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ERRATA SHEET

Errata to Moderna's Briefing Document for June 18, 2026 Vaccines and Related Biological Products Committee Meeting

This document contains errata to the original Moderna mRNA-1010 Briefing Document. The erroneous text is followed by the correction in bold below.

1. Page 13, Section 2
   Original: In the Study 304 population, 56.9% of participants were considered at high risk for severe ILI, and 25% of participants ≥65 years were considered of vulnerable or frail status.

   Corrected: In the Study 304 population, 56.9% of participants were considered at high risk for severe ILI, and **26.5**% of participants ≥65 years were considered of vulnerable or frail status.

2. Page 35, Table 3
   Original: Footnote stated, "a. Numbers are based on planned vaccination group and percentages are based on the number of participants in the Randomization Set."

   Corrected: Footnote should state, "a: Percentages are based on the number of participants in the Randomization Set."

3. Page 35, Section 6.3.1.2
   Original: In the total Safety Set of 40,303 participants…

   Corrected: In the total Safety Set of **40,703** participants…

4. Page 36, Table 4
   Original: The row for Native Hawaiian or Other Pacific Islander shows 38 (0.4) for mRNA-1010 and 49 (0.5) for active SD comparator in the 50-64 Years group.

   Corrected: The number of participants in the Native Hawaiian or Other Pacific Islander row should be **17 (<0.1)** mRNA-1010 and **13 (<0.1)** Active SD Comparator in the 50 – 64 Years group. *The corrected part of the table is shown below*.

	≥50 Years		50–64 Years		≥65 Years	
	mRNA-1010 37.5 µg (N=20350)	**Active SD Comparator (N=20353)**	**mRNA-1010 37.5 µg (N=10624)**	**Active SD Comparator (N=10615)**	**mRNA-1010 37.5 µg (N=9726)**	**Active SD Comparator (N=9738)**
Race, n (%)						
White	16814 (82.6)	16811 (82.6)	8,423 (79.3)	8,419 (79.3)	8,391 (86.3)	8,392 (86.2)
Black or African American	2687 (13.2)	2698 (13.3)	1,655 (15.6)	1,626 (15.3)	1,032 (10.6)	1,072 (11.0)
Asian	496 (2.4)	483 (2.4)	326 (3.1)	332 (3.1)	170 (1.8)	151 (1.6)
American Indian or Alaska Native	72 (0.4)	86 (0.4)	38 (0.4)	49 (0.5)	34 (0.3)	37 (0.4)
Native Hawaiian or Other Pacific Islander	20 (<0.1)	19 (<0.1)	**17 (<0.1)**	**13 (<0.1)**	3 (<0.1)	6 (<0.1)

5. Page 38, Table 6
   Original: Footnote stated, "a. b. Safety Set and Solicited Safety Set were based on the actual study vaccine received."

   Corrected: Footnote should state, "a. Percentages are based on the number of participants in the Randomization Set." Footnote b should be deleted, and its references in the table should also be deleted.

6. Page 52, Section 8.3.2.1
   Original: In adults ≥65 years in Study 304, analyses of GMR (mRNA-1010 Day 29 GMT/SD comparator Day 29 GMT) showed that mRNA-1010 induced higher HAI Ab levels than did the SD comparator (all point estimates ≥1.6 [95% CI LBs were ≥1.5]).

   Corrected: In adults ≥65 years in Study 304, analyses of GMR (mRNA-1010 Day 29 GMT/SD comparator Day 29 GMT) showed that mRNA-1010 induced higher HAI Ab levels than did the SD comparator (all point estimates ≥1.6 [95% CI LBs were ≥**1.49**]).

7. Page 57, Section 9
   Original: Integrated safety data from participants ≥50 years in the 4 completed Phase 3 studies, in which 71,916 adults received mRNA-1010 TIV or QIV (12.5 µg per strain) or SD/HD comparator (TIV or QIV) and had at least 6 months of safety follow-up.

   Corrected: Integrated safety data from participants ≥50 years in the 4 completed Phase 3 studies, in which 71,916 adults received mRNA-1010 TIV or

QIV (12.5 μg per strain) or SD/HD comparator (TIV or QIV), **with a median follow-up of 198 days.**

8. Page 71, Table 14
   Original: For the Fluarix SD or Fluzone HD column, the n % for fatal events throughout is shown as 97 (<0.1).

   Corrected: For the Fluarix SD or Fluzone HD column, the n % for fatal events throughout the study should be 97 (**0.3**). The corrected part of the table is shown below.

	mRNA-1010 (N = 35,965)	Fluarix SD (N = 34,461)	Fluzone HD (N = 1,490)	Fluarix SD or Fluzone HD (N = 35,951)
Participants with unsolicited AEs throughout the study, regardless of relationship to study vaccination				
Serious	1129 (3.1)	989 (2.9)	38 (2.6)	1027 (2.9)
Fatal	102 (0.3)	96 (0.3)	1 (<0.1)	97 **(0.3)**
AE of Special Interest	36 (0.1)	36 (0.1)	1 (<0.1)	37 (0.1)

AE: adverse event; HD: high dose; ISS: integrated summary of safety; SD: standard dose

9. Page 75, Section 9.3.3.6
   Original: The frequency of SAEs, fatal events and AESIs was similar between vaccine groups through 28 days after injection and up to Day 181 in both the 50 to 64 year-old subgroup and the ≥ 65-year-old subgroup as shown in Table 15.

   Corrected: The frequency of SAEs, fatal events and AESIs was similar between vaccine groups through 28 days after injection and through end of study in both the 50 to 64 year-old subgroup and the ≥ 65-year-old subgroup as shown in Table 15.

10. Page 80, Section 11.3
    Original: An exploratory efficacy analysis showed that mRNA-1010 reduced ILI-associated healthcare encounters (hospitalization, ER visit, or urgent care visit) relative to SD comparator (rVE of 62.9% [95% CI: 11.6, 88.4]).

    Corrected: An exploratory efficacy analysis showed that mRNA-1010 reduced ILI-associated healthcare encounters (hospitalization, ER visit, or urgent care visit) relative to SD comparator (rVE of **65.1% [95% CI: 17.4, 85.2]**).

11. Page 80, Section 11.3

Original: The superior clinical efficacy of mRNA-1010 relative to SD comparator in Study 304 was paralleled by higher immune responses (HAI Ab) for all vaccine-included influenza strains: GMR point estimates were all >1.6 (95% CI LBs were >1.5) and SCR differences were all positive (95% CI LBs were >16%).

Corrected: The superior clinical efficacy of mRNA-1010 relative to SD comparator in Study 304 was paralleled by higher immune responses (HAI Ab) for all vaccine-included influenza strains: GMR point estimates were all >1.6 (95% CI LBs were >**1.488**) and SCR differences were all positive (95% CI LBs were >16%).

12. Page 94, Table 18

Original: Erythema Grade 3 in ≥65 Active SD Comparator is shown as 76 (5.0).

Corrected: Erythema Grade 3 in ≥65 Active SD Comparator should be **1 (<0.1).** The corrected part of the table is shown below.

	Study 304 50-64 year		**Study 304 ≥65 year**	
	mRNA-1010 37.5 µg (N=1,510) n (%)	**Active SD Comparator (N=1,502) n (%)**	**mRNA-1010 37.5 µg (N=1,505) n (%)**	**Active (SD) Comparator (N=1,495) n (%)**
Erythema (redness)				
Any	66 (4.4)	19 (1.3)	51 (3.4)	19 (1.3)
Grade 3	4 (0.3)	1 (<0.1)	6 (0.4)	**1 (<0.1)**
Grade 4	0	0	0	0

AR: adverse reaction; CI: confidence interval; SD: standard dose