Press release

TxCell provides details of CAR-Treg manufacturing process at CAR-TCR Summit Europe

First process ready for clinical testing

Valbonne, France, February 21, 2018, 5.45pm CET – TxCell SA (FR0010127662 – TXCL), a developer of cellular immunotherapies based on regulatory T cells (Tregs) for inflammation, autoimmunity and transplantation, today announces details of its CAR-Treg manufacturing process presented at the CAR-TCR Summit Europe, held in London, UK, on February 20-22, 2018. Dr. Pierre Heimendinger, VP Pharmaceutical Development, TxCell, will deliver an oral presentation describing how TxCell has succeeded in developing the industry's very first CAR-Treg Good Manufacturing Practice (GMP) process ready for clinical testing.

TxCell selected a population of Treg cells with the CD4+ CD25+ CD45RA+ phenotype (CD45RA+ Tregs). TxCell's CD45RA+ Tregs display both strong anti-inflammatory activity and stability. This starting Treg subset is rare, accounting for less than 5% of CD4+ T lymphocytes. TxCell's process enables the manufacturing of clinical doses of CD45RA+ based CAR-Tregs in under two weeks, ready for post-production quality control. Key achievements to be highlighted during Dr. Heimendinger's presentation include a demonstration of the stability of the TxCell Treg phenotype after both expansion of the CAR-Treg cells and thawing of the final drug product.

TxCell has conducted several full-scale pilot batches using clinical-grade raw and ancillary materials, as well as equipment to be used by the contract manufacturing organization (CMO) for GMP production. Key findings from these pilot batches are:

- Cells extracted from leukapheresis keep their Treg identity after cell transduction with a CAR and cell expansion throughout the process. This is achieved with limited donor to donor variability.
- A high cell purity of the selected CD45RA+ Treg subset is achieved at the end of the expansion phase.
- Expression of the Foxp3 intracellular cell marker remains constant throughout the process. Foxp3 expression is known to be related to the suppressive capacity of Treg cells.
- Importantly, the drug product could be both frozen and thawed with no change in phenotype and function.

"*Completing TxCell's first CAR-Treg manufacturing process is a major step towards the clinical phase in CAR-Treg development,*" said Francois Meyer, Chairman and Head of Research of TxCell. "*To the best of our knowledge, this is the very first CAR-Treg GMP process in the industry. The production lead-time, not including quality control, is already under two weeks, in line with general CAR-T standards and with reasonable associated costs. The*

CAR-TCR Summit gives us the opportunity to share our Quality by Design methodology with the industry."

Transfer of TxCell's CAR-Treg GMP process to a CMO has started in early February. TxCell expects to disclose the name of the CMO in the coming weeks, and to file its first CTA and/or IND late in Q4 2018. TxCell maintains its goal of being the first company to ever start clinical development with a CAR-Treg program.

TxCell is also releasing today an animated video explaining its process and CAR-Treg approach: https://vimeo.com/256395803. Details of the TxCell overall process can also be seen on the Company's website.

Methodology

TxCell used the Quality by Design (QbD) approach to achieve its GMP manufacturing process. Critical steps included Treg cell subset isolation, CAR transduction, CAR-Treg activation, CAR-Treg expansion and freezing and thawing. These steps were studied and optimized by using Design of Experiment (DoE). For every step, all commercially-available solutions were screened to select the best for TxCell's requirements. Statistical plans were then used to determine optimal values for each process parameter identified as critical or key.

Presentation details

- **Title:** *CAR-Treg cells for clinical use.*
- **Speaker**: Dr. Pierre Heimendinger, VP Pharmaceutical Development of TxCell.
- **Event:** CAR-TCR Summit Europe, February 20-22, 2018, London, United Kingdom.
- **Presentation date & time:** February 22, 2018, 2.30 pm GMT.

About TxCell – www.txcell.com

TxCell is a biotechnology company that develops platforms for innovative, personalized T cell immunotherapies for the treatment of severe inflammatory and autoimmune diseases with high unmet medical need. TxCell is targeting transplant rejection as well as a range of autoimmune diseases (both T-cell and B-cell-mediated), including multiple sclerosis, lupus nephritis and bullous pemphigoid.

TxCell's cellular immunotherapies are based on regulatory T lymphocytes (Tregs). Tregs are a T cell population discovered in the nineties for which anti-inflammatory properties have been demonstrated. Contrary to conventional approaches based on non-specific polyclonal Tregs, TxCell is exclusively developing engineered antigen-specific Tregs, where the antigen specificity is brought by a Chimeric Antigen Receptor (CAR) (CAR-Treg cells).

Based in Sophia-Antipolis, France, TxCell is listed on Euronext Paris and currently has 49 employees.

Upcoming events

Scientific and medical conferences

Feb 20-22	CAR-TCR Summit Europe	London (UK)
Mar 20-22	Combined CAR-T Congress USA	Boston (US)
Apr 17	ARM 6th Annual Cell & Gene Therapy Investor Day	New York (US)
May 22-24	Treg Directed Therapies for Autoimmune Disorders Summit	Boston (US)
May 29-30	3rd Annual Bioprocessing of Advanced Cellular Therapies Congress	Frankfurt (Germany)

Financial and business conferences

Mar 14	ARM's 8th Annual Advanced Therapies Summit	Amsterdam (NL)
Apr 16-17	SmallCap Event	Paris (France)
May 14-16	BioEquity	Ghent (Belgium)
May 29	Gilbert Dupont 16th Annual Healthcare Conference	Paris (France)

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Forward-Looking Statements

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 affects 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 2016 *document de référence* (registration document) approved by the AMF on April 26, 2017 under number R.17-024. 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.