InflaRx Announces Presentation of New Clinical Data with Lead Candidate IFX-1 in Hidradenitis Suppurativa

- *Retrospective long-term results from phase IIa trial indicate sustained remission post IFX-1 treatment*
- *Baseline characteristics from ongoing phase IIb SHINE trial in line with expectations; on track for topline results Q2 2019*

Jena, Germany, February 6, 2019 – 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 new clinical data with IFX-1, a first-in-class anti-human complement factor C5a antibody, in patients with moderate to severe Hidradenitis Suppurativa (HS) are to be presented this week at the 8th Conference of the European Hidradenitis Suppurativa Foundation in Wrocław, Poland. HS is a painful and debilitating chronic inflammatory skin disease with limited treatment options.

Retrospective long-term data from phase IIa trial:

As previously reported, an open-label phase IIa clinical trial in 12 patients with severe HS showed a response of 75% according to HS Clinical Response (HiSCR) criteria at the end of an 8-week treatment period and 83% at the end of a 12-week treatment-free follow-up period. The results to be reported on February 8th are from an additional retrospective evaluation of the long-term effect of IFX-1post treatment. Ten of the 12 patients were available for this analysis. The median observation period after the last IFX-1 treatment was 226 days (range 119 to 324 days). The long-term efficacy was assessed by the abscess and inflammatory nodule count (AN count), number of draining fistulas, HiSCR assessment, and the occurrence of flares. Flares were defined as deterioration of HS requiring antibiotic therapy.

Two flares occurred during the treatment period, and two flares occurred during the scheduled follow-up period. In the long-term follow-up, there were 26 flares, ranging from two to four per patient. The median time to the first flare after stopping IFX-1 treatment was 209 days (range 54 to 318 days), while off of medication, 50% of patients had no flares to day 203.

Further analyses of AN count, number of draining fistulas, and HiSCR supported the assumption of the long-lasting effect of IFX-1 after stopping treatment.

Prof. Dr. med. Evangelos J. Giamarellos-Bourboulis, ATTIKON University Hospital in Athens, Greece, the principal investigator of this trial, commenting on the IFX-1 data, said: “It is

gratifying to see that sustained remission was observed in most patients treated with IFX-1. It is notable that after only 8 weeks of treatment, the median time to the first flare was almost seven months. With limited options for Hidradenitis Suppurativa, there is a major need to find more effective therapies that can provide relief over an extended period of time. I look forward to seeing the results from the ongoing randomized study with IFX-1 in this indication, which should give us additional insight into the efficacy and safety of this novel treatment for this debilitating condition."

Baseline characteristics from ongoing phase IIb trial:

Dr. Giamarellos-Bourboulis is also to present the blinded baseline characteristics from an ongoing prospective, randomized, multicenter, double-blind, placebo-controlled phase IIb trial evaluating IFX-1 in patients with moderate to severe HS. The primary objective of the trial is to evaluate a dose response signal of IFX-1 with HiSCR at week 16. InflaRx announced completion of enrollment in November 2018. A blinded snapshot of the clinical database was performed, and available data from 179 patients at baseline are being reported. 56% of the patients are female, and 44% are male, with a mean age of 37.1 years old, and mean body weight of 92.2 kg. The median duration of HS was 8 years (range 1 to 39 years); while 59% and 41% of patients were classified as Hurley Stage 2 or 3, respectively. The median inflammatory nodule count at baseline was 9 (range 3 to 58). These baseline demographical data and characteristics are in-line with the overall moderate to severe HS population, and similar to that of other clinical studies in this field.

Topline results from the phase IIb study are expected during the second quarter of 2019.

Othmar Zenker, M.D., Chief Medical Officer of InflaRx, said: "We are pleased that the phase IIb study in Hidradenitis Suppurativa is advancing according to plan. The goal with this trial is to determine the optimal dose regimen, as well as assess both the long-term efficacy and safety of IFX-1 in patients with this disease. We look forward to advancing to the next stages of development in this important indication."

About Hidradenitis Suppurativa (HS)

HS is a chronic debilitating systemic skin disease which results in painful inflammation of the hair follicles, typically in the armpit, groin and genitalia regions. HS patients suffer primarily from pain driven by inflamed nodules and abscess formation and significant discomfort resulting from the constant formation of pus, particularly in the areas described above, leading to social isolation. HS is typically present after adolescence and often develops into a life-long debilitating chronic disease. In the United States, up to 200,000 patients are affected annually with moderate to severe disease (Hurley stages 2 to 3), with a current increase in recognition

and diagnoses being expected and discussed amongst key opinion leaders. In Europe, the number of affected patients is considered to be higher with a trend of more cases of HS in countries with overall warmer climates. The standard of care for HS patients includes antibiotic treatment, which often only provides temporary symptomatic relief. In some cases, patients also undergo surgery. The only approved biological drug in this indication for moderate to severe HS patients is an anti-TNF-alpha monoclonal antibody.

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 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, MI and New York, NY.

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’ 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.