TiGenix obtains FDA's endorsement through Special Protocol Assessment for its Cx601 Phase III registration trial in the US

Leuven (BELGIUM) – August 7, 2015 – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platform of allogeneic stem cells, announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for its Phase III registration trial of Cx601 in the U.S. for the treatment of complex perianal fistulas in Crohn's disease patients.

"We are very pleased with the FDA´s agreement on our clinical design and planned analysis as it represents a clearly defined development and regulatory pathway for approval of Cx601 in the U.S.," said Dr Maria Pascual, VP Regulatory Affairs & Corporate Quality of TiGenix. "Cx601 constitutes a novel mechanism of action to treat perianal fistulas, for which there is still no cure. In the U.S. alone, every year more than 50,000 new patients are waiting for an effective treatment for this debilitating disease."

The agreed pivotal trial is a randomised, double-blind, parallel group, placebo-controlled and multicentre study in complex perianal fistulas in Crohn's disease patients. The study will enroll approximately 224 patients to assess the efficacy and safety of Cx601 24 and 52 weeks after a single dose administration of the product. The SPA describes the primary endpoint as combined remission, defined as clinical assessment by week 24 of closure of all treated external openings draining at baseline despite gentle compression, and absence of collections > 2cm confirmed by MRI. This primary endpoint is in line with the one for the European Phase III trial, which results are expected later this quarter. The company expects to complete the process of manufacturing technology transfer to its U.S.-based CMO, Lonza, and thereafter will start its Phase III trial of Cx601 in the U.S. in the second half of 2016.

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About Special Protocol Assessments

A Special Protocol Assessment (SPA) is a written agreement between a sponsor and the U.S. FDA on the trial design, execution and analysis needed to support FDA product approval. It is intended to form the basis for the marketing application. For more information on SPA, please visit http://1.usa.gov/1w2ODoJ

About Cx601

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASCs) delivered locally through intra-lesional injection. Cx601 is being developed for the treatment of perianal fistulas in Crohn's disease patients. Crohn's disease is a chronic inflammatory disease of the intestine and patients can suffer from complex perianal fistulas for which there is currently no effective treatment. In 2009, the European Commission granted Cx601 orphan designation for the treatment of anal fistulas, recognising the debilitating nature of the disease and the lack of treatment options. In a Phase II clinical trial, Cx601 showed efficacy at 24 weeks in 56% of treated fistula tracts, which is more than two times higher than the current standard of care (TNF inhibitors). Efficacy was measured as the complete closure and re-epithelisation of the fistula being treated with an absence of drainage. Additionally, 69.2% of patients demonstrated a reduction in the number of initially draining tracts. The trial also confirmed the safety of the use of allogeneic stem cells for the treatment of perianal fistula. Based on these results, TiGenix sought scientific advice from the European Medicines Agency (EMA) on the future development path of Cx601. TiGenix then initiated a randomised, double-blind, placebo-controlled Phase III trial in Europe and Israel designed to comply with the requirements laid down by the EMA. 'Madrid Network', an organisation within the Autonomous Region of Madrid which helps companies to grow through high-technology innovation, issued a soft loan to help finance this Phase III study. The programme is funded by The Secretary of State for Research, Development and Innovation (Ministry of Economy and Competitiveness) within the framework of the INNTEGRA plan. This pivotal study is intended to enable filing for marketing authorisation in Europe and to serve as a key supportive study in filing for approval in other territories, including the US. The study's primary endpoint is combined remission, defined as clinical assessment by week 24 of closure of all treated external openings draining at baseline despite gentle finger compression, and absence of collections >2cm confirmed by MRI. The trial has a first complete analysis of results at 24 weeks, with a follow-up analysis to be performed at 52 weeks post-treatment. Recruitment of the whole sample of patients was completed in the fourth quarter of 2014. The first clinical report is expected to be available in the third quarter of 2015. With positive results, TiGenix intends to submit a request for marketing authorisation with the EMA early in 2016. TiGenix is preparing to develop Cx601 for the US market.

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 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 is in Phase II for early rheumatoid arthritis, and has completed 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 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

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

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