CervoMed Announces Presentation at AAIC 2024 on Plasma Biomarker Data That Are Consistent with Neflamapimod Impacting the Underlying Disease Process in Patients with Dementia with Lewy bodies (DLB)

July 29, 2024

- Baseline data from the AscenD-LB Phase 2a trial in DLB demonstrated that plasma glial fibrillary acidic protein (GFAP) was highly correlated to scores on the CDR-SB; plasma GFAP shown to increase with neurodegenerative progression in DLB –

- AscenD-LB Phase 2a results demonstrated neflamapimod treatment led to significant reduction compared to placebo in plasma GFAP levels in patients with DLB and the effects of neflamapimod on plasma GFAP were associated with improvement in CDR-SB -

BOSTON, July 29, 2024 (GLOBE NEWSWIRE) -- CervoMed Inc. (NASDAQ: CRVO), a clinical stage company focused on developing treatments for age-related neurologic disorders, today announced that plasma biomarker data from the AscenD-LB Phase 2a trial of neflamapimod in patients with dementia with Lewy bodies (DLB), was featured in a poster presentation at the Alzheimer's Association International Conference® (AAIC), being held in Philadelphia from July 28-August 1, 2024.

“Recent developments in the field support the use of plasma GFAP to evaluate the therapeutic effects on DLB-specific disease processes, and baseline data from AscenD-LB, our Phase 2a trial, further validate the utility of this biomarker,” said John Alam, MD, Chief Executive Officer of CervoMed. “We observed a clear association between plasma GFAP and dementia severity in patients with DLB. Additionally, growing data highlights the effects of neflamapimod on GFAP—particularly its association with the positive effects on clinical outcomes —and underscore the potential to address the underlying disease process in early-stage DLB. With these critical learnings from the AscenD-LB Phase 2a trial, we believe our fully enrolled RewinD-LB Phase 2b trial is optimized for success and we remain on track to report topline data in December 2024.”

The ePoster (91713) is accessible on the conference portal, and additional details are provided below. A PDF copy of the GFAP poster presentation will be available on the “Presentations and Publications” section of the CervoMed website.

- Title: Neflamapimod treatment reduces plasma glial fibrillary acidic protein GFAP levels in patients with dementia with Lewy bodies (DLB) who do not have co-existing AD co-pathology
- Authors: John Alam, Marleen Koel-Simmelink, Jennifer Conway, Inge Verberk, Charlotte Teunissen; CervoMed Inc (JA and JC) and Amsterdam Medical Center (MKS, IV, CT)

Key Takeaways from the presentation: The effects of neflamapimod on plasma GFAP were evaluated in both the overall and early-stage DLB patient population, and the treatment effects of GFAP correlated to clinical outcomes:

- Baseline (BL) plasma GFAP level was highly correlated to the baseline Clinical Dementia Rating Sum of Boxes (CDR-SB) score and was significantly higher in patients with AD Co-Pathology (BL ptau181 ≥ 2.2 pg/mL) compared to patients without AD co-pathology (baseline ptau181 < 2.2 pg/mL). Plasma GFAP was significantly elevated in both groups compared to levels in healthy controls in the literature.
- In early-stage DLB patients (i.e., patients with pre-treatment plasma ptau181 below the cutoff for AD-related co-pathology), there was a mean 14.1 pg/mL increase in the placebo treatment group (N=13) vs. mean 10.6 pg/mL reduction with neflamapimod treatment (N=15; p=0.04 for the difference). In patients with advanced DLB (i.e., patients with pre-treatment plasma ptau181 above the cutoff for AD-related co-pathology), there was a mean 6.0 pg/mL decrease in the placebo group (N=14) vs. mean 14.0 pg/mL reduction with neflamapimod treatment (N=15; the difference was not significant).
- In the early-stage DLB patient population, in participants treated with neflamapimod there was a significant correlation (r=0.54, p=0.04) between the effects of GFAP and clinical outcomes assessed by change from baseline to week 16 in CDR-SB, with increased GFAP being associated with worsening CDR-SB, while reduction in GFAP was associated with improvement on CDR-SB. The correlation was not seen in placebo-recipients (r=0.31, p=NS).

Recent developments in the field support the use of plasma GFAP as a biomarker of the underlying disease process in DLB:

- Data from the Mayo Clinic (Diaz-Galvan et al, 2024) show that in patients with prodromal DLB plasma GFAP is elevated relative to healthy controls, while plasma neurofilament light chain and plasma ptau181 are not. As patients at this stage have cholinergic degeneration in the basal forebrain without significant cortical atrophy (Kantarci et al, 2022), GFAP elevation in this context appears to reflect the disease in the basal forebrain cholinergic system that is the primary driver of disease expression and progression in early-stage DLB (Okkels et al, 2024).
- Data from the European Dementia with Lewy Bodies consortium (Bolsewig et al, 2024), show that in patients with DLB, plasma GFAP is associated with rate of cognitive decline, but not with CSF amyloid status, suggesting that GFAP elevation has potential to evaluate DLB-specific disease processes.

About the RewinD-LB Phase 2b Study in Dementia with Lewy Bodies
CervoMed’s ongoing Phase 2b study, RewinD-LB, is a randomized, 16-week, double-blind, placebo-controlled clinical trial evaluating oral neflamapimod (40mg TID) in up to 160 patients with very mild or mild dementia due to DLB. Patients completing the 16-week placebo-controlled study period will be able to continue in the study while receiving open label neflamapimod treatment for an additional 32 weeks. Patients with Alzheimer’s Disease-related co-pathology, assessed by a blood biomarker (plasma ptau181), will be excluded. The primary endpoint in the study is change in the Clinical Dementia Rating Sum of Boxes, and secondary endpoints include the Timed Up and Go test, a cognitive test battery, and the Clinician’s Global Impression of Change. The RewinD-LB study is funded by a $21.0 million grant from the National Institutes of Health’s National Institute on Aging,

which will be disbursed over the course of the study as costs are incurred. The study includes 43 sites (32 in the United States, eight in the United Kingdom, and three in the Netherlands). More information on the RewinD-LB study, is available at clinicaltrials.gov. The study completed enrollment in June 2024 and topline primary efficacy results are expected in December 2024.

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 CervoMed Inc. (the Company), including, but not limited to, the therapeutic potential of neflamapimod, the anticipated timing and achievement of clinical and development milestones, including the completion and achievement of primary endpoints of the RewinD-LB Phase 2b clinical trial and the Company's announcement of topline data therefrom, 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, and the Company's clinical development plans. 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 U.S. Food and Drug Administration; 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, 2023 filed with the U.S. Securities and Exchange Commission (SEC) on March 29, 2024, 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:

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