A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled Study of AG-120 in Combination With Azacitidine in Subjects ≥18 Years of Age With Previously Untreated Acute Myeloid Leukemia (AML) With an Isocitrate Dehydrogenase 1 (IDH1) Mutation

**Status:** Enrolling Globally

**Study population (selected criteria):**
- Previously untreated AML (World Health Organization criteria) with ≥20% bone marrow blasts
- Has an IDH1 mutation
- Excludes patients who are candidates for and willing to receive intensive chemotherapy
- No prior hypomethylating agents for myelodysplastic syndrome

**Primary endpoints:**
- Overall survival

**Secondary endpoints:**
- Event-free survival
- Complete remission (CR) rate
- CR + CR with partial hematologic recovery rate
- Objective response rate

1:1 Randomization

28-day cycles

**AG-120 (ivosidenib)**
- 500 mg PO Daily
- + Azacitidine
- 75 mg/m² SC or IV on Days 1-7 or 5-2-2

**Placebo**
- PO Daily
- + Azacitidine
- 75 mg/m² SC or IV on Days 1-7 or 5-2-2

The safety and efficacy of the agents and use under investigation have not been established.
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PARTICIPATING COUNTRIES

- Australia
- Austria
- Brazil
- Canada
- China
- Czech Republic
- France
- Germany
- Israel
- Italy
- Japan
- Korea
- Mexico
- Netherlands
- Poland
- Russia
- Spain
- Taiwan
- United Kingdom
- United States

For additional details about Agios study AG120-C-009, including the study design, study location, or other information, please visit www.ClinicalTrials.gov (Identifier: NCT03173248) or contact Agios Medical Information: email: medinfo@agios.com; Phone: 833-228-8474.