

April 13, 2023



ClearPoint Neuro Announces ANVISA Approval of Neuro Navigation Portfolio in Brazil

SOLANA BEACH, Calif., April 13, 2023 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (NASDAQ: CLPT) (the "Company"), a global therapy-enabling platform company providing navigation and delivery to the brain, today announced successful registration of its Neuro Navigation portfolio with the Brazilian regulatory body, Agência Nacional de Vigilância Sanitária (ANVISA).

"I have had the opportunity to see the ClearPoint Neuro Navigation System in action several times and was thrilled to hear that it has been finally approved by Brazil's regulatory agency," stated Raquel Rodrigues, MD, M.Sc, Pediatric Neurosurgeon and Neuro-oncologist in Brazil. "With a very intuitive interface and software, I personally believe it's easy to manage its features, even for a neurosurgeon only trained in traditional neuro navigation methods. With ClearPoint we plan, for the very first time in Latin America, to offer to our patients unprecedented medical treatments, such as Convection Enhanced Delivery (CED) for brain cancer and neurodegenerative disorders with intra-procedural MRI guidance. Furthermore, with this system we hope to refine our DBS implants, deep brain biopsies and laser ablations. I am honored to lead the neurosurgical team that will perform the first neurosurgery with this splendid technology here in Brazil."

"We are incredibly proud to have obtained ANVISA approval after an extensive review," explained Megan Faulkenberry, Vice President of Quality at ClearPoint Neuro. "Our first approval in Latin America is an important milestone supporting our 4th growth pillar: international expansion. Each global approval we attain helps us and our pharmaceutical partners to provide new therapies, both clinically and in clinical trials, for patients with some of the most devastating neurological disorders."

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, 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 more than 65 sites in North America, Europe, and South America. ClearPoint

Neuro is partnered with more than 50 biologics/pharmaceutical companies, academic centers, and contract research organizations, providing solutions for direct CNS delivery of therapeutics in pre-clinical studies and clinical trials worldwide. To date, more than 6,000 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. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

Statements in this press release concerning the Company's plans, growth and strategies may be forward-looking statements within the context of the federal securities laws. Statements regarding the Company's future events, developments and future performance, the size of total addressable markets or the market opportunity for the Company's products and services, 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, global instability, supply chain disruptions, labor shortages, and macroeconomic 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, development, and regulatory approval 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, 2022, which has been filed with the Securities and Exchange Commission.

An image accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/d778fbc6-552a-41f2-957f-bc70e235d5a8>

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