Study code: MS200569_0041 Enpatoran (M5049)
Study Sponsor: Merck Healthcare KGaA
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neptunia

ADULTS WITH DERMATOMYOSITIS OR POLYMYOSITIS NEED MORE TREATMENT OPTIONS.

Dermatomyositis Polymyositis

if you are an adult living with Dermatomyositis (DM) or Polymyositis (PM), you may consider participating in a clinical research study.

STUDY OVERVIEW

- NEPTUNIA clinical research study is enrolling participants between the ages of 18 and 75 who have been diagnosed with DM or PM (diagnosis must be confirmed by a health care provider)
- NEPTUNIA will evaluate the efficacy and safety of enpatoran tablets (the "Investigational Medication") that will be administered twice daily
- Enpatoran is designed to potentially block specific cell pathways that may contribute to an overreaction of the immune system in people with myositis
- Participants will be randomly assigned to receive enpatoran or placebo
- The duration of the study consists of a screening period (up to 5 weeks), treatment period (24 weeks) and a 2-week follow-up period
- All Participants completing the 24 weeks of enpatoran or placebo are offered an additional 24 weeks of enpatoran treatment (the open label extension) to the extent locally permissible.

IMPORTANT INFORMATION ABOUT THIS STUDY

To qualify for this study, you must:

- Have a confirmed diagnosis of an active DM or PM, with moderate to severe myopathy or moderate to severe rash with mild myopathy, while receiving treatment for myositis
- Have completed some eligibility assessments to determine if the study is suitable for you

The study doctor will provide full information on all study assessments and requirements before you make the decision whether to participate.

WHAT HAPPENS IF I PARTICIPATE

Eligible patients will:

- Undergo a screening period (up to 5 weeks) to check your eligibility
- Participate in a 24-week double-blind treatment period, with a maximum of 9 on-site study visits with various assessments
- Keep a diary to record timing of study drug intake as well as timing of meal
- Have the opportunity to participate in the extension open-label period to receive enpatoran for additional 24 weeks, with a maximum of 5 on-site study visits with various assessments to the extent locally permissible.

Eligible patients enrolled in the study will be closely monitored by a physician at regular visits while receiving one of the following:

- Daily Enpatoran
- Daily placebo

Patients may be allowed to continue to take the medications they are currently taking for their disease. The study doctor will explain more about this.

How Can I Participate?

Speak with your physician to learn more about how you may be able to participate in this clinical study

To LEARN MORE, VISIT

www.clinicaltrials.merckgroup.com/en/

For more information about this clinical study

https://clinicaltrials.merckgroup.com/en/trial-details/?id=MS200569_0041

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