

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

***Oncologic Drugs Advisory Committee (ODAC) Meeting***  
April 30, 2026

**DRAFT QUESTIONS**

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**Morning session**

1. **VOTE:** Based on the results of SERENA-6, has clinically meaningful benefit for camizestrant been demonstrated for the treatment of patients with HR+/HER2- metastatic breast cancer with a tumor ESR1 mutation detected while on aromatase inhibitor and CDK4/6 inhibitor treatment, prior to radiographic progression?

**Afternoon session**

1. **VOTE:** Based on the CAPItello-281 results, does the benefit of adding capivasertib to abiraterone and prednisone outweigh the risk for the proposed indication?