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PRESS RELEASE

TiGenix Cx601 positive Phase III results to be presented at Digestive Disease Week in the USA

Leuven (BELGIUM) – May 18, 2016, 7:00am CET – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercializing novel therapeutics from its proprietary platforms of allogeneic expanded stem cells, is proud to present the week 24 positive results from its Phase III ADMIRE-CD pivotal study of Cx601 at the 2016 Digestive Disease Week (DDW) in San Diego, California (USA).

The ADMIRE-CD Phase III 24-week positive results will be presented by Professor Julian Panés, Head of the Gastroenterology Department, at the Hospital Clinic of Barcelona and Chairman of the TiGenix ADMIRE-CD Scientific Advisory Board in Europe, at the DDW session dedicated to Controlled Clinical Trials in Inflammatory Bowel Diseases on May 24, 2016 at 8:00am PDT. The DDW is the largest congress with international attendees organized in the US for this therapeutic field of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery.

In this double-blind, placebo controlled, randomized Phase III study, Cx601 met the primary endpoint of combined remission of complex perianal fistulas at week 24. As recently reported, Cx601 continued to show a sustained effect at week 52, while confirming the favorable safety and tolerability profile of the treatment. Combined remission is defined as the clinical assessment of the closure of all treated external openings draining at baseline combined with the absence of collection >2 of the treated perianal fistulas confirmed by central blinded MRI, and it is a more stringent definition of remission than the one commonly used in clinical trials on perianal fistulizing disease.

“The sustained effect of Cx601 after single injection is remarkable, particularly considering that a majority of patients treated were refractory to available therapies,” said Dr. Julián Panés. “Cx601 has shown to provide a durable, effective and safe therapeutic alternative to address this serious clinical condition,” he continued.

“Having been selected to present at DDW for an oral presentation, speaks of the quality of the ADMIRE-CD study,” remarked Dr. Marie Paule Richard, Chief Medical Officer at TiGenix. “We are honored to present our Phase III results to the US medical community at such a prestigious congress, and are confident this will raise the awareness of Cx601, especially as we prepare to initiate our pivotal Phase III trial for registration in the United States,” she said.

“Following the FDA´s agreement on the new Phase III design and planned analysis, Cx601 benefits from a clearly defined development and regulatory path for approval in the U.S.,” commented Dr. William J. Sandborn, Professor of Medicine and Adjunct Professor of Surgery, Chief of Gastroenterology, and Director of the UCSD Inflammatory Bowel Disease Center, University of California San Diego and UC San Diego Health System, San Diego. Dr. Sandborn; who is also the Chairman of TiGenix’s US Scientific Advisory Board, affirmed, “Cx601 has proven to be a novel approach to treat complex perianal fistulas, for which there is still no cure. In the US alone, 30,000 patients are waiting for an effective treatment for this debilitating disease.”

This is the first ever positive Phase III trial with an allogeneic stem cell product, which confirms TiGenix’s leadership position in the field of cell therapy. TiGenix submitted a Marketing Authorization Application for Cx601 in first quarter of 2016 to the European Medicines Agency, and expects to begin marketing in European markets in the second half of 2017.

For more information, please contact:

TiGenix
Claudia D'Augusta
Chief Financial Officer
T: +34 91 804 92 64
claudia.daugusta@tigenix.com

About TiGenix

TiGenix NV (Euronext Brussels: TIG) is an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platforms of allogeneic, or donor-derived, expanded stem cells. Two products from the adipose-derived stem cell technology platform are currently in clinical development. Cx601 is in Phase III for the treatment of complex perianal fistulas in Crohn's disease patients. Cx611 has completed a Phase I sepsis challenge trial and a Phase I/II trial in rheumatoid arthritis. Effective July 31, 2015, TiGenix acquired Coretherapix, whose lead cellular product, AlloCSC-01, is currently in a Phase II clinical trial in acute myocardial infarction (AMI). In addition, the second product candidate from the cardiac stem cell-based platform acquired from Coretherapix, AlloCSC-02, is being developed in a chronic indication. TiGenix also developed ChondroCelect, an autologous cell therapy product for cartilage repair of the knee, which was the first Advanced Therapy Medicinal Product (ATMP) to be approved by the European Medicines Agency (EMA). From June 2014, the marketing and distribution rights of ChondroCelect were exclusively licensed to Sobi for the European Union (except for Finland, where it is distributed by the Finnish Red Cross Blood Service), Norway, Russia, Switzerland and Turkey, and the countries of the Middle East and North Africa. TiGenix is headquartered in Leuven (Belgium) and has operations in Madrid (Spain). For more information, please visit www.tigenix.com.

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About Cx601

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) injected intra-lesionally. Cx601 is being developed for the treatment of complex perianal fistulas in Crohn's disease patients. Crohn's disease is a chronic inflammatory disease of the intestine and patients can suffer from complex perianal fistulas for which there is currently no effective treatment. In 2009, the European Commission granted Cx601 orphan designation for the treatment of anal fistulas, recognising the debilitating nature of the disease and the lack of treatment options. Based on positive Phase II results, TiGenix sought scientific advice from the European Medicines Agency (EMA) on the future development path of Cx601. TiGenix then initiated a randomised, double-blind, placebo-controlled Phase III trial in Europe and Israel designed to comply with the requirements laid down by the EMA (the ADMIRE-CD trial). 'Madrid Network', an organisation within the Autonomous Region of Madrid which helps companies to grow through high-technology innovation, issued a soft loan to help finance this Phase III study. The programme is funded by The Secretary of State for Research, Development and Innovation (Ministry of Economy and Competitiveness) within the framework of the INNTEGRA plan. The study's primary endpoint was combined remission, defined as clinical assessment at week 24 of closure of all treated external openings draining at baseline despite gentle finger compression, and absence of collections >2cm confirmed by MRI. In the ADMIRE-CD trial, the results of which were reported in August 2015, Cx601 achieved statistically significant superiority ($p<0.025$) on the primary endpoint with 49.5% combined remission at week 24 compared to 34.3% in the placebo arm in the ITT[1] population. These results translate into a relative risk of 1.44, meaning that patients receiving Cx601 had a 44% greater probability of achieving combined remission than placebo patients. Efficacy results were robust and consistent across all statistical populations. Treatment-emergent adverse events (non-serious and serious) and discontinuations due to adverse events were comparable between Cx601 and placebo arms. The ADMIRE-CD trial has completed a follow-up analysis at 52 weeks post-treatment. Based on the positive 24 week Phase III results, TiGenix has submitted a Marketing Authorisation Application to the EMA in early 2016. TiGenix is preparing to develop Cx601 for the US market after having reached an agreement with the FDA through a special protocol assessment, or SPA, procedure on its proposed protocol on August 7, 2015.

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.

[1] ITT: Intention to Treat i.e. all patients randomized.