

**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

DRAFT 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

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DRAFT 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 PRESENTATIONS

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