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GSK Medicine: gE/AS01B (HZV): GSK Biologicals' recombinant Herpes Zoster (HZ) vaccine.
Study Number: 108494 (Zoster-003), 108516 (Zoster-011 EXT 003 Y1), 108518 (Zoster-012 EXT 003 Y2), 108520 (Zoster-013 EXT 003 Y3))
Title: A phase II, single-blind, randomized, controlled, multicentre vaccination study to evaluate the safety and immune response of the GSK Biologicals Zoster vaccine, gE/AS01B, and to compare 3 doses of gE with AS01B adjuvant in healthy elderly subjects, aged 60 to 69 years and 70 years and above.
Rationale: The purpose of this study was to evaluate the immunogenicity and safety of HZV vaccine when using different doses of glycoprotein E (gE) in different vaccination schedules and adjuvanted with AS01B. The non-adjuvanted HZV vaccine was used as control. The aim was also to evaluate the persistence of the immune response induced by the vaccine during a long term period.
Phase: II
Study Period: 108494 [Zoster-003] :14 February 2007 to 04 October 2007 108516 [Zoster-011 (EXT-003 Y1)]: 07 February 2008 to 10 July 2008 108518 [Zoster-012 (EXT-003 Y2)]: 26 January 2009 to 13 July 2009 108520 [Zoster-013 (EXT-003 Y3)]: 03 February 2010 to 14 July 2010:
Study Design: Single blind, randomised (1:3:3:3:3), controlled, multicentric study with 5 parallel groups. Note: staggered enrolment (in German centres only)
Centres: 11 centres (6 centres in Germany, 2 centres in The Netherlands, 2 centres in Sweden and 1 centre in Czech Republic)
Indication: Immunization of healthy elderly subjects aged 60-69 and 70 years and above against HZ.
Treatment: The study groups were as follows: <ul style="list-style-type: none"> • HZV-1 Group: subjects received 2 doses of HZV formulation 1 vaccine • HZV-2 Group: subjects received 2 doses of HZV formulation 2 vaccine • HZV-3 Group: subjects received 2 doses of HZV formulation 3 vaccine • Control/ HZV-3 Group: subjects received 1st vaccination of saline and 2nd vaccination of HZV formulation 3 vaccine • Control Group: subjects received 2 doses of unadjuvanted HZV vaccine reconstituted with saline The vaccines were administered by intramuscular injection in the upper deltoid site of the left arm according to a 0, 2- month schedule.
Objectives: To compare the cluster of differentiation 4 (CD4) T cell response to gE of HZV study vaccines at Month 3 in healthy elderly subjects of 70 years of age and older.
Primary Outcome/Efficacy Variable: <ul style="list-style-type: none"> • Frequencies of CD4 T cells with at least 2 antigen-specific activation marker (Interferon gamma [IFN-γ], Interleukin-2 [IL-2], Tumour Necrosis Factor alpha [TNF-α], CD-40 Ligand [CD40L]) to gE as determined by intracellular cytokine staining (ICS) one month after the second vaccination (Month 3) in HZV vaccine groups of subjects 70 year of age and above.
Secondary Outcome/Efficacy Variable(s): <i>Immunogenicity:</i> <ul style="list-style-type: none"> • Frequencies of CD4/CD8 T cells with antigen-specific IFN-γ and/or IL-2 and/or TNF-α and/or CD40L secretion/expression to gE as determined by ICS in all groups at Months 0, 2 and 3. • Anti-gE and anti- Varicella Zoster Virus (VZV) antibody (Ab) concentrations by Enzyme-linked immunosorbent assay (ELISA) in all groups at Months 0, 2 and 3. • Frequencies of CD4/CD8 T cells* with antigen-specific IFN-γ and/or IL-2 and/or TNF-α and/or CD40L secretion/expression to gE as determined by ICS in all groups at Months 12, 24 and 36. • Anti-gE and anti-VZV Ab concentrations by ELISA in all groups at Months 12, 24 and 36. • Frequencies of gE specific memory B-cells (measured by B-cell ELISPOT) in a subset of subjects at Months 0 and 3. <i>Safety:</i> <ul style="list-style-type: none"> • Occurrence, intensity and relationship to vaccination of solicited local and general adverse events (AEs) during 7 days (Days 0-6) after each vaccination. • Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0-29) after each vaccination. • Occurrence and relationship to vaccination of all serious adverse events (SAEs) during the whole study period.

<ul style="list-style-type: none"> • Occurrence of clinically diagnosed HZ episodes during the whole study period. • Haematological and biochemical parameters measured at Months 0, 2, and 3. • Biochemical parameters (calcium, fibrinogen, Lactate Dehydrogenase [LDH], total protein and electrophoresis (globulins and albumin/globulin ratio)** measured 1 week after each vaccination, and Prothrombin Time [PT] and Partial Thromboplastin Time [PTT] measured 1 week after the second vaccination, in a subset of 104 (German) subjects. <p>*CMI analyses on CD8 T cells were not performed as no detectable CD8 T cell response was measured to any of the vaccine formulation in the Zoster-003 study.</p> <p>**Values for electrophoresis (globulins and albumin/globulin ratio) were not displayed.</p>					
<p>Statistical Methods:</p> <p>The analyses were performed on the Total Vaccinated cohort, Total cohort for persistence at Months 12, 24 and 36 and According-To-Protocol (ATP) cohort for Immunogenicity.</p> <ul style="list-style-type: none"> • The Total Vaccinated cohort included all subjects with a least one vaccine administration documented. • The Total cohort for persistence at Months 12, 24 and 36 included all vaccinated subjects in the vaccination phase (Zoster-003) who were contacted at Months 12, 24 and 36 respectively. The ATP cohort for Immunogenicity included all evaluable subjects (i.e., those meeting all eligibility criteria, complying with the procedures defined in the protocol, with no elimination criteria during the study) for whom data concerning immunogenicity outcome measures were available. <p>Analysis of immunogenicity</p> <p>Analysis of immunogenicity was performed on the ATP cohort for Immunogenicity and Total cohort for persistence Months 12, 24 & 36.</p> <p><i>Descriptive analysis:</i></p> <p>For cell-mediated immunity (CMI) response, descriptive statistics of the frequency of CD4/CD8 T cells secreting at least 2 activation markers in response to the gE antigen were evaluated, overall and by age cohort (60-69 YOA and ≥ 70 YOA), for each group at Months 0, 2 and 3. Also, the descriptive statistics on the frequency of CD4 T cells identified as secreting specific sets of 2 activation markers (IFN-γ, IL-2, TNF-α, and CD40L in combination with at least 1 other cytokine, respectively) in response to the gE antigen were evaluated, overall for each group at Months 12, 24 and 36.</p> <p>For B-cell memory response, descriptive statistics of the frequency of gE specific B-cell were tabulated by vaccine groups at Months 0 and 3 in a subset of subjects ≥ 70 YOA.</p> <p>For the humoral response, seropositivity rates and Geometric Mean Concentrations (GMCs) of anti-gE and anti-VZV antibodies were calculated for each group with 95% CIs at Months 0, 2 and 3, 12, 24 and 36.</p> <p><i>Inferential analysis:</i></p> <p>Comparison of the CMI and humoral immune response at Month 3 between all vaccine formulations was performed using a one-way ANOVA with study vaccine as fixed effect. Multiple comparisons to control were made, according to Hsu's procedure to select the best treatment.</p> <p>Analysis of safety</p> <p>Analysis of safety was performed on Total Vaccinated cohort and Total cohort for persistence Months 12, 24 & 36.</p> <p>The percentage of subjects reporting each individual solicited local and general symptom during the 7-day (Days 0 - 6) solicited follow-up period after each vaccination was tabulated by each treatment group, after each dose and across doses, with exact 95% CI. The same tabulations were performed for symptoms with intensity of grade 3, as well as for solicited general symptoms assessed by the investigator as related to vaccination. All solicited local AEs were assessed as causally related to the vaccination. The percentage of subjects with at least one report of an unsolicited AEs classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred term and reported during a 30-day (Days 0 - 29) follow-up period after vaccination was tabulated. The same tabulation was performed for Grade 3 unsolicited AEs and for unsolicited AEs assessed by the investigator as related to vaccination. The percentage of subjects with haematology and biochemistry laboratory values below, within or above normal ranges was tabulated by treatment group at Month 0, Month 0 and 1 week, Month 2, Month 2 and 1 week and Month 3 respectively. The percentage of German subjects with haematology and biochemistry laboratory values below, within or above normal ranges was tabulated by treatment group at Month 0 and 1 week and Month 2 respectively. The percentage of subjects with clinically diagnosed HZ episodes and with SAEs classified according to the MedDRA preferred terms, for each treatment group, were tabulated from Months 0 to 3, Months 3 to 12, Months 12 to 24 and Months 24 to 36 respectively.</p> <p>Study Population: Male or female subjects aged 60 years or older at the time of first vaccination. Subjects were excluded if they had previous vaccination against HZ or history of HZ. Written informed consent was obtained from the subjects before study entry.</p>					
Number of Subjects (Months 0-3):	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3 Group	Control Group

Planned, N	165	165	165	165	55
Randomised, N (Total Vaccinated cohort)	164	166	165	165	54
Completed at Month 3, n (%)	161 (98.2)	164 (98.8)	161 (97.6)	164 (99.4)	51 (94.4)
Total Number Subjects Withdrawn, n (%)	3 (1.8)	2 (1.2)	4 (2.4)	1 (0.6)	3 (5.6)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	1 (0.6)	2 (1.2)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Withdrawn for other reasons, n (%)	3 (1.8)	1 (0.6)	2 (1.2)	1(0.6)	3 (5.6)
Demographics	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3 Group	Control Group
N (Total Vaccinated cohort)	164	166	165	165	54
Females: Males	88:76	100:66	85:80	95:70	36:18
Mean Age, years (SD)	72.8 (5.51)	72.9 (5.13)	73.0 (5.69)	73.1 (5.94)	72.1 (5.25)
White-Caucasian/European heritage, n	162 (98.8)	163 (98.2)	164 (99.4)	165 (100)	54 (100)
Number of Subjects (Month 12) :	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3 Group	Control Group
Planned, N	164	166	165	165	54
Enrolled, N (Total cohort for persistence Month 12)	156	159	159	161	50
Completed, n (%)	156 (100)	159 (100)	159 (100)	161 (100)	50 (100)
Total Number Subjects Withdrawn, n (%)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Demographics	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3 Group	Control Group
N (Total cohort for persistence Month 12)	156	159	159	161	50
Females: Males	85:71	97:62	82:77	91:70	34:16
Mean Age, years (SD)	72.8 (5.59)	72.8 (5.12)	73 (5.70)	73 (5.91)	71.9 (5.36)
White-Caucasian/European heritage, n	Not available	Not available	Not available	Not available	Not available
Number of Subjects (Month 24) :	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3 Group	Control Group
Planned, N	Not applicable				
Enrolled, N (Total cohort for persistence Month 24)	150	155	154	157	49
Completed, n (%)	150 (100)	155 (100)	154 (100)	157 (100)	49 (100)
Total Number Subjects Withdrawn, n (%)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Demographics	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3 Group	Control Group
N (Total cohort for persistence Month 24)	150	155	154	157	49
Females: Males	80:70	95:60	78:76	88:69	34:15
Mean Age, years (SD)	72.6 (5.49)	72.8 (5.10)	72.8 (5.63)	72.9 (5.91)	71.9 (5.42)
White-Caucasian/European heritage, n	Not available	Not available	Not available	Not available	Not available
Number of Subjects (Month 36) :	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3 Group	Control Group
Planned, N	Not applicable				
Enrolled, N (Total cohort for persistence Month 36)	147	147	150	155	47
Completed, n (%)	147 (100)	147 (100)	150 (100)	155 (100)	47 (100)
Total Number Subjects Withdrawn, n (%)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Demographics	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3 Group	Control Group
N (Total cohort for persistence Month 36)	147	147	150	155	47
Females: Males	79:68	90:57	75:75	87:68	34:13
Mean Age, years (SD)	72.6 (5.48)	72.7 (5.04)	72.7 (5.68)	72.8 (5.89)	71.7 (5.36)
White-Caucasian/European heritage, n	Not available	Not available	Not available	Not available	Not available
Primary Efficacy Results: Frequency of gE-specific CD4 T-cells secreting at least 2 different activation markers per million cells (ALL DOUBLES activation markers) one month following the last vaccination (Month 3) (ATP cohort for Immunogenicity)					
Age group	Treatment Group	N	Median	p-value^s	
70y+	HZV-1	119	1801.23	0.2997	

	HZV-2	120		1722.83		0.7449
	HZV-3	117		1778.48		-
	Control/HZV-3	118		491.03		< 0.0001
	Control	36		388.49		< 0.0001
N = Number of subjects with data						
70y+ = ≥ 70 year of age						
§ p-value according to Hsu's procedure for best treatment selection by multiple comparisons between vaccination groups Inferiority to the Best Treatment p-value = the smallest alpha level at which the population mean of this group can be rejected as the best treatment						
Primary Efficacy Results: Frequency odds ratio of gE-specific CD4 T-cells secreting at least 2 different activation markers (ALL DOUBLES activation markers) one month following the last vaccination (Month 3) (ATP cohort for Immunogenicity)						
Age group	Treatment Group	N	GM	Ratio over Best LCL	Ratio over Best UCL	p-value [§]
70y+	HZV-1	119	9.07	0.641	1.041	0.1095
	HZV-2	120	9.94	0.703	1.140	0.3947
	HZV-3	117	11.10	0.877	1.422	-
	Control/HZV-3	118	3.98	0.281	1.000	< 0.0001
	Control	36	3.14	0.199	1.000	< 0.0001
N = Number of subjects with data						
70y+ = ≥ 70 year of age						
GM = geometric mean of ratios between induction frequency odds and background frequency odds						
LCL = Lower confidence limit; UCL = Upper confidence limit						
§ p-value according to Hsu's procedure for best treatment selection by multiple comparisons between vaccination groups Inferiority to the Best Treatment p-value = the smallest alpha level at which the population mean of this group can be rejected as the best treatment						
Primary Efficacy Results: Descriptive statistics of frequency of gE-specific CD4 T cells secreting at least 2 different activation markers (ALL DOUBLES activation markers) per million cells, by age group (ATP Cohort for Immunogenicity)						
Age cohort	Timing	Treatment Group	N	Mean	SD	Median
60-69y	PRE	HZV-1	31	173.55	175.60	165.59
		HZV-2	23	159.68	127.97	134.28
		HZV-3	25	206.84	234.37	159.92
		Control/HZV-3	29	243.91	212.08	216.42
		Control	11	128.50	82.34	124.86
	PI(M2)	HZV-1	30	450.12	311.60	353.71
		HZV-2	28	490.02	338.89	404.75
		HZV-3	25	541.36	454.92	466.02
		Control/HZV-3	29	161.54	152.95	108.84
		Control	11	222.19	281.64	116.29
	PII(M3)	HZV-1	32	2158.75	2155.36	1748.30
		HZV-2	28	2072.59	679.03	1909.78
		HZV-3	27	3086.65	2872.14	2549.45
		Control/HZV-3	30	627.81	282.47	639.08
		Control	11	673.01	388.22	601.09
70y+	PRE	HZV-1	121	199.84	224.27	150.26
		HZV-2	123	237.77	399.22	118.34
		HZV-3	117	199.96	231.23	151.98
		Control/HZV-3	120	193.99	224.07	127.69
		Control	37	151.14	182.63	96.48
	PI(M2)	HZV-1	122	461.20	421.46	372.72
		HZV-2	122	481.19	444.46	382.57
		HZV-3	117	478.36	417.74	355.22
		Control/HZV-3	121	176.88	188.58	123.16
		Control	37	232.69	244.94	160.89
	PII(M3)*	HZV-1*	119	2269.84	1934.55	1801.23
		HZV-2*	120	2441.95	2055.11	1722.83

		HZV-3*	117	2449.90	1808.00	1778.48
		Control/HZV-3*	118	681.73	665.17	491.03
		Control	36	512.55	463.35	388.49
60-69y = 60-69 year of age 70y+ = ≥ 70 year of age N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post Dose I at Month 2 PII(M3) = Post Dose II at Month 3 *Primary outcome variable						
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting IFNγ and at least one other activation marker per million cells (ATP cohort for Immunogenicity)						
Timing	Treatment Group	N	Mean	SD	Median	
PRE	HZV-1	149	156.54	199.12	93.61	
	HZV-2	144	169.01	326.34	87.45	
	HZV-3	139	152.28	220.50	84.66	
	Control/HZV-3	148	157.13	180.00	88.43	
	Control	48	118.35	125.08	91.82	
PI(M2)	HZV-1	151	279.39	343.61	195.91	
	HZV-2	150	279.20	336.29	193.89	
	HZV-3	142	292.15	345.65	185.72	
	Control/HZV-3	147	124.05	151.42	71.70	
	Control	46	168.34	213.83	93.41	
PII(M3)	HZV-1	151	1179.29	1021.14	964.14	
	HZV-2	148	1296.04	1132.18	1046.34	
	HZV-3	144	1417.40	1303.60	1017.12	
	Control/HZV-3	148	363.23	364.74	269.34	
	Control	46	341.36	313.79	240.50	
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post Dose I at Month 2 PII(M3) = Post Dose II at Month 3						
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting IL-2 and at least one other activation marker per million cells (ATP cohort for Immunogenicity).						
Timing	Treatment Group	N	Mean	SD	Median	
PRE	HZV-1	152	171.21	208.49	120.88	
	HZV-2	146	191.28	307.40	110.00	
	HZV-3	142	180.85	193.48	130.67	
	Control/HZV-3	149	172.41	184.32	130.19	
	Control	48	125.22	134.81	91.05	
PI(M2)	HZV-1	152	416.12	369.85	324.73	
	HZV-2	150	442.17	363.10	368.13	
	HZV-3	142	438.27	378.81	349.10	
	Control/HZV-3	150	150.47	160.29	90.29	
	Control	48	199.34	224.39	131.05	
PII(M3)	HZV-1	151	2077.06	1860.40	1602.17	
	HZV-2	148	2156.40	1697.78	1629.56	
	HZV-3	144	2315.84	1847.24	1629.85	
	Control/HZV-3	148	597.76	531.07	481.40	
	Control	47	491.06	396.39	399.92	

N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post Dose I at Month 2 PII(M3) = Post Dose II at Month 3					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting TNF- α and at least one other activation marker per million cells (ATP cohort for Immunogenicity).					
Timing	Treatment Group	N	Mean	SD	Median
PRE	HZV-1	152	97.28	137.06	58.52
	HZV-2	144	121.05	296.79	62.96
	HZV-3	141	116.91	173.65	79.96
	Control/HZV-3	149	110.66	162.02	59.49
	Control	48	81.40	107.44	48.78
PI(M2)	HZV-1	152	251.94	277.71	175.01
	HZV-2	150	256.15	304.91	198.89
	HZV-3	142	263.39	284.96	183.70
	Control/HZV-3	150	95.84	125.15	56.78
	Control	47	120.73	148.24	73.41
PII(M3)	HZV-1	151	1317.39	1304.53	946.56
	HZV-2	148	1282.96	1183.69	924.28
	HZV-3	144	1389.62	1231.76	1005.06
	Control/HZV-3	148	350.23	380.60	267.07
	Control	47	252.86	253.55	160.71
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post Dose I at Month 2 PII(M3) = Post Dose II at Month 3					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting CD40L and at least one other activation marker per million cells (ATP cohort for Immunogenicity).					
Timing	Treatment Group	N	Mean	SD	Median
PRE	HZV-1	152	142.88	169.52	103.68
	HZV-2	144	153.80	214.95	95.97
	HZV-3	142	151.37	160.38	124.69
	Control/HZV-3	149	155.90	187.47	102.22
	Control	48	111.55	126.92	92.73
PI(M2)	HZV-1	152	385.34	348.25	291.37
	HZV-2	150	405.95	359.46	305.98
	HZV-3	142	417.20	361.59	335.24
	Control/HZV-3	149	132.62	144.06	94.35
	Control	48	182.82	195.36	133.97
PII(M3)	HZV-1	151	2014.37	1849.25	1580.91
	HZV-2	148	2154.81	1799.64	1565.08
	HZV-3	144	2303.13	1987.94	1639.14
	Control/HZV-3	148	567.33	566.48	451.90
	Control	47	433.56	391.64	350.08
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post Dose I at Month 2 PII(M3) = Post Dose II at Month 3					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD8 T-cells secreting at least 2 different activation markers (ALL DOUBLES activation markers) per million cells (ATP cohort for Immunogenicity)					
Timing	Treatment Group	N	Mean	SD	Median
PRE	HZV-1	112	74.62	118.02	1.00
	HZV-2	117	98.88	164.52	66.59

PI(M2)	HZV-3	118	122.37	221.20	66.34
	Control/HZV-3	109	80.54	121.84	21.79
	Control	32	108.21	330.11	1.00
	HZV-1	102	85.29	139.32	1.00
	HZV-2	120	106.23	141.63	66.67
PII(M3)	HZV-3	118	86.35	168.10	28.64
	Control/HZV-3	108	120.06	221.20	43.08
	Control	39	98.97	299.34	1.00
	HZV-1	126	96.43	155.37	43.22
	HZV-2	118	88.77	140.95	66.67
PII(M3)	HZV-3	112	117.70	196.09	66.67
	Control/HZV-3	119	112.99	165.52	66.67
	Control	38	116.41	450.85	1.00

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post Dose I at Month 2

PII(M3) = Post Dose II at Month 3

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD8 T-cells secreting IFN γ and at least one other activation marker per million cells (ATP cohort for Immunogenicity).

