



Press Release

TxCell achieves positive results for Col-Treg in a model of autoimmune uveitis

TxCell set for phase I/II proof of principle clinical study in Q2 2015 for its second therapeutic candidate in this rare eye disease

Valbonne, France, October 28, 2014. – TxCell SA (FR0010127662 – TXCL), a biotechnology company developing innovative, economically viable, personalized T cell immunotherapies using antigen specific regulatory T-cells (Ag-Tregs) for severe chronic inflammatory and autoimmune diseases, announces today that TxCell researchers have achieved positive results for Col-Treg, its second product candidate from its ASTRiA platform, in a model of autoimmune uveitis, a leading cause of blindness with very limited treatment options.

TxCell demonstrated clear efficacy and tolerability of Col-Treg for the treatment of autoimmune uveitis. The results generated in the model include pharmacodynamic and pharmacokinetic data that shows a reduction in the severity of uveitis on clinical and histologic measures. In addition, TxCell has also generated GLP toxicology results that indicate a good safety profile for Col-Treg. TxCell intends to submit these results for publication in a recognized, peer-reviewed journal.

“The new data obtained with Col-Treg have provided further confirmation of the potential of Col-Treg, TxCell’s second product candidate from its ASTRiA platform, as a much-needed new treatment for autoimmune uveitis,” said Arnaud Foussat, VP Research and New Products at TxCell. “After strong phase I/IIa results in Crohn’s disease with Ovasave[®], these results with Col-Treg confirm the versatility and robustness of our innovative proprietary technological platform, ASTRiA, of personalized T cell immunotherapies for severe chronic inflammatory and autoimmune diseases.”

Autoimmune uveitis has been characterised as a disease in which there is a dysfunction of the T regulatory cell compartment of the immune system. Recent scientific studies have demonstrated that the administration or induction of regulatory T (Treg) cells in vivo can be used as therapeutic tools for the control of ocular inflammation, including that seen in autoimmune uveitis. As a result, TxCell is developing Col-Treg as a personalized T cell immunotherapy based on the regulatory properties of autologous collagen-II specific regulatory T lymphocytes. Col-Treg is specifically designed to exert a multi-target, multi-mechanism suppressive and anti-inflammatory action locally in the eye upon recognition of collagen-II, a protein present in the vitreous body of both the eye and retina.

TxCell has ensured that Col-Treg will benefit from a robust manufacturing process, utilising its experience with Ovasave®, TxCell's lead product for inflammatory bowel diseases. Manufacturing of Col-Treg will take place in TxCell's own GMP accredited French manufacturing facility.

"TxCell intends to advance rapidly with the development of Col-Treg. We will be looking to obtain orphan drug designations in the European Union and in the United States. Following that, we intend to launch a placebo-controlled proof of principle clinical study for the treatment of patients with autoimmune uveitis that are refractory to approved treatments," said Miguel Forte, Sr. VP Clinical Development and Regulatory Affairs of TxCell. "TxCell plans to start this study in Q2 2015. The trial will be undertaken in a number of specialist ophthalmology centres in Europe."

"This successful demonstration of the therapeutic potential of Col-Treg is another important milestone for TxCell," said Damian Marron, CEO TxCell. "This achievement is central to TxCell's strategy of targeting orphan/niche indications with poor or no treatment options. We will run the proof of principle clinical study with Col-Treg along with developing the other products in our portfolio, including TxCell's lead product Ovasave for inflammatory bowel diseases, which is approaching the start of a phase IIb study in refractory Crohn's disease and is partnered with Ferring International Center."

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 35-50/100,000¹. Autoimmune Uveitis constitutes 80-90% of cases². 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 alone² and affects around 168,000 people in Europe³.

About Col-Treg

Col-Treg is a personalized T cell immunotherapy product, based on the properties of autologous collagen II-specific regulatory T lymphocytes. Col-Treg is classified Advanced Therapy Medicinal Product (ATMP), by the European Medicines Agency (EMA). Col-Treg has already shown efficacy and safety in several different autoimmune disease models and has shown no toxicity in a toxicology study performed under Good Laboratory Practice (GLP). The next step in this program will be a phase I/II proof of principle clinical trial to start in Q2 2015.

About TxCell

TxCell is developing innovative, economically viable, personalized T cell immunotherapies for the treatment of severe chronic inflammatory diseases with high medical need. TxCell uses a 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. TxCell has a strategic partnership for Ovasave with the Swiss company Ferring International Center. 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 49 employees based at its headquarters and at its manufacturing site in Besançon.

For more information, please visit www.txcell.com

¹ According to EU Regulatory Workshop – EMA/450332/2012

² According to GlobalData Report GDHC008POA - Dec. 2013

³ According to EMA/COMP/105735/2013

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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