Phase I Study of Inotuzumab With Augmented BFM Re-Induction for Patients With Relapsed/Refractory B-cell ALL

Status: Recruiting

Eligibility Criteria

Age: 16 years to 60 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Provision of signed and dated informed consent form 2. Stated willingness to comply with all study procedures and availability for the duration of the study 3. Diagnosed with CD-22 positive* B-cell Acute Lymphoblastic Leukemia or B-cell Lymphoblastic Lymphoma (Philadelphia chromosome negative) * For the purposes of this study, CD-22 positive will be defined based on the analysis completed for diagnostic purposes. 4. Male or female, aged 16-60 years 5. ECOG performance status of 0-2 6. Left ventricular ejection fraction ≥ 50% measured by echocardiogram or MUGA 7. Either relapsed following remission after initial induction therapy or refractory to induction therapy 8. Adequate organ function, including serum creatinine ≤ 1.6 mg/dL OR creatinine clearance >50 ml/min by Cockgroft-Gault formula, bilirubin ≤ 1.5 mg/dL (except in patients with Gilbert's disease), AST, ALT and alkaline phosphatase ≤ 3 x upper limit of normal (elevation exceeding this threshold of either AST OR ALT would not meet eligibility) 9. For females of reproductive potential: negative pregnancy test 10. For females and males of reproductive potential: agreement to use adequate contraception during study participation and for an additional 1 year after the end of study treatment 11. Agreement to adhere to Lifestyle Considerations throughout study duration and for 1 year following last study treatment.

Exclusion Criteria:

1. Past receipt of a total of ≥ 300 mg/m^2 doxorubicin equivalents (600 mg/m^2 daunorubicin, 60 mg/m^2 idarubicin, 75 mg/m^2 mitoxantrone) 2. Current or past history of pancreatitis 3. QT interval on electrocardiogram (ECG) > 0.45 by Framingham formula 4. Known congestive heart failure 5. Known allergy to asparaginase (only an exclusion criteria for participants enrolling in part 2) 6. Presence of central nervous system (CNS) disease 7. Pregnancy or lactation 8. Chronic liver disease including chronic active hepatitis and/or cirrhosis 9. Active Hepatitis B virus (HBV) by core antibody, surface antigen (HBsAg) or viral load 10. Active Hepatitis C virus (HCV) (positive antibody test confirmed by viral load if antibody test is positive) 11. Known history of infection with Human Immunodeficiency Virus (HIV) 12. Active or uncontrolled infections 13. Abnormal baseline hepatic ultrasound (including Dopplers) 14. Prior allogeneic stem cell transplant 15. Prior use of inotuzumab ozogamicin 16. Known diagnosis of hemochromatosis with iron overload 17. Treatment with steroids or hydroxyurea for more than 7 days with each within the 2 weeks prior to registration -that is, each is allowed for up to 7 days 18. Gastrointestinal tract disease causing the inability to take oral medication, malabsorption syndrome, a requirement for intravenous (IV) alimentation, prior surgical procedures affecting absorption, uncontrolled inflammatory GI disease, or inability to swallow medications. 19. Philadelphia chromosome positive B-cell ALL

Conditions & Interventions

Interventions:
Drug: Inotuzumab ozogamicin, Drug: Prednisone Pill, Drug: Daunorubicin, Drug: Vincristine, Drug: Cytarabine, Drug: Methotrexate, Drug: Pegaspargase
Conditions:
B-cell Acute Lymphoblastic Leukemia

More Information

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