ClarIDHy Clinical Trial

Focus on isocitrate dehydrogenase 1 (IDH1) mutations in your approach to advanced cholangiocarcinoma

About the ClarIDHy Clinical Trial:

ClarIDHy is a multicenter, Phase 3, double-blind, placebo-controlled study of AG-120 for patients with advanced cholangiocarcinoma (nonresectable or metastatic) and an IDH1 mutation.[1]

Targeting IDH1 Mutations:

Mutations in IDH1 may be present in 13%-15% of patients with cholangiocarcinoma.[2,3]AG-120 is an investigational agent that targets the mutated IDH1 enzyme.

Is the ClarIDHy Clinical Trial Right for Your Patient?

ClarIDHy is for patients with advanced cholangiocarcinoma with IDH1 mutations.

Inclusion Criteria:

1. Be ≥18 years of age.
2. Have a histopathological diagnosis (fresh or banked tumor biopsy sample, preferably collected within the last 3 years) of nonresectable or metastatic cholangiocarcinoma and are not eligible for curative resection, transplantation, or ablative therapies.
3. Have documented IDH1 gene-mutated disease (from a fresh tumor biopsy or the most recent banked tumor tissue available) based on central laboratory testing (R132C/L/G/H/S mutation variants tested).
4. Have an ECOG PS score of 0 or 1.
5. Have an expected survival of ≥3 months.
6. Have at least one evaluable and measurable lesion as defined by RECIST v1.1. Subjects who have received prior local therapy (including, but not limited to, embolization, chemoembolization, radiofrequency ablation, or radiation therapy) are eligible provided measurable disease falls outside of the treatment field or within the field and has shown ≥20% growth in size since post-treatment assessment.
7. Have documented disease progression following at least 1 and no more than 2 prior systemic regimens for advanced disease (nonresectable or metastatic). Subjects must have received at least 1 gemcitabine- or 5-FU–containing regimen for advanced cholangiocarcinoma. Subjects who have received systemic adjuvant chemotherapy will be permitted provided there is documented disease progression during or within 6 months of completing the therapy.

How To Participate

If you think your patient might be eligible to participate in the ClarIDHy clinical trial or to find the ClarIDHy clinical trial sites near you, visit www.clinicaltrials.gov or contact Agios Medical Affairs:

Email: medinfo@agios.com

Phone: 844.MEDAFFAIRS (844.633.2332)

Visit www.claridhy.com to learn more about the ClarIDHy clinical trial

The safety and efficacy of AG-120 has not been established. There is no guarantee that AG-120 will receive health authority approval or become commercially available for the use being investigated.

References

1. Study of AG-120 in Previously Treated Advanced Cholangiocarcinoma With IDH1 Mutations (ClarIDHy). ClinicalTrials.gov. U.S. National Institutes of Health. https://www.clinicaltrials.gov/ct2/show/study/NCT02989857. Accessed December 14, 2016.
2. Borger DR, Tanabe KK, Fan KC, et al. Frequent mutation of isocitrate dehydrogenase (IDH)1 and IDH2 in cholangiocarcinoma identified through broad-based tumor genotyping. *Oncologist*. 2012;17(1):72-79.
3. Kipp BR, Voss JS, Kerr SE, et al. Isocitrate dehydrogenase 1 and 2 mutations in cholangiocarcinoma. *Hum Pathol*. 2012;43(10):1552-1558.

agios