

## **EIP Pharma Announces Positive Phase 2 Results for Neflamapimod in Mild-to-Moderate Dementia with Lewy bodies (DLB)**

*AscenD-LB study met primary objective of improving cognition as assessed by the Neuropsychological Test Battery*

*Full results to be presented during late-breaking session at Clinical Trials in Alzheimer's Disease (CTAD) meeting*

**Boston, Mass., October 6, 2020** – EIP Pharma, Inc. ([www.eippharma.com](http://www.eippharma.com)), a CNS-focused therapeutics company, today announced that the Phase 2 AscenD-LB study in patients with mild-to-moderate dementia with Lewy bodies (DLB) met its primary endpoint of demonstrating an improvement in cognition as assessed by the Neuropsychological Test Battery (NTB). In the double-blind placebo-controlled study, patients receiving neflamapimod three times daily (TID) demonstrated significant improvement on the NTB compared to those who received either placebo or neflamapimod twice daily (BID);  $p=0.015$ , effect size (Cohen's  $d$ )=0.52. In addition, statistically significant improvements ( $p<0.05$ ) or trends ( $p<0.1$ ) were evident on multiple secondary clinical endpoints. The full results have been accepted as a late-breaking abstract and will be shared on November 7, 2020 during an oral presentation at the 13<sup>th</sup> Clinical Trials in Alzheimer's Disease (CTAD) meeting.

"The data from the trial of neflamapimod in DLB are very encouraging," said Jeffrey L. Cummings, MD, ScD, Joy Chambers-Grundy Professor of Brain Science and Director of the Chambers-Grundy Center for Transformative Science at the UNLV School of Integrated Health Sciences. "Not only was the prespecified primary outcome met for the three times daily dose arm but supportive trends were observed in several of the secondary outcomes, setting the stage for more extensive testing. There are no approved treatments for DLB, the second most common cause of neurodegenerative dementia, and there is an urgent need to find therapies for this and related disorders such as Alzheimer's disease."

Based on the Phase 2 study results which demonstrate proof-of-concept of neflamapimod as a treatment for patients with DLB, the company plans to advance development of neflamapimod into Phase 3.

"The exciting results of the Phase 2 AscenD-LB study showing benefit of the investigational drug neflamapimod for cognition in DLB will bring hope to patients and their caregivers," said Stephen Gomperts, MD, PhD, Director, Lewy Body Dementia Unit and Assistant Professor of Neurology at Massachusetts General Hospital. "If these findings are confirmed in a Phase 3 study, the potential impact for patients with DLB will be significant."

Neflamapimod was very well tolerated with no treatment discontinuation in the study due to study drug-related adverse events. There were 10 early treatment

discontinuations, four due to intercurrent medical illness (two each in placebo and neflamapimod BID recipients) and six due to withdrawal of consent and/or disease worsening (two in placebo and four in neflamapimod BID). There were four serious adverse events (SAEs) reported in the placebo group and three in neflamapimod BID recipients, all of which were considered unrelated to study drug administration. There were no SAEs or early treatment discontinuations amongst neflamapimod TID recipients.

Neflamapimod as a treatment for DLB received Fast Track designation from the Division of Neurology Products at the U.S. Food and Drug Administration in November 2019.

### **About the Phase 2 AscenD-LB Study**

AscenD-LB was a Phase 2 double-blind, placebo-controlled, 16-week treatment proof-of-concept study (“AscenD-LB”) of neflamapimod in mild-to-moderate dementia with Lewy bodies (DLB) conducted at 22 centers in the United States and two centers in the Netherlands. 91 patients were enrolled between October 2019 and March 2020 and randomized to receive 40 mg neflamapimod capsules or matching placebo capsules (randomized 1:1) for 16 weeks. The dosing regimen was based on weight, with study participants weighing less than 80 kg receiving capsules twice-daily (BID) and those weighing greater than or equal to 80 kg received capsules three-times-a-day (TID). The primary objective was to evaluate the effect of neflamapimod on cognition as assessed in a study-specific Neuropsychological Test Battery (NTB) that was designed to primarily evaluate attention and executive function. The NTB was comprised of four computerized tests from the Cogstate® battery (Detection, Identification, One Card Learning, One Back) and two tests recorded on paper (Letter Fluency, Category Fluency). For the primary endpoint evaluation, the NTB was analyzed as a composite in which the individual tests were equally weighted. Secondary endpoints included additional composites built from a subset of tests in the NTB, ten-item Neuropsychiatric Inventory, Timed Up and Go test, and the Clinical Dementia Rating scale Sum of Boxes. The AscenD-LB study is registered at [clinicaltrials.gov](https://clinicaltrials.gov/study/NCT04001517) as study [NCT04001517](https://clinicaltrials.gov/study/NCT04001517).

### **About Neflamapimod**

Neflamapimod is an investigational drug that is a brain-penetrant, oral small molecule that inhibits the intra-cellular enzyme p38 MAP kinase alpha (p38 $\alpha$ ). P38 $\alpha$ , which is expressed in neurons under conditions of stress and disease, plays a major role in inflammation-induced synaptic toxicity, leading to impairment of synaptic function. Synaptic dysfunction is known to be a major driver of the deficits in cognitive function that are defining characteristics of many CNS diseases. Results of a 152-patient, 24-week treatment double-blind placebo-controlled study of neflamapimod in early AD were reported at the 12<sup>th</sup> CTAD meeting in December 2019, and further at the AAT-AD/PD™ Focus Meeting in April 2020. In the early AD study, neflamapimod demonstrated target engagement, with significant reduction relative to placebo in CSF p-tau and tau; and suggested that cognition was improved in the patients with the highest tertile of trough plasma drug concentration.

### **About Dementia with Lewy Bodies**

Dementia with Lewy bodies (DLB) is a serious disease representing 15 to 20 percent of the dementia population, with an estimated up to 1.4 million affected individuals in the US. DLB is characterized by progressive dementia and fluctuating cognition (deficits in memory and attention), sleep disturbances, visual hallucination and parkinsonism (tremor and gait disturbances). Although it is a separate disease, it can be difficult to differentiate from the related dementias of Alzheimer's disease (AD) and Parkinson's disease (PD). The prognosis for DLB is even more severe than that of AD with an average time from diagnosis to death of just four to seven years. There are no approved treatments for DLB.

**About EIP Pharma Inc**

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

For more information, please visit [www.eippharma.com](http://www.eippharma.com).

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