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ClearPoint Neuro Congratulates Partner PTC Therapeutics on Receiving Positive CHMP Opinion for Gene Therapy to Treat AADC Deficiency

First Gene Therapy Directly Infused into the Brain to be Administered with ClearPoint's SmartFlow® Cannula

SOLANA BEACH, Calif., May 20, 2022 (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 PTC Therapeutics for receiving a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending its gene therapy treatment Upstaza™ (eladocagene exuparvovec), formerly PTC-AADC, for the treatment of aromatic L-amino acid decarboxylase (AADC) deficiency. The use of ClearPoint Neuro's proprietary CE Marked SmartFlow® Neuro Ventricular Cannula for minimally invasive infusion of the gene therapy is included in the submission for administration of Upstaza.

"This is a significant milestone for PTC Therapeutics, for ClearPoint and for biologics researchers everywhere as it marks the very first positive CHMP recommendation for direct injection to the brain of a gene therapy to treat a severe, highly morbid and fatal neurological disorder," commented Joe Burnett, President and CEO of ClearPoint Neuro. "This milestone is incredibly important for a couple of reasons. First, it provides a potential path for other therapies to follow and sets an important precedent for regulatory approval of direct administered gene therapies to the brain. And second, we see this as a validation of ClearPoint's biologics partnership strategy and our rigorous bench, preclinical and clinical experience. We believe this announcement will give our 45 existing and future pharmaceutical, academic and biotech partners the confidence that SmartFlow is able to pass through the necessary regulatory scrutiny and can de-risk the commercialization efforts of many different drugs to multiple targets in the brain."

About aromatic L-amino acid decarboxylase (AADC) deficiency

AADC deficiency is a fatal, rare genetic disorder that typically causes severe disability and suffering from the first months of life, affecting every aspect of life – physical, mental, and behavioral. The suffering of children with AADC deficiency may be exacerbated by episodes

of distressing seizure-like oculogyric crises, which can happen daily and last for hours, causing the eyes to roll up in the head, frequent vomiting, behavioral problems, difficulty sleeping, and life-threatening complications such as respiratory infections and gastrointestinal problems.

There is no disease-modifying treatment approved for AADC deficiency, and the lives of affected children are severely impacted, and shortened, with the use of many different medications to help manage symptoms. Ongoing physical, occupational and speech therapy, and interventions, including surgery, to manage potentially life-threatening complications such as infections, severe feeding, and breathing problems also are often required.

About the SmartFlow® Cannula

With over 5,000 cannulas sold to date, SmartFlow is the only co-labeled device to gain approval by a regulatory agency for delivery of an approved gene therapy to the brain. The industry-leading cannula is used by many of ClearPoint Neuro's 45 pharmaceutical, academic, and biotech partners to bypass the blood brain barrier and deliver therapeutics to regions of interest using Convection Enhanced Delivery (CED) under direct image guidance. The SmartFlow cannula has received 510(k) clearance from the FDA for use in the United States for the aspiration of cerebrospinal fluid or injection of the chemotherapy drug Cytarabine into the ventricles. It has also been CE marked to deliver approved fluids into the brain or aspiration of CSF. SmartFlow is being utilized in approved clinical and preclinical studies for various research and drug trials. This device is not intended for implant and is intended for single patient use only.

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 biologics/pharmaceutical companies and academic centers, providing solutions for direct CNS delivery of therapeutics in preclinical 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, 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.

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