



Press release

TxCell and Ospedale San Raffaele launch collaboration for the development of CAR-Tregs in Lupus Nephritis

Collaboration agreement between TxCell and Ospedale San Raffaele also includes dedicated research program on CAR-Treg biology

Valbonne, France and Milan, Italy, April 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, and **Ospedale San Raffaele (OSR)**, one of the most prestigious research institutions in Europe in the field of cell and gene therapy, today announce they have entered into a strategic R&D collaboration. The collaboration will include a development arm focused on Lupus Nephritis, as well as a research program dedicated to CAR-Treg biology.

The development part of the collaboration will focus on the non-clinical development of Chimeric-Antigen-Receptor engineered regulatory T (CAR-Treg) cells for the treatment of Lupus Nephritis. Lupus Nephritis is one of the most serious complications of Lupus, a chronic autoimmune disease affecting over 5 million people worldwide. TxCell scientists identified a first relevant antigenic target for its CAR-Treg cellular therapy product. They successfully created a CAR-Treg product candidate by engineering FoxP3+ Treg cells with a CAR. This CAR integrates the binding domain of a pathogenic antibody from patients suffering from Lupus Nephritis.

As per the terms of the agreement announced today, TxCell and OSR will conduct the non-clinical pharmacology and toxicology studies with CAR-Treg cells to prepare for a first-in-man study in Lupus Nephritis patients.

“The R&D partnership between TxCell and the world-leading Ospedale San Raffaele is an important development for TxCell. We have already achieved very quick progress with ENTrIA, our new CAR-Treg platform. TxCell will use both the collaboration with OSR as well as guidance from our newly appointed Scientific Advisory Board to accelerate further development,” said Dr. Arnaud Foussat, CSO of TxCell. “TxCell looks forward to leveraging its unparalleled technology to contribute to treatments for Lupus Nephritis, one of the world's most devastating yet underserved diseases. In addition to our first program in Lupus Nephritis, TxCell expects to start two additional CAR-Treg programs later this year on the back of additional in vitro and in vivo data.”

In parallel, the collaboration will also include a research arm, where OSR will perform research for TxCell on the design and biology of other chimeric antigen receptors for use in Treg cell products addressing other autoimmune indications.

Dr. Attilio Bondanza, Head of the Innovative Immunotherapies Unit at Ospedale San Raffaele, will lead the OSR team both in the development of CAR-Tregs in Lupus Nephritis and in the research program on CAR-Treg biology. Prof. Fabio Ciceri, Head of the Hematology and Bone Marrow Transplantation Unit and Deputy Director of the Division of Regenerative Medicine, Stem Cells and Gene Therapy of OSR, will also join the collaboration members. As a result of his pioneering experience in the field of clinical T-cell gene therapy, he will steer the collaboration towards a first-in-man study.

“We are very excited about this collaboration with TxCell, which certainly constitutes a major and unparalleled step forward towards the validation of the CAR technology outside the oncology field,” said Dr. Attilio Bondanza. “We enthusiastically accept the challenges of adapting the design of CARs to the distinctive biology of Tregs and we are really looking forward to developing robust protocols for the production of safe and effective cellular products that may benefit patients suffering from severe autoimmune diseases such as Lupus Nephritis.”

Financial terms of the collaboration have not been disclosed.

About Lupus Nephritis

Lupus Nephritis is one of the most serious complications of Lupus (also called systemic lupus erythematosus, SLE). Lupus is a chronic autoimmune disease involving many systems and organs in the human body, including joints, kidneys, central nervous system, heart and the hematological system. The biologic basis of Lupus is a defect in the immune (defense) system. This leads to production of self (auto) antibodies, attacking the normal organs and causing irreversible damage. Lupus Nephritis occurs when systemic Lupus causes an inflammation in the kidney, due to the formation and deposit of immune complexes in the kidney. If this inflammation is not controlled, Lupus Nephritis can lead to kidney failure. According to the Lupus Foundation of America, at least 5 million people worldwide have Lupus, with more than 16,000 new cases diagnosed each year in the US alone. The majority of patients are women of childbearing age. It is estimated that up to 60% of Lupus patients will develop clinically relevant Nephritis at some time in the course of their illness.

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, 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.

About Ospedale San Raffaele (OSR) – www.hsr.it

Ospedale San Raffaele (OSR) is a clinical-research-university hospital established in 1971 to provide international-level specialised care for the most complex and difficult health conditions. Since 2012, OSR is part of Gruppo Ospedaliero San Donato, the leading hospital group in Italy. The hospital is a multi-specialty centre with over 50 clinical specialties and has over 1,300 beds. Research at OSR focuses on integrating basic, translational and clinical activities to provide the most advanced care to our patients. It counts on over 1,800 doctors, scientists, technicians and on state-of-the-art facilities and technology platforms. OSR is recognized as a global authority in molecular medicine and gene therapy, and is at the forefront of research in many other fields.

Contacts - TxCell

TxCell

Caroline Courme
IR & Communication Director
Tel: +33(0) 4 97 21 83 00
caroline.courme@txcell.com

Image Box – Press relations

Neil Hunter / Michelle Boxall
Tel: +44(0) 20 8943 4685
neil.hunter@imageboxpr.co.uk
michelle.boxall@imageboxpr.co.uk

NewCap – Investor relations

Julien Perez / Pierre Laurent
Tel: +33 (0)1 44 71 98 52
txcell@newcap.eu

Ospedale San Raffaele Press Office

Gea Gardini
Tel: +39 0226436255 / 4466
ufficio.stampa@hsr.it

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.