MGFA Study Web Content:

**Study Title:**

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase 3 Trial to Evaluate the Efficacy, Safety and Tolerability of ARGX-113 in Patients With Myasthenia Gravis Having Generalized Muscle Weakness

**Study Purpose:**

The primary objective of this study is to evaluate the efficacy of ARGX-113 as assessed by the percentage of "Myasthenia Gravis Activities of Daily Living [MG-ADL] responders" after the first treatment cycle in the acetylcholine receptor [AChR]-antibody [Ab] seropositive population.

**Recruitment Information:**

**Study Type:** This interventional study is a randomized, double-blind, placebo controlled, multicenter Phase 3 trial to evaluate the efficacy, safety, tolerability, quality of life and impact on normal daily activities of ARGX-113 in patients with generalized Myasthenia Gravis [gMG]. Further, this is the first study to address both acetylcholine receptor [AChR] autoantibody positive as well as AChR autoantibody negative patients.

**Status:** Recruiting

**Target Patient:** A male or female [aged 18 years or older] with a diagnosis of myasthenia gravis [MG] with generalized muscle weakness meeting the clinical criteria for diagnosis of MG as defined by the Myasthenia Gravis Foundation of America (MGFA) Class II, III, IVa, and IVb.

**Eligible Ages:** Male or female patients aged ≥ 18 years.

*Link to appropriate websites*


**Inclusion and Exclusion Criteria:**

**Inclusion Criteria:** Patients with the ability to understand the requirements of the trial, provide written informed consent, and comply with the trial protocol procedures. Male or female patients aged ≥ 18 years. Diagnosis of MG with generalized muscle weakness meeting the clinical criteria for diagnosis of MG as defined by the Myasthenia Gravis Foundation of America (MGFA) class II, III, IVa and IVb. Other, more specific inclusion criteria are defined in the protocol.
Exclusion Criteria: Pregnant and lactating women, and those intending to become pregnant during the trial or within 90 days after the last dosing. Male patients who are sexually active and do not intend to use effective methods of contraception during the trial or within 90 days after the last dosing or male patients who plan to donate sperm during the trial or within 90 days after the last dosing. MGFA Class I and V patients. Patients with worsening muscle weakness secondary to concurrent infections or medications. Patients with known seropositivity or who test positive for an active viral infection at Screening with: Hepatitis B Virus [HBV] [except patients who are seropositive because of HBV vaccination] Hepatitis C Virus [HCV] Human Immunodeficiency Virus [HIV]. Other, more specific exclusion criteria are further defined in the protocol.

Study Information:

Sponsor: argenx BVBA

Type of Study: Interventional

Study Duration: 26 weeks

Single Center/Multi-center: Multi-center

Travel Funds Available: ☒ Y ☐ N

For more information, contact: clinicaltrials@argenx.com