InflaRx Reports Encouraging Topline Results from the Exploratory Phase II Part of the Adaptive Randomized Phase II/III Trial of IFX-1 in COVID-19

- IFX-1 treatment showed a trend in lower 28-day all-cause mortality rate, along with trends of maintained kidney function, faster normalization in lymphocyte counts and greater reduction in LDH in patients with severe COVID-19 pneumonia
- InflaRx is now evaluating the continuation into a placebo-controlled Phase III part of the trial with 28-day all-cause mortality as the primary endpoint

Jena, Germany, 17 June 2020 – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today interim results from the first 30 patients treated in the adaptive randomized Phase II/III trial in patients with severe COVID-19 pneumonia.

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. Relative change (%) from baseline to day 5 in oxygenation index (defined as PaO2/FiO2 ratio) was assessed as the primary endpoint along with additional clinical parameters until day 28. Relative change in the oxygenation index at day 5 showed no differences between treatment groups. However, IFX-1 treatment was associated with a lower 28-day all-cause mortality when compared to the best supportive care group, along with trends in disease improvement, as evidenced by fewer patients experiencing renal impairment assessed by estimated glomerular filtration rates, more patients showing reversal of blood lymphocytopenia and a greater lowering of lactate dehydrogenase concentrations. In IFX-1-treated patients, pulmonary embolisms reported as serious adverse events were lower compared to the best supportive care arm. Also, a temporary increase of D-dimer levels, as potential expression of induction of blood clot lysis, was detected in the first days after initiation of IFX-1 treatment. The data are being prepared for submission to a scientific journal[1].

[1] Data and trends reflect the knowledge at the time of the press release, with ongoing data cleaning not fully completed. Data will be submitted for publication upon completion of data cleaning activities.

Dr. Korinna Pilz, Global Head of Clinical R&D at InflaRx, commented: “These are encouraging preliminary data which suggest that C5a inhibition might be beneficial in treating critically ill COVID-19 patients.”

A total of 30 patients were randomized in the trial, and 15 patients were treated in each arm: IFX-1 plus best supportive care or best supportive care alone. Over a treatment period of 28 days, patients in the IFX-1 arm received a maximum of seven doses of 800 mg IFX-1 intravenously on separate days. At randomization, 18 patients were intubated (60%), and 12 patients (40%) had other oxygen supply. A higher number of patients with 2 or more comorbidities associated with increased COVID-19 mortality were reported in the IFX-1 treatment group compared to best supportive care group. Twenty-eight-day all-cause mortality in the IFX-1 treatment group was 13% (2 out of 15) versus 27% (4 out of 15) in the control group. In the best supportive care group, four patients died of COVID-19-induced multi-organ failure, and three of them had pulmonary embolisms reported as a serious adverse event. In the IFX-1 arm, one patient died after an acute ventilator tube complication (leakage) and one patient with a history of severe chronic obstructive pulmonary disease died of pulmonary failure.

Prof. Niels Riedemann, CEO and co-founder of InflaRx, commented: “InflaRx’s core expertise in the acute care field and our development work with IFX-1 in sepsis and viral lung injury put InflaRx in a scientifically strong position to develop IFX-1 in COVID-19. We are encouraged by these preliminary data.”

Serious adverse event (SAE) rates were comparable between groups, but the rate of pulmonary embolisms reported as SAEs was substantially lower in the IFX-1 treatment group. Upon review of the safety data, the independent data safety monitoring board recommended continuation of the trial into the Phase III part.

This Phase II part of the trial was exploratory in nature and was not powered to show statistically significant differences in clinical endpoints. Relative change (%) from baseline to day 5 in the oxygenation index, chosen as the primary endpoint for the Phase II part, showed a large variability and dependency on patient positioning and intubation status which excludes this endpoint from being used in a confirmatory study.

InflaRx is now evaluating continuing the study in an adequately powered, placebo-controlled, double blinded, Phase III part using 28-day all-cause mortality as the primary endpoint, an accepted regulatory primary endpoint for critical care studies.

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.

Contacts:

InflaRx N.V.

Jordan Zwick – Global Head of Business Development & Corporate Strategy
Email: jordan.zwick[at]inflarx.de
Tel: +1 917-338-6523

MC Services AG

Katja Arnold, Laurie Doyle, Andreas Jungfer
Email: inflarx[at]mc-services.eu
Europe: +49 89-210 2280 US: +1-339-832-0752

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 a potential 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 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.