ADVL2322; A Phase 1/2, Open-label Study Evaluating the Efficacy, Safety, and Pharmacokinetics (PK) of Luveltamab Tazevibulin (STRO-002) in Infants and Children < 12 years of age with CBFA2T3::GLIS2 Acute Myeloid Leukemia (AML); REFRaME-P1

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Age: < 12 years. - Diagnosis: relapsed or refractory Acute Myeloid Leukemia (AML) with CBFA2T3::GLIS2 fusion - Required documentation of the CBFA2T3::GLIS2 translocation by Next Generation Sequencing FoundationOne® Heme assay. - see link to clinicaltrials.gov for complete inclusion & exclusion criteria

Exclusion Criteria:

- Active CNS disease at the time of enrollment - Subjects with the following constitutional conditions are not eligible: Fanconi anemia, Shwachman Diamond syndrome, subjects with constitutional trisomy 21 or with constitutional mosaicism of trisomy 21, telomere disorders, germline predispositions known, or suspected by the treating physician to increase risk of toxicity with AML therapy.

Conditions & Interventions

Interventions:
Drug: Luveltamab tazevibulin
Conditions:
Blood Disorders, Cancer
Keywords:
Acute Myeloid Leukemia (AML), refractory, relapsed

More Information

Description: This study is testing a new treatment, luveltamab tazevibulin, for infants and children under 12 with relapsed/refractory CBFA2T3::GLIS2 AML with ≥ 5% bone marrow involvement with leukemic blasts. The treatment will be given at two dose levels (3.5 or 4.3 mg/kg every 2 weeks), and participants will be randomly assigned to one dose level.
Study Contact: Allison Fullenkamp - fulle631@umn.edu
Principal Investigator: Robin Williams
Phase: PHASE1
IRB Number: STUDY00022403