

TiGenix enrolls first patients in pivotal Phase III trial with lead product Cx601 in perianal fistulas

ADMIRE CD trial to enroll over 200 patients in 46 centers across 8 countries

Leuven (BELGIUM) – July 10, 2012 – TiGenix (NYSE Euronext: TIG) announced today the enrolment of the first patients in the ADMIRE-CD trial, its pivotal Phase III clinical trial with Cx601 in perianal fistulas in Crohn’s disease patients at Hospital Clínic, Barcelona, Spain. Cx601 is an adipose derived allogeneic stem cell therapy.

ADMIRE-CD is a multicenter, randomized, double-blind, placebo-controlled Phase III trial of Cx601 in approximately 200 Crohn’s disease patients suffering from complex perianal fistulas. The main objectives of the study are to demonstrate safety and superior efficacy over placebo in perianal fistulas in Crohn’s disease patients after failure with their previous treatment, in most cases biologicals, and to confirm the strong safety and efficacy results from the Phase II trial completed in 2011. To date, the company has already received approvals from Ethical Committees or Regulatory Agencies in 7 out of 8 countries, which should allow the company to accelerate patient enrolment in the study.

Dr. Jose Luis Bravo, VP Global Medical Affairs & Clinical Development of TiGenix, said: “We are delighted to enrol the first patient in the ADMIRE-CD trial. Hospital Clínic has pioneered the use of stem cell therapies to treat Crohn’s disease, and we believe that Cx601 may prove to be a breakthrough in the treatment of complex perianal fistula in Crohn’s disease, which is a debilitating condition that seriously affects quality of life.”

Eduardo Bravo, CEO of TiGenix, said: “With the enrolment, ahead of schedule, of the first patient in this international Phase III trial we have achieved a major milestone in the development of Cx601, our company, and the cell therapy space. Complex perianal fistulas in Crohn’s disease constitute a true unmet medical need. We have demonstrated excellent safety and efficacy in our Phase II study, far outperforming biologicals, and are optimistic that the ADMIRE-CD trial will result in an effective treatment for this serious disorder.”

About Cx601

Cx601 is a suspension of expanded allogeneic adult stem cell product derived from human adipose (fat) tissue (expanded Adipose derived Stem Cells or ‘eASCs’) that is delivered locally in the fistula through intra-lesional injection. Cx601 has Orphan Drug designation in Europe. Based on the phase II clinical trial report, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) stated that it considered the presented preclinical data package sufficient for a Marketing Authorisation Application (MAA) submission. CHMP also indicated that the proposed single phase III study might be sufficient to support an MAA.

About ADMIRE-CD

The ADMIRE-CD (Adipose Derived Mesenchymal stem cells for Induction of REmission in perianal fistulising Crohn's Disease) Phase III trial has been designed in accordance with EMA requirements. It is a randomized, double-blind, placebo controlled international trial conducted in 46 centers, across 8 countries. Approximately 200 patients are to be enrolled. Key inclusion criteria are up to 2 internal openings and up to 3 external openings, and non-active luminal Crohn's disease. The objective is to demonstrate safety and efficacy, which is defined as closure and/or remission after 24 weeks. The company has received approvals from Ethical Committees/Regulatory Agencies in 7 out of 8 countries (Spain, Italy, Austria, Belgium, Germany, France and the Netherlands). Final results of ADMIRE-CD are expected towards the end of 2014. TiGenix has received a EUR 5M soft loan from Madrid Network to support funding of the Phase III trial.

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About TiGenix

TiGenix NV (NYSE Euronext Brussels: TIG) is a leading European cell therapy company with a marketed product for cartilage repair, ChondroCelect®, and a strong pipeline with clinical stage allogeneic adult stem cell programs for the treatment of autoimmune and inflammatory diseases. TiGenix is based out of Leuven (Belgium) and has operations in Madrid (Spain), and Sittard-Geleen (the Netherlands). For more information please visit www.tigenix.com.

Forward-looking information

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