



## Clinical trial results:

### Phase I Open-Label, Age De-escalation Safety and Immunogenicity Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Healthy Adolescents, Children, Toddlers, and Infants in China Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2025-000103-23  |
| Trial protocol           | Outside EU/EEA  |
| Global end of trial date | 22 October 2024 |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 02 May 2025  |
| First version publication date | 02 May 2025  |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | MEQ00075 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |                 |
|------------------------------------|-----------------|
| ISRCTN number                      | -               |
| ClinicalTrials.gov id (NCT number) | -               |
| WHO universal trial number (UTN)   | U1111-1256-9026 |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Sanofi Pasteur Inc.  |
| Sponsor organisation address | Discovery Drive, Swiftwater, Pennsylvania, United States, 18370-0187 |
| 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                       | 27 March 2025   |
| Is this the analysis of the primary completion data? | No              |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 22 October 2024 |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

To describe the safety profile of meningococcal polysaccharide (serogroups A, C, Y, and W) tetanus toxoid (MenACYW) conjugate vaccine and the safety profiles of the control vaccines (locally-licensed MenAC conjugate vaccines: Royal or Green Bamboo)

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                          | 12 August 2023 |
| 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 | China: 300 |
| Worldwide total number of subjects   | 300        |
| 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)  | 180 |
| Children (2-11 years)                     | 100 |
| Adolescents (12-17 years)                 | 20  |
| Adults (18-64 years)                      | 0   |
| From 65 to 84 years                       | 0   |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted in China.

### Pre-assignment

Screening details:

A total of 300 participants were randomly assigned to 1 of 10 study groups in 1:1 ratio in 5 Cohorts.

### 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>             | Group 1: MenACYW Conjugate Vaccine (7-17 Years) |

Arm description:

Participants aged 7 to 17 years received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine 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 form of liquid solution on Day 1.

|                  |  |
|------------------|--|
| <b>Arm title</b> | Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years) |
|------------------|--|

Arm description:

Participants aged 7 to 17 years received a single dose of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection on Day 1.

|  |  |
|--|--|
| Arm type                               | Active comparator                      |
| Investigational medicinal product name | Green Bamboo's MenAC Conjugate Vaccine |
| Investigational medicinal product code |  |
| Other name                             | Mening A Con                           |
| Pharmaceutical forms                   | Suspension for injection               |
| Routes of administration               | Intramuscular use                      |

Dosage and administration details:

Green Bamboo's MenAC conjugate vaccine 0.5 mL IM injection was administered as a single dose in the form of suspension on Day 1.

|                  |  |
|------------------|--|
| <b>Arm title</b> | Group 3: MenACYW Conjugate Vaccine (2-6 Years) |
|------------------|--|

Arm description:

Participants aged 2 to 6 years received a single dose of 0.5 mL MenACYW conjugate vaccine 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 form of liquid solution on Day 1.

|                  |  |
|------------------|--|
| <b>Arm title</b> | Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years) |
|------------------|--|

**Arm description:**

Participants aged 2 to 6 years received a single dose of 0.5 mL Royal's MenAC conjugate vaccine IM injection on Day 1.

|  |                                 |
|--|---------------------------------|
| Arm type                               | Active comparator               |
| Investigational medicinal product name | Royal's MenAC Conjugate Vaccine |
| Investigational medicinal product code |                                 |
| Other name                             |                                 |
| Pharmaceutical forms                   | Powder for injection            |
| Routes of administration               | Intramuscular use               |

**Dosage and administration details:**

Royal's MenAC conjugate vaccine 0.5 mL IM injection was administered as a single dose in the form of lyophilized powder on Day 1.

|                  |   |
|------------------|---|
| <b>Arm title</b> | Group 5: MenACYW Conjugate Vaccine (12-23 Months) |
|------------------|---|

**Arm description:**

Participants aged 12 to 23 months received a single dose of 0.5 mL MenACYW conjugate vaccine 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 form of liquid solution on Day 1.

|                  |   |
|------------------|---|
| <b>Arm title</b> | Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months) |
|------------------|---|

**Arm description:**

Participants aged 12 to 23 months received a single dose of 0.5 mL Royal's MenAC conjugate vaccine IM injection on Day 1. An additional dose of Royal's MenAC conjugate vaccine was offered by the Investigator to participants in Group 6 after the study procedure on the last visit of blood sampling to comply with product's approved vaccination schedule. This second dose of Royal's vaccine was not a part of the study assessment and was administered at least 31 days after the study vaccination.

|  |                                 |
|--|---------------------------------|
| Arm type                               | Active comparator               |
| Investigational medicinal product name | Royal's MenAC Conjugate Vaccine |
| Investigational medicinal product code |                                 |
| Other name                             |                                 |
| Pharmaceutical forms                   | Powder for injection            |
| Routes of administration               | Intramuscular use               |

**Dosage and administration details:**

Royal's MenAC conjugate vaccine 0.5 mL IM injection was administered as 2 doses in the form of lyophilized powder on Days 1 and 31.

|                  |  |
|------------------|--|
| <b>Arm title</b> | Group 7: MenACYW Conjugate Vaccine (6-11 Months) |
|------------------|--|

**Arm description:**

Participants aged 6 to 11 months received 2 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1 and 31.

|  |                           |
|--|---------------------------|
| 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 2 doses in the form of liquid solution on Days 1 and 31.

|                  |  |
|------------------|--|
| <b>Arm title</b> | Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months) |
|------------------|--|

**Arm description:**

Participants aged 6 to 11 months received 2 doses of 0.5 mL Royal's MenAC conjugate vaccine IM injection each on Days 1 and 31.

|  |                                 |
|--|---------------------------------|
| Arm type                               | Active comparator               |
| Investigational medicinal product name | Royal's MenAC Conjugate Vaccine |
| Investigational medicinal product code |                                 |
| Other name                             |                                 |
| Pharmaceutical forms                   | Powder for injection            |
| Routes of administration               | Intramuscular use               |

**Dosage and administration details:**

Royal's MenAC conjugate vaccine 0.5 mL IM injection was administered as 2 doses in the form of lyophilized powder on Days 1 and 31.

|                  |   |
|------------------|---|
| <b>Arm title</b> | Group 9: MenACYW Conjugate Vaccine (3-5 Months) |
|------------------|---|

**Arm description:**

Participants aged 3 to 5 months received 3 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1, 31 and 61.

|  |                           |
|--|---------------------------|
| 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 3 doses in the form of liquid solution on Days 1, 31 and 61.

|                  |   |
|------------------|---|
| <b>Arm title</b> | Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months) |
|------------------|---|

**Arm description:**

Participants aged 3 to 5 months received 3 doses of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection each on Days 1, 31 and 61.

|  |  |
|--|--|
| Arm type                               | Active comparator                      |
| Investigational medicinal product name | Green Bamboo's MenAC Conjugate Vaccine |
| Investigational medicinal product code |  |
| Other name                             | Mening A Con                           |
| Pharmaceutical forms                   | Suspension for injection               |
| Routes of administration               | Intramuscular use                      |

**Dosage and administration details:**

Green Bamboo's MenAC conjugate vaccine 0.5 mL IM injection was administered as 3 doses in the form of suspension on Days 1, 31 and 61.

| Number of subjects in period 1             | Group 1: MenACYW Conjugate Vaccine (7-17 Years) | Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years) | Group 3: MenACYW Conjugate Vaccine (2-6 Years) |
|--|---|--|--|
|  |   |  |  |
| Started                                    | 30  | 30   | 30   |
| Completed                                  | 30  | 30   | 30   |
| Not completed                              | 0   | 0  | 0  |
| Randomized but did not receive vaccination | -   | -  | -  |

| Number of subjects in period 1             | Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years) | Group 5: MenACYW Conjugate Vaccine (12-23 Months) | Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months) |
|--|--|---|---|
|  |  |   |   |
| Started                                    | 30   | 30  | 30  |
| Completed                                  | 30   | 30  | 30  |
| Not completed                              | 0  | 0   | 0   |
| Randomized but did not receive vaccination | -  | -   | -   |

| Number of subjects in period 1             | Group 7: MenACYW Conjugate Vaccine (6-11 Months) | Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months) | Group 9: MenACYW Conjugate Vaccine (3-5 Months) |
|--|--|--|---|
|  |  |  |   |
| Started                                    | 30   | 30   | 30  |
| Completed                                  | 30   | 28   | 30  |
| Not completed                              | 0  | 2  | 0   |
| Randomized but did not receive vaccination | -  | 2  | -   |

| Number of subjects in period 1             | Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months) |
|--|---|
| Started                                    | 30  |
| Completed                                  | 30  |
| Not completed                              | 0   |
| Randomized but did not receive vaccination | -   |

