PRESS RELEASE

TiGenix starts Cx601 Marketing Authorisation Application process

Letter of intent submitted to the European Medicines Agency

Leuven (BELGIUM) – 11 June, 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, or eASC's, in inflammatory and autoimmune diseases, announced today that it has submitted to the European Medicines Agency (EMA) a letter of intent to file, and a request for the assignment of Rapporteur/Co-Rapporteur, for the Marketing Authorisation Application (MAA) of Cx601 in the treatment of complex perianal fistulas in patients with Crohn's disease.

The letter of intent, which must be filed at least seven months prior to the submission of a MAA, initiates a process to address a number of pre-submission requirements, including the assignment of a Rapporteur and Co-Rapporteur, who are members of the Committee for Advanced Therapies (CAT), and two Co-ordinators from the Committee for Human Medicinal Products (CHMP). For advanced-therapy medicines, CAT prepares a draft opinion on the product's quality, safety and efficacy, based on which the CHMP adopts a final opinion.

In parallel, TiGenix has submitted the request in order to be eligible for the centralised procedure for the approval of medicinal products in the European Union (EU). Cx601 falls within the mandatory scope of the procedure because it is an Advanced Therapy Medicinal Product and an Orphan-designated product. Confirmation of eligibility by the EMA does not necessarily mean that the EMA will approve the MAA. For eligible drugs, the centralised procedure offers the benefit of only having to submit a single marketing application to the EMA. If approved, a drug can then be marketed in all EU member countries, as well as in Iceland, Liechtenstein and Norway, instead of having to seek approval in each country, thereby reducing the time to market.

"This is a key step in the potential submission of Cx601 for marketing authorisation in Europe for the treatment of complex perianal fistulas in patients with Crohn's disease" said María Pascual, VP Regulatory Affairs and Corporate Quality at TiGenix. "It represents another important milestone, achieved according to plan, to bring Cx601 to Crohn's disease patients in Europe."

Cx601 is currently completing a randomised, double-blind, placebo-controlled Phase III trial in Europe and Israel designed to comply with the requirements laid down by the EMA. TiGenix expects to receive the first clinical report during the third quarter of 2015. With positive results, the Company intends to submit a request for marketing authorisation with the EMA in early 2016.

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 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

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