CLINICAL TRIAL FACT SHEET

Clinicaltrials.gov Identifier: NCT02368301

Expanded Access Treatment Protocol CA204-143

An Expanded Access Program for Elotuzumab with Lenalidomide (Revlimid®) and Dexamethasone for Patients with Relapsed or Refractory Multiple Myeloma

**Trial Description:** “Expanded Access” is a process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Elotuzumab is the first monoclonal antibody developed to treat multiple myeloma. In previous clinical trials, we learned that it works better in combination with the immunomodulatory agent Revlimid and the steroid dexamethasone than it does by itself.

**Trial Objectives:** To provide treatment with elotuzumab in combination with Revlimid and dexamethasone for patients with relapsed or refractory myeloma at sites in the United States where licensed physicians determine medical need.

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for Patients with Relapsed or Refractory Multiple Myeloma

Key Eligibility Criteria:
- You must be 18 years or older
- You must have active, relapsed, or refractory myeloma
- You must have received at least one prior line of myeloma therapy
- You may have had a prior line of treatment that included Revlimid only if both of the following are true:
  - your myeloma did not progress while you were taking Revlimid or within 60 days after your last dose, and
  - you did not discontinue taking Revlimid because you had a serious side effect related to Revlimid

Key Exclusion Criteria:
- You must not have plasma cell leukemia
- You must not have serious side effects from previous therapy that interfere with your ability to perform the activities of daily living
- You must not have significant heart disease, including cardiac amyloidosis
- You must not have HIV infection or hepatitis A, B, or C
- You must not have previously participated in a randomized phase III study of elotuzumab, Revlimid, dexamethasone vs Revlimid and dexamethsone or of elotuzumab, Velcade, dexamethsone vs Velcade and dexamethsone.
- You must not have inadequately recovered from prior surgery or myeloma therapy
- You must not have moderate to severe graft-versus-host disease from a prior allogeneic transplant
- You must not have any medical condition that, in the opinion of a physician, would impose excessive risk to you if you were to participate in the study
- You must not have certain abnormal physical or laboratory findings
- You must not have hypersensitivity to Revlimid, dexamethasone, or anything in the elotuzumab formulation.

If, through discussions with your physician, it is decided that the expanded access program is appropriate for you, your physician must submit a request for access to elotuzumab through the treatment use protocol (CA204-143) for patients with relapsed or refractory multiple myeloma who have been treated with 1 prior line of therapy. The application form may be accessed through the following link:

http://www.bms.com/clinical_trials/investigator_sponsored_research/Pages/expanded-access-program.aspx

(trial sites on next page)
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Recruiting Locations: an up-to-date list can be found at https://clinicaltrials.gov/show/NCT02368301

Cancer Specialists of North Florida
Jacksonville, FL
Contact Mehdi Moezi, 904-272-3139

Medical Associates of Brevard
Melbourne, FL
Contact Sumeet Chandra, 321-254-4776

Center for Cancer and Blood Disorders
Bethesda, MD
Contact Ralph Boccia, 301-571-0988

St. Louis Care
Bridgeton, MO
Contact Juan Cuevas, 314-201-3312

Southeast Nebraska Cancer Center
Lincoln, NE
Contact Steven Dunder, 402-420-7000

Oncology Hematology West
Omaha, NE
Contact Stefano Tarantolo, 402-280-4364

Randolph Cancer Center
Asheboro, NC
Contact James Granfortuna, 336-832-1100

Cone Health Cancer Center
Burlington, NC
Contact James Granfortuna, 336-832-1100

Cone Health Cancer Center
Greensboro, NC
Contact James Granfortuna, 336-832-1100

University of Tennessee Medical Center
Knoxville, TN
Contact Wahid Hanna, 865-305-9171

Northern Utah Associates
Ogden, UT
Contact Vincent Hansen, 801-387-7166

Virginia Cancer Institute
Richmond, VA
Contact Maurice Schwartz, 804-288-7159