



InflaRx announces positive phase IIa top-line results from the SCIENS trial investigating IFX-1, a first-in-class anti-complement C5a antibody

Jena, Germany, January 28th 2016 - InflaRx, the biopharmaceutical company developing new therapeutics in the terminal complement space, announced today positive results from its SCIENS phase IIa clinical trial of IFX-1, a first-in-class monoclonal anti-C5a antibody. The trial reached all primary endpoints and demonstrated safety, tolerability and biological proof of concept of IFX-1 in patients suffering from early septic organ dysfunction.

IFX-1 highly statistically significantly reduced and effectively blocked C5a in a dose-dependent manner. In addition, the data showed positive trends in various other clinically relevant efficacy endpoints, such as organ dysfunction score (SOFA score), need for ventilator support and length of stay on the ICU. IFX-1 is the first monoclonal anti-C5a antibody introduced into clinical development, which has now successfully completed a clinical phase II study in patients.

Prof. Niels Riedemann, co-founder and CEO of InflaRx commented, "After 15 years of focused research and development around C5a, one of the most promising targets in inflammation, we are excited that we can now demonstrate the power of our technology in patients. We developed IFX-1 to become a game-changer in the intensive care field and these new results bring us a big step closer to this goal."

The SCIENS trial enrolled 72 patients suffering from early septic organ dysfunction in a placebo controlled double blinded dose escalation design and was conducted within the SepNet study trial group in 15 German Intensive Care Units. The study investigated the pharmacokinetics/pharmacodynamics (PK/PD), safety and tolerability of IFX-1 as well as various exploratory secondary clinical endpoints. Furthermore, it represents a first-in-class clinical trial in the infectious acute care space, as it enrolled focus-selected patients with early organ dysfunction within only 3.5 hours after screening, to evaluate the benefits of an early intervention.

"We designed this study to gain in-depth knowledge about IFX-1 consumption and complement activation in this patient population. We will use the upcoming weeks to carefully

analyze all data in order to tailor the planned phase IIb trial in this vital area of unmet medical need,” Dr. Othmar Zenker, Head of Clinical R&D noted.

“InflaRx has taken a highly innovative clinical trial approach in investigating this very promising antibody to tackle one of the most life-threatening events within the entire acute care field: inflammation induced organ failure. Based on these encouraging results, we are optimistic that the further development of IFX-1 could be of significant benefit to patients and doctors in this devastating condition, where thus far no therapy is available,” concluded Prof. Michael Bauer, study PI appointed Chairman of Anesthesiology and Intensive Care Medicine and Chairman of the Center for Sepsis Control and Care at the Jena University Hospital.

About septic organ dysfunction and complement C5a: In serious infections, the body’s immune system activates inflammatory response mechanisms which have been described as cause of self-induced tissue and organ damage, such as oxygen radical formation, enzyme and cytokine release by activated blood cells and various others. This damage quickly results in organ dysfunction and ultimately organ failure which is the lead cause of death of patients in most intensive care units worldwide. Similar mechanisms have been described in other infectious settings such as Malaria, Dengue Fever and others, but also in non-infectious inflammation, such as large operations, burn or trauma. Various international scientific groups and the InflaRx’ founders have identified C5a as a key “amplifying factor” of most such acute inflammatory responses. In experimental models, early blockade of C5a resulted in a preservation of organ function and improved survival by down-regulation of the immune cell induced tissue damage and various other inflammatory responses.

About IFX-1: IFX-1 is a first-in-class monoclonal anti-human complement C5a antibody which demonstrates a complete biological blocking activity and selectivity towards its target, C5a, leaving the important defense mechanism of C5b-9 formation intact. IFX-1 is thought to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response. IFX-1 is currently in clinical phase II development for various different acute and life-threatening inflammatory indications.

About [InflaRx](#): InflaRx is a biopharmaceutical company focusing on the development of new therapeutics controlling the inflammatory response based on its proprietary technology.. InflaRx has developed a pipeline of first-in-class antibodies directed against the terminal complement component C5a. While IFX-1 focuses on the acute care space, its product candidates, IFX-2 and IFX-3, are being developed in chronic inflammatory disease indications. InflaRx was founded in 2007 and is headquartered in Jena, Germany, with long

standing research collaborations in the US and China. The team consists of renowned experts in complement research and clinical acute care. InflaRx is privately owned and financed by bm-t Beteiligungsmanagement Thüringen GmbH, KfW banking group and various international family offices.

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