PRESS RELEASE

TiGenix granted Orphan Drug Designation from the U.S. FDA for Cx601

Leuven (BELGIUM) – October 23, 2017, 7:00h CEST – 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 U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to Cx601 for the treatment of patients with fistulizing Crohn´s disease.

TiGenix started a global pivotal Phase III clinical trial in the first half of 2017 with the aim of submitting a future U.S. Biologics License Application (BLA) to the FDA for Cx601, a first-in-class allogeneic cell therapy product for the treatment of complex perianal fistulas in patients with Crohn's disease who have had an inadequate response to at least one conventional or biologic therapy. In parallel, TiGenix is exploring expedited pathways to accelerate the submission and review process for U.S. regulatory approval.

"The granting of orphan drug status by the FDA is a significant step forward in the Cx601 development program" said Dr. María Pascual, Vice President Regulatory Affairs and Corporate Quality at TiGenix. "The FDA's recognition of Cx601 as an orphan drug brings a number of potential financial benefits and is aligned with our ongoing work seeking expedited pathways towards product approval in the U.S."

The FDA grants orphan status for novel products to treat conditions affecting fewer than 200,000 people in the U.S. Orphan designation, which is intended to facilitate drug development for rare diseases, provides substantial benefits to the sponsor, including seven years of market exclusivity following marketing approval, tax credits for clinical research costs, eligibility for orphan product grants and the waiver of certain administrative fees.

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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. 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[1]. A follow-up analysis was completed at 52 weeks and 104 weeks post-treatment, confirming the sustained efficacy and safety profile of the product[2]. The 24-week results of the Phase III ADMIRE-CD trial were published in The Lancet in July 2016.[1] 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.

Forward-looking information

This press release may contain forward-looking statements and estimates with respect to the anticipated future performance of TiGenix and the market in which it operates. Certain of these statements, forecasts and estimates can be recognised by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and similar expressions. They include all matters that are not historical facts. Such statements, forecasts and estimates are based on various assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable when made but may or may not prove to be correct. Actual events are difficult to predict and may depend upon factors that are beyond the Company's control. Therefore, actual results, the financial condition, performance or achievements of TiGenix, or industry results, may turn out to be materially different from any future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of the publication of this press release. TiGenix disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in the Company's expectations with regard thereto, or any change in events, conditions or

[1] 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.

[2] 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

circumstances on which any such statement, forecast or estimate is based, except to the extent required by Belgian law.