Oral Azacitidine in Transplant-Eligible Patients With Acute Myeloid Leukemia (AML) Suffering From Health-Inequality

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have histologically or cytologically confirmed non-Acute Promyelocytic (APL) FLT3 negative AML and have completed induction and consolidation as defined by the treating physician and must be in complete response (CR), Complete response with partial hematologic recovery (CRh), or Complete response with incomplete count recovery (CRi) at time of study enrollment * For patients in CR1, AML disease phenotype must be one that is considered for allo HCT in CR1 (intermediate or high risk by European Leukemia Net (ELN), MRD+ CR, slow clearance of MRD) or any AML phenotype (aside from FLT3+ and APL) in CR2 and beyond * Medically eligible for allogeneic hematopoietic cell transplant (allo HCT) as defined by either: treating physician discretion, transplant physician discretion, or hematopoietic cell transplantation-specific Comorbidity index (HCT-CI) index of 5 or less * Age ≥ 18 years * Enrollment must occur within 4 months of completion of therapy * A patient or staff identified health disparity in 1 of the 5 Centers for Disease Control (CDC) defined social determinants of health (SDOH). This may include financial difficulties, lack of caregiver support, difficulties with medical literacy, rurality, appropriate access to health care, lack of an appropriate allogeneic hematopoietic cell transplant (allo HCT) donor, substance abuse * Patient must have adequate organ function defined as: Creatinine clearance (by Cockroft-Gault formula) greater than or equal to 29 mL/min, total bilirubin and aspartate aminotransferase/ alanine transaminase (AST/ALT) ≤ to institutional 2x upper limit of normal (except Gilbert's syndrome, which may enroll if \< 2x patient's baseline total bilirubin) * Eastern Cooperative Oncology Group (ECOG) 0,1,2,3 * Ability to take oral medications * No history of malabsorption syndrome which, in the investigator's opinion, may inhibit absorption of oral medications * Women of childbearing potential must consent to effective contraception during study treatment and at least 6 months following the last dose. Women who are breastfeeding are also excluded * Male patients must consent to effective contraception during study and at least 3 months after last dose * Ability to understand and the willingness to sign a written informed consent document Exclusion Criteria A patient who meets any of the following exclusion criteria is ineligible to participate in the study. * FMS-like tyrosine kinase 3 (FLT3 ITD) or tyrosine kinase domain (TKD) mutation * Uncontrolled central nervous system (CNS) involvement * History of hypersensitivity or allergic reaction to azacitidine or its components * Stem cell transplant within previous 3 months prior to initiation of study therapy * Uncontrolled intercurrent illness or infection * History of prior therapy with oral azacitidine * Female patients who are pregnant or intend to donate eggs during the study or for 6 months after receiving their last dose of study drug * Male patients who intend to donate sperm during the course of this study or for 3 months after last dose * Other malignancy for which the patient is currently receiving therapy (except excisable skin cancer) * 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: Oral Azacitidine
Conditions:
Acute Myeloid Leukemia

More Information

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