

Supplemental Material to:

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Immunogenicity and safety of the HPV-16/18 AS04-adjuvanted vaccine in healthy Chinese girls and women aged 9 to 45 years: Results from two randomized controlled trials

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SUPPLEMENTARY MATERIAL

Supplementary Table 1 Seropositivity rates and GMTs for anti-HPV-16 antibodies by age strata: vaccine group

Antibody	Age (years)	Pre-vaccination status	Time	N	Seropositive		GMT (EU/mL)		
					n	%	Value	LL	UL
Anti-HPV-16	9–11	Seronegative	Pre	99	0	0.0	4.0	4.0	4.0
			Month 7	99	99	100	25093.4	21714.6	28998.0
		Seropositive	Pre	9	9	100	21.5	13.4	34.6
			Month 7	9	9	100	25092.3	14001.2	44969.4
		Total	Pre	108	9	8.3	4.6	4.2	5.1
			Month 7	108	108	100	25093.4	21855.2	28811.3
	12–14	Seronegative	Pre	113	0	0.0	4.0	4.0	4.0
			Month 7	113	113	100	20017.2	17470.4	22935.3
		Seropositive	Pre	10	10	100	18.6	12.8	27.2
			Month 7	10	10	100	17548.6	10306.6	29879.0
		Total	Pre	123	10	8.1	4.5	4.2	4.9
			Month 7	123	123	100	19804.2	17387.7	22556.4
	15–17	Seronegative	Pre	114	0	0.0	4.0	4.0	4.0
			Month 7	114	114	100	13503.7	11735.3	15538.7
		Seropositive	Pre	17	17	100	19.8	15.1	25.9
			Month 7	17	17	100	11275.1	7300.7	17413.1
		Total	Pre	131	17	13.0	4.9	4.5	5.4
			Month 7	131	131	100	13191.3	11552.4	15062.8
	18–25	Seronegative	Pre	244	0	0.0	4.0	4.0	4.0
			Month 7	244	244	100	6996.2	6211.7	7879.7
		Seropositive	Pre	107	107	100	27.6	22.8	33.4
			Month 7	107	107	100	5698.0	4702.6	6904.1
		Total	Pre	351	107	30.5	7.2	6.5	8.0
			Month 7	351	351	100	6571.8	5939.0	7272.2
26–35	Seronegative	Pre	190	0	0.0	4.0	4.0	4.0	
		Month 7	190	190	100	7599.8	6759.1	8545.1	
	Seropositive	Pre	111	111	100	33.0	27.5	39.5	
		Month 7	111	111	100	6674.9	5841.2	7627.5	
	Total	Pre	301	111	36.9	8.7	7.6	9.9	
		Month 7	301	301	100	7244.7	6629.9	7916.5	
36–45	Seronegative	Pre	155	0	0.0	4.0	4.0	4.0	
		Month 7	155	155	100	6329.8	5587.4	7170.9	
	Seropositive	Pre	140	140	100	32.2	28.1	36.9	
		Month 7	140	140	100	5095.5	4462.4	5818.3	
	Total	Pre	295	140	47.5	10.8	9.4	12.3	
		Month 7	295	295	100	5710.6	5212.8	6256.0	

Data are shown for the ATP cohort for immunogenicity for subjects in the HPV vaccine group.

GMT, geometric mean antibody titre; LL, lower limit of 95% confidence interval; N, number of

subjects with results available; n/%, number/percentage of subjects in the specified category; UL, upper limit of 95% confidence interval. Data for females aged 9–11, 12–14 and 15–17 years are from Study HPV-058. Data for females aged 18–25 years are from Study HPV-039. Data for females aged 26–35 and 36–45 years are from Study HPV-069. HPV-16 seropositivity defined as an ELISA concentration ≥ 8 EU/mL.

Supplementary Table 2 Seropositivity rates and GMTs for anti-HPV-18 antibodies by age strata: vaccine group

Antibody	Age (years)	Pre-vaccination status	Time	N	Seropositive		GMT (EU/mL)		
					n	%	Value	LL	UL
Anti-HPV-18	9–11	Seronegative	Pre	103	0	0.0	3.5	3.5	3.5
			Month 7	103	101	98.1	8716.1	6672.3	11385.9
		Seropositive	Pre	5	5	100	29.2	9.5	89.7
			Month 7	5	5	100	24164.6	18808.3	31046.4
		Total	Pre	108	5	4.6	3.9	3.5	4.2
			Month 7	108	106	98.1	9137.4	7059.3	11827.3
	12–14	Seronegative	Pre	115	0	0.0	3.5	3.5	3.5
			Month 7	115	115	100	8995.6	7741.8	10452.4
		Seropositive	Pre	8	8	100	25.4	17.7	36.3
			Month 7	8	8	100	10125.5	4911.6	20874.3
		Total	Pre	123	8	6.5	4.0	3.6	4.4
			Month 7	123	123	100	9065.1	7840.8	10480.5
	15–17	Seronegative	Pre	120	0	0.0	3.5	3.5	3.5
			Month 7	120	120	100	6371.0	5569.6	7287.7
		Seropositive	Pre	11	11	100	17.3	11.8	25.3
			Month 7	11	11	100	5453.5	3486.4	8530.7
		Total	Pre	131	11	8.4	4.0	3.7	4.3
			Month 7	131	131	100	6288.3	5536.8	7142.0
	18–25	Seronegative	Pre	289	0	0.0	3.5	3.5	3.5
			Month 7	289	288	99.7	3309.4	2941.9	3722.8
		Seropositive	Pre	62	62	100	20.7	16.9	25.4
			Month 7	62	62	100	3242.2	2735.8	3842.4
		Total	Pre	351	62	17.7	4.8	4.4	5.2
			Month 7	351	350	99.7	3297.4	2980.2	3648.5
26–35	Seronegative	Pre	193	0	0.0	3.5	3.5	3.5	
		Month 7	193	193	100	3824.8	3386.5	4319.8	
	Seropositive	Pre	108	108	100	17.1	14.9	19.7	
		Month 7	108	108	100	3722.6	3172.1	4368.7	
	Total	Pre	301	108	35.9	6.2	5.6	6.8	
		Month 7	301	301	100	3787.8	3439.9	4170.9	
36–45	Seronegative	Pre	172	0	0.0	3.5	3.5	3.5	
		Month 7	172	170	98.8	3476.0	2936.0	4115.3	
	Seropositive	Pre	123	123	100	16.1	14.3	18.1	
		Month 7	123	123	100	3176.9	2787.9	3620.1	
	Total	Pre	295	123	41.7	6.6	6.0	7.3	
		Month 7	295	293	99.3	3348.0	2993.1	3744.9	

Data are shown for the ATP cohort for immunogenicity for subjects in the HPV vaccine group.

GMT, geometric mean antibody titre; LL, lower limit of 95% confidence interval; N, number of subjects with results available; n/%, number/percentage of subjects in the specified category; UL, upper limit of 95% confidence interval. Data for females aged 9–11, 12–14 and 15–17 years are

from Study HPV-058. Data for females aged 18–25 years are from Study HPV-039. Data for females aged 26–35 and 36–45 years are from Study HPV-069. HPV-18 seropositivity defined as an ELISA concentration ≥ 7 EU/mL.