

## TiGenix opens US headquarters in Cambridge, MA

- Decision follows NASDAQ IPO in 2016 and the launch of the global phase III trial for Cx601
- Operations to be based in Cambridge at heart of Boston area biotech hub
- High-level team of professionals being recruited to support clinical and regulatory operations in the US

Leuven (BELGIUM) – June 29, 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 it has opened an U.S. office in Cambridge, Massachusetts. Establishing U.S. operations is a significant step for TiGenix and will support its strategic goal of developing and commercializing its lead product, Cx601, for the treatment of complex perianal fistulas in Crohn’s disease patients, in the United States.

TiGenix’ US operations are based at the Cambridge Innovation Center in Kendall Square, at the epicenter of the Boston-area biotech hub. TiGenix is in the process of appointing a senior team to support the U.S. and Canadian launch of TiGenix’ global pivotal Phase III trial for Cx601, which started in Europe and Israel in June 2017, and the upcoming regulatory discussions with the FDA.

TiGenix has already been actively progressing clinical start-up activities in the U.S. and anticipates starting recruitment for the trial in North American centers in H1 2018. The global trial is designed to support a future U.S. Biologics License Application (BLA) to the Food and Drug Administration (FDA) for Cx601 for the treatment of complex perianal fistulas in patients with Crohn’s disease. In parallel, TiGenix is also exploring further expedited pathways to accelerate the submission and review process for U.S. approval.

**Eduardo Bravo**, CEO at TiGenix said: “It is very exciting to be establishing TiGenix at the heart of one of the world’s leading biotechnology hubs. We are working hard to progress the development of Cx601 in the U.S. and having a team based in Cambridge will add further momentum to these efforts to bring a new treatment option to U.S patients suffering from this severe and debilitating complication of Crohn’s disease.”

### For more information

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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, 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). 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 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 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. Based on the positive 24 weeks Phase III study results, TiGenix submitted a Marketing Authorization Application to the European Medicines Agency (EMA) and a decision is expected in 2017. A global Phase III clinical trial 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). 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 circumstances on which any such statement, forecast or estimate is based, except to the extent required by Belgian law.*