## Baseline characteristics

### Reporting groups

|  |   |
|--|---|
| Reporting group title  | Group 1: MenACYW Conjugate Vaccine (7-17 Years)               |
| Reporting group description:   |   |
| Participants aged 7 to 17 years received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine intramuscular (IM) injection on Day 1.   |   |
| Reporting group title  | Group 2: Green Bamboo’s MenAC Conjugate Vaccine (7-17 Years)  |
| Reporting group description:   |   |
| Participants aged 7 to 17 years received a single dose of 0.5 mL Green Bamboo’s MenAC conjugate vaccine IM injection on Day 1.   |   |
| Reporting group title  | Group 3: MenACYW Conjugate Vaccine (2-6 Years)                |
| Reporting group description:   |   |
| Participants aged 2 to 6 years received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.   |   |
| Reporting group title  | Group 4: Royal’s MenAC Conjugate Vaccine (2-6 Years)          |
| Reporting group description:   |   |
| Participants aged 2 to 6 years received a single dose of 0.5 mL Royal’s MenAC conjugate vaccine IM injection on Day 1.   |   |
| Reporting group title  | Group 5: MenACYW Conjugate Vaccine (12-23 Months)             |
| Reporting group description:   |   |
| Participants aged 12 to 23 months received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.  |   |
| Reporting group title  | Group 6: Royal’s MenAC Conjugate Vaccine (12-23 Months)       |
| Reporting group description:   |   |
| Participants aged 12 to 23 months received a single dose of 0.5 mL Royal’s MenAC conjugate vaccine IM injection on Day 1. An additional dose of Royal’s MenAC conjugate vaccine was offered by the Investigator to participants in Group 6 after the study procedure on the last visit of blood sampling to comply with product’s approved vaccination schedule. This second dose of Royal’s vaccine was not a part of the study assessment and was administered at least 31 days after the study vaccination. |   |
| Reporting group title  | Group 7: MenACYW Conjugate Vaccine (6-11 Months)              |
| Reporting group description:   |   |
| Participants aged 6 to 11 months received 2 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1 and 31.  |   |
| Reporting group title  | Group 8: Royal’s MenAC Conjugate Vaccine (6-11 Months)        |
| Reporting group description:   |   |
| Participants aged 6 to 11 months received 2 doses of 0.5 mL Royal’s MenAC conjugate vaccine IM injection each on Days 1 and 31.  |   |
| Reporting group title  | Group 9: MenACYW Conjugate Vaccine (3-5 Months)               |
| Reporting group description:   |   |
| Participants aged 3 to 5 months received 3 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1, 31 and 61.   |   |
| Reporting group title  | Group 10: Green Bamboo’s MenAC Conjugate Vaccine (3-5 Months) |
| Reporting group description:   |   |
| Participants aged 3 to 5 months received 3 doses of 0.5 mL Green Bamboo’s MenAC conjugate vaccine IM injection each on Days 1, 31 and 61.  |   |

| Reporting group values | Group 1: MenACYW Conjugate Vaccine (7-17 Years) | Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years) | Group 3: MenACYW Conjugate Vaccine (2-6 Years) |
|------------------------|---|--|--|
| Number of subjects     | 30  | 30   | 30   |

|  |                |                |               |
|--|----------------|----------------|---------------|
| Age Categorical<br>Units: Participants                                   |                |                |               |
| Age Continuous<br>Units: months<br>arithmetic mean<br>standard deviation | 124.8<br>± 1.7 | 136.8<br>± 2.4 | 61.2<br>± 1.2 |
| Gender Categorical<br>Units: Participants                                |                |                |               |
| Female   | 22             | 17             | 13            |
| Male   | 8              | 13             | 17            |

|  |  |   |  |
|--|--|---|--|
| <b>Reporting group values</b>          | Group 4: Royal's<br>MenAC Conjugate<br>Vaccine (2-6 Years) | Group 5: MenACYW<br>Conjugate Vaccine<br>(12-23 Months) | Group 6: Royal's<br>MenAC Conjugate<br>Vaccine (12-23<br>Months) |
| Number of subjects                     | 30   | 30  | 30   |
| Age Categorical<br>Units: Participants |  |   |  |

|  |               |               |               |
|--|---------------|---------------|---------------|
| Age Continuous<br>Units: months<br>arithmetic mean<br>standard deviation | 61.2<br>± 1.1 | 20.7<br>± 2.3 | 19.4<br>± 2.9 |
| Gender Categorical<br>Units: Participants                                |               |               |               |
| Female   | 16            | 14            | 14            |
| Male   | 14            | 16            | 16            |

|  |  |   |   |
|--|--|---|---|
| <b>Reporting group values</b>          | Group 7: MenACYW<br>Conjugate Vaccine<br>(6-11 Months) | Group 8: Royal's<br>MenAC Conjugate<br>Vaccine (6-11<br>Months) | Group 9: MenACYW<br>Conjugate Vaccine<br>(3-5 Months) |
| Number of subjects                     | 30   | 30  | 30  |
| Age Categorical<br>Units: Participants |  |   |   |

|  |              |              |              |
|--|--------------|--------------|--------------|
| Age Continuous<br>Units: months<br>arithmetic mean<br>standard deviation | 7.0<br>± 1.4 | 6.9<br>± 1.3 | 4.0<br>± 0.8 |
| Gender Categorical<br>Units: Participants                                |              |              |              |
| Female   | 14           | 13           | 17           |
| Male   | 16           | 17           | 13           |

|  |  |       |  |
|--|--|-------|--|
| <b>Reporting group values</b>          | Group 10: Green<br>Bamboo's MenAC<br>Conjugate Vaccine<br>(3-5 Months) | Total |  |
| Number of subjects                     | 30   | 300   |  |
| Age Categorical<br>Units: Participants |  |       |  |



|                     |       |     |  |
|---------------------|-------|-----|--|
| Age Continuous      |       |     |  |
| Units: months       |       |     |  |
| arithmetic mean     | 4.1   |     |  |
| standard deviation  | ± 0.8 | -   |  |
| Gender Categorical  |       |     |  |
| Units: Participants |       |     |  |
| Female              | 18    | 158 |  |
| Male                | 12    | 142 |  |

## End points

### End points reporting groups

|  |   |
|--|---|
| Reporting group title  | Group 1: MenACYW Conjugate Vaccine (7-17 Years)               |
| Reporting group description:<br>Participants aged 7 to 17 years received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine intramuscular (IM) injection on Day 1.   |   |
| Reporting group title  | Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)  |
| Reporting group description:<br>Participants aged 7 to 17 years received a single dose of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection on Day 1.   |   |
| Reporting group title  | Group 3: MenACYW Conjugate Vaccine (2-6 Years)                |
| Reporting group description:<br>Participants aged 2 to 6 years received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.   |   |
| Reporting group title  | Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)          |
| Reporting group description:<br>Participants aged 2 to 6 years received a single dose of 0.5 mL Royal's MenAC conjugate vaccine IM injection on Day 1.   |   |
| Reporting group title  | Group 5: MenACYW Conjugate Vaccine (12-23 Months)             |
| Reporting group description:<br>Participants aged 12 to 23 months received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.  |   |
| Reporting group title  | Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)       |
| Reporting group description:<br>Participants aged 12 to 23 months received a single dose of 0.5 mL Royal's MenAC conjugate vaccine IM injection on Day 1. An additional dose of Royal's MenAC conjugate vaccine was offered by the Investigator to participants in Group 6 after the study procedure on the last visit of blood sampling to comply with product's approved vaccination schedule. This second dose of Royal's vaccine was not a part of the study assessment and was administered at least 31 days after the study vaccination. |   |
| Reporting group title  | Group 7: MenACYW Conjugate Vaccine (6-11 Months)              |
| Reporting group description:<br>Participants aged 6 to 11 months received 2 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1 and 31.  |   |
| Reporting group title  | Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)        |
| Reporting group description:<br>Participants aged 6 to 11 months received 2 doses of 0.5 mL Royal's MenAC conjugate vaccine IM injection each on Days 1 and 31.  |   |
| Reporting group title  | Group 9: MenACYW Conjugate Vaccine (3-5 Months)               |
| Reporting group description:<br>Participants aged 3 to 5 months received 3 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1, 31 and 61.   |   |
| Reporting group title  | Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months) |
| Reporting group description:<br>Participants aged 3 to 5 months received 3 doses of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection each on Days 1, 31 and 61.  |   |

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

|                 |   |
|-----------------|---|
| End point title | Number of Participants With Immediate Unsolicited Adverse Events (AEs) <sup>[1]</sup> |
|-----------------|---|

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, that was, pre-listed in the case report form (CRF) in terms of diagnosis and onset window post-vaccination. All participants were observed for 30 minutes after vaccination, and any unsolicited AEs occurred during that time were recorded as immediate unsolicited AEs. Analysis was performed on the safety analysis set which included participants who received at least 1 dose of the study vaccine and had any safety data available.

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

End point timeframe:

Up to 30 minutes after each and any study vaccination

Notes:

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

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

| End point values            | Group 1:<br>MenACYW<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 2: Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 3:<br>MenACYW<br>Conjugate<br>Vaccine (2-6<br>Years) | Group 4:<br>Royal's MenAC<br>Conjugate<br>Vaccine (2-6<br>Years) |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed | 30  | 30  | 30   | 30   |
| Units: participants         | 0   | 0   | 0  | 0  |

| End point values            | Group 5:<br>MenACYW<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 6:<br>Royal's MenAC<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 7:<br>MenACYW<br>Conjugate<br>Vaccine (6-11<br>Months) | Group 8:<br>Royal's MenAC<br>Conjugate<br>Vaccine (6-11<br>Months) |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed | 30  | 30  | 30   | 28   |
| Units: participants         | 0   | 0   | 0  | 0  |

| End point values            | Group 9:<br>MenACYW<br>Conjugate<br>Vaccine (3-5<br>Months) | Group 10:<br>Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (3-5<br>Months) |  |  |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed | 30  | 30  |  |  |
| Units: participants         | 0   | 2   |  |  |

**Statistical analyses**

## 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>[2]</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 and considered as related to the study intervention administered. An injection site reaction was an AR at and around the injection site and were commonly inflammatory reactions. Solicited systemic reactions were systemic AEs and those occurring during the specified collection period were always considered related to the intervention even if there was evidence of alternative etiology. Analysis was performed on the safety analysis set which included participants who received at least 1 dose of the study vaccine and had any safety data available.

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

End point timeframe:

Up to 7 days after each and any study vaccination

Notes:

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

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

| End point values            | Group 1:<br>MenACYW<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 2: Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 3:<br>MenACYW<br>Conjugate<br>Vaccine (2-6<br>Years) | Group 4:<br>Royal's MenAC<br>Conjugate<br>Vaccine (2-6<br>Years) |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed | 30  | 30  | 30   | 30   |
| Units: participants         |   |   |  |  |
| Injection site reactions    | 7   | 9   | 9  | 5  |
| Systemic reactions          | 3   | 2   | 5  | 2  |

| End point values            | Group 5:<br>MenACYW<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 6:<br>Royal's MenAC<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 7:<br>MenACYW<br>Conjugate<br>Vaccine (6-11<br>Months) | Group 8:<br>Royal's MenAC<br>Conjugate<br>Vaccine (6-11<br>Months) |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed | 30  | 30  | 30   | 28   |
| Units: participants         |   |   |  |  |
| Injection site reactions    | 2   | 2   | 3  | 1  |
| Systemic reactions          | 7   | 6   | 17   | 8  |

| End point values | Group 9:<br>MenACYW<br>Conjugate<br>Vaccine (3-5<br>Months) | Group 10:<br>Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (3-5 |  |  |
|------------------|---|--|--|--|
|                  |   |  |  |  |

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 30              | 30              |  |  |
| Units: participants         |                 |                 |  |  |
| Injection site reactions    | 1               | 3               |  |  |
| Systemic reactions          | 19              | 12              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Serious Adverse Events (SAEs)

|                 |  |
|-----------------|--|
| End point title | Number of Participants With Serious Adverse Events (SAEs) <sup>[3]</sup> |
|-----------------|--|

End point description:

An SAE was defined as 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 an important medical event. Analysis was performed on the safety analysis set which included participants who received at least 1 dose of the study vaccine and had any safety data available.

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

End point timeframe:

From date of first vaccination (Day 1) up to 6 months after the last study vaccination, approximately 180 days for Groups 1 to 6, 210 days for Groups 7, 8 and 240 days for Groups 9, 10

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            | Group 1:<br>MenACYW<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 2: Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 3:<br>MenACYW<br>Conjugate<br>Vaccine (2-6<br>Years) | Group 4:<br>Royal's MenAC<br>Conjugate<br>Vaccine (2-6<br>Years) |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed | 30  | 30  | 30   | 30   |
| Units: participants         | 0   | 1   | 4  | 3  |

| End point values            | Group 5:<br>MenACYW<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 6:<br>Royal's MenAC<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 7:<br>MenACYW<br>Conjugate<br>Vaccine (6-11<br>Months) | Group 8:<br>Royal's MenAC<br>Conjugate<br>Vaccine (6-11<br>Months) |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed | 30  | 30  | 30   | 28   |
| Units: participants         | 7   | 8   | 13   | 14   |

| End point values | Group 9:<br>MenACYW<br>Conjugate | Group 10:<br>Green<br>Bamboo's |  |  |
|------------------|----------------------------------|--------------------------------|--|--|
|------------------|----------------------------------|--------------------------------|--|--|

|                             | Vaccine (3-5 Months) | Conjugate Vaccine (3-5 Months) |  |  |
|-----------------------------|----------------------|--------------------------------|--|--|
| Subject group type          | Reporting group      | Reporting group                |  |  |
| Number of subjects analysed | 30                   | 30                             |  |  |
| Units: participants         | 15                   | 14                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Unsolicited Adverse Events

|                 |   |
|-----------------|---|
| End point title | Number of Participants With Unsolicited Adverse Events <sup>[4]</sup> |
|-----------------|---|

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, that was, pre-listed in the CRF in terms of diagnosis and/or onset window post-vaccination. Analysis was performed on the safety analysis set which included participants who received at least 1 dose of the study vaccine and had any safety data available.

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

End point timeframe:

Up to 30 days after each and any study vaccination

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            | Group 1:<br>MenACYW<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 2: Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 3:<br>MenACYW<br>Conjugate<br>Vaccine (2-6<br>Years) | Group 4:<br>Royal's MenAC<br>Conjugate<br>Vaccine (2-6<br>Years) |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed | 30  | 30  | 30   | 30   |
| Units: participants         | 6   | 7   | 11   | 10   |

| End point values            | Group 5:<br>MenACYW<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 6:<br>Royal's MenAC<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 7:<br>MenACYW<br>Conjugate<br>Vaccine (6-11<br>Months) | Group 8:<br>Royal's MenAC<br>Conjugate<br>Vaccine (6-11<br>Months) |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed | 30  | 30  | 30   | 28   |
| Units: participants         | 15  | 15  | 26   | 23   |

| End point values | Group 9:<br>MenACYW | Group 10:<br>Green Bamboo' |  |  |
|------------------|---------------------|----------------------------|--|--|
|------------------|---------------------|----------------------------|--|--|

|                             | Conjugate Vaccine (3-5 Months) | s MenAC Conjugate Vaccine (3-5 Months) |  |  |
|-----------------------------|--------------------------------|--|--|--|
| Subject group type          | Reporting group                | Reporting group                        |  |  |
| Number of subjects analysed | 30                             | 30                                     |  |  |
| Units: participants         | 28                             | 25                                     |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: All Groups: Percentage of Participants With Vaccine Seroresponse by Serum Bactericidal Assay Using Rabbit Complement (rSBA)

|                 |   |
|-----------------|---|
| End point title | All Groups: Percentage of Participants With Vaccine Seroresponse by Serum Bactericidal Assay Using Rabbit Complement (rSBA) |
|-----------------|---|

End point description:

The rSBA vaccine seroresponse to meningococcal serogroups A, C, Y, and W for MenACYW conjugate vaccine and to serogroups A and C for comparators was defined as follows: 30 days post-vaccination rSBA titers  $\geq 1:8$  for participants with pre-vaccination rSBA titers  $< 1:8$  OR at least 4-fold increase in rSBA titers from pre to 30 days post-vaccination for participants with pre vaccination rSBA titers  $\geq 1:8$ . Analysis was performed on the per-protocol analysis set which was the subset of full analysis set (FAS: participants who received at least 1 dose of the study vaccine and had a valid post-vaccination serology result). Here, n=0 indicates that response to only serogroups A and C were determined for the comparators and not Y and W. Hence the corresponding data is reported as 9999 indicating 'not applicable'. Percentages are rounded off to the tenth decimal place.

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

End point timeframe:

Day 1 (all Groups) and Day 31 for Groups 1 to 6, Day 61 for Groups 7 and 8 and Day 91 for Groups 9 and 10

| End point values                                 | Group 1: MenACYW Conjugate Vaccine (7-17 Years) | Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years) | Group 3: MenACYW Conjugate Vaccine (2-6 Years) | Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years) |
|--|---|--|--|--|
| Subject group type                               | Reporting group                                 | Reporting group  | Reporting group                                | Reporting group                                      |
| Number of subjects analysed                      | 28  | 26   | 25   | 29   |
| Units: percentage of participants                |   |  |  |  |
| number (confidence interval 95%)                 |   |  |  |  |
| Serogroup A<br>(n=28,26,25,29,29,27,25,21,19,18) | 82.1 (63.1 to 93.9)                             | 19.2 (6.6 to 39.4)   | 88.0 (68.8 to 97.5)                            | 82.8 (64.2 to 94.2)                                  |
| Serogroup C<br>(n=28,26,25,29,29,27,25,21,19,18) | 96.4 (81.7 to 99.9)                             | 30.8 (14.3 to 51.8)  | 100 (86.3 to 100)                              | 100 (88.1 to 100)                                    |
| Serogroup Y<br>(n=28,0,25,0,29,0,25,0,19,0)      | 89.3 (71.8 to 97.7)                             | 9999 (9999 to 9999)  | 92.0 (74.0 to 99.0)                            | 9999 (9999 to 9999)                                  |
| Serogroup W<br>(n=28,0,25,0,29,0,25,0,19,0)      | 96.4 (81.7 to 99.9)                             | 9999 (9999 to 9999)  | 96.0 (79.6 to 99.9)                            | 9999 (9999 to 9999)                                  |

| End point values                                 | Group 5:<br>MenACYW<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 6:<br>Royal's MenAC<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 7:<br>MenACYW<br>Conjugate<br>Vaccine (6-11<br>Months) | Group 8:<br>Royal's MenAC<br>Conjugate<br>Vaccine (6-11<br>Months) |
|--|---|---|--|--|
| Subject group type                               | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed                      | 29  | 27  | 25   | 21   |
| Units: percentage of participants                |   |   |  |  |
| number (confidence interval 95%)                 |   |   |  |  |
| Serogroup A<br>(n=28,26,25,29,29,27,25,21,19,18) | 96.6 (82.2 to<br>99.9)  | 88.9 (70.8 to<br>97.6)  | 96.0 (79.6 to<br>99.9)                                       | 76.2 (52.8 to<br>91.8)   |
| Serogroup C<br>(n=28,26,25,29,29,27,25,21,19,18) | 100 (88.1 to<br>100)  | 100 (87.2 to<br>100)  | 100 (86.3 to<br>100)   | 100 (83.9 to<br>100)   |
| Serogroup Y<br>(n=28,0,25,0,29,0,25,0,19,0)      | 89.7 (72.6 to<br>97.8)  | 9999 (9999 to<br>9999)  | 88.0 (68.8 to<br>97.5)                                       | 9999 (9999 to<br>9999)   |
| Serogroup W<br>(n=28,0,25,0,29,0,25,0,19,0)      | 93.1 (77.2 to<br>99.2)  | 9999 (9999 to<br>9999)  | 96.0 (79.6 to<br>99.9)                                       | 9999 (9999 to<br>9999)   |

| End point values                                 | Group 9:<br>MenACYW<br>Conjugate<br>Vaccine (3-5<br>Months) | Group 10:<br>Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (3-5<br>Months) |  |  |
|--|---|---|--|--|
| Subject group type                               | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed                      | 19  | 18  |  |  |
| Units: percentage of participants                |   |   |  |  |
| number (confidence interval 95%)                 |   |   |  |  |
| Serogroup A<br>(n=28,26,25,29,29,27,25,21,19,18) | 94.7 (74.0 to<br>99.9)                                      | 11.1 (1.4 to<br>34.7)   |  |  |
| Serogroup C<br>(n=28,26,25,29,29,27,25,21,19,18) | 100 (82.4 to<br>100)  | 38.9 (17.3 to<br>64.3)  |  |  |
| Serogroup Y<br>(n=28,0,25,0,29,0,25,0,19,0)      | 100 (82.4 to<br>100)  | 9999 (9999 to<br>9999)  |  |  |
| Serogroup W<br>(n=28,0,25,0,29,0,25,0,19,0)      | 100 (82.4 to<br>100)  | 9999 (9999 to<br>9999)  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: All Groups: Geometric Mean Titers Against Meningococcal Serogroups as Measured by rSBA

|   |  |
|---|--|
| End point title   | All Groups: Geometric Mean Titers Against Meningococcal Serogroups as Measured by rSBA |
| End point description:<br>Antibody titers against meningococcal serogroups A, C, Y, and W for MenACYW conjugate vaccine and serogroups A and C for comparators were measured by rSBA. Analysis was performed on the per-protocol analysis set which was the subset of FAS which included participants who received at least 1 dose of the study vaccine and had a valid post-vaccination serology result. Here, n=0 indicates that response to only serogroups A and C were determined for the comparators and not Y and W. Hence the corresponding data is reported as 9999 indicating 'not applicable'. |  |
| End point type  | Secondary  |



