



InflaRx Submits Request for Emergency Use Authorization to US FDA for Vilobelimab for Treatment of Critically Ill COVID-19 Patients

- Company also earns FDA Fast Track designation for vilobelimab to treat critically ill COVID-19 patients
- EUA submission based on Phase III results in critically ill COVID-19 patients, recently published in *The Lancet Respiratory Medicine*
- Request for EUA follows encouraging interactions with FDA in Type B meeting
- “Gohibic” conditionally accepted by FDA as proprietary name for vilobelimab

Jena, Germany, September 29, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today submitted a request for Emergency Use Authorization (EUA) following encouraging interactions with the US Food and Drug Administration (FDA) at a Type B meeting held this summer. Additionally, InflaRx has been granted Fast Track designation from the FDA for vilobelimab for the treatment of critically ill, intubated, mechanically ventilated COVID-19 patients.

The EUA submission and Fast Track designation are based on the results of the PANAMO trial, one of the largest, global, 1:1 randomized, placebo-controlled Phase III studies conducted in invasively mechanically ventilated, critically ill COVID-19 patients. The detailed results of the study were recently published in the peer-reviewed journal, [The Lancet Respiratory Medicine](#).

Prof. Niels C. Riedemann, CEO and Founder of InflaRx, said: “The EUA submission is an exciting milestone for InflaRx in the development of our lead candidate, vilobelimab. We believe that the data from our Phase III study strongly support the potential of vilobelimab to reduce the number of deaths in critically ill, invasively mechanically ventilated COVID-19 patients. Patients are still progressing to this critical status despite the availability of vaccines and other treatments for earlier disease stages and continue to show high mortality rates.”

He continued: “The FDA’s granting of Fast Track designation for vilobelimab in this indication underscores the need for effective new therapies to treat COVID-19 patients who have progressed to critical disease with viral sepsis and organ failure. We look forward to working with the FDA on the review of our application with the goal of making vilobelimab available to patients in need.”



The FDA's Fast Track designation is designed to facilitate the development and expedite the review of treatments for serious medical conditions, thereby addressing unmet medical needs. Therapies that are included in this program may be eligible for more frequent interactions with the FDA to discuss the development path, and, if the program criteria are met, eligibility for a potential Rolling Review, Accelerated Approval, and Priority Review.

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, which is not the case for molecules blocking the cleavage of C5. Vilobelimab has been demonstrated in pre-clinical studies to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key "amplifier" of this response. Vilobelimab is believed to be the first monoclonal anti-C5a antibody introduced into clinical development. Vilobelimab has been shown to be well tolerated within clinical trials in different disease settings. Vilobelimab is currently being developed for various indications, including pyoderma gangrenosum and critical COVID-19. Vilobelimab is also in Phase II development for patients suffering from cutaneous squamous cell carcinoma.

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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 and C5aR. Complement C5a and 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.



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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 ongoing and planned pre-clinical development and clinical trials, including the development of vilobelimab in several indications, including to treat pyoderma gangrenosum (PG) and critical COVID-19; our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways; our submission of an application to the FDA for emergency use authorization for vilobelimab to treat critical COVID-19 and the FDA’s review of the application; 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 InflaRx’ 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.