



Clinical trial results:

A phase IIIb, open-label, multi-country, multi-centre, long-term follow-up study (ZOE-LTFU) of studies 110390 and 113077 (ZOSTER-006/022) to assess the prophylactic efficacy, safety, and immunogenicity persistence of GSK Biologicals' Herpes Zoster subunit (HZ/su) vaccine and assessment of 1 or 2 additional doses on a 0 or 0, 2-month schedule in two subgroups of older adults

Summary

EudraCT number	2015-001778-17
Trial protocol	FI EE CZ GB DE ES IT
Global end of trial date	28 June 2023

Results information

Result version number	v1
This version publication date	14 July 2024
First version publication date	14 July 2024

Trial information

Trial identification

Sponsor protocol code	201190
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02723773
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 December 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	28 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the vaccine efficacy (VE) in the prevention of Herpes Zoster (HZ) over the total duration of the ZOSTER-049 study as measured by the reduction in HZ risk in subjects ≥ 50 years of age (YOA) overall at the time of first vaccination in the ZOSTER-006/022 studies.

Protection of trial subjects:

Administration of the study vaccination was to be preceded by a review of the participants' medical history (especially with regards to previous vaccination and possible occurrence of undesirable events) and a clinical examination. As with all injectable vaccines, appropriate medical treatment and supervision was readily available in case of an anaphylactic event following the administration of the vaccine.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 April 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 63
Country: Number of subjects enrolled	Brazil: 309
Country: Number of subjects enrolled	Canada: 407
Country: Number of subjects enrolled	Czechia: 420
Country: Number of subjects enrolled	Germany: 616
Country: Number of subjects enrolled	Estonia: 824
Country: Number of subjects enrolled	Spain: 565
Country: Number of subjects enrolled	Finland: 1131
Country: Number of subjects enrolled	France: 259
Country: Number of subjects enrolled	Hong Kong: 188
Country: Number of subjects enrolled	Italy: 70
Country: Number of subjects enrolled	Japan: 235
Country: Number of subjects enrolled	Korea, Republic of: 213
Country: Number of subjects enrolled	Mexico: 211
Country: Number of subjects enrolled	Sweden: 639
Country: Number of subjects enrolled	Taiwan: 717
Country: Number of subjects enrolled	United Kingdom: 315
Country: Number of subjects enrolled	United States: 352

Worldwide total number of subjects	7534
EEA total number of subjects	4524

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	2047
From 65 to 84 years	4818
85 years and over	669

Subject disposition

Recruitment

Recruitment details:

Potentially eligible participants who participated and received at least one dose of the HZ/su vaccine in the ZOSTER-006 (NCT01165177) and ZOSTER-022 (NCT01165229) primary studies were contacted and considered for entry in the current ZOSTER-049 EXT:006-022 (NCT02723773) study.

Pre-assignment

Screening details:

Out of the 7534 participants enrolled in the current ZOSTER-049 EXT:006-022 study, 5 participants originally enrolled in the Long-term follow-up (LTFU) group were eliminated due to data modification post-investigator signature, and hence 7529 participants were included in the Total Vaccinated Cohort and started the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	LTFU Group

Arm description:

Participants who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study were followed up for long-term vaccine efficacy and safety.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	1-Additional Dose Group

Arm description:

Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies received 1 additional dose of the HZ/su vaccine at Month 0 in the current ZOSTER-049:EXT 006-022 study.

Arm type	Experimental
Investigational medicinal product name	Herpes Zoster subunit (HZ/su) vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants were administered 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies and 1 additional dose of the HZ/su vaccine at Month 0 in the current ZOSTER-049:EXT 006-022 study.

Arm title	Revaccination Group
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Arm description:

Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies were revaccinated with 2 additional doses of the HZ/su vaccine at Month 0 and Month 2 in the current ZOSTER-049:EXT 006-022 study.

Arm type	Experimental
Investigational medicinal product name	Herpes Zoster subunit (HZ/su) vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants were administered 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies and 2 additional doses of the HZ/su vaccine at Month 0 and Month 2 in the current ZOSTER-049:EXT 006-022 study.

Arm title	Control Group
Arm description: Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, but who served as a control for the 2 groups that received 1 or 2 additional doses (1-Additional Dose Group and Revaccination Group).	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1^[1]	LTFU Group	1-Additional Dose Group	Revaccination Group
Started	7289	61	60
Completed	5570	52	51
Not completed	1719	9	9
Consent withdrawn by subject	360	5	6
Adverse event, non-fatal	934	3	1
Migrated/moved from study area	37	-	-
Unspecified	189	1	2
Lost to follow-up	198	-	-
Protocol deviation	1	-	-

Number of subjects in period 1^[1]	Control Group
Started	119
Completed	97
Not completed	22
Consent withdrawn by subject	10
Adverse event, non-fatal	9
Migrated/moved from study area	1
Unspecified	2
Lost to follow-up	-
Protocol deviation	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Out of the 7534 participants enrolled in the current ZOSTER-049 EXT:006-022 study, 5 participants originally enrolled in the Long-term follow-up (LTFU) group were eliminated due to data modification post-investigator signature, and hence 7529 participants were included in the Total Vaccinated Cohort and started the study.

Baseline characteristics

Reporting groups

Reporting group title	LTFU Group
Reporting group description: Participants who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study were followed up for long-term vaccine efficacy and safety.	
Reporting group title	1-Additional Dose Group
Reporting group description: Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies received 1 additional dose of the HZ/su vaccine at Month 0 in the current ZOSTER-049:EXT 006-022 study.	
Reporting group title	Revaccination Group
Reporting group description: Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies were revaccinated with 2 additional doses of the HZ/su vaccine at Month 0 and Month 2 in the current ZOSTER-049:EXT 006-022 study.	
Reporting group title	Control Group
Reporting group description: Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, but who served as a control for the 2 groups that received 1 or 2 additional doses (1-Additional Dose Group and Revaccination Group).	

Reporting group values	LTFU Group	1-Additional Dose Group	Revaccination Group
Number of subjects	7289	61	60
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1962	21	21
From 65-84 years	4669	36	35
85 years and over	658	4	4
Age Continuous Units: Years			
arithmetic mean	72.6	70.4	70.2
standard deviation	± 9.4	± 9.2	± 9.4
Sex: Female, Male Units: Participants			
Female	4432	30	36
Male	2857	31	24
Race/Ethnicity, Customized Units: Subjects			
African Heritage / African American	66	0	0
Asian - East Asian Heritage	1115	0	0
Asian - Japanese Heritage	265	0	0

Other, Deidentified	5843	61	60
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Reporting group values	Control Group	Total	
Number of subjects	119	7529	
Age categorical Units: Participants			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	40	2044	
From 65-84 years	76	4816	
85 years and over	3	669	
Age Continuous Units: Years			
arithmetic mean	70.2		
standard deviation	± 8.6	-	
Sex: Female, Male Units: Participants			
Female	69	4567	
Male	50	2962	
Race/Ethnicity, Customized Units: Subjects			
African Heritage / African American	0	66	
Asian - East Asian Heritage	0	1115	
Asian - Japanese Heritage	0	265	
Other, Deidentified	119	6083	

End points

End points reporting groups

Reporting group title	LTFU Group
Reporting group description: Participants who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study were followed up for long-term vaccine efficacy and safety.	
Reporting group title	1-Additional Dose Group
Reporting group description: Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies received 1 additional dose of the HZ/su vaccine at Month 0 in the current ZOSTER-049:EXT 006-022 study.	
Reporting group title	Revaccination Group
Reporting group description: Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies were revaccinated with 2 additional doses of the HZ/su vaccine at Month 0 and Month 2 in the current ZOSTER-049:EXT 006-022 study.	
Reporting group title	Control Group
Reporting group description: Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, but who served as a control for the 2 groups that received 1 or 2 additional doses (1-Additional Dose Group and Revaccination Group).	
Subject analysis set title	LTFU+Control ≥ 50 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants 50 years of age or above (≥ 50 YOA) (at the time of primary vaccination in the ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.	
Subject analysis set title	Historical Control ≥ 50 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants ≥ 50 YOA (at time of primary vaccination in ZOSTER-006/022 studies).	
Subject analysis set title	LTFU+Control 50-59 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants between 50 and 59 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.	
Subject analysis set title	LTFU+Control 60-69 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants between 60 and 69 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.	
Subject analysis set title	LTFU+Control ≥ 60 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants ≥ 60 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.	

Subject analysis set title	LTFU+Control >=70 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants >=70 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.	
Subject analysis set title	Historical Control 50-59 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants between 50 and 59 YOA (at time of primary vaccination in ZOSTER-006/022 studies).	
Subject analysis set title	Historical Control 60-69 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants between 60 and 69 YOA (at time of primary vaccination in ZOSTER-006/022 studies).	
Subject analysis set title	Historical Control >=60 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants >=60 YOA (at time of primary vaccination in ZOSTER-006/022 studies).	
Subject analysis set title	Historical Control >=70 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants >=70 YOA (at time of primary vaccination in ZOSTER-006/022 studies).	
Subject analysis set title	HZ/su >=50 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants >=50 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies, among which participants who did not enroll in the current ZOSTER-049:EXT 006-022 study only contributed to data for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start. '999' is a placeholder value for '13881', which is the actual number of participants included in this sub-group for the specified analysis.	
Subject analysis set title	HZ/su 50-59 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants between 50 and 59 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies, among which participants who did not enroll in the current ZOSTER-049:EXT 006-022 study only contributed to data for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start.	
Subject analysis set title	HZ/su 60-69 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants between 60 and 69 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies, among which participants who did not enroll in the current ZOSTER-049:EXT 006-022 study only contributed to data for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start.	
Subject analysis set title	HZ/su >=60 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants >=60 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received 2	

doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies, among which participants who did not enroll in the current ZOSTER-049:EXT 006-022 study only contributed to data for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start.

'999' is a placeholder value for '10390', which is the actual number of participants included in this sub-group for the specified analysis.

Subject analysis set title	HZ/su >=70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants >=70 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies, among which participants who did not enroll in the current ZOSTER-049:EXT 006-022 study only contributed to data for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start.

'999' is a placeholder value for '8250', which is the actual number of participants included in this sub-group for the specified analysis.

Subject analysis set title	Placebo/Historical control >=50 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants >=50 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) from the Placebo groups in the ZOSTER-006/022 primary studies for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start and from the hypothetical Historical control group in the current ZOSTER-049:EXT 006-022 study for Year 6 and onwards were combined into this group.

'999' is a placeholder value for '14035', which is the actual number of participants included in this sub-group for the specified analysis.

Subject analysis set title	Placebo/Historical control 50-59 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 50 and 59 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) from the Placebo groups in the ZOSTER-006/022 primary studies for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start and from the hypothetical Historical control group in the current ZOSTER-049:EXT 006-022 study for Year 6 and onwards were combined into this group.

Subject analysis set title	Placebo/Historical control 60-69 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 60 and 69 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) from the Placebo groups in the ZOSTER-006/022 primary studies for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start and from the hypothetical Historical control group in the current ZOSTER-049:EXT 006-022 study for Year 6 and onwards were combined into this group.

Subject analysis set title	Placebo/Historical control >=60 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants >=60 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) from the Placebo groups in the ZOSTER-006/022 primary studies for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start and from the hypothetical Historical control group in the current ZOSTER-049:EXT 006-022 study for Year 6 and onwards were combined into this group.

'999' is a placeholder value for '10512', which is the actual number of participants included in this sub-group for the specified analysis.

Subject analysis set title	Placebo/Historical control >=70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants >=70 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) from the Placebo groups in the ZOSTER-006/022 primary studies for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start and from the hypothetical Historical control group in the current ZOSTER-049:EXT 006-022 study for Year 6 and onwards were combined into this group.

'999' is a placeholder value for '8346', which is the actual number of participants included in this sub-group for the specified analysis.

Subject analysis set title	LTFU+Control >=50 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants >=50 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group

and Control group in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU+Control 50-59 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 50 and 59 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU+Control 60-69 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 60 and 69 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU+Control ≥ 60 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 60 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU+Control ≥ 70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 70 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	Historical Control ≥ 50 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants ≥ 50 YOA (at time of primary vaccination in ZOSTER-006/022 studies).

Subject analysis set title	Historical Control 50-59 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants between 50 and 59 YOA (at time of primary vaccination in ZOSTER-006/022 studies).

