

NextCell reports encouraging numerical results in younger children - strategy for adults remains unchanged

NextCell Pharma AB (publ) ("NextCell" or the "Company") today announces the 12-month results from ProTrans-Young. In the predefined age group of 7–11 years, children treated with NXTCL-T1D had, on average, preserved a greater proportion of their endogenous insulin production after 12 months and experienced a smaller increase in insulin requirements compared with those receiving placebo. The study did not meet its primary efficacy endpoint in the overall study population. A preliminary analysis of 24-month data from the older age group shows no clear treatment effect, although the data have not yet been fully analysed or validated. NextCell's commercialisation strategy for adults remains unchanged, while the Company intends to refine its treatment strategy for children and adolescents, focusing on treatment timing and the number of administrations. Further analyses are also planned to investigate how age and individual disease progression may influence treatment response.

"In the younger children, we see a consistent numerical trend in favour of treatment, both in terms of preserved endogenous insulin production and insulin requirements. Although the differences are not statistically significant, the findings are encouraging and support further investigation of the treatment's potential in younger children. We now need to explore whether children and adolescents would benefit from treatment earlier in the disease course or from repeated administrations. For adults, our strategy remains unchanged: a single infusion within two years of diagnosis, with the aim of preserving endogenous insulin production for many years," says Mathias Svahn, CEO of NextCell Pharma.

Numerically favourable results in children aged 7–11 years

ProTrans-Young evaluates NextCell's cell therapy candidate NXTCL-T1D (formerly ProTrans) in children and adolescents with newly diagnosed type 1 diabetes. The randomised part of the study enrolled 60 patients, with 15 patients in each treatment arm within the 7–11 and 12–21-year age groups, respectively.

Preliminary 12-month results for the 12–21-year age group were announced in April 2025 and showed no clear difference between treatment and placebo. The current announcement provides the 12-month results for the younger age group and the combined analysis of both age groups.

After 12 months, children aged 7–11 years treated with NXTCL-T1D had, on average, retained 64 per cent of their baseline endogenous insulin production, compared with 51 per cent in the placebo group. Peak C-peptide production and changes in daily insulin requirements also showed numerical differences favouring NXTCL-T1D. These findings are descriptive, and no statistically significant treatment effect has been demonstrated.

<u>Efficacy measures at 12 months, children aged 7–11 years</u>	<u>NXTCL-T1D</u>	<u>Placebo</u>
Preserved endogenous insulin production (C-peptide-AUC) *	64 %	51 %
Increase in daily insulin requirement	+0.15 units/kg	+0.24 units/kg

**The percentages for preserved insulin production represent the mean of the individual patients' percentages of baseline C-peptide AUC retained at 12 months.*

In the overall study population, the adjusted treatment difference in C-peptide AUC was +0.0426 AUC units (95% confidence interval –0.0722 to +0.1574; p=0.46). In the descriptive analysis, patients treated with NXTCL-T1D had, on average, retained 69 per cent of their baseline endogenous insulin production after 12 months, compared with 62 per cent in the placebo group. The primary statistical analysis included 55 patients and was adjusted for baseline C-peptide and age group. The difference was not statistically significant.

The adjusted treatment difference was also numerically positive at six months and remained similar in sensitivity analyses addressing missing data. None of the secondary efficacy endpoints analysed showed statistically significant treatment differences in the overall study population.

In the younger age group, 12-month data were unavailable for four of the 15 patients in the treatment group, whereas data were available for all 15 patients in the placebo group. This limits the conclusions that can be drawn from the numerically favourable differences. Additional sensitivity analyses addressing missing data were conducted for the overall study population and continued to yield numerically positive treatment effect estimates. However, these analyses do not establish a treatment effect specifically in the younger age group.

Preliminary 24-month follow-up in the older age group

NextCell has also conducted a preliminary review of 24-month data from patients aged 12–21 years. The initial analysis shows no clear difference in the preservation of endogenous insulin production between the treatment and placebo groups, consistent with the previously announced 12-month results for this age group.

The dataset has not yet been fully analysed or validated. NextCell plans to conduct further exploratory analyses of individual treatment responses, considering factors such as age and residual insulin production at baseline.

One potential approach is to compare patients' observed C-peptide levels with those expected based on their individual characteristics and the anticipated course of the disease. Such analyses may help identify patterns that are not apparent from group averages and inform the design of future studies. They do not, however, replace the study's prespecified primary analysis. NextCell intends to report the full 24-month results once the analyses have been completed.

