PRESS RELEASE

TiGenix to present positive 52-week Phase III results of Cx601 at World Congress of Gastroenterology at ACG 2017 meeting

Leuven (BELGIUM) – October 5, 2017, 07:00h CET – TiGenix NV (Euronext Brussels and NASDAQ: TIG), an advanced biopharmaceutical company focused on exploiting the anti-inflammatory properties of allogeneic, or donor-derived, stem cells to develop novel therapies for serious medical conditions, today announces that the positive 52-week results from its ADMIRE-CD Phase III clinical trial of Cx601 for the treatment of complex perianal fistulas in patients with Crohn's disease has been selected for an oral presentation at the World Congress of Gastroenterology at the American Congress of Gastroenterology 2017 Annual Scientific Meeting (WCOG/ACG) taking place from October 13-18, 2017 in Orlando, Florida, USA.

Oral Presentation

Title:	Paper 82: One-year Efficacy and Safety of a Single Dose of Cx601, Allogeneic Expanded Adipose-Derived Mesenchymal Stem Cells, for Complex Perianal Fistulas in Crohn's Disease: Long-Term Results of a Phase 3, Randomized, Double-Blind Clinical Trial
Session Date:	Wednesday, October 18, 2017
Session Time:	10:00am – 10:10am (EDT)
Presenter:	Daniel C. Baumgart, MD, PhD

"We are pleased that the positive 52-week results from the ADMIRE-CD Phase III trial demonstrating the long-term efficacy and safety of Cx601 for treatment-refractory complex perianal fistulas in Crohn's disease patients has been selected for an oral presentation at the WCOG/ACG meeting," said Dr. Mary Carmen Diez, Vice President, Medical Affairs and Commercialisation at TiGenix. "These data have been used to further support our marketing authorisation application for TiGenix, for which we anticipate a CHMP opinion in 2017. In parallel, we continue to progress our global pivotal Phase III trial for a future filing in the US."

For more information
Claudia D'Augusta
Chief Financial Officer
T: +34 91 804 92 64
claudia.daugusta@tigenix.com

About TiGenix

TiGenix NV (Euronext Brussels and NASDAQ: TIG) is an advanced biopharmaceutical company developing novel therapies for serious medical conditions by exploiting the anti-inflammatory properties of allogeneic, or donor-derived, expanded stem cells.

TiGenix´ lead product, Cx601, has successfully completed a European Phase III clinical trial for the treatment of complex perianal fistulas - a severe, debilitating complication of Crohn's disease. Cx601 has been filed for regulatory approval in Europe and a global Phase III trial intended to support a future U.S. Biologic License Application (BLA) started in 2017. TiGenix has entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to develop and commercialize Cx601 for complex perianal fistulas outside the U.S. TiGenix' second adipose-derived product, Cx611, is undergoing a Phase I/II trial in severe sepsis – a major cause of mortality in the developed world. Finally, AlloCSC-01, targeting acute ischemic heart disease, has demonstrated positive results in a Phase I/II trial in acute myocardial infarction (AMI). TiGenix is headquartered in Leuven (Belgium) and has operations in Madrid (Spain) and Cambridge, MA (USA). For more information, please visit http://www.tigenix.com.

About Cx601

Cx601 is a local administration of allogeneic (or donor derived) expanded adipose-derived stem cells (eASCs) for the treatment of complex perianal fistulas in Crohn's disease patients that have previously failed conventional or biologic therapy. Crohn's disease is a chronic inflammatory disease of the intestine and complex perianal fistulas are a severe and debilitating complication for which there is currently no effective treatment. Cx601 was granted orphan drug designation by the European Commission in 2009. TiGenix completed a European Phase III clinical trial (ADMIRE-CD) in August 2015. The 24-week data were published in the Lancet and showed both the primary endpoint and the safety and efficacy profile were met.[i] A follow-up analysis was completed at 52 weeks and 104 weeks post-treatment, confirming the sustained efficacy and safety profile of the product.[ii] The 24-week results of the Phase III ADMIRE-CD trial were published in The Lancet in July 2016.[i] Based on the positive 24 weeks Phase III study results, TiGenix submitted a Marketing Authorization Application to the European Medicines Agency (EMA) and a CHMP opinion is expected in 2017. A global Phase III clinical trial (ADMIRE_CD_II) intended to support a future U.S. Biologic License Application (BLA) started in 2017, based on a trial protocol that has been agreed with the Food and Drug Administration (FDA) through a special protocol assessment procedure (SPA) (clinicaltrials.gov; NCT03279081). In July 2016, TiGenix entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired exclusive rights to develop and commercialize Cx601 for complex perianal fistulas in Crohn's patients outside of the U.S.

---

[i] Panés J, García-Olmo D, Van Assche G *et al.*, Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn's disease: a phase 3 randomized, double-blind controlled trial. *The Lancet.* 2016; 388(10051):1281-90.

[ii] Panes, J. *et al.*, OP009 Long-term efficacy and safety of Cx601, allogeneic expanded adipose-derived mesenchymal stem cells, for complex perianal fistulas in Crohn's disease: 52-week results of a phase III randomised controlled trial. *J Crohn's Colitis*. 2017; 11: S5-S5.