

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 June 2023

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

EXPLANATORY NOTE

On June 21, 2023, InflaRx N.V. issued a press release titled “InflaRx Announces Commercial Launch of Gohibic (vilobelimab) in the U.S. for the Treatment of Critically Ill COVID-19 Patients.” A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated June 21, 2023

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: June 21, 2023

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer



InflaRx Announces Commercial Launch of Gohibic (vilobelimab) in the U.S. for the Treatment of Critically Ill COVID-19 Patients

- Gohibic is now commercially available for hospitals in the U.S.
- Gohibic can be used under an Emergency Use Authorization (EUA) granted by the FDA for treatment of certain critically ill COVID-19 patients

Jena, Germany, June 21, 2023 – InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today the commercial launch of Gohibic (vilobelimab) in the U.S. In April 2023, Gohibic was granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).

Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx, commented: “We are excited to make Gohibic available to certain critically ill COVID-19 patients in the U.S. Our team is proud to contribute to the fight against this terrible virus with a potentially lifesaving therapeutic option for some of the most critically ill COVID-19 patients.”

The data supporting the EUA were based on the previously announced results of the multicenter Phase III PANAMO trial, which showed that vilobelimab treatment improved survival with a relative reduction in 28-day all-cause mortality of 23.9% compared to placebo in the global data set. The data have been published in *The Lancet Respiratory Medicine*.

Gohibic is currently the only drug directed against the complement factor C5a that is authorized for the treatment of certain critically ill COVID-19 patients. InflaRx is continuing discussions with the FDA related to the submission of a Biologics License Application (BLA) for a potential future full approval of Gohibic.

Dr. Thomas Taapken, Chief Financial Officer of InflaRx, commented: “We have built an excellent core commercial team to support the launch and distribution to U.S. hospitals. We also have worked out a time- and cost-efficient model for distribution. We continue to adapt our investments to create a commercial and logistical infrastructure as well as additional manufacturing capacity.”



InflaRx has also completed encouraging meetings with the rapporteur and co-rapporteur member state teams of the European Committee for Medicinal Products for Human Use (CHMP) related to a planned Marketing Authorization Application with the European Medicines Agency (EMA). The Company will provide updates on the status of regulatory submissions in the U.S. and elsewhere once available.

Information for Healthcare Providers related to Ordering Gohibic (vilobelimab)

Healthcare providers can order Gohibic from ASD Healthcare (i) by calling 1-800-746-6273 or (ii) by e-mailing service@asdhealthcare.com. Please provide the product and notational drug code (NDC): Gohibic (NDC 83000-0110-04).

About the Emergency Use Authorization (EUA) for Gohibic (vilobelimab)

The U.S. Food and Drug Administration (FDA) has issued an EUA for the emergency use of Gohibic for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO.

Gohibic has not been approved but has been authorized for emergency use by FDA under an EUA for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO.

The emergency use of Gohibic is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

Important Information about Gohibic (vilobelimab)

Vilobelimab is a first-in-class monoclonal anti-human complement factor C5a antibody that has been granted an EUA for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO.

Vilobelimab is an investigational drug that has not been approved by the FDA for any indication, including for the treatment of COVID-19. There is limited information known about the safety and effectiveness of using Gohibic to treat people in the hospital with COVID-19.

Please see additional information in the Fact Sheet for Healthcare Providers, Fact Sheet for Patients and Parents/Caregivers and FDA Letter of Authorization on the Gohibic website (www.gohibic.com).



Important Safety Information about Gohibic (vilobelimab)

There are limited clinical data available for Gohibic. Serious and unexpected adverse events (AEs) may occur that have not been previously reported with Gohibic use.

Gohibic has been associated with an increase of serious infections. In patients with COVID-19, monitor for signs and symptoms of new infections during and after treatment with Gohibic.

Hypersensitivity reactions have been observed with Gohibic. If a severe hypersensitivity reaction occurs, administration of Gohibic should be discontinued and appropriate therapy initiated.

The most common adverse reactions (incidence $\geq 3\%$) are pneumonia, sepsis, delirium, pulmonary embolism, hypertension, pneumothorax, deep vein thrombosis, herpes simplex, enterococcal infection, bronchopulmonary aspergillosis, hepatic enzyme increased, urinary tract infection, hypoxia, thrombocytopenia, pneumomediastinum, respiratory tract infection, supraventricular tachycardia, constipation and rash.

