REGULATED INFORMATION
PRESS RELEASE

TiGenix reports its full year 2014 results

Leuven, Belgium – 17 March, 2015 – 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, reported its results for 2014 today.

Business highlights

- Strategic refocusing successfully completed
    - All resources focused on advancing the allogeneic expanded adipose-derived stem cell (eASCs) product pipeline. ChondroCelect marketing and distribution rights licensed to Sobi and Dutch manufacturing facility sold to PharmaCell
    - Management team strengthened with the appointment of Chief Medical Officer and VP Medical Affairs & New Product Commercialisation
- Patient recruitment of Cx601 European Phase III study completed
    - Results at 24 week of the ADMIRE Phase III study expected in the third quarter of 2015
    - Key adipose-derived stem cell composition patent obtained in Europe
- Cx601 development for the United States progressed according to plan
    - Phase III trial design submitted to the Food and Drug Administration (FDA) for a Special Protocol Assessment (SPA)
    - Agreement signed with Lonza for the manufacture of Cx601 in the US
- Development plan for Cx611 announced and implementation started
    - Cx611 to be developed for early rheumatoid arthritis and severe sepsis
    - Phase I trial of Cx611 in a clinical challenge study for severe sepsis begun

Financial highlights

- Loss for the period of Euro 13.0 million, a reduction of 29% compared to 2013
- Cash and cash equivalents at year end of Euro 13.5 million
- Additional funds of Euro 25 million secured in February 2015 through convertible bond issue

"We are very pleased with our progress in the last year," said Eduardo Bravo, CEO of TiGenix. "We have transformed the operational focus of the Company to exploit the potential of our proprietary technology platform of allogeneic eASCs. From this, we have an advanced pipeline of products in areas of high unmet medical need in inflammatory and autoimmune diseases, including Cx601 which will deliver Phase III results in the third quarter of this year, and Cx611 which will enter Phase IIb in early rheumatoid arthritis in the fourth quarter of this year, and which is already in Phase I in severe sepsis. Finally, through a convertible bond issue in February 2015, we have refinanced the Company. TiGenix is re-positioned with an enhanced clinical pipeline and a bright future".

Business Update

Strategic refocusing of the Company successfully completed

In 2014, management refocused the resources of the Company on to the development of the product pipeline from its allogeneic expanded adipose-derived stem cell (eASCs) technology platform.

In April, the marketing and distribution rights in Europe, the Middle East and North Africa for ChondroCelect, the cell-based medicinal product for the repair of cartilage defects of the knee, were licensed to the international specialty healthcare company dedicated to rare diseases, Swedish Orphan Biovitrum AB ('Sobi'). TiGenix receives a royalty of 22% of the net sales of ChondroCelect in the first year of the agreement, and 20% thereafter. In July, the Committee for Medicinal Products for Human Use (CHMP) renewed for an additional five years its marketing authorisation for ChondroCelect in all of the 31 countries of the European Union (EU) and European Economic Area (EEA).

In June, TiGenix completed the sale of its Dutch production facility to PharmaCell, a leading European contract manufacturing organisation active in the areas of cell therapy and regenerative medicine.

In September, TiGenix announced that it had appointed Dr Marie Paule Richard as the Company's Chief Medical Officer, and Dr Mary Carmen Diez as its Vice President Medical Affairs and New Product Commercialisation. Dr Richard will be responsible for the development of Cx611 in both early rheumatoid arthritis and severe sepsis, for the completion of the ongoing European pivotal Phase III trial with Cx601, and for the preparation and implementation of the development plan of Cx601 in the United States. Dr Diez will be responsible for the Medical Affairs function across all the Company's assets and she will be directly in charge of preparing the launch of Cx601 in Europe.

The business model and operational focus of the Company have been transformed and are now concentrated on those assets with the greatest potential to deliver value.

