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ClearPoint Neuro Announces EU MDR Certification for the SmartFlow Cannula

SOLANA BEACH, CA / ACCESS Newswire / February 12, 2025 / 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 announced receipt of European Medical Device Regulation (EU MDR) approval for the SmartFlow Neuro Cannula.

The SmartFlow Cannula was previously cleared under the Medical Device Directive 93/42/EEC (MDD) and has now successfully achieved the more rigorous EU MDR certification well ahead of the 2027 deadline for Class III devices. In addition, the updated certification has extended the shelf life of the SmartFlow Cannula to 48 months in the European Union (EU), an increase from the prior shelf life of 24 months.

"Receiving EU MDR clearance for SmartFlow shows our commitment to the European market and to supporting our partners who are running clinical trials or commercializing their therapies in the region," stated Megan Faulkenberry, Vice President of Quality at ClearPoint Neuro. "We are also happy to announce the longer 48 month shelf life, which now matches our shelf life in the United States and Brazil, as this will help our customers with inventory management and improve sustainability by reducing waste. We are proud to have achieved this milestone so far in advance of the required timeframe."

"This approval is made possible by the significant global clinical trial history of the SmartFlow Cannula," said Jeremy Stigall, Chief Business Officer of ClearPoint Neuro. "Under EU MDR, the EU is placing greater emphasis on safety measures, risk management, post-market surveillance, and data collection of medical devices for companies who wish to obtain European market access. The many years of trial experience with the SmartFlow Cannula contributed greatly to its successful review and approval. This approval will give our over 50 biopharma partners, some of whom are headquartered in the EU, the confidence that we can support clinical trials and eventual commercialization globally."

In the EU, SmartFlow has received CE mark for the delivery of approved fluids into the brain during intracranial procedures, as well as injection of Cytarabine or removal of CSF (14 gauge cannulas only) from the ventricles. PTC Therapeutics' Upstaza, the first marketed gene therapy approved for direct infusion into the brain, includes the use of SmartFlow for minimally invasive infusion of the gene therapy in the Summary of Product Characteristics.

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, including the Company's expectation for the future market of its products and services, and other performance and results. 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 September 30, 2024, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2024, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2025. The Company does not assume any obligation to update these forward-looking statements.

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