HM2025-23: Phase 3 Randomized, Double-Blind, Placebo-controlled Studies Assessing Ziftomenib in Combination with Either Standard of Care Nonintensive Venetoclax+Azacitidine) or Intensive (7+3) Therapy in Patients with Untreated NPM1 mutated or KMT2A Rearranged Acute Myeloid Leukemia

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosis of Acute Myeloid Leukemia (AML) - able to walk and do all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - must agree to use a highly effective method of birth control - see link to clincialtrials.gov for complete Inclusion criteria

Exclusion Criteria:

- received prior therapy for AML - involvement of central nervous system - history of another type of cancer - women who are pregnant or breastfeeding - other significant medical illness, - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Acute Myeloid Leukemia, AML

More Information

Description: AML is a type of blood cancer where infection fighting cells called white blood cells (WBCs) don't grow up or "mature" like they are supposed to. Instead, they stay stuck as infant or immature "blast" cells. This study will investigate the potential risks and benefits of adding a targeted therapy called ziftomenib to intensive therapy (7+3) OR non-intensive (Venetoclax + Azacitidine) for patients whose cancers are found to have KMT2A rearrangements or mutations in the NPM1 gene. We will also see if the use of ziftomenib as maintenance therapy following consolidation is beneficial.
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