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MEDICAL AFFAIRS

Scan for Clinical Trial Information

ClinicalTrials.gov identifiers: NCT06558279

A Study to Assess the Efficacy and Safety of Efgartigimod rHuPH20 SC in Adults with Ocular Myasthenia Gravis (ADAPT Oculus)

Speak to One of Our Representatives to Learn More

Ocular Myasthenia Gravis

Changes in Eye Anatomy in OMG

Key features of OMG include[1,4]:

- Ptosis
- Diplopia
- Unilateral eyelid retraction
- Weakness of the orbicularis muscles

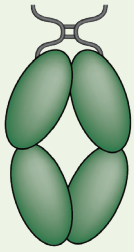
- MG is a rare, chronic, IgG autoantibody-mediated disease characterized by local or generalized muscle weakness and fatigue that worsen with use[1]
- ≈80% of patients with MG initially present with ocular symptoms, with up to 92% showing ocular symptoms at any point during the course of disease[2,a]
- While many patients with ocular symptoms will eventually progress to generalized disease, in ≈15%-25% of patients with MG, symptoms remain restricted to the ocular muscles in a condition known as OMG[1-3,a]
- The overall incidence of OMG is ≈1.13 per 100,000 persons per year[2,a]

Design of Efgartigimod alfa[5-8]

Efgartigimod alfa is a human IgG1 antibody Fc fragment with an affinity to neonatal Fc receptor (FcRn)

- FcRn contributes to the homeostasis of IgG by recycling circulating IgG and extending their half-lives
- Binding of efgartigimod alfa to FcRn prevents FcRn-mediated recycling of endogenous IgG, leading to a reduction in levels of circulating IgGs including potentially pathogenic autoantibodies
- Efgartigimod rHuPH20 SC is a coformulation of efgartigimod alfa with recombinant human hyaluronidase

Efgartigimod alfa Fc fragment



Efgartigimod alfa rHuPH20 is not approved by the FDA for the treatment of patients with OMG as safety and efficacy have not been established

[a]As determined in a population-based retrospective cohort study using the Rochester Epidemiology Project multicenter medical records-linkage system to identify 65 adult patients diagnosed with MG in Olmstead County, Minnesota, USA, between 1990 and 2017.[2]
[b]An interim analysis will be performed when at least 41 participants have completed part A. Based on futility/efficacy evaluation of this interim analysis, additional participants will be enrolled (up to 92 or 124 participants).
[c]No shorter than 7 days.

Abbreviations: AChEi, acetylcholinesterase inhibitor; AChR-Ab, anti-acetylcholine receptor antibodies; CS, corticosteroids; E, examination; Efgartigimod rHuPH20 SC, efgartigimod alfa coformulated with recombinant human hyaluronidase for subcutaneous injection; FcRn, neonatal Fc receptor; IgG, immunoglobulin G; IVIg, intravenous immunoglobulin; MG, myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MGII, Myasthenia Gravis Impairment Index; NSIST, nonsteroidal anti-inflammatory therapy; OMG, ocular myasthenia gravis; PBO, placebo; PLEX, plasma exchange; PR, patient-reported

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ADAPT Oculus Clinical Trial, Now Enrolling

ADAPT Oculus (ARGX-113-2315): A Randomized, Double-Blinded, Placebo-Controlled, Phase 3, Parallel-Group Design Study Evaluating the Efficacy and Safety of Efgartigimod PH20 SC Administered by Prefilled Syringe in Adult Participants With Ocular Myasthenia Gravis[8]

adapt Oculus myasthenia gravis study

Key Inclusion Criteria[8]

- Diagnosis of MG supported by:
  - Seropositivity for AChR-Ab, OR
  - Abnormal neuromuscular transmission, AND
  - History of positive edrophonium chloride test, as evidenced by improvement in ptosis or diplopia, or demonstrated improvement in MG signs with treatment such as oral AChEis, PLEX, IVIg, or CS
- MGFA class I demonstrating ocular muscle weakness
- MGII (PRO) ocular score of ≥6 with at least 2 ocular items with a score of ≥2
- On a stable dose of MG therapy prior to screening (AChEI, CS, NSISTs, alone or in combination)
- Symptom onset <3 years before screening

Key Exclusion Criteria[8]

- Presence of other autoimmune diseases that would interfere with an accurate assessment of clinical symptoms of OMG
- Baseline IgG levels <4 g/L
- History of malignancy, active infection, or any clinically significant disease or condition that may put the participant at undue risk
- Other diseases that cause eyelid drooping, peripheral muscle weakness, or diplopia
- Thymectomy <3 months prior to screening

Additional inclusion and exclusion criteria apply.[8]

ADAPT Oculus Study Design[8]

Screening (≈5 weeks)

Adult participants who meet criteria at screening

Part A: Double-Blind, PBO-Controlled Period (≤7 weeks)

1000 mg efgartigimod rHuPH20 SC once weekly

N≤124[b]

Randomized 1:1

Week 0 1 2 3 — 4-week follow-up

PBO 2000 u/mL rHuPH20 SC once weekly

Week 0 1 2 3 — 4-week follow-up

Primary endpoint (week 4)

▲Efgartigimod rHuPH20 SC

▲Placebo rHuPH20 SC

Part B: Open-Label Period (≤2 years)

1000 mg efgartigimod rHuPH20 SC once weekly

3-week treatment period: C1 C1 C2 C2 C3 C3

Intertreatment period

Variable

From Cycle 3 onward, participants will receive 3-week treatment cycles with intertreatment periods of variable duration, depending on clinical response[c]

Primary Endpoint:

- MGII (PR) ocular score change from baseline to week 4 (day 29)

Key Secondary Endpoints:

- MGII (PR+E) ocular score change from baseline to week 4 (day 29)
- MG-ADL ocular domain score change from baseline to week 4 (day 29)
- MGII total score change from baseline to week 4 (day 29)

This clinical trial investigating efgartigimod rHuPH20 SC for the treatment of ocular MG is now enrolling. Speak to one of our representatives to learn more

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References

1. Shuey NH. *Clin Exp Optom.* 2022;105(2):205-213. **2.** Hendricks TM, et al. *Am J Ophthalmol.* 2019;205:99-105. **3.** Kerty E, et al. *Eur J Neurol.* 2014;21(5):687-689. **4.** Nair AG, et al. *Indian J Ophthalmol.* 2014;62(10):985-991. **5.** Wolfe GI, et al. *J Neurol Sci.* 2021;430:118074. **6.** Vaccaro C, et al. *Nat Biotechnol.* 2005;23(10):1283-1288. **7.** Ulrichts P, et al. *J Clin Invest.* 2018;128(10):4372-4386. **8.** Study ARGX-113-2315 Clinical Trial Protocol v1.0 June 2024.