



**JOHN WAYNE
CANCER INSTITUTE**
at Providence Saint John's Health Center

For more information, contact
the Neurosciences
Clinical Trial Team at:
Neuro.Trials@pacificneuro.org
310-829-8265

Clinical Trial Investigators

William G. Buxton, MD
Jose Carrillo, MD
Santosh Kesari, MD, PhD
David A. Merrill, MD
Stella Panos, PhD
Melita Petrossian, MD
Verna R. Porter, MD
Marlon Garzo Saria, PhD, RN
Naveed Wagle, MD

Clinical Trial Team

Ashley Archer, CRA
ArcherA@jwci.org
Jaya Mini Gill, RN, BSN
Jaya.Gill@providence.org
Annie Heng, RN, BSN
Annie.Heng@providence.org
Hanh Nguyen, CRA
NguyenThuyH@jwci.org
Shelly Trujillo, CRA
Shelly.Trujillo@providence.org

Sponsor

EIP Pharma, Inc.

**Saint John's
Health Center**

 **PROVIDENCE** Health & Services

CLINICAL TRIAL ANNOUNCEMENT

A Phase 2 Trial to Evaluate the Effect of Neflamapimod in Patients with Lewy Body Dementia

Official Title:

A Double-Blind, Placebo-Controlled 16-Week Study of the Cognitive Effects of the Oral P38 Alpha Kinase Inhibitor Neflamapimod in Dementia with Lewy Bodies (DLB)

The clinical presentation of DLB demonstrates progressive cognitive decline accompanied by mild-to-moderate motor symptoms that are similar to those seen in Parkinson's Disease. DLB is a progressive disorder and there are no treatments approved for the underlying disease process and only symptomatic treatments for parkinsonian symptoms. Although not approved for DLB, cholinesterase inhibitors are often used .

Neflamapimod is a highly specific inhibitor of protein kinase 14 (p38 α). In the brain, p38 α is thought to regulate inflammation through effects on microglia. Targeting p38 has been recognized as a therapeutic target to improve synaptic function.

This is a 16-week clinical trial in subjects with DLB. Eligible subjects will be randomized 1:1 to receive neflamapimod/placebo capsules. During the 16-week treatment period, subjects will return to the clinic every 2 weeks for the first month and then every 4 weeks thereafter .

Key Inclusion Criteria:

- Age ≥ 55
- MMSE score of 15-28, inclusive, during Screening
- Mild-to-Moderate Probable DLB and identified cognitive deficits, specifically one core clinical feature and a positive DaTscan. If a negative DaTscan, but the subject has historical PSG-verified RBD, the subject would also qualify
- No history of learning difficulties

Key Exclusion Criteria:

- Diagnosis of any other central nervous system (CNS) condition other than DLB
- History of previous neurosurgery to the brain