



Clinical trial results:

A Phase 3, Randomized, Placebo-Controlled, Observer-Blinded Trial to Evaluate the Safety of a 6-Valent OspA -Based Lyme Disease Vaccine (VLA15) in Healthy Children 5 Through 17 Years of Age

Summary

EudraCT number	2025-000441-15
Trial protocol	Outside EU/EEA
Global end of trial date	21 July 2025

Results information

Result version number	v1 (current)
This version publication date	01 March 2026
First version publication date	01 March 2026

Trial information

Trial identification

Sponsor protocol code	C4601012
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05634811
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	66 Hudson Boulevard East, New York, United States, NY 10001
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-003130-PIP02-23
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 December 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 July 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety profile of VLA15 as measured by the percentage of participants reporting local reactions, systemic events, adverse events (AEs), newly diagnosed chronic medical conditions (NDCMCs), and serious adverse event (SAEs).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 December 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 3533
Worldwide total number of subjects	3533
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)	1896
Adolescents (12-17 years)	1637
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 3646 participants were enrolled, of which 3547 participants were randomised (2653 to PF-07307405 [VLA15] and 894 to placebo) and 3533 were vaccinated (2645 to PF-07307405 [VLA15] and 888 to placebo).

Pre-assignment

Screening details:

This study was conducted across 57 sites across the United States of America (USA).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Double blind study

Arms

Are arms mutually exclusive?	Yes
Arm title	VLA15: 5 to 11 Years

Arm description:

Participants aged 5 to 11 years were randomised to receive VLA15, 180 micrograms (ug), 0.5 milliliter (mL) intramuscular (IM) injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.

Arm type	Experimental
Investigational medicinal product name	PF-07307405
Investigational medicinal product code	
Other name	VLA15
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received VLA15 0.5mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose at Month 18 if there was no protocol violation.

Arm title	Placebo: 5 to 11 Years
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Arm description:

Participants aged 5 to 11 years were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.

Arm type	Placebo
Investigational medicinal product name	Normal Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline 0.5mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose at Month 18 if there was no protocol violation.

Arm title	VLA15: 12 to 17 Years
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Arm description:

Participants aged 12 to 17 years were randomised to receive VLA15, 180 ug, 0.5 mL IM injection at

Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.

Arm type	Experimental
Investigational medicinal product name	PF-07307405
Investigational medicinal product code	
Other name	VLA15
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received VLA15 0.5mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose at Month 18 if there was no protocol violation.

Arm title	Placebo: 12 to 17 Years
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Arm description:

Participants aged 12 to 17 years were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.

Arm type	Placebo
Investigational medicinal product name	Normal Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline 0.5mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose at Month 18 if there was no protocol violation.

Number of subjects in period 1	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years
Started	1429	467	1219
Completed	1209	389	997
Not completed	220	78	222
Consent withdrawn by subject	45	12	49
Physician decision	9	3	5
Withdrawal by parent or guardian	50	18	42
No longer met eligibility criteria	3	-	7
Medication error without associated adverse event	2	-	-
Unspecified	5	1	3
Lost to follow-up	96	43	106
Adverse Event, Not serious	7	1	4
Adverse Event, Serious non-fatal	3	-	6

Number of subjects in period 1	Placebo: 12 to 17 Years
Started	418
Completed	350
Not completed	68
Consent withdrawn by subject	16
Physician decision	2

Withdrawal by parent or guardian	11
No longer met eligibility criteria	1
Medication error without associated adverse event	-
Unspecified	-
Lost to follow-up	34
Adverse Event, Not serious	2
Adverse Event, Serious non-fatal	2

Baseline characteristics

Reporting groups

Reporting group title	VLA15: 5 to 11 Years
Reporting group description:	
Participants aged 5 to 11 years were randomised to receive VLA15, 180 micrograms (ug), 0.5 milliliter (mL) intramuscular (IM) injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.	
Reporting group title	Placebo: 5 to 11 Years
Reporting group description:	
Participants aged 5 to 11 years were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.	
Reporting group title	VLA15: 12 to 17 Years
Reporting group description:	
Participants aged 12 to 17 years were randomised to receive VLA15, 180 ug, 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.	
Reporting group title	Placebo: 12 to 17 Years
Reporting group description:	
Participants aged 12 to 17 years were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.	

