Six-year data demonstrate a durable disease-modifying effect of ProTrans in type 1 diabetes

NextCell Pharma AB ("NextCell" or the "Company") today announces that six-year follow-up data indicate that a single infusion of ProTrans provides a long-lasting and clinically relevant preservation of endogenous insulin production in patients with newly-diagnosed type 1 diabetes. Patients treated with ProTrans continue to exhibit clinically relevant levels of stimulated C-peptide well beyond expected levels as seen with the natural course of the disease.

- Durable effect ≥6 years
- Approximately 50% of insulin-producing function preserved
- Strategy confirmed: a single infusion may be sufficient for clinical efficacy

Previously reported long-term data up to five years demonstrated that ProTrans-treated patients, at the group level, preserved approximately 60% of their endogenous insulin production, compared with around 15% with placebo treatment. The six-year follow-up demonstrates that this clinically meaningful separation is maintained, with ProTrans-treated patients continuing to retain around half of their baseline insulin production at the group level, years after receipt of treatment.

In the placebo arm, endogenous insulin production was, as expected with disease progression, largely lost earlier, and at this late time point the number of patients completing long-term follow-up is therefore limited. The Company therefore considers the six-year data to primarily reflect durability of treatment response, rather than to serve as a basis for further quantitative group-level comparisons.

"After six years of follow-up, all patients treated with ProTrans retain higher endogenous insulin production than any patient in the placebo group. This pattern has been consistent since three years post-treatment, without any observed differences in adverse events between the groups," says Mathias Svahn, CEO of NextCell.

In light of the clear and sustained clinical effect, the Company intends to advance ProTrans toward market approval as a single-infusion treatment for type 1 diabetes. In parallel, NextCell continues to develop ProTrans with the aim of further enhancing and prolonging the treatment effect through repeated infusions, which are being evaluated in the ongoing ProTrans-Repeat study. Results from ProTrans-Repeat, including follow-up data up to seven years, are expected to be reported shortly.

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Certified Adviser

The company's shares are listed on the Nasdaq First North Growth Market.
RedEye AB is assigned as Certified Adviser.

About NextCell Pharma AB

NextCell Pharma is a clinical-stage cell therapy company developing ProTrans, a patent-protected platform based on allogeneic mesenchymal stromal cells (MSCs) from umbilical cord. Using a proprietary selection algorithm, ProTrans delivers optimised cell tailored to specific indications. In type 1 diabetes, a single infusion has been shown to preserve insulin production and delay disease progression for at least five years. A Phase III trial is planned to commence upon securing a commercial partner. ProTrans is also being evaluated for other autoimmune and inflammatory conditions. NextCell's subsidiaries include Cellaviva, Scandinavia's largest private stem cell bank, and QVance, the Nordic region's first dedicated provider of quality services for developers of advanced therapies.