

18 October 2012 EMA/251551/2013 Committee for Medicinal Products for Human Use (CHMP)

Cervarix

(human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed))

Procedure No. EMEA/H/C/000721/P46/058/059/060/061/062/063

CHMP assessment report for paediatric use studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

Assessment Report as adopted by the CHMP with all information of a commercially confidential nature deleted

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1. RECOMMENDATION

Based on the review of the paediatric data on safety and immunogenicity collected in studies HPV-030 Month 12, HPV-025 Month 72, HPV-048 (Months 18, 24 and 36) as well as in study HPV-058 the Rapporteur considers that the benefit-risk balance for the above mentioned product remains unchanged and therefore does not require further regulatory action on the marketing authorisation for Cervarix. The SmPC and PIL remain unchanged.

The Company is requested to submit the Month 12 interim analysis of study HPV-040, as well as the results of study HPV-100, in due time (see Background information below).

For study HPV-025, follow-up data up to Month 120 are needed to fulfil FUM019. For study HPV-048, the final report at Month 60 is needed to fulfil commitment FUM021.

2. BACKGROUND

According to Article 46 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006, the Company hereby submits to the EMA the clinical study reports for the following paediatric studies: HPV-030 Month 12, HPV-025 Month 72, HPV-048 (Months 18, 24 and 36) as well as HPV-058.

The applicant states that, in accordance with Article 16(2) of Regulation (EC) No 726/2004, the data submitted do not influence the benefit-risk balance for the above mentioned product and therefore do not require taking further regulatory action on the marketing authorisation for Cervarix.

The Company is also taking the opportunity to inform the EMA that there is a delay for the submission of the following HPV studies according to Article 46 regulation:

- HPV-040 Interim analysis at Month 12 to evaluate the immunogenicity in all subjects
- HPV-100 Post-Marketing Study (PMS) in the Philippines
- HPV-025 EXT 013 Interim Analysis at Month 84 (Year 7) to evaluate the long-term immunogenicity and safety.

HPV-040 interim analysis at Month 12 to evaluate immunogenicity in all subjects

Last Subject Last Visit: 20 April 2011

The last subject completed the Month 12 visit on 20 April 2011, the Company had to wait until November 2011 for the download of registry data (Hilmo, Finland). With more than 32,000 enrolled subjects and the complicated study design it was not feasible to perform all analysis-related activities such as data cleaning, investigator's review on medical records of each potential immune-mediated disease (pIMD) case and investigator's signature in clinical database for each individual Subject'S Case Report Form (CRF). A commitment is made to the EMEA (FUM034) for this interim analysis with submission due date of December 2012 and for the final analysis with submission due date of June 2015.

Currently planned completion date of study report: October 2012

HPV-100 Post-marketing Study (PMS) in the Philippines

Last Subject Last Visit: 02August 2011

This study was prematurely terminated, after which the Clinical Trial Assistants faced difficulties in getting all required information for completing the Case Report Forms (CRFs) from the principal investigator. Completion of the last CRF information is expected by the end of May 2012. The cleaning of the clinical database is ongoing.

Currently planned completion date of study report: October 2012

HPV-025 EXT 013 interim analysis at Month 84 (Year 7) to evaluate long-term immunogenicity and safety

Last Subject Last Visit: 20 January 2012

Since the Company considered that the Article 46 legislation was applicable to the submission of the study report within 6 months after LSLV of each study and not within 6 months after LSLV of each study epoch, and the HPV-025 EXT 013 interim analyses at Months 72, 84, 96 and 108 were not requested to be submitted to the EMEA, the Company previously did not track the submission of the HPV-025 EXT 013 interim analysis at Month 84 as an Article 46 submission. There was only a commitment made to the EMEA to submit the first HPV-025 EXT 013 interim analysis at Month 60 (done in December 2010) and the HPV-025 EXT 013 final analysis at Month 120 with due date of December 2015.

Currently planned completion date of study report: September 2012

3. SCIENTIFIC DISCUSSION

Study HPV-030 Month 12

The HPV-030 PRI Report dated 17 June 2010 was previously submitted as a type II variation (II-19). The newly submitted Annex Report 1 supplements the report dated 17 June 2010 with safety results reported during Month 7 till Month 12 and during the entire study period (Month 0 till Month 12).

- Occurrence of any, Grade 3 and causally related to vaccination SAEs in all groups throughout the ESFU phase and during the entire study period.
- Occurrence of medically significant conditions in all groups throughout the throughout the ESFU phase and during the entire study period regardless of causal relationship to vaccination and intensity.

It was concluded that in 9-15 year old girls, Cervarix and the GSK Biologicals' hepatitis B vaccine (Engerix) appeared to be generally well tolerated up to six months after the last vaccine dose when given alone or when co-administered with Engerix.

Study HPV-025 Month 72

Study HPV-025 EXT 013 is a long-term follow-up of the primary Study HPV-013 to extend the total duration of the study up to 10 years to assess persistence of immunogenicity (including any indication of waning immunity) and long-term follow-up safety as was requested by the CHMP (commitment FUM019). Annual interim analyses at Months 60, 72, 84, 96 and 108 are foreseen. The submission of

the final analysis at Month 120 (Year 10) to fulfil the commitment is currently planned in August 2015. No vaccine was administered in Study HPV-025 EXT 013, and only subjects who were included in the immunogenicity subset and received three doses of Cervarix in study HPV -013 and participated in the HPV-013 extension studies HPV-013 Ext M18, M24, M36 and M48 were eligible to participate in Study HPV-025. Subjects who did/do not participate at a particular persistence time point in study HPV- 025 EXT-013 might still be eligible to be included/continue at later time points.

The HPV-013 Final Report (Month 7) and Annex Reports (Months 12, 18, 24, 36 and 48) were previously submitted as FUM019, FUM019.1 and FUM019.2. The HPV-025 EXT 013 Interim Report (M60) dated 11 October 2010 was previously submitted to fulfil the commitment FUM019.3 on 14 December 2010. Table 8 and Table 9 below show the seropositivity rates and GMTs by prevaccination status. Figure 1 and Figure 2 show the kinetics of HPV-16 antibodies and HPV-18 for subjects seronegative for at pre-vaccination. It can be concluded that the immunogenicity was sustained up to 72 months among pre-teen and adolescent females vaccinated in study HPV-013 both in terms of anti-HPV-16/18 GMTs and seropositivity rates with an acceptable safety profile.

Assessor's comment

The safety data from study HPV-025 are not shown here since none of the serious adverse events that occurred among 74 subjects were considered as being related to vaccination. The MAH is expected to submit the final study results to fulfil commitment 019 in due time (expected in August 2015).

					1	≥ 8 E	L.U/m	L		GMT			
							95%	6 CI		95%	6 CI		
Antibody	Group	Pre-vacc	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
		status											
Anti-HPV-16	HPV	S-	PRE	475	0	0.0	0.0	0.8	4.0	4.0	4.0	<8.0	<8.0
			PII(M2)	475	473	99.6	98.5	99.9	4640.6	4297.4	5011.2	<8.0	46001.0
			PIII(M7)	475	475	100	99.2	100	19776.7	18341.7	21324.0	706.0	244471.0
			[M12-M16]	409	407	99.5	98.2	99.9	4460.2	4021.3	4947.1	<8.0	162392.0
			PIII(M18)	475	475	100	99.2	100	3823.7	3526.8	4145.6	156.0	67894.0
			PIII(M24)	472	472	100	99.2	100	3148.5	2909.7	3406.9	215.0	44630.0
			PIII(M36)	471	471	100	99.2	100	2602.6	2406.0	2815.2	146.0	46642.0
			PIII(M48)	468	468	100	99.2	100	2284.9	2112.6	2471.2	126.0	28259.0
			PIII(M60)	351	351	100	99.0	100	2244.1	2044.2	2463.6	110.0	30868.0
			PIII(M72)	475	475	100	99.2	100	1962.0	1811.3	2125.3	113.0	28063.0
		S+	PRÉ	27	27	100	87.2	100	15.7	11.4	21.5	8.0	141.0
			PII(M2)	27	27	100	87.2	100	6757.9	5116.9	8925.2	2565.0	26626.0
			PIII(M7)	27	27	100	87.2	100	24915.1	19405.4	31989.2	6662.0	67566.0
			[M12-M16]	23	23	100	85.2	100	5405.7	3894.5	7503.3	886.0	22603.0
			PIII(M18)	27	27	100	87.2	100	4338.8	3217.2	5851.4	605.0	15320.0
			PIII(M24)	27	27	100	87.2	100	3828.4	2904.9	5045.5	561.0	11861.0
			PIII(M36)	25	25	100	86.3	100	2964.5	2248.4	3908.8	388.0	7730.0
			PIII(M48)	25	25	100	86.3	100	2726.6	2015.0	3689.6	307.0	7799.0
			PIII(M60)	21	21	100	83.9	100	2515.6	1785.0	3545.2	241.0	7345.0
			PIII(M72)	27	27	100	87.2	100	2194.4	1674.8	2875.1	244.0	5965.0
		Total	PRE	502	27	5.4	3.6	7.7	4.3	4.2	4.4	<8.0	141.0
			PII(M2)	502	500	99.6	98.6	100	4735.3	4395.8	5101.2	<8.0	46001.0
			PIII(M7)	502	502	100	99.3	100	20023.9	18623.3	21529.9	706.0	244471.0
			[M12-M16]	432	430	99.5	98.3	99.9	4506.1	4079.4	4977.4	<8.0	162392.0
			PIII(M18)	502	502	100	99.3	100	3849.8	3561.0	4162.1	156.0	67894.0
			PIII(M24)	499	499	100	99.3	100	3182.0	2949.1	3433.3	215.0	44630.0
			PIII(M36)	496	496	100	99.3	100	2619.7	2428.7	2825.8	146.0	46642.0
			PIII(M48)	493	493	100	99.3	100	2305.5	2137.1	2487.2	126.0	28259.0
			PIII(M60)	372	372	100	99.0	100	2258.6	2064.6	2470.9	110.0	30868.0
			PIII(M72)	502	502	100	99.3	100	1973.9	1827.9	2131.6	113.0	28063.0

Seropositivity rates and GMTs for anti-HPV-16 antibodies by prevaccination status (Month 72 ATP cohort for immunogenicity)

Footnote: cf. Table 9.

					2	27 EL	U/m	L		GMT			
							95%	6 CI		95	% CI		
Antibody	Group	Pre-vacc	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
		status											
Anti-HPV-18	HPV	S-	PRE	478	0	0.0	0.0	0.8	3.5	3.5	3.5	<7.0	<7.0
			PII(M2)	478	477	99.8	98.8	100	3731.5	3464.4	4019.1	<7.0	47111.0
			PIII(M7)	478	478	100	99.2	100	8100.6	7489.5	8761.6	567.0	187560.0
			[M12-M16]	413	412	99.8	98.7	100	1744.3	1575.7	1930.8	<7.0	53993.0
			PIII(M18)	478	478	100	99.2	100	1481.2	1357.1	1616.5	38.0	57489.0
			PIII(M24)	475	475	100	99.2	100	1184.3	1087.2	1290.1	38.0	34318.0
			PIII(M36)	472	472	100	99.2	100	929.3	852.7	1012.8	57.0	27854.0
			PIII(M48)	470	470	100	99.2	100	821.3	753.2	895.5	42.0	27951.0
			PIII(M60)	354	354	100	99.0	100	754.9	680.4	837.6	38.0	18021.0
			PIII(M72)	478	478	100	99.2	100	749.6	687.7	817.0	39.0	15982.0
		S+	PRE	24	24	100	85.8	100	18.3	13.8	24.3	7.0	86.0
			PII(M2)	24	24	100	85.8	100	3873.1	2787.6	5381.3	1124.0	14514.0
			PIII(M7)	24	24	100	85.8	100	10589.9	7227.1	15517.4	2244.0	61522.0
			[M12-M16]	19	19	100	82.4	100	2885.8	1650.9	5044.3	362.0	19000.0
			PIII(M18)	24	24	100	85.8	100	2148.2	1360.7	3391.4	333.0	12858.0
			PIII(M24)	24	24	100	85.8	100	1782.6	1152.2	2757.9	241.0	10257.0
			PIII(M36)	24	24	100	85.8	100	1451.0	941.8	2235.4	143.0	6202.0
			PIII(M48)	23	23	100	85.2	100	1311.7	828.7	2076.3	132.0	6750.0
			PIII(M60)	18	18	100	81.5	100	1196.9	679.1	2109.4	115.0	5009.0
			PIII(M72)	24	24	100	85.8	100	1081.0	696.3	1678.3	114.0	4881.0
		Total	PRE	502	24	4.8	3.1	7.0	3.8	3.7	3.9	<7.0	86.0
			PII(M2)	502	501	99.8	98.9	100	3738.1	3477.8	4018.0	<7.0	47111.0
			PIII(M7)	502	502	100	99.3	100	8205.0	7598.9	8859.6	567.0	187560.0
			[M12-M16]	432	431	99.8	98.7	100	1783.3	1613.4	1971.2	<7.0	53993.0
			PIII(M18)	502	502	100	99.3	100	1507.7	1383.5	1643.1	38.0	57489.0
			PIII(M24)	499	499	100	99.3	100	1207.8	1110.4	1313.8	38.0	34318.0
			PIII(M36)	496	496	100	99.3	100	949.5	872.5	1033.3	57.0	27854.0
			PIII(M48)	493	493	100	99.3	100	839.4	770.8	914.1	42.0	27951.0
			PIII(M60)	372	372	100	99.0	100	772.0	696.8	855.2	38.0	18021.0
			PIII(M72)	502	502	100	99.3	100	762.8	701.0	830.1	39.0	15982.0

Table 9 Seropositivity rates and GMTs for anti-HPV-18 antibodies by prevaccination status (Month 72 ATP cohort for immunogenicity)

HPV = HPV-16/18 L1 VLP AS04

S- = seronegative subjects (antibody concentration < 7 EL.U/mL) prior to vaccination

S+ = seropositive subjects (antibody concentration ≥ 7 EL.U/mL) prior to vaccination

GMT = geometric mean antibody 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

MIN/MAX = Minimum/Maximum

PRE = Pre-vaccination

PII (M2) = Post Dose II (Month 2)

PIII (M7) = Post Dose III (Month 7)

[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)

PIII (M60) = Post Dose III (Month 60)

PIII (M72) = Post Dose III (Month 72)





HPV = HPV-16/18 L1 VLP AS04 Nat-inf = GMTs from subjects who had cleared HPV-16 infection (study HPV-008) Plateau = GMTs at the plateau level in study HPV-001/007 (Month 45 – 50)

Figure 2 Kinetics of HPV-18 antibodies for subjects seronegative for HP\ at pre-vaccination (Month 72 ATP cohort for immunogenicity)



HPV = HPV-16/18 L1 VLP AS04 Nat-inf = GMTs from subjects who had cleared HPV-16 infection (study HPV-008) Plateau = GMTs at the plateau level in study HPV-001/007 (Month 45 – 50)

Study HPV-048

The HPV-048 PRI study report M7 and Annex Report MI2 were previously submitted in order to fulfill the commitments FUM021, 021.1 and 021.2. The Annex Reports 2 (MI8), 3 (M24) and 4 (M36) are now submitted. Study HPV-48 PRI is still ongoing and 2 more study visits at Months 48 and 60 are foreseen. The submission of the final report at Month 60 to fulfil commitment FUM021 is currently planned in October 2013.

From the results reported at M18, M24 and M36 it is concluded that in all age groups (9-25 years) a sustained immune response against both HPV-16 and HPV-18 antigens was observed in all vaccine groups up to 36 months after the first vaccination. Cervarix was generally well tolerated. Table 19 and Table 20 show seropositivity rates and GMTs by pre-vaccination status. Table 21 and Table 22 show seropositivity rates and GMTs by pre-vaccination status and by age stratum (strata: 9-14, 15-19, 20-25 years). Figure 1 and Figure 2 show the persistence of ELISA antibody titers in subjects seronegative

at baseline. Assessor's note: the only relevant group is the HPV group receiving the 20 μ g/20 μ g Cervarix formulation that is currently commercially available and used according to the 0, 1, 6 month vaccination schedule.

						2	2 8 E	LU/M	L		GMT			
								95%	6 CI		95	% CI		
Antibody	Group	Sub-	Pre-	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
		group	vacc											
			status											
HPV	V40_02	9_14	S-	PRE	60	0	0.0	0.0	6.0	4.0	4.0	4.0	<8.0	<8.0
16.VLP														
IGG														
				PII(M3)	60	60	100	94.0	100	7301.2	5921.7	9002.0	966.0	45534.0
				PIII(M7)	60	60	100	94.0	100	2008.4	1569.3	2570.5	208.0	26271.0
				PIII(M12)	60	60	100	94.0	100	1418.6	1101.3	1827.2	143.0	17994.0
				PIII(M18)	59	59	100	93.9	100	1359.9	1043.1	1772.9	138.0	11507.0
				PIII(M24)	59	59	100	93.9	100	1136.9	881.1	1466.9	124.0	9500.0
				PIII(M36)	60	60	100	94.0	100	998.1	//9.2	12/8.6	117.0	10491.0
			S+	PRE	1	1	100	2.5	100	15.0	-	-	15.0	15.0
				PII(M3)	1	1	100	2.5	100	63/8.0	-	-	6378.0	6378.0
				PIII(M/)	1	1	100	2.5	100	1159.0	-	-	1159.0	1159.0
				PIII(M12)	1	1	100	2.5	100	940.0	-	-	940.0	940.0
				PIII(M18)	1	1	100	2.5	100	955.0	-	-	955.0	955.0
				PIII(M24)	1	1	100	2.5	100	602.0	-	-	602.0	602.0
			Tetal	PIII(M36)	1	1	100	2.5	100	422.0	-	-	422.0	422.0
			TOLAI	PILE DII/M2)	61	61	1.0	0.0	100	7295.0	5.5	9050.9	<0.0 966.0	10.0
				PII(M3)	61	61	100	04.1	100	1000 4	1560.7	2529.5	208.0	40004.0
				PIII(M//) DIII/M12)	61	61	100	04.1	100	1409.0	1008.2	2030.0	143.0	17994 0
				PIII(M12)	60	60	100	94.1	100	1351.0	1030.2	1755.0	138.0	11507.0
				PIII(M10)	00	60	100	94.0	100	1124.9	874.8	1446.4	124.0	9500.0
				PIII(M36)	61	61	100	94.0	100	984.1	770.2	1257.5	117.0	10491.0
		15.25	S.	PRE	96	0	0.0	0.0	3.8	4.0	4.0	4.0	<8.0	<8.0
			Ĩ.	PII/M3)	96	96	100	96.2	100	4953.9	4200.1	5843.0	233.0	30994.0
				PIII(M7)	96	96	100	96.2	100	1128.6	945.2	1347 7	80.0	6111.0
				PIII(M12)	96	96	100	96.2	100	799.9	666.4	960.3	53.0	5112.0
				PIII(M18)	95	95	100	96.2	100	724.4	591.9	886.6	32.0	5415.0
				PIII(M24)	94	94	100	96.2	100	624.8	517.6	754.1	24.0	4111.0
				PIII(M36)	96	96	100	96.2	100	547.2	453.9	659.7	29.0	2717.0
			S+	PRE	9	9	100	66.4	100	44.2	18.2	107.4	9.0	413.0
				PII(M3)	9	9	100	66.4	100	4440.4	2350.6	8388.1	1744.0	20636.0
				PIII(M7)	9	9	100	66.4	100	1632.7	756.7	3523.0	521.0	11429.0
				PIII(M12)	9	9	100	66.4	100	1252.6	599.0	2619.4	338.0	7667.0
				PIII(M18)	9	9	100	66.4	100	1050.8	516.1	2139.3	281.0	5156.0
				PIII(M24)	9	9	100	66.4	100	824.1	371.3	1829.3	184.0	6264.0
				PIII(M36)	9	9	100	66.4	100	704.2	296.8	1670.6	120.0	5741.0
			Total	PRE	105	9	8.6	4.0	15.6	4.9	4.3	5.7	<8.0	413.0
				PII(M3)	105	105	100	96.5	100	4907.7	4193.7	5743.1	233.0	30994.0
				PIII(M7)	105	105	100	96.5	100	1164.9	981.1	1383.3	80.0	11429.0
				PIII(M12)	105	105	100	96.5	100	831.3	696.9	991.5	53.0	7667.0
				PIII(M18)	104	104	100	96.5	100	748.1	617.4	906.5	32.0	5415.0
				PIII(M24)	103	103	100	96.5	100	640.1	534.0	767.3	24.0	6264.0
				PIII(M36)	105	105	100	96.5	100	559.2	466.4	670.4	29.0	5741.0

Seropositivity rates and GMTs for HPV 16.VLP IGG antibodies by pre-vaccination status in subjects aged 9-14 years and 15-25 years (Month 36 ATP Immunogenicity Cohort)

						2	2 8 EI	LU/M	L		GMT		, ,	
								95%	6 CI		95	% CI		
Antibody	Group	Sub-	Pre-	Timing	Ν	n	%	LL	UL	value	LL	UL	Min	Max
		group	vacc											
			status											
	V40_06	9_14	S-	PRE	50	0	0.0	0.0	7.1	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	50	50	100	92.9	100	368.6	277.6	489.5	43.0	7324.0
				PIII(M7)	50	50	100	92.9	100	16994.1	13914.2	20755.8	2713.0	57135.0
				PIII(M12)	50	50	100	92.9	100	4535.4	3617.3	5686.6	877.0	30300.0
				PIII(M18)	50	50	100	92.9	100	3016.8	2416.1	3766.8	600.0	12570.0
				PIII(M24)	49	49	100	92.7	100	2176.6	1738.2	2725.7	341.0	9840.0
				PIII(M36)	50	50	100	92.9	100	1762.7	1419.9	2188.3	239.0	8472.0
			Total	PRE	50	0	0.0	0.0	7.1	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	50	50	100	92.9	100	368.6	277.6	489.5	43.0	7324.0
				PIII(M7)	50	50	100	92.9	100	16994.1	13914.2	20755.8	2713.0	57135.0
				PIII(M12)	50	50	100	92.9	100	4535.4	3617.3	5686.6	877.0	30300.0
				PIII(M18)	50	50	100	92.9	100	3016.8	2416.1	3766.8	600.0	12570.0
				PIII(M24)	49	49	100	92.7	100	2176.6	1738.2	2725.7	341.0	9840.0
				PIII(M36)	50	50	100	92.9	100	1762.7	1419.9	2188.3	239.0	8472.0
		15_25	S-	PRE	85	0	0.0	0.0	4.2	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	85	85	100	95.8	100	318.2	257.3	393.5	45.0	4601.0
				PIII(M7)	85	85	100	95.8	100	10407.8	8748.1	12382.3	1211.0	48115.0
				PIII(M12)	84	84	100	95.7	100	3129.7	2608.6	3754.9	109.0	20072.0
				PIII(M18)	83	83	100	95.7	100	2138.7	1779.4	2570.5	107.0	15410.0
				PIII(M24)	83	83	100	95.7	100	1653.2	1385.6	1972.6	138.0	11571.0
				PIII(M36)	85	85	100	95.8	100	1378.1	1164.0	1631.7	283.0	7742.0
			S+	PRE	24	24	100	85.8	100	69.4	36.0	133.9	8.0	1006.0
				PII(M3)	24	24	100	85.8	100	1763.4	941.0	3304.7	139.0	23592.0
				PIII(M7)	24	24	100	85.8	100	6894.8	5082.8	9352.8	1831.0	33723.0
				PIII(M12)	24	24	100	85.8	100	2755.4	1934.5	3924.7	499.0	11023.0
				PIII(M18)	24	24	100	85.8	100	2112.8	1409.3	3167.5	284.0	8738.0
				PIII(M24)	24	24	100	85.8	100	1659.6	1127.9	2441.9	288.0	6774.0
				PIII(M36)	23	23	100	85.2	100	1212.1	815.4	1801.8	157.0	7224.0
			Total	PRE	109	24	22.0	14.6	31.0	7.5	5.8	9.8	<8.0	1006.0
				PII(M3)	109	109	100	96.7	100	463.9	361.3	595.7	45.0	23592.0
				PIII(M7)	109	109	100	96.7	100	9505.6	8161.4	11071.3	1211.0	48115.0
				PIII(M12)	108	108	100	96.6	100	3042.3	2593.6	3568.8	109.0	20072.0
				PIII(M18)	107	107	100	96.6	100	2132.8	1807.0	2517.5	107.0	15410.0
				PIII(M24)	107	107	100	96.6	100	1654.7	1411.5	1939.7	138.0	11571.0
				PIII(M36)	108	108	100	96.6	100	1341.0	1148.9	1565.2	157.0	7742.0
	V20_06	9_14	S-	PRE	53	0	0.0	0.0	6.7	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	53	53	100	93.3	100	276.0	213.3	357.2	73.0	6037.0
				PIII(M7)	53	53	100	93.3	100	11957.2	9657.2	14804.9	2687.0	60582.0
				PIII(M12)	53	53	100	93.3	100	3632.8	2973.9	4437.6	737.0	21151.0
				PIII(M18)	53	53	100	93.3	100	2385.9	1931.6	2947.0	516.0	10395.0
				PIII(M24)	52	52	100	93.2	100	1836.0	1494.3	2255.7	452.0	7302.0
				PIII(M36)	53	53	100	93.3	100	1595.1	1298.2	1960.0	356.0	7249.0
			S+	PRE	2	2	100	15.8	100	10.8	1.0	111.9	9.0	13.0
				PII(M3)	2	2	100	15.8	100	216.6	16.7	2812.8	177.0	265.0
				PIII(M7)	2	2	100	15.8	100	10464.9	271.6	403258.3	7851.0	13949.0
				PIII(M12)	2	2	100	15.8	100	2833.5	246.4	32584.4	2338.0	3434.0
			1	PIII(M18)	2	2	100	15.8	100	2002.8	878.4	4566.4	1877.0	2137.0
				PIII(M24)	2	2	100	15.8	100	1021.0	188.9	5519.7	894.0	1166.0
				PIII(M36)	2	2	100	15.8	100	810.1	71.2	9219.5	669.0	981.0

Lipschild Construct Construct Construct Antibody Group group status Pre- status Timing vacc N n % LL UL Value LL UL Min Max PII(M3) 55 100 93.5100 273.6 213.4 350.8 73.0 0037.0 0037.0 0037.0 0037.0 12867.4 4367.7 73.7 21151.0 PIII(M3) 55 55 100 93.5100 12867.4 4367.7 73.7 21151.0 PIII(M48) 55 55 100 93.5100 1555.3 1272.3 190.7 356.0 7249.0 7249.0 PIII(M39) 93 100 96.1100 1055.1 115.7 110.7 144.9 277.4 10.7 748.0 748.0 PIII(M21) 93 93 100 96.1100 145.7 191.0 15.7 101.0 15.7 101.0 15.7 100.7 10.0 120.7 14.0 763.												AUT	ex iveboi	14 (NI	30) i inai
Antibody Group group Sub- group Pre- total Timing yacc status N n % h LL UL Value LL UL UL Min Max Antibody Fotal PRE 55 2 3.6 0.4 12.5 4.1 3.9 4.4 6037.0 6037.0 PIII(M2) 55 55 100 935.100 11899.3 98681.5 14425.2 287.0 60582.0 PIII(M2) 55 55 100 93.5 100 189.4 2907.4 4367.7 777.0 21151.0 PIII(M2) 55 55 100 93.5 100 186.1 1400.7 240.0 73.0 4702.0 PIII(M3) 33 100 96.1 100 1216.7 181.4 257.4 280.0 103.0 120.0 161.0 121.6 73.0 4782.0 PIII(M3) 33 100 96.1 100 17.1 48.0 <							"	28 E	LU/M	L		GMI			
Antibody Group Sub- group Pre- status Imming N n % LL UL Value LL UL Min Max Fotal PRE Total PRE 55 100 93.5100 207.36 213.4 350.8 73.0 6037.0 PIII(M3) 55 55 100 93.5100 20001 297.6 247.7 77.70 60582.0 700.0 6035.10 150.3 500.7 150.3 350.0 150.3 150.0 150.7 150.0 150.7 150.0 15	A	0	0.1						95%	6 CI		95	% CI		
group vacc status PRE 55 2 3.6 0.4 1.2 4.1 3.9 4.4 <8.0	Antibody	Group	Sub-	Pre-	Timing	N	n	%	LL	UL	value	LL	UL	Min	мах
PRE 55 2 3.6 0.4 12.5 4.1 3.9 4.4			group	vacc											
India Price 35 2 3.6 0.4 12.9 1.3.9 4.4 48.0 13.0 PIII(M7) 55 55 100 93.5 100 11899.3 9681.5 14825.2 2887.0 60582.0 PIII(M12) 55 55 100 93.5 100 370.0 11894.2 2905.8 516.0 10385.0 PIII(M2) 55 55 100 93.5 100 156.3 1272.3 1903.7 356.0 7249.0 PIII(M3) 93 93 100 96.1 100 215.5 133.7 210.7 748.0 PIII(M7) 93 93 100 96.1 100 148.9 2574.8 290.0 13560.0 PIII(M4) 92 100 96.1 100 145.0 171.7 148.9 2574.8 290.0 13560.0 PIII(M4) 92.1 100 96.1 100 1450.1 1143.3 1215.4 175.9			<u> </u>	status	005		_			40.5					40.0
HIVM 5 55 100 97.3 100 27.36 213.4 350.8 100.9052 PIIII(M12) 55 55 100 93.5 100 1189.3 286.7 148.25 2887.0 00652.0 PIIII(M12) 55 55 100 93.5 100 159.6 1470.1 2195.3 452.0 732.0 21151.0 PIIII(M24) 54 55 100 93.5 100 1556.3 1272.3 1903.7 356.0 7249.0 15_25 S- PRE 93 100 96.1 100 215.5 137.2 210.7 73.0 73.0 4787.0 PIII(M7) 93 93 100 96.1 100 152.7 150.0 173.0 4783.0 PIII(M419 92 100 96.1 100 148.3 175.9 1086.7 80.0 5658.0 S+ PRE 14 100 76.8 100 143.3 20.0 1255.				lotal	PRE	55	2	3.6	0.4	12.5	4.1	3.9	4.4	<8.0	13.0
PIII(MT) b5 55 100 93.5 100 39681.5 1462.2 2687.0 8002.0 PIII(MT8) 55 55 100 93.5 100 2370.8 1934.2 2905.8 516.0 10396.0 PIII(MT8) 55 55 100 93.5 100 556.3 1272.3 1903.7 356.0 7249.0 15_25 S- PRE 93 0.0 98.1 100 265.1 1272.3 1903.7 356.0 7249.0 PIII(MT9) 93 100 96.1 100.708.0 568.3 8424.0 973.0 4787.0 PIII(MT9) 93 91.00 96.1 100.127.1 948.9 1338.8 149.0 768.0 1338.8 149.0 768.0 1338.8 149.0 768.0 100.3 20.0 1356.0 PIII(MT9) 14 14 100 76.8 100.4 134.3 340.0 256.0 1338.8 149.0 268.0 24.1 1250.0<					PII(M3)	55	55	100	93.5	100	273.6	213.4	350.8	73.0	6037.0
HIV 10 93.5 100 93.5 100 230.6 134.2 290.5 730.0 21151.0 PIII(M24) 54 100 93.5 100 175.6 170.1 2195.3 452.0 730.2 0 15_25 S- PRE 93.0 0.0 0.0 94.0 7.0 7.7 3.0 0.0 7.0 7.7 3.0 0.0 7.0 7.7 3.0 0.0 7.0 7.7 3.0 0.0 7.0 7.7 3.0 0.0 7.0 7					PIII(M7)	55	55	100	93.5	100	11899.3	9681.5	14625.2	2687.0	60582.0
HIV 9-10					PIII(M12)	55	55	100	93.5	100	3600.1	2967.4	4367.7	737.0	21151.0
PIII(M24) 54 140 093,4100 1796,5 1470,1 2195,3 452.0 7302.0 15_25 S. PRE 93 0.0 0.0 3.9 4.0 2.0 4.0 2.0 2.0 2.0 2.0 2.0 2.0 2.0 2.					PIII(M18)	55	55	100	93.5	100	2370.8	1934.2	2905.8	516.0	10395.0
Image: https://www.image.org/piiiii/wwwwwwwwwwwwwwwwwwwwwwwwwwwwwww					PIII(M24)	54	54	100	93.4	100	1796.5	1470.1	2195.3	452.0	7302.0
15_25 S- PRE 93 0 0.0 0.0 0.3 9.4 0.4				_	PIII(M36)	55	55	100	93.5	100	1556.3	1272.3	1903.7	356.0	7249.0
PII(M3) 93 93 100 96.1 100 713.0 7463.0 PIII(M12) 93 93 100 96.1 100 718.0 7872.0 PIII(M12) 93 93 100 96.1 100 718.4 220.0 13560.0 PIII(M2) 92 100 96.1 100 1127.1 948.9 2574.8 280.0 13560.0 PIII(M3) 92 20 96.1 100 142.7 138.8 149.0 763.0 775.9 1086.7 88.0 5658.0 S+ PRE 14 14 100 76.8 100 142.3 2800.1 6867.4 1290.0 2666.0 210.5 553.0 73.0 773.0 4745.20 PIII(M12) 14 14 100 76.8 100 122.5 34.4 81.0 6867.0 PIII(M2) 107 100 76.8 100 122.5 1460.0 321.0 5553.0 <t< td=""><td></td><td></td><td>15_25</td><td>S-</td><td>PRE</td><td>93</td><td>0</td><td>0.0</td><td>0.0</td><td>3.9</td><td>4.0</td><td>4.0</td><td>4.0</td><td><8.0</td><td><8.0</td></t<>			15_25	S-	PRE	93	0	0.0	0.0	3.9	4.0	4.0	4.0	<8.0	<8.0
PIII(M7) 93 93 100 96.1 100 2163.7 1814.9 2574.8 290.0 13560.0 PIII(M18) 92 92.1 100 96.1 100 1456.5 1215.4 175.0.2 155.0 12109.0 PIII(M24) 92.2 100 96.1 100 142.7 194.9 133.8 149.0 763.8 0 5658.0 PIII(M36) 93 30 00 96.1 100 142.3 775.9 1086.7 88.0 5658.0 PIII(M3) 14 14 100 76.8 100 142.3 342.3 31.0 9225.0 PIII(M12) 14 14 100 76.8 100 1828.9 1086.0 3285.3 204.0 1254.0 PIII(M21) 14 14 100 76.8 100 1237.4 642.2 2384.4 81.0 6867.0 PIII(M31) 14 14 100 76.8 100 126.3					PII(M3)	93	93	100	96.1	100	231.5	183.7	291.7	21.0	7463.0
PIII(M12)[93] 93 100 96.1 100 2161.7 1814.9 2574.8 290.0 13560.0 PIII(M24)[92 20 100 96.1 100 1458.5 1215.4 1750.2 159.0 12109.0 PIII(M24)[92 20 100 96.1 100 1458.5 1215.4 175.2 1086.7 88.0 5658.0 S+ PRE 14 14 100 76.8 100 442.6 24.1 75.2 110.3 14.1 PIII(M12) 14 14 100 76.8 100 42.6 24.1 75.2 120.0 26064.0 PIII(M12) 14 14 100 76.8 100 126.2 534.5 1969.9 99.0 734.3 PIII(M12) 14 100 76.8 100 876.3 525.9 1460.0 321.0 555.0 Total PRE 107 100 96.6 100 944.3 334.2 973.0					PIII(M7)	93	93	100	96.1	100	7088.0	5963.9	8424.0	973.0	47872.0
PIIII(M12) 92 100 96.1 100 1458.5 121.4 175.0 176.8 PIIII(M24) 92 100 96.1 100 1127.1 348.9 1338.8 149.0 7638.0 PIIII(M36) 33 100 96.1 100 916.3 775.9 1086.7 88.0 568.0 PRE 14 14 100 76.8 100 423.3 31.0 9225.0 PIIII(M12) 14 14 100 76.8 100 188.9 1825.3 204.0 1254.0 PIIII(M12) 14 14 100 76.8 100 188.9 188.9 182.0 1249.0 PIIII(M12) 14 14 100 76.8 100 123.4 642.2 238.4 81.0 686.7 733.0 7872.0 PIIII(M2) 107 107 100 96.6 100 124.3 184.0 273.0 47872.0 PIII(M12) 107					PIII(M12)	93	93	100	96.1	100	2161.7	1814.9	2574.8	290.0	13560.0
PIII(M24) 92 92 100 96.1 100 91.3 775.9 108.67 88.0 5658.0 S+ PRE 14 100 76.8 100 44.2 24.1 75.2 11.0 314.0 PIII(M3) 14 14 100 76.8 100 442.3 280.0.1 6987.4 1290.0 26064.0 PIII(M12) 14 14 100 76.8 100 142.3 280.0.1 6987.4 1290.0 26064.0 PIII(M12) 14 14 100 76.8 100 128.7 642.2 238.4 81.0 6867.0 PIII(M26) 14 14 100 76.8 100 126.2 534.5 1969.9 99.0 734.3.0 PIII(M26) 14 14 100 76.8 100 284.3 13.0 9225.0 PIII(M3) 107 107 100 96.6 100 214.3 733.2 10.0 254.7					PIII(M18)	92	92	100	96.1	100	1458.5	1215.4	1750.2	159.0	12109.0
PIII(M36) 93 93 100 96.1100 918.3 775.9 1086.7 88.0 5658.0 S+ PRE 14 14 100 76.8 100 42.6 14.7 75.2 11.0 314.0 PIII(M71) 14 14 100 76.8 100 442.3 342.3 31.0 9225.0 PIII(M12) 14 14 100 76.8 100 442.3 280.1 6987.4 1290.0 26064.0 PIII(M12) 14 14 100 76.8 100 127.4 642.2 238.4 81.0 6867.0 PIII(M36) 14 14 100 76.8 100 275.5 4.6 6.4 321.0 555.3 Total PRE 107 107 100 96.6 100 273.3 273.0 478.2 973.0 478.2 973.0 478.2 973.0 478.2 973.0 478.2 973.0 478.2 973.0<					PIII(M24)	92	92	100	96.1	100	1127.1	948.9	1338.8	149.0	7638.0
S+ PRE PII(M3) 14 14 100 76.8 100 42.6 24.1 75.2 11.0 314.0 9225.0 PIII(M7) 14 14 100 76.8 100 423.3 320.0.1 6987.4 129.0.0 26064.0 PIII(M12) 14 14 100 76.8 100 1888.9 1086.0 3285.3 204.0 12549.0 PIII(M18) 14 14 100 76.8 100 1888.9 1086.0 3285.3 204.0 12549.0 PIII(M18) 14 14 100 76.8 100 188.9 1086.0 321.0 5553.0 Total PRE 107 14 13.17.3 21.0 666.0 3566.4 783.4 379.3 21.0 9225.0 PIII(M2) 107 107 100 96.6 100 1427.2 1196.9 170.7 81.0 12109.0 PIII(M2) 106 100 96.6 100					PIII(M36)	93	93	100	96.1	100	918.3	775.9	1086.7	88.0	5658.0
PII(M3) 14 14 100 76.8 100 1450.1 614.3 3423.3 31.0 9225.0 PIII(M7) 14 14 100 76.8 100 4423.3 2800.1 6987.4 1290.0 2804.0 12549.0 PIII(M18) 14 14 100 76.8 100 1237.4 642.2 2384.4 81.0 6867.0 PIII(M36) 14 14 100 76.8 100 1237.4 642.2 2384.4 81.0 6867.0 PIII(M36) 14 14 100 76.8 100 187.5 4.6 6.4 .80.3 314.0 PIII(M30) 107 107 96.6 100 294.3 228.4 379.3 21.0 9225.0 PIII(M12) 107 107 100 96.6 100 214.3 181.6 108.2 973.0 47872.0 PIII(M12) 107 107 100 96.6 100 112.7 <t< td=""><td></td><td></td><td></td><td>S+</td><td>PRE</td><td>14</td><td>14</td><td>100</td><td>76.8</td><td>100</td><td>42.6</td><td>24.1</td><td>75.2</td><td>11.0</td><td>314.0</td></t<>				S+	PRE	14	14	100	76.8	100	42.6	24.1	75.2	11.0	314.0
HPV 9_11(M7) 14 14 100 76.8 100 4423.3 2800.1 6987.4 1290.0 26064.0 PIII(M12) 14 14 100 76.8 100 1888.9 1086.0 3285.3 204.0 12549.0 PIII(M12) 14 14 100 76.8 100 1237.4 642.2 2384.4 81.0 6867.0 PIII(M20) 14 14 100 76.8 100 1237.4 642.2 2384.4 81.0 3645.0 PIII(M3) 107 107 76.8 100 876.3 525.9 1460.0 321.0 555.0.0 PIII(M12) 107 107 100 96.6 100 266.3 566.4 7834.2 973.0 47872.0 PIII(M12) 107 107 100 96.6 100 1427.2 1196.9 1701.7 81.0 12109.0 PIII(M12) 107 100 96.6 100 1427.2 119					PII(M3)	14	14	100	76.8	100	1450.1	614.3	3423.3	31.0	9225.0
HPV 9_111(M12) 14 14 100 76.8 100 1888.9 1086.0 3285.3 204.0 12549.0 PIIII(M18) 14 14 100 76.8 100 1237.4 642.2 2384.4 81.0 6867.0 PIIII(M24) 14 140 076.8 100 876.3 525.9 1460.0 321.0 5553.0 Total PRE 107 14 13.1 7.3 21.0 5.5 4.6 6.4 <8.0					PIII(M7)	14	14	100	76.8	100	4423.3	2800.1	6987.4	1290.0	26064.0
HPV 9_14 S- PRE 50 100 92.9 100 1237.4 642.2 2384.4 81.0 6867.0 PIII(M36) 14 14 100 76.8 100 1026.2 534.5 1969.9 99.0 7343.0 PIII(M3) 14 14 100 76.8 100 876.3 525.9 1460.0 321.0 5553.0 PIII(M3) 107 107 100 96.6 100 294.3 228.4 379.3 21.0 9225.0 PIII(M12) 107 107 100 96.6 100 243.3 284.4 39.3 21.0 9225.0 PIII(M12) 107 107 100 96.6 100 212.3 1801.0 2504.7 204.0 13560.0 PIII(M18) 106 100 96.6 100 1427.2 1196.9 1701.7 81.0 12109.0 PIII(M24) 106 100 96.6 100 122.7 <t< td=""><td></td><td></td><td></td><td></td><td>PIII(M12)</td><td>14</td><td>14</td><td>100</td><td>76.8</td><td>100</td><td>1888.9</td><td>1086.0</td><td>3285.3</td><td>204.0</td><td>12549.0</td></t<>					PIII(M12)	14	14	100	76.8	100	1888.9	1086.0	3285.3	204.0	12549.0
PIII(M24) 14 14 100 76.8 100 1026.2 534.5 1969.9 99.0 7343.0 PIII(M36) 14 14 100 76.8 100 876.3 525.9 1460.0 321.0 5553.0 Total PRE 107 14 13.1 7.3 21.0 55 4.6 6.4 -80.0 314.0 PIII(M7) 107 107 100 96.6 100 294.3 228.4 379.3 21.0 9225.0 PIII(M7) 107 107 100 96.6 100 2123.9 1801.0 2504.7 204.0 13560.0 PIII(M24) 106 106 100 96.6 100 141.7 111.2 941.4 1316.4 99.0 7638.0 PIII(M24) 106 106 100 96.6 100 912.7 779.6 1068.5 88.0 5688.0 HPV 9_14 S- PRE 50 10					PIII(M18)	14	14	100	76.8	100	1237.4	642.2	2384.4	81.0	6867.0
PIII(M36) 14 14 100 76.8 100 876.3 525.9 1460.0 321.0 5553.0 Total PRE 107 14 13.1 7.3 21.0 5.5 4.6 6.4 8.0 314.0 PIII(M3) 107 107 100 96.6 100 294.3 228.4 379.3 21.0 9225.0 PIII(M12) 107 107 100 96.6 100 2123.9 1801.0 2504.7 204.0 13560.0 PIII(M12) 107 107 100 96.6 100 1213.9 1801.0 2504.7 240.0 13560.0 PIII(M12) 106 106 100 96.6 100 1113.2 941.4 1316.4 99.0 7638.0 PIII(M24) 106 107 107 100 96.6 100 127.7 779.6 1068.5 88.0 5658.0 HPV 9_14 S- PRE 50					PIII(M24)	14	14	100	76.8	100	1026.2	534.5	1969.9	99.0	7343.0
Total PRE 107 14 13.1 7.3 21.0 5.5 4.6 6.4 <8.0 314.0 PIII(M3) 107 107 100 96.6 100 294.3 228.4 379.3 21.0 9225.0 PIII(M7) 107 107 100 96.6 100 2123.9 1801.0 2504.7 204.0 13560.0 PIII(M12) 107 107 96.6 100 1427.2 1196.9 1701.7 81.0 12109.0 PIII(M2) 106 106 100 96.6 100 113.2 91.4 1316.4 99.0 7638.0 PIII(M12) 107 107 90.96.6 100 912.7 779.6 1068.5 88.0 5658.0 HPV 9_14 S- PRE 50 0 0.0 0.7.1 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0					PIII(M36)	14	14	100	76.8	100	876.3	525.9	1460.0	321.0	5553.0
PII(M3) 107 107 100 96.6 100 294.3 228.4 379.3 21.0 9225.0 PIII(M7) 107 100 96.6 100 6663.9 5668.4 7834.2 973.0 47872.0 PIII(M12) 107 100 96.6 100 1213.9 1801.0 2504.7 204.0 13560.0 PIII(M18) 106 106 100 96.6 100 1427.2 1196.9 1701.7 81.0 12109.0 PIII(M24) 106 106 100 96.6 100 11427.2 1196.9 1701.7 81.0 12109.0 PIII(M24) 106 106 100 96.6 100 1142.7 1316.4 99.0 7638.0 PIII(M7) 50 0 0 0 0 2214.7 17936.9 30045.5 3932.0 149951.0 PIII(M12) 50 100 92.9 100 5441.6 4078.1 7260.8 600.0 <				Total	PRE	107	14	13.1	7.3	21.0	5.5	4.6	6.4	<8.0	314.0
PIII(M7) 107 107 107 100 96.6 100 6663.9 5668.4 7834.2 973.0 47872.0 PIII(M12) 107 100 96.6 100 2123.9 1801.0 2504.7 204.0 13560.0 PIII(M12) 106 106 100 96.6 100 1427.2 1196.9 1701.7 81.0 12109.0 PIII(M24) 106 106 100 96.6 100 1113.2 941.4 1316.4 99.0 7638.0 PIII(M24) 106 107 107 100 96.6 100 912.7 779.6 1068.5 88.0 5658.0 HPV 9_14 S- PRE 50 0 0.0 0.7 1.4 4.0					PII(M3)	107	107	100	96.6	100	294.3	228.4	379.3	21.0	9225.0
PIII(M12) 107 100 96.6 100 2123.9 1801.0 2504.7 204.0 13560.0 PIII(M18) 106 100 96.6 100 1427.2 1196.9 1701.7 81.0 12109.0 PIII(M24) 106 100 96.6 100 1113.2 941.4 1316.4 99.0 7638.0 PIII(M36) 107 107 100 96.6 100 912.7 779.6 1068.5 88.0 5658.0 HPV 9_14 S- PRE 50 0 0.0 0.7 1.4.0 4.0 4.0 <8.0					PIII(M7)	107	107	100	96.6	100	6663.9	5668.4	7834.2	973.0	47872.0
PIII(M18) 106 100 96.6 100 1427.2 1196.9 1701.7 81.0 12109.0 PIII(M24) 106 100 100 96.6 100 1113.2 941.4 1316.4 99.0 7638.0 PIII(M36) 107 107 100 96.6 100 912.7 779.6 1068.5 88.0 5658.0 HPV 9_14 S- PRE 50 0 0.0 7.1 4.0 4.0 4.0 <8.0					PIII(M12)	107	107	100	96.6	100	2123.9	1801.0	2504.7	204.0	13560.0
PIII (M24) 106 100 96.6 100 911.4 1316.4 99.0 7638.0 PIII (M36) 107 107 100 96.6 100 912.7 779.6 1068.5 88.0 5658.0 HPV 9_14 S- PRE 50 0 0.0 0.7.1 4.0 4.0 4.0 <8.0					PIII(M18)	106	106	100	96.6	100	1427.2	1196.9	1701.7	81.0	12109.0
PIII.(M36) 107 100 96.6 100 912.7 779.6 1068.5 88.0 5658.0 HPV 9_14 \$- PRE 50 0 0.0 0.1 7.1 4.0 4.0 4.0 <8.0					PIII(M24)	106	106	100	96.6	100	1113.2	941.4	1316.4	99.0	7638.0
HPV 9_14 S- PRE 50 0 0.0 7.1 4.0 4.0 4.0 <8.0 <8.0 PIII(M7) 50 50 100 92.9 100 23214.7 17936.9 30045.5 3932.0 149951.0 PIII(M12) 50 50 100 92.9 100 8069.7 5939.4 10964.0 992.0 59262.0 PIII(M18) 50 50 100 92.9 100 5441.6 4078.1 7260.8 600.0 37234.0 PIII(M24) 49 49 100 92.7 100 4184.1 3098.9 5649.5 557.0 31073.0 PIII(M36) 50 50 100 92.9 100 3501.7 2621.7 4677.0 428.0 30440.0 S+ PRE 7 7 100 59.0 100 17621.9 9057.5 34284.6 8602.0 53482.0 PIII(M12) 7 7 100 59.0 </td <td></td> <td></td> <td></td> <td></td> <td>PIII(M36)</td> <td>107</td> <td>107</td> <td>100</td> <td>96.6</td> <td>100</td> <td>912.7</td> <td>779.6</td> <td>1068.5</td> <td>88.0</td> <td>5658.0</td>					PIII(M36)	107	107	100	96.6	100	912.7	779.6	1068.5	88.0	5658.0
PIII(M7) 50 50 100 92.9 100 23214.7 17936.9 30045.5 3932.0 149951.0 PIII(M12) 50 50 100 92.9 100 8069.7 5939.4 10964.0 992.0 59262.0 PIII(M18) 50 50 100 92.9 100 5441.6 4078.1 7260.8 600.0 37234.0 PIII(M24) 49 49 100 92.7 100 4184.1 3098.9 5649.5 557.0 31073.0 PIII(M36) 50 50 100 92.9 100 3501.7 2621.7 4677.0 428.0 30440.0 S+ PRE 7 7 100 59.0 100 17621.9 9057.5 34284.6 8602.0 53482.0 PIII(M12) 7 7 100 59.0 100 7441.0 4508.7 12280.4 3755.0 17083.0 PIII(M12) 7 7 100 59.0 100 </td <td></td> <td>HPV</td> <td>9_14</td> <td>S-</td> <td>PRÈ</td> <td>50</td> <td>0</td> <td>0.0</td> <td>0.0</td> <td>7.1</td> <td>4.0</td> <td>4.0</td> <td>4.0</td> <td><8.0</td> <td><8.0</td>		HPV	9_14	S-	PRÈ	50	0	0.0	0.0	7.1	4.0	4.0	4.0	<8.0	<8.0
PIII(M12) 50 50 100 92.9 100 8069.7 5939.4 10964.0 992.0 59262.0 PIII(M18) 50 50 100 92.9 100 5441.6 4078.1 7260.8 600.0 37234.0 PIII(M24) 49 49 100 92.7 100 4184.1 3098.9 5649.5 557.0 31073.0 PIII(M36) 50 50 100 92.9 100 3501.7 2621.7 4677.0 428.0 30440.0 S+ PRE 7 7 100 59.0 100 13.3 9.5 18.7 9.0 26.0 PIII(M12) 7 7 100 59.0 100 17621.9 9057.5 34284.6 8602.0 53482.0 PIII(M12) 7 7 100 59.0 100 7641.0 4508.7 12280.4 3755.0 17083.0 PIII(M12) 7 7 100 59.0 100 36					PIII(M7)	50	50	100	92.9	100	23214.7	17936.9	30045.5	3932.0	149951.0
PIII (M18) 50 50 100 92.9 100 5441.6 4078.1 7260.8 600.0 37234.0 PIII (M24) 49 49 100 92.7 100 4184.1 3098.9 5649.5 557.0 31073.0 PIII (M36) 50 50 100 92.9 100 3501.7 2621.7 4677.0 428.0 30440.0 S+ PRE 7 7 100 59.0 100 13.3 9.5 18.7 9.0 26.0 PIII (M12) 7 7 100 59.0 100 17621.9 9057.5 34284.6 8602.0 53482.0 PIII (M12) 7 7 100 59.0 100 7641.0 4508.7 12280.4 3755.0 17083.0 PIII (M18) 7 7 100 59.0 100 5065.8 3441.4 7456.8 2757.0 9524.0 PIII (M24) 7 7 100 59.0 100 <t< td=""><td></td><td></td><td></td><td></td><td>PIII(M12)</td><td>50</td><td>50</td><td>100</td><td>92.9</td><td>100</td><td>8069.7</td><td>5939.4</td><td>10964.0</td><td>992.0</td><td>59262.0</td></t<>					PIII(M12)	50	50	100	92.9	100	8069.7	5939.4	10964.0	992.0	59262.0
PIII (M24) 49 49 100 92.7 100 4184.1 3098.9 5649.5 557.0 31073.0 PIII (M36) 50 50 100 92.9 100 3501.7 2621.7 4677.0 428.0 30440.0 S+ PRE 7 7 100 59.0 100 13.3 9.5 18.7 9.0 26.0 PIII (M7) 7 7 100 59.0 100 17621.9 9057.5 34284.6 8602.0 53482.0 PIII (M12) 7 7 100 59.0 100 7641.0 4508.7 12280.4 3755.0 17083.0 PIII (M18) 7 7 100 59.0 100 5065.8 3441.4 7456.8 2757.0 9524.0 PIII (M24) 7 7 100 59.0 100 3970.0 2878.4 5475.7 212.0 5895.0 Total PRE 57 7 12.3 5.1 23.7 </td <td></td> <td></td> <td></td> <td></td> <td>PIII(M18)</td> <td>50</td> <td>50</td> <td>100</td> <td>92.9</td> <td>100</td> <td>5441.6</td> <td>4078.1</td> <td>7260.8</td> <td>600.0</td> <td>37234.0</td>					PIII(M18)	50	50	100	92.9	100	5441.6	4078.1	7260.8	600.0	37234.0
PIII (M36) 50 50 100 92.9 100 3501.7 2621.7 4677.0 428.0 30440.0 S+ PRE 7 7 100 59.0 100 13.3 9.5 18.7 9.0 26.0 PIII (M7) 7 7 100 59.0 100 17621.9 9057.5 34284.6 8602.0 53482.0 PIII (M12) 7 7 100 59.0 100 7621.9 9057.5 34284.6 8602.0 53482.0 PIII (M12) 7 7 100 59.0 100 7641.0 4508.7 12280.4 3755.0 17083.0 PIII (M24) 7 7 100 59.0 100 5065.8 3441.4 7456.8 2757.0 9524.0 PIII (M24) 7 7 100 59.0 100 3970.0 2878.4 5475.7 212.0 5895.0 Total PRE 57 7 12.3 5.1 23.7 </td <td></td> <td></td> <td></td> <td></td> <td>PIII(M24)</td> <td>49</td> <td>49</td> <td>100</td> <td>92.7</td> <td>100</td> <td>4184.1</td> <td>3098.9</td> <td>5649.5</td> <td>557.0</td> <td>31073.0</td>					PIII(M24)	49	49	100	92.7	100	4184.1	3098.9	5649.5	557.0	31073.0
S+ PRE 7 7 100 59.0 100 13.3 9.5 18.7 9.0 26.0 PIII(M7) 7 7 100 59.0 100 17621.9 9057.5 34284.6 8602.0 53482.0 PIII(M12) 7 7 100 59.0 100 7621.9 9057.5 34284.6 8602.0 53482.0 PIII(M12) 7 7 100 59.0 100 7641.0 4508.7 12280.4 3755.0 17083.0 PIII(M24) 7 7 100 59.0 100 5065.8 3441.4 7456.8 2757.0 9524.0 PIII(M24) 7 7 100 59.0 100 3970.0 2878.4 5475.7 2120.0 5895.0 Total PRE 57 7 12.3 5.1 23.7 4.6 4.2 5.2 <8.0					PIII(M36)	50	50	100	92.9	100	3501.7	2621.7	4677.0	428.0	30440.0
PIII(M7) 7 7 100 59.0 100 17621.9 9057.5 34284.6 8602.0 53482.0 PIII(M12) 7 7 100 59.0 100 7441.0 4508.7 12280.4 3755.0 17083.0 PIII(M18) 7 7 100 59.0 100 5065.8 3441.4 7456.8 2757.0 9524.0 PIII(M24) 7 7 100 59.0 100 4256.5 3030.9 5977.6 2567.0 8511.0 PIII(M36) 7 7 100 59.0 100 3970.0 2878.4 5475.7 2120.0 5895.0 Total PRE 57 7 12.3 5.1 23.7 4.6 4.2 5.2 <8.0				S+	PRE	7	7	100	59.0	100	13.3	9.5	18.7	9.0	26.0
PIII(M12) 7 100 59.0 100 7441.0 4508.7 12280.4 3755.0 17083.0 PIII(M18) 7 100 59.0 100 5065.8 3441.4 7456.8 2757.0 9524.0 PIII(M24) 7 7 100 59.0 100 4256.5 3030.9 5977.6 2567.0 8511.0 PIII(M36) 7 7 100 59.0 100 3970.0 2878.4 5475.7 2120.0 5895.0 Total PRE 57 7 12.3 5.1 23.7 4.6 4.2 5.2 <8.0					PIII(M7)	7	7	100	59.0	100	17621.9	9057.5	34284.6	8602.0	53482.0
PIII(M18) 7 100 59.0 100 5065.8 3441.4 7456.8 2757.0 9524.0 PIII(M24) 7 7 100 59.0 100 4256.5 3030.9 5977.6 2567.0 8511.0 PIII(M36) 7 7 100 59.0 100 3970.0 2878.4 5475.7 2120.0 5895.0 Total PRE 57 7 12.3 5.1 23.7 4.6 4.2 5.2 <8.0					PIII(M12)	7	7	100	59.0	100	7441.0	4508.7	12280.4	3755.0	17083.0
PIII (M24) 7 7 100 59.0 100 4256.5 3030.9 5977.6 2567.0 8511.0 PIII (M36) 7 7 100 59.0 100 3970.0 2878.4 5475.7 2120.0 5895.0 Total PRE 57 7 12.3 5.1 23.7 4.6 4.2 5.2 <8.0					PIII(M18)	7	7	100	59.0	100	5065.8	3441.4	7456.8	2757.0	9524.0
PIII (M36) 7 100 59.0 100 3970.0 2878.4 5475.7 2120.0 5895.0 Total PRE 57 7 12.3 5.1 23.7 4.6 4.2 5.2 <8.0					PIII(M24)	7	7	100	59.0	100	4256.5	3030.9	5977.6	2567.0	8511.0
Total PRE 57 7 12.3 5.1 23.7 4.6 4.2 5.2 <8.0 26.0 PIII(M7) 57 57 100 93.7 100 22442.0 17741.7 28387.6 3932.0 149951.0 PIII(M12) 57 57 100 93.7 100 7989.7 6087.8 10485.9 992.0 59262.0 PIII(M18) 57 57 100 93.7 100 5394.0 4181.7 6957.7 600.0 37234.0 PIII(M24) 56 56 100 93.6 100 4193.1 3221.7 5457.5 557.0 31073.0 PIII(M36) 57 57 100 93.7 100 3556.1 2756.2 4588.0 428.0 30440.0					PIII(M36)	7	7	100	59.0	100	3970.0	2878.4	5475.7	2120.0	5895.0
PIII(M7) 57 57 100 93.7 100 22442.0 17741.7 28387.6 3932.0 149951.0 PIII(M12) 57 57 100 93.7 100 7989.7 6087.8 10485.9 992.0 59262.0 PIII(M18) 57 57 100 93.7 100 5394.0 4181.7 6957.7 600.0 37234.0 PIII(M24) 56 56 100 93.6 100 4193.1 3221.7 5457.5 557.0 31073.0 PIII(M36) 57 57 100 93.7 100 3556.1 2756.2 4588.0 428.0 30440.0				Total	PRE	57	7	12.3	5.1	23.7	4.6	4.2	5.2	<8.0	26.0
PIII(M12) 57 57 100 93.7 100 7989.7 6087.8 10485.9 992.0 59262.0 PIII(M18) 57 57 100 93.7 100 5394.0 4181.7 6957.7 600.0 37234.0 PIII(M24) 56 56 100 93.6 100 4193.1 3221.7 5457.5 557.0 31073.0 PIII(M36) 57 57 100 93.7 100 3556.1 2756.2 4588.0 428.0 30440.0					PIII(M7)	57	57	100	93.7	100	22442.0	17741.7	28387.6	3932.0	149951.0
PIII(M18) 57 57 100 93.7 100 5394.0 4181.7 6957.7 600.0 37234.0 PIII(M24) 56 56 100 93.6 100 4193.1 3221.7 5457.5 557.0 31073.0 PIII(M36) 57 57 100 93.7 100 3556.1 2756.2 4588.0 428.0 30440.0					PIII(M12)	57	57	100	93.7	100	7989.7	6087.8	10485.9	992.0	59262.0
PIII(M24) 56 56 100 93.6 100 4193.1 3221.7 5457.5 557.0 31073.0 PIII(M36) 57 57 100 93.7 100 3556.1 2756.2 4588.0 428.0 30440.0					PIII(M18)	57	57	100	93.7	100	5394.0	4181.7	6957.7	600.0	37234.0
PIII(M36) 57 57 100 93.7 100 3556.1 2756.2 4588.0 428.0 30440.0					PIII(M24)	56	56	100	93.6	100	4193.1	3221.7	5457.5	557.0	31073.0
					PIII(M36)	57	57	100	93.7	100	3556.1	2756.2	4588.0	428.0	30440.0