Subject analysis set title	Historical Control 60-69 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants between 60 and 69 YOA (at time of primary vaccination in ZOSTER-006/022 studies).

Subject analysis set title	Historical Control ≥ 60 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants ≥ 60 YOA (at time of primary vaccination in ZOSTER-006/022 studies).

Subject analysis set title	Historical Control ≥ 70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants ≥ 70 YOA (at time of primary vaccination in ZOSTER-006/022 studies).

in ZOSTER-006/022 studies).

Subject analysis set title	Placebo/Historical control ≥ 60 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between ≥ 60 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) from the Placebo groups in the ZOSTER-006/022 primary studies for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start and from the hypothetical Historical control group in the current ZOSTER-049:EXT 006-022 study for Year 6 and onwards were combined into this group.

'999' is a placeholder value for '10512', which is the actual number of participants included in this sub-group for the specified analysis.

Subject analysis set title	LTFU+Control ≥ 50 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 50 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU+Control ≥ 60 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 60 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU+Control ≥ 70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 70 YOA (at time of primary vaccination in ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	Historical Control ≥ 50 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants ≥ 50 YOA (at time of primary vaccination in ZOSTER-006/022 studies).

Subject analysis set title	Historical Control ≥ 60 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants ≥ 60 YOA (at time of primary vaccination in ZOSTER-006/022 studies).

Subject analysis set title	Historical Control ≥ 70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Hypothetical control group formed by using incidence rates estimated from actual placebo data in the ZOSTER-006/022 primary studies collected from participants ≥ 70 YOA (at time of primary vaccination in ZOSTER-006/022 studies).

Subject analysis set title	HZ/su 60-69 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 60 to 69 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies, among which participants who did not enroll in the current ZOSTER-049:EXT 006-022 study only contributed to data for Year 1 through Year 4.

Subject analysis set title	LTFU ≥ 50 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 50 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU 50-59 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 50 and 59 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU 60-69 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 60 and 69 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU ≥ 60 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 60 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU ≥ 70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 70 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU ≥ 50 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 50 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU 50-59 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 50 and 59 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU 60-69 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants between 60 and 69 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU ≥ 60 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 60 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU ≥ 70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants ≥ 70 YOA (at the time of primary vaccination in ZOSTER-006/022 studies) who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study.

Subject analysis set title	LTFU+Control >=50 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants >=50 YOA (at the time of primary vaccination in the ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.	
Subject analysis set title	LTFU+Control >=50 YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants >=50 YOA (at the time of primary vaccination in the ZOSTER-006/022 studies) who received at least one dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049:EXT 006-022 study, i.e., combined group of LTFU group and Control group in the current ZOSTER-049:EXT 006-022 study.	
Primary: Number of participants having at least one confirmed Herpes Zoster (HZ) case during the total duration of ZOSTER-049:EXT 006-022 study, overall	
End point title	Number of participants having at least one confirmed Herpes Zoster (HZ) case during the total duration of ZOSTER-049:EXT 006-022 study, overall
End point description:	
A suspected case of HZ is defined as a new unilateral rash accompanied by pain and no alternative diagnosis. A confirmed case of HZ was diagnosed by Polymerase Chain Reaction (PCR) and/or by HZ Ascertainment Committee (HZAC) determination, as per the algorithm pre-specified in the protocol. As pre-specified in the protocol:	
-due to the high VE observed in ZOSTER-006/022 studies, recipients of placebo in both studies were offered cross-vaccination with HZ/su. Since there was no placebo group in this study, historic controls were used for VE assessment. Incidence rates estimations on Historical Control group were done by utilizing Poisson regression model using placebo data from ZOSTER-006/022 studies to obtain the coefficients by age ranges.	
-the participants in Control group were a subset of LTFU group that were randomized to serve as control for those who were vaccinated in this study, otherwise they were treated similarly as LTFU group, hence LTFU and Control groups were combined.	
End point type	Primary
End point timeframe:	
During the total duration of ZOSTER-049:EXT 006-022 study (From Month 0 to Month 72)	

End point values	LTFU+Control >=50 YOA Group	Historical Control >=50 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	7258	7258		
Units: Participants	69	341		

Statistical analyses

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between LTFU+Control >=50 YOA Group and Historical Control >=50 YOA Group.	
Comparison groups	LTFU+Control >=50 YOA Group v Historical Control >=50 YOA Group

Number of subjects included in analysis	14516
Analysis specification	Pre-specified
Analysis type	other ^[1]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	79.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	73.72
upper limit	84.61

Notes:

[1] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - the relative risk (RR). RR = the ratio of the incidence rates of LTFU+Control \geq 50 YOA Group over Historical Control \geq 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Secondary: Number of participants having at least one confirmed HZ case during the total duration of ZOSTER-049:EXT 006-022 study, by age ranges

End point title	Number of participants having at least one confirmed HZ case during the total duration of ZOSTER-049:EXT 006-022 study, by age ranges
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End point description:

A suspected case of HZ is defined as a new unilateral rash accompanied by pain and no alternative diagnosis. A confirmed case of HZ was diagnosed by PCR and/or by the HZAC determination, as per the algorithm pre-specified in the protocol.

The age ranges assessed were: 50-59 YOA, 60-69 YOA, \geq 60 YOA and \geq 70 YOA at time of primary vaccination in ZOSTER-006/022 studies.

The analysis was performed on the mTVC – LTFU+Control group, which included all participants in the LTFU and Control groups combined, with efficacy data available for the specified analysis and age ranges during the specified period, minus those participants who were not administered with the second vaccination during the ZOSTER-006/022 studies, or who developed a confirmed case of HZ prior to 1 month after the second vaccination in the ZOSTER-006/022 studies.

End point type	Secondary
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End point timeframe:

During the total duration of ZOSTER-049:EXT 006-022 study (From Month 0 to Month 72)

End point values	LTFU+Control 50-59 YOA Group	LTFU+Control 60-69 YOA Group	LTFU+Control \geq 60 YOA Group	LTFU+Control \geq 70 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2043	1242	5215	3973
Units: Participants	12	9	57	48

End point values	Historical Control 50-59 YOA Group	Historical Control 60-69 YOA Group	Historical Control \geq 60 YOA Group	Historical Control \geq 70 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2043	1242	5215	3973
Units: Participants	90	70	249	179

Statistical analyses

Statistical analysis title	Vaccine efficacy
Statistical analysis description: Comparison of vaccine efficacy (VE) in prevention of HZ between LTFU+Control 50-59 YOA Group and Historical Control 50-59 YOA Group.	
Comparison groups	LTFU+Control 50-59 YOA Group v Historical Control 50-59 YOA Group
Number of subjects included in analysis	4086
Analysis specification	Pre-specified
Analysis type	other ^[2]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	86.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	75.55
upper limit	93.36

Notes:

[2] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control 50-59 YOA Group over Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description: Comparison of vaccine efficacy (VE) in prevention of HZ between LTFU+Control 60-69 YOA Group and Historical Control 60-69 YOA Group.	
Comparison groups	LTFU+Control 60-69 YOA Group v Historical Control 60-69 YOA Group
Number of subjects included in analysis	2484
Analysis specification	Pre-specified
Analysis type	other ^[3]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	87.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	74.17
upper limit	94.35

Notes:

[3] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control 60-69 YOA Group over Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between LTFU+Control ≥ 60 YOA Group and Historical Control ≥ 60 YOA Group.	
Comparison groups	LTFU+Control ≥ 60 YOA Group v Historical Control ≥ 60 YOA Group
Number of subjects included in analysis	10430
Analysis specification	Pre-specified
Analysis type	other ^[4]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	77.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	69.37
upper limit	83.14

Notes:

[4] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = $1 - RR$. RR = the ratio of the incidence rates of LTFU+Control ≥ 60 YOA Group over Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between LTFU+Control ≥ 70 YOA Group and Historical Control ≥ 70 YOA Group.	
Comparison groups	LTFU+Control ≥ 70 YOA Group v Historical Control ≥ 70 YOA Group
Number of subjects included in analysis	7946
Analysis specification	Pre-specified
Analysis type	other ^[5]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	73.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.94
upper limit	80.92

Notes:

[5] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = $1 - RR$. RR = the ratio of the incidence rates of LTFU+Control ≥ 70 YOA Group over Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Secondary: Number of participants having at least one confirmed HZ case from one month post-Dose 2 in ZOSTER-006/022 studies until the end of ZOSTER-049:EXT 006-022 study, overall and by age ranges

End point title	Number of participants having at least one confirmed HZ case from one month post-Dose 2 in ZOSTER-006/022 studies until
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End point description:

A suspected case of HZ is defined as a new unilateral rash accompanied by pain and no alternative diagnosis. A confirmed case of HZ was diagnosed by PCR and/or by the HZAC determination, as per the algorithm pre-specified in the protocol.

The age ranges assessed were: ≥ 50 YOA (overall), 50-59 YOA, 60-69 YOA, ≥ 60 YOA and ≥ 70 YOA at time of primary vaccination in ZOSTER-006/022 studies.

As pre-specified in the protocol:

- participants from the Placebo groups in the ZOSTER-006/022 studies for Year 1 through Year 4 preceding the ZOSTER-049 EXT:006-022 study start and from the hypothetical Historical control group in the ZOSTER-049:EXT 006-022 study for Year 6 and onwards were combined in the Placebo/Historical control group.

The analysis was performed on the mTVC pooled.

End point type	Secondary
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End point timeframe:

From one month post-Dose 2 (Month 3) in ZOSTER-006/022 primary studies until the end of ZOSTER-049:EXT 006-022 study (Month 72), a period of approximately 12 years

End point values	HZ/su ≥ 50 YOA Group	HZ/su 50-59 YOA Group	HZ/su 60-69 YOA Group	HZ/su ≥ 60 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13881 ^[6]	3491	2140	10390 ^[7]
Units: Participants	101	16	12	85

Notes:

[6] - '999' is a placeholder value for '13881', which is the actual number of participants analyzed.

[7] - '999' is a placeholder value for '10390', which is the actual number of participants analyzed.

End point values	HZ/su ≥ 70 YOA Group	Placebo/Historical control ≥ 50 YOA Group	Placebo/Historical control 50-59 YOA Group	Placebo/Historical control 60-69 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8250 ^[8]	14035 ^[9]	3523	2166
Units: Participants	73	818	193	160

Notes:

[8] - '999' is a placeholder value for '8250', which is the actual number of participants analyzed.

[9] - '999' is a placeholder value for '14035', which is the actual number of participants analyzed.

End point values	Placebo/Historical control ≥ 60 YOA Group	Placebo/Historical control ≥ 70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10512 ^[10]	8346 ^[11]		
Units: Participants	623	463		

Notes:

[10] - '999' is a placeholder value for '10512', which is the actual number of participants analyzed.

[11] - '999' is a placeholder value for '8346', which is the actual number of participants analyzed.

Statistical analyses

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 60 YOA Group and

Placebo/Historical Control ≥ 60 YOA Group.

Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[12]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	86.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	82.98
upper limit	89.33

Notes:

[12] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 YOA Group.

Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[13]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	87.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	84.89
upper limit	90.12

Notes:

[13] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 50 YOA Group over Placebo/Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group.

Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
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Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[14]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	84.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	79.91
upper limit	87.93

Notes:

[14] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[15]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	86.66
upper limit	96.24

Notes:

[15] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[16]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	91.74

Confidence interval	
level	95 %
sides	2-sided
lower limit	86.25
upper limit	95.37

Notes:

[16] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Secondary: Number of participants having at least one confirmed HZ case over the follow-up years from one month post-Dose 2 in ZOSTER-006/022 studies until the end of ZOSTER-049:EXT 006-022 study, overall and by age ranges

End point title	Number of participants having at least one confirmed HZ case over the follow-up years from one month post-Dose 2 in ZOSTER-006/022 studies until the end of ZOSTER-049:EXT 006-022 study, overall and by age ranges
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End point description:

A suspected case of HZ is defined as a new unilateral rash accompanied by pain and no alternative diagnosis. A confirmed case of HZ was diagnosed by PCR and/or by the HZAC determination, as per the algorithm pre-specified in the protocol. The age ranges assessed were: ≥ 50 YOA (overall), 50-59 YOA, 60-69 YOA, ≥ 60 YOA and ≥ 70 YOA at time of primary vaccination in ZOSTER-006/022 studies.

Confirmed HZ cases data was not collected for the participants included in the HZ/su and Placebo/Historical control groups during Year 5, as this was a gap year between end of ZOSTER-006/-022 studies and start of ZOSTER-049:EXT-006-022 study.

