S1905; A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) In Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Age: >= 12 years of age. - Diagnosis of relapsed or refractory T-cell acute lymphoblastic leukemia (T-ALL) based on WHO classification or relapsed/refractory T-cell lymphoblastic lymphoma if lymphoblasts are >= 5% in the bone marrow or in the peripheral blood by morphology or flow cytometry. - Evidence of acute leukemia in their peripheral blood or bone marrow; >= 5% lymphoblasts. - Patients >= 18 years of age must be refractory to or have relapsed following a standard induction chemotherapy.

•Patients <18 years of age must have relapsed or must be refractory after 2 or more chemotherapy cycles.

Exclusion Criteria:

- Received chemotherapy or investigational agents within 14 days prior to registration. - Experiencing toxicities from radiation therapy. - Undergone allogeneic hematopoietic transplant within 90 days prior to registration. - Evidence of active ≥ Grade 2 acute graft versus host disease (GVHD) or moderate or severe limited chronic GVHD - No uncontrolled systemic fungal, bacterial, viral or other infection.

Conditions & Interventions

Conditions:
Cancer
Keywords:
Refractory, Relapsed, T-ALL, T-Cell Acute Lymphoblastic Leukemia, T-Cell Lymphoblastic Lymphoma, T-LBL

More Information

Description: This phase II trial studies how well OBI-3424 works in treating patients with T-cell acute lymphoblastic leukemia that has come back (relapsed) or does not response to treatment (refractory). Drugs used in chemotherapy, such as OBI-3424, work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. OBI-3424 may reduce the amount of leukemia in the body.
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