January 22, 2024

ClearPoint Neuro Announces First EU MDR Certification Success and Approval to Ship Product to Europe

SOLANA BEACH, Calif., Jan. 22, 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 announced receipt of European Medical Device Regulation (EU MDR) clearance for the manual SmartTwist® MR Hand Drill and SmartTip® MR Drill Kit. Additionally, the Company received updated certification from its Notified Body allowing for shipment of products manufactured at its new Carlsbad, California facility to Europe.

European Medical Device Regulation 2017/745 (EU MDR), the new medical device regulation applicable in Europe, replaces the previous Medical Device Directive 93/42/EEC (MDD) regulation. With the introduction of 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.

“EU MDR is much more rigorous than MDD, forcing many medical device companies in our space who wish to enter or continue commercialization in Europe to closely assess every product before committing the time and resources necessary to meet its requirements,” stated Megan Faulkenberry, Vice President of Quality at ClearPoint Neuro. “Our team has risen to this challenge, especially given the importance of the EU to our pharmaceutical partners.”

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, regulatory and development plans, 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, 2022, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2023, 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, 2023, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2024. The Company does not assume any obligation to update these forward-looking statements.

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