

SUPPLEMENTARY TABLES

Table S1. Analysis of efficacy against HPV 6/11/16/18-related high-grade cervical lesions (CIN 2 or worse) by additional categories of baseline covariates

	Per-protocol population						Intention-to-treat population					
	Quadrivalent HPV vaccine		Placebo		Efficacy (%)	95% CI	Quadrivalent HPV vaccine		Placebo		Reduction (%)	95% CI
	Cases/n	Rate	Cases/n	Rate			Cases/n	Rate	Cases/n	Rate		
<b>Number of sexual partners in the 6 months before enrollment</b>												
0	1/5,192	0.0	62/5,071	0.4	98.4	(90.9, 100.0)	91/5,825	0.5	168/5,731	0.9	47.0	(31.1, 59.4)
1	1/1,881	0.0	32/1,929	0.6	96.8	(81.0, 99.9)	46/2,127	0.6	92/2,185	1.2	48.6	(26.1, 64.8)
≥2	0/326	0.0	8/355	0.8	100.0	(37.8, 100.0)	4/370	0.3	25/402	1.8	83.1	(51.1, 95.7)
Covariate by efficacy interaction	<i>p</i> = 1.00						<i>p</i> = 0.090					
<b>Day 1 PCR Status</b>												
Negative to HPV 6/11/16/18	2/6,741	0.0	98/6,780	0.5	98.0	(92.4, 99.8)	4/7,385	0.0	135/7,474	0.5	97.0	(92.2, 99.2)
Positive to HPV 6/11/16/18	0/1,082	0.0	12/1,054	0.4	100.0	(65.6, 100.0)	137/1,298	3.4	155/1,275	3.9	12.9	(<0.0, 31.3)
Covariate by efficacy interaction	<i>p</i> = 1.00						<i>p</i> < 0.001					
<b>Day 1 Sero Status</b>												
Negative to HPV 6/11/16/18	2/6,417	0.0	96/6,420	0.5	97.9	(92.3, 99.8)	45/7,086	0.2	184/7,112	0.7	75.6	(66.0, 82.8)
Positive to HPV 6/11/16/18	0/1,446	0.0	14/1,445	0.3	100.0	(70.1, 100.0)	97/1,729	1.7	109/1,739	1.9	10.4	(<0.0, 32.5)
Covariate by efficacy interaction	<i>p</i> = 1.00						<i>p</i> < 0.001					
<b>Day 1 PCR/Sero Status</b>												
Negative to HPV 6/11/16/18	2/5,847	0.0	89/5,875	0.5	97.7	(91.6, 99.7)	4/6,359	0.0	123/6,423	0.5	96.7	(91.4, 99.1)
Positive to HPV 6/11/16/18	0/1,993	0.0	21/1,970	0.4	100.0	(81.3, 100.0)	138/2,359	1.8	168/2,346	2.2	18.3	(<0.0, 35.2)
Covariate by efficacy interaction	<i>p</i> = 1.00						<i>p</i> < 0.001					

n = number of subjects evaluable, i.e., number of subjects in the given population who also have at least one follow-up visit; CI = confidence interval; Rate = rate per 100 person years at risk.

Table S2. Analysis of efficacy against HPV 6/11/16/18-related high-grade vulvar and vaginal lesions by additional categories of baseline covariates

	Per-protocol population						Intention-to-treat population					
	Quadrivalent HPV vaccine		Placebo		Efficacy (%)	95% CI	Quadrivalent HPV vaccine		Placebo		Reduction (%)	95% CI
	Cases/n	Rate	Cases/n	Rate			Cases/n	Rate	Cases/n	Rate		
<b>Number of sexual partners in the 6 months before enrollment</b>												
0	0/5,212	0.0	10/5,093	0.1	100.0	(56.4, 100.0)	6/5,907	0.0	20/5,794	0.1	70.6	(24.0, 90.3)
1	0/1,896	0.0	7/1,941	0.1	100.0	(29.1, 100.0)	2/2,161	0.0	13/2,211	0.2	84.2	(30.1, 98.3)
≥2	0/327	0.0	5/357	0.5	100.0	(<0.0, 100.0)	1/375	0.1	9/407	0.6	88.2	(14.7, 99.7)
Covariate by efficacy interaction	<i>p</i> = 1.00						<i>p</i> = 0.698					
<b>Day 1 PCR Status</b>												
Negative to HPV 6/11/16/18	0/6,747	0.0	22/6,794	0.1	100.0	(81.6, 100.0)	1/7,501	0.0	36/7,561	0.1	97.2	(83.3, 99.9)
Positive to HPV 6/11/16/18	0/1,112	0.0	1/1,077	0.0	100.0	(<0.0, 100.0)	8/1,313	0.2	7/1,295	0.2	<0.0	(<0.0, 64.4)
Covariate by efficacy interaction	<i>p</i> = 1.00						<i>p</i> <0.001					
<b>Day 1 Sero Status</b>												
Negative to HPV 6/11/16/18	0/6,430	0.0	22/6,436	0.1	100.0	(81.7, 100.0)	3/7,193	0.0	39/7,197	0.2	92.3	(75.8, 98.5)
Positive to HPV 6/11/16/18	0/1,469	0.0	1/1,466	0.0	100.0	(<0.0, 100.0)	6/1,755	0.1	4/1,763	0.1	<0.0	(<0.0, 64.2)
Covariate by efficacy interaction	<i>p</i> = 1.00						<i>p</i> = 0.001					
<b>Day 1 PCR/Sero Status</b>												
Negative to HPV 6/11/16/18	0/5,851	0.0	22/5,883	0.1	100.0	(81.6, 100.0)	1/6,458	0.0	35/6,497	0.2	97.1	(82.9, 99.9)
Positive to HPV 6/11/16/18	0/2,025	0.0	1/1,999	0.0	100.0	(<0.0, 100.0)	8/2,391	0.1	8/2,381	0.1	0.2	(<0.0, 67.4)
Covariate by efficacy interaction	<i>p</i> = 1.00						<i>p</i> <0.001					

n = number of subjects evaluable, i.e., number of subjects in the given population who also have at least one follow-up visit; CI = confidence interval; Rate = rate per 100 person years at risk.