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GSK Medicine: Herpes zoster vaccine gE/AS01 _B (GSK 1437173A)
Study Number: 112673 (Zoster-015)
Title: Safety and immunogenicity of GlaxoSmithKline (GSK) Biologicals' herpes zoster vaccine (HZV) 1437173A in adult HIV-infected subjects. GSK 1437173A (HZV): GSK Biologicals' herpes zoster vaccine.
Rationale: The purpose of this study was to evaluate the safety and immunogenicity of the gE/AS01 _B vaccine in HIV-infected adults 18 years of age and older who were at high risk for herpes zoster (HZ) due to their HIV infection.
Phase: I/IIa
Study Period: From 30 September 2010 until: <ul style="list-style-type: none"> – 6 July 2012 (study active phase completion date) – 14 May 2013 (extended follow-up phase completion date)
Study Design: This was a randomized, controlled, self-contained study.
Centres: Multi-center study with 16 centers: 4 in the UK, 7 in Germany, 5 in the US.
Indication: Vaccination against HZ in adult Human Immunodeficiency Virus (HIV) infected subjects.
Treatment: The study groups were as follows: <ul style="list-style-type: none"> • HZV Group: subjects received three doses of gE/AS01_B vaccine (Months 0, 2 and 6). • Placebo Group: subjects received three doses of placebo (Months 0, 2 and 6). The vaccines were administered intramuscularly, in the deltoid muscle of the non-dominant arm. The study population was sub-divided into three cohorts of HIV-infected subjects: <ul style="list-style-type: none"> • Antiretroviral therapy (ART) High CD4 cohort (ARTHCD4): ART-treated subjects with a high CD4 T-cells count: ≥ 200 cells/mm³ • ART Low CD4 cohort (ARTLCD4): ART-treated subjects with a low CD4 T-cells count: 50-199 cells/mm³ • Non-ART High CD4 cohort (NARTHCD): ART-naïve HIV-infected subjects with a high CD4 T-cells count of ≥ 500 cells/mm³ Note: The duration of the study for each subject was approximately 7 months (active phase), followed by an extended follow up phase of 11 months. A screening (SCR) visit was to take place up to 21 days prior to the visit at the Month 0 timepoint.
Objectives: <ul style="list-style-type: none"> • To evaluate the safety of the HZV vaccine in HIV-infected subjects, by ART and CD4 count cohorts*, and overall • To estimate the Glycoprotein E (gE)-specific humoral and cellular immune responses at Month 7 (1 month post-final vaccination) in subjects who received three doses of HZV vaccine (Months 0, 2 and 6) in comparison to subjects who received placebo, in ART and non-ART cohorts presenting high CD4 counts at enrolment. <p>* The safety analyses by sub-group (by ART and CD4 T-cell count) as planned in the protocol were not performed because of the low number of subjects enrolled into the ART low CD4 and non-ART high CD4 cohorts</p>
Primary Outcome/Efficacy Variable: <ul style="list-style-type: none"> • Serious Adverse Events (SAEs): <ul style="list-style-type: none"> – Occurrence and relationship to vaccination of all SAEs from Month 0 onwards until study end, in each cohort* and overall – Occurrence of SAEs related to study participation or to a concurrent GSK medication/vaccine during the entire study period in each cohort* and overall – Occurrence of any fatal SAEs during the entire study period in each cohort* and overall; • Occurrence of pre-defined AEs: <ul style="list-style-type: none"> – Occurrence and relationship to vaccination of any new onset of autoimmune diseases (NOADs) and other immune mediated inflammatory disorders from administration of the first dose of vaccine/placebo until end of the trial, in each cohort*, and overall • Solicited local and general symptoms: <ul style="list-style-type: none"> – Occurrence, intensity of each solicited local symptom (within 7 days after each vaccination) in each cohort*, and overall – Occurrence, intensity and relationship to vaccination of each solicited general symptom (within 7 days after each vaccination) in each cohort*, and overall • Unsolicited AEs: <ul style="list-style-type: none"> – Occurrence, intensity and relationship to vaccination of unsolicited AEs (within 30 days after each vaccination), according to the Medical Dictionary for Regulatory Activities (MedDRA) classification, in each cohort*, and overall

- Haematological and biochemical parameters:
 - Haematological and biochemical parameters and changes of haematological and biochemical parameters from baseline at the Screening visit and at Months 1, 2, 3, 6 and 7 in each cohort*, and overall
- Worsening of the HIV condition:
 - Significant change to ART (including ART initiation in the non-ART High CD4 cohort) from administration of the first dose of vaccine/placebo until end of the trial, in each cohort, and overall
 - Occurrence of an AIDS-defining condition from administration of the first dose of vaccine/placebo until end of the trial, in each cohort, and overall
 - Occurrence of study pre-defined HIV-related changes in HIV Viral Load (VL) at Months 1, 3 and 7, and changes in CD4 count at Months 1, 2, 3, 6 and 7, in each cohort, and overall
- Cell-mediated immunogenicity (CMI) at Month 7:
 - Frequency of gE-specific CD4 T cells expressing at least 2 cytokines (among interferon-gamma (IFN- γ), interleukin-2 (IL-2), tumour necrosis factor-alpha (TNF- α) and/or CD40 ligand (CD40L)) as determined by in vitro intracellular cytokine staining (ICS) at Month 7 in ART and non-ART cohorts presenting high CD4 counts at enrolment
- Humoral immune response at Month 7:
 - Anti-gE antibody (Ab) concentrations as determined by Enzyme-Linked Immunosorbent Assay (ELISA) at Month 7 in ART and non-ART cohorts presenting high CD4 counts at enrolment.

* The safety analyses by sub-group (by ART and CD4 T-cell count) as planned in the protocol were not performed because of the low number of subjects enrolled into the ART low CD4 and non-ART high CD4 cohorts

Secondary Outcome/Efficacy Variable(s):

- CMI at Months 0, 1, 2, 3, 6, 7 and 18:
 - Frequencies of Varicella-Zoster Virus (VZV)- and gE-specific CD4 T cells expressing at least 2 cytokines (among IFN- γ , IL-2, TNF- α and/or CD40L as determined by ICS at Months 0, 1, 2, 3, 6, 7 and 18, in each cohort, and overall
- Humoral immune response at Months 0, 1, 2, 3, 6, 7 and 18, in each group, and overall:
 - Anti-gE and anti-VZV Ab concentrations as determined by ELISA at Months 0, 1, 2, 3, 6, 7 and 18, in each cohort, and overall
- Occurrence, duration and severity of HZ cases and complications:
 - Occurrence of confirmed HZ cases occurring from administration of the first dose of vaccine/placebo until end of the trial and the time to onset of HZ, in each cohort[§], and overall
 - HZ pain severity[§] as determined by a measure of HZ-associated pain integrated over a 4-week period following the onset of the HZ rash in subjects with confirmed HZ, in each cohort, and overall
 - Occurrence of postherpetic neuralgia (PHN)[§] from administration of the first dose of vaccine/placebo until end of the trial as measured by the duration of HZ associated clinically significant pain, in each cohort, and overall
 - Occurrence of other HZ-associated complications[§] following the onset of HZ rash in subjects with confirmed HZ from administration of the first dose of vaccine/placebo until end of the trial in each cohort, and overall
- CD4 count and HIV VL:
 - CD4 count and change of CD4 count from baseline at Screening visit at Months 1, 2, 3, 6, 7 and 18, in each cohort
 - HIV VL and change in HIV VL from baseline at Screening visit at Months 1, 2, 3, 6, 7 and 18, in each cohort

[§] Due to the low number of confirmed HZ cases, these analyses were not performed.

Statistical Methods:

The analysis was performed on the Total Vaccinated cohort, the According-to-Protocol (ATP) cohort for immunogenicity and the ATP cohort for persistence.

- The Total Vaccinated cohort included all vaccinated subjects with at least one vaccine administration documented.
- 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 measures were available at the considered time points (ie, up to month 7).
- The ATP cohort for persistence 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 measures were available at the Month 18 time point.

Analysis of immunogenicity

The analysis was performed on the ATP cohort for immunogenicity (up to Month 7) and ATP cohort for persistence (for the Month 18 time point). (Subjects in one ATP population may not have been included in the other).

A likelihood-based Analysis of Covariance (ANCOVA) model was used to analyse post-vaccination log-transformed anti-gE and anti-VZV ELISA Antibody concentrations at Month 7 in the ART and non-ART subjects presenting a high CD4 T cell count at the enrolment. Geometric means (GMs) of post-vaccination Antibody concentrations were calculated at Month 7 conditionally to the

means of the log-transformed concentrations at pre-vaccination calculated across the treatment groups. For each group, adjusted means and difference of means between treatment groups were calculated together with 95% Confidence Intervals (CIs) (2-sided) and back-transformed to the original units which provided Geometric Mean Concentrations (GMCs) and GM ratios.

Seropositivity* rates and GMCs with their 95% CIs were tabulated for each group and for anti-gE and anti-VZV antibodies determined by ELISA at Months 0, 1, 2, 3, 6, 7 and 18 in all subjects by HIV status and overall.

*A seropositive subject was defined as a subject with concentration \geq the predefined cut-off value specific to the antigen/antibody under consideration:

- For anti-gE antibody concentrations: 18 mIU/mL, and
- For anti-VZV antibody concentrations: 25 mIU/mL

The primary evaluation of the vaccine on CMI outcome was analysed using a likelihood-based ANCOVA model and the treatment comparison of the frequency of gE-specific CD4 T cells secreting at least 2 activation markers (CD4[2+]) at Month 7 in the ART and non-ART subjects presenting a high CD4 T cell count at the enrolment. .

Descriptive statistics of the frequency of gE-specific and VZV-specific CD4 T cells secreting at least 2 activation markers (CD4 [2+]) at Months 0, 1, 2, 3, 6, 7 and 18 in all subjects by HIV status and overall were tabulated.

Analysis of safety

The analysis was performed on the Total Vaccinated cohort.

The percentage of subjects reporting each individual solicited local and general symptoms during the 7-day (Days 0-6) after each vaccination for each dose and across doses was tabulated with exact 95% CIs. The same tabulations were performed for grade 3 symptoms and for solicited general symptoms assessed by the investigators as related to vaccination. The percentage of subjects with at least one report of unsolicited AE classified by Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms occurring within 30 days after each vaccination was tabulated. The same tabulation was performed for grade 3 unsolicited AEs and for unsolicited AEs assessed by the investigators as casually related to vaccination. The percentage of subjects reporting SAEs, pIMDs and other immune mediated inflammatory disorders from administration of the first dose of vaccine/placebo until end of the trial were summarized and classified according to MedDRA preferred terms and those assessed by the investigators to be causally related to vaccination were also tabulated. The percentage of subjects reporting SAEs related to study participation or to a concurrent GSK medication/vaccine during the entire study period was also tabulated. The percentage of subjects with haematology and biochemistry parameters and changes from baseline with respect to normal laboratory ranges were tabulated at Screening and Months 1, 2, 3, 6 and 7. The percentage of subjects reporting events indicative of worsening of HIV condition from the first administered dose until study end were tabulated by overall and HIV status. Descriptive statistics of HIV VL and CD4 T cell counts and the proportion of subjects with results \geq 40 Copies/mL in HIV VL up to Month 18, by HIV status were tabulated. No analysis was done for the HZ pain severity, occurrence of PHN, duration for resolution of HZ-related pain and other HZ-associated complications as there was only 1 case of confirmed HZ reported, hence, a listing was presented.

Study population: le or female, at least 18 years old at the time of the first vaccination, known to be HIV-1 infected, and diagnosed at least 1 year prior to enrolment. Female subjects of childbearing potential could be enrolled in the study, if they had practiced adequate contraception for 30 days prior to vaccination, had a negative pregnancy test on the day of vaccination, and had agreed to continue adequate contraception during the entire treatment period and for 2 months after completion of the vaccination series. Written informed consent was obtained from the subjects prior to enrolment in the study.

