

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 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 January 11, 2021, InflaRx N.V. (the “Company”) issued a press release titled “InflaRx Provides Update on Vilobelimab (IFX-1) Development.” The press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

In connection with a conference held by J.P. Morgan, on January 11, 2021, 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 is also available on the Company’s website located at www.inflarx.de, and the presentation will be available both live and in recorded form on the Company’s website, as well.

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 11, 2021

By: /s/Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated January 11, 2021
99.2	InflaRx N.V. January 2021 Corporate Presentation



InflaRx Provides Update on Vilobelimab (IFX-1) Development

- Multiple data readouts expected in 2021
- Phase II trial in patients with cutaneous squamous cell carcinoma expected to start in the first half of 2021

Jena, Germany, January 11, 2021 – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today provided an update on the ongoing development of vilobelimab (IFX-1), a first-in-class anti-C5a antibody.

Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx, said: “Despite the challenges of COVID-19, we made strong development progress with vilobelimab in 2020. We also are happy to be able to do our part in fighting the ongoing pandemic as we evaluate vilobelimab in patients with severe COVID-19, who as we all know are in desperate need of safe and effective treatments. Looking to the year ahead, we expect to have several important data readouts. We are also excited that we will soon start our first trial in oncology, an important new indication for vilobelimab.”

Oncology

The Company today announced plans to start an open label, multicenter Phase II study evaluating vilobelimab alone and in combination with pembrolizumab in patients with PD-1 or PD-L1 inhibitor resistant/refractory locally advanced or metastatic cutaneous squamous cell carcinoma (cSCC).

cSCC is the second most common nonmelanoma skin cancer/keratinocyte carcinoma and represents 20% to 50% of all skin cancers. Although the majority of cSCCs are successfully excised surgically, a subset has features associated with a higher likelihood of recurrence, metastasis, and death.

The non-comparative two-stage Phase II trial is expected to start in the first half of 2021 and will be a multi-national study, including sites in Europe, the US and elsewhere. The study investigates two independent arms: vilobelimab alone and vilobelimab in combination with pembrolizumab. The main objectives of the trial are to assess the antitumor activity and safety of vilobelimab monotherapy and to determine the maximum tolerated or recommended dose, safety and antitumor activity in the combination arm.



Hidradenitis Suppurativa (HS)

The Company has been assessing different strategies to progress the clinical development of vilobelimab for HS in the United States. InflaRx plans to submit a Special Protocol Assessment (SPA) to the Food & Drug Administration (FDA) for the Phase III trial in Hidradenitis Suppurativa in the first quarter of 2021. Details on the Phase III design will be provided once an agreement has been reached with the FDA.

SPA is a process in which a company may ask to meet with the FDA to reach an agreement on the design and size of a trial to determine if it adequately addresses scientific and regulatory requirements for a study that could support marketing approval. An SPA agreement indicates concurrence by FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses) for a study intended to support a future marketing application.

InflaRx believes the SPA provides the best way forward to reach an agreement on the trial design for its pivotal Phase III program with the FDA.

In Europe, as previously reported in 2020, InflaRx had positive scientific advice from the European Medicines Agency (EMA) about the European pathway for regulatory approval, including supporting the use of a new primary endpoint, the International Hidradenitis Suppurativa Severity Score (IHS4). The Company is working diligently to address the additional feedback received to achieve alignment with the US strategy for a global Phase III development program in HS.

Severe COVID-19

The Phase III part of the global Phase II/III trial evaluating vilobelimab in mechanically ventilated patients with COVID-19 was initiated in mid-September, and recruitment is currently ongoing in Europe, with other regions in the process of being added. The study is enrolling as planned with a total goal of 360 patients. A blinded interim analysis is planned after 180 patients, with a potential early stop of the trial for efficacy or futility. Topline data from the trial are expected to be available in 2021.



InflaRx is a founding member of the Biotech Emergency Alliance for Therapies against COVID-19 (BEAT-COV), an association of four German medium-sized biotechnology companies with promising COVID-19 therapeutic approaches in late stages of clinical development. The initiative calls on policymakers in Germany to take clear decisions to promote the development of therapeutics for COVID-19 patients. BEAT-COV calls for significant government support to finance and to speed up late-stage clinical development, production, approval, and market launch of targeted treatment options.

ANCA-associated Vasculitis (AAV)

InflaRx recently reported the completion of enrollment in the European Phase II IXCHANGE study of vilobelimab in AAV. Topline data from the randomized, double-blind, placebo-controlled trial with 57 patients are expected by the end of 2021.

Vilobelimab is also being studied in the US Phase II IXPLORE study in patients with AAV. The main objective of this randomized, double-blind, placebo-controlled study is to evaluate the safety of vilobelimab, as this is the first time the drug is being administered to patients with AAV in the US. Topline results are expected by mid-2021.

Pyoderma Gangraenosum

The Phase IIa open label trial continues to enroll patients in the higher dose groups. Promising initial data from the first five patients in the study were announced in 2020. Results from the higher dose groups are expected in 2021.

About vilobelimab (IFX-1):

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. Approximately 300 people have been treated with vilobelimab in clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various indications, including Hidradenitis Suppurativa, ANCA-associated vasculitis, Pyoderma Gangraenosum, cancer and severe COVID-19.



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 pre-clinical development and clinical 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 2021



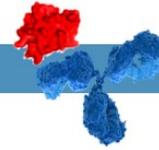
IMPORTANT NOTICE AND DISCLAIMER

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.

Investment Highlights



☆ LEADING PROPRIETARY ANTI-C5A TECHNOLOGY

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

☆ ESTABLISHED CLINICAL EFFICACY FOR 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**

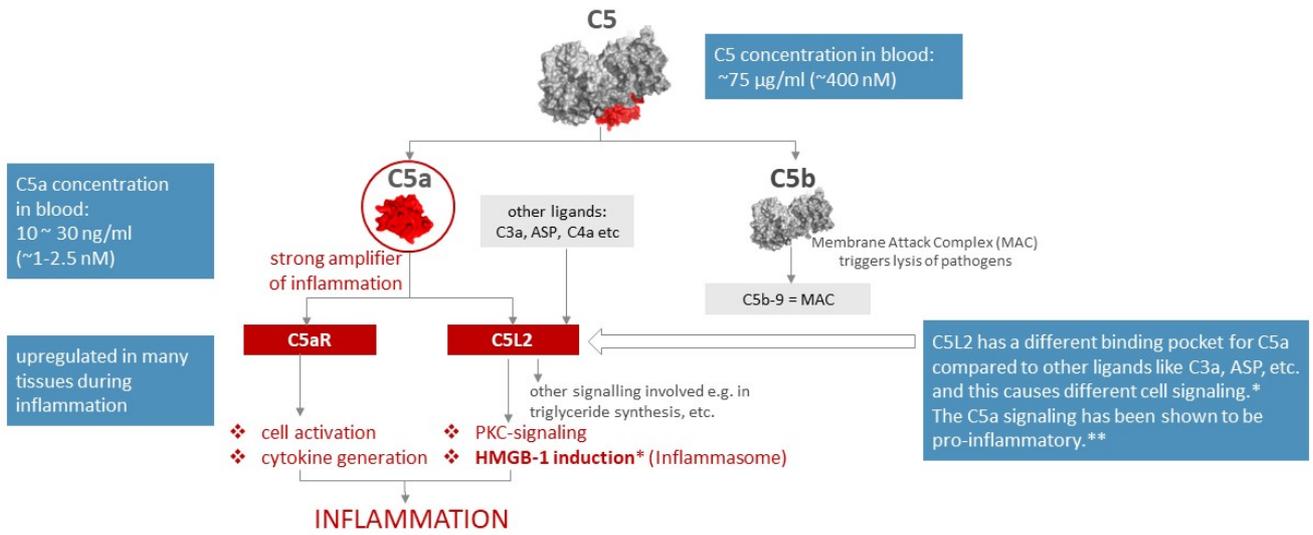
☆ MULTIPLE ONGOING STUDIES

- **Severe COVID-19:** Phase III part of study is enrolling
- **HS:** Plan to submit Special Protocol Assessment (SPA) to the FDA for the Phase III in Q1 2021; positive scientific advice from European Medicines Agency (EMA)
- **ANCA-associated vasculitis (AAV) & Pyoderma Gangraenosum (PG):** clinical data readouts expected in 2021

Pipeline with Multiple Opportunities

	PROPOSED INDICATIONS	PREVALENCE	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	UPDATE
Vilobelimab (IFX-1) <i>CSa Inhibitor</i>	Severe COVID-19	<ul style="list-style-type: none"> Currently unknown 					<ul style="list-style-type: none"> Phase II/III study; Phase II part: results published; Phase III part is enrolling
	Hidradenitis Suppurativa	<ul style="list-style-type: none"> Up to 200,000 patients in the US Over 200,000 patients in Europe 					<ul style="list-style-type: none"> Phase IIb completed Positive EMA advice on pivotal program with new primary endpoint; SPA for the Phase III to be submitted to the FDA in Q1 '21
	ANCA-Associated Vasculitis	<ul style="list-style-type: none"> ~40,000 patients in the US ~75,000 patients in Europe 					<ul style="list-style-type: none"> Phase II: treatment completed in US; fully enrolled in Europe
	Pyoderma Gangraenosum	<ul style="list-style-type: none"> ~50,000 patients in the US and Europe are affected 					<ul style="list-style-type: none"> Phase IIa open label; enrollment ongoing
	Cutaneous Squamous Cell Carcinoma (cSCC)	<ul style="list-style-type: none"> PD-1 or PD-L1 Resistant/Refractory Locally Advanced or Metastatic 					<ul style="list-style-type: none"> Phase II to be initiated in FH 2021
IFX-2 <i>CSa Inhibitor</i>	Undisclosed Chronic Inflammatory and Autoimmune Diseases	<ul style="list-style-type: none"> Not applicable 					<ul style="list-style-type: none"> Developing for optimized use for other chronic inflammatory indications

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 (IFX-1) FOR SEVERE COVID-19

Coronavirus Disease 2019 (COVID-19)

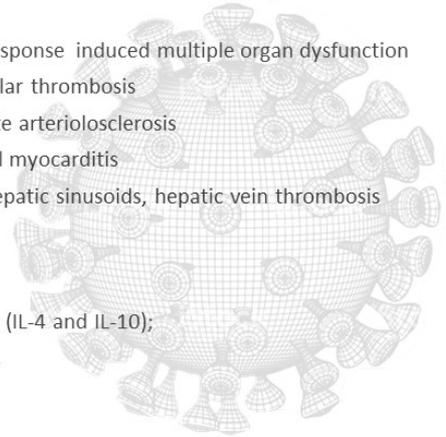
A VIRAL PNEUMONIA WITH A BROAD SPECTRUM OF IMMUNE-MEDIATED INJURY

CLINICAL & PATHOLOGY FEATURES

- Death is typically caused by respiratory failure and viral sepsis in presence of immune-response induced multiple organ dysfunction
- Pathology in lung: extensive inflammation, diffuse alveolar damage, marked microvascular thrombosis
 - in kidney: thrombotic microangiopathy within the glomeruli; mild to moderate arteriosclerosis
 - in heart: scattered individual cell myocyte necrosis, not sufficient sign of viral myocarditis
 - in liver: macro-vesicular steatosis, cirrhosis, platelet-fibrin microthrombi in hepatic sinusoids, hepatic vein thrombosis

LABORATORY FINDINGS

- Systemic inflammation: lymphocytopenia (>80%) + elevated CRP (>60%) at admission
- Moderately elevated levels of both Th1 cytokines (IL-6, TNF- α , IFN- γ) and TH2 cytokines (IL-4 and IL-10);
- Other frequently increased markers: LDH, AST, ALT, troponin-I, ESR, serum ferritin et al.
- Coagulopathy markers: increased levels of D-dimer, fibrinogen, VWF, Factor VIII et al.
- Complement activation markers: C5a, sC5b-9

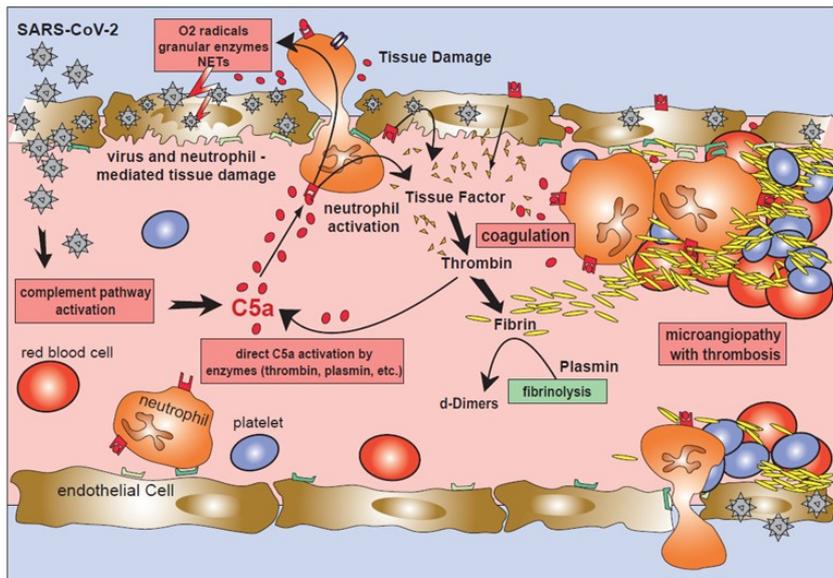


Source: <https://www.chinalawtranslate.com/en/coronavirus-treatment-plan-7/>;

