InflaRx Provides Update on Planned Phase III Study Design in Pyoderma Gangrenosum with Vilobelimab and Status of its EUA Application in Critically Ill COVID-19 Patients

- *Multi-national, randomized, controlled adaptive Phase III design for vilobelimab in ulcerative pyoderma gangrenosum (PG)*
- *Trial size to be adapted upon interim analysis with planned total patient number between approximately 50 and 100 patients*
- *FDA review of application for emergency use authorization (EUA) of vilobelimab for the treatment of critically ill COVID-19 patients ongoing*
- *InflaRx's management team to host investor and business meetings during JPM Week, January 9 – 12, 2023 in San Francisco, California*

Jena, Germany, January 5, 2023 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced details related to the design of its planned Phase III study with vilobelimab in ulcerative PG, a rare neutrophilic and inflammatory skin disease with destructive, painful cutaneous ulcers.

The planned Phase III study is designed to enroll patients in the US, Europe and selected countries in other regions. The enrollment period is projected to be at least two years, depending on the total trial size after sample size adaptation. The design is based on detailed feedback and recommendations from the FDA Division of Dermatology and Dentistry and was developed in close collaboration with the Company´s advisors from the US, Europe and other regions.

The multi-national, randomized, double-blind, placebo-controlled Phase III trial will have two arms: vilobelimab (2400mg every other week) plus a low dose of corticosteroids and placebo plus the same low dose of corticosteroids. In both arms, corticosteroid treatment will be initiated on day 1 and will be tapered off within the first 8 weeks of the trial. The primary endpoint of the study will be complete closure of the target ulcer at any time up to 26 weeks after initiation of treatment. Treatment will be discontinued for patients whose disease progresses or fails to improve at defined time points during the study.

The study has an adaptive trial design with an interim analysis blinded for the sponsor and investigators (but unblinded for the independent data safety monitoring committee) planned upon enrollment of approximately 30 patients (15 per arm). The interim analysis with a set of predefined rules will take into account the then-observed difference in complete target ulcer closure between the two arms and, accordingly, the trial sample size will be adapted or the trial will be stopped due to futility.

“We are excited to take vilobelimab into the planned Phase III study in this rare neutrophilic skin disease with high unmet medical need for which there are currently no approved therapies in the US or in Europe,” said Prof. Niels C. Riedemann, CEO and founder of InflaRx. “We are grateful for the detailed advice we received from the FDA related to our planned Phase III trial, which has certainly helped improve the study design.”

As previously announced, the Company recently conducted a multi-center, proof-of-concept Phase IIa study with a total of 19 patients. Over a period of 26 weeks, patients were treated biweekly with vilobelimab 800mg, 1600mg or 2400mg, after an initial run-in phase with three doses of 800mg on days 1, 4 and 8, followed by a two-month observation period. Efficacy was assessed with the physician global assessment score (PGA). In the high dose cohort, 6 out of 7 patients (85.7%) demonstrated complete target ulcer closure, and treatment response rates in the different dosing cohorts correlated with suppression of C5a levels in patients’ plasma over time. The Company has received Fast Track and Orphan Drug (OD) designations by the FDA as well as OD designation by the European Medicines Agency (EMA) for the treatment of PG.

FDA review of EUA application for vilobelimab in treatment of critically ill COVID-19 patients remains ongoing

In September 2022, the Company submitted its application for emergency use authorization (EUA) of vilobelimab for the treatment of critically ill, intubated, mechanically ventilated COVID-19 patients with the FDA. The Company is in active dialogue with, and has received several requests for information from, the FDA, which the Company addressed. There is no

set timeline for a decision from the FDA related to the EUA. The Company will continue to interact closely with the FDA and will provide a timely update when appropriate.

InflaRx to host investor and business meetings in San Francisco next week

The Company´s management team will host investor and business meetings in San Francisco, California January 9 – 12 during JPM Week.

About Pyoderma Gangrenosum (PG)

Ulcerative pyoderma gangrenosum (PG) is a rare, non-infectious, neutrophilic dermatosis characterized by painful, necrolytic, cutaneous ulcers that can rapidly progress. PG is considered an autoimmune disease of the skin, but the underlying cause of PG is not known in detail. PG lesions are histologically characterized by pronounced infiltration of neutrophils and activated neutrophils surrounding the ulcers are believed to be disease drivers. PG typically occurs in patients between 40 and 60 years of age, and PG patients often also suffer from other autoimmune disorders, such as inflammatory bowel diseases and rheumatoid arthritis. There are no drugs currently approved for the treatment of PG in the US or in Europe, and there is no established standard of care based on controlled studies.

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 (PG) and critical COVID-19. Vilobelimab is also in Phase II development for the treatment of 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 anti-C5a and C5aR technologies to discover and develop first-in-class or best-in-class, potent and specific inhibitors of the complement activation factor known as C5a and its receptor known as C5aR. Complement C5a and its receptor 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.de.

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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 the Company’s intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the Company’s ongoing and planned pre-clinical development, including the development of vilobelimab in several indications, and clinical trials, including the planned Phase III study of vilobelimab for the treatment of ulcerative pyoderma gangrenosum (PG); the Company’s interactions with regulators regarding the results of clinical trials, clinical trial design and potential regulatory approval pathways; the

Company's 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 the Company; the timing and its ability to commence and conduct clinical trials; potential results from current or potential future collaborations; its ability to make regulatory filings, obtain positive guidance from regulators, and obtain and maintain regulatory approvals for its product candidates; its intellectual property position; its ability to develop commercial functions; expectations regarding clinical trial data; decisions regarding the strategic direction of the Company; its results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies; the industry in which the Company operates; the trends that may affect the industry or the Company's business; and the risks, uncertainties and other factors described under the heading "Risk Factors" in Company'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 the Company's 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 the Company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.