



## InflaRx Initiates Phase II Clinical Trial with IFX-1 in ANCA-Associated Vasculitis with First Patient Dosing

**Jena, Germany October 30, 2018 – InflaRx N.V.** (Nasdaq:IFRX), a biopharmaceutical company developing innovative therapeutics to treat devastating inflammatory diseases by targeting the complement system, a key component of the innate immune system, today announced that the first patient has been dosed in a phase II study to determine the safety and efficacy of IFX-1, a first-in-class anti-human complement factor C5a antibody, in patients with ANCA-associated vasculitis (AAV).

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

The randomized, double-blind, placebo-controlled phase II study is planned to enroll approximately 36 patients at about 20 sites in the U.S. (NCT 03712345). The study compares two different dose regimens of IFX-1 to placebo. All patients will receive current standard of care immunosuppressive therapy and high dose glucocorticoids. The main objective of the study is to evaluate the safety of IFX-1, as this will be the first time the drug is being administered to patients with AAV. Additional objectives are efficacy and the generation of pharmacokinetic/pharmacodynamics (PK/PD) data. The primary efficacy parameter is response rate based on the Birmingham Vasculitis Score (BVAS), a validated and well-established score in AAV. Patients will be treated for sixteen weeks followed by an observation period of eight weeks.

Othmar Zenker, M.D., Chief Medical Officer of InflaRx, said: “With the launch of this phase II trial, InflaRx now has studies underway in two orphan diseases with high unmet medical need (ANCA-associated vasculitis and hidradenitis suppurativa). In clinical testing to date, IFX-1 has been shown to effectively and selectively control C5a activation. Given the role that C5a is thought to play in amplifying the neutrophil driven vessel wall inflammation and damage in AAV, we believe that IFX-1 may have the potential to help patients suffering from this devastating disease.”

Peter A. Merkel, MD, MPH, Chief of Rheumatology and Professor of Medicine and Epidemiology at the University of Pennsylvania, said: “ANCA-associated vasculitis is an organ and life-threatening disease. While current treatment options have improved outcomes, substantial unmet medical needs remain. More effective, safer therapies are needed,



particularly regimens that reduce the need for high-dose glucocorticoids, which have significant side effects. I look forward to the insights we will gain from this trial evaluating IFX-1.”

**About IFX-1:**

IFX-1 is a first-in-class monoclonal anti-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 the first monoclonal anti-C5a antibody introduced into clinical development and has, to date, successfully completed three clinical phase II studies. In total, over 150 people have so far been treated with IFX-1, which was well tolerated. IFX-1 is currently being developed for various inflammatory indications, including hidradenitis suppurativa and ANCA-associated vasculitis.

**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, Michigan. InflaRx is listed on the Nasdaq Global Select Market in the United States under the trading symbol “IFRX”.

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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,” “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 timing of and our ability to make regulatory filings 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.