

**Clinical trial results:**

Phase 2, Observer-Blind, Placebo-Controlled, Randomized, Multi-Center Extension Study to Evaluate the Safety and Immunogenicity of a Booster Dose of a MenABCWY Vaccine Administered 24 Months Following the Primary Series to Adolescents and Young Adults Who Participated in V102_03.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2012-003937-41 |
| Trial protocol | PL |
| Global end of trial date | 17 April 2015 |

Results information

| | |
|--------------------------------|---|
| Result version number | v2 (current) |
| This version publication date | 23 October 2016 |
| First version publication date | 30 April 2016 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Correction of data required. Moreover, a back-up user needs to be assigned as the sponsorship is now changed for the study. |

Trial information**Trial identification**

| | |
|-----------------------|-----------|
| Sponsor protocol code | V102_03E1 |
|-----------------------|-----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01992536 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | GlaxoSmithKline Biologicals |
| Sponsor organisation address | Rue de l'Institut 89, Rixensart, Belgium, B-1330 |
| Public contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-001260-PIP01-11 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No | Yes |

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 17 April 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 30 May 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 17 April 2015 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

1. To evaluate the immune response against meningococcal serogroups A, C, W and Y as measured by percentage of subjects having seroresponse at Day 30 following administration of a booster dose of MenABCWY in subjects who previously received the same vaccine formulation in study V102_03.

2. To evaluate the immune response against strains of serogroup B as measured by percentage of subjects having human serum bactericidal activity (hSBA) titers $\geq 1:5$ at Day 30 following administration of a booster dose of MenABCWY in subjects who previously received the same vaccine formulation in study V102_03.

Seroresponse to N. meningitidis serogroups A, C, W and Y is defined as:

- For subjects with a pre-vaccination hSBA titer $< 1:4$, a post-vaccination hSBA titer $\geq 1:8$.
- For subjects with a pre-vaccination hSBA titer $\geq 1:4$, an increase in hSBA titer of at least four times the pre-vaccination titer.

Protection of trial subjects:

This clinical study was designed and shall be implemented and reported in accordance with the International Conference on Harmonisation of Technical requirements (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), with applicable local regulations including European Directive 2001/20/EC and US Code of Federal Regulations (CFR) Title 21 and with the ethical principles laid down in the Declaration of Helsinki (European Council 2001, US CFR, ICH 1997).

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 16 December 2013 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects**Subjects enrolled per country**

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United States: 117 |
| Country: Number of subjects enrolled | Poland: 77 |
| Worldwide total number of subjects | 194 |
| EEA total number of subjects | 77 |

Notes:

| Subjects enrolled per age group | |
|---|----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 95 |
| Adults (18-64 years) | 99 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 5 study sites in Poland and from 8 study sites in US.

Pre-assignment

Screening details:

All enrolled subjects were included in the study.

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, Monitor, Data analyst, Assessor |

Blinding implementation details:

Observer blind

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|----------|
| Arm title | 2OMV_OMV |
|------------------|----------|

Arm description:

Subjects who previously received two doses of MenABCWY + outer membrane vesicle (OMV) in the parent study, received one booster dose of same vaccine in this study.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + OMV NZ) liquid suspension |
| Investigational medicinal product code | MenACWY + rMenB + OMV NZ |
| Other name | |
| Pharmaceutical forms | Powder and suspension for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL

| | |
|------------------|----------|
| Arm title | 2OMV_Pbo |
|------------------|----------|

Arm description:

Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one dose of saline solution in this study.

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

Dosage and administration details:

0.5 mL

| | |
|------------------|------------|
| Arm title | 2qOMV_qOMV |
|------------------|------------|

Arm description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one booster dose of same vaccine in this study.

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

| | |
|--|--|
| Investigational medicinal product name | Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + ¼ OMV NZ) liquid suspension |
| Investigational medicinal product code | MenACWY + rMenB + ¼ OMV NZ |
| Other name | |
| Pharmaceutical forms | Powder and suspension for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL

| | |
|------------------|-----------|
| Arm title | 2qOMV_Pbo |
|------------------|-----------|

Arm description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one dose of saline solution in this study.

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

Dosage and administration details:

0.5 mL

| | |
|------------------|--------|
| Arm title | 2B_OMV |
|------------------|--------|

Arm description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + OMV in this study.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + OMV NZ) liquid suspension |
| Investigational medicinal product code | MenACWY + rMenB + OMV NZ |
| Other name | |
| Pharmaceutical forms | Powder and suspension for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL

| | |
|------------------|---------|
| Arm title | 2B_qOMV |
|------------------|---------|

Arm description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + ¼ OMV NZ) liquid suspension |
| Investigational medicinal product code | MenACWY + rMenB + ¼ OMV NZ |
| Other name | |
| Pharmaceutical forms | Powder and suspension for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL

| | |
|------------------|--------|
| Arm title | 1M_OMV |
|------------------|--------|

Arm description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + OMV in this study.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Combined MenACWY vaccine (MenACWY lyophilized) + (rMenB + OMV NZ) liquid suspension |
| Investigational medicinal product code | MenACWY + rMenB + OMV NZ |
| Other name | |
| Pharmaceutical forms | Powder and suspension for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL

| | |
|------------------|---------|
| Arm title | 1M_qOMV |
|------------------|---------|

Arm description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenACWY + ¼ OMV in this study.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Combined MenACWY vaccine (MenACWY lyophilized) + (rMenB + ¼ OMV NZ) liquid suspension |
| Investigational medicinal product code | MenACWY + rMenB + ¼ OMV NZ |
| Other name | |
| Pharmaceutical forms | Powder and suspension for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL

| | |
|------------------|--------|
| Arm title | 1M_Pbo |
|------------------|--------|

Arm description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of saline solution in this study.

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

Dosage and administration details:

0.5 mL

| | |
|------------------|--------|
| Arm title | 2B_Pbo |
|------------------|--------|

Arm description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of Placebo in this study.

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

Dosage and administration details:

0.5 mL

| Number of subjects in period 1^[1] | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV |
|---|----------|----------|------------|
| Started | 26 | 25 | 17 |
| Completed | 22 | 22 | 16 |
| Not completed | 4 | 3 | 1 |
| Consent withdrawn by subject | - | 1 | - |
| Lost to follow-up | 4 | 2 | 1 |
| Administrative reason | - | - | - |

| Number of subjects in period 1^[1] | 2qOMV_Pbo | 2B_OMV | 2B_qOMV |
|---|-----------|--------|---------|
| Started | 24 | 11 | 21 |
| Completed | 22 | 11 | 20 |
| Not completed | 2 | 0 | 1 |
| Consent withdrawn by subject | 2 | - | - |
| Lost to follow-up | - | - | 1 |
| Administrative reason | - | - | - |

| Number of subjects in period 1^[1] | 1M_OMV | 1M_qOMV | 1M_Pbo |
|---|--------|---------|--------|
| Started | 21 | 19 | 19 |
| Completed | 21 | 18 | 18 |
| Not completed | 0 | 1 | 1 |
| Consent withdrawn by subject | - | - | - |
| Lost to follow-up | - | 1 | 1 |
| Administrative reason | - | - | - |

| Number of subjects in period 1^[1] | 2B_Pbo |
|---|--------|
| Started | 7 |
| Completed | 0 |
| Not completed | 7 |
| Consent withdrawn by subject | - |
| Lost to follow-up | - |
| Administrative reason | 7 |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Four subjects in the 194 enrolled were not assigned to any treatment and therefore were not included in any group.

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | 2OMV_OMV |
|-----------------------|----------|

Reporting group description:

Subjects who previously received two doses of MenABCWY + outer membrane vesicle (OMV) in the parent study, received one booster dose of same vaccine in this study.

| | |
|-----------------------|----------|
| Reporting group title | 2OMV_Pbo |
|-----------------------|----------|

Reporting group description:

Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one dose of saline solution in this study.

| | |
|-----------------------|------------|
| Reporting group title | 2qOMV_qOMV |
|-----------------------|------------|

Reporting group description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one booster dose of same vaccine in this study.

| | |
|-----------------------|-----------|
| Reporting group title | 2qOMV_Pbo |
|-----------------------|-----------|

Reporting group description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one dose of saline solution in this study.

| | |
|-----------------------|--------|
| Reporting group title | 2B_OMV |
|-----------------------|--------|

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + OMV in this study.

| | |
|-----------------------|---------|
| Reporting group title | 2B_qOMV |
|-----------------------|---------|

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

| | |
|-----------------------|--------|
| Reporting group title | 1M_OMV |
|-----------------------|--------|

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + OMV in this study.

| | |
|-----------------------|---------|
| Reporting group title | 1M_qOMV |
|-----------------------|---------|

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

| | |
|-----------------------|--------|
| Reporting group title | 1M_Pbo |
|-----------------------|--------|

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of saline solution in this study.

| | |
|-----------------------|--------|
| Reporting group title | 2B_Pbo |
|-----------------------|--------|

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of Placebo in this study.

| Reporting group values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV |
|------------------------|----------|----------|------------|
| Number of subjects | 26 | 25 | 17 |

| | | | |
|--|----------------|----------------|--------------|
| Age categorical Units: Subjects | | | |
| Age continuous Units: months arithmetic mean standard deviation | 18.8 ± 5.19 | 17.1 ± 4.31 | 18 ± 5.05 |
| Gender categorical Units: Subjects | | | |
| Female | 8 | 13 | 9 |
| Male | 18 | 12 | 8 |

| | | | |
|------------------------------------|-----------|--------|---------|
| Reporting group values | 2qOMV_Pbo | 2B_OMV | 2B_qOMV |
| Number of subjects | 24 | 11 | 21 |
| Age categorical Units: Subjects | | | |

| | | | |
|--|-------------|----------------|----------------|
| Age continuous Units: months arithmetic mean standard deviation | 19 ± 5.4 | 20.9 ± 3.99 | 19.7 ± 5.36 |
| Gender categorical Units: Subjects | | | |
| Female | 14 | 2 | 15 |
| Male | 10 | 9 | 6 |

| | | | |
|------------------------------------|--------|---------|--------|
| Reporting group values | 1M_OMV | 1M_qOMV | 1M_Pbo |
| Number of subjects | 21 | 19 | 19 |
| Age categorical Units: Subjects | | | |

| | | | |
|--|----------------|---------------|----------------|
| Age continuous Units: months arithmetic mean standard deviation | 16.8 ± 4.65 | 19.2 ± 6.1 | 17.6 ± 5.19 |
| Gender categorical Units: Subjects | | | |
| Female | 12 | 12 | 11 |
| Male | 9 | 7 | 8 |

| | | | |
|------------------------------------|--------|-------|--|
| Reporting group values | 2B_Pbo | Total | |
| Number of subjects | 7 | 190 | |
| Age categorical Units: Subjects | | | |

| | | | |
|--|----------------|---|--|
| Age continuous Units: months arithmetic mean standard deviation | 17.9 ± 4.67 | - | |
|--|----------------|---|--|

| | | | |
|--------------------|---|----|--|
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 3 | 99 | |
| Male | 4 | 91 | |

End points

End points reporting groups

| | |
|---|--------------------|
| Reporting group title | 2OMV_OMV |
| Reporting group description: Subjects who previously received two doses of MenABCWY + outer membrane vesicle (OMV) in the parent study, received one booster dose of same vaccine in this study. | |
| Reporting group title | 2OMV_Pbo |
| Reporting group description: Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one dose of saline solution in this study. | |
| Reporting group title | 2qOMV_qOMV |
| Reporting group description: Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one booster dose of same vaccine in this study. | |
| Reporting group title | 2qOMV_Pbo |
| Reporting group description: Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one dose of saline solution in this study. | |
| Reporting group title | 2B_OMV |
| Reporting group description: Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + OMV in this study. | |
| Reporting group title | 2B_qOMV |
| Reporting group description: Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + ¼ OMV in this study. | |
| Reporting group title | 1M_OMV |
| Reporting group description: Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + OMV in this study. | |
| Reporting group title | 1M_qOMV |
| Reporting group description: Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + ¼ OMV in this study. | |
| Reporting group title | 1M_Pbo |
| Reporting group description: Subjects who previously received one dose of MenACWY in the parent study, received one dose of saline solution in this study. | |
| Reporting group title | 2B_Pbo |
| Reporting group description: Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of Placebo in this study. | |
| Subject analysis set title | All Enrolled |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: All screened subjects who have been enrolled (i.e., attended the first clinic visit and received a subject ID). | |
| Subject analysis set title | Exposed |

| | |
|--|--|
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: All subjects in the Enrolled Population, who received a study vaccination. | |
| Subject analysis set title | Full Analysis Set (FAS) Day 1 (Persistence) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: All subjects in the enrolled population who provided an evaluable serum sample at Visit Day 1. | |
| Subject analysis set title | Full Analysis Set (FAS) Day 30 (Booster) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: All subjects in the enrolled population who were randomised, received the study vaccination in the current study and provided an evaluable serum sample at Visit Day 30 (for Seroresponse, Day 1 and Day 30 samples). | |
| Subject analysis set title | Full Analysis Set (FAS) Day 365 (Persistence of Booster) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: All subjects in the enrolled population who were randomised, received the study vaccination in the current study and provided an evaluable serum sample at Visit Day 365. | |
| Subject analysis set title | Safety set (Solicited AEs) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: All subjects in the Exposed Set with any solicited adverse event (AE) data. | |
| Subject analysis set title | Safety set (Unsolicited AEs) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: All subjects in the Exposed Set with unsolicited AE data. | |
| Subject analysis set title | Safety set (overall) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: All subjects in the exposed population who have either post-vaccination adverse event or safety records. | |
| Subject analysis set title | ABCWY+OMV |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects received two doses of MenABCWY+OMV administered two months apart in parent study. | |
| Subject analysis set title | ABCWY+qOMV |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects received two doses of MenABCWY+qOMV administered two months apart in parent study. | |
| Subject analysis set title | rMenB+OMV |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects received two doses of rMenB + OMV, administered two months apart in parent study. | |
| Subject analysis set title | Menveo |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: Subjects received one dose of placebo followed by one dose of MenACWY administered two months apart in parent study. | |

Primary: 1. Percentages of subjects with HT-hSBA seroresponse against N. meningitidis serogroups A, C, W and Y.

| | |
|-----------------|--|
| End point title | 1. Percentages of subjects with HT-hSBA seroresponse against N. meningitidis serogroups A, C, W and Y. ^{[1][2]} |
|-----------------|--|

End point description:

Percentages of subjects having HT-hSBA seroresponse against N. meningitidis serogroups A, C, W and Y, following administration of a booster dose of MenABCWY in the present study, in subjects who previously received the same MenABCWY vaccine formulation in study V102_03.

Seroresponse to N. meningitidis serogroups A, C, W and Y is defined as: for subjects with a pre-vaccination hSBA titer < 1:4, a post-vaccination hSBA titer ≥ 1:8; for subjects with a pre-vaccination hSBA titer ≥ 1:4, an increase in hSBA titer of at least four times the pre-vaccination titer.

Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, day 1 and day 30 samples were required).

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

End point timeframe:

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: The scope of this endpoint was descriptive, no statistical analyses were conducted.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2qOMV_qOMV | | |
|----------------------------------|-------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 25 | 16 | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A | 96 (79.6 to 99.9) | 94 (69.8 to 99.84) | | |
| Men C | 85 (62.1 to 96.8) | 100 (69.2 to 100) | | |
| Men W | 85 (62.1 to 96.8) | 85 (54.6 to 98.1) | | |
| Men Y | 96 (79.6 to 99.9) | 100 (76.8 to 100) | | |

Statistical analyses

No statistical analyses for this end point

Primary: 2. Percentage of subjects with HT-hSBA titers ≥ 1:5 against strains of N. meningitidis serogroup B.

| | |
|-----------------|---|
| End point title | 2. Percentage of subjects with HT-hSBA titers ≥ 1:5 against strains of N. meningitidis serogroup B. ^{[3][4]} |
|-----------------|---|

End point description:

Percentage of subjects reporting HT-hSBA titers ≥ 1:5 against strains of N. meningitidis serogroup B at Day 1 (24 months after the last vaccination in the primary series of study V102_03) and one month (Day 30) following administration of a booster dose of MenABCWY in the present study, in subjects who previously received the same MenABCWY vaccine formulation in study V102_03.

Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

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

End point timeframe:

Day 1 and Day 30

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: The scope of this endpoint was descriptive, no statistical analyses were conducted.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2qOMV_qOMV | | |
|----------------------------------|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 25 | 17 | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 24 (9.4 to 45.1) | 7 (0.17 to 31.9) | | |
| M14459 (fHBP) (Day 30) | 92 (74 to 99) | 88 (63.6 to 98.5) | | |
| M01-0240364 (NadA) (Day 1) | 25 (9.8 to 46.7) | 20 (4.3 to 48.1) | | |
| M01-0240364 (NadA) (Day 30) | 100 (86.3 to 100) | 100 (80.5 to 100) | | |
| NZ98/254 (PorA) (Day 1) | 16 (4.5 to 36.1) | 7 (0.17 to 31.9) | | |
| NZ98/254 (PorA) (Day 30) | 92 (74 to 99) | 71 (44 to 89.7) | | |
| M07-0241084 (NHBA) (Day 1) | 36 (18 to 57.5) | 27 (7.8 to 55.1) | | |
| M07-0241084 (NHBA) (Day 30) | 100 (86.3 to 100) | 88 (63.6 to 98.5) | | |
| H44/76 (fHBP) (Day 1) | 16 (4.5 to 36.1) | 13 (1.6 to 38.3) | | |
| H44/76 (fHBP) (Day 30) | 96 (79.6 to 99.9) | 100 (80.5 to 100) | | |
| 5/99 (NadA) (Day 1) | 76 (54.9 to 90.6) | 87 (59.5 to 98.3) | | |
| 5/99 (NadA) (Day 30) | 100 (86.3 to 100) | 100 (80.5 to 100) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 3. Percentage of subjects with HT-hSBA titer \geq 1:8 to N. meningitidis serogroups A, C, W, Y.

| | |
|-----------------|---|
| End point title | 3. Percentage of subjects with HT-hSBA titer \geq 1:8 to N. meningitidis serogroups A, C, W, Y. |
|-----------------|---|

End point description:

Percentage of subjects with HT-hSBA titer \geq 1:8 in serogroups A, C, W, Y against N. meningitidis assessed prior to the administration of MenABCWY booster vaccination or placebo.

Pre vaccination is 24 months after completion of the primary vaccination series, in subjects who previously received the same vaccine formulation in study V102_03.

Analysis was done on FAS Day 1 (Persistence) population. All subjects in the enrolled population who provided an evaluable serum sample at Day 1.

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

End point timeframe:

Day 1 (Pre vaccination)

| End point values | ABCWY+OMV | ABCWY+qOMV | rMenB+OMV | Menveo |
|----------------------------------|----------------------|----------------------|----------------------|----------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 51 | 40 | 38 | 59 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 27 (15.9 to 41.7) | 28 (14.6 to 43.9) | 29 (15.4 to 45.9) | 31 (19.5 to 44.5) |
| Men C (Day 1) | 67 (51.6 to 79.6) | 68 (51.3 to 82.5) | 45 (28.6 to 61.7) | 57 (43.2 to 69.8) |
| Men W (Day 1) | 92 (80.8 to 97.8) | 75 (57.8 to 87.9) | 76 (59.8 to 88.6) | 68 (54 to 79.7) |
| Men Y (Day 1) | 65 (50.1 to 77.6) | 50 (33.4 to 66.6) | 16 (6 to 31.3) | 46 (32.7 to 59.2) |

Statistical analyses

No statistical analyses for this end point

Secondary: 4. Percentage of subjects with HT-hSBA titer \geq 1:5 to N. meningitidis strains of serogroup B.

| | |
|--|--|
| End point title | 4. Percentage of subjects with HT-hSBA titer \geq 1:5 to N. meningitidis strains of serogroup B. |
| End point description: | |
| Percentage of subjects with HT-hSBA titer \geq 1:5 against N. meningitidis strains of serogroup B assessed prior to the administration of MenABCWY booster vaccination or placebo. | |
| Pre vaccination is 24 months after completion of the primary vaccination series, in subjects who previously received the same vaccine formulation in study V102_03. | |
| Analysis was done on FAS Day 1 (Persistence) population. All subjects in the enrolled population who provided an evaluable serum sample at Day 1. | |
| End point type | Secondary |
| End point timeframe: | |
| Day 1 (Pre vaccination) | |

| End point values | ABCWY+OMV | ABCWY+qOMV | rMenB+OMV | Menveo |
|----------------------------------|----------------------|----------------------|----------------------|----------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 51 | 39 | 38 | 59 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 29 (17.5 to 43.8) | 13 (4.3 to 27.4) | 26 (13.4 to 43.1) | 14 (6 to 25) |
| M01-0240364 (NadA) (Day 1) | 24 (13.1 to 38.2) | 16 (6.2 to 32) | 35 (20.2 to 52.5) | 7 (1.9 to 16.7) |
| NZ98/254 (PorA) (Day 1) | 24 (12.8 to 37.5) | 8 (1.6 to 20.9) | 16 (6 to 31.3) | 3 (0.41 to 11.7) |
| M07-0241084 (NHBA) (Day 1) | 37 (24.1 to 51.9) | 29 (15.4 to 45.9) | 50 (33.4 to 66.6) | 22 (12.3 to 34.7) |

| | | | | |
|-----------------------|-------------------|-------------------|-------------------|------------------|
| H44/76 (fHBP) (Day 1) | 22 (11.3 to 35.3) | 18 (7.5 to 33.5) | 34 (19.6 to 51.4) | 3 (0.41 to 11.7) |
| 5/99 (NadA) (Day 1) | 76 (62.5 to 87.2) | 87 (71.9 to 95.6) | 94 (81.3 to 99.3) | 19 (9.7 to 30.9) |

Statistical analyses

No statistical analyses for this end point

Secondary: 5. The HT-hSBA geometric mean titers (GMTs) against N. meningitidis serogroups A, C, W, Y.

| | |
|-----------------|--|
| End point title | 5. The HT-hSBA geometric mean titers (GMTs) against N. meningitidis serogroups A, C, W, Y. |
|-----------------|--|

End point description:

The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y prior to the administration of MenABCWY booster vaccination or placebo.

Pre vaccination is 24 months after completion of the primary vaccination series, in subjects who previously received the same vaccine formulation in study V102_03.

Analysis was done on FAS Day 1 (Persistence) population. All subjects in the enrolled population who provided an evaluable serum sample at Day 1.

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

End point timeframe:

Day 1 (Pre vaccination)

| End point values | ABCWY+OMV | ABCWY+qOMV | rMenB+OMV | Menveo |
|--|----------------------|----------------------|----------------------|----------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 51 | 40 | 38 | 59 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Men A (Day 1) | 3.34 (2.19 to 5.08) | 3.3 (1.95 to 5.6) | 2.96 (1.7 to 5.17) | 4.14 (2.75 to 6.23) |
| Men C (Day 1) | 18 (11 to 30) | 13 (8 to 20) | 6.05 (4.28 to 8.55) | 10 (6.36 to 17) |
| Men W (Day 1) | 35 (24 to 52) | 23 (12 to 45) | 20 (11 to 34) | 17 (9.65 to 29) |
| Men Y (Day 1) | 13 (7.01 to 23) | 8.85 (4.24 to 18) | 1.8 (1.25 to 2.6) | 6.49 (3.72 to 11) |

Statistical analyses

No statistical analyses for this end point

Secondary: 6. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

| | |
|-----------------|---|
| End point title | 6. The HT-hSBA GMTs against N. meningitidis strains of serogroup B. |
|-----------------|---|

End point description:

The HT-hSBA GMTs against N. meningitidis strains of serogroup B prior the administration of MenABCWY booster vaccination or placebo.

Pre vaccination is 24 months after completion of the primary vaccination series, in subjects who previously received the same vaccine formulation in study V102_03.
Analysis was done on the FAS Day 1 (Persistence) population. All subjects in the enrolled population who provided an evaluable serum sample at Day 1.

| | |
|-------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 1 (Pre vaccination) | |

| End point values | ABCWY+OMV | ABCWY+qOMV | rMenB+OMV | Menveo |
|--|----------------------|----------------------|----------------------|----------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 51 | 39 | 38 | 59 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) | 2.67 (1.92 to 3.7) | 1.94 (1.48 to 2.56) | 2.82 (2 to 3.96) | 1.87 (1.43 to 2.43) |
| M01-0240364 (NadA) | 2.67 (1.7 to 4.2) | 2.1 (1.21 to 3.65) | 4.72 (2.44 to 9.13) | 1.37 (1.06 to 1.78) |
| NZ98/254 (PorA) | 2.03 (1.43 to 2.89) | 1.46 (1.15 to 1.85) | 1.75 (1.24 to 2.47) | 1.16 (1 to 1.34) |
| M07-0241084 (NHBA) | 3.76 (2.55 to 5.56) | 2.42 (1.7 to 3.45) | 4.56 (2.97 to 7.01) | 2.35 (1.68 to 3.28) |
| H44/76 (fHBP) | 2.54 (1.69 to 3.82) | 1.78 (1.26 to 2.53) | 3.22 (2.18 to 4.76) | 1.32 (1.06 to 1.65) |
| 5/99 (NadA) | 16 (11 to 24) | 33 (19 to 54) | 39 (25 to 62) | 2.46 (1.73 to 3.51) |

Statistical analyses

No statistical analyses for this end point

Secondary: 7. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.

| | |
|-----------------|---|
| End point title | 7. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y. ^[5] |
|-----------------|---|

End point description:

The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y at Day 1 and one month after the administration of MenABCWY booster vaccination or placebo.
Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

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

End point timeframe:

Day 1 and Day 30

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|--|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 25 | 16 | 23 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Men A (Day 1) | 3.41 (1.87 to 6.22) | 2.92 (1.59 to 5.36) | 2.86 (1.23 to 6.63) | 2.73 (1.41 to 5.27) |
| Men A (Day 30) | 259 (174 to 383) | 4.28 (2.03 to 9.03) | 333 (199 to 559) | 3.07 (1.51 to 6.25) |
| Men C (Day 1) | 23 (9.45 to 57) | 16 (7.06 to 36) | 17 (5.98 to 51) | 11 (6.24 to 19) |
| Men C (Day 30) | 660 (401 to 1084) | 17 (7.6 to 38) | 612 (245 to 1524) | 11 (5.51 to 22) |
| Men W (Day 1) | 34 (20 to 59) | 33 (17 to 65) | 30 (8.9 to 101) | 18 (7.3 to 46) |
| Men W (Day 30) | 792 (516 to 1216) | 34 (16 to 71) | 880 (671 to 1154) | 26 (11 to 59) |
| Men Y (Day 1) | 10 (4.89 to 21) | 15 (5.5 to 43) | 15 (4.33 to 53) | 5.66 (2.25 to 14) |
| Men Y (Day 30) | 464 (294 to 734) | 16 (5.65 to 48) | 697 (435 to 1116) | 5.17 (2.16 to 12) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|--|---------------------|---------------------|-------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 18 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Men A (Day 1) | 2.26 (0.96 to 5.31) | 3.94 (1.58 to 9.85) | 6.62 (2.85 to 15) | 2.09 (1.28 to 3.41) |
| Men A (Day 30) | 438 (287 to 670) | 416 (198 to 871) | 138 (84 to 229) | 46 (24 to 87) |
| Men C (Day 1) | 5.45 (2.41 to 12) | 9.02 (5.24 to 16) | 7.75 (4.19 to 14) | 7.53 (2.38 to 24) |
| Men C (Day 30) | 292 (75 to 1142) | 135 (69 to 261) | 338 (205 to 558) | 304 (124 to 742) |
| Men W (Day 1) | 25 (7.98 to 79) | 29 (13 to 64) | 28 (12 to 66) | 9.37 (2.85 to 31) |
| Men W (Day 30) | 392 (252 to 610) | 363 (278 to 473) | 629 (384 to 1032) | 364 (180 to 736) |
| Men Y (Day 1) | 2.4 (1.05 to 5.47) | 1.84 (1.07 to 3.14) | 6.43 (2.86 to 14) | 5.79 (1.77 to 19) |
| Men Y (Day 30) | 48 (14 to 157) | 39 (13 to 120) | 658 (431 to 1003) | 419 (217 to 809) |

| End point values | 1M_Pbo | | | |
|--|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 18 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |

| | | | | |
|----------------|-------------------|--|--|--|
| Men A (Day 1) | 5.02 (2.06 to 12) | | | |
| Men A (Day 30) | 4.91 (2 to 12) | | | |
| Men C (Day 1) | 17 (6.6 to 44) | | | |
| Men C (Day 30) | 20 (7.2 to 56) | | | |
| Men W (Day 1) | 9.42 (3.03 to 29) | | | |
| Men W (Day 30) | 16 (4.87 to 53) | | | |
| Men Y (Day 1) | 5.32 (1.81 to 16) | | | |
| Men Y (Day 30) | 6.36 (1.91 to 21) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 8. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

| | |
|-----------------|--|
| End point title | 8. The HT-hSBA GMTs against N. meningitidis strains of serogroup B. ^[6] |
|-----------------|--|

End point description:

The HT-hSBA GMTs against N. meningitidis strains of serogroup B at Day 1 and one month after the administration of MenABCWY booster vaccination or placebo.
Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

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

End point timeframe:

Day 1 and Day 30

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|--|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 25 | 17 | 23 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 2.57 (1.57 to 4.22) | 2.58 (1.62 to 4.12) | 1.6 (0.97 to 2.65) | 2.27 (1.61 to 3.2) |
| M14459 (fHBP) (Day 30) | 31 (18 to 54) | 2.18 (1.39 to 3.42) | 20 (11 to 37) | 2.33 (1.62 to 3.35) |
| M01-0240364 (NadA) (Day 1) | 2.28 (1.3 to 3.98) | 3.11 (1.44 to 6.68) | 2.67 (0.87 to 8.24) | 1.36 (0.83 to 2.23) |
| M01-0240364 (NadA) (Day 30) | 685 (397 to 1182) | 3.21 (1.4 to 7.37) | 856 (454 to 1614) | 1.94 (1.02 to 3.69) |
| NZ98/254 (PorA) (Day 1) | 1.65 (1.09 to 2.48) | 2.11 (1.28 to 3.49) | 1.32 (0.94 to 1.84) | 1.58 (1.11 to 2.27) |
| NZ98/254 (PorA) (Day 30) | 29 (18 to 47) | 2.03 (1.21 to 3.4) | 12 (5.04 to 31) | 1.87 (1.11 to 3.16) |
| M07-0241084 (NHBA) (Day 1) | 3.53 (2.09 to 5.95) | 3.54 (1.98 to 6.31) | 2.16 (1.15 to 4.08) | 2.52 (1.58 to 4.03) |

| | | | | |
|-----------------------------|--------------------|---------------------|---------------------|---------------------|
| M07-0241084 (NHBA) (Day 30) | 50 (31 to 79) | 3.66 (2.02 to 6.64) | 29 (14 to 58) | 2.48 (1.55 to 3.96) |
| H44/76 (fHBP) (Day 1) | 2.92 (1.5 to 5.67) | 2.03 (1.23 to 3.34) | 1.46 (0.96 to 2.21) | 1.92 (1.11 to 3.32) |
| H44/76 (fHBP) (Day 30) | 97 (60 to 157) | 2.36 (1.39 to 4.01) | 56 (32 to 97) | 2.54 (1.42 to 4.53) |
| 5/99 (NadA) (Day 1) | 17 (9.56 to 29) | 16 (8.32 to 30) | 35 (14 to 92) | 30 (15 to 60) |
| 5/99 (NadA) (Day 30) | 1131 (716 to 1787) | 20 (10 to 42) | 1598 (900 to 2840) | 34 (20 to 59) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|--|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 19 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 3.11 (1.74 to 5.56) | 3.18 (1.87 to 5.41) | 1.91 (1.14 to 3.2) | 1.45 (1.03 to 2.05) |
| M14459 (fHBP) (Day 30) | 56 (27 to 117) | 35 (21 to 58) | 3.44 (2.05 to 5.75) | 2.57 (1.51 to 4.37) |
| M01-0240364 (NadA) (Day 1) | 2.46 (0.72 to 8.4) | 6.81 (2.47 to 19) | 1.34 (0.84 to 2.13) | 1.23 (0.88 to 1.71) |
| M01-0240364 (NadA) (Day 30) | 1336 (810 to 2202) | 1275 (794 to 2048) | 3.5 (1.32 to 9.3) | 3.42 (1.19 to 9.8) |
| NZ98/254 (PorA) (Day 1) | 1.72 (0.99 to 2.98) | 2.07 (1.17 to 3.66) | 1.18 (0.84 to 1.66) | 1.18 (0.9 to 1.54) |
| NZ98/254 (PorA) (Day 30) | 17 (6.22 to 45) | 28 (17 to 44) | 2.48 (1.31 to 4.69) | 1.58 (0.96 to 2.59) |
| M07-0241084 (NHBA) (Day 1) | 4.1 (1.89 to 8.9) | 6.08 (3.18 to 12) | 2.08 (1.26 to 3.42) | 2.06 (1.13 to 3.77) |
| M07-0241084 (NHBA) (Day 30) | 68 (33 to 142) | 69 (36 to 129) | 3.26 (1.75 to 6.06) | 2.15 (1.13 to 4.07) |
| H44/76 (fHBP) (Day 1) | 3.45 (1.81 to 6.57) | 3.24 (1.76 to 5.94) | 1.09 (0.96 to 1.22) | 1.47 (0.92 to 2.36) |
| H44/76 (fHBP) (Day 30) | 132 (64 to 271) | 79 (42 to 149) | 5.27 (2.54 to 11) | 3.85 (1.85 to 8.02) |
| 5/99 (NadA) (Day 1) | 27 (8.61 to 86) | 43 (24 to 77) | 2.97 (1.58 to 5.59) | 1.74 (1.01 to 3.03) |
| 5/99 (NadA) (Day 30) | 2205 (1560 to 3117) | 2576 (1716 to 3867) | 28 (11 to 67) | 30 (11 to 78) |

| End point values | 1M_Pbo | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 18 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 2.37 (1.31 to 4.29) | | | |
| M14459 (fHBP) (Day 30) | 2.93 (1.14 to 7.53) | | | |
| M01-0240364 (NadA) (Day 1) | 1.63 (0.86 to 3.11) | | | |

| | | | | |
|-----------------------------|---------------------|--|--|--|
| M01-0240364 (NadA) (Day 30) | 1.76 (0.75 to 4.09) | | | |
| NZ98/254 (PorA) (Day 1) | 1.12 (0.94 to 1.34) | | | |
| NZ98/254 (PorA) (Day 30) | 1.71 (0.84 to 3.5) | | | |
| M07-0241084 (NHBA) (Day 1) | 3.01 (1.38 to 6.56) | | | |
| M07-0241084 (NHBA) (Day 30) | 3.86 (1.4 to 11) | | | |
| H44/76 (fHBP) (Day 1) | 1.18 (0.97 to 1.44) | | | |
| H44/76 (fHBP) (Day 30) | 1.63 (0.75 to 3.52) | | | |
| 5/99 (NadA) (Day 1) | 2.81 (1.3 to 6.06) | | | |
| 5/99 (NadA) (Day 30) | 3.41 (1.2 to 9.73) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 9. Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains.

| | |
|-----------------|---|
| End point title | 9. Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains. ^[7] |
|-----------------|---|

End point description:

Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains, from baseline to one month after the administration of MenABCWY booster vaccination or placebo. Four-fold rise is defined as follows: for subjects with a pre-vaccination titer < 1:2, a post-titer of ≥ 1:8; for subjects with a pre-vaccination titer ≥ 1:2 at least a four-fold increase.

Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

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

End point timeframe:

Day 30

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|----------------------------------|-------------------|-----------------|--------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 25 | 16 | 23 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) | 72 (50.6 to 87.9) | 0 (0 to 13.7) | 87 (59.5 to 98.3) | 0 (0 to 14.8) |
| M01-0240364 (NadA) | 100 (85.8 to 100) | 4 (0.1 to 20.4) | 93 (68.1 to 99.83) | 5 (0.13 to 24.9) |
| NZ98/254 (PorA) | 76 (54.9 to 90.6) | 0 (0 to 13.7) | 67 (38.4 to 88.2) | 4 (0.11 to 21.9) |
| M07-0241084 (NHBA) | 76 (54.9 to 90.6) | 0 (0 to 13.7) | 87 (59.5 to 98.3) | 0 (0 to 15.4) |

| | | | | |
|---------------|-------------------|-----------------|--------------------|---------------|
| H44/76 (fHBP) | 84 (63.9 to 95.5) | 4 (0.1 to 20.4) | 94 (69.8 to 99.84) | 0 (0 to 15.4) |
| 5/99 (NadA) | 100 (86.3 to 100) | 4 (0.1 to 20.4) | 93 (68.1 to 99.83) | 0 (0 to 15.4) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|----------------------------------|-------------------|--------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 19 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) | 100 (71.5 to 100) | 76 (52.8 to 91.8) | 15 (3.2 to 37.9) | 5 (0.13 to 26) |
| M01-0240364 (NadA) | 100 (69.2 to 100) | 90 (69.6 to 98.8) | 20 (5.7 to 43.7) | 22 (6.4 to 47.6) |
| NZ98/254 (PorA) | 82 (48.2 to 97.7) | 67 (43 to 85.4) | 19 (5.4 to 41.9) | 5 (0.13 to 26) |
| M07-0241084 (NHBA) | 82 (48.2 to 97.7) | 62 (38.4 to 81.9) | 14 (3 to 36.3) | 0 (0 to 17.6) |
| H44/76 (fHBP) | 100 (71.5 to 100) | 76 (52.8 to 91.8) | 37 (16.3 to 61.6) | 26 (9.1 to 51.2) |
| 5/99 (NadA) | 100 (66.4 to 100) | 95 (76.2 to 99.88) | 57 (34 to 78.2) | 79 (54.4 to 93.9) |

| End point values | 1M_Pbo | | | |
|----------------------------------|------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 18 | | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) | 6 (0.14 to 27.3) | | | |
| M01-0240364 (NadA) | 6 (0.14 to 27.3) | | | |
| NZ98/254 (PorA) | 6 (0.14 to 27.3) | | | |
| M07-0241084 (NHBA) | 6 (0.14 to 27.3) | | | |
| H44/76 (fHBP) | 6 (0.14 to 27.3) | | | |
| 5/99 (NadA) | 6 (0.14 to 27.3) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 10. Percentage of subjects with HT-hSBA titer \geq 1:8 against N. meningitidis serogroups A ,C, W, Y.

| | |
|-----------------|---|
| End point title | 10. Percentage of subjects with HT-hSBA titer \geq 1:8 against N. |
|-----------------|---|

End point description:

Percentage of subjects with HT-hSBA titer $\geq 1:8$ to N. meningitidis serogroups A, C, W, Y at Day 1 and 30 Days after the administration of a booster dose of MenABCWY vaccine or placebo in this study. Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

End point type

Secondary

End point timeframe:

Day 1 and Day 30

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|----------------------------------|--------------------|-------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 25 | 16 | 23 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 32 (14.9 to 53.5) | 20 (6.8 to 40.7) | 19 (4 to 45.6) | 27 (10.7 to 50.2) |
| Men A (Day 30) | 100 (86.3 to 100) | 36 (18 to 57.5) | 100 (79.4 to 100) | 27 (10.7 to 50.2) |
| Men C (Day 1) | 70 (45.7 to 88.1) | 65 (42.7 to 83.6) | 70 (34.8 to 93.3) | 68 (45.1 to 86.1) |
| Men C (Day 30) | 100 (83.9 to 100) | 63 (40.6 to 81.2) | 100 (71.5 to 100) | 61 (38.5 to 80.3) |
| Men W (Day 1) | 95 (75.1 to 99.87) | 88 (67.6 to 97.3) | 77 (46.2 to 95) | 71 (47.8 to 88.7) |
| Men W (Day 30) | 100 (83.2 to 100) | 79 (57.8 to 92.9) | 100 (79.4 to 100) | 77 (54.6 to 92.2) |
| Men Y (Day 1) | 64 (42.5 to 82) | 64 (42.5 to 82) | 64 (35.1 to 87.2) | 41 (20.7 to 63.6) |
| Men Y (Day 30) | 100 (86.3 to 100) | 60 (38.7 to 78.9) | 100 (79.4 to 100) | 39 (19.7 to 61.5) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|----------------------------------|-------------------|--------------------|-------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 18 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 27 (6 to 61) | 33 (14.6 to 57) | 47 (24.4 to 71.1) | 6 (0.16 to 30.2) |
| Men A (Day 30) | 100 (71.5 to 100) | 95 (76.2 to 99.88) | 100 (82.4 to 100) | 94 (71.3 to 99.85) |
| Men C (Day 1) | 43 (9.9 to 81.6) | 63 (35.4 to 84.8) | 57 (34 to 78.2) | 44 (21.5 to 69.2) |
| Men C (Day 30) | 100 (59 to 100) | 100 (79.4 to 100) | 100 (83.9 to 100) | 89 (65.3 to 98.6) |
| Men W (Day 1) | 82 (48.2 to 97.7) | 79 (54.4 to 93.9) | 83 (58.6 to 96.4) | 53 (27.8 to 77) |
| Men W (Day 30) | 100 (71.5 to 100) | 100 (82.4 to 100) | 100 (82.4 to 100) | 100 (80.5 to 100) |

| | | | | |
|----------------|-------------------|-------------------|-------------------|-------------------|
| Men Y (Day 1) | 36 (10.9 to 69.2) | 10 (1.2 to 30.4) | 52 (29.8 to 74.3) | 39 (17.3 to 64.3) |
| Men Y (Day 30) | 82 (48.2 to 97.7) | 76 (52.8 to 91.8) | 100 (83.9 to 100) | 100 (81.5 to 100) |

| End point values | 1M_Pbo | | | |
|----------------------------------|-------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 18 | | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 39 (17.3 to 64.3) | | | |
| Men A (Day 30) | 39 (17.3 to 64.3) | | | |
| Men C (Day 1) | 65 (38.3 to 85.8) | | | |
| Men C (Day 30) | 61 (35.7 to 82.7) | | | |
| Men W (Day 1) | 53 (26.6 to 78.7) | | | |
| Men W (Day 30) | 63 (35.4 to 84.8) | | | |
| Men Y (Day 1) | 39 (17.3 to 64.3) | | | |
| Men Y (Day 30) | 39 (17.3 to 64.3) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 11. Percentage of subjects with HT-hSBA titer \geq 1:5 against N. meningitidis serogroup B strains.

| | |
|-----------------|--|
| End point title | 11. Percentage of subjects with HT-hSBA titer \geq 1:5 against N. meningitidis serogroup B strains. ^[9] |
|-----------------|--|

End point description:

Percentage of subjects with HT-hSBA titer \geq 1:5 to N. meningitidis serogroup B strains at Day 1 and 30 Days after the administration of a booster dose of MenABCWY vaccine or placebo in this study. Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

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

End point timeframe:

Day 1 and Day 30

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|----------------------------------|-------------------|-------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 25 | 17 | 23 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 24 (9.4 to 45.1) | 32 (14.9 to 53.5) | 7 (0.17 to 31.9) | 17 (5 to 38.8) |
| M14459 (fHBP) (Day 30) | 92 (74 to 99) | 28 (12.1 to 49.4) | 88 (63.6 to 98.5) | 30 (13.2 to 52.9) |
| M01-0240364 (NadA) (Day 1) | 25 (9.8 to 46.7) | 24 (9.4 to 45.1) | 20 (4.3 to 48.1) | 5 (0.13 to 24.9) |
| M01-0240364 (NadA) (Day 30) | 100 (86.3 to 100) | 24 (9.4 to 45.1) | 100 (80.5 to 100) | 18 (5.2 to 40.3) |
| NZ98/254 (PorA) (Day 1) | 16 (4.5 to 36.1) | 28 (12.1 to 49.4) | 7 (0.17 to 31.9) | 9 (1.1 to 28) |
| NZ98/254 (PorA) (Day 30) | 92 (74 to 99) | 20 (6.8 to 40.7) | 71 (44 to 89.7) | 13 (2.8 to 33.6) |
| M07-0241084 (NHBA) (Day 1) | 36 (18 to 57.5) | 36 (18 to 57.5) | 27 (7.8 to 55.1) | 27 (10.7 to 50.2) |
| M07-0241084 (NHBA) (Day 30) | 100 (86.3 to 100) | 40 (21.1 to 61.3) | 88 (63.6 to 98.5) | 30 (13.2 to 52.9) |
| H44/76 (fHBP) (Day 1) | 16 (4.5 to 36.1) | 24 (9.4 to 45.1) | 13 (1.6 to 38.3) | 18 (5.2 to 40.3) |
| H44/76 (fHBP) (Day 30) | 96 (79.6 to 99.9) | 24 (9.4 to 45.1) | 100 (80.5 to 100) | 26 (10.2 to 48.4) |
| 5/99 (NadA) (Day 1) | 76 (54.9 to 90.6) | 76 (54.9 to 90.6) | 87 (59.5 to 98.3) | 86 (65.1 to 97.1) |
| 5/99 (NadA) (Day 30) | 100 (86.3 to 100) | 84 (63.9 to 95.5) | 100 (80.5 to 100) | 91 (72 to 98.9) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|----------------------------------|--------------------|--------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 19 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 36 (10.9 to 69.2) | 29 (11.3 to 52.2) | 10 (1.2 to 31.7) | 11 (1.3 to 33.1) |
| M14459 (fHBP) (Day 30) | 100 (71.5 to 100) | 95 (76.2 to 99.88) | 35 (15.4 to 59.2) | 32 (12.6 to 56.6) |
| M01-0240364 (NadA) (Day 1) | 20 (2.5 to 55.6) | 43 (21.8 to 66) | 5 (0.13 to 24.9) | 6 (0.14 to 27.3) |
| M01-0240364 (NadA) (Day 30) | 100 (71.5 to 100) | 100 (83.9 to 100) | 25 (8.7 to 49.1) | 26 (9.1 to 51.2) |
| NZ98/254 (PorA) (Day 1) | 9 (0.23 to 41.3) | 24 (8.2 to 47.2) | 5 (0.12 to 23.8) | 5 (0.13 to 26) |
| NZ98/254 (PorA) (Day 30) | 82 (48.2 to 97.7) | 95 (76.2 to 99.88) | 19 (5.4 to 41.9) | 16 (3.4 to 39.6) |
| M07-0241084 (NHBA) (Day 1) | 64 (30.8 to 89.1) | 52 (29.8 to 74.3) | 19 (5.4 to 41.9) | 16 (3.4 to 39.6) |
| M07-0241084 (NHBA) (Day 30) | 91 (58.7 to 99.77) | 95 (76.2 to 99.88) | 33 (14.6 to 57) | 21 (6.1 to 45.6) |
| H44/76 (fHBP) (Day 1) | 45 (16.7 to 76.6) | 29 (11.3 to 52.2) | 0 (0 to 17.6) | 5 (0.13 to 26) |
| H44/76 (fHBP) (Day 30) | 100 (71.5 to 100) | 100 (83.9 to 100) | 58 (33.5 to 79.7) | 32 (12.6 to 56.6) |

| | | | | |
|----------------------|--------------------|--------------------|-------------------|-------------------|
| 5/99 (NadA) (Day 1) | 89 (51.8 to 99.72) | 95 (76.2 to 99.88) | 19 (5.4 to 41.9) | 16 (3.4 to 39.6) |
| 5/99 (NadA) (Day 30) | 100 (71.5 to 100) | 100 (83.9 to 100) | 76 (52.8 to 91.8) | 84 (60.4 to 96.6) |

| End point values | 1M_Pbo | | | |
|----------------------------------|------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 18 | | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 22 (6.4 to 47.6) | | | |
| M14459 (fHBP) (Day 30) | 22 (6.4 to 47.6) | | | |
| M01-0240364 (NadA) (Day 1) | 11 (1.4 to 34.7) | | | |
| M01-0240364 (NadA) (Day 30) | 11 (1.4 to 34.7) | | | |
| NZ98/254 (PorA) (Day 1) | 0 (0 to 18.5) | | | |
| NZ98/254 (PorA) (Day 30) | 6 (0.14 to 27.3) | | | |
| M07-0241084 (NHBA) (Day 1) | 33 (13.3 to 59) | | | |
| M07-0241084 (NHBA) (Day 30) | 33 (13.3 to 59) | | | |
| H44/76 (fHBP) (Day 1) | 0 (0 to 18.5) | | | |
| H44/76 (fHBP) (Day 30) | 6 (0.14 to 27.3) | | | |
| 5/99 (NadA) (Day 1) | 22 (6.4 to 47.6) | | | |
| 5/99 (NadA) (Day 30) | 22 (6.4 to 47.6) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 12. Percentage of subjects with seroresponse to N. meningitidis serogroups A, C, W and Y, at Day 30 after booster vaccination.

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|-----------------|--|
| End point title | 12. Percentage of subjects with seroresponse to N. meningitidis serogroups A, C, W and Y, at Day 30 after booster vaccination. ^[10] |
|-----------------|--|

End point description:

Percentage of subjects with seroresponse to N. meningitidis serogroups A, C, W and Y at Day 30 after the administration of a booster dose of MenABCWY vaccine or placebo in this study, versus baseline. Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

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

End point timeframe:

Day 30

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|----------------------------------|-------------------|------------------|--------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 25 | 16 | 23 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A overall | 96 (79.6 to 99.9) | 12 (2.5 to 31.2) | 94 (69.8 to 99.84) | 0 (0 to 15.4) |
| Men C overall | 85 (62.1 to 96.8) | 4 (0.11 to 21.9) | 100 (69.2 to 100) | 0 (0 to 15.4) |
| Men W overall | 85 (62.1 to 96.8) | 4 (0.11 to 21.1) | 85 (54.6 to 98.1) | 5 (0.12 to 23.8) |
| Men Y overall | 96 (79.6 to 99.9) | 4 (0.1 to 20.4) | 100 (76.8 to 100) | 0 (0 to 15.4) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|----------------------------------|-------------------|-------------------|--------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 18 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A overall | 100 (71.5 to 100) | 86 (63.7 to 97) | 84 (60.4 to 96.6) | 94 (69.8 to 99.84) |
| Men C overall | 100 (59 to 100) | 81 (54.4 to 96) | 95 (76.2 to 99.88) | 78 (52.4 to 93.6) |
| Men W overall | 82 (48.2 to 97.7) | 68 (43.4 to 87.4) | 83 (58.6 to 96.4) | 76 (50.1 to 93.2) |
| Men Y overall | 73 (39 to 94) | 62 (38.4 to 81.9) | 95 (76.2 to 99.88) | 89 (65.3 to 98.6) |

| End point values | 1M_Pbo | | | |
|----------------------------------|------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 18 | | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A overall | 0 (0 to 18.5) | | | |
| Men C overall | 6 (0.15 to 28.7) | | | |
| Men W overall | 20 (4.3 to 48.1) | | | |
| Men Y overall | 6 (0.14 to 27.3) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 13. Percentage of subjects with HT-hSBA titer $\geq 1:8$ to N. meningitidis serogroups A, C, W, Y.

| | |
|-----------------|--|
| End point title | 13. Percentage of subjects with HT-hSBA titer $\geq 1:8$ to N. meningitidis serogroups A, C, W, Y. ^[11] |
|-----------------|--|

End point description:

Percentage of subjects with HT-hSBA titer $\geq 1:8$ against N. meningitidis serogroups A, C, W, Y at 24 and 36 months after the primary vaccination.

Analysis was done on the FAS Day 365 (Persistence of Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

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

End point timeframe:

Day 1 and Day 365

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|----------------------------------|--------------------|--------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 22 | 16 | 20 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 38 (18.1 to 61.6) | 18 (5.2 to 40.3) | 20 (4.3 to 48.1) | 30 (11.9 to 54.3) |
| Men A (Day 365) | 67 (43 to 85.4) | 23 (7.8 to 45.4) | 88 (61.7 to 98.4) | 25 (8.7 to 49.1) |
| Men C (Day 1) | 65 (40.8 to 84.6) | 68 (43.4 to 87.4) | 71 (41.9 to 91.6) | 65 (40.8 to 84.6) |
| Men C (Day 365) | 100 (83.9 to 100) | 62 (38.4 to 81.9) | 100 (79.4 to 100) | 50 (27.2 to 72.8) |
| Men W (Day 1) | 95 (75.1 to 99.87) | 95 (77.2 to 99.88) | 75 (42.8 to 94.5) | 70 (45.7 to 88.1) |
| Men W (Day 365) | 100 (83.9 to 100) | 82 (59.7 to 94.8) | 100 (79.4 to 100) | 65 (40.8 to 84.6) |
| Men Y (Day 1) | 62 (38.4 to 81.9) | 62 (38.4 to 81.9) | 71 (41.9 to 91.6) | 40 (19.1 to 63.9) |
| Men Y (Day 365) | 95 (76.2 to 99.88) | 52 (29.8 to 74.3) | 100 (79.4 to 100) | 40 (19.1 to 63.9) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|----------------------------------|--------------------|-------------------|-------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 20 | 20 | 18 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 30 (6.7 to 65.2) | 35 (15.4 to 59.2) | 45 (23.1 to 68.5) | 12 (1.5 to 36.4) |
| Men A (Day 365) | 90 (55.5 to 99.75) | 85 (62.1 to 96.8) | 85 (62.1 to 96.8) | 50 (26 to 74) |

| | | | | |
|-----------------|--------------------|-------------------|-------------------|-------------------|
| Men C (Day 1) | 36 (10.9 to 69.2) | 58 (33.5 to 79.7) | 58 (33.5 to 79.7) | 50 (26 to 74) |
| Men C (Day 365) | 82 (48.2 to 97.7) | 95 (74 to 99.87) | 100 (82.4 to 100) | 89 (65.3 to 98.6) |
| Men W (Day 1) | 82 (48.2 to 97.7) | 75 (50.9 to 91.3) | 82 (56.6 to 96.2) | 61 (35.7 to 82.7) |
| Men W (Day 365) | 91 (58.7 to 99.77) | 100 (83.2 to 100) | 100 (82.4 to 100) | 100 (81.5 to 100) |
| Men Y (Day 1) | 36 (10.9 to 69.2) | 11 (1.4 to 34.7) | 55 (31.5 to 76.9) | 44 (21.5 to 69.2) |
| Men Y (Day 365) | 45 (16.7 to 76.6) | 72 (46.5 to 90.3) | 100 (83.2 to 100) | 89 (65.3 to 98.6) |

| End point values | 1M_Pbo | | | |
|----------------------------------|-------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 41 (18.4 to 67.1) | | | |
| Men A (Day 365) | 35 (14.2 to 61.7) | | | |
| Men C (Day 1) | 75 (47.6 to 92.7) | | | |
| Men C (Day 365) | 65 (38.3 to 85.8) | | | |
| Men W (Day 1) | 56 (29.9 to 80.2) | | | |
| Men W (Day 365) | 65 (38.3 to 85.8) | | | |
| Men Y (Day 1) | 41 (18.4 to 67.1) | | | |
| Men Y (Day 365) | 47 (23 to 72.2) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 14. Percentage of subjects with HT-hSBA titer \geq 1:5 to N. meningitidis strains of serogroup B.

| | |
|-----------------|---|
| End point title | 14. Percentage of subjects with HT-hSBA titer \geq 1:5 to N. meningitidis strains of serogroup B. ^[12] |
|-----------------|---|

End point description:

Percentage of subjects with HT-hSBA titer \geq 1:5 against N. meningitidis strains of serogroup B at 24 and 36 months after the primary vaccination.

Analysis was done on FAS Day 30 (Booster) and FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 30 and Day 365.

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

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|----------------------------------|--------------------|-------------------|--------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 22 | 16 | 20 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 24 (8.2 to 47.2) | 36 (17.2 to 59.3) | 7 (0.18 to 33.9) | 15 (3.2 to 37.9) |
| M14459 (fHBP) (Day 30) | 95 (76.2 to 99.88) | 32 (13.9 to 54.9) | 88 (61.7 to 98.4) | 20 (5.7 to 43.7) |
| M14459 (fHBP) (Day 365) | 57 (34 to 78.2) | 18 (5.2 to 40.3) | 38 (15.2 to 64.6) | 5 (0.13 to 24.9) |
| M01-0240364 (NadA) (Day 1) | 24 (8.2 to 47.2) | 27 (10.7 to 50.2) | 21 (4.7 to 50.8) | 6 (0.14 to 27.3) |
| M01-0240364 (NadA) (Day 30) | 100 (83.9 to 100) | 27 (10.7 to 50.2) | 100 (79.4 to 100) | 6 (0.15 to 28.7) |
| M01-0240364 (NadA) (Day 365) | 71 (47.8 to 88.7) | 32 (13.9 to 54.9) | 75 (47.6 to 92.7) | 6 (0.14 to 27.3) |
| NZ98/254 (PorA) (Day 1) | 19 (5.4 to 41.9) | 32 (13.9 to 54.9) | 7 (0.18 to 33.9) | 5 (0.13 to 24.9) |
| NZ98/254 (PorA) (Day 30) | 95 (76.2 to 99.88) | 23 (7.8 to 45.4) | 75 (47.6 to 92.7) | 10 (1.2 to 31.7) |
| NZ98/254 (PorA) (Day 365) | 29 (11.3 to 52.2) | 14 (2.9 to 34.9) | 31 (11 to 58.7) | 5 (0.13 to 24.9) |
| M07-0241084 (NHBA) (Day 1) | 38 (18.1 to 61.6) | 41 (20.7 to 63.6) | 29 (8.4 to 58.1) | 25 (8.7 to 49.1) |
| M07-0241084 (NHBA) (Day 30) | 100 (83.9 to 100) | 45 (24.4 to 67.8) | 94 (69.8 to 99.84) | 25 (8.7 to 49.1) |
| M07-0241084 (NHBA) (Day 365) | 62 (38.4 to 81.9) | 32 (13.9 to 54.9) | 50 (24.7 to 75.3) | 20 (5.7 to 43.7) |
| H44/76 (fHBP) (Day 1) | 19 (5.4 to 41.9) | 27 (10.7 to 50.2) | 13 (1.7 to 40.5) | 15 (3.2 to 37.9) |
| H44/76 (fHBP) (Day 30) | 95 (76.2 to 99.88) | 27 (10.7 to 50.2) | 100 (79.4 to 100) | 15 (3.2 to 37.9) |
| H44/76 (fHBP) (Day 365) | 76 (52.8 to 91.8) | 18 (5.2 to 40.3) | 44 (19.8 to 70.1) | 10 (1.2 to 31.7) |
| 5/99 (NadA) (Day 1) | 76 (52.8 to 91.8) | 82 (59.7 to 94.8) | 86 (57.2 to 98.2) | 85 (62.1 to 96.8) |
| 5/99 (NadA) (Day 30) | 100 (83.9 to 100) | 86 (65.1 to 97.1) | 100 (79.4 to 100) | 90 (68.3 to 98.8) |
| 5/99 (NadA) (Day 365) | 95 (76.2 to 99.88) | 77 (54.6 to 92.2) | 100 (79.4 to 100) | 80 (56.3 to 94.3) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|----------------------------------|-------------------|-------------------|------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 20 | 21 | 18 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 36 (10.9 to 69.2) | 30 (11.9 to 54.3) | 10 (1.2 to 30.4) | 11 (1.4 to 34.7) |

| | | | | |
|------------------------------|--------------------|--------------------|-------------------|-------------------|
| M14459 (fHBP) (Day 30) | 100 (71.5 to 100) | 95 (75.1 to 99.87) | 35 (15.4 to 59.2) | 33 (13.3 to 59) |
| M14459 (fHBP) (Day 365) | 82 (48.2 to 97.7) | 60 (36.1 to 80.9) | 14 (3 to 36.3) | 11 (1.4 to 34.7) |
| M01-0240364 (NadA) (Day 1) | 20 (2.5 to 55.6) | 42 (20.3 to 66.5) | 5 (0.13 to 24.9) | 6 (0.15 to 28.7) |
| M01-0240364 (NadA) (Day 30) | 100 (71.5 to 100) | 100 (82.4 to 100) | 21 (6.1 to 45.6) | 28 (9.7 to 53.5) |
| M01-0240364 (NadA) (Day 365) | 100 (71.5 to 100) | 95 (74 to 99.87) | 15 (3.2 to 37.9) | 11 (1.4 to 34.7) |
| NZ98/254 (PorA) (Day 1) | 9 (0.23 to 41.3) | 26 (9.1 to 51.2) | 5 (0.12 to 23.8) | 6 (0.14 to 27.3) |
| NZ98/254 (PorA) (Day 30) | 82 (48.2 to 97.7) | 95 (74 to 99.87) | 19 (5.4 to 41.9) | 17 (3.6 to 41.4) |
| NZ98/254 (PorA) (Day 365) | 45 (16.7 to 76.6) | 42 (20.3 to 66.5) | 19 (5.4 to 41.9) | 6 (0.14 to 27.3) |
| M07-0241084 (NHBA) (Day 1) | 64 (30.8 to 89.1) | 58 (33.5 to 79.7) | 19 (5.4 to 41.9) | 17 (3.6 to 41.4) |
| M07-0241084 (NHBA) (Day 30) | 91 (58.7 to 99.77) | 95 (74 to 99.87) | 33 (14.6 to 57) | 22 (6.4 to 47.6) |
| M07-0241084 (NHBA) (Day 365) | 82 (48.2 to 97.7) | 74 (48.8 to 90.9) | 29 (11.3 to 52.2) | 17 (3.6 to 41.4) |
| H44/76 (fHBP) (Day 1) | 45 (16.7 to 76.6) | 30 (11.9 to 54.3) | 5 (0.12 to 23.8) | 6 (0.14 to 27.3) |
| H44/76 (fHBP) (Day 30) | 100 (71.5 to 100) | 100 (83.2 to 100) | 58 (33.5 to 79.7) | 33 (13.3 to 59) |
| H44/76 (fHBP) (Day 365) | 82 (48.2 to 97.7) | 65 (40.8 to 84.6) | 19 (5.4 to 41.9) | 11 (1.4 to 34.7) |
| 5/99 (NadA) (Day 1) | 89 (51.8 to 99.72) | 95 (74 to 99.87) | 19 (5.4 to 41.9) | 17 (3.6 to 41.4) |
| 5/99 (NadA) (Day 30) | 100 (71.5 to 100) | 100 (82.4 to 100) | 76 (52.8 to 91.8) | 83 (58.6 to 96.4) |
| 5/99 (NadA) (Day 365) | 100 (71.5 to 100) | 100 (82.4 to 100) | 43 (21.8 to 66) | 33 (13.3 to 59) |

| End point values | 1M_Pbo | | | |
|----------------------------------|------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 24 (6.8 to 49.9) | | | |
| M14459 (fHBP) (Day 30) | 25 (7.3 to 52.4) | | | |
| M14459 (fHBP) (Day 365) | 24 (6.8 to 49.9) | | | |
| M01-0240364 (NadA) (Day 1) | 12 (1.5 to 36.4) | | | |
| M01-0240364 (NadA) (Day 30) | 13 (1.6 to 38.3) | | | |
| M01-0240364 (NadA) (Day 365) | 18 (3.8 to 43.4) | | | |
| NZ98/254 (PorA) (Day 1) | 0 (0 to 19.5) | | | |
| NZ98/254 (PorA) (Day 30) | 6 (0.16 to 30.2) | | | |
| NZ98/254 (PorA) (Day 365) | 6 (0.15 to 28.7) | | | |

| | | | | |
|------------------------------|-------------------|--|--|--|
| M07-0241084 (NHBA) (Day 1) | 35 (14.2 to 61.7) | | | |
| M07-0241084 (NHBA) (Day 30) | 38 (15.2 to 64.6) | | | |
| M07-0241084 (NHBA) (Day 365) | 35 (14.2 to 61.7) | | | |
| H44/76 (fHBP) (Day 1) | 0 (0 to 19.5) | | | |
| H44/76 (fHBP) (Day 30) | 6 (0.16 to 30.2) | | | |
| H44/76 (fHBP) (Day 365) | 6 (0.15 to 28.7) | | | |
| 5/99 (NadA) (Day 1) | 24 (6.8 to 49.9) | | | |
| 5/99 (NadA) (Day 30) | 25 (7.3 to 52.4) | | | |
| 5/99 (NadA) (Day 365) | 18 (3.8 to 43.4) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 15. Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains.

| | |
|-----------------|---|
| End point title | 15. Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains. ^[13] |
|-----------------|---|

End point description:

Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains at 36 months after the primary vaccination.

Four-fold rise is defined as follows: for subjects with a pre-vaccination titer < 1:2, a post-titer of ≥ 1:8; for subjects with a pre-vaccination titer ≥ 1:2 at least a four-fold increase.

Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

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

End point timeframe:

Day 30 and Day 365

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|----------------------------------|-------------------|------------------|--------------------|------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 22 | 15 | 20 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 30) | 76 (52.8 to 91.8) | 0 (0 to 15.4) | 86 (57.2 to 98.2) | 0 (0 to 16.8) |
| M14459 (fHBP) (Day 365) | 24 (8.2 to 47.2) | 0 (0 to 15.4) | 0 (0 to 23.2) | 0 (0 to 16.8) |
| M01-0240364 (NadA) (Day 30) | 100 (83.9 to 100) | 5 (0.12 to 22.8) | 93 (66.1 to 99.82) | 6 (0.15 to 28.7) |
| M01-0240364 (NadA) (Day 365) | 62 (38.4 to 81.9) | 5 (0.12 to 22.8) | 64 (35.1 to 87.2) | 6 (0.14 to 27.3) |

| | | | | |
|------------------------------|-------------------|------------------|--------------------|------------------|
| NZ98/254 (PorA) (Day 30) | 81 (58.1 to 94.6) | 0 (0 to 15.4) | 71 (41.9 to 91.6) | 5 (0.13 to 24.9) |
| NZ98/254 (PorA) (Day 365) | 10 (1.2 to 30.4) | 0 (0 to 15.4) | 14 (1.8 to 42.8) | 0 (0 to 16.8) |
| M07-0241084 (NHBA) (Day 30) | 81 (58.1 to 94.6) | 0 (0 to 15.4) | 93 (66.1 to 99.82) | 0 (0 to 16.8) |
| M07-0241084 (NHBA) (Day 365) | 19 (5.4 to 41.9) | 0 (0 to 15.4) | 0 (0 to 23.2) | 0 (0 to 16.8) |
| H44/76 (fHBP) (Day 30) | 81 (58.1 to 94.6) | 5 (0.12 to 22.8) | 93 (68.1 to 99.83) | 0 (0 to 16.8) |
| H44/76 (fHBP) (Day 365) | 38 (18.1 to 61.6) | 0 (0 to 15.4) | 20 (4.3 to 48.1) | 0 (0 to 16.8) |
| 5/99 (NadA) (Day 30) | 100 (83.9 to 100) | 5 (0.12 to 22.8) | 93 (66.1 to 99.82) | 0 (0 to 16.8) |
| 5/99 (NadA) (Day 365) | 67 (43 to 85.4) | 5 (0.12 to 22.8) | 86 (57.2 to 98.2) | 0 (0 to 16.8) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|----------------------------------|--------------------|-------------------|-------------------|-------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 20 | 21 | 18 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 30) | 100 (71.5 to 100) | 75 (50.9 to 91.3) | 15 (3.2 to 37.9) | 6 (0.14 to 27.3) |
| M14459 (fHBP) (Day 365) | 36 (10.9 to 69.2) | 25 (8.7 to 49.1) | 10 (1.2 to 30.4) | 0 (0 to 18.5) |
| M01-0240364 (NadA) (Day 30) | 100 (69.2 to 100) | 89 (66.9 to 98.7) | 16 (3.4 to 39.6) | 24 (6.8 to 49.9) |
| M01-0240364 (NadA) (Day 365) | 90 (55.5 to 99.75) | 79 (54.4 to 93.9) | 15 (3.2 to 37.9) | 6 (0.15 to 28.7) |
| NZ98/254 (PorA) (Day 30) | 82 (48.2 to 97.7) | 63 (38.4 to 83.7) | 19 (5.4 to 41.9) | 6 (0.14 to 27.3) |
| NZ98/254 (PorA) (Day 365) | 9 (0.23 to 41.3) | 5 (0.13 to 26) | 10 (1.2 to 30.4) | 0 (0 to 18.5) |
| M07-0241084 (NHBA) (Day 30) | 82 (48.2 to 97.7) | 58 (33.5 to 79.7) | 14 (3 to 36.3) | 0 (0 to 18.5) |
| M07-0241084 (NHBA) (Day 365) | 27 (6 to 61) | 5 (0.13 to 26) | 0 (0 to 16.1) | 0 (0 to 18.5) |
| H44/76 (fHBP) (Day 30) | 100 (71.5 to 100) | 75 (50.9 to 91.3) | 37 (16.3 to 61.6) | 28 (9.7 to 53.5) |
| H44/76 (fHBP) (Day 365) | 64 (30.8 to 89.1) | 30 (11.9 to 54.3) | 10 (1.2 to 30.4) | 0 (0 to 18.5) |
| 5/99 (NadA) (Day 30) | 100 (66.4 to 100) | 100 (82.4 to 100) | 57 (34 to 78.2) | 78 (52.4 to 93.6) |
| 5/99 (NadA) (Day 365) | 89 (51.8 to 99.72) | 74 (48.8 to 90.9) | 29 (11.3 to 52.2) | 28 (9.7 to 53.5) |

| End point values | 1M_Pbo | | | |
|----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |

| | | | | |
|------------------------------|------------------|--|--|--|
| M14459 (fHBP) (Day 30) | 6 (0.16 to 30.2) | | | |
| M14459 (fHBP) (Day 365) | 6 (0.15 to 28.7) | | | |
| M01-0240364 (NadA) (Day 30) | 6 (0.16 to 30.2) | | | |
| M01-0240364 (NadA) (Day 365) | 6 (0.15 to 28.7) | | | |
| NZ98/254 (PorA) (Day 30) | 6 (0.16 to 30.2) | | | |
| NZ98/254 (PorA) (Day 365) | 6 (0.15 to 28.7) | | | |
| M07-0241084 (NHBA) (Day 30) | 6 (0.16 to 30.2) | | | |
| M07-0241084 (NHBA) (Day 365) | 6 (0.15 to 28.7) | | | |
| H44/76 (fHBP) (Day 30) | 6 (0.16 to 30.2) | | | |
| H44/76 (fHBP) (Day 365) | 6 (0.15 to 28.7) | | | |
| 5/99 (NadA) (Day 30) | 6 (0.16 to 30.2) | | | |
| 5/99 (NadA) (Day 365) | 6 (0.15 to 28.7) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 16. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.

| | |
|-----------------|---|
| End point title | 16. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y. ^[14] |
|-----------------|---|

End point description:

The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y at 24 and 36 months after the primary vaccination.

Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

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

End point timeframe:

Day 1 and Day 365

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|--|------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 22 | 16 | 20 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Men A (Day 1) | 3.98 (1.98 to 8) | 2.73 (1.44 to 5.15) | 3.07 (1.26 to 7.47) | 2.98 (1.38 to 6.42) |

| | | | | |
|-----------------|------------------|---------------------|------------------|--------------------|
| Men A (Day 365) | 25 (11 to 59) | 2.62 (1.39 to 4.94) | 44 (18 to 105) | 3.03 (1.3 to 7.06) |
| Men C (Day 1) | 18 (8.21 to 39) | 19 (7.54 to 49) | 19 (8.13 to 44) | 10 (5.52 to 19) |
| Men C (Day 365) | 128 (75 to 217) | 15 (5.82 to 39) | 177 (102 to 305) | 9.14 (4.07 to 21) |
| Men W (Day 1) | 36 (21 to 62) | 43 (24 to 79) | 30 (7.82 to 112) | 17 (6.88 to 43) |
| Men W (Day 365) | 190 (133 to 272) | 28 (13 to 59) | 213 (135 to 337) | 16 (5.58 to 47) |
| Men Y (Day 1) | 10 (4.39 to 24) | 16 (4.85 to 54) | 24 (6.62 to 90) | 5.39 (2.06 to 14) |
| Men Y (Day 365) | 116 (58 to 231) | 18 (5.05 to 62) | 235 (147 to 376) | 5.93 (1.97 to 18) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|--|---------------------|--------------------|-------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 20 | 20 | 18 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Men A (Day 1) | 2.27 (0.87 to 5.94) | 4.22 (1.63 to 11) | 6.31 (2.82 to 14) | 2.49 (1.52 to 4.09) |
| Men A (Day 365) | 54 (17 to 174) | 53 (22 to 130) | 34 (16 to 69) | 6.52 (2.71 to 16) |
| Men C (Day 1) | 5.2 (2.8 to 9.65) | 7.83 (4.51 to 14) | 7.89 (4.26 to 15) | 8.45 (2.64 to 27) |
| Men C (Day 365) | 29 (10 to 82) | 32 (16 to 67) | 81 (46 to 141) | 72 (27 to 191) |
| Men W (Day 1) | 25 (7.98 to 79) | 23 (9.81 to 52) | 28 (11 to 70) | 15 (4.54 to 47) |
| Men W (Day 365) | 80 (26 to 246) | 96 (72 to 127) | 172 (97 to 306) | 104 (49 to 221) |
| Men Y (Day 1) | 2.4 (1.05 to 5.47) | 1.9 (1.02 to 3.55) | 7.05 (3.08 to 16) | 6.83 (2.11 to 22) |
| Men Y (Day 365) | 7.17 (1.91 to 27) | 20 (6.92 to 58) | 193 (123 to 301) | 101 (36 to 280) |

| End point values | 1M_Pbo | | | |
|--|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Men A (Day 1) | 5.48 (2.18 to 14) | | | |
| Men A (Day 365) | 3.54 (1.4 to 8.92) | | | |
| Men C (Day 1) | 24 (9.34 to 61) | | | |
| Men C (Day 365) | 24 (8.98 to 66) | | | |
| Men W (Day 1) | 10 (3.53 to 30) | | | |
| Men W (Day 365) | 16 (5.27 to 49) | | | |
| Men Y (Day 1) | 7.03 (1.99 to 25) | | | |

| | | | | |
|-----------------|-------------------|--|--|--|
| Men Y (Day 365) | 9.56 (2.44 to 37) | | | |
|-----------------|-------------------|--|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: 17. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

| | |
|-----------------|--|
| End point title | 17. The HT-hSBA GMTs against N. meningitidis strains of serogroup B. ^[15] |
|-----------------|--|

End point description:

The HT-hSBA GMTs against N. meningitidis strains of serogroup B at 24 and 36 months after the primary vaccination.

Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

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

End point timeframe:

Day 1 and Day 365

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|--|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 22 | 16 | 20 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 2.69 (1.51 to 4.78) | 2.94 (1.77 to 4.89) | 1.54 (0.9 to 2.63) | 2.01 (1.4 to 2.88) |
| M14459 (fHBP) (Day 365) | 7.19 (3.89 to 13) | 1.67 (1.07 to 2.6) | 2.94 (1.49 to 5.8) | 1.47 (1.07 to 2.03) |
| M01-0240364 (NadA) (Day 1) | 2.33 (1.25 to 4.36) | 3.39 (1.43 to 8.05) | 2.87 (0.86 to 9.59) | 1.26 (0.89 to 1.8) |
| M01-0240364 (NadA) (Day 365) | 30 (9.54 to 93) | 3.55 (1.56 to 8.07) | 74 (18 to 300) | 1.23 (0.91 to 1.68) |
| NZ98/254 (PorA) (Day 1) | 1.73 (1.06 to 2.81) | 2.34 (1.33 to 4.1) | 1.34 (0.94 to 1.93) | 1.48 (1.01 to 2.17) |
| NZ98/254 (PorA) (Day 365) | 3.49 (2.12 to 5.74) | 1.71 (1.14 to 2.57) | 2.67 (1.27 to 5.61) | 1.23 (0.9 to 1.69) |
| M07-0241084 (NHBA) (Day 1) | 3.68 (2.07 to 6.54) | 4.2 (2.25 to 7.85) | 2.28 (1.16 to 4.48) | 2.36 (1.51 to 3.7) |
| M07-0241084 (NHBA) (Day 365) | 7.96 (4.6 to 14) | 3.28 (2.16 to 4.97) | 4.09 (2.3 to 7.25) | 2.04 (1.43 to 2.92) |
| H44/76 (fHBP) (Day 1) | 3.58 (1.66 to 7.71) | 2.23 (1.28 to 3.9) | 1.49 (0.96 to 2.33) | 1.73 (0.97 to 3.1) |
| H44/76 (fHBP) (Day 365) | 12 (5.18 to 26) | 1.93 (1.2 to 3.1) | 4.19 (1.93 to 9.11) | 1.83 (1.07 to 3.15) |
| 5/99 (NadA) (Day 1) | 18 (9.47 to 34) | 18 (9.5 to 34) | 31 (12 to 85) | 31 (15 to 65) |
| 5/99 (NadA) (Day 365) | 175 (79 to 385) | 13 (6.07 to 29) | 305 (149 to 625) | 23 (11 to 47) |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|--|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 20 | 21 | 18 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 3.11 (1.74 to 5.56) | 3.37 (1.95 to 5.81) | 1.85 (1.13 to 3.04) | 1.48 (1.03 to 2.13) |
| M14459 (fHBP) (Day 365) | 11 (4.41 to 28) | 7.12 (3.59 to 14) | 2.09 (1.33 to 3.29) | 1.38 (0.98 to 1.93) |
| M01-0240364 (NadA) (Day 1) | 2.46 (0.72 to 8.4) | 6.29 (2.22 to 18) | 1.24 (0.79 to 1.94) | 1.24 (0.88 to 1.77) |
| M01-0240364 (NadA) (Day 365) | 303 (174 to 527) | 155 (69 to 350) | 1.61 (0.99 to 2.63) | 1.71 (0.86 to 3.42) |
| NZ98/254 (PorA) (Day 1) | 1.72 (0.99 to 2.98) | 2.24 (1.2 to 4.17) | 1.18 (0.84 to 1.66) | 1.19 (0.9 to 1.58) |
| NZ98/254 (PorA) (Day 365) | 3.28 (1.66 to 6.49) | 3.77 (1.98 to 7.18) | 1.65 (1.04 to 2.61) | 1.19 (0.91 to 1.54) |
| M07-0241084 (NHBA) (Day 1) | 4.1 (1.89 to 8.9) | 7.35 (3.82 to 14) | 2.08 (1.26 to 3.42) | 2.15 (1.14 to 4.05) |
| M07-0241084 (NHBA) (Day 365) | 10 (4.51 to 24) | 11 (6.35 to 18) | 2.45 (1.59 to 3.79) | 1.91 (1.14 to 3.23) |
| H44/76 (fHBP) (Day 1) | 3.45 (1.81 to 6.57) | 3.43 (1.83 to 6.43) | 1.34 (0.85 to 2.13) | 1.51 (0.91 to 2.48) |
| H44/76 (fHBP) (Day 365) | 21 (6 to 71) | 11 (4.68 to 25) | 1.96 (1.21 to 3.19) | 1.92 (1.17 to 3.17) |
| 5/99 (NadA) (Day 1) | 27 (8.61 to 86) | 39 (21 to 74) | 2.97 (1.58 to 5.59) | 1.8 (1.01 to 3.22) |
| 5/99 (NadA) (Day 365) | 587 (351 to 983) | 491 (258 to 936) | 6.05 (3.1 to 12) | 4.23 (1.48 to 12) |

| End point values | 1M_Pbo | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 2.55 (1.37 to 4.77) | | | |
| M14459 (fHBP) (Day 365) | 2.17 (1.07 to 4.41) | | | |
| M01-0240364 (NadA) (Day 1) | 1.68 (0.85 to 3.33) | | | |
| M01-0240364 (NadA) (Day 365) | 2.03 (0.9 to 4.58) | | | |
| NZ98/254 (PorA) (Day 1) | 1.13 (0.94 to 1.37) | | | |
| NZ98/254 (PorA) (Day 365) | 1.28 (0.85 to 1.92) | | | |
| M07-0241084 (NHBA) (Day 1) | 3.5 (1.57 to 7.8) | | | |

| | | | | |
|------------------------------|---------------------|--|--|--|
| M07-0241084 (NHBA) (Day 365) | 3.92 (1.9 to 8.07) | | | |
| H44/76 (fHBP) (Day 1) | 1.19 (0.97 to 1.47) | | | |
| H44/76 (fHBP) (Day 365) | 1.49 (0.9 to 2.48) | | | |
| 5/99 (NadA) (Day 1) | 3.2 (1.44 to 7.09) | | | |
| 5/99 (NadA) (Day 365) | 2.45 (1 to 5.99) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 18. Percentage of subjects with HT-hSBA titer \geq 1:8 to N. meningitidis serogroups A, C, W, Y.

| | |
|-----------------|--|
| End point title | 18. Percentage of subjects with HT-hSBA titer \geq 1:8 to N. meningitidis serogroups A, C, W, Y. ^[16] |
|-----------------|--|

End point description:

Percentage of subjects with HT-hSBA titer \geq 1:8 against N. meningitidis serogroups A, C, W, Y at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination.

Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

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

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2qOMV_qOMV | 2B_OMV | 2B_qOMV |
|----------------------------------|--------------------|-------------------|-------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 16 | 11 | 20 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 38 (18.1 to 61.6) | 20 (4.3 to 48.1) | 30 (6.7 to 65.2) | 35 (15.4 to 59.2) |
| Men C (Day 1) | 65 (40.8 to 84.6) | 71 (41.9 to 91.6) | 36 (10.9 to 69.2) | 58 (33.5 to 79.7) |
| Men W (Day 1) | 95 (75.1 to 99.87) | 75 (42.8 to 94.5) | 82 (48.2 to 97.7) | 75 (50.9 to 91.3) |
| Men Y (Day 1) | 62 (38.4 to 81.9) | 71 (41.9 to 91.6) | 36 (10.9 to 69.2) | 11 (1.4 to 34.7) |
| Men A (Day 30) | 100 (83.9 to 100) | 100 (78.2 to 100) | 100 (69.2 to 100) | 95 (75.1 to 99.87) |
| Men C (Day 30) | 100 (80.5 to 100) | 100 (69.2 to 100) | 100 (59 to 100) | 100 (76.8 to 100) |
| Men W (Day 30) | 100 (81.5 to 100) | 100 (78.2 to 100) | 100 (71.5 to 100) | 100 (81.5 to 100) |
| Men Y (Day 30) | 100 (83.9 to 100) | 100 (78.2 to 100) | 82 (48.2 to 97.7) | 83 (58.6 to 96.4) |

| | | | | |
|-----------------|--------------------|-------------------|--------------------|-------------------|
| Men A (Day 365) | 67 (43 to 85.4) | 88 (61.7 to 98.4) | 90 (55.5 to 99.75) | 85 (62.1 to 96.8) |
| Men C (Day 365) | 100 (83.9 to 100) | 100 (79.4 to 100) | 82 (48.2 to 97.7) | 95 (74 to 99.87) |
| Men W (Day 365) | 100 (83.9 to 100) | 100 (79.4 to 100) | 91 (58.7 to 99.77) | 100 (83.2 to 100) |
| Men Y (Day 365) | 95 (76.2 to 99.88) | 100 (79.4 to 100) | 45 (16.7 to 76.6) | 72 (46.5 to 90.3) |

| End point values | 1M_OMV | 1M_qOMV | | |
|----------------------------------|-------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 18 | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 45 (23.1 to 68.5) | 12 (1.5 to 36.4) | | |
| Men C (Day 1) | 58 (33.5 to 79.7) | 50 (26 to 74) | | |
| Men W (Day 1) | 82 (56.6 to 96.2) | 61 (35.7 to 82.7) | | |
| Men Y (Day 1) | 55 (31.5 to 76.9) | 44 (21.5 to 69.2) | | |
| Men A (Day 30) | 100 (81.5 to 100) | 94 (69.8 to 99.84) | | |
| Men C (Day 30) | 100 (82.4 to 100) | 88 (63.6 to 98.5) | | |
| Men W (Day 30) | 100 (80.5 to 100) | 100 (79.4 to 100) | | |
| Men Y (Day 30) | 100 (83.2 to 100) | 100 (80.5 to 100) | | |
| Men A (Day 365) | 85 (62.1 to 96.8) | 50 (26 to 74) | | |
| Men C (Day 365) | 100 (82.4 to 100) | 89 (65.3 to 98.6) | | |
| Men W (Day 365) | 100 (82.4 to 100) | 100 (81.5 to 100) | | |
| Men Y (Day 365) | 100 (83.2 to 100) | 89 (65.3 to 98.6) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 19. Percentage of subjects with HT-hSBA titer $\geq 1:5$ to N. meningitidis in strains of serogroup B.

| | |
|-----------------|--|
| End point title | 19. Percentage of subjects with HT-hSBA titer $\geq 1:5$ to N. meningitidis in strains of serogroup B. ^[17] |
|-----------------|--|

End point description:

Percentage of subjects with HT-hSBA titer $\geq 1:5$ against N. meningitidis in strains of serogroup B at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination.

Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable

serum sample at Day 365.

| | |
|---------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 1, Day 30 and Day 365 | |

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2qOMV_qOMV | 2B_OMV | 2B_qOMV |
|----------------------------------|--------------------|--------------------|--------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 16 | 11 | 20 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 24 (8.2 to 47.2) | 7 (0.18 to 33.9) | 36 (10.9 to 69.2) | 30 (11.9 to 54.3) |
| M01-0240364 (NadA) (Day 1) | 24 (8.2 to 47.2) | 21 (4.7 to 50.8) | 20 (2.5 to 55.6) | 42 (20.3 to 66.5) |
| NZ98/254 (PorA) (Day 1) | 19 (5.4 to 41.9) | 7 (0.18 to 33.9) | 9 (0.23 to 41.3) | 26 (9.1 to 51.2) |
| M07-0241084 (NHBA) (Day 1) | 38 (18.1 to 61.6) | 29 (8.4 to 58.1) | 64 (30.8 to 89.1) | 58 (33.5 to 79.7) |
| H44/76 (fHBP) (Day 1) | 19 (5.4 to 41.9) | 13 (1.7 to 40.5) | 45 (16.7 to 76.6) | 30 (11.9 to 54.3) |
| 5/99 (NadA) (Day 1) | 76 (52.8 to 91.8) | 86 (57.2 to 98.2) | 89 (51.8 to 99.72) | 95 (74 to 99.87) |
| M14459 (fHBP) (Day 30) | 95 (76.2 to 99.88) | 88 (61.7 to 98.4) | 100 (71.5 to 100) | 95 (75.1 to 99.87) |
| M01-0240364 (NadA) (Day 30) | 100 (83.9 to 100) | 100 (79.4 to 100) | 100 (71.5 to 100) | 100 (82.4 to 100) |
| NZ98/254 (PorA) (Day 30) | 95 (76.2 to 99.88) | 75 (47.6 to 92.7) | 82 (48.2 to 97.7) | 95 (74 to 99.87) |
| M07-0241084 (NHBA) (Day 30) | 100 (83.9 to 100) | 94 (69.8 to 99.84) | 91 (58.7 to 99.77) | 95 (74 to 99.87) |
| H44/76 (fHBP) (Day 30) | 95 (76.2 to 99.88) | 100 (79.4 to 100) | 100 (71.5 to 100) | 100 (83.2 to 100) |
| 5/99 (NadA) (Day 30) | 100 (83.9 to 100) | 100 (79.4 to 100) | 100 (71.5 to 100) | 100 (82.4 to 100) |
| M14459 (fHBP) (Day 365) | 57 (34 to 78.2) | 38 (15.2 to 64.6) | 82 (48.2 to 97.7) | 60 (36.1 to 80.9) |
| M01-0240364 (NadA) (Day 365) | 71 (47.8 to 88.7) | 75 (47.6 to 92.7) | 100 (71.5 to 100) | 95 (74 to 99.87) |
| NZ98/254 (PorA) (Day 365) | 29 (11.3 to 52.2) | 31 (11 to 58.7) | 45 (16.7 to 76.6) | 42 (20.3 to 66.5) |
| M07-0241084 (NHBA) (Day 365) | 62 (38.4 to 81.9) | 50 (24.7 to 75.3) | 82 (48.2 to 97.7) | 74 (48.8 to 90.9) |
| H44/76 (fHBP) (Day 365) | 76 (52.8 to 91.8) | 44 (19.8 to 70.1) | 82 (48.2 to 97.7) | 65 (40.8 to 84.6) |
| 5/99 (NadA) (Day 365) | 95 (76.2 to 99.88) | 100 (79.4 to 100) | 100 (71.5 to 100) | 100 (82.4 to 100) |

| End point values | 1M_OMV | 1M_qOMV | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 21 | 18 | | |

| | | | | |
|----------------------------------|-------------------|-------------------|--|--|
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 10 (1.2 to 30.4) | 11 (1.4 to 34.7) | | |
| M01-0240364 (NadA) (Day 1) | 5 (0.13 to 24.9) | 6 (0.15 to 28.7) | | |
| NZ98/254 (PorA) (Day 1) | 5 (0.12 to 23.8) | 6 (0.14 to 27.3) | | |
| M07-0241084 (NHBA) (Day 1) | 19 (5.4 to 41.9) | 17 (3.6 to 41.4) | | |
| H44/76 (fHBP) (Day 1) | 5 (0.12 to 23.8) | 6 (0.14 to 27.3) | | |
| 5/99 (NadA) (Day 1) | 19 (5.4 to 41.9) | 17 (3.6 to 41.4) | | |
| M14459 (fHBP) (Day 30) | 35 (15.4 to 59.2) | 33 (13.3 to 59) | | |
| M01-0240364 (NadA) (Day 30) | 21 (6.1 to 45.6) | 28 (9.7 to 53.5) | | |
| NZ98/254 (PorA) (Day 30) | 19 (5.4 to 41.9) | 17 (3.6 to 41.4) | | |
| M07-0241084 (NHBA) (Day 30) | 33 (14.6 to 57) | 22 (6.4 to 47.6) | | |
| H44/76 (fHBP) (Day 30) | 58 (33.5 to 79.7) | 33 (13.3 to 59) | | |
| 5/99 (NadA) (Day 30) | 76 (52.8 to 91.8) | 83 (58.6 to 96.4) | | |
| M14459 (fHBP) (Day 365) | 14 (3 to 36.3) | 11 (1.4 to 34.7) | | |
| M01-0240364 (NadA) (Day 365) | 15 (3.2 to 37.9) | 11 (1.4 to 34.7) | | |
| NZ98/254 (PorA) (Day 365) | 19 (5.4 to 41.9) | 6 (0.14 to 27.3) | | |
| M07-0241084 (NHBA) (Day 365) | 29 (11.3 to 52.2) | 17 (3.6 to 41.4) | | |
| H44/76 (fHBP) (Day 365) | 19 (5.4 to 41.9) | 11 (1.4 to 34.7) | | |
| 5/99 (NadA) (Day 365) | 43 (21.8 to 66) | 33 (13.3 to 59) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 20. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.

| | |
|-----------------|---|
| End point title | 20. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y. ^[18] |
|-----------------|---|

End point description:

The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination. Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

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

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2qOMV_qOMV | 2B_OMV | 2B_qOMV |
|--|-------------------|---------------------|---------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 16 | 11 | 20 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Men A (Day 1) | 3.98 (1.98 to 8) | 3.07 (1.26 to 7.47) | 2.27 (0.87 to 5.94) | 4.22 (1.63 to 11) |
| Men C (Day 1) | 18 (8.21 to 39) | 19 (8.13 to 44) | 5.2 (2.8 to 9.65) | 7.83 (4.51 to 14) |
| Men W (Day 1) | 36 (21 to 62) | 30 (7.82 to 112) | 25 (7.98 to 79) | 23 (9.81 to 52) |
| Men Y (Day 1) | 10 (4.39 to 24) | 24 (6.62 to 90) | 2.4 (1.05 to 5.47) | 1.9 (1.02 to 3.55) |
| Men A (Day 30) | 275 (174 to 435) | 348 (202 to 601) | 445 (277 to 715) | 428 (196 to 931) |
| Men C (Day 30) | 737 (459 to 1183) | 766 (325 to 1804) | 292 (75 to 1142) | 102 (57 to 181) |
| Men W (Day 30) | 844 (535 to 1333) | 890 (665 to 1190) | 392 (252 to 610) | 395 (321 to 487) |
| Men Y (Day 30) | 444 (257 to 768) | 748 (463 to 1208) | 48 (14 to 157) | 54 (17 to 171) |
| Men A (Day 365) | 25 (11 to 59) | 44 (18 to 105) | 54 (17 to 174) | 53 (22 to 130) |
| Men C (Day 365) | 128 (75 to 217) | 177 (102 to 305) | 29 (10 to 82) | 32 (16 to 67) |
| Men W (Day 365) | 190 (133 to 272) | 213 (135 to 337) | 80 (26 to 246) | 96 (72 to 127) |
| Men Y (Day 365) | 116 (58 to 231) | 235 (147 to 376) | 7.17 (1.91 to 27) | 20 (6.92 to 58) |

| End point values | 1M_OMV | 1M_qOMV | | |
|--|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 18 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Men A (Day 1) | 6.31 (2.82 to 14) | 2.49 (1.52 to 4.09) | | |
| Men C (Day 1) | 7.89 (4.26 to 15) | 8.45 (2.64 to 27) | | |
| Men W (Day 1) | 28 (11 to 70) | 15 (4.54 to 47) | | |
| Men Y (Day 1) | 7.05 (3.08 to 16) | 6.83 (2.11 to 22) | | |
| Men A (Day 30) | 140 (82 to 239) | 46 (23 to 91) | | |
| Men C (Day 30) | 322 (186 to 556) | 307 (118 to 795) | | |
| Men W (Day 30) | 620 (354 to 1085) | 360 (169 to 765) | | |

| | | | | |
|-----------------|-------------------|-------------------|--|--|
| Men Y (Day 30) | 662 (424 to 1032) | 404 (201 to 811) | | |
| Men A (Day 365) | 34 (16 to 69) | 6.52 (2.71 to 16) | | |
| Men C (Day 365) | 81 (46 to 141) | 72 (27 to 191) | | |
| Men W (Day 365) | 172 (96 to 306) | 104 (49 to 221) | | |
| Men Y (Day 365) | 193 (123 to 301) | 101 (36 to 280) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 21. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

| | |
|-----------------|--|
| End point title | 21. The HT-hSBA GMTs against N. meningitidis strains of serogroup B. ^[19] |
|-----------------|--|

End point description:

The HT-hSBA GMTs against N. meningitidis strains of serogroups B at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination.

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

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2qOMV_qOMV | 2B_OMV | 2B_qOMV |
|--|---------------------|---------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 16 | 11 | 20 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 2.69 (1.51 to 4.78) | 1.54 (0.9 to 2.63) | 3.11 (1.74 to 5.56) | 3.37 (1.95 to 5.81) |
| M01-0240364 (NadA) (Day 1) | 2.33 (1.25 to 4.36) | 2.87 (0.86 to 9.59) | 2.46 (0.72 to 8.4) | 6.29 (2.22 to 18) |
| NZ98/254 (PorA) (Day 1) | 1.73 (1.06 to 2.81) | 1.34 (0.94 to 1.93) | 1.72 (0.99 to 2.98) | 2.24 (1.2 to 4.17) |
| M07-0241084 (NHBA) (Day 1) | 3.68 (2.07 to 6.54) | 2.28 (1.16 to 4.48) | 4.1 (1.89 to 8.9) | 7.35 (3.82 to 14) |
| H44/76 (fHBP) (Day 1) | 3.58 (1.66 to 7.71) | 1.49 (0.96 to 2.33) | 3.45 (1.81 to 6.57) | 3.43 (1.83 to 6.43) |
| 5/99 (NadA) (Day 1) | 18 (9.47 to 34) | 31 (12 to 85) | 27 (8.61 to 86) | 39 (21 to 74) |
| M14459 (fHBP) (Day 30) | 39 (21 to 70) | 20 (10 to 39) | 56 (27 to 117) | 35 (21 to 60) |
| M01-0240364 (NadA) (Day 30) | 679 (352 to 1310) | 903 (463 to 1761) | 1336 (810 to 2202) | 1261 (746 to 2131) |
| NZ98/254 (PorA) (Day 30) | 32 (19 to 52) | 15 (5.93 to 36) | 17 (6.22 to 45) | 28 (17 to 47) |
| M07-0241084 (NHBA) (Day 30) | 59 (36 to 98) | 36 (20 to 64) | 68 (33 to 142) | 66 (35 to 124) |
| H44/76 (fHBP) (Day 30) | 104 (59 to 184) | 57 (32 to 102) | 132 (64 to 271) | 79 (40 to 153) |

| | | | | |
|------------------------------|---------------------|---------------------|---------------------|---------------------|
| 5/99 (NadA) (Day 30) | 1147 (665 to 1980) | 1598 (864 to 2956) | 2205 (1560 to 3117) | 2816 (1856 to 4273) |
| M14459 (fHBP) (Day 365) | 7.19 (3.89 to 13) | 2.94 (1.49 to 5.8) | 11 (4.41 to 28) | 7.12 (3.59 to 14) |
| M01-0240364 (NadA) (Day 365) | 30 (9.54 to 93) | 74 (18 to 300) | 303 (174 to 527) | 155 (69 to 350) |
| NZ98/254 (PorA) (Day 365) | 3.49 (2.12 to 5.74) | 2.67 (1.27 to 5.61) | 3.28 (1.66 to 6.49) | 3.77 (1.98 to 7.18) |
| M07-0241084 (NHBA) (Day 365) | 7.96 (4.6 to 14) | 4.09 (2.3 to 7.25) | 10 (4.51 to 24) | 11 (6.35 to 18) |
| H44/76 (fHBP) (Day 365) | 12 (5.18 to 26) | 4.19 (1.93 to 9.11) | 21 (6 to 71) | 11 (4.68 to 25) |
| 5/99 (NadA) (Day 365) | 175 (79 to 385) | 305 (149 to 625) | 587 (351 to 983) | 491 (258 to 936) |

| End point values | 1M_OMV | 1M_qOMV | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 21 | 18 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| M14459 (fHBP) (Day 1) | 1.85 (1.13 to 3.04) | 1.48 (1.03 to 2.13) | | |
| M01-0240364 (NadA) (Day 1) | 1.24 (0.79 to 1.94) | 1.24 (0.88 to 1.77) | | |
| NZ98/254 (PorA) (Day 1) | 1.18 (0.84 to 1.66) | 1.19 (0.9 to 1.58) | | |
| M07-0241084 (NHBA) (Day 1) | 2.08 (1.26 to 3.42) | 2.15 (1.14 to 4.05) | | |
| H44/76 (fHBP) (Day 1) | 1.34 (0.85 to 2.13) | 1.51 (0.91 to 2.48) | | |
| 5/99 (NadA) (Day 1) | 2.97 (1.58 to 5.59) | 1.8 (1.01 to 3.22) | | |
| M14459 (fHBP) (Day 30) | 3.44 (2.05 to 5.75) | 2.71 (1.56 to 4.7) | | |
| M01-0240364 (NadA) (Day 30) | 2.68 (1.15 to 6.25) | 3.66 (1.21 to 11) | | |
| NZ98/254 (PorA) (Day 30) | 2.48 (1.31 to 4.69) | 1.62 (0.96 to 2.74) | | |
| M07-0241084 (NHBA) (Day 30) | 3.26 (1.75 to 6.06) | 2.24 (1.14 to 4.38) | | |
| H44/76 (fHBP) (Day 30) | 5.27 (2.54 to 11) | 3.89 (1.79 to 8.47) | | |
| 5/99 (NadA) (Day 30) | 28 (11 to 67) | 29 (10 to 80) | | |
| M14459 (fHBP) (Day 365) | 2.09 (1.33 to 3.29) | 1.38 (0.98 to 1.93) | | |
| M01-0240364 (NadA) (Day 365) | 1.61 (0.99 to 2.63) | 1.71 (0.86 to 3.42) | | |
| NZ98/254 (PorA) (Day 365) | 1.65 (1.04 to 2.61) | 1.19 (0.91 to 1.54) | | |
| M07-0241084 (NHBA) (Day 365) | 2.45 (1.59 to 3.79) | 1.91 (1.14 to 3.23) | | |
| H44/76 (fHBP) (Day 365) | 1.96 (1.21 to 3.19) | 1.92 (1.17 to 3.17) | | |
| 5/99 (NadA) (Day 365) | 6.05 (3.1 to 12) | 4.23 (1.48 to 12) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 22. Percentage of subjects with Ht-hSBA titer $\geq 1:8$ to N. meningitidis serogroups A, C, W, Y at 12 months after booster vaccination.

| | |
|-----------------|---|
| End point title | 22. Percentage of subjects with Ht-hSBA titer $\geq 1:8$ to N. meningitidis serogroups A, C, W, Y at 12 months after booster vaccination. ^[20] |
|-----------------|---|

End point description:

Percentage of subjects with HT-hSBA titer $\geq 1:8$ to N. meningitidis serogroups A, C, W, Y at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination in this study.

Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

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

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

| End point values | 2OMV_OMV | 2qOMV_qOMV | 2B_OMV | 2B_qOMV |
|----------------------------------|--------------------|-------------------|--------------------|--------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 21 | 16 | 11 | 20 |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 38 (18.1 to 61.6) | 20 (4.3 to 48.1) | 30 (6.7 to 65.2) | 35 (15.4 to 59.2) |
| Men C (Day 1) | 65 (40.8 to 84.6) | 71 (41.9 to 91.6) | 36 (10.9 to 69.2) | 58 (33.5 to 79.7) |
| Men W (Day 1) | 95 (75.1 to 99.87) | 75 (42.8 to 94.5) | 82 (48.2 to 97.7) | 75 (50.9 to 91.3) |
| Men Y (Day 1) | 62 (38.4 to 81.9) | 71 (41.9 to 91.6) | 36 (10.9 to 69.2) | 11 (1.4 to 34.7) |
| Men A (Day 30) | 100 (83.9 to 100) | 100 (78.2 to 100) | 100 (69.2 to 100) | 95 (75.1 to 99.87) |
| Men C (Day 30) | 100 (80.5 to 100) | 100 (69.2 to 100) | 100 (59 to 100) | 100 (76.8 to 100) |
| Men W (Day 30) | 100 (81.5 to 100) | 100 (78.2 to 100) | 100 (71.5 to 100) | 100 (81.5 to 100) |
| Men Y (Day 30) | 100 (83.9 to 100) | 100 (78.2 to 100) | 82 (48.2 to 97.7) | 83 (58.6 to 96.4) |
| Men A (Day 365) | 67 (43 to 85.4) | 88 (61.7 to 98.4) | 90 (55.5 to 99.75) | 85 (62.1 to 96.8) |
| Men C (Day 365) | 100 (83.9 to 100) | 100 (79.4 to 100) | 82 (48.2 to 97.7) | 95 (74 to 99.87) |

| | | | | |
|-----------------|--------------------|-------------------|--------------------|-------------------|
| Men W (Day 365) | 100 (83.9 to 100) | 100 (79.4 to 100) | 91 (58.7 to 99.77) | 100 (83.2 to 100) |
| Men Y (Day 365) | 95 (76.2 to 99.88) | 100 (79.4 to 100) | 45 (16.7 to 76.6) | 72 (46.5 to 90.3) |

| End point values | 1M_OMV | 1M_qOMV | | |
|----------------------------------|-------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 18 | | |
| Units: Percentage | | | | |
| number (confidence interval 95%) | | | | |
| Men A (Day 1) | 45 (23.1 to 68.5) | 12 (1.5 to 36.4) | | |
| Men C (Day 1) | 58 (33.5 to 79.7) | 50 (26 to 74) | | |
| Men W (Day 1) | 82 (56.6 to 96.2) | 61 (35.7 to 82.7) | | |
| Men Y (Day 1) | 55 (31.5 to 76.9) | 44 (21.5 to 69.2) | | |
| Men A (Day 30) | 100 (81.5 to 100) | 94 (69.8 to 99.84) | | |
| Men C (Day 30) | 100 (82.4 to 100) | 88 (63.6 to 98.5) | | |
| Men W (Day 30) | 100 (80.5 to 100) | 100 (79.4 to 100) | | |
| Men Y (Day 30) | 100 (83.2 to 100) | 100 (80.5 to 100) | | |
| Men A (Day 365) | 85 (62.1 to 96.8) | 50 (26 to 74) | | |
| Men C (Day 365) | 100 (82.4 to 100) | 89 (65.3 to 98.6) | | |
| Men W (Day 365) | 100 (82.4 to 100) | 100 (81.5 to 100) | | |
| Men Y (Day 365) | 100 (83.2 to 100) | 89 (65.3 to 98.6) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 23. Number of subjects with solicited local and systemic AEs following booster vaccination in this study.

| | |
|-----------------|---|
| End point title | 23. Number of subjects with solicited local and systemic AEs following booster vaccination in this study. |
|-----------------|---|

End point description:

Number of subjects reporting solicited local and systemic AEs after receiving a booster dose of MenABCWY vaccine or placebo.

Analysis was done on the Solicited Safety Set, i.e. all exposed subjects who provide post vaccination solicited adverse event data.

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

End point timeframe:

From Day 1 (6 hours) through Day 7 after any vaccination.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 24 | 17 | 23 |
| Units: Subjects | | | | |
| Any local | 23 | 7 | 15 | 8 |
| Injection site pain | 20 | 6 | 14 | 7 |
| Injection site induration | 7 | 2 | 5 | 2 |
| Injection site erythema | 11 | 2 | 7 | 3 |
| Any systemic | 12 | 9 | 12 | 6 |
| Chills | 3 | 1 | 0 | 0 |
| Nausea | 0 | 2 | 3 | 1 |
| Fatigue | 9 | 6 | 8 | 2 |
| Myalgia | 6 | 2 | 5 | 0 |
| Arthralgia | 3 | 2 | 3 | 1 |
| Loss of appetite | 2 | 1 | 4 | 2 |
| Headache | 7 | 6 | 8 | 3 |
| Rash | 0 | 0 | 1 | 0 |
| Body temperature (> 38 °C) | 2 | 0 | 0 | 1 |
| Use of analgesics/antipyretics | 0 | 0 | 1 | 0 |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 19 |
| Units: Subjects | | | | |
| Any local | 11 | 18 | 19 | 17 |
| Injection site pain | 11 | 17 | 19 | 17 |
| Injection site induration | 9 | 6 | 7 | 4 |
| Injection site erythema | 6 | 7 | 6 | 9 |
| Any systemic | 5 | 10 | 15 | 10 |
| Chills | 1 | 2 | 5 | 1 |
| Nausea | 3 | 5 | 4 | 5 |
| Fatigue | 5 | 8 | 11 | 6 |
| Myalgia | 1 | 4 | 8 | 4 |
| Arthralgia | 0 | 2 | 4 | 2 |
| Loss of appetite | 1 | 3 | 8 | 3 |
| Headache | 5 | 4 | 12 | 5 |
| Rash | 0 | 1 | 1 | 2 |
| Body temperature (> 38 °C) | 0 | 0 | 0 | 0 |
| Use of analgesics/antipyretics | 0 | 0 | 0 | 0 |

| End point values | 1M_Pbo | 2B_Pbo | | |
|------------------|--------|--------|--|--|
|------------------|--------|--------|--|--|

| Subject group type | Reporting group | Reporting group | | |
|--------------------------------|-----------------|-----------------|--|--|
| Number of subjects analysed | 19 | 6 | | |
| Units: Subjects | | | | |
| Any local | 5 | 1 | | |
| Injection site pain | 4 | 1 | | |
| Injection site induration | 1 | 0 | | |
| Injection site erythema | 2 | 0 | | |
| Any systemic | 5 | 1 | | |
| Chills | 1 | 0 | | |
| Nausea | 1 | 0 | | |
| Fatigue | 5 | 0 | | |
| Myalgia | 1 | 0 | | |
| Arthralgia | 3 | 0 | | |
| Loss of appetite | 2 | 0 | | |
| Headache | 2 | 1 | | |
| Rash | 0 | 0 | | |
| Body temperature (> 38 °C) | 0 | 0 | | |
| Use of analgesics/antipyretics | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 24. Number of subjects with unsolicited (any AEs and possibly related AEs) following booster vaccination in this study.

| | |
|-----------------|---|
| End point title | 24. Number of subjects with unsolicited (any AEs and possibly related AEs) following booster vaccination in this study. |
|-----------------|---|

End point description:

Number of subjects reporting unsolicited AEs (any AEs and at least possibly related AEs) after receiving a booster dose of MenABCWY vaccine or placebo from Day 1 to Day 30.

Analysis was done on the Unsolicited Safety Set. All subjects in the exposed population who provided information about post-vaccination AEs or safety records at Day 30.

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

End point timeframe:

Day 1 through Day 30

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 24 | 17 | 23 |
| Units: Subjects | | | | |
| Any AEs | 6 | 4 | 5 | 2 |
| At least possibly related | 3 | 1 | 3 | 0 |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|------------------|--------|---------|--------|---------|
|------------------|--------|---------|--------|---------|

| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Number of subjects analysed | 11 | 21 | 21 | 19 |
| Units: Subjects | | | | |
| Any AEs | 3 | 7 | 6 | 5 |
| At least possibly related | 2 | 3 | 2 | 3 |

| End point values | 1M_Pbo | 2B_Pbo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 6 | | |
| Units: Subjects | | | | |
| Any AEs | 4 | 1 | | |
| At least possibly related | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 25. Number of subjects with unsolicited AEs following booster vaccination in this study.

| | |
|-----------------|--|
| End point title | 25. Number of subjects with unsolicited AEs following booster vaccination in this study. |
|-----------------|--|

End point description:

Number of subjects reporting any serious unsolicited AEs (SAEs), possibly related SAEs, medically attended AEs, unsolicited AEs leading to withdrawal and deaths after receiving a booster dose of MenABCWY vaccine or placebo, are reported for the entire study period.

Analysis was done on the Unsolicited Safety Set. All subjects in the exposed population who provided information about post-vaccination AEs or safety records at Day 365.

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

End point timeframe:

Day 1 through Day 365

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 24 | 17 | 23 |
| Units: Subjects | | | | |
| Any SAEs | 0 | 0 | 1 | 1 |
| At Least Possibly related SAEs | 0 | 0 | 0 | 0 |
| NOCD | 0 | 3 | 2 | 0 |
| Medically attended AEs | 12 | 10 | 12 | 9 |
| AEs leading to withdrawal | 0 | 0 | 0 | 0 |
| Deaths | 0 | 0 | 0 | 0 |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 19 |
| Units: Subjects | | | | |
| Any SAEs | 0 | 1 | 0 | 1 |
| At Least Possibly related SAEs | 0 | 0 | 0 | 0 |
| NOCD | 0 | 1 | 1 | 1 |
| Medically attended AEs | 6 | 9 | 13 | 11 |
| AEs leading to withdrawal | 0 | 0 | 0 | 0 |
| Deaths | 0 | 0 | 0 | 0 |

| End point values | 1M_Pbo | 2B_Pbo | | |
|--------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 6 | | |
| Units: Subjects | | | | |
| Any SAEs | 1 | 0 | | |
| At Least Possibly related SAEs | 0 | 0 | | |
| NOCD | 1 | 0 | | |
| Medically attended AEs | 11 | 1 | | |
| AEs leading to withdrawal | 0 | 0 | | |
| Deaths | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: 26. Number of subjects with unsolicited AEs leading to New Onset Chronic Disease (NOCD) before study vaccination.

| | |
|-----------------|---|
| End point title | 26. Number of subjects with unsolicited AEs leading to New Onset Chronic Disease (NOCD) before study vaccination. |
|-----------------|---|

End point description:

Number of subjects reporting New Onset Chronic Disease (NOCD), from the end of the primary parental study V102_03 up to Day 1 visit in V102_03E1 study, is reported. (Any NOCD AEs: NOCD V102_03 vs. NOCD- Day 1, Pre vaccination, V102_03E1).

Analysis was done on the all enrolled set population. All screened subjects who have been enrolled (ie, attended the first clinic visit and received a subject ID).

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

End point timeframe:

From primary parent study completion up to Day 1 in this study.

| End point values | 2OMV_OMV | 2OMV_Pbo | 2qOMV_qOMV | 2qOMV_Pbo |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 25 | 17 | 24 |
| Units: Subjects | | | | |
| NOCD (SOC/PT) Day 1, V102_03E1) | 2 | 4 | 0 | 1 |

| End point values | 2B_OMV | 2B_qOMV | 1M_OMV | 1M_qOMV |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 21 | 21 | 19 |
| Units: Subjects | | | | |
| NOCD (SOC/PT) Day 1, V102_03E1) | 0 | 2 | 2 | 2 |

| End point values | 1M_Pbo | 2B_Pbo | | |
|---------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 19 | 7 | | |
| Units: Subjects | | | | |
| NOCD (SOC/PT) Day 1, V102_03E1) | 1 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs between Day 1 (from 30 minutes) to Day 7; any unsolicited AEs from Day 1 (from 30 minutes) to Day 30, and SAEs, medically attended AEs, AEs leading to withdrawal, death and NOCD from Day 1 to Day 365.

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 18.1 |

Reporting groups

| | |
|-----------------------|--------|
| Reporting group title | 2B_Pbo |
|-----------------------|--------|

Reporting group description: -

| | |
|-----------------------|----------|
| Reporting group title | 2OMV_OMV |
|-----------------------|----------|

Reporting group description:

Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one booster dose of same vaccine in this study.

| | |
|-----------------------|----------|
| Reporting group title | 2OMV_Pbo |
|-----------------------|----------|

Reporting group description:

Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one dose of saline solution in this study.

| | |
|-----------------------|------------|
| Reporting group title | 2qOMV_qOMV |
|-----------------------|------------|

Reporting group description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one booster dose of same vaccine in this study.

| | |
|-----------------------|-----------|
| Reporting group title | 2qOMV_Pbo |
|-----------------------|-----------|

Reporting group description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one dose of saline solution in this study.

| | |
|-----------------------|--------|
| Reporting group title | 2B_OMV |
|-----------------------|--------|

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + OMV in this study.

| | |
|-----------------------|---------|
| Reporting group title | 2B_qOMV |
|-----------------------|---------|

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

| | |
|-----------------------|--------|
| Reporting group title | 1M_OMV |
|-----------------------|--------|

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + OMV in this study.

| | |
|-----------------------|---------|
| Reporting group title | 1M_qOMV |
|-----------------------|---------|

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

| | |
|-----------------------|--------|
| Reporting group title | 1M_Pbo |
|-----------------------|--------|

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of saline solution in this study.

| Serious adverse events | 2B_Pbo | 2OMV_OMV | 2OMV_Pbo |
|---|---------------|----------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Facial bones fracture | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (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 |
| Limb injury | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Syncope | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Appendicitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (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 | 2qOMV_qOMV | 2qOMV_Pbo | 2B_OMV |
|---|----------------|----------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 24 (4.17%) | 0 / 11 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Facial bones fracture | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 24 (4.17%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Limb injury | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Syncope | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Appendicitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (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 | 2B_qOMV | 1M_OMV | 1M_qOMV |
|---|----------------|----------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 21 (0.00%) | 1 / 19 (5.26%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Facial bones fracture | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (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 |
| Limb injury | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 1 / 19 (5.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Syncope | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Appendicitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | | 1M_Pbo | | |
|---|--|----------------|--|--|
| Total subjects affected by serious adverse events | | | | |
| subjects affected / exposed | | 1 / 19 (5.26%) | | |
| number of deaths (all causes) | | 0 | | |
| number of deaths resulting from adverse events | | 0 | | |
| Injury, poisoning and procedural complications | | | | |
| Facial bones fracture | | | | |
| alternative assessment type: Non-systematic | | | | |
| subjects affected / exposed | | 0 / 19 (0.00%) | | |
| occurrences causally related to treatment / all | | 0 / 0 | | |
| deaths causally related to treatment / all | | 0 / 0 | | |
| Limb injury | | | | |
| alternative assessment type: Non-systematic | | | | |
| subjects affected / exposed | | 0 / 19 (0.00%) | | |
| occurrences causally related to treatment / all | | 0 / 0 | | |
| deaths causally related to treatment / all | | 0 / 0 | | |
| Nervous system disorders | | | | |
| Syncope | | | | |
| alternative assessment type: Non-systematic | | | | |
| subjects affected / exposed | | 0 / 19 (0.00%) | | |
| occurrences causally related to treatment / all | | 0 / 0 | | |
| deaths causally related to treatment / all | | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Asthma | | | | |
| alternative assessment type: Non-systematic | | | | |
| subjects affected / exposed | | 1 / 19 (5.26%) | | |
| occurrences causally related to treatment / all | | 0 / 1 | | |
| deaths causally related to treatment / all | | 0 / 0 | | |
| Infections and infestations | | | | |
| Appendicitis | | | | |
| alternative assessment type: Non-systematic | | | | |
| subjects affected / exposed | | 0 / 19 (0.00%) | | |
| occurrences causally related to treatment / all | | 0 / 0 | | |
| deaths causally related to treatment / all | | 0 / 0 | | |

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

| Non-serious adverse events | 2B_Pbo | 2OMV_OMV | 2OMV_Pbo |
|---|----------------|------------------|------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4 / 6 (66.67%) | 25 / 27 (92.59%) | 16 / 24 (66.67%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Skin papilloma | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Essential hypertension | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 27 (11.11%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 3 | 2 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 9 / 27 (33.33%) | 8 / 24 (33.33%) |
| occurrences (all) | 0 | 9 | 11 |
| Induration | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 11 / 27 (40.74%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 12 | 2 |
| Injection site induration | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 27 (25.93%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 7 | 2 |
| Injection site pain | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 21 / 27 (77.78%) | 7 / 24 (29.17%) |
| occurrences (all) | 1 | 23 | 7 |

| | | | |
|---|----------------|----------------|----------------|
| Pyrexia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 27 (7.41%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 2 | 1 |
| Vaccination site erythema | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 27 (3.70%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vaccination site pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Breast mass | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 27 (7.41%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Investigations | | | |
| Blood iron decreased | | | |

| | | | |
|--|----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Body temperature increased | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 27 (7.41%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 2 | 1 |
| Post vaccination syndrome | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Dizziness postural | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 8 / 27 (29.63%) | 6 / 24 (25.00%) |
| occurrences (all) | 2 | 8 | 6 |
| Syncope | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |

| | | | |
|--|--------------------|---------------------|---------------------|
| Photophobia subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Myopia subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 1 / 27 (3.70%) 1 | 0 / 24 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 2 / 24 (8.33%) 2 |
| Nausea subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 1 / 27 (3.70%) 1 | 2 / 24 (8.33%) 2 |
| Tooth impacted subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 2 / 27 (7.41%) 2 | 1 / 24 (4.17%) 1 |
| Dermatitis contact subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Dermatitis subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Erythema subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Urticaria | | | |

| | | | |
|---|--------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 1 / 27 (3.70%) 1 | 0 / 24 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 4 / 27 (14.81%) 4 | 2 / 24 (8.33%) 2 |
| Myalgia subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 6 / 27 (22.22%) 6 | 2 / 24 (8.33%) 2 |
| Myositis subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Scoliosis subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 1 / 27 (3.70%) 1 | 0 / 24 (0.00%) 0 |
| Costochondritis subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Joint effusion subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Temporomandibular joint syndrome subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
| Infections and infestations Bronchitis subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 2 / 24 (8.33%) 2 |
| Influenza | | | |

| | | | |
|-----------------------------------|---------------|----------------|----------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 27 (3.70%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lice infestation | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 27 (3.70%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 1 | 2 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 27 (7.41%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Pneumonia mycoplasmal | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 27 (3.70%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 27 (7.41%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 27 (7.41%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 27 (3.70%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Conjunctivitis | | | |

| | | | |
|------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 27 (3.70%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Abnormal weight gain | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 2 / 27 (7.41%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 3 | 2 |
| Obesity | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 27 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |

| | | | |
|--|--------------------|---------------------|---------------------|
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 0 / 6 (0.00%) 0 | 0 / 27 (0.00%) 0 | 0 / 24 (0.00%) 0 |
|--|--------------------|---------------------|---------------------|

| Non-serious adverse events | 2qOMV_qOMV | 2qOMV_Pbo | 2B_OMV |
|---|------------------------|----------------------|-------------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 16 / 17 (94.12%) | 14 / 24 (58.33%) | 11 / 11 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) Skin papilloma subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Vascular disorders Essential hypertension subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| General disorders and administration site conditions Chills subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 1 / 11 (9.09%) 3 |
| Fatigue subjects affected / exposed occurrences (all) | 8 / 17 (47.06%) 9 | 2 / 24 (8.33%) 2 | 5 / 11 (45.45%) 5 |
| Induration subjects affected / exposed occurrences (all) | 1 / 17 (5.88%) 1 | 0 / 24 (0.00%) 0 | 1 / 11 (9.09%) 1 |
| Injection site erythema subjects affected / exposed occurrences (all) | 7 / 17 (41.18%) 8 | 3 / 24 (12.50%) 3 | 7 / 11 (63.64%) 7 |
| Injection site induration subjects affected / exposed occurrences (all) | 6 / 17 (35.29%) 6 | 3 / 24 (12.50%) 3 | 10 / 11 (90.91%) 11 |
| Injection site pain subjects affected / exposed occurrences (all) | 14 / 17 (82.35%) 14 | 7 / 24 (29.17%) 7 | 11 / 11 (100.00%) 11 |
| Pyrexia | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 1 / 24 (4.17%) 1 | 0 / 11 (0.00%) 0 |
| Vaccination site erythema subjects affected / exposed occurrences (all) | 1 / 17 (5.88%) 1 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Injection site pruritus subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Vaccination site pain subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 1 / 11 (9.09%) 1 |
| Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Reproductive system and breast disorders Breast mass subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Dysmenorrhoea subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all) | 1 / 17 (5.88%) 2 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 1 / 17 (5.88%) 1 | 1 / 24 (4.17%) 1 | 0 / 11 (0.00%) 0 |
| Rhinitis allergic subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Investigations Blood iron decreased subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| Body temperature increased subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Limb injury subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Post vaccination syndrome subjects affected / exposed occurrences (all) | 1 / 17 (5.88%) 1 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Concussion subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Head injury subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Joint dislocation subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Nervous system disorders | | | |
| Dizziness postural subjects affected / exposed occurrences (all) | 1 / 17 (5.88%) 1 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 8 / 17 (47.06%) 9 | 3 / 24 (12.50%) 3 | 5 / 11 (45.45%) 7 |
| Syncope subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 1 / 11 (9.09%) 1 |
| Ear and labyrinth disorders | | | |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Eye disorders | | | |
| Photophobia | | | |

| | | | |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Myopia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 3 / 17 (17.65%) | 1 / 24 (4.17%) | 3 / 11 (27.27%) |
| occurrences (all) | 4 | 1 | 3 |
| Tooth impacted | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Urticaria | | | |

| | | | |
|---|----------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 2 / 11 (18.18%) 2 |
| Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 3 / 17 (17.65%) 3 | 1 / 24 (4.17%) 1 | 0 / 11 (0.00%) 0 |
| Myalgia subjects affected / exposed occurrences (all) | 5 / 17 (29.41%) 5 | 0 / 24 (0.00%) 0 | 1 / 11 (9.09%) 1 |
| Myositis subjects affected / exposed occurrences (all) | 1 / 17 (5.88%) 1 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Scoliosis subjects affected / exposed occurrences (all) | 2 / 17 (11.76%) 2 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Costochondritis subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Joint effusion subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Temporomandibular joint syndrome subjects affected / exposed occurrences (all) | 0 / 17 (0.00%) 0 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Infections and infestations Bronchitis subjects affected / exposed occurrences (all) | 2 / 17 (11.76%) 2 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
| Influenza | | | |

| | | | |
|-----------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lice infestation | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 24 (4.17%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 1 | 3 |
| Pharyngitis | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 0 / 24 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 2 | 0 | 1 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia mycoplasmal | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 24 (4.17%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 24 (4.17%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 1 / 24 (4.17%) | 1 / 11 (9.09%) |
| occurrences (all) | 2 | 1 | 1 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |

| | | | |
|------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 24 (4.17%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 1 | 1 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Abnormal weight gain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 4 / 17 (23.53%) | 2 / 24 (8.33%) | 1 / 11 (9.09%) |
| occurrences (all) | 5 | 2 | 1 |
| Obesity | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 24 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|---------------------|---------------------|---------------------|
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 1 / 17 (5.88%) 1 | 0 / 24 (0.00%) 0 | 0 / 11 (0.00%) 0 |
|--|---------------------|---------------------|---------------------|

| Non-serious adverse events | 2B_qOMV | 1M_OMV | 1M_qOMV |
|---|------------------|------------------|------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 19 / 21 (90.48%) | 20 / 21 (95.24%) | 17 / 19 (89.47%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Skin papilloma | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all) | 0 | 0 | 1 |
| Vascular disorders | | | |
| Essential hypertension | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 2 / 21 (9.52%) | 6 / 21 (28.57%) | 1 / 19 (5.26%) |
| occurrences (all) | 2 | 6 | 1 |
| Fatigue | | | |
| subjects affected / exposed | 8 / 21 (38.10%) | 11 / 21 (52.38%) | 6 / 19 (31.58%) |
| occurrences (all) | 9 | 11 | 7 |
| Induration | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 7 / 21 (33.33%) | 7 / 21 (33.33%) | 9 / 19 (47.37%) |
| occurrences (all) | 7 | 8 | 9 |
| Injection site induration | | | |
| subjects affected / exposed | 7 / 21 (33.33%) | 11 / 21 (52.38%) | 9 / 19 (47.37%) |
| occurrences (all) | 9 | 13 | 9 |
| Injection site pain | | | |
| subjects affected / exposed | 18 / 21 (85.71%) | 19 / 21 (90.48%) | 17 / 19 (89.47%) |
| occurrences (all) | 19 | 19 | 19 |
| Pyrexia | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Vaccination site erythema subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Injection site pruritus subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Vaccination site pain subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Reproductive system and breast disorders Breast mass subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Dysmenorrhoea subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 1 / 21 (4.76%) 1 | 0 / 19 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 21 (4.76%) 1 | 0 / 19 (0.00%) 0 |
| Rhinitis allergic subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Investigations Blood iron decreased subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |

| | | | |
|--|----------------------|------------------------|----------------------|
| Body temperature increased subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Limb injury subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 1 / 21 (4.76%) 1 | 0 / 19 (0.00%) 0 |
| Post vaccination syndrome subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Concussion subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 21 (4.76%) 1 | 1 / 19 (5.26%) 1 |
| Head injury subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Joint dislocation subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Nervous system disorders | | | |
| Dizziness postural subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 4 / 21 (19.05%) 5 | 14 / 21 (66.67%) 15 | 5 / 19 (26.32%) 5 |
| Syncope subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Ear and labyrinth disorders | | | |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Eye disorders | | | |
| Photophobia | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Myopia subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Gastrointestinal disorders | | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Nausea subjects affected / exposed occurrences (all) | 5 / 21 (23.81%) 5 | 4 / 21 (19.05%) 4 | 5 / 19 (26.32%) 6 |
| Tooth impacted subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 1 / 21 (4.76%) 1 | 0 / 19 (0.00%) 0 |
| Dermatitis contact subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 1 / 21 (4.76%) 1 | 3 / 21 (14.29%) 3 | 2 / 19 (10.53%) 2 |
| Dermatitis subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Erythema subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Urticaria | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 2 / 21 (9.52%) 2 | 4 / 21 (19.05%) 4 | 2 / 19 (10.53%) 2 |
| Myalgia subjects affected / exposed occurrences (all) | 4 / 21 (19.05%) 4 | 8 / 21 (38.10%) 8 | 4 / 19 (21.05%) 4 |
| Myositis subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Scoliosis subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Costochondritis subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Joint effusion subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Temporomandibular joint syndrome subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 1 / 19 (5.26%) 1 |
| Infections and infestations Bronchitis subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Influenza | | | |

| | | | |
|-----------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed | 2 / 21 (9.52%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lice infestation | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 2 / 21 (9.52%) | 1 / 21 (4.76%) | 0 / 19 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 2 / 21 (9.52%) | 0 / 19 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 21 (4.76%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pneumonia mycoplasmal | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 21 (4.76%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 21 (4.76%) | 2 / 21 (9.52%) | 2 / 19 (10.53%) |
| occurrences (all) | 1 | 2 | 2 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 21 (0.00%) | 2 / 21 (9.52%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 2 / 21 (9.52%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 1 / 19 (5.26%) |
| occurrences (all) | 0 | 0 | 1 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 1 / 21 (4.76%) | 1 / 19 (5.26%) |
| occurrences (all) | 0 | 3 | 2 |
| Metabolism and nutrition disorders | | | |
| Abnormal weight gain | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 3 / 21 (14.29%) | 8 / 21 (38.10%) | 4 / 19 (21.05%) |
| occurrences (all) | 3 | 9 | 4 |
| Obesity | | | |
| subjects affected / exposed | 0 / 21 (0.00%) | 0 / 21 (0.00%) | 0 / 19 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---------------------|---------------------|
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 0 / 21 (0.00%) 0 | 0 / 21 (0.00%) 0 | 0 / 19 (0.00%) 0 |
| Non-serious adverse events | 1M_Pbo | | |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 15 / 19 (78.95%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) Skin papilloma subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 | | |
| Vascular disorders Essential hypertension subjects affected / exposed occurrences (all) | 1 / 19 (5.26%) 1 | | |
| General disorders and administration site conditions Chills subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Induration subjects affected / exposed occurrences (all) Injection site erythema subjects affected / exposed occurrences (all) Injection site induration subjects affected / exposed occurrences (all) Injection site pain subjects affected / exposed occurrences (all) Pyrexia | 1 / 19 (5.26%) 1 5 / 19 (26.32%) 7 0 / 19 (0.00%) 0 2 / 19 (10.53%) 2 1 / 19 (5.26%) 1 6 / 19 (31.58%) 6 | | |

| | | | |
|---|--|--|--|
| <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Vaccination site erythema</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Injection site pruritus</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Vaccination site pain</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Immune system disorders</p> <p>Hypersensitivity</p> <p>subjects affected / exposed</p> <p>1 / 19 (5.26%)</p> <p>occurrences (all)</p> <p>1</p> | | | |
| <p>Reproductive system and breast disorders</p> <p>Breast mass</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Dysmenorrhoea</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Respiratory, thoracic and mediastinal disorders</p> <p>Asthma</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>Rhinitis allergic</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |
| <p>Investigations</p> <p>Blood iron decreased</p> <p>subjects affected / exposed</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> | | | |

| | | | |
|--|---|--|--|
| Body temperature increased subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 | | |
| Injury, poisoning and procedural complications Limb injury subjects affected / exposed occurrences (all) Post vaccination syndrome subjects affected / exposed occurrences (all) Concussion subjects affected / exposed occurrences (all) Head injury subjects affected / exposed occurrences (all) Joint dislocation subjects affected / exposed occurrences (all) | 1 / 19 (5.26%) 1 0 / 19 (0.00%) 0 0 / 19 (0.00%) 0 0 / 19 (0.00%) 0 0 / 19 (0.00%) 0 | | |
| Nervous system disorders Dizziness postural subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Syncope subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 2 / 19 (10.53%) 2 0 / 19 (0.00%) 0 | | |
| Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all) | 1 / 19 (5.26%) 1 | | |
| Eye disorders Photophobia | | | |

| | | | |
|--|----------------|--|--|
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myopia | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nausea | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Tooth impacted | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Rash | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urticaria | | | |

| | | | |
|---|----------------------|--|--|
| subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 | | |
| Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all) | 1 / 19 (5.26%) 1 | | |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 3 / 19 (15.79%) 4 | | |
| Myalgia subjects affected / exposed occurrences (all) | 1 / 19 (5.26%) 1 | | |
| Myositis subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 | | |
| Scoliosis subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 | | |
| Back pain subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 | | |
| Costochondritis subjects affected / exposed occurrences (all) | 2 / 19 (10.53%) 2 | | |
| Joint effusion subjects affected / exposed occurrences (all) | 1 / 19 (5.26%) 1 | | |
| Temporomandibular joint syndrome subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 | | |
| Infections and infestations Bronchitis subjects affected / exposed occurrences (all) | 1 / 19 (5.26%) 1 | | |
| Influenza | | | |

| | | | |
|-----------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lice infestation | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 2 | | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonia mycoplasmal | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 2 | | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acute sinusitis | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Conjunctivitis | | | |

| | | | |
|------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Croup infectious | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Onychomycosis | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Otitis media | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth abscess | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Viral pharyngitis | | | |
| subjects affected / exposed | 1 / 19 (5.26%) | | |
| occurrences (all) | 1 | | |
| Metabolism and nutrition disorders | | | |
| Abnormal weight gain | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |
| Decreased appetite | | | |
| subjects affected / exposed | 2 / 19 (10.53%) | | |
| occurrences (all) | 3 | | |
| Obesity | | | |
| subjects affected / exposed | 0 / 19 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|---------------------|--|--|
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 0 / 19 (0.00%) 0 | | |
|--|---------------------|--|--|

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 09 May 2013 | <ul style="list-style-type: none">• Modified schedule for booster dose administration.• To ensure an adequate number of subjects in each treatment group, the sample size and randomisation ratios per group have been adjusted.• Collection of data related to NOCD at the time of study entry and during the trial was added.• Updated Protocol to new Protocol Template. All Novartis approved language on topics relating to Diary Cards, safety data collection, visit procedures, protocol deviations, withdrawal from study criteria, and AE reporting are incorporated into the current protocol amendment 1.0, version 2.0 dated 09 May 13. |
| 19 November 2013 | Increased window time for Day 1 visit (for U.S. study sites). |
| 06 May 2014 | <ul style="list-style-type: none">• Increased window time for Day 1 visit (extended to all study sites).• Added approach for interim and final analyses. Added administration of Bexsero for Group IVc outside the scope of study per request of Polish Ethics Committee.• Defined "End of Study" to align with Novartis standards.• Added public database posting and AE/SAE reporting requirements to align with Novartis standards. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported