



Aspen Neuroscience Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for Sasineprocel (ANPD001) to Treat Parkinson's Disease

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SAN DIEGO, July 30, 2026 /PRNewswire/ — Aspen Neuroscience, Inc., a clinical-stage regenerative medicine biotechnology company developing personalized, autologous cell therapies, today announced that sasineprocel (ANPD001), its lead investigational product, for the treatment of Parkinson's Disease (PD) was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration (FDA).

RMAT designation provides increased FDA guidance and expedited development support, including potential eligibility for priority review and accelerated approval pathways for regenerative therapies that are deemed to be transformative. Aspen previously received FDA Fast Track designation for sasineprocel. These designations underscore its clinical promise, innovative iPSC-derived cell therapy platform, and the potential to modify the course of PD.

The RMAT designation for sasineprocel is based on results from the ongoing Phase 1/2a ASPIRO trial*, which has demonstrated encouraging early clinical activity and a favorable safety profile. The ASPIRO study is an open-label, multicohort, multicenter trial evaluating the safety, tolerability and activity of the surgical delivery of autologous dopaminergic neuron precursor cells (DANPCs) into the putamen, the part of the brain where restoration of dopamine signaling is needed.

"This significant milestone highlights the transformative nature of sasineprocel as a potentially disease-modifying therapy for patients facing a serious disease with substantial unmet medical need," said Damien McDevitt, Ph.D., president and chief executive officer of Aspen Neuroscience. "We stand with the Parkinson's community realizing the urgency around the serious and growing unmet need in PD and are unwavering in our commitment to bring sasineprocel to patients as soon as possible."

"FDA has created this collaborative regulatory framework to facilitate early and frequent interactions, align on development requirements and potentially support more efficient pathways to approval," said Ana Sousa, chief regulatory officer. "Our team is working tirelessly to advance this investigational therapy designed to regenerate neural networks and restore lost neuronal function with the vision to potentially improve motor function, enhance quality of life, and reverse disease progression for patients."

What is RMAT Designation?

The Regenerative Medicine Advanced Therapy (RMAT) designation was established under the 21st Century Cures Act to expedite the development and review of regenerative medicine therapies intended to treat, modify, reverse, or cure serious conditions. To qualify, a product must show preliminary clinical evidence indicating its potential to address unmet medical needs. RMAT designation offers sponsors benefits such as early and frequent FDA interactions, potential eligibility for priority review, and potential accelerated approval.

About Aspen Neuroscience

Aspen Neuroscience is a leading, clinical-stage regenerative medicine biotechnology company developing autologous induced pluripotent stem cell-derived (iPSC) therapies beginning with neurodegenerative diseases of high unmet need including PD.

Its lead product candidate is sasineprocel (ANPD001), the most advanced autologous investigational cell therapy in the United States for treating PD.

About Sasineprocel (ANPD001)

Sasineprocel is a single-dose, autologous iPSC-based cell therapy being evaluated for the treatment of PD. We believe sasineprocel has the potential to be disease-modifying by replacing a patient's lost dopaminergic (DA) neurons with DANPCs and aiming to reconstruct the underlying neural circuitry lost in the progression of disease.

Specifically, sasineprocel is created from a patient's own cells via a small skin punch biopsy, reprogrammed to iPSCs (turning back the biological clock of the cells to a pre-disease state), and differentiated into DANPCs. Our proprietary cell composition is then delivered via image-guided administration to the putamen, the part of the brain where restoration of dopamine signaling is needed.

This approach is designed to establish a biologically active cellular microenvironment that supports engraftment, survival and functional integration of the transplanted cells to achieve durable clinical benefits for PD patients with the goal of slowing or halting disease progression.

Since it is autologous (using a patient's own cells), immunosuppression, which is required for donor-derived (allogeneic) cell therapies, is not needed.

For more information, visit www.aspenneuroscience.com.

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