The Swedish Medical Products Agency approves subgroup analysis in NextCell's ProTrans-Young study

NextCell Pharma AB ("NextCell" or the "Company") today announces that the Swedish Medical Products Agency has approved an application to conduct a subgroup analysis of the treatment effect of ProTrans in 30 adolescents in the age group 12-21 years, treated in the ProTrans-Young study. Principal Investigator Professor Per-Ola Carlsson and his team treated the last patient in the age group in February 2024. The approval for the subgroup analysis by the Swedish Medical Products Agency means that the primary efficacy endpoint readout is available after 12 months. The primary efficacy endpoint is measured as a difference in endogenous insulin production comparing ProTrans and placebo-treated patients one year after treatment. Results from the subgroup analysis are planned to be presented in the second quarter of 2025.

ProTrans-Young started in 2022 and is an investigator-initiated clinical study led by Uppsala University together with Linköping University and Lund University. The aim is to evaluate ProTrans for the treatment of paediatric patients with newly diagnosed type 1 diabetes.

The first part of the study is an open-label safety study with 6 children aged 7 – 18 years who have recently been diagnosed with type 1 diabetes. All patients have been treated and the data safety monitoring board recommended to continue with a phase 2 part of the study in which two age groups with 30 patients in each are treated with ProTrans or placebo. The 30 patients aged 12 – 21 years have undergone treatment; the last patient was treated in February. One year of efficacy data can thus be collected in early spring 2025 and presented before summer 2025.

"The subgroup analysis may be crucial for contract discussions regarding the out-licensing of ProTrans for type-1 diabetes. The number of patients is significant if, and hopefully the efficacy data will be at least as promising as in the previous ProTrans-1 and ProTrans-2 studies", says CEO Mathias Svahn.

The subgroup analysis is done for business reasons and does not affect the continuation of the study. The study's primary endpoint is the change in endogenous insulin production after 12 months, by measuring the concentration of c-peptide after a meal test. Thus, the subgroup analysis will prematurely present the change over 12 months at the group level, ProTrans compared to placebo, without assessment of statistical significance.

Recruitment of 30 patients in the younger subgroup of children aged 7 – 11 years is planned after the summer this year and is expected to last until the summer of 2025. Final data from all of ProTrans-Young patients is expected to be presented in the second half of 2026. NextCell's goal is to take ProTrans to a marketing approval for the treatment of type-1 diabetes together with a partner. The subgroup analysis Q2-2025 may lead to interesting discussions about license agreements to enable the start of pivotal study immediately after completion of the child study.

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FNCA Sweden AB is the appointed Certified Adviser.

About NextCell Pharma AB:

NextCell is a cell therapy company that is in phase 2 studies with the drug candidate ProTrans for the treatment of type 1 diabetes. The focus is to obtain market approval of ProTrans via a phase 3 study. ProTrans is manufactured utilizing the patented platform technology for selection of optimal cells with potency to treat inflammatory disorders including autoimmune diseases. NextCell owns Cellaviva, the largest stem cell bank in the Nordics and QVance, a quality analysis CRO company in upstart.