# 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 compassional).

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

Institution

## Networks

Cleanweb

## Contact details

**Study institution contact**

Delphine BERZIN

Study contact

delphine.berzin@pfizer.com

**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