# 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





# Administrative details

**Study description** 

EU PAS number	
EUPAS26530	
Study ID	
28461	
DARWIN FIL® study	
DARWIN EU® study	
No	
Study countries	
Japan	

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. 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: 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

### 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

#### **Medicinal product name**

**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)</li>
- Adults (75 to < 85 years)</li>
- 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

# **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)**

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