EIP Pharma Announces First Patient Dosed in RewinD-LB Phase 2b Clinical Trial Evaluating Neflamapimod in Dementia with Lewy Bodies

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BOSTON, Aug. 14, 2023 /PRNewswire/ -- EIP Pharma Inc. ("EIP Pharma" or the "Company"), a privately held clinical-stage company focused on developing treatments for neurodegenerative diseases, today announced that the first patient has been dosed in the Company's RewinD-LB Phase 2b clinical trial of neflamapimod for the treatment of patients with dementia with Lewy bodies (DLB).

"The dosing of the first patient in phase 2b is a major step forward in our journey towards bringing potentially life-changing treatments to patients living with DLB and other neurodegenerative diseases," said John Alam, MD, Chief Executive Officer of EIP Pharma, and co-principal investigator of the study. "The results of this trial could help substantiate the positive readout we saw in Phase 2a, in which neflamapimod significantly improved cognition and function in patients with DLB. More notably, positive results in the RewinD-LB study would bring us closer to the first approved therapy to patients living with DLB".

"DLB is a progressive neurodegenerative disease for which there is no approved treatment. Patients with DLB have deficits in both cognition and motor function, and often have neuropsychiatric symptoms, which together severely affect their day-to-day living and as the disease progresses eventually inhibits their ability to live independently," added Dr. James Galvin, founding director of the Comprehensive Center for Brain Health at the University of Miami Miller School of Medicine and co-principal investigator of the study. "The preclinical and clinical studies to date suggest that neflamapimod, through treating the underlying disease process, has the potential to address multiple aspects of DLB. If confirmed in the RewinD-LB study, this treatment could transform the course of the disease by reducing the burden of disease on DLB patients and their caregivers".

"The Lewy Body Dementia Association, or LBDA, is committed to advancing the study of potential new treatments in DLB. We're delighted that more than 50% of LBDA's Research Centers of Excellence sites will be participating in the RewinD-LB study. On behalf of the LBDA RCOE program, we are pleased to be able to be involved in progressing neflamapimod into and through this important clinical study", said Angela Taylor, VP Strategic Partnerships at the Lewy Body Dementia Association (LBDA).

The RewinD-LB study is a randomized, 16-week double-blind, placebo-controlled phase 2b clinical trial of oral 40mg neflamapimod, three-times-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.

The study is funded by a $21 million grant to EIP Pharma from the National Institutes of Health's National Institute on Aging (NIA), which will be disbursed over the course of the study as costs are incurred. This grant, in part, funds a public-private partnership between the Miller School of Medicine in Miami, EIP Pharma and the LBDA, to support the management of and raise awareness of, the study in the patient and clinician communities.

About RewinD-LB

RewinD-LB is a randomized, double-blind, placebo-controlled phase 2b clinical trial of neflamapimod in patients living with DLB. A total of 160 participants diagnosed with early-stage DLB (Clinical Dementia Rating, CDR, global score of 0.5 or 1.0) will be randomized into the trial at clinical sites in the US, UK and Netherlands. Patients with Alzheimer's disease-related co-pathology, as evidenced by elevated levels of plasma tau phosphorylated at residue 181 (ptau181), will be excluded. Neflamapimod will be administered orally, 40 mg TID, with half the participants receiving matching placebo in the main study. All participants who complete the main study will continue into 32-week extension, during which all participants will receive neflamapimod on an open label basis. The primary objective is to confirm that neflamapimod, compared with placebo, improves dementia severity, as assessed by Clinical Dementia Rating Sum of Boxes (CDR-SB), in participants with DLB. Secondary objectives include studying safety of neflamapimod and confirming treatment effects on (1) motor function, specifically gait, as assessed by the Timed Up and Go test; (2) cognition, as assessed by a DLB-specific cognitive test battery; and (3) global rating of treatment effect, assessed by the Alzheimer's Disease Cooperative Study-Clinician Global Impression of Change scale. More information on the RewinD-LB trial is available at clinicaltrials.gov, please click here.

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 that disease.

