Press Release

TxCell announces FDA acceptance of IND for Ovasave

IND grants TxCell option of extending current phase 2b study from EU to US

Valbonne, France, June 29, 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, announces today that the United States Food and Drug Administration (FDA) has accepted TxCell's Investigational New Drug (IND) application for the company's lead product, Ovasave®, currently in a phase 2b clinical trial for the treatment of patients with refractory Crohn's disease. The study is currently one of largest ever-controlled studies for a personalized T cell immunotherapy product.

The activation of the IND authorizes TxCell to extend the CATS29 study to the United States. The CATS29 study is currently on-going in Europe following its start in December 2014. There are currently 30 study sites operating the study in 6 countries in the EU. It has been designed to include 160 severe refractory Crohn's disease patients. The extension of this study to U.S. sites could be initiated in the first part of 2016. Ovasave® materials manufactured in a US or EU GMP facility will be required to start enrolment in a clinical trial under the IND.

"This active US IND is a very important milestone for TxCell as it is the first ever obtained by the Company with one of its products," said Stéphane Boissel, Chief Executive Officer of TxCell. "It is a sign of maturity for TxCell and, importantly, for its cellular immunotherapy technology based on regulatory T cells products, a field in which our Company is a pioneer and a world leader."

"The receipt of the IND for the CATS29 study with Ovasave® from the FDA will give TxCell an option to extend the trial in the US. The extension to this trial, already one of largest ever-controlled studies for a personalized T cell immunotherapy product, could give additional resources, namely in terms of patient recruitment, to accelerate the study," said Miguel Forte, Chief Operating Officer of TxCell. "The IND provides further opportunities for

Ovasave to progress smoothly and rapidly to phase 3 and commercialization. It also opens the possibility to assess the benefit of our antigen specific T regulatory cell therapy in refractory Crohn's disease patients who have no alternative treatment options, from US sites."

About CATS29

The CATS29 study is a multi-center, randomized, double-blinded, placebo-controlled, multi-dose and multi-injection, 4 parallel groups study. The study is currently on-going in 30 study sites in 6 countries (Austria, Belgium, France, Germany, Italy and United Kingdom). This study could now be extended to include US sites. The trial has been designed to include 160 severe refractory Crohn's disease patients. The primary objective of the CATS29 study is the evaluation of the response rate for a single intravenous injection of 1.10^6 cells dose of Ovasave (ovalbumin-specific autologous Treg cells (Ova-Treg)) compared to placebo 6 weeks post administration. Response is defined as a decrease ≥100 points in the Crohn's Disease Activity Index (CDAI), the gold standard regulatory measure of response in Crohn' disease. Patients will receive, double-blinded, two intravenous (iv) injections 8 weeks apart of either 1.10^4, 1.10^6, or 1.10^7 cells of Ovasave or placebo. Patients will then receive either an open-label treatment with 2 additional iv injections of 1.10^6 cells of Ovasave or a safety follow-up with no injection. Finally, there will be an extended safety follow-up for all patients.

About TxCell

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 has a strategic partnership for the development of Ovasave with the Swiss company Trizell Holding SA and Ferring International Center remains the intended final commercializing party. Both companies are affiliates of the Dr Frederik Paulsen Foundation. 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. For further information visit www.txcell.com

Practical Information about TxCell shares:

ISIN code FR0010127662

Ticker code TXCL

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.

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