

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
February 9, 2021

DRAFT AGENDA

The committee will discuss supplemental biologics license application (sBLA) 125514/s-089, for KEYTRUDA (pembrolizumab), submitted by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. The proposed indication (use) for this product is for the treatment of patients with high-risk, early-stage triple-negative breast cancer, in combination with chemotherapy as neoadjuvant treatment, then as a single agent as adjuvant treatment after surgery.

10:00 a.m.	Call to Order	Philip C. Hoffman, MD Chairperson, ODAC
10:05 a.m.	Introduction of Committee and Conflict of Interest Statement	She-Chia Chen, PharmD Designated Federal Officer, ODAC
10:15 a.m.	FDA Introductory Comments	Christy Osgood, MD Cross-Discipline Team Leader Breast and Gynecologic Malignancies Team Division of Oncology 1 (DO1) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:30 a.m.	APPLICANT PRESENTATIONS	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
	Introduction	Sunita Zalani, PhD Vice President Oncology and In-Vitro Diagnostics, Global Regulatory Affairs and Clinical Safety Merck & Co., Inc.
	Treatment Landscape and Unmet Need in Triple Negative Breast Cancer	Joyce O'Shaughnessy, MD Celebrating Women Chair in Breast Cancer Research Baylor University Medical Center Chair, Breast Cancer Program Texas Oncology US Oncology Research

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Efficacy and Safety

Vassiliki Karantza, MD, PhD
Associate Vice President
Global Clinical Development
Women's Cancers, Sub-Section Head for Breast
Cancer
Merck & Co., Inc.

Clinical Perspective

Hope S. Rugo, MD
Professor of Medicine
Director of Breast Oncology and Clinical Trials
Education
University of California San Francisco
Comprehensive Cancer Center

11:15 a.m.

FDA PRESENTATION

BLA 125514 Supplement 89 -
Pembrolizumab

Mirat Shah, MD
Clinical Reviewer
Breast and Gynecologic Malignancies Team
DO1, OOD, OND, CDER, FDA

11:45 a.m.

Clarifying Questions to Presenters

12:15 p.m.

BREAK

12:30 p.m.

OPEN PUBLIC HEARING

1:30 p.m.

Questions to the Committee/Committee
Discussion

2:30 p.m.

ADJOURNMENT