The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: 104798 (HPV-032)

Title: A double-blind (observer-blind), randomized, controlled, phase II study to assess the efficacy, immunogenicity and safety of GlaxoSmithKline Biologicals' HPV-16/18 L1 *VLP* AS04 vaccine administered intramuscularly according to a 0, 1, 6 month schedule in healthy Japanese female subjects aged 20 - 25 years.
HPV-16/18 L1 VLP AS04 vaccine: GlaxoSmithKline (GSK) Biologicals' virus-like particle (VLP) vaccine against human papillomaviruses (HPV) 16/18.

Rationale: The aim of this study was to evaluate the safety & immunogenicity of HPV vaccine and to evaluate the vaccine efficacy in the prevention of persistent HPV-16 or HPV-18 cervical infection lasting at least 6 months in Japanese healthy adult women (20 - 25 years of age) over 24 months of follow-up. The efficacy of vaccine against associated abnormal cervical cytology and cervical intraepithelial neoplasia (CIN) biopsies associated with HPV-16 and/or HPV-18 was also evaluated. The control Group received Aimmugen™ vaccine.
Aimmugen™: Kaketsuken's freeze-dried inactivated tissue culture Hepatitis A vaccine (HAV).

Phase: II

Study Period: 26 April 2006 to 26 November 2008 (last study visit)

Study Design: Double-blind (observer-blind), controlled, randomized (1:1) multi-centric study with 2 parallel groups.

Centers: 13 study centers in Japan.

Indication: Active immunization of girls and women from 10 years of age onwards for the prevention of persistent human papillomavirus (HPV) infections and related clinical outcomes (cytological abnormalities and precancerous lesions) caused by oncogenic HPV types 16 and 18.

Treatment: The treatment groups were as follows:

- HPV Group: subjects received 3 doses of HPV vaccine.
- HAV Group: subjects received 3 doses of HAV vaccine.

All vaccines were administered intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6-month schedule.

Objectives:
To determine the efficacy of the HPV vaccine compared with control in the prevention of persistent infection (6-month definition) with HPV-16 or HPV-18 (by polymerase chain reaction [PCR]) post Dose 3 in Japanese healthy adult women (20-25 years of age) who were, for the corresponding HPV type, seronegative at Month 0 and HPV Deoxyribonucleic acid (DNA) negative (by PCR) at Month 0 and Month 6.

Primary Outcome/Efficacy Variable:
Persistent cervical infection with HPV-16 or HPV-18.
Persistent HPV-16 or HPV-18 infection is defined as at least 2 positive HPV DNA PCR assays for the same viral genotype with no negative DNA sample between the 2 positive DNA samples, over an approximate interval of 6 months (> 150 days) [as assessed in women who were, for the corresponding HPV type, seronegative at Month 0 and HPV DNA negative (by PCR) at Month 0 and Month 6].

Secondary Outcome/Efficacy Variable(s):
Efficacy

- Incident cervical infection with HPV-16 or HPV-18.
  HPV-16 or HPV-18 incident infection is defined as at least one positive HPV-16 or HPV-18 DNA PCR assay at Month 12, 18 or 24 in women who were, for the corresponding HPV type, seronegative at Month 0 and HPV DNA negative (by PCR) at Month 0 and Month 6.
- Cytologically confirmed or histopathologically confirmed low-grade squamous intraepithelial lesions (ASC-US† / LSIL or CIN1, respectively), high-grade squamous intraepithelial lesions (HSIL or CIN 2/3, respectively), squamous cell cancer, or adenocarcinoma concurrently associated with HPV-16 or HPV-18 cervical infection at Months 12, 18, or 24 [as assessed in women who were, for the corresponding HPV type, seronegative at Month 0 and HPV DNA negative (by PCR) at Month 0 and Month 6].

†ASCUS: Atypical Squamous Cells of Undetermined Significance; histopathology results were expressed using the Cervical Intraepithelial Neoplasia (CIN) classification system where CIN 1 corresponds to LSIL and CIN 2 and CIN 3 correspond to HSIL

- Incident cervical infection with any oncogenic HPV types (including HPV-16, -18, -31, -33, -35, -39, -45, -51, -52, -56, -58, -59, -66 and -68; by PCR).
  Incident infection for oncogenic HPV types is defined as at least one positive oncogenic HPV type DNA PCR assay at

Month 12, 18 or 24 in women who were, for the corresponding HPV type, HPV DNA negative (by PCR) at Month 0 and Month 6.

- Persistent cervical infection with any oncogenic HPV types (including HPV-16, -18, -31, -33, -35, -39, -45, -51, -52, -56, -58, -59, -66 and -68; by PCR).
  Persistent infection for oncogenic HPV types is defined as at least 2 positive HPV DNA PCR assays for the same viral genotype with no negative DNA sample between the 2 positive DNA samples, over an approximate interval of 6 months (> 150 days) [as assessed in women who were, for the corresponding HPV type, HPV DNA negative (by PCR) at Month 0 and Month 6].
- Cytologically confirmed or histopathologically confirmed low-grade squamous intraepithelial lesions (ASC-US / LSIL or CIN1, respectively), high-grade squamous intraepithelial lesions (HSIL or CIN 2/3, respectively), squamous cell cancer, or adenocarcinoma concurrently associated with cervical infection with any oncogenic HPV type (including HPV-16, -18, -31, -33, -35, -39, -45, -51, -52, -56, -58, -59, -66 and -68; by PCR) at Months 12, 18 or 24 [as assessed in women who were, for the corresponding HPV type, HPV DNA negative (by PCR) for the corresponding type at Month 0 and Month 6].

Immunogenicity

- HPV-16 and HPV-18 seroconversion rates (SCR) (at Months 6, 7, 12, 18**,** or 24), seropositivity rates and geometric mean antibody titers (GMTs) (at Months 0, 6, 7, 12, 18 or 24), assessed by ELISA.

Safety

- Occurrence, intensity and relationship to vaccination of solicited local and general symptoms within 7 days (Days 0 – 6) after each and any vaccination.
- Occurrence, intensity and causal relationship to vaccination of unsolicited symptoms within 30 days (Days 0 – 29) after any vaccination.
- Occurrence and relationship to vaccination of serious adverse events (SAEs) throughout the study period (up to Month 24).
- Occurrence of new onset chronic diseases (NOCD) and other medically significant** conditions prompting emergency room visits or physician visits that are not related to common diseases throughout the study period (up to Month 24) regardless of causal relationship to vaccination and intensity.
- Outcome of all pregnancies throughout the study period (up to Month 24, even if delivery occurs after the end of study period).
- Hematological, biochemical and urine laboratory results from blood and urine samples taken from all subjects at Month 0 and Month 7.

***Medically significant conditions were defined as adverse events (AEs) prompting emergency room or physician visits that are not (1) related to common diseases or (2) routine visits for physical examination or vaccination, or SAEs that are not related to common diseases. Common diseases include: upper respiratory infections, sinusitis, pharyngitis, gastroenteritis, urinary tract infections, cervicovaginal yeast infections, menstrual cycle abnormalities and injury.*

Statistical Methods:

The analyses were performed on the Total Vaccinated Cohort, According-to- Protocol (ATP) for efficacy, and the ATP cohort for immunogenicity.

- The Total Vaccinated Cohort included all vaccinated subjects for whom data were available
- The ATP cohort for efficacy included all evaluable subjects (i.e. those meeting all eligibility criteria, complying with the procedures defined in the protocol, with no elimination violations) with efficacy data available, who had a normal or low-grade cytology (negative or ASC-US or LSIL) at Month 0 and had received 3 doses of the vaccine (study vaccine or control vaccine).
- The ATP cohort for immunogenicity included all evaluable subjects (i.e. those meeting all eligibility criteria, complying with the procedures and intervals adapted from the protocol, with no elimination criteria during the study) with immunogenicity data available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen after vaccination. Subjects who acquired either HPV-16 or HPV-18 infection during the study were excluded from the ATP cohort for immunogenicity.

Analysis of efficacy

The analysis was performed on the ATP cohort for efficacy.

The vaccine efficacy (VE) for all outcome variables was estimated using a conditional exact method. This method computed an exact confidence interval (CI) around the rate ratio (ratio of the event rates in the vaccinated versus control group) and took the follow-up time of the subjects within each group into account. VE is defined as 1 minus the rate ratio. Statistical significance is defined as the lower limit of the 99% CI above 0% (alpha of 1%). In addition, P-values were calculated using the Fisher's exact test to compare the attack rates between both groups.

Vaccine efficacy was calculated as follows:

$VE=1-[(n_1/T_1) / (n_2/T_2)]$

where

$n_{1=}$ number of subjects reporting at least one event in the HPV Group,

$n_{2=}$ number of subjects reporting at least one event in the HAV Group,

T_1 (years) = sum of follow-up period (censored at the first occurrence of an event) expressed in years in HPV Group

T_2 (years) = sum of follow-up period (censored at the first occurrence of an event) expressed in years in HAV Group

VE(%) = vaccine efficacy

Analysis of immunogenicity

The analysis was performed on the ATP cohort for immunogenicity.

For each treatment group, at each time point for which a serological result was available: GMTs with 95% CI, SCR and seropositivity rates with exact 95% CI for anti-HPV-16 and anti-HPV-18 were calculated.

A seronegative subject was a subject whose titer is below the cut-off value. Seroconversion is defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the sera of subjects seronegative before vaccination.

Analysis of safety

The analysis was performed on the Total Vaccinated Cohort.

The percentage of subjects reporting each individual solicited local and general symptom within 7 days (Days 0 – 6) during the solicited follow-up period was tabulated with exact 95% CI. The same tabulation was performed for Grade 3 symptoms and for general symptoms assessed by the investigators as related to vaccination. The proportion of subjects with at least one report of unsolicited AE classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred terms and reported up to 30 days (Day 0 -29) after vaccination was tabulated with exact 95% CI. The same tabulation was performed for Grade 3 unsolicited AEs and for unsolicited AEs assessed by the investigators as related to vaccination. The proportion of subjects with at least one report of NOCD and medically significant AE classified by MedDRA, whenever available, and reported during the entire study period was tabulated with exact 95% CI. The percentage of subjects with abnormal laboratory findings (clinical chemistry, hematology, urinary tests) was calculated at Month 0 and Month 7. SAEs reported during the entire study period were tabulated by MedDRA preferred terms.

Study Population: Healthy Japanese women, between and including, 20 to 25 years at the time of first vaccination, with a negative urine pregnancy test were enrolled in the study; if of childbearing potential, subject was abstinent or using adequate contraceptive precautions for 30 days prior to the first vaccination and agreeing to continue such precautions for 2 months after completion of the vaccination series. Subjects were free of obvious health problems as established by medical history and clinical examination before entering into the study. Subjects had to have intact cervix (e.g. no history of cauterization or surgical treatment involving damage to the transformation zone of the cervix). Subjects who had received no previous vaccination against HPV, hepatitis A, had no history of hepatitis A disease or of having had colposcopy to evaluate an abnormal cervical cytology were enrolled. Written informed consent was obtained from the subject prior to enrolment.

