

## **Press Release**

# TxCell and Trizell amend collaboration agreement to accelerate Ovasave® development

- Trizell initially advances up to €1.1 million of funding
- TxCell appoints the Cell Therapy Catapult to perform process and manufacturing development

Valbonne, France, April 23, 2015 – TxCell SA (FR0010127662 – TXCL), a biotechnology company developing innovative, cost-effective, personalized T-cell immunotherapies using antigen specific regulatory T-cells (Ag-Tregs) for severe chronic inflammatory and autoimmune diseases, announces today an amendment to the Ovasave® collaboration option, development and license agreement (Ovasave Agreement) with Trizell Holding SA (Trizell). In the agreement, TxCell will undertake a program to bring forward the preparation of Ovasave for phase 3 development and commercialization, notably in the areas of process and manufacturing development. To finance this program, Trizell will advance up to €1.1 million in funding that was initially due after the future exercise of Trizell's option to Ovasave. In Trizell's sole discretion it may finance a further €4.3 million. TxCell has appointed the Cell Therapy Catapult, a leading cell therapy organization, to undertake the process and manufacturing development of TxCell's ASTrIA product platform under TxCell's leadership. Ovasave, TxCell's lead product, is currently in a phase IIb clinical trial for refractory Crohn's disease (CATS29 study – see release of Dec 4, 2014). Top line results of this study are expected at the end of 2016 / early 2017.

Initiating the program detailed in the latest amendment to the agreement is intended to enable Ovasave to be moved seamlessly into phase III development following the ongoing phase IIb study. It also aims to ensure that the phase III program is performed with the same cost-effective manufacturing processes that will be used for future commercial products. In addition, the process will be designed and automated to allow it to be easily and economically upscaled in line with future demand. The program allows other activities to be performed including formulation selection and any necessary pre-clinical studies.

TxCell will own all results and intellectual property generated, which can be used across TxCell's ASTrIA product platform. TxCell will grant Trizell an exclusive license to use the

results and IP specifically for Ovasave in IBD (Inflammatory Bowel Diseases) in line with the Ovasave Agreement.

Trizell has initially committed €1.1 million of funding to the phase III preparation program and may, in its sole discretion, commit up to a further €4.3 million. This funding will be offset against the potential total payments of up to €76 million due to TxCell under the Ovasave Agreement.

"This additional amendment to our agreement including the significant investments advanced by Trizell, is the latest important development for the Ovasave program and for TxCell's ASTrIA product platform. It provides further support for Ovasave to progress smoothly and rapidly to phase III and commercialization," said Miguel Forte, SVP Clinical and Regulatory, TxCell. "Ovasave, TxCell's lead personalized T-cell immunotherapy, offers the chance of a new therapeutic innovation for refractory Crohn's disease patients who have no alternative treatment options. In addition to this, TxCell has a portfolio of further personalized T-cell immunotherapies from the ASTrIA product platform. This includes TxCell's second product Col-Treg for refractory non-infectious uveitis, which is planned to start a placebo-controlled, dose-ranging clinical study mid-2015."

Keith Thompson, CEO of the Cell Therapy Catapult said: "The Cell Therapy Catapult is delighted to work with TxCell to undertake the process and manufacturing development of TxCell's ASTrIA product platform and lead product Ovasave, an important potential treatment for refractory Crohn's disease. Through the value of our offering as an international partner we will be able to add considerable cell therapy industry expertise to help TxCell develop cost-effective and scalable manufacturing processes that will be flexible for TxCell's future requirements."

## **About the Ovasave Agreement**

The exclusive worldwide Ovasave license option agreement was signed by Ferring International Center (SA) (Ferring) and TxCell in December 2013. Its assignment to Trizell was announced on January 2, 2015. Ferring and Trizell are both affiliates of the Dr Frederik Paulsen Foundation. Ferring secured the option from TxCell for €3 million (of which €2 million has been received by TxCell) and is the intended final commercializing party for Ovasave for the treatment of Inflammatory Bowel Disease (IBD), including Crohn's disease and ulcerative colitis. The agreement includes supplementary development, commercial and manufacturing milestone payments of up to €73 million, plus royalties on future sales of Ovasave. Trizell Holding SA is a company dedicated to advanced therapies, i.e. cellular and gene therapies. Ovasave will benefit from the additional focus and expertise that Trizell will supply. Ferring remains the intended final commercializing party.

#### **About TxCell**

TxCell develops innovative, cost-effective, 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. A placebocontrolled, dose-ranging proof of principle clinical study is planned to start mid-2015. 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 65 employees based at its headquarters and at its manufacturing site in Besançon. For more information, please visit www.txcell.com

## **About the Cell Therapy Catapult**

The Cell Therapy Catapult is a centre of translational excellence for cell therapy and regenerative medicine. Its vision is for the UK to be a global leader in the development, delivery and commercialisation of cell therapy, making it a location for business start-up and growth. Based in London at Guy's Hospital, the centre takes products into early clinical trials, providing clinical, technical, manufacturing, regulatory, health economics and market access expertise. There is a focus on collaboration and lowering barriers to investment and funding, and operations have grown rapidly since inception. UK Trade & Investment has valued the global regenerative medicine industry at just over £500 million, and estimates that it will be generating revenues of over £5 billion by 2021. For more information go to <a href="https://www.ct.catapult.org.uk">www.ct.catapult.org.uk</a>

# **About Catapults**

Catapult centres are being established and overseen by Innovate UK as a new addition to its range of programmes to stimulate innovation. They are places where the best of the UK's innovative businesses and researchers work together to bring new products and services more quickly to commercialisation. Focusing on areas with great market potential, Catapults will open up global opportunities for the UK and generate economic growth for the future. For more information, please visit www.catapult.org.uk

## **About Innovate UK**

Innovate UK is the new name for the Technology Strategy Board – the UK's innovation agency. Taking a new idea to market is a challenge. Innovate UK funds, supports and connects innovative businesses through a unique mix of people and programmes to accelerate sustainable economic growth. For further information visit <a href="https://www.innovateuk.org">www.innovateuk.org</a>

## **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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