

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
April 12, 2024

QUESTIONS

1. **DISCUSSION:** Discuss the adequacy of the available data to support the use of minimal residual disease (MRD) as an accelerated approval endpoint in multiple myeloma (MM).
2. **DISCUSSION:** Discuss whether the available data supports the use of MRD as an endpoint in the different MM disease settings.
 - Newly diagnosed MM
 - Relapsed/Refractory MM
3. **DISCUSSION:** Discuss the acceptability of the timepoints for MRD assessment:
 - 9-months, 12-months, MRD negative complete response at any time
 - Requirement for assessment of durability
4. **VOTE:** Does the evidence support the use of MRD as an accelerated approval endpoint in MM clinical trials?