Real-World (RW) Elranatamab Administration: Step Up Dosing (SUD), Treatment Patterns, and Healthcare Resource Utilization (HCRU) in Japan MDV Data (SUMMIT)

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Study | Ongoing

Administrative details

EU PAS number

EUPAS1000000503

Study ID

1000000503

DARWIN EU® study

No

Study countries

Japan

Study description

This retrospective cohort study will assess the demographics, clinical history, SUD process, HCRU, and safety of elranatamab in multiple myeloma (MM) patients with an elranatamab hospital claim.
De-identified data from the Japan Medical Data Vision (MDV) will be used.

A retrospective cohort design was chosen because it allows for efficient use of existing RW data to evaluate treatment patterns and outcomes in a newly approved therapy, without the need for prospective data collection. This design is well-suited for descriptive analyses and enables timely insights into the early use of elranatamab in a RW setting.

The primary endpoints include patient demographics, clinical characteristics, and treatment patterns. Secondary endpoints include HCRU and safety outcomes. No formal measures of effect will be calculated. All analysis will be descriptive, with no a priori hypotheses or statistical comparisons between exposure groups.

The study population will be comprised of individuals aged 18 and older who initiated elranatamab between March 26, 2024, the PMDA approval date for elranatamab, and the end of data availability. The study period will be from the start of data availability, April 2008, to the end of data availability in MDV. The study period will remain the same for all study objectives.
The patient baseline period will be from MM diagnosis to the start of the index treatment.
The patient index date will be determined as the date of first hospital claim with an administration of elranatamab. The follow-up period will be defined as the period between the index date and the end of the hospital claim of the last elranatamab administration inclusive.
The SUD period will be defined as the period between the date of the first

44mg/1.1mL vial and the first 76mg/1.9mL vial of elranatamab.

Study status

Ongoing

Research institutions and networks

Networks

STATLOG Inc. and Medical Data Vision (MDV)

Contact details

Study institution contact

Aster Meche aster.meche@pfizer.com

Study contact

aster.meche@pfizer.com

Primary lead investigator

Andreea Mafteuta

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/02/2025

Study start date
Planned: 15/07/2025

Actual: 07/07/2025

Date of final study report
Planned: 30/11/2026

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

C1071048_Non-Interventional Study Protocol_V1_25JUN2025_Redacted.pdf

(4.65 MB)

C1071048_Non-Interventional Study Protocol_V2.0_15SEP2025_Redacted.pdf

(584.25 KB)

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:

Disease /health condition

Human medicinal product

Study topic, other:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Other

If ‘other’, further details on the scope of the study

Treatment patterns with secondary collection of structured data

Data collection methods:

No individual level data collected for the purpose of the study

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Study design:

This is a retrospective observational study utilizing de-identified data from Japan Hospital administrative claims data (Medical Data Vision [MDV]).
The study population will include all adults aged 18 years or older with an MM diagnosis who initiate elranatamab on or after March 26, 2024.

Main study objective:

Research question and objectives:

Research question: What are the characteristics of adult patients with MM who

initiate elranatamab in Japan, and the SUD process, treatment patterns, HCRU, and safety associated with elranatamab administration?

The following objectives will be assessed among patients with MM receiving elranatamab:

Primary objectives:
Objective 1: To describe patients with MM initiating elranatamab, including demographics, treatment and medical history.
Objective 2: To describe and characterize elranatamab utilization, including timing, administration and dosing, during the follow-up period, including the step-up dosing (SUD) period.

Secondary objectives:
Objective 3: To describe HCRU and costs associated with elranatamab usage during the follow-up period, including the SUD period.
Objective 4: To describe the use of other treatments for MM including supportive therapy during the follow-up period.
Objective 5: To describe incidence and prevalence of cytokine release syndrome (CRS), immune effector cell associated neurotoxicity syndrome (ICANS), and cytopenias during the SUD period.
Objective 6: To describe infection incidence and prevalence during the follow-up period.

Exploratory objectives:
Exploratory Objective 1: To describe the use of supportive medications during the SUD
period and administration of IVIG within the 30-day post-index period.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective cohort study

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

The study population will comprise of individuals aged 18 and older who initiated elranatamab between March 26, 2024, the PMDA approval date for elranatamab, and the end of data availability.
All patients who meet the inclusion and exclusion criteria will be extracted from MDV and included in the study.

Inclusion criteria:

- First hospital health claim with an administration of elranatamab on or after March 26, 2024.
- Have a diagnosis of MM.
- Aged ≥18 years at the time of first hospital claim for elranatamab (i.e., index date).

Exclusion Criteria:
- Evidence of administration of elranatamab as part of a clinical trial.

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)

Study design details

Setting

The study population will be extracted from MDV, a comprehensive resource based on hospital claims data and Diagnosis Procedure Combination (DPC) data. Information on demographics, mortality, laboratory tests, IP, OP, and ED claims, treatments, procedures, and costs are available for approximately 50 million patients. Patients will be identified using the inclusion and exclusion criteria below:

Inclusion Criteria

Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:
First hospital health claim with an administration of elranatamab on or after March 26, 2024.
Have a diagnosis of MM.
Aged ≥18 years at the time of first hospital claim for elranatamab (i.e., index date).
Exclusion Criteria
Patients meeting any of the following criteria will not be included in the study.
Evidence of administration of elranatamab as part of a clinical trial.

The inclusion and exclusion criteria ensure the study captures patients with MM who initiate elranatamab treatment in RW setting after its approval date in Japan. The exclusion criterion removes patients treated within clinical trials to avoid bias from controlled study conditions and ensure generalizability to routine clinical practice. These criteria may limit the number of eligible patients, especially early in the elranatamab post-approval period.

Outcomes

Study endpoints include: elranatamab timing and dosing (i.e., types of doses, time between doses, relative administration intensity), HCRU and costs (i.e., IP/OP/ED claims and associated costs, degree of nursing), other MM treatment post elranatamab administration (i.e., PIs, SCT, supportive therapy), known adverse events (i.e., CRS events occurrence, frequency and associated length of stay, time from index to CRS event), infection (i.e., any infection occurrence, time from index to infection, antibiotics), and supportive medication (i.e., IVIG, acetaminophen, dexamethasone).

Data analysis plan

All analysis will be descriptive in nature and no formal statistical comparisons will be performed between groups. All characteristics and endpoints will be reported separately for each assessment period and patient stratification of interest.

Dichotomous and categorical variables will be summarized by the number and percentage of patients in each category. Continuous variables will be described using mean, standard deviation (SD), median, interquartile range (IQR), minimum, and maximum. If applicable, the frequency and percentage of patients with missing data for each variable will be described. For reporting conventions, mean, median, and SD will be rounded to 1 decimal place. Percentages will be rounded to 1 decimal place.

RAI will be calculated as the cumulative frequency of administration received over the expected number of administrations. Treatment exposure will be assessed across the different follow-up periods. Patients will be censored at last hospital claim for elranatamab.

All-cause HCRU will be measured as the total number IP, OP, and ED that occurred over the follow-up period. Health claims will only be counted once per day to estimate visits. Additionally, the total length of IP stays will be reported among patients with at least one IP visit.

PPPM standardizes HCRU by calculating the average of a specific variable or a number of specific events (e.g., ED health claims, IP health claims) per month for each patient. In this study, PPPM will be used to report ED, IP and OP visits for the follow-up period.

This calculation will allow meaningful comparisons across patients with varying

follow-up period lengths, by normalizing resource use to a monthly rate. Summary statistics (mean, median, min, max) will then be reported to understand average monthly utilization patterns across patients.

No sensitivity analysis will be conducted as a part of this analysis.

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 source(s), other

Japan Medical Data Vision (MDV)

Data sources (types)

Drug 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