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ASIA EDITION

Agios's Phase 3 ClarIDHy trial of TIBSOVO meet its primary endpoint

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In June 2018, CStone entered into an exclusive collaboration and license agreement with Agios to develop and commercialize TIBSOVO in Greater China region.



The partner of CStone Pharmaceuticals, Agios Pharmaceuticals has announced that the global Phase 3 ClarIDHy trial of TIBSOVO (ivosidenib) in previously treated cholangiocarcinoma patients with an isocitrate dehydrogenase 1 (IDH1) mutation met its primary endpoint. Treatment with TIBSOVO demonstrated a statistically significant improvement in progression-free survival (PFS) by independent radiology review compared with patients who received placebo. The safety profile observed in the study was consistent with previously published data.

A full analysis of the ClarIDHy trial will be submitted for presentation at the European Society for Medical Oncology Congress in 2019. Agios plans to submit a supplemental new drug application for TIBSOVO in previously treated IDH1 mutant cholangiocarcinoma by the end of 2019.

Cholangiocarcinoma is a very aggressive tumor for which surgical resection is the primary treatment option. Many patients are undiagnosed until the mid-to-late stages when they have missed the time window for surgery. At present, there is no standard second- and third-line treatment for patients with advanced cholangiocarcinoma. Patients typically suffer a poor prognosis and short-term survival.

China is among the countries with the highest incidence of Cholangiocarcinoma which is associated with a variety of high-risk factors including hepatitis B and Clonorchis sinensis infection, diseases that are endemic in the country.

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ClarIDHy Phase 3 Trial

The ClarIDHy trial is a global, randomized Phase 3 trial in previously treated IDH1 mutant cholangiocarcinoma patients who have documented disease progression following one or two systemic therapies in the advanced setting. As of theJanuary 31, 2019 data cutoff, 185 patients were randomized.

- Patients were randomized 2:1 to receive either single-agent TIBSOVO 500 mg once daily or placebo with crossover to TIBSOVO permitted at the time of documented radiographic progression per RECIST 1.1.
- The primary endpoint of the trial is PFS as evaluated by independent radiology review with secondary endpoints including investigator evaluated PFS, safety and tolerability, overall response rate, overall survival, duration of response, PK/PD and quality of life assessments.
- The study was designed with 96% power to detect a hazard ratio of 0.5 for PFS (TIBSOVO vs. placebo), with a one-sided alpha of 0.025.
- Thermo Fisher Scientific is providing next-generation sequencing to detect IDH1 mutations for all tumor samples as inclusion criteria for enrollment in the study and will develop and commercialize the validated companion diagnostic.

TIBSOVO is not approved in any country for the treatment of patients with advanced cholangiocarcinoma.