

Venetoclax and HMA Treatment of Older and Unfit Adults With FLT3 Mutated Acute Myeloid Leukemia (AML) (A MyeloMATCH Treatment Trial)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patient must be ≥ 60 years of age or adults < 60 who in the opinion of the treating physician are better served by azanucleoside-based therapy rather than intensive, cytarabine-based induction based on clinical status (i.e., performance status, age > 75 years), organ dysfunction, or disease biology * Patient must have a morphologically confirmed diagnosis of AML according to the World Health Organization (WHO) 2016 classification excluding acute promyelocytic leukemia (APL) with PML-RARA, AML with RUNX1-RUNX1T1, or AML with CBFB-MYH11 * Patient must have no prior therapy for AML with the exception of hydroxyurea and all-trans retinoic acid (ATRA), or leukapheresis. Patients with cytarabine-based emergency therapy prior to the start of therapy on this trial are eligible * Patient must have no prior therapy with hypomethylating agents or FLT3 inhibitors * Patient must have the FLT3-ITD or D835 mutation based on MyeloMATCH Master Screening and Reassessment Protocol (MSRP) * Patient must be assigned to this protocol by the myeloMATCH MSRP * Patient must not be pregnant or breast-feeding due to the potential harm to an unborn fetus and possible risk for adverse events in nursing infants with the treatment regimens being used. * All patients of childbearing potential must have a blood test or urine study within 14 days prior to registration to rule out pregnancy. * A patient of childbearing potential is defined as anyone, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy; or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * Patient of childbearing potential and/or sexually active patients must not expect to conceive or father children by using an accepted and effective method(s) of contraception or by abstaining from sexual intercourse for the duration of their participation in the study. Contraception measures must continue for 30 days after the last dose of venetoclax for all patients and for 6 months after the last dose of gilteritinib for patients of childbearing potential and for 4 months after the last dose of gilteritinib for male patients with partners of childbearing potential. Patient must not breastfeed during treatment and for 2 months after treatment ends * Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible * Total bilirubin $2X \leq$ institutional upper limit of normal (ULN) (unless thought to be elevated due to disease involvement or Gilbert's syndrome) * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase [SGOT])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase [SGPT]) $\leq < 3.0 \times$ institutional ULN * Either measured or estimated by Cockcroft-Gault equation * Creatinine clearance of ≥ 30 mL/min/1.73m² * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of registration/randomization are eligible for this trial * Patients must not have a baseline corrected QT interval ≥ 480 msec using Fredericia correction (QTcF). NOTE: Since older patients are at risk for prolonged QTc and many will require supportive care with agents that affect the QTc, an ECG is recommended if clinically indicated. If the QTc is prolonged, they should be treated on tier advancement process (TAP) instead of EA02 * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * Patient must not have the medical necessity for ongoing treatment with a strong CYP3A4 inducing drug * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better * Patients must not have an active or uncontrolled infection

Conditions & Interventions

Interventions:

DRUG: Azacitidine, PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Aspiration, PROCEDURE: Bone Marrow Biopsy, DRUG: Gilteritinib, DRUG: Venetoclax

Conditions:

Acute Myeloid Leukemia

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT06317649

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