Retrospective observational study of the conditions of use, safety and efficacy of MYLOTARG® (Gemtuzumab Ozogamicin, GO) in the treatment of patients with newly diagnosed CD33-positive acute myeloid leukaemia (AML). (MYLobs)

First published: 07/01/2022

Last updated: 18/12/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS44551

Study ID

49206

DARWIN EU® study

No

Study countries

France

Study description

A multicentre retrospective observational study, with no impact on the treatment of patients. The target population will include previously untreated CD33-positive AML patients having initiated a MYLOTARG® treatment between 01 December 2014 and 31th October 2022. For each patient, monitoring will extend from the initiation date of the MYLOTARG® treatment, to the date of death or the end of data collection (between 01 January 2022 and 30 June 2022 at the latest), the earliest of these 2 dates.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Karin GOGAT MARCHAND Karin.GogatMarchant@pfizer.com

Study contact

Karin.GogatMarchant@pfizer.com

Primary lead investigator

Karin GOGAT MARCHAND

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/06/2021

Actual: 10/11/2021

Study start date

Planned: 01/01/2022

Actual: 07/04/2022

Date of final study report

Planned: 31/03/2023

Actual: 19/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The purpose of this study is to describe the use, efficacy and safety of MYLOTARG® in real-world conditions.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicentre retrospective observational study

Study drug and medical condition

Medical condition to be studied

Acute myeloid leukaemia

Additional medical condition(s)

untreated CD33-positive acute myeloid leukaemia (AML) patients aged 15 years and older, with the exception of acute promyelocytic leukaemia (APL)

Population studied

Age groups

- Adolescents (12 to < 18 years)
- 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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

130

Study design details

Data analysis plan

For continuous variables, the usual statistics (n, missing n, mean, standard deviation (SD), median, first and third quartile (Q1 and Q3), minimum and maximum) are presented. For discrete variables, the usual statistics (n, missing n, frequency and percentage) will be given. Unless stated otherwise in the SAP, percentages are only calculated for items completed and missing data will be excluded. The EFS endpoint criterion will be presented using the Kaplan-Meier method with the associated survival curve. Standard statistics will be used to summarise the response endpoint, tolerance endpoints, patient and disease characteristics at initiation of treatment and subsequent treatments. An exploratory analysis will also be performed of patients treated under the ATU and those treated post-ATU. The percentage of VOD cases will be provided with its two2-sided 95% confidence interval (Clopper-Pearson exact method). Methodology for summary and statistical analyses of data collected in SAP.

Documents

Study report

B1761036_MYLObs_CSR_v1.0_clean Final_19Dec2023.pdf (3.42 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

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes