PRESS RELEASE
REGULATED INFORMATION

TiGenix Business and Financial Update for the third quarter of 2014

Leuven (BELGIUM) – 4 November, 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 in inflammatory and autoimmune diseases, issued today its business and financial update for the third quarter of 2014.

Business highlights

- Cx601: Phase III trial in Europe on track to deliver clinical results in third quarter of 2015
- Cx601: paediatric investigation plan accepted by European Medicines Agency (EMA)
- Cx601: US advisory board appointed
- Cx611: Phase I trial in healthy volunteers approved by Dutch regulatory authority
- Chief Medical Officer and Vice President Medical Affairs and New Product Commercialisation appointed

Financial highlights

- Liquidity position of Euro 17.7 million

"In the third quarter of this year, TiGenix has continued to prepare its most advanced product candidate for market readiness and commercialisation," said Eduardo Bravo, CEO of TiGenix. "We have added the necessary skills and experience to the team, we remain on track with our Phase III study of Cx601 in Europe. We have received approval for our paediatric investigation plan, and we have been able to attract to our US Advisory Board six leading clinical experts in gastroenterology and inflammatory bowel disease in North America. We are committed to bringing Cx601 to the more than 100,000 patients in Europe and the US that are suffering from this serious and debilitating condition as quickly as possible."

Business Update

During the third quarter of 2014, TiGenix has maintained focus on achieving completion of patient recruitment in its European Phase III trial of Cx601, a locally injected stem cell product for the treatment of complex perianal fistulas in Crohn's disease patients. Clinical results are expected in the third quarter of 2015.

In September, the Paediatric Committee of the 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. Building on the strength of the adult development programme and the body of data to be collected during the post-marketing phase, a very focused trial has been agreed with the Agency. The study will not begin before 2020, three years after the anticipated launch of Cx601 in 2017.

For Cx601 in the United States, TiGenix will file a special protocol assessment (SPA) with the Food and Drug Administration (FDA) by the end of the year. To oversee the optimal content of that file, and the subsequent Phase III trial in the US, TiGenix has appointed an advisory board of six leading clinical experts in gastroenterology and inflammatory bowel disease in North America:

- **Jean-Frederic Colombel**, *MD, Professor of Medicine and Director of the Leona M. and Harry B. Helmsley Charitable Trust Inflammatory Bowel Disease Center, Icahn School of Medicine at Mount Sinai, New York*
- **Brian G. Feagan**, *MD, FRCPC, Professor, Departments of Medicine (Gastroenterology), and Epidemiology & Biostatistics, University of Western Ontario, London, Ontario, Canada; CEO and Senior Scientific Director, Robarts Clinical Trials Inc., Robarts Research Institute*
- **Stephen B. Hanauer**, *MD, Professor of Medicine and Medical Director of the Digestive Health Center, Northwestern University Feinberg School of Medicine, Chicago*
- **William J. Sandborn**, *MD, Professor of Medicine and Adjunct Professor of Surgery, Chief of Gastroenterology, and Director of the UCSD Inflammatory Bowel Disease Center, University of California San Diego and UC San Diego Health System, San Diego*
- **Bruce E. Sands**, *MD, MS, Chief of the Henry D. Janowitz Division of Gastroenterology, Dr. Burrill B. Crohn Professor of Medicine, Icahn School of Medicine at Mount Sinai, New York*
- **David A. Schwartz**, *MD, FACG, AGAF, Professor of Medicine and Director of the Inflammatory Bowel Disease Center, Vanderbilt University Medical Center, Nashville*

For Cx611, the Dutch regulatory authority, Centrale Commissie Mensgebonden Onderzoek (CCMO), and the ethics committee of the Academic Medical Centre in Amsterdam, have approved the Company's Phase I study design in healthy volunteers challenged with a bacterial endotoxin (lipopolysaccharide) which elicits an inflammatory response inducing sepsis-like clinical symptoms. The trial is a placebo-controlled dose-ranging study (3 doses) in which 32 healthy male volunteers will be randomised to receive Cx611 or placebo in a ratio of 3:1, with primary endpoints of vital signs and symptoms, laboratory measures and functional assays of innate immunity. Recruitment is expected to start during the first quarter of 2015.

Also during the third quarter, TiGenix 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. Doctors Richard and Diez bring with them a wealth of experience and ability in areas which will be key for the success of the company in the near future: namely, completing the development of Cx601 in Europe and in the US, gaining regulatory approval and preparing for its launch, and guiding the clinical development of Cx611 in early rheumatoid arthritis and severe sepsis.

Financial highlights

At 30 September 2014, the Company had a liquidity position (cash, cash equivalents and receivables from reverse repurchase agreements) of Euro 17.7 million. This includes the last available tranche from the Kreos loan facility of Euro 2.5 million, which was drawn down during the third quarter. The average monthly cash burn during the third quarter was Euro 1.3 million. At this rate of expenditure, TiGenix continues to expect to be funded at least until the clinical results from the European Phase III trial of Cx601 become available in the third quarter of 2015.

Outlook

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

- 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 recruitment of the Phase I trial for Cx611 in severe sepsis in the first quarter of 2015, and communicate the results in Q3 2015
- Communicate clinical results from the European Phase III trial of Cx601 in complex perianal fistulas in Crohn's disease in Q3 2015
- Start patient recruitment for a Phase IIb study of Cx611 in early rheumatoid arthritis in Q3 2015

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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 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 endpoint 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). Recruitment of the whole sample of patients is expected to be completed by the end 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 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 design of a new Phase III study to be run in the US 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). 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 cinical 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 third quarter of 2015 and TiGenix would expect final results to be available by the first half of 2017. In severe sepsis, as well as additional animal model testing, 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 an inflammatory response inducing sepsis-like clinical symptoms. TiGenix expects to complete this study by the third 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.