UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

# FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13A-16 OR 15D-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of November, 2021

Commission File Number: 001-38283

# InflaRx N.V.

(Translation of registrant's name into English)

Winzerlaer Str. 2
07745 Jena, Germany
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☐ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFLARX N.V.

On November 15, 2021, InflaRx N.V. issued a press release titled “InflaRx Announces Positive Data from Phase II IXCHANGE Study with Vilobelimab in ANCA-associated Vasculitis (AAV).” A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

In connection with a conference held by H.C. Wainwright & Co., LLC the Company updated and presented its corporate presentation (the “Corporate Deck”). The Corporate Deck is attached hereto as Exhibit 99.2 and is incorporated by reference herein. The Corporate Deck and the presentation are also available on the Company’s website located at www.inflarx.de.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INFLARX N.V.

Date: November 15, 2021

By: /s/ Niels Riedemann
Name: Niels Riedemann
Title: Chief Executive Officer

EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release, dated November 15, 2021 |
| 99.2 | InflaRx N.V. November 2021 Corporate Presentation |

Exhibit 99.1

InflaRx Announces Positive Data from Phase II IXCHANGE Study with Vilobelimab in ANCA-associated Vasculitis (AAV)

- Proof of concept established for potential of vilobelimab to reduce use of corticosteroids in AAV patients; vilobelimab demonstrated comparable efficacy to standard of care
- Use of vilobelimab instead of glucorticoids led to substantially lower observed glucocorticoid toxicity
- Vilobelimab demonstrated a good safety and tolerability profile; vilobelimab only treatment arm had lowest number of reported treatment emergent adverse events

Jena, Germany, November 15, 2021 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced positive data from the European phase II IXCHANGE study of vilobelimab, a first-in-class anti-C5a antibody, in patients with ANCA-associated vasculitis (AAV). The study achieved its principal objective, demonstrating comparable clinical response of vilobelimab to standard of care, while significantly reducing the need for glucocorticoid (GC) treatment in this life-threatening indication.

“We are pleased to report that vilobelimab monotherapy has shown similar efficacy compared to a standard dose of glucocorticoids in patients with ANCA-associated vasculitis in this trial,” said Dr. Korinna Pilz, Chief Development Officer. “Vilobelimab treatment led to a considerably reduced use of glucocorticoids, resulting in remarkably less treatment emergent adverse events and a reduction in the glucocorticoid toxicity index.”

“The results of the IXCHANGE trial regarding the evidence that vilobelimab has the potential to induce remission of ANCA-associated vasculitis with significant reduction in the dose and associated toxicity of glucocorticoids are exciting," said Peter A. Merkel, MD, MPH, Professor of Medicine and Epidemiology at the University of Pennsylvania, Director of the Penn Vasculitis Center, and coordinating investigator for the study. “The strong efficacy and safety data in the trial are quite encouraging for the development of this novel agent for the treatment against this organ- and life-threatening disease.”

The randomized, double-blind, placebo-controlled, two-part, Phase II IXCHANGE study enrolled 57 patients (30 in part 1; 27 in part 2) with AAV throughout Europe. Part 1 of the study compared vilobelimab plus a reduced dose of GC (RDGC) therapy to a standard dose of GC (SDGC) therapy, while part 2 compared vilobelimab alone to SDGC. All patients received standard of care immunosuppressive therapy (rituximab or cyclophosphamide). After loading doses administered at days 1, 4, and 8, patients were given 800mg of vilobelimab every two weeks for 16 weeks, followed by an eight-week observation period. The principal objective of the trial was to evaluate the efficacy of vilobelimab treatment as a replacement for GC therapy in patients with Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA). The primary efficacy evaluation was clinical response, primarily defined based on a 50% reduction in Birmingham Vasculitis Activity Score (BVAS) and no worsening in any body system from baseline. Clinical remission was a secondary endpoint and was defined as the number of patients achieving a BVAS of zero at week 16. The study was not statistically powered to demonstrate non-inferiority of vilobelimab alone compared to a standard dose of GC therapy. Other secondary endpoints included the vasculitis damage index (VDI), estimated glomerular filtration rate (eGFR) and the glucocorticoid toxicity index (GTI).

The mean total accumulative dose of GC administered after the screening period until end of study in the different groups was 541.9 mg in the vilobelimab only group, 3751.3 mg in the SDG group and 1485.8 mg in the vilobelimab + RDGC group. The cumulative mean GC dose received during the 28 days prior to randomization was comparable amongst the three arms with 1894.7 mg (vilobelimab only), 1750.1 mg (SDGC) and 2438.8 mg (vilobelimab + RDGC), respectively.

Clinical response as well as clinical remission were achieved in comparably high rates in all three arms: Clinical response at week 16 in evaluable patients was observed in 16 out of 18 (88.9%) patients in the treatment group receiving vilobelimab alone; in 22 out of 23 (95.7%) patients receiving SDGC; and in 10 out of 13 (76.9%) patients in the vilobelimab + RDGC group.

Clinical remission at week 16 is summarized in the following table:

| Dose Groups<br>No. of evaluable patients | vilobelimab (No GC)<br>N=18 | SDGC<br>N=23 | vilobelimab + RDGC<br>N=13 | Pooled vilobelimab<br>N=31 |
|---|---|---|---|---|
| Clinical Remission at Week 16 [N (%)] | 14 (77.8%) | 20 (87.0%) | 10 (76.9%) | 24 (77.4%) |
| No Clinical Remission [N (%)] | 4 (22.2%) | 3 (13.0%) | 3 (23.1%) | 7 (22.6%) |
| Missing at week 16 | 0 | 1 | 2 | 2 |

The GTI composite score at week 16 was substantially lowered in the vilobelimab alone group (mean value of 0.8) when compared to the SDGC group (mean value of 44.9) and the vilobelimab + RDGC group (mean value of 26.1).

Assessment of the VDI at week 16 suggested comparable values between groups with the vilobelimab only group showing the lowest value: vilobelimab only group (1.0), SDGC group (1.5) and vilobelimab + RDGC group (1.9).

eGFR, a secondary endpoint of the study, demonstrated no observed medically meaningful changes in all three arms.

The vilobelimab only group had the lowest number of reported treatment emergent adverse events (TEAEs) as well as related TEAEs as summarized in the following table:

| | vilobelimab (No GC) N=18 | | | SDGC N=24 | | | vilobelimab + RDGC N=15 | | |
|---|---|---|---|---|---|---|---|---|---|
| | Pat N | (Pat %) | Events | Pat N | (Pat %) | Events | Pat N | (Pat %) | Events |
| TEAEs | 16 | (88.9%) | 81 | 24 | (100.0%) | 180 | 15 | (100.0%) | 89 |
| Serious TEAEs | 5 | (27.8%) | 5 | 4 | (16.7%) | 6 | 3 | (20.0%) | 3 |
| TEAEs rated as related to vilobelimab | 6 | (33.3%) | 8 | 18 | (75.0%) | 40 | 6 | (40.0%) | 9 |
| TEAEs rated as related to GC | 7 | (38.9%) | 21 | 18 | (75.0%) | 105 | 11 | (73.3%) | 24 |
| Serious TEAEs rated as related to vilobelimab | 1 | (5.6%) | 1 | 1 | (4.2%) | 1 | 0 | (0.0%) | 0 |
| Serious TEAEs rated as related to GC | 2 | (11.1%) | 2 | 3 | (12.5%) | 4 | 0 | (0.0%) | 0 |

There was one fatal event of pneumocystis jiroveci pneumonia in the vilobelimab only treatment group. This event started on Day 6 after the patient's randomization in the study and lasted for 30 days until the patient's death. The patient had newly diagnosed GPA and was treated with rituximab prior to and during the screening period and received glucocorticoids as part of the standard premedication regimen. The patient received 3 doses of vilobelimab before onset of the event which led to discontinuation of treatment. The event was judged as unlikely related to vilobelimab by the Company. The patient had received a cumulative dose of 6.57 grams of prednisolone equivalent and 4 doses of rituximab (4 x 740 mg) prior to randomization and prior to onset of the event (38 days). Based on an investigator decision, the patient did not receive the guideline and protocol-recommended antibiotic prophylaxis for pneumocystis jiroveci pneumonia, which is a known and described serious infection and potential cause of death for patients diagnosed with and treated for AAV. (Sarica et al., Rheumatology 2020;0:1-9).

Another serious adverse event of pneumocystis jiroveci pneumonia was detected in the standard GC group in a patient who had undergone a comparable AAV induction therapy.

In May 2021, InflaRx reported positive topline data from the US IXPLORE Phase II study of vilobelimab in AAV. The results indicated that vilobelimab, when given in addition to best standard of care, was well tolerated.

The Company plans to discuss the data from both the US and EU studies with regulatory authorities to determine next steps with the program.

About ANCA-Associated Vasculitis (AAV)

AAV is a rare and life-threatening autoimmune disease in which activation of the complement system, and specifically the generation of larger amounts of C5a, is believed to play a key role in the neutrophil-driven vessel inflammation that defines the disease. AAV affects approximately 40,000 and 75,000 patients in the United States and Europe, respectively.

About vilobelimab:

Vilobelimab is a first-in-class monoclonal anti-human complement factor C5a antibody, which highly and effectively blocks the biological activity of C5a and demonstrates high selectivity towards its target in human blood. Thus, vilobelimab leaves the formation of the membrane attack complex (C5b-9) intact as an important defense mechanism, which is not the case for molecules blocking the cleavage of C5. Vilobelimab has been demonstrated to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response in pre-clinical studies. Vilobelimab is believed to be the first monoclonal anti-C5a antibody introduced into clinical development. Over 300 people have been treated with vilobelimab in completed clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various inflammatory indications, including hidradenitis suppurativa, ANCA-associated vasculitis and pyoderma gangraenosum, as well as severe COVID-19 and cutaneous squamous cell carcinoma (cSCC).

About InflaRx N.V.:

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of C5a. Complement C5a is a powerful inflammatory mediator involved in the progression of a wide variety of autoimmune and other inflammatory diseases. InflaRx was founded in 2007, and the group has offices and subsidiaries in Jena and Munich, Germany, as well as Ann Arbor, MI, USA. For further information please visit www.inflarx.com.

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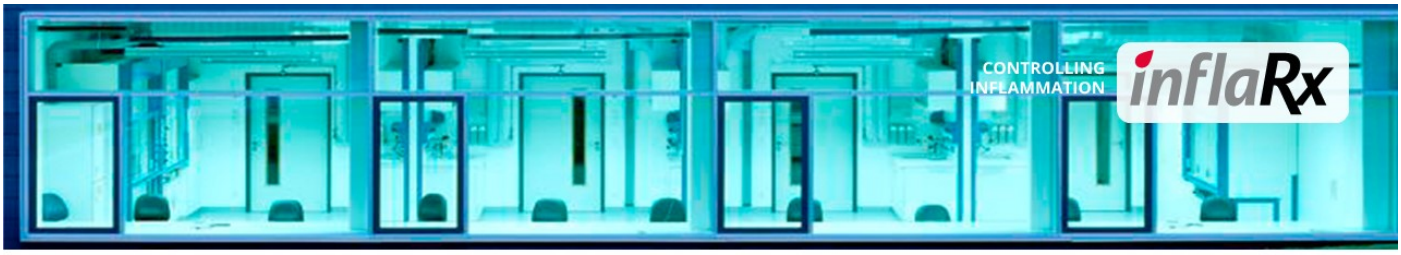
FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential” or “continue” and similar expressions. Forward-looking statements appear in a number of places throughout this release and may include statements regarding our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, our ongoing and planned clinical trials of vilobelimab as treatment of ANCA-associated Vasculitis and the safety and efficacy results of those trials ; the impact of the COVID-19 pandemic on the Company; the timing and our ability to commence and conduct clinical trials; potential results from current or potential future collaborations; our ability to make regulatory filings, obtain positive guidance from regulators, and obtain and maintain regulatory approvals for our product candidates; our intellectual property position; our ability to develop commercial functions; expectations regarding clinical trial data; our results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies; the industry in which we operate; the trends that may affect the industry or us and the risks, uncertainties and other factors described under the heading “Risk Factors” in InflaRx’s periodic filings with the Securities and Exchange Commission. These statements speak only as of the date of this press release and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.

Exhibit 99.2


inflaRx
CONTROLLING
INFLAMMATION
CORPORATE PRESENTATION
November 2021

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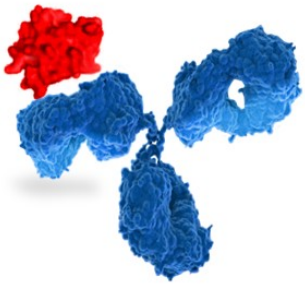
This presentation may contain forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. All statements other than statements of historical facts contained in this presentation, including statements regarding future results of operations and financial position, business strategy, current and prospective product candidates, planned clinical trials and preclinical activities, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, expectations regarding market acceptance and size, plans and objectives of management for future operations, and future results of anticipated product candidates, are forward-looking statements. These risks and uncertainties include those described under the heading "Risk Factors" in InflaRx's periodic filings with the Securities and Exchange Commission. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and InflaRx's own internal estimates and research. While InflaRx believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

InflaRx N.V. has an effective shelf registration statement (including a prospectus) on file with the SEC. This presentation does not constitute an offer to sell, or the solicitation of an offer to buy, any of the Company's securities. Any offering of securities will be made only by means of a prospectus supplement, which will be filed with the SEC. In the event that, the Company conducts an offering, you may obtain a copy of the prospectus supplement and accompanying prospectus for the offering for free by visiting EDGAR on the SEC website at www.sec.gov. Alternatively, the Company will arrange to send such information if you request it.

# Investment Highlights

## InflaRx's Approach: Targeting Complement to Control Autoimmune Diseases



### 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

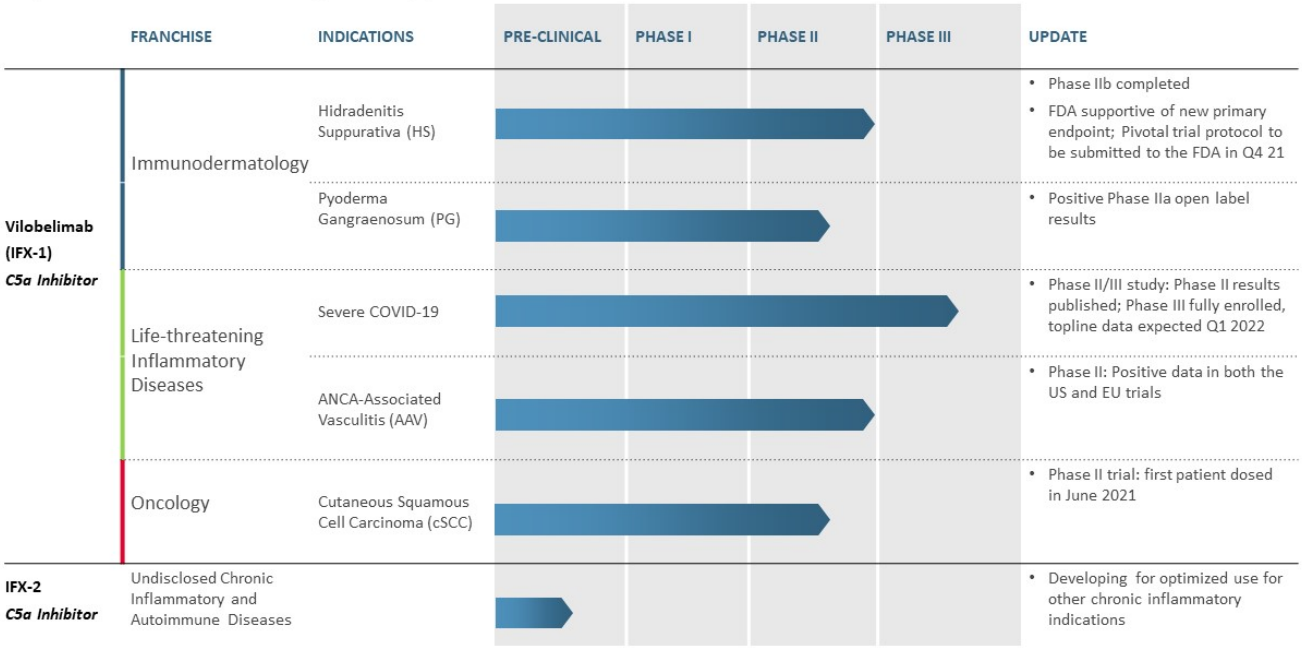
### Established Clinical Efficacy for Vilobelimab (IFX-1):

- Proven anti-inflammatory effect in multiple Phase II studies; favorable safety profile & excellent tolerability in >300 patients
- Statistically significant reduction of inflammatory lesions and impressive long-term efficacy in Hidradenitis Suppurativa (HS)
- Encouraging Phase II data in patients with Severe COVID-19 and positive Phase IIa data in Pyoderma Gangraenosum (PG)
- Positive Phase II data in both the US & EU ANCA-associated vasculitis (AAV) trials

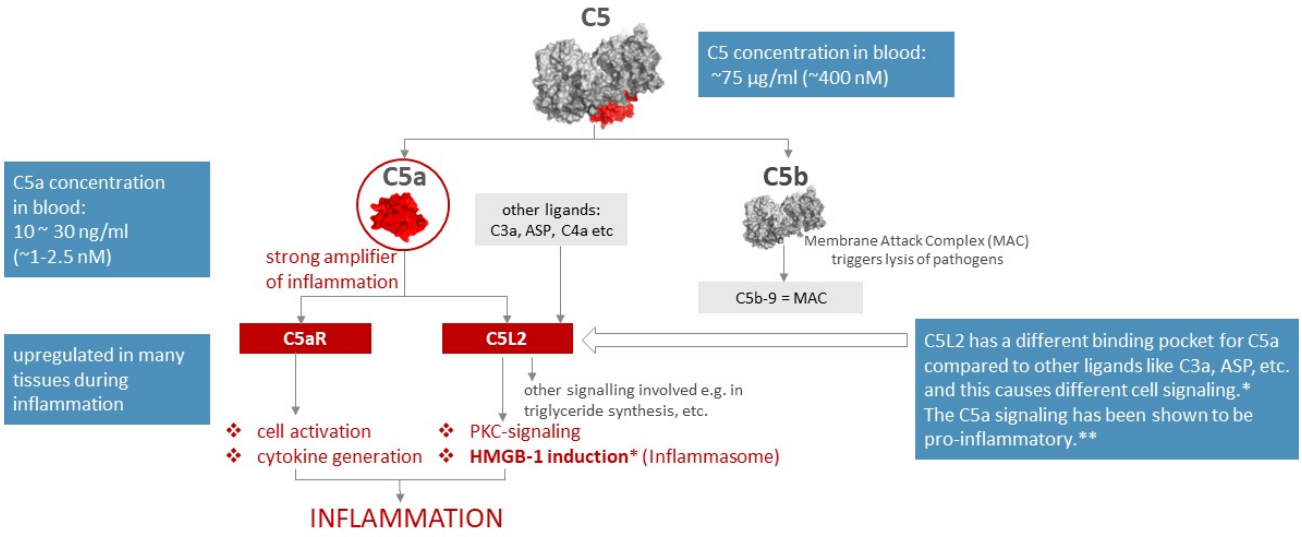
### Multiple Near-Term Inflection Points

- **HS**: FDA supportive of pivotal study program that focuses on patients with active draining tunnels and a new primary endpoint that will measure the reduction of all three HS lesions - including draining tunnels; Pivotal trial protocol to be submitted to the FDA in Q4 21
- **Severe COVID-19**: Phase III trial enrollment finalized; topline data expected in Q1 2022

# Pipeline with Multiple Opportunities



# The Terminal Complement Pathway



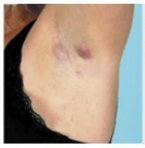

* Kalant D. et. al. J. Biol. Chem. 2003, 278 (13) 11123–11129
**Rittirsch et al. Nat Med. 2008 May ; 14(5): 551; Colley et al. MABS. 2018,10 (1), 104Songlin et. al. J. Biol. Chem. 2019; 294(21) 8384–839 Muenstermann et al.. Virulence, 2020; 10(1) 677-694


# VILOBELIMAB (IFX-1) FOR HIDRADENITIS SUPPURATIVA

# Hidradenitis Suppurativa (HS)

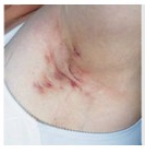
A chronic severely debilitating C5a-driven inflammatory skin condition with high unmet need

## HURLEY STAGING FOR HS



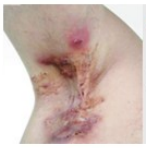
**Stage I**

Single / multiple abscesses but no sinus tracts or scarring



**Stage II**

Single or multiple separated, recurrent abscesses with tract formation and scarring



**Stage III**

Multiple interconnected tracts and abscesses involving an entire anatomic region

### CLINICAL FEATURES

- Chronic, inflammatory, recurrent, debilitating skin disease of the hair follicles
- Most commonly in the armpit, groin and genital regions
- Extremely painful inflammatory nodules, boils or abscesses
- Draining fistulas leading to considerable scarring and functional disability
- Hurley staging system used to classify progression / chronicity (Stage I – III)

### PREVALENCE

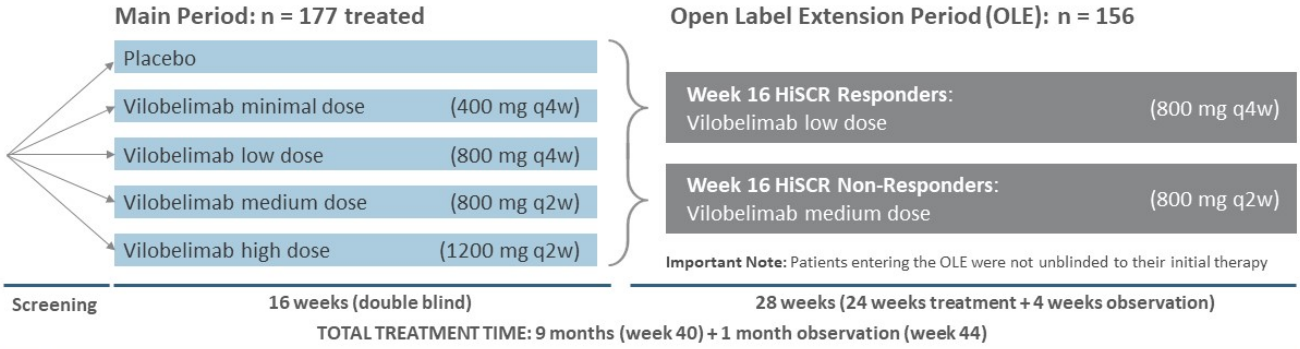
- Up to 200,000 moderate to severe (Hurley II+III) HS patients in US
- Higher prevalence in Europe with reports > 1% total HS prevalence

### CURRENT TREATMENT – MEDICAL NEED

- Humira®(adalimumab) (TNF-alpha inhibitor) from AbbVie is the only approved biological in US and Europe
- Accepted (but not approved) standard of care (SOC) includes topical, oral or i.v. antibiotics
- In some instances, surgery is required
- Approximately 50% of patients with moderate to severe HS do not respond and about 50% of responder patients lose response to Humira*

* Combined Phase III trial data for Humira: response measured by HiSCR 50 and KOL quotes in LifeSci Capital initiation report 12/2018

# Hidradenitis Suppurativa (HS)
# Phase IIb SHINE study details




## MAIN GOALS

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

*HiSCR response defined as: At least 50% reduction in total AN count (abscesses & inflammatory nodules) with no increase in the number of abscesses from baseline and no increase in the number of draining fistulas from baseline

# SHINE Study and Next Steps in HS Development

## RESULTS

- HiSCR primary endpoint and dose response signal not met but there was a signal towards improved AN count
- Statistically significant change in draining tunnels (DT) and in ANdT count detected
- Open label extension: in the responder group, 71% maintain HiSCR response by week 40; In the non-responder group, 42% become HiSCR responders by week 40

## OUR CONCLUSIONS

- HiSCR is burdened by high variability (driven by AN count variability) and does not capture reduction of draining tunnels
- Evidence for a high C5a turnover rate in HS, leading to increased dose requirements of vilobelimab
- Vilobelimab leads to marked reduction in all inflammatory lesions, with a durable long-term effect detected even at sub-optimal doses
- Vilobelimab long-term treatment was well tolerated, no drug related serious adverse events (SAEs) in OLE phase

## CURRENT STATUS & NEXT STEPS

- **FDA Type A Meeting (August 2021)**
  - Received feedback from FDA within its Type A meeting **supportive of a new primary endpoint measuring reductions in all three inflammatory HS lesions** – including **draining tunnels**
  - Pivotal development program will focus on patients suffering from **moderate to severe HS with active draining disease**, as supported by the FDA
  - FDA feedback will be incorporated in pivotal study protocol and **submitted in Q4 2021. Study activities will begin upon protocol approval by FDA**

*At end-of-Phase II meeting in June 2020, FDA agreed to the Phase III dosing regimen, a higher dose than studied in the Phase IIB SHINE study.*

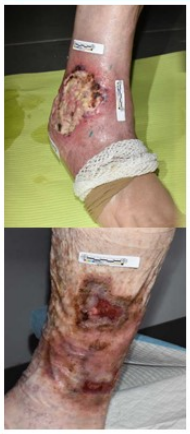


ANdT Count = Total number of combined inflammatory nodules, abscesses and draining tunnels
AN Count = Total number of combined inflammatory nodules and abscesses


# VILOBELIMAB (IFX-1) FOR PYODERMA GANGRAENOSUM

# Pyoderma Gangraenosum (PG)

## AN AUTOIMMUNE CONDITION WITH HIGH UNMET NEED



### CLINICAL FEATURES

- PG is a rare but potentially life-threatening skin disorder that can lead to chronic, highly painful and difficult-to-treat wounds
- Many PG patients also suffer from other autoimmune disorders, such as ulcerative colitis, rheumatoid arthritis, and hematological diseases
- Patients suffer from severe pain, long healing times, and frequent relapses

### INCIDENCE

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

### CURRENT TREATMENT – MEDICAL NEED

- No drugs currently approved in the US or EU
- For less severe cases, topical or intralesional treatments can be used, including topical steroids
- Use of systemic immunosuppression in rapidly progressing cases
- Mixed reports about efficacy, long treatment durations, relapses are frequently seen

**› Strong rationale for treatment with vilobelimab: PG associated with neutrophilic skin infiltration in affected areas and lesions, potentially triggered by C5a.**

Photo Source: InflaRx study

# PGA Score – Physician's Global Assessment Score

## PGA SCORE IN THIS TRIAL

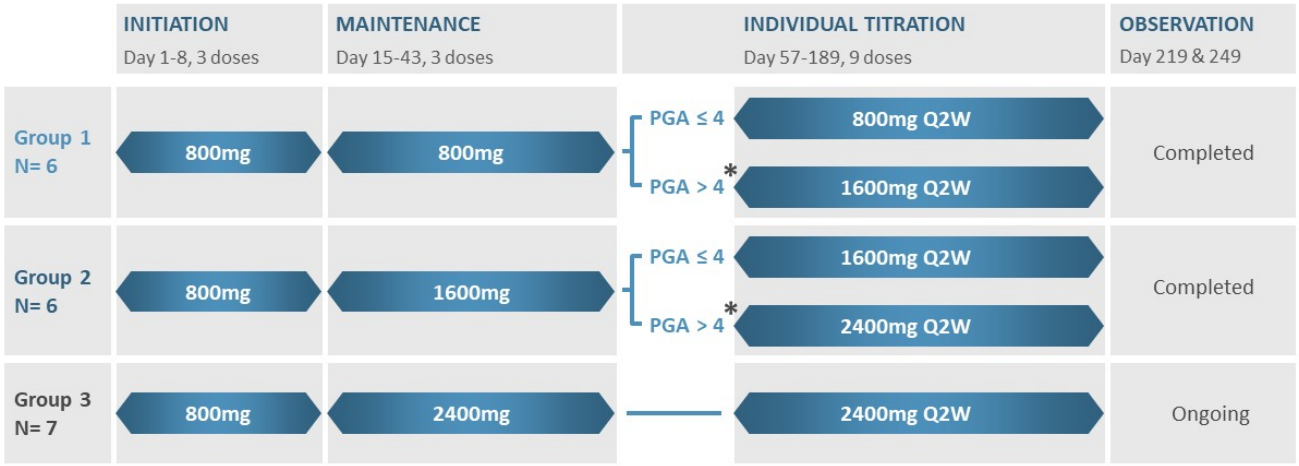
- PGA classifies physician-assessed target ulcer improvement compared to photography at Day 1
- No PGA score at baseline (Day 1)
- PGA score is collected from Day 4 until end of study
- **PGA score of ≤ 3 is considered clinical response**
- **PGA score of ≤ 1 is considered clinical remission and closure of target ulcer**

## PGA SCORE

| | | |
|---|---|---|
| 0 | Completely clear | except for possible residual hyperpigmentation |
| 1 | Almost clear | very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration |
| 2 | Marked improvement | significant improvement (about 75%); however, a small amount of disease remaining (i.e., remaining ulcers, although have decreased in size, minimal erythema and/or barely perceptible border elevation) |
| 3 | Moderate improvement | intermediate between slight and marked; representing about 50% improvement |
| 4 | Slight improvement | some improvement (about 25% up to 50%); however, significant disease remaining (i.e., remaining ulcers with only minor decrease in size, erythema or border elevation) |
| 5 | No change from baseline | |
| 6 | Worse | |

# Phase IIa Study Design

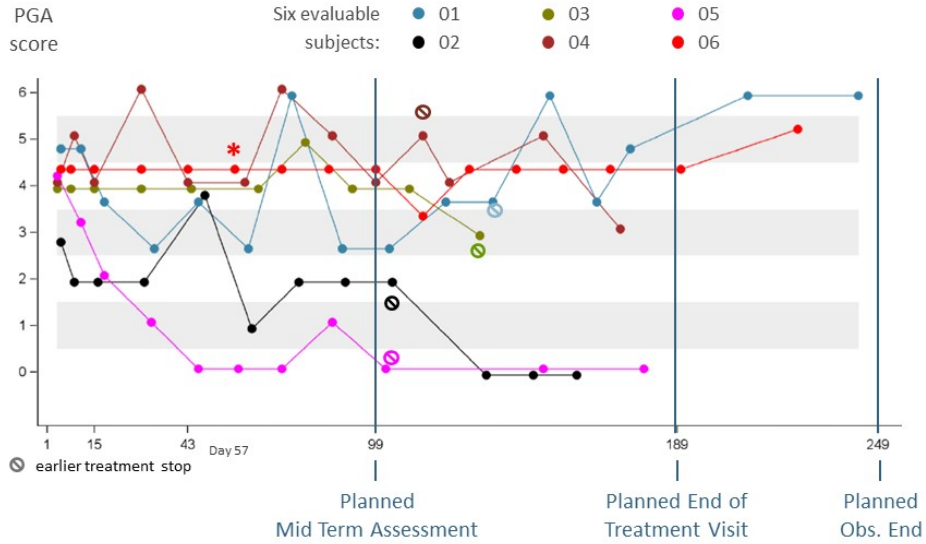
- Sequential enrollment of 19 patients reached in April 2021
- **Primary endpoint:** Safety
- **Key secondary endpoints:** Responder rate defined as PGA ≤3; Time to complete closure of target ulcer




*Uptitration to the next dose on day 57 **if** PGA > 4 and at least 5 patients treated with the current dose showed no safety issues

# Study Results – Group 1 (Low Dose)

## PGA-line plot of absolute values over time by patient (Actual days displayed acc. to visit windows)



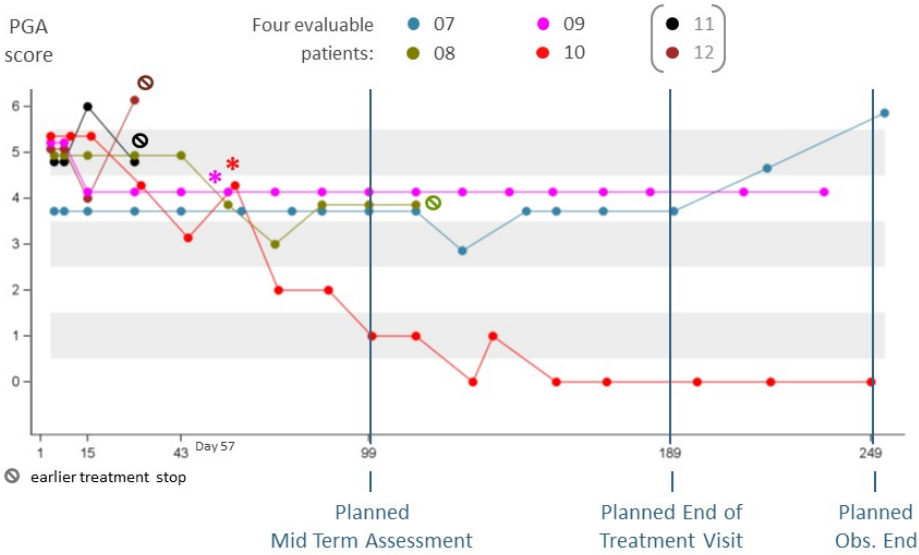

### Group 1 Results

- Two patients (02 and 05) achieved **complete remission of target ulcer**
- One patient (01) with initial response and fluctuating PGA
- Patients 02 and 05 stopped treatment before Day 189 based on investigator decision because of complete disease remission
- Patient 03 dosed until Day 130 but stopped treatment due to Covid situation. No follow up.

