CervoMed Announces Completion of Enrollment in Phase 2b RewinD-LB Clinical Trial of Neflamapimod for the Treatment of Patients with Dementia with Lewy Bodies

June 11, 2024

- Topline data expected in December 2024 -

- Phase 2b design optimized for success; clear path to market in this high value indication expected with positive result -

BOSTON, June 11, 2024 (GLOBE NEWSWIRE) -- CervoMed Inc. (NASDAQ: CRVO), a clinical stage company focused on developing treatments for age-related neurologic disorders, today announced that it has completed enrollment in RewinD-LB, a Phase 2b trial evaluating neflamapimod in patients with dementia with Lewy bodies (DLB).

“Drug development for the major dementias over the past decade has progressively focused on earlier stages of disease. In our phase 2a data with neflamapimod in patients with DLB, the treatment response in patients with pure DLB was substantial and greater than the response seen in patients who had biomarker evidence of Alzheimer’s disease (AD)-related co-pathology, the latter representing patients with more advanced disease,” said John Alam, MD, Chief Executive Officer of CervoMed. “The completion of enrollment demonstrates, for the first time, the feasibility of enrolling a pure DLB patient population into an adequately powered trial. The expeditious nature of the enrollment reflects the level of engagement across our clinical trial sites and the execution of our clinical team and partners, as well as the finding that most patients who entered into screening did not have AD-related co-pathology, as measured by plasma ptau181 testing. We expect to report topline data in December 2024, which we believe will bring us one step closer to potentially delivering the first DLB specific FDA-approved therapy.”

Kelly Blackburn, CervoMed’s SVP of Clinical Development, added, “Completing enrollment in the RewinD-LB trial marks a significant milestone and I would like to congratulate the CervoMed team and our partners, and most importantly, thank the patients and their families for participating in the neflamapimod clinical development program. The rapid pace of enrollment once all sites were activated points to the high unmet medical need and patient interest in novel treatments for DLB.”

Eligibility criteria to be randomized included: (1) a diagnosis of DLB by consensus criteria, (2) Clinical Dementia Rating Global Score (CDR-GS) of 0.5 or 1.0, and (3) absence of AD co-pathology, as evidenced by plasma phosphorylated tau at position 181 (ptau181) of less than the protocol-defined cutoff of 2.4 pg/mL. Approximately two-thirds of patients undergoing ptau181 testing met the associated eligibility criteria, with no difference in the rate of eligibility between patients with CDR-GS=0.5 and those with CDR-GS=1.0.

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 up to 160 patients with very mild or mild dementia due to DLB. 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. Patients with Alzheimer’s Disease-related co-pathology, assessed by a blood biomarker (plasma ptau181), will be excluded. The primary endpoint in the study is 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 will be disbursed over the course of the study as costs are incurred. The study includes 43 sites (32 in the United States, eight in the United Kingdom, and three in the Netherlands), all of which have been initiated. More information on the RewinD-LB study, including contact information on active clinical trial sites, is available at clinicaltrials.gov.

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 CervoMed Inc. (the Company), including, but not limited to, the therapeutic potential of neflamapimod, 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, any other expected or implied benefits or results, including that any initial clinical results observed with respect to neflamapimod in the RewinD-LB Trial will be replicated in later trials, and the Company’s clinical development plans. 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.

Investor Contact:
PJ Kelleher
LifeSci Advisors
Investors@cervomed.com

617-430-7579

Source: CervoMed Inc.