An International, Multicenter, Non-interventional Post-Authorization Safety Study to Evaluate the Effectiveness and Safety of Elranatamab in Patients with Relapsed/Refractory Multiple Myeloma (RRMM) treated in Real-World Settings (MagnetisMM-16)

First published: 25/08/2023

Last updated: 15/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS106401

Study ID

106402

DARWIN EU® study

No

Study countries

- [ ] Brazil
- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

This prospective, international, longitudinal cohort study will evaluate the effectiveness and safety of elranatamab in routine clinical practice in patients 18 years and older. Approximately 198 patients will be recruited from primary care centers, hematology/oncology clinics, and academic centers in the Germany, the United Kingdom, Brazil, Spain and Italy. Each patient’s treatment will be consistent with routine practice, at the discretion of the treating physician and according to the local Health Authority approved product label. After Health Authority approval, multiple myeloma patients receiving at least one dose of elranatamab who satisfy the inclusion and exclusion criteria may be enrolled. Patients will be followed prospectively for up to 3 years after enrollment in the study or until withdrawal, physician discretion, loss to follow-up, death, or study termination, whichever occurs the earliest.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

iOMEDICO

Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Non-Pharmaceutical company

Contact details

Study institution contact

Rebecca Levin rebecca.levin@pfizer.com

Study contact

rebecca.levin@pfizer.com

Primary lead investigator

Rebecca Levin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/04/2023

Actual: 27/07/2023

Study start date

Planned: 01/11/2023

Actual: 09/07/2024

Data analysis start date

Planned: 30/08/2029

Date of final study report

Planned: 24/11/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C1071016_Protocol_Elranatamab NIS_V1.0_31Aug2023_FINAL_redacted.pdf (800.55 KB)

C1071016_Protocol_Elranatamab NIS_V2.0_04Jun2024_FINAL_Signed_Redacted.pdf (950.05 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:

Human medicinal product

Study topic, other:

Real World Safety and Effectiveness

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Study design:

This prospective, international, longitudinal cohort study will follow patients for up to 3 years or until withdrawal, physician discretion (i.e., patient health), loss to follow up, death, or study termination. Effectiveness outcomes and adverse events will be evaluated descriptively.

Main study objective:

To evaluate the effectiveness of elranatamab through the collection and analysis of the following clinical outcomes (defined according to the IMWG consensus criteria for response and minimal residual disease assessment in MM): Overall response rate (ORR), Time to response (TTR), Duration of response (DOR), Progression free survival (PFS), Overall survival (OS), Time to next treatment (TTNT).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELREXFIO

Medicinal product name, other

Elranatamab

Medical condition to be studied

Plasma cell myeloma refractory

Population studied

Short description of the study population

Male or female patients, age ≥18 years, with RRMM who are newly treated with elranatamab according to the local Health Authority approved product label (routine-care).

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

198

Study design details

Setting

Patients will be recruited from primary care centers, hematology/oncology clinics, and academic treatment centers to ensure broad physician and patient representation. Recruitment of sites will begin with invitations to hematologists/oncologists who are most likely to treat patients with RRMM and will continue until the target number of patients has been met or 2 years after the first patient is enrolled. Approximately 198 patients will be recruited from primary care centers, hematology/oncology clinics, and academic centers from Germany, the United Kingdom, Brazil, Italy and Spain. Study will aim to enroll patients with a diverse distribution of characteristics (e.g., race, ethnicity, sex) that is representative of the real-world patient population being treated with elranatamab in clinical practice. Thus, both urban/university hospitals and rural community centers are included in this study.

Outcomes

Effectiveness outcomes include ORR, TTR, DOR, PFS, and OS according to the IMWG consensus criteria for response in MM. TTNT will be defined as the time from elranatamab initiation to next treatment. Safety event will be collected, reported and summarized by the enrolling physician or other treatment team member for up to 90 days after the last dose of elranatamab.

Data analysis plan

The characteristics captured during baseline and follow up will be summarized using descriptive statistics. Frequencies and percentages will be used for categorical variables and mean (standard deviation STD) and median (interquartile range IQR) will be used for continuous variables. For the effectiveness outcomes of interest, ORR will be summarized using frequencies and percentages and time-to-event outcomes (DOR, TTR, PFS, OS, TTNT) will be evaluated using Kaplan-Meier (KM) methods. KM curves will be illustrated and the median survival and corresponding 95% confidence interval (95% CI) will be computed. To evaluate the safety of elranatamab, AEs and SAEs will be

collected on a structured data collection tool Adverse Event Monitoring (AEM) form and will be characterized by type, grade, timing, seriousness, and relationship to elranatamab. Crude cumulative incidence will be calculated as appropriate.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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