* Uptitration to 1600mg on day 57 **if** PGA > 4 and at least 5 patients treated with 800mg show no safety issues. Applied to patient 06

# Study Results – Group 2 (Medium Dose)

## PGA-line plot of absolute values over time by patient (Actual days displayed acc. to visit windows)



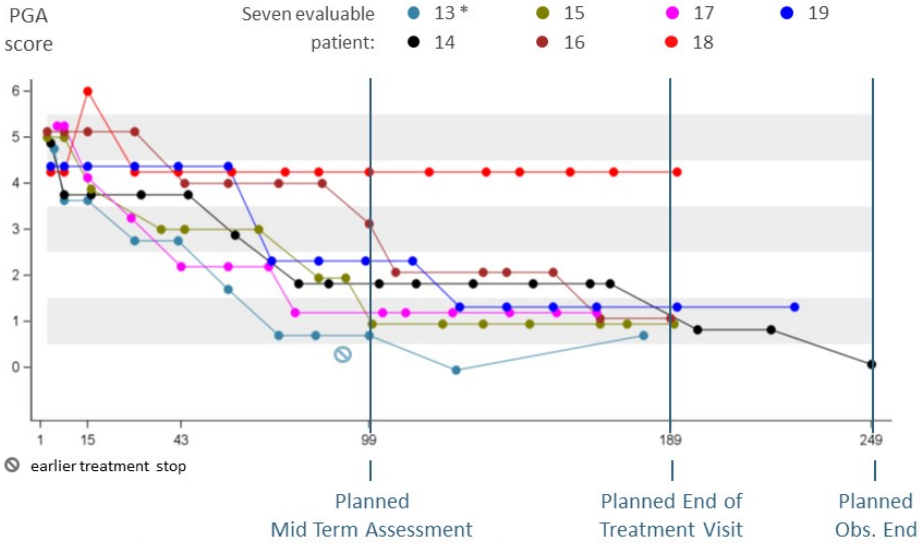

### Group 2 Results

- One patient (10) out of four **healed upon up-titration to 2400mg group on day 57** with PGA = 0 since visit 12 (closure of large target ulcer area)
- Two patients (08, 09) showed temporary response, not considered responder
- Two patients (11, 12) discontinued early in study and were non-evaluable

*Uptitration to 2400mg on day 57 **if** PGA > 4 and at least 5 patients treated with 1600mg show no safety issues. Applied to patients 09 and 10.

# Study Results – Group 3 (High Dose)

## PGA-line plot of absolute values over time by patient (Actual days displayed acc. to visit windows)

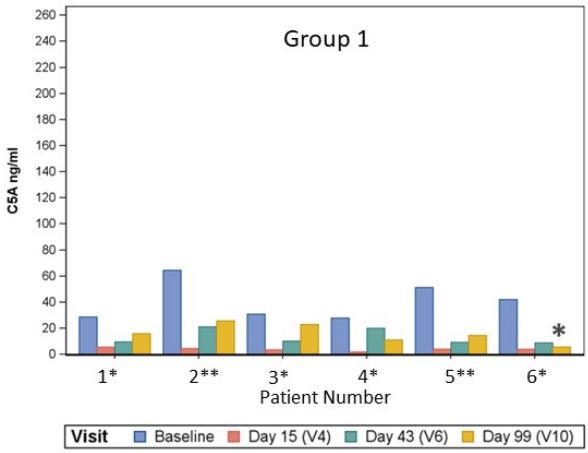


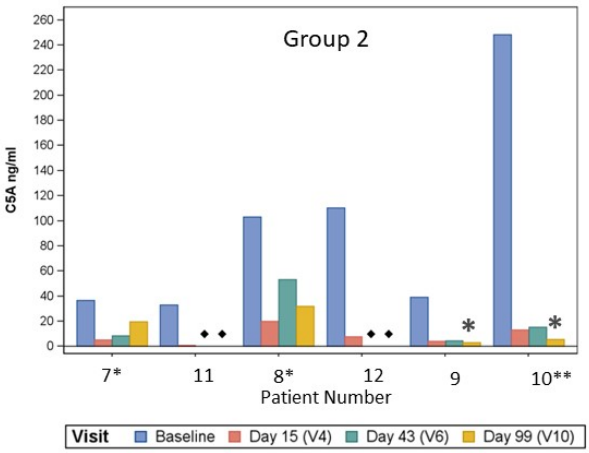

* Patient 13 was discontinued from treatment after day 71 due to delayed availability of pos. baseline TB testing result (exclusion criterion). No re-activation of TB reported up to end of observation.

### Group 3 Results

- Six patients out of 7 achieved PGA score of ≤ 1 (remission)
- One patient (18) experienced target ulcer area decrease >50%; however, new PG lesions developed
- Patient 19 with complicated disease course
  - Pre-existing diabetes and wound infection in target ulcer area on day 1 with start of antibiotics
  - Wound infection and local progression in target ulcer area on day 50
  - Broad spectrum antibiotics and cyclosporin A starting day 50
  - Closure of target ulcer on day 127
- Patient 16 started 10 mg/d prednisone on day 72 (allowed per protocol)

# Study Results – Group 1 and Group 2
## C5a levels




## Clinical observations

- Patient 10 in Group 2 reached clinical remission at Day 99 after uptitration to 2400mg at Day 57

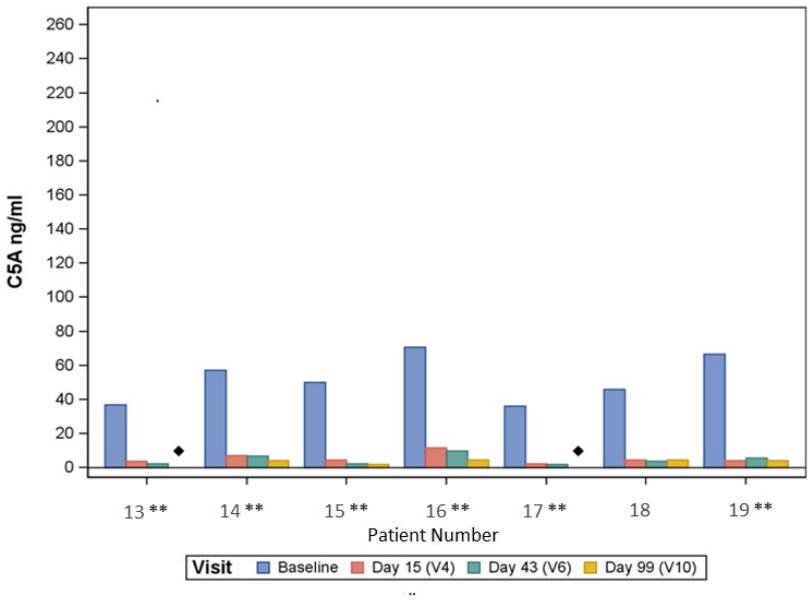
* Responder (PGA Score ≤3)

** Responder in remission (PGA ≤1)

♦ Values not available

✱Patients 6, 9, and 10 were uptitrated on day 57

# Study Results – Group 3
## C5a levels




### Clinical observations

- Six patients reached PGA≤1
- Patient 18 only showed minor improvement of target ulcer but no remission

