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

Antimicrobial Drugs Advisory Committee *(AMDAC) Meeting*
March 16, 2023

AGENDA (cont.)

The committee will discuss new drug application (NDA) 217188, for PAXLOVID (nirmatrelvir and ritonavir co-packaged tablets) for oral use, submitted by Pfizer, Inc. The proposed indication is treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

9:00 a.m.	Call to Order	**Lindsey R. Baden, MD** Chairperson, AMDAC
9:10 a.m.	Introduction of Committee and Conflict of Interest Statement	**Joyce Frimpong, PharmD** Acting Designated Federal Officer, AMDAC
9:15 a.m.	FDA Opening Remarks	**John Farley, MD, MPH** Director Office of Infectious Diseases (OID) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	**APPLICANT PRESENTATIONS**	**Pfizer, Inc.**
	Introduction	**James Rusnak, MD, PhD** Senior Vice President Chief Development Officer Internal Medicine, Anti-infectives, and Hospital Global Product Development Pfizer, Inc.
	Efficacy from EPIC Randomized Clinical Trials	**Jennifer Hammond, PhD** Vice President Development Head Antivirals Global Product Development Pfizer, Inc.
	Effectiveness from Real-world Studies	**John McLaughlin, PhD** Vice President, Global Medical Lead Covid & Influenza Pfizer, Inc.
	Efficacy Conclusions and Safety from EPIC Randomized Clinical Trials	**Jennifer Hammond, PhD**

APPLICANT PRESENTATIONS (CONT.)

Safety from Post-Marketing Surveillance	**Lubna Merchant, MS, PharmD** Director, Risk Management Center of Excellence, Worldwide Safety Pfizer Inc.
COVID-19 Rebound, Continued Development, and Conclusions	**James Rusnak, MD, PhD**

10:35 a.m. **BREAK**

10:45 a.m. **FDA PRESENTATIONS**

Overview	**Glen Huang, DO** Clinical Reviewer Division of Antivirals (DAV) OID, OND, CDER, FDA
<u>Efficacy Issues</u>	
Efficacy of PAXLOVID in High-Risk Adults Who Were Previously Vaccinated Against COVID-19 or Had a Prior SARS-CoV-2 Infection	**Stephanie Troy, MD** Clinical Reviewer DAV, OID, OND, CDER, FDA
Efficacy of PAXLOVID in the Setting of the SARS-CoV-2 Omicron Variant	**Jonathan Rawson, PhD** Clinical Virology Reviewer DAV, OID, OND, CDER, FDA
Impact of PAXLOVID on COVID-19 Rebound	**Patrick Harrington, PhD** Clinical Virology Reviewer DAV, OID, OND, CDER, FDA
Optimal Duration of PAXLOVID Treatment in Immunocompromised Patients	**Stephanie Troy, MD**

AGENDA (cont.)

	FDA PRESENTATIONS (CONT.)	
	Safety Issue	
	Serious Adverse Reactions Due to DDIs	**Stephanie Troy, MD**
11:55 a.m.	**LUNCH**	
12:40 p.m.	Clarifying Questions	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Charge to the Committee	**Debra Birnkrant, MD** Director DAV, OID, OND, CDER, FDA
2:35 p.m.	Questions to the Committee/Committee Discussion	
3:35 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	