Peripheral T-cell Lymphoma
Fol-CHOP Trial Phase I

Pralatrexate in combination with CHOP in patients with newly diagnosed PTCL

A Phase 1, Randomized, Dose-Finding, Study of Folotyn® (Pralatrexate Injection) Plus Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) in Patients with Peripheral T-Cell Lymphoma (PTCL).

Endpoints:

Primary Objectives:
- To evaluate the maximum tolerated dose (MTD) of Folotyn in combination with Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) regimen in patients with Peripheral T-Cell Lymphoma (PTCL).

Secondary Objectives:
- To evaluate the safety and tolerability of Folotyn in combination with CHOP (Fol-CHOP)
- To evaluate the objective response rate (ORR) of 6 cycles of Fol-CHOP
- To evaluate the pharmacokinetics (PK) of Folotyn when given in combination with CHOP

Select Inclusion Criteria‡
- Newly diagnosed with histologically confirmed PTCL
- At least 18 years of age
- Adequate hematologic, hepatic and renal function
- ECOG ≤ 2

Select Exclusion Criteria‡
- Active concurrent malignancy (except non-melanoma skin cancer or carcinoma in situ of the cervix) or life-threatening disease
- Congestive heart failure Class III/IV according to the New York Heart Association (NYHA) Functional Classification
- Uncontrolled hypertension
- Known CNS metastasis
- Had major surgery within 30 days prior to enrollment
- Had previous exposure to Folotyn
- Any use of investigational therapies within 30 days prior to initiation of study treatment

Target Enrollment: 30
Start Date: December, 2014
Study Sites: 10
Est. Completion Date: December, 2015
Study ID Numbers: SPI-FOL-101

Pralatrexate was granted accelerated approval by the FDA for the treatment of patients with relapsed or refractory PTCL and has not been approved for use in front-line peripheral T-cell lymphoma.

‡ Among several others

For information about participating in this trial, please contact:
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Figure 1  Pralatrexate Escalation Schematic

DLT=Dose-Limiting Toxicity
MTD=Maximum Tolerated Dose
MAD=Maximum Administered Dose