Tecartus Survey: Quantitative Testing of Health Care Professional Knowledge About Tecartus® Risk Minimisation Measures

First published: 11/04/2023

Last updated: 24/02/2025

Study Finalised

Administrative details

EU PAS number

EUPAS104052

Study ID

105577

DARWIN EU® study

No

Study countries

- Czechia
- France
- Germany
- Italy

Portugal

Sweden

United Kingdom

Study description

KT-EU-472-5966: The study was a non-interventional, cross-sectional survey of health care professionals (HCPs) based in Europe. The survey was conducted ≥ 12 months after Tecartus® had marketed approval in Europe. The survey was distributed to HCPs who have received training on additional risk minimisation measures (RMMs) and prescribe, handle, dispense, or administer Tecartus or manage patients experiencing Tecartus-related adverse events (AEs). The primary objective of the study was to measure the HCPs awareness and knowledge of RMMs for Tecartus.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

Last updated: 12/02/2024

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

Actual: 29/03/2021

Study start date

Planned: 21/04/2023

Actual: 09/06/2023

Date of final study report

Planned: 21/03/2024

Actual: 19/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Kite, A Gilead Company

Study protocol

KT-EU-472-5966-appendix-16.1.1-Protocol Amendment 2_f-redact.pdf (1.27 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The main objective of this study was to measure the HCPs awareness and knowledge of RMMs for Tecartus, as described in the Risk Management Plan (RMP), specifically, to conduct a survey to measure knowledge and understanding of the key messages in the HCP-directed additional RMMs and the Summary of Product Characteristics (SmPC) for Tecartus.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey study

Study drug and medical condition

Medicinal product name

TECARTUS

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

BREXUCABTAGENE AUTOLEUCEL

Anatomical Therapeutic Chemical (ATC) code

(L01XL06) brexucabtagene autoleucel

brexucabtagene autoleucel

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

100

Study design details

Outcomes

Measured HCPs knowledge of known important identified risks associated with Tecartus and assessed HCPs understanding of how to identify and treat cytokine release syndrome and serious neurologic AEs and understanding of handling and administration of Tecartus to maintain product viability, and awareness of the patient alert card (PAC), distribute the PAC, and inform patients about the PAC’s content.

Data analysis plan

Responses to questions for all completed surveys were analysed using descriptive statistics (count, ranges, proportions, and scores). HCPs knowledge was evaluated and expressed as proportions or scores. The results were presented overall, as well as by country and HCP specialty where sample size allows. Categorical variables were described by the number and proportion in each category. Frequency point-estimates with 2-sided 95% confidence intervals using the binomial distribution (eg, Wald or Clopper-Pearson method, as appropriate) were constructed to describe the proportion of HCPs aware of

the specified risks. Key questions within the survey were identified as being essential to measure HCPs knowledge of the additional RMMs. Given the complexity of some of the key messages included in the Tecartus RMMs, an acceptable level of knowledge on these essential questions is set at 80%.

Documents

Study report

report-body_f-redact.pdf (434.82 KB)

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)

Other

Data sources (types), other

Self-administered surveys via Confirmit, a web-based survey platform specifically designed for the creation and delivery of multi-lingual surveys. The survey was opened for 6 months and sent to HCPs who received training on the educational materials and prescribed, handled, dispensed, or administered

Tecartus, or managed patients experiencing Tecartus-related AEs.

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