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CONTROLLING INFLAMMATION

SVB Leerink Global Healthcare Conference 2020

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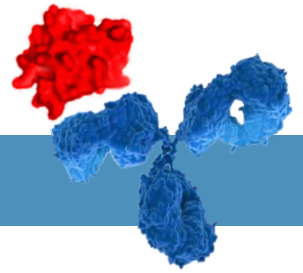
Investment Highlights



LEADING PROPRIETARY ANTI-C5A TECHNOLOGY

- Complete and selective blockade of the biological activity of C5a in vitro and in vivo
- Strong patent coverage on anti-C5a technology until end of 2030 / 2035 with extension

ESTABLISHED CLINICAL EFFICACY FOR LEAD DRUG IFX-1

- Proven anti-inflammatory effect in multiple Phase II studies
- Statistically significant reduction of inflammatory lesions in Phase IIb Hidradenitis Suppurativa study and impressive long-term efficacy
- Full data set analysis warrants continued development towards Phase III despite missing the primary endpoint (HiSCR) in Phase IIb study
- Favorable safety profile and excellent tolerability (n > 300 patients)

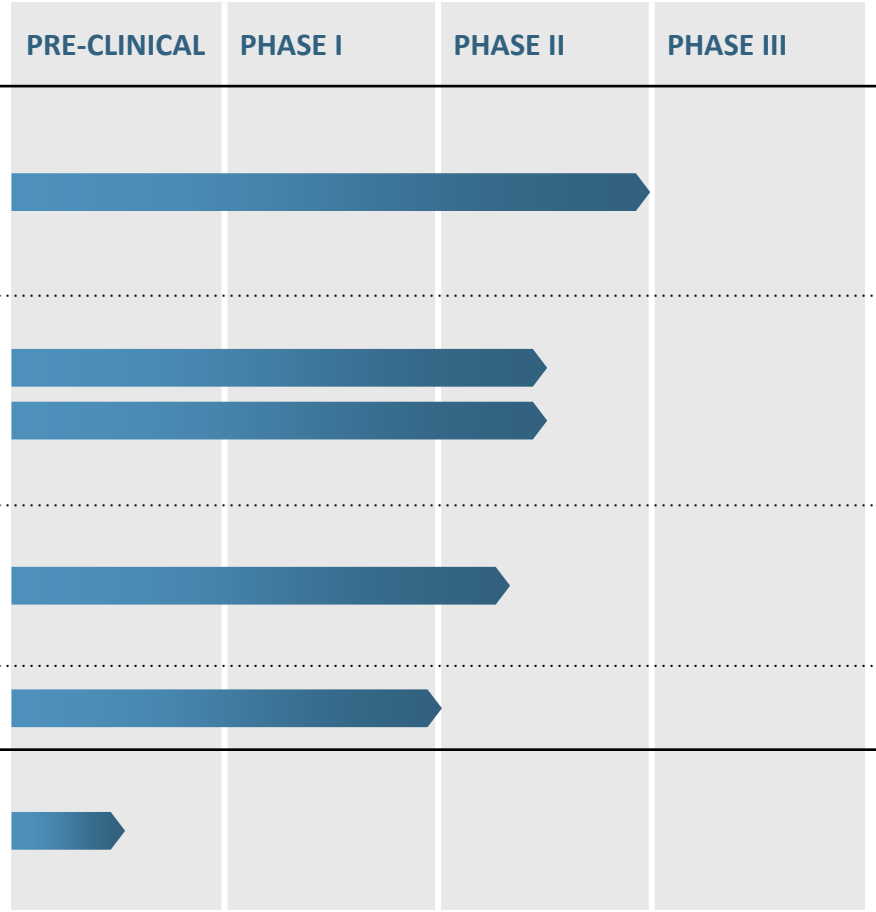
MULTIPLE ONGOING STUDIES AND INDICATION + PIPELINE EXTENSION

- Ongoing Phase IIb studies in ANCA-associated vasculitis in the US and EU
- Ongoing Phase IIa open label study in Pyoderma Gangraenosum in US and Canada
- Follow-on anti-C5a mAb IFX-2 in pipeline (pre-clinical stage)
- Pipeline extension of IFX-1 in other inflammatory diseases & oncology

Pipeline with Multiple Opportunities

We have multiple ongoing Phase II studies with potential to expand into further indications

	PROPOSED INDICATIONS	PREVALENCE	UPDATE
IFX-1 ***C5a Inhibitor***	Hidradenitis Suppurativa (HS)	• Up to 200,000 patients in the US • Over 200,000 patients in Europe	• Phase IIb completed • Planning for next steps
	ANCA-Associated Vasculitis	• ~40,000 patients in the US • ~75,000 patients in Europe	• Phase IIb enrollment ongoing in both Europe and US
	Pyoderma Gangraenosum	• ~50,000 patients in the US and Europe are affected	• Phase IIa open label enrollment ongoing in US and Canada
	Oncology	• Undisclosed Indication	• Development of TPP ongoing
IFX-2 ***C5a Inhibitor***	Undisclosed Chronic Inflammatory and Autoimmune Diseases	• Not applicable	• Developing as injectable with optimized use for other chronic inflammatory indications



These compounds and/or uses of approved products are investigational and have not been approved by the FDA or any other regulatory agency for the uses under investigation. The safety and efficacy of these agents have not been established.

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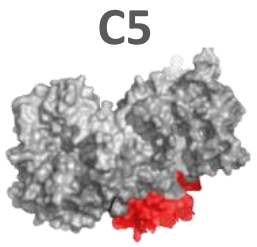
The Terminal Complement Pathway

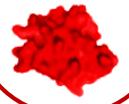


C5

C5 concentration in blood:
~75 µg/ml (~400 nM)

C5a concentration in blood:
10 ~ 30 ng/ml (~1-2.5 nM)

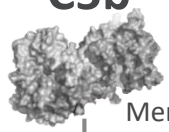
C5a



strong amplifier
of inflammation

other ligands:
C3a, ASP, C4a etc

C5b



Membrane Attack Complex (MAC)
triggers lysis of pathogens

C5b-9 = MAC

upregulated in
many tissues
during
inflammation

C5aR

C5L2

other signalling involved e.g.
in triglyceride synthesis, etc.

- cell activation
- cytokine generation

- PKC-signaling
- **HMGB-1 induction*** (Inflammasome)

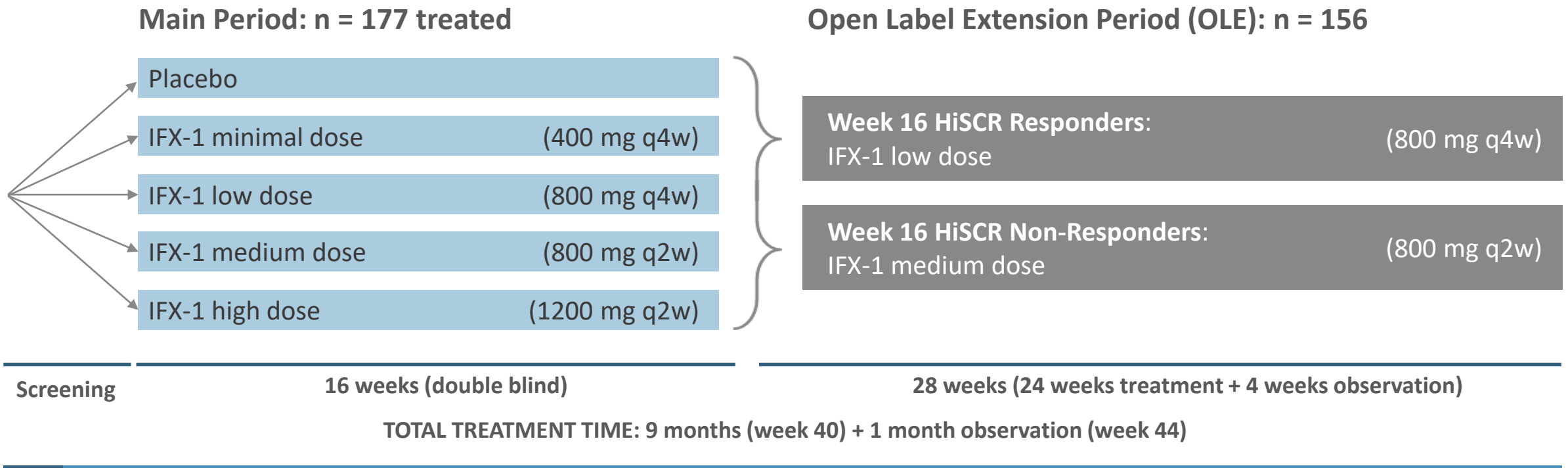
Inflammation

C5L2 has a different binding pocket for C5a compared to other ligands like C3a, ASP, etc. and this causes different cell signaling.*
The C5a signaling has been shown to be pro-inflammatory.**

* Kalant D. et. al. J. Biol. Chem. 2003, 278 (13) 11123–11129

**Rittirsch et al. Nat Med. 2008 May ; 14(5): 551;
Colley et al. *MABS*. 2018,10 (1), 104
Songlin et. al. J. Biol. Chem. 2019; 294(21) 8384–839
Muenstermann et al.. Virulence, 2020; 10(1) 677-694

IFX-1 in HS:
SHINE Study Details



TOTAL TREATMENT TIME: 9 months (week 40) + 1 month observation (week 44)

MAIN GOALS

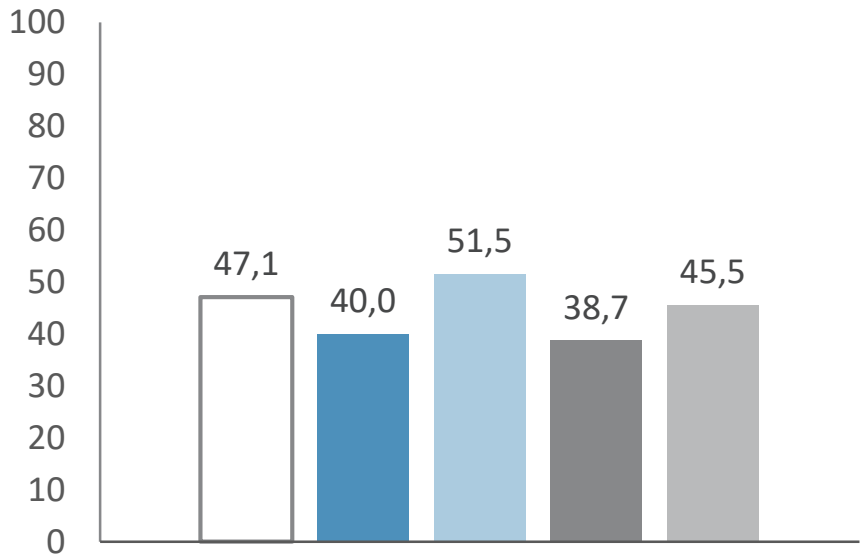
- Test a dose-dependent effect of IFX-1 on HiSCR response at week 16 (primary endpoint)
- Assess long-term safety of IFX-1
- Test durability of response with lower maintenance therapy in open label extension period

Important Note: Patients entering the OLE were not unblinded to their initial therapy

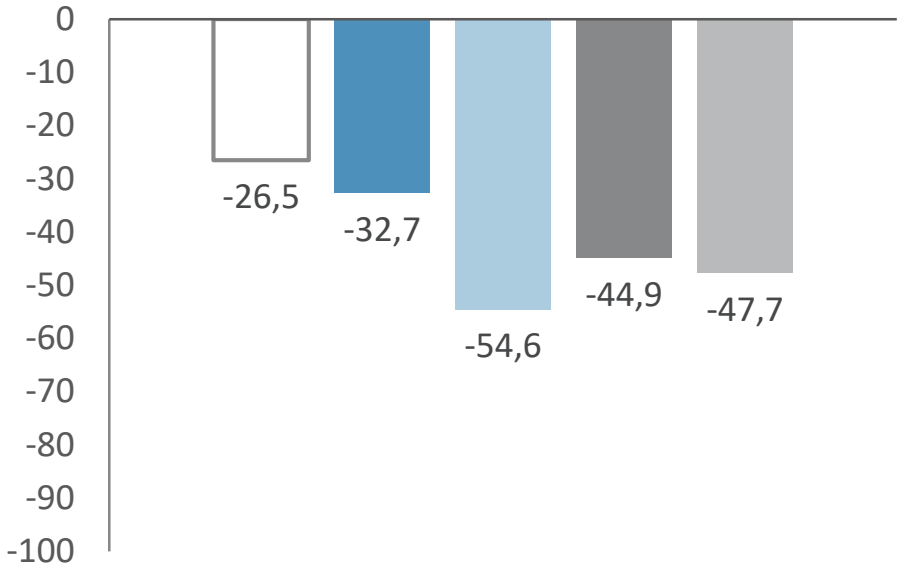
SHINE Study:
Primary Outcome HiSCR at Week 16 versus AN Count Reduction

HiSCR response rate (%) week 16*

n = approx. 35/ group



AN count score change (mean %) week 16*



Treatment groups: placebo | minimum | low | medium | high

Primary endpoint: HiSCR dose response signal not met but signal towards improved AN count

* Full analysis set

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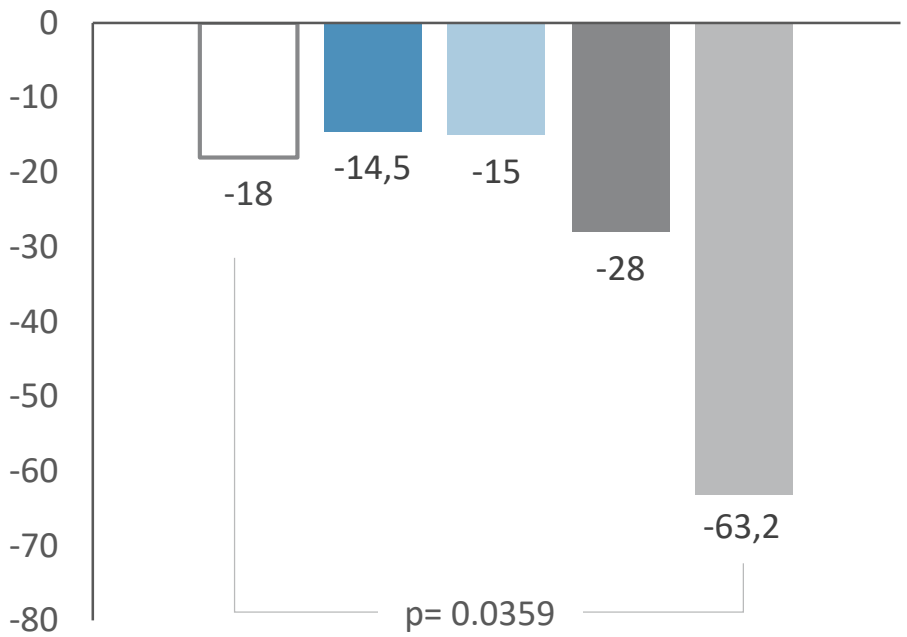
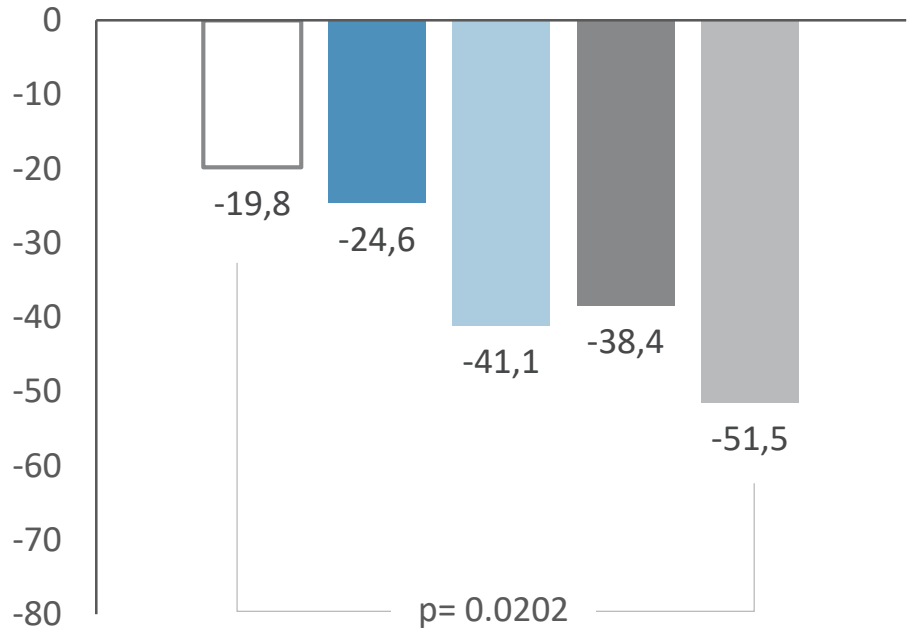
SHINE Study:
Outcome on Draining Fistula and IHS-4 Score Reduction – Week 16

Draining fistula change (mean %)*



IHS-4 score change (mean %)**



Treatment groups: placebo | minimum | low | medium | high

Statistically significant change in DF and in IHS-4 scores detected

* Full analysis set for patients with at least 1 DF at baseline, baseline adjusted

** Full analysis set – baseline adjusted

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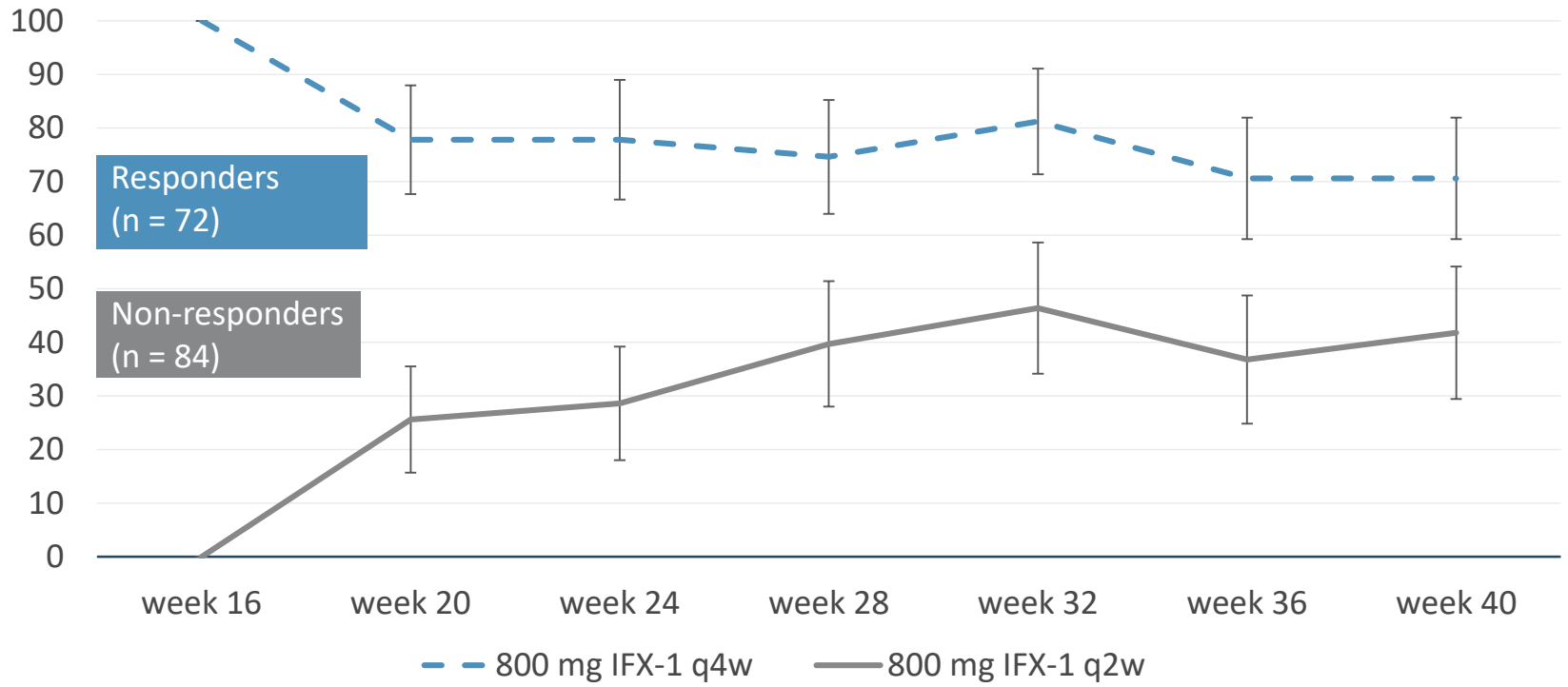
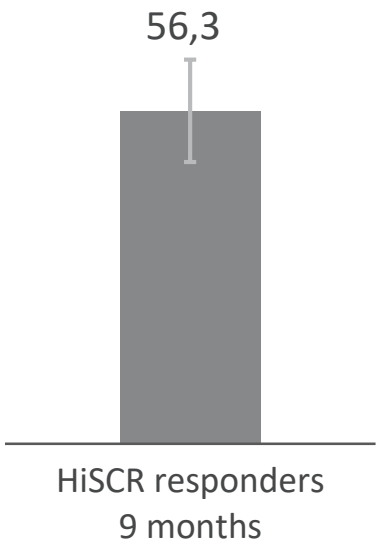
Comparison of HiSCR for Week 16 Responder versus Non-responder Groups (OLE) Over Time

HiSCR response rate (%) per visit* (OLE) – with 95% CI



All OLE patients



Responders: 71% maintain HiSCR response with low dose IFX-1
Non-responders: 42% become HiSCR responders with medium dose IFX-1

