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

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# Administrative details

EU PAS number		
EUPAS100000019		
Study ID		
100000019		
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.

#### **Study status**

Ongoing

#### Research institutions and networks

### Institutions

United BioSource Corporation (UBC)		
Switzerland		
First published: 25/04/2013		
Last updated: 06/03/2024		
Institution Non-Pharmaceutical company ENCePP partner		

## Contact details

#### **Study institution contact**

Sabine Coppieters Clinicaltrials@argenx.com

**Study contact** 

Clinicaltrials@argenx.com

#### **Primary lead investigator**

Not yet assigned

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Planned: 31/03/2024

#### Study start date

Actual: 14/12/2023

#### 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?

#### 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

#### Study type:

Non-interventional study

#### 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

#### 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

#### **Medicinal product name**

**VYVGART** 

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

#### Medical condition to be studied

Myasthenia gravis

# Population studied

#### Age groups

- Adult and elderly population (≥18 years)
  - Adults (18 to < 65 years)</li>
    - Adults (18 to < 46 years)

- Adults (46 to < 65 years)</li>
- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

#### **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.

#### **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

#### **Check completeness**

Unknown

#### **Check stability**

Unknown

#### **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No