The committee will discuss biologics license application (BLA) 761024, for ABP 501, a proposed biosimilar to AbbVie Inc.’s HUMIRA (adalimumab), submitted by Amgen, Inc. The proposed indications (uses) for this product are: (1) Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs)); (2) reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years of age and older (alone or in combination with methotrexate); (3) reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (alone or in combination with non-biologic DMARDs); (4) reducing signs and symptoms in adult patients with active ankylosing spondylitis; (5) reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy (ABP 501 would be indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab); (6) inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP) (the effectiveness of ABP-501 would not be established in patients who have lost response to or were intolerant to TNF blockers); and (7) treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate (only to be administered to patients who will be closely monitored and have regular follow-up visits with a physician).

7:30 a.m. Call to Order and Introduction of Committee

Daniel Solomon, MD, MPH
Acting Chairperson, AAC

7:35 a.m. Conflict of Interest Statement

Moon Hee Choi, PharmD
Acting Designated Federal Officer, AAC

7:40 a.m. FDA Opening Remarks

Janet Woodcock, MD
Director
CDER, FDA

7:50 a.m. Overview of the Regulatory Pathway and FDA’s Guidance for the Development and Approval of Biosimilar Products in the US

Leah Christl, PhD
Associate Director, Therapeutic Biologics
Therapeutic Biologics and Biosimilars Staff
Office of New Drugs (OND), CDER, FDA

8:20 a.m. Clarifying Questions to the FDA

8:25 a.m. FDA Introductory Remarks

Nikolay P. Nikolov, MD
Clinical Team Leader
Division of Pulmonary, Allergy & Rheumatology Products (DPARP)
Office of Drug Evaluation II (ODE-II)
OND, CDER, FDA
8:30 a.m. **APPLICANT PRESENTATIONS**

**Introduction**

*Richard Markus, MD, PhD*
Vice President, Global Biosimilars Development
Amgen, Inc.

Analytical and Nonclinical Similarity to Adalimumab

*Simon Hotchin*
Executive Director, Global Biosimilars Regulatory Affairs
Amgen, Inc.

**ABP 501 Clinical Similarity**

*Richard Markus, MD, PhD*

Conclusions

*Steven Galson, MD, MPH*
Senior Vice President, Global Regulatory Affairs & Safety
Amgen, Inc.

10:00 a.m. Clarifying Questions to Applicant

10:15 a.m. **BREAK**

10:30 a.m. **FDA PRESENTATIONS**

**Product Quality Review**

*Joel Welch, PhD*
Product Quality Team Leader
Division of Biotechnology Review and Research II
Office of Biotechnology Products
Office of Pharmaceutical Quality, CDER, FDA

**ABP 501 Statistical Equivalence Testing for Bioactivity**

*Meiyu Shen, PhD*
Lead Mathematical Statistician
Division of Biometrics VI
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

**Clinical Pharmacology Review**

*Jianmeng Chen, MD, PhD*
Clinical Pharmacology Reviewer
Division of Clinical Pharmacology II
Office of Clinical Pharmacology, OTS, CDER, FDA

**Clinical Efficacy Review**

*Yongman Kim, PhD*
Mathematical Statistician
Division of Biometrics II, OB, OTS, CDER, FDA

*Kathleen Fritsch, PhD*
Mathematical Statistician
Division of Biometrics III, OB, OTS, CDER, FDA
AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

Safety and Immunogenicity Review  
Keith M. Hull, MD, PhD  
Medical Officer  
DPARP, ODE-II, OND, CDER, FDA

Considerations for Extrapolation and Summary  
Nikolay P. Nikolov, MD

12:00 p.m. Clarifying Questions to FDA

12:15 a.m. LUNCH

1:15 p.m. OPEN PUBLIC HEARING

2:45 p.m. Charge to the Committee  
Nikolay P. Nikolov, MD

3:00 p.m. Questions to the Committee/Committee Discussion

3:30 p.m. BREAK

3:45 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. ADJOURNMENT