BLENREP Effectiveness and Safety in Multiple Myeloma (BEaMM) – Real-World Evidence on Patients Taking Belantamab Mafodotin in Europe (217240)

First published: 10/05/2022

Last updated: 12/03/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS44701

Study ID

49148

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Germany

Greece

Italy

Norway

Spain

Study description

This multinational, multisite, non-interventional study aims to collect real-world data on the use, safety and effectiveness of belantamab mafodotin in RRMM patients from Europe.

Background data at the time of the first dose of belantamab mafodotin (i.e., demographics, disease status, clinical characteristics and treatment history) will be collected to characterize RRMM patients treated with belantamab mafodotin per routine clinical care.

In addition, data will be collected on the occurrence, duration and management of ocular AESIs, the frequency and timing of ophthalmic examinations, persistence and adherence with belantamab mafodotin, treatment discontinuations, interruptions/delays and decreased dosing, and effectiveness in terms of treatment response and survival.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/05/2021

Actual: 10/05/2021

Study start date

Planned: 05/09/2022

Actual: 05/09/2022

Data analysis start date

Planned: 01/03/2022

Date of final study report

Planned: 20/12/2024

Actual: 20/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-217240-protocol-amend1-redact.pdf (1.19 MB)

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Other

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

Ocular safety, Patient characterization (demographic, clinical, treatment history)

Main study objective:

The purpose of this study is to collect real-world data on the use, safety and effectiveness of belantamab mafodotin in RRMM patients in Europe.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BLENREP

Study drug International non-proprietary name (INN) or common name

BELANTAMAB MAFODOTIN

Medical condition to be studied

Plasma cell myeloma

Population studied

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

150

Study design details

Outcomes

Characterize RRMM patients treated with belantamab mafodotin per routine clinical care in terms of demographics, disease status, clinical characteristics and treatment history (overall and by line of treatment), Characterize patients with ocular AESI by belantamab mafodotin treatment, ophthalmic disease history & ocular AESI type, duration & severity (overall and by line of treatment), Describe frequency & timing of ophthalmic monitoring visits relative to belantamab mafodotin administration (for each cycle, overall & by line of treatment occurrence of ocular AESI as well as treatment dose & frequency).

Data analysis plan

Analysis populations:

Two analysis populations will be defined:

• Enrolled Population (EP)

- All patients for whom written informed consent has been obtained,

• Safety Population (SP)

- All patients in EP who received at least one dose of belantamab mafodotin.

The SP will be used for descriptive, safety & effectiveness analyses.

Data analysis:

The following measures will be reported:

• Exposure-adjusted incidence & event rates with 95% confidence intervals of ocular AESIs (i.e. at patient level & event level): overall & by SOC & PT terms (MedDRA classification).

• Median, 95% confidence intervals (CIs) and 25th & 75th percentiles using Kaplan-Meier (KM) method for time to event outcomes (i.e. OS, rwPFS, DoR, time to discontinuation, time to first specific ocular AESI)

• OS rates with 95% CIs at specified time points, including 12- & 15-months of follow-up

• Overall response rate (ORR) with 95% CIs calculated based on exact binomial distribution (Clopper-Pearson method).

Documents

Study report

Clinical Study Report Anonymised 03 Feb 2025.pdf (1.4 MB)

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)

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