

LONG-TERM RESULTS FROM A PHASE 2A CLINICAL STUDY WITH IFX-1 IN SEVERE HIDRADENITIS SUPPURATIVA

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ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
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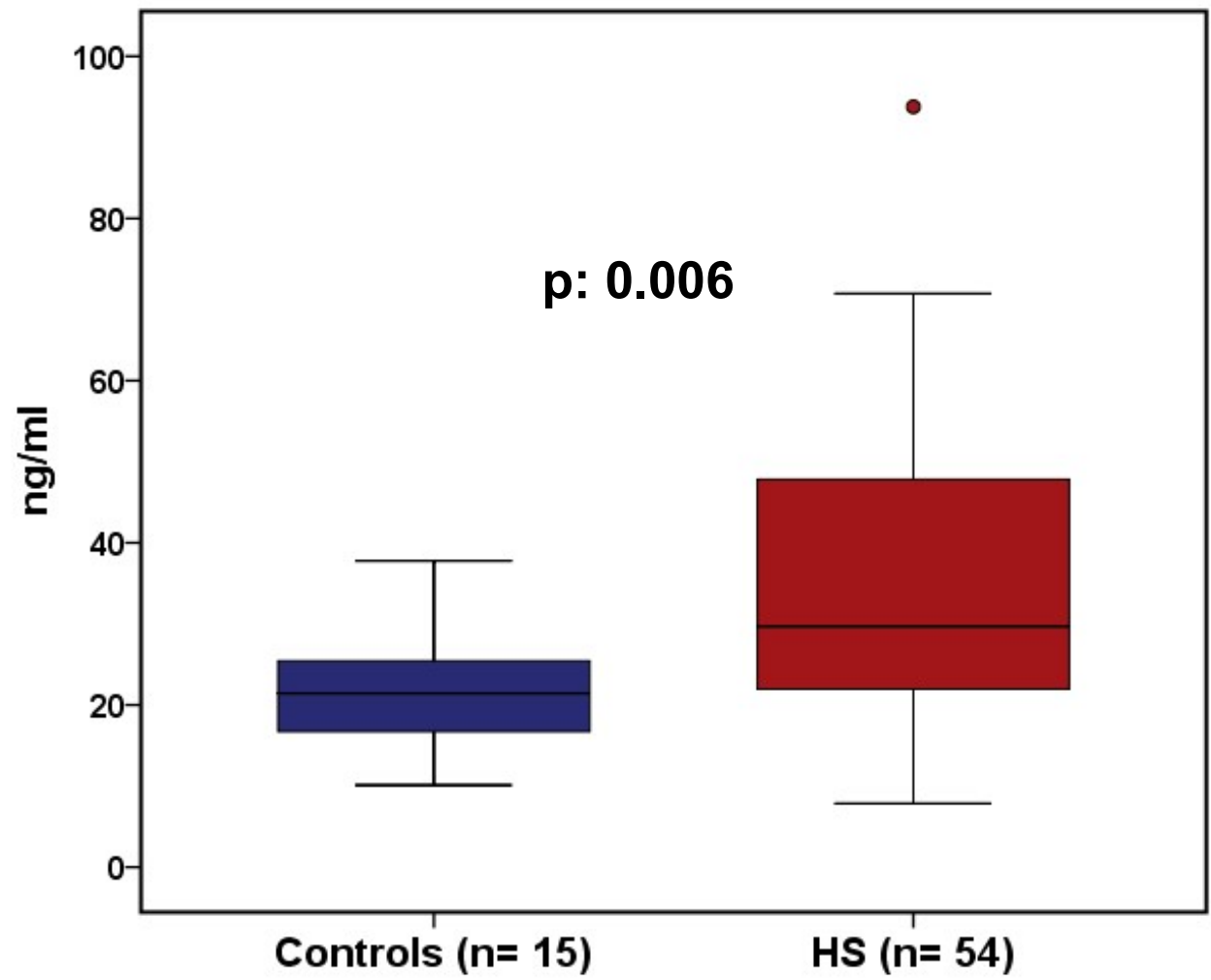
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DISCLOSURE OF INTERESTS

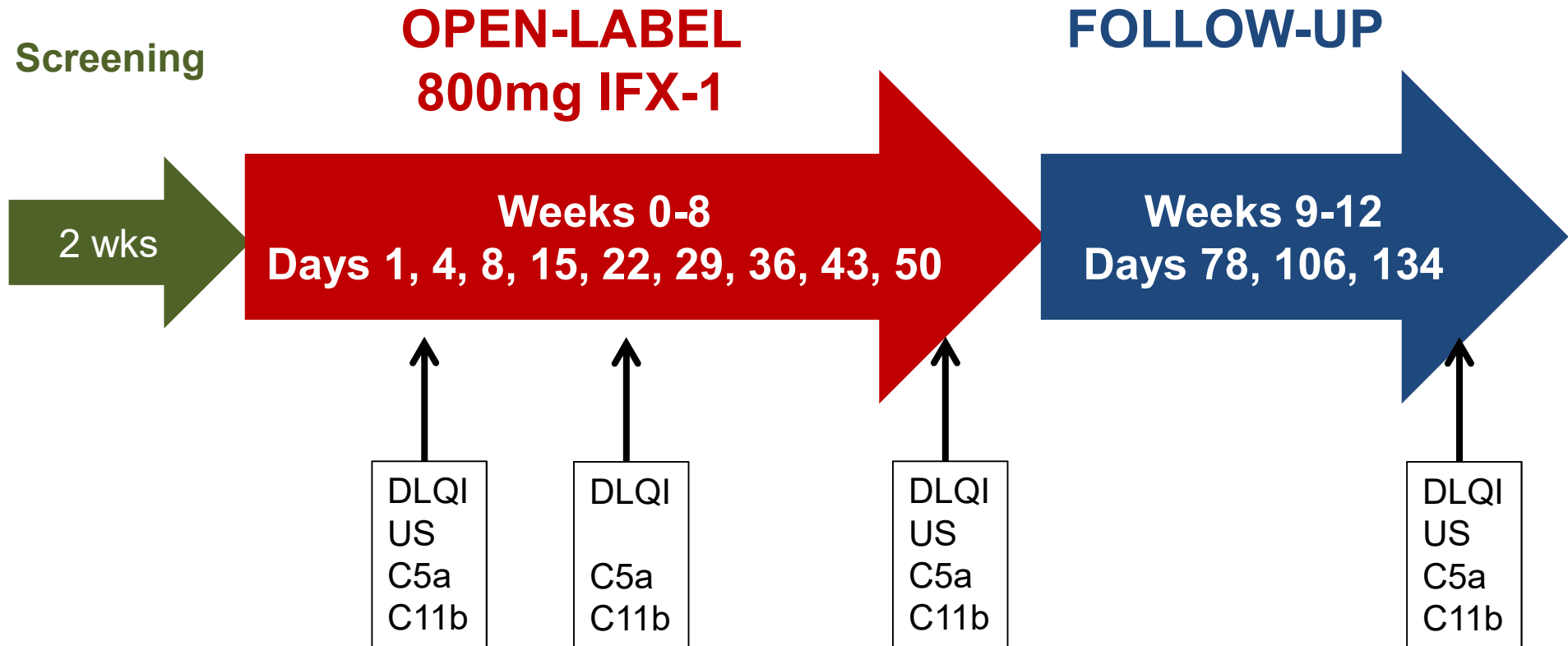
- Evangelos Giamarellos-Bourboulis has received honoraria (paid to the University of Athens) from AbbVie, Biotest, Brahms GmbH, and The Medicines Company; has received compensation as a consultant for Astellas Greece, InflaRx GmbH, Germany and for XBiotech (paid to the University of Athens); and has received independent educational grants (paid to the University of Athens) from AbbVie and InflaRx. He is funded by the FrameWork 7 program HemoSpec (granted to the University of Athens) and by the Horizon2020 Marie-Curie Grant European Sepsis Academy (granted to the University of Athens).
- Maria Argyropoulou does not have any conflict of interest to disclose
- Theodora Kanni has received honorarium from XBiotech
- Jens Hennenberg and Othmar Zenker are employees at InflaRx GmbH, Germany

BACKGROUND: C5a IS INCREASED IN HS

(Kanni T, et al. *Br J Dermatol* 2018; 179: 413-419)



**IFX-1: humanized monoclonal IgG4κ antibody
specifically binding to the soluble human complement
split product C5a**

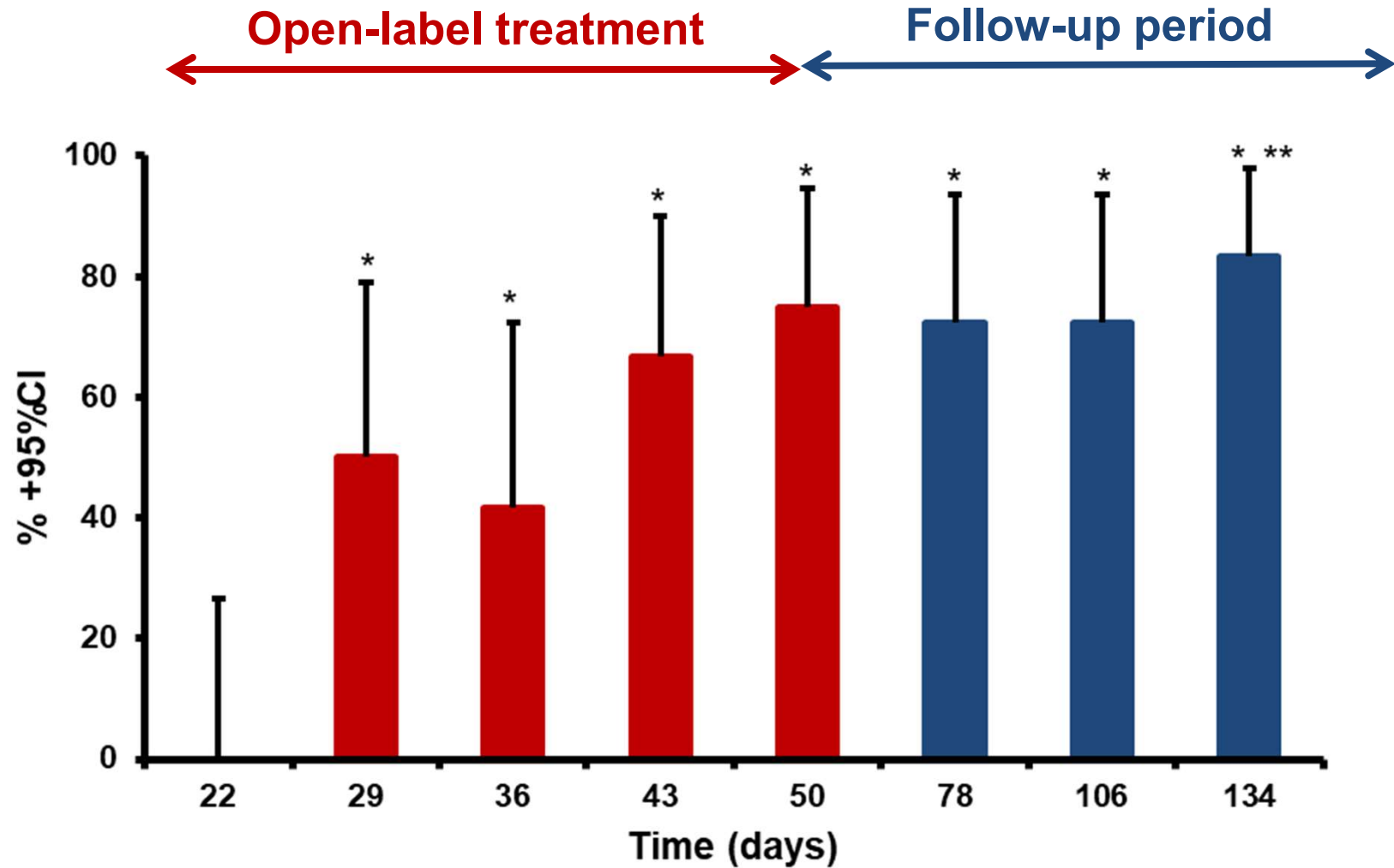


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National Ethics Committee (approval 92/16)
National Organization for Medicines (approval IS 90/16)
ClinicalTrials.gov NCT03001622

ALL visits

- HiSCR
- HS-Physicians Global assessment
- Modified Sartorius Score

HiSCR REpondERS



*p<0.05 compared to day 22

**p: 0.089 compared to day 50

AIM OF THE STUDY

To assess the long-term clinical efficacy of IFX-1 after cessation of the treatment.

METHODOLOGY

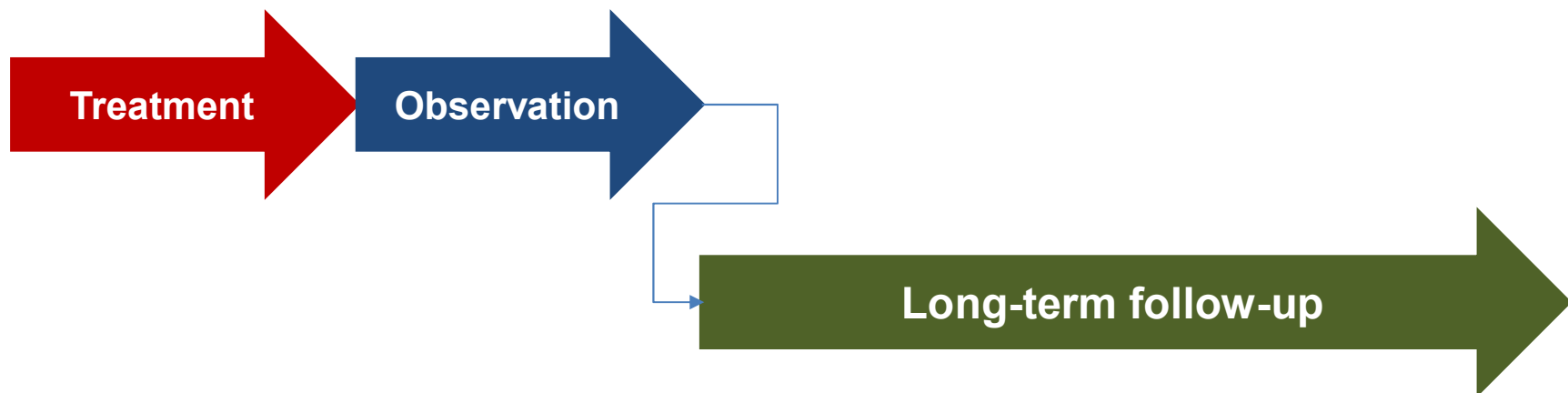
- Retrospective chart review until December 2017
- Recording of regular follow-up visits/consultations

Clinical benefit assessment

- Total AN count
- Total draining fistulas
- Flare-ups (time)
- HiSCR

Flare-up

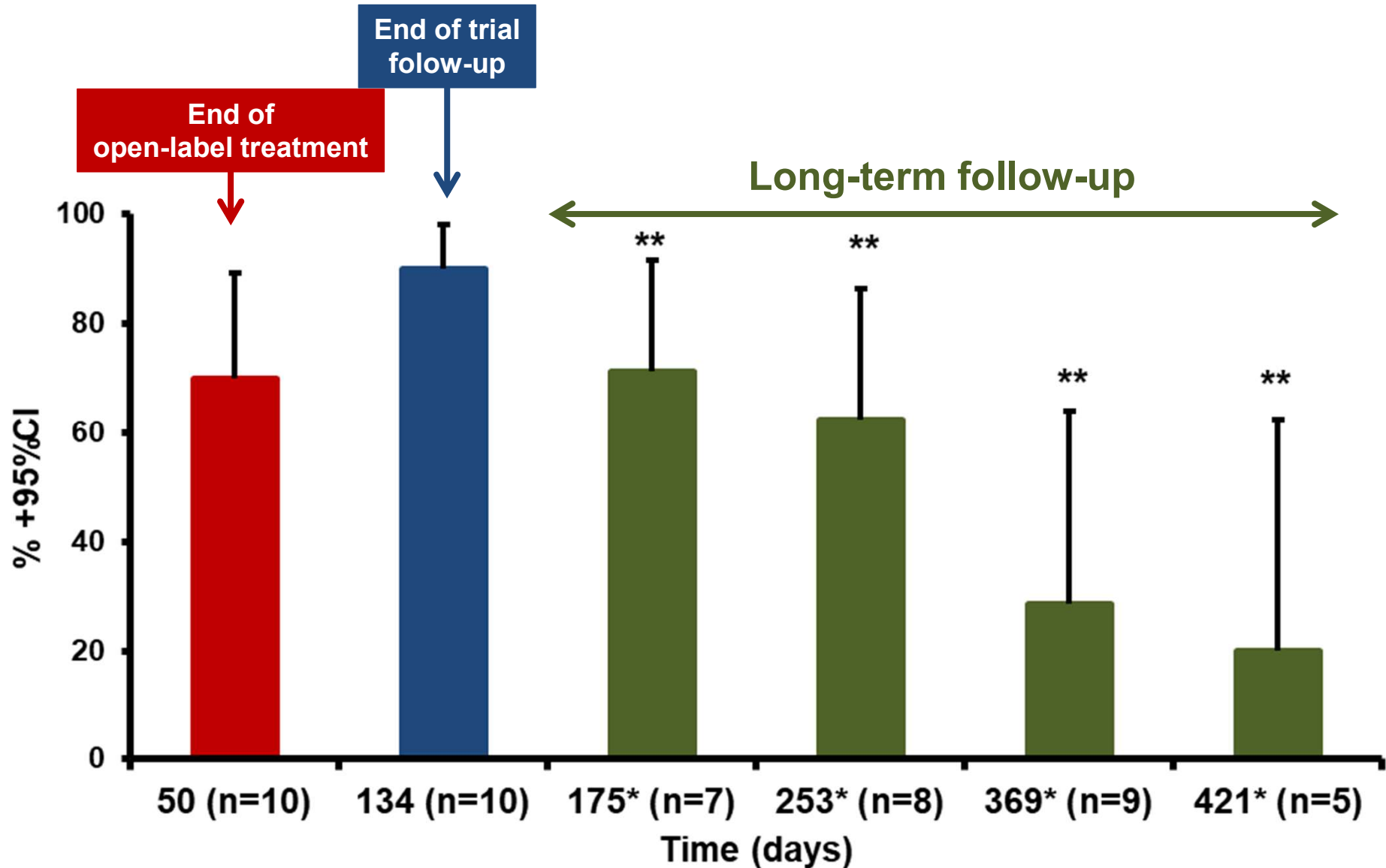
Exacerbation of HS requiring oral or intravenous antibiotic therapy.



TOTAL 35 FOLLOW-UP VISITS: 10 PATIENTS

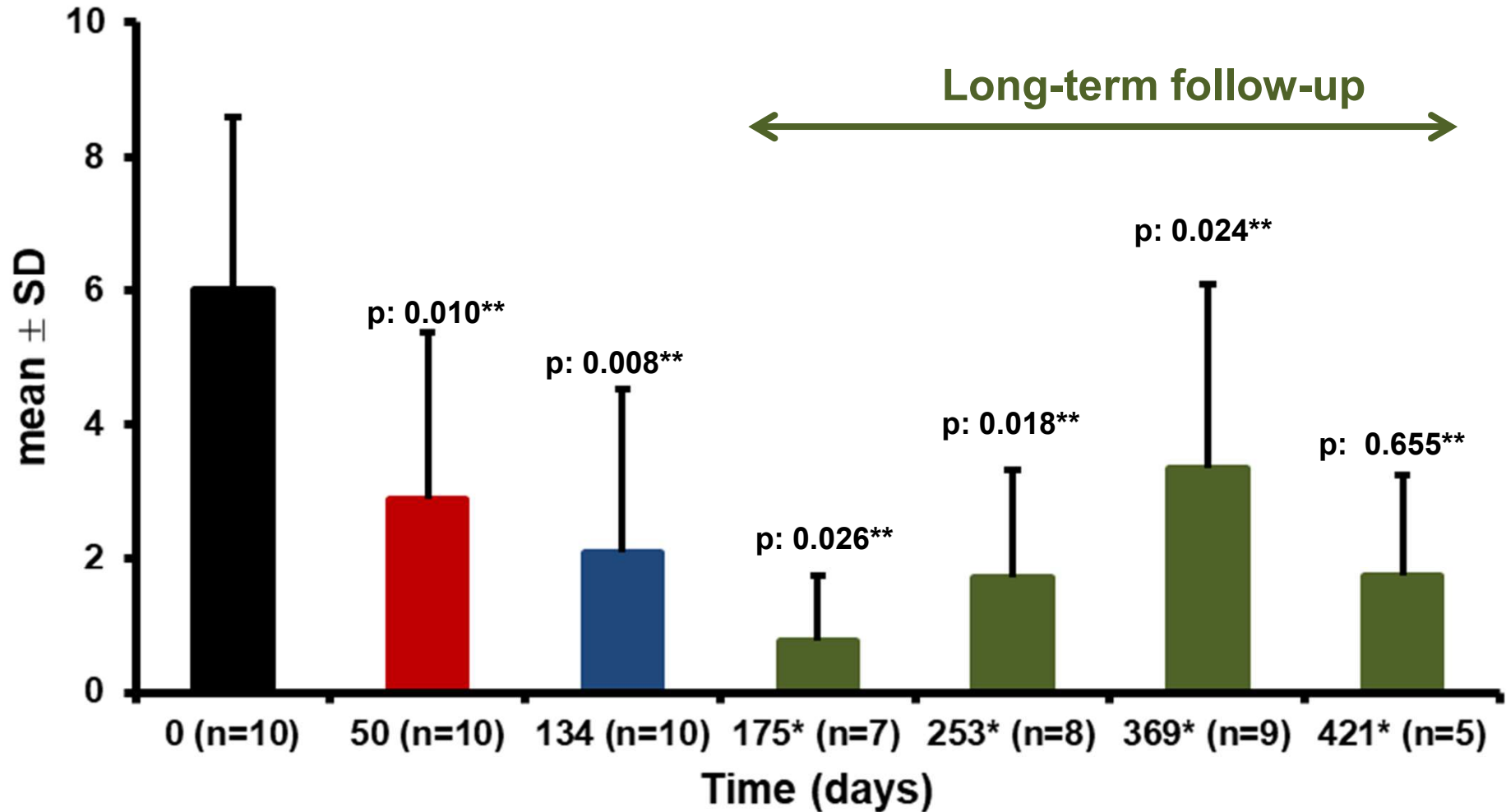
Number of visits	Days since start of IFX-1	Median (days)	Number of patients
9	139-198	175	7
11	234-296	253	8
11	302-391	369	9
4	408-488	421	5

HiSCR REPONDERS



*median period (n of patients); **pNS compared to day 134

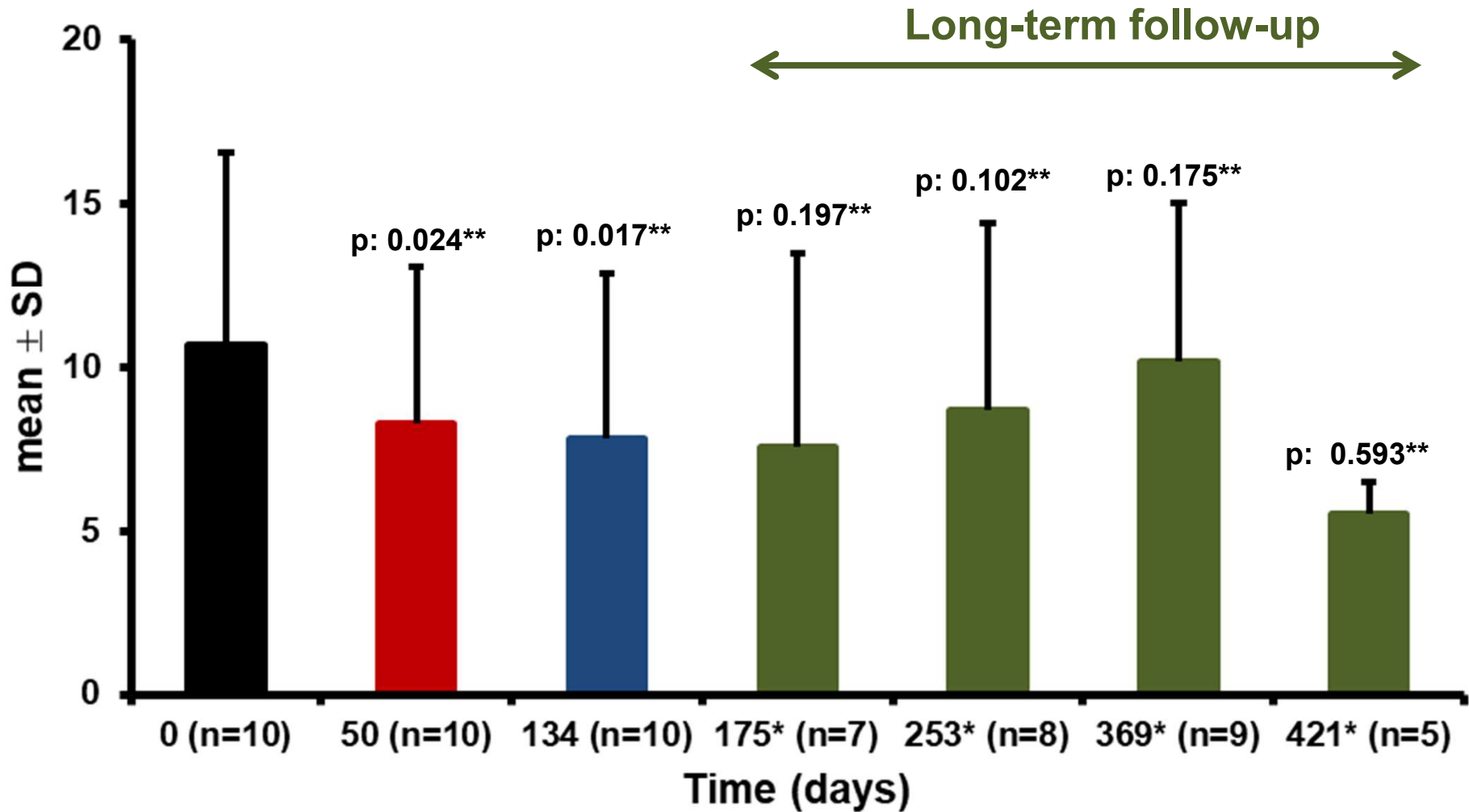
TOTAL AN COUNT



*median period (n of patients)

**compared to day 0 by Wilcoxon rank sum test

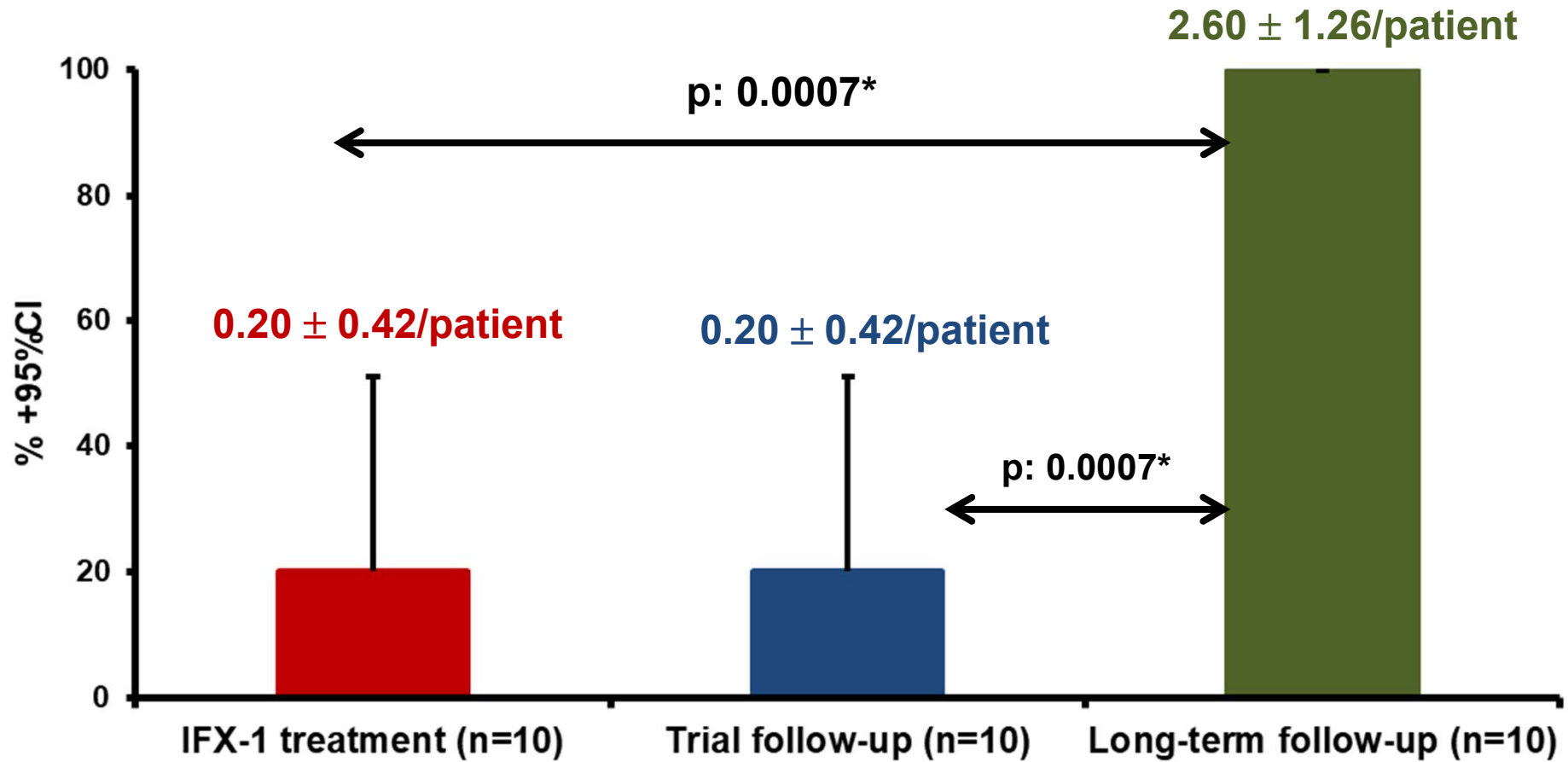
TOTAL FISTULA COUNT



*median period (n of patients)

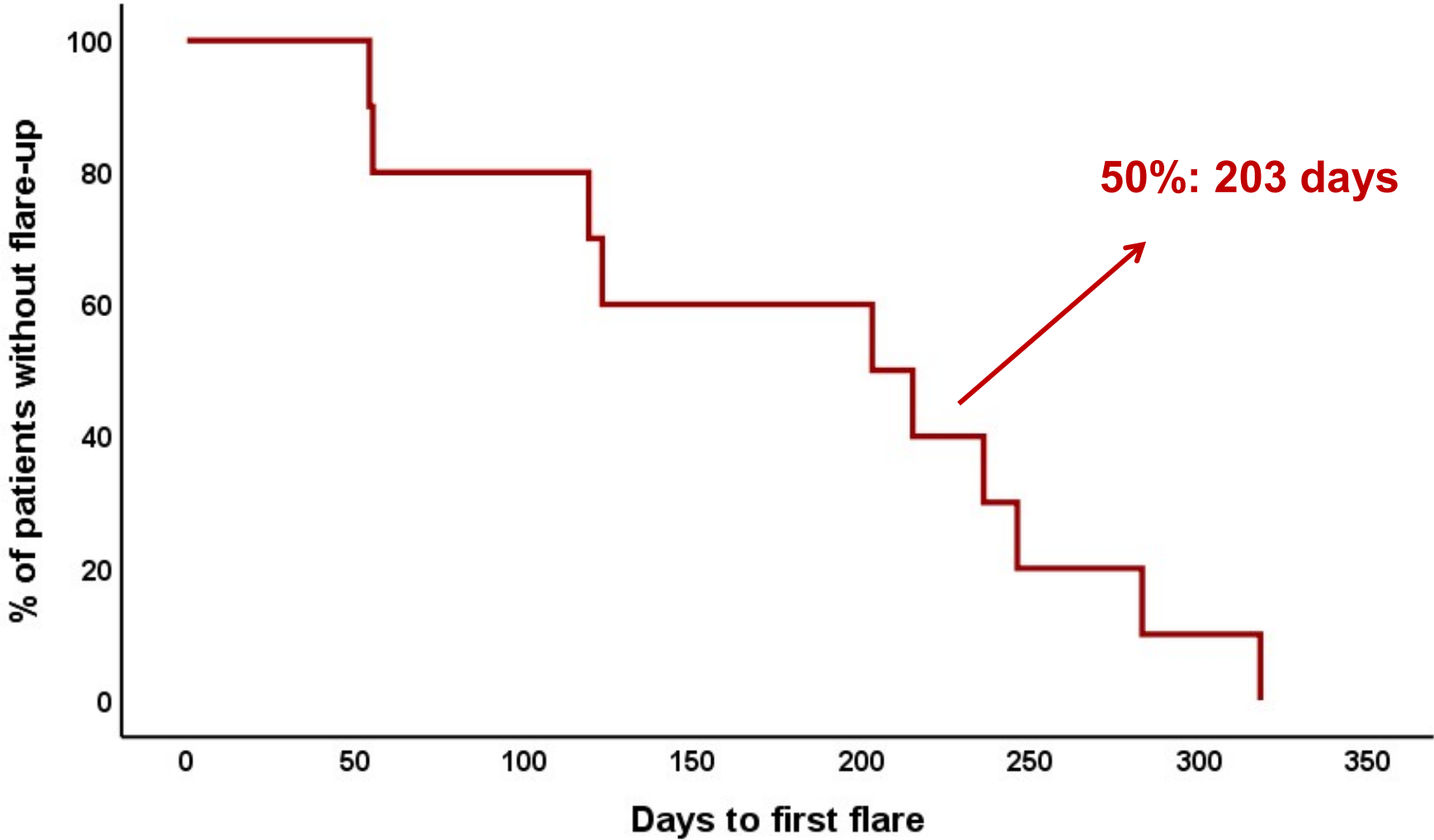
**compared to day 0 by Wilcoxon rank sum test

HS FLARE-UPS OVER TRIAL PERIODS



*by the Fisher exact test

SUSTAINABILITY OF RESPONSE: TIME TO FIRST FLARE-UP



CONCLUSIONS

Following 8 weeks of treatment with IFX-1 for severe HS

- HiSCR response is sustained until days 234-296
- All patients experience flare-ups at a rate greater than the first 134 days
- Although off medication, 50% of patients have no flare up to day 203
- Data support the further development of IFX-1 in HS.