



## Press release

### **TxCell: financial information for the 3<sup>rd</sup> quarter of 2016**

**Valbonne, France, November 8, 2016 – TxCell SA (FR0010127662 – TXCL)**, a biotechnology company developing innovative, personalized cellular immunotherapies using regulatory T cells (Treg) to treat severe chronic inflammatory and autoimmune diseases, today reports its revenues for the third quarter of 2016 and its cash position as of September 30, 2016.

#### **Cash position and revenues as of September 30, 2016**

As of September 30, 2016, TxCell's cash and cash equivalents amounted to €4.6 million<sup>1</sup>, vs. €3.2 million as of June 30, 2016. In August 2016, TxCell received €2.9 million net following the issue of a first tranche of convertible notes (with an additional potential €1.5 million should the attached warrants be fully exercised), as part of the €20 million financing (plus 50% warrants coverage) facility. In August 2016, TxCell also received €1.1 million for the partial financing of its 2016 research tax credit.

A second tranche of convertible notes amounting to €2 million was exercised on November 3, 2016 (with an additional potential €1 million should the attached warrants be fully exercised).

TxCell also has access to a standby facility for the pre-financing of its research tax credit, as well as a standby equity facility (SEF<sup>®</sup>, PACEO<sup>®</sup>) implemented on December 22, 2015. To date, TxCell has not used its PACEO<sup>®</sup> facility.

As expected, TxCell did not generate revenues during the third quarter of 2016 and confirms its operating cash burn guidance for 2016, from €15 million initially down to approximately €12 million.

#### **Key operational highlights**

##### **TxCell initiated over 10 new CAR-Treg programs, including a major collaboration with UBC**

- TxCell has intensified the research efforts on its second technology platform, ENTrIA, composed of engineered regulatory T cells (CAR-Treg). Over the last months, these efforts have led to the initiation of more than 10 new CAR development programs. Initially, TxCell is focusing on 4 to 5 programs with the following objectives: firstly, to generate additional preclinical proof-of-concept data regularly and, secondly, to start at least one first-in-man clinical study before the end of 2018.

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<sup>1</sup> Unaudited data.

- In October 2016, TxCell started a collaboration with the University of British Columbia (UBC). This agreement covers the development of a CAR-Treg-based cellular immunotherapy for the prevention of graft rejection in the context of Solid Organ Transplantation (SOT). The activities will be led by Professor Megan Levings, who earlier this year established a first-ever preclinical proof of concept with human HLA-A2-specific CAR-Treg cells in a preclinical transplantation model<sup>2</sup>. This followed the initiation of two other collaborations with leading European academic laboratories in the first half of 2016, Ospedale San Raffaele (OSR) and the Lübeck Institute of Experimental Dermatology (LIED).

### **TxCell continues to work with world-leading experts in cellular therapy**

- Li Zhou, PhD, was appointed Vice President, Cell Engineering of TxCell in September 2016. Dr. Zhou brings extensive pharmaceutical experience in antibody engineering and T-cell engineering to strengthen and accelerate the development of TxCell's ENTrIA CAR-Treg platform. Dr. Zhou was notably Lab Head, Investigator at the Novartis Biologics Center in Cambridge (Massachusetts, US), from 2009 to 2016. In this role, he led the discovery and engineering activities on Chimeric Antigen Receptor (CAR) T cells (CAR-T) for cancer immunotherapy, with lead candidates now in clinical trials. In his new role at TxCell, he leads the discovery and engineering activities on Chimeric Antigen Receptor in Treg cells (CAR-Treg) for immunotherapy of severe chronic autoimmune and inflammatory diseases as well as organ transplantation.
- In August 2016, TxCell appointed Olivier Danos, PhD, Senior Vice President of Cell and Gene Therapy at Biogen and a world-leading expert in the field of Gene Therapy for hematological and neurological diseases, to its Scientific Advisory Board (SAB). TxCell's SAB met for the first time in September 2016. Priority ranking of the ENTrIA programs was among the key topics during this meeting.

### **Manufacturing process improvement with the ASTRiA platform and update on Ovasave®**

- In September 2016, TxCell announced it had identified a new isolation method for its non-engineered Treg cells (ASTriA platform). This innovative procedure should enable a reduction of approximately 50% of both the production costs and the overall manufacturing leadtime, as well as a reduction of the risk of non-compliant manufacturing for future clinical trials and a potential commercial launch. Combining these encouraging preliminary results and TxCell's strict cost control policy, TxCell has decided to finalize and GMP-prove this new manufacturing process prior to the initiation of clinical trials from the ASTRiA platform. Resulting from this decision, the clinical development of Ovasave® in refractory Crohn's disease will not restart immediately.

### **Next financial milestone**

- Q4 2016 revenues and cash position as of December 31, 2016: January 25, 2017 (after market close).

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<sup>2</sup> MacDonald KG, Hoeppli RE, Huang Q, Gillies J, Luciani DS, Orban PC, Broady R, Levings MK. Alloantigen-specific regulatory T cells generated with a chimeric antigen receptor. *J Clin Invest.* 2016, 126(4):1413-1424.

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

TxCell is a 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 targeting a range of autoimmune diseases (both T-cell and B-cell-mediated) including Crohn's disease, lupus nephritis, bullous pemphigoid and multiple sclerosis, as well as transplantation-related inflammatory disorders.

TxCell is the only clinical-stage cellular therapy company fully 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. Contrary to conventional approaches based on non-specific polyclonal Tregs, TxCell is exclusively developing antigen-specific Tregs. This antigen specificity may either come from pre-existing Treg cell T-Cell Receptor (TCR) or from genetic modifications with Chimeric Antigen Receptor (CAR). TxCell is developing two proprietary technology platforms, ASTrIA, which is composed of non-modified naturally antigen-specific Tregs, and ENTrIA, which is composed of genetically-engineered Tregs.

Based in Sophia-Antipolis, France, TxCell is listed on Euronext Paris and currently has 49 employees.

## Next events

### Financial and business conferences

Nov 7-9, 2016	BIO Europe	Cologne (Germany)
Nov 16-17, 2016	Jefferies London Healthcare Conference	London (UK)
Nov 18-19, 2016	Actionaria	Paris (France)
Nov 21-23, 2016	German Equity Forum	Frankfurt (Germany)
Nov 30-Dec 1, 2016	BioFIT	Lille (France)

### Scientific conferences

Nov 29-30, 2016	Cell Therapy Manufacturing & Gene Therapy Congress	Amsterdam (NL)
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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 2015 *document de référence* approved by the AMF on May 24, 2016 under number R.16-048. 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.