

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

Oncologic Drugs Advisory Committee (ODAC) Meeting

FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center
The Great Room (Room 1503), Silver Spring, MD 20993-0002
July 13, 2017

DRAFT AGENDA

During the morning session, the committee will discuss biologics license application (BLA) 761028 for ABP 215, a proposed biosimilar to Genentech/Roche's AVASTIN (bevacizumab), submitted by Amgen Inc. The proposed indications/uses for this product are: (1) For the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy; (2) in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line ABP 215-containing regimen; (3) for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel; (4) for the treatment of glioblastoma with progressive disease in adult patients following prior therapy as a single agent; (5) for the treatment of metastatic renal cell carcinoma in combination with interferon alfa; and, (6) in combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.

8:00 a.m.	Call to Order and Introduction of Committee	Bruce J. Roth, MD Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	Jay R. Fajiculay, PharmD Acting Designated Federal Officer, ODAC
8:10 a.m.	Overview of the Regulatory Framework and FDA's Guidance for the Development and Approval of Biosimilar Products in the US	Sue Lim, MD Team Leader Office of New Drugs (OND), Therapeutic Biologics and Biosimilars Staff (TBBS), CDER, FDA
8:40 a.m.	APPLICANT PRESENTATIONS	Amgen, Inc.
	Introduction to Bevacizumab Amgen, Inc. – Biosimilar to Genentech/Roche's Avastin®	Richard Markus, MD, PhD Global Development, Amgen
	Analytical Similarity	Simon Hotchin Regulatory Affairs, Amgen
	Non-Clinical and Clinical Similarity and Extrapolation to All Indications	Richard Markus, MD, PhD Global Development, Amgen
	Conclusion	Lisa Bollinger, MD Regulatory Affairs and Safety, Amgen

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 13, 2017

DRAFT AGENDA (cont.)

9:20 a.m. **FDA PRESENTATIONS**

Product Quality Review

Jee Chung, PhD

CMC Reviewer

Division of Biotechnology Review and Research IV

Office of Biotechnology Products (OBP)

Office of Pharmaceutical Quality (OPQ), CDER, FDA

Statistical Equivalence Testing for
Tier 1 Quality Attributes

Tianhua Wang, PhD

CMC Statistical Reviewer

Division of Biometrics VI (DBVI)

Office of Biostatistics (OB)

Office of Translational Sciences (OTS), CDER, FDA

Clinical Pharmacology

Edwin C. Y. Chow, PhD

Clinical Pharmacology Reviewer

Division of Clinical Pharmacology V

Office of Clinical Pharmacology, OTS, CDER, FDA

Comparative Clinical Study

Weishi Yuan, PhD

Biostatistician

Division of Biometrics V (DBV)

OB, OTS, CDER, FDA

Summary of Safety
Extrapolation
Summary of FDA Analysis of Similarity

Sandra Casak, MD

Medical Officer

Gastrointestinal Cancer Team

Division of Oncology Products 2 (DOP2)

Office of Hematology and Oncology Products (OHOP)

OND, CDER, FDA

10:00 a.m. Clarifying Questions to Presenters

10:30 a.m. **BREAK**

10:45 a.m. **OPEN PUBLIC HEARING**

11:15 a.m. Questions to the Committee/Committee Discussion

12:00 p.m. **LUNCH**

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 13, 2017

DRAFT AGENDA

During the afternoon session, the committee will discuss biologics license application (BLA) 761074 for MYL-14010, a proposed biosimilar to Genentech Inc.'s HERCEPTIN (trastuzumab), submitted by Mylan GmbH. The proposed indications/uses for this product are: (1) For adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer (a) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; (b) with docetaxel and carboplatin; or (c) as a single agent following multi-modality anthracycline based therapy; (2) in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer; (3) as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease; and, (4) in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.

1:00 p.m.	Call to Order and Introduction of Committee	Bruce J. Roth, MD Chairperson, ODAC
1:05 p.m.	Conflict of Interest Statement	Jay R. Fajiculay, PharmD Acting Designated Federal Officer, ODAC
1:10 p.m.	Opening Remarks	Laleh Amiri-Kordestani, MD Clinical Team Leader, Breast Cancer Team Division of Oncology Products 1 (DOP1) Office of Hematology and Oncology Products (OHOP), OND, CDER, FDA
1:15 p.m.	APPLICANT PRESENTATIONS	Mylan GmbH
	Introduction	Arnd Annweiler, PhD Head of Research and Development, Mylan
	Analytical and Nonclinical Demonstration of Similarity	Patrick T. Vallano, PhD Head of Global Biologics Scientific Affairs, Mylan
	Confirmatory Clinical Efficacy and Safety	Abhijit Barve, M.D., PhD Head of Global Clinical Research, Mylan
	Clinical Perspective	Hope S. Rugo, MD Professor of Medicine, UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA
	Totality of the Evidence and Concluding Remarks	Arnd Annweiler, PhD Head of Research and Development, Mylan

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
July 13, 2017

DRAFT AGENDA (cont.)

1:55 p.m. **FDA PRESENTATIONS**

Product Quality

Kristen Nickens, PhD
Product Quality Reviewer
Division of Biotechnology Review and Research I (DBRRI)
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ)
CDER, FDA

Meiyu Shen, PhD
Expert Mathematical Statistician – Team Leader
Division of Biometrics VI (DBVI)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS)
CDER, FDA

Clinical Pharmacology

Brian D. Furmanski, PhD
Senior Clinical Pharmacology Reviewer
Division of Clinical Pharmacology V (DCPV)
Office of Clinical Pharmacology (OCP)
OTS, CDER, FDA

Clinical Efficacy and Safety

Jennifer Gao, MD
Medical Officer
Breast Cancer Team
DOP1, OHOP, OND, CDER, FDA

Summary of FDA Findings

Jennifer Gao, MD

2:35 p.m. Clarifying Questions to Presenters

3:05 p.m. **BREAK**

3:20 p.m. **OPEN PUBLIC HEARING**

4:00 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**