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

Oncologic Drugs Advisory Committee (ODAC) Meeting
April 21, 2022

QUESTIONS

Discussion of the appropriate approach to develop phosphatidylinositol 3-kinase (PI3K) inhibitors in patients with hematologic malignancies and whether randomized data should be required to support a demonstration of substantial evidence of effectiveness and that the drug is safe for its intended use in the proposed population.

---

1. **DISCUSSION:** Please discuss the observed toxicity of the PI3K inhibitor class and whether randomized data are warranted with an assessment of overall survival (OS) to support the evaluation of benefit-risk in patients with hematologic malignancies.

2. **VOTE:** Given the observed toxicities with this class, previous randomized trials with a potential detriment in OS, and a narrow range between effective and toxic doses, should future approvals of PI3K inhibitors be supported by randomized data?