TiGenix

PRESS RELEASE

TiGenix submits MAA to EMA for Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients

Leuven (BELGIUM) – March 2, 2016, 19:00h 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 the submission of a centralized Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Cx601 for the treatment of complex perianal fistulas in adult patients with Crohn's disease.

TiGenix has submitted a European MAA for its lead product Cx601, consisting of a suspension of allogeneic expanded adipose-derived stem cells (eASC), following the positive results from the pivotal ADMIRE-CD Phase III study in Crohn's disease patients suffering from complex perianal fistulas.

A complex perianal fistula consists of abnormal tracts between the rectum and the skin surface near the anus, and is commonly associated with Crohn's disease. It is a serious clinical condition leading to pain, discharge and that can cause severe incontinence. Complex perianal fistulas are associated with depression and may constitute a risk for anorectal carcinoma. Up to 120,000 adult Crohn's disease patients in Europe and the United States may eventually benefit from Cx601 in an indication for which there is no alternative satisfactory treatment.

"The submission of this application to the EMA represents another important achievement in TiGenix efforts to bring Cx601 to those Crohn's disease patients who currently lack an effective treatment for this serious and debilitating condition," said María Pascual, VP Regulatory Affairs of TiGenix. "Meeting this milestone brings us one step closer to fulfilling our ultimate goal of making our therapy available to European patients in the second half of 2017."

"The EMA filing is the culmination of the milestones set by TiGenix over the last eight months," said Eduardo Bravo CEO. "This achievement follows the completion of the ADMIRE-CD trial in August, the recently granted license to manufacture Cx601 commercially in Europe and the agreement from the FDA through a Special Protocol Assessment (SPA) on our proposal to conduct a Phase III pivotal trial in the United States. Our capacity to execute timely on these objectives reassures us about our ultimate goal of launching Cx601 in the coming years at both sides of the Atlantic."

As recently announced, the results of the ADMIRE-CD have been accepted for oral presentation at the upcoming Annual Congress of European Crohn's and Colitis Organisation (ECCO) in Amsterdam on 17th and 18th March 2016. 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.

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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[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 a follow-up analysis to be performed at 52 weeks post-treatment. Based on the positive 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

[1] ITT: Intention to treat population i.e. randomized patients.

“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.