Administration of elranatamab in the real-world: Treatement patterns, healthcare resource utilization, costs, effectiveness, and safety (ALTITUDE)

First published: 10/09/2024

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Study | Finalised

Administrative details

EU PAS number

EUPAS1000000229

Study ID

1000000229

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

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Primary lead investigator

Marco DiBonaventura

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/02/2024

Actual: 27/02/2024

Study start date

Planned: 15/08/2024

Actual: 15/08/2024

Date of final study report

Planned: 28/02/2026

Actual: 04/09/2026

Study protocol

C1071039 Non Interventional Protocol Study Real-world usage of ELREXFIO (ALTITUDE) V1.0 31 July 2024_Redacted.pdf (1.13 MB)

C1071039_Real-world usage of ELREXFIO (ALTITUDE)_NI Study Protocol_V2.0_31July2025_Redacted.pdf (1.15 MB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Effectiveness study (incl. comparative)

Healthcare resource utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This retrospective descriptive cohort study will assess the demographic, clinical, treatment characteristics, HCRU, costs, effectiveness, and safety of MM patients with an elranatamab claim and will use de-identified data from Komodo Health.

Main study objective:

Primary

- Objective 1: Describe the demographics, clinical history, and treatment history of patients in the study
- Objective 2: Describe the administration and treatment management of elranatamab
- Objective 3: Describe all-cause and MM-related HCRU and costs by place of service of patients in the study

Exploratory

 Exploratory Objective 1: Describe the tolerability and real-world safety of elranatamab

 Exploratory Objective 2: Describe the effectiveness of elranatamab in terms of

TTNT/D and OS

 Exploratory Objective 3: In a separate cohort, replicate all objectives for patients with the same indication as elranatamab who initiated teclistamab

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELREXFIO

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

ELRANATAMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX32) elranatamab

elranatamab

Population studied

Short description of the study population

All individuals enrolled in Komodo Health with medical and pharmacy benefit coverage between 01 January 2016 and 25 October 2025.

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

56

Study design details

Setting

This study will evaluate adult patients with RRMM who initiate elranatamab. Patients will enter (ie.e., index) on the first observed elranatamab claim between 14 August 2023, and March 2024. Limited eligibility criteria will be applied.

Documents

Study report

C1071039_ALTITUDE_Study Report_V1.0_29Sept2026_Redacted.pdf (11.53 MB)

Data management

Data source(s), other

Komodo Health's Healthcare Map

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes