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

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
November 17, 2023

AGENDA

The Committee will discuss new drug application 215010, for gefapixant oral tablets, submitted by Merck Sharp & Dohme Corp., for the proposed indication of treatment of adults with refractory or unexplained chronic cough.

9:00 a.m.	Call to Order	**Paula Carvalho, MD, FCCP** Acting Chairperson, PADAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Designated Federal Officer, PADAC
9:10 a.m.	FDA Opening Remarks	**Stacy Chin, MD** Clinical Team Leader Division of Pulmonology, Allergy, and Critical Care (DPACC) Office of Immunology and Inflammation (OII) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	**APPLICANT PRESENTATIONS**	**Merck Sharp and Dohme LLC**
	Introduction	**Lisa Bollinger, MD** Vice President, Regulatory Affairs Merck Sharp and Dohme LLC
	Disease Background and Unmet Need	**Peter Dicpinigaitis, MD** Professor of Medicine Albert Einstein College of Medicine Director, Cough Center Montefiore Medical Center, New York
	Program Overview and Efficacy Data	**George Philip, MD** Executive Director, Medical Affairs Merck Sharp and Dohme LLC
	Patient Reported Outcomes	**Allison Martin Nguyen, MS** Executive Director, Epidemiology Patient-Centered Endpoints and Strategy (PaCES) Group Merck Sharp and Dohme LLC

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AGENDA (cont.)

APPLICANT PRESENTATIONS (cont.)

	Clinical Safety	**English Willis, MD** Executive Director Clinical Safety and Risk Management Merck Sharp and Dohme LLC
	Clinical Perspective on the Benefit-Risk Relationship	**Jaclyn Smith, MD, ChB, FRCP, PhD** Division of Infection, Immunity and Respiratory Medicine University of Manchester, United Kingdom
	Closing Summary	**Lisa Bollinger, MD**
10:35 a.m.	**BREAK**	
10:45 a.m.	**FDA PRESENTATIONS**	
	Overview of the Clinical Program and Review of Safety	**Rachel Bean, MD** Medical Officer DPACC, OII, OND, CDER, FDA
	Statistical Review of Efficacy	**Susan Mayo, MS** Statistical Reviewer Division of Biometrics III Office of Biostatistics Office of Translational Sciences CDER, FDA
	Clinical Considerations	**Rachel Bean, MD**
11:55 a.m.	Clarifying Questions	
12:40 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Charge to the Committee	**Stacy Chin, MD**

AGENDA (cont.)

2:35 p.m.	Questions to the Committee/Committee Discussion
3:30 p.m.	**BREAK**
3:40 p.m.	Questions to the Committee/Committee Discussion (cont.)
5:00 p.m.	**ADJOURNMENT**