Safety and Efficacy of Pomalidomide, Bortezomib and Low-dose Dexamethasone in Subjects With Relapsed or Refractory Multiple Myeloma (OPTIMISMM)

Purpose

The purpose of this study is to compare the efficacy of the combination of Pomalidomide, Bortezomib and Dexamethasone to the combination of Bortezomib and Dexamethasone in patients with relapsed/refractory multiple myeloma. This study will also assess how safe the combination of Pomalidomide, Bortezomib and Dexamethasone is compared to the combination of Bortezomib and Dexamethasone.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Multiple Myeloma</td>
<td>Drug: Pomalidomide</td>
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<tr>
<td></td>
<td>Drug: Bortezomib</td>
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<td>Drug: Dexamethasone</td>
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</table>

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 Phase 3, Multicenter, Randomized, Open-label Study to Compare the Efficacy and Safety of Pomalidomide (POM), Bortezomib (BTZ) and Low-Dose Dexamethasone (LD-DEX) Versus Bortezomib and Low-Dose Dexamethasone in Subjects With Relapsed or Refractory Multiple Myeloma (MM)

Resource links provided by NLM:

MedlinePlus related topics: Multiple Myeloma

Drug Information available for: Dexamethasone, Dexamethasone sodium phosphate, Pomalidomide, Dexamethasone acetate, Bortezomib

Genetic and Rare Diseases Information Center resources: Multiple Myeloma

U.S. FDA Resources

Further study details as provided by Celgene Corporation:

Primary Outcome Measures:

* Progression Free Survival [Time Frame: Up to 1 year] [Designated as safety issue: No]
  The length of time during and after the treatment that participants in the study live without the disease getting worse
Secondary Outcome Measures:
- Overall Survival [Time Frame: Up to 5 years] [Designated as safety issue: No]
  The length of time from start of study treatment that participants in the study are alive
- Adverse Event [Time Frame: Up to 1 year] [Designated as safety issue: Yes]
  Number of participants with adverse events
- Overall Response Rate [Time Frame: Up to 1 year] [Designated as safety issue: No]
  The percentage of participants who respond to study treatment
- Duration of Response [Time Frame: Up to 1 year] [Designated as safety issue: No]
  The length of time from when participants respond to the study treatment to when their disease gets worse

Estimated Enrollment: 450
Study Start Date: January 2013
Estimated Study Completion Date: April 2022
Estimated Primary Completion Date: April 2018 (Final data collection date for primary outcome measure)

