



CervoMed Announces Neflamapimod Awarded Innovation Passport Designation Under the UK Innovative Licensing and Access Pathway (ILAP) for Treatment of Dementia with Lewy Bodies (DLB)

August 04, 2026

Innovation Passport award designed to support accelerated time to market and help expedite patient access to potentially transformative new investigational medicines

Neflamapimod selected for the ILAP by joint consensus — recognized for being an innovative therapy that addresses a condition of high unmet need, with the demonstrated potential to offer a major therapeutic advantage in DLB treatment

Program provides CervoMed with early and coordinated guidance from the UK Medicines and Healthcare products Regulatory Agency (MHRA), the National Health System (NHS), and health technology assessment (HTA) bodies

BOSTON, Aug. 04, 2026 (GLOBE NEWSWIRE) – CervoMed Inc. (NASDAQ: CRVO), a clinical-stage biotechnology company developing treatments for age-related brain disorders (CervoMed or the Company), today announced that neflamapimod, its oral, small molecule drug candidate targeting neuroinflammation-driven disease processes underlying degenerative disorders of the brain, has been granted an Innovation Passport to enter the UK's ILAP for neflamapimod's development in DLB. Focusing on potentially transformative investigational treatments that address unmet clinical needs, the ILAP is designed to accelerate time to market and facilitate patient access to new medicines in the UK.

"We're proud that neflamapimod has been granted entry into this unique and selective program, which recognizes both the highly significant need for an effective treatment for DLB and the transformative potential of neflamapimod for people with DLB and their families," said Dr. Mark De Rosch, Ph.D., Executive Vice President, Regulatory and Government Affairs, and Program Management of CervoMed. "Very few drugs have been granted this opportunity through the ILAP since the entry criteria into the program were revised and the scientific hurdle for receiving the designation was increased in early 2025. We look forward to working with the UK regulators, the HTA bodies, and all NHS partners as we prepare for our planned Phase 3 trial and work diligently to get neflamapimod to the patients who may benefit."

"DLB is the second most common progressive dementia in older people in the UK, yet it remains poorly understood and is often misdiagnosed. It is encouraging for the DLB community to see an investigational treatment for this devastating disease included in a program like ILAP. We are hopeful that the coordination between MHRA, the HTA bodies, and the NHS can bring us closer to patients having access to the UK's first approved treatment for DLB," said Jacqui Cannon, Chief Executive of the Lewy Body Society.

The Innovation Passport designation provides access to a single integrated platform for sustained collaboration between biopharmaceutical companies and the ILAP Partners: the MHRA, NHS, the HTA bodies – the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC), the All Wales Therapeutics and Toxicology Centre (AWTTC), and the Department of Health Northern Ireland. This includes priority access to services such as clinical trials support and NHS engagement, to help speed up access for patients where current treatment options are limited or non-existent.

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 positive effects on key markers of neurodegeneration, one by structural MRI and one a blood-based biomarker. 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 the Lewy Body Society

The Lewy Body Society was the first Lewy body dementia charity in Europe.

The charity campaigns for greater recognition and resources for Lewy body dementia, funding cutting-edge research projects at leading universities across the UK to improve the diagnosis, treatment and care of people living with Lewy body dementia and their families.

It also provides information, advice and support to people affected by Lewy body dementia and their caregivers, as well as healthcare professionals and decision-makers.

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. CervoMed has obtained alignment with the FDA and global regulatory authorities 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 (through a strategic partnership or otherwise) for any Phase 3 trial in patients with DLB; expectations with respect to regulatory submissions and potential approvals thereof related to neflamapimod, if any, in DLB or any other indication, including the impact, if any, of the Innovation Passport Designation on any future regulatory milestone or the timing thereof; 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 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; 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 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.

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