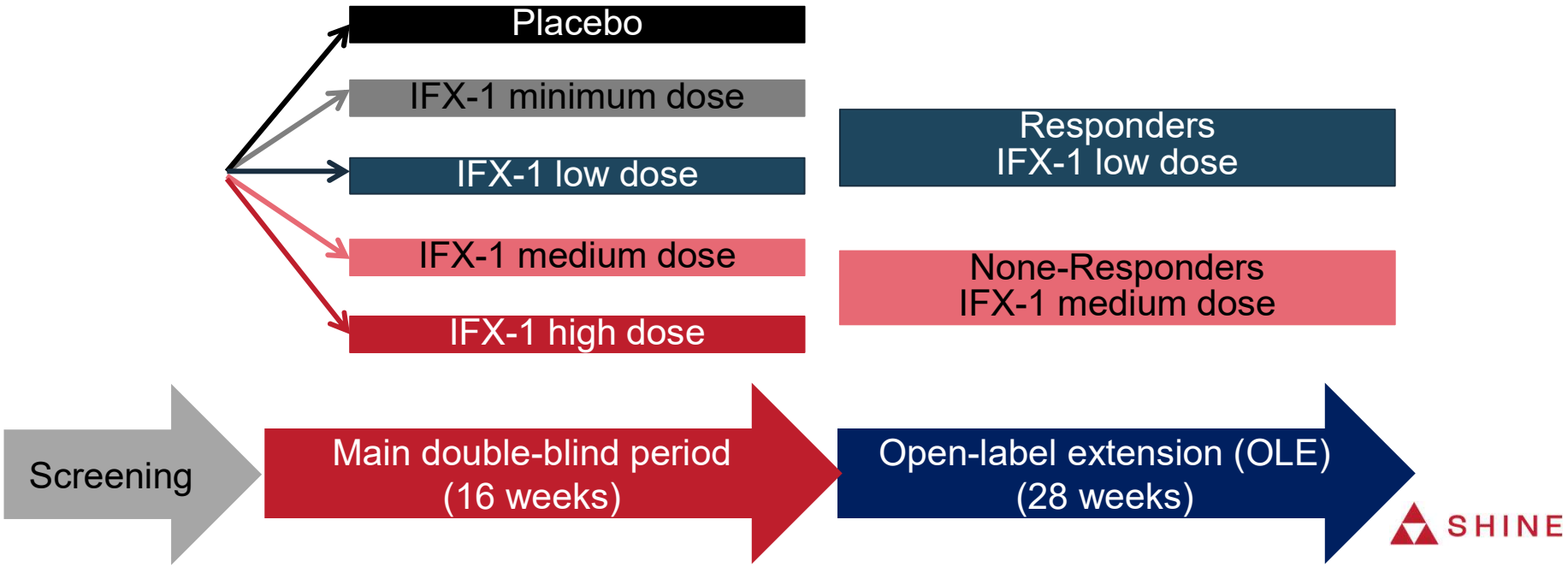
SHINE Study Design

- Prospective, randomized, 2-period, double-blind, placebo-controlled multicenter study, n = 175
- Patients who develop a worsening of disease (for responders) or absence of improvement (for non-responders) on 2 consecutive visits during the OLE phase will be discontinued from the study



SHINE Study Population

- *Key inclusion criteria*
  - Diagnosis of HS more than 1 year
  - Moderate or severe HS
  - Stable HS for at least 2 months before Screening
  - Total abscess and inflammatory nodule (AN) count of ≥ 3

- *Key exclusion criteria*
  - More than 20 draining fistulas
  - Prior treatment with adalimumab or another biologic product during the 24 weeks before Screening

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SHINE Study-Criteria for Evaluation

- *Primary endpoint*
  - Percentage of subjects with a response on the basis of the HiSCR determined at Week 16

- *Secondary endpoints*
  - Modified Sartorius Score
  - Number of draining fistula
  - Dermatology Life Quality Index (DLQI) score from Day 1 by time point
  - Patient's Global Assessment of Skin Pain (Numeric Rating Scale [NRS])

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SHINE Study: Demographics

Gender	Male (44%)	Female (56%)
Race	Black (9.5%)	White (85%)
Ethnicity	Hispanic or Latino (0.04%)	Not hispanic or Latino (96%)
Age (mean +/- SD)	37.1 +/- 11.45 years	

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SHINE Study: Baseline characteristics

Hurley Stage II	59.2%		Mean weight +/- SD	92.2 +/-18.3 kg
Hurley Stage III	40.8%		Tobacco use	64.8%
Median AN count	9 (3–58)		Alcohol use	34.1%
Median abscess count	1 (0 – 21)		Median duration of HS	8 years (1 to 39)
Median draining fistula count	2 (0 – 20)		Family history of HS	22.9%
Median inflammatory nodules	7 (0 – 57)		Prior HS treatment with biologics	24.0
			Prior HS surgeries or procedures	46.9%

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Comparisons VS PIONEER studies (1)

Baseline characteristics			
	SHINE	**PIONEER I**	**PIONEER II**
Mean weight +/- SD	92.2 +/-18.3 kg	98.2 +/- 25.0	92.9 +/- 24.0
Tobacco use	64.8%	65.8%	56.4%
Alcohol use	34.1%	53.4%	58.9%
Median duration of HS	8 years (1 to 39)	9	9
Family history of HS	22.9%	23.1%	25.2%
Prior HS surgery or procedure	46.9%	13.8%	11.1%

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Comparisons VS PIONEER studies (2)

Baseline characteristics			
	SHINE	**PIONEER I**	**PIONEER II**
Hurley Stage II	59.2%	52.4%	53.7%
Hurley Stage III	40.8%	47.6%	46.3%
Median AN count	9 (3-58)	14.3 (3-141)	8 (3-66)
Median abscess count	1 (0-21)	2 (0-24)	1 (0-16)
Median draining fistula count	2 (0-20)	2(0-20)	1 (0-20)
Median inflammatory nodules	7 (0-57)	8 (0-138)	1(0-20)

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SHINE Study – the right study population was chosen

Demographics and baseline characteristics of the SHINE study match:

- Data previously reported in phase II and III programs for the development of adalimumab in HS[1]
  - Globally similar patient population
  - Main differences: gender distribution (SHINE population at present about 10% more male patients, about 32% of patients from the SHINE study had previous HS-related surgery)

- Recently collected epidemiological data[2-4]
  - Age, smoking habits, weight, Hurley Stage distribution
  - Main difference: gender distribution, SHINE study present about 10-15% fewer females
- Recently published data from UNITE registry[5]
  - Hurley Stage distribution, age, body weight, mean count on draining fistulas, inflammatory nodules

1. Kimball AB, et al. *N Engl J Med* 2016; 375: 422-434
2. Delany E, et al. *J Eur Acad Dermatol Venereol* 2018; 32: 467-476
3. Katoulis AC, et al. *Skin Appendage Disord* 2017; 3: 197-201
4. Garg A, et al. *JAMA Dermatol* 2017; 153: 760-764
5. Prens EP, at al. *JAAD* 2017; 76 Suppl 1: AB55

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Conclusions

- The SHINE study is being performed to establish a dose response relationship for IFX-1 in patients with moderate to severe HS and to confirm the mode of action.
- The patient demographic data and baseline characteristics of patients recruited into the SHINE trial are comparable to that of the PIONEER I and II trials and the general patient population suffering from HS.

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