							≥ 8 EI	LU/M	L		GMT			
								95%	6 CI		95	% CI		
Antibody	Group	Sub- group	Pre- vacc	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
			status											
		15_25	S-	PRE	85	0	0.0	0.0	4.2	4.0	4.0	4.0	<8.0	<8.0
				PIII(M7)	85	85	100	95.8	100	10559.9	8410.9	13257.9	1322.0	148276.0
				PIII(M12)	84	84	100	95.7	100	3600.3	2858.7	4534.2	182.0	81240.0
				PIII(M18)	83	83	100	95.7	100	2373.7	1890.8	2979.8	116.0	45075.0
				PIII(M24)	84	84	100	95.7	100	1875.0	1502.2	2340.4	112.0	35172.0
				PIII(M36)	85	85	100	95.8	100	1592.0	1282.6	1975.9	73.0	23603.0
			S+	PRE	11	11	100	71.5	100	46.7	17.4	125.8	9.0	745.0
				PIII(M7)	11	11	100	71.5	100	8133.8	3557.0	18599.8	2482.0	99665.0
				PIII(M12)	11	11	100	71.5	100	3915.0	1692.8	9054.4	1156.0	51632.0
				PIII(M18)	11	11	100	71.5	100	3169.9	1354.6	7417.8	951.0	52061.0
				PIII(M24)	11	11	100	71.5	100	2431.2	1052.8	5614.2	812.0	37420.0
				PIII(M36)	11	11	100	71.5	100	2160.9	931.8	5011.5	621.0	36109.0
			Total	PRE	96	11	11.5	5.9	19.6	5.3	4.4	6.4	<8.0	745.0
				PIII(M7)	96	96	100	96.2	100	10248.7	8246.8	12736.6	1322.0	148276.0
				PIII(M12)	95	95	100	96.2	100	3635.4	2918.2	4528.8	182.0	81240.0
				PIII(M18)	94	94	100	96.2	100	2455.4	1973.6	3054.8	116.0	52061.0
				PIII(M24)	95	95	100	96.2	100	1932.3	1561.6	2391.0	112.0	37420.0
				PIII(M36)	96	96	100	96.2	100	1648.7	1338.0	2031.5	73.0	36109.0

V40_06 = HPV-16/18(40,40) AS04 0,6m

V20_06 = HPV-16/18(20,20) AS04 0,6 m

HPV = HPV-16/18(20,20) AS04 0,1,6m

S- = seronegative subjects (antibody concentration < 8 ELU/ML) prior to vaccination

S+ = seropositive subjects (antibody concentration ≥ 8 ELU/ML) prior to vaccination

GMT = geometric mean titers concentration 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

MIN/MAX = Minimum/Maximum

PRE = pre-vaccination

PII(M3) = Post Dose II, Month 3

PIII(M7) = Post Dose III, Month 7

PIII(M12) = Post Dose III, Month 12

PIII(M18) = Post Dose III, Month 18

PIII(M24) = Post Dose III,Month 24

PIII(M36) = Post Dose III, Month 36

Seropositivity rates and GMTs for HPV 18.VLP IGG antibodies by pre-vaccination status in subjects aged 9-14 years and 15-25 years (Month 36 ATP Immunogenicity Cohort)

						2	7 EL	U/MI	L		GMT			
								95%	6 CI		95%	% CI		
Antibody	Group	Sub- group	Pre- vacc	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
			status											
HPV 18.VLP IGG	V40_02	9_14	S-	PRE	56	0	0.0	0.0	6.4	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	56	56	100	93.6	100	5112.6	4090.2	6390.6	562.0	33045.0
				PIII(M7)	56	56	100	93.6	100	1133.1	870.7	1474.5	69.0	7965.0
				PIII(M12)	56	56	100	93.6	100	605.1	457.5	800.4	35.0	5521.0
				PIII(M18)	55	55	100	93.5	100	490.1	376.0	638.8	50.0	3262.0
				PIII(M24)	55	55	100	93.5	100	420.4	320.3	551.8	37.0	3257.0
				PIII(M36)	56	56	100	93.6	100	402.3	305.1	530.6	29.0	6446.0
			S+	PRE	5	5	100	47.8	100	15.7	8.9	27.9	8.0	24.0
				PII(M3)	5	5	100	47.8	100	4361.8	1615.3	11778.3	2098.0	14980.0
				PIII(M7)	5	5	100	47.8	100	962.8	365.5	2536.5	286.0	2502.0
				PIII(M12)	5	5	100	47.8	100	458.8	134.5	1564.7	111.0	1205.0
				PIII(M18)	5	5	100	47.8	100	382.4	122.1	1197.9	115.0	1292.0
				PIII(M24)	5	5	100	47.8	100	429.6	116.9	1579.1	89.0	1189.0
				PIII(M36)	5	5	100	47.8	100	418.5	83.5	2097.5	86.0	2081.0
			Total	PRE	61	5	8.2	2.7	18.1	4.0	3.5	4.4	<7.0	24.0
				PII(M3)	61	61	100	94.1	100	5046.5	4085.2	6234.1	562.0	33045.0
				PIII(M7)	61	61	100	94.1	100	1118.1	873.5	1431.2	69.0	7965.0
				PIII(M12)	61	61	100	94.1	100	591.5	453.8	771.0	35.0	5521.0
				PIII(M18)	60	60	100	94.0	100	480.1	373.6	616.8	50.0	3262.0
				PIII(M24)	60	60	100	94.0	100	421.2	325.3	545.4	37.0	3257.0
			-	PIII(M36)	61	61	100	94.1	100	403.6	308.9	527.5	29.0	6446.0
		15_25	S-	PRE	88	0	0.0	0.0	4.1	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	88	88	100	95.9	100	2988.5	2442.5	3656.5	148.0	22529.0
				PIII(M7)	88	88	100	95.9	100	651.4	530.4	800.1	73.0	4507.0
				PIII(M12)	88	88	100	95.9	100	370.6	295.2	465.2	25.0	6173.0
				PIII(M18)	87	8/	100	95.8	100	301.7	240.8	378.0	15.0	3266.0
				PIII(M24)	86	86	100	95.8	100	258.8	207.0	323.6	12.0	2442.0
			C .	PIII(M36)	88	88	100	95.9	100	247.4	195.1	313.6	10.0	3051.0
			0+	PILE	47	47	100	00.5	100	22.0	11.0	44.U	074.0	310.0
				PII(M3)	17	17	100	00.5	100	31/0./	19/3.0	5119.1	455.0	33321.0
					47	47	100	00.5	100	531.0	246.J	020.0	100.0	2445.0
				PIII(M12) DIII/M18)	17	17	100	80.5	100	468.0	260.4	930.0	63.0	3091.0
				PIII(M10)	47	47	100	00.5 00.5	100	400.0	200.4	725.4	46.0	2222.0
				PIII(M24) DIII/M36)	17	17	100	80.5	100	405.0	168.7	120.4 537.3	35.0	1826.0
			Total	DRE	105	17	16.2	9.7	24.7	4.7	4.0	56	27.0	510.0
			Total	PIKE PII/M31	105	105	10.2	96.5	100	3018.5	2514.5	3623.5	148.0	33321 (
				PIII/M7)	105	105	100	96.5	100	690.2	570.4	835.2	73.0	7467.0
				PIII(M12)	105	105	100	96.5	100	393.2	319.2	484.4	25.0	6173.0
				PIII(M18)	104	104	100	96.5	100	324.2	262.8	399.8	15.0	3266.0
				DIII/MOA	102	102	100	0C E	100	270.4	2262.0	242.5	12.0	2442.0
·				1 C 1 1 1 1 1 2 1 2 1 2 1 2 1 2 1 2 1 2						1112	1101			1 Martin 1

