PRESS RELEASE

TiGenix Enrolls First Patient in Phase Ib/IIa Clinical Trial of Cx611 in Severe Sepsis

Leuven (BELGIUM) – 31st January, 2017, 07:00h CET – TiGenix NV (Euronext Brussels and Nasdaq: TIG), an advanced biopharmaceutical company focused on developing and commercializing novel therapeutics from its proprietary platforms of allogeneic expanded stem cells, today announced that the first patient has been enrolled and treated in its Phase Ib/IIa clinical trial for Cx611 (SEPCELL) in the treatment of severe sepsis in community-acquired pneumonia (CAP).

Cx611 is an intravenously-administered product of allogeneic expanded adipose-derived stem cells (eASCs), which are known for their broad range of immunomodulatory properties. The SEPCELL trial focuses on patients with severe community-acquired bacterial pneumonia (or life threatening pneumonia acquired outside a hospital setting), admitted to intensive care units due to severe sepsis, requiring mechanical ventilation and/or vasopressors. This study is a multicenter, international clinical trial to evaluate Cx611 safety profile at 90 days, the reduction in the duration of mechanical ventilation and/or vasopressors, as well as the overall survival rate, clinical cure, and other efficacy-related endpoints. Enrolled patients will receive one dose of either Cx611 or placebo on days one and three - total two doses - in addition to the standard of care.

Sepsis is a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs. Sepsis affects over 26 million people worldwide, each year, and has a mortality rate of up to forty percent. This condition clearly represents a major unmet medical need and a huge social burden. In western countries sepsis is still the leading cause of death, representing exorbitant in-patient costs of approximately 24 billion US dollars each year, and growing. Patients suffering from severe sepsis display a much higher level and persistence of inflammation. Cx611, given its multi-dimensional immunomodulatory properties, may have the potential to modulate and restore the deregulated immune response in patients with severe community-acquired pneumonia.

"Patients suffering from severe sepsis are in need of new therapies; however the development of new drugs has proven to be difficult due to the variety of patient profiles. We have built on lessons learned from past experiences and designed the SEPCELL trial with strict inclusion and exclusion criteria, within a very specific patient population therefore addressing one of the major pitfalls of previous clinical trials in this indication," said Professor Pierre-François Laterre, principal investigator within the SEPCELL project, and Chief of the Intensive Care Service at Cliniques Universitaires Saint-Luc, Catholic University of Leuven, Belgium.

"Cx611, with its immunomodulatory action, represents a novel approach to address severe sepsis. The SEPCELL trial will provide valuable information on the safety, tolerability and efficacy of Cx611 as a candidate for the treatment of patients with severe sepsis," said Dr. Marie Paule Richard, Chief Medical Officer of TiGenix.

Along with TiGenix, the SEPCELL project is represented by a group of five European research institutes that bring together the necessary competencies, expertise and resources to achieve the project's goals. SEPCELL has been awarded a EUR 5.4 million grant by the European Union under the Horizon 2020 Research and Innovation Programme under Grant Agreement 681031. For more information about sepsis, the SEPCELL project, objectives and funding, please consult this link: http://www.sepcell.eu

For more information

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TiGenix

About TiGenix

TiGenix NV (Euronext Brussels and Nasdaq: 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; and 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 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 showing a favorable safety and tolerability profile for Cx611. Based on the results of this study, TiGenix is now sponsoring a Phase Ib/IIa clinical trial (the SEPCELL study) in severe sepsis secondary to community-acquired pneumonia (CAP). SEPCELL is a randomized, double-blind, placebo-controlled, Phase Ib/IIa 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.

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.