Olutasidenib Single Plus Combo Therapy in IDH1mut AML After Induction and Consolidation

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Histologically or cytologically confirmed non-acute promyelocytic isocitrate dehydrogenase (1 IDH1) mutant acute myeloid leukemia (AML). IDH1 mutation may be identified by NGS or PCR based methods and identified at time of diagnosis or any other time point prior to enrollment. * Completed induction and/or consolidation intended as per treating physician to reach complete response (CR),complete response with partial hematologic recovery (CRh), or complete response with incomplete hematologic recovery (CRi), or morphologic leukemia free state (MLFS) at time of study enrollment Patients must be within 90 days of their last cycle of upfront therapy. * Age ≥18 years * Calculated creatinine clearance (by Cockroft-Gault) ≥30 mL/min * Total bilirubin ≤2 × upper limit of normal (ULN) Note: patients with Gilbert's syndrome may be included if total bilirubin is ≤3 × ULN and direct bilirubin is ≤2 × ULN * Serum aspartate aminotransferase/ alanine aminotransferase (AST/ALT) ≤3 × ULN * Eastern Cooperative Oncology Group (ECOG) 0, 1, or 2 or KPS \>50% * Able to take oral medications * Women of childbearing potential must consent to effective contraception during study treatment and at least 6 months following the last dose. Effective methods of contraception include oral or injectable hormonal birth control, intrauterine device (IUD), and double- barrier methods. (ie, combination of male condom with either cap, diaphragm or sponge with spermicide) * Male participants who are sexually active with a woman of childbearing potential and who have not had vasectomies must be willing to use a barrier method of contraception and refrain from sperm donation from initial study drug until 90 days after last dose of study drug.

Exclusion Criteria:

* History of hypersensitivity or allergic reaction to olutasidenib or its components * Corrected Q-T interval (QTc) (Fredericia calculation) \> 450 ms (after corrective action is taken) * History of Torsades de Pointes * Any gastrointestinal condition thought by the treating investigator to impair oral absorption of medication * Stem cell transplant eligible and planned within 60 days of study start date in the opinion of the treating investigator * Uncontrolled intercurrent illness or infection (those with controlled human immunodeficiency virus (HIV), hepatitis, or other chronic infections are eligible) * Female participants who are pregnant or intend to donate eggs during the study or for 6 months after receiving their last dose of study drug * Nursing women, women of childbearing potential with positive pregnancy test, or women of childbearing potential who are not willing to maintain adequate contraception. (Appropriate method(s) of contraception include oral or injectable hormonal birth control, IUD, and double-barrier methods) * Male participants who intend to donate sperm during the course of this study or for 3 months after last dose * Participants receiving, or are expected to require during the study, any concomitant medications that may interfere with efficacy, metabolism, or safety of the investigational agent, including drugs known to cause QT prolongation. for which drug interactions with olutasidenib would be prohibitory * Concurrent chemotherapy for non-AML malignancy that is expected to interfere with the efficacy, metabolism, or safety of the agent under investigation * Received non-intensive upfront therapy including hypomethylating agents (HMA) /Venetoclax based * Currently receiving other targeted therapies or AML directed therapies, including but not limited to other IDH1 or IDH2 inhibitors, FMS-like tyrosine kinase 3 (FLT3) inhibitors, B-cell lymphoma 2 (BCL-2) inhibitors, menin inhibitors * Other investigational agents in another clinical trial within 4 weeks prior to enrollment * Systemic corticosteroids above physiologic replacement doses (10mg/day prednisone or equivalent), unless used to tread IDH differentiation syndrome or as part of a pre-specified protocol exception * Medical, psychological, or social condition that, in the opinion of the investigator, may increase the participant's risk or limit the participant's adherence with study requirements

Conditions & Interventions

Interventions:
DRUG: Olutasidenib Investigational Agent Administration
Conditions:
Acute Myeloid Leukemia
Keywords:
Acute Myeloid Leukemia

More Information

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