InflaRx Announces Positive Topline Results for Vilobelimab from the U.S. Phase II ANCA-Associated Vasculitis IXPLORE Study

- U.S. IXPLORE Phase II trial achieved its objective; vilobelimab was shown to be safe and well tolerated in patients with ANCA-associated vasculitis when added to current standard of care
- EU IXCHANGE Phase II trial is fully enrolled with results expected by the end of 2021

Jena, Germany, May 11, 2021 – InflaRx (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today positive topline results from its U.S. Phase II IXPLORE study with vilobelimab in patients with anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis, or AAV.

“ANCA-associated vasculitis is an organ and life-threatening disease. Although current treatments for AAV are quite helpful in many patients, there are still unmet needs for fast-acting, effective, and safe treatments and alternatives to the regular use of high-dose glucocorticoids,” said Dr. Peter A. Merkel, Chief of Rheumatology and Professor of Medicine at the University of Pennsylvania. “Research suggests C5a has an important role in the pathogenesis of AAV, and blockade of C5a offers the opportunity to address several of these unmet needs. The results of the IXPLORE trial show C5a blockade by vilobelimab is safe and well tolerated when added to standard of care therapy for AAV. These results support the continued study of vilobelimab for the treatment of AAV.”

“We are pleased to report that vilobelimab was safe and well tolerated in combination with standard of care for patients with ANCA-associated vasculitis in the U.S. IXPLORE Phase II trial,” said Dr. Korinna Pilz, Global Head of Clinical Research and Development. “We are looking forward to our EU IXCHANGE Phase II trial results later this year where we are further evaluating the potential efficacy of vilobelimab alone compared to a standard dose of glucocorticoids. The results from these two trials will provide us good insight to plan our next development steps in this important indication.”

U.S. Phase II IXPLORE Study Design and Topline Results

The randomized, double-blind, placebo-controlled Phase II study enrolled 19 patients in the U.S. (NCT 03712345). The study compared two different dose regimens of vilobelimab to placebo. All patients received current standard of care immunosuppressive therapy and high dose glucocorticoids (SOC). The primary endpoint of the study was to evaluate the safety of vilobelimab, as this was the first time the drug was being administered to patients with AAV in the U.S. Important efficacy parameters included response and remission rates based on the Birmingham Vasculitis Score (BVAS), a validated and well-established score in AAV. Patients were randomized into three groups:

- SOC plus placebo;
- SOC plus 400 mg vilobelimab q2w; and
- SOC plus 800 mg vilobelimab q2w

Patients were treated for 16 weeks (including a fractionated loading dose at days 4 and 8) followed by an observation period of 8 weeks.

The IXPLORE safety study met its primary objective: Across all groups, a similar number of patients experienced one or more treatment-emergent adverse events (TEAEs).

- TEAEs:
    - 5 of 6 patients (SOC plus placebo)
    - 7 of 7 patients (SOC plus vilobelimab 400 mg)
    - 6 of 6 patients (SOC plus vilobelimab 800 mg)

In addition, a similar number of patients experienced TEAEs rated as drug-related by investigators:

- Any drug-related TEAE:
    - 3 of 6 patients (SOC plus placebo)
    - 3 of 7 patients (SOC plus vilobelimab 400 mg)
    - 2 of 6 patients (SOC plus vilobelimab 800 mg)

Overall, no safety signal of concern could be detected in the study, as observed TEAEs are reflective of the disease and SOC treatment.

At baseline, patients in the higher dose vilobelimab group (800 mg) showed a higher Birmingham Vasculitis Activity Score (BVAS) of 17.5 mean / 16.5 median, when compared to the baseline

BVAS scores of the SOC group (13.8 mean / 13.5 median) and the 400 mg vilobelimab group (13.1 mean / 12.0 median).

The IXPLORE study was not powered to show statistical significance on efficacy endpoints; however, clinical response and remission for each treatment group was measured at week 16 as secondary efficacy endpoints using the BVAS. The proportion of patients achieving a clinical response was defined as a 50% reduction in BVAS at week 16 (and no worsening in any body system) compared to baseline, and clinical remission was defined as BVAS=0.

Although the sample size of the trial was small and it is difficult to interpret results not powered to show statistical significance, patients across all three treatment groups demonstrated a strong response at week 16, and more patients treated with SOC plus vilobelimab had clinical remissions at various timepoints throughout the study compared to SOC plus placebo:

Clinical Response at Week 16:

Dose	SOC plus placebo N=6	SOC plus 400 mg vilobelimab N=7	SOC plus 800 mg vilobelimab N=5*
Responders	6 (100%)	6 (85.7%)	5 (100%)

*one patient at week 16 did not attend the visit

Clinical Remission at various timepoints:

Dose	SOC plus placebo N=6	SOC plus 400 mg vilobelimab N=7	SOC plus 800 mg vilobelimab N=6	Combined vilobelimab groups N=13
Remissions at Week 4	1 (16.7%)	3 (42.9%)	1 (20%)*	4 (33.3%)*
Remissions at Week 8	1 (16.7%)	4 (57.1%)	2 (33.3%)	6 (46.2 %)
Remissions at Week 12	3 (50%)	5 (71.4 %)	3 (50%)	8 (61.5%)
Remissions at Week 16	4 (66.7%)	6 (85.7%)	3 (60%)*	9 (75%)*
Remissions at Week 20	3 (50%)	5 (71.4%)	3 (75%)**	8 (72.7%)**
Remissions at Week 24	3 (50%)	5 (71.4%)	4 (80%)*	9 (75%)*

*one patient did not attend the visit at timepoint

**two patients did not attend the visit at timepoint

InflaRx plans to present more detailed trial results at a future medical meeting.

As previously reported, both Part 1 and Part 2 of the AAV Phase II study in Europe (IXCHANGE) are fully enrolled. Data from the randomized, double-blind, placebo-controlled trial with 57 patients are expected by the end of 2021.

About ANCA-associated vasculitis (AAV):

AAV is a rare and life-threatening autoimmune disease in which activation of the complement system, and specifically the generation of larger amounts 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.

About vilobelimab:

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, cutaneous squamous cell carcinoma and severe COVID-19.

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.

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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,” “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.