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

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Study Ongoing

Administrative details

EU PAS number

EUPAS45813

Study ID

50709

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Canada
- [ ] Czechia
- [ ] France
- [ ] Germany
- [ ] Israel
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

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.

Study status

Ongoing

Research institutions and networks

Institutions

Kite

Contact details

Study institution contact

Kite Study Director ClinicalTrialDisclosure@gilead.com

Study contact

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

Study start date

Planned: 28/04/2023

Actual: 18/04/2023

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

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

Study type:

Non-interventional study

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

Non-interventional study design, other

Secondary use of EBMT and CIBMTR data

Study drug and medical condition

Medicinal product name

TECARTUS

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

BREXUCABTAGENE AUTOLEUCEL

Anatomical Therapeutic Chemical (ATC) code

(L01X) OTHER ANTINEOPLASTIC AGENTS

OTHER ANTINEOPLASTIC AGENTS

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)

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.

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No