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ClearPoint Neuro Announces Expanded International Clearances for Key Therapy Delivery Product; Now Totaling 34 Countries Worldwide

The clearly established history across global regulatory bodies is expected to de-risk BioPharma partners' pathways towards achieving global scale and standardization.

SOLANA BEACH, CALIFORNIA / ACCESS Newswire / October 6, 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 several expanded regulatory approvals for product use in Canada, Hong Kong, and Taiwan. This most recent batch of strategically selected geographical clearances establishes a total of 34 countries worldwide in which BioPharma partners will have a reliable and familiar delivery system for clinical use. Each clearance is intended to serve programs with regional clinical trial needs by simplifying trial design, and longer term should provide partners with expanded pathways for achieving global commercial scale.

"The importance of these international regulatory clearances is well established and continually discussed with each partner within our portfolio of 60+ BioPharma sponsors," commented Mary McNamara-Cullinane, VP of Regulatory Affairs at ClearPoint Neuro. "The extensive regulatory support we provide partners evolves with each new therapy development program. After we support the early pre-clinical work and INDs, these expanded international clearances can play a role in localized trials and simplify pathways to commercialization from one country to the next. We leverage our team's expertise to anticipate what each regulatory body will need to reduce complexity for our partners."

"Each clearance is expected to provide a decisive advantage for all sponsors trusting us to support their new therapy development as our products have extensive testing, credible history, and technical dossiers on-file across various geographies," added Megan Falkenberry, VP of Quality at ClearPoint Neuro. "We believe that this is essential for speeding up the cell and gene therapy clinical trial process, reducing technical risks, and reducing surgical risks. The ClearPoint Neuro team is incredibly motivated to do our part in ensuring more patients can be treated by these first-of-kind, breakthrough restorative gene and cell therapies being developed by our partners. By standardizing and simplifying every possible aspect of the surgical workflow, ClearPoint Neuro hopes to reduce barriers to adoption and allow partners' therapies improved chances to succeed."

The company plans to demonstrate US-cleared products at the 75th Annual Congress of Neurological Surgeons (CNS) in Los Angeles October 13th-15th.

The SmartFlow Neuro Cannula has received 510(k) clearance from the FDA for the aspiration of CSF, injection of the chemotherapy drug Cytarabine into the ventricles, or delivery of the gene therapy KEBILIDI to the brain parenchyma. This device is not intended for implant and is single patient use. Not all products are cleared in all territories.

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 expectations regarding regulatory timelines, pathways, and outcomes for therapeutic products delivered with the Company's cleared or approved products in various geographies, and the future commercial success and market acceptance of the Company's therapy delivery 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: macroeconomic and inflationary conditions; regulatory and policy uncertainty; delay impacts from the effects of government shutdowns or reduced agency operations; the introduction of or changes in tariffs, sanctions, or trade barriers; changes in monetary policy; geopolitical trends, such as protectionism and economic nationalism; 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 regulatory approval and 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 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, regulatory approval and commercialization of the Company's new products and the new therapeutics of its BioPharma partners, including the ability to obtain and maintain regulatory clearances, manufacturing scale-up, supply chain and quality system readiness, intellectual property protection and freedom to operate,

market acceptance and competitive dynamics. 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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