

InflaRx Provides Development Update for Vilobelimab in Pyoderma Gangrenosum and Severe COVID-19

- Orphan Drug Designation granted for treatment of pyoderma gangrenosum (PG) from US FDA and EMA
- Productive end-of-phase II meeting with FDA held for PG; dialogue ongoing related to Phase III program design
- Type B meeting scheduled with FDA; dialogue ongoing with EMA for development in severe COVID-19

Jena, Germany, June 29, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, provided a development update today for its first-in-class monoclonal anti-C5a antibody, vilobelimab, in pyoderma gangrenosum (PG) and severe COVID-19.

Vilobelimab has been granted orphan drug designation for the treatment of PG by both the Food and Drug Administration (FDA) in the US and the European Medicines Agency (EMA) in Europe. In addition, the Company had a productive end-of-phase II meeting with the FDA related to its plans for a Phase III development program in PG. The FDA indicated its support for a randomized, controlled Phase III development program during the meeting and offered to review the study protocol, recognizing PG as a serious and rare condition. Based on the Agency's feedback and recommendations, InflaRx is now finalizing the design for a Phase III trial and continues to be in dialogue with the agency related to this.

Following the encouraging Phase III results from the randomized, placebo-controlled, multinational PANAMO study in mechanically ventilated severe COVID-19 patients announced earlier this year, InflaRx requested a meeting with the FDA to obtain guidance with respect to a potential emergency use authorization submission. This has been scheduled as a Type B meeting for early Q3. In addition, the Company is in ongoing dialogue with the EMA related to next steps in the development of vilobelimab in mechanically ventilated severe COVID-19 patients towards a potential filing for approval for this indication.

"We are pleased to see our development in pyoderma gangrenosum moving forward with the granting of the orphan drug designation by FDA and EMA and with the productive discussions we have had with the FDA regarding our pivotal development program for this disease which is painful and debilitating for patients and can be life threatening," said Prof. Niels C.



Riedemann, CEO and Founder of InflaRx. "We also are looking forward to discussing our vilobelimab results in severe COVID-19 with the regulatory agencies in the US and Europe in greater detail to understand next steps towards a potential emergency use authorization or approval. Our team believes that the robust survival results from our COVID-19 PANAMO study provide important scientific insights in the potential benefits of C5a inhibition even beyond COVID-19."

The Company further reports that Jordan Zwick, Chief Strategy Officer, has left InflaRx to pursue an opportunity in business development. Mr. Zwick has agreed to continue to serve as an advisor to the Company. Prof. Riedemann commented: "Jordan has been a great member of our team and contributed to important developments in the Company with his experience and always positive energy. While he will be missed by our team, we wish him all the best in his future career, and we look forward to staying connected."

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 severe COVID-19. The Company has recently reported positive Phase IIa results in PG and encouraging Phase III results in mechanically ventilated COVID-19 patients. Vilobelimab is also in Phase II development for patients suffering from cutaneous squamous cell carcinoma.

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 <u>www.inflarx.com</u>.

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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. Forwardlooking 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 severe COVID-19, and related communications with the FDA; 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 company; 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; our status as an emerging growth company and/or foreign private issuer; and the risks, uncertainties and other factors described under the heading "Risk Factors" in InflaRx's 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.