TiGenix

REGULATED INFORMATION

PRESS RELEASE

TiGenix announces positive 52-week Phase III results of Cx601 in complex perianal fistulas in Crohn's disease patients

- **A single injection of Cx601 was statistically superior to placebo in achieving combined remission at week 52 in the treatment of complex perianal fistulas in Crohn's disease patients with inadequate response to previous therapies, including anti-TNFs**
- **54.2% of patients treated with Cx601 achieved combined remission at week 52 compared to 37.1% in the placebo arm**
- **75.0% of Cx601 treated patients who achieved combined remission at week 24 remained in combined remission at week 52 compared to only 55.9% in the placebo arm**
- **The results confirm the favorable safety and tolerability profile of Cx601 already reported at week 24**

Leuven (BELGIUM) – March 7, 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 that a single injection of Cx601 was statistically superior to placebo in achieving combined remission at week 52 in the Phase III ADMIRE-CD trial in Crohn's disease patients with complex perianal fistulas with inadequate response to previous therapies, including anti-TNFs. The one-year data also confirm the favorable safety and tolerability profile of Cx601 already reported at week 24.

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 in the treatment of complex perianal fistulas in Crohn's disease patients. In total, 212 patients were randomized in 7 European countries and Israel. Patients included in this study had an inadequate response to at least one previous therapy, including anti-TNFs. Continuation of medical standard of care was allowed during the duration of the trial in both groups. The study primary endpoint was combined remission at week 24, defined as closure of all treated external openings draining at baseline despite gentle finger compression, and absence of collections >2cm confirmed by MRI[1]. This same endpoint of combined remission has been analyzed after 52 weeks as a secondary variable.

In the ITT[2] population (n=212), Cx601 achieved statistical superiority (p=0.012) with 54.2% combined remission at week 52 compared to 37.1% in the placebo arm. In the mITT[3] population (n=204), the combined remission at week 52 was 56.3% and 38.6% for Cx601 and placebo respectively (p=0.010). Efficacy results were robust and consistent across all statistical analyses.

The week 52 data also shows a higher rate of sustained closure in those patients treated with Cx601 and in combined remission at week 24 (75.0%) compared to patients in the placebo group (55.9%).

[1] MRI: Magnetic Resonance Imaging
[2] ITT: Intention to treat i.e. all patients randomised in the trial.
[3] mITT: modified Intention to Treat i.e. all patients randomized and treated, and had at least one post-baseline efficacy evaluation.

Treatment-emergent adverse events (non-serious and serious) and discontinuations due to adverse events were comparable between Cx601 and placebo groups.

"We are delighted with the remarkable consistency of these results with respect to those reported at 24 weeks. In particular, the 75% persistence in the combined remission from week 24 to week 52 confirms Cx601 as a promising therapeutic solution for a hard to treat population that is refractory to existing treatments including anti-TNFs," said Dr Marie Paule Richard, Chief Medical Officer of TiGenix. "The improvement brought by Cx601 compared to the best standard of care available could make a real difference to the life of patients suffering from this chronic disease".

"The one year results of this large robust controlled study open up a new paradigm for the treatment of perianal fistulising Crohn's disease, one of the most severe manifestations of this process. With a single injection of Cx601 more than 50% of patients are in remission at one year with a favourable safety profile. Remarkably, most patients that were already in remission at six months continue to benefit from the treatment six months later, a major breakthrough in this field", said Dr Julián Panés, Head of the Gastroenterology Department, Head of the Inflammatory Bowel Diseases Unit, and Associate Professor of Medicine at the Hospital Clínic of Barcelona, President-Elect of ECCO, and Chairman of TiGenix ADMIRE-CD Scientific Advisory Board.

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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.