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.: 580299/013 (HPV-013) & 104896 (EXT HPV-013 Month 18) & 104902 (EXT HPV-013 Month 24) & 104904 (EXT HPV-013 Month 36) & 104918 (EXT HPV-013 Month 48)

Title:
580299/013 (HPV-013): A Phase III, double-blind, randomized, controlled study to evaluate the safety and immunogenicity of GlaxoSmithKline Biologicals' HPV-16/18 L1/AS04 vaccine administered intramuscularly according to a 0, 1, 6 month schedule in healthy female subjects aged 10-14 years.

104896 (EXT HPV-013 Month 18), 104902 (EXT HPV-013 Month 24), 104904 (EXT HPV-013 Month 36) & 104918 (EXT HPV-013 Month 48) : A long-term, open follow-up of the immunogenicity and safety of GlaxoSmithKline Biologicals' HPV-16/18 L1 AS04 vaccine in healthy female subjects vaccinated in study HPV-013.
HPV-16/18 L1 AS04 vaccine: GlaxoSmithKline (GSK) Biologicals' human papillomavirus vaccine

Rationale: The aim of the study was to evaluate the safety and immunogenicity of the HPV-16/18 L1/AS04 vaccine in pre-teen and adolescent female subjects aged 10 - 14 years. Havrix was used as a control vaccine.
Havrix: GSK Biologicals' hepatitis A vaccine (HAV).

Phase: III

Study Period:
580299/013 (HPV-013): 30 June 2004 to 04 August 2005
104896 (EXT HPV-013 Month 18): 19 October 2005 to 13 July 2006
104902 (EXT HPV-013 Month 24): 26 May 2006 to 15 February 2007
104904 (EXT HPV-013 Month 36): 26 April 2007 to 14 February 2008
104918 (EXT HPV-013 Month 48): 02 April 2008 to 20 January 2009

Study Design: Multicentric, double-blinded*, randomized (1:1), controlled study with 2 parallel groups.
* Due to differences in the appearance of the HPV vaccine and the HAV control vaccine, the study was conducted observer-blinded. The long-term follow-up study was blinded until the primary study was unblinded, and thereafter was conducted in an open fashion.
Subjects who had received the HAV control vaccine attended one further visit as their last study visit, i.e. depending on time of their enrolment, either at Month 18 or at Month 24.
At Month 24, all subjects were unblinded and only the subjects who had received the HPV vaccine were to continue the study until Month 48, i.e. were invited to participate in studies 104904 (EXT HPV-013 Month 36) & 104918 (EXT HPV-013 Month 48)

Centers:
580299/013 (HPV-013): study was conducted in 57 centers located in Australia, Colombia, Czech Republic, France, Germany, Honduras, Korea, Norway, Panama, Spain, Sweden and Taiwan.
104896 (EXT HPV-013 Month 18), 104902 (EXT HPV-013 Month 24) & 104904 (EXT HPV-013 Month 36): study was conducted in 34 centers located in Taiwan, Germany, Honduras, Panama and Colombia.
104918 (EXT HPV-013 Month 48): study was conducted in 31 centers located in Taiwan, Germany, Honduras, Panama and Colombia.

Indication: Active immunization of girls 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 study groups were as follows:
- One group received 3 doses of HPV vaccine (HPV Group).
- One group (control group) received 3 doses of HAV vaccine (HAV Group).

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

Objectives:
580299/013 (HPV-013):
To compare between the HPV vaccine group and the control group (HAV Group) the occurrence of serious adverse events (SAEs) throughout the study period (up to Month 7).
104896 (EXT HPV-013 Month 18) & 104902 (EXT HPV-013 Month 24) & 104904 (EXT HPV-013 Month 36) & 104918 (EXT HPV-013 Month 48):
To evaluate the long-term HPV-16/18 virus-like particles (VLP)/AS04 vaccine immunogenicity (for all subjects in the HPV

Vaccine Group) by ELISA.

Primary Outcome/Efficacy Variable:

580299/013 (HPV-013):

- Occurrence of SAEs throughout the study period (up to Month 7).

104896 (EXT HPV-013 Month 18), 104902 (EXT HPV-013 Month 24) & 104904 (EXT HPV-013 Month 36) & 104918 (EXT HPV-013 Month 48):

- Anti-HPV-16/18 antibody titers in all study subjects in the HPV Group (ELISA).

Secondary Outcome/Efficacy Variable(s):

Primary study and follow-up at Month 12-16:

Immunogenicity

- Anti-HPV-16/18 antibody titers (by ELISA) assessed at Months 0, 2 and 7.
- Anti-MPL (3-*O*-desacyl 4'-monophosphoryl lipid A) antibody titers (by ELISA) assessed at Months 0, 2 and 7.
- Comparison of anti-HPV-16/18 antibody titers (by ELISA) assessed in sera from 10 - 14 year olds 580299/013 (HPV-013) subjects and in sera from adults in study 580299/001 at Month 7.

Safety

- Occurrence of New Onset Chronic Disease (NOCD) and other medically significant conditions prompting emergency room visits or physician visits that were not related to common diseases throughout the study period (up to Month 7) regardless of causal relationship to vaccination and intensity.
- Occurrence of clinically relevant abnormalities in biochemical and hematological parameters assessed at Months 0, 2 and 7.
- Occurrence, intensity and relationship to vaccination of solicited general symptoms, and occurrence and intensity of solicited local symptoms within 7 days (Day 0-6) after each and any vaccination.
- Occurrence, intensity and causal relationship to vaccination of unsolicited symptoms within 30 days (Day 0-29) after any vaccination.
- Occurrence of SAEs, NOCD and other medically significant conditions up to Month 12 (extended safety follow-up).

Extension studies

Immunogenicity

- Anti-MPL antibody titers (ELISA).
- Anti-HPV-16/18 antibody sera titers (ELISA) from HPV-001 adult subjects*

*The immune response of the vaccine in the Ext HPV-013 study population was compared to the HPV-007 (i.e. HPV-001 long-term follow-up study) plateau immunogenicity.

Safety

- Occurrence of pregnancies, SAEs, NOCDs, and conditions prompting emergency room visits or physician visits that were not related to common diseases (the following did not require reporting as long as they were not considered as SAEs: upper respiratory infections, sinusitis, pharyngitis, gastroenteritis, urinary tract infections, injury, visits for routine physical examination or visits for vaccination) throughout the entire study period (including from the Month 12 telephone contact of the primary HPV-013 study until Month 12-16 of the Ext HPV-013 study).

Statistical Methods:

Analyses were performed on the Total Vaccinated cohort and on the According-To-Protocol (ATP) cohort for immunogenicity.

- The Total Vaccinated Cohort included all subjects with at least one vaccine administration documented for whom data were available at the considered time points, including those of the extension studies.
- The ATP cohort for immunogenicity included all evaluable subjects (i.e. those meeting all eligibility criteria, complying with the procedures defined in the protocol, with no elimination criteria during the study) with available immunogenicity data. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination at the considered time points, including those of the extension studies.

Primary study and follow-up at Month 12-16:

Analysis of immunogenicity

The analysis was based on the ATP cohort for immunogenicity.

In the HPV Group at each time point that a blood sample was available, the range and distribution of anti-HPV-16/18 antibody titers measured by ELISA were tabulated by geometric mean titers (GMTs) with their 95% confidence intervals (CI) along with seroconversion* rates. The range and distribution of anti-HPV-16 and anti-HPV-18 antibody titers measured by ELISA in the HPV-001 reference group (study HPV-001) were tabulated by GMTs with their 95% CI, before vaccination and at Month 7, along with seroconversion rates. For each group at each time point that a blood sample was available, the range and distribution of anti-MPL measured by ELISA were tabulated by GMTs with their 95% CI, along with seroconversion rates. For GMT calculations, antibody titers below the assay cut-off were given an arbitrary value of half the cut-off.

A seropositive subject was a subject whose titer was ≥ the cut-off values (anti-HPV-16 titer ≥ 8 EL.U/mL, anti-HPV-18 titer ≥ 7 EL.U/mL and anti-MPL titer ≥ 59 EL.U/mL).
*Seroconversion was defined as the appearance of antibodies (anti-HPV-16 titer ≥ 8 EL.U/mL, anti-HPV-18 titer ≥ 7 EL.U/mL and anti-MPL titer ≥ 59 EL.U/mL) in the sera of subjects seronegative before vaccination.

Analysis of safety
The analysis was performed on the Total Vaccinated Cohort.
The two-sided standardized asymptotic 95% CI for the difference in percentage of subjects with at least one SAE (HAV Group minus HPV Group). The comparison was done considering individual SAEs classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred terms.
The percentage of subjects reporting each individual solicited local and general symptom during the 7-day (Day 0-6) 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 investigator as related to vaccination.
The percentage of subjects with unsolicited adverse events (AEs) classified by MedDRA preferred terms and reported up to 30 days (Day 0-29) after vaccination was tabulated. The same tabulation was performed for Grade 3 and for related unsolicited AEs.
The percentage of subjects with NOCDs and other medically significant conditions prompting emergency room visits or physician visits that were not related to common diseases throughout the study period (up to Month 7), all classified by MedDRA, were tabulated with exact 95% CI. The occurrence of clinically relevant abnormalities in biochemical and hematological parameters (creatinine, alanine aminotransferase (ALT), hematocrit, white and red blood cell counts, differential white blood cell count and platelets count) assessed at Months 2 and 7 were tabulated.

Extension studies at Month 18, at Month 24, at Month 36 and Month 48
Analysis of immunogenicity
The analysis was performed on the ATP cohort for immunogenicity.
For the follow-up studies, the following antibodies were analyzed: anti-HPV-16, anti-HPV-18 and anti-MPL. All analyses were stratified according to serostatus at Day 0 in the primary HPV-013 study. The GMTs (measured by ELISA) with their 95% CI and seroconversion/seropositivity rates were tabulated for anti-HPV-16 (in HPV group), anti-HPV-18 (in HPV group) and anti-MPL (HPV and HAV groups) antibodies, at each time point. A descriptive comparison of anti-HPV-16 and anti-HPV-18 serology results between 104896 (EXT HPV-013 Month 18) and HPV-001 was performed. A descriptive comparison of anti-HPV-16 and anti-HPV-18 serology results between 104902 (EXT HPV-013 Month 24), 104904 (Ext HPV-013 Month 36), 104918 (EXT HPV-013 Month 48) and HPV-007 was performed.

Analysis of safety
The analysis was performed on the Total Vaccinated Cohort. .
For each group, the percentages of subjects with at least one NOCD and medically significant conditions from Month 0 to Month 12, from Month 12 to Month 18, from Month 18 to Month 24, from Month 24 to Month 36 and from Month 36 to Month 48 were tabulated with exact 95% CI, regardless of causal relationship to vaccination and intensity. The outcome of pregnancies reported from Month 0 to Month 18, from Month 18 to 24, from Month 24 to Month 36 and from Month 36 to Month 48 was tabulated. The occurrences of SAEs during the periods from Month 0 to Month 12, from Month 12 to Month 18, from Month 18 to 24, from Month 24 to Month 36 and from Month 36 to Month 48 were tabulated per group. SAEs, NOCDs and medically significant conditions were classified according to MedDRA preferred terms.

Study Population: *For primary study (HPV-013):* Healthy female subjects between 10 and 14 years of age, free of obvious health problems as established by medical history and clinical examination and having a negative urine pregnancy test. Subjects had to be of non-childbearing potential or, if of childbearing potential, had to be abstinent or using effective birth control methods for 30 days prior to vaccination and had to agree to continue such precautions for 2 months after completion of vaccination series. Subjects who reached menarche during the study had to agree to follow the same precautions.
For the Extension (Ext HPV-013): Female subjects from the immunogenicity subset of the primary HPV-013 study who completed the study and had received 3 doses of HPV-16/18 L1 AS04 vaccine or HAV control vaccine were invited to enroll into the Ext HPV-013 study. Written informed assent and written informed consent were obtained respectively from each subject and each subject's parent/legally acceptable representative prior to the performance of any extension study-specific procedures.

Number of subjects	**HPV Group**	**HAV Group**
Planned, N	1000	1000
Randomized, N (Total Vaccinated Cohort)	1035	1032
Completed, n (%) up to Month 12	1017 (98.3)	1010 (97.9)
Total Number Subjects Withdrawn, n (%)	18 (1.7)	22 (2.1)

Withdrawn due to Adverse Events, n (%)	0 (0.0)	3 (0.3)
Withdrawn due to Lack of Efficacy, n (%)	Not applicable	Not applicable
Withdrawn for other reasons, n (%)	18 (1.7)	19 (1.8)
Demographics	**HPV Group**	**HAV Group**
N (Total Vaccinated Cohort)	1035	1032
Females: Males	1035:0	1032:0
Mean Age, years (SD)	12.1 (1.4)	12.1 (1.4)
White/Caucasian, n (%)	571 (55.2)	564 (54.7)

Primary Efficacy Results:
Percentage of subjects reporting the occurrence of Serious Adverse Events classified by MedDRA Preferred Term, up to Month 7 (Total Vaccinated Cohort)

All SAEs	**HPV Group (N = 1035)**				**HAV Group (N = 1032)**				**Difference between HAV – HPV Groups**		
	n	**%**	**95% CI**		**n**	**%**	**95% CI**		**%**	**95% CI***	
			LL	**UL**			**LL**	**UL**		**LL**	**UL**
At least one SAE	11	1.1	0.5	1.9	13	1.3	0.7	2.1	0.20†	-0.78	1.20
Lymphadenitis	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Abdominal pain	2	0.2	0.0	0.7	0	0.0	0.0	0.4	-0.19	-0.70	0.18
Constipation	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Gastritis	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Appendicitis	0	0.0	0.0	0.4	5	0.5	0.2	1.1	0.48	0.11	1.13
Enterobiasis	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Gastroenteritis	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Herpangina	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Ludwig angina	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Pneumonia bacterial	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Pseudocroup	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Upper respiratory tract infection	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Urinary tract infection	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Concussion	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Drug toxicity	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Gun shot wound	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Injury	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Ulna fracture	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Transaminases increased	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Dehydration	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Headache	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Syncope	1	0.1	0.0	0.5	0	0.0	0.0	0.4	-0.10	-0.55	0.27
Anorexia nervosa	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55
Ovarian cyst ruptured	0	0.0	0.0	0.4	1	0.1	0.0	0.5	0.10	-0.27	0.55

At least one SAE = at least one SAE experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the SAE
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit
95% CI* = 95% confidence interval for difference in proportions (Standardized asymptotic)
†The SAE rates in the 2 groups were similar.

Primary Efficacy Results:
Seropositivity rates and GMTs for anti-HPV-16 antibodies by pre-vaccination status (HPV Group, ATP cohort for immunogenicity)

Pre-vaccination status	**Timing**	**N**	**≥ 8 EL.U/mL**				**GMT (EL.U/mL)**		
			n	**%**	**95% CI**		**Value**	**95% CI**	
					LL	**UL**		**LL**	**UL**
S-	PRE	630	0	0.0	0.0	0.6	4.0	4.0	4.0
	PII(M2)	625	622	99.5	98.6	99.9	4696.9	4388.6	5026.8
	PIII(M7)	619	619	100	99.4	100	19882.0	18626.7	21221.9

	PIII[M12-16]	477a	475	99.6	98.5	99.9	4561.3	4145.1	5019.2
	PIII(M18)	556	556	100	99.3	100	3888.8	3605.0	4195.0
	PIII(M24)	518	517	99.8	98.9	100	3198.0	2952.8	3463.6
	PIII(M36)	542	542	100	99.3	100	2675.5	2484.9	2880.8
	PIII(M48)	531	531	100	99.3	100	2374.9	2205.7	2557.0
S+	PRE	40	40	100	91.2	100	15.1	11.8	19.3
	PII(M2)	37	37	100	90.5	100	5402.9	4162.4	7013.1
	PIII(M7)	37	37	100	90.5	100	22437.5	17807.6	28271.1
	PIII[M12-16]	27 a	27	100	87.2	100	5173.2	3728.6	7177.4
	PIII(M18)	32	32	100	89.1	100	4131.7	3088.3	5527.6
	PIII(M24)	31	31	100	88.8	100	3736.6	2883.8	4841.5
	PIII(M36)	29	29	100	88.1	100	2945.7	2261.6	3836.7
	PIII(M48)	28	28	100	87.7	100	2828.8	2139.6	3740.1
Total	PRE	670	40	6.0	4.3	8.0	4.3	4.2	4.5
	PII(M2)	662	659	99.5	98.7	99.9	4733.8	4433.1	5054.9
	PIII(M7)	656	656	100	99.4	100	20018.1	18799.3	21315.9
	PIII[M12-16]	504a	502	99.6	98.6	100	4592.2	4188.3	5034.9
	PIII(M18)	588	588	100	99.4	100	3901.6	3626.2	4198.0
	PIII(M24)	549	548	99.8	99.0	100	3226.3	2988.4	3483.1
	PIII(M36)	571	571	100	99.4	100	2688.6	2503.6	2887.3
	PIII(M48)	559	559	100	99.3	100	2395.8	2230.5	2573.3

[a] The number of subjects at M12-M16 was reduced compared to that at M7 and M18 because at the time of the protocol amendment to implement the extension study, some subjects were too late for the M12-M16 Visit and directly attended the Month 18 Visit.
S- = seronegative subjects (antibody titer < 8 EL.U/mL) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 8 EL.U/mL) prior to vaccination
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with antibody titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination
PII(M2) = Post Dose II (Month 2)
PIII(M7) = Post Dose III (Month 7)
PIII[M12-M16] = Post Dose III (Month 12- Month 16)
PIII(M18) = Post Dose III (Month 18)
PIII(M24) = Post Dose III (Month 24)
PIII(M36) = Post Dose III (Month 36)
PIII(M48) = Post Dose III (Month 48)

Primary Efficacy Results:
Seropositivity rates and GMTs for anti-HPV-18 antibodies by pre-vaccination status (HPV Group, ATP cohort for immunogenicity)

Pre-vaccination status	**Timing**	**N**	**≥ 7 EL.U/mL**				**GMT (EL.U/mL)**		
			n	**%**	**95% CI**		**Value**	**95% CI**	
					LL	**UL**		**LL**	**UL**
S-	PRE	639	0	0.0	0.0	0.6	3.5	3.5	3.5
	PII(M2)	633	631	99.7	98.9	100	3741.7	3499.3	4000.9
	PIII(M7)	628	628	100	99.4	100	8262.0	7725.0	8836.2
	PIII[M12-16]	483[a]	482	99.8	98.9	100	1815.8	1654.3	1993.1
	PIII(M18)	562	562	100	99.3	100	1539.4	1418.8	1670.3
	PIII(M24)	525	525	100	99.3	100	1251.3	1152.7	1358.3
	PIII(M36)	545	545	100	99.3	100	972.0	896.5	1054.0
	PIII(M48)	535	535	100	99.3	100	864.8	796.9	938.4
S+	PRE	29	29	100	88.1	100	19.7	15.0	25.8
	PII(M2)	28	28	100	87.7	100	3825.9	2840.4	5153.3
	PIII(M7)	27	27	100	87.2	100	10981.1	7202.5	16742.0
	PIII[M12-16]	20[a]	20	100	83.2	100	3452.4	1806.7	6597.4
	PIII(M18)	25	25	100	86.3	100	2472.5	1463.3	4177.8

	PIII(M24)	23	23	100	85.2	100	1575.1	958.8	2587.7
	PIII(M36)	25	25	100	86.3	100	1657.0	1008.9	2721.5
	PIII(M48)	24	24	100	85.8	100	1505.7	892.3	2540.8
Total	PRE	668	29	4.3	2.9	6.2	3.8	3.7	3.9
	PII(M2)	661	659	99.7	98.9	100	3745.2	3508.8	3997.7
	PIII(M7)	655	655	100	99.4	100	8359.4	7820.8	8935.1
	PIII[M12-16]	503[a]	502	99.8	98.9	100	1862.8	1697.1	2044.7
	PIII(M18)	587	587	100	99.4	100	1570.8	1448.3	1703.7
	PIII(M24)	548	548	100	99.3	100	1263.4	1165.1	1370.1
	PIII(M36)	570	570	100	99.4	100	995.0	918.1	1078.4
	PIII(M48)	559	559	100	99.3	100	885.6	816.3	960.8

[a] The number of subjects at M12-M16 was reduced compared to that at M7 and M18 because at the time of the protocol amendment to implement the extension study, some subjects were too late for the M12-M16 Visit and directly attended the Month 18 Visit.
S- = seronegative subjects (antibody titer < 7 EL.U/mL) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 7 EL.U/mL) prior to vaccination
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with antibody titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination
PII(M2) = Post Dose II (Month 2)
PIII(M7) = Post Dose III (Month 7)
PIII[M12-M16] = Post Dose III (Month 12- Month 16)
PIII(M18) = Post Dose III (Month 18)
PIII(M36) = Post Dose III (Month 36)
PIII(M48) = Post Dose III (Month 48)

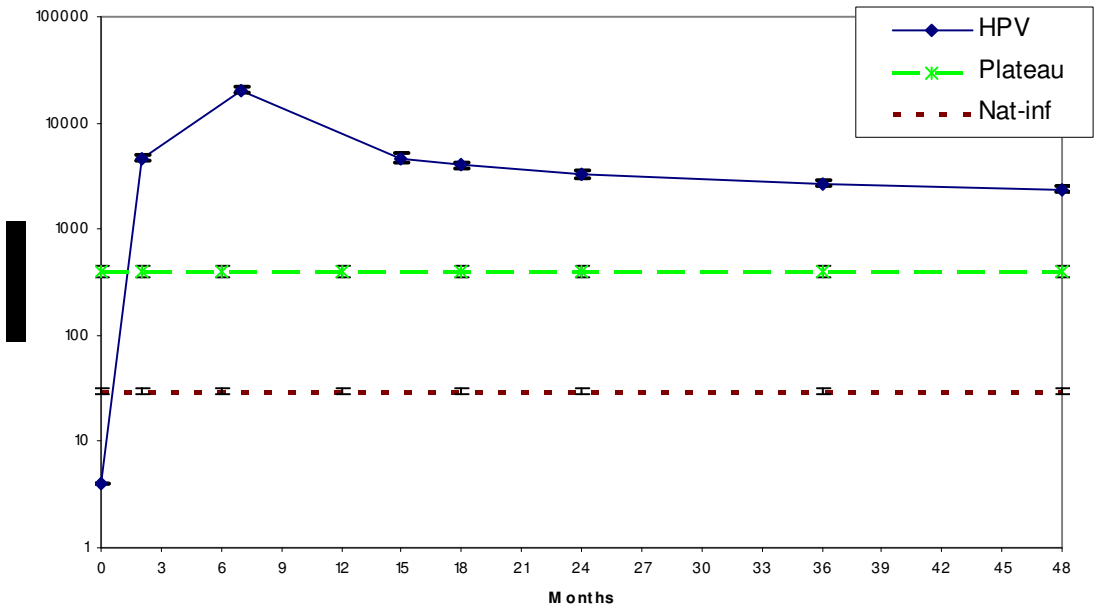
Secondary Outcome Variable (s):
Seropositivity rates and GMTs for anti-MPL antibodies by pre-vaccination status (ATP cohort for immunogenicity)

Group	**Pre-vaccination status**	**Timing**	**N**	**≥ 59 EL.U/mL**				**GMT (EL.U/mL)**		
				n	**%**	**95% CI**		**Value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
HPV	S-	PRE	6	0	0.0	0.0	45.9	29.5	29.5	29.5
		PII(M2)	6	5	83.3	35.9	99.6	133.5	52.0	343.0
		PIII(M7)	6	6	100	54.1	100	274.1	152.3	493.5
		PIII(M12)	5	3	60.0	14.7	94.7	96.8	24.8	377.8
		PIII(M18)	5	3	60.0	14.7	94.7	91.7	23.3	361.8
		PIII(M24)	99	85	85.9	77.4	92.0	187.8	155.8	226.4
		PIII(M36)	103	67	65.0	55.0	74.2	141.4	111.2	179.9
		PIII(M48)	102	71	69.6	59.7	78.3	116.2	94.8	142.4
	S+	PRE	132	132	100	97.2	100	156.3	141.8	172.3
		PII(M2)	132	132	100	97.2	100	423.5	373.9	479.8
		PIII(M7)	130	130	100	97.2	100	741.5	639.9	859.2
		PIII(M12)	113	112	99.1	95.2	100	380.5	330.5	438.1
		PIII(M18)	123	121	98.4	94.2	99.8	366.5	316.1	424.8
		PIII(M24)	452	430	95.1	92.7	96.9	294.3	272.1	318.4
		PIII(M36)	468	392	83.8	80.1	87.0	248.8	225.6	274.5
		PIII(M48)	456	389	85.3	81.7	88.4	185.1	169.6	202.0
	Total	PRE	138	132	95.7	90.8	98.4	145.4	130.3	162.2
		PII(M2)	138	137	99.3	96.0	100	402.8	354.0	458.3
		PIII(M7)	136	136	100	97.3	100	709.7	613.2	821.3
		PIII(M12)	118	115	97.5	92.7	99.5	359.1	309.5	416.6
		PIII(M18)	128	124	96.9	92.2	99.1	347.2	297.8	404.7
		PIII(M24)	551	515	93.5	91.1	95.4	271.5	252.2	292.3
		PIII(M36)	571	459	80.4	76.9	83.6	224.7	204.8	246.6
		PIII(M48)	558	460	82.4	79.0	85.5	170.0	156.6	184.4
HAV	S-	PRE	13	0	0.0	0.0	24.7	29.5	29.5	29.5

		PII(M2)	13	2	15.4	1.9	45.4	34.1	27.5	42.3
		PIII(M7)	13	1	7.7	0.2	36.0	32.4	26.4	39.7
		PIII(M12)	6	1	16.7	0.4	64.1	36.8	20.9	64.9
		PIII(M18)	7	2	28.6	3.7	71.0	43.1	23.6	78.8
		PIII(M24)	63	5	7.9	2.6	17.6	33.2	30.0	36.8
	S+	PRE	128	128	100	97.2	100	149.5	137.5	162.5
		PII(M2)	127	120	94.5	89.0	97.8	138.9	124.4	155.1
		PIII(M7)	127	118	92.9	87.0	96.7	140.6	124.2	159.2
		PIII(M12)	113	95	84.1	76.0	90.3	135.7	117.0	157.4
		PIII(M18)	122	99	81.1	73.1	87.7	124.7	107.3	144.9
		PIII(M24)	275	158	57.5	51.4	63.4	88.9	78.6	100.5
	Total	PRE	141	128	90.8	84.7	95.0	128.7	115.4	143.6
		PII(M2)	140	122	87.1	80.4	92.2	121.9	107.9	137.8
		PIII(M7)	140	119	85.0	78.0	90.5	122.7	107.2	140.3
		PIII(M12)	119	96	80.7	72.4	87.3	127.1	109.2	147.8
		PIII(M18)	129	101	78.3	70.2	85.1	117.7	101.3	136.8
		PIII(M24)	338	163	48.2	42.8	53.7	74.0	66.3	82.6

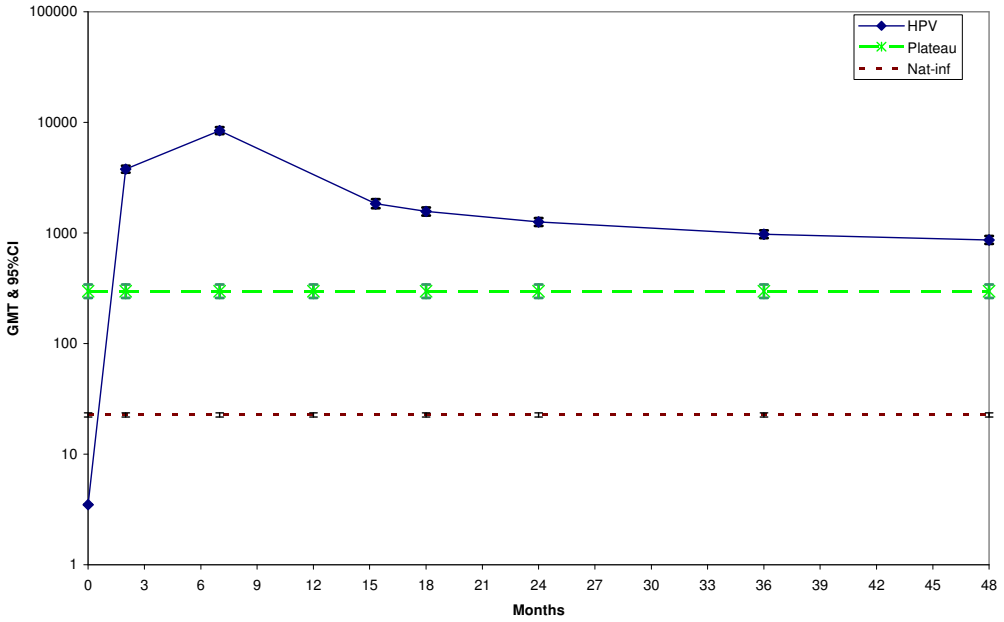
S- = seronegative subjects (antibody titer < 59 EL.U/ML) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 59 EL.U/ML) prior to vaccination
N = number of subjects with pre-vaccination results available
n (%) = number (percentage) of subjects with antibody titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit;
PRE = Pre-vaccination
PII(M2) = Post Dose II (Month 2)
PIII(M7) = Post Dose III (Month 7)
PIII(M12) = Post Dose III (Month 12)
PIII(M18) = Post Dose III (Month 18)
PIII(M36) = Post Dose III (Month 36)
PIII(M48) = Post Dose III (Month 48)

Secondary Outcome Variable (s):
Kinetic of anti-HPV-16 antibodies for subjects seronegative for HPV-16 at pre-vaccination up to Month 48 (HPV Group; ATP cohort for immunogenicity)



Nat Inf = Subjects in study HPV-008 who were HPV DNA negative or seropositive at enrolment.
Plateau = Subjects in study HPV-007 at the Month 45 - Month 50 time point, i.e., during the plateau phase.

Secondary Outcome Variable (s):
Kinetic of anti-HPV-18 antibodies for subjects seronegative for HPV-18 at pre-vaccination up to Month 48 (HPV Group; ATP cohort for immunogenicity)



Nat Inf = Subjects in study HPV-008 who were HPV DNA negative or seropositive at enrolment.
Plateau = Subjects in study HPV-007 at the Month 45 - Month 50 time point, i.e., during the plateau phase.

Secondary Outcome Variable (s):
Percentage of subjects reporting the occurrence of New Onset Chronic Diseases (GSK assessment) classified by MedDRA Preferred Term, up to Month 7 (Total Vaccinated Cohort)

New Onset Chronic Diseases (Month 0-7)	HPV Group N = 1035				HAV Group N = 1032			
	n	%	95% CI		n	%	95% CI	
			LL	UL			LL	UL
Subjects with any NOCD(s)	25	2.4	1.6	3.5	21	2.0	1.3	3.1
Rhinitis allergic	8	0.8	0.3	1.5	5	0.5	0.2	1.1
Asthma	4	0.4	0.1	1.0	3	0.3	0.1	0.8
Hypersensitivity	4	0.4	0.1	1.0	3	0.3	0.1	0.8
Urticaria	4	0.4	0.1	1.0	1	0.1	0.0	0.5
Dermatitis allergic	2	0.2	0.0	0.7	2	0.2	0.0	0.7
Conjunctivitis allergic	1	0.1	0.0	0.5	2	0.2	0.0	0.7
Dermatitis atopic	1	0.1	0.0	0.5	1	0.1	0.0	0.5
Hyperthyroidism	0	0.0	0.0	0.4	2	0.2	0.0	0.7
Seasonal allergy	0	0.0	0.0	0.4	2	0.2	0.0	0.7
Food allergy	1	0.1	0.0	0.5	0	0.0	0.0	0.4
Goitre	1	0.1	0.0	0.5	0	0.0	0.0	0.4

Subjects with any NOCD(s) = at least one NOCD experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the NOCD
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Percentage of subjects reporting the occurrence of New Onset Chronic Diseases (GSK assessment) classified by MedDRA Preferred Term, reported during the Month 0 to Month 12 follow-up period (Total Vaccinated Cohort)

New Onset Chronic Diseases (Month 0-12)	HPV Group N = 1035			HAV Group N = 1032		
	n	%	95% CI	n	%	95% CI

			LL	UL			LL	UL
Subjects with any NOCD(s)	32	3.1	2.1	4.3	28	2.7	1.8	3.9
Rhinitis allergic	10	1.0	0.5	1.8	5	0.5	0.2	1.1
Asthma	7	0.7	0.3	1.4	4	0.4	0.1	1.0
Hypersensitivity	4	0.4	0.1	1.0	3	0.3	0.1	0.8
Urticaria	4	0.4	0.1	1.0	2	0.2	0.0	0.7
Dermatitis allergic	2	0.2	0.0	0.7	2	0.2	0.0	0.7
Conjunctivitis allergic	1	0.1	0.0	0.5	2	0.2	0.0	0.7
Seasonal allergy	0	0.0	0.0	0.4	3	0.3	0.1	0.8
Dermatitis atopic	1	0.1	0.0	0.5	1	0.1	0.0	0.5
Dermatitis contact	2	0.2	0.0	0.7	0	0.0	0.0	0.4
Hyperthyroidism	0	0.0	0.0	0.4	2	0.2	0.0	0.7
Asthmatic crisis	0	0.0	0.0	0.4	1	0.1	0.0	0.5
Autoimmune thyroiditis	0	0.0	0.0	0.4	1	0.1	0.0	0.5
Food allergy	1	0.1	0.0	0.5	0	0.0	0.0	0.4
Goitre	1	0.1	0.0	0.5	0	0.0	0.0	0.4
House dust allergy	0	0.0	0.0	0.4	1	0.1	0.0	0.5
Hypothyroidism	0	0.0	0.0	0.4	1	0.1	0.0	0.5

Subjects with any NOCD(s) = at least one NOCD experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the NOCD
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Percentage of subjects reporting the occurrence of New Onset of Chronic Diseases (GSK assessment) classified by MedDRA Preferred Term, during the extension follow-up (Month 12 to Month 18) (Total Vaccinated Cohort)

New Onset Chronic Diseases (Month 12-18)	**HPV Group N = 626**				**HAV Group N = 619**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with any NOCD(s)	7	1.1	0.5	2.3	3	0.5	0.1	1.4
Asthma	2	0.3	0.0	1.1	1	0.2	0.0	0.9
Goitre	2	0.3	0.0	1.1	1	0.2	0.0	0.9
Dermatitis atopic	2	0.3	0.0	1.1	0	0.0	0.0	0.6
Hypersensitivity	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Psoriasis	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Vitiligo	1	0.2	0.0	0.9	0	0.0	0.0	0.6

Subjects with any NOCD(s) = at least one NOCD experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the NOCD
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Percentage of subjects reporting the occurrence of New Onset of Chronic Diseases (GSK assessment) classified by MedDRA Preferred Term, during the extension follow-up (Month 18 to Month 24) (Total Vaccinated Cohort)

New Onset Chronic Diseases (Month 18-24)	**HPV Group N = 617**				**HAV Group N = 571**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with any NOCD(s)	5	0.8	0.3	1.9	3	0.5	0.1	1.5
Psoriasis	1	0.2	0.0	0.9	1	0.2	0.0	1.0
Arthritis bacterial	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Asthma	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Autoimmune thyroiditis	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Dermatitis atopic	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Henoch-schonlein purpura	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Hypersensitivity	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Rhinitis allergic	0	0.0	0.0	0.6	1	0.2	0.0	1.0

Subjects with any NOCD(s) = at least one NOCD experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the NOCD
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Percentage of subjects reporting the occurrence of New Onset of Chronic Diseases (GSK assessment) classified by MedDRA Preferred Term, during the extension follow-up (Month 24 to Month 36) (Total Vaccinated Cohort)

New Onset Chronic Diseases (Month 24-36)	**HPV Group N = 601**				**HAV Group**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with any NOCD(s)	7	1.2	0.5	2.4	-	-	-	-
Idiopathic thrombocytopenic purpura	1	0.2	0	0.9	-	-	-	-
Goitre	1	0.2	0	0.9	-	-	-	-
Seasonal allergy	3	0.5	0.1	1.5	-	-	-	-
Asthma	2	0.3	0	1.2	-	-	-	-
Asthmatic crisis	1	0.2	0	0.9	-	-	-	-

Subjects with any NOCD(s) = at least one NOCD experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the NOCD
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Percentage of subjects reporting the occurrence of New Onset of Chronic Diseases (GSK assessment) classified by MedDRA Preferred Term, during the extension follow-up (Month 36 to Month 48) (Total Vaccinated Cohort)

New Onset Chronic Diseases (Month 36-48)	**HPV N = 588**				**HAV Group**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with any NOCD(s)	6	1.0	0.4	2.2	-	-	-	-
Autoimmune thyroiditis	2	0.3	0.0	1.2	-	-	-	-
Goitre	1	0.2	0.0	0.9	-	-	-	-
Hypersensitivity	1	0.2	0.0	0.9	-	-	-	-
Henoch-schonlein purpura	1	0.2	0.0	0.9	-	-	-	-
Psoriasis	1	0.2	0.0	0.9	-	-	-	-
Urticaria	1	0.2	0.0	0.9	-	-	-	-

Subjects with any NOCD(s) = at least one NOCD experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the NOCD
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Number (%) of subjects with medically significant adverse events reported up to Month 7 (Total Vaccinated Cohort)

Most frequent Medically significant AEs (Month 0-7)	**HPV Group N = 1035**				**HAV Group N = 1032**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with at least one AE	197	19.0	16.7	21.6	223	21.6	19.1	24.2
Influenza	7	0.7	0.3	1.4	17	1.6	1.0	2.6
Bronchitis	10	1.0	0.5	1.8	10	1.0	0.5	1.8
Rhinitis allergic	10	1.0	0.5	1.8	7	0.7	0.3	1.4
Viral infection	7	0.7	0.3	1.4	9	0.9	0.4	1.6
Cough	7	0.7	0.3	1.4	8	0.8	0.3	1.5
Headache	5	0.5	0.2	1.1	9	0.9	0.4	1.6
Pharyngolaryngeal pain	9	0.9	0.4	1.6	5	0.5	0.2	1.1

Acne	4	0.4	0.1	1.0	8	0.8	0.3	1.5
Otitis media	5	0.5	0.2	1.1	7	0.7	0.3	1.4
Asthma	6	0.6	0.2	1.3	4	0.4	0.1	1.0
Influenza like illness	5	0.5	0.2	1.1	5	0.5	0.2	1.1
Lice infestation	3	0.3	0.1	0.8	7	0.7	0.3	1.4
Abdominal pain	6	0.6	0.2	1.3	3	0.3	0.1	0.8
Migraine	6	0.6	0.2	1.3	2	0.2	0.0	0.7
Rash	3	0.3	0.1	0.8	5	0.5	0.2	1.1
Ear infection	5	0.5	0.2	1.1	2	0.2	0.0	0.7
Impetigo	2	0.2	0.0	0.7	5	0.5	0.2	1.1
Joint sprain	1	0.1	0.0	0.5	5	0.5	0.2	1.1

At least one symptom = at least one medically significant AE experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the symptom
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Number (%) of subjects with medically significant adverse events during the Month 0-12 follow-up period (Total Vaccinated Cohort)

Most frequent Medically significant AEs (Month 0-12)	**HPV Group N = 1035**				**HAV Group N = 1032**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with at least one AE	214	20.7	18.2	23.3	244	23.6	21.1	26.4
Bronchitis	13	1.3	0.7	2.1	11	1.1	0.5	1.9
Influenza	7	0.7	0.3	1.4	17	1.6	1.0	2.6
Rhinitis allergic	10	1.0	0.5	1.8	7	0.7	0.3	1.4
Viral infection	7	0.7	0.3	1.4	9	0.9	0.4	1.6
Cough	7	0.7	0.3	1.4	8	0.8	0.3	1.5
Headache	6	0.6	0.2	1.3	9	0.9	0.4	1.6
Asthma	8	0.8	0.3	1.5	6	0.6	0.2	1.3
Pharyngolaryngeal pain	9	0.9	0.4	1.6	5	0.5	0.2	1.1
Abdominal pain	10	1.0	0.5	1.8	3	0.3	0.1	0.8
Dermatitis	5	0.5	0.2	1.1	1	0.1	0.0	0.5
Ear infection	5	0.5	0.2	1.1	2	0.2	0.0	0.7
Influenza like illness	5	0.5	0.2	1.1	5	0.5	0.2	1.1
Impetigo	2	0.2	0.0	0.7	6	0.6	0.2	1.3
Otitis media	5	0.5	0.2	1.1	8	0.8	0.3	1.5
Acne	4	0.4	0.1	1.0	8	0.8	0.3	1.5
Lice infestation	3	0.3	0.1	0.8	7	0.7	0.3	1.4
Migraine	6	0.6	0.2	1.3	2	0.2	0.0	0.7

At least one symptom = at least one medically significant AE experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose.
N (%) = number (percentage) of subjects reporting at least once the medically significant AE
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Number (%) of subjects with medically significant adverse events during the Month 12-18 follow-up period (Total Vaccinated Cohort)

Most frequent Medically significant AEs (Month 12-18)	**HPV Group N = 626**				**HAV Group N = 619**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with at least one AE	53	8.5	6.4	10.9	27	4.4	2.9	6.3
Bronchitis	5	0.8	0.3	1.9	5	0.8	0.3	1.9
Abdominal pain	2	0.3	0.0	1.1	2	0.3	0.0	1.2
Acne	2	0.3	0.0	1.1	2	0.3	0.0	1.2
Arthralgia	3	0.5	0.1	1.4	0	0.0	0.0	0.6

Asthma	2	0.3	0.0	1.1	1	0.2	0.0	0.9
Conjunctivitis	3	0.5	0.1	1.4	0	0.0	0.0	0.6
Eczema	3	0.5	0.1	1.4	0	0.0	0.0	0.6
Goitre	2	0.3	0.0	1.1	1	0.2	0.0	0.9
Migraine	1	0.2	0.0	0.9	2	0.3	0.0	1.2
Ovarian cyst	2	0.3	0.0	1.1	1	0.2	0.0	0.9
Syncope	1	0.2	0.0	0.9	2	0.3	0.0	1.2
Bacterial infection	2	0.3	0.0	1.1	0	0.0	0.0	0.6
Cellulitis	0	0.0	0.0	0.6	2	0.3	0.0	1.2
Dermatitis atopic	2	0.3	0.0	1.1	0	0.0	0.0	0.6
Facial palsy	1	0.2	0.0	0.9	1	0.2	0.0	0.9
Headache	1	0.2	0.0	0.9	1	0.2	0.0	0.9
Ludwig angina	1	0.2	0.0	0.9	1	0.2	0.0	0.9
Lymphadenitis	2	0.3	0.0	1.1	0	0.0	0.0	0.6
Psoriasis	1	0.2	0.0	0.9	1	0.2	0.0	0.9
Skin papilloma	2	0.3	0.0	1.1	0	0.0	0.0	0.6
Breast cyst	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Infectious mononucleosis	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Orthostatic hypotension	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Otitis externa	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Abdominal pain upper	1	0.2	0.0	0.9	1	0.2	0.0	0.9
Gastritis	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Suicide attempt	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Tinea pedis	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Vaginal discharge	0	0.0	0.0	0.6	1	0.2	0.0	0.9
Wound	0	0.0	0.0	0.6	1	0.2	0.0	0.9

At least one symptom = at least one medically significant AE experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose.
N (%) = number (percentage) of subjects reporting at least once the medically significant AE
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Number (%) of subjects with medically significant adverse events during the Month 18-24 follow-up period (Total Vaccinated Cohort)

Most frequent Medically significant AEs (Month 18-24)	**HPV Group N = 617**				**HAV Group N = 571**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with at least one AE	40	6.5	4.7	8.7	21	3.7	2.3	5.6
Abdominal pain	5	0.8	0.3	1.9	1	0.2	0.0	1.0
Eczema	4	0.6	0.2	1.7	0	0.0	0.0	0.6
Acne	1	0.2	0.0	0.9	2	0.4	0.0	1.3
Headache	2	0.3	0.0	1.2	1	0.2	0.0	1.0
Syncope	2	0.3	0.0	1.2	1	0.2	0.0	1.0
Cellulitis	2	0.3	0.0	1.2	0	0.0	0.0	0.6
Dermatitis atopic	1	0.2	0.0	0.9	1	0.2	0.0	1.0
Exposure to communicable disease	1	0.2	0.0	0.9	1	0.2	0.0	1.0
Hypersensitivity	2	0.3	0.0	1.2	0	0.0	0.0	0.6
Pneumonia	1	0.2	0.0	0.9	1	0.2	0.0	1.0
Rhinitis allergic	0	0.0	0.0	0.6	2	0.4	0.0	1.3
Skin fissures	2	0.3	0.0	1.2	0	0.0	0.0	0.6
Abdominal hernia	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Abdominal pain upper	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Alopecia	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Arthritis bacterial	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Asthma	1	0.2	0.0	0.9	0	0.0	0.0	0.6

Attention deficit/hyperactivity disorder	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Autoimmune thyroiditis	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Back pain	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Blood pressure decreased	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Bronchial hyperreactivity	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Bronchitis	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Bronchitis chronic	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Constipation	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Contusion	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Dermoid cyst of ovary	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Dizziness	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Enteritis	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Gastritis	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Henoch-schonlein purpura	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Herpes zoster	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Lice infestation	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Loss of consciousness	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Melanocytic naevus	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Nail tinea	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Neurodermatitis	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Pityriasis rosea	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Premature labor	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Psoriasis	1	0.2	0.0	0.9	1	0.2	0.0	1.0
Oral herpes	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Ovarian cyst	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Sialoadenitis	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Sinus tachycardia	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Skull fractured base	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Splenic rupture	0	0.0	0.0	0.6	1	0.2	0.0	1.0
Suicide attempt	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Subcutaneous abscess	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Tinea pedis	1	0.2	0.0	0.9	0	0.0	0.0	0.6
Uterine leiomyoma	1	0.2	0.0	0.9	0	0.0	0.0	0.6

At least one symptom = at least one medically significant AE experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose.
N (%) = number (percentage) of subjects reporting at least once the medically significant AE
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Number (%) of subjects with medically significant adverse events during the Month 24-36 follow-up period (Total Vaccinated Cohort)

Most frequent Medically significant AEs (Month 24-36)	**HPV Group N = 601**				**HAV Group**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
Subjects with at least one AE	41	6.8	4.9	9.1	-	-	-	-
Idiopathic thrombocytopenic purpura	1	0.2	0.0	0.9	-	-	-	-
Iron deficiency anaemia	1	0.2	0.0	0.9	-	-	-	-
Mitral valve disease	1	0.2	0.0	0.9	-	-	-	-
Palpitations	1	0.2	0.0	0.9	-	-	-	-
Abdominal pain	2	0.3	0.0	1.2	-	-	-	-
Constipation	2	0.3	0.0	1.2	-	-	-	-
Dyspepsia	1	0.2	0.0	0.9	-	-	-	-
Gastritis	3	0.5	0.1	1.5	-	-	-	-
Umbilical hernia	1	0.2	0.0	0.9	-	-	-	-
Chest pain	1	0.2	0.0	0.9	-	-	-	-

Pyrexia	1	0.2	0.0	0.9	-	-	-	-
Seasonal allergy	3	0.5	0.1	1.5	-	-	-	-
Bronchitis	1	0.2	0.0	0.9	-	-	-	-
Parotitis	1	0.2	0.0	0.9	-	-	-	-
Pilonidal cyst	1	0.2	0.0	0.9	-	-	-	-
Postpartum sepsis	1	0.2	0.0	0.9	-	-	-	-
Subcutaneous abscess	1	0.2	0.0	0.9	-	-	-	-
Concussion	1	0.2	0.0	0.9	-	-	-	-
Joint sprain	1	0.2	0.0	0.9	-	-	-	-
Thermal burn	1	0.2	0.0	0.9	-	-	-	-
Traumatic brain injury	1	0.2	0.0	0.9	-	-	-	-
Upper limb fracture	1	0.2	0.0	0.9	-	-	-	-
Dehydration	1	0.2	0.0	0.9	-	-	-	-
Arthralgia	1	0.2	0.0	0.9	-	-	-	-
Back pain	1	0.2	0.0	0.9	-	-	-	-
Pain in extremity	1	0.2	0.0	0.9	-	-	-	-
Tendonitis	1	0.2	0.0	0.9	-	-	-	-
Convulsion	1	0.2	0.0	0.9	-	-	-	-
Migraine	3	0.5	0.1	1.5	-	-	-	-
Presyncope	1	0.2	0.0	0.9	-	-	-	-
Syncope	1	0.2	0.0	0.9	-	-	-	-
Bulimia nervosa	1	0.2	0.0	0.9	-	-	-	-
Depressed mood	1	0.2	0.0	0.9	-	-	-	-
Depression	2	0.3	0.0	1.2	-	-	-	-
Amenorrhea	1	0.2	0.0	0.9	-	-	-	-
Breast pain	1	0.2	0.0	0.9	-	-	-	-
Ovarian cyst	1	0.2	0.0	0.9	-	-	-	-
Ovarian cyst torsion	1	0.2	0.0	0.9	-	-	-	-
Asthma	2	0.3	0.0	1.2	-	-	-	-
Asthmatic crisis	2	0.3	0.0	1.2	-	-	-	-

At least one symptom = at least one medically significant AE experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the medically significant AE
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Number (%) of subjects with medically significant adverse events during the Month 36-48 follow-up period (Total Vaccinated Cohort)

Most frequent Medically significant AEs (Month 36-48)	**HPV N = 588**				**HAV Group**			
	n	**%**	**95% CI**		**n**	**%**	**95% CI**	
			LL	**UL**			**LL**	**UL**
At least one symptom	50	8.5	6.4	11.1	-	-	-	-
Sickle cell anaemia	1	0.2	0.0	0.9	-	-	-	-
Tinnitus	1	0.2	0.0	0.9	-	-	-	-
Autoimmune thyroiditis	2	0.3	0.0	1.2	-	-	-	-
Abdominal pain	2	0.3	0.0	1.2	-	-	-	-
Diarrhoea	1	0.2	0.0	0.9	-	-	-	-
Gastritis	5	0.9	0.3	2.0	-	-	-	-
Malocclusion	1	0.2	0.0	0.9	-	-	-	-
Cholelithiasis	1	0.2	0.0	0.9	-	-	-	-
Drug hypersensitivity	1	0.2	0.0	0.9	-	-	-	-
Food allergy	1	0.2	0.0	0.9	-	-	-	-
Hypersensitivity	1	0.2	0.0	0.9	-	-	-	-
Cystitis	1	0.2	0.0	0.9	-	-	-	-
Herpes zoster	1	0.2	0.0	0.9	-	-	-	-
Infectious mononucleosis	1	0.2	0.0	0.9	-	-	-	-

Ludwig angina	1	0.2	0.0	0.9	-	-	-	-
Meningitis viral	1	0.2	0.0	0.9	-	-	-	-
Otitis media	1	0.2	0.0	0.9	-	-	-	-
Pertussis	1	0.2	0.0	0.9	-	-	-	-
Alcohol poisoning	1	0.2	0.0	0.9	-	-	-	-
Concussion	1	0.2	0.0	0.9	-	-	-	-
Foot fracture	1	0.2	0.0	0.9	-	-	-	-
Hand fracture	1	0.2	0.0	0.9	-	-	-	-
Humerus fracture	1	0.2	0.0	0.9	-	-	-	-
Joint sprain	1	0.2	0.0	0.9	-	-	-	-
Lower limb fracture	1	0.2	0.0	0.9	-	-	-	-
Wound	2	0.3	0.0	1.2	-	-	-	-
Investigation	1	0.2	0.0	0.9	-	-	-	-
Back pain	2	0.3	0.0	1.2	-	-	-	-
Kyphosis	1	0.2	0.0	0.9	-	-	-	-
Pituitary tumour benign	1	0.2	0.0	0.9	-	-	-	-
Migraine	3	0.5	0.1	1.5	-	-	-	-
Abortion spontaneous	1	0.2	0.0	0.9	-	-	-	-
Abortion spontaneous incomplete	1	0.2	0.0	0.9	-	-	-	-
Pre-eclampsia	1	0.2	0.0	0.9	-	-	-	-
Breast pain	1	0.2	0.0	0.9	-	-	-	-
Polycystic ovaries	3	0.5	0.1	1.5	-	-	-	-
Vaginal discharge	1	0.2	0.0	0.9	-	-	-	-
Asthmatic crisis	2	0.3	0.0	1.2	-	-	-	-
Bronchial hyperreactivity	1	0.2	0.0	0.9	-	-	-	-
Bronchospasm	1	0.2	0.0	0.9	-	-	-	-
Henoch-schonlein purpura	1	0.2	0.0	0.9	-	-	-	-
Psoriasis	1	0.2	0.0	0.9	-	-	-	-
Urticaria	1	0.2	0.0	0.9	-	-	-	-

At least one symptom = at least one medically significant AE experienced (regardless of the MedDRA Preferred Term)
N = number of subjects with at least one administered dose
n (%) = number (percentage) of subjects reporting at least once the medically significant AE
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
Outcome of reported pregnancies (Month 0 to Month 18) (Total Vaccinated Cohort)

Outcome	**HPV Group**	**HAV Group**
Healthy baby	4	2
Premature birth	0	1
Elective abortion	1	1
Ongoing	3	5
Unknown	1	0
Total	**9**	**9**

Secondary Outcome Variable (s):
Outcome of reported pregnancies (Month 18 to Month 24) (Total Vaccinated Cohort)

Outcome	**HPV Group**	**HAV Group**
Healthy baby	4	1
Ongoing	3	0
Unknown	1	0
Total	**8**	**1**

Secondary Outcome Variable (s):
Outcome of reported pregnancies (Month 24 to Month 36) (Total Vaccinated Cohort)

Outcome	**HPV Group**	**HAV Group**
Healthy baby	3	-
Total	**3**	**-**

Secondary Outcome Variable (s):
Outcome of reported pregnancies (Month 36 to Month 48) (Total Vaccinated Cohort)

Outcome	HPV Group	HAV Group
Healthy infant	9	-
Premature infant	1	-
Miscarriage /spontaneous abortion /fetal death	1	-
Total	11	-

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

Laboratory test	Pre-vaccination	Timing	Parameters or Categories	HPV Group		HAV Group	
				Value or n	%	Value or n	%
ALT	Normal	PII(M2)	N	668	-	678	-
			Normal	653	98.0	662	98.2
			Below	2	0.3	6	0.9
			Above	11	1.7	6	0.9
			Missing	2	-	4	-
		PIII(M7)	N	662	-	672	-
			Normal	642	97.0	652	97.5
			Below	7	1.1	10	1.5
			Above	13	2.0	7	1.0
			Missing	0	0.0	3	-
	Below	PII(M2)	N	8	-	8	-
			Normal	7	87.5	7	87.5
			Below	1	12.5	1	12.5
		PIII(M7)	N	8	-	8	-
			Normal	5	62.5	6	75.0
			Below	3	37.5	2	25.0
	Above	PII(M2)	N	17	-	7	-
			Normal	13	76.5	3	42.9
			Above	4	23.5	4	57.1
		PIII(M7)	N	17	-	7	-
			Normal	16	94.1	5	71.4
			Above	1	5.9	2	28.6
Basophils	Normal	PII(M2)	N	674	-	677	-
			Normal	660	98.1	660	97.8
			Above	13	1.9	15	2.2
			Missing	1	-	2	-
		PIII(M7)	N	668	-	670	-
			Normal	652	98.0	658	98.5
			Above	13	2.0	10	1.5
			Missing	3	-	2	-
	Below	PII(M2)	N	1	-	0	-
			Normal	1	100	0	0.0
		PIII(M7)	N	1	-	0	-
			Normal	1	100	0	0.0
	Above	PII(M2)	N	19	-	13	-
			Normal	13	68.4	7	53.8
			Above	6	31.6	6	46.2
		PIII(M7)	N	19	-	13	-
			Normal	17	94.4	11	84.6
			Above	1	5.6	2	15.4
			Missing	1	-	0	0.0
Creatinine	Normal	PII(M2)	N	667	-	658	-
			Normal	643	96.8	630	96.3
			Below	21	3.2	24	3.7
			Missing	3	-	4	-

		PIII(M7)	N	661	-	649	-
			Normal	639	96.8	626	96.6
			Below	17	2.6	18	2.8
			Above	4	0.6	4	0.6
			Missing	1	-	1	-
	Below	PII(M2)	N	21	-	30	-
			Normal	10	47.6	12	40.0
			Below	11	52.4	18	60.0
		PIII(M7)	N	21	-	30	-
			Normal	13	61.9	16	53.3
			Below	8	38.1	14	46.7
	Above	PII(M2)	N	4	-	3	-
			Normal	2	50.0	3	100
			Below	1	25.0	0	0.0
			Above	1	25.0	0	0.0
		PIII(M7)	N	4	-	3	-
			Normal	2	50.0	3	100
			Below	1	25.0	0	0.0
			Above	1	25.0	0	0.0
Eosinophils	Normal	PII(M2)	N	566	-	555	-
			Normal	500	88.5	498	89.9
			Below	7	1.2	4	0.7
			Above	58	10.3	52	9.4
			Missing	1	-	1	-
		PIII(M7)	N	561	-	549	-
			Normal	491	88.2	489	89.2
			Below	7	1.3	3	0.5
			Above	59	10.6	56	10.2
			Missing	4	-	1	-
	Below	PII(M2)	N	6	-	10	-
			Normal	5	83.3	6	60.0
			Below	1	16.7	3	30.0
			Above	0	0.0	1	10.0
		PIII(M7)	N	7	-	10	-
			Normal	6	85.7	6	60.0
			Below	1	14.3	3	30.0
			Above	0	0.0	1	10.0
	Above	PII(M2)	N	122	-	126	-
			Normal	49	40.2	64	50.8
			Below	1	0.8	0	0.0
			Above	72	59.0	62	49.2
		PIII(M7)	N	120	-	125	-
			Normal	61	50.8	72	57.6
			Above	59	49.2	53	42.4
Hematocrit	Normal	PII(M2)	N	589	-	584	-
			Normal	544	92.4	542	92.8
			Below	33	5.6	34	5.8
			Above	12	2.0	8	1.4
		PIII(M7)	N	583	-	580	-
			Normal	525	90.8	539	92.9
			Below	34	5.9	28	4.8
			Above	19	3.3	13	2.2
			Missing	5	-	0	0.0
	Below	PII(M2)	N	95	-	102	-
			Normal	44	46.3	42	41.2

			Below	51	53.7	60	58.8
		PIII(M7)	N	94	-	100	-
			Normal	46	48.9	48	48.0
			Below	48	51.1	52	52.0
	Above	PII(M2)	N	10	-	7	-
			Normal	6	60.0	7	100
			Above	4	40.0	0	0.0
		PIII(M7)	N	10	-	7	-
			Normal	6	60.0	5	71.4
			Above	4	40.0	2	28.6
Lymphocytes	Normal	PII(M2)	N	559	-	554	-
			Normal	498	89.1	498	90.1
			Below	21	3.8	15	2.7
			Above	40	7.2	40	7.2
			Missing	0	0.0	1	-
		PIII(M7)	N	552	-	547	-
			Normal	476	86.9	488	89.2
			Below	21	3.8	9	1.6
			Above	51	9.3	50	9.1
			Missing	4	-	0	0.0
	Below	PII(M2)	N	20	-	13	-
			Normal	16	84.2	9	69.2
			Below	2	10.5	4	30.8
			Above	1	5.3	0	0.0
			Missing	1	-	0	0.0
		PIII(M7)	N	20	-	13	-
			Normal	13	65.0	8	61.5
			Below	6	30.0	5	38.5
			Above	1	5.0	0	0.0
	Above	PII(M2)	N	115	-	124	-
			Normal	54	47.0	62	50.0
			Below	1	0.9	3	2.4
			Above	60	52.2	59	47.6
		PIII(M7)	N	115	-	124	-
			Normal	54	47.8	66	53.7
			Below	5	4.4	0	0.0
			Above	54	47.8	57	46.3
			Missing	2	-	1	-
Monocytes	Normal	PII(M2)	N	645	-	655	-
			Normal	621	96.4	626	95.9
			Below	9	1.4	6	0.9
			Above	14	2.2	21	3.2
			Missing	1	-	2	-
		PIII(M7)	N	638	-	648	-
			Normal	603	95.1	622	96.3
			Below	12	1.9	7	1.1
			Above	19	3.0	17	2.6
			Missing	4	-	2	-
	Below	PII(M2)	N	15	-	12	-
			Normal	11	73.3	9	75.0
			Below	4	26.7	3	25.0
		PIII(M7)	N	15	-	12	-
			Normal	13	86.7	10	83.3
			Below	2	13.3	2	16.7
	Above	PII(M2)	N	34	-	24	-

			Normal	24	70.6	16	66.7
			Above	10	29.4	8	33.3
		PIII(M7)	N	34	-	24	-
			Normal	25	73.5	16	66.7
			Above	9	26.5	8	33.3
Neutrophils	Normal	PII(M2)	N	572	-	558	-
			Normal	498	87.2	504	90.6
			Below	54	9.5	38	6.8
			Above	19	3.3	14	2.5
			Missing	1	-	2	-
		PIII(M7)	N	568	-	551	-
			Normal	487	86.5	488	88.6
			Below	54	9.6	51	9.3
			Above	22	3.9	12	2.2
			Missing	5	-	0	0.0
	Below	PII(M2)	N	99	-	115	-
			Normal	47	47.5	51	44.3
			Below	52	52.5	64	55.7
		PIII(M7)	N	99	-	115	-
			Normal	47	48.5	52	45.6
			Below	48	49.5	62	54.4
			Above	2	2.1	0	0.0
			Missing	2	-	1	-
	Above	PII(M2)	N	15	-	9	-
			Normal	10	71.4	9	100
			Above	4	28.6	0	0.0
			Missing	1	-	0	0.0
		PIII(M7)	N	14	-	9	-
			Normal	10	71.4	6	66.7
			Above	4	28.6	3	33.3
Platelets	Normal	PII(M2)	N	664	-	664	-
			Normal	648	97.6	645	97.1
			Below	2	0.3	2	0.3
			Above	14	2.1	17	2.6
		PIII(M7)	N	659	-	657	-
			Normal	641	98.0	644	98.0
			Below	5	0.8	4	0.6
			Above	8	1.2	9	1.4
			Missing	5	-	0	0.0
	Below	PII(M2)	N	7	-	4	-
			Normal	3	42.9	0	0.0
			Below	4	57.1	4	100
		PIII(M7)	N	7	-	5	-
			Normal	4	57.1	3	60.0
			Below	3	42.9	2	40.0
	Above	PII(M2)	N	23	-	25	-
			Normal	10	43.5	12	48.0
			Above	13	56.5	13	52.0
		PIII(M7)	N	21	-	25	-
			Normal	15	71.4	18	72.0
			Above	6	28.6	7	28.0
Red blood cells	Normal	PII(M2)	N	561	-	592	-
			Normal	522	93.2	560	94.6
			Below	21	3.8	19	3.2
			Above	17	3.0	13	2.2

			Missing	1	-	0	0.0
		PIII(M7)	N	558	-	589	-
			Normal	517	93.3	550	93.4
			Below	22	4.0	24	4.1
			Above	15	2.7	15	2.5
			Missing	4	-	0	0.0
	Below	PII(M2)	N	61	-	42	-
			Normal	30	49.2	22	52.4
			Below	30	49.2	20	47.6
			Above	1	1.6	0	0.0
		PIII(M7)	N	60	-	39	-
			Normal	35	58.3	25	64.1
			Below	23	38.3	14	35.9
			Above	2	3.3	0	0.0
	Above	PII(M2)	N	72	-	59	-
			Normal	18	25.0	15	25.4
			Above	54	75.0	44	74.6
		PIII(M7)	N	69	-	59	-
			Normal	23	33.8	19	32.2
			Below	0	0.0	1	1.7
			Above	45	66.2	39	66.1
			Missing	1	-	0	0.0
White blood cells	Normal	PII(M2)	N	645	-	647	-
			Normal	601	93.2	607	93.8
			Below	27	4.2	22	3.4
			Above	17	2.6	18	2.8
		PIII(M7)	N	639	-	643	-
			Normal	589	92.9	590	91.8
			Below	24	3.8	28	4.4
			Above	21	3.3	25	3.9
			Missing	5	-	0	0.0
	Below	PII(M2)	N	20	-	25	-
			Normal	12	60.0	17	68.0
			Below	8	40.0	8	32.0
		PIII(M7)	N	20	-	24	-
			Normal	12	60.0	18	75.0
			Below	8	40.0	6	25.0
	Above	PII(M2)	N	29	-	21	-
			Normal	20	69.0	17	81.0
			Below	1	3.4	0	0.0
			Above	8	27.6	4	19.0
		PIII(M7)	N	28	-	20	-
			Normal	23	82.1	15	75.0
			Above	5	17.9	5	25.0

N = number of subjects with available results
n = number of subjects in a given category
Value = value of the considered parameter
% = n / N x 100
PII(M2) = Post Dose II (Month 2)
PIII(M7) = Post Dose III (Month 7)

Secondary Outcome Variable (s):
Incidence of solicited local symptoms reported during the 7-day (Day 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	1028	800	77.8	75.2	80.3	1027	498	48.5	45.4	51.6
	Grade 3	1028	53	5.2	3.9	6.7	1027	8	0.8	0.3	1.5
Redness	Any	1028	287	27.9	25.2	30.8	1027	160	15.6	13.4	17.9
	> 50 mm	1028	4	0.4	0.1	1.0	1027	1	0.1	0.0	0.5
Swelling	Any	1028	215	20.9	18.5	23.5	1027	97	9.4	7.7	11.4
	> 50 mm	1028	12	1.2	0.6	2.0	1027	4	0.4	0.1	1.0
Dose 2											
Pain	Any	1021	680	66.6	63.6	69.5	1021	393	38.5	35.5	41.6
	Grade 3	1021	45	4.4	3.2	5.9	1021	2	0.2	0.0	0.7
Redness	Any	1021	258	25.3	22.6	28.1	1021	136	13.3	11.3	15.6
	> 50 mm	1021	2	0.2	0.0	0.7	1021	2	0.2	0.0	0.7
Swelling	Any	1021	217	21.3	18.8	23.9	1021	88	8.6	7.0	10.5
	> 50 mm	1021	6	0.6	0.2	1.3	1021	3	0.3	0.1	0.9
Dose 3											
Pain	Any	1016	670	65.9	62.9	68.9	1010	372	36.8	33.8	39.9
	Grade 3	1016	56	5.5	4.2	7.1	1010	16	1.6	0.9	2.6
Redness	Any	1016	305	30.0	27.2	32.9	1010	122	12.1	10.1	14.2
	> 50 mm	1016	5	0.5	0.2	1.1	1010	1	0.1	0.0	0.6
Swelling	Any	1016	289	28.4	25.7	31.3	1010	76	7.5	6.0	9.3
	> 50 mm	1016	18	1.8	1.1	2.8	1010	0	0.0	0.0	0.4
Across Doses*											
Pain	Any	1028	888	86.4	84.1	88.4	1027	659	64.2	61.1	67.1
	Grade 3	1028	116	11.3	9.4	13.4	1027	24	2.3	1.5	3.5
Redness	Any	1028	466	45.3	42.3	48.4	1027	259	25.2	22.6	28.0
	> 50 mm	1028	11	1.1	0.5	1.9	1027	2	0.2	0.0	0.7
Swelling	Any	1028	430	41.8	38.8	44.9	1027	178	17.3	15.1	19.8
	> 50 mm	1028	30	2.9	2.0	4.1	1027	5	0.5	0.2	1.1

N = number of subjects with a 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 = occurrence of any solicited local symptom regardless of their intensity grade.
Grade 3 pain = pain that prevented normal activity
*Across doses means 'overall per subject'

Secondary Outcome Variable (s):
Incidence of solicited general symptoms reported during the 7-day (Day 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	1029	135	13.1	11.1	15.3	1027	118	11.5	9.6	13.6
	Grade 3	1029	4	0.4	0.1	1.0	1027	2	0.2	0.0	0.7
	Related	1029	89	8.6	7.0	10.5	1027	73	7.1	5.6	8.9
Fatigue	Any	1029	335	32.6	29.7	35.5	1027	313	30.5	27.7	33.4
	Grade 3	1029	16	1.6	0.9	2.5	1027	14	1.4	0.7	2.3
	Related	1029	197	19.1	16.8	21.7	1027	183	17.8	15.5	20.3
Fever (axillary)	≥ 37.5°C	1029	71	6.9	5.4	8.6	1027	62	6.0	4.7	7.7
	> 39.0°C	1029	7	0.7	0.3	1.4	1027	4	0.4	0.1	1.0
	Related	1029	41	4.0	2.9	5.4	1027	29	2.8	1.9	4.0
Gastro-intestinal	Any	1029	154	15.0	12.8	17.3	1027	143	13.9	11.9	16.2
	Grade 3	1029	13	1.3	0.7	2.2	1027	5	0.5	0.2	1.1
	Related	1029	69	6.7	5.3	8.4	1027	64	6.2	4.8	7.9

Headache	Any	1029	324	31.5	28.7	34.4	1027	331	32.2	29.4	35.2
	Grade 3	1029	27	2.6	1.7	3.8	1027	16	1.6	0.9	2.5
	Related	1029	158	15.4	13.2	17.7	1027	173	16.8	14.6	19.3
Myalgia	Any	1029	349	33.9	31.0	36.9	1027	217	21.1	18.7	23.8
	Grade 3	1029	17	1.7	1.0	2.6	1027	4	0.4	0.1	1.0
	Related	1029	270	26.2	23.6	29.0	1027	143	13.9	11.9	16.2
Rash	Any	1029	46	4.5	3.3	5.9	1027	36	3.5	2.5	4.8
	Grade 3	1029	2	0.2	0.0	0.7	1027	1	0.1	0.0	0.5
	Related	1029	32	3.1	2.1	4.4	1027	21	2.0	1.3	3.1
Urticaria	Any	1029	34	3.3	2.3	4.6	1027	27	2.6	1.7	3.8
	Grade 3	1029	3	0.3	0.1	0.8	1027	2	0.2	0.0	0.7
	Related	1029	20	1.9	1.2	3.0	1027	9	0.9	0.4	1.7
Dose 2											
Arthralgia	Any	1021	107	10.5	8.7	12.5	1021	87	8.5	6.9	10.4
	Grade 3	1021	7	0.7	0.3	1.4	1021	0	0.0	0.0	0.4
	Related	1021	71	7.0	5.5	8.7	1021	61	6.0	4.6	7.6
Fatigue	Any	1021	268	26.2	23.6	29.1	1021	229	22.4	19.9	25.1
	Grade 3	1021	16	1.6	0.9	2.5	1021	12	1.2	0.6	2.0
	Related	1021	163	16.0	13.8	18.4	1021	132	12.9	10.9	15.1
Fever (axillary)	≥ 37.5°C	1021	74	7.2	5.7	9.0	1021	64	6.3	4.9	7.9
	> 39.0°C	1021	7	0.7	0.3	1.4	1021	6	0.6	0.2	1.3
	Related	1021	35	3.4	2.4	4.7	1021	24	2.4	1.5	3.5
Gastro-intestinal	Any	1021	116	11.4	9.5	13.5	1021	111	10.9	9.0	12.9
	Grade 3	1021	11	1.1	0.5	1.9	1021	8	0.8	0.3	1.5
	Related	1021	59	5.8	4.4	7.4	1021	56	5.5	4.2	7.1
Headache	Any	1021	281	27.5	24.8	30.4	1021	239	23.4	20.8	26.1
	Grade 3	1021	28	2.7	1.8	3.9	1021	18	1.8	1.0	2.8
	Related	1021	146	14.3	12.2	16.6	1021	110	10.8	8.9	12.8
Myalgia	Any	1021	268	26.2	23.6	29.1	1021	157	15.4	13.2	17.7
	Grade 3	1021	20	2.0	1.2	3.0	1021	3	0.3	0.1	0.9
	Related	1021	203	19.9	17.5	22.5	1021	111	10.9	9.0	12.9
Rash	Any	1021	43	4.2	3.1	5.6	1021	24	2.4	1.5	3.5
	Grade 3	1021	5	0.5	0.2	1.1	1021	1	0.1	0.0	0.5
	Related	1021	33	3.2	2.2	4.5	1021	10	1.0	0.5	1.8
Urticaria	Any	1021	28	2.7	1.8	3.9	1021	22	2.2	1.4	3.2
	Grade 3	1021	4	0.4	0.1	1.0	1021	3	0.3	0.1	0.9
	Related	1021	16	1.6	0.9	2.5	1021	10	1.0	0.5	1.8
Dose 3											
Arthralgia	Any	1016	127	12.5	10.5	14.7	1009	78	7.7	6.2	9.6
	Grade 3	1016	11	1.1	0.5	1.9	1009	3	0.3	0.1	0.9
	Related	1016	97	9.5	7.8	11.5	1009	50	5.0	3.7	6.5
Fatigue	Any	1016	290	28.5	25.8	31.4	1009	210	20.8	18.3	23.5
	Grade 3	1016	16	1.6	0.9	2.5	1009	9	0.9	0.4	1.7
	Related	1016	186	18.3	16.0	20.8	1009	137	13.6	11.5	15.8
Fever (axillary)	≥ 37.5°C	1016	94	9.3	7.5	11.2	1009	82	8.1	6.5	10.0
	> 39.0°C	1016	7	0.7	0.3	1.4	1009	7	0.7	0.3	1.4
	Related	1016	51	5.0	3.8	6.5	1009	36	3.6	2.5	4.9
Gastro-intestinal	Any	1016	112	11.0	9.2	13.1	1009	92	9.1	7.4	11.1
	Grade 3	1016	7	0.7	0.3	1.4	1009	10	1.0	0.5	1.8
	Related	1016	61	6.0	4.6	7.6	1009	55	5.5	4.1	7.0
Headache	Any	1016	286	28.1	25.4	31.0	1009	208	20.6	18.2	23.2
	Grade 3	1016	27	2.7	1.8	3.8	1009	14	1.4	0.8	2.3
	Related	1016	163	16.0	13.8	18.4	1009	118	11.7	9.8	13.8
Myalgia	Any	1016	273	26.9	24.2	29.7	1009	148	14.7	12.5	17.0
	Grade 3	1016	28	2.8	1.8	4.0	1009	7	0.7	0.3	1.4

	Related	1016	222	21.9	19.3	24.5	1009	112	11.1	9.2	13.2
Rash	Any	1016	48	4.7	3.5	6.2	1009	20	2.0	1.2	3.0
	Grade 3	1016	2	0.2	0.0	0.7	1009	1	0.1	0.0	0.6
	Related	1016	34	3.3	2.3	4.6	1009	8	0.8	0.3	1.6
Urticaria	Any	1016	20	2.0	1.2	3.0	1009	16	1.6	0.9	2.6
	Grade 3	1016	2	0.2	0.0	0.7	1009	1	0.1	0.0	0.6
	Related	1016	13	1.3	0.7	2.2	1009	10	1.0	0.5	1.8
Across Doses*											
Arthralgia	Any	1029	259	25.2	22.5	27.9	1027	204	19.9	17.5	22.4
	Grade 3	1029	21	2.0	1.3	3.1	1027	5	0.5	0.2	1.1
	Related	1029	184	17.9	15.6	20.4	1027	132	12.9	10.9	15.1
Fatigue	Any	1029	499	48.5	45.4	51.6	1027	434	42.3	39.2	45.3
	Grade 3	1029	40	3.9	2.8	5.3	1027	30	2.9	2.0	4.1
	Related	1029	327	31.8	28.9	34.7	1027	274	26.7	24.0	29.5
Fever (axillary)	≥ 37.5°C	1029	193	18.8	16.4	21.3	1027	164	16.0	13.8	18.4
	> 39.0°C	1029	19	1.8	1.1	2.9	1027	14	1.4	0.7	2.3
	Related	1029	103	10.0	8.2	12.0	1027	74	7.2	5.7	9.0
Gastro-intestinal	Any	1029	265	25.8	23.1	28.5	1027	253	24.6	22.0	27.4
	Grade 3	1029	26	2.5	1.7	3.7	1027	22	2.1	1.3	3.2
	Related	1029	139	13.5	11.5	15.7	1027	137	13.3	11.3	15.6
Headache	Any	1029	516	50.1	47.0	53.2	1027	464	45.2	42.1	48.3
	Grade 3	1029	68	6.6	5.2	8.3	1027	40	3.9	2.8	5.3
	Related	1029	292	28.4	25.6	31.2	1027	262	25.5	22.9	28.3
Myalgia	Any	1029	509	49.5	46.4	52.6	1027	340	33.1	30.2	36.1
	Grade 3	1029	57	5.5	4.2	7.1	1027	13	1.3	0.7	2.2
	Related	1029	392	38.1	35.1	41.1	1027	238	23.2	20.6	25.9
Rash	Any	1029	98	9.5	7.8	11.5	1027	69	6.7	5.3	8.4
	Grade 3	1029	8	0.8	0.3	1.5	1027	3	0.3	0.1	0.9
	Related	1029	70	6.8	5.3	8.5	1027	34	3.3	2.3	4.6
Urticaria	Any	1029	70	6.8	5.3	8.5	1027	55	5.4	4.1	6.9
	Grade 3	1029	9	0.9	0.4	1.7	1027	6	0.6	0.2	1.3
	Related	1029	39	3.8	2.7	5.1	1027	23	2.2	1.4	3.3

N = number of subjects with a 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 = occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination.
Grade 3 arthralgia, fatigue, headache, gastrointestinal, myalgia, rash = symptom that prevented normal activity
Grade 3 urticaria = urticaria distributed on at least 4 body areas
Related = general symptom assessed by the investigator as causally related to the study vaccination
*Across doses means 'overall per subject'

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 = 1035**	**HAV Group N = 1032**
Subjects with any AE(s), n (%)	386 (37.3)	427 (41.4)
Subjects with Grade 3* AE(s), n (%)	46 (4.4)	53 (5.1)
Subjects with related** AE(s), n (%)	52 (5.0)	47 (4.6)
Upper respiratory tract infection	60 (5.8)	69 (6.7)
Nasopharyngitis	56 (5.4)	61 (5.9)
Headache	27 (2.6)	34 (3.3)
Pharyngolaryngeal pain	28 (2.7)	22 (2.1)
Pharyngitis	22 (2.1)	23 (2.2)
Dysmenorrhea	17 (1.6)	20 (1.9)
Tonsillitis	24 (2.3)	13 (1.3)
Cough	20 (1.9)	15 (1.5)
Dizziness	14 (1.4)	15 (1.5)

Injection site hemorrhage	10 (1.0)	11 (1.1)
Influenza	6 (0.6)	13 (1.3)
*Grade 3 AE: AE that prevented normal activity **Related AE: AE assessed by the investigator as causally related to the study vaccination		
Safety Results: Number (%) of subjects with serious adverse events (SAEs) (Total Vaccinated Cohort) during the active study period (up to Month 7).		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV Group N = 1035**	**HAV Group N = 1032**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	11 (1.1) [0]	13 (1.3) [1]
Appendicitis	0 (0.0) [0]	5 (0.5) [0]
Abdominal pain	2 (0.2) [0]	0 (0.0) [0]
Anorexia nervosa	0 (0.0) [0]	1 (0.1) [0]
Concussion	0 (0.0) [0]	1 (0.1) [0]
Constipation	0 (0.0) [0]	1 (0.1) [0]
Dehydration	1 (0.1) [0]	0 (0.0) [0]
Drug toxicity	1 (0.1) [0]	0 (0.0) [0]
Enterobiasis	1 (0.1) [0]	0 (0.0) [0]
Gastritis	0 (0.0) [0]	1 (0.1) [0]
Gastroenteritis	1 (0.1) [0]	0 (0.0) [0]
Gun shot wound	1 (0.1) [0]	0 (0.0) [0]
Headache	0 (0.0) [0]	1 (0.1) [0]
Herpangina	1 (0.1) [0]	0 (0.0) [0]
Injury	1 (0.1) [0]	0 (0.0) [0]
Ludwig angina	0 (0.0) [0]	1 (0.1) [0]
Lymphadenitis	0 (0.0) [0]	1 (0.1) [0]
Ovarian cyst ruptured	0 (0.0) [0]	1 (0.1) [0]
Pneumonia bacterial	1 (0.1) [0]	0 (0.0) [0]
Pseudocroup	1 (0.1) [0]	0 (0.0) [0]
Syncope	1 (0.1) [0]	0 (0.0) [0]
Transaminases increased	0 (0.0) [0]	1 (0.1) [1]
Ulna fracture	1 (0.1) [0]	0 (0.0) [0]
Upper respiratory tract infection	1 (0.1) [0]	0 (0.0) [0]
Urinary tract infection	0 (0.0) [0]	1 (0.1) [0]
Fatal SAEs	**HPV Group N = 1035**	**HAV Group N = 1032**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Safety Results: Number (%) of subjects with Serious Adverse Events during the Month 0-12 follow-up period (Total Vaccinated Cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV Group N = 1035**	**HAV Group N = 1032**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	22 (2.1) [0]	23 (2.2) [1]
Lymphadenitis	0 (0.0) [0]	1 (0.1) [0]
Tympanic membrane perforation	1 (0.1) [0]	0 (0.0) [0]
Autoimmune thyroiditis	0 (0.0) [0]	1 (0.1) [0]
Abdominal pain	4 (0.4) [0]	0 (0.0) [0]
Constipation	0 (0.0) [0]	1 (0.1) [0]
Gastritis	0 (0.0) [0]	1 (0.1) [0]
Pyrexia	0 (0.0) [0]	1 (0.1) [0]
Appendicitis	0 (0.0) [0]	5 (0.5) [0]
Bronchitis acute	1 (0.1) [0]	0 (0.0) [0]
Cellulitis	1 (0.1) [0]	0 (0.0) [0]
Enterobiasis	1 (0.1) [0]	0 (0.0) [0]
Gastroenteritis	1 (0.1) [0]	0 (0.0) [0]

Gastroenteritis viral	0 (0.0) [0]	1 (0.1) [0]
Herpangina	1 (0.1) [0]	0 (0.0) [0]
Ludwig angina	0 (0.0) [0]	1 (0.1) [0]
Mastoiditis	1 (0.1) [0]	0 (0.0) [0]
Pneumonia	0 (0.0) [0]	1 (0.1) [0]
Pneumonia bacterial	1 (0.1) [0]	0 (0.0) [0]
Pseudocroup	1 (0.1) [0]	0 (0.0) [0]
Upper respiratory tract infection	1 (0.1) [0]	0 (0.0) [0]
Urinary tract infection	0 (0.0) [0]	1 (0.1) [0]
Concussion	1 (0.1) [0]	1 (0.1) [0]
Drug toxicity	1 (0.1) [0]	0 (0.0) [0]
Gun shot wound	1 (0.1) [0]	0 (0.0) [0]
Injury	1 (0.1) [0]	0 (0.0) [0]
Ulna fracture	1 (0.1) [0]	0 (0.0) [0]
Transaminases increased	0 (0.0) [0]	1 (0.1) [1]
Dehydration	1 (0.1) [0]	0 (0.0) [0]
Ganglion	0 (0.0) [0]	1 (0.1) [0]
Convulsion	1 (0.1) [0]	0 (0.0) [0]
Headache	0 (0.0) [0]	1 (0.1) [0]
Migraine with aura	1 (0.1) [0]	0 (0.0) [0]
Syncope	1 (0.1) [0]	0 (0.0) [0]
Acute psychosis	0 (0.0) [0]	1 (0.1) [0]
Anorexia nervosa	0 (0.0) [0]	2 (0.2) [0]
Intentional self-injury	1 (0.1) [0]	0 (0.0) [0]
Suicide attempt	0 (0.0) [0]	1 (0.1) [0]
Dysmenorrhea	1 (0.1) [0]	1 (0.1) [0]
Ovarian cyst	2 (0.2) [0]	1 (0.1) [0]
Ovarian cyst ruptured	0 (0.0) [0]	1 (0.1) [0]
Dyspnea	0 (0.0) [0]	1 (0.1) [0]
Fatal SAEs	**HPV Group N = 1035**	**HAV Group N = 1032**
Subjects with fatal SAEs, n (%) [assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Safety Results: Number (%) of subjects with Serious Adverse Events during the Month 12-18 follow-up period (Total Vaccinated Cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV Group N = 626**	**HAV Group N = 619**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	7 (1.1) [0]	2 (0.3) [0]
Appendicitis	1 (0.2) [0]	0 (0.0) [0]
Arthralgia	1 (0.2) [0]	0 (0.0) [0]
Dengue fever	1 (0.2) [0]	0 (0.0) [0]
Epstein-barr virus infection	1 (0.2) [0]	0 (0.0) [0]
Ligament rupture	1 (0.2) [0]	0 (0.0) [0]
Myalgia	1 (0.2) [0]	0 (0.0) [0]
Ovarian cyst	1 (0.2) [0]	0 (0.0) [0]
Ovarian cyst ruptured	1 (0.2) [0]	0 (0.0) [0]
Pyelonephritis acute	1 (0.2) [0]	0 (0.0) [0]
Schizophreniform disorder	1 (0.2) [0]	0 (0.0) [0]
Splenomegaly	1 (0.2) [0]	0 (0.0) [0]
Suicide attempt	0 (0.0) [0]	1 (0.2) [0]
Syncope	0 (0.0) [0]	1 (0.2) [0]
Fatal SAEs	**HPV Group N = 626**	**HAV Group N = 619**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]

Safety Results: Number (%) of subjects with Serious Adverse Events during the Month 18-24 follow-up period (Total Vaccinated Cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV Group N = 617**	**HAV Group N = 571**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	8 (1.3) [0]	5 (0.9) [0]
Abdominal pain	2 (0.3) [0]	0 (0.0) [0]
Cellulitis	1 (0.2) [0]	0 (0.0) [0]
Constipation	1 (0.2) [0]	0 (0.0) [0]
Dermoid cyst of ovary	0 (0.0) [0]	1 (0.2) [0]
Loss of consciousness	0 (0.0) [0]	1 (0.2) [0]
Ovarian cyst	0 (0.0) [0]	1 (0.2) [0]
Pneumonia	0 (0.0) [0]	1 (0.2) [0]
Premature labour	1 (0.2) [0]	0 (0.0) [0]
Skull fractured base	1 (0.2) [0]	0 (0.0) [0]
Splenic rupture	0 (0.0) [0]	1 (0.2) [0]
Suicide attempt	1 (0.2) [0]	0 (0.0) [0]
Uterine leiomyoma	1 (0.2) [0]	0 (0.0) [0]
Fatal SAEs	**HPV Group N = 617**	**HAV Group N = 571**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Safety Results: Number (%) of subjects with Serious Adverse Events during the Month 24-36 follow-up period (Total Vaccinated Cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV Group N = 601**	**HAV Group**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	10 (1.7) [0]	-
Abdominal pain	1 (0.2) [0]	-
Constipation	1 (0.2) [0]	-
Umbilical hernia	1 (0.2) [0]	-
Pyrexia	1 (0.2) [0]	-
Appendicitis	2 (0.3) [0]	-
Campylobacter gastroenteritis	1 (0.2) [0]	-
Helicobacter gastritis	1 (0.2) [0]	-
Subcutaneous abscess	1 (0.2) [0]	-
Traumatic brain injury	1 (0.2) [0]	-
Dehydration	1 (0.2) [0]	-
Depressed mood	1 (0.2) [0]	-
Ovarian cyst	1 (0.2) [0]	-
Ovarian cyst torsion	1 (0.2) [0]	-
Fatal SAEs	**HPV Group N = 601**	**HAV Group**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	-
Safety Results: Number (%) of subjects with Serious Adverse Events during the Month 36-48 follow-up period (Total Vaccinated Cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV Group N = 588**	**HAV Group**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	15 (2.6) [0]	-
Appendicitis	3 (0.5) [0]	-
Abortion spontaneous incomplete	1 (0.2) [0]	-
Acute tonsillitis	1 (0.2) [0]	-
Alcohol poisoning	1 (0.2) [0]	-
Asthmatic crisis	1 (0.2) [0]	-
Cholelithiasis	1 (0.2) [0]	-
Concussion	1 (0.2) [0]	-

Gastroenteritis	1 (0.2) [0]	-
Gastroenteritis viral	1 (0.2) [0]	-
Investigation	1 (0.2) [0]	-
Lower limb fracture	1 (0.2) [0]	-
Malocclusion	1 (0.2) [0]	-
Meningitis viral	1 (0.2) [0]	-
Pre-eclampsia	1 (0.2) [0]	-
Fatal SAEs	**HPV Group N = 588**	**HAV Group**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	-

Conclusion: For results up to month 7, please refer to the full text publication below.
Between Month 0 and Month 12, SAEs were reported for 22 (2.1%) and 23 (2.2%) subjects in the HPV and HAV groups, respectively. Unsolicited AEs were reported by 386 (37.3%) and 427 (41.4%) subjects in the HPV and HAV groups, respectively. Of these unsolicited AEs, 46 (4.4%) and 53 (5.1%) were rated Grade 3 in the HPV and HAV groups, respectively, and 52 (5.0%) and 47 (4.6%) were assessed by the investigators as related to the study vaccination in the HPV and HAV groups, respectively.
Between Month 12 and Month 18, SAEs were reported for 7 (1.1%) and 2 (0.3%) subjects in the HPV and HAV groups, respectively; from Month 18 to 24, SAEs were reported for 8 (1.3%) and 5 (0.9%) subjects in the HPV and HAV groups, respectively.
From Month 24 to 36, SAEs were reported for 10 (1.7%) subjects and from Month 36 to 48, SAEs were reported for 15 (2.6%) subjects in the HPV Group.
None of the SAEs reported between months 12 and 48 were assessed by the investigators as related to the study vaccination.
In the HPV Group, at Month 7, all subjects were seropositive for anti-HPV-16 and for anti-HPV-18 with GMTs of 20018.1 and 8359.4, respectively; at Month 18, all subjects were seropositive for anti-HPV-16 and for anti-HPV-18 with GMTs of 3901.6 and 1570.8, respectively; at Month 24, 99.8% of subjects were seropositive for anti-HPV-16 antibodies with a GMT of 3226.3 and all subjects were seropositive for anti-HPV-18 antibodies with a GMT of 1263.4; at Month 36, all subjects were seropositive for anti-HPV-16 and for anti-HPV-18 with GMTs of 2688.6 and 995.0, respectively, at Month 48, all subjects were seropositive for anti-HPV-16 and for anti-HPV-18 with GMTs of 2395.8 and 885.6, respectively.
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
Descamps D et al. (2009) Safety of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine for cervical cancer prevention: A pooled analysis of 11 clinical trials. Hum Vaccin. 5(5):51-59.
Medina DMR et al. (2010) Safety and immunogenicity of the HPV-16/18 AS04-adjuvanted vaccine: a randomised, controlled trial in adolescent girls. J Adolesc Health. 46(5):414-421.

Rombo L et al. Tolerability of HPV-16/18 AS04-adjuvanted cervical cancer vaccine. Abstract presented at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) International Multidisciplinary Conference. Nice, France, 12-15 November 2008.
Descamps D et al. Safety of human papillomavirus (HPV)-16/18 AS04 adjuvanted vaccine for cervical cancer prevention: integrated summary of 11 clinical trials. Abstract presented at the 26th Annual Meeting of the ESPID. Graz, Austria, 13-17 May 2008.
Schwarz TF et al. Long-term safety and immunogenicity of an AS04 adjuvanted cervical cancer vaccine in girls aged 10-14 years. Abstract presented at the 26th Annual Meeting of the ESPID. Graz, Austria, 13-17 May 2008.
Rombo L et al. Long-term safety and immunogenicity of a cervical cancer candidate vaccine in 10- to 14-year-old adolescent girls. Abstract presented at the 25th Annual Meeting of the ESPID. Porto, Portugal, 2-4 May 2007.
Rombo L et al. AS04 adjuvanted human papillomavirus (HPV) 16/18 L1 virus-like particle (VLP) vaccine for the prevention of cervical cancer is well-tolerated and immunogenic in 10- to 14-year-old adolescent girls. Abstract presented at the 24th Annual Meeting of the ESPID. Basel, Switzerland 3-5 May 2006.
Schwarz T et al. Long-term safety and immunogenicity of a human papillomavirus (HPV)-16/18 AS04 adjuvanted cervical cancer vaccine in girls aged 10-14 years: 36-month follow-up. Abstract presented at the 27th annual ESPID meeting, Brussels, Belgium, 9-13 June 2009.
Schwarz TF et al. Safety and immunogenicity of the HPV-16/18 AS04-adjuvanted vaccine in adolescent girls: long-term

follow-up of a randomised trial. Abstract presented at the 28th annual ESPID meeting, Nice, France, 4-8 May 2010.

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