Results from the ZOSTER-006/022 studies were pooled for each year after vaccination with methods used in these studies. For overlapping years between ZOSTER-006/022 studies and this study, all the data were pooled. For the non-overlapping years only the data from ZOSTER-049:EXT 006-022 study was used.

The analysis was performed on the mTVC pooled.

End point type	Secondary
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End point timeframe:

Over the follow-up years (Year 1, Year 2, Year 3, Year 4, Year 6, Year 7, Year 8, Year 9, Year 10 and Year 11) from one month post-Dose 2 (Month 3) in ZOSTER-006/022 primary studies until the end of ZOSTER-049:EXT 006-022 study (Month 72)

End point values	HZ/su ≥ 50 YOA Group	HZ/su 50-59 YOA Group	HZ/su 60-69 YOA Group	HZ/su ≥ 60 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13881 ^[17]	3491	2140	10390 ^[18]
Units: Participants				
Year 1	3	1	0	2
Year 2	10	2	1	8
Year 3	9	0	0	9
Year 4	10	1	2	9
Year 6	10	2	1	8
Year 7	10	1	2	9
Year 8	10	2	2	8
Year 9	15	5	3	10
Year 10	15	0	1	15
Year 11	9	2	0	7

Notes:

[17] - '999' is a placeholder value for '13881', which is the actual number of participants analyzed.

[18] - '999' is a placeholder value for '10390', which is the actual number of participants analyzed.

End point values	HZ/su \geq 70 YOA Group	Placebo/Historical control \geq 50 YOA Group	Placebo/Historical control 50-59 YOA Group	Placebo/Historical control 60-69 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8250 ^[19]	14035 ^[20]	3523	2166
Units: Participants				
Year 1	2	130	31	16
Year 2	7	136	27	22
Year 3	9	116	29	29
Year 4	7	95	16	23
Year 6	7	62	16	13
Year 7	7	61	15	13
Year 8	6	58	15	13
Year 9	7	57	15	11
Year 10	14	53	15	10
Year 11	7	50	15	10

Notes:

[19] - '999' is a placeholder value for '8250', which is the actual number of participants analyzed.

[20] - '999' is a placeholder value for '14035', which is the actual number of participants analyzed.

End point values	Placebo/Historical control \geq 60 YOA Group	Placebo/Historical control \geq 70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10512 ^[21]	8346 ^[22]		
Units: Participants				
Year 1	99	83		
Year 2	109	87		
Year 3	87	58		
Year 4	79	56		
Year 6	47	35		
Year 7	46	33		
Year 8	43	31		
Year 9	42	29		
Year 10	38	27		
Year 11	34	25		

Notes:

[21] - '999' is a placeholder value for '10512', which is the actual number of participants analyzed.

[22] - '999' is a placeholder value for '8346', which is the actual number of participants analyzed.

Statistical analyses

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su \geq 70 YOA Group and Placebo/Historical Control \geq 70 YOA Group over Year 1.	
Comparison groups	HZ/su \geq 70 YOA Group v Placebo/Historical control \geq 70 YOA Group

Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[23]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	97.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	90.96
upper limit	99.71

Notes:

[23] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 60 YOA Group and Placebo/Historical Control ≥ 60 YOA Group over Year 1.

Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[24]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	97.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	92.46
upper limit	99.76

Notes:

[24] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 1.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[25]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100

Confidence interval	
level	95 %
sides	2-sided
lower limit	79.32
upper limit	100

Notes:

[25] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 1.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[26]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	96.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	80.57
upper limit	99.92

Notes:

[26] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥50 YOA Group and Placebo/Historical Control ≥50 YOA Group over Year 1.

Comparison groups	HZ/su ≥50 YOA Group v Placebo/Historical control ≥50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[27]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	97.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	93.07
upper limit	99.53

Notes:

[27] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su \geq 50 YOA Group over Placebo/Historical Control \geq 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su \geq 50 YOA Group and Placebo/Historical Control \geq 50 YOA Group over Year 2.	
Comparison groups	HZ/su \geq 50 YOA Group v Placebo/Historical control \geq 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[28]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	86.15
upper limit	96.57

Notes:

[28] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su \geq 50 YOA Group over Placebo/Historical Control \geq 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su \geq 50 YOA Group and Placebo/Historical Control \geq 50 YOA Group over Year 3.	
Comparison groups	HZ/su \geq 50 YOA Group v Placebo/Historical control \geq 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[29]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	84.98
upper limit	96.59

Notes:

[29] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su \geq 50 YOA Group over Placebo/Historical Control \geq 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group over Year 2.

Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[30]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	82.82
upper limit	96.88

Notes:

[30] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 60 YOA Group and Placebo/Historical Control ≥ 60 YOA Group over Year 2.

Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[31]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	85.13
upper limit	96.93

Notes:

[31] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 2.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
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Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[32]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	95.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	72.11
upper limit	99.89

Notes:

[32] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 2.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[33]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.78
upper limit	99.15

Notes:

[33] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 3.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[34]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100

Confidence interval	
level	95 %
sides	2-sided
lower limit	89.2
upper limit	100

Notes:

[34] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 3.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[35]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	89.39
upper limit	100

Notes:

[35] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥60 YOA Group and Placebo/Historical Control ≥60 YOA Group over Year 3.

Comparison groups	HZ/su ≥60 YOA Group v Placebo/Historical control ≥60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[36]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	89.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	79.81
upper limit	95.51

Notes:

[36] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group over Year 3.	
Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[37]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	84.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.99
upper limit	93.35

Notes:

[37] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 Group over Year 4.	
Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[38]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	89.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	80.31
upper limit	95.24

Notes:

[38] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 50 YOA Group over Placebo/Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 4.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[39]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	93.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	60.62
upper limit	99.85

Notes:

[39] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 4.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[40]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	91.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	66.1
upper limit	99.04

Notes:

[40] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥60 YOA Group and Placebo/Historical Control ≥60 YOA Group over Year 6.

Comparison groups	HZ/su ≥60 YOA Group v Placebo/Historical control ≥60 YOA Group
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Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[41]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	82.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	63.64
upper limit	93.05

Notes:

[41] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group over Year 4.

Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[42]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	87.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	73.3
upper limit	95.33

Notes:

[42] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 YOA Group over Year 6.

Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[43]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	83.87

Confidence interval	
level	95 %
sides	2-sided
lower limit	68.31
upper limit	92.63

Notes:

[43] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su \geq 50 YOA Group over Placebo/Historical Control \geq 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 6.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[44]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	87.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.83
upper limit	98.61

Notes:

[44] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 6.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[45]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	48.79
upper limit	99.82

Notes:

[45] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 60 YOA Group and Placebo/Historical Control ≥ 60 YOA Group over Year 4.	
Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[46]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	88.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	77.96
upper limit	95.13

Notes:

[46] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group over Year 6.	
Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[47]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	80
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.3
upper limit	92.5

Notes:

[47] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 60 YOA Group and Placebo/Historical Control ≥ 60 YOA Group over Year 8.

Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[48]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	81.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.97
upper limit	92.45

Notes:

[48] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = $1 - RR$. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 8.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[49]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	84.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.04
upper limit	98.31

Notes:

[49] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = $1 - RR$. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 8.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
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Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[50]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	86.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.67
upper limit	98.52

Notes:

[50] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 YOA Group over Year 8.

Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[51]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	82.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	65.98
upper limit	92.14

Notes:

[51] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 50 YOA Group over Placebo/Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group over Year 7.

Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[52]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	78.79

Confidence interval	
level	95 %
sides	2-sided
lower limit	51.24
upper limit	92.08

Notes:

[52] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 60 YOA Group and Placebo/Historical Control ≥ 60 YOA Group over Year 7.

Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[53]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	80.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.54
upper limit	91.58

Notes:

[53] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 7.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	84.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.04
upper limit	98.31

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 7.	
Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[54]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	93.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	56.67
upper limit	99.84

Notes:

[54] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 YOA Group over Year 7.	
Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[55]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	83.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	67.76
upper limit	92.51

Notes:

[55] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 50 YOA Group over Placebo/Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group over Year 8.	

Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	80.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.91
upper limit	93.4

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 YOA Group over Year 9.

Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[56]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	73.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.89
upper limit	86.16

Notes:

[56] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 50 YOA Group over Placebo/Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 YOA Group over Year 10.

Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[57]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	71.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	49.03
upper limit	85.18

Notes:

[57] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su \geq 50 YOA Group over Placebo/Historical Control \geq 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 10.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	77.89
upper limit	100

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 10.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[58]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	90
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.71
upper limit	99.77

Notes:

[58] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 60 YOA Group and Placebo/Historical Control ≥ 60 YOA Group over Year 10.	
Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[59]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	60.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.55
upper limit	79.83

Notes:

[59] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group over Year 9.	
Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[60]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	75.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.69
upper limit	91.07

Notes:

[60] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 9.	

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[61]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	66.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.52
upper limit	90.52

Notes:

[61] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 9.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[62]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	72.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.24
upper limit	95.11

Notes:

[62] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su >=60 YOA Group and Placebo/Historical Control >=60 YOA Group over Year 9.

Comparison groups	HZ/su >=60 YOA Group v Placebo/Historical control >=60 YOA Group
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Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[63]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	76.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.78
upper limit	89.35

Notes:

[63] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su \geq 60 YOA Group over Placebo/Historical Control \geq 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su \geq 60 YOA Group and Placebo/Historical Control \geq 60 YOA Group over Year 11.

Comparison groups	HZ/su \geq 60 YOA Group v Placebo/Historical control \geq 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[64]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	79.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.82
upper limit	92.3

Notes:

[64] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su \geq 60 YOA Group over Placebo/Historical Control \geq 60 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su \geq 70 YOA Group and Placebo/Historical Control \geq 70 YOA Group over Year 10.

Comparison groups	HZ/su \geq 70 YOA Group v Placebo/Historical control \geq 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[65]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	48.15

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.41
upper limit	74.87

Notes:

[65] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 YOA Group over Year 11.

Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[66]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	82
Confidence interval	
level	95 %
sides	2-sided
lower limit	63.03
upper limit	92.22

Notes:

[66] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 50 YOA Group over Placebo/Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group over Year 11.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[67]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	86.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.67
upper limit	98.52

Notes:

[67] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group over Year 11.	
Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[68]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	65.07
upper limit	100

Notes:

[68] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ between HZ/su >=70 YOA Group and Placebo/Historical Control >=70 YOA Group over Year 11.	
Comparison groups	HZ/su >=70 YOA Group v Placebo/Historical control >=70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[69]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	72
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.41
upper limit	89.77

Notes:

[69] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su >=70 YOA Group over Placebo/Historical Control >=70 YOA Group. The VE of HZ/su vaccine against HZ in this study was descriptively summarized by age strata and overall.

Secondary: Number of participants having at least one post-herpetic neuralgia (PHN) case during the total duration of ZOSTER-049:EXT 006-022 study, overall and

by age ranges

End point title	Number of participants having at least one post-herpetic neuralgia (PHN) case during the total duration of ZOSTER-049:EXT 006-022 study, overall and by age ranges
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End point description:

PHN is defined by the presence of HZ-associated severe worst pain persisting or appearing more than 90 days after onset of the HZ rash. Severe worst pain is defined as HZ-associated pain rated as 3 or greater on the worst pain question on the Zoster Brief Pain Inventory (ZBPI) questionnaire. The ZBPI questionnaire uses a 0 to 10 point numeric and visual intensity scale, in which 0 represents the minimum value and 10 the maximum value on the scale.

The age ranges assessed were: ≥ 50 YOA (overall), 50-59 YOA, 60-69 YOA, ≥ 60 YOA and ≥ 70 YOA at time of primary vaccination in ZOSTER-006/022 studies.

The analysis was performed on the mTVC – LTFU+Control group.

End point type	Secondary
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End point timeframe:

During the total duration of ZOSTER-049:EST 006-022 study (From Month 0 to Month 72)

End point values	LTFU+Control ≥ 50 YOA Group	LTFU+Control 50-59 YOA Group	LTFU+Control 60-69 YOA Group	LTFU+Control ≥ 60 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7271	2046	1243	5225
Units: Participants	4	0	1	4

End point values	LTFU+Control ≥ 70 YOA Group	Historical Control ≥ 50 YOA Group	Historical Control 50-59 YOA Group	Historical Control 60-69 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3982	7271	2046	1243
Units: Participants	3	32	7	2

End point values	Historical Control ≥ 60 YOA Group	Historical Control ≥ 70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5225	3982		
Units: Participants	25	23		

Statistical analyses

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of PHN between LTFU+Control 60-69 YOA Group and Historical Control 60-69 YOA Group.