Reporting group values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years
Number of subjects	1429	467	1219
Age Categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	8.2	8.2	14.3
standard deviation	± 2.0	± 2.0	± 1.7
Gender categorical			
Units: Subjects			
Male	776	253	623
Female	653	214	596
Race			
Units: Subjects			
White	1081	342	947
Black or African American	262	99	208
American Indian or Alaska Native	2	2	5
Native Hawaiian or other Pacific Islander	2	0	2
Asian	32	12	27
Multiracial	37	8	20
Not reported	13	4	10
Ethnicity			
Units: Subjects			
Hispanic or Latino	240	75	268
Non-Hispanic or non-Latino	1181	391	944
Not reported	8	1	7

Reporting group values	Placebo: 12 to 17 Years	Total	
Number of subjects	418	3533	
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	14.3 ± 1.7	-	
Gender categorical Units: Subjects			
Male	236	1888	
Female	182	1645	
Race Units: Subjects			
White	320	2690	
Black or African American	72	641	
American Indian or Alaska Native	0	9	
Native Hawaiian or other Pacific Islander	0	4	
Asian	12	83	
Multiracial	9	74	
Not reported	5	32	
Ethnicity Units: Subjects			
Hispanic or Latino	90	673	
Non-Hispanic or non-Latino	327	2843	
Not reported	1	17	

End points

End points reporting groups

Reporting group title	VLA15: 5 to 11 Years
Reporting group description: Participants aged 5 to 11 years were randomised to receive VLA15, 180 micrograms (ug), 0.5 milliliter (mL) intramuscular (IM) injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.	
Reporting group title	Placebo: 5 to 11 Years
Reporting group description: Participants aged 5 to 11 years were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.	
Reporting group title	VLA15: 12 to 17 Years
Reporting group description: Participants aged 12 to 17 years were randomised to receive VLA15, 180 ug, 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.	
Reporting group title	Placebo: 12 to 17 Years
Reporting group description: Participants aged 12 to 17 years were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.	
Subject analysis set title	VLA15: Overall
Subject analysis set type	Safety analysis
Subject analysis set description: Participants were randomised to receive VLA15, 180 ug, 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.	
Subject analysis set title	Placebo: Overall
Subject analysis set type	Safety analysis
Subject analysis set description: Participants were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.	

Primary: Percentage of Participants With Local Reactions for up to 7 Days Following Study Vaccination 1

End point title	Percentage of Participants With Local Reactions for up to 7 Days Following Study Vaccination 1 ^[1]
End point description: Local reactions included pain at injection site, redness and swelling and were recorded by participants in the electronic diary (e-diary) or by investigators in case report form (CRF) after vaccination. Local reactions were graded per the 'Local Reaction Grading Scale' per protocol based on Center for Biologics Evaluation and Research (CBER) toxicity guidelines. Percentage of participants with at least 1 local reaction of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.	
End point type	Primary
End point timeframe: From Day 1 through Day 7 after Study Vaccination 1 [Vaccination on Day 1, Month 0]	

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1408	457	1206	410
Units: Percentage of participants				
number (confidence interval 95%)	80.8 (78.6 to 82.8)	34.8 (30.4 to 39.4)	80.6 (78.3 to 82.8)	14.6 (11.4 to 18.4)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2614	867		
Units: Percentage of participants				
number (confidence interval 95%)	80.7 (79.1 to 82.2)	25.3 (22.4 to 28.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Local Reactions for up to 7 Days Following Study Vaccination 2

End point title	Percentage of Participants With Local Reactions for up to 7 Days Following Study Vaccination 2 ^[2]
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End point description:

Local reactions included pain at injection site, redness and swelling and were recorded by participants in the e-diary or by investigators in CRF after vaccination. Local reactions were graded per the 'Local Reaction Grading Scale' per protocol based on CBER toxicity guidelines. Percentage of participants with at least 1 local reaction of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Day 7 after Study Vaccination 2 [Vaccination on Day 1, Month 2]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1297	431	1112	386
Units: Percentage of participants				
number (confidence interval 95%)	72.6 (70.0 to 75.0)	29.0 (24.8 to 33.5)	71.4 (68.6 to 74.0)	11.7 (8.6 to 15.3)

