

# 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>

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### EU PAS number

EUPAS29685

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### Study ID

33033

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### DARWIN EU® study

No

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## Study countries

Japan

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## Study description

To investigate the incidence of CTCAE grade  $\geq 3$  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

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## 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](mailto: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

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### Study start date

Planned: 20/12/2019

Actual: 08/01/2020

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### Data analysis start date

Planned: 30/09/2024

Actual: 30/09/2024

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### 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

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### **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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

To investigate the incidence of CTCAE grade  $\geq 3$  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

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

BLINATUMOMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L01FX07) blinatumomab

blinatumomab

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**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)

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## **Estimated number of subjects**

40

# Study design details

## **Outcomes**

The incidence of CTCAE grade  $\geq 3$  events of each safety specification

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## **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

## Data sources

## **Data sources (types)**

Other

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No