Errata to the FDA Briefing Document for June 8, 2023 Antimicrobial Drugs Advisory Committee Meeting

Corrections:

1. On page 8, the incidence of rash in the nirsevimab arm in RSV season 1 of Trial 05 is reported as 0.4%; the corrected incidence of rash in the nirsevimab arm in RSV season 1 of Trial 05 is 0.3%.

2. On page 8, pyrexia is incorrectly described as the most commonly reported adverse event in Trial 05, Season 2. Upper respiratory tract infection was the most commonly reported adverse event, followed by pyrexia.

3. On page 23, Figure 5, entitled "Primary Cohort: Subgroup Analyses of MA RSV LRTI in Trial 04," the number of subjects with MA RSV LRTI events/number of subjects who received nirsevimab in infants weighing ≥5kg is listed incorrectly as 18/301. The correct number of subjects with MA RSV LRTI events/number of subjects who received nirsevimab in infants weighing ≥ 5kg is 5/581.

4. On page 31, under Sources of Data for Safety, it incorrectly states that there were 3,245 subjects who received the proposed dose of nirsevimab. The corrected number of subjects who received the proposed dose is 3,285.

5. Adverse events of special interest (AESI) are discussed on page 34. This information differs from the information presented by the Applicant. The information on page 34 is based on the definition provided for AESI in the study protocols for Trials 03, 04, and 05. AESI were defined in the protocols as hypersensitivity/anaphylaxis, immune complex disease and thrombocytopenia. As a result, the FDA definition of AESI was much more narrowly focused. Safety data from Trial 08 was not included because of confounding from subjects' underlying diseases and treatments and lack of a control group. Finally, rashes considered as possible hypersensitivity reactions are summarized separately in the FDA briefing document.