End point timeframe:

30 days after vaccination (Day 31 for Groups 1 to 6, Day 61 for Groups 7 and 8 and Day 91 for Groups 9 and 10)

| End point values                                 | Group 1:<br>MenACYW<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 2: Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 3:<br>MenACYW<br>Conjugate<br>Vaccine (2-6<br>Years) | Group 4:<br>Royal's MenAC<br>Conjugate<br>Vaccine (2-6<br>Years) |
|--|---|---|--|--|
| Subject group type                               | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed                      | 28  | 26  | 25   | 29   |
| Units: titer                                     |   |   |  |  |
| geometric mean (confidence interval 95%)         |   |   |  |  |
| Serogroup A<br>(n=28,26,25,29,29,27,25,21,19,18) | 742 (517 to 1066)   | 60.7 (29.1 to 126)  | 572 (400 to 817)   | 349 (243 to 502)   |
| Serogroup C<br>(n=28,26,25,29,29,27,25,21,19,18) | 565 (370 to 864)  | 3.89 (1.89 to 8.03)   | 695 (463 to 1042)  | 433 (325 to 577)   |
| Serogroup Y<br>(n=28,0,25,0,29,0,25,0,19,0)      | 353 (205 to 609)  | 9999 (9999 to 9999)   | 294 (209 to 413)   | 9999 (9999 to 9999)  |
| Serogroup W<br>(n=28,0,25,0,29,0,25,0,19,0)      | 238 (163 to 346)  | 9999 (9999 to 9999)   | 118 (74.7 to 186)  | 9999 (9999 to 9999)  |

| End point values                                 | Group 5:<br>MenACYW<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 6:<br>Royal's MenAC<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 7:<br>MenACYW<br>Conjugate<br>Vaccine (6-11<br>Months) | Group 8:<br>Royal's MenAC<br>Conjugate<br>Vaccine (6-11<br>Months) |
|--|---|---|--|--|
| Subject group type                               | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed                      | 29  | 27  | 25   | 21   |
| Units: titer                                     |   |   |  |  |
| geometric mean (confidence interval 95%)         |   |   |  |  |
| Serogroup A<br>(n=28,26,25,29,29,27,25,21,19,18) | 256 (160 to 409)  | 91.7 (42.0 to 200)  | 89.3 (47.8 to 167)   | 40.3 (13.0 to 125)   |
| Serogroup C<br>(n=28,26,25,29,29,27,25,21,19,18) | 550 (407 to 744)  | 284 (199 to 404)  | 211 (151 to 295)   | 47.6 (34.4 to 65.8)  |
| Serogroup Y<br>(n=28,0,25,0,29,0,25,0,19,0)      | 54.1 (36.4 to 80.5)   | 9999 (9999 to 9999)   | 39.9 (23.4 to 68.1)  | 9999 (9999 to 9999)  |
| Serogroup W<br>(n=28,0,25,0,29,0,25,0,19,0)      | 36.9 (21.5 to 63.6)   | 9999 (9999 to 9999)   | 45.9 (28.5 to 73.8)  | 9999 (9999 to 9999)  |

| End point values            | Group 9:<br>MenACYW<br>Conjugate<br>Vaccine (3-5<br>Months) | Group 10:<br>Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (3-5<br>Months) |  |  |
|-----------------------------|---|---|--|--|
| Subject group type          | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed | 19  | 18  |  |  |

|  |                    |                      |  |  |
|--|--------------------|----------------------|--|--|
| Units: titer                                     |                    |                      |  |  |
| geometric mean (confidence interval 95%)         |                    |                      |  |  |
| Serogroup A<br>(n=28,26,25,29,29,27,25,21,19,18) | 82.6 (34.3 to 199) | 1.71 (0.786 to 3.74) |  |  |
| Serogroup C<br>(n=28,26,25,29,29,27,25,21,19,18) | 159 (112 to 227)   | 3.30 (1.58 to 6.89)  |  |  |
| Serogroup Y<br>(n=28,0,25,0,29,0,25,0,19,0)      | 128 (91.6 to 179)  | 9999 (9999 to 9999)  |  |  |
| Serogroup W<br>(n=28,0,25,0,29,0,25,0,19,0)      | 82.6 (55.1 to 124) | 9999 (9999 to 9999)  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: All Groups: Percentage of Participants With rSBA Titers $\geq 1:8$ and $\geq 1:128$

|                 |   |
|-----------------|---|
| End point title | All Groups: Percentage of Participants With rSBA Titers $\geq 1:8$ and $\geq 1:128$ |
|-----------------|---|

End point description:

Seropositivity (rSBA titers  $\geq 1:8$ ) and antibody responses of rSBA titers  $\geq 1:128$  to meningococcal serogroups A, C, Y, and W for MenACYW conjugate vaccine and meningococcal serogroups A and C for MenAC conjugate vaccine were determined. Analysis was performed on the per-protocol analysis set which was the subset of FAS which included participants who received at least 1 dose of the study vaccine and had a valid post-vaccination serology result. Here, n=0 indicates that response to only serogroups A and C were determined for the comparators and not Y and W. Hence the corresponding data is reported as 9999 indicating 'not applicable'. SG: serogroup. Percentages are rounded off to the tenth decimal place.

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

End point timeframe:

30 days after vaccination (Day 31 for Groups 1 to 6, Day 61 for Groups 7 and 8 and Day 91 for Groups 9 and 10)

| End point values  | Group 1:<br>MenACYW<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 2: Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (7-17<br>Years) | Group 3:<br>MenACYW<br>Conjugate<br>Vaccine (2-6<br>Years) | Group 4:<br>Royal's MenAC<br>Conjugate<br>Vaccine (2-6<br>Years) |
|---|---|---|--|--|
| Subject group type                                      | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed                             | 28  | 26  | 25   | 29   |
| Units: percentage of participants                       |   |   |  |  |
| number (confidence interval 95%)                        |   |   |  |  |
| SG A, $\geq 1:8$<br>(n=28,26,25,29,29,27,25,21,19,18)   | 100 (87.7 to 100)   | 84.6 (65.1 to 95.6)   | 100 (86.3 to 100)  | 100 (88.1 to 100)  |
| SG A, $\geq 1:128$<br>(n=28,26,25,29,29,27,25,21,19,18) | 96.4 (81.7 to 99.9)   | 50.0 (29.9 to 70.1)   | 96.0 (79.6 to 99.9)  | 93.1 (77.2 to 99.2)  |
| SG C,<br>$\geq 1:8$ (n=28,26,25,29,29,27,25,21,19,      | 100 (87.7 to 100)   | 38.5 (20.2 to 59.4)   | 100 (86.3 to 100)  | 100 (88.1 to 100)  |
| SG C, $\geq 1:128$<br>(n=28,26,25,29,29,27,25,21,19,18) | 100 (87.7 to 100)   | 7.7 (0.9 to 25.1)   | 100 (86.3 to 100)  | 100 (88.1 to 100)  |
| SG Y, $\geq 1:8$<br>(n=28,0,25,0,29,0,25,0,19,0)        | 96.4 (81.7 to 99.9)   | 9999 (9999 to 9999)   | 100 (86.3 to 100)  | 9999 (9999 to 9999)  |

|   |                     |                     |                     |                     |
|---|---------------------|---------------------|---------------------|---------------------|
| SG Y, >=1:128<br>(n=28,0,25,0,29,0,25,0,19,0) | 92.9 (76.5 to 99.1) | 9999 (9999 to 9999) | 96.0 (79.6 to 99.9) | 9999 (9999 to 9999) |
| SG W, >=1:8<br>(n=28,0,25,0,29,0,25,0,19,0)   | 100 (87.7 to 100)   | 9999 (9999 to 9999) | 96.0 (79.6 to 99.9) | 9999 (9999 to 9999) |
| SG W, >=1:128<br>(n=28,0,25,0,29,0,25,0,19,0) | 89.3 (71.8 to 97.7) | 9999 (9999 to 9999) | 72.0 (50.6 to 87.9) | 9999 (9999 to 9999) |

| End point values                                   | Group 5:<br>MenACYW<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 6:<br>Royal's MenAC<br>Conjugate<br>Vaccine (12-23<br>Months) | Group 7:<br>MenACYW<br>Conjugate<br>Vaccine (6-11<br>Months) | Group 8:<br>Royal's MenAC<br>Conjugate<br>Vaccine (6-11<br>Months) |
|--|---|---|--|--|
| Subject group type                                 | Reporting group   | Reporting group   | Reporting group  | Reporting group  |
| Number of subjects analysed                        | 29  | 27  | 25   | 21   |
| Units: percentage of participants                  |   |   |  |  |
| number (confidence interval 95%)                   |   |   |  |  |
| SG A, >=1:8<br>(n=28,26,25,29,29,27,25,21,19,18)   | 100 (88.1 to 100)   | 88.9 (70.8 to 97.6)   | 96.0 (79.6 to 99.9)  | 76.2 (52.8 to 91.8)  |
| SG A, >=1:128<br>(n=28,26,25,29,29,27,25,21,19,18) | 79.3 (60.3 to 92.0)   | 63.0 (42.4 to 80.6)   | 56.0 (34.9 to 75.6)  | 42.9 (21.8 to 66.0)  |
| SG C,<br>>=1:8(n=28,26,25,29,29,27,25,21,19,       | 100 (88.1 to 100)   | 100 (87.2 to 100)   | 100 (86.3 to 100)  | 100 (83.9 to 100)  |
| SG C, >=1:128<br>(n=28,26,25,29,29,27,25,21,19,18) | 100 (88.1 to 100)   | 88.9 (70.8 to 97.6)   | 84.0 (63.9 to 95.5)  | 14.3 (3.0 to 36.3)   |
| SG Y, >=1:8<br>(n=28,0,25,0,29,0,25,0,19,0)        | 96.6 (82.2 to 99.9)   | 9999 (9999 to 9999)   | 92.0 (74.0 to 99.0)  | 9999 (9999 to 9999)  |
| SG Y, >=1:128<br>(n=28,0,25,0,29,0,25,0,19,0)      | 34.5 (17.9 to 54.3)   | 9999 (9999 to 9999)   | 24.0 (9.4 to 45.1)   | 9999 (9999 to 9999)  |
| SG W, >=1:8<br>(n=28,0,25,0,29,0,25,0,19,0)        | 93.1 (77.2 to 99.2)   | 9999 (9999 to 9999)   | 96.0 (79.6 to 99.9)  | 9999 (9999 to 9999)  |
| SG W, >=1:128<br>(n=28,0,25,0,29,0,25,0,19,0)      | 27.6 (12.7 to 47.2)   | 9999 (9999 to 9999)   | 28.0 (12.1 to 49.4)  | 9999 (9999 to 9999)  |

