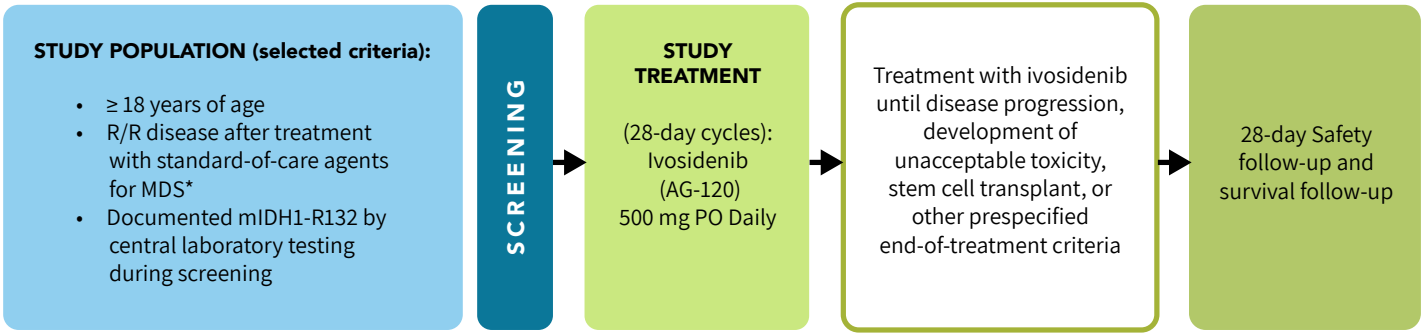
Ivosidenib (AG-120) in patients with IDH1-mutant relapsed/refractory myelodysplastic syndrome (MDS)

STATUS: **ENROLLING**

BACKGROUND: Ivosidenib is approved in the US for the treatment of AML with a susceptible IDH1 mutation as detected by an FDA-approved test in adults with newly diagnosed AML who are ≥ 75 years of age or who have comorbidities that preclude the use of intensive induction chemotherapy and in adults with relapsed or refractory (R/R) AML.

OBJECTIVE: Asses the safety, tolerability, and clinical activity of ivosidenib 500 mg in patients with IDH1-mutant R/R MDS.

STUDY DESIGN



*Includes treatment with high-intensity chemotherapy (ie, standard induction chemotherapy as well as intensive combination chemotherapy that may include investigational agent) and HMA-based therapies treatment.

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.

Ivosidenib is not approved for the treatment of MDS.

For additional details about Agios study AG120-C-001, including the study design, study location, or other information, please visit www.ClinicalTrials.gov (Identifier: NCT02074839) or contact Agios Medical Information: e-mail, medinfo@agios.com; Phone, 833-228-8474.

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