

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

***Antimicrobial Drugs Advisory Committee (AMDAC) Meeting***  
June 8, 2023

**DRAFT AGENDA**

*The committee will discuss biologics license application (BLA) 761328, for nirsevimab, a long-acting Respiratory Syncytial Virus (RSV) F protein inhibitor monoclonal antibody for intramuscular use, submitted by AstraZeneca AB. The proposed indication is prevention of RSV lower respiratory tract disease in:*

- *Neonates and infants born during or entering their first RSV season.*
- *Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.*

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9:30 a.m.	Call to Order	<b>Lindsey R. Baden, MD</b> Chairperson, AMDAC
9:40 a.m.	Introduction of Committee and Conflict of Interest Statement	<b>She-Chia Jankowski, PharmD</b> Designated Federal Officer, AMDAC
9:45 a.m.	FDA Opening Remarks	<b>John Farley, MD, MPH</b> Director Office of Infectious Diseases (OID) Office of New Drugs (OND), CDER, FDA
9:55 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>AstraZeneca AB</b>
	Introduction	<b>Tonya Villafana, PhD, MPH</b> Vice President, Global Franchise Head Vaccines and Immune Therapies AstraZeneca
	Efficacy	<b>Amanda Leach, MRCPCH</b> Global Clinical Head AstraZeneca
	Safety	<b>Manish Shroff, MBBS, MS, MBA</b> Senior Director Global Patient Safety, AstraZeneca
	Clinical Perspective	<b>William Muller, MD, PhD</b> Professor, Pediatrics, Northwestern University Feinberg School of Medicine Scientific Director, Office of Clinical and Community Trials, Ann & Robert H. Lurie Children's Hospital of Chicago

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**DRAFT AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

Benefit-Risk & Conclusions **Tonya Villafana, PhD, MPH**

10:55 a.m. **BREAK**

11:05 a.m. **FDA PRESENTATIONS**

Overview

**Melisse Baylor, MD**  
Clinical Reviewer  
Division of Antivirals (DAV)  
OID, OND, CDER, FDA

**Yang Zhao, PhD**  
Clinical Pharmacology Reviewer  
Division of Infectious Disease Pharmacology  
Office of Clinical Pharmacology (OCP)  
Office of Translational Science (OTS)  
CDER, FDA

Efficacy and Safety Issues

**Anna Kettermann, Dipl.-Math, MA**  
Statistics Reviewer  
Division of Biostatistics IV  
Office of Biostatistics  
OTS, CDER, FDA

**Melisse Baylor, MD**

**Justin Earp, PhD**  
Pharmacometrics Reviewer  
Division of Pharmacometrics  
OCP, OTS, CDER, FDA

Proposed Pharmacovigilance Strategy

**Neha Gada, PharmD, BCPS**  
Cross Discipline Safety Advisor  
Office of Pharmacovigilance and  
Epidemiology  
Office of Surveillance and Epidemiology  
CDER, FDA

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**FDA PRESENTATIONS (CONT.)**

Overall Summary **Melisse Baylor, MD**

12:05 p.m. **CLARIFYING QUESTIONS**

12:50 p.m. **LUNCH**

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

2:30 p.m. Charge to the Committee **Yodit Belew, MD**  
Associate Director for Therapeutic Review  
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**