

TiGenix strengthens US operations with senior appointments

- Dr. Gregory Gordon appointed as Head of Medical Department (U.S.)
- Annette Valles-Sukkar appointed as Associate Director, Clinical Project

Leuven (BELGIUM) – September 12, 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 it has strengthened its U.S. operations with two senior appointments.

Dr. Gregory Gordon has been appointed Head of Medical Department (U.S.) and will report to Dr. Marie Paule Richard, Chief Medical Officer at TiGenix. Dr. Gordon has a strong background in clinical and academic medicine and extensive experience in the pharmaceutical industry driving broad-based, cross-functional teams in executing all aspects of clinical development. He joins TiGenix from Nestle Health Science where he was Global Clinical Affairs Lead, Gastrointestinal Health. In this role he helped design a pharmaceutical development strategy for gastroenterology and oversaw clinical development programs in the GI field. He previously held roles at Stealth BioTherapeutics, Inc., Ironwood Pharmaceuticals, and Parexel International. Dr. Gordon was awarded his MD by the State University of New York at Stony Brook School of Medicine and is a qualified lawyer and member of the New York State Bar.

Annette Valles-Sukkar has been appointed Associate Director, Clinical Project and will also join Dr. Richard's team. Ms Valles-Sukkar has a successful track record in the clinical research industry and joins TiGenix from Alexion Pharmaceuticals, where she was responsible for all aspects of clinical trial development including management of a global Phase III clinical trial in neurology. Annette previously held a number of clinical development roles across a range of indications and technology areas, leading multiple global clinical trials from Phase I through Phase III and to successful completion. Ms Valles-Sukkar was awarded a Masters in Health Policy from Northeastern University, Bouve College of Health Sciences in Boston, MA.

Dr. Marie Paule Richard, Chief Medical Officer at TiGenix said: "We are delighted to welcome Gregory and Annette to TiGenix and to further build the team at our U.S. headquarters in Cambridge, MA. Gregory has exceptional experience in drug development generally and specifically with gastrointestinal products. Annette has proven ability to manage large-scale late-stage clinical trials. Together with the rest of the TiGenix team, I am confident both will make significant contributions as we continue to work hard on the development of Cx601 in the U.S. for the treatment of patients suffering from complex perianal fistulas and in other indications in the future."

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

ⁱ 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.

ⁱⁱ 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.