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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td><strong>Experimental: Pomalidomide, Bortezomib and Low Dose Dexamethasone</strong>&lt;br&gt;4 mg of Pomalidomide will be taken orally on Days 1-14 of a 21-day cycle along with 1.3 mg/m² of Bortezomib administered subcutaneously on Days 1, 4, 8 and 11 of 21 days for cycles 1-8 and on days 1, 8 of 21 days for cycle 9 and onward until disease progression, and Dexamethasone 20 mg/day [≤ 75 years old] or 10 mg/day [&gt; 75 years old] orally on days 1, 2, 4, 5, 8, 9, 11, 12 of 21 days for cycles 1-8 and on days 1, 2, 8, 9 of 21 days for cycles 9 and onward until disease progression.</td>
<td>Drug: Pomalidomide&lt;br&gt;Pomalidomide 4 mg will be taken orally on Days 1-14 of a 21-day cycle. Other Names:&lt;br&gt;- Oral Pomalidomide&lt;br&gt;- CC-4047&lt;br&gt;Drug: Bortezomib&lt;br&gt;Bortezomib 1.3 mg/m² will be administered subcutaneously on Days 1, 4, 8 and 11 of 21 days for cycles 1-8 and on Days 1, 8 of 21 days for cycle 9 and onward until disease progression. Other Name: Velcade&lt;br&gt;Drug: Dexamethasone&lt;br&gt;Dexamethasone 20 mg/day [≤ 75 years old] or 10 mg/day [&gt; 75 years old] will be taken orally on Days 1, 2, 4, 5, 8, 9, 11, 12 of 21 days for cycles 1-8 and on Days 1, 2, 8, 9 of 21 days for cycles 9 and onward until disease progression.</td>
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<tr>
<td><strong>Active Comparator: Bortezomib and Low Dose Dexamethasone</strong>&lt;br&gt;1.3 mg/m² of Bortezomib will be administered subcutaneously on Days 1, 4, 8 and 11 of 21 days for cycles 1-8 and on Days 1, 8 of 21 days for cycle 9 and onward until disease progression along with Dexamethasone 20 mg/day [≤ 75 years old] or 10 mg/day [&gt; 75 years old] orally on days 1, 2, 4, 5, 8, 9, 11, 12 of 21 days for cycles 1-8 and on Days 1, 2, 8, 9 of 21 days for cycles 9 and onward until disease progression.</td>
<td>Drug: Bortezomib&lt;br&gt;Bortezomib 1.3 mg/m² will be administered subcutaneously on Days 1, 4, 8 and 11 of 21 days for cycles 1-8 and on Days 1, 8 of 21 days for cycle 9 and onward until disease progression. Other Name: Velcade&lt;br&gt;Drug: Dexamethasone&lt;br&gt;Dexamethasone 20 mg/day [≤ 75 years old] or 10 mg/day [&gt; 75 years old] will be taken orally on Days 1, 2, 4, 5, 8, 9, 11, 12 of 21 days for cycles 1-8 and on Days 1, 2, 8, 9 of 21 days for cycles 9 and onward until disease progression.</td>
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Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Must be ≥ 18yrs at the time of signing informed consent.
- Must have documented diagnosis of multiple myeloma and have measureable disease by serum and urine protein electrophoresis.
- Must have had at least 1 but no greater than 3 prior anti-myeloma regimens.
- Must have documented disease progression during or after their last anti-myeloma therapy.
- All subjects must have received prior treatment with a lenalidomide containing regimen for at least 2 consecutive cycles.

Exclusion Criteria:
- Refractory to prior Bortezomib-containing therapy under the 1.3 mg/m2 dose twice weekly dosing schedule.
- Peripheral neuropathy Grade 3, Grade 4 or Grade 2 within 14 days prior to randomization.
- Non-secretory multiple myeloma.
- Subjects with severe renal impairment requiring dialysis.
- Previous therapy with pomalidomide.

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: NCT01734928

Contacts

Contact: Eva Budz 908-673-9576 ebudz@celgene.com
Contact: Jovanka Solorzano 415-839-7016 jsolorzano@celgene.com

Show 177 Study Locations

Sponsors and Collaborators

Celgene Corporation

Investigators

Study Director: Amine Bensmaine, MD Celgene Corporation

More Information

No publications provided

Responsible Party: Celgene Corporation
ClinicalTrials.gov Identifier: NCT01734928 History of Changes
Other Study ID Numbers: CC-4047-MM-007
Study First Received: November 23, 2012
Last Updated: October 30, 2015
Health Authority: United States: Food and Drug Administration

Keywords provided by Celgene Corporation:
Multiple Myeloma
Pomalidomide

Additional relevant MeSH terms:
Multiple Myeloma
Neoplasms, Plasma Cell
Blood Protein Disorders
Cardiovascular Diseases
Hematologic Diseases
Hemorrhagic Disorders
Bortezomib
Dexamethasone
Dexamethasone 21-phosphate
Dexamethasone acetate
Pomalidomide
Thalidomide
Hemostatic Disorders
Immune System Diseases
Immunoproliferative Disorders
Lymphoproliferative Disorders
Neoplasms
Neoplasms by Histologic Type
Paraproteinemias
Vascular Diseases
BB 1101

Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Anti-Bacterial Agents
Anti-Infective Agents
Anti-Inflammatory Agents
Antiemetics
Antineoplastic Agents
Antineoplastic Agents, Hormonal
Autonomic Agents