CPX-351 and Ivosidenib for the Treatment of IDH1 Mutated Acute Myeloid Leukemia or High-Risk Myelodysplastic Syndrome

NCT04493164

Status	RECRUITING
Phase	Phase 2
Sponsor	M.D. Anderson Cancer Center
Enrollment	30 participants

Plain Language Summary

This study tests a combination of CPX-351 (a chemotherapy drug) and ivosidenib (a targeted drug) for patients with acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (MDS) that has a specific genetic mutation called IDH1. This mutation causes abnormal cell growth that ivosidenib is designed to block.

You may be eligible if...
- You have AML or high-risk MDS with a confirmed IDH1 mutation (specifically the R132 variant)
- You are newly diagnosed or your disease has relapsed or is refractory
- You are eligible for intensive chemotherapy
- Your liver and kidney function meet minimum requirements

You may NOT be eligible if...
- You do not have an IDH1 mutation
- You are unable to tolerate intensive chemotherapy
- You have significant QT interval prolongation on ECG
- You are pregnant or breastfeeding

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (8)

- Eastern Cooperative Oncology Group (ECOG) performance status of d 2
- IDH1-R132 mutated disease status as assessed by local laboratory. 2HG-producing IDH1 variants outside of R132 (i.e. R100) may be eligible after discussion with the principal investigator (PI)
- Treatment naive or relapsed/refractory AML who are eligible for intensive chemotherapy. Patients with high-risk MDS or MPN (defined as International Prognostic Scoring System Revised \[IPSS-R\] score e 4 or dynamic \[D\]-IPSS e 3) may also be eligible after discussion with the PI
- Adequate hepatic function (direct bilirubin d 2 x upper limit of normal (ULN), Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) d 3 x ULN unless deemed to be related to underlying leukemia
- Adequate renal function including creatinine clearance e 30 ml/min based on the Cockcroft-Gault equation.

... and 3 more (see full listing online)

Exclusion (14)

- Patients who have previously received CPX-351.
- Patients with any concurrent uncontrolled clinically significant medical condition including infection, laboratory abnormality, or psychiatric illness, which could place the patient at unacceptable risk of study treatment.
- The use of other chemotherapeutic agents or anti-leukemic agents is not permitted during study with the following exceptions (1) intrathecal chemotherapy for prophylactic use or for controlled CNS leukemia. (2) use of hydroxyurea, and/or cytarabine (1 or 2 doses; up to 2 g/m2) for patients with rapidly proliferative disease is allowed before the start of study therapy.

• Patients with active graft-versus-host-disease (GVHD) status post stem cell transplant (patients without active GVHD on chronic suppressive immunosuppression and/or phototherapy for chronic skin GVHD are permitted after discussion with the PI).

• Patients with any severe gastrointestinal or metabolic condition which could interfere with the absorption of oral study medications.

... and 9 more (see full listing online)

Locations (1 total)

M D Anderson Cancer Center, Houston, Texas, United States