

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 January 10, 2022

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 January 10, 2022, InflaRx N.V. (the “Company”) issued a press release titled “InflaRx Announces New Pipeline Program -- Oral C5aR Inhibitor.”

On January 10, 2022, the Company announced a new pipeline program, INF904, an oral small molecule inhibitor of C5aR. The Company expects to initiate a Phase I program in the second half of 2022 and plans to study INF904 in complement-mediated, chronic autoimmune and inflammatory diseases where oral administration is the preferred choice for patients. A copy of the press release is attached hereto as Exhibit 99.1 and is being furnished and shall not be deemed filed or incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

In connection with a conference to be held by H.C. Wainwright & Co. going live on January 10, 2022 and a conference to be held by J.P. Morgan on January 13, 2022, the Company has updated its corporate presentation (the “Corporate Presentation”). A copy of the Corporate Presentation is attached hereto as Exhibit 99.2 and is being furnished and shall not be deemed filed or incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.. The Corporate Presentation will also be made available in the Investors section on the Company’s website 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: January 10, 2022

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated January 10, 2022
99.2	InflaRx N.V. Corporate Presentation



InflaRx Announces New Pipeline Program – Oral C5aR Inhibitor

- Regulatory discussions on Phase I program have been initiated
- First-in-human study expected to start in the second half of 2022

Jena, Germany, January 10, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced a new pipeline program, INF904, an oral small molecule inhibitor of C5aR.

“Inhibition of the C5a/C5aR axis provides strong anti-inflammatory effects in a variety of diseases. Blockade of C5a using highly specific antibodies, such as vilobelimab, may offer a fast, effective, and safe way to control C5a-induced inflammation. In addition to this approach, inhibition of C5aR by oral small molecules may provide the ease of administration required for effective long-term treatment for more chronic inflammatory diseases. In INF904, we have discovered a small molecule C5aR inhibitor, which has shown best-in-class potential in preclinical studies. We believe that INF904 could become a powerful inflammation-fighting tool that is highly complementary to vilobelimab,” said Prof. Renfeng Guo, Chief Scientific Officer and Founder of InflaRx.

InflaRx recently has been granted a composition of matter patent for INF904 and associated compounds by the US Patent and Trademark Office and has completed IND-enabling (preclinical) studies that demonstrated no obvious toxicological findings even in the highest dose groups in required GLP toxicity analyses. In these preclinical studies, oral INF904 showed higher plasma exposure in animals, including non-human primates, and improved inhibitory activity in a hamster neutropenia model compared to the marketed C5aR inhibitor. Anti-inflammatory therapeutic effects in several preclinical disease models were also demonstrated by INF904. Further, in contrast to the marketed C5aR inhibitor, in vitro experiments showed INF904 has substantially less inhibition of the cytochrome P450 3A4/5 (CYP3A4/5) enzymes, which play an important role in the metabolism of a variety of drugs, including glucocorticoids.

InflaRx expects to initiate a Phase I program in the second half of 2022 and plans to study INF904 in complement-mediated, chronic autoimmune and inflammatory diseases where oral administration is the preferred choice for patients.



About InflaRx N.V.:

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary technology to discover and develop first-in-class or best-in-class, potent and specific inhibitors of C5a and C5aR. Complement C5a and C5aR are powerful inflammatory mediators 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.

Contacts:

InflaRx N.V.

Jordan Zwick – Chief Strategy Officer

Jason Stewart – Strategy & Investor Relations

Email: IR@inflarx.de

Tel: +1 917-338-6523

MC Services AG

Katja Arnold, Laurie Doyle, Andreas Jungfer

Email: inflarx@mc-services.eu

Europe: +49 89-210 2280

US: +1-339-832-0752

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 preclinical trials and planned clinical trials of INF904 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.



inflaRx

CONTROLLING
INFLAMMATION

CORPORATE PRESENTATION

January 2022



IMPORTANT NOTICE AND DISCLAIMER

This presentation has been prepared by InflaRx N.V. ("InflaRx"), a US-Nasdaq publicly listed Dutch company having its principal place of business in Germany. This presentation is made for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy securities. The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this presentation unless stated otherwise, and neither the delivery of this presentation at any time, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

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.



