

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
April 28, 2023

DRAFT AGENDA

The committee will discuss supplemental new drug application (sNDA) 208558/S-025, for LYNPARZA (olaparib) tablets, submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) for this product is in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC).

11:00 a.m.	Call to Order	Jorge Garcia, MD, FACP Chairperson, ODAC
11:05 a.m.	Introduction of Committee and Conflict of Interest Statement	She-Chia Jankowski, PharmD Designated Federal Officer, ODAC
11:10 a.m.	FDA Introductory Comments	
	Olaparib with Abiraterone for Metastatic Castration-Resistant Prostate Cancer (mCRPC)	Chana Weinstock, MD Supervisory Associate Director (Acting) Division of Oncology 1 (DO1) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
11:30 a.m.	APPLICANT PRESENTATIONS	AstraZeneca Pharmaceuticals LP
	Introduction	Cristian Massacesi, MD Chief Medical Officer and Oncology Chief Development Officer AstraZeneca
	Disease Background and Unmet Needs in mCRPC	Neal Shore, MD, FACS Chief Medical Officer Surgical Oncology and Urology GenesisCare
	Clinical Efficacy	Laurence Toms, MD Global Clinical Head Late Development Oncology AstraZeneca
	Clinical Safety	Simon Turner, PhD Executive Director, Patient Safety Oncology AstraZeneca

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DRAFT AGENDA (cont.)

Clinical Perspective

Daniel George, MD

Professor of Medicine and Surgery
Divisions of Medical Oncology and Urology
Director, Genitourinary Oncology
Duke Cancer Institute
Duke University School of Medicine

Summary

Cristian Massacesi, MD

12:15 p.m.

FDA PRESENTATION

Olaparib with Abiraterone for Metastatic
Castration-Resistant Prostate Cancer
(mCRPC)

Jaleh Fallah, MD

Clinical Reviewer
Genitourinary Malignancies
DO1, OOD, OND, CDER, FDA

1:00 p.m.

Clarifying Questions to Presenters

1:45 p.m.

BREAK

2:15 p.m.

OPEN PUBLIC HEARING

3:15 p.m.

Questions to the Committee/Committee
Discussion

4:30 p.m.

ADJOURNMENT