

Repeated treatment with ProTrans is immunologically safe

NextCell Pharma AB ("NextCell" or the "Company") today announces that multiple treatments with ProTrans cell therapy does not induce donor specific antibodies in type-1 diabetes patients. A detailed analysis of how the immune system reacts to infusion of ProTrans cells show that treatment can be given to any adult type 1 diabetic, irrespective of pre-existing HLA antibodies.

"This finding is very good news" says Mathias Svahn, CEO for NextCell Pharma. He went on to add, "These data demonstrate not only the safety profile for ProTrans, and its use as an off-the-shelf product, but also that treatment with ProTrans does not limit the patient's ability to receive blood transfusions or tissue transplants in the future.

NextCell has previously reported the efficacious effect of ProTrans therapy in maintaining insulin production in newly diagnosed type 1 diabetes patients enrolled in the ProTrans Repeat Study. As part of the long-term follow-up study of these treated patients, the expression of anti-HLA (human leukocyte antigen) antibodies has been investigated.

All cells express HLA molecules on their surface, helping the body to establish what is foreign and self. In the case of blood transfusion or tissue matching for transplantation the donor HLA pattern is matched, where possible, to the HLA pattern of the recipient. This prevents a reaction, or rejection, by the patient upon treatment. One of the major advantages of ProTrans treatment is the lack of need to match donor cells to recipients, allowing for the development of a true off-the-shelf allogeneic therapy suitable for immediate usage.

Analysis of patient samples prior to treatment and post-treatment (1 month post-second infusion) with two doses of ProTrans (equivalent to exposure to ten individual cell donors) demonstrated no anti-HLA antibodies against any donor material.

NextCell will continue their long-term follow-up of these patients for a total of five years. Data to date is very promising with no serious adverse events or safety concerns.

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About NextCell Pharma AB

NextCell is a cell therapy company in Phase 2 trials with the drug candidate ProTrans for the treatment of type 1 diabetes. The focus is to obtain market approval of ProTrans via a Phase 3 trial. In addition to type 1 diabetes, ProTrans is used in two clinical trials for COVID-19, in Örebro and in Montreal, Canada. The company is in the process of establishing its own GMP-facility for the production of ProTrans. Furthermore, NextCell owns 8.5% in FamicordTX, a CAR-T start-up in oncology, and 100% of Cellaviva, Scandinavia's largest private stem cell bank licensed by the Swedish Health Authority (IVO) to preserve and store stem cells from umbilical cord blood and umbilical cord tissue for family use.