PRESS RELEASE
REGULATED INFORMATION

TiGenix reports 2015 full year results

Leuven (BELGIUM) – April 12, 2016, 07:00h CET – 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, reported today its business and financial highlights for 2015 and post year-end events.

Key 2015 and post year-end highlights

- Cx601 reached major value inflection points:
  - Cx601 met the primary endpoint of ADMIRE-CD, a pivotal Phase III trial in complex perianal fistulas in Crohn's disease patients with inadequate response to previous therapies, including anti-TNFs. Results were presented at the plenary session of the 11th Annual Congress of the European Crohn's and Colitis Organization (ECCO) in March 2016
  - Cx601 delivered positive follow-up results at 52 weeks, confirming its sustained efficacy and safety profile in March 2016
  - Solid progress was made on the regulatory front. In Europe, the Cx601 Marketing Authorization Application was submitted to the European Medicines Agency (EMA) in March 2016. In the United States, the Food and Drug Administration (FDA) agreed with the design of the US pivotal Phase III trial through a Special Protocol Assessment (SPA) procedure
  - The Cx601 patent portfolio was strengthened with the grant of two key patents in Europe and in the United States
- The safety and tolerability of Cx611 was confirmed by Phase I sepsis challenge trial results. The upcoming Phase II study in severe sepsis was awarded EUR 5.4 million by the European Commission
- Acquisition of allogeneic cardiac stem cells platform. The Phase I/II trial of AlloCSC-01 for the treatment of acute myocardial infarction (AMI) is ongoing (CAREMI study). Enrolment has been completed and 6 month interim data are expected during the second half of 2016
- The cash position at 31 December 2015 was of EUR 18.0 million. EUR 23.8 million raised in March 2016

"In 2015 we have laid the ground for our future growth. Cx601, our fully owned lead product, has successfully delivered positive Phase III results and is one step closer to market authorization in Europe, while in the US the FDA's agreement on our clinical design and analysis plan has clarified the regulatory pathway for approval in the US" said Eduardo Bravo, CEO of TiGenix. "Simultaneously, we have further developed our platform in severe sepsis, expanded our pipeline in the cardiology space with a Phase II asset in a very large indication, strengthened our financial resources with specialized investors and prepared the company to list on NASDAQ as soon as conditions are right. We are a stronger company with an exciting pipeline and well-defined value creation milestones for 2016".

Business Highlights

Cx601 reached major value inflection points

In August 2015, Cx601 – our fully owned lead product - met the primary endpoint in the pivotal ADMIRE-CD Phase III study (ITT, n=212). A single treatment 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. Efficacy results were robust and consistent across all statistical populations. The abstract describing the 24-week results of Cx601 ADMIRE-CD Phase III study was selected as one of the thirty best abstracts deserving an oral presentation at the plenary session of the 11th Annual Congress of the European Crohn's and Colitis Organization (ECCO) held in March 2016.

In March 2016, the top line follow-up data of the ADMIRE-CD study showed that a single injection of Cx601 was statistically superior to placebo in achieving combined remission at week 52 in line with the primary endpoint results at week 24. In particular, 54.2% of patients treated with Cx601 achieved combined remission at week 52 compared to 37.1% in the placebo arm. Moreover, 75.0% of Cx601 treated patients who achieved combined remission at week 24 remained in combined remission at week 52 compared to only 55.9% in the placebo arm. The results also confirmed the favorable safety and tolerability profile of Cx601 already reported at week 24. The sustained benefit of Cx601 at one year was highlighted by Prof. Panés, Global Study Coordinator, as a remarkable breakthrough in the treatment of complex perianal fistulas in Crohn's disease patients.

Following the positive results at week 24 of the pivotal ADMIRE-CD Phase III study, TiGenix filed a centralized European MAA for Cx601 in March 2016. Such application is eligible for parallel evaluation under the centralized 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, the centralized 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. In parallel, in February 2016, TiGenix obtained the license for commercial production of Cx601 from the Spanish Medicines Agency (AEMPS). Meeting these goals on schedule is in line with the expectation of making Cx601 available to European patients in the second half of 2017.

In August 2015, 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. The design submitted to the SPA defines the primary endpoint as combined remission, which combines clinical assessment of closure of all treated external openings draining at baseline, despite gentle finger compression, with absence of collections > 2cm confirmed by MRI by week 24. This primary endpoint is equivalent to the one used in the ADMIRE-CD Phase III study. The Phase III trial in the United States will be initiated in the first half of 2017. An agreement has been made with Lonza to manufacture the material for the trial in its cell therapy production facility in Walkersville, Maryland (US).

Finally, the Cx601 patent portfolio was strengthened with the granting of two patents by the European and United States patent offices.

Cx611 progressing in Sepsis

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

In May 2015, TiGenix announced that Cx611 Phase I proof-of-principle study for Cx611 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.

On the basis of such results TiGenix designed its SEPCELL Phase Ib/IIa study in severe sepsis secondary to severe community-acquired pneumonia (sCAP) expected to start in the second half of 2016. In October 2015, the SEPCELL consortium led by TiGenix, was awarded a EUR 5.4 million fund from the European Commission.

Current treatments for sepsis are insufficient and mainly symptomatic. The incidence has dramatically increased over the last decade reaching over 15 million cases worldwide in 2012 according to The Lancet. In the United States only, sepsis generates $20 billion in hospital related costs and is the most expensive condition billed to Medicare. Thus, severe sepsis represents an important unmet medical need and a relevant market opportunity.

Expansion of the pipeline into cardiology

In July 2015, TiGenix expanded its pipeline in the cardiology space with the acquisition of an allogeneic cardiac stem cell platform. Its lead product, AlloCSC-01, is currently in a Phase I/II clinical trial (the CAREMI trial) for acute myocardial infarction (AMI). The CAREMI study has already completed recruitment and a six-month interim analysis is expected in the second half of 2016 with final results due in the first half of 2017.

Cardiovascular disease remains a very large and costly indication. Up to 1.9 million people annually are diagnosed with acute myocardial infarction in the United States, Europe and Japan. In 2015, the American Heart Association estimated that the direct and indirect cost of coronary heart disease, the main cause of myocardial infarction, was $182 billion and is expected to reach $322 billion in 2030.

TiGenix

Financial Highlights

Key figures for the full year 2015 (consolidated)

EUR Million, except for share data (EUR)	31 Dec 2015	31 Dec 2014
Revenues	**2.24**	**6.29**
Royalties	0.54	0.34
Grants and other operating income	1.70	5.95
Operating charges	**(26.32)**	**(18.85)**
Research and development expenses	(19.64)	(11.44)
General and administrative expenses	(6.68)	(7.41)
Operating Loss	**(24.08)**	**(12.56)**
Financial income	0.14	0.11
Interest on borrowing and other finance costs	(6.65)	(1.03)
Fair value gains/(losses)(1)	(6.65)	0.06
Impairment and gains/(losses) on disposal of financial instruments	(0.16)	-
Foreign exchange differences,net	1.00	1.10
Income tax benefits	1.33	0.93
Loss for the year from continuing operations	**(35.07)**	**(11.39)**
Loss for the year from discontinued operations	-	(1.60)
Loss for the year	**(35.07)**	**(12.99)**
Basic (diluted) loss per share from continuing operations (EUR)	**(0.21)**	**(0.07)**
Cash and cash equivalents at end of period (2)	**17.98**	**13.47**

1) *Fair value gain/losses refers to the increase in fair values of the warrant component of the convertible bonds, the warrants issued for Kreos loan and the contingent consideration related to the acquisition of Coretherapix*
2) *In March 2016 TiGenix raised EUR 23.8 million through a private placement*

Revenues for 2015 amounted to EUR 2.2 million, compared to EUR 6.3 million in 2014. The decrease is mainly driven by the fact that revenues in 2014 were positively impacted by grants related to government loans received at below market rate in previous years and fully recognized in 2014 (Euro 4.5 million). In addition to grants recognized in 2015 amounting to EUR 0.8 million, revenues for the year include EUR 0.5 million of royalties from net sales of ChondroCelect and EUR 0.9 million of other operating income.

Total operating charges for 2015 amounted to EUR 26.3 million, compared to EUR 18.9 million in 2014. The augment is mainly due to the increase in Research and Development (R&D) expenses, driven by Cx601 clinical development progress, the clinical activities related to Cx611 in sepsis and AlloCSC-01 in AMI after the acquisition of Coretherapix in late July 2015. General and Administrative (G&A) expenses were reduced to EUR 6.7 million from EUR 7.4 million in 2014 despite the Coretherapix acquisition.

As a result of the foregoing the operating loss increased in 2015 to EUR 24.1 million, from EUR 12.6 million in 2014.

The interest on borrowings and other finance costs for 2015 amounted to EUR 6.7 million. These costs include both cash financial expenditures (for EUR 2.2 million) and non-cash financial expenditures resulting mainly from the recording of the financial liabilities at amortized cost (Kreos loan, the ordinary note component of the convertible bond and the governmental loans). The fair value gains/(losses) for 2015 amounted to EUR 6.7 million. These costs include non-cash expenses resulting from the change in fair value of the warrant component of the convertible bonds (mainly as a result of the higher share price at year-end compared to the share price at the time of the convertible bond issuance), the warrants issued for the Kreos loan

and the contingent consideration for the acquistion of Coretherapix. Income tax benefits amounted to EUR 1.3 million and refer to the tax deductions under Spanish tax law obtained from R&D activities.

As a result of the above, the loss for the year 2015 amounted to EUR 35.1 million, compared to EUR 13.0 milion in 2014.

Cash and cash equivalents amounted to EUR 18.0 million on 31 December 2015. On March 14, 2016, TiGenix raised 23.8 million euros in gross proceeds through a private placement to specialist investors in Europe and the United States. Net cash used in operating activities in 2015 amounted to EUR 19.6 million.

Outlook

TiGenix expectations for the next 18 months include:

- 2H 2016 interim analysis of Phase I/II trial of AlloCSC-01 (CAREMI) in acute myocardial infarct
- 2H 2016 start of Cx611 Phase Ib/IIa trial in severe sepsis
- 1H 2017 final results of the Phase II trial of AlloSCS-01 (CAREMI) in acute myocardial infarction
- 1H 2017 start of Cx601 US pivotal Phase III trial
- 2H 2017 grant of European Market Authorisation to Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients

Auditor's report

The statutory auditor of the Company, BDO Bedrijfsrevisoren Burg. Ven. CBVA, has completed its audit of the financial statements of the Company for the year ended on 31 December 2015 and issued an unqualified audit opinion. The auditor's report on the consolidated financial statements can be found in the Newsroom section of the TiGenix website, www.tigenix.com.

Financial statements

The financial statements for the year ended 31 December 2015 can be found in the Newsroom section of the TiGenix website, www.tigenix.com. TiGenix will publish its audited Annual Report for the year ended 31 December 2015 via the Company's website on or around 29 April 2016.

Webcast

On Tuesday, 12 April, 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 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:

London, United Kingdom:	+44(0)20 3427 1904	Madrid, Spain:	+3491 114 6582
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Paris, France:	+33(0)1 70 48 01 66	Amsterdam, Netherlands:	+31(0)20 716 8256
Brussels, Belgium:	+32(0)2 404 0660	Stockholm, Sweden:	+46(0)8 5065 3938

Confirmation Code: **3587419**

The webcast can be followed live online via the link: http://edge.media-server.com/m/p/zmiz5jiz

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) injected intra-lesionally. 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 (the ADMIRE-CD trial). '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 INTEGRA plan. The study's primary endpoint was 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. In the ADMIRE-CD trial, the results of which were reported in August 2015, Cx601 achieved statistically significant superiority (p<0.025) on the primary endpoint with 49.5% combined remission at week 24 compared to 34.3% in the placebo arm in the ITT[1] population. These results translate into a relative risk of 1.44, meaning that patients receiving Cx601 had a 44% greater probability of achieving combined remission than placebo patients. Efficacy results were robust and consistent across all statistical populations. Treatment-emergent adverse events (non-serious and serious) and discontinuations due to adverse events were comparable between Cx601 and placebo arms. The ADMIRE-CD trial has also completed a follow-up analysis at 52 weeks post-treatment. Based on the positive 24 week Phase III results, TiGenix has submitted a Marketing Authorisation Application to the EMA in early 2016. TiGenix is preparing to develop Cx601 for the US market after having reached an agreement with the FDA through a special protocol assessment, or SPA, procedure on its proposed protocol on August 7, 2015.

About Cx611 in Severe Sepsis

Cx611 is an intravenously-administered product of allogeneic expanded adipose-derived stem cells (eASCs). In May 2015, TiGenix completed a Phase I sepsis challenge trial demonstrating the favourable safety and tolerability profile of Cx611. Based on the results of this study, TiGenix has

1 ITT: Intention to Treat i.e. all patients randomized.

designed a Phase Ib/IIa trial in severe sepsis secondary to severe community-acquired pneumonia (sCAP) which is expected to enroll 180 patients across Europe (the SEPCELL project). SEPCELL has been awarded a €5.4M grant by the European Union under the Horizon 2020 Research and Innovation Programme under Grant Agreement 681031.

About AlloCSC-01

AlloCSC-01 is a cellular product consisting 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. AlloCSC-01 is currently in clinical development in a Phase I/II clinical trial (CAREMI). The CAREMI trial comprises two consecutive phases: an open-label dose-escalation phase (n=6) and a 2:1 randomised, double-blind, placebo-controlled phase (n=49). The objective of this clinical trial is to evaluate the safety and the efficacy of the cardiac stem cells product AlloCSC-01 in the acute phase of ischemic heart disease. The primary endpoint of the CAREMI Phase I study is all-cause mortality within 30 days and all adverse events of any cause from the patient's inclusion until 7 days after treatment administration. Secondary safety endpoints throughout the study include all AEs within 30 days, then monthly up to 6 months, then quarterly post-AlloCSC-01, all-cause mortality and death from cardiovascular cause at 12 months, and MACE measured at 6 and 12 months. Secondary efficacy endpoints for the randomised phase include MRI parameters (evolution of infarct size and evolution of biomechanical parameters) and clinical parameters (including the 6 minute walking test and the New York Heart Association class). Eight centers are participating in Spain and Belgium and patient recruitment is now finished. The CAREMI trial has benefitted from the support of the CARE-MI consortium (Grant Number 242038) funded by the Seventh Framework Programme of the European Commission under the coordination of the Centro Nacional the Investigaciones Cardiovasculares (CNIC) and the participation of research institutions and companies from nine EU countries. Final results will be released in the first half of 2017 with a six-month interim analysis of blinded and exploratory efficacy data in the second half of 2016.

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 stem cell 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 sepsis challenge trial and a Phase I/II trial in rheumatoid arthritis. Effective 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). In addition, the second product candidate from the cardiac stem cell-based platform acquired from Coretherapix, AlloCSC-02, is being developed in a chronic indication. 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 press release 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

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