

## TiGenix obtains commercial production license for Cx601

**Leuven (BELGIUM) – February 23, 2016, 07:00h 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 it has successfully obtained the license for commercial production of Cx601, TiGenix’s product for the treatment of complex perianal fistulas in Crohn’s disease patients.**

The issuance of the manufacturing license from the Spanish Medicines Agency (AEMPS) represents a relevant achievement in bringing Cx601 closer to commercial launch.

“We are very pleased with this approval which confirms our state-of-the-art GMP manufacturing capabilities in the stem cell field” said Wilfried Dalemans, Chief Technical Officer. “The commercial GMP license in addition to the current GMP license for clinical manufacturing is a clear recognition of our proven capabilities in the field and sets the stage for gearing-up the manufacturing of Cx601 commercial lots, making TiGenix a leading reference in the development of cell therapy medicinal products once more”.

Following the successful completion of its Phase III ADMIRE-CD clinical trial in August, the approval marks a new milestone in TiGenix’s mission to bring Cx601 to European patients suffering from complex perianal fistulas, a complication of Crohn’s disease for which there is currently no effective treatment.

“This timely and successful achievement fulfils one of the final requirements for our plan to file a Marketing Approval Application for Cx601 at the European Medicines Agency (EMA) in the coming weeks,” said Maria Pascual, VP Regulatory Affairs. “In this way our plan remains in line with the expectation to make Cx601 available to European patients 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](http://www.tigenix.com).

## **About Cx601**

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) injected intralesionally. 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 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.