Non-interventional study to assess the safety profile of idelalisib in patients with refractory follicular lymphoma (FL)

First published: 27/06/2017

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS19618

Study ID

49406

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- France
- Germany

Greece
Ireland
Italy
Portugal
Spain
Sweden
United Kingdom

Study description

GS-EU-313-4172: The objective of this study was to assess the overall safety profile of idelalisib monotherapy in patients with refractory FL.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

Last updated: 12/02/2024

Institution | Pharmaceutical company

Multiple centres: 83 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: 18/08/2016

Actual: 18/08/2016

Study start date

Planned: 02/04/2018

Actual: 25/05/2018

Data analysis start date

Planned: 31/05/2022

Date of interim report, if expected

Planned: 29/03/2019

Actual: 24/06/2019

Date of final study report

Planned: 30/03/2023

Actual: 17/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

GS-EU-313-4172 Protocol Final V1.1 13Jun2017.pdf (679.41 KB)

GS-EU-313-4172-16.1.1-appendix-protocol Amendment 4.1_f-redact.pdf (6.55 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The objective of this study was to assess the overall safety profile of idelalisib monotherapy in patients with refractory FL. Serious Adverse Events (SAEs) were collected and according rates will be estimated. Focus was given to special health outcomes of interest (HOIs) as listed in the Zydelig Risk Management Plan (RMP) for the EU (Version 2.4).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multi-centre, observational, retrospective study

Study drug and medical condition

Medical condition to be studied

Non-Hodgkin's lymphoma refractory

Population studied

Short description of the study population

Patients aged 18 years or older treated with idelalisib for refractory follicular lymphoma (FL) in routine clinical practice.

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)

Special population of interest

Other

Special population of interest, other

Patients with refractory follicular lymphoma

Estimated number of subjects

257

Study design details

Outcomes

To assess the overall safety profile of idelalisib monotherapy in patients with refractory FL. To assess the effectiveness of idelalisib monotherapy in patients with refractory FL. The effectiveness of idelalisib was assessed by overall response rate (ORR), duration of response (DOR), progression-free survival (PFS), time to next treatment (TTNT), and overall survival (OS).

Data analysis plan

Continuous variables were summarized by mean, standard deviation, median, lower quartile, upper quartile, minimum and maximum. Categorical variables were summarized by number and percentage of patients in each categorical definition including 95% confidence intervals. Multivariate Poisson regression analyses were used to estimate adjusted rates of ADRs, SADRs, and HOIs. Kaplan Meier were used to illustrate time-to-event analyses. Stratified analyses were used to account for potential behavioural changes of the site staff after the initiation of the study that might introduce bias between retrospective and prospective data collection.

Documents

Study results

GS-EU-313-4172_Final Report Abstract_v2.0_01September2022_Approved_f-redact.pdf (832.36 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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective patient-based data collection

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