CervoMed Announces New Clinical, Plasma Biomarker and Imaging Data at AAIC 2026 for Neflamapimod in the Treatment of Dementia with Lewy Bodies (DLB)

July 14, 2026

BOSTON, July 14, 2026 (GLOBE NEWSWIRE) -- **CervoMed Announces New Clinical, Plasma Biomarker and Imaging Data at AAIC 2026 for Neflamapimod in the Treatment of Dementia with Lewy Bodies (DLB)**

New analyses of Phase 2b clinical trial reinforce treatment effect of neflamapimod observed relative to placebo in "pure" DLB and support selection of 50 mg TID for planned Phase 3 study in DLB

Neflamapimod produced durable slowing of basal forebrain atrophy and increased basal forebrain connectivity relative to placebo in trial, reinforcing the basal forebrain as a key therapeutic target in DLB

New Phase 2 study showed an 80 mg twice-daily dose of neflamapimod met its primary safety, tolerability, and pharmacokinetic objectives, with encouraging secondary findings on clinical activity

BOSTON, July 14, 2026 —CervoMed Inc. (NASDAQ: CRVO) (CervoMed or the Company) presented new analyses this week highlighting insights into neflamapimod's treatment effects in DLB at the Alzheimer's Association International Conference (AAIC) 2026 in London. The analyses included treatment effects during the placebo-controlled portion of CervoMed's Phase 2b clinical trial, as well as the impact of achieving higher plasma drug concentrations relative to placebo during the trial's extension phase. They also included pharmacokinetic-pharmacodynamic (PK-PD) relationships for neflamapimod and its effects on MRI measures of the underlying disease process in DLB.

"The analyses presented at AAIC provide consistent evidence across clinical, plasma biomarker, and imaging studies that neflamapimod has the potential to address the underlying cause of DLB and sharpen our understanding of the optimal dosing strategies to help achieve this outcome," said Dr. John Alam, Chief Executive Officer of CervoMed. "These studies provide important insights for the implementation of neflamapimod's planned Phase 3 trial, and we're thrilled to be able to share them with the DLB community."

Data presented at the conference included new analyses from the 159-patient Phase 2b RewinD-LB trial of neflamapimod, a 16-week randomized, double-blind, placebo-controlled study followed by a 32-week neflamapimod-only extension, as well as additional preclinical and clinical studies. Collectively, these analyses span neflamapimod's effects on disease progression, biomarkers of neurodegeneration, and basal forebrain atrophy in DLB, along with the first data on the safety, tolerability, pharmacokinetics, and clinical activity of an 80 mg twice-daily (BID) dose.

Analyses Reinforce Observed Treatment Effect of Neflamapimod in "Pure" DLB and Support Planned Phase 3 Dose

In the placebo-controlled phase of the RewinD-LB trial, neflamapimod did not replicate the positive results seen in its earlier Phase 2a study, in which it improved outcomes on the Clinical Dementia Rating – Sum of Boxes (CDR-SB) scale versus placebo. CDR-SB is a scoring scale used to stage the severity of Alzheimer's disease and other dementias. The analyses presented at AAIC indicate that the failure of the study to replicate the Phase 2a results can be attributed to a combination of a higher-than-targeted proportion of patients with Alzheimer's disease (AD) co-pathology (as determined by elevated plasma pTau181 levels at screening), and use of a neflamapimod drug product batch that did not achieve expected plasma drug concentrations. Specifically, exploratory analyses from RewinD-LB provide evidence that neflamapimod slowed worsening of DLB in patients with low plasma pTau181 and in those who achieved expected plasma drug concentrations.

Exploratory analyses of the placebo-controlled phase of RewinD-LB identified treatment effects favoring neflamapimod on CDR-SB, with a consistently improving treatment effect at progressively lower plasma pTau181 levels. The plasma pTau181 cut-off of <21 pg/mL has recently been identified in scientific literature as the optimal cut-off to exclude AD pathology. Further, the improvement relative to placebo observed in the subset of participants with pTau181 <21 pg/mL was limited to those patients who were above the median trough plasma drug concentration for the study as a whole.

