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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# Administrative details

EU PAS number
EUPAS100000769
Study ID
100000769
DARWIN EU® study
DARWIN FU(R) STUOV
No
No
No  Study countries
No

#### **Study description**

KT-EU-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: 08/10/2025

#### Date of final study report

Planned: 10/01/2040

## Study protocol

982-0910-appendix-16.1.9-protocol f-redact.pdf (1.59 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
Study Design
Non-interventional study design Other

#### Non-interventional study design, other

Observational study

# Study drug and medical condition

#### **Medicinal product name**

YESCARTA

**TECARTUS** 

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

AXICABTAGENE CILOLEUCEL

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

#### **Age groups**

- Adult and elderly population (≥18 years)
  - $\circ$  Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)</li>

- Adults (75 to < 85 years)
- Adults (85 years and over)

## 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.

## 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