



InflaRx Completes Enrollment of Vilobelimab Phase IIa Study in Pyoderma Gangraenosum

- Target enrollment of 18 patients reached across three different dose groups
- Interim results will be available by the end of 2021 with final results expected in 2022
- Initial positive data from the first 5 patients previously announced in Q1 2020

Jena, Germany, April 15, 2021 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today the achievement of target enrollment of the Phase IIa open label study of vilobelimab in patients with Pyoderma Gangraenosum (PG).

Dr. Korinna Pilz, Global Head of Clinical Research and Development of InflaRx, commented: “The full enrollment of our PG study is a significant milestone for the clinical development of vilobelimab as we continue to build the evidence that C5a is an important target for neutrophil-driven skin diseases. PG is a devastating autoimmune disease, and we hope our program can play a vital role in helping these patients.”

This open-label Phase IIa proof-of-concept study has reached the target enrollment goal of 18 patients with moderate to severe PG at sites in the US, Canada and Europe. Patients in three different ascending dose groups are being treated with vilobelimab for 27 weeks with a two-month follow-up period. The main objectives of the study are the evaluation of the safety and efficacy of vilobelimab in patients with PG. Efficacy will be evaluated by (i) a responder rate defined as Physician Global Assessment ≤ 3 of the target ulcer at various timepoints and (ii) time to complete closure of the target ulcer. Both endpoints will be compared with historical data. Additional clinical endpoints include a photographic documentation and analysis of the ulcer size and several patient-reported outcome parameters, such as pain score and Dermatology Life Quality Index (DLQI).

In 2020, InflaRx announced positive initial data from the first five patients in the lowest dose group. Of these five initial patients, two patients achieved complete closure of the target ulcer and complete healing of all other PG ulcers. The drug was well tolerated and no drug-related severe adverse events (SAEs) have been recorded to date in the study.



A second interim analysis, including six patients treated in the second dose group until day 99, will be available by the end of 2021. Final results from all patients, including the highest dose group, are expected in 2022.

For more information about the study, visit [www.clinicaltrials.gov \(NCT03971643\)](http://www.clinicaltrials.gov/NCT03971643).

About vilobelimab:

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. Approximately 300 people have been treated with vilobelimab in clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various indications, including hidradenitis suppurativa, ANCA-associated vasculitis, pyoderma gangraenosum, cutaneous squamous cell carcinoma and severe COVID-19.

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. It occurs in people in their 40s and 50s. The exact prevalence of PG is not yet known, but it is estimated that up to 50,000 people in the US and Europe are affected by this disease. 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.

Patients suffer from severe pain, long healing times, and frequent relapses. There are currently no FDA approved drugs for the treatment of PG. 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 an important 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 the 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.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,” “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; 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.