InflaRx Announces Encouraging Phase III Topline Results from PANAMO Trial of Vilobelimab in Severe COVID-19 Patients

- Vilobelimab treatment results in relative reduction in 28-day all-cause mortality of 23.9% compared to placebo (p-value=0.094), but did not show statistical significance on the pre-specified primary endpoint
- Pre-specified sensitivity analysis of the primary endpoint results in p-values of <0.05 in three out of four planned analyses in favor of vilobelimab treatment
- 43% relative reduction in 28-day all-cause mortality detected in pre-specified subgroup analysis in Western European patients comparing vilobelimab to placebo treatment (n=209, p-value=0.014)
- Additional pre-specified subgroup analyses in patients with more severe disease confirm treatment benefit for vilobelimab, resulting in p-values of <0.05
- Company plans to discuss results with regulatory authorities
- Company to host a conference call today at 8:30 am EDT/2:30 pm CEST

Jena, Germany, March 31, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today that the Phase III part of the Phase II/III PANAMO study with mechanically ventilated COVID-19 patients showed a relative reduction in 28-day all-cause mortality of 23.9% (vilobelimab 31.7% versus placebo 41.6%, p=0.094), which was not statistically significant using site-stratified Cox regression analysis as pre-specified in the final statistical analysis plan of the study. All patients in the study received standard of care.

At the recommendation of regulatory authorities, during the course of the trial, the Company changed the statistical analysis method for the primary endpoint. The original protocol specified a non-stratified Cox regression analysis, and the final statistical analysis plan specified a site-stratified analysis intended to account for the site stratification of patients at randomization. The original protocol specified analysis would have resulted in a p-value of 0.027 (statistically significant). Additionally, logistic regression analyses of the 28-day mortality resulted in p-values of <0.05 for 3 out of the 4 pre-specified analyses. These analyses and other results will be discussed in more detail on today's conference call.

A pre-specified analysis of patients from Western European countries (n=209) showed a relative reduction in 28-day all-cause mortality of 43% (vilobelimab 21.2% versus placebo 37.2%, hazard ratio: 0.5, p=0.014), suggesting an improvement in mortality in line with the reported Phase II data of the PANAMO Phase II/III study.

Prof. Niels C. Riedemann, CEO and Founder of InflaRx, commented: “The successful conduct of this study was only possible through the support of many involved parties, among them our patients and their loved ones, our dedicated investigators, including principal investigator Prof. Alexander Vlaar from the Amsterdam University Medical Center, and our team members. We want to express our sincere gratitude to all of these involved individuals. As we have all seen, severe COVID-19 is an extremely complex, difficult-to-treat disease which continues to take lives in the most severely affected patients. Although the study results in the pre-specified primary outcome analysis were not statistically significant, we believe that data from the study suggest that vilobelimab treatment resulted in a robust signal for survival improvement when compared to placebo, particularly in those patients from Western Europe and those with higher baseline severity. Especially encouraging is the fact that the analysis of patients treated in Europe is in line with the published Phase II results of the PANAMO study. We plan to discuss the data with regulatory authorities to determine potential next steps in the development of vilobelimab for this indication.”

Three pre-specified subgroup analyses assessed the treatment effect of vilobelimab in patients with higher baseline disease severity. These analyses all showed a signal towards a reduction in 28-day all-cause mortality in the vilobelimab arm compared to the placebo arm in intubated patients suffering from one or more additional organ support captured as baseline ordinal scale of 7 (n=237, p=0.028); in patients with severe acute respiratory distress syndrome (ARDS) and PaO2/FiO2 <100 (n=98, p=0.044); and in patients with kidney impairment, captured by estimated glomerular filtration rate (eGFR) of <60 mL/min/1.73m² (n=108, p=0.036).

Sixty-day all-cause mortality, a key secondary endpoint, showed a continued reduction of mortality in the vilobelimab arm (36.5% vilobelimab versus 47.2% placebo; p=0.082, applying the site-stratified Cox regression analysis as pre-specified in the final statistical analysis plan, and p=0.016, applying the originally planned non-stratified Cox regression analysis).

The randomized, double-blind, placebo-controlled Phase III part of the PANAMO Phase II/III study randomized 369 mechanically ventilated patients with COVID-19 across sites in the EU, South America and other regions. Patients were randomized 1:1 to receive either vilobelimab or placebo; both groups received standard of care, including steroids. The primary endpoint

was 28-day all-cause mortality; secondary endpoints included 60-day all-cause mortality as well as assessment of organ support and disease improvement on the ordinal scale.

In this study, vilobelimab appeared to be safe and well-tolerated. Frequency and quality of adverse events (AEs) and serious adverse events (SAEs) were comparable between treatment arms.

Approximately 97% of patients received concomitant corticosteroids and 98% received concomitant anticoagulation treatment.

InflaRx intends to publish detailed results from this study in a peer-reviewed journal and present the findings at a medical meeting in the coming months. The Company plans to discuss data from the PANAMO study with regulatory authorities in due course.

The work described herein was partly funded by the German Federal Government through grant number 16LW0113 (Vilo-Covid). All responsibility for the content of this work lies with InflaRx.

Conference call scheduled for today at 8:30 am EST/2:30 pm CET

InflaRx will host a conference call to discuss the Phase III PANAMO study results today, Thursday, March 31st at 8:30 am EDT (2:30 pm CEST). To participate in the conference call, participants may pre-register here and will receive a dedicated link and dial-in details to easily and quickly access the call. A replay of the event will be available on the InflaRx website in the Investors - Events & Presentations section.

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. Over 300 people have

been treated with vilobelimab in completed clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various indications, including hidradenitis suppurativa, and has recently reported positive Phase II results in ANCA-associated vasculitis and Phase IIa results in pyoderma gangrenosum. Vilobelimab is also in Phase II development for patients suffering from cutaneous squamous cell carcinoma (cSCC).

About InflaRx N.V.

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary technology to discover and develop first-in-class or best-in-class, potent and specific inhibitors of C5a and C5aR. Complement C5a and 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.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 development of vilobelimab for mechanically ventilated COVID-19 patients, future analysis of our Phase II/III PANAMO trial and interactions with regulators regarding the results of the trial and potential regulatory approval pathways; 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; decisions regarding the strategic direction of the Company; 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.