First age group treated in paediatric diabetes study with ProTrans

NextCell Pharma AB ("NextCell") today announces that all three children in the age group 12-18 years have been treated with ProTrans. Professor Per-Ola Carlsson and the study team are now moving forward with younger patients, three children in the age group 7-11 years.

The first part of the study is a safety part (phase Ib) where all patients are treated at Uppsala University Hospital. The Safety Committee consists of Chairman Professor Ulf Smith, Sahlgrenska Hospital and Professor Mikael Rydén, Karolinska University Hospital and Professor Anders Fasth, Queen Silvia Children's Hospital. They will evaluate whether it is safe to proceed to the phase II part of the study, based on 3 months of follow-up of the total of six children.

In the second part of the study, patients are randomized to ProTrans or placebo (1:1). First, 30 patients in the 12-21 age group will be treated and based on safety evaluation after six months, 30 patients in the 7-11 age group will also be treated.

The principal investigator is Professor Per-Ola Carlsson, Uppsala University and Uppsala University Hospital with co-investigators Professor Helena Elding Larsson, Skåne University Hospital and Professor Johnny Ludvigsson, Linköping University Hospital. The second part is randomised and placebo-controlled (phase II) and a total of 60 children and adolescents with type 1 diabetes should be treated, of which 30 with ProTrans and 30 with placebo. Recruitment will take place at the three participating hospitals in Uppsala, Linköping and Malmö.

"*Our assessment is that we will be able to include all patients in the safety part during the spring and hopefully be able to start recruiting patients to the second part after the summer*," says Professor Carlsson.

Akademiska sjukhuset is a sponsor of the study, which is funded with research grants. NextCell is contributing ProTrans and placebo in the study. In addition, the company will support the trial with logistics, documentation and expertise.

The full name of the study is: “A Double-blinded, Randomized, Parallel, Placebo-controlled trial of Wharton´s Jelly-derived Allogeneic Mesenchymal Stromal Cells to treat Type I Diabetes in Children and Adolescents” (EudraCT 2020-004520-42).

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About NextCell Pharma AB

NextCell is a phase II cell therapy company with the drug candidate ProTrans for the 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 production of ProTrans. 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 stem cells from umbilical cord blood and umbilical cord tissue with permission from the Swedish Health and Social Care Inspectorate (IVO).