French Observational study on patients' Characteristics, Utilization and Survival outcomes in Gilteritinib-treated patients (FOCUS)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000597

Study ID

1000000597

DARWIN EU® study

No

Study countries

☐ France

Study description

Acute myeloid leukemia (AML) is a type of cancer when the bone marrow makes too many abnormal white blood cells. Gilteritinib is an approved treatment for people with AML with the faulty FLT3 gene who haven’t responded to previous treatment, or their cancer came back after previous treatment.

Study status

Planned

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Franck Bruon

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/01/2025

Actual: 07/01/2025

Study start date
Planned: 31/05/2025

Data analysis start date
Planned: 30/06/2025

Date of interim report, if expected
Planned: 31/08/2025

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd.

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

2215-MA-3585

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

This is a longitudinal cohort study of patients with an Acute Myeloid Leukemia (AML), using the Magellan database. Magellan is a copy of the French national Health insurance claims data from Système National des Données de Santé (SNDS).

Main study objective:
The main aims of this study are to understand how people with AML are managed in France. This includes how often new cases of this AML occur, how many take gilteritinib and how long before they started taking it.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medicinal product name
XOSPATA 40 MG - FILM-COATED TABLET

Study drug International non-proprietary name (INN) or common name
GILTERITINIB

Anatomical Therapeutic Chemical (ATC) code
(L01EX13) gilteritinib
gilteritinib

Medical condition to be studied
Acute myeloid leukaemia

Population studied

Short description of the study population

This study will use information from the French national health database and health insurance records in France to learn more about people with AML who use gilteritinib. This study will check what happened to people who received specialist care between 2019 and 2023.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

15000

Study design details

Outcomes

Population 1 – patients with AML diagnosis over the study period

• Incidence of AML patient

• Prevalence of AML patients

• Time-to gilteritinib initiation

Population 2 – patients with AML diagnosis and treated with gilteritinib over the study period

• Incidence of AML patient

• Prevalence of AML patients

Population 3 – patients with AML diagnosis, treated with gilteritinib and with HSCT over the study period

• Overall survival from HSCT

Data analysis plan

Incidence and Prevalence: Count of the annual number of patients with AML receiving secondary care each year. Count of the monthly number of patients treated with gilteritinib.

Overall Survival from HSCT: Population-based summary: Kaplan-Meier curve, censoring patients at end of study.

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 source(s)

Système National des Données de Santé (French national health system main database)

Data sources (types)

Administrative healthcare records (e.g., claims)

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