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.

GSK Medicine: GSK 1437173A

Study Number: 114825 (ZOSTER-024 EXT 003)

Title: Long term immunogenicity and safety of GSK Biologicals' Herpes Zoster vaccine 1437173A in healthy subjects
HZ vaccine (GSK 1437173A): GlaxoSmithKline (GSK) Biologicals' lyophilised formulation of the Herpes Zoster (HZ) vaccine.

Rationale:
The purpose of this study was to evaluate the immune responses to and safety of HZ vaccine in subjects who had previously participated in study ZOSTER-003 (108494) and who were in the group receiving 2 doses of candidate HZ vaccine formulation, at Months 48, 60 and 72 post-vaccination in healthy subjects aged 60 years of age and older.

Phase: II

Study Period: From 28-February-2011 to 20-June-2013.

Study Design: Open-label, multi-centric, single group, unblinded study.

Centres: 11 Centres: 1 in the Czech Republic, 6 in Germany, 2 in the Netherlands and 2 in Sweden

Indication: Evaluation of persistence of immune responses following immunisation of healthy elderly subjects (60-69 and ≥70 years) against HZ.

Treatment: The study group was:
HZ vaccine group: Subjects who received 2 doses of HZ vaccine in the intermediate dose study group in study 108494 (Zoster-003). No treatment was given in this study.
For details about the treatment groups and vaccine administration, please refer to study 108494.

Objectives:
To evaluate cell-mediated and humoral immune responses of the study vaccine in healthy elderly adults overall and within each age cohort (60-69 years of age [YOA] and ≥ 70 YOA) at Months 48, 60 and 72.

Primary Outcome/Efficacy Variable

- Cell-Mediated Immunity (CMI) in terms of frequencies of antigen-specific CD4 T cells at Months 48, 60 and 72
  - Frequencies of CD4 T cells with antigen-specific Interferon gamma (IFN-γ) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (TNF-α) and/or CD40 Ligand (CD40L) secretion/expression to glycoprotein E (gE) and Varicella Zoster Virus (VZV) as determined by Intracellular Cytokine Staining (ICS) at Months 48, 60 and 72 for all subjects
- Antigen-specific Antibody (Ab) concentrations at Months 48, 60 and 72
  - Anti-gE and anti-VZV Ab concentrations as determined by Enzyme-Linked Immunosorbent Assay (ELISA) at Months 48, 60 and 72 for all subjects.

Secondary Outcome/Efficacy Variable(s):

- Serious Adverse events (SAEs)
  - Occurrence of all SAEs related to ZOSTER-024 study participation during the entire study period;
  - Occurrence of all SAEs related to previous vaccination with HZ vaccine during the whole study period or following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, and ZOSTER-013) and not already documented.
  - Occurrence of all Fatal SAEs during the entire study period.
- Occurrence of pre-defined Adverse events (AEs)
  - Occurrence of suspected cases of HZ episodes during the whole study period or following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, ZOSTER-013) and not already documented;
  - Occurrence and relationship to vaccination of any Potential Immune-Mediated Diseases (pIMDs) during the entire study period or following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, and ZOSTER-013) and not already documented.

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

- The Total cohort of persistence included all eligible subjects who accepted to be part of the ZOSTER-024 study analysis.
- The ATP cohort for immunogenicity included all evaluable subjects (i.e. those meeting all eligibility criteria,

complying with the procedures defined in the protocol and with no elimination criteria during the study).

Analysis of Immunogenicity:
The analysis of immunogenicity was performed on the ATP cohort for immunogenicity.
The descriptive statistics of the frequency of gE and VZV-specific CD4 T cells producing at least 2 immunological activation markers (IFN-γ, IL-2, TNF-α and/or CD40L following stimulation with gE or VZV by overall and age category at each time point was analysed. Seropositivity rates and geometric mean concentrations (GMCs) for anti-gE antibodies were computed by overall and age category with their 95% confidence intervals (CIs) by ELISA at each time point.

Analysis of Safety
The analysis of safety was performed on the Total cohort of persistence.
The percentage of subjects with clinically diagnosed HZ episodes during the whole study period or following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, ZOSTER-013) and not already documented were tabulated. The percentage of subjects with any pIMDs and those pIMDs that are related to vaccination during the entire study period or following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, and ZOSTER-013) and not already documented were also tabulated. The percentage of subjects with all SAEs related to ZOSTER-024 study participation during the entire study period was tabulated according to the Medical Dictionary of Regulatory Affairs (MedDRA) preferred term. Also, the percentage of subjects with all SAEs related to previous vaccination with HZ vaccine during the whole study period or following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, ZOSTER-013) and not already documented was tabulated according to the MedDRA preferred term. The percentage of subjects with all fatal SAEs during the entire study period was tabulated according to the MedDRA preferred term.