Number of Subjects:	**HPV Group**	**HAV Group**
Planned, N	500	500
Randomized, N (Total Vaccinated Cohort)	519	521
Completed up to Month 24, n (%)	442 (85.2)	436 (83.7)
Total Number Subjects Withdrawn, n (%)	77 (14.8)	85 (16.3)
Withdrawn due to Adverse Events n (%)	6 (1.1)	1 (0.2)
Withdrawn due to Lack of Efficacy n (%)	Not applicable	Not applicable
Withdrawn for other reasons n (%)	71 (13.7)	84 (16.1)
Demographics	**HPV Group**	**HAV Group**
N, (Total Vaccinated Cohort)	519	521
Females: Males	519:0	521:0
Mean Age, years (SD)	22.4 (1.7)	22.5 (1.6)
Asian - Japanese heritage, n (%)	519 (100)	521 (100)

Primary Efficacy Results: Incidence rates and vaccine efficacy against persistent infection (6-month definition) with HPV-16 and/or HPV-18 (by PCR) in HPV DNA negative and seronegative subjects at baseline (ATP cohort for efficacy)

Event type	Group	N	n	T(year)	Person-year rate			VE			P-value
					n/T (Per 100)	LL	UL	%	LL	UL	
HPV-16/18	HPV	387	0	559.79	0.00	0.00	0.68	100	71.3	100	<0.0001
	HAV	392	15	559.13	2.68	1.48	4.47	-	-	-	-
HPV-16	HPV	332	0	482.40	0.00	0.00	0.79	100	58.4	100	0.0009
	HAV	340	11	486.99	2.26	1.11	4.09	-	-	-	-
HPV-18	HPV	346	0	499.45	0.00	0.00	0.76	100	-12.7	100	0.0301
	HAV	343	5	495.52	1.01	0.32	2.39	-	-	-	-

N=number of subjects included in each group
Subjects have at least 5 months of follow-up after Month 12
For single type: Subjects DNA negative at Month 0 and Month 6 and seronegative at Month 0 for the corresponding HPV type
For combined types: Subjects DNA negative at Month 0 and Month 6 and seronegative at Month 0 for at least one HPV type
n=number of subjects reporting at least one event in each group
Subjects with an event are DNA negative at Month 0 and Month 6 and seronegative at Month 0 for the corresponding HPV type
T(years)=sum of follow-up period (censored at the first occurrence of an event) expressed in years in each group
Follow-up period starts at day after Dose 3
n/T=Incidence rate of subjects reporting at least one event
VE(%)=Vaccine Efficacy (conditional exact method)
LL,UL=95.5% Lower and Upper confidence limits
P-value=Two-sided Fisher Exact test

Secondary Outcome Variable(s): Incidence rates and vaccine efficacy against incident infection with HPV-16 and/or HPV-18 (by PCR) in HPV DNA negative and seronegative subjects at baseline (ATP cohort for efficacy)

Event Type	Group	N	n	T(year)	Person-year rate			VE		
					n/T (Per 100)	LL	UL	%	LL	UL
HPV-16/18	HPV	408	7	572.86	1.22	0.48	2.55	82.5	59.8	93.6
	HAV	406	39	558.66	6.98	4.92	9.60	-	-	-
HPV-16	HPV	351	4	496.20	0.81	0.21	2.10	82.0	45.8	95.6
	HAV	353	22	492.54	4.47	2.77	6.82	-	-	-
HPV-18	HPV	359	3	507.54	0.59	0.12	1.76	83.7	42.9	97.1
	HAV	355	18	496.94	3.62	2.12	5.78	-	-	-

N = number of subjects included in each group
For single type: Subjects DNA negative at Month 0 and Month 6 and seronegative at Month 0 for the corresponding HPV type
For combined types: Subjects DNA negative at Month 0 and Month 6 and seronegative at Month 0 for at least one HPV type
n = number of subjects reporting at least one event in each group
Subjects with an event are DNA negative at Month 0 and Month 6 and seronegative at Month 0 for the corresponding HPV type
T(years) = sum of follow-up period (censored at the first occurrence of an event) expressed in years in each group
Follow-up period starts at day after Dose 3
n/T = Incidence rate of subjects reporting at least one event
VE(%) = Vaccine Efficacy (conditional exact method)
LL,UL = 95.5% Lower and Upper confidence limits

Secondary Outcome Variable(s): Incidence rates and vaccine efficacy against cytological abnormalities (ASC-US+) associated with HPV-16 and/or HPV-18 (by PCR) in HPV DNA negative and seronegative subjects at baseline (ATP cohort for efficacy)

Event Type	Group	N	n	T(year)	Person-year rate			VE		
					n/T (Per 100)	LL	UL	%	LL	UL
HPV-16/18	HPV	408	1	568.64	0.18	0.00	1.00	91.7	42.1	99.8
	HAV	406	12	569.10	2.11	1.07	3.72	-	-	-
HPV-16	HPV	351	0	493.61	0.00	0.00	0.77	100	39.3	100
	HAV	353	8	493.43	1.62	0.69	3.23	-	-	-
HPV-18	HPV	359	1	501.17	0.20	0.00	1.14	75.0	-162.4	99.5
	HAV	355	4	500.34	0.80	0.21	2.08	-	-	-

N = number of subjects included in each group
For single type: Subjects DNA negative at Month 0 and Month 6 and seronegative at Month 0 for the corresponding HPV type
For combined types: Subjects DNA negative at Month 0 and Month 6 and seronegative at Month 0 for at least one HPV type
n = number of subjects reporting at least one event in each group
Subjects with an event are DNA negative at Month 0 and Month 6 and seronegative at Month 0 for the corresponding HPV type
T(years)=sum of follow-up period (censored at the first occurrence of an event) expressed in years in each group
Follow-up period starts at day after Dose 3
n/T = Incidence rate of subjects reporting at least one event

VE(%) = Vaccine Efficacy (conditional exact method)
LL,UL = 95.5% Lower and Upper confidence limits
ASC-US+ = ASC-US, LSIL, HSIL, ASC-H (cannot exclude HSIL) and AGC (Atypical Glandular Cells)

Secondary Outcome Variable(s): Incidence rates and vaccine efficacy against CIN1+ associated with HPV-16 and/or HPV-18 (by PCR) in HPV DNA negative and seronegative subjects at baseline (ATP cohort for efficacy)

Event Type	Group	N	n	T(year)	Person-year rate			VE		
					n/T (Per 100)	LL	UL	%	LL	UL
HPV-16/18	HPV	408	0	573.30	0.00	0.00	0.66	100	-156.8	100
	HAV	407	3	579.16	0.52	0.10	1.54	-	-	-
HPV-16	HPV	351	0	495.92	0.00	0.00	0.77	100	-472.2	100
	HAV	353	2	500.76	0.40	0.05	1.47	-	-	-
HPV-18	HPV	359	0	505.76	0.00	0.00	0.75	100	-4244.5	100
	HAV	356	1	505.77	0.20	0.00	1.13	-	-	-

N=number of subjects included in each group
For single type: Subjects DNA negative at Month 0 and Month 6 and seronegative at Month 0 for the corresponding HPV type
For combined types: Subjects DNA negative at Month 0 and Month 6 and seronegative at Month 0 for at least one HPV type
n = number of subjects reporting at least one event in each group
Subjects with an event are DNA negative at Month 0 and Month 6 and seronegative at Month 0 for the corresponding HPV type
T(years) = sum of follow-up period (censored at the first occurrence of an event) expressed in years in each group
Follow-up period starts at day after Dose 3
n/T = Incidence rate of subjects reporting at least one event
VE(%) = Vaccine Efficacy (conditional exact method)
LL,UL = 95.5% Lower and Upper confidence limits

Secondary Outcome Variable(s): Incidence rates and vaccine efficacy against incident infection with any oncogenic HPV type (by PCR) in HPV DNA negative subjects at baseline (ATP cohort for efficacy)

Event Type	Group	N	n	T(year)	Person-year rate			VE		
					n/T (Per 100)	LL	UL	%	LL	UL
HPV-16	HPV	419	5	589.89	0.85	0.27	2.01	80.3	46.5	94.3
	HAV	398	24	556.56	4.31	2.73	6.47	-	-	-
HPV-18	HPV	428	4	603.72	0.66	0.17	1.72	81.1	42.5	95.5
	HAV	407	20	570.55	3.51	2.12	5.46	-	-	-
HPV-31	HPV	428	8	599.43	1.33	0.56	2.66	-13.0	-275.4	65.1
	HAV	416	7	592.63	1.18	0.46	2.47	-	-	-
HPV-33	HPV	444	2	627.30	0.32	0.04	1.17	60.4	-150.2	96.4
	HAV	435	5	621.00	0.81	0.25	1.91	-	-	-
HPV-35	HPV	443	7	624.73	1.12	0.44	2.34	-73.1	-735.1	57.2
	HAV	432	4	617.86	0.65	0.17	1.68	-	-	-
HPV-39	HPV	422	13	591.74	2.20	1.15	3.80	6.9	-117.5	60.4
	HAV	418	14	593.57	2.36	1.27	4.00	-	-	-
HPV-45	HPV	446	0	631.83	0.00	0.00	0.60	.	.	.
	HAV	433	0	621.89	0.00	0.00	0.61	-	-	-
HPV-51	HPV	413	14	576.97	2.43	1.31	4.11	51.9	4.7	76.9
	HAV	412	29	574.93	5.04	3.35	7.30	-	-	-
HPV-52	HPV	404	30	557.92	5.38	3.59	7.73	9.8	-55.1	47.7
	HAV	383	32	536.80	5.96	4.04	8.47	-	-	-
HPV-56	HPV	423	15	589.74	2.54	1.40	4.24	0.9	-121.3	55.6
	HAV	414	15	584.58	2.57	1.42	4.27	-	-	-
HPV-58	HPV	432	12	606.42	1.98	1.01	3.49	11.4	-114.5	63.7
	HAV	411	13	582.05	2.23	1.17	3.86	-	-	-
HPV-59	HPV	443	8	622.63	1.28	0.54	2.56	-56.6	-527.2	56.0
	HAV	427	5	609.41	0.82	0.26	1.94	-	-	-

HPV-66	HPV	426	6	599.14	1.00	0.36	2.21	55.3	-28.6	86.4
	HAV	410	13	580.26	2.24	1.17	3.87	-	-	-
HPV-68	HPV	436	8	613.75	1.30	0.55	2.60	34.7	-77.3	77.4
	HAV	424	12	601.42	2.00	1.01	3.52	-	-	-
HRW-HPV	HPV	446	90	580.69	15.50	12.40	19.13	23.3	-2.8	42.8
	HAV	436	113	559.59	20.19	16.57	24.37	-	-	-
HR-HPV	HPV	446	98	574.64	17.05	13.78	20.87	31.2	9.5	47.8
	HAV	436	134	540.99	24.77	20.67	29.44	-	-	-

N = number of subjects included in each group
For single type: Subjects DNA negative for the corresponding HPV type at Month 0 and Month 6
For combined types: Subjects DNA negative for at least one HPV type at Month 0 and Month 6
n = number of subjects reporting at least one event in each group
Subjects with an event are DNA negative for the corresponding HPV type at Month 0 and Month 6
HR = High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
HRW = High-risk (oncogenic) HPV types without HPV-16 or HPV-18: HPV-31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
T(years) = sum of follow-up period (censored at the first occurrence of an event) expressed in years in each group
Follow-up period starts at day after Dose 3
n/T = Incidence rate of subjects reporting at least one event
VE(%) = Vaccine Efficacy (conditional exact method)
LL,UL = 95.5% Lower and Upper confidence limits

Secondary Outcome Variable(s): Incidence rates and vaccine efficacy against persistent infection (6-month definition) with any oncogenic HPV type (by PCR) in HPV DNA negative subjects at baseline (ATP cohort for efficacy)

Event Type	Group	N	n	T(year)	Person-year rate			VE		
					n/T (Per 100)	LL	UL	%	LL	UL
HPV-16	HPV	398	0	576.23	0.00	0.00	0.66	100	64.5	100
	HAV	384	12	550.53	2.18	1.11	3.85	-	-	-
HPV-18	HPV	408	0	590.20	0.00	0.00	0.64	100	-9.7	100
	HAV	394	5	570.21	0.88	0.28	2.08	-	-	-
HPV-31	HPV	406	4	584.75	0.68	0.18	1.78	-100.5	-2249.1	72.3
	HAV	403	2	586.08	0.34	0.04	1.26	-	-	-
HPV-33	HPV	422	0	610.86	0.00	0.00	0.62	100	-467.6	100
	HAV	421	2	611.89	0.33	0.04	1.20	-	-	-
HPV-35	HPV	422	1	610.34	0.16	0.00	0.93	0.3	-8617.0	98.9
	HAV	418	1	608.84	0.16	0.00	0.94	-	-	-
HPV-39	HPV	401	2	579.43	0.35	0.04	1.27	49.1	-268.5	95.7
	HAV	406	4	589.38	0.68	0.18	1.76	-	-	-
HPV-45	HPV	424	0	613.80	0.00	0.00	0.62	.	.	.
	HAV	419	0	611.35	0.00	0.00	0.62	-	-	-
HPV-51	HPV	395	5	567.26	0.88	0.28	2.09	49.5	-66.0	86.9
	HAV	398	10	573.19	1.74	0.82	3.24	-	-	-
HPV-52	HPV	383	11	547.79	2.01	0.99	3.63	-115.5	-715.4	32.5
	HAV	371	5	536.65	0.93	0.29	2.21	-	-	-
HPV-56	HPV	403	4	579.59	0.69	0.18	1.79	43.0	-130.2	88.2
	HAV	400	7	577.69	1.21	0.48	2.53	-	-	-
HPV-58	HPV	410	4	590.26	0.68	0.18	1.76	51.2	-87.0	89.6
	HAV	399	8	576.42	1.39	0.59	2.77	-	-	-
HPV-59	HPV	422	1	609.92	0.16	0.00	0.93	.	.	97.7
	HAV	413	0	601.94	0.00	0.00	0.63	-	-	-
HPV-66	HPV	404	0	585.08	0.00	0.00	0.65	100	-150.2	100
	HAV	396	3	575.75	0.52	0.10	1.55	-	-	-
HPV-68	HPV	415	2	599.55	0.33	0.04	1.23	-99.0	-12964.3	90.3
	HAV	410	1	596.42	0.17	0.00	0.95	-	-	-
HRW-HPV	HPV	424	27	593.12	4.55	2.97	6.67	31.6	-15.9	60.2
	HAV	422	39	585.90	6.66	4.70	9.16	-	-	-
HR-HPV	HPV	424	27	593.12	4.55	2.97	6.67	50.6	19.3	70.5
	HAV	422	53	574.77	9.22	6.86	12.13	-	-	-

