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# ClearPoint Neuro Announces Progression of Key Partner Milestones throughout the Global Biologics and Drug Delivery Portfolio

**SOLANA BEACH, CALIFORNIA / ACCESS Newswire / August 4, 2025 /**ClearPoint Neuro, Inc. (NASDAQ:CLPT) ("Company"), a global device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine, today announced multiple key milestones demonstrating the progression of the Company's Biologics and Drug Delivery Portfolio including first commercial infusions in the United States, additional partners accepted for expedited review, creation of cell and gene infusion ICD-10 codes, and record clinical trial patients treated globally in the month of July.

The first commercial treatments for **KEBILIDI™ (eladocagene exuparvovec-tneq)**, a gene therapy approved for pediatric and adult patients with aromatic L-amino acid decarboxylase (AADC) deficiency-a rare, life-threatening neurological disorder, have been performed in the United States using the Company's **SmartFlow® Neuro Cannula**. KEBILIDI is delivered directly to the putamen region of the brain through a stereotactic neurosurgical procedure.

The **SmartFlow® Neuro Cannula is** the only FDA authorized device indicated for use to administer KEBILIDI.

These groundbreaking treatment procedures were carried out by physician teams separately at hospitals in Texas and Boston, led by neurosurgeons who are part of the **IGNITE** (Image-Guided Biologic Therapies: Neurosurgeons Innovating Treatment Excellence) working group. The IGNITE consortium, which has been hosted and sponsored by the Company, focuses on driving the field of neuro gene and cell therapy forward, and recently published a peer-reviewed article in the Journal of Neurosurgery: https://thejns.org/view/journals/j-neurosurg/aop/article-10.3171-2025.1.JNS241967/article-10.3171-2025.1.JNS241967.xml

"The future of cell and gene therapy is not coming…it is already here," commented Joe Burnett, President and CEO at ClearPoint Neuro. "The pivotal milestone of the first commercial gene therapy treatments in the US ever delivered to the brain should serve as both a sign of hope to patients, and as a clear headline to hospitals around the world that it is time to get ready for these transformational new medicines."

"In medicine, technology changes all the time, but true transformation in patient therapy is

very rare," commented Dr. Daniel J. Curry, Director, Functional Neurosurgery and Epilepsy Surgery at Texas Children's Hospital and Professor, Neurosurgery and Surgery at Baylor College of Medicine. "Direct delivery of cell and gene therapy into the brain represents such a transformation in care, in that we can finally potentially restore the defects responsible for devastating pediatric neurological disease in this condition and eventually many other conditions that were previously relegated to comfort care. We can now treat the disease, not just the symptoms, and improve quality of life and life expectancy, as we've seen in children with AADC deficiency. Our team and institution are proud to help lead this exciting chapter of neurosurgical drug delivery."

"This important milestone has been years in the making, and we are proud to have successfully delivered this novel gene therapy," commented Dr. Scellig S. D. Stone, Director, Stereotactic and Functional Neurosurgery at Boston Children's Hospital. "While AADC deficiency is a rare childhood genetic disorder, we believe that this is the first of many new restorative therapies. Days like today make all our training and preparation truly worthwhile."

"We at ClearPoint expect to play an essential role not only in the delivery of KEBILIDI, but in supporting a broad range of commercial cell and gene therapies in the future," said Burnett. "Our complete ecosystem of drug delivery solutions including pre-planning software, peri-procedural neuro navigation hardware, cannula-based routes of administration, A.I.-informed quality control documentation, and expert clinical support are being used preclinically and in clinical trials for more than 60 active biopharma partners. Multiple partners have already been accepted to one of the FDA Expedited Review programs, of which PTC Therapeutics was the first to be approved. And as seen with KEBILIDI, if ClearPoint technology continues to be included in the labeling itself as a combination product, it is hard to imagine a situation where ClearPoint is not an essential part of any hospital that wants to participate meaningfully in the neuro cell and gene therapy market."

In addition, the ICD-10 Coordination & Maintenance committee has included new, neuro infusion specific ICD-10-PCS codes which will be effective October 1, 2025, and will assist in tracking commercial use of the SmartFlow cannula, and eventually other device technologies directly to the brain. The application for these new codes was submitted by the Company earlier this year.

The Company also announced a record number of cell and gene therapy infusions in July, performed either commercially or as part of registered clinical trials - including 17 global patients treated across 11 different drug platforms. This demonstrates the continued progression of the Company's more than 60 active partners through the regulatory approval process.

This progression of patients enrolled has led to two additional biologics and drug delivery partners being selected for expedited review by the FDA, which brings the total number of Company partners accepted into expedited review to nine.

**About the SmartFlow Neuro Cannula**

With over 9000 cannulas sold to date, SmartFlow is the only co-labeled device to gain approval by regulatory bodies in both the U.S. and EU for delivery of an approved gene therapy to the brain. The industry-leading cannula is used by many of ClearPoint Neuro's

60+ pharmaceutical, academic, and biotech partners to bypass the blood brain barrier and deliver therapeutics to regions of interest using Convection Enhanced Delivery (CED) under direct image guidance. The SmartFlow Neuro Cannula has received De Novo FDA approval for the intraputaminal administration of the gene therapy KEBILIDI™ (eladocagene exuparvovec-tneq) for the treatment of aromatic L-amino acid decarboxylase (AADC) deficiency. SmartFlow is also 510(k) cleared by the FDA for use in the United States for the aspiration of cerebrospinal fluid or injection of the chemotherapy drug Cytarabine into the ventricles. The cannula is CE marked to deliver cytarabine and other approved fluids into the brain or perform aspiration of CSF. SmartFlow is being utilized in approved clinical and preclinical studies for various research and drug trials.

**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 preclinical 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.

*Disclosure Statement: Dr. Scellig S. D. Stone has consulted for ClearPoint Neuro, Inc. and PTC Therapeutics.*

**Forward Looking Statements**

This press release contains forward-looking statements within the context of the federal securities laws, including the Company's expectation for future development, regulatory approval and the market for cell and gene therapies, and the adoption of the Company's products and services for use in the delivery of gene and cell therapies.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: macroeconomic and inflationary conditions; regulatory and policy uncertainty; the introduction of or changes in tariffs, sanctions, or trade barriers; changes in monetary policy; geopolitical trends, such as protectionism and economic nationalism; 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 ability to maintain its current relationships with biologics and drug delivery partners or enter into new relationships with such partners; 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 the Company's new products and services and the new products of its biologics and drug delivery partners. 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, 2024, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, both of which have been filed with the Securities and Exchange Commission,and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2025, which the Company intends to file with the Securities and Exchange Commission on or before August 14, 2025. The Company does not assume any obligation to update these forward-looking statements.

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