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:

- Overall survival

Secondary endpoints:

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

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

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.

IVO-US-0207 11/1/2019

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