							> 7 FI	LI/MI		1	GMT			-,
<u> </u>						<u> </u>		0.59			0.050		<u> </u>	
Antibody	Crown	Cub	Dro	Timina	N	_	0/	337		value	33		Min	Max
Anubody	Group	Sub-	PIE-	rinning	N	"	70		UL	value		UL	MIN	Max
		group	otatuo											
	V40_06	9.14	c	DRE	50	0	0.0	0.0	c 9	2.5	2.5	2.5	<7.0	<7.0
	V40_00	5_14	0-		52	50	100	0.0	100	3.5	201.6	242.0	46.0	2450.0
				PII(M3) DIII/M7)	52	52	100	93.2	100	203.3	201.0	343.0	40.0	60059.0
					52	52	100	00.2	100	0000.0	4007.0	2005.0	1202.0	20560.0
				PIII(M12)	52	52	100	33.Z	100	102.5	040.0	2000.0 4600.5	102.0	44555.0
				PIII(MIO)	52	52	100	93.2	100	1230.5	940.0 702.4	1009.0	195.0	0.000.0
				PIII(M24)	51	51	100	93.0	100	926.9	703.1	1222.0	184.0	6809.0
			Tetal	PIII(M36)	52	02	100	93.Z	00	750.0	2/4.1	300.0	124.0	4014.0
			TOLA	PRE	52	0	0.0	0.0	0.0	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	52	52	100	93.2	100	203.3	201.6	343.8	46.0	3159.0
				PIII(M7)	52	52	100	93.Z	100	00000.0	0945.3	10/09./	1202.0	000000.0
				PIII(M12)	52	52	100	93.Z	100	2162.9	1667.8	2805.0	361.0	20569.0
				PIII(M18)	52	52	100	93.2	100	1230.5	940.8	1609.5	193.0	11555.0
				PIII(M24)	51	51	100	93.0	100	926.9	/03.1	1222.0	184.0	6809.0
			-	PIII(M36)	52	52	100	93.2	100	/50.0	5/4.1	980.0	124.0	4814.0
		15_25	S-	PRE	93	0	0.0	0.0	3.9	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	93	93	100	96.1	100	195.4	157.6	242.2	13.0	7952.0
				PIII(M7)	93	93	100	96.1	100	5750.8	4783.8	6913.3	412.0	91976.0
				PIII(M12)	92	92	100	96.1	100	1/0/.0	1386.0	2102.2	1/6.0	34/43.0
				PIII(M18)	91	91	100	96.0	100	991.8	791.7	1242.5	102.0	19845.0
				PIII(M24)	92	92	100	96.1	100	771.6	621.8	957.4	73.0	15066.0
				PIII(M36)	93	93	100	96.1	100	668.8	537.7	831.8	50.0	15050.0
			S+	PRE	16	16	100	79.4	100	28.7	14.3	57.5	9.0	387.0
				PII(M3)	16	16	100	79.4	100	796.4	373.6	1697.5	135.0	23563.0
				PIII(M7)	16	16	100	79.4	100	6111.1	3477.0	10740.7	619.0	25115.0
				PIII(M12)	16	16	100	79.4	100	1966.7	1055.5	3664.4	240.0	9748.0
				PIII(M18)	16	16	100	79.4	100	1264.7	681.5	2347.0	218.0	7798.0
				PIII(M24)	15	15	100	78.2	100	1128.9	596.0	2138.1	155.0	8456.0
				PIII(M36)	15	15	100	78.2	100	887.1	440.0	1788.6	116.0	6960.0
			Total	PRE	109	16	14.7	8.6	22.7	4.8	4.0	5.6	<7.0	387.0
				PII(M3)	109	109	100	96.7	100	240.2	191.0	302.0	13.0	23563.0
				PIII(M7)	109	109	100	96.7	100	5802.3	4877.3	6902.8	412.0	91976.0
				PIII(M12)	108	108	100	96.6	100	1743.2	1433.2	2120.3	176.0	34743.0
				PIII(M18)	107	107	100	96.6	100	1028.5	834.3	1268.0	102.0	19845.0
				PIII(M24)	107	107	100	96.6	100	813.9	664.1	997.4	73.0	15066.0
				PIII(M36)	108	108	100	96.6	100	695.6	565.2	856.0	50.0	15050.0
	V20_06	9_14	S-	PRE	52	0	0.0	0.0	6.8	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	52	52	100	93.2	100	215.8	159.9	291.3	41.0	5333.0
				PIII(M7)	52	52	100	93.2	100	5819.2	4763.7	7108.6	1094.0	36047.0
				PIII(M12)	52	52	100	93.2	100	1666.5	1297.3	2140.8	178.0	12222.0
				PIII(M18)	52	52	100	93.2	100	947.4	728.2	1232.6	95.0	8328.0
				PIII(M24)	51	51	100	93.0	100	731.7	561.2	954.0	92.0	5622.0
				PIII(M36)	52	52	100	93.2	100	689.3	530.4	895.9	103.0	5844.0
			S+	PRE	3	3	100	29.2	100	8.0	5.8	10.9	7.0	9.0
				PII(M3)	3	3	100	29.2	100	207.3	76.6	561.3	140.0	312.0
				PIII(M7)	3	3	100	29.2	100	8010.4	2256.9	28431.7	4474.0	11551.0
				PIII(M12)	3	3	100	29.2	100	2115.0	502.1	8908.4	1102.0	3329.0
				PIII(M18)	3	3	100	29.2	100	1075.2	277.2	4169.8	636.0	1890.0
				PIII(M24)	3	3	100	29.2	100	909.5	327.0	2529.1	678.0	1456.0
				PIII(M36)	3	3	100	29.2	100	686.4	188.7	2497.3	457.0	1233.0

Antibody Group Sub- group Pre- vacc status Timing N n % LL UL Value LL UL Min Max Antibody Group Sub- group Yaac S5 11 15 37 35 39 -7.0 9.0 PIII(M3) 55 55 100 93.5 100 152.1 162.1 286.0 141.0 5333.0 PIII(M2) 55 51 100 93.5 100 188.4 132.9 143.5 178.0 12222.0 PIII(M2) 55 51 100 93.5 100 188.4 130.2 143.5 135.0 36.0 35.0								27 EL	U/ML	L		GMT		<u>`</u>	,
Antibody Group group Pre- vacc status Timing vacc status N n % N LL UL Value LL UL									95%	6 CI		959	% CI		
group vacc status PRE 55 3 5.5 1.1 15.1 3.7 3.5 3.9 <7.0	Antibody	Group	Sub-	Pre-	Timina	N	n	%	11	U	value	LL	UL	Min	Max
Image: status Image: s	,		group	vacc			Ľ.								
Total PRE 55 3 5.5 1.1 15.1 3.7 3.5 3.9 <7.0 9.0 PII(M3) 55 55 100 93.5 100 215.1 126.1 286.0 14.0 533.3 PIII(M12) 55 55 100 93.5 100 188.4 1329.8 2143.5 178.0 1222.0 PIII(M412) 55 55 100 93.5 100 688.4 1329.8 2143.5 178.0 1222.0 PIII(M3) 87 100 95.6 100 166.2 131.7 229.6 20.0 4646.0 PIII(M12) 87 71.00 95.8 100 186.4 131.7 229.9 90.0 1016.3 PIII(M3) 87 87 100 95.8 100 887.8 116.8 1039.9 45.0 5847 PIII(M3) 87 87 100 95.8 100 887.1 74.0 30.3 3			a	status											
Her Product Pr				Total	PRF	55	3	5.5	11	15.1	37	3.5	39	<70	9.0
Pill(M3) Do Do <thdo< th=""> Do Do <t< td=""><td></td><td></td><td></td><td></td><td>PII/M3)</td><td>55</td><td>55</td><td>100</td><td>93.5</td><td>100</td><td>215.3</td><td>162.1</td><td>286.0</td><td>41.0</td><td>5333.0</td></t<></thdo<>					PII/M3)	55	55	100	93.5	100	215.3	162.1	286.0	41.0	5333.0
PIII(M12) DS DS <thds< th=""> DS DS <</thds<>					PIII/M7)	55	55	100	93.5	100	5921.6	4888.4	7173.2	1094.0	36047.0
HIM 12 100 100 1000 1132.0 1125.0 110.0 100 1125.0 100 100 1125.0 100 100 1125.0 100 110 100 <td></td> <td></td> <td></td> <td></td> <td>DIII/M12)</td> <td>55</td> <td>55</td> <td>100</td> <td>03.5</td> <td>100</td> <td>1688.4</td> <td>1329.8</td> <td>21/3.5</td> <td>178.0</td> <td>12222.0</td>					DIII/M12)	55	55	100	03.5	100	1688.4	1329.8	21/3.5	178.0	12222.0
PIII(M12) D3 D3 <thd3< th=""> D3 D3 <</thd3<>					DIII/M18)	55	55	100	93.5	100	954.0	742.9	1225.0	95.0	8328.0
Prill(M36) 55 55 100 83.1 1000 74.03 57.4 83.3 10.00 58.4 10.00 58.4 10.00 58.4 10.00 58.4 10.00 58.4 10.00 58.4 10.00 166.2 13.1 20.8 62.0 446.4 0.00 42.3 55.3 55.3 55.5 77.0 <th77.0< th=""> 77.0 <th77.0< t<="" td=""><td></td><td></td><td></td><td></td><td>DIII/M24)</td><td>55</td><td>50</td><td>100</td><td>02.4</td><td>100</td><td>740.6</td><td>576.0</td><td>952.2</td><td>92.0</td><td>5622.0</td></th77.0<></th77.0<>					DIII/M24)	55	50	100	02.4	100	740.6	576.0	952.2	92.0	5622.0
15_25 S- PRE 70 <th< td=""><td></td><td></td><td></td><td></td><td>DIII/M36)</td><td>55</td><td>55</td><td>100</td><td>03.4</td><td>100</td><td>689.2</td><td>570.0 537 A</td><td>883.9</td><td>103.0</td><td>5844.0</td></th<>					DIII/M36)	55	55	100	03.4	100	689.2	570.0 537 A	883.9	103.0	5844.0
HO_LS Or Or <tho< td=""><td></td><td></td><td>15.25</td><td>c</td><td>DRE</td><td>87</td><td>0</td><td>0.0</td><td>0.0</td><td>4.2</td><td>3.5</td><td>3.5</td><td>3.5</td><td><7.0</td><td><7.0</td></tho<>			15.25	c	DRE	87	0	0.0	0.0	4.2	3.5	3.5	3.5	<7.0	<7.0
HII(M3) 67 100 93.0 100 180.2 21418.9 592.10 200.0 4496.0 PIII(M12) 87 100 95.8 100 1808.4 1592.10 626.0 34562.0 PIII(M12) 87 100 95.8 100 887.5 556.7 851.5 540.7 685.5 556.7 851.5 430.0 4269.0 223.7 100 95.8 100 856.5 556.7 851.5 430.0 3297.0 PIII(M3) 20 100 83.2 100 23.2 140.0 35.4 7.0 4199.0 120.7 73.0 4199.0 120.7 120.7 120.0 120.7 120.0 120.7 120.0 120.0 120.7 120.0 120.			15_25	0-		07	07	100	0.0	4.2	466.0	424.7	200.6	20.0	ACAC 0
HII(M12) 100 100 93.0.2 100 93.0.2 10183.0 99.0.2 10183.0 PIII(M24) 100 95.8 100 98.0 10193.0 199.9 45.0 5847.0 PIII(M24) 100 95.8 100 98.5 100 68.5 55.6 78.5.7 83.0 4669.0 PIII(M24) 100 95.8 100 98.5.7 100.3 35.4 7.0 87.0 PIII(M20) 20 100 83.2 100.0 22.3 14.0 35.4 7.0 87.0 PIII(M12) 20 100 83.2 100 429.4 144.5 6231.2 1459.0 18651.0 PIII(M12) 20 100 83.2 100 83.2 160.7 73.0 4199.0 PIII(M12) 20 100 83.2 100.0 13.5 173.3 1865.7 173.0 229.0 Total PRE 107 108.3.2 100 813.5 <td></td> <td></td> <td></td> <td></td> <td>PII(M3)</td> <td>97</td> <td>97</td> <td>100</td> <td>90.0 QE 0</td> <td>100</td> <td>100.2</td> <td>131.7</td> <td>205.0</td> <td>20.0</td> <td>24562.0</td>					PII(M3)	97	97	100	90.0 QE 0	100	100.2	131.7	205.0	20.0	24562.0
HII(M12) 67 100 95.8 100 139.8 11.1 172.3 93.0 1018.3 PIII(M12) 67 87 100 95.8 100 87.8 716.6 1099.9 45.0 5547.0 PIII(M36) 67 87 100 95.8 100 681.5 556.7 851.5 43.0 4669.0 PIII(M30) 67 87 100 95.8 100 601.1 483.1 747.9 30.0 3297.0 PIII(M12) 20 100 83.2 100 340.8 120.3 667.5 73.0 4199.0 PIII(M12) 20 100 83.2 100 1340.9 96.0 3527.0 PIII(M2) 20 100 83.2 100 81.0 88.9 171.0 2966.0 PIII(M3) 107 107 90.6 6100 138.5 54.8 100.3 240.9 20.0 4464.0 PIII(M21) 107 107<						07	07	100	90.0 05 0	100	4300.2	4100.5	4722.0	020.0	40462.0
PIII(M15)(P) B7 100 95.8 100 667.6 71.6 103.9 94.5.0 54.0 6469.0 PIII(M24))66 86 100 95.8 100 661.1 483.1 747.9 30.0 3297.0 S+ PRE 20 20 100 83.2 100 263.1 20.0 364.1 20.0 364.1 20.0 667.5 73.0 4199.0 PIII(M12) 20 100 83.2 100 348.1 20.3 667.5 73.0 4199.0 PIII(M12) 20 100 83.2 100 1340.9 906.3 1983.8 267.0 7031.0 PIII(M13) 19 100 82.2 100 83.2 100 516.1 361.5 363.0 446.3 888.9 171.0 2956.0 PIII(M21) 107 100 86.10 103.2 446.3 888.9 171.0 2956.0 PIII(M31) 107 107 100					PIII(M12)	07	07	100	32.0	100	1396.4	746.6	1723.9	39.0	10163.0
PIII(M24) [86 86 100 95.8 100 680.5 951.7 43.0 4969.0 S+ PRE 20 100 83.2 100 22.3 14.0 35.4 7.0 87.9 PIII(M7) 20 20 100 83.2 100 442.9 314.5 6231.2 145.90 18651.0 PIII(M7) 20 20 100 83.2 100 1340.9 906.3 1983.8 267.0 703.0 4199.0 PIII(M12) 20 20 100 83.2 100 1340.9 906.3 1983.8 267.0 703.1 2956.0 PIII(M36) 20 20 100 83.2 100 616.1 3145.5 576.4 626.0 3456.0 PIII(M36) 107 107 100 96.6 100 192.8 154.3 240.9 20.0 4646.0 PIII(M71) 107 107 100 96.6 100 187.3 165.3 99.0 1063.3 99.0 1063.3					P111(M16)	0/	0/	100	32.0	100	001.0	/10.0	1099.9	45.0	0047.0
PRE 20 100 95.8 100 96.3 100 22.3 14.0 35.4 7.0 87.0 S+ PRE 20 100 83.2 100 22.3 14.0 35.4 7.0 87.0 PII(M3) 20 20 100 83.2 100 368.1 203.0 667.5 7.3.0 4199.0 PIII(M12) 20 20 100 83.2 100 134.9 906.3 1883.8 267.0 7031.0 PIII(M21) 20 20 100 83.2 100 516.1 361.5 76.7 133.0 2292.0 Total PRE 107 20 18.7 11.8 27.4 4.9 4.2 5.8 <7.0					PIII(M24)	86	86	100	95.8	100	666.5	556.7	851.5	43.0	4669.0
S+ PKE 20 20 100 83.2 100 22.3 14.0 33.4 7.0 87.0 PII(M3) 20 20 100 83.2 100 4429.4 3148.5 667.5 73.0 4199.0 PIII(M12) 20 20 100 83.2 100 4429.4 3148.5 667.5 73.0 4199.0 PIII(M12) 20 20 100 83.2 100 4429.4 3148.5 667.5 73.0 4199.0 PIII(M12) 20 20 100 83.2 100 429.4 3148.5 667.4 80.0 33.0 2292.0 Total PRE 107 20 18.7 11.8 27.4 4.9 4.2 5.8 <7.0				_	PIII(M36)	87	87	100	95.8	100	601.1	483.1	(4(.9	30.0	3297.0
HPV 9_114 S- 100 83.2 100 4429.4 3148.5 623.1.2 1459.0 18651.0 PIII(M12) 20 20 100 83.2 100 4429.4 3148.5 6231.2 1459.0 18651.0 PIII(M12) 20 20 100 83.2 100 4429.4 3148.5 6231.2 1459.0 18651.0 PIII(M12) 20 20 100 83.2 100 629.8 446.3 888.9 171.10 2956.0 PIII(M24) 20 20 100 83.2 100 516.1 361.5 73.0 47.0 70.0 <t< td=""><td></td><td></td><td></td><td>S+</td><td>PRE</td><td>20</td><td>20</td><td>100</td><td>83.2</td><td>100</td><td>22.3</td><td>14.0</td><td>35.4</td><td>7.0</td><td>87.0</td></t<>				S+	PRE	20	20	100	83.2	100	22.3	14.0	35.4	7.0	87.0
HPV 9_11(M7) 20 20 100 83.2 100 4429.4 3145.5 6231.2 1459.0 11861.0 PIII(M12) 20 20 100 83.2 100 1340.9 906.3 1983.8 267.0 7031.0 PIII(M24) 20 20 100 83.2 100 629.8 446.3 888.9 171.0 2966.0 3527.0 PIII(M24) 20 20 100 83.2 100 516.1 361.5 736.7 133.0 2292.0 Total PRE 107 107 100 96.6 100 194.3 240.9 20.0 4646.0 PIII(M7) 107 107 100 96.6 100 874.3 165.3 39.0 10163.0 PIII(M12) 107 107 100 96.6 100 874.0 72.9 1053.8 45.0 5847.0 PIII(M21) 106 106 100 96.6 100 584					PII(M3)	20	20	100	83.2	100	368.1	203.0	667.5	/3.0	4199.0
HPV 9_114 S- PRE 51 100 83.2 100 134.0.9 906.3 1983.8 267.0 7031.0 PIII(M18) 19 19 100 82.4 100 813.5 548.8 1205.8 206.0 3527.0 PIII(M24) 20 20 100 83.2 100 518.1 381.5 738.7 133.0 2292.0 Total PRE 107 20 18.7 11.8 27.4 4.9 4.2 5.8 <7.0					PIII(M7)	20	20	100	83.2	100	4429.4	3148.5	6231.2	1459.0	18651.0
PIII.(M18) 19 100 82.4 100 81.3 5 64.8 1205.8 206.0 3527.0 PIII.(M24) 20 20 100 83.2 100 516.1 361.5 736.7 133.0 2292.0 Total PRE 107 20 18.7 11.8 27.4 4.9 4.2 5.8 <7.0					PIII(M12)	20	20	100	83.2	100	1340.9	906.3	1983.8	267.0	7031.0
PIII(M24) 20 20 100 83.2 100 629.8 446.3 888.9 171.0 2956.0 PIII(M36) 20 20 100 83.2 100 619.5 736.7 133.0 2292.0 Total PRE 107 20 18.7 11.8 61.0 192.8 154.3 240.9 20.0 4646.0 PIII(M7) 107 107 100 96.6 100 874.0 724.9 1053.8 45.0 5847.0 PIII(M12) 107 107 100 96.6 100 874.0 724.9 1053.8 45.0 5847.0 PIII(M24) 106 106 100 96.6 100 874.0 93.0 30.0 3297.0 PIII(M24) 106 106 100 96.6 100 584.2 484.1 704.9 30.0 3297.0 PIII(M7) 51 51 0.0 93.0 100 1670.4 1251.3 2230.0 247.0					PIII(M18)	19	19	100	82.4	100	813.5	548.8	1205.8	206.0	3527.0
PIII(M36) 20 20 100 83.2100 51.61 361.5 736.7 133.0 2292.0 Total PRE 107 20 18.7 11.8 27.4 4.9 4.2 5.8 <7.0					PIII(M24)	20	20	100	83.2	100	629.8	446.3	888.9	171.0	2956.0
Total PRE 107 20 18.7 11.8 127.4 4.9 4.2 5.8 <7.0 87.0 PII(M3) 107 107 100 96.6 100 192.8 154.3 240.9 20.0 4646.0 PIII(M12) 107 107 100 96.6 100 4872.3 4183.5 5674.4 626.0 34562.0 PIII(M12) 107 107 100 96.6 100 874.0 724.9 1053.8 45.0 5847.0 PIII(M24) 106 106 100 96.6 100 874.0 724.9 1053.8 45.0 5847.0 PIII(M24) 106 106 100 96.6 100 584.2 484.1 704.9 30.0 3297.0 PIII(M35) 107 107 100 96.6 100 70 3.5 3.5 3.5 7.0 <7.0					PIII(M36)	20	20	100	83.2	100	516.1	361.5	736.7	133.0	2292.0
PII(M3) 107 107 100 96.6 100 192.8 154.3 240.9 20.0 4646.0 PIII(M7) 107 107 100 96.6 100 4872.3 4183.5 5674.4 626.0 34562.0 PIII(M12) 107 107 100 96.6 100 1385.9 1153.3 1665.3 99.0 10163.0 PIII(M12) 106 106 100 96.6 100 874.0 724.9 1053.8 450.0 5847.0 PIII(M36) 107 107 100 96.6 100 677.0 564.3 812.3 43.0 4669.0 PIII(M36) 107 107 100 93.0 100 77.0 54.2 84.1 704.9 30.0 3297.0 HPV 9_14 S- PRE 51 100 93.0 100 7911.3 6188.8 10113.3 1680.0 37491.0 PIII(M12) 51 51 100				Total	PRE	107	20	18.7	11.8	27.4	4.9	4.2	5.8	<7.0	87.0
PIII(M7) 107 107 100 96.6 100 4872.3 4183.5 5674.4 626.0 34562.0 PIII(M12) 107 107 100 96.6 100 1385.9 1153.3 1665.3 99.0 10163.0 PIII(M12) 106 106 100 96.6 100 874.0 724.9 1053.8 45.0 5847.0 PIII(M24) 106 106 100 96.6 100 677.0 564.3 812.3 43.0 4669.0 PIII(M36) 107 107 100 96.6 100 677.0 564.3 812.3 43.0 4669.0 PIII(M36) 107 107 100 96.6 100 54.2 484.1 704.9 30.0 3297.0 PRE 51 0 0.0 0.7 3.5 3.5 <7.0					PII(M3)	107	107	100	96.6	100	192.8	154.3	240.9	20.0	4646.0
PIII(M12) 107 107 100 96.6 100 1385.9 1153.3 1665.3 99.0 10163.0 PIII(M18) 106 106 100 96.6 100 874.0 724.9 1053.8 45.0 5847.0 PIII(M24) 106 106 100 96.6 100 677.0 564.3 812.3 43.0 4669.0 PIII(M36) 107 107 100 96.6 100 577.0 564.3 812.3 43.0 4669.0 PIII(M36) 107 107 100 96.6 100 577.0 57.0 27.0 27.0 PRE 51 0 0.0 0.0 70.1 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.5 3.6 8.0 43.0 100.0 100 1670.4 1251.3 2230.0 247.0 877.3.0					PIII(M7)	107	107	100	96.6	100	4872.3	4183.5	5674.4	626.0	34562.0
PIII(M18) 106 106 100 96.6 100 874.0 724.9 1053.8 45.0 5847.0 PIII(M24) 106 106 100 96.6 100 677.0 564.3 812.3 43.0 4669.0 PIII(M36) 107 107 100 96.6 100 584.2 484.1 704.9 30.0 3297.0 HPV 9_14 S PRE 51 0 0.0 0.0 7.0 3.5 3.5 7.0 <7.0					PIII(M12)	107	107	100	96.6	100	1385.9	1153.3	1665.3	99.0	10163.0
PIII(M24) 106 100 96.6 100 677.0 564.3 812.3 43.0 4669.0 PIII(M36) 107 107 100 96.6 100 584.2 484.1 704.9 30.0 3297.0 HPV 9_14 S- PRE 51 0 0.0 7.0 3.5 3.5 <7.0					PIII(M18)	106	106	100	96.6	100	874.0	724.9	1053.8	45.0	5847.0
PIII(M36) 107 107 100 96.6 100 584.2 484.1 704.9 30.0 3297.0 HPV 9_14 S- PRE 51 0 0.0 7.0 3.5 3.5 3.5 <7.0					PIII(M24)	106	106	100	96.6	100	677.0	564.3	812.3	43.0	4669.0
HPV 9_14 S- PRE 51 0 0.0 7.0 3.5 3.5 3.5 <7.0 <7.0 PIII(M7) 51 51 100 93.0 100 7911.3 6188.8 10113.3 1680.0 37491.0 PIII(M12) 51 51 100 93.0 100 2642.1 1936.3 3605.1 33.9.0 19004.0 PIII(M12) 51 51 100 93.0 100 1670.4 1251.3 2230.0 247.0 8773.0 PIII(M24) 50 50 100 92.9 100 1359.1 1012.7 1824.0 187.0 8369.0 PIII(M24) 50 50 100 93.0 100 1197.6 903.1 1588.3 139.0 8194.0 S+ PRE 6 6 100 54.1 100 112.6 3530.0 10584.4 2806.0 11503.0 PIII(M12) 6 6 100 54.1					PIII(M36)	107	107	100	96.6	100	584.2	484.1	704.9	30.0	3297.0
PIII(M7) 51 51 100 93.0 100 7911.3 6188.8 10113.3 1680.0 37491.0 PIII(M12) 51 51 100 93.0 100 2642.1 1936.3 3605.1 339.0 19004.0 PIII(M18) 51 51 100 93.0 100 1670.4 1251.3 2230.0 247.0 8773.0 PIII(M24) 50 50 100 92.9 100 1359.1 1012.7 1824.0 187.0 8369.0 PIII(M36) 51 51 100 93.0 100 1177.6 903.1 1588.3 139.0 8194.0 S+ PRE 6 6 100 54.1 100 159.7 7.6 33.6 8.0 43.0 PIII(M7) 6 6 100 54.1 100 1183.2 3906.5 687.0 3126.0 PIII(M12) 6 6 100 54.1 100 1207.2 641.8		HPV	9_14	S-	PRE	51	0	0.0	0.0	7.0	3.5	3.5	3.5	<7.0	<7.0
PIII(M12) 51 51 100 93.0 100 2642.1 1936.3 3605.1 339.0 19004.0 PIII(M18) 51 51 100 93.0 100 1670.4 1251.3 2230.0 247.0 8773.0 PIII(M24) 50 50 100 92.9 100 1359.1 1012.7 1824.0 187.0 8369.0 PIII(M36) 51 51 100 93.0 100 1197.6 903.1 1588.3 139.0 8194.0 S+ PRE 6 6 100 54.1 100 15.9 7.6 33.6 8.0 43.0 PIII(M7) 6 6 100 54.1 100 6112.6 3530.0 10584.4 2806.0 11503.0 PIII(M12) 6 6 100 54.1 100 121.6 3530.0 10584.4 2806.0 11503.0 PIII(M12) 6 6 100 54.1 100 1519.1 <td></td> <td></td> <td></td> <td></td> <td>PIII(M7)</td> <td>51</td> <td>51</td> <td>100</td> <td>93.0</td> <td>100</td> <td>7911.3</td> <td>6188.8</td> <td>10113.3</td> <td>1680.0</td> <td>37491.0</td>					PIII(M7)	51	51	100	93.0	100	7911.3	6188.8	10113.3	1680.0	37491.0
PIII(M18) 51 51 100 93.0 100 1670.4 1251.3 2230.0 247.0 8773.0 PIII(M24) 50 50 100 92.9 100 1359.1 1012.7 1824.0 187.0 8369.0 PIII(M36) 51 51 100 93.0 100 1197.6 903.1 1588.3 139.0 8194.0 S+ PRE 6 6 100 54.1 100 15.9 7.6 33.6 8.0 43.0 PIII(M7) 6 6 100 54.1 100 6112.6 3530.0 10584.4 2806.0 11503.0 PIII(M12) 6 6 100 54.1 100 1519.1 787.4 2930.4 466.0 2997.0 PIII(M18) 6 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 PIII(M24) 6 6 100 54.1 100 1207.2					PIII(M12)	51	51	100	93.0	100	2642.1	1936.3	3605.1	339.0	19004.0
PIII(M24) 50 50 100 92.9 100 1359.1 1012.7 1824.0 187.0 8369.0 PIII(M36) 51 51 100 93.0 100 1197.6 903.1 1588.3 139.0 8194.0 S+ PRE 6 6 100 54.1 100 15.9 7.6 33.6 8.0 43.0 PIII(M7) 6 6 100 54.1 100 6112.6 3530.0 10584.4 2806.0 11503.0 PIII(M12) 6 6 100 54.1 100 1519.1 787.4 2930.4 466.0 2997.0 PIII(M12) 6 6 100 54.1 100 1206.3 635.7 2289.1 420.0 2477.0 PIII(M24) 6 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 Total PRE 57 6 10.5 4.0 21.5 4					PIII(M18)	51	51	100	93.0	100	1670.4	1251.3	2230.0	247.0	8773.0
PIII(M36) 51 51 100 93.0 100 1197.6 903.1 1588.3 139.0 8194.0 S+ PRE 6 6 100 54.1 100 15.9 7.6 33.6 8.0 43.0 PIII(M7) 6 6 100 54.1 100 6112.6 3530.0 10584.4 2806.0 11503.0 PIII(M12) 6 6 100 54.1 100 1519.1 787.4 2930.4 466.0 2997.0 PIII(M12) 6 6 100 54.1 100 1519.1 787.4 2930.4 466.0 2997.0 PIII(M24) 6 6 100 54.1 100 1206.3 635.7 2289.1 420.0 2477.0 PIII(M24) 6 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 Total PRE 57 6 10.5 4.0 21.5 4.1<					PIII(M24)	50	50	100	92.9	100	1359.1	1012.7	1824.0	187.0	8369.0
S+ PRE 6 6 100 54.1 100 15.9 7.6 33.6 8.0 43.0 PIII(M7) 6 6 100 54.1 100 6112.6 3530.0 10584.4 2806.0 11503.0 PIII(M12) 6 6 100 54.1 100 2149.9 1183.2 3906.5 687.0 3126.0 PIII(M12) 6 6 100 54.1 100 1519.1 787.4 2930.4 466.0 2997.0 PIII(M24) 6 6 100 54.1 100 1206.3 635.7 2289.1 420.0 2477.0 PIII(M24) 6 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 Total PRE 57 6 10.5 4.0 21.5 4.1 3.6 4.7 <7.0					PIII(M36)	51	51	100	93.0	100	1197.6	903.1	1588.3	139.0	8194.0
PIII(M7) 6 6 100 54.1 100 6112.6 3530.0 10584.4 2806.0 11503.0 PIII(M12) 6 6 100 54.1 100 2149.9 1183.2 3906.5 687.0 3126.0 PIII(M12) 6 6 100 54.1 100 1519.1 787.4 2930.4 466.0 2997.0 PIII(M24) 6 6 100 54.1 100 1206.3 635.7 2289.1 420.0 2477.0 PIII(M36) 6 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 Total PRE 57 6 10.5 4.0 21.5 4.1 3.6 4.7 <7.0				S+	PRE	6	6	100	54.1	100	15.9	7.6	33.6	8.0	43.0
PIII(M12) 6 6 100 54.1 100 2149.9 1183.2 3906.5 687.0 3126.0 PIII(M18) 6 100 54.1 100 1519.1 787.4 2930.4 466.0 2997.0 PIII(M24) 6 6 100 54.1 100 1206.3 635.7 2289.1 420.0 2477.0 PIII(M36) 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 Total PRE 57 6 10.5 4.0 21.5 4.1 3.6 4.7 <7.0					PIII(M7)	6	6	100	54.1	100	6112.6	3530.0	10584.4	2806.0	11503.0
PIII(M18) 6 6 100 54.1 100 1519.1 787.4 2930.4 466.0 2997.0 PIII(M24) 6 6 100 54.1 100 1206.3 635.7 2289.1 420.0 2477.0 PIII(M36) 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 Total PRE 57 6 10.5 4.0 21.5 4.1 3.6 4.7 <7.0					PIII(M12)	6	6	100	54.1	100	2149.9	1183.2	3906.5	687.0	3126.0
PIII(M24) 6 6 100 54.1 100 1206.3 635.7 2289.1 420.0 2477.0 PIII(M36) 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 Total PRE 57 6 10.5 4.0 21.5 4.1 3.6 4.7 <7.0					PIII(M18)	6	6	100	54.1	100	1519.1	787.4	2930.4	466.0	2997.0
PIII(M36) 6 100 54.1 100 1207.2 641.8 2270.5 475.0 2582.0 Total PRE 57 6 10.5 4.0 21.5 4.1 3.6 4.7 <7.0					PIII(M24)	6	6	100	54.1	100	1206.3	635.7	2289.1	420.0	2477.0
Total PRE 57 6 10.5 4.0 21.5 4.1 3.6 4.7 <7.0 43.0 PIII(M7) 57 57 100 93.7 100 7699.4 6155.5 9630.5 1680.0 37491.0 PIII(M12) 57 57 100 93.7 100 2585.4 1951.7 3424.9 339.0 19004.0 PIII(M12) 57 57 100 93.7 100 1653.8 1272.1 2150.0 247.0 8773.0 PIII(M24) 56 56 100 93.6 100 1341.9 1028.0 1751.6 187.0 8369.0 PIII(M36) 57 57 100 93.7 100 1198.6 927.8 1548.6 139.0 8194.0					PIII(M36)	6	6	100	54.1	100	1207.2	641.8	2270.5	475.0	2582.0
PIII(M7) 57 57 100 93.7 100 7699.4 6155.5 9630.5 1680.0 37491.0 PIII(M12) 57 57 100 93.7 100 2585.4 1951.7 3424.9 33.9.0 19004.0 PIII(M18) 57 57 100 93.7 100 1653.8 1272.1 2150.0 247.0 8773.0 PIII(M24) 56 56 100 93.6 100 1341.9 1028.0 1751.6 187.0 8369.0 PIII(M36) 57 57 100 93.7 100 1198.6 1927.8 1548.6 139.0 8194.0				Total	PRE	57	6	10.5	4.0	21.5	4.1	3.6	4.7	<7.0	43.0
PIII(M12) 57 57 100 93.7 100 2585.4 1951.7 3424.9 339.0 19004.0 PIII(M18) 57 57 100 93.7 100 1653.8 1272.1 2150.0 247.0 8773.0 PIII(M24) 56 56 100 93.6 100 1341.9 1028.0 1751.6 187.0 8369.0 PIII(M24) 56 57 100 93.7 100 1198.6 927.8 1548.6 139.0 8194.0					PIII(M7)	57	57	100	93.7	100	7699.4	6155.5	9630.5	1680.0	37491.0
PIII(M18) 57 57 100 93.7 100 1653.8 1272.1 2150.0 247.0 8773.0 PIII(M24) 56 56 100 93.6 100 1341.9 1028.0 1751.6 187.0 8369.0 PIII(M26) 57 57 100 93.7 100 1198.6 927.8 1548.6 139.0 8194.0					PIII(M12)	57	57	100	93.7	100	2585.4	1951.7	3424.9	339.0	19004.0
PIII(M24) 56 56 100 93.6 100 1341.9 1028.0 1751.6 187.0 8369.0 PIII(M36) 57 57 100 93.7 100 1198.6 927.8 1548.6 139.0 8194.0					PIII(M18)	57	57	100	93.7	100	1653.8	1272.1	2150.0	247.0	8773.0
PIII(M36) 57 57 100 93.7 100 1198.6 927.8 1548.6 139.0 8194.0					PIII(M24)	56	56	100	93.6	100	1341.9	1028.0	1751.6	187.0	8369.0
					PIII(M36)	57	57	100	93.7	100	1198.6	927.8	1548.6	139.0	8194.0

