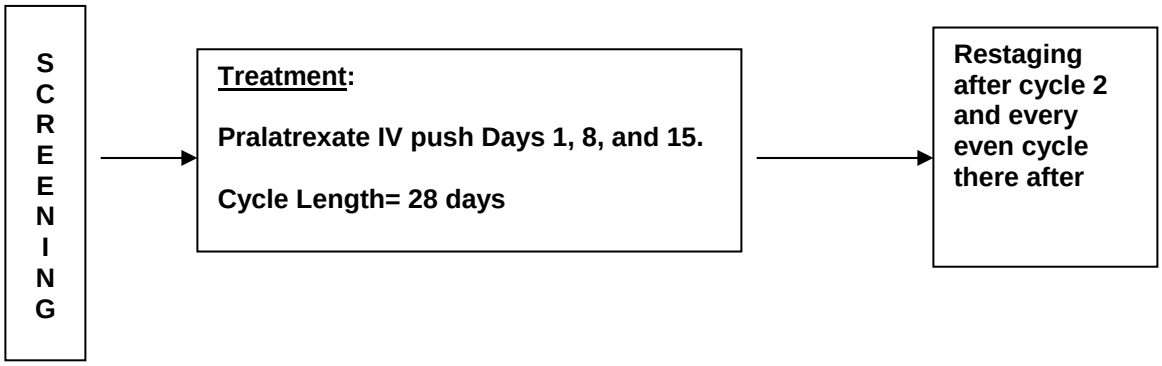
HO09401: Phase II Study Single-arm, Open-label, Multi-center Study of Pralatrexate in Patients with Aggressive Relapsed or Refractory B-cell Non-Hodgkin's Lymphoma



MAJOR ELIGIBILITY CRITERIA:

- Histologically/Cytologically confirmed B-cell NHL, with PD or persistent disease after at least 1 prior treatment.
- Measurable disease (at least 1 cm on spiral CT, 2 cm on conventional CT)
- At least 4 weeks from the most recent cytotoxic therapy, biologic therapy, or RT (6 weeks for nitrosoureas or mitomycin C)
- Lab values: ANC ≥ 1000/ uL; Platelet ≥ 100,000 /uL; total bilirubin ≤ 1.5 mg/dL ; AST, ALT, GGT ≤ 2.5 x ULN; Creatinine ≤ 1.5 mg/dL or calculated Creatinine Clearance ≥ 50 mL/min
- Must have been on 1 mg PO QD folic acid for at least 7 days prior to treatment
- Must receive 1 mg IM of Vitamin B12 within 10 weeks of planned start date of treatment.
- Age ≥18 years with an ECOG performance status of ≤ 2.

EXCLUSIONS:

- Must NOT be Relapsed DLBCL who are candidates for high-dose therapy and autologous stem cell transplant or for whom for high-dose therapy and autologous stem cell transplant is standard curative option.
- Must NOT have uncontrolled hypertension or class III/IV CHF
- Must NOT have CNS metastases
- Must NOT have HIV + diagnosis.
- Must NOT have any active concurrent Malignancy (except Non-melanoma skin cancer or carcinoma in situ of the cervix) If there is history of prior malignancies, patient must be disease free for > 5 years. Patients with other prior malignancies les than 5 years before study entry may still be enrolled if they have received treatment resulting in complete resolution of the cancer and currently have no clinical, radiologic, or laboratory evidence of active or recurrent disease.
- Must NOT have undergone allogeneic stem cell transplant, or relapsed < 100 days from an autologous stem cell transplant
- Must NOT have had major surgery within 14 days of enrollment.
- Must NOT have had previous exposure to Pralatrexate
- Must not have received systemic corticosteroids w/in 1 week of study treatment unless on a continous dose <= 10 mg/day of prednisone/equivalent for at least 1 month

PRE-STUDY LABS AND TESTS:

≤ 21 days of first dose:

PET scan
CT scans with oral and IV contrast (chest, abdomen, neck and pelvis)
Bone Marrow Biopsy/Aspirate only if done as part of standard of care.

LABS: CBC w/ diff, Creatinine, total bilirubin, AST, ALT, GGT, Uric acid, albumin, calcium, serum pregnancy test, LDH, hcy, MMA,
SPEP/UPEP (as applicable per disease)

Notes:

- Patient must give consent and be entered into the billing system prior to obtaining the HCY, MMA.
- C1D1 is given on CTRC with a full day of pK sampling. Patients must return at 24 and 48 hours for pK draws.

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