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
August 2, 2017

DRAFT AGENDA

The committee will discuss biologics license application (BLA) 761057, for sirukumab injection (proposed trade name PLIVENSIA), submitted by Janssen Biotech, Inc., for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to one or more disease modifying anti-rheumatic drugs. The discussion will include dose selection, efficacy, radiographic progression study, and safety.

8:00 a.m.	Call to Order and Introduction of Committee	**Daniel H. Solomon, MD, MPH** Chairperson, AAC
8:05 a.m.	Conflict of Interest Statement	**Philip A. Bautista, PharmD** Acting Designated Federal Officer, AAC
8:10 a.m.	FDA Introductory Remarks	**Janet Maynard, MD, MHS** Clinical Team Leader Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Janssen Biotech, Inc.**
	Introduction	**Liza O'Dowd, MD** Vice President Global Regulatory Affairs - Immunology Janssen R&D
	Unmet Medical Need	**Sergio Schwartzman, MD** Professor of Clinical Medicine Weill Cornell Medical College
	Efficacy	**George Vratsanos, MD** Vice President Translational Medicine Janssen R&D
	Safety	**Newman Yeilding, MD** Head of Immunology Development Clinical Development Janssen R&D
	Conclusion	**Lisa O'Dowd, MD**
9:45 a.m.	Clarifying Questions	

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DRAFT AGENDA (cont.)

10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Introduction and Clinical Overview	**Mark Borigini, MD** Medical Officer DPARP, ODE II, OND, CDER, FDA
	Dose Selection Considerations: Phase 2 Study Results	**Dipak Pisal, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology II Office of Clinical Pharmacology Office of Translational Science (OTS), CDER, FDA
	Review of Efficacy	**William Koh, PhD** Statistical Reviewer Division of Biometrics II Office of Biostatistics, OTS, CDER, FDA
	Safety Assessment and Risk/Benefit Considerations	**Mark Borigini, MD**
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Charge to the Committee	**Janet Maynard, MD, MHS**
2:15 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	