



## TxCell 2014 results: strengthening of cash position and development of ASTrIA product platform

- **IPO and receipt of milestone payments: cash at €13.9 million end of 2014**
- **Start of the international phase IIb study for Ovasave® in Crohn's disease**
- **Positive results for Col-Treg, second product candidate, in an auto-immune uveitis model**

**Valbonne, France, April 1, 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 2014 financial results and activities.

The fiscal 2014 accounts have been approved for issue by the Board of Directors in its meeting held on March 30, 2015. The accounts for fiscal year 2014 have been audited and the auditor's report is pending.

"TxCell in 2014 has seen a number of very important events. The Initial Public Offering of the company gives medium term financial visibility and allows us to accelerate the clinical development of our targeted T-cell immunotherapies in 2015 and beyond," said Damian Marron, Chief Executive Officer TxCell. "The start of the phase IIb study for Ovasave®, our lead product candidate in refractory Crohn's disease, was a key step in the development of TxCell. We also obtained the GMP certificate for TxCell's manufacturing platform. In addition, we obtained positive results for our second product candidate Col-Treg for the treatment of autoimmune uveitis. Col-Treg also obtained the classification of Innovative Medication Therapy by the European Medicines Agency as well as the orphan drug designation from the European Commission. This program, for which we expect to start a clinical trial phase I/II in 2015 to establish the proof of concept, will not only allow TxCell to expand its portfolio of cellular immunotherapy products in clinical stage, but also to demonstrate the potential and growth of its ASTrIA product platform."

### **Product candidate pipeline progress during the fiscal year 2014:**

- **Ovasave**, lead product candidate from ASTrIA product platform
  - Finalization of the manufacturing process for the phase IIb clinical study
  - Start of the international phase IIb clinical study (CATS29) in December 2014
- **Col-Treg**, second product candidate from ASTrIA
  - Start of Col-Treg development in autoimmune uveitis
  - Classification of Innovative Medication Therapy by the European Medicines Agency
  - Presentation of positive results obtained in an autoimmune uveitis model
  - Obtaining of European orphan drug designation

### **Other highlights of the period:**

- Initial Public Offering on April 11, 2014 on Euronext market, Compartment C, with a gross fundraising of €16.2 million, the correlative conversion of the convertible bond loan of €3.5 million in February 2014, completed by an additional gross fundraising of €1.5 million in May 2014;

- Issuance by the French *Agence Nationale de Sécurité du Médicament (ANSM)* of the certificate of compliance with Good Manufacturing Practices (GMP) for TxCell's cell therapy production unit in Besançon, France;
- Launch and grant award of €417 thousand for the collaborative project POSITIVE (including €250 thousand for TxCell). This project focuses on the development and implementation of procedures to automate the first step of Ovasave manufacturing process;
- Obtaining of a €1.7 million zero rate loan (*Prêt à Taux Zéro Innovation (PTZI)*) granted by Bpifrance to advance Ovasave through clinical development;
- Assignment of the collaboration agreement from Ferring to Trizell, an affiliate of the Dr Frederik Paulsen Foundation, which allows Ovasave to benefit from the additional focus and expertise that Trizell will supply in advanced therapies area, i.e. cellular and gene therapies.

### **2015 highlights to date and next milestones:**

- Grant of a key US patent by the American patent and trademarks office (USPTO) that protects Ovasave until 2030 minimum.

#### Next 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.

### **Results for the year under the IFRS standard:**

- The revenue of €1.3 million comes exclusively from the Ovasave partnership with Ferring/Trizell. This corresponds to:
  - The revenue of €0.3 million relating to the amortization until December 31, 2016 of the payment of the first milestone after the agreement signature;
  - The revenue of €1.0 million relating to the accounting of the second milestone of this agreement corresponding to the first patient enrolment in the Ovasave phase IIb clinical study.
- Other operating revenues correspond to public funding for research expenditures. As of December 31, 2014, they mainly include the 2014 French research tax credit for an amount of €2.0 million.
- Operating expenses include 78% of research and development expenses which increased over the year mainly due to:
  - Starting of Col-Treg development and costs related to essential preclinical requirements to the launch of a clinical phase I/II study planned for mid-2015;
  - Preparing and starting the Ovasave phase IIb clinical study in December 2014;
  - Incurred expenses for the GMP certificate issuance by the ANSM in June 2014 for the manufacturing unit of the company.

Also note the accounting of expenses related to share-based payments for stock option plan granted to employees and directors for €1.6 million.

- Net loss for the year amounted to €8.3 million against €5.5 million in 2013, an increase of €1.2 million, excluding expenses related to share-based payments.
- Cash and cash equivalents stood at €13.9 million at December 31, 2014, thanks to the payment of the first milestone of Ferring agreement, capital increases for €21.2 million gross, 2013 research tax credit for €1.8 million and PTZI for €1.7 million gross as well as a tight control of cash flows from operating activities.

The IFRS income statement at December 31, 2014 is as follows (in euros):

In thousands of €	12/31/2014	12/31/2013
Revenue	1 327	17
Other income	2 094	1 757
<b>Revenue and other income</b>	<b>3 421</b>	<b>1 774</b>
Research and development expenses	7 836	5 673
General and administrative expenses	2 243	1 550
Expenses related to share-based payments	1 615	1
<b>Net operating expenses</b>	<b>-8 273</b>	<b>-5 450</b>
Income from cash and cash equivalents	68	1
Cost of gross financial debt	60	0
<b>Cost of net financial debt</b>	<b>8</b>	<b>1</b>
Other financial income	1	1
Other financial costs	5	3
<b>Net income / (loss) before tax</b>	<b>-8 269</b>	<b>-5 451</b>
Tax expenses	0	0
<b>Net income / (loss)</b>	<b>-8 269</b>	<b>-5 451</b>

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#### Next financial releases:

- 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 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 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 65 employees based at its headquarters and at its manufacturing site in Besançon. For more information, please visit [www.txcell.com](http://www.txcell.com)



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**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 [www.amf-france.org](http://www.amf-france.org), or directly from TxCell. Forward-looking statements contained herein are made as of the date of this press release.