TiGenix

PRESS RELEASE

SEPCELL project in severe sepsis receives €5.4M grant from the EU's Horizon 2020

- **TiGenix is leading the SEPCELL project which aims to accelerate the clinical development of Cx611 in severe sepsis**
- **The €5.4M grant will fund the SEPCELL Phase Ib/IIa trial of Cx611 in patients with severe sepsis secondary to severe community-acquired pneumonia (sCAP)**

Leuven (BELGIUM) – 2 November 2015 – TiGenix NV (Euronext Brussels: TIG), an advanced biopharmaceutical company focused on developing and commercialising novel therapeutics from its proprietary platforms, today announced that the SEPCELL project has been awarded a €5.4M grant from the European Commission under Horizon 2020, the European Union's framework programme for research and innovation, to conduct a clinical Phase Ib/IIa trial of Cx611 in patients with severe sepsis secondary to severe community-acquired pneumonia (sCAP).

The SEPCELL project is a Phase Ib/IIa randomised, double-blind, parallel group, placebo-controlled, multicentre study designed to evaluate the safety and efficacy of Cx611 for the treatment of adult patients with severe sepsis secondary to sCAP and admitted to the intensive care unit. Cx611 is an intravenously-administered suspension of allogeneic expanded adipose-derived stem cells (eASCs). The trial is expected to enroll a total of 180 patients across Europe.

Cx611 is an innovative approach to the treatment of severe sepsis, using the immunomodulatory properties of eASCs to target different pathways. Current standard of care is palliative and supportive, primarily aimed at controlling symptoms and treating the underlying infection through the use of anti-inflammatory drugs and antibiotics.

"The award of €5.4M grant to SEPCELL by the European Commission underscores the relevance and innovative character of our project and will allow TiGenix to significantly advance the development of a new therapy for severe sepsis secondary to severe CAP, a life-threatening condition with high mortality rates of around 28-50%" said Dr Marie Paule Richard, Chief Medical Officer of TiGenix.

The unique properties of Cx611 have made SEPCELL one of the few clinical projects to obtain the support of the European Commission under the Horizon 2020 programme. In addition to TiGenix, the SEPCELL consortium comprises the Centre Hospitalier Universitaire of Limoges, the Cliniques Universitaires Saint-Luc in Brussels, the Hospital Clínico San Carlos of the Servicio Madrileño de Salud in Madrid, and the Academic Medical Center of the University of Amsterdam. TiGenix, as project coordinator, will lead the project, receiving €1.3M of non-dilutive funds, and will be responsible for managing the remaining €4.1M to fund the activities of the consortium's clinical and research partners.

For more information please contact

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

About Severe Sepsis

Sepsis is a systemic inflammatory response to infection, which includes activation of leukocytes, the release of cytokines and chemokines, the activation of the coagulation system and activation of endothelial cells. An international consensus panel proposed the term 'severe sepsis' to describe instances in which sepsis is complicated by acute organ dysfunctions, while the term 'septic shock' was defined as sepsis complicated by either hypotension that is refractory to fluid resuscitation or by hyperlactatemia. Severe sepsis and septic shock have a significant and increasing impact on public health, and are one of the leading causes of mortality in intensive care units. The epidemiology of sepsis, severe sepsis and septic shock shows an incidence of 3 cases per 1,000 population and is increasing due to the ageing of the population, an increase in drug-resistant bacteria and the weakening of the immune system caused by several factors.

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 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 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).

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,

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