Aspen Neuroscience Completes Phase 1/2a ASPIRO Trial Cohort Three Dosing and State-of-the-Art Manufacturing Expansion, Paving the Way for Developing Transformative Therapies for Patients

January 8, 2026

Facility Enters Qualification to Support Late-Stage Pivotal Manufacturing and Commercial Readiness

SAN DIEGO, Jan. 8, 2026 /PRNewswire/ — Aspen Neuroscience, Inc., a clinical-stage biotechnology company pioneering autologous regenerative therapies, today announced completion of Cohort Three* dosing in the company's ASPIRO Phase 1/2a trial of ANPD001, a personalized dopaminergic neuronal precursor cell (DANPC) therapy for moderate to advanced Parkinson's disease (PD). The company also announced the completion of construction of its current GMP manufacturing build-out in San Diego.

"Cohort Three dosing marks a meaningful inflection point for Aspen. With dosing complete and our facility build-out finished and entering qualification, we are positioned to move decisively into late-stage development while preserving the personalized quality that defines autologous medicine," said Damien McDevitt, Ph.D., President & Chief Executive Officer.

Cohort Three: Commercial-Ready Formulation and Streamlined Clinical Workflow
Cohort Three used Aspen's commercial formulation of ANPD001, designed to support scalable, reproducible manufacturing and a cryopreserved "thaw-and-inject" drug product that enables cells to be ready for dosing upon arrival at the institution—streamlining surgical procedures and minimizing impact on hospital cell processing labs.

Manufacturing Build-Out Completed
The North Torrey Pines manufacturing facility expansion project brings the total facility size to nearly 22,000 sq. ft. The facility's new state-of-the-art ISO 7 automated manufacturing cleanroom suites and ISO 8 support areas provide advanced environmental controls essential for high-quality cell therapy production, ensuring product integrity and supporting Aspen's late-stage clinical and commercial manufacturing needs. These new cleanroom suites serve as a template for future automated facility build-outs and support increased manufacturing capacity.

"Guided by Aspen's vision to transform the lives of people living with Parkinson's disease, this world-class facility represents a bold step forward in delivering personalized, life-changing therapies," said Kim Raineri, Chief Technology Officer. "This facility also serves as our template for future scale-out. By building a model for automation, we gain valuable insight into the additional technological advances that will be used to further increase efficiency and scalability in our state-of-the-art manufacturing process."

Building on Cohort One & Two Progress
Data reported from earlier cohorts at six months have demonstrated safety and tolerability, with clinician- and patient-reported improvements, achieved without the need for immunosuppression, consistent with Aspen's autologous approach.

In January 2025, Aspen announced completion of the first two cohorts and dose escalation, confirming continued progress of the ASPIRO study and the transition toward the commercial formulation employed in Cohort Three.

About ANPD001
ANPD001 is the most advanced autologous investigational cell therapy in the United States for treating Parkinson's disease.

Aspen's personalized approach means that patients do not require immunosuppressive (IS) drugs to dampen the body's immune response against foreign cells. This approach will eliminate IS-associated adverse events, IS drug-monitoring requirements, and enable dosing for those with contraindications to IS therapies.

Aspen's manufacturing process starts from a small biopsy of the patient's own skin cells, followed by reprogramming to induced pluripotent stem cells (iPSCs) and then differentiation of the iPSCs into DANPCs. These DANPCs are transplanted into the posterior putamen, replacing cells that were lost or damaged due to disease. The quality of each person's cells is assessed at every manufacturing stage using Aspen's proprietary machine-learning-based genomics tests.

ANPD001 has received Fast Track designation by the U.S. Food and Drug Administration (FDA).

About the ASPIRO Trial
ASPIRO is the first multi-patient, multi-center clinical trial of an autologous cell therapy for Parkinson's disease. It is evaluating safety, tolerability, and preliminary efficacy of ANPD001 in levodopa-responsive patients aged 50–70. Primary endpoints will be reported at 12 months, with long-term follow-up extending to 15 years.

More information about the Phase 1/2a trial is available at clinicaltrials.gov (NCT06344026)

For more information, visit www.aspenneuroscience.com.

** Cohort Three builds on funding provided by the California Institute for Regenerative Medicine (CIRM), a state of California agency that supports regenerative medicine, stem cell, and gene therapy research, which enabled Cohorts 1 and 2.*

CONTACT:
Samantha Murphy
Vice President, Corporate Development
smurphy@aspenneuro.com

Kerry Beth Daly
Corporate Communications
kbdaly@aspenneuro.com

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