CervoMed Announces Completion of Merger with EIP Pharma

August 16, 2023

Shares of CervoMed to commence trading on Nasdaq under new ticker symbol "CRVO" on August 17, 2023

CervoMed will be focused on advancing oral stress kinase inhibitor neflamapimod for the treatment of dementia with Lewy bodies and other degenerative diseases of the brain

CervoMed has a cash runway through Phase 2b clinical data which is expected during 2H 2024

BOSTON, Aug. 16, 2023 /PRNewswire/ -- CervoMed Inc. (formerly known as Diffusion Pharmaceuticals Inc.) (NASDAQ: CRVO), now a clinical-stage company focused on developing treatments for degenerative diseases of the brain, today announced the closing of its previously announced merger with EIP Pharma Inc. The combined company will operate under the name CervoMed Inc., and its shares will commence trading on a 1-for-1.5 reverse split adjusted basis on August 17, 2023, on the Nasdaq Capital Market under the ticker symbol "CRVO". CervoMed's focus will be on advancing its lead drug candidate neflamapimod, an oral stress kinase inhibitor, which is currently being developed for the treatment of dementia with Lewy bodies (DLB) and other degenerative diseases of the brain.

"This merger with Diffusion, launch of CervoMed and entry into the public market is a transformative event that will accelerate the advancement of neflamapimod, first, and over the coming year, for the treatment of DLB, and later in Alzheimer's disease and stroke recovery," said John Alam, MD, Chief Executive Officer of CervoMed. "We are excited about the potential for neflamapimod to be the first-to-market disease-modifying drug therapy for DLB, with the potential to reverse and slow the progression of synaptic dysfunction that contributes to the typical cognitive and motor function decline associated with this devastating disease. Now that our Phase 2b DLB study, named RewinD-LB is underway, we anticipate completing enrollment during the first half of next year and reporting data from the placebo-controlled portion of the study during the second half of next year. We are well-funded through these catalysts and believe we are well-positioned to achieve our goal of creating new medicines for the brain."

"I am pleased by the close of this merger and the value I believe it will bring to Diffusion shareholders thanks to CervoMed's encouraging CNS pipeline. I would particularly like to thank our executive team and board of directors for their significant efforts throughout the process leading to the closing of this merger," said Robert J. Cobuzzi, Jr., Ph.D., former Chief Executive Officer of Diffusion Pharmaceuticals and Chief Operating Officer of CervoMed. "I look forward to the opportunity to serve CervoMed in my new role as COO, contributing to the Company's efforts in our mission of bringing new medicines to patients living with degenerative diseases of the brain."

Upcoming Anticipated Catalysts/Milestones

The Company has several anticipated catalysts and development milestones for neflamapimod through the end of 2024, including:

- Publication of additional results from the Phase 2a clinical study in DLB in a peer-reviewed medical journal in the second half of 2023
- Oral presentation of the RewinD-LB Phase 2b clinical study design at the Clinical Trials in Alzheimer's Disease (CTAD) conference in October 2023
- Completion of enrollment into the RewinD-LB Phase 2b clinical study in DLB in the first half of 2024
- Reporting of data from placebo-controlled portion of RewinD-LB during the second half of 2024

As announced on August 14, 2023, by EIP Pharma, following first-patient dosing, the RewinD-LB study is a randomized, 16-week double-blind, placebo-controlled phase 2b clinical trial of oral 40mg neflamapimod, three-times-per-day, in 160 patients with prodromal DLB or mild dementia due to DLB. Patients with Alzheimer's disease-related co-pathology, assessed by a blood biomarker, will be excluded. All patients completing the placebo-controlled main study will receive an additional 32 weeks of neflamapimod on an open-label basis.

EIP Pharma was previously awarded a $21 million grant from the National Institutes of Health's National Institute on Aging (NIA) which will fully fund development costs associated with the ongoing Phase 2b DLB study. The NIA grant funds will be disbursed over the course of the study as costs are incurred.

Transaction Details

In connection with the closing of the merger, Diffusion Pharmaceuticals enacted a 1-for-1.5 reverse stock split of its common stock. Following the reverse stock split and closing of the merger, there will be approximately 5.7 million shares of the combined company's common stock outstanding, with prior EIP Pharma shareholders owning approximately 77.95% and prior Diffusion Pharmaceuticals shareholders owning 22.05%. CervoMed, Inc. will trade on the Nasdaq Capital Market under a new ticker symbol, "CRVO".

The management team of EIP Pharma has become the management team of the CervoMed, led by John Alam, MD, as Chief Executive Officer and President. In addition, Robert J. Cobuzzi, Jr., PhD, the former Chief Executive Officer of Diffusion Pharmaceuticals, will serve as the Chief Operating Officer of CervoMed. The board of directors is comprised of seven directors including Dr. Alam, Sylvie Grégoire, PharmD, who will serve as Chair, Jeff Poulton, Chief Financial Officer at Alnylam, who will serve chair of the audit committee, and Diffusion Pharmaceuticals' former Chair of the board of directors, Jane Hollingsworth, JD.

EIP Pharma Inc. is now a wholly owned subsidiary of CervoMed.

Canaccord Genuity served as financial advisor and Dechert LLP provided legal counsel to Diffusion Pharmaceuticals. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. provided legal counsel to EIP Pharma.

About Neflamapimod

Neflamapimod is an investigational drug that is an orally administered small molecule brain penetrant that inhibits p38MAP kinase alpha (p38a). P38a, which is expressed in neurons under conditions of stress and disease, plays a major role in inflammation-induced synaptic toxicity, leading to synaptic dysfunction. Neflamapimod is currently being developed for the treatment of dementia with Lewy bodies (DLB) and is the first treatment with the potential to have a positive impact on cognition, function and motor function.

In preclinical studies, neflamapimod reversed synaptic dysfunction, including and particularly within the part of the brain most impacted in DLB – the basal forebrain cholinergic system. In Phase 1 and Phase 2 clinical studies involving more than 300 participants, neflamapimod has been shown to be generally well tolerated. Results from the AscenD-LB Phase 2a clinical study demonstrated that neflamapimod significantly improved dementia severity compared to placebo and also showed significant improvement on motor function compared to placebo. At the highest dose evaluated, neflamapimod improved cognition. The combined preclinical and clinical data are consistent with neflamapimod treating the underlying DLB disease process and suggest it has the potential to be the first disease-modifying treatment for DLB. Neflamapimod was granted Fast Track status by the U.S. Food and Drug Administration for the treatment of DLB and EIP Pharma was recently awarded a $21 million grant from the National Institutes of Health's National Institute on Aging (NIA) to evaluate neflamapimod in a Phase 2b clinical study in DLB. The NIA grant funds will be disbursed over the course of study as the costs are incurred.

About CervoMed

CervoMed Inc. is a clinical-stage biotechnology company advancing CNS-focused therapeutics to benefit patients with a range of degenerative diseases of the brain. The Company is currently developing neflamapimod, an investigational orally administered small molecule brain penetrant that inhibits p38MAP kinase alpha (p38a). Neflamapimod has the potential to treat synaptic dysfunction, the reversible aspect of the underlying neurodegenerative processes that cause disease in dementia with Lewy bodies (DLB) and certain other major neurological disorders. Neflamapimod is currently being evaluated in a Phase 2b study in patients with DLB. For more information, please visit www.cervomed.com.

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 management's intentions, plans, beliefs, expectations or forecasts for the future, including, but not limited to, the potential benefits of the transaction between Diffusion Pharmaceuticals and EIP Pharma; the therapeutic potential of neflamapimod; anticipated milestones related to the development of the combined company's clinical programs and reporting of data; the expected ownership percentages of the combined company; and the expected management team and board of directors of the combined company. Terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," or other words that convey uncertainty of future events or outcomes 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 parties' 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 the cash balances of the combined company following the closing; the ability of the combined company to remain listed on the Nasdaq Capital Market, as well as comply with any Nasdaq rules and regulations; the price of the combined company's securities, which may be volatile due to a variety of factors, including changes in the competitive and highly regulated industries in which the combined company operates; variations in operating performance across competitors; changes in laws and regulations affecting the combined company's business; the ability to implement business plans, forecasts, and other expectations after the completion of the proposed transaction; 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 most recent Annual Report on Form 10-K, in the proxy statement/prospectus /information statement that is included in the registration statement on Form S-4 (File No. 333-271823) that was filed with the SEC, 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). New factors emerge from time to time, and it is not possible for us to predict all such factors, nor can we assess the impact of each such factor on the businesses or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. The Company does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this release, except to the extent required by law.

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