InflaRx Hosts R&D Event Highlighting the Promise of INF904

- *Thought leaders in complement inhibition, chronic spontaneous urticaria (CSU) and hidradenitis suppurativa (HS) provide compelling new insights into the strong development rationales, potential differentiation and medical role of INF904 in initially targeted indications and inflammation & immunology (I&I) more broadly*
- *Additional details provided on INF904 Phase 2a trial design in moderate-to-severe CSU and HS, with study initiation expected by the calendar year-end of 2024 and a goal of generating additional safety and pharmacokinetic (PK) data, and showing meaningful clinical benefit*
- *INF904 Phase 2a data expected in summer 2025, with Phase 2b trial initiation expected in 2025*
- *Commercial assessment indicates CSU and HS both represent multi-billion-dollar market opportunities, with tremendous patient need for effective new mechanisms of action*
- *InflaRx's strong financial position is expected to fund company operations into 2026, allowing for advancement of clinical programs towards next milestones*

Jena, Germany, June 5, 2024 – InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company pioneering anti-inflammatory therapeutics by targeting the complement system, today hosted a virtual R&D event focused on the company's oral small molecule C5aR inhibitor, INF904. Speakers provided additional details on development rationales and plans for INF904, as well as additional insight into its potential role in CSU and HS and its broader therapeutic potential in the immuno-inflammation field.

Presenting key opinion leaders (KOLs) included: **Prof. Dr. Marcus Maurer** (Professor of Dermatology and Allergology, Institute of Allergology, Charité – Universitätsmedizin Berlin, Germany), **Christopher Sayed, MD** (Prof. of Dermatology, University of North Carolina, Medical School; and Secretary of the HS Foundation) and **Prof. Dr. Jörg Köhl** (Director of the Institute for Systemic Inflammation Research, University of Lübeck, Lübeck, Germany).

Supplemental information related to today's event, including presentations conducted by the KOLs and InflaRx management can be found in the accompanying slide deck here.

Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx, commented: "InflaRx has been eager to provide additional details of its development plans for INF904 and to further showcase the tremendous promise of our approach to C5aR inhibition, initially in CSU and HS, and more broadly in I&I. We see the immense potential of INF904 in its ability to address multiple significant unmet medical needs not addressed by drugs currently in development, as well as the ability for this potentially best-in-class compound to find market acceptance in a number of sizable patient settings. We expect to progress expeditiously in our two initially selected immuno-derm indications, CSU and HS, and look forward to achieving additional milestones with INF904 in 2025."

INF904 CSU and HS clinical development program

As previously disclosed, InflaRx will pursue two initial immuno-dermatology indications with INF904 in a single Phase 2a basket trial that is expected to begin by the end of 2024. The Phase 2a trial will be a multi-center, open-label study dosing 75 patients and evaluating multiple INF904 dosing regimens over 4 weeks of treatment in patients with moderate-to-severe CSU and moderate-to-severe HS.

Outcome measures will be assessed via weekly visits to evaluate safety, PK and preliminary signs of efficacy. After the 4-week treatment period, patients will be followed for an additional 4 weeks. Data from this study are expected in the summer of 2025, with the subsequent initiation of a larger Phase 2b study anticipated in 2025 as well.

In the CSU group, patients in Study Arms 1 and 2 will be dosed with INF904 at 30 mg and 90 mg BID (twice daily), respectively. Patients in Study Arm 3 will be comprised of anti-IgE non-responders and dosed at 90 mg BID. In total, the CSU group will dose 45 patients randomized at a 1:1:1 ratio. In addition to safety and PK parameters, assessed CSU efficacy measures will include change of the Urticaria Activity Score 7 (UAS7), Hives Severity Score (HSS7) and Itch Severity Score (ISS7) from baseline to the end of week 4. Biomarkers and Patient-Reported Outcome (PRO) endpoints related to urticaria control and quality of life will also be assessed.

In the HS group, 30 patients will be randomized at a 1:1:1 ratio to 3 doses of INF904 at 30 mg, 60 mg or 90 mg BID. In addition to safety and PK parameters, assessed HS efficacy measures will include change in total abscess, inflammatory nodule and draining tunnel (dT) count, HS lesions-related scores and Clinician's Global Impression of Change (CGI-C) at 4 weeks. PRO endpoints related to HS disease control and quality of life will also be assessed.

As previously disclosed, the company is currently conducting additional pre-clinical studies with INF904, including chronic toxicology studies, as part of its effort to enable longer-term dosing of INF904 in future clinical trials.

INF904 as a "pipeline-in-a-product"

Given the potential of INF904 to have a broad commercial footprint, InflaRx believes INF904 could address meaningful markets in immuno-dermatology and in immuno-inflammation, including in nephrology, neurology and hematology. While InflaRx intends to focus its resources on its immediate goals addressing CSU and HS, we continue to assess and monitor the value of pursuing additional areas and applications via potential future collaborations with partners.

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.

About InflaRx N.V.

InflaRx (Nasdaq: IFRX) is a biopharmaceutical 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 is also developing INF904, an orally administered small molecule inhibitor of C5a-induced signaling via the C5a receptor. 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.de.

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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 EUA and in the future if approved for commercial use in the

U.S. or elsewhere; our ability to successfully implement The InflaRx Commitment Program, the success of our future clinical trials for vilobelimab's treatment of COVID-19 and other debilitating or life-threatening inflammatory indications, including PG, 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 FDA, 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 SEC. 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.