Timing	Treatment Group	N	Mean	SD	Median
PRE	HZV-1	94	60.35	97.12	1.00
	HZV-2	90	75.79	114.55	7.87
	HZV-3	95	106.39	199.96	65.61
	Control/HZV-3	92	70.69	121.23	49.94
	Control	26	123.99	360.75	17.66
PI(M2)	HZV-1	87	65.97	111.02	1.00
	HZV-2	87	106.74	133.15	66.67
	HZV-3	98	72.58	92.99	66.66
	Control/HZV-3	90	106.02	184.40	66.67
	Control	30	95.05	326.45	1.00
PII(M3)	HZV-1	98	88.62	136.13	66.67
	HZV-2	91	76.92	123.74	66.61
	HZV-3	97	95.01	138.77	66.67
	Control/HZV-3	95	96.91	161.10	66.67
	Control	32	125.69	480.05	1.00

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post Dose I at Month 2

PII(M3) = Post Dose II at Month 3

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD8 T-cells secreting IL-2 and at least one other activation marker per million cells (ATP cohort for Immunogenicity).

Timing	Treatment Group	N	Mean	SD	Median
PRE	HZV-1	74	81.42	108.62	33.81
	HZV-2	79	83.13	131.07	66.10
	HZV-3	84	90.71	140.18	66.67
	Control/HZV-3	78	63.56	89.18	32.76
	Control	27	43.03	58.88	13.66
PI(M2)	HZV-1	72	61.05	106.36	1.00
	HZV-2	86	78.18	92.65	66.67
	HZV-3	78	83.07	186.88	50.77
	Control/HZV-3	81	82.47	126.08	66.53
	Control	25	68.98	85.29	66.67
PII(M3)	HZV-1	97	69.06	97.12	66.47

	HZV-2	91	65.08	83.71	66.63
	HZV-3	88	103.17	179.57	66.64
	Control/HZV-3	90	82.95	99.47	66.67
	Control	26	56.42	120.85	1.00
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post Dose I at Month 2 PII(M3) = Post Dose II at Month 3					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD8 T-cells secreting TNF- α and at least one other activation marker per million cells (ATP cohort for Immunogenicity).					
Timing	Treatment Group	N	Mean	SD	Median
PRE	HZV-1	97	74.94	113.07	57.13
	HZV-2	98	87.33	117.28	66.67
	HZV-3	108	111.54	204.36	66.67
	Control/HZV-3	94	81.54	119.17	66.67
	Control	26	122.68	362.64	1.00
PI(M2)	HZV-1	92	71.42	96.41	1.00
	HZV-2	102	83.01	124.50	66.67
	HZV-3	104	75.88	129.33	1.00
	Control/HZV-3	91	111.15	217.08	22.10
	Control	27	115.82	356.29	1.00
PII(M3)	HZV-1	100	86.81	120.39	66.67
	HZV-2	101	76.75	137.37	61.21
	HZV-3	98	99.07	139.42	66.67
	Control/HZV-3	97	106.97	167.59	66.67
	Control	33	136.22	470.58	10.86
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post Dose I at Month 2 PII(M3) = Post Dose II at Month 3					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD8 T-cells secreting CD40L and at least one other activation marker per million cells (ATP cohort for Immunogenicity).					
Timing	Treatment Group	N	Mean	SD	Median
PRE	HZV-1	65	41.35	54.48	1.00
	HZV-2	70	61.30	118.43	3.21
	HZV-3	77	56.85	78.31	1.00
	Control/HZV-3	67	35.96	69.51	1.00
	Control	23	59.94	75.13	1.00
PI(M2)	HZV-1	62	63.87	82.02	59.61
	HZV-2	70	66.76	90.29	60.97
	HZV-3	63	47.20	64.54	1.00
	Control/HZV-3	69	71.20	93.18	66.67
	Control	25	54.63	69.92	1.00
PII(M3)	HZV-1	78	69.50	105.36	66.57
	HZV-2	69	65.34	64.17	66.67
	HZV-3	74	85.57	105.34	66.67
	Control/HZV-3	76	76.19	72.44	66.67
	Control	23	33.12	47.32	1.00
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post Dose I at Month 2 PII(M3) = Post Dose II at Month 3					
Secondary Outcome Variable(s): Seropositivity rates and GMCs of anti-gE Antibodies (ATP cohort for Immunogenicity)					

				≥ 109 EU/mL				GMC (EU/mL)		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
Anti-gE	HZV-1	PRE	157	147	93.6	88.6	96.9	351.6	306.2	403.8
		PI(M2)	157	157	100	97.7	100	3667.6	3158.6	4258.7
		PII(M3)	155	155	100	97.6	100	9315.3	8283.2	10476.1
	HZV-2	PRE	156	141	90.4	84.6	94.5	312.8	268.1	365.0
		PI(M2)	156	154	98.7	95.4	99.8	4139.4	3443.8	4975.4
		PII(M3)	156	156	100	97.7	100	12898.0	11681.2	14241.6
	HZV-3	PRE	151	145	96.0	91.6	98.5	416.1	355.0	487.7
		PI(M2)	151	151	100	97.6	100	5485.6	4657.2	6461.3
		PII(M3)	151	151	100	97.6	100	15626.5	14030.3	17404.3
	Control/ HZV-3	PRE	153	144	94.1	89.1	97.3	337.2	285.8	397.7
		PI(M2)	153	144	94.1	89.1	97.3	361.5	304.6	429.0
		PII(M3)	153	153	100	97.6	100	6287.2	5372.0	7358.3
	Control	PRE	50	46	92.0	80.8	97.8	323.7	245.2	427.3
		PI(M2)	50	49	98.0	89.4	99.9	2148.9	1461.8	3158.9
		PII(M3)	49	49	100	92.7	100	4298.3	3220.0	5737.7

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 at Day 0

PI(M2) = Post Dose I at Month 2

PII(M3) = Post Dose II at Month 3

Secondary Outcome Variable(s): Seropositivity rates and GMCs of anti-VZV Antibodies (ATP cohort for Immunogenicity)

				≥ 50 mIU/mL				GMC (mIU/mL)		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
Anti- VZV IGG	HZV-1	PRE	157	156	99.4	96.5	100	1334.9	1181.9	1507.7
		PI(M2)	157	156	99.4	96.5	100	4408.1	3847.7	5050.1
		PII(M3)	155	155	100	97.6	100	8821.6	7959.3	9777.4
	HZV-2	PRE	156	156	100	97.7	100	1212.0	1063.9	1380.7
		PI(M2)	156	156	100	97.7	100	5131.9	4469.8	5892.0
		PII(M3)	156	156	100	97.7	100	11451.0	10507.9	12478.7
	HZV-3	PRE	151	151	100	97.6	100	1510.7	1336.4	1707.7
		PI(M2)	151	151	100	97.6	100	6511.7	5723.1	7409.0
		PII(M3)	151	151	100	97.6	100	14143.5	12876.9	15534.7
	Control/HZV-3	PRE	153	153	100	97.6	100	1356.3	1184.9	1552.6
		PI(M2)	153	153	100	97.6	100	1341.6	1177.7	1528.3
		PII(M3)	153	153	100	97.6	100	6432.2	5591.8	7398.9
	Control	PRE	50	50	100	92.9	100	1422.5	1153.4	1754.5
		PI(M2)	50	50	100	92.9	100	3481.2	2756.0	4397.3
		PII(M3)	49	49	100	92.7	100	5357.6	4297.3	6679.4

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 at Day 0

PI(M2) = Post Dose I at Month 2

PII(M3) = Post Dose II at Month 3

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least 2 different activation markers per million cells (Total cohort for persistence Month 12)

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	151	200.5	220.7	152.1

HZV-2	PI(M2)	151	472.6	407.0	377.6
	PII(M3)	152	2263.2	1975.1	1761.1
	PII(M12)	150	1135.8	936.0	947.5
	PRE	149	218.4	359.3	120.5
HZV-3	PI(M2)	152	478.6	422.9	378.2
	PII(M3)	151	2348.8	1876.3	1730.1
	PII(M12)	148	1275.5	1195.4	911.8
	PRE	150	198.9	227.4	155.6
Control/HZV-3	PI(M2)	150	486.8	412.9	390.5
	PII(M3)	152	2603.6	2057.0	1882.2
	PII(M12)	151	1274.0	995.0	973.8
	PRE	156	203.3	218.9	142.8
Control	PI(M2)	157	172.2	179.1	127.2
	PII(M3)	156	648.6	596.1	503.4
	PII(M12)	146	340.4	296.8	276.2
	PRE	48	150.7	163.2	114.1
Control	PI(M2)	48	238.2	249.6	161.6
	PII(M3)	47	565.9	448.4	500.7
	PII(M12)	45	274.5	217.3	260.5
	PRE	48	150.7	163.2	114.1

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least IFN γ and another activation marker per million cells (Total cohort for persistence Month 12)

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	151	161.2	203.6	93.6
	PI(M2)	151	290.5	352.8	201.1
	PII(M3)	152	1199.9	1034.8	948.9
	PII(M12)	150	659.9	594.3	512.6
HZV-2	PRE	149	159.5	311.5	79.8
	PI(M2)	152	276.7	333.9	193.9
	PII(M3)	151	1260.9	1116.0	1013.9
	PII(M12)	148	767.8	895.1	550.1
HZV-3	PRE	150	148.8	214.4	85.1
	PI(M2)	150	294.6	338.7	188.1
	PII(M3)	152	1438.9	1291.3	1045.2
	PII(M12)	151	718.9	634.2	553.7
Control/HZV-3	PRE	156	156.3	178.1	90.3
	PI(M2)	157	119.8	147.9	71.0
	PII(M3)	156	351.3	355.4	260.9
	PII(M12)	146	235.5	244.7	178.8
Control	PRE	48	120.4	124.2	91.8
	PI(M2)	48	168.8	210.0	95.2
	PII(M3)	47	355.3	319.3	244.2
	PII(M12)	45	176.8	152.7	157.7

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least IL-2 and another activation marker per million cells (Total cohort for persistence Month 12)

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	151	177.8	214.6	124.6
	PI(M2)	151	430.7	375.7	336.0
	PII(M3)	152	2092.1	1858.1	1602.5
	PII(M12)	150	1056.2	901.0	853.5
HZV-2	PRE	149	186.0	297.9	109.6
	PI(M2)	152	436.6	362.7	368.1
	PII(M3)	151	2134.0	1702.7	1610.8
	PII(M12)	148	1164.7	1029.1	840.4
HZV-3	PRE	150	178.3	191.3	130.4
	PI(M2)	150	437.5	370.1	362.8
	PII(M3)	152	2347.1	1855.1	1667.4
	PII(M12)	151	1168.3	935.4	915.2
Control/HZV-3	PRE	156	172.9	184.3	130.4
	PI(M2)	157	149.8	159.2	95.0
	PII(M3)	156	579.9	522.1	473.4
	PII(M12)	146	291.7	266.6	224.6
Control	PRE	48	126.2	134.2	91.1
	PI(M2)	48	203.8	224.0	142.4
	PII(M3)	47	505.5	398.1	467.4
	PII(M12)	45	243.9	204.8	223.5

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least TNF α and another activation marker per million cells (Total cohort for persistence Month 12)

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	151	100.3	139.5	58.6
	PI(M2)	151	257.9	278.6	188.4
	PII(M3)	152	1319.6	1299.3	951.0
	PII(M12)	150	673.7	616.0	488.5
HZV-2	PRE	149	116.9	292.4	57.5
	PI(M2)	152	252.0	302.4	194.6
	PII(M3)	151	1264.1	1169.4	911.1
	PII(M12)	148	736.2	878.5	483.6
HZV-3	PRE	150	111.9	169.4	72.0
	PI(M2)	150	255.8	278.7	172.7
	PII(M3)	152	1396.3	1220.1	1040.7
	PII(M12)	151	736.7	660.7	535.0
Control/HZV-3	PRE	156	110.2	159.7	58.9
	PI(M2)	157	93.9	123.5	55.7
	PII(M3)	156	338.0	373.8	253.3
	PII(M12)	146	193.2	239.4	145.4
Control	PRE	48	85.9	107.6	50.0
	PI(M2)	48	121.5	146.4	83.6
	PII(M3)	47	261.2	253.0	180.6
	PII(M12)	45	136.0	132.8	87.3

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least CD40L and another activation marker per million cells (Total cohort for persistence Month 12)					
Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	151	144.1	171.4	103.5
	PI(M2)	151	395.9	353.2	296.2
	PII(M3)	152	2025.0	1844.4	1575.3
	PII(M12)	150	969.0	811.8	769.5
HZV-2	PRE	149	147.5	210.2	95.4
	PI(M2)	152	402.1	357.7	302.7
	PII(M3)	151	2136.1	1802.4	1556.9
	PII(M12)	148	1057.2	943.4	757.3
HZV-3	PRE	150	147.3	159.2	116.7
	PI(M2)	150	412.0	354.4	330.6
	PII(M3)	152	2330.4	1983.9	1718.5
	PII(M12)	151	1062.8	850.3	836.6
Control/HZV-3	PRE	156	155.7	187.2	101.8
	PI(M2)	157	130.8	143.5	92.7
	PII(M3)	156	548.4	555.8	419.8
	PII(M12)	146	267.5	246.0	216.1
Control	PRE	48	114.0	126.2	96.4
	PI(M2)	48	190.0	194.1	138.5
	PII(M3)	47	436.3	392.7	350.1
	PII(M12)	45	221.0	180.9	190.2
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post-vaccination Dose I at Month 2 PII(M3) = Post-vaccination Dose II at Month 3 PII(M12) = Post-vaccination Dose II at Month 12					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least 2 different activation markers per million cells (Total cohort for persistence Month 24)					
Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	145	204.9	223.2	158.2
	PI(M2)	145	476.4	412.8	393.0
	PII(M3)	146	2305.8	2002.8	1802.4
	PII(M12)	144	1156.1	944.4	980.5
	PII(M24)	143	1004.1	838.8	760.5
HZV-2	PRE	146	219.9	362.4	119.4
	PI(M2)	148	475.2	421.7	377.6
	PII(M3)	147	2373.2	1895.5	1780.5
	PII(M12)	144	1286.5	1207.6	921.4
	PII(M24)	147	1195.5	1375.5	782.2
HZV-3	PRE	145	202.6	230.1	159.9
	PI(M2)	145	493.6	417.3	392.8
	PII(M3)	147	2643.6	2073.4	1884.8
	PII(M12)	146	1290.5	998.6	986.2
	PII(M24)	145	1079.9	948.0	776.8
Control/HZV-3	PRE	152	203.8	221.0	142.8
	PI(M2)	153	170.3	178.5	123.2
	PII(M3)	152	627.3	539.7	503.4
	PII(M12)	143	339.1	297.5	277.5
	PII(M24)	151	244.1	233.2	186.7
Control	PRE	47	151.1	164.9	111.4
	PI(M2)	47	243.3	249.8	162.2
	PII(M3)	46	569.9	452.5	523.2

	PII(M12)	44	274.7	219.8	255.0
	PII(M24)	45	285.2	255.6	241.4
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post-vaccination Dose I at Month 2 PII(M3) = Post-vaccination Dose II at Month 3 PII(M12) = Post-vaccination Dose II at Month 12 PII(M24) = Post-vaccination Dose II at Month 24					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least IFN γ and another activation marker per million cells (Total cohort for persistence Month 24)					
Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	145	164.8	206.7	94.5
	PI(M2)	145	293.4	357.8	202.8
	PII(M3)	146	1218.9	1047.5	969.4
	PII(M12)	144	671.2	599.8	534.2
	PII(M24)	143	541.9	503.1	373.3
HZV-2	PRE	146	161.3	314.3	79.4
	PI(M2)	148	271.8	330.2	193.9
	PII(M3)	147	1271.3	1128.2	1039.4
	PII(M12)	144	770.6	902.6	550.1
	PII(M24)	147	668.9	1140.6	450.9
HZV-3	PRE	145	151.6	217.4	85.6
	PI(M2)	145	300.0	343.0	191.7
	PII(M3)	147	1463.9	1301.7	1046.2
	PII(M12)	146	730.5	638.0	567.8
	PII(M24)	145	543.6	554.7	386.7
Control/HZV-3	PRE	152	157.8	180.0	90.3
	PI(M2)	153	119.1	148.6	68.0
	PII(M3)	152	342.1	332.0	257.7
	PII(M12)	143	235.4	245.4	181.2
	PII(M24)	151	157.0	183.4	118.5
Control	PRE	47	122.5	124.8	92.6
	PI(M2)	47	172.4	210.8	95.7
	PII(M3)	46	359.6	321.4	266.9
	PII(M12)	44	178.7	154.0	164.9
	PII(M24)	45	181.2	158.4	148.9
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post-vaccination Dose I at Month 2 PII(M3) = Post-vaccination Dose II at Month 3 PII(M12) = Post-vaccination Dose II at Month 12 PII(M24) = Post-vaccination Dose II at Month 24					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least IL-2 and another activation marker per million cells (Total cohort for persistence Month 24).					
Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	145	180.9	217.5	124.6
	PI(M2)	145	435.2	381.6	336.7
	PII(M3)	146	2133.0	1883.3	1622.3
	PII(M12)	144	1075.5	909.1	874.2
	PII(M24)	143	943.0	809.5	720.5
HZV-2	PRE	146	187.8	300.5	109.4
	PI(M2)	148	434.0	361.1	363.5
	PII(M3)	147	2159.7	1718.3	1641.8
	PII(M12)	144	1176.4	1038.8	845.0

	PII(M24)	147	1100.2	1158.9	720.8
HZV-3	PRE	145	182.9	192.9	133.1
	PI(M2)	145	443.4	373.7	363.1
	PII(M3)	147	2383.1	1870.0	1679.1
	PII(M12)	146	1183.5	939.3	937.4
	PII(M24)	145	1007.8	909.5	753.4
Control/HZV-3	PRE	152	172.6	186.3	130.4
	PI(M2)	153	147.8	158.1	91.6
	PII(M3)	152	559.6	461.8	473.4
	PII(M12)	143	290.6	267.4	226.3
	PII(M24)	151	213.0	207.4	160.0
Control	PRE	47	126.9	135.5	89.7
	PI(M2)	47	208.1	224.4	151.0
	PII(M3)	46	509.8	401.5	473.5
	PII(M12)	44	244.0	207.2	211.1
	PII(M24)	45	233.0	244.5	196.2

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

PII(M24) = Post-vaccination Dose II at Month 24

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least TNF α and another activation marker per million cells (Total cohort for persistence Month 24).

