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

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

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AGENDA (cont.)

9:25 a.m.	**FDA PRESENTATIONS**	
	Product Quality Review	**Jee Chung, PhD** Product Quality 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** Product Quality 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 (Vivian) Yuan, PhD** Statistical Reviewer Division of Biometrics V (DBV) OB, OTS, CDER, FDA
	Summary of Safety Extrapolation Summary of FDA Analysis of Similarity	**Sandra Casak, MD** Clinical Reviewer Gastrointestinal Cancer Team Division of Oncology Products 2 (DOP2) Office of Hematology and Oncology Products (OHOP) OND, CDER, FDA
10:10 a.m.	Clarifying Questions to Presenters	
10:35 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**	

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During the afternoon session, the committee will discuss biologics license application (BLA) 761074 for MYL-1401O, 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** Medical Officer 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

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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**	