From China's First Approved Stem Cell Therapy to Its First Exosome IND: CytoNiche Enables Dual Industry Firsts

Singapore, Singapore Jul 9, 2026 (Issuewire.com) - China's Centre for Drug Evaluation (CDE) has officially granted Investigational New Drug (IND) clearance to **STX11101 Injection**, developed by Shanghai Stexo Biotechnology Co., Ltd. for the treatment of acute liver failure. This landmark approval marks the **first-ever exosome-based therapeutic to receive IND clearance in China**, shifting extracellular vesicle (EV) research from laboratory innovation into regulated, industrial-scale clinical development.

This milestone also represents a major achievement for Singapore-based **CytoNiche Biotech**, whose proprietary **3D FloTrix™ platform** served as a key technology partner enabling the therapy's manufacturing infrastructure and CMC development. Having previously supported the manufacturing behind China's first approved stem cell therapy (*Amimestrocel Injection*), CytoNiche has now enabled another national first, reinforcing its position as a trusted technological backbone for mesenchymal stem cell (MSC) and MSC-derived therapeutics.

Overcoming the Exosome Manufacturing Bottleneck

While MSC-derived exosomes possess powerful anti-inflammatory and regenerative properties, transitioning them into clinical-grade pharmaceuticals has traditionally been blocked by scalability and Chemistry, Manufacturing, and Controls (CMC) compliance. Traditional 2D culture methods suffer from high batch-to-batch variability and low yields.

The clearance of STX11101 shatters this industrial bottleneck, proving that high-purity, reproducible exosome therapeutics can be manufactured at a commercial scale under a standardised, closed, and fully regulated CMC framework.

"By enabling both China's first approved stem cell therapy and its first approved exosome IND, CytoNiche has demonstrated the profound versatility of the 3D FloTrix™ platform across the entire spectrum of living cells and their derivatives," said Dr Yan Xiaojun, Co-founder & CTO of CytoNiche. "We have transitioned from a component supplier to a comprehensive industrial ally, de-risking the most complex engineering phases for advanced therapy medicinal product (ATMP) enterprises globally."

The 3D FloTrix™ Advantage: Scale Up and Pure Quality

The manufacturing workflow for STX11101 replaces flat plastic 2D cultures with a biomimetic 3D microenvironment using CytoNiche's proprietary dissolvable microcarriers. This allows MSCs to expand naturally in suspension, optimising cell health and secretion consistency.

To meet the rigorous standards required for Stexo's IND application, CytoNiche deployed an integrated, closed-loop solution managing the entire downstream processing lifecycle:

- **Biomimetic 3D Cell Expansion:** Ensures stable, high-density MSC expansion, providing a premium foundation for exosome secretion.
- **Continuous Perfusion Harvesting:** Utilises a closed, perfusion-based culture process to maximise yield without compromising cell viability.
- **Automated Downstream Processing:** Deploys the *3D FloTrix™ vivaSPIN-SU* and *3D FloTrix™ vivaEXO* systems for rapid concentration and high-purity isolation, minimising contamination risks.
- **CMC-Oriented Manufacturing:** Delivers a fully scalable, repeatable production blueprint tailored to strict clinical and regulatory demands.

As global regulatory frameworks introduce tighter guidance for cell-derived secretomes, CytoNiche's validated blueprint provides ATMP enterprises worldwide with a transparent, cost-effective, and highly accelerated pathway from lab bench discovery to life-saving clinical reality.

About CytoNiche Biotech

CytoNiche™ is advancing the cell and gene therapy (CGT) industry through its scalable 3D FloTrix™ platform, providing end-to-end solutions for industrial-scale cell manufacturing. Its portfolio includes GMP-grade dissolvable microcarriers, serum-free media for mesenchymal stromal/stem cells (MSCs), and GMP-compliant equipment and consumables that support the complete manufacturing workflow.

Supported by FDA Master Files and adopted across multiple clinical programmes and a commercialised cell therapy product, CytoNiche's technologies enable scalable manufacturing for MSCs, exosomes and next-generation cell therapies. Guided by its vision of leading a new era of cell industrialisation and its mission of advancing global access to cell technologies through disruptive and scalable manufacturing innovations, CytoNiche is committed to accelerating the development and commercialisation of advanced cell therapies worldwide.

About Shanghai Stexo Biotechnology Co., Ltd.

Shanghai Stexo Biotechnology Co., Ltd. is dedicated to the research, development and commercialisation of stem cell-derived extracellular vesicle (EV)/exosome therapeutics. The company has established a proprietary platform for genetically engineered stem cell-derived exosomes and is supported by a robust R&D system, a quality management framework, and a strong intellectual property portfolio.

With cGMP-compliant manufacturing and quality control capabilities for large-scale exosome production, Stexo is advancing a pipeline of innovative exosome therapeutics targeting acute liver failure, stroke, lung injury, neurodegenerative diseases and autoimmune disorders, with the aim of addressing significant unmet medical needs.

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