

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
December 17, 2019

QUESTION

sNDA 208558/010
Lynparza (olaparib) tablets
Applicant: AstraZeneca Pharmaceuticals LP

PROPOSED INDICATION: Maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic adenocarcinoma of the pancreas whose disease has not progressed on first-line platinum-based chemotherapy.

1. **VOTE:** Is the risk-benefit assessment for olaparib as a maintenance therapy in patients with gBRCAm pancreatic cancer favorable?