Molecular profiling of tissue samples from patients who received a Kite-manufactured gene-modified cell therapy and have developed a secondary malignancy of T-cell origin

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Study Planned

Administrative details

EU PAS number

EUPAS1000000769

Study ID

1000000769

DARWIN EU® study

No

Study countries

European Union

United Kingdom

Study description

KT-US-982-0910: This is an observational study of patients who received a Kite-manufactured chimeric antigen receptor (CAR) T-cell therapy (axicabtagene ciloleucel or brexucabtagene) and have reported a secondary malignancy of T-cell origin.

The primary objective of this study is to assess potential chimeric antigen receptor (CAR) transgene involvement by performing molecular profiling of tissue and blood samples obtained or are about to be obtained during clinical evaluation, from patients who were treated with axicabtagene ciloleucel or brexucabtagene autoleucel and are suspected to have developed a secondary T-cell malignancy.

Study status

Planned

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Kite, a Gilead Company

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: 08/11/2025

Study start date

Planned: 31/12/2026

Date of final study report

Planned: 10/01/2040

Study protocol

982-0910-appendix-16.1.9-protocol_f-redact-FCLTCL0YM74.pdf (2.11 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Feasibility analysis

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Observational study

Main study objective:
To assess potential CAR transgene involvement by performing molecular profiling of tissue samples obtained or are about to be obtained in the course of routine clinical practice from patients who were treated with axicabtagene ciloleucel or brexucabtagene autoleucel and developed a secondary T-cell malignancy.

The molecular profiling will include the following, as applicable:

• The presence of the CAR transgene in the blood and/or tumor and/or bone marrow biopsy, as
well as the CAR level, if the CAR transgene was detected.

• Presence of RCR.

Study drug and medical condition

Medicinal product name
YESCARTA
TECARTUS

Study drug International non-proprietary name (INN) or common name
AXICABTAGENE CILOLEUCEL
BREXUCABTAGENE AUTOLEUCEL

Anatomical Therapeutic Chemical (ATC) code
(L01XL03) axicabtagene ciloleucel
axicabtagene ciloleucel

(L01XL06) brexucabtagene autoleucel

brexucabtagene autoleucel

Medical condition to be studied

Diffuse large B-cell lymphoma

Mantle cell lymphoma

Follicular lymphoma

Acute lymphocytic leukaemia

Primary mediastinal large B-cell lymphoma

Population studied

Short description of the study population

Patients who have received a Kite-manufactured CAR T-cell therapy (axicabtagene ciloleucel or brexucabtagene autoleucel) and have reported a suspected secondary malignancy of T-cell origin.

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

This observational study will be conducted in the EEA and UK and will enroll patients on an ongoing basis.

Outcomes

The following laboratory parameters will be used for molecular profiling:

• The presence of the CAR transgene in the blood and/or tumor and/or bone marrow biopsy.

• The CAR level, if the CAR transgene was detected in the blood and/or tumor and/or bone marrow biopsy.

• Presence of RCR.

• Presence of somatic mutations that are common in hematologic malignancies.

• Transgene integration site analysis results.

• Transcriptome/RNA analysis results

Data analysis plan

No statistical analysis is planned. The molecular profiling results will be described for each patient tested.

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 sources (types)

Electronic healthcare records (EHR)

Laboratory tests and analyses

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown