



Clinical trial results:

A Phase 1, Randomized, Single Dose, Blinded, Dose-Escalation Study to Assess Safety, Tolerability and Immunogenicity of ASP3772, a Pneumococcal Vaccine, in Toddlers 12 to 15 Months of Age in Comparison to an Active Comparator

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2019-004503-12 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 06 April 2022 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 26 October 2022 |
| First version publication date | 26 October 2022 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | 3772-CL-2001 |
|-----------------------|--------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04525599 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Affinivax |
| Sponsor organisation address | 301 Binney Street, Suite 302, Cambridge, Massachusetts (MA), United States, 02142 |
| Public contact | Affinivax, Affinivax, 1 617-465-0865, contact@affinivax.com |
| Scientific contact | Affinivax, Affinivax, 1 617-465-0865, contact@affinivax.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-002641-PIP01-19 |
| 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 | 15 September 2022 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 06 April 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 06 April 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of 3 dose levels of ASP3772, in comparison to the active comparator PCV13 in toddlers approximately 12 to 15 months of age who have previously been administered the routine 3-dose series of PCV13.

Protection of trial subjects:

The toddlers were observed for safety reactogenicity events, including daily body temperature measurements and both local and systemic tolerability assessments. Oversight of safety and dose escalation was provided by Dose Escalation Committee.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 22 September 2020 |
| 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: 75 |
| Worldwide total number of subjects | 75 |
| 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) | 75 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

1 of 75 subjects was randomized to PCV13 group but administered ASP3772. Therefore, all the primary analysis and immunogenicity analysis were done on the Safety Analysis Set based on the treatment actually received, and the results are presented here.

Pre-assignment

Screening details:

Of 85 subjects with informed consent: 7 were screen failures, 3 were withdrawn by their parent/guardian. 75 subjects were randomized and dosed. 1 subject randomized to PCV13 group received ASP3772 5µg dose instead of PCV13, thus contributed to ASP3772 5µg group.

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, Monitor, Assessor |

Arms

| | |
|------------------------------|---------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Group 1, ASP3772 Low Dose |

Arm description:

Healthy toddlers aged approximately 12 to 15 months received a single intramuscular (IM) injection of low dose (1 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | ASP3772 |
| Investigational medicinal product code | |
| Other name | AFX3772 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Low dose of ASP3772 was administered into anterolateral right or left thigh muscle on Day 1.

| | |
|------------------|------------------------------|
| Arm title | Group 2, ASP3772 Medium Dose |
|------------------|------------------------------|

Arm description:

Healthy toddlers aged approximately 12 to 15 months received a single IM injection of medium dose (2 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | ASP3772 |
| Investigational medicinal product code | |
| Other name | AFX3772 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Medium dose of ASP3772 was administered into anterolateral right or left thigh muscle on Day 1.

| | |
|------------------|----------------------------|
| Arm title | Group 3, ASP3772 High Dose |
|------------------|----------------------------|

Arm description:

Healthy toddlers aged approximately 12 to 15 months received a single IM injection of high dose (5 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|--------------------------|
| Investigational medicinal product name | ASP3772 |
| Investigational medicinal product code | |
| Other name | AFX3772 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

High dose of ASP3772 was administered into anterolateral right or left thigh muscle on Day 1.

| | |
|------------------|------------------|
| Arm title | Comparator PCV13 |
|------------------|------------------|

Arm description:

Healthy toddlers aged approximately 12 to 15 months received a single IM injection of the approved dose of PCV13 into anterolateral right or left thigh muscle on Day 1.

| | |
|--|--------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | PCV13 |
| Investigational medicinal product code | |
| Other name | Pevnar 13 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

PCV13 was administered into anterolateral right or left thigh muscle on Day 1.

| Number of subjects in period 1 | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose |
|---------------------------------------|------------------------------|---------------------------------|-------------------------------|
| Started | 15 | 15 | 16 |
| Completed | 15 | 14 | 16 |
| Not completed | 0 | 1 | 0 |
| Lost to follow-up | - | 1 | - |

| Number of subjects in period 1 | Comparator PCV13 |
|---------------------------------------|------------------|
| Started | 29 |
| Completed | 29 |
| Not completed | 0 |
| Lost to follow-up | - |

Baseline characteristics

Reporting groups

| | |
|------------------------------|--|
| Reporting group title | Group 1, ASP3772 Low Dose |
| Reporting group description: | Healthy toddlers aged approximately 12 to 15 months received a single intramuscular (IM) injection of low dose (1 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1. |
| Reporting group title | Group 2, ASP3772 Medium Dose |
| Reporting group description: | Healthy toddlers aged approximately 12 to 15 months received a single IM injection of medium dose (2 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1. |
| Reporting group title | Group 3, ASP3772 High Dose |
| Reporting group description: | Healthy toddlers aged approximately 12 to 15 months received a single IM injection of high dose (5 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1. |
| Reporting group title | Comparator PCV13 |
| Reporting group description: | Healthy toddlers aged approximately 12 to 15 months received a single IM injection of the approved dose of PCV13 into anterolateral right or left thigh muscle on Day 1. |

| Reporting group values | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose |
|--|---------------------------|------------------------------|----------------------------|
| Number of subjects | 15 | 15 | 16 |
| Age Categorical | | | |
| The Age characteristics analysis was performed on the Safety Analysis Set (SAF). | | | |
| Units: Subjects | | | |
| 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) | 15 | 15 | 16 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous | | | |
| The Age characteristics analysis was performed on the Safety Analysis Set (SAF). | | | |
| Units: months | | | |
| arithmetic mean | 13.3 | 13.1 | 13.3 |
| standard deviation | ± 1.3 | ± 0.8 | ± 1.1 |
| Gender Categorical | | | |
| The Gender categorical analysis was performed on the Safety Analysis Set (SAF). | | | |
| Units: Subjects | | | |
| Female | 7 | 11 | 6 |
| Male | 8 | 4 | 10 |
| Race/Ethnicity, Customized | | | |
| The Race/Ethnicity analysis was performed on the Safety Analysis Set (SAF). | | | |
| Units: Subjects | | | |
| White | 10 | 12 | 10 |

