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ClearPoint Neuro Announces FDA Clearance for ClearPoint Navigation Software Version 3.0

SOLANA BEACH, CALIFORNIA / ACCESS Newswire / January 27, 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 it has received 510(k) clearance for its ClearPoint Navigation Software Version 3.0.

"As we prepare for the wave of new patients that will be treated with cell and gene therapies in the years ahead, it is crucial that ClearPoint helps healthcare providers be ready by providing simplified workflows, offering solutions to increase surgical capacity and expanding access to our hardware and software," commented Joe Burnett, President and CEO at ClearPoint Neuro. "The newest ClearPoint 3.0 platform is designed to do exactly that by offering one of the fastest and most accurate navigation systems available while enabling the flexibility to be used in both the MRI suite and the operating room. Today, more than nighty-five percent of all stereotactic procedures in the United States take place in the operating room using Computed Tomography (CT) as the imaging modality. Using CT, the ClearPoint Software now supports the entire operating room procedure, eliminating the need for additional third-party navigation systems. Hospitals can use ClearPoint in either or both settings, benefiting from a consistent workflow that streamlines procedures and builds proficiency. We believe that this single, flexible solution will benefit our 50+ global biopharma partners with the potential to standardize cell and gene therapy delivery around the world, starting here in the United States."

ClearPoint Navigation Software Version 3.0 introduces an intraoperative CT workflow that builds on over a decade of experience in enabling MRI-guided stereotactic procedures. While previous versions of ClearPoint software supported MRI-guided workflows exclusively, the latest release extends ClearPoint navigation capabilities to the operating room. With compatibility for intraoperative CT and Conebeam CT imaging, this enhancement broadens access to precision-guided neurosurgery for facilities without intraoperative MRI capabilities. The ClearPoint Navigation Software Version 3.0 when used in conjunction with the SmartFrame® XG stereotactic frame, is intended to provide precise stereotactic guidance when placing instruments or devices during neurosurgical procedures. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (asleep or awake) lead placement.

The Company plans to initiate a limited market release for ClearPoint Navigation Version 3.0

in Q1 2025, with a planned full market release in the second half of 2025.

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, 2023, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2024, 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, 2024, which the Company intends to file with the Securities and Exchange Commission on or before March 31, 2025. The Company does not assume any obligation to update these forward-looking statements.

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