LEAD PRODUCT CANDIDATE WITH PIVOTAL PROGRAM FOCUS ON IMMUNODERMATOLOGICAL DISEASES



Clinical Efficacy and Clean Safety Profile enabling Vilobelimab to Advance in Multiple Indications

- **Hidradenitis Suppurativa (HS):** Initiated **pivotal study program in Q1 2022** after receiving no comments from the FDA in the 30-day review period
- **Pyoderma Gangraenosum (PG):** Positive Phase IIa data reported – gathering regulatory input on next steps for a pivotal program
- **Severe COVID-19:** Phase III enrollment completed; **topline data expected in Q1 2022**
- **ANCA-associated vasculitis (AAV):** Positive Phase II data enabling further development
- **Cutaneous squamous cell carcinoma (cSCC):** Phase II study ongoing

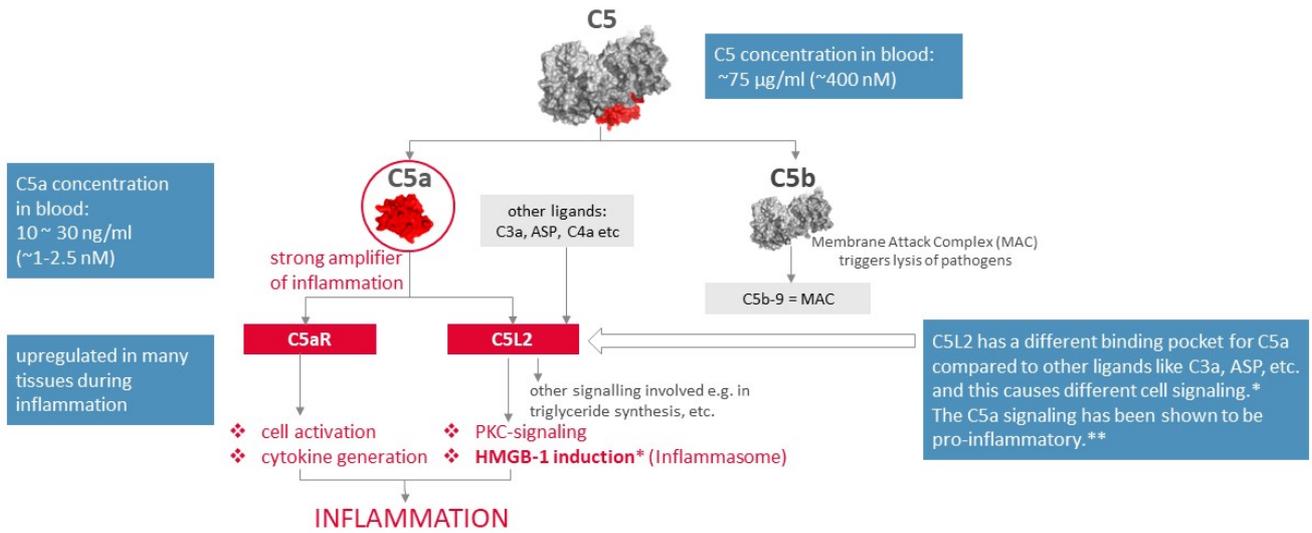
New Program: Oral C5aR Inhibitor INF904 to Enter Clinic in H2 2022

- INF904 shows promising activity and clean safety profile in animals
- Best-in-class potential
- US patent issued in October 2021

Pipeline with Multiple Opportunities

	FRANCHISE	INDICATIONS	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	UPDATE
Vilobelimab <i>CSa Inhibitor</i>	Immunodermatology	Hidradenitis Suppurativa (HS)					Pivotal trial initiated with new primary endpoint
		Pyoderma Gangraenosum (PG)					Positive preliminary Phase IIa open label results
	Life-threatening Inflammatory Diseases	Severe COVID-19					Phase II/III study: Phase II results published; Phase III fully enrolled, topline data expected Q1 2022
		ANCA-Associated Vasculitis (AAV)					Positive data in two Phase II trials
Oncology	Cutaneous Squamous Cell Carcinoma (cSCC)					Phase II trial ongoing: first patient dosed in June 2021	
IFX002 <i>CSa Inhibitor</i>	Undisclosed Chronic Inflammatory and Autoimmune Diseases						Developing for optimized use for other chronic inflammatory indications
INF904 <i>Oral CSaR inhibitor</i>	Undisclosed Chronic Inflammatory and Autoimmune Diseases						First-in-human study to be initiated in H2 2022

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), 104 Songlin et. al. J. Biol. Chem. 2019; 294(21) 8384-839 Muenstermann et al.. Virulence, 2020; 10(1) 677-694



Vilobelimab

Immunodermatology Focus

- Hidradenitis Suppurativa (HS)
 - Pyoderma Gangraenosum (PG)
-

Hidradenitis Suppurativa (HS)

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 tunnels leading to considerable scarring and functional disability
- Hurley staging system used to classify progression / chronicity (Stage I – III)

Prevalence

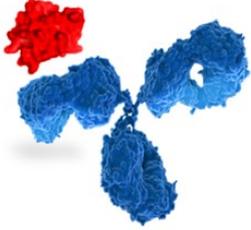
- Likely > 200,000 moderate to severe (Hurley II+III) HS patients in US
- Higher prevalence in Europe with reports > 1% total HS prevalence

Current Treatment – Medical Need

- Humira®(adalimumab) (TNF-alpha inhibitor) is the only approved biological in US and Europe
- Established (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*
- No treatment approved for or targeted at reducing draining tunnels as most burdensome lesion

SHINE Phase II Study

Results and Conclusions



» RESULTS

- HiSCR primary endpoint and dose response signal not met but signal towards improved AN count for the highest dose cohort
- Statistically significant change in draining tunnels (dTs) and in ANdT count detected for the highest dose cohort
- **Pharmacodynamic studies suggests that higher doses are needed for optimized efficacy**
- Open label extension (OLE): in the responder group, 71% maintain HiSCR response by week 40; signals of sustainable reduction of lesion counts during long term treatment detected (with sub-optimal long-term dosing)

» OUR CONCLUSIONS

- **HiSCR is burdened by high variability** (driven by AN count variability) and does not capture reduction of dTs
- **Increased dose required** for full vilobelimab efficacy
- **Reduction in all inflammatory lesions achieved with vilobelimab high-dose** with a durable long-term effect detected even at sub-optimal doses
- **Long-term vilobelimab treatment was well tolerated**, no drug-related serious adverse events (SAEs) in OLE phase

HS Phase III Development

Study Initiation



FDA MEETINGS & NEXT STEPS

FDA Type A meeting (August 2021)

- Received feedback from FDA **supportive of a new primary endpoint measuring reductions in all three inflammatory HS lesions**, including **Draining Tunnels**
 - FDA had previously agreed to the Phase III dosing regimen, a higher dose than studied in the Phase IIB SHINE study
- Pivotal development program to focus on patients suffering from **moderate to severe HS with active draining disease**, as supported by FDA
- FDA feedback incorporated in pivotal study protocol and **submitted in Q4 2021**; The FDA had no comments during the 30-day review period

InflaRx has initiated the Phase III with a new primary endpoint, the modified HiSCR

- Details about the new endpoint and the Phase III study design to be shared at virtual R&D event on February 3



InflaRx has initiated the Phase III with a new primary endpoint, the modified HiSCR

