Long-term, Non-interventional Study of Recipients of Yescarta® for Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma, Primary Mediastinal Large B-Cell Lymphoma, and Follicular Lymphoma

First published: 06/12/2019

Last updated: 31/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS32539

Study ID

47191

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium

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

Study description

KT-EU-471-0117: This is a long-term, non-interventional study of patients with relapsed/refractory (r/r) diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL) or with relapsed/refractory follicular lymphoma (FL), who have been treated with YESCARTA. Data for this study will be retrieved from ongoing Registry holders EBMT and CIBMTR.

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 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: 31/03/2020

Actual: 23/05/2020

Study start date

Planned: 30/06/2020

Actual: 21/08/2020

Date of final study report
Planned: 30/06/2039

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Kite, A Gilead Company

Study protocol

KT-EU-471-0117-appendix-16.1.1-protocol amendment 3_f-redact_reducedsize.pdf(4.76 MB)

KT-EU-471-0117-appendix-16.1.1-protocol amendment 5_f-redact_reducedsize.pdf(9.98 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:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

The primary objective is to evaluate the incidence rate and severity of adverse drug reactions (ADRs) in patients treated with YESCARTA (pooled and by indication), including secondary malignancies, cytokine release syndrome (CRS), neurologic events, serious infections, prolonged cytopenias, hypogammaglobulinemia, and
pregnancy outcomes in female patients of childbearing potential or partners of male patients.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Secondary use of EBMT and CIBMTR data

Study drug and medical condition

Name of medicine

YESCARTA

Medical condition to be studied

Diffuse large B-cell lymphoma

Primary mediastinal large B-cell lymphoma

Follicular 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

2550

Study design details

Outcomes

Incidence rates of secondary malignancies, CRS, neurologic events, prolonged cytopenias, serious infections, hypogammaglobulinemia and pregnancies, and as applicable severity, time to onset, type and location, management and resolution of these events. Use of replacement immunoglobulin therapy and pregnancy outcome among females with childbearing potential. Overall survival, time to next treatment, relapse or progression of the primary disease, primary and secondary endpoints on subgroups by gender, age, and in special populations. Incidence rates, resolution and time to onset of TLS (also severity) and aggravation of GvHD (chronic and acute, for acute also severity and

relationship to cell therapy), frequency of detection of RCR.

Data analysis plan

Analysis of endpoints for this study will include all eligible Yescarta patients within the EBMT Registry and CIBMTR Registry. The following will be summarized descriptively: Categorical variables by number and percentage of patients, including 95% confidence intervals, Continuous variables by mean, standard deviation, median, lower quartile, upper quartile, minimum and maximum. The following analyses will be provided: patient incidence of endpoint events, Multivariate Poisson regression analyses for cumulative incidence rates adjusted for follow-up period, specified subgroups and other potential confounders (demographics and baseline characteristics), Kaplan-Meier curves for all time-to-event data, Competing risk analysis method for time to onset and duration of endpoint events, time to relapse or progression, time to next treatment, and cumulative incidence at specified time points, Cox-proportional Hazard models for multivariate time-to-event data adjusted for subgroups and other potential confounders.

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