InflaRx Receives Corrected Advice Letter from FDA Related to Phase III Program for Vilobelimab in Hidradenitis Suppurativa

Jena, Germany, March 17, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today reported that the Company has received a corrected advice letter from the U.S. Food and Drug Administration (FDA) related to its Phase III program with vilobelimab for the treatment of hidradenitis suppurativa (HS). In this corrected letter, FDA no longer recommends that the Company use the Hidradenitis Suppurativa Clinical Response Score ("HiSCR") as the primary endpoint for the chosen patient population but gives recommendations related to implementation of the modified HiSCR (m-HiSCR).[1] The written advice letter received in February 2022 had stated that the Agency recommended using the HiSCR as the primary endpoint in the Phase III trial, which was inconsistent with the minutes from a Type A advice meeting held between InflaRx and the FDA in the third quarter of 2021.

"We appreciate the prompt feedback from the FDA clarifying the advice received in February," stated Dr. Korinna Pilz, Chief Clinical Development Officer.

In light of this corrected advice from FDA, InflaRx believes that further development in HS is feasible. Given the additional financing needs for a full Phase III HS program and the recent promising data in another immuno-dermatological disease, pyoderma gangrenosum, InflaRx is currently evaluating its strategic options on how to most efficiently develop vilobelimab in this disease space.

The Company plans to update the markets on its pipeline development strategy in the second quarter of 2022.

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

[1] m-HiSCR is defined as achieving both i) total body inflammatory lesion count (ANdT) reduction from Baseline of at least 50% and ii) a draining tunnel (dT) count reduction from Baseline of at least 50% at the end of Week 16.

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 in Phase III development for the treatment of critically ill COVID-19 patients and 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 ongoing and planned pre-clinical development and clinical trials, in particular our Phase III trial in HS and related communications with the FDA, in particular addressing the FDA’s advice in various communications to us regarding the primary endpoint for the Phase III trial; 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.