A Phase 3, Multicenter, Randomized, Double Blind, Placebo-Controlled Study to Confirm the Safety, Tolerability, and Efficacy of Zilucoplan in Subjects With Generalized Myasthenia Gravis

Study Purpose: The RAISE study is a multicenter, randomized, double-blind, placebo-controlled study to confirm the efficacy, safety, and tolerability of zilucoplan in subjects with generalized Myasthenia Gravis. Subjects will be randomized in a 1:1 ratio to receive daily SC doses of 0.3 mg/kg zilucoplan or placebo for 12 weeks. After the 12-week treatment period, subjects will have the option to receive zilucoplan in a separate open-label extension study.

Recruitment Information:

Study Type: Interventional

Status: Recruiting

Target Patient: Patients with generalized Myasthenia Gravis, positive for acetylcholine receptor (AChR) binding antibodies

Eligible Ages: 18-75 years

www.rapharma.com/for-patients/

https://clinicaltrials.gov/ct2/show/NCT04115293

Key Inclusion and Exclusion Criteria:

Key Inclusion Criteria:

- Diagnosis of gMG [Myasthenia Gravis Foundation of America (MGFA) Class II-IV] at Screening
- Positive serology for acetylcholine receptor (AChR) autoantibodies
- MG-ADL Score of ≥ 6 at Screening and Baseline
- QMG score ≥ 12 at Screening and Baseline
- No change in corticosteroid dose for at least 30 days prior to Baseline or anticipated to occur during the 12-week Treatment Period
- No change in immunosuppressive therapy, including dose, for at least 30 days prior to Baseline or anticipated to occur during the 12-week Treatment Period

Key Exclusion Criteria:

- Thymectomy within 12 months prior to Baseline or scheduled to occur during the 12-week Treatment Period
- History of meningococcal disease
- Current or recent systemic infection within 2 weeks prior to Baseline or injection requiring intravenous (IV) antibiotics within 4 weeks prior to Baseline

Study Information:

Sponsor: Ra Pharmaceuticals

Type of Study: Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled

Study Duration: 12 weeks

Single Center/Multi-center: Multi-center

Travel Funds Available: ☒ Y ☐ N

Find A Center Near You:

Mobile, AL
Phoenix, AZ
Los Angeles, CA
Orange, CA
San Francisco, CA
New Haven, CT
Washington, DC
Jacksonville, FL
Tampa, FL
Augusta, GA
Indianapolis, IN
Kansas City, KS
Boston, MA
Detroit, MI
East Lansing, MI
Minneapolis, MN
Columbia, MO
Chapel Hill, NC
Durham, NC
Lincoln, NE
Las Vegas, NV
Buffalo, NY
Great Neck, NY
New York, NY
Cleveland, OH
Columbus, OH
Portland, OR
Pittsburgh, PA
Charleston, SC
Austin, TX
Dallas, TX
Salt Lake City, UT
Charlottesville, VA
Seattle, WA
Milwaukee, WI

For more information, please contact **trials@rapharma.com.**