

## TiGenix Business Update & Financial Highlights for Q3 of 2013

- **ChondroCelect: sales up 21% for first nine months and advanced discussions to monetize the Dutch manufacturing facility ongoing**
- **Cx601: European ADMIRE-CD Phase III enrollment on schedule and partnering discussions ongoing for non-European territories**
- **EUR 6.4 million cash on hand on September 30. Cash burn for the third quarter reduced to EUR 1.1 million per month**

**Leuven (BELGIUM) – November 5, 2013 –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, 2013.**

### **Business update**

#### **ChondroCelect sales on track to become cash flow positive in 2014**

ChondroCelect sales for the nine months ended September 30 have grown 21% to EUR 3.1 million, compared to EUR 2.6 million in the same period of last year on a like-for-like basis. ChondroCelect sales for the third quarter amounted to EUR 0.8 million. The company expects a sales growth rate above 20% for the full year, with revenues mainly fueled by sales in Belgium and the Netherlands.

With centers coming on stream in Spain and the UK, sales from these countries will contribute to increased growth in 2014. All in all, sales are progressing according to plan for ChondroCelect to become a cash flow positive asset in the course of 2014.

#### **TiGenix renews GMP license for Dutch manufacturing facility**

In October, Dutch authorities renewed TiGenix's GMP license for its state-of-the-art cell therapy manufacturing facility in Sittard-Geleen, the Netherlands. This renewal allows the Company to move forward unimpeded with its advanced negotiations to monetize the facility.

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

Patient enrollment in the ADMIRE-CD trial, the Company's pivotal European Phase III clinical trial with Cx601, is progressing on plan. Recruitment is ongoing at more than 45 centers in 8 countries. If results are positive, this trial will allow TiGenix to file for European marketing approval of Cx601 in 2015.

#### **Cx601 partnering discussions ongoing for non-European territories**

TiGenix continues to advance discussions with a number of parties regarding the ex-Europe commercial rights to its lead program Cx601. To maximize the value of the asset, the company is progressing with all activities required to move forward in the US in the near future. TiGenix has requested a pre-IND meeting with the FDA to confirm the regulatory and clinical pathway for the



product in the US market and negotiations are ongoing to secure capacity to manufacture Cx601 for the US clinical trial.

### **Cx611 clinical development plan progressing**

In October, TiGenix presented the positive results of its Phase IIa study of Cx611 in refractory rheumatoid arthritis in a plenary session of the American College of Rheumatology Annual Meeting. Working closely together with an advisory board of international key opinion leaders on the appropriate design of follow-up studies for Cx611 in RA and other autoimmune disorders, TiGenix expects to finalize the development plan before year-end. At that point the Company will decide which indication to pursue and whether to do it alone or with a partner.

### **Financial update**

#### **Capital increase of EUR 6.5 million in July 2013**

The company raised EUR 6.5 million through a private placement via an accelerated book building procedure with mainly international healthcare specialist investors.

#### **Cash position of EUR 6.4 million on September 30, 2013**

On September 30, 2013, the Company had a cash position of EUR 6.4 million. Net cash used during the third quarter of 2013 (excluding the impact of the capital increase of July) was EUR 1.1 million per month, significantly below management guidance.

"We keep diligently executing on our action plan to grow ChondroCelect sales, monetize our Dutch manufacturing facility, focus on our lead asset Cx601, prepare the development plan for Cx611 and secure the means to be able to execute our strategy," said Eduardo Bravo, CEO of TiGenix. "We are making continuous progress on each of these initiatives and we expect to communicate on some concrete achievements in the next few weeks".

### **Outlook next 12 months**

- Continued ramp-up of ChondroCelect sales
- Finalize recruitment of Cx601 phase III trial in complex perianal fistula in Crohn's patients
- Partnering agreement for Cx601 for territories outside of Europe
- Monetization of the Dutch cell therapy manufacturing facility
- Completion of clinical development plan for Cx611
- Strengthening of balance sheet

#### **For more information:**

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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](http://www.tigenix.com).*

**Forward-looking information**

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