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

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

DRAFT QUESTIONS

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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?