N = number of subjects included in each group
Subjects have at least 5 months of follow-up after Month 12
For single type: Subjects DNA negative for the corresponding HPV type at Month 0 and Month 6
For combined types: Subjects DNA negative for at least one HPV type at Month 0 and Month 6
n = number of subjects reporting at least one event in each group
Subjects with an event are DNA negative for the corresponding HPV type at Month 0 and Month 6
HR = High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
HRW = High-risk (oncogenic) HPV types without HPV-16 or HPV-18: HPV-31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
T(years) = sum of follow-up period (censored at the first occurrence of an event) expressed in years in each group
Follow-up period starts at day after Dose 3
n/T = Incidence rate of subjects reporting at least one event
VE(%) = Vaccine Efficacy (conditional exact method)
LL,UL = 95.5% Lower and Upper confidence limits

Secondary Outcome Variable(s): Incidence rates and vaccine efficacy against cytological abnormalities (ASC-US+) associated with any oncogenic HPV type (by PCR) in HPV DNA negative subjects at baseline using conditional exact method (ATP cohort for efficacy)

Event Type	Group	N	n	T(year)	Person-year rate			VE		
					n/T (Per 100)	LL	UL	%	LL	UL
HPV-16	HPV	419	0	586.26	0.00	0.00	0.65	100	50.1	100
	HAV	398	9	558.40	1.61	0.72	3.10	-	-	-
HPV-18	HPV	428	1	596.97	0.17	0.00	0.95	75.9	-153.1	99.6
	HAV	407	4	575.01	0.70	0.18	1.81	-	-	-
HPV-31	HPV	428	2	595.75	0.34	0.04	1.24	.	.	82.5
	HAV	416	0	589.69	0.00	0.00	0.64	-	-	-
HPV-33	HPV	444	1	619.24	0.16	0.00	0.92	50.4	-912.4	99.2
	HAV	435	2	614.74	0.33	0.04	1.20	-	-	-
HPV-35	HPV	443	2	619.55	0.32	0.04	1.19	-97.6	-12876.8	90.3
	HAV	432	1	612.19	0.16	0.00	0.93	-	-	-
HPV-39	HPV	422	3	589.54	0.51	0.10	1.51	39.8	-219.7	91.1
	HAV	418	5	591.47	0.85	0.27	2.00	-	-	-
HPV-45	HPV	446	0	623.27	0.00	0.00	0.61	.	.	.
	HAV	433	0	614.20	0.00	0.00	0.62	-	-	-
HPV-51	HPV	413	4	576.37	0.69	0.18	1.80	19.2	-287.6	84.5
	HAV	412	5	582.10	0.86	0.27	2.03	-	-	-
HPV-52	HPV	404	6	562.35	1.07	0.38	2.35	17.6	-193.8	77.8
	HAV	383	7	540.37	1.30	0.51	2.70	-	-	-
HPV-56	HPV	423	5	589.53	0.85	0.27	2.01	17.4	-234.2	80.7
	HAV	414	6	584.23	1.03	0.37	2.27	-	-	-
HPV-58	HPV	432	4	600.64	0.67	0.18	1.73	61.3	-37.6	91.4
	HAV	411	10	581.86	1.72	0.81	3.20	-	-	-
HPV-59	HPV	443	3	617.75	0.49	0.10	1.44	2.4	-661.7	87.5
	HAV	427	3	603.22	0.50	0.10	1.48	-	-	-
HPV-66	HPV	426	1	595.05	0.17	0.00	0.96	67.5	-323.8	99.4
	HAV	410	3	580.12	0.52	0.10	1.54	-	-	-
HPV-68	HPV	436	3	608.68	0.49	0.10	1.47	41.1	-213.0	91.2
	HAV	424	5	597.89	0.84	0.26	1.98	-	-	-
HRW-HPV	HPV	446	23	615.43	3.74	2.34	5.65	35.3	-14.1	63.9
	HAV	436	35	606.44	5.77	3.99	8.08	-	-	-
HR-HPV	HPV	446	24	614.19	3.91	2.48	5.86	43.9	4.2	67.9
	HAV	436	42	602.98	6.97	4.98	9.47	-	-	-

N = number of subjects included in each group
For single type: Subjects DNA negative for the corresponding HPV type at Month 0 and Month 6
For combined types: Subjects DNA negative for at least one HPV type at Month 0 and Month 6
n = number of subjects reporting at least one event in each group
Subjects with an event are DNA negative for the corresponding HPV type at Month 0 and Month 6
HR = High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
HRW = High-risk (oncogenic) HPV types without HPV-16 or HPV-18: HPV-31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

T(years) = sum of follow-up period (censored at the first occurrence of an event) expressed in years in each group
Follow-up period starts at day after Dose 3
n/T = Incidence rate of subjects reporting at least one event
VE(%) = Vaccine Efficacy (conditional exact method)
LL,UL = 95.5% Lower and Upper confidence limits
ASC-US+ = ASC-US, LSIL, HSIL, ASC-H and AGC

Secondary Outcome Variable(s): Incidence rates and vaccine efficacy against CIN1+ associated with any oncogenic HPV type (by PCR) in HPV DNA negative subjects at baseline using conditional exact method (ATP cohort for efficacy)

Event Type	Group	N	n	T(year)	Person-year rate			VE		
					n/T (Per 100)	LL	UL	%	LL	UL
HPV-16	HPV	419	0	589.82	0.00	0.00	0.64	100	-144.6	100
	HAV	400	3	567.49	0.53	0.10	1.57	-	-	-
HPV-18	HPV	428	0	602.29	0.00	0.00	0.63	100	-4096.4	100
	HAV	409	1	581.75	0.17	0.00	0.98	-	-	-
HPV-31	HPV	428	0	600.28	0.00	0.00	0.63	.	.	.
	HAV	417	0	595.25	0.00	0.00	0.64	-	-	-
HPV-33	HPV	444	0	624.39	0.00	0.00	0.61	100	-4237.4	100
	HAV	437	1	623.38	0.16	0.00	0.91	-	-	-
HPV-35	HPV	443	0	624.09	0.00	0.00	0.61	.	.	.
	HAV	434	0	619.72	0.00	0.00	0.61	-	-	-
HPV-39	HPV	422	0	595.19	0.00	0.00	0.64	100	-4270.8	100
	HAV	419	1	598.80	0.17	0.00	0.95	-	-	-
HPV-45	HPV	446	0	627.34	0.00	0.00	0.60	.	.	.
	HAV	435	0	620.95	0.00	0.00	0.61	-	-	-
HPV-51	HPV	413	2	580.33	0.34	0.04	1.27	-1.5	-1385.5	93.1
	HAV	413	2	589.04	0.34	0.04	1.25	-	-	-
HPV-52	HPV	404	3	568.12	0.53	0.10	1.57	42.3	-206.6	91.4
	HAV	385	5	546.64	0.91	0.29	2.17	-	-	-
HPV-56	HPV	423	0	594.47	0.00	0.00	0.64	.	.	.
	HAV	415	0	591.96	0.00	0.00	0.64	-	-	-
HPV-58	HPV	432	1	606.13	0.16	0.00	0.94	80.6	-80.1	99.6
	HAV	413	5	589.30	0.85	0.27	2.01	-	-	-
HPV-59	HPV	443	0	622.81	0.00	0.00	0.61	100	-4163.8	100
	HAV	429	1	611.26	0.16	0.00	0.93	-	-	-
HPV-66	HPV	426	0	599.02	0.00	0.00	0.63	.	.	.
	HAV	412	0	585.04	0.00	0.00	0.65	-	-	-
HPV-68	HPV	436	0	613.60	0.00	0.00	0.62	100	-459.5	100
	HAV	425	2	605.81	0.33	0.04	1.22	-	-	-
HRW-HPV	HPV	446	6	625.89	0.96	0.34	2.12	57.4	-20.5	86.9
	HAV	438	14	622.90	2.25	1.21	3.81	-	-	-
HR-HPV	HPV	446	6	625.89	0.96	0.34	2.12	64.9	4.9	89.0
	HAV	438	17	622.44	2.73	1.57	4.41	-	-	-

N = number of subjects included in each group
For single type: Subjects DNA negative for the corresponding HPV type at Month 0 and Month 6
For combined types: Subjects DNA negative for at least one HPV type at Month 0 and Month 6
n = number of subjects reporting at least one event in each group
Subjects with an event are DNA negative for the corresponding HPV type at Month 0 and Month 6
HR = High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
HRW = High-risk (oncogenic) HPV types without HPV-16 or HPV-18: HPV-31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
T(years) = sum of follow-up period (censored at the first occurrence of an event) expressed in years in each group
Follow-up period starts at day after Dose 3
n/T = Incidence rate of subjects reporting at least one event
VE(%) = Vaccine Efficacy (conditional exact method)
LL,UL = 95.5% Lower and Upper confidence limits

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HPV-16 VLP IgG antibodies by pre-vaccination status (ATP cohort for immunogenicity)

Antibody	Group	Pre-vacc	Timing	N	≥ 8 EL.U/mL	GMT (EL.U/mL)

		status			n	%	95% CI		Value	95% CI	
							LL	UL		LL	UL
HPV-16 VLP IgG	HPV	S-	PRE	347	0	0.0	0.0	1.1	4.0	4.0	4.0
			PII(M6)	347	347	100	98.9	100	639.2	585.6	697.8
			PIII(M7)	346	346	100	98.9	100	7770.3	7100.9	8502.8
			PIII(M12)	317	317	100	98.8	100	2899.3	2616.9	3212.1
			PIII(M18)	302	302	100	98.8	100	1831.1	1648.2	2034.2
			PIII(M24)	298	298	100	98.8	100	1521.5	1372.1	1687.2
		S+	PRE	64	64	100	94.4	100	30.5	23.8	39.0
			PII(M6)	64	64	100	94.4	100	1236.9	970.1	1577.1
			PIII(M7)	64	64	100	94.4	100	5887.5	4848.6	7149.0
			PIII(M12)	56	56	100	93.6	100	2758.5	2221.7	3425.0
			PIII(M18)	54	54	100	93.4	100	2065.3	1633.8	2610.9
			PIII(M24)	53	53	100	93.3	100	1593.5	1271.4	1997.2
		Total	PRE	411	64	15.6	12.2	19.4	5.5	5.1	5.9
			PII(M6)	411	411	100	99.1	100	708.4	650.1	772.0
			PIII(M7)	410	410	100	99.1	100	7441.0	6854.3	8077.8
			PIII(M12)	373	373	100	99.0	100	2877.7	2623.1	3156.9
			PIII(M18)	356	356	100	99.0	100	1864.8	1694.5	2052.2
			PIII(M24)	351	351	100	99.0	100	1532.2	1395.1	1682.7
	HAV	S-	PRE	342	0	0.0	0.0	1.1	4.0	4.0	4.0
			PII(M6)	342	9	2.6	1.2	4.9	4.2	4.0	4.3
			PIII(M7)	338	6	1.8	0.7	3.8	4.1	4.0	4.3
			PIII(M12)	298	15	5.0	2.8	8.2	4.3	4.1	4.4
			PIII(M18)	272	9	3.3	1.5	6.2	4.2	4.1	4.4
			PIII(M24)	261	10	3.8	1.9	6.9	4.4	4.1	4.6
		S+	PRE	51	51	100	93.0	100	33.5	24.1	46.6
			PII(M6)	51	46	90.2	78.6	96.7	28.6	19.9	41.3
			PIII(M7)	49	46	93.9	83.1	98.7	30.2	21.4	42.6
			PIII(M12)	36	31	86.1	70.5	95.3	33.2	21.5	51.2
			PIII(M18)	35	30	85.7	69.7	95.2	29.7	19.2	46.0
			PIII(M24)	34	28	82.4	65.5	93.2	26.4	16.8	41.4
		Total	PRE	393	51	13.0	9.8	16.7	5.3	4.9	5.7
			PII(M6)	393	55	14.0	10.7	17.8	5.4	4.9	5.8
			PIII(M7)	387	52	13.4	10.2	17.2	5.3	4.9	5.8
			PIII(M12)	334	46	13.8	10.3	17.9	5.3	4.9	5.8
			PIII(M18)	307	39	12.7	9.2	17.0	5.3	4.8	5.8
			PIII(M24)	295	38	12.9	9.3	17.2	5.4	4.9	5.9

