

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

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

QUESTIONS

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?