



## InflaRx Announces Initiation of its Commitment Program for GOHIBIC®(vilobelimab) to Help Broaden Access for Eligible Patients

- *InflaRx to cover costs of GOHIBIC for patients who are treated in line with its Emergency Use Authorization (EUA) but do not survive.*
- *InflaRx is determined to support broader access to GOHIBIC for eligible patients.*

**Ann Arbor, Mich., USA, January 25, 2024** – InflaRx Pharmaceuticals Inc., a subsidiary of InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company pioneering anti-inflammatory therapeutics by targeting the complement system, announced today that the Company has launched [The InflaRx Commitment Program](#) (Commitment Program). Pursuant to the Commitment Program, the cost of GOHIBIC (vilobelimab) will be refunded for up to six (6) administered inpatient doses (the full treatment course) to institutions that meet the eligibility requirements\*, for patients who were administered GOHIBIC in line with its EUA and who died due to COVID-19 in the intensive care unit.

In April 2023, the U.S. Food and Drug Administration (FDA) issued an EUA for GOHIBIC for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of the patient receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO). While GOHIBIC has been FDA authorized, it is not FDA approved for this use.

The Commitment Program is designed to encourage medical facilities across the United States to stock GOHIBIC, since the initiation of treatment is time critical, and to ultimately provide the opportunity for patients to access this potentially life-saving therapy.

According to the Centers for Disease Control, there has been a recent increase in COVID-19 fatality rates, with reported deaths related to this disease in the range of 1,500 deaths per week in the U.S.<sup>1</sup>

Christian Sandrock, M.D., M.P.H., FCCP, Division Vice Chair of Internal Medicine, Director of Critical Care, Professor of Medicine, UC Davis Health, said: *“Once a patient with COVID-19 reaches the point of intubation, there are extremely limited treatments available outside of*

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\* Eligibility Requirements, Terms and Conditions apply. Please see the full Terms and Conditions provided on the webpage: [The InflaRx Commitment Program](#).

<sup>1</sup> [Centers for Disease Control and Prevention. COVID data tracker.](#)



*supportive care and mechanical ventilatory support. With COVID-19 deaths again on the rise, it is critical that doctors have access to more therapies to help save the lives of these patients, particularly for those that have progressed to require mechanical ventilation. With the emergency use authorization of GOHIBIC, the FDA recognized a critical unmet need and provided those of us on the frontlines, fighting this disease, an important new option which has been specifically developed as a potentially life-saving therapy for these sickest patients.”*

He added: *“Many hospitals struggle to provide patient access to all available medicines, even those that may be lifesaving. So, it is reassuring that InflaRx is willing to reimburse the cost of their medicine in cases where the patient does not survive. This shows me that InflaRx is confident in their product, is doing everything it can to support hospitals and get GOHIBIC to patients who are in critical need of intervention.”*

Prof. Niels C. Riedemann, Chief Executive Officer, and Founder of InflaRx, commented: *“COVID-19 continues to take far too many lives. Despite this unacceptable situation, patients do not always have access to approved or authorized treatment options. With today’s announcement, we are demonstrating our strong commitment to help make GOHIBIC available for the most affected COVID-19 patients as a potential life-saving therapy. There are currently no approved or authorized alternatives to GOHIBIC, and we believe that all eligible patients and the physicians responsible for their care should have access to this treatment.”*

The data supporting the EUA for GOHIBIC was based on a multicenter Phase III (PANAMO) trial, one of the largest 1:1 randomized, double-blind placebo-controlled trials in invasively mechanically ventilated COVID-19 patients in intensive care units. The results showed that treatment with GOHIBIC 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 has been published in [The Lancet Respiratory Medicine](#). GOHIBIC is the only drug directed against the complement factor C5a that is authorized for the treatment of certain critically ill COVID-19 patients.

### **Information for Healthcare Facilities for Ordering GOHIBIC (vilobelimab)**

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

For detailed information about the Commitment Program and to file a claim, please visit this link: [The InflaRx Commitment Program](#).

### **About the EUA for GOHIBIC (vilobelimab)**



The 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](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, 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](http://www.FDA.gov/medwatch). In addition, side effects can be reported to InflaRx at: [pvusa@inflarx.de](mailto:pvusa@inflarx.de)**

**For the full prescribing information and 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.

### **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 biotechnology company pioneering anti-inflammatory therapeutics by applying its proprietary anti-C5a and anti-C5aR technologies to discover, develop and commercialize highly potent and specific inhibitors of the complement activation factor C5a and its receptor C5aR. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of inflammatory diseases. InflaRx's lead product candidate, vilobelimab, is a novel, intravenously delivered, first-in-class, anti-C5a monoclonal antibody that selectively binds to free C5a and has demonstrated disease-modifying clinical activity and tolerability in multiple clinical studies in different indications. 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," "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 and related treatment recommendations by medical/healthcare institutes and other third-party organizations, our ability to successfully commercialize and 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, estimated returns and return accruals for, and clinical utility of Gohibic (vilobelimab) in its approved or authorized indication or for vilobelimab and any other product candidates, under an Emergency Use Authorization and in the future if approved for commercial use in the United States or elsewhere; our ability to successfully implement the Commitment Program, the success of our future clinical trials for vilobelimab's treatment of COVID-19 and other debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum, and any other product candidates, including INF904, and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials; the timing, progress and results of pre-clinical studies and 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 Marketing Authorization Application submission for vilobelimab and our biologics license application submission for Gohibic (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or Gohibic (vilobelimab) for any indication; whether the U.S. Food and Drug Administration, the European Medicines Agency 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 oversight; 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 U.S. 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.