Dose Optimization Study of Idelalisib in Follicular Lymphoma

First published: 08/09/2016
Last updated: 23/05/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/33743

EU PAS number
EUPAS15094

Study ID
33743

DARWIN EU® study
No

Study countries
Australia
Canada
Czechia
France
Israel
Italy
Poland
Romania
Spain
United Kingdom

Study description
GS-US-313-1580: The study was terminated early due to enrollment challenges (after enrollment of 96 participants), therefore, the primary objective of the study to establish a safe and effective dosing regimen of idelalisib (IDL) in participants with relapsed or refractory follicular lymphoma (FL) who have no other therapeutic options could not be determined.

Study status
Finalised

Research institution and networks

Institutions

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

Multiple centres: 44 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:
01/09/2015
Actual:
12/06/2015

Study start date
Planned:
14/01/2016
Actual:
14/01/2016

Date of interim report, if expected
Planned:
26/12/2017
Actual:
07/12/2017

Date of final study report
Planned:
31/12/2026
Actual:
25/03/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences

Study protocol

amd-2-prot GS-US-313-1580-synopsis only.pdf(194.63 KB)

GS-US-313-1580-appendix-16.1.1-protocol Amendment 6_f-redact.pdf(3.37 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:
Disease /health condition
Human medicinal product

Study type:
Clinical trial

Main study objective:
Primary objective: To establish a safe and effective dosing regimen of idelalisib in participants with relapsed or refractory follicular lymphoma (FL) who have no other therapeutic options.

Study Design

Clinical trial randomisation
Randomised clinical trial

Study drug and medical condition

Medical condition to be studied
Follicular lymphoma

Population studied

Short description of the study population
Patients aged 18 years or older diagnosed with relapsed or refractory lymphoma who had received at least 2 lines of prior therapy and have no other available therapeutic options randomized with the treatment arm of idelalisib.
Inclusion criteria:
1) Male or female ?18 years of age
2) Histologically confirmed diagnosis of B-cell FL, and grade limited to 1, 2, or 3a based on criteria established by the World Health Organization (WHO) 2008 classification of tumors of hematopoietic and lymphoid tissues
3) Relapsed or refractory FL and have received at least 2 lines of prior therapy for FL and have no other available therapeutic options.
4) Ann Arbor Stage 2 (non-contiguous), 3, or 4 disease per Lugano Classification
5) Radiographically measurable lymphadenopathy or extranodal lymphoid malignancy as determined by the IRC (defined as the presence of ? 1 lesion that measures ? 1.5 cm in the LD and ?1.0 cm in the longest perpendicular dimension [LPD] as assessed by PET-CT, CT, or MRI).
6) Have adequate performance status (such as Eastern Cooperative Oncology Group [ECOG] Performance Status of ?2 or Karnofsky Performance Status of ? 60)
7) Required baseline laboratory data (within 4-weeks prior to start of study therapy) as shown in the table.
8) For female subjects of childbearing potential, willingness to use a protocol-recommended method of contraception during heterosexual intercourse from the signing of informed consent throughout the study treatment period and up to 30 days from the last dose of idelalisib.
9) For male subjects of reproductive potential having intercourse with females of childbearing potential, willingness to use a protocol-recommended method of contraception during heterosexual intercourse and to refrain from sperm donation throughout the study treatment period and for 90 days following discontinuation of idelalisib.
10) Lactating females must agree to discontinue nursing before study drug administration and until at least 30 days following last dose of idelalisib
11) Indicate willingness to comply with scheduled visits, drug administration plan, imaging studies, laboratory tests, other study procedures, and study restrictions, including mandatory prophylaxis for PJ
12) Evidence of a signed informed consent indicating that the subject is aware of the neoplastic nature of their disease and has been informed of the procedures to be followed, the experimental nature of the therapy, alternatives, potential benefits, possible side effects, potential risks and discomforts, and other pertinent aspects of study participation.

Exclusion Criteria:
1) History of lymphoid malignancy other than FL (eg, diffuse large B-cell lymphoma).
2) Known history of, or clinically apparent, central nervous system (CNS) lymphoma or leptomeningeal lymphoma.
3) Known presence of intermediate- or high-grade myelodysplastic syndrome.
4) Known history of serious allergic reaction including anaphylaxis or Stevens-Johnson syndrome/toxic epidermal necrolysis
5) History of a non-lymphoid malignancy except for the following: adequately treated local

basal cell or squamous cell carcinoma of the skin, cervical carcinoma in situ, superficial bladder cancer, asymptomatic prostate cancer without known metastatic disease and with no requirement for therapy or requiring only hormonal therapy and with normal prostate-specific antigen for ? 1 year prior to enrollment, or any other cancer or malignancy that has been in complete remission for ? 5 years
6) Evidence of ongoing systemic infection (eg, bacterial, fungal, viral) at the time of enrollment
7) Known history of drug-induced liver injury, chronic active hepatitis B virus (HBV), chronic active hepatitis C virus (HCV), alcoholic liver disease, non-alcoholic steatohepatitis, cirrhosis of the liver, portal hypertension, primary biliary cirrhosis, or ongoing extrahepatic obstruction caused by cholelithiasis
8) History of or ongoing drug-induced pneumonitis
9) History of or ongoing inflammatory bowel disease
10) Known human immunodeficiency virus (HIV) infection
11) CMV: Ongoing infection, treatment, or specifically CMV antiviral prophylaxis within 28 days prior to the Screening Visit CMV test
12) Presence of any condition that could, in the opinion of the investigator, compromise the subject’s ability to participate in the study, such as history of substance abuse, alcoholism, or a psychiatric condition
13) History of prior allogeneic bone marrow progenitor cell or solid organ transplantation
14) Ongoing immunosuppressive therapy, including systemic corticosteroids (> 10 mg prednisone or equivalent/day) with the exception of the use of topical, enteric, or inhaled corticosteroids as therapy for comorbid conditions or systemic corticosteroids for autoimmune anemia and/or thrombocytopenia
15) Concurrent participation in another therapeutic clinical study
16) Prior or ongoing clinically significant illness, medical condition, surgical history, physical finding, electrocardiogram (ECG) finding, or laboratory abnormality that, in the investigator’s opinion, could adversely affect the safety of the subject or impair the assessment of study results
17) Prior treatment with PI3K inhibitors

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 follicular lymphoma

Estimated number of subjects
96

Study design details

Outcomes
Overall response rate, Incidence of Grade ? 4 Treatment-Emergent Adverse Events (TEAEs), Duration of response, overall response rate by Week 24, Overall safety profile of idelalisib, time to onset of adverse events of interest (AEI), progression-free survival, overall survival, and idelalisib trough and peak plasma concentrations

Data analysis plan
Data summaries involving continuous variables, data tables contained following information: sample size, mean, standard deviation (StD), standard error of the mean, median, minimum, and maximum. For categorical variables, the following information was presented: sample size, proportion, and 95% confidene intervals (CIs) based on exact binomial proportion. For the primary efficacy analysis, the ORR was estimated with 95% Clopper-Pearson exact CI provided.

Documents

Study results
GS-US-313-1580 - CSR Synopsis_f-redact.pdf(630.65 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