Protocol Title: A Phase II Trial of Intravenous Fenretinide (N-(4-hydroxyphenyl) Retinamide, 4-HPR) Emulsion for Patients with Relapsed / Refractory Peripheral T-cell Lymphomas (PTCL)

Target Population: Peripheral T-cell Lymphoma (PTCL)

Summary: This is an open-label, multicenter, single arm efficacy and safety study in patients with relapsed or refractory peripheral T-cell lymphoma, who have failed at least one prior system therapy.

Key Inclusion Criteria:
- Adult patients > 18 years with histologically or cytologically confirmed Peripheral T-cell lymphoma (PTCL).
- Diseases refractory/relapsed after ≥ 1 systemic cytotoxic therapies.
- Patients with an ECOG Performance Status of 0, 1, or 2, and estimated survival of > 12 Weeks.
- Patients with at least 1 of the following sites of measurable disease:
  - Measurable tumor on MRI or CT scan.
  - Bone marrow with tumor cells seen on routine morphology (not by NSE staining only) of bilateral aspirate and/or biopsy on 1 bone marrow sample, except for patient who tested positive subsequent to their last treatment regimen or patients who had a negative marrow within three months of study entry.

Key Exclusion Criteria:
- Patients who have received chemotherapy within 3 Weeks of first Fenretinide treatment, or who have received investigational drugs within 6 Weeks of first Fenretinide treatment.
- Patient is not eligible if radiation was given to the only site of measurable disease unless there has been subsequent disease progression at that site, or a biopsy of that site showed viable tumor at least 4 Weeks after radiation was completed.
- Patients who have uncontrolled systemic infections, coagulation disorders, or other major medical illnesses of the cardiovascular or respiratory systems.
- Patients with any active hepatitis infections.
- Patients with fasting serum triglycerides > 300 and/or with hypertriglyceridemia requiring medication.
- Patients with an identified familial hyperlipidemia disorder.
- Patients who have poorly controlled diabetes mellitus with fasting serum glucose concentration over 200 mg/dl or a hemoglobin A1C over 7.5%.
- Patients with any known significant cardiac abnormality.
- Patients with uncontrolled hypertension.

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For additional information: [https://clinicaltrials.gov/ct2/show/NCT02495415](https://clinicaltrials.gov/ct2/show/NCT02495415)