InflaRx Completes Enrollment in Vilobelimab (IFX-1) European Phase II Study in ANCA-associated Vasculitis

Jena, Germany, January 5, 2021 – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today the European phase II IXCHANGE study of vilobelimab (IFX-1), a first-in-class anti-C5a antibody, in ANCA-associated vasculitis (AAV) has completed enrollment.

“We are pleased to have met our enrollment goal in the vilobelimab European phase II trial in AAV,” said Dr. Korinna Pilz, Global Head of Clinical Research and Development of InflaRx. “ANCA-associated vasculitis is a rare but recurring and life-threatening disease for which new treatment options are urgently needed. Given the suggested important role of the C5a signaling pathway, especially for the life-threatening flare phases in this disease, we believe that vilobelimab could be a promising therapeutic option and look forward to seeing the results from this trial and the US safety trial later this year.”

The randomized, double-blind, placebo-controlled phase II study enrolled 57 patients with AAV throughout Europe. The main objective of the study is to evaluate the safety and efficacy of vilobelimab in AAV. The study is being conducted in two parts. Part 1 compares vilobelimab plus a reduced dose of glucocorticoids versus a standard dose of glucocorticoids, while part 2 compares vilobelimab alone versus a standard dose of glucocorticoids. All patients receive standard of care immunosuppressive therapy (rituximab or cyclophosphamide). Each part of the study has a sixteen-week treatment period with an eight-week observational period. The primary efficacy endpoint of the study is the proportion of patients achieving a clinical response defined as a 50% reduction in Birmingham Vasculitis Activity Score (BVAS) at week 16 compared to baseline, a well-established endpoint that has been used in previous AAV studies. Secondary endpoints include clinical remission, evaluation of the Vasculitis Damage Index, reduction of glucocorticoid toxicity, several relevant other parameters such as glomerular filtration rate and patient reported outcomes. Part 1 of the study enrolled 30 patients while part 2 enrolled an additional 27 patients. Final results are expected by the end of 2021.

Vilobelimab is also being studied in a randomized, double-blind, placebo-controlled US phase II IXPLORE study in patients with AAV. The study compares two different dose regimens of

vilobelimab to placebo. All patients receive current standard of care immunosuppressive therapy and high dose glucocorticoids. The main objective of the IXPLORE study is to evaluate the safety of vilobelimab, as this is the first time the drug is being administered to patients with AAV in the US. Efficacy endpoints include response rate based on BVAS and other, similar efficacy endpoints used in the European study. The study also has a sixteen-week treatment period with an eight-week observational period. All 19 patients enrolled have completed the study. Final results are expected by mid-2021.

AAV is a rare and life-threatening autoimmune disease in which activation of the complement system, and specifically the generation of larger amounts of C5a, is believed to play a key role in the neutrophil-driven vessel inflammation that defines the disease. AAV affects approximately 40,000 and 75,000 patients in the United States and Europe, respectively.

About vilobelimab (IFX-1):

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 to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response in pre-clinical studies. Vilobelimab is believed to be the first monoclonal anti-C5a antibody introduced into clinical development. Approximately 300 people have been treated with vilobelimab in clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various indications, including Hidradenitis Suppurativa, ANCA-associated vasculitis, Pyoderma Gangraenosum and severe COVID-19.

About InflaRx N.V.:

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of C5a. Complement C5a is a powerful inflammatory mediator 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; the impact of the COVID-19 pandemic on the Company; 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’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.