**Press Release** 



# TxCell to lead POSITIVE project to automate first production step of Ovasave<sup>®</sup>, its lead personalised cellular immunotherapy

# Grant of over EUR 400,000 awarded by the Conseil Régional Provence-Alpes-Côte-D'azur to the consortium of TxCell, Gene and Cell therapy Unit, Nice (UTCG) and Biosafe

**Valbonne, France, July 3, 2014.** – TxCell SA, a biotech developing innovative, personalized cell-based immunotherapies using antigen-specific regulatory T-cells (Ag-Tregs) for chronic inflammatory and autoimmune diseases, announces today the launch of, and funding awarded to, the POSITIVE project in collaboration with the Gene and Cell therapy Unit (UTCG) developing new antiviral cell-based immunotherapies and Biosafe, a Swiss private company, a developer of innovative solutions for cell processing.

The POSITIVE project will focus on the development and establishment of a procedure to automate the first step of manufacturing of Ovasave, TxCell's lead innovative, personalized cellular immunotherapy for severe refractory Crohn's disease patients. Biosafe's Sepax system will enable the automated and standardized separation of mononuclear white blood cells for the production of cellular immunotherapy.

This collaborative project, accredited by the French competitive cluster Eurobiomed, is supported by APRF funding (Appel à Projet Recherche Finalisée), from the Conseil Régional Provence-Alpes-Côte-D'azur. The grant totals EUR 417,000, of which TxCell will receive a grant of EUR 250,000 and UTCG will receive EUR 167,000. Both grants will be for the performance of experiments by TxCell and UTCG and the optimization of the resulting new automated and standardized procedure. Biosafe will also utilise its Sepax technology expertise and know-how to optimize the dedicated software and protocol.

"Participating in the POSITIVE project, and automating the TxCell manufacturing process for Ovasave is very important to us following the partnership with Ferring announced earlier this year with a potential value of EUR 76 million plus royalties," said Damian Marron, CEO, TxCell. "Working with our highly qualified partners from UTCG and Biosafe, and backed by the Conseil Régional Provence-Alpes-Côte-D'azur, Ovasave will be able to pave the way for scale up, industrialisation and commercialisation of cellular immunotherapies for TxCell, other biotech companies and public institutions. This is the next step following the announcement of our certification of GMP by the ANSM."

The process developed by the POSITIVE project will be applicable to a wide range of other cellular immunotherapies, allowing to overcome the constraints of manual methods and to move towards standardized large scale manufacturing in closed systems.

"The industrialization of cellular immunotherapies is crucial for those operating in the sector as well as for TxCell," said Eric Pottier, VP Supply Chain at TxCell. "New industrial tools are needed to enable commercial scale manufacturing. This could make cellular immunotherapies available to the large number of patients with a variety of conditions with unmet medical need that are waiting for innovative therapeutic options."

#### 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 antigenspecific regulatory T lymphocytes (Ag-Tregs). The company has completed a phase I/IIa study of its lead product candidate, Ovasave<sup>®</sup> 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<sup>®</sup> 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:

ISIN codeFR0010127662Ticker codeTXCL

#### **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.

#### About UTCG Nice

Cell and Gene Therapy Unit (UTCG) is a highly specialized technological hospital-university, located in the Pasteur Hospital in Nice, France. This unit is equipped to produce clinical grade cell-based products according to regulatory authorities and employs a dozen people.

UTCG labs includes controlled environment and qualified cleanrooms. This cell culture unique tool organized around a system of quality management with certification ongoing, provides to external partners the ability to produce cells in a controlled environment and by a specialized team.

#### About Biosafe

Founded in 1997 the Biosafe Group is active in the design, manufacture and marketing of automated cell processing systems. Headquartered in Switzerland and privately-owned, the Biosafe Group operates through regional subsidiaries (Geneva, Houston, Hong-Kong, Shanghai and São Paulo) and is present in more than 45 countries, either directly or through distributors.

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