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UniXell secures FDA clearance for iPSC-derived Parkinsonâ??s cell therapy

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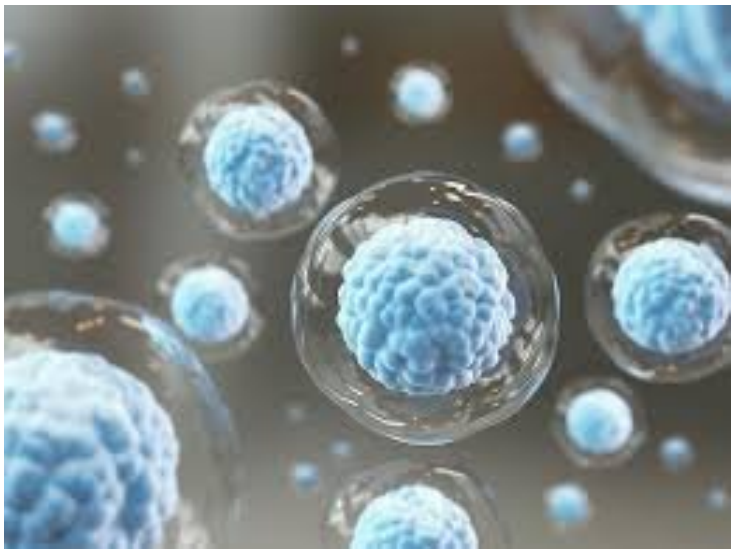
The clearance allows UX-DA003 to advance in parallel clinical development across China and the United States.



UniXell Biotechnology has received U.S. FDA Investigational New Drug clearance for UX-DA003, its allogeneic induced pluripotent stem cell-derived therapy for Parkinson's disease.

The clearance follows prior IND approval from China's National Medical Products Administration on 3 June 2026, allowing the programme to move into clinical development in both China and the United States. The milestone supports UniXell's dual-country regulatory strategy for iPSC-based therapies in neurodegenerative disease.

This is relevant because Parkinson's disease remains a progressive neurological disorder with limited disease-modifying treatment options. Existing therapies largely manage symptoms linked to dopamine deficiency, but they do not replace lost dopaminergic neurons or stop disease progression.

UX-DA003 is an allogeneic iPSC-derived midbrain dopaminergic progenitor cell therapy. It is designed as an off-the-shelf product based on UniXell's clinical-grade, GMP-compliant iPSC seed cell bank, with verified genetic stability and consistent differentiation capacity.

The therapy is built on UniXell's SISBAR lineage tracing platform and high-precision directed differentiation system. The company said preclinical data showed functional dopaminergic neurons reached 50 to 60 per cent of the graft, compared with an industry average of 2 to 15 per cent.

This level of purity is important because cell composition can affect safety, efficacy and dose requirements in regenerative medicine. UniXell said the optimised cell purity may reduce the required clinical dose by 50 to 80 per cent compared with conventional cell therapy regimens.

Safety is also central to the programme. The company reported a proliferating cell rate of 0.23 per cent at six months post-transplantation, below the reported range of 0.5 to 11 per cent. Lower proliferative activity may help reduce long-term safety concerns associated with cell-based therapies.

The candidate complements UniXell's autologous iPSC therapy UX-DA001, which is currently in a Phase I clinical trial at Ruijin Hospital in Shanghai. UX-DA001 is developed from a patient's own cells to reduce immune rejection risk, while UX-DA003 is positioned as a scalable allogeneic therapy designed for wider accessibility.

The dual-pathway strategy is commercially relevant. Autologous therapies may offer personalised treatment advantages but can be expensive and complex to manufacture. Allogeneic products may be easier to standardise, scale and distribute, but they must manage immunogenicity, durability and long-term safety.

Adoption will depend on early clinical safety, evidence of graft survival, motor function outcomes, immune management, manufacturing consistency and regulatory alignment across markets. Parkinson's cell therapy remains technically demanding, and clinical development will need to show that cell replacement can deliver durable benefit beyond symptomatic care.

The development reflects the growing maturity of iPSC-based regenerative medicine in Asia. If UX-DA003 progresses successfully, it could support broader industrialisation of off-the-shelf cell therapies for neurodegenerative diseases, where scalable manufacturing and long-term safety remain key barriers.