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 (specifically, gait) 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 EIP Pharma

EIP Pharma, Inc. is a privately held clinical-stage biotechnology company advancing CNS-focused therapeutics to benefit patients with a range of

debilitating neurodegenerative diseases. EIP Pharma 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. Current institutional investors in EIP Pharma include Access Industries, Adage Capital Management, Mossrock Capital and Rock Springs Capital.

For more information, please visit www.eippharma.com or engage with us on Twitter and LinkedIn.

No Offer or Solicitation

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, a public off will not be made directly or indirectly in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including, without limitation, facsimile transmission, telephone, or Internet) of interstate or foreign commerce, or any facility or a national securities exchange, of any such jurisdiction.

Important Additional Information and Where to Find It

In connection with the proposed transaction between Diffusion Pharmaceuticals and EIP Pharma, Diffusion Pharmaceuticals has filed with the SEC a registration statement on Form S-4 (as amended, the "Registration Statement") containing a proxy statement/prospectus/information statement (the "Definitive Proxy Statement") related to a special meeting of its stockholders. Diffusion Pharmaceuticals has mailed the Definitive Proxy Statement to Diffusion Pharmaceuticals' stockholders as of the record date of July 10, 2023, describing the proposals set forth therein to be voted on at the special meeting. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND STOCKHOLDERS ARE URGED TO READ THESE MATERIALS – INCLUDING THE REGISTRATION STATEMENT, THE DEFINITIVE PROXY STATEMENT, ANY AMENDMENTS OR SUPPLEMENTS THERETO, AND ANY DOCUMENTS INCORPORATED THEREIN – CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT DIFFUSION PHARMACEUTICALS, EIP PHARMA, THE PROPOSED TRANSACTION AND OTHER RELATED MATTERS. This communication is not a substitute for the Registration Statement, Definitive Proxy Statement or any other documents that Diffusion Pharmaceuticals may file with the SEC or send to Diffusion Pharmaceuticals' stockholders in connection with the proposed transaction. Investors and stockholders may obtain free copies of the proxy statement, prospectus and other documents filed by Diffusion Pharmaceuticals with the SEC through the website maintained by the SEC at www.sec.gov. In addition, stockholders may obtain free copies of the Definitive Proxy Statement and other documents filed by Diffusion Pharmaceuticals with the SEC through the "Investors" section of Diffusion Pharmaceuticals' website, www.diffusionpharma.com.

Participants in the Solicitation

Diffusion Pharmaceuticals and EIP Pharma, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information regarding these persons and their interests in the transaction is or will be included in the Definitive Proxy Statement relating to the transaction and other relevant materials that are or will be filed with the SEC. Additional information regarding Diffusion Pharmaceuticals' directors and officers is included in Diffusion Pharmaceuticals' Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 24, 2023. Other information regarding the participants in the proxy solicitation and a description of their interests in the proposed transaction, by security holdings or otherwise, is included in the Definitive Proxy Statement and other relevant materials that are or will be filed with the SEC regarding the proposed transaction. Investors should read the Definitive Proxy Statement carefully before making any voting or investment decisions. These documents can be obtained free of charge from the sources indicated above.

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 timing and potential outcome of the proposed 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 to the completion of the proposed transaction, including the need for stockholder approval and the satisfaction of closing conditions; the cash balances of the combined company following the closing, if completed, of the proposed transaction; the ability of Diffusion Pharmaceuticals to remain listed on the Nasdaq Capital Market, as well as comply with any Nasdaq rules and regulations related to the proposed transaction; the price of Diffusion Pharmaceuticals' securities, which may be volatile due to a variety of factors, including changes in the competitive and highly regulated industries in which Diffusion Pharmaceuticals and/or EIP Pharma operates; variations in operating performance across competitors; changes in laws and regulations affecting Diffusion Pharmaceuticals' or EIP Pharma'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 Diffusion Pharmaceuticals' most recent Annual Report on Form 10-K and other filings 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. These risks, as well as other risks associated with the merger, will be more fully discussed in the proxy statement/prospectus that will be included in the registration statement that will be filed with the SEC in connection with the proposed transaction and, except as required by applicable law, rule, or regulation, neither Diffusion Pharmaceuticals nor EIP Pharma undertakes any obligation to update any such statements after the date hereof.

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