



## InflaRx Doses First Patient in Multicenter Phase II Clinical Trial in Cutaneous Squamous Cell Carcinoma with Vilobelimab

- Proof-of-concept trial will evaluate vilobelimab alone and in combination with pembrolizumab

**Jena, Germany, June 8, 2021** – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced the enrollment of the first patient in an open-label, multicenter Phase II clinical study evaluating vilobelimab alone and in combination with pembrolizumab in patients with PD-1 or PD-L1 inhibitor resistant/refractory locally advanced or metastatic cutaneous squamous cell carcinoma (cSCC).

The Phase II clinical trial is expected to enroll approximately 70 patients at sites in Europe, the U.S. and elsewhere. The study will investigate two independent arms: vilobelimab alone and vilobelimab in combination with pembrolizumab. The main objectives of the trial are to assess the safety and antitumor activity of vilobelimab monotherapy and to determine the maximum tolerated or recommended dose, safety and antitumor activity in the combination arm.

Dr. Korinna Pilz, Global Head of Clinical Research and Development at InflaRx, said: “We are pleased to initiate the first clinical trial to evaluate vilobelimab in cancer. Scientific data suggest C5a involvement in tumor formation and progression, as well as in immunosuppression. Additionally, there is pre-clinical evidence of synergies between PD-1 and C5a/C5aR inhibitors in inducing anti-tumor responses. Based on this, we believe that vilobelimab has the potential alone and in combination with the PD-1 checkpoint inhibitor pembrolizumab to treat the advanced stages of this potentially deadly skin cancer.”

The C5a/C5aR pathway has been implied as a potential driver for tumorigenesis, metastases and avoidance of immune cell destruction, particularly in the context of cSCC.

Several independent pre-clinical studies showed that the combination of a C5a or C5aR pathway inhibitor with inhibition of the PD-1/PD-L1 axis leads to an antitumoral effect, which was stronger than inhibition of one of the axes alone. This provides a pre-clinical rationale for the combined blockade of PD-1 and C5a to restore antitumor immune responses and to inhibit tumor cell growth.



### **About cutaneous squamous cell carcinoma (cSCC)**

cSCC is the second most common form of skin cancer and, if caught early, it is generally curable. In the U.S. alone, according to the Skin Cancer Foundation, an estimated 1.8 million cases are diagnosed each year, which translates to about 205 cases diagnosed every hour. The incidence of cSCC has increased up to 200 percent in the past three decades. Over 15,000 people in the U.S. die each year from this disease. Approximately 5% of patients with cSCC develop locally advanced or metastatic disease. These forms of cSCC have a poor prognosis with low survival rates.

### **About vilobelimab (IFX-1):**

Vilobelimab 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, vilobelimab 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. Vilobelimab 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. Vilobelimab is believed to be the first monoclonal anti-C5a antibody introduced into clinical development. Approximately 300 people have been treated with vilobelimab in clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various indications, including Hidradenitis Suppurativa, ANCA-associated vasculitis, Pyoderma Gangraenosum and COVID-19 pneumonia.

### **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, USA. For further information, please visit [www.inflarx.com](http://www.inflarx.com).

### **Contacts:**

#### **InflaRx N.V.**

Jordan Zwick – Chief Strategy Officer



Email: IR@inflarx.de

Tel: +1 917-338-6523

**MC Services AG**

Katja Arnold, Laurie Doyle, Andreas Jungfer

Email: inflarx@mc-services.eu

Europe: +49 89-210 2280

US: +1-339-832-0752

**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,” “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 impact of the COVID-19 pandemic on the Company; the timing and our ability to commence and conduct clinical trials; potential results from current or potential future collaborations; our ability to make regulatory filings, obtain positive guidance from regulators, 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.