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# ClearPoint Neuro Congratulates Partner PTC Therapeutics on Being Granted Marketing Authorization by the European Commission for Upstaza<sup>™</sup> - First Disease-Modifying Treatment for AADC Deficiency

## First Gene Therapy Approved for Direct Infusion into the Brain will be Administered with ClearPoint's SmartFlow® Neuro Cannula

SOLANA BEACH, Calif., July 21, 2022 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global therapy-enabling platform company providing navigation and delivery to the brain, congratulates partner PTC Therapeutics for being granted marketing authorization for Upstaza<sup>™</sup> (eladocagene exuparvovec) by the European Commission. Upstaza is the first approved disease-modifying treatment for aromatic L-amino acid decarboxylase (AADC) deficiency, a rare and life-threatening disease impacting children, and is the first marketed gene therapy approved for direct infusion into the brain. The use of ClearPoint Neuro's proprietary CE Marked SmartFlow<sup>®</sup> Neuro Cannula for minimally invasive infusion of the gene therapy is included in the Upstaza SmPC (Summary of Product Characteristics). The marketing authorization, approved for patients 18 months and older, is applicable to all 27 European Union member states, as well as Iceland, Norway and Liechtenstein.

"The approval of Upstaza by the European Commission will have an immense impact on patients, their families, and the global gene therapy research community. Upstaza is the first gene therapy approved anywhere in the world to be dosed by direct infusion into the brain using ClearPoint's SmartFlow Cannula during a minimally invasive neurosurgical procedure," commented Joe Burnett, President and CEO of ClearPoint Neuro. "We believe the precedent set by this regulatory approval provides a pathway for our 45 current and future pharmaceutical, academic and biotech partners. We are incredibly proud of our partnership with PTC and look forward to having our team continue in-person support of patients and providers during these procedures at neurosurgery centers around the world."

## 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 causing the eyes to roll up in the head, frequent vomiting, behavioral problems, and difficulty sleeping.

The lives of affected children are severely impacted and shortened. Ongoing physical, occupational and speech therapy, and interventions, including surgery, also are often required to manage potentially life-threatening complications such as infections, severe feeding and breathing problems.

## About the SmartFlow<sup>®</sup> 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 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 and for aspiration of cerebrospinal fluid. SmartFlow is utilized in approved clinical and preclinical studies for various research and drug trials.

## 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 <u>www.clearpointneuro.com</u>

#### **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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