MGFA Study Web Content:

Phase 3 Study to Evaluate Efficacy of Amifampridine Phosphate in Lambert-Eaton Myasthenic Syndrome (LEMS)

Study Purpose: This study evaluates the effect of withdrawing amifampridine phosphate treatment from patients with LEMS. One half of the patients will continue to receive amifampridine phosphate and the other half will receive placebo, during this double-blind study.

Recruitment Information:

Study Type: Interventional

Status: Active

Target Patient: Male and female patients, 18 Years and older diagnosed with LEMS.

Eligible Ages: 18 Years and older (Adult, Senior)

Link to appropriate websites https://clinicaltrials.gov/ct2/show/NCT02970162
ClinicalTrials.gov Identifier: NCT02970162

Inclusion and Exclusion Criteria:

Inclusion Criteria: 1. Male or female ≥18 years of age and currently receiving amifampridine phosphate for LEMS. 2. Diagnosis of LEMS by antibody testing or electromyography (EMG). 3. Completion of anti-cancer treatment at least 3 months (90 days) prior to Screening. 4. If receiving peripherally acting cholinesterase inhibitors (e.g. pyridostigmine), a stable dose of cholinesterase inhibitors is required for at least 7 days prior to randomization and throughout the study 5. If receiving permitted oral immunosuppressants

(prednisone or other corticosteroid), a stable dose is required for at least 30 days prior to randomization and throughout the study. 6. Female patients of childbearing potential must practice an effective, reliable contraceptive regimen during the study. 7. Able to perform all study procedures and assessments. 8. Willing and able to travel to study site and attend all clinic study visits. 9. Willing and able to provide written informed consent.

Exclusion Criteria: 1. Clinically significant long corrected QT (QTc) interval on ECG in previous 12 months. 2. Seizure disorder. 3. Active brain metastases. 4. Unable to ambulate. 5. Pregnant or lactating females. 6. Any other condition which, in the opinion of the Investigator, might interfere with the patient's participation in the study or confound the assessment of the patient.

Study Information:

Sponsor: Catalyst Pharmaceuticals, Inc. 355 Alhambra Circle, Suite 1250 Coral Gables, FL 33134 Telephone: 1-844-347-3277

Principal Investigator: Perry Shieh, MD, PhD University of California, Los Angeles

Study Coordinator: Angela Ho, T: (310) 825-3264, E: ALHo@mednet.ucla.edu

Type of Study: This study evaluates the effect of withdrawing amifampridine phosphate treatment from patients with LEMS. One half of the patients will continue to receive amifampridine phosphate and the other half will receive placebo, during this double-blind study.

Study Duration: 5-7 days at clinical study sites in Miami, FL or Los Angeles, CA

Single Center/Multi-center: Multi-center

Travel Funds Available: ☒ Y ☐ N

Find A Center Near You:

List Sites Here

Site: UCLA, Los Angeles, California, United States, 90095

PI: Perry Shieh, MD, PhD University of California, Los Angeles

Coordinator: Angela Ho, T: (310) 825-3264, E: ALHo@mednet.ucla.edu

Site: There will be a site in Miami, FL; awaiting IRB approval

PI: Awaiting IRB approval

Coordinator: Awaiting IRB approval