TiGenix

REGULATED INFORMATION

PRESS RELEASE

TiGenix announces Cx601 meets primary endpoint in pivotal Phase III trial

- **A single injection of Cx601 was statistically superior to placebo in achieving combined remission at week 24 of complex perianal fistulas in Crohn's disease patients with inadequate response to previous therapies, including anti-TNFs**
- **More than 50% of patients treated with Cx601 achieved combined remission at week 24**
- **A higher number of Cx601-treated patients had their fistulas closed by week 6**
- **The results confirm the favourable safety and tolerability profile of Cx601**
- **These positive data allow for European filing in the first quarter of 2016 and moving forward in the US with the SPA[1]-approved pivotal study**

Leuven (BELGIUM) – 23 August 2015 – 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 its lead compound Cx601 met the primary endpoint in the Phase III ADMIRE-CD trial in Crohn's disease patients with complex perianal fistulas. Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) injected intra-lesionally. A single injection of Cx601 was statistically superior to placebo in achieving combined remission at week 24, in patients with inadequate response to previous therapies, including anti-TNFs. The study results confirm the favourable safety and tolerability profile of Cx601.

ADMIRE-CD is a randomised, 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, 289 patients were recruited across 50 active sites in 7 European countries and Israel. Patients included had an inadequate response to previous therapies, 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[2].

In the ITT[3] population (n=212), Cx601 achieved statistically significant superiority ($p<0.025$) with 49.5% combined remission at week 24 compared to 34.3% in the placebo arm. In the mITT[4] population (n=204), the combined remission rates at week 24 were 51.5% and 35.6% for Cx601 and placebo, respectively ($p<0.025$). These results translate into an observed relative risk of 1.44, meaning that patients receiving Cx601 had 44% more chances to achieve 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.

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[1] SPA: Special Protocol Assessment
[2] MRI: Magnetic Resonance Imaging
[3] ITT: Intention To Treat i.e. patients randomised
[4] mITT: modified ITT i.e. patients randomized and treated, and with at least one post-baseline efficacy value

"We are extremely excited about the results of Cx601 in this severely debilitating and difficult to treat condition. Achieving more than 50% combined remission in patients who have not responded adequately to previous treatments, including anti-TNFs, is a remarkable accomplishment", said Dr Marie Paule Richard, Chief Medical Officer of TiGenix. "We are committed to submit these data to the EMA and to bring this innovative new treatment to patients whose life is impacted by the challenges of this serious condition".

Full efficacy and safety results will be presented at the 11th Congress of ECCO (European Crohn's and Colitis Organisation).

"The results of this large robust controlled study are clinically relevant and open a completely new avenue for the treatment of perianal fistulising Crohn's disease, one of the most severe manifestation of this process. The therapy affords a 44% increased chance for patients of closing their fistula with a single injection, which is a major breakthrough", 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.

"This is a landmark achievement for TiGenix", said Eduardo Bravo, CEO of TiGenix. "These positive results, together with the recent endorsement by the FDA of our Phase III trial design for the US, let us move full steam ahead making Cx601 available to the more than 100.000 patients who every year suffer from this serious condition".

Webcast and conference call

On Monday 24 August, at 15:00h CET/9:00h EDT, TiGenix will conduct a conference call and webcast. The following speakers will present the Top-Line results of the trial, explain the next steps for Cx601 and the Company, and will take questions:

- Mr Eduardo Bravo, Chief Executive Officer of TiGenix
- Dr Marie Paule Richard, Chief Medical Officer of TiGenix
- Dr Julián Panés, Head Gastroenterology Department, Head IBD Unit, and Associate Professor of Medicine at Hospital Clínic of Barcelona, President-Elect of ECCO, and Chairman of TiGenix ADMIRE-CD Scientific Advisory Board

Please dial one of the following numbers to participate:

Belgium:	+32 (0) 2404 0662	Spain:	+34 91 453 3445
Canada:	+1 514 841 2154	Sweden:	+46 (0) 8 5065 3936
France:	+33 (0) 1 76 77 22 26	United Kingdom:	+44 (0) 20 3427 1900
Netherlands:	+31 (0) 20 716 8257	United States of America:	+1 646 254 3365

Confirmation code: 8585083

The webcast can be followed live online via the link: http://edge.media-server.com/m/p/kvidxhyn

The press release and the webcast slide presentation will be made available in the Newsroom section of the TiGenix website. A replay of the webcast will be available on the website shortly after the live webcast has finished.

For more information

Claudia D'Augusta
Chief Financial Officer
T: +34 91 804 92 64
claudia.daugusta@tigenix.com

Ana Pombo
Strategic Planning and IR Manager
T: + 34 91 804 92 64
ana.pombo@tigenix.com

About Cx601

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) intra-lesionally injected. 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 primary endpoint is 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 has 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 EMA early 2016. TiGenix is preparing to develop Cx601 for the US market after having obtained FDA's endorsement of its pivotal Phase III trial through SPA 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 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/II trial in rheumatoid arthritis, as well as a Phase I sepsis challenge trial. Effective as of 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). Coretherapix is planning to initiate the clinical evaluation of AlloCSC-01 in the chronic setting as well and is also involved in the pre-clinical development of a pharmaceutical formulation of growth factors to treat AMI. Finally, 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

Forward-looking information

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