



## InflaRx Announces First Patient Dosed in Phase 2a Study for Oral C5aR Inhibitor INF904

**Jena, Germany, December 20, 2024** – InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company pioneering anti-inflammatory therapeutics targeting the complement system, today announced that the first patient has been dosed in its Phase 2a basket study in chronic spontaneous urticaria (CSU) and hidradenitis suppurativa (HS), investigating the Company's oral C5aR inhibitor, INF904.

**Camilla Chong, MD, Chief Medical Officer of InflaRx, commented:** "We are pleased to have started our Phase 2a trial for INF904 with the first patient dosed at one of our U.S. sites, and I am very proud of our team who implemented this important study so rapidly. We believe there is strong evidence of INF904's anti-inflammatory properties and that its best-in-class potential will go a long way to serve unmet medical needs in both chronic spontaneous urticaria and hidradenitis suppurativa, and in other immuno-inflammatory conditions as well."

### **INF904 Phase 2a Study**

The Phase 2a trial is a multi-center, open-label study expected to include a total of 75 patients with moderate-to-severe CSU and moderate-to-severe HS. The trial will evaluate multiple INF904 dosing regimens over 4 weeks of treatment to generate additional safety and pharmacokinetic (PK) data and to provide signs of clinical benefit. As previously disclosed, this basket study is utilizing a commercially viable formulation of INF904, providing a range of drug exposures comparable to the reported levels in the [Phase 1 study](#). 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 a goal of informing the design of a larger, longer-term Phase 2b study by year-end 2025.

In the CSU group, a total of 45 patients will be dosed in three study arms. Patients in Study Arms 1 and 2 will be randomized at a 1:1 ratio to 2 doses of INF904 at 60 mg or 120 mg BID (twice daily), a range of drug exposures comparable to the Phase 1 trial. Patients in Study Arm 3 will be comprised of anti-IgE treatment non-responders and dosed at 120 mg BID. In addition to safety and PK parameters, assessed CSU efficacy measures will include change in the Urticaria Activity Score 7 (UAS7), Hives Severity Score (HSS7) and Itch Severity Score (ISS7) from baseline to the end of



week 4. Responder analyses, 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 60 mg, 90 mg or 120 mg BID, a range of drug exposures comparable to the Phase 1 trial. 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, pain and quality of life will also be assessed.

InflaRx believes CSU and HS each has potential addressable markets of \$1 billion or more for INF904. The Company also believes INF904 could address meaningful opportunities in additional immuno-dermatology and immuno-inflammatory indications, including in nephrology, neurology and hematology. While InflaRx intends to focus its resources on its immediate goals addressing CSU and HS, the Company continues 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 the C5a receptor that has shown 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. PK / pharmacodynamic data support the best-in-class potential of INF904 with a  $\geq 90\%$  blockade of C5a-induced neutrophil activation achieved over the 14-day dosing period.

#### ***About InflaRx***

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 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.com](http://www.inflarx.com).

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

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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, current expectations and the risks, uncertainties and other factors described under the heading "Risk Factors" and "Cautionary statement regarding forward looking statements" 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.