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

Oncologic Drugs Advisory Committee (ODAC)

April 30, 2026

DRAFT 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

DRAFT 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 PRESENTATIONS**	
	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.	**LUNCH**	

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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DRAFT AGENDA (cont.)

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