



## Press Release

### **TxCell announces peer-reviewed publication of preclinical efficacy results for Col-Treg in autoimmune uveitis in a leading ophthalmology journal**

**Results published in Investigative Ophthalmology and Visual Science (IOVS) provide details on the demonstration of Col-Treg's therapeutic potential in autoimmune uveitis and will support its ongoing clinical development**

**Valbonne, France, September 8, 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, today announces the publication of preclinical efficacy results for Col-Treg, TxCell's second therapeutic candidate from its ASTRiA platform, in a model of autoimmune (non-infectious) uveitis. The results are being published in Investigative Ophthalmology & Visual Science (IOVS), a prominent journal in the field of ophthalmic and vision research.

The publication is entitled *"Inhibition of non-infectious uveitis using intravenous administration of collagen-II specific Type 1 regulatory (Col-Treg) T cells."* The published study evaluated the therapeutic potential of Col-Treg immunotherapy for the treatment of non-infectious uveitis using in vitro and in vivo assays. Specifically, *in vivo* administration of Col-Treg in the model of autoimmune uveitis significantly inhibited clinical symptoms, retinal tissue lesions as well as ocular proinflammatory cell infiltration. In addition, authors dissected the mechanism of action of Col-Treg and showed that cells are using several distinct immune-regulatory pathways to dampen inflammation. The publication will be available in October.

Investigative Ophthalmology & Visual Science (IOVS) is an official journal of the Association for Research in Vision and Ophthalmology (ARVO), an international organization dedicated to encouraging and assisting research, training, publication, and the dissemination of knowledge in the areas of vision and ophthalmology. Activity and tolerance data for Col-Treg were presented at the 2015 ARVO Annual Meeting, May 3-7, 2015, in Denver, Colorado, US.

Col-Treg is a personalized T cell immunotherapy product, based on the properties of autologous collagen II-specific regulatory T lymphocytes. In addition, Col-Treg has shown very promising preclinical efficacy and tolerability data in models of inflammatory arthritis (*Arthritis Res Ther. 2014 May 22;16(3):R115, Asgnali et al., Type 1 regulatory T cells specific for collagen type II as an efficient cell-based therapy in arthritis*).

"Following the previous demonstration of Col-Treg preclinical efficacy in models of inflammatory arthritis, these results published in IOVS demonstrate the therapeutic potential of Col-Treg in non-infectious uveitis and will support its ongoing clinical development," said Arnaud Foussat, Chief Scientific Officer of TxCell. "The support TxCell has seen from the ophthalmologic community provides additional confirmation of the potential of, and requirement for, Col-Treg as a much needed new potential treatment for autoimmune

uveitis, a rare and debilitating eye disease with very limited therapeutic options. There are approximately 30,000 autoimmune uveitis patients per year that are refractory to approved steroids treatments in the US and EU alone and this is a clear unmet medical need.”

Col-Treg has been classified as an Advanced Therapy Medicinal Product by the European Medicine Agency (EMA). Col-Treg has also received an Orphan Drug Designation for the treatment of non-infectious (autoimmune) uveitis from the EMA in December 2014. A first-in-man clinical study with Col-Treg for severe autoimmune uveitis patients that become refractory to steroid compounds, is scheduled to start in 2016.

**About Autoimmune Uveitis:**

Autoimmune Uveitis is a serious inflammatory condition of the eye and often results in permanent vision damage. Uveitis is classified as a rare disease with a prevalence of around 35-50/100,000<sup>1</sup>. Autoimmune Uveitis constitutes 80-90% of cases<sup>2</sup>. 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<sup>3</sup> and affects around 168,000 people in Europe<sup>4</sup>. 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](http://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 66 employees based both at the headquarters located in the Sophia Antipolis technology park, Nice, France and at its manufacturing site in Besançon.

**CONTACTS**

<p><b>TxCell</b>          BD &amp; Communication Department          Tel: +33(0) 497 218 300          Fax: +33(0) 493 641 580  <a href="mailto:contact@txcell.com">contact@txcell.com</a></p>	<p><b>Image Box – Press relations</b>          Neil Hunter / Emma Marshall          Tel: +44(0) 20 8943 4685  <a href="mailto:emma.marshall@imageboxpr.co.uk">emma.marshall@imageboxpr.co.uk</a>  <a href="mailto:neil.hunter@imageboxpr.co.uk">neil.hunter@imageboxpr.co.uk</a></p>	<p><b>NewCap – Investor relations</b>          Julien Perez / Pierre Laurent          Tel: +33 (0)1 44 71 98 52  <a href="mailto:txcell@newcap.fr">txcell@newcap.fr</a></p>
---	--	---

<sup>1</sup> According to EU Regulatory Workshop – EMA/450332/2012  
<sup>2</sup> According to GlobalData Report GDHC008POA - Dec. 2013  
<sup>3</sup> According to GlobalData Report GDHC008POA - Dec. 2013  
<sup>4</sup> According to EMA/COMP/105735/2013

**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.