



## InflaRx Announces Positive Data from Second Interim Analysis of Ongoing Phase IIa Open Label Study with Vilobelimab in Pyoderma Gangraenosum

- Four out of 10 evaluable patients showed clinical response (PGA score  $\leq 3$ ), three of whom achieved complete closure of target lesion
- Treatment was well tolerated; no adverse events associated with dose escalation
- Treatment of the third cohort with the 2400 mg dose is ongoing

**Jena, Germany, August 10, 2021** – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announces positive data from the first 10 evaluable patients in the ongoing Phase IIa open label study with vilobelimab in Pyoderma Gangraenosum (PG).

As previously announced, enrollment in the proof-of-concept study was completed with 19 patients, with 12 in the first two dose cohorts. Two out of the 12 withdrew from the study before reaching day 99 of the treatment, so only 10 patients were evaluable for the efficacy assessment on day 99.

Over a treatment period of 26 weeks (until day 189), patients were treated biweekly with vilobelimab 800mg, 1600mg or 2400mg, after an initial run-in phase with three doses of 800mg on days 1, 4 and 8. There was a subsequent three-month observational period. Per protocol, a dose increase to the next higher dosing group was possible upon disease assessment on day 57 in the study, if at least five patients in the cohort had been treated without safety concerns and the patient was assessed with a Physician Global Assessment (PGA) score of 4 or higher.

The main objectives of the study are the evaluation of the safety and efficacy of vilobelimab in patients with PG. Efficacy is being evaluated by a responder rate defined as a PGA score of  $\leq 3$  of the target ulcer at various timepoints and time to complete closure (remission) of the target ulcer. Out of the 10 patients evaluable for efficacy at day 99, four patients met the response criteria, with three of them achieving complete closure of the target ulcer. The three patients who showed clinical response with a PGA score of  $\leq 3$  with complete target ulcer closure had elevated C5a levels at baseline. InflaRx previously reported the clinical response for two of these three patients in February 2020. The third patient demonstrating complete



target ulcer closure had been increased from the 1600mg dose group to the highest dose of 2400mg dose on day 57 of the study and closed the ulcer after the dose escalation. The other six patients (three patients of which the results had been previously disclosed in February 2020) all showed slight improvement in their condition according to the PGA definition (PGA score = 4).

“We are encouraged by these promising signs of drug activity for vilobelimab in PG and look forward to seeing the results from the highest dose cohort, which has been fully enrolled,” commented Dr. Korinna Pilz, Chief Clinical Development Officer of InflaRx. “We are also very happy to see the favorable safety profile of vilobelimab being confirmed in these severely ill patients,” she added.

Overall, vilobelimab was well-tolerated and no new safety findings emerged. One patient experienced a delayed hypersensitivity in form of a skin rash which resolved upon discontinuation of vilobelimab.

#### **About vilobelimab (IFX-1):**

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 to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response in pre-clinical studies. 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 inflammatory indications, including hidradenitis suppurativa, ANCA-associated vasculitis and pyoderma gangraenosum as well as severe COVID-19 and cutaneous squamous cell carcinoma (cSCC).

#### **About Pyoderma Gangraenosum (PG):**

PG is a rare and debilitating neutrophil-driven, autoinflammatory skin disease, characterized by an acute, destructive ulcerating process of the skin, primarily occurring on the legs but also other regions of the body. PG can lead to chronic painful and difficult to treat wounds with long healing times. Patients frequently suffer from severe pain and frequent relapses. It typically occurs in people in their 40s and 50s. Many PG patients also suffer from other autoimmune



disorders, including inflammatory bowel diseases like ulcerative colitis, arthritides like rheumatoid arthritis, and hematological diseases such as multiple myeloma.

The exact prevalence of PG is not yet known, but it is estimated that up to 50,000 patients in the US and Europe are affected by this disease. There are currently no approved therapies for the treatment of PG in the USA or Europe. Current treatment options include the use of systemic immunosuppression in rapidly progressing cases.

C5a is a key factor for neutrophil tissue infiltration and neutrophil activation which are believed to play a key amplifying role in PG. Thus, C5a inhibition may be able to prevent neutrophil infiltration and activation in PG patients. Given the detected activity of C5a inhibition by vilobelimab in another neutrophil-driven skin disorder, hidradenitis suppurativa, InflaRx is currently conducting a Phase IIa clinical study to investigate a potential benefit of vilobelimab for patients suffering from PG.

#### **About InflaRx N.V.:**

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of C5a. Complement C5a is a powerful inflammatory mediator 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](http://www.inflarx.com).

#### **Contacts:**

##### **InflaRx N.V.**

Jordan Zwick – Chief Strategy Officer

Jason Stewart – Investor Relations

Email: [IR@inflarx.de](mailto:IR@inflarx.de)

Tel: +1 917-338-6523

##### **MC Services AG**

Katja Arnold, Laurie Doyle, Andreas Jungfer

Email: [inflarx@mc-services.eu](mailto:inflarx@mc-services.eu)

Europe: +49 89-210 2280

US: +1-339-832-0752

#### **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 preclinical development and clinical trials, including when we expect to report final data from our clinical trial of vilobelimab in PG and the safety and efficacy results of the 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.