Errata #2 to the FDA Briefing Document for June 8, 2023 Antimicrobial Drugs Advisory Committee Meeting

Corrections:

On page 6, Section 1.2, the third paragraph should be changed:

From: Palivizumab is also a recombinant neutralizing **humanized** human immunoglobulin G1 kappa monoclonal antibody against the RSV fusion (F) protein and has a similar mechanism of action as nirsevimab, but targets antigenic site II on the RSV F protein which is exposed in both prefusion and postfusion conformations.

To: Palivizumab is a recombinant neutralizing **humanized** monoclonal antibody against the RSV fusion (F) protein and has a similar mechanism of action as nirsevimab, but targets antigenic site II on the RSV F protein which is exposed in both prefusion and postfusion conformations.

On page 10, Section 2.1, the following should be changed:

From: Palivizumab, like-nirsevimab, is a recombinant humanized monoclonal antibody directed against a conserved epitope on the RSV fusion (F) protein.

To: Palivizumab is a recombinant humanized monoclonal antibody directed against a conserved epitope on the RSV fusion (F) protein.

Page 8, Section 1.2, footnote 4:
Footnote 4 is incorrect. The corrected footnote should read as follows:
Results based on the Poisson regression adjusted for age and multiple imputations for missing data.

Section 3.13., Page 17, Figure 2:

The numbers presented in the Forest plot for the subgroups of gestational age, weight, and race are incorrect. The correct numbers for these subgroups are as follows:

	Nirsevimab	*Placebo*
Gestational Age >= 29 To <= 32 Weeks	10/363	21/185
Gestational Age > 32 Weeks	15/606	25/299

	Nirsevimab	*Placebo*
Weight <= 2.5 kg	2/186	9/96
Weight > 2.5 to <= 5 kg	6/399	17/200
Weight > 5 kg	17/379	20/185

	Nirsevimab	*Placebo*
White	*21/693*	*38/355*
Other	*4/276*	*8/129*

Page 29, Section 3.1.4:

The following bullet should be revised as follows:

From: The CLD/CHD cohort included 24% subjects with CLD and 11% subjects with CHD. Of infants in the CLD/CHD cohort, 40% were <29 weeks GA, 28% of infants were ≥29 weeks to <35 weeks GA; and 15% were ≥35 weeks GA.

To: *Trial 05* included 24% subjects with CLD and 11% subjects with CHD. In the CLD/CHD cohort, 70% had CLD; 34% had hemodynamically significant CHD. Of infants in the CLD/CHD cohort, 40% were <29 weeks GA, 28% of infants were ≥29 weeks to <35 weeks GA; and *32%* were ≥35 weeks GA.

Section 3.1.4, Table 9, page 31 The incorrect numbers in Table 9 are revised as follows:

RSV Season	**Extreme Preterm Infants <29 Weeks GA Without CLD or CHD**	**CLD**	**CHD**
RSV Season 1	93.6% (44/47)	94.1% (128/136)	80.3% (53/66)
RSV Season 2	NA	97.7% (129/132) ~~93.9% (124/132)~~	100% (58/58) ~~91.4% (53/58)~~

Appendix, page 55.

The statement about the ADA results from Trial 05 should be revised to clarify that the results were from *Season 1*.