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

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

QUESTIONS

BLA 761328

nirsevimab

Applicant: AstraZeneca AB

PROPOSED INDICATION:

- Prevention of respiratory syncytial virus (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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1. **VOTE:** Is the overall benefit-risk assessment favorable for the use of nirsevimab for the prevention of RSV lower respiratory disease in neonates and infants born during or entering their first RSV season?
    a. If yes, please discuss your rationale.
    b. If no, please comment on what additional clinical data are needed to support this indication.

2. **DISCUSSION:** Please comment on the benefits and risks for nirsevimab when assessed by chronological and gestational age groups. Discuss the population or subpopulation for whom nirsevimab administration in the first RSV season would be most appropriate.

3. **VOTE:** Is the overall benefit-risk assessment favorable for the use of nirsevimab for the prevention of RSV lower respiratory tract disease in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season?
    a. If yes, please discuss your rationale.
    b. If no, please comment on what additional clinical data are needed to support this indication.

4. **DISCUSSION:** In the context of potential, future availability of maternal RSV vaccine to protect infants from RSV disease during their first RSV season, what additional data may be helpful to inform future recommendations regarding the use of nirsevimab in infants born to mothers who received RSV vaccination?