Clinical trial results:
A Phase 3 Open-Label Clinical Trial to Study the Immunogenicity, Safety and Tolerability of Recombinant Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine (V501) in Chinese Girls Aged 9-19 Years and Young Women Aged 20-26 Years

Summary

EudraCT number	2023-001144-29
Trial protocol	Outside EU/EEA
Global end of trial date	07 March 2024

Results information

Result version number	v2 (current)
This version publication date	26 March 2025
First version publication date	20 September 2024
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	V501-213

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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?	
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 October 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 October 2023
Global end of trial reached?	Yes
Global end of trial date	07 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

A Study to Evaluate the Immunogenicity, Safety and Tolerability of Quadrivalent Human Papillomavirus Vaccine (V501) in Chinese Girls Aged 9-19 Years and Young Women Aged 20-26 This study is designed to evaluate the immunogenicity, safety, and tolerability of Gardasil® (quadrivalent human papillomavirus [qHPV] vaccine, V501) in Chinese girls aged 9-19 years and young women aged 20-26 years. The study consisted of Base and Extension Stage. The primary hypothesis of the study states that at 1 month postdose 3, a 3-dose regimen of V501 induces non-inferior geometric mean titers (GMTs) for serum anti-HPV 6, anti-HPV 11, anti-HPV 16, anti-HPV 18 in girls aged 9-19 years compared to young women aged 20-26 years. After Base Stage, girls aged 9-19 years old entered Extension Stage to evaluate persistence of immune responses for up to 60 months postvacciantion 1.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 August 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	60 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	China: 766
Worldwide total number of subjects	766
EEA total number of subjects	0

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)	102
Adolescents (12-17 years)	187
Adults (18-64 years)	477
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Chinese girls aged 9 to19 years and young women aged 20 to 26 years were enrolled

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Chinese Girls Aged 9 to 19 Years

Arm description:

Participants received V501 0.5 mL intramuscular injection at Day 1, Month 2, and Month 6

Arm type	Experimental
Investigational medicinal product name	V501
Investigational medicinal product code	
Other name	(Gardasil®) human papillomavirus (types 6, 11, 16, 18) recombinant vaccine qHPV
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection in the deltoid muscle at Day 1, Month 2, and Month 6

Arm title	Chinese Young Women Aged 20 to 26 Years

Arm description:

Participants received V501 0.5 mL intramuscular injection at Day 1, Month 2, and Month 6

Arm type	Active comparator
Investigational medicinal product name	V501
Investigational medicinal product code	
Other name	(Gardasil®) human papillomavirus (types 6, 11, 16, 18) recombinant vaccine qHPV
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection in the deltoid muscle at Day 1, Month 2, and Month 6

Number of subjects in period 1	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years
Started	383	383
Vaccination 1	383	383
Vaccination 2	379 [1]	378 [2]
Vaccination 3	378 [3]	377 [4]

Completed	383	379
Not completed	0	4
Consent withdrawn by subject	-	4

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: The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected the number of subjects will be greater than, or equal to the number that completed minus those that left.
[2] - 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: Some participants missed Vaccination visits 2 (month 2) and 3 (month 3) but returned to Month 60 visit.
[3] - 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: Some participants missed Vaccination visits 2 (month 2) and 3 (month 3) but returned to Month 60 visit.
[4] - 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: Some participants missed Vaccination visits 2 (month 2) and 3 (month 3) but returned to Month 60 visit.

Period 2

Period 2 title	Extension Study
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Extension Study: Chinese Girls Aged 9 to 19 Years

Arm description:

In base study, participants received V501 0.5 mL intramuscular injection at Day 1, Month 2, and Month 6 and followed up to Month 7. In the extension studies after Month 7, the participants were followed up for safety and immunogenicity up to Month 60 (EXT).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2[5]	Extension Study: Chinese Girls Aged 9 to 19 Years
Started	365
Completed	338
Not completed	27
Consent withdrawal by parent/guardian	2
Consent withdrawn by subject	25

Notes:

[5] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Per protocol, the subject disposition for this extension study included only 1 treatment arm: Chinese Girls Aged 9 to 19 Years.

Baseline characteristics

Reporting groups	
Reporting group title	Chinese Girls Aged 9 to 19 Years
Reporting group description:	
Participants received V501 0.5 mL intramuscular injection at Day 1, Month 2, and Month 6	
Reporting group title	Chinese Young Women Aged 20 to 26 Years
Reporting group description:	
Participants received V501 0.5 mL intramuscular injection at Day 1, Month 2, and Month 6	

Reporting group values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years	Total
Number of subjects	383	383	766
Age categorical Units: Subjects			
Chinese Girls Aged 9 to 19 years	383	0	383
Chinese Young Women Aged 20 to 26 Years	0	383	383
Age Continuous Units: years			
arithmetic mean	14.3	23.4	
standard deviation	± 3.3	± 1.8	-
Sex: Female, Male Units:			
Female	383	383	766
Male	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	383	383	766
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	383	383	766
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Chinese Girls Aged 9 to 19 Years
Reporting group description:	
Participants received V501 0.5 mL intramuscular injection at Day 1, Month 2, and Month 6	
Reporting group title	Chinese Young Women Aged 20 to 26 Years
Reporting group description:	
Participants received V501 0.5 mL intramuscular injection at Day 1, Month 2, and Month 6	
Reporting group title	Extension Study: Chinese Girls Aged 9 to 19 Years
Reporting group description:	
In base study, participants received V501 0.5 mL intramuscular injection at Day 1, Month 2, and Month 6 and followed up to Month 7. In the extension studies after Month 7, the participants were followed up for safety and immunogenicity up to Month 60 (EXT).	

Primary: Base Stage: Geometric Mean Titers (GMTs) for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 Assessed by Competitive Luminex Immunoassay (cLIA)

End point title	Base Stage: Geometric Mean Titers (GMTs) for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 Assessed by Competitive Luminex Immunoassay (cLIA)
End point description:	
Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using a Competitive Luminex Immunoassay (cLIA). Antibody titers were expressed as milli Merck Units/milliliter (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years and Chinese young women aged 20 to 26 years (base study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.	
End point type	Primary
End point timeframe:	
Month 7 (1 month postdose 3)	

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n= 343; 315)	975.2 (905.6 to 1050.2)	686.6 (635.5 to 741.7)		
Anti-HPV 11 (n= 343; 315)	807.4 (749.8 to 869.4)	580.2 (537.0 to 626.8)		
Anti-HPV 16 (n=354; 330)	4573.7 (4244.5 to 4928.3)	2989.2 (2766.7 to 3229.6)		

Anti-HPV 18 (n=333; 318)	1176.5 (1069.0 to 1294.8)	708.6 (642.4 to 781.6)		

Statistical analyses

Statistical analysis title	GMT Ratio for HPV 6
Statistical analysis description:	
Anti-HPV 6	
Comparison groups	Chinese Girls Aged 9 to 19 Years v Chinese Young Women Aged 20 to 26 Years
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANOVA
Parameter estimate	GMT Ratio
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.28
upper limit	1.58

Statistical analysis title	GMT Ratio for HPV 11
Statistical analysis description:	
Anti-HPV 11	
Comparison groups	Chinese Girls Aged 9 to 19 Years v Chinese Young Women Aged 20 to 26 Years
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANOVA
Parameter estimate	GMT Ratio
Point estimate	1.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	1.55

Statistical analysis title	GMT Ratio for HPV 16
Statistical analysis description:	
Anti-HPV 16	

Comparison groups	Chinese Girls Aged 9 to 19 Years v Chinese Young Women Aged 20 to 26 Years
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANOVA
Parameter estimate	GMT Ratio
Point estimate	1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.37
upper limit	1.7

Statistical analysis title	GMT Ratio for HPV 18
Statistical analysis description:	
Anti-HPV 18	
Comparison groups	Chinese Girls Aged 9 to 19 Years v Chinese Young Women Aged 20 to 26 Years
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANOVA
Parameter estimate	GMT Ratio
Point estimate	1.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.45
upper limit	1.9

Primary: Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 24 Assessed by cLIA

End point title	Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 24 Assessed by cLIA[1]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using a Competitive Luminex Immunoassay (cLIA). Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 24 post-vaccination 1

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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=322)	137.9 (125.5 to 151.4)			
Anti-HPV 11 (n=322)	110.3 (101.0 to 120.6)			
Anti-HPV 16 (n=333)	522.6 (472.1 to 578.5)			
Anti-HPV 18 (n=316)	157.2 (142.7 to 173.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 12 Assessed by cLIA

End point title	Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 12 Assessed by cLIA[2]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using a Competitive Luminex Immunoassay (cLIA). Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 12 post-vaccination 1

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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval				

95%)				
Anti-HPV 6 (n=328)	259.1 (237.6 to 282.4)			
Anti-HPV 11 (n=328)	206.7 (190.5 to 224.3)			
Anti-HPV 16 (n=338)	1149.8 (1054.6 to 1253.7)			
Anti-HPV 18 (n=320)	284.2 (257.3 to 313.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 48 Assessed by cLIA

End point title	Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 48 Assessed by cLIA[3]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using a Competitive Luminex Immunoassay (cLIA). Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 48 post-vaccination 1

Notes:

[3] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=311)	103.0 (94.4 to 112.4)			
Anti-HPV 11 (n=311)	81.8 (74.8 to 89.3)			
Anti-HPV 16 (n=321)	347.5 (310.0 to 389.6)			
Anti-HPV 18 (n=305)	130.3 (118.9 to 142.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 36 Assessed by cLIA

End point title	Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 36 Assessed by cLIA[4]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using a Competitive Luminex Immunoassay (cLIA). Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 36 post-vaccination 1

Notes:

[4] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=318)	110.6 (101.3 to 120.7)			
Anti-HPV 11 (n=318)	87.0 (79.6 to 95.2)			
Anti-HPV 16 (n=329)	400.8 (359.5 to 446.8)			
Anti-HPV 18 (n=312)	131.9 (120.2 to 144.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV

Types 6, 11, 16, and 18 at Month 12 Assessed by cLIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 12 Assessed by cLIA[5]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using cLIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 12 post-vaccination 1

Notes:

[5] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=328)	99.1 (97.4 to 99.8)			
Anti-HPV 11 (n=328)	99.7 (98.3 to 100.0)			
Anti-HPV 16 (n=338)	100.0 (98.9 to 100.0)			
Anti-HPV 18 (n=320)	96.9 (94.3 to 98.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 60 Assessed by cLIA

End point title	Extension Stage: GMTs for Serum Anti-Human Papillomavirus (HPV) Types 6, 11, 16, and 18 at Month 60 Assessed by cLIA[6]

End point description:

Serum antibody titers (Geometric mean titers) for HPV virus-like particles (VLPs) Types 6, 11, 16, and 18 were measured. Antibodies were measured using a Competitive Luminex Immunoassay (cLIA). Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 60 post-vaccination 1

Notes:

[6] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=307)	87.6 (80.4 to 95.4)			
Anti-HPV 11 (n=307)	67.3 (61.6 to 73.5)			
Anti-HPV 16 (n=317)	283.2 (250.8 to 319.8)			
Anti-HPV 18 (n=302)	113.6 (103.7 to 124.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 24 Assessed by cLIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 24 Assessed by cLIA[7]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using cLIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 24 post-vaccination 1

Notes:

[7] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=322)	88.8 (84.9 to 92.0)			
Anti-HPV 11 (n=322)	95.3 (92.4 to 97.4)			
Anti-HPV 16 (n=333)	99.7 (98.3 to 100.0)			
Anti-HPV 18 (n=316)	87.7 (83.5 to 91.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 48 Assessed by cLIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 48 Assessed by cLIA[8]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using cLIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 48 post-vaccination 1

Notes:

