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

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/28467

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 institution and networks

Institutions

Gilead Sciences
First published: 12/02/2024
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~~12/02/2024~~
Institution
Pharmaceutical company

Multiple centres: 142 centres are involved in the study

Contact details

Study institution contact
Gilead Study Director
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

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

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