All Case Post Marketing Drug Use Result Survey for Blinatumomab in Japan (20170655) (Blinatumomab All Case PMS Japan)

First published: 28/11/2018

Last updated: 20/09/2023

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28461

EU PAS number

EUPAS26530

Study ID

28461

DARWIN EU® study

No

Study countries

Japan

Study description

To assess the risk factors of neurologic events, the treatment for Cytokine release syndrome (CRS) and the incidence of each safety concerns in the patients with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL) for treatment of blinatumomab in a real world medical practice in Japan, with particular focus on the safety specifications as described in Japanese Risk Management Plan, Neurologic events, CRS, Infections and Pancreatitis as important identified risks.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 250 centres are involved in the study

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: 19/12/2018

Study start date

Planned: 22/02/2019

Actual: 19/02/2019

Data analysis start date

Planned: 30/09/2023

Actual: 07/09/2022

Date of final study report
Planned: 31/03/2024

Actual: 19/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Study_20170655_Blinatumomab_Japan_PMS_Protocol_Amgen Format_ver1.0.pdf
(647.7 KB)

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To explore the risk factors of neurologic events, and evaluate the treatments taken against CRS and the incidence of each safety specification

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective observational study

Study drug and medical condition

Name of medicine

BLINCYTO

Medical condition to be studied

B precursor type acute leukaemia

Population studied

Short description of the study population

The study population included patients with relapsed or refractory B-cell acute lymphoblastic leukemia (ALL) received treatment with blinatumomab in a real world medical practice in Japan.

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

Other

Special population of interest, other

Patients with relapsed or refractory B-cell acute lymphoblastic leukemia

Estimated number of subjects

390

Study design details

Outcomes

Risk factors of neurologic events, treatments taken against CRS, incidence of each safety specification

Data analysis plan

The odds ratio and 95% confidence interval of high-risk population for low risk population in neurological events are calculated. Also, the treatment for CRS are tabulated. The number of patients and the incidence rates are tabulated for each safety specifications and all adverse drug reactions during the survey.

Documents

Study results

20170655 ORSR Abstract_Redacted.pdf(127.45 KB)

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