InflaRx Receives European Commission Approval for GOHIBIC® (vilobelimab) for the Treatment of SARS-CoV-2-Induced Acute Respiratory Distress Syndrome (ARDS)

Jena, Germany, January 15, 2025– InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company pioneering anti-inflammatory therapeutics targeting the complement system, today announced that the European Commission (EC) has granted marketing authorization under exceptional circumstances for GOHIBIC® (vilobelimab) for the treatment of adult patients with SARS-CoV-2-induced acute respiratory distress syndrome (ARDS) who are receiving systemic corticosteroids as part of standard of care and receiving invasive mechanical ventilation (IMV) with or without extracorporeal membrane oxygenation (ECMO). GOHIBIC is the first and only treatment approved in the European Union for the treatment of SARS-CoV-2-induced ARDS.

Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx, commented: "The European Commission's approval of GOHIBIC, the first approval of its kind, reflects our commitment to ICU patients with SARS-CoV-2-induced ARDS, a pressing medical setting in need of more effective therapeutic options. I would like to thank the entire InflaRx team for its dedication and diligence resulting in this successful marketing authorization, and we are grateful for the support provided by the intensive care physicians, patients and their families who participated in the PANAMO study which supported the marketing authorization application."

The marketing authorization under exceptional circumstances for GOHIBIC is valid in all 27 EU member states as well as Iceland, Liechtenstein, and Norway. InflaRx is considering commercial partnering and distribution options in the EU and does not expect this approach will have a meaningfully negative impact on its cash burn rate.

Important Information about GOHIBIC (vilobelimab)

In the EU, GOHIBIC (vilobelimab) has been granted marketing authorization under exceptional circumstances for the treatment of adult patients with SARS-CoV-2-induced acute respiratory distress syndrome (ARDS) who are receiving systemic corticosteroids as part of standard of care and receiving invasive mechanical ventilation (IMV) (with or without extracorporeal membrane

oxygenation (ECMO)). The EU approval of GOHIBIC is supported by the previously announced results of the multicenter Phase 3 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 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 were published in *The Lancet Respiratory Medicine*.

A marketing authorization under exceptional circumstances is recommended when the benefit/risk assessment is determined to be positive but, due to the rarity of the disease, it's unlikely that comprehensive data can be obtained under normal conditions of use. Under the terms of GOHIBIC's approval in the EC, InflaRx will provide annual updates to EMA on the previously announced clinical platform study planned by the Biomedical Advanced Research and Development Authority (BARDA). Vilobelimab is included in this study as one of three new potential therapies for treating ARDS.

In the U.S., GOHIBIC (vilobelimab) has been granted an Emergency Use Authorization by the Food and Drug Administration (FDA) 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.

GOHIBIC (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 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 ≥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 AEs or deaths that occur during GOHIBIC treatment and are 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 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.

Vilobelimab is being developed for various debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum (PG). Vilobelimab has been granted orphan drug designation

for the treatment of PG by both the FDA and the EMA, as well as fast track designation by the FDA.

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 (Nasdaq: IFRX) is a biopharmaceutical 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 is also developing INF904, an orally administered small molecule inhibitor of the C5a receptor. 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.

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

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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, current expectations and the risks, uncertainties and other factors described under the heading “Risk Factors” and “Cautionary statement regarding forward looking statements” 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.