

## TiGenix Reports on Sales of ChondroCelect

**Leuven (BELGIUM) – March 9, 2010 – TiGenix NV (NYSE Euronext: TIG) provides an update on the launch of ChondroCelect and the status of reimbursement applications.**

TiGenix has begun the commercial launch of its lead product, ChondroCelect, for the treatment of cartilage damage in the knee, in the initial target markets which include Germany, Belgium, United Kingdom and the Netherlands. The first commercial patients have been treated and initial revenues have been generated. Reimbursement dossiers have also been submitted in the target markets and negotiations on pricing and reimbursement with local health insurance authorities and payers are ongoing and are progressing as planned, with feedback expected in the second half of this year.

The first “pre-reimbursement” commercial ChondroCelect patients have been treated under a variety of payment and reimbursement mechanisms, ranging from self-pay, private insurance, workers compensation, payment from hospital or primary care trust budgets in the UK and reimbursement by one of the German health insurance funds.

In Germany, ChondroCelect has been awarded “innovative new treatment method” status (“Neue Untersuchungs und Behandlungsmethode” or “NUB”) by the German Institute for the Hospital Remuneration System (InEK GmbH). The NUB status has been approved in thirty hospitals in Germany and gives these hospitals the right to negotiate reimbursement of ChondroCelect with their health insurance funds. Most of these negotiations are expected to take place in the second and third quarter of this year.

To support to launch and sales of ChondroCelect, TiGenix is reinforcing its commercial team in Germany, the Netherlands, Scandinavia, Spain and France. This specialised sales team will support the launch of ChondroCelect in about 80 targeted reference centres across Europe. TiGenix expects a gradual treatment uptake in the second half of the year as reimbursement decisions are confirmed in the target markets.

*“With ChondroCelect being the first cell-based therapeutic product registered by EMEA, we are entering a new era in regenerative medicine. As of now, we are able to offer our patients this truly validated, regenerative solution for their cartilage. As a surgeon, I see it as a privilege to be a pioneer in bringing this new technology into the general surgical practice of our center,”* comments Dr. Philipp Niemeyer, Department of Orthopedic Surgery and Traumatology, Freiburg University Hospital, the first surgeon to administer ChondroCelect after the approval.

Gil Beyen, Chief Executive Officer of TiGenix adds: *“The first steps of commercial launch of ChondroCelect in these markets are important milestones for TiGenix. Pricing and reimbursement discussions are progressing as planned and we are pleased to already have established sales in our first target markets. After 10 years of development it is good to see that ChondroCelect is becoming available to orthopedic surgeons and their patients.”*

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## **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.