Inotuzumab Ozogamicin and Blinatumomab With or Without Ponatinib in Treating Patients With Newly Diagnosed, Recurrent, or Refractory CD22-Positive B-Lineage Acute Lymphoblastic Leukemia

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* STEP 0: Submission of bone marrow aspirate and peripheral blood for MRD analysis is mandatory prior to registration; the bone marrow sample should be from the first aspiration (i.e. first pull). Aspirate needle should be redirected if needed to get first pull bone marrow aspirate. It should be initiated as soon as possible after pre-registration. The specimens should be sent to the HEME Biobank. * Lumbar Puncture (Spinal Tap) and Intrathecal Methotrexate: * Patients may receive the day 1 of course IA dose of intrathecal (IT) methotrexate during the prior-to-registration lumbar puncture (or the venous line placement) to avoid a second lumbar puncture. If the dose is administered prior to registration, then systemic chemotherapy must begin within 7 days of this IT chemotherapy. * STEP 1: Morphologic diagnosis of precursor B-cell acute lymphoblastic leukemia (ALL) based on World Health Organization (WHO) criteria. Patients with Burkitt lymphoma/leukemia are not eligible. * STEP 1: CD22-positive disease defined as CD22 expression by \>= 20% of lymphoblasts by local hematopathology evaluation. * STEP 1: Philadelphia chromosome/BCR-ABL1-negative or Philadelphia chromosome/BCR-ABL1-positive B-cell ALL by cytogenetics, fluorescence in situ hybridization (FISH), and/or polymerase chain reaction (PCR). * STEP 1: No active central nervous system (CNS) leukemia (i.e. only CNS-1 disease allowed). Active CNS leukemia is defined as morphologic evidence of lymphoblasts in the cerebrospinal fluid (CSF), use of CNS-directed local treatment for active disease within 28 days prior to registration, symptomatic CNS leukemia (i.e. cranial nerve palsies or other significant neurological dysfunction) within the 28 days prior to registration, and/or known asymptomatic parenchymal CNS mass lesions; see below for additional guidance. Prophylactic intrathecal medication alone is not an exclusion. * Categories of CNS Involvement for CNS Evaluation Prior to Registration: * CNS 1: CSF has \< 5 WBC/uL with cytospin negative for blasts; or \>= 10 red blood cell (RBC)/uL with cytospin negative for blasts. * CNS 2: CSF has \< 5 WBC/uL with cytospin positive for blasts; or \>= 10 RBC/uL with cytospin positive for blasts; or \>= 10 RBC/uL, WBC/uL \>= 5 but less than Steinherz/Bleyer algorithm with cytospin positive for blasts (see below). * CNS 3: CSF has \>= 5 WBC/uL with cytospin positive for blasts; or \>= 10 RBC/uL, \>= 5 WBC/uL and positive by Steinherz/Bleyer algorithm (see below); or clinical signs of CNS leukemia (such as facial nerve palsy, brain/eye involvement or hypothalamic syndrome). Steinherz/Bleyer Method of Evaluating Initial Traumatic Lumbar Punctures: * If the patient has leukemia cells in the peripheral blood and the lumbar puncture is traumatic and contains \>= 5 WBC/uL with blasts, the following algorithm should be used to define CNS disease: CSF WBC/CSF RBC \> 2 x (Blood WBC/Blood RBC count) * STEP 1: Patients with known or suspected testicular involvement by leukemia are allowed provided that the patient receives concomitant scrotal/testicular radiotherapy. * Unilateral or bilateral testicular enlargement should be assessed by ultrasound or other imaging technique. Biopsy is recommended if clinical findings are equivocal or suggestive of hydrocele or a non-leukemic mass, but further assessments are per treating physician discretion. * STEP 1: Not pregnant and not nursing. * This study involves agents that have known genotoxic, mutagenic, and teratogenic effects. Therefore, for women of childbearing potential only, a negative pregnancy test done =\< 7 days prior to registration is required. * STEP 1: Eastern Cooperative Oncology Group (ECOG) performance status: 0-2 * STEP 1: No unstable cardiac disease such as myocardial infarction, angina pectoris, uncontrolled heart failure, or uncontrolled cardiac arrhythmia within 6 months of registration. * STEP 1: No impaired cardiac function, defined as left ventricular ejection fraction (LVEF) \< 45% or New York Heart Association (NYHA) stage III or IV congestive heart failure (CHF). * STEP 1: Patients with known human immunodeficiency virus (HIV) infection are eligible if they have been on effective antiretroviral therapy with an undetectable viral load tested within 6 months of registration. * STEP 1: Patients with hepatitis B virus (HBV) are eligible only if they meet all the following: * On HBV-suppressive therapy. * No evidence of active virus. * No evidence of HBV-related liver damage. * STEP 1: Patients with hepatitis C virus (HCV) are eligible only if they meet all the following: * Successfully completed complete-eradication therapy with undetectable viral load. * No evidence of HCV-related liver damage. * STEP 1: No history of clinically relevant neurologic disorder such as epilepsy, seizure, aphasia, stroke, severe brain injury, structural brain abnormality, benign brain tumor, dementia, Parkinson's disease, movement disorder, cerebellar disease, or other significant CNS abnormalities. * STEP 1: No prior additional malignancy (i.e. in addition to ALL) except adequately treated basal- or squamous-cell skin cancer, in situ cervical cancer, stage I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease-free for \>= 2 years. * STEP 1: No history of clinically significant ventricular arrhythmia, unexplained non-vasovagal syncope, or chronic bradycardic states such as sinoatrial block or higher degree of atrioventricular block unless a permanent pacemaker has been implanted. * STEP 1: No history of chronic liver disease, including cirrhosis. * STEP 1: No history of sinusoidal occlusion syndrome/veno-occlusive disease of the liver. * STEP 1: No uncontrolled infection or recent history (within 4 months prior to registration) of deep tissue infections such as fasciitis or osteomyelitis. * STEP 1: Total bilirubin, serum =\< 1.5 x upper limit of normal (ULN)* * Except in the event of: 1) Gilbert disease, in which case total bilirubin must be =\< 2 x ULN, or 2) elevated bilirubin believed by investigator to be due to leukemic infiltration, in which case total bilirubin must be =\< 2 x ULN. * STEP 1: Aspartate aminotransferase (AST)/alanine aminotransferase (ALT) =\< 2.5 x ULN * STEP 1: Creatinine, serum =\< 1.5 ULN OR creatinine clearance \>= 40 mL/min * STEP 1: QT interval by Fridericia's correction formula (QTcF) =\< 470 msec * COHORT 1: Age \>= 60 years. * COHORT 1: Diagnosis of Philadelphia chromosome/BCR-ABL1-negative B-cell ALL. * COHORT 1: No prior treatment for ALL except a single dose of intrathecal chemotherapy, corticosteroids, hydroxyurea, and/or leukapheresis to reduce peripheral blast count and prevent ALL complications. Allowed therapy may be administered for no more than 14 days and must be completed \>= 24 hours prior to the initiation of protocol therapy. * COHORT 1: No plan for allogeneic or autologous hematopoietic cell transplantation (HCT). * COHORT 2: Age \>= 18 years. * COHORT 2: Diagnosis of Philadelphia chromosome/BCR-ABL1-negative B-cell ALL. * COHORT 2: Relapsed or refractory disease in salvage 1 or 2. * COHORT 2: No isolated extramedullary relapse. * COHORT 2: Prior allogeneic HCT permitted. * COHORT 2: Patients with prior allogeneic HCT must have completed transplantation \>= 4 months prior to registration. * COHORT 2: Patients with prior allogeneic HCT must have no evidence of graft-versus-host disease and must have completed immunosuppressive therapy \>= 30 days prior to registration. * COHORT 2: Prior treatment with inotuzumab ozogamicin, blinatumomab, other CD22-directed therapy, or other CD19-directed therapy is not allowed. * COHORT 2: Prior treatment with rituximab must be completed \>= 7 days prior to registration. * COHORT 2: Prior treatment with other monoclonal antibodies must be completed \>= 6 weeks prior to registration. * COHORT 2: Prior treatment for ALL must be completed \>= 14 days prior to registration with the following exceptions: intrathecal chemotherapy, hydroxyurea, corticosteroids, 6-mercaptopurine, methotrexate, vincristine, and/or leukapheresis to reduce circulating absolute lymphoblast count to =\< 10,000/uL or prevent complications related to ALL are allowed but must be completed \>= 24 hours prior to the initiation of protocol therapy. * COHORT 2: Patients should have resolution of any acute non-hematologic toxicities of prior therapy to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version (v)5.0 grade =\< 1. * COHORT 2: Peripheral blood absolute lymphoblast count =\< 10,000/uL (treatment allowed as above to reduce blast count to =\< 10,000/uL) * COHORT 3: Age ≥ 75 years OR age ≥ 18 years AND ineligible for hyperfractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone (HyperCVAD) regimens * COHORT 3: Diagnosis of Philadelphia chromosome/BCR-ABL1-positive B-cell ALL * COHORT 3: No prior treatment for ALL except a single dose of intrathecal chemotherapy, corticosteroids, hydroxyurea, BCR-ABL1-targeted tyrosine kinase inhibitor, and/or leukapheresis to reduce peripheral blast count and prevent ALL complications. Allowed non-protocol therapy may be administered for no more than 14 days and must be completed ≥ 24 hours prior to the initiation of protocol therapy. * COHORT 3: No chronic, strong CYP3A4 inducers

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, BIOLOGICAL: Blinatumomab, PROCEDURE: Bone Marrow Aspiration, PROCEDURE: Bone Marrow Biopsy, BIOLOGICAL: Inotuzumab Ozogamicin, PROCEDURE: Lumbar Puncture, DRUG: Ponatinib
Conditions:
B Acute Lymphoblastic Leukemia, Philadelphia Chromosome Negative, Recurrent B Acute Lymphoblastic Leukemia, Refractory B Acute Lymphoblastic Leukemia

More Information

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