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Kidswell Bio Corporation (TSE:4584)

S-Quatre Corporation

PR Release

Clinical Study Using SHED for the Treatment of Cerebral Palsy
Final Analysis Results Disclosed

Tokyo, November 12, 2026 - Kidswell Bio Group is engaged in the research and development of novel cell-based therapies (regenerative medicine products) utilizing stem cells from human exfoliated deciduous teeth (SHED), with the aim of developing new treatments for pediatric and rare diseases for which no effective therapies currently exist. SHED developed using our proprietary cell culture and manufacturing processes is referred to within the Group as “SQ-SHED.”

One of the key initiatives involving SQ-SHED is a clinical study led by Nagoya University entitled “A clinical trial to evaluate the safety and tolerability of stem cells from human exfoliated deciduous teeth in children with cerebral palsy”. In November 2025, S-Quatre reported that the results of an interim analysis evaluating all three pediatric patients through 12 weeks following SHED administration has been released. Subsequently, all evaluations through 52 weeks following SHED administration have now been completed, and a paper presenting the final analysis results of the study has been posted online today by Nagoya University as a preprint (The content of the preprint may be revised or amended in the course of peer review and other subsequent processes).
https://www.researchsquare.com/article/rs-11215315/v1

The preprint presents an analysis of safety data and exploratory efficacy data collected over a one-year period following a single administration of SHED in each patient. The results showed that the safety and tolerability of SHED administration continued to be confirmed in all three patients. With respect to motor function, improvements were maintained over the one-year period following administration, and the reported rate of improvement exceeded those previously reported for other stem cell therapies. Exploratory MRI analyses also suggested increased nerve fiber density in white matter tracts involved in information transmission within the brain—including the corpus callosum, cingulum, and arcuate fasciculus—in two of the three patients, and the preprint discusses the possibility of structural changes in the brain. In addition, all three patients showed increases in developmental measures associated with adaptation to activities of daily living, which were reported as potentially indicating developmental progress. However, as this clinical study involved only a small number of patients, further studies are required to evaluate the efficacy.

These findings are consistent with the efficacy of SHED demonstrated in an animal model of chronic-stage cerebral palsy in a joint study by Nagoya University and S-Quatre, published in January 2026. They may provide important insights for advancing the clinical development of cell therapies for children with cerebral palsy.

S-Quatre will continue to advance its research and development efforts with the aim of delivering innovative therapy to patients and their families affected by cerebral palsy and other intractable diseases.

Key Research Findings

The study enrolled three pediatric patients aged 6 to 11 years with cerebral palsy resulting from perinatal hypoxic-ischemic encephalopathy. Each patient received a single intravenous administration of autologous SHED at a dose of 3×10^6 cells per kilogram of body weight. Evaluation over the one-year period following administration yielded the following findings:

- SHED administration was well tolerated, with no related adverse events and no abnormalities identified in clinical laboratory assessments.

- The exploratory efficacy assessment identified the following key improvements
  - Consistent trend toward improvement in motor function were observed. The Gross Motor Function Measure (GMFM [1])-66 score increased by an average of 3.2 points at 12 weeks after administration, with the improvement sustained in all patients throughout the one-year follow-up period. By the end of the follow-up period, the GMFM-66 score had increased by an average of 4.5 points from baseline, and a difference compared with the pre-administration level was reported.
  - The mean final GMFM Evolution Ratio (GMFMER [2]) was 19.7, which was reported to be higher than previously reported mean value of 6.0 reported for other stem cell therapies.
  - In the assessment of muscle tone, improvements in knee extension and ankle dorsiflexion were reported.
  - Exploratory analysis of brain diffusion MRI suggested an increase in nerve fiber density in white matter tracts, including the corpus callosum, cingulum, and arcuate fasciculus, and also indicated the possibility of structural changes in the brain.
  - In the assessment using the Kyoto Scale of Psychological Development, increases in evaluation scores were reported for both the “Cognitive-Adaptive” and “Language-Social” domains in all three patients.

Overall, this clinical research was reported to demonstrate that intravenous administration of autologous SHED can be safely performed in pediatric patients with chronic-stage cerebral palsy, while also suggesting its potential to improve motor function and promote structural recovery of the brain. These findings are based on a preprint that has not yet undergone peer review, and the efficacy and clinical significance of the treatment will need to be carefully evaluated through further studies.

1. Gross Motor Function Measure (GMFM)
   A quantitative assessment tool used to evaluate gross motor function, including whole-body movements involving the muscles of the trunk and limbs.

2. Gross Motor Function Measure Evolution Ratio (GMFMER)
   An index used to assess the degree of improvement in GMFM, calculated by dividing the observed change in GMFM by the improvement expected from natural development based on the patient’s age and severity.

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