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.: 111567 (HPV-026 PRI)

Title: Immunogenicity and safety of a commercially available vaccine when co-administered with GlaxoSmithKline Biologicals' HPV vaccine (580299) in healthy female subjects.
Cervarix™ (HPV): GlaxoSmithKline (GSK) Biologicals' licensed prophylactic human papillomavirus (HPV) vaccine

Rationale: The purpose of the study was to evaluate the immunogenicity and safety of Engerix-B™ when given according to the accelerated 0, 1, 2, 12-month vaccination schedule with co-administration of HPV vaccine according to a 0, 1, 6-month vaccination schedule in healthy female subjects aged 20 to 25 years.
Engerix-B™ (HBV): GSK Biologicals' licensed hepatitis B vaccine.

Phase: IIIb

Study Period: 11 March 2008 to 18 June 2009 (up to study end)

Study Design: Open, randomized (1:1), controlled and multi-center study.

Centers: 2 study centers in Belgium.

Indication: Immunization against HPV-16 and HPV-18 infection, HPV-16 and HPV-18 associated cervical neoplasia and against hepatitis B in healthy female subjects.

Treatment: The study groups were as follows:

- HPV + HepB Group: subjects received 3 doses of HPV vaccine and 4 doses of HBV vaccine.
- HepB Group: subjects received 4 doses of HBV vaccine.

The vaccines were administered intramuscularly. HPV vaccine was administered into the deltoid muscle of the non-dominant arm. HBV vaccine was administered into the deltoid muscle of the dominant arm when co-administered with HPV vaccine (at months 0 & 1) and into the deltoid muscle of the non-dominant arm when administered alone.
Visits 1, 2, 3, 4, 5, 6, 7 & 8 correspond to months 0, 1, 2, 3, 6, 7, 12 & 13 in the schedule for the group receiving HPV and HBV vaccines.
Visits 1, 2, 3, 4, 5, 6, & 7 correspond to months 0, 1, 2, 3, 7, 12 & 13 in the schedule for the group receiving HBV vaccine only.

Objectives: To evaluate, one month after the third dose of hepatitis B vaccine (Month 3), the immune response against hepatitis B with respect to seroprotection rates and geometric mean titers (GMTs) in both study groups.

Primary Outcome/Efficacy Variable:
Immunogenicity:

- Anti-hepatitis B (HBs) seroprotection status at Month 3 in both groups.
- Anti-HBs antibody titers at Month 3 in both groups.

Secondary Outcome/Efficacy Variable(s):
Immunogenicity

- Anti-HPV-16/18 seroconversion status at Months 2 and 7 in the group receiving the HPV vaccine.
- Anti-HPV-16/18 antibody titers at Months 2 and 7 in the group receiving the HPV vaccine.
- Anti-HBs seroconversion status at Months 2, 3 and 13 in both groups.
- Anti-HBs seroprotection status and antibody titers at Month 2 and 13 in both groups.

Safety:

- Occurrence of any and Grade 3 solicited local symptoms (injection site pain, redness and swelling) during the 7-day period (Days 0 – 6) following each vaccination.
- Occurrence of any Grade 3 and causally related to vaccination solicited general symptoms during the 7-day period (Days 0 – 6) following each vaccination.
- Occurrence of any Grade 3 and causally related to vaccination unsolicited adverse events (AEs) during the 30-day period (Days 0 – 29) following each vaccination.
- Occurrence of any serious adverse events (SAEs) in both groups throughout the study.
- Occurrence of medically significant conditions in both groups throughout the study regardless of causal relationship to vaccination and intensity.

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

- The Total Vaccinated Cohort included all vaccinated subjects for whom data were available.
- The ATP cohort for immunogenicity included all evaluable subjects (i.e. those meeting all eligibility criteria, complying with the procedures and intervals defined in the protocol, with no elimination criteria during the study)

for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

Analysis of immunogenicity:

The analysis was performed on the ATP cohort for immunogenicity.

In both groups, seroprotection rates, seroconversion rates and GMTs for anti-HBs antibodies at months 2, 3 and 13 were calculated with their 95% confidence interval (CI). In the group receiving the HPV vaccine, seroconversion rates and antibody titers for anti-HPV antibodies at months 2 and 7 were calculated with their 95% CI. Antibody titers below the cut-off of the assay were given an arbitrary value of half the cut-off.

A subject seroprotected against HBV is a subject with anti-HBs antibody titers ≥ 10 mIU/mL

Anti-HBs seroconversion is defined as the appearance of anti-HBs antibodies (i.e. titer ≥ 3.3 mIU/mL) in the sera of subjects seronegative (with titers below the cut-off value) before vaccination.

Anti-HPV-16/18 seroconversion is defined as the appearance of anti-HPV-16 antibodies (i.e. titer ≥ 8 EL.U/mL) and of anti-HPV-18 antibodies (i.e. titer ≥ 7 EL.U/mL) in the sera of subjects seronegative (with titers below the cut-off value) 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 during the 7-day follow-up was tabulated with 95% CI. The same tabulation was performed for grade 3 symptoms and for general symptoms with relationship to vaccination. The percentage of subjects with at least one report of unsolicited adverse events, grade 3 unsolicited AEs and AEs assessed by the investigators as related to study vaccination and reported during the 30 days after each vaccination was tabulated, classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred term. The occurrences of SAEs and of medically significant conditions regardless of causal relationship to vaccination and intensity were tabulated per group according to the MedDRA preferred terms.

Study Population: Healthy female subjects between and including 20 and 25 years of age at the time of first vaccination and having a negative urine pregnancy test were enrolled in the study. If of childbearing potential, subjects had to practice adequate contraception for 30 days prior to vaccination, to have a negative pregnancy test and agreed to continue such precautions for 2 months after completion of the vaccination series. Written informed consent was obtained from the subjects prior to study start.

Number of subjects	**HPV + HepB Group**	**HepB Group**
Planned, N	76	76
Randomized, N (Total Vaccinated Cohort)	76	76
Completed to Visit 4, n (%)	76 (100)	76 (100)
Completed to Visit 5, n (%)	-	75 (98.7)
Completed to Visit 6, n (%)	74 (97.4)	-
Completed to Visit 7, n (%)	-	75 (98.7)
Completed to Visit 8, n (%)	73 (96.1)	Not applicable
Total Number Subjects Withdrawn, n (%)	3 (3.9)	1 (1.3)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	Not applicable	Not applicable
Withdrawn for other reasons, n (%)	3 (3.9)	1 (1.3)
Demographics	**HPV + HepB Group**	**HepB Group**
N (Total Vaccinated Cohort)	76	76
Females: Males	76:0	76:0
Mean Age, years (SD)	22.4 (1.51)	22.1 (1.32)
White – Caucasian / European heritage, n (%)	74 (97.4)	73 (96.1)

Primary Efficacy Results: Seropositivity rates and geometric mean titers (GMT) for anti-HBs antibody titers on the subset of subjects negative for anti-HBc before vaccination (ATP cohort for immunogenicity)

Group	**Pre-vacc status**	**Timing**	**N**	**≥ 3.3 mIU/mL**				**≥ 10 mIU/mL***				**GMT***		
				n	**%**	**95% CI**		**n**	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**			**LL**	**UL**		**LL**	**UL**
HPV+ HepB	S-	PRE	55	0	0.0	0.0	6.5	0	0.0	0.0	6.5	1.7	1.7	1.7
		PII(M2)	55	46	83.6	71.2	92.2	32	58.2	44.1	71.3	10.5	7.7	14.3
		PIII(M3)*	55	55	100	93.5	100	53	96.4	87.5	99.6	60.2	40.0	90.5
	S+	PRE	17	17	100	80.5	100	10	58.8	32.9	81.6	27.0	11.7	62.2

		PII(M2)	17	17	100	80.5	100	15	88.2	63.6	98.5	1596.4	221.5	11508.1
		PIII(M3)*	17	17	100	80.5	100	17	100	80.5	100	3410.5	653.1	17810.7
	Total	PRE	72	17	23.6	14.4	35.1	10	13.9	6.9	24.1	3.2	2.3	4.5
		PII(M2)	72	63	87.5	77.6	94.1	47	65.3	53.1	76.1	34.4	17.1	69.5
		PIII(M3)*	72	72	100	95.0	100	70	97.2	90.3	99.7	156.1	83.7	291.3
HepB	S-	PRE	64	0	0.0	0.0	5.6	0	0.0	0.0	5.6	1.7	1.7	1.7
		PII(M2)	64	54	84.4	73.1	92.2	45	70.3	57.6	81.1	14.8	10.9	20.3
		PIII(M3)*	64	63	98.4	91.6	100	62	96.9	89.2	99.6	71.3	53.9	94.3
	S+	PRE	11	11	100	71.5	100	7	63.6	30.8	89.1	129.9	12.0	1404.0
		PII(M2)	11	11	100	71.5	100	11	100	71.5	100	5829.7	534.4	63598.1
		PIII(M3)*	11	11	100	71.5	100	11	100	71.5	100	9514.4	1414.6	63991.4
	Total	PRE	75	11	14.7	7.6	24.7	7	9.3	3.8	18.3	3.1	2.0	5.0
		PII(M2)	75	65	86.7	76.8	93.4	56	74.7	63.3	84.0	35.7	18.9	67.1
		PIII(M3)*	75	74	98.7	92.8	100	73	97.3	90.7	99.7	146.2	86.6	246.9

S- = seronegative subjects (antibody titer < 3.3 mIU/mL) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 3.3 mIU/mL) prior to vaccination
GMT = geometric mean titers calculated in the subset of subjects negative for anti-HBc before vaccination
N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M2) = Post Dose 2, Month 2
PIII(M3) = Post Dose 3, Month 3
PRE = pre-vaccination
* Primary results

Secondary Outcome Variable(s): Seropositivity rates and geometric mean titers (GMT) for anti-HPV-16 antibody titers (ATP cohort for immunogenicity)

Group	**Pre-vacc status**	**Timing**	**N**	**≥ 8 ELU/mL**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
HPV + HepB	S-	PRE	62	0	0.0	0.0	5.8	4.0	4.0	4.0
		PII(M2)	62	62	100	94.2	100	3354.5	2763.8	4071.6
		PII(M3)	62	62	100	94.2	100	2116.4	1714.4	2612.8
		PIII(M7)	61	61	100	94.1	100	9217.9	7396.6	11487.7
	S+	PRE	9	9	100	66.4	100	25.7	11.9	55.5
		PII(M2)	9	9	100	66.4	100	4659.5	2257.8	9616.2
		PII(M3)	9	9	100	66.4	100	3201.8	1672.2	6130.5
		PIII (M7)	9	9	100	66.4	100	6013.0	3196.1	11312.8
	Total	PRE	71	9	12.7	6.0	22.7	5.1	4.3	6.0
		PII(M2)	71	71	100	94.9	100	3497.2	2902.3	4214.1
		PII(M3)	71	71	100	94.9	100	2230.5	1829.6	2719.2
		PIII (M7)	70	70	100	94.9	100	8725.2	7105.7	10714.0

S- = seronegative subjects (antibody titer < 8 ELU/mL) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 8 ELU/mL) prior to vaccination
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with pre-vaccination results available
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M2) = Post dose 2, month 2
PII(M3) = Post dose 3, month 3
PIII (M7) = Post dose 3, month 7
PRE = pre-vaccination

Secondary Outcome Variable(s): Seropositivity rates and geometric mean titers (GMT) for anti-HPV-18 antibody titers (ATP cohort for immunogenicity)

Group	**Pre-vacc**	**Timing**	**N**	**≥ 7 ELU/mL**	**GMT**

	status			n	%	95% CI		value	95% CI	
						LL	UL		LL	UL
HPV + HepB	S-	PRE	68	0	0.0	0.0	5.3	3.5	3.5	3.5
		PII(M2)	68	68	100	94.7	100	2785.9	2292.6	3385.3
		PII(M3)	68	68	100	94.7	100	1547.2	1249.2	1916.3
		PIII (M7)	67	67	100	94.6	100	4726.8	3718.5	6008.4
	S+	PRE	4	4	100	39.8	100	20.7	2.9	150.1
		PII(M2)	4	4	100	39.8	100	2605.5	1257.9	5396.8
		PII(M3)	4	4	100	39.8	100	1682.7	715.4	3957.9
		PIII (M7)	4	4	100	39.8	100	3733.6	1249.6	11155.2
	Total	PRE	72	4	5.6	1.5	13.6	3.9	3.4	4.3
		PII(M2)	72	72	100	95.0	100	2775.6	2306.5	3340.1
		PII(M3)	72	72	100	95.0	100	1554.4	1268.2	1905.2
		PIII (M7)	71	71	100	94.9	100	4664.4	3709.9	5864.3

S- = seronegative subjects (antibody titer < 7 ELU/mL) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 7 ELU/mL) prior to vaccination
GMT = geometric mean antibody titer calculated on all subjects
N = number of subjects with pre-vaccination results available
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M2) = Post dose 2, month 2
PII(M3) = Post dose 3, month 3
PIII(M7) = Post dose 3, month 7
PRE = pre-vaccination

Secondary Outcome Variable(s):: Seropositivity rates and geometric mean titers (GMT) for anti-HBs antibody titers (ATP cohort for immunogenicity at Month 13)

Group	Pre-vacc status	Timing	N	≥ 3.3 mIU/mL				≥ 10 mIU/mL				GMT		
				n	%	95% CI		n	%	95% CI		value	95% CI	
						LL	UL			LL	UL		LL	UL
HPV+ HepB	S-	Pre	52	0	0.0	0.0	6.8	0	0.0	0.0	6.8	1.7	1.7	1.7
		PII (M2)	52	44	84.6	71.9	93.1	32	61.5	47.0	74.7	11.2	8.2	15.3
		PIII (M3)	52	52	100	93.2	100	50	96.2	86.8	99.5	63.3	41.3	97.2
		PIV (M13)	52	52	100	93.2	100	52	100	93.2	100	17416.7	10294.3	29466.9
	S+	Pre	17	17	100	80.5	100	10	58.8	32.9	81.6	27.0	11.7	62.2
		PII (M2)	17	17	100	80.5	100	15	88.2	63.6	98.5	1596.4	221.5	11508.1
		PIII (M3)	17	17	100	80.5	100	17	100	80.5	100	3410.5	653.1	17810.7
		PIV (M13)	17	17	100	80.5	100	17	100	80.5	100	29846.3	15879.1	56099.0
	Total	Pre	69	17	24.6	15.1	36.5	10	14.5	7.2	25.0	3.3	2.3	4.6
		PII (M2)	69	61	88.4	78.4	94.9	47	68.1	55.8	78.8	38.0	18.4	78.3
		PIII (M3)	69	69	100	94.8	100	67	97.1	89.9	99.6	169.1	88.8	322.2
		PIV (M13)	69	69	100	94.8	100	69	100	94.8	100	19888.4	13042.6	30327.5
HepB	S-	Pre	63	0	0.0	0.0	5.7	0	0.0	0.0	5.7	1.7	1.7	1.7
		PII (M2)	63	53	84.1	72.7	92.1	44	69.8	57.0	80.8	14.9	10.9	20.5
		PIII (M3)	63	62	98.4	91.5	100	61	96.8	89.0	99.6	71.5	53.8	94.9
		PIV (M13)	63	63	100	94.3	100	63	100	94.3	100	14470.2	9824.6	21312.4
	S+	Pre	11	11	100	71.5	100	7	63.6	30.8	89.1	129.9	12.0	1404.0
		PII (M2)	11	11	100	71.5	100	11	100	71.5	100	5829.7	534.4	63598.1

		PIII (M3)	11	11	100	71.5	100	11	100	71.5	100	9514.4	1414.6	63991.4
		PIV (M13)	11	11	100	71.5	100	11	100	71.5	100	41565.1	17940.0	96301.8
	Total	Pre	74	11	14.9	7.7	25.0	7	9.5	3.9	18.5	3.2	2.0	5.1
		PII (M2)	74	64	86.5	76.5	93.3	55	74.3	62.8	83.8	36.2	19.1	68.7
		PIII (M3)	74	73	98.6	92.7	100	72	97.3	90.6	99.7	147.9	87.0	251.5
		PIV (M13)	74	74	100	95.1	100	74	100	95.1	100	16927.5	11854.1	24172.3

S- = seronegative subjects (antibody titer < 3.3 mIU/mL) prior to vaccination
S+ = seropositive subjects (antibody titer ≥ 3.3 mIU/mL) prior to vaccination
GMT = geometric mean titers calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with titer within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M2) = Post Dose 2, Month 2
PIII(M3) = Post Dose 3, Month 3
PV(M13) = Post Dose 5, Month 13
PIV(M13) = Post Dose 4, Month 13
PRE = pre-vaccination

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)

Symptoms	Intensity	HPV + HepB Group					HepB Group				
					95% CI					95% CI	
		N	n	%	LL	UL	N	n	%	LL	UL
Dose 1											
Pain	Any	76	75	98.7	92.9	100	76	50	65.8	54.0	76.3
	Grade 3	76	4	5.3	1.5	12.9	76	1	1.3	0.0	7.1
Redness	Any	76	15	19.7	11.5	30.5	76	6	7.9	3.0	16.4
	>50 mm	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
Swelling	Any	76	15	19.7	11.5	30.5	76	7	9.2	3.8	18.1
	>50 mm	76	1	1.3	0.0	7.1	76	0	0.0	0.0	4.7
Dose 2											
Pain	Any	76	69	90.8	81.9	96.2	75	43	57.3	45.4	68.7
	Grade 3	76	2	2.6	0.3	9.2	75	1	1.3	0.0	7.2
Redness	Any	76	16	21.1	12.5	31.9	75	8	10.7	4.7	19.9
	>50 mm	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
Swelling	Any	76	16	21.1	12.5	31.9	75	4	5.3	1.5	13.1
	>50 mm	76	1	1.3	0.0	7.1	75	0	0.0	0.0	4.8
Dose 3											
Pain	Any	76	27	35.5	24.9	47.3	75	39	52.0	40.2	63.7
	Grade 3	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
Redness	Any	76	7	9.2	3.8	18.1	75	6	8.0	3.0	16.6
	>50 mm	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
Swelling	Any	76	5	6.6	2.2	14.7	75	3	4.0	0.8	11.2
	>50 mm	76	0	0.0	0.0	4.7	75	1	1.3	0.0	7.2
Dose 4											
Pain	Any	75	61	81.3	70.7	89.4	-	-	-	-	-
	Grade 3	75	1	1.3	0.0	7.2	-	-	-	-	-
Redness	Any	75	14	18.7	10.6	29.3	-	-	-	-	-
	>50 mm	75	0	0.0	0.0	4.8	-	-	-	-	-
Swelling	Any	75	13	17.3	9.6	27.8	-	-	-	-	-
	>50 mm	75	0	0.0	0.0	4.8	-	-	-	-	-
Across 3 doses											
Pain	Any	76	76	100	95.3	100	76	62	81.6	71.0	89.5

	Grade 3	76	6	7.9	3.0	16.4	76	2	2.6	0.3	9.2
Redness	Any	76	22	28.9	19.1	40.5	76	12	15.8	8.4	26.0
	>50 mm	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
Swelling	Any	76	22	28.9	19.1	40.5	76	10	13.2	6.5	22.9
	>50 mm	76	2	2.6	0.3	9.2	76	1	1.3	0.0	7.1
Across 4 doses											
Pain	Any	76	76	100	95.3	100	-	-	-	-	-
	Grade 3	76	7	9.2	3.8	18.1	-	-	-	-	-
Redness	Any	76	26	34.2	23.7	46.0	-	-	-	-	-
	>50 mm	76	0	0.0	0.0	4.7	-	-	-	-	-
Swelling	Any	76	26	34.2	23.7	46.0	-	-	-	-	-
	>50 mm	76	2	2.6	0.3	9.2	-	-	-	-	-

Any = occurrence of any local symptom regardless of intensity grade
Grade 3 pain = pain that prevented normal activity
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

Secondary Outcome Variable(s): Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following the 4th dose of HBV vaccine (Total vaccinated cohort)

		HPV + HepB Group					**HepB Group**				
					95 % CI					**95 % CI**	
Symptom	**Intensity**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Pain	Any	74	36	48.6	36.9	60.6	75	44	58.7	46.7	69.9
	Grade 3	74	2	2.7	0.3	9.4	75	0	0.0	0.0	4.8
Redness	Any	74	8	10.8	4.8	20.2	75	13	17.3	9.6	27.8
	>50 mm	74	0	0.0	0.0	4.9	75	0	0.0	0.0	4.8
Swelling	Any	74	12	16.2	8.7	26.6	75	10	13.3	6.6	23.2
	>50 mm	74	0	0.0	0.0	4.9	75	0	0.0	0.0	4.8

Any = occurrence of any local symptom regardless of intensity grade
Grade 3 pain = pain that prevented normal activity
N = number of subjects with the 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

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)

Symptoms	**Intensity/ relationship**	**HPV + HepB Group**					**HepB Group**				
					95% CI					**95% CI**	
		N	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Dose 1											
Arthralgia	Any	76	5	6.6	2.2	14.7	76	8	10.5	4.7	19.7
	Grade 3	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
	Related	76	5	6.6	2.2	14.7	76	7	9.2	3.8	18.1
Fatigue	Any	76	35	46.1	34.5	57.9	76	36	47.4	35.8	59.2
	Grade 3	76	0	0.0	0.0	4.7	76	2	2.6	0.3	9.2
	Related	76	32	42.1	30.9	54.0	76	32	42.1	30.9	54.0
Gastrointestinal	Any	76	9	11.8	5.6	21.3	76	25	32.9	22.5	44.6
	Grade 3	76	0	0.0	0.0	4.7	76	2	2.6	0.3	9.2
	Related	76	8	10.5	4.7	19.7	76	18	23.7	14.7	34.8
Headache	Any	76	25	32.9	22.5	44.6	76	28	36.8	26.1	48.7
	Grade 3	76	0	0.0	0.0	4.7	76	1	1.3	0.0	7.1
	Related	76	21	27.6	18.0	39.1	76	20	26.3	16.9	37.7
Myalgia	Any	76	20	26.3	16.9	37.7	76	26	34.2	23.7	46.0
	Grade 3	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
	Related	76	20	26.3	16.9	37.7	76	22	28.9	19.1	40.5

Rash	Any	76	1	1.3	0.0	7.1	76	3	3.9	0.8	11.1
	Grade 3	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
	Related	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
Temperature (Axillary)	≥37.5°C	76	3	3.9	0.8	11.1	76	3	3.9	0.8	11.1
	> 39.0°C	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
	Related	76	3	3.9	0.8	11.1	76	2	2.6	0.3	9.2
Urticaria	Any	76	1	1.3	0.0	7.1	76	1	1.3	0.0	7.1
	Grade 3	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
	Related	76	1	1.3	0.0	7.1	76	0	0.0	0.0	4.7
Dose 2											
Arthralgia	Any	76	5	6.6	2.2	14.7	75	5	6.7	2.2	14.9
	Grade 3	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Related	76	5	6.6	2.2	14.7	75	4	5.3	1.5	13.1
Fatigue	Any	76	31	40.8	29.6	52.7	75	31	41.3	30.1	53.3
	Grade 3	76	0	0.0	0.0	4.7	75	2	2.7	0.3	9.3
	Related	76	30	39.5	28.4	51.4	75	30	40.0	28.9	52.0
Gastrointestinal	Any	76	10	13.2	6.5	22.9	75	11	14.7	7.6	24.7
	Grade 3	76	0	0.0	0.0	4.7	75	2	2.7	0.3	9.3
	Related	76	7	9.2	3.8	18.1	75	10	13.3	6.6	23.2
Headache	Any	76	24	31.6	21.4	43.3	75	20	26.7	17.1	38.1
	Grade 3	76	0	0.0	0.0	4.7	75	1	1.3	0.0	7.2
	Related	76	20	26.3	16.9	37.7	75	17	22.7	13.8	33.8
Myalgia	Any	76	8	10.5	4.7	19.7	75	14	18.7	10.6	29.3
	Grade 3	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Related	76	8	10.5	4.7	19.7	75	13	17.3	9.6	27.8
Rash	Any	76	2	2.6	0.3	9.2	75	3	4.0	0.8	11.2
	Grade 3	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Related	76	1	1.3	0.0	7.1	75	2	2.7	0.3	9.3
Temperature (Axillary)	≥37.5°C	76	1	1.3	0.0	7.1	75	1	1.3	0.0	7.2
	> 39.0°C	76	0	0.0	0.0	4.7	75	1	1.3	0.0	7.2
	Related	76	1	1.3	0.0	7.1	75	1	1.3	0.0	7.2
Urticaria	Any	76	0	0.0	0.0	4.7	75	2	2.7	0.3	9.3
	Grade 3	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Related	76	0	0.0	0.0	4.7	75	2	2.7	0.3	9.3
Dose 3											
Arthralgia	Any	76	0	0.0	0.0	4.7	75	1	1.3	0.0	7.2
	Grade 3	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Related	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
Fatigue	Any	76	20	26.3	16.9	37.7	75	29	38.7	27.6	50.6
	Grade 3	76	2	2.6	0.3	9.2	75	1	1.3	0.0	7.2
	Related	76	16	21.1	12.5	31.9	75	27	36.0	25.2	47.9
Gastrointestinal	Any	76	8	10.5	4.7	19.7	75	6	8.0	3.0	16.6
	Grade 3	76	1	1.3	0.0	7.1	75	1	1.3	0.0	7.2
	Related	76	5	6.6	2.2	14.7	75	5	6.7	2.2	14.9
Headache	Any	76	16	21.1	12.5	31.9	75	22	29.3	19.4	41.0
	Grade 3	76	0	0.0	0.0	4.7	75	5	6.7	2.2	14.9
	Related	76	12	15.8	8.4	26.0	75	16	21.3	12.7	32.3
Myalgia	Any	76	4	5.3	1.5	12.9	75	8	10.7	4.7	19.9
	Grade 3	76	0	0.0	0.0	4.7	75	2	2.7	0.3	9.3
	Related	76	2	2.6	0.3	9.2	75	8	10.7	4.7	19.9
Rash	Any	76	0	0.0	0.0	4.7	75	1	1.3	0.0	7.2
	Grade 3	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Related	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
Temperature	≥37.5°C	76	3	3.9	0.8	11.1	75	1	1.3	0.0	7.2

(Axillary)	> 39.0°C	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Related	76	3	3.9	0.8	11.1	75	1	1.3	0.0	7.2
Urticaria	Any	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Grade 3	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
	Related	76	0	0.0	0.0	4.7	75	0	0.0	0.0	4.8
Dose 4											
Arthralgia	Any	75	1	1.3	0.0	7.2	-	-	-	-	-
	Grade 3	75	0	0.0	0.0	4.8	-	-	-	-	-
	Related	75	1	1.3	0.0	7.2	-	-	-	-	-
Fatigue	Any	75	31	41.3	30.1	53.3	-	-	-	-	-
	Grade 3	75	1	1.3	0.0	7.2	-	-	-	-	-
	Related	75	27	36.0	25.2	47.9	-	-	-	-	-
Gastrointestinal	Any	75	6	8.0	3.0	16.6	-	-	-	-	-
	Grade 3	75	0	0.0	0.0	4.8	-	-	-	-	-
	Related	75	4	5.3	1.5	13.1	-	-	-	-	-
Headache	Any	75	25	33.3	22.9	45.2	-	-	-	-	-
	Grade 3	75	1	1.3	0.0	7.2	-	-	-	-	-
	Related	75	18	24.0	14.9	35.3	-	-	-	-	-
Myalgia	Any	75	9	12.0	5.6	21.6	-	-	-	-	-
	Grade 3	75	0	0.0	0.0	4.8	-	-	-	-	-
	Related	75	7	9.3	3.8	18.3	-	-	-	-	-
Rash	Any	75	0	0.0	0.0	4.8	-	-	-	-	-
	Grade 3	75	0	0.0	0.0	4.8	-	-	-	-	-
	Related	75	0	0.0	0.0	4.8	-	-	-	-	-
Temperature (Axillary)	≥37.5°C	75	3	4.0	0.8	11.2	-	-	-	-	-
	> 39.0°C	75	0	0.0	0.0	4.8	-	-	-	-	-
	Related	75	2	2.7	0.3	9.3	-	-	-	-	-
Urticaria	Any	75	0	0.0	0.0	4.8	-	-	-	-	-
	Grade 3	75	0	0.0	0.0	4.8	-	-	-	-	-
	Related	75	0	0.0	0.0	4.8	-	-	-	-	-
Across 3 doses											
Arthralgia	Any	76	8	10.5	4.7	19.7	76	10	13.2	6.5	22.9
	Grade 3	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
	Related	76	8	10.5	4.7	19.7	76	9	11.8	5.6	21.3
Fatigue	Any	76	43	56.6	44.7	67.9	76	52	68.4	56.7	78.6
	Grade 3	76	2	2.6	0.3	9.2	76	4	5.3	1.5	12.9
	Related	76	41	53.9	42.1	65.5	76	47	61.8	50.0	72.8
Gastrointestinal	Any	76	20	26.3	16.9	37.7	76	31	40.8	29.6	52.7
	Grade 3	76	1	1.3	0.0	7.1	76	4	5.3	1.5	12.9
	Related	76	15	19.7	11.5	30.5	76	25	32.9	22.5	44.6
Headache	Any	76	43	56.6	44.7	67.9	76	42	55.3	43.4	66.7
	Grade 3	76	0	0.0	0.0	4.7	76	6	7.9	3.0	16.4
	Related	76	38	50.0	38.3	61.7	76	33	43.4	32.1	55.3
Myalgia	Any	76	24	31.6	21.4	43.3	76	33	43.4	32.1	55.3
	Grade 3	76	0	0.0	0.0	4.7	76	2	2.6	0.3	9.2
	Related	76	23	30.3	20.2	41.9	76	29	38.2	27.2	50.0
Rash	Any	76	3	3.9	0.8	11.1	76	5	6.6	2.2	14.7
	Grade 3	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7
	Related	76	1	1.3	0.0	7.1	76	2	2.6	0.3	9.2
Temperature (Axillary)	≥37.5°C	76	6	7.9	3.0	16.4	76	5	6.6	2.2	14.7
	> 39.0°C	76	0	0.0	0.0	4.7	76	1	1.3	0.0	7.1
	Related	76	6	7.9	3.0	16.4	76	4	5.3	1.5	12.9
Urticaria	Any	76	1	1.3	0.0	7.1	76	3	3.9	0.8	11.1
	Grade 3	76	0	0.0	0.0	4.7	76	0	0.0	0.0	4.7

	Related	76	1	1.3	0.0	7.1	76	2	2.6	0.3	9.2
Across 4 doses											
Arthralgia	Any	76	9	11.8	5.6	21.3	-	-	-	-	-
	Grade 3	76	0	0.0	0.0	4.7	-	-	-	-	-
	Related	76	9	11.8	5.6	21.3	-	-	-	-	-
Fatigue	Any	76	49	64.5	52.7	75.1	-	-	-	-	-
	Grade 3	76	3	3.9	0.8	11.1	-	-	-	-	-
	Related	76	45	59.2	47.3	70.4	-	-	-	-	-
Gastrointestinal	Any	76	24	31.6	21.4	43.3	-	-	-	-	-
	Grade 3	76	1	1.3	0.0	7.1	-	-	-	-	-
	Related	76	18	23.7	14.7	34.8	-	-	-	-	-
Headache	Any	76	49	64.5	52.7	75.1	-	-	-	-	-
	Grade 3	76	1	1.3	0.0	7.1	-	-	-	-	-
	Related	76	44	57.9	46.0	69.1	-	-	-	-	-
Myalgia	Any	76	28	36.8	26.1	48.7	-	-	-	-	-
	Grade 3	76	0	0.0	0.0	4.7	-	-	-	-	-
	Related	76	26	34.2	23.7	46.0	-	-	-	-	-
Rash	Any	76	3	3.9	0.8	11.1	-	-	-	-	-
	Grade 3	76	0	0.0	0.0	4.7	-	-	-	-	-
	Related	76	1	1.3	0.0	7.1	-	-	-	-	-
Temperature (Axillary)	≥37.5°C	76	9	11.8	5.6	21.3	-	-	-	-	-
	> 39.0°C	76	0	0.0	0.0	4.7	-	-	-	-	-
	Related	76	8	10.5	4.7	19.7	-	-	-	-	-
Urticaria	Any	76	1	1.3	0.0	7.1	-	-	-	-	-
	Grade 3	76	0	0.0	0.0	4.7	-	-	-	-	-
	Related	76	1	1.3	0.0	7.1	-	-	-	-	-

Any = occurrence of any general symptom regardless of intensity grade
Grade 3 = symptoms that prevented normal activities
Grade 3 urticaria = urticaria distributed on at least 4 body areas
Related = general symptom assessed by the investigator as casually related to the study vaccination
For each dose and across doses
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

Secondary Outcome Variable(s): Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following the 4th dose of HBV vaccine (Total vaccinated cohort)

		HPV + HepB Group					**HepB Group**				
					95 % CI					**95 % CI**	
Symptom	**Intensity/ Relationship**	**N**	**n**	**%**	**LL**	**UL**	**N**	**n**	**%**	**LL**	**UL**
Arthralgia	Any	74	1	1.4	0.0	7.3	75	4	5.3	1.5	13.1
	Grade 3	74	0	0.0	0.0	4.9	75	0	0.0	0.0	4.8
	Related	74	1	1.4	0.0	7.3	75	3	4.0	0.8	11.2
Fatigue	Any	74	26	35.1	24.4	47.1	75	34	45.3	33.8	57.3
	Grade 3	74	1	1.4	0.0	7.3	75	0	0.0	0.0	4.8
	Related	74	24	32.4	22.0	44.3	75	29	38.7	27.6	50.6
Gastrointestinal	Any	74	3	4.1	0.8	11.4	75	13	17.3	9.6	27.8
	Grade 3	74	1	1.4	0.0	7.3	75	0	0.0	0.0	4.8
	Related	74	3	4.1	0.8	11.4	75	12	16.0	8.6	26.3
Headache	Any	74	21	28.4	18.5	40.1	75	25	33.3	22.9	45.2
	Grade 3	74	1	1.4	0.0	7.3	75	0	0.0	0.0	4.8
	Related	74	19	25.7	16.2	37.2	75	17	22.7	13.8	33.8
Myalgia	Any	74	4	5.4	1.5	13.3	75	18	24.0	14.9	35.3
	Grade 3	74	1	1.4	0.0	7.3	75	1	1.3	0.0	7.2

	Related	74	3	4.1	0.8	11.4	75	15	20.0	11.6	30.8
Rash	Any	74	1	1.4	0.0	7.3	75	0	0.0	0.0	4.8
	Grade 3	74	0	0.0	0.0	4.9	75	0	0.0	0.0	4.8
	Related	74	1	1.4	0.0	7.3	75	0	0.0	0.0	4.8
Temperature/ (Axillary) (°C)	≥37.5°C	74	3	4.1	0.8	11.4	75	0	0.0	0.0	4.8
	> 39.0°C	74	0	0.0	0.0	4.9	75	0	0.0	0.0	4.8
	Related	74	3	4.1	0.8	11.4	75	0	0.0	0.0	4.8
Urticaria	Any	74	0	0.0	0.0	4.9	75	0	0.0	0.0	4.8
	Grade 3	74	0	0.0	0.0	4.9	75	0	0.0	0.0	4.8
	Related	74	0	0.0	0.0	4.9	75	0	0.0	0.0	4.8

Any = occurrence of any general symptom regardless of intensity grade
Grade 3 = symptoms that prevented normal activities
Grade 3 urticaria = urticaria distributed on at least 4 body areas
Related = general symptom assessed by the investigator as casually related to the study vaccination
N= number of subjects with the 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

Secondary Outcome variable(s) : Percentage of subjects reporting the occurrence of medically significant conditions (MSCs), reported up to Month 7 (Total vaccinated cohort)

Most frequent MSCs up to Month 7	**HPV + HepB Group N = 76**	**HepB Group N = 76**
Subjects with any MSC(s), n (%)	30 (39.5)	21 (27.6)
Cystitis	5 (6.6)	3 (3.9)
Hypotension	2 (2.6)	1 (1.3)
Influenza like illness	-	3 (3.9)
Malaise	2 (2.6)	1 (1.3)
Bronchitis	2 (2.6)	1 (1.3)
Dizziness	2 (2.6)	-
Headache	-	1 (1.3)
Localised infection	2 (2.6)	-
Oropharyngeal pain	2 (2.6)	-
Torticollis	3 (3.9)	-
Anemia	-	1 (1.3)
Arthralgia	-	1 (1.3)
Asthma	-	1 (1.3)
Conjunctivitis	-	1 (1.3)
Constipation	-	1 (1.3)
Diarrhoea	-	1 (1.3)
Ear infection	2 (2.6)	-
Gastritis	-	1 (1.3)
Hypocalcaemia	-	1 (1.3)
Inflammation	2 (2.6)	-
Muscle strain	-	1 (1.3)
Oesophagitis	-	1 (1.3)
Pain in extremity	-	1 (1.3)
Pyelonephritis	-	1 (1.3)
Rhinitis allergic	-	1 (1.3)
Tooth abscess	-	1 (1.3)
Urticaria	-	1 (1.3)
Vestibulitis	-	1 (1.3)
Vulvovaginal pruritus	-	1 (1.3)
Wound	-	1 (1.3)

- : MSC absent or not meeting the selected rule: > 30 subjects per treatment group and ≤ 3 groups: display the most frequent 10 events in each group

Secondary Outcome variable(s) : Percentage of subjects reporting the occurrence of medically significant conditions (MSCs), reported during the entire follow-up period up to Month 13 (Total vaccinated cohort)		
Most frequent MSCs	**HPV + HepB Group N = 74**	**HepB Group N = 75**
Subjects with any MSC(s), n (%)	37 (50.0)	32 (42.7)
Anaemia	-	1 (1.3)
Lymphadenopathy	-	1 (1.3)
Palpitations	-	1 (1.3)
Conjunctivitis	-	1 (1.3)
Constipation	-	1 (1.3)
Diarrhoea	-	1 (1.3)
Gastric disorder	-	1 (1.3)
Gastritis	-	1 (1.3)
Oesophagitis	-	2 (2.7)
Fatigue	2 (2.7)	-
Inflammation	2 (2.7)	-
Influenza like illness	-	3 (4.0)
Malaise	2 (2.7)	1 (1.3)
Vestibulitis	-	1 (1.3)
Bronchitis	3 (4.1)	3 (4.0)
Cystitis	6 (8.1)	6 (8.0)
Ear infection	2 (2.7)	-
Localised infection	2 (2.7)	-
Papilloma viral infection	-	1 (1.3)
Pyelonephritis	-	1 (1.3)
Tooth abscess	-	1 (1.3)
Joint sprain	-	1 (1.3)
Muscle strain	-	1 (1.3)
Procedural pain	-	1 (1.3)
Wound	-	1 (1.3)
Hypocalcaemia	-	1 (1.3)
Type 1 diabetes mellitus	-	1 (1.3)
Arthralgia	-	1 (1.3)
Pain in extremity	-	1 (1.3)
Tendonitis	-	1 (1.3)
Torticollis	3 (4.1)	-
Dizziness	2 (2.7)	-
Headache	-	1 (1.3)
Migraine	-	1 (1.3)
Depression	2 (2.7)	-
Insomnia	-	1 (1.3)
Panic reaction	-	1 (1.3)
Vulvovaginal pruritus	-	1 (1.3)
Asthma	-	1 (1.3)
Oropharyngeal pain	2 (2.7)	-
Rhinitis allergic	-	1 (1.3)
Urticaria	-	1 (1.3)
Hypertension	-	1 (1.3)
Hypotension	2 (2.7)	2 (2.7)
- : MSC absent or not meeting the selected rule: > 30 subjects per treatment group and ≤ 3 groups: display the most frequent 10 events in each group		
Safety Results: Number (%) of subjects with unsolicited adverse events after 3 doses in HepB Group and after 4 doses in HPV + HepB Group (Total vaccinated cohort)		
Most frequent adverse events -	**HPV + HepB Group**	**HepB Group**

On-Therapy (occurring within the 30 days following vaccination)	**N = 76**	**N = 76**
Subjects with any AE(s), n (%)	56 (73.7)	47 (61.8)
Subjects with grade 3 AE(s), n (%)	17 (22.4)	12 (15.8)
Subjects with related AE(s), n (%)	13 (17.1)	8 (10.5)
Headache	12 (15.8)	13 (17.1)
Upper respiratory tract infection	7 (9.2)	5 (6.6)
Dysmenorrhoea	7 (9.2)	6 (7.9)
Cystitis	5 (6.6)	4 (5.3)
Nasopharyngitis	6 (7.9)	3 (3.9)
Oropharyngeal pain	7 (9.2)	-
Injection site haematoma	3 (3.9)	3 (3.9)
Rhinitis	6 (7.9)	-
Abdominal pain	-	5 (6.6)
Cough	4 (5.3)	-
Influenza like illness	-	4 (5.3)
Pharyngitis	-	4 (5.3)
Dizziness	3 (3.9)	-
Hypotension	3 (3.9)	-
Migraine	-	3 (3.9)
Myalgia	3 (3.9)	-
Sinusitis	-	3 (3.9)
Grade 3 AEs = AEs that prevented normal activities Related AEs = AEs assessed by the investigator as casually related to the study vaccination - : Adverse event absent or not meeting the selected rule: > 30 subjects per treatment group and ≤ 3 groups: display the most frequent 10 events in each group		
Safety Results: Number (%) of subjects with unsolicited adverse events reported after the 4th dose of HBV vaccine (Total vaccinated cohort)		
Most frequent adverse events - On-Therapy (occurring within Day 0-30 following vaccination)	**HPV+HepB Group N = 74**	**HepB Group N = 75**
Subjects with any AE(s), n (%)	20 (27.0)	22 (29.3)
Subjects with grade 3 AE(s), n (%)	5 (6.8)	3 (4.0)
Subjects with related AE(s), n (%)	3 (4.1)	9 (12.0)
Cystitis	2 (2.7)	2 (2.7)
Headache	2 (2.7)	1 (1.3)
Oropharyngeal pain	2 (2.7)	2 (2.7)
Gastroenteritis	3 (4.1)	-
Injection site pruritus	1 (1.4)	2 (2.7)
Injection site reaction	-	3 (4.0)
Nasopharyngitis	1 (1.4)	2 (2.7)
Fatigue	1 (1.4)	1 (1.3)
Injection site haematoma	-	2 (2.7)
Lymphadenopathy	1 (1.4)	1 (1.3)
Vulvovaginitis	1 (1.4)	1 (1.3)
Abdominal pain	1 (1.4)	-
Abdominal pain upper	-	1 (1.3)
Abscess oral	1 (1.4)	-
Arthritis	-	1 (1.3)
Bronchitis	-	1 (1.3)
Depression	1 (1.4)	-
Eyelid irritation	1 (1.4)	-
Hypertension	-	1 (1.3)
Hypotension	-	1 (1.3)
Influenza like illness	1 (1.4)	-
Injection site haemorrhage	-	1 (1.3)

Joint sprain	-	1 (1.3)
Malaise	-	1 (1.3)
Meniscus lesion	1 (1.4)	-
Migraine	-	1 (1.3)
Nausea	-	1 (1.3)
Pain	1 (1.4)	-
Palpitations	-	1 (1.3)
Pharyngitis	1 (1.4)	-
Rhinitis	-	1 (1.3)
Rhinotracheitis	1 (1.4)	-
Tonsillitis	-	1 (1.3)
Toothache	1 (1.4)	-
Upper respiratory tract infection	1 (1.4)	-
Urinary tract infection	-	1 (1.3)
Grade 3 AEs = AEs that prevented normal activities Related AEs = AEs assessed by the investigator as casually related to the study vaccination - : Adverse event absent		
Safety Results: Number (%) of subjects with serious adverse events reported up to Month 7 (Total vaccinated cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV + HepB Group N = 76**	**HepB Group N = 76**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**HPV + HepB Group N = 76**	**HepB Group N = 76**
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 up to Month 13 (Total vaccinated cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	**HPV + HepB Group N = 76**	**HepB Group N = 76**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	2 (2.6) [0]	2 (2.6) [0]
Abortion spontaneous complete	1 (1.3) [0]	0 (0.0) [0]
Graves-Basedow's disease.	1 (1.3) [0]	0 (0.0) [0]
Endometriosis	1 (1.3) [0]	0 (0.0) [0]
Gastroenteritis viral	0 (0.0) [0]	1 (1.3) [0]
Type 1 diabetes mellitus	0 (0.0) [0]	1 (1.3) [0]
Fatal SAEs	**HPV + HepB Group N = 76**	**HepB Group N = 76**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]

Conclusion: One month after the third dose of hepatitis B vaccine (Month 3), among the subjects who were initially seronegative for anti-HBs and anti-HBc, 96.4% of subjects in HPV + HepB Group and 96.9% of subjects in HepB Group had anti HBs antibody titer ≥ 10 mIU/mL (geometric mean titers were 60.2 in HPV + HepB Group and 71.3 mIU/mL in HepB Group).
After 3 doses of HBV vaccine in HepB Group and 3 doses of HBV vaccine & 3 doses of HPV vaccine in HPV + HepB Group, unsolicited adverse events were reported in 56 (73.7%) subjects in HPV + HepB Group and 47 (61.8%) subjects in HepB Group. After the 4th dose of HBV vaccine, 20 (27.0%) subjects in HPV + HepB Group and 22 (29.3%) subjects in HepB Group reported at least one unsolicited AE. During the entire study period, 2 subjects in each group reported SAEs. None of the reported SAEs were assessed by the investigators as related to the study vaccination. No fatal SAEs were reported. Please also refer to the publication citations.

Date updated: 20-October-2014