A Safety Study of Lenalidomide in Previously Untreated Adult Multiple Myeloma Patients Who Are Not Eligible for Transplant

ClinicalTrials.gov Identifier: NCT03106324

Recruitment Status: Recruiting
First Posted: April 10, 2017
Last Update Posted: July 3, 2018

See Contacts and Locations

Sponsor:
Celgene

Information provided by (Responsible Party):
Celgene

Study Description

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Brief Summary:
This post authorization safety study is designed as prospective non interventional study for patients with newly diagnosed multiple myeloma who are not eligible for transplant. The objective is to compare the incidence of cardiovascular events between patients treated with a first-line lenalidomide containing regimen and those treated with a first-line non-lenalidomide containing regimen. Treatment in both cohorts will be done according to standard care. The study will gather risk factor information at baseline and throughout follow-up. Any cardiovascular event occurring will be assessed by an independent committee. Other safety endpoints will be collected through standard procedures. Observation period will be 3 years on treatment, with an additional evaluation of cardiovascular events 6 months' post treatment and a follow up period until 5 years after inclusion. During follow up the incidence of second primary malignancies (SPM) and overall survival will be assessed.

Condition or disease	Intervention/treatment
Multiple Myeloma	Drug: Revlimid (lenalidomide)

Study Design

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Study Type: Observational [Patient Registry]
Estimated Enrollment: 888 participants

Observational Model:	Cohort
Time Perspective:	Prospective
Target Follow-Up Duration:	8 Years
Official Title:	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])
Actual Study Start Date:	March 31, 2017
Estimated Primary Completion Date:	March 31, 2025
Estimated Study Completion Date:	March 31, 2025

Resource links provided by the National Library of Medicine

Genetics Home Reference related topics:
Multiple myeloma

MedlinePlus related topics: Multiple Myeloma

Drug Information available for: Lenalidomide

Genetic and Rare Diseases Information Center resources:
Multiple Myeloma

U.S. FDA Resources

Groups and Cohorts

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Group/Cohort	Intervention/treatment
TNE NDMM patients treated with lenalidomide regimen Newly diagnosed multiple myeloma patients who are not eligible for transplant and who are treated with a first-line regimen containing lenalidomide	Drug: Revlimid (lenalidomide) Treatment with first line Revlimid containing regimen as prescribed in routine clinical practice
TNE NDMM patients treated with non-lenalidomide Newly diagnosed multiple myeloma patients who are not eligible for transplant and who are treated with a first-line regimen not containing lenalidomide	Drug: Revlimid (lenalidomide) Treatment with first line Revlimid containing regimen as prescribed in routine clinical practice

Outcome Measures

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Primary Outcome Measures:

1. Incidence of cardiovascular events [Time Frame: Approximately 8 years]

   Number of participants with cardiovascular adverse events

Secondary Outcome Measures:

1. Incidence of renal impairment in NDMM patients [Time Frame: Approximately 8 years]

To document renal function among TNE NDMM patients treated with a first-line regimen

2. Incidence of infections in NDMM patients [Time Frame: Approximately 8 years]

   To document the severity of infections among TNE NDMM patients treated with a first-line regimen.

3. Incidence of Second primary malignancy (SPM) in TNE NDMM patients treated with any first line regimen [Time Frame: Approximately 8 years]

   Secondary primary malignancies will be categorized according to whether they are invasive and non-invasive malignancies.

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

Patients with newly diagnosed multiple myeloma (NDMM) who are not eligible for transplant (TNE) starting their first treatment for multiple myeloma. Patients receiving any first line regimen can be included into the study. Decision for treatment needs to be done before inclusion into the trial.

Criteria

Inclusion Criteria:

1. Must have understood and voluntarily signed the Informed Consent Form (ICF)
2. Age ≥ 18 years at the time of signing the ICF
3. Newly diagnosed with multiple myeloma
4. Must not be eligible for transplant
5. Will be treated with a first-line lenalidomide-containing or nonlenalidomide-containing regimen, or currently is being treated with a first-line regimen and has received less than 2 cycles.

Exclusion Criteria:

1. Prior treatment for Monoclonal gammopathy of undetermined significance (MGUS) or smoldering myeloma with lenalidomide, thalidomide, or pomalidomide or any agent considered to be a first-line Multiple myeloma (MM) therapy.
2. Prior treatment with lenalidomide, thalidomide, or pomalidomide or any agent considered to be a first-line MM therapy through clinical trial participation or patient access program
3. Two or more complete cycles of first-line therapy or any agent considered to be a firstline MM therapy for

newly diagnosed multiple myeloma (NDMM) treatment before study enrollment

4. Refusal to participate in the Revlimid Transplant noneligible (TNE) Newly diagnosed multiple myeloma (NDMM) Post-authorization safety study (PASS) or current participation in the treatment phase of an interventional clinical trial.

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03106324***

Contacts

Contact: Associate Director Clinical Trial Disclosure 1-888-260-1599 clinicaltrialdisclosure@celgene.com

Show 85 Study Locations

Sponsors and Collaborators

Celgene

Investigators

Study Director: Elisabeth Kueenburg, MD Study physician for Celgene

More Information

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Responsible Party:	Celgene
ClinicalTrials.gov Identifier:	NCT03106324 History of Changes
Other Study ID Numbers:	CC-5013-MM-034
	U1111-1194-5810 (Other Identifier: World Health Organization)
First Posted:	April 10, 2017 Key Record Dates
Last Update Posted:	July 3, 2018
Last Verified:	July 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Keywords provided by Celgene:

Multiple Myeloma	PASS
Non transplant eligible	Non-interventional
Revlimid	Lenalidomide

Additional relevant MeSH terms:

Multiple Myeloma	Lenalidomide
Neoplasms, Plasma Cell	Thalidomide
Neoplasms by Histologic Type	Immunologic Factors
Neoplasms	Physiological Effects of Drugs

Hemostatic Disorders
Vascular Diseases
Cardiovascular Diseases
Paraproteinemias
Blood Protein Disorders
Hematologic Diseases
Hemorrhagic Disorders
Lymphoproliferative Disorders
Immunoproliferative Disorders
Immune System Diseases

Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Growth Substances
Growth Inhibitors
Antineoplastic Agents
Immunosuppressive Agents
Leprostatic Agents
Anti-Bacterial Agents
Anti-Infective Agents