TiGenix

PRESS RELEASE

USPTO issues key US patent to TiGenix for the use of adipose-derived stromal cells in the treatment of fistulas

Leuven (BELGIUM) – 8 April, 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 the United States Patent and Trademark Office (USPTO) has issued US Patent 8,999,709 relating to the use of an adipose-derived stromal cell population in the treatment of fistula. The patent, entitled "Use of adipose tissue-derived stromal stem cells in treating fistula", expires in 2030 and provides coverage for the company's lead development product, Cx601, in the key US market.

"The issuance by the USPTO of this patent is a key achievement in our strategy for the development and commercialisation of Cx601 in the American market", said Wilfried Dalemans, Chief Technical Officer of TiGenix. "It further builds our intellectual property position in the use of eASCs in the indication we are pursuing. As such, it is an essential component of the business case for making the product available to patients in the US."

The issuance of this patent further strengthens TiGenix's intellectual property portfolio of 24 patent families which now includes 15 granted patents related specifically to its eASC platform. The pending and granted patents in TiGenix's intellectual property portfolio include patent families that are directed to its eASC platform; more specifically, to eASC compositions and therapeutic applications as well as to cell therapy delivery mechanisms and other eASC technology improvements.

Cx601 is a solution of expanded adipose-derived stem cells (eASCs) for local injection currently in Phase III of clinical development for the treatment of complex perianal fistulas in patients with Crohn's disease. Clinical results from the on-going European Phase III trial are expected in the third quarter of 2015. Following the positive feedback received at a meeting with the Center for Biologics Evaluation and Research within the Food and Drug Administration (FDA), TiGenix is moving ahead with the development of Cx601 for the United States market. The Company has submitted to the FDA the required documentation for a Special Protocol Assessment (SPA) of its pivotal Phase III trial design for Cx601 in the treatment of complex perianal fistulas in patients with Crohn's disease in the United States. Agreement with the FDA on the SPA will ensure that the trial design is aligned with the FDA's requirements for the future approval of Cx601. The Phase III trial in the US, if successful, together with positive data from the European Phase III trial, would enable the Company to file a biologics license application (BLA) with the FDA. The Company expects to complete the process of manufacturing technology transfer to its US-based contract manufacturing organisation (CMO), Lonza, in the first half of 2016, after which the Phase III trial of Cx601 in the US can begin.

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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 closure of all treated external openings draining at baseline despite gentle finger compression confirmed by MRI (no collections > 2cm). 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. 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 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

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