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

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. **DISCUSSION:** Discuss whether the results of the RELAY trial, with a demonstrated improvement in PFS, support a positive benefit/risk assessment given the uncertain effect on OS and the increased toxicity associated with the addition of ramucirumab to erlotinib.

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