



## Press release

### **TxCell 2015 results and update on strategy and outlook**

**Conference call and webcast in English: Friday March 11 at 3:30pm CET**

**Valbonne, France, March 10, 2016 – TxCell SA (FR0010127662 – TXCL)**, a biotechnology company developing innovative, personalized cell immunotherapies using regulatory T-cells for the treatment of severe chronic inflammatory and autoimmune diseases, today announces its financial results for 2015 and provides an update on its strategy and outlook.

“TxCell has implemented a shift in strategy during 2015 by transferring its production activities in order to refocus solely on the core business with high added-value, i.e. research, clinical development and strategic partnerships. TxCell now intends to fully leverage its technological breakthrough and to extend it to new autoimmune diseases with high unmet medical needs, such as lupus, multiple sclerosis and pemphigus,” said Stéphane Boissel, CEO of TxCell. “TxCell is now set to deliver on a very ambitious plan with five-year objectives. These include starting first registration trials and moving up to three new product candidates into clinical development. For ENTrIA, TxCell’s new platform of engineered CAR-Tregs, we expect to be able to release the first proof-of-concept data sets this year. As we progress, TxCell will aim to enter into new partnerships with pharma companies in order to accelerate its development.”

“TxCell is currently assessing several options, including signing strategic partnerships with pharma companies and/or new equity financing to fund its R&D activities up to its next meaningful clinical milestones, in particular phase IIb clinical results for Ovasave® in Crohn's disease expected in late 2017 or early 2018,” said Raphael Flipo, CFO of TxCell. “TxCell is convinced that its ambitious and voluntary strategy could present shareholders with a unique opportunity to participate in our growth.”

#### **Main developments since January 1, 2015:**

- Changes in the management team, including the appointment of Stéphane Boissel as the new CEO, and governance structure strengthened with the appointment of Dr. David Horn Solomon as a new independent director
- Capital increase through a private placement of approximately €8 million, representing around 9.95% of the total capital, with the majority of investors based outside of France and specializing in healthcare
- Review of TxCell’s production strategy with the decision to outsource all current and future production activities in order to focus on core, high-added-value activities, i.e. research, clinical development and strategic partnerships:

- Outsourcing agreement with MaSThercell for the production of the phase IIb clinical supplies for Ovasave. MaSThercell has been appointed as TxCell's exclusive production partner in Europe for all cell therapy products arising from the ASTrIA platform for a 5-year period.
- Closure of TxCell's Besançon production site
- Successful production of the first test batches of Ovasave by MaSTherCell, allowing plans to resume the phase IIb study in Crohn's disease in the second quarter of 2016
- Launch of new laboratories for developing production processes and the TxCell Academy for Technology Transfer.
- Major regulatory progress in the USA:
  - Fast Track Designation granted by the FDA (US Food and Drug Administration) for Ovasave
  - IND (Investigational New Drug) request accepted to extend to the United States CATS29, the phase IIb trial for Ovasave as a treatment for Crohn's disease
  - Key patent for Ovasave in the treatment of inflammatory bowel diseases delivered by the US Patent and Trademark Office
  - Orphan Drug Designation (ODD) granted by the FDA for Col-Treg, TxCell's product-candidate for the treatment of non-infectious uveitis.
- Development of ENTrIA, a new platform for cellular immunotherapy products made up of genetically modified regulatory T cells (CAR-Tregs). Also, signature of an agreement with Yeda, the technology transfer arm of the world-famous Weizmann Institute of Sciences, granting TxCell an option to an exclusive license on CAR-Tregs patent applications.
- Signature in December 2015 of an agreement terminating the Ovasave collaboration, option, development and licensing agreement with Trizell. This will allow TxCell to reacquire all rights pertaining to Ovasave which were previously granted to Trizell, in exchange for payments which could total up to €15 million<sup>1</sup>.
- Notification from the Japan Patent Office of its intention to grant a key patent for Ovasave in Japan.

**Financial highlights:**

The financial statements for the year ended December 31, 2015 were approved by TxCell's Board of Directors on March 8, 2016. The 2015 financial statements have been audited and the auditors' report was issued on March 9, 2016. TxCell's annual financial report, included in the registration document, will be available in April 2016.

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<sup>1</sup> As per the terms of this agreement, TxCell terminates Trizell's option to obtain an exclusive license to Ovasave, in exchange for payments which could total a minimum of €6 million and a maximum of €15 million, generally split as follows:

- An upfront payment of €2 million to be paid upon signature. This payment was made by TxCell in December 2015.
- Two milestones payments of €2 million to be paid 2 years and 3 years post-signature, respectively, within the limit of a maximum total amount of €15 million overall
- Potential royalties based on revenues generated by Ovasave, within the limit of a maximum total amount of €15 million overall.

Financial highlights are as follows:

- Cash burn of €12.3 million in 2015, including an upfront payment of €2 million to Trizell as per the terms of the termination agreement for Ovasave.
- Cash and cash equivalents of €9.2 million at December 31, 2015 (€13.9 million at December 31, 2014) before receipt of the 2015 research tax credit of around €3 million.
- Revenue and other income of €4.6 million (€3.4 million in 2014), mainly due to the research tax credit (€3.0 million) and the pharmaceutical partnership regarding Ovasave that was terminated on December 2, 2015 (€1.5 million).
- R&D expenditure of €10.8 million (€7.8 million in 2014) representing 73% of the Company's current operating expenses. The increase was mainly due to higher outsourcing costs resulting from the increase in developments underway.
- Other operating expenses of €1.2 million, consisting of restructuring costs related to the closure of the Besançon site.
- Full-year net loss of €11.3 million (€8.3 million in 2014), representing a €1.9 million increase in losses excluding restructuring costs.

The IFRS income statement for the year ended December 31, 2015 is as follows:

In thousands of euros	31/12/2015	31/12/2014
Revenue	920	1,327
Other income	3,718	2,094
<b>Revenue and other income</b>	<b>4,637</b>	<b>3,421</b>
Research and development expenses	10,839	7,836
General and administrative expenses	3,460	2,243
Expenses related to share-based payments	483	1,615
<b>Current operating income / (loss)</b>	<b>(10,145)</b>	<b>(8,273)</b>
Other operating expenses	(1,189)	0
Other operating income	22	0
<b>Operating income / (loss)</b>	<b>(11,312)</b>	<b>(8,273)</b>
Income from cash and cash equivalents	42	68
Cost of gross financial debt	0	60
<b>Cost of net financial debt</b>	<b>42</b>	<b>8</b>
Other financial income	10	1
Other financial expenses	37	5
<b>Net income / (loss) before tax</b>	<b>(11,297)</b>	<b>(8,269)</b>
Income taxes	0	0
<b>Net income / (loss)</b>	<b>(11,297)</b>	<b>(8,269)</b>
Basic earnings per share (€)	-0.92	-0.78

It should be noted that, on the basis of TxCell's development plan, including the continuation of clinical trials on Ovasave® and the start of clinical trials on Col-Treg, the company's cash burn is likely to be around €15 million in 2016.

### **Main objectives for 2016:**

TxCell's main objectives for the current year are as follows:

- Resumption of phase IIb trial on Ovasave in the second quarter of 2016. The first results are expected in late 2017 or early 2018.
- Completion of pre-clinical development and regulatory dossier for Col-Treg, with the aim of starting the first clinical trial in non-infectious uveitis in the near future
- Generation of pre-clinical proof of concept data on the ENTrIA platform
- Signature of strategic partnerships with major pharmaceuticals and biotech players to further speed up development of ASTrIA and ENTrIA platforms
- Improvements to TxCell's production process for the ASTrIA platform and initiation of the development of a production process for the ENTrIA platform
- Selection of a CMO (Contract Manufacturing Organization) in the USA to expand TxCell's geographical production offering
- Creation of a SAB (Scientific Advisory Board) to strengthen the Company's scientific expertise and strategic decision-making in relation to the development of its new ENTrIA platform.

### **Conference call and webcast in English:**

A conference call and webcast will be held on Friday, March 11, at 3:30pm CET.

To take part:

- Telephone number: +33 (0)1 70 77 09 44
- Link to the webcast:  
<http://www.anywhereconference.com?UserAudioMode=DATA&Name=&Conference=135299977&PIN=73954371>

Following the live call, a replay will be available for 90 days. To listen to the replay, please dial: +33 (0)1 72 00 15 00 / 299977#

### **Forthcoming financial events:**

- First quarter 2016 revenue and cash position: April 20, 2016 (after market)
- Shareholders' general meeting: April 21, 2016

### **About ASTrIA**

ASTrIA (Antigen Specific Treg for Inflammation and Autoimmunity) is a TxCell proprietary cellular immunotherapy product platform composed of autologous antigen specific Type 1 Regulatory T cells (Ag-Treg). Ag-Treg based products from the ASTrIA platform are produced from the peripheral blood of patients. After white blood cell isolation, CD4+ T cells are educated to recognize a specific antigen. Antigen educated Treg cells are then isolated and expanded ex-vivo. Ovasave®, the first Ag-Treg product candidate from the ASTrIA platform, has been developed for the treatment of Inflammatory Bowel Disease (IBD) and is composed of ovalbumin-specific Type 1 Treg cells. Ovasave is currently in a European Phase IIb clinical study in severe Crohn's Disease, entitled CATS29. Col-Treg is the second candidate from the ASTrIA platform and is composed of type-2 Collagen-specific Type 1 Treg cells. Col-Treg is developed for the treatment of steroid-refractory non-infectious uveitis.

## About ENTrIA

ENTrIA (Engineered Treg for Inflammation and Autoimmunity) is the second TxCell proprietary cellular immunotherapy product platform and is composed of Chimeric Antigen Receptor engineered Foxp3+ Regulatory T cells (CAR-Treg). After their isolation from the blood of patients, Foxp3+ Treg cells are genetically modified by transduction with Chimeric Antigen Receptors (CAR). The CAR introduced into FoxP3+ Treg cells is designed to allow Foxp3+ Treg cell activation and immuno-modulation through in vivo recognition of a protein present in inflamed areas in patients suffering from autoimmune and chronic inflammatory diseases.

## About TxCell: [www.txcell.com](http://www.txcell.com)

TxCell is a publicly listed biotechnology company that develops platforms for innovative, personalized T cell immunotherapies for the treatment of severe chronic inflammatory and autoimmune diseases with high unmet medical need. TxCell is the only clinical stage cellular therapy company dedicated to the science of regulatory T lymphocytes (Tregs). Tregs are a recently discovered T cell population for which anti-inflammatory properties have been demonstrated. Ovasave®, TxCell's lead product candidate, is currently in a phase IIb clinical trial in refractory Crohn's disease patients. Col-Treg, the TxCell's second drug candidate developed as a treatment for autoimmune uveitis, is expected to enter in clinical studies in the near future. Based in Sophia-Antipolis, France, TxCell is listed on Euronext Paris and currently has 47 employees.

## Contacts:

### TxCell

Raphaël Flipo

CFO

Tél: +33 4 97 21 83 00

[contact@txcell.com](mailto:contact@txcell.com)

### NewCap

Financial Communication

Julien Perez / Pierre Laurent

Tél: +33 1 44 71 94 94

[txcell@newcap.eu](mailto:txcell@newcap.eu)



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## Forward-Looking Statements - TxCell

This press release contains certain forward-looking statements relating to the business of TxCell, which shall not be considered *per se* as historical facts, including TxCell's ability to develop, market, commercialize and achieve market acceptance for specific products, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements, needs for additional financing. In addition, even if the actual results or development of TxCell are consistent with the forward-looking statements contained in this press release, those results or developments of TxCell may not be indicative of their in the future.

In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. Although the management of TxCell believes that these forward-looking statements are reasonably made, they are based largely on the current expectations of TxCell as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of TxCell could be affected by, among other things, uncertainties involved in the development of the Company's products, which may not succeed, or in the delivery of TxCell's products marketing authorizations by the relevant regulatory authorities and, in general, any factor that could affect TxCell capacity to commercialize the products it develops, as well as, any other risk and uncertainties developed or identified in any public documents filed by TXcell with the AMF, included those listed in chapter 4 "Risk factors" of the 2014 *document de référence* approved by the AMF on June 11, 2015 under number R.15-049 and in section 5.1 of its *actualisation* filed with the AMF on January 25, 2016 under number D.15-0402-A01. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made in this press release will in fact be realized. Notwithstanding the compliance with article 223-1 of the General Regulation of the AMF (the information disclosed must be "accurate, precise and fairly presented"), TxCell is providing the information in these materials as of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.