

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, 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 5, 2022, InflaRx N.V. (the “Company”) issued a press release titled “InflaRx Initiates Phase III Clinical Program with Vilobelimab in Hidradenitis Suppurativa.”

InflaRx announced on January 5, 2022 that having received no comments from the FDA following the 30-day review period after the Phase III protocol was submitted, it will initiate the Phase III program with vilobelimab in hidradenitis suppurativa patients with active draining tunnels. The new primary endpoint, called modified HiSCR (Hidradenitis Suppurativa Clinical Response), will include measuring the reduction of all three types of lesions - inflammatory nodules, abscesses and draining tunnels.

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.

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 5, 2022

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated January 5, 2022



InflaRx Initiates Phase III Clinical Program with Vilobelimab in Hidradenitis Suppurativa

- Phase III study to include a new primary endpoint, the modified HiSCR
- New primary endpoint and Phase III trial design to be discussed in detail at virtual R&D event on February 3rd
- Phase III program to focus on HS patients with active draining tunnels and will start enrolling patients in Q2

Jena, Germany, January 5, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced the initiation of the Phase III program with vilobelimab in hidradenitis suppurativa (HS) patients with active draining tunnels. The new primary endpoint, called modified HiSCR (Hidradenitis Suppurativa Clinical Response), as suggested by the FDA, will include measuring the reduction of all three types of lesions – inflammatory nodules, abscesses and draining tunnels.

“We are excited to be able to move into pivotal testing with vilobelimab for the treatment of hidradenitis suppurativa, a debilitating and painful disease with limited treatment options,” said Dr. Korinna Pilz, Chief Clinical Development Officer. “We have incorporated the FDA’s feedback into the trial design and can now move forward with initiating the Phase III trial. We expect to begin patient recruitment in the second quarter of this year.”

InflaRx completed a Type A meeting with the U.S. Food & Drug Administration (FDA) in September 2021 to align on the Phase III HS study design. The FDA response was supportive of a pivotal study program that focuses on patients with active draining tunnels and a new primary efficacy endpoint that includes measuring the reduction of all three lesions – inflammatory nodules, abscesses and draining tunnels. InflaRx incorporated the FDA’s input and submitted the Phase III protocol to the Agency in late November 2021. The FDA had no comments during the 30-day review period; so, InflaRx will now begin the study, including bringing on clinical sites. Enrollment is slated to start in Q2 2022.

Virtual R&D event to highlight vilobelimab in HS, including Phase III study design

InflaRx will host a virtual R&D event on Thursday, February 3rd, beginning at 8:30 AM EST/2:30 PM CET. The Company will provide an update on vilobelimab development in HS, including details on the Phase III program. To participate in the conference call, participants may pre-register [here](#) and will receive a dedicated link and dial-in details to easily and quickly access the call.



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. 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 indications, including hidradenitis suppurativa, ANCA-associated vasculitis and pyoderma gangraenosum, as well as other areas, including critical 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 technology to discover and develop first-in-class or best-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.

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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 completed, planned and ongoing clinical trials of vilobelimab in hidradenitis suppurativa 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, including based on the modified HiSCR as the primary endpoint for the Company’s Phase III trial of vilobelimab in HS; 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.
