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.

Richard Markus, MD, PhD
Global Development, Amgen

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Amgen, Inc.

Richard Markus, MD, PhD
Global Development, Amgen

8:40 a.m.  APPLICANT PRESENTATIONS
Amgen, Inc.
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**
  - **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**
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 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.

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<tr>
<th>Time</th>
<th>Agenda Item</th>
<th>Presenter</th>
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<tr>
<td>1:00 p.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>Bruce J. Roth, MD</td>
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<td>Chairperson, ODAC</td>
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<td>1:05 p.m.</td>
<td>Conflict of Interest Statement</td>
<td>Jay R. Fajiculay, PharmD</td>
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<td>Acting Designated Federal Officer, ODAC</td>
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<td>1:10 p.m.</td>
<td>Opening Remarks</td>
<td>Laleh Amiri-Kordestani, MD</td>
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<td>Clinical Team Leader, Breast Cancer Team</td>
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<td>Division of Oncology Products 1 (DOP1)</td>
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<td>Office of Hematology and Oncology Products (OHOP)</td>
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<td>OND, CDER, FDA</td>
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<td>1:15 p.m.</td>
<td><strong>APPLICANT PRESENTATIONS</strong></td>
<td>Mylan GmbH</td>
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<td>Introduction</td>
<td>Arnd Annweiler, PhD</td>
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<td>Analytical and Nonclinical Demonstration of Similarity</td>
<td>Patrick T. Vallano, PhD</td>
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<td>Confirmatory Clinical Efficacy and Safety</td>
<td>Abhijit Barve, M.D., PhD</td>
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<td>Clinical Perspective</td>
<td>Hope S. Rugo, MD</td>
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<td>Totality of the Evidence and Concluding Remarks</td>
<td>Arnd Annweiler, PhD</td>
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<td>Head of Research and Development, Mylan</td>
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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