Real-World Observational Study of Outcomes for Acute Myeloid Leukemia (AML) Patients Treated With Glasdegib or Venetoclax in US Community Oncology Practices

First published: 25/09/2020

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS37385

Study ID

43120

DARWIN EU® study

No

Study countries

United States

Study description

Glasdegib (GLAS) and venetoclax (VEN) were approved in November 2018 for the treatment of AML in patients who are 75 years old or older or who have comorbidities that preclude intensive induction chemotherapy. Limited real-world observational studies of treatment patterns and outcomes for patients treated with either therapy have been conducted.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Slaven Sikirica

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/07/2019

Actual: 24/07/2019

Study start date
Planned: 30/09/2020

Actual: 30/09/2020

Data analysis start date
Planned: 09/12/2020

Actual: 09/12/2020

Date of final study report
Planned: 17/02/2021

Actual: 11/05/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer inc

Study protocol

B1371039 PFI_AML CRF_Study Protocol_Final_EUQPPV_11May2020.pdf (505.42 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

B1371039

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Treatment Patterns

Data collection methods:

Secondary use of data

Main study objective:

Understand patient demographic, clinical, and disease-related characteristics of AML patients who initiated treatment with GLAS-based regimen. Assess treatment patterns of AML patients who initiated treatment with GLAS-based regimen Estimate clinical outcomes of AML patients who initiated treatment with GLAS-based regimen.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

Medical condition to be studied

Acute myeloid leukaemia

Population studied

Short description of the study population

All patients treated by the providers with a GLAS-based regimen were identified during study feasibility. Unique identification numbers were then assigned to each patient. Cardinal Health randomized these patients and provided links to the eCRF in the random order they were sorted. Providers completed data abstraction sequentially according to the randomization order until all eligible patients were completed, or the provider was not able to perform data collection.

Inclusion criteria

Patients must have met all the following inclusion criteria to be eligible for inclusion in the study. Providers were asked to confirm the criteria are met by answering a set of questions in the patient eligibility portion of the eCRF which correspond to these criteria. Automatic date and logic checks were employed to ensure that a patient identified was eligible for the study.

For this study, the following inclusion criteria were used:

• Patients newly diagnosed with AML.

• Initiated 1L or later therapy (i.e., index therapy) for newly diagnosed AML with GLAS-based regimen or initiated 1L therapy with VEN-based regimen in the following time periods*

o Initiated 1L or later therapy for AML with GLAS-based regimen between 01 December 2018 and 31 December 2019.

o Initiated 1L therapy for AML with VEN-based regimen between 01 December 2018 and 31 December 2019.
• ≥18 years of age at index therapy initiation.
• ≥6 months of follow-up from initiation of index therapy unless died, with known date of death.
• Known cytogenetic risk profile at the time of index therapy.
• ≥1 bone marrow biopsy completed following index therapy initiation.

Exclusion criteria
Patients meeting any of the following criteria were not included in the study:
• Patients who received treatment for AML as part of a clinical trial.
• Patients with diagnosis of any other malignancy (except for non-melanoma skin cancer) at the time of treatment of AML.
o Patients with diagnosis of AML and non-melanoma skin cancer at the time of treatment of AML were not excluded.
• A patient with a record of 1 or more of the following confounding diagnoses at any time during data availability: acute lymphoblastic leukemia; acute promyelocytic leukemia, aggressive systemic mastocytosis; hypereosinophilic syndrome and/or chronic eosinophilic leukemia; dermatofibrosarcoma protuberans; or gastrointestinal stromal tumors.

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

Acute Myeloid Leukemia (AML) Patients

Estimated number of subjects

150

Study design details

Outcomes

Disease response, Transfusion independence (TI), event-free/relapse-free survival (EFS/RFS), and overall survival (OS) for AML patients treated with GLAS-based regimen

Data analysis plan

Each cohort will be described independently, no comparisons of patient characteristics or outcomes between GLAS- and VEN-treated patients will be conducted. The primary clinical outcomes of interest include TI, duration of therapy, disease response, duration of response, EFS, RFS, and OS. Time to event outcomes will be analyzed using the Kaplan-Meier method. Comparisons of time to event outcomes will be made using a Cox proportional hazards model or other parametric techniques as appropriate. Experience of toxicities will only be described for the VEN-treated cohort. Details of the data analysis will be provided in the statistical analysis plan.

Documents

Study results

PFI_AML Glasdegib CRF_Final Report 20210207_vFinal_EU-PASS_Upload.pdf
(1.11 MB)

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)

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