A Study of CD19 Targeted CAR T Cell Therapy in Pediatric Patients With Relapsed or Refractory B Cell Acute Lymphoblastic Leukemia (B ALL) and Aggressive Mature B-cell Non-Hodgkin Lymphoma (B NHL)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 0 years to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
INCLUSION CRITERIA:

- < 18 years old at screening
- ≥ 6 kg body weight at screening

Pediatric patients with r/r B ALL

r/r CD19-positive aggressive mature B including the B NHL subtypes: i) diffuse large B cell lymphoma, ii) Burkitt's lymphoma, iii) primary mediastinal large B cell lymphoma, iv) high-grade B cell lymphoma (not otherwise specified).

- Karnofsky (age ≥ 10 years) or Lansky (age < 10 year) performance status score ≥ 50%.
- In participants with B ALL, local documentation of CD19 expression on leukemic blasts in the BM, peripheral blood, or cerebrospinal fluid or biopsy done no more than 30 days prior to consent.
- Adequate renal, hepatic, pulmonary, and cardiac function.

EXCLUSION CRITERIA:

- Diagnosis of chronic myelogenous leukemia in lymphoid blast crisis.
- History or presence of clinically relevant central nervous system (CNS) pathology unrelated to CNS leukemia.
- Presence of active or uncontrolled fungal, bacterial, viral, or other infection requiring systemic antimicrobials for management.
- Received prior (< 3 months before obe cel infusion) stem cell transplantation.
- Prior CD19 targeted therapy other than blinatumomab.
- Experienced Grade ≥ 3 neurotoxicity following blinatumomab.

Conditions & Interventions

Interventions:
BIOLOGICAL: AUTO1
Conditions:
Relapsed or Refractory B Cell Acute Lymphoblastic Leukemia, Relapsed or Refractory B Cell Non-Hodgkin Lymphoma
Keywords:
B cell acute lymphoblastic leukemia, B cell Non-Hodgkin lymphoma, Relapsed B cell acute lymphoblastic leukemia, Relapsed B cell Non-Hodgkin lymphoma, Refractory B cell acute lymphoblastic leukemia, Refractory B cell Non-Hodgkin lymphoma, Aggressive mature B cell Non-Hodgkin lymphoma, Pediatric ALL, Pediatric NHL, Obecabtagene autoleucel, CD19-positive CAR T cell, Obe-cel

More Information

Description:
This is a Phase 1b/2 study to evaluate the safety and efficacy of autologous T cells engineered with a chimeric antigen receptor (CAR) targeting cluster of differentiation (CD)19 in pediatric patients with relapsed or refractory (r/r) B cell acute lymphoblastic leukemia (B ALL) and r/r B cell Non-Hodgkin lymphoma (B NHL).

Contact(s): - cancer@cchmc.org
Phase: PHASE1
System ID: NCT06173518

Thank you for choosing StudyFinder. Please visit http://studyfinder.cchmc.org to find a Study which is right for you and contact clinicalstudies@cchmc.org if you have questions or need assistance.