SPIMM-301 Protocol Update for Advocacy Group Posting

MMPOWER-3 Trial

- MMPOWER-3 is a phase 3, randomized, double-blind, parallel-group, placebo-controlled trial to evaluate the efficacy and safety of daily subcutaneous (under the skin) injections of elamipretide in patients with primary mitochondrial myopathy (PMM) followed by an open-label treatment extension.

Eligibility*

- Have previous genetic testing results available.
- Able to walk.
- Between 16 years to 80 years of age.
- Diagnosed with PMM in the opinion of the investigator.

*Other eligibility criteria applied

Trial Enrollment

- The trial will assess approximately 200 patients, aged 16-80, across North America and Europe. Visit ClinicalTrials.gov for a list of trial sites.

Frequently Asked Questions About MMPOWER-3

What will MMPOWER-3 study?

- MMPOWER-3 is a phase 3, randomized, double-blind, parallel-group, placebo-controlled trial to evaluate the efficacy and safety of daily subcutaneous injections of elamipretide in patients with PMM followed by an open-label treatment extension.
- The trial will primarily assess the change in distance walked during the 6MWT and patient-reported fatigue using a PMM-specific questionnaire, the Primary Mitochondrial Myopathy Symptom Assessment (PMMSA). Secondarily, the trial will also evaluate changes in fatigue during activities using the PMMSA, quality of life, impact on the patient's most bothersome symptom on the PMMSA, and safety and tolerability of treatment with elamipretide.

What is the drug being studied, and how does it work?

- In MMPOWER-3, Stealth is evaluating elamipretide delivered by subcutaneous (under the skin) injection. Elamipretide is an investigational drug that associates with cardiolipin, a key structural component of the inner mitochondrial membrane (IMM), and has shown to improve mitochondrial function in preclinical and early clinical studies.

How will investigators select patients to participate in the MMPOWER-3 trial?

- Patients that have a genetic confirmation of mitochondrial disease are potentially eligible for participation in MMPOWER-3. The clinical trial investigator will identify potential patients.

How long does MMPOWER-3 last?

- Subjects enrolled in the trial will receive daily injections of elamipretide or placebo for six months. At the end of the six month period, subjects may elect to participate in the open-label treatment extension and will receive elamipretide for the duration of the trial.

At this time, Stealth is providing access to elamipretide only through clinical trials. For further information on available clinical trials, visit ClinicalTrials.gov.

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