

EIP Pharma Initiates New Study with Neflamapimod for the Treatment of Cognitive Deficits in Patients with Huntington's Disease



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EIP Pharma, Inc. →
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CAMBRIDGE, Mass., July 9, 2019 /PRNewswire/ -- EIP Pharma, Inc., a CNS-focused therapeutics company, today announced the initiation of a new Phase 2 proof-of-concept study evaluating neflamapimod as a treatment for the cognitive dysfunction associated with Huntington's disease, a rare, genetically inherited disease that causes the nerve cells of the brain to progressively degenerate. The primary objective of the study is to determine whether neflamapimod, a brain-penetrant, oral small molecule that inhibits the enzyme p38 alpha, can reverse the hippocampal synaptic dysfunction associated with early Huntington's disease.

"We believe that neflamapimod has the potential to treat cognitive impairments associated with Huntington's disease and can therefore benefit patients early in the course of their disease. The initiation of this trial represents an important milestone for EIP as we expand our development pipeline and seek to bring new treatment options to patients affected by CNS diseases," said John Alam, MD, founder and CEO of EIP Pharma.

Though Huntington's disease is often defined as a movement disorder, cognitive deficits generally precede the motor deficits. Recently, impairment in hippocampus-dependent cognitive function was defined as one of the earliest clinical manifestations of Huntington's disease. Previous studies in multiple animal models have demonstrated dysregulation of hippocampal synaptic dysfunction.

This Phase 2 proof-of-concept study is a double-blind, placebo-controlled, two-period, 10-week treatment, within-subject, crossover study of neflamapimod in early-stage Huntington's disease (HD), with a washout period of eight to 12 weeks between the two treatment periods. The primary objective is to determine whether neflamapimod can reverse hippocampal dysfunction in patients with early-stage HD, as assessed by the virtual water maze test for evaluating spatial learning and selected tests on the Cambridge Neuropsychological Test Automated Battery (CANTAB). The study will be conducted at one clinical site in Cambridge, UK and will evaluate 16 patients in the cross-over design. Data from the study are expected to be reported in the second half of 2020.

About Neflamapimod

Neflamapimod is a brain-penetrant, oral small molecule that inhibits the intracellular enzyme p38 MAP kinase alpha (p38 α). P38 α , 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. Neflamapimod is currently being studied in a Phase 2b trial for early Alzheimer's disease.

About Huntington's Disease

Huntington's disease (HD), sometimes called Huntington's chorea, is a rare, genetically inherited disease that causes the nerve cells of the brain to progressively degenerate. After visible symptoms present, Huntington's patients typically have a life expectancy of somewhere between 15 and 20 years. Due to the neurologically degenerative nature of the disease, the physical and cognitive affects are often severe, with patients developing a decline in their reasoning and thinking abilities and changes in personality are often detectable. Huntington's is usually inherited from one of the parents, expressed on an autosomal dominant

gene, meaning that only one parent needs to pass on a copy of the faulty gene for the child to later develop HD. However, there are rare cases where individuals develop Huntington's without having the gene passed from a parent.

About EIP Pharma Inc

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

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