Press Release

TxCell receives EU Orphan Drug Designation for Col-Treg in the treatment of non-infectious uveitis

- ***Recognition of the therapeutic potential of Col-Treg in non-infectious (autoimmune) uveitis***
- ***A proof of principle clinical study is planned to start in the first half of 2015, with top line results of this study expected mid-2016***

Valbonne, France, December 17, 2014 – TxCell SA (FR0010127662 – TXCL), a biotechnology company developing innovative, cost-effective, personalized T cell immunotherapies using antigen specific regulatory T-cells (Ag-Tregs) for severe chronic inflammatory and autoimmune diseases, announces today that the European Commission (EC) has granted orphan drug designation to TxCell's investigational medicinal product Col-Treg, a personalized T cell immunotherapy using collagen-II specific regulatory T-cells, for the treatment of autoimmune uveitis.

"Obtaining orphan drug designation for Col-Treg in the European Union is a recognition of the therapeutic potential of Col-Treg in autoimmune uveitis. Whilst this is a rare disease, it is a leading cause of blindness in the developed world. TxCell estimates around 30,000 autoimmune uveitis patients per year in the US and EU alone, for whom existing treatments do not work, could benefit significantly from the development of Col-Treg," said Miguel Forte, Sr. VP Clinical Development and Regulatory Affairs, TxCell. *"We are moving rapidly to undertake a placebo-controlled, dose-ranging proof of principle clinical study in autoimmune uveitis. This is planned to start in the first half of 2015. The top line results of this study are expected mid-2016."*

Autoimmune uveitis is a debilitating inflammatory condition of the eye, often resulting in permanent vision damage. Uveitis is one of the leading causes of blindness in the developed world. It is a rare disease with a prevalence of around 35-50/100,000[1]. Autoimmune uveitis constitutes 80-90% of cases[2]. No treatment is currently approved for the patients that become refractory to corticosteroid compounds. In addition, these

products are known to cause serious side effects when used for a prolonged period. Because of the low safety and the increased resistance to existing drugs, the development of new and safer class of therapeutics to treat autoimmune uveitis is essential.

In the EU, the benefits of Orphan Drug Designation from the European Commission include protocol assistance and possible exemptions or reductions in regulatory fees during development. Another benefit from the classification is 10 years of market exclusivity from product launch.

"The achievement of these designations for Col-Treg, our second product candidate, is a result of the strength of TxCell's ASTrIA platform to generate innovative personalized T cell immunotherapy treatments for severe autoimmune diseases. After moving Col-Treg into a first clinical study in the first half of 2015, TxCell will then look to pursue a streamlined development program towards the market, given the very significant need for new treatments for this severe disease," said Damian Marron, CEO, TxCell. *"TxCell will continue to push forward the Col-Treg program in addition to its lead product, Ovasave®, for which a phase IIb clinical in refractory Crohn's disease was recently started, to bring novel solutions to patients in need and value to the whole community."*

About Col-Treg

Col-Treg (Col-Treg cells), is a personalized T cell immunotherapy product, based on the properties of autologous collagen-II specific regulatory T lymphocytes. A placebo-controlled, dose-ranging proof of principle clinical study in autoimmune uveitis, a rare disease of the eye, is planned to start in the first half of 2015. Top line results of this study are expected mid-2016. After administration, Col-Treg cells home to the site of inflammation where they are activated by the specific antigen. The Col-Tregs then act by locally releasing immune suppressive factors, cell-cell contacts and cytotoxic activity to treat the inflammation. Col-Treg has Orphan Drug Designation in the EU and is classified as an Advanced Therapy Medicinal Product (ATMP), by the European Medicines Agency (EMA).

About Autoimmune Uveitis

Autoimmune uveitis is a serious inflammatory condition of the eye and often results in permanent vision damage. Uveitis is a rare disease with a prevalence of around 35-50/100,000[1]. Autoimmune uveitis constitutes 80-90% of cases[2]. Despite its rarity, in developed countries this autoimmune disease causes 10-15% of legal blindness. The condition also leads to 30,000 new cases of blindness per year in the US alone[2] and affects

[1] *According to EU Regulatory Workshop – EMA/450332/2012*

[2] *According to GlobalData Report GDHC008POA - Dec. 2013*

around 168,000 people in Europe[3].

About TxCell

TxCell develops innovative, cost-effective, personalized T cell immunotherapies for the treatment of severe chronic inflammatory diseases with high medical need. TxCell has created ASTrIA, a unique and proprietary technology 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 Ovasave with the Swiss company Ferring International Center. TxCell's second product candidate, Col-Treg is for the treatment of autoimmune uveitis, a rare disease of the eye. A placebo-controlled, dose-ranging proof of principle clinical study is planned to start in the first half of 2015. 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 55 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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[3] *According to EMA/COMP/105735/2013*