Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of V114 in Children with Sickle Cell Disease (PNEU-SICKLE)

Summary

EudraCT number	2018-001152-35
Trial protocol	GR IT
Global end of trial date	08 June 2020

Results information

Result version number	v1 (current)
This version publication date	25 April 2021
First version publication date	25 April 2021

Trial information

Trial identification

Sponsor protocol code	V114-023

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03731182
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
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?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 November 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 June 2020
Global end of trial reached?	Yes
Global end of trial date	08 June 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study is designed to describe the safety, tolerability, and immunogenicity of V114 in children with sickle cell disease.

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	23 January 2019
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	Brazil: 17
Country: Number of subjects enrolled	Colombia: 14
Country: Number of subjects enrolled	Dominican Republic: 22
Country: Number of subjects enrolled	Greece: 6
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Panama: 15
Country: Number of subjects enrolled	United States: 25
Worldwide total number of subjects	104
EEA total number of subjects	11

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)	57

Adolescents (12-17 years)	47
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study enrolled children with sickle cell disease. Other inclusion criteria applied.

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, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	V114

Arm description:

Participants received a single 0.5 mL intramuscular (IM) injection of V114 on Day 1.

Arm type	Experimental
Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

15-valent pneumococcal capsular polysaccharide with serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), and serotype 6B (4 mcg) in each 0.5 mL dose

Arm title	Prevnar 13™

Arm description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1.

Arm type	Active comparator
Investigational medicinal product name	Prevnar 13™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

13-valent pneumococcal capsular polysaccharide with serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F (2.2 mcg) and 6B (4.4 mcg) in each 0.5 ml dose

Number of subjects in period 1	V114	Prevnar 13™
Started	70	34
V114 or Prevnar 13™ vaccination (Day 1)	69	34
Completed	65	34
Not completed	5	0
Physician decision	1	-
Withdrawal By Parent/Guardian	2	-
Lost to follow-up	2	-

Baseline characteristics

Reporting groups	
Reporting group title	V114
Reporting group description:	
Participants received a single 0.5 mL intramuscular (IM) injection of V114 on Day 1.	
Reporting group title	Prevnar 13™
Reporting group description:	
Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1.	

Reporting group values	V114	Prevnar 13™	Total
Number of subjects	70	34	104
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	38	19	57
Adolescents (12-17 years)	32	15	47
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	10.8	10.8	
standard deviation	± 3.5	± 3.3	-
Gender Categorical Units: Participants			
Female	33	14	47
Male	37	20	57
Race Units: Subjects			
American Indian or Alaska Native	9	3	12
Black or African American	38	25	63
Multiple	13	4	17
White	10	2	12
Ethnicity Units: Subjects			
Hispanic or Latino	44	24	68
Not Hispanic or Latino	26	10	36

End points

End points reporting groups

Reporting group title	V114
Reporting group description:	
Participants received a single 0.5 mL intramuscular (IM) injection of V114 on Day 1.	
Reporting group title	Prevnar 13™
Reporting group description:	
Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1.	

Primary: Percentage of Participants with a Solicited Injection-site Adverse Event

End point title	Percentage of Participants with a Solicited Injection-site Adverse Event[1]

End point description:

An adverse event (AE) is any untoward medical occurrence in a 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 erythema (redness), injection-site induration (hard lump), injection-site pain (tenderness), and injection-site swelling. The analysis population for this endpoint included all randomized participants who received at least 1 dose of study vaccination.

End point type	Primary

End point timeframe:

Up to 14 days post-vaccination

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: There were no pre-defined between-group statistical analyses for this endpoint.

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	34		
Units: Percentage of participants				
number (confidence interval 95%)				
Injection site erythema	4.3 (0.9 to 12.2)	5.9 (0.7 to 19.7)		
Injection site induration	8.7 (3.3 to 18.0)	8.8 (1.9 to 23.7)		
Injection site pain	60.9 (48.4 to 72.4)	67.6 (49.5 to 82.6)		
Injection site swelling	27.5 (17.5 to 39.6)	35.3 (19.7 to 53.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with a Solicited Systemic Adverse Event

End point title	Percentage of Participants with a Solicited Systemic Adverse Event[2]

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. Solicited systemic AEs included arthralgia (joint pain), fatigue (tiredness), headache, myalgia (muscle pain), and urticaria (hives or welts). The analysis population for this endpoint included all randomized participants who received at least 1 dose of study vaccination.

End point type	Primary

End point timeframe:

Up to 14 days post-vaccination

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: There were no pre-defined between-group statistical analyses for this endpoint.

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	34		
Units: Percentage of participants				
number (confidence interval 95%)				
Arthralgia	2.9 (0.4 to 10.1)	8.8 (1.9 to 23.7)		
Fatigue	13.0 (6.1 to 23.3)	20.6 (8.7 to 37.9)		
Headache	24.6 (15.1 to 36.5)	17.6 (6.8 to 34.5)		
Myalgia	23.2 (13.9 to 34.9)	11.8 (3.3 to 27.5)		
Urticaria	0.0 (0.0 to 5.2)	2.9 (0.1 to 15.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with a Vaccine-related Serious Adverse Event

End point title	Percentage of Participants with a Vaccine-related Serious Adverse Event[3]

End point description:

A serious adverse event (SAE) is an AE that results in death, is life-threatening, requires or prolongs an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect, or is another important medical event deemed such by medical or scientific judgment. SAEs that were reported by the investigator to be at least possibly related to the study vaccination were summarized. The analysis population for this endpoint included all randomized participants who received at least 1 dose of study vaccination.

End point type	Primary

End point timeframe:

Up to 6 months post-vaccination

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: There were no pre-defined between-group statistical analyses for this endpoint.

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	34		
Units: Percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 5.2)	0.0 (0.0 to 10.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentration (GMC) of Serotype-specific Immunoglobulin G (IgG) at Day 30

End point title	Geometric Mean Concentration (GMC) of Serotype-specific Immunoglobulin G (IgG) at Day 30[4]

End point description:

The GMC of IgG serotype-specific antibodies to the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13™ and 2 serotypes (22F and 33F) unique to V114 were quantitated from participants' sera by a multiplex electrochemiluminescence (ECL) assay. The analysis population included all randomized participants without deviations from the protocol that may have substantially affected the results of this immunogenicity endpoint and who had sufficient data to perform the analyses.

End point type	Primary

End point timeframe:

Day 30

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: There were no pre-defined between-group statistical analyses for this endpoint.

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	34		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=66, 32)	2.12 (1.63 to 2.75)	2.76 (1.95 to 3.91)		
Serotype 3 (n=66, 31)	1.09 (0.87 to 1.38)	1.07 (0.70 to 1.65)		
Serotype 4 (n=66, 31)	1.58 (1.18 to 2.10)	2.90 (2.00 to 4.20)		
Serotype 5 (n=66, 31)	4.44 (3.19 to 6.17)	6.56 (4.09 to 10.52)		
Serotype 6A (n=66, 31)	23.29 (17.22 to 31.52)	15.97 (8.82 to 28.91)		
Serotype 6B (n=66, 31)	38.38 (28.53 to 51.64)	22.94 (13.60 to 38.71)		
Serotype 7F (n=66, 32)	5.81 (4.42 to 7.64)	4.65 (3.06 to 7.06)		
Serotype 9V (n=66, 32)	4.46 (3.44 to 5.78)	5.36 (3.45 to 8.33)		
Serotype 14 (n=66, 31)	16.03 (11.23 to 22.90)	20.53 (12.39 to 34.03)		

Serotype 18C (n=66, 32)	6.11 (4.47 to 8.35)	4.20 (2.66 to 6.62)		
Serotype 19A (n=66, 32)	19.86 (14.77 to 26.70)	21.65 (14.45 to 32.44)		
Serotype 19F (n=66, 32)	13.88 (9.96 to 19.35)	12.80 (9.10 to 18.01)		
Serotype 23F (n=63, 31)	5.38 (3.88 to 7.46)	6.88 (4.01 to 11.83)		
Serotype 22F (n=66, 30)	7.30 (5.68 to 9.36)	0.49 (0.33 to 0.73)		
Serotype 33F (n=66, 32)	4.46 (3.38 to 5.87)	0.97 (0.62 to 1.51)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer (GMT) of Serotype-specific Opsonophagocytic Activity (OPA) at Day 30

End point title	Geometric Mean Titer (GMT) of Serotype-specific Opsonophagocytic Activity (OPA) at Day 30

End point description:

Sera from participants was used to measure GMT of 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13™ and 2 serotypes (22F and 33F) unique to V114 using the multiplexed opsonophagocytic assay (MOPA). The analysis population included all randomized participants without deviations from the protocol that may have substantially affected the results of this immunogenicity endpoint and who had sufficient data to perform the analyses.

