CervoMed Announces Topline Data from RewinD-LB Phase 2b Clinical Trial in Patients with Dementia with Lewy Bodies

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—Neflamapimod did not demonstrate statistically significant effects versus placebo on primary and secondary endpoints at 16 weeks—

—Favorable safety and tolerability results with no new safety signal identified—

—Target plasma drug concentrations not achieved during 16-week double-blind phase of the trial—

— Trial participants continue to receive neflamapimod during open-label extension—

BOSTON, Dec. 10, 2024 (GLOBE NEWSWIRE) -- CervoMed Inc. (NASDAQ: CRVO) ("CervoMed" or the "Company"), a clinical-stage company focused on developing treatments for age-related neurologic disorders, today announced topline data from the RewinD-LB Phase 2b clinical trial evaluating neflamapimod for the treatment of patients with dementia with Lewy bodies (DLB). The trial did not meet statistical significance thresholds for its primary endpoint of change in the Clinical Dementia Rating Sum of Boxes (CDR-SB) or any of its key secondary endpoints – change from baseline in Timed Up and Go (TUG) test, change from baseline in a Neuropsychological Test Battery (NTD) and the Clinician's Global Impression of Change (CGIC). Initial analysis shows that target plasma drug concentrations were not achieved during the double-blind phase of the trial, which may have adversely impacted trial results.

"Obviously, we are disappointed with these results, particularly given our prior clinical experience with neflamapimod in patients with early-stage DLB and we are investigating the reasons for the lower-than-expected plasma drug concentrations. We continue to believe neflamapimod may have potential as a treatment for DLB, and we will thoroughly analyze the clinical and pharmacokinetic data from the trial to better understand its outcome and potential future development paths for the drug. This includes data expected to be available in the first half of 2025 from the first 16 weeks of the open label extension trial which we believe may be valuable to our investigation. In the meantime, we are pausing all preparations for our previously planned Phase 3 trial in early-stage DLB until the full analysis is complete," said John Alam, MD, Chief Executive Officer of CervoMed.

In the RewinD-LB Phase 2b trial, neflamapimod demonstrated a favorable safety and tolerability profile that is consistent with prior clinical studies, with no new safety signal identified.

"We are grateful to the entire DLB community, including trial participants, their caregivers and families, and all of our investigators, sites and coordinators," said Kelly Blackburn, CervoMed's SVP of Clinical Development.

The full data set from the double-blind phase of the RewinD-LB trial is expected to be available to the Company in January 2025 and the data from the first 16 weeks of the open label extension portion of the trial are expected to be available in the late second quarter of 2025. CervoMed will announce the timing of any presentation of additional data from the RewinD-LB trial at a later date upon completion of the first 16 weeks of the open label extension portion of the trial and CervoMed's analysis of all such data.

About Dementia with Lewy Bodies (DLB)

DLB is the third most common degenerative disease of the brain (after Alzheimer's disease and Parkinson's disease), with approximately 700,000 individuals affected in each of the United States (U.S.) and European Union. Patients with this disease accumulate protein deposits, called Lewy bodies, in the brain's nerve cells. This negatively affects cognitive ability, including attention, judgement, and reasoning, along with motor function. Patients with DLB incur higher healthcare costs, have longer hospitalizations, report lower quality of life, and have caregivers with higher levels of distress when compared to patients with Alzheimer's disease. No treatments for DLB have been approved by the U.S. Food and Drug Administration (FDA) or European Medicines Agency, and there are few drugs in development. The current standard of care is cholinesterase inhibitor therapy, which is approved for use in Alzheimer's disease, but in DLB patients typically improves cognition transiently, and does not impact the motor component of the disease.

About Neflamapimod

Neflamapimod is an investigational, orally administered small molecule brain penetrant drug designed to inhibit alpha isoform of the p38MAP kinase. Following preclinical studies in which neflamapimod reversed synaptic dysfunction, results from CervoMed's AscenD-LB Phase 2a clinical trial demonstrated that, compared to placebo, treatment with neflamapimod 40 mg TID significantly improved dementia severity, functional mobility and performance on a cognitive test battery, with the treatment response most substantial among patients with early-stage DLB. With a design guided by learnings from AscenD-LB, CervoMed's RewinD-LB trial was the first trial to successfully enroll an exclusively early-stage DLB patient population.

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

CervoMed's Phase 2b trial, 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 more than 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 – were excluded from the trial. The primary endpoint in the trial is a change in CDR-SB, and secondary endpoints include the TUG test, a cognitive test battery, and the CGIC. The RewinD-LB trial is funded by a $21.3 million grant from the National Institutes of Health's National Institute on Aging, which is being disbursed over the course of the trial as costs are incurred. The trial includes 43 sites across the United States, the United Kingdom, and the Netherlands.

About CervoMed

CervoMed Inc. 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 designed to inhibit 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 certain major neurological disorders.

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 in DLB or any other indication; the anticipated timing and achievement of clinical and development milestones, including the announcement of additional data from the RewinD-LB trial, any meeting with the FDA, the initiation of any future clinical trials, or the commercial approval, if any, of neflamapimod by the FDA or any other regulatory authority; any other expected or implied benefits or results, including that any initial clinical results observed with respect to neflamapimod in the AscenD-LB Trial or RewinD-LB Trial will be replicated in later trials; and the results of the Company's ongoing investigation of the lower than expected blood concentration levels observed in the double-blind portion of the RewinD-LB trial. 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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