

# An observational study describing the effectiveness and safety of BLINCYTO® in Chinese adults with Philadelphia chromosome-positive relapsed or refractory B-cell precursor Acute Lymphoblastic Leukemia (Ph+ R/R B-cell precursor ALL) (20210061)

**First published:** 05/01/2024

**Last updated:** 14/07/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS107858

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### Study ID

107859

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### DARWIN EU® study

No

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## Study countries

 China

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Amgen

 United States

**First published:** 01/02/2024

**Last updated:** 27/03/2026

Institution

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

Global Development Leader Amgen Inc.

## Study timelines

### **Date when funding contract was signed**

Actual: 12/12/2022

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### **Study start date**

Planned: 06/02/2024

Actual: 20/02/2024

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### **Data analysis start date**

Planned: 24/10/2024

Actual: 24/10/2024

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### **Date of interim report, if expected**

Planned: 01/11/2024

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### **Date of final study report**

Planned: 18/03/2025

Actual: 20/03/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

# Study protocol

[Protocol-Published Original blinatumomab 20210061 .pdf](#) (784.85 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## 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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##### **Main study objective:**

The main objective of the study is to estimate the percentage of patients with complete remission/complete remission with partial hematological recovery (CR/CRh) within two cycles of treatment with BLINCYTO® in Chinese adults with

Ph+ R/R B-cell precursor ALL, and to estimate the incidence of adverse events of interest (EOI).

## Study Design

### **Non-interventional study design**

Other

## Study drug and medical condition

### **Medicinal product name**

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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### **Additional medical condition(s)**

Philadelphia chromosome-positive relapsed or refractory B-cell precursor Acute Lymphoblastic Leukemia (Ph+ R/R B-cell precursor ALL)

## Population studied

### **Age groups**

- 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**

30

## Study design details

### **Outcomes**

- To estimate the percentage of patients with CR/CRh within two cycles of treatment with BLINCYTO in Chinese adults with Ph+ R/R B-cell precursor ALL
  - To estimate the incidence of adverse EOI (recorded within 6 months of first infusion of BLINCYTO),
  - To describe the treatment patterns of BLINCYTO and tyrosine kinase inhibitors in clinical practice
  - To estimate the occurrence of allogeneic haemopoietic stem cell transplant after BLINCYTO treatment
  - To estimate the percentage of patients achieving minimal residual disease negative status after CR/CRh
  - To estimate relapse-free survival at 6 months To estimate overall survival at 6 months
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### **Data analysis plan**

Analyses will be descriptive in nature. Demographic and patient characteristics will be summarized by descriptive statistics.

Continuous variables will be summarized by n, mean, standard deviation,

median, Q1 (25th percentile), Q3 (75th percentile), and ranges.

Categorical variables will be summarized by counts and percentages for each category. Proportion and 95% CIs will be reported for patients with CR/CRh, MRD negative status, and alloHSCT.

For time-to-event outcomes, the Kaplan-Meier (K-M) method will be used to estimate the 6-month OS probability, including survival rates at selected timepoints (eg, 3-or 6-month, 12-month).

## Documents

### Study results

[20210061\\_ORSR\\_abstract\\_Redacted \(1\).pdf](#) (1.38 MB)

[20210061 ORSR abstract V2.0\\_Redacted.pdf](#) (1.9 MB)

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## 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)

[Electronic healthcare records \(EHR\)](#)

## 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