

## TiGenix announces acceptance of Cx601 abstract for presentation at ECCO 2016 Congress

Leuven (BELGIUM) – January 11, 2016, 7:00h CET – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platforms of allogeneic expanded stem cells, announced today that the abstract related to the positive results of the ADMIRE-CD pivotal Phase III trial of Cx601 for complex perianal fistulas in Crohn's disease patients after 24 weeks has been accepted for oral presentation at the upcoming 11th Annual Congress of the European Crohn's and Colitis Organisation (ECCO) to be held from the 16th to 19th March in Amsterdam, The Netherlands.

As recently announced, a single injection of Cx601 met the primary endpoint of the ADMIRE-CD trial. ADMIRE-CD is a randomized, double-blind, placebo-controlled Phase III study designed to confirm 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) injected intra-lesionally. The results of the ADMIRE-CD trial will be presented by Prof. Dr. Julián Panés, Global Study Coordinator of the ADMIRE-CD study and Head of the Gastroenterology Department, Head of the Inflammatory Bowel Disease Unit, and Associate Professor of Medicine at the Hospital Clínic of Barcelona.

"We are delighted that the results of the ADMIRE-CD trial of Cx601 after 24 weeks have been accepted for oral presentation at ECCO 2016", said Dr. Marie Paule Richard, Chief Medical Officer of TiGenix. "The acceptance of the abstract confirms the relevance of the results and positions Cx601 as a truly innovative treatment for complex perianal fistulas in Crohn's disease patients, a severe, debilitating and difficult to treat condition."

Details of the abstract and timing of the oral presentation are provided below.

- Session name:** Scientific session 1: Cell therapy: Ready for clinical practice?
- Session date:** Thursday, March 17, 2016
- Session time:** 13:00-14:30h
- Session hall:** Plenary hall (Hall 11)
- Address:** RAI Amsterdam, Europaplein, NL 1078 GZ Amsterdam
- Abstract A-2175:** A phase III randomised controlled trial of Cx601, expanded allogeneic adipose-derived mesenchymal stem cells (eASC), for complex perianal fistulas in Crohn's disease
- Lead author:** Prof Dr Julián Panés  
Department of Gastroenterology, Hospital Clínic, Barcelona, Spain
- Presentation time:** 13:20-13:30h



### **For more information**

TiGenix

Claudia D'Augusta

Chief Financial Officer

T: +34 91 804 92 64

[claudia.daugusta@tigenix.com](mailto:claudia.daugusta@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. '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. The trial had a first complete analysis of results at 24 weeks, with a follow-up analysis to be performed at 52 weeks post-treatment. Recruitment of the whole sample of patients was completed in the fourth quarter of 2014. Based on the positive Phase III results, TiGenix will submit 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 our proposed protocol on the 7th of August 2015.*

### **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](http://www.tigenix.com).*

### **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*

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*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.*