# CervoMed Announces Pharmacokinetic Results with New Neflamapimod Oral Tablet Formulation and Secures FDA Removal of Drug Exposure Limit

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*New 50 mg tablet formulation delivers an improved pharmacokinetic profile and enables greater exposure and patient convenience*

*FDA removal of the prior drug exposure limit provides greater dosing flexibility in future clinical trials*

*CervoMed plans to advance a 100 mg twice-daily regimen expected to achieve higher plasma trough drug concentrations than those associated with clinical activity in prior trials*

BOSTON, Sept. 28, 2026 (GLOBE NEWSWIRE) -- CervoMed Inc. ("CervoMed" or the "Company") (NASDAQ: CRVO), a clinical-stage biotechnology company developing treatments for age-related brain disorders, today announced pharmacokinetic (PK), regulatory, and manufacturing advances that enable a higher-dose, twice-daily (BID) oral regimen of neflamapimod in future clinical trials.

The developments include a new neflamapimod 50 mg oral tablet formulation with a PK profile favorable for twice-daily dosing, the U.S. Food and Drug Administration's (FDA) removal of the previous plasma drug exposure limit, and the implementation of a controlled manufacturing process designed to support reproducible, large-scale tablet production.

"The new 50 mg tablet addresses the formulation issue identified during the Phase 2b RewinD-LB study and we intend to move forward with it in future clinical development," said John J. Alam, M.D., Chief Executive Officer of CervoMed. "Combined with the FDA's removal of the prior exposure limit, the new pharmacokinetic profile enables us to advance a 100 mg twice-daily regimen that we expect will achieve substantially higher trough drug concentrations than those associated with clinical activity in previous trials, while reducing dosing frequency from three times to twice daily. These developments substantially reduce both clinical execution and manufacturing risk as we move the neflamapimod program forward."

**Supporting Data and Details**

**Formulation and manufacturing: New 50 mg tablet**
The new 50 mg tablet contains the most stable crystalline form of neflamapimod, addressing the manufacturing variability seen with the 40 mg capsule used in the Phase 2b RewinD-LB study. This updated formulation is designed to provide a consistent drug product for future trials and, if approved, commercial supply. The new controlled manufacturing process enables reproducible, large-scale production of the tablet, thus reducing chemistry, manufacturing and controls (CMC) risk.

The new tablet was evaluated in a Phase 1 food-effect and drug-exposure study that met its primary objectives. After single-dose administration, the 50 mg tablet and the prior 40 mg capsule (previously referred to as "DP Batch B") produced similar overall plasma drug exposure. However, the new tablet demonstrated a PK profile better suited to BID administration, with approximately 20% lower peak plasma concentration ($C_{max}$) and approximately 20% higher plasma concentration 12 hours post dose ($C_{trough}$, with BID dosing).

**Regulatory: FDA removal of drug exposure limit**
A 39-week dog toxicology study completed in the first half of 2026 established a no-observed-adverse-effect level (NOAEL) based on plasma drug levels, that was three-fold higher than in prior dog toxicology studies, and more than 30-fold higher than the pharmacologically and clinically active exposure range observed in previously completed clinical trials of neflamapimod in central nervous system disorders. After reviewing these data, the FDA removed the plasma drug exposure limit that had constrained neflamapimod dosing, providing CervoMed greater dosing flexibility in future clinical trials.

**Dose selection: 100 mg twice daily**
Based on the observed PK profile and pharmacokinetic pharmacodynamic (PK-PD) relationships across the neflamapimod clinical trials, CervoMed plans to advance a 100 mg BID regimen in future clinical trials. PK modeling indicates that the higher daily dose is expected to increase trough plasma drug concentrations by approximately 33% relative to the 40 mg three times a day (TID) regimen used in the Phase 2a clinical trial and the extension phase of the Phase 2b clinical trial in dementia with Lewy bodies (DLB).

The clinical safety and tolerability of the planned higher dose regimen are further supported by clinical data with neflamapimod administered at 80 mg BID (two 40 mg capsules), presented at the Alzheimer's Association International Conference (AAIC) in July 2026. Compared with 80 mg BID, the planned 100 mg BID tablet regimen is expected to provide similar overall plasma drug exposure, with a higher $C_{trough}$ and lower $C_{max}$.

These PK characteristics are particularly relevant to neflamapimod because previously reported PK-PD analyses indicate that clinical activity is associated with $C_{trough}$, while safety and tolerability are more closely related to $C_{max}$. The planned regimen is therefore designed to increase pharmacologically relevant trough concentrations without a commensurate increase in peak drug exposure.

**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, ALS, 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 expected pharmacokinetic profile, drug exposure, or other characteristics of the new 50 mg tablet formulation or the planned 100 mg twice-daily dosing regimen, including initial biomarker data from the Company's Phase 2a trial in nfvPPA; the anticipated timing and achievement of clinical and development milestones, including the Company's initiation of any Phase 3 trial in patients with DLB or the impact, if any, of the Innovation Passport Designation on any future regulatory milestone or the timing thereof; 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; and any other expected or implied benefits, results, or expectations, including the extent (if any) to which neflamapimod may demonstrate efficacy or other clinical or biomarker improvements in patients with DLB or in 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 a 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 U.S. 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:**
Lisa Guiterman
Biongage Communications
lisa.guiterman@gmail.com
202-330-3431

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