InflaRx receives IND acceptance to proceed with a Phase IIb Trial with lead candidate IFX-1 in Hidradenitis Suppurativa

Jena, Germany, January 9, 2018 – InflaRx N.V. (Nasdaq:IFRX), the biopharmaceutical company developing new therapeutics in the terminal complement space, today announced the acceptance of their Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA). The open IND will allow InflaRx to conduct a phase IIb study to determine efficacy and safety of IFX-1, a first-in-class anti-human complement factor C5a antibody, in patients with moderate or severe Hidradenitis Suppurativa. The randomized, double-blind and placebo-controlled multicenter study is planned to be conducted at approximately 50 sites in several countries and expected to enroll approximately 175 patients, divided equally into five cohorts. InflaRx intends to initiate the study in the first quarter of 2018.

Hidradenitis Suppurativa (HS) is a painful, chronic and debilitating inflammatory skin disease. The study’s primary goal is to evaluate the dose-response signal of IFX-1 in patients with HS according to the Hidradenitis Suppurativa Clinical Response (HiSCR) at week 16 during the study period. Secondary goals are assessment of further efficacy and patient-reported outcome parameters, as well as the safety and tolerability of IFX-1. After the placebo-controlled double-blind phase, the study will be extended into an open label extension phase to assess long-term efficacy and safety. The study will be coordinated by the principal investigator Prof. Dr. med. Evangelos J. Giamarellos-Bourboulis at the ATTIKON University Hospital in Athens, Greece.

Othmar Zenker, M.D., Chief Medical Officer of InflaRx, said: “With the experience gained from an earlier study of IFX-1 in patients with Hidradenitis Suppurativa, which demonstrated good safety and encouraging efficacy signals, this trial is designed to find the optimal dose range as well as to assess long term efficacy and safety of IFX-1. C5a blockade with IFX-1 offers an entirely new mode of action to treat this disease in which the terminal complement system is highly activated. This study will help us evaluate a potential new way to treat Hidradenitis Suppurativa.”

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. InflaRx is listed on the Nasdaq Global Select Market in the United States under the trading symbol “IFRX”. For further information please visit www.inflarx.com.

Contacts:
InflaRx N.V.
Prof. Dr. Niels C. Riedemann - CEO
Email: info[at]inflarx.de
Tel: +49-3641-508180

MC Services AG
Katja Arnold, Andreas Jungfer
Email: inflarx[at]mc-services.eu
Tel: +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.