Study Population: Healthy, male and female subjects aged 60 years or older at the time of enrolment, who had been part of the intermediate dose group in study Zoster-003, where they had received the complete 2-dose vaccination course. Subjects who received any HZ vaccine after study 108494 were excluded from the current study. Written informed consent was obtained from each subject.

Number of Subjects:	**HZ vaccine Group**
Planned, N	146
Enrolled, N (Total cohort of persistence)	129
Completed, n (%)	119 (92.2)
Total Number Subjects Withdrawn, n (%)	10 (7.8)
Withdrawn due to Adverse Events, n (%)	2 (1.6)
Withdrawn due to Lack of Efficacy, n (%)	Not Applicable
Withdrawn for other reasons, n (%)	8 (6.2)
Demographics	**HZ vaccine Group**
N (Total cohort of persistence)	129
Sex, n (%)	
Females	78 (60.5)
Males	51 (39.5)
Mean Age, years (SD)	72.8 (4.96)
Median	73.0
Minimum, Maximum	60, 84
African Heritage / African American, n (%)	1(0.8)
White - Caucasian / European Heritage, n (%)	128 (99.2)

Primary Efficacy Results: Descriptive statistics of the frequency of gE-specific CD4(2+) T-cells at Months 0, 3, 12, 24, 36, 48, 60 and 72 (ATP cohort for immunogenicity)

Immune marker	**Group**	**Timing**	**N**	**Mean**	**SD**	**Median**
CD4[2+]	HZ vaccine	PRE	118	229.34	390.60	119.4
		PII(M3)	120	2471.24	2007.82	1818.8
		PII(M12)	116	1326.30	1285.74	971.1
		PII(M24)	119	1262.95	1496.89	786.7
		PII(M36)	117	1019.70	1105.86	640.0
		PII(M48)*	118	726.19	1051.77	446.0
		PII(M60)*	48	744.43	810.14	500.9

		PII(M72)*	75	630.76	548.14	477.3

N = number of subjects with available results
SD = Standard Deviation
PRE = Pre-vaccination (Month 0)
CD4[2+] T-cells = CD4+ T-cells producing at least 2 activation markers (IFN-γ, IL-2, TNF-α and/or CD40L)
PII(M3) = Post-vaccination Dose II (Month 3)
PII(M12) = Post-vaccination Dose II (Month 12)
PII(M24) = Post-vaccination Dose II (Month 24)
PII(M36) = Post-vaccination Dose II (Month 36)
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)
*Primary outcome variables.

Primary Efficacy Results: Descriptive statistics of the frequency of gE-specific CD4(2+) T-cells at Months 0, 3, 12, 24, 36, 48, 60 and 72 by age group (ATP cohort for immunogenicity)

Immune marker	Sub-group	Timing	N	Mean	SD	Median
CD4[2+]	60-69 YOA	PRE	22	144.15	121.15	113.1
		PII(M3)	26	2211.45	932.67	1928.8
		PII(M12)	22	1245.36	622.07	1157.9
		PII(M24)	26	1274.56	800.83	1094.3
		PII(M36)	25	971.09	632.68	687.5
		PII(M48)*	25	718.72	410.81	650.6
		PII(M60)*	12	760.01	620.67	649.1
		PII(M72)*	14	575.63	344.79	496.3
	≥70 YOA	PRE	96	248.86	427.31	119.4
		PII(M3)	94	2543.09	2213.70	1755.9
		PII(M12)	94	1345.24	1398.18	900.2
		PII(M24)	93	1259.70	1643.05	693.3
		PII(M36)	92	1032.91	1205.20	628.2
		PII(M48)*	93	728.20	1167.38	395.3
		PII(M60)*	36	739.24	871.88	499.3
		PII(M72)*	61	643.42	586.46	438.6

N = number of subjects with available results
SD = Standard Deviation
CD4[2+] T-cells = CD4+ T-cells producing at least 2 activation markers (IFN-γ, IL-2, TNF-α and/or CD40L)
PRE = Pre-vaccination (Month 0)
PII(M3) = Post-vaccination Dose II (Month 3)
PII(M12) = Post-vaccination Dose II (Month 12)
PII(M24) = Post-vaccination Dose II (Month 24)
PII(M36) = Post-vaccination Dose II (Month 36)
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)
*Primary outcome variables.

