Neptunia A Phase IIa, Randomized, Parallel, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Enpatoran in Dermatomyositis and Polymyositis Participants receiving Standard of Care

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

Adults with primarily diagnosed with Dermatomyositis (DM) or Polymyositis (PM)

Exclusion Criteria:

Diagnosis of myositis within 3 years of cancer

Conditions & Interventions

Interventions:
Drug: M5049 high dose, Drug: Placebo
Conditions:
Dermatology (Skin, Hair & Nails)
Keywords:
Dermatomyositis (DM), Polymyositis (PM)

More Information

Description: This research is studying enpatoran (M5049) as a possible treatment for dermatomyositis (DM) and polymyositis (PM). The study will last for approximately 31 weeks (upto 9 study visits) and an additional optional 24 weeks (upto 5 study visits) if you agree to participate in the extension period for a total of up to 14 months (55 weeks). It will include approximately up to 3 telephone calls from the study center. The main activities in the study include: providing consent to participate, performing tests to check your health throughout the study (such as physical exams, electrocardiogram (ECG) testing, collection of urine and blood draws for laboratory testing), study drug dosing and recording relevant information in the study diary, and performing tests, completing questionnaires and assess signs and symptoms of your condition. This is a Phase 2a study. and it is anticipated that approximately 40 people will participate in this study.
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