TiGenix

PRESS RELEASE

AlloCSC-01 Phase I Data Presented at the Congress of the European Society of Cardiology

- **CAREMI dose-escalation open-label phase data presented at the Congress of the European Society of Cardiology (ESC) confirm the good safety profile of AlloCSC-01 in patients suffering from Acute Myocardial Infarction (AMI)**

- **AMI patients treated in the dose-escalation open-label phase showed a reduction in infarct size and improvement of left ventricular ejection fraction (LVEF) on Magnetic Resonance Imaging (MRI) after the administration of AlloCSC-01 over a six-month period**

Leuven (BELGIUM) – 23 September 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 the CAREMI dose-escalation open-label phase data were presented at the Congress of the European Society of Cardiology.

CAREMI is a two phase study: an open-label dose-escalation phase and a randomised, double-blind, placebo-controlled phase, aiming at evaluating the safety and efficacy of intracoronary infusion of AlloCSC-01, a suspension of allogeneic human cardiac stem cells (CSC). In the dose-escalation open-label phase, 6 patients were treated with AlloCSC-01 and 5 of them were followed up for 6 months. Patients received a single injection of 11 million (M), 22M or 35M cells of AlloCSC-01 (n=2 each) by intracoronary infusion 5 to 7 days after Percutaneous Coronary Intervention (PCI). Data presented show that AlloCSC-01 has a good safety profile as no adverse events or Major Adverse Cardiac Events (MACE) were observed during the 6 month follow-up period. Of note, preliminary efficacy data showed a reduction in the infarct size, and a LVEF improvement on MRI, over the 6-month follow-up period ($n=5$; $p<0.05$ for both parameters).

AlloCSC-01 may become a new approach to prevent cardiac remodelling and the onset of Cardiac 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.

“We are encouraged with the successful completion of the dose escalation phase of the CAREMI trial and with the over 70% recruitment rate of the ongoing randomised, double-blind, placebo-controlled phase”, said Marie Paule Richard, Chief Medical Officer at TiGenix. “CAREMI is expected to complete recruitment in 4Q 2015 and deliver 6-month interim exploratory efficacy data during 2H 2016. Final results will be released in the 1H 2017. There is a huge need for effective treatments that prevent the severe consequences that follow a myocardial infarction and AlloCSC-01 may represent an innovative approach for treating those patients”.

For more information

Claudia D'Augusta
Chief Financial Officer
T: +34 91 804 92 64
claudia.daugusta@tigenix.com

Ana Pombo
Strategic Planning and IR Manager
T: + 34 91 804 92 64
ana.pombo@tigenix.com

About AlloCSC-01

AlloCSC-01 is a cellular product consists 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 in an advanced stage. Final results will be released in the first half of 2017 with a six-month interim exploratory analysis expected to provide 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

This document may contain forward-looking statements and estimates with respect to the anticipated future performance of TiGenix and the market in which it operates. Certain of these statements, forecasts and estimates can be recognised by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and similar expressions. They include all matters that are not historical facts. Such statements, forecasts and estimates are based on various assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable when made but may or may not prove to be correct. Actual events are difficult to predict and may depend upon factors that are beyond the Company's control. Therefore, actual results, the financial condition, performance or achievements of TiGenix, or industry results, may turn out to be materially different from any future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of the publication of this document. TiGenix disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in the Company's expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement, forecast or estimate is based, except to the extent required by Belgian law.