Number of subjects (Active Phase)	HZV Group	Placebo Group
Planned, N	81	54
Randomized, N (Total Vaccinated cohort)	74	49
Completed up to Month 7, n (%)	69 (93.2)	47 (95.9)
Total Number Subjects Withdrawn, n (%)	5 (6.8)	2 (4.1)
Withdrawn due to Adverse Events, n (%)	1 (1.4)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	Not Applicable	Not Applicable
Withdrawn for other reasons, n (%)	4 (5.4)	2 (4.1)
Number of subjects (Extended Follow-up Phase)	HZV Group	Placebo Group
Planned, N	81	54
Randomized, N (Total Vaccinated cohort)	74	49
Completed up to Month 18, n (%)	67 (90.5)	45 (91.8)
Total Number Subjects Withdrawn, n (%)	7 (9.5)	4 (8.2)
Withdrawn due to Adverse Events, n (%)	1 (1.4)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	Not Applicable	Not Applicable
Withdrawn for other reasons, n (%)	6 (8.1)	4 (8.2)
Demographics	HZV Group	Placebo Group
N (Total Vaccinated cohort)	74	49

Gender, n (%)					5 (6.8)		2 (4.1)				
Females					69 (93.2)		47 (95.9)				
Males					46.6 (10.68)		45.1 (11.36)				
Mean Age, years (SD)					47.5		44.0				
Median					23, 74		26, 71				
Minimum, Maximum					66 (89.2)		42 (85.7)				
White - Caucasian / European heritage, n (%)											
Primary Outcome Results: Geometric means and ratio of HZV Group over placebo Group in anti-gE antibody ELISA concentrations at Month 7 in subjects with high CD4 T-cell count at enrolment (ATP cohort for immunogenicity)											
	Geometric Mean				Geometric Mean Ratio						
	95 % CI					90 % CI		P-value			
Group	N	Value	LL	UL	Value	LL	UL				
HZV	48	56305.23	38854.59	81593.42	46.22	33.63	63.53	<0.0001			
Placebo	33	1218.17	1080.80	1373.01							
N = number of subjects in a given category with available results											
LL = Lower Limit, UL = Upper Limit and CI = Confidence Interval											
P-value is relative to the null hypothesis H ₀ : HZV / Placebo ≤ 1											
Primary Outcome Results: Geometric means and ratio of HZV Group over Placebo Group in the frequency of gE-specific CD4 T-cells at Month 7 for subjects with high CD4 T-cell count at enrolment (ATP cohort for immunogenicity)											
		Geometric Mean			Geometric Mean Ratio						
		95 % CI				70 % CI		P-value			
Group	N	Value	LL	UL	Value	LL	UL				
HZV	18	2541.54	1835.89	3477.43	21.95	12.67	38.02	<.0001			
Placebo	17	115.78	0.97	270.81							
N = number of subjects in a given category with available results											
LL, UL = Lower and Upper confidence limits											
P-value is relative to the null hypothesis H ₀ : HZV / Placebo ≤ 1											
Primary Outcome Results: : Number (%) of subjects reporting solicited local symptoms during the 7-day (Days 0-6) post-vaccination period following each dose and across doses (Total Vaccinated cohort)											
		HZV Group					Placebo Group				
					95 % CI					95 % CI	
Symptom	Intensity	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1											
Pain	Any	72	69	95.8	88.3	99.1	48	4	8.3	2.3	20.0
	Grade 3	72	4	5.6	1.5	13.6	48	0	0.0	0.0	7.4
Redness	Any	72	17	23.6	14.4	35.1	48	0	0.0	0.0	7.4
	>100 mm	72	2	2.8	0.3	9.7	48	0	0.0	0.0	7.4
Swelling	Any	72	12	16.7	8.9	27.3	48	0	0.0	0.0	7.4
	>100 mm	72	1	1.4	0.0	7.5	48	0	0.0	0.0	7.4
Dose 2											
Pain	Any	66	57	86.4	75.7	93.6	44	3	6.8	1.4	18.7
	Grade 3	66	8	12.1	5.4	22.5	44	0	0.0	0.0	8.0
Redness	Any	66	19	28.8	18.3	41.3	44	0	0.0	0.0	8.0
	>100 mm	66	1	1.5	0.0	8.2	44	0	0.0	0.0	8.0
Swelling	Any	66	11	16.7	8.6	27.9	44	0	0.0	0.0	8.0
	>100 mm	66	0	0.0	0.0	5.4	44	0	0.0	0.0	8.0
Dose 3											
Pain	Any	53	43	81.1	68.0	90.6	38	1	2.6	0.1	13.8
	Grade 3	53	7	13.2	5.5	25.3	38	0	0.0	0.0	9.3
Redness	Any	53	9	17.0	8.1	29.8	38	0	0.0	0.0	9.3
	>100 mm	53	2	3.8	0.5	13.0	38	0	0.0	0.0	9.3
Swelling	Any	53	5	9.4	3.1	20.7	38	0	0.0	0.0	9.3
	>100 mm	53	0	0.0	0.0	6.7	38	0	0.0	0.0	9.3
Across Doses											
Pain	Any	73	72	98.6	92.6	100	48	6	12.5	4.7	25.2
	Grade 3	73	12	16.4	8.8	27.0	48	0	0.0	0.0	7.4

Redness	Any	73	28	38.4	27.2	50.5	48	0	0.0	0.0	7.4
	>100 mm	73	4	5.5	1.5	13.4	48	0	0.0	0.0	7.4
Swelling	Any	73	20	27.4	17.6	39.1	48	0	0.0	0.0	7.4
	>100 mm	73	1	1.4	0.0	7.4	48	0	0.0	0.0	7.4

N= number of subjects with at least one documented dose

n/%= number/percentage of subjects reporting the symptom at least once

95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit

Any = incidence of a particular symptom regardless of their intensity grade

Grade 3 pain = symptom that prevented normal everyday activities

Primary Outcome Results: Number (%) of subjects reporting solicited general symptoms during the 7-day (Days 0-6) post-vaccination period following each dose and across doses (Total Vaccinated cohort)

		HZV Group					Placebo Group				
					95 % CI					95 % CI	
Symptom	Intensity/Relationship	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1											
Fatigue	Any	72	30	41.7	30.2	53.9	48	13	27.1	15.3	41.8
	Grade 3	72	0	0.0	0.0	5.0	48	3	6.3	1.3	17.2
	Related	72	17	23.6	14.4	35.1	48	8	16.7	7.5	30.2
Gastrointestinal*	Any	72	13	18.1	10.0	28.9	48	8	16.7	7.5	30.2
	Grade 3	72	0	0.0	0.0	5.0	48	0	0.0	0.0	7.4
	Related	72	6	8.3	3.1	17.3	48	6	12.5	4.7	25.2
Headache	Any	72	25	34.7	23.9	46.9	48	10	20.8	10.5	35.0
	Grade 3	72	0	0.0	0.0	5.0	48	1	2.1	0.1	11.1
	Related	72	16	22.2	13.3	33.6	48	6	12.5	4.7	25.2
Myalgia	Any	72	34	47.2	35.3	59.3	48	6	12.5	4.7	25.2
	Grade 3	72	4	5.6	1.5	13.6	48	0	0.0	0.0	7.4
	Related	72	26	36.1	25.1	48.3	48	6	12.5	4.7	25.2
Shivering	Any	72	19	26.4	16.7	38.1	48	5	10.4	3.5	22.7
	Grade 3	72	0	0.0	0.0	5.0	48	0	0.0	0.0	7.4
	Related	72	11	15.3	7.9	25.7	48	5	10.4	3.5	22.7
Temperature/(Oral/Axillary)	>37.5°C	72	7	9.7	4.0	19.0	48	2	4.2	0.5	14.3
	>39.0°C	72	0	0.0	0.0	5.0	48	0	0.0	0.0	7.4
	Related	72	2	2.8	0.3	9.7	48	2	4.2	0.5	14.3
Dose 2											
Fatigue	Any	66	41	62.1	49.3	73.8	44	8	18.2	8.2	32.7
	Grade 3	66	7	10.6	4.4	20.6	44	3	6.8	1.4	18.7
	Related	66	25	37.9	26.2	50.7	44	5	11.4	3.8	24.6
Gastrointestinal*	Any	66	18	27.3	17.0	39.6	44	3	6.8	1.4	18.7
	Grade 3	66	1	1.5	0.0	8.2	44	1	2.3	0.1	12.0
	Related	66	8	12.1	5.4	22.5	44	1	2.3	0.1	12.0
Headache	Any	66	32	48.5	36.0	61.1	44	3	6.8	1.4	18.7
	Grade 3	66	3	4.5	0.9	12.7	44	0	0.0	0.0	8.0
	Related	66	18	27.3	17.0	39.6	44	1	2.3	0.1	12.0
Myalgia	Any	66	33	50.0	37.4	62.6	44	4	9.1	2.5	21.7
	Grade 3	66	1	1.5	0.0	8.2	44	1	2.3	0.1	12.0
	Related	66	24	36.4	24.9	49.1	44	2	4.5	0.6	15.5
Shivering	Any	66	23	34.8	23.5	47.6	44	1	2.3	0.1	12.0
	Grade 3	66	4	6.1	1.7	14.8	44	0	0.0	0.0	8.0
	Related	66	17	25.8	15.8	38.0	44	1	2.3	0.1	12.0
Temperature/(Oral/Axillary)	>37.5°C	66	12	18.2	9.8	29.6	44	1	2.3	0.1	12.0
	>39.0°C	66	0	0.0	0.0	5.4	44	0	0.0	0.0	8.0
	Related	66	10	15.2	7.5	26.1	44	0	0.0	0.0	8.0
Dose 3											
Fatigue	Any	53	36	67.9	53.7	80.1	38	6	15.8	6.0	31.3
	Grade 3	53	7	13.2	5.5	25.3	38	1	2.6	0.1	13.8

	Related	53	24	45.3	31.6	59.6	38	3	7.9	1.7	21.4
Gastrointestinal*	Any	53	8	15.1	6.7	27.6	38	4	10.5	2.9	24.8
	Grade 3	53	1	1.9	0.0	10.1	38	0	0.0	0.0	9.3
	Related	53	5	9.4	3.1	20.7	38	2	5.3	0.6	17.7
Headache	Any	53	33	62.3	47.9	75.2	38	7	18.4	7.7	34.3
	Grade 3	53	4	7.5	2.1	18.2	38	1	2.6	0.1	13.8
	Related	53	21	39.6	26.5	54.0	38	3	7.9	1.7	21.4
Myalgia	Any	53	32	60.4	46.0	73.5	38	1	2.6	0.1	13.8
	Grade 3	53	6	11.3	4.3	23.0	38	0	0.0	0.0	9.3
	Related	53	22	41.5	28.1	55.9	38	1	2.6	0.1	13.8
Shivering	Any	53	20	37.7	24.8	52.1	38	1	2.6	0.1	13.8
	Grade 3	53	7	13.2	5.5	25.3	38	0	0.0	0.0	9.3
	Related	53	14	26.4	15.3	40.3	38	1	2.6	0.1	13.8
Temperature/(Oral/Axillary)	>37.5°C	53	11	20.8	10.8	34.1	38	1	2.6	0.1	13.8
	>39.0°C	53	0	0.0	0.0	6.7	38	0	0.0	0.0	9.3
	Related	53	6	11.3	4.3	23.0	38	0	0.0	0.0	9.3

Across Doses

Fatigue	Any	73	55	75.3	63.9	84.7	48	14	29.2	17.0	44.1
	Grade 3	73	12	16.4	8.8	27.0	48	4	8.3	2.3	20.0
	Related	73	41	56.2	44.1	67.8	48	8	16.7	7.5	30.2
Gastrointestinal*	Any	73	28	38.4	27.2	50.5	48	11	22.9	12.0	37.3
	Grade 3	73	2	2.7	0.3	9.5	48	1	2.1	0.1	11.1
	Related	73	16	21.9	13.1	33.1	48	7	14.6	6.1	27.8
Headache	Any	73	47	64.4	52.3	75.3	48	15	31.3	18.7	46.3
	Grade 3	73	6	8.2	3.1	17.0	48	2	4.2	0.5	14.3
	Related	73	34	46.6	34.8	58.6	48	8	16.7	7.5	30.2
Myalgia	Any	73	54	74.0	62.4	83.5	48	9	18.8	8.9	32.6
	Grade 3	73	10	13.7	6.8	23.8	48	1	2.1	0.1	11.1
	Related	73	44	60.3	48.1	71.5	48	8	16.7	7.5	30.2
Shivering	Any	73	37	50.7	38.7	62.6	48	5	10.4	3.5	22.7
	Grade 3	73	11	15.1	7.8	25.4	48	0	0.0	0.0	7.4
	Related	73	29	39.7	28.5	51.9	48	5	10.4	3.5	22.7
Temperature/(Oral/Axillary)	>37.5°C	73	22	30.1	19.9	42.0	48	3	6.3	1.3	17.2
	>39.0°C	73	0	0.0	0.0	4.9	48	0	0.0	0.0	7.4
	Related	73	17	23.3	14.2	34.6	48	2	4.2	0.5	14.3

N= number of subjects with at least one documented dose

n/%= number/percentage of subjects reporting the symptom at least once

95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit

Any = incidence of a particular symptom regardless of their intensity grade or relationship to vaccination

Grade 3 = symptom which prevented normal everyday activities.

