

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
November 16, 2023

QUESTIONS

1. **DISCUSSION:** Discuss the delays in post-approval confirmatory trials for pralatrexate and belinostat, and whether the current plan to verify the clinical benefit of these products in patients with peripheral T-cell lymphoma is reasonable considering the Sponsor's proposed timelines.
2. **DISCUSSION:** Discuss strategies to promote timely completion of the confirmatory trial for pralatrexate and belinostat, and insights from this experience that may facilitate completion of confirmatory trials for future accelerated approvals.