

# TxCell reports revenues for 2014 and updates on upcoming milestones

**Valbonne, France, February 4, 2015 - TxCell (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, today reports its revenues<sup>1</sup> as of December 31, 2014 and updates on forthcoming milestones.

## **Revenues:**

During the year 2014, the company generated revenues of  $\leq 1,327$  thousand, including  $\leq 1,083$  thousand for the fourth quarter of 2014. This compares with a revenue of  $\leq 17$  thousand for the year 2013, recorded during the fourth quarter of 2013.

The revenue of €1,083 thousand for the fourth quarter of 2014 comes exclusively from the Ovasave<sup>®</sup> partnership with Ferring/Trizell. This corresponds to:

- The revenue of €83 thousand relating to the amortization of the payment of €1 million received after the agreement signature on December 12, 2013;
- The revenue of €1,000 thousand relating to the first patient enrolment in the Ovasave phase IIb clinical study.

#### Cash and cash equivalents:

Cash and cash equivalents stood at  $\leq 13.9$  million at December 31, 2014, compared with  $\leq 14.9$  million at September 30, 2014 and  $\leq 0.7$  million at December 31, 2013. This amount includes the gross payment of  $\leq 1.7$  million zero rate loan (*Prêt à Taux Zéro Innovation (PTZI)*) granted by Bpifrance to advance Ovasave through clinical development. The PTZI is not deductible from the credit base of Research Tax Credit and represents an additional financing tool for research and development activities.

# **Highlights of the period:**

- Start of the international and multi-center phase IIb study for Ovasave, TxCell's lead product candidate from its ASTrIA platform for refractory Crohn's disease. This study will enroll 160 patients and will be conducted in 6 European countries.
- **Obtaining Orphan Drug Designation in Europe for Col-Treg,** TxCell's second product candidate, in noninfectious uveitis (autoimmune uveitis), a rare disease and a leading cause of blindness in the developed world and with currently few therapeutic options. This designation follows the presentation of Col-Treg efficacy and good tolerability results, obtained in an auto-immune uveitis model.
- Assignment of Ovasave collaboration, option, development and license agreement to Trizell Ferring remains the intended final commercializing party. Both companies are affiliates of the Dr Frederik Paulsen Foundation. Ovasave will benefit from the additional focus and expertise that Trizell will supply in advanced therapies area, i.e. cellular and gene therapies.

<sup>&</sup>lt;sup>1</sup> Unaudited and not subject to approval by the Board of Directors



## Upcoming milestones:

- Start of Col-Treg "proof of principle" clinical study in steroid refractory auto-immune uveitis patients, planned to start mid-2015;
- Ovasave and Col-Treg regulatory status update in the United States, expected mid-2015;
- Opinion of the First Data and Safety Monitoring Board (DSMB) meeting for Ovasave phase IIb study, expected end of 2015;
- Top line results of Col-Treg "proof of principle" clinical study, expected mid-2016;
- Top line results of Ovasave phase IIb clinical study, expected at the end of 2016 to early 2017.

"The results from TxCell's fourth quarter of 2014 confirms our pipeline advancement continues on schedule, with positive results obtained for Col-Treg in an auto-immune uveitis model and the launch of one of the largest controlled clinical study for Ovasave, a personalized T-cell immunotherapy product," said Damian Marron, CEO, TxCell. "During this period, TxCell moved its innovative programs forward in line with plans while maintaining a tight control on expenditure. The year 2015 should be rich in key milestones to further develop the company and its products, with the aim to further create value."

## Next events:

- 27<sup>th</sup> Annual ROTH Conference, March 8-11, 2015
- ARM's (Alliance for Regenerative Medicine) 3<sup>rd</sup> Annual Regen Med Investor Day, March 25, 2015
- ARVO (Association for Research in Vision and Ophthalmology) 2015 Annual Meeting, May 3-7, 2015
- 18th Annual ISCT (International Society for Cellular Therapy) Meeting, May 27-30, 2015
- The European Society of Ophthalmology (SOE) 2015 Congress, June 6-9, 2015

# Next financial releases:

- Annual 2014 results on April 1, 2015 (before market)
- First quarter 2015 revenues on May 6, 2015 (after market)

#### **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 technology 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 placebo-controlled, dose-ranging proof of principle clinical study is planned to start in the first half of 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 56 employees based at its headquarters and at its manufacturing site in Besançon. For more information, please visit www.txcell.com



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#### **Important Disclaimers:**

**Forward Looking Statements**. This press release contains forward-looking statements with notably respect to the strategy and outlook of TxCell. Although TxCell believes that such forward-looking statements are based on reasonable assumptions, such statements are not guarantees of future performance of the company. Actual results may differ materially from the forward-looking statements as a result of a number of risks and uncertainties, many of which are outside our control, including but not limited to the risks described in the documents TxCell filed with the Autorité des Marchés Financiers (French securities regulator). Investors and security holders may obtain a free copy of documents filed by TxCell with the Autorité des Marchés Financiers at <u>www.amf-france.org</u>, or directly from TxCell. Forward-looking statements contained herein are made as of the date of this press release.