

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
October 28, 2022

DRAFT QUESTIONS

BLA 761176

¹³¹I-omburtamab solution for injection

Applicant: Y-mAbs Therapeutics, Inc.

INDICATION:

- the treatment of central nervous system/leptomeningeal (CNS/LM) metastases in pediatric patients with neuroblastoma following standard multimodality treatment for CNS disease.
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1. **DISCUSSION:** Discuss whether data provided by the Applicant isolates the treatment effect of ¹³¹I-omburtamab from the effects of multimodality therapy for CNS/LM relapse or if additional data are needed.
2. The Applicant has provided a comparison of ¹³¹I-omburtamab following multimodality treatment in single-arm Study 03-133 to an external control derived from a German registry.

VOTE: Has the Applicant provided sufficient evidence to conclude that ¹³¹I-omburtamab improves overall survival?