

# A non-interventional, post-authorisation safety study of patients treated with efgartigimod alfa

**First published:** 13/03/2024

**Last updated:** 13/03/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000019

### Study ID

1000000019

### DARWIN EU® study

No

### Study countries

☐ European Union

☐ United States

### Study description

This is a non-interventional, prospective, post authorization safety study. Patients with gMG who are expected to start treatment with efgartigimod at enrolment or are within their first cycle of efgartigimod at enrolment will be eligible to enroll into the efgartigimod cohort. Patients with gMG who have not been exposed to efgartigimod and for whom it is not planned to start treatment with efgartigimod at enrolment will be eligible to enroll into the non-efgartigimod cohort.

Enrolment of patients will be over at least a 5-year period. The follow up of patients will continue for 5 years from the time the last patient has been enrolled. Patients will be followed up regardless of whether they continue or discontinue efgartigimod.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### United BioSource Corporation (UBC)

☐ Switzerland

**First published:** 25/04/2013

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**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

### Contact details

### Study institution contact

Sabine Coppieters Clinicaltrials@argenx.com

Study contact

[Clinicaltrials@argenx.com](mailto:Clinicaltrials@argenx.com)

### Primary lead investigator

Not yet assigned

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 31/03/2024

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### Study start date

Actual: 14/12/2023

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### Date of final study report

Planned: 01/06/2034

## Study protocol

[ARGX-113-PASS-2208-Protocol\\_Redacted.pdf](#) (451.46 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Post-Authorization Safety Study (PASS)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Study design:**

This is a non-interventional, prospective, post authorisation safety study.

**Main study objective:**

A non-interventional 10-year Post-Authorization Safety Study (PASS) in a post-marketing setting comparing cohorts of patients with gMG treated with efgartigimod to those treated with other MG medication, in order to estimate the incidence rates of serious infection and other safety events.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Name of medicine**

VYVGART

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### **Study drug International non-proprietary name (INN) or common name**

EFGARTIGIMOD ALFA

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### **Medical condition to be studied**

Myasthenia gravis

## Population studied

### **Age groups**

Adult and elderly population ( $\geq 18$  years)

Adults (18 to  $< 65$  years)

Adults (18 to  $< 46$  years)

Adults (46 to < 65 years)  
Elderly ( $\geq$  65 years)  
Adults (65 to < 75 years)  
Adults (75 to < 85 years)  
Adults (85 years and over)

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### **Estimated number of subjects**

680

## Study design details

### **Setting**

Patients with gMG who are expected to start treatment with efgartigimod at enrolment or are within their first cycle of efgartigimod at enrolment will be eligible to enrol into the efgartigimod cohort. Patients with gMG who have not been exposed to efgartigimod and for whom it is not planned to start treatment with efgartigimod at enrolment will be eligible to enrol into the non-efgartigimod cohort.

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### **Outcomes**

To evaluate the overall long-term safety of efgartigimod including the occurrence of serious infections in gMG patients treated with efgartigimod compared to gMG patients not exposed to efgartigimod.

## Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No