EVALUATION OF THE EFFECTIVENESS OF THE ADDITIONAL RISK MINIMISATION MEASURES FOR GLOFITAMAB: A PASS SURVEY AMONG HEALTHCARE PROFESSIONALS IN EUROPEAN COUNTRIES

First published: 08/01/2026

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Study Planned

Administrative details

EU PAS number

EUPAS1000000863

Study ID

1000000863

DARWIN EU® study

No

Study countries

Austria

Belgium

- Bulgaria
- Croatia
- France
- Germany
- Greece
- Italy
- Norway
- Portugal
- Sweden

Study description

This study focuses on the important identified risk of Tumor Flare (TF) for Glofitamab and its additional Risk Minimisation Measures (aRMMs), in the form of an Health Care Professional (HCP) brochure. The HCP brochure is intended to educate and increase HCP awareness and understanding of the key signs and symptoms of TF so that HCPs can identify and manage the risks in a timely and appropriate manner.

Therefore, the study aims to evaluate the effectiveness of the HCP brochure on physicians prescribing Glofitamab to ensure that prescribers are able to recognise early signs and symptoms of TF and provide appropriate management.

To fulfil a Category III Post-Authorisation Safety Study (PASS), the Marketing Authorisation Holder (MAH) proposed a non-interventional (NI) PASS through an HCP survey as detailed in the Risk Management Plan (RMP) for Glofitamab, to evaluate the effectiveness of the aRMMs. The survey will assess awareness, knowledge, and adherence of Glofitamab prescribers to the aRMMs plan.

Study status

Planned

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

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Primary lead investigator

Sophie Jouaville Abrouk

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/05/2022

Actual: 30/05/2022

Study start date
Planned: 01/04/2026

Date of final study report
Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd

Study protocol

Protocol - BO44309 - COLUMVI - v3 - redacted.pdf (1.03 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Data collection methods:

Primary data collection

Study design:

Primary data collection via a web-based questionnaire of HCPs (in countries where applicable only) who have prescribed Glofitamab. The self-reported survey will be an anonymous, cross-sectional, multinational, conducted in 11 countries within the European Economic Area (EEA).

Main study objective:

The study aims to evaluate, through a self-reported survey, the effectiveness of the aRMMs included in the RMP for Glofitamab in terms of key process indicators. In this study key process indicators encompass prescribers' awareness of the Educational Materials (EMs), knowledge/comprehension of the important identified risk of TF and adherence with respect to the safety messages in the HCP brochure.

The primary objectives are:

1. To assess prescribers' awareness of the Glofitamab EMs by estimating the proportion of prescribers who acknowledge having received the EMs and read the HCP brochure.
2. To assess prescribers' knowledge of the risk of TF that may occur with

Glofitamab use and on the specific guidance for risk minimisation measures for TF, as described in the HCP brochure, by estimating the proportion of prescribers with correct responses to the risk knowledge questions.
3. To assess prescribers' adherence with respect to the aRMMs by estimating the proportion of prescribers whose responses to the practice-related questions are consistent with the guidance provided in the HCP brochure.
The secondary objective is:
1. To assess whether the prescribers self-reported the HCP brochure as useful for their clinical practice.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

COLUMVI

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

GLOFITAMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FX28) glofitamab

glofitamab

Population studied

Short description of the study population

HCPs from geographically dispersed countries within the European Economic Area (EEA) (Austria, Belgium, Bulgaria, Croatia, France, Germany, Greece, Italy, Portugal, Norway, and Sweden) where Glofitamab is approved and reimbursed will be targeted for participating to this survey.

The study population will be restricted to physicians(oncologists/haematologists/haematologist-oncologists/others) who meet the following inclusion criteria for study entry:

- Having prescribed Glofitamab to patients with relapsed or refractory (R/R) Diffuse large B-cell lymphoma (DLBCL) in routine clinical practice.
- Willing to participate in the survey.

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)

Estimated number of subjects

120

Study design details

Setting

The survey will be conducted among HCPs who prescribed Glofitamab in inpatient
and/or outpatient settings in 11 countries within the EEA. The survey will start within at
least 12 months following the implementation of the local aRMMs as per European
guideline on Good Pharmacovigilance Practices (GVP), Module XVI (Rev 3) (EMA 2017c).

Data analysis plan

All the analyses will be descriptive, and no comparative analysis will be reported. The statistical results will be presented by prescribers' specialty and per country (if possible, given the number of respondents), and overall. Continuous variables will be described by their mean, standard deviation, and median, first quartile (Q1), third quartile (Q3), minimum and maximum. Categorical variables will be described as the total number and relative percentage per category. Confidence Interval (CI) of 95% will be evaluated, when applicable. The analysis of participation rate will be conducted reporting response rate, partial response rate and refusal rate. The analysis of questionnaires will be conducted using completed questionnaires submitted by the participants.

Specifically, the proportions of answers among participants will be evaluated by reporting the
frequency of each option provided by the participants. Success of the aRMMs for HCPs is defined as an 80% threshold based on the percentage of prescribers classified as aware of, knowledgeable about and/or adherent to the aRMMs. Overall results will be presented both unweighted (results obtained from raw data) and weighted. A weight variable will be applied to each statistical unit (i.e., the HCPs) during the results calculation to correct any over- or under-

sampling that may have occurred for a country.
This weight variable will indicate how many unit(s) of the population of interest an observation will count in a statistical procedure. Its value will change per country.

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

OneKeyTM database

Data sources (types)

Patient surveys

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