REGULATED INFORMATION
26 AUGUST, 2014

TiGenix Business and Financial Update for the First Half of 2014

Leuven, Belgium – 26 August, 2014 – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platform of allogeneic, expanded adipose-derived stem cells, or eASC's, in inflammatory and autoimmune diseases, issued an update on business and financial progress in the first half of this year today.

Business highlights

- eASC technology platform
    - Patient recruitment for the European Phase III study of Cx601 in complex perianal fistulas in Crohn's disease is 95% complete and is expected to finish ahead of schedule. Final results from the study should now be available earlier than previously expected in Q3 2015, and European filing for marketing authorisation is planned for H1 2016
    - TiGenix confirmed its strategy for developing Cx601 for the US market
    - The clinical development plans for Cx611 in early rheumatoid arthritis and severe sepsis were completed and implementation has begun
- ChondroCelect
    - The licensing of marketing and distribution rights and the sale of the Dutch manufacturing facility was completed
    - Marketing authorisation for ChondroCelect was renewed by the European Medicines Agency (EMA)

Financial highlights

- Sales for ChondroCelect increased by 16% compared with the same period last year
- Loss for the period from continuing operations decreased by 2% compared with the same period last year
- Liquidity position of Euro 19.2 million at 30 June 2014

"We made significant progress in the first half of 2014," said Eduardo Bravo, CEO of TiGenix. "We have transformed the operations of TiGenix to enable the company to fully focus on realising the value in its development pipeline. Our Phase III trial of Cx601 is on track to deliver results earlier than anticipated, and our intravenously administered stem cell product, Cx611, has been endorsed by international clinical experts to move forward in two areas of high unmet medical need and significant commercial potential, early rheumatoid arthritis and severe sepsis."

Business Update

Cx601 Phase III trial on track to deliver results in Q3 2015; development plans for the US market advancing

The enrolment of patients into the ADMIRE-CD Phase III study of Cx601 for complex perianal fistulas in Crohn's disease is 95% complete and is expected to finish ahead of schedule before the end of this year. Study results are expected to be available earlier than previously expected in Q3 2015, which should allow TiGenix to file for marketing authorisation in Europe during H1 2016. ADMIRE-CD is a multi-centre, randomised, double-blind, placebo-controlled pivotal Phase III trial, which will enrol 278 patients at 52 centres across seven European countries and Israel.

TiGenix has made significant progress in clarifying the way forward for Cx601 in the US market, as follows: a) the Food and Drug Administration (FDA) has confirmed that the ADMIRE-CD Phase III trial, if successful, can serve as supportive evidence for a Biologics Licence Application (BLA); b) TiGenix is in the process of appointing a contract manufacturing organisation (CMO), and expects to start the technology transfer process to enable production of Cx601 in the US by the end of 2014; c) TiGenix is appointing a Scientific Advisory Board of clinical experts in the US to provide guidance on the clinical development of Cx601 in the US; d) by the end of 2014, the company will apply for a Special Protocol Assessment (SPA) from the FDA to ensure that the ADMIRE-CD Phase III study design is aligned with the Agency's requirements for future approval of Cx601.

Development plan for Cx611 in early rheumatoid arthritis and in severe sepsis announced

Having considered the demonstrated therapeutic effects of allogeneic stem cells, the animal and clinical data for Cx611 collected so far, the potential applications in areas of high unmet medical need, and advice from clinical experts in Europe and in the United States, TiGenix will focus the development of its intravenously administered stem cell product, Cx611, in early rheumatoid arthritis and in severe sepsis.

In early rheumatoid arthritis, Cx611 could offer patients a therapy which delays the need to progress to biological drugs. "There is a need for a treatment with an alternative mechanism of action that could induce minimal disease activity in a greater proportion of patients and reduce the need to progress to chronic, sequential and expensive biological therapies", said Frank Luyten, Professor and Chairman of Rheumatology, University Hospital of Leuven, Belgium.

In severe sepsis, Cx611 could be a therapy with a mechanism of action that, when combined with standard treatment, delivers faster recovery and improved survival rates. "Even today, patients with severe sepsis have a low survival rate so there is a critical need to improve the effectiveness of current therapy," said Professor Pierre-François Laterre, Professor of Medicine and Head of Intensive Care, Saint Luc University Hospital, Brussels, Belgium. "Only a small number of new molecular entities are currently in development for severe sepsis. Based on the available data, I believe there is a strong rationale to study Cx611 in this patient population."

