Press Release

TxCell receives Fast Track Designation from FDA for Ovasave®

TxCell's lead product designated for the treatment of moderate to severe Crohn's disease

Valbonne, France, July 27, 2015 – TxCell SA (Euronext Paris: FR0010127662 – TXCL), a biotechnology company developing innovative, personalized cell-based 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 granted Fast Track Designation to TxCell's lead product Ovasave® for the treatment of moderate to severe Crohn's disease. Ovasave already has an active IND (Investigational New Drug) with the FDA.

The FDA Fast Track program aims to facilitate the development and review of new drugs intended to treat serious or life-threatening conditions that have already demonstrated the potential to address unmet medical needs. The granting of Fast Track Designation will enable TxCell to work more closely with the FDA with the intent to accelerate the drug development program through to approval in order to make relevant medications available to patients sooner.

"The granting of Fast Track Designation by the FDA to TxCell's Ovasave is in part due to the strong unmet medical need experienced by patients with moderate to severe Crohn's disease. This FTD is also a sign of confidence from the FDA in the potential of Ovasave to address that need," stated Miguel Forte, MD, PhD, Chief Operating Officer of TxCell. "In addition to the recent opening of the IND, this Fast Track status will help us to facilitate the timely development of Ovasave as a high priority program for TxCell and a significant potential opportunity for the treatment of refractory Crohn's disease patients with no other option."

Ovasave is an antigen specific autologous T regulatory somatic cell therapy in development for the treatment of Inflammatory Bowel Disease. Ovasave is currently in a randomised controlled phase IIb study entitled CATS29. The study aims to confirm the benefit of Ovasave for the treatment of patients with refractory Crohn's disease. The CATS29 study follows an initial phase IIa study entitled CATS1.

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 conducted in 30 study sites in 6 countries (Austria, Belgium, France, Germany, Italy and United Kingdom). This study may 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 10e6 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's disease. Patients will receive, double-blinded, two intravenous (iv) injections 8 weeks apart of either 10e4, 10e6, or 10e7 cells of Ovasave or placebo. Patients will then receive either an open-label treatment with 2 additional iv injections of 10e6 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: 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 has a strategic collaboration for the development of Ovasave with the Swiss company Trizell Holding S.A. and Ferring International Center S.A. 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.

CONTACTS

TxCell	**Image Box – Press relations**	**NewCap – Investor relations**
BD & Communication Department	Neil Hunter / Michelle Boxall	Julien Perez / Pierre Laurent
Tel: +33(0) 497 218 300	Tel: +44(0) 20 8943 4685	Tel: +33 (0)1 44 71 98 52
Fax: +33(0) 493 641 580	michelle.boxall@imageboxpr.co.uk	txcell@newcap.fr
contact@txcell.com	neil.hunter@imageboxpr.co.uk	

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.