Related = symptom assessed by the investigator as causally related to study vaccination

*Gastrointestinal symptoms included nausea, vomiting, diarrhoea and/or abdominal pain

Primary Outcome Results: Distribution of haematology and biochemistry with respect to normal laboratory ranges (Total Vaccinated cohort)

		HZV Group N = 74										Placebo Group N = 49									
				Unknown		Below		Within		Above		Unknown n		Below		Within		Above			
Laboratory parameter	Timing	N*	n	%	n	%	n	%	n	%	N*	n	%	n	%	n	%	n	%	n	%
Alanine Aminotransferase	SCR	74	0	0.0	0	0.0	70	94.6	4	5.4	49	0	0.0	0	0.0	41	83.7	8	16.3		
	PI(M1)	73	0	0.0	0	0.0	67	91.8	6	8.2	45	0	0.0	0	0.0	41	91.1	4	8.9		
	PI(M2)	71	0	0.0	0	0.0	67	94.4	4	5.6	47	1	2.1	0	0.0	40	85.1	6	12.8		
	PII(M3)	72	1	1.4	0	0.0	66	91.7	5	6.9	47	2	4.3	0	0.0	36	76.6	9	19.1		
	PII(M6)	71	0	0.0	0	0.0	67	94.4	4	5.6	47	0	0.0	0	0.0	41	87.2	6	12.8		
	PIII(M7)	68	1	1.5	0	0.0	64	94.1	3	4.4	47	1	2.1	0	0.0	42	89.4	4	8.5		

Albumin	SCR	74	0	0.0	0	0.0	72	97.3	2	2.7	49	0	0.0	0	0.0	47	95.9	2	4.1
	PI(M1)	73	0	0.0	0	0.0	69	94.5	4	5.5	45	0	0.0	0	0.0	43	95.6	2	4.4
	PI(M2)	71	0	0.0	0	0.0	67	94.4	4	5.6	47	1	2.1	0	0.0	44	93.6	2	4.3
	PII(M3)	72	1	1.4	0	0.0	67	93.1	4	5.6	47	2	4.3	0	0.0	43	91.5	2	4.3
	PII(M6)	71	0	0.0	0	0.0	68	95.8	3	4.2	47	0	0.0	0	0.0	44	93.6	3	6.4
	PIII(M7)	68	1	1.5	0	0.0	64	94.1	3	4.4	47	1	2.1	1	2.1	41	87.2	4	8.5
Alkaline Phosphatase	SCR	74	0	0.0	0	0.0	70	94.6	4	5.4	49	0	0.0	0	0.0	44	89.8	5	10.2
	PI(M1)	73	0	0.0	0	0.0	71	97.3	2	2.7	45	0	0.0	0	0.0	43	95.6	2	4.4
	PI(M2)	71	0	0.0	0	0.0	68	95.8	3	4.2	47	1	2.1	0	0.0	42	89.4	4	8.5
	PII(M3)	72	1	1.4	0	0.0	67	93.1	4	5.6	47	2	4.3	0	0.0	40	85.1	5	10.6
	PII(M6)	71	0	0.0	0	0.0	67	94.4	4	5.6	47	0	0.0	0	0.0	42	89.4	5	10.6
	PIII(M7)	68	1	1.5	0	0.0	63	92.6	4	5.9	47	1	2.1	0	0.0	42	89.4	4	8.5
Aspartate Aminotransferase	SCR	74	0	0.0	0	0.0	69	93.2	5	6.8	49	0	0.0	0	0.0	45	91.8	4	8.2
	PI(M1)	73	0	0.0	0	0.0	69	94.5	4	5.5	45	0	0.0	0	0.0	42	93.3	3	6.7
	PI(M2)	71	0	0.0	0	0.0	67	94.4	4	5.6	47	1	2.1	0	0.0	43	91.5	3	6.4
	PII(M3)	72	1	1.4	0	0.0	68	94.4	3	4.2	47	2	4.3	0	0.0	41	87.2	4	8.5
	PII(M6)	71	0	0.0	0	0.0	66	93.0	5	7.0	47	0	0.0	0	0.0	45	95.7	2	4.3
	PIII(M7)	68	1	1.5	0	0.0	65	95.6	2	2.9	47	1	2.1	0	0.0	43	91.5	3	6.4
Basophils	SCR	74	0	0.0	0	0.0	74	100	0	0.0	49	0	0.0	0	0.0	49	100	0	0.0
	PI(M1)	73	1	1.4	0	0.0	72	98.6	0	0.0	45	0	0.0	0	0.0	45	100	0	0.0
	PI(M2)	71	1	1.4	0	0.0	70	98.6	0	0.0	47	2	4.3	0	0.0	45	95.7	0	0.0
	PII(M3)	72	0	0.0	0	0.0	72	100	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M6)	71	2	2.8	0	0.0	69	97.2	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
	PIII(M7)	68	0	0.0	0	0.0	68	100	0	0.0	47	0	0.0	0	0.0	47	100	0	0.0
Total Bilirubin	SCR	74	0	0.0	0	0.0	65	87.8	9	12.2	49	0	0.0	0	0.0	46	93.9	3	6.1
	PI(M1)	73	0	0.0	0	0.0	65	89.0	8	11.0	45	0	0.0	0	0.0	42	93.3	3	6.7
	PI(M2)	71	0	0.0	0	0.0	64	90.1	7	9.9	47	1	2.1	0	0.0	44	93.6	2	4.3
	PII(M3)	72	1	1.4	0	0.0	61	84.7	10	13.9	47	2	4.3	0	0.0	43	91.5	2	4.3
	PII(M6)	71	0	0.0	0	0.0	60	84.5	11	15.5	47	0	0.0	0	0.0	45	95.7	2	4.3
	PIII(M7)	68	1	1.5	0	0.0	57	83.8	10	14.7	47	1	2.1	0	0.0	43	91.5	3	6.4
Bilirubin Conjugated / Direct	SCR	74	0	0.0	0	0.0	73	98.6	1	1.4	49	0	0.0	0	0.0	49	100	0	0.0
	PI(M1)	73	0	0.0	0	0.0	73	100	0	0.0	45	0	0.0	0	0.0	44	97.8	1	2.2
	PI(M2)	71	0	0.0	0	0.0	69	97.2	2	2.8	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M3)	72	1	1.4	0	0.0	70	97.2	1	1.4	47	2	4.3	0	0.0	44	93.6	1	2.1
	PII(M6)	71	0	0.0	0	0.0	68	95.8	3	4.2	47	0	0.0	0	0.0	46	97.9	1	2.1
	PIII(M7)	68	1	1.5	0	0.0	67	98.5	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
Creatinine	SCR	74	0	0.0	6	8.1	68	91.9	0	0.0	49	0	0.0	8	16.3	40	81.6	1	2.0
	PI(M1)	73	0	0.0	4	5.5	66	90.4	3	4.1	45	0	0.0	7	15.6	38	84.4	0	0.0
	PI(M2)	71	0	0.0	5	7.0	65	91.5	1	1.4	47	1	2.1	7	14.9	39	83.0	0	0.0
	PII(M3)	72	1	1.4	5	6.9	66	91.7	0	0.0	47	2	4.3	7	14.9	37	78.7	1	2.1
	PII(M6)	71	0	0.0	7	9.9	62	87.3	2	2.8	47	0	0.0	7	14.9	39	83.0	1	2.1
	PIII(M7)	68	1	1.5	7	10.3	57	83.8	3	4.4	47	1	2.1	6	12.8	39	83.0	1	2.1
Eosinophils	SCR	74	0	0.0	14	18.9	59	79.7	1	1.4	49	0	0.0	10	20.4	38	77.6	1	2.0
	PI(M1)	73	1	1.4	13	17.8	57	78.1	2	2.7	45	0	0.0	6	13.3	39	86.7	0	0.0
	PI(M2)	71	1	1.4	9	12.7	61	85.9	0	0.0	47	2	4.3	7	14.9	37	78.7	1	2.1
	PII(M3)	72	0	0.0	12	16.7	59	81.9	1	1.4	47	1	2.1	5	10.6	41	87.2	0	0.0
	PII(M6)	71	2	2.8	13	18.3	55	77.5	1	1.4	47	1	2.1	9	19.1	36	76.6	1	2.1
	PIII(M7)	68	0	0.0	11	16.2	56	82.4	1	1.5	47	0	0.0	7	14.9	39	83.0	1	2.1
Glucose	SCR	74	0	0.0	0	0.0	69	93.2	5	6.8	49	0	0.0	1	2.0	43	87.8	5	10.2
	PI(M1)	73	0	0.0	2	2.7	62	84.9	9	12.3	45	0	0.0	1	2.2	34	75.6	10	22.2
	PI(M2)	71	0	0.0	2	2.8	59	83.1	10	14.1	47	1	2.1	0	0.0	38	80.9	8	17.0
	PII(M3)	72	1	1.4	2	2.8	62	86.1	7	9.7	47	2	4.3	0	0.0	38	80.9	7	14.9
	PII(M6)	71	0	0.0	1	1.4	62	87.3	8	11.3	47	0	0.0	1	2.1	37	78.7	9	19.1
	PIII(M7)	68	1	1.5	0	0.0	63	92.6	4	5.9	47	1	2.1	0	0.0	39	83.0	7	14.9
Bicarbonate	SCR	74	0	0.0	5	6.8	69	93.2	0	0.0	49	0	0.0	2	4.1	47	95.9	0	0.0
	PI(M1)	73	0	0.0	7	9.6	66	90.4	0	0.0	45	0	0.0	1	2.2	44	97.8	0	0.0

Haemoglobin	PI(M2)	71	0	0.0	2	2.8	69	97.2	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M3)	72	1	1.4	5	6.9	66	91.7	0	0.0	47	2	4.3	2	4.3	43	91.5	0	0.0
	PII(M6)	71	0	0.0	7	9.9	63	88.7	1	1.4	47	0	0.0	7	14.9	40	85.1	0	0.0
	PIII(M7)	68	1	1.5	6	8.8	61	89.7	0	0.0	47	1	2.1	4	8.5	42	89.4	0	0.0
	SCR	74	0	0.0	13	17.6	58	78.4	3	4.1	49	0	0.0	5	10.2	42	85.7	2	4.1
	PI(M1)	73	1	1.4	12	16.4	57	78.1	3	4.1	45	0	0.0	3	6.7	40	88.9	2	4.4
	PI(M2)	71	1	1.4	15	21.1	53	74.6	2	2.8	47	2	4.3	5	10.6	38	80.9	2	4.3
Potassium	PII(M3)	72	0	0.0	14	19.4	57	79.2	1	1.4	47	1	2.1	5	10.6	37	78.7	4	8.5
	PII(M6)	71	2	2.8	13	18.3	55	77.5	1	1.4	47	1	2.1	6	12.8	37	78.7	3	6.4
	PIII(M7)	68	0	0.0	19	27.9	49	72.1	0	0.0	47	0	0.0	6	12.8	40	85.1	1	2.1
	SCR	74	0	0.0	0	0.0	74	100	0	0.0	49	0	0.0	0	0.0	49	100	0	0.0
	PI(M1)	73	0	0.0	0	0.0	73	100	0	0.0	45	0	0.0	1	2.2	44	97.8	0	0.0
	PI(M2)	71	0	0.0	0	0.0	70	98.6	1	1.4	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M3)	72	1	1.4	0	0.0	71	98.6	0	0.0	47	2	4.3	0	0.0	45	95.7	0	0.0
Lymphocytes	PII(M6)	70	0	0.0	0	0.0	70	100	0	0.0	47	0	0.0	0	0.0	47	100	0	0.0
	PIII(M7)	68	1	1.5	1	1.5	66	97.1	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
	SCR	74	0	0.0	0	0.0	74	100	0	0.0	49	0	0.0	1	2.0	48	98.0	0	0.0
	PI(M1)	73	1	1.4	1	1.4	71	97.3	0	0.0	45	0	0.0	0	0.0	45	100	0	0.0
	PI(M2)	71	1	1.4	0	0.0	68	95.8	2	2.8	47	2	4.3	1	2.1	44	93.6	0	0.0
	PII(M3)	72	0	0.0	0	0.0	72	100	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M6)	71	2	2.8	4	5.6	65	91.5	0	0.0	47	1	2.1	3	6.4	42	89.4	1	2.1
Monocytes	PIII(M7)	68	0	0.0	0	0.0	67	98.5	1	1.5	47	0	0.0	1	2.1	46	97.9	0	0.0
	SCR	74	0	0.0	2	2.7	71	95.9	1	1.4	49	0	0.0	4	8.2	45	91.8	0	0.0
	PI(M1)	73	1	1.4	6	8.2	66	90.4	0	0.0	45	0	0.0	3	6.7	42	93.3	0	0.0
	PI(M2)	71	1	1.4	4	5.6	66	93.0	0	0.0	47	2	4.3	4	8.5	41	87.2	0	0.0
	PII(M3)	72	0	0.0	6	8.3	66	91.7	0	0.0	47	1	2.1	6	12.8	40	85.1	0	0.0
	PII(M6)	71	2	2.8	2	2.8	67	94.4	0	0.0	47	1	2.1	4	8.5	42	89.4	0	0.0
	PIII(M7)	68	0	0.0	5	7.4	63	92.6	0	0.0	47	0	0.0	2	4.3	45	95.7	0	0.0
Sodium	SCR	74	0	0.0	1	1.4	73	98.6	0	0.0	49	0	0.0	0	0.0	49	100	0	0.0
	PI(M1)	73	0	0.0	0	0.0	73	100	0	0.0	45	0	0.0	1	2.2	44	97.8	0	0.0
	PI(M2)	71	0	0.0	0	0.0	70	98.6	1	1.4	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M3)	72	1	1.4	0	0.0	71	98.6	0	0.0	47	2	4.3	0	0.0	45	95.7	0	0.0
	PII(M6)	71	0	0.0	0	0.0	71	100	0	0.0	47	0	0.0	0	0.0	47	100	0	0.0
	PIII(M7)	68	1	1.5	0	0.0	67	98.5	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
	SCR	74	0	0.0	5	6.8	69	93.2	0	0.0	49	0	0.0	3	6.1	45	91.8	1	2.0
Neutrophils	PI(M1)	73	1	1.4	8	11.0	64	87.7	0	0.0	45	0	0.0	3	6.7	40	88.9	2	4.4
	PI(M2)	71	1	1.4	7	9.9	63	88.7	0	0.0	47	2	4.3	1	2.1	43	91.5	1	2.1
	PII(M3)	72	0	0.0	6	8.3	66	91.7	0	0.0	47	1	2.1	5	10.6	39	83.0	2	4.3
	PII(M6)	71	2	2.8	5	7.0	64	90.1	0	0.0	47	1	2.1	5	10.6	37	78.7	4	8.5
	PIII(M7)	68	0	0.0	7	10.3	61	89.7	0	0.0	47	0	0.0	1	2.1	44	93.6	2	4.3
	SCR	74	0	0.0	4	5.4	70	94.6	0	0.0	49	0	0.0	1	2.0	48	98.0	0	0.0
	PI(M1)	73	1	1.4	2	2.7	70	95.9	0	0.0	45	0	0.0	3	6.7	42	93.3	0	0.0
Platelets	PI(M2)	71	1	1.4	1	1.4	69	97.2	0	0.0	47	2	4.3	2	4.3	43	91.5	0	0.0
	PII(M3)	72	0	0.0	3	4.2	69	95.8	0	0.0	47	1	2.1	2	4.3	44	93.6	0	0.0
	PII(M6)	71	2	2.8	2	2.8	67	94.4	0	0.0	47	1	2.1	2	4.3	44	93.6	0	0.0
	PIII(M7)	68	0	0.0	2	2.9	66	97.1	0	0.0	47	0	0.0	1	2.1	46	97.9	0	0.0
	SCR	74	1	1.4	3	4.1	69	93.2	1	1.4	49	0	0.0	0	0.0	47	95.9	2	4.1
	PI(M1)	73	1	1.4	5	6.8	67	91.8	0	0.0	45	0	0.0	4	8.9	39	86.7	2	4.4
	PI(M2)	71	1	1.4	6	8.5	64	90.1	0	0.0	47	2	4.3	2	4.3	41	87.2	2	4.3
White Blood Cells	PII(M3)	72	0	0.0	5	6.9	67	93.1	0	0.0	47	1	2.1	7	14.9	37	78.7	2	4.3
	PII(M6)	71	2	2.8	6	8.5	62	87.3	1	1.4	47	1	2.1	4	8.5	39	83.0	3	6.4
	PIII(M7)	68	0	0.0	6	8.8	62	91.2	0	0.0	47	0	0.0	1	2.1	44	93.6	2	4.3

N = number of subjects with laboratory results for the specified visit and laboratory parameter.

n/% = number/percentage of subjects in a given category

Unknown = value unknown for the specified visit and laboratory parameter

Below = value below the laboratory reference range defined for the specified visit and laboratory parameter

Within = value within the laboratory reference range defined for the specified visit and laboratory parameter																			
Above = value above the laboratory reference range defined for the specified visit and laboratory parameter																			
SCR = screening time point																			
PI(M1) = Post-vaccination Dose I (Month 1)																			
PI(M2) = Post-vaccination Dose I (Month 2)																			
PII(M3) = Post-vaccination Dose II (Month 3)																			
PII(M6) = Post-vaccination Dose II (Month 6)																			
PIII(M7) = Post-vaccination Dose III (Month 7)																			
* In case of retest at the screening time point, the last value available was considered. For the post vaccination, the retests were not considered																			
Primary Outcome Results: Distribution of Changes from baseline in haematology and biochemistry with respect to normal laboratory ranges (Total Vaccinated cohort)																			

			HZV Group N = 74										Placebo Group N = 47							
			Unknown			Below		Within		Above		Unknown			Below		Within		Above	
Laboratory parameter	Timing	Baseline	N*	n	%	n	%	n	%	n	%	N*	n	%	n	%	n	%	n	%
Alanine Aminotransferase	PI(M1)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	69	0	0.0	0	0.0	67	97.1	2	2.9	39	0	0.0	0	0.0	39	100	0	0.0
		Above	4	0	0.0	0	0.0	0	0.0	4	100	6	0	0.0	0	0.0	2	33.3	4	66.7
	PI(M2)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	68	0	0.0	0	0.0	67	98.5	1	1.5	40	1	2.5	0	0.0	37	92.5	2	5.0
		Above	3	0	0.0	0	0.0	0	0.0	3	100	7	0	0.0	0	0.0	3	42.9	4	57.1
	PII(M3)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	69	1	1.4	0	0.0	66	95.7	2	2.9	40	2	5.0	0	0.0	34	85.0	4	10.0
		Above	3	0	0.0	0	0.0	0	0.0	3	100	7	0	0.0	0	0.0	2	28.6	5	71.4
	PII(M6)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	68	0	0.0	0	0.0	67	98.5	1	1.5	40	0	0.0	0	0.0	40	100	0	0.0
		Above	3	0	0.0	0	0.0	0	0.0	3	100	7	0	0.0	0	0.0	1	14.3	6	85.7
	PIII(M7)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	65	1	1.5	0	0.0	63	96.9	1	1.5	40	1	2.5	0	0.0	38	95.0	1	2.5
		Above	3	0	0.0	0	0.0	1	33.3	2	66.7	7	0	0.0	0	0.0	4	57.1	3	42.9
Albumin	PI(M1)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	71	0	0.0	0	0.0	67	94.4	4	5.6	43	0	0.0	0	0.0	41	95.3	2	4.7
		Above	2	0	0.0	0	0.0	2	100	0	0.0	2	0	0.0	0	0.0	2	100	0	0.0
	PI(M2)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	69	0	0.0	0	0.0	65	94.2	4	5.8	45	1	2.2	0	0.0	42	93.3	2	4.4
		Above	2	0	0.0	0	0.0	2	100	0	0.0	2	0	0.0	0	0.0	2	100	0	0.0
	PII(M3)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	70	1	1.4	0	0.0	66	94.3	3	4.3	45	2	4.4	0	0.0	42	93.3	1	2.2
		Above	2	0	0.0	0	0.0	1	50.0	1	50.0	2	0	0.0	0	0.0	1	50.0	1	50.0
	PII(M6)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	69	0	0.0	0	0.0	66	95.7	3	4.3	45	0	0.0	0	0.0	44	97.8	1	2.2
		Above	2	0	0.0	0	0.0	2	100	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100
	PIII(M7)	Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	66	1	1.5	0	0.0	62	93.9	3	4.5	45	1	2.2	1	2.2	40	88.9	3	6.7

Alkaline Phosphatase	PI(M1)	Above	2	0	0.0	0	0.0	2	100	0	0.0	2	0	0.0	0	0.0	1	50.0	1	50.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	69	0	0.0	0	0.0	69	100	0	0.0	41	0	0.0	0	0.0	41	100	0	0.0
	PI(M2)	Above	4	0	0.0	0	0.0	2	50.0	2	50.0	4	0	0.0	0	0.0	2	50.0	2	50.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	67	0	0.0	0	0.0	67	100	0	0.0	42	1	2.4	0	0.0	39	92.9	2	4.8
	PII(M3)	Above	4	0	0.0	0	0.0	1	25.0	3	75.0	5	0	0.0	0	0.0	3	60.0	2	40.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	68	1	1.5	0	0.0	65	95.6	2	2.9	42	2	4.8	0	0.0	38	90.5	2	4.8
	PII(M6)	Above	4	0	0.0	0	0.0	2	50.0	2	50.0	5	0	0.0	0	0.0	2	40.0	3	60.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	67	0	0.0	0	0.0	65	97.0	2	3.0	42	0	0.0	0	0.0	40	95.2	2	4.8
	PIII(M7)	Above	4	0	0.0	0	0.0	2	50.0	2	50.0	5	0	0.0	0	0.0	2	40.0	3	60.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	64	1	1.6	0	0.0	61	95.3	2	3.1	42	1	2.4	0	0.0	40	95.2	1	2.4
Aspartate Aminotransferase	PI(M1)	Above	4	0	0.0	0	0.0	2	50.0	2	50.0	5	0	0.0	0	0.0	2	40.0	3	60.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	68	0	0.0	0	0.0	66	97.1	2	2.9	41	0	0.0	0	0.0	40	97.6	1	2.4
	PI(M2)	Above	5	0	0.0	0	0.0	3	60.0	2	40.0	4	0	0.0	0	0.0	2	50.0	2	50.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	67	0	0.0	0	0.0	64	95.5	3	4.5	43	1	2.3	0	0.0	40	93.0	2	4.7
	PII(M3)	Above	4	0	0.0	0	0.0	3	75.0	1	25.0	4	0	0.0	0	0.0	3	75.0	1	25.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	68	1	1.5	0	0.0	65	95.6	2	2.9	43	2	4.7	0	0.0	37	86.0	4	9.3
	PII(M6)	Above	4	0	0.0	0	0.0	3	75.0	1	25.0	4	0	0.0	0	0.0	4	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	67	0	0.0	0	0.0	64	95.5	3	4.5	43	0	0.0	0	0.0	42	97.7	1	2.3
	PIII(M7)	Above	4	0	0.0	0	0.0	2	50.0	2	50.0	4	0	0.0	0	0.0	3	75.0	1	25.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	65	1	1.5	0	0.0	63	96.9	1	1.5	43	1	2.3	0	0.0	39	90.7	3	7.0
Basophils	PI(M1)	Above	3	0	0.0	0	0.0	2	66.7	1	33.3	4	0	0.0	0	0.0	4	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	73	1	1.4	0	0.0	72	98.6	0	0.0	45	0	0.0	0	0.0	45	100	0	0.0
	PI(M2)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	71	1	1.4	0	0.0	70	98.6	0	0.0	47	2	4.3	0	0.0	45	95.7	0	0.0
	PII(M3)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	72	0	0.0	0	0.0	72	100	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M6)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	71	2	2.8	0	0.0	69	97.2	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0

Total Bilirubin	PIII(M7)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	68	0	0.0	0	0.0	68	100	0	0.0	47	0	0.0	0	0.0	47	100	0	0.0
	PI(M1)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	64	0	0.0	0	0.0	63	98.4	1	1.6	43	0	0.0	0	0.0	40	93.0	3	7.0
	PI(M2)	Above	9	0	0.0	0	0.0	2	22.2	7	77.8	2	0	0.0	0	0.0	2	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	62	0	0.0	0	0.0	61	98.4	1	1.6	45	1	2.2	0	0.0	43	95.6	1	2.2
	PII(M3)	Above	9	0	0.0	0	0.0	3	33.3	6	66.7	2	0	0.0	0	0.0	1	50.0	1	50.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	63	1	1.6	0	0.0	60	95.2	2	3.2	45	2	4.4	0	0.0	42	93.3	1	2.2
	PII(M6)	Above	9	0	0.0	0	0.0	1	11.1	8	88.9	2	0	0.0	0	0.0	1	50.0	1	50.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	62	0	0.0	0	0.0	59	95.2	3	4.8	45	0	0.0	0	0.0	43	95.6	2	4.4
	PIII(M7)	Above	9	0	0.0	0	0.0	1	11.1	8	88.9	2	0	0.0	0	0.0	2	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	59	1	1.7	0	0.0	55	93.2	3	5.1	45	1	2.2	0	0.0	41	91.1	3	6.7
Bilirubin Conjugated / Direct	PI(M1)	Above	9	0	0.0	0	0.0	2	22.2	7	77.8	2	0	0.0	0	0.0	2	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	72	0	0.0	0	0.0	72	100	0	0.0	45	0	0.0	0	0.0	44	97.8	1	2.2
	PI(M2)	Above	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	70	0	0.0	0	0.0	69	98.6	1	1.4	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M3)	Above	1	0	0.0	0	0.0	0	0.0	1	100	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	71	1	1.4	0	0.0	70	98.6	0	0.0	47	2	4.3	0	0.0	44	93.6	1	2.1
	PII(M6)	Above	1	0	0.0	0	0.0	0	0.0	1	100	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	70	0	0.0	0	0.0	68	97.1	2	2.9	47	0	0.0	0	0.0	46	97.9	1	2.1
	PIII(M7)	Above	1	0	0.0	0	0.0	0	0.0	1	100	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	67	1	1.5	0	0.0	66	98.5	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
Creatinine	PI(M1)	Above	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	6	0	0.0	2	33.3	4	66.7	0	0.0	8	0	0.0	5	62.5	3	37.5	0	0.0
		Within	67	0	0.0	2	3.0	62	92.5	3	4.5	36	0	0.0	2	5.6	34	94.4	0	0.0
	PI(M2)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	0	0.0	5	100	0	0.0	8	0	0.0	6	75.0	2	25.0	0	0.0
		Within	66	0	0.0	5	7.6	60	90.9	1	1.5	38	1	2.6	1	2.6	36	94.7	0	0.0
	PII(M3)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	1	20.0	4	80.0	0	0.0	8	0	0.0	5	62.5	3	37.5	0	0.0
		Within	67	1	1.5	4	6.0	62	92.5	0	0.0	38	2	5.3	2	5.3	33	86.8	1	2.6