Patient recruitment of Cx601 European Phase III study completed

In November 2014, TiGenix completed the patient recruitment for its Phase III trial of Cx601 in Europe, codenamed ADMIRE. The trial is a randomised, double-blind, placebo-controlled Phase III study designed to confirm the efficacy and safety of Cx601, a locally-injected product of eASCs, in the treatment of complex perianal fistulas in Crohn's disease patients. It has recruited 289 patients across 51 centres in 7 European countries and Israel. The study's primary endpoint is combined remission of fistulous disease, defined as closure of all treated external openings draining at baseline despite gentle finger compression confirmed by MRI (no collections > 2cm). The complete analysis of results at week 24 will be available in the third quarter of 2015. This pivotal study is intended to allow filing for marketing authorisation in Europe, and to serve as a key supportive study in filing for approval in other territories, including the United States.

In September 2014, the Paediatric Committee of the European Medicines Agency (EMA) issued a positive opinion on the Company's Paediatric Investigation Plan (PIP) for Cx601. An accepted PIP is a requirement for the filing for marketing authorisation of a new medicinal product with the EMA. It describes how a company intends to evaluate the use of the new product in children. On completion of the PIP, the company is awarded an additional six months' patent exclusivity for the product. Cx601 received Orphan Drug designation from the EMA in 2009 giving it ten years' market exclusivity from the date of marketing authorisation.

In January 2015, the European Patent Office (EPO) granted TiGenix European Patent EP2292736 relating to an adipose-derived stem cell composition. The claims of the granted patent cover both a specified population of expanded adipose-derived multipotent cells and their therapeutic uses. The issuance of this patent reinforces TiGenix's intellectual property portfolio of 24 patent families, which now includes 14 granted patents related specifically to its eASC platform. The pending and granted patents in TiGenix's intellectual property portfolio include patent families that are directed to its eASC platform; and more specifically, to eASC

compositions and therapeutic applications as well as to cell therapy delivery mechanisms and other eASC technology improvements.

Successful Phase III results for Cx601 permitting, the Company is now poised to realise the value of its most advanced asset.

Cx601 development for the United States progressed according to plan

In 2014, the Company's strategy to capture the value of Cx601 in its most important opportunity, the US market, was significantly advanced. In December 2014, TiGenix submitted to the Food and Drug Administration (FDA) the required documentation for a Special Protocol Assessment (SPA) of its pivotal Phase III trial design for Cx601 in the United States. The planned US study design is similar to the ongoing Phase III trial in Europe. The US trial design protocol incorporates guidance both from the FDA and from the Company's US Scientific Advisory Board of six leading North American clinical experts in gastroenterology and inflammatory bowel disease. On completion of the SPA review process, and of the technology transfer of its cell manufacturing process to its contract manufacturing partner in the US, TiGenix will submit its investigational new drug application (IND) for this Phase III study to the FDA.

In February 2015, TiGenix and Lonza signed an agreement whereby Lonza will manufacture Cx601 for the US Phase III trial at Lonza's cell therapy production facility in Walkersville, Maryland (US).

As a result of this progress, at the time of the European Phase III study results in Q3 2015, the company will have in the US an approved Phase III trial protocol and the possibility of completing the development of Cx601 in its most important market.

Development plan for Cx611 completed and implementation begun

In June 2014, TiGenix announced that it will develop its intravenous-administered allogeneic stem cell product, Cx611, for patients suffering from early rheumatoid arthritis and for patients afflicted with severe sepsis, a potentially life-threatening complication of infection. The Company considered the demonstrated therapeutic effects of allogeneic stem cells, the animal and clinical data for Cx611 collected so far, the potential applications into areas of high unmet medical need, and the advice from clinical experts in Europe and in the United States. In early rheumatoid arthritis, Cx611 could offer patients a therapy with an alternative mechanism of action that delays the need to progress to biological drugs. In severe sepsis, Cx611 could be a therapy with a mechanism of action that provides significant advantages when combined with normal standards of care, delivering faster recovery and improved survival rates.

In December 2014, the development of Cx611 in severe sepsis began with the enrollment of the first subject in a sepsis challenge Phase I study, codenamed CELLULA. The trial is designed to confirm the safety and demonstrate the anti-inflammatory effect of Cx611 on the sepsis-like clinical symptoms and immunological response elicited by an intravenous administration of a bacterial endotoxin (lipopolysaccharide) in healthy volunteers. The trial is a placebo-controlled dose-ranging study (3 doses of Cx611) in 32 healthy male volunteers. It is being conducted in the Academic Medical Center of the University of Amsterdam in the Netherlands which is a centre of excellence for such trials. Recruitment and dosing of all 32 subjects in the trial was completed in early March 2015. Results are expected in the second quarter of 2015.

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

TiGenix

Financial Update

Financial results for the full year 2014

Key figures (thousands of Euro, except share data)

Thousands of euros except per share data	Years ended December 31 2014	2013*
CONSOLIDATED INCOME STATEMENT		
CONTINUING OPERATIONS		
Revenues		
Royalties	338	
Grants and other operating income	5.948	883
Total revenues	**6.286**	**883**
Research and development expenses	-11.443	-9.843
General and administrative expenses	-7.406	-5.829
Total operating charges	**-18.849**	**-15.672**
Operating Loss	**-12.563**	**-14.789**
Financial income	115	7
Financial expenses	-966	-45
Foreign exchange differences	1.101	-352
Profit/(Loss) before taxes	**-12.313**	**-15.179**
Income taxes	927	59
Profit/(Loss) for the period from continuing operations	**-11.386**	**-15.120**
DISCONTINUED OPERATIONS		
Profit/(Loss) for the period from discontinued operations	-1.605	-3.270
Profit/(Loss) for the period	**-12.990**	**-18.390**
Basic and diluted loss per share (EURO)	-0,08	-0,16
Basic and diluted loss per share from continuing operations (EURO)	-0,07	-0,13
Basic and diluted loss per share from discontinued operations (euro)	-0,01	-0,03
Cash and cash equivalents	13.471	15.565

*The consolidated income statements for the 2013 have been restated to present the ChondroCelect operations as discontinued operations

Loss for the period reduced by 29%

In 2014, the operating loss was reduced by 15%, from Euro 14.8 million in 2013 to Euro 12.6 million, resulting from a significant increase in total revenues together with a lower increase in operating expenses.

Total revenues for the period amounted to Euro 6.3 million. Grants income, Euro 5.6 million, significantly increased during 2014. Growth has been mainly driven by grants related to soft loans received in previous years (Euro 4.5 million). In addition to grants, total revenues include Euro 0.3 million of royalties from the net sales of ChondroCelect, and Euro 0.4 million of other operating income.

Total operating charges for the period amounted to Euro 18.8 million. The increase over 2013 is mainly due to progress made with the clinical development of Cx601 in Phase III as well as the launch of the Phase I sepsis challenge trial for Cx611.

The financial result (the balance of financial income, financial expenses and foreign exchange differences) improved from a negative result of Euro –0.4 million in 2013 to a positive result of Euro 0.3 million in 2014. This was due to the combined effect of an increase in financial expenses related to the Kreos loan (which was signed in 2013 but only came into effect in 2014), positive

exchange differences coming from loans receivable in foreign currency (the US dollar strengthened significantly against the Euro in 2014), and improved financial income from bank deposits.

Loss for the period from continuing operations has been reduced by 25% compared to 2013, from Euro 15.1 million to Euro 11.4 million, as a consequence of the significant increase in total revenues and the lower increase in operating expenses.

Income taxes increased to Euro 0.9 million due to fiscal benefits obtained from research and development activities performed in 2013.

Loss for the period from discontinued operations decreased 51%, from Euro 3.3 million to Euro 1.6 million. During the first half of 2014, the Group discontinued ChondroCelect operations through the combination of the sale of the Dutch manufacturing facility and a licensing agreement for the marketing and distribution rights of the product from which TiGenix will receive royalties.

As a result of the above, the loss for the period decreased significantly by 29%, from Euro 18.4 million to Euro 13.0 million, in 2014.

Cash and cash equivalents at year-end of Euro 13.5 million

As at 31 December, 2014, cash and cash equivalents amounted to Euro 13.5 million. Average monthly cash burn from operating activities for the year amounted to Euro 1.1 million.

On 6 March, 2015, the Company issued senior, unsecured convertible bonds due 2018 for a total principal amount of Euro 25 million, thus strengthening its cash position.

Outlook

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

- Q2 2015: clinical results of the Phase I sepsis challenge trial of Cx611
- Q3 2015: FDA agreement on the US Phase III trial protocol for Cx601 in complex perianal fistulas in Crohn's disease
- Q3 2015: clinical results from the European Phase III trial of Cx601 in complex perianal fistulas in Crohn's disease
- Q4 2015: start Phase IIb study of Cx611 in early rheumatoid arthritis
- Q4 2015: start Phase IIa study of Cx611 in severe sepsis
- Q1 2016: file for marketing authorisation for Cx601 in Europe
- H1 2016: complete technology transfer to Lonza

Auditor's review

The statutory auditor of the Company, BDO Bedrijfsrevisoren Burg. Ven. CBVA, has completed its review of the financial statements of the Company for the year ended on 31 December 2014 and issued an unqualified audit opinion with an explanatory paragraph with respect to the Company as a going concern.

Financial statements

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

Webcast

On Tuesday, 17 March, at 15:00h CET/9.00am ET, TiGenix will conduct a conference call and webcast. The following speakers will present the full year results for 2014 and an update on the business, 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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France: +33 1 76 77 22 31

Netherlands: +31 20 721 9158

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Confirmation code: 1392650

The webcast can be followed live online via the link:

http://edge.media-server.com/m/p/cetgefb3

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.

For more information

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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 designed to comply with the requirements laid down by the EMA. 'Madrid Network', an organisation within the Autonomous Region of Madrid which helps companies to grow through high-technology innovation, issued a soft loan to help finance this Phase III study. The programme is funded by The Secretary of State for Research, Development and Innovation (Ministry of Economy and Competitiveness) within the framework of the INNTEGRA plan. 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 endpoint is closure of all treated external openings draining at baseline despite gentle finger compression confirmed by MRI (no collections > 2cm). 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. Recruitment of the whole sample of patients was completed in the fourth quarter 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. TiGenix is preparing to develop Cx601 for the US market. The company has filed for a Special Protocol Assessment (SPA) by the Food and Drug Administration (FDA) to ensure that the design of a new Phase III study to be conducted in the US is aligned with the FDA's requirements for the future approval of Cx601. The company has appointed Lonza as its contract manufacturing organisation (CMO) for the clinical development of Cx601 in the US.

About Cx611

Cx611 is an intravenously-administered product of allogeneic expanded adipose-derived stem cells (eASCs). TiGenix is currently developing Cx611 for patients with early rheumatoid arthritis and for patients with severe sepsis. For the first of these two indications, 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[1], ACR50[1], ACR70[1], EULAR[2] response rates, and the disease activity score, DAS28[3]. 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. The Company is currently working with clinical experts to complete a protocol for a randomised, double-blind, comparative Phase II study to test the efficacy of Cx611 in patients exhibiting substantial disease activity of rheumatoid arthritis despite treatment with methotrexate and corticosteroids, but unexposed to a biological drug. Recruitment for the proposed study could start in the fourth quarter of 2015 and TiGenix would expect final results to be available by the end of 2017. In severe sepsis, as well as additional animal model testing, TiGenix is running 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 an inflammatory response inducing sepsis-like clinical symptoms. Subject recruitment is completed and TiGenix expects to have results from this study during the second quarter of 2015 and then to follow up with a phase II trial of Cx611 as an add-on therapy to the standard of care in patients with severe sepsis.

[1] 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.
[2] EULAR, European League Against Rheumatism
[3] 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 ChondroCelect, an autologous cell therapy product for cartilage repair of the knee, which was the first Advanced Therapy Medicinal Product (ATMP) to be approved by the European Medicines Agency (EMA). 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, 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.