

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
October 23, 2015

AGENDA

The committee will discuss new drug application (NDA) 207988, lesinurad oral tablets, submitted by Ardea Biosciences, Inc., for the treatment of hyperuricemia associated with gout, in combination with a xanthine oxidase inhibitor.

8:00 a.m.	Call to Order and Introduction of Committee	Tuhina Neogi, MD, PhD Acting Chairperson, AAC
8:10 a.m.	Conflict of Interest Statement	Philip A. Bautista, PharmD Acting Designated Federal Officer, AAC
8:15 a.m.	FDA Introductory Remarks	Sarah Yim, MD Supervisory Associate Director Division of Pulmonary, Allergy & Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	SPONSOR PRESENTATIONS	Ardea Biosciences, Inc.
	Introduction	Kimberly Manhard Senior Vice President Regulatory Affairs & Development Operations Ardea Biosciences, Inc.
	Medical Need for Uncontrolled Gout	Kenneth Saag, MD, MSc Professor of Medicine University of Alabama at Birmingham
	Efficacy	Chris Storgard, MD Vice President Clinical Research and Development Ardea Biosciences, Inc.
	General and Cardiovascular Safety	Nihar Bhakta, MD Executive Medical Director Ardea Biosciences, Inc.
	Renal Safety	Scott Adler, MD Sr. Medical Director, Inflammation AstraZeneca
	Benefit-Risk Summary & Risk Management Proposal	Chris Storgard, MD

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AGENDA (cont.)

SPONSOR PRESENTATIONS (cont.)

Clinician Perspective

Michael Becker, MD
Professor Emeritus
University of Chicago

10:00 a.m. Clarifying Questions

10:15 a.m. **BREAK**

10:30 a.m. **FDA PRESENTATIONS**

Introduction and Clinical Overview

Rosemarie Neuner, MD, MPH
Medical Officer
DPARP, ODE II, OND, CDER, FDA

Clinical Pharmacology Considerations

Jianmeng Chen, MD, PhD
Senior Clinical Pharmacology Reviewer
Division of Clinical Pharmacology II
Office of Clinical Pharmacology
Office of Translational Sciences (OTS), CDER, FDA

Statistical Considerations on Efficacy

Yu Wang, PhD
Statistical Reviewer
Division of Biometrics II
Office of Biostatistics, OTS, CDER, FDA

Safety Overview

Rosemarie Neuner, MD, MPH

11:50 p.m. Clarifying Questions

12:05 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Charge to the Committee

Sarah Yim, MD

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

5:00 p.m. **ADJOURN**