

Title: A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induciton, in Patients with Previously Untreated Multiple Myeloma Without an Intent for Immediate Autologous Stem Cell Transplant

Sponsor: Southwest Oncology Group

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Phase: III

Purpose: This study has the following objective:

- To compare progression-free survival (PFS) in patients with newly diagnosed myeloma treated with lenalidomide plus low dose dexamethasone versus bortezomib plus lenalidomide and low dose dexamethasone.

Eligibility: Patients must have newly diagnosed multiple myeloma with measurable disease. Patients with non-secretory MM based upon standard M-component criteria (i.e., measurable serum/urine M-component) are not eligible for this study. *Exception:* Patients with non-secretory MM will be eligible only if the baseline serum Freelite is elevated.

Treatment: Patients will proceed to the treatment prescribed for Arm 1 (lenalidomide/dexamethasone) or Arm 2 (bortezomib/lenalidomide/dexamethasone). For patients who will proceed to transplant, stem cell harvest is to be performed after the second cycle of treatment therapy for both Arms.

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