| | | | |
|----------------------------------|---|---|---|
| Black or African American | 5 | 1 | 3 |
| American Indian or Alaska Native | 0 | 0 | 1 |
| Other | 0 | 2 | 2 |

| Reporting group values | Comparator PCV13 | Total | |
|--|------------------|-------|--|
| Number of subjects | 29 | 75 | |
| Age Categorical | | | |
| The Age characteristics analysis was performed on the Safety Analysis Set (SAF). | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 29 | 75 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age Continuous | | | |
| The Age characteristics analysis was performed on the Safety Analysis Set (SAF). | | | |
| Units: months | | | |
| arithmetic mean | 13.1 | | |
| standard deviation | ± 1.1 | - | |
| Gender Categorical | | | |
| The Gender categorical analysis was performed on the Safety Analysis Set (SAF). | | | |
| Units: Subjects | | | |
| Female | 13 | 37 | |
| Male | 16 | 38 | |
| Race/Ethnicity, Customized | | | |
| The Race/Ethnicity analysis was performed on the Safety Analysis Set (SAF). | | | |
| Units: Subjects | | | |
| White | 21 | 53 | |
| Black or African American | 5 | 14 | |
| American Indian or Alaska Native | 0 | 1 | |
| Other | 3 | 7 | |

End points

End points reporting groups

| | |
|--|------------------------------|
| Reporting group title | Group 1, ASP3772 Low Dose |
| Reporting group description: Healthy toddlers aged approximately 12 to 15 months received a single intramuscular (IM) injection of low dose (1 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1. | |
| Reporting group title | Group 2, ASP3772 Medium Dose |
| Reporting group description: Healthy toddlers aged approximately 12 to 15 months received a single IM injection of medium dose (2 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1. | |
| Reporting group title | Group 3, ASP3772 High Dose |
| Reporting group description: Healthy toddlers aged approximately 12 to 15 months received a single IM injection of high dose (5 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1. | |
| Reporting group title | Comparator PCV13 |
| Reporting group description: Healthy toddlers aged approximately 12 to 15 months received a single IM injection of the approved dose of PCV13 into anterolateral right or left thigh muscle on Day 1. | |

Primary: Number of Subjects with Treatment Emergent Adverse Events (TEAEs)

| | |
|--|--|
| End point title | Number of Subjects with Treatment Emergent Adverse Events (TEAEs) ^[1] |
| End point description: An AE is any untoward medical occurrence in a subject administered a study vaccine, and which does not necessarily have to have a causal relationship with this vaccination. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product whether or not considered related to the medicinal product. A TEAE is defined as any AE with onset within 30 days from study vaccine administration (Day 1-Day 30). Analysis was performed on the Safety Analysis Set (SAF) which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received. | |
| End point type | Primary |
| End point timeframe: Day 1 to Day 30 | |

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: This is a descriptive endpoint with no statistical analyses.

| End point values | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose | Comparator PCV13 |
|-----------------------------|---------------------------|------------------------------|----------------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 15 | 15 | 16 | 29 |
| Units: Subjects | | | | |
| Vaccine-Related TEAEs | 1 | 1 | 0 | 2 |
| Serious TEAEs | 0 | 0 | 0 | 2 |
| Always Serious TEAE | 0 | 0 | 0 | 1 |
| Medically Attended TEAE | 5 | 6 | 9 | 14 |

Statistical analyses

No statistical analyses for this end point

Primary: Maximum Body Temperature over 7 days Post-vaccination

End point title | Maximum Body Temperature over 7 days Post-vaccination^[2]

End point description:

Body temperature was assessed by Grades range from 1 to 4. Grade 1= mild (38.0 – 38.4 Degrees Celsius [°C]); Grade 2 = moderate (38.5 – 38.9°C); Grade 3 = severe (39.0 – 40°C); Grade 4 = potentially life-threatening (> 40).

Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

End point type | Primary

End point timeframe:

7 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: This is a descriptive endpoint with no statistical analyses.

| End point values | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose | Comparator PCV13 |
|-----------------------------|---------------------------------|------------------------------------|----------------------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 15 | 15 | 16 | 29 |
| Units: Subjects | | | | |
| No Fever | 14 | 15 | 15 | 25 |
| 38.0 – 38.4°C | 1 | 0 | 0 | 2 |
| 38.5 – 38.9°C | 0 | 0 | 1 | 1 |
| 39.0 – 40.0°C | 0 | 0 | 0 | 1 |
| > 40.0°C | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Primary: Reactogenicity Assessed by Number of Solicited Local Reactions

End point title | Reactogenicity Assessed by Number of Solicited Local

End point description:

Assessed solicited local reactions were tenderness, redness/erythema, induration, swelling and administration site movement restriction.

Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

End point type | Primary

End point timeframe:

Day 1 to Day 7

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: This is a descriptive endpoint with no statistical analyses.

| End point values | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose | Comparator PCV13 |
|---|---------------------------------|------------------------------------|----------------------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 15 | 15 | 16 | 29 |
| Units: Subjects | | | | |
| Tenderness | 9 | 7 | 4 | 8 |
| Erythema/Redness | 4 | 7 | 2 | 8 |
| Induration | 4 | 5 | 3 | 10 |
| Swelling | 3 | 4 | 2 | 6 |
| Administration Site Movement Restriction | 0 | 2 | 2 | 2 |

Statistical analyses

No statistical analyses for this end point

Primary: Reactogenicity assessed by Number of Solicited Systemic Reactions

| | |
|-----------------|--|
| End point title | Reactogenicity assessed by Number of Solicited Systemic Reactions ^[4] |
|-----------------|--|

End point description:

Assessed solicited systemic reactions were irritability, diarrhea, decrease of appetite, increase or decrease in sleep, vomiting, and fever.

Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Day 1 to Day 7

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: This is a descriptive endpoint with no statistical analyses.

| End point values | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose | Comparator PCV13 |
|-----------------------------|---------------------------------|------------------------------------|----------------------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 15 | 15 | 16 | 29 |
| Units: Subjects | | | | |
| Irritability | 10 | 10 | 8 | 17 |
| Diarrhea | 4 | 7 | 7 | 5 |
| Decrease of Appetite | 5 | 5 | 4 | 9 |
| Increase in Sleep | 3 | 4 | 4 | 9 |
| Decrease in Sleep | 4 | 2 | 2 | 6 |
| Vomiting | 3 | 4 | 2 | 6 |
| Fever | 1 | 0 | 1 | 4 |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Serotype-specific Immunoglobulin G (IgG) Concentration of greater than or equal to (\geq) 0.35 microgram per millilitre ($\mu\text{g}/\text{mL}$)

| | |
|-----------------|---|
| End point title | Percentage of Subjects with Serotype-specific Immunoglobulin G (IgG) Concentration of greater than or equal to (\geq) 0.35 microgram per millilitre ($\mu\text{g}/\text{mL}$) |
|-----------------|---|

End point description:

Immunogenicity was measured in terms of percentage of subjects with serotype-specific IgG concentration $\geq 0.35 \mu\text{g}/\text{mL}$.

Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 1 and Day 30

| End point values | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose | Comparator PCV13 |
|------------------------------------|---------------------------|------------------------------|----------------------------|-----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 15 | 15 | 16 | 29 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1, Day1 (N=12,14,10,22) | 80.0 (51.9 to 95.7) | 93.3 (68.1 to 99.8) | 62.5 (35.4 to 84.8) | 75.9 (56.5 to 89.7) |
| Serotype 1, Day30 (N=14,15,15,27) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (87.2 to 100.0) |
| Serotype 3, Day1 (N=0,5,4,4) | 0 (0.0 to 21.8) | 33.3 (11.8 to 61.6) | 25.0 (7.3 to 52.4) | 13.8 (3.9 to 31.7) |
| Serotype 3, Day30 (N=14,15,14,26) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 93.3 (68.1 to 99.8) | 96.3 (81.0 to 99.9) |
| Serotype 4, Day1 (N=6,8,9,11) | 40.0 (16.3 to 67.7) | 53.3 (26.6 to 78.7) | 56.3 (29.9 to 80.2) | 37.9 (20.7 to 57.7) |
| Serotype 4, Day30 (N=14,15,14,27) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 93.3 (68.1 to 99.8) | 100.0 (87.2 to 100.0) |
| Serotype 5, Day1 (N=8,10,11,15) | 53.3 (26.6 to 78.7) | 66.7 (38.4 to 88.2) | 68.8 (41.3 to 89.0) | 51.7 (32.5 to 70.6) |
| Serotype 5, Day30 (N=13,15,15,27) | 92.9 (66.1 to 99.8) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (87.2 to 100.0) |
| Serotype 6A, Day1 (N=14,13,12,23) | 93.3 (68.1 to 99.8) | 86.7 (59.5 to 98.3) | 75.0 (47.6 to 92.7) | 79.3 (60.3 to 92.0) |
| Serotype 6A, Day30 (N=14,15,15,27) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (87.2 to 100.0) |
| Serotype 6B, Day1 (N=7,10,10,17) | 46.7 (21.3 to 73.4) | 66.7 (38.4 to 88.2) | 62.5 (35.4 to 84.8) | 58.6 (38.9 to 76.5) |

| | | | | |
|-------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Serotype 6B, Day30 (N=14,15,15,27) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (87.2 to 100.0) |
| Serotype 7F, Day1 (N=15,13,14,29) | 100.0 (78.2 to 100.0) | 86.7 (59.5 to 98.3) | 87.5 (61.7 to 98.4) | 100.0 (88.1 to 100.0) |
| Serotype 7F, Day30 (N=14,15,14,28) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 93.3 (68.1 to 99.8) | 100.0 (87.2 to 100.0) |
| Serotype 9V, Day1 (N=7,5,8,14) | 46.7 (21.3 to 73.4) | 33.3 (11.8 to 61.6) | 50.0 (24.7 to 75.3) | 48.3 (29.4 to 67.5) |
| Serotype 9V, Day30 (N=14,15,15,27) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (87.2 to 100.0) |
| Serotype 14, Day1 (N=11,15,14,27) | 73.3 (44.9 to 92.2) | 100.0 (78.2 to 100.0) | 87.5 (61.7 to 98.4) | 93.1 (77.2 to 99.2) |
| Serotype 14, Day30 (N=13,15,14,27) | 92.9 (66.1 to 99.8) | 100.0 (78.2 to 100.0) | 93.3 (68.1 to 99.8) | 100.0 (87.2 to 100.0) |
| Serotype 18C, Day1 (N=8,11,11,19) | 53.3 (26.6 to 78.7) | 73.3 (44.9 to 92.2) | 68.8 (41.3 to 89.0) | 65.5 (45.7 to 82.1) |
| Serotype 18C, Day30 (N=13,15,14,27) | 92.9 (66.1 to 99.8) | 100.0 (78.2 to 100.0) | 93.3 (68.1 to 99.8) | 100.0 (87.2 to 100.0) |
| Serotype 19A, Day1 (N=3,7,8,15) | 20.0 (4.3 to 48.1) | 46.7 (21.3 to 73.4) | 50.0 (24.7 to 75.3) | 51.7 (32.5 to 70.6) |
| Serotype 19A, Day30 (N=14,15,14,27) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 93.3 (68.1 to 99.8) | 100.0 (87.2 to 100.0) |
| Serotype 19F, Day1 (N=10,10,11,19) | 66.7 (38.4 to 88.2) | 66.7 (38.4 to 88.2) | 68.8 (41.3 to 89.0) | 65.5 (45.7 to 82.1) |
| Serotype 19F, Day30 (N=14,15,15,27) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (87.2 to 100.0) |
| Serotype 23F, Day1 (N=9,9,11,14) | 60.0 (32.3 to 83.7) | 60.0 (32.3 to 83.7) | 68.8 (41.3 to 89.0) | 48.3 (29.4 to 67.5) |
| Serotype 23F, Day30 (N=13,15,14,27) | 92.9 (66.1 to 99.8) | 100.0 (78.2 to 100.0) | 93.3 (68.1 to 99.8) | 100.0 (87.2 to 100.0) |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Serotype 1, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 4.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -24.7 |
| upper limit | 27.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 1, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 17.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.8 |
| upper limit | 37.5 |

