Comparing New Treatments for People With Newly Diagnosed Acute Myeloid Leukemia That Has an IDH2 Gene Change (A MyeloMATCH Treatment Trial)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have been registered to the MYELOMATCH Master Screening and Reassessment Protocol prior to consenting to this study. Participants must have disease with a detectable IDH2 mutation based on central testing through the MYELOMATCH and be assigned to this clinical trial via MATCHBox prior to registration to this study * Note: Pre-enrollment/diagnosis labs must have already been performed under MYELOMATCH * Participants must have newly diagnosed, untreated acute myeloid leukemia (AML) defined by having ≥ 20% blasts in the bone marrow and/or peripheral blood, excluding acute promyelocytic leukemia (APL) with PML-RARA * Participants must not be receiving or planning to receive any other investigational agents while on protocol therapy * Participants must not have received prior therapy for AML or myelodysplastic syndrome (MDS) and/or myeloproliferative neoplasm (MPN) with the exception of hydroxyurea, all-trans retinoic acid (ATRA), colony-stimulating factors, erythropoiesis-stimulating agents, immunosuppressive therapy, intrathecal chemotherapy, a single dose of cytarabine for cytoreduction, and/or leukapheresis * Participants must not be currently receiving any cytarabine-containing therapy other than up to 1 g/m\^2 of cytarabine, which is allowed for urgent cytoreduction. The use of prior hydroxyurea, all-trans retinoic acid (ATRA), BCR-ABL directed tyrosine kinase inhibitor, erythropoiesis-stimulating agent, thrombopoietin receptor agonist and lenalidomide are allowed. Participants may receive hydroxyurea prior to treatment assignment on this substudy for cytoreduction but must agree to discontinue hydroxyurea prior to beginning treatment on this substudy * White blood cell (WBC) must be \< 25 x 10\^9/L. Hydroxyurea, leukapheresis, and cytarabine \< 1 g/m\^2 are permitted to control the WBC prior to enrollment and initiation of protocol-defined therapy but must be stopped prior to initiation of protocol therapy * Participants must be ≥ 60 years old; OR must be ≥ 18 years old and considered not eligible for cytarabine-based induction therapy * Participants must have Zubrod Performance Status of 0-3 as determined by a history and physical (H\&P) exam completed within 14 days prior to registration * Participants must have a complete medical history and physical exam within 14 days prior to registration * Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN) unless history of Gilbert's syndrome. Participants with history of Gilbert's syndrome must have total bilirubin ≤ 3 x institutional ULN (within 14 days prior to registration) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT) (serum glutamic pyruvic transaminase \[SGPT\]) ≤ 3 × institutional ULN, unless considered to be elevated due to disease involvement (within 14 days prior to registration) * Participants must have adequate kidney function as evidenced by creatinine clearance ≥ 30mL/min (by Cockcroft Gault) within 14 days prior to registration * Participants must not have a baseline corrected QT interval ≥ 480 msec using Fridericia correction (QTcF). * NOTE: Since older participants are at risk for prolonged QTc and may require supportive care with agents that affect QTc, an electrocardiogram (ECG) is recommended if clinically indicated. If the QTc is prolonged, they should be treated on MYELOMATCH TAP instead of MM1OA-S03 * Participants must have adequate cardiac function in the assessment of their treating physician. Participants with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, must have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, participants must be class 2 or better * Participants with known human immunodeficiency virus (HIV)-infection must be on effective anti-retroviral therapy at registration and have undetectable viral load test on the most recent test results obtained within 6 months prior to registration * Participants with a known history of chronic hepatitis B virus (HBV) infection must have undetectable HBV viral load while on suppressive therapy on the most recent test results obtained within 6 months prior to registration, if indicated * Participants with a known history of hepatitis C virus (HCV) infection must have been treated and cured. Participants currently being treated for HCV infection must have undetectable HCV viral load test on the most recent test results obtained within 6 months prior to registration, if indicated * Participants must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the safety or efficacy assessment of the investigational regimen * Participants must not be pregnant or nursing (nursing includes breast milk fed to an infant by any means, including from the breast, milk expressed by hand, or pumped). Individuals who are of reproductive potential must have agreed to use an effective contraceptive method with details provided as a part of the consent process. A person who has had menses at any time in the preceding 12 consecutive months or who has semen likely to contain sperm is considered to be of "reproductive potential." In addition to routine contraceptive methods, "effective contraception" also includes refraining from sexual activity that might result in pregnancy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen * Participants must be able to swallow and retain oral medications and have no known gastrointestinal disorders likely to interfere with absorption of oral medications * Participants must have agreed to have specimens submitted for translational medicine for MRD under MYELOMATCH and specimens must be submitted * Enrollment to this treatment study requires prior enrollment into the myeloMATCH Master Protocol (MYELOMATCH). Participants enrolled in MYELOMATCH will submit bone marrow samples, peripheral blood samples, and buccal swabs to the Molecular Diagnostics Network (MDNet), the Clinical Laboratory Improvement Act (CLIA) laboratory network for myeloMATCH * In addition to the MYELOMATCH specimens, there will be specimens obtained on treatment for this substudy. These specimens will be derived from procedures performed as part of standard assessments in the clinical care and management of AML with material being sent to the MDNet laboratories as specified. After performing the required tests on the specimens, the MDNet laboratories will send the residual material for biobanking and future research. Therefore, participants must be asked for their consent for the biobanking of specimens for future unspecified research. Participants may refuse this, but it is mandatory for sites to ask participants * Participants must be offered the opportunity to participate in specimen banking * NOTE: As a part of the Oncology Patient Enrollment Network (OPEN) registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system * Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines. For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and Central Institutional Review Board (CIRB) regulations

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Aspiration, PROCEDURE: Bone Marrow Biopsy, DRUG: Decitabine and Cedazuridine, DRUG: Enasidenib, DRUG: Venetoclax

Conditions:

Acute Myeloid Leukemia

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: PHASE2

IRB

Number:
System ID: NCT06672146

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