MGFA Web Study Content:

Efgartigimod Expanded Access for Generalized Myasthenia Gravis

Sponsor: argenx

Study Purpose: This expanded access protocol applies to patients with gMG who are not enrolled in an ongoing clinical trial. The aim of the trial is to provide patients with generalized myasthenia gravis (gMG), who are ineligible to participate in a clinical trial, access to **efgartigimod** treatment before regulatory approval.

Recruitment Information:

Study Type: Expanded Access
Status: Available
Phase:
Intervention Treatment: Biological: **efgartigimod**, an intravenous infusion of **efgartigimod** Other Name: ARGX-113
Target Patient: Patients with gMG not eligible for other studies.
Eligible Ages: 18 Years and older (Adult, Older Adult)

Link to Appropriate Websites:

clinicaltrials@argenx.com

https://clinicaltrials.gov/ct2/show/study/NCT04777734?term=efgartigimod&cond=Myasthenia+Gravis&draw=2&rank=4

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Key Inclusion and Exclusion Criteria:

Inclusion Data:

- Patient is ≥18 years of age, at the time of signing the informed consent
- Patient has a diagnosis of MG (AChR-Ab seropositive or seronegative) with generalized muscle weakness
- Patient has been vaccinated against COVID-19 or has had a negative COVID-19 test result in the 2 weeks before enrollment
- Patient has documented IgG >6 g/L within one month of screening
- Patient agrees to contraceptive use consistent with local regulations and scientific rationale regarding the methods of contraception and:

1. Male patients: must agree to use an acceptable method of contraception and to not donate sperm from the time of providing informed consent until the end of the program
2. Female patients: Women of childbearing potential must use a highly effective or acceptable method of contraception and have a negative serum pregnancy test at screening

- Patient provides signed informed consent, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and this protocol
- Patients with a history of hepatitis B, hepatitis C, or HIV must have a documented negative test for an active viral infection.

Exclusion Data:

- Patient has clinically significant uncontrolled active or chronic bacterial, viral, or fungal infection at screening
- Patient has a known autoimmune disease that, in the opinion of the treating physician, would interfere with an accurate assessment of clinical symptoms of gMG or put the patient at undue risk
- Patient has a history of malignancy unless it is deemed to be cured by adequate treatment with no evidence of recurrence for ≥3 years before the first administration of the IMP. Patients with documentation of adequate treatment of the following cancers can be included at any time: basal cell or squamous cell skin cancer; carcinoma in situ of the cervix; carcinoma in situ of the breast; incidental histological finding of prostate cancer (TNM stage T1a or T1b)
- Patient has clinical evidence of other significant serious diseases, has recently had major surgery, or has any other condition that, in the opinion of the treating physician, could put the patient at undue risk
- Patient may be excluded based upon review of clinical medical records and screening clinical safety laboratory test results
- Patient has received a live or a live-attenuated vaccination during the month before screening
- Patient is pregnant and/or lactating or intends to become pregnant during the program or within 90 days after the last dose
- Patient is an unsterilized male who is sexually active while participating in the program and does not intend to use effective methods of contraception during the program through 90 days after the last dose or plans to donate sperm during the program or through 90 days after the last dose.
- The patient has previously received rituximab, and the last rituximab dose was received less than 6 months before the first dose of efgartigimod

Study Information

Sponsor: argenx
Type of Study: Expanded Access
Study Duration:
Single Center/Multi-center:

Find a Center Near You:

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