

# Expanded access of Blincyto® in patients with acute lymphoblastic leukaemia: a retrospective observational study (Neuf Study) (20160441)

**First published:** 15/08/2017

**Last updated:** 05/06/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/50762>

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### **EU PAS number**

EUPAS19961

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### **Study ID**

50762

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### **DARWIN EU® study**

No

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### Study countries

- France
  - Italy
  - Spain
  - United Kingdom
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### Study description

The primary objective is to describe the clinical characteristics and treatment patterns of patients with B precursor acute lymphoblastic leukemia, having received Blincyto® in the expanded access setting and identify clinically relevant subgroups

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### Amgen

- United States

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

**Last updated:** 21/02/2024

**Institution**

Multiple centres: 55 centres are involved in the study

## 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: 09/06/2017

Actual: 07/09/2017

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### Study start date

Planned: 15/01/2018

Actual: 11/01/2018

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### Data analysis start date

Planned: 28/08/2018

Actual: 04/12/2018

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

Planned: 30/09/2020

Actual: 14/12/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20160441 Summary Protocol V1.0.pdf](#)(80.76 KB)

[EUPAS19961-23311.pdf](#)(175.25 KB)

## Regulatory

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

No

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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:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation  
Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective is to describe the clinical characteristics and treatment patterns of patients with B precursor acute lymphoblastic leukemia, having received Blincyto in the expanded access setting and identify clinically relevant subgroups

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective, observational, multi-centre study

## Study drug and medical condition

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

BLINATUMOMAB

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### **Medical condition to be studied**

B precursor type acute leukaemia

## **Population studied**

### **Short description of the study population**

The study population involved patients with B-precursor acute lymphoblastic leukemia (ALL) treated with Blincyto reported from five countries: France, Italy, Spain, UK and Russia identified from the 1st January 2014 up until 30th June 2017.

Inclusion criteria:

- B-precursor ALL patients who have initiated Blincyto in an expanded access setting from 1st January 2014 up until 30th June 2017.

Exclusion:

- Patients enrolled in Amgen expanded access protocol 20130320.
  - Patients who do not provide informed consent, where required per country regulations.
  - Patient's medical chart is not available for data extraction.
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### **Age groups**

Paediatric Population (< 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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### **Special population of interest**

Other

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### **Special population of interest, other**

Acute lymphoblastic leukemia patients

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### **Estimated number of subjects**

350

## Study design details

### **Outcomes**

To describe the clinical characteristics and treatment patterns of patients with B precursor ALL, having received Blincyto in the expanded access setting and identify clinically relevant subgroups, To describe the effectiveness of Blincyto within identified subgroups as outlined in Section 9.6.2.5 of the protocol To describe Blincyto utilization within identified subgroups as outlined in Section 9.6.2.5 of the protocol

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### **Data analysis plan**

All analyses will be descriptive. Continuous variables will be summarized by mean, median, standard deviation, lower and upper quartiles, and minimum and maximum values. Categorical variables will be summarized by number and percentage of patients in each category. For categorical outcomes, 95% confidence intervals (CIs) will also be presented where appropriate. For time-to-event endpoints, Kaplan-Meier (KM) curves and KM proportions at select time points, the number of subjects with events and the number of subjects censored will be used to summarise the data. Analyses will be presented by the identified

clinically relevant subgroups (listed in Section 9.7.2.5 of the protocol and identified by means of the primary endpoints), country and year of Blincyto initiation.

## Documents

### Study results

[01.47.01.02 Observational Research Study Report Redacted.pdf](#)(226.53 KB)

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## Data management

### Data sources

#### Data sources (types)

[Other](#)

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#### Data sources (types), other

Medical records

### 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