

<参考>

各 HPV 型に対する GMT の比較 (Month 7)

—9~15 歳の日本人女性 (008 試験) と 16~26 歳の日本人女性 (001 試験) の比較—

(PPI 解析対象集団†) (008 試験、001 試験)

Assay (cLIA)	Comparison Group				Estimated Fold Difference Group A / Group B‡ (95% CI)	p-Value for Non-Inferiority‡
	Subjects aged 9 to 15 (Comparison Group A) (N = 100)		Subjects aged 16 to 26 (Comparison Group B) (N = 127)			
	n	Estimated GMT‡ (mMU/mL)	n	Estimated GMT‡ (mMU/mL)		
Anti-HPV 6	97	1,836.5	93	839.7	2.19 (1.78, 2.68)	<0.001
Anti-HPV 11	97	1,331.3	93	611.1	2.18 (1.75, 2.72)	<0.001
Anti-HPV 16	99	6,823.6	96	2,672.7	2.55 (2.09, 3.13)	<0.001
Anti-HPV 18	98	2,159.9	99	688.7	3.14 (2.43, 4.05)	<0.001
Anti-HPV 31	97	2,052.5	104	672.3	3.05 (2.43, 3.84)	<0.001
Anti-HPV 33	98	994.8	109	398.3	2.50 (2.04, 3.05)	<0.001
Anti-HPV 45	99	811.0	111	258.5	3.14 (2.45, 4.01)	<0.001
Anti-HPV 52	99	1,069.1	98	306.3	3.49 (2.78, 4.38)	<0.001
Anti-HPV 58	95	1,488.2	95	459.6	3.24 (2.65, 3.96)	<0.001

† The per-protocol immunogenicity population includes all subjects who were not general protocol violators, received all 3 vaccinations within acceptable day ranges, were seronegative at Day 1 for the relevant HPV-type(s), and had a Month 7 serum sample collected within an acceptable day range. In addition, subjects were required to be seronegative at Day 1 and (for 16- to 26-year-old women) PCR negative from Day 1 through Month 7 only for the HPV type being analyzed.

‡ The estimated GMT, fold difference, associated confidence intervals, and p-value are based on an ANCOVA model with a response of the natural log of individual titers and fixed effects for comparison group. The noninferiority criterion for endpoints reported in this table is defined as statistically less than 1.5-fold decrease in Group A compared to Group B. Noninferiority of GMT in Group A relative to Group B is demonstrated if the lower limit of the 95% CI for the fold difference is greater than 0.67.

N = Number of subjects randomized to the respective vaccination group who received at least 1 injection.

n = Number of subjects contributing to the analysis.

CI = Confidence interval; GMT = Geometric mean titer; mMU = Milli Merck units; cLIA = 9 valent Competitive Luminex immunoassay.