



## InflaRx Receives IND Approval from the FDA to Start its Phase II Clinical Trial of IFX-1 in ANCA-Associated Vasculitis

**Jena, Germany, June 28, 2018 – InflaRx N.V.** (Nasdaq: IFRX), a biopharmaceutical company developing innovative therapeutics to treat life-threatening inflammatory diseases by targeting the complement system, a key component of the innate immune system, today announced the approval of their Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA). The open IND will allow InflaRx to start their planned 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 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: “FDA IND approval marks another important milestone for InflaRx, allowing us to conduct parallel clinical development of IFX-1 in two indications, following the successful launch of the SHINE study in patients with moderate or severe Hidradenitis Suppurativa (HS) earlier this year. A growing body of research suggests C5a may play a critical role in amplifying inflammatory responses in AAV. IFX-1 has been shown to effectively control C5a activation in several clinical phase II studies to date and our team is eager to study the potential clinical benefit this antibody candidate could bring to patients suffering from this life-threatening disease.”

The phase II study will enroll approximately 36 patients in approximately 20 sites in the U.S. The main objective of the study is to evaluate the safety and efficacy of two different dose regimens of IFX-1 in comparison with placebo on top of current standard of care.

### **About IFX-1:**

IFX-1 is a first-in-class monoclonal anti-complement factor C5a antibody which completely blocks biological activity in and demonstrates high selectivity towards its target, C5a 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 different inflammatory indications.

**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 has offices in Jena and Munich, Germany and a research facility in 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.