TiGenix

REGULATED INFORMATION
NOVEMBER 8, 2012

TiGenix Business Update & Financial Highlights for Q3 of 2012

- **ChondroCelect Sales EUR 3.2 Million for First Nine Months**
- **Cx611 RA Program on Track to Report Preliminary Results in Q4**
- **Cx601 Partnering Discussions On-going**
- **Company Sufficiently Financed to Keep Executing on Plan**

Leuven (BELGIUM) – November 8, 2012 –TiGenix NV (Euronext Brussels: TIG), the European leader in cell therapy, gives an update of its business activities and provides the financial highlights for the third quarter ending September 30, 2012.

Business highlights

- ChondroCelect:
  - ChondroCelect sales benefit from continued uptake in Belgium and in the Netherlands
- Progress development pipeline
  - ADMIRE-CD Phase III trial (Cx601) enrollment on-going
  - Cx601 Phase II study published in international peer-reviewed journal
  - Cx611 Phase IIa in rheumatoid arthritis (RA) to report preliminary results in Q4
- Corporate:
  - Jean Stéphenne appointed chairman & Russell Greig appointed member of the board of directors
  - European central facility obtains EMA approval for commercial production of ChondroCelect
  - Partnering discussion for lead program Cx601 on-going

Financial highlights

- ChondroCelect sales for the first nine months of 2012 amounted to EUR 3.2 million, comprising of EUR 2.5 million from 2012 sales, up 130% compared to same period of last year, and EUR 0.7 million of deferred sales from 2011
- ChondroCelect sales of the third quarter amounted to EUR 1.1 million, a 152% increase compared to the same period of 2011
- EUR 8 million cash on hand

"We are very pleased with our continued progress on all fronts," says Eduardo Bravo, CEO of TiGenix. "We anticipate delivering on a number of key milestones in the months ahead, such as reimbursement of ChondroCelect in at least one major market, partnering of Cx601, and preliminary and final results of our state-of-the-art Cx611 Phase II trial in RA. Based on our current cash position, and achieving our short-term milestones we are sufficiently financed to reach the end of 2013"

Business update

ChondroCelect sales up substantially

ChondroCelect sales for the third quarter of 2012 amounted to EUR 1.1 million, compared to sales of EUR 0.4 million in the same period of last year, reflecting the continued uptake in Belgium and the Netherlands. For the nine months ended September 30, ChondroCelect sales have grown 130% to

EUR 2.5 million, compared to EUR 1.1 million in the same period of last year, excluding deferred sales of 2011.

Discussions to obtain national reimbursement keep advancing in Spain, France, and Germany, and the company expects a positive decision in at least one of these countries in the months ahead.

Patient enrollment on plan in ADMIRE-CD Phase III trial (Cx601) in complex perianal fistulas

Since July, after enrolling the first patient in the ADMIRE-CD trial, its pivotal Phase III clinical trial with Cx601, enrollment is progressing on plan. Cx601 is an adipose derived allogeneic stem cell suspension for the treatment of complex perianal fistulas in Crohn's disease patients. ADMIRE-CD is a multicenter, randomized, double-blind, placebo-controlled Phase III trial that will enroll approximately 278 patients at 46 centers across 7 European countries and Israel. The main objectives of the study are to demonstrate safety and superior efficacy over placebo in perianal fistulas in Crohn's disease patients who failed to respond to previous treatment(s), in most cases biologicals, and to confirm the strong safety and efficacy results from the Phase II trial completed in 2011. Final results of the trial are expected in H2 2014, and, if positive, will allow the Company to file for marketing authorization with the European Medicines Agency.

In early October, the study results of the Phase II trial of Cx601 were published online ahead of print in the peer-reviewed International Journal of Colorectal Disease.

Cx611 Phase IIa in rheumatoid arthritis to report preliminary safety results in Q4

On August 8, the Company completed enrollment in its Phase IIa trial of Cx611 in rheumatoid arthritis (RA). This is the most advanced clinical trial in the world with stem cells in RA and the Company expects to report preliminary results in Q4 and final results no later than April 2013. Although the primary objective is to demonstrate safety, feasibility, tolerance and optimal dosing, this 53-subject, randomized, placebo controlled, multicenter study will follow patients for 6 months after three injections of Cx611. It will therefore provide a strong first indication of the duration of the efficacy of Cx611 in this very difficult patient population – enrolled patients have previously failed to respond to at least one biological – and will set the stage not only for the further development of Cx611 in RA, but also in a wide range of other autoimmune disorders.

Jean Stéphenne appointed chairman & Russell Greig appointed member of the board of directors

On September 20, TiGenix appointed Jean Stéphenne chairman and Russell Greig member of the board of directors. Both are former members of the Corporate Executive Team of GlaxoSmithKline (GSK), and have a sterling track record that will be of immense value as TiGenix enters into a pivotal phase of its growth with the commercial roll-out of ChondroCelect and the advanced clinical development of its cell therapy programs.

European production facility obtains EMA approval

On October 9, TiGenix obtained approval from the European Medicines Agency to manufacture ChondroCelect at its European manufacturing plant in Sittard-Geleen in the Netherlands. The state-of-the-art manufacturing site is unique in Europe as it is 100% geared towards the production of innovative cell therapy products. The plant provides TiGenix with manufacturing capabilities to support the anticipated growth in demand for ChondroCelect.

Partnering discussion for lead program Cx601 on-going

TiGenix keeps advancing its discussions with a number of parties regarding the commercial rights to Cx601 to maximize the value of its lead program.

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Financial results for the first nine months of 2012

ChondroCelect sales for the first 9 months of EUR 3.2 million

ChondroCelect sales for the first nine months of 2012 amounted to EUR 3.2 million, comprising of EUR 2.5 million of sales from 2012, and EUR 0.7 million in deferred sales from 2011. Sales for Q3 2012 were EUR 1.1 million, representing a 152% increase compared to Q3 2011.

Cash position of EUR 8 million on September 30, 2012

On September 30, the Company had a cash position of EUR 8 million. Net cash used during the first nine months of 2012 was EUR 11.7 million, in line with management's guidance. Based on its current cash position, anticipated commercial revenues from ChondroCelect sales, partnering of Cx601, already allocated grants, and new grants, the company believes it is sufficiently financed to keep executing on its business plan.

Outlook next 12 months

- National reimbursement decisions in major European countries for ChondroCelect
- ChondroCelect distribution agreements in selected countries
- First commercial batches of ChondroCelect produced at Sittard-Geleen manufacturing facility
- Preliminary results of Cx611 in Rheumatoid Arthritis in Q4, 2012
- Partnering agreement for Cx601
- Final results of Cx611 in RA in April, 2013
- Additional non dilutive funding through R&D grants and soft loan programs

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About TiGenix

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