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ClearPoint Neuro Announces Canadian Approval for its Navigation System Further Expanding Our Drug Delivery Ecosystem and Global Footprint

Combined clearance of the navigation and drug delivery technologies enables Canadian neurosurgery centers to leverage the Company's flagship image-guidance workflow and advances ClearPoint Neuro's overall global infrastructure in support of its strategy to enable 20,000 cell and gene therapy procedures annually.

SOLANA BEACH, CA / ACCESS Newswire / April 20, 2026 /ClearPoint Neuro, Inc. (NASDAQ:CLPT) ("Company"), a global device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine, today announced receipt of a Medical Device License (MDL) from Health Canada for its Neuro Navigation System, further expanding our Drug Delivery ecosystem and global footprint. Covering both ClearPoint MRI-guidance and new iCT-guidance workflows in Canada, the MDL builds on the previously announced therapy delivery product clearance for the SmartFlow Neuro Cannula received in October 2025. This milestone reinforces ClearPoint's role as a global leader in integrated navigation and therapy delivery solutions and will enable the Company's biopharma partners to operate Canadian clinical trial and commercial sites using the same platform and standardized workflow already in use in the United States.

Canada represents a strategically important market for cell and gene therapy development, given its concentration of leading academic medical centers, proximity to U.S. trial infrastructure, and established regulatory framework. With both the navigation and delivery components of ClearPoint's platform now cleared in Canada, biopharma sponsors can design Canadian trial sites with greater consistency in workflow, which may reduce trial complexity, minimize surgical variability, and accelerate the path from clinical development to commercial scale.

"What we announced in October established Canada as part of our 34-country regulatory network for therapy delivery," said Mary McNamara-Cullinane, Senior Vice President of Regulatory Affairs at ClearPoint Neuro. "With today's navigation clearance, Canada is now fully integrated into ClearPoint's global regulatory and clinical infrastructure. Our goal is to continue to demonstrate to our biopharma partners that working with ClearPoint Neuro provides access to a growing global installed base where patients can be enrolled across an expanding number of geographies and, over time, prepare programs for broader

commercialization. Expanding regulatory approvals internationally is a core component of our drug delivery ecosystem, and this level of standardization provides a unique asset as partners' therapies advance through clinical development and toward global deployment."

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. Statements regarding the Company's future events, developments and future performance, including the potential benefits and impact of the Medical Device License in Canada for the Company's products; the Company's future expansion of regulatory clearances and approvals in other countries and jurisdictions; the ability of Canadian care centers and biopharma partners to utilize the Company's image-guidance and therapy delivery workflows; the potential to support Canadian clinical trial and commercial sites using workflows already in use; the potential to reduce trial complexity, minimize surgical variability, accelerate clinical development and commercialization, advance the Company's global infrastructure, and support the Company's goal of enabling 20,000 cell and gene therapy procedures annually; and the Company's belief that workflow standardization may represent a clinical and regulatory asset that could reduce risk for partners as therapies move from clinical trials into global commercial deployment, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. These forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed in or implied by such forward-looking statements. Particular risks and uncertainties include, among others, risks related to regulatory developments and timing, market acceptance and adoption of the Company's products and services, the ability of the Company's biopharma partners to advance clinical programs and achieve commercial success, the Company's ability to support global scale-up and commercialization, competitive developments, supply chain and macroeconomic conditions, and risks inherent in the research, development and regulatory approval of new products. For a detailed description of the Company's risks and uncertainties, you are encouraged to review its documents filed with the SEC including the Company's recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements

to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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