Long-term Follow-up of Adult Philadelphia Chromosome-negative Acute Lymphoblastic Leukemia Relapsed Refractory Patients Enrolled in Study 00103311 (TOWER Follow-up Study)

First published: 18/04/2019

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS27382

Study ID

39068

DARWIN EU® study

No

Study countries

Australia

Austria

- Belgium
- Bulgaria
- Canada
- France
- Germany
- Greece
- Ireland
- Israel
- Italy
- Korea, Republic of
- Mexico
- Poland
- Russian Federation
- Spain
- Taiwan
- Türkiye
- United Kingdom
- United States

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

Multiple centres: 65 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: 31/01/2019

Actual: 31/01/2019

Study start date
Planned: 06/12/2019

Actual: 02/12/2019

Data analysis start date
Planned: 25/09/2020

Actual: 07/09/2020

Date of final study report
Planned: 30/12/2020

Actual: 07/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20180138_01.02.06 Public Redacted Protocol Ver 1.0 2019-01-25 English.pdf

(175.13 KB)

20180138_01.02.06 Public Redacted Protocol Ver 1.0 2019-08-29 English.pdf

(1.96 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The objective of this study is to update the overall survival (OS) Kaplan-Meier probability estimates and the plot last reported in the randomized Phase 3

blinatumomab 00103311 study.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

One-time follow-up on patients that were alive and still participating in the Phase III Study 00103311 at the end of the 00103311 study results being reported.

Study drug and medical condition

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

BLINATUMOMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX07) blinatumomab

blinatumomab

Medical condition to be studied

Acute lymphocytic leukaemia

Population studied

Short description of the study population

The population in this study will be the patients who were enrolled originally in the 00103311 trial (A Phase 3, Randomized, Open Label Study Investigating the Efficacy of the BiTE Antibody Blinatumomab Versus Standard of Care Chemotherapy in Adult Subjects With Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (ALL) (TOWER Study)). This study (20180138) will be a one-time follow-up on patients that were alive and still participating in the Phase III Study 00103311 at the end of the 00103311 study results being reported.

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)

Special population of interest

Other

Special population of interest, other

Acute lymphocytic leukaemia patients

Estimated number of subjects

108

Study design details

Outcomes

Overall survival

Data analysis plan

The endpoint in this study is overall survival. Overall survival is defined as time from randomization of blinatumomab or investigator choice chemotherapy (the two treatment arms in the 00103311 trial) until the event of death or censoring at end of follow-up.For the analysis, overall survival Kaplan-Meier probabilities and plot last reported in the 00103311 study will be updated to provide a final table of survival probabilities at defined time points (3 months, 6 months, 12 months, 18 months, 24 months, 36 months) with relevant 95% confidence intervals and a final plot.A sensitivity analysis will be conducted assessing whether patients in thestandard of care arm who had blinatumomab use during the 00103311 trial and after the study's termination had an effect on the survival outcomes of this group.

Documents

Study results

01.47.01.01 Observational Research Study Report Published Report v1 final Analysis.pdf (100.73 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

Clinical trials database, Sites/patients from existing blinatumomab study number 00103311

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