Periodic Knowledge, Attitudes, and Behavior (KAB) Survey of Patients and/or Caregivers to Assess Understanding of the Risks with the BKEMV™ Risk Evaluation and Mitigation Strategy (REMS) (20240214)

First published: 03/02/2025

Last updated: 03/02/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000368

EU PAS number

EUPAS1000000368

Study ID

1000000368

DARWIN EU® study

No

Study countries

United States

Study description

The proposed study is a Risk Evaluation and Mitigation Strategy (REMS) post-marketing safety program that will be monitored by the FDA to ensure the drug (ABP 959 – BKEMV) benefits outweigh its risks.

The study will survey patients who are at least 18 years of age and caregivers of patients of all ages who have been dispensed at least 1 dose of BKEMV to assess their knowledge and understanding of the risk of severe meningococcal infections with BKEMV, the BKEMV REM requirements, and the REMS goals and materials.

Study status

Planned

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/11/2024

Actual: 07/08/2023

Study start date

Planned: 03/09/2025

Data analysis start date

Planned: 30/03/2026

Date of interim report, if expected
Planned: 28/05/2027

Date of final study report
Planned: 28/05/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This is a study funded by Amgen.

Study protocol

Protocol-Published Original eculizumab biosimilar 20240214 .pdf(2.47 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

20240214

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

US-based, observational, cross-sectional survey of patients who are at least 18 years of age and caregivers of patients of all ages who have been dispensed at least 1 dose of BKEMV.

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

This US-based, observational, cross-sectional survey involves patients and caregivers who received at least one dose of BKEMV. It is self-administered via secure internet/telephone using the validated United BioSource LLC (UBC)

Pathways® Knowledge Survey System.

Main study objective:
The primary objectives of the study are:

To describe patient and/or caregiver knowledge of:
• Key Message Domain 1: Patients should understand that receiving treatment with BKEMV increases the chance of getting serious meningococcal infections, which may quickly become life-threatening and cause death if not recognized and treated early.
• Key Message Domain 2: Patients should understand the need to be vaccinated against meningococcal infection and receive antibacterial drug prophylaxis if needed.
• Key Message Domain 3: Patients should be able to recognize the signs and symptoms of meningococcal infection and the need for immediate medical evaluation.

Study Design

Non-interventional study design
Cross-sectional

Study drug and medical condition

Name of medicine, other
Eculizumab-aeeb (BKEMV)

Medical condition to be studied
Paroxysmal nocturnal haemoglobinuria

Atypical haemolytic uraemic syndrome

Myasthenia gravis

Population studied

Short description of the study population

The study will include patients who are at least 18 years of age and caregivers of patients of all ages who have been dispensed at least 1 dose of BKEMV.

Age groups

Adult and elderly population (≥18 years)

Estimated number of subjects

153

Study design details

Setting

Online survey

Comparators

N/A

Outcomes

The primary endpoint of the study is:

• The number of respondents who score 80% or greater in each key message domain

Data analysis plan

Statistical analyses will be descriptive in nature. Counts and percentages will be calculated for each question/item in the questionnaire. 95% confidence intervals (CIs) for the survey end points will be calculated to provide an estimate of precision; however no formal hypothesis will be tested.
All CIs around the percentages will be exact binomial 2-sided 95% CIs calculated according to the method of Clopper-Pearson. Analyses will be performed at the respondent level; therefore, within-respondent variation is not relevant.

Data management

Data sources

Data source(s), other

We are conducting primary data collection, therefore we are not using any of these data sources.

Data sources (types)

Other

Data sources (types), other

We are conducting primary data collection, therefore we are not using any of these data sources.

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

Not applicable