PRESS RELEASE

Takeda and TiGenix announce that Swissmedic has accepted for review the file on Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients

Pfäffikon, SZ, June 19, 2017, and Leuven, Belgium, June 19, 2017 – Takeda Pharma AG (TSE: 4502) ("Takeda") and TiGenix NV (Euronext Brussels and Nasdaq: TIG) ("TiGenix") today announced that the Swiss Agency for Therapeutic Products (Swissmedic) has accepted for review the file on investigational compound Cx601 to treat complex perianal fistulas in patients with Crohn's disease.

Filing follows Swissmedic granting orphan drug status for Cx601 in September 2016,[1] which recognizes the rare and debilitating nature of the disease. The marketing authorization application (MAA) for Cx601 is already under review for the same indication by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) locally administered for the treatment of complex perianal fistulas in patients with Crohn's disease, who have had an inadequate response to at least one conventional or biologic therapy.[2] The Swissmedic filing submission included the Phase III ADMIRE-CD trial data for Cx601. The ADMIRE-CD trial is a randomized, double-blind, controlled, Phase III trial designed to investigate the efficacy and safety of investigational compound Cx601.[2] 24- and 52-week data were included in the Swissmedic filing submission. The 24-week data were published in the *Lancet* and showed both the primary endpoint and the safety and efficacy profile were met.[3]

"Cx601 may have the potential to offer an alternative treatment option to current therapies, which are often associated with complications and a high failure rate for a disease that is difficult to treat and often leads to pain, swelling, infection and incontinence." said Julie Puype, General Manager, Takeda Pharma Switzerland. "The submission to Swissmedic is a key milestone in the commercialization of Cx601 and reflects Takeda's continued commitment to delivering innovative, therapeutic options for patients with gastrointestinal diseases."

"Complications from Crohn's disease, such as complex perianal fistulas, can have a severe impact on the lives of those affected." said Dr. María Pascual, VP of Regulatory Affairs and Corporate QA at TiGenix. "This submission by our partner Takeda reflects our joined continued efforts to make Cx601 available to patients and physicians beyond the European Union."

Crohn's disease is a chronic inflammatory disease of the gastrointestinal tract, which is thought to affect an estimated 6,100 people in Switzerland[4] and up to 1.6 million people in Europe.[5] Complex perianal fistulas are a complication for people living with Crohn's disease. Despite modern medical

and surgical advancements, they remain challenging for clinicians to treat[6] and are considered one of the most disabling manifestations of Crohn's disease.[7]

Takeda's Commitment to Gastroenterology

More than 70 million people worldwide are impacted by gastrointestinal (GI) diseases,[8] which can be complex, debilitating and life-changing. Takeda is driven to improving the lives of patients with GI diseases through innovative medicines, dedicated patient disease management support and the evolution of the healthcare environment. Takeda is leading in gastroenterology through the delivery of innovative medicines in areas associated with high unmet needs, such as inflammatory bowel disease, GI acid-related diseases and GI motility diseases. Our GI research & development team is also exploring solutions in celiac disease and nonalcoholic steatohepatitis (NASH), as well as scientific advancements through microbiome therapies. With more than 25 years of experience in this area, our broad approach to treating many diseases that impact the GI system and our global network of collaborators, Takeda aims to advance how patients manage their disease.

About Takeda Pharmaceutical Company

Takeda Pharmaceutical Company Limited is a global, R&D-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its research efforts on oncology, gastroenterology and central nervous system therapeutic areas. It also has specific development programs in specialty cardiovascular diseases as well as late-stage candidates for vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology and gastroenterology, as well as its presence in emerging markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

Takeda in Switzerland

The headquarters in Glattpark, near Zurich, look after Takeda's activities in Europe and in Canada. The branch for the Swiss market is located in Pfäffikon SZ. In total, nearly 500 employees work for Takeda in both locations. You can find more information about Takeda Pharma AG at http://www.takeda.ch.

About TiGenix

TiGenix NV (Euronext Brussels and NASDAQ: TIG) is an advanced biopharmaceutical company developing novel therapies for serious medical conditions by exploiting the anti-inflammatory properties of allogeneic, or donor-derived, expanded stem cells.

TiGenix' lead product, Cx601, has successfully completed a European Phase III clinical trial for the treatment of complex perianal fistulas - a severe, debilitating complication of Crohn's disease. Cx601 has been filed for regulatory approval in Europe and a global Phase III trial intended to support a future U.S. Biologic License Application (BLA) is expected to start in 2017. TiGenix has entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to develop and commercialize Cx601 for complex perianal fistulas outside the U.S. TiGenix' second adipose-derived product, Cx611, is undergoing a Phase I/II trial in severe sepsis – a major cause of mortality in the developed world. Finally, AlloCSC-01, targeting acute ischemic heart disease, has demonstrated positive results in a Phase I/II trial in acute myocardial infarction (AMI). 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 local administration of allogeneic expanded adipose-derived stem cells (eASCs) for the treatment of complex perianal fistulas in Crohn's disease patients that have previously failed

conventional therapy. Crohn's disease is a chronic inflammatory disease of the intestine and complex perianal fistulas are a severe and debilitating complication for which there is currently no effective treatment. Cx601 was granted orphan drug designation by the European Commission in 2009. TiGenix completed a European Phase III clinical trial (ADMIRE-CD) in August. The 24-week data were published in the *Lancet* and showed both the primary endpoint and the safety and efficacy profile were met.[3] A follow-up analysis was completed at 52 weeks and 104 weeks post-treatment, confirming the sustained efficacy and safety profile of the product. The 24-week results of the Phase III ADMIRE-CD trial were published in The Lancet in July 2016.[3] Based on the positive 24 weeks Phase III study results, TiGenix submitted a Marketing Authorization Application to the European Medicines Agency (EMA) and a decision is expected in 2017. A global Phase III clinical trial intended to support a future U.S. Biologic License Application (BLA) is expected to start in 2017, based on a trial protocol that has been agreed with the Food and Drug Administration (FDA) through a special protocol assessment procedure (SPA). In July 2016, TiGenix entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired exclusive rights to develop and 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.

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