



Press release

TxCell appoints PCT as its US manufacturing partner

Valbonne, France, March 15, 2016 – TxCell SA (FR0010127662 – TXCL), a biotechnology company developing innovative, personalized cellular immunotherapies using regulatory T-cells to treat severe chronic inflammatory and autoimmune diseases, announces today the appointment of PCT, a Caladrius Company, as its contract manufacturing organization (CMO) in the US. The initial relationship could transition to a technology transfer, and to PCT having responsibility for the future manufacturing of TxCell’s clinical supply in the US.

PCT, a subsidiary of Caladrius Biosciences, Inc. (NASDAQ: CLBS) is a leading development and manufacturing partner to the cell therapy industry. PCT has been set up to overcome fundamental challenges of its clients’ cell therapy manufacturing with a wide range of services, from process development to GMP manufacturing and logistics.

Initially, PCT will operate a preliminary strategic evaluation of the existing TxCell manufacturing processes. These processes were designed by TxCell for its first platform of antigen specific regulatory T cells products (the ASTriA platform). Following completion, TxCell could start transferring its technology to PCT. This will achieve a source of clinical supply in the US for use when required.

“Entering into a strategic relationship with PCT for the future manufacturing of TxCell’s products in the US is yet another step in the advancement of the clinical development of TxCell’s product portfolio,” said Miguel Forte, MD, PhD, Senior Vice-president, Chief Operating Officer of TxCell. “Ovasave®, TxCell’s lead product developed in refractory Crohn disease, now has both an open IND as well as a Fast Track Designation in the US. In addition, Col-Treg, TxCell’s second most advanced product, has recently obtained Orphan Drug Designation status for the treatment of non-infectious uveitis in the US. TxCell is positioning itself to lever these regulatory statuses to conduct a first clinical trial with our products in the US with materials manufactured by PCT. TxCell also will plan to examine options for manufacturing in Asia, and specifically Japan.”

“PCT is proud that such an innovative cell therapy developer as TxCell has chosen PCT as its US external development and manufacturing partner. Their decision adds further credence to PCT’s international reputation as the partner of choice for cell-based therapy companies,” said Robert A. Preti, PhD, President of PCT and Senior Vice President, Manufacturing and Technical Operations and Chief Technology Officer, Caladrius Biosciences, Inc.

About PCT, a Caladrius Company

PCT, a subsidiary of Caladrius Biosciences, is a leading development and manufacturing partner to the cell therapy industry. PCT works with its clients to overcome the fundamental challenges of cell therapy manufacturing by providing a wide range of innovative services including product and process development, GMP manufacturing, engineering and automation, cell and tissue processing, logistics, storage and distribution, as well as expert consulting and regulatory support. PCT and Hitachi Chemical Co. have entered into a strategic global collaboration to accelerate the creation of a global commercial cell therapy development and manufacturing enterprise with deep engineering expertise. For more information, visit www.pctcaladrius.com.

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 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 product candidate, is currently in a phase IIb clinical trial in refractory Crohn's disease patients. Col-Treg, its second product candidate, for the treatment of 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 49 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 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.