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

Study Finalised

Administrative details

EU PAS number

EUPAS16606

Study ID

28467

DARWIN EU® study

No

Study countries

France

Germany

Italy

Spain

United Kingdom

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® 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

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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