Comparison groups	LTFU+Control 60-69 YOA Group v Historical Control 60-69 YOA Group
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Number of subjects included in analysis	2486
Analysis specification	Pre-specified
Analysis type	other ^[70]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	-860.45
upper limit	99.15

Notes:

[70] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control 60-69 YOA Group over Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against PHN in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy in prevention of PHN between LTFU+Control ≥ 60 YOA Group and Historical Control ≥ 60 YOA Group.

Comparison groups	LTFU+Control ≥ 60 YOA Group v Historical Control ≥ 60 YOA Group
Number of subjects included in analysis	10450
Analysis specification	Pre-specified
Analysis type	other ^[71]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	84
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.66
upper limit	95.95

Notes:

[71] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control ≥ 60 YOA Group over Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against PHN in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of PHN between LTFU+Control 50-59 YOA Group and Historical Control 50-59 YOA Group.

Comparison groups	LTFU+Control 50-59 YOA Group v Historical Control 50-59 YOA Group
Number of subjects included in analysis	4092
Analysis specification	Pre-specified
Analysis type	other ^[72]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100

Confidence interval	
level	95 %
sides	2-sided
lower limit	46.59
upper limit	100

Notes:

[72] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control 50-59 YOA Group over Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against PHN in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of PHN between LTFU+Control ≥ 50 YOA Group and Historical Control ≥ 50 YOA Group.

Comparison groups	LTFU+Control ≥ 50 YOA Group v Historical Control ≥ 50 YOA Group
Number of subjects included in analysis	14542
Analysis specification	Pre-specified
Analysis type	other ^[73]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	87.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	64.75
upper limit	96.79

Notes:

[73] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control ≥ 50 YOA Group over Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against PHN in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy in prevention of PHN between LTFU+Control ≥ 70 YOA Group and Historical Control ≥ 70 YOA Group.

Comparison groups	LTFU+Control ≥ 70 YOA Group v Historical Control ≥ 70 YOA Group
Number of subjects included in analysis	7964
Analysis specification	Pre-specified
Analysis type	other ^[74]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	86.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	56.83
upper limit	97.49

Notes:

[74] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control ≥ 70 YOA Group over Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against PHN in this study was descriptively summarized by age strata and overall.

Secondary: Number of participants having at least one PHN case from one month post-Dose 2 in ZOSTER-006/022 primary studies until the end of ZOSTER-049:EXT 006-022 study, overall and by age ranges

End point title	Number of participants having at least one PHN case from one month post-Dose 2 in ZOSTER-006/022 primary studies until the end of ZOSTER-049:EXT 006-022 study, overall and by age ranges
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End point description:

PHN is defined by the presence of HZ-associated severe worst pain persisting or appearing more than 90 days after onset of the HZ rash. Severe worst pain is defined as HZ-associated pain rated as 3 or greater on the worst pain question on the ZBPI questionnaire. The ZBPI questionnaire uses a 0 to 10 point numeric and visual intensity scale, in which 0 represents the minimum value and 10 the maximum value on the scale.

The age ranges assessed were: ≥ 50 YOA (overall), 50-59 YOA, 60-69 YOA, ≥ 60 YOA and ≥ 70 YOA at time of primary vaccination in ZOSTER-006/022 studies.

The analysis was performed on the mTVC pooled, which included participants from the mTVC in ZOSTER-006/-022 studies and participants from the mTVC in ZOSTER-049:EXT 006-022 study with efficacy data available for the specified analysis and age ranges during the specified period.

End point type	Secondary
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End point timeframe:

From one month post-Dose 2 (Month 3) in ZOSTER-006/022 primary studies until the end of ZOSTER-049:EXT 006-022 study (Month 72), a period of approximately 12 years

End point values	HZ/su ≥ 50 YOA Group	HZ/su 50-59 YOA Group	HZ/su 60-69 YOA Group	HZ/su ≥ 60 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13881 ^[75]	3491	2140	10390 ^[76]
Units: Participants	8	0	1	8

Notes:

[75] - '999' is a placeholder value for '13881', which is the actual number of participants analyzed.

[76] - '999' is a placeholder value for '10390', which is the actual number of participants analyzed.

End point values	HZ/su ≥ 70 YOA Group	Placebo/Historical control ≥ 50 YOA Group	Placebo/Historical control 50-59 YOA Group	Placebo/Historical control 60-69 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8250 ^[77]	14035 ^[78]	3523	2166
Units: Participants	7	78	15	4

Notes:

[77] - '999' is a placeholder value for '8250', which is the actual number of participants analyzed.

[78] - '999' is a placeholder value for '14035', which is the actual number of participants analyzed.

End point values	Placebo/Historical control ≥ 60 YOA Group	Placebo/Historical control ≥ 70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10512 ^[79]	8346 ^[80]		
Units: Participants	63	59		

Notes:

[79] - '999' is a placeholder value for '10512', which is the actual number of participants analyzed.

[80] - '999' is a placeholder value for '8346', which is the actual number of participants analyzed.

Statistical analyses

Statistical analysis title	Vaccine efficacy
Statistical analysis description: Comparison of vaccine efficacy (VE) in prevention of PHN between HZ/su >=50 YOA Group and Placebo/Historical Control >=50 YOA Group.	
Comparison groups	HZ/su >=50 YOA Group v Placebo/Historical control >=50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[81]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	89.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	78.67
upper limit	95.7

Notes:

[81] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su >=50 YOA Group over Placebo/Historical Control >=50 YOA Group. The VE of HZ/su vaccine against PHN in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description: Comparison of vaccine efficacy (VE) in prevention of PHN between HZ/su >=70 YOA Group and Placebo/Historical Control >=70 YOA Group.	
Comparison groups	HZ/su >=70 YOA Group v Placebo/Historical control >=70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	88.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	73.87
upper limit	95.41

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of PHN between HZ/su ≥ 60 YOA Group and Placebo/Historical Control ≥ 60 YOA Group.

Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	87.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	73.29
upper limit	94.72

Statistical analysis title

Vaccine efficacy

Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of PHN between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group.

Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[82]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	77.79
upper limit	100

Notes:

[82] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = $1 - RR$. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against PHN in this study was descriptively summarized by age strata and overall.

Statistical analysis title

Vaccine efficacy

Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of PHN between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group.

Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
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Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[83]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	74.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-155.17
upper limit	99.49

Notes:

[83] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against PHN in this study was descriptively summarized by age strata and overall.

Secondary: Number of participants having at least one HZ related complications (other than PHN) case during the total duration of ZOSTER-049:EXT 006-022 study, overall and by age ranges

End point title	Number of participants having at least one HZ related complications (other than PHN) case during the total duration of ZOSTER-049:EXT 006-022 study, overall and by age ranges
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End point description:

HZ complications include HZ vasculitis, disseminated disease, ophthalmic disease, neurologic disease, visceral disease or stroke. If a recorded complication was associated with a case of suspected HZ, and that case was finally not considered to be a confirmed case, the associated complication would not be considered as a complication of HZ.

The age ranges assessed were: ≥ 50 YOA (overall), 50-59 YOA, 60-69 YOA, ≥ 60 YOA and ≥ 70 YOA at time of primary vaccination in ZOSTER-006/022 studies.

The analysis was performed on the mTVC – LTFU+Control group, which included all participants in the LTFU and Control groups combined with efficacy data available for the specified analysis and age ranges during the specified period, minus those participants who were not administered with the second vaccination during the ZOSTER-006/022 studies, or who developed a confirmed case of HZ prior to 1 month after the second vaccination in the ZOSTER-006/022 studies.

End point type	Secondary
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End point timeframe:

During the total duration of ZOSTER-049:EXT 006-022 study (From Month 0 to Month 72)

End point values	LTFU+Control 50-59 YOA Group	LTFU+Control 60-69 YOA Group	Historical Control 50-59 YOA Group	Historical Control 60-69 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	2046	1243	2046	1243
Units: Participants	0	0	0	2

End point values	LTFU+Control ≥ 50 YOA Group	LTFU+Control ≥ 60 YOA Group	LTFU+Control ≥ 70 YOA Group	Historical Control ≥ 50 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7273	5227	3984	7273

Units: Participants	1	1	1	12
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End point values	Historical Control ≥ 60 YOA Group	Historical Control ≥ 70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5227	3984		
Units: Participants	11	9		

Statistical analyses

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ related complications between LTFU+Control ≥ 50 YOA Group and Historical Control ≥ 50 YOA Group.	
Comparison groups	LTFU+Control ≥ 50 YOA Group v Historical Control ≥ 50 YOA Group
Number of subjects included in analysis	14546
Analysis specification	Pre-specified
Analysis type	other ^[84]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	91.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.68
upper limit	99.81

Notes:

[84] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = $1 - RR$. RR = the ratio of the incidence rates of LTFU+Control ≥ 50 YOA Group over Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ related complications between LTFU+Control ≥ 70 YOA Group and Historical Control ≥ 70 YOA Group.	
Comparison groups	LTFU+Control ≥ 70 YOA Group v Historical Control ≥ 70 YOA Group
Number of subjects included in analysis	7968
Analysis specification	Pre-specified
Analysis type	other ^[85]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	88.89

Confidence interval	
level	95 %
sides	2-sided
lower limit	19.81
upper limit	99.75

Notes:

[85] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control ≥ 70 YOA Group over Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ related complications between LTFU+Control ≥ 60 YOA Group and Historical Control ≥ 60 YOA Group.

Comparison groups	LTFU+Control ≥ 60 YOA Group v Historical Control ≥ 60 YOA Group
Number of subjects included in analysis	10454
Analysis specification	Pre-specified
Analysis type	other ^[86]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	90.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.45
upper limit	99.79

Notes:

[86] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control ≥ 60 YOA Group over Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
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Statistical analysis description:

Comparison of vaccine efficacy (VE) in prevention of HZ related complications between LTFU+Control 60-69 YOA Group and Historical Control 60-69 YOA Group.

Comparison groups	LTFU+Control 60-69 YOA Group v Historical Control 60-69 YOA Group
Number of subjects included in analysis	2486
Analysis specification	Pre-specified
Analysis type	other ^[87]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	-247.21
upper limit	100

Notes:

[87] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of LTFU+Control 60-69 YOA Group over Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Secondary: Number of participants having at least one HZ related complications (other than PHN) case from one month post-dose 2 (Month 3) in ZOSTER-006/022 primary studies until the end of ZOSTER-049:EXT 006-022 study, overall and by age ranges

End point title	Number of participants having at least one HZ related complications (other than PHN) case from one month post-dose 2 (Month 3) in ZOSTER-006/022 primary studies until the end of ZOSTER-049:EXT 006-022 study, overall and by age ranges
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End point description:

HZ complications include HZ vasculitis, disseminated disease, ophthalmic disease, neurologic disease, visceral disease or stroke. If a recorded complication was associated with a case of suspected HZ, and that case was finally not considered to be a confirmed case, the associated complication would not be considered as a complication of HZ.

The age ranges assessed were: ≥ 50 YOA (overall), 50-59 YOA, 60-69 YOA, ≥ 60 YOA and ≥ 70 YOA at time of primary vaccination in ZOSTER-006/022 studies.

The analysis was performed on the mTVC pooled, which included participants from the mTVC in ZOSTER-006/-022 studies and participants from the mTVC in ZOSTER-049:EXT 006-022 study with efficacy data available for the specified analysis and age ranges during the specified period.

End point type	Secondary
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End point timeframe:

From one month post-Dose 2 (Month 3) in ZOSTER-006/022 primary studies until the end of ZOSTER-049:EXT 006-022 study (Month 72), a period of approximately 12 years

End point values	HZ/su ≥ 50 YOA Group	HZ/su 50-59 YOA Group	HZ/su 60-69 YOA Group	HZ/su ≥ 60 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13881 ^[88]	3491	2140	10390 ^[89]
Units: Participants	2	0	0	2

Notes:

[88] - '999' is a placeholder value for '13881', which is the actual number of participants analyzed.

[89] - '999' is a placeholder value for '10390', which is the actual number of participants analyzed.

End point values	HZ/su ≥ 70 YOA Group	Placebo/Historical control ≥ 50 YOA Group	Placebo/Historical control 50-59 YOA Group	Placebo/Historical control 60-69 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8250 ^[90]	14035 ^[91]	3523	2166
Units: Participants	2	28	1	5

Notes:

[90] - '999' is a placeholder value for '8250', which is the actual number of participants analyzed.

[91] - '999' is a placeholder value for '14035', which is the actual number of participants analyzed.

End point values	Placebo/Historical control ≥ 60 YOA Group	Placebo/Historical control ≥ 70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10512 ^[92]	8346 ^[93]		

Units: Participants	26	21		
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Notes:

[92] - '999' is a placeholder value for '10512', which is the actual number of participants analyzed.

[93] - '999' is a placeholder value for '8346', which is the actual number of participants analyzed.

Statistical analyses

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ related complications between HZ/su ≥ 50 YOA Group and Placebo/Historical Control ≥ 50 YOA Group.	
Comparison groups	HZ/su ≥ 50 YOA Group v Placebo/Historical control ≥ 50 YOA Group
Number of subjects included in analysis	27916
Analysis specification	Pre-specified
Analysis type	other ^[94]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	71.57
upper limit	99.17

Notes:

[94] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = $1 - RR$. RR = the ratio of the incidence rates of HZ/su ≥ 50 YOA Group over Placebo/Historical Control ≥ 50 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ related complications between HZ/su 50-59 YOA Group and Placebo/Historical Control 50-59 YOA Group.	
Comparison groups	HZ/su 50-59 YOA Group v Placebo/Historical control 50-59 YOA Group
Number of subjects included in analysis	7014
Analysis specification	Pre-specified
Analysis type	other ^[95]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1830.98
upper limit	100

Notes:

[95] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = $1 - RR$. RR = the ratio of the incidence rates of HZ/su 50-59 YOA Group over Placebo/Historical Control 50-59 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ related complications between HZ/su 60-69 YOA Group and Placebo/Historical Control 60-69 YOA Group.	
Comparison groups	HZ/su 60-69 YOA Group v Placebo/Historical control 60-69 YOA Group
Number of subjects included in analysis	4306
Analysis specification	Pre-specified
Analysis type	other ^[96]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.55
upper limit	100

Notes:

[96] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su 60-69 YOA Group over Placebo/Historical Control 60-69 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ related complications between HZ/su ≥ 60 YOA Group and Placebo/Historical Control ≥ 60 YOA Group.	
Comparison groups	HZ/su ≥ 60 YOA Group v Placebo/Historical control ≥ 60 YOA Group
Number of subjects included in analysis	20902
Analysis specification	Pre-specified
Analysis type	other ^[97]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	92.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	69.17
upper limit	99.11

Notes:

[97] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 60 YOA Group over Placebo/Historical Control ≥ 60 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Statistical analysis title	Vaccine efficacy
Statistical analysis description:	
Comparison of vaccine efficacy (VE) in prevention of HZ related complications between HZ/su ≥ 70 YOA Group and Placebo/Historical Control ≥ 70 YOA Group.	

Comparison groups	HZ/su ≥ 70 YOA Group v Placebo/Historical control ≥ 70 YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	other ^[98]
Method	Poisson regression method
Parameter estimate	Vaccine efficacy
Point estimate	90.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	60.93
upper limit	98.91

Notes:

[98] - The statistical analyses performed for the study objectives were descriptive. No success criteria were defined for the statistical analyses conducted in this study.

VE = 1 - RR. RR = the ratio of the incidence rates of HZ/su ≥ 70 YOA Group over Placebo/Historical Control ≥ 70 YOA Group. The VE of HZ/su vaccine against HZ related complications in this study was descriptively summarized by age strata and overall.

Secondary: Anti-glycoprotein (gE) antibody concentrations for humoral immunity (HI) subset at Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies, overall and by age ranges in the LTFU group

End point title	Anti-glycoprotein (gE) antibody concentrations for humoral immunity (HI) subset at Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies, overall and by age ranges in the LTFU group
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End point description:

Anti-gE antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA) and expressed as geometric mean concentrations (GMCs) in milli-international units per milliliter (mIU/mL). The age ranges assessed were: ≥ 50 YOA (overall), 50-59 YOA, 60-69 YOA, ≥ 60 YOA and ≥ 70 YOA at time of primary vaccination in ZOSTER-006/022 studies.

The analysis was performed on a subset of participants from the Adapted ATP cohort for humoral persistence - LTFU, who were included in the immunogenicity subset during ZOSTER-006/022 studies, continued participation in this study and had humoral persistence results available at the specified time points.

End point type	Secondary
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End point timeframe:

At Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies

End point values	LTFU ≥ 50 YOA Group	LTFU 50-59 YOA Group	LTFU 60-69 YOA Group	LTFU ≥ 60 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	786	219	230	567
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Year 5 (N=214,51,35,163,128)	8043.5 (7224.9 to 8954.7)	8044.2 (6106.6 to 10596.6)	8715.1 (6807.0 to 11158.1)	8043.2 (7180.7 to 9009.3)
Year 6 (N=786,219,230,567,337)	8536.6 (8113.5 to 8981.7)	8584.3 (7739.9 to 9520.7)	8913.4 (8155.1 to 9742.3)	8518.3 (8036.5 to 9028.9)
Year 7 (N=757,215,222,542,320)	8375.1 (7941.0 to 8833.0)	8325.6 (7483.0 to 9263.1)	8869.6 (8084.4 to 9731.1)	8394.8 (7895.3 to 8925.8)

Year 8 (N=732,215,219,517,298)	8231.2 (7778.2 to 8710.6)	8318.0 (7412.7 to 9333.9)	8680.0 (7901.2 to 9535.5)	8195.4 (7683.4 to 8741.5)
Year 9 (N=641,199,195,442,247)	7219.4 (6803.4 to 7660.9)	7097.6 (6341.6 to 7943.7)	7706.7 (6994.6 to 8491.4)	7275.0 (6784.2 to 7801.3)
Year 10 (N=606,197,187,409,222)	6861.5 (6433.2 to 7318.3)	7007.0 (6228.4 to 7882.9)	7060.8 (6304.2 to 7908.3)	6792.5 (6288.2 to 7337.3)
Year 11 (N=612,196,192,416,224)	7039.3 (6589.0 to 7520.5)	7146.9 (6294.9 to 8114.3)	7159.8 (6406.3 to 8001.9)	6989.2 (6470.8 to 7549.2)
Year 12 (N=435,151,161,284,123)	6844.3 (6335.2 to 7394.3)	6737.1 (5900.9 to 7691.7)	6943.4 (6071.3 to 7940.7)	6902.0 (6272.0 to 7595.3)

End point values	LTFU >=70 YOA Group			
Subject group type	Subject analysis set			
Number of subjects analysed	337			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Year 5 (N=214,51,35,163,128)	7868.7 (6915.4 to 8953.5)			
Year 6 (N=786,219,230,567,337)	8258.7 (7646.0 to 8920.4)			
Year 7 (N=757,215,222,542,320)	8080.4 (7446.1 to 8768.7)			
Year 8 (N=732,215,219,517,298)	7856.6 (7193.3 to 8581.0)			
Year 9 (N=641,199,195,442,247)	6951.3 (6295.8 to 7674.9)			
Year 10 (N=606,197,187,409,222)	6574.4 (5913.8 to 7308.8)			
Year 11 (N=612,196,192,416,224)	6846.3 (6148.5 to 7623.3)			
Year 12 (N=435,151,161,284,123)	6848.2 (5976.0 to 7847.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of antigen-specific CD4 (2+) T-cells for cell mediated immunity (CMI) subset at Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies, overall and by age ranges in the LTFU group

End point title	Frequency of antigen-specific CD4 (2+) T-cells for cell mediated immunity (CMI) subset at Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies, overall and by age ranges in the LTFU group
End point description:	
Frequency of CD4 (2+) T-cells with antigen-specific Interferon gamma (IFN-γ) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (TNF-α) and/or CD40 Ligand (CD40L) secretion/expression to gE was determined by Intracellular Cytokine Staining (ICS) and expressed in CD4 (2+) T-cells/million cells.	
The age ranges assessed were: ≥50 YOA (overall), 50-59 YOA, 60-69 YOA, ≥60 YOA and ≥70 YOA at time of primary vaccination in ZOSTER-006/022 studies.	
The analysis was performed on a subset of participants from the Adapted ATP cohort for CMI persistence - LTFU, who were included in the CMI subset during ZOSTER-006/022 studies, continued participation in this study and had CMI results available at the specified time points.	
'99999' was entered as a placeholder value in those instances where mean/standard deviation could not be calculated as there were 0 or only 1 participant with frequency of antigen-specific CD4 (2+) T-cells data available at the specified time point.	
End point type	Secondary
End point timeframe:	
At Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies	

End point values	LTFU ≥50 YOA Group	LTFU 50-59 YOA Group	LTFU 60-69 YOA Group	LTFU ≥60 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	39	38	61
Units: CD4 (2+) T-cells/million cells				
arithmetic mean (standard deviation)				
Year 5 (N= 3,2,0,1,1)	698.00 (± 531.11)	858.92 (± 639.37)	99999 (± 99999)	376.16 (± 99999)
Year 6 (N=100,39,38,61,23)	886.15 (± 869.09)	1174.70 (± 1103.76)	839.31 (± 644.97)	701.66 (± 621.26)
Year 7 (N=100,39,37,61,24)	859.46 (± 881.80)	1141.00 (± 1074.96)	745.36 (± 572.57)	679.46 (± 683.15)
Year 8 (N=97,37,38,60,22)	896.26 (± 925.58)	1217.84 (± 1155.53)	737.78 (± 602.91)	697.96 (± 688.76)
Year 9 (N=84,34,35,50,15)	1099.20 (± 1151.15)	1403.78 (± 1435.49)	930.89 (± 796.20)	892.09 (± 865.29)
Year 10 (N=80,35,31,45,14)	1016.13 (± 992.38)	1210.28 (± 1216.92)	952.86 (± 763.05)	865.13 (± 755.35)
Year 11 (N=83,36,33,47,14)	909.95 (± 1025.40)	1113.90 (± 1317.91)	884.65 (± 712.45)	753.74 (± 703.75)
Year 12 (N=73,32,29,41,12)	853.77 (± 815.20)	1030.37 (± 971.86)	828.62 (± 666.18)	715.95 (± 647.90)

End point values	LTFU ≥70 YOA Group			
Subject group type	Subject analysis set			
Number of subjects analysed	24			
Units: CD4 (2+) T-cells/million cells				
arithmetic mean (standard deviation)				
Year 5 (N= 3,2,0,1,1)	376.16 (± 99999)			
Year 6 (N=100,39,38,61,23)	474.23 (± 515.96)			

Year 7 (N=100,39,37,61,24)	577.87 (± 828.60)			
Year 8 (N=97,37,38,60,22)	629.18 (± 827.35)			
Year 9 (N=84,34,35,50,15)	801.54 (± 1033.67)			
Year 10 (N=80,35,31,45,14)	670.87 (± 726.96)			
Year 11 (N=83,36,33,47,14)	445.15 (± 597.48)			
Year 12 (N=73,32,29,41,12)	443.65 (± 531.44)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-gE antibody concentrations for participants in LTFU+Control ≥50 YOA Group (with a confirmed HZ episode) at Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies

End point title	Anti-gE antibody concentrations for participants in LTFU+Control ≥50 YOA Group (with a confirmed HZ episode) at Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies
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End point description:

Anti-gE antibody concentrations were determined by ELISA and expressed as GMCs in mIU/mL. The analysis was performed on a HZ subset for HI, which included participants who developed confirmed HZ during ZOSTER-006 or ZOSTER-022 studies, or who developed HZ during the interval between the end of the ZOSTER-006/022 studies and the beginning of the current ZOSTER-049:EXT 006-022 study, or who developed suspected HZ during the current ZOSTER-049:EXT 006-022 study and with immunogenicity results available for the specified analysis at the specified time points.

