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: 30/10/2025





Administrative details

Study description

EU PAS number	
EUPAS29685	
Study ID	
33033	
DARWIN EU® study	
No	
Study countries	
Japan	

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

Finalised

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. medinfo@amgen.com

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: 23/01/2025

Date of final study report

Planned: 23/01/2026 Actual: 15/08/2025

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)

blinatumomab_20180238_abstract ORSR_Redacted.pdf (51.52 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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

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

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 \geq 3 events of each safety specification

Data analysis plan

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

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)

Non-interventional study

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