| | |
|---|---|
| Statistical analysis title | Serotype 1, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -13.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -41.4 |
| upper limit | 13.7 |

| | |
|---|--|
| Statistical analysis title | Serotype 3, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -13.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.8 |
| upper limit | 8 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 3, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 19.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.6 |
| upper limit | 47.1 |

| | |
|---|---|
| Statistical analysis title | Serotype 3, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 11.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.8 |
| upper limit | 38.2 |

| | |
|---|--|
| Statistical analysis title | Serotype 4, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 2.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -26.4 |
| upper limit | 32.1 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 4, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 15.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -15 |
| upper limit | 43.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 4, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 18.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.9 |
| upper limit | 45.7 |

| | |
|---|--|
| Statistical analysis title | Serotype 5, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 1.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -28.5 |
| upper limit | 30.9 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 5, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 14.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -16.2 |
| upper limit | 41.8 |

| | |
|---|---|
| Statistical analysis title | Serotype 5, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 17 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.5 |
| upper limit | 43.1 |

| | |
|---|--|
| Statistical analysis title | Serotype 6A, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.9 |
| upper limit | 33.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 6A, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 7.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -20.3 |
| upper limit | 28.8 |

| | |
|---|---|
| Statistical analysis title | Serotype 6A, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -4.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -32.3 |
| upper limit | 19.8 |

| | |
|---|--|
| Statistical analysis title | Serotype 6B, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -40.6 |
| upper limit | 18.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 6B, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -22.7 |
| upper limit | 35.1 |

| | |
|---|---|
| Statistical analysis title | Serotype 6B, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -26 |
| upper limit | 31.5 |

| | |
|---|--|
| Statistical analysis title | Serotype 7F, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 7F, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -13.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -38.2 |
| upper limit | -0.3 |

| | |
|---|---|
| Statistical analysis title | Serotype 7F, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -12.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -36.3 |
| upper limit | 0.4 |

| | |
|---|--|
| Statistical analysis title | Serotype 9V, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -1.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.9 |
| upper limit | 28.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 9V, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -14.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -41.8 |
| upper limit | 16.2 |

| | |
|---|--|
| Statistical analysis title | Serotype 14, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -19.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -46.5 |
| upper limit | 1.8 |

| | |
|---|---|
| Statistical analysis title | Serotype 14, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 6.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -14.4 |
| upper limit | 22.2 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 14, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -5.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.4 |
| upper limit | 12.5 |

| | |
|---|--|
| Statistical analysis title | Serotype 18C, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -12.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -41.2 |
| upper limit | 17.3 |

| | |
|---|---|
| Statistical analysis title | Serotype 18C, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 7.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -22.4 |
| upper limit | 33.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 18C, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -26.3 |
| upper limit | 29.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 19A, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -31.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -55 |
| upper limit | -0.8 |

| | |
|---|---|
| Statistical analysis title | Serotype 19A, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -5.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -34.2 |
| upper limit | 25.2 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 19A, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.9 |
| upper limit | 27.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 19F, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -29 |
| upper limit | 28.3 |

| | |
|---|---|
| Statistical analysis title | Serotype 19F, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -29 |
| upper limit | 28.3 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 19F, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -26.3 |
| upper limit | 29.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 23F, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 11.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19.2 |
| upper limit | 39.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 23F, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 11.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19.2 |
| upper limit | 39.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 23F, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 20.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.2 |
| upper limit | 46.3 |

| | |
|---|--|
| Statistical analysis title | Serotype 1, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 1, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 1, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 3, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -18.6 |
| upper limit | 18.5 |

| | |
|---|---|
| Statistical analysis title | Serotype 3, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -17.4 |
| upper limit | 18.5 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 3, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -27 |
| upper limit | 13.1 |

| | |
|---|--|
| Statistical analysis title | Serotype 4, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 4, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 4, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -6.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.2 |
| upper limit | 6.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 5, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -7.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -31.9 |
| upper limit | 6.2 |

| | |
|---|---|
| Statistical analysis title | Serotype 5, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 5, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 6A, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 6A, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 6A, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 6B, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 6B, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 6B, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 7F, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 7F, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 7F, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -6.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.2 |
| upper limit | 6.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 9V, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 9V, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 9V, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 14, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -7.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -31.9 |
| upper limit | 6.2 |

| | |
|---|---|
| Statistical analysis title | Serotype 14, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 14, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -6.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.2 |
| upper limit | 6.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 18C, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -7.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -31.9 |
| upper limit | 6.2 |

| | |
|---|---|
| Statistical analysis title | Serotype 18C, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 18C, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -6.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.2 |
| upper limit | 6.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 19A, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 19A, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 19A, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -6.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.2 |
| upper limit | 6.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 19F, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 19F, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 19F, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 23F, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -7.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -31.9 |
| upper limit | 6.2 |

| | |
|---|---|
| Statistical analysis title | Serotype 23F, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Serotype 23F, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -6.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.2 |
| upper limit | 6.6 |

| | |
|---|---|
| Statistical analysis title | Serotype 9V, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -3.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -27.6 |
| upper limit | 30.9 |

