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European Medicines Agency accepts TiGenix Paediatric Investigation Plan for Cx601

Leuven (BELGIUM) – 8 September, 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 the Paediatric Committee of the European Medicines Agency (EMA) has issued a positive opinion on the Company's Paediatric Investigation Plan (PIP) for Cx601, a locally injected stem cell product in Phase III of clinical development for the treatment of complex perianal fistulas in patients with Crohn´s disease.

An accepted PIP is a requirement for the filing for marketing authorisation of a new medicinal product with the EMA. It describes how a company intends to evaluate the use of the new product in children. On completion of the PIP, the company is awarded an additional six months' patent exclusivity for the product. Cx601 received Orphan Drug designation from the EMA in 2009 giving it ten years' market exclusivity from the date of marketing authorisation.

The PIP for Cx601 consists of one open-label, multi-centre, non-comparative trial to evaluate the activity of Cx601 for the treatment of complex anal fistulas in at least 20 Crohn´s disease patients aged from 4-17 years. The study will assess efficacy and safety. The primary endpoint will be remission of perianal fistulising Crohn´s disease at week 24, defined as closure of all external openings that were draining at the start of the study. The study will have a follow-up period of one year.

"We are pleased with the EMA's positive opinion on our PIP for Cx601 which allows us to keep moving towards our filing for marketing authorisation for Cx601 in the first half of 2016," said Maria Pascual, VP Regulatory Affairs and Corporate Quality at TiGenix. "Building on the strength of the adult development program and the body of data to be accumulated at the post-marketing phase, a very focused trial has been agreed with the Agency. The study will not begin before 2020, three years after our planned launch of Cx601 in 2017."

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 (278 recruited patients, 8 countries, 52 centres) 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 end-point 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). The Phase III clinical trial began patient recruitment in mid-2012, and recruitment of the whole sample of patients is expected to be completed in the course 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, so that a decision by the European Commission could be expected towards the end of 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 FDA to ensure that the design of a new Phase III study to be done 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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