



Press Release

TxCell announces a temporary partial hold of activities at its pilot manufacturing unit

Company expects only potential limited impact on clinical product timeline

Valbonne, France, June 24, 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 it has temporarily put its pilot manufacturing facility activities at Besançon, France on partial hold. The decision was made in agreement with the French regulator, *Agence Nationale de Sécurité du Médicament*, (ANSM).

The decision was made so that TxCell could take action to ensure future compliance with Good Manufacturing Practice (GMP) for the Besançon facility. The manufacturing site in Besançon obtained manufacturing authorization on September 23, 2013 (amended on June 5, 2014) as well as GMP certification on June 10, 2014. This pilot manufacturing unit in Besançon is temporary as TxCell intends to move all production to a new commercial GMP manufacturing facility by 2018.

Specifically, the actions taken by TxCell aim at eliminating the risk of microbial contamination of released drug products. At the current time, no contamination has been found in any product manufactured and released from the TxCell Besançon site.

Manufacturing of new products by TxCell at Besançon will pause until compliance is ensured. TxCell expects to complete this by the end of the summer. TxCell will then demonstrate GMP compliance. This is expected before the end of the year.

Treatment of patients in the CATS29 study (an ongoing phase 2b clinical trial with Ovasave to treat refractory Crohn patients) for whom at least one injection had been given, will continue. This is subject to the implementation of a risk analysis pre-approved by ANSM.

"Since the decision was already made to engage a supplier (Contract Manufacturing Organization, or 'CMO') to enable an acceleration of recruitment in clinical trials from 2016 to 2018, this partial hold should have only potential limited impact on clinical timelines communicated in May 2015 and will not change TxCell's development plan in the long run," said Stéphane Boissel, CEO, TxCell. "We will work closely with ANSM, the French regulatory agency, to make sure that all potential issues at Besançon are addressed and hopefully resume to normal production activity at this site by the end of the year. Importantly, no production-related safety event was reported from the beginning of the CATS29 study in December 2014".

About TxCell

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 has a strategic partnership for the development of Ovasave with the Swiss company Trizell Holding SA and Ferring International Center remains the intended final commercializing party. Both companies are affiliates of the Dr Frederik Paulsen Foundation. 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 70 employees based both at the headquarters located in the Sophia Antipolis technology park, Nice, France and at its manufacturing site in Besançon. For further information 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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