Secondary: Percentage of Subjects with Serotype-specific Opsonophagocytic Activity (OPA) Antibody Titer \geq Lower Limit of Quantification (LLOQ)

| | |
|-----------------|--|
| End point title | Percentage of Subjects with Serotype-specific Opsonophagocytic Activity (OPA) Antibody Titer \geq Lower Limit of Quantification (LLOQ) |
|-----------------|--|

End point description:

Immunogenicity was measured in terms of percentage of subjects with OPA Antibody Titer \geq LLOQ. Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 1 and Day 30

| End point values | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose | Comparator PCV13 |
|-------------------------------------|---------------------------------|------------------------------------|----------------------------------|-----------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 15 | 15 | 16 | 29 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1, Day1 (N=6,6,10,7) | 40.0 (16.3 to 67.7) | 46.2 (19.2 to 74.9) | 62.5 (35.4 to 84.8) | 25.0 (10.7 to 44.9) |
| Serotype 1, Day30 (N=11,13,12,26) | 78.6 (49.2 to 95.3) | 100.0 (75.3 to 100.0) | 92.3 (64.0 to 99.8) | 100.0 (86.8 to 100.0) |
| Serotype 3, Day1 (N=14,13,16,27) | 93.3 (68.1 to 99.8) | 100.0 (75.3 to 100.0) | 100.0 (79.4 to 100.0) | 96.4 (81.7 to 99.9) |
| Serotype 3, Day30 (N=13,15,14,25) | 100.0 (75.3 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (76.8 to 100.0) | 100.0 (86.3 to 100.0) |
| Serotype 4, Day1 (N=10,9,14,22) | 71.4 (41.9 to 91.6) | 75.0 (42.8 to 94.5) | 87.5 (61.7 to 98.4) | 78.6 (59.0 to 91.7) |
| Serotype 4, Day30 (N=12,15,15,25) | 100.0 (73.5 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (86.3 to 100.0) |
| Serotype 5, Day1 (N=13,12,15,24) | 100.0 (75.3 to 100.0) | 85.7 (57.2 to 98.2) | 93.8 (69.8 to 99.8) | 82.8 (64.2 to 94.2) |
| Serotype 5, Day30 (N=14,14,12,25) | 100.0 (76.8 to 100.0) | 100.0 (76.8 to 100.0) | 100.0 (73.5 to 100.0) | 100.0 (86.3 to 100.0) |
| Serotype 6A, Day1 (N=13,13,15,28) | 100.0 (75.3 to 100.0) | 92.9 (66.1 to 99.8) | 93.8 (69.8 to 99.8) | 96.6 (82.2 to 99.9) |
| Serotype 6A, Day30 (N=14,15,15,24) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (85.8 to 100.0) |
| Serotype 6B, Day1 (N=13,12,13,21) | 86.7 (59.5 to 98.3) | 85.7 (57.2 to 98.2) | 81.3 (54.4 to 96.0) | 77.8 (57.7 to 91.4) |
| Serotype 6B, Day30 (N=13,15,15,25) | 100.0 (75.3 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (86.3 to 100.0) |
| Serotype 7F, Day1 (N=15,14,16,29) | 100.0 (78.2 to 100.0) | 100.0 (76.8 to 100.0) | 100.0 (79.4 to 100.0) | 100.0 (88.1 to 100.0) |
| Serotype 7F, Day30 (N=11,15,15,22) | 100.0 (71.5 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (84.6 to 100.0) |
| Serotype 9V, Day1 (12,10,14,21) | 100.0 (73.5 to 100.0) | 83.3 (51.6 to 97.9) | 93.3 (68.1 to 99.8) | 91.3 (72.0 to 98.9) |
| Serotype 9V, Day30 (N=12,13,15,24) | 100.0 (73.5 to 100.0) | 100.0 (75.3 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (85.8 to 100.0) |
| Serotype 14, Day1 (12,14,15,25) | 85.7 (57.2 to 98.2) | 100.0 (76.8 to 100.0) | 93.8 (69.8 to 99.8) | 92.6 (75.7 to 99.1) |
| Serotype 14, Day30 (N=12,15,14,24) | 92.3 (64.0 to 99.8) | 100.0 (78.2 to 100.0) | 93.3 (68.1 to 99.8) | 100.0 (85.8 to 100.0) |
| Serotype 18C, Day1 (N=14,10,14,24) | 100.0 (76.8 to 100.0) | 83.3 (51.6 to 97.9) | 87.5 (61.7 to 98.4) | 85.7 (67.3 to 96.0) |
| Serotype 18C, Day30 (N=11,15,15,25) | 100.0 (71.5 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (86.3 to 100.0) |
| Serotype 19A, Day1 (N=12,13,15,24) | 85.7 (57.2 to 98.2) | 100.0 (75.3 to 100.0) | 93.8 (69.8 to 99.8) | 85.7 (67.3 to 96.0) |
| Serotype 19A, Day30 (N=14,15,15,26) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (86.8 to 100.0) |
| Serotype 19F, Day1 (N=11,12,14,22) | 100.0 (71.5 to 100.0) | 85.7 (57.2 to 98.2) | 87.5 (61.7 to 98.4) | 81.5 (61.9 to 93.7) |
| Serotype 19F, Day30 (N=14,14,15,23) | 100.0 (76.8 to 100.0) | 100.0 (76.8 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (85.2 to 100.0) |
| Serotype 23F, Day1 (N=15,12,16,26) | 100.0 (78.2 to 100.0) | 100.0 (73.5 to 100.0) | 100.0 (79.4 to 100.0) | 89.7 (72.6 to 97.8) |
| Serotype 23F, Day30 (N=13,15,15,23) | 100.0 (75.3 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (78.2 to 100.0) | 100.0 (85.2 to 100.0) |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Serotype 1, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.2 |
| upper limit | 43.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 1, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 21.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.1 |
| upper limit | 50.5 |

| | |
|---|---|
| Statistical analysis title | Serotype 1, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 37.5 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.1 |
| upper limit | 62.1 |

