A Non-Interventional Post-Authorisation Safety Study to Characterize Toxicity following Gemtuzumab Ozogamicin Treatment and Hematopoietic Stem Cell Transplantation in Adult Patients with Acute Myeloid Leukemia.

First published: 02/10/2020

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Study Planned

Administrative details

EU PAS number

EUPAS37475

Study ID

37476

DARWIN EU® study

No

Study countries

United States

Study description

This non-interventional study is being conducted to characterize toxicity after hematopoietic stem cell transplantation (HSCT) in adult patients who receive GO post-approval in the US

Study status

Planned

Research institutions and networks

Institutions

Center for International Blood and Marrow Transplant Research (CIBMTR)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kofi Asomaning

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/07/2020

Study start date

Planned: 02/09/2021

Date of final study report

Planned: 30/03/2026

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

Other study registration identification numbers and links

B1761034

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

This non-interventional study is being conducted to characterize toxicity after hematopoietic stem cell transplantation (HSCT) in adult patients who receive GO post-approval in the US

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC05) gemtuzumab ozogamicin

gemtuzumab ozogamicin

Medical condition to be studied

Acute myeloid leukaemia

Population studied

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

200

Study design details

Outcomes

<IF YES, DESCRIBE, MAX 400 CHARACTERS>Patient-, disease- and HSCT-related characteristics, including details of all prior anti-cancer therapiesTiming of GO treatment prior to HSCT, Incidence of post-HSCT safety events of interest including hepatic VOD/SOS,Transplant-related mortality, non-transplant related mortality, relapse, event-free survival, survival, cause of death

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Data analysis plan

Descriptive statistics (ie, frequency, percent, mean, median, standard deviation as appropriate depending on data type) will be used to summarize demographic and baseline clinical characteristics of patients accrued in the study. The cumulative incidence of each safety outcome will be estimated using the cumulative incidence approach (incidence proportion).Cumulative Incidence = (Total new cases during follow-up period / Total persons at risk during follow-up period)

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)

Disease registry

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