



InflaRx Commences Second Phase II Clinical Trial of IFX-1 in ANCA-Associated Vasculitis with First Patient Treated in Europe

Jena, Germany, 14 May 2019 – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced the treatment of the first patient in IXchange, a Phase II study with IFX-1 in patients with ANCA-associated vasculitis (AAV) ([NCT03895801](https://clinicaltrials.gov/ct2/show/study/NCT03895801)).

AAV is a rare and life-threatening autoimmune disease in which activation of the complement system, and specifically generation of C5a, is believed to play a key role in the neutrophil-driven vessel inflammation that defines the disease. The disease affects approximately 40,000 and 75,000 patients in the United States and Europe, respectively.

The main objective of this randomized, double-blind, placebo-controlled Phase II study is to evaluate the efficacy and safety of IFX-1 in patients with moderate to severe AAV. The trial is planned to enroll approximately 80 patients at about 60 sites in up to 12 European countries and Russia. The study will be conducted in two parts. In Part 1, patients are being randomized to receive either IFX-1 plus a reduced dose of glucocorticoids, or placebo plus a standard dose of glucocorticoids. Patients in both arms will receive the standard of care dosing of immunosuppressive therapy (rituximab or cyclophosphamide).

Prior to starting Part 2 of the study, an independent data monitoring committee will evaluate the efficacy and safety results from Part 1 and recommend if the study should continue. Part 2 will evaluate if treatment with IFX-1 alone is as effective as IFX-1 in combination with glucocorticoids. Thus, in Part 2 patients will be randomized to receive IFX-1 plus placebo glucocorticoids versus placebo plus a standard dose of glucocorticoids. Patients in both arms will receive standard of care immunosuppressive therapy (rituximab or cyclophosphamide).

The primary endpoint of the study is a 50% reduction in Birmingham Vasculitis Activity Score (BVAS) at week 16, a well-established endpoint that has been used in the previous AAV studies. Secondary efficacy endpoints being analyzed include clinical remission, evaluation of the Vasculitis Damage Index, reduction of glucocorticoid toxicity, several relevant biomarkers like glomerular filtration rate, and patient reported outcomes.

“With the treatment of the first patient in the IXchange study, we now have two Phase II clinical studies with IFX-1 in AAV ongoing – one in Europe and one in the US,” said Othmar Zenker, MD, Chief Medical Officer at InflaRx. “We are excited to continue our evaluation of both the



effectiveness of IFX-1 compared to standard of care, as well as the potential of IFX-1 to replace glucocorticoids in treating this devastating disease.”

In October 2018, InflaRx started a US Phase II study to evaluate the safety and efficacy of IFX-1 in patients with AAV.

About IFX-1:

IFX-1 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, IFX-1 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. IFX-1 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. IFX-1 is believed to be the first monoclonal anti-C5a antibody introduced into clinical development and has, to date, successfully completed three clinical Phase II studies. More than 150 people have been treated with IFX-1 in these completed clinical trials, and the antibody has been shown to be well tolerated. IFX-1 is currently being developed for various inflammatory indications, including Hidradenitis Suppurativa, ANCA-associated vasculitis and Pyoderma Gangraenosum.

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 and New York, NY, USA. For further information please visit www.inflarx.com.

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FORWARD-LOOKING STATEMENTS

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