

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

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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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.

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

2:15 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