

Observational study to assess the characteristics and outcomes of patients with refractory/relapsed diffuse large B cell lymphoma who received R-GemOx as second line or above treatment (MK-2140-012)

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Study

Planned

Administrative details

EU PAS number

EUPAS1000000973

Study ID

1000000973

DARWIN EU® study

No

Study countries

Study description

This epidemiological study aims to provide the real-world data on 2L+ rituximab-gemcitabine-oxaliplatin (R-GemOx) treated patients with refractory/relapsed diffuse large B cell lymphoma (R/R DLBCL) in China. The primary objective of this study is to assess the demographic and clinical characteristics, treatment characteristics, and outcomes among all eligible patients.

Study status

Planned

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

 United States

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Institution

Pharmaceutical company

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/03/2026

Study start date

Planned: 30/06/2026

Data analysis start date

Planned: 15/12/2026

Date of final study report

Planned: 31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

This is a retrospective observational study of secondary data use, utilizing the structured and unstructured data of medical records from multi-centers (at least 4 selected tertiary hospitals).

Main study objective:

The main objectives are to evaluate the demographic and clinical characteristics, treatment characteristics, and clinical outcomes among patients with Refractory or Relapsed Diffuse large B-cell Lymphoma (R/R DLBCL), who initiated 2+ line treatment with R-GemOx, in China.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective observational study of secondary data use

Study drug and medical condition

Medicinal product name, other

Rituximab-gemcitabine-oxaliplatin (R-GemOx)

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

RITUXIMAB

OXALIPLATIN

Anatomical Therapeutic Chemical (ATC) code

(L01FA01) rituximab

rituximab

(L01XA03) oxaliplatin

oxaliplatin

(L01BC05) gemcitabine

gemcitabine

Medical condition to be studied

Diffuse large B-cell lymphoma

Population studied

Short description of the study population

Adult participants with Refractory or Relapsed Diffuse large B-cell Lymphoma (R/R DLBCL), who received Rituximab-gemcitabine-oxaliplatin (R-GemOx) as 2nd-line or above treatment during the study identification period (January 01, 2015 through December 31, 2024).

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)

Study design details

Setting

Adult patients with Refractory or Relapsed Diffuse large B-cell Lymphoma (R/R DLBCL) included in medical records in multi-centers in China.

Outcomes

Variable of clinical outcomes will be presented using real-world Response Rate (rwRR), real-world Duration of Response (rwDOR) real-world Progression Free Survival (rwPFS), real-world Overall Survival (rwOS), real-world Time to Treatment Discontinuation (rwTTD), and real-world Time to next treatment (rwTTNT).

Data analysis plan

The analyses will be of descriptive nature in this study. The study is not aimed at testing any pre-specified hypothesis. Analyses will be performed by the sponsor upon the delivery of the validated dataset. Continuous variables (i.e., age) will be summarized using standard descriptive statistics, specifically mean, standard deviation, median, and range (minimum and maximum). Continuous variables may also be categorized into mutually exclusive groups (i.e., age categories) and examined as categorical or ordinal variables.

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

Electronic medical records; hospital information systems; laboratory information management systems (LIS); radiology information systems (RIS); picture archiving and communication systems (PACS); China Center for Disease Control and Prevention (China CDC); Other medical records

Data sources (types)

[Non-interventional study](#)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings**CDM name**

CDISC SDTM

CDM website

<https://www.cdisc.org/standards/foundational/sdtm>

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes