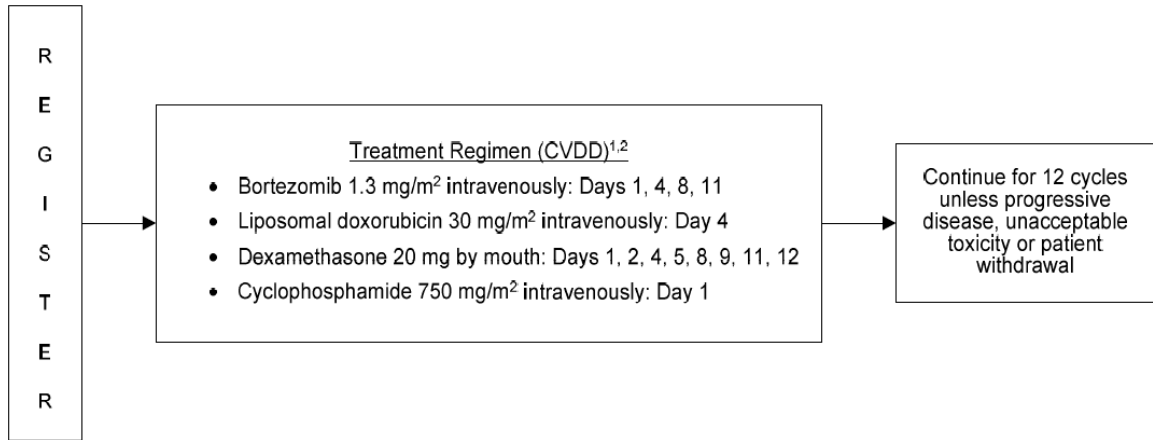


E2A08: Phase II Study of Bortezomib, Liposomal Doxorubicin, Dexamethasone, and Cyclophosphamide in Patients with Multiple Myeloma Relapsing Within 12 Months of Autologous Stem Cell Transplant



Major Eligibility Criteria:

- Age \geq 18 years.
- ECOG performance status \leq 2.
- Diagnosed with symptomatic Multiple Myeloma that was symptomatic at time of diagnosis. Must have measurable disease (1g/dL SPEP, 200mg/24hour urine, or plasmaytoma).
- Relapsed myeloma <12 months after an autologous SCT
- Must not have had more than 2 lines of therapy for their MM, including autologous SCT AND must not have had any therapy for relapsed disease following SCT.
- Must have normal LVEF.
- Prior palliative and/or localized radiation therapy is permitted, provided at least 14 days have passed from date of last radiation therapy to registration date.
- Must not have active, uncontrolled seizure disorder. Must have had no seizures in the last 6 months.
- Must not have prior doxorubicin exposure more than 240 mg/m².
- Must not have uncontrolled inter-current illness that would limit compliance with the study.
- Must not have grade 2 or higher peripheral neuropathy.
- Patients with prior history of malignancy are eligible provided they were treated curatively and have not relapsed in 5 years.
- Women must not be pregnant or breastfeeding.
- Must not have a known allergy to bortezomib or anthracyclines.
- Must not have had any prior allogeneic stem cell transplantation.

PRE-STUDY LABS AND TESTS:

< 4 weeks prior to registration:

Bone Marrow aspiration/biopsy, ECHO/ MUGA, EKG, skeletal survey, chest X-ray, urinalysis, plasmacytoma eval

< 2 weeks prior to registration:

CBC diff, chemistries, SFLC (if no measurable disease in serum or urine), B2M, CRP, LD, SPEP with Ifix, IgGAM, UPEP with ifix, 24 hour urine creatinine clearance, pregnancy test if WOCBP