Healthcare providers and/or their designee are responsible for mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths occurring during Gohibic treatment and considered to be potentially attributable to Gohibic.

Report side effects to the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. In addition, side effects can be reported to InflaRx at: pvusa@inflarx.de

For the full prescribing information and additional important safety information, please visit www.gohibic.com

About Viral Sepsis in SARS-CoV-2 Infection

Invasively mechanically ventilated patients who have tested positive for COVID-19 fulfill the criteria set by the current third international consensus definitions for sepsis, which define sepsis as a “life-threatening organ dysfunction caused by a dysregulated host response to infection.” Viral infection-mediated sepsis is believed to be driven by the inflammatory immune response of a patient to the virus. Observational studies have suggested that the inflammatory response, endothelial permeability and coagulopathy observed in severe COVID-19 are associated with strong complement activation and C5a generation as part of the human innate immune response. By targeting the complement component C5a in critically ill and invasively mechanically ventilated COVID-19 patients, vilobelimab is believed to block a key mediator of this inflammatory host response induced by severe SARS-CoV-2 infection and, thus, potentially offers a mechanism of action that may be independent of the viral variant that has caused such inflammatory response. Inhibition of the C5a / C5aR pathway has been demonstrated to be beneficial or lifesaving in various pre-clinical models of viral lung injury and viral sepsis, including models investigating influenza and corona viruses.



About Vilobelimab

Vilobelimab is a first-in-class monoclonal anti-human complement factor C5a antibody, which highly and effectively blocks the biological activity of C5a and demonstrates high selectivity towards its target in human blood. Thus, vilobelimab leaves the formation of the membrane attack complex (C5b-9) intact as an important defense mechanism of the innate immune system, which is not the case for molecules blocking C5. In pre-clinical studies, vilobelimab has been shown to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response. In addition to development in COVID-19, vilobelimab is also being developed for various debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum and cutaneous squamous cell carcinoma.

The COVID-19 related work described herein is partly funded by the German Federal Government through grant number 16LW0113 (VILO-COVID). All responsibility for the content of this work lies with InflaRx.

About InflaRx

InflaRx GmbH (Germany) and InflaRx Pharmaceuticals Inc. (USA) are wholly owned subsidiaries of InflaRx N.V. (together, “InflaRx”).

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary anti-C5a / C5aR technologies to discover and develop first-in-class or best-in-class, potent and specific inhibitors of C5a and C5aR. Complement C5a and its receptor 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.de.

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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,” “estimate,” “believe,” “predict,” “potential” or “continue,” among others. 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, the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals or our other product candidates; our expectations regarding the size of the patient populations for, market opportunity for, coverage and reimbursement for and clinical utility of Gohibic in its approved or authorized indication or for vilobelimab and any other product candidates, under an EUA and in the future if approved for commercial use in the U.S. or elsewhere; the success of our future clinical trials for vilobelimab and any other product candidates and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials; the timing, progress and results of clinical trials of our product candidates, and statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, the costs of such trials and our research and development programs generally; our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways, including related to our BLA submission for Gohibic (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or Gohibic (vilobelimab) for any indication; whether the FDA, the EMA, or any comparable foreign regulatory authority will accept or agree with the number, design, size, conduct or implementation of our clinical trials, including any proposed primary or secondary endpoints for such trials; our expectations regarding the scope of any approved indication for vilobelimab; our ability to leverage our proprietary anti-C5a and C5aR technologies to discover and develop therapies to treat complement-mediated autoimmune and inflammatory diseases; our ability to protect, maintain and enforce our intellectual property protection for vilobelimab and any other product candidates, and the scope of such protection; our manufacturing capabilities and strategy, including the scalability and cost of our manufacturing methods and processes and the optimization of our manufacturing methods and processes, and our ability to continue to rely on our existing third-party manufacturers and our ability to engage additional third-party manufacturers for our planned future clinical trials and for commercial supply of vilobelimab and for the finished product Gohibic (vilobelimab); our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing; our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if approved, any commercial sales; if any of our product candidates obtain regulatory approval, our ability to comply with and satisfy ongoing obligations and continued regulatory overview; our ability to comply with enacted and future legislation in seeking marketing approval and commercialization; our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel; and our competitive position and the development of and projections relating to our competitors in the development of C5a and C5aR inhibitors or our industry; and the risks, uncertainties and other factors described under the heading “Risk Factors” in our 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.
