



## InflaRx Receives FDA Emergency Use Authorization for Gohibic (vilobelimab) for Treatment of Critically Ill COVID-19 Patients

- Vilobelimab is the first authorized drug to control complement factor C5a, a protein that plays an important and often harmful role in the body's immune response
- FDA granted EUA based on Phase III clinical trial results showing a significant relative reduction in 28-day all-cause mortality of 23.9% compared to placebo in critically ill invasively mechanically ventilated COVID-19 patients
- InflaRx continues the dialogue with FDA to discuss next steps towards a Biologics License Application submission for full approval
- Encouraging pre-submission meetings held with EMA in Europe; InflaRx plans to apply for full approval to treat critically ill COVID-19 patients
- Company to host a conference call tomorrow, April 5th at 8:30 am EDT/2:30 pm CEST

**Jena, Germany, April 04, 2023** – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced that Gohibic (vilobelimab), a first-in-class monoclonal anti-human complement factor C5a antibody, has been granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) for the treatment of coronavirus disease 19 (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, CEO and Founder of InflaRx, said: "We are thrilled and very proud that the FDA has issued an EUA for vilobelimab to treat this very sick patient group, recognizing the lifesaving potential of this first-in-class drug. Despite the availability of vaccines and other treatments for earlier disease stages of COVID-19, many patients are still developing viral sepsis and are progressing to critical status, which often requires invasive mechanical ventilation. As a consequence, we continue to see mortality rates in the range of approximately 2,000 COVID-19-reported deaths per week in the U.S. as reported by the U.S. Centers for Disease Control and Prevention. Today's announcement brings new hope to these patients and their loved ones, and we will work diligently to make this important new treatment available to patients as rapidly as possible."



The data supporting the EUA were based on the previously announced results of the multicenter Phase III PANAMO trial. PANAMO is one of the largest 1:1 randomized, double-blind placebo-controlled trials in invasively mechanically ventilated COVID-19 patients in intensive care units. A total of 369 patients were randomly assigned to the vilobelimab treatment group (six 800-mg infusions) or the placebo group. Both groups also received standard of care, which included treatment with anti-coagulants, dexamethasone and other immunomodulators. The data 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*.

InflaRx continues discussions with FDA related to submission of a BLA for full approval of Gohibic in this COVID-19 indication. InflaRx has also completed encouraging meetings with the rapporteur and co-rapporteur 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). In addition, InflaRx is continuing to develop vilobelimab in other indications, including pyoderma gangrenosum, for which the Company is currently initiating a Phase III trial.

Prof. Renfeng Guo, M.D., Chief Scientific Officer and Founder of InflaRx, said: “This EUA is a great recognition of our COVID-19-related research, which was based on over two decades of groundbreaking work on the tissue and organ-damaging effect of the complement factor C5a as part of the body’s immune response. InflaRx will evaluate broadening our development of vilobelimab in other areas of viral lung injury and viral sepsis where the mechanism has already been researched in pre-clinical models. Our COVID-19 results underscore the anti-inflammatory potential of inhibition of the terminal C5a and C5a receptor pathway in other inflammatory diseases.”

#### **Availability and Distribution Information**

InflaRx has a supply of Gohibic (vilobelimab) available and is working to ramp up production at its third-party manufacturer to roll out supply in the U.S. as soon as possible. The Company is assessing all options for supplying drug to hospitals to enable the treatment of patients. The Company will provide more detailed information once available.



### **Conference call scheduled for Wednesday, April 5, 2023 at 8:30 am EDT/2:30 pm CEST**

InflaRx will host a conference call to discuss today's news on April 5th at 8:30 am EDT (2:30 pm CEST). 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. A replay will be available on the InflaRx website in the Investors - Events & Presentations section.

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

The US 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 invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (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](http://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, supra-ventricular 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](http://www.FDA.gov/medwatch). In addition, side effects can be reported to InflaRx at: [pvusa@inflarx.de](mailto:pvusa@inflarx.de)**

**For additional important safety information, please visit [www.gohibic.com](http://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 (in 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.com](http://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, the status of the EUA for vilobelimab; the timing of supplying COVID-19 patients with, and the availability of, vilobelimab; our ongoing and planned pre-clinical development and clinical trials, including the development of vilobelimab in several indications; our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways; the impact of the COVID-19 pandemic on us; 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; decisions regarding the strategic direction of our business; 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 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.