A Phase II, Randomized, Double-Blind, Placebo-Controlled Dose-Ranging, Parallel and;Adaptive Study to Evaluate the Efficacy and Safety of Enpatoran in Systemic Lupus Erythematosus and in Cutaneous Lupus Erythematosus (Subacute&Cutaneous Lupus Erythematosus and/or Discoid Lupus Erythematosus) 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 18-75 years of age - disease duration at least 6 months of either active discoid or subacute cutaneous lupus OR active systemic lupus - on stable dose(s) of standard-of-care therapies for lupus - willing to use contraception for the study period

Exclusion Criteria:

- Drug-induced lupus, within 3 months of induction therapy for lupus nephritis, or active CNS lupus - history of epilepsy, significant cardiovascular events including arrhythmia, solid organ transplantation, or malignancy - active infection including HIV, HBV, HCV, or tuberculosis - there are specified wait times for people taking certain prior drugs (study staff will review)

Conditions & Interventions

Conditions:
Arthritis & Rheumatic Diseases, Dermatology (Skin, Hair & Nails), Rare Diseases
Keywords:
lupus, discoid, SLE, CLE, DLE, SCLE, WILLOW, enpatoran, M5049, Merck, EMD Serono, Pearson

More Information

Description: The main purpose of this research study is to see whether enpatoran works for people with SLE or CLE, and to find out more about how safe and well tolerated it is. Participation in this research study will last for approximately 33 weeks (this includes a 24-week study drug period).
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