PRESS RELEASE
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TiGenix reports 2016 full year results

(Conference call and webcast today at 13:00 CEST)

Leuven (BELGIUM) – April 6, 2017, 07:00h CEST – TiGenix NV (Euronext Brussels and NASDAQ: TIG), an advanced biopharmaceutical company developing and commercializing novel therapeutics which exploit the anti-inflammatory properties of allogeneic, or donor-derived, stem cells, today reported its business and financial highlights for 2016 and post year-end events.

Key 2016 and post year-end highlights:

- **Cx601 reached significant value inflection points in Europe and the U.S.**
  - Day 120 List of Questions responses submitted to the European Medicines Agency (EMA) to support the Marketing Authorization Approval (MAA) for Cx601 following submission of the application in March 2016
  - Day 180 List of Outstanding Issues (LoOI) received from the Committee for Medicinal Products for Human Use (CHMP) of the EMA
  - European Commission decision anticipated in 2017, triggering a payment of EUR 15.0 million from Takeda Pharmaceuticals upon approval of the market authorization
  - The global pivotal Phase III trial for the U.S. registration of Cx601 is expected to begin in the first half of 2017. TiGenix is also exploring further expedited pathways to accelerate the submission and review process for its future Biologics License Application (BLA)
  - Cx601 delivered positive follow-up results at 52 and 104 weeks, confirming the long-term safety and efficacy profile
- **Strong relationship with Takeda Pharmaceuticals**
  - Licensing agreement for the ex-U.S. rights of Cx601 signed in July 2016 for up to EUR 355.0 million in regulatory and sales milestones and EUR 25.0 million on signing
  - EUR 10.0 million in equity investment realized in December 2016
  - Exercised option to develop and commercialize Cx601 in both Japan and Canada
- **Continued progress with pipeline**
  - First patient enrolled in Phase I/II clinical trial of Cx611 for the treatment of severe sepsis
  - Promising Phase I/II trial results of AlloCSC-01 in Acute Myocardial Infarction (AMI)
- **Strong cash position at December 31, 2016 of EUR 78.0 million, due to:**
  - Equity raise of EUR 23.8 million in March 2016 with marquee investors
  - Upfront cash payment of EUR 25.0 million from Takeda deal in July 2016 and EUR 10.0 million of equity investment in December
  - EUR 34.1 million (USD 35.7 million) raised with Nasdaq IPO
- **Strategic appointments**
  - Dr. June Almenoff appointed as an Independent Director to the Board

"The past year has been truly transformational for TiGenix. We have reached the final phase before our first allogeneic product potentially enters the market in Europe, published our positive Phase III data in *The Lancet*[i], signed a major licensing deal with a world-class partner, raised substantial funds and advanced our pipeline," said Eduardo Bravo, CEO of TiGenix. "I am proud of what has been achieved and enormously excited about the rest of the year, including taking the next steps in developing Cx601 for the U.S. market and in further indications."

Business highlights

Cx601 reached major value inflection points

2016 has been an extraordinary year for TiGenix as we continue the transformation of the company to focus on products from our allogeneic stem cell platforms. Our most advanced product, Cx601, reached significant major value inflection points and the vision of bringing this innovative medicine to patients suffering a severe, debilitating complication of Crohn's disease has become tangible with the signing of an exclusive licensing agreement for the development and commercialization of Cx601 outside the U.S. with Takeda, a world leader in gastroenterology.

In July, TiGenix received a payment of EUR 25.0 million upon signing the licensing agreement with Takeda. TiGenix is eligible to receive additional regulatory and sales milestone payments for up to a potential total of EUR 355.0 million and double digit royalties on net sales. In addition to these financial benefits, we believe the partnership with Takeda has increased the probability of commercial success by drawing on the reimbursement and commercial expertise of one of the leaders in the gastroenterology field.

Since signing of the licensing agreement, Takeda has made an additional equity investment of EUR 10.0 million in the share capital of TiGenix, has exercised the option to develop and commercialize Cx601 in both Japan and Canada, and has launched a series of key activities to ensure the timely launch of Cx601 as soon as the marketing approval is obtained.

Cx601 has continued to produce impressive results following the meeting of the primary endpoint at week 24. The positive 24-week results were presented at the two major congresses for gastrointestinal specialists on both sides of the Atlantic and published in *The Lancet*[i], one of the most reputable peer reviewed publications in the scientific community. In March 2016, TiGenix announced positive follow-up results at 52 weeks for Cx601, confirming its sustained efficacy and safety profile. A single administration of Cx601 was statistically superior to control (placebo) in achieving combined remission at week 52, in line with the primary endpoint results at week 24. In March 2017, Cx601 delivered positive follow-up results at 104 weeks, confirming its long-term safety and efficacy profile.

In March 2016, TiGenix filed a centralized European MAA for Cx601. In March 2017, we received the Day 180 List of Outstanding Issues from the CHMP. Having reviewed the LoOI, we remain confident that Cx601 is on track to receive Marketing Authorization. A CHMP opinion and decision by the European Commission is expected in 2017 and upon obtaining the Marketing Authorization, TiGenix is eligible to receive from Takeda a EUR 15.0 million milestone payment. The path to European commercialization was also further advanced in October 2016 when Cx601 was granted Orphan Drug Designation (ODD) in Switzerland.

In parallel to the progress in Europe, we have been advancing our program to bring Cx601 to U.S. patients. In January 2017, the FDA agreed to an improved protocol for the global Phase III trial of Cx601, which has now been formally endorsed by a new SPA. With these amendments, the FDA has agreed that a Biologics License Application (BLA) could be filed based on the efficacy and safety follow-up of patients assessed at week 24, instead of week 52. Furthermore, the FDA has agreed to accept fewer patients than originally planned in the study, and has endorsed a broader target population that will ultimately facilitate the recruitment process. With these adjustments, the study will benefit from an expedited recruitment process that should lead to shorter timelines, an earlier filing, and the possibility of an earlier approval in the U.S. As a result of these modifications, the trial design is even more similar to the European ADMIRE-CD than before.

The global pivotal Phase III trial for the U.S. registration of Cx601 is expected to begin in the first half of 2017. In parallel, TiGenix is exploring further expedited pathways to accelerate the submission and review process for its future BLA.

Progress with pipeline

In June 2016, TiGenix announced preliminary interim six-month results for the Phase I/II (CAREMI) study of AlloCSC-01 in Acute Myocardial Infarction (AMI) and in March 2017 announced the top-line results of the study. CAREMI is the first-in-human clinical trial with the primary objective being safety and evaluating the feasibility of an intracoronary infusion of AlloCSCs in patients with AMI and left ventricular dysfunction treated within the first week post-AMI. Importantly, the trial is the first cardiac stem cell study to integrate a highly discriminatory magnetic resonance imaging (MRI) strategy to select patients at increased risk of heart failure and late adverse outcomes. CAREMI was not powered to establish efficacy therefore no conclusion can be drawn on the secondary efficacy end-points.

All safety objectives of the study have been met. No mortality or major cardiac adverse events (MACE) have been found at 30 days meeting the primary end-point of the study. Moreover neither mortality nor MACE have been found at 6 months or 12 months follow-up. Of particular relevance to this allogeneic approach, no immune-related adverse events have been recorded at one-year follow-up. A larger reduction in infarct size was found in one pre-specified subgroup associated with poor long-term prognosis which represents more than half of the patient population of the randomization phase of the study. This finding has revealed valuable insight, and provides a specific direction for potential studies in a targeted subset of high-risk patients and we expect to announce next steps in the development of AlloCSC-01 later in 2017.

Cx611, our second eASC-based product candidate, is a potential first-in-class intravenous injectable allogeneic (or donor derived) stem cell therapy intended for the treatment of severe sepsis, a major cause of mortality in the developed world. We believe that Cx611 represents a highly innovative potential treatment for this indication. The Phase I/II SEPCELL study was launched in the second half of 2016 and the first patient was dosed in January 2017. Data is expected to be available in 2019.

In July, 2016, TiGenix announced the initiation of the withdrawal of the marketing authorization for ChondroCelect. TiGenix decided to initiate the withdrawal process for commercial reasons. After the effective day, November 30, 2016, TiGenix no longer expects to generate any revenues from this product. Ultimately, this decision is in line with TiGenix's strategy to concentrate its resources and capabilities on its allogeneic stem cell platforms.

Corporate development

In September 2016 TiGenix announced the appointment of Dr. June Almenoff as an independent director. June Almenoff MD, PhD has more than 20 years' pharmaceutical industry experience including leading the process towards FDA approval for a GI product, broad experience in clinical development, scientific licensing and business development, an expertise in infectious diseases, and a clear focus on the U.S. market.

TiGenix

Financial highlights for 2016

Key figures for the full year 2016 (consolidated)

EUR Million, except for share data (EUR)	31 Dec 2016	31 Dec 2015
Revenues	**26.8**	**2.2**
Royalties	0.4	0.5
License revenues	25.0	-
Grants and other operating income	1.4	1.7
Operating charges	**(29.8)**	**(26.3)**
Research and development expenses	(21.4)	(19.6)
General and administrative expenses	(8.4)	(6.7)
Operating Loss	**(3.0)**	**(24.1)**
Financial income	0.2	0.2
Interest on borrowing and other finance costs	(7.3)	(6.6)
Fair value gains/(losses)	11.6	(6.7)
Impairment and losses on disposal of financial instruments	-	(0.2)
Foreign exchange differences,net	0.2	1.0
Income tax benefits	2.1	1.3
Profit (Loss) for the year	**3.8**	**(35.1)**
Basic income (loss) per share (EUR)	**0.02**	**(0.21)**
Cash and cash equivalents at the end of the year	**78.0**	**18.0**
Net cash (used in)/provided by operating activities	3.5	(19.6)

Revenues for 2016 amounted to EUR 26.8 million, compared to EUR 2.2 million in 2015. The increase is mainly driven by License revenues obtained from the licensing agreement signed in July 2016 with Takeda. The decrease in Royalties and Grants and other operating income during the year is due to the withdrawal of the marketing authorization of ChondroCelect for commercial reasons.

Total operating charges for 2016 amounted to EUR 29.8 million, compared to EUR 26.3 million in 2015. The increase is mainly due to the increase in Research and Development expenses, driven by Cx601 clinical development progress (including U.S. Cx601 clinical start-up activities), the clinical activities related to the Cx611 Phase I/II clinical trial in severe sepsis (SEPCELL) and those related to the AlloCSC-01 Phase I/II in AMI (CAREMI). General and Administrative expenses increased to EUR 8.4 million from EUR 6.7 million in 2015 mainly driven by the expenses related to the Nasdaq IPO.

As a result of the above, the operating loss decreased in 2016 to EUR 3.0 million, from EUR 24.1 million in 2015.

The Interest on borrowings and other finance costs for 2016 amounted to EUR 7.3 million. These costs include both cash financial expenditures (for EUR 3.5 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 bonds and the governmental loans). The fair value gains for 2016 amounted to EUR 11.6 million. These gains include non-cash income resulting from the change in the fair value of the warrant component of the convertible bonds (mainly as a result of the lower share price at year-end 2016 compared to the share price at year-end 2015) and the warrants issued for the Kreos loan. Income tax benefits amounted to EUR 2.1 million and refer to the tax deductions under Spanish tax law obtained from R&D activities.

As a result of the above, the profit for the year 2016 amounted to EUR 3.8 million compared to a loss of EUR 35.1 million in 2015.

Cash and cash equivalents amounted to EUR 78.0 million on December 31, 2016. We end the year in a strong financial position following the equity raise of EUR 23.8 million in March 2016 with marquee investors, upfront cash payment of EUR 25.0 million from the Takeda deal in July 2016, EUR 10.0 million of equity investment from Takeda in December and EUR 34.1 million (USD 35.7 million) raised with the Nasdaq IPO. Net cash provided by operating activities in 2016 amounted to EUR 3.5 million.

Outlook for the rest of 2017

- 1H 2017 - Opening of U.S. operations
- 1H 2017 - Start of global phase III for Cx601 BLA
- 2H 2017 - Cx601 EU approval decision
- 2H 2017 - EUR 15,0 million milestone potential payment by Takeda
- 2H 2017 - Plan on new indications for Cx601
- 1H 2018 - Takeda to launch Cx601 in EU markets
- 1H 2018 - Cx601 IND and start of recruitment in U.S. centers

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 2016 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, on or around 6 April 2017.

Financial statements

The financial statements for the year ended 31 December 2016 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 2016 via the Company's website on or around 6 April 2017.

Webcast

TiGenix will conduct a conference call on 6 April 2017, at 13:00pm CEST / 7:00am EDT, which will also be webcast. To participate in the conference call, please call on the following numbers to participate:

Confirmation Code: 1332273

London, United Kingdom:	+44 (0)20 3427 1908
New York, United States of America:	+1 212 444 0896
Paris, France:	+33 (0)1 76 77 22 28
Brussels, Belgium:	+32 (0)2 402 3092
Madrid, Spain:	+34 91 453 34 34
Amsterdam, Netherlands:	+31 (0)20 716 8295

The webcast can be followed live online via the link: http://edge.media-server.com/m/p/hmntjv4f

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 TiGenix

TiGenix NV (Euronext Brussels [and NASDAQ]: TIG) is a biopharmaceutical company developing and commercializing novel therapeutics which exploit the anti-inflammatory properties of allogeneic, or donor-derived, stem cells generated by its proprietary platform technologies.

TiGenix's lead product, Cx601, has successfully completed a European Phase III for the treatment of complex perianal fistulas - a severe, debilitating complication of Crohn's disease. Cx601 has been filed for regulatory approval in Europe and a global Phase III trial intended to support a future U.S. Biologic License Application (BLA) is expected to start in 2017. TiGenix has 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 U.S. Our second adipose-derived product, Cx611, is undergoing a Phase I/II trial in severe sepsis – a major cause of mortality in Western world hospitals. Finally, AlloCSC-01, targeting acute ischemic heart disease, has demonstrated positive results in a Phase I/II trial in acute myocardial infarction (AMI). 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. Based on positive Phase II results, TiGenix sought scientific advice from the European Medicines Agency (EMA) and launched in Europe and Israel a Phase III study (ADMIRE-CD) a randomized, double-blind, placebo-controlled Phase III trial designed to comply with the requirements laid down by the EMA. 'Madrid Network', an organization 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 program 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 ADMIRE-CD 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. The ADMIRE-CD study reported positive results 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 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 24-week results of the Phase III ADMIRE-CD trial investigating Cx601 have been published in The Lancet[i].The ADMIRE-CD study has completed a follow-up analysis at 52 weeks and at 104 weeks post-treatment. Based on the positive 24 weeks Phase III study results, TiGenix has submitted a Marketing Authorization Application to the EMA and a decision is expected in 2017. 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 July 2016 TiGenix entered into a licensing agreement with Takeda, a pharmaceutical company leader in gastroenterology, whereby Takeda acquired exclusive rights to develop and commercialize Cx601 for complex perianal fistulas in Crohn's patients outside of the U.S.

About Cx611

Cx611 is an intravenously-administered product of allogeneic (or donor derived) expanded adipose-derived stem cells (eASCs). In May 2015, TiGenix completed a Phase I sepsis challenge trial showing a favorable safety and tolerability profile for Cx611. Based on the results of this study, TiGenix is now sponsoring a Phase I/II clinical trial (the SEPCELL study) in severe sepsis secondary to community-acquired pneumonia (CAP). SEPCELL is a randomized, double-blind, placebo-controlled, Phase I/II study in patients with CAP requiring mechanical ventilation and/or vasopressors. The trial is expected to enroll 180 patients, and will be conducted in multiple European centers. Subjects will be randomized 1:1 to receive either active investigational product (Cx611) or placebo. Additionally all patients will be treated with the standard of care, which generally includes antibiotics and anti-inflammatory drugs. The primary endpoint is the number, frequency and type of adverse events during a 90 day period with an exploratory follow-up reaching up to two years. Secondary endpoints include the reduction in the duration of mechanical ventilation and/or vasopressors, improved survival, clinical cure of sCAP, and other infection-related endpoints.

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 has recently concluded a Phase I/II clinical trial (CAREMI). The CAREMI trial comprised 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 was 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. 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. The study met all safety objectives, demonstrating that allogeneic cardiac stem cells can be transplanted safely through the coronary tree. Furthermore, study results indicated a larger reduction in infarct size in one pre-specified subgroup associated with poor long-term prognosis (patients with a large myocardial infarction). 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.

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 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.

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[i] *Panés P, et al. Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn's disease: a phase 3 randomised, 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.*