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, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
April 12, 2016

FINAL AGENDA

The committee will discuss new drug application (NDA) 208542 rociletinib tablets, application submitted by Clovis Oncology, Inc. The proposed indication (use) for this product is for the treatment of patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation as detected by an FDA approved test.

8:30 a.m.	Call to Order and Introduction of Committee	**Deborah Armstrong, MD** Chairperson, ODAC
8:35 a.m.	Conflict of Interest Statement	**LCDR Jennifer A. Shepherd, RPh** Acting Designated Federal Officer, ODAC
8:40 a.m.	Opening Remarks	**Gideon Blumenthal, MD** Medical Team Leader Thoracic/Head & Neck Cancer Team Division of Oncology Products 2 (DOP2) Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	**APPLICANT PRESENTATIONS**	**Clovis Oncology, Inc.**
	Introduction	**Lindsey Rolfe, MBCHB, MRCP** Chief Medical Officer Clovis Oncology
	Unmet Need in EGFR Mutant NSCLC	**David Carbone, MD, PhD** Professor, Internal Medicine Director, James Thoracic Center The Ohio State University
	Efficacy	**Sergey Yurasov, MD, PhD** Senior Vice President Clinical Development Clovis Oncology
	Safety and Dose Selection	**Lindsey Rolfe, MBCHB, MRCP**

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FINAL AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Perspective and Benefit-Risk	**Ross Camidge, MD, PhD** Professor of Medicine/Oncology Joyce Zeff Chair in Lung Cancer Research University of Colorado Cancer Center
9:30 a.m.	**FDA PRESENTATIONS**	
	NDA 208542 - Rociletinib	**'Lola Fashoyin-Aje, MD, MPH** Medical Officer Thoracic/Head & Neck Cancer Team DOP2, OHOP, OND, CDER, FDA **Chao Liu, PhD** Pharmacometrics Reviewer Division of Pharmacometrics (DPM) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS) CDER, FDA
10:15 a.m.	Clarifying Questions to the Presenters	
10:45 a.m.	**BREAK**	
11:00 a.m.	Open Public Hearing	
12:00 pm	Questions to the Committee/Committee Discussion	
1:00 p.m.	**ADJOURNMENT**	