Periodic Knowledge, Attitudes, and Behavior (KAB) Survey of Certified Prescribers to Assess Understanding of the Risks with the BKEMV™ Risk Evaluation and Mitigation Strategy (REMS) (20240216)

First published: 04/04/2025

Last updated: 04/04/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000367

EU PAS number

EUPAS1000000367

Study ID

1000000367

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 healthcare providers (HCP) who are currently prescribing and those who have potential to prescribe BKEMV, who are part of the REMS Communication Plan Outreach, and who have not been debarred or sanctioned in order 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

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Networks

United BioSource Corporation (UBC)

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Annette Konikiewicz

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/08/2023

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 study is funded by Amgen.

Study protocol

Redacted Protocol-Published Original eculizumab biosimilar 20240216.pdf(2.21 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

20240216

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

US-based, observational, cross-sectional survey of HCPs who are currently prescribing or with potential to prescribe BKEMV.

Study type:

Non-interventional study

Study design:

This US-based, observational, cross-sectional survey involves healthcare providers (HCPs) certified in BKEMV REMS and not debarred or sanctioned.
It is self-administered via internet/telephone using a validated United BioSource LLC (UBC) Pathways® Knowledge Survey System for data collection.

Main study objective:

HCPs must understand the increased risk of meningococcal infections with BKEMV use, the need for vaccination against Neisseria meningitidis serogroups A, C, W, Y, and B per ACIP guidelines, and the importance of counseling patients on signs and symptoms using the Patient Safety Card and Guide.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

SOLIRIS

Name of medicine, other

BKEMV (eculizumab-aeeb)

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

ECULIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AJ01) eculizumab

eculizumab

Additional medical condition(s)

PNH, atypical hemolytic uremic syndrome (aHUS) and myasthenia gravis

Population studied

Short description of the study population

The survey will target BKEMV REMS-certified prescribers identified via the BKEMV REMS-database and who have not been debarred or sanctioned.

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

83

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

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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 databases.

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