Updates regarding NextCell's Clinical Trials with ProTrans

NextCell Pharma has several ongoing clinical trials with ProTrans. The largest ongoing study ProTrans Young, which includes 66 patients, is progressing well. All 30 patients in the older age group have been recruited and will be treated with ProTrans. In the long-term follow-up studies ProTrans-Obs and ProTrans-Repeat the first diabetes patients have now completed the studies after five years of follow-up.

ProTrans-Young – completed recruitment of the older age group

The study was started in 2021 and is an investigator-initiated clinical study led by Uppsala University in collaboration with Linköping University and Lund University. The goal for this Phase 1/2 study is to evaluate ProTrans for the treatment of paediatric patients newly diagnosed with type 1 diabetes.

The first part of the study was an open Phase 1 safety study with 6 children (ages 7-18) who had recently received their diagnosis. The study progressed well, and therefore the safety committee recommended continuing with Phase 2 of the study, which has been ongoing since the end of 2022. The Phase 2 part of ProTrans-Young is a randomised, placebo-controlled double-blind trial with 30 patients aged 12 – 21 years, and 30 patients aged 7 – 11 years. All patients in the older age group have now been recruited and the last patient in this age group is expected to receive treatment in February of this year. After further safety checks, 30 patients in the age group 7–11 will be recruited. That part of the study is expected to begin in August.

ProTrans-Obs – patients will soon be evaluated

ProTrans-Obs is long-term follow-up of 11 patients who previously participated in ProTrans-2. The first diabetes patients will soon have completed the study after being observed for five years. During the summer, all patients will have completed the study, which can then be evaluated.

Of the patients who completed ProTrans-2, 6 ProTrans-treated and 5 placebo-treated patients accepted an invitation to participate in the follow-up study ProTrans-Obs after completion of the ProTrans-2 study. In this study, the patients' own body insulin production is measured every six months, and a follow-up after three years has already been carried out. The result from this interim analysis shows a statistically significant treatment effect on the body's own insulin production at all analysed times up to three years ($p<0.05$) as compared to the placebo group.

ProTrans-Repeat – patients will soon be evaluated

ProTrans-Repeat, which started in May 2019, is an open-label follow-up study in which the patients who participated in ProTrans-1 were invited to participate in a second study. The aim is to verify if a second treatment can prolong or maintain a possible effect of ProTrans over a longer period of time, with preserved

safety. In this study as well, the first patients have completed the study, and all patients will have completed the trial following their five-year follow-up during the winter.

ProTrans19+SE – first patient in the high dose group treated

In December 2023, the seventh patient with severe viral pneumonia received treatment with ProTrans, and they were also the first patient in the high dose group.

ProTrans is an immunomodulatory cell therapy currently being evaluated for the treatment of patients with type 1 diabetes. However, the mechanism of immune modulation is expected to be applicable in other autoimmune and inflammatory conditions. When COVID-19 patients deteriorate, it is usually because the immune system becomes hyperactive and attacks organs, including the lungs. In this open Phase 1b study, a total of three groups of three patients each will be treated with different doses of ProTrans. Today, 7 out of 9 patients have undergone treatment and only 2 patients in the high-dose group remain to be treated.

At the beginning of 2023, the Swedish Medical Products Agency approved the expansion of the clinical trial to include patients with other forms of virally induced pneumonia. Initially, patients with severe pneumonia caused by SARS-CoV-2 (COVID-19) infection were treated, but now patients with the same clinical symptoms caused by influenza A, respiratory syncytial virus (RSV) and human metapneumovirus (MPV) are also included. The treatment is aimed at patients who are hospitalised and who run a high risk of having to be put on a ventilator. ProTrans is given intravenously to reduce the hyperinflammation in the lungs. The goal of the treatment is to shorten the hospital stay and rehabilitation time, and to save lives.

ProTrans19+CA – terminated prematurely

The study was approved in February 2021. McGill University in Montreal, Canada, sponsored a Phase 2 trial for the treatment of patients with severe pneumonia caused by COVID-19. The aim of the study was to include 48 patients who were randomised to ProTrans (24 patients) or placebo (24 patients). The study was terminated by McGill after 19 patients were treated, due to less patients meeting the criteria for inclusion as the vaccine programme was rolled out.

ProTrans-1 – completed Phase 1 study

The study was started in January 2018 and completed in 2019. An open-label dose-escalation Phase 1 study in 9 patients with type 1 diabetes. ProTrans's safety and impact on the patient's own insulin production were evaluated by measuring insulin production before and one year after treatment. The study showed a) good safety, and b) a dose-dependent effect regarding preservation of the body's own insulin production one year after treatment.

ProTrans-2 – completed Phase 2 study

The study was started in 2019 and completed in 2020. A randomised, double-blinded placebo-controlled Phase 2 study with the main objective of evaluating effectiveness. The study included fifteen newly diagnosed patients with type 1 diabetes. The results showed that patients treated with ProTrans maintained 90% of their body's own insulin production at the time of treatment one year after treatment, compared to

53% in the placebo group. Data from this study have been published in *Diabetologia*, the official journal of the European Association for the Study of Diabetes (Carlsson et al. 2023 Aug;66(8):1431-1441).

For more information about NextCell Pharma AB, please contact:

Mathias Svahn, CEO
Patrik Fagerholm, CFO
Tel: 0+46 8-735 5595
E-mail: info@nextcellpharma.com
Website: www.nextcellpharma.com

LinkedIn: https://www.linkedin.com/company/15255207/
Twitter: https://twitter.com/NextCellPharma

For information about Cellaviva, please contact:

Sofie Falk Jansson, Head of Cellaviva
Tel: 08-735 2010
E-mail: info@cellaviva.se
Website: www.cellaviva.se

Facebook: https://www.facebook.com/cellavivasverige
Twitter: https://www.instagram.com/cellaviva/

About NextCell Pharma AB

NextCell is a cell therapy company in Phase II trials with the drug candidate ProTrans for the treatment of type 1 diabetes. The focus is to obtain market approval of ProTrans via a phase III trial. In addition to type 1 diabetes, ProTrans is used in two clinical trials for COVID-19, in Örebro and in Montreal, Canada. The company is in the process of establishing its own GMP-facality for the production of ProTrans. Furthermore, NextCell owns 8.5% in FamicordTX, a CAR-T start-up in oncology, and 100% of Cellaviva, Scandinavia's largest private stem cell bank licensed by the Swedish Health Authority (IVO) to preserve and store stem cells from umbilical cord blood and umbilical cord tissue for family use.