* Full analysis set

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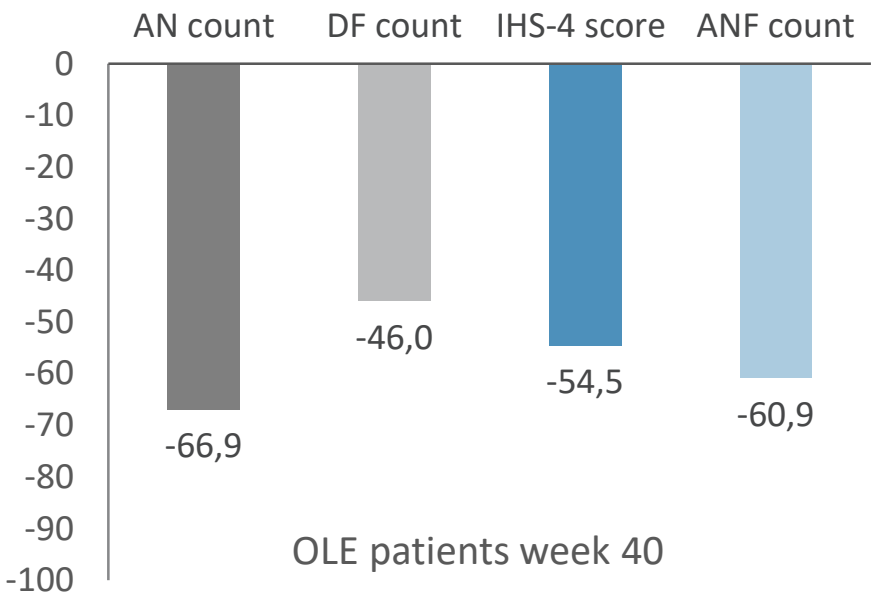
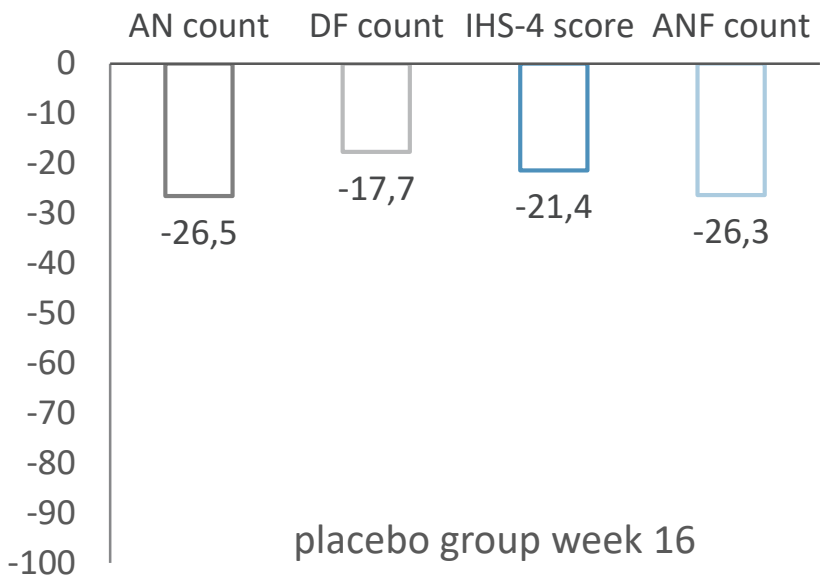
Inflammatory Lesion Reductions in All OLE Patients at End of Treatment (Week 40) Compared to Placebo Group Performance in Main Period (Week 16)

Relative reduction (% mean) of counts / scores compared to respective baseline (Day 1)*

of all OLE patients at week 40 (n=116)



of placebo patients at week 16



Marked improvement of all inflammatory lesions over time – not explainable by placebo effect

* Full analysis set (unadjusted)

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SHINE Study and Next Steps in HS Development

OUR CONCLUSIONS

- HiSCR is burdened by high variability (driven by AN count variability) and by a lack of capturing reduction of draining fistula
- Evidence for a high C5a turnover rate in HS, leading to increased dose requirements of IFX-1
- IFX-1 leads to a marked reduction of all inflammatory lesions in HS with a durable long-term effect detected even at non-optimal doses
- IFX-1 long-term treatment was well tolerated, no drug related SAEs* in the open label extension phase

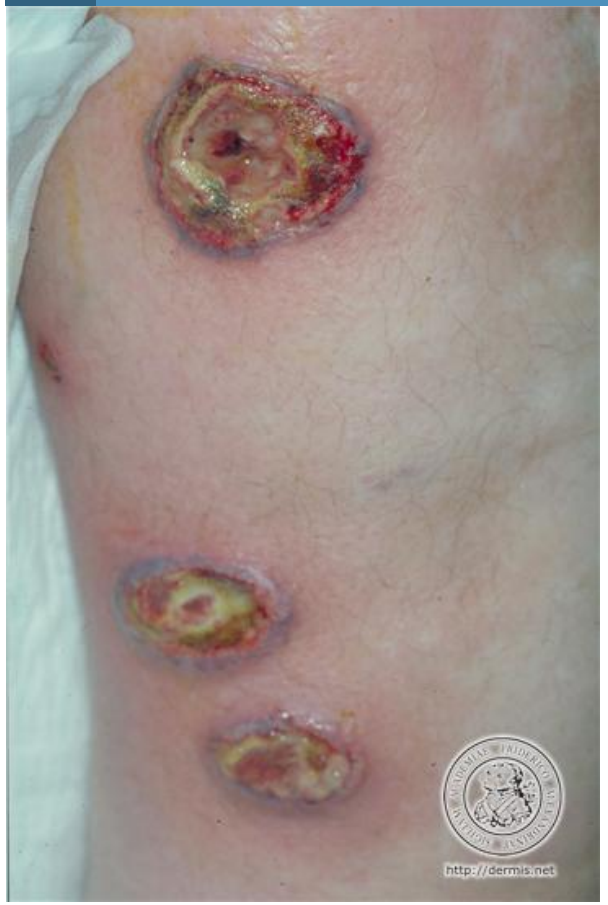
NEXT STEPS

- Request End-of-Phase II FDA Meeting in Q1 2020
- Discuss with FDA the path forward for regulatory approval towards a Phase III pivotal program
- Depending on meeting timing and feedback: define path forward by 2H 2020

* Serious adverse events

Pyoderma Gangraenosum (PG)

AN AUTOIMMUNE CONDITION WITH HIGH UNMET NEED



Source: Demis.net

CLINICAL FEATURES

- PG is a rare ulcerative skin disorder that can lead to chronic painful and difficult-to-treat wounds / ulcers occurring predominantly in people in their 40s and 50s
- Many PG patients also suffer from other autoimmune disorders, including inflammatory bowel diseases like ulcerative colitis, rheumatoid arthritis, and hematological diseases
- Patients suffer from severe pain, long healing times, and frequent relapses
- Diagnosis is based on the exclusion of other conditions and typical ulcers

INCIDENCE

- Rare - Estimated that up to 50,000 patients in the US and Europe are affected
- Orphan drug market

CURRENT TREATMENT – MEDICAL NEED

- No drugs currently approved in the US or EU
- Current treatment options include the use of systemic immunosuppression in rapidly progressing cases or, for less severe cases, topical or intralesional treatments can be used, including topical steroids

Overview of IFX-1 Phase IIa Study in PG - Study Design

STUDY OBJECTIVE

- Assessing safety and efficacy of IFX-1 in PG
- **Rationale:**
  PG is associated with a neutrophilic leukocytosis, which is likely to be triggered by C5a. Pyoderma Gangraenosum lesions have pronounced neutrophilic infiltration and the expression of interleukin (IL)-1β, IL-17, tumor necrosis factor (TNF)-alpha, and their receptors are significantly elevated, indicating auto-inflammatory conditions.
- **Primary endpoint:**
  Safety
- **Key secondary endpoints:**
  Responder rate defined as Physicians Global Assessment ≤3 of target ulcer at visits V4, V6, V10, and V16 (end of treatment); Time to complete closure of Pyoderma Gangraenosum target ulcer (investigator assessment)

STUDY DESIGN

- Open label
- Multi-center in US and Canada
- Target enrollment – **18 patients**
- First patient dosed – June 2019

TREATMENTS

- Trial started with 1 dose group: amendment approved to introduce a dose escalation to test 3 dose groups
- Subjects receive IFX-1 dosing every other week
- Dose: 800 mg biweekly first 5 patients

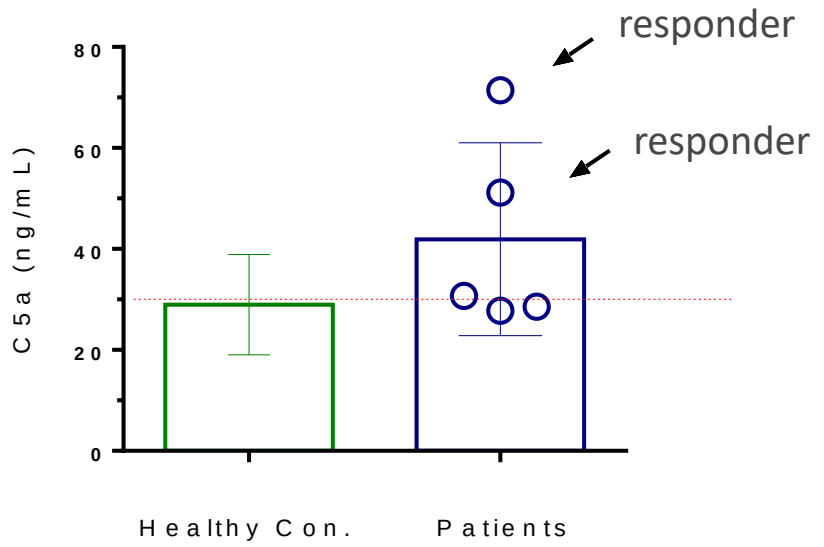
Pyoderma Gangraenosum (PG)

