

## TiGenix Business and Financial Update for the first quarter of 2014

### ChondroCelect® agreements enable short and long term value creation

**Leuven, Belgium - 13 May, 2014** – TiGenix NV (Euronext Brussels: TIG), the European leader in cell therapy, issued today a business and financial update for the first three months of 2014.

#### Business highlights

- Agreement to license the marketing and distribution rights of ChondroCelect to Sobi, a leading European specialty pharmaceutical company dedicated to niche disease indications, signed in April
- Agreement to sell the Dutch manufacturing facility to PharmaCell for a total consideration of Euro 5.75 million
- Patient recruitment in the European Phase III trial of Cx601 on track
- Selection of a US Contract Manufacturing Organisation (CMO) for Cx601 technology transfer ongoing
- Post-Phase IIa development plan for Cx611 being finalised following consultation with experts in several inflammatory and autoimmune disorders

#### Financial highlights

- ChondroCelect® sales up 26% compared with first quarter 2013
- Total funds of Euro 25.7 million available

“The agreements to license the marketing and distribution rights of ChondroCelect to Sobi, and to sell our Dutch manufacturing facility to PharmaCell, were the highlights in the first quarter of this year,” said Eduardo Bravo, CEO of TiGenix. “Together, these two deals mark a transformational milestone for TiGenix enabling us to realise both immediate and long-term value from the ChondroCelect business for our shareholders, and to bring ChondroCelect to many more patients in many more countries. Looking ahead, TiGenix can focus exclusively on progressing its promising late-stage clinical assets to patients suffering from diseases with high unmet medical needs.”

## **Business Update**

### **Agreements to license the marketing and distribution rights of ChondroCelect to Sobi, and to sell the Dutch manufacturing facility to PharmaCell, signed**

To expand the commercial reach for ChondroCelect, and to realise the immediate and long-term value potential of this asset, a licensing agreement was signed in April with Sobi, Swedish Orphan Biovitrum AB, a leading European specialty pharmaceutical company focused on niche disease indications.

The success of ChondroCelect requires a substantial upfront investment to obtain reimbursement, to prepare the market, to open and train medical centres, and to provide the medical education necessary to establish ChondroCelect as the gold standard for the right patients. Sobi has the infrastructure, capabilities, experience, financial resources, and a much broader geographic coverage with which to bring ChondroCelect to many more patients in many more countries.

Under the terms of the agreement, which is effective 1 June 2014, Sobi gains the marketing and distribution rights to ChondroCelect for the European markets where the product is currently available, and for the registration, reimbursement, marketing and distribution of ChondroCelect in other markets in Europe, Turkey and Russia, and for markets in the Middle East and North Africa. In exchange, Sobi will pay TiGenix a royalty of 20% (22% for the first year) of the net sales of ChondroCelect, and the vast majority of all expenses associated with the product. This will give TiGenix a cash flow-positive asset and a significantly higher operating margin for the product going forward.

The agreement to sell the Dutch production facility, expected to close during the second quarter, completes the strategic repositioning of the business. For a total consideration of Euro 5.75 million, including an upfront payment of Euro 3.5 million, the facility will be sold to PharmaCell, a leading European contract manufacturing organisation active in the areas of cell therapy and regenerative medicine. ChondroCelect will continue to be manufactured at the facility under a long-term manufacturing agreement.

The combination of the two deals will bring an immediate cash inflow of Euro 3.5 million to TiGenix, and a reduction in annual operating costs for manufacturing, sales and marketing of at least Euro 5 million. In time, the broader geographical reach for ChondroCelect offered by Sobi, will give TiGenix the potential for greater value generation in the long-term.

### **Patient recruitment on track with Cx601**

Patient recruitment for the European Phase III ADMIRE-CD study of Cx601 in complex perianal fistulas in Crohn's disease is on track to complete by the end of 2014. This should enable study results to be obtained in the third quarter of 2015, which would allow for filing for marketing authorisation with the European Medicines Agency (EMA) in early 2016.

### **Post-Phase IIa development plan for Cx611 to be completed shortly**

With the encouraging results of the Phase IIa study of Cx611 in rheumatoid arthritis, TiGenix is working closely with international key opinion leaders on the appropriate design of follow-up studies for Cx611 in inflammatory and autoimmune disorders. TiGenix expects to finalise and announce the next steps of the development plan during the second quarter of this year.

## **Financial update**

### **ChondroCelect sales continue to grow steadily**

During the first three months ending 31 March 2014, ChondroCelect sales grew 26% to Euro 1.3 million, compared to Euro 1.0 million in the same period last year.

## **Funds available will enable TiGenix to secure Cx601 study results**

With cash in hand at 31 March 2014 of Euro 17.2 million, outstanding funds of Euro 5 million available from the Kreos loan facility, and Euro 3.5 million to be paid to TiGenix by PharmaCell on the sale of the Dutch manufacturing facility, total funds of Euro 25.7 million are available to TiGenix. This will enable the company to secure the study results from the European Phase III trial of Cx601.

## **Operational expectations for the next 12 months**

- To complete patient recruitment for the European Phase III study of Cx601 by the end of 2014
- To hire a Contract Manufacturing Organisation (CMO) in the United States and to begin technology transfer for Cx601
- To file for a Special Protocol Assessment (SPA) for Cx601 with the Food and Drug Administration (FDA)
- To complete, and communicate, the post-Phase IIa development plan for Cx611 in Europe

## **For more information**

Richard Simpson  
Senior Consultant, Comfi sprl  
T: +32 494 578 278  
[richard@comfi.be](mailto:richard@comfi.be)

## **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 headquartered in Leuven (Belgium) with operations in Madrid (Spain). 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 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.*