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

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 17, 2019

DRAFT AGENDA

During the morning session, the committee will discuss supplemental new drug application (sNDA) 208558/010 for LYNPARZA (olaparib) tablets, submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) for this product is for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic adenocarcinoma of the pancreas whose disease has not progressed on first-line platinum-based chemotherapy.

8:00 a.m.	Call to Order and Introduction of Committee	**Philip C. Hoffman, MD** Chairperson, ODAC
	Conflict of Interest Statement	**Lauren Tesh Hotaki, PharmD, BCPS, BCIDP** Designated Federal Officer, ODAC
8:10 a.m.	FDA Opening Remarks	**Martha Donoghue, MD** Cross-Discipline Team Leader Gastrointestinal Cancers Team Division of Oncology 3 (DO3) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**AstraZeneca Pharmaceuticals LP**
	Introduction	**Susan Galbraith, MB, BChir, PhD, MRCP, FRCR, FMedSci** Senior Vice President Head of Research and Early Development Oncology R&D, AstraZeneca
	Disease Background and Unmet Need	**Hedy Kindler, MD** Professor of Medicine University of Chicago
	POLO Clinical Development Program and Efficacy	**Carsten Goessl, MD** Global Development Lead for Olaparib AstraZeneca
	Clinical Safety	**Mayur Patel, PharmD** Vice President, Patient Safety Oncology/Immuno Oncology, AstraZeneca

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Perspective	**Margaret Tempero, MD** Director, UCSF Pancreas Center University of California at San Francisco
	Summary	**Susan Galbraith, MB, BChir , PhD, MRCP, FRCR, FMedSci**
9:00 a.m.	**FDA PRESENTATION**	
	sNDA 208558 s10: Olaparib	**Naomi Horiba, MD, MPH** Clinical Reviewer Gastrointestinal Cancers Team DO3, OOD, OND, CDER, FDA
9:50 a.m.	Clarifying Questions to Presenters	
10:15 a.m.	**BREAK**	
10:30 a.m.	**OPEN PUBLIC HEARING**	
11:00 a.m.	Questions to the Committee/Committee Discussion	
12:00 p.m.	**LUNCH**	

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DRAFT AGENDA (cont.)

During the afternoon session, the committee will discuss supplemental biologics license application (sBLA) 125514/066 for KEYTRUDA (pembrolizumab) for injection, submitted by Merck Sharpe & Dohme Corp. The proposed indication (use) for this product is for the treatment of patients with bacillus Calmette-Guérin-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in-situ with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

1:00 p.m.	Call to Order and Introduction of Committee	**Philip C. Hoffman, MD** Chairperson, ODAC
	Conflict of Interest Statement	**Lauren Tesh Hotaki, PharmD, BCPS, BCIDP** Designated Federal Officer, ODAC
1:10 p.m.	FDA Opening Remarks	**Daniel Suzman, MD** Acting Clinical Team Leader Genitourinary Team 2 Division of Oncology 1 (DO1) OOD, OND, CDER, FDA
1:15 p.m.	**APPLICANT PRESENTATIONS**	**Merck Sharpe & Dohme Corp**
	Introduction	**Jeffrey N. Stuart, PhD** Executive Director, Global Regulatory Affairs Merck & Co., Inc.
	Unmet Need	**Gary D. Steinberg, MD** Professor and Director Goldstein Bladder Cancer Program NYU Langone Health
	Efficacy and Safety	**Ekta Kapadia, MD** Senior Clinical Director, Oncology Merck & Co., Inc.

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Perspective	**Ashish M. Kamat, MD, MBBS, FACS** Professor of Urologic Oncology (Surgery) Wayne B. Duddlesten Professor of Cancer Research MD Anderson Cancer Center, Houston, Texas President, International Bladder Cancer Group (IBCG) Co-President, International Bladder Cancer Network (IBCN)
	Benefit-Risk	**Scot Ebbinghaus, MD** Vice President, Clinical Research, Oncology Merck & Co., Inc.
2:00 p.m.	**FDA PRESENTATION**	
	Keytruda® (pembrolizumab)	**Jamie Brewer, MD** Clinical Reviewer Genitourinary Team 2 DO1, OOD, OND, CDER, FDA
2:45 p.m.	Clarifying Questions to Presenters	
3:15 p.m.	**BREAK**	
3:30 p.m.	**OPEN PUBLIC HEARING**	
4:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	