** Responder in remission (PGA ≤1)

♦ Values not available

# Summary and Conclusion

## SAFETY CONCLUSION

- No infusion-related reactions observed
- For 2 patients, related SAEs were reported:
  - Erysipelas leading to hospitalization (judged as non-related by sponsor)
  - Rash due to delayed hypersensitivity reaction
- Observed AE profile in line with patients' underlying diseases
- No dose-related AE detected

## CLINICAL RESPONSE CONCLUSION

- Out of 17 evaluable patients at end of treatment visit or day of last drug administration
  - Clinical Remission (PGA ≤ 1): 9 patients (53%)
  - Clinical Response (PGA ≤ 3): 1 additional patient (6%)
  - Slight Improvement (PGA = 4): 7 patients (41%)
- **High Dose Group shows highest rate of target ulcer closure and clinical remission (85.7%)**

WE WILL MEET WITH FDA TO DISCUSS NEXT STEPS

**Vilobelimab Q2W shows good safety and tolerability**
**Evidence for dose-dependent drug activity in PG**


# Patient Case Studies in PG

# Patient 10 Case Study

## TARGET ULCER REAPPEARED IN AUGUST 2020

**MH:** PG since Jun 2019, Hypertension since 1998; **Study Day 1:** Feb 2021

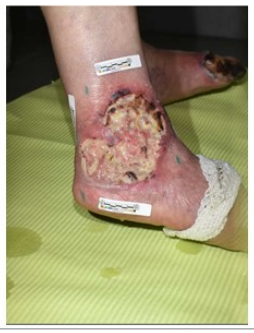
**Cohort 2: 1600** mg Q2W, individual uptitration to 2400 mg at D57, treatment completed

**Previous PG medication:** Methylprednisolone only in Jun 2019, Dapsone Jun 2019- Aug 2020, Cyclosporine Oct 2019- Aug 2020 -> ulcer healed and reappeared soon after discontinuation of immunosuppressants

**Concomitant Medication:** Prednisone 10 mg for PG since October 2020

### Baseline

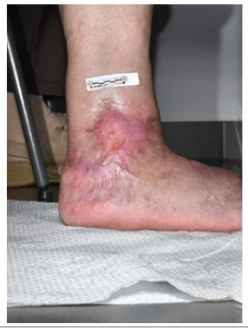
Area: 3695 $mm^2$



### Day 99

PGA = 1

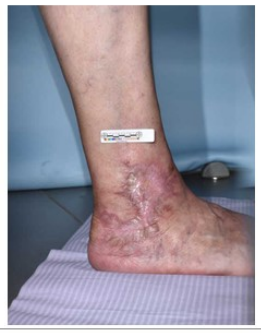
Area: 0.00 $mm^2$



### Day 189, V16 (20 days after last vilo. admin.)

PGA = 1

Area: 0.00 $mm^2$



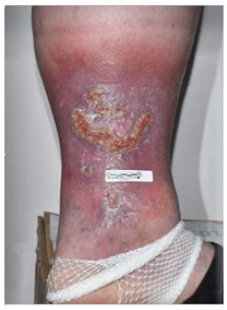
# Patient 14 Case Study

## PG TREATMENT HISTORY: CICLOSPORIN, DAPSONE

**MH:** PG since October 2018, Obesity since longer time (no exact day available)
**Treatment Start:** February 2021
**Cohort 3:** 2400 mg Q2W treatment completed
**Previous PG medication:** Ciclosporin and methylprednisolone October 2018 – September 2019, failed. Dapsone September 2020 – November 2020.
**Concomitant Medication:** Prednisone 10 mg since October 2018

### Baseline

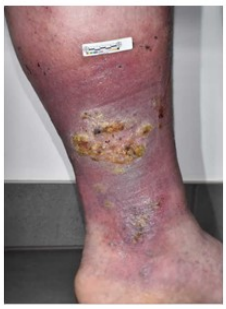
Area: 1285 $mm^2$



### Day 99

PGA = 2

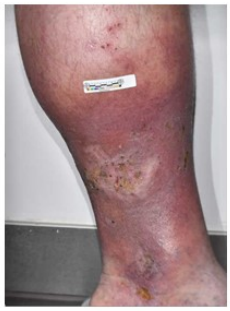
Area: 0.0 $mm^2$



### Day 189, V16 (20 days after last IFX-1 admin.)

PGA = 1

Area: calculation not yet available



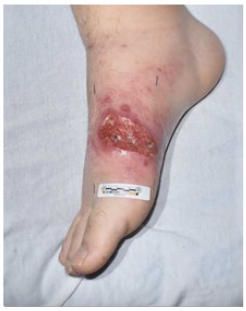
# Patient 13 Case Study

## TARGET ULCER OPENED IN NOVEMBER 2020 WHILE ON STABLE ADALIMUMAB

**MH:** PG since August 2020, Psoriasis since 2017
**Treatment Start:** March 2021
**Previous PG medication:** None
**Cohort 3:** 2400 mg Q2W up to Day 85 → exclusion after 9 doses due to delayed availability of pos. baseline TB testing result (no TB activation!)
**Concomitant Medication:** Adalimumab for psoriasis 40 mg QD since 2017

### Baseline

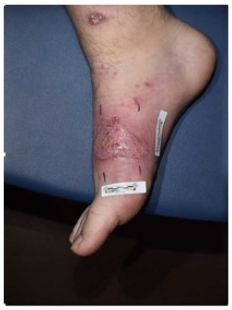
Area: 1136 $mm^2$



### Day 85

PGA = 1

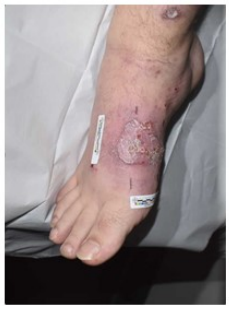
Area: 0.00 $mm^2$



### Day 89, end of treatment visit

PGA = 1

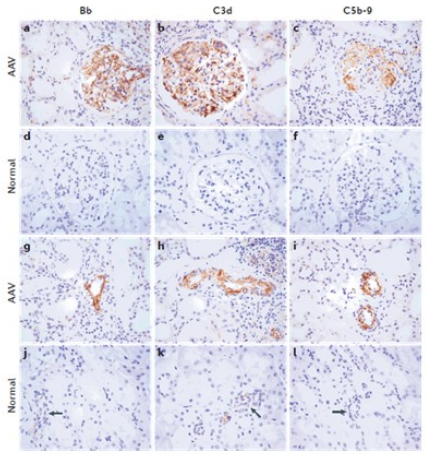
Area: calculation not yet available




# VILOBELIMAB (IFX-1) FOR ANCA-ASSOCIATED VASCULITIS

# ANCA-Associated Vasculitis (AAV)

## A LIFE-THREATENING AUTOIMMUNE CONDITION




Source: Chen, Jayne and Zhao. Complement in ANCA-associated vasculitis: mechanism and implication for management

### CLINICAL FEATURES

- Rare, life-threatening autoimmune disease, characterized by necrotizing vasculitis
- Life-threatening flare phases affect organs, leading to potentially fatal organ dysfunction and failure
- Predominantly affects small vessels associated with anti-neutrophil cytoplasmic antibodies, or ANCA
- Disease activity is assessed using Birmingham Vasculitis Activity Score v3 (BVAS)

### PREVALENCE

- Approx. 40,000 AAV patients in the US
- Approx. 75,000 AAV patients in Europe
- Orphan drug market

### CURRENT TREATMENT – MEDICAL NEED

- Induction of remission critical during flare phases – induction treatment differs from maintenance therapy and consists of high dose corticosteroids plus either cyclophosphamide or rituximab plus recently approved avacopan
- Induction of remission therapy with high-dose corticosteroids has significant side effects

