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

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 12, 2016

DRAFT AGENDA

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.	351(k) Regulatory Pathway	**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

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DRAFT AGENDA (cont.)

8:30 a.m.	**APPLICANT PRESENTATIONS**	**Amgen, Inc.**
	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 Research and Review II Office of Biotechnology Products Office of Pharmaceutical Quality, CDER, FDA
	Statistical Equivalence Review	**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	**Kathleen Fritsch, PhD** Mathematical Statistician Division of Biometrics III, OB, OTS, CDER, FDA
		Yongman Kim, PhD Mathematical Statistician Division of Biometrics II, OB, OTS, CDER, FDA

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DRAFT AGENDA (cont.)

	FDA PRESENTATIONS (CONT.)	
	Clinical 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**	