End point values	VLA15: Overall	Placebo:		
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		Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2409	817		
Units: Percentage of participants				
number (confidence interval 95%)	72.0 (70.2 to 73.8)	20.8 (18.1 to 23.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Local Reactions for up to 7 Days Following Study Vaccination 3

End point title	Percentage of Participants With Local Reactions for up to 7 Days Following Study Vaccination 3 ^[3]
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End point description:

Local reactions included pain at injection site, redness and swelling and were recorded by participants in the e-diary or by investigators in CRF after vaccination. Local reactions were graded per the 'Local Reaction Grading Scale' per protocol based on CBER toxicity guidelines. Percentage of participants with at least 1 local reaction of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Day 7 after Study Vaccination 3 [Vaccination on Day 1, Month 6]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1225	391	1054	372
Units: Percentage of participants				
number (confidence interval 95%)	73.5 (70.9 to 75.9)	25.1 (20.8 to 29.7)	69.6 (66.8 to 72.4)	9.7 (6.9 to 13.1)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2279	763		
Units: Percentage of participants				
number (confidence interval 95%)	71.7 (69.8 to 73.5)	17.6 (14.9 to 20.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Local Reactions for up to 7 Days Following Study Vaccination 4

End point title	Percentage of Participants With Local Reactions for up to 7 Days Following Study Vaccination 4 ^[4]
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End point description:

Local reactions included pain at injection site, redness and swelling and were recorded by participants in the e-diary or by investigators in CRF after vaccination. Local reactions were graded per the 'Local Reaction Grading Scale' per protocol based on CBER toxicity guidelines. Percentage of participants with at least 1 local reaction of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Day 7 after Study Vaccination 4 [Vaccination on Day 1, Month 18]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1169	384	979	349
Units: Percentage of participants				
number (confidence interval 95%)	77.0 (74.5 to 79.4)	24.7 (20.5 to 29.4)	71.6 (68.7 to 74.4)	11.7 (8.6 to 15.6)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2148	733		
Units: Percentage of participants				
number (confidence interval 95%)	74.5 (72.6 to 76.4)	18.6 (15.8 to 21.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With any Local Reaction for up to 7 Days After any Study Vaccination

End point title	Percentage of Participants With any Local Reaction for up to 7 Days After any Study Vaccination ^[5]
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End point description:

Local reactions included pain at injection site, redness and swelling and were recorded by participants in the electronic diary (e-diary) or by investigators in case report form (CRF) after vaccination. Local reactions were graded per the 'Local Reaction Grading Scale' per protocol based on Center for Biologics Evaluation and Research (CBER) toxicity guidelines. Percentage of participants with at least 1 local reaction of any grade were reported in this endpoint. Safety population included all enrolled participants

who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Day 7 after any study vaccination

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1428	466	1212	415
Units: Percentage of participants				
number (confidence interval 95%)	88.3 (86.5 to 89.9)	56.0 (51.4 to 60.6)	90.0 (88.2 to 91.6)	31.6 (27.1 to 36.3)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2640	881		
Units: Percentage of participants				
number (confidence interval 95%)	89.1 (87.8 to 90.3)	44.5 (41.2 to 47.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events for up to 7 Days Following Study Vaccination 1

End point title	Percentage of Participants With Systemic Events for up to 7 Days Following Study Vaccination 1 ^[6]
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End point description:

Systemic events included fever, fatigue, headache, muscle pain and joint pain and were recorded by participants in the e-diary or by investigators in CRF after vaccination. Systemic events were graded per the 'Systemic Events Grading Scale' per protocol based on CBER toxicity guidelines. Percentage of participants with at least 1 systemic event of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Day 7 after Study Vaccination 1 [Vaccination on Day 1, Month 0]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1406	456	1205	410
Units: Percentage of participants				
number (confidence interval 95%)	56.0 (53.3 to 58.6)	41.0 (36.5 to 45.7)	62.2 (59.4 to 64.9)	48.8 (43.8 to 53.7)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2611	866		
Units: Percentage of participants				
number (confidence interval 95%)	58.8 (56.9 to 60.7)	44.7 (41.3 to 48.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events for up to 7 Days Following Vaccination After Dose 2

End point title	Percentage of Participants With Systemic Events for up to 7 Days Following Vaccination After Dose 2 ^[7]
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End point description:

Systemic events included fever, fatigue, headache, muscle pain and joint pain and were recorded by participants in the e-diary or by investigators in CRF after vaccination. Systemic events were graded per the 'Systemic Events Grading Scale' per protocol based on CBER toxicity guidelines. Percentage of participants with at least 1 systemic event of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Day 7 after Study Vaccination 2 [Vaccination on Day 1, Month 2]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1296	430	1111	386
Units: Percentage of participants				
number (confidence interval 95%)	48.1 (45.3 to 50.8)	30.2 (25.9 to 34.8)	55.3 (52.3 to 58.2)	31.6 (27.0 to 36.5)

End point values	VLA15: Overall	Placebo:		
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		Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2407	816		
Units: Percentage of participants				
number (confidence interval 95%)	51.4 (49.4 to 53.4)	30.9 (27.7 to 34.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events for up to 7 Days Following Vaccination After Dose 3

End point title	Percentage of Participants With Systemic Events for up to 7 Days Following Vaccination After Dose 3 ^[8]
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End point description:

Systemic events included fever, fatigue, headache, muscle pain and joint pain and were recorded by participants in the e-diary or by investigators in CRF after vaccination. Systemic events were graded per the 'Systemic Events Grading Scale' per protocol based on CBER toxicity guidelines. Percentage of participants with at least 1 systemic event of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Day 7 after Study Vaccination 3 [Vaccination on Day 1, Month 6]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1224	391	1055	371
Units: Percentage of participants				
number (confidence interval 95%)	47.5 (44.6 to 50.3)	27.6 (23.2 to 32.3)	51.6 (48.5 to 54.6)	26.1 (21.7 to 30.9)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2279	762		
Units: Percentage of participants				
number (confidence interval 95%)	49.4 (47.3 to 51.4)	26.9 (23.8 to 30.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events for up to 7 Days Following Vaccination After Dose 4

End point title	Percentage of Participants With Systemic Events for up to 7 Days Following Vaccination After Dose 4 ^[9]
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End point description:

Systemic events included fever, fatigue, headache, muscle pain and joint pain and were recorded by participants in the e-diary or by investigators in CRF after vaccination. Systemic events were graded per the 'Systemic Events Grading Scale' per protocol based on CBER toxicity guidelines. Percentage of participants with at least 1 systemic event of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Day 7 after Study Vaccination 4 [Vaccination on Day 1, Month 18]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1169	384	977	349
Units: Percentage of participants				
number (confidence interval 95%)	53.5 (50.6 to 56.4)	28.1 (23.7 to 32.9)	54.8 (51.6 to 57.9)	28.4 (23.7 to 33.4)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2146	733		
Units: Percentage of participants				
number (confidence interval 95%)	54.1 (51.9 to 56.2)	28.2 (25.0 to 31.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With any Systemic Events for up to 7 Days After any Study Vaccination

End point title	Percentage of Participants With any Systemic Events for up to 7 Days After any Study Vaccination ^[10]
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End point description:

Systemic events included fever, fatigue, headache, muscle pain and joint pain and were recorded by participants in the e-diary or by investigators in CRF after vaccination. Systemic events were graded per the 'Systemic Events Grading Scale' per protocol based on CBER toxicity guidelines. Percentage of participants with at least 1 systemic event of any grade were reported in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here,

"subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
End point timeframe:	
From Day 1 through Day 7 after any study vaccination	

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1427	466	1212	415
Units: Percentage of participants				
number (confidence interval 95%)	77.8 (75.5 to 79.9)	60.1 (55.5 to 64.6)	82.1 (79.8 to 84.2)	63.1 (58.3 to 67.8)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2639	881		
Units: Percentage of participants				
number (confidence interval 95%)	79.8 (78.2 to 81.3)	61.5 (58.2 to 64.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) Through 1 Month Following Study Vaccination 1

End point title	Percentage of Participants With Adverse Events (AEs) Through 1 Month Following Study Vaccination 1 ^[11]
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End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Only AEs collected by non-systematic assessment (excluding local reactions and systematic events) after dose 1 were included in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
End point timeframe:	
From Day 1 through Month 1 after Study Vaccination 1 [Vaccination on Day 1, Month 0]	

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1426	467	1219	418
Units: Percentage of participants				
number (confidence interval 95%)	3.4 (2.6 to 4.5)	3.0 (1.6 to 5.0)	3.1 (2.2 to 4.3)	4.5 (2.8 to 7.0)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2645	885		
Units: Percentage of participants				
number (confidence interval 95%)	3.3 (2.6 to 4.0)	3.7 (2.6 to 5.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) Through 1 Month Following Study Vaccination 2

End point title	Percentage of Participants With Adverse Events (AEs) Through 1 Month Following Study Vaccination 2 ^[12]
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End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Only AEs collected by non-systematic assessment (excluding local reactions and systematic events) after dose 2 were included in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Month 1 after Study Vaccination 2 [Vaccination on Day 1, Month 2]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1371	452	1173	406
Units: Percentage of participants				
number (confidence interval 95%)	2.4 (1.7 to 3.4)	2.2 (1.1 to 4.0)	1.5 (0.9 to 2.4)	2.2 (1.0 to 4.2)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2544	858		

Units: Percentage of participants				
number (confidence interval 95%)	2.0 (1.5 to 2.6)	2.2 (1.3 to 3.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) Through 1 Month Following Study Vaccination 3

End point title	Percentage of Participants With Adverse Events (AEs) Through 1 Month Following Study Vaccination 3 ^[13]
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End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Only AEs collected by non-systematic assessment (excluding local reactions and systematic events) after dose 3 were included in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Month 1 after Study Vaccination 3 [Vaccination on Day 1, Month 6]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1313	428	1126	397
Units: Percentage of participants				
number (confidence interval 95%)	4.6 (3.5 to 5.8)	3.5 (2.0 to 5.7)	4.6 (3.5 to 6.0)	4.3 (2.5 to 6.8)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2439	825		
Units: Percentage of participants				
number (confidence interval 95%)	4.6 (3.8 to 5.5)	3.9 (2.7 to 5.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) Through 1 Month Following Study Vaccination 4

End point title	Percentage of Participants With Adverse Events (AEs) Through 1 Month Following Study Vaccination 4 ^[14]
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End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Only AEs collected by non-systematic assessment (excluding local reactions and systematic events) after dose 4 were included in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through Month 1 after Study Vaccination 4 [Vaccination on Day 1, Month 18]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1226	396	1019	360
Units: Percentage of participants				
number (confidence interval 95%)	4.1 (3.0 to 5.3)	2.5 (1.2 to 4.6)	4.1 (3.0 to 5.5)	4.7 (2.8 to 7.5)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2245	756		
Units: Percentage of participants				
number (confidence interval 95%)	4.1 (3.3 to 5.0)	3.6 (2.4 to 5.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) Through 1 Month Following any Study Vaccination

End point title	Percentage of Participants With Adverse Events (AEs) Through 1 Month Following any Study Vaccination ^[15]
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End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Only AEs collected by non-systematic assessment (excluding local reactions and systematic events) after any dose were included in this endpoint. Safety population included all enrolled participants who received at least 1 dose of the study intervention. Here, "subjects analysed" signifies number of participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From Day 1 through 1 Month after any study vaccination

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1429	467	1219	418
Units: Percentage of participants				
number (confidence interval 95%)	11.7 (10.1 to 13.5)	8.6 (6.2 to 11.5)	11.2 (9.5 to 13.1)	12.2 (9.2 to 15.7)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2648	885		
Units: Percentage of participants				
number (confidence interval 95%)	11.5 (10.3 to 12.8)	10.3 (8.4 to 12.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With NDCMCs Throughout the Study

End point title	Percentage of Participants With NDCMCs Throughout the Study
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End point description:

An NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or was otherwise long-lasting in its effects. NDCMCs included conditions that were undiagnosed prior to study entry (diagnosed while in the study and confirmed not to be a preexisting condition) and that were not considered temporary conditions based upon the expected natural history of the condition. Safety population included all enrolled participants who received at least 1 dose of the study intervention.

End point type	Primary
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End point timeframe:

From study Vaccination 1 throughout the study [6 months post study Vaccination 4: maximum up to 24 months]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1429	467	1219	418
Units: Percentage of participants				
number (confidence interval 95%)	2.7 (1.9 to 3.7)	1.9 (0.9 to 3.6)	2.1 (1.4 to 3.1)	3.3 (1.8 to 5.6)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2648	885		
Units: Percentage of participants				
number (confidence interval 95%)	2.5 (1.9 to 3.1)	2.6 (1.7 to 3.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With SAEs Throughout the Study

End point title	Percentage of Participants With SAEs Throughout the Study ^[17]
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End point description:

An SAE was defined as any untoward medical occurrence that, at any dose, met one or more of the following criteria: resulted in death, was life-threatening, required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, any other important medical event. Safety population included all enrolled participants who received at least 1 dose of the study intervention.

End point type	Primary
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End point timeframe:

From study Vaccination 1 throughout the study [6 months post study Vaccination 4: maximum up to 24 months]

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: Only descriptive data was planned for this endpoint

End point values	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: 12 to 17 Years	Placebo: 12 to 17 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1429	467	1219	418
Units: Percentage of participants				
number (confidence interval 95%)	1.0 (0.6 to 1.7)	0.9 (0.2 to 2.2)	2.2 (1.5 to 3.2)	2.4 (1.2 to 4.4)

End point values	VLA15: Overall	Placebo: Overall		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2648	885		
Units: Percentage of participants				
number (confidence interval 95%)	1.6 (1.1 to 2.1)	1.6 (0.9 to 2.6)		

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Local reactions and systemic events: Day 1 to Day 7 after each study vaccination; SAEs, All-cause mortality: From Day 1 throughout the study (up to 24 months); Other AEs: From Day 1 through 1 Month after any study vaccination

Adverse event reporting additional description:

Same event may appear as both other AE (non-SAE) and SAE but are distinct events. An event may be categorized as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and other AE (non-SAE). Safety population included all enrolled participants who received at least 1 dose of the study intervention.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	v28.0
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Reporting groups

Reporting group title	VLA15: 5 to 11 Years
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Reporting group description:

Participants aged 5 to 11 years were randomised to receive VLA15, 180 micrograms (ug), 0.5 milliliter (mL) intramuscular (IM) injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.

Reporting group title	Placebo: 5 to 11 Years
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Reporting group description:

Participants aged 5 to 11 years were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.

Reporting group title	VLA15: Overall
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Reporting group description:

Participants were randomised to receive VLA15, 180 ug, 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.

Reporting group title	Placebo: 12 to 17 Years
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Reporting group description:

Participants aged 12 to 17 years were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.

Reporting group title	Placebo: Overall
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Reporting group description:

Participants were randomised to receive placebo (normal saline) 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a placebo IM injection at Month 18.

Reporting group title	VLA15: 12 to 17 Years
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Reporting group description:

Participants aged 12 to 17 years were randomised to receive VLA15, 180 ug, 0.5 mL IM injection at Month 0, 2 and 6. Eligible participants received a booster dose of VLA15 at Month 18.

Serious adverse events	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: Overall
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 1429 (1.05%)	4 / 467 (0.86%)	42 / 2648 (1.59%)
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)			
Hodgkin's disease nodular sclerosis stage IV			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Forearm fracture			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
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 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Arnold-Chiari malformation			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Central nervous system lesion			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			

subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tethered cord syndrome			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Food allergy			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal fistula			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
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			
Asthma			
subjects affected / exposed	1 / 1429 (0.07%)	1 / 467 (0.21%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Asthmatic crisis	subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease	subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
	occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal oedema	subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal stenosis	subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
	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				
Angioedema	subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria	subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders				
Depression	subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	3 / 2648 (0.11%)
	occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disruptive mood dysregulation disorder	subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Drug abuse			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oppositional defiant disorder			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 1429 (0.00%)	1 / 467 (0.21%)	3 / 2648 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	2 / 2648 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Chronic recurrent multifocal osteomyelitis			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 1429 (0.07%)	1 / 467 (0.21%)	3 / 2648 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			

subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	2 / 2648 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza myocarditis			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycoplasma infection			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital abscess			
subjects affected / exposed	0 / 1429 (0.00%)	1 / 467 (0.21%)	0 / 2648 (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
Periorbital cellulitis			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	2 / 2648 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subperiosteal abscess			
subjects affected / exposed	1 / 1429 (0.07%)	0 / 467 (0.00%)	1 / 2648 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 1429 (0.00%)	0 / 467 (0.00%)	0 / 2648 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	2 / 1429 (0.14%)	0 / 467 (0.00%)	2 / 2648 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo: 12 to 17	Placebo: Overall	VLA15: 12 to 17
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	Years		Years
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 418 (2.39%)	14 / 885 (1.58%)	27 / 1219 (2.21%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hodgkin's disease nodular sclerosis stage IV			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Forearm fracture			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 418 (0.00%)	1 / 885 (0.11%)	0 / 1219 (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
Vulvovaginal injury			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
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	1 / 418 (0.24%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Arnold-Chiari malformation			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Central nervous system lesion			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tethered cord syndrome			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal fistula			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
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			
Asthma			
subjects affected / exposed	0 / 418 (0.00%)	1 / 885 (0.11%)	0 / 1219 (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
Asthmatic crisis			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal oedema			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal stenosis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
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			
Angioedema			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			

subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	2 / 1219 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug abuse			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oppositional defiant disorder			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 418 (0.00%)	1 / 885 (0.11%)	3 / 1219 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced psychotic disorder			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	2 / 1219 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Chronic recurrent multifocal osteomyelitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 418 (0.00%)	1 / 885 (0.11%)	2 / 1219 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	2 / 1219 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza myocarditis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycoplasma infection			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital abscess			
subjects affected / exposed	0 / 418 (0.00%)	1 / 885 (0.11%)	0 / 1219 (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
Periorbital cellulitis			

subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	1 / 1	0 / 0
Pneumonia			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
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 tract infection viral			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	1 / 1219 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subperiosteal abscess			
subjects affected / exposed	0 / 418 (0.00%)	0 / 885 (0.00%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	2 / 418 (0.48%)	2 / 885 (0.23%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			

subjects affected / exposed	1 / 418 (0.24%)	1 / 885 (0.11%)	0 / 1219 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	VLA15: 5 to 11 Years	Placebo: 5 to 11 Years	VLA15: Overall
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1290 / 1429 (90.27%)	341 / 467 (73.02%)	2411 / 2648 (91.05%)
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 1429 (0.14%)	5 / 467 (1.07%)	7 / 2648 (0.26%)
occurrences (all)	2	5	7
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	750 / 1429 (52.48%)	192 / 467 (41.11%)	1484 / 2648 (56.04%)
occurrences (all)	750	192	1484
General disorders and administration site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	875 / 1429 (61.23%)	219 / 467 (46.90%)	1644 / 2648 (62.08%)
occurrences (all)	875	219	1644
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	1245 / 1429 (87.12%)	250 / 467 (53.53%)	2329 / 2648 (87.95%)
occurrences (all)	1245	250	2329
Injection site swelling			
subjects affected / exposed	20 / 1429 (1.40%)	0 / 467 (0.00%)	27 / 2648 (1.02%)
occurrences (all)	21	0	30
Injection site pain			
subjects affected / exposed	40 / 1429 (2.80%)	4 / 467 (0.86%)	69 / 2648 (2.61%)
occurrences (all)	53	4	90

Injection site erythema subjects affected / exposed occurrences (all)	20 / 1429 (1.40%) 23	0 / 467 (0.00%) 0	32 / 2648 (1.21%) 37
Swelling (SWELLING) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	752 / 1429 (52.62%) 752	45 / 467 (9.64%) 45	1029 / 2648 (38.86%) 1029
Pyrexia (FEVER) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	193 / 1429 (13.51%) 193	29 / 467 (6.21%) 29	282 / 2648 (10.65%) 282
Skin and subcutaneous tissue disorders Erythema (REDNESS) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	891 / 1429 (62.35%) 891	76 / 467 (16.27%) 76	1196 / 2648 (45.17%) 1196
Psychiatric disorders Attention deficit hyperactivity disorder subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all)	27 / 1429 (1.89%) 27 2 / 1429 (0.14%) 2	8 / 467 (1.71%) 8 1 / 467 (0.21%) 1	34 / 2648 (1.28%) 34 11 / 2648 (0.42%) 11
Musculoskeletal and connective tissue disorders Arthralgia (JOINT PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	375 / 1429 (26.24%) 375	64 / 467 (13.70%) 64	728 / 2648 (27.49%) 728
Myalgia (MUSCLE PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	717 / 1429 (50.17%) 717	112 / 467 (23.98%) 112	1354 / 2648 (51.13%) 1354
Infections and infestations			

COVID-19			
subjects affected / exposed	18 / 1429 (1.26%)	2 / 467 (0.43%)	28 / 2648 (1.06%)
occurrences (all)	18	2	28
Pharyngitis streptococcal			
subjects affected / exposed	47 / 1429 (3.29%)	14 / 467 (3.00%)	59 / 2648 (2.23%)
occurrences (all)	50	15	63
Upper respiratory tract infection			
subjects affected / exposed	31 / 1429 (2.17%)	13 / 467 (2.78%)	55 / 2648 (2.08%)
occurrences (all)	32	13	57
Influenza			
subjects affected / exposed	12 / 1429 (0.84%)	6 / 467 (1.28%)	17 / 2648 (0.64%)
occurrences (all)	12	6	17

Non-serious adverse events	Placebo: 12 to 17 Years	Placebo: Overall	VLA15: 12 to 17 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	295 / 418 (70.57%)	636 / 885 (71.86%)	1121 / 1219 (91.96%)
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	3 / 418 (0.72%)	8 / 885 (0.90%)	5 / 1219 (0.41%)
occurrences (all)	3	8	5
Nervous system disorders			
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	180 / 418 (43.06%)	372 / 885 (42.03%)	734 / 1219 (60.21%)
occurrences (all)	180	372	734
General disorders and administration site conditions			
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	193 / 418 (46.17%)	412 / 885 (46.55%)	769 / 1219 (63.08%)
occurrences (all)	193	412	769
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	130 / 418 (31.10%)	380 / 885 (42.94%)	1084 / 1219 (88.93%)
occurrences (all)	130	380	1084

Injection site swelling subjects affected / exposed occurrences (all)	0 / 418 (0.00%) 0	0 / 885 (0.00%) 0	7 / 1219 (0.57%) 9
Injection site pain subjects affected / exposed occurrences (all)	4 / 418 (0.96%) 4	8 / 885 (0.90%) 8	29 / 1219 (2.38%) 37
Injection site erythema subjects affected / exposed occurrences (all)	0 / 418 (0.00%) 0	0 / 885 (0.00%) 0	12 / 1219 (0.98%) 14
Swelling (SWELLING) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	7 / 418 (1.67%) 7	52 / 885 (5.88%) 52	277 / 1219 (22.72%) 277
Pyrexia (FEVER) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	19 / 418 (4.55%) 19	48 / 885 (5.42%) 48	89 / 1219 (7.30%) 89
Skin and subcutaneous tissue disorders Erythema (REDNESS) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	12 / 418 (2.87%) 12	88 / 885 (9.94%) 88	305 / 1219 (25.02%) 305
Psychiatric disorders Attention deficit hyperactivity disorder subjects affected / exposed occurrences (all)	5 / 418 (1.20%) 5	13 / 885 (1.47%) 13	7 / 1219 (0.57%) 7
Depression subjects affected / exposed occurrences (all)	7 / 418 (1.67%) 7	8 / 885 (0.90%) 8	9 / 1219 (0.74%) 9
Musculoskeletal and connective tissue disorders Arthralgia (JOINT PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	65 / 418 (15.55%) 65	129 / 885 (14.58%) 129	353 / 1219 (28.96%) 353
Myalgia (MUSCLE PAIN)			

alternative assessment type: Systematic			
subjects affected / exposed	110 / 418 (26.32%)	222 / 885 (25.08%)	637 / 1219 (52.26%)
occurrences (all)	110	222	637
Infections and infestations			
COVID-19			
subjects affected / exposed	9 / 418 (2.15%)	11 / 885 (1.24%)	10 / 1219 (0.82%)
occurrences (all)	9	11	10
Pharyngitis streptococcal			
subjects affected / exposed	5 / 418 (1.20%)	19 / 885 (2.15%)	12 / 1219 (0.98%)
occurrences (all)	5	20	13
Upper respiratory tract infection			
subjects affected / exposed	16 / 418 (3.83%)	29 / 885 (3.28%)	24 / 1219 (1.97%)
occurrences (all)	17	30	25
Influenza			
subjects affected / exposed	4 / 418 (0.96%)	10 / 885 (1.13%)	5 / 1219 (0.41%)
occurrences (all)	4	10	5

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