These effects were also demonstrated by the extension-phase results, where a batch of capsules (DP Batch B) achieved higher plasma drug concentrations than the batch used during the placebo-controlled phase (DP Batch A). A within-participant comparison of DP Batch B demonstrated a significant improvement in change in CDR-SB compared to placebo (0.17 increase with DP Batch B during the extension vs. 0.95 with placebo in the same patients, p=0.005; NOTE: an increase in CDR-SB score indicates worsening of disease), while a within-subject improvement was not seen with DP Batch A.

Together, these analyses corroborate that the study's primary result was affected by the inclusion of patients with AD co-pathology and by lower-than-expected neflamapimod exposure in some patients. These findings support the patient population and dose selected for the Company's planned Phase 3 trial in patients with DLB, for which the Company has gained alignment with US Food and Drug Administration (FDA), European Medicines Agency, Medicines and Healthcare products Regulatory Agency, and Pharmaceuticals and Medicines Devices Agency.

Neflamapimod Demonstrated Durable Slowing of Basal Forebrain Atrophy

Over the 16 weeks of the placebo-controlled period of the RewinD-LB trial, neflamapimod-treated participants demonstrated increased right basal forebrain (BF) volume relative to placebo, as measured by structural and functional MRI. BF atrophy is the primary pathogenic driver of disease expression and progression in DLB. Right basal forebrain volume remained stable over 48 weeks (placebo-controlled phase + extension) in participants receiving neflamapimod in both phases and stabilized after treatment initiation in the extension in prior placebo recipients.

Increases in functional connectivity between the right BF and the right default mode network (DMN) were also observed during the neflamapimod-only extension. Disruption in BF-DMN connectivity, marked by abnormal activity in these regions, has been linked to neurodegenerative disorders such as DLB.

The laterality of the treatment effect is consistent with published data showing that, in DLB, the neurodegeneration is more advanced in the left basal forebrain, potentially allowing for positive treatment effects to be more achievable on the right side.

New PK-PD Analysis and Phase 2 Study Results for Neflamapimod 80 mg BID in DLB Strengthen Understanding of Dosing

PK-PD Analysis

A new analysis showed that a consistent pharmacokinetic-pharmacodynamic relationship has been observed across nonclinical and clinical studies of neflamapimod, with a plasma trough drug concentration (C_{trough}) threshold (~4 ng/mL) associated with biomarker and clinical improvements. The 4 ng/mL plasma threshold exceeds the *in vitro* concentration necessary to produce neflamapimod's primary pharmacologic effect, inhibition of interleukin-1β neurotoxic signaling.

Across the Company's trials in DLB, observed clinical outcomes with neflamapimod have tracked with the proportion of patients who achieved the plasma C_{trough} threshold of ~4 ng/mL:

	% of Patients Achieving C_{trough} ≥ 4 ng/mL	*Observed Clinical Outcomes*
40 mg BID (Phase 2a only)	25%	No discernible activity
40 mg TID Batch A (Phase 2b)	50%	Marginal clinical activity, except potentially in those who achieve C_{trough} target
40 mg TID Batch B (Phase 2b)	75%	Demonstrated improvement on CDR-SB, CGIC and plasma GFAP

BID: twice daily; CDR-SB: Clinical Dementia Rating scale – Sum of Boxes; CGIC: clinical global impression of change; GFAP: glial fibrillary acidic protein; TID: three times daily

Based on the above findings, the dose for the Company's planned future trials has been selected to be 50 mg TID, which is expected to achieve at or above the plasma C_{trough} threshold of ~4 ng/mL in approximately 90% of patients.

Phase 2 Study of Neflamapimod 80 mg BID in Patients with DLB

A separate study evaluated an alternative dose of neflamapimod, 80 mg BID, which met its primary objectives for safety, tolerability, and pharmacokinetics. The regimen was well tolerated, with no new safety signals identified over 24 weeks in 26 participants with DLB and achieved target trough plasma concentrations predicted to optimize p38α inhibition, though the increase in C_{trough} observed relative to the 40 mg TID dose utilized in the Company's prior clinical trials was not dose proportional.

"Our clinical study of neflamapimod 80 mg twice daily met its primary objectives for safety, tolerability and pharmacokinetics. Although the clinical findings should be interpreted cautiously because this was an open-label study, the findings on the secondary objective of clinical activity are also very encouraging and consistent with the findings in prior studies of neflamapimod in patients with DLB, showing stabilization of executive function and of global cognition and function, along with evidence of reduced neuropsychiatric symptoms," said Professor Frederic Blanc, the 80 mg BID study's principal investigator, professor of geriatrics, and neurologist at Strasbourg University Hospitals.

Evaluation of other exploratory clinical, plasma biomarker, and MRI endpoints is ongoing.

CervoMed's poster presentations of the results described above will be accessible in the Events and Presentations section of CervoMed's website, https://www.cervomed.com/, following the presentation.

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 primary progressive aphasia.

In nonclinical 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 neflamapimod-only 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 without AD 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 patients with DLB, enriched for those

without AD co-pathology. In November 2025, CervoMed announced alignment with the FDA on a potential registration path for neflamapimod in DLB, and the Company is currently focused on identifying a strategic partner to advance neflamapimod into a Phase 3 trial in DLB. CervoMed also recently completed enrollment in its ongoing Phase 2a clinical trial evaluating neflamapimod in nfvPPA, a subtype of frontotemporal disorders, from which interim biomarker data is anticipated in the early fourth quarter of 2026, and expects the first patient to be dosed with neflamapimod in the EXPERTS-ALS Phase 2a clinical trial in the fourth quarter 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 Company's need to acquire sufficient funding, including funding (through a strategic partnership or otherwise) for any Phase 3 trial in patients with DLB; the Company's plan to focus on strategic partnering to advance neflamapimod into Phase 3 for DLB and the timing of entering into any such partnership, if at all; the therapeutic potential of neflamapimod in DLB, nfvPPA, amyotrophic lateral sclerosis, or any other indication, including the degree of sustainability of any therapeutic effects, its potential impact on the rate of disease progression and/or clinical worsening, the optimal dosing regimen to achieve therapeutic effects, or any other treatment effects observed in any clinical trial on any clinical, biomarker, or other outcome measure; the anticipated timing and achievement of clinical and development milestones, including the Company's initiation of any Phase 3 trial in patients with DLB; the anticipated data readouts from the Company's Phase 2a trial in nfvPPA and the anticipated dosing of the first patient with neflamapimod in the EXPERTS-ALS trial; any other expected or implied benefits or results, including the extent (if any) to which neflamapimod may demonstrate efficacy or other clinical or biomarker improvements in patients; and expectations with respect to neflamapimod, including the timing of any regulatory submissions and potential approvals thereof, if any, in DLB or any other indication. Terms such as "believes," "estimates," "anticipates," "expects," "plans," "aims," "seeks," "intends," "may," "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, the availability of additional funds on acceptable terms or at all, and the Company's ability to continue as a going concern; the results of the Company's clinical trials; the Company's ability to successfully enter into a partnership to advance neflamapimod into Phase 3 for DLB in a timely manner, on acceptable terms, or at all; the likelihood and timing of any regulatory approval of neflamapimod or the nature of any feedback the Company may receive from the FDA or other regulators; the Company's ability to maintain the intellectual property protection afforded by the Company's patent portfolio; 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, 2025 filed with the US Securities and Exchange Commission (SEC) on March 13, 2026, 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.

Contacts

Media:
Biongage Communications
lisa.guiterman@gmail.com
202-330-3431

Investor Relations:
Argot Partners
cervomed@argotpartners.com
212-600-1902

CERVOMED