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ClearPoint Neuro Announces Initiation of Limited Market Release for the SmartFrame OR™ Stereotactic System

More than Ten Operating Room Procedures Complete with Multiple Sites Reordering and Scheduling Cases

SOLANA BEACH, Calif., April 24, 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 initiated the Limited Market Release for its SmartFrame OR™ Stereotactic System.

"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. "We estimate that 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 allows for complete procedures to be performed in the operating room, enabling ClearPoint's access to more hospitals, and to support an order of magnitude more patients than our legacy portfolio. In just the first month of limited market release, we have already completed more than ten cases and all of the active sites have now either reordered product or scheduled additional patients. To put that in perspective, if these hospitals continue on their current pace, then we would have the potential to increase our total, company-wide annual clinical procedure volume by more than 10% from just a handful of active sites. Notably, these are situations where MRI guidance was not a possibility, demonstrating how the new SmartFrame OR product is opening access to a new market opportunity for ClearPoint."

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 stereotactic 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 has initiated limited market release, with a planned full market release in the

second half of 2024.

“Importantly, the SmartFrame OR is compatible with capital hardware and software already present in many neurosurgical operating rooms,” continued Burnett. “As a result, we expect this to be the fastest product launch in our history. The SmartFrame OR can ‘plug-and-play’ into already existing commonly used hospital imaging equipment. Given our initial experience, we now expect to enter full market release by the end of Q2 generating meaningful product revenue in the second half of the year.”

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, which include the Company’s expectations for the future performance, market, and revenue of its products. 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, 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, 2024, which the Company intends to file with the Securities and Exchange Commission on or before May 15, 2024. The Company does not assume any obligation to update these

forward-looking statements.

A photo accompanying this announcement is available

at: <https://www.globenewswire.com/NewsRoom/AttachmentNg/ce047802-3cf7-4571-bd39-697d03dc0d44>

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Source: ClearPoint Neuro, Inc.

SmartFrame OR logo



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