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 18, 2019

AGENDA

The committee will discuss new drug application (NDA) 211723 for tazemetostat tablets, submitted by Epizyme, Inc. The proposed indication (use) for this product is for the treatment of patients with metastatic or locally advanced epithelioid sarcoma not eligible for curative surgery.

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	**Ashley Ward, MD** Cross-Discipline Team Leader Division of Oncology 3 (DO3) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Epizyme, Inc.**
	Introduction	**Shefali Agarwal, MD** Chief Medical Officer Epizyme, Inc.
	Unmet Need	**Shreyaskumar R. Patel, MD** Center Medical Director Department of Sarcoma Medical Oncology Division of Cancer Medicine The University of Texas MD Anderson Cancer Center Houston, Texas
	Tazemetostat Efficacy in Patients with Epithelioid Sarcoma	**Shefali Agarwal, MD**
	Tazemetostat Safety	**George D. Demetri, MD** Professor, Medicine, Harvard Medical School Director, Center for Sarcoma and Bone Oncology, Dana-Farber Cancer Institute

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
December 18, 2019

AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Perspective	**Gary K. Schwartz, MD** Division of Hematology/Oncology Division Chief, Hematology/Oncology Deputy Director Herbert Irving Comprehensive Cancer Center Columbia University
9:00 a.m.	**FDA PRESENTATION**	
	Efficacy & Safety Analyses and Issues	**Leslie Doros, MD** Clinical Reviewer DO3, OOD, OND, CDER, FDA
9:45 a.m.	Clarifying Questions to Presenters	
10:15 a.m.	**BREAK**	
10:30 a.m.	**OPEN PUBLIC HEARING**	
11:30 a.m.	Questions to the Committee/Committee Discussion	
12:30 p.m.	**ADJOURNMENT**	