InflaRx Announces Top-Line SHINE Phase IIb Results for IFX-1 in Hidradenitis Suppurativa

- ***IFX-1 did not demonstrate a statistical significant dose dependent effect on Hidradenitis Suppurativa Clinical Response (HiSCR) rate at week 16 as primary endpoint***

- ***IFX-1 treatment achieved a maximum HiSCR rate of 51.5 % at week 16, while placebo treatment resulted in a HiSCR rate of 47.1 %***

Jena, Germany, June 5th, 2019 – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics targeting the complement system, today reported the top-line results of the international SHINE Phase IIb study, investigating the safety and efficacy of IFX-1, a first-in-class anti-human complement factor C5a monoclonal antibody, in patients suffering from moderate to severe Hidradenitis Suppurativa (HS), a painful and debilitating chronic inflammatory skin disease with limited treatment options.

The randomized, double-blind, placebo-controlled, multicenter study enrolled a total of 179 patients in four active dose arms and a placebo arm at over 40 sites in 9 countries in North America and Europe. The primary endpoint of the trial was a dose response signal, assessed by the Hidradenitis Suppurativa Clinical Response (HiSCR) score at week 16. The primary statistical analysis by multiple-comparison procedure modelling (MCP-mod) showed no significant dose response for the IFX-1 treatment.

The individual HiSCR rates at week 16 for the four different dose arms and the placebo arm are outlined below:

IFX-1				**Placebo**
Minimal dose	**Low dose**	**Medium dose**	**High dose**	placebo Q2W
400mg every 4 weeks (Q4W)	800mg every 4 weeks (Q4W)	800mg every 2 weeks (Q2W)	1200mg every 2 weeks (Q2W)	
40.0%	51.5%	38.7%	45.5%	47.1%

A statistically significant reduction of the dermatology life quality index (DLQI) could be detected comparing the overall treatment arms with the placebo arm at week 16 (p=0.031) using the

Kruskal-Wallis statistical analysis. The median DLQI reduction at week 16 compared to pre-dose values was highest in the medium dose group (-5.5 points) when compared to the reduction in the placebo group (-1.5 points). There was a trend in the reduction of the overall AN count comparing the placebo group (median reduction of -3.0) and the low, medium and high dose group (-5.0, -5.0, and -4.5, respectively).

IFX-1 was well tolerated. No difference could be detected in treatment emergent adverse events between placebo and treatment groups. Overall, 72% of placebo treated patients experienced a treatment emergent adverse event when compared to 66% of the combined IFX-1 treated groups. The most common treatment emergent adverse events were exacerbation of Hidradenitis Suppurativa and nasopharyngitis.

Othmar Zenker, Chief Medical Officer of InflaRx, said: “We are disappointed that we were not able to demonstrate a significant signal on dose response for the treatment with IFX-1. While we are still analyzing additional data, we note that the trial demonstrated an unusually high placebo HiSCR rate at week 16”.

More detailed analyses of other endpoints and additional data from the ongoing 28-week open label extension (OLE) part of the SHINE trial will be conducted as they become available.

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, ANCA-associated vasculitis and Pyoderma Gangraenosum.

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, USA. For further information please visit www.inflarx.com.

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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.