InflaRx Announces Positive Topline Results from the Multiple Ascending Dose (MAD) Phase I Study with C5aR Inhibitor INF904

- *MAD pharmacokinetic and pharmacodynamic data support best-in-class potential of INF904 over tested dose range of 30 mg once per day (QD) to 90 mg twice per day (BID) for 14 days:*
  - *Achieved ≥90% blockade of C5a-induced neutrophil activation over 14-day dosing period*
  - Achieved *favorable concentration-time profiles with target exposures of therapeutic potential*
  - *Well tolerated with no safety signals of concern over entire dose range*
- *Company to advance INF904 into Phase II clinical development*
- *Company to host a conference call today, January 4, 2024 at 8:30 a.m. EST/14:30 CET*

Jena, Germany, January 4, 2024 – InflaRx N.V. (Nasdaq: IFRX), a biotechnology company pioneering anti-inflammatory therapeutics targeting the complement system, announced today topline results from the multiple ascending dose (MAD) part of its randomized, double-blind, placebo-controlled Phase I trial for INF904, an orally administered low molecular weight C5aR inhibitor. The pharmacokinetic (PK) and pharmacodynamic (PD) parameters confirm the favorable data InflaRx reported recently from the single ascending dose (SAD) part of the study, which provides support for the best-in-class potential of this drug candidate. INF904 was well tolerated and there were no adverse safety events of concern after repeated dosing in participants over the entire tested dose range.

In the MAD part of the randomized, double-blind, placebo-controlled Phase I trial, 24 participants received multiple doses of INF904 for 14 days of either 30 mg once per day (QD), 30 mg twice per day (BID) or 90 mg BID. The study's primary objective was to evaluate the safety and tolerability of repeated dosing. Several PK parameters were analyzed as secondary endpoints, and the effect of the dosing scheme on C5a-induced neutrophil activation in blood samples from the participants was also explored in an ex vivo assay.

"We are very pleased that the MAD part of the Phase I study exceeded the already compelling results from the SAD part of the study. The PK and PD profiles suggest that INF904 allows for highly effective inhibition of the C5a/C5aR pathway and that INF904 should enable consistent control of C5aR signaling in patients. In addition, we have the potential to apply a broad dose range up to high doses for the planned development of INF904 in chronic immune-inflammatory

conditions," said Camilla Chong, MD, Chief Medical Officer of InflaRx. *"We are excited to advance this highly promising oral C5aR inhibitor into Phase II clinical development."*

The safety analysis of INF904 in the MAD part of the Phase I study demonstrated that it was well tolerated in participants over the entire dose range and resulted in no safety signals of concern. The overall percentage of adverse events (AEs) in INF904 treated participants was 77.8%, which was lower than the 83.3% observed in the placebo group. There were no serious or severe AEs observed at any dosing level.

Analysis of the PK profile showed that potential target $AUC_{0\text{-}12h}$, $C_{max,}$ and trough values were achieved rapidly within 14 days of 30 mg BID dosing. INF904 exposure further increased proportionally with dosing up to 90 mg BID. These results were demonstrated even when participants ingested the drug in a fasted state, suggesting that food is not required to achieve potentially therapeutic drug levels.

Analysis of the PD profile showed that the blocking activity of C5a-induced neutrophil activation by INF904 reached equal to or above 90% over the 14-day dosing period for all tested doses in an ex vivo challenge assay where physiological and disease-relevant levels of C5a were added to blood samples provided by the trial participants.

InflaRx previously reported the data from the SAD part of the trial with 62 healthy volunteers in a press release and conference call. The SAD part showed a favorable dose-proportional systemic exposure with desired blocking activity (>90%) of C5a-induced neutrophil activation at disease-relevant C5a levels for doses of 30 mg to 240 mg 24 hours post-administration.

In parallel, InflaRx has progressed with the development of a commercially viable formulation of INF904 which the Company plans to introduce into Phase II development towards the end of 2024.

InflaRx is currently conducting additional required pre-clinical studies, including long-term chronic toxicology studies, to enable longer-term dosing of INF904 for chronic inflammatory diseases. InflaRx currently plans to initiate a short-term dosing Phase II study towards the end of 2024, followed by a longer-term dosing Phase II study in 2025. Further details of this clinical development plan with selection of indications will be announced in due course.

Conference call scheduled for today, January 4, 2024

InflaRx will host a conference call today, January 4, 2024 at 8:30 a.m. EST (14:30 CET) to provide more details about the announced topline results of the MAD part of its Phase I study of INF904 in healthy human subjects. 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 will be available on the InflaRx website in the Investors – Events & Presentations section after the live conference call has concluded.

InflaRx's management team will host investor and business meetings during JPM Week from January 8 to 11, 2024 in San Francisco, California.

About INF904

INF904 is an orally administered small molecule inhibitor of C5a-induced signaling via the receptor C5aR. INF904 showed anti-inflammatory therapeutic effects in several pre-clinical disease models. Further, in contrast to the marketed C5aR inhibitor, in vitro experiments demonstrated that INF904 has minimal inhibition of the cytochrome P450 3A4/5 (CYP3A4/5) enzymes, which play an important role in the metabolism of a variety of metabolites and drugs, including glucocorticoids. Reported results from a first-in-human study demonstrated that INF904 is well tolerated in treated subjects and exhibits no safety signals of concern in single doses ranging from 3 mg to 240 mg or multiple doses ranging from 30 mg once per day (QD) to 90 mg twice per day (BID) for 14 days. Pharmacokinetic / pharmacodynamic data support best-in-class potential of INF904 with a ≥90% blockade of C5a-induced neutrophil activation achieved over the 14-day dosing period. InflaRx plans to bring INF904 into clinical Phase II development towards the end of 2024.

About InflaRx

InflaRx GmbH (Germany) and InflaRx Pharmaceuticals Inc. (USA) are wholly owned subsidiaries of InflaRx N.V. (together, InflaRx).

InflaRx (Nasdaq: IFRX) is a biotechnology company pioneering anti-inflammatory therapeutics by applying its proprietary anti-C5a and anti-C5aR technologies to discover, develop and commercialize highly potent and specific inhibitors of the complement activation factor C5a and its receptor C5aR. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of inflammatory diseases. InflaRx's lead product candidate, vilobelimab, is a novel, intravenously delivered, first-in-class, anti-C5a monoclonal antibody that selectively binds to free C5a and has demonstrated disease-modifying clinical activity and tolerability in multiple clinical studies in different indications. 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,” “estimate,” “believe,” “predict,” “potential” or “continue,” among others. 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, the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals and related treatment recommendations by medical/healthcare institutes and other third-party organizations, our ability to successfully commercialize and the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals or our other product candidates; our expectations regarding the size of the patient populations for, market opportunity for, coverage and reimbursement for, estimated returns and return accruals for, and clinical utility of Gohibic (vilobelimab) in its approved or authorized indication or for vilobelimab and any other product candidates, under an Emergency Use Authorization and in the future if approved for commercial use in the United States or elsewhere; the success of our future clinical trials for vilobelimab’s treatment of COVID-19 and other debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum, and any other product candidates, including INF904, and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials; the timing, progress and results of pre-clinical studies and clinical trials of our product candidates and statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, the costs of such trials and our research and development programs generally; our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways, including related to our Marketing Authorization Application submission for vilobelimab and our biologics license application submission for Gohibic (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or Gohibic (vilobelimab) for any indication; whether the U.S. Food and Drug Administration, the

European Medicines Agency or any comparable foreign regulatory authority will accept or agree with the number, design, size, conduct or implementation of our clinical trials, including any proposed primary or secondary endpoints for such trials; our expectations regarding the scope of any approved indication for vilobelimab; our ability to leverage our proprietary anti-C5a and C5aR technologies to discover and develop therapies to treat complement-mediated autoimmune and inflammatory diseases; our ability to protect, maintain and enforce our intellectual property protection for vilobelimab and any other product candidates, and the scope of such protection; our manufacturing capabilities and strategy, including the scalability and cost of our manufacturing methods and processes and the optimization of our manufacturing methods and processes, and our ability to continue to rely on our existing third-party manufacturers and our ability to engage additional third-party manufacturers for our planned future clinical trials and for commercial supply of vilobelimab and for the finished product Gohibic (vilobelimab); our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing; our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if approved, any commercial sales; if any of our product candidates obtain regulatory approval, our ability to comply with and satisfy ongoing obligations and continued regulatory overview; our ability to comply with enacted and future legislation in seeking marketing approval and commercialization; our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel; and our competitive position and the development of and projections relating to our competitors in the development of C5a and C5aR inhibitors or our industry; and the risks, uncertainties and other factors described under the heading “Risk Factors” in our periodic filings with the U.S. 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.