

# Long-term, Non-interventional Study of Recipients of Tecartus for Treatment of Adult Patients With Relapsed or Refractory (R/R) Mantle Cell Lymphoma (MCL) or Adult Patients With R/R B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)

**First published:** 01/03/2022

**Last updated:** 04/12/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS45813

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### Study ID

50709

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### DARWIN EU® study

No

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### Study countries

-  Austria
  -  Canada
  -  Czechia
  -  France
  -  Germany
  -  Israel
  -  Italy
  -  Netherlands
  -  Poland
  -  Portugal
  -  Spain
  -  Switzerland
  -  United Kingdom
  -  United States
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### **Study description**

KT-EU-472-6036: This is a long-term, non-interventional study of adult patients with relapsed/refractory (r/r) mantle cell lymphoma (MCL), who have been treated with Tecartus® after 2 or more lines of systemic therapy including a Bruton's tyrosine kinase inhibitor (BTK), and of adult patients (26 years of age and above in the EU and Great Britain [GB]; and 18 years of age and above in the US, Canada and Switzerland) treated with Tecartus for r/r B-cell precursor ALL.

The primary objective of this study is to evaluate effectiveness of Tecartus in terms of overall response rate for MCL and overall complete remission for ALL.

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### **Study status**

Ongoing

## Research institutions and networks

# Institutions

Kite

## Contact details

### Study institution contact

Kite Study Director [ClinicalTrialDisclosure@gilead.com](mailto:ClinicalTrialDisclosure@gilead.com)

Study contact

[ClinicalTrialDisclosure@gilead.com](mailto:ClinicalTrialDisclosure@gilead.com)

### Primary lead investigator

Kite Study Director

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 31/08/2022

Actual: 18/01/2023

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### Study start date

Planned: 28/04/2023

Actual: 18/04/2023

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### Date of final study report

Planned: 31/03/2043

## Sources of funding

## More details on funding

Kite, A Gilead Company

## Study protocol

[KT-EU-472-6036-appendix-16.1.1-protocol version 1.2\\_f-redact\\_reducedsize.pdf](#)  
(8 MB)

[KT-EU-472-6036-appendix-16.1.1-protocol amendment 3.0\\_f-redact.pdf](#) (13.94 MB)

[KT-EU-472-6036-appendix-16.1.1-protocol amendment 5-version 2.2-f-redact 1.pdf](#) (11.21 MB)

## Regulatory

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

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## 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:**

Effectiveness study (incl. comparative)  
Safety study (incl. comparative)

**Main study objective:**

To evaluate the effectiveness of Tecartus by indication in terms of ORR (complete response [CR] + partial response [PR]) for MCL and OCR,CR + complete remission with incomplete hematologic recovery [CRi]) for ALL.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Secondary use of EBMT and CIBMTR data

## Study drug and medical condition

**Medicinal product name**

TECARTUS

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

BREXUCABTAGENE AUTOLEUCEL

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## **Anatomical Therapeutic Chemical (ATC) code**

(L01X) OTHER ANTINEOPLASTIC AGENTS

OTHER ANTINEOPLASTIC AGENTS

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## **Medical condition to be studied**

Mantle cell lymphoma

Acute lymphocytic leukaemia

## Population studied

### **Age groups**

- **Adult and elderly population (≥18 years)**

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- Elderly (≥ 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**

1600

## Study design details

## **Outcomes**

Overall response rate, Overall survival, complete remission, duration of response, time to next treatment, relapse or progression of the primary disease, safety & effectiveness profile by gender, age, and in special populations. Incidence rates & severity of adverse drug reactions, including secondary malignancies, Cytokine Release Syndrome (CRS), neurologic events, serious infections, prolonged cytopenias, non-relapse mortality (NRM) and hypogammaglobulinemia causes of death, risk of tumor lysis syndrome & aggravated Graft Versus Host Disease, and detection of replication-competent retrovirus.

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## **Data analysis plan**

Analysis of all endpoints will include all eligible patients who are documented within the EBMT, CIBMTR, and are treated with Tecartus.

Categorical variables will be summarized descriptively by number and percentage of patients in each categorical definition with 95% confidence intervals.

Continuous variables will be summarized descriptively by mean, standard deviation, median, lower quartile, upper quartile, minimum and maximum.

Patient incidence of endpoint events will be provided. Poisson regression will be used to determine follow-up adjusted incidence rate.

Kaplan-Meier (KM) curves will be used to illustrate all time-to-event data without competing risks. For endpoints with competing risks, cumulative incidence will be provided based on competing risks methods.

## **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 source(s), other**

EBMT and CIBMTR

## 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