Rapkiewicz et al, EclinicalMedicine(2020) 100434; Goshua et al., Lancet Haematol 2020 June 30; Cugno et al., J Allergy Clin Immunol July 2020:215;

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

- 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 as well as 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

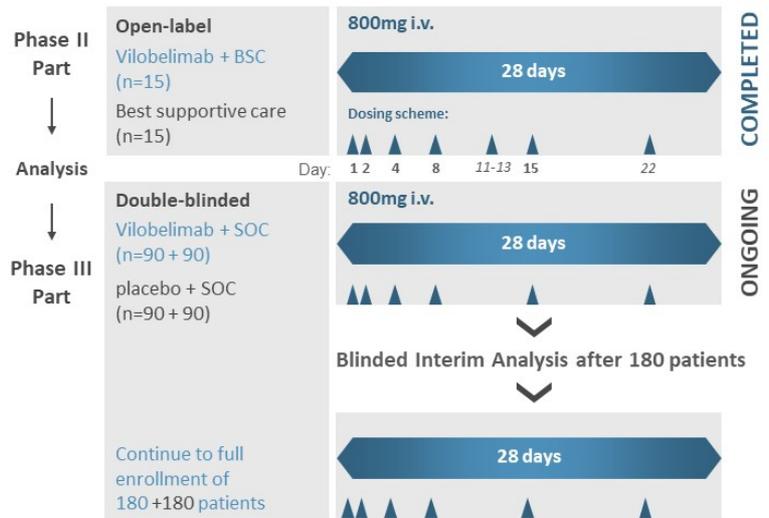
Design of Phase II/III study with Vilobelimab in Severe COVID-19

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, assessment of disease improvement on the ordinal scale

STATUS

- **Phase 2 part completed:**
Encouraging Topline Results published
- **Phase 3 part ongoing:**
Blinded Interim Analysis after 180 patients
Potential for an early stop for efficacy or futility



SOC: Standard of Care

SOC includes venous thromboembolism prophylaxis at a minimum and may include other specific recommended treatments for COVID-19 per the locally adopted treatment recommendations.

* in phase III part eligible patients must be early intubated, in the phase II part, patients were enrolled if either being early intubated or dependent on oxygen delivery

Phase II Part Results: Overview



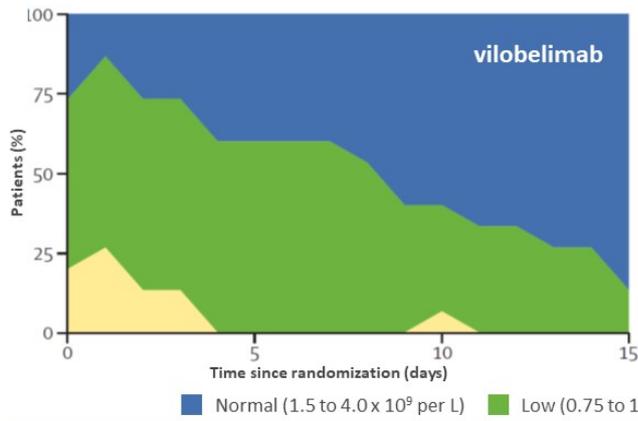
PHASE II STUDY RESULTS*

- **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 in vilobelimab treatment arm compared to best standard of care arm:**
 - **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 of D-dimer levels** in first days after vilobelimab administration - **potential signal of induction of blood clot lysis**

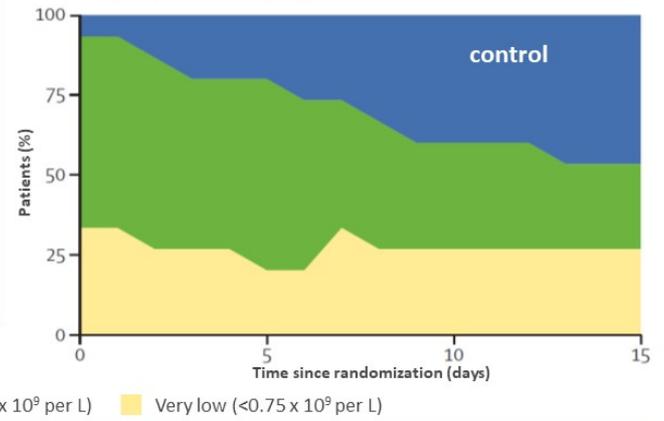
* Vlaar, A et al. *Lancet Rheumatol* 2020. [https://doi.org/10.1016/S2665-9913\(20\)30341-6](https://doi.org/10.1016/S2665-9913(20)30341-6)

