

**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

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	George Vratsanos, MD Vice President Translational Medicine Janssen R&D
	Unmet Medical Need	Sergio Schwartzman, MD Professor of Clinical Medicine Weill Cornell Medical College
	Efficacy	George Vratsanos, MD
	Safety	Newman Yeilding, MD Head of Immunology Development Clinical Development Janssen R&D
	Conclusion	George Vratsanos, MD
9:45 a.m.	Clarifying Questions	
10:00 a.m.	BREAK	

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AGENDA (cont.)

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**