Eosinophils	PII(M6)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	3	60.0	2	40.0	0	0.0	8	0	0.0	3	37.5	5	62.5	0	0.0
		Within	66	0	0.0	4	6.1	60	90.9	2	3.0	38	0	0.0	4	10.5	33	86.8	1	2.6
	PIII(M7)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	2	40.0	3	60.0	0	0.0	8	0	0.0	4	50.0	4	50.0	0	0.0
		Within	63	1	1.6	5	7.9	54	85.7	3	4.8	38	1	2.6	2	5.3	34	89.5	1	2.6
	PI(M1)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	14	0	0.0	8	57.1	6	42.9	0	0.0	8	0	0.0	4	50.0	4	50.0	0	0.0
		Within	58	1	1.7	5	8.6	51	87.9	1	1.7	37	0	0.0	2	5.4	35	94.6	0	0.0
	PI(M2)	Above	1	0	0.0	0	0.0	0	0.0	1	100	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	13	1	7.7	6	46.2	6	46.2	0	0.0	9	0	0.0	3	33.3	6	66.7	0	0.0
		Within	57	0	0.0	3	5.3	54	94.7	0	0.0	37	2	5.4	4	10.8	31	83.8	0	0.0
	PII(M3)	Above	1	0	0.0	0	0.0	1	100	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	13	0	0.0	6	46.2	7	53.8	0	0.0	9	1	11.1	3	33.3	5	55.6	0	0.0
		Within	58	0	0.0	6	10.3	52	89.7	0	0.0	37	0	0.0	2	5.4	35	94.6	0	0.0
	PII(M6)	Above	1	0	0.0	0	0.0	0	0.0	1	100	1	0	0.0	0	0.0	1	100	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	12	0	0.0	8	66.7	4	33.3	0	0.0	9	0	0.0	6	66.7	3	33.3	0	0.0
		Within	58	2	3.4	5	8.6	51	87.9	0	0.0	37	1	2.7	3	8.1	33	89.2	0	0.0
	PIII(M7)	Above	1	0	0.0	0	0.0	0	0.0	1	100	1	0	0.0	0	0.0	0	0.0	1	100
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	12	0	0.0	7	58.3	5	41.7	0	0.0	9	0	0.0	4	44.4	5	55.6	0	0.0
		Within	55	0	0.0	4	7.3	51	92.7	0	0.0	37	0	0.0	3	8.1	34	91.9	0	0.0
Glucose	PI(M1)	Above	1	0	0.0	0	0.0	0	0.0	1	100	1	0	0.0	0	0.0	0	0.0	1	100
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	68	0	0.0	2	2.9	59	86.8	7	10.3	39	0	0.0	1	2.6	31	79.5	7	17.9
	PI(M2)	Above	5	0	0.0	0	0.0	3	60.0	2	40.0	5	0	0.0	0	0.0	2	40.0	3	60.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	66	0	0.0	2	3.0	55	83.3	9	13.6	41	1	2.4	0	0.0	34	82.9	6	14.6
	PII(M3)	Above	5	0	0.0	0	0.0	4	80.0	1	20.0	5	0	0.0	0	0.0	3	60.0	2	40.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	67	1	1.5	2	3.0	57	85.1	7	10.4	41	2	4.9	0	0.0	33	80.5	6	14.6
	PII(M6)	Above	5	0	0.0	0	0.0	5	100	0	0.0	5	0	0.0	0	0.0	4	80.0	1	20.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	66	0	0.0	1	1.5	58	87.9	7	10.6	41	0	0.0	1	2.4	34	82.9	6	14.6
	PIII(M7)	Above	5	0	0.0	0	0.0	4	80.0	1	20.0	5	0	0.0	0	0.0	2	40.0	3	60.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	63	1	1.6	0	0.0	59	93.7	3	4.8	41	1	2.4	0	0.0	36	87.8	4	9.8
Bicarbonate	PI(M1)	Above	5	0	0.0	0	0.0	4	80.0	1	20.0	5	0	0.0	0	0.0	2	40.0	3	60.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	2	40.0	3	60.0	0	0.0	2	0	0.0	1	50.0	1	50.0	0	0.0
		Within	68	0	0.0	5	7.4	63	92.6	0	0.0	43	0	0.0	0	0.0	43	100	0	0.0
	PI(M2)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	1	20.0	4	80.0	0	0.0	2	0	0.0	0	0.0	2	100	0	0.0
		Within	66	0	0.0	1	1.5	65	98.5	0	0.0	45	1	2.2	0	0.0	44	97.8	0	0.0

		PII(M3)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	5	0	0.0	1	20.0	4	80.0	0	0.0	2	0	0.0	0	0.0	2	100	0	0.0
			Within	67	1	1.5	4	6.0	62	92.5	0	0.0	45	2	4.4	2	4.4	41	91.1	0	0.0
		PII(M6)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	5	0	0.0	3	60.0	2	40.0	0	0.0	2	0	0.0	0	0.0	2	100	0	0.0
			Within	66	0	0.0	4	6.1	61	92.4	1	1.5	45	0	0.0	7	15.6	38	84.4	0	0.0
		PIII(M7)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	5	0	0.0	2	40.0	3	60.0	0	0.0	2	0	0.0	0	0.0	2	100	0	0.0
			Within	63	1	1.6	4	6.3	58	92.1	0	0.0	45	1	2.2	4	8.9	40	88.9	0	0.0
	Haemoglobin	PI(M1)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	13	0	0.0	9	69.2	4	30.8	0	0.0	5	0	0.0	3	60.0	2	40.0	0	0.0
			Within	57	1	1.8	3	5.3	52	91.2	1	1.8	38	0	0.0	0	0.0	37	97.4	1	2.6
		PI(M2)	Above	3	0	0.0	0	0.0	1	33.3	2	66.7	2	0	0.0	0	0.0	1	50.0	1	50.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	13	0	0.0	11	84.6	2	15.4	0	0.0	5	0	0.0	2	40.0	3	60.0	0	0.0
			Within	55	1	1.8	4	7.3	50	90.9	0	0.0	40	2	5.0	3	7.5	34	85.0	1	2.5
		PII(M3)	Above	3	0	0.0	0	0.0	1	33.3	2	66.7	2	0	0.0	0	0.0	1	50.0	1	50.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	13	0	0.0	8	61.5	5	38.5	0	0.0	5	0	0.0	3	60.0	2	40.0	0	0.0
			Within	56	0	0.0	6	10.7	50	89.3	0	0.0	40	1	2.5	2	5.0	35	87.5	2	5.0
		PII(M6)	Above	3	0	0.0	0	0.0	2	66.7	1	33.3	2	0	0.0	0	0.0	0	0.0	2	100
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	13	1	7.7	7	53.8	5	38.5	0	0.0	5	0	0.0	4	80.0	1	20.0	0	0.0
			Within	55	1	1.8	6	10.9	48	87.3	0	0.0	40	1	2.5	2	5.0	36	90.0	1	2.5
		PIII(M7)	Above	3	0	0.0	0	0.0	2	66.7	1	33.3	2	0	0.0	0	0.0	0	0.0	2	100
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	12	0	0.0	10	83.3	2	16.7	0	0.0	5	0	0.0	4	80.0	1	20.0	0	0.0
			Within	53	0	0.0	9	17.0	44	83.0	0	0.0	40	0	0.0	2	5.0	38	95.0	0	0.0
	Potassium	PI(M1)	Above	3	0	0.0	0	0.0	3	100	0	0.0	2	0	0.0	0	0.0	1	50.0	1	50.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Within	73	0	0.0	0	0.0	73	100	0	0.0	45	0	0.0	1	2.2	44	97.8	0	0.0
		PI(M2)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Within	71	0	0.0	0	0.0	70	98.6	1	1.4	47	1	2.1	0	0.0	46	97.9	0	0.0
		PII(M3)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Within	72	1	1.4	0	0.0	71	98.6	0	0.0	47	2	4.3	0	0.0	45	95.7	0	0.0
		PII(M6)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Within	70	0	0.0	0	0.0	70	100	0	0.0	47	0	0.0	0	0.0	47	100	0	0.0
		PIII(M7)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Within	68	1	1.5	1	1.5	66	97.1	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0
	Lymphocytes	PI(M1)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
			Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
			Within	73	1	1.4	1	1.4	71	97.3	0	0.0	44	0	0.0	0	0.0	44	100	0	0.0

Monocytes	PI(M2)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	1	100	0	0.0	0	0.0
		Within	71	1	1.4	0	0.0	68	95.8	2	2.8	46	2	4.3	0	0.0	44	95.7	0	0.0
	PII(M3)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	72	0	0.0	0	0.0	72	100	0	0.0	46	1	2.2	0	0.0	45	97.8	0	0.0
	PII(M6)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	1	100	0	0.0	0	0.0
		Within	71	2	2.8	4	5.6	65	91.5	0	0.0	46	1	2.2	2	4.3	42	91.3	1	2.2
	PIII(M7)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	1	100	0	0.0	0	0.0
		Within	68	0	0.0	0	0.0	67	98.5	1	1.5	46	0	0.0	0	0.0	46	100	0	0.0
Monocytes	PI(M1)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	0	0.0	2	100	0	0.0	0	0.0	4	0	0.0	0	0.0	4	100	0	0.0
		Within	70	1	1.4	4	5.7	65	92.9	0	0.0	41	0	0.0	3	7.3	38	92.7	0	0.0
	PI(M2)	Above	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	0	0.0	1	50.0	1	50.0	0	0.0	4	0	0.0	0	0.0	4	100	0	0.0
		Within	68	1	1.5	3	4.4	64	94.1	0	0.0	43	2	4.7	4	9.3	37	86.0	0	0.0
	PII(M3)	Above	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	0	0.0	2	100	0	0.0	0	0.0	4	0	0.0	2	50.0	2	50.0	0	0.0
		Within	69	0	0.0	4	5.8	65	94.2	0	0.0	43	1	2.3	4	9.3	38	88.4	0	0.0
	PII(M6)	Above	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	0	0.0	1	50.0	1	50.0	0	0.0	4	0	0.0	0	0.0	4	100	0	0.0
		Within	68	2	2.9	1	1.5	65	95.6	0	0.0	43	1	2.3	4	9.3	38	88.4	0	0.0
	PIII(M7)	Above	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	2	0	0.0	2	100	0	0.0	0	0.0	4	0	0.0	1	25.0	3	75.0	0	0.0
		Within	65	0	0.0	3	4.6	62	95.4	0	0.0	43	0	0.0	1	2.3	42	97.7	0	0.0
Sodium	PI(M1)	Above	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	72	0	0.0	0	0.0	72	100	0	0.0	45	0	0.0	1	2.2	44	97.8	0	0.0
	PI(M2)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	70	0	0.0	0	0.0	69	98.6	1	1.4	47	1	2.1	0	0.0	46	97.9	0	0.0
	PII(M3)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	71	1	1.4	0	0.0	70	98.6	0	0.0	47	2	4.3	0	0.0	45	95.7	0	0.0
	PII(M6)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	70	0	0.0	0	0.0	70	100	0	0.0	47	0	0.0	0	0.0	47	100	0	0.0
	PIII(M7)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	67	1	1.5	0	0.0	66	98.5	0	0.0	47	1	2.1	0	0.0	46	97.9	0	0.0

Neutrophils	PI(M1)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	3	60.0	2	40.0	0	0.0	3	0	0.0	3	100	0	0.0	0	0.0
		Within	68	1	1.5	5	7.4	62	91.2	0	0.0	41	0	0.0	0	0.0	40	97.6	1	2.4
	PI(M2)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	2	40.0	3	60.0	0	0.0	3	0	0.0	1	33.3	2	66.7	0	0.0
		Within	66	1	1.5	5	7.6	60	90.9	0	0.0	43	2	4.7	0	0.0	41	95.3	0	0.0
	PII(M3)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	1	20.0	4	80.0	0	0.0	3	0	0.0	3	100	0	0.0	0	0.0
		Within	67	0	0.0	5	7.5	62	92.5	0	0.0	43	1	2.3	2	4.7	39	90.7	1	2.3
	PII(M6)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	2	40.0	2	40.0	1	20.0	0	0.0	3	0	0.0	3	100	0	0.0	0	0.0
		Within	66	0	0.0	3	4.5	63	95.5	0	0.0	43	1	2.3	2	4.7	37	86.0	3	7.0
	PIII(M7)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	5	0	0.0	4	80.0	1	20.0	0	0.0	3	0	0.0	1	33.3	2	66.7	0	0.0
		Within	63	0	0.0	3	4.8	60	95.2	0	0.0	43	0	0.0	0	0.0	42	97.7	1	2.3
Platelets	PI(M1)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	4	0	0.0	2	50.0	2	50.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	69	1	1.4	0	0.0	68	98.6	0	0.0	44	0	0.0	3	6.8	41	93.2	0	0.0
	PI(M2)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	0	0.0	1	33.3	2	66.7	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	68	1	1.5	0	0.0	67	98.5	0	0.0	46	2	4.3	2	4.3	42	91.3	0	0.0
	PII(M3)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	4	0	0.0	2	50.0	2	50.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	68	0	0.0	1	1.5	67	98.5	0	0.0	46	1	2.2	2	4.3	43	93.5	0	0.0
	PII(M6)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	4	0	0.0	2	50.0	2	50.0	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	67	2	3.0	0	0.0	65	97.0	0	0.0	46	1	2.2	2	4.3	43	93.5	0	0.0
	PIII(M7)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	0	0.0	1	33.3	2	66.7	0	0.0	1	0	0.0	0	0.0	1	100	0	0.0
		Within	65	0	0.0	1	1.5	64	98.5	0	0.0	46	0	0.0	1	2.2	45	97.8	0	0.0
White Blood Cells	PI(M1)	Above	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Unknown	1	0	0.0	1	100	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	0	0.0	1	33.3	2	66.7	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	68	1	1.5	3	4.4	64	94.1	0	0.0	43	0	0.0	4	9.3	39	90.7	0	0.0
	PI(M2)	Above	1	0	0.0	0	0.0	1	100	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100
		Unknown	1	0	0.0	1	100	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	0	0.0	1	33.3	2	66.7	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	66	1	1.5	4	6.1	61	92.4	0	0.0	45	2	4.4	2	4.4	41	91.1	0	0.0
	PII(M3)	Above	1	0	0.0	0	0.0	1	100	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100
		Unknown	1	0	0.0	1	100	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	0	0.0	0	0.0	3	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	67	0	0.0	4	6.0	63	94.0	0	0.0	45	1	2.2	7	15.6	36	80.0	1	2.2
	PII(M6)	Above	1	0	0.0	0	0.0	1	100	0	0.0	2	0	0.0	0	0.0	1	50.0	1	50.0
		Unknown	1	0	0.0	1	100	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
	PII(M6)	Within	66	0	0.0	5	7.6	60	90.9	1	1.5	45	1	2.2	4	8.9	39	86.7	1	2.2

