



Lonza

Press release

TxCell names Lonza as its CAR-Treg cellular product manufacturer

- **Master Service Agreement signed between Lonza Pharma & Biotech and TxCell for the manufacture of TxCell's HLA-A2 CAR-Treg cellular product (TX200)**
- **Lonza Pharma & Biotech to manufacture clinical batches of TxCell's HLA-A2 CAR-Treg cellular product from its production site in Geleen (NL)**

Valbonne, France and Basel, Switzerland, May 31 2018, 17h45 CEST – TxCell SA (FR0010127662 – TXCL), a developer of cellular immunotherapies based on regulatory T cells (Tregs) for inflammation, autoimmunity and transplantation, and Lonza Pharma & Biotech, one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets, today announced entering into a Master Service Agreement for the manufacture of TxCell's HLA-A2 CAR-Treg cellular product (TX200), which is in development for the prevention of chronic rejection after organ transplantation.

"Lonza is a tremendous partner with a highly successful track record in manufacturing cell and gene therapies, including CAR-T," said Stéphane Boissel, CEO of TxCell. "Lonza's skill and know-how will provide the support and expertise necessary to develop our lead CAR-Treg program, which is on track to enter the clinic. Our therapy has the potential to offer transplanted patients a new option to prevent graft rejection, an area of significant unmet medical need."

"We have been following TxCell's progress closely in the buoyant cellular immunotherapy space," said Andreas Weiler, Global Business Unit Head, Emerging Technologies, Lonza Pharma & Biotech. "TxCell's trust in Lonza further demonstrates our leadership role in the cell and gene therapy space. We are keen to remain at the forefront of cell therapy manufacturing, by working with TxCell on their highly innovative CAR-Treg platform and taking part in their pioneering clinical study."

TxCell recently finalized its CAR-Treg manufacturing process (see [TxCell press release dated February 21, 2018](#)) and the transfer to Lonza started in February 2018. According to Lonza's timeline, completion of transfer activities and start of clinical manufacturing is now expected by Q1 2019. Accordingly, TxCell now expects to file its first CTA with TX200 in the first part of 2019.

Lonza will manufacture clinical batches of TxCell's HLA-A2 CAR-Treg cellular product from its production site in Geleen (NL). The final product could be shipped in a frozen state to clinical sites in Europe and the United States, as TxCell has already demonstrated that the drug product could be both frozen and thawed with no change in cellular phenotype and function.

About TxCell's HLA-A2 CAR-Treg

The HLA-A2 CAR-Treg is TxCell's most advanced CAR-Treg product candidate. It is based on a subset of Treg cells with the CD4⁺ CD25⁺ CD45RA⁺ phenotype (CD45RA⁺ Tregs). It targets HLA-A2, a common mismatch antigen in transplantation, and is in development for the prevention of chronic rejection after organ transplantation. HLA-A2 CAR-Treg has shown strong efficacy in a preclinical GvHD model^{1,2} and is now on track to start a first-in-man study in transplanted patients.

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.

In June 2017, TxCell appointed Lentigen Technology, Inc. (LTI) as its contract manufacturing organization (CMO) for the GMP production of the product's lentiviral vector.

About Lonza – www.lonza.com

Lonza is one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets. As an integrated solutions provider, Lonza is boosting its value creation along and beyond the healthcare continuum with a strong focus on patient healthcare, consumer preventive healthcare and consumer's healthy environment.

Lonza harnesses science and technology to create products that support safer and healthier living and that enhance the overall quality of life. With the recent Capsugel acquisition, Lonza now offers products and services from the custom development and manufacturing of active pharmaceutical ingredients to innovative dosage forms for the pharma and consumer health and nutrition industries.

Benefiting from its regulatory expertise, Lonza is able to transfer its know-how from pharma to hygiene and fast-moving consumer goods all the way to coatings and composites and the preservation and protection of agricultural goods and other natural resources.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 100 sites and offices and approximately 14,500 full-time employees worldwide. The company generated sales of CHF 5.1 billion in 2017 with a CORE EBITDA of CHF 1.3 billion.

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 transplantation as well as a range of autoimmune

¹ MacDonald KG, Hoeppli RE, Huang Q, Gillies J, Luciani DS, Orban PC, Broady R, Levings MK. Alloantigen-specific regulatory T cells generated with a chimeric antigen receptor. *J Clin Invest.* 2016, 126(4):1413-1424.

² Levings M. Alloantigen-specific regulatory T-cells generated with a chimeric antigen receptor. Oral presentation at the 18th Congress of the European Society for Organ Transplantation (ESOT), September 24-27, 2017, Barcelona, Spain.

diseases (both T-cell and B-cell-mediated), such as multiple sclerosis, rheumatoid arthritis, inflammatory bowel diseases or inflammatory skin diseases.

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 46 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 2017 *document de référence* (registration document) submitted to the AMF on April 25, 2018. 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.