AGENDA

The committee will discuss Emergency Use Authorization (EUA) 000108, submitted by Merck & Co. Inc., for emergency use of molnupiravir oral capsules for treatment of mild to moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization.

9:00 a.m. Call to Order
Lindsey R. Baden, MD
Chairperson, AMDAC

9:10 a.m. Conflict of Interest Statement and Introduction of Committee
Joyce Yu, PharmD
Acting Designated Federal Officer, AMDAC

9:15 a.m. FDA Introductory Remarks
John Farley, MD, MPH
Director
Office of Infectious Diseases (OID)
Office of New Drugs (OND), CDER, FDA

9:25 a.m. SPONSOR PRESENTATIONS
Merck & Co., Inc.

Introduction
Sean Curtis, MD, MPH
Senior Vice President
Global Regulatory Affairs & Clinical Safety
Merck & Co., Inc

Mechanism of Action
Daria J. Hazuda, PhD
Vice President, Infectious Disease and Vaccines
Merck & Co., Inc

Nonclinical Safety
Kerry Blanchard, PhD
Senior Vice President, Preclinical Development
Merck & Co., Inc

Clinical Efficacy and Safety
Nicholas Kartsonis, MD
Senior Vice President
Clinical Research, Infectious Diseases/Vaccines
Merck & Co., Inc

Benefit-Risk Conclusion
Nicholas Kartsonis, MD

10:35 a.m. BREAK
10:45 a.m. **FDA PRESENTATIONS**

- **Emergency Use Authorization (EUA)**
  - Request 108 Molnupiravir (MOV) Capsules
  - **Aimee Hodowanec, MD**
  - Senior Medical Officer
  - Division of Antivirals (DAV)
  - OID, OND, CDER, FDA

- **Molnupiravir: Nonclinical Toxicology Findings**
  - **Mark Seaton, PhD, DABT**
  - Research Officer
  - Division of Pharmacology/Toxicology-Infectious Diseases
  - OID, OND, CDER, FDA

- **Genotoxicity Safety Assessment of Molnupiravir**
  - **Robert H. Heflich, PhD**
  - Director
  - Division of Genetic and Molecular Toxicology
  - National Center for Toxicological Research
  - Office of the Chief Scientist
  - Office of the Commissioner, FDA

- **Clinical Overview**
  - **Aimee Hodowanec, MD**

- **FDA Clinical Virology Review of Molnupiravir**
  - **Patrick R. Harrington, PhD**
  - Senior Clinical Virology Reviewer
  - DAV, OID, OND, CDER, FDA

- **Review Issues and Proposed Risk Mitigation Strategies**
  - **Aimee Hodowanec, MD**

11:45 a.m. **Clarifying Questions for Presenters**

12:45 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. **Charge to the Committee**

- **Debra Birnkrant, MD**
  - Director
  - DAV, OID, OND, CDER, FDA
## AGENDA (cont.)

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<td>2:45 p.m.</td>
<td>Questions to the Committee/Committee Discussion</td>
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<td>3:50 p.m.</td>
<td>BREAK</td>
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<td>4:00 p.m.</td>
<td>Questions to the Committee/Committee Discussion (cont.)</td>
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<td>5:00 p.m.</td>
<td>ADJOURNMENT</td>
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