July 31, 2026

ClearPoint Neuro Congratulates Partner Aspen Neuroscience on FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for Sasineprocel

RMAT Designation Supports an Expedited FDA Development and Review Pathway for Aspen's Investigational Autologous Cell Replacement Therapy for Parkinson's Disease.

SOLANA BEACH, CA / ACCESS Newswire / July 31, 2026 / ClearPoint Neuro, Inc. (Nasdaq:CLPT) (the "Company"), a global device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine, today congratulated its partner Aspen Neuroscience, Inc. on receiving Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) for sasineprocel (ANPD001), Aspen's investigational autologous dopaminergic neuron cell replacement therapy for Parkinson's disease.

Highlights

- The FDA has granted RMAT designation for sasineprocel, Aspen Neuroscience's investigational autologous cell replacement therapy for Parkinson's disease.
- RMAT designation provides benefits such as early and frequent interactions with the FDA, and potential eligibility for priority review and/or accelerated approval.
- The ClearPoint Neuro Navigation System and the SmartFlow® Cannula have been used for the transplantation procedure in Aspen's ASPIRO clinical trial, as announced in June 2024.
- ClearPoint currently supports 60+ biologics and drug delivery partner programs, of which 10+ have received one or more expedited review designations to-date.

About the RMAT Designation

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 or life-threatening conditions. The designation confers the benefits

of the FDA's Fast Track and Breakthrough Therapy programs, including early and frequent interaction with FDA review staff, and establishes potential eligibility for accelerated approval and priority review. RMAT designation is granted on the basis of preliminary clinical evidence, and does not constitute FDA approval.

ClearPoint Neuro's Role in the ASPIRO Trial

Aspen's ASPIRO trial is evaluating sasineprocel in participants with moderate to severe Parkinson's disease. As announced in June 2024, the ClearPoint Neuro Navigation System has been used for the transplantation procedure in the ASPIRO trial, in combination with the SmartFlow Cannula, to support accurate, minimally invasive delivery of cells to the intended anatomical target.

"We want to congratulate the entire team at Aspen on this milestone. RMAT designation reflects the FDA's recognition of the seriousness of Parkinson's disease and the need for new approaches, and it opens the door to a closer working relationship with the agency as Aspen advances sasineprocel," commented Dr. Paul Larson, Chief Medical Officer at ClearPoint Neuro. "ClearPoint is proud to support this program, and we remain focused on being the partner our collaborators rely on to deliver their therapies accurately and consistently."

ClearPoint Neuro partners with pharmaceutical and biotechnology companies, academic centers, and contract research organizations to support direct delivery of therapeutics to the central nervous system in preclinical studies and clinical trials.

About Aspen Neuroscience & Its Work in PD

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.

Sasineprocel is a single-dose, autologous iPSC-based cell therapy 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. The 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.

About ClearPoint Neuro

ClearPoint Neuro is a device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine. The Company uniquely provides both established clinical products as well as pre-clinical development services for controlled drug and device delivery. The Company's flagship product, the ClearPoint Neuro Navigation System, has FDA clearance and is CE-marked. ClearPoint Neuro is engaged with healthcare and research centers in North America, Europe, Asia, and South America. The Company is also partnered with the most innovative pharmaceutical/biotech companies, academic centers, and contract research organizations, providing solutions for direct Central Nervous System delivery of therapeutics in pre-clinical studies and clinical trials worldwide. To date, thousands of procedures have been performed and supported by the Company's field-based clinical specialist team, which offers support and services to our customers and partners worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release concerning the Company's plans, growth and strategies may include forward-looking statements within the meaning of the federal securities laws. Particular uncertainties and risks include: the fact that RMAT designation does not constitute FDA approval, is granted on the basis of preliminary clinical evidence, may be rescinded by the FDA, and does not ensure that sasineprocel will be developed on any particular timeline, will receive accelerated approval or priority review, or will be approved at all; the possibility that results observed to date in the ASPIRO trial are not replicated in later or larger studies, or that the trial is delayed, modified, suspended or discontinued; the Company's lack of control over Aspen Neuroscience's development program, clinical and regulatory strategy, funding and public disclosures; the Company's biotech partners' continued use of the Company's products and services in the delivery of their gene and cell therapies, including in later stage trials and, if approved, commercially; the Company's ability to maintain its current relationships with its biotech partners or enter into relationships with new partners; the possibility that partner programs are discontinued, deprioritized, delayed or transferred, and that expedited review designations received by partner programs do not result in approval or in revenue to the Company; the Company's ability to market, commercialize and achieve broader market acceptance for the products and services offered by the Company; the regulatory requirements for approval and pace of market adoption of the gene and cell therapies under development by the Company's biotech partners; and the Company's ability to continue to build and maintain the infrastructure and personnel needed to allow for widespread adoption of intracranial administration of gene and cell therapies.

Statements in this press release regarding Aspen Neuroscience, sasineprocel, and the ASPIRO trial are based on information made publicly available by Aspen Neuroscience. The Company has not independently verified that information and undertakes no obligation to update it.

For a detailed description of the Company's risks and uncertainties, you are encouraged to review its documents filed with the SEC including the Company's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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SOURCE: ClearPoint Neuro, Inc.