End point type	Secondary

End point timeframe:

Day 30

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	34		
Units: 1/dil				
geometric mean (confidence interval 95%)				
Serotype 1 (n=51, 22)	484.0 (327.5 to 715.4)	504.0 (254.8 to 997.0)		
Serotype 3 (n=51, 22)	264.8 (193.4 to 362.4)	234.3 (133.0 to 412.6)		
Serotype 4 (n=51, 22)	4670.8 (2965.9 to 7355.6)	7015.5 (3994.0 to 12322.6)		
Serotype 5 (n=51, 22)	1383.9 (957.1 to 2000.9)	1198.2 (638.1 to 2250.0)		
Serotype 6A (n=50, 22)	27305.7 (19797.6 to 37661.2)	20277.1 (11740.2 to 35021.7)		
Serotype 6B (n=51, 22)	31560.4 (24134.1 to 41272.1)	18531.0 (11024.7 to 31148.1)		

Serotype 7F (n=51, 22)	19411.5 (15195.9 to 24796.5)	16928.1 (11107.4 to 25799.0)		
Serotype 9V (n=51, 22)	4561.8 (3240.7 to 6421.4)	3941.7 (2659.6 to 5841.7)		
Serotype 14 (n=51, 22)	6597.6 (4706.8 to 9248.0)	8112.2 (4827.2 to 13632.8)		
Serotype 18C (n=50, 22)	9684.6 (6642.1 to 14120.7)	5685.1 (3329.4 to 9707.6)		
Serotype 19A (n=51, 22)	14067.7 (9972.8 to 19843.9)	9224.9 (5015.5 to 16967.1)		
Serotype 19F (n=51, 22)	4931.8 (3387.8 to 7179.7)	3313.3 (2039.4 to 5383.1)		
Serotype 23F (n=50, 22)	17190.9 (12066.0 to 24492.4)	19197.1 (10511.1 to 35061.1)		
Serotype 22F (n=51, 19)	7257.5 (5278.5 to 9978.3)	1013.2 (477.4 to 2150.1)		
Serotype 33F (n=51, 22)	24013.6 (17612.4 to 32741.4)	4824.8 (3216.3 to 7237.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) in Serotype-specific IgG from Day 1 (Baseline) to Day 30

End point title	Geometric Mean Fold Rise (GMFR) in Serotype-specific IgG from Day 1 (Baseline) to Day 30

End point description:

IgG for the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13™ and 2 serotypes unique to V114 (22F and 33F) was determined using an electrochemiluminescence assay. GMFR is defined as the geometric mean of the ratio of concentration at Day 30 after vaccination divided by concentration at baseline (Day 1, pre-vaccination). The analysis population included all randomized participants without protocol deviations that could have substantially impacted the results of these immunogenicity analyses and who had sufficient data to perform the analyses.

End point type	Secondary

End point timeframe:

Day 1 (Baseline) and Day 30

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	34		
Units: Ratio				
geometric mean (confidence interval 95%)				
Serotype 1 (n=66, 30)	6.2 (4.6 to 8.5)	6.0 (3.7 to 9.9)		
Serotype 3 (n=66, 29)	4.8 (3.5 to 6.6)	4.1 (2.6 to 6.7)		
Serotype 4 (n=66, 29)	6.0 (4.3 to 8.3)	9.3 (5.4 to 16.2)		
Serotype 5 (n=66, 29)	5.3 (3.8 to 7.4)	6.4 (3.8 to 10.8)		
Serotype 6A (n=66, 29)	54.7 (37.9 to 78.9)	40.6 (22.9 to 71.9)		
Serotype 6B (n=66, 29)	37.2 (25.8 to 53.6)	25.0 (13.8 to 45.3)		
Serotype 7F (n=66, 30)	11.6 (8.3 to 16.0)	9.8 (6.3 to 15.3)		
Serotype 9V (n=66, 30)	7.4 (5.3 to 10.3)	8.1 (4.9 to 13.2)		
Serotype 14 (n=65, 29)	10.8 (6.8 to 17.2)	7.2 (3.5 to 14.8)		
Serotype 18C (n=66, 30)	10.8 (7.7 to 15.1)	7.6 (4.5 to 12.8)		
Serotype 19A (n=66, 30)	8.2 (5.4 to 12.4)	8.6 (5.0 to 14.9)		
Serotype 19F (n=66, 30)	8.3 (5.6 to 12.3)	7.6 (4.5 to 12.8)		
Serotype 23F (n=63, 29)	9.3 (6.1 to 14.2)	13.1 (7.4 to 23.4)		
Serotype 22F (n=66, 28)	15.0 (10.1 to 22.1)	1.1 (0.9 to 1.3)		
Serotype 33F (n=66, 30)	9.0 (6.7 to 12.1)	1.3 (1.0 to 1.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR in Serotype-specific OPA from Day 1 (Baseline) to Day 30

End point title	GMFR in Serotype-specific OPA from Day 1 (Baseline) to Day 30

End point description:

Activity for the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in V114 and Prevnar 13™ and 2 serotypes unique to V114 (22F and 33F) was determined using a MOPA. GMFR is defined as the geometric mean of the ratio of concentration at Day 30 after vaccination divided by concentration at baseline (Day 1, pre-vaccination). The analysis population included all randomized participants without protocol deviations that could have substantially affected the results of these immunogenicity analyses and who had sufficient data to perform the analyses.

End point type	Secondary

End point timeframe:

Day 1 (Baseline) and Day 30

End point values	V114	Prevnar 13™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	34		
Units: Ratio				
geometric mean (confidence interval 95%)				
Serotype 1 (n=49, 20)	24.1 (14.9 to 39.1)	13.3 (5.1 to 34.2)		
Serotype 3 (n=50, 21)	4.9 (3.5 to 7.0)	3.1 (1.8 to 5.6)		
Serotype 4 (n=49, 21)	10.2 (6.3 to 16.6)	18.5 (8.8 to 38.9)		
Serotype 5 (n=49, 21)	23.7 (15.0 to 37.5)	13.8 (6.6 to 28.6)		
Serotype 6A (n=47, 21)	20.7 (13.3 to 32.1)	11.2 (4.8 to 26.2)		
Serotype 6B (n=47, 19)	21.7 (12.7 to 36.9)	13.7 (6.8 to 27.7)		
Serotype 7F (n=50, 21)	5.4 (3.8 to 7.7)	5.4 (3.2 to 9.1)		
Serotype 9V (n=48, 20)	4.4 (3.0 to 6.5)	6.1 (3.6 to 10.4)		
Serotype 14 (n=50, 21)	6.9 (4.3 to 11.1)	4.6 (2.1 to 10.2)		
Serotype 18C (n=45, 20)	14.0 (8.9 to 22.0)	4.8 (2.5 to 9.3)		
Serotype 19A (n=50, 21)	9.0 (5.4 to 15.0)	7.8 (4.4 to 14.0)		
Serotype 19F (n=50, 20)	6.4 (4.3 to 9.7)	6.6 (3.3 to 12.9)		
Serotype 23F (n=48, 20)	10.4 (5.8 to 18.4)	18.1 (8.8 to 37.1)		
Serotype 22F (n=48, 17)	6.5 (3.7 to 11.3)	0.9 (0.7 to 1.2)		
Serotype 33F (n=50, 21)	3.8 (2.7 to 5.2)	0.8 (0.7 to 1.0)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious AEs: up to 14 days post-vaccination; serious AEs and deaths (all causes): up to 6 months post-vaccination

Adverse event reporting additional description:

The safety analysis population included all randomized participants who received at least 1 dose of study vaccination.

The analysis population for number of deaths (all causes) included all randomized participants.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Prevnar 13

Reporting group description: -

Reporting group title	V114

Reporting group description: -

Serious adverse events	Prevnar 13	V114	
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 34 (23.53%)	13 / 69 (18.84%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Medical observation			
subjects affected / exposed	0 / 34 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 34 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			

subjects affected / exposed	0 / 34 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	6 / 34 (17.65%)	7 / 69 (10.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute chest syndrome			
subjects affected / exposed	0 / 34 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 34 (2.94%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 69 (1.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 34 (2.94%)	0 / 69 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Prevnar 13	V114	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 34 (79.41%)	52 / 69 (75.36%)	
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 34 (17.65%)	17 / 69 (24.64%)	
occurrences (all)	10	25	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	7 / 34 (20.59%)	9 / 69 (13.04%)	
occurrences (all)	7	9	
Injection site erythema			
subjects affected / exposed	2 / 34 (5.88%)	3 / 69 (4.35%)	
occurrences (all)	2	3	
Injection site induration			
subjects affected / exposed	3 / 34 (8.82%)	6 / 69 (8.70%)	
occurrences (all)	3	6	
Injection site pain			
subjects affected / exposed	23 / 34 (67.65%)	42 / 69 (60.87%)	
occurrences (all)	25	48	
Injection site swelling			
subjects affected / exposed	12 / 34 (35.29%)	19 / 69 (27.54%)	
occurrences (all)	14	21	
Pyrexia			
subjects affected / exposed	1 / 34 (2.94%)	4 / 69 (5.80%)	
occurrences (all)	1	4	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 34 (8.82%)	2 / 69 (2.90%)	
occurrences (all)	4	3	

Back pain			
subjects affected / exposed	1 / 34 (2.94%)	4 / 69 (5.80%)	
occurrences (all)	1	4	
Myalgia			
subjects affected / exposed	4 / 34 (11.76%)	16 / 69 (23.19%)	
occurrences (all)	7	20	

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