**PRESS RELEASE**
**REGULATED INFORMATION**

# TiGenix announces six-month Phase I/II results of AlloCSC-01 in Acute Myocardial Infarction

**Leuven (BELGIUM) – June, 17, 2016, 08:30 PM CEST– TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on the development and commercialization of novel therapeutics from its proprietary platforms of allogeneic expanded stem cells, today announced preliminary six-month results from the CAREMI clinical trial, an exploratory Phase I/II study of AlloCSC-01, TiGenix's expanded cardiac stem cell treatment for acute myocardial infarction.**

CAREMI is the "first-in-human" clinical trial to evaluate the safety and efficacy over twelve months intracoronary infusion of AlloCSC-01, a suspension of allogeneic human expanded cardiac stemcells (CSCs), in patients with acute myocardial infarction (AMI) and left ventricular dysfunction. Enrollment was completed in November 2015 with 49 patients randomized (AlloCSC-01: placebo; 2:1). The preliminary interim data is comprised of the six-month follow up of the 49 randomized patients plus two patients from the escalation phase who received similar target doses of 35 million cells (51 in total). Eight centers are participating in the CAREMI trial led by Prof. Fernández-Avilés, Head of the Department of Cardiology at the Hospital General Universitario Gregorio Marañón in Madrid (Spain), and Prof. Janssens, Head of the Department of Cardiovascular Diseases, University Hospital, Leuven (Belgium), as principal investigators.

"We are happy to report the preliminary interim results from our exploratory study of AlloCSC-01 in AMI that broadens our clinical development pipeline in a large area of unmet need", said Dr. Marie Paule Richard, Chief Medical Officer at TiGenix. "The safety results confirm that intracoronary delivery of AlloCSC-01 is well tolerated during the acute and sub-acute phases of the infarct, fulfilling the principal goal of the study at six months."

As per the protocol design, the primary objective of this study is to provide evidence of the acute and long-term safety profile of AlloCSC-01. On the primary acute safety endpoint, no mortality of any cause within one month was recorded for both placebo and AlloCSC-01 groups. Similarly, no major adverse cardiac event (MACE) was recorded within one month in either group. Importantly for the long term safety evaluation, no MACE was recorded in either two group at six months. Preliminary secondary efficacy data at six months was limited to infarct size evolution, defined as a percent of the left ventricular mass measured by magnetic resonance imaging. The mean absolute change in infarct size from baseline to six months was similar in both groups. The final full set of safety and efficacy study results at twelve months will be reported in first half of 2017.

"The positive data reported today shows the safety of early intracoronary delivery of AlloCSC-01 post-AMI" said Prof. Fernández-Avilés. "We are encouraged by the safety outcome and are optimistic that this first-in-human trial with a novel cell population will be an important milestone in our quest to find a better treatment for patients at high risk of cardiac remodeling and heart failure."

"A key question of the CAREMI study was the safety of a relatively early administration of allogeneic cardiac stem cells. This has now been addressed. We now look forward to the final safety and efficacy analysis" concluded Prof. Janssens.

**For more information, please contact:**

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

***About TiGenix***

*TiGenix NV (Euronext Brussels: TIG) is an advanced biopharmaceutical company focused on the development and commercialization of novel therapeutics from its proprietary platforms of allogeneic, or donor-derived, expanded stem cells. Two products from the adipose-derived stem cell 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 sepsis challenge trial and a Phase I/II trial in rheumatoid arthritis. Effective July 31, 2015, TiGenix acquired Coretherapix, whose lead cellular product, AlloCSC-01, is currently in a Phase I/II clinical trial in acute myocardial infarction (AMI). In addition, the second product candidate from the cardiac stem cell-based platform acquired from Coretherapix, AlloCSC-02, is being developed in a chronic indication. 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.*

***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 randomized, 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 study 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 the randomization 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). MACE is a broader safety endpoint that covers all-cause mortality as well as new AMI, hospitalization due to heart failure, sustained ventricular tachycardia, ventricular fibrillation and stroke. Eight centers are participating in Spain and Belgium and patient recruitment is now finished. The eight participating centres are Hospital General Universitario Gregorio Marañon - Madrid, Hospital de Navarra, Hospital Clínico Universitario de Valladolid, Hospital Universitario de Donostia, Hospital Universitario de Salamanca, Hospital Clínico Universitario de Valencia, and Hospital Virgen de la Victoria de Málaga all in Spain and UZ Leuven in Belgium. The CAREMI trial has benefitted from the support of the CARE-MI consortium (Grant Number 242038, http://www.caremiproject.eu/) 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. The six-month interim analysis of blinded and exploratory efficacy data has been reported in June 2016. Final results will be released in the first half of 2017.*

***Forward-looking information***

*This press release 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 recognized 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 press release. 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.*