

**Food and Drug Administration
Center for Drug Evaluation and Research**

**Final Summary Minutes of the Oncologic Drugs Advisory Committee Meeting
April 30, 2026**

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, Maryland. The public also had the option to participate via an online teleconferencing and/or video conferencing platform, and the meeting presentations were heard, viewed, captioned, and recorded through an online video conferencing platform.

Topic: On the morning of April 30, 2026, the Committee discussed 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 discussed supplemental new drug application (sNDA) 218197/S-004, for Truqap (capiwasertib) 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.

These summary minutes for the April 30, 2026 meeting of the Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration were approved on May 26, 2026.

I certify that I attended the April 30, 2026 meeting of the ODAC of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
Joyce Frimpong, PharmD
Acting Designated Federal Officer, ODAC

/s/
Neil Vasan, MD, PhD
Acting Chairperson, ODAC

Summary Minutes of the Oncologic Drugs Advisory Committee Meeting April 30, 2026

The Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration, Center for Drug Evaluation and Research met on April 30, 2026, at the FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503), 10903 New Hampshire Avenue, Silver Spring, Maryland. The public also had the option to participate via an online teleconferencing and/or video conferencing platform, and the meeting presentations were heard, viewed, captioned, and recorded through an online video conferencing platform. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA and AstraZeneca Pharmaceuticals LP. The meeting was called to order by Dr. Neil Vassan (Acting Chairperson). The conflict of interest statement was read into the record by Joyce Frimpong, PharmD (Acting Designated Federal Officer). There were approximately 1,850 people in attendance. There were 7 Open Public Hearing (OPH) speaker presentations during the morning session and 6 OPH speaker during the afternoon session.

A verbatim transcript will be available, in most instances, at approximately ten to twelve weeks following the meeting date.

Agenda: On the morning of April 30, 2026, the Committee discussed 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.

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Attendance:

Oncologic Drugs Advisory Committee Members Present (Voting): Toni K. Choueiri, MD; William J. Gradishar, MD (*via video conferencing platform*); Neil Vasan, MD, PhD

Oncologic Drugs Advisory Committee Members Not Present (Voting): Daniel Spratt, MD

Oncologic Drugs Advisory Committee Member Present (Non-Voting): Tara L. Frenkl, MD, MPH (*Industry Representative*)

Temporary Members (Voting): Karla V. Ballman, PhD, FASCO; Sarah Colonna, MD, MSCI (*Morning Session Only*); Natalie Compagni-Porits, PsyD, MFT (*Patient Representative; Morning Session Only*); Paul T. Conway (*Patient Representative; Afternoon Session Only; via video conferencing platform*); Lori E. Dodd, PhD (*Morning Session Only*); Franklin Huang, MD,

PhD (*Afternoon Session Only*); Michael J. Kelley, MD (*Morning Session Only*); Stanley Lipkowitz, MD, PhD (*Morning Session Only*); Brian Rini, MD (*Afternoon Session Only, via video conferencing platform*); Kyle Robinson, MD (*Afternoon Session Only*); Aihua Edward Yen, MD (*Afternoon Session Only*)

FDA Participants (Non-Voting): R. Angelo de Claro, MD; Laleh Amiri-Kordestani, MD; Daniel Suzman, MD (*Afternoon Session Only*); Mirat Shah, MD (*Morning Session Only*); Elaine Chang, MD (*Afternoon Session Only*); Joshua Donaldson, MD, PhD (*Morning Session Only*); Suparna Wedam, MD (*Morning Session Only*); Daniel Lee, MD, PhD (*Afternoon Session Only*); Daeyoung Lim, PhD (*Morning Session Only*)

Designated Federal Officer (Non-Voting): Joyce Frimpong, PharmD

Open Public Hearing Speakers:

Morning session: Ming- Hei Tai, PharmD; Diana Zuckerman PhD (National Center for Health Research); Joyce O'Shaughnessy, MD (Baylor University Medical Center/ Sarah Cannon Research Institute); Sarah Sammons, MD (Dana-Farber Cancer Institute); Caroline Koffke, RN (Living Beyond Breast Cancer (LBBC)); Kacie Flaherty; Deanna Hirsch (statement read by Caroline Koffke)

Afternoon session: Diana Zuckerman, PhD (National Center for Health Research); Neeraj Agarwal, MD (Huntsman Cancer Institute at the University of Utah); Michael Philbin, PhD (Facing Our Risk of Cancer Empowered-FORCE); Neal D. Shore, MD (START CANCER RESEARCH/Atlantic Urology Specialists); Gina B. Carithers (Prostate Cancer Foundation (PCF)); Courtney Bugler (ZERO Prostate Cancer)

The agenda was as follows:

Call to Order and Introduction of Committee

Neil Vasan, MD, PhD
Acting Chairperson, ODAC

Conflict of Interest Statement

Joyce Frimpong, PharmD
Acting Designated Federal Officer, ODAC

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

OPEN PUBLIC HEARING

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
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
FDA PRESENTATION	Joshua Donaldson, MD, PhD Clinical Reviewer DO1, OOD, OND, CDER, FDA
NDA 220359 Camizestrant	
BREAK	
Clarifying Questions	
Questions to the Committee/Committee Discussion	
LUNCH	
Call to Order and Introduction of Committee	Neil Vasan, MD, PhD Acting Chairperson, ODAC
Conflict of Interest Statement	Joyce Frimpong, PharmD Acting Designated Federal Officer, ODAC
FDA Opening Remarks	Elaine Chang, MD Clinical Team Leader DO1, OOD, OND, CDER, FDA
OPEN PUBLIC HEARING	
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

FDA PRESENTATION

Capivasertib with Abiraterone and
Prednisone for PTEN-deficient mHSPC

Daniel Lee, MD, PhD
Clinical Reviewer
DO1, OOD, OND, CDER, FDA

BREAK

Clarifying Questions

ADJOURNMENT

Questions to the Committee:

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?

Vote Result: Yes: 3 No: 6 Abstain: 0

Committee Discussion: A majority of the Committee did not find that a clinically meaningful benefit for camizestrant had been demonstrated. Committee members who voted yes emphasized that the trial showed a delay in disease progression, with supportive signals in other endpoints and no detriment to overall survival. They viewed the results as clinically meaningful because they could delay disease progression and potentially postpone the need for more toxic therapies, such as chemotherapy. These members also highlighted the potential of using circulating tumor DNA (ctDNA) to identify resistance earlier, viewing this as an important step forward for the field.

Committee members who voted no emphasized that there was no demonstrated overall survival benefit and felt that overall survival is a critical endpoint for changing the current treatment paradigm. Members also stated that the trial did not adequately answer the central question of whether treating earlier based on a mutation is better than waiting for standard clinical or radiographic progression. Some members said the results were difficult to interpret because of how and when patients were tested, while others raised concerns about the trial design, including differences in treatment after progression and the fact that intervening when the biomarker was detected has not yet been proven to predict clinical benefit. Members also shared concerns about the quality of the patient-reported outcomes information and stated that this information was not indicative of clinical benefit.

Please see the transcript for details of the committee discussion.

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?

Vote Result: Yes: 7 No: 1 Abstain: 1

Committee Discussion: The Committee voted 7 yes, 1 no, and 1 abstention, with most members supporting that the benefits of adding capivasertib to abiraterone and prednisone outweighed the risks for the proposed patient population. Members who voted yes discussed that the trial met its primary endpoint with a statistically significant improvement in radiographic progression-free survival (rPFS), and that the demonstrated median improvement in rPFS may be clinically meaningful for some patients. Some members felt that the biomarker selection criteria may need more refining. Several members highlighted that this would not be a treatment for every patient, but rather an additional useful option for a distinct subgroup of men with metastatic prostate cancer who may benefit from a targeted approach. Members also discussed the importance of patient choice and individualized decision-making, noting that some patients may prefer this option over chemotherapy despite the added monitoring and toxicity management requirements. Some members expressed confidence that these toxicities would be manageable in real-world practice, e.g., drawing on experience with immunotherapy in GU cancers and PI3K pathway inhibitors in breast cancer.

The one member who voted no cited concerns that the magnitude of benefit appeared relatively modest compared with the toxicity burden and duration of treatment. The member who abstained stated that they were divided between recognizing the statistically significant efficacy signal and concerns about real-world implementation and safety monitoring. Overall, while members largely agreed on the value of expanding treatment options for this biomarker-defined population, differing views on the magnitude of benefit, toxicity burden, and real-world implementation reflected the complexity of benefit-risk assessment.

Please see the transcript for details of the committee discussion.

The meeting was adjourned at approximately 4:53 p.m.