

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

*Oncologic Drugs Advisory Committee (ODAC) Meeting*  
February 10, 2022

**DRAFT QUESTIONS**

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1. **DISCUSSION:** Discuss the generalizability of ORIENT-11 to a U.S. population and U.S. medical practice.
2. **DISCUSSION:** Discuss potential clinical trials which may address issues of applicability of ORIENT-11 to a U.S. population.
3. **VOTE:** Given that ORIENT-11 may not be applicable to U.S. patients or U.S. medical practice, should additional clinical trial(s) demonstrating applicability be required prior to a final regulatory decision?

DRAFT