TiGenix

PRESS RELEASE

TiGenix Cx601 positive long-term results to be presented at Digestive Disease Week

Leuven (BELGIUM) – May 4, 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, is honoured to announce that the positive 52-week results from its Cx601 ADMIRE-CD Phase III clinical trial for the treatment of complex perianal fistulas in patients with Crohn's disease will be presented at the 2017 Digestive Disease Week (DDW) annual meeting taking place from May 6-9 in Chicago, IL, USA.

The long-term results will be presented by Professor Julian Panés, Head of the Gastroenterology Department, at the Hospital Clinic of Barcelona (Spain) and President of the European Crohn's and Colitis Organization (ECCO), at the DDW session dedicated to Controlled Clinical Trials in Inflammatory Bowel Diseases.

> **Lecture presentation title:** Cx601, Allogeneic Expanded Adipose-Derived Mesenchymal Stem Cells (eASC), For Complex Perianal Fistulas In Crohn's Disease: Long-Term Results From A Phase III Randomized Controlled Trial
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> **Lecture presentation time and venue:** May 9, 2017 from 11:15 AM to 11:30 AM (CT) at the Conference Center, McCormick Place, Chicago, IL.

The DDW annual meeting is one of the foremost GI events and the world's largest gathering of physicians, researchers and industry in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery.

"We are delighted that the positive 52-week results from the ADMIRE-CD Phase III trial demonstrating the long-term safety and efficacy of Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients will be presented at a dedicated lecture at the DDW," said Dr. Marie Paule Richard, Chief Medical Officer at TiGenix. "The DDW is one of the most prestigious congresses in GI. We are honoured that these data will be presented to the US medical community, a key milestone in the preparation for the launch of our global pivotal Phase III trial in the first half of 2017."

TiGenix will also be hosting a key opinion leader (KOL) event at the Westin Chicago River North on May 8 2017 from 5:00 PM to 6:00 PM (CT), where leading experts in the GI field will discuss the unmet medical need in treating complex perianal fistulas, review the clinical data of Cx601, and provide insight into why Cx601 has the potential to become a breakthrough therapy in the management of complex perianal fistulas in patients with Crohn's disease.

Speakers include:

- **Dr. William J. Sandborn, MD**, Professor of Medicine and Adjunct Professor of Surgery Chief, Division of Gastroenterology Vice Chair for Clinical Operations, Department of Medicine Director, UCSD IBD Center University of California San Diego and UC San Diego Health System
- **Dr. Julian Panes,** Chief of Department of Gastroenterology, Hospital Clinic de Barcelona and President of the European Chron's and Colitis Organization
- **Uthra Sundaram,** VP GI Therapeutic Area, Global Commercial Leader, Takeda Pharmaceuticals

The event will be introduced and chaired by:

- **Dr. Marie Paule Richard,** Chief Medical Officer, TiGenix

Interested parties can follow the presentations of the KOL event via a webcast that can be accessed through http://www.wsw.com/webcast/cc/tig

For more information

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About TiGenix

TiGenix NV (Euronext Brussels and NASDAQ: TIG) is 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.

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.