Post-authorisation safety study of allogeneic haematopoietic cell transplantation in patients treated with mogamulizumab

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Study Planned

Administrative details

EU PAS number

EUPAS31436

Study ID

31437

DARWIN EU® study

No

Study countries

☐ United States

Study status

Planned

Research institutions and networks

Institutions

Center for International Blood and Marrow Transplant Research (CIBMTR)

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Institution

Networks

Center for International Blood and Marrow Transplant Research (CIBMTR)

Contact details

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Study contact

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Primary lead investigator

Mehdi Hamadani

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 12/08/2019

Study start date
Planned: 01/01/2019

Date of final study report
Planned: 31/07/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Kyowa Kirin Services

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

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:

The primary objective is to assess non-relapse mortality (death without prior relapse or progression) among patients who were either treated with mogamulizumab, (alone as a single agent or in combination with other therapies) within one year prior to alloHCT, or treated with mogamulizumab, (alone as a single agent or in combination with other therapies), within 18 months after alloHCT.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC25) mogamulizumab

mogamulizumab

Medical condition to be studied

Cutaneous T-cell lymphoma

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

50

Study design details

Outcomes

Cumulative incidence of non-relapse death (NRM) at day 100, day 180, 1-year and 2-years: Time to death without evidence of relapse. Relapse is the competing risk. The secondary objectives are to evaluate the cumulative incidence of: acute GVHD by grade, steroid-refractory GVHD, chronic GVHD, GVHD-free survival, critical illness, primary graft failure, potentially immune-mediated adverse events, hepatic veno-occlusive disease and incidence of relapse.

Data analysis plan

Tabulations of summary statistics, graphical presentations, and statistical analyses will be performed using SAS system as validated software. Descriptive statistics (mean, standard deviation SD, median, minimum, and maximum) for continuous variables and frequency distributions and percentages for discrete variables will be utilized.

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)

Other

Data sources (types), other

Prospective patient-based data collection, Modified Transplant Essential Data (TED)

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