CervoMed's neflamapimod elected for inclusion in UK EXPERTS-ALS platform designed to prioritize promising treatments for Amyotrophic Lateral Sclerosis

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Neflamapimod endorsement based on targeted mechanism of action, demonstrated clinical activity in neurodegenerative diseases, and encouraging translational data in ALS-relevant neurotoxicity models

UK-based trial first to evaluate neflamapimod in ALS; first person with ALS expected to be dosed by end of 2026

Trial costs funded by United Kingdom government and leading motor neuron disease charities

BOSTON, Feb. 18, 2026 (GLOBE NEWSWIRE) -- CervoMed Inc. (NASDAQ: CRVO), a clinical-stage biotechnology company developing treatments for age-related brain disorders, today announced that neflamapimod, an oral small molecule drug candidate targeting critical disease processes underlying degenerative disorders of the brain, has been selected for inclusion in the EXPERTS-ALS platform. EXPERTS-ALS facilitates rapid testing of potential treatments for amyotrophic lateral sclerosis (ALS) to identify promising drug candidates and potentially accelerate their path to regulatory approval.

Funded by the United Kingdom (UK) National Institute for Health and Care Research (NIHR) and leading motor neuron disease charities and sponsored by Sheffield Teaching Hospitals NHS Foundation Trust, EXPERTS-ALS assesses potential therapies through a randomized, multicenter, open-label, multi-arm trial that evaluates investigational medicines through the measurement of the blood biomarker neurofilament light chain (NfL). NfL levels are significantly elevated in ALS patients due to accelerated neuroaxonal damage and correlate with the rate of disability progression and survival. Neflamapimod will be initially evaluated in approximately 35 participants with ALS for 18-24 weeks to determine its impact on NfL levels, with the potential for further evaluation in up to a total of 80 patients. Secondary and exploratory endpoints include several clinical and survival measures.

"Neflamapimod is a promising investigational therapy for neurodegenerative diseases, and we're excited to add it to the EXPERTS-ALS platform as we try to rapidly identify therapies that have the potential to slow disease progression in ALS," said Chris McDermott, MBChB, FRCP, PhD, Professor of Translational Neurology, University of Sheffield. "The scientific rationale for neflamapimod's mechanism of action, combined with its positive clinical data in dementia with Lewy bodies, including a potent effect on blood biomarkers of the neurodegenerative process, and its favorable safety profile, make it a strong candidate for our platform. We look forward to working with CervoMed and helping to further the development of neflamapimod for the ALS community."

"Multiple studies identify persistent p38 activation as a key driver of ALS pathology, with its inhibition shown to reduce neurotoxicity across several disease models, including in IPS-derived neurons from patients with ALS," said James Shorter, Ph.D., Professor of Biochemistry and Biophysics, Perelman School of Medicine at The University of Pennsylvania. "The ability of neflamapimod to cross the blood brain barrier and selectively inhibit p38 activity, along with demonstrated target engagement and activity in clinical trials to date, provides a compelling rationale for its inclusion in the EXPERTS-ALS platform.

"ALS is a devastating disease that places an enormous burden on patients and their families. We are proud to collaborate with EXPERTS-ALS to evaluate whether neflamapimod can offer meaningful hope to this community," said Dr. John Alam, Chief Executive Officer of CervoMed. "Inclusion in the EXPERTS-ALS platform serves to further validate neflamapimod's potential in neurodegenerative diseases and allows for rapid evaluation of neflamapimod in ALS within a clinical trial platform purposefully built to fast-track promising therapies for that disease, while we maintain our primary focus on DLB and take the steps necessary to initiate our planned Phase 3 trial in that indication later this year."

About ALS
Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord that control voluntary muscle movement and breathing. Over the course of the disease, people lose the ability to move, sometimes also to speak, and eventually, to breathe. There are no approved therapies that stop or reverse the progression of ALS. Approximately 168,000 people worldwide live with ALS, with an estimated 90–95% of cases occurring without a family history of the condition[1]

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 dementia with Lewy bodies (DLB), recovery after ischemic stroke, and primary progressive aphasia.

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 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 EXPERTS-ALS
EXPERTS-ALS is a groundbreaking project that provides a platform to rapidly test drugs for their potential to slow the progression of ALS based on a human biomarker of disease activity. This allows prioritization of drugs for the trials needed to establish clinical benefit. EXPERTS-ALS is funded by the United Kingdom's National Institute for Health & Care Research (NIHR) through the Department of Health and Social Care (DHSC) and involves 11

motor neuron disease centers in the UK, soon to increase 17. Patient advocacy organizations, including the MND Association, My Name'5 Doddie Foundation, and the medical research charity LifeArc, provide additional support to extend the study to five years and support additional lab research. Candidate drugs are evaluated on a serial basis in 3–6-month enrollment cycles. Currently the next available opening is anticipated to be in the fourth quarter of 2026.

The mission of the National Institute for Health and Care Research (NIHR) is to improve the health and wealth of the nation through research. We do this by:

- Funding high quality, timely research that benefits the NHS, public health and social care;
- Investing in world-class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services;
- Partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research;
- Attracting, training and supporting the best researchers to tackle complex health and social care challenges;
- Collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system;
- Funding applied global health research and training to meet the needs of the poorest people in low and middle income countries.

NIHR is funded by the Department of Health and Social Care. Its work in low and middle income countries is principally funded through UK international development funding from the UK government.

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, subject to available funding.

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 in ALS, DLB, or any other indication, including the degree of sustainability of any therapeutic effects; the anticipated timing and achievement of clinical and development milestones, including the Company's initiation in the EXPERTS-ALS platform and the announcement of any data therefrom; 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 with ALS, in its planned inclusion in the EXPERTS-ALS clinical trial the Company's need to acquire sufficient funding, including funding its operations throughout the period during which neflamapimod is anticipated to be evaluated in the EXPERTS-ALS clinical trial and for its planned Phase 3 trial of neflamapimod in patients with DLB; expectations with respect to neflamapimod, including the timing of any regulatory submissions and potential approvals thereof, if any, in ALS, DLB, or any other indication; and the potential market for any ALS or DLB treatment that may be approved in the future. 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, and the Company's ability to continue as a going concern; 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.

References

1. Brown CA, Lally C, Kupelian V, Flanders WD. Estimated Prevalence and Incidence of Amyotrophic Lateral Sclerosis and SOD1 and C9orf72 Genetic Variants. Neuroepidemiology. 2021;55(5):342-353. doi: 10.1159/000516752. Epub 2021 Jul 9.

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