**Press Release**

# TxCell granted Certificate of GMP Compliance from ANSM for Cell Therapy Manufacturing Facility

## Confirmation of quality of TxCell's manufacturing platform by ANSM enables regulatory submissions for Ovasave® phase IIb clinical study

**Valbonne, France, June 12, 2014. – TxCell SA (FR0010127662 – TXCL),** a biotechnology company developing innovative, personalized cell-based immunotherapies using antigen specific regulatory T-cells (Ag-Tregs) for severe chronic inflammatory and autoimmune diseases, announces today that it has been granted Certificate of Good Manufacturing Practice (GMP) compliance for its cell therapy manufacturing facility in Besançon, France.

The certificate was granted by French National Agency for Drug Safety (ANSM), the French authority for the quality, safety and efficacy of medicines and health products. This certificate follows the Manufacturing Accreditation, also delivered by ANSM on December 3, 2013.

"The certificate of GMP compliance for our manufacturing facility is a key step in TxCell's development for our lead candidate Ovasave. We believe this is a product that may offer a breakthrough innovation for the treatment of refractory Crohn's disease. There are currently 160,000 such patients per year in Europe and in the US for Crohn's Disease alone[1]," said Damian Marron, Chief Executive Officer, TxCell. "This in turn allows us to accelerate the development of all our innovative, personalized cellular immunotherapies. These therapies target niche and orphan indications for which there are few or no treatment options and high unmet medical needs."

This certificate is further official confirmation of the compliance of the TxCell cell therapy manufacturing facility in Besançon with the high and ever increasing standards of the pharmaceutical industry and regulators. This confirms TxCell as a leader in both the

[1] According to PharMetrics Analysis, September 2008

development and manufacture of economically viable personalized cellular immunotherapies in Europe.

The certificate of Good Manufacturing Practice (GMP) compliance covers the manufacture, testing, blinding activities and release of investigational biological and cell therapy products. The certificate is valid for three years. It authorizes the manufacture of phase IIb clinical batches of Ovasave, personalized cell-based immunotherapy using ovalbumin-specific regulatory T-cells (Ova-Tregs) for refractory Crohn's disease. This clinical study is planned to start in the second half of 2014, once necessary regulatory approvals are obtained.

"This certificate of Good Manufacturing Practices compliance is a result of the outstanding work of the TxCell's teams. We have now achieved another of our strategic objectives to be able to offer a new therapeutic option for patients without effective treatment," said Eric Pottier, VP Supply Chain & Qualified Person, TxCell.

**About TxCell**

TxCell is developing innovative personalized cell-based immunotherapies for the treatment of severe chronic inflammatory diseases with high medical need using its 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 38 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**:

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| **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.

## CONTACTS


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