PRESS RELEASE

TiGenix completes enrolment of its Phase I/II study in acute myocardial infarction

Leuven (BELGIUM) – 19th November 2015 – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platforms of allogeneic expanded stem cells, announced today that it has completed enrolment of its Phase II study in acute myocardial Infarction (CAREMI study).

CAREMI is a two phase study consisting of an open-label dose-escalation phase I completed in June 2015, and a randomised, double-blind, placebo-controlled phase II, aiming at evaluating the safety and efficacy of intracoronary infusion of AlloCSC-01, a suspension of allogeneic human cardiac stem cells (CSCs), in patients that have suffered an acute myocardial infarction (AMI). Enrolment of this second phase has been completed with the treatment of the last of the planned 49 patients. The trial has now entered in its 12 month follow-up period.

"We are very satisfied with the timely completion of the enrolment of the randomised phase of the trial. We see this as evidence of the close collaboration maintained with our clinical partners in the cardiology space", said Dr. Marie Paule Richard, Chief Medical Officer at TiGenix, "This achievement will enable us to perform a 6-month interim blinded exploratory analysis and obtain preliminary efficacy data early in the second half of 2016, with final results in the first half of 2017."

We believe AlloCSC-01 may become a new approach to prevent cardiac remodelling and the onset of Chronic Heart Failure (CHF) after AMI. In the United States and Europe, approximately 1.5 million AMIs are treated annually. Current AMI management therapeutic options including Percutaneous Transluminal Coronary Angioplasty (PTCA), combined with stent implantation, are in most cases successful in re-establishing the perfusion of the ischemic myocardium and have helped to reduce the immediate mortality after infarct. However, these treatments are not able to recover the injured tissue. In fact all currently approved therapeutic approaches are palliative and designed to preserve the function of the surviving myocardium.

The CAREMI trial will help to establish AlloCSC-01 as a potential means to reduce the damage caused by the infarct and improve the prognosis of AMI patients in this very large indication. Eight clinical centers of reference in cardiology have participated in the CAREMI trial led by Prof. Fernández-Avilés of Hospital Gregorio Marañón in Madrid, Spain, and Prof. Stefan Janssens of KU Leuven, Belgium, as principal investigators. The CAREMI trial has been supported by the Seventh Framework Programme of the European Commission, a transnational research funding initiative, as part of the CARE-MI project (Grant Number 242038).

For more information

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About AlloCSC-01

AlloCSC-01 is a cellular product consisting of adult allogeneic cardiac stem cells isolated from the right atrial appendages of donors, and expanded in vitro. Pre-clinical data has shown evidence of the strong cardio-protective and immune-regulatory activity of AlloCSC-01. In vivo studies suggest that AlloCSC-01 has cardio-reparative potential by activating endogenous regenerative pathways and by promoting the formation of new cardiac tissue. In addition, AlloCSC-01 has displayed a strong tropism for the heart enabling a high retention of cells in the myocardium after intracoronary administration. AlloCSC-01 is currently in clinical development in a Phase I/II clinical trial (CAREMI). The CAREMI trial comprises two consecutive phases: an open-label dose-escalation phase (n=6) and a 2:1 randomised, double-blind, placebo-controlled phase (n=49). The objective of this clinical trial is to evaluate the safety and the efficacy of the cardiac stem cells product AlloCSC-01 in the acute phase of ischemic heart disease. The primary endpoint of the CAREMI Phase I is all-cause mortality within 30 days and all adverse events of any cause from the patient's inclusion until 7 days after treatment administration. Secondary endpoints for this dose escalation phase include efficacy MRI parameters (evolution of infarct size and evolution of biomechanical parameters), clinical parameters (including the 6 minute walking test and the New York Heart Association scale) and safety (all AEs within 30 days, then monthly up to 6 months, then quarterly post-AlloCSC-01, all-cause mortality and death from cardiovascular cause at 12 months, and MACE measured at 6 and 12 months). Eight centers are participating in Spain and Belgium and patient recruitment is now finished. The CAREMI trial has benefitted from the support of the CARE-MI consortium (Grant Number 242038) funded by the Seventh Framework Programme of the European Commission under the coordination of the Centro Nacional the Investigaciones Cardiovasculares (CNIC) and the participation of research institutions and companies from nine EU countries. Final results will be released in the first half of 2017 with a six-month interim analysis of blinded and exploratory efficacy data in the second half of 2016.

About TiGenix

TiGenix NV (Euronext Brussels: TIG) is an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platforms of allogeneic, or donor-derived, expanded stem cells. Two products from the adipose-derived technology platform are currently in clinical development. Cx601 is in Phase III for the treatment of complex perianal fistulas in Crohn's disease patients. Cx611 has completed a Phase I/II trial in rheumatoid arthritis, as well as a Phase I sepsis challenge trial. Effective as of July 31, 2015, TiGenix acquired Coretherapix, whose lead cellular product (AlloCSC-01) is currently in a Phase II clinical trial in acute myocardial infarction (AMI). Coretherapix is planning to initiate the clinical evaluation of AlloCSC-01 in the chronic setting as well and is also involved in the pre-clinical development of a pharmaceutical formulation of growth factors to treat AMI. Finally, TiGenix also developed ChondroCelect, an autologous cell therapy product for cartilage repair of the knee, which was the first Advanced Therapy Medicinal Product (ATMP) to be approved by the European Medicines Agency (EMA). From June 2014, the marketing and distribution rights of ChondroCelect were exclusively licensed to Sobi for the European Union (except for Finland, where it is distributed by the Finnish Red Cross Blood Service), Norway, Russia, Switzerland and Turkey, and the countries of the Middle East and North Africa. TiGenix is headquartered in Leuven (Belgium) and has operations in Madrid (Spain).

For more information, please visit www.tigenix.com

Forward-looking information

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