Long-Term, Observational, Global Registry of Patients With Generalized Myasthenia Gravis Who Have Received Treatment With Complement C5 Inhibition Therapies

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000478

EU PAS number

EUPAS1000000478

Study ID

1000000478

DARWIN EU® study

Yes

Study countries

- [ ] Austria
- [ ] Canada
- [ ] China
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Kuwait
- [ ] Saudi Arabia
- [ ] Türkiye
- [ ] United Arab Emirates
- [ ] United States

Study description

Brief Summary:

Long-term, multicenter, multinational, observational, registry of patients with gMG that is designed to collect data on clinical outcomes and safety in patients prescribed Alexion C5 inhibitor therapies (C5IT) such as eculizumab (Soliris®) and ravulizumab (Ultomiris®).

Detailed Description:

At the time of enrollment in the Registry, participant records will be queried for retrospective information about the participants' medical history and gMG disease treatment history. Following enrollment, prospective data collection will be performed using data obtained as part of the routine clinical care and through patient-reported outcome methods in use. Data will be collected using an electronic data capture system. The duration of data collection for the Registry will be up to 5 years from the day of enrollment.

Study status

Ongoing

Research institutions and networks

Institutions

Alexion Pharmaceuticals, Inc.

Contact details

Study institution contact

Alexion Pharmaceuticals, Inc Alexion Pharmaceuticals, Inc

Study contact

clinicaltrials@alexion.com

Primary lead investigator

N/A N/A

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/12/2019

Actual: 02/12/2019

Study start date

Planned: 02/12/2019

Actual: 02/12/2019

Date of final study report
Planned: 31/12/2029

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

ECU-MG-501 protocol final 10Jul2019(2)_signed.pdf(367.79 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

ClinicalTrials.gov ID: NCT04202341

Regulatory Agency Identifying Number(s): IND 101,219

https://www.clinicaltrials.gov/study/NCT04202341

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Hypothesis generation (including signal detection)

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Longitudinal observational registry

Study drug and medical condition

Name of medicine

SOLIRIS

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

ECULIZUMAB

Data management

Data sources

Data source(s)

Other data source

Data source(s), other

Disease registry, Subject medical records

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