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ClearPoint Neuro Announces FDA Clearance for SmartFrame OR™ Stereotactic System

Limited Market Release of First Purpose-Built OR Product to Begin in First Half of 2024

SOLANA BEACH, Calif., Jan. 16, 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 it has received 510(k) clearance for its SmartFrame OR™ Stereotactic System.

The SmartFrame OR Stereotactic System is composed of two main components: the SmartFrame OR, and the ClearPointer™ Optical Navigation Wand. The SmartFrame OR is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction with the use of a compatible optical stereotaxic navigation system using preoperative MR and/or CT imaging. These procedures include biopsies, catheter placement and electrode introduction. The ClearPointer is intended to be used in conjunction with the SmartFrame OR and a compatible stereotactic optical navigation system for patient registration and navigation. SmartFrame OR may be used with or without available bone screw fiducials. The Company plans to commence limited market release in the first half of 2024, with a planned full market release in the second half of 2024.

"Expanding ClearPoint's portfolio beyond the MRI into the operating room is of key strategic significance to the Company in 2024 and beyond," stated Joe Burnett, President and CEO at ClearPoint Neuro. "More than 95% of all stereotactic neuro-navigation procedures take place in the OR, supporting DBS, Laser Ablation, Biopsy, sEEG, and more. This product is the first in ClearPoint's history that does not require the use of MRI during the procedure, allowing us to access more hospitals, and to support an order of magnitude more patients than our legacy portfolio. Importantly, the SmartFrame OR is compatible with capital hardware and software already present in many neurosurgical operating rooms and should not require the approval by hospital capital committees for surgeons to try this new product."

"SmartFrame OR embodies over a decade of accumulated expertise in MRI-guided navigation, now enhanced with the latest OR imaging technology," said Rob Rubio, Segment Leader for Neuromodulation at ClearPoint Neuro. "It offers surgeons flexible workflows,

including iCT forward projection, enabling precise image-based corrections to achieve submillimetric accuracy.”

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, 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.

A video accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/a2ebbab0-b838-4d64-b33f-d57fdb80a9a6

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