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TiGenix Announces Top-Line Phase I/II Results of AlloCSC-01 in Acute Myocardial Infarction

Leuven (BELGIUM) – March 13, 2017, 07:00h CET – TiGenix NV (Euronext Brussels and Nasdaq: TIG), an advanced biopharmaceutical company focused on developing novel therapeutics from its two proprietary platforms of donor-derived expanded adipose derived stem cells (eASC) and donor-derived expanded cardiac stem cells (AlloCSCs), today announced top-line one-year results from the CAREMI clinical trial, an exploratory Phase I/II study of AlloCSCs in acute myocardial infarction (AMI).

CAREMI is the first-in-human clinical trial with the primary objective being safety and evaluating the feasibility of an intracoronary infusion of 35 million of AlloCSCs in patients with AMI and left ventricular dysfunction treated within the first week post-AMI. Importantly, the trial is the first cardiac stem cell study to integrate a highly discriminatory magnetic resonance imaging (MRI) strategy to select patients at increased risk of heart failure and late adverse outcomes. CAREMI was not powered to establish efficacy therefore no conclusion can be drawn on the secondary efficacy end-points.

The main findings of this study are:

- All safety objectives of the study have been met. No mortality or major cardiac adverse events (MACE) have been found at 30 days meeting the primary end-point of the study. Moreover no mortality and MACE have been found at 6 months or 12 months follow-up
- Of particular relevance to this allogeneic approach, no immune-related adverse events have been recorded at one-year follow-up
- A larger reduction in infarct size was found in one pre-specified subgroup associated with poor long-term prognosis and representing more than half of the patient population of the randomization phase of the study. This finding has revealed valuable insight, and provides a specific direction for potential studies in a targeted subset of high-risk patients

“This is the first trial in which it has been demonstrated that allogeneic cardiac stem cells can be transplanted safely through the coronary tree, and in the worst possible setting represented by patients with an acute heart attack with left ventricular dysfunction,” commented Professor Fernández-Avilés, Head of the Department of Cardiology at the Hospital General Universitario Gregorio Marañón in Madrid (Spain), principal investigator on the trial in Spain. “It is especially encouraging that no cardiac or immunological side effects were observed.”

“This is the first study in which we have used a state of the art comprehensive MRI analysis to include patients with a large myocardial infarction in an innovative cell therapy protocol,” said Professor Janssens, Head of the Department of Cardiovascular Diseases, University Hospital, Leuven (Belgium), and principal investigator on the trial in Belgium. “Serial MRI analysis and extensive immunological profiling will allow us to further explore the encouraging signals we observed in cell treated patients with the worst MRI signature. These findings offer an exciting prospect for targeted follow-up studies in these high-risk patients.”

“Besides confirming the long term safety of the treatment these results suggest interesting opportunities in populations with high unmet medical need,” said Dr. Marie Paule Richard, Chief Medical Officer at TiGenix. “We look forward to working with our advisors to analyze the data in depth and determine the best way forward with AlloCSC-01 during the second half of this year.”

Full data results from the CAREMI study will be presented at an upcoming medical congress.

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For more information

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About TiGenix

TiGenix NV (Euronext Brussels and Nasdaq: TIG) is an advanced biopharmaceutical company focused on developing and commercializing 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 in Phase III for the treatment of complex perianal fistulas in Crohn's disease patients; Cx611 which 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, has concluded a Phase 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. On July 4, 2016, TiGenix entered into a licensing agreement with Takeda, a large pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to commercialize Cx601 for complex perianal fistulas outside the United States. TiGenix is headquartered in Leuven (Belgium) and has operations in Madrid (Spain). For more information, please visit http://www.tigenix.com.

About AlloCSC-01

AlloCSC-01 is a cellular product consisting of adult expanded 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.

About CAREMI

The CAREMI trial comprised 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 safety endpoint are all-cause mortality within 30 days and percentage of patients with major adverse cardiac events (MACE) within 30 days after treatment. 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. Secondary safety endpoints include percentage of patients with MACE at 6 and 12 months after treatment, all-cause mortality at 12 months after treatment and percentage of patients with AE during the study. Secondary efficacy include MRI parameters (evolution of infarct size and evolution of biomechanical parameters) and clinical parameters (including the 6 minute walking test and the New York Heart Association scale). The CAREMI study has been conducted at the Hospital General Universitario Gregorio Marañon, Madrid, UZ Leuven, 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. 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.

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 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 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.