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

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

DRAFT 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.

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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?