PRESS RELEASE
REGULATED INFORMATION

TiGenix Business and Financial Update for the First Half 2016

(Conference call and webcast today at 10:00am CET)

Leuven (BELGIUM) – September 20, 2016, 07:00h CET – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercializing novel therapeutics from its proprietary platforms of allogeneic expanded stem cells, today reported its business and financial highlights for the first half of 2016.

Below are the key business and financial highlights for the first half of 2016, ending June 30, 2016, as well as other post period events:

- **Cx601 continued to reach significant major value inflection points**
  - Cx601 delivered positive follow-up results at 52 weeks, confirming its sustained efficacy and safety profile. Cx601's positive Phase III 24-week results were presented at the European Crohn's and Colitis Organization (ECCO), at the Digestive Disease Week (DDW) in the US and published in *The Lancet*
  - Significant progress was also made on the regulatory front. Based on the data from the pivotal Phase III trial in Europe, TiGenix submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA). Cx601's marketing authorization is expected to be granted in the second half of 2017
  - Licensing agreement for the ex-US rights of Cx601 signed in July with Takeda for up to EUR 380 million in regulatory and sales milestones, of which EUR 25 million at signing, and double digit royalties on net sales. Takeda committed to a EUR 10 million equity investment within the 12 months following the signing
  - TiGenix retains 100% of the US rights, estimated to be 50% of the global market as well as the right to further develop Cx601 in new indications
- **Significant progress with the pipeline and strategic focus reconfirmed**
- **Broadening of the shareholder base with European and US marquee investors**
- **Cash position at June 30, 2016 of EUR 24.1 million, further strengthened in July by the upfront cash payment of EUR 25 million received from Takeda**

"It has been an extremely positive first half of the year for us. We have made solid progress both on the operations and in the financial front," said Eduardo Bravo, CEO of TiGenix. "With our recent licensing agreement with Takeda, with their solid track record and strong leadership position in gastroenterology, we have the best partner with the needed capabilities and resources to secure the commercial success of Cx601. We have also gained the financial strength to move forward with the clinical development of Cx601 in the US and continue to make progress with the rest of the assets in development such as AlloCSC-01 in Acute Myocardial Infarction and Cx611 for Severe Sepsis. TiGenix is in an excellent position with clear value-creation catalysts in the medium-to-short term."

Business Highlights for the first half 2016 and post June 30, 2016

Cx601 continued to reach significant major value inflection points

In February TiGenix secured the license for the commercial production of cell therapy products, a relevant achievement to secure the needed commercial manufacturing capacity for the forthcoming launch of Cx601 as well as for the fulfillment of the final requirements to file a Marketing Authorization Application (MAA) for Cx601 with the European Medicines Agency (EMA).

In March TiGenix announced positive follow-up results at 52 weeks for Cx601, reporting sustained efficacy and safety profile. Top line follow-up data showed that in the ITT[1] population (n=212), Cx601 achieved statistical superiority (p=0.012) with 54% combined remission at week 52 compared to 37% in the placebo arm. The 52-week data also showed a higher rate of sustained closure in those patients treated with Cx601 and in combined remission at week 24 (75.0%) compared to patients in the placebo group (55.9%). In terms of safety, treatment-emergent adverse events (non-serious and serious) and discontinuations due to adverse events were comparable between Cx601 and placebo groups.

In March TiGenix submitted a centralized European MAA for Cx601.The centralized procedure offers a substantial benefit for the marketing authorization holder as it allows to market the medicine and make it available to patients and healthcare professionals throughout the European Union on the basis of a single marketing authorization. Once granted, the centralized marketing authorization is valid in all European Union member states as well as in the European Economic Area (EEA) countries, as well as Iceland, Liechtenstein and Norway. TiGenix is currently preparing the responses to the Day 120 List of Questions received from the Committee of Human Medicinal Products (CHMP within EMA). We expect a marketing authorization by the European Commission could be forthcoming by the second half 2017.

The relevance of the 24-week results of Cx601 and its potential as a truly innovative treatment for complex perianal fistulas in Crohn's disease patients was further confirmed by their selection for oral presentation at the two most important medical congresses in this field: in March in Europe at the ECCO, the main European congress for Crohn's and Colitis specialists, with more than 6,000 delegates registered this year; in May in the US at the Digestive Disease Week, the largest congress with international attendees and organized in the US for the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Furthermore, in July, the 24-week results were published by *The Lancet*[2], one of the most highly regarded and well-known medical journals in the world. This publication will increase awareness of Cx601 results ahead of the initiation of the pivotal Phase III trial for registration of Cx601 in the US.

In July TiGenix entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to develop and commercialize Cx601 for complex perianal fistulas outside the US. Under the terms of the licensing agreement, TiGenix received a cash payment of EUR 25 million after signing. In addition TiGenix is eligible to receive additional regulatory and sales milestone payments for up to a potential total of EUR 355 million plus double-digit royalties on net sales. The first anticipated milestone payment will be EUR 15 million upon obtaining the marketing authorization of Cx601 in Europe. Takeda has also committed to an equity investment of EUR 10 million within 12 months from signing the agreement. This agreement increases the probability of commercial success of Cx601 by drawing on the reimbursement and commercial expertise of one of the leaders in the field. Finally, this agreement provides TiGenix with the financial strength necessary to move forward with the development of Cx601 for registration in the US and advance with the other assets in its allogeneic stem cell platforms.

---

[1] *ITT: Intention to treat i.e. all patients randomized in the trial.*

[2] *Panés P, et al. Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn's disease: a phase 3 randomized, double-blind controlled trial. The Lancet [online]. Published online July 28, 2016, available at http://dx.doi.org/10.1016/S0140-6736(16)31203-X.*

TiGenix retains 100% of the US rights, estimated to be 50% of Cx601 global market, as well as the right to further develop Cx601 in new indications. The US Food and Drug Administration, or FDA, agreed through a special protocol assessment procedure (SPA) in 2015 that the pivotal Phase III trial, if successful, could, together with the European Phase III data, serve as supportive evidence for filing a biologics license application, or BLA, for regulatory approval of Cx601 with the FDA. TiGenix expects to initiate such trial in the first half of 2017. TiGenix is currently exploring different expedited pathways, which could facilitate and accelerate Cx601 development and the review of its future BLA.

Progress with Pipeline and strategic focus reconfirmed

In June, TiGenix announced the preliminary interim six-month Phase I/II results of AlloCSC-01 in Acute Myocardial Infarction. As per the protocol design, the primary objective of this study is to provide evidence of the acute and long-term safety profile of AlloCSC-01. On the primary acute safety endpoint, no mortality from any cause within one month was recorded for both placebo and AlloCSC-01 groups, as was reported at six months. Similarly, no major adverse cardiac event (MACE) was recorded within one month in either group. Importantly for the long-term safety evaluation, no MACE was recorded in either of the two groups at six months. The safety results confirm that the intracoronary delivery of AlloCSC-01 is well tolerated during the acute and sub-acute phases of the infarct, fulfilling the principal goal of the study at six months. Preliminary secondary efficacy data at six months was limited to infarct size evolution, defined as a percent of the left ventricular mass measured by magnetic resonance imaging. The mean absolute change in infarct size from baseline to six months was similar in both groups. The final full set of safety and efficacy study results at twelve months will be reported in the first half of 2017.

With respect to Cx611, our second allogeneic expanded adipose-derived stem cell based (eASCs)-product candidate intravenously-administered, TiGenix has made solid progress in the preparation activities for the Phase Ib/IIa clinical trial in severe sepsis secondary to severe community-acquired pneumonia (sCAP). The study is a randomized, double blind, placebo controlled multicenter trial expecting to enroll 180 patients across Europe (the SEPCELL study). TiGenix expects to enroll the first patient of this study in the second half of 2016. SEPCELL has been awarded a EUR 5.4 million grant by the European Union under the Horizon 2020 Research and Innovation Programme.

In July TiGenix announced the initiation of the withdrawal of the marketing authorization for ChondroCelect for commercial reasons. This decision is in line with TiGenix's strategy to concentrate its resources and capabilities on its allogeneic stem cell platforms.

TiGenix

Financial Highlights for the first half 2016

Thousands of euros (€), except for share data (in euros)	SIX-MONTH PERIOD ENDED JUNE 30, 2016	2015
CONSOLIDATED INCOME STATEMENTS		
CONTINUING OPERATIONS		
Revenues		
Royalties	293	333
Grants and other operating income	650	605
Total revenues	943	938
Research and development expenses	(9,702)	(7,656)
General and administrative expenses	(4,322)	(2,833)
Total operating charges	(14,024)	(10,489)
Operating Loss	(13,081)	(9,551)
Financial income	57	34
Interest on borrowings and other financial costs	(3,766)	(3,080)
Fair value gains	7,750	1,285
Foreign exchange differences	(292)	747
Loss before taxes	(9,332)	(10,565)
Income taxes	(48)	-
Loss for the period	(9,380)	(10,565)
Attributable to equity holders of TiGenix NV	(9,380)	(10,565)
Basic (diluted) loss per share	**(0.05)**	**(0.07)**
Basic (diluted) loss per share from continuing operations	**(0.05)**	**(0.07)**

During the first half 2016, total revenues remained stable at EUR 0.9 million when compared to the same period of 2015. Revenues mainly represented royalties and other operating income received from Sobi.

Research and development expenses for the first half 2016 amounted to EUR 9.7 million, compared to EUR 7.7 million for the same period in 2015, a 26% increase which is mainly attributable to clinical activities in connection with the ongoing Phase I/II clinical trial for AlloCSC-01 in acute myocardial infarction, the preparation activities for the launching of the pivotal Phase III trial for the registration of Cx601 in the US and the Phase Ib/IIa clinical trial for Cx611 in severe sepsis as well as other key activities related to the filing of Cx601 MAA in Europe.

General and administrative expenses in the first half of 2016 increased by 54% and amounted to EUR 4.3 million. This increase was mainly attributable to non-recurrent expenses related to advisory fees for the preparation of the US IPO and the Takeda licensing agreement.

As a result of the above, the operating loss amounted to EUR 13.1 million compared to EUR 9.6 million during the same period of 2015.

The net financial income of the first six months of 2016 amounted to EUR 3.8 million compared to the net financial loss of EUR 1.0 million during the same period of 2015. Net financial income/(loss) comprised of financial income, interest on borrowings and other financial costs, fair value gains/(losses) and foreign exchange differences. The main driver that explains the

evolution during the first half of 2016 is the change in the fair value (mainly non-cash) of the embedded derivative on the convertible bonds issued in March 2015.

As a result, the loss for the first half 2016 amounted to EUR 9.4 million, compared to EUR 10.6 million for the same period in 2015, which represents a decrease of 11%.

At the end of June 2016, the Company had cash and cash equivalents of EUR 24.1 million, compared to EUR 18.0 million at the beginning of the year. This increase is mainly due to gross proceeds of EUR 23.8 million raised through the March private placement via an accelerated book-building procedure with specialist investors in Europe and in the US. Net cash used in operating activities in the first half of 2016 amounted to EUR 12.6 million. Additionally in July TiGenix obtained a cash payment of EUR 25.0 million after the signing of the licensing agreement with Takeda.

Outlook

TiGenix anticipates announcing the following key milestones over the next 18 months:

- 2H 2016: initiate enrolment of Cx611 Phase Ib/IIa trial in severe sepsis
- 1H 2017: announce final results of the Phase II trial of AlloSCS-01 (CAREMI) in acute myocardial infarction
- 1H 2017: start of Cx601 pivotal Phase III trial for registration in the US
- 2H 2017: grant of Market Authorisation in the European Economic Area (EEA) to Cx601 for the treatment of complex perianal fistulas in Crohn's disease patients. If granted, Takeda will become the marketing authorization holder and will be responsible for all commercialization and regulatory activities of Cx601 in the EEA

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 Interim Financial Information for the first half of 2016 in the investor section of the TiGenix website at *http://www.tigenix.com*.

Interim financial statements

The interim financial information for the first half of 2016 can be found in the investor section of the TiGenix website at *http://www.tigenix.com*

Webcast

On Tuesday, September 20, 2016 at 10:00 am CET, TiGenix will conduct a conference call and webcast. The following speakers will present the first half 2016 business and financial update, and take questions afterwards:

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 1919	Madrid, Spain:	+34 91 114 6583
New York, USA:	+1 646 254 3362	Amsterdam, Netherlands:	+31 (0)20 721 9158
Paris, France:	+33 (0)1 76 77 22 31	Brussels, Belgium:	+32 (0)2 620 0138

Confirmation Code: 7918051

The webcast can be followed live online via the link: http://edge.media-server.com/m/p/obci8p55

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

Claudia D'Augusta
Chief Financial Officer
T: +34 91 804 92 64
claudia.daugusta@tigenix.com

About TiGenix

TiGenix NV (Euronext Brussels: TIG) is an advanced biopharmaceutical company focused on developing and commercializing 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 in Phase III for the treatment of complex perianal fistulas in Crohn's disease patients; Cx611 which 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. On July 4, 2016, TiGenix entered into a licensing agreement with Takeda, a large pharmaceutical company active in gastroenterology, under which Takeda acquired the exclusive right to commercialize Cx601 for complex perianal fistulas outside the United States. TiGenix is headquartered in Leuven (Belgium) and has operations in Madrid (Spain). For more information, please visit http://www.tigenix.com

About Cx601

Cx601 is a suspension of allogeneic expanded adipose-derived stem cells (eASC) locally injected. Cx601 is an investigational agent being developed for the treatment of complex perianal fistulas in Crohn's disease patients that failed conventional therapy including antibiotics, immunosuppressant, or anti-TNF therapy. 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, recognizing the debilitating nature of the disease and the lack of treatment options. Cx601 has met the primary end-point in the Phase III ADMIRE-CD study in Crohn's disease patients with complex perianal fistula, a randomized, double-blind, placebo-controlled trial run in Europe and Israel and designed to comply with the requirements laid down by the EMA. 'Madrid Network' issued a soft loan to help finance this Phase III study, which was 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'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 ITT population (n=212), Cx601 achieved statistically significant superiority (p=0.024) on the primary endpoint with 50% combined remission at week 24 compared to 34% in the placebo arm. 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 24-weeks results have been published by The Lancet, one of the most highly regarded and well-known medical journals in the world. The Phase III study has completed a follow-up analysis at 52 weeks confirming its sustained efficacy and safety profile. Top line follow-up data showed that in the ITT population Cx601 achieved statistical superiority (p=0.012) with 54% combined remission at week 52 compared to 37% in the placebo arm. The 52-week data also showed a higher rate of sustained closure in those patients treated with Cx601 and in combined remission at week 24 (75.0%) compared to patients in the placebo group (55.9%). Based on the positive 24-weeks Phase III study results, TiGenix has submitted a Marketing Authorization Application to the EMA in early 2016. TiGenix is preparing to develop Cx601 in the U.S. after having reached an agreement with the FDA through a special protocol assessment procedure (SPA) in 2015. On July 4, 2016 TiGenix entered into a licensing agreement with Takeda, a pharmaceutical company leader in gastroenterology, whereby Takeda acquired an exclusive right to commercialize Cx601 for complex perianal fistulas in Crohn's patients outside of the U.S.

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 randomized, 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 endpoints for the randomization phase include efficacy MRI parameters (evolution of infarct size and evolution of biomechanical parameters), clinical parameters (including the 6 minute walking test and the New York Heart Association scale) and safety (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). MACE is a broader safety endpoint that covers all-cause mortality as well as new AMI, hospitalization due to heart failure, sustained ventricular tachycardia, ventricular fibrillation and stroke. Eight centers are participating in Spain

and Belgium and patient recruitment is now finished. The eight participating centers are Hospital General Universitario Gregorio Marañón - Madrid, Hospital de Navarra, Hospital Clínico Universitario de Valladolid, Hospital Universitario de Donostia, Hospital Universitario de Salamanca, Hospital Clínico Universitario de Valencia, and Hospital Virgen de la Victoria de Málaga all in Spain and UZ Leuven in Belgium. The CAREMI trial has benefitted from the support of the CARE-MI consortium (Grant Number 242038, http://www.caremiproject.eu/) 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. The six-month interim analysis of blinded and exploratory efficacy data has been reported in June 2016. Final results will be released in the first half of 2017.

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 favorable safety and tolerability profile of Cx611. Based on the results of this study, TiGenix has designed a Phase Ib/IIa trial in severe sepsis secondary to severe community-acquired pneumonia (sCAP) which is expected to enrol 180 patients across Europe (the SEPCELL project). The SEPCELL Phase Ib/IIa study in severe sepsis is expected to start in the second half of 2016. SEPCELL has been awarded a EUR 5.4M grant by the European Union under the Horizon 2020 Research and Innovation Programme under Grant Agreement 681031.

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 recognized 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 press release. 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.