

TiGenix obtains commercial production license for expanded manufacturing facility

- Provides capacity for potential European commercial roll out of investigational stem cell therapy, Cx601
- Expanded facility also secures manufacturing for other pipeline products

Leuven (BELGIUM) – September 05, 2017, 7:00h CEST – TiGenix NV (Euronext Brussels and NASDAQ: TIG), an advanced biopharmaceutical company exploiting the anti-inflammatory properties of allogeneic, or donor-derived, stem cells to develop novel therapies for serious medical conditions, announces today that it has obtained a license for the commercial production of expanded adipose-derived stem cells (eASCs) at its expanded manufacturing facility in Madrid.

The manufacturing license follows an inspection by the Spanish Medicines Agency (AEMPS), and provides production capacity for the potential initial European commercial roll out of Cx601, an investigational stem cell therapy, for the treatment of complex perianal fistulas in patients with Crohn's disease. The expanded facility will also provide sufficient capacity for the manufacturing of other pipeline products under development by TiGenix, including Cx611, currently undergoing a Phase I/II trial in severe sepsis.

TiGenix has submitted a marketing authorization (MA) application for Cx601 to the European Medicines Agency (EMA) on the basis of results from its Phase III ADMIRE-CD trial with a decision expected in 2017. An MA would allow Cx601 to be marketed in all 28 member states of the EU plus Norway, Iceland and Lichtenstein. Cx601 has been licensed to Takeda for exclusive development and commercialization outside of the U.S.

"We are very pleased with this approval for our expanded facility, which confirms our state-of-the-art GMP manufacturing capabilities in the stem cell field," said Wilfried Dalemans, Chief Technical Officer at TiGenix. "We have now significantly increased our manufacturing capacity, a key step in the preparation for commercialization of Cx601 in Europe and in the further development of our pipeline."

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. 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 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.

About Cx611

Cx611 is an intravenous administration of allogeneic expanded adipose-derived stem cells (eASCs) for the treatment of severe sepsis. Sepsis is a life-threatening complication of infection leading to systemic inflammation and organ failure and is the leading cause of death in the developed world. In May 2015, TiGenix completed a Phase I sepsis challenge trial (CELLULA) that demonstrated a favorable safety and tolerability profile for Cx611. Based on the results of this study, TiGenix launched a Phase I/II clinical trial (SEPCELL) in 2016 evaluating Cx611 for the treatment of severe sepsis secondary to community-acquired pneumonia (sCAP) in patients who require mechanical ventilation and/or vasopressors. The first patient was dosed in January 2017 and data is expected in 2019. The trial has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 681031 and is being carried out through the SEPCELL consortium, which gathers six partners from four European countries. See www.sepcell.eu for more information.

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.

References

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 Panés, 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.