

**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 3, 2017

DRAFT AGENDA

The committee will discuss supplemental new drug applications (sNDAs) 203214 supplement 17, for XELJANZ (tofacitinib) tablets and 208246 supplement 3, for XELJANZ XR (tofacitinib) extended release tablets submitted by Pfizer Inc., for the treatment of adult patients with active psoriatic arthritis. The committee will discuss the efficacy and safety data and benefit-risk considerations.

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	Pfizer, Inc.
	Introduction	Nancy McKay Director, Regulatory Affairs Pfizer, Inc.
	Psoriatic Arthritis: A Physician's Perspective/Unmet Medical Need	Philip Mease, MD, MACR Director, Rheumatology Research Swedish-Providence-St. Joseph Health Systems Clinical Professor University of Washington, School of Medicine
	Tofacitinib PsA Development Program and Efficacy	Keith Kanik, MD, FACR Senior Director, Global Clinical Lead PsA Inflammation and Immunology Pfizer, Inc.
	Tofacitinib PsA Safety	Daniela Graham, MD Clinician, PsA Development Program Inflammation and Immunology Pfizer, Inc.
	Risk Management	Thomas Jones, MD Senior Director, Safety Risk Management Pfizer, Inc.

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (cont.)

- Benefit: Risk and Conclusions **Michael Corbo, PhD**
Senior VP
Chief Development Officer, Inflammation and
Immunology
Pfizer, Inc
- 9:15 a.m. Clarifying Questions
- 9:30 a.m. **FDA PRESENTATIONS**
- Introduction and Clinical Overview **Raj Nair, MD**
Medical Officer
DPARP, ODE II, CDER, FDA
- Statistical Considerations on Efficacy **Rebecca Rothwell, PhD**
Mathematical Statistician
Division of Biometrics II (DB II)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA
- Summary of Safety and Risk/Benefit
Considerations **Raj Nair, MD**
- 10:15 a.m. Clarifying Questions
- 10:30 a.m. **BREAK**
- 10:45 a.m. **OPEN PUBLIC HEARING**
- 11:45 a.m. Charge to the Committee **Janet Maynard, MD, MHS**
- 12:00 p.m. Questions to the Committee/Committee Discussion
- 1:00 p.m. **ADJOURNMENT**