Study to Test OBI-3424 in Patients With T-Cell Acute Lymphoblastic Leukemia (T-ALL) or T-Cell Lymphoblastic Lymphoma (T-LBL)

Status: RECRUITING

Eligibility Criteria

Age: 12 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have a diagnosis of relapsed or refractory T-cell acute lymphoblastic leukemia (T-ALL) based on World Health Organization (WHO) classification. Patients with relapsed/refractory T-cell lymphoblastic lymphoma are eligible if lymphoblasts are \>= 5% in the bone marrow or in the peripheral blood by morphology or flow cytometry * Patients must have evidence of acute leukemia in their peripheral blood or bone marrow. Patients must have \>= 5% lymphoblasts in the peripheral blood or bone marrow within 14 days prior to registration. Patients with only extramedullary disease are not eligible * 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 (example: induction and consolidation) * A standard chemotherapy induction regimen is defined as any program of treatment that includes: * Vincristine and corticosteroids plus at least one more chemotherapy agent * Cytarabine and anthracycline, or * High dose cytarabine (defined as at least 1 gr/m\^2 per individual dose unless adjustments were required for renal/liver function) * Patients must have no evidence of central nervous system disease within 28 days prior to registration based on cerebrospinal fluid (CSF) studies. Patients with clinical signs or symptoms consistent with central nervous system (CNS) involvement must have a lumbar puncture which is negative for CNS involvement; the lumbar puncture must be completed within 28 days prior to registration. Patients with CNS1 or CNS2 are eligible; however patients with CNS3 are not eligible * Note that the patients may receive intrathecal chemotherapy with the initial lumbar puncture. This may count as the first dose of intrathecal therapy required as part of the study * Prior nelarabine therapy is not required. In addition, for patients ≥ 18 years of age who received nelarabine during initial induction or post-remission treatment are eligible only if the physician does not feel they would benefit from other, multi-agent chemotherapy * Patients must not have had chemotherapy or investigational agents within 14 days prior to registration except for corticosteroids, oral 6-mercaptopurine, oral methotrexate, vincristine, intrathecal chemotherapy, or hydroxyurea. For participants who have received radiation therapy, at least 7 days must have elapsed from the end of radiation prior to registration and participants must not currently be experiencing toxicities from radiation therapy * Patients must not have undergone allogeneic hematopoietic transplant within 90 days prior to registration * Patients must have no evidence of active \>= grade 2 acute graft versus host disease (GVHD) or moderate or severe limited chronic GVHD. Patients must have no history of extensive GVHD of any severity within 90 days prior to registration. Patients who are post-transplant must be off calcineurin inhibitors for at least 21 days to be eligible. Extensive GVHD is defined as 1) generalized skin involvement or 2) localized skin involvement and/or hepatic dysfunction plus liver histology or cirrhosis or involvement of eye or minor salivary organ or oral mucosa or any other target organ * Patients must be \>= 12 years of age * Patients ≥ 16 years of age must have a Zubrod Performance Status of 0-3. Patients \< 16 years of age must have a Lansky score of ≥ 50 * Patients must not have systemic fungal, bacterial, viral or other infection that is not controlled (defined as exhibiting ongoing signs/symptoms related to the infection and without improvement, despite appropriate antibiotics or other treatment) within 14 days prior to registration * Patients ≥ 18 years of age must have creatinine clearance \> 30 mL/min within 14 days prior to registration according to the Cockcroft Gault equation * Patients 12-17 years of age must have adequate renal function within 14 days prior to registration defined as serum creatinine ≤ 1.5 x institutional upper limit of normal (ULN) according to age or a calculated estimated glomerular filtration rate (eGFR) (based on Schwartz formula) or radioisotope glomerular filtration rate (GFR) ≥ 50ml/min/1.73 m\^2 * Patients must have direct bilirubin =\< 1.5 x institutional upper limit of normal (ULN) within 14 days prior to registration * Patients must have alanine aminotransferase (ALT) =\< 3.0 x institutional upper limit of normal (ULN) or =\< 5.0 x ULN (if thought to be related to leukemic involvement) within 14 days prior to registration * Prothrombin time (PT)/partial thromboplastin time (PTT)/ fibrinogen (as clinically indicated for example but not limited to history of bleeding or active bleeding, concern for disseminated intravascular coagulation) (within 14 days prior to registration to obtain baseline measurements) * From metabolic panel (comprehensive or basic): sodium, potassium, chloride, carbon dioxide (CO2), and blood urea nitrogen (BUN) (within 14 days prior to registration to obtain baseline measurements) * Patients must be able to safely discontinue use of strong inhibitors/inducers of CYP3A4 or PgP-g-p and must be able to safely discontinue use of naproxen for 48 hours before and after each dose of OBI-3424 * Patients with known human immunodeficiency virus (HIV)-infection are eligible providing they are on effective anti-retroviral therapy and have undetectable viral load at their most recent viral load test within 6 months prior to registration. (HIV viral load testing is required only for patients with known HIV infection). Patients must not be receiving antiviral therapies that are known strong inhibitors or inducers of CYP3A4 * Patients with evidence of chronic hepatitis B virus (HBV) infection may be eligible provided that they have an undetectable HBV viral load within 28 days prior to registration. Patients may be currently receiving HBV treatment. (HBV viral load testing is required only for patients with known HBV infection). Patients must not be receiving antiviral therapies that are known strong inhibitors or inducers of CYP3A4 * Patients with known history of hepatitis C virus (HCV) infection may be eligible provided that they have an undetectable HCV viral load within in 28 days prior to registration. Patients may be currently receiving treatment. (HCV viral load testing is required only for patients with known HCV infection). Patients must not be receiving antiviral therapies that are known strong inhibitors or inducers of CYP3A4 * Patients must not have a known history of prolonged QT interval by Fridericia (QTcF) (interval \> 450 msec for males; \> 470 msec for females). Patients that had transient prolongation of QTc secondary to medications or electrolyte abnormalities are not excluded if the QTc normalized and remain within acceptable QTcF range (interval \> 450 msec for males; \> 470 msec for females). Additionally, suspected medications should be no longer required or used, and electrolyte abnormalities must have normalized * Patients must not be pregnant or nursing due to the teratogenic potential of the drug used on this study. Females of reproductive potential must have a negative serum pregnancy test within 14 days prior to registration. Women/men of reproductive potential must have agreed to use an effective contraceptive method during and up to 6 months after treatment. A woman is considered to be of "reproductive potential" if she has had menses at any time in the preceding 12 consecutive months. In addition to routine contraceptive methods, "effective contraception" also includes heterosexual celibacy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) defined as a hysterectomy, bilateral oophorectomy or bilateral tubal ligation. However, if at any point a previously celibate patient chooses to become heterosexually active during the time period for use of contraceptive measures outlined in the protocol, he/she is responsible for beginning contraceptive measures * Patients must not have other active malignancies for which they have received treatments within 6 months prior to registration excluding localized malignancies that do not require systemic treatment * Patients must agree to have bone marrow and blood specimens submitted for MRD testing * Patients must be offered the opportunity to participate in specimen banking. With patient consent, residuals from specimens submitted will be retained and banked for future research * Patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with fedral, local, institutional and Central Institutional Review Board (CIRB) guidelines unless they are unable to provide consent based on age (\< 18 years) or based on impaired decision-making capabilities. For patients \< 18 years of age or with impaired decision making capabilities, parents or other legally authorized representatives must sign and give informed consent on behalf of study participants in accordance with applicable federal, local, institutional and CIRB regulations * As a part of the Oncology Patient Enrollment Network (OPEN) registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system * This trial will use a slot reservation system to enroll the Phase I portion of the study. Patients planning to enroll at this phase of the study must first have a slot reserved in advance of the registration. All site staff will use OPEN to create a slot reservation

Conditions & Interventions

Interventions:

DRUG: AKR1C3-activated Prodrug AST-3424; PROCEDURE: Biopsy Procedure; PROCEDURE: Biospecimen Collection; PROCEDURE: Bone Marrow Aspiration

DRUG: ARRY-380-activated Prodrug AST-3424; PROCEDURE: Biopsy Procedure; PROCEDURE: Biospecimen Collection; PROCEDURE: Bone Marrow Aspiration; PROCEDURE: Computed Tomography

Conditions:

Recurrent T Acute Lymphoblastic Leukemia, Refractory T Acute Lymphoblastic Leukemia, Refractory T Lymphoblastic Lymphoma, T Lymphoblastic Lymphoma

More Information

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Phase: PHASE1
IRB Number: HM20021956
System ID: NCT04315324
