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A Study to Evaluate 3 Dose Schedules of Daratumumab in Participants With Smoldering Multiple Myeloma

This study is currently recruiting participants. (see Contacts and Locations)

Verified November 2015 by Janssen Research & Development, LLC

Sponsor:
Janssen Research & Development, LLC

Information provided by (Responsible Party):
Janssen Research & Development, LLC

ClinicalTrials.gov Identifier:
NCT02316106

First received: December 10, 2014
Last updated: November 27, 2015
Last verified: November 2015
History of Changes

Purpose

The purpose of this study is to evaluate three daratumumab dose schedules in participants with Smoldering Multiple Myeloma.

Condition	Intervention	Phase
Smoldering Multiple Myeloma (SMM)	Drug: daratumumab	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Randomized Phase 2 Trial to Evaluate Three Daratumumab Dose Schedules in Smoldering Multiple Myeloma

Resource links provided by NLM:

MedlinePlus related topics: Multiple Myeloma

Genetic and Rare Diseases Information Center resources: Multiple Myeloma

U.S. FDA Resources

Further study details as provided by Janssen Research & Development, LLC:

Primary Outcome Measures:

- The percentage of participants who achieve a complete response (CR) [Time Frame: Up to approximately 24 months] [Designated as safety issue: No]

  CR, defined having negative immunofixation on the serum and urine, and <5% plasma cells (PCs) in bone marrow.

- The percentage of participants that have an event (disease progression or death) per patient-year [Time Frame: Up to approximately 30 months] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- The percentage of participants who are minimal residual disease (MRD) negative [Time Frame: Up to 5.5 years] [Designated as safety issue: No]

- Time to next treatment (TNT) [Time Frame: Up to 5.5 years] [Designated as safety issue: No]

  TNT, defined as the time from the date of randomization to the date of the first subsequent multiple myeloma treatment.

- The percentage of participants who achieve a Complete Response (CR) or a Partial Response (PR) [Time Frame: Up to 5.5 years] [Designated as safety issue: No]

  See definition of CR above. PR, defined as ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 hours.

- The median time of progression free survival (PFS) [Time Frame: Up to 5.5 years] [Designated as safety issue: No]

  PFS, defined as the time from the date of randomization to the date of initial documented disease progression (PD) or date of death, whichever occurs first.

- The percentage of participants with symptomatic multiple myeloma [Time Frame: Up to 5.5 years] [Designated as safety issue: No]
- Response to first subsequent multiple myeloma treatment [Time Frame: Up to 5.5 years] [Designated as safety issue: No]
- Overall survival rate [Time Frame: Up to 5.5 years] [Designated as safety issue: No]

Estimated Enrollment:	120
Study Start Date:	May 2015
Estimated Study Completion Date:	November 2020
Estimated Primary Completion Date:	November 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Arm A (Long Intense)	Drug: daratumumab 16 mg/kg administered by intravenous (IV) infusion once every week in Cycle 1, every other week in Cycle 2 and Cycle 3, every 4 weeks in Cycle 4 to Cycle 7, and from Cycle 8 to Cycle 20 on Day 1 of each cycle. Treatment cycles are 8 weeks in length.
Experimental: Arm B (Intermediate)	Drug: daratumumab 16 mg/kg administered by IV infusion once every week in Cycle 1, and then on Day 1 of each cycle from Cycle 2 to Cycle 20. Treatment cycles are 8 weeks in length.
Experimental: Arm C (Short Intense)	Drug: daratumumab 16 mg/kg administered by IV infusion once every week in Cycle 1 only. Treatment cycles are 8 weeks in length.

Detailed Description:

This is a randomized, open-label (identity of assigned treatment will be known to participants and study staff), 3-arm (3 treatment groups), multicenter study of daratumumab in participants diagnosed with intermediate or high-risk Smoldering Multiple Myeloma (SMM [ie, early disease without any symptoms]). Participants will be randomized (assigned by chance) to one of 3 treatment groups to receive daratumumab. Each treatment group will investigate 1 of 3 dosing schedules of daratumumab. The study will include a 28-Day Screening Phase, a Treatment Phase of 1 to 20 treatment cycles (each cycle is 8 weeks in duration for total period of 8 to 160 weeks), and a Follow up Phase of 4-weeks from the last dose of study drug. The Follow-up Phase will continue until death, lost to follow up, consent withdrawal, or study end, whichever occurs first. The end of the study will occur approximately 4 years after the last participant enrolled receives a first dose of study drug. Disease assessments will be performed every 8 weeks in the first year and then every 16 weeks until disease progression. Safety will be monitored throughout the study.

Eligibility

Ages Eligible for Study:	18 Years to 99 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Diagnosis of smoldering multiple myeloma (SMM) for less than 5 years
- Have a confirmed diagnosis of intermediate or high-risk SMM, and an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1.

Exclusion Criteria:

- Active multiple myeloma,requiring treatment as defined by the study protocol
- Primary systemic AL (immunoglobulin light chain) amyloidosis

- Prior or concurrent exposure to any of the following: approved or investigational treatments for SMM or/and multiple myeloma, daratumumab or other anti CD-38 therapies, treatment with corticosteroids with a dose greater than (>) 10 milligram (mg) prednisone per day or equivalent and bone-protecting agents (eg, bisphosphonates, denosumab) or are only allowed if given in a stable dose and for a nonmalignant condition, or received an investigational drug (including investigational vaccines) or used an invasive investigational medical device within 4 weeks before Cycle 1, Day 1
- History of malignancy (other than SMM) within 3 years before the date of randomization, except for the following if treated and not active: basal cell or nonmetastatic squamous cell carcinoma of the skin, cervical carcinoma in situ, ductal carcinoma in situ of breast, or International Federation of Gynecology and Obstetrics (FIGO) Stage 1 carcinoma of the cervix
- Known chronic obstructive pulmonary disease (COPD) OR moderate or severe persistent asthma within the past 2 years
- Any concurrent medical or psychiatric condition or disease (eg, autoimmune disease, active systemic disease, myelodysplasia) that is likely to interfere with the study procedures or results, or that in the opinion of the investigator, would constitute a hazard for participating in this study

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02316106

Contacts

Contact: Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions: JNJ.CT@sylogent.com

Show 73 Study Locations

Sponsors and Collaborators

Janssen Research & Development, LLC

Investigators

Study Director: Janssen Research & Development, LLC Clinical Trial Janssen Research & Development, LLC

More Information

Additional Information:

To learn how to participate in this trial please click here.

No publications provided

Responsible Party:	Janssen Research & Development, LLC
ClinicalTrials.gov Identifier:	NCT02316106 History of Changes
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Study First Received:	December 10, 2014
Last Updated:	November 27, 2015
Health Authority:	Australia: Therapeutic Goods Administration Canada: Health Canada Czech Republic: State Institute for Drug Control France: Agence Nationale de Sécurité du Médicament et des produits de santé Germany: Paul-Ehrlich-Institut United Kingdom: Medicines and Healthcare Products Regulatory Agency Israel: State of Israel - Ministry of Health Italy: Italian Medicines Agency Netherlands: Medicines Evaluation Board Russia: Ministry of Health of the Russian Federation Turkey: Ministry of Health United States: Food and Drug Administration Germany: Ethics Commission Great Britain: Medicines and Healthcare Products Regulatory Agency

Keywords provided by Janssen Research & Development, LLC:
Smoldering multiple myeloma (SMM)
Daratumumab

Additional relevant MeSH terms:

Multiple Myeloma	Lymphoproliferative Disorders
Neoplasms, Plasma Cell	Neoplasms
Blood Protein Disorders	Neoplasms by Histologic Type
Cardiovascular Diseases	Paraproteinemias
Hematologic Diseases	Vascular Diseases
Hemorrhagic Disorders	Antibodies, Monoclonal
Hemostatic Disorders	Immunologic Factors
Immune System Diseases	Pharmacologic Actions
Immunoproliferative Disorders	Physiological Effects of Drugs

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