

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

*Oncologic Drugs Advisory Committee (ODAC) Meeting*  
March 14, 2024

**DRAFT QUESTIONS**

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1. **DISCUSSION:** Discuss the efficacy of imetelstat for patients with lower-risk myelodysplastic syndromes (MDS) based on the results of the MDS3001 trial considering the safety profile.
2. **VOTE:** Do the benefits of imetelstat outweigh its risks for the treatment of transfusion-dependent anemia in adult patients with International Prognosis Scoring System (IPSS) low- to intermediate-1 risk MDS who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents?

DRAFT