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
July 11, 2017

DRAFT AGENDA

The committee will discuss biologics license application (BLA) 761060, MYLOTARG® (gemtuzumab ozogamicin) for intravenous use, submitted by Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc. The proposed indication (use) for this product is in combination therapy with daunorubicin (DNR) and cytarabine (AraC) for the treatment of adult patients with previously untreated, de novo acute myeloid leukemia (AML).

12:30 p.m.	Call to Order and Introduction of Committee	**Bruce J. Roth, MD** Chairperson, ODAC
12:35 p.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, ODAC
12:40 p.m.	FDA Introductory Remarks	**Donna Przepiorka, MD, PhD** Cross-Discipline Team Leader Division of Hematology Products (DHP) Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
12:45 p.m.	**APPLICANT PRESENTATIONS**	**Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.**
	Introduction	**Mace Rothenberg, MD** Chief Development Officer, Oncology Global Product Development Pfizer Inc.
	AML Treatment Landscape	**Richard Stone, MD** Chief of Staff and Director of the Adult Acute Leukemia Program Dana Farber Cancer Institute Boston, MA
	Mylotarg in Patients with Previously Untreated De Novo AML	**Iain Webb, MD** Global Clinical Lead, Hematologic Malignancies Pfizer Inc.
	Mylotarg Safety Considerations	**Debbie Chirnomas, MD, MPH** Mylotarg Medical Monitor Pfizer Inc.

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DRAFT AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Mylotarg Benefit/Risk: Clinical Perspective	**Jorge E. Cortes, MD** Deputy Chair in the Department of Leukemia MD Anderson Cancer Center University of Texas, Houston, TX
1:30 p.m.	Clarifying Questions	
1:45 p.m.	**FDA PRESENTATIONS**	
	BLA 761060: MYLOTARG	**Emily Jen, MD, PhD** Clinical Reviewer DHP, OHOP, OND, CDER, FDA
	Rationale for the Fractionated Gemtuzumab Ozogamicin (GO) Dosing Regimen	**Jee Eun Lee, PhD** Pharmacometrics Reviewer Division of Pharmacometrics (DPM) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS) CDER, FDA
	Efficacy Evaluation in the First Line AML	**Chia-Wen Ko, PhD** Statistical Reviewer Division of Biometrics V (DBV) Office of Biostatistics (OB) OTS, CDER, FDA
	Safety Analysis	**Emily Jen, MD, PhD**
2:30 p.m.	Clarifying Questions	
2:45 p.m.	**BREAK**	
3:00p.m.	**OPEN PUBLIC HEARING**	
4:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	