TiGenix

**PRESS RELEASE**

# TiGenix Presents 24 Week Results of its Cx601 Phase III Trial at ECCO 2016

**Leuven (BELGIUM) – March 17, 2016, 19:00h 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, announced today the presentation of the 24 week results from the Phase III ADMIRE-CD pivotal trial of Cx601 for complex perianal fistulas in Crohn's disease patients, in a plenary session at the 11th Annual Congress of the European Crohn's and Colitis Organisation (ECCO) in Amsterdam, The Netherlands.**

ADMIRE-CD is a randomized, double-blind, placebo-controlled, Phase III study, designed to investigate the efficacy and safety of a single injection of Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients. Cx601 is a suspension of allogeneic, expanded, adipose-derived stem cells (eASC) for intralesional injection.

As already reported, a single injection of Cx601 achieved statistically significant superiority vs. placebo in the primary efficacy endpoint of combined remission at week 24 (defined as clinical assessment of closure of all treated external openings draining at baseline, despite gentle finger compression, and absence of collections >2cm confirmed by MRI; p=0.024). This definition of remission is more stringent than those commonly used in clinical trials on perianal fistulizing disease, as it includes both clinical and radiological assessment by MRI[1].

ECCO is the main European congress for Crohn's and Colitis specialists with more than 6,000 delegates registered this year. The abstract describing the 24-week results of Cx601 was selected as one of the thirty best abstracts deserving an oral presentation at the meeting's plenary session. The presentation was given by Prof. Dr. Julián Panés, Global Study Coordinator and Head of the Inflammatory Bowel Diseases Unit at the Hospital Clínic of Barcelona, on Thursday, March 17.

During his talk, Prof. Panés emphasized the demanding design of this study as the first, large scale, randomized clinical trial, specifically treating complex perianal fistulas in Crohn's disease patients, highlighting that 38.5% of the patients treated in the study suffered from fistulas with multiple tracts. Prof. Panés also pointed out that the included population was selected from patients whose fistulas had been refractory to conventional or anti-TNF treatment, representing a relevant clinical need.

Prof. Panés described the consistency of the 24 week secondary endpoints which on the treated population showed improvements in both response (clinical closure of at least 50% of all treated external openings that were draining at baseline; p=0.039) and clinical remission (clinical closure of all treated external openings that were draining at baseline despite gentle finger compression; p=0.052). Furthermore, the PDAI[2] score, an index that measures the severity of the disease, fell by more than 30% in the Cx601 group and maintained a statistically significant difference at 6, 12 and 18 weeks over placebo. Finally, Prof. Panés underlined the favorable safety and tolerability profile of the local treatment with Cx601, in contrast to the systemic immunosuppression of anti-TNF therapy and thiopurines, currently used in treating fistulizing Crohn´s disease.

Today's presentation will be followed tomorrow by a Symposium organized by TiGenix and chaired by Prof. Dr. Gert Van Assche, Head of the Division of Gastroenterology and Hepatology at the University Hospitals, Leuven. In this symposium, which will probe deeper into the relevance of the trial results, Dr. Krisztina B. Gecse, Gastroenterologist at the First Department of Medicine at Semmelweis University, Budapest, will review the evidence behind the limited efficacy and high relapse rate of

[1] Magnetic Resonance Imaging
[2] PDAI: Perianal Disease Activity Index

existing therapeutic approaches and the difficulty in advancing new treatments due to the scarcity of randomized control trials with fistula healing as their primary endpoint.

In relation to this challenge, Prof. Van Assche has anticipated: "The results of Cx601 in the ADMIRE-CD study open new therapeutic possibilities in our quest for an effective treatment for complex perianal fistulas. It is therefore of particular note that Cx601 displayed a short time to clinical remission of 6.7 weeks, twice as fast as observed in the placebo group (14.6 weeks)".

"We believe the data presented at ECCO reinforces the promise embodied by Cx601 in giving some hope to a difficult-to-treat patient population whose needs remain unmet", said Dr Marie Paule Richard, Chief Medical Officer of TiGenix. "These results, together with the week 52 data recently announced, strengthen TiGenix' confidence in the value that Cx601 will bring to Crohn's disease patients suffering from complex perianal fistulas and the clinicians treating them".

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***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.*

***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 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.*