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

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

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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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**	