June 2, 2022

ClearPoint Neuro Announces Receipt of MDSAP Certification

SOLANA BEACH, Calif., June 02, 2022 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global therapy-enabling platform company providing navigation and delivery to the brain, today announced the receipt of certification for the Medical Device Single Audit Program (MDSAP).

MDSAP allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory jurisdictions or authorities enabling appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on the industry. The program currently represents Australia's Therapeutic Goods Administration, Brazil's Agência Nacional de Vigilância Sanitária, Health Canada, Japan's Ministry of Health, Labour and Welfare and Pharmaceutical and Medical Devices Agency, and the U.S. Food and Drug Administration's Center for Devices and Radiological Health.

"The fourth pillar of ClearPoint's growth strategy is global expansion for which MDSAP certification is essential. This certification validates our ongoing commitment to maintaining the highest quality assurance standards within the medical device industry as required by regulatory authorities across the world," said Megan Faulkenberry, Vice President of Quality and Regulatory at ClearPoint Neuro. "While many medical device companies experience difficulties with expansion into key geographies due to the many requirements in play across various regulations, our team has succeeded in achieving this significant accomplishment. This milestone demonstrates the high level of quality and regulatory compliance we maintain as we continue to push forward globally. We have invested to make our quality system a strength that our biologics and drug delivery partners can count on as they navigate regulatory and commercial approvals for their drug platforms."

About ClearPoint Neuro

ClearPoint Neuro's mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders with pinpoint accuracy. Applications of the Company's current product portfolio include deep brain stimulation, laser ablation, biopsy, neuro-aspiration, and delivery of drugs, biologics, and gene therapy to the brain. The ClearPoint® Neuro Navigation System has FDA clearance, is CE-marked, and is installed in over 60 active sites in the United States, Canada, and Europe. ClearPoint Neuro is partnered with approximately 45 biologics/pharmaceutical companies and academic centers, providing solutions for direct CNS delivery of therapeutics

in pre-clinical studies and clinical trials worldwide. To date, more than 5,000 cases 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 herein concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. Uncertainties and risks 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: the impact of the COVID-19 pandemic and the measures adopted to contain its spread; future revenue from sales of the Company's ClearPoint Neuro Navigation System products; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System products; and risks inherent in the research and development 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, 2021, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2022, both of which have been filed with the Securities and Exchange Commission.

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