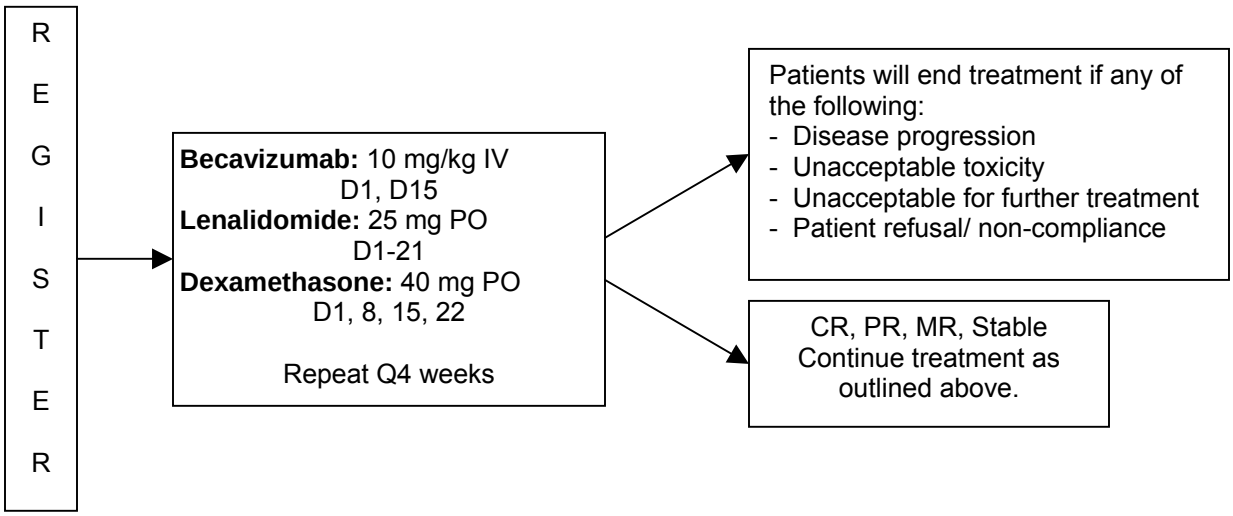
HO06401: Phase II Trial of Bevacizumab Combined with Lenalidomide and Dexamethasone (BEV/REV/DEX) in Relapsed or Refractory Multiple Myeloma



MAJOR ELIGIBILITY CRITERIA:

- Histologically or cytologically confirmed symptomatic Multiple Myeloma, Salmon-Durie Stage II or III or International Staging System II or III.
- At least 2 cycles treatment with a specific therapy, to which pt has shown progressive or refractory disease. No prior lenalidomide is allowed. At least 4 weeks since last treatment. At least 4 weeks since prior radiation.
- Bone marrow plasmacytosis with > 10% plasma cells, or sheets of plasma cells, or biopsy proven plasmacytoma which must be obtained within 4 weeks prior to registration (6 weeks for women of CBP).
- Measurable levels of monoclonal protein (M protein): > 1.0 g/dL on serum protein electrophoresis or > 200 mg of monoclonal light chain on a 24 hour urine protein electrophoresis which must be obtained within 4 weeks prior to registration.
- Age $\geq$18 years and a life expectancy of greater than 6 months.
- ECOG performance status $\leq$2 (PS=3 ok if due to pain that would likely improve with treatment).
- Within 4 weeks prior to registration: Hgb>9gm%, leukocytes$\geq$2,000/ml, ANC$\geq$1,000/ml, platelets$\geq$75,000/mcL, total bilirubin$\leq$2.5 mg/dl, AST(SGOT)/ALT(SGPT)$\leq$5 x ULN, creatinine<2.5 mg/dl.
- Female patients must not be pregnant or breastfeeding. Women of CBP must have 4 weeks of documented, acceptable contraceptive use before starting therapy.
- Patients may not be receiving any other investigational agents.
- If patient is on full-dose anticoagulants, the following criteria should be met: must not have active bleeding or pathological conditions that carry high risk of bleeding (e.g. tumor involving major vessels, known varices), must not have thrombocytopenia requiring transfusion, must have a platelet count >75,000, must have stable INR between 2-3.
- Do not have any of the following: known brain metastases, gr. III or IV heart failure, blood pressure of >150/90mmHg, unstable angina or myocardial infarction ≤6 months, stroke ≤6 months, clinically significant peripheral vascular disease, evidence of bleeding diathesis or coagulopathy, major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to registration, anticipation of need for major surgical procedure during the course of the study, minor surgical procedures, fine needle aspirations or core biopsies ≤7 days prior to registration. For BM biopsy or Central Veinous access placement, only 24 hrs is required prior to starting treatment. Active infections requiring oral or intravenous antibiotics are not eligible for entry onto the study until resolution of the infection and completion of antibiotics. Patients must be off IV antibiotics within one week prior to study entry.

PRE-STUDY LABS AND TESTS:

<6 weeks prior to registration:	Skeletal survey, prestudy scans and x-rays
<4 weeks prior to registration:	SPEP AND UPEP, CBC with diff and platelets, calcium, electrolytes, creatinine, BUN, glucose, total bilirubin, AST/ALT, alk. phos., albumin, 24h urine collection for total protein and quantitative light chains, immunofixation (serum and urine), β-2-microglobulin, LDH, quantitative immunoglobulins. Bone marrow aspirate/biopsy with cytogenetics and FISH (for women of CBP, BM Bx can be up to 6 wks prior)
Pregnancy Testing (Women of CBP)	Negative test 10-14 days prior AND 24 hours prior to starting therapy. Weekly testing for the first 4 weeks, then every 2-4 weeks while on treatment.
Baseline Correlates	5 ml bone marrow aspirate, and BM core, Blood for DNA paxgene tube and 2 x 10 ml EDTA tubes.

For more information call: Martha Raschko at (608) 265-3794 2/7/07