CervoMed Highlights Neflamapimod's Potential Benefits in Session on Dementia with Lewy Bodies at the 150th Annual American Neurology Association Conference

September 17, 2025

BOSTON, Sept. 17, 2025 (GLOBE NEWSWIRE) -- CervoMed Inc. (NASDAQ: CRVO), a clinical stage company focused on developing treatments for age-related neurologic disorders (CervoMed or the Company), today announced that the promising development program and potential benefits of neflamapimod for the treatment of Dementia with Lewy Bodies (DLB) were highlighted in a presentation on advances in DLB drug development by Dr. James Galvin at the 150th Annual American Neurological Association (ANA) conference held September 13-16, 2025 in Baltimore, Maryland.

"We are excited to continue showcasing neflamapimod's promising disease-modifying benefit at ANA. Following the positive data showing neflamapimod reduced the risk of clinically significant worsening on the Clinical Dementia Rating Sum of Boxes (CDR-SB) in our Phase 2b trial, including a 74% risk reduction relative to placebo in patients who have a low likelihood of having concomitant AD pathology, we are actively preparing to begin a Phase 3 trial in DLB patients and expect to reach alignment on the design of that trial with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2025," said John Alam, MD, Co-Principal Investigator of the RewinD LB trial and CEO of CervoMed. "We are focused on rapidly advancing this potentially effective and tolerable therapeutic agent for a disease state with profound unmet need which is devastating for patients and their families."

Details of the ANA presentation are as follows:
Session: Behavioral Neurology and Dementia: Therapeutic Advances in Neurodegenerative Diseases
Presenter: James E. Galvin, MD, MPH, Professor of Neurology at the Miller School of Medicine in Miami, Co-Principal Investigator of the RewinD-LB study and member of the Board at the Lewy Body Dementia Association (LBDA)
Date: September 16, 2025
Time: 11:00 AM to 12:30 PM

The slides from the presentation that included neflamapimod results will be accessible in the Investor section of CervoMed's website, https://www.cervomed.com/, following the presentation.

About the RewinD-LB Phase 2b Trial in Dementia with Lewy Bodies
The initial phase of RewinD-LB was a randomized, 16-week, double-blind, placebo-controlled clinical trial evaluating oral neflamapimod (40mg TID) in 159 patients with DLB, followed by a 32-week neflamapimod-only treatment Extension phase. Patients with AD co-pathology, as assessed by plasma ptau181 levels, were excluded from the trial. Compared to patients with "pure" DLB – who may comprise up to 50% of the total diagnosed DLB patient population at any given time – DLB patients with AD co-pathology have significant, irreversible neuronal loss in the hippocampus that limits response to treatment. The primary endpoint in the trial is change in the CDR-SB, and secondary endpoints include the Alzheimer's Disease Cooperative Study — Clinical Global Impression of Change, the Timed Up and Go test, and a cognitive test battery. The RewinD-LB trial was funded primarily by a $21.3 million grant from the National Institutes of Health's National Institute on Aging, disbursed over the course of the trial as costs were incurred. The trial included 43 sites across in the United States, the United Kingdom, and the Netherlands. The initial phase of the study did not effectively evaluate the clinical activity of 40mg TID neflamapimod compared to placebo because the batch of neflamapimod capsules utilized during the placebo-controlled phase of the study did not lead to the plasma drug concentrations expected with such a dose. However, in the Extension phase, a portion of patients were administered a more recently manufactured batch of capsules that achieved targeted plasma drug concentrations, allowing the effects of 40 mg TID neflamapimod treatment to be effectively evaluated during the Extension phase, with patients receiving the newer capsules serving as an active drug arm. Outcomes in these patients were compared with those in the subset of patients who continued to receive the older batch of capsules during the Extension phase, which served as a control arm.

About CervoMed
CervoMed 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 cause disease in DLB and certain other major neurological disorders. The Company's recently completed Phase 2b trial evaluated neflamapimod in patients with 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, including the degree of sustainability of any therapeutic effects; the anticipated timing and achievement of clinical and development milestones, including the Company's announcement of additional data, if any, from the RewinD-LB Phase 2b clinical trial and any meeting or correspondence between the Company and the FDA; 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 timing of the initiation of any potential future trials or interactions with regulatory authorities, including the Company's need to acquire sufficient funding for any Phase 3 trial of neflamapimod in DLB. 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 FDA; 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, 2024 filed with the U.S. Securities and Exchange Commission (SEC) on March 17, 2025, 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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