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ClearPoint Neuro Announces CE Marking of Velocity Alpha MR High Speed Surgical Drill System, Further Expanding Drug Delivery Ecosystem and Global Footprint

SOLANA BEACH, CA / ACCESS Newswire / May 13, 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 that the Velocity Alpha® MR High Speed Surgical Drill System has received CE Marking in addition to the existing FDA 510(k) clearance in the United States.

The Velocity Alpha MR High Speed Surgical Drill System is manufactured by German-based surgical equipment leader Adeor Medical AG. It is a versatile pneumatic drill system designed to streamline ClearPoint procedures and improve case efficiency in both MR and operating room environments. The drill is purpose-built to uniquely integrate with ClearPoint Neuro's SmartFrame navigation platform, featuring specialized drill bits and cutters that further differentiate it from conventional surgical drills. Designed to support multi-trajectory procedures, including investigational cell and gene therapy cases, the system integrates into complex neurosurgical workflows, offering scalability and potential to support a broader range of programs within the Company's partnered biologics portfolio.

"Approval of this drill in Europe underscores the Company's strategy to expand its integrated product portfolio with complementary technologies designed to enhance procedural workflows, strengthen the ClearPoint Neuro ecosystem, and support long-term growth," said Jeremy Stigall, Chief Business Officer & General Manager of Biologics & Drug Delivery at ClearPoint Neuro. "With both FDA clearance and CE Marking of the drill, we believe this solution provides a pathway to support neurosurgical procedures globally."

About the Velocity Alpha MR High Speed Surgical Drill System

The Velocity Alpha MR High Speed Surgical Drill System is FDA 510(k) cleared in the United States and CE Marked for use in trephination, incision, cutting, removal, shaping, and sawing of soft and hard tissue, bone, and biomaterials in or near a magnetic field of 3.0 Tesla or less for use in Neurosurgery. A universal cutter system with one-click coupling and integrated telescoping functionality is designed to support the needs of today's OR personnel. The system is designed for ease of handling and operates at up to 80,000 rpm with a low noise profile.

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 the Velocity Alpha MR High Speed Surgical Drill System, and the product's other performance and results, including the product's ability to reduce procedural time, streamline complex workflows, enhance overall case efficiency, and advance commercial adoption of therapies. 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: 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. 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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