Food and Drug Administration
Center for Drug Evaluation and Research

Final Summary Minutes of the Oncologic Drugs Advisory Committee Meeting
April 28, 2023

Location: Please note that due to the impact of the COVID-19 pandemic, all meeting participants joined this advisory committee meeting via an online teleconferencing platform.

Topic: The committee discussed 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).

These summary minutes for the April 28, 2023 meeting of the ODAC of the Food and Drug Administration were approved on May 31, 2023.

I certify that I attended the April 28, 2023 meeting of the ODAC of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
She-Chia Chen, PharmD
Designated Federal Officer, ODAC

/s/
Jorge A. Garcia, MD, FACP
Chairperson, ODAC

Final Summary Minutes of the Oncologic Drugs Advisory Committee Meeting
April 28, 2023

The Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration, Center for Drug Evaluation and Research met on April 28, 2023. The meeting presentations were heard, viewed, captioned, and recorded through an online teleconferencing 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 Jorge A. Garcia, MD, FACP (Chairperson). The conflict of interest statement was read into the record by She-Chia Jankowski, PharmD (Designated Federal Officer). There were approximately 1,124 people online. There were three Open Public Hearing (OPH) speaker presentations.

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

Agenda: The committee discussed 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).

Attendance:
ODAC Members Present (Voting): Mark Conaway, PhD; Jorge A. Garcia, MD, FACP (Chairperson); Christopher H. Lieu, MD; Ravi A. Madan, MD; David E. Mitchell (Consumer Representative); Jorge J. Nieva, MD; Ashley Rosko, MD; Neil Vasan, MD, PhD

ODAC Members Not Present (Voting): Ranjana H. Advani, MD; Jaffer A. Ajani, MD; Pamela L. Kunz, MD; Alberto S. Pappo, MD; Anthony D. Sung, MD

ODAC Member Not Present (Non-Voting): Jonathan D. Cheng, MD (Industry Representative)

Acting Industry Representative to the Committee (Non-Voting): Michael Bui, DDS, JD

Temporary Members (Voting): Rhonda Bitting, MD; Julie Graff, MD; Andrea L. Harzstark, MD; Terrence M. Kungel, MBA (Patient Representative); Brian I. Rini, MD, FASCO

FDA Participants (Non-Voting): Richard Pazdur, MD; Paul Kluetz, MD; Laleh Amiri-Kordestani, MD; Daniel Suzman, MD; Chana Weinstock, MD; Jaleh Fallah, MD

Designated Federal Officer (Non-Voting): She-Chia Jankowski, PharmD

Open Public Hearing Speaker: Deepak Kilari, MD (spoke on behalf of Rana McKay, MD); Leonard Santoro; E. David Crawford, MD

The agenda was as follows:

Call to Order	**Jorge A. Garcia, MD, FACP** Chairperson, ODAC
Introduction of Committee and Conflict of Interest Statement	**She-Chia Jankowski, PharmD** Designated Federal Officer, ODAC
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
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
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
FDA PRESENTATION	
Olaparib with Abiraterone for Metastatic Castration-Resistant Prostate Cancer (mCRPC)	**Jaleh Fallah, MD** Clinical Reviewer Genitourinary Malignancies DO1, OOD, OND, CDER, FDA

Clarifying Questions to Presenters

BREAK

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Questions to the Committee:

1. **VOTE:** As FDA reviews the proposed indication for olaparib in combination with abiraterone for initial treatment of mCRPC, should the indication be restricted to patients whose tumors have a *BRCA* mutation?

   If you feel the combination should not be approved for any indication, please abstain from voting and explain your thinking regarding approvability during the post-voting discussion period.

   Vote Result: Yes: 11 No: 1 Abstain: 1

   Committee Discussion: *The majority of the Committee members voted "Yes", indicating that the proposed indication for olaparib in combination with abiraterone for initial treatment of mCRPC should be restricted to patients whose tumors have a BRCA mutation. These Committee members noted that the study did not show clinical benefit in the subgroup of patients without a BRCA mutation. One Committee member voted against the restriction, suggesting that a restricted indication in patients with HRR mutation might be more appropriate. Another Committee member abstained from voting, explaining that it was difficult to make the choice based on a suboptimal study design in which some patients with known BRCA mutation did not receive any PARP inhibitor, even after disease progression. Please see the transcript for details of the Committee's discussion.*

The meeting was adjourned at approximately 4:10 p.m. Eastern Time.