GO-First: Real-world treatment patterns and effectiveness outcomes associated with gemtuzumab ozogamicin in first-line Acute Myeloid Leukaemia

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Last updated: 22/07/2024

Study Planned

Administrative details

EU PAS number

EUPAS49268

Study ID

50630

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium
- ☐ Germany

Study description

Gemtuzumab ozogamicin (GO) Mylotarg® is an antibody-drug conjugate used for the treatment of acute myeloid leukemia (AML) patients with myeloid cells that express the CD33 receptor. The ALFA 0701 was a multi-centre Phase 3 trial investigating the efficacy of GO combined with chemotherapy or chemotherapy alone as a treatment for first-line CD33+ AML. There is limited real-world knowledge of GO in combination with chemotherapy in a population similar to the trial, using GO similar to the trial. The 'GO-First' study will retrospectively identify real-world patients from Austria, Belgium and Germany who have been treated with GO in a first-line AML setting and their associated treatment patterns and outcomes.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

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Institution

University of Cologne

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Medical University of Vienna

Austria

First published: 01/02/2024

Last updated: 26/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

University of Cologne Germany, UZ Leuven Belgium, AZ Sint Jan Brugge Belgium, UZ Brussel Belgium, Medical University of Vienna Austria, Arbeitsgemeinschaft Medikamentöse Tumortherapie (AGMT) Austria

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Russell-Smith Alexander

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/01/2023

Study start date
Planned: 16/01/2023

Date of final study report
Planned: 30/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

B1761038 GO-First Protocol 12Oct22 v1.0_FINAL.pdf(695.13 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

Pfizer study number B1761038

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

This study aims to describe treatment patterns and outcomes of front-line AML patients treated with Mylotarg in the real-world in Austria, Belgium and Germany.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

MYLOTARG

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

Co-Primary objectives: - To describe the patient demographics and clinical characteristics of patients treated with GO in intermediate and favourable

cytogenetic risk, de novo AML. - To describe GO treatment patterns in the study population, including the number of doses of GO and the timing of GO doses in first line (1L) treatment. To describe first-line (1L) treatment effectiveness outcomes for the study population, including: - Time-to-next treatment - Survival (event-free survival EFS, relapse-free survival RFS, overall survival OS)

Data analysis plan

Frequencies and percentages will be reported for categorical variables, including the percentage of missing/unknown data, while counts, number of missing, means, medians, standard deviations (SDs), standard errors (SEs), first and third quartiles, minimum and maximum values will be reported for continuous numeric variables. Where applicable, all estimates will be described with accompanying 95% confidence intervals (CI). Time to event analyses will be conducted, with Kaplan-Meier (KM) curves and 95% CI estimated for KM curves outputted. Finally, Sankey diagrams will be generated to aid in interpretation of the analysis of treatment patterns. Data analysis will be aligned with data extracted/collected from all data sets. Where specific variables or outcomes cannot be assessed/described subgroup analyses could be conducted for a subset of patients from certain data sources.

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), other

Arbeitsgemeinschaft Medikamentöse Tumortherapie (AGMT) Austria

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