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

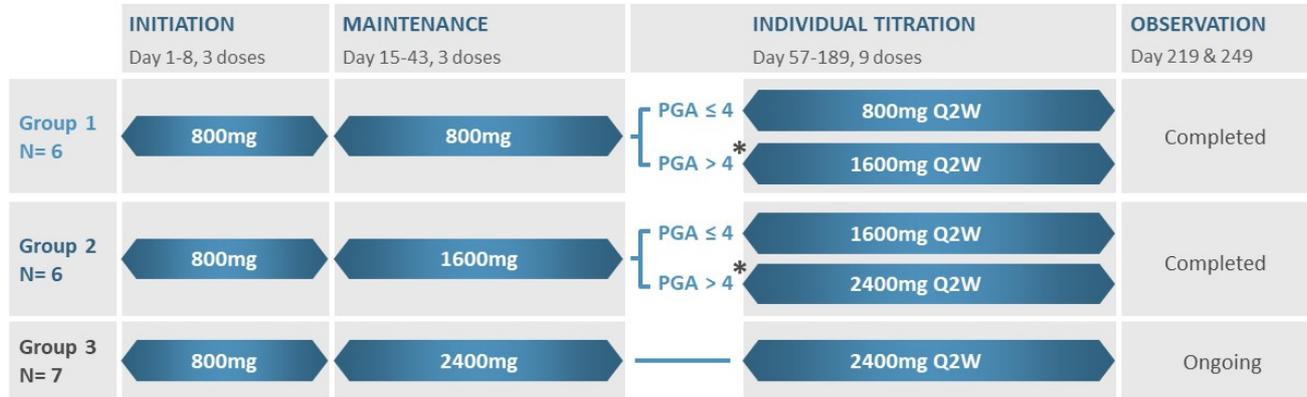


> **Strong rationale for treatment with vilobelimab: PG associated with neutrophilic skin infiltration in affected areas and lesions, potentially triggered by C5a**

PG Phase IIa

Study Design

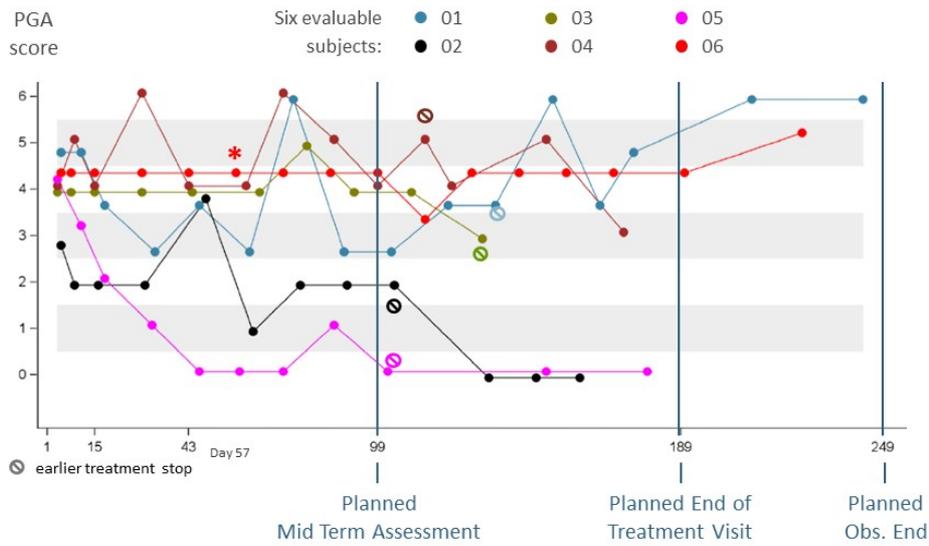
- 19 patients enrolled in the study
- **Primary endpoint:** Safety
- **Key secondary endpoints:** Responder rate defined as PGA ≤ 3 (PGA of ≤ 1 is considered clinical remission and closure of target ulcer); Time to complete closure of target ulcer



* 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)



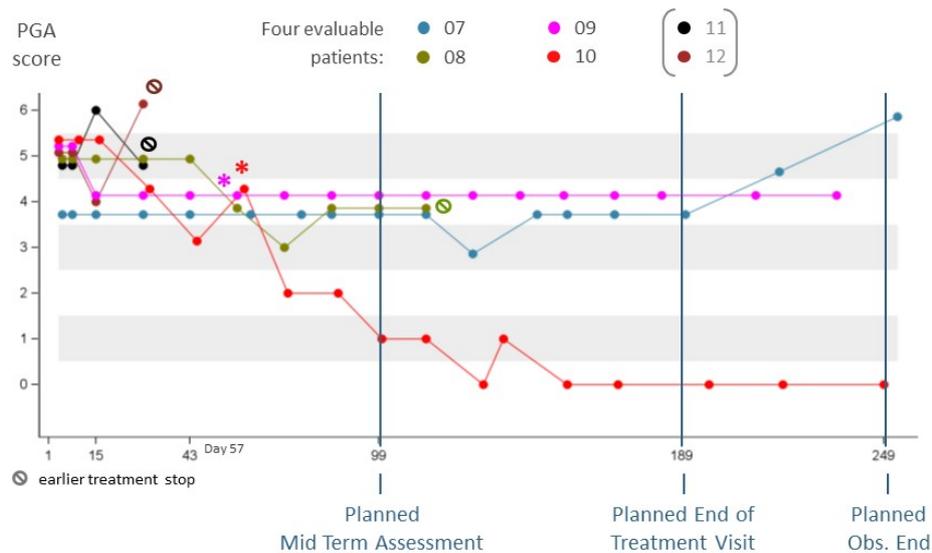
GROUP 1 RESULTS

- 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)



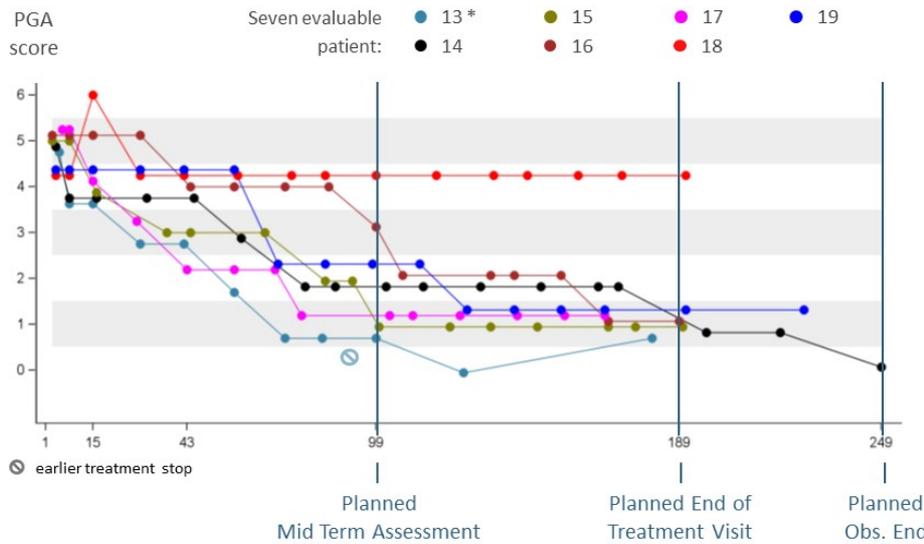
GROUP 2 RESULTS

- 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)

PG Phase IIa

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 mm²



▶ Day 99

PGA = 1

Area: 0.00 mm²



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

PGA = 1

Area: 0.00 mm²



PG Phase IIa

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: Cyclosporin and methylprednisolone October 2018 – September 2019, failed. Dapsone September 2020 – November 2020.

Concomitant Medication: Prednisone 10 mg since October 2018

▶ Baseline

Area: 1285 mm²



▶ Day 99

PGA = 2

Area: 0.0 mm²



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

PGA = 1

Area: calculation not yet available



PG Phase IIa

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 mm²



▶ Day 85

PGA = 1

Area: 0.00 mm²



▶ Day 89, end of treatment visit

PGA = 1

Area: calculation not yet available



PG Phase IIa Study Results

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 AEs detected



CLINICAL RESPONSE CONCLUSION

- Out of 17 evaluable patients at end of treatment visit or day of last drug administration
 - Clinical Remission (PGA \leq 1): 9 patients (53%)
 - Clinical Response (PGA \leq 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 of dose-dependent drug activity in PG



