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ClearPoint Neuro Congratulates Blackrock Neurotech on Receiving Breakthrough Device Designation from the FDA for the MoveAgain Brain-Computer Interface System

SOLANA BEACH, Calif., Nov. 17, 2021 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global therapy-enabling platform company providing navigation and delivery to the brain, today congratulates partner Blackrock Neurotech for receiving Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its groundbreaking MoveAgain Brain Computer Interface (BCI) system.

There are an estimated 5.35 million¹ people in the United States who suffer from paralysis due to central nervous system disorders, autoimmune diseases, and spinal cord injuries. Blackrock's MoveAgain BCI system is comprised of an array which, when implanted in the brain, has demonstrated in scientific studies that it can read, analyze, and translate neuronal activity into commands that are relayed to output devices, such as a wheelchair. With the decoding of these signals, Blackrock aims to improve the mobility, independence, and quality of life for patients with paralysis.

Under the terms of a [recently announced joint agreement](#), ClearPoint is leveraging its 20+ year expertise innovating novel neuro-navigation platforms and software, with the aim of developing a new surgical solution to allow neurosurgeons to efficiently implant Blackrock's BCIs in a hospital setting.

"We are proud to be partnered with the leader in brain-computer interface technology," stated Joe Burnett, President and CEO of ClearPoint Neuro. "Every step towards commercialization, including this important designation from the FDA, as well as the great strides our innovation team is making towards development of a new surgical solution, will bring this novel BCI system closer to patients suffering from the most debilitating 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, 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 40 biologics/pharmaceutical companies and academic centers, 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 herein 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; 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, 2020, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2021, both of which have been filed with the Securities and Exchange Commission.

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¹ <https://www.prnewswire.com/news-releases/blackrock-neurotechs-moveagain-brain-computer-interface-system-receives-breakthrough-device-designation-from-the-fda-301425013.html>



Source: ClearPoint Neuro, Inc.