

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

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

QUESTIONS

1. **DISCUSSION:** Discuss the generalizability of ORIENT-11 to a U.S. population and U.S. medical practice.
2. **DISCUSSION:** Discuss potential clinical trials (if any) which may address issues of applicability of ORIENT-11 to a U.S. population.
3. **VOTE:** Should additional clinical trial(s) demonstrating applicability to U.S. patients and U.S. medical care be required prior to a final regulatory decision?