Non-interventional retrospective study evaluating the real-life idelalisib use in the population enrolled in the French cohort Temporary Authorization for Use (ATUc) in Chronic Lymphocytic Leukemia (CLL) and indolent Non-Hodgkin Lymphoma (iNHL) (REALIST)

First published: 30/06/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/30894

EU PAS number

EUPAS19711

Study ID

30894

DARWIN EU® study

No

Study countries

☐ France

Study description

GS-FR-312-2033: This real-life retrospective study will collect and describe effectiveness and safety data of idelalisib in monotherapy or in combination with rituximab in adult patients who were previously enrolled in the cohort Authorization for Temporary Use (ATUc) program.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

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Institution | Pharmaceutical company

Multiple centres: 40 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: 18/04/2016

Actual: 15/08/2016

Study start date

Planned: 28/07/2017

Actual: 11/09/2017

Data analysis start date

Planned: 27/11/2017

Actual: 14/06/2018

Date of final study report

Planned: 31/05/2019

Actual: 21/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences SAS

Study protocol

Realist study_GS-FR-312-2033_V2 12oct2016_signed with noEU PASS register.pdf(2.99 MB)

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 type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to describe the effectiveness of idelalisib ± rituximab 6 months after the idelalisib initiation following the enrollment of patients in the ATUc program Overall Response Rate (ORR)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ZYDELIG

Medical condition to be studied

Chronic lymphocytic leukaemia

Non-Hodgkin's lymphoma unspecified histology indolent stage IV

Population studied

Short description of the study population

Adult patients who have been enrolled in the ATUc for either CLL or iNHL according to the ATUc indications and who initiated treatment with idelalisib alone, or in combination with rituximab.

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

110

Study design details

Outcomes

This non-interventional study is designed to generate long-term (up to 12 months) real-life effectiveness and safety data in the patients enrolled in this ATUc. From the initiation of idelalisib treatment, the retrospective duration of follow-up will be up to 12 months for each patient which will allow collecting information about therapeutic strategies prescribed after idelalisib discontinuation, -Effectiveness outcome,-Outcome of adverse drug reactions (ADRs),serious adverse drug reactions (SADRs), fatal adverse events (fatal

AEs),-Health Economics and Outcomes Research (HEOR) data including iNHL and CLL resource utilization and costs in clinical practice and treatment options

Data analysis plan

The statistical analysis will be essentially descriptive, using SAS in the version 9.4 or higher. The risk is fixed to 5% in two-sided situation for all the analyses. A statistical analysis plan will be finalized and approved before the database lock.Summary statistics will be presented per patients' group (CLL, iNHL) and include:• Nominal variables: number of missing values, frequencies and percentages.• Ordinal variables: number of missing values, frequencies, percentages, median, minimum and maximum.• Continuous variables: number (N) of observations, number of missing values, mean, standard deviation, 25th percentile, median, 75th percentile, minimum and maximumWhen applicable, p-values will be presented as two-sided p-values and the level of significance is set to 5% (two-sided). Additionally, corresponding 95%-CI will be provided, when applicable.Methods for comparative analysis will be used, as appropriate.

Documents

Study results

GS-FR-312-2033-csr-body_f-redact.pdf(2.8 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Adult patients who have been enrolled in the ATUc for either CLL or iNHL according to the ATUc indications

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

Unknown