



Press release

TxCell and University of British Columbia start collaboration to develop CAR-Tregs in solid organ transplantation

Regulatory T cells have already demonstrated potential to address transplant rejection, a major challenge in transplantation

Major collaboration between TxCell and UBC team results from recently published first-ever proof of concept with human CAR-Treg cells in a preclinical model of transplantation

Valbonne, France, October 19, 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 announces the signature of a strategic R&D collaboration agreement with the University of British Columbia (UBC) in Vancouver, Canada, a leading global center for multidisciplinary research and teaching.

“As stated in our recent strategic update, TxCell continues to intensify its efforts on its ENTrIA platform of engineered regulatory T cells. TxCell has launched a third CAR-Treg collaboration in order to strengthen its recently initiated transplantation program,” said Stéphane Boissel, Chief Executive Officer of TxCell. *“Thanks to TxCell’s unparalleled expertise in the Treg space, we have secured access to the most advanced CAR-Treg programs worldwide. We expect this to help us achieve our goal of launching a first-in-man clinical study with a first CAR-Treg in 2018.”*

This collaboration 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). Activities relating to this program will be primarily conducted in the UBC laboratories. The activities will be led by Professor Megan Levings, who earlier this year established a first preclinical proof of concept with human HLA-A2-specific CAR-Treg cells in a preclinical transplantation model¹. UBC will conduct non-clinical pharmacology studies with CAR-Treg cells with the aim of initiating a first-in-man study in transplantation patients as soon as possible.

“The recent in vivo proof of concept published by UBC in a leading international scientific journal is a critical milestone in the pioneering field of CAR-Treg cells,” said Arnaud Foussat, Senior Vice President, Corporate Development and Head of External Collaborations & Alliance

¹ 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.

Management of TxCell. *“In contrast to existing approaches based on polyclonal Tregs already tested in clinical trials, we have chosen to bring antigen specificity through a CAR, with the aim of increasing the potential to address the vast unmet medical need in transplantation. We are honoured that Prof. Levings has chosen TxCell as its partner for this program and we are looking forward to our collaboration towards a common goal of initiating a first-in-man study as rapidly as possible.”*

“TxCell has unique experience in the development of Treg-based cellular immunotherapies and we are excited to collaborate to develop CAR-Treg therapy for unmet medical needs in transplantation,” said Dr. Megan Levings, Professor, Department of Surgery, UBC and Head, Childhood Diseases Research Theme, BC Children's Hospital. *“The collaboration will allow us to assess the potential of CAR-Treg cells in preclinical models of solid organ transplantation.”*

The UBC team demonstrated that, in a preclinical xenogeneic Graft-vs-Host Disease (GvHD) model, human CAR-engineered Treg cells that are specific for the molecule HLA-A2 were more effective than polyclonal Treg cells in reducing GvHD-related inflammation. The model used by Dr. Levings' team is based on xenogeneic GvHD induced in immunodeficient mice through the injection of human HLA-A2+ white blood cells. These human white blood cells (graft) attack the immunodeficient mice (host), resulting in an inflammatory reaction (Graft-vs-Host Disease, GvHD). The CAR used in this experiment was designed to specifically recognize the HLA-A2 molecule found solely on graft cells. These data will constitute the basis for the first product development under the new TxCell/UBC collaboration announced today.

Whilst the UBC team is focused on product development activities, it will in parallel perform research activities in the CAR-Treg field with the aim of optimizing and broadening the new product platform for transplantation.

TxCell has an exclusive option on programs and products developed under this agreement. Financial terms of the collaboration have not been disclosed.

About Organ Transplantation

Solid Organ Transplantation (SOT) consists in moving an organ (graft) from one body (donor) to another body (recipient or host), to replace the recipient's damaged or absent organ. More than 30,000 organ transplants were performed in the US in 2015², and more than 31,000 in Europe in 2013³. Transplant rejection is one of the key challenges of transplantation. In order to avoid such rejection, the most appropriate donor-recipient match is sought and immunosuppressant drugs can be used. In 2014, the global market of immunosuppressant drugs used in transplantation was estimated to reach \$5.1 billion⁴. In the US alone, the cost of long term oral maintenance immunosuppression and other prescription drugs represents between \$10,000 and \$14,000 per patient per year on average, and can exceed \$2,500 per month for certain patients⁵. Novel strategies aiming at inducing or restoring immune tolerance

² US Department of Health & Human Services. 'More than 30,000 transplants performed annually for first time in United States' January 9, 2016.

³ European Commission, Journalist workshop on organ donation and transplantation, November 26, 2014.

⁴ Organ Transplant Immunosuppressant Drugs Market, Transparency Market Research 2015.

⁵ James A, Mannon RB. The Cost of Transplant Immunosuppressant Therapy: Is This Sustainable? Curr. Transplant. Rep. 2015, 2(2):113-121.

to a graft are expected to be less toxic and more efficient on the long-term than classical pharmacological immunosuppressive approaches.

About UBC – www.ubc.ca

The University of British Columbia is a global centre for research and teaching, consistently ranked among the top 20 public universities in the world. Since 1915, UBC's West Coast spirit has embraced innovation and challenged the status quo. UBC encourages its students, staff and faculty to challenge convention, lead discovery and explore new ways of learning. At UBC, bold thinking is given a place to develop into ideas that can change the world.

About TxCell – 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

Oct 26, 2016	GGs Equity Forum	Heilbronn (Germany)
Nov 3, 2016	ARM EU Advanced Therapies Investor Day	London (UK)
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)

Scientific conferences

Oct 15-19, 2016	United European Gastroenterology Week 2016	Vienna (Austria)
Oct 18-21, 2016	European Society of Gene and Cell Therapy (ESGCT) Annual Meeting 2016	Firenze (Italy)
Nov 29-30, 2016	Cell Therapy Manufacturing & Gene Therapy Congress	Amsterdam (NL)

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Disclaimer

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.