



Press Release

Col-Treg granted Advanced Therapy Medicinal Product (ATMP) classification by the European Medicines Agency (EMA)

Valbonne, France, May 22, 2014. – TxCell SA (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 Col-Treg, its second therapeutic candidate from its ASTRiA platform, has been granted Advanced Therapy Medicinal Product (ATMP) classification by the Committee for Advanced Therapies (CAT) of the European Medicines Agency (EMA).

“The grant of ATMP classification for Col-Treg, TxCell’s second full development programme, is a further step for TxCell to potentially create a novel, personalized cellular immunotherapy approach to reduce the terrible burden of uveitis,” said Damian Marron, Chief Executive Officer of TxCell. “Col-Treg is a key programme within our pipeline of products focused on chronic inflammatory diseases where current treatments show limited efficacy, limited tolerability and for which many of the patients treated develop resistance.”

ATMP classified products are innovative, regenerative therapies that combine aspects of medicine, cell biology, science and engineering for the purpose of regenerating, repairing or replacing damaged tissues or cells. ATMPs comprise of gene- and cell-therapy and tissue-engineered medicinal products. The classification is defined by Regulation (EC) No. 1394/2007, which establishes the legal and regulatory framework for ATMP in the European Union.

Col-Treg is TxCell’s second therapeutic candidate from its ASTRiA platform after Ovasave®, TxCell’s lead autologous Ag-Treg cell-based immunotherapy. TxCell initiated a full development program in Q1 2014 with Col-Treg for the treatment of Autoimmune Uveitis. Autoimmune Uveitis is a serious inflammatory condition of the eye that often results in permanent vision damage. Uveitis is classified as a rare disease with a total incidence of around 35-50/100,000¹. Col-Treg cells are purified autologous type 1

regulatory T lymphocytes specific for human type II collagen.

“Col-Treg is a novel potential personalized therapeutic option with a local, multi target inhibition of inflammation. Col-Treg has been developed for steroid refractory autoimmune uveitis patients that have very limited treatment alternatives,” said Miguel Forte, Sr. VP Clinical Development and Regulatory Affairs, TxCell. “TxCell will now complete the requirements for applying for orphan drug designations for Autoimmune Uveitis in the European Union and in the United States and prepare for a phase II proof of principle study to start in 2015.”

¹*According to 21 January 2013 – EMA/COMP/450332/2012 Committee for Medicinal Products*

About Col-Treg

Col-Treg is a personalized cell-based immunotherapy product, based on the properties of autologous collagen II-specific regulatory T lymphocytes. Col-Treg has already shown efficacy and safety in several different autoimmune disease models and has shown the absence of tumourigenicity and confirmed the limited life span of the cells in vitro and in vivo. The next step in this program will be a phase I/II proof of principle clinical trial to start in 2015.

About ATMPs and European Regulation on ATMPs

The aim of the ATMP classification is to regulate cell and gene therapy and tissue-engineered medicinal products, providing a benchmark for a level of quality compliance for pharmaceutical practices. The regulation provides guidelines to developers for non-clinical and manufacturing development as well as product quality testing. The regulation also offers incentives to companies involved in developing ATMPs in the European Union, including fee reductions for scientific advice, scientific recommendations on ATMP classification and evaluation and certification of quality and non-clinical data.

About TxCell

TxCell is developing innovative personalized cell-based immunotherapies for the treatment of severe chronic inflammatory diseases with high medical need using its unique and proprietary ASTRiA technology platform based on the properties of autologous antigen-specific regulatory T lymphocytes (Ag-Tregs). The company has completed a phase I/IIa study of its lead product candidate, Ovasave® in refractory Crohn’s disease patients and has reported good tolerability and positive clinical efficacy. The company plans to initiate a phase IIb study in the same patient population.

Listed on Euronext-Paris, TxCell, a spin-off of Inserm (France's National Institute for Health and Medical Research) is located in the Sophia Antipolis technology park, Nice, France. The company has 38 employees based at its headquarters and at its manufacturing site in Besançon. For more information, please 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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