Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Oncologic Drugs Advisory Committee
July 11, 2017

Location: FDA White Oak Campus, 10903 New Hampshire Avenue, Building 31 Conference Center, the Great Room (Rm. 1503), , Silver Spring, Maryland.

Topic: The committee discussed 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).

These summary minutes for the July 11, 2017, meeting of the Oncologic Drugs Advisory Committee of the Food and Drug Administration were approved on July 31, 2017.

I certify that I attended the July 11, 2017, meeting of the Oncologic Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
Jennifer Shepherd, RPh
Acting Designated Federal Officer, ODAC

/s/
Bruce J. Roth, MD
Chairperson, ODAC

Summary Minutes
Oncologic Drugs Advisory Committee Meeting
July 11, 2017

The following is the final report of the Oncologic Drugs Advisory Committee (ODAC) meeting held on July 11, 2017. A verbatim transcript will be available in approximately six weeks, sent to the Office of Hematology and Oncology Products and posted on the FDA website at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/ucm547155.htm

All external requests for the meeting transcript should be submitted to the CDER Freedom of Information Office.

The Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration, Center for Drug Evaluation and Research met on July 11, 2017 at the FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, Maryland. Prior to the meeting, members and temporary voting members were provided copies of the briefing materials from the FDA, and Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc. The meeting was called to order by Bruce J. Roth, MD, (Chairperson). The conflict of interest statement was read into the record by Jennifer Shepherd, RPh (Acting Designated Federal Officer). There were approximately 175 people in attendance. There were two Open Public Hearing (OPH) speakers.

Issue: The committee discussed 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).

Attendance:
ODAC Members Present (Voting): Grzegorz S. Nowakowski, MD; Bruce J. Roth, MD (Chairperson)

ODAC Members Not Present (Voting): Harold J. Burstein, MD, PhD; Philip C. Hoffman, MD; Heidi D. Klepin, MD, MS; Vassilliki A. Papadimitrakopoulou, MD; Alberto S. Pappo, MD; Courtney J. Preusse, MA (Consumer Representative); Gregory J. Riley, MD, PhD; Brian I. Rini, MD, FACP; Alice T. Shaw, MD, PhD; Thomas S. Uldrick, MD, MS

ODAC Member Present (Non-Voting): Phuong Khanh (P.K.) Morrow, MD, FACP

Temporary Members (Voting): Andy I. Chen, MD, PhD; Bernard F. Cole, PhD; David P. Harrington, PhD; Anthony D. Sung, MD; Wayne Taylor, MD (Patient Representative)

FDA Participants (**Non-Voting):** Ann T. Farrell, MD; Emily Jen, MD, PhD; Chia-Wen Ko, PhD; Jee Eun Lee, PhD; Richard Pazdur, MD; Donna Przepiorka, MD, PhD

Acting Designated Federal Officer (Non-Voting): Jennifer Shepherd, RPh

Open Public Hearing Speakers: Kristen Santiago (Cancer Support Community); Jack Mitchell (National Center for Health Research)

The Agenda proceeded as follows:

Call to Order and Introduction of Committee	**Bruce J. Roth, MD** Chairperson, ODAC
Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, ODAC
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
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.
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
FDA PRESENTATIONS	
BLA 761060: MYLOTARG	**Emily Jen, MD, PhD** Clinical Reviewer DHP, OHOP, OND, CDER, FDA

FDA PRESENTATIONS (CONT.)

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**

Clarifying Questions

BREAK

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Question to the Committee:

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1. **VOTE:** Do the results of ALFA-0701 demonstrate a favorable risk:benefit for gemtuzumab ozogamicin 3 mg/m^2 days 1, 4 and 7 added to DA for patients with newly-diagnosed CD33-positive AML? Please explain the reasons for your vote.

   YES: 6 NO: 1 ABSTAIN: 0

   Committee Discussion: *The majority of the panel voted yes, that the results of ALFA-0701 demonstrate a favorable risk:benefit for gemtuzumab ozogamicin (GO) 3 mg/m^2 days 1, 4 and 7 added to DA for patients with newly-diagnosed CD33- positive AML. Many stated that event free survival (EFS) is an acceptable clinical endpoint for trials of patients with newly-diagnosed AML being treated with curative intent, and that the benefit of GO in terms of EFS has been proven. Two panel members stated that the fractionated dosing regimen proposed by the applicant has improved upon the original safety profile of GO. Two panel members stated that GO may increase quality of life in those patients who experience delayed relapse as a result of treatment. The panel member that voted "No" stated that for patients with adverse cytogenetics, there did not appear to be any benefit and there was potential for harm due to toxicities, such as veno-occlusive disease. Please see the transcript for details of the committee discussion.*

The meeting on July 11, 2017 was adjourned at approximately 3:26 p.m.