TiGenix

REGULATED INFORMATION

TiGenix Business and Financial Update for the First Half of 2015

Leuven (BELGIUM) – 15 September 2015 – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platforms of allogeneic expanded stem cells, today announced its Business and Financial Update for the first half of 2015 and recent significant events.

- Cx601 reached major value inflection points
    - Cx601 met the primary endpoint of its European Phase III trial in complex perianal fistulas in Crohn's disease patients. The positive results confirm the efficacy and safety of Cx601 and allow for filing for marketing authorisation in Europe in the first quarter of 2016
    - Clear approval path for Cx601 in the United States with the Food and Drug Administration's (FDA) endorsement of the Company's pivotal Phase III trial through a Special Protocol Assessment (SPA). Manufacturing for the clinical trial, scheduled to start towards the end of 2016, secured with Lonza
    - Significant strengthening of intellectual property with two key patents granted, one in Europe and the other in the United States
- Expansion of TiGenix pipeline into cardiology with a new platform of allogeneic cardiac stem cells through the acquisition of Coretherapix and its lead product, AlloCSC-01, which is in a Phase II clinical trial for acute myocardial infarction
- Safety and tolerability of Cx611 confirmed in a Phase I sepsis challenge trial. Phase II efficacy study in severe sepsis expected to be initiated in the fourth quarter of 2015
- Cash position at 30 June 2015 of EUR 22.7 million

"The major achievements recently announced are highly significant steps towards fully realising our potential and will have a tremendous impact on the company and its future", said Eduardo Bravo, CEO of TiGenix. "We have full commercial rights to Cx601 with positive Phase III data, ready for filing in Europe, with a clear, FDA endorsed pathway for filing in the United States, in a potential two billion Euro market. We have recently acquired Coretherapix, a company with a platform of cardiac stem cells, whose lead compound AlloCSC-01 for acute myocardial infarction is in a very advanced Phase II clinical trial. And, with Cx611, we expect to start a Phase II trial in severe sepsis, the leading cause of death in hospitals in the western world. We are extremely proud of being one of the few companies that can offer such a promising near-term future."

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Business Update

Cx601 reached major value inflection points

Cx601 met the primary efficacy endpoint of its European Phase III trial in complex perianal fistulas in Crohn's disease patients

In August, the Company communicated that its lead compound, Cx601, met the primary endpoint in the Phase III ADMIRE-CD trial in Crohn's disease patients with complex perianal fistulas. Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) injected intra-lesionally. A single injection of Cx601 was statistically superior to placebo in achieving combined remission at week 24 in patients with inadequate response to previous therapies, including anti-TNFs. More than 50% of patients treated with Cx601 achieved combined remission at week 24 and a higher number of Cx601-treated patients had their fistulas closed by week 6.

In the ITT[1] population (n=212), Cx601 achieved statistically significant superiority ($p<0.025$) with 49.5% combined remission at week 24 compared to 34.3% in the placebo arm. In the mITT[2] population (n=204), the combined remission rates at week 24 were 51.5% and 35.6% for Cx601 and placebo respectively ($p<0.025$). These clinically significant results translate into an observed relative risk of 1.44, meaning that patients receiving Cx601 had a 44% greater chance of achieving combined remission than placebo patients. Efficacy results were robust and consistent across all statistical populations. The study results confirm the favourable safety and tolerability profile of Cx601. Full efficacy and safety results will be presented at the 11th Congress of ECCO (European Crohn's and Colitis Organisation).

TiGenix now intends to file for marketing authorisation in Europe in the first quarter of 2016, which should allow for a product launch in Europe in 2017.

FDA endorsed Special Protocol Assessment for the Cx601 Phase III registration trial in the United States

In August, TiGenix reached an agreement with the US Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for its Phase III registration trial of Cx601 in the US for the treatment of complex perianal fistulas in Crohn's disease patients. The SPA describes the primary endpoint as combined remission, defined as clinical assessment by week 24 of closure of all treated external openings draining at baseline despite gentle finger compression, and absence of collections > 2cm confirmed by MRI. This primary endpoint is exactly the same as the one for the European Phase III trial for which positive results were announced in August. The company expects to begin Phase III trial enrolment in the United States towards the end of 2016.

TiGenix started the marketing authorisation application process for Cx601 in Europe

In June, TiGenix submitted to the European Medicines Agency (EMA) a letter of intent to file, and a request for the assignment of Rapporteur and Co-Rapporteur, for the Marketing Authorisation Application (MAA) for Cx601 in the treatment of complex perianal fistulas in patients with Crohn's disease. The letter of intent, which must be filed at least seven months prior to the submission of a MAA, initiates a process to address a number of pre-submission requirements, including the assignment of a Rapporteur and Co-Rapporteur, who are members of the Committee for Advanced Therapies (CAT), and two Co-ordinators from the Committee for Human Medicinal Products (CHMP). For advanced-therapy medicines, CAT prepares a draft opinion on the product's quality, safety and efficacy, based on which the CHMP adopts a final opinion.

[1] ITT: Intention To Treat, i.e. patients randomised
[2] mITT: modified ITT, i.e. patients randomised and treated, and with at least one post-baseline efficacy value

In addition, TiGenix has submitted this request to be eligible for parallel evaluation under the centralised procedure for the approval of medicinal products in the European Union (EU). Cx601 falls within the mandatory scope of the procedure because it is an Advanced Therapy Medicinal Product and an orphan-designated product. For eligible drugs, however, the centralised procedure offers the substantial benefit of having to submit only a single marketing application to the EMA. If approved, a drug can then be marketed in all EU member countries, as well as in Iceland, Liechtenstein and Norway, instead of having to seek approval in each individual country, thus reducing the time to market significantly.

Patent and Trademark Office issued a key US patent to TiGenix for the use of adipose-derived stromal cells in the treatment of fistulas

In April, the United States Patent and Trademark Office issued US Patent 8,999,709 relating to the use of an adipose-derived stromal cell population in the treatment of fistula. The patent entitled, "Use of adipose tissue-derived stromal stem cells in treating fistula", expires in 2030 and provides coverage for the company's lead development product, Cx601, in the key US market. This is an important milestone in the Company's strategy for the development and commercialisation or licensing of Cx601 in the United States market.

TiGenix and Lonza signed an agreement for the manufacture of Cx601 in the US

In February, Lonza, a global leader in biological and cell therapy manufacturing, and TiGenix announced an agreement for the supply of Cx601 in the United States. Under the agreement, Lonza will manufacture material for the Phase III trial of Cx601 in the United States at Lonza's cell therapy production facility in Walkersville, Maryland (US). Technology transfer is underway and is expected to be completed in the second half of 2016.

Patent Office issued a key patent to TiGenix for expanded adipose-derived stem cell compositions

In January, the European Patent Office (EPO) issued European Patent EP2292736 relating to an adipose-derived stem cell composition. The patent is entitled "Identification and isolation of multipotent cells from non-osteochondral mesenchymal tissue". The claims of the granted patent cover both a specified population of expanded adipose-derived multipotent cells and their therapeutic uses, as well as pharmaceutical compositions of such cells.

Expansion of the pipeline and entry into cardiology

Acquisition of Coretherapix and its allogeneic cardiac stem cell product, AlloCSC-01, for acute myocardial infarction

In July, TiGenix announced its acquisition of the cardiology-focused cell therapy company Coretherapix S.L., which was owned by Genetrix S.L. Its lead programme, AlloCSC-01, is an allogeneic cardiac stem cell product currently in a Phase II clinical trial for acute myocardial infarction, and in preclinical development for ventricular tachycardia. This acquisition expands the TiGenix development pipeline into cardiology indications. TiGenix paid €1.2M in cash and €5.5M in equity. Genetrix may receive up to €15M in new TiGenix shares depending on the results of the ongoing clinical trial of AlloCSC-01. Based on, and subject to, future sales milestones, Genetrix may receive up to an additional €245M in milestone payments plus certain percentages of the direct net sales of the first product, or certain percentages of any third party royalties and sales milestones for the first product. Sales milestones start when annual net sales reach €150M and the final milestone payment will be due once annual net sales are above €750M. Also, Genetrix will receive a €25M milestone payment for each additional product reaching the market.

The ongoing randomised, placebo-controlled, multicentre Phase II study of AlloCSC-01 is being conducted in 8 hospitals in Belgium and Spain. After a successful open-label dose escalation Phase I of 6 patients, the Phase II clinical trial is aiming at recruiting 49 additional patients who will be randomised 2:1 to receive either AlloCSC-01 or placebo by intracoronary injection 5 to 7 days after the myocardial infarction. The primary endpoint is all-cause mortality and MACE (Major Adverse Cardiac Events) at 30 days and at 1 year. Secondary endpoints include efficacy MRI parameters (evolution of infarct size, evolution of biomechanical parameters, and evolution of edema, all measured at 6 and 12 months), and clinical parameters (including the 6-minute walking test and the New York Heart Association (NYHA) scale). More than 70% of patients have already been recruited and the final results are expected in the first half of 2017. A six-month interim analysis is expected to provide data in the second half of 2016. Existing efficacy and safety data, gathered in relevant pre-clinical studies in pigs and rodents, have demonstrated the efficacy of AlloCSC-01 in reducing scar size, thus limiting cardiac remodeling.

Cx611 progressing in Sepsis

Safety and tolerability of Cx611 confirmed in the Phase I Sepsis Challenge trial

In May, TiGenix announced that a Phase I proof-of-principle study for Cx611, an intravenously-administered product of eASCs, had demonstrated a favourable safety and tolerability profile, consistent with a previous Phase IIa study of the product in patients with rheumatoid arthritis. No serious adverse events were reported with any of the three doses tested. TiGenix is finalising preparations for a Phase II trial for Cx611 in severe sepsis which is expected to start towards the end of this year.

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Financial Update

Thousands of euros (€), except for share data (in euros)	SIX-MONTH PERIOD ENDED June 30 2015	2014
CONSOLIDATED INCOME STATEMENTS		
CONTINUING OPERATIONS		
Revenues		
Royalties	333	-
Grants and other operating income	605	821
Total revenues	**938**	**821**
Research and development	(7,656)	(5,097)
General and administrative expenses	(2,833)	(2,859)
Total operating charges	(10,489)	(7,956)
Operating Loss	**(9,551)**	**(7,135)**
Financial income	1,319	25
Financial expenses	(3,080)	(369)
Foreign exchange differences	747	170
Loss before taxes	**(10,565)**	**(7,309)**
Income taxes	-	-
Loss for the period from continuing operations	**(10,565)**	**(7,309)**
DISCONTINUED OPERATIONS		
Loss for the period from discontinued operations	-	(1,842)
Loss for the period	**(10,565)**	**(9,151)**
Attributable to equity holders of TiGenix NV	(10,565)	(9,151)
Basic (diluted) loss per share (EURO)	**(0.07)**	**(0.06)**
Basic (diluted) loss per share from continuing operations (EURO)	**(0.07)**	**(0.05)**
Basic (diluted) loss per share from discontinued operations	**-**	**(0.01)**

Financial results for the first half-year of 2015

During the first six-month period of 2015, total revenues increased by 14% to EUR 0.9 million compared to EUR 0.8 million in the same period of 2014, mainly driven by royalties and other operating income received from Sobi.

Research and development expenses for the first six-month period of 2015 amounted to EUR 7.7 million, compared to EUR 5.1 million for the same period in 2014, representing a 51% increase which is mainly attributable to clinical trial activities such as the conclusion of the ADMIRE pivotal Phase III trial for Cx601 and the Phase I Sepsis Challenge trial of Cx611, as well as other key activities necessary in filing for marketing authorisation for Cx601 in Europe.

General and administrative expenses remain at the same level as the previous period and amounted to EUR 2.8 million.

As a result of the above, the operating loss amounted to EUR 9.6 million compared to EUR 7.1 million during the same period of 2014. This increase is attributable to a higher spend on research and development activities.

The net financial loss of the first six months of 2015 amounted to EUR 1.1 million compared to EUR 0.2 million during the same period of 2014. Net financial loss comprises financial income, financial expenses and foreign exchange differences.

During the first six months of 2015, the loss from discontinued operations amounted to EUR 0.0 million compared to EUR 1.8 million in the same period in 2014.

As a result of the above, the loss for the first six-month period amounted to EUR 10.6 million, compared to EUR 9.2 million for the same period in 2014, representing an increase of 15%.

Cash position at 30 June 2015 of EUR 22.7 million

At the end of June 2015, the Company had cash and cash equivalents of EUR 22.7 million, compared to EUR 13.5 million at the beginning of the year. The net increase is mainly due to the net proceeds from the convertible bonds issued in March 2015. The cash used in operating activities during the first six months of 2015 amounted to EUR 9.0 million.

Outlook

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

- Q4 2015: start Phase IIa study of Cx611 in severe sepsis
- Q4 2015: complete patient enrolment for Phase II trial for AlloCSC-01 in acute myocardial infarction
- Q1 2016: file for marketing authorisation for Cx601 in Europe
- H2 2016 begin patient enrolment for Phase III trial of Cx601 in complex perianal fistulas in Crohn's disease patients in the United States
- H2 2016: interim analysis of Phase II trial of AlloCSC-01 in acute ischaemic cardiac disease

Auditor's limited review

The review of the statutory auditor of the Company, BDO Bedrijfsrevisoren Burg. Ven. CBVA, can be found in the Condensed Consolidated Financial Statements for the first half of 2015 in the investor section of the TiGenix website, www.tigenix.com

Interim financial statements

The interim financial statements for the first half of 2015 can be found in the investor section of the TiGenix website, www.tigenix.com

Webcast

Today, 15 September, at 18:45h CET/12:45h EDT, TiGenix will conduct a conference call and webcast. The following speakers will present the half-year results for 2015 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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Confirmation Code: **9894390**

The webcast can be followed live online via the link: http://edge.media-server.com/m/p/g4kvinkh

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 (eASC) intra-lesionally injected. Cx601 is being developed for the treatment of complex 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. Based on positive Phase II 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. The study primary endpoint is combined remission, defined as clinical assessment at week 24 of closure of all treated external openings draining at baseline despite gentle finger compression, and absence of collections >2cm confirmed by MRI. 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. Based on the positive Phase III results, TiGenix will submit a Marketing Authorisation Application to EMA early 2016. TiGenix is preparing to develop Cx601 for the US market after having obtained FDA's endorsement of its pivotal Phase III trial through SPA on the 7th of August 2015.

About AlloCSC-01

AlloCSC-01 consists of adult allogeneic cardiac stem cells isolated from the right atrial appendages of donors, and expanded in vitro. Pre-clinical data has shown evidence of the strong cardio-protective and immune-regulatory activity of AlloCSC-01. In vivo studies suggest that AlloCSC-01 has cardio-reparative potential by activating endogenous regenerative pathways and by promoting the formation of new cardiac tissue. In addition, AlloCSC-01 has displayed a strong tropism for the heart enabling a high retention of cells in the myocardium after intracoronary administration.

About Cx611

Cx611 is an intravenously-administered product of allogeneic expanded adipose-derived stem cells (eASC's). 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. A Phase I sepsis challenge trial was completed in May 2015 demonstrating the favourable safety and tolerability profile of Cx611.

About TiGenix

TiGenix NV (Euronext Brussels: TIG) is an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platforms of allogeneic, or donor-derived, expanded stem cells. Two products from the adipose-derived 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 has completed a Phase I/II trial in rheumatoid arthritis, as well as a Phase I sepsis challenge trial. Effective as of July 31, 2015, TiGenix acquired Coretherapix, whose lead cellular product (AlloCSC-01) is currently in a Phase II clinical trial in acute myocardial infarction (AMI). Coretherapix is planning to initiate the clinical evaluation of AlloCSC-01 in the chronic setting as well and is also involved in the pre-clinical development of a pharmaceutical formulation of growth factors to treat AMI. Finally, 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 were 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.