National Institute on Aging (NIA) awards $21M grant to support key phase 2b study of EIP Pharma's neflamapimod in dementia with Lewy bodies

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BOSTON, MA, January 18th, 2022 /PRNewswire/ – EIP Pharma Inc., a clinical stage company focused on developing treatments for neurodegenerative diseases today announced that the National Institute on Aging (NIA) of the National Institutes of Health (NIH) awarded the Company a grant of $21 million to support a 160-patient phase 2b study of neflamapimod in individuals with dementia with Lewy bodies (DLB).

EIP Pharma CEO, John Alam, MD, stated "we are grateful to the NIA that, based on the peer-review scientific evaluation of the project, they have awarded a grant that will fund the costs of a proof a concept trial for neflamapimod in patients with DLB. The outcome of this phase 2b study could allow us to confirm the positive findings from our phase 2a study and definitively demonstrate the potential for neflamapimod to treat patients suffering from the second most common dementia, DLB. There are currently no approved treatments for this rapidly progressing disease. Therefore, it is with a heightened sense of responsibility and urgency that we look forward to moving the study forward with the phase 2b study commencing within the next few months".

Dr James Galvin from the University of Miami, co-principal investigator for the study, commented "DLB is the second most common neurodegenerative dementia, after Alzheimer's disease. There are no approved therapies for the treatment of the disease and standard of care does not alter the inevitable progression of the disease. Patients suffer from deficits in attention, cognition and gait function and these issues create an inordinate burden of care not only for the patients but also for the caregivers. To date, in animal models and in a phase 2a clinical trial of patients with DLB, neflamapimod has demonstrated the potential to treat the disease process in the basal forebrain cholinergic system, the area of the brain most prominently affected in patients with DLB. The NIA grant will fund a study that will be instrumental in fully understanding whether neflamapimod has the potential to become an important treatment for patients with DLB".

The upcoming NIA-funded phase 2b study, designed to confirm the clinical findings from a recently published phase 2a clinical study of neflamapimod in DLB, is expected to enroll approximately 160 patients with DLB, randomized to receive neflamapimod 40mg or placebo three-times daily for16 weeks. Following the placebo-controlled portion of the study, all patients will be able to continue to be a part of the trial and receive neflamapimod on an open-label basis for 32 weeks. The primary endpoint will be change in Clinical Dementia Rating Sum of Boxes (CDR-SB) and secondary endpoints will include changes in a cognitive test battery that assesses attention and executive function, the Timed Up and Go test that assesses functional mobility, and the Clinicians Global Impression of Change (CGIC). In addition, the study will measure neuropsychiatric outcomes and cognitive fluctuations, as well as EEG and a selection of biomarkers to assess changes in the disease process.

About Neflamapimod: Neflamapimod is an investigational drug that is a brain penetrant, orally administered small molecule that inhibits the intra-cellular enzyme 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. In pre-clinical studies, neflamapimod reverses synaptic dysfunction, including and particularly within the part of the brain most impacted in DLB – the basal forebrain cholinergic system. Neflamapimod has been studied in Phase 1 and Phase 2 clinical trials involving more than 300 participants and has been shown to be generally safe and well tolerated. Results from the AscenD-LB phase 2a clinical study demonstrated that neflamapimod significantly improved dementia severity as compared with placebo, as measured by the gold-standard dementia rating test, the Clinical Dementia Rating Sum-of-Boxes (CDR-SB); and also showed significant improvement compared to placebo on motor function measured by the Timed Up and Go (TUG) test. In addition, at the highest dose evaluated in the study, neflamapimod improved cognition, as assessed by a DLB-specific Neuropsychological Test Battery (NTB) designed to evaluate attention and executive function. Neflamapimod is the first treatment with potential impact on cognition, function and motor function in patients with DLB. The combined pre-clinical and clinical data are consistent with neflamapimod treating the underlying disease process and having the potential to be the first disease-modifying treatment for DLB.

About EIP Pharma: EIP Pharma, Inc. is a private Boston, MA company advancing CNS-focused therapeutics to benefit patients with neurodegenerative diseases.

For more information, please visit www.eippharma.com

Reference: Jiang, Y, Alam, JJ, Gomperts SN et al., "Preclinical and Randomized Clinical Evaluation of the p38α Kinase Inhibitor Neflamapimod for Basal Forebrain Cholinergic Degeneration," *Nature Communications*, 13, Article number: 5308 (2022). https://www.nature.com/articles/s41467022–32944–3

Source EIP Pharma, Inc.

About EIP

Are you a patient, caregiver, clinician or professional and want to learn more about EIP Pharma's approach? Please contact us.

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