Treatment start of severe pneumonia with high dose of ProTrans

NextCell Pharma AB ("NextCell" or the "Company") announces that the clinical trial ProTrans 19+SE (also called Protrans V) can start recruiting patients in the high dose group, which is the last dose group. Three patients treated with medium dose of ProTrans have been clinically evaluated and the data has been reviewed by the Data Safety Monitoring Board, which now allows continued treatment with high-dose ProTrans for severe pneumonia caused by COVID-19, Influenza, Human Metapneumovirus and RSV.

The Data and Safety Monitoring Board has analyzed the safety aspects of the clinical trial: "Treatment of Respiratory Complications Associated with COVID-19 Infection Using Wharton's Jelly (WJ) Umbilical Cord (UC) Mesenchymal Stromal Cells {ProTrans®): open Phase IB Clinical Trial", described in EudraCT 2020-002078-29.

The meeting was held on Monday 3 of July 2023. The members of the Board are Professor Åke Lernmark, Doctor Magnus Nisell and Professor Peter Bergman (Chairman). The Data and Safety Monitoring Board had access to full data collection forms including adverse events.

ProTrans is being developed as an immunomodulatory cell therapy currently being evaluated for the treatment of patients with type 1 diabetes. However, the mechanism of immunomodulation is expected to be applicable in other autoimmune diseases and inflammatory conditions. When the condition of COVID-19 patients worsens, it is because the immune system becomes hyperactive and attacks organs, including the lungs. In this open-label phase Ib study, a total of three groups, consisting of three patients each will be treated with different doses of ProTrans. Now 6 out of 9 patients have undergone treatment and only 3 patients in the high dose group remain.

Early this year, the Swedish Medical Products Agency approved the study, which initially only treated patients with severe pneumonia caused by SARS-CoV-2 infection, to also include patients with the same symptoms caused by influenza A, respiratory syncytial (RS) and human metapneumo (HMP) virus. The treatment is designed for patients who are hospitalized and who are at high risk of needing to be put on a ventilator. ProTrans is given intravenously to reduce hyperinflammation in the lungs. The goal of the treatment is to shorten the hospital stay, rehabilitation time and to save lives.

The principal investigator of the study is Associate Professor Josefin Sundh, Örebro University Hospital. The protocol was written by Professor Dominique Farge, St. Louis Hospital in France, and Dr. Lindsay Davies, CSO NextCell Pharma. The steering committe consists of chairman Professor Farge and members Professor Edvard Smith (NextCell) and Dr Tomasz Oldak (PBKM).

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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 process 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).