



InflaRx Receives European Approval to Initiate Phase II Clinical Trial with IFX-1 in ANCA-Associated Vasculitis

Jena, Germany, December 19, 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 the approval of an Investigational Medicinal Product Dossier (IMPD) from the European regulatory authorities, allowing InflaRx to initiate a phase II study with 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 generation 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.

Othmar Zenker, M.D., Chief Medical Officer of InflaRx, said: “We are pleased to be able to move forward with the second phase II study in AAV with IFX-1. AAV is an orphan disease with high unmet medical need. Together with the first study already ongoing in the US, we have initiated a state-of-the-art phase II program to evaluate the impact of IFX-1 on this often life-threatening disease.”

The randomized, double-blind, placebo-controlled phase II study is planned to enroll approximately 80 patients with AAV at about 60 sites in Europe. The main objective of the study is to evaluate the efficacy and safety of IFX-1 in this patient population. The study will be conducted in two parts. Part 1 will compare IFX-1 plus a reduced dose of glucocorticoids versus a standard dose of glucocorticoids, while part 2 will compare IFX-1 alone versus a standard dose of glucocorticoids. All patients will receive standard of care immunosuppressive therapy (rituximab or cyclophosphamide). The study is expected to initiate in the first quarter of 2019.

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. To date, more than 150 people have been treated with IFX-1, which has been shown to be well tolerated. IFX-1 is currently being developed for various inflammatory diseases, 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.

Contacts:

Investor Relations

InflaRx N.V.

Jordan Silverstein

Head of Corporate Development and Strategy

Jordan.silverstein[at]inflarx.de

+1-917-837-1709

Media Relations

MC Services AG

Katja Arnold, Laurie Doyle, Andreas Jungfer

inflarx[at]mc-services.eu

+49-89-210 2280

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.