# InflaRx Announces Initiation of Phase III Part of Phase II/III Clinical Trial with IFX-1 in Severe COVID-19 Induced Pneumonia

- First site initiated for enrollment in the Netherlands
- Regulatory approval granted to start trial in Germany
- Additional sites to be added in the US, EU and other regions
- Encouraging Phase II data accepted for publication in The Lancet Rheumatology

**Jena, Germany, 14 September 2020** – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today the start of the global Phase III part of its Phase II/III trial with IFX-1 in severe COVID-19 induced pneumonia with the initiation of the first clinical site in the Netherlands. In parallel, the German regulatory authority, the Paul-Ehrlich-Institut (PEI), has approved the Phase III clinical trial in Germany.

The randomized, double-blinded and placebo-controlled Phase III part of the Phase II/III trial plans to enroll approximately 360 early intubated, critically ill patients with COVID-19 induced pneumonia across sites in the US, EU, South America and other regions. Patients will be randomized 1:1 to receive either IFX-1 or placebo; all patients will receive standard of care. The primary endpoint will be 28-day all-cause mortality; key secondary endpoints will include assessment of organ support and disease improvement. An interim analysis is planned after enrollment of 180 patients, with a potential for an early stop for efficacy or futility.

Dr. Korinna Pilz, Global Head of Clinical R&D at InflaRx, noted: “Encouraged by our initial Phase II results, we are now rolling out the international Phase III part of the trial. Our team is driven by the prospect of adding to the global efforts in the fight against this pandemic and by advancing the development of a potential therapeutic for the sickest COVID-19 patients.”

The data from the Phase II part of the study, which evaluated IFX-1 treatment plus best supportive care and best supportive care alone in 30 patients, have been accepted for publication in the peer-reviewed journal, The Lancet Rheumatology.

Dr. Alexander Vlaar, the principal investigator of the study from Amsterdam University, Department of Intensive Care Medicine, commented: “We are very pleased that a

distinguished, peer-reviewed journal has recognized the significance of the Phase II data for patients with severe COVID-19 induced pneumonia. The results demonstrate promising early efficacy signals, including lower mortality and organ dysfunction rates, and suggest that C5a inhibition might be beneficial in critically ill COVID-19 patients. However, these effects need to be confirmed in the large, well-powered Phase III part of the trial."

IFX-1, which has recently been granted the International Nonproprietary Name (INN), vilobelimab, currently has additional ongoing Phase II studies in ANCA-associated vasculitis and Pyoderma Gangraenosum and has completed Phase IIb development in Hidradenitis Suppurativa, for which a Phase III clinical development strategy is currently being developed.

**About IFX-1:**

IFX-1 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, IFX-1 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. IFX-1 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. IFX-1 is believed to be the first monoclonal anti-C5a antibody introduced into clinical development. Approximately 300 people have been treated with IFX-1 in clinical trials, and the antibody has been shown to be well tolerated. IFX-1 is currently being developed for various indications, including Hidradenitis Suppurativa, ANCA-associated vasculitis, Pyoderma Gangraenosum and COVID-19 pneumonia.

**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 preclinical 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.