

A french AMBispective, multisite, non-interventional Real-life effectiveness and safety of ELranatanab for the treatment of patients with relapse or refractory multiple myeloma (RRMM) - (AMbreLA)

First published: 12/04/2024

Last updated: 12/04/2024

Study

Planned

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1000000074>

EU PAS number

EUPAS1000000074

Study ID

1000000074

DARWIN EU® study

No

Study countries

France

Study description

Non-interventional study conducted in France, an ambispective study based on the inclusion of patient under elranatamb Pfizer product received thanks to an early access program also conducted in France (not compassionate).

Long-term, non-interventional studies (NIS) that reflect routine care are desirable to continue monitoring the effectiveness and safety of elranatamab after product approval. The existing evidence has been generated from interventional studies, however, the participants enrolled in such interventional studies may not be representative of the real-life population of patients who will receive elranatamab treatment in routine care.

Therefore, this NIS aims to evaluate the effectiveness and safety of elranatamab in real-life clinical settings.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Networks

Cleanweb

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Aurore PERROT

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/04/2024

Study start date

Planned: 30/04/2024

Date of interim report, if expected

Planned: 30/04/2026

Date of final study report

Planned: 31/03/2028

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 type:

Non-interventional study

Scope of the study:

Other

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

Effectiveness only for elranatamab in routine care

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This ambispective, French, longitudinal cohort study will evaluate the effectiveness and safety of elranatamab in routine clinical practice in patients 18 years and older who have initiated elranatamab as part of the setting of the French early access program.

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 disease assessment in MM).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ELREXFIO

Name of medicine, other

elranatamab

Additional medical condition(s)

Relapsed or Refractory Multiple Myeloma (RRMM)

Population studied

Short description of the study population

The study will retrospectively and prospectively enroll patients with RRMM who receive elranatamab according to the early access approved product label (routine-care).

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

200

Study design details

Setting

INCLUSION CRITERIA

The study will retrospectively and prospectively enroll patients with RRMM who receive elranatamab according to the early access approved product label

(routine-care).

Patients must meet the following criteria to be eligible for inclusion in the study:

- 1) Male or female patient age ≥ 18 years
- 2) Patient with a diagnosis of RRMM, as defined according to IMWG criteria
- 3) Patient included in who has initiated treatment with ELRANATAMAB only during elranatamab early access program
- 4) For a patient alive at the moment of the inclusion in the study: eEvidence of a personally signed and dated informed consent document indicating that the patient (or a legally acceptable representative) has been informed of all pertinent aspects of the study.
- 5) For a patient who died before the inclusion in the study: the patient (during his lifetime) must not be opposed in writing to the collection of his data
- 6) Patient benefiting from a social security scheme according to local regulations.

NON-INCLUSION CRITERIA

Patients meeting any of the following criteria will not be included in the study:

- 1) For a patient alive at the moment of the inclusion in the study: patient without liberty, under tutelage, or unable to give oral consent.
- 2) Patient who received elranatamab in an interventional clinical study or through the compassionate use program.

Comparators

None

Outcomes

The outcomes of interest will be effectiveness (i.e., ORR, TTR, DOR, PFS, OS, TTNT), safety and PRO (patient-reported outcomes), only for prospectively enrolled patients, i.e. QOL questionnaires.

Data analysis plan

Descriptive analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the sample studied.

Effectiveness and safety will be assessed on a Full Analysis Set (FAS) and a Safety Analysis Set (SAF), respectively.

ORR will be reported with a 95% CI using the Clopper-Pearson method. Time-to-event outcomes (death and disease progression) will be assessed using Kaplan-Meier (KM) analyses.

Summary results

In the event of any prohibition or restriction imposed (e.g., clinical hold) by an applicable competent authority in any area of the world, or if the investigator is aware of any new information which might influence the evaluation of the benefits and risks of a Pfizer product, Pfizer should be informed immediately. In addition, the investigator will inform Pfizer immediately of any urgent safety measures taken by the investigator to protect the study patients against any immediate hazard, and of any serious breaches of this NI study protocol that the investigator becomes aware of.

Data management

Data sources

Data source(s), other

Cleanweb

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

Unknown