| End point values                                   | Group 9:<br>MenACYW<br>Conjugate<br>Vaccine (3-5<br>Months) | Group 10:<br>Green<br>Bamboo's<br>MenAC<br>Conjugate<br>Vaccine (3-5 |  |  |
|--|---|--|--|--|
| Subject group type                                 | Reporting group   | Reporting group  |  |  |
| Number of subjects analysed                        | 19  | 18   |  |  |
| Units: percentage of participants                  |   |  |  |  |
| number (confidence interval 95%)                   |   |  |  |  |
| SG A, >=1:8<br>(n=28,26,25,29,29,27,25,21,19,18)   | 94.7 (74.0 to 99.9)   | 11.1 (1.4 to 34.7)   |  |  |
| SG A, >=1:128<br>(n=28,26,25,29,29,27,25,21,19,18) | 47.4 (24.4 to 71.1)   | 11.1 (1.4 to 34.7)   |  |  |
| SG C,<br>>=1:8(n=28,26,25,29,29,27,25,21,19,       | 100 (82.4 to 100)   | 38.9 (17.3 to 64.3)  |  |  |
| SG C, >=1:128<br>(n=28,26,25,29,29,27,25,21,19,18) | 84.2 (60.4 to 96.6)   | 0 (0 to 18.5)  |  |  |
| SG Y, >=1:8<br>(n=28,0,25,0,29,0,25,0,19,0)        | 100 (82.4 to 100)   | 9999 (9999 to 9999)  |  |  |
| SG Y, >=1:128<br>(n=28,0,25,0,29,0,25,0,19,0)      | 73.7 (48.8 to 90.9)   | 9999 (9999 to 9999)  |  |  |

|   |                        |                        |  |  |
|---|------------------------|------------------------|--|--|
| SG W, >=1:8<br>(n=28,0,25,0,29,0,25,0,19,0)   | 100 (82.4 to<br>100)   | 9999 (9999 to<br>9999) |  |  |
| SG W, >=1:128<br>(n=28,0,25,0,29,0,25,0,19,0) | 52.6 (28.9 to<br>75.6) | 9999 (9999 to<br>9999) |  |  |

**Statistical analyses**

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From date of first vaccination (Day 1) up to 6 months after the last study vaccination, approximately 180 days for Groups 1 to 6, 210 days for Groups 7, 8 and 240 days for Groups 9, 10

Adverse event reporting additional description:

Analysis was performed on the safety population.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 27.0 |
|--------------------|------|

### Reporting groups

|                       |   |
|-----------------------|---|
| Reporting group title | Group 1: MenACYW Conjugate Vaccine (7-17 Years) |
|-----------------------|---|

Reporting group description:

Participants aged 7 to 17 years received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.

|                       |  |
|-----------------------|--|
| Reporting group title | Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years) |
|-----------------------|--|

Reporting group description:

Participants aged 7 to 17 years received a single dose of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection on Day 1.

|                       |  |
|-----------------------|--|
| Reporting group title | Group 3: MenACYW Conjugate Vaccine (2-6 Years) |
|-----------------------|--|

Reporting group description:

Participants aged 2 to 6 years received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.

|                       |  |
|-----------------------|--|
| Reporting group title | Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years) |
|-----------------------|--|

Reporting group description:

Participants aged 2 to 6 years received a single dose of 0.5 mL Royal's MenAC conjugate vaccine IM injection on Day 1.

|                       |   |
|-----------------------|---|
| Reporting group title | Group 5: MenACYW Conjugate Vaccine (12-23 Months) |
|-----------------------|---|

Reporting group description:

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

|                       |   |
|-----------------------|---|
| Reporting group title | Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months) |
|-----------------------|---|

Reporting group description:

Participants aged 12 to 23 months received a single dose of 0.5 mL Royal's MenAC conjugate vaccine IM injection on Day 1. An additional dose of Royal's MenAC conjugate vaccine was offered by the Investigator to participants in Group 6 after the study procedure on the last visit of blood sampling to comply with product's approved vaccination schedule. This second dose of Royal's vaccine was not a part of the study assessment and was administered at least 31 days after the study vaccination.

|                       |  |
|-----------------------|--|
| Reporting group title | Group 7: MenACYW Conjugate Vaccine (6-11 Months) |
|-----------------------|--|

Reporting group description:

Participants aged 6 to 11 months received 2 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1 and 31.

|                       |  |
|-----------------------|--|
| Reporting group title | Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months) |
|-----------------------|--|

Reporting group description:

Participants aged 6 to 11 months received 2 doses of 0.5 mL Royal's MenAC conjugate vaccine IM injection each on Days 1 and 31.

|                       |   |
|-----------------------|---|
| Reporting group title | Group 9: MenACYW Conjugate Vaccine (3-5 Months) |
|-----------------------|---|

Reporting group description:

Participants aged 3 to 5 months received 3 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1, 31 and 61.

|                       |   |
|-----------------------|---|
| Reporting group title | Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months) |
|-----------------------|---|

Reporting group description:

Participants aged 3 to 5 months received 3 doses of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection each on Days 1, 31 and 61.

| <b>Serious adverse events</b>                        | <b>Group 1: MenACYW Conjugate Vaccine (7-17 Years)</b> | <b>Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)</b> | <b>Group 3: MenACYW Conjugate Vaccine (2-6 Years)</b> |
|--|--|---|---|
| Total subjects affected by serious adverse events    |  |   |   |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 1 / 30 (3.33%)  | 4 / 30 (13.33%)                                       |
| number of deaths (all causes)                        | 0  | 0   | 0   |
| number of deaths resulting from adverse events       | 0  | 0   | 0   |
| Nervous system disorders                             |  |   |   |
| Febrile Convulsion                                   |  |   |   |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 0 / 30 (0.00%)  | 0 / 30 (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   |
| General disorders and administration site conditions |  |   |   |
| Pyrexia  |  |   |   |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 0 / 30 (0.00%)  | 0 / 30 (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   |
| Eye disorders  |  |   |   |
| Blepharitis  |  |   |   |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 1 / 30 (3.33%)  | 0 / 30 (0.00%)  |
| occurrences causally related to treatment / all      | 0 / 0  | 0 / 1   | 0 / 0   |
| deaths causally related to treatment / all           | 0 / 0  | 0 / 0   | 0 / 0   |
| Gastrointestinal disorders                           |  |   |   |
| Incarcerated Inguinal Hernia                         |  |   |   |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 0 / 30 (0.00%)  | 0 / 30 (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   |
| Functional Gastrointestinal Disorder                 |  |   |   |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 0 / 30 (0.00%)  | 0 / 30 (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   |
| Intestinal Obstruction                               |  |   |   |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                |                |                |
| Asthma  |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Skin and subcutaneous tissue disorders          |                |                |                |
| Urticaria                                       |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Appendicitis Perforated                         |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Bronchitis                                      |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Complicated Appendicitis                        |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastroenteritis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Febrile Infection                               |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 1 / 30 (3.33%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Diarrhoea Infectious                            |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Gastrointestinal Infection                      |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Hand-Foot-And-Mouth Disease                     |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Herpangina                                      |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Herpes Pharyngitis                              |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Influenza                                       |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Pharyngitis                                     |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Pneumonia                                       |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Upper Respiratory Tract Infection Bacterial     |                |                |                |



|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Upper Respiratory Tract Infection               |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Tonsillitis Bacterial                           |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Varicella                                       |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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>Serious adverse events</b>                        | Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years) | Group 5: MenACYW Conjugate Vaccine (12-23 Months) | Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months) |
|--|--|---|---|
| Total subjects affected by serious adverse events    |  |   |   |
| subjects affected / exposed                          | 3 / 30 (10.00%)                                      | 7 / 30 (23.33%)                                   | 8 / 30 (26.67%)   |
| number of deaths (all causes)                        | 0  | 0   | 0   |
| number of deaths resulting from adverse events       | 0  | 0   | 0   |
| Nervous system disorders                             |  |   |   |
| Febrile Convulsion                                   |  |   |   |
| subjects affected / exposed                          | 0 / 30 (0.00%)                                       | 1 / 30 (3.33%)                                    | 0 / 30 (0.00%)  |
| occurrences causally related to treatment / all      | 0 / 0  | 0 / 1   | 0 / 0   |
| deaths causally related to treatment / all           | 0 / 0  | 0 / 0   | 0 / 0   |
| General disorders and administration site conditions |  |   |   |
| Pyrexia  |  |   |   |
| subjects affected / exposed                          | 0 / 30 (0.00%)                                       | 0 / 30 (0.00%)                                    | 1 / 30 (3.33%)  |
| occurrences causally related to treatment / all      | 0 / 0  | 0 / 0   | 0 / 1   |
| deaths causally related to treatment / all           | 0 / 0  | 0 / 0   | 0 / 0   |
| Eye disorders  |  |   |   |
| Blepharitis  |  |   |   |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Gastrointestinal disorders                      |                |                |                |
| Incarcerated Inguinal Hernia                    |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Functional Gastrointestinal Disorder            |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Intestinal Obstruction                          |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                |                |                |
| Asthma  |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Skin and subcutaneous tissue disorders          |                |                |                |
| Urticaria                                       |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Appendicitis Perforated                         |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (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          |
| Bronchitis                                      |                |                |                |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed                     | 3 / 30 (10.00%) | 2 / 30 (6.67%) | 4 / 30 (13.33%) |
| occurrences causally related to treatment / all | 0 / 3           | 0 / 2          | 0 / 5           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0           |
| Complicated Appendicitis                        |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 0 / 30 (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           |
| Gastroenteritis                                 |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 1 / 30 (3.33%) | 0 / 30 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0           |
| Febrile Infection                               |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 0 / 30 (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           |
| Diarrhoea Infectious                            |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 0 / 30 (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           |
| Gastrointestinal Infection                      |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 1 / 30 (3.33%) | 0 / 30 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0           |
| Hand-Foot-And-Mouth Disease                     |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 0 / 30 (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           |
| Herpangina                                      |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 1 / 30 (3.33%)  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0           |
| Herpes Pharyngitis                              |                 |                |                 |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 30 (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           |
| Influenza                                       |                |                 |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%) | 1 / 30 (3.33%)  | 2 / 30 (6.67%)  |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 1           | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Pharyngitis                                     |                |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 2 / 30 (6.67%)  | 0 / 30 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Pneumonia                                       |                |                 |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%) | 4 / 30 (13.33%) | 4 / 30 (13.33%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 5           | 0 / 5           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Upper Respiratory Tract Infection Bacterial     |                |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 30 (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           |
| Upper Respiratory Tract Infection               |                |                 |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%) | 0 / 30 (0.00%)  | 0 / 30 (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           |
| Tonsillitis Bacterial                           |                |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 30 (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           |
| Varicella                                       |                |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 30 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |

## Serious adverse events

Group 7: MenACYW  
Conjugate Vaccine

Group 8: Royal's  
MenAC Conjugate

Group 9: MenACYW  
Conjugate Vaccine

|  | (6-11 Months)    | Vaccine (6-11 Months) | (3-5 Months)     |
|--|------------------|-----------------------|------------------|
| Total subjects affected by serious adverse events    |                  |                       |                  |
| subjects affected / exposed                          | 13 / 30 (43.33%) | 14 / 28 (50.00%)      | 15 / 30 (50.00%) |
| number of deaths (all causes)                        | 0                | 0                     | 0                |
| number of deaths resulting from adverse events       | 0                | 0                     | 0                |
| Nervous system disorders                             |                  |                       |                  |
| Febrile Convulsion                                   |                  |                       |                  |
| subjects affected / exposed                          | 1 / 30 (3.33%)   | 0 / 28 (0.00%)        | 0 / 30 (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            |
| General disorders and administration site conditions |                  |                       |                  |
| Pyrexia  |                  |                       |                  |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 0 / 28 (0.00%)        | 0 / 30 (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            |
| Eye disorders  |                  |                       |                  |
| Blepharitis  |                  |                       |                  |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 0 / 28 (0.00%)        | 0 / 30 (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            |
| Gastrointestinal disorders                           |                  |                       |                  |
| Incarcerated Inguinal Hernia                         |                  |                       |                  |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 1 / 28 (3.57%)        | 0 / 30 (0.00%)   |
| occurrences causally related to treatment / all      | 0 / 0            | 0 / 1                 | 0 / 0            |
| deaths causally related to treatment / all           | 0 / 0            | 0 / 0                 | 0 / 0            |
| Functional Gastrointestinal Disorder                 |                  |                       |                  |
| subjects affected / exposed                          | 1 / 30 (3.33%)   | 0 / 28 (0.00%)        | 1 / 30 (3.33%)   |
| occurrences causally related to treatment / all      | 0 / 1            | 0 / 0                 | 0 / 1            |
| deaths causally related to treatment / all           | 0 / 0            | 0 / 0                 | 0 / 0            |
| Intestinal Obstruction                               |                  |                       |                  |
| subjects affected / exposed                          | 0 / 30 (0.00%)   | 1 / 28 (3.57%)        | 0 / 30 (0.00%)   |
| occurrences causally related to treatment / all      | 0 / 0            | 0 / 2                 | 0 / 0            |
| deaths causally related to treatment / all           | 0 / 0            | 0 / 0                 | 0 / 0            |
| Respiratory, thoracic and mediastinal disorders      |                  |                       |                  |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| Asthma  |                |                 |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 28 (0.00%)  | 0 / 30 (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          |
| Skin and subcutaneous tissue disorders          |                |                 |                |
| Urticaria                                       |                |                 |                |
| subjects affected / exposed                     | 1 / 30 (3.33%) | 0 / 28 (0.00%)  | 0 / 30 (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          |
| Infections and infestations                     |                |                 |                |
| Appendicitis Perforated                         |                |                 |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 28 (0.00%)  | 0 / 30 (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          |
| Bronchitis                                      |                |                 |                |
| subjects affected / exposed                     | 2 / 30 (6.67%) | 4 / 28 (14.29%) | 2 / 30 (6.67%) |
| occurrences causally related to treatment / all | 0 / 2          | 0 / 4           | 0 / 4          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Complicated Appendicitis                        |                |                 |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 28 (0.00%)  | 0 / 30 (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          |
| Gastroenteritis                                 |                |                 |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 28 (0.00%)  | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Febrile Infection                               |                |                 |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 28 (0.00%)  | 0 / 30 (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          |
| Diarrhoea Infectious                            |                |                 |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 28 (0.00%)  | 0 / 30 (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          |

|   |                 |                 |                  |
|---|-----------------|-----------------|------------------|
| Gastrointestinal Infection                      |                 |                 |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 28 (0.00%)  | 0 / 30 (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            |
| Hand-Foot-And-Mouth Disease                     |                 |                 |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 28 (0.00%)  | 1 / 30 (3.33%)   |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1            |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0            |
| Herpangina                                      |                 |                 |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 1 / 28 (3.57%)  | 3 / 30 (10.00%)  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 3            |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0            |
| Herpes Pharyngitis                              |                 |                 |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 1 / 28 (3.57%)  | 0 / 30 (0.00%)   |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0            |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0            |
| Influenza                                       |                 |                 |                  |
| subjects affected / exposed                     | 1 / 30 (3.33%)  | 3 / 28 (10.71%) | 1 / 30 (3.33%)   |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 3           | 0 / 1            |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0            |
| Pharyngitis                                     |                 |                 |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 28 (0.00%)  | 0 / 30 (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            |
| Pneumonia                                       |                 |                 |                  |
| subjects affected / exposed                     | 7 / 30 (23.33%) | 6 / 28 (21.43%) | 12 / 30 (40.00%) |
| occurrences causally related to treatment / all | 0 / 8           | 0 / 6           | 0 / 17           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0            |
| Upper Respiratory Tract Infection Bacterial     |                 |                 |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 28 (0.00%)  | 1 / 30 (3.33%)   |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1            |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0            |
| Upper Respiratory Tract Infection               |                 |                 |                  |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 28 (0.00%) | 0 / 30 (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>Tonsillitis Bacterial</b>                    |                 |                |                |
| subjects affected / exposed                     | 4 / 30 (13.33%) | 1 / 28 (3.57%) | 1 / 30 (3.33%) |
| occurrences causally related to treatment / all | 0 / 4           | 0 / 1          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| <b>Varicella</b>                                |                 |                |                |
| subjects affected / exposed                     | 1 / 30 (3.33%)  | 0 / 28 (0.00%) | 0 / 30 (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>                               | Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months) |  |  |
| Total subjects affected by serious adverse events           |   |  |  |
| subjects affected / exposed                                 | 14 / 30 (46.67%)  |  |  |
| number of deaths (all causes)                               | 0   |  |  |
| number of deaths resulting from adverse events              | 0   |  |  |
| <b>Nervous system disorders</b>                             |   |  |  |
| Febrile Convulsion  |   |  |  |
| subjects affected / exposed                                 | 0 / 30 (0.00%)  |  |  |
| occurrences causally related to treatment / all             | 0 / 0   |  |  |
| deaths causally related to treatment / all                  | 0 / 0   |  |  |
| <b>General disorders and administration site conditions</b> |   |  |  |
| Pyrexia   |   |  |  |
| subjects affected / exposed                                 | 0 / 30 (0.00%)  |  |  |
| occurrences causally related to treatment / all             | 0 / 0   |  |  |
| deaths causally related to treatment / all                  | 0 / 0   |  |  |
| <b>Eye disorders</b>  |   |  |  |
| Blepharitis   |   |  |  |
| subjects affected / exposed                                 | 0 / 30 (0.00%)  |  |  |
| occurrences causally related to treatment / all             | 0 / 0   |  |  |
| deaths causally related to treatment / all                  | 0 / 0   |  |  |
| <b>Gastrointestinal disorders</b>                           |   |  |  |



|   |                 |  |  |
|---|-----------------|--|--|
| Incarcerated Inguinal Hernia<br>subjects affected / exposed         | 0 / 30 (0.00%)  |  |  |
| occurrences causally related to<br>treatment / all                  | 0 / 0           |  |  |
| deaths causally related to<br>treatment / all                       | 0 / 0           |  |  |
| Functional Gastrointestinal Disorder<br>subjects affected / exposed | 0 / 30 (0.00%)  |  |  |
| occurrences causally related to<br>treatment / all                  | 0 / 0           |  |  |
| deaths causally related to<br>treatment / all                       | 0 / 0           |  |  |
| Intestinal Obstruction<br>subjects affected / exposed               | 0 / 30 (0.00%)  |  |  |
| occurrences causally related to<br>treatment / all                  | 0 / 0           |  |  |
| deaths causally related to<br>treatment / all                       | 0 / 0           |  |  |
| Respiratory, thoracic and mediastinal<br>disorders                  |                 |  |  |
| Asthma<br>subjects affected / exposed                               | 1 / 30 (3.33%)  |  |  |
| occurrences causally related to<br>treatment / all                  | 0 / 1           |  |  |
| deaths causally related to<br>treatment / all                       | 0 / 0           |  |  |
| Skin and subcutaneous tissue disorders                              |                 |  |  |
| Urticaria<br>subjects affected / exposed                            | 0 / 30 (0.00%)  |  |  |
| occurrences causally related to<br>treatment / all                  | 0 / 0           |  |  |
| deaths causally related to<br>treatment / all                       | 0 / 0           |  |  |
| Infections and infestations   |                 |  |  |
| Appendicitis Perforated<br>subjects affected / exposed              | 0 / 30 (0.00%)  |  |  |
| occurrences causally related to<br>treatment / all                  | 0 / 0           |  |  |
| deaths causally related to<br>treatment / all                       | 0 / 0           |  |  |
| Bronchitis<br>subjects affected / exposed                           | 3 / 30 (10.00%) |  |  |
| occurrences causally related to<br>treatment / all                  | 0 / 3           |  |  |
| deaths causally related to<br>treatment / all                       | 0 / 0           |  |  |
| Complicated Appendicitis  |                 |  |  |

|   |                |  |  |  |
|---|----------------|--|--|--|
| subjects affected / exposed                     | 0 / 30 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Gastroenteritis                                 |                |  |  |  |
| subjects affected / exposed                     | 1 / 30 (3.33%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Febrile Infection                               |                |  |  |  |
| subjects affected / exposed                     | 0 / 30 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Diarrhoea Infectious                            |                |  |  |  |
| subjects affected / exposed                     | 1 / 30 (3.33%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 1          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Gastrointestinal Infection                      |                |  |  |  |
| subjects affected / exposed                     | 0 / 30 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Hand-Foot-And-Mouth Disease                     |                |  |  |  |
| subjects affected / exposed                     | 2 / 30 (6.67%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 2          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Herpangina                                      |                |  |  |  |
| subjects affected / exposed                     | 2 / 30 (6.67%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 2          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Herpes Pharyngitis                              |                |  |  |  |
| subjects affected / exposed                     | 0 / 30 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |  |
| Influenza                                       |                |  |  |  |

|   |                 |  |  |  |
|---|-----------------|--|--|--|
| subjects affected / exposed                     | 0 / 30 (0.00%)  |  |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |  |
| Pharyngitis                                     |                 |  |  |  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  |  |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |  |
| Pneumonia                                       |                 |  |  |  |
| subjects affected / exposed                     | 9 / 30 (30.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 9           |  |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |  |
| Upper Respiratory Tract Infection Bacterial     |                 |  |  |  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  |  |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |  |
| Upper Respiratory Tract Infection               |                 |  |  |  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  |  |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |  |
| Tonsillitis Bacterial                           |                 |  |  |  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  |  |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |  |
| Varicella                                       |                 |  |  |  |
| subjects affected / exposed                     | 0 / 30 (0.00%)  |  |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |  |

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

| <b>Non-serious adverse events</b>   | <b>Group 1: MenACYW<br/>Conjugate Vaccine<br/>(7-17 Years)</b>   | <b>Group 2: Green<br/>Bamboo's MenAC<br/>Conjugate Vaccine<br/>(7-17 Years)</b>   | <b>Group 3: MenACYW<br/>Conjugate Vaccine<br/>(2-6 Years)</b>  |
|---|--|---|--|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed  | 10 / 30 (33.33%)   | 11 / 30 (36.67%)  | 14 / 30 (46.67%)   |
| Investigations<br>Myocardial Necrosis Marker Increased<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0  | 0 / 30 (0.00%)<br>0   | 0 / 30 (0.00%)<br>0  |
| Nervous system disorders<br>Somnolence<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0<br><br>2 / 30 (6.67%)<br>2   | 0 / 30 (0.00%)<br>0<br><br>1 / 30 (3.33%)<br>1  | 0 / 30 (0.00%)<br>0<br><br>1 / 30 (3.33%)<br>1   |
| General disorders and administration site conditions<br>Crying<br>subjects affected / exposed<br>occurrences (all)<br><br>Injection Site Erythema<br>subjects affected / exposed<br>occurrences (all)<br><br>Injection Site Pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Injection Site Swelling<br>subjects affected / exposed<br>occurrences (all)<br><br>Malaise<br>subjects affected / exposed<br>occurrences (all)<br><br>Pyrexia<br>subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0<br><br>3 / 30 (10.00%)<br>3<br><br>7 / 30 (23.33%)<br>7<br><br>2 / 30 (6.67%)<br>2<br><br>2 / 30 (6.67%)<br>2<br><br>1 / 30 (3.33%)<br>1 | 0 / 30 (0.00%)<br>0<br><br>3 / 30 (10.00%)<br>3<br><br>8 / 30 (26.67%)<br>8<br><br>3 / 30 (10.00%)<br>3<br><br>0 / 30 (0.00%)<br>0<br><br>0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0<br><br>5 / 30 (16.67%)<br>5<br><br>6 / 30 (20.00%)<br>6<br><br>3 / 30 (10.00%)<br>3<br><br>2 / 30 (6.67%)<br>2<br><br>4 / 30 (13.33%)<br>4 |
| Gastrointestinal disorders  |  |   |  |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| Functional Gastrointestinal Disorder            |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Diarrhoea                                       |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 1 / 30 (3.33%)  |
| occurrences (all)                               | 0               | 0              | 1               |
| Vomiting  |                 |                |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%)  | 0 / 30 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 1               | 0              | 0               |
| Respiratory, thoracic and mediastinal disorders |                 |                |                 |
| Cough   |                 |                |                 |
| subjects affected / exposed                     | 2 / 30 (6.67%)  | 2 / 30 (6.67%) | 6 / 30 (20.00%) |
| occurrences (all)                               | 2               | 2              | 6               |
| Rhinorrhoea                                     |                 |                |                 |
| subjects affected / exposed                     | 3 / 30 (10.00%) | 1 / 30 (3.33%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 4               | 1              | 0               |
| Skin and subcutaneous tissue disorders          |                 |                |                 |
| Rash  |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Psychiatric disorders                           |                 |                |                 |
| Irritability                                    |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Musculoskeletal and connective tissue disorders |                 |                |                 |
| Myalgia   |                 |                |                 |
| subjects affected / exposed                     | 2 / 30 (6.67%)  | 1 / 30 (3.33%) | 2 / 30 (6.67%)  |
| occurrences (all)                               | 2               | 1              | 2               |
| Infections and infestations                     |                 |                |                 |
| Influenza                                       |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Nasopharyngitis                                 |                 |                |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%)  | 0 / 30 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 1               | 0              | 0               |
| Upper Respiratory Tract Infection               |                 |                |                 |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0 | 1 / 30 (3.33%)<br>1 | 2 / 30 (6.67%)<br>3 |
| Metabolism and nutrition disorders<br>Decreased Appetite<br>subjects affected / exposed<br>occurrences (all) | 1 / 30 (3.33%)<br>2 | 0 / 30 (0.00%)<br>0 | 0 / 30 (0.00%)<br>0 |

| <b>Non-serious adverse events</b>   | Group 4: Royal's<br>MenAC Conjugate<br>Vaccine (2-6 Years)   | Group 5: MenACYW<br>Conjugate Vaccine<br>(12-23 Months)   | Group 6: Royal's<br>MenAC Conjugate<br>Vaccine (12-23<br>Months)                                     |
|---|--|---|--|
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed   | 10 / 30 (33.33%)   | 15 / 30 (50.00%)  | 15 / 30 (50.00%)   |
| Investigations<br>Myocardial Necrosis Marker<br>Increased<br>subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0  | 2 / 30 (6.67%)<br>2   | 0 / 30 (0.00%)<br>0  |
| Nervous system disorders<br>Somnolence<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0<br><br>2 / 30 (6.67%)<br>2   | 0 / 30 (0.00%)<br>0<br><br>0 / 30 (0.00%)<br>0  | 1 / 30 (3.33%)<br>1<br><br>0 / 30 (0.00%)<br>0   |
| General disorders and administration<br>site conditions<br>Crying<br>subjects affected / exposed<br>occurrences (all)<br><br>Injection Site Erythema<br>subjects affected / exposed<br>occurrences (all)<br><br>Injection Site Pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Injection Site Swelling<br>subjects affected / exposed<br>occurrences (all)<br><br>Malaise | 0 / 30 (0.00%)<br>0<br><br>2 / 30 (6.67%)<br>2<br><br>3 / 30 (10.00%)<br>3<br><br>3 / 30 (10.00%)<br>3 | 3 / 30 (10.00%)<br>3<br><br>0 / 30 (0.00%)<br>0<br><br>2 / 30 (6.67%)<br>2<br><br>0 / 30 (0.00%)<br>0 | 2 / 30 (6.67%)<br>2<br><br>1 / 30 (3.33%)<br>1<br><br>1 / 30 (3.33%)<br>1<br><br>0 / 30 (0.00%)<br>0 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 30 (3.33%)  | 0 / 30 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                               | 1               | 0               | 0               |
| Pyrexia   |                 |                 |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%)  | 6 / 30 (20.00%) | 5 / 30 (16.67%) |
| occurrences (all)                               | 1               | 6               | 6               |
| Gastrointestinal disorders                      |                 |                 |                 |
| Functional Gastrointestinal Disorder            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                               | 0               | 0               | 0               |
| Diarrhoea                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 3 / 30 (10.00%) | 2 / 30 (6.67%)  |
| occurrences (all)                               | 0               | 3               | 2               |
| Vomiting  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%)  | 3 / 30 (10.00%) | 3 / 30 (10.00%) |
| occurrences (all)                               | 1               | 3               | 3               |
| Respiratory, thoracic and mediastinal disorders |                 |                 |                 |
| Cough   |                 |                 |                 |
| subjects affected / exposed                     | 4 / 30 (13.33%) | 6 / 30 (20.00%) | 3 / 30 (10.00%) |
| occurrences (all)                               | 6               | 6               | 3               |
| Rhinorrhoea                                     |                 |                 |                 |
| subjects affected / exposed                     | 3 / 30 (10.00%) | 3 / 30 (10.00%) | 5 / 30 (16.67%) |
| occurrences (all)                               | 3               | 3               | 5               |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Rash  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                               | 0               | 0               | 0               |
| Psychiatric disorders                           |                 |                 |                 |
| Irritability                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 2 / 30 (6.67%)  | 2 / 30 (6.67%)  |
| occurrences (all)                               | 0               | 2               | 2               |
| Musculoskeletal and connective tissue disorders |                 |                 |                 |
| Myalgia   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 30 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)                               | 0               | 0               | 0               |
| Infections and infestations                     |                 |                 |                 |

|                                    |                |                |                 |
|------------------------------------|----------------|----------------|-----------------|
| Influenza                          |                |                |                 |
| subjects affected / exposed        | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Nasopharyngitis                    |                |                |                 |
| subjects affected / exposed        | 0 / 30 (0.00%) | 0 / 30 (0.00%) | 1 / 30 (3.33%)  |
| occurrences (all)                  | 0              | 0              | 1               |
| Upper Respiratory Tract Infection  |                |                |                 |
| subjects affected / exposed        | 0 / 30 (0.00%) | 2 / 30 (6.67%) | 2 / 30 (6.67%)  |
| occurrences (all)                  | 0              | 2              | 2               |
| Metabolism and nutrition disorders |                |                |                 |
| Decreased Appetite                 |                |                |                 |
| subjects affected / exposed        | 0 / 30 (0.00%) | 2 / 30 (6.67%) | 3 / 30 (10.00%) |
| occurrences (all)                  | 0              | 2              | 3               |

| <b>Non-serious adverse events</b>                        | Group 7: MenACYW<br>Conjugate Vaccine<br>(6-11 Months) | Group 8: Royal's<br>MenAC Conjugate<br>Vaccine (6-11<br>Months) | Group 9: MenACYW<br>Conjugate Vaccine<br>(3-5 Months) |
|--|--|---|---|
| Total subjects affected by non-serious<br>adverse events |  |   |   |
| subjects affected / exposed                              | 26 / 30 (86.67%)                                       | 23 / 28 (82.14%)  | 28 / 30 (93.33%)                                      |
| Investigations   |  |   |   |
| Myocardial Necrosis Marker<br>Increased                  |  |   |   |
| subjects affected / exposed                              | 0 / 30 (0.00%)   | 2 / 28 (7.14%)  | 2 / 30 (6.67%)  |
| occurrences (all)  | 0  | 2   | 2   |
| Nervous system disorders                                 |  |   |   |
| Somnolence   |  |   |   |
| subjects affected / exposed                              | 2 / 30 (6.67%)   | 0 / 28 (0.00%)  | 3 / 30 (10.00%)                                       |
| occurrences (all)  | 2  | 0   | 3   |
| Headache   |  |   |   |
| subjects affected / exposed                              | 0 / 30 (0.00%)   | 0 / 28 (0.00%)  | 0 / 30 (0.00%)  |
| occurrences (all)  | 0  | 0   | 0   |
| General disorders and administration<br>site conditions  |  |   |   |
| Crying   |  |   |   |
| subjects affected / exposed                              | 4 / 30 (13.33%)  | 0 / 28 (0.00%)  | 7 / 30 (23.33%)                                       |
| occurrences (all)  | 5  | 0   | 9   |
| Injection Site Erythema                                  |  |   |   |
| subjects affected / exposed                              | 2 / 30 (6.67%)   | 0 / 28 (0.00%)  | 1 / 30 (3.33%)  |
| occurrences (all)  | 2  | 0   | 1   |
| Injection Site Pain                                      |  |   |   |



|  |                        |                        |                        |
|--|------------------------|------------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)   | 1 / 30 (3.33%)<br>1    | 1 / 28 (3.57%)<br>1    | 0 / 30 (0.00%)<br>0    |
| Injection Site Swelling<br>subjects affected / exposed<br>occurrences (all)  | 1 / 30 (3.33%)<br>1    | 0 / 28 (0.00%)<br>0    | 0 / 30 (0.00%)<br>0    |
| Malaise<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    | 0 / 28 (0.00%)<br>0    | 0 / 30 (0.00%)<br>0    |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)  | 19 / 30 (63.33%)<br>31 | 11 / 28 (39.29%)<br>12 | 15 / 30 (50.00%)<br>22 |
| Gastrointestinal disorders<br>Functional Gastrointestinal Disorder<br>subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0    | 0 / 28 (0.00%)<br>0    | 2 / 30 (6.67%)<br>2    |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)  | 3 / 30 (10.00%)<br>3   | 0 / 28 (0.00%)<br>0    | 5 / 30 (16.67%)<br>7   |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)   | 5 / 30 (16.67%)<br>5   | 3 / 28 (10.71%)<br>3   | 3 / 30 (10.00%)<br>3   |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)           | 10 / 30 (33.33%)<br>11 | 12 / 28 (42.86%)<br>15 | 16 / 30 (53.33%)<br>23 |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)  | 10 / 30 (33.33%)<br>11 | 12 / 28 (42.86%)<br>14 | 10 / 30 (33.33%)<br>11 |
| Skin and subcutaneous tissue disorders<br>Rash<br>subjects affected / exposed<br>occurrences (all)                     | 1 / 30 (3.33%)<br>1    | 0 / 28 (0.00%)<br>0    | 2 / 30 (6.67%)<br>2    |
| Psychiatric disorders<br>Irritability<br>subjects affected / exposed<br>occurrences (all)                              | 2 / 30 (6.67%)<br>3    | 0 / 28 (0.00%)<br>0    | 5 / 30 (16.67%)<br>5   |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| Musculoskeletal and connective tissue disorders |                 |                |                 |
| Myalgia   |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 0 / 28 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 0               | 0              | 0               |
| Infections and infestations                     |                 |                |                 |
| Influenza                                       |                 |                |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%)  | 2 / 28 (7.14%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 1               | 2              | 0               |
| Nasopharyngitis                                 |                 |                |                 |
| subjects affected / exposed                     | 2 / 30 (6.67%)  | 0 / 28 (0.00%) | 0 / 30 (0.00%)  |
| occurrences (all)                               | 2               | 0              | 0               |
| Upper Respiratory Tract Infection               |                 |                |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%)  | 1 / 28 (3.57%) | 4 / 30 (13.33%) |
| occurrences (all)                               | 0               | 1              | 4               |
| Metabolism and nutrition disorders              |                 |                |                 |
| Decreased Appetite                              |                 |                |                 |
| subjects affected / exposed                     | 4 / 30 (13.33%) | 0 / 28 (0.00%) | 3 / 30 (10.00%) |
| occurrences (all)                               | 4               | 0              | 3               |

|   |   |  |  |
|---|---|--|--|
| <b>Non-serious adverse events</b>                     | Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months) |  |  |
| Total subjects affected by non-serious adverse events |   |  |  |
| subjects affected / exposed                           | 27 / 30 (90.00%)  |  |  |
| Investigations  |   |  |  |
| Myocardial Necrosis Marker Increased                  |   |  |  |
| subjects affected / exposed                           | 3 / 30 (10.00%)   |  |  |
| occurrences (all)                                     | 3   |  |  |
| Nervous system disorders                              |   |  |  |
| Somnolence  |   |  |  |
| subjects affected / exposed                           | 4 / 30 (13.33%)   |  |  |
| occurrences (all)                                     | 4   |  |  |
| Headache  |   |  |  |
| subjects affected / exposed                           | 0 / 30 (0.00%)  |  |  |
| occurrences (all)                                     | 0   |  |  |
| General disorders and administration site conditions  |   |  |  |

|  |                        |  |  |
|--|------------------------|--|--|
| Crying<br>subjects affected / exposed<br>occurrences (all)   | 3 / 30 (10.00%)<br>4   |  |  |
| Injection Site Erythema<br>subjects affected / exposed<br>occurrences (all)  | 2 / 30 (6.67%)<br>2    |  |  |
| Injection Site Pain<br>subjects affected / exposed<br>occurrences (all)  | 2 / 30 (6.67%)<br>2    |  |  |
| Injection Site Swelling<br>subjects affected / exposed<br>occurrences (all)  | 1 / 30 (3.33%)<br>1    |  |  |
| Malaise<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    |  |  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)  | 14 / 30 (46.67%)<br>22 |  |  |
| Gastrointestinal disorders<br>Functional Gastrointestinal Disorder<br>subjects affected / exposed<br>occurrences (all) | 1 / 30 (3.33%)<br>1    |  |  |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)  | 1 / 30 (3.33%)<br>1    |  |  |
| Vomiting<br>subjects affected / exposed<br>occurrences (all)   | 4 / 30 (13.33%)<br>4   |  |  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)           | 18 / 30 (60.00%)<br>27 |  |  |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)  | 12 / 30 (40.00%)<br>13 |  |  |
| Skin and subcutaneous tissue disorders   |                        |  |  |

|  |  |  |  |
|--|--|--|--|
| Rash<br>subjects affected / exposed<br>occurrences (all)   | 2 / 30 (6.67%)<br>2  |  |  |
| Psychiatric disorders<br>Irritability<br>subjects affected / exposed<br>occurrences (all)  | 4 / 30 (13.33%)<br>5   |  |  |
| Musculoskeletal and connective tissue disorders<br>Myalgia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0  |  |  |
| Infections and infestations<br>Influenza<br>subjects affected / exposed<br>occurrences (all)<br><br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)<br><br>Upper Respiratory Tract Infection<br>subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0<br><br>1 / 30 (3.33%)<br>1<br><br>3 / 30 (10.00%)<br>3 |  |  |
| Metabolism and nutrition disorders<br>Decreased Appetite<br>subjects affected / exposed<br>occurrences (all)   | 3 / 30 (10.00%)<br>3   |  |  |

**More information**

**Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment  |
|-----------------|--|
| 10 January 2024 | The main reason for this amendment was to add an interim analysis for Cohorts 1 and 2 (participants from 2 through 17 years of age). |

Notes:

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**Interruptions (globally)**

Were there any global interruptions to the trial? No

**Limitations and caveats**

None reported