Phase II Part Results: Lymphocyte Count Normalization

LYMPHOCYTES - VILOBELIMAB+BEST SUPPORTIVE CARE*



LYMPHOCYTES - BEST SUPPORTIVE CARE ONLY*



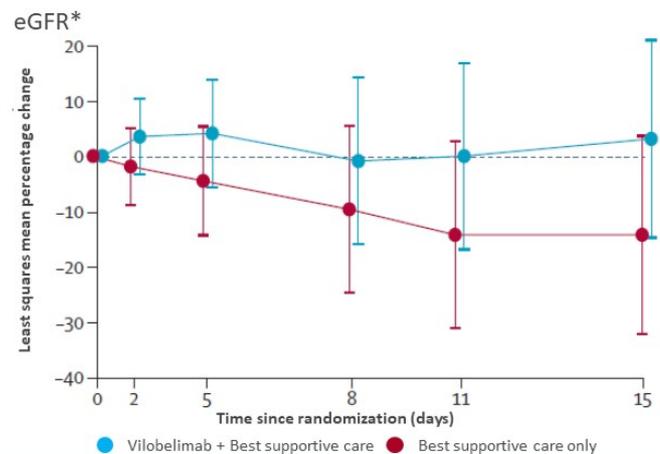
➤ **87% of vilobelimab treated patients showed normalized lymphocytes counts vs 47 % in control group (p=0.050)**

* Shift Plot Lymphocytes – all randomized, n=15 per arm
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)

Phase II Part Results: eGFR Level Stability

eGFR LEVEL

- At day 15, mean eGFR showed a 3% change from baseline in the vilobelimab group versus -14% in the best supportive care group
- Only 1 patient developed a kidney injury in the vilobelimab group vs 4 patients in the control group developed acute renal failure with moderately to severely decreased eGFR (7% vs. 27%)
- **eGFR higher and mean unchanged in vilobelimab-treated patients** while a trend to worsening could be detected in the best supportive care group



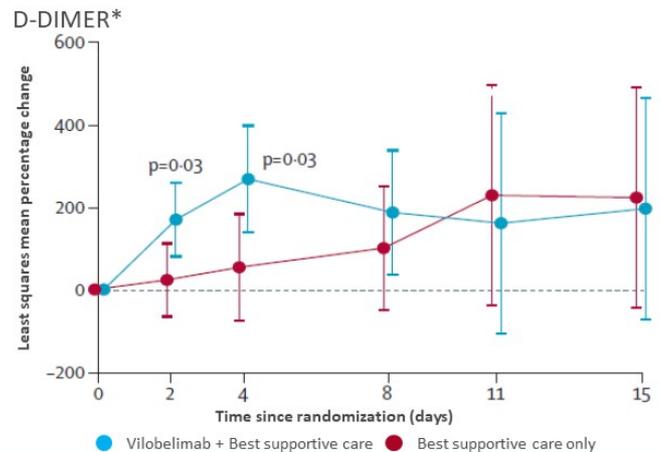
> **Kidney function in vilobelimab treated patients remained mostly within normal limits or declined only mildly**

eGFR: estimated glomerular filtration rate
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)

Phase II Part Results: Vilobelimab Treatment Associated Significant Increase in D-dimer Levels

LEVELS OF D-DIMER

- **Significant temporary D-dimer increase** observed directly upon initiation of vilobelimab therapy (day 2)
- Possible sign of induction of a direct or indirect pro-fibrinolytic effect
- In line with observed 3-fold lower rate in pulmonary embolisms reported as SAE's in vilobelimab treatment arm and may be mechanistically linked to observed lower death rate
- Hypothesis: Inhibition of C5a by vilobelimab may lead to a **decrease in C5a-induced coagulation** and **directly or indirectly fostered thrombolysis**



