REGULATED INFORMATION
1 JULY, 2014

European Medicines Agency renews Marketing Authorisation for ChondroCelect

Leuven (BELGIUM) – 1 July, 2014 –TiGenix NV (Euronext Brussels: TIG), the European leader in cell therapy, announced today that the Committee for Medicinal Products for Human Use (CHMP) has renewed for an additional five years its marketing authorisation for ChondroCelect in all of the 31 countries of the European Union (EU) and European Economic Area (EEA).

"ChondroCelect was the first Advanced Therapy Medicinal Product (ATMP) to be approved by the European Medicines Agency (EMA) in October 2009, and it is the first ATMP to have its marketing authorisation renewed. The decision confirms the proven capability of TiGenix to develop and bring cell therapy products of real medical benefit to patients," said Maria Pascual, Vice-President of Clinical Operations and Regulatory Affairs at TiGenix. "After five years of post-commercialisation activity, and with an accumulated experience of over 1,000 patients, the CHMP confirms with its renewal that the benefit-risk balance remains positive for ChondroCelect."

Legislation of the European Union (EU) requires manufacturers of prescription medicines to apply for renewal of the marketing authorisation after a five year term and based on a re-evaluation of mainly safety data, only products that continue to have a positive risk-benefit ratio have their marketing authorisation renewed.

In parallel to its commercialisation efforts, TiGenix is conducting an open-label, multicentre, non-interventional study in patients treated with ChondroCelect for single symptomatic cartilage lesions of the knee of at least 2cm^2 and symptom onset of less than 3 years. The results from an interim analysis of 153 patients in this study indicate statistically and clinically significant improvement in all KOOS[1] subscale scores versus baseline. These data from treatment in daily clinical practice confirm the positive results from previous randomised clinical trials.

[1] KOOS stands for Knee Injury and Osteoarthritis Outcome Score

For more information

For TiGenix:
Richard Simpson
Senior Consultant, Comfi sprl
T: +32 494 578 278
richard@comfi.be

About ChondroCelect

ChondroCelect, indicated for cartilage repair in the knee, was the first cell-based product approved in Europe that successfully completed the entire development track from research through clinical development to European approval and received European Marketing Authorisation in October 2009 as the first Advanced Therapy Medicinal Product. It was approved for reimbursement in Belgium in February 2011, in the Netherlands in June 2012 (retroactively to January 2011) and in Spain in March 2013. Effective 1 June 2014, the company has entered into a distribution agreement with Sobi (Swedish Orphan Biovitrum AB) for the exclusive marketing and distribution rights with respect to ChondroCelect in Europe (excluding Finland, where TiGenix has a pre-exisiting distribution agreement with Finnish Red Cross Blood Services), the Middle East and North Africa.

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 grades III or IV) in adults.

Treatment with ChondroCelect comprises a two-step surgical procedure. In the first step, a cartilage biopsy is obtained arthroscopically from healthy articular cartilage from a lesser-weight bearing area of the patient's knee. Chondrocytes, the cells that produce and maintain the cartilage matrix, are isolated from the biopsy, expanded in vitro through a process based on cell characterisation, and delivered as a suspension for implantation in the same patient. ChondroCelect can be delivered nine weeks from the day of biopsy.

About TiGenix

TiGenix NV (Euronext Brussels: TIG) is a leading European cell therapy company with a marketed product for cartilage repair, ChondroCelect, and a pipeline of clinical stage allogeneic adult stem cell programmes for the treatment of autoimmune and inflammatory diseases. TiGenix is based in Leuven (Belgium) and has operations in Madrid (Spain). For more information please visit www.tigenix.com.

Forward-looking information

This document 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 document. 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.