

# 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:

1. Must be competent and able to comprehend, sign, and date an Ethics Committee (EC)- or Institutional Review Board (IRB)-approved ICF before performance of any trial-specific procedures or tests. 2.  $\geq 18$  years or the minimum legal adult age (whichever is greater) and  $\leq 70$  years (at Screening). 3. Newly diagnosed, morphologically documented primary AML based on the World Health Organization (WHO) 2016 classification (at Screening) 4. Eastern Cooperative Oncology Group (ECOG) performance status (at the time the participant signs their ICF) of 0-2. 5. Participant is a candidate for standard "7+3" induction chemotherapy regimen as specified in the protocol per investigator assessment Key

### Exclusion Criteria:

1. 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). 2. Diagnosis of AML secondary to prior chemotherapy or radiotherapy. 3. Diagnosis of AML with known antecedent myelodysplastic syndrome (MDS) or a myeloproliferative neoplasm (MPN) or MDS/MPNs including chronic myelomonocytic leukemia (CMML), atypical chronic myeloid leukemia (aCML), juvenile myelomonocytic leukemia (JMML) and others. 4. Participants with newly diagnosed AML with FLT3-ITD mutations (FLT3-ITD  $\setminus [+ \setminus ]$ ) present at  $\geq 5\%$  VAF (or  $\geq 0.05$  SR) based on a validated FLT3 mutation assay. 5. Prior treatment for AML, except for the following allowances prior to Day 1 of chemotherapy: 1. Leukapheresis; 2. Treatment for hyperleukocytosis with hydroxyurea; 3. Cranial radiotherapy for central nervous system (CNS) leukostasis; 4. Prophylactic intrathecal chemotherapy

## 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:

IRB

Number:

System ID: NCT06578247

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