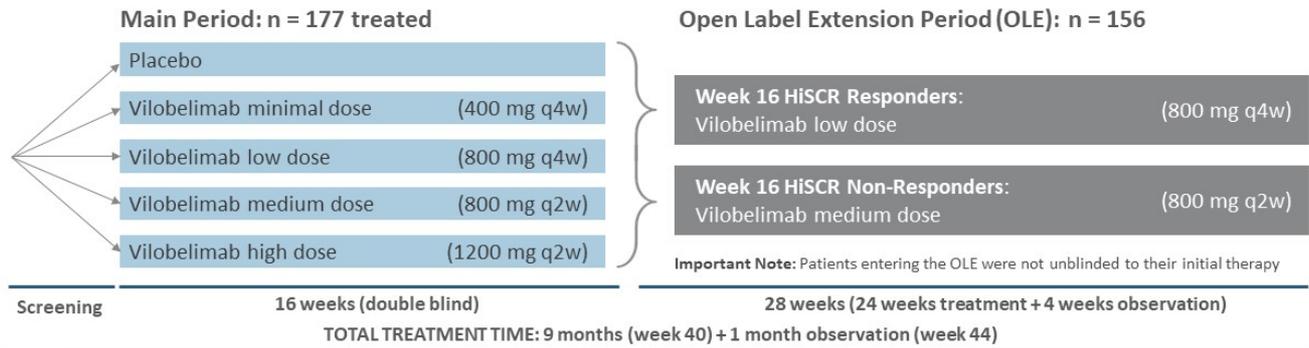
> Vilobelimab treatment was associated with significant increase of D-dimer levels, suggesting potential pro-fibrinolytic activity of anti-C5a treatment



VILOBELIMAB (IFX-1) FOR HIDRADENITIS SUPPURATIVA

Hidradenitis Suppurativa (HS) Phase IIb SHINE Study Details

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



MAIN GOALS

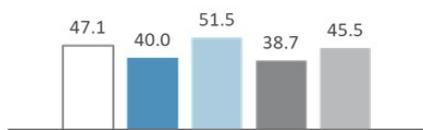
- Test a dose-dependent effect of vilobelimab on HiSCR* response at week 16 (primary endpoint)
- Assess long-term safety of vilobelimab
- Test durability of response with lower maintenance therapy in open label extension period

*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

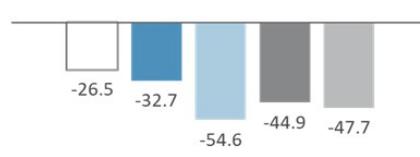
SHINE Study: Outcome at Week 16

HISCR RESPONSE RATE (%) WEEK 16*

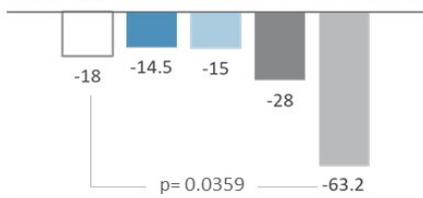
n = approx. 35/group



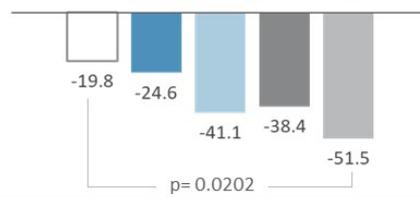
AN COUNT SCORE CHANGE (MEAN %) WEEK 16*



DRAINING FISTULA CHANGE (MEAN %) **



IHS-4 SCORE CHANGE (MEAN %) **



Treatment group:

- placebo
- minimum
- low
- medium
- high

> **Primary Endpoint HiSCR Dose Response Signal not met but Signal towards Improved AN count**
Statistically significant change in DF and in IHS-4 scores detected

* Full analysis set

** Full analysis set – baseline adjusted

IHS-4 Points = Sum of the number of inflammatory nodules (x1), number of abscesses (x2) and number of draining fistulas (x4)
 AN Count = Total number of combined inflammatory nodules and abscesses

CONTROLLING
INFLAMMATION

inflaRx

INNOVATION

TEAMWORK

DISCOVERY

COMPLEMENT

SHINE Study and Next Steps in HS Development



OUR CONCLUSIONS

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



CURRENT STATUS & NEXT STEPS

- **Scientific Advice received from EMA in July 2020**
 - EMA agreed to key proposals for pivotal program** including change of primary endpoint to support MAA submission
 - Acknowledged that HiSCR response does not account for the clinical relevance of a reduction in draining fistulas.
 - Agreed that **IHS4 could be an appropriate tool to evaluate the efficacy of a novel compound in HS as primary endpoint**
- **End-of-Phase II meeting with FDA held in June 2020**
 - FDA agreed to key proposals** to support BLA submission
 - FDA did not agree that IHS4 score is fit for purpose as a primary efficacy endpoint tool to support labeling
 - Recommended that IFRX obtain HS patient input to help determine validity
- **Plan to submit Special Protocol Assessment (SPA) to the FDA for the Phase III in Q1 2021**

* Serious adverse events

** including aspects of the Ph III design, vilobelimab dosing, target study population, nonclinical & clinical pharmacology packages



