

GlaxoSmithKline Biologicals

VRBPAC Meeting
13 September 2017

Errata to the Sponsor Briefing Document

BLA number: 125614 (HZ/su)

The following text regarding the adjuvant was omitted from the document at the first mention of QS-21: The use of the saponin molecule (QS-21) purified from plant extract *Quillaja saponaria* Molina, as a component in GSK's AS01 adjuvant, has been contractually authorized to GSK by Antigenics LLC, a wholly owned subsidiary of Agenus Inc., a Delaware, USA corporation.

The tables on Page 10 of the Executive Summary (Table 1) and on Page 68 of the Briefing Document (Table 5), "*ZOSTER-006: Vaccine Efficacy Against First or Only Episode of HZ During the Entire Study Period in ≥ 50 YOA, Overall and by Age Strata*", should be corrected for the incidence rate of subjects reporting at least one event [n/T (per 1000)] for subjects ≥ 70 YOA.

The value of 9.0 is replaced with the correct value of 9.4.

The updated tables are provided below.

In the Executive Summary, the following information is provided to complete the footnotes of Table 1 (Page 10), Table 2 (Page 10) and Table 3 (Page 12), as the "***" and "*" used in these tables are not explained.

*: VE adjusted by region

**: VE adjusted by age strata and region

The lower limit of the 95% confidence interval (43.4%) for the statement on subjects ≥ 70 YOA in the second paragraph of Page 77 is corrected to 43.3%: "*When considering all adults ≥ 70 YOA ($N = 16,596$), VE was 91.6% (95% CI: 43.3, 99.8), with one case in the HZ/su group vs. 12 cases in the Placebo group*".

Executive Summary (Table 1, Page 10):

Table 1 ZOSTER-006 (Final Analysis): Vaccine efficacy against first or only episode of HZ during the entire study period in adults ≥ 50 YOA, overall and by age strata (mTVC)

Age strata	HZ/su				Placebo				Vaccine Efficacy		
	N	n	T(year)	n/T (per 1000)	N	n	T(year)	n/T (per 1000)	%	95% CI	
										LL	UL
≥ 50 YOA **	7344	6	23297.0	0.3	7415	210	23170.5	9.1	97.2	93.7	99.0
50-59 YOA *	3492	3	11161.3	0.3	3525	87	11134.7	7.8	96.6	89.6	99.4
60-69 YOA *	2141	2	7007.9	0.3	2166	75	6952.7	10.8	97.4	90.1	99.7
≥ 70 YOA**	1711	1	5127.9	0.2	1724	48	5083.0	9.4	97.9	87.9	100

N = number of subjects included in each group
 n = number of subjects having at least one confirmed HZ episode
 *: VE adjusted by region
 **: VE adjusted by age strata and region

Briefing Document (Table 5, Page 68):

Table 5 ZOSTER-006: Vaccine Efficacy Against First or Only Episode of HZ During the Entire Study Period in ≥ 50 YOA, Overall and by Age Strata (mTVC, Final Analysis)

Age strata	HZ/su				Placebo				Vaccine Efficacy		
	N	n	T(year)	n/T (per 1000)	N	n	T(year)	n/T (per 1000)	%	95% CI	
										LL	UL
≥ 50 YOA **	7344	6	23297.0	0.3	7415	210	23170.5	9.1	97.2	93.7	99.0
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≥ 70 YOA**	1711	1	5127.9	0.2	1724	48	5083.0	9.4	97.9	87.9	100

N = number of subjects included in each group; n = number of subjects having at least one HZ confirmed case
 T (year) = sum of follow-up period (censored at the first occurrence of a HZ confirmed case) expressed in years
 n/T (per 1000)= Incidence rate of subjects reporting at least one event
 VE (%) = Vaccine Efficacy (Poisson method); LL, UL = 95% Lower and Upper confidence limits
 *: VE adjusted by region
 **: VE adjusted by age strata and region