Real-world Persistency, Effectiveness, and Safety Among Patients with NMOSD Treated with Inebilizumab (20250110)

First published: 08/04/2026

Last updated: 08/04/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000958

Study ID

1000000958

DARWIN EU® study

No

Study countries

☐ United States

Study status

Ongoing

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/04/2025

Actual: 22/04/2025

Study start date

Planned: 25/02/2026

Actual: 25/02/2026

Data analysis start date

Planned: 25/02/2026

Actual: 25/02/2026

Date of interim report, if expected

Planned: 20/03/2026

Date of final study report
Planned: 10/04/2026

Study protocol

Protocol-Published Original inebilizumab-cdon 20250110 .pdf (1.91 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

This is a descriptive longitudinal study of subjects diagnosed with NMOSD enrolled in the CorEvitas Synergy of Prospective Health & Experimental Research for Emerging Solutions (SPHERES) Registry from June 2, 2021 to December 31, 2025 or most recent data as of protocol approval date.

Main study objective:

The main objectives of this study are:

1. To estimate persistence of inebilizumab use among participants with NMOSD in the CorEvitas SPHERES Registry.
2. To estimate the time to first attack and annualized attack rate of NMOSD in participants while treated with inebilizumab.
3. To estimate the exposure adjusted incidence rate (EAIR) of adverse events (AEs) and adverse events of special interest (AESIs) and the event incidence rate (EIR) for AESIs in participants while treated with inebilizumab.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive longitudinal study

Study drug and medical condition

Medicinal product name, other

Inebilizumab

Population studied

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

69

Study design details

Outcomes

The primary outcomes of this study are:

1. Time from inebilizumab initiation to physician reported date of discontinuation of inebilizumab.

2. Time from inebilizumab initiation to first attack, total attacks, annualized attack rate.

3. For adverse events (AEs) and adverse events of special interest (AESIs), exposure-adjusted incidence rates (EAIRs) were computed as the number of patients with ≥1 event divided by the total person-years (PY) at risk, and event

incidence rates (EIRs) were calculated as the total number of events divided by total PY of exposure.

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.

Data sources

Data sources (types)

Disease registry

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