



Application for clinical trial submitted to the Medical Products Agency, ProTrans-2.

NextCell Pharma AB ("NXTCL") today announced that a new application to conduct a clinical trial with ProTrans has been submitted to the Swedish Medical Products Agency. The purpose of the study is to evaluate repeated treatment with ProTrans, including patients with type 1 diabetes who participated in the dose escalating part of the original NXTCL trial.

The ongoing clinical trial called ProTrans-1, was initiated with a dose escalation phase for 9 patients all followed for 12 months. After their last visit in the study, patients will be asked if they want to participate in a new study where they will receive another treatment with ProTrans, provided that the Swedish Medical Products Agency approves the application for this new "ProTrans-2 study". The ProTrans-1 study is now entering Phase 2, where ProTrans is administered in a randomized placebo-controlled manner, not to be confused with ProTrans-2, a new study for patients included in the ProTrans-1 dose escalating part.

The study title for ProTrans-2 is: An open label, parallel single centre trial of Wharton's jelly derived allogeneic mesenchymal stromal cells repeated treatment to preserve endogenous insulin production in adult patients diagnosed with type 1 diabetes. Principal investigator is Professor Per-Ola Carlsson and the sponsor is NXTCL. The study is conducted in collaboration with Karolinska Trial Alliance at Karolinska University Hospital in Huddinge.

Furthermore, the prerequisites for a clinical trial with ProTrans to evaluate rejection associated with renal transplantation have been evaluated. NXTCL has established contacts with transplant surgeons and immunologists who jointly plan to apply for funding for a clinical trial where patients receiving a kidney from a deceased donor are treated with ProTrans in addition to standard treatment.

CEO Mathias Svahn comments

"The new clinical trial will provide us with valuable data on repetitive treatments with ProTrans. We have a fantastic study team and enough ProTrans available to provide our patients with a second treatment."

This information is the information that NextCell Pharma AB is required to disclose under the EU Market Abuse Regulation. The information was provided by the below contact person for publication on 5th of November 2018.

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About NextCell Pharma AB:

Stem cells are expected to change the way how many of today's life-threatening diseases are treated. NextCell

NextCell Pharma AB
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Pharma AB develops ProTrans, a drug candidate consisting of stem cells for the primary treatment of autoimmune and inflammatory diseases as well as for use in kidney transplants. ProTrans consists of selected stem cells derived from the umbilical cord tissue with NextCell Pharma AB's proprietary method. In addition, the company has a service called Cellaviva, Sweden's first and only IVO-approved stem cell bank for the family-saving of stem cells from umbilical cord blood and umbilical cord tissue.