



## InflaRx initiates phase II trial with IFX-1, a first-in-class anti-complement C5a antibody, in patients undergoing complex cardiac surgery

Jena, Germany, June 7<sup>th</sup> 2016 - InflaRx, the biopharmaceutical company developing new therapeutics in the terminal complement space, announced today that the first patient has been dosed preventively in a phase II clinical trial of IFX-1, a first-in-class monoclonal anti-complement C5a antibody, in patients undergoing complex cardiac surgery.

The “CARDIAC” trial is a four-arm, prospective, randomized, double blind, placebo-controlled multicenter study that will enroll 100 patients in 10 centers across Germany. The patients must undergo a complex cardiac surgery defined as “invasive open heart” and / or “aortic trunk surgical procedures” requiring the use of a heart-lung-machine, otherwise known as cardiopulmonary bypass (CPB).

The aim is to evaluate whether the prophylactic treatment with IFX-1 protects patients from severe systemic inflammation and subsequent organ dysfunction. The reduction of interleukin (IL)-6 levels, as one of the key inflammatory markers, is the primary endpoint. Secondary endpoints include clinical efficacy, safety, and pharmacokinetic parameters. After the recent successful completion of the first phase IIa SCIENS trial, this is the second indication in which IFX-1 is being tested in a phase II clinical trial. IFX-1 has demonstrated an exceptional ability to specifically bind and completely block free complement C5a.

“Complement activation is known to be one of the major factors responsible for systemic inflammation, therefore, the preventive blockade of C5a should strongly reduce inflammation and aid patient recovery,” explained Othmar Zenker, Head of Clinical Research and Development of InflaRx. “The CARDIAC trial is the first of three additional phase II trials planned to be initiated with IFX-1 in different indications”, he continued.

**About complex cardiac surgery and complement C5a:** Complex cardiac surgery is characterized by an open heart combination surgery procedure requiring the use of a heart-lung machine (cardiopulmonary bypass “CPB”) with long cardiac bypass times.

Hereby, the blood is bypassing the heart and lung in tubes while being oxygenated. The blood contact with the artificial surfaces of the tubes as well as the tissue injury during such

invasive surgery are known activators of the complement system and lead to the generation of the terminal complement split product C5a, resulting in a substantial acute inflammatory response. This inflammation frequently causes a life-threatening situation for the patient affecting the cardiovascular and other organ systems. This phenomenon is generally recognized in large scale surgeries but is especially pronounced in complex cardiac surgery.

**About IFX-1:** IFX-1 is a first-in-class monoclonal anti-complement C5a antibody which offers a complete biological blocking activity and selectivity towards its target, C5a. 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 thus far successfully completed a clinical phase IIa study in patients suffering from septic organ dysfunctions in which all primary endpoints were met. IFX-1 is currently being developed in four different indications.

**About [InflaRx](#):** InflaRx is a biopharmaceutical company focusing on the development of new breakthrough therapeutics controlling inflammation resulting from terminal complement activation. It’s lead drug IFX-1 takes a global lead status in the area of targeted complement C5a inhibition, which the company believes to hold vast potential as a game changer in inflammation. The company also develops additional molecules (IFX-2 and IFX-3) targeting chronic and inflammation related diseases. InflaRx was founded in 2007 and is headquartered in Jena, Germany. The team consists of renowned experts in complement and clinical research. InflaRx is financed by bm-t Beteiligungsmanagement Thüringen GmbH, KfW banking group and various international family offices.

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