

September 23, 2022



## **ClearPoint Neuro Announces FDA Clearance for ClearPoint Prism™ Neuro Laser Therapy System**

SOLANA BEACH, Calif., Sept. 22, 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 its Swedish partner, Clinical Laserthermia Systems (CLS), has received 510(k) clearance for its laser which the Company plans to commercialize as the ClearPoint Prism™ Neuro Laser Therapy System.



The ClearPoint Prism Neuro Laser Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under 3.0T magnetic resonance imaging (MRI) guidance. Full indications for use can be found here:

<https://www.clearpointneuro.com/terms-of-service/label-indications/>

ClearPoint Neuro has exclusive global rights to commercialize the CLS magnetic resonance (MR) guided laser interstitial thermal therapy (MRgLITT) system for neuro applications. The system comprises a clinical solution combining the ClearPoint navigation platform, the laser

technology from CLS, and a thermal ablation monitoring software called Thermoguide from France-based medical device company Image Guided Therapy SA (IGT).

“It’s wonderful to see new innovation in the space of laser interstitial thermal therapy. Laser ablation is an important and growing part of our surgical armamentarium and offers minimally invasive and powerful treatments for a variety of neurological diseases,” stated John Rolston, MD, PhD, Director of the Mapping & Engineering Neural Dynamics (MEND) Laboratory at Brigham & Women’s Hospital and Harvard Medical School. “The new laser system offered by ClearPoint has several exciting technical innovations that are expected to make this therapy simpler and more accessible to surgeons and their patients.”

“Over the past decade, the ClearPoint Neuro Navigation System has offered an efficient one-room solution to assist neurosurgeons in the United States and Europe to accurately place laser fibers and help treat brain tumors, radiation necrosis and epileptic foci in thousands of patients,” commented Joe Burnett, President and CEO of ClearPoint Neuro. “We look forward to leading the expansion of laser therapy treatment options for patients and neurosurgeons in the United States and beyond in the coming years. This is another example of the innovation that ClearPoint is delivering to the neurosurgery and spine community through our team and our expert partners.”

The ClearPoint Prism Neuro Laser Therapy System is currently in limited market release at select academic medical centers across the United States.

### **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 more than 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](http://www.clearpointneuro.com).

### **Forward-Looking Statements**

Statements in this press release 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 global instability, supply chain disruptions, labor shortages, and inflationary conditions; future revenue from sales of the Company’s ClearPoint Neuro Navigation System and other new products offered by the

Company; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation System and other new products offered by the Company; 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 June 30, 2022, both of which have been filed with the Securities and Exchange Commission.

**Contact:**

Jacqueline Keller, Vice President, Marketing  
1 (888) 287-9109  
[info@clearpointneuro.com](mailto:info@clearpointneuro.com)

Caroline Corner, Investor Relations  
[ir@clearpointneuro.com](mailto:ir@clearpointneuro.com)

A photo accompanying this announcement is available at:  
<https://www.globenewswire.com/NewsRoom/AttachmentNg/66f919ac-c17e-402e-a88e-1211e8044e7c>

The photo is also available via AP PhotoExpress.



Source: ClearPoint Neuro, Inc.

**The ClearPoint Prism™ Neuro Laser Therapy System**



**The ClearPoint Prism™ Neuro Laser Therapy System**