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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 25, 2024

DRAFT QUESTIONS

Supplemental Biologics License Application (sBLA) 761069/S-043, for IMFINZI (durvalumab) Injection, Submitted by AstraZeneca UK Limited

PROPOSED INDICATION:
IMFINZI in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

1. **DISCUSSION:** In light of the uncertainty around the need for both phases of treatment, discuss whether an additional trial should be conducted to clarify the contribution of treatment phase for the durvalumab perioperative regimen prior to approval.

Future Perioperative Trial Designs to Support Contribution of Sequence

1. **VOTE:** Should FDA require that new trial design proposals for perioperative regimens for resectable NSCLC include adequate within trial assessment of contribution of treatment phase?