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

Study No.: 111712 (HPV-056 EXT 035)

Title: Safety study of GSK Biologicals' human papillomavirus vaccine (GSK-580299) in healthy female subjects. *Cervarix*[™] - GSK 580299 (HPV): GlaxoSmithKline (GSK) Biologicals' human papillomavirus (HPV) vaccine containing HPV types 16 and 18

Rationale: This study was conducted to enable women who were enrolled in the placebo group of the HPV-035 (106001) study and who were unable to receive all three doses of HPV vaccine before they were 25 years of age, to receive the HPV vaccine; the aim of the study was to collect safety in terms of serious adverse events (SAEs) data following vaccine administration.

Please refer to the 106001 CTRS for data on the HPV-035 study.

Phase: III

Study Period: 15 May 2009 to 09 September 2010.

Study Design: Open, single-group, single centre study.

Centre: 1 centre in Hong Kong.

Indication: Active immunisation in healthy females from 10 years of age onwards for the prevention of cervical cancer (squamous-cell carcinoma and adenocarcinoma) by protecting against incident and persistent infections, cytological abnormalities including atypical squamous cells of undetermined significance (ASC-US) and cervical intraepithelial neoplasia (CIN), CIN1 and pre-cancerous lesions (CIN2 and CIN3), caused by oncogenic HPV types 16 and 18.

Treatment: The study group was as follows:

HPV Group: subjects received 3 doses of HPV vaccine

HPV vaccine was administered intramuscularly in the deltoid of the non-dominant arm according to a 0, 1, 6-month schedule.

Objective:

To assess the safety of HPV vaccine throughout the study period.

Primary Outcome/Efficacy Variable:

• Occurrence of any SAEs and SAEs with a causal relationship to vaccination as assessed by the investigator, reported up to Month 12.

Secondary Outcome/Efficacy Variable(s):

Outcome variables were not differentiated into primary and secondary in the study protocol, hence all were considered as primary outcome variables.

Statistical Methods:

The analysis was performed on the Total Vaccinated Cohort.

- The Total Vaccinated Cohort included all vaccinated subjects with at least one vaccine administration documented.

Analysis of safety:

The analysis was performed on the Total Vaccinated Cohort.

The occurrence of SAEs up to Month 12 after the first vaccination was tabulated by Medical Dictionary for Regulatory Activities (MedDRA).Preferred Terms. SAEs were evaluated for their relationship to vaccination as assessed by the investigator.

Study Population: Healthy female subjects who received a placebo in study 106001 (HPV-035), who had not been vaccinated with HPV vaccine previously and were unable to receive all 3 doses of commercially available HPV vaccine before their 25th birthday, were enrolled in the study. Women were to be of non-childbearing potential or if of childbearing potential, had to practice adequate contraception for 30 days prior to vaccination, to have a negative pregnancy test, and were to continue such precautions for 2 months after completion of the vaccination series. Written informed consent was obtained from the subject prior to study entry.

Number of subjects	HPV Group
Planned, N	114
Randomised, N (Total Vaccinated Cohort)	92
Completed, n (%)	92 (100)
Total Number Subjects Withdrawn, n (%)	0 (0.0)
Withdrawn due to Adverse Events, n (%)	0 (0.0)

Withdrawn due to Lack of Efficacy, n (%)	Not applicable	
Withdrawn for other reasons, n (%)	0 (0.0)	
Demographics	HPV Group	
N (Total Vaccinated Cohort)	92	
Females:Males	92:0	
Mean Age, years (SD)	30.8 (4.14)	
Chinese, n (%)	92 (100)	
Primary Efficacy Results: Please refer to the safety section of the document.		
Secondary Outcome Variable(s): Not applicable.		
Safety results: No information about unsolicited adverse events was collected during this study		
Safety results: Number (%) of subjects with serious adverse events throughout the study period (Total Vaccinated Cohort)		
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	HPV Group	
	N = 92	
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	3 (3.3) [0]	
Abortion missed	1 (1.1) [0]	
Benign hydatidiform mole	1 (1.1) [0]	
Hepatic enzyme increased	1 (1.1) [0]	
Fatal SAEs	HPV Group	
	N = 92	
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	

Conclusion: Throughout the study period (up to Month 12), 3 SAEs were reported by 3 (3.3%) subjects in the HPV Group. All these SAEs were assessed by the investigator as not causally related to the study vaccination. No fatal SAEs were reported during the study.

Publications: None.

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