April 29, 2024

ClearPoint Neuro Announces FDA Clearance of Prism Bone Anchor Accessory

Key Accessory to the ClearPoint Prism® Neuro Laser Therapy Will Enable Operating Room Placement of Laser Fibers

SOLANA BEACH, Calif., April 29, 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 Prism Bone Anchor Accessory. This clearance marks the Company's second new product introduction within the first four months of 2024.

"Similar to the recent launch of our SmartFrame OR platform, the introduction of the Prism Bone Anchor Accessory for use with the ClearPoint Prism Neuro Laser Therapy System supports our continued expansion beyond the MRI into the operating room. This is where most laser applicators are placed today," stated Chris Osswald, PhD, Director, Global Segment Leader for Laser Therapy at ClearPoint Neuro. "We are pleased to round out our laser portfolio and look forward to working with hospitals in the United States interested in the Prism System that may have challenges with MRI access. We plan to begin our limited market release on schedule here in the second quarter, with a full market release in the second half of 2024."

The Prism Bone Anchor Accessory is intended to be used with commercially available stereotactic systems for intracranial and neurosurgical procedures which require accurate positioning of compatible small surgical instruments or accessories in the cranium, brain or nervous systems. It is designed to provide short-term fixation and positioning of compatible neurosurgical instruments or accessories under image-guidance.

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 may 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/66f919ac-c17e-402e-a88e-1211e8044e7c

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Source: ClearPoint Neuro, Inc.

The ClearPoint Prism® Neuro Laser Therapy System

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