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: 02/04/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107859

EU PAS number

EUPAS107858

Study ID

107859

DARWIN EU® study

No

Study countries

China

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.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 12/12/2022

Study start date
Planned: 06/02/2024

Actual: 20/02/2024

Data analysis start date
Planned: 24/10/2024

Actual: 24/10/2024

Date of interim report, if expected
Planned: 01/11/2024

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

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

Name of medicine

BLINCYTO

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

BLINATUMOMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX07) blinatumomab

blinatumomab

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)

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)

Data management

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No