PRESS RELEASE

TiGenix Announces Orphan Drug Designation (ODD) for Cx601 in Switzerland

Leuven (BELGIUM) – October 17, 2016, 07:00h CET – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercializing novel therapeutics from its proprietary platforms of allogeneic expanded stem cells, today announced that Cx601, its lead product candidate being developed for the treatment of complex perianal fistulas in Crohn's disease patients, has been granted Orphan Drug Designation status in Switzerland. This is the second orphan drug designation granted to Cx601.

Developed by TiGenix and recently licensed to Takeda Pharmaceutical Company Limited ("Takeda"), for the exclusive development and commercialization outside the US, Cx601 is a suspension of allogeneic adipose-derived stem cells (eASC) injected intra-lesionally for the treatment of complex perianal fistulas in patients with Crohn's disease that have had an inadequate response to at least one conventional or biologic treatment. Crohn's disease is a chronic inflammatory disease of the gastrointestinal tract. People living with Crohn's disease can experience complex perianal fistulas for which there are limited treatment options.

On September 15, 2016, Takeda received orphan drug status from the Swiss Agency for Therapeutic Products (Swissmedic) regarding the application dossier for Cx601, or eASCs, adipose-derived stem cells for the rare disease anal fistulas. This decision was based on the recognition of the European Commission's Orphan Drug Designation in 2009, as well as the supporting data provided to the agency, which addressed proof of quality, efficacy and safety, as well as the rarity of the disease.

"The preparation and success of this dossier was a great start to our recently formalized partnership with Takeda and speaks to the important medicinal value of Cx601 in an area of high unmet medical need," said Maria Pascual, Vice President Regulatory Affairs and Corporate Quality of TiGenix.

Orphan drug designations are granted to drugs or biologics that are being investigated for the treatment of a rare disease or condition. In Europe, including Switzerland, this applies to diseases affecting fewer than five in 10,000 people. Orphan Drug Designation offers the sponsor incentives, which can include the possibility of a prioritized evaluation by Swissmedic.

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For more information

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TiGenix

About TiGenix

TiGenix NV (Euronext Brussels: TIG) is an advanced biopharmaceutical company focused on developing and commercializing 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 in Phase III for the treatment of complex perianal fistulas in Crohn's disease patients; Cx611 which 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. On July 4, 2016, TiGenix entered into a licensing agreement with Takeda, a large pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to commercialize Cx601 for complex perianal fistulas outside the United States. TiGenix is headquartered in Leuven (Belgium) and has operations in Madrid (Spain). For more information, please visit http://www.tigenix.com

About Cx601

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) locally injected. Cx601 is an investigational agent being developed for the treatment of complex perianal fistulas in Crohn's disease patients with inadequate response to at least one conventional or biologic therapy including antibiotics, immunosuppressants, or anti-TNF agents. 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, recognizing the debilitating nature of the disease and the lack of treatment options. Cx601 has met the primary end-point in the Phase III ADMIRE-CD study in Crohn's disease patients with complex perianal fistula, a randomized, double-blind, placebo-controlled trial run in Europe and Israel and designed to comply with the requirements laid down by the EMA. 'Madrid Network' issued a soft loan to help finance this Phase III study, which was 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 ITT population (n=212), Cx601 achieved statistically significant superiority (p=0.024) on the primary endpoint with 50% combined remission at week 24 compared to 34% in the placebo arm. 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 24-weeks results have been published by The Lancet, one of the most highly regarded and well known medical journals in the world. The Phase III study has completed a follow-up analysis at 52 weeks confirming its sustained efficacy and safety profile. Top line follow-up data showed that in the ITT population Cx601 achieved statistical superiority (p=0.012) with 54% combined remission at week 52 compared to 37% in the placebo arm. The 52-week data also showed 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%). Based on the positive 24-weeks Phase III study results, TiGenix has submitted a Marketing Authorization Application to the EMA in early 2016. TiGenix is preparing to develop Cx601 in the U.S. after having reached an agreement with the FDA through a special protocol assessment procedure (SPA) in 2015. On July 4, 2016 TiGenix entered into a licensing agreement with Takeda, a pharmaceutical company leader in gastroenterology, whereby Takeda acquired an exclusive right to commercialize Cx601 for complex perianal fistulas in Crohn's patients outside of the U.S.

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.