TiGenix

PRESS RELEASE

TiGenix completes patient recruitment for the European Phase III trial of Cx601 ahead of schedule

Leuven (BELGIUM) – 12 November, 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 in inflammatory and autoimmune diseases, announced today that it has completed the patient recruitment for its Phase III trial of Cx601 in Europe for the treatment of complex perianal fistulas in Crohn's patients.

The trial is a randomised, double-blind, placebo-controlled Phase III study designed to confirm the efficacy and safety of Cx601 in the treatment of complex perianal fistulas in Crohn's disease patients. The trial has recruited more than 278 patients across 51 centres in 7 European countries and Israel. The study's primary endpoint is 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 to be performed at 52 weeks post-treatment. Evaluation of healing includes both clinical assessment and MRI confirmation (lack of abscesses larger than 2 cm^2). This pivotal study is intended to allow filing for marketing authorisation in Europe, and to serve as a key supportive study in filing for approval in other territories, including the United States.

"I'm delighted to announce that TiGenix has completed the patient recruitment for this important study ahead of schedule" said Eduardo Bravo, CEO of TiGenix. "Clinical results are expected in the third quarter of 2015. With positive results, we expect to submit a request for marketing authorisation with the EMA early in 2016, so that a decision by the European Commission would allow for marketing in Europe in 2017."

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 will start the process of technology transfer to a US-based contract manufacturing organization (CMO) later this year. Also by the end of this year, TiGenix will file a special protocol assessment (SPA) with the FDA in order to be able to file an investigational new drug (IND) application for a Phase III trial in the United States. That SPA file will be prepared by the company in cooperation with its US advisory board of North American clinical experts in gastroenterology and inflammatory bowel disease. 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.

Crohn's disease is a chronic inflammatory disease of the intestine, of which complex fistulas are a complication that appear in around 10% of patients. There are approximately 100,000 new cases every year in Europe and the US. A fistula is an abnormal tract connecting two surfaces, and a perianal fistula is a tract between the perianal space and the epithelial surface next to the anus. A complex perianal fistula is a serious condition that affects the anal sphincter, can have multiple tracts, and is associated with a perianal abscess. Individuals who suffer from the condition are often unable to carry out ordinary daily activities and experience a significant reduction in their quality of life due to the recurring nature of the condition. They generally endure severe discomfort, pain and embarrassment and, in many cases, have significant psychological problems, requiring additional treatment which creates substantial additional burdens for healthcare systems. In the longer term, these patients suffer an increased risk of developing anal epithelial carcinoma. Current treatment options, which include antibiotics, immunosuppressants and biologics are mainly symptomatic and do not offer a long term solution. The risk of recurrence is high. Surgical intervention may be required in severe cases with an increased risk of anal incontinence.

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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 intends to appoint a contract manufacturing organisation (CMO) in the US with whom it will then begin the technology transfer to enable production of Cx601 in the US; and the company will file for a Special Protocol Assessment (SPA) from the Food and Drug Administration (FDA) to ensure that the design of a new Phase III study to be run in the US is aligned with the Agency's requirements for future approval of Cx601.

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

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