Positive feedback on the paediatric plan of the EMA

NextCell Pharma AB ("NextCell") has received positive comments and recommendations for the pediatric investigational plan (PIP) submitted to the Europeans Medicines Agency's (EMA) pediatric committee (PDCO).

As previously announced, NextCell submitted a proposal in Q4 outlining how ProTrans should be developed for the treatment of children with type-1 diabetes. The agency has returned with comments and recommendations that aiming to ensure that children younger than 7 years old can also receive treatment in the future.

"The PDCO has been very helpful with the development plan and the proposed changes strengthen our proposal. We will of course implement these before the PIP is finally submitted for approval", says Mathias Svahn, CEO.

A PIP is a development plan aimed at ensuring that all necessary safety and efficacy data are obtained through clinical studies in children, prior to application for authorisation of a medicine for pediatric usage. All applications for marketing authorisation for new medicines have to include the results of studies as described in an agreed PIP.

Only small changes have been requested by EMA, aimed at allowing even younger age groups to be treated after a possible market approval than what is treated in the ongoing pediatric study, ie children younger than 7 years. The changes do not affect the study design of the planned phase 3 study.

In addition to clinical trials, the plan also includes preclinical studies of biodistribution and toxicology. NextCell is currently reviewing the recommendations by the PDCO and amending the proposal prior to submitting for approval.

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About NextCell Pharma AB

NextCell is a cell therapy company in clinical phase II. The company has developed a proprietary and patented platform technology to produce mesenchymal stromal cells adapted for allogeneic treatment of various autoimmune and immunological diseases. The drug candidate ProTrans is now being tested for the treatment of type-1 diabetes as well as respiratory complications caused by Sars-CoV-2 infection. The focus is to take ProTrans to market approval for type-1 diabetes via a phase III study. ProTrans is evaluated in two clinical COVID-19 studies, in Sweden and Canada. NextCell is working on completing its own GMP facility for the manufacture of ProTrans. The GMP facility is expected to be ready for manufacturing smaller quantities of ProTrans in 2023. NextCell also owns 8.5% of FamicordTX, a start-up company in CAR-T and oncology, and 100% of Cellaviva, Scandinavia's largest stem cell bank for family savings of stem cells from umbilical cord blood and umbilical cord tissue with permission from the Swedish Health and Social Care Inspectorate (IVO).