



Press Release

TxCell appoints MaSTherCell for the manufacturing of lead product Ovasave®

Valbonne, France, July 29, 2015 – TxCell SA (Euronext Paris: 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 it has entered into an agreement for the production of clinical batches of Ovasave® with MaSTherCell, a Contract Manufacturing Organization (CMO), based in Belgium.

The contract signed between TxCell and MaSTherCell is a Memorandum of Understanding for the manufacturing by MaSTherCell of clinical batches of TxCell's Ovasave. These Ovasave batches will be used by TxCell in the ongoing phase IIb trial with the product in refractory Crohn's disease patients (CATS29 study). The transfer of technology will start immediately. It is intended that first clinical batches could be manufactured as soon as Q2 2016.

In addition, TxCell is currently taking action at its existing pilot Besançon manufacturing unit in order to ensure future compliance with Good Manufacturing Practice (GMP) and recommence full manufacturing activities following a partial, temporary hold at the site. TxCell will then file to reobtain its GMP certificate as production will resume after the GMP certificate is granted back by the French regulator ANSM.

Ovasave clinical batches for the CATS29 study will be manufactured in parallel by MaSTherCell and TxCell's own facility. As previously disclosed, the Company expects to deliver top-line data from this study in 2017.

"This strategic relationship with MaSTherCell, a European leader in cellular therapy products manufacturing with a significant track record in production of clinical materials, is very important to TxCell," said Stéphane Boissel, Chief Executive Officer of TxCell. "We have immediately taken the appropriate actions at our manufacturing site in Besançon and the agreement with MaSTherCell should enable us to rapidly increase the efficiency of our manufacturing. This should both speed up enrollment in CATS29 and accelerate development on other products."

As part of the Memorandum of Understanding with MaSTherCell, TxCell and MaSTherCell also agree to enter into discussion for the long-term clinical and commercial manufacturing by MaSTherCell of Ovasave and other TxCell products. These discussions will take place in Q4 2015.

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 greater than or equal to 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 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 MaSTherCell: www.masthercell.com

MaSTherCell SA (Manufacturing Synergies for Therapeutic Cells), a spin-off from ULB (Université Libre de Bruxelles) launched in 2011, is a technology-driven, quality-minded and customer-oriented Contract Development and Manufacturing Organization (CDMO) specialized in cell therapy development for advanced medicinal products. The company is an affiliate of Orgenesis Inc. (ORGS) located in Gosselies, Belgium and provides GMP manufacturing for cell therapy companies. Its mission is to combine expertise, quality systems and infrastructure to help its customers bring highly potent cell therapy products faster to the market.

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.

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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.