Venetoclax Combined With Vyxeos (CPX-351) for Participants With Relapsed or Refractory Acute Leukemia

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 year to 39 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Ages 1 Year to 39 Years
- Diagnosis of one of the following:
    - Acute myeloid leukemia (AML), any subtype except
    - Patients with acute promyelocytic leukemia (APML) are NOT eligible
    - Patients with ML-DS are NOT eligible
    - Myeloid sarcoma
    - Acute leukemia of ambiguous lineage (ALAL)
    - Acute undifferentiated leukemia (AUL)
    - T/myeloid mixed phenotype acute leukemia (MPAL)
    - B/myeloid MPAL
    - MPAL with KMT2A-rearrangement MPAL with t (9;22) are NOT eligible
    - T-cell acute lymphoblastic leukemia (T ALL)
    - Early thymocyte precursor (ETP) ALL
    - KMT2A-rearranged ALL
- Disease Status
    - Relapsed/Refractory AML, MPA, and AUL
    - Untreated therapy related AML
    - Relapsed/Refractory KMT2A-rearranged ALL, T-cell ALL, ETEP ALL
- Karnofsky/Lanksy performance level score of greater than or equal to 50 percent.
- Prior therapy requirements
    - Fully recovered from acute toxicities of Hematopoietic Stem Cell Transplant (HSCT) or Anthracycline Exposure
    - 14 days must have elapsed since the completion of systemic cytotoxic therapy other than hydroxyurea, decitabine or azacitidine
    - 2 weeks must have elapsed for local palliative radiotherapy (RT); 6 months must have elapsed if prior craniospinal RT or if 50% radiation of pelvis, and at least 6 weeks must have elapsed if other substantial bone marrow radiation
- Adequate renal, liver, cardiac, and central nervous system (CNS) function

Exclusion Criteria:

- Diagnosis of one of the following:
    - Myeloid Leukemia associated with Down Syndrome (ML-DS)
    - Acute Promyelocytic Leukemia (APML)
    - Acute leukemia with CNS status 3 involvement
    - Philadelphia chromosome t(9;22) positive leukemia (Ph+ ALL, AML, MPAL, or AUL)
    - Fanconi Anemia, Shwachman-Diamond syndrome, or any other bone marrow failure syndrome or DNA repair disorder
    - Wilson's Disease or other copper-metabolism disorder
- Pregnant or breastfeeding
- Uncontrolled infection
- Received greater than 13.6 Gray (Gy) prior radiation to the mediastinum
- Receipt of growth factors within 7 days prior to enrollment
- Currently receiving another investigational drug
- Currently receiving anti-cancer agents (with the exception of intrathecal (IT) agents or hydroxyurea)
- Unable to comply with the safety monitoring requirements of the study

Conditions & Interventions

Interventions:
DRUG: Vyxeos, DRUG: Venetoclax
Conditions:
Leukemia

Leukemia
Keywords:
relapsed, refractory, Vyxeos, Venetoclax, acute myeloid leukemia, acute myeloid leukemia, childhood, mixed-lineage leukemia (MLL), AML, CPX-351, Venclexta, Histone-lysine N-methyltransferase 2A (KmT2A)

More Information

Description:
This study evaluates the safety and tolerability of combining venetoclax with Vyxeos (CPX-351) in pediatric and young adult patients with acute leukemia that has come back or not responded to treatment.

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IRB Number:
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