# AAV, Life-threatening Autoimmune Condition
# Clinical PoC established for role of C5a / C5aR pathway in AAV

## ROLE OF C5A IN AAV

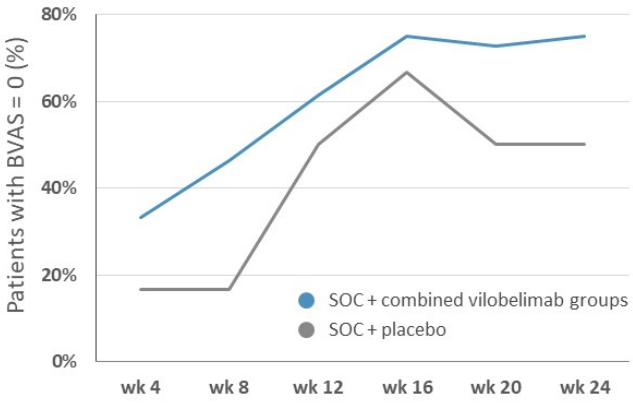
- Anti-neutrophil cytoplasmic auto-antibodies induce C5a activation leading to neutrophil-endothelial cell adherence and neutrophil activation --- causing neutrophil-driven vascular damage[1,2]
- C5a shown in mouse model to be essential for development of MPA-ANCA crescentic glomerulonephritis[3]
- Role of C5a / C5aR pathway in AAV established through recent approval of chemical C5aR inhibitor
- Both C5a receptors, C5aR and C5L2, are involved in C5a-induced neutrophil degranulation in ANCA primed neutrophils[4]


1. Halbwachs et al. J Am Soc Nephrol. 2012 23(9):1449
2. Chen et al. Nat Rev Nephrol. 2017 13(6):359
3. Schreiber et al. J Am Soc Nephrol. 2009 20(2): 289
4. Hao et al. Plos One. 2013 8(6):e66305

# Phase II Study in AAV in the US (IXPLORE) Results

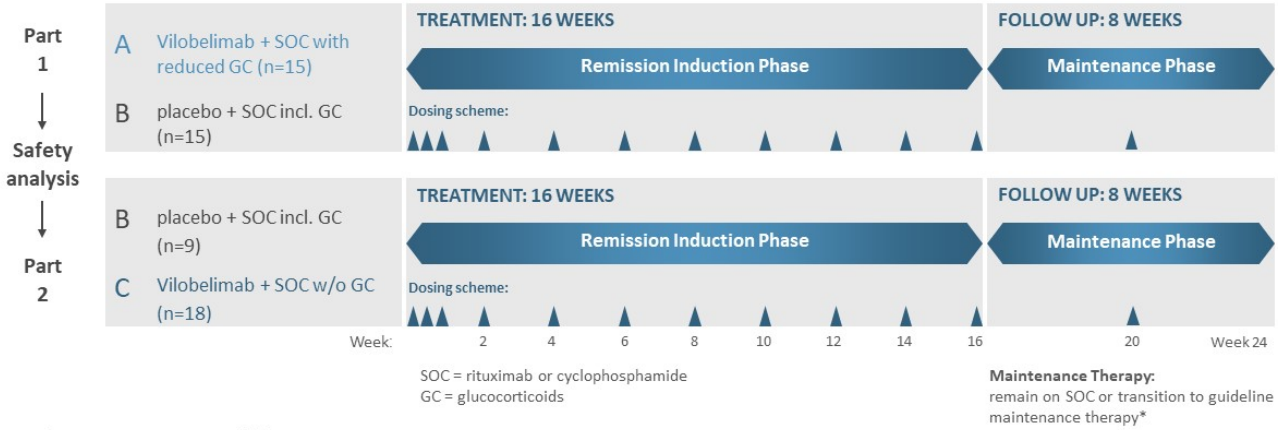
## PHASE II TOPLINE RESULTS

- Three-arm, placebo-controlled trial with 16 weeks of treatment and 8 weeks follow-up (n=19)
- **Primary endpoint met: safe and well-tolerated** in patients with AAV when added to SOC;
  - Observed TEAEs are reflective of the disease and SOC treatment
- **Efficacy endpoints** (study not powered for statistical significance)**:**
  - All three treatment groups showed **a strong clinical response** (50% reduction in BVAS) **at week 16**
  - **Clinical remission** (BVAS = 0): **higher number & percentage of patients in remission in vilobelimab groups at various timepoints** compared to SOC plus placebo




TEAEs: Treatment-emergent adverse events

# Phase II Study in AAV in EU (IXCHANGE)
# Study Design




SOC = rituximab or cyclophosphamide
GC = glucocorticoids

**Maintenance Therapy:**
remain on SOC or transition to guideline maintenance therapy*

**Study (total enrolled: n=57**)**

- Primary objective: Proof of concept for efficacy of vilobelimab **as replacement for** glucocorticoid (GC) therapy in GPA and MPA
- Secondary objectives: To assess safety and tolerability of vilobelimab & compare toxicity of standard-dose GC with vilobelimab

* Guideline maintenance allows for: azathioprin / methotrexate / mycophenolate mofetil / low dose corticosteroids
** Enrolled two more patients on Part 2 over the goal

# Phase II Study in AAV in the EU (IXCHANGE) Results

## PHASE II TOPLINE RESULTS (IXCHANGE)

- Study demonstrated proof of concept for the use of vilobelimab to reduce use of GC therapy in subjects with Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA); achieved comparable efficacy to standard of care GC therapy
- Use of vilobelimab instead of GC led to a substantially lower observed glucocorticoid toxicity when compared to the SDGC and RDGC groups
- Total mean accumulative dose of GC administered after screening until end of study was approximately 7 times lower in vilobelimab only group compared to the SDGC
- Lowest vasculitis damage index (VDI) total score at week 16 in vilobelimab only group
- Vilobelimab demonstrated good safety and tolerability with lowest reported TEAEs in the vilobelimab only treatment arm

**BVAS Week 16 Endpoint Phase II IXCHANGE Trial**

| Treatment Groups | BVAS 50% (Clinical Response) | BVAS=0 (Clinical Remission) |
|---|---|---|
| Vilobelimab + no GC | 16/18 (89%) | 14/18 (78%) |
| High dose steroid SOC (SDGC) | 22/23* (96%) | 20/23* (87%) |
| Vilobelimab + low dose GC (RDGC) | 10/13** (77%) | 10/13** (77%) |
| Total vilobelimab | 26/31** (84%) | 24/31** (77%) |

SDGC = High dose steroid SOC; RDGC = Reduced dose GC

*1 missing at week 16 ; **2 missing at week 16

# Phase II Study in AAV in the EU (IXCHANGE): Use of GC and GC-induced toxicity

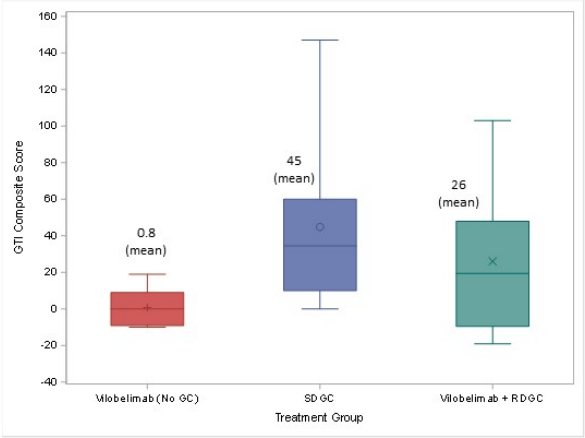
## Cumulative Glucocorticoid intake (Day -28 to Day 1)

| Prednisone equivalent dose (mg) | Vilobelimab (No GC) (N=18) | SDGC (N=24) | Vilobelimab + RDGC (N=15) |
|---|---|---|---|
| Subjects with no GC intake within period | 1 | 1 | 1 |
| Subjects with GC intake within period | 17 | 23 | 14 |
| Mean | 1894.7 | 1750.1 | 2438.8 |

## Cumulative Glucocorticoid intake during study (after screening)

| Prednisone equivalent dose (mg) | Vilobelimab (No GC) (N=18) | SDGC (N=24) | Vilobelimab + RDGC (N=15) |
|---|---|---|---|
| Subjects with no GC intake within period | 2 | 0 | 0 |
| Subjects with GC intake within period | 16 | 24 | 15 |
| Mean | 541.9 | 3751.3 | 1485.8 |

## Boxplot of GTI* composite score at week 16




* GTI=Glucocorticoid Toxicity Index (version 1). This index scores change in Body Mass Index, change in glucose tolerance, change in blood pressure, change in blood lipids, steroid myopathy, skin toxicity, neuropsychiatric toxicity, infections and other. Score can vary from -35 to +410, with higher numbers indicating higher observed toxicity.


# VILOBELIMAB (IFX-1) FOR SEVERE COVID-19

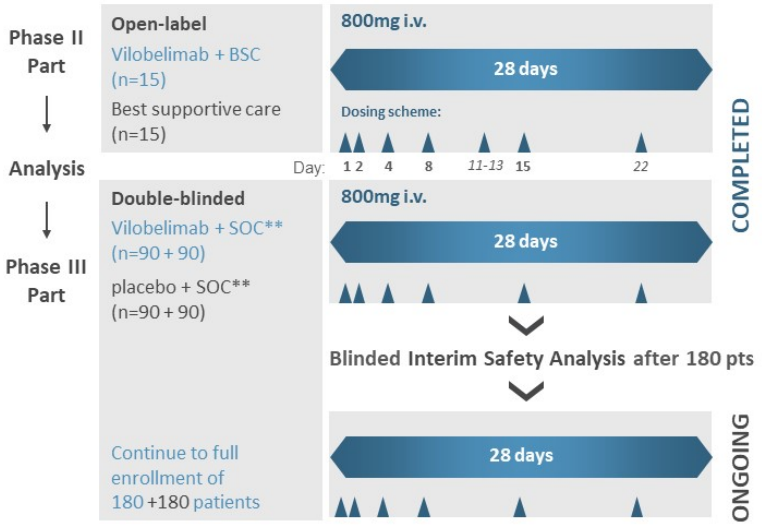
# Design of Phase II/III study with Vilobelimab in Severe COVID-19

## STUDY DESIGN

- Critically ill intubated* patients with COVID-19 induced pneumonia
- Phase III primary endpoint: 28-day all-cause mortality
- Other key endpoints include assessments of organ support, disease improvement on ordinal scale

## STATUS

- **Phase 2 part completed:** Encouraging topline results published
- **Phase 3 part fully enrolled: *369 patients*** Topline data expected by Q1 2022
- IDMC recommended continuing the trial at interim analysis (180 patients evaluated)




* In Phase III part, eligible patients must be early intubated. In the Phase II part, patients were enrolled if either early intubated or dependent on oxygen delivery
** SOC includes venous thromboembolism prophylaxis at a minimum and may include other specific recommended treatments for COVID-19 per the locally adopted treatment recommendation

# Phase II Part Results: Overview

## PHASE II STUDY RESULTS*

- **Primary endpoint:** No difference detected in improvements between groups in PaO2/FiO2 ratio
  - High variability between patients
  - Conclusion: Endpoint not suitable as response parameter
- **Key secondary and other endpoints - Observed effects with vilobelimab compared to best standard of care:**
  - **50% lower all-cause mortality rate** (13% in vilobelimab group vs 27% for control group)
  - **Fewer patients experienced renal impairment** assessed by estimated glomerular filtration rates
  - **Faster reversal of blood lymphocytopenia**
  - **Reduction in tissue damage**: Greater lowering of lactate dehydrogenase concentrations
  - Temporary but **statistically significant increase in D-dimer levels** in first days after vilobelimab administration - **potential signal of induction of blood clot lysis**

* Vlaar, A et al. *Lancet Rheumatol 2020.* https://doi.org/10.1016/S2665-9913(20)30341-6


# VILOBELIMAB (IFX-1) IN ONCOLOGY

# Cutaneous Squamous Cell Carcinoma (cSCC)

## *PD-1 or PD-L1 Inhibitor Resistant/Refractory Locally Advanced or Metastatic Patients*

### POTENTIAL ROLE OF C5A IN ONCOLOGY & cSCC

- **C5a induces an immunosuppressive tumor microenvironment**
  - Accumulation of immunosuppressive MDSC and M2 macrophages[1]
  - Induction of PD-L1 expression on TAM[1,2]
  - PD-L1 + TAM are predictive of worse outcome of PD-1 inhibitor treatment[3]
- **C5a promotes metastases**
  - Increase of EMT, tumor cell motility and vascular permeability[4]
- **C5a is readily available in the tumor environment and may promote tumor growth directly**
  - Tumor cells, immune cells and coagulation pathway generate C5a[5]
  - Tumor cells inhibit complement deactivation[2]
  - C5aR expression increased in many epithelial tumors, incl. cSCC[1]

### DISEASE INFORMATION cSCC

- Risk factors include HS, cumulative UV radiation, irradiation, chronic inflammatory processes, immunosuppression, β-HPV infection, BRAF-inhibitor treatment (e.g., vemurafinib, dabrafenib)[6]
- **Estimated incidence: 15-35 per 100,000 people**; expected to increase 2-4% per year; **Metastasizes in approximately 2-5%** of cases[7,8,10]
- Advanced SCC 10-year survival rates **<20%** with regional lymph node involvement and **<10%** with distant metastases. Distant metastases have median survival of <2 years[7,9]
- PD-1 checkpoint inhibitors pembrolizumab or cemiplimab are FDA approved for locally advanced, recurrent or metastatic cSCC (see FDA labeling)
- No treatment is available for PD-1 or PD-L1 resistant or refractory patients

**› Inhibition of C5a signaling in the tumor microenvironment may decrease tumor growth**
**Combination of C5a with PD-1 checkpoint inhibition could reverse resistance to PD-1 or PD-L1 inhibitor therapy**

EMT: epithelial–mesenchymal transition; MDSC: myeloid-derived suppressor cell; TAM: tumor-associated macrophages


1. Medler et al., 2018; 2. Bonavita, 2015; 3. Liu, et al., 2019; 4. Hu et al., 2016; 5. Corrales et al., 2012; 6. Que et al., 2018; 7. Stratigos et al., 2015; 8. Burton et al., 2016; 9. Hillen et al., 2018; 10. Li et al, 2015

# Cutaneous Squamous Cell Carcinoma (cSCC): Phase II Study Underway

## INCLUSION CRITERIA

- Locally advanced or metastatic cSCC
- Refractory or resistant to PD-1 or PD-L1 inhibitor
- Locally advanced cSCC not amenable to curative treatment
- Metastatic cSCC resistant to all approved therapies

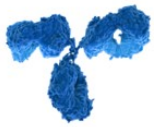
## Primary Endpoints

- Arm A:
  Assess antitumor activity of vilobelimab
- Arm B:
  Determine maximum tolerated dose (MTD) or recommended Phase II dose (RP2D)
  Assess antitumor activity and safety profile of vilobelimab + pembrolizumab


DLT: Dose limiting toxicity; CR: complete response; PR: partial response


# STRATEGY AND OUTLOOK

# Medium Term Deliverables and Strategic Objectives



## GOALS AND STRATEGY

Advance vilobelimab in **HS and PG towards Phase III and ultimate approval based on regulatory guidance**

Complete **Phase III development of vilobelimab** in **Severe COVID-19; submit for approval** if results positive

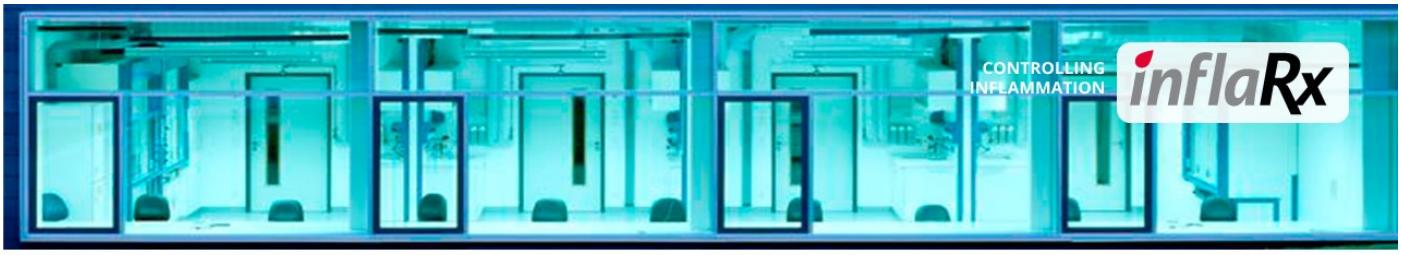
Plan to discuss next steps for the **AAV program** with regulatory authorities

Continue to explore application of vilobelimab **oncology in clinical development**

Explore extension of pipeline with initiation of clinical development of vilobelimab in **other complement-mediated autoimmune / inflammatory diseases**

**Pursue development of early-stage pipeline** and continue to expand the breadth of our anti-C5a technology

› **Strong cash balance to pursue these activities: €120.6 million as of September 30, 2021**

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