ProTrans cell therapy maintains insulin production effect 3.5 years after treatment

NextCell Pharma AB ("NextCell" or the "Company") today announces that type-1 diabetes patients receiving two treatments with a high dose of ProTrans cell therapy maintain a significantly higher endogenous insulin production than patients treated with low or medium doses.

Type I diabetes patients enrolled in the ProTrans Repeat Study, treated with the highest dose of ProTrans, maintained a significantly higher preserved endogenous insulin production than patients treated with low and medium doses ($p<0.05$). On average, the 3 patients treated in each of the low, medium and high-dose cohorts have maintained 41%, 45% and 81% of their insulin production capacity at the time of treatment i.e. 3.5–4 years ago.

In 2018, 9 patients were treated in the Phase I ProTrans-1 dose escalation study. Treatment with ProTrans demonstrated a dose-dependent therapeutic effect, with medium and high-doses maintaining a statistically significant higher insulin production than patients receiving low-dose therapy. Patients treated with low dose ProTrans reduced an average of 28% of their endogenous insulin production, compared to 6% in medium and high-dose treated patients.

All the 9 patients, who participated in ProTrans-1 above, agreed to be included in a continuation study, ProTrans-Repeat. All patients received an additional treatment of ProTrans, with the same dose that they previously received (one year after the initial treatment), with evaluation subsequently performed twelve months later, i.e. 2 to 2.5 years after the initial treatment. The study was designed to evaluate the safety of repeated treatments. All doses were shown to be safe and did not result in any antibody responses to the allogeneic treatment. Maintained insulin production after 2 years was 94% for high, 56% for medium and 51% for low dose.

An interim analysis is now presented that concludes that high-dose treatment provides the highest and longest-lasting therapeutic effect in type I diabetic patients. Maintenance of insulin production has been assessed on 3 occasions for each patient- after 1 year, 2 years and 3.5 years where the average for high dose was 96%, 94% and 81% compared to medium dose 91%, 56% and 45% and low dose 72%, 51% and 41%. The ProTrans-Repeat study is set to last for 5 years i.e. a total of 6-6.5 years from inclusion in ProTrans-1.

This disclosure contains information that NextCell Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 18th October 2022 at 13.20 CET.

For more information about NextCell Pharma AB, please contact:

Mathias Svahn, CEO
Patrik Fagerholm, CFO

Tel: +46 8-735 5595
E-mail: info@nextcellpharma.com
Home page: www.nextcellpharma.com

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

About NextCell Pharma AB

NextCell is a phase II cell therapy company. It's lead candidate drug ProTrans is being developed for the prevention and treatment of type 1 diabetes. The focus is to take ProTrans to market approval via a Phase III study. ProTrans is in addition to diabetes, used in two clinical trials for Covid-19, in Örebro and Montreal (Canada). The Company is in the processes of establishing its own GMP facility for ProTrans manufacturing. The GMP facility is expected to be ready for production of smaller quantities of ProTrans in 2023. NextCell furthermore owns 8,5% in FamicordTX, a CAR-T start-up in oncology and 100 % of Cellaviva, Scandinavia's largest stem cell bank for family saving of stem cells from umbilical cord blood and umbilical cord tissue with permission from the Swedish Health and Social Care Inspectorate (IVO).