April 28, 2022

ClearPoint Neuro Announces FDA Clearance of the SmartFrame Array™ Version 1.1

Next Generation Neuro Navigation System Designed for Use in Both the MRI Suite and Operating Room

SOLANA BEACH, Calif., April 28, 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 that it has received FDA clearance for version 1.1 of its next generation SmartFrame Array Neuro Navigation System and Software.

The 'Array' System, which was designed to streamline laser catheter insertion, brain biopsy, and drug delivery clinical trial procedures, has been in limited market release (LMR) since May 2021. During the limited release, SmartFrame Array was used in over 50 pre-clinical, clinical trial, and clinical procedures at 10 hospitals and clinical research organizations across North America. Version 1.1 adds a pre-planning module that will further enhance workflows and reduce procedure time in both the MRI Suite and in the Operating Room (OR). The SmartFrame Array will be on display from April 29 – May 1 in the ClearPoint Neuro booth at the 2022 American Association of Neurological Surgeons Annual Scientific Meeting in Philadelphia, PA.

"Throughout the LMR, Array has enabled shorter procedure times and unique multi-trajectory workflows for gene therapy clinical trials and preclinical studies," commented Stephanie Korszen, Director of Business Development for Biologics & Drug Delivery. "Neurosurgeons have appreciated the increased rigidity and lower profile of the Array frame, reporting faster and more stable drilling. SmartFrame Array's compatibility with probes and trackers from Optical Navigation systems also allows surgeons to start procedures in the Operating Room. This important evolution in ClearPoint's overall strategy leverages our expertise in MRI-guided neuro navigation to incorporate other OR-based imaging modalities."

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 approximately 60 active sites in the United States, Canada, and Europe. ClearPoint Neuro is partnered with approximately 40 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, which has been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2022, which the Company intends to file with the Securities and Exchange Commission on or before May 16, 2022.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/04274d60-0406-46f6-9e19-c0651420e9c1

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