

## TiGenix reports on regulatory path for ChondroCelect in the US

**Leuven (BELGIUM) – March 16, 2010 - TiGenix (NYSE EURONEXT: TIG) has obtained clarity from the American Food and Drug Administration (FDA) on the regulatory path towards approval of its lead product ChondroCelect in the US.**

The FDA has reviewed the summary of the clinical data from the pivotal trial that formed the base for the European marketing authorization for ChondroCelect which was approved in Europe in October 2009 as the first and still only product approved under the new Advanced Therapy Medicinal Product (ATMP) regulation.

In a meeting on Monday, March 15, the FDA requested an additional study before the filing of a Biologic License Application (BLA) and invited TiGenix to seek Special Protocol Assessment.

The European Medicines Agency (EMA) did also ask for an additional confirmatory study as a part of the requested risk management plan. This request was in the form of a post-approval commitment.

The protocol for this European confirmatory study, for which the design was recently agreed upon in a scientific advice meeting with the EMA, was presented during the meeting to the FDA. The initial feedback on the proposed protocol has been positive and it is likely that the outline of the study can also be used for the US. The company will interact with the regulatory agencies to assess the possibility for alignment of the protocol for it to fit the combined purpose of the confirmatory trial in Europe and the additional study in the US, and decide on the steps forward.

Gil Beyen, CEO of TiGenix comments: *“This request for an additional study highlights the general difficulty to bring innovative products to market. The path will be longer than anticipated, but we believe that our 8 years of clinical trial experience with ChondroCelect will help us to remain at the forefront of the field.”*

In the US only one cell-based product has obtained a Biologics License to date, and this occurred in 1997.

### **For more information, please contact:**

Gil Beyen  
Chief Executive Officer  
T: +32 16 39 60 60

Kris Motmans  
Corporate Communications  
investor@tigenix.com

## **About TiGenix**

Based in Leuven, Belgium, TiGenix NV (NYSE Euronext Brussels: TIG) is a biomedical company that focuses on 'Regenerating Motion'. The company is exploiting the power of Regenerative Medicine to develop durable treatments, validated through controlled clinical trials, for damaged and osteoarthritic joints.

TiGenix is developing a portfolio of products that address specific musculoskeletal problems. The lead indication among these is cartilage damage, which is a debilitating affliction affecting the mobility and functioning of patients. Western societies are characterised by ageing populations that place an increasing emphasis on high quality of life and life-long mobility, and, as such, cartilage problems represent a large and growing unmet medical need. Current therapies do not provide satisfying, long-term durable repair and TiGenix therefore believes there is a need for more effective treatments for cartilage damage.

## **About ChondroCelect®**

ChondroCelect®, the company's lead product for cartilage regeneration in the knee, is an implantation suspension of characterised viable autologous cartilage cells expanded in vivo and expressing specific marker proteins. The product is administered to patients in an autologous chondrocyte implantation procedure (ACI), a surgical procedure to treat cartilage defects, in conjunction with debridement (preparation of the defect bed), a physical seal of the lesion (placement of a biological membrane, preferentially a collagen membrane) and rehabilitation.

ChondroCelect is indicated for the repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society [ICRS] grade III or IV) in adults with or without concomitant asymptomatic cartilage lesions (ICRS grade I or II).

Demonstration of efficacy is based on a randomised controlled trial evaluating the efficacy of ChondroCelect in patients with lesions between 1-5 cm<sup>2</sup>. In the randomised controlled trial, the most common adverse reactions were arthralgia (47.1%), cartilage hypertrophy (27.4%), joint crepitation (17.6%) and joint swelling (13.7%). Most of the reported adverse reactions were expected as related to the open-knee surgical procedure. The most frequently occurring reactions reported immediately after surgery include joint swelling, arthralgia and pyrexia. These were generally mild and disappeared in the weeks following surgery. Cartilage hypertrophy occurred only at a rate of 1.8% in the 370-patient Compassionate Use Program, where a collagen membrane instead of a periosteal flap was used to seal the defect. Please consult full prescribing information ([www.emea.eu](http://www.emea.eu)) for details on appropriate use and safety information.

ChondroCelect is the first cell-based product that successfully completed the entire development track from research, over clinical development to central European registration as a medicinal product. On October 5, 2009 ChondroCelect received European marketing authorisation as the first approved Advanced Therapy Medicinal Product (ATMP).

## **Forward-looking information**

This document contains 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.