Clinical trial results:
A phase IIIB, open label, long term follow-up study to assess persistence of immune responses to GSK's HZ/su vaccine 4-7 years after primary vaccination; and immunogenicity and safety assessment of revaccination with 2 additional doses of HZ/su vaccine, administered 1-2 months apart, 6-8 years after primary vaccination of adults with renal transplant from study ZOSTER-041

Summary

EudraCT number	2019-001815-21
Trial protocol	BE FI
Global end of trial date	27 June 2024

Results information

Result version number	v1 (current)
This version publication date	13 July 2025
First version publication date	13 July 2025

Trial information

Trial identification

Sponsor protocol code	212340

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04176939
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	24 October 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Long term follow-up (LTFU) phase - Immunogenicity assessment:
• To evaluate persistence of humoral immunity after primary vaccination course.
Revaccination active phase - Immunogenicity assessment:
• To evaluate humoral immunity of HZ/su vaccine post-revaccination Doses 1 & 2.

Protection of trial subjects:

An internal Safety Review Team oversaw the safety and wellbeing of the study participants.
All participants were supervised/observed for 30 mins after vaccine administration with appropriate medical treatment readily available in case if serious allergic reaction to vaccination.
Study procedures including vaccine administration and blood sampling were performed by qualified/trained personnel.
Study vaccine was administered only to eligible participants that had no contraindications to any components of the vaccine.
Participants were followed up for 2 years in the LTFU phase of the current extension ZOSTER-073 study, representing up to 6-8 years after the vaccination in the primary ZOSTER-041 study.
Also, participants were followed up for 24 months after the second revaccination dose received in the current ZOSTER-073 study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Regulatory reason
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Canada: 7
Country: Number of subjects enrolled	Finland: 3
Country: Number of subjects enrolled	Korea, Republic of: 10
Country: Number of subjects enrolled	Panama: 3
Country: Number of subjects enrolled	Spain: 40
Country: Number of subjects enrolled	Taiwan: 3
Worldwide total number of subjects	68
EEA total number of subjects	45

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)	47
From 65 to 84 years	20
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Eligible participants from the Herpes Zoster (HZ/su) treatment group of ZOSTER-041 (NCT02058589) study who had a complete primary vaccination course (2 doses of HZ/su vaccine) were offered enrollment in the current ZOSTER-073 study (NCT04176939). A total of 68 participants met the eligibility criteria and consented to participate in this study.

Pre-assignment

Screening details:

Out of the 68 participants originally enrolled in the current ZOSTER-073 study (Enrolled Set), 21 participants did not receive any revaccination doses, hence only 47 participants were vaccinated with at least one revaccination dose and included in the Exposed Set for revaccination phase in this study.

Period 1

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

Blinding implementation details:

This is an open-label study with one treatment group.

Arms

Arm title	HZ/su Group

Arm description:

Participants with renal transplant who completed the 2-dose Herpes Zoster (HZ/su) vaccination course in the primary ZOSTER-041 (NCT02058589) study were enrolled in the current ZOSTER-073 (NCT04176939) study.
47 of these participants further received 1 or 2 additional doses of HZ/su vaccine in the revaccination phase of the current ZOSTER-073 (NCT04176939) study, first dose at Month 24 and second dose at Month 25.

Arm type	Experimental
Investigational medicinal product name	HZ/su vaccine
Investigational medicinal product code	
Other name	GSK1437173A
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 additional doses of the HZ/su vaccine were administered intramuscularly at Month 24 and at Month 25 in the revaccination phase of the study.

Number of subjects in period 1	HZ/su Group
Started	68
Revaccinated	47 [1]
Completed	49
Not completed	19
Adverse Event Requiring Expedited Reporting	7
Consent withdrawn by subject	5

Migrated / Moved From The Study Area	1
Unspecified reason	4
Lost to follow-up	2

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Out of the 68 participants originally enrolled in the current ZOSTER-073 study (Enrolled Set), only 47 participants were vaccinated with at least one revaccination dose and included in the Exposed Set for revaccination phase in this study.

Baseline characteristics

Reporting groups	
Reporting group title	HZ/su Group
Reporting group description:	
Participants with renal transplant who completed the 2-dose Herpes Zoster (HZ/su) vaccination course in the primary ZOSTER-041 (NCT02058589) study were enrolled in the current ZOSTER-073 (NCT04176939) study. 47 of these participants further received 1 or 2 additional doses of HZ/su vaccine in the revaccination phase of the current ZOSTER-073 (NCT04176939) study, first dose at Month 24 and second dose at Month 25.	

Reporting group values	HZ/su Group	Total	
Number of subjects	68	68	
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)	47	47	
From 65-84 years	20	20	
85 years and over	1	1	
Age Continuous			
Descriptive summaries of Age at the time of enrollment in the current ZOSTER-073 study are presented for the participants enrolled in this study (Enrolled Set).			
Units: Years			
arithmetic mean	58.5		
standard deviation	± 12.3	-	
Sex: Female, Male			
Descriptive summaries of Sex at the time of enrollment in the current ZOSTER-073 study are presented for the participants enrolled in this study (Enrolled Set).			
Units: Participants			
Female	22	22	
Male	46	46	
Race/Ethnicity, Customized			
Descriptive summaries of Race/Ethnicity at the time of enrollment in the current ZOSTER-073 study are presented for the participants enrolled in this study (Enrolled Set).			
Units: Subjects			
ASIAN	14	14	
BLACK OR AFRICAN AMERICAN	3	3	
WHITE	46	46	
OTHER - UNSPECIFIED	5	5	

End points

End points reporting groups

Reporting group title	HZ/su Group

Reporting group description:

Participants with renal transplant who completed the 2-dose Herpes Zoster (HZ/su) vaccination course in the primary ZOSTER-041 (NCT02058589) study were enrolled in the current ZOSTER-073 (NCT04176939) study.
47 of these participants further received 1 or 2 additional doses of HZ/su vaccine in the revaccination phase of the current ZOSTER-073 (NCT04176939) study, first dose at Month 24 and second dose at Month 25.

Primary: Anti-glycoprotein E (anti-gE) antibody concentrations, as assessed in the Long term follow-up (LTFU) phase of the current ZOSTER-073 study

End point title	Anti-glycoprotein E (anti-gE) antibody concentrations, as assessed in the Long term follow-up (LTFU) phase of the current ZOSTER-073 study[1]

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). Analysis was performed on the Per Protocol Set for analysis of persistence (LTFU phase), which included evaluable participants from the Enrolled Set with a complete vaccination course (2 doses of HZ/su vaccine) in the ZOSTER-041 study, who met the eligibility criteria and signed informed consent in the current study and for whom persistence immunogenicity results after primary vaccination course were available at the specified time points in the current study, regardless of revaccination status.

End point type	Primary

End point timeframe:

At Day 1, Month 12 and Month 24 (pre-revaccination) in the current ZOSTER-073 study

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
At Day 1 (N=56)	3729.8 (2736.2 to 5084.0)			
At Month 12 (N=60)	3440.2 (2499.0 to 4735.7)			
At Month 24 (N=49)	3075.8 (2091.8 to 4522.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Anti-gE antibody concentrations, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Anti-gE antibody concentrations, as assessed in the Revaccination active phase of the current ZOSTER-073 study[2]

End point description:

Anti-gE antibody concentrations were determined by ELISA and expressed as GMCs in mIU/mL. Analysis was performed on the Per Protocol Set for Immunogenicity after revaccination course (Revaccination active phase), which included evaluable participants who were administered 1 or 2 doses of revaccination as per the revaccination schedule and who had immunogenicity data available for the specified analysis at the specified time points in the current study.

End point type	Primary

End point timeframe:

At Month 24 (pre-revaccination), Month 25 (1 month post-revaccination Dose 1) and Month 26 (1 month post-revaccination Dose 2) in the current ZOSTER-073 study

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	45			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
At Month 24 (N=45)	2828.5 (1886.6 to 4240.5)			
At Month 25 (N=44)	27655.5 (17882.7 to 42769.1)			
At Month 26 (N=44)	31517.0 (21581.1 to 46027.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of gE-specific Cluster of Differentiation 4 (CD4) (2+) T-cells, as assessed in the LTFU phase of the current ZOSTER-073 study

End point title	Frequency of gE-specific Cluster of Differentiation 4 (CD4) (2+) T-cells, as assessed in the LTFU phase of the current ZOSTER-073 study

End point description:

Frequency of gE-specific CD4 (2+) T-cells expressing two or more activation markers (from among interferon gamma [IFN-γ], interleukin-2 [IL-2], tumour necrosis factor alpha [TNF-α] and CD40 Ligand [CD40L]) was determined by intracellular cytokine staining (ICS) as measured by cytokine flow cytometry (CFC) and expressed in CD4(2+) T-cells per million cells [CD4(2+) T-cells/million cells]. Analysis was performed on a sub-cohort of participants from the Per Protocol Set for analysis of persistence (LTFU phase), for whom an additional blood sample for cell-mediated immunity (CMI) analysis was collected and who had CMI results available for the specified analysis at the specified time points in the current study.

End point type	Secondary

End point timeframe:

At Day 1, Month 12 and Month 24 (pre-revaccination) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: CD4(2+) T-cells/million cells				
median (inter-quartile range (Q1-Q3))				
At Day 1 (N=28)	608.9 (167.2 to 993.6)			
At Month 12 (N=18)	299.4 (105.3 to 1068.4)			
At Month 24 (N=19)	711.0 (309.9 to 1211.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with serious adverse events (SAEs) related to primary vaccination in ZOSTER-041 study, as assessed in the LTFU phase of the current ZOSTER-073 study

End point title	Number of participants with serious adverse events (SAEs) related to primary vaccination in ZOSTER-041 study, as assessed in the LTFU phase of the current ZOSTER-073 study

End point description:

SAEs assessed included any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization or resulted in disability/incapacity or was a congenital anomaly/birth defect in the offspring of a study participant. SAEs related to primary vaccination in ZOSTER-041 study were assessed by the investigator.
Analysis was performed on the Enrolled Set, which included all participants with a complete vaccination course (2 doses of HZ/su vaccine) in ZOSTER-041 study who met the eligibility criteria and signed informed consent in the current study.

End point type	Secondary

End point timeframe:

From Month 13 (last visit) in ZOSTER-041 study until Month 24 in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with suspected or confirmed Herpes Zoster (HZ) cases, as assessed in the LTFU phase of the current ZOSTER-073 study

End point title	Number of participants with suspected or confirmed Herpes Zoster (HZ) cases, as assessed in the LTFU phase of the current ZOSTER-073 study

End point description:

A suspected HZ case was defined as a new unilateral rash accompanied by pain (broadly defined to include allodynia, pruritus or other sensations) without alternative diagnosis.
A confirmed HZ case was diagnosed by an algorithm that included Polymerase Chain Reaction (PCR) and the HZ Ascertainment Committee (HZAC) determination.
Analysis was performed on the Enrolled Set, which included all participants with a complete vaccination course (2 doses of HZ/su vaccine) in ZOSTER-041 study who met the eligibility criteria and signed informed consent in the current study.

End point type	Secondary

End point timeframe:

From Month 13 (last visit) in ZOSTER-041 study until Day 1 (first visit) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Participants				
Confirmed HZ case (N=68)	0			
Suspected HZ case (N=68)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with confirmed HZ cases, as assessed in the LTFU phase of the current ZOSTER-073 study

End point title	Number of participants with confirmed HZ cases, as assessed in the LTFU phase of the current ZOSTER-073 study

End point description:

A confirmed HZ case was diagnosed by an algorithm that included Polymerase Chain Reaction (PCR) and the HZ Ascertainment Committee (HZAC) determination.
Analysis was performed on the Enrolled Set, which included all participants with a complete vaccination course (2 doses of HZ/su vaccine) in ZOSTER-041 primary study who met the eligibility criteria and signed informed consent in the current study.

End point type	Secondary

End point timeframe:

From Day 1 until Month 24 in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Participants	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with suspected or biopsy-proven allograft rejections, as assessed in the LTFU phase of the current ZOSTER-073 study

End point title	Number of participants with suspected or biopsy-proven allograft rejections, as assessed in the LTFU phase of the current ZOSTER-073 study

End point description:

The number of participants with biopsy for clinical indication (suspected) or surveillance protocol that was not biopsy-proven rejection and with biopsy-proven allograft rejections are reported. Biopsy-proven allograft rejections are defined as adverse events of specific interest (AESIs).
Analysis was performed on the Enrolled Set, which included all participants with a complete vaccination course (2 doses of HZ/su vaccine) in ZOSTER-041 study who met the eligibility criteria and signed informed consent in the current study.

End point type	Secondary

End point timeframe:

From Month 13 (last visit) in ZOSTER-041 study until Day 1 (first visit) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Participants				
Biopsy-proven allograft rejection (N=68)	0			
Biopsy for clinical indication/surveillance (N=68)	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with biopsy-proven allograft rejections, as assessed in the LTFU phase of the current ZOSTER-073 study

End point title	Number of participants with biopsy-proven allograft rejections, as assessed in the LTFU phase of the current ZOSTER-073 study

End point description:

Biopsy-proven allograft rejection is defined as an adverse event of specific interest (AESI).
Analysis was performed on the Enrolled Set, which included all participants with a complete vaccination course (2 doses of HZ/su vaccine) in ZOSTER-041 study who met the eligibility criteria and signed informed consent in the current study.

End point type	Secondary

End point timeframe:

From Day 1 until Month 24 in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Participants	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with allograft dysfunction related to allograft rejection episodes, as assessed in the LTFU phase of the current ZOSTER-073 study

End point title	Number of participants with allograft dysfunction related to allograft rejection episodes, as assessed in the LTFU phase of the current ZOSTER-073 study

End point description:

Declining allograft function (allograft dysfunction) was assessed through all clinically obtained serum creatinine values from 2 months prior to an episode of biopsy-proven rejection and up to 2 months after rejection resolution and cessation of therapeutic immunosuppressive therapy. Allograft dysfunction is defined as having a fold increase in serum creatinine of 1.2 greater from the reference timepoint (2 months prior to an episode of biopsy-proven rejection).
Analysis was performed on the Enrolled Set, which included all participants with a complete vaccination course (2 doses of HZ/su vaccine) in ZOSTER-041 primary study who met the eligibility criteria and signed informed consent in the current study.

End point type	Secondary

End point timeframe:

From Month 13 (last visit) in ZOSTER-041 study until Month 24 in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with allograft dysfunction related to HZ episodes, as assessed in the LTFU phase of the current ZOSTER-073 study

End point title	Number of participants with allograft dysfunction related to HZ

	episodes, as assessed in the LTFU phase of the current ZOSTER-073 study

End point description:

Declining allograft function was assessed through all clinically obtained serum creatinine values from 2 months prior to an episode of HZ and up to 2 months after HZ rash resolution. Allograft dysfunction is defined as having a fold increase in serum creatinine of 1.2 greater from the reference timepoint (2 months prior to an episode of HZ).
Analysis was performed on the Enrolled Set, which included all participants with a complete vaccination course (2 doses of HZ/su vaccine) in ZOSTER-041 study who met the eligibility criteria and signed informed consent in the current study.

End point type	Secondary

End point timeframe:

From Month 13 (last visit) in ZOSTER-041 study until Month 24 in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	68			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of gE-specific CD4(2+) T-cells, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Frequency of gE-specific CD4(2+) T-cells, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point description:

Frequency of gE-specific CD4 (2+) T-cells expressing two or more activation markers (from among IFN-γ, IL-2, TNF-α and CD40L) was determined by ICS as measured by CFC and expressed in CD4(2+) T-cells/million cells.
Analysis was performed on a sub-cohort of participants from the Per Protocol Set for Immunogenicity after revaccination course (Revaccination active phase), for whom an additional blood sample for CMI analysis was collected and who had CMI results available for the specified analysis at the specified time points in the current study.

End point type	Secondary

End point timeframe:

At Month 24 (pre-revaccination), Month 25 (1 month post-revaccination Dose 1) and Month 26 (1 month post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: CD4(2+) T-cells/million cells				
median (inter-quartile range (Q1-Q3))				
At Month 24 (N=23)	793.5 (309.9 to 1235.8)			

At Month 25 (N=20)	4476.2 (3136.7 to 7704.6)			
At Month 26 (N=18)	3747.3 (2758.1 to 8906.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-gE antibody concentrations, as assessed in the Revaccination follow-up phase of the current ZOSTER-073 study

End point title	Anti-gE antibody concentrations, as assessed in the Revaccination follow-up phase of the current ZOSTER-073 study

End point description:

Persistence of humoral immunity after the revaccination course was evaluated in terms of anti-gE antibody concentrations. Anti-gE antibody concentrations were determined by ELISA and expressed as GMCs in mIU/mL.
Analysis was performed on the Per Protocol Set for persistence after revaccination course (Revaccination follow-up phase), which included evaluable participants who received 2 doses of revaccination in the current ZOSTER-073 study and for whom immunogenicity persistence results after revaccination were available for the specified analysis at the specified time points in the current study.

End point type	Secondary

End point timeframe:

At Month 37 (12 months post-revaccination Dose 2) and Month 49 (24 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	44			
Units: mIU/mL				
geometric mean (confidence interval 95%)				
At Month 37 (N=44)	23989.4 (17539.6 to 32811.0)			
At Month 49 (N=36)	9985.8 (5917.8 to 16850.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of gE-specific CD4(2+) T-cells, as assessed in the Revaccination follow-up phase of the current ZOSTER-073 study

End point title	Frequency of gE-specific CD4(2+) T-cells, as assessed in the

	Revaccination follow-up phase of the current ZOSTER-073 study

End point description:

Frequency of gE-specific CD4 (2+) T-cells expressing two or more activation markers (from among IFN-γ, IL-2, TNF-α and CD40L) was determined by ICS as measured by CFC and expressed in CD4(2+) T-cells/million cells.
Analysis was performed on a sub-cohort of participants from the Per Protocol Set for persistence after revaccination course (Revaccination follow-up phase), for whom an additional blood sample for CMI analysis was collected and who had CMI results available for the specified analysis at the specified time points in the current study.

End point type	Secondary

End point timeframe:

At Month 37 (12 months post-revaccination Dose 2) and Month 49 (24 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: CD4(2+) T-cells/million cells				
median (inter-quartile range (Q1-Q3))				
At Month 37 (N=20)	1777.4 (1297.7 to 2505.4)			
At Month 49 (N=16)	1144.9 (818.1 to 2724.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any and Grade 3 solicited administration site events after each revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Number of participants with any and Grade 3 solicited administration site events after each revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point description:

Assessed solicited administration site events included erythema, pain and swelling at injection site. Any = occurrence of the event regardless of intensity grade. Any erythema/swelling at injection site = erythema/swelling at injection site with a diameter larger than (>) 20 millimeters (mm). Grade 3 pain = significant pain at rest, which prevented normal, everyday activities. Grade 3 erythema/swelling at injection site = erythema/swelling at injection site with a diameter >100 mm.
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and with the solicited administration site events diary card data available after the corresponding revaccination, for the specified duration.

End point type	Secondary

End point timeframe:

Within 7 days after each revaccination dose (administered at Month 24 [Dose 1] and at Month 25 [Dose 2]) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	45			
Units: Participants				
Any Erythema, after revacc. Dose 1 (N=45)	9			
Grade 3 Erythema, after revacc. Dose 1 (N=45)	0			
Any Erythema, after revacc. Dose 2 (N=45)	6			
Grade 3 Erythema, after revacc. Dose 2 (N=45)	0			
Any Pain, after revacc. Dose 1 (N=45)	37			
Grade 3 Pain, after revacc. Dose 1 (N=45)	7			
Any Pain, after revacc. Dose 2 (N=45)	31			
Grade 3 Pain, after revacc. Dose 2 (N=45)	2			
Any Swelling, after revacc. Dose 1 (N=45)	7			
Grade 3 Swelling, after revacc. Dose 1 (N=45)	0			
Any Swelling, after revacc. Dose 2 (N=45)	4			
Grade 3 Swelling, after revacc. Dose 2 (N=45)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration in days of solicited administration site events after each revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Duration in days of solicited administration site events after each revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point description:

Duration is the number of days in which a participant experienced the solicited administration site event within the 7-day solicited follow-up period. Assessed solicited administration site events included erythema, pain and swelling at injection site.
Analysis was performed on the Exposed Set for revaccination phase, which included participants with at least one HZ/su revaccination dose administered in the current study, with solicited diary data available after the corresponding revaccination, who experienced the specified solicited administration site event within 7 days following the respective revaccination dose and with the duration documented.

End point type	Secondary

End point timeframe:

Within 7 days after each revaccination dose (administered at Month 24 [Dose 1] and at Month 25 [Dose 2]) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: Days				
median (inter-quartile range (Q1-Q3))				
Erythema, after revacc. Dose 1 (N=9)	4.0 (1.0 to 5.0)			
Pain, after revacc. Dose 1 (N=37)	3.0 (2.0 to 4.0)			
Swelling, after revacc. Dose 1 (N=6)	3.0 (2.0 to 3.0)			
Erythema, after revacc. Dose 2 (N=6)	3.0 (2.0 to 3.0)			
Pain, after revacc. Dose 2 (N=31)	2.0 (2.0 to 3.0)			
Swelling, after revacc. Dose 2 (N=4)	2.5 (1.5 to 3.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any, Grade 3 and related solicited systemic events after each revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Number of participants with any, Grade 3 and related solicited systemic events after each revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point description:

Assessed solicited systemic events included fatigue, gastrointestinal symptoms (including nausea, vomiting, diarrhea and/or abdominal pain), headache, myalgia, shivering and fever (temperature >=38.0°C/100.4°F). Any AE = occurrence of the event regardless of intensity grade. Grade 3 fatigue, gastrointestinal symptoms, headache, myalgia, shivering = event that prevented normal, everyday activities. Grade 3 fever = temperature >39°C/102.2°F. Related fatigue, gastrointestinal symptoms, headache, myalgia, shivering, fever = event assessed by the investigator as related to the revaccination. The preferred route for measuring temperature in this study was oral.
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and with the solicited systemic events diary card data available after the corresponding revaccination, for the specified duration.

End point type	Secondary

End point timeframe:

Within 7 days after each revaccination dose (administered at Month 24 [Dose 1] and at Month 25 [Dose 2]) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Participants				
Any Fatigue, after revacc. Dose 1 (N=46)	26			
Grade 3 Fatigue, after revacc. Dose 1 (N=46)	2			

Related Fatigue, after revacc. Dose 1 (N=46)	22			
Any Fatigue, after revacc. Dose 2 (N=45)	23			
Grade 3 Fatigue, after revacc. Dose 2 (N=45)	2			
Related Fatigue, after revacc. Dose 2 (N=45)	21			
Any Gastrointest., after revacc. Dose 1 (N=46)	11			
Grade 3 Gastrointest., after revacc. Dose 1 (N=46)	0			
Related Gastrointest., after revacc. Dose 1 (N=46)	10			
Any Gastrointest., after revacc. Dose 2 (N=45)	10			
Grade 3 Gastrointest., after revacc. Dose 2 (N=45)	1			
Related Gastrointest., after revacc. Dose 2 (N=45)	9			
Any Headache, after revacc. Dose 1 (N=46)	22			
Grade 3 Headache, after revacc. Dose 1 (N=46)	3			
Related Headache, after revacc. Dose 1 (N=46)	19			
Any Headache, after revacc. Dose 2 (N=45)	16			
Grade 3 Headache, after revacc. Dose 2 (N=45)	0			
Related Headache, after revacc. Dose 2 (N=45)	16			
Any Myalgia, after revacc. Dose 1 (N=46)	21			
Grade 3 Myalgia, after revacc. Dose 1 (N=46)	1			
Related Myalgia, after revacc. Dose 1 (N=46)	17			
Any Myalgia, after revacc. Dose 2 (N=45)	19			
Grade 3 Myalgia, after revacc. Dose 2 (N=45)	1			
Related Myalgia, after revacc. Dose 2 (N=45)	16			
Any Shivering, after revacc. Dose 1 (N=46)	15			
Grade 3 Shivering, after revacc. Dose 1 (N=46)	3			
Related Shivering, after revacc. Dose 1 (N=46)	13			
Any Shivering, after revacc. Dose 2 (N=45)	10			
Grade 3 Shivering, after revacc. Dose 2 (N=45)	1			
Related Shivering, after revacc. Dose 2 (N=45)	9			
Any Fever, after revacc. Dose 1 (N=46)	4			
Grade 3 Fever, after revacc. Dose 1 (N=46)	1			
Related Fever, after revacc. Dose 1 (N=46)	4			
Any Fever, after revacc. Dose 2 (N=45)	4			

Grade 3 Fever, after revacc. Dose 2 (N=45)	1			
Related Fever, after revacc. Dose 2 (N=45)	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration in days of solicited systemic events after each revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Duration in days of solicited systemic events after each revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point description:

Duration is the number of days in which a participant experienced the solicited systemic event within the 7-day solicited follow-up period. Assessed solicited systemic events included fatigue, gastrointestinal symptoms (including nausea, vomiting, diarrhea and/or abdominal pain), headache, myalgia, shivering and fever.
Analysis was performed on the Exposed Set for revaccination phase, which included participants with at least one HZ/su revaccination dose administered in the current study, with solicited diary data available after the corresponding revaccination, who experienced the specified solicited systemic event within 7 days following the respective revaccination dose and with the duration documented.

End point type	Secondary

End point timeframe:

Within 7 days after each revaccination dose (administered at Month 24 [Dose 1] and at Month 25 [Dose 2]) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Days				
median (inter-quartile range (Q1-Q3))				
Fatigue, after revacc. Dose 1 (N=26)	3.0 (2.0 to 3.0)			
Gastrointest., after revacc. Dose 1 (N=11)	2.0 (1.0 to 2.0)			
Headache, after revacc. Dose 1 (N=22)	2.0 (1.0 to 3.0)			
Myalgia, after revacc. Dose 1 (N=21)	2.0 (2.0 to 4.0)			
Shivering, after revacc. Dose 1 (N=15)	1.0 (1.0 to 2.0)			
Fever, after revacc. Dose 1 (N=4)	1.5 (1.0 to 2.0)			
Fatigue, after revacc. Dose 2 (N=23)	2.0 (2.0 to 4.0)			
Gastrointest., after revacc. Dose 2 (N=10)	1.5 (1.0 to 2.0)			
Headache, after revacc. Dose 2 (N=16)	2.0 (1.0 to 3.0)			
Myalgia, after revacc. Dose 2 (N=19)	2.0 (1.0 to 4.0)			
Shivering, after revacc. Dose 2 (N=10)	2.0 (1.0 to 2.0)			
Fever, after revacc. Dose 2 (N=4)	1.0 (1.0 to 1.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any, Grade 3 and related unsolicited adverse events (AEs) post-revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Number of participants with any, Grade 3 and related unsolicited adverse events (AEs) post-revaccination, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point description:

An unsolicited AE was defined as any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms was reported as an unsolicited AE. Any = occurrence of the event regardless of intensity grade or relation to revaccination. Grade 3 = event that prevented normal, everyday activities. Related = event assessed by the investigator as related to revaccination.
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom unsolicited AEs data were available for the specified duration.

End point type	Secondary

End point timeframe:

Within 30 days (across revaccination doses) post-revaccination period in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Participants				
Any unsolicited AE(s) (N=47)	12			
Grade 3 unsolicited AE(s) (N=47)	3			
Related unsolicited AE(s) (N=47)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any serious adverse events (SAEs) and fatal SAEs, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Number of participants with any serious adverse events (SAEs) and fatal SAEs, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point description:

SAEs assessed included any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization or resulted in disability/incapacity or was a congenital anomaly/birth defect in the offspring of a study participant. Any = occurrence of the SAE regardless of intensity grade or relation to revaccination. Fatal = SAE resulting in the death of the participant.
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom SAEs data were available for the specified duration.

End point type	Secondary

End point timeframe:

From Month 24 (pre-revaccination) until Month 37 (12 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Participants				
Any SAE(s) (N=47)	9			
Fatal SAE(s) (N=47)	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with related SAEs and related-fatal SAEs, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point title	Number of participants with related SAEs and related-fatal SAEs, as assessed in the Revaccination active phase of the current ZOSTER-073 study

End point description:

SAEs assessed included any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization or resulted in disability/incapacity or was a congenital anomaly/birth defect in the offspring of a study participant. Related = SAE assessed by the investigator as related to revaccination. Related-fatal = SAE resulting in the death of the participant assessed by the investigator as related to revaccination.
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom SAEs data were available for the specified duration.

End point type	Secondary

End point timeframe:

From Month 24 (pre-revaccination) until Month 49 (24 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Participants				
Related SAE(s) (N=47)	0			
Related-fatal SAE(s) (N=47)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any and related biopsy-proven allograft rejections, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point title	Number of participants with any and related biopsy-proven allograft rejections, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point description:

Biopsy-proven allograft rejection is defined as an adverse event of special interest (AESI) and is recorded in serious adverse event (SAE) screens, irrespective of the seriousness of the event. Related biopsy proven allograft rejections = biopsy-proven allograft rejections assessed by the investigator as related to revaccination.
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom biopsy-proven allograft rejections data were available for the specified duration.

End point type	Secondary

End point timeframe:

From Month 24 (pre-revaccination) until Month 49 (24 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Participants				
Any biopsy-proven allograft rejection (N=47)	1			
Related biopsy-proven allograft rejection (N=47)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any and related potential immune-mediated diseases (pIMDs), as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point title	Number of participants with any and related potential immune-mediated diseases (pIMDs), as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

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 etiology. Any = occurrence of the pIMD regardless of intensity grade or relation to revaccination. Related = pIMDs assessed by the investigator as related to revaccination.
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom pIMDs data were available for the specified duration.

End point type	Secondary

End point timeframe:

From Month 24 (pre-revaccination) until Month 37 (12 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Participants				
Any pIMD(s) (N=47) Related pIMD(s) (N=47)	1 0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with confirmed HZ cases, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point title	Number of participants with confirmed HZ cases, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point description:

A confirmed HZ case was diagnosed by an algorithm that included Polymerase Chain Reaction (PCR) and the HZ Ascertainment Committee (HZAC) determination.
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom HZ cases data were available for the specified duration.

End point type	Secondary

End point timeframe:

From Month 24 (pre-revaccination) until Month 49 (24 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with allograft dysfunction related to allograft rejection, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point title	Number of participants with allograft dysfunction related to allograft rejection, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point description:

Declining allograft function was assessed through all clinically obtained serum creatinine values from 2 months prior to an episode of biopsy-proven rejection and up to 2 months after rejection resolution and cessation of therapeutic immunosuppressive therapy. Allograft dysfunction is defined as having a fold increase in serum creatinine of 1.2 greater from the reference timepoint (2 months prior to an episode of biopsy-proven rejection).
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom allograft dysfunction related to allograft rejection data were available for the specified duration.

End point type	Secondary

End point timeframe:

From Month 24 (pre-revaccination) until Month 49 (24 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with allograft dysfunction following revaccination, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point title	Number of participants with allograft dysfunction following revaccination, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point description:

Declining allograft function was assessed through all clinically obtained serum creatinine values from 3 months before the first revaccination dose until 3 months after the last revaccination dose. Allograft dysfunction is defined as having a fold increase in serum creatinine of 1.2 greater from the reference timepoint (3 months prior to revaccination).
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom allograft dysfunction following revaccination data were available for the specified duration.

End point type	Secondary

End point timeframe:

From Month 24 (pre-revaccination) until Month 37 (12 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Participants	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with allograft dysfunction related to HZ episodes, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point title	Number of participants with allograft dysfunction related to HZ episodes, as assessed in the Revaccination active and follow-up phases of the current ZOSTER-073 study

End point description:

Declining allograft function was assessed through all clinically obtained serum creatinine values from 2 months prior to an episode of HZ and up to 2 months after HZ resolution. Allograft dysfunction is defined as having a fold increase in serum creatinine of 1.2 greater from the reference timepoint (2 months prior to an episode of HZ).
Analysis was performed on the Exposed Set for revaccination phase, which included all participants with at least one HZ/su revaccination dose administered in the current study and for whom allograft dysfunction related to HZ episodes data were available for the specified duration.

End point type	Secondary

End point timeframe:

From Month 24 (pre-revaccination) until Month 49 (24 months post-revaccination Dose 2) in the current ZOSTER-073 study

End point values	HZ/su Group			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: Participants	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, after any revaccination; SAEs & pIMDs: from Month 24 until Month 37; Deaths, Related SAEs and biopsy-proven allograft rejections: from Day 1 until Month 49, in the current ZOSTER-073 study.

Adverse event reporting additional description:

As pre-specified in Protocol, deaths and events presented in the SAEs module were assessed in both non-revaccinated and revaccinated participants from the Enrolled Set. In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	HZ/su Group

Reporting group description:

Participants with renal transplant who completed the 2-dose Herpes Zoster (HZ/su) vaccination course in the primary ZOSTER-041 (NCT02058589) study were enrolled in the current ZOSTER-073 (NCT04176939) study. 47 of these participants further received 1 or 2 additional doses of HZ/su vaccine in the revaccination phase of the current ZOSTER-073 (NCT04176939) study, first dose at Month 24 and second dose at Month 25.

Serious adverse events	HZ/su Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 68 (33.82%)		
number of deaths (all causes)	7		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Liposarcoma			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin squamous cell carcinoma metastatic			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Renal neoplasm			

subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung carcinoma cell type unspecified recurrent				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Clear cell renal cell carcinoma				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Meniscus injury				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haemorrhage				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiac disorders				
Cardiac failure				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Nervous system disorders				
Cerebral haemorrhage				

subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Syncope				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intracranial pressure increased				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	2 / 68 (2.94%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Kidney transplant rejection				
subjects affected / exposed	3 / 68 (4.41%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Diarrhoea				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Respiratory distress				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Bronchiectasis				

subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Disorientation			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 68 (2.94%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Klebsiella urinary tract infection			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	6 / 68 (8.82%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	1 / 68 (1.47%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

COVID-19 pneumonia				
subjects affected / exposed	2 / 68 (2.94%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Cytomegalovirus infection				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes Zoster				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	2 / 68 (2.94%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Staphylococcal bacteriaemia				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Cachexia				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	HZ/su Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 68 (63.24%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed[1]	1 / 47 (2.13%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed[2]	27 / 47 (57.45%)		
occurrences (all)	39		
General disorders and administration site conditions			
Chills			
subjects affected / exposed[3]	19 / 47 (40.43%)		
occurrences (all)	25		
Fatigue			
subjects affected / exposed[4]	31 / 47 (65.96%)		
occurrences (all)	50		
Administration site pain			
subjects affected / exposed[5]	40 / 47 (85.11%)		
occurrences (all)	68		
Administration site swelling			
subjects affected / exposed[6]	16 / 47 (34.04%)		
occurrences (all)	25		
Administration site erythema			
subjects affected / exposed[7]	14 / 47 (29.79%)		
occurrences (all)	22		
Pyrexia			
subjects affected / exposed[8]	6 / 47 (12.77%)		
occurrences (all)	9		
Peripheral swelling			
subjects affected / exposed[9]	1 / 47 (2.13%)		
occurrences (all)	1		
Injection site pruritus			

subjects affected / exposed[10]	1 / 47 (2.13%)		
occurrences (all)	1		
Eye disorders			
Blindness			
subjects affected / exposed[11]	1 / 47 (2.13%)		
occurrences (all)	1		
Visual impairment			
subjects affected / exposed[12]	1 / 47 (2.13%)		
occurrences (all)	1		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed[13]	1 / 47 (2.13%)		
occurrences (all)	1		
Gastrointestinal disorder			
subjects affected / exposed[14]	16 / 47 (34.04%)		
occurrences (all)	21		
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed[15]	1 / 47 (2.13%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed[16]	26 / 47 (55.32%)		
occurrences (all)	41		
Infections and infestations			
COVID-19			
subjects affected / exposed[17]	3 / 47 (6.38%)		
occurrences (all)	3		
Onychomycosis			
subjects affected / exposed[18]	1 / 47 (2.13%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed[19]	1 / 47 (2.13%)		
occurrences (all)	1		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.
[19] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: In this study, only revaccinated participants from the Exposed Set had their events in the Non-SAEs module assessed, and non-SAEs were not assessed in non-revaccinated participants.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 June 2020	The purpose of the amendment was to: • Outline measures to be applied during special circumstances (e.g., COVID-19 pandemic), to protect participant's welfare and safety, and, as far as possible, to ensure the potential benefit to the participant and promote study integrity. • Define study procedures/assessments to allow participation of non-revaccinated participants in an extended long-term follow-up phase.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
18 March 2020	The trial was put on temporary global enrollment hold due to COVID-19 restrictions. Delayed enrollees were enrolled at Visit 2 and hence missed their Visit 1 blood draw.	07 October 2020

Notes:

Limitations and caveats

None reported