InflaRx Reports Topline Phase IIa Clinical Results of IFX-1 for the Treatment of Hidradenitis Suppurativa

IFX-1 demonstrates disease modifying activity

Jena, Germany, September 7th 2017 - InflaRx, the biopharmaceutical company developing new therapeutics in the terminal complement space, announced today positive topline data from an exploratory Phase IIa clinical trial with lead compound 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, chronic and debilitating inflammatory skin disease.

This open label, single center study recruited twelve patients with moderate to severe HS, who were not eligible for or failed to respond to previous therapy with biologicals. Patients were treated with weekly intravenous injections of IFX-1 for eight consecutive weeks and were then followed up for an additional period of twelve weeks. The study was conducted to primarily assess the safety and tolerability of IFX-1 in HS patients. Initial efficacy of treatment was assessed through response rate, as measured by the validated and clinically relevant Hidradenitis Suppurativa Clinical Response (HiSCR) score. This score is defined as a reduction of 50% or higher in inflammatory lesion count (abscesses and inflammatory nodules) and no increase in abscesses or draining fistulas when compared with baseline. The severity and extent of HS was assessed using the Hurley Stages scoring system, which describes three distinct clinical stages of HS.

In the study, all twelve patients were categorized as Hurley Stage III and therefore most progressed diseased patients, demonstrating a mean duration of HS of 19.9 years. Nine out of the twelve patients had previously failed to respond to an anti-TNF-alpha antibody, the only approved biological treatment in this indication. The mean combined number of lesions (abscesses and inflammatory nodules) and draining fistulas at baseline was 6.4. and 11.2, respectively. Assessment of the HiSCR score demonstrated a response rate of 75% (nine out of twelve patients) at the end of the treatment period and 83% (ten out of twelve) at the end of the twelve week follow up period. The weekly intravenous infusions of IFX-1 were well tolerated. No drug-related adverse events were detected and no infusion-related, allergic or anaphylactic reactions were observed.

In addition, positive trends of clinical improvement were also detected with other relevant parameters, including the dermatology life-quality index, a patient-reported outcome measure.

“These positive results in some of the sickest and most debilitated of our HS patients are very encouraging and exciting for both, the study team and myself. 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,” commented Professor Giamarellos-Bourboulis of the National and Kapodistrian University of Athens, principle investigator of the study. “IFX-1 may offer a new treatment option for patients suffering from this terrible disease and the results certainly warrant further clinical trials,” he added.

“Our results show improvement in a patient population that is generally recognized as the most difficult-to-treat. For this reason, this trial provides exciting evidence of a new therapeutic approach,” said Othmar Zenker, Chief Medical Officer of InflaRx. “We feel encouraged by these results and are currently planning the initiation of an international, multi-center, randomized, placebo-controlled Phase IIb trial in HS,” he concluded.

InflaRx will present further details on these results at the 16th European Meeting on Complement in Human Disease, taking place in Copenhagen from September 8 to 12 as well as the 26th Meeting of the European Academy of Dermatology and Venerology in Geneva from September 13 to 17.

About Hidradenitis Suppurativa:

HS is a chronic debilitating systemic skin disease which results in painful inflammatory nodules, abscesses and fistulas mostly affecting areas with hair follicles, such as the armpit, groin and genitalia regions. HS patients suffer primarily from pain and significant discomfort resulting from the constant formation of pus, often resulting in social isolation and a significant adverse impact on patients’ quality of life. It is estimated that approximately up to 200,000 patients in the United States are suffering from moderate to severe HS, and this number appears to be larger in Europe. The standard of care for HS patients includes topical, oral or intravenous 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-complement factor C5a antibody which offers a complete biological blocking activity and high selectivity towards its target, C5a in human blood. Thus, IFX-1 leaves the formation of the membrane attack complex (C5b-9) intact to work 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 3 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:

InflaRx is a clinical-stage biopharmaceutical company focusing on applying its proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of C5a. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of autoimmune and other inflammatory diseases. The company is also developing additional molecules targeting chronic and inflammation-related diseases. InflaRx was founded in 2007 and has offices in Jena and Munich, Germany. The team consists of renowned experts in complement and clinical research.

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