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ClearPoint Neuro Announces FDA Clearance Expanding Compatibility of the ClearPoint Prism Neuro Laser Therapy System with 1.5T MRI Scanners

SOLANA BEACH, CALIFORNIA / ACCESS Newswire / September 4, 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, today announced that the ClearPoint Prism® Neuro Laser Therapy System ("ClearPoint Prism") received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to include 1.5T MRI guidance in addition to the previously cleared 3T MRI guidance.

This expanded labeling could significantly increase ClearPoint Prism's market opportunity within the United States, where 1.5T MRI systems account for approximately 60% of clinical use.[1] As the Company considers future development within key markets, 1.5T systems represent over 70% of the global installed MRI base,[2] well-positioning ClearPoint Prism for future growth as the company continues to expand internationally.

"The expanded labeling for ClearPoint Prism is perfect timing for the Company as it delivers added fuel to our 2025 growth initiatives, which we call Fast Forward," commented Joe Burnett, President & CEO at ClearPoint Neuro. "This product will contribute meaningfully to these goals, both today and tomorrow. In the immediate term, we are excited to bring the benefits of ClearPoint Prism to hospitals that did not have the previously cleared MRI scanner available. As a reminder, our Functional Neurosurgery disposable products, including ClearPoint Prism laser applicators, grew 70% in the first quarter and 33% in the second quarter of this year. That growth was accomplished with one hand tied behind our back as we had access to less than 50% of the neuro LITT market. That hand is no longer tied."

"The longer-term benefits are more subtle but equally important," continued Burnett. "As a company, we are still at the very early stages of our biggest value driver in commercial cell and gene therapy delivery. The expanded labeling helps us in this exciting and adjacent market in two ways. First, we gain scale because we will have another product in our commercial bag that will allow us to hire expert clinical specialists into cities that have greater volume, increasing hospital consistency and relationships, while at the same time reducing travel expenses. Second, we believe there is no procedure that surgeons can do

clinically today that better mimics a drug delivery procedure than laser ablation. ClearPoint Prism cases cover many different trajectories, are minimally invasive through tiny burr holes, are performed under MRI guidance, and deliver a volume-driven therapy to the patient. Every ClearPoint Prism case a surgical team does today helps them to build a new capability for the exciting future of cell and gene therapy."

"We're dedicated to providing our customers an adaptable, forward-thinking system that is designed for a streamlined setup, consistent performance, and optimized surgical workflows," stated Chris Osswald, PhD, Director and Global Segment Leader for Laser Therapy. "With this clearance, we've maintained our high-performance specifications and are well-positioned to build upon our momentum. Since the full market release on 3T MRI last year, we are encouraged by the number of inquiries from sites without 3T access, reflecting strong market interest. We believe surgeons are eager to use ClearPoint Prism on 1.5T, enabling more patients to benefit from advanced laser therapy. Given the significant and positive early experience that we've had on 3T, we plan to enter full market release on 1.5T immediately."

ClearPoint Prism is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under 1.5T and 3.0T magnetic resonance imaging (MRI) guidance in neurosurgery for a wavelength of 1064nm.

[1] Moser E, Laistler E, Schmitt F and Kontaxis G (2017) Ultra-High Field NMR and MRI-The Role of Magnet Technology to Increase Sensitivity and Specificity. *Front Phys*. 5:33. doi: 10.3389/fphy.2017.00033.

[2] IMV Medical Information Division. *2015 MR Market Outlook Report.* IMVinfo, 2015.

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 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, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2025, both of which have been filed with the Securities and Exchange Commission. The Company does not assume any obligation to update these forward-looking statements.

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