

## TiGenix to participate and present at key investor and business development meetings

Leuven (BELGIUM) – September 28, 2017, 07:00h CET – TiGenix NV (Euronext Brussels and NASDAQ: TIG), an advanced biopharmaceutical company focused on exploiting the anti-inflammatory properties of allogeneic, or donor-derived, stem cells to develop novel therapies for serious medical conditions, today announces that Eduardo Bravo, Chief Executive Officer of TiGenix, will be participating in key investor and business development meetings in 2017.

### **4<sup>th</sup> Annual KBC Biotech and Healthcare Conference**

**Date: September 28, 2017**

**Venue: Convene Grand Central - 101 Park Avenue, New York, NY.**

Organized by KBC Securities, the event provides European companies with the opportunity to meet top level US investors on a one-to-one basis.

### **2017 Cell & Gene Meeting on the Mesa**

**Date: October 4-6, 2017**

**Venue: La Jolla Ballroom 1, La Jolla California, CA**

The largest partnering meeting organized specifically for the cell and gene therapy sector, this event provides the opportunity for participants to establish key relationships and accelerate business development.

Eduardo Bravo will give a company presentation on **October 4th at 5pm PST** in the La Jolla Ballroom 1 as well as participate in workshops around the development and globalization of cellular therapies. Please visit [www.meetingonthemesa.com](http://www.meetingonthemesa.com) for full information.

### **ARM's 5th Annual EU Advanced Therapies Investor Day**

**Date: November 9, 2017**

**Venue: 30 Euston Square, London**

Organized by the Alliance for Regenerative Medicine (ARM), the ARM EU Advanced Therapies Investor Day gives the sector's leading advanced therapy companies the opportunity to present to 200+ analysts and investors.

### **For more information**

Claudia D'Augusta

Chief Financial Officer

T: +34 91 804 92 64

[claudia.daugusta@tigenix.com](mailto:claudia.daugusta@tigenix.com)

## **About TiGenix**

TiGenix NV (Euronext Brussels and NASDAQ: TIG) is an advanced biopharmaceutical company developing novel therapies for serious medical conditions by exploiting the anti-inflammatory properties of allogeneic, or donor-derived, expanded stem cells.

TiGenix' lead product, Cx601, has successfully completed a European Phase III clinical trial 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) started in 2017. TiGenix has 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 U.S. TiGenix' second adipose-derived product, Cx611, is undergoing a Phase I/II trial in severe sepsis – a major cause of mortality in the developed world. 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 local administration of allogeneic (or donor derived) expanded adipose-derived stem cells (eASCs) for the treatment of complex perianal fistulas in Crohn's disease patients that have previously failed conventional therapy. Crohn's disease is a chronic inflammatory disease of the intestine and complex perianal fistulas are a severe and debilitating complication for which there is currently no effective treatment. Cx601 was granted orphan drug designation by the European Commission in 2009. TiGenix completed a European Phase III clinical trial (ADMIRE-CD) in August 2015. The 24-week data were published in the *Lancet* and showed both the primary endpoint and the safety and efficacy profile were met.<sup>i</sup> A follow-up analysis was completed at 52 weeks and 104 weeks post-treatment, confirming the sustained efficacy and safety profile of the product.<sup>ii</sup> The 24-week results of the Phase III ADMIRE-CD trial were published in *The Lancet* in July 2016.<sup>i</sup> Based on the positive 24 weeks Phase III study results, TiGenix submitted a Marketing Authorization Application to the European Medicines Agency (EMA) and a CHMP opinion is expected in 2017. A global Phase III clinical trial intended to support a future U.S. Biologic License Application (BLA) started in 2017, based on a trial protocol that has been agreed with the Food and Drug Administration (FDA) through a special protocol assessment procedure (SPA). In July 2016, TiGenix entered into a licensing agreement with Takeda, a global pharmaceutical company active in gastroenterology, under which 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 intravenous administration of allogeneic expanded adipose-derived stem cells (eASCs) for the treatment of severe sepsis. Sepsis is a life-threatening complication of infection leading to systemic inflammation and organ failure and is the leading cause of death in the developed world. In May 2015, TiGenix completed a Phase I sepsis challenge trial (CELLULA) that demonstrated a favorable safety and tolerability profile for Cx611. Based on the results of this study, TiGenix launched a Phase I/II clinical trial (SEPCELL) in 2016 evaluating Cx611 for the treatment of severe sepsis secondary to community-acquired pneumonia (sCAP) in patients who require mechanical ventilation and/or vasopressors. The first patient was dosed in January 2017 and data is expected in 2019. The trial has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 681031 and is being carried out through the SEPCELL consortium, which gathers six partners from four European countries. See [www.sepcell.eu](http://www.sepcell.eu) for more information.

## **About AlloCSC-01**

AlloCSC-01 is an intracoronary administration of allogeneic cardiac stem cells for the treatment of ischemic heart disease. A phase I/II clinical trial (CAREMI) evaluating AlloCSC-01 in Acute Myocardial Infarction (AMI) met its primary endpoint with no mortality or major cardiac adverse events (MACE) found after 30 days of treatment. No mortality or MACE were found at 6 or 12 months follow-up and

there were no immune-related adverse events at 12 months follow-up. The CAREMI trial has benefitted from the support of the CAREMI 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 Centro Nacional de Biotecnología and the participation of research institutions and companies from nine EU countries.

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<sup>i</sup> Panés J, García-Olmo D, Van Assche G *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*. 2016; 388(10051):1281-90.

<sup>ii</sup> Panes, J. *et al.*, OP009 Long-term efficacy and safety of Cx601, allogeneic expanded adipose-derived mesenchymal stem cells, for complex perianal fistulas in Crohn's disease: 52-week results of a phase III randomised controlled trial. *J Crohn's Colitis*. 2017; 11: S5-S5.