AGILE

AGios study for IDH1 mutation in acute myeloid LEukemia

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

1:1 Randomization

28-day cycles

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

Placebo
PO Daily
+
Azacitidine
75 mg/m^2
SC or IV on Days 1–7
or 5-2-2

Primary endpoint:

- Event-free survival

Secondary endpoints:

- Overall survival
- Complete remission (CR) rate
- CR + CR with partial hematologic recovery rate
- Objective response rate

The safety and efficacy of the agents and uses under investigation have not been established. There is no guarantee that the agents will receive health authority approval or become commercially available in any country for the uses being investigated.

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.

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