

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC)

April 30, 2026

AGENDA

On the morning of April 30, 2026, the Committee will discuss new drug application (NDA) 220359, for camizestrant tablets, submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) is in combination with a CDK4/6 inhibitor (palbociclib, ribociclib or abemaciclib) for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer upon emergence of ESR1 mutation during first-line endocrine-based therapy, based on an FDA approved test.

On the afternoon of April 30, 2026, the Committee will discuss supplemental new drug application (sNDA) 218197/S-004, for Truqap (capivasertib) tablets, submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) is in combination with abiraterone for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) that is PTEN-deficient as detected by an FDA-approved test.

Morning Session

8:00 a.m.	Call to Order and Introduction of Committee	Neil Vasan, MD, PhD Acting Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	Joyce Frimpong, PharmD Acting Designated Federal Officer, ODAC
8:10 a.m.	FDA Opening Remarks	Mirat Shah, MD Clinical Team Leader Division of Oncology 1 (DO1) Office of Oncologic Diseases (OOD), Office of New Drugs (OND), CDER, FDA
8:25 a.m.	OPEN PUBLIC HEARING	
8:55 a.m.	APPLICANT PRESENTATIONS	AstraZeneca Pharmaceuticals LP
	Introduction	Ingrid Mayer, MD, MSCI Vice President Global Clinical Strategy Head, Breast/GYN Cancers Late Development Oncology, Research & Development AstraZeneca
	Disease Background & Unmet Need	Massimo Cristofanilli, MD, FACP Scientific Director of the Englander Institute of Precision Medicine Weill-Cornell Medicine and NY Presbyterian
	SERENA-6 Efficacy and PROs	Cynthia Huang-Bartlett, MD Global Clinical Head – Camizestrant AstraZeneca

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

SERENA-6 Clinical Safety

Andrew Walding, MSc
Global Safety Head – Camizestrant
AstraZeneca

Clinical Perspective

Kevin Kalinsky, MD, MS, FASCO
Director of the Glenn Family Breast Center at
Winship Cancer Center
Emory University School of Medicine

Concluding Remarks

Ingrid Mayer, MD MSCI

9:40 a.m.

FDA PRESENTATION

NDA 220359 Camizestrant

Joshua Donaldson, MD, PhD
Clinical Reviewer
DO1, OOD, OND, CDER, FDA

10:25 a.m.

BREAK

10:35 a.m.

Clarifying Questions

11:00 a.m.

Questions to the Committee/Committee
Discussion

12:00 p.m.

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AGENDA (cont.)

Afternoon Session

1:00 p.m.	Call to Order and Introduction of Committee	Neil Vasan, MD, PhD Acting Chairperson, ODAC
1:05 p.m.	Conflict of Interest Statement	Joyce Frimpong, PharmD Acting Designated Federal Officer, ODAC
1:10 p.m.	FDA Opening Remarks	Elaine Chang, MD Clinical Team Leader DO1, OOD, OND, CDER, FDA
1:25 p.m.	OPEN PUBLIC HEARING	
1:55 p.m.	APPLICANT PRESENTATIONS	AstraZeneca Pharmaceuticals LP
	Introduction	Andrew Foxley, MFPM (Hon) Vice President Late Development Franchise Head Oncology Small Molecules AstraZeneca
	Disease Background & Unmet Need	Elisabeth I. Heath, MD, FACP Chair, Department of Oncology Professor of Oncology Mayo Clinic Rochester, Minnesota
	CAPItello-281 Clinical Efficacy	Gaia Schiavon, MD, PhD Global Clinical Head – Capivasertib AstraZeneca
	CAPItello-281 Clinical Safety & PROs	Mayur Patel, PharmD Vice President Patient Safety, Oncology AstraZeneca
	Benefit: Risk & Clinical Perspective	Daniel J. George, MD Professor of Medicine and Surgery Divisions of Medical Oncology and Urology Director, Genitourinary Oncology Duke Cancer Institute Duke University School of Medicine

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AGENDA (cont.)

2:40 p.m. **FDA PRESENTATION**

Capivasertib with Abiraterone and Prednisone
for PTEN-deficient mHSPC

Daniel Lee, MD, PhD

Clinical Reviewer

DO1, OOD, OND, CDER, FDA

3:25 p.m. **BREAK**

3:35 p.m. Clarifying Questions

4:00 p.m. Questions to the Committee/Committee
Discussion

5:00 p.m. **ADJOURNMENT**