TiGenix

PRESS RELEASE

TiGenix's Phase III trial design for Cx601 endorsed by President-Elect of ECCO

Leuven (BELGIUM) – 23 February, 2015 –TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platform of allogeneic expanded adipose-derived stem cells in inflammatory and autoimmune diseases, announced today that Dr Julian Panés, a leading clinical specialist in inflammatory bowel disease, endorsed the design of the Company's Phase III trial of Cx601 for the treatment of complex perianal fistulas in patients with Crohn's disease during his presentation last week at the 10th Annual Congress of the European Crohn's and Colitis Organisation (ECCO) held in Barcelona, Spain.

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASCs) delivered locally through intra-lesional injection that is being developed for the treatment of perianal fistulas in Crohn's disease patients. Such fistulas cause severe complications and are difficult to manage, and have a significant negative impact on patient quality of life and psychological well-being. 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.

TiGenix is conducting a randomised, double-blind, placebo-controlled Phase III trial in Europe and Israel designed to comply with the requirements laid down by the European Medicines Agency (EMA). This pivotal study, codenamed 'ADMIRE', has recruited 289 patients across 52 centres in 7 European countries and Israel. The results of the study will be available in the third quarter of 2015 and, if positive, will allow TiGenix to submit a request for marketing authorisation to the EMA early in 2016.

Dr. Julian Panés, who is Head of the Gastroenterology Department, Head of the Inflammatory Bowel Diseases Unit, and Associate Professor of Medicine at the Hospital Clínic of Barcelona, President-elect of ECCO and Chairman of the TiGenix ADMIRE Scientific Advisory Board, made his comments during a presentation last week at the Annual Congress of ECCO in a session entitled, 'Mesenchymal Stem Cells in Inflammatory Bowel Disease: promises and pitfalls'.

"I strongly believe that there are not in general adequately designed and controlled studies of the role of stem cells in the treatment of perianal fistulas in Crohn's disease patients," Dr. Panes said. "In the pivotal Phase III ADMIRE trial of TiGenix, we finally have the robust, controlled study that we have been waiting for."

"The positive evaluation of our Phase III study by Dr. Panés is strong recognition of the quality of our study design", commented Dr. Marie-Paule Richard, Chief Medical Officer at TiGenix. "We remain committed to bringing this new treatment to the thousands of patients who suffer from this debilitating condition".

For more information:

Richard Simpson
Senior Consultant, Comfi sprl
T: +32 494 578 278
richard@comfi.be

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 remission of the fistulous disease, defined as 100% healing of the tracts. 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. Evaluation of healing includes both clinical assessment and MRI confirmation (lack of abscesses larger than 2 cm²). 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. The company has filed for a Special Protocol Assessment (SPA) by the Food and Drug Administration (FDA) to ensure that the design of a new Phase III study to be conducted in the US is aligned with the FDA's requirements for the future approval of Cx601. The company has appointed Lonza as its contract manufacturing organisation (CMO) for the clinical development of Cx601 in the US.

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 adipose-derived stem cells, known as eASCs, in inflammatory and autoimmune diseases. 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 in Phase Ib for severe sepsis. 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 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

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