

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 EXPLORE 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.

Contacts:

InflaRx N.V.

Jordan Zwick – Chief Strategy Officer

Email: jordan.zwick@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 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.










































