

## TiGenix Reports Positive Results of ChondroCelect Compassionate Use Program

**Study confirms benefits of ChondroCelect in daily practice, significantly  
expands data set, and underpins commercial potential**

**Leuven (BELGIUM) – January 9, 2011** – TiGenix (NYSE Euronext: TIG), a leading biopharmaceutical company that commercializes and develops cell therapies, today announced data from a ChondroCelect® compassionate use program (CUP), involving 43 orthopedic centers in 7 European countries, treating 370 patients with ChondroCelect over the span of four years.

Data from the study have been published in advance online in *Cartilage*, the official journal of the International Cartilage Repair Society. The authors, led by principal investigator Johan Vanlauwe MD of the University Hospitals Leuven in Belgium, note that the Implantation of ChondroCelect resulted in a positive benefit/risk ratio when used in an unselected, heterogeneous population, irrespective of the follow-up period, lesion size and type of lesion treated. Importantly, the CUP study significantly expands the data set of the randomized clinical trial used to obtain approval for ChondroCelect by the European Medicines Agency in 2009, increasing eight-fold, from 43 to 334, the number of patients with long-term follow up data. To date more than 650 patients have been treated with ChondroCelect.

“On the back of the positive 5-year follow-up data of ChondroCelect procedures that were recently announced, this study offers compelling additional evidence that the results of our randomized clinical trial can be extrapolated to a broader population reflecting daily clinical practice.” said Eduardo Bravo, CEO of TiGenix. “In addition, the CUP study provides proof that the efficacy we measured in the randomized trial translates into very solid effectiveness in the real world. Furthermore, the large number of patients treated in this study strengthens our belief in the strong commercial potential of ChondroCelect.”

### **About the Study**

The study’s objective was to assess the clinical outcome of patients treated with Autologous Chondrocyte Implantation using ChondroCelect in daily practice within the context of a compassionate use program, involving 43 orthopedic centers in 7 European countries. Safety data were collected from 334 patients (90.3%) and effectiveness data from 282 (76.2%) of the 370 patients treated. A therapeutic effect was reported in 89% (234/264) of patients overall. Rates of much or very much improved patients were similar in patients with short-term follow-up (<18mo: 70.6% (115/163)) and longer-term follow-up (>18mo: 68% (70/103)), and were independent of lesion size (>4 cm<sup>2</sup>: 37/49 (75.5%); ≤4 cm<sup>2</sup>: 111/164 (67.7%)). Implantation of ChondroCelect appeared to result in a positive benefit/risk ratio when used in an unselected heterogeneous population, irrespective of the follow-up period, lesion size and type of lesion treated. The safety profile was in line with what was reported in the randomized clinical trial. However, there was a difference in the rate of cartilage

hypertrophy with only 2.1% in the CUP vs. 25% in the randomized trial. This is most likely due to the use of a biological membrane (92.2% in the CUP) vs. a periosteal flap in the randomized trial.

**For more information:**

Eduardo Bravo

Chief Executive Officer

[eduardo.bravo@tigenix.com](mailto:eduardo.bravo@tigenix.com)

Gil Beyen

Chief Business Officer

[gil.beyen@tigenix.com](mailto:gil.beyen@tigenix.com)

Hans Herklots

Director Investor & Media Relations

[hans.herklots@tigenix.com](mailto:hans.herklots@tigenix.com)

+32 474 88 30 46

**About TiGenix**

TiGenix NV (NYSE Euronext Brussels: TIG) is a leading European cell therapy company with two marketed products, ChondroCelect and ChondroMimetic, and a strong pipeline with clinical stage adult stem cell programs for the treatment of autoimmune and inflammatory diseases. TiGenix is based out of Leuven (Belgium), and Madrid (Spain), and has facilities in Cambridge (UK) and Sittard-Geleen (the Netherlands). For more information please visit [www.tigenix.com](http://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 TiGenix’ 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 TiGenix’ 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.*