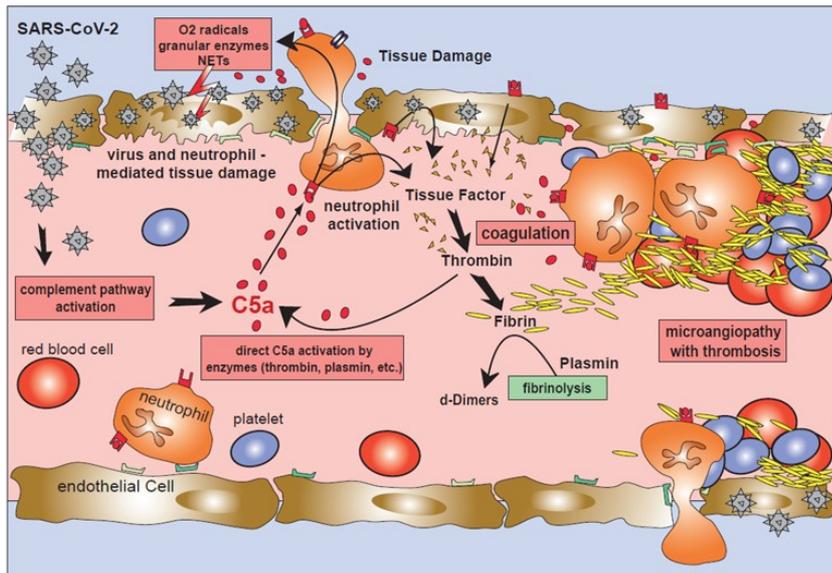
Vilobelimab

Life-threatening Inflammatory Diseases

- COVID-19
 - ANCA Associated Vasculitis (AAV)
-

COVID-19 induced Vascular Injury – Potential Role of C5a

Model for Proposed Mode of Action of C5a in COVID-19 induced vascular injury



Source: InflaRx GmbH

OUR HYPOTHESIS

- Endothelial damage is induced by SARS-CoV-2 infection which also activates the complement system leading to C5a generation.
- C5a activates neutrophils via C5aR, leading to increased adherence to endothelial cells and damage through generation of oxidative radicals, granular enzyme release and neutrophil extracellular traps (NETs).
- C5a induces release of tissue factor from neutrophils & endothelial cells, which promotes coagulation, leading to Fibrin formation.
- Thrombin, plasmin and other enzymes can further induce direct C5a activation (through direct cleavage of C5), which may establish a vicious circle leading to microangiopathy with thrombosis

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](https://doi.org/10.1016/S2665-9913(20)30341-6)

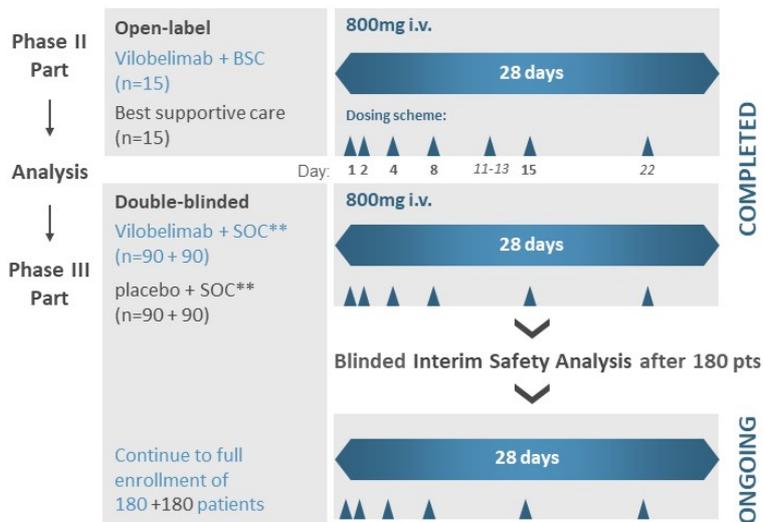
Design of Phase II/III Study with Vilobelimab in Severe COVID-19

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 II part completed:**
Topline results published
- **Phase III 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 Studies in AAV

Results



EU PHASE II TOPLINE RESULTS (N=57 TOTAL)



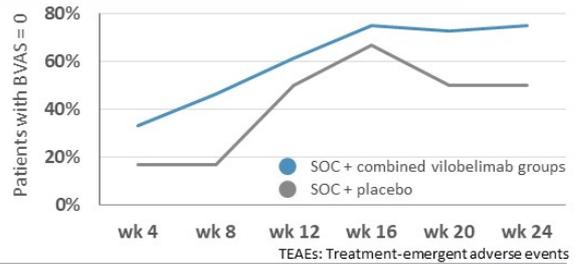
- Demonstrated **Proof of concept** for vilobelimab to reduce use of **glucocorticoid (GC)** therapy in AAV
- Achieved comparable efficacy to standard of care GC therapy
- Use of vilobelimab instead of GC led to a **substantially lower observed glucocorticoid toxicity**
- Lowest vasculitis damage index (VDI) total score at week 16 in vilobelimab only group



US PHASE II TOPLINE RESULTS (N=19)



- **Primary endpoint met; safe and well-tolerated** in patients with AAV
Observed TEAEs are reflective of the disease and SOC treatment
- 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**





Vilobelimab Oncology

- Cutaneous Squamous Cell Carcinoma (cSCC)
-

Cutaneous Squamous Cell Carcinoma (cSCC)

Phase II Study Underway

POTENTIAL ROLE OF C5A IN ONCOLOGY & cSCC

- C5a induces an immunosuppressive tumor microenvironment
- C5a promotes metastases
- C5a is readily available in the tumor environment and may promote tumor growth directly