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	145	102.6	141.3	59.7
	PI(M2)	145	260.7	282.5	188.5
	PII(M3)	146	1346.2	1317.7	1007.7
	PII(M12)	144	686.1	621.5	492.1
	PII(M24)	143	567.9	527.7	400.0
HZV-2	PRE	146	117.4	295.1	56.4
	PI(M2)	148	251.2	303.7	194.6
	PII(M3)	147	1279.5	1181.0	937.4
	PII(M12)	144	745.1	888.8	490.9
	PII(M24)	147	663.1	1097.0	426.7
HZV-3	PRE	145	113.4	171.7	70.9
	PI(M2)	145	260.9	281.7	178.9
	PII(M3)	147	1416.6	1231.8	1051.3
	PII(M12)	146	746.1	664.1	538.6
	PII(M24)	145	591.5	586.6	380.5
Control/HZV-3	PRE	152	111.9	161.4	58.9
	PI(M2)	153	92.9	124.2	53.6
	PII(M3)	152	328.1	357.8	250.9
	PII(M12)	143	193.5	241.2	142.5
	PII(M24)	151	144.1	196.1	80.0
Control	PRE	47	85.8	108.8	48.9
	PI(M2)	47	124.1	146.9	84.5
	PII(M3)	46	263.4	255.4	187.5
	PII(M12)	44	134.4	133.9	84.4
	PII(M24)	45	133.0	158.1	88.1

N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post-vaccination Dose I at Month 2 PII(M3) = Post-vaccination Dose II at Month 3 PII(M12) = Post-vaccination Dose II at Month 12 PII(M24) = Post-vaccination Dose II at Month 24					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least CD40L and another activation marker per million cells (Total cohort for persistence Month 24)					
Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	145	147.7	173.1	103.9
	PI(M2)	145	399.4	358.1	296.2
	PII(M3)	146	2070.5	1865.4	1600.8
	PII(M12)	144	983.1	819.2	797.6
	PII(M24)	143	935.2	801.5	681.1
HZV-2	PRE	146	147.6	211.6	94.0
	PI(M2)	148	398.7	354.3	302.7
	PII(M3)	147	2159.8	1820.8	1571.6
	PII(M12)	144	1065.8	951.9	757.3
	PII(M24)	147	1079.9	1040.1	720.0
HZV-3	PRE	145	149.7	160.9	117.8
	PI(M2)	145	418.5	357.7	337.4
	PII(M3)	147	2369.3	1998.4	1722.6
	PII(M12)	146	1075.3	849.8	855.1
	PII(M24)	145	981.6	890.9	666.7
Control/HZV-3	PRE	152	155.6	189.0	100.3
	PI(M2)	153	129.0	142.3	92.7
	PII(M3)	152	527.2	497.7	419.8
	PII(M12)	143	265.4	245.3	216.3
	PII(M24)	151	210.8	187.2	173.3
Control	PRE	47	114.2	127.6	94.8
	PI(M2)	47	194.0	194.2	139.5
	PII(M3)	46	438.2	396.9	349.5
	PII(M12)	44	222.0	182.8	192.4
	PII(M24)	45	270.3	248.6	200.0
N = number of subjects with available results SD = Standard Deviation PRE = Pre-vaccination at Day 0 PI(M2) = Post-vaccination Dose I at Month 2 PII(M3) = Post-vaccination Dose II at Month 3 PII(M12) = Post-vaccination Dose II at Month 12 PII(M24) = Post-vaccination Dose II at Month 24					
Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least 2 different activation markers per million cells (Total cohort for persistence Month 36)					
Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	142	208.1	224.3	162.5
	PI(M2)	142	481.5	415.6	396.9
	PII(M3)	143	2326.1	2016.0	1803.6
	PII(M12)	141	1171.6	947.3	1011.4
	PII(M24)	141	1012.2	841.1	770.5
	PII(M36)	137	827.3	922.9	586.2
HZV-2	PRE	139	224.6	369.1	123.8
	PI(M2)	141	480.3	428.8	377.4
	PII(M3)	140	2356.3	1914.1	1755.4
	PII(M12)	137	1264.8	1215.1	903.9
	PII(M24)	140	1194.0	1401.2	781.1

	PII(M36)	138	969.7	1034.9	642.9
HZV-3	PRE	141	202.1	233.2	159.2
	PI(M2)	141	493.8	422.2	388.1
	PII(M3)	143	2651.8	2082.9	1884.8
	PII(M12)	142	1289.3	1008.7	978.6
	PII(M24)	142	1086.3	954.0	788.4
	PII(M36)	142	896.3	770.4	699.1
Control/HZV-3	PRE	150	201.5	219.4	142.8
	PI(M2)	151	173.2	181.1	123.2
	PII(M3)	150	646.0	606.2	500.8
	PII(M12)	141	346.2	300.3	288.0
	PII(M24)	148	243.7	233.7	186.7
	PII(M36)	146	239.7	181.7	211.6
Control	PRE	46	152.1	166.6	114.1
	PI(M2)	45	239.1	253.6	160.9
	PII(M3)	45	573.4	457.0	545.7
	PII(M12)	42	278.4	220.2	255.0
	PII(M24)	45	285.2	255.6	241.4
	PII(M36)	44	229.7	217.1	153.3

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

PII(M24) = Post-vaccination Dose II at Month 24

PII(M36) = Post-vaccination Dose II at Month 36

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least IFN γ and another activation marker (Total cohort for persistence Month 36)

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	142	166.4	208.6	94.5
	PI(M2)	142	296.3	360.9	205.4
	PII(M3)	143	1229.1	1054.3	974.6
	PII(M12)	141	680.0	602.7	562.4
	PII(M24)	141	547.1	504.5	373.3
	PII(M36)	137	491.8	604.1	347.7
HZV-2	PRE	139	167.1	321.0	86.6
	PI(M2)	141	275.6	337.2	191.7
	PII(M3)	140	1257.6	1141.9	1012.9
	PII(M12)	137	756.6	916.1	540.0
	PII(M24)	140	665.7	1162.2	450.1
	PII(M36)	138	583.3	819.0	393.5
HZV-3	PRE	141	150.7	220.3	82.8
	PI(M2)	141	299.1	347.1	189.0
	PII(M3)	143	1464.6	1310.3	1046.2
	PII(M12)	142	729.9	645.8	557.5
	PII(M24)	142	546.2	559.6	386.7
	PII(M36)	142	492.3	437.0	364.1
Control/HZV-3	PRE	150	156.9	180.5	90.3
	PI(M2)	151	119.9	149.2	68.0
	PII(M3)	150	351.0	361.4	256.1
	PII(M12)	141	239.1	247.6	184.2
	PII(M24)	148	157.5	184.1	119.2
	PII(M36)	146	172.2	155.1	133.3
Control	PRE	46	122.4	126.2	91.8

PI(M2)	45	171.2	215.3	94.7
PII(M3)	45	362.5	324.4	289.6
PII(M12)	42	182.6	155.2	164.9
PII(M24)	45	181.2	158.4	148.9
PII(M36)	44	162.0	151.4	129.8

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

PII(M24) = Post-vaccination Dose II at Month 24

PII(M36) = Post-vaccination Dose II at Month 36

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least IL-2 and another activation marker (Total cohort for persistence Month 36).

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	142	183.6	218.7	125.9
	PI(M2)	142	440.2	384.0	341.4
	PII(M3)	143	2151.2	1896.0	1623.4
	PII(M12)	141	1090.1	912.3	894.4
	PII(M24)	141	950.8	812.2	721.3
	PII(M36)	137	768.9	871.5	508.1
HZV-2	PRE	139	191.4	306.1	110.4
	PI(M2)	141	437.8	366.6	361.6
	PII(M3)	140	2141.6	1729.9	1627.7
	PII(M12)	137	1154.7	1041.0	832.9
	PII(M24)	140	1097.5	1180.0	713.2
	PII(M36)	138	890.2	883.3	595.3
HZV-3	PRE	141	181.8	195.3	130.9
	PI(M2)	141	444.3	377.8	362.6
	PII(M3)	143	2391.7	1877.4	1688.8
	PII(M12)	142	1182.7	948.2	937.4
	PII(M24)	142	1013.3	915.8	754.6
	PII(M36)	142	834.7	743.9	614.3
Control/HZV-3	PRE	150	170.6	184.6	130.4
	PI(M2)	151	150.7	160.7	95.0
	PII(M3)	150	578.4	531.0	471.5
	PII(M12)	141	297.2	269.3	241.9
	PII(M24)	148	212.6	208.5	160.0
	PII(M36)	146	205.8	154.5	181.1
Control	PRE	46	129.0	136.3	91.1
	PI(M2)	45	204.8	228.9	133.7
	PII(M3)	45	516.3	403.6	479.6
	PII(M12)	42	249.3	208.6	211.1
	PII(M24)	45	233.0	244.5	196.2
	PII(M36)	44	213.9	202.2	151.8

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

PII(M24) = Post-vaccination Dose II at Month 24

PII(M36) = Post-vaccination Dose II at Month 36

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least TNF α and another activation marker (Total cohort for persistence Month 36).

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	142	104.1	142.4	59.8
	PI(M2)	142	262.3	285.2	188.4
	PII(M3)	143	1359.3	1327.1	1024.6
	PII(M12)	141	695.7	624.4	507.7
	PII(M24)	141	574.0	528.9	407.2
	PII(M36)	137	497.4	652.5	316.8
HZV-2	PRE	139	120.9	301.3	63.6
	PI(M2)	141	255.3	309.8	197.5
	PII(M3)	140	1275.2	1195.0	924.3
	PII(M12)	137	735.2	900.5	486.4
	PII(M24)	140	665.9	1121.3	420.3
	PII(M36)	138	567.9	808.4	340.8
HZV-3	PRE	141	113.8	173.8	69.4
	PI(M2)	141	262.6	284.5	178.9
	PII(M3)	143	1416.0	1223.0	1067.3
	PII(M12)	142	748.4	670.3	538.6
	PII(M24)	142	596.1	591.2	370.2
	PII(M36)	142	510.7	522.1	381.1
Control/HZV-3	PRE	150	111.0	160.9	60.1
	PI(M2)	151	95.1	124.9	55.7
	PII(M3)	150	335.9	379.6	249.3
	PII(M12)	141	194.0	242.3	142.5
	PII(M24)	148	143.1	196.7	80.0
	PII(M36)	146	117.9	151.7	80.2
Control	PRE	46	86.6	109.8	50.0
	PI(M2)	45	119.5	148.4	82.8
	PII(M3)	45	262.6	258.2	180.6
	PII(M12)	42	137.7	135.5	84.4
	PII(M24)	45	133.0	158.1	88.1
	PII(M36)	44	98.1	116.0	63.3

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

PII(M24) = Post-vaccination Dose II at Month 24

PII(M36) = Post-vaccination Dose II at Month 36

Secondary Outcome Variable(s): Descriptive statistics of frequency of gE-specific CD4 T-cells secreting at least CD40L and another activation marker (Total cohort for persistence Month 36)

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	142	150.3	174.0	106.3
	PI(M2)	142	403.6	360.7	306.1
	PII(M3)	143	2087.6	1878.6	1617.5
	PII(M12)	141	996.2	821.9	822.9
	PII(M24)	141	942.6	804.0	681.1
	PII(M36)	137	753.0	852.9	508.7
HZV-2	PRE	139	149.7	213.9	95.4
	PI(M2)	141	403.1	359.2	302.7
	PII(M3)	140	2144.4	1836.2	1557.7
	PII(M12)	137	1048.1	948.0	727.1
	PII(M24)	140	1077.4	1053.2	706.7
	PII(M36)	138	912.9	1009.2	622.9
HZV-3	PRE	141	148.9	162.4	115.6

	PI(M2)	141	418.4	362.1	333.0
	PII(M3)	143	2370.9	2008.1	1722.6
	PII(M12)	142	1069.4	857.2	843.9
	PII(M24)	142	987.3	896.7	666.7
	PII(M36)	142	823.0	727.9	619.6
	PRE	150	154.1	186.0	100.3
Control/HZV-3	PI(M2)	151	131.8	145.3	94.4
	PII(M3)	150	544.5	564.7	417.1
	PII(M12)	141	271.5	249.0	221.2
	PII(M24)	148	211.7	188.7	173.3
	PII(M36)	146	202.5	166.3	186.7
	PRE	150	154.1	186.0	100.3
Control	PI(M2)	46	115.7	128.6	96.4
	PII(M3)	45	441.7	400.6	350.6
	PII(M12)	42	222.8	181.7	192.4
	PII(M24)	45	270.3	248.6	200.0
	PII(M36)	44	202.8	187.1	142.7
	PRE	46	115.7	128.6	96.4

N = number of subjects with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

PII(M12) = Post-vaccination Dose II at Month 12

PII(M24) = Post-vaccination Dose II at Month 24

PII(M36) = Post-vaccination Dose II at Month 36

Secondary Outcome Variable(s): Seropositivity rates and GMCs of anti-gE Antibodies (Total cohort for persistence Month 12)

				≥ 109 EU/mL				GMC (EU/mL)		
						95% CI		value	95% CI	
Antibody	Group	Timing	N	n	%	LL	UL		LL	UL
Anti-gE	HZV-1	PRE	156	147	94.2	89.3	97.3	349.3	304.1	401.1
		PI(M2)	156	156	100	97.7	100	3737.3	3217.7	4340.9
		PII(M3)	155	155	100	97.6	100	9476.6	8433.7	10648.4
		PII(M12)	156	156	100	97.7	100	3384.8	2987.2	3835.4
	HZV-2	PRE	159	144	90.6	84.9	94.6	320.0	274.3	373.4
		PI(M2)	159	157	98.7	95.5	99.8	4116.5	3435.2	4932.8
		PII(M3)	159	159	100	97.7	100	12998.5	11791.2	14329.3
		PII(M12)	159	159	100	97.7	100	4280.3	3818.4	4798.0
	HZV-3	PRE	159	153	96.2	92.0	98.6	419.3	360.2	488.1
		PI(M2)	159	159	100	97.7	100	5591.9	4781.2	6540.1
		PII(M3)	159	159	100	97.7	100	15443.3	13948.3	17098.5
		PII(M12)	159	159	100	97.7	100	5258.2	4725.2	5851.3
	Control/HZV-3	PRE	161	151	93.8	88.9	97.0	343.2	292.4	402.8
		PI(M2)	161	151	93.8	88.9	97.0	364.0	308.3	429.7
		PII(M3)	161	161	100	97.7	100	6167.7	5306.9	7168.1
		PII(M12)	160	160	100	97.7	100	1664.5	1443.7	1919.1
	Control	PRE	50	46	92.0	80.8	97.8	340.7	260.0	446.4
		PI(M2)	50	49	98.0	89.4	99.9	2478.9	1727.3	3557.4
		PII(M3)	49	49	100	92.7	100	4788.0	3679.4	6230.8
		PII(M12)	50	50	100	92.9	100	1888.2	1452.7	2454.1

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 at Day 0 PI(M2) = Post-vaccination Dose I at Month 2 PII(M3) = Post-vaccination Dose II at Month 3 PII(M12) = Post-vaccination Dose II at Month 12										
Secondary Outcome Variable(s): Seropositivity rates and GMCs of anti-gE Antibodies (Total Cohort for persistence Month 24)										
				≥ 109 EU/mL				GMC (EU/mL)		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
Anti-gE	HZV-1	PRE	150	141	94.0	88.9	97.2	350.1	303.9	403.4
		PI(M2)	150	150	100	97.6	100	3713.1	3180.3	4335.2
		PII(M3)	149	149	100	97.6	100	9526.2	8453.0	10735.6
		PII(M12)	149	149	100	97.6	100	3340.2	2937.9	3797.6
		PII(M24)	149	149	100	97.6	100	2363.8	2081.0	2685.0
	HZV-2	PRE	155	140	90.3	84.5	94.5	319.5	272.9	374.1
		PI(M2)	155	153	98.7	95.4	99.8	4109.2	3416.1	4943.0
		PII(M3)	155	155	100	97.6	100	13038.6	11824.8	14377.1
		PII(M12)	155	155	100	97.6	100	4312.5	3846.1	4835.3
		PII(M24)	155	155	100	97.6	100	2784.6	2494.0	3109.1
	HZV-3	PRE	154	148	96.1	91.7	98.6	421.2	360.1	492.6
		PI(M2)	154	154	100	97.6	100	5609.9	4776.9	6588.2
		PII(M3)	154	154	100	97.6	100	15462.5	13934.6	17157.9
		PII(M12)	154	154	100	97.6	100	5335.6	4786.3	5948.0
		PII(M24)	154	154	100	97.6	100	3390.0	3013.6	3813.5
	Control/HZV-3	PRE	157	148	94.3	89.4	97.3	337.5	289.6	393.4
		PI(M2)	157	148	94.3	89.4	97.3	360.1	305.9	423.9
		PII(M3)	157	157	100	97.7	100	6108.2	5246.6	7111.2
		PII(M12)	157	157	100	97.7	100	1676.1	1451.5	1935.4
		PII(M24)	157	157	100	97.7	100	1126.3	982.2	1291.6
	Control	PRE	49	45	91.8	80.4	97.7	337.0	255.9	443.7
		PI(M2)	49	48	98.0	89.1	99.9	2487.3	1720.1	3596.6
		PII(M3)	48	48	100	92.6	100	4865.3	3725.1	6354.6
		PII(M12)	49	49	100	92.7	100	1929.8	1482.1	2512.7
		PII(M24)	48	48	100	92.6	100	1339.1	1038.3	1727.0
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 at Day 0 PI(M2) = Post-vaccination Dose I at Month 2 PII(M3) = Post-vaccination Dose II at Month 3 PII(M12) = Post-vaccination Dose II at Month 12 PII(M24) = Post-vaccination Dose II at Month 24										
Secondary Outcome Variable(s): Seropositivity rates and GMCs of anti-gE Antibodies (Total cohort for persistence Month 36)										
				≥ 109 EU/mL				GMC (EU/mL)		
						95% CI			95% CI	
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
Anti-gE	HZV-1	PRE	147	139	94.6	89.6	97.6	353.7	306.9	407.7
		PI(M2)	147	147	100	97.5	100	3742.6	3196.4	4382.0
		PII(M3)	146	146	100	97.5	100	9746.2	8667.8	10958.7
		PII(M12)	146	146	100	97.5	100	3411.8	3010.2	3867.0
		PII(M24)	146	146	100	97.5	100	2422.5	2142.6	2738.9

	PII(M36)	146	146	100	97.5	100	2064.1	1834.6	2322.3
HZV-2	PRE	147	132	89.8	83.7	94.2	322.8	273.9	380.4
	PI(M2)	147	145	98.6	95.2	99.8	4271.5	3532.9	5164.5
	PII(M3)	147	147	100	97.5	100	13222.0	11942.5	14638.5
	PII(M12)	147	147	100	97.5	100	4389.5	3897.0	4944.2
	PII(M24)	147	147	100	97.5	100	2835.7	2529.7	3178.7
	PII(M36)	146	146	100	97.5	100	2444.3	2175.2	2746.8
HZV-3	PRE	150	144	96.0	91.5	98.5	415.9	354.6	487.8
	PI(M2)	150	150	100	97.6	100	5616.6	4788.0	6588.5
	PII(M3)	150	150	100	97.6	100	15644.4	14098.2	17360.0
	PII(M12)	150	150	100	97.6	100	5396.7	4833.6	6025.3
	PII(M24)	150	150	100	97.6	100	3423.5	3035.7	3860.8
	PII(M36)	150	150	100	97.6	100	2956.4	2653.6	3293.7
Control/HZV-3	PRE	155	146	94.2	89.3	97.3	344.3	292.6	405.2
	PI(M2)	155	146	94.2	89.3	97.3	365.2	308.6	432.1
	PII(M3)	155	155	100	97.6	100	6225.1	5340.5	7256.3
	PII(M12)	155	155	100	97.6	100	1688.7	1461.9	1950.6
	PII(M24)	154	154	100	97.6	100	1135.0	988.4	1303.5
	PII(M36)	152	151	99.3	96.4	100	959.5	831.0	1107.9
Control	PRE	47	43	91.5	79.6	97.6	330.3	248.3	439.5
	PI(M2)	47	46	97.9	88.7	99.9	2397.4	1637.4	3509.9
	PII(M3)	47	47	100	92.5	100	4846.7	3689.4	6367.1
	PII(M12)	47	47	100	92.5	100	1946.1	1479.4	2560.1
	PII(M24)	47	47	100	92.5	100	1347.2	1039.1	1746.7
	PII(M36)	47	46	97.9	88.7	99.9	973.9	755.4	1255.6

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 at Day 0

PI(M2) = Post Dose I at Month 2

PII(M3) = Post Dose II at Month 3

PII(M12) = Post Dose II at Month 12

PII(M24) = Post Dose II at Month 24

PII(M36) = Post Dose II at Month 36

Secondary Outcome Variable(s): Seropositivity rates and GMCs of anti-VZV Antibodies (Total cohorts for persistence Month 12)

Antibody	Group	Timing	N	≥ 50 mIU/mL				GMC (mIU/mL)		
				n	%	95% CI		value	95% CI	
						LL	UL		LL	U
Anti-VZV	HZV-1	PRE	147	146	99.3	96.3	100	1297.3	1140.7	1475.4
		PI(M2)	147	146	99.3	96.3	100	4381.4	3796.5	5056.3
		PII(M3)	146	146	100	97.5	100	9090.0	8173.1	10109.9
		PII(M12)	146	146	100	97.5	100	4190.1	3845.4	4565.8
	HZV-2	PRE	147	147	100	97.5	100	1243.0	1084.6	1424.5
		PI(M2)	147	147	100	97.5	100	5335.3	4627.7	6151.2
		PII(M3)	147	147	100	97.5	100	11826.0	10802.9	12945.8
		PII(M12)	147	147	100	97.5	100	4761.3	4367.0	5191.3
	HZV-3	PRE	150	150	100	97.6	100	1518.8	1345.0	1715.2
		PI(M2)	150	150	100	97.6	100	6577.2	5805.4	7451.5
		PII(M3)	150	150	100	97.6	100	14225.5	13000.0	15566.5
		PII(M12)	150	150	100	97.6	100	5559.1	5141.5	6010.7
	Control/HZV-3	PRE	155	155	100	97.6	100	1345.3	1175.6	1539.4
		PI(M2)	155	155	100	97.6	100	1327.7	1167.4	1510.1
		PII(M3)	155	155	100	97.6	100	6356.1	5544.4	7286.7
		PII(M12)	155	155	100	97.6	100	2704.1	2424.5	3016.0

	Control	PRE	47	47	100	92.5	100	1388.7	1117.7	1725.3
		PI(M2)	47	47	100	92.5	100	3604.5	2872.3	4523.3
		PII(M3)	47	47	100	92.5	100	5677.4	4564.3	7061.8
		PII(M12)	47	47	100	92.5	100	2733.8	2208.8	3383.7

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 at Day 0

PI(M2) = Post Dose I at Month 2

PII(M3) = Post Dose II at Month 3

PII(M12) = Post Dose II at Month 12

Secondary Outcome Variable(s): Seropositivity rates and GMCs of anti-VZV Antibodies (Total cohort for persistence Month 24)

				≥ 50 mIU/mL				GMC (mIU/mL)		
				95% CI				95% CI		
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
VZV IGG	HZV-1	PRE	150	149	99.3	96.3	100	1300.7	1146.3	1475.8
		PI(M2)	150	149	99.3	96.3	100	4375.6	3802.5	5035.1
		PII(M3)	149	149	100	97.6	100	8970.5	8070.3	9971.1
		PII(M12)	149	149	100	97.6	100	4156.1	3818.0	4524.1
		PII(M24)	149	149	100	97.6	100	2557.4	2397.5	2727.8
	HZV-2	PRE	155	155	100	97.6	100	1250.5	1096.3	1426.3
		PI(M2)	155	155	100	97.6	100	5196.2	4524.6	5967.5
		PII(M3)	155	155	100	97.6	100	11688.5	10708.5	12758.2
		PII(M12)	155	155	100	97.6	100	4714.3	4339.2	5121.9
		PII(M24)	155	155	100	97.6	100	2673.6	2523.8	2832.3
	HZV-3	PRE	154	154	100	97.6	100	1509.0	1338.4	1701.3
		PI(M2)	154	154	100	97.6	100	6560.2	5782.0	7443.1
		PII(M3)	154	154	100	97.6	100	14026.4	12802.0	15367.9
		PII(M12)	154	154	100	97.6	100	5483.7	5070.2	5931.0
		PII(M24)	154	154	100	97.6	100	2976.0	2819.5	3141.3
	Control/HZV-3	PRE	157	157	100	97.7	100	1327.1	1168.4	1507.3
		PI(M2)	157	157	100	97.7	100	1318.1	1164.3	1492.2
		PII(M3)	157	157	100	97.7	100	6247.5	5462.5	7145.3
		PII(M12)	157	157	100	97.7	100	2697.8	2422.9	3003.9
		PII(M24)	157	157	100	97.7	100	1849.3	1701.8	2009.5
	Control	PRE	49	49	100	92.7	100	1413.1	1146.0	1742.5
		PI(M2)	49	49	100	92.7	100	3744.2	2991.8	4685.8
		PII(M3)	48	48	100	92.6	100	5757.7	4642.1	7141.4
		PII(M12)	49	49	100	92.7	100	2772.0	2257.8	3403.4
		PII(M24)	48	48	100	92.6	100	1922.6	1643.1	2249.6

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 at Day 0

PI(M2) = Post Dose I at Month 2

PII(M3) = Post Dose II at Month 3

PII(M12) = Post Dose II at Month 12

PII(M24) = Post Dose II at Month 24

Secondary Outcome Variable(s): Seropositivity rates and GMCs of anti-VZV Antibodies (Total cohort for persistence Month 36)

				≥ 50 mIU/mL				GMC (mIU/mL)		
				95% CI				95% CI		
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
Anti-VZV	HZV-1	PRE	147	146	99.3	96.3	100	1297.3	1140.7	1475.4
		PI(M2)	147	146	99.3	96.3	100	4381.4	3796.5	5056.3

		PII(M3)	146	146	100	97.5	100	9090.0	8173.1	10109.9
		PII(M12)	146	146	100	97.5	100	4190.1	3845.4	4565.8
		PII(M24)	146	146	100	97.5	100	2569.2	2407.2	2742.1
		PII(M36)	146	146	100	97.5	100	2426.6	2257.2	2608.8
	HZV-2	PRE	147	147	100	97.5	100	1243.0	1084.6	1424.5
		PI(M2)	147	147	100	97.5	100	5335.3	4627.7	6151.2
		PII(M3)	147	147	100	97.5	100	11826.0	10802.9	12945.8
		PII(M12)	147	147	100	97.5	100	4761.3	4367.0	5191.3
		PII(M24)	147	147	100	97.5	100	2692.3	2535.9	2858.3
		PII(M36)	146	146	100	97.5	100	2555.0	2385.8	2736.3
	HZV-3	PRE	150	150	100	97.6	100	1518.8	1345.0	1715.2
		PI(M2)	150	150	100	97.6	100	6577.2	5805.4	7451.5
		PII(M3)	150	150	100	97.6	100	14225.5	13000.0	15566.5
		PII(M12)	150	150	100	97.6	100	5559.1	5141.5	6010.7
		PII(M24)	150	150	100	97.6	100	3004.7	2846.4	3171.9
		PII(M36)	150	150	100	97.6	100	2826.7	2648.4	3017.0
	Control/HZV-3	PRE	155	155	100	97.6	100	1345.3	1175.6	1539.4
		PI(M2)	155	155	100	97.6	100	1327.7	1167.4	1510.1
		PII(M3)	155	155	100	97.6	100	6356.1	5544.4	7286.7
		PII(M12)	155	155	100	97.6	100	2704.1	2424.5	3016.0
		PII(M24)	154	154	100	97.6	100	1852.1	1702.8	2014.5
		PII(M36)	155	155	100	97.6	100	1729.9	1582.5	1891.1
	Control	PRE	47	47	100	92.5	100	1388.7	1117.7	1725.3
		PI(M2)	47	47	100	92.5	100	3604.5	2872.3	4523.3
		PII(M3)	47	47	100	92.5	100	5677.4	4564.3	7061.8
		PII(M12)	47	47	100	92.5	100	2733.8	2208.8	3383.7
		PII(M24)	47	47	100	92.5	100	1917.4	1633.2	2251.0
		PII(M36)	47	47	100	92.5	100	1739.9	1481.0	2044.0

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 at Day 0

PI(M2) = Post Dose I at Month 2

PII(M3) = Post Dose II at Month 3

PII(M12) = Post Dose II at Month 12

PII(M24) = Post Dose II at Month 24

PII(M36) = Post Dose II at Month 36

Secondary Outcome Variable(s): Descriptive Statistics of frequency of gE-specific memory B cells per million memory B cells, in subjects aged 70 years and above (Total cohort for persistence Month 12)

Treatment Group	Timing	N	Mean	SD	Median
HZV-1	PRE	18	336.5	359.5	155.5
	PI(M2)	17	1911.5	2079.6	1705.0
	PII(M3)	19	5699.3	8166.2	2922.0
	PII(M12)	12	1557.8	1239.3	1216.0
HZV-2	PRE	23	490.4	704.7	357.0
	PI(M2)	23	1546.5	1573.6	769.0
	PII(M3)	21	5997.1	5034.6	4679.0
	PII(M12)	22	3443.5	3770.2	2504.0
HZV-3	PRE	19	356.6	348.0	213.0
	PI(M2)	20	1595.6	1685.4	1109.0
	PII(M3)	23	9707.5	8787.1	7509.0
	PII(M12)	19	5230.4	4836.3	3476.0
Control/HZV-3	PRE	18	332.3	404.9	195.5
	PI(M2)	18	645.6	1119.9	247.0
	PII(M3)	21	1583.7	2266.0	779.0

	PII(M12)	19	1092.8	813.8	772.0
Control	PRE	8	380.6	299.7	375.0
	PI(M2)	5	1005.0	1384.6	487.0
	PII(M3)	6	1042.2	1139.9	688.0
	PII(M12)	6	813.2	728.9	482.0

N = number of subjects in the subsets with available results

SD = Standard Deviation

PRE = Pre-vaccination at Day 0

PI(M2) = Post-vaccination Dose I at Month 2

PII(M3) = Post-vaccination Dose II at Month 3

Secondary Outcome Variable(s): Distribution of haematology and biochemistry with respect to normal laboratory ranges
(Total Vaccinated cohort)

		HZV-3 Group										Control Group									
			Unknown			Below		Within		Above			Unknown			Below		Within		Above	
Laboratory parameter	Timing	N	n	%	n	%	n	%	n	%	N	n	%	n	%	n	%	n	%		
Albumin	PRE	75	0	0.0	14	18.7	59	78.7	2	2.7	24	0	0.0	4	16.7	19	79.2	1	4.2		
	PI(W1)	24	0	0.0	12	50.0	12	50.0	0	0.0	8	0	0.0	4	50.0	4	50.0	0	0.0		
	PI(M2)	74	0	0.0	11	14.9	62	83.8	1	1.4	22	0	0.0	6	27.3	16	72.7	0	0.0		
	PII(W1)	22	0	0.0	10	45.5	12	54.5	0	0.0	8	0	0.0	3	37.5	5	62.5	0	0.0		
	PII(M3)	73	1	1.4	9	12.3	61	83.6	2	2.7	21	0	0.0	4	19.0	17	81.0	0	0.0		
ALT(SGPT)	PRE	164	0	0.0	0	0.0	152	92.7	12	7.3	54	1	1.9	0	0.0	50	92.6	3	5.6		
	PI(M2)	162	0	0.0	0	0.0	155	95.7	7	4.3	51	0	0.0	0	0.0	48	94.1	3	5.9		
	PII(M3)	161	1	0.6	0	0.0	154	95.7	6	3.7	51	0	0.0	0	0.0	46	90.2	5	9.8		
AST(SGOT)	PRE	164	0	0.0	1	0.6	156	95.1	7	4.3	54	0	0.0	0	0.0	51	94.4	3	5.6		
	PI(M2)	162	0	0.0	0	0.0	151	93.2	11	6.8	51	0	0.0	0	0.0	51	100	0	0.0		
	PII(M3)	161	2	1.2	0	0.0	153	95.0	6	3.7	51	0	0.0	0	0.0	48	94.1	3	5.9		
Basophils	PRE	164	5	3.0	0	0.0	153	93.3	6	3.7	54	1	1.9	1	1.9	50	92.6	2	3.7		
	PI(M2)	162	1	0.6	1	0.6	152	93.8	8	4.9	51	0	0.0	1	2.0	47	92.2	3	5.9		
	PII(M3)	161	0	0.0	2	1.2	147	91.3	12	7.5	51	0	0.0	1	2.0	48	94.1	2	3.9		
Calcium	PRE	75	0	0.0	2	2.7	72	96.0	1	1.3	24	0	0.0	0	0.0	23	95.8	1	4.2		
	PI(W1)	24	0	0.0	1	4.2	21	87.5	2	8.3	8	0	0.0	0	0.0	8	100	0	0.0		
	PI(M2)	74	0	0.0	5	6.8	68	91.9	1	1.4	22	0	0.0	0	0.0	22	100	0	0.0		
	PII(W1)	22	0	0.0	2	9.1	20	90.9	0	0.0	8	0	0.0	0	0.0	8	100	0	0.0		
	PII(M3)	73	1	1.4	2	2.7	70	95.9	0	0.0	21	0	0.0	0	0.0	21	100	0	0.0		
Eosinophils	PRE	164	5	3.0	12	7.3	135	82.3	12	7.3	54	1	1.9	2	3.7	47	87.0	4	7.4		
	PI(M2)	162	1	0.6	15	9.3	128	79.0	18	11.1	51	0	0.0	3	5.9	43	84.3	5	9.8		
	PII(M3)	161	0	0.0	12	7.5	126	78.3	23	14.3	51	0	0.0	2	3.9	45	88.2	4	7.8		
Fibrinogen	PRE	75	4	5.3	0	0.0	36	48.0	35	46.7	24	0	0.0	0	0.0	10	41.7	14	58.3		
	PI(W1)	24	0	0.0	0	0.0	10	41.7	14	58.3	8	0	0.0	0	0.0	4	50.0	4	50.0		
	PI(M2)	74	2	2.7	0	0.0	37	50.0	35	47.3	22	0	0.0	0	0.0	12	54.5	10	45.5		
	PII(W1)	22	0	0.0	0	0.0	9	40.9	13	59.1	8	0	0.0	0	0.0	4	50.0	4	50.0		
	PII(M3)	73	1	1.4	0	0.0	40	54.8	32	43.8	21	0	0.0	0	0.0	9	42.9	12	57.1		
Hematocrit	PRE	164	0	0.0	27	16.5	129	78.7	8	4.9	54	0	0.0	4	7.4	50	92.6	0	0.0		
	PI(M2)	162	1	0.6	25	15.4	131	80.9	5	3.1	51	0	0.0	4	7.8	46	90.2	1	2.0		
	PII(M3)	161	0	0.0	25	15.5	134	83.2	2	1.2	51	0	0.0	6	11.8	45	88.2	0	0.0		
Hemo-globin	PRE	164	0	0.0	19	11.6	142	86.6	3	1.8	54	0	0.0	8	14.8	46	85.2	0	0.0		
	PI(M2)	162	1	0.6	26	16.0	134	82.7	1	0.6	51	0	0.0	6	11.8	45	88.2	0	0.0		
	PII(M3)	161	0	0.0	26	16.1	133	82.6	2	1.2	51	0	0.0	7	13.7	44	86.3	0	0.0		
Leucocytes	PRE	164	0	0.0	2	1.2	153	93.3	9	5.5	54	0	0.0	1	1.9	52	96.3	1	1.9		
	PI(M2)	162	1	0.6	3	1.9	153	94.4	5	3.1	51	0	0.0	0	0.0	46	90.2	5	9.8		
	PII(M3)	161	0	0.0	5	3.1	149	92.5	7	4.3	51	0	0.0	0	0.0	50	98.0	1	2.0		
Lymphocytes	PRE	164	5	3.0	24	14.6	130	79.3	5	3.0	54	1	1.9	5	9.3	44	81.5	4	7.4		
	PI(M2)	162	1	0.6	23	14.2	131	80.9	7	4.3	51	0	0.0	7	13.7	42	82.4	2	3.9		
	PII(M3)	161	0	0.0	19	11.8	138	85.7	4	2.5	51	0	0.0	7	13.7	42	82.4	2	3.9		
LDH	PRE	75	0	0.0	0	0.0	66	88.0	9	12.0	24	0	0.0	0	0.0	24	100	0	0.0		

