



InflaRx Announces Decision to Enter Phase III Development of IFX-1 in Severe COVID-19 Induced Pneumonia

- 50% lower all-cause mortality rate and other efficacy trends were shown with IFX-1 in initial data from the randomized exploratory Phase II part of the Phase II/III trial
- Subject to regulatory approval, a randomized, double-blinded, placebo-controlled, multinational Phase III part of the trial will be initiated
- Primary endpoint of the planned Phase III part to be 28-day all-cause mortality

Jena, Germany, 21 July 2020 – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today that the Company has decided to continue development with IFX-1 in severe COVID-19 induced pneumonia. The Company plans to initiate a double-blinded, randomized, placebo-controlled Phase III trial that will be adequately powered for statistical analyses.

In the Phase III part of the study, subject to regulatory approval, the Company plans to enroll approximately 360 early intubated, critically ill patients with COVID-19 induced pneumonia. InflaRx plans to conduct the study at sites in the US, Europe, South America and potentially other regions. An interim analysis is currently planned after enrollment of 180 patients, with the potential for an early stop for efficacy or futility. In addition to the primary endpoint of 28-day all-cause mortality, other planned key endpoints include assessments of organ support and assessment of disease improvement on the ordinal scale.

Dr. Korinna Pilz, Global Head of Clinical R&D at InflaRx, noted: “Data from the initial exploratory Phase II part of the study in patients with severe COVID-19 induced pneumonia suggested a positive impact of IFX-1 treatment on the all-cause mortality rate and other endpoints. Based on these encouraging results, we are excited to initiate the Phase III part of the trial, which we anticipate starting in the coming months.”

The Phase II part of the study evaluated IFX-1 treatment plus best supportive care compared to best supportive care alone for up to 28 days. The Phase II part was randomized and enrolled a total of 30 patients. The 28-day all-cause mortality rate was 13% (n = 2 out of 15)



in the IFX-1 treatment arm compared to 27% (n = 4 out of 15) in the best supportive care arm. All deaths in the best supportive care arm occurred in COVID-19 induced multi-organ failure. In the IFX-1 treatment arm, one patient died after an acute ventilator tube complication (leakage) leading to hypoxia and one patient who met an exclusion criterion with a history of severe chronic obstructive pulmonary disease, which was not known at time point of enrollment, died of pulmonary failure. In the IFX-1 treatment arm fewer patients experienced renal impairment assessed by estimated glomerular filtration rates and more patients showed reversal of blood lymphocytopenia and a greater lowering of lactate dehydrogenase concentrations as a sign of reduction in tissue damage. A temporary, but statistically significant increase of D-dimer levels in the first days following IFX-1 administration was noted, as a potential signal for induction of blood clot lysis. No statistically significant group differences on the chosen primary endpoint of relative change (%) from baseline to day 5 in oxygenation index (defined as PaO₂/FiO₂ ratio) were detected.

The Phase II results have been submitted for publication to a peer-reviewed medical journal along with a preprint server.

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 induced 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, including the planned continuation into a Phase III part trial in patients with severe COVID-19 pneumonia; 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



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