



Press release

TxCell obtains authorization from European regulatory authorities to restart Ovasave® Phase IIb clinical trial

Valbonne, France, May 25, 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, announces today that it has received authorization from European regulatory authorities to restart its Phase IIb, placebo-controlled clinical trial with lead product Ovasave® in patients with moderate to severe Crohn’s disease refractory to existing treatments (CATS29).

The authorization for TxCell to restart the CATS29 clinical study includes using a new manufacturer, the Contract Manufacturing Organization (CMO) MaSTherCell, and an amended protocol, through the Voluntary Harmonized Procedure (VHP). In February 2016, TxCell achieved the key milestone in the transfer of its manufacturing technology to MaSTherCell – the successful conduct of a series of contractually defined validation runs of Ovasave® at MaSTherCell’s site.

TxCell is therefore preparing to resume CATS29 as soon as possible. Topline data are expected within 18 to 21 months of trial resumption.

“Obtaining the authorization to restart our Phase IIb study in refractory Crohn’s patients as per the timeline announced mid-2015 is an important milestone for TxCell,” said Stéphane Boissel, CEO of TxCell. *“TxCell has made major internal structural changes over the past year. These decisions include the reacquisition of the full rights to Ovasave®, the decision to outsource our manufacturing activities, the appointment of MaSTherCell and PCT as our CMOs in Europe and in the US respectively and the start of ENTrIA, TxCell’s second platform, based on CAR-Treg cells. TxCell is now entirely focused on value-added activities in a new chapter for the company. With the CATS29 study, TxCell should obtain important controlled clinical data that will help us to position both our lead product as well as TxCell’s wider technology for the treatment of severe autoimmune and inflammatory disorders.”*

The CATS29 clinical study aims primarily at comparing Ovasave® at the 10⁶ dose vs. placebo. The objective is to achieve a response rate of 70% in the experimental arm vs. 30% in the control arm. 56 patients with moderate to severe refractory Crohn’s disease will be evaluated. The patients will be recruited in 29 clinical centers in 6 European countries. The 32-week treatment will be split into two phases: firstly an 8-week blinded phase, where patients will receive at week 0 either placebo or Ovasave® 10⁶ (randomized 1:1) and secondly a 24-week unblinded phase, where all patients will receive Ovasave® 10⁶ (three further open label

injections at 8-week intervals). TxCell now plans to amend its US IND (Investigational New Drug) accordingly.

The CATS29 Data and Safety Monitoring Board (DSMB) met ahead of the VHP approval to review all available data on previously treated patients, as well as updates on the study design and plans for the resumption of the study. The objective of the DSMB is to monitor patient safety during the conduct of the study. Upon reviewing of the data, the DSMB also allowed TxCell to proceed with the resumption of the CATS29 study as planned.

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 drug 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 drug 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

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 drug candidate, is currently in a Phase IIb clinical trial in refractory Crohn's disease patients. Col-Treg, its second drug candidate, is in preclinical development for the treatment of autoimmune uveitis. Based in Sophia-Antipolis, France, TxCell is listed on Euronext Paris and currently has 50 employees.

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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.