

ProTrans study in COVID-19 expanded to include treatment of severe pneumonia induced by influenza A, RSV and HMP virus

NextCell Pharma AB ("NextCell") today announces that the Swedish Medical Products Agency has approved the expansion of their Swedish COVID-19 study, to include patients with severe pneumonia due to influenza A, respiratory syncytial virus (RSV) and human metapneumovirus (HMP). The treatment is aimed at patients who are hospitalized and at high risk of needing ventilator life support. ProTrans is given intravenously to suppress hyperinflammation in the lungs. The goal of treatment is to shorten hospitalization and time for rehabilitation, and to save lives.

"Expansion with three common emerging viruses greatly increases ProTrans' potential future use case. There is reason to believe that lung disease is a particularly well-suited area for ProTrans as infused stromal cells are well documented to traffic to the lungs. ProTrans is given to treat a complication, pneumonia, or hyperinflammation of the lung, which manifests in breathing difficulties and injury to the lung irrespective of which virus causes it," says Mathias Svahn, CEO.

ProTrans19+SE is carried out at the University Hospital in Örebro in collaboration with the Division of Clinical Trials and Karolinska Trial Alliance. The Principal Investigator is Associate Professor Josefin Sundh. So far, a total of 5 patients with SARS-CoV-2 infection have been treated.

Full revised study title is: " Treatment of Respiratory Complications Associated with COVID-19, Influenza A, Metapneumovirus, Respiratory Syncytial Virus (RSV) Infection Using Wharton's Jelly (WJ)-Umbilical Cord (UC) Mesenchymal Stromal Cells (ProTrans®): a Randomized Phase IB Controlled Clinical Trial", (EudraCT 2020-002078-29). NextCell is sponsoring the study which will include nine patients with severe pneumonia and confirmed viral infection, who are treated with low dose (3 patients) medium dose (3 patients) and high dose (3 patients) of ProTrans.

The study is registered on clinicaltrials.gov with number NCT04896853.

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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 stem 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 and respiratory complications caused by Sars-CoV-2 infection. The focus is to take ProTrans to a market approval for type-1 diabetes via a phase III study. ProTrans is also used 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).