An AUTOIMMUNE CONDITION with high unmet need

STUDY UPDATE

- 5 patients have been treated
- 2 out of the first 5 patients showed complete closure of the target ulcer with one patient in full disease remission and second in almost complete disease remission
- In one additional patient, initial wound healing activity was detected in the first 2-3 weeks of treatment – but no wound size decrease or closure detected
- 2 additional patients with extensive disease (very large ulceration / ulcer reaching the entire circumference of the leg) did not heal the target ulcer and are still under treatment
- The “responders” have higher baseline C5a levels
- PD analysis (C5a levels) warrants higher dosing
- Dose escalation recently approved by relevant authorities

C5A LEVELS AT BASELINE



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Pyoderma Gangreaosum (PG)

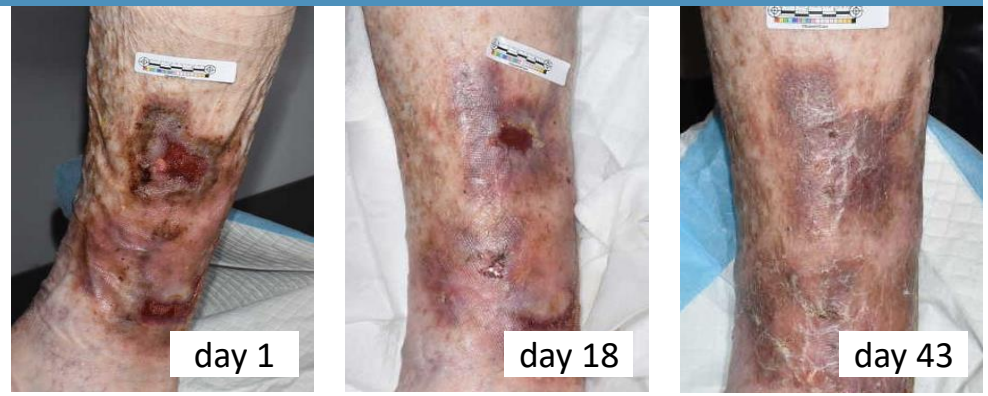
Two patients show complete wound closure with IFX-1 treatment

PATIENT EXAMPLE 1

- Female patient with extensive genital PG disease and target ulcer on lower extremity
- Various failed treatment attempts including high dose corticosteroids, etc.
- Significantly elevated baseline C5a levels
- Patient completely healed of all PG lesions and off drug now for 2 months

PATIENT EXAMPLE 2

- Male patient with treatment resistant PG disease and Addison´s disease from high-dose GC
- Significantly elevated baseline C5a levels
- Target ulcer is completely healed, and the patient is still on treatment (still one other lesion with minimal opening at different body location)



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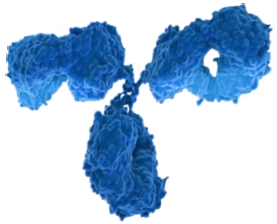
Our Strategy



GOALS AND STRATEGY

- **Advance** our lead program **IFX-1 for HS towards Phase III / approval based on regulatory guidance**
- Explore application of IFX-1 for **AAV, PG and within the oncology field in Phase II clinical development**
- Extend pipeline with initiation of **clinical development of IFX-1** in other complement-mediated autoimmune / inflammatory diseases
- Pursue the **development of IFX-2** and continue to expand the breadth of our anti-C5a technology
- **Continue to explore broadening the R&D pipeline beyond** anti-C5a technology as part of diversification strategy

We have a strong cash balance to pursue these activities (End of Q3 2019: ~US$151 million)

INFLARX N.V.

Winzerlaer Str. 2
07745 Jena, Germany

Email: info@inflarx.com

Tel: +49-3641-508180

Fax: +49-3641-508181

www.inflarx.com

INVESTOR RELATIONS INFLARX N.V.

Jordan Zwick
Global Head of Business Development & Corporate Strategy

Email: jordan.zwick@inflarx.de