

Quizartinib or Placebo Plus Chemotherapy in Newly Diagnosed Patients With FLT3-ITD Negative AML

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 70 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* Must be competent and able to comprehend, sign, and date an Ethics Committee (EC)- or Institutional Review Board (IRB)-approved Informed Consent Form (ICF) before performance of any trial-specific procedures or tests. * ≥ 18 years or the minimum legal adult age (whichever is greater) and 70 years (at Screening). * Newly diagnosed, morphologically documented primary AML based on the World Health Organization (WHO) 2016 classification (at Screening) * Eastern Cooperative Oncology Group (ECOG) performance status (at the time the participant signs their ICF) of 0-2. * Participant is receiving standard "7+3" induction chemotherapy regimen as specified in the protocol Key

Exclusion Criteria:

* Diagnosis of acute promyelocytic leukemia (APL), French-American-British classification M3 or WHO classification of APL with translocation, t(15;17)(q22;q12), or BCR-ABL positive leukemia (ie, chronic myelogenous leukemia in blast crisis); participants who undergo diagnostic workup for APL and treatment with all-trans retinoic acid (ATRA), but who are found not to have APL, are eligible (treatment with ATRA must be discontinued before starting induction chemotherapy). * Diagnosis of AML secondary to prior chemotherapy or radiotherapy for other neoplasms or autoimmune/rheumatologic conditions. * Diagnosis of AML secondary to myelodysplastic syndrome (MDS) or a myeloproliferative neoplasm (MPN) or MDS/MPNs including CMML, aCML, JMML and others. * Participants with newly diagnosed AML with FLT3-ITD mutations (FLT3-ITD \backslash [+] \backslash) present at $\geq 5\%$ VAF (or ≥ 0.05 SR) based on a validated FLT3 mutation assay. * Prior treatment for AML, except for the following allowances: 1. Leukapheresis; 2. Treatment for hyperleukocytosis with hydroxyurea; 3. Cranial radiotherapy for central nervous system (CNS) leukostasis; 4. Prophylactic intrathecal chemotherapy; 5. Growth factor/cytokine support.

Conditions & Interventions

Interventions:

DRUG: Quizartinib, DRUG: Placebo, DRUG: Chemotherapy

Conditions:

Leukemia

Keywords:

acute myeloid leukemia, quizartinib, FLT3, FLT3-ITD, Chemotherapy, FLT3-WT

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06578247

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