PRESS RELEASE

TiGenix submits its pivotal US trial design for Cx601 to the FDA for Special Protocol Assessment

Leuven (BELGIUM) – 22 December, 2014 –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 Food and Drug Administration (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 planned US study design is similar to the ongoing Phase III trial in Europe, whose results are expected in the third quarter of 2015. The US trial design protocol incorporates guidance both from the FDA and from the Company's US Scientific Advisory Board of six leading North American clinical experts in gastroenterology and inflammatory bowel disease.

The randomised, double-blind, placebo-controlled Phase III trial in the US is designed to confirm the efficacy and safety of Cx601 in the treatment of complex perianal fistulas in Crohn's disease patients. It will enrol approximately 180 patients and its primary endpoint will be the remission of fistulous disease, defined as 100% healing of the tracts. The first complete analysis of results will be at 24 weeks, with a follow-up analysis at 52 weeks post-treatment.

As discussed with the FDA, TiGenix plans to use data from both the Phase III trial in Europe and from this Phase III trial in the US as the basis for its eventual submission of a Biologics License Application (BLA). On completion of the SPA review process, and of the technology transfer of its cell manufacturing process to a contract manufacturing organisation (CMO) in the US, TiGenix will submit its investigational new drug application (IND) for this Phase III study to the FDA.

"This is another important milestone, achieved according to plan, to prepare Cx601 for approval in the United States, the largest healthcare market in the world", said María Pascual, VP Regulatory Affairs and Corporate Quality at TiGenix. "The product's novel mechanism of action in treating perianal fistulas, and its advanced stage of clinical development in Europe, enables Cx601 to move directly into Phase III in the US, significantly shortening timelines, and the financial burden, of bringing the product to Crohn's disease patients in the US."

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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. 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 intends to appoint a contract manufacturing organisation (CMO) in the US with whom it will then begin the transfer of technology to enable production 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

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