VILOBELIMAB (IFX-1) FOR ANCA-ASSOCIATED VASCULITIS

AAV, Life-threatening Autoimmune Condition

Clinical PoC established for Role of C5a / C5aR Pathway in AAV



LEADING PROPRIETARY ANTI-C5A TECHNOLOGY

- C5a is essential for development of MPA-ANCA crescentic glomerulonephritis in a mouse model
- Complement activation in active AAV patients is significant
- Evidence for role of C5a / C5aR pathway through recent Phase III success of an oral C5aR inhibitor*



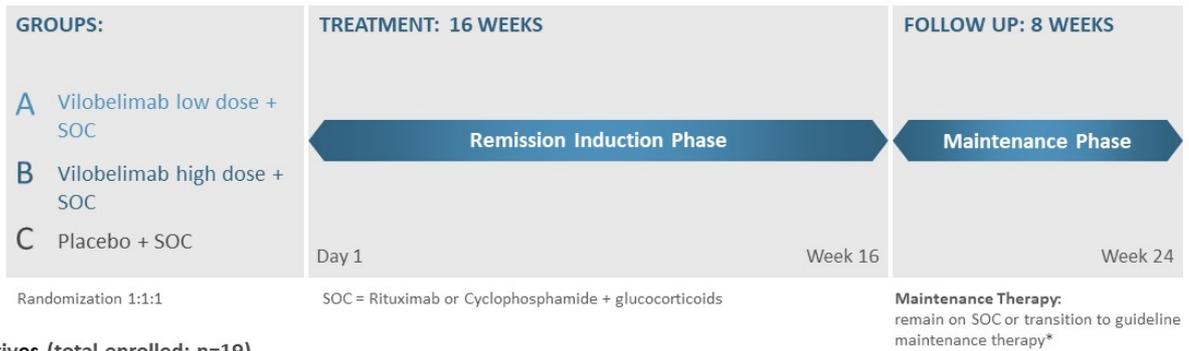
POTENTIAL ADVANTAGES OF VILOBELIMAB (IFX-1) FOR AAV

- **Rapid onset of action:** intravenous administration with fast onset of action, inhibiting C5a signaling completely protecting from C5a induced priming and activation of neutrophils → potentially quicker induction of remission compared to the SOC
- **Potential potency difference:** by blocking upstream ligand C5a, which inhibits signaling through both receptors, C5aR and C5L2; C5a pro-inflammatory MoA through both C5aR and C5L2 has been shown to be important for ANCA-primed and C5a-induced neutrophil degranulation as key disease-driving mechanism in AAV.**

* ChemoCentryx. (25 November 2019). ChemoCentryx and VFMCRP Announce Positive Topline Data from Pivotal Phase III ADVOCATE Trial Demonstrating Avacopan's Superiority Over Standard of Care in ANCA-Associated Vasculitis; (9 July 2020) ChemoCentryx Submits New Drug Application to the U.S. FDA for Avacopan in ANCA-Associated Vasculitis

** Hao & Wang et al 2013, PLoS ONE, 8(6)

Phase II Study in AAV in the US (IXPLORE) Study Design



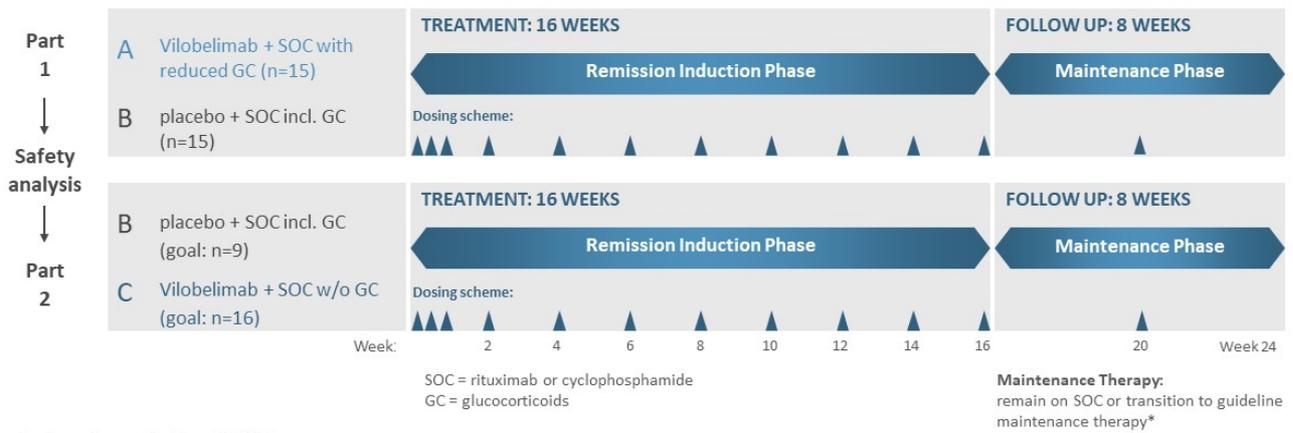
Study objectives (total enrolled: n=19)