[8] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=311)	68.5 (63.0 to 73.6)			
Anti-HPV 11 (n=311)	85.2 (80.8 to 89.0)			
Anti-HPV 16 (n=321)	91.9 (88.4 to 94.6)			

Anti-HPV 18 (n=305)	64.6 (58.9 to 70.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 36 Assessed by cLIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 36 Assessed by cLIA[9]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using cLIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 36 post-vaccination 1

Notes:

[9] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=318)	83.6 (79.1 to 87.5)			
Anti-HPV 11 (n=318)	92.1 (88.6 to 94.8)			
Anti-HPV 16 (n=329)	98.8 (96.9 to 99.7)			
Anti-HPV 18 (n=312)	84.0 (79.4 to 87.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 12 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)

End point title	Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 12 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)[10]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using IgG LIA. Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 12 post-vaccination 1

Notes:

[10] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=328)	217.0 (198.1 to 237.6)			
Anti-HPV 11 (n=328)	172.1 (158.3 to 187.1)			
Anti-HPV 16 (n=338)	1025.8 (945.5 to 1113.0)			
Anti-HPV 18 (n=320)	228.0 (204.4 to 254.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 60 Assessed by cLIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 60 Assessed by cLIA[11]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using cLIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 60 post-vaccination 1

Notes:

[11] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=307)	61.9 (56.2 to 67.3)			
Anti-HPV 11 (n=307)	74.9 (69.7 to 79.7)			
Anti-HPV 16 (n=317)	87.1 (82.9 to 90.6)			
Anti-HPV 18 (n=302)	58.3 (52.5 to 63.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 24 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)

End point title	Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 24 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)[12]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using IgG LIA. Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 24 post-vaccination 1

Notes:

[12] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=322)	85.5 (76.4 to 95.6)			
Anti-HPV 11 (n=322)	68.6 (61.6 to 76.4)			
Anti-HPV 16 (n=333)	394.9 (354.6 to 439.9)			
Anti-HPV 18 (n=316)	76.9 (67.0 to 88.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 36 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)

End point title	Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 36 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)[13]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using IgG LIA. Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 36 post-vaccination 1

Notes:

[13] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=318)	66.5 (59.6 to 74.1)			
Anti-HPV 11 (n=318)	52.7 (47.2 to 58.8)			

Anti-HPV 16 (n=329)	304.0 (272.2 to 339.5)			
Anti-HPV 18 (n=312)	57.5 (50.0 to 66.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 48 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)

End point title	Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 48 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)[14]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using IgG LIA. Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 48 post-vaccination 1

Notes:

[14] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=311)	63.4 (56.8 to 70.8)			
Anti-HPV 11 (n=311)	51.1 (45.9 to 56.9)			
Anti-HPV 16 (n=321)	289.6 (258.7 to 324.2)			
Anti-HPV 18 (n=305)	55.3 (47.8 to 63.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 60 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)

End point title	Extension Stage: GMTs for Serum Anti-HPV Types 6, 11, 16, and 18 at Month 60 Assessed by Immunoglobulin G Luminex Immunoassay (IgG LIA)[15]

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using IgG LIA. Antibody titers were expressed as (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 60 post-vaccination 1

Notes:

[15] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=307)	58.6 (52.5 to 65.4)			
Anti-HPV 11 (n=307)	47.2 (42.4 to 52.5)			
Anti-HPV 16 (n=317)	264.3 (235.8 to 296.3)			
Anti-HPV 18 (n=302)	51.0 (44.0 to 59.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 12 Assessed by IgG LIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 12 Assessed by IgG LIA[16]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using IgG LIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 12 post-vaccination 1

Notes:

[16] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=328)	100.0 (98.9 to 100.0)			
Anti-HPV 11 (n=328)	100.0 (98.9 to 100.0)			
Anti-HPV 16 (n=338)	100.0 (98.9 to 100.0)			
Anti-HPV 18 (n=320)	100.0 (98.9 to 100.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 24 Assessed by IgG LIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 24 Assessed by IgG LIA[17]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using IgG LIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 24 post-vaccination 1

Notes:

[17] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=322)	98.4 (96.4 to 99.5)			
Anti-HPV 11 (n=322)	98.4 (96.4 to 99.5)			
Anti-HPV 16 (n=333)	100.0 (98.9 to 100.0)			
Anti-HPV 18 (n=316)	98.1 (95.9 to 99.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 36 Assessed by IgG LIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 36 Assessed by IgG LIA[18]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using IgG LIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 36 post-vaccination 1

Notes:

[18] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=318)	98.1 (95.9 to 99.3)			
Anti-HPV 11 (n=318)	99.4 (97.7 to 99.9)			
Anti-HPV 16 (n=329)	100.0 (98.9 to 100.0)			

Anti-HPV 18 (n=312)	96.2 (93.4 to 98.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 48 Assessed by IgG LIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 48 Assessed by IgG LIA[19]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using IgG LIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 48 post-vaccination 1

Notes:

[19] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n =311)	97.4 (95.0 to 98.9)			
Anti-HPV 11 (n =311)	98.4 (96.3 to 99.5)			
Anti-HPV 16 (n =321)	100.0 (98.9 to 100.0)			
Anti-HPV 18 (n =305)	95.1 (92.0 to 97.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 60 Assessed by IgG LIA

End point title	Extension Stage: Percentage of Participants with Seropositivity to HPV Types 6, 11, 16, and 18 at Month 60 Assessed by IgG LIA[20]

End point description:

The percentage of participants who are seropositive to each of HPV Types 6, 11, 16, and 18 were assessed. Antibodies were measured using IgG LIA. Per protocol, the analysis population included Chinese girls aged 9 to 19 years (in extension study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Primary

End point timeframe:

Month 60 post-vaccination 1

Notes:

[20] - 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: No statistical analyses were planned for this outcome measure.

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (confidence interval 95%)				
Anti-HPV 6 (n=307)	96.7 (94.1 to 98.4)			
Anti-HPV 11 (n=307)	98.4 (96.2 to 99.5)			
Anti-HPV 16 (n=317)	100.0 (98.8 to 100.0)			
Anti-HPV 18 (n=302)	95.4 (92.3 to 97.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Base Stage: Percentage of Participants with Seroconversion for HPV Types 6, 11, 16, and 18: cLIA

End point title	Base Stage: Percentage of Participants with Seroconversion for HPV Types 6, 11, 16, and 18: cLIA

End point description:

Seroconversion is defined as changing serostatus from seronegative at Day 1 to seropositive at 1 month post dose 3. Antibodies were measured using a Competitive Luminex Immunoassay (cLIA). Antibody titers were expressed as milli Merck Units/milliliter (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years and Chinese young women aged 20 to 26 years (base study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Secondary

End point timeframe:

Month 7 (1 month postdose 3)

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: Percentage of Participants				
number (not applicable)				
Anti-HPV 6 (n=343; 315)	100.0	100.0		
Anti-HPV 11 (n=343; 315)	100.0	100.0		
Anti-HPV 16 (n=354; 330)	100.0	100.0		
Anti-HPV 18 (n=333; 318)	100.0	100.0		

Statistical analyses

Statistical analysis title	Difference of Seroconversion percentage HPV 6
Statistical analysis description: Anti-HPV 6	
Comparison groups	Chinese Girls Aged 9 to 19 Years v Chinese Young Women Aged 20 to 26 Years
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Miettinen & Nurminen method
Parameter estimate	Difference in percentages (%)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	1.2

Statistical analysis title	Difference of Seroconversion percentage HPV 16
Statistical analysis description: Anti-HPV 16	
Comparison groups	Chinese Girls Aged 9 to 19 Years v Chinese Young Women Aged 20 to 26 Years
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Miettinen & Nurminen method
Parameter estimate	Difference in %
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	1.2

Statistical analysis title	Difference of Seroconversion percentage HPV 18
Statistical analysis description: Anti-HPV 18	
Comparison groups	Chinese Girls Aged 9 to 19 Years v Chinese Young Women Aged 20 to 26 Years
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Miettinen & Nurminen method
Parameter estimate	Difference in %
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	1.2

Statistical analysis title	Difference of Seroconversion percentage HPV 11
Statistical analysis description: Anti-HPV 11	
Comparison groups	Chinese Girls Aged 9 to 19 Years v Chinese Young Women Aged 20 to 26 Years
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Miettinen & Nurminen method
Parameter estimate	Difference in %
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	1.2

Secondary: Base Stage: Percentage of Participants with Seroconversion for HPV Types 6, 11, 16, and 18: IgG LIA

End point title	Base Stage: Percentage of Participants with Seroconversion for

	HPV Types 6, 11, 16, and 18: IgG LIA

End point description:

Seroconversion is defined as changing serostatus from seronegative at Day 1 to seropositive at 1 month post dose 3. Antibodies were measured using a IgG LIA. Antibody titers were expressed as milli Merck Units/milliliter (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years and Chinese young women aged 20 to 26 years (base study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Secondary

End point timeframe:

Month 7 (1 month postdose 3)

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: Percentage of Participants				
number (not applicable)				
Anti-HPV 6 (n=343; 315)	100.0	100.0		
Anti-HPV 11 (n=343; 315)	100.0	100.0		
Anti-HPV 16 (n=354; 330)	100.0	100.0		
Anti-HPV 18 (n=333; 318)	100.0	100.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Base Stage: Geometric Mean Titers for Serum Anti-HPV Types 6, 11, 16, and 18: IgG LIA

End point title	Base Stage: Geometric Mean Titers for Serum Anti-HPV Types 6, 11, 16, and 18: IgG LIA

End point description:

Serum antibody titers (Geometric mean titers) for HPV Types 6, 11, 16, and 18 were measured. Antibodies were measured using a IgG LIA. Antibody titers were expressed as milli Merck Units/milliliter (mMU/mL). Per protocol, the analysis population included Chinese girls aged 9 to 19 years and Chinese young women aged 20 to 26 years (base study) with immune response to each of the 4 HPV types (6, 11, 16, and 18), who received 3 vaccinations and met following criteria: received all 3 vaccinations within acceptable day ranges, seronegative at Day 1 for HPV type(s), had a Day 1 through Month 7 serum sample collected within an acceptable day range, and had no protocol violation that potentially interfered with the evaluation of immune responses to the qHPV vaccine.

End point type	Secondary

End point timeframe:

Month 7 (1 month postdose 3)

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: mMU/mL				
geometric mean (confidence interval 95%)				
Anti-HPV 6 (n=343; 315)	902.7 (831.2 to 980.3)	604.5 (554.7 to 658.8)		
Anti-HPV 11 (n=343; 315)	756.2 (695.7 to 821.9)	518.7 (475.5 to 565.9)		
Anti-HPV 16 (n=354; 330)	4170.0 (3849.3 to 4517.4)	2659.3 (2447.8 to 2889.0)		
Anti-HPV 18 (n=333; 318)	1012.8 (918.7 to 1116.5)	612.0 (553.9 to 676.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Base Stage: Percentage of Participants With a Solicited Injection-site Adverse Event (AE)

End point title	Base Stage: Percentage of Participants With a Solicited Injection-site Adverse Event (AE)

End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Solicited injection-site AEs included injection-site redness, swelling, induration, pain, and pruritus. The analysis population concisted of participants who recieved at least one dose of study vaccination.

End point type	Secondary

End point timeframe:

Up to 15 days after any vaccination

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: Percentage of Participants				
number (not applicable)	36.6	40.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Base Stage: Percentage of Participants With a Solicited Systemic AE

End point title	Base Stage: Percentage of Participants With a Solicited Systemic AE

End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Solicited systemic AEs included hypersensitivity, headache, fatigue, vomiting, nausea, diarrhea, myalgia, pyrexia, and cough. The analysis population concisted of participants who recieved at least one dose of study vaccination.

End point type	Secondary

End point timeframe:

Up to 15 days after any vaccination

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: Percentage of Participants				
number (not applicable)	39.9	42.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Base Stage: Maximum Axillary Temperature: Merck Sharp & Dohme (MSD) Criteria

End point title	Base Stage: Maximum Axillary Temperature: Merck Sharp & Dohme (MSD) Criteria

End point description:

In the global studies, fever is defined as an oral temperature of ≥37.8°C or 100.0°F, which is equivalent to axillary temperature of ≥37.2°C, while the definition of fever is axillary temperature of ≥37.1°C in Chinese criteria. To be compliant to Chinese criteria, axillary temperatures of ≥37.1°C was considered as a fever in this study. Body temperature readings assessed orally were converted to the axillary equivalent. The percentage of participants with a maximum axillary or converted axillary temperature was summarized by temperature range. The analysis population concisted of participants who recieved at least one dose of study vaccination.

End point type	Secondary

End point timeframe:

Up to 5 days after any vaccination

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: Percentage of Participants				
number (not applicable)				
< 37.2 °C (99.0 °F)	87.2	84.9		

≥37.2 °C (99.0 °F) and < 38.3 °C (100.9 °F)	12.3	14.9		
≥ 38.3 °C (100.9 °F) and < 39.3 °C (102.7 °F)	0.3	0.3		
≥ 39.3 °C (102.7 °F) and < 40.3 °C (104.5 °F)	0.3	0.0		
≥ 40.3 °C (104.5 °F)	0.0	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Base Stage: Percentage of Participants With Any AE

End point title	Base Stage: Percentage of Participants With Any AE

End point description:

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. The analysis population concisted of participants who recieved at least one dose of study vaccination.

End point type	Secondary

End point timeframe:

Up to 31 days after any vaccination

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: Percentage of Participants				
number (not applicable)	61.6	68.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Base Stage: Percentage of Participants Who Have a Serious Adverse Event (SAE)

End point title	Base Stage: Percentage of Participants Who Have a Serious Adverse Event (SAE)

End point description:

An SAE is an AE that results in death, is life threatening, requires hospitalization or prolongs an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, according to medical or scientific judgment, may jeopardize the participant or requires medical or surgical intervention to prevent one of the other outcomes listed in the above definition. The analysis population concisted of participants who recieved at least one dose of study vaccination.

End point type	Secondary

End point timeframe:

Up to Month 7 (1 month postdose 3)

End point values	Chinese Girls Aged 9 to 19 Years	Chinese Young Women Aged 20 to 26 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	383	383		
Units: Percentage of Participants				
number (not applicable)	1.6	2.87		

Statistical analyses

No statistical analyses for this end point

Secondary: Extension Stage: Percentage of Participants Who Have a Serious Adverse Event

End point title	Extension Stage: Percentage of Participants Who Have a Serious Adverse Event

End point description:

The percentage of participants with an SAE were assessed. An SAE is an AE that results in death, is life threatening, requires hospitalization or prolongs an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, according to medical or scientific judgment, may jeopardize the participant or requires medical or surgical intervention to prevent one of the other outcomes listed in the above definition. The analysis population consisted of all participants who received at least 1 dose of study vaccination and had clinical follow-up for safety.

End point type	Secondary

End point timeframe:

Month 7 up to Month 60

End point values	Extension Study: Chinese Girls Aged 9 to 19 Years			
Subject group type	Reporting group			
Number of subjects analysed	365			
Units: Percentage of Participants				
number (not applicable)	2.2			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Base Stage only: Up to approximately 7 months
Extension Stage: Month 7 up to approximately 60 Months

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Chinese Girls Aged 9 to 19 Years (Base Study)
Reporting group description: -	
Reporting group title	Chinese Girls Aged 9 to 19 Years (Extension Study)
Reporting group description: -	
Reporting group title	Chinese Young Women Aged 20 to 26 Years (Base Study)
Reporting group description: -	

Serious adverse events	Chinese Girls Aged 9 to 19 Years (Base Study)	Chinese Girls Aged 9 to 19 Years (Extension Study)	Chinese Young Women Aged 20 to 26 Years (Base Study)
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 383 (1.57%)	8 / 365 (2.19%)	11 / 383 (2.87%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian germ cell teratoma benign			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ependymoma			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (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			
Peroneal nerve injury			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rib fracture			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatic nerve injury			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 383 (0.26%)	0 / 365 (0.00%)	0 / 383 (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
Ankle fracture			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			

subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (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
Ulna fracture			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (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
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	1 / 383 (0.26%)	0 / 365 (0.00%)	0 / 383 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion missed			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Oligohydramnios			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperemesis gravidarum			
subjects affected / exposed	0 / 383 (0.00%)	2 / 365 (0.55%)	0 / 383 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion threatened			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (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
Foetal distress syndrome			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (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
Gastrointestinal disorders			
Haemorrhoids			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 365 (0.00%)	0 / 383 (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
Gastrointestinal disorder			
subjects affected / exposed	1 / 383 (0.26%)	0 / 365 (0.00%)	0 / 383 (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
Hypertrophic anal papilla			

subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic adhesions			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mammary duct ectasia			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrosalpinx			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval eczema			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (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
Renal and urinary disorders			
Calculus urethral			

subjects affected / exposed	1 / 383 (0.26%)	0 / 365 (0.00%)	0 / 383 (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
Psychiatric disorders			
Gastrointestinal somatic symptom disorder			
subjects affected / exposed	1 / 383 (0.26%)	0 / 365 (0.00%)	0 / 383 (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
Infections and infestations			
Helicobacter infection			
subjects affected / exposed	1 / 383 (0.26%)	0 / 365 (0.00%)	0 / 383 (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
Complicated appendicitis			
subjects affected / exposed	1 / 383 (0.26%)	0 / 365 (0.00%)	0 / 383 (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
Bacterial vulvovaginitis			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 383 (0.00%)	0 / 365 (0.00%)	1 / 383 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 383 (0.00%)	1 / 365 (0.27%)	0 / 383 (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

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Chinese Girls Aged 9 to 19 Years (Base Study)	Chinese Girls Aged 9 to 19 Years (Extension Study)	Chinese Young Women Aged 20 to 26 Years (Base Study)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	216 / 383 (56.40%)	0 / 365 (0.00%)	238 / 383 (62.14%)
Nervous system disorders			
Headache			
subjects affected / exposed	32 / 383 (8.36%)	0 / 365 (0.00%)	42 / 383 (10.97%)
occurrences (all)	47	0	51
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	122 / 383 (31.85%)	0 / 365 (0.00%)	152 / 383 (39.69%)
occurrences (all)	189	0	233
Injection site pruritus			
subjects affected / exposed	32 / 383 (8.36%)	0 / 365 (0.00%)	16 / 383 (4.18%)
occurrences (all)	33	0	20
Pyrexia			
subjects affected / exposed	104 / 383 (27.15%)	0 / 365 (0.00%)	108 / 383 (28.20%)
occurrences (all)	196	0	194
Fatigue			
subjects affected / exposed	41 / 383 (10.70%)	0 / 365 (0.00%)	42 / 383 (10.97%)
occurrences (all)	59	0	57
Injection site swelling			
subjects affected / exposed	22 / 383 (5.74%)	0 / 365 (0.00%)	11 / 383 (2.87%)
occurrences (all)	25	0	14
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	15 / 383 (3.92%)	0 / 365 (0.00%)	31 / 383 (8.09%)
occurrences (all)	18	0	33
Respiratory, thoracic and mediastinal disorders			

Oropharyngeal pain			
subjects affected / exposed	16 / 383 (4.18%)	0 / 365 (0.00%)	29 / 383 (7.57%)
occurrences (all)	16	0	30
Cough			
subjects affected / exposed	37 / 383 (9.66%)	0 / 365 (0.00%)	41 / 383 (10.70%)
occurrences (all)	40	0	47

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported