



## Clinical trial results:

### A Single-blind, Randomized, Phase 1/2 Trial of the Safety, Tolerability, and Immunogenicity of Meningococcal Group B rLP2086 Vaccine in Healthy Infants

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2008-001457-18 |
| Trial protocol           | ES             |
| Global end of trial date | 02 March 2011  |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 29 June 2016 |
| First version publication date | 29 July 2015 |

#### Trial information

##### Trial identification

|                       |             |
|-----------------------|-------------|
| Sponsor protocol code | 6108K2-2000 |
|-----------------------|-------------|

##### Additional study identifiers

|                                    |                 |
|------------------------------------|-----------------|
| ISRCTN number                      | -               |
| ClinicalTrials.gov id (NCT number) | NCT00798304     |
| WHO universal trial number (UTN)   | -               |
| Other trial identifiers            | Alias: B1971008 |

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Pfizer Inc.   |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017  |
| Public contact               | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact           | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

#### Paediatric regulatory details

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

Notes:

## Results analysis stage

|  |               |
|--|---------------|
| Analysis stage                                       | Final         |
| Date of interim/final analysis                       | 24 June 2011  |
| Is this the analysis of the primary completion data? | No            |
| Global end of trial reached?                         | Yes           |
| Global end of trial date                             | 02 March 2011 |
| Was the trial ended prematurely?                     | Yes           |

Notes:

## General information about the trial

Main objective of the trial:

1. To assess the immunogenicity of 60 microgram (mcg), 120 mcg, and 200 mcg of recombinant lipoprotein 2086 (rLP2086) as measured by serum bactericidal assay (SBA) to meningococcal serogroup B (MnB) strains expressing LP2086 subfamily A and B proteins in healthy infants 1 month after the infant series.
2. To assess the safety and tolerability of 20 mcg, 60 mcg, 120 mcg, and 200 mcg of rLP2086 when given with routine childhood vaccines in healthy infants and toddlers.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

|   |                 |
|---|-----------------|
| Actual start date of recruitment                          | 09 January 2009 |
| Long term follow-up planned                               | No              |
| Independent data monitoring committee (IDMC) involvement? | Yes             |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |           |
|--------------------------------------|-----------|
| Country: Number of subjects enrolled | Spain: 46 |
| Worldwide total number of subjects   | 46        |
| EEA total number of subjects         | 46        |

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)  | 46 |
| Children (2-11 years)                     | 0  |
| Adolescents (12-17 years)                 | 0  |
| Adults (18-64 years)                      | 0  |
| From 65 to 84 years                       | 0  |

|                   |   |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

## Subject disposition

### Recruitment

Recruitment details:

In this study, subjects were to receive rLP2086 vaccine at 2, 4, 6 and 12 months of age. Due to premature termination of study, only single dose of 20 or 60 mcg of rLP2086 vaccine was administered at 2 months and planned treatments of rLP2086 vaccine 120 mcg and 200 mcg were not administered.

### Pre-assignment

Screening details:

A total of 744 subjects were planned to be enrolled in this study. Of which 46 subjects were randomized and assigned to treatment.

### Period 1

|                              |                          |
|------------------------------|--------------------------|
| Period 1 title               | Stage 1 (overall period) |
| Is this the baseline period? | Yes                      |
| Allocation method            | Randomised - controlled  |
| Blinding used                | Single blind             |
| Roles blinded                | Subject                  |

### Arms

|                              |         |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes     |
| <b>Arm title</b>             | Control |

Arm description:

Routine childhood vaccines (InfanrixHexa, Meningitec, Prevenar and Rotarix) according to local practice.

|  |                   |
|--|-------------------|
| Arm type                               | Active comparator |
| Investigational medicinal product name | InfanrixHexa      |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received InfanrixHexa at 2 months of age.

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Meningitec                        |
| Investigational medicinal product code |                                   |
| Other name                             | Meningococcal Serogroup C vaccine |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received Meningococcal Serogroup C vaccine at 2 months of age.

|  |                                |
|--|--------------------------------|
| Investigational medicinal product name | Prevenar                       |
| Investigational medicinal product code |                                |
| Other name                             | Pneumococcal Conjugate Vaccine |
| Pharmaceutical forms                   | Injection                      |
| Routes of administration               | Intramuscular use              |

Dosage and administration details:

Subjects received 0.5 milliliter (mL) of Prevenar at 2 months of age.

|  |                   |
|--|-------------------|
| Investigational medicinal product name | Rotarix           |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received Rotarix at 2 months of age.

|                  |                |
|------------------|----------------|
| <b>Arm title</b> | rLP2086 20 mcg |
|------------------|----------------|

Arm description:

rLP2086 20 mcg vaccine along with routine childhood vaccines according to local practice.

|  |                              |
|--|------------------------------|
| Arm type                               | Experimental                 |
| Investigational medicinal product name | Recombinant lipoprotein 2086 |
| Investigational medicinal product code |                              |
| Other name                             |                              |
| Pharmaceutical forms                   | Suspension for injection     |
| Routes of administration               | Intramuscular use            |

Dosage and administration details:

Subjects received single 20 mcg dose of rLP2086.

|  |                   |
|--|-------------------|
| Investigational medicinal product name | InfanrixHexa      |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received InfanrixHexa at 2 months of age.

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Meningitec                        |
| Investigational medicinal product code |                                   |
| Other name                             | Meningococcal Serogroup C vaccine |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received Meningococcal Serogroup C vaccine at 2 months of age.

|  |                                |
|--|--------------------------------|
| Investigational medicinal product name | Prevenar                       |
| Investigational medicinal product code |                                |
| Other name                             | Pneumococcal Conjugate Vaccine |
| Pharmaceutical forms                   | Injection                      |
| Routes of administration               | Intramuscular use              |

Dosage and administration details:

Subjects received 0.5 milliliter (mL) of Prevenar at 2 months of age.

|  |                   |
|--|-------------------|
| Investigational medicinal product name | Rotarix           |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received Rotarix at 2 months of age.

|                  |                |
|------------------|----------------|
| <b>Arm title</b> | rLP2086 60 mcg |
|------------------|----------------|

Arm description:

rLP2086 60 mcg vaccine along with routine childhood vaccines according to local practice.

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

|   |                                   |
|---|-----------------------------------|
| Investigational medicinal product name                                  | Recombinant lipoprotein 2086      |
| Investigational medicinal product code                                  |                                   |
| Other name  |                                   |
| Pharmaceutical forms  | Suspension for injection          |
| Routes of administration  | Intramuscular use                 |
| Dosage and administration details:                                      |                                   |
| Subjects received single 60 mcg dose of rLP2086.                        |                                   |
| Investigational medicinal product name                                  | InfanrixHexa                      |
| Investigational medicinal product code                                  |                                   |
| Other name  |                                   |
| Pharmaceutical forms  | Injection                         |
| Routes of administration  | Intramuscular use                 |
| Dosage and administration details:                                      |                                   |
| Subjects received InfanrixHexa at 2 months of age.                      |                                   |
| Investigational medicinal product name                                  | Meningitec                        |
| Investigational medicinal product code                                  |                                   |
| Other name  | Meningococcal Serogroup C vaccine |
| Pharmaceutical forms  | Injection                         |
| Routes of administration  | Intramuscular use                 |
| Dosage and administration details:                                      |                                   |
| Subjects received Meningococcal Serogroup C vaccine at 2 months of age. |                                   |
| Investigational medicinal product name                                  | Prevenar                          |
| Investigational medicinal product code                                  |                                   |
| Other name  | Pneumococcal Conjugate Vaccine    |
| Pharmaceutical forms  | Injection                         |
| Routes of administration  | Intramuscular use                 |
| Dosage and administration details:                                      |                                   |
| Subjects received 0.5 milliliter (mL) of Prevenar at 2 months of age.   |                                   |
| Investigational medicinal product name                                  | Rotarix                           |
| Investigational medicinal product code                                  |                                   |
| Other name  |                                   |
| Pharmaceutical forms  | Injection                         |
| Routes of administration  | Intramuscular use                 |
| Dosage and administration details:                                      |                                   |
| Subjects received Rotarix at 2 months of age.                           |                                   |

| <b>Number of subjects in period 1</b> | Control | rLP2086 20 mcg | rLP2086 60 mcg |
|---------------------------------------|---------|----------------|----------------|
| Started                               | 14      | 22             | 10             |
| Completed                             | