Press Release

TxCell granted US Orphan Drug Designation for Col-Treg in the treatment of chronic non-infectious uveitis

A first-in-man clinical study is planned to start in 2016, with top line results expected end 2017

Valbonne, France, September 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 the U.S. Food and Drug Administration's Office of Orphan Products Development has granted Orphan Drug Designation (ODD) to TxCell's Col-Treg, a personalized T cell immunotherapy using collagen-II specific regulatory T-cells, for the treatment of chronic non-infectious uveitis. This followed the ODD already received for the product in Europe.

Autoimmune uveitis is a severe inflammatory condition of the eye, often resulting in permanent vision damage. Uveitis is one of the leading causes of blindness in the developed world. No treatment is currently approved for the patients that become refractory to corticosteroid compounds.

“The Orphan Drug Designation in both the US and EU is the latest significant step for the development of Col-Treg, a novel and promising therapeutic approach for autoimmune uveitis, resulting from TxCell’s ASTrIA platform. TxCell applied for and received Orphan Drug Designation in the US and EU, which will allow us to expedite Col-Treg through development. This ultimately will benefit those suffering from autoimmune uveitis, a truly debilitating condition of the eye. TxCell plans to move Col-Treg into a first clinical study in 2016, with top line results expected end 2017,” said Stephane Boissel, CEO, TxCell.

The FDA Orphan Drug Designation provides a special status to drugs and biologics intended to treat, diagnose or prevent rare diseases and disorders. Rare diseases and disorders are defined as affecting fewer than 200,000 people in the United States. In particular, this designation provides for a seven-year marketing exclusivity period against competition as well as certain incentives, including federal grants and tax credits. This adds to the benefits of the EU ODD, which includes 10 years of market exclusivity from product launch as well as protocol assistance and possible exemptions or reductions in regulatory fees during development.

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 first-in-man clinical study in autoimmune uveitis, a rare disease of the eye, is planned to start in 2016. After intravenous 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 in the US 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 around 168,000 people in Europe[3]. It is estimated that 30,000 autoimmune uveitis patients per year are refractory to approved steroids treatments in the US and EU alone.

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'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 66 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 / Emma Marshall	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	emma.marshall@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.

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

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

[3] *According to EMA/COMP/105735/2013*