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

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