Tibsovo® (ivosidenib) – New indication

- On August 27, 2021, Servier Pharmaceuticals announced the FDA approval of Tibsovo (ivosidenib), for the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

- Tibsovo is also approved for newly-diagnosed acute myeloid leukemia (AML) and relapsed or refractory AML.

- The approval of Tibsovo for the new indication was based on a randomized, double-blind, placebo-controlled study in 185 adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation. Patients were randomized to receive either Tibsovo or placebo until disease progression or unacceptable toxicity. The major efficacy measure was progression free survival (PFS).

    — Progressive disease or death occurred in 61% of patients treated with Tibsovo vs. 82% with placebo (hazard ratio [HR] 0.37, 95% CI 0.25, 0.54; $p < 0.0001$).
    — The median overall survival (OS) for Tibsovo was 10.3 months vs. 7.5 months for placebo (HR 0.79, 95% CI: 0.56, 1.12; $p = 0.093$).

- Tibsovo carries a boxed warning for differentiation syndrome in AML.

- The most common adverse reactions (≥ 15%) with Tibsovo use in cholangiocarcinoma were fatigue, nausea, abdominal pain, diarrhea, cough, decreased appetite, ascites, vomiting, anemia, and rash.

- The most common laboratory abnormalities (≥ 10%) with Tibsovo use in cholangiocarcinoma were decreased hemoglobin, increased aspartate aminotransferase, and increased bilirubin.

- The recommended dose of Tibsovo is 500 mg taken orally once daily until disease progression or unacceptable toxicity.

    — Patients should be selected for the treatment of locally advanced or metastatic cholangiocarcinoma with Tibsovo based on the presence of IDH1 mutations. Information on FDA-approved tests for the detection of IDH1 mutations is available at http://www.fda.gov/CompanionDiagnostics.
    — Consult the Tibsovo drug label for dosing recommendations for AML.