# InflaRx Announces Positive Data from Third Cohort of Phase IIa Open-Label Study with Vilobelimab in Pyoderma Gangraenosum

- 6 out of 7 patients (85.7%) showed clinical remission (PGA score ≤ 1) and closure of target ulcer in the highest dose cohort
- Treatment was well tolerated; no dose-related adverse events observed
- Final post treatment observational data will be available in the first half of 2022
- InflaRx to host conference call today at 8:30 am EDT / 2:30 pm CEST

**Jena, Germany, October 27, 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 third cohort of patients in the Phase IIa open-label study with vilobelimab in Pyoderma Gangraenosum (PG).

“We are happy to see more patients responding with the highest dose of vilobelimab in patients with Pyoderma Gangraenosum,” commented Dr. Korinna Pilz, Chief Clinical Development Officer of InflaRx. “There is a need for better treatment options for this painful and debilitating condition. With the good safety profile and promising efficacy results we have seen in this trial, we will seek FDA guidance on next steps towards a pivotal program.”

As previously announced, a total of 19 patients were enrolled in the multi-center, proof-of-concept study, with seven patients enrolled in the third cohort. Over a treatment period of 26 weeks, 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. Following the treatment period, patients continued to be observed for a period of two months, which is ongoing for the third cohort. Per protocol, a dose increase to the next higher dosing group was possible upon disease assessment on day 57, 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 ≤3 of the target ulcer at various timepoints and time to complete closure (remission) of the target ulcer.

In the third dosing cohort at 2400mg biweekly, all seven patients were evaluated at least on the day of last drug administration. Six of the seven patients achieved clinical remission with a PGA score of ≤1, which reflects a closure of the target ulcer. All patients in cohort 3 had

elevated C5a levels at baseline that were continuously suppressed after initiation of vilobelimab.

InflaRx previously reported data for ten evaluable patients in the first two dose cohorts at day 99. The patient in the second dosing cohort 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 the ulcer closed after the dose escalation. At day 99, this patient had a PGA score of 1, and by the end of the treatment period at day 189 had a PGA score of 0.

Overall, vilobelimab was well tolerated. From all cohorts, two patients had related serious adverse events (SAEs) that were reported: One patient experienced an erysipelas leading to hospitalization (judged as non-related by sponsor); another developed a rash due to a delayed hypersensitivity reaction and withdrew from study (which had been previously disclosed from cohort 2). No dose-related adverse events (AEs) were found. Overall, the observed AE profile was in line with the underlying diseases.

InflaRx will host a conference call and live audio webcast to discuss the clinical data from this study today at 8:30 am EDT / 2:30 pm CEST. To participate in the conference call, participants may pre-register and will receive dedicated dial-in details to easily and quickly access the call: https://services.choruscall.de/DiamondPassRegistration/register?confirmationNumber=9635740&linkSecurityString=10c5273014

Alternatively, if you have not registered in advance, you can enter the conference assisted by an operator. To reach an operator, please dial one of the following numbers:

| | |
|---|---|
| Germany: | +49 (0) 69 566 037 000 |
| United Kingdom: | +44 (0) 203 059 58 69 |
| United States: | +1 760 294 1674 |

To access the webcast online, please use the following link: https://services.choruscall.com/mediaframe/webcast.html?webcastid=5Pe5acAk

After the presentation, a Q&A session will be held. Participants may submit questions via the integrated chat window online or ask questions live by phone. The archived webcast will be made available in the Investors section of the Company's website at www.inflarx.com.

**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.

**Contacts:**

**InflaRx N.V.**
Jordan Zwick – Chief Strategy Officer
Jason Stewart – Strategy & Investor Relations
Email: IR@inflarx.de
Tel: +1 917-338-6523

**MC Services AG**
Katja Arnold, Laurie Doyle, Andreas Jungfer
Email: 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 of 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.

.