Post-Authorisation Safety Study (PASS) to Evaluate the Risk of Malignancies in Patients with Myasthenia Gravis (MG) Treated with Efgartigimod

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Study Planned

Administrative details

EU PAS number

EUPAS1000000915

Study ID

1000000915

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] United Kingdom
- [ ] United States

Study description

This is a multinational, longitudinal database cohort study which aims to assess the risk of malignancy in patients with MG exposed to at least one dose of efgartigimod compared to MG patients with no record of exposure to efgartigimod by analysing data from three claims databases. The reference cohort will consist of patients with a diagnosis code for MG without efgartigimod exposure but are on any other therapy for the treatment of MG during the study period.

Patients will be followed from study entry to at least 10 years following inclusion in the study.

Study status

Planned

Research institutions and networks

Institutions

argenx BV

Contact details

Study institution contact

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Study contact

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Primary lead investigator

argenx BV

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 08/09/2023

Study start date
Planned: 01/09/2026

Data analysis start date
Planned: 01/09/2026

Date of final study report
Planned: 01/09/2039

Study protocol

ARGX-113-PASS-2316-protocol malignancy v1.0 24July2025_Redacted.pdf (1.69 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

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, longitudinal database cohort post authorisation safety study.

Main study objective:

To evaluate the long-term risk of malignancies overall and by type in patients with MG treated with efgartigimod compared to MG patients on any other MG therapy and who do not have malignancy history in the lookback period, in a real-world setting.

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

Anatomical Therapeutic Chemical (ATC) code

(L04AA58) efgartigimod alfa

efgartigimod alfa

Medical condition to be studied

Myasthenia gravis

Population studied

Short description of the study population

The study will identify two cohorts from each selected database:

- Efgartigimod Cohort: Patients with an MG diagnosis and who have initiated efgartigimod.
- Reference Cohort: Patients with an MG diagnosis and who have not initiated efgartigimod but are on any other therapy for the treatment of MG. Immunoglobulins and plasmapheresis are not considered here, as they are usually used for acute management of MG crisis.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)

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

Estimated number of subjects

4074

Study design details

Setting

The observational study will identify two cohorts from each targeted database:
- Efgartigimod Cohort: Patients with an MG diagnosis and who have initiated efgartigimod.
- Reference Cohort: Patients with an MG diagnosis and who have not initiated efgartigimod but are on any other therapy for the treatment of MG. Immunoglobulins and plasmapheresis are not considered here, as they are usually used for acute management of MG crisis.

Outcomes

- Long-term risk of malignancies overall and by type in patients with MG treated with efgartigimod compared to MG patients on any other MG therapy and who do not have malignancy history in the lookback period, in a real-world setting.
- Long-term risk of malignancies overall and by type in MG patients with malignancy history in the lookback period.
- Long-term risk of malignancies by duration of efgartigimod exposure.
- Long-term risk of malignancies in subpopulations with increased risk for malignancy: elderly (age 65 years and older); chronic use (i.e., ≥1 year) of

corticosteroids.

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