

TiGenix reconfirms its strategic focus on its allogeneic stem cell platforms

Leuven (BELGIUM) – July 5, 2016, 8:00h CEST – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on the development and commercialization of novel therapeutics based on its proprietary platforms of allogeneic expanded stem cells, today announced the initiation of the withdrawal of the Marketing Authorization for ChondroCelect® due to commercial reasons. This decision is in line with TiGenix’s strategy to concentrate its resources and capabilities on its allogeneic stem cell platforms, its upcoming Cx601 Phase III US trial and its other clinical stage assets.

Due to the regulatory environment around autologous chondrocyte-based cell therapy products in Europe leading to a difficult competitive landscape for ChondroCelect, together with the lack of reimbursement in key European countries, TiGenix has been prompted to initiate the withdrawal process of the Marketing Authorization for ChondroCelect® for commercial reasons. Consequently, TiGenix has come to an agreement with Sobi for the early termination of their existing commercial relationship and will also terminate its manufacturing agreement with PharmaCell.

“TiGenix continues to be committed to bring novel therapeutics based on our proprietary allogeneic stem cell platforms to patients with high unmet medical need, as was evidenced by the recently announced licensing agreement with Takeda Pharmaceutical for the ex-US rights to commercialize Cx601 for the treatment of perianal fistula in Crohn’s disease,” said Eduardo Bravo, CEO of TiGenix. “To deliver shareholder value we need to focus all our efforts and internal resources on the upcoming Cx601 Phase III US trial while advancing with our other clinical stage assets, namely AlloCSC-01 in acute myocardial infarction and Cx611 in severe sepsis.”

TiGenix will be working with the regulatory agencies on this withdrawal, and is in the process of notifying healthcare professionals and remind them of the availability of therapeutic alternatives for patients with cartilage lesions of the knee.

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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 ChondroCelect

ChondroCelect, indicated for cartilage repair in the knee, was the first approved cell-based product in Europe that successfully completed the entire development track from research through clinical development to European approval through the centralised procedure. ChondroCelect received Marketing Authorization in October 2009 as the first Advanced Therapy Medicinal Product.

ChondroCelect is a cell-based medicinal product for use in autologous chondrocyte implantation in which cells are taken from the patient's own knee, multiplied to reach a large quantity, and then re-implanted at the site of the defect. ChondroCelect is indicated for the repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society grade III or IV) in adults.

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.