Long-term, Non-interventional Study of Recipients of Tecartus for Treatment of Adult Patients With Relapsed or Refractory Mantle Cell Lymphoma (MCL)

First published: 01/03/2022

Last updated: 22/08/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50709

EU PAS number

EUPAS45813

Study ID

50709

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom

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). The primary objective of this study is to evaluate effectiveness of Tecartus in terms of overall response rate.

Study status

Ongoing

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Kite

Contact details

Study institution contact

Kite Study Director

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

- Pharmaceutical company and other private sector

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)

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The primary objective is to evaluate effectiveness of Tecartus in terms of overall response rate.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Secondary use of EBMT data

Study drug and medical condition

Name of medicine

TECARTUS

Medical condition to be studied

Mantle cell lymphoma

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

350

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, 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 Registry 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. Multivariate Poisson regression analyses will be used to estimate cumulative incidence rates adjusted for the follow-up period and predefined characteristics, to estimate their prognostic effect on the outcome. Kaplan-Meier (KM) curves will be used to illustrate all time-to-event data. The analysis of the effectiveness endpoints will be conducted when effectiveness data from approximately 200 eligible patients has been documented. Time-to-event endpoints will be analyzed using the KM method.

Data management

Data source(s), other

EBMT

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