

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
April 28, 2023

QUESTION

NDA 208558/S-025

LYNPARZA (olaparib)

Applicant: AstraZeneca Pharmaceuticals LP

PROPOSED INDICATION:

- in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC).
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1. **VOTE:** As FDA reviews the proposed indication for olaparib in combination with abiraterone for initial treatment of mCRPC, should the indication be restricted to patients whose tumors have a *BRCA* mutation?

If you feel the combination should not be approved for any indication, please abstain from voting and explain your thinking regarding approvability during the post-voting discussion period.