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.

AGENDA

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
AGENDA (cont.)

10:15 a.m.  **FDA PRESENTATIONS**

- **Introduction and Clinical Overview**
  - **Mark Boragini, 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 Boragini, 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**