PRESS RELEASE

TiGenix announces approval of trade name for lead development candidate Cx601 in Europe

International Nonproprietary Name (INN), darvadstrocel, approved for Cx601

Leuven (BELGIUM) – November 16, 2017, 7h:00 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, announces today that the European Medicines Agency's (EMA) Committee for Human Medicinal Products (CHMP) has approved the company's proposed trade name Alofisel for its proprietary investigational compound Cx601, a treatment for complex perianal fistulas in patients with Crohn's disease.

The trade name Alofisel, a registered trademark owned by TiGenix, will be used from now onwards in the ongoing centralized drug approval process of Cx601 with the EMA, covering all 28 member states of the EU, plus Norway, Iceland and Lichtenstein, as well as from the time of launch following marketing authorization.

TiGenix has also received approval from the United States Adopted Names (USAN) Council and the International Nonproprietary Names (INN) Expert Group at the World Health Organization (WHO) for the use of the nonproprietary name darvadstrocel for Cx601. Darvadstrocel will be included in the forthcoming list of recommended INNs published by the WHO. INNs are simple, informative and unique nonproprietary names for drugs based on pharmacological and/or chemical relationships to allow for clear identification and communication among health professionals.

TiGenix has submitted a Marketing Authorization (MA) Application for Alofisel to the EMA for the treatment of complex perianal fistulas in adult patients with non-active/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. A CHMP opinion is expected in 2017.

For more information please contact:

TiGenix
Claudia Jiménez
Senior Director IIRR and Communications
T: +34 91 804 92 64
claudia.jimenez@tigenix.com

PR Enquiries
Consilium Strategic Communications
Chris Gardner, Sukaina Virji, Melissa Gardiner
Tel: +44 (0)20 3709 5700
TiGenix@consilium-comms.com

TiGenix

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, 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 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 and by the U.S. Food and Drug Administration (FDA) in 2017. TiGenix completed a European Phase III clinical trial (ADMIRE-CD) in August 2015 in which both the primary endpoint and the safety and efficacy profile were met, with patients receiving Cx601 showing a 44% greater probability of achieving combined remission compared to control (placebo). A follow-up analysis was completed at 52 weeks[1] and 104 weeks post-treatment, confirming the sustained efficacy and safety profile of the product. The 24-week results of the Phase III ADMIRE-CD trial were published in The Lancet in July 2016[2]. 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). ADMIRE-CD II is a randomized, double-blind, placebo-controlled study designed to confirm the efficacy and safety of a single administration of Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients. 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.

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[1] 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.

[2] 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.