InflaRx Announces Plans to Apply for Emergency Use Authorization from the US FDA for Vilobelimab for Treatment of Critically Ill COVID-19 Patients

- Completed encouraging Type B meeting with US FDA
- Application for EUA planned to be submitted in Q3 2022

Jena, Germany, July 26, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced plans to submit a request for Emergency Use Authorization (EUA) following encouraging interactions with the US Food and Drug Administration (FDA) at a recently held Type B meeting. As previously announced, the company had requested the meeting to discuss a potential EUA submission and the development of its first-in-class anti-C5a monoclonal antibody vilobelimab in critically ill, invasively mechanically ventilated COVID-19 patients.

In the meeting with the FDA, the company discussed in detail the completed Phase III part of the PANAMO study in invasively mechanically ventilated, critically ill COVID-19 patients. The company also obtained guidance from the agency on deliverables related to its planned submission for EUA. InflaRx also committed to additional discussions with the agency regarding its further development of vilobelimab for critically ill invasively mechanically ventilated COVID-19 patients.

“With emerging COVID-19 variants and cases and hospitalizations again on the rise, there remains an urgent need for new treatment options, especially for the sickest patients who suffer from an inflammatory response, leading to organ failure. Our constructive interactions with the FDA and the helpful guidance they provided have encouraged us to move forward with applying for EUA for vilobelimab in critically ill COVID-19 patients,” said Prof. Niels C. Riedemann, CEO and Founder of InflaRx. “Our team has committed to submitting the request for an EUA by the end of Q3 2022 and is dedicated to achieving that ambitious goal.”

The company had previously announced encouraging topline results from the PANAMO Phase III study, an international, double-blind, placebo-controlled, randomized clinical trial

investigating vilobelimab in invasively mechanically ventilated COVID-19 patients. The primary efficacy endpoint was 28-day all-cause mortality. In this trial, vilobelimab treatment resulted in a 23.9% relative reduction in 28-day all-cause mortality when compared to the placebo arm in the global data set (n=368 patients). A pre-specified analysis of patients from Western European countries (n=209) showed a 43% relative reduction in 28-day all-cause mortality in the vilobelimab treatment arm when compared to the placebo arm.

For more information please see the press release and the presentation of the data from March 31, 2022.

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.

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 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.

Contacts:

InflaRx N.V.

Email: IR@inflarx.de

MC Services AG

Katja Arnold, Laurie Doyle, Andreas Jungfer
Email: inflarx@mc-services.eu
Europe: +49 89-210 2280
US: +1-339-832-0752

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 to treat pyoderma gangrenosum (PG) and critical COVID-19; the submission of an application to the FDA in the third quarter of 2022 for emergency use authorization for vilobelimab to treat critical COVID-19; 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; 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.