



Press Release

TxCell consortium granted €1.28 million for TRUST project on process and clinical development of Col-Treg for autoimmune uveitis treatment

French Government and local authorities award grant from the Unique Interministerial Fund (FUI) to the consortium composed of TxCell, Provepep, Hospital La Pitié Salpêtrière (APHP) and Quinze-Vingts Hospital Center (Paris)

Valbonne, France, August 24, 2015 – TxCell SA (FR0010127662 – TXCL), a biotechnology company developing innovative, personalized T-cell immunotherapies using antigen specific regulatory T-cells (Ag-Tregs) for severe chronic inflammatory and autoimmune diseases, today announces that the French government's Unique Interministerial Fund (FUI) has granted €1.28 million to the TRUST project (TRegs in Uveitis Study). The FUI panel awarded the TRUST funding application the highest score, and as a result, the project qualified for the maximum percentage of funding from the French government. The TRUST project will be run by a consortium headed by TxCell and will be dedicated to process and clinical development of Col-Treg, TxCell's second lead product, for the treatment of autoimmune uveitis.

The TRUST project will first focus on the process development of Col-Treg, TxCell's autologous collagen type II specific Treg immunotherapy product for the treatment of autoimmune uveitis. To optimize the production process of Col-Treg, TxCell has selected Provepep, a company specialized in the manufacturing and formulation of synthetic peptides under good manufacturing practices (GMP). Provepep will bring innovative solutions based on the use of synthetic immuno-peptides specific to type II collagen to improve the quality of Col-Treg.

The second focus of the TRUST project will be a first-in-man clinical study for severe and refractory autoimmune uveitis patients, scheduled to start in 2016 as previously disclosed. TxCell will be the sponsor of the study. TxCell has also appointed to the consortium two European leading ophthalmology centers in Paris. These centers will be represented by Pr. Barham Bodaghi at the hospital La Pitié Salpêtrière (APHP) and by Dr. Marie-Hélène Errera at the Quinze-Vingts hospital center of ophthalmology.

This collaborative project has been accredited by two leading European competitive clusters Eurobiomed and Medicen. The project will be financially supported by the French Government, the Provence-Alpes-Côte-D'Azur region and the Pays D'Aix agglomeration community.

The grant totals €1,281,850. TxCell, as leader of the consortium will receive €842,736. Provepep will receive €290,852, the hospital La Pitié Salpêtrière (APHP) will receive €48,686 and the Quinze-Vingt hospital center will receive €99,576.

“The combination of the funding and the selection of the highly specialized consortium members by TxCell, represents additional important steps to accelerate the development of the orphan drug Col-Treg, as a new therapeutic option for refractory autoimmune uveitis patients,” said Arnaud Foussat, Chief Scientific Officer of TxCell. “This funding for the TRUST project will also allow TxCell to bring a second product from ASTrIA, TxCell’s first product platform, to the clinic. Critically, this will benefit sufferers of autoimmune uveitis, a leading cause of blindness in the developed world, with approximately 30,000 patients in the US and EU alone that are refractory to other treatments. This will also further strengthen TxCell’s product pipeline of personalized T cell immunotherapies for the treatment of severe chronic inflammatory diseases with high medical need.”

TxCell’s Col-Treg has been classified as an Advanced Therapy Medicinal Product by the European Medicine Agency (EMA). Col-Treg has shown very promising preclinical efficacy and tolerability data in models of autoimmune uveitis. Col-Treg has also received an Orphan Drug Designation for the treatment of non-infectious (autoimmune) uveitis from the EMA in December 2014.

About University Hospital La Pitié Salpêtrière

The University Hospital La Pitié Salpêtrière is a public health establishment and part of the Assistance Publique - Hôpitaux of Paris (AP-HP). As a proximity, speciality, teaching and research hospital, the University Hospital La Pitié Salpêtrière is the largest French hospital group. Located in the 13th arrondissement of Paris, it brings together, in 90 buildings on 33 hectares, 77 services grouped into 11 clusters representing all existing medical activities.

About Quinze-Vingts Hospital Center of ophthalmology

The Quinze-Vingts Hospital Center of ophthalmology, the cradle of French ophthalmology and located in the 12th arrondissement of Paris, ensures, in addition to home and emergency care, a mission of teaching, research and prevention. It is bound by a university hospital partnership agreement with the Assistance Publique - Hôpitaux de Paris. Its care activities cover most ophthalmic diseases, whether medical, surgical or neuro-ophthalmological. Since 2008, it has accommodated a research institute (the Institut of Vision) whose purpose is not only to promote basic research on vision, but also to allow the development of companies involved in prevention and treatment of eye conditions.

About Provepep

Provepep is a CRO / CMO focused on the development and the chemical synthesis of long and / or complex peptides and small proteins. Provepep is certified GMP since 2006 and has completed numerous development and manufacturing of peptides particularly in the vaccine field. Provepep has experience in the development of immunogenic peptides for the treatment of cancers, auto-immune diseases and also for vaccine candidates in infectious and parasitic diseases.

Since 2010, with a production unit of nearly 2500 sqm in Fuveau, near Aix en Provence, Provepep development has been focused on the production, by chemical synthesis, of therapeutic proteins as an alternative way to productions by recombinant techniques: its proprietary ligation technology (SEA ligation), licensed by the CNRS, enables it to produce natural or modified proteins and/or polypeptides with high purity, in a fast, reliable, cost-effective way.

Provepep is integrated within the technology group Provence (Marseille), which has 45 employees in the field of chemistry and pharmacy.

About TxCell: www.txcell.com

TxCell develops innovative, personalized T cell immunotherapies for the treatment of severe chronic inflammatory diseases with high medical need. TxCell has created ASTrIA, a unique and proprietary product platform based on the properties of autologous antigen-specific regulatory T lymphocytes (Ag-Tregs). The company has initiated a phase IIb study of its lead product candidate, Ovasave® in refractory Crohn's disease patients. This follows a phase I/IIa study in the same patient population reporting positive clinical efficacy and good tolerability. TxCell's second product candidate, Col-Treg is for the treatment of autoimmune uveitis, a rare disease of the eye. Listed on the regulated market Euronext Paris, TxCell is a spin-off of Inserm (France's National Institute for Health and Medical Research). TxCell has 70 employees based both at the headquarters located in the Sophia Antipolis technology park, Nice, France and at its manufacturing site in Besançon.

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Disclaimer:

This press release contains certain forward-looking statements. Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated.