April 28, 2025

ClearPoint Neuro, Together with its Partner Clinical Laserthermia Systems, Announces FDA Submission to Expand the Labeling of ClearPoint Prism(R) to Include 1.5 T MRI

SOLANA BEACH, CA / ACCESS Newswire / April 28, 2025 / ClearPoint Neuro, Inc. (NASDAQ:CLPT) (the "Company"), a global device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine, announces that today its partner, Clinical Laserthermia Systems AB (publ) (CLS), completed the submission of its 510(k) application to the FDA, expanding the indication of the ClearPoint Prism Neuro Laser Therapy System to include 1.5 T MRI guidance.

ClearPoint Prism has already seen rapid adoption across functional and oncological neurosurgical LITT procedures. "We anticipate that we will achieve clearance for 1.5 T in the second half of this year, unlocking more than 50% of the neuro LITT market in the United States that we do not have access to today," commented Joe Burnett, President and CEO.

"This submission is a result of great collaboration between our companies. At CLS, we're proud to support ClearPoint Neuro in expanding access to the neuro LITT Market and driving global adoption of ClearPoint Prism," said Dan J. Mogren, CEO of CLS.

ClearPoint Prism is currently indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under 3.0 T magnetic resonance imaging (MRI) guidance in medicine and surgery in neurosurgery for a wavelength of 1064nm.

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 preclinical 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 central nervous system delivery of therapeutics in preclinical 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 regulatory review timelines and outcomes, 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: macroeconomic and inflationary conditions; regulatory and policy uncertainty; the introduction of or changes in tariffs, sanctions, or trade barriers; changes in monetary policy; geopolitical trends, such as protectionism and economic nationalism; 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 ability to maintain its current relationships with biologics and drug delivery partners or enter into new relationships with such partners; 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 the Company's new products and the new products of its biologics and drug delivery partners. 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, 2024, 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, 2025, which the Company intends to file with the Securities and Exchange Commission on or before May 15, 2025. The Company does not assume any obligation to update these forward-looking statements.

Contact Information

Danilo D'Alessandro
Chief Financial Officer
ir@clearpointneuro.com
(888) 287-9109 ext. 3

SOURCE: ClearPoint Neuro, Inc.