Eptacog Beta post marketing safety surveillance using the PedNet registry (F7TG2207 – PedNet Registry)

First published: 12/07/2023

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS105707

Study ID

105708

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ France
- ☐ Germany
- ☐ Italy

Netherlands

Spain

United Kingdom

Study description

This Post Marketing Surveillance study is based on observational data collection from the Pediatric Network Hemophilia Registry (PedNet) cohort. PedNet (Pediatric Network on haemophilia management) is a collaborative platform for (pediatric) physicians treating children with haemophilia. The PedNet Haemophilia Registry is a database containing observational data of children with haemophilia A and B. PedNet will transmitt to the sponsor, LFB Biotechnologies, annuals reports of adverse events.

Study status

Ongoing

Research institutions and networks

Institutions

PedNet Haemophilia Research Foundation

Netherlands

First published: 01/02/2024

Last updated: 01/02/2024

Institution **Not-for-profit**

1 site Belgium, 3 sites France, 2 sites Germany, 1 site Italy, 3 sites Spain, 4 sites UK, 2 sites Netherlands

Contact details

Study institution contact

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Study contact

barthez@lfb.fr

Primary lead investigator

Emmanuelle LAGRUE

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/03/2023

Study start date

Actual: 01/01/2023

Date of final study report

Planned: 30/06/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

LFB Biotechnologies

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)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective will be to determine the number and incidence of important potential risks defined as: - Hypersensitivity reactions (including

anaphylactic reactions) - Thromboembolic events (including those due to drug-drug interactions with activated or nonactivated prothrombin complex or other haemostatic agents) - Immunogenicity - Death

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post marketing safety study based on PedNed Registry

Study drug and medical condition

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

EPTACOG BETA (ACTIVATED)

Medical condition to be studied

Factor VIII deficiency

Factor IX deficiency

Additional medical condition(s)

with inhibitors

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

15

Study design details

Outcomes

- Number of allergic reactions, thromboembolic events, and unexpected poor efficacy secondary to immunogenicity - Incidence of allergic reactions, thromboembolic events, and unexpected poor efficacy secondary to immunogenicity - Incidence of antidrug antibodies

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Data analysis plan

Data management is under the responsibility of the PedNet Registry according to the current version of the PedNet Protocol. Data are collected by centres in the PedNet registry and monitored to improve data quality. The study duration will be 5 years with a detailed annual report provided by the PedNet registry after each full year of surveillance. The number and incidence of subjects with Treatment-emergent AEs (TEAEs), specifically allergic, thromboembolic events and unexpected poor efficacy secondary to immunogenicity will be assessed and presented in a final report.

Data management

Data sources

Data source(s)

PedNet Haemophilia registry

Data sources (types)

Other

Data sources (types), other

Case-control surveillance database

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