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ClearPoint Neuro Announces FDA Clearance for ClearPoint Maestro™ Brain Model

SOLANA BEACH, Calif., Aug. 09, 2022 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global therapy-enabling platform company providing navigation and delivery to the brain, today announced it has received 510(k) clearance for its ClearPoint Maestro™ Brain Model. Maestro is intended for automatic labeling, visualization, volumetric and shape quantification of segmentable brain structures from a set of MRI images. This software is intended to automate the process of identifying, labelling, and quantifying the volume and shape of brain structures visible in MRI images.

This first-generation anatomical segment analysis tool emerged over 10 years ago from research aimed at detecting subtle volumetric and shape abnormalities in patients with mild traumatic brain injury. That first publication was featured on the cover of the Journal of Neurotrauma. The unique methodology of the Maestro Brain Model combines deformable surfaces with active shape models and machine learning. More importantly, it provides point-based correspondence longitudinally and across patients. Cross-validation on more than 1,000 scans demonstrate highly reproducible results with sub-millimeter accuracy and normative values from 560 healthy subjects provide reference ranges for patient-specific assessments.

"This is a tremendous milestone for ClearPoint and our collaboration with Philips as we are thrilled to introduce this new commercial tool into our portfolio," commented Joe Burnett, President and CEO at ClearPoint Neuro. "This is a crucial first step in our path to make the Maestro Brain Model the 'engine' in our navigation system supporting multiple new applications in the future. Now that the standalone patient analysis tool is cleared, our development team will work to embed this software directly into the ClearPoint Navigation platform and add new functionality based on the priorities of the business. We are very proud of the ClearPoint and Philips co-development team who have delivered another innovative product and further demonstrated our focus and commitment to being an innovative leader in neurosurgery."

"Having spent more than 10 years developing the Maestro software inside of Philips and now here at ClearPoint, I know firsthand the capability and potential of this software inside the ClearPoint platform," commented Lyubomir Zagorchev, Vice President of Clinical Science and Applications at ClearPoint Neuro. "The current version will enable reproducible analysis of patient data which will provide immediate value for our current and future

biologics and drug delivery partners as they study volumetric infusion characteristics and longitudinal patient comparisons as part of their safety and pivotal trials. However, the goal of our future applications once embedded into the ClearPoint Navigation software will enable more advanced patient-specific target identification and trajectory planning across all ClearPoint applications. Our plan is to quantify drug delivery using intraoperative imaging and simulate patient-specific infusions in targeted brain regions. The unique shape representation in Maestro will provide reproducible lead placement for deep brain stimulation and micro electrode recording. Surface meshes of segmented anatomical regions will define safety zones and optimal trajectories for patient-specific laser ablations. This is really just the beginning of what is possible and we are excited to execute the limited market release of this product through the end of 2022."

About ClearPoint Neuro

ClearPoint Neuro's mission is to improve and restore quality of life to patients and their families by enabling therapies for the most complex neurological disorders with pinpoint accuracy. Applications of the Company's current product portfolio include deep brain stimulation, laser ablation, biopsy, neuro-aspiration, and delivery of drugs, biologics, and gene therapy to the brain. The ClearPoint® Neuro Navigation System has FDA clearance, is CE-marked, and is installed in over 60 active sites in the United States, Canada, and Europe. ClearPoint Neuro is partnered with approximately 45 pharmaceutical and biotech companies, academic institutions, and contract research organizations providing solutions for direct CNS delivery of therapeutics in pre-clinical studies and clinical trials worldwide. To date, more than 5,000 cases 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

Statements in this press release and in the teleconference referenced above concerning the Company's plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, 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. Uncertainties and risks 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 impact of the COVID-19 pandemic and the measures adopted to contain its spread; future revenue from sales of the Company's ClearPoint Neuro Navigation System products; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System products; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of our products and services in their delivery of therapies; and risks inherent in the research and development 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, 2021, and the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2022, both of which have been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2022, which the Company intends to file

with the Securities and Exchange Commission on or before August 15, 2022.

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