N = number of subjects with pre-vaccination results available
n (%)= number (percentage) of subjects with titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
S- = seronegative subjects (antibody concentration < 8 EL.U/mL) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 8 EL.U/mL) prior to vaccination
GMT = geometric mean antibody concentration calculated on all subjects
PRE = pre-vaccination
PII(M6) = post Dose II (Month 6)
PIII(M7) = post Dose III (Month 7)
PIII(M12) = post Dose III (Month 12)
PIII(M18) = post Dose III (Month 18)
PIII(M24) = post Dose III (Month 24)

Secondary Outcome Variable(s): Seropositivity rates and GMTs for HPV-18 VLP IgG antibodies by pre-vaccination status (ATP cohort for immunogenicity)

Antibody	Group	Pre-vacc status	Timing	N	≥ 7 EL.U/mL				GMT (EL.U/mL)		
					n	%	95% CI		Value	95% CI	
							LL	UL		LL	UL

HPV-18 VLP IgG	HPV	S-	PRE	349	0	0.0	0.0	1.1	3.5	3.5	3.5
			PII(M6)	349	349	100	98.9	100	491.3	449.9	536.6
			PIII(M7)	348	348	100	98.9	100	4039.6	3718.3	4388.7
			PIII(M12)	318	318	100	98.8	100	1352.2	1218.4	1500.6
			PIII(M18)	304	304	100	98.8	100	787.4	701.2	884.3
			PIII(M24)	300	300	100	98.8	100	627.4	561.2	701.5
		S+	PRE	61	61	100	94.1	100	18.5	14.2	24.2
			PII(M6)	61	61	100	94.1	100	587.8	463.5	745.6
			PIII(M7)	61	61	100	94.1	100	2706.8	2151.7	3405.0
			PIII(M12)	54	54	100	93.4	100	1210.8	959.0	1528.7
			PIII(M18)	51	51	100	93.0	100	750.5	574.8	980.0
			PIII(M24)	50	50	100	92.9	100	630.1	475.6	834.8
		Total	PRE	410	61	14.9	11.6	18.7	4.5	4.2	4.8
			PII(M6)	410	410	100	99.1	100	504.6	464.6	548.1
			PIII(M7)	409	409	100	99.1	100	3805.4	3515.6	4119.1
			PIII(M12)	372	372	100	99.0	100	1330.7	1210.2	1463.2
			PIII(M18)	355	355	100	99.0	100	782.0	703.4	869.5
			PIII(M24)	350	350	100	99.0	100	627.8	566.3	696.0
	HAV	S-	PRE	342	0	0.0	0.0	1.1	3.5	3.5	3.5
			PII(M6)	340	11	3.2	1.6	5.7	3.6	3.6	3.7
			PIII(M7)	339	13	3.8	2.1	6.5	3.7	3.6	3.8
			PIII(M12)	290	20	6.9	4.3	10.5	3.8	3.7	4.0
			PIII(M18)	266	12	4.5	2.4	7.7	3.7	3.6	3.8
			PIII(M24)	255	15	5.9	3.3	9.5	3.8	3.6	4.0
		S+	PRE	48	48	100	92.6	100	21.8	15.7	30.1
			PII(M6)	48	42	87.5	74.8	95.3	17.4	12.3	24.5
			PIII(M7)	46	41	89.1	76.4	96.4	19.4	13.9	27.2
			PIII(M12)	39	35	89.7	75.8	97.1	15.2	10.9	21.2
			PIII(M18)	36	28	77.8	60.8	89.9	14.7	9.9	21.7
			PIII(M24)	33	23	69.7	51.3	84.4	13.2	8.4	20.6
		Total	PRE	390	48	12.3	9.2	16.0	4.4	4.1	4.7
			PII(M6)	388	53	13.7	10.4	17.5	4.4	4.1	4.7
			PIII(M7)	385	54	14.0	10.7	17.9	4.5	4.2	4.8
			PIII(M12)	329	55	16.7	12.8	21.2	4.5	4.2	4.8
			PIII(M18)	302	40	13.2	9.6	17.6	4.4	4.1	4.7
			PIII(M24)	288	38	13.2	9.5	17.7	4.4	4.1	4.8

N = number of subjects with pre-vaccination results available
n (%)= number (percentage) of subjects with titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
S- = seronegative subjects (antibody concentration < 7 El.U/mL) prior to vaccination
S+ = seropositive subjects (antibody concentration ≥ 7 El.U/mL) prior to vaccination
GMT = geometric mean antibody concentration calculated on all subjects
PRE = pre-vaccination
PII(M6) = post Dose II (Month 6)
PIII(M7) = post Dose III (Month 7)
PIII(M12) = post Dose III (Month 12)
PIII(M18) = post Dose III (Month 18)
PIII(M24) = post Dose III (Month 24)

Secondary Outcome Variable(s): Number and percentage of subjects outside the normal ranges for hematological parameters (Total Vaccinated Cohort)

Parameter	**Pre-vaccination**	**Timing**	**Parameters or Categories**	**HPV Group N = 519**		**HAV Group N = 521**	
				n	**%**	**n**	**%**
Hemoglobin	**Normal**	PIII(M7)	Normal	436	87.4	437	87.8
			Below	6	1.2	8	1.6
			Above	7	1.4	6	1.2

			Unknown	50	10.0	47	9.4
	Below	PIII(M7)	Normal	11	61.1	6	28.6
			Below	6	33.3	14	66.7
			Above	0	0.0	0	0.0
			Unknown	1	5.6	1	4.8
	Above	PIII(M7)	Normal	0	0.0	1	50.0
			Below	0	0.0	0	0.0
			Above	0	0.0	1	50.0
			Unknown	1	100	0	0.0
	Unknown	PIII(M7)	Normal	1	100	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	PIII(M7)	Normal	448	86.3	444	85.2
			Below	12	2.3	22	4.2
			Above	7	1.3	7	1.3
			Unknown	52	10.0	48	9.2
Hematocrit	**Normal**	PIII(M7)	Normal	437	87.2	447	88.3
			Below	4	0.8	9	1.8
			Above	9	1.8	3	0.6
			Unknown	51	10.2	47	9.3
	Below	PIII(M7)	Normal	9	64.3	6	60.0
			Below	4	28.6	4	40.0
			Above	0	0.0	0	0.0
			Unknown	1	7.1	0	0.0
	Above	PIII(M7)	Normal	1	33.3	3	60.0
			Below	0	0.0	0	0.0
			Above	2	66.7	1	20.0
			Unknown	0	0.0	1	20.0
	Unknown	PIII(M7)	Normal	1	100	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	PIII(M7)	Normal	448	86.3	456	87.5
			Below	8	1.5	13	2.5
			Above	11	2.1	4	0.8
			Unknown	52	10.0	48	9.2
Mean Corpuscular Hemoglobin	**Normal**	PIII(M7)	Normal	431	88.1	435	88.6
			Below	9	1.8	10	2.0
			Above	0	0.0	0	0.0
			Unknown	49	10.0	46	9.4
	Below	PIII(M7)	Normal	9	31.0	4	13.3
			Below	17	58.6	24	80.0
			Above	0	0.0	0	0.0
			Unknown	3	10.3	2	6.7
	Unknown	PIII(M7)	Normal	1	100	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	PIII(M7)	Normal	441	85.0	439	84.3
			Below	26	5.0	34	6.5
			Above	0	0.0	0	0.0
			Unknown	52	10.0	48	9.2
Mean Corpuscular	**Normal**	PIII(M7)	Normal	432	87.3	424	86.9
			Below	12	2.4	18	3.7

Hemoglobin Concentration			Above	0	0.0	0	0.0
			Unknown	51	10.3	46	9.4
	Below	PIII(M7)	Normal	9	39.1	10	30.3
			Below	13	56.5	21	63.6
			Above	0	0.0	0	0.0
			Unknown	1	4.3	2	6.1
	Unknown	PIII(M7)	Normal	1	100	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	PIII(M7)	Normal	442	85.2	434	83.3
			Below	25	4.8	39	7.5
			Above	0	0.0	0	0.0
			Unknown	52	10.0	48	9.2
Mean Corpuscular Volume	**Normal**	PIII(M7)	Normal	449	89.1	455	90.1
			Below	2	0.4	2	0.4
			Above	2	0.4	1	0.2
			Unknown	51	10.1	47	9.3
	Below	PIII(M7)	Normal	6	46.2	1	6.3
			Below	6	46.2	14	87.5
			Above	0	0.0	0	0.0
			Unknown	1	7.7	1	6.3
	Above	PIII(M7)	Normal	1	100	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Unknown	PIII(M7)	Normal	1	100	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	PIII(M7)	Normal	457	88.1	456	87.5
			Below	8	1.5	16	3.1
			Above	2	0.4	1	0.2
			Unknown	52	10.0	48	9.2
Platelet Count	**Normal**	PIII(M7)	Normal	447	88.7	458	89.1
			Below	1	0.2	1	0.2
			Above	4	0.8	7	1.4
			Unknown	52	10.3	48	9.3
	Below	PIII(M7)	Normal	0	-	1	50.0
			Below	0	-	1	50.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Above	PIII(M7)	Normal	8	61.5	2	40.0
			Below	0	0.0	0	0.0
			Above	5	38.5	3	60.0
			Unknown	0	0.0	0	0.0
	Unknown	PIII(M7)	Normal	1	50.0	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	1	50.0	0	-
	Overall total	PIII(M7)	Normal	456	87.9	461	88.5
			Below	1	0.2	2	0.4
			Above	9	1.7	10	1.9
			Unknown	53	10.2	48	9.2
Red Blood Cell	**Normal**	PIII(M7)	Normal	454	88.3	459	89.1

Count			Below	4	0.8	5	1.0
			Above	4	0.8	4	0.8
			Unknown	52	10.1	47	9.1
	Below	PIII(M7)	Normal	2	100	2	100
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Above	PIII(M7)	Normal	0	0.0	2	50.0
			Below	0	0.0	0	0.0
			Above	2	100	1	25.0
			Unknown	0	0.0	1	25.0
	Unknown	PIII(M7)	Normal	1	100	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	PIII(M7)	Normal	457	88.1	463	88.9
			Below	4	0.8	5	1.0
			Above	6	1.2	5	1.0
			Unknown	52	10.0	48	9.2
White Blood Cell count	**Normal**	PIII(M7)	Normal	422	85.1	435	87.2
			Below	3	0.6	3	0.6
			Above	22	4.4	14	2.8
			Unknown	49	9.9	47	9.4
	Below	PIII(M7)	Normal	9	90.0	7	87.5
			Below	1	10.0	1	12.5
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Above	PIII(M7)	Normal	8	66.7	11	78.6
			Below	0	0.0	0	0.0
			Above	1	8.3	2	14.3
			Unknown	3	25.0	1	7.1
	Unknown	PIII(M7)	Normal	1	100	0	-
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	PIII(M7)	Normal	440	84.8	453	86.9
			Below	4	0.8	4	0.8
			Above	23	4.4	16	3.1
			Unknown	52	10.0	48	9.2

N = number of subjects
n = number of subjects in a given category
% = n / Number of subjects with available results x 100
PIII(M7) = post Dose III (Month 7)

Secondary Outcome Variable(s): Number and percentage of subjects outside the normal ranges for biochemical parameters (Total Vaccinated Cohort)

Parameter	**Pre-vaccination**	**Timing**	**Parameters or Categories**	**HPV Group N = 519**		**HAV Group N = 521**	
				n	**%**	**n**	**%**
Albumin	**Normal**	PIII(M7)	Normal	466	89.8	472	90.6
			Below	1	0.2	2	0.4
			Above	0	0.0	0	0.0
			Unknown	52	10.0	47	9.0
	Overall total	Overall total	Normal	466	89.8	472	90.6
			Below	1	0.2	2	0.4
			Above	0	0.0	0	0.0

			Unknown	52	10.0	47	9.0
Albumin/Globulin ratio	**Normal**	PIII(M7)	Normal	405	83.9	423	86.7
			Below	8	1.7	9	1.8
			Above	18	3.7	10	2.0
			Unknown	52	10.8	46	9.4
	Below	PIII(M7)	Normal	8	50.0	9	69.2
			Below	8	50.0	3	23.1
			Above	0	0.0	0	0.0
			Unknown	0	0.0	1	7.7
	Above	PIII(M7)	Normal	8	40.0	11	55.0
			Below	0	0.0	0	0.0
			Above	12	60.0	9	45.0
			Unknown	0	0.0	0	0.0
	Overall total	Overall total	Normal	421	81.1	443	85.0
			Below	16	3.1	12	2.3
			Above	30	5.8	19	3.6
			Unknown	52	10.0	47	9.0
Alkaline Phosphatase	**Normal**	PIII(M7)	Normal	443	88.6	439	88.3
			Below	3	0.6	10	2.0
			Above	3	0.6	3	0.6
			Unknown	51	10.2	45	9.1
	Below	PIII(M7)	Normal	7	43.8	11	55.0
			Below	9	56.3	8	40.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	1	5.0
	Above	PIII(M7)	Normal	1	33.3	3	75.0
			Below	0	0.0	0	0.0
			Above	1	33.3	0	0.0
			Unknown	1	33.3	1	25.0
	Overall total	Overall total	Normal	451	86.9	453	86.9
			Below	12	2.3	18	3.5
			Above	4	0.8	3	0.6
			Unknown	52	10.0	47	9.0
Alanine amino-transferase	**Normal**	PIII(M7)	Normal	452	88.6	468	90.3
			Below	0	0.0	0	0.0
			Above	7	1.4	3	0.6
			Unknown	51	10.0	47	9.1
	Below	PIII(M7)	Normal	0	0.0	0	0.0
			Below	1	100	0	-
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Above	PIII(M7)	Normal	5	62.5	3	100
			Below	0	0.0	0	0.0
			Above	2	25.0	0	0.0
			Unknown	1	12.5	0	0.0
	Overall total	PIII(M7)	Normal	457	88.1	471	90.4
			Below	1	0.2	0	0.0
			Above	9	1.7	3	0.6
			Unknown	52	10.0	47	9.0
Aspartate Aminotransferase	**Normal**	PIII(M7)	Normal	461	89.3	472	90.8
			Below	0	0.0	2	0.4
			Above	3	0.6	0	0.0
			Unknown	52	10.1	46	8.8
	Above	PIII(M7)	Normal	3	100	0	0.0
			Below	0	0.0	0	0.0

			Above	0	0.0	0	0.0
			Unknown	0	0.0	1	100
	Overall total	Overall total	Normal	464	89.4	472	90.6
			Below	0	0.0	2	0.4
			Above	3	0.6	0	0.0
			Unknown	52	10.0	47	9.0
Blood Urea Nitrogen	**Normal**	PIII(M7)	Normal	374	83.1	399	85.6
			Below	32	7.1	27	5.8
			Above	1	0.2	1	0.2
			Unknown	43	9.6	39	8.4
	Below	PIII(M7)	Normal	38	61.3	32	61.5
			Below	15	24.2	12	23.1
			Above	0	0.0	0	0.0
			Unknown	9	14.5	8	15.4
	Above	PIII(M7)	Normal	5	71.4	3	100
			Below	0	0.0	0	0.0
			Above	2	28.6	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	Overall total	Normal	417	80.3	434	83.3
			Below	47	9.1	39	7.5
			Above	3	0.6	1	0.2
			Unknown	52	10.0	47	9.0
Calcium	**Normal**	PIII(M7)	Normal	459	89.0	467	90.0
			Below	3	0.6	2	0.4
			Above	3	0.6	4	0.8
			Unknown	51	9.9	46	8.9
	Above	PIII(M7)	Normal	2	66.7	1	50.0
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	1	33.3	1	50.0
	Overall total	Overall total	Normal	461	88.8	468	89.8
			Below	3	0.6	2	0.4
			Above	3	0.6	4	0.8
			Unknown	52	10.0	47	9.0
Total Cholesterol	**Normal**	PIII(M7)	Normal	312	76.7	307	76.4
			Below	37	9.1	37	9.2
			Above	17	4.2	18	4.5
			Unknown	41	10.1	40	10.0
	Below	PIII(M7)	Normal	27	38.6	43	50.6
			Below	39	55.7	34	40.0
			Above	0	0.0	2	2.4
			Unknown	4	5.7	6	7.1
	Above	PIII(M7)	Normal	16	38.1	17	50.0
			Below	0	0.0	0	0.0
			Above	19	45.2	16	47.1
			Unknown	7	16.7	1	2.9
	Overall total	Overall total	Normal	355	68.4	367	70.4
			Below	76	14.6	71	13.6
			Above	36	6.9	36	6.9
			Unknown	52	10.0	47	9.0
Chlorine	**Normal**	PIII(M7)	Normal	465	89.8	470	90.7
			Below	1	0.2	2	0.4
			Above	0	0.0	0	0.0
			Unknown	52	10.0	46	8.9

	Below	PIII(M7)	Normal	1	100	2	100
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Above	PIII(M7)	Normal	0	0.0	0	0.0
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	-	1	100
	Overall total	Overall total	Normal	466	89.8	472	90.6
			Below	1	0.2	2	0.4
			Above	0	0.0	0	0.0
			Unknown	52	10.0	47	9.0
Creatine Phosphokinase	**Normal**	PIII(M7)	Normal	378	82.9	386	85.0
			Below	23	5.0	23	5.1
			Above	7	1.5	4	0.9
			Unknown	48	10.5	41	9.0
	Below	PIII(M7)	Normal	23	46.0	26	48.1
			Below	22	44.0	24	44.4
			Above	1	2.0	0	0.0
			Unknown	4	8.0	4	7.4
	Above	PIII(M7)	Normal	11	84.6	8	61.5
			Below	0	0.0	0	0.0
			Above	2	15.4	3	23.1
			Unknown	0	0.0	2	15.4
	Overall total	Overall total	Normal	412	79.4	420	80.6
			Below	45	8.7	47	9.0
			Above	10	1.9	7	1.3
			Unknown	52	10.0	47	9.0
Creatinine	**Normal**	PIII(M7)	Normal	449	88.0	460	90.4
			Below	8	1.6	3	0.6
			Above	2	0.4	2	0.4
			Unknown	51	10.0	44	8.6
	Below	PIII(M7)	Normal	3	42.9	4	50.0
			Below	3	42.9	3	37.5
			Above	0	0.0	0	0.0
			Unknown	1	14.3	1	12.5
	Above	PIII(M7)	Normal	1	50.0	2	50.0
			Below	0	0.0	0	0.0
			Above	1	50.0	0	0.0
			Unknown	0	0.0	2	50.0
	Overall total	Overall total	Normal	453	87.3	466	89.4
			Below	11	2.1	6	1.2
			Above	3	0.6	2	0.4
			Unknown	52	10.0	47	9.0
C reactive protein	**Normal**	PIII(M7)	Normal	55	51.9	37	52.9
			Below	0	0.0	0	0.0
			Above	8	7.5	2	2.9
			Unknown	43	40.6	31	44.3
	Above	PIII(M7)	Normal	6	50.0	2	18.2
			Below	0	0.0	0	0.0
			Above	2	16.7	1	9.1
			Unknown	4	33.3	8	72.7
	Unknown	PIII(M7)	Normal	65	16.2	57	13.0
			Below	0	0.0	0	0.0

			Above	10	2.5	13	3.0
			Unknown	326	81.3	370	84.1
	Overall total	Overall total	Normal	126	24.3	96	18.4
			Below	0	0.0	0	0.0
			Above	20	3.9	16	3.1
			Unknown	373	71.9	409	78.5
Direct Bilirubin	**Normal**	PIII(M7)	Normal	446	89.2	444	89.9
			Below	0	0.0	0	0.0
			Above	4	0.8	6	1.2
			Unknown	50	10.0	44	8.9
	Above	PIII(M7)	Normal	11	57.9	14	51.9
			Below	0	0.0	0	0.0
			Above	6	31.6	10	37.0
			Unknown	2	10.5	3	11.1
	Overall total	Overall total	Normal	457	88.1	458	87.9
			Below	0	0.0	0	0.0
			Above	10	1.9	16	3.1
			Unknown	52	10.0	47	9.0
Gamma-glutamyl-transferase	**Normal**	PIII(M7)	Normal	455	89.2	467	90.7
			Below	0	0.0	0	0.0
			Above	4	0.8	1	0.2
			Unknown	51	10.0	47	9.1
	Above	PIII(M7)	Normal	4	44.4	4	66.7
			Below	0	0.0	0	0.0
			Above	4	44.4	2	33.3
			Unknown	1	11.1	0	0.0
	Overall total	Overall total	Normal	459	88.4	471	90.4
			Below	0	0.0	0	0.0
			Above	8	1.5	3	0.6
			Unknown	52	10.0	47	9.0
Glucose	**Normal**	PIII(M7)	Normal	374	79.9	378	81.5
			Below	32	6.8	29	6.3
			Above	13	2.8	17	3.7
			Unknown	49	10.5	40	8.6
	Below	PIII(M7)	Normal	28	68.3	37	78.7
			Below	10	24.4	4	8.5
			Above	1	2.4	1	2.1
			Unknown	2	4.9	5	10.6
	Above	PIII(M7)	Normal	7	70.0	8	72.7
			Below	1	10.0	1	9.1
			Above	1	10.0	0	0.0
			Unknown	1	10.0	2	18.2
	Overall total	Overall total	Normal	409	78.8	423	81.0
			Below	43	8.3	34	6.5
			Above	15	2.9	18	3.4
			Unknown	52	10.0	47	9.0
Potassium	**Normal**	PIII(M7)	Normal	453	89.0	462	90.8
			Below	0	0.0	0	0.0
			Above	4	0.8	2	0.4
			Unknown	52	10.2	45	8.8
	Below	PIII(M7)	Normal	0	-	1	100
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0

	Above	PIII(M7)	Normal	9	90.0	7	63.6
			Below	0	0.0	0	0.0
			Above	1	10.0	2	18.2
			Unknown	0	0.0	2	18.2
	Overall total	Overall total	Normal	462	89.0	470	90.2
			Below	0	0.0	0	0.0
			Above	5	1.0	4	0.8
			Unknown	52	10.0	47	9.0
Leucine Amino Peptidase	**Normal**	PIII(M7)	Normal	455	89.2	461	90.0
			Below	0	0.0	2	0.4
			Above	3	0.6	3	0.6
			Unknown	52	10.2	46	9.0
	Below	PIII(M7)	Normal	2	40.0	0	0.0
			Below	2	40.0	7	87.5
			Above	1	20.0	0	0.0
			Unknown	0	0.0	1	12.5
	Above	PIII(M7)	Normal	3	75.0	1	100
			Below	0	0.0	0	0.0
			Above	1	25.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	Overall total	Normal	460	88.6	462	88.7
			Below	2	0.4	9	1.7
			Above	5	1.0	3	0.6
			Unknown	52	10.0	47	9.0
Lactate dehydrogenase	**Normal**	PIII(M7)	Normal	420	86.4	430	87.6
			Below	14	2.9	17	3.5
			Above	5	1.0	2	0.4
			Unknown	47	9.7	42	8.6
	Below	PIII(M7)	Normal	11	35.5	6	20.7
			Below	15	48.4	18	62.1
			Above	0	0.0	0	0.0
			Unknown	5	16.1	5	17.2
	Above	PIII(M7)	Normal	2	100	1	100
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	0	0.0
	Overall total	Overall total	Normal	433	83.4	437	83.9
			Below	29	5.6	35	6.7
			Above	5	1.0	2	0.4
			Unknown	52	10.0	47	9.0
Sodium	**Normal**	PIII(M7)	Normal	466	89.8	474	91.0
			Below	0	0.0	0	0.0
			Above	1	0.2	0	0.0
			Unknown	52	10.0	47	9.0
	Overall total	Overall total	Normal	466	89.8	474	91.0
			Below	0	0.0	0	0.0
			Above	1	0.2	0	0.0
			Unknown	52	10.0	47	9.0
Total Bilirubin	**Normal**	PIII(M7)	Normal	418	88.6	406	87.1
			Below	0	0.0	0	0.0
			Above	8	1.7	17	3.6
			Unknown	46	9.7	43	9.2
	Above	PIII(M7)	Normal	22	46.8	37	67.3
			Below	0	0.0	0	0.0

			Above	19	40.4	14	25.5
			Unknown	6	12.8	4	7.3
	Overall total	Overall total	Normal	440	84.8	443	85.0
			Below	0	0.0	0	0.0
			Above	27	5.2	31	6.0
			Unknown	52	10.0	47	9.0
Triglyceride	**Normal**	PIII(M7)	Normal	203	63.8	216	66.7
			Below	62	19.5	56	17.3
			Above	19	6.0	19	5.9
			Unknown	34	10.7	33	10.2
	Below	PIII(M7)	Normal	59	33.3	60	34.1
			Below	101	57.1	100	56.8
			Above	2	1.1	2	1.1
			Unknown	15	8.5	14	8.0
	Above	PIII(M7)	Normal	13	54.2	14	66.7
			Below	1	4.2	2	9.5
			Above	7	29.2	5	23.8
			Unknown	3	12.5	0	0.0
	Overall total	Overall total	Normal	275	53.0	290	55.7
			Below	164	31.6	158	30.3
			Above	28	5.4	26	5.0
			Unknown	52	10.0	47	9.0
Total Protein	**Normal**	PIII(M7)	Normal	448	87.8	455	89.4
			Below	10	2.0	8	1.6
			Above	1	0.2	2	0.4
			Unknown	51	10.0	44	8.6
	Below	PIII(M7)	Normal	1	33.3	0	0.0
			Below	2	66.7	1	50.0
			Above	0	0.0	0	0.0
			Unknown	0	0.0	1	50.0
	Above	PIII(M7)	Normal	5	83.3	8	80.0
			Below	0	0.0	0	0.0
			Above	0	0.0	0	0.0
			Unknown	1	16.7	2	20.0
	Overall total	Overall total	Normal	454	87.5	463	88.9
			Below	12	2.3	9	1.7
			Above	1	0.2	2	0.4
			Unknown	52	10.0	47	9.0
Uric acid	**Normal**	PIII(M7)	Normal	463	89.9	472	90.8
			Below	0	0.0	0	0.0
			Above	1	0.2	1	0.2
			Unknown	51	9.9	47	9.0
	Above	PIII(M7)	Normal	2	50.0	1	100
			Below	0	0.0	0	0.0
			Above	1	25.0	0	0.0
			Unknown	1	25.0	0	0.0
	Overall total	Overall total	Normal	465	89.6	473	90.8
			Below	0	0.0	0	0.0
			Above	2	0.4	1	0.2
			Unknown	52	10.0	47	9.0
pH	**Normal**	PIII(M7)	Normal	398	85.4	399	86.4
			Below	0	0.0	0	0.0
			Above	21	4.5	21	4.5
			Unknown	47	10.1	42	9.1

Above	PIII(M7)	Normal	40	76.9	43	72.9
		Below	0	0.0	0	0.0
		Above	7	13.5	11	18.6
		Unknown	5	9.6	5	8.5
Unknown	PIII(M7)	Normal	0	0.0	0	0.0
		Below	0	0.0	0	0.0
		Above	0	0.0	0	0.0
		Unknown	1	100	0	-
Overall total	Overall total	Normal	438	84.4	442	84.8
		Below	0	0.0	0	0.0
		Above	28	5.4	32	6.1
		Unknown	53	10.2	47	9.0

N = number of subjects
n = number of subjects in a given category
% = n / Number of subjects with available results x 100
PIII(M7) = post Dose III (Month 7)

Secondary Outcome Variable(s): Urinary tests at Month 0 and Month 7 (Total Vaccinated Cohort)

Parameter	**Group**							
Protein			**Value at Month 0**					**Total**
			(-)	**(+-)**	**(+)**	**2(+)**	**(3+)**	**Unknown**	
	HPV	Frequency	496	10	9	2	1	1	519
		Percent	47.69	0.96	0.87	0.19	0.10	0.10	49.90
		Row Pct	95.57	1.93	1.73	0.39	0.19	0.19	
		Col Pct	50.20	47.62	36.00	66.67	50.00	100	
	HAV	Frequency	492	11	16	1	1	0	521
		Percent	47.31	1.06	1.54	0.10	0.10	0.00	50.10
		Row Pct	94.43	2.11	3.07	0.19	0.19	0.00	
		Col Pct	49.80	52.38	64.00	33.33	50.00	0.00	
	Total	Frequency	988	21	25	3	2	1	1040
		Percent	95.00	2.02	2.40	0.29	0.19	0.10	100
			Value at Month 7					**Total**
			(-)	**(+-)**	**(+)**	**(2+)**	**Unknown**	
	HPV	Frequency	444	10	11	1	53	519
		Percent	42.69	0.96	1.06	0.10	5.10	49.90
		Row Pct	85.55	1.93	2.12	0.19	10.21	
		Col Pct	49.78	47.62	44.00	50.00	53.00	
	HAV	Frequency	448	11	14	1	47	521
		Percent	43.08	1.06	1.35	0.10	4.52	50.10
		Row Pct	85.99	2.11	2.69	0.19	9.02	
		Col Pct	50.22	52.38	56.00	50.00	47.00	
	Total	Frequency	892	21	25	2	100	1040
		Percent	85.77	2.02	2.40	0.19	9.62	100
Glucose			**Value at Month 0**					**Total**
			(-)	**(+-)**	**(2+)**	**(3+)**	**Unknown**	
	HPV	Frequency	513	3	0	2	1	519
		Percent	49.33	0.29	0.00	0.19	0.10	49.90
		Row Pct	98.84	0.58	0.00	0.39	0.19	
		Col Pct	49.66	100	0.00	100	100	
	HAV	Frequency	520	0	1	0	0	521
		Percent	50.00	0.00	0.10	0.00	0.00	50.10
		Row Pct	99.81	0.00	0.19	0.00	0.00	
		Col Pct	50.34	0.00	100	0.00	0.00	
	Total	Frequency	1033	3	1	2	1	1040
		Percent	99.33	0.29	0.10	0.19	0.10	100
			Value at Month 7					**Total**
			(-)	**(+-)**	**(+)**	**(2+)**	**Unknown**	

	HPV	Frequency	459	2	2	3	53	519
		Percent	44.13	0.19	0.19	0.29	5.10	49.90
		Row Pct	88.44	0.39	0.39	0.58	10.21	
		Col Pct	49.35	50.00	66.67	100	53.00	
	HAV	Frequency	471	2	1	0	47	521
		Percent	45.29	0.19	0.10	0.00	4.52	50.10
		Row Pct	90.40	0.38	0.19	0.00	9.02	
		Col Pct	50.65	50.00	33.33	0.00	47.00	
	Total	Frequency	930	4	3	3	100	1040
		Percent	89.42	0.38	0.29	0.29	9.62	100
Urobilinogen			**Value at Month 0**					**Total**
			(+-)	**(+)**	**(2+)**	**(3+)**	**Unknown**	
	HPV	Frequency	506	11	1	0	1	519
		Percent	48.65	1.06	0.10	0.00	0.10	49.90
		Row Pct	97.50	2.12	0.19	0.00	0.19	
		Col Pct	50.20	42.31	33.33	0.00	100	
	HAV	Frequency	502	15	2	2	0	521
		Percent	48.27	1.44	0.19	0.19	0.00	50.10
		Row Pct	96.35	2.88	0.38	0.38	0.00	
		Col Pct	49.80	57.69	66.67	100	0.00	
	Total	Frequency	1008	26	3	2	1	1040
		Percent	96.92	2.50	0.29	0.19	0.10	100
			Value at Month 7					**Total**
			(+-)	**(+)**	**(2+)**	**(3+)**	**Unknown**	
	HPV	Frequency	460	6	0	0	53	519
		Percent	44.23	0.58	0.00	0.00	5.10	49.90
		Row Pct	88.63	1.16	0.00	0.00	10.21	
		Col Pct	50.00	33.33	0.00	0.00	53.00	
	HAV	Frequency	460	12	1	1	47	521
		Percent	44.23	1.15	0.10	0.10	4.52	50.10
		Row Pct	88.29	2.30	0.19	0.19	9.02	
		Col Pct	50.00	66.67	100	100	47.00	
	Total	Frequency	920	18	1	1	100	1040
		Percent	88.46	1.73	0.10	0.10	9.62	100
Bilirubin			**Value at Month 0**			**Total**
			(-)	**(+)**	**Unknown**	
	HPV	Frequency	517	1	1	519
		Percent	49.71	0.10	0.10	49.90
		Row Pct	99.61	0.19	0.19	
		Col Pct	49.86	50.00	100	
	HAV	Frequency	520	1	0	521
		Percent	50.00	0.10	0.00	50.10
		Row Pct	99.81	0.19	0.00	
		Col Pct	50.14	50.00	0.00	
	Total	Frequency	1037	2	1	1040
		Percent	99.71	0.19	0.10	100
			Value at Month 7			**Total**
			(-)	**Unknown**	
	HPV	Frequency	466	53	519
		Percent	44.81	5.10	49.90
		Row Pct	89.79	10.21	
		Col Pct	49.57	53.00	
	HAV	Frequency	474	47	521
		Percent	45.58	4.52	50.10
		Row Pct	90.98	9.02	
		Col Pct	50.43	47.00	

	Total	Frequency	940			100			1040
		Percent	90.38			9.62			100
Occult Blood			**Value at Month 0**						**Total**
			(-)	**(+-)**	**(+)**	**(2+)**	**(3+)**	**Unknown**	
	HPV	Frequency	483	11	11	9	4	1	519
		Percent	46.44	1.06	1.06	0.87	0.38	0.10	49.90
		Row Pct	93.06	2.12	2.12	1.73	0.77	0.19	
		Col Pct	49.39	61.11	55.00	52.94	66.67	100	
	HAV	Frequency	495	7	9	8	2	0	521
		Percent	47.60	0.67	0.87	0.77	0.19	0.00	50.10
		Row Pct	95.01	1.34	1.73	1.54	0.38	0.00	
		Col Pct	50.61	38.89	45.00	47.06	33.33	0.00	
	Total	Frequency	978	18	20	17	6	1	1040
		Percent	94.04	1.73	1.92	1.63	0.58	0.10	100
			Value at Month 7						**Total**
			(-)	**(+-)**	**(+)**	**(2+)**	**(3+)**	**Unknown**	
	HPV	Frequency	393	22	19	22	10	53	519
		Percent	37.79	2.12	1.83	2.12	0.96	5.10	49.90
		Row Pct	75.72	4.24	3.66	4.24	1.93	10.21	
		Col Pct	49.68	44.00	48.72	55.00	50.00	53.00	
	HAV	Frequency	398	28	20	18	10	47	521
		Percent	38.27	2.69	1.92	1.73	0.96	4.52	50.10
		Row Pct	76.39	5.37	3.84	3.45	1.92	9.02	
		Col Pct	50.32	56.00	51.28	45.00	50.00	47.00	
	Total	Frequency	791	50	39	40	20	100	1040
		Percent	76.06	4.81	3.75	3.85	1.92	9.62	100
Ketone Body			**Value at Month 0**						**Total**
			(-)	**(+)**	**(2+)**	**(3+)**	**Unknown**		
	HPV	Frequency	501	9	7	1	1		519
		Percent	48.17	0.87	0.67	0.10	0.10		49.90
		Row Pct	96.53	1.73	1.35	0.19	0.19		
		Col Pct	49.75	52.94	53.85	50.00	100		
	HAV	Frequency	506	8	6	1	0		521
		Percent	48.65	0.77	0.58	0.10	0.00		50.10
		Row Pct	97.12	1.54	1.15	0.19	0.00		
		Col Pct	50.25	47.06	46.15	50.00	0.00		
	Total	Frequency	1007	17	13	2	1		1040
		Percent	96.83	1.63	1.25	0.19	0.10		100
			Value at Month 7						**Total**
			(-)	**(+)**	**(2+)**	**(3+)**	**Unknown**		
	HPV	Frequency	452	10	3	1	53		519
		Percent	43.46	0.96	0.29	0.10	5.10		49.90
		Row Pct	87.09	1.93	0.58	0.19	10.21		
		Col Pct	49.56	50.00	50.00	50.00	53.00		
	HAV	Frequency	460	10	3	1	47		521
		Percent	44.23	0.96	0.29	0.10	4.52		50.10
		Row Pct	88.29	1.92	0.58	0.19	9.02		
		Col Pct	50.44	50.00	50.00	50.00	47.00		
	Total	Frequency	912	20	6	2	100		1040
		Percent	87.69	1.92	0.58	0.19	9.62		100

Frequency = number of subjects in each category
Percent= percentage of subjects in each category (=Frequency in a category*100/ Total Frequency in Total column)
Row Pct= % of subjects in each category in the row(=Frequency in a category*100/ Total Frequency of the row)
Col Pct= % of subjects in each category in the column(=Frequency in a category*100/ Total Frequency of the column)
Protein Normal range (-) or (+-): - ≤ 10 mg/dl, +- = 10-25 mg/dl, + = 25-85 mg/dl, 2+ = 85-250 mg/dl, 3+ = 250-800 mg/dl
Glucose Normal range (-) or (+-): - ≤ 30 mg/dl, +- = 30-60 mg/dl, + = 60-125 mg/dl, 2+ = 125-250 mg/dl, 3+ = 250-750 mg/dl

Urobilinogen Normal range (+-): +- ≤ 1.5 mg/dl, + = 1.5-3.5 mg/dl, 2+ = 3.5-7.0 mg/dl, 3+ = 7.0-14 mg/dl
Bilirubin Normal range (-): - ≤ 0.35 mg/dl, + = 0.35-1.5 mg/dl, 2+ = 1.5-5.0 mg/dl, 3+ = 5.0-12.0 mg/dl
Occult Blood Normal range (-): - ≤ 0.015 mg/dl, +- = 0.015-0.045 mg/dl, + = 0.045-0.15 mg/dl, 2+ = 0.15-0.75 mg/dl, 3+ ≥ 0.75 mg/dl
Ketone body Normal range (-): - ≤ 2.5 mg/dl, +- = 2.5-7.5mg/dl, + = 7.5-30 mg/dl, 2+ = 30-70 mg/dl, 3+ = 70-125 mg/dl

Secondary Outcome Variable(s): Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total Vaccinated cohort)

Symptom	Intensity	HPV Group					HAV Group				
		N	n	%	95% CI		N	n	%	95% CI	
					LL	UL				LL	UL
Dose 1											
Pain	Any	512	497	97.1	95.2	98.4	510	137	26.9	23.1	30.9
	Grade 3	512	39	7.6	5.5	10.3	510	0	0.0	0.0	0.7
Redness	> 0 mm	512	376	73.4	69.4	77.2	510	238	46.7	42.3	51.1
	> 50 mm	512	17	3.3	1.9	5.3	510	0	0.0	0.0	0.7
Swelling	> 0 mm	512	308	60.2	55.8	64.4	510	120	23.5	19.9	27.5
	> 50 mm	512	13	2.5	1.4	4.3	510	0	0.0	0.0	0.7
Dose 2											
Pain	Any	480	446	92.9	90.2	95.0	481	124	25.8	21.9	29.9
	Grade 3	480	15	3.1	1.8	5.1	481	0	0.0	0.0	0.8
Redness	> 0 mm	480	365	76.0	72.0	79.8	481	178	37.0	32.7	41.5
	> 50 mm	480	17	3.5	2.1	5.6	481	0	0.0	0.0	0.8
Swelling	> 0 mm	480	300	62.5	58.0	66.8	481	96	20.0	16.5	23.8
	> 50 mm	480	8	1.7	0.7	3.3	481	0	0.0	0.0	0.8
Dose 3											
Pain	Any	460	427	92.8	90.1	95.0	464	114	24.6	20.7	28.7
	Grade 3	460	14	3.0	1.7	5.1	464	1	0.2	0.0	1.2
Redness	> 0 mm	460	349	75.9	71.7	79.7	464	169	36.4	32.0	41.0
	> 50 mm	460	22	4.8	3.0	7.2	464	0	0.0	0.0	0.8
Swelling	> 0 mm	460	300	65.2	60.7	69.6	464	80	17.2	13.9	21.0
	> 50 mm	460	19	4.1	2.5	6.4	464	0	0.0	0.0	0.8
Across Doses											
Pain	Any	512	508	99.2	98.0	99.8	510	214	42.0	37.6	46.4
	Grade 3	512	54	10.5	8.0	13.5	510	1	0.2	0.0	1.1
Redness	> 0 mm	512	455	88.9	85.8	91.5	510	287	56.3	51.8	60.6
	> 50 mm	512	44	8.6	6.3	11.4	510	0	0.0	0.0	0.7
Swelling	> 0 mm	512	401	78.3	74.5	81.8	510	165	32.4	28.3	36.6
	> 50 mm	512	34	6.6	4.6	9.2	510	0	0.0	0.0	0.7

For each dose and across doses (=overall/subject):
N= number of subjects with at least one documented dose
n (%) = number (percentage) of subjects reporting at least once the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Any = any solicited local symptom irrespective of intensity grade
Grade 3 Pain = pain that prevented normal activity

Secondary Outcome Variable(s): Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total Vaccinated cohort)

Symptom	Intensity/ relationship	HPV Group					HAV Group				
		N	n	%	95% CI		N	n	%	95% CI	
					LL	UL				LL	UL
Dose 1											
Arthralgia	Any	512	62	12.1	9.4	15.3	511	36	7.0	5.0	9.6
	Related	512	56	10.9	8.4	14.0	511	30	5.9	4.0	8.3
	Grade 3	512	4	0.8	0.2	2.0	511	0	0.0	0.0	0.7
Fatigue	Any	512	269	52.5	48.1	56.9	511	224	43.8	39.5	48.3
	Related	512	242	47.3	42.9	51.7	511	185	36.2	32.0	40.5

	Grade 3	512	12	2.3	1.2	4.1	511	6	1.2	0.4	2.5
Fever (Axillary)	≥ 37.5°C	512	14	2.7	1.5	4.5	511	17	3.3	1.9	5.3
	> 39.0°C	512	1	0.2	0.0	1.1	511	0	0.0	0.0	0.7
	Related	512	9	1.8	0.8	3.3	511	13	2.5	1.4	4.3
Gastro-intestinal	Any	512	103	20.1	16.7	23.9	511	108	21.1	17.7	24.9
	Related	512	79	15.4	12.4	18.9	511	78	15.3	12.3	18.7
	Grade 3	512	4	0.8	0.2	2.0	511	9	1.8	0.8	3.3
Headache	Any	512	162	31.6	27.6	35.9	511	159	31.1	27.1	35.3
	Related	512	125	24.4	20.8	28.4	511	130	25.4	21.7	29.4
	Grade 3	512	5	1.0	0.3	2.3	511	4	0.8	0.2	2.0
Myalgia	Any	512	204	39.8	35.6	44.2	511	78	15.3	12.3	18.7
	Related	512	198	38.7	34.4	43.0	511	70	13.7	10.8	17.0
	Grade 3	512	6	1.2	0.4	2.5	511	1	0.2	0.0	1.1
Rash	Any	512	16	3.1	1.8	5.0	511	15	2.9	1.7	4.8
	Related	512	14	2.7	1.5	4.5	511	14	2.7	1.5	4.6
	Grade 3	512	0	0.0	0.0	0.7	511	0	0.0	0.0	0.7
Urticaria	Any	512	9	1.8	0.8	3.3	511	11	2.2	1.1	3.8
	Related	512	8	1.6	0.7	3.1	511	9	1.8	0.8	3.3
	Grade 3	512	1	0.2	0.0	1.1	511	2	0.4	0.0	1.4
Dose 2											
Arthralgia	Any	480	61	12.7	9.9	16.0	481	19	4.0	2.4	6.1
	Related	480	57	11.9	9.1	15.1	481	12	2.5	1.3	4.3
	Grade 3	480	1	0.2	0.0	1.2	481	0	0.0	0.0	0.8
Fatigue	Any	480	200	41.7	37.2	46.2	481	156	32.4	28.3	36.8
	Related	480	178	37.1	32.7	41.6	481	121	25.2	21.3	29.3
	Grade 3	480	8	1.7	0.7	3.3	481	2	0.4	0.1	1.5
Fever (Axillary)	≥ 37.5°C	480	15	3.1	1.8	5.1	481	4	0.8	0.2	2.1
	> 39.0°C	480	0	0.0	0.0	0.8	481	1	0.2	0.0	1.2
	Related	480	13	2.7	1.4	4.6	481	2	0.4	0.1	1.5
Gastro-intestinal	Any	480	74	15.4	12.3	19.0	481	73	15.2	12.1	18.7
	Related	480	56	11.7	8.9	14.9	481	55	11.4	8.7	14.6
	Grade 3	480	2	0.4	0.1	1.5	481	2	0.4	0.1	1.5
Headache	Any	480	129	26.9	23.0	31.1	481	98	20.4	16.9	24.3
	Related	480	97	20.2	16.7	24.1	481	75	15.6	12.5	19.1
	Grade 3	480	5	1.0	0.3	2.4	481	5	1.0	0.3	2.4
Myalgia	Any	480	145	30.2	26.1	34.5	481	40	8.3	6.0	11.2
	Related	480	138	28.8	24.7	33.0	481	30	6.2	4.2	8.8
	Grade 3	480	2	0.4	0.1	1.5	481	0	0.0	0.0	0.8
Rash	Any	480	13	2.7	1.4	4.6	481	7	1.5	0.6	3.0
	Related	480	13	2.7	1.4	4.6	481	6	1.2	0.5	2.7
	Grade 3	480	0	0.0	0.0	0.8	481	1	0.2	0.0	1.2
Urticaria	Any	480	4	0.8	0.2	2.1	481	5	1.0	0.3	2.4
	Related	480	4	0.8	0.2	2.1	481	4	0.8	0.2	2.1
	Grade 3	480	0	0.0	0.0	0.8	481	3	0.6	0.1	1.8
Dose 3											
Arthralgia	Any	460	54	11.7	8.9	15.0	464	23	5.0	3.2	7.3
	Related	460	53	11.5	8.8	14.8	464	19	4.1	2.5	6.3
	Grade 3	460	4	0.9	0.2	2.2	464	1	0.2	0.0	1.2
Fatigue	Any	460	210	45.7	41.0	50.3	464	144	31.0	26.8	35.5
	Related	460	180	39.1	34.6	43.8	464	114	24.6	20.7	28.7
	Grade 3	460	6	1.3	0.5	2.8	464	3	0.6	0.1	1.9
Fever (Axillary)	≥ 37.5°C	460	15	3.3	1.8	5.3	464	9	1.9	0.9	3.7
	> 39.0°C	460	2	0.4	0.1	1.6	464	0	0.0	0.0	0.8
	Related	460	8	1.7	0.8	3.4	464	5	1.1	0.4	2.5
Gastro-	Any	460	67	14.6	11.5	18.1	464	54	11.6	8.9	14.9

intestinal	Related	460	48	10.4	7.8	13.6	464	39	8.4	6.0	11.3
	Grade 3	460	2	0.4	0.1	1.6	464	1	0.2	0.0	1.2
Headache	Any	460	106	23.0	19.3	27.2	464	91	19.6	16.1	23.5
	Related	460	78	17.0	13.6	20.7	464	62	13.4	10.4	16.8
	Grade 3	460	3	0.7	0.1	1.9	464	2	0.4	0.1	1.5
Myalgia	Any	460	140	30.4	26.3	34.9	464	44	9.5	7.0	12.5
	Related	460	133	28.9	24.8	33.3	464	37	8.0	5.7	10.8
	Grade 3	460	6	1.3	0.5	2.8	464	0	0.0	0.0	0.8
Rash	Any	460	12	2.6	1.4	4.5	464	3	0.6	0.1	1.9
	Related	460	11	2.4	1.2	4.2	464	3	0.6	0.1	1.9
	Grade 3	460	1	0.2	0.0	1.2	464	0	0.0	0.0	0.8
Urticaria	Any	460	7	1.5	0.6	3.1	464	8	1.7	0.7	3.4
	Related	460	5	1.1	0.4	2.5	464	6	1.3	0.5	2.8
	Grade 3	460	2	0.4	0.1	1.6	464	2	0.4	0.1	1.5
Across Doses											
Arthralgia	Any	512	123	24.0	20.4	28.0	511	61	11.9	9.3	15.1
	Related	512	113	22.1	18.6	25.9	511	48	9.4	7.0	12.3
	Grade 3	512	8	1.6	0.7	3.1	511	1	0.2	0.0	1.1
Fatigue	Any	512	341	66.6	62.3	70.7	511	300	58.7	54.3	63.0
	Related	512	316	61.7	57.4	65.9	511	254	49.7	45.3	54.1
	Grade 3	512	23	4.5	2.9	6.7	511	10	2.0	0.9	3.6
Fever (Axillary)	≥ 37.5°C	512	41	8.0	5.8	10.7	511	28	5.5	3.7	7.8
	> 39.0°C	512	3	0.6	0.1	1.7	511	1	0.2	0.0	1.1
	Related	512	28	5.5	3.7	7.8	511	19	3.7	2.3	5.7
Gastro-intestinal	Any	512	172	33.6	29.5	37.9	511	167	32.7	28.6	36.9
	Related	512	135	26.4	22.6	30.4	511	124	24.3	20.6	28.2
	Grade 3	512	8	1.6	0.7	3.1	511	12	2.3	1.2	4.1
Headache	Any	512	250	48.8	44.4	53.3	511	222	43.4	39.1	47.9
	Related	512	201	39.3	35.0	43.6	511	181	35.4	31.3	39.7
	Grade 3	512	12	2.3	1.2	4.1	511	11	2.2	1.1	3.8
Myalgia	Any	512	262	51.2	46.7	55.6	511	128	25.0	21.3	29.0
	Related	512	252	49.2	44.8	53.6	511	109	21.3	17.9	25.1
	Grade 3	512	12	2.3	1.2	4.1	511	1	0.2	0.0	1.1
Rash	Any	512	33	6.4	4.5	8.9	511	24	4.7	3.0	6.9
	Related	512	30	5.9	4.0	8.3	511	22	4.3	2.7	6.4
	Grade 3	512	1	0.2	0.0	1.1	511	1	0.2	0.0	1.1
Urticaria	Any	512	16	3.1	1.8	5.0	511	20	3.9	2.4	6.0
	Related	512	14	2.7	1.5	4.5	511	17	3.3	1.9	5.3
	Grade 3	512	3	0.6	0.1	1.7	511	6	1.2	0.4	2.5

For each dose and across doses (=overall/subject):
N = number of subjects with at least one documented dose
n (%) = number (percentage) of subjects reporting at least once the symptom
Any = any solicited general symptom irrespective of intensity grade or relationship to vaccination
Grade 3 symptom = symptom that prevented normal activity
Grade 3 Urticaria = urticaria distributed on at least 4 body areas
Related = symptom assessed by the investigator to have a causal relationship to vaccination

Secondary Outcome Variable(s): Occurrence of new onset chronic diseases (NOCD - GSK assessment) (Total Vaccinated Cohort)

New onset chronic diseases occurring up to Month 24 following vaccination	**HPV Group N = 519**	**HAV Group N = 521**
Subjects with any AE(s), n (%)	5 (1.0)	6 (1.2)
Urticaria	2 (0.4)	4 (0.8)
Asthma	2 (0.4)	-
Allergic granulomatous angiitis	1 (0.2)	-
Drug eruption	-	1 (0.2)

Rheumatoid arthritis	1 (0.2)	-
Rhinitis allergic	-	1 (0.2)

- : NOCD absent

Secondary Outcome Variable(s): Occurrence of medically significant conditions (Total Vaccinated Cohort)

Medically significant adverse events occurring up to Month 24 following vaccination	**HPV Group N = 519**	**HAV Group N = 521**
Subjects with any AE(s), n (%)	91 (17.5)	107 (20.5)
Cystitis	4 (0.8)	9 (1.7)
Abortion spontaneous	3 (0.6)	3 (0.6)
Eczema	3 (0.6)	3 (0.6)
Oropharyngeal pain	3 (0.6)	3 (0.6)
Enterocolitis	-	5 (1.0)
Acne	4 (0.8)	-
Bronchitis	4 (0.8)	-
Candidiasis	-	4 (0.8)
Asthma	3 (0.6)	-
Chlamydial infection	-	3 (0.6)
Dental caries	-	3 (0.6)
Depression	3 (0.6)	-
Dermatitis atopic	3 (0.6)	-
Genital herpes	3 (0.6)	-
Pyrexia	-	3 (0.6)
Urticaria	-	3 (0.6)

- : medically significant adverse event absent or not meeting the counting rule: > 30 subjects per treatment group and ≤ 3 groups, display most frequent 10 primary preferred terms

Secondary Outcome Variable(s): Number of subjects with pregnancies and their outcomes overall (Total vaccinated cohort)

Categories	**HPV Group N = 46**		**HAV Group N = 43**	
	n	**%**	**n**	**%**
Normal infant	20	43.5	19	44.2
Premature birth	1	2.2	0	0.0
Abnormal infant	0	0.0	0	0.0
Elective termination	14	30.4	16	37.2
Therapeutic abortion	0	0.0	0	0.0
Ectopic pregnancy	0	0.0	0	0.0
Spontaneous abortion*	5	10.9	3	7.0
Still birth	0	0.0	0	0.0
Lost to follow up	1	2.2	0	0.0
Not applicable	0	0.0	0	0.0
Pregnancy ongoing	5	10.9	5	11.6

N = number of pregnancies
n = number of pregnancies in a given category
Value = value of the considered parameter
% = n / Number of case id with available results x 100
*Spontaneous abortion includes missed abortion

Safety results: Number (%) of subjects with unsolicited adverse events (Total Vaccinated Cohort)

Most frequent adverse events–On-Therapy (occurring within Day 0-29 following vaccination)	**HPV Group N = 519**	**HAV Group N = 521**
Subjects with any AE(s), n (%)	294 (56.6)	266 (51.1)
Subjects with grade 3* AE(s), n (%)	28 (5.4)	26 (5.0)
Subjects with related** AE(s), n (%)	171 (32.9)	80 (15.4)
Nasopharyngitis	110 (21.2)	91 (17.5)
Injection site pruritus	83 (16.0)	15 (2.9)
Injection site warmth	69 (13.3)	-

Headache	19 (3.7)	27 (5.2)
Pharyngolaryngeal pain	12 (2.3)	17 (3.3)
Dysmenorrhoea	6 (1.2)	15 (2.9)
Vaginal candidiasis	6 (1.2)	12 (2.3)
Diarrhoea	9 (1.7)	8 (1.5)
Constipation	6 (1.2)	9 (1.7)
Stomach discomfort	7 (1.3)	-
Nausea	-	8 (1.5)
Cystitis	-	8 (1.5)
Dizziness	7 (1.3)	
Insect site haemorrhage	6 (1.2)	-
Metrorrhagia	6 (1.2)	-
* Grade 3 AE: AE that prevented normal activity ** Related AE: AE assessed by the investigator to be causally related to the study vaccination - : Adverse event absent or not meeting the selected counting rule: > 30 subjects per treatment group and ≤ 3 groups, display most frequent 10 primary preferred terms		
Safety results: Number (%) of subjects with serious adverse events (SAEs) throughout the study period (Total Vaccinated Cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV Group N = 519**	**HAV Group N = 521**
Subjects with any SAE(s), n (%)[n assessed by investigator as related]	18 (3.5) [1]	19 (3.6) [0]
Abortion spontaneous	3 (0.6) [1]	3 (0.6) [0]
Abortion threatened	1 (0.2) [0]	1 (0.2) [0]
Acute tonsillitis	0 (0.0) [0]	2 (0.4) [0]
Appendicitis	1 (0.2) [0]	1 (0.2) [0]
Hepatitis acute	1 (0.2) [0]	1 (0.2) [0]
Threatened labour	1 (0.2) [0]	1 (0.2) [0]
Abortion missed	1 (0.2) [0]	0 (0.0) [0]
Abortion spontaneous incomplete	1 (0.2) [0]	0 (0.0) [0]
Acute abdomen	0 (0.0) [0]	1 (0.2) [0]
Allergic granulomatous angiitis	1 (0.2) [0]	0 (0.0) [0]
Avulsion fracture	0 (0.0) [0]	1 (0.2) [0]
Borderline personality disorder	1 (0.2) [0]	0 (0.0) [0]
Brain contusion	1 (0.2) [0]	0 (0.0) [0]
Completed suicide	1 (0.2) [0]	0 (0.0) [0]
Contusion	0 (0.0) [0]	1 (0.2) [0]
Depression	1 (0.2) [0]	0 (0.0) [0]
Enterocolitis	0 (0.0) [0]	1 (0.2) [0]
Eyeball rupture	1 (0.2) [0]	0 (0.0) [0]
Fatigue	0 (0.0) [0]	1 (0.2) [0]
Gastritis	0 (0.0) [0]	1 (0.2) [0]
Ligament injury	1 (0.2) [0]	0 (0.0) [0]
Ligament rupture	0 (0.0) [0]	1 (0.2) [0]
Mastitis postpartum	0 (0.0) [0]	1 (0.2) [0]
Moyamoya disease	0 (0.0) [0]	1 (0.2) [0]
Ovarian haemorrhage	1 (0.2) [0]	0 (0.0) [0]
Panic disorder	1 (0.2) [0]	0 (0.0) [0]
Pneumonia	0 (0.0) [0]	1 (0.2) [0]
Pneumothorax	1 (0.2) [0]	0 (0.0) [0]
Polycystic ovaries	0 (0.0) [0]	1 (0.2) [0]
Pyelonephritis acute	1 (0.2) [0]	0 (0.0) [0]
Road traffic accident	1 (0.2) [0]	0 (0.0) [0]
Schizophrenia	0 (0.0) [0]	1 (0.2) [0]
Skull fracture	1 (0.2) [0]	0 (0.0) [0]

Fatal SAEs	HPV Group N = 519	HAV Group N = 521
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	1 (0.2) [0]	0 (0.0) [0]
Completed suicide	1 (0.2) [0]	0 (0.0) [0]

Conclusion: Vaccine efficacy against persistent infection (6-month definition) with HPV-16 and/or HPV-18 was 100% in the HPV Group.
During the 30-day follow-up period after vaccination, unsolicited adverse events were reported by 294 (56.6%) and 266 (51.1%) subjects in the HPV and HAV groups, respectively. Throughout the study period, 18 (3.5%) & 19 (3.6%) subjects reported SAEs in the HPV and HAV groups, respectively; 1 SAE in the HPV Group was assessed by the investigator as related to the study vaccination; 1 fatal SAE was reported in the HPV Group; it was assessed by the investigator as not related to the study vaccination.
Please refer also to the publications below.

Publications:
Verstraeten T et al. (2008) Analysis of adverse events of potential autoimmune aetiology in a large integrated safety database of AS04 adjuvanted vaccines. Vaccine. 26(51):6630–6638.
Konno R et al. (2009) Immunogenicity, reactogenicity, and safety of human papillomavirus 16/18 AS04-adjuvanted vaccine in Japanese women: interim analysis of a phase II, double-blind, randomized controlled trial at month 7. Int J Gynecol Cancer. 19(5):905-911.
Konno R et al. (2010) Efficacy of human papillomavirus 16/18 AS04-adjuvanted vaccine in Japanese women aged 20 to 25 years: interim analysis of a phase 2 double-blind, randomized, controlled trial. Int J Gynecol Can. 20(3):404-410.
Konno R et al. Efficacy, immunogenicity and safety of HPV 16/18 AS04-adjuvanted vaccine in Japanese women. Abstract presented at European Research Organization on Genital Infection and Neoplasia 2010 (EUROGIN). Monte Carlo, Monaco, 17-20 February 2010.
Konno R et al. Interim analysis of clinical trial of HPV-16/18-AS04 vaccine in Japan. Abstract presented at the 25th International Papillomavirus Conference. Malmö, Sweden, 8-14 May 2009.
Konno R et al. (2011) Prevalence and type distribution of human papillomavirus in healthy Japanese women aged 20 to 25 years old enrolled in a clinical study. Cancer Science. 102(4):877-882.
Konno R et al. Prevalence and type distribution of human papillomavirus in healthy Japanese women aged 20 to 25 years old enrolled in a clinical study. Abstract presented at European Research Organization on Genital Infection and Neoplasia 2011 (EUROGIN). Lisbon, Portugal, 8-11 May 2011.

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