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

DISEASE INFORMATION cSCC

- **Estimated incidence: 15-35 per 100,000 people**; expected to increase 2-4% per year; **Metastasizes in approximately 2-5%** of cases^{1,2,4}
- 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**^{1,3}
- 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



INF904

New Pipeline Program

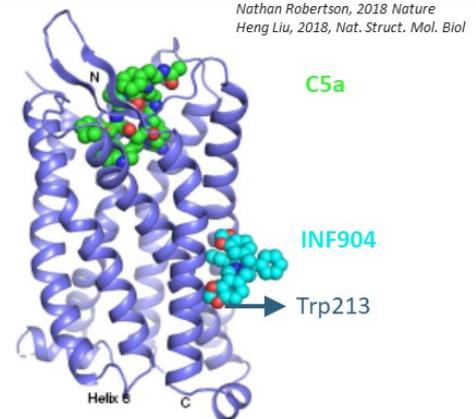


Background

C5aR and its allosteric inhibitor INF904

☆ C5a and INF904

- **C5a receptor (C5aR):**
 - a 7-transmembrane G-protein-coupled-receptor expressed primarily on granulocytes, mediates the major pathophysiological effects of C5a
 - C5aR proven to be an important drug target with FDA approval of a chemical C5aR inhibitor in AAV in 2021
- INF904 binds to a well-known allosteric site in C5aR
- INF904 has a novel Markush structure
- US patent was issued in October 2021



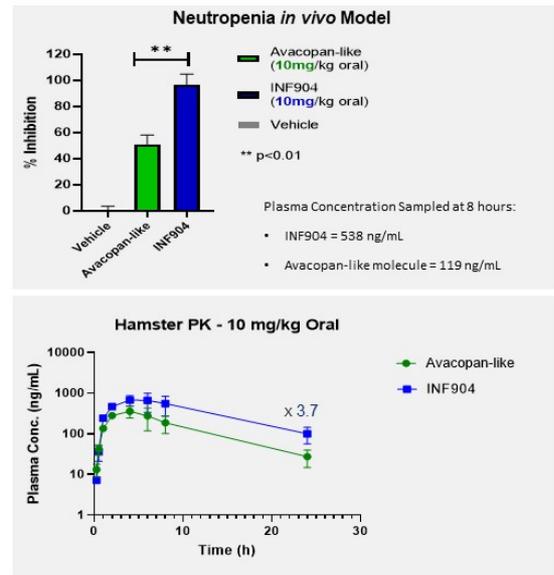
> C5a binds to orthosteric binding site on the top
INF904 bind to allosteric binding site on the side

INF904

Potential for Best in Class C5aR Inhibition

PROGRAM DETAILS

- INF904 shows **no obvious toxicological findings** even in the highest dose groups in required GLP toxicity analyses
- INF904 shows a **high in vitro potency** with a desired IC50 (<1nM) in calcium mobilization assay
- In vitro analysis of INF904's effect on CYP3A against Avacopan-like molecule shows **significantly less CYP3A4/5 inhibition** which play an important role of metabolic clearance of glucocorticoids
- Oral INF904 shows **higher plasma exposures** in several in-vivo models vs. Avacopan-like molecule
- Oral INF904 shows a **better potency in in-vivo neutropenia model** vs. Avacopan-like molecule
- Oral INF904 shows **therapeutic benefit / efficacy** in renal disease models and peritonitis model
- **Regulatory discussions on Phase I program have been initiated**
- **First-in-human clinical trial expected to start in H2 2022**





Strategy and Outlook



Strategic Objectives

Immuno-dermatology Focus



- **HS: Initiate Phase III program** with vilobelimab, incorporating novel endpoint
- **PG: Advance vilobelimab towards Phase III based on regulatory guidance**

Additional Potential Upside



- **Severe COVID-19: Complete Phase III** with vilobelimab; **Submit for approval** if results are positive
- **AAV:** Discuss next steps for vilobelimab with regulatory authorities
- **Oncology:** Continue to explore clinical application of vilobelimab
- **Advance INF904 into first-in-human study**

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



CONTROLLING
INFLAMMATION

inflaRx

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
Chief Strategy Officer

 Email: IR@inflarx.de
