



## Clinical trial results:

**Phase IV, open-label, randomized study to enrol healthy adult volunteers, naïve to any previous meningococcal vaccination or meningococcal disease, aged 18-50 years, to be either vaccinated with GSK MenACWY vaccine (Menveo) or GSK rMenB+OMV NZ vaccine (Bexsero), and serve as donors of human blood for conversion into serum to use in the development, qualification, validation and maintenance of immunological assays and to support preclinical research activities, clinical development and life cycle management of GSK Biologicals vaccines**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2017-002919-33 |
| Trial protocol           | DE             |
| Global end of trial date | 22 June 2022   |

### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1           |
| This version publication date  | 11 June 2023 |
| First version publication date | 11 June 2023 |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 207911 |
|-----------------------|--------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |                                                                                    |
|------------------------------|------------------------------------------------------------------------------------|
| Sponsor organisation name    | GlaxoSmithKline                                                                    |
| Sponsor organisation address | Rue de l'Institut, 89, Rixensart, Belgium, 1330                                    |
| Public contact               | GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com |
| Scientific contact           | GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com |

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

|                                                      |                   |
|------------------------------------------------------|-------------------|
| Analysis stage                                       | Final             |
| Date of interim/final analysis                       | 28 September 2022 |
| Is this the analysis of the primary completion data? | Yes               |
| Primary completion date                              | 27 May 2022       |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 22 June 2022      |
| Was the trial ended prematurely?                     | No                |

Notes:

## General information about the trial

Main objective of the trial:

To collect baseline (Visit 1, Visit 2 or Visit 3, depending on the study group) and post vaccination (Visits 5, 8; Visits 5, 9; Visits 6, 9 or Visits 7, 9, depending on the study group) blood sample donations to serve for the development, qualification, validation and maintenance of immunological assays and to support the preclinical research activities, clinical development and life cycle management of GSK Biologicals' vaccines.

Protection of trial subjects:

Blood samples were obtained by trained professionals, and medical assistance was readily available. Blood was collected only from eligible subjects who did not present any reason for deferring the blood draw. All subjects were supervised for 30 minutes after vaccination, with appropriate medical treatment readily available. Vaccines were administered according to their marketing indication and SmPC (summary of product characteristics) only to eligible subjects who had no contraindications to any components of the vaccines/products.

Background therapy: -

Evidence for comparator: -

|                                                           |               |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment                          | 08 March 2018 |
| 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 | Australia: 463 |
| Country: Number of subjects enrolled | Germany: 558   |
| Worldwide total number of subjects   | 1021           |
| EEA total number of subjects         | 558            |

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)                | 0    |
| Adults (18-64 years)                     | 1021 |
| From 65 to 84 years                      | 0    |
| 85 years and over                        | 0    |

## Subject disposition

### Recruitment

Recruitment details:

To adhere to local health guidelines (Australian Red Cross, 2016), 3 MenACWY groups were formed to ensure minimum 90-day interval between blood drawn at Days -83, -60, -30, 31, 61, and 151. The rMenB+OMV NZ group was not split due to sufficient intervals between post-vaccination blood sampling points (Day 8 and Day 98).

### Pre-assignment

Screening details:

Out of 1021 participants enrolled, 60 participants did not receive vaccination as they did not meet the eligibility criteria or withdrew from the study, therefore only 961 participants were included in the Exposed Set and started the study.

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Randomised - controlled        |
| Blinding used                | Not blinded                    |

### Arms

|                              |                    |
|------------------------------|--------------------|
| Are arms mutually exclusive? | Yes                |
| <b>Arm title</b>             | rMenB+OMV NZ Group |

Arm description:

Participants vaccinated intramuscularly with Bexsero vaccine at Day 1 and Day 61 and blood samples were collected at Day -83, Day 8, and Day 98.

|                                        |                          |
|----------------------------------------|--------------------------|
| Arm type                               | Experimental             |
| Investigational medicinal product name | rMenB+OMV NZ             |
| Investigational medicinal product code |                          |
| Other name                             |                          |
| Pharmaceutical forms                   | Suspension for injection |
| Routes of administration               | Intramuscular use        |

Dosage and administration details:

Two doses of rMenB+OMV NZ vaccine at Day 1 and Day 61

|                  |                 |
|------------------|-----------------|
| <b>Arm title</b> | MenACWY 1 Group |
|------------------|-----------------|

Arm description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -83, Day 8, and Day 151.

|                                        |                                                                     |
|----------------------------------------|---------------------------------------------------------------------|
| Arm type                               | Experimental                                                        |
| Investigational medicinal product name | MenACWY                                                             |
| Investigational medicinal product code |                                                                     |
| Other name                             |                                                                     |
| Pharmaceutical forms                   | Effervescent powder, Powder and solution for solution for injection |
| Routes of administration               | Intramuscular use                                                   |

Dosage and administration details:

1 dose of MenACWY vaccine at Day 1

|                  |                 |
|------------------|-----------------|
| <b>Arm title</b> | MenACWY 2 Group |
|------------------|-----------------|

Arm description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -60, Day 31, and Day 151.

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

|                                        |                                                                     |
|----------------------------------------|---------------------------------------------------------------------|
| Investigational medicinal product name | MenACWY                                                             |
| Investigational medicinal product code |                                                                     |
| Other name                             |                                                                     |
| Pharmaceutical forms                   | Effervescent powder, Powder and solution for solution for injection |
| Routes of administration               | Intramuscular use                                                   |

Dosage and administration details:

1 dose of MenACWY vaccine at Day 1

|                  |                 |
|------------------|-----------------|
| <b>Arm title</b> | MenACWY 3 Group |
|------------------|-----------------|

Arm description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -30, Day 61, and Day 151.

|                                        |                                                                     |
|----------------------------------------|---------------------------------------------------------------------|
| Arm type                               | Experimental                                                        |
| Investigational medicinal product name | MenACWY                                                             |
| Investigational medicinal product code |                                                                     |
| Other name                             |                                                                     |
| Pharmaceutical forms                   | Effervescent powder, Powder and solution for solution for injection |
| Routes of administration               | Intramuscular use                                                   |

Dosage and administration details:

1 dose of MenACWY vaccine at Day 1

| <b>Number of subjects in period 1<sup>[1]</sup></b> | rMenB+OMV NZ Group | MenACWY 1 Group | MenACWY 2 Group |
|-----------------------------------------------------|--------------------|-----------------|-----------------|
| Started                                             | 470                | 165             | 165             |
| Completed                                           | 454                | 161             | 163             |
| Not completed                                       | 16                 | 4               | 2               |
| Consent withdrawn by subject                        | 9                  | 3               | 1               |
| Adverse event, non-fatal                            | -                  | 1               | -               |
| Other                                               | 2                  | -               | 1               |
| Lost to follow-up                                   | 5                  | -               | -               |

| <b>Number of subjects in period 1<sup>[1]</sup></b> | MenACWY 3 Group |
|-----------------------------------------------------|-----------------|
| Started                                             | 161             |
| Completed                                           | 157             |
| Not completed                                       | 4               |
| Consent withdrawn by subject                        | 1               |
| Adverse event, non-fatal                            | -               |
| Other                                               | -               |
| Lost to follow-up                                   | 3               |

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: Out of 1021 participants enrolled, 60 participants did not receive vaccination as they did not meet the eligibility criteria or withdrew from the study, therefore only 961 participants were included

in the Exposed Set and started the study.

## Baseline characteristics

### Reporting groups

|                                                                                                                                                                                  |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Reporting group title                                                                                                                                                            | rMenB+OMV NZ Group |
| Reporting group description:<br>Participants vaccinated intramuscularly with Bexsero vaccine at Day 1 and Day 61 and blood samples were collected at Day -83, Day 8, and Day 98. |                    |
| Reporting group title                                                                                                                                                            | MenACWY 1 Group    |
| Reporting group description:<br>Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -83, Day 8, and Day 151.            |                    |
| Reporting group title                                                                                                                                                            | MenACWY 2 Group    |
| Reporting group description:<br>Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -60, Day 31, and Day 151.           |                    |
| Reporting group title                                                                                                                                                            | MenACWY 3 Group    |
| Reporting group description:<br>Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -30, Day 61, and Day 151.           |                    |

| Reporting group values                 | rMenB+OMV NZ Group | MenACWY 1 Group | MenACWY 2 Group |
|----------------------------------------|--------------------|-----------------|-----------------|
| Number of subjects                     | 470                | 165             | 165             |
| Age Categorical<br>Units: Participants |                    |                 |                 |

|                                                                         |               |               |               |
|-------------------------------------------------------------------------|---------------|---------------|---------------|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 32.8<br>± 8.8 | 33.3<br>± 9.1 | 33.3<br>± 9.0 |
| Sex: Female, Male<br>Units: Participants                                |               |               |               |
| Female                                                                  | 295           | 99            | 105           |
| Male                                                                    | 175           | 66            | 60            |
| Race (NIH/OMB)<br>Units: Subjects                                       |               |               |               |
| American Indian or Alaska Native                                        | 0             | 0             | 0             |
| Asian                                                                   | 29            | 13            | 15            |
| Native Hawaiian or Other Pacific Islander                               | 0             | 0             | 0             |
| Black or African American                                               | 0             | 0             | 0             |
| White                                                                   | 430           | 150           | 149           |
| More than one race                                                      | 9             | 2             | 1             |
| Unknown or Not Reported                                                 | 2             | 0             | 0             |

| Reporting group values                 | MenACWY 3 Group | Total |  |
|----------------------------------------|-----------------|-------|--|
| Number of subjects                     | 161             | 961   |  |
| Age Categorical<br>Units: Participants |                 |       |  |

|                                                                         |               |     |  |
|-------------------------------------------------------------------------|---------------|-----|--|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 32.9<br>± 8.8 | -   |  |
| Sex: Female, Male<br>Units: Participants                                |               |     |  |
| Female                                                                  | 109           | 608 |  |
| Male                                                                    | 52            | 353 |  |
| Race (NIH/OMB)<br>Units: Subjects                                       |               |     |  |
| American Indian or Alaska Native                                        | 0             | 0   |  |
| Asian                                                                   | 8             | 65  |  |
| Native Hawaiian or Other Pacific<br>Islander                            | 0             | 0   |  |
| Black or African American                                               | 0             | 0   |  |
| White                                                                   | 147           | 876 |  |
| More than one race                                                      | 6             | 18  |  |
| Unknown or Not Reported                                                 | 0             | 2   |  |



## End points

### End points reporting groups

|                                                                                                                                                                                  |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Reporting group title                                                                                                                                                            | rMenB+OMV NZ Group |
| Reporting group description:<br>Participants vaccinated intramuscularly with Bexsero vaccine at Day 1 and Day 61 and blood samples were collected at Day -83, Day 8, and Day 98. |                    |
| Reporting group title                                                                                                                                                            | MenACWY 1 Group    |
| Reporting group description:<br>Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -83, Day 8, and Day 151.            |                    |
| Reporting group title                                                                                                                                                            | MenACWY 2 Group    |
| Reporting group description:<br>Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -60, Day 31, and Day 151.           |                    |
| Reporting group title                                                                                                                                                            | MenACWY 3 Group    |
| Reporting group description:<br>Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -30, Day 61, and Day 151.           |                    |

### Primary: Number of human blood samples collected for conversion into serum at Day -83

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Number of human blood samples collected for conversion into serum at Day -83 <sup>[1][2]</sup> |
| End point description:<br>The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against <i>Neisseria meningitidis</i> . To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day -83, blood samples were collected only for rMenB+OMV NZ group and MenACWY 1 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints. |                                                                                                |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Primary                                                                                        |
| End point timeframe:<br>At Day -83 [83 days before first vaccination (Day 1)]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                |

#### Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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: On Day -83, blood samples were collected only for the rMenB+OMV NZ and MenACWY 1 groups. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

| End point values                 | rMenB+OMV NZ Group | MenACWY 1 Group |  |  |
|----------------------------------|--------------------|-----------------|--|--|
| Subject group type               | Reporting group    | Reporting group |  |  |
| Number of subjects analysed      | 470                | 165             |  |  |
| Units: Blood samples             |                    |                 |  |  |
| Number of Blood Samples Analyzed | 5578               | 1936            |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of human blood samples collected for conversion into serum at Day 8

|                 |                                                                                                          |
|-----------------|----------------------------------------------------------------------------------------------------------|
| End point title | Number of human blood samples collected for conversion into serum at Day 8 <sup>[3]</sup> <sup>[4]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------|

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against *Neisseria meningitidis*. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 8, blood samples were collected only for rMenB+OMV NZ group and MenACWY 1 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

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

End point timeframe:

At Day 8

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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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: On Day 8, blood samples were collected only for the rMenB+OMV NZ and MenACWY 1 groups. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

| End point values                 | rMenB+OMV NZ Group | MenACWY 1 Group |  |  |
|----------------------------------|--------------------|-----------------|--|--|
| Subject group type               | Reporting group    | Reporting group |  |  |
| Number of subjects analysed      | 462                | 162             |  |  |
| Units: Blood samples             |                    |                 |  |  |
| Number of Blood Samples Analyzed | 5396               | 1907            |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of human blood samples collected for conversion into serum at Day 98

|                 |                                                                                                           |
|-----------------|-----------------------------------------------------------------------------------------------------------|
| End point title | Number of human blood samples collected for conversion into serum at Day 98 <sup>[5]</sup> <sup>[6]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------|

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against *Neisseria meningitidis*. To comply with local health authorities

and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 98, blood samples were collected only for rMenB+OMV NZ group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

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

End point timeframe:

At Day 98

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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: On Day 98, blood samples were collected only for the rMenB+OMV NZ group. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

|                                  |                       |  |  |  |
|----------------------------------|-----------------------|--|--|--|
| <b>End point values</b>          | rMenB+OMV<br>NZ Group |  |  |  |
| Subject group type               | Reporting group       |  |  |  |
| Number of subjects analysed      | 454                   |  |  |  |
| Units: Blood samples             |                       |  |  |  |
| Number of Blood Samples Analyzed | 5204                  |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of human blood samples collected for conversion into serum at Day 151

|                 |                                                                                                |
|-----------------|------------------------------------------------------------------------------------------------|
| End point title | Number of human blood samples collected for conversion into serum at Day 151 <sup>[7][8]</sup> |
|-----------------|------------------------------------------------------------------------------------------------|

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against *Neisseria meningitidis*. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 151, blood samples were collected only for MenACWY 1, 2 and 3 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

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

End point timeframe:

At Day 151

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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: On Day 151, blood samples were collected only for MenACWY 1, 2, and 3 groups. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

| End point values                 | MenACWY 1 Group | MenACWY 2 Group | MenACWY 3 Group |  |
|----------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type               | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed      | 161             | 162             | 156             |  |
| Units: Blood samples             |                 |                 |                 |  |
| Number of Blood Samples Analyzed | 1869            | 1866            | 1752            |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of human blood samples collected for conversion into serum at Day -60

|                 |                                                                                                 |
|-----------------|-------------------------------------------------------------------------------------------------|
| End point title | Number of human blood samples collected for conversion into serum at Day -60 <sup>[9][10]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------|

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against *Neisseria meningitidis*. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day -60, blood samples were collected only for MenACWY 2 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

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

End point timeframe:

At Day -60 [60 days before first vaccination (Day 1)]

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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: On Day -60, blood samples were collected only for the MenACWY 2 group. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

| End point values                 | MenACWY 2 Group |  |  |  |
|----------------------------------|-----------------|--|--|--|
| Subject group type               | Reporting group |  |  |  |
| Number of subjects analysed      | 165             |  |  |  |
| Units: Blood samples             |                 |  |  |  |
| Number of Blood Samples Analyzed | 1957            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of human blood samples collected for conversion into serum at Day-30

|                 |                                                                                                 |
|-----------------|-------------------------------------------------------------------------------------------------|
| End point title | Number of human blood samples collected for conversion into serum at Day-30 <sup>[11][12]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------|

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**End point description:**

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against *Neisseria meningitidis*. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day -30, blood samples were collected only for MenACWY 3 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

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

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**End point timeframe:**

At Day -30 [30 days before first vaccination (Day 1)]

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**Notes:**

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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: On Day -30, blood samples were collected only for the MenACWY 3 group. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

| End point values                 | MenACWY 3 Group |  |  |  |
|----------------------------------|-----------------|--|--|--|
| Subject group type               | Reporting group |  |  |  |
| Number of subjects analysed      | 161             |  |  |  |
| Units: Blood samples             |                 |  |  |  |
| Number of Blood Samples Analyzed | 1894            |  |  |  |

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**Statistical analyses**

No statistical analyses for this end point

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**Primary: Number of human blood samples collected for conversion into serum at Day 31**

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|                 |                                                                                                 |
|-----------------|-------------------------------------------------------------------------------------------------|
| End point title | Number of human blood samples collected for conversion into serum at Day 31 <sup>[13][14]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------|

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**End point description:**

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against *Neisseria meningitidis*. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 31, blood samples were collected only for MenACWY 2 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

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

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**End point timeframe:**

At Day 31

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**Notes:**

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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: On Day 31, blood samples were collected only for the MenACWY 2 group. The participants

included in this outcome measure are based on the data collected at specific blood sampling time points.

| End point values                 | MenACWY 2 Group |  |  |  |
|----------------------------------|-----------------|--|--|--|
| Subject group type               | Reporting group |  |  |  |
| Number of subjects analysed      | 163             |  |  |  |
| Units: Blood samples             |                 |  |  |  |
| Number of Blood Samples Analyzed | 1920            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of human blood samples collected for conversion into serum at Day 61

|                 |                                                                                                 |
|-----------------|-------------------------------------------------------------------------------------------------|
| End point title | Number of human blood samples collected for conversion into serum at Day 61 <sup>[15][16]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------|

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against *Neisseria meningitidis*. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 61, blood samples were collected only for MenACWY 3 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

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

End point timeframe:

At Day 61

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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: On Day 61, blood samples were collected only for the MenACWY 3 group. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

| End point values                 | MenACWY 3 Group |  |  |  |
|----------------------------------|-----------------|--|--|--|
| Subject group type               | Reporting group |  |  |  |
| Number of subjects analysed      | 159             |  |  |  |
| Units: Blood samples             |                 |  |  |  |
| Number of Blood Samples Analyzed | 1809            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

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**Secondary: Number of participants with atleast one Serious Adverse Events (SAEs) related to vaccination**

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|                 |                                                                                              |
|-----------------|----------------------------------------------------------------------------------------------|
| End point title | Number of participants with atleast one Serious Adverse Events (SAEs) related to vaccination |
|-----------------|----------------------------------------------------------------------------------------------|

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End point description:

An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of hospitalization, results in disability/incapacity in a subject or is a congenital anomaly/ birth defect in the offspring of a study subject. AE(s) considered as SAE(s) also include invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization, as per the medical or scientific judgement of the physician. Related=AE assessed by the investigator as related to the vaccination. Analysis was performed on blood samples collected from exposed set, which included all participants subjects in the exposed set who provide safety data.

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

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End point timeframe:

Throughout the study period (approximately 4 years)

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| End point values            | rMenB+OMV<br>NZ Group | MenACWY 1<br>Group | MenACWY 2<br>Group | MenACWY 3<br>Group |
|-----------------------------|-----------------------|--------------------|--------------------|--------------------|
| Subject group type          | Reporting group       | Reporting group    | Reporting group    | Reporting group    |
| Number of subjects analysed | 470                   | 165                | 165                | 161                |
| Units: Participants         | 0                     | 0                  | 0                  | 0                  |

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**Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

Serious Adverse Events (SAEs) were collected throughout the study period (Upto 4 years)

Adverse event reporting additional description:

According to the pre-specified protocol, only serious adverse events and pregnancy-related events were to be collected. As no pregnancies have been reported in this study, the total number of participants at risk and affected by any other adverse events is zero.

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 25.0 |
|--------------------|------|

### Reporting groups

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | rMenB+OMV NZ Group |
|-----------------------|--------------------|

Reporting group description:

Participants vaccinated intramuscularly with Bexsero vaccine at Day 1 and Day 61.

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | MenACWY 3 Group |
|-----------------------|-----------------|

Reporting group description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1.

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | MenACWY 2 Group |
|-----------------------|-----------------|

Reporting group description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1.

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | MenACWY 1 Group |
|-----------------------|-----------------|

Reporting group description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: According to the pre-specified protocol, only serious adverse events and pregnancy-related events were to be collected. As no pregnancies have been reported in this study, the total number of participants at risk and affected by any other adverse events is zero.

| Serious adverse events                            | rMenB+OMV NZ Group | MenACWY 3 Group | MenACWY 2 Group |
|---------------------------------------------------|--------------------|-----------------|-----------------|
| Total subjects affected by serious adverse events |                    |                 |                 |
| subjects affected / exposed                       | 3 / 470 (0.64%)    | 0 / 161 (0.00%) | 1 / 165 (0.61%) |
| number of deaths (all causes)                     | 0                  | 0               | 0               |
| number of deaths resulting from adverse events    |                    |                 |                 |
| Nervous system disorders                          |                    |                 |                 |
| Depressed level of consciousness                  |                    |                 |                 |
| subjects affected / exposed                       | 0 / 470 (0.00%)    | 0 / 161 (0.00%) | 1 / 165 (0.61%) |
| occurrences causally related to treatment / all   | 0 / 0              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all        | 0 / 0              | 0 / 0           | 0 / 0           |
| Blood and lymphatic system disorders              |                    |                 |                 |
| Immune thrombocytopenia                           |                    |                 |                 |



|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 470 (0.00%) | 0 / 161 (0.00%) | 0 / 165 (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           |
| <b>Gastrointestinal disorders</b>               |                 |                 |                 |
| Inguinal hernia                                 |                 |                 |                 |
| subjects affected / exposed                     | 1 / 470 (0.21%) | 0 / 161 (0.00%) | 0 / 165 (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           |
| <b>Reproductive system and breast disorders</b> |                 |                 |                 |
| Adnexal torsion                                 |                 |                 |                 |
| subjects affected / exposed                     | 1 / 470 (0.21%) | 0 / 161 (0.00%) | 0 / 165 (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           |
| <b>Psychiatric disorders</b>                    |                 |                 |                 |
| Depression                                      |                 |                 |                 |
| subjects affected / exposed                     | 1 / 470 (0.21%) | 0 / 161 (0.00%) | 0 / 165 (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           |

|                                                   |                 |  |  |
|---------------------------------------------------|-----------------|--|--|
| <b>Serious adverse events</b>                     | MenACWY 1 Group |  |  |
| Total subjects affected by serious adverse events |                 |  |  |
| subjects affected / exposed                       | 1 / 165 (0.61%) |  |  |
| number of deaths (all causes)                     | 0               |  |  |
| number of deaths resulting from adverse events    |                 |  |  |
| <b>Nervous system disorders</b>                   |                 |  |  |
| Depressed level of consciousness                  |                 |  |  |
| subjects affected / exposed                       | 0 / 165 (0.00%) |  |  |
| occurrences causally related to treatment / all   | 0 / 0           |  |  |
| deaths causally related to treatment / all        | 0 / 0           |  |  |
| <b>Blood and lymphatic system disorders</b>       |                 |  |  |
| Immune thrombocytopenia                           |                 |  |  |
| subjects affected / exposed                       | 1 / 165 (0.61%) |  |  |
| occurrences causally related to treatment / all   | 0 / 1           |  |  |
| deaths causally related to treatment / all        | 0 / 0           |  |  |
| <b>Gastrointestinal disorders</b>                 |                 |  |  |

|                                                 |                 |  |  |
|-------------------------------------------------|-----------------|--|--|
| Inguinal hernia                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 165 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Reproductive system and breast disorders        |                 |  |  |
| Adnexal torsion                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 165 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Psychiatric disorders                           |                 |  |  |
| Depression                                      |                 |  |  |
| subjects affected / exposed                     | 0 / 165 (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: 0 %

| <b>Non-serious adverse events</b>                     | rMenB+OMV NZ Group | MenACWY 3 Group | MenACWY 2 Group |
|-------------------------------------------------------|--------------------|-----------------|-----------------|
| Total subjects affected by non-serious adverse events |                    |                 |                 |
| subjects affected / exposed                           | 0 / 470 (0.00%)    | 0 / 161 (0.00%) | 0 / 165 (0.00%) |

| <b>Non-serious adverse events</b>                     | MenACWY 1 Group |  |  |
|-------------------------------------------------------|-----------------|--|--|
| Total subjects affected by non-serious adverse events |                 |  |  |
| subjects affected / exposed                           | 0 / 165 (0.00%) |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date              | Amendment                                                                                                                                                                                                                                                      |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 18 September 2017 | Detailed title, Primary Objective was reworded. Duration of the study for individual subjects was updated. Minor edits and wordings update have been made.                                                                                                     |
| 19 January 2018   | Discrepancies have been noted in Study Design Overview and Intervals between study visits Table. Further, day number for Visits 5 to 9 needed to reflect in the following way: Visit 5: Day 8, Visit 6: Day 31, Visit 7: Day 61, Visit 8: 98 and Visit 9: 151. |
| 13 September 2019 | To clarify the minimum interval between first (blood draw) study visit and next (vaccination) study visit for all study groups                                                                                                                                 |
| 28 April 2020     | The purpose of the amendment is to protect participant's welfare, and as far as possible ensure the potential benefit to the participant and promote data integrity.                                                                                           |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported