

ClearPoint Neuro Congratulates its Partner AviadoBio on First Patient Treated in its ASPIRE-FTD Clinical Trial Evaluating AVB-101 for Frontotemporal Dementia with GRN Mutations

ASPIRE-FTD Sites in the EU and U.S. to Use ClearPoint® Navigation Together With SmartFlow® Cannula for Intrathalamic Gene Therapy Administration

SOLANA BEACH, Calif., April 16, 2024 (GLOBE NEWSWIRE) -- ClearPoint Neuro, Inc. (Nasdaq: CLPT) (the "Company"), a global device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine, today congratulates its partner AviadoBio on treating its first patient in the ASPIRE-FTD Phase 1/2 clinical trial evaluating its investigational gene therapy AVB-101 in people with frontotemporal dementia (FTD) with progranulin (GRN) mutations.

"FTD is an important cause of dementia in people under 65 and has a devastating impact on patients and families. The importance of accurately delivering this one-time gene therapy to the thalamus, while minimizing systemic exposure, is the precise use case of ClearPoint's minimally invasive platform for gene and cell delivery," stated Jeremy Stigall, Chief Business Officer at ClearPoint Neuro. "We are proud to support AviadoBio and the team at Mazowiecki Szpital Bródnowski Hospital, as well as other clinical trial sites to come in Europe and the United States."

More information about the ASPIRE-FTD study can be found at https://clinicaltrials.gov/study/NCT06064890.

About Frontotemporal Dementia with Progranulin Mutations (FTD-GRN)

FTD is a devastating form of early-onset dementia that typically leads to death within seven to 13 years of symptom onset and three to 10 years from diagnosis. ^{1,2} People with FTD commonly experience personality changes, behavioral disturbance, loss of language, apathy, and reduced mobility. ³

FTD is a leading cause of dementia in people under the age of 65 with an estimated prevalence at any one time of up to 4.6 cases per 1,000 people. FTD typically strikes younger than Alzheimer's disease and the majority of FTD cases occur between 45 and 68 years of age. Given the early onset, FTD can have a substantially greater impact on work, family, and finances than Alzheimer's disease. Genetic FTD cases account for about one-third of cases and are associated with autosomal dominant mutations in three genes, including the GRN (progranulin) gene. Approximately 11,000 people in the U.S. and EU are living with FTD-GRN with approximately 2,200 new cases per year. Some FTD cases may be misidentified, and diagnostic delay is common. As disease education, genetics knowledge, and research and treatment options grow, these numbers are expected to increase.

About ClearPoint Neuro

ClearPoint Neuro is a device, cell, and gene therapy-enabling company offering precise navigation to the brain and spine. The Company uniquely provides both established clinical products as well as pre-clinical development services for controlled drug and device delivery. The Company's flagship product, the ClearPoint Neuro Navigation System, has FDA clearance and is CE-marked. ClearPoint Neuro is engaged with healthcare and research centers in North America, Europe, Asia, and South America. The Company is also partnered with the most innovative pharmaceutical/biotech companies, academic centers, and contract research organizations, providing solutions for direct CNS delivery of therapeutics in preclinical studies and clinical trials worldwide. To date, thousands of 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 worldwide. For more information, please visit www.clearpointneuro.com.

Forward-Looking Statements

This press release contains forward-looking statements within the context of the federal securities laws, which may include the Company's expectation for the future market of its products and services, and other performance and results. These forward-looking

¹ Onvike CU. Neuroepidemiology, 2011;37;166–167

² Riedl L et al. Neuropsychiatr Dis Treat. 2014;10:297–310

³ Pressman P and Miller BL. Biol Psychiatry. 2014;75(7):574–581

⁴ Hendriks S, Peetoom K, Bakker C, et al. Global Prevalence of Young-Onset Dementia: A Systematic Review and Meta-analysis. JAMA Neurol. 2021;78(9):1080–1090. doi:10.1001/jamaneurol.2021.216

⁵ Hogan DB et al. Can J Neurol Sci. 2016;43 (Suppl 1):S96–S109

⁶ Moore KM et al. Lancet Neurol. 19(2):145–156

⁷ Kansal K et al. Dement Geriatr Cogn Disord. 2016;41:109–122

⁸ Galvin JE et al. Neurology. 89(20):2049–2056

⁹ Young JJ et al. Ther Adv Psychopharmacol. 2018;8(1):33–48

¹⁰ Kuang, L., et. al. Frontotemporal dementia non-sense mutation of progranulin rescued by aminoglycosides. Human Molecular Genetics 2020;29(4):624-634

statements are based on management's current expectations and are subject to the risks inherent in the business, which 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: global and political instability, supply chain disruptions, labor shortages, and macroeconomic and inflationary conditions; future revenue from sales of the Company's products and services; the Company's ability to market, commercialize and achieve broader market acceptance for new products and services offered by the Company; the ability of our biologics and drug delivery partners to achieve commercial success, including their use of the Company's products and services in their delivery of therapies; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; the Company's ability to obtain additional funding to support its research and development programs; the ability of the Company to manage the growth of its business; the Company's ability to attract and retain its key employees; 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, 2023, which has been filed with the Securities and Exchange Commission. The Company does not assume any obligation to update these forward-looking statements.

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