

Seven-year follow-up data from ProTrans-Repeat demonstrate sustained disease-modifying effects of ProTrans in type 1 diabetes

NextCell Pharma AB (“NextCell” or the “Company”) today announces long-term follow-up data from the ProTrans-Repeat study showing sustained preservation of endogenous insulin production in patients with newly diagnosed type 1 diabetes. The data extends to approximately 6 years after the last ProTrans infusion, corresponding to 7 to 7.5 years since the first infusion.

- Durable effect observed ≥ 7 years from first infusion
- Sustained preservation of endogenous insulin production at group level
- Clear dose-dependent trends over long-term follow-up

At the latest follow-up, patients in the high-dose group demonstrate preserved endogenous insulin production at group level. Two of three patients continue to show insulin production close to baseline, while one patient shows a more pronounced decline. Intermediate-dose patients show limited preservation, whereas the low-dose group demonstrates a progressive decline over time.

The durability of preserved insulin production more than 7 years after the first infusion is unexpected in type 1 diabetes and supports the conclusion that ProTrans has the potential to modify the underlying disease rather than providing only transient benefit directly after treatment. The observed dose-dependent trends further strengthen the biological rationale for ProTrans.

“A single infusion of ProTrans has demonstrated such a high and durable clinical impact that our strategy is to bring this treatment to patients as quickly as possible. At the same time, I am encouraged by the long-term results from ProTrans-Repeat, which show sustained efficacy over extended follow-up and confirm that ProTrans can also be safely and effectively administered repeatedly if needed,” says Mathias Svahn, CEO of NextCell.

Previously reported data from ProTrans-OBS and ProTrans-Repeat demonstrated clinically meaningful preservation of endogenous insulin production five years after the last infusion. Applying the same reporting logic, the present analysis extends follow-up to six years after the last infusion in the ProTrans-Repeat study. At later timepoints, patient numbers are limited due to discontinuation, and minor numerical differences are considered likely to fall within the expected variability of the C-peptide AUC assay. Accordingly, the results are interpreted as descriptive trends at group level, consistent with earlier disclosures.

Based on the strength and durability of the clinical effect observed after a single infusion, NextCell's primary objective is to bring ProTrans to patients as a single-infusion treatment, where the Company's data is most extensive, and to pursue market approval on this basis. Following market approval, NextCell intends to extend its label with the addition of paediatric patients. The Company will also explore the possibility to further optimise the treatment regimen by evaluating repeated ProTrans infusions as a strategy to maximise and prolong the therapeutic effect in selected patient populations.

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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.