End point type	Secondary
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End point timeframe:

At Years 5, 6, 7, 8, 9, 10, 11 and 12 after the primary vaccination in ZOSTER-006/022 studies

End point values	LTFU+Control ≥50 YOA Group			
Subject group type	Subject analysis set			
Number of subjects analysed	62			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Year 5 (N=6)	12455.1 (8549.9 to 18144.1)			
Year 6 (N=22)	8138.7 (5770.6 to 11478.7)			
Year 7 (N=30)	6888.0 (4919.2 to 9644.7)			

Year 8 (N=39)	5831.9 (4435.1 to 7668.6)			
Year 9 (N=38)	7706.8 (5941.6 to 9996.5)			
Year 10 (N=48)	6800.1 (5048.6 to 9159.2)			
Year 11 (N=62)	6214.7 (4807.3 to 8034.2)			
Year 12 (N=30)	4770.7 (3523.6 to 6459.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-gE antibody concentrations for 1-Additional Dose, Revaccination and Control groups at Month 1 in the current ZOSTER-049:EXT 006-022 study

End point title	Anti-gE antibody concentrations for 1-Additional Dose, Revaccination and Control groups at Month 1 in the current ZOSTER-049:EXT 006-022 study ^[99]
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End point description:

Anti-gE antibody concentrations were determined by ELISA and expressed as GMCs in mIU/mL. The analysis was performed on Adapted ATP cohort for immunogenicity, which included all participants who met all eligibility criteria, received all doses as per assignment*, for whom administration site of study vaccine was known*, who did not receive any other vaccine, who complied with the procedures defined in protocol, vaccination* and blood sample schedule and with immunogenicity data available for the specified analysis at the specified time point.

*only applicable for the participants revaccinated in the current study.

End point type	Secondary
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End point timeframe:

At Month 1 in the current ZOSTER-049:EXT 006-022 study

Notes:

[99] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose, Revaccination and Control groups.

End point values	1-Additional Dose Group	Revaccination Group	Control Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	55	117	
Units: mIU/mL				
geometric mean (confidence interval 95%)	73834.4 (60603.6 to 89953.7)	79419.8 (65089.6 to 96904.9)	9655.2 (8316.9 to 11208.8)	

Statistical analyses

Secondary: Frequency of antigen-specific CD4 (2+) T-cells for participants in LTFU+Control >=50 YOA Group (with a confirmed HZ episode) at Years 5, 6, 7, 8, 9 and 10 after the primary vaccination in ZOSTER-006/022 studies

End point title	Frequency of antigen-specific CD4 (2+) T-cells for participants in LTFU+Control >=50 YOA Group (with a confirmed HZ episode) at Years 5, 6, 7, 8, 9 and 10 after the primary vaccination in ZOSTER-006/022 studies
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End point description:

Frequency of CD4 (2+) T-cells with antigen-specific IFN- γ and/or IL-2 and/or TNF- α and/or CD40L secretion/expression to gE was determined by ICS and expressed in CD4 (2+) T-cells/million cells. The analysis was performed on a HZ subset for CMI, which included participants who developed confirmed HZ during ZOSTER-006 or ZOSTER-022 studies, or who developed HZ during the interval between the end of the ZOSTER-006/022 studies and the beginning of the current ZOSTER-049:EXT 006-022 study, or who developed suspected HZ during the current ZOSTER-049:EXT 006-022 study and with CMI results available for the specified analysis at the specified time points. '99999' was entered as a placeholder value in those instances where standard deviation could not be calculated as there was only 1 participant with frequency of antigen-specific CD4 (2+) T-cells data available at the specified time point.

End point type	Secondary
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End point timeframe:

At Years 5, 6, 7, 8, 9, and 10 after the primary vaccination in ZOSTER-006/022 studies

End point values	LTFU+Control >=50 YOA Group			
Subject group type	Subject analysis set			
Number of subjects analysed	2			
Units: CD4 (2+) T-cells/million cells				
arithmetic mean (standard deviation)				
Year 5 (N=1)	683.76 (\pm 99999)			
Year 6 (N=2)	398.70 (\pm 164.34)			
Year 7 (N=2)	347.43 (\pm 138.41)			
Year 8 (N=1)	509.67 (\pm 99999)			
Year 10 (N=1)	749.75 (\pm 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of antigen-specific CD4 (2+) T-cells for Revaccination and Control groups at Month 3 in the current ZOSTER-049:EXT 006-022 study

End point title	Frequency of antigen-specific CD4 (2+) T-cells for Revaccination and Control groups at Month 3 in the current ZOSTER-049:EXT 006-022 study ^[100]
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End point description:

Frequency of CD4 (2+) T-cells with antigen-specific IFN- γ and/or IL-2 and/or TNF- α and/or CD40L secretion/expression to gE was determined by ICS and expressed in CD4 (2+) T-cells/million cells. The analysis was performed on Adapted ATP cohort for immunogenicity, which included all participants who met all eligibility criteria, received all doses as per assignment*, for whom administration site of study vaccine was known*, who did not receive any other vaccine, who complied with the procedures defined in protocol, vaccination* and blood sample schedule and with immunogenicity data available for the specified analysis at the specified time point.

*only applicable for the participants revaccinated in the current study.

End point type	Secondary
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End point timeframe:

At Month 3 in the current ZOSTER-049:EXT 006-022 study

Notes:

[100] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the Revaccination and Control groups.

End point values	Revaccination Group	Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	107		
Units: CD4 (2+) T-cells/million cells				
arithmetic mean (standard deviation)	2443.17 (\pm 3896.14)	739.07 (\pm 659.78)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of antigen-specific CD4(2+) T-cells for 1-Additional Dose, Revaccination and Control groups at Month 1 in the current ZOSTER-049:EXT 006-022 study

End point title	Frequency of antigen-specific CD4(2+) T-cells for 1-Additional Dose, Revaccination and Control groups at Month 1 in the current ZOSTER-049:EXT 006-022 study ^[101]
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End point description:

Frequency of CD4 (2+) T-cells with antigen-specific IFN- γ and/or IL-2 and/or TNF- α and/or CD40L secretion/expression to gE was determined by ICS and expressed in CD4 (2+) T-cells/million cells. The analysis was performed on Adapted ATP cohort for immunogenicity, which included all participants who met all eligibility criteria, received all doses as per assignment*, for whom administration site of study vaccine was known*, who did not receive any other vaccine, who complied with the procedures defined in protocol, vaccination* and blood sample schedule and with immunogenicity data available for the specified analysis at the specified time point.

*only applicable for the participants revaccinated in the current study.

End point type	Secondary
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End point timeframe:

At Month 1 in the current ZOSTER-049:EXT 006-022 study

Notes:

[101] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose, Revaccination and Control groups.

End point values	1-Additional Dose Group	Revaccination Group	Control Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	52	46	104	
Units: CD4 (2+) T-cells/million cells				
arithmetic mean (standard deviation)	3899.69 (± 3243.16)	2803.96 (± 1544.14)	716.01 (± 635.32)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-gE antibody concentrations for Revaccination and Control groups at Month 3 in the current ZOSTER-049:EXT 006-022 study

End point title	Anti-gE antibody concentrations for Revaccination and Control groups at Month 3 in the current ZOSTER-049:EXT 006-022 study ^[102]
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End point description:

Anti-gE antibody concentrations were determined by ELISA and expressed as GMCs in mIU/mL. The analysis was performed on Adapted ATP cohort for immunogenicity, which included all participants who met all eligibility criteria, received all doses as per assignment*, for whom administration site of study vaccine was known*, who did not receive any other vaccine, who complied with the procedures defined in protocol, vaccination* and blood sample schedule and with immunogenicity data available for the specified analysis at the specified time point.

*only applicable for the participants revaccinated in the current study.

End point type	Secondary
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End point timeframe:

At Month 3 in the current ZOSTER-049:EXT 006-022 study

Notes:

[102] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the Revaccination and Control groups.

End point values	Revaccination Group	Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55	117		
Units: mIU/mL				
geometric mean (confidence interval 95%)	64603.0 (54008.4 to 77275.9)	9428.1 (8154.4 to 10900.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-gE antibody concentrations for 1-Additional Dose, Revaccination and Control groups at Month 0 and Years 1, 2, 3, 4, 5 and 6 in the current ZOSTER-049:EXT 006-022 study

End point title	Anti-gE antibody concentrations for 1-Additional Dose,
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End point description:

Anti-gE antibody concentrations were determined by ELISA and expressed as GMCs in mIU/mL. The analysis was performed on Adapted ATP cohort for immunogenicity, which included all participants who met all eligibility criteria, received all doses as per assignment*, for whom administration site of study vaccine was known*, who did not receive any other vaccine, who complied with the procedures defined in protocol, vaccination* and blood sample schedule and with immunogenicity data available for the specified analysis at the specified time points.

*only applicable for the participants revaccinated in the current study.

End point type	Secondary
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End point timeframe:

At Month 0 and Years 1, 2, 3, 4, 5 and 6 in the current ZOSTER-049:EXT 006-022 study

Notes:

[103] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose, Revaccination and Control groups.

End point values	1-Additional Dose Group	Revaccination Group	Control Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	55	117	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Month 0 (N=58,55,117)	10149.5 (8640.2 to 11922.4)	11548.5 (9386.8 to 14208.0)	10232.0 (8836.7 to 11847.5)	
Year 1 (N=60,52,115)	24663.6 (20790.2 to 29258.7)	26167.5 (21755.6 to 31474.2)	8825.4 (7616.3 to 10226.5)	
Year 2 (N=59,51,112)	19417.9 (16460.7 to 22906.4)	19973.2 (16538.1 to 24121.8)	8643.3 (7450.5 to 10027.0)	
Year 3 (N=57,51,108)	16335.6 (13890.4 to 19211.3)	16264.7 (13417.7 to 19715.7)	8314.9 (7080.3 to 9764.7)	
Year 4 (N=48,44,94)	18676.4 (15562.0 to 22414.2)	16363.2 (13219.3 to 20254.9)	8581.7 (7195.2 to 10235.3)	
Year 5 (N=52,47,99)	14797.3 (12340.7 to 17742.9)	14595.7 (11767.0 to 18104.4)	7238.7 (6004.3 to 8727.0)	
Year 6 (N=50,46,91)	12868.4 (11048.3 to 14988.2)	13534.0 (11107.7 to 16490.2)	6858.8 (5698.0 to 8256.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of antigen-specific CD4(2+) T-cells for 1-Additional Dose, Revaccination and Control groups at Month 0 and Years 1, 2, 3, 4, 5 and 6 in the current ZOSTER-049:EXT 006-022 study

End point title	Frequency of antigen-specific CD4(2+) T-cells for 1-Additional Dose, Revaccination and Control groups at Month 0 and Years
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End point description:

Frequency of CD4 (2+) T-cells with antigen-specific IFN- γ and/or IL-2 and/or TNF- α and/or CD40L secretion/expression to gE was determined by ICS and expressed in CD4 (2+) T-cells/million cells. The analysis was performed on Adapted ATP cohort for immunogenicity, which included all participants who met all eligibility criteria, received all doses as per assignment*, for whom administration site of study vaccine was known*, who did not receive any other vaccine, who complied with the procedures defined in protocol, vaccination* and blood sample schedule and with immunogenicity data available for the specified analysis at the specified time points.

*only applicable for the participants revaccinated in the current study.

End point type	Secondary
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End point timeframe:

At Month 0 and Years 1, 2, 3, 4, 5 and 6 in the current ZOSTER-049:EXT 006-022 study

Notes:

[104] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose, Revaccination and Control groups.

End point values	1-Additional Dose Group	Revaccination Group	Control Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	54	109	
Units: CD4(2+) T-cells/million cells				
arithmetic mean (standard deviation)				
Month 0 (N=55,54,109)	843.55 (\pm 792.93)	876.23 (\pm 784.84)	817.97 (\pm 809.77)	
Year 1 (N=53,50,97)	1798.39 (\pm 2119.46)	1155.04 (\pm 714.97)	665.50 (\pm 603.93)	
Year 2 (N=58,46,109)	1634.47 (\pm 1900.93)	1154.97 (\pm 818.16)	712.02 (\pm 715.32)	
Year 3 (N=51,45,95)	2112.90 (\pm 2564.29)	1219.13 (\pm 889.76)	836.62 (\pm 921.57)	
Year 4 (N=45,43,83)	2047.92 (\pm 2477.92)	1083.64 (\pm 669.54)	901.57 (\pm 917.41)	
Year 5 (N=48,47,93)	1649.03 (\pm 2407.72)	917.93 (\pm 648.92)	720.32 (\pm 726.20)	
Year 6 (N=48,41,82)	1682.94 (\pm 2694.90)	844.81 (\pm 651.28)	736.01 (\pm 724.10)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any and Grade 3 solicited local symptoms

End point title	Number of participants with any and Grade 3 solicited local symptoms ^[105]
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End point description:

The assessed solicited local symptoms included pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade or relation to vaccination. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimeters (mm) of injection site.

The analysis was performed on the Total Vaccinated Cohort (for 1-Additional Dose and Revaccination groups), which included all participants who received at least 1 dose of the study treatment in ZOSTER-049:EXT 006-022 and who have documented solicited symptoms (i.e., diary card for solicited AEs

completed and returned) after each vaccination.

