A Study of Venetoclax in Combination With Conventional Chemotherapy in Pediatric Patients With Acute Myeloid Leukemia

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 29 days to 21 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Patients with preexisting conditions that may affect chemotherapy tolerance (e.g., bone marrow failure syndrome, cardiac disease, pulmonary disease, and history of significant hepatic impairment) should be discussed with study PI in detail to enable review of the medical history prior to enrollment onto AML23 study.

Inclusion Criteria:

- Diagnosis of AML fulfilling the criteria of the WHO classification of myeloid neoplasms or < 20% marrow myeloblasts and evidence of a clonal de novo AML genetic abnormality or myeloid sarcoma or primary myelodysplastic syndrome (MDS) with ≥ 10% blasts or a complete blood count with the presence of at least 1,000 blasts/µL (e.g., a WBC count ≥ 10,000/µL with ≥ 10% blasts or a WBC count ≥ 5,000/µL with ≥ 20% blasts
- Age > 28 days and < 22 years
- No prior therapy for this malignancy except for one dose of intrathecal therapy and hydroxyurea or low-dose cytarabine (≤ 200 mg/m^2 per day for ≤ 7 days)
- Female patients of childbearing potential must have a negative pregnancy test within 2 weeks prior to enrollment
- Male and female participants of reproductive potential must agree to use an effective contraceptive method during the study and for 6 months after study treatment
- Written informed consent from the patient and/or parent/legal guardian
- Direct bilirubin ≤ 1.5 x institutional upper limit of normal

Exclusion Criteria:

- Patients with treatment-related AML, Down syndrome, acute promyelocytic leukemia, chronic myeloid leukemia in blast crisis, juvenile myelomonocytic leukemia, Fanconi anemia, Kostmann syndrome, Shwachman syndrome, or other bone marrow failure syndromes are not eligible
- Uncontrolled systemic fungal, bacterial, or viral infection or significant concurrent disease that would compromise patient safety or compliance, study participation, follow up, or interpretation of study results
- Prior exposure to any dose of anthracycline or anthracenedione
- Patients may not receive strong or moderate CYP3A inducers, such as rifampin, within 3 days of enrollment
- Patients may not receive moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, voriconazole, posaconazole) within 3 days of enrollment.

Conditions & Interventions

Interventions:
DRUG: Venetoclax, DRUG: Azacitidine, DRUG: Cytarabine, DRUG: Gemtuzumab Ozogamicin, DRUG: Daunorubicin Hydrochloride, DRUG: Fludarabine Phosphate, DRUG: Idarubicin Hydrochloride, DRUG: Mitoxantrone Hydrochloride, DRUG: Etoposide, DRUG: Gilteritinib
Conditions:
Acute Myeloid Leukemia

More Information

Description:
This is a phase 2 study to test the hypothesis that venetoclax in combination with standard chemotherapy will be tolerable and active in pediatric patients with newly diagnosed acute myeloid leukemia (AML). Primary Objectives: * Establish the tolerability adding venetoclax to standard chemotherapy in pediatric patients with AML * Estimate the proportion of patients who become minimal residual disease (MRD) negative by flow cytometry after one course of venetoclax-based induction therapy Secondary Objectives: \- Estimate the rates of complete remission (CR), event-free survival (EFS), and overall survival (OS) in pediatric patients who receive venetoclax-based chemotherapy

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