CervoMed Announces Alignment with FDA on Registration Path for Neflamapimod in Dementia with Lewy Bodies

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FDA feedback enables CervoMed to proceed with proposed endpoints, patient enrichment strategy, and other key aspects of Phase 3 trial design to support potential New Drug Application

CervoMed is advancing preparations for global pivotal trial initiation in the second half of 2026

BOSTON, Nov. 04, 2025 (GLOBE NEWSWIRE) -- CervoMed Inc. (NASDAQ: CRVO) (CervoMed or the Company), a clinical-stage biotechnology company developing treatments for age-related brain disorders, today announced it has received written feedback from the U.S. Food and Drug Administration (FDA) aligning on key aspects of CervoMed's proposed Phase 3 clinical trial of neflamapimod, an oral, small molecule, drug candidate targeting critical disease processes underlying degenerative disorders of the brain, for the treatment of dementia with Lewy bodies (DLB) to support a potential New Drug Application (NDA) submission. There are currently no approved therapies for DLB in the United States or European Union.

Phase 3 Trial Design and Regulatory Alignment

Based on FDA feedback, CervoMed plans to initiate a single, global, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of neflamapimod in approximately 300 patients with DLB by consensus clinical criteria in the second half of 2026. The trial will exclude patients who have historical evidence of Alzheimer's disease (AD) co-pathology by brain imaging scan or cerebrospinal fluid sampling. In addition, the trial will be further enriched for patients who do not have AD co-pathology by excluding patients via a validated blood plasma test (potential participants with plasma ptau181 ≥ 21.0 pg/mL at screening will be excluded). Participants will be randomized 1:1 to receive either oral neflamapimod or placebo for 32 weeks, followed by a neflamapimod only extension for 48 weeks.

Worsening of global cognition and function as measured by change in the Clinical Dementia Rating-Sum of Boxes (CDR-SB) – the same primary endpoint as in the Company's recently completed Phase 2b trial in DLB – will be the primary endpoint for the planned Phase 3 trial. Secondary endpoints will include the percentage of participants who have a greater than 1.5-point increase in CDR-SB and other well-established measures of cognitive and motor function. The trial will also include assessments of key biomarkers of the neurodegenerative process, such as glial fibrillary acidic protein, to further support regulatory review and clinical interpretation.

Advancing Toward Registration

"We are very pleased to have achieved alignment with the FDA on key aspects of our Phase 3 design for neflamapimod in DLB, including our selected endpoints and patient enrichment strategy" said Dr. John Alam, Chief Executive Officer of CervoMed. "This important feedback marks a major milestone for CervoMed, reinforcing our scientific approach and providing a regulatory pathway toward potential approval. With critical elements of the Phase 3 trial design matching our Phase 2a and Phase 2b trials that demonstrated positive treatment effects of neflamapimod, we believe that the Phase 3 trial – which will be the first ever targeting cognitive and functional decline in DLB patients – is well-positioned to achieve its primary objective. DLB remains a devastating disease with no approved therapies, and we believe neflamapimod has the potential to transform care for these patients and their families as a first-in-class treatment for DLB."

CervoMed expects feedback from other global regulators in the coming months and to announce additional details regarding the planned Phase 3 trial design in early 2026 following these interactions.

About Dementia with Lewy Bodies

DLB is the second most common progressive dementia after AD, affecting millions worldwide. Patients may experience a combination of decline in cognitive function, cognitive fluctuations, visual hallucinations, and sleep disorders, as well as motor symptoms similar to Parkinson's disease. There are no approved treatments for DLB in the United States or European Union, and the current standard-of-care therapies only temporarily relieve symptoms.

About Neflamapimod
Neflamapimod is an investigational, orally administered small-molecule drug that readily crosses the blood–brain barrier and selectively inhibits the alpha isoform of p38 MAP kinase, a key driver of neuroinflammation and synaptic dysfunction. By targeting the critical disease processes underlying degenerative disorders of the brain, neflamapimod has the potential to reverse synaptic dysfunction, improve neuron health, and slow or prevent disease progression. Neflamapimod is currently in clinical development for the treatment of DLB, recovery after ischemic stroke, and frontotemporal dementia.

In non-clinical studies, neflamapimod restored synaptic function within the basal forebrain cholinergic system, the brain region most affected in DLB. Across Phase 1 and 2 clinical trials involving more than 800 participants, the drug has been generally well tolerated and demonstrated consistent signals of efficacy. In the 91-patient Phase 2a AscenD-LB trial, neflamapimod significantly improved dementia severity and functional mobility in patients with DLB. Results from the 159-patient Phase 2b RewinD-LB trial, a 16-week randomized, double-blind, placebo-controlled trial followed by a 32-week open-label extension, further supported neflamapimod's potential to deliver meaningful clinical benefit, improving both cognitive and functional outcomes and showing a positive effect on a key blood biomarker of neurodegeneration during the extension phase. Across both studies, the greatest benefits were observed in patients with "pure" DLB – those without Alzheimer's disease co-pathology. Collectively, these findings underscore the therapeutic promise and scientific validity of neflamapimod as a potential treatment for DLB and other degenerative brain disorders.

About CervoMed

CervoMed is a clinical-stage company developing treatments for age-related brain disorders. Its lead drug candidate – neflamapimod – is an oral,

small molecule targeting critical disease processes underlying degenerative disorders of the brain by inhibiting a key enzyme involved in neuroinflammation and neurodegeneration. CervoMed's recently completed Phase 2b RewinD-LB trial evaluated neflamapimod in DLB patients who have a low likelihood of AD co-pathology, and the Company plans to initiate a global, pivotal Phase 3 trial in the same patient population in the second half of 2026.

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 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, including the Company's planned Phase 3 clinical trial evaluating the efficacy and safety of neflamapimod in patients with DLB; the timing of the initiation of, and the design and endpoints of, any potential future trials, including the Company's planned Phase 3 clinical trial evaluating the efficacy and safety of neflamapimod in patients with DLB; the Company's need to acquire sufficient funding for any Phase 3 trial of neflamapimod in DLB; expectations with respect to neflamapimod, including the timing of any regulatory submissions and potential approvals thereof, if any; the timing of the Company's potential submission of an NDA, if any; and the potential market for any DLB treatment that may be approved in the future. 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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