| | |
|---|--|
| Statistical analysis title | Serotype 3, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -3.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -27.1 |
| upper limit | 12.5 |

| | |
|---|---|
| Statistical analysis title | Serotype 3, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -20 |
| upper limit | 18 |

| | |
|---|---|
| Statistical analysis title | Serotype 3, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.6 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -16.4 |
| upper limit | 18 |

| | |
|---|--|
| Statistical analysis title | Serotype 4, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -7.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -36.9 |
| upper limit | 18.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 4, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -3.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -35.3 |
| upper limit | 22 |

| | |
|---|---|
| Statistical analysis title | Serotype 4, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 8.9 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -17.9 |
| upper limit | 30.5 |

| | |
|---|--|
| Statistical analysis title | Serotype 5, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 17.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.3 |
| upper limit | 34.8 |

| | |
|---|---|
| Statistical analysis title | Serotype 5, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -25.4 |
| upper limit | 24.3 |

| | |
|---|---|
| Statistical analysis title | Serotype 5, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 11 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.5 |
| upper limit | 30.1 |

| | |
|---|--|
| Statistical analysis title | Serotype 6A, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -20.1 |
| upper limit | 17.4 |

| | |
|---|---|
| Statistical analysis title | Serotype 6A, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -3.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -28.8 |
| upper limit | 11.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 6A, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -2.8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -25.7 |
| upper limit | 12.3 |

| | |
|---|--|
| Statistical analysis title | Serotype 6B, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 8.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19.1 |
| upper limit | 31.2 |

| | |
|---|---|
| Statistical analysis title | Serotype 6B, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 7.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -21.2 |
| upper limit | 30.6 |

| | |
|---|---|
| Statistical analysis title | Serotype 6B, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Post-hoc |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 3.5 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -24.4 |
| upper limit | 27 |

| | |
|---|--|
| Statistical analysis title | Serotype 7F, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 7F, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 7F, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 9V, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 8.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -16.9 |
| upper limit | 27.1 |

| | |
|---|---|
| Statistical analysis title | Serotype 9V, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -38 |
| upper limit | 14.6 |

| | |
|---|---|
| Statistical analysis title | Serotype 9V, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -22.8 |
| upper limit | 21.9 |

| | |
|---|--|
| Statistical analysis title | Serotype 14, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Group 3, ASP3772 High Dose |
| Number of subjects included in analysis | 31 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -6.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -34 |
| upper limit | 12.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 14, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 7.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -15.2 |
| upper limit | 23.6 |

| | |
|---|---|
| Statistical analysis title | Serotype 14, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 1.2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -22.3 |
| upper limit | 18.7 |

| | |
|---|--|
| Statistical analysis title | Serotype 18C, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 14.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.8 |
| upper limit | 31.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 18C, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -2.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -32.9 |
| upper limit | 19.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 18C, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 1.8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -24.1 |
| upper limit | 22.3 |

| | |
|---|--|
| Statistical analysis title | Serotype 19A, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -28 |
| upper limit | 21.2 |

| | |
|---|---|
| Statistical analysis title | Serotype 19A, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 14.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.1 |
| upper limit | 31.7 |

| | |
|---|---|
| Statistical analysis title | Serotype 19A, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -16.2 |
| upper limit | 27 |

| | |
|---|--|
| Statistical analysis title | Serotype 19F, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 18.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.4 |
| upper limit | 37 |

| | |
|---|---|
| Statistical analysis title | Serotype 19F, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 4.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -24.4 |
| upper limit | 26.5 |

| | |
|---|---|
| Statistical analysis title | Serotype 19F, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 6 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -20.5 |
| upper limit | 27.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 23F, Day 1 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 10.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.2 |
| upper limit | 26.6 |

| | |
|---|--|
| Statistical analysis title | Serotype 1, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -21.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -47.9 |
| upper limit | -6.5 |

| | |
|---|---|
| Statistical analysis title | Serotype 1, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 1, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -7.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -33.7 |
| upper limit | 6.2 |

| | |
|---|--|
| Statistical analysis title | Serotype 3, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 3, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 3, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 4, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 4, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 4, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 5, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 5, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 5, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 6A, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 6A, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 6A, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 6B, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 6B, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 6B, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 7F, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 7F, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 7F, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 9V, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 9V, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 9V, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 14, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -7.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -33.8 |
| upper limit | 7.2 |

| | |
|---|---|
| Statistical analysis title | Serotype 14, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 14, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | -6.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -30.2 |
| upper limit | 8 |

| | |
|---|--|
| Statistical analysis title | Serotype 18C, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 18C, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 18C, Day 30 |
| Comparison groups | Comparator PCV13 v Group 3, ASP3772 High Dose |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 19A, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 19A, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 19A, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 19F, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 19F, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 19F, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|--|
| Statistical analysis title | Serotype 23F, Day 30 |
| Comparison groups | Group 1, ASP3772 Low Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 23F, Day 30 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 23F, Day 30 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0 |
| upper limit | 0 |

| | |
|---|---|
| Statistical analysis title | Serotype 23F, Day 1 |
| Comparison groups | Group 2, ASP3772 Medium Dose v Comparator PCV13 |
| Number of subjects included in analysis | 44 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 10.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -15.2 |
| upper limit | 26.6 |

| | |
|---|---|
| Statistical analysis title | Serotype 23F, Day 1 |
| Comparison groups | Group 3, ASP3772 High Dose v Comparator PCV13 |
| Number of subjects included in analysis | 45 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in proportion |
| Point estimate | 10.3 |

| Confidence interval | |
|---------------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.1 |
| upper limit | 26.6 |

Secondary: Geometric Mean Titer (GMT) for Serotype-specific OPA

| | |
|-----------------|--|
| End point title | Geometric Mean Titer (GMT) for Serotype-specific OPA |
|-----------------|--|

End point description:

Immunogenicity was measured in terms of OPA GMTs and expressed as titers.

Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At Day 1 and Day 30

| End point values | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose | Comparator PCV13 |
|--|---------------------------------|------------------------------------|----------------------------------|----------------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 15 | 15 | 16 | 29 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1, Day1 (N=15,13,16,28) | 10.2 (5.7 to 18.2) | 15.9 (6.5 to 39.4) | 20.7 (9.9 to 42.9) | 10.1 (6.0 to 17.3) |
| Serotype 1, Day30 (N=14,13,13,26) | 54.7 (21.0 to 142.4) | 170.5 (67.2 to 432.1) | 172.8 (70.3 to 424.8) | 188.6 (120.5 to 295.1) |
| Serotype 3, Day1 (N=15,13,16,28) | 55.4 (32.8 to 93.4) | 101.7 (51.8 to 199.7) | 118.4 (70.2 to 199.8) | 125.0 (81.9 to 191.0) |
| Serotype 3, Day30 (N=13,15,14,25) | 339.1 (273.6 to 420.1) | 467.1 (318.1 to 686.1) | 692.5 (386.3 to 1241.4) | 450.1 (338.4 to 598.6) |
| Serotype 4, Day1 (N=14,12,16,28) | 32.6 (11.6 to 91.3) | 83.9 (24.2 to 290.7) | 130.4 (46.9 to 363.2) | 51.5 (26.2 to 101.4) |
| Serotype 4, Day30 (N=12,15,15,25) | 427.5 (230.2 to 794.0) | 1142.5 (725.1 to 1800.1) | 1071.8 (541.2 to 2122.6) | 2217.0 (1685.4 to 2916.3) |
| Serotype 5, Day1 (N=13,14,16,29) | 119.0 (76.9 to 184.1) | 158.2 (48.0 to 521.3) | 192.5 (81.3 to 455.9) | 52.9 (28.4 to 98.5) |
| Serotype 5, Day30 (N=14,14,12,25) | 694.4 (336.7 to 1432.1) | 978.1 (385.3 to 2483.2) | 984.3 (410.9 to 2357.7) | 797.8 (503.7 to 1263.5) |
| Serotype 6A, Day1 (N=13,14,16,29) | 1664.2 (1005.7 to 2753.9) | 983.7 (402.5 to 2404.3) | 938.2 (373.1 to 2359.5) | 816.7 (490.6 to 1359.6) |
| Serotype 6A, Day30 (N=14,15,15,24) | 2790.1 (1995.2 to 3901.6) | 3312.4 (2221.4 to 4939.3) | 2471.5 (1219.7 to 5008.1) | 9502.0 (6137.0 to 14712.1) |
| Serotype 6B, Day1 (N=15,14,16,27) | 412.3 (148.9 to 1141.1) | 241.4 (82.3 to 707.8) | 236.2 (73.0 to 764.9) | 150.5 (65.3 to 347.1) |
| Serotype 6B, Day30 (N=13,15,15,25) | 1955.8 (1128.5 to 3389.3) | 1489.5 (999.2 to 2220.6) | 1387.4 (582.6 to 3304.3) | 5134.9 (3428.0 to 7691.9) |

| | | | | |
|-------------------------------------|---------------------------|---------------------------|---------------------------|-----------------------------|
| Serotype 7F, Day1 (N=15,14,16,29) | 1409.4 (829.6 to 2394.6) | 1075.6 (526.7 to 2196.3) | 1077.1 (640.3 to 1811.7) | 1436.1 (1003.0 to 2056.3) |
| Serotype 7F, Day30 (N=11,15,15,22) | 2326.1 (1260.9 to 4291.2) | 2615.8 (1539.4 to 4444.9) | 2563.5 (1338.0 to 4911.3) | 8442.5 (4987.7 to 14290.3) |
| Serotype 9V, Day1 (N=12,12,15,23) | 2311.2 (872.7 to 6120.6) | 360.7 (60.3 to 2158.4) | 602.2 (219.2 to 1654.6) | 345.0 (134.4 to 885.3) |
| Serotype 9V, Day30 (N=12,13,15,24) | 4080.3 (2654.5 to 6271.9) | 3636.3 (1908.0 to 6930.2) | 2347.9 (1429.3 to 3856.9) | 5142.6 (3544.9 to 7460.3) |
| Serotype 14, Day1 (N=14,14,16,27) | 259.6 (90.5 to 744.6) | 650.6 (302.7 to 1398.2) | 489.4 (187.5 to 1277.7) | 476.8 (270.1 to 841.7) |
| Serotype 14, Day30 (N=13,15,15,24) | 556.9 (201.3 to 1540.8) | 1842.4 (1124.2 to 3019.6) | 1090.4 (440.0 to 2702.7) | 2922.4 (1985.7 to 4300.8) |
| Serotype 18C, Day1 (N=14,12,16,28) | 249.4 (93.6 to 664.9) | 267.4 (67.3 to 1061.6) | 276.6 (105.2 to 726.8) | 229.4 (118.6 to 443.6) |
| Serotype 18C, Day30 (N=11,15,15,25) | 1481.9 (935.7 to 2347.0) | 1772.6 (1132.9 to 2773.4) | 1935.4 (1042.9 to 3591.9) | 5268.2 (3876.1 to 7160.3) |
| Serotype 19A, Day1 (N=14,13,16,28) | 177.7 (59.9 to 526.6) | 241.8 (80.3 to 728.1) | 320.0 (137.5 to 744.7) | 176.3 (88.6 to 350.6) |
| Serotype 19A, Day30 (N=14,15,15,26) | 1851.6 (1055.9 to 3246.7) | 2621.7 (1802.2 to 3813.8) | 1919.7 (1040.0 to 3543.5) | 5801.8 (4546.2 to 7404.1) |
| Serotype 19F, Day1 (N=11,14,16,27) | 373.2 (175.9 to 791.9) | 326.3 (97.5 to 1091.4) | 315.6 (118.1 to 843.4) | 230.3 (111.0 to 477.7) |
| Serotype 19F, Day30 (N=14,14,15,23) | 1998.7 (1328.7 to 3006.4) | 2601.4 (1776.3 to 3809.6) | 2704.6 (1412.0 to 5180.5) | 4678.9 (3559.7 to 6150.1) |
| Serotype 23F, Day1 (N=15,12,16,29) | 760.1 (310.7 to 1859.1) | 766.4 (260.2 to 2257.6) | 1005.8 (423.8 to 2386.8) | 410.5 (189.4 to 889.5) |
| Serotype 23F, Day30 (N=13,15,15,23) | 1711.8 (1118.0 to 2620.9) | 1702.5 (1104.1 to 2625.3) | 3462.8 (1320.2 to 9082.4) | 12510.5 (7488.7 to 20900.0) |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs were collected from Day 1 to Day 180 (study end). Non-serious adverse events were collected from Day 1 to Day 30.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 23.0 |

