TiGenix

PRESS RELEASE

TiGenix confirms strategic focus on Cx601 and its adipose derived stem cell (eASC) platform

Leuven (BELGIUM) – December 20, 2017, 7:00h CET – TiGenix NV (Euronext Brussels and NASDAQ: TIG) ("TiGenix" or "the Company"), 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 Company plans to focus its resources and capabilities on its eASC platform technology and its product candidates Cx601 and Cx611.

This decision follows the recent positive CHMP opinion for Cx601 to treat complex perianal fistulas in Crohn's disease[i], which is a further step in making this product commercially available in Europe and highlights the potential of using allogeneic adipose-derived stem cells in the treatment of inflammatory conditions associated with immune-mediated diseases.

"With Cx601 now having received a positive regulatory opinion in Europe, we have reviewed our pipeline priorities beyond our continued commitment to the development of Cx601 for the US market and Cx611 for sepsis," said Eduardo Bravo, CEO of TiGenix. "We believe that Cx601 has great potential in other indications and that we will deliver greater shareholder value by directing our resources to targeted trials in those areas. We have undertaken a comprehensive scoping exercise and have identified three new attractive indications where we plan to develop Cx601 to expand its addressable market."

On December 15, 2017, TiGenix announced that Cx601 had received a positive CHMP opinion 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[i]. Takeda Pharmaceuticals, a leading pharmaceutical company in the gastroenterology space, acquired an exclusive right to develop and commercialize Cx601 for complex perianal fistulas in Crohn's disease patients outside of the U.S. in a deal signed in July 2016. TiGenix retains full rights to the product in the U.S. and is currently conducting a global Phase III clinical trial (ADMIRE-CD II) intended to support a future U.S. Biologic License Application (BLA).

TiGenix retains full rights to the development of Cx601 in other indications and has identified a number of areas across fistulising disease where serious unmet medical needs exist, and which share similarities with complex perianal fistulas in Crohn's disease in terms of disease development and treatment approaches. The Company is working with its Scientific Advisory Board on the most appropriate clinical development plan for each of these indications prior to discussing with Regulators in Scientific Advice meetings.

TiGenix is also advancing its Phase I/II clinical SEPCELL trial to evaluate Cx611 for the treatment of severe sepsis secondary to community-acquired pneumonia (sCAP) in patients who require mechanical ventilation and/or vasopressors. Sepsis is a life-threatening complication of infection and affects more than 15 million patients every year[ii], resulting in death in half of the cases.[iii] There is a critical need to improve current therapy, and Cx611's novel mechanism of action may offer an innovative alternative treatment of severe sepsis by targeting the underlying immune dysfunction. eASCs have shown their capacity to modulate inflammation and reduce mortality in animal models of sepsis. A favorable safety and tolerability profile for Cx611 was demonstrated in a Phase I sepsis challenge trial completed in 2015.

Given the focus on Cx601 and the allogeneic adipose-derived stem cell technology, TiGenix will not be investing in further R&D of its allogeneic cardiac stem cell technology and will review alternatives for further investment in this technology.

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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 adult Crohn's disease patients that have previously shown an inadequate response to at least one conventional therapy or biologic 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).[iv] A follow-up analysis was completed at 52 weeks[v] 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.[iv] Based on the positive 24 weeks Phase III study results, TiGenix submitted a Marketing Authorization Application to the European Medicines Agency (EMA) and received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in December 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 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.

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.

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[i] European Medicines Agency. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/12/news_detail_002873.jsp&mid=WC0b01ac058004d5c1. Accessed December 15, 2017.

[ii] The Lancet Infectious Diseases; Volume 12; issue 2; page 89; February 2012

[iii] Martin GS Expert Rev Anti Infect Ther. 2012 June; 10(6): 701–706.

[iv] 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): 1281-1290.

[v] Panés J, García-Olmo D, Van Assche G, *et al.*, 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 randomized controlled trial. ECCO 2017; Barcelona: Abstract OP009.