Strategy for adults remains unchanged – long-term data support the path towards marketing authorisation

NextCell's strategy remains to commercialise NXTCL-T1D as a single-infusion treatment for adults with residual endogenous insulin production who are within two years of diagnosis. This approach is supported by the published randomised adult study, which demonstrated a statistically significant difference in preserved C-peptide production after 12 months.

Previously reported long-term data from the adult studies show that the difference between treated patients and placebo has persisted over several years and was greater at five years than after the first year. After five years, treated patients had, on average, retained 57 per cent of their baseline endogenous insulin production, compared with 15 per cent in the placebo group. The corresponding figures after one year were 89 and 53 per cent, respectively.

The results now reported for children aged 7–11 years cover the first 12 months following treatment. The long-term adult data provide a scientific rationale for investigating whether the numerically favourable differences observed in younger children persist or become more pronounced with longer follow-up. However, a similar pattern has not yet been demonstrated in children.

Further development of the pediatric programme – focus on disease stage and treatment intensity

Newly diagnosed type 1 diabetes in children and adolescents is characterised by considerable biological heterogeneity. The date of diagnosis marks when the disease is detected, rather than when the autoimmune process began. Consequently, patients may have different levels of residual endogenous insulin production and be at different stages of disease progression at diagnosis. The remission phase, subsequent decline in insulin production and biological maturation also vary between individuals.

The challenges of evaluating disease-modifying therapies for type 1 diabetes are discussed in a recent scientific article published in the journal *Diabetes*. The authors highlight age and residual C-peptide production at treatment initiation as important factors influencing subsequent disease progression. More precise patient selection, better characterisation of disease stage and appropriately designed clinical trials may therefore improve the evaluation of new therapies.

For comparison, the Phase III PROTECT trial of teplizumab included 328 children and adolescents. Patients in the active treatment group received two courses of treatment, with the primary efficacy endpoint assessed at 78 weeks. The trial demonstrated a statistically significant difference in preserved C-peptide production. Although the studies are not directly comparable, they illustrate differences in patient numbers, treatment regimens and follow-up duration between clinical development programmes.

Based on the ProTrans-Young results, NextCell intends to work with clinical experts to assess the optimal timing of treatment in children and whether repeated administrations could improve the preservation of endogenous insulin production. This work builds on the Company's experience with both single and repeated administrations in adult clinical studies, as well as the favourable safety profile observed to date for NXTCL-T1D. No treatment-related serious adverse events have been reported in the clinical studies.

A further important question is why disease progression, and treatment outcomes vary between patients. Research conducted through the international TrialNet network has demonstrated that individual C-peptide outcomes can be assessed against expected disease progression, considering factors such as patient age and baseline insulin production. NextCell intends to investigate whether such exploratory analyses could provide additional insights into which patient populations and treatment approaches should be prioritised in future studies.

NextCell has also discussed the potential role of screening children and adolescents with leading researchers and clinicians in type 1 diabetes. Screening can identify early stages of the disease before clinical symptoms develop, potentially enabling disease-modifying therapies to be investigated earlier in the disease course.

The Company therefore intends to assess the feasibility of future studies involving children identified through screening and treated before clinical onset. This represents a potential future direction for clinical development. NXTCL-T1D has not yet been investigated in these earlier stages of the disease.

About ProTrans-Young

ProTrans-Young is an investigator-initiated clinical trial sponsored by Uppsala University, with Professor Per-Ola Carlsson as Principal Investigator. The randomised part of the trial enrolled 60 children and adolescents aged 7–21 years with newly diagnosed type 1 diabetes and evaluates NXTCL-T1D against placebo. NXTCL-T1D is an investigational cell therapy based on allogeneic mesenchymal stromal cells, being developed with the aim of preserving patients' endogenous insulin production.

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 October 26, 2026, about 07:45 AM CET.

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The company's shares are listed on the Nasdaq First North Growth Market.

RedEye Noridc Growth AB is the company's Certified Adviser.

About NextCell Pharma AB

NextCell is a clinical-stage cell therapy company developing the proprietary NXTCL™ platform for the treatment of immune-mediated diseases, with a primary candidate in type 1 diabetes. NXTCL is designed to enable allogeneic cell therapies with controlled immunomodulation, consistent potency and scalable manufacturing. The company's lead program in type 1 diabetes has shown potential to preserve insulin production and slow disease progression for several years after a single treatment. The group also includes the wholly owned subsidiaries NextCell Sverige, NextCell Hong Kong, Cellaviva and QVance. The company was founded in 2014 and is headquartered in Huddinge next to the Karolinska University Hospital.