Reporting groups

| | |
|-----------------------|---------------------------|
| Reporting group title | Group 1, ASP3772 Low Dose |
|-----------------------|---------------------------|

Reporting group description:

Healthy toddlers aged approximately 12 to 15 months received a single intramuscular (IM) injection of low dose of ASP3772 into anterolateral right or left thigh muscle on Day 1.

| | |
|-----------------------|------------------------------|
| Reporting group title | Group 2, ASP3772 Medium Dose |
|-----------------------|------------------------------|

Reporting group description:

Healthy toddlers approximately 12 to 15 months received a single IM injection of medium dose of ASP3772 into anterolateral right or left thigh muscle on Day 1.

| | |
|-----------------------|----------------------------|
| Reporting group title | Group 3, ASP3772 High Dose |
|-----------------------|----------------------------|

Reporting group description:

Healthy toddlers approximately 12 to 15 months received a single IM injection of high dose of ASP3772 into anterolateral right or left thigh muscle on Day 1.

| | |
|-----------------------|------------------|
| Reporting group title | PCV13 Comparator |
|-----------------------|------------------|

Reporting group description:

Healthy toddlers aged approximately 12 to 15 months received a single IM injection of approved dose of PCV13 into anterolateral right or left thigh muscle on Day 1.

| Serious adverse events | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose |
|---|------------------------------|---------------------------------|-------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 0 / 16 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Seizure | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 0 / 16 (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 | | | |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 0 / 16 (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 |

| Serious adverse events | PCV13 Comparator | | |
|---|------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 29 (6.90%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Nervous system disorders | | | |
| Seizure | | | |
| subjects affected / exposed | 1 / 29 (3.45%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 1 / 29 (3.45%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | Group 1, ASP3772 Low Dose | Group 2, ASP3772 Medium Dose | Group 3, ASP3772 High Dose |
|---|------------------------------|---------------------------------|-------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4 / 15 (26.67%) | 4 / 15 (26.67%) | 9 / 16 (56.25%) |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Exposure to SARS-CoV-2 | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 1 / 15 (6.67%) | 1 / 16 (6.25%) |
| occurrences (all) | 1 | 1 | 1 |

| | | | |
|---|-----------------|----------------|-----------------|
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 0 | 0 | 2 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 15 (6.67%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 1 | 1 |
| Teething | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 1 / 15 (6.67%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 15 (6.67%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting projectile | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 15 (6.67%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal congestion | | | |
| subjects affected / exposed | 2 / 15 (13.33%) | 1 / 15 (6.67%) | 0 / 16 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Cough | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 15 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |

| | | | |
|------------------------------------|----------------|----------------|----------------|
| Irritability | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 15 (6.67%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 15 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 15 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 15 (6.67%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 15 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 15 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ear infection | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 15 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|------------------|--|--|
| Non-serious adverse events | PCV13 Comparator | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 9 / 29 (31.03%) | | |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Exposure to SARS-CoV-2 | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 29 (3.45%) | | |
| occurrences (all) | 1 | | |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 29 (3.45%) | | |
| occurrences (all) | 1 | | |
| Teething | | | |
| subjects affected / exposed | 2 / 29 (6.90%) | | |
| occurrences (all) | 2 | | |
| Flatulence | | | |
| subjects affected / exposed | 1 / 29 (3.45%) | | |
| occurrences (all) | 1 | | |
| Vomiting projectile | | | |

| | | | |
|--|---------------------|--|--|
| subjects affected / exposed occurrences (all) | 0 / 29 (0.00%) 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cough | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wheezing | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 2 / 29 (6.90%) | | |
| occurrences (all) | 2 | | |
| Psychiatric disorders | | | |
| Irritability | | | |
| subjects affected / exposed | 1 / 29 (3.45%) | | |
| occurrences (all) | 1 | | |
| Insomnia | | | |
| subjects affected / exposed | 2 / 29 (6.90%) | | |
| occurrences (all) | 2 | | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 29 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---------------------|--|--|
| Hand-foot-and-mouth disease subjects affected / exposed occurrences (all) | 0 / 29 (0.00%) 0 | | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 0 / 29 (0.00%) 0 | | |
| Otitis media subjects affected / exposed occurrences (all) | 0 / 29 (0.00%) 0 | | |
| Otitis media acute subjects affected / exposed occurrences (all) | 1 / 29 (3.45%) 1 | | |
| Pharyngitis subjects affected / exposed occurrences (all) | 0 / 29 (0.00%) 0 | | |
| Viral infection subjects affected / exposed occurrences (all) | 1 / 29 (3.45%) 1 | | |
| Ear infection subjects affected / exposed occurrences (all) | 0 / 29 (0.00%) 0 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 21 February 2020 | <ul style="list-style-type: none"><li data-bbox="418 360 1426 450">• The objectives were reorganized such that comparison of the GMT for functional OPA for each serotype post-vaccination was moved from the exploratory to the secondary list of objectives.<li data-bbox="418 450 1426 539">• The list of exclusion criteria was updated to include the exclusion of subjects who had previously received an approved (other than PCV13) or investigational pneumococcal vaccine. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported