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

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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

p: 0.006
IFX-1: humanized monoclonal IgG4κ antibody specifically binding to the soluble human complement split product C5a

SCREENING

OPEN-LABEL
800mg IFX-1

Weeks 0-8
Days 1, 4, 8, 15, 22, 29, 36, 43, 50

FOLLOW-UP

Weeks 9-12
Days 78, 106, 134

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

EudraCT number 2016-002988-33
National Ethics Committee (approval 92/16)
National Organization for Medicines (approval IS 90/16)
ClinicalTrials.gov NCT03001622
HiSCR REPONDERS

Open-label treatment

Follow-up period

* \( p < 0.05 \) compared to day 22

** \( p: 0.089 \) compared to day 50

Giamarellos-Bourboulis EJ, et al. JAAD submitted
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.

Treatment → Observation → Long-term follow-up
TOTAL 35 FOLLOW-UP VISITS: 10 PATIENTS

<table>
<thead>
<tr>
<th>Number of visits</th>
<th>Days since start of IFX-1</th>
<th>Median (days)</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>139-198</td>
<td>175</td>
<td>7</td>
</tr>
<tr>
<td>11</td>
<td>234-296</td>
<td>253</td>
<td>8</td>
</tr>
<tr>
<td>11</td>
<td>302-391</td>
<td>369</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>408-488</td>
<td>421</td>
<td>5</td>
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</tbody>
</table>
HiSCR RESPONDERS

End of open-label treatment

End of trial follow-up

Long-term follow-up

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

Diagram showing changes over time with specific time points and percentage changes.
Total AN Count

Long-term follow-up

*median period (n of patients)

**compared to day 0 by Wilcoxon rank sum test

*mean ± SD

0 (n=10) 50 (n=10) 134 (n=10) 175* (n=7) 253* (n=8) 369* (n=9) 421* (n=5)

Time (days)

p: 0.010**
p: 0.008**
p: 0.026**
p: 0.018**
p: 0.024**
p: 0.655**
TOTAL FISTULA COUNT

Long-term follow-up

*median period (n of patients)
**compared to day 0 by Wilcoxon rank sum test

*mean ± SD

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>0 (n=10)</th>
<th>50 (n=10)</th>
<th>134 (n=10)</th>
<th>175* (n=7)</th>
<th>253* (n=8)</th>
<th>369* (n=9)</th>
<th>421* (n=5)</th>
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<tbody>
<tr>
<td>p</td>
<td>0.024**</td>
<td>0.017**</td>
<td>0.197**</td>
<td>0.102**</td>
<td>0.175**</td>
<td>0.593**</td>
<td></td>
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</table>
HS FLARE-UPS OVER TRIAL PERIODS

*by the Fisher exact test
SUSTAINABILITY OF RESPONSE: TIME TO FIRST FLARE-UP

Days to first flare

% of patients without flare-up

50%: 203 days
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.