PEPN2413; A Phase 1 study of oral cedazuridine and decitabine combination (ASTX727, IND# 175393, NSC# 820631) and filgrastim as maintenance therapy post-hematopoietic stem cell transplant in children with high-risk acute myeloid leukemia

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- less than 21 years old - newly diagnosed, relapsed, or treatment-resistant Acute Myeloid Leukemia (AML) that is in remission before a planned donor stem cell (bone marrow) transplant - planning to receive your first donor stem cell (bone marrow), peripheral blood stem cell, or cord blood transplant - see the ClinicalTrials.gov listing for complete inclusion criteria

Exclusion Criteria:

- currently receiving another investigational treatment or certain anti-cancer medications - previous solid organ transplant - pregnant or breastfeeding - see the ClinicalTrials.gov listing for complete exclusion criteria

Conditions & Interventions

Interventions:
Procedure: Biospecimen Collection, Procedure: Bone Marrow Aspiration, Procedure: Bone Marrow Biopsy, Drug: Decitabine, Drug: Decitabine and Cedazuridine, Biological: Filgrastim, Procedure: Imaging Procedure, Procedure: Lumbar Puncture
Conditions:
Cancer
Keywords:
Acute Myeloid Leukemia, AML, blood cancer

More Information

Description: This study is evaluating a new treatment after stem cell transplant for children with high-risk acute myeloid leukemia (AML). Researchers hope to identify a safe dose, better understand possible side effects, and learn how the treatment works in the body.
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Principal Investigator: Robin Williams
Phase: PHASE1
IRB Number: STUDY00027685