		PI(W1)	24	0	0.0	0	0.0	20	83.3	4	16.7	8	0	0.0	0	0.0	8	100	0	0.0	
		PI(M2)	74	0	0.0	0	0.0	64	86.5	10	13.5	22	0	0.0	0	0.0	21	95.5	1	4.5	
		PII(W1)	22	0	0.0	0	0.0	16	72.7	6	27.3	8	0	0.0	0	0.0	8	100	0	0.0	
		PII(M3)	73	1	1.4	0	0.0	66	90.4	6	8.2	21	0	0.0	0	0.0	20	95.2	1	4.8	
		PRE	164	5	3.0	1	0.6	147	89.6	11	6.7	54	1	1.9	1	1.9	49	90.7	3	5.6	
Monocytes		PI(M2)	162	1	0.6	2	1.2	146	90.1	13	8.0	51	0	0.0	0	0.0	48	94.1	3	5.9	
		PII(M3)	161	0	0.0	1	0.6	145	90.1	15	9.3	51	0	0.0	0	0.0	49	96.1	2	3.9	
		PRE	164	5	3.0	3	1.8	147	89.6	9	5.5	54	1	1.9	3	5.6	48	88.9	2	3.7	
Neutrophils		PI(M2)	162	1	0.6	4	2.5	144	88.9	13	8.0	51	0	0.0	1	2.0	47	92.2	3	5.9	
		PII(M3)	161	0	0.0	7	4.3	145	90.1	9	5.6	51	0	0.0	2	3.9	46	90.2	3	5.9	
		PRE	164	5	3.0	2	3.8	42	79.2	6	11.3	16	0	0.0	0	0.0	11	68.8	5	31.3	
Partial Thrombo- plastin Time		PI(W1)	2	2	100	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	
		PI(M2)	72	3	4.2	6	8.3	57	79.2	6	8.3	22	0	0.0	0	0.0	20	90.9	2	9.1	
		PII(W1)	22	0	0.0	2	9.1	20	90.9	0	0.0	8	0	0.0	0	0.0	8	100	0	0.0	
		PII(M3)	73	1	1.4	6	8.2	59	80.8	7	9.6	21	0	0.0	1	4.8	18	85.7	2	9.5	
		PRE	164	0	0.0	9	5.5	149	90.9	6	3.7	54	0	0.0	2	3.7	49	90.7	3	5.6	
Platelets		PI(M2)	162	1	0.6	11	6.8	145	89.5	5	3.1	51	0	0.0	1	2.0	49	96.1	1	2.0	
		PII(M3)	161	0	0.0	9	5.6	147	91.3	5	3.1	51	0	0.0	3	5.9	46	90.2	2	3.9	
		PRE	53	3	5.7	5	9.4	42	79.2	3	5.7	16	0	0.0	5	31.3	11	68.8	0	0.0	
Pro Thrombin Time		PI(W1)	2	1	50.0	0	0.0	0	0.0	1	50.0	0	0	0.0	0	0.0	0	0.0	0	0.0	
		PI(M2)	72	3	4.2	6	8.3	61	84.7	2	2.8	22	0	0.0	3	13.6	19	86.4	0	0.0	
		PII(W1)	22	0	0.0	0	0.0	22	100	0	0.0	8	0	0.0	0	0.0	8	100	0	0.0	
		PII(M3)	73	1	1.4	6	8.2	63	86.3	3	4.1	21	0	0.0	2	9.5	19	90.5	0	0.0	
		PRE	164	2	1.2	25	15.2	128	78.0	9	5.5	54	0	0.0	9	16.7	42	77.8	3	5.6	
Red Blood Cells		PI(M2)	162	1	0.6	27	16.7	128	79.0	6	3.7	51	0	0.0	8	15.7	42	82.4	1	2.0	
		PII(M3)	161	0	0.0	26	16.1	131	81.4	4	2.5	51	0	0.0	5	9.8	46	90.2	0	0.0	
		PRE	164	1	0.6	3	1.8	128	78.0	32	19.5	54	0	0.0	0	0.0	43	79.6	11	20.4	
Serum Creatinine		PI(M2)	162	0	0.0	1	0.6	129	79.6	32	19.8	51	0	0.0	2	3.9	38	74.5	11	21.6	
		PII(M3)	161	1	0.6	2	1.2	130	80.7	28	17.4	51	0	0.0	0	0.0	42	82.4	9	17.6	
		PRE	75	0	0.0	9	12.0	66	88.0	0	0.0	24	0	0.0	1	4.2	23	95.8	0	0.0	
Total Protein		PI(W1)	24	0	0.0	2	8.3	22	91.7	0	0.0	8	0	0.0	0	0.0	8	100	0	0.0	
		PI(M2)	74	0	0.0	9	12.2	65	87.8	0	0.0	22	0	0.0	2	9.1	20	90.9	0	0.0	
		PII(W1)	22	0	0.0	2	9.1	20	90.9	0	0.0	8	0	0.0	0	0.0	8	100	0	0.0	
		PII(M3)	73	1	1.4	13	17.8	58	79.5	1	1.4	21	0	0.0	0	0.0	21	100	0	0.0	
		PRE	164	0	0.0	9	5.5	149	90.9	6	3.7	54	0	0.0	2	3.7	49	90.7	3	5.6	
		HZV-1										HZV-2 Group									
			Unknown		Below		Within		Above				Unknown		Below		Within		Above		
Laboratory parameter	Timing	N	n	%	n	%	n	%	n	%	N	n	%	n	%	n	%	n	%		
Albumin	PRE	74	0	0.0	13	17.6	57	77.0	4	5.4	77	0	0.0	12	15.6	64	83.1	1	1.3		
	PI(W1)	23	0	0.0	11	47.8	12	52.2	0	0.0	24	0	0.0	12	50.0	12	50.0	0	0.0		
	PI(M2)	72	0	0.0	13	18.1	57	79.2	2	2.8	77	0	0.0	14	18.2	61	79.2	2	2.6		
	PII(W1)	20	1	5.0	6	30.0	13	65.0	0	0.0	24	0	0.0	8	33.3	16	66.7	0	0.0		
	PII(M3)	70	0	0.0	8	11.4	61	87.1	1	1.4	77	0	0.0	12	15.6	62	80.5	3	3.9		
ALT(SGPT)	PRE	164	0	0.0	1	0.6	150	91.5	13	7.9	166	0	0.0	2	1.2	151	91.0	13	7.8		
	PI(M2)	162	0	0.0	1	0.6	152	93.8	9	5.6	164	0	0.0	1	0.6	149	90.9	14	8.5		
	PII(M3)	160	0	0.0	1	0.6	152	95.0	7	4.4	164	0	0.0	2	1.2	150	91.5	12	7.3		
AST(SGOT)	PRE	164	0	0.0	0	0.0	156	95.1	8	4.9	166	0	0.0	1	0.6	154	92.8	11	6.6		
	PI(M2)	162	0	0.0	0	0.0	150	92.6	12	7.4	164	0	0.0	1	0.6	151	92.1	12	7.3		
	PII(M3)	160	0	0.0	0	0.0	151	94.4	9	5.6	164	0	0.0	3	1.8	146	89.0	15	9.1		
Basophils	PRE	164	7	4.3	0	0.0	148	90.2	9	5.5	166	11	6.6	1	0.6	147	88.6	7	4.2		
	PI(M2)	162	0	0.0	0	0.0	153	94.4	9	5.6	164	0	0.0	1	0.6	155	94.5	8	4.9		
	PII(M3)	160	0	0.0	0	0.0	150	93.8	10	6.3	164	0	0.0	0	0.0	151	92.1	13	7.9		
Calcium	PRE	74	0	0.0	3	4.1	70	94.6	1	1.4	77	0	0.0	1	1.3	76	98.7	0	0.0		
	PI(W1)	23	0	0.0	2	8.7	21	91.3	0	0.0	24	0	0.0	1	4.2	23	95.8	0	0.0		
	PI(M2)	72	0	0.0	4	5.6	68	94.4	0	0.0	77	0	0.0	1	1.3	75	97.4	1	1.3		

Eosinophils	PII(W1)	20	1	5.0	1	5.0	17	85.0	1	5.0	24	0	0.0	0	0.0	24	100	0	0.0
	PII(M3)	70	0	0.0	5	7.1	64	91.4	1	1.4	77	0	0.0	1	1.3	76	98.7	0	0.0
	PRE	164	8	4.9	13	7.9	130	79.3	13	7.9	166	11	6.6	11	6.6	127	76.5	17	10.2
	PI(M2)	162	0	0.0	11	6.8	140	86.4	11	6.8	164	0	0.0	8	4.9	138	84.1	18	11.0
Fibrinogen	PII(M3)	160	1	0.6	10	6.3	127	79.4	22	13.8	164	0	0.0	9	5.5	144	87.8	11	6.7
	PRE	74	1	1.4	0	0.0	36	48.6	37	50.0	77	4	5.2	0	0.0	34	44.2	39	50.6
	PI(W1)	23	0	0.0	0	0.0	9	39.1	14	60.9	24	0	0.0	0	0.0	5	20.8	19	79.2
	PI(M2)	72	0	0.0	0	0.0	40	55.6	32	44.4	77	1	1.3	0	0.0	35	45.5	41	53.2
Hematocrit	PII(W1)	20	1	5.0	0	0.0	8	40.0	11	55.0	24	0	0.0	0	0.0	9	37.5	15	62.5
	PII(M3)	70	0	0.0	0	0.0	40	57.1	30	42.9	77	1	1.3	0	0.0	36	46.8	40	51.9
	PRE	164	1	0.6	21	12.8	141	86.0	1	0.6	166	4	2.4	16	9.6	143	86.1	3	1.8
	PI(M2)	162	0	0.0	27	16.7	133	82.1	2	1.2	164	0	0.0	19	11.6	144	87.8	1	0.6
Hemoglobin	PII(M3)	160	0	0.0	30	18.8	128	80.0	2	1.3	164	0	0.0	23	14.0	137	83.5	4	2.4
	PRE	164	1	0.6	23	14.0	138	84.1	2	1.2	166	4	2.4	14	8.4	142	85.5	6	3.6
	PI(M2)	162	0	0.0	26	16.0	134	82.7	2	1.2	164	0	0.0	22	13.4	140	85.4	2	1.2
	PII(M3)	160	0	0.0	27	16.9	131	81.9	2	1.3	164	0	0.0	21	12.8	141	86.0	2	1.2
Leucocytes	PRE	164	1	0.6	3	1.8	153	93.3	7	4.3	166	4	2.4	5	3.0	147	88.6	10	6.0
	PI(M2)	162	0	0.0	3	1.9	152	93.8	7	4.3	164	0	0.0	7	4.3	148	90.2	9	5.5
	PII(M3)	160	0	0.0	2	1.3	150	93.8	8	5.0	164	0	0.0	8	4.9	150	91.5	6	3.7
	PRE	164	7	4.3	18	11.0	137	83.5	2	1.2	166	11	6.6	13	7.8	140	84.3	2	1.2
Lymphocytes	PI(M2)	162	0	0.0	15	9.3	144	88.9	3	1.9	164	0	0.0	18	11.0	144	87.8	2	1.2
	PII(M3)	160	0	0.0	12	7.5	144	90.0	4	2.5	164	0	0.0	8	4.9	154	93.9	2	1.2
	PRE	74	1	1.4	0	0.0	68	91.9	5	6.8	77	1	1.3	0	0.0	68	88.3	8	10.4
	PI(W1)	23	0	0.0	0	0.0	19	82.6	4	17.4	24	0	0.0	0	0.0	22	91.7	2	8.3
LDH	PI(M2)	72	0	0.0	0	0.0	64	88.9	8	11.1	77	0	0.0	0	0.0	65	84.4	12	15.6
	PII(W1)	20	1	5.0	0	0.0	15	75.0	4	20.0	24	0	0.0	0	0.0	20	83.3	4	16.7
	PII(M3)	70	0	0.0	0	0.0	63	90.0	7	10.0	77	0	0.0	0	0.0	63	81.8	14	18.2
	PRE	164	7	4.3	1	0.6	148	90.2	8	4.9	166	11	6.6	4	2.4	142	85.5	9	5.4
Monocytes	PI(M2)	162	0	0.0	0	0.0	153	94.4	9	5.6	164	0	0.0	0	0.0	155	94.5	9	5.5
	PII(M3)	160	0	0.0	2	1.3	145	90.6	13	8.1	164	0	0.0	1	0.6	151	92.1	12	7.3
	PRE	164	8	4.9	3	1.8	145	88.4	8	4.9	166	11	6.6	2	1.2	141	84.9	12	7.2
	PI(M2)	162	1	0.6	2	1.2	150	92.6	9	5.6	164	0	0.0	5	3.0	152	92.7	7	4.3
Neutrophils	PII(M3)	160	1	0.6	7	4.4	146	91.3	6	3.8	164	0	0.0	3	1.8	157	95.7	4	2.4
	PRE	53	3	5.7	5	9.4	42	79.2	3	5.7	55	4	7.3	2	3.6	42	76.4	7	12.7
	PI(W1)	0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100	0	0.0	0	0.0	0	0.0
	PI(M2)	72	0	0.0	7	9.7	59	81.9	6	8.3	74	1	1.4	4	5.4	58	78.4	11	14.9
Partial Thrombo- plastin Time	PII(W1)	20	1	5.0	0	0.0	18	90.0	1	5.0	24	0	0.0	1	4.2	22	91.7	1	4.2
	PII(M3)	70	0	0.0	4	5.7	62	88.6	4	5.7	77	0	0.0	4	5.2	61	79.2	12	15.6
	PRE	164	1	0.6	6	3.7	147	89.6	10	6.1	166	4	2.4	4	2.4	150	90.4	8	4.8
	PI(M2)	162	0	0.0	6	3.7	150	92.6	6	3.7	164	0	0.0	7	4.3	152	92.7	5	3.0
Platelets	PII(M3)	160	0	0.0	6	3.8	149	93.1	5	3.1	164	0	0.0	6	3.7	153	93.3	5	3.0
	PRE	53	3	5.7	4	7.5	44	83.0	2	3.8	55	3	5.5	9	16.4	38	69.1	5	9.1
	PI(W1)	0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100	0	0.0	0	0.0	0	0.0
	PI(M2)	72	0	0.0	5	6.9	65	90.3	2	2.8	74	1	1.4	10	13.5	62	83.8	1	1.4
Pro Thrombin Time	PII(W1)	20	1	5.0	1	5.0	18	90.0	0	0.0	24	0	0.0	1	4.2	23	95.8	0	0.0
	PII(M3)	70	0	0.0	5	7.1	62	88.6	3	4.3	77	0	0.0	10	13.0	64	83.1	3	3.9
	PRE	164	1	0.6	23	14.0	137	83.5	3	1.8	166	5	3.0	21	12.7	135	81.3	5	3.0
	PI(M2)	162	0	0.0	25	15.4	136	84.0	1	0.6	164	1	0.6	23	14.0	138	84.1	2	1.2
Red Blood Cells	PII(M3)	160	1	0.6	27	16.9	129	80.6	3	1.9	164	0	0.0	23	14.0	138	84.1	3	1.8
	PRE	164	1	0.6	4	2.4	130	79.3	29	17.7	166	1	0.6	2	1.2	132	79.5	31	18.7
	PI(M2)	162	0	0.0	3	1.9	135	83.3	24	14.8	164	0	0.0	2	1.2	131	79.9	31	18.9
	PII(M3)	160	0	0.0	3	1.9	132	82.5	25	15.6	164	0	0.0	3	1.8	127	77.4	34	20.7
Serum Creatinine	PRE	74	0	0.0	6	8.1	68	91.9	0	0.0	77	0	0.0	2	2.6	75	97.4	0	0.0
	PI(W1)	23	0	0.0	0	0.0	23	100	0	0.0	24	0	0.0	0	0.0	24	100	0	0.0
	PI(M2)	72	0	0.0	6	8.3	66	91.7	0	0.0	77	0	0.0	2	2.6	75	97.4	0	0.0
	PI(M2)	72	0	0.0	6	8.3	66	91.7	0	0.0	77	0	0.0	2	2.6	75	97.4	0	0.0
Total Protein	PI(M2)	72	0	0.0	6	8.3	66	91.7	0	0.0	77	0	0.0	2	2.6	75	97.4	0	0.0
	PI(M2)	72	0	0.0	6	8.3	66	91.7	0	0.0	77	0	0.0	2	2.6	75	97.4	0	0.0
	PI(M2)	72	0	0.0	6	8.3	66	91.7	0	0.0	77	0	0.0	2	2.6	75	97.4	0	0.0
	PI(M2)	72	0	0.0	6	8.3	66	91.7	0	0.0	77	0	0.0	2	2.6	75	97.4	0	0.0

	PII(W1)	20	1	5.0	0	0.0	19	95.0	0	0.0	24	0	0.0	0	0.0	24	100	0	0.0
	PII(M3)	70	0	0.0	3	4.3	67	95.7	0	0.0	77	0	0.0	7	9.1	70	90.9	0	0.0
		Control/HZV-3 Group																	
			Unknown			Below		Within		Above									
Laboratory parameter	Timing	N	n	%	n	%	n	%	n	%	n	%							
Albumin	PRE	75	0	0.0	12	16.0	61	81.3	2	2.7									
	PI(W1)	23	0	0.0	11	47.8	12	52.2	0	0.0									
	PI(M2)	75	0	0.0	17	22.7	55	73.3	3	4.0									
	PII(W1)	22	0	0.0	10	45.5	12	54.5	0	0.0									
	PII(M3)	75	0	0.0	17	22.7	55	73.3	3	4.0									
ALT(SGPT)	PRE	165	0	0.0	1	0.6	154	93.3	10	6.1									
	PI(M2)	164	0	0.0	1	0.6	150	91.5	13	7.9									
	PII(M3)	164	0	0.0	1	0.6	150	91.5	13	7.9									
AST(SGOT)	PRE	165	0	0.0	3	1.8	148	89.7	14	8.5									
	PI(M2)	164	0	0.0	0	0.0	151	92.1	13	7.9									
	PII(M3)	164	0	0.0	0	0.0	153	93.3	11	6.7									
Basophils	PRE	165	6	3.6	0	0.0	153	92.7	6	3.6									
	PI(M2)	164	0	0.0	1	0.6	154	93.9	9	5.5									
	PII(M3)	164	0	0.0	0	0.0	155	94.5	9	5.5									
Calcium	PRE	75	0	0.0	3	4.0	71	94.7	1	1.3									
	PI(W1)	23	0	0.0	0	0.0	22	95.7	1	4.3									
	PI(M2)	75	0	0.0	3	4.0	71	94.7	1	1.3									
	PII(W1)	22	0	0.0	0	0.0	22	100	0	0.0									
	PII(M3)	75	0	0.0	5	6.7	69	92.0	1	1.3									
Eosinophils	PRE	165	6	3.6	10	6.1	137	83.0	12	7.3									
	PI(M2)	164	0	0.0	10	6.1	142	86.6	12	7.3									
	PII(M3)	164	0	0.0	8	4.9	134	81.7	22	13.4									
Fibrinogen	PRE	75	1	1.3	0	0.0	39	52.0	35	46.7									
	PI(W1)	23	0	0.0	0	0.0	16	69.6	7	30.4									
	PI(M2)	75	1	1.3	1	1.3	35	46.7	38	50.7									
	PII(W1)	22	0	0.0	0	0.0	12	54.5	10	45.5									
	PII(M3)	75	0	0.0	1	1.3	39	52.0	35	46.7									
Hematocrit	PRE	165	0	0.0	20	12.1	137	83.0	8	4.8									
	PI(M2)	164	0	0.0	28	17.1	132	80.5	4	2.4									
	PII(M3)	164	1	0.6	25	15.2	132	80.5	6	3.7									
Hemoglobin	PRE	165	0	0.0	22	13.3	137	83.0	6	3.6									
	PI(M2)	164	0	0.0	26	15.9	134	81.7	4	2.4									
	PII(M3)	164	1	0.6	24	14.6	136	82.9	3	1.8									
Leucocytes	PRE	165	0	0.0	6	3.6	153	92.7	6	3.6									
	PI(M2)	164	0	0.0	6	3.7	147	89.6	11	6.7									
	PII(M3)	164	0	0.0	6	3.7	150	91.5	8	4.9									
Lymphocytes	PRE	165	6	3.6	17	10.3	137	83.0	5	3.0									
	PI(M2)	164	0	0.0	15	9.1	147	89.6	2	1.2									
	PII(M3)	164	0	0.0	20	12.2	142	86.6	2	1.2									
LDH	PRE	75	0	0.0	0	0.0	70	93.3	5	6.7									
	PI(W1)	23	0	0.0	0	0.0	23	100	0	0.0									
	PI(M2)	75	0	0.0	0	0.0	70	93.3	5	6.7									
	PII(W1)	22	0	0.0	0	0.0	21	95.5	1	4.5									
	PII(M3)	75	0	0.0	0	0.0	68	90.7	7	9.3									
Monocytes	PRE	165	6	3.6	0	0.0	148	89.7	11	6.7									
	PI(M2)	164	0	0.0	0	0.0	145	88.4	19	11.6									
	PII(M3)	164	0	0.0	3	1.8	148	90.2	13	7.9									
Neutrophils	PRE	165	6	3.6	3	1.8	146	88.5	10	6.1									
	PI(M2)	164	0	0.0	6	3.7	151	92.1	7	4.3									
	PII(M3)	164	0	0.0	6	3.7	149	90.9	9	5.5									

Partial Thromboplastin Time	PRE	51	0	0.0	3	5.9	43	84.3	5	9.8
	PI(W1)	0	0	0.0	0	0.0	0	0.0	0	0.0
	PI(M2)	74	1	1.4	3	4.1	64	86.5	6	8.1
	PII(W1)	22	0	0.0	1	4.5	19	86.4	2	9.1
	PII(M3)	75	0	0.0	5	6.7	62	82.7	8	10.7
Platelets	PRE	165	0	0.0	10	6.1	148	89.7	7	4.2
	PI(M2)	164	0	0.0	12	7.3	145	88.4	7	4.3
	PII(M3)	164	1	0.6	12	7.3	148	90.2	3	1.8
ProThrombin Time	PRE	51	0	0.0	5	9.8	44	86.3	2	3.9
	PI(W1)	0	0	0.0	0	0.0	0	0.0	0	0.0
	PI(M2)	74	1	1.4	7	9.5	65	87.8	1	1.4
	PII(W1)	22	0	0.0	2	9.1	20	90.9	0	0.0
	PII(M3)	75	0	0.0	8	10.7	64	85.3	3	4.0
Red Blood Cells	PRE	165	1	0.6	23	13.9	136	82.4	5	3.0
	PI(M2)	164	0	0.0	24	14.6	135	82.3	5	3.0
	PII(M3)	164	1	0.6	23	14.0	136	82.9	4	2.4
Serum Creatinine	PRE	165	0	0.0	3	1.8	135	81.8	27	16.4
	PI(M2)	164	0	0.0	3	1.8	131	79.9	30	18.3
	PII(M3)	164	0	0.0	2	1.2	134	81.7	28	17.1
Total protein	PRE	75	0	0.0	3	4.0	72	96.0	0	0.0
	PI(W1)	23	0	0.0	1	4.3	22	95.7	0	0.0
	PI(M2)	75	0	0.0	4	5.3	71	94.7	0	0.0
	PII(W1)	22	0	0.0	2	9.1	20	90.9	0	0.0
	PII(M3)	75	0	0.0	6	8.0	69	92.0	0	0.0

N = Total number of subjects with available results

n = Number of subjects in the appropriate category

% = Percentage of subjects based on the total number of subjects with available results

Pre = Pre-vaccination at Day 0

PI(W1) = 1-week Post-vaccination 1

PI(M2) = 2-months Post-vaccination 1

PII(W1) = 1-week Post-vaccination 2

PII(M3) = 1-month Post-vaccination 2

ALT= Alanine amino-transferase AST=

Aspartate amino-transferase LDH= Lactate

Dehydrogenase

Secondary Outcome Variable(s): Proportion of German subjects with haematology and biochemistry parameters below, within or above normal ranges at PI(W1) and PI(M2) time points (Total Vaccinated cohort)

			PI(W1)							PI(M2)									
			Below			Within		Above	Missing	Below				Within		Above		Missing	
Laborat. parameter	Treatmnt Group	Pre-vac. status	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Albumin	HZV-1	Below	8	8	100	0	0.00	0	0.00	0	0.00	7	87.50	0	0.00	0	0.00	1	12.50
		Within	16	3	18.75	12	75.00	0	0.00	1	6.25	1	6.25	14	87.50	0	0.00	1	6.25
	HZV-2	Below	7	7	100	0	0.00	0	0.00	0	0.00	4	57.14	3	42.86	0	0.00	0	0.00
		Within	17	5	29.41	12	70.59	0	0.00	0	0.00	4	23.53	12	70.59	1	5.88	0	0.00
	HZV-3	Below	10	10	100	0	0.00	0	0.00	0	0.00	9	90.00	1	10.00	0	0.00	0	0.00
		Within	14	2	14.29	12	85.71	0	0.00	0	0.00	1	7.14	12	85.71	0	0.00	1	7.14
	Control/ HZV-3	Below	7	7	100	0	0.00	0	0.00	0	0.00	7	100	0	0.00	0	0.00	0	0.00
		Within	17	4	23.53	12	70.59	0	0.00	1	5.88	4	23.53	13	76.47	0	0.00	0	0.00
	Control	Below	2	2	100	0	0.00	0	0.00	0	0.00	2	100	0	0.00	0	0.00	0	0.00
		Within	6	2	33.33	4	66.67	0	0.00	0	0.00	2	33.33	4	66.67	0	0.00	0	0.00
Calcium	HZV-1	Below	2	1	50.00	1	50.00	0	0.00	0	0.00	2	100	0	0.00	0	0.00	0	0.00
		Within	21	1	4.76	19	90.48	0	0.00	1	4.76	0	0.00	19	90.48	0	0.00	2	9.52
		Above	1	0	0.00	1	100	0	0.00	0	0.00	0	0.00	1	100	0	0.00	0	0.00

	HZV-2	Below	1	1	100	0	0.00	0	0.00	0	0.00	1	100	0	0.00	0	0.00	0	0.00
		Within	23	0	0.00	23	100	0	0.00	0	0.00	0	0.00	22	95.65	1	4.35	0	0.00
	HZV-3	Within	24	1	4.17	21	87.50	2	8.33	0	0.00	1	4.17	22	91.67	0	0.00	1	4.17
		Control/ HZV-3	Within	24	0	0.00	22	91.67	1	4.17	1	4.17	0	0.00	24	100	0	0.00	0
Fibrinogen	Control	Within	8	0	0.00	8	100	0	0.00	0	0.00	0	0.00	8	100	0	0.00	0	0.00
	HZV-1	Within	15	0	0.00	9	60.00	6	40.00	0	0.00	0	0.00	13	86.67	1	6.67	1	6.67
		Above	9	0	0.00	0	0.00	8	88.89	1	11.11	0	0.00	1	11.11	7	77.78	1	11.11
	HZV-2	Within	13	0	0.00	5	38.46	8	61.54	0	0.00	0	0.00	11	84.62	2	15.38	0	0.00
		Above	11	0	0.00	0	0.00	11	100	0	0.00	0	0.00	3	27.27	8	72.73	0	0.00
	HZV-3	Within	12	0	0.00	8	66.67	4	33.33	0	0.00	0	0.00	7	58.33	4	33.33	1	8.33
		Above	12	0	0.00	2	16.67	10	83.33	0	0.00	0	0.00	7	58.33	5	41.67	0	0.00
	Control/ HZV-3	Within	16	0	0.00	13	81.25	3	18.75	0	0.00	0	0.00	12	75.00	4	25.00	0	0.00
		Above	8	0	0.00	3	37.50	4	50.00	1	12.50	0	0.00	2	25.00	6	75.00	0	0.00
	Control	Within	5	0	0.00	4	80.00	1	20.00	0	0.00	0	0.00	5	100	0	0.00	0	0.00
		Above	3	0	0.00	0	0.00	3	100	0	0.00	0	0.00	0	0.00	3	100	0	0.00
LDH	HZV-1	Within	21	0	0.00	18	85.71	2	9.52	1	4.76	0	0.00	19	90.48	0	0.00	2	9.52
		Above	2	0	0.00	1	50.00	1	50.00	0	0.00	0	0.00	0	0.00	2	100	0	0.00
		Missing	1	0	0.00	0	0.00	1	100	0	0.00	0	0.00	0	0.00	1	100	0	0.00
	HZV-2	Within	19	0	0.00	19	100	0	0.00	0	0.00	0	0.00	1	73.68	5	26.3	0	0.00
		Above	5	0	0.00	3	60.00	2	40.00	0	0.00	0	0.00	4	80.00	1	20.0	0	0.00
	HZV-3	Within	20	0	0.00	19	95.00	1	5.00	0	0.00	0	0.00	1	85.00	2	10.0	1	5.00
		Above	4	0	0.00	1	25.00	3	75.00	0	0.00	0	0.00	1	25.00	3	75.0	0	0.00
	Control/ HZV-3	Within	23	0	0.00	22	95.65	0	0.00	1	4.35	0	0.00	1	78.26	5	21.7	0	0.00
		Above	1	0	0.00	1	100	0	0.00	0	0.00	0	0.00	1	100	0	0.00	0	0.00
	Control	Within	8	0	0.00	8	100	0	0.00	0	0.00	0	0.00	7	87.50	1	12.5	0	0.00
	Partial Thrombo- plastin Time	HZV-1	Missing	22	0	0.00	0	0.00	0	0.00	2	100	2	9.09	1	81.82	2	9.09	0
HZV-2		Missing	24	0	0.00	0	0.00	0	0.00	2	100	2	8.33	1	75.00	1	4.17	3	12.50
HZV-3		Missing	23	0	0.00	0	0.00	0	0.00	2	100	4	17.39	1	69.57	0	0.00	3	13.04
	Control/ HZV-3	Missing	24	0	0.00	0	0.00	0	0.00	2	100	1	4.17	2	87.50	1	4.17	1	4.17
Pro Thrombin Time	Control	Missing	8	0	0.00	0	0.00	0	0.00	8	100	0	0.00	8	100	0	0.00	0	0.00
	HZV-1	Missing	22	0	0.00	0	0.00	0	0.00	2	100	1	4.55	2	95.45	0	0.00	0	0.00
	HZV-2	Missing	24	0	0.00	0	0.00	0	0.00	2	100	1	4.17	2	83.33	0	0.00	3	12.50
Total Protein	HZV-3	Missing	23	0	0.00	0	0.00	1	4.35	2	95.6	0	0.00	2	86.96	0	0.00	3	13.04
		Control/ HZV-3	Missing	24	0	0.00	0	0.00	0	0.00	2	100	2	8.33	2	87.50	0	0.00	1
	Control	Missing	8	0	0.00	0	0.00	0	0.00	8	100	0	0.00	8	100	0	0.00	0	0.00
	Total Protein	HZV-1	Below	2	0	0.00	2	100	0	0.00	0	0.00	2	100	0	0.00	0	0.00	0
Within			22	0	0.00	21	95.45	0	0.00	1	4.55	0	0.00	2	90.91	0	0.00	2	9.09
HZV-2		Within	24	0	0.00	24	100	0	0.00	0	0.00	0	0.00	2	100	0	0.00	0	0.00
HZV-3		Below	1	0	0.00	1	100	0	0.00	0	0.00	0	0.00	1	100	0	0.00	0	0.00
		Within	23	2	8.70	21	91.30	0	0.00	0	0.00	3	13.04	1	82.61	0	0.00	1	4.35
Control/ HZV-3	Within	24	1	4.17	22	91.67	0	0.00	1	4.17	2	8.33	2	91.67	0	0.00	0	0.00	
Control	Within	8	0	0.00	8	100	0	0.00	0	0.00	1	12.50	7	87.50	0	0.00	0	0.00	

N = Total number of subjects with available results n

= Number of subjects in the appropriate category

% = Percentage of subjects based on the total number of subjects with available results

PI(W1) = 1-week Post-vaccination 1

PI(M2) = 2 months Post-vaccination 1

LDH= Lactate Dehydrogenase

Secondary Outcome Variable(s): Proportion of German subjects with haematology and biochemistry parameters below, within or above normal ranges at PII(W1) and PII(M2) time points (Total Vaccinated cohort)

				PII(W1)								PII(M2)							
				Below		Within		Above		Missing		Below		Within		Above		Missing	
Laborat. parameter	Treatmnt Group	Pre-vac. status	N	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Albumin	HZV-1	Below	8	4	50.00	1	12.50	0	0.00	3	37.50	5	62.50	2	25.00	0	0.00	1	12.50
		Within	16	2	12.50	12	75.00	0	0.00	2	12.50	0	0.00	15	93.75	0	0.00	1	6.25
	HZV-2	Below	7	6	85.71	1	14.29	0	0.00	0	0.00	4	57.14	3	42.86	0	0.00	0	0.00
		Within	17	2	11.76	15	88.24	0	0.00	0	0.00	0	0.00	17	100	0	0.00	0	0.00
	HZV-3	Below	10	8	80.00	1	10.00	0	0.00	1	10.00	6	60.00	4	40.00	0	0.00	0	0.00
		Within	14	2	14.29	11	78.57	0	0.00	1	7.14	2	14.29	10	71.43	0	0.00	2	14.29
	Control/HZV-3	Below	7	6	85.71	0	0.00	0	0.00	1	14.29	6	85.71	1	14.29	0	0.00	0	0.00
		Within	17	4	23.53	12	70.59	0	0.00	1	5.88	5	29.41	12	70.59	0	0.00	0	0.00
	Control	Below	2	2	100	0	0.00	0	0.00	0	0.00	1	50.00	1	50.00	0	0.00	0	0.00
		Within	6	1	16.67	5	83.33	0	0.00	0	0.00	2	33.33	4	66.67	0	0.00	0	0.00
Calcium	HZV-1	Below	2	1	50.00	0	0.00	0	0.00	1	50.00	2	100	0	0.00	0	0.00	0	0.00
		Within	21	0	0.00	16	76.19	1	4.76	4	19.05	0	0.00	19	90.48	0	0.00	2	9.52
		Above	1	0	0.00	1	100	0	0.00	0	0.00	0	0.00	0	0.00	1	100	0	0.00
	HZV-2	Below	1	0	0.00	1	100	0	0.00	0	0.00	0	0.00	1	100	0	0.00	0	0.00
		Within	23	0	0.00	23	100	0	0.00	0	0.00	0	0.00	23	100	0	0.00	0	0.00
		Above	0	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Fibrinogen	HZV-3	Within	24	2	8.33	20	83.33	0	0.00	2	8.33	0	0.00	22	91.67	0	0.00	2	8.33
		Control/	24	0	0.00	22	91.67	0	0.00	2	8.33	1	4.17	23	95.83	0	0.00	0	0.00
	Control	Within	8	0	0.00	8	100	0	0.00	0	0.00	0	0.00	8	100	0	0.00	0	0.00
		Above	0	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	HZV-1	Within	15	0	0.00	8	53.33	5	33.33	2	13.33	0	0.00	12	80.00	2	13.33	1	6.67
		Above	9	0	0.00	0	0.00	6	66.67	3	33.33	0	0.00	2	22.22	6	66.67	1	11.11
LDH	HZV-2	Within	13	0	0.00	8	61.54	5	38.46	0	0.00	0	0.00	11	84.62	2	15.38	0	0.00
		Above	11	0	0.00	1	9.09	10	90.91	0	0.00	0	0.00	4	36.36	7	63.64	0	0.00
	HZV-3	Within	12	0	0.00	6	50.00	5	41.67	1	8.33	0	0.00	9	75.00	1	8.33	2	16.67
		Above	12	0	0.00	3	25.00	8	66.67	1	8.33	0	0.00	4	33.33	8	66.67	0	0.00
	Control/HZV-3	Within	16	0	0.00	11	68.75	3	18.75	2	12.50	1	6.25	11	68.75	4	25.00	0	0.00
		Above	8	0	0.00	1	12.50	7	87.50	0	0.00	0	0.00	3	37.50	5	62.50	0	0.00
	Control	Within	5	0	0.00	4	80.00	1	20.00	0	0.00	0	0.00	4	80.00	1	20.00	0	0.00
		Above	3	0	0.00	0	0.00	3	100	0	0.00	0	0.00	1	33.33	2	66.67	0	0.00
	HZV-1	Within	21	0	0.00	14	66.67	2	9.52	5	23.81	0	0.00	17	80.95	2	9.52	2	9.52
		Above	2	0	0.00	0	0.00	2	100	0	0.00	0	0.00	1	50.00	1	50.00	0	0.00
		Missing	1	0	0.00	1	100	0	0.00	0	0.00	0	0.00	1	100	0	0.00	0	0.00
Partial Thrombo-plastin Time	HZV-2	Within	19	0	0.00	16	84.21	3	15.79	0	0.00	0	0.00	16	84.21	3	15.79	0	0.00
		Above	5	0	0.00	4	80.00	1	20.00	0	0.00	0	0.00	2	40.00	3	60.00	0	0.00
	HZV-3	Within	20	0	0.00	15	75.00	3	15.00	2	10.00	0	0.00	17	85.00	2	10.00	1	5.00
		Above	4	0	0.00	1	25.00	3	75.00	0	0.00	0	0.00	1	25.00	2	50.00	1	25.00
	Control/HZV-3	Within	23	0	0.00	20	86.96	1	4.35	2	8.70	0	0.00	19	82.61	4	17.39	0	0.00
		Above	1	0	0.00	1	100	0	0.00	0	0.00	0	0.00	1	100	0	0.00	0	0.00
	Control	Within	8	0	0.00	8	100	0	0.00	0	0.00	0	0.00	7	87.50	1	12.50	0	0.00
		Above	0	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Pro Thrombin Time	HZV-1	Missing	22	1	4.55	18	81.82	1	4.55	3	13.64	1	4.55	20	90.91	1	4.55	0	0.00
		Within	24	1	4.17	22	91.67	1	4.17	0	0.00	2	8.33	20	83.33	2	8.33	0	0.00
	HZV-2	Missing	23	2	8.70	20	86.96	0	0.00	1	4.35	4	17.39	18	78.26	0	0.00	1	4.35
		Within	24	1	4.17	19	79.17	2	8.33	2	8.33	2	8.33	21	87.50	1	4.17	0	0.00
	Control/	Missing	8	0	0.00	8	100	0	0.00	0	0.00	1	12.50	7	87.50	0	0.00	0	0.00

Total Protein	HZV-3																		
	Control	Missing	8	0	0.00	8	100	0	0.00	0	0.00	0	0.00	8	100	0	0.00	0	0.00
	HZV-1	Below	2	0	0.00	0	0.00	0	0.00	2	100	0	0.00	2	100	0	0.00	0	0.00
		Within	22	0	0.00	19	86.36	0	0.00	3	13.64	0	0.00	20	90.91	0	0.00	2	9.09
	HZV-2	Within	24	0	0.00	24	100	0	0.00	0	0.00	2	8.33	22	91.67	0	0.00	0	0.00
	HZV-3	Below	1	0	0.00	1	100	0	0.00	0	0.00	1	100	0	0.00	0	0.00	0	0.00
		Within	23	2	8.70	19	82.61	0	0.00	2	8.70	1	4.35	20	86.96	0	0.00	2	8.70
	Control/ HZV-	Within	24	2	8.33	20	83.33	0	0.00	2	8.33	3	12.50	21	87.50	0	0.00	0	0.00
	Control	Within	8	0	0.00	8	100	0	0.00	0	0.00	0	0.00	8	100	0	0.00	0	0.00

N = Total number of subjects with available results n =

Number of subjects in the appropriate category

% = Percentage of subjects based on the total number of subjects with available results

PII(W1) = 1 week Post-vaccination 2

PII(M3) = 1 month Post-vaccination 2

LDH= Lactate Dehydrogenase

Secondary Outcome Variable(s): Number (%) of subjects with solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and across doses (Total Vaccinated cohort)

		HZV-1 Group					HZV-2 Group					HZV-3 Group				
					95 % CI					95 % CI					95 % CI	
Symptom	Intensity	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Pain	Any	164	94	57.3	49.4	65.0	166	11	66.3	58.5	73.4	165	99	60.0	52.1	67.5
	Grade 3	164	0	0.0	0.0	2.2	166	0	0.0	0.0	2.2	165	3	1.8	0.4	5.2
Redness	Any	164	40	24.4	18.0	31.7	166	49	29.5	22.7	37.1	165	43	26.1	19.5	33.5
	>100 mm	164	2	1.2	0.1	4.3	166	2	1.2	0.1	4.3	165	3	1.8	0.4	5.2
Swelling	Any	164	26	15.9	10.6	22.4	166	21	12.7	8.0	18.7	165	24	14.5	9.5	20.9
	>100 mm	164	1	0.6	0.0	3.4	166	2	1.2	0.1	4.3	165	2	1.2	0.1	4.3
Dose 2																
Pain	Any	159	99	62.3	54.2	69.8	164	93	56.7	48.8	64.4	161	99	61.5	53.5	69.0
	Grade 3	159	4	2.5	0.7	6.3	164	3	1.8	0.4	5.3	161	3	1.9	0.4	5.3
Redness	Any	159	51	32.1	24.9	39.9	164	54	32.9	25.8	40.7	161	52	32.3	25.2	40.1
	>100 mm	159	1	0.6	0.0	3.5	164	3	1.8	0.4	5.3	161	2	1.2	0.2	4.4
Swelling	Any	159	30	18.9	13.1	25.8	164	23	14.0	9.1	20.3	161	30	18.6	12.9	25.5
	>100 mm	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2	161	1	0.6	0.0	3.4
Across doses																
Pain	Any	164	115	70.1	62.5	77.0	166	12	72.9	65.5	79.5	165	122	73.9	66.5	80.5
	Grade 3	164	4	2.4	0.7	6.1	166	3	1.8	0.4	5.2	165	6	3.6	1.3	7.7
Redness	Any	164	68	41.5	33.8	49.4	166	66	39.8	32.3	47.6	165	68	41.2	33.6	49.1
	>100 mm	164	2	1.2	0.1	4.3	166	5	3.0	1.0	6.9	165	4	2.4	0.7	6.1
Swelling	Any	164	44	26.8	20.2	34.3	166	33	19.9	14.1	26.8	165	45	27.3	20.6	34.7
	>100 mm	164	1	0.6	0.0	3.4	166	2	1.2	0.1	4.3	165	2	1.2	0.1	4.3
		Control/HZV-3 Group					Control Group									
					95 % CI					95 % CI					95 % CI	
Symptom	Intensity	N	n	%	LL	U	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Pain	Any	165	2	1.2	0.1	4.3	54	7	13.0	5.4	24.9					
	Grade 3	165	0	0.0	0.0	2.2	54	0	0.0	0.0	6.6					
Redness	Any	165	1	0.6	0.0	3.3	54	2	3.7	0.5	12.7					
	>100 mm	165	0	0.0	0.0	2.2	54	0	0.0	0.0	6.6					
Swelling	Any	165	3	1.8	0.4	5.2	54	1	1.9	0.0	9.9					
	>100 mm	165	0	0.0	0.0	2.2	54	0	0.0	0.0	6.6					
Dose 2																
Pain	Any	163	93	57.1	49.1	64.8	51	4	7.8	2.2	18.9					

	Grade 3	163	3	1.8	0.4	5.3	51	0	0.0	0.0	7.0					
Redness	Any	163	48	29.4	22.6	37.1	51	2	3.9	0.5	13.5					
	>100 mm	163	2	1.2	0.1	4.4	51	0	0.0	0.0	7.0					
Swelling	Any	163	27	16.6	11.2	23.2	51	0	0.0	0.0	7.0					
	>100 mm	163	0	0.0	0.0	2.2	51	0	0.0	0.0	7.0					
Across doses																
Pain	Any	165	93	56.4	48.4	64.1	54	9	16.7	7.9	29.3					
	Grade 3	165	3	1.8	0.4	5.2	54	0	0.0	0.0	6.6					
Redness	Any	165	49	29.7	22.8	37.3	54	2	3.7	0.5	12.7					
	>100 mm	165	2	1.2	0.1	4.3	54	0	0.0	0.0	6.6					
Swelling	Any	165	30	18.2	12.6	24.9	54	1	1.9	0.0	9.9					
	>100 mm	165	0	0.0	0.0	2.2	54	0	0.0	0.0	6.6					
N= number of subjects with at least one documented dose n/%= number/percentage of subjects reporting at least once the symptom 95% CI= Exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit Any= occurrence of any local symptom regardless of intensity grade Grade 3 pain= pain that prevented normal activity																
Secondary Outcome Variable(s): Number (%) of subjects with solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and across doses (Total Vaccinated cohort)																
		HZV-1 Group					HZV-2 Group					HZV-3 Group				
					95 % CI					95 % CI					95 % CI	
Symptom	Intensity/ Relationship	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Fatigue	Any	164	36	22.0	15.9	29.1	166	48	28.9	22.2	36.4	165	46	27.9	21.2	35.4
	Grade 3	164	1	0.6	0.0	3.4	166	2	1.2	0.1	4.3	165	2	1.2	0.1	4.3
	Related	164	30	18.3	12.7	25.1	166	34	20.5	14.6	27.4	165	34	20.6	14.7	27.6
Fever/ (Orally)	≥ 37.5°C	164	7	4.3	1.7	8.6	166	7	4.2	1.7	8.5	165	5	3.0	1.0	6.9
	> 39.0°C	164	0	0.0	0.0	2.2	166	0	0.0	0.0	2.2	165	0	0.0	0.0	2.2
	Related	164	7	4.3	1.7	8.6	166	5	3.0	1.0	6.9	165	3	1.8	0.4	5.2
Headache	Any	164	23	14.0	9.1	20.3	166	25	15.1	10.0	21.4	165	24	14.5	9.5	20.9
	Grade 3	164	0	0.0	0.0	2.2	166	0	0.0	0.0	2.2	165	2	1.2	0.1	4.3
	Related	164	19	11.6	7.1	17.5	166	17	10.2	6.1	15.9	165	13	7.9	4.3	13.1
Myalgia	Any	164	48	29.3	22.4	36.9	166	57	34.3	27.2	42.1	165	46	27.9	21.2	35.4
	Grade 3	164	1	0.6	0.0	3.4	166	2	1.2	0.1	4.3	165	2	1.2	0.1	4.3
	Related	164	41	25.0	18.6	32.3	166	52	31.3	24.4	39.0	165	41	24.8	18.5	32.2
Dose 2																
Fatigue	Any	159	56	35.2	27.8	43.2	164	70	42.7	35.0	50.6	161	52	32.3	25.2	40.1
	Grade 3	159	2	1.3	0.2	4.5	164	6	3.7	1.4	7.8	161	4	2.5	0.7	6.2
	Related	159	47	29.6	22.6	37.3	164	48	29.3	22.4	36.9	161	43	26.7	20.1	34.2
Fever/ (Orally)	≥ 37.5°C	159	13	8.2	4.4	13.6	164	13	7.9	4.3	13.2	161	18	11.2	6.8	17.1
	> 39.0°C	159	0	0.0	0.0	2.3	164	1	0.6	0.0	3.4	161	0	0.0	0.0	2.3
	Related	159	12	7.5	4.0	12.8	164	12	7.3	3.8	12.4	161	18	11.2	6.8	17.1
Headache	Any	159	39	24.5	18.1	32.0	164	47	28.7	21.9	36.2	161	39	24.2	17.8	31.6
	Grade 3	159	2	1.3	0.2	4.5	164	3	1.8	0.4	5.3	161	2	1.2	0.2	4.4
	Related	159	32	20.1	14.2	27.2	164	32	19.5	13.7	26.4	161	35	21.7	15.6	28.9
Myalgia	Any	159	59	37.1	29.6	45.1	164	71	43.3	35.6	51.2	161	59	36.6	29.2	44.6
	Grade 3	159	4	2.5	0.7	6.3	164	7	4.3	1.7	8.6	161	4	2.5	0.7	6.2
	Related	159	52	32.7	25.5	40.6	164	61	37.2	29.8	45.1	161	57	35.4	28.0	43.3
Across doses																
Fatigue	Any	164	69	42.1	34.4	50.0	166	85	51.2	43.3	59.0	165	73	44.2	36.5	52.2
	Grade 3	164	3	1.8	0.4	5.3	166	7	4.2	1.7	8.5	165	6	3.6	1.3	7.7
	Related	164	57	34.8	27.5	42.6	166	60	36.1	28.8	44.0	165	59	35.8	28.5	43.6
Fever/ (Orally)	≥37.5°C	164	19	11.6	7.1	17.5	166	18	10.8	6.6	16.6	165	22	13.3	8.5	19.5
	> 39.0°C	164	0	0.0	0.0	2.2	166	1	0.6	0.0	3.3	165	0	0.0	0.0	2.2

)	Related	164	18	11.0	6.6	16.8	166	15	9.0	5.1	14.5	165	20	12.1	7.6	18.1
Headache	Any	164	47	28.7	21.9	36.2	166	59	35.5	28.3	43.3	165	51	30.9	24.0	38.6
	Grade 3	164	2	1.2	0.1	4.3	166	3	1.8	0.4	5.2	165	4	2.4	0.7	6.1
	Related	164	39	23.8	17.5	31.0	166	41	24.7	18.3	32.0	165	42	25.5	19.0	32.8
Myalgia	Any	164	74	45.1	37.4	53.1	166	89	53.6	45.7	61.4	165	70	42.4	34.8	50.3
	Grade 3	164	5	3.0	1.0	7.0	166	8	4.8	2.1	9.3	165	6	3.6	1.3	7.7
	Related	164	66	40.2	32.7	48.2	166	80	48.2	40.4	56.1	165	67	40.6	33.0	48.5
		Control/HZV-3 Group								Control Group						
						95 % CI							95 % CI			
Symptom	Intensity/ Relationship	N	n	%	LL	UL	N	n	%	LL	UL					
Dose 1																
Fatigue	Any	165	20	12.1	7.6	18.1	54	8	14.8	6.6	27.1					
	Grade 3	165	2	1.2	0.1	4.3	54	1	1.9	0.0	9.9					
	Related	165	12	7.3	3.8	12.4	54	6	11.1	4.2	22.6					
Fever/ (Orally)	≥37.5°C	165	4	2.4	0.7	6.1	54	0	0.0	0.0	6.6					
	> 39.0°C	165	0	0.0	0.0	2.2	54	0	0.0	0.0	6.6					
	Related	165	4	2.4	0.7	6.1	54	0	0.0	0.0	6.6					
Headache	Any	165	13	7.9	4.3	13.1	54	7	13.0	5.4	24.9					
	Grade 3	165	0	0.0	0.0	2.2	54	0	0.0	0.0	6.6					
	Related	165	6	3.6	1.3	7.7	54	6	11.1	4.2	22.6					
Myalgia	Any	165	11	6.7	3.4	11.6	54	8	14.8	6.6	27.1					
	Grade 3	165	1	0.6	0.0	3.3	54	0	0.0	0.0	6.6					
	Related	165	10	6.1	2.9	10.9	54	6	11.1	4.2	22.6					
Dose 2																
Fatigue	Any	163	38	23.3	17.1	30.6	51	9	17.6	8.4	30.9					
	Grade 3	163	1	0.6	0.0	3.4	51	0	0.0	0.0	7.0					
	Related	163	27	16.6	11.2	23.2	51	7	13.7	5.7	26.3					
Fever/ (Orally)	≥37.5°C	163	5	3.1	1.0	7.0	51	0	0.0	0.0	7.0					
	> 39.0°C	163	0	0.0	0.0	2.2	51	0	0.0	0.0	7.0					
	Related	163	5	3.1	1.0	7.0	51	0	0.0	0.0	7.0					
Headache	Any	163	27	16.6	11.2	23.2	51	7	13.7	5.7	26.3					
	Grade 3	163	0	0.0	0.0	2.2	51	0	0.0	0.0	7.0					
	Related	163	21	12.9	8.2	19.0	51	5	9.8	3.3	21.4					
Myalgia	Any	163	46	28.2	21.5	35.8	51	5	9.8	3.3	21.4					
	Grade 3	163	2	1.2	0.1	4.4	51	0	0.0	0.0	7.0					
	Related	163	41	25.2	18.7	32.5	51	4	7.8	2.2	18.9					
Across doses																
Fatigue	Any	165	47	28.5	21.7	36.0	54	1	22.2	12.0	35.6					
	Grade 3	165	3	1.8	0.4	5.2	54	1	1.9	0.0	9.9					
	Related	165	33	20.0	14.2	26.9	54	9	16.7	7.9	29.3					
Fever/ (Orally)	≥37.5°C	165	9	5.5	2.5	10.1	54	0	0.0	0.0	6.6					
	> 39.0°C	165	0	0.0	0.0	2.2	54	0	0.0	0.0	6.6					
	Related	165	9	5.5	2.5	10.1	54	0	0.0	0.0	6.6					
Headache	Any	165	36	21.8	15.8	28.9	54	9	16.7	7.9	29.3					
	Grade 3	165	0	0.0	0.0	2.2	54	0	0.0	0.0	6.6					
	Related	165	25	15.2	10.1	21.5	54	7	13.0	5.4	24.9					
Myalgia	Any	165	49	29.7	22.8	37.3	54	9	16.7	7.9	29.3					
	Grade 3	165	3	1.8	0.4	5.2	54	0	0.0	0.0	6.6					
	Related	165	46	27.9	21.2	35.4	54	7	13.0	5.4	24.9					

N= number of subjects with at least one documented dose n/= number/percentage of subjects reporting at least once the symptom 95% CI= Exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit Any= occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination Grade 3 symptoms = symptoms that prevented normal activity Related= general symptom assessed by the investigator as causally related to the study vaccination					
Secondary Outcome Variable(s): Percentage of subjects reporting the occurrence of clinically diagnosed HZ episodes from Month 0 to Month 3 (Total Vaccinated cohort)					
HZ rash	HZV-1 Group (N = 164)	HZV-2 Group (N = 166)	HZV-3 Group (N=165)	Control/HZV-3 Group (N = 165)	Control Group (N = 54)
Subjects with any HZ rash, n (%)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Secondary Outcome Variable(s): Percentage of subjects reporting the occurrence of clinically diagnosed HZ episodes from Month 3 to Month 12 (Total cohort for persistence Month 12)					
HZ rash	HZV-1 Group (N = 156)	HZV-2 Group (N = 159)	HZV-3 Group (N=159)	Control/ HZV-3 Group (N = 161)	Control Group (N = 50)
Subjects with any HZ rash, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)
Secondary Outcome Variable(s): Percentage of subjects reporting the occurrence of clinically diagnosed HZ episodes from Month 12 to Month 24 (Total cohort for persistence Month 24)					
HZ rash	HZV-1 Group (N = 150)	HZV-2 Group (N = 155)	HZV-3 Group (N=154)	Control/ HZV-3 Group (N = 157)	Control Group (N = 49)
Subjects with any HZ rash, n (%)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Secondary Outcome Variable(s): Percentage of subjects reporting the occurrence of clinically diagnosed HZ episodes from Month 24 to Month 36 (Total cohort for persistence Month 36)					
HZ rash	HZV-1 Group (N = 147)	HZV-2 Group (N = 147)	HZV-3 Group (N=150)	Control/ HZV-3 Group (N = 155)	Control Group (N = 47)
Subjects with any HZ rash, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Safety Results: Number (%) of subjects with unsolicited AEs within the 30-day (Days 0-29) post-vaccination period (Total Vaccinated cohort)					
Most frequent adverse events - On-Therapy (occurring within Days 0-29 following vaccination)	HZV-1 Group N= 164	HZV-2 Group N = 166	HZV-3 Group N = 165	Control/HZV-3 Group N = 165	Control Group N = 54
Subjects with any AE(s), n (%)	55 (33.5)	52 (31.3)	54 (32.7)	41 (24.8)	16 (29.6)
Subjects with grade 3 AE(s), n (%)	7 (4.3)	10 (6.0)	10 (6.1)	5 (3.0)	4 (7.4)
Subjects with related AE(s), n (%)	20 (12.2)	22 (13.3)	24 (14.5)	13 (7.9)	2 (3.7)
Cataract	-	-	-	2 (1.2)	-
Retinal disorder	-	-	-	-	1 (1.9)
Diarrhoea	-	3 (1.8)	-	-	-
Gastritis	2 (1.2)	-	-	-	-
Nausea	-	3 (1.8)	3 (1.8)	2 (1.2)	1 (1.9)
Asthenia	-	-	-	-	1 (1.9)
Chills	4 (2.4)	4 (2.4)	-	-	-
Feeling cold	2 (1.2)	-	-	-	-
Influenza like illness	4 (2.4)	-	-	-	-
Injection site erythema	-	-	-	2 (1.2)	-
Injection site haematoma	-	-	-	2 (1.2)	2 (3.7)
Injection site pruritus	3 (1.8)	-	7 (4.2)	3 (1.8)	-
Injection site warmth	2 (1.2)	-	-	-	-
Bronchitis	2 (1.2)	-	-	-	1 (1.9)
Genital herpes	-	-	-	-	1 (1.9)
Influenza	2 (1.2)	-	-	-	-
Nasopharyngitis	-	3 (1.8)	3 (1.8)	2 (1.2)	1 (1.9)
Oral herpes	-	-	-	-	1 (1.9)

Pharyngitis	-	-	-	-	1 (1.9)
Pharyngitis bacterial	-	-	-	-	1 (1.9)
Urinary tract infection	-	3 (1.8)	-	2 (1.2)	-
Foot fracture	-	-	-	-	1 (1.9)
Wound	-	--	-	-	1 (1.9)
Arthralgia	-	-	4 (2.4)	-	1 (1.9)
Arthritis	2 (1.2)	-	-	-	-
Back pain	7 (4.3)	-	5 (3.0)	-	1 (1.9)
Muscle spasms	2 (1.2)	-	-	-	-
Osteoarthritis	-	-	-	2 (1.2)	-
Pain in extremity	2 (1.2)	-	-	3 (1.8)	-
Breast cancer	-	-	-	-	1 (1.9)
Dizziness	2 (1.2)	3 (1.8)	-	-	-
Headache	2 (1.2)	-	-	-	-
Tremor	2 (1.2)	-	3 (1.8)	-	-
Asthma	-	-	-	-	1 (1.9)
Cough	2 (1.2)	-	-	-	-
Pharyngolaryngeal pain	-	-	-	-	1 (1.9)
Eczema	2 (1.2)	-	-	2 (1.2)	-
Pruritus	-	-	-	-	1 (1.9)
Aortic stenosis	-	-	-	-	1 (1.9)
Hypertension	-	-	-	-	1 (1.9)
Varicose vein	-	-	-	-	1 (1.9)

Counting rule applied: As there were more than 30 subjects per treatment group and > 3 groups, only the 5 most frequent events in each treatment group are to be listed.

- : Implies that adverse event was not reported in the particular group or that the adverse event was reported in the particular group but did not fall within the pre-defined counting rule of 5 most frequent events for that group

Grade 3 AE= event which prevented normal, everyday activities

Related AE= event assessed by the investigator as causally related to the study vaccine

Safety Results: Number (%) of subjects with SAEs from Month 0 up to Month 3 (Total Vaccinated cohort)

Serious adverse events, n (%) [n considered by the investigator to be related to the medication]

All SAEs	HZV-1 Group N = 164	HZV-2 Group N = 166	HZV-3 Group N= 165	Control/HZV-3 Group N = 165	Control Group N = 54
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	2 (1.2) [0]	4 (2.4) [0]	3 (1.8) [0]	6 (3.6) [0]	3 (5.6) [0]
Coronary artery disease	2 (1.2) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Anaemia	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Haemorrhoidal haemorrhage	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Hypertension	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Ankle fracture	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Cerebral ischemia	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Colitis ulcerative	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Angina pectoris	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	1 (0.6) [0]	0 (0.0) [0]
Drowning	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Venous thrombosis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Atrial fibrillation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Diverticulitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Bronchial carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Gastritis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Cholecystitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Colon cancer	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Retinal detachment	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (1.9) [0]
Aortic stenosis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (1.9) [0]
Breast cancer	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (1.9) [0]

Fatal SAEs	HZV-1 Group N = 164	HZV-2 Group N = 166	HZV-3 Group N = 165	Control/HZV-3 Group N = 165	Control Group N = 54
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	1 (0.6) [0]*	0 (0.0) [0]
Drowning	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Bronchial carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
*The subject received one dose of saline at first vaccination and died during the long-term safety follow-up period after Month 3.					
Safety results: Number (%) of subjects with SAEs from Month 3 to Month 12 (Total cohort for persistence Month 12)					
Serious adverse events, n (%) [n considered by the investigator to be related to the medication]					
All SAEs	HZV-1 Group N = 156	HZV-2 Group N = 159	HZV-3 Group N	Control/HZV-3 Group N = 161	Control Group N = 50
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	11 (7.1) [0]	14 (8.8) [0]	11 (6.9)	16 (9.9) [0]	3 (6.0) [0]
Angina pectoris	0 (0.0) [0]	1 (0.6) [0]	1 (0.6)	1 (0.6) [0]	0 (0.0) [0]
Transient ischaemic attack	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	2 (1.2) [0]	0 (0.0) [0]
Atrial fibrillation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	2 (1.2) [0]	0 (0.0) [0]
Gastric ulcer	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Inguinal hernia	0 (0.0) [0]	1 (0.6) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Rectal cancer	1 (0.6) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Spinal column stenosis	1 (0.6) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Syncope	2 (1.2) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Allergy to arthropod bite	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Anaemia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Ankle fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Arteriosclerosis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Arthralgia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	1 (2.0) [0]
Bile duct stone	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Bone cyst	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Breast cancer	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Bronchitis	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Cardiac failure	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Cerebellar infarction	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Cerebrovascular accident	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Cervical vertebral fracture	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Chest pain	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Cholecystitis	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Chronic obstructive pulmonary disease	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Circulatory collapse	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Colon adenoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Colon cancer	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Contusion	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Coronary artery stenosis	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Diabetic gangrene	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Diverticulitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Duodenal ulcer	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
General physical health deterioration	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Haemorrhage	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Humerus fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Ileus paralytic	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Joint dislocation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Ligament rupture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	1 (2.0) [0]
Lymphangitis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Malignant melanoma	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]

Meniere's disease	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Meniscus lesion	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Myocardial infarction	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Osteoarthritis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Osteoporotic fracture	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Pancreatitis acute	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Radius fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Rib fracture	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Sick sinus syndrome	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Subileus	0 (0.0) [0]	1 (0.6) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Tenosynovitis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Tooth injury	1 (0.6) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	0 (0.0) [0]
Uterine prolapse	0 (0.0) [0]	0 (0.0) [0]	1 (0.6)	0 (0.0) [0]	0 (0.0) [0]
Vertigo	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	0 (0.0) [0]	1 (2.0) [0]
Wrist fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Fatal SAEs	HZV-1 Group N = 156	HZV-2 Group N = 159	HZV-3 Group N	Control/HZV-3 Group N = 161	Control Group N = 50
Subjects with fatal SAE (s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Diabetic gangrene	0 (0.0) [0]	0 (0.0) [0]	0 (0.0)	1 (0.6) [0]	0 (0.0) [0]
Safety results: Number (%) of subjects with SAEs from Month 12 to Month 24 (Total Cohort for persistence Month 24)					
Serious adverse events, n (%) [n considered by the investigator to be related to the medication]					
All SAEs	HZV-1 Group N = 150	HZV-2 Group N = 155	HZV-3 Group N=154	Control/HZV-3 Group N = 157	Control Group N = 49
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	21 (14.0) [0]	27 (17.4) [0]	29 (18.8) [0]	25 (15.9) [0]	11 (22.4) [0]
Asbestosis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Angina pectoris	0 (0.0) [0]	1 (0.6) [0]	2 (1.3) [0]	0 (0.0) [0]	0 (0.0) [0]
Amyloidosis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Appendicitis	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Atrial fibrillation	0 (0.0) [0]	2 (1.3) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Atrioventricular block first degree	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Inguinal hernia	0 (0.0) [0]	2 (1.3) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Salivary gland neoplasm	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Spinal column stenosis	0 (0.0) [0]	2 (1.3) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Arrhythmia supraventricular	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Humerus fracture	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Angiomyolipoma	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Varicose vein	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Orthostatic hypotension	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Back disorder	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Back pain	1 (0.7) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Breast cancer	1 (0.7) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Benign prostatic hyperplasia	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Bladder cancer	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	1 (0.6) [0]	0 (0.0) [0]
Bile duct stenosis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Bradyarrhythmia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (4.1) [0]
Cardiac failure	2 (1.3) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Cardiomyopathy	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Cerebral ischaemia	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Cerebrovascular accident	1 (0.7) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Cardiac failure congestive	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Carpal tunnel syndrome	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Chest pain	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]

Carotid artery stenosis	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Chronic obstructive pulmonary disease	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Confusional state	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Cystocele	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Hypertension	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Hypertensive crisis	0 (0.0) [0]	0 (0.0) [0]	2 (1.3) [0]	0 (0.0) [0]	0 (0.0) [0]
Syncope	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Cyst	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Colitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Colon cancer	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Drop attacks	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Coronary artery disease	1 (0.7) [0]	2 (1.3) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Depression	1 (0.7) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	1 (2.0) [0]
Dehydration	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Device dislocation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Diverticulitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Dizziness	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Dyspnoea	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Epilepsy	0 (0.0) [0]	1 (0.6) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Femoral neck fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Femoral arterial stenosis	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Femur fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Gait disturbance	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Haemangiopericytoma	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Haematuria	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Hand fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Helicobacter gastritis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Intestinal polyp	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Gastric ulcer	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Gastroenteritis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Gastrointestinal angiodysplasia	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Gastrointestinal haemorrhage	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Groin pain	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Hypopharyngeal cancer stage iii	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Intervertebral disc protrusion	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Lumbar spinal stenosis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Lung neoplasm malignant	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Sinoatrial block	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Sinusitis aspergillus	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Melanoma recurrent	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Malignant melanoma	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Partial seizures	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Peripheral arterial occlusive disease	1 (0.7) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Peptic ulcer perforation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Post procedural haematoma	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	1 (0.6) [0]	0 (0.0) [0]
Pleural mesothelioma	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Prostate cancer	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Prostate cancer recurrent	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Muscle atrophy	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Myocardial infarction	1 (0.7) [0]	1 (0.6) [0]	1 (0.6) [0]	1 (0.6) [0]	0 (0.0) [0]
Myocardial ischaemia	1 (0.7) [0]	1 (0.6) [0]	2 (1.3) [0]	1 (0.6) [0]	0 (0.0) [0]
Osteoarthritis	1 (0.7) [0]	1 (0.6) [0]	2 (1.3) [0]	1 (0.6) [0]	1 (2.0) [0]
Oliguria	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Rash	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Renal failure acute	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Renal cancer	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]

Rectal prolapse	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Radius fracture	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Rotator cuff syndrome	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Renal neoplasm	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Squamous cell carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Transient ischaemic attack	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Tachyarrhythmia	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Tibia fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	1 (2.0) [0]
Tooth disorder	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Upper respiratory tract infection	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Upper gastrointestinal haemorrhage	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Uterine polyp	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Urinary tract infection	1 (0.7) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Urosepsis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Vascular encephalopathy	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Vestibular disorder	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Pneumonia	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Pseudomembranous colitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Metastases to bone/liver	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Bronchitis chronic	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Sudden death	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Pancreatic carcinoma metastatic	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Transitional cell carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Fatal SAEs	HZV-1 Group	HZV-2 Group	HZV-3 Group	Control/HZV-3	Control
	N = 150	N = 155	N=154	Group N = 157	Group N = 49
Subjects with fatal SAE (s), n (%) [n assessed by the investigator as related]	2 (1.3) [0]	3 (2.0) [0]	2 (1.2) [0]	3 (1.9) [0]	1 (2.0) [0]
Peripheral arterial occlusive disease	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Lung neoplasm malignant	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Metastases to bone/liver	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Hypopharyngeal cancer stage III	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Sudden death	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Amyloidosis	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Pancreatic carcinoma metastatic	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Transitional cell carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Myocardial infarction	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Squamous cell carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Peptic ulcer perforation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.0) [0]
Safety results: Number (%) of subjects with SAEs after Month 24 to Month 36 (Total cohort for persistence Month 36)					
Serious adverse events, n (%) [n considered by the investigator to be related to the medication]					
All SAEs	HZV-1 Group N = 147	HZV-2 Group N = 147	HZV-3 Group N=150	Control/HZV-3 Group N = 155	Control Group (N = 47)
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	19 (12.9) [0]	12 (8.2) [0]	25 (16.7) [0]	20 (12.9) [0]	5 (10.6) [0]
Cholelithiasis	1 (0.7) [0]	1 (0.7) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Breast cancer	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Cerebrovascular accident	1 (0.7) [0]	0 (0.0) [0]	2 (1.3) [0]	0 (0.0) [0]	0 (0.0) [0]
Crohn's disease	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Colon neoplasm	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Retinal vein thrombosis	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Gastric ulcer	1 (0.7) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Circulatory collapse	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
VIIIth nerve paralysis	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Gastroenteritis clostridial	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Arthropathy	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Clostridial infection	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Febrile infection	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Synovial cyst	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Hyperthyroidism	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Tendon rupture	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Medical device complication	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Transient ischaemic attack	1 (0.7) [0]	0 (0.0) [0]	1 (0.7) [0]	1 (0.6) [0]	0 (0.0) [0]
Haemangiopericytoma	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Chest pain	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Neuroborreliosis	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Haematuria	1 (0.7) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Cardiac failure	1 (0.7) [0]	1 (0.7) [0]	1 (0.7) [0]	0 (0.0) [0]	1 (2.1) [0]
Chronic myeloid leukaemia	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Osteoarthritis	1 (0.7) [0]	0 (0.0) [0]	2 (1.3) [0]	2 (1.3) [0]	0 (0.0) [0]
Pneumonia	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Pancreatitis	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Urethral stenosis	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Back pain	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Psoriasis	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Rosacea	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Trigger finger	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Duodenal ulcer	0 (0.0) [0]	1 (0.7) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Atrial fibrillation	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Femoral neck fracture	0 (0.0) [0]	1 (0.7) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Cardiac failure congestive	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Varicose vein	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Diabetic gastropathy	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Dyspnoea	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Aortic aneurysm	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Colon cancer	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Breast pain	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Glomerulonephritis	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Cerebrovascular disorder	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Pancreatic abscess	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Cyst	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Erysipelas	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	1 (0.6) [0]	0 (0.0) [0]
Femur fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Haemorrhage intracranial	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Prostatitis	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Benign prostatic hyperplasia	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Enteritis	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Stress urinary incontinence	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Subarachnoid haemorrhage	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	1 (0.6) [0]	0 (0.0) [0]
Cystitis	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Somnolence	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Coronary artery disease	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Facial bones fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Acute myocardial infarction	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	1 (2.1) [0]
Vascular pseudoaneurysm	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Osteoporotic fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Iron deficiency anaemia	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Helicobacter gastritis	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Bone pain	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Lumbar vertebral fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]

Dementia	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Spinal fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.7) [0]	1 (0.6) [0]	0 (0.0) [0]
Ankle fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Ischaemic stroke	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	1 (2.1) [0]
Ovarian neoplasm	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Epilepsy	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Cataract	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Diverticulitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Angina pectoris	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Gastroenteritis aeromonas	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Ovarian fibroma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Postoperative ileus	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Anaemia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Skull fracture/fractured base	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Lung neoplasm malignant	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Dehydration	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Pneumonia primary atypical	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Renal failure	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Angina unstable	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Right ventricular failure	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Hyperglycaemia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Hypertensive crisis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (1.3) [0]	0 (0.0) [0]
Cholecystitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Syncope	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Appendicitis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Intervertebral disc protrusion	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Bronchitis chronic	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Atrial flutter	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Radius fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Atrioventricular block	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Microcytic anaemia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Arthralgia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Neuropathy peripheral	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Multiple fractures	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Bradyarrhythmia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.1) [0]
Fatal SAEs	HZV-1 Group (N = 147)	HZV-2 Group (N = 147)	HZV-3 Group (N=150)	Control/HZV-3 Group (N = 155)	Control Group (N = 47)
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Conclusion:

At Month 3, the mean of frequency of gE-specific CD4 T cell secreting at least 2 different activation markers in subjects ≥ 70 years of age was 2269.84 in the HZV-1 Group, 2441.95 in the HZV-2 Group, 2449.90 in the HZV-3 Group, 681.73 in the Control/HZV-3 Group and 512.55 in the Control Group.

At Month 3, the median frequencies of gE-specific CD4 T cells secreting at least 2 different activation markers in subjects ≥ 70 years of age was 1801.23 in the HZV-1 Group; 1722.83 in the HZV-2 Group; 1778.48 in the HZV-3 Group; 491.03 in the Control/HZV-3 Group and 388.49 in the Control Group.

During the 30-day (Days 0-29) post-vaccination period, at least one unsolicited AE was reported for 55 (33.5%), 52 (31.3%), 54 (32.7%), 41 (24.8%), 16 (29.6%) subjects in the HZV-1, HZV-2, HZV-3, Control/HZV-3 and Control groups, respectively.

During the same period, at least one Grade 3 unsolicited AE was reported for 7 (4.3%), 10 (6.0%), 10 (6.1%), 5 (3.0%) and 4 (7.4%) subjects in the HZV-1, HZV-2, HZV-3, Control/HZV-3 and Control groups, respectively. During the same period, at least one unsolicited AE assessed by the investigator as related to the study vaccination was reported for 20 (12.2%), 22 (13.3%), 24 (14.5%), 13 (7.9%) and 2 (3.7%) subjects in the HZV-1, HZV-2, HZV-3, Control/HZV-3 and Control groups, respectively.

During the Month 0 to Month 3 period, at least one SAE was reported for 2 (1.2%), 4 (2.4%), 3 (1.8%), 6 (3.6%) and 3 (5.6%)

subjects in the HZV-1, HZV-2, HZV-3, Control/HZV-3 and Control groups, respectively. Fatal SAE(s) was reported for 1 (0.6%) subject in the HZV-3 Group and 1 (0.6%) subject in the Control/HZV-3 Group.

During the Month 3 to Month 12 period, at least one SAE was reported for 11 (7.1%), 14 (8.8%), 11 (6.9%), 16 (9.9%) and 3 (6.0%) subjects in the HZV-1, HZV-2, HZV-3, Control/HZV-3 and Control groups, respectively. Fatal SAE(s) was reported for 1 (0.6%) subject in the Control/HZV-3 Group.

During the Month 12 to Month 24 period, at least one SAE was reported for 21 (14.0%), 27 (17.4%), 29 (18.8%), 25 (15.9%) and 11 (22.4%) subjects in the HZV-1, HZV-2, HZV-3, Control/HZV-3 and Control groups, respectively. Fatal SAE(s) was reported for 2 (1.3%) subjects in the HZV-1 Group, 3 (2.0%) subjects in the HZV-2 Group, 2 (1.2%) subjects in the HZV-3 Group, 3 (1.9%) subjects in the Control/HZV-3 Group and 1 (2.0%) subject in the Control Group.

During the Month 24 to Month 36 period, at least one SAE was reported for 19 (12.9%), 12 (8.2%), 25 (16.7%), 20 (12.9%), 5 (10.6%) subjects in the the HZV-1, HZV-2, HZV-3, Control/HZV-3 and Control groups, respectively. No fatal SAEs were reported during the Month 24 to Month 36 period. None of the SAEs reported during entire study period were assessed by the investigators as causally related to the study vaccination.