

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
February 26, 2020

DRAFT QUESTIONS

sNDA 125477/S-034

CYRAMZA (ramucirumab) injection for intravenous use
Applicant: Eli Lilly and Company

PROPOSED INDICATION: In combination with erlotinib, for first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) substitution mutations.

1. **VOTE:** Is the benefit/risk profile of ramucirumab plus erlotinib favorable for patients with untreated metastatic EGFR-positive non-small cell lung cancer?