241302: POST-MARKETING non-interventional safety evaluation of obizur in the treatment of bleeding episodes for patients with acquired hemophilia A (241302: US Post-Marketing Safety Study)

First published: 17/08/2020

Last updated: 02/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS36659

Study ID

43028

DARWIN EU® study

No

Study countries

United States

Study description

The overall objective is to enroll patients with acquired hemophilia A (AHA) who are prescribed and treated with Obizur, to assess safety, and to describe factors related to safety, utilization and effectiveness in a real-world setting.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

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Institution

Multiple centres: 18 centres are involved in the study

Contact details

Study institution contact

Call Center Shire clinicaltransparency@shire.com

Study contact

clinicaltransparency@shire.com

Primary lead investigator

Call Center Shire

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 29/10/2015

Study start date
Actual: 30/12/2015

Data analysis start date
Actual: 07/06/2019

Date of final study report
Actual: 22/06/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Baxalta Innovations GmbH, now part of Takeda and Baxalta US Inc.

Study protocol

241302-protocol-original-redact.pdf (831.52 KB)

241302-protocol-amendment-3-redact.pdf (882.4 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

NCT02610127,https://clinicaltrials.gov/ct2/show/NCT02610127?term=NCT02610127&draw

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to determine the incidence of therapy-related serious adverse events (SAEs) in patients with AHA who are prescribed and treated with Obizur in routine clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective and retrospective post-marketing safety surveillance study

Study drug and medical condition

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

ANTIHEMOPHILIC FACTOR (RECOMBINANT) FORMULATED WITH SUCROSE

Medical condition to be studied

Acquired haemophilia

Population studied

Short description of the study population

Patients with acquired hemophilia A (AHA) were eligible for participation in this study if they were treated with Obizur in a hospital setting. All patients were required to be prescribed Obizur by a physician, prior to the decision to enroll in the study.

Inclusion Criteria

Subjects who meet ALL of the following criteria are eligible for this study:

1. Subject is ≥18 years of age at the time of informed consent.
2. Subject has AHA, and is being treated/was treated with Obizur.
3. Subject or subject’s legally authorized representitive is willing and able to provide informed consent, unless informed consent is not required (e.g., deceased subjects, as local regulations allow).

Exclusion Criteria

Subjects who meet ANY of the following criteria are not eligible for this study:

1. Subject has a known anaphylactic reaction to the active substance, to any of the excipients, or to hamster protein.
2. Subject has a concomitant bleeding disorder(s) other than AHA.
3. Subject has participated in another clinical study involving a medicinal

product or device within 30 days prior to enrollment or is scheduled to participate in another clinical study involving a medicinal product or device during the course of the study.

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)

Special population of interest

Other

Special population of interest, other

Acquired hemophilia A patients

Estimated number of subjects

53

Study design details

Outcomes

Incidence of therapy-related Serious Adverse Events (SAEs), Hemostatic effectiveness assessment for resolution of bleeding, Time to bleeding resolution, participant study termination, or switch to another treatment, Number of Obizur units/kg and infusions required for control of bleeding, Titer of anti-pFVIII inhibitors, Impact of inhibitor on hemostatic efficacy, Occurrence of hypersensitivity reactions, Occurrence of any thrombogenic event

Data analysis plan

SAEs will be described in listings and tables, and incidence rates will be calculated. Tables outlining the hemostatic effectiveness and immunogenicity of Obizur, frequency, total dose, and total number of infusions of Obizur required to control bleeding episodes will be developed.

Documents

Study results

241302-clinical-study-report-redact.pdf (687.88 KB)

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)

Other

Data sources (types), other

Patient medical charts

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