# A Cross-Sectional Post-Authorization Safety Study to Assess Healthcare Provider Awareness of Risks Associated with Zydelig® in the European Union

First published: 27/07/2017 Last updated: 16/02/2024



### Administrative details

#### **EU PAS number**

EUPAS16606

#### **Study ID**

28467

#### DARWIN EU® study

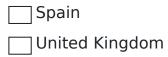
No

#### **Study countries**

France

Germany

∣ltaly



#### **Study description**

GS-EU-313-4226: Non interventional, cross sectional survey of medical oncologists and hematologists in the European Union.The primary objective of this study was to determine the HCPs' level of knowledge about the newly identified infection risks associated with Zydelig treatment and the corresponding recommendations to minimize these risks.

**Study status** 

Finalised

### Research institutions and networks

### Institutions

### **Gilead Sciences**

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Institution

Pharmaceutical company

Multiple centres: 142 centres are involved in the study

### Contact details

#### Study institution contact

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator Gilead Study Director

Primary lead investigator

### Study timelines

#### Date when funding contract was signed

Planned: 09/01/2017 Actual: 09/01/2017

**Study start date** Planned: 27/11/2017 Actual: 29/11/2017

Data analysis start date Planned: 17/07/2018 Actual: 22/10/2018

Date of final study report Planned: 20/12/2018 Actual: 12/12/2018

### Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

Gilead Sciences Europe, Ltd.

## Study protocol

protocol+GS-EU-313-4226-19apr2017.pdf(789.38 KB)

## 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 Other

#### If 'other', further details on the scope of the study

To Assess Healthcare Provider Awareness of Risks Associated with Zydelig $\ensuremath{\mathbb{B}}$  in the European Union

#### Data collection methods:

Primary data collection

#### Main study objective:

To determine the HCPs' level of knowledge about the newly identified infection risks associated with Zydelig treatment and the corresponding recommendations to minimize these risks.

## Study Design

#### Non-interventional study design

Cross-sectional

Other

#### Non-interventional study design, other

Survey of medical oncologists and hematologists in the European Union

## Population studied

#### Short description of the study population

Practicing oncologists and hematologists in the United Kingdom, Italy, Spain, France and Germany who treat patients with Chronic lymphocytic leukemia (CLL) or Follicular lymphoma (FL) representing specialties considered likely to prescribe Zydelig.

Patients with following criteria were included:

1. Registered oncologists and hematologists

2. Registered medical doctors who are currently enrolled in an advanced training program leading to specialization in oncology and/or hematology

#### 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

150

## Study design details

#### Data analysis plan

Responses to questions for all completed surveys were analyzed using descriptive statistics. Continuous variables were described by the mean, standard deviation, median and range. Categorical variables were described by the number and proportion in each category. The amount of missing data for each variable were reported. Data were presented by summary tables and/or graphs. No formal hypothesis testing was conducted. An 80% threshold for prescriber awareness was generally considered acceptable. The numbers of invitees and respondents were recorded, and the response rates were reported overall and by country.

### Documents

**Study results** 

CSR-Final-PASS-GS-EU-313-4226.pdf(349.57 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

Survey study

## 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