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

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

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.*

9:30 a.m.	Call to Order	**Lindsey R. Baden, MD** Chairperson, AMDAC
9:40 a.m.	Introduction of Committee and Conflict of Interest Statement	**She-Chia Jankowski, PharmD** Designated Federal Officer, AMDAC
9:45 a.m.	FDA Opening Remarks	**John Farley, MD, MPH** Director Office of Infectious Diseases (OID) Office of New Drugs (OND), CDER, FDA
9:55 a.m.	**APPLICANT PRESENTATIONS**	**AstraZeneca AB**
	Introduction	**Tonya Villafana, PhD, MPH** Vice President, Global Franchise Head Vaccines and Immune Therapies AstraZeneca
	Efficacy	**Amanda Leach, MRCPCH** Global Clinical Head AstraZeneca
	Safety	**Manish Shroff, MBBS, MS, MBA** Senior Director Global Patient Safety, AstraZeneca
	Clinical Perspective	**William Muller, MD, PhD** 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

---

	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

AGENDA (cont.)

	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**	