'99999' was entered as a placeholder value in those instances where no data are available post-Dose 2, since the participants in the 1-Additional Dose group only received Dose 1 of HZ/su vaccine.

End point type	Secondary
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End point timeframe:

Within 7 days after each vaccination (vaccination occurring at Month 0 for 1-Additional Dose Group and at Months 0 and 2 for Revaccination Group) in the current ZOSTER-049:EXT 006-022 study

Notes:

[105] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose and Revaccination groups.

End point values	1-Additional Dose Group	Revaccination Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	60		
Units: Participants				
Any pain, post-Dose 1 (N=61,60)	42	52		
Grade 3 pain, post-Dose 1 (N=61,60)	1	3		
Any redness, post-Dose 1 (N=61,60)	13	20		
Grade 3 redness, post-Dose 1 (N=61,60)	4	1		
Any swelling, post-Dose 1 (N=61,60)	7	12		
Grade 3 swelling, post-Dose 1 (N=61,60)	1	0		
Any pain, post-Dose 2 (N=0,55)	99999	37		
Grade 3 pain, post-Dose 2 (N=0,55)	99999	2		
Any redness, post-Dose 2 (N=0,55)	99999	20		
Grade 3 redness, post-Dose 2 (N=0,55)	99999	3		
Any swelling, post-Dose 2 (N=0,55)	99999	13		
Grade 3 swelling, post-Dose 2 (N=0,55)	99999	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration in days of solicited local symptoms

End point title	Duration in days of solicited local symptoms ^[106]
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End point description:

Duration is the number of days in which a participant experienced the symptom within the 7-day solicited follow-up period. The assessed solicited local symptoms included pain, redness and swelling. The analysis was performed on the Total Vaccinated Cohort (for 1-Additional Dose and Revaccination groups), which included all participants who received at least 1 dose of the study treatment in ZOSTER-049:EXT 006-022, with diary data available after each vaccination and who experienced the specified solicited local symptom within 7 days following the respective vaccine dose.

'99999' was entered as a placeholder value in those instances where no data are available post-Dose 2, since the participants in the 1-Additional Dose group only received Dose 1 of HZ/su vaccine.

End point type	Secondary
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End point timeframe:

Within 7 days after each vaccination (vaccination occurring at Month 0 for 1-Additional Dose Group and at Months 0 and 2 for Revaccination Group) in the current ZOSTER-049:EXT 006-022 study

Notes:

[106] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose and Revaccination groups.

End point values	1-Additional Dose Group	Revaccination Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	60		
Units: Days				
median (inter-quartile range (Q1-Q3))				
Pain, post-Dose 1 (N=61,60)	3.0 (2.0 to 3.0)	3.0 (2.0 to 3.5)		
Pain, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	2.0 (2.0 to 3.0)		
Redness, post-Dose 1 (N=61,60)	3.0 (2.0 to 4.0)	3.0 (2.0 to 4.0)		
Redness, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	2.5 (1.0 to 4.5)		
Swelling, post-Dose 1 (N=61,60)	2.0 (2.0 to 3.0)	3.0 (1.0 to 5.0)		
Swelling, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	2.0 (1.0 to 3.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any, Grade 3 and related solicited general symptoms

End point title	Number of participants with any, Grade 3 and related solicited general symptoms ^[107]
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End point description:

The assessed solicited general symptoms included fatigue, fever [defined as oral temperature ≥ 37.5 degrees Celsius ($^{\circ}\text{C}$)], gastrointestinal symptoms, headache, myalgia, and shivering. Any = occurrence of the symptom regardless of intensity grade or relation to vaccination. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever $> 39.0^{\circ}\text{C}$. Related = symptom assessed by the investigator as related to the vaccination.

The analysis was performed on the Total Vaccinated Cohort (for 1-Additional Dose and Revaccination groups), which included all participants who received at least 1 dose of the study treatment in ZOSTER-049:EXT 006-022 and who have documented solicited symptoms (i.e., diary card for solicited AEs completed and returned) after each vaccination.

'99999' was entered as a placeholder value in those instances where no data are available post-Dose 2, since the participants in the 1-Additional Dose group only received Dose 1 of HZ/su vaccine.

End point type	Secondary
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End point timeframe:

Within 7 days after each vaccination (vaccination occurring at Month 0 for 1-Additional Dose Group and at Months 0 and 2 for Revaccination Group) in the current ZOSTER-049:EXT 006-022 study

Notes:

[107] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose and Revaccination groups.

End point values	1-Additional Dose Group	Revaccination Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	60		
Units: Participants				
Any fatigue, post-Dose 1(N=61,60)	32	24		
Grade 3 fatigue, post-Dose 1 (N=61,60)	0	2		
Related fatigue, post-Dose 1 (N=61,60)	32	23		
Any fever, post-Dose 1(N=61,60)	18	13		
Grade 3 fever, post-Dose 1 (N=61,60)	0	0		
Related fever, post-Dose 1,(N=61,60)	18	13		
Any gastrointestinal, post-Dose1 (N=61,60)	9	9		
Grade 3 gastrointestinal, post-Dose 1 (N=61,60)	0	2		
Related gastrointestinal, post-Dose1 (N=61,60)	9	8		
Any headache, post-Dose 1 (N=61,60)	23	17		
Grade 3 headache, post-Dose 1 (N=61,60)	0	2		
Related headache, post-Dose 1 (N=61,60)	23	17		
Any myalgia, post-Dose 1 (N=61,60)	27	22		
Grade 3 myalgia, post-Dose 1 (N=61,60)	0	2		
Related myalgia, post-Dose 1 (N=61,60)	27	21		
Any shivering, post-Dose 1 (N=61,60)	25	15		
Grade 3 shivering, post-Dose 1, N=61,60	2	4		
Related shivering, post-Dose 1 (N=61,60)	25	15		
Any fatigue, post-Dose 2 (N=0,55)	99999	22		
Grade 3 fatigue, post-Dose 2 (N=0,55)	99999	3		
Related fatigue, post-Dose 2 (N=0,55)	99999	21		
Any fever, post-Dose 2 (N=0,55)	99999	7		
Grade 3 fever, post-Dose 2 (N=0,55)	99999	0		
Related fever, post-Dose 2 (N=0,55)	99999	4		
Any gastrointestinal, post-Dose 2 (N=0,55)	99999	4		
Grade 3 gastrointestinal, post-Dose 2 (N=0,55)	99999	0		
Related gastrointestinal, post-Dose 2 (N=0,55)	99999	4		
Any headache, post-Dose 2,N=0,55	99999	15		
Grade 3 headache, post-Dose 2 (N=0,55)	99999	1		
Related headache, post-Dose 2 (N=0,55)	99999	14		
Any myalgia, post-Dose 2 (N=0,55)	99999	12		
Grade 3 myalgia, post-Dose 2 (N=0,55)	99999	1		
Related myalgia, post-Dose 2 (N=0,55)	99999	11		
Any shivering, post-Dose 2 (N=0,55)	99999	7		
Grade 3 shivering, post-Dose 2 (N=0,55)	99999	0		
Related shivering, post-Dose 2 (N=0,55)	99999	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration in days of solicited general symptoms

End point title	Duration in days of solicited general symptoms ^[108]
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End point description:

Duration is the number of days in which a participant experienced the symptom within the 7-day solicited follow-up period. The assessed solicited general symptoms included fatigue, fever [defined as oral temperature $\geq 37.5^{\circ}\text{C}$], gastrointestinal symptoms, headache, myalgia, and shivering.

The analysis was performed on the Total Vaccinated Cohort (for 1-Additional Dose and Revaccination groups), which included all participants who received at least 1 dose of the study treatment in ZOSTER-049:EXT 006-022, with diary data available after each vaccination and who experienced the specified solicited general symptom within 7 days following the respective vaccine dose.

'99999' was entered as a placeholder value in those instances where no data are available post-Dose 2, since the participants in the 1-Additional Dose group only received Dose 1 of HZ/su vaccine.

End point type	Secondary
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End point timeframe:

Within 7 days after each vaccination (vaccination occurring at Month 0 for 1-Additional Dose Group and at Months 0 and 2 for Revaccination Group) in the current ZOSTER-049:EXT 006-022 study

Notes:

[108] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose and Revaccination groups.

End point values	1-Additional Dose Group	Revaccination Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	60		
Units: Days				
median (inter-quartile range (Q1-Q3))				
Fatigue, post-Dose 1 (N=61,60)	2.0 (1.0 to 3.0)	2.0 (1.0 to 2.0)		
Fatigue, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	2.0 (1.0 to 3.0)		
Fever, post-Dose 1 (N=61,60)	1.0 (1.0 to 1.0)	1.0 (1.0 to 2.0)		
Fever, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	1.0 (1.0 to 2.0)		
Gastrointestinal symptoms, post-Dose 1 (N=61,60)	1.0 (1.0 to 2.0)	1.0 (1.0 to 3.0)		
Gastrointestinal symptoms, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	1.5 (1.0 to 2.0)		
Headache, post-Dose 1 (N=61,60)	1.0 (1.0 to 2.0)	2.0 (1.0 to 3.0)		
Headache, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	2.0 (1.0 to 3.0)		
Myalgia, post-Dose 1 (N=61,60)	2.0 (1.0 to 2.0)	1.0 (1.0 to 3.0)		
Myalgia, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	1.5 (1.0 to 2.5)		
Shivering, post-Dose 1 (N=61,60)	1.0 (1.0 to 2.0)	1.0 (1.0 to 2.0)		

Shivering, post-Dose 2 (N=0,55)	99999 (99999 to 99999)	1.0 (1.0 to 2.0)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any unsolicited adverse events (AEs)

End point title	Number of participants with any unsolicited adverse events (AEs) ^[109]
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End point description:

An unsolicited AE is defined as any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any = occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

The analysis was performed on the Total Vaccinated Cohort (for 1-Additional Dose and Revaccination groups), which included all participants who received at least 1 dose of the study treatment in ZOSTER-049:EXT 006-022.

End point type	Secondary
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End point timeframe:

Within 30 days after any vaccination (vaccination occurring at Month 0 for 1-Additional Dose Group and at Months 0 and 2 for Revaccination Group) in the current ZOSTER-049:EXT 006-022 study

Notes:

[109] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose and Revaccination groups.

End point values	1-Additional Dose Group	Revaccination Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	60		
Units: Participants	13	15		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any and related serious adverse events (SAEs)

End point title	Number of participants with any and related serious adverse events (SAEs) ^[110]
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End point description:

An SAE is defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study participant. Any SAE = occurrence of the SAE regardless of intensity or relation to study vaccination. Related SAE = SAE assessed by the investigator as related to vaccination.

The analysis was performed on Total Vaccinated cohort, which included all participants who received at least 1 dose of the study treatment in ZOSTER-049:EXT 006-022 (1-Additional Dose and Revaccination

groups) and all participants who came for Month 0 visit (Control group).

End point type	Secondary
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End point timeframe:

From Month 0 to Month 12 (1-Additional Dose and Control groups) and from Month 0 until 12 months after last HZ/su vaccination (Revaccination group)

Notes:

[110] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose, Revaccination and Control groups.

End point values	1-Additional Dose Group	Revaccination Group	Control Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	119	
Units: Participants				
Any SAEs	4	4	11	
Related SAEs	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any and related potential immune-mediated diseases (pIMDs)

End point title	Number of participants with any and related potential immune-mediated diseases (pIMDs) ^[111]
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End point description:

pIMDs are defined as a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune aetiology. Any pIMDs = occurrence of a pIMD regardless of relation to vaccination. Related pIMD = a pIMD assessed by the investigator as related to the study vaccination.

Analysis was performed on Total Vaccinated cohort, which included all participants who received at least 1 dose of the study treatment in ZOSTER-049:EXT 006-022 (1-Additional Dose and Revaccination groups) and all participants who came for Month 0 visit (Control group).

End point type	Secondary
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End point timeframe:

From Month 0 to Month 12 (1-Additional Dose and Control groups) and from Month until 12 months after last HZ/su vaccination (Revaccination group)

Notes:

[111] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting values for the participants in the 1-Additional Dose, Revaccination and Control groups.

End point values	1-Additional Dose Group	Revaccination Group	Control Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	119	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with SAEs related to investigational vaccine, related to study participation or to GSK concomitant medication/vaccine

End point title	Number of participants with SAEs related to investigational vaccine, related to study participation or to GSK concomitant medication/vaccine
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End point description:

An SAE is defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study participant.