						2	27 El	U/MI	L		GMT			
								95%	6 CI		959	% CI		
Antibody	Group	Sub-	Pre-	Timing	Ν	n	%	LL	UL	value	LL	UL	Min	Max
		group	vacc											
			status											
		15_25	S-	PRE	81	0	0.0	0.0	4.5	3.5	3.5	3.5	<7.0	<7.0
				PIII(M7)	81	81	100	95.5	100	4314.9	3525.2	5281.5	885.0	69885.0
				PIII(M12)	80	80	100	95.5	100	1467.4	1167.1	1845.0	167.0	26768.0
				PIII(M18)	79	79	100	95.4	100	997.7	784.6	1268.7	65.0	19963.0
				PIII(M24)	80	80	100	95.5	100	794.3	626.5	1007.0	39.0	13295.0
				PIII(M36)	81	81	100	95.5	100	712.3	560.3	905.6	25.0	9702.0
			S+	PRE	15	15	100	78.2	100	14.7	9.6	22.4	7.0	130.0
				PIII(M7)	15	15	100	78.2	100	4008.4	2043.7	7861.7	926.0	81284.0
				PIII(M12)	15	15	100	78.2	100	1544.2	755.0	3158.3	363.0	47033.0
				PIII(M18)	15	15	100	78.2	100	1122.1	558.5	2254.3	197.0	29745.0
				PIII(M24)	15	15	100	78.2	100	841.0	412.4	1714.7	176.0	24394.0
				PIII(M36)	15	15	100	78.2	100	796.1	385.8	1642.9	206.0	24703.0
			Total	PRE	96	15	15.6	9.0	24.5	4.4	3.9	4.9	<7.0	130.0
				PIII(M7)	96	96	100	96.2	100	4265.5	3511.1	5181.9	885.0	81284.0
				PIII(M12)	95	95	100	96.2	100	1479.3	1190.3	1838.5	167.0	47033.0
				PIII(M18)	94	94	100	96.2	100	1016.6	811.8	1273.0	65.0	29745.0
				PIII(M24)	95	95	100	96.2	100	801.5	641.0	1002.1	39.0	24394.0
				PIII(M36)	96	96	100	96.2	100	724.8	578.1	908.8	25.0	24703.0

V40_06 = HPV-16/18(40,40) AS04 0,6m

V20_06 = HPV-16/18(20,20) AS04 0,6 m

HPV = HPV-16/18(20,20) AS04 0,1,6m

S- = seronegative subjects (antibody concentration < 7 ELU/ML) prior to vaccination

S+ = seropositive subjects (antibody concentration ≥ 7 ELU/ML) prior to vaccination

GMT = geometric mean titers concentration 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

MIN/MAX = Minimum/Maximum

PRE = pre-vaccination

PII(M3) = Post Dose II, Month 3

PIII(M7) = Post Dose III, Month 7

PIII(M12) = Post Dose III, Month 12

PIII(M18) = Post Dose III, Month 18

PIII(M24) = Post Dose III,Month 24

PIII(M36) = Post Dose III, Month 36

Table 21 Seropositivity rates and GMTs for HPV 16.VLP IGG antibodies by pre-vaccination status and by age stratum (Month 36 ATP Immunogenicity Cohort)

							≥ 8 EI	LU/M	L		GMT			
								95%	6 CI		95	% CI		
Antibody	Group	Sub- group	Pre- vacc status	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
HPV 16.VLP IGG	V40_02	9_14y	S-	PRE	60	0	0.0	0.0	6.0	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	60	60	100	94.0	100	7301.2	5921.7	9002.0	966.0	45534.0
				PIII(M7)	60	60	100	94.0	100	2008.4	1569.3	2570.5	208.0	26271.0
				PIII(M12)	60	60	100	94.0	100	1418.6	1101.3	1827.2	143.0	17994.0
				PIII(M18)	59	59	100	93.9	100	1359.9	1043.1	1772.9	138.0	11507.0
				PIII(M24)	59	59	100	93.9	100	1136.9	881.1	1466.9	124.0	9500.0
				PIII(M36)	60	60	100	94.0	100	998.1	779.2	1278.6	117.0	10491.0
			S+	PRE	1	1	100	2.5	100	15.0	-	-	15.0	15.0
				PII(M3)	1	1	100	2.5	100	6378.0	-	-	6378.0	6378.0
				PIII(M7)	1	1	100	2.5	100	1159.0	-	-	1159.0	1159.0
				PIII(M12)	1	1	100	2.5	100	940.0	-	-	940.0	940.0
				PIII(M18)	1	1	100	2.5	100	955.0	-	-	955.0	955.0
				PIII(M24)	1	1	100	2.5	100	602.0	-	-	602.0	602.0
			Tatal	PIII(M36)	1	1	100	2.5	100	422.0	-	-	422.0	422.0
			Total	PKE	61	1	1.6	0.0	0.0	4.1	3.9	4.3	<8.0	15.0
				PII(M3)	01	01	100	34.1	100	1200.0	3828.3	0500.0	300.0	40004.0
				PIII(M7) DIII(M12)	61	61	100	94.1	100	1990.4	1009.2	2030.0	200.0	17004.0
				DIII/M18)	60	60	100	94.1	100	1351.0	1030.2	1755.0	138.0	11507.0
				PIII(M10) DIII(M24)	60	60	100	94.0	100	1124.9	874.8	1446.4	124.0	9500.0
				DIII/M36)	61	61	100	94.0	100	984.1	770.2	1257.5	117.0	10491.0
		15 19v	S.	PRE	57	0	0.0	0.0	6.3	4.0	4.0	4.0	<8.0	<8.0
		10_10,	0 -	PII/M3)	57	57	100	937	100	5191 4	41727	6458.7	233.0	30994.0
				PIII(M7)	57	57	100	93.7	100	1136.9	902.3	1432.5	148.0	6111.0
				PIII(M12)	57	57	100	937	100	825.6	652.7	1044.2	123.0	5112.0
				PIII(M18)	56	56	100	93.6	100	745.8	576.3	965.0	96.0	4620.0
				PIII(M24)	55	55	100	93.5	100	652.0	514.5	826.3	100.0	4111.0
				PIII(M36)	57	57	100	93.7	100	566.1	444.4	721.1	71.0	2717.0
			S+	PRÈ	3	3	100	29.2	100	30.7	12.1	77.5	20.0	40.0
				PII(M3)	3	3	100	29.2	100	5788.0	2330.9	14372.6	3811.0	7540.0
				PIII(M7)	3	3	100	29.2	100	2093.3	1237.7	3540.2	1698.0	2592.0
				PIII(M12)	3	3	100	29.2	100	1225.4	535.1	2806.1	893.0	1736.0
				PIII(M18)	3	3	100	29.2	100	1382.4	601.6	3176.1	1006.0	1961.0
				PIII(M24)	3	3	100	29.2	100	891.2	583.3	1361.8	735.0	1017.0
				PIII(M36)	3	3	100	29.2	100	862.1	447.2	1661.8	677.0	1143.0
			Total	PRE	60	3	5.0	1.0	13.9	4.4	3.9	5.0	<8.0	40.0
				PII(M3)	60	60	100	94.0	100	5219.7	4239.5	6426.6	233.0	30994.0
				PIII(M7)	60	60	100	94.0	100	1172.1	938.6	1463.8	148.0	6111.0
				PIII(M12)	60	60	100	94.0	100	842.0	672.7	1054.0	123.0	5112.0
				PIII(M18)	59	59	100	93.9	100	769.5	600.9	985.5	96.0	4620.0
				PIII(M24)	58	58	100	93.8	100	662.7	529.1	830.0	100.0	4111.0
				PIII(M36)	60	60	100	94.0	100	578.1	458.8	728.5	71.0	2717.0

							> 8 FI	11/M			CMT	ох перо	(H) F	30) i ina
						-		0.54			001	% CI		
Antibody	Group	Sub	Dre	Timina	N	n	96	337		value	33		Min	Max
Antibody	oroup	aroun	Vacc	, mind		Ľ	/0		0	Value		UL		max
		group	status											
<u> </u>	<u> </u>	20 25v	S.	PRF	39	0	0.0	0.0	9.0	4.0	40	4.0	<8.0	<8.0
		20_200,		PII/M3)	39	39	100	91.0	100	4626.2	3560.6	6010.9	668.0	22930.0
				PIII(M7)	39	39	100	91.0	100	1116 7	836.0	1491.6	80.0	5616.0
				PIII(M12)	39	39	100	91.0	100	763.9	564.2	1034.4	53.0	3727.0
				PIII(M18)	39	39	100	91.0	100	694.7	495.3	974.5	32.0	5415.0
				PIII(M24)	39	39	100	91.0	100	588.3	427.7	809.3	24.0	2959.0
				PIII(M36)	39	39	100	91.0	100	520.7	383.1	707.8	29.0	2701.0
			S+	PRÈ	6	6	100	54.1	100	53.1	12.2	230.3	9.0	413.0
				PII(M3)	6	6	100	54.1	100	3889.3	1377.1	10984.2	1744.0	20636.0
				PIII(M7)	6	6	100	54.1	100	1442.0	394.1	5276.7	521.0	11429.0
				PIII(M12)	6	6	100	54.1	100	1266.4	361.2	4440.0	338.0	7667.0
				PIII(M18)	6	6	100	54.1	100	916.1	282.6	2970.2	281.0	5156.0
				PIII(M24)	6	6	100	54.1	100	792.5	201.4	3119.2	184.0	6264.0
				PIII(M36)	6	6	100	54.1	100	636.4	146.6	2761.9	120.0	5741.0
			Total	PRE	45	6	13.3	5.1	26.8	5.6	4.2	7.6	<8.0	413.0
				PII(M3)	45	45	100	92.1	100	4520.4	3529.6	5789.4	668.0	22930.0
				PIII(M7)	45	45	100	92.1	100	1155.4	873.0	1529.2	80.0	11429.0
				PIII(M12)	45	45	100	92.1	100	817.2	610.0	1094.8	53.0	7667.0
				PIII(M18)	45	45	100	92.1	100	720.8	526.5	986.8	32.0	5415.0
				PIII(M24)	45	45	100	92.1	100	612.2	450.6	831.6	24.0	6264.0
				PIII(M36)	45	45	100	92.1	100	534.8	396.0	722.4	29.0	5741.0
	V40_06	9_14y	S-	PRE	50	0	0.0	0.0	7.1	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	50	50	100	92.9	100	368.6	277.6	489.5	43.0	7324.0
				PIII(M7)	50	50	100	92.9	100	16994.1	13914.2	20755.8	2713.0	57135.0
				PIII(M12)	50	50	100	92.9	100	4535.4	3617.3	5686.6	877.0	30300.0
				PIII(M18)	50	50	100	92.9	100	3016.8	2416.1	3766.8	600.0	12570.0
				PIII(M24)	49	49	100	92.7	100	2176.6	1738.2	2725.7	341.0	9840.0
				PIII(M36)	50	50	100	92.9	100	1762.7	1419.9	2188.3	239.0	8472.0
			Total	PRE	50	0	0.0	0.0	7.1	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	50	50	100	92.9	100	368.6	277.6	489.5	43.0	7324.0
				PIII(M7)	50	50	100	92.9	100	16994.1	13914.2	20755.8	2713.0	57135.0
				PIII(M12)	50	50	100	92.9	100	4535.4	3617.3	5686.6	877.0	30300.0
				PIII(M18)	50	50	100	92.9	100	3016.8	2416.1	3766.8	600.0	12570.0
				PIII(M24)	49	49	100	92.7	100	2176.6	1738.2	2725.7	341.0	9840.0
			_	PIII(M36)	50	50	100	92.9	100	1762.7	1419.9	2188.3	239.0	8472.0
		15_19y	S-	PRE	49	0	0.0	0.0	1.3	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	49	49	100	92.7	100	340.0	257.8	448.3	61.0	4601.0
				PIII(M7)	49	49	100	92.7	100	11861.7	94/9.3	14842.7	1426.0	42/98.0
				PIII(M12)	49	49	100	92.7	100	3860.9	3147.9	4/35.4	389.0	13/72.0
				PIII(M18)	49	49	100	92.7	100	2502.3	2022.9	3095.4	516.0	11355.0
				PIII(M24)	48	48	100	92.6	100	1932.0	1558.5	2394.9	352.0	8639.0
			<u></u>	PIII(M36)	49	49	100	92.7	100	1606.3	1292.1	1997.1	283.0	//42.0
			S+	PRE	7	1	100	59.0	100	/4.5	12.6	438.7	12.0	900.0
				PII(M3)	1	1	100	59.0	100	1090.3	204.9	41/2.8	1/3.0	0052.0
				PIII(M/)	7	7	100	59.0	100	10334.9	0105.3	0754.0	0935.0	33723.0
				PIII(M12)	7	7	100	59.0	100	3021.5	1301.5	0/04.0	09/.0	11023.0
				PIII(M18)	7	7	100	59.0	100	1995.0	772.6	4602.7	204.0	6774.0
				PIII(M24)	7	7	100	59.0	100	1406.6	475.0	4003.7	157.0	7224.0
1	1	1	1	[FIII(M30)	1	1	100	05.0	100	1400.0	410.5	101.1	107.0	1224.0

							≥ 8 FI	U/M			GMT	an noper	(
						<u> </u>		959	6 CI		95	% CI		
Antibody	Group	Sub-	Pre-	Timina	N	n	%	LL	UL	value	LL	UL	Min	Мах
,		group	vacc		· ·	-								
			status											
			Total	PRE	56	7	12.5	5.2	24.1	5.8	4.2	7.9	<8.0	900.0
				PII(M3)	56	56	100	93.6	100	393.3	293.7	526.7	61.0	6052.0
				PIII(M7)	56	56	100	93.6	100	11659.1	9529.2	14265.1	1426.0	42798.0
				PIII(M12)	56	56	100	93.6	100	3744 4	3081.0	4550.5	389.0	13772.0
				PIII(M18)	56	56	100	93.6	100	2480.4	2012.9	3056.4	284.0	11355.0
				PIII(M24)	55	55	100	93.5	100	1926.0	1567.7	2366.3	352.0	8639.0
				PIII(M36)	56	56	100	93.6	100	1579.9	1272.4	1961.7	157.0	7742.0
		20 25v	S-	PRE	36	0	0.0	0.0	9.7	4.0	4.0	4.0	<8.0	<8.0
				PII(M3)	36	36	100	90.3	100	290.8	205.9	410.8	45.0	3769.0
				PIII(M7)	36	36	100	90.3	100	8710.9	6611.0	11477.8	1211.0	48115.0
				PIII(M12)	35	35	100	90.0	100	2332.5	1698.2	3203.8	109.0	20072.0
				PIII(M18)	34	34	100	89.7	100	1705.5	1230.4	2364.2	107.0	15410.0
				PIII(M24)	35	35	100	90.0	100	1335.2	993.6	1794.3	138.0	11571.0
				PIII(M36)	36	36	100	90.3	100	1118.7	859.6	1455.8	288.0	7105.0
			S+	PRE	17	17	100	80.5	100	67.4	32.0	142.0	8.0	1006.0
				PII(M3)	17	17	100	80.5	100	2149.5	994.4	4646.5	139.0	23592.0
				PIII(M7)	17	17	100	80.5	100	5836.4	4010 1	8494 4	1831.0	29466.0
				PIII(M12)	17	17	100	80.5	100	2652.8	1715.1	4103.3	499.0	8153.0
				PIII(M18)	17	17	100	80.5	100	2028.6	1255.0	3279.0	344.0	8738.0
				PIII(M24)	17	17	100	80.5	100	1574.5	982.0	2524.6	288.0	6699.0
				PIII(M36)	16	16	100	794	100	1135.7	734.6	1755.9	234.0	2968.0
			Total	PRE	53	17	32.1	19.9	46.3	9.9	6.4	15.2	<8.0	1006.0
				PII(M3)	53	53	100	93.3	100	552.4	364.3	837.7	45.0	23592.0
				PIII(M7)	53	53	100	93.3	100	7660.9	6137.6	9562.2	1211.0	48115.0
				PIII(M12)	52	52	100	93.2	100	2432.7	1896.9	3119.9	109.0	20072.0
				PIII(M18)	51	51	100	93.0	100	1807.0	1391.3	2347.0	107.0	15410.0
				PIII(M24)	52	52	100	93.2	100	1409.1	1104.8	1797.4	138.0	11571.0
				PIII(M36)	52	52	100	93.2	100	1123.9	903.8	1397.5	234.0	7105.0
	V20_06	9 14v	S-	PRE	53	0	0.0	0.0	6.7	4.0	4.0	4.0	<8.0	<8.0
	_			PII(M3)	53	53	100	93.3	100	276.0	213.3	357.2	73.0	6037.0
				PIII(M7)	53	53	100	93.3	100	11957.2	9657.2	14804.9	2687.0	60582.0
				PIII(M12)	53	53	100	93.3	100	3632.8	2973.9	4437.6	737.0	21151.0
				PIII(M18)	53	53	100	93.3	100	2385.9	1931.6	2947.0	516.0	10395.0
				PIII(M24)	52	52	100	93.2	100	1836.0	1494.3	2255.7	452.0	7302.0
				PIII(M36)	53	53	100	93.3	100	1595.1	1298.2	1960.0	356.0	7249.0
			S+	PRÈ	2	2	100	15.8	100	10.8	1.0	111.9	9.0	13.0
				PII(M3)	2	2	100	15.8	100	216.6	16.7	2812.8	177.0	265.0
				PIII(M7)	2	2	100	15.8	100	10464.9	271.6	403258.3	7851.0	13949.0
				PIII(M12)	2	2	100	15.8	100	2833.5	246.4	32584.4	2338.0	3434.0
				PIII(M18)	2	2	100	15.8	100	2002.8	878.4	4566.4	1877.0	2137.0
				PIII(M24)	2	2	100	15.8	100	1021.0	188.9	5519.7	894.0	1166.0
				PIII(M36)	2	2	100	15.8	100	810.1	71.2	9219.5	669.0	981.0
			Total	PRE	55	2	3.6	0.4	12.5	4.1	3.9	4.4	<8.0	13.0
				PII(M3)	55	55	100	93.5	100	273.6	213.4	350.8	73.0	6037.0
				PIII(M7)	55	55	100	93.5	100	11899.3	9681.5	14625.2	2687.0	60582.0
				PIII(M12)	55	55	100	93.5	100	3600.1	2967.4	4367.7	737.0	21151.0
				PIII(M18)	55	55	100	93.5	100	2370.8	1934.2	2905.8	516.0	10395.0
				PIII(M24)	54	54	100	93.4	100	1796.5	1470.1	2195.3	452.0	7302.0
				PIII(M36)	55	55	100	93.5	100	1556.3	1272.3	1903.7	356.0	7249.0

Bit is a start is start a start is a start is a start is a start is a start								> 8 FI	U/M	-		GMT	ox nopoi	(- ()	50) T IIIai
Antibody Group group Yacc status Timing vacc status N n % LL UL UL UL Min Max 15_19 S PRE 53 0 0.0 0.0 6.7 4.0 5.0 7.0 1356.0 7.6 10.0 4.0 5.0 7.6 198.4 11.0 31.4 4.0 10.0 3.0 10.0 4.0 5.0 2.0 10.0 4.0 5.0 2.7 9.0 2.00.0 10.0							<u> </u>		959	6 CI		95	% CI		
Kindbory Vacc status Filling Pressort	Antibody	Group	Sub.	Pre-	Timing	N	n	%	11		value	33		Min	Max
Image: status PRE 53 0 0.0 0.0 6.7 4.0 4.0 <6.0 <6.0 PII(M3) 53 53 100 93.3 100 255.8 184.0 355.6 21.0 7463.0 PIII(M17) 53 53 100 93.3 100 255.8 164.0 355.6 21.0 7463.0 PIII(M17) 53 53 100 93.3 100 2591.9 2098.6 3201.3 377.0 13560.0 PIII(M18)52 52 100 93.2 100 1414.7 1163.8 171.98 256.0 7683.0 PIII(M3) 5 5 100 47.8 100 180.1 1202.0 10884.0 1109.0 10984.3 1.0 230.0 PIII(M19) 5 100 47.8 100 122.5 1171.16 1209.0 10884.0 110.0 268.0 1100.0 208.0 1100.0 224.1 135.6 21.0 7463.0 1209.0	Andbody	oroup	aroun	vacc		Ľ		~			Talac				max
15_19y S- PRE 53 0 0.0 0 6.7 4.0 4.0 4.0 <8.0 <8.0 PIII(M3) 53 53 100 93.3 100 255.8 184.0 355.6 21.0 7483.0 PIII(M12) 53 53 100 93.3 100 289.6 3201.3 377.0 1356.0 PIII(M12) 55 51 100 93.2 100 1852.6 1494.2 2296.9 246.0 12109.0 PIII(M24) 52 52 100 93.2 100 1857.6 198.4 11.0 314.0 PIII(M36) 55 51 100 47.8 100 3845.3 1262.5 11711.6 1290.0 10884.0 PIII(M12) 5 100 47.8 100 671.3 144.3 4017.0 831.0 1280.0 1084.0 PIII(M12) 5 100 47.8 100 671.3 144.4 321.0			group	status											
International and the state in the		<u> </u>	15 19v	S.	PRF	53	0	0.0	0.0	67	4.0	40	40	<8.0	<8.0
Piii(M7) 53 53 100 933.3 100 838.4 6701.7 10489.5 1436.0 47872.0 Piii(M12) 53 53 100 933.3 100 258.4 6701.7 10489.5 1436.0 47872.0 Piii(M12) 53 53 100 93.3 100 152.6 1494.2 2296.9 246.0 12109.0 Piii(M24) 52 100 93.3 100 1197.6 991.9 1445.9 221.0 568.0 PIII(M36) 53 100 93.3 100 1197.6 991.9 1445.9 221.0 5688.0 PIII(M35) 5 100 47.8 100 388.7 6 198.4 11.0 314.0 PIII(M12) 5 100 47.8 100 1631.1 144.3 4017.0 81.0 286.0 PIII(M12) 5 100 47.8 100 633.6 155.9 54.3 31.0 302.0			10_10,		PII/M3)	53	53	100	933	100	255.8	184.0	355.6	21.0	7463.0
Pril(M12) Sister S					PIII(M7)	53	53	100	93.3	100	8384.4	6701.7	10489.5	1436.0	47872.0
PIII(M18) PIII(M24) PIIII(M24) PIIII(M24) PIIII(M24) PIIII(M24) PIIIIIII PIIIIIII PIIIIIII PIIIIIII PIIIIIII PIIIIIII PIIIIIII PIIIIIII PIIIIIII PIIIIIIII PIIIIIIII PIIIIIIIIII PIIIIIIIIIIIIIIIII PIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII					PIII/M12)	53	53	100	93.3	100	2591.9	2098.6	3201 3	377.0	13560.0
PIII(M24) 52 52 100 93.2 100 144.7 1183.8 1719.8 256.0 7638.0 PIII(M36) 53 53 100 93.3 100 194.7 1183.8 1719.8 256.0 7638.0 S+ PRE 5 100 47.8 100 38.8 7.6 198.4 11.0 314.0 PIII(M3) 5 100 47.8 100 3845.3 1262.5 11711.6 1290.0 10884.0 PIII(M12) 5 100 47.8 100 761.3 144.3 4017.0 81.0 2868.0 PIII(M12) 5 100 47.8 100 661.1 322.4 135.8 321.0 1302.0 PIII(M36) 5 100 47.8 100 661.1 322.4 135.8 321.0 1342.0 PIII(M12) 58 58 100 93.8 100 783.8 683.3 1290.0 4782.0 PIII(M12) 58					PIII(M18)	52	52	100	93.2	100	1852.6	1494.2	2296.9	246.0	12109.0
Imitima 1 Imitima 1 <thimitima 1<="" th=""> <thimitima 1<="" th=""> <thi< td=""><td></td><td></td><td></td><td></td><td>PIII(M24)</td><td>52</td><td>52</td><td>100</td><td>93.2</td><td>100</td><td>1414 7</td><td>1163.8</td><td>1719.8</td><td>256.0</td><td>7638.0</td></thi<></thimitima></thimitima>					PIII(M24)	52	52	100	93.2	100	1414 7	1163.8	1719.8	256.0	7638.0
S+ PRE 5 5 100 47.8 100 38.8 7.6 198.4 11.0 314.0 PIII(M3) 5 5 100 47.8 100 3845.3 1262.5 11711.6 1290.0 10884.0 PIII(M12) 5 100 47.8 100 1271.2 296.9 5442.3 204.0 4980.0 PIII(M12) 5 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M36) 5 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M36) 5 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M31) 58 58 100 93.8 100 269.9 140.0 375.6 21.0 7463.0 PIII(M12) 58 58 100 93.8 100 138.7 164.3 3024.0 204.0 13560.0 <td></td> <td></td> <td></td> <td></td> <td>PIII(M36)</td> <td>53</td> <td>53</td> <td>100</td> <td>93.3</td> <td>100</td> <td>1197.6</td> <td>991.9</td> <td>1445.9</td> <td>221.0</td> <td>5658.0</td>					PIII(M36)	53	53	100	93.3	100	1197.6	991.9	1445.9	221.0	5658.0
PII(M3) 5 5 100 47.8 100 477.6 47.1 4843.6 31.0 5330.0 PIII(M12) 5 5 100 47.8 100 3845.3 1262.5 11711.6 1290.0 10884.0 PIII(M12) 5 5 100 47.8 100 1271.2 296.9 5442.3 204.0 4980.0 PIII(M12) 5 5 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M36) 5 100 47.8 100 661.1 322.4 1355.8 321.0 1302.0 PIII(M3) 58 58 100 93.8 100 269.9 194.0 375.6 21.0 7463.0 PIII(M12) 58 58 100 93.8 100 2437.5 1964.8 3024.0 204.0 13560.0 PIII(M12) 58 58 100 93.8 100 1318.5 1075.1 161				S+	PRE	5	5	100	47.8	100	38.8	7.6	198.4	11.0	314.0
PIII(M7) 5 5 100 47.8 100 3845.3 1262.5 11711.6 1290.0 10884.0 PIII(M12) 5 100 47.8 100 1271.2 296.9 5442.3 204.0 4980.0 PIII(M12) 5 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M24) 5 5 100 47.8 100 631.1 322.4 1355.8 321.0 1302.0 PIII(M36) 5 5 100 47.8 100 661.1 322.4 1355.8 321.0 1302.0 PIII(M3) 58 58 100 93.8 100 269.9 194.0 375.6 21.0 7463.0 PIII(M12) 58 58 100 93.8 100 1437.5 1964.8 3024.0 204.0 1356.0 PIII(M12) 58 58 100 93.8 100 1437.8 948.6 1364.7 <					PII(M3)	5	5	100	47.8	100	477.6	47.1	4843.6	31.0	5330.0
PIII(M12) 5 5 100 47.8 100 1271.2 296.9 5442.3 204.0 4980.0 PIII(M18) 5 5 100 47.8 100 761.3 144.3 4017.0 81.0 2886.0 PIII(M24) 5 5 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M3) 58 58 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M3) 58 58 100 93.8 100 269.9 194.0 375.6 21.0 7463.0 PIII(M12) 58 58 100 93.8 100 2437.5 1964.8 3024.0 204.0 13560.0 PIII(M18) 57 57 100 93.7 100 1137.8 948.6 1364.7 221.0 5658.0 20_25y S- PRE 40 0 0.0.0.8 84.0 4.0					PIII(M7)	5	5	100	47.8	100	3845.3	1262.5	11711.6	1290.0	10884.0
PIII(M18) 5 5 100 47.8 100 761.3 144.3 4017.0 81.0 2686.0 PIII(M24) 5 5 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M36) 5 5 100 47.8 100 661.1 322.4 1355.8 321.0 1302.0 Total PRE 58 5 8.6 2.9 19.0 4.9 4.0 5.9 314.0 PIII(M12) 58 58 100 93.8 100 269.9 194.0 375.6 21.0 7463.0 PIII(M12) 58 58 100 93.8 100 243.7 1964.8 3024.0 204.0 1356.0 PIII(M12) 58 58 100 93.7 100 1713.5 1364.7 2151.4 81.0 12109.0 PIII(M18) 57 57 100 93.7 100 1318.5 1075.1 <td></td> <td></td> <td></td> <td></td> <td>PIII(M12)</td> <td>5</td> <td>5</td> <td>100</td> <td>47.8</td> <td>100</td> <td>1271.2</td> <td>296.9</td> <td>5442.3</td> <td>204.0</td> <td>4980.0</td>					PIII(M12)	5	5	100	47.8	100	1271.2	296.9	5442.3	204.0	4980.0
PIII(M24) 5 100 47.8 100 633.6 155.9 2575.7 99.0 2089.0 PIII(M36) 5 100 47.8 100 661.1 322.4 1355.8 321.0 1302.0 Total PRE 58 5 8.6 2.9 19.0 4.9 4.0 5.9 8.0 314.0 PIII(M3) 58 58 100 93.8 100 269.9 194.0 375.6 21.0 7463.0 PIII(M12) 58 58 100 93.8 100 2437.5 1964.8 3024.0 204.0 13560.0 PIII(M18) 57 57 100 93.7 100 1713.5 1364.7 210.0 5658.0 20_25y S- PRE 40 0 0.0 0.8 8.4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0					PIII(M18)	5	5	100	47.8	100	761.3	144.3	4017.0	81.0	2686.0
PIII(M36) 5 100 47.8 100 661.1 322.4 1355.8 321.0 1302.0 Total PRE 58 5 8.6 2.9 19.0 4.9 4.0 5.9 <8.0					PIII(M24)	5	5	100	47.8	100	633.6	155.9	2575.7	99.0	2089.0
Total PRE 58 5 8.6 2.9 19.0 4.9 4.0 5.9 <8.0 314.0 PII(M3) 58 58 100 93.8 100 269.9 194.0 375.6 21.0 7463.0 PIII(M12) 58 58 100 93.8 100 7839.5 6283.8 9780.3 1290.0 47872.0 PIII(M12) 58 58 100 93.7 100 1713.5 1364.7 2151.4 81.0 12109.0 PIII(M24) 57 57 100 93.7 100 1318.5 1075.1 1617.0 99.0 7638.0 PIII(M36) 58 58 100 93.8 100 1137.8 948.6 1364.7 221.0 5658.0 20_25y S- PRE 40 0 0.0 8.8 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0 4.0					PIII(M36)	5	5	100	47.8	100	661.1	322.4	1355.8	321.0	1302.0
PII(M3) 58 58 100 93.8 100 269.9 194.0 375.6 21.0 7463.0 PIII(M7) 58 58 100 93.8 100 7839.5 6283.8 9780.3 1290.0 47872.0 PIII(M12) 58 58 100 93.7 100 1713.5 1364.7 2151.4 81.0 12109.0 PIII(M24) 57 57 100 93.7 100 1318.5 1075.1 1617.0 99.0 7638.0 PIII(M36) 58 58 100 93.8 100 1137.8 948.6 1364.7 221.0 5658.0 20_25y S- PRE 40 0 0.0 8.8 4.0 4.0 4.0 40.0 48.0 PIII(M3) 40 40 100 91.2 100 267.7 7398.3 973.0 26064.0 PIII(M12) 40 40 100 91.2 100 1689.7 745.3<				Total	PRE	58	5	8.6	2.9	19.0	4.9	4.0	5.9	<8.0	314.0
PIII(M7) 58 58 100 93.8 100 7839.5 6283.8 9780.3 1290.0 47872.0 PIII(M12) 58 58 100 93.8 100 2437.5 1964.8 3024.0 204.0 13560.0 PIII(M12) 58 57 100 93.7 100 1713.5 1364.7 2151.4 81.0 12109.0 PIII(M24) 57 57 100 93.7 100 1318.5 1075.1 1617.0 99.0 7638.0 PIII(M36) 58 58 100 93.8 100 1137.8 948.6 1364.7 221.0 5658.0 20_25y S- PRE 40 0 0.0 8.8 4.0 <td></td> <td></td> <td></td> <td></td> <td>PII(M3)</td> <td>58</td> <td>58</td> <td>100</td> <td>93.8</td> <td>100</td> <td>269.9</td> <td>194.0</td> <td>375.6</td> <td>21.0</td> <td>7463.0</td>					PII(M3)	58	58	100	93.8	100	269.9	194.0	375.6	21.0	7463.0
PIII(M12) 58 58 100 93.8 100 2437.5 1964.8 3024.0 204.0 13560.0 PIII(M18) 57 57 100 93.7 100 1713.5 1364.7 2151.4 81.0 12109.0 PIII(M24) 57 57 100 93.7 100 1318.5 1075.1 1617.0 99.0 7638.0 PIII(M36) 58 58 100 93.8 100 1137.8 948.6 1364.7 221.0 5658.0 20_25y S- PRE 40 0 0.0 0.8 8 4.0 <td></td> <td></td> <td></td> <td></td> <td>PIII(M7)</td> <td>58</td> <td>58</td> <td>100</td> <td>93.8</td> <td>100</td> <td>7839.5</td> <td>6283.8</td> <td>9780.3</td> <td>1290.0</td> <td>47872.0</td>					PIII(M7)	58	58	100	93.8	100	7839.5	6283.8	9780.3	1290.0	47872.0
PIII(M18) 57 57 100 93.7 100 1713.5 1364.7 2151.4 81.0 12109.0 PIII(M24) 57 57 100 93.7 100 1318.5 1075.1 1617.0 99.0 7638.0 PIII(M36) 58 58 100 93.8 100 1137.8 948.6 1364.7 221.0 5658.0 20_25y S- PRE 40 0 0.0 0.8 4.0 4.0 4.0					PIII(M12)	58	58	100	93.8	100	2437.5	1964.8	3024.0	204.0	13560.0
PIII(M24) 57 57 100 93.7 100 1318.5 1075.1 1617.0 99.0 7638.0 PIII(M36) 58 58 100 93.8 100 1137.8 948.6 1364.7 221.0 5658.0 20_25y S PRE 40 0 0.0 0.0 8.8 4.0 4.0 4.0 <8.0					PIII(M18)	57	57	100	93.7	100	1713.5	1364.7	2151.4	81.0	12109.0
PIII(M36) 58 58 100 93.8 100 1137.8 948.6 1364.7 221.0 5658.0 20_25y S- PRE 40 0 0.0 0.0 8.8 4.0 4.0 4.0 <8.0					PIII(M24)	57	57	100	93.7	100	1318.5	1075.1	1617.0	99.0	7638.0
20_25y S- PRE 40 0 0.0 0.0 8.8 4.0 4.0 4.0 <8.0 <8.0 PII(M3) 40 40 100 91.2 100 202.9 146.5 280.9 25.0 1396.0 PIII(M7) 40 40 100 91.2 100 5673.7 4351.2 7398.3 973.0 26064.0 PIII(M12) 40 40 100 91.2 100 1689.6 1273.6 2268.2 290.0 12488.0 PIII(M12) 40 40 100 91.2 100 1689.6 1273.6 2268.2 290.0 12488.0 PIII(M12) 40 40 100 91.2 100 168.7 795.3 1436.1 159.0 7017.0 PIII(M24) 40 40 100 91.2 100 645.9 491.3 849.1 88.0 4054.0 S+ PRE 9 100 66.4 100 26					PIII(M36)	58	58	100	93.8	100	1137.8	948.6	1364.7	221.0	5658.0
PII(M3) 40 40 100 91.2 100 202.9 146.5 280.9 25.0 1396.0 PIII(M7) 40 40 100 91.2 100 5673.7 4351.2 7388.3 973.0 26064.0 PIII(M12) 40 40 100 91.2 100 1699.6 1273.6 2268.2 290.0 12488.0 PIII(M18) 40 40 100 91.2 100 1689.6 1273.6 2268.2 290.0 12488.0 PIII(M18) 40 40 100 91.2 100 168.7 795.3 1436.1 159.0 7017.0 PIII(M24) 40 40 100 91.2 100 645.9 491.3 849.1 88.0 4054.0 S+ PRE 9 9 100 66.4 100 287.5 1441.4 5010.9 908.0 9225.0 PII(M3) 9 9 100 66.4 100 2833.8			20_25y	S-	PRE	40	0	0.0	0.0	8.8	4.0	4.0	4.0	<8.0	<8.0
PIII(M7) 40 40 100 91.2 100 5673.7 4351.2 7398.3 973.0 26064.0 PIII(M12) 40 40 100 91.2 100 1699.6 1273.6 2268.2 290.0 12488.0 PIII(M18) 40 40 100 91.2 100 1669.6 1273.6 2268.2 290.0 12488.0 PIII(M18) 40 40 100 91.2 100 1668.7 795.3 1436.1 159.0 7017.0 PIII(M24) 40 40 100 91.2 100 838.7 628.9 1118.6 149.0 5366.0 PIII(M36) 40 40 100 91.2 100 645.9 491.3 849.1 88.0 4054.0 S+ PRE 9 9 100 66.4 100 2687.5 1441.4 5010.9 908.0 9225.0 PII(M3) 9 9 100 66.4 100 2353.8					PII(M3)	40	40	100	91.2	100	202.9	146.5	280.9	25.0	1396.0
PIII(M12)40 40 100 91.2 100 1699.6 1273.6 2288.2 290.0 12488.0 PIII(M18)40 40 100 91.2 100 1068.7 795.3 1436.1 159.0 7017.0 PIII(M24)40 40 100 91.2 100 838.7 628.9 1118.6 149.0 5366.0 PIII(M36)40 40 100 91.2 100 645.9 491.3 849.1 88.0 4054.0 S+ PRE 9 9 100 66.4 100 2687.5 1441.4 5010.9 908.0 9225.0 PIII(M3) 9 9 100 66.4 100 2833.8 1263.7 4384.3 970.0 12549.0 PIII(M12) 9 100 66.4 100 2353.8 1263.7 4384.3 970.0 12549.0 PIII(M12) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0					PIII(M7)	40	40	100	91.2	100	5673.7	4351.2	7398.3	973.0	26064.0
PIII(M18) 40 40 91.2 100 196.7 795.3 1436.1 159.0 7017.0 PIII(M24) 40 100 91.2 100 838.7 628.9 1118.6 149.0 5366.0 PIII(M36) 40 40 100 91.2 100 645.9 491.3 849.1 88.0 4054.0 S+ PRE 9 9 100 66.4 100 2687.5 1441.4 5010.9 908.0 9225.0 PIII(M3) 9 9 100 66.4 100 2353.8 1263.7 4384.3 970.0 12549.0 PIII(M12) 9 100 66.4 100 2353.8 1263.7 4384.3 970.0 12549.0 PIII(M12) 9 100 66.4 100 1320.9 760.2 3455.9 628.0 6867.0 PIII(M18) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0 <					PIII(M12)	40	40	100	91.2	100	1699.6	1273.6	2268.2	290.0	12488.0
PIII(M24)40 40 100 91.2 100 838.7 628.9 1118.6 149.0 5366.0 PIII(M36)40 40 100 91.2 100 645.9 491.3 849.1 88.0 4054.0 S+ PRE 9 9 100 66.4 100 2687.5 1441.4 5010.9 908.0 9225.0 PIII(M3) 9 9 100 66.4 100 2833.8 1263.7 4384.3 970.0 12549.0 PIII(M12) 9 100 66.4 100 2353.8 1263.7 4384.3 970.0 12549.0 PIII(M12) 9 100 66.4 100 1321.3 576.0 3123.6 384.0 7343.0 PIII(M18) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0 PIII(M36) 9 100 66.4 100 1024.8 470.4 2232.4 360.0 5553.0					PIII(M18)	40	40	100	91.2	100	1068.7	795.3	1436.1	159.0	7017.0
PRE 9 100 64.10 491.3 849.1 88.0 4054.0 S+ PRE 9 9 100 66.4 100 44.8 23.5 85.5 11.0 132.0 PII(M3) 9 9 100 66.4 100 2687.5 1441.4 5010.9 908.0 9225.0 PIII(M7) 9 9 100 66.4 100 275.3 1441.4 5010.9 908.0 9225.0 PIII(M12) 9 100 66.4 100 2353.8 1263.7 4384.3 970.0 12549.0 PIII(M12) 9 100 66.4 100 1321.3 576.0 3123.6 384.0 7343.0 PIII(M24) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7553.0 PIII(M36) 9 100 66.4 100 1024.8 470.4 2232.4 360.0 5553.0 PIII(M36) 9					PIII(M24)	40	40	100	91.2	100	838.7	628.9	1118.6	149.0	5366.0
S+ PRE 9 9 100 66.4 100 24.8 23.5 85.5 11.0 132.0 PII(M3) 9 9 100 66.4 100 2687.5 1441.4 5010.9 908.0 9225.0 PIII(M7) 9 9 100 66.4 100 275.0 1894.0 26064.0 PIII(M12) 9 100 66.4 100 2353.8 1263.7 4384.3 970.0 12549.0 PIII(M18) 9 100 66.4 100 1321.0 3455.9 628.0 6867.0 PIII(M18) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0 PIII(M36) 9 100 66.4 100 1024.8 470.4 2232.4 360.0 5553.0 Total PRE 49 9 184.8 83.20.6 24.7 8.3 <50.0				<u>.</u>	PIII(M36)	40	40	100	91.2	100	645.9	491.3	849.1	88.0	4054.0
PII(M3) 9 9 100 66.4 100 2687.5 1441.4 5010.9 908.0 9225.0 PIII(M7) 9 9 100 66.4 100 4781.1 2639.0 8661.9 1894.0 26064.0 PIII(M12) 9 9 100 66.4 100 2353.8 1263.7 4384.3 970.0 12549.0 PIII(M18) 9 9 100 66.4 100 1620.9 760.2 3455.9 628.0 6867.0 PIII(M24) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0 PIII(M36) 9 100 66.4 100 1024.8 470.4 2232.4 360.0 5553.0 Total PRE 49 9 18.4 8.3 2.0 6.2 4.7 8.3 <5.0				5+	PRE	3	9	100	00.4	100	44.0	23.5	00.0	11.0	132.0
PIII(M12) 9 100 66.4 100 2353.6 3661.5 1334.0 20064.0 PIII(M12) 9 100 66.4 100 2353.8 1263.7 4384.3 970.0 12549.0 PIII(M12) 9 100 66.4 100 1253.8 1263.7 4384.3 970.0 12549.0 PIII(M18) 9 9 100 66.4 100 1620.9 760.2 3455.9 628.0 6867.0 PIII(M24) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0 PIII(M36) 9 100 66.4 100 1024.8 470.4 2232.4 360.0 5553.0 Total PRE 49 9 18.4 8.3 32.0 6.2 4.7 8.3 <8.0					PII(M3)	3	9	100	00.4	100	2007.0	2620.0	90010.9	1904.0	9225.0
PIII(M12) 9 100 66.4 100 2333.6 1263.7 4364.3 970.0 12549.0 PIII(M18) 9 9 100 66.4 100 1620.9 760.2 3455.9 628.0 6867.0 PIII(M24) 9 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0 PIII(M36) 9 9 100 66.4 100 1024.8 470.4 2232.4 360.0 5553.0 Total PRE 49 9 18.4 8.3 32.0 62.2 4.7 8.3 <8.0					PIII(M7)	3	9	100	00.4 CC 4	100	4/01.1	4062.7	4204.2	070.0	20004.0
PIII(M24) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0 PIII(M36) 9 100 66.4 100 1341.3 576.0 3123.6 384.0 7343.0 PIII(M36) 9 100 66.4 100 1024.8 470.4 2232.4 360.0 5553.0 Total PRE 49 9 18.4 8.3 32.0 62.2 4.7 8.3 <8.0					PIII(M12) DIII/M18)	3	9	100	66.4	100	1620.9	760.2	4304.3 3455 Q	970.0 628.0	6867.0
PIII(M324) 9 100 66.4 100 1341.3 376.0 3123.6 364.0 7343.0 PIII(M36) 9 100 66.4 100 1024.8 470.4 2232.4 360.0 5553.0 Total PRE 49 9 18.4 8.3 32.0 6.2 4.7 8.3 <8.0					PIII(M 10)	9	9	100	66.4	100	1020.5	F76.0	2400.5	294.0	7242.0
Total PRE 49 9 18.4 8.8 32.0 6.2 4.7 8.3 <8.0 132.0					PIII(M24) DIII/M36)	3	9	100	66.4	100	1024.8	376.0 470.4	2222.0	360.0	7343.0 5553.0
				Total	PRE	49	9	18.4	8.8	32.0	6.2	470.4	8.3	<8.0	132.0
E E E E E E E E E E E E E E E E E E E					PII(M3)	49	49	100	92.7	100	326.1	217.8	488.2	25.0	9225.0
PIII(M7) 49 49 100 92.7 100 5498.1 4351.0 6947.6 973.0 26064.0					PIII(M7)	49	49	100	92.7	100	5498.1	4351.0	6947.6	973.0	26064.0
PIII(M12) 49 49 100 92 7 100 1804 4 1398 5 2328 0 290 0 12549 0					PIII(M12)	49	49	100	92.7	100	1804.4	1398.5	2328.0	290.0	12549.0
PIII(M18) 49 49 100 92.7 100 1153.7 1880.9 1510.9 159.0 7017.0					PIII(M18)	49	49	100	92.7	100	1153.7	880.9	1510.9	159.0	7017.0
PIII(M24) 49 49 100 92.7 100 914.3 696.8 1199.5 149.0 7343.0					PIII(M24)	49	49	100	92.7	100	914.3	696.8	1199.5	149.0	7343.0
PIII(M36)49 49 100 92.7 100 703.0 543.9 908.7 88.0 5553.0					PIII(M36)	49	49	100	92.7	100	703.0	543.9	908.7	88.0	5553.0

							> 8 FI	U/M			GMT	ех пероі	1 4 (IVI)	50) T Inai
						<u> </u>	- 0 - 1	059	6.01		0.001	% CI		
Antibody	Group	Sub.	Pre-	Timina	N	n	%	11		value	33		Min	Max
	0.000	aroup	vacc				1							
		0r	status											
	HPV	9_14v	S-	PRE	50	0	0.0	0.0	7.1	4.0	4.0	4.0	<8.0	<8.0
				PIII(M7)	50	50	100	92.9	100	23214.7	17936.9	30045.5	3932.0	149951.0
				PIII(M12)	50	50	100	92.9	100	8069.7	5939.4	10964.0	992.0	59262.0
				PIII(M18)	50	50	100	92.9	100	5441.6	4078.1	7260.8	600.0	37234.0
				PIII(M24)	49	49	100	92.7	100	4184.1	3098.9	5649.5	557.0	31073.0
				PIII(M36)	50	50	100	92.9	100	3501.7	2621.7	4677.0	428.0	30440.0
			S+	PRÉ	7	7	100	59.0	100	13.3	9.5	18.7	9.0	26.0
				PIII(M7)	7	7	100	59.0	100	17621.9	9057.5	34284.6	8602.0	53482.0
				PIII(M12)	7	7	100	59.0	100	7441.0	4508.7	12280.4	3755.0	17083.0
				PIII(M18)	7	7	100	59.0	100	5065.8	3441.4	7456.8	2757.0	9524.0
				PIII(M24)	7	7	100	59.0	100	4256.5	3030.9	5977.6	2567.0	8511.0
				PIII(M36)	7	7	100	59.0	100	3970.0	2878.4	5475.7	2120.0	5895.0
			Total	PRE	57	7	12.3	5.1	23.7	4.6	4.2	5.2	<8.0	26.0
				PIII(M7)	57	57	100	93.7	100	22442.0	17741.7	28387.6	3932.0	149951.0
				PIII(M12)	57	57	100	93.7	100	7989.7	6087.8	10485.9	992.0	59262.0
				PIII(M18)	57	57	100	93.7	100	5394.0	4181.7	6957.7	600.0	37234.0
				PIII(M24)	56	56	100	93.6	100	4193.1	3221.7	5457.5	557.0	31073.0
				PIII(M36)	57	57	100	93.7	100	3556.1	2756.2	4588.0	428.0	30440.0
		15_19y	S-	PRE	44	0	0.0	0.0	8.0	4.0	4.0	4.0	<8.0	<8.0
				PIII(M7)	44	44	100	92.0	100	12352.2	9002.6	16948.0	1322.0	148276.0
				PIII(M12)	43	43	100	91.8	100	3826.6	2734.2	5355.3	182.0	70532.0
				PIII(M18)	43	43	100	91.8	100	2394.6	1744.0	3288.0	116.0	31934.0
				PIII(M24)	43	43	100	91.8	100	1891.8	1371.4	2609.8	112.0	27936.0
				PIII(M36)	44	44	100	92.0	100	1664.9	1222.4	2267.7	73.0	23603.0
			S+	PRE	3	3	100	29.2	100	41.1	1.6	1082.5	9.0	94.0
				PIII(M7)	3	3	100	29.2	100	21593.5	180.4	2585025	2482.0	99665.0
				PIII(M12)	3	3	100	29.2	100	10933.4	77.5	1543120	1156.0	51632.0
				PIII(M18)	3	3	100	29.2	100	9710.7	60.6	1555426	998.0	52061.0
				PIII(M24)	3	3	100	29.2	100	6949.9	53.8	89/6/2.6	812.0	3/420.0
			7.1.1	PIII(M36)	3	3	100	29.2	100	6620.7	47.3	92/660.6	/41.0	36109.0
			lotal	PRE	4/	3	6.4	1.3	17.5	4.6	3.8	5.6	<8.0	94.0
				PIII(M7)	4/	4/	100	92.5	100	12800.5	9289.5	1/638.4	1322.0	1482/6.0
				PIII(M12)	40	40	100	92.3	100	4097.0	2090.9	0/92.0	102.0	70532.0
				PIII(M18)	46	46	100	92.3	100	2023.0	18/0.4	3660.0	116.0	27420.0
				PIII(M24) DIII/M36)	40	40	100	92.5	100	1818.3	1308.8	2007.7	73.0	36109.0
		20.254	c	DDE	41	4/	0.0	32.5	0.0	1010.3	1300.0	2020.1	<pre>/3.0</pre>	<9.0
		20_25y	0-	DIII/M7)	41	41	100	91 4	100	9924 7	6393.1	4.0	1379.0	125818.0
				DIII/M12)	41	41	100	01.4	100	3377.3	2431.7	12400.0	601.0	81240.0
				PIII(M12)	40	40	100	91.4	100	2351.3	1671.7	3307.2	243.0	45075.0
				DIII/M24)	41	41	100	91 4	100	1857.6	1351.1	2554.0	290.0	35172.0
				PIII(M36)	41	41	100	91.4	100	1517.2	1107.9	2077 7	325.0	20763.0
			S+	PRF	8	8	100	63.1	100	49.1	12.8	188.7	9.0	745.0
				PIII(M7)	8	8	100	63.1	100	5640 1	3045.1	10446.5	2632.0	25899.0
				PIII(M12)	8	8	100	63.1	100	2663.7	1502.4	4722.5	1208.0	9249.0
				PIII(M18)	8	8	100	63.1	100	2083.1	1264.7	3431.0	951.0	6012.0
				PIII(M24)	8	8	100	63.1	100	1639.7	922.8	2913.5	870.0	5401.0
				PIII(M36)	8	8	100	63.1	100	1420.0	853.9	2361.3	621.0	4027.0

						2	2 8 EI	_U/M	L		GMT			
								95%	6 CI		95	% CI		
Antibody	Group	Sub-	Pre-	Timing	Ν	n	%	LL	UL	value	LL	UL	Min	Max
		group	vacc											
			status											
			Total	PRE	49	8	16.3	7.3	29.7	6.0	4.4	8.3	<8.0	745.0
				PIII(M7)	49	49	100	92.7	100	8280.5	6178.3	11097.9	1379.0	125818.0
				PIII(M12)	49	49	100	92.7	100	3248.9	2445.3	4316.6	601.0	81240.0
				PIII(M18)	48	48	100	92.6	100	2304.3	1723.8	3080.3	243.0	45075.0
				PIII(M24)	49	49	100	92.7	100	1820.1	1382.0	2397.1	290.0	35172.0
				PIII(M36)	49	49	100	92.7	100	1500.9	1146.1	1965.4	325.0	20763.0

V40_06 = HPV-16/18(40,40) AS04 0,6m

V20_06 = HPV-16/18(20,20) AS04 0,6 m

HPV = HPV-16/18(20,20) AS04 0,1,6m

S- = seronegative subjects (antibody concentration < 8 ELU/ML) prior to vaccination

S+ = seropositive subjects (antibody concentration ≥ 8 ELU/ML) prior to vaccination

GMT = geometric mean titers concentration 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

MIN/MAX = Minimum/Maximum

PRE = pre-vaccination

PII(M3) = Post Dose II, Month 3

PIII(M7) = Post Dose III, Month 7

PIII(M12) = Post Dose III, Month 12

PIII(M18) = Post Dose III, Month 18

PIII(M24) = Post Dose III,Month 24

PIII(M36) = Post Dose III, Month 36

						2	27 EI	U/MI	L		GMC			
								95%	6 CI		95	i% CI		
Antibody	Group	Sub- aroup	Pre-vacc status	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
HPV 18.VLP IGG	V40_02	9_14y	S-	PRE	56	0	0.0	0.0	6.4	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	56	56	100	93.6	100	5112.6	4090.2	6390.6	562.0	33045.0
				PIII(M7)	56	56	100	93.6	100	1133.1	870.7	1474.5	69.0	7965.0
				PIII(M12)	56	56	100	93.6	100	605.1	457.5	800.4	35.0	5521.0
				PIII(M18)	55	55	100	93.5	100	490.1	376.0	638.8	50.0	3262.0
				PIII(M24)	55	55	100	93.5	100	420.4	320.3	551.8	37.0	3257.0
				PIII(M36)	56	56	100	93.6	100	402.3	305.1	530.6	29.0	6446.0
			S+	PRE	5	5	100	47.8	100	15.7	8.9	27.9	8.0	24.0
				PII(M3)	5	5	100	47.8	100	4361.8	1615.3	11778.3	2098.0	14980.0
				PIII(M7)	5	5	100	47.8	100	962.8	365.5	2536.5	286.0	2502.0
				PIII(M12)	5	5	100	47.8	100	458.8	134.5	1564.7	111.0	1205.0
				PIII(M18)	5	5	100	47.8	100	382.4	122.1	1197.9	115.0	1292.0
				PIII(M24)	5	5	100	47.8	100	429.6	116.9	1579.1	89.0	1189.0
				PIII(M36)	5	5	100	47.8	100	418.5	83.5	2097.5	86.0	2081.0
			Total	PRE	61	5	8.2	2.7	18.1	4.0	3.5	4.4	<7.0	24.0
				PII(M3)	61	61	100	94.1	100	5046.5	4085.2	6234.1	562.0	33045.0
				PIII(M7)	61	61	100	94.1	100	1118.1	873.5	1431.2	69.0	7965.0
				PIII(M12)	61	61	100	94.1	100	591.5	453.8	771.0	35.0	5521.0
				PIII(M18)	60	60	100	94.0	100	480.1	373.6	616.8	50.0	3262.0
				PIII(M24)	60	60	100	94.0	100	421.2	325.3	545.4	37.0	3257.0
				PIII(M36)	61	61	100	94.1	100	403.6	308.9	527.5	29.0	6446.0
		15_19y	S-	PRE	56	0	0.0	0.0	6.4	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	56	56	100	93.6	100	2882.1	2244.7	3700.6	148.0	22529.0
				PIII(M7)	56	56	100	93.6	100	660.3	513.6	849.0	107.0	4507.0
				PIII(M12)	56	56	100	93.6	100	382.5	288.1	507.8	40.0	6173.0
				PIII(M18)	55	55	100	93.5	100	289.9	219.9	382.1	42.0	3266.0
				PIII(M24)	54	54	100	93.4	100	243.2	183.7	322.0	26.0	2442.0
				PIII(M36)	56	56	100	93.6	100	245.0	179.9	333.8	18.0	3051.0
			S+	PRE	4	4	100	39.8	100	25.7	4.4	149.2	8.0	114.0
				PII(M3)	4	4	100	39.8	100	10395.4	2701.9	39995.7	4727.0	33321.0
				PIII(M7)	4	4	100	39.8	100	2838.7	1011.5	7966.5	1864.0	7467.0
				PIII(M12)	4	4	100	39.8	100	1257.2	426.7	3704.4	779.0	3415.0
				PIII(M18)	4	4	100	39.8	100	1220.6	317.7	4689.7	543.0	3091.0
				PIII(M24)	4	4	100	39.8	100	930.6	274.4	3156.2	493.0	2332.0
				PIII(M36)	4	4	100	39.8	100	707.8	228.4	2193.9	403.0	1826.0
			Total	PRE	60	4	6.7	1.8	16.2	4.0	3.5	4.6	<7.0	114.0
				PII(M3)	60	60	100	94.0	100	3139.5	2439.8	4039.8	148.0	33321.0
				PIII(M7)	60	60	100	94.0	100	727.8	563.8	939.5	107.0	7467.0
				PIII(M12)	60	60	100	94.0	100	414.1	313.6	546.7	40.0	6173.0
				PIII(M18)	59	59	100	93.9	100	319.6	241.9	422.2	42.0	3266.0
				PIII(M24)	58	58	100	93.8	100	266.8	201.7	352.8	26.0	2442.0
				PIII(M36)	60	60	100	94.0	100	263.0	195.1	354.6	18.0	3051.0

Table 22 Seropositivity rates and GMTs for HPV 18.VLP IGG antibodies by pre-vaccination status and by age stratum (Month 36 ATP Immunogenicity Cohort)

						>	7 FI	11/M			CMC	riopon		0,1110
						-	. / LI	0.50			0110	% CI		
Antibody	Group	Sub-	Pre-vacc	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
		group	status	DPE	20	0	0.0	0.0	10.9	2.5	2.5	2.5	<7.0	<7.0
		20_259	0-		32	22	100	90.0	10.5	2194.1	2.2	4560.4	442.0	19057.0
				PII(M3)	32	32	100	89.1	100	636.1	2223.J	4000.1	73.0	3672.0
				FIII(M7)	22	32	100	03.1	100	250.7	224.0	520.1	25.0	4739.0
				PIII(M12) DIII/M18)	32	32	100	90.1	100	202.7	234.0	020.0 AGE 0	25.0	1591.0
				PIII(M10)	32	32	100	89.1	100	323.2 287.4	195.1	403.0	12.0	1568.0
				PIII(M24) DIII(M36)	32	32	100	89.1	100	207.4	170.7	423.4	10.0	2104.0
			C+	PRF	13	13	100	75.3	100	201.0	9.6	50.3	7.0	510.0
			· ·	DII/M3)	13	13	100	75.3	100	2207.5	1540.9	3162.7	671.0	4154.0
				PIII(M3)	13	13	100	75.3	100	660.7	386.5	1129.3	155.0	2427.0
				DIII/M12)	13	13	100	75.3	100	410.5	216.5	778.3	84.0	1594.0
				PIII(M12)	13	13	100	75.3	100	348.5	182.1	667.1	63.0	1298.0
				DIII/M24)	13	13	100	75.3	100	317.6	163.2	618.1	46.0	1112.0
				PIII(M24) DIII(M36)	13	13	100	75.3	100	231.5	117.9	454.4	35.0	1075.0
			Total	DRE	45	13	28.9	16.4	44.3	5.9	4.3	83	<7.0	510.0
			rotai	DII/M3)	45	45	100	92.1	100	2864.4	2180.7	3762.4	443.0	19057.0
				DIII/M7	45	45	100	92.1	100	643.1	478.0	965.2	73.0	3672.0
				PIII(M12)	45	45	100	92.1	100	367.0	264.7	509.0	25.0	1728.0
				PIII(M12)	45	45	100	92.1	100	330.3	237.2	460.0	15.0	1591.0
				DIII/M24)	45	45	100	92.1	100	295.8	214.5	408.1	12.0	1568.0
				PIII(M24) DIII(M36)	45	45	100	92.1	100	235.0	177.8	339.2	10.0	2104.0
	V40.06	Q 1/y	c	DRE	50	40	0.0	0.0	6.8	245.0	2.5	2.5	<7.0	2704.0
	V40_08	5_14y	0-	DII/M3)	52	52	100	0.0	100	263.3	201.6	3/3.8	46.0	3159.0
					52	52	100	02.2	100	203.3	201.0 COAE 2	40700 7	40.0	C0050 0
				PIII(M7) DIII(M42)	52	52	100	93.2	100	2162.0	1667.8	2805.0	361.0	20569.0
				FIII(M12)	52	52	100	02.2	100	2102.5 4020 E	040.0	1000.0	102.0	14555.0
				PIII(M10) DIII/M24)	52	52	100	93.2	100	1230.5	340.0 703.1	1009.0	193.0	6809.0
				P111(M24)	51	51	100	93.0	100	320.3	703.1	1222.0	104.0	4944.0
			Total	PIII(M36)	52	02	0.0	93.2	00	2.5	2/4.1	300.0	124.0	4014.0
			TULAI	PILE DIV/M2V	52	50	100	0.0	100	0.0 060.0	3.5 204.6	3.3	<7.0 AC 0	2450.0
				PII(M3)	52	52	100	93.2	100	203.3	201.0	343.0	40.0	00050.0
				PIII(M7) DIII/M42)	52	52	100	93.2	100	2462.0	1667.0	2005.0	261.0	20569.0
				FIII(M12)	52	52	100	02.2	100	102.5	040.0	1000.0	102.0	11555.0
				PIII(M10)	52	52	100	93.2	100	1230.5	540.0 703.1	1009.0	193.0	6809.0
				FIII(M24)	51	50	100	02.0	100	750.0	674.4	000.0	104.0	4914.0
		15 19v	c	DRE	52	0	0.0	0.0	67	3.5	3.5	3.5	24.0	4014.0
		15_159	0-	DII/M3)	53	52	100	0.0	100	209.9	159.2	276.8	38.0	7952.0
				PII(M3)	53	53	100	93.3	100	209.9	5380.3	270.0	412.0	01076.0
				FIII(M7)	55	55	100	02.2	100	2205.7	4692.7	2001 4	412.0	24742.0
				P111(M12) D111/M18)	53	53	100	93.3	100	1200.7	1602.1 965.6	1724.0	102.0	19845.0
				PIII(MIO)	55	55	100	93.3	100	1200.2	757.4	1724.0	72.0	45066.0
				P111(M24) D111(M26)	52	52	100	93.2	100	945.2	620.2	1338.5	10.0	15066.0
			C+	PIII(M36)	2	2	100	33.3	100	040.2 5/ 1	029.3	5279.2	10.0	387.0
			0 T		2	2	100	29.2	100	4520.4	0.0	000007.0	10.0	22562.0
				DIII(M3)	3	2	100	29.2	100	1000.1	2.9	500031.0	3444.0	23003.0
				DIII(M42)	2	2	100	20.2	100	4012.4	100.0	96799.0	976.0	0749.0
				PIII(M12)	2	2	100	29.2	100	4012.1	100.0	00/00.U	620.0	7799.0
				PIII(M10)	2	2	100	29.2	100	2323.1	02.2	55210.1	630.0	9450.0
				PIII(M24)	2	2	100	29.2	100	4627.0	03.Z	55270.9	425.0	0400.0
	1	1	I	PIII(M36)	2	2	100	29.2	100	1037.0	0.10	51776.0	433.0	0.0060

						>	7 FI	U/M			GMC		1	-,
								959	6 CI	<u> </u>	95	% CI		
Antibody	Group	Sub- group	Pre-vacc status	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
			Total	PRE	56	3	5.4	1.1	14.9	4.1	3.3	4.9	<7.0	387.0
				PII(M3)	56	56	100	93.6	100	233.6	170.1	320.7	38.0	23563.0
				PIII(M7)	56	56	100	93.6	100	6943.5	5505.8	8756.8	412.0	91976.0
				PIII(M12)	56	56	100	93.6	100	2277.6	1745.8	2971.4	190.0	34743.0
				PIII(M18)	56	56	100	93.6	100	1331.5	1002.8	1768.1	102.0	19845.0
				PIII(M24)	55	55	100	93.5	100	1049.5	791.9	1390.8	73.0	15066.0
				PIII(M36)	56	56	100	93.6	100	875.7	655.0	1170.7	50.0	15050.0
		20_25y	S-	PRE	40	0	0.0	0.0	8.8	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	40	40	100	91.2	100	177.7	125.0	252.6	13.0	2442.0
				PIII(M7)	40	40	100	91.2	100	4564.9	3447.5	6044.6	845.0	34350.0
				PIII(M12)	39	39	100	91.0	100	1204.9	888.0	1634.9	176.0	10669.0
				PIII(M18)	38	38	100	90.7	100	687.2	490.1	963.5	103.0	6285.0
				PIII(M24)	40	40	100	91.2	100	545.8	400.0	744.6	84.0	4062.0
				PIII(M36)	40	40	100	91.2	100	490.5	359.3	669.5	57.0	3260.0
			S+	PRE	13	13	100	75.3	100	24.8	12.0	51.2	9.0	329.0
				PII(M3)	13	13	100	75.3	100	684.1	346.5	1350.7	152.0	9081.0
				PIII(M7)	13	13	100	75.3	100	5600.4	2855.8	10982.7	619.0	25115.0
				PIII(M12)	13	13	100	75.3	100	1668.3	839.1	3316.9	240.0	9524.0
				PIII(M18)	13	13	100	75.3	100	1099.2	551.3	2191.7	218.0	5313.0
				PIII(M24)	12	12	100	73.5	100	961.5	473.7	1951.7	155.0	4545.0
				PIII(M36)	12	12	100	73.5	100	761.1	344.1	1683.3	116.0	4368.0
			Total	PRE	53	13	24.5	13.8	38.3	5.7	4.3	7.5	<7.0	329.0
				PII(M3)	53	53	100	93.3	100	247.3	175.7	348.3	13.0	9081.0
				PIII(M7)	53	53	100	93.3	100	4799.7	3710.2	6209.1	619.0	34350.0
				PIII(M12)	52	52	100	93.2	100	1307.0	991.5	1722.9	176.0	10669.0
				PIII(M18)	51	51	100	93.0	100	774.6	573.8	1045.6	103.0	6285.0
				PIII(M24)	52	52	100	93.2	100	622.0	467.8	827.0	84.0	4545.0
				PIII(M36)	52	52	100	93.2	100	542.8	405.6	726.4	57.0	4368.0
	V20_06	9_14y	S-	PRE	52	0	0.0	0.0	6.8	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	52	52	100	93.2	100	215.8	159.9	291.3	41.0	5333.0
				PIII(M7)	52	52	100	93.2	100	5819.2	4763.7	7108.6	1094.0	36047.0
				PIII(M12)	52	52	100	93.2	100	1666.5	1297.3	2140.8	178.0	12222.0
				PIII(M18)	52	52	100	93.2	100	947.4	728.2	1232.6	95.0	8328.0
				PIII(M24)	51	51	100	93.0	100	731.7	561.2	954.0	92.0	5622.0
				PIII(M36)	52	52	100	93.2	100	689.3	530.4	895.9	103.0	5844.0
			S+	PRE	3	3	100	29.2	100	8.0	5.8	10.9	7.0	9.0
				PII(M3)	3	3	100	29.2	100	207.3	76.6	561.3	140.0	312.0
				PIII(M7)	3	3	100	29.2	100	8010.4	2256.9	28431.7	4474.0	11551.0
				PIII(M12)	3	3	100	29.2	100	2115.0	502.1	8908.4	1102.0	3329.0
				PIII(M18)	3	3	100	29.2	100	1075.2	277.2	4169.8	636.0	1890.0
				PIII(M24)	3	3	100	29.2	100	909.5	327.0	2529.1	678.0	1456.0
				PIII(M36)	3	3	100	29.2	100	686.4	188.7	2497.3	457.0	1233.0
			Total	PRE	55	3	5.5	1.1	15.1	3.7	3.5	3.9	<7.0	9.0
				PII(M3)	55	55	100	93.5	100	215.3	162.1	286.0	41.0	5333.0
				PIII(M7)	55	55	100	93.5	100	5921.6	4888.4	7173.2	1094.0	36047.0
				PIII(M12)	55	55	100	93.5	100	1688.4	1329.8	2143.5	178.0	12222.0
				PIII(M18)	55	55	100	93.5	100	954.0	742.9	1225.0	95.0	8328.0
				PIII(M24)	54	54	100	93.4	100	740.6	576.0	952.3	92.0	5622.0
	1			PIII(M36)	55	55	100	93.5	100	689.2	537.4	883.9	103.0	5844.0

						2	7 FI	U/M	1		GMC			,
								959	6 CI		95	% CI		
Antibody	Group	Sub-	Pre-vacc	Timina	N	n	%	11	UI	value		UI	Min	Max
, and be up	C.COP	aroup	status			r -	~							
		15 19v	S-	PRE	53	0	0.0	0.0	6.7	3.5	3.5	3.5	<7.0	<7.0
		,	-	PII(M3)	53	53	100	93.3	100	201.2	147.8	274.0	26.0	4646.0
				PIII(M7)	53	53	100	93.3	100	5443.8	4477 4	66187	1406.0	34562.0
				PIII(M12)	53	53	100	93.3	100	1560.2	1241.6	1960.5	231.0	10163.0
				PIII(M18)	53	53	100	93.3	100	1015.8	807.5	1277.9	117.0	5847.0
				PIII(M24)	52	52	100	93.2	100	783.3	621.1	987.8	120.0	4669.0
				PIII(M36)	53	53	100	93.3	100	701.1	552.8	889.1	86.0	3297.0
			S+	PRF	5	5	100	47.8	100	26.8	8.1	88.7	11.0	76.0
			<u>.</u>	DII/M3)	5	5	100	47.8	100	455.8	54.5	3811.3	73.0	4199.0
				DIII/M7)	5	5	100	47.8	100	2807.8	1226.0	6430.8	1459.0	8252.0
				DIII/M12)	5	5	100	47.8	100	585.3	303.0	1130.4	267.0	1000.0
				PIII(M12)	<u>л</u>	4	100	30.8	100	373.0	167.1	832.5	206.0	689.0
				DIII(M10)	4 C	4 C	100	47.9	100	246.7	199.7	632.0	171.0	596.0
				P111(M24) D111(M26)	5	5	100	47.0	100	340.7	140.9	033.5 097 A	122.0	747.0
			Total	PIII(M36)	0	D E	0.0	41.0	100	4.2	140.0	4.0	-7.0	76.0
			TOLAT	PILE DIVM2	00	0	0.0	2.3	19.0	9.2	3.0	4.3 204 0	\$7.0	10.0
				PII(M3)	00	00	100	33.0	100	210.9	100.1	234.3	20.0	4040.0
				PIII(M7)	00	00	100	33.0	100	5141.0	4249.9	0220.0	1406.0	34562.0
				PIII(M12)	58	58	100	93.8	100	1433.7	1146.4	1/93.0	231.0	10163.0
				PIII(M16)	5/	5/	100	93.7	100	346.9	700.0	1100.7	117.0	0.1400
				PIII(M24)	5/	5/	100	93.7	100	729.2	583.7	911.0	120.0	4669.0
		00.05	~	PIII(M36)	58	58	100	93.8	100	653.7	519.8	822.0	86.0	3297.0
		20_25y	5-	PKE	34	0	0.0	0.0	10.3	3.5	3.5	3.5	<7.0	<7.0
				PII(M3)	34	34	100	89.7	100	123.4	87.5	1/3.8	20.0	664.0
				PIII(M7)	34	34	100	89.7	100	4335.0	3117.3	6028.5	626.0	24791.0
				PIII(M12)	34	34	100	89.7	100	11/4./	115.8	1//8.8	99.0	6105.0
				PIII(M18)	34	34	100	89.7	100	719.7	471.6	1098.1	45.0	4618.0
				PIII(M24)	34	34	100	89.7	100	565.2	374.5	853.1	43.0	3424.0
				PIII(M36)	34	34	100	89.7	100	472.9	309.6	722.2	30.0	2911.0
			S+	PRE	15	15	100	78.2	100	20.9	11.8	36.9	7.0	87.0
				PII(M3)	15	15	100	78.2	100	342.8	180.7	650.3	98.0	3482.0
				PIII(M7)	15	15	100	78.2	100	5156.2	3491.5	7614.6	2156.0	18651.0
				PIII(M12)	15	15	100	78.2	100	1767.7	1175.4	2658.4	499.0	7031.0
				PIII(M18)	15	15	100	78.2	100	1001.5	656.2	1528.4	258.0	3527.0
				PIII(M24)	15	15	100	78.2	100	768.4	519.8	1136.0	209.0	2956.0
				PIII(M36)	15	15	100	78.2	100	610.9	405.6	920.0	152.0	2292.0
			Total	PRE	49	15	30.6	18.3	45.4	6.0	4.5	8.1	<7.0	87.0
				PII(M3)	49	49	100	92.7	100	168.7	121.9	233.5	20.0	3482.0
				PIII(M7)	49	49	100	92.7	100	4571.5	3555.8	5877.3	626.0	24791.0
				PIII(M12)	49	49	100	92.7	100	1331.3	976.2	1815.6	99.0	7031.0
				PIII(M18)	49	49	100	92.7	100	796.3	581.2	1091.0	45.0	4618.0
				PIII(M24)	49	49	100	92.7	100	621.0	458.0	841.8	43.0	3424.0
				PIII(M36)	49	49	100	92.7	100	511.4	374.0	699.3	30.0	2911.0

						>	7 FI	U/M			GMC	riopon	1 (110	0,111101
						-		959	6.01		95	% CI		
Antibody	Group	Sub-	Pre-vacc	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
		group	status											
	HPV	9_14y	S-	PRE	51	0	0.0	0.0	7.0	3.5	3.5	3.5	<7.0	<7.0
				PIII(M7)	51	51	100	93.0	100	7911.3	6188.8	10113.3	1680.0	37491.0
				PIII(M12)	51	51	100	93.0	100	2642.1	1936.3	3605.1	339.0	19004.0
				PIII(M18)	51	51	100	93.0	100	1670.4	1251.3	2230.0	247.0	8773.0
				PIII(M24)	50	50	100	92.9	100	1359.1	1012.7	1824.0	187.0	8369.0
				PIII(M36)	51	51	100	93.0	100	1197.6	903.1	1588.3	139.0	8194.0
			S+	PRE	6	6	100	54.1	100	15.9	7.6	33.6	8.0	43.0
				PIII(M7)	6	6	100	54.1	100	6112.6	3530.0	10584.4	2806.0	11503.0
				PIII(M12)	6	6	100	54.1	100	2149.9	1183.2	3906.5	687.0	3126.0
				PIII(M18)	6	6	100	54.1	100	1519.1	787.4	2930.4	466.0	2997.0
				PIII(M24)	6	6	100	54.1	100	1206.3	635.7	2289.1	420.0	2477.0
				PIII(M36)	6	6	100	54.1	100	1207.2	641.8	2270.5	475.0	2582.0
			Total	PRE	57	6	10.5	4.0	21.5	4.1	3.6	4.7	<7.0	43.0
				PIII(M7)	57	57	100	93.7	100	7699.4	6155.5	9630.5	1680.0	37491.0
				PIII(M12)	57	57	100	93.7	100	2585.4	1951.7	3424.9	339.0	19004.0
				PIII(M18)	57	57	100	93.7	100	1653.8	1272.1	2150.0	247.0	8773.0
				PIII(M24)	56	56	100	93.6	100	1341.9	1028.0	1751.6	187.0	8369.0
			_	PIII(M36)	57	57	100	93.7	100	1198.6	927.8	1548.6	139.0	8194.0
		15_19y	S-	PRE	42	0	0.0	0.0	8.4	3.5	3.5	3.5	<7.0	<7.0
				PIII(M7)	42	42	100	91.6	100	4703.8	3480.0	6357.9	1144.0	69885.0
				PIII(M12)	41	41	100	91.4	100	1388.1	9/9.2	1967.6	167.0	25/3/.0
				PIII(M18)	41	41	100	91.4	100	953.8	658.4	1381./	65.0	19963.0
				PIII(M24)	41	41	100	91.4	100	/88.9	547.9	1136.0	39.0	10419.0
			_	PIII(M36)	42	42	100	91.6	100	/12.4	492.2	1031.1	25.0	9702.0
			S+	PRE	5	5	100	47.8	100	12.2	8.3	17.8	8.0	17.0
				PIII(M/)	5	5	100	47.8	100	5/30.5	686.5	4/838.1	926.0	81284.0
				PIII(M12)	5	5	100	47.8	100	2255.5	204.2	24914.1	363.0	4/033.0
				PIII(M18)	5	5	100	47.8	100	13/0.2	112.8	16642.1	197.0	29/45.0
				PIII(M24)	5	5	100	47.8	100	1129.2	102.8	12402.1	1/6.0	24394.0
			Tetel	PIII(M36)	5	5	100	41.8	100	11/5.6	104.3	13253.7	206.0	24/03.0
			lotal	PKE	4/	5	10.6	3.5	23.1	4.0	3.6	4.5	<7.0	17.0
				PIII(M7)	4/	4/	100	92.5	100	4803.6	3534.9	0027.0	926.0	01204.0
				PIII(M12)	40	40	100	92.3	100	1463.3	1024.3	2090.3	167.0	47033.0
				PIII(MIO)	40	40	100	92.3	100	992.1 930.2	5001.0	1444.1	20.0	20140.0
				PIII(M24) DIII/M26)	40	40	100	92.3	100	020.3 764 A	500.1 517.6	1090.6	39.0	24394.0
		20. 25.	c	PIII(M30)	4/ 20	4/	0.0	92.5	00	25	25	2.5	25.0	24703.0
		20_259	o-	PILE DIII/M7\	20	20	100	0.0	3.0	3.5	3.5	3.3 E400.0	\$7.0	<7.0
				FIII(MI7)	20	20	100	91.0	100	4555 0	2310.1	2110.0	289.0	26769.0
				P111(M12) D111/M18)	38	38	100	91.0	100	1007.3	762.7	1/38.3	151.0	15458.0
				PIII(M10)	20	20	100	90.7	100	709.0	592.2	1000.0	96.0	12205.0
				PIII(M24)	30	30	100	91.0	100	712.3	518.4	978 7	70.0	9202.0
			S+	PRE	10	10	100	69.2	100	16.2	84	31.1	7.0	130.0
			· ·	DIII(M7)	10	10	100	69.2	100	3352.4	1702.5	6601.0	1067.0	34621.0
				PIII(M12)	10	10	100	69.2	100	1277 7	670.1	2436.3	564.0	10702.0
				PIII(M18)	10	10	100	69.2	100	1015.4	573.4	1798.2	420.0	6262.0
				PIII(M24)	10	10	100	69.2	100	725.7	375.8	1401.7	289.0	4519.0
				PIII(M36)	10	10	100	69.2	100	655.1	339.5	1264.0	289.0	3701.0
					1.0		100		100		200.0	1000 1100	200.0	ALC: NOT A

						2	27 El	_U/MI	L		GMC			
								95%	6 CI		95	% CI		
Antibody	Group	Sub-	Pre-vacc	Timing	Ν	n	%	LL	UL	value	LL	UL	Min	Max
		group	status											
			Total	PRE	49	10	20.4	10.2	34.3	4.8	3.9	5.9	<7.0	130.0
				PIII(M7)	49	49	100	92.7	100	3806.0	2966.3	4883.4	885.0	48127.0
				PIII(M12)	49	49	100	92.7	100	1494.5	1141.9	1955.9	289.0	26768.0
				PIII(M18)	48	48	100	92.6	100	1040.6	795.5	1361.2	151.0	15458.0
				PIII(M24)	49	49	100	92.7	100	784.2	595.3	1033.0	96.0	13295.0
				PIII(M36)	49	49	100	92.7	100	700.2	531.6	922.4	70.0	9202.0

V40_06 = HPV-16/18(40,40) AS04 0,6m

V20_06 = HPV-16/18(20,20) AS04 0,6 m

HPV = HPV-16/18(20,20) AS04 0,1,6m

S- = seronegative subjects (antibody concentration < 7 ELU/ML) prior to vaccination

S+ = seropositive subjects (antibody concentration ≥ 7 ELU/ML) prior to vaccination

GMT = geometric mean titers concentration 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

MIN/MAX = Minimum/Maximum

PRE = pre-vaccination

PII(M3) = Post Dose II, Month 3

PIII(M7) = Post Dose III, Month 7

PIII(M12) = Post Dose III, Month 12

PIII(M18) = Post Dose III, Month 18

PIII(M24) = Post Dose III,Month 24 PIII(M36) = Post Dose III, Month 36





V40_02 = HPV-16/18(40,40) AS04 0,2 m; V40_06 = HPV-16/18(40,40) AS04 0,6 m; V20_06 = HPV-16/18(20,20) AS04 0,6 m; HPV = HPV-16/18(20,20) AS04 0,1,6 m; Nat-inf = Subjects who had cleared HPV-16 infection had GMTs of 29.8 EL.I//mL (95% CI: [28.5; 31.1]) in Study HPV-008; Plateau = The GMTs at the plateau level in Study HPV-007 (Month 45-50 time point) were 397.8 EL.U/mL (95% CI: [344.7; 459.1]) for HPV-16 antibodies.

Figure 2 Persistence of HPV-18 antibody titers (ELISA) in subjects seronegative at baseline (Month 36 ATP cohort for immunogenicity)



V40_02 = HPV-16/18(40,40) AS04 0,2 m; V40_06 = HPV-16/18(40,40) AS04 0,6 m; V20_06 = HPV-16/18(20,20) AS04 0,6 m; HPV = HPV-16/18(20,20) AS04 0,1,6 m; Nat-inf = Subjects who had cleared HPV-18 infection had GMTs of 22.7 EL. U/mL (95% CI: [21.7; 23.7]) in Study HPV-008; Plateau = The GMTs at the plateau level in Study HPV-007 (Month 45-50 time point) were 297.3 EL. U/mL (95% CI: [258.2; 342.2]) for HPV-18 antibodies.

Assessor's comment

In study HPV-048, during the follow-up period from Month 24 to Month 36, 63 subjects reported at least one medically significant condition (MSC), 6 subjects reported at least one new onset chronic disease (NOCD), 5 subjects reported at least one new onset autoimmune disease (NOAD) and 14 subjects at least one serious adverse event (SAE). A sustained immune response against both HPV-16 and HPV-18 antigens was observed in all vaccine groups up to 36 months after the first vaccination.

Study HPV-058

Study HPV058 was a phase III, randomized, double-blind, single centre study in healthy preadolescent and adolescent Chinese females aged 9-17 years. This study was conducted in one single study centre in China. A total of 750 subjects were randomized (1: 1) and allocated to two treatment groups: 374 subjects received Cervarix (HPV group) and 376 subjects received a control (AI[OHh, control group), all according to a Month 0, 1, 6 schedule. The duration of the study was approximately 12 months for each subject. A total of 709 subjects were included in the extended safety follow-up (ESFU) phase of Study HPV-058: 359 and 350 subjects in the HPV and control groups, respectively. Enrolment was age stratified 9-11 year, 12-14 year, 15-17 year). The primary objective was to demonstrate the non-inferiority of the immune response one month post-dose 3 for all subjects included in the ATP cohort for immunogenicity versus Chinese women aged 18-25 years old, enrolled in study HPV039. The objective was considered to be reached if for each HPV antigen the upper limit of the 95% confidence interval for the geometric mean titre (GMT) ratio (GMTs in subjects aged 18-25 years with immunogenicity results at Month 7 who receive Cervarix in the HPV-039 study divided by the GMTs of subjects aged 9-17 years who receive Cervarix in the HPV-058 study) was below 2. Secondary objectives were seroconversion rates to HPV-16 and HPV-18 as assessed by ELISA at Month 7 as well as safety and reactogenicity in Cervarix recipients and the control group after each dose as well as throughout the study period.

Study results

Immunogenicity

Table 32 shows the non-inferiority assessment of the immune response (study HPV058 versus study HPV039) in the ATP cohort for immunogenicity.

Assessor's note: the primary objective of the study was to demonstrate the non-inferiority of HPV immune response at one month post-dose 3 in Chinese female subjects aged 9-17 years from the current study versus Chinese women aged 18-25 years enrolled in study HPV-039 that was conducted at 4 different areas in China. Non-inferiority (one month after the third vaccine dose) was considered to be reached if for each HPV antigen, the upper limit of the 95% confidence interval for the GMT ratio in subjects aged 18-25 years study HPV-039 divided by the GMTs of subjects aged 9-17 years in study HPV-058 was below 2.

Table 32 Non-inferiority assessment of HPV immune response in Chinese female subjects aged 9-17 years from the current study (HPV-058) versus Chinese women aged 18-25 years enrolled in the HPV-039 study (eTrack No. 107638), one month Post Dose III in initially seronegative subjects (ATP cohort for immunogenicity)

					(HPV	GMT ratio -039 / HPV	/-058)
	HP	V-039	HP	V-058		95%	6 CI
Antibody (EL.U/mL)	N	GMT	N	GMT	Value	LL	UL
Anti-HPV-16	244	6996.2	326	18682.4	0.37	0.32	0.43
Anti-HPV-18	289	3309.4	338	7882.4	0.42	0.36	0.49

GMT = geometric mean antibody titre

N = Number of subjects with post-vaccination results available

95% CI = 95% confidence interval for the GMC ratio (ANOVA model - pooled variance); LL = lower limit, UL = upper limit

The primary objective of the study was met: No confirmatory analysis was performed on the secondary objectives.

Safety

Assessor's note: the solicited and unsolicited symptoms are described in the Clinical Study Report for study HPV-058 up to Month 12 and not represented here.

The percentage of subjects for whom at least one unsolicited symptom was reported during the 30 day post-vaccination follow-up period was 37.2% (95% CI: 32.3%; 42.3%) of subjects in the HPV group and 33.2% (95% CI: 28.5%; 38.3%) of subjects in the control group. No fatal SAEs were reported throughout the study period (Month 0 to Month 12). The percentage of subjects for whom at least one SAE was reported during the entire study period (Month 0 to Month 12) was 1.3% (95% CI: 0.4%; 3.1%) of subjects in the HPV group and 0.5% (95% CI: 0.1%; 1.9%) of subjects in the control group. None of these SAEs were considered by the investigator to be related to vaccination.

4. MAH'S OVERALL CONCLUSION

The data submitted do not influence the benefit-risk balance for Cervarix. No further regulatory action is required.

5. RAPPORTEUR'S CONCLUSION

The MAH's conclusion is endorsed.

6. REQUEST FOR SUPPLEMENTARY INFORMATION

The MAH is requested to submit the full clinical study report of study HPV039 (only the synopsis of the Interim Report at Month 7 is available in the PSUR Full Report dated 11 January 2011 p. 987-995).