

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 25, 2018

AGENDA

The committee will discuss the supplemental biologics license application (sBLA) 125526 for mepolizumab for injection, submitted by GlaxoSmithKline for add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD) guided by blood eosinophil counts.

8:00 a.m.	Call to Order and Introduction of Committee	Jeffrey S. Wagener, MD Chairperson, PADAC
8:05 a.m.	Conflict of Interest Statement	Jennifer Shepherd, RPh Acting Designated Federal Officer, PADAC
8:10 a.m.	FDA Introductory Remarks	Banu A. Karimi-Shah, MD Clinical Team Leader Division of Pulmonary, Allergy, Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	APPLICANT PRESENTATIONS	GlaxoSmithKline (GSK)
	Introduction - NUCALA® Mepolizumab for Patients with COPD	Steven Yancey, MS Vice President, Medicines Development Leader for Mepolizumab, GSK
	Eosinophilic COPD	Ian Pavord, MD Professor of Respiratory Medicine University of Oxford Honorary Consultant Physician University of Oxford Hospitals NHS Trust
	Clinical Efficacy	Eric Bradford, MD, MSc Director, Project Physician Lead for Mepolizumab GSK
	Clinical Safety	Olga Gumieniak, MD, MMSc Medical Director, Global Clinical Safety and Pharmacovigilance, GSK

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	GSK
	Physician's Perspective	Gerard Criner, MD Professor and Chair, Department of Thoracic Medicine and Surgery Lewis Katz School of Medicine at Temple University
	Closing Comments	Steven Yancey, MS
9:55 a.m.	Clarifying Questions	
10:15 a.m.	BREAK	
10:30 a.m.	FDA PRESENTATIONS	
	Overview of the Clinical Program	Robert Busch, MD, MMSc Clinical Reviewer DPARP, ODE II, OND, CDER, FDA
	Statistical Review of Efficacy	Yu (Jade) Wang, PhD Statistical Reviewer Division of Biometrics II (DB II) Office of Biometrics (OB) Office of Translational Sciences (OTS) CDER, FDA
	Review of Safety	Robert Busch, MD, MMSc
	Clinical Considerations and Benefit-Risk Assessment	Robert Busch, MD, MMSc
12:00 p.m.	Clarifying Questions	
12:15 p.m.	LUNCH	
1:15 p.m.	Open Public Hearing	
2:15 p.m.	Charge to the Committee	Banu A. Karimi-Shah, MD
2:25 p.m.	Questions to the Committee/Committee Discussion	

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- 3:00 p.m. **BREAK**
- 3:15 p.m. Questions to the Committee/Committee
Discussion
- 4:00 p.m. **ADJOURNMENT**