

Real-world treatment patterns and clinical outcomes for patients with relapsed/refractory multiple myeloma who received elranatamab

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Study

Ongoing

Administrative details

EU PAS number

EUPAS1000000852

Study ID

1000000852

DARWIN EU® study

No

Study countries

United States

Study description

Elranatamab, a bispecific antibody that targets B-cell maturation antigen (BCMA), received accelerated approval by the U.S. Food and Drug Administration (FDA) in 2023 for the treatment of adult patients with relapsed/refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy. Although clinical trials provide critical efficacy and safety data, real-world evidence (RWE) is needed to understand treatment patterns, effectiveness, and safety outcomes in broader patient populations outside of controlled trial settings. This study aims to fill this evidence gap by comprehensively characterizing the treatment patterns, real-world overall response rate (rwORR), and adverse events (AEs) among RRMM patients treated with elranatamab.

This is a retrospective, observational cohort study using de-identified electronic health record (EHR)-derived data from the Flatiron Health Research database (FHRD). The study will evaluate real-world patient characteristics, treatment patterns, rwORR, and AEs among RRMM patients treated with elranatamab and in specific sub-populations of interest. The FHRD is a longitudinal database derived from EHRs from cancer care providers across the United States. Study population is US patients diagnosed with Multiple Myeloma (MM) on or after January 1, 2013, who received elranatamab treatment. Approximately 120 patients' data is expected to be included in the study.

Descriptive statistics will be used to summarize demographics, clinical characteristics, treatment patterns, incidence of AEs, and rwORR. For continuous variables, the descriptive statistics will include medians, interquartile range (IQR), means, standard deviations, and minimum and maximum values (as applicable). For categorical variables, frequencies and percentages will be generated. The number of patients with missing data will be reported for all variables. Levels of categorical variables may be combined to account for small sample sizes.

Study status

Ongoing

Contact details

Study institution contact

Chai Kim Chai.Kim@pfizer.com

Study contact

Chai.Kim@pfizer.com

Primary lead investigator

Chai Kim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/08/2025

Actual: 29/08/2025

Study start date

Planned: 30/01/2026

Actual: 07/01/2026

Date of final study report

Planned: 01/02/2027

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

Pfizer Protocol ID C1071050

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

Safety study (incl. comparative)

If 'other', further details on the scope of the study

Real-world evidence

Data collection methods:

Secondary use of data

Study design:

This is a retrospective, observational cohort study using de-identified electronic health record (EHR)-derived data from the Flatiron Health Research database (FHRD)

Main study objective:

This study aims to fill this evidence gap by comprehensively characterizing the treatment patterns, real-world overall response rate (rwORR), and adverse events (AEs) among RRMM patients treated with elranatamab.

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

Study population is US patients diagnosed with Multiple Myeloma (MM) on or after January 1, 2013, who received elranatamab treatment. Approximately 120 patients' data is expected to be included in the study.

Study design details

Data analysis plan

Descriptive statistics will be used to summarize demographics, clinical characteristics, treatment patterns, incidence of AEs, and rwORR. For continuous variables, the descriptive statistics will include medians, interquartile range (IQR), means, standard deviations, and minimum and maximum values (as applicable). For categorical variables, frequencies and percentages will be generated. The number of patients with missing data will be reported for all variables. Levels of categorical variables may be combined to account for small sample sizes.

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)

[Electronic healthcare records \(EHR\)](#)

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