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: 16/02/2024

Study   Planned

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
Planned

Research institution 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

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 sources

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