FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting
September 13, 2024

QUESTIONS

Proposed Indication:

To reduce the risk of death, liver transplant, and hepatic decompensation in adults with Primary Biliary Cholangitis (PBC) without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

1. **DISCUSSION**: Discuss whether the evidence generated post-approval verify the benefit of obeticholic acid (OCA, Ocaliva®) on clinical outcomes (hepatic decompensation, liver transplant, and death) in adults with PBC? Specifically, discuss the evidence generated in the:
    a. Post-marketing required Study 302, and
    b. Observational Study 405

2. **DISCUSSION**: Discuss the safety of OCA, including the incidence of liver transplant and all-cause death in the United States Prescribing Information (USPI)-labeled and the overall study population.

3. **VOTE:** Does the available evidence verify the benefit of OCA on clinical outcomes (hepatic decompensation, liver transplant, and death) in the USPI-labeled population?
    - Provide a rationale for your vote.

4. **VOTE**: Is the benefit-risk profile of OCA favorable in the USPI-labeled population?
    - Provide a rationale for your vote.