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

First published: 10/09/2024

Last updated: 06/02/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000229

EU PAS number

EUPAS1000000229

Study ID

1000000229

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Ivan Cordero

Study contact

ivan.cordero@pfizer.com

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

Date of final study report
Planned: 01/02/2026

Study protocol

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

Assessment of risk minimisation measure implementation or effectiveness

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 RRMM who initiated teclistamab

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ELREXFIO

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

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.

Data management

Data sources

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