

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

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

**DRAFT QUESTION**

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**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.