Analysis was performed on Total Vaccinated cohort, which included all participants who received at least 1 dose of the study treatment in ZOSTER-049:EXT 006-022 (1-Additional Dose and Revaccination groups) and all participants who came for Month 0 visit (LTFU and Control groups).

End point type	Secondary
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End point timeframe:

During the total duration of ZOSTER-049:EXT 006-022 study (from Month 0 to Month 72)

End point values	LTFU Group	1-Additional Dose Group	Revaccination Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7289	61	60	119
Units: Participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs: within 7 days & Unsolicited AEs: within 30 days across HZ/su doses. SAEs: Month (M) 0 to M72 (only related SAEs for LTFU group), M0 to M12 (1-Additional Dose & Control groups) & M0 until 12 months post-last HZ/su dose (Revaccination group).

Adverse event reporting additional description:

As pre-specified in protocol, data in the Non-Serious Adverse Events module was only collected for the revaccinated participants in ZOSTER-049:EXT 006-022 study (1-Additional Dose and Revaccination groups).

As per the amended information in protocol, for the LTFU group, AEs/SAEs that were not considered related were not analyzed.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	LTFU Group
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Reporting group description:

Participants who received at least 1 dose of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049 study were followed up for long-term vaccine efficacy and safety.

Reporting group title	Revaccination Group
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Reporting group description:

Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies and got revaccinated with 2 additional doses of the HZ/su vaccine at Month 0 and Month 2 in the current ZOSTER-049 study.

Reporting group title	Control Group
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Reporting group description:

Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies and no additional doses of the HZ/su vaccine in the current ZOSTER-049 study, but who served as a control for the 2 groups that received 1 or 2 additional doses (1-Additional Dose Group and Revaccination Group).

Reporting group title	1-Additional Dose Group
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Reporting group description:

Participants who received 2 doses of the HZ/su vaccine in the ZOSTER-006/022 primary studies and 1 additional dose of the HZ/su vaccine at Month 0 in the current ZOSTER-049 study.

Serious adverse events	LTFU Group	Revaccination Group	Control Group
Total subjects affected by serious adverse events			
subjects affected / exposed	62 / 7289 (0.85%)	4 / 60 (6.67%)	11 / 119 (9.24%)
number of deaths (all causes)	56	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			

subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer stage IV			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mantle cell lymphoma			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			

subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurofibrosarcoma			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	5 / 7289 (0.07%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	2 / 7289 (0.03%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute pulmonary oedema			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Extradural haematoma			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic			

disorders			
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	14 / 7289 (0.19%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	3 / 7289 (0.04%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorder			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac hypertrophy			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	5 / 7289 (0.07%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 7289 (0.01%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Adams-stokes syndrome			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	2 / 7289 (0.03%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			

subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	2 / 7289 (0.03%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	2 / 119 (1.68%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar stroke			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Pancreatitis necrotising			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pharyngo-oesophageal diverticulum			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	5 / 7289 (0.07%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	1 / 7289 (0.01%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pertussis			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	1-Additional Dose Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 61 (6.56%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Small cell lung cancer				
subjects affected / exposed	0 / 61 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer stage IV				
subjects affected / exposed	0 / 61 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatocellular carcinoma				
subjects affected / exposed	0 / 61 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	0 / 61 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mantle cell lymphoma				
subjects affected / exposed	0 / 61 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to peritoneum				
subjects affected / exposed	0 / 61 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Papillary thyroid cancer				
subjects affected / exposed	0 / 61 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer				
subjects affected / exposed	0 / 61 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neurofibrosarcoma				

subjects affected / exposed	1 / 61 (1.64%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			

subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute pulmonary oedema			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Extradural haematoma			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			

subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorder			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac hypertrophy			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adams-stokes syndrome			

subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure chronic			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dementia			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			

subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebellar stroke			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Pancreatitis necrotising			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pharyngo-oesophageal diverticulum			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus paralytic			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Septic shock			

subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Labyrinthitis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis infective			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pertussis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	LTFU Group	Revaccination Group	Control Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 7289 (0.00%)	58 / 60 (96.67%)	0 / 119 (0.00%)
Investigations			
Prostatic specific antigen increased			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Headache			
subjects affected / exposed	0 / 7289 (0.00%)	23 / 60 (38.33%)	0 / 119 (0.00%)
occurrences (all)	0	33	0
Hypoaesthesia			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 7289 (0.00%)	19 / 60 (31.67%)	0 / 119 (0.00%)
occurrences (all)	0	22	0
Chest pain			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Swelling			
subjects affected / exposed	0 / 7289 (0.00%)	16 / 60 (26.67%)	0 / 119 (0.00%)
occurrences (all)	0	25	0
Pyrexia			
subjects affected / exposed	0 / 7289 (0.00%)	17 / 60 (28.33%)	0 / 119 (0.00%)
occurrences (all)	0	20	0
Pain			
subjects affected / exposed	0 / 7289 (0.00%)	53 / 60 (88.33%)	0 / 119 (0.00%)
occurrences (all)	0	89	0
Injection site pruritus			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 7289 (0.00%)	33 / 60 (55.00%)	0 / 119 (0.00%)
occurrences (all)	0	46	0
Eye disorders			
Vitreous floaters			
subjects affected / exposed	0 / 7289 (0.00%)	0 / 60 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 7289 (0.00%)	1 / 60 (1.67%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

Gastroesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0
Gastrointestinal disorder subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	10 / 60 (16.67%) 13	0 / 119 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0
Hepatobiliary disorders Cholelithiasis subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	0 / 60 (0.00%) 0	0 / 119 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	0 / 60 (0.00%) 0	0 / 119 (0.00%) 0
Aphonia subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0
Blister subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0
Papule subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	0 / 60 (0.00%) 0	0 / 119 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	28 / 60 (46.67%) 42	0 / 119 (0.00%) 0
Ecchymosis subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	0 / 60 (0.00%) 0	0 / 119 (0.00%) 0

Psychiatric disorders Nightmare subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	0 / 60 (0.00%) 0	0 / 119 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	2 / 60 (3.33%) 2	0 / 119 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	26 / 60 (43.33%) 34	0 / 119 (0.00%) 0
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0
Osteoporosis subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 2	0 / 119 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	2 / 60 (3.33%) 2	0 / 119 (0.00%) 0
Nail infection subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	0 / 60 (0.00%) 0	0 / 119 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0
Metabolism and nutrition disorders Iron deficiency subjects affected / exposed occurrences (all)	0 / 7289 (0.00%) 0	1 / 60 (1.67%) 1	0 / 119 (0.00%) 0

Non-serious adverse events	1-Additional Dose Group		
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	54 / 61 (88.52%)		
Investigations			
Prostatic specific antigen increased			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed	24 / 61 (39.34%)		
occurrences (all)	25		
Hypoaesthesia			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	26 / 61 (42.62%)		
occurrences (all)	26		
Chest pain			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Swelling			
subjects affected / exposed	7 / 61 (11.48%)		
occurrences (all)	7		
Pyrexia			
subjects affected / exposed	18 / 61 (29.51%)		
occurrences (all)	18		
Pain			
subjects affected / exposed	42 / 61 (68.85%)		
occurrences (all)	42		
Injection site pruritus			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	32 / 61 (52.46%)		
occurrences (all)	32		
Eye disorders			

Vitreous floaters subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1		
Macular degeneration subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0		
Gastrointestinal disorders Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0		
Gastrointestinal disorder subjects affected / exposed occurrences (all)	9 / 61 (14.75%) 9		
Gastritis subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0		
Hepatobiliary disorders Cholelithiasis subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 61 (1.64%) 1		
Aphonia subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0		
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0		
Blister subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0		
Papule			

subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	13 / 61 (21.31%)		
occurrences (all)	13		
Ecchymosis			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	2		
Psychiatric disorders			
Nightmare			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	27 / 61 (44.26%)		
occurrences (all)	27		
Osteoarthritis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Osteoporosis			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 61 (0.00%)		
occurrences (all)	0		
Nail infection			
subjects affected / exposed	1 / 61 (1.64%)		
occurrences (all)	1		
Pneumonia			

subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0		
Metabolism and nutrition disorders Iron deficiency subjects affected / exposed occurrences (all)	0 / 61 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 February 2016	This amendment was done for countries that recruited subjects in the 1-Additional Dose, Revaccination and Control groups. Administrative changes were done for Germany and Japan. The additional inclusion and exclusion criteria for the 1-Additional Dose and Revaccination groups were also made applicable to the Control group to allow non-biased randomisation of subjects into the 3 groups and an additional exclusion criterion has been added for 1-Additional Dose, Revaccination and Control groups. The reference to "GSK Japan" has been changed to "Japan Vaccine Co., Ltd." The study period indicated was also corrected as per local request in the requirements for Japan. Typographical errors were corrected in addition to the term "ZOSTER-056" that was corrected to "ZOSTER-049" in the requirements for Germany.
19 January 2017	<p>This protocol was amended after study start, because this being a long-term follow-up study and considering the age of the study population and the study duration (6 years), the current safety data collection requirement of the protocol would lead to collection of safety data that is not relevant for assessing the safety profile of the vaccine. This amendment was done to qualify that for the recording of AEs/SAEs leading to withdrawal which are not related to: investigational vaccine, study participation, GSK concomitant medication/vaccine, HZ complications. Only the name (diagnosis/description) of the event was recorded in the eCRF. No other details about these types of AEs/SAEs were recorded during the entire study (for the LTFU group), after 12 months from Visit Month 0 (for the Control and 1-Additional Dose groups) and after 12 months from last HZ/su vaccination (for the Revaccination group).</p> <p>The footnote was added to Synopsis Table 1 and Tables 1 and 16 for clarity that all subjects entering the study would have a humoral immunogenicity (HI) blood sample at Visit Month 0 and for subjects in the LTFU group, who did not belong to any subset, these samples would be stored and tested for HI only if the subject develops HZ during the ZOSTER-049 study or if there are other reasons requiring the HI testing of these samples. Although no confirmed signals related to hypersensitivity reactions (including anaphylaxis) have been identified during the HZ/su clinical program, a mitigation strategy for the potential risk has been added to the Risk Assessment Section. The CMI Vaccine Response Rate (VRR) for gE was defined to align with the Statistical Analysis Plan (SAP).</p>
16 March 2018	<p>The protocol was amended following a request by the European Medicines Agency (EMA). Vaccine efficacy (VE) in prevention of Herpes Zoster (HZ) related complications (other than Postherpetic Neuralgia [PHN]) in the overall study population and VE in the prevention of PHN over each year of follow-up from one month post dose 2 in the ZOSTER-006/022 studies until the end of the ZOSTER-049 study would be assessed. The corresponding objectives and endpoints were added. In addition, as per EMA's request, a sensitivity analysis would be performed to assess the impact on VE of HZ episodes occurring during the interval between the end of the ZOSTER-006/022 studies and beginning of the ZOSTER-049.</p> <p>Evaluation of memory B cell responses would be performed. The corresponding tertiary objectives and endpoints were added. Description of the Enzyme-linked ImmunoSpot (ELISPOT) assay and descriptive statistics were also added.</p> <p>Since the HZ/su vaccine was first approved in Canada and the United States in October 2017, the Trademarks were updated to include the trade name Shingrix.</p>

23 October 2018	This amendment was related to the time frame of completing the Zoster Brief Pain Inventory (ZBPI) questionnaire. This change would ensure thorough reporting of postherpetic neuralgia cases. Subjects with suspected herpes zoster (HZ) were required to complete the questionnaire until a 4-week pain-free period was documented and beyond Day HZ-91, if applicable. This amendment removed the stipulation "or until Day HZ-91" and therefore, if pain developed after Day HZ-91 to capture of cases of postherpetic neuralgia according to the protocol definition. Reporting of cytotoxic chemotherapy as a concomitant medication was clarified. Other minor changes included correcting and updating text regarding country approvals of Shingrix, and correcting minor typographical errors.
11 May 2020	This amendment outlined measures that may have been applicable during special circumstances (e.g., during COVID-19 pandemic). The purpose of the amendment was to introduce measures that may have allowed protection of subject's welfare and safety, as well as maintaining the integrity of the study. The classification of HZ cases by HZAC has been clarified with the addition of "not able to decide" to be classified as "not HZ" for confirmation of suspected HZ by the HZAC. The timelines concerning data entry into the eCRF for France have been updated to align with the timelines presented in the data management plan.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported