A non-interventional post authorisation registry of patients treated with pomalidomide for relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy (CC-4047-MM-015 (ARTIMiDs))

First published: 03/09/2014

Last updated: 20/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS7252

Study ID

39569

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] Germany
- [ ] Italy
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

Patients will be recruited from approximately 80 hematology/oncology sites in European countries. In all cases, the decision to treat the patient will be made prior to the decision to enroll the patient into the registry. The registry will remain open until 500 patients will have received at least 3 cycles of pomalidomide. As the anticipated withdrawal rate before the end of cycle 2 is estimated to be approximately 24% (based on Celgene-sponsored pivotal study CC-4047-MM-003) approximately 750 MM patients will need to be enrolled. Following completion of treatment, patients will be followed up after 30 days and then every 6 months to assess status. All patients registered will be followed up prospectively for up to 3 years following the end of pomalidomide treatment. During this time the incidence of second primary malignancies (SPM), overall survival and any occurrence of a pregnancy will be assessed. Patients will be recruited consecutively. If the reason for discontinuation for patients from the registry is due to an adverse event, the follow up of the adverse event will not be time limited and will continue until resolution or stabilization or when, no additional useful information can be obtained from the

event or the patient withdraws consent to anymore data being collected.

Study status

Ongoing

Research institutions and networks

Institutions

Celgene International

First published: 01/02/2024

Last updated: 01/02/2024

Institution

See attached document for site list See attached document for site list

Contact details

Study institution contact

Medical Affairs Celgene International Sarl

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Study contact

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Primary lead investigator

Medical Affairs Celgene International Sarl

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/11/2013

Study start date

Planned: 01/11/2014

Actual: 26/06/2014

Date of final study report

Planned: 31/08/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celgene International Sarl

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition 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

Drug utilisation

Main study objective:

To characterize the safety profile of pomalidomide in a non interventional post-authorisation setting in previously treated MM patients to enhance real world safety knowledge beyond the clinical trial safety observed

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AX06) pomalidomide

pomalidomide

Medical condition to be studied

Plasma cell myeloma

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

750

Study design details

Outcomes

To characterize and determine the incidence of important identified and potential risks as outlined in the risk management plan (RMP) among previously treated MM patients who are currently being treated with pomalidomide in a post-marketing setting. -To describe and assess the effectiveness, implementation and compliance of the Celgene PPP for patients recruited in this registry.-To describe the type of myeloma treatment administered immediately prior to receiving pomalidomide.

Data analysis plan

Data from all patients who receive at least one dose of treatment will be analyzed.For demographic and baseline characteristics data, descriptive statistics (mean, standarddeviation, median, minimum, and maximum) will be

provided for continuous variables,categorical variables will be summarized using frequency tabulations.Kaplan-Meier and/or competing risk procedures will be used to characterize time to onset for adverse events of special interest, when appropriate. For SPM analyses, product limit estimators will be calculated with and without consideration of competing risks.Univariate and (when feasible) multivariate Cox proportional hazards models will be employed to identify demographic and clinical factors predictive of key identified and potential risks.

Documents

Study, other information

ARTIMiDs-CC-4047-MM015_Activated site addresses-ENCePP-16Mar2015 i.pdf (21.96 KB)

CC-4047-MM-015_Site List Encepp 31Dec2020.pdf(23.93 KB)

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

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