Primary Efficacy Results: Descriptive statistics of the frequency of VZV-specific CD4(2+) T-cells at Months 36, 48, 60 and 72 (ATP cohort for immunogenicity)

Immune marker	Group	Timing	N	Mean	SD	Median
CD4[2+]	HZ vaccine	PII(M36)	117	725.29	635.36	555.5
		PII(M48)*	118	567.52	531.31	428.2
		PII(M60)*	48	697.75	550.17	602.7
		PII(M72)*	76	473.06	449.71	322.7

N = number of subjects with available results
SD = Standard Deviation
CD4[2+] T-cells = CD4+ T-cells producing at least 2 activation markers (IFN-γ, IL-2, TNF-α and/or CD40L)
PII(M36) = Post-vaccination Dose II (Month 36)
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)

PII(M72) = Post-vaccination Dose II (Month 72)
*Primary outcome variable

Primary Efficacy Results: Descriptive statistics of the frequency of VZV-specific CD4(2+) T-cells at Months 36, 48, 60 and 72 by age group (ATP cohort for immunogenicity)

Immune marker	Sub-group	Timing	N	Mean	SD	Median
CD4[2+]	60-69 YOA	PII(M36)	25	834.61	507.43	706.7
		PII(M48)	25	650.05	497.42	463.3
		PII(M60)	12	551.69	404.42	515.6
		PII(M72)	15	532.71	488.91	455.1
	≥70 YOA	PII(M36)	92	695.58	665.20	507.8
		PII(M48)	93	545.33	540.46	420.6
		PII(M60)	36	746.43	587.63	613.1
		PII(M72)	61	458.40	442.63	305.7

N = number of subjects with available results
SD = Standard Deviation
CD4[2+] T-cells = CD4+ T-cells producing at least 2 activation markers (IFN-γ, IL-2, TNF-α and/or CD40L)
PII(M36) = Post-vaccination Dose II (Month 36)
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)

Primary Efficacy Results: Descriptive statistics of anti-VZV antibody ELISA concentrations (mIU/ml) at Months 48, 60 and 72 (ATP cohort for immunogenicity)

Immune marker	Group	Timing	N	Mean	SD	Median
anti-VZV antibody	HZ vaccine	PII(M48)	108	3435.55	2376.71	2738.7
		PII(M60)	95	3588.77	2799.27	2706.2
		PII(M72)	107	3646.68	2534.16	2809.2

N = number of subjects with available results
SD = Standard Deviation
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)

Primary Efficacy Results: Descriptive statistics of anti-VZV antibody ELISA concentrations (mIU/ml) at Months 48, 60 and 72 by age group (ATP cohort for immunogenicity)

Immune marker	Sub-group	Timing	N	Mean	SD	Median
anti-VZV antibody	60-69 YOA	PII(M48)	24	3403.61	2556.87	2601.5
		PII(M60)	21	3809.02	2892.38	2601.4
		PII(M72)	23	3798.12	2662.39	2921.4
	≥70 YOA	PII(M48)	84	3444.67	2338.83	2848.2
		PII(M60)	74	3526.26	2789.29	2735.8
		PII(M72)	84	3605.21	2512.89	2701.9

N = number of subjects with available results
SD = Standard Deviation
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)

Primary Efficacy Results: Seropositivity rates and GMCs of anti-gE antibody at Months 0, 3, 12, 24, 36, 48, 60 and 72 (ATP cohort for immunogenicity)

				≥ 18 mIU/mL				GMC (mIU/mL)		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	Value	LL	UL
anti-gE	HZ vaccine	PRE	126	126	100	97.1	100	1207.0	998.4	1459.1
		PII(M3)	126	126	100	97.1	100	43158.5	39230.9	47479.4
		PII(M12)	126	126	100	97.1	100	16180.9	14406.0	18174.6
		PII(M24)	126	126	100	97.1	100	11434.4	10163.7	12863.9
		PII(M36)	125	125	100	97.1	100	10508.6	9277.3	11903.4
		PII(M48)*	126	126	100	97.1	100	9093.2	8041.3	10282.6

		PII(M60)*	121	121	100	97.0	100	8831.3	7767.2	10041.3
		PII(M72)*	116	116	100	96.9	100	7711.3	6810.8	8730.9

Seropositivity rate = Anti-gE antibody concentration ≥ 18 mIU/mL
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination (Month 0)
PII(M3) = Post-vaccination Dose II (Month 3)
PII(M12) = Post-vaccination Dose II (Month 12)
PII(M24) = Post-vaccination Dose II (Month 24)
PII(M36) = Post-vaccination Dose II (Month 36)
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)
*Primary outcome variables.

Primary Efficacy Results: Seropositivity rates and GMCs of anti-gE antibody at Months 0, 3, 12, 24, 36, 48, 60 and 72 by age group (ATP cohort for immunogenicity)

				≥ 18 mIU/mL				GMC (mIU/mL)		
						95% CI			95% CI	
Antibody	**Sub-group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**Value**	**LL**	**UL**
anti-gE	60-69 YOA	PRE	26	26	100	86.8	100	1249.6	828.5	1884.7
		PII(M3)	26	26	100	86.8	100	42176.2	34911.2	50953.1
		PII(M12)	26	26	100	86.8	100	16355.8	13153.1	20338.4
		PII(M24)	26	26	100	86.8	100	11355.9	8800.4	14653.6
		PII(M36)	26	26	100	86.8	100	10084.2	7651.4	13290.5
		PII(M48)	26	26	100	86.8	100	8023.3	6213.1	10360.9
		PII(M60)	26	26	100	86.8	100	8546.8	6496.0	11245.1
		PII(M72)	25	25	100	86.3	100	7586.9	5712.4	10076.5
	≥70 YOA	PRE	100	100	100	96.4	100	1196.1	962.4	1486.5
		PII(M3)	100	100	100	96.4	100	43417.6	38846.9	48526.2
		PII(M12)	100	100	100	96.4	100	16135.8	14073.9	18499.8
		PII(M24)	100	100	100	96.4	100	11454.8	10008.1	13110.7
		PII(M36)	99	99	100	96.3	100	10623.0	9216.2	12244.5
		PII(M48)	100	100	100	96.4	100	9394.0	8155.8	10820.1
		PII(M60)	95	95	100	96.2	100	8910.9	7686.4	10330.3
		PII(M72)	91	91	100	96.0	100	7745.8	6729.2	8916.0

Seropositivity rate = Anti-gE antibody concentration ≥ 18 mIU/mL
GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration within the specified range
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination (Month 0)
PII(M3) = Post-vaccination Dose II (Month 3)
PII(M12) = Post-vaccination Dose II (Month 12)
PII(M24) = Post-vaccination Dose II (Month 24)
PII(M36) = Post-vaccination Dose II (Month 36)
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)

Primary Efficacy Results: Seropositivity rates and GMCs of anti-VZV antibodies at Months 48, 60 and 72 (ATP cohort for immunogenicity)

				≥ 25 mIU/ml				GMC (mIU/ml)		
					95% CI				95% CI	
Antibody	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-VZV	HZ vaccine	PII(M48)	108	108	100	96.6	100	2869.9	2565.5	3210.5
		PII(M60)	95	95	100	96.2	100	2890.0	2536.0	3293.4

		PII(M72)	107	107	100	96.6	100	2933.4	2577.7	3338.1

GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)

Primary Efficacy Results: Seropositivity rates and GMCs of anti-VZV antibodies at Months 48, 60 and 72 by age group (ATP cohort for immunogenicity)

				≥ 25 mIU/ml				**GMC (mIU/ml)**		
						95% CI			**95% CI**	
Antibody	**Sub-grp**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
anti-VZV	60-69 YOA	PII(M48)	24	24	100	85.8	100	2837.5	2225.7	3617.5
		PII(M60)	21	21	100	83.9	100	3103.6	2335.1	4124.9
		PII(M72)	23	23	100	85.2	100	3111.7	2369.8	4086.0
	≥70 YOA	PII(M48)	84	84	100	95.7	100	2879.3	2530.6	3276.0
		PII(M60)	74	74	100	95.1	100	2832.1	2436.8	3291.5
		PII(M72)	84	84	100	95.7	100	2886.4	2485.7	3351.7

GMC = geometric mean antibody concentration calculated on all subjects
N = number of subjects with available results
n/% = number/percentage of subjects with concentration equal to or above specified value
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
PII(M48) = Post-vaccination Dose II (Month 48)
PII(M60) = Post-vaccination Dose II (Month 60)
PII(M72) = Post-vaccination Dose II (Month 72)

Secondary Outcome Results: Number (%) of subjects with suspected cases of HZ episodes during the whole study period (Total cohort of persistence)

HZ episodes	**HZ vaccine Group N=129**
Subjects with any HZ episodes, n (%)	1 (0.8)
Localized HZ rash in the left femur	1 (0.8)

Secondary Outcome Results: Number (%) of subjects with suspected cases of HZ episodes following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, ZOSTER-013) and not already documented (Total cohort of persistence)

HZ episodes	**HZ vaccine Group N=129**
Subjects with any HZ episodes, n (%)	0 (0.0)

Secondary Outcome Results: Number (%) of subjects and relationship to vaccination of any pIMDs during the entire study period (Months 36 to 72) (Total cohort of persistence)

All pIMDs	**HZ vaccine Group N=129**
Subjects with any pIMDs, n (%)	2 (1.6)
Subjects with related pIMDs, n (%)	0 (0.0)
Polymyalgia rheumatica	1 (0.8)
Crohn's disease	1 (0.8)

Secondary Outcome Results: Number (%) of subjects and relationship to vaccination of any pIMDs following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, ZOSTER-013) and not already documented (Total cohort of persistence)

All pIMDs	**HZ vaccine Group N=129**
Subjects with any pIMDs, n (%)	0 (0.0)

Safety Results: Number (%) of subjects of all SAEs related to ZOSTER-024 study participation during the entire study period (Months 36 to 72) (Total cohort of persistence)

Serious Adverse Events, n (%) [n considered by the investigator to be related to study medication]

All SAEs	**HZ vaccine Group N=129**
Subjects with any SAEs, n (%) [n assessed by the investigator as related]	2 (1.6) [0]
Anaemia	1 (0.8) [0]
Crohn's disease	1 (0.8) [0]
Fatal SAEs	**HZ vaccine Group N = 129**
Subjects with fatal SAEs, n (%) [n assessed by the investigator as related]	2 (1.6) [0]
Circulatory collapse	1 (0.8) [0]
Death	1 (0.8) [0]
Safety Results: Number (%) of subjects of all SAEs related to previous vaccination with HZ vaccine during the whole study period or following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, ZOSTER-013) and not already documented (Total cohort of persistence)	
Serious Adverse Events, n (%) [n considered by the investigator to be related to study medication]	
All SAEs	**HZ vaccine Group N=129**
Subjects with any SAEs, n (%)[n assessed by the investigator as related]	0 (0.0) [0]
Fatal SAEs	**HZ vaccine Group N=129**
Subjects with any SAEs, n (%)[n assessed by the investigator as related]	0 (0.0) [0]
Safety Results: Number (%) of subjects of all fatal SAEs during the entire study period (Total cohort of persistence)	
Serious Adverse Events, n (%) [n considered by the investigator to be related to study medication]	
All SAEs	**HZ vaccine Group N=129**
Subjects with fatal SAEs, n (%) [n assessed by the investigator as related]	2 (1.6) [0]
Circulatory collapse	1 (0.8) [0]
Death	1 (0.8) [0]

Conclusion:

The mean frequencies of VZV gE-specific CD4 T cells at Months 48, 60 and 72 were 726.19, 744.43 and 630.76 CD4 (2+) T cells/10^6 $CD4^+$ T cells, respectively.

The mean anti-VZV antibody ELISA concentrations were 3435.55, 3588.77 and 3646.68 mIU/mL respectively, at the same timepoints.

At Months 48, 60 and 72, the Anti-gE antibody concentrations as determined by ELISA were 9093.2, 8831.3 and 7711.3 mIU/mL, respectively.

At Months 48, 60 and 72, the Geometric Mean Concentrations of Anti-VZV antibodies as determined by ELISA were 2869.9, 2890.0 and 2933.4 mIU/mL, respectively.

During the entire ZOSTER-024 study period, (Months 36 to 72), non-fatal SAEs were reported for 2 (1.6%) subjects, none assessed by the investigator as being related to the study vaccination. During the same period, fatal SAEs were reported for 2 (1.6%) subjects, none assessed by the investigator as being related to the study vaccination.

During the whole study period or following participation in ZOSTER-003 or any of the follow-up studies (ZOSTER-011, ZOSTER-012, ZOSTER-013) and not already documented, no SAEs were reported.

Date Updated: 28-September-2015