Press Release

TxCell announces successful key milestone in the technology transfer to CMO partner MaSTherCell and updates on Ovasave® clinical trial status

Successful manufacturing validation runs of Ovasave paving the way for a resumption of the CATS29 phase IIb trial in Crohn's disease in Q2 2016 as planned

Valbonne, France, February 25, 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 it has successfully concluded the most important milestone in the transfer of its manufacturing technology to MaSTherCell, its contract manufacturing organization ("CMO") for the European manufacturing of TxCell's product portfolio, including its lead product Ovasave®.

MaSTherCell successfully completed the manufacturing of a series of contractually defined validation runs of Ovasave. Validation runs are conducted as a test to demonstrate the capacity of a new manufacturing unit to manufacture products according to specifications. Validation runs are an industry-defined marker of the successful transfer of technology to a CMO.

TxCell announced the signing of a strategic agreement with MaSTherCell in December 2015 for European manufacturing of all products from TxCell's first product platform ASTrIA. This was an extension to the agreement in July 2015 for the manufacturing of TxCell's lead product Ovasave for the ongoing CATS29 study. This trial is a phase IIb clinical study with TxCell's Ovasave in refractory Crohn's disease.

Following the successful validation runs at MaSTherCell, TxCell has submitted an amendment of its CATS29 clinical protocol. Specifically, the amendment refers to site change approval for the European national competent authority agencies that initially approved the CATS29 study through the Voluntary Harmonized Procedure (VHP). This should enable TxCell to resume CATS29 in Q2 2016, as per the planning previously announced. Should the trial restarts effectively in Q2 2016, TxCell expects to complete recruitment in CATS29 at the end of 2017 and announce topline data by Q4 2017 or Q1 2018.

The amendment will also be submitted to the FDA, where CATS29's Investigational New Drug (IND) dossier has been active since August 2015.

"The achievement of critical transfer technology milestones with successful validation runs in only a few months, especially regarding stringent specifications that go with cellular therapy products is a major achievement for both TxCell's team and its strategic production partner MaSTherCell. TxCell is now on target for the resumption of the CATS29 trial of our lead product Ovasave in Q2 2016 as planned," said Stephane Boissel, CEO, TxCell. "This new strategy and the technology transfer will allow TxCell to fully concentrate on our key strengths of research, clinical development and new partnerships. This has given us the confidence to set ambitious product development schedules from our two discovery platforms based on Ag-Tregs (ASTrIA) and CAR-Tregs (ENTrIA). To accelerate further, TxCell expects to also rapidly secure a CMO agreement for production of its products in the USA, where Ovasave has both an open IND as well as a Fast Track Designation by the FDA and where Col-Treg, TxCell's second most advanced product, has obtained the orphan drug designation status in 2015."

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

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, should enter clinical trials in 2016. Based in Sophia-Antipolis, France, TxCell is listed on Euronext Paris and currently has 44 employees.

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