Prospective non-interventional post authorization safety study (PASS) of idelalisib in Germany

First published: 27/04/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44651

EU PAS number

EUPAS9564

Study ID

44651

DARWIN EU® study

No

Study countries

☐ Germany

Study description

GS-DE-312-1750: This was a multicenter, non-interventional, two cohort (CLL and FL), prospective post authorization safety study (PASS) to evaluate the clinical effectiveness and safety of idelalisib for treatment of patients with Chronic Lymphocytic Leukemia (CLL) or Follicular Lymphoma (FL). This design was chosen to assess the effectiveness and safety of therapy with idelalisib up to 3 years per patient in clinical routine. The study enrolled adult patients with either CLL or FL with initiation of treatment with idelalisib alone or in combination with other antineoplastic agents and/or monoclonal antibodies in accordance with the approved label for Zydelig in the European Union (EU) and the current Zydelig EU SmPC. Participating study sites (hospitals and private practitioners) were specialized on treating oncology patients. All study sites were located in Germany. 87 medical centers distributed over all states of Germany participated in the study. The study included 179 adult patients with CLL or 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: 30 centres are involved in the study

Contact details

Study institution contact

Study Director Gilead

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Study Director Gilead

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/05/2015

Actual: 07/05/2015

Study start date

Planned: 30/09/2015

Actual: 30/09/2015

Data analysis start date

Planned: 31/12/2020

Date of interim report, if expected
Actual: 06/09/2017

Date of final study report
Planned: 31/12/2021

Actual: 10/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

amd-4-prot-GS-DE-312-1750.pdf(1.62 MB)

protocol-GS-DE-312-1750-FINAL-COMPLETE.pdf(857.15 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objectives of this study are to assess: Progression-Free Survival (PFS) (rate and time to progression) Overall Response Rate (ORR) Overall Survival (OS) (rate and survival duration)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic lymphocytic leukaemia

Follicular lymphoma

Population studied

Short description of the study population

The study population will include 300 adult patients (≥ 18 years) with Chronic lymphocytic leukaemia (CLL) or Follicular lymphoma (FL).

Inclusion Criteria CLL

1) Diagnosis of chronic lymphocytic leukemia (CLL) and decision for treatment with idelalisib

2) Indication approved for Zydelig in the European Union (EU) (refer to current Zydelig EU SmPC)

3) Understand and voluntarily sign an informed consent form

4) Male or female ≥18 years of age at the time of signing the informed consent form

Exclusion Criteria CLL

1) Patients with suspected systemic bacterial, fungal or viral infection

2) Patients with history of another primary malignancy that is currently clinically significant or currently requires active intervention

3) Pregnant or breast feeding women

4) Concurrent participation in another therapeutic clinical trial

Inclusion / Exclusion Criteria FL (Cohort B)

Inclusion Criteria FL

1) Histopathologically confirmed diagnosis of Follicular Lymphoma and decision for treatment with idelalisib

2) Indication approved for Zydelig in the European Union (EU) (refer to current

Zydelig EU SmPC)
3) Understand and voluntarily sign an informed consent form
4) Male or female ≥18 years of age at the time of signing the informed consent form

Exclusion Criteria FL
1) Patients with suspected systemic bacterial, fungal or viral infection
2) Patients with history of another primary malignancy that is currently clinically significant or currently requires active intervention
3) Patients must not have received autologous stem cell transplant at least within 12 weeks prior to study treatment. If patients received autologous stem cell transplant more than 12 weeks ago, they must be fully recovered from the side effects of such treatment
4) Pregnant or breast feeding women
5) Concurrent participation in another therapeutic clinical trial

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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)

Special population of interest

Other

Special population of interest, other

Chronic lymphocytic leukaemia (CLL) or Follicular lymphoma (FL) patients

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Estimated number of subjects

179

Study design details

Outcomes

The primary objectives of this study are to assess: Progression-Free Survival (PFS) (rate and time to progression) Overall Response Rate (ORR) Overall Survival (OS) (rate and survival duration), Incidence of adverse drug reactions (ADRs), serious ADRs, fatal events (regardless of causality) and cause of death Incidence, risk factors, management & outcome of diarrhea/colitis, pneumonitis and liver enzyme elevation Type and incidence of Special Situation Reports Health resource utilization Patient Reported Outcome (health-related quality of life & health status)

Data analysis plan

Summary statistics were presented by cohort (CLL or FL) and included: -nominal variables: frequencies and percentages. -ordinal variables: frequencies, percentages, median, minimum and maximum. -continuous variables: number (N) of observations, mean, standard deviation, 25th percentile, median, 75th percentile, minimum and maximum. For ADR events, in addition to frequencies and percentages, incidence rate in person-time were calculated by dividing number of new cases by the total number of person-time at risk to account for varying length of follow-up. Kaplan-Meier plots of progression-free survival, overall response rate, and overall survival were produced. The median duration of progression-free survival, overall response rate, and overall survival were determined. If not otherwise specified, p-values were presented as two-sided and the level of significance was set to 5% (two-sided). 95%-confidence intervals were provided, where applicable.

Documents

Study results

GS-DE-312-1750-csr-abstract_f-redact.pdf(189.67 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective 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