Phase III Study of Lenalidomide and Dexamethasone With or Without Elotuzumab to Treat Newly Diagnosed, Previously Untreated Multiple Myeloma

**Trial Description:** A phase 3, randomized, open-label trial of lenalidomide (Revlimid®) /dexamethasone with or without elotuzumab (a monoclonal antibody formerly known as HuLuc63) in previously untreated multiple myeloma.

**Trial Objectives:** To determine whether the addition of elotuzumab to lenalidomide/low-dose dexamethasone will increase progression-free survival.

**Assigned Interventions:** Arm 1) lenalidomide + dexamethasone (active comparator arm); Arm 2) lenalidomide + dexamethasone + elotuzumab (experimental arm)

**Inclusion Criteria:**
- 18 years of age or older
- Newly diagnosed patients with symptomatic myeloma who have not received any prior systemic anti-myeloma therapy AND have measurable disease AND are not candidates for high-dose therapy plus stem-cell transplantation because of age (≥65 years) or coexisting conditions

**Exclusion Criteria:**
- Subjects with non-secretory or oligo-secretory or free light-chain only myeloma
- Smoldering MM, defined as asymptomatic MM with absence of lytic bone lesions
- Monoclonal Gamopathy of Undetermined Significance (MGUS)
- Active plasma cell leukemia
- Positive hepatitis B, C, or Human Immunodeficiency Virus (HIV)

**Currently Recruiting Locations and Telephone Contacts are shown on other side**

For site information outside the United States, please contact clinical.trials@bms.com
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(continued)

Currently Recruiting Locations and Telephone Contacts:

For site information outside the United States, please contact clinical.trials@bms.com (check clinicaltrials.gov for updates on site information)

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Birmingham Hematology & Oncology Associates
Birmingham, Alabama
Contact: Dr. Kevin S. Windsor, 205-803-4389

Arizona
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Tucson, Arizona
Contact: Dr. Manuel R. Modiano, 520-290-2510

California
Alta Bates Summit Comprehensive Cancer Center
Berkeley, California
Contact: Dr. Rajesh Behl, 510-204-3428
Compassionate Care Medical Group
Corona, California
Contact: Dr. Haresh S. Jhangiani, 951-371-2411
Marin Cancer Care
Greenbrae, California
Contact: Dr. Peter D. Eisenberg, 415-925-5000
Medical Oncology Care Association
Orange, California
Contact: Dr. Birlal Bhaskar, 714-541-6622
Sharp Memorial Hospital
San Diego, California
Contact: Dr. Rajesh Belani, 858-637-7888

Connecticut
Yale University School of Medicine
New Haven, Connecticut
Contact: Dr. Madhur Dhadapkar, 203-785-4144/4191

Florida
Florida Cancer Specialists
Fort Myers, Florida
Contact: Dr. James Reeves, Jr., 239-274-9930
Florida Cancer Specialists and Research Institute
Gainesville, Florida
Contact: Dr. Peter Acs, 352-332-3990
Integrated Community Oncology Network
Orange Park, Florida
Contact: Dr. Mehdi Mozei, 904-272-3139
Palm Beach Cancer Institute
West Palm Beach, Florida
Contact: Dr. Shachar Peles, 561-366-4128
Pasco Hernando Oncology Associates
Brooksville, Florida
Contact: Dr. Ruiu Rao, 352-596-1401
Pasco Hernando Oncology Associates
New Port Richey, Florida
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University of Chicago Medical Center
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Contact: Cara Rosenbaum, 773-702-0167

Indiana
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Indianapolis, Indiana
Contact: Dr. Robert F Manges, 317-297-2208
Northern Indiana Cancer Research Consortium
South Bend, Indiana
Contact: Dr. Jose Buffal, 574-677-7390

Iowa
University of Iowa Hospitals and Clinics
Iowa City, Iowa
Contact: Dr. Raymond Hohl, 319-356-8110

Kentucky
Central Baptist Hospital
Lexington, Kentucky
Contact: Dr. Arvinda Padmanabh, 859-276-0414

Louisiana
Cancer Center of Acadiana
Lafayette, Louisiana
Contact: Dr. Victoria Panelli, 337-289-8400
Wills-Kingston Cancer Center
Shreveport, Louisiana
Contact: Dr. Michael Moore, 318-212-8620

Maryland
Greater Baltimore Cancer Center
Baltimore, Maryland
Contact: Dr. Gary Cohen, 443-849-3051
The Harry and Jeanette Weinberg Cancer Institute
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Contact: Dr. Stephen Noga, 443-777-7147

Massachusetts
Dana-Farber Cancer Institute
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Contact: Dr. Jacob Lauthbich, 617-582-7102

Michigan
Henry Ford Health System
Detroit, Michigan
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Missouri
Capitol Comprehensive Cancer Care Clinic
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Contact: Dr. Ali Khoshefat, 573-442-6800
Mercy Medical Research Institute
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Contact: Dr. V. Roger Holden, 417-820-9742
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New York
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St. Luke’s-Roosevelt Hospital Center
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Contact: Dr. Peter Wiernik, 212-636-3338

North Carolina
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Piedmont Hematology Oncology Associates
Winston-Salem, North Carolina
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Cleveland Clinic Wooster Cancer Center
Wooster, Ohio
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The Ohio State University Medical Center
Columbus, Ohio
Contact: Dr. Don Benson Jr., 614-293-8605
Signal Point Clinical Research Center, LLC
Middletown, Ohio
Contact: Dr. Nandagopal Vrindavanam

Oklahoma
Cancer Care Associates
Tulsa, Oklahoma
Contact: Dr. Charles Strnad, 918-292-8085

Pennsylvania
Oncology Hematology of Lehigh Valley
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West Virginia
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Wisconsin
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Dean Medical Center
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