



## Clinical trial results:

**A Phase III, open-label, single-center study to describe the immunogenicity and safety of a single dose of MenACYW Conjugate Vaccine in participants aged 12 months and older in Vietnam**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2021-001699-41 |
| Trial protocol           | Outside EU/EEA |
| Global end of trial date | 31 March 2024  |

### Results information

|                                |                   |
|--------------------------------|-------------------|
| Result version number          | v1 (current)      |
| This version publication date  | 14 September 2025 |
| First version publication date | 14 September 2025 |

### Trial information

#### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | MEQ00074 |
|-----------------------|----------|

#### Additional study identifiers

|                                    |                 |
|------------------------------------|-----------------|
| ISRCTN number                      | -               |
| ClinicalTrials.gov id (NCT number) | NCT06228586     |
| WHO universal trial number (UTN)   | U1111-1256-9172 |

Notes:

### Sponsors

|                              |                                                                |
|------------------------------|----------------------------------------------------------------|
| Sponsor organisation name    | Sanofi Pasteur                                                 |
| Sponsor organisation address | 14 Espace Henry Vallée, Lyon, France, 69007                    |
| Public contact               | Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com |
| Scientific contact           | Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.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? | Yes |

Notes:

## Results analysis stage

|                                                      |               |
|------------------------------------------------------|---------------|
| Analysis stage                                       | Final         |
| Date of interim/final analysis                       | 14 April 2025 |
| Is this the analysis of the primary completion data? | No            |
| Global end of trial reached?                         | Yes           |
| Global end of trial date                             | 31 March 2024 |
| Was the trial ended prematurely?                     | No            |

Notes:

## General information about the trial

Main objective of the trial:

To describe the antibody responses to meningococcal serogroups A, C, W, and Y before and 30 days after the administration of a single dose of meningococcal polysaccharide (serogroups A, C, W, and Y) tetanus toxoid conjugate vaccine (MenACYW conjugate vaccine).

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Participants with allergy to any of the vaccine components were not vaccinated. After vaccination, participants were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment                          | 18 January 2024 |
| 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 | Viet Nam: 447 |
| Worldwide total number of subjects   | 447           |
| EEA total number of subjects         | 0             |

Notes:

### Subjects enrolled per age group

|                                           |     |
|-------------------------------------------|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 223 |
| Children (2-11 years)                     | 74  |
| Adolescents (12-17 years)                 | 47  |
| Adults (18-64 years)                      | 88  |
| From 65 to 84 years                       | 15  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

This study was conducted at 4 investigational sites (1 main site and 3 satellite sites) in Vietnam.

### Pre-assignment

Screening details:

A total of 447 participants (223 participants aged 12-23 months and 224 participants aged  $\geq 24$  months) were enrolled in this study.

### Period 1

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

### Arms

|                              |                                                |
|------------------------------|------------------------------------------------|
| Are arms mutually exclusive? | Yes                                            |
| <b>Arm title</b>             | MenACYW Conjugate Vaccine: 12-23 Months of Age |

Arm description:

Participants aged 12-23 months received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 1.

|                                        |                           |
|----------------------------------------|---------------------------|
| Arm type                               | Experimental              |
| Investigational medicinal product name | MenACYW Conjugate Vaccine |
| Investigational medicinal product code |                           |
| Other name                             | MenQuadfi                 |
| Pharmaceutical forms                   | Solution for injection    |
| Routes of administration               | Intramuscular use         |

Dosage and administration details:

MenACYW conjugate vaccine 0.5 mL IM injection was administered as a single dose in the anterolateral area of the thigh or deltoid muscle on Day 1.

|                  |                                                       |
|------------------|-------------------------------------------------------|
| <b>Arm title</b> | MenACYW Conjugate Vaccine: 24 Months of Age and Above |
|------------------|-------------------------------------------------------|

Arm description:

Participants aged  $\geq 24$  months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.

|                                        |                           |
|----------------------------------------|---------------------------|
| Arm type                               | Experimental              |
| Investigational medicinal product name | MenACYW Conjugate Vaccine |
| Investigational medicinal product code |                           |
| Other name                             | MenQuadfi                 |
| Pharmaceutical forms                   | Solution for injection    |
| Routes of administration               | Intramuscular use         |

Dosage and administration details:

MenACYW conjugate vaccine 0.5 mL IM injection was administered as a single dose in the anterolateral area of the thigh or deltoid muscle on Day 1.

| <b>Number of subjects in period 1</b>        | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above |
|----------------------------------------------|------------------------------------------------|-------------------------------------------------------|
| Started                                      | 223                                            | 224                                                   |
| Vaccinated                                   | 223                                            | 223                                                   |
| Completed                                    | 220                                            | 223                                                   |
| Not completed                                | 3                                              | 1                                                     |
| Withdrawal by Participant or Parent/Guardian | 3                                              | 1                                                     |

## Baseline characteristics

### Reporting groups

|                       |                                                |
|-----------------------|------------------------------------------------|
| Reporting group title | MenACYW Conjugate Vaccine: 12-23 Months of Age |
|-----------------------|------------------------------------------------|

Reporting group description:

Participants aged 12-23 months received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 1.

|                       |                                                       |
|-----------------------|-------------------------------------------------------|
| Reporting group title | MenACYW Conjugate Vaccine: 24 Months of Age and Above |
|-----------------------|-------------------------------------------------------|

Reporting group description:

Participants aged  $\geq 24$  months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.

| Reporting group values                              | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above | Total |
|-----------------------------------------------------|------------------------------------------------|-------------------------------------------------------|-------|
| Number of subjects                                  | 223                                            | 224                                                   | 447   |
| Age Categorical<br>Units: participants              |                                                |                                                       |       |
| $\leq 18$ years                                     | 223                                            | 121                                                   | 344   |
| Between 18 and 65 years                             | 0                                              | 88                                                    | 88    |
| $\geq 65$ years                                     | 0                                              | 15                                                    | 15    |
| Sex: Female, Male<br>Units: participants            |                                                |                                                       |       |
| Female                                              | 118                                            | 130                                                   | 248   |
| Male                                                | 105                                            | 94                                                    | 199   |
| Race and Ethnicity Not Collected<br>Units: Subjects |                                                |                                                       |       |
| Not collected                                       | 223                                            | 224                                                   | 447   |

## End points

### End points reporting groups

|                                                                                                                                                     |                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| Reporting group title                                                                                                                               | MenACYW Conjugate Vaccine: 12-23 Months of Age        |
| Reporting group description:                                                                                                                        |                                                       |
| Participants aged 12-23 months received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 1. |                                                       |
| Reporting group title                                                                                                                               | MenACYW Conjugate Vaccine: 24 Months of Age and Above |
| Reporting group description:                                                                                                                        |                                                       |
| Participants aged $\geq 24$ months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.                          |                                                       |

### Primary: Geometric Mean Titers (GMTs) of Antibodies Against Meningococcal Serogroups A, C, Y, and W

|                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                 | Geometric Mean Titers (GMTs) of Antibodies Against Meningococcal Serogroups A, C, Y, and W <sup>[1]</sup> |
| End point description:                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                           |
| Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay utilizing the human complement (hSBA). Analysis was performed on the per-protocol analysis set (PPAS) which was a subset of the full analysis set (FAS). The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. |                                                                                                           |
| End point type                                                                                                                                                                                                                                                                                                                                                                                  | Primary                                                                                                   |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                           |
| Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on 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: As the endpoint is descriptive in nature, statistical analysis is not presented.

| End point values                         | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above |  |  |
|------------------------------------------|------------------------------------------------|-------------------------------------------------------|--|--|
| Subject group type                       | Reporting group                                | Reporting group                                       |  |  |
| Number of subjects analysed              | 200                                            | 221                                                   |  |  |
| Units: titer                             |                                                |                                                       |  |  |
| geometric mean (confidence interval 95%) |                                                |                                                       |  |  |
| Serogroup A: Day 1                       | 4.44 (4.00 to 4.92)                            | 7.58 (6.76 to 8.51)                                   |  |  |
| Serogroup A: Day 31                      | 39.0 (32.9 to 46.2)                            | 43.2 (34.6 to 54.1)                                   |  |  |
| Serogroup C: Day 1                       | 2.61 (2.34 to 2.91)                            | 5.65 (4.82 to 6.62)                                   |  |  |
| Serogroup C: Day 31                      | 1226 (1076 to 1398)                            | 895 (781 to 1026)                                     |  |  |
| Serogroup Y: Day 1                       | 2.86 (2.55 to 3.20)                            | 4.08 (3.47 to 4.78)                                   |  |  |
| Serogroup Y: Day 31                      | 132 (112 to 156)                               | 288 (244 to 340)                                      |  |  |
| Serogroup W: Day 1                       | 2.26 (2.09 to 2.44)                            | 4.33 (3.81 to 4.92)                                   |  |  |
| Serogroup W: Day 31                      | 99.4 (85.6 to 115)                             | 166 (139 to 198)                                      |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Titers $\geq 4$ -Fold Rise From Pre-Vaccination to Post-Vaccination<sup>[2]</sup>

|                 |                                                                                                                                                                    |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Serum Bactericidal Assay Using Human Complement Titers $\geq 4$ -Fold Rise From Pre-Vaccination to Post-Vaccination <sup>[2]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured by hSBA. Percentages are rounded off to the tenth decimal place. Analysis was performed on the PPAS which was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post vaccination serology result.

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

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

Notes:

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

Justification: As the endpoint is descriptive in nature, statistical analysis is not presented.

| End point values                  | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above |  |  |
|-----------------------------------|------------------------------------------------|-------------------------------------------------------|--|--|
| Subject group type                | Reporting group                                | Reporting group                                       |  |  |
| Number of subjects analysed       | 200                                            | 221                                                   |  |  |
| Units: percentage of participants |                                                |                                                       |  |  |
| number (confidence interval 95%)  |                                                |                                                       |  |  |
| Serogroup A                       | 81.5 (75.4 to 86.6)                            | 66.5 (59.9 to 72.7)                                   |  |  |
| Serogroup C                       | 99.5 (97.2 to 100)                             | 97.7 (94.8 to 99.3)                                   |  |  |
| Serogroup Y                       | 96.5 (92.9 to 98.6)                            | 95.5 (91.8 to 97.8)                                   |  |  |
| Serogroup W                       | 94.5 (90.4 to 97.2)                            | 95.5 (91.8 to 97.8)                                   |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Titers $\geq 1:4$ and $\geq 1:8$

|                 |                                                                |
|-----------------|----------------------------------------------------------------|
| End point title | Percentage of Participants With Serum Bactericidal Assay Using |
|-----------------|----------------------------------------------------------------|

## End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured by hSBA. Percentages are rounded off to the tenth decimal place. Analysis was performed on the PPAS which was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result.

## End point type

Primary

## End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

## 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: As the endpoint is descriptive in nature, statistical analysis is not presented.

| End point values                  | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above |  |  |
|-----------------------------------|------------------------------------------------|-------------------------------------------------------|--|--|
| Subject group type                | Reporting group                                | Reporting group                                       |  |  |
| Number of subjects analysed       | 200                                            | 221                                                   |  |  |
| Units: percentage of participants |                                                |                                                       |  |  |
| number (confidence interval 95%)  |                                                |                                                       |  |  |
| Serogroup A: Day 1: $\geq 1:4$    | 79.5 (73.2 to 84.9)                            | 94.1 (90.2 to 96.8)                                   |  |  |
| Serogroup A: Day 1: $\geq 1:8$    | 25.0 (19.2 to 31.6)                            | 59.7 (52.9 to 66.3)                                   |  |  |
| Serogroup A: Day 31: $\geq 1:4$   | 97.5 (94.3 to 99.2)                            | 89.1 (84.3 to 92.9)                                   |  |  |
| Serogroup A: Day 31: $\geq 1:8$   | 93.5 (89.1 to 96.5)                            | 84.6 (79.2 to 89.1)                                   |  |  |
| Serogroup C: Day 1: $\geq 1:4$    | 16.5 (11.6 to 22.4)                            | 64.3 (57.6 to 70.6)                                   |  |  |
| Serogroup C: Day 1: $\geq 1:8$    | 8.5 (5.0 to 13.3)                              | 38.5 (32.0 to 45.2)                                   |  |  |
| Serogroup C: Day 31: $\geq 1:4$   | 100 (98.2 to 100)                              | 100 (98.3 to 100)                                     |  |  |
| Serogroup C: Day 31: $\geq 1:8$   | 100 (98.2 to 100)                              | 100 (98.3 to 100)                                     |  |  |
| Serogroup Y: Day 1: $\geq 1:4$    | 21.0 (15.6 to 27.3)                            | 35.3 (29.0 to 42.0)                                   |  |  |
| Serogroup Y: Day 1: $\geq 1:8$    | 15.5 (10.8 to 21.3)                            | 26.2 (20.6 to 32.6)                                   |  |  |
| Serogroup Y: Day 31: $\geq 1:4$   | 99.5 (97.2 to 100)                             | 99.1 (96.8 to 99.9)                                   |  |  |
| Serogroup Y: Day 31: $\geq 1:8$   | 98.5 (95.7 to 99.7)                            | 99.1 (96.8 to 99.9)                                   |  |  |
| Serogroup W: Day 1: $\geq 1:4$    | 7.0 (3.9 to 11.5)                              | 51.6 (44.8 to 58.3)                                   |  |  |
| Serogroup W: Day 1: $\geq 1:8$    | 4.0 (1.7 to 7.7)                               | 32.1 (26.0 to 38.7)                                   |  |  |
| Serogroup W: Day 31: $\geq 1:4$   | 99.5 (97.2 to 100)                             | 100 (98.3 to 100)                                     |  |  |
| Serogroup W: Day 31: $\geq 1:8$   | 98.5 (95.7 to 99.7)                            | 100 (98.3 to 100)                                     |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Vaccine Seroresponse for Serogroups A, C, Y, and W

|                 |                                                                                                                                                   |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Serum Bactericidal Assay Using Human Complement Vaccine Seroresponse for Serogroups A, C, Y, and W <sup>[4]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured by hSBA. hSBA vaccine seroresponse was defined as follows: for a participant with a pre-vaccination titer <1:8, the post-vaccination titer must be ≥1:16, and for a participant with a pre-vaccination titer ≥1:8, the post-vaccination titer must be at least 4-fold greater than the pre-vaccination titer. Percentages are rounded off to the tenth decimal place. Analysis was performed on the PPAS which was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result.

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

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

Notes:

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

Justification: As the endpoint is descriptive in nature, statistical analysis is not presented.

| End point values                  | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above |  |  |
|-----------------------------------|------------------------------------------------|-------------------------------------------------------|--|--|
| Subject group type                | Reporting group                                | Reporting group                                       |  |  |
| Number of subjects analysed       | 200                                            | 221                                                   |  |  |
| Units: percentage of participants |                                                |                                                       |  |  |
| number (confidence interval 95%)  |                                                |                                                       |  |  |
| Serogroup A                       | 81.5 (75.4 to 86.6)                            | 66.5 (59.9 to 72.7)                                   |  |  |
| Serogroup C                       | 99.5 (97.2 to 100)                             | 97.7 (94.8 to 99.3)                                   |  |  |
| Serogroup Y                       | 96.5 (92.9 to 98.6)                            | 95.5 (91.8 to 97.8)                                   |  |  |
| Serogroup W                       | 94.5 (90.4 to 97.2)                            | 95.5 (91.8 to 97.8)                                   |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Immediate Unsolicited Systemic Adverse Events (AEs)

|                 |                                                                                                |
|-----------------|------------------------------------------------------------------------------------------------|
| End point title | Number of Participants With Immediate Unsolicited Systemic Adverse Events (AEs) <sup>[5]</sup> |
|-----------------|------------------------------------------------------------------------------------------------|

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study vaccine, whether or not considered related to the study vaccine. An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, i.e., pre-listed in the case report form (CRF) in terms of diagnosis and onset window post-vaccination. Immediate events were recorded

to capture medically relevant unsolicited systemic AEs (including those related to the study vaccine administered) which occurred within the first 30 minutes after vaccination. The safety analysis set (SafAS) included participants who received the study vaccine and had any safety data available.

|                                            |         |
|--------------------------------------------|---------|
| End point type                             | Primary |
| End point timeframe:                       |         |
| Up to 30 minutes post-vaccination on Day 1 |         |

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: As the endpoint is descriptive in nature, statistical analysis is not presented.

|                             |                                                |                                                       |  |  |
|-----------------------------|------------------------------------------------|-------------------------------------------------------|--|--|
| <b>End point values</b>     | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above |  |  |
| Subject group type          | Reporting group                                | Reporting group                                       |  |  |
| Number of subjects analysed | 223                                            | 223                                                   |  |  |
| Units: participants         | 0                                              | 1                                                     |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants With Solicited Injection Site Reactions and Systemic Reactions

|                 |                                                                                                      |
|-----------------|------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants With Solicited Injection Site Reactions and Systemic Reactions <sup>[6]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------|

End point description:

A solicited reaction was an “expected” adverse reaction (AR) (sign or symptom) observed and reported under the conditions (nature and onset) pre-listed in the protocol and CRF. An injection site reaction was an AR at and around the injection site considered to be related to the study vaccine administered and were commonly inflammatory reactions. Systemic ARs were all ARs that were not injection site reactions and included systemic manifestations such as headache, fever, as well as localized or topical manifestations. The SafAS included participants who received the study vaccine and had any safety data available.

|                                                                                          |         |
|------------------------------------------------------------------------------------------|---------|
| End point type                                                                           | Primary |
| End point timeframe:                                                                     |         |
| From the study vaccine administration (Day 1) up to 7 days post-vaccination, up to Day 8 |         |

Notes:

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

Justification: As the endpoint is descriptive in nature, statistical analysis is not presented.

|                                    |                                                |                                                       |  |  |
|------------------------------------|------------------------------------------------|-------------------------------------------------------|--|--|
| <b>End point values</b>            | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above |  |  |
| Subject group type                 | Reporting group                                | Reporting group                                       |  |  |
| Number of subjects analysed        | 223                                            | 223                                                   |  |  |
| Units: participants                |                                                |                                                       |  |  |
| Solicited injection site reactions | 29                                             | 29                                                    |  |  |
| Solicited systemic reactions       | 34                                             | 24                                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Unsolicited Non-Serious Adverse Events

|                 |                                                                                   |
|-----------------|-----------------------------------------------------------------------------------|
| End point title | Number of Participants With Unsolicited Non-Serious Adverse Events <sup>[7]</sup> |
|-----------------|-----------------------------------------------------------------------------------|

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study vaccine, whether or not considered related to the study vaccine. An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, i.e., pre-listed in the CRF in terms of diagnosis and onset window post-vaccination. The SafAS included participants who received the study vaccine and had any safety data available.

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

End point timeframe:

From the study vaccine administration (Day 1) up to 30 days post-vaccination (Day 31)

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: As the endpoint is descriptive in nature, statistical analysis is not presented.

|                             |                                                |                                                       |  |  |
|-----------------------------|------------------------------------------------|-------------------------------------------------------|--|--|
| <b>End point values</b>     | MenACYW Conjugate Vaccine: 12-23 Months of Age | MenACYW Conjugate Vaccine: 24 Months of Age and Above |  |  |
| Subject group type          | Reporting group                                | Reporting group                                       |  |  |
| Number of subjects analysed | 223                                            | 223                                                   |  |  |
| Units: participants         | 48                                             | 11                                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESIs)

|                 |                                                                                                                         |
|-----------------|-------------------------------------------------------------------------------------------------------------------------|
| End point title | Number of Participants With Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESIs) <sup>[8]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study vaccine, whether or not considered related to the study vaccine. An SAE was any AE that, at any dose, resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect or was other medically important event. An AESI (serious or non-serious) was one of scientific and medical concern specific to the Sponsor's study vaccine or program, for which ongoing monitoring and rapid communication by the investigator to the Sponsor was appropriate. The SafAS included participants who received the study vaccine and had any safety data available.

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

End point timeframe:

From the study vaccine administration (Day 1) up to 30 days post-vaccination (Day 31)

Notes:

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

Justification: As the endpoint is descriptive in nature, statistical analysis is not presented.

| End point values            | MenACYW<br>Conjugate<br>Vaccine: 12-23<br>Months of Age | MenACYW<br>Conjugate<br>Vaccine: 24<br>Months of Age<br>and Above |  |  |
|-----------------------------|---------------------------------------------------------|-------------------------------------------------------------------|--|--|
| Subject group type          | Reporting group                                         | Reporting group                                                   |  |  |
| Number of subjects analysed | 223                                                     | 223                                                               |  |  |
| Units: participants         |                                                         |                                                                   |  |  |
| SAEs                        | 3                                                       | 2                                                                 |  |  |
| AESIs                       | 0                                                       | 0                                                                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

AEs, SAEs and all-cause mortality (deaths) were collected from the study vaccine administration (Day 1) up to 30 days post-vaccination (Day 31)

Adverse event reporting additional description:

Analysis was performed on the SafAS.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 28.0 |
|--------------------|------|

### Reporting groups

|                       |                                                       |
|-----------------------|-------------------------------------------------------|
| Reporting group title | MenACYW Conjugate Vaccine: 24 Months of Age and Above |
|-----------------------|-------------------------------------------------------|

Reporting group description:

Participants aged  $\geq 24$  months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.

|                       |                                                |
|-----------------------|------------------------------------------------|
| Reporting group title | MenACYW Conjugate Vaccine: 12-23 Months of Age |
|-----------------------|------------------------------------------------|

Reporting group description:

Participants aged 12-23 months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.

| <b>Serious adverse events</b>                     | MenACYW Conjugate Vaccine: 24 Months of Age and Above | MenACYW Conjugate Vaccine: 12-23 Months of Age |  |
|---------------------------------------------------|-------------------------------------------------------|------------------------------------------------|--|
| Total subjects affected by serious adverse events |                                                       |                                                |  |
| subjects affected / exposed                       | 2 / 223 (0.90%)                                       | 3 / 223 (1.35%)                                |  |
| number of deaths (all causes)                     | 0                                                     | 0                                              |  |
| number of deaths resulting from adverse events    | 0                                                     | 0                                              |  |
| Injury, poisoning and procedural complications    |                                                       |                                                |  |
| Rib Fracture                                      |                                                       |                                                |  |
| subjects affected / exposed                       | 1 / 223 (0.45%)                                       | 0 / 223 (0.00%)                                |  |
| occurrences causally related to treatment / all   | 0 / 1                                                 | 0 / 0                                          |  |
| deaths causally related to treatment / all        | 0 / 0                                                 | 0 / 0                                          |  |
| Immune system disorders                           |                                                       |                                                |  |
| Anaphylactic Reaction                             |                                                       |                                                |  |
| subjects affected / exposed                       | 0 / 223 (0.00%)                                       | 1 / 223 (0.45%)                                |  |
| occurrences causally related to treatment / all   | 0 / 0                                                 | 0 / 1                                          |  |
| deaths causally related to treatment / all        | 0 / 0                                                 | 0 / 0                                          |  |
| Infections and infestations                       |                                                       |                                                |  |
| Pneumonia                                         |                                                       |                                                |  |

|                                                 |                 |                 |  |
|-------------------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed                     | 0 / 223 (0.00%) | 3 / 223 (1.35%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 3           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Appendicitis                                    |                 |                 |  |
| subjects affected / exposed                     | 1 / 223 (0.45%) | 0 / 223 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |

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

| <b>Non-serious adverse events</b>                     | MenACYW Conjugate Vaccine: 24 Months of Age and Above | MenACYW Conjugate Vaccine: 12-23 Months of Age |  |
|-------------------------------------------------------|-------------------------------------------------------|------------------------------------------------|--|
| Total subjects affected by non-serious adverse events |                                                       |                                                |  |
| subjects affected / exposed                           | 39 / 223 (17.49%)                                     | 59 / 223 (26.46%)                              |  |
| General disorders and administration site conditions  |                                                       |                                                |  |
| Injection Site Pain                                   |                                                       |                                                |  |
| subjects affected / exposed                           | 23 / 223 (10.31%)                                     | 26 / 223 (11.66%)                              |  |
| occurrences (all)                                     | 23                                                    | 26                                             |  |
| Injection Site Erythema                               |                                                       |                                                |  |
| subjects affected / exposed                           | 11 / 223 (4.93%)                                      | 13 / 223 (5.83%)                               |  |
| occurrences (all)                                     | 11                                                    | 13                                             |  |
| Crying                                                |                                                       |                                                |  |
| subjects affected / exposed                           | 0 / 223 (0.00%)                                       | 13 / 223 (5.83%)                               |  |
| occurrences (all)                                     | 0                                                     | 13                                             |  |
| Malaise                                               |                                                       |                                                |  |
| subjects affected / exposed                           | 13 / 223 (5.83%)                                      | 0 / 223 (0.00%)                                |  |
| occurrences (all)                                     | 13                                                    | 0                                              |  |
| Pyrexia                                               |                                                       |                                                |  |
| subjects affected / exposed                           | 7 / 223 (3.14%)                                       | 16 / 223 (7.17%)                               |  |
| occurrences (all)                                     | 8                                                     | 16                                             |  |
| Musculoskeletal and connective tissue disorders       |                                                       |                                                |  |
| Myalgia                                               |                                                       |                                                |  |
| subjects affected / exposed                           | 15 / 223 (6.73%)                                      | 0 / 223 (0.00%)                                |  |
| occurrences (all)                                     | 15                                                    | 0                                              |  |
| Infections and infestations                           |                                                       |                                                |  |

|                                                                                                              |                      |                        |  |
|--------------------------------------------------------------------------------------------------------------|----------------------|------------------------|--|
| Upper Respiratory Tract Infection<br>subjects affected / exposed<br>occurrences (all)                        | 2 / 223 (0.90%)<br>2 | 22 / 223 (9.87%)<br>22 |  |
| Metabolism and nutrition disorders<br>Decreased Appetite<br>subjects affected / exposed<br>occurrences (all) | 0 / 223 (0.00%)<br>0 | 17 / 223 (7.62%)<br>17 |  |

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported