TiGenix expands pipeline and enters the cardiology field with clinical-stage company acquisition

TiGenix acquires Coretherapix, a cell therapy company with an ongoing Phase II clinical trial of allogeneic cardiac stem cells in acute myocardial infarction (AMI)

Leuven (BELGIUM) – July 30, 2015 – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platform of allogeneic adipose-derived stem cells, announced today the acquisition of cardiology-focused cell therapy company Coretherapix S.L., currently owned by Genetrix S.L. Its lead programme, AlloCSC-01, is an allogeneic cardiac stem cell product currently in a Phase II clinical trial in acute myocardial infarction (AMI), with interim data expected in the second half of 2016. The product is also in pre-clinical development for another cardiac disease. This acquisition expands TiGenix´ pipeline into cardiology indications and is expected to be closed on July 31, 2015, subject to certain conditions precedent.

TiGenix acquires Coretherapix for an upfront payment of approximately €1.2M in cash and approximately €5.5M in new TiGenix shares. Additionally, Genetrix may receive up to €15M in new TiGenix shares depending on the results of the ongoing clinical trial of Coretherapix. Based on and subject to future sales milestones, Genetrix may receive in addition up to €245M plus certain percentages of the direct net sales of the first product, or certain percentages of any third party royalties and sales milestones for the first product. Sales milestones start when annual net sales reach €150M and the last one will be payable once annual net sales are above €750M. Also, Genetrix will receive a €25M milestone payment per additional product reaching the market. The new shares to be issued on closing of the transaction will be subject to lock-up undertakings for up to 12 months, part of which will be gradually released from the lock-up over the 12-months´ period.

“The acquisition of this technology of allogeneic cardiac stem cells enhances our existing platform and builds on our extensive knowledge and experience in cell therapy development”, commented Eduardo Bravo, CEO of TiGenix. “Tactically, it broadens our current pipeline with another Phase II programme which targets a very significant commercial opportunity. Strategically, it allows us to enter completely new markets with a platform of cardiac stem cells which could be developed in several attractive cardiology indications. We have Cx601 delivering Phase III results in the treatment of perianal fistulas in Crohn’s disease patients, later this quarter and preparing for a second Phase III in the US, and we have Cx611 ready to enter into Phase II in severe sepsis and early rheumatoid arthritis around the end of the year. The addition of AlloCSC-01, finalizing the recruitment of this Phase II in AMI and already being studied in other cardiac indications clearly positions TiGenix pipeline as one of the most advanced and diverse in the industry. This acquisition is an important step towards our ambition to become one of the world leaders in the cell therapy space”.

The ongoing randomised, placebo-controlled, multicentre Phase II study in AMI is being conducted in 9 hospitals in Belgium and Spain. After a successful open-label dose escalation phase of 6 patients, the clinical trial is aiming at recruiting 49 additional patients who will be randomised 2:1 to receive either AlloCSC-01 or placebo by intracoronary injection 5 to 8 days after the myocardial infarction. The primary endpoint is all-cause mortality and MACE (Major Adverse Cardiac Events) at 30 days. Secondary endpoints 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 all-cause

mortality and MACE, all measured at 6 and 12 months. More than 60% of patients have already been recruited and the final results are expected in the first half of 2017. A six-month interim analysis is expected to provide data in the second half of 2016.

Efficacy and safety data of AlloCSC-01 has been gathered in relevant pre-clinical studies in swine and rodents. In the pig infarct model, PET data shows strong cardiac tropism, coronary clearance and myocardial retention of AlloCSC-01. MRI efficacy data in the same animal model has proven that the product significantly prevents cardiac remodeling after infarction, preserving heart function. Histological analysis shows that AlloCSC-01 reduces scar sizethereby preserving cardiac tissue.

Acute Myocardial Infarction (AMI) remains a significant unmet medical need with an estimated incidence of 1.9 million new patients each year in the US and EU. An effective management of AMI patients is considered to be key in reducing the continually increasing number of patients suffering from Heart Failure (HF), currently around 26 million people worldwide. In the US alone, the economic burden from HF disease is expected to increase sharply from USD 39 billion to USD 70 billion in 2030.

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About TiGenix

TiGenix NV (Euronext Brussels: TIG) is an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platform of allogeneic, or donor-derived, expanded stem cells. Two products from this 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 is in Phase IIb for early rheumatoid arthritis, and has completed a Phase I sepsis challenge trial. 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 have been 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 Coretherapix

Coretherapix, S.L. was founded in 2006 with the aim of developing effective and off-the-shelf products for the treatment of ischemic cardiac disease. Coretherapix's lead cellular product (AlloCSC-01) is currently in a Phase II clinical trial in acute myocardial infarction. The primary endpoint of this randomized, placebo-controlled, multicentre study is to show safety while collecting data on efficacy. The trial, for which recruitment has already started and more than 60% of patients have been successfully enrolled, is expected to deliver interim data in the

second half of 2016 and final results in the first half of 2017. 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.

About AlloCSC-01

This 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.

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.