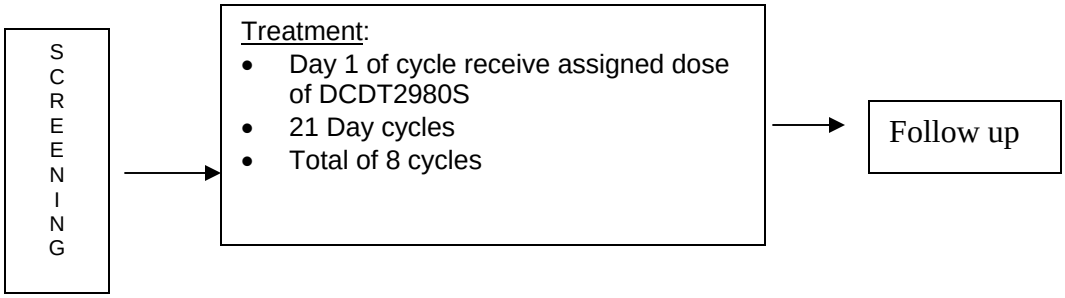
HO10411: An Open Label, Multicenter, Phase I Trial of the Safety and Pharmacokinetics of Escalating Doses of DCDT2980S in Patients with Relapsed or Refractory B-Cell NHL and CLL



Major Eligibility Criteria:

- ECOG PS of $\leq$ 2.
- Histologically documented hematologic malignancy that is expected to express the CD22 antigen and for which no effective standard therapy exists.
    - Indolent NHL (Including 1-3a follicular lymphoma; MZL; SLL)
    - DLBCL
    - MCL
    - CLL
- All patients MUST have at least one bi-dimensionally measurable lesion (>1.5cm)
- Lab values:
    - AST/ALT $\leq$ 2.5 x ULN
    - Total Bilirubin $\leq$ 1.5 ULN
    - Platelet count $\geq$75 /uL
    - ANC $\geq$ 1000 /uL
    - Hgb $\geq$ 9 g/dL
    - Creatinine $\leq$ 2.0 mg/dL or CrCl $\geq$ 50 mL/min
- Must NOT have had monoclonal Ab within 8 weeks of Tx
- Must NOT have had tx with radiotherapy, any chemo or Tx with any other investigation anti-cancer agent within 4 weeks prior to Tx
- Must NOT have had Autologous stem cell transplant within 6 months prior to Tx
- No prior ALLOgenic Stem cell transplant
- Must NOT have history of severe allergic or anaphylactic reaction to monoclonal antibody therapy.
- No history of other malignancy which could effect compliance with protocol (exception: curatively treated basal cell, Squamous cell carcinoma of the skin or in situ carcinoma of the cervix) Patients with a malignancy that has been treated with curative intent will also be allowed if the malignancy has been in remission without treatment for > 2 years prior to Cycle 1 Day 1.
- NO Current or history of CNS lymphoma
- No Evidence of significant, uncontrolled concomitant diseases which could affect compliance with protocol or interpretation of results including significant cardiovascular disease, or pulmonary disease.
- No Known active bacterial, viral, fungal mycobacterial, parasitic, or other infection at study enrollment, or any other major episode of infection requiring treatment with IV antibiotics or hospitalization within 4 weeks.
- No recent major surgery within 4 weeks.
- No Presence of positive test results for Hep B or Hp C
- No known HIV
- No ongoing corticosteroid use >30mg/day prednisone.

Pre Study Labs and Tests:

< 28 days prior to first dose-

Labs: CBC w/ diff, Electrolytes, glucose, BUN, Creatinine, Calcium, total bilirubin, direct bilirubin, Total protein, albumin, ALT, AST, Alk phos, Uric Acid, Immunoglobulins, aPTT, INR, Serum Pregnancy test, B2M

Radiology: ECG, CT Chest/Abd/Pelvis (Neck if clinically indicated), Bone Marrow Biopsy (with optional research sample).

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