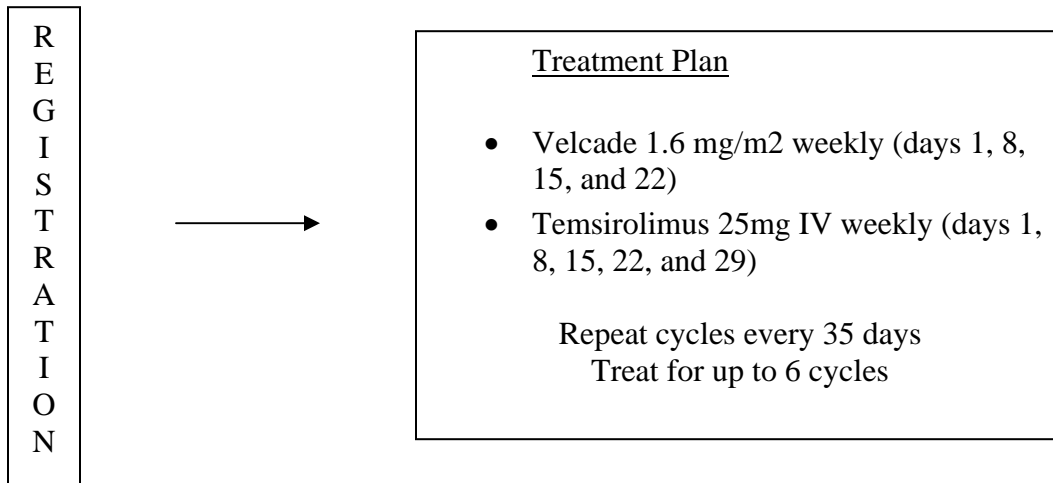


HO010407 A Phase II Study of Velcade and temsirolimus for relapsed or refractory B-cell non-Hodgkins lymphoma
FAST FACTS



MAJOR ELIGIBILITY CRITERIA:

- Histologically confirmed diagnosis of relapsed or refractory B-cell non-Hodgkins lymphoma. (large B-cell; follicular grades 1,2,3; mantle cell; SLL; marginal zone; lymphoplasmatic lymphoma; B-cell lymphoblastic lymphoma; Burkitt lymphoma; transformed or composite accepted as long as most recent positive histology is from above)
- At least 1 measureable tumor mass > 1.5cmX1.0cm
- ECOG performance status of 0, 1, or 2
- Patients must have received ≥1 prior chemotherapy regimen for disease.
- No clinical or radiographic evidence of CNS lymphoma
- ANC ≥ 1500/uL, Platelet count ≥100,000/uL, ALT and AST ≤ 3X ULN unless liver is infiltrated by lymphoma, Total bilirubin ≤ 2X ULN, creatinine clearance ≥ 40 mL/min
- Must be disease free of prior malignancies for ≥2yrs with the exception of basal or squamous cell skin carcinoma
- Creatinine Clearance of ≥40mL/min
- No prior therapy with both Velcade and temsirolimus concurrently.
- No antineoplastic therapy within 14 days of enrollment
- No history of allogeneic stem cell transplant. No autologous stem cell within 3 months of Day 1.
- No ongoing therapy with glucocorticoids. Prednisone ≤15mg per day is allowed.
- No Grade 2 or higher peripheral neuropathy within 14 days.
- No myocardial infarction within 6 months or diagnosed cardiomyopathy.
- No diagnosed other malignancy within 2 years except basal or squamous cell carcinoma.
- No radiation therapy within 3 weeks of registration.
- No treatment with strong CYP3A inducers for 7 days prior to Day1

PRE-STUDY LABS AND TESTS:

- * ≤ 14 days prior to enrollment: Hematology Profile, electrolytes, calcium, magnesium, phosphorus, glucose, albumin, total protein, uric acid, BUN, creatinine, LDH, β₂-microglobulin, total bilirubin, AST, ALT, alk phos, Hepatitis B Surface antigen, TSH, serum pregnancy
- * Within 6 weeks of enrollment: CT chest/abd/pelvis, PET (if clinically indicated), Bone Marrow Biopsy

For more information call: Leslie Gilbert (608) 262-9818