

ClearPoint Neuro Congratulates Neurona Therapeutics on IND Clearance for Neural Cell Therapy NRTX-1001 in Chronic Focal Epilepsy Patients

SOLANA BEACH, Calif., Nov. 08, 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 Neurona Therapeutics on clearance by the U.S. Food and Drug Administration (FDA) of its Investigational New Drug (IND) application to initiate its first-in-human Phase 1/2 clinical trial evaluating the safety and efficacy of NRTX-1001 in patients with drug-resistant mesial temporal lobe epilepsy (MTLE).

Epilepsy is one of the most common neurological disorders affecting over three million people in the U.S. and approximately one-third have drug-resistant disease¹. In the first stage of this multi-center, Phase 1/2 clinical trial, Neurona plans to enroll up to 10 patients with MTLE to evaluate the safety, tolerability, and efficacy of a single administration of NRTX-1001. In a subsequent study phase, Neurona plans to enroll up to 30 patients with MTLE in a randomized blinded investigation of NRTX-1001, compared to a control group to determine safety and efficacy.

"We are very excited to be working with Neurona on potentially the first human cell therapy candidate to enter clinical trials for epilepsy," stated Jeremy Stigall, Vice President, Biologics and Drug Delivery. "Every day our clinical specialist team supports laser ablation procedures to treat chronic focal epilepsy. The potential of an expanded treatment option will provide additional hope for millions of patients worldwide."

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 over 35 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 4,500 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.

https://www.neuronatherapeutics.com/wp-content/uploads/2021/11/2021_11_01_-INDClearance_FINALVersion.pdf

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 June 30, 2021, both of which has been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2021, which the Company intends to file with the Securities and Exchange Commission on or before November 15, 2021.

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