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ClearPoint Neuro Congratulates Partner Aspen Neuroscience on Use of the ClearPoint® Navigation System for All Enrolled Patients in ASPIRO Clinical Trial

Parkinson's Disease Clinical Trial Uses Intraoperative MRI to Guide Precision Implantation of Patients' Own Autologous Replacement Neurons

SOLANA BEACH, Calif., June 20, 2024 (GLOBE NEWSWIRE) -- 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 congratulates its partner Aspen Neuroscience, Inc. on use of the ClearPoint Neuro Navigation System to transplant dopaminergic neuron precursor cells (DANPCs) for all enrolled patients with Parkinson's Disease (PD) in its recently launched ASPIRO Phase 1/2a clinical trial. ASPIRO is an open label trial to assess safety and tolerability of ANPD001, an autologous, dopaminergic neuron cell replacement therapy for participants with moderate to severe PD.

The DANPCs are transplanted to the putamen, a small structure located in the mid-brain, in a single transplantation procedure using ClearPoint MRI guidance, the SmartFlow® Cannula, and the Aspen Metered Delivery Syringe (AMDS). This surgical approach was developed by the trial's lead neurosurgeon and renowned MRI-guided stereotactic neurosurgery pioneer Paul Larson, MD, FAANS, professor of neurosurgery at the University of Arizona College of Medicine - Tucson and neurosurgeon at Banner University Medical Center, Tucson.

"We are thrilled to partner with Aspen to support the first multi-center trial for an autologous neuron replacement therapy for Parkinson's disease," commented Jeremy Stigall, Chief Business Officer at ClearPoint Neuro. "We also applaud Aspen's decision to standardize the surgical approach across all enrolled patients with ClearPoint, as we believe this reduces surgical variability and de-risks study results."

The ClearPoint Neuro Navigation System utilizes intraprocedural MR images to provide navigational instruction for the neurosurgeon, and confirmation that the desired anatomical target has been reached with submillimetric accuracy. Combined with the SmartFlow® Cannula, which is less than 2 millimeters in diameter, this allows for minimally invasive delivery of therapeutic agents in a patient's brain.

About the ASPIRO Trial

The Autologous-derived Study of a Parkinson's Investigational Regenerative therapy in an Open-label trial (ASPIRO) is a Phase 1/2a clinical trial to assess the safety, tolerability, and potential efficacy of ANPD001 in patients with moderate to severe Parkinson's disease. The dose escalation study includes patients aged 50–70 years of age and excludes patients with cognitive impairment and other comorbidities that could preclude treatment. All enrolled patients are under the care of a movement disorder specialist.

The primary study endpoint is safety and tolerability of ANPD001. Secondary endpoints include improvement in "on" time, when patients experience periods of symptom control, and improvements in motor symptoms and quality of life based on standard Parkinson's disease rating scales.

About ANPD001

ANPD001 is an investigational autologous neuronal replacement therapy being studied as a regenerative therapy for PD. Aspen's personalized approach means that patients do not require immunosuppressive drugs to counteract the body's immune response against foreign cells.

Aspen's manufacturing process starts from a small sample of the patient's own skin cells, followed by reprogramming to induced pluripotent stem cells (iPSCs) and then differentiation of the iPSCs into dopaminergic neuron precursor cells (DANPCs). These DANPCs are transplanted into the 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.

About Aspen Neuroscience

Headquartered in San Diego, Aspen Neuroscience, Inc. is a clinical development-stage, private company focused on autologous regenerative medicine. The company's patient-derived iPSC platform is used to create personalized therapies to address diseases with high unmet medical needs, beginning with autologous neuron replacement for Parkinson's disease.

Aspen combines cell biology with the latest machine learning and genomic approaches to investigate patient-specific, restorative cell treatments. The company has developed a best-in-class platform to create and optimize pluripotent-derived cell therapies, which includes in-house bioinformatics, manufacturing and quality control. For more information and important updates, please visit https://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 CNS 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

This press release contains forward-looking statements within the context of the federal securities laws, which may include the Company's expectations for the future performance, market, and revenue of its products and services. These forward-looking statements are based on management's current expectations and are subject to the risks inherent in the business, which may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: global and political instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; future revenue from sales of the Company's products and services; the Company's ability to market, commercialize and achieve broader market acceptance for new products and services offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of the Company's products and services in their delivery of therapies; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; the Company's ability to obtain additional funding to support its research and development programs; the ability of the Company to manage the growth of its business; the Company's ability to attract and retain its key employees; and risks inherent in the research, development, and regulatory approval of new products. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2024, both of which have been filed with the Securities and Exchange Commission. The Company does not assume any obligation to update these forward-looking statements.

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