A prospective non-interventional post-authorization safety study (PASS) of lenalidomide in previously untreated adult multiple myeloma patients who are not eligible for transplant (“transplant noneligible” [TNE]) (“Revlimid® TNE NDMM PASS”) (CC-5013-MM-034)

First published: 12/05/2017

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS10153

Study ID

39598

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

The purpose of the Revlimid TNE NDMM Registry is to provide accurate clinical information regarding the safety profile of lenalidomide relative to other first-line regimens when prescribed for TNE NDMM patients across a variety of diverse clinical settings, particularly with respect to the cardiovascular safety profile of lenalidomide. The study will gather extensive risk factor information at baseline and throughout follow-up to aid in the interpretation of any observed differences in the incidence of cardiovascular events between the two cohorts. Other safety endpoints of interest will be characterized through standard follow-up procedures.

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

ctt.group@bms.com

Study contact

ctt.group@bms.com

Primary lead investigator

Medical Affairs Celgene International Sarl

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 10/05/2016

Actual: 10/05/2016

Study start date
Planned: 31/03/2017

Actual: 31/03/2017

Date of final study report
Planned: 13/10/2026

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)

Other study registration identification numbers and links

UTN number: U1111-1194-5810

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 compare the incidence of cardiovascular events between TNE NDMM patients treated with a first-line lenalidomide-containing regimen and those treated with a first-line nonlenalidomide-containing regimen.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

888

Study design details

Outcomes

To identify, quantify, and characterize risk factors for cardiovascular events in this population of TNE NDMM patients. Document renal function throughout therapy and to ascertain the incidence of renal dysfunctionDocument the incidence and severity of infections, including but not limited to pneumoniaDescribe the incidence of SPM (including hematologic and nonhematologic invasive malignancies and non-melanoma skin cancers) Characterize the safety profile of first-line regimens among TNE NDMM patients

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Data analysis plan

Continuous demographic and baseline variables will be summarized using descriptive statistics while categorical variables will be summarized using

frequency tabulations. Dose and duration information for lenalidomide and other first-line MM therapies other medications included in the treatment regimen other supportive care medications, concomitant medications for thromboprophylaxis, and concomitant medications used for lenalidomide, cardiovascular/cerebrovascular disease/diabetes will be summarized. Pertinent risk factor information for cardiovascular events will be tabulated and presented separately for patients treated with a lenalidomide-containing regimen and patients treated with other first-line regimens. Patients treated with other first-line regimens will be subgrouped by main therapy for descriptive purposes Individual patient listings will be provided. All concomitant treatment usage documented during the study period will be summarized in frequency tabulations

Documents

Study, other information

MM034_Site list_CT.gov_12May17.pdf(121.84 KB)

Site list_ENCEPP_CC-5013-MM-034_01Feb2021.pdf(82.51 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