		Above	1	0	0.0	0	0.0	1	100	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100
	PIII(M7)	Unknown	1	0	0.0	0	0.0	1	100	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Below	3	0	0.0	2	66.7	1	33.3	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0
		Within	63	0	0.0	4	6.3	59	93.7	0	0.0	45	0	0.0	1	2.2	43	95.6	1	2.2
		Above	1	0	0.0	0	0.0	1	100	0	0.0	2	0	0.0	0	0.0	1	50.0	1	50.0

N= number of subjects with laboratory results for the specified visit and laboratory parameter

n/% = number/percentage of subjects in a given category

Unknown = value unknown for the specified visit and laboratory parameter

Below = value below the laboratory reference range defined for the specified visit and laboratory parameter

Within = value within the laboratory reference range defined for the specified visit and laboratory parameter

Above = value above the laboratory reference range defined for the specified visit and laboratory parameter

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

* In case of retest at the screening time point, the last value available was considered. For the post vaccination, the retests were not considered

Primary Outcome Results: Number (%) of subjects reporting potential Immune Mediated Diseases (pIMDs) and inflammatory disorders from the first administered dose up to study end (Total Vaccinated cohort)

All pIMDs	HZV Group N = 74	Placebo Group N = 49
Subjects with any pIMD (s), n (%)	0 (0.0)	0 (0.0)

Primary Outcome Results: Number (%) of subjects reporting events indicative of worsening of HIV condition from the first administered dose up to study end (Total Vaccinated cohort)

	HZV Group N = 74		Placebo Group N = 49	
Categories	n	%	n	%
At least one event	9	12.2	5	10.2
Change in HIV viral load (Months 1-7)	3	4.1	1	2.0
Change in CD4 cells count (Months 1-7)	7	9.5	4	8.2
AIDS defining conditions (Months 0-18)	0	0	0	0
Significant change to ART due to failure to control HIV viral load (Months 0-18)	0	0	0	0
Significant change to ART due to failure to maintain high CD4 cells count (Months 0-18)	0	0	0	0

N = number of subjects in each group

n = number of subjects in a given category

% = n/Number of subjects in each group x 100

Primary Outcome Results: Number (%) of subjects reporting events indicative of worsening of HIV condition from the first administered dose up to study end by HIV status (Total Vaccinated cohort)

	ARTHCD4				ARTLCD4				NARTHCD			
	HZV Group N = 56		Placebo Group N = 38		HZV Group N = 9		Placebo Group N = 5		HZV Group N = 9		Placebo Group N = 6	
Categories	n	%	n	%	n	%	n	%	n	%	n	%
At least one event	5	8.9	3	7.9	2	22.2	1	20.0	2	22.2	1	16.7
Change in HIV viral load (Months 1-7)	1	1.8	0	0.0	1	11.1	0	0.0	1	11.1	1	16.7
Change in CD4 cells count (Months 1-7)	5	8.9	3	7.9	1	11.1	1	20.0	1	11.1	0	0.0
AIDS defining conditions (Months 0-18)	0	0	0	0	0	0	0	0	0	0	0	0
Significant change to ART due to failure to control HIV viral load (Months 0-18)	0	0	0	0	0	0	0	0	0	0	0	0
Significant change to ART due to failure to maintain high CD4 cells count (Months 0-18)	0	0	0	0	0	0	0	0	0	0	0	0

N = number of subjects in each group

n = number of subjects in a given category

% = n/Number of subjects in each group x 100

Primary Outcome Results: Please refer to the safety section of this document for the results pertaining to SAEs.

Secondary Outcome Results: Seropositivity rates and GMCs of anti-gE antibodies at Months 0, 1, 2, 3, 6, 7 (ATP cohort for

immunogenicity) and 18 (ATP cohort for persistence)										
			≥ 18 mIU/mL					GMC (mIU/mL)		
						95% CI				
								95% CI		
Antibody	Group	Timing	N	n	%	LL	UL	Value	LL	UL
Anti-gE	HZV	PRE	53	53	100	93.3	100	1218.4	895.0	1658.7
		PI(M1)	54	54	100	93.4	100	24113.2	18317.4	31743.0
		PI(M2)	53	53	100	93.3	100	17112.6	12929.5	22649.1
		PII(M3)	54	54	100	93.4	100	50443.0	40899.6	62213.2
		PII(M6)	54	54	100	93.4	100	34159.4	27221.0	42866.2
		PIII(M7)	54	54	100	93.4	100	63812.6	51183.6	79557.7
		PIII(M18)	49	49	100	92.7	100	25242.2	19618.9	32477.3
	Placebo	PRE	37	36	97.3	85.8	99.9	849.5	551.1	1309.4
		PI(M1)	36	36	100	90.3	100	1059.0	749.4	1496.5
		PI(M2)	37	36	97.3	85.8	99.9	903.3	590.9	1380.9
		PII(M3)	37	36	97.3	85.8	99.9	992.9	647.4	1522.6
		PII(M6)	37	36	97.3	85.8	99.9	1013.1	660.5	1553.7
		PIII(M7)	36	35	97.2	85.5	99.9	1028.4	658.9	1605.0
		PIII(M18)	37	36	97.3	85.8	99.9	918.0	588.0	1433.1

Seropositivity rate = Anti-gE antibody concentration ≥ 18 mIU/mL

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with concentration within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PRE = Pre-vaccination (Day 0)

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

Secondary Outcome Results: Seropositivity rates and GMCs of anti-gE antibodies at Months 0, 1, 2, 3, 6, 7 (ATP cohort for immunogenicity) and 18 by HIV status (ATP cohort for persistence)

				≥ 18 mIU/mL					GMC (mIU/mL)		
							95% CI				
									95% CI		
Antibody	Sub-group	Group	Timing	N	n	%	LL	UL	value	LL	UL
Anti-gE	ARTHCD4	HZV	PRE	43	43	100	91.8	100	1113.2	794.3	1560.3
			PI(M1)	44	44	100	92.0	100	25530.6	19158.6	34021.9
			PI(M2)	43	43	100	91.8	100	18208.6	13537.4	24491.6
			PII(M3)	44	44	100	92.0	100	54777.7	44077.1	68076.1
			PII(M6)	44	44	100	92.0	100	38068.2	29964.3	48363.7
			PIII(M7)	44	44	100	92.0	100	71309.6	57019.3	89181.5
			PIII(M18)	40	40	100	91.2	100	28854.6	22512.5	36983.3
		Placebo	PRE	30	29	96.7	82.8	99.9	791.0	490.7	1275.1
			PI(M1)	29	29	100	88.1	100	1029.5	719.5	1473.1
			PI(M2)	30	29	96.7	82.8	99.9	839.8	524.6	1344.4
			PII(M3)	30	29	96.7	82.8	99.9	955.6	590.6	1546.2
			PII(M6)	30	29	96.7	82.8	99.9	932.8	582.6	1493.3
			PIII(M7)	29	28	96.6	82.2	99.9	928.8	566.8	1522.1
			PIII(M18)	29	28	96.6	82.2	99.9	849.4	514.6	1401.9
	ARTLCD4	HZV	PRE	5	5	100	47.8	100	1845.1	465.1	7319.1
			PI(M1)	5	5	100	47.8	100	18767.2	2219.4	158697.1
			PI(M2)	5	5	100	47.8	100	13106.4	1619.0	106104.2
			PII(M3)	5	5	100	47.8	100	36592.6	7026.0	190581.1
			PII(M6)	5	5	100	47.8	100	24725.0	5143.2	118862.3
			PIII(M7)	5	5	100	47.8	100	47382.6	9151.2	245336.2
			PIII(M18)	4	4	100	39.8	100	18995.8	1733.3	208181.4

	NARTHCD	Placebo	PRE	3	3	100	29.2	100	2420.7	512.0	11445.2
			PI(M1)	3	3	100	29.2	100	2328.1	446.4	12141.8
			PI(M2)	3	3	100	29.2	100	2465.5	561.9	10817.4
			PII(M3)	3	3	100	29.2	100	2166.3	618.9	7583.1
			PII(M6)	3	3	100	29.2	100	2629.2	561.7	12306.8
			PIII(M7)	3	3	100	29.2	100	2553.0	610.1	10683.1
			PIII(M18)	4	4	100	39.8	100	1953.7	572.7	6665.3
		HZV	PRE	5	5	100	47.8	100	1748.6	308.5	9912.2
			PI(M1)	5	5	100	47.8	100	18742.3	6616.7	53089.1
			PI(M2)	5	5	100	47.8	100	13100.6	4828.6	35543.7
			PII(M3)	5	5	100	47.8	100	33662.4	20665.6	54833.0
			PII(M6)	5	5	100	47.8	100	18189.6	11258.0	29389.0
			PIII(M7)	5	5	100	47.8	100	32334.6	17277.6	60513.4
			PIII(M18)	5	5	100	47.8	100	10869.2	4435.4	26635.7
		Placebo	PRE	4	4	100	39.8	100	661.2	43.8	9984.8
			PI(M1)	4	4	100	39.8	100	720.0	50.6	10238.5
			PI(M2)	4	4	100	39.8	100	735.0	52.7	10245.9
			PII(M3)	4	4	100	39.8	100	736.6	52.1	10414.5
			PII(M6)	4	4	100	39.8	100	920.6	54.8	15461.5
			PIII(M7)	4	4	100	39.8	100	1087.6	60.2	19641.4
			PIII(M18)	4	4	100	39.8	100	757.8	34.8	16519.1

Seropositivity rate = Anti-gE antibody concentration ≥ 18 mIU/mL

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with concentration within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PRE = Pre-vaccination (Day 0)

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

Secondary Outcome Results: Seropositivity rates and GMCs of anti-VZV antibody at Months 0, 1, 2, 3, 6, 7 (ATP cohort for immunogenicity) and 18 in all subjects (ATP cohort for persistence)

				≥ 25 mIU/mL				GMC (mIU/mL)		
							95% CI			
Antibody	Group	Timing	N	n	%	LL	UL	value	LL	UL
VZV Ab.IgG	HZV	PRE	48	48	100	92.6	100	1292.7	999.8	1671.4
		PI(M1)	43	43	100	91.8	100	6953.8	5425.1	8913.3
		PI(M2)	45	45	100	92.1	100	5170.9	4032.7	6630.4
		PII(M3)	50	50	100	92.9	100	11119.7	9190.8	13453.3
		PII(M6)	49	49	100	92.7	100	8244.0	6678.6	10176.3
		PIII(M7)	49	49	100	92.7	100	14560.8	11849.0	17893.1
		PIII(M18)	46	46	100	92.3	100	7493.3	5926.7	9473.9
	Placebo	PRE	36	34	94.4	81.3	99.3	1074.7	672.7	1717.0
		PI(M1)	33	32	97.0	84.2	99.9	1173.8	762.9	1805.8
		PI(M2)	33	31	93.9	79.8	99.3	987.6	596.3	1635.8
		PII(M3)	33	31	93.9	79.8	99.3	1037.8	620.2	1736.5
		PII(M6)	34	32	94.1	80.3	99.3	1069.8	653.3	1751.7
		PIII(M7)	32	30	93.8	79.2	99.2	999.3	598.3	1669.2
		PIII(M18)	29	27	93.1	77.2	99.2	922.9	521.1	1634.6

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 (anti-VZV Ab concentration ≥ 25 mIU/mL)

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PRE = Pre-vaccination (Month 0)

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

Secondary Outcome Results: Seropositivity rates and GMCs of anti-VZV antibody at Months 0, 1, 2, 3, 6, 7 (ATP cohort for immunogenicity) and 18 by HIV status (ATP cohort for persistence)

Antibody	Sub-group	Group	Timing	N	≥ 25 mIU/mL				GMC(mIU/mL)		
					n	%	95% CI		value	95% CI	
							LL	UL		LL	UL
VZV Ab.IgG	ARTHCD4	HZV	PRE	38	38	100	90.7	100	1161.5	900.3	1498.6
			PI(M1)	34	34	100	89.7	100	7017.8	5441.2	9051.3
			PI(M2)	38	38	100	90.7	100	5056.5	3973.9	6434.0
			PII(M3)	41	41	100	91.4	100	11631.9	9523.8	14206.6
			PII(M6)	39	39	100	91.0	100	9027.6	7225.1	11279.6
			PIII(M7)	40	40	100	91.2	100	15278.5	12420.2	18794.5
			PIII(M18)	37	37	100	90.5	100	8242.2	6484.1	10476.9
		Placebo	PRE	29	27	93.1	77.2	99.2	985.1	568.7	1706.4
			PI(M1)	26	25	96.2	80.4	99.9	1059.6	641.1	1751.2
			PI(M2)	27	25	92.6	75.7	99.1	886.9	498.6	1577.4
			PII(M3)	28	26	92.9	76.5	99.1	1002.7	565.8	1777.1
			PII(M6)	27	25	92.6	75.7	99.1	957.0	537.2	1705.0
			PIII(M7)	26	24	92.3	74.9	99.1	930.5	511.6	1692.3
			PIII(M18)	24	22	91.7	73.0	99.0	838.1	435.9	1611.5
	ARTLCD4	HZV	PRE	5	5	100	47.8	100	2272.6	559.1	9236.6
			PI(M1)	4	4	100	39.8	100	6731.0	572.7	79107.0
			PI(M2)	4	4	100	39.8	100	5649.6	418.4	76276.9
			PII(M3)	5	5	100	47.8	100	9110.7	2224.8	37308.9
			PII(M6)	5	5	100	47.8	100	7634.7	2054.6	28369.5
			PIII(M7)	5	5	100	47.8	100	14763.2	2859.6	76216.1
			PIII(M18)	4	4	100	39.8	100	6106.2	748.6	49809.5
		Placebo	PRE	3	3	100	29.2	100	2511.9	693.0	9104.4
			PI(M1)	3	3	100	29.2	100	2871.0	1386.7	5944.3
			PI(M2)	2	2	100	15.8	100	2902.1	1.9	4493973
			PII(M3)	1	1	100	2.5	100	2479.3	-	-
			PII(M6)	3	3	100	29.2	100	3164.8	510.5	19621.7
			PIII(M7)	2	2	100	15.8	100	2177.3	8.7	544573.1
			PIII(M18)	2	2	100	15.8	100	1955.3	188.8	20249.5
	NARTHCD	HZV	PRE	5	5	100	47.8	100	1658.0	315.9	8701.1
			PI(M1)	5	5	100	47.8	100	6706.0	2477.9	18148.5
			PI(M2)	3	3	100	29.2	100	6100.0	480.4	77462.7
			PII(M3)	4	4	100	39.8	100	8990.7	5233.1	15446.6
			PII(M6)	5	5	100	47.8	100	4384.3	2322.5	8276.5
			PIII(M7)	4	4	100	39.8	100	8845.8	5463.6	14321.5
			PIII(M18)	5	5	100	47.8	100	4361.7	1721.5	11050.9
		Placebo	PRE	4	4	100	39.8	100	1068.5	117.3	9735.4
			PI(M1)	4	4	100	39.8	100	1167.3	130.1	10475.4
			PI(M2)	4	4	100	39.8	100	1191.1	119.6	11860.7
			PII(M3)	4	4	100	39.8	100	1062.0	81.1	13906.2
			PII(M6)	4	4	100	39.8	100	1006.3	115.7	8754.6

			PIII(M7)	4	4	100	39.8	100	1076.7	109.5	10591.1
			PIII(M18)	3	3	100	29.2	100	1209.2	13.9	105230.8

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 (anti-VZV Ab concentration \geq 25 mIU/mL)

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PRE = Pre-vaccination (Month 0)

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

"-" = indicates there were not enough subjects for a LL and UL to be computed

Secondary Outcome Results: Descriptive statistics of the frequency of gE-specific CD4 [2+] T-cells at Months 0, 1, 2, 3, 6, 7 (ATP cohort for immunogenicity) and 18 (ATP cohort for persistence)

Immune marker	Group	Timing	N	Mean	SD	Median
CD4.polypositives CD40L+IL2+TNFa+IFNg	HZV	PRE	33	218.26	254.94	106.9
		PI(M1)	40	704.06	614.49	549.6
		PI(M2)	38	649.68	555.51	539.1
		PII(M3)	41	3503.69	2971.74	2809.7
		PII(M6)	29	2647.71	1972.00	2229.9
		PIII(M7)	30	4684.50	5376.83	2578.4
		PIII(M18)	49	1929.30	1603.50	1533.0
	Placebo	PRE	27	123.15	170.79	52.1
		PI(M1)	26	132.49	213.05	16.6
		PI(M2)	26	140.95	197.99	58.1
		PII(M3)	28	160.10	220.32	42.0
		PII(M6)	19	133.70	137.94	113.0
		PIII(M7)	20	158.64	151.15	122.6
		PIII(M18)	35	139.50	219.57	71.8

N = number of subjects with available results

SD = Standard Deviation

CD4.polypositives CD40L+IL2+TNFa+IFNg = CD4+ T cells expressing at least 2 immune markers among CD40L, IL-2, TNFa & IFNg

PRE = Pre-vaccination (Month 0)

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

Secondary Outcome Results: Descriptive statistics of the frequency of gE-specific CD4 [2+] T-cells at Months 0, 1, 2, 3, 6, 7 (ATP cohort for immunogenicity) and 18 by HIV status (ATP cohort for persistence)

Immune marker	Sub-group	Group	Timing	N	Mean	SD	Median
CD4.polypositives CD40L+IL2+TNFa+IFNg	ARTHCD4	HZV	PRE	28	215.99	266.22	103.0
			PI(M1)	30	682.62	595.89	544.2
			PI(M2)	29	610.30	558.27	516.4
			PII(M3)	33	3722.21	2789.70	2956.8
			PII(M6)	25	2386.40	1571.28	2229.9
			PIII(M7)	26	3649.92	3112.69	2546.4
			PIII(M18)	40	2071.17	1583.58	1695.9
		Placebo	PRE	24	136.29	176.85	65.0
			PI(M1)	22	134.21	224.96	16.6
			PI(M2)	22	157.92	208.48	63.7
			PII(M3)	22	190.58	233.81	131.1
			PII(M6)	16	152.52	141.50	149.0
			PIII(M7)	19	166.94	150.54	126.1

ARTLCD4	HZV	PIII(M18)	28	159.05	239.50	85.8
		PRE	2	51.15	70.92	51.1
		PI(M1)	5	584.10	652.67	436.3
		PI(M2)	4	960.39	632.86	998.7
		PII(M3)	3	4754.94	6004.05	2021.6
		PII(M6)	3	5403.79	3326.03	5505.5
		PIII(M7)	3	14925.30	10934.07	12547.8
		PIII(M18)	4	2035.18	2100.82	1659.6
	Placebo	PRE	1	1.00	-	1.0
		PI(M1)	2	161.73	227.30	161.7
		PI(M2)	2	94.19	131.79	94.2
		PII(M3)	3	1.00	0.00	1.0
		PII(M6)	1	97.99	-	98.0
		PIII(M7)	1	1.00	-	1.0
		PIII(M18)	3	109.97	93.90	58.8
NARTHCD	HZV	PRE	3	350.86	161.96	441.2
		PI(M1)	5	952.65	763.24	962.1
		PI(M2)	5	629.54	513.99	799.6
		PII(M3)	5	1310.76	670.56	1681.5
		PII(M6)	1	912.30	-	912.3
		PIII(M7)	1	861.21	-	861.2
		PIII(M18)	5	709.62	1011.03	226.0
	Placebo	PRE	2	26.57	36.17	26.6
		PI(M1)	2	84.33	117.84	84.3
		PI(M2)	2	1.00	0.00	1.0
		PII(M3)	3	95.71	164.04	1.0
		PII(M6)	2	1.00	0.00	1.0
		PIII(M7)	0	-	-	-
		PIII(M18)	4	24.81	47.63	1.0

N = number of subjects with available results

SD = Standard Deviation

CD4.polypositives CD40L+IL2+TNFa+IFNg = CD4+ T cells expressing at least 2 immune markers among CD40L, IL-2, TNFa & IFNg

PRE = Pre-vaccination (Month 0)

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

Secondary Outcome Results: Descriptive statistics of the frequency of VZV-specific CD4 [2+] T-cells at Months 0, 1, 2, 3, 6, 7 (ATP cohort for immunogenicity) and 18 (ATP cohort for persistence)

Immune marker	Group	Timing	N	Mean	SD	Median
CD4.polypositives CD40L+IL2+TNFa+IFNg	HZV	PRE	32	750.20	989.36	332.4
		PI(M1)	40	768.60	739.68	543.1
		PI(M2)	37	734.09	680.34	579.1
		PII(M3)	41	1878.81	1615.20	1386.3
		PII(M6)	29	1646.83	1202.32	1386.0
		PIII(M7)	30	2626.71	2514.40	1437.7
		PIII(M18)	48	995.35	842.96	684.6
	Placebo	PRE	27	835.80	1949.39	163.7
		PI(M1)	26	913.87	2262.66	228.9
		PI(M2)	26	874.13	2027.95	393.2
		PII(M3)	28	987.24	1988.86	461.8
		PII(M6)	19	674.20	657.00	396.0
		PIII(M7)	20	1204.44	1911.53	524.6
		PIII(M18)	35	531.24	579.63	312.0

Secondary Outcome Results: Descriptive statistics of the frequency of VZV-specific CD4 [2+] T-cells at Month 0, 1, 2, 3, 6, 7 (ATP cohort for immunogenicity) and 18 by HIV status (ATP cohort for persistence)

N = number of subjects with available results

SD = Standard Deviation

CD4.polypositives CD40L+IL2+TNFa+IFNg = CD4+ T cells expressing at least 2 immune markers among CD40L, IL-2, TNFa & IFNg

PRE = Pre-vaccination (Month 0)

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

Secondary Outcome Results: Proportion of subjects with results ≥ 40 copies/mL in HIV VL at all time points up to Month 18, by HIV status (Total Vaccinated cohort)

					≥ 40 Copies/mL			
							95% CI	
Test Name	Sub-group	Group	Timing	N*	n	%	LL	UL
RNA-HIV	ARTHCD4	HZV	SCR	56	0	0.0	0.0	6.4
			PI(M1)	54	1	1.9	0.0	9.9
			PI(M2)	53	3	5.7	1.2	15.7
			PII(M3)	55	3	5.5	1.1	15.1
			PII(M6)	55	4	7.3	2.0	17.6
			PIII(M7)	54	3	5.6	1.2	15.4
			PIII(M18)	49	3	6.1	1.3	16.9
		Placebo	SCR	38	0	0.0	0.0	9.3
			PI(M1)	33	0	0.0	0.0	10.6
			PI(M2)	37	1	2.7	0.1	14.2
			PII(M3)	36	0	0.0	0.0	9.7
			PII(M6)	37	1	2.7	0.1	14.2
			PIII(M7)	36	4	11.1	3.1	26.1
			PIII(M18)	35	3	8.6	1.8	23.1
	ARTLCD4	HZV	SCR	9	1	11.1	0.3	48.2
			PI(M1)	9	1	11.1	0.3	48.2
			PI(M2)	9	2	22.2	2.8	60.0
			PII(M3)	9	1	11.1	0.3	48.2
			PII(M6)	9	2	22.2	2.8	60.0
			PIII(M7)	8	1	12.5	0.3	52.7
			PIII(M18)	7	1	14.3	0.4	57.9
		Placebo	SCR	5	0	0.0	0.0	52.2
			PI(M1)	5	0	0.0	0.0	52.2
			PI(M2)	5	0	0.0	0.0	52.2
			PII(M3)	5	0	0.0	0.0	52.2
			PII(M6)	4	1	25.0	0.6	80.6
			PIII(M7)	5	0	0.0	0.0	52.2
			PIII(M18)	5	0	0.0	0.0	52.2
	NARTHCD	HZV	SCR	9	9	100	66.4	100
			PI(M1)	9	9	100	66.4	100
			PI(M2)	8	8	100	63.1	100
			PII(M3)	8	8	100	63.1	100
			PII(M6)	7	7	100	59.0	100
			PIII(M7)	7	7	100	59.0	100
			PIII(M18)	7	7	100	59.0	100
		Placebo	SCR	6	6	100	54.1	100
			PI(M1)	5	5	100	47.8	100
			PI(M2)	4	4	100	39.8	100
			PII(M3)	5	5	100	47.8	100
			PII(M6)	5	5	100	47.8	100
			PIII(M7)	5	5	100	47.8	100
			PIII(M18)	5	5	100	47.8	100

N = number of subjects with available results

n/% = number/percentage of subjects with concentration equal to or above specified value

95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

RNA-HIV = Ribonucleic Acid - Human Immunodeficiency Virus

SCR = Screening timepoint

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

* In case of retest at the screening visit the last value available was considered. For the post vaccination, the retests were not considered.

