Long Term Post Marketing Drug Use Result Survey for Blinatumomab in Japan (20180238) (Blinatumomab Long Term PMS Japan)

First published: 09/05/2019

Last updated: 12/12/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33033

EU PAS number

EUPAS29685

Study ID

33033

DARWIN EU® study

No

Study countries

Japan

Study description

To investigate the incidence of CTCAE grade ≥ 3 events of each safety specification of the Japan Risk Management Plan (neurologic events, infections, cytokine release syndrome, tumor lysis syndrome, myelosuppression and Pancreatitis) in patients receiving long term administration of blinatumomab

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

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: 27/11/2018

Actual: 18/12/2018

Study start date

Planned: 20/12/2019

Actual: 08/01/2020

Data analysis start date

Planned: 30/09/2024

Actual: 30/09/2024

Date of final study report

Planned: 31/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen Inc.

Study protocol

Protocol-Published Original blinatumomab 20180238 .pdf(1.03 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

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To investigate the incidence of CTCAE grade ≥ 3 events of each safety specification of the Japan Risk Management Plan (neurologic events, infections, cytokine release syndrome, tumor lysis syndrome, myelosuppression and Pancreatitis) in patients receiving long term administration of blinatumomab

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BLINCYTO

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

BLINATUMOMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX07) blinatumomab

blinatumomab

Medical condition to be studied

B precursor type acute leukaemia

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)

Estimated number of subjects

40

Study design details

Outcomes

The incidence of CTCAE grade ≥ 3 events of each safety specification

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Data analysis plan

The number of patients and the incidence rates of CTCAE grade ≥ 3 events are tabulated for each safety specifications and other adverse drug reactions during the survey.

Data management

Data sources

Data sources (types)

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