- Assess safety and efficacy of vilobelimab in AAV
- Primary objective: Safety
- Secondary objectives: Efficacy (Response rate based on the Birmingham Vasculitis Score (BVAS), various other)

Status:

- Blinded interim analysis completed
- Enrollment finalized early following assessment of interim analysis and of potential impact of COVID-19 pandemic; patients have finished treatment and data is expected in the first half of 2021

Phase II study in AAV in Europe (IXCHANGE) Study Design



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
- Status: Blinded interim analysis of Part 1 completed. Part 2: enrollment finalized. Final results expected in 2021



VILOBELIMAB (IFX-1) FOR PYODERMA GANGRAENOSUM

Pyoderma Gangraenosum (PG)

Rationale and Phase IIa Study Overview



STUDY OBJECTIVE

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



STUDY DESIGN

- Open label
- Multicenter
- Target enrollment – **18 patients**
- First patient dosed – June 2019



TREATMENT

- The first 5 patients were dosed at 800mg biweekly and have finished treatment
- Two additional biweekly higher dose groups have been added; enrollment is ongoing, and patients are under treatment
- **Additional data in the higher dose groups expected in 2021**

Status and Next Steps

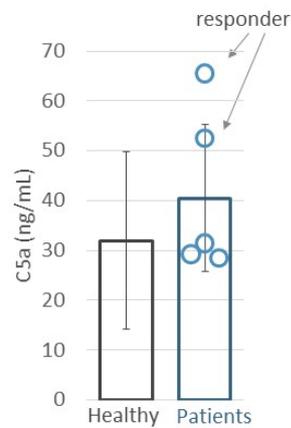
PHASE IIA STUDY UPDATE

Data reported on first 5 patients treated in Feb 2020

- 2 of 5 pts: **complete closure of target ulcer; full disease remission**; remained healed even after finishing the study
- Additional patient: **initial wound healing activity** in first 2-3 weeks of treatment; no wound size decrease or closure detected
- Remaining 2 pts had extensive disease*: target ulcer did not heal, were still under treatment
- The "responders" showed higher baseline C5a levels
- PD analysis (C5a levels) warranted higher dosing
- Two additional higher dose groups are enrolling, and patients are undergoing treatment
- **Additional data with higher doses expected in 2021**

* very large ulceration / ulcer reaching entire circumference of leg

C5A LEVELS AT BASELINE



TREATMENTS

Two Patients Show Complete Wound Closure with Vilobelimab Treatment





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 macrophages¹
 - Induction of PD-L1 expression on tumor-associated macrophages (TAM)^{1,2}
 - PD-L1+ TAM are predictive for worse outcome of PD-1 inhibitor treatment³
- **C5a promotes metastases**
 - Increase of EMT, tumor cell motility and vascular permeability⁴
- **C5a is readily available in the tumor environment and may promote tumor growth directly**
 - Tumor cells, immune cells and coagulation pathway generate C5a⁵
 - Tumor cells inhibit complement deactivation²
 - C5aR expression increased in many epithelial tumors, incl. cSCC¹

DISEASE INFORMATION cSCC

- Risk factors include Hidradenitis Suppurativa, cumulative UV radiation, irradiation, chronic inflammatory processes, immunosuppression, β -HPV infection, BRAF-inhibitor treatment (e.g., vemurafinib, dabrafenib)⁶
- **Incidence is estimated at 15-35 per 100,000 people**; expected to increase 2-4% per year; **Metastasizes in approximately 2-5%** of cases overall^{7,8,10}
- Advanced SCC 10-year survival rates are **less than 20%** with regional lymph node involvement and **less than 10%** with distant metastases: Distant metastases have median survival of less than 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

Study in Cutaneous Squamous Cell Carcinoma (cSCC)

INCLUSION CRITERIA

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

Primary Endpoints

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



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



STRATEGY AND OUTLOOK



GOALS AND STRATEGY

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

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

Explore application of vilobelimab for **AAV, PG and 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

Continue to explore broadening the R&D pipeline beyond anti-C5a technology as part of diversification strategy



We have a strong cash balance to pursue these activities (€95.7 million as of September 30, 2020)



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