Secondary Outcome Results: Descriptive statistics in HIV VL at Months 0, 1, 2, 3, 6, 7 and 18, by HIV status (Total Vaccinated cohort)

Test Name	Sub-group	Group	Timing	N*	Mean	SD	Median
RNA-HIV	ARTHCD4	HZV	PI(M1)	1	42.00	-	42.0
			PI(M2)	3	48.67	10.79	44.0
			PII(M3)	3	75.00	37.75	70.0
			PII(M6)	4	19699.25	39272.50	72.0
			PIII(M7)	3	530.67	785.50	108.0
			PIII(M18)	3	70.33	29.54	72.0
		Placebo	PI(M2)	1	55.00	-	55.0
			PII(M6)	1	112.00	-	112.0
			PIII(M7)	4	55.75	6.29	55.0
			PIII(M18)	3	92.67	64.53	72.0
	ARTLCD4	HZV	SCR	1	62.00	-	62.0
			PI(M1)	1	48.00	-	48.0
			PI(M2)	2	48.00	2.83	48.0
			PII(M3)	1	84.00	-	84.0
			PII(M6)	2	66053.50	93328.90	66053.5
			PIII(M7)	1	248.00	-	248.0
			PIII(M18)	1	48.00	-	48.0
		Placebo	PII(M6)	1	51.00	-	51.0
	NARTHCD	HZV	SCR	9	23014.11	18435.10	21831.0
			PI(M1)	9	24538.89	19056.10	26904.0
			PI(M2)	8	24134.25	13753.92	22706.0
			PII(M3)	8	19453.50	11878.74	18419.5
			PII(M6)	7	37091.29	33678.60	33354.0
			PIII(M7)	7	35534.00	39549.42	27641.0
			PIII(M18)	7	60597.00	48313.15	46204.0
		Placebo	SCR	6	16022.17	23652.18	3726.0
			PI(M1)	5	14415.80	9289.92	11448.0
			PI(M2)	4	18188.25	15199.35	15023.0
			PII(M3)	5	16270.00	15785.91	15565.0
			PII(M6)	5	46429.60	52567.42	30024.0
			PIII(M7)	5	25774.60	27360.66	13547.0
			PIII(M18)	5	14742.60	18306.17	6026.0

N = number of subjects with available results ≥ 40 copies/mL

SD = Standard Deviation

RNA-HIV = Ribonucleic Acid - Human Immunodeficiency Virus

SCR = Screening timepoint

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

* In case of retest at the screening visit the last value available was considered. For the post vaccination, the retests were not considered.

Secondary Outcome Results: Descriptive statistics in CD4 T-cells counts at Months 0, 1, 2, 3, 6, 7 and 18, by HIV status (Total Vaccinated cohort)

Immune marker	Sub-group	Group	Timing	N*	Mean	SD	Median
CD4+	ARTHCD4	HZV	SCR	56	631.46	236.36	603.5
			PI(M1)	55	630.55	241.78	601.0
			PI(M2)	54	667.69	309.22	606.0
			PII(M3)	55	633.60	228.75	594.0
			PII(M6)	53	655.02	264.67	580.0
			PIII(M7)	54	654.69	271.31	616.0
			PIII(M18)	51	679.71	247.57	620.0
		Placebo	SCR	38	683.39	228.29	661.0
			PI(M1)	35	694.69	307.98	635.0
			PI(M2)	36	656.14	262.43	598.0
			PII(M3)	36	640.14	238.05	664.0
			PII(M6)	36	668.28	308.64	579.0
			PIII(M7)	37	658.81	246.53	614.0
			PIII(M18)	35	651.06	247.30	605.0
	ARTLCD4	HZV	SCR	9	152.11	38.39	153.0
			PI(M1)	9	151.11	38.72	134.0
			PI(M2)	8	131.13	39.57	138.0
			PII(M3)	9	153.11	54.27	144.0
			PII(M6)	9	145.33	29.74	145.0
			PIII(M7)	8	170.25	44.52	172.0
			PIII(M18)	7	168.43	58.49	156.0
		Placebo	SCR	5	132.20	11.19	130.0
			PI(M1)	5	163.00	53.66	167.0
			PI(M2)	4	133.75	31.86	142.5
			PII(M3)	5	142.60	36.49	155.0
			PII(M6)	5	145.20	43.18	144.0
			PIII(M7)	5	150.40	35.11	159.0
			PIII(M18)	5	151.40	57.48	130.0
	NARTHCD	HZV	SCR	9	805.33	132.38	801.0
			PI(M1)	9	879.67	277.37	860.0
			PI(M2)	8	808.75	211.32	796.5
			PII(M3)	8	783.63	239.92	797.5
			PII(M6)	7	776.43	303.30	765.0
			PIII(M7)	7	869.14	297.04	822.0
			PIII(M18)	7	720.00	228.77	636.0
		Placebo	SCR	6	901.67	177.61	912.5
			PI(M1)	5	773.40	144.85	774.0
			PI(M2)	5	804.00	199.09	714.0
			PII(M3)	5	762.60	185.66	835.0
			PII(M6)	5	1082.80	649.82	811.0
			PIII(M7)	5	866.00	144.30	937.0
			PIII(M18)	5	824.40	207.57	761.0

N = number of subjects with available results

SD = Standard Deviation

SCR = Screening time point

PI(M1) = Post-vaccination Dose I (Month 1)

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

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

PII(M6) = Post-vaccination Dose II (Month 6)

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

PIII(M18) = Post-vaccination Dose III (Month 18)

* In case of retest at the screening visit the last value available was considered. For the post vaccination, the retests was not used

Secondary Outcome Results: Listing of HZ confirmed cases reported from the first administered dose until the study end (Total Vaccinated cohort)

Group	Subject Number	PCR result	Expert evaluation	Last dose	Onset day
HZV	58	Test not performed	Classified as HZ cases	1	83

PCR = Polymerase Chain Reaction

Safety Results: Number (%) of subjects with unsolicited AEs occurring within 30 days (Days 0-29) post-vaccination period (Total Vaccinated cohort)

Most frequent adverse events - On-Therapy (occurring within Days 0-29 following vaccination)	HZV Group N = 74	Placebo Group N = 49
Subjects with any AE(s), n (%)	41 (55.4)	26 (53.1)
Subjects with grade 3 AE(s), n (%)	4 (5.4)	2 (4.1)
Subjects with related AE(s), n (%)	11 (14.9)	3 (6.1)
Influenza like illness	6 (8.1)	1 (2.0)
Nasopharyngitis	4 (5.4)	2 (4.1)
Oropharyngeal pain	4 (5.4)	1 (2.0)
Upper respiratory tract infection	5 (6.8)	-
Sinusitis	3 (4.1)	1 (2.0)
Arthralgia	2 (2.7)	1 (2.0)
Arthropod bite	2 (2.7)	1 (2.0)
Cough	2 (2.7)	1 (2.0)
Diarrhoea	3 (4.1)	-
Back pain	2 (2.7)	-
Chest pain	2 (2.7)	-
Giardiasis	2 (2.7)	-
Injection site pruritus	2 (2.7)	-
Injection site reaction	2 (2.7)	-
Night sweats	2 (2.7)	-
Pain	2 (2.7)	-
Pyrexia	-	2 (4.1)
Rhinorrhoea	-	2 (4.1)
Arteriosclerosis	-	1 (2.0)
Bladder dysfunction	-	1 (2.0)
Blister	-	1 (2.0)
Chills	-	1 (2.0)
Conjunctivitis	-	1 (2.0)
Depression	-	1 (2.0)
Drug abuse	-	1 (2.0)
Dry mouth	-	1 (2.0)
Ear discomfort	-	1 (2.0)
Fatigue	-	1 (2.0)
Feeling abnormal	-	1 (2.0)
Gout	-	1 (2.0)
Head discomfort	-	1 (2.0)
Headache	-	1 (2.0)
Influenza	-	1 (2.0)
Injection site pain	-	1 (2.0)
Joint injury	-	1 (2.0)
Lower limb fracture	-	1 (2.0)
Lower respiratory tract infection	-	1 (2.0)
Lymphadenopathy	-	1 (2.0)
Musculoskeletal stiffness	-	1 (2.0)
Oral herpes	-	1 (2.0)
Pain in extremity	-	1 (2.0)

Penile erythema	-	1 (2.0)
Radiculopathy	-	1 (2.0)
Rash	-	1 (2.0)
Rhinitis	-	1 (2.0)
Sciatica	-	1 (2.0)
Sleep disorder	-	1 (2.0)
Swelling	-	1 (2.0)
Toothache	-	1 (2.0)
Treponema test positive	-	1 (2.0)
Urethritis noninfective	-	1 (2.0)
Viral upper respiratory tract infection	-	1 (2.0)

Grade 3 = event which prevented normal activities

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

Counting rule applied: As there were more than 30 subjects per treatment group and ≤ 3 groups, only the 10 most frequent events in each treatment group are to be listed.

-: Implies that 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 10 most frequent events for that group.

Safety Results: Number (%) of subjects with SAEs related to study participation or related to a concurrent GSK medication during the entire study period (Total Vaccinated cohort)

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

All SAEs	HZV Group N = 74	Placebo Group N = 49
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	HZV Group N = 74	Placebo Group N = 49
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]

Safety Results: Number (%) of subjects with SAEs reported from the first administered dose until study end (Total Vaccinated cohort)

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

All SAEs	HZV Group N = 74	Placebo Group N = 49
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	6 (8.1) [0]	2 (4.1) [0]
Anal abscess	1 (1.4) [0]	0 (0.0) [0]
Coronary artery disease	1 (1.4) [0]	0 (0.0) [0]
Drug abuse	0 (0.0) [0]	1 (2.0) [0]
Epididymitis	1 (1.4) [0]	0 (0.0) [0]
Laryngeal cancer recurrent	1 (1.4) [0]	0 (0.0) [0]
Oesophageal varices haemorrhage	1 (1.4) [0]	0 (0.0) [0]
Partial seizures	1 (1.4) [0]	0 (0.0) [0]
Peripheral vascular disorder	0 (0.0) [0]	1 (2.0) [0]
Portal hypertension	1 (1.4) [0]	0 (0.0) [0]
Fatal SAEs	HZV Group N = 74	Placebo Group N = 49
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]

Conclusion:

From the first vaccination until 30 days after the last vaccination, no NOADs or other immune mediated inflammatory disorders were identified in any study group.

During the 7-day post vaccination period, pain was the most common solicited symptom, reported by 72 subjects (98.6%) from the HZV Group and 6 subjects (12.5%) from the Placebo Group. Pain was also the most common Grade 3 solicited symptom, reported by 12 subjects (16.4%) in the HZV Group, while no Grade 3 solicited symptoms were reported for the Placebo Group.

During the same post-vaccination period, fatigue was the most common solicited general symptom in the HZV Group, reported by 55 subjects (75.3%) and headache was the most common solicited general symptom in the Placebo Group, reported by 15 subjects (31.3%). Fatigue was also the most common Grade 3 solicited general symptom, with reports from 12 subjects (16.4%) in the HZV Group and 4 subjects (8.3%) in the Placebo Group. Myalgia was the most common solicited symptom considered related to the study

vaccination in the HZV Group, reported by 44 subjects (60.3 %), while in the Placebo Group, the most common solicited related symptoms were myalgia, headache and fatigue, each reported by 8 subjects (16.7%).

Over 72% of subjects in HZV group and over 75% of subjects in Placebo group had values of haematological and biochemical parameters within the normal range at all time points.

Over 83% of subjects in HZV group and over 80% of subjects in Placebo group who were within normal range at baseline maintained values of haematological and biochemical parameters within the normal range through Month 7.

During the entire duration of the study, from administration of the first dose of vaccine/placebo until end of the trial, there was at least one event indicative of protocol-defined worsening of HIV condition reported for 14 subjects. All were reports of changes in CD4 count and/or HIV VL, for 9 subjects in the HZV group, and 5 in the Placebo group. There were no reports of significant change to ART (including ART initiation in the non-ART High CD4 cohort) and no occurrences of AIDS-defining conditions.

In terms of the gE-specific humoral immune response at Month 7 (one month after the third vaccination) in subjects with high CD4 T cell count (≥ 200 cells/mm³ for subjects on ART and ≥ 500 cells/mm³ for ART-naïve subjects) at enrolment, the geometric mean values in anti-gE antibody ELISA concentrations were 56305.23 in the HZV Group, and 1218.7 in the Placebo Group.

In terms of the gE-specific CD4[2+] T cell frequency, at Month 7 (one month after the third vaccination) in subjects with high CD4 T cell count (≥ 200 cells/mm³ for subjects on ART and ≥ 500 cells/mm³ for ART-naïve subjects) at enrolment, the geometric mean values were 2541.54 in the HZV Group, and 115.78 in the Placebo Group.

From the first vaccination (Month 0) until the end of the study, SAEs were reported for 6 subjects in the HZV Group and 2 subjects in the Placebo Group: The following SAEs were reported, each time for 1 subject in the HZV group: anal abscess, coronary artery disease, epididymitis, laryngeal cancer recurrent, oesophageal varices haemorrhage, partial seizures, portal hypertension, and each time for 1 subject in the Placebo Group: drug abuse and peripheral vascular disorder. None of the SAEs were considered by the investigator to be related to the study medication. No fatal SAEs were reported for the entire duration of the study.

Date Updated: 30-October-2015