"Intergroup Randomized Phase II Four Arm Study In Patients With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab+ Bendamustine Followed By Rituximab Consolidation (RB → R); Arm B = Rituximab + Bendamustine + Bortezomib Followed By Rituximab Consolidation (RBV→ R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB → LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV → LR)"

Protocol

E1411

Purpose

To determine whether the addition of bortezomib (RBV) to an induction regimen of rituximab-bendamustine (RB) improves progression-free survival (PFS) compared to RB alone in patients with previously untreated mantle cell lymphoma.

Investigator

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Eligibility Criteria:

-Histologically confirmed untreated mantle cell lymphoma, with documented cyclin D1 (BCL1) by immunohistochemical stains and/or t(11;14) by cytogenetics or FISH.
-Patients must have at least one objective measurable disease parameter. Baseline measurements and evaluations must be obtained within 4 weeks of registration to the study. Abnormal PET scans will not constitute evaluable disease, unless verified by CT scan or other appropriate imaging. Measurable disease in the liver is required if the liver is the only site of lymphoma. If the only radiographically assessable disease is splenomegaly (without discrete measurable nodules), the patient can be enrolled, but for such patients CR cannot be differentiated from PR. (The spleen and/or liver, if considered enlarged prior to therapy on the basis of a physical examination or CT scan, should not be palpable on physical examination, and nodules related to lymphoma should disappear. However, no normal size can be specified because of the difficulties in accurately evaluating splenic and hepatic size and involvement. For instance, a spleen considered normal size may contain lymphoma, whereas an enlarged spleen may not necessarily reflect the presence of lymphoma, but variations in anatomy, blood volume, the use of hematopoietic growth factors, or other causes). While the spleen will be considered nodal with respect to criteria for PD (Measurable extranodal disease should be assessed in a manner similar to that for nodal disease. For these response criteria, the spleen is considered nodal disease. Disease that is only assessable (e.g., pleural effusions, bone

lesions) will be recorded as present or absent only, unless, while an abnormality is still noted by imaging studies or physical examination, it is found to be histologically negative).
*NOTE: Complete Remission/unconfirmed (CRu): Using the above definition for CR and that below for PR eliminates the category of CRu.
-ECOG performance status between 0-2.
-Hematologic parameters (unless due to marrow involvement) obtained within 4 weeks prior to registration.

Ineligibility:

-No evidence of prior malignancy except adequately treated non-melanoma skin cancer, adequately treated in situ carcinoma or any surgically- or radiation-cured malignancy continuously disease free for = 3 years so as not to interfere with interpretation of radiographic response.
-No prior therapy for MCL, except < 1 week of steroid therapy for symptom control.
-Patient must have no known CNS involvement.
-Patient agrees that if randomized to Arms C or D, and proceeding onto Arms G or H, they must register into the mandatory RevAssist program, and be willing and able to comply with the requirements of RevAssist.
-Patients must have no medical contra-indications to, and be willing to take, DVT prophylaxis as all patients registering to the lenalidomide/rituximab Arms G and H will be required to have deep vein thrombosis (DVT) prophylaxis. Patients randomized to Arms G or H who have a history of a thrombotic vascular event will be required to have full anticoagulation, therapeutic doses of low molecular weight heparin or warfarin to maintain an INR between 2.0 – 3.0, or any other accepted full anticoagulation regimen (e.g. direct thrombin inhibitors or Factor Xa inhibitors) with appropriate monitoring for that agent.

For more information about this study and to inquire about eligibility, please contact the Research Staff at 410-601-6120.

Locations

Sinai Hospital of Baltimore, Inc.
Northwest Hospital Center

ClinicalTrials.gov
Visit **ClinicalTrials.gov** for full clinical trial description