# **Press Release**



# TxCell reviews its manufacturing strategy to focus on R&D and strategic partnerships - its core, high added value businesses

Valbonne, France, October 14, 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 it is operating a strategic review that should result in the outsourcing of all existing and future clinical and commercial manufacturing operations to contract manufacturing organizations (CMOs).

The strategic review, which is being discussed with TxCell employee's representatives, should enable TxCell to focus on its key strengths of research, clinical development and new partnerships. The Company will retain, as well as further strengthen its critical process development capabilities and GMP-proving activities with key recruitments and opening of a dedicated laboratory.

"The cellular therapy production sector is making significant progress in key specialized areas that are required by TxCell. There are now a number of CMOs globally that have the capability to operate reliably in the cellular therapy space," said Stéphane Boissel, Chief Executive Officer of TxCell. "The reorganization proposed by TxCell should enable us to focus on key high-value creation activities that will also further accelerate our own development. Specifically, TxCell would concentrate on discovery, research, clinical development and manufacturing process improvement. We would then have the capability to bring at least three new products from its two platforms, including innovative Chimeric Antigen Receptor (CAR)-engineered Treg cell products, to clinical development within five years. This would result from a combination of stand-alone development and co-development with strategic partners."

As a result of the proposed reorganization, TxCell intends to open a new, GMP-proving laboratory, based within or close to TxCell's existing headquarters in Sophia Antipolis (France). This laboratory will finalize process improvement and development and ensure the transfer of technology to CMOs.

TxCell will seek CMO partnerships in EU, US and Asia for the GMP manufacturing of its clinical and commercial products. These partnerships will be in addition to existing relationships with MaSTherCell (BE) and Cell Therapy Catapult (UK), both based in Europe.

Following a consultation period for the employee's representatives, TxCell intends to rapidly close its own Besançon pilot manufacturing facility. This has been designed to be a temporary site for TxCell. The Company is currently evaluating options for its local 26 employees that would be impacted by this closure.

"It is our responsibility to best help the impacted Besançon staff to rapidly find new job opportunities," said Raphael Flipo, Chief Financial Officer of TxCell. "The employees in Besançon, who are all very qualified and well trained, have done an excellent job since the opening of the facility in 2013. Our decision to close the Besançon facility is only driven by strategic and economic considerations."

The changes in TxCell manufacturing strategy should have no impact on the timelines for both Ovasave<sup>®</sup> and Col-Treg clinical development. The CMO MaSTherCell is scheduled to start manufacturing batches of Ovasave in Q2 2016.

## 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<sup>®</sup> 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 62 employees.

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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.