Luveltamab Tazevibulin (STRO-002) in Infants and Children < 12 Years of Age with Relapsed/Refractory CBFA2T3::GLIS2 AML

Status: RECRUITING

Eligibility Criteria

Age: 1 day to 12 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* AML with CBFA2T3::GLIS2 gene fusion centrally confirmed * Refractory or relapsed disease with ≥ 5% bone marrow involvement with leukemic blasts by morphology * Age \< 12 years. * Lansky performance of ≥ 50 * Adequate organ functions

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Exclusion Criteria:

* Active central nervous system (CNS) disease (CNS3) * Pre-existing clinically significant corneal disorders or constitutional diseases associated with an increased risk of AML treatment toxicities * Active or uncontrolled infections or other active severe intercurrent illnesses, * Prior treatment with a FOLR1- targeting ADCs or with ADCs that contain a tubulin inhibitor * History of allogeneic hematopoietic stem cell transplant or any organ transplant in the prior 84 days * Graft versus host disease (GVHD) of any grade or GVHD treatment with exception of low dose steroids

Conditions & Interventions

Interventions:
DRUG: Luveltamab tazevibulin
Conditions:
Acute Myeloid Leukemia (AML)
Keywords:
CBFA2T3::GLIS2 Fusion, CBFA2T3::GLIS2 AML, RAM Phenotype (CD56pos), CD45, CD38, HLA-DR weak or absent), REFRaME, AML, Child, Pediatric AML, Levelatamab, REFRaME-P1

More Information

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