CervoMed Announces Last Patient Last Visit in Phase 2b RewinD-LB Trial of Neflamapimod for the Treatment of Early-Stage Dementia with Lewy Bodies (DLB)

October 15, 2024

• On track to report topline data from the Phase 2b trial in December 2024

• Neflamapimod has the potential to restore function and improve cognitive and motor functions in DLB patients

• 96% of patients enrolled in RewinD-LB completed the 16-week portion of the study, of which 98% continued into the open label extension

BOSTON, Oct. 15, 2024 (GLOBE NEWSWIRE) -- CervoMed Inc. (NASDAQ: CRVO), a clinical-stage company focused on developing treatments for age-related neurologic disorders, today announced the Last Patient Last Visit in RewinD-LB, a Phase 2b clinical trial evaluating neflamapimod in patients with early-stage dementia with Lewy bodies (DLB). CervoMed remains on track to report topline efficacy and safety data in December 2024.

"Completion of the last patient visit in the RewinD-LB Phase 2b trial is an important milestone in our neflamapimod program for DLB," said John Alam, MD, Chief Executive Officer of CervoMed. "There has been a high level of enthusiasm from the clinical sites, trial investigators, and patients, reflecting the significant unmet need in the DLB patient population for which no treatment is currently approved. We are also encouraged by the fact that 96% of the patients enrolled into the study completed the 16-week double-blind placebo-controlled portion of the study, of which 98% continued into the open label extension. Furthermore, our independent Data Safety Monitoring Board recently met to conduct a pre-specified review of the available safety data and concluded that the study may proceed without modification. We look forward to sharing topline data in December 2024.

Dr. Alam continued; "We are also pleased to deliver late-breaking oral presentations at the upcoming Clinical Trials on Alzheimer's Disease (CTAD) conference, where we will discuss plasma biomarker data and their relevance to our ongoing trial. Leveraging insights from our Phase 2a trial and the baseline characteristics of patients enrolled in RewinD-LB, we think that we have enrolled the appropriate early DLB patient population we were targeting when we designed the study, namely participants who both have substantial clinical deficits and are still able to show improvements in their underlying disease process. [Combined with the use of a clinically meaningful primary endpoint, these data further increase our confidence that we are well positioned in the trial as we approach the topline readout in December. With a positive result, we believe we'll have demonstrated true clinical proof-of-concept for neflamapimod as a specific treatment for patients with DLB."

The full details on CervoMed's upcoming oral late-breaking presentations at CTAD can be found here.

About the RewinD-LB Phase 2b Study in Dementia with Lewy Bodies

CervoMed's ongoing Phase 2b study, RewinD-LB, is a randomized, 16-week, double-blind, placebo-controlled clinical trial evaluating oral neflamapimod (40mg TID) in 159 patients with early-stage DLB. In early-stage DLB patients – who are estimated to comprise approximately 50% of the total diagnosed DLB patient population at any given time – the disease has not progressed to a point where the patient has significant neuronal loss in the hippocampus. Patients with advanced DLB – in whom there is a significant, irreversible neuronal loss in the hippocampus and associated Alzheimer's Disease co-pathology -- as assessed by a blood biomarker (plasma ptau181), were excluded from the study. The primary endpoint in the study is a change in the Clinical Dementia Rating Sum of Boxes, and secondary endpoints include the Timed Up and Go test, a cognitive test battery, and the Clinician's Global Impression of Change. The RewinD-LB study is funded by a $21.0 million grant from the National Institutes of Health's National Institute on Aging, which is being disbursed over the course of the study as costs are incurred. The study includes 43 sites (32 in the United States, 8 in the United Kingdom, and 3 in the Netherlands) and completed enrollment in June 2024, with topline data expected in December 2024. Patients completing the 16-week placebo-controlled study period will be able to continue in the study while receiving open-label neflamapimod treatment for an additional 32 weeks. More information on the RewinD-LB study, including contact information on active clinical trial sites, is available at clinicaltrials.gov (NCT05869669).

About CervoMed

CervoMed Inc. (the "Company") is a clinical-stage company focused on developing treatments for age-related neurologic disorders. The Company is currently developing neflamapimod, an investigational, orally administered small molecule brain penetrant that inhibits p38 mitogen-activated protein kinase alpha. Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that causes disease in DLB and certain other major neurological disorders. Neflamapimod is currently being evaluated in a Phase 2b study in patients with early-stage DLB.

Forward-Looking Statements

This press release includes express and implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, regarding the intentions, plans, beliefs, expectations or forecasts for the future of the Company, including, but not limited to, the therapeutic potential of neflamapimod and the anticipated timing and achievement of clinical and development milestones, including the completion and achievement of primary endpoints of the RewinD-LB Phase 2b clinical trial and the Company's announcement of topline data therefrom. Terms such as "believes," "estimates," "anticipates," "expects," "plans," "aims," "seeks," "intends," "may," "might," "could," "might," "will," "should," "approximately," "potential," "target," "project," "contemplate," "predict," "forecast," "continue," or other words that convey uncertainty of future events or outcomes (including the negative of these terms) may identify these forward-looking statements. Although there is believed to be reasonable basis for each forward-looking statement contained herein, forward-looking statements by their nature involve risks and uncertainties, known and unknown, many of which are beyond the Company's control and, as a result, actual results could differ materially from those expressed or implied in any forward-looking statement. Particular risks and uncertainties include, among other things, those related to: the Company's available cash resources and the availability of additional funds on acceptable terms; the results of the Company's clinical trials, including RewinD-LB; the likelihood and timing of any regulatory approval of neflamapimod or the nature of any feedback the Company may receive from the U.S. Food and Drug Administration; the ability to implement business plans, forecasts, and other expectations in the future; general economic, political, business, industry, and market conditions,

inflationary pressures, and geopolitical conflicts; and the other factors discussed under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 filed with the U.S. Securities and Exchange Commission (SEC) on March 29, 2024, and other filings that the Company may file from time to time with the SEC. Any forward-looking statements in this press release speak only as of the date hereof (or such earlier date as may be identified). The Company does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release, except to the extent required by law.

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