Supplementary Materials

Phase 3 Randomized, Multicenter, Placebo-Controlled Study to Evaluate Safety, Immunogenicity, and Lot-to-Lot Consistency of an Adjuvanted Cell Culture-Derived, H5N1 Subunit Influenza Virus Vaccine in Healthy Adult Subjects

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Table S1. Immune responses (GMT and GMR) against aH5N1 on Days 1, 22, 43, and 183 by CHMP age group.[a.]

	Age 18 to <60 years		**Age ≥60 years**	
	aH5N1c	**Placebo**	**aH5N1c**	**Placebo**
Day 1, n	980	331	1269	408
GMT (95% CI)	13.0 (12.3–13.8)	13.4 (12.2–14.7)	20.1 (19.1–21.3)	20.1 (18.3–22.0)
Day 22, n	979	329	1266	407
GMT (95% CI)	51.1 (47.9–54.6)	11.2 (10.0–12.5)	42.9 (40.5–45.3)	14.4 (13.1–15.9)
GMR, Day 22/Day 1 (95% CI)	**3.92** (3.67–4.18)	0.85 (0.76–0.96)	**2.22** (2.10–2.35)	0.75 (0.68–0.82)
Day 43, n	947	309	1209	391
GMT (95% CI)	177.4 (166.2–189.4)	10.7 (9.5–11.9)	100.7 (95.0–106.7)	16.2 (14.7–17.9)
GMR, Day 43/Day 1 (95% CI)	**13.44** (12.59–14.35)	0.81 (0.72–0.90)	**5.18** (4.88–5.49)	0.83 (0.76–0.92)
Day 183, n	899	302	1180	385
GMT (95% CI)	20.4 (19.3–21.7)	6.7 (6.0–7.4)	19.3 (18.3–20.4)	8.5 (7.7–9.3)
GMR, Day 183/Day 1 (95% CI)	1.56 (1.47–1.66)	0.51 (0.46–0.57)	0.99 (0.94–1.05)	0.44 (0.40–0.48)

Abbreviations: CHMP, Committee for Medicinal Products for Human Use; CI, confidence interval; GMT, geometric mean titer; GMR, geometric mean ratio. [a] Boldface indicates CHMP criteria for GMR were met, i.e., GMR >2.5 for subjects aged 18 to <60 years and >2.0 for subjects aged ≥60 years.

Table S2. Percentages of subjects (95% CI) achieving seroconversion in HI titer.[a]

	Age 18 to <60 years		Age ≥60 years	
	aH5N1c	**Placebo**	**aH5N1c**	**Placebo**
Day 22, n	979	329	1266	407
Seroconversion, % (95% CI)	**42.2** (39.1–45.4)	1.5 (0.5–3.5)	24.6 (22.2–27.0)	0.7 (0.2–2.1)
Day 43, n	947	309	1209	391
Seroconversion, % (95% CI)	**81.6** (79.0–84.0)	0.3 (0.0–1.8)	**55.4** (52.6–58.2)	1.5 (0.6–3.3)
Day 183, n	899	302	1180	385
Seroconversion, % (95% CI)	17.0 (14.6–19.6)	0.3 (0.0–1.8)	8.2 (6.7–9.9)	1.0 (0.3–2.6)

Abbreviations: CHMP, Committee for Medicinal Products for Human Use; CI, confidence interval; HI, hemagglutination inhibition. [a] Seroconversion was defined as either a prevaccination (baseline) HI titer <1:10 and postvaccination HI titer ≥1:40 or a prevaccination HI titer ≥1:10 and a ≥4-fold increase in postvaccination HI antibody titer. Boldface indicates CHMP criteria for seroconversion were met, i.e., the percentage of subjects with seroconversion was ≥40% for subjects aged <60 years and ≥30% for subjects aged ≥60 years.