# 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





### Administrative details

<b>EU PAS number</b> 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

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**

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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**

### **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No