Success in either of these indications would represent a major medical and commercial opportunity for Cx611.

In early rheumatoid arthritis, TiGenix is working with a group of leading clinical experts to complete the protocol for a randomised, double-blind, comparative Phase IIb study to test the efficacy of Cx611 in patients exhibiting substantial disease activity from rheumatoid arthritis despite treatment with methotrexate and corticosteroids, but unexposed to a biological drug. Recruitment for the proposed study could start in the third quarter of 2015 and could produce final results in the first half of 2017.

In severe sepsis, the company is working on the development of Cx611 with international experts. As well as additional animal model testing, in early 2015 TiGenix will start a randomised, placebo-controlled trial to test the mechanism of action of Cx611 in healthy volunteers challenged with a bacterial endotoxin (lipopolysaccharide), a potent pro-

inflammatory constituent of the outer membrane of Gram-negative bacteria, which elicits a strong inflammatory response inducing sepsis-like clinical symptoms. This trial's protocol has now been prepared and submitted in the Netherlands to the Centrale Commissie Mensgebonden Onderzoek (CCMO or Central Committee on Research involving Human Subjects). TiGenix expects to complete this study by the third quarter of 2015, and then follow up with a phase II trial of Cx611 as an add-on therapy to the standard of care in patients with severe sepsis.

ChondroCelect: marketing and distribution out-licensed, manufacturing facility sold, and marketing authorisation for Europe renewed

During the first half of 2014, TiGenix closed a licensing agreement and sold the Dutch manufacturing facility. The combination of the two deals has brought an immediate cash inflow of Euro 3.5 million to TiGenix and is expected to reduce annual operating costs for manufacturing, sales and marketing by at least Euro 5 million.

On 1 June, TiGenix completed the licensing of the marketing and distribution rights of ChondroCelect to Swedish Orphan Biovitrum AB ('Sobi', NASDAQ OMX Stockholm: SOBI), the international specialty healthcare company dedicated to rare diseases. Sobi will continue to market and distribute the product where it is currently available and has also acquired the exclusive rights to expand the product's availability to patients in multiple additional territories. TiGenix will receive a royalty of 22% of the net sales of ChondroCelect in the first year of the agreement, and 20% of the net sales of ChondroCelect thereafter. Sobi will also reimburse nearly all of TiGenix's costs associated with the product.

To further rationalise its operations, TiGenix completed the sale of its Dutch production facility to PharmaCell BV, 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.

On 30 June, marketing authorisation for ChondroCelect in all of the 31 countries of the European Union (EU) and European Economic Area (EEA) was renewed by the EMA's Committee for Medicinal Products for Human Use (CHMP).

Sales of ChondroCelect in the first half of 2014 were Euro 2.6 million, representing a 16% increase over the same period in 2013.

Financial Update

Thousands of euros (€), except for share data (in euros)	Period ended June 30 2014	2013
CONSOLIDATED INCOME STATEMENT		
CONTINUING OPERATIONS		
Revenues		
Royalties	-	-
Grants	821	736
Total revenues	**821**	**736**
Research and development expenses	-5.097	-5.314
General and administrative expenses	-2.859	-2.735
Total operating charges	**-7.956**	**-8.049**
Operating Loss	**-7.135**	**-7.313**
Financial income	25	5
Financial expenses	-369	-28
Foreign exchange differences	170	-38
Loss before taxes	**-7.309**	**-7.374**
Income taxes	-	42
Loss for the period from continuing operations	**-7.309**	**-7.332**
DISCONTINUED OPERATIONS		
Loss for the period from discontinued operations	-1.842	-1.505
Loss for the period	**-9.151**	**-8.837**
Attributable to equity holders of TiGenix NV	*-9.151*	*-8.837*
Basic (diluted) loss per share (EURO)	**-0,06**	**-0,09**
Basic (diluted) loss per share from continuing operations (EURO)	**-0,05**	**-0,07**
Basic (diluted) loss per share from discontinuing operations (EURO)	**-0,01**	**-0,02**

Sales and expenses for ChondroCelect recorded as 'discontinued operations'

During the first half of 2014, the operations of TiGenix have been substantially transformed to enable the Company to fully focus on realising the value of its eASC platform and pipeline. The discontinuation of ChondroCelect operations through the licensing of marketing and distribution rights, and the selling of the Dutch manufacturing facility, has changed the presentation of the income statement of the Company.

For comparative purposes, figures for the first half of 2013 have been adapted to show ChondroCelect as discontinued operations. Sales of ChondroCelect for the first half of 2014 (Euro 2.6 million, representing a 16% increase over the same period in 2013) have been recorded, together with all expenses related to the product, as 'Discontinued Operations'. Royalties during the first half of the year amounted to zero as the licensing agreement with Sobi became effective only in June 2014.

Loss for the period for continuing operations decreased by 2%

The loss for the first six months of 2014, including both continuing and discontinued operations, amounted to Euro 9.2 million, compared to Euro 8.8 million in the same period of 2013. This increase of 4% is the direct result of the loss from discontinued operations and the

increase of financial expenses related to the Kreos loan facility. The loss for the period from continuing operations decreased by 2% compared with the same period last year.

Liquidity position of Euro 19.2 million at 30 June 2014

At the end of June 2014, the Company had a liquidity position (cash, cash equivalents and receivables from reverse repurchase agreements) of Euro 19.2 million, compared with Euro 15.9 million at the beginning of the year (including discontinued operations). During the first half of 2014, the Company drew down two tranches of Euro 5 million in January and Euro 2.5 million in May respectively from the debt financing facility secured with Kreos Capital in December 2013. In May 2014, through the sale of the Dutch manufacturing facility, the Company obtained Euro 3.5 million. With its cash position at the end of June 2014 plus additional available funds from the Kreos loan facility of Euro 2.5 million, the Company has sufficient cash to finance the Company until at least September 2015.

Outlook

TiGenix expects to take the following steps within the next 12 to 18 months:

- Complete patient recruitment for the Phase III study of Cx601 in complex perianal fistulas in Crohn's disease, and communicate trial results in Q3 2015
- Appoint a contract manufacturing organisation for Cx601 in the US, and to begin technology transfer by the end of 2014
- File for a Special Protocol Assessment for Cx601 with the FDA by the end of 2014
- Start a mechanism of action trial of Cx611 in severe sepsis in early 2015 and communicate the results in Q3 2015
- Start patient recruitment for a Phase IIb study of Cx611 in early rheumatoid arthritis in Q3 2015

Auditor's limited review

The review of the statutory auditors, BDO Bedrijfsrevisoren Burg. Ven. CBVA, can be found in the Condensed Consolidated Financial Statements for H1 2014 in the investor section of the TiGenix website, www.tigenix.com

Interim financial statements

The interim financial statements for H1 2014 can be found in the investor section of the TiGenix website, www.tigenix.com

Webcast

On Tuesday, 26 August, at 15:00h CEST/9.00am EDT, TiGenix will conduct a conference call webcast. The following speakers will present more details on this half year update, and will take questions:

- Eduardo Bravo, Chief Executive Officer, TiGenix
- Claudia D'Augusta, Chief Financial Officer, TiGenix

Please dial one of the following numbers to participate:

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+33 1 76 77 22 23	France
+31 20 713 2998	Netherlands
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+44 20 3427 1909	UK
+1 646 254 3367	USA

Confirmation code: 5899239

The webcast can be followed live online via the link:

http://www.media-server.com/m/p/4snzq4rq

The press release and the webcast slide presentation will be made available in the Newsroom section of the TiGenix website. A replay of the webcast will be available on the website shortly after the live webcast has finished.

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About Cx601

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASCs) delivered locally through intra-lesional injection. Cx601 is being developed for the treatment of perianal fistulas in Crohn's disease patients. Crohn's disease is a chronic inflammatory disease of the intestine and patients can suffer from complex perianal fistulas for which there is currently no effective treatment. In 2009, the European Commission granted Cx601 orphan designation for the treatment of anal fistulas, recognising the debilitating nature of the disease and the lack of treatment options. In a Phase II clinical trial, Cx601 showed efficacy at 24 weeks in 56% of treated fistula tracts, which is more than two times higher than the current standard of care (TNF inhibitors). Efficacy was measured as the complete closure and re-epithelisation of the fistula being treated with an absence of drainage. Additionally, 69.2% of patients demonstrated a reduction in the number of initially draining tracts. The trial also confirmed the safety of the use of allogeneic stem cells for the treatment of perianal fistula. Based on these results, TiGenix sought scientific advice from the European Medicines Agency (EMA) on the future development path of Cx601. TiGenix then initiated a randomised, double-blind, placebo-controlled Phase III trial in Europe and Israel (278 recruited patients, 8 countries, 52 centres) designed to comply with the requirements laid down by the EMA. This pivotal study is intended to enable filing for marketing authorisation in Europe and to serve as a key supportive study in filing for approval in other territories, including the US. The study's primary end-point is remission of the fistulous disease, defined as 100% healing of the tracts. The trial has a first complete analysis of results at 24 weeks, with a follow-up analysis to be performed at 52 weeks post-treatment. Evaluation of healing includes both clinical assessment and MRI confirmation (lack of abscesses larger than 2 cm²). The Phase III clinical trial began patient recruitment in mid-2012, and recruitment of the whole sample of patients is expected to be completed in the course of 2014. The first clinical report is expected to be available in the third quarter of 2015. With positive results, TiGenix intends to submit a request for marketing authorisation with the EMA early in 2016, so that a decision by the European Commission could be expected towards the end of 2016. TiGenix is preparing to develop Cx601 for the US market. The company intends to appoint a contract manufacturing organisation (CMO) in the US with whom it will then begin the technology transfer to enable production of Cx601 in the US; and the company will file for a Special Protocol Assessment (SPA) from the FDA to ensure that the ADMIRE-CD Phase III study design is aligned with the Agency's requirements for future approval of Cx601.

About Cx611

Cx611 is an intravenously-administered product of allogeneic expanded adipose-derived stem cells (eASC's). In 2013, TiGenix reported positive 6-month safety data from its Phase IIa study of Cx611 in refractory rheumatoid arthritis, as well as a first indication of therapeutic activity using standard outcome measures and biologic markers of inflammation for at least three

months after dosing. The multicentre, randomised, double-blind, placebo-controlled Phase IIa trial enrolled 53 patients with active refractory rheumatoid arthritis (mean time since diagnosis 15 years), under treatment with at least one non-biologic disease-modifying anti-rheumatic drug (DMARD), who failed to respond to at least two biologic drugs (mean previous treatment: 3 or more DMARDs and 3 or more biologic drugs). The study design was based on a three-cohort dose-escalating protocol. For both the low and medium dose regimens, 20 patients received active treatment versus 3 patients on placebo; for the high dose regimen, 6 patients received active treatment versus 1 on placebo. Patients were dosed at Days 1, 8, and 15 and were followed up monthly over a six-month period. Follow-up consisted of a detailed monthly work-up of all patients, measuring all pre-defined parameters. The aim was to evaluate the safety, tolerability and optimal dosing over the full 6 months of the trial, as well as exploring therapeutic activity. Only one patient suffered serious adverse events that led to a discontinuation of treatment. All other side effects were mild and transient indicating that eASCs are well tolerated and associated with an overall acceptable safety profile. Measured clinical activity scores were ACR20[2], ACR50[2], ACR70[2], EULAR[3] response rates, and the disease activity score, DAS28[4]. To gain a first insight into therapeutic activity, these parameters were evaluated every month for six months. Patients receiving Cx611 had higher ACR scores, a better EULAR response, and higher DAS28 scores than patients receiving placebo over three months, and a sustained benefit over six months.

[2] ACR 20 means a 20% improvement in tender or swollen joint counts as well as 20% improvement in at least three of the following five criteria: patient assessment, physician assessment, erythrocyte sedimentation rate, pain scale and functional questionnaire. The ACR50 and ACR70 categories adhere to the same criteria, but for 50% and 70% improvement, respectively.
[3] EULAR, European League Against Rheumatism
[4] DAS28, Disease Activity Score 28 joint count

About TiGenix

TiGenix NV (Euronext Brussels: TIG) is an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platform of allogeneic, or donor-derived, expanded adipose-derived stem cells, known as eASCs, in inflammatory and autoimmune diseases. Two products from this technology platform are currently in clinical development. Cx601 is in Phase III for the treatment of complex perianal fistulas in Crohn's disease patients. Cx611 is in Phase IIb for early rheumatoid arthritis, and in Phase Ib for severe sepsis. TiGenix also developed the first Advanced Therapy Medicinal Product (ATMP) to be approved by the European Medicines Agency (EMA), ChondroCelect, an autologous cell therapy product for cartilage repair of the knee. From June 2014, the marketing and distribution rights of ChondroCelect have been exclusively licensed to Sobi for the European Union (except for Finland where it is distributed by the Finnish Red Cross Blood Service), Norway, Russia, Switzerland and Turkey, and the countries of the Middle East and North Africa. TiGenix is headquartered in Leuven (Belgium) and has operations in Madrid (Spain). For more information, please visit 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,

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