PRESS RELEASE

TiGenix provides regulatory update on Cx601 EU Marketing Authorization Application procedure

Leuven (BELGIUM) – May 31, 2017, 07:00h 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 it will submit responses to the Cx601 Marketing Authorization Application Day 180 List of Outstanding Issues (LoOI) during the month of August.

The submission of the responses to the Committee for Medicinal Products for Human Use (CHMP) Day 180 LoOI is part of the standard regulatory procedure, under which on the so called Day 181 the European Medicines Agency (EMA) continues the review of a file following a clock stop. The Day 181 for the Cx601 file falls within the first week of September, which may trigger a CHMP opinion in October. TiGenix is confident in its ability to provide detailed and clarifying responses to the CHMP and remains on track to receive a Marketing Authorization (MA) decision for Cx601 in 2017.

“This submission represents another important step forward in working towards a European approval decision for Cx601 during 2017," said Dr. María Pascual, VP of Regulatory Affairs and Corporate QA of TiGenix. “In parallel, we have advanced the preparations for the start of a global Phase III clinical trial intended to support a future US Biologics License Application (BLA) with first submissions to regulatory bodies performed. We look forward to providing updates on this dual path over the coming months.”

Cx601 has been developed for the treatment of complex perianal fistulas in Crohn’s disease patients as a first indication. The Company submitted a Marketing Authorization (MA) Application to the EMA, which is supported by positive 24 and 52 week Phase III data and is now expecting a decision on the European approval of the Product. Cx601 has been licensed to Takeda Pharmaceuticals International AG (Takeda) for the exclusive development and commercialization outside of the US. Receipt of the MA in Europe will trigger a milestone payment from Takeda to TiGenix of Euro 15 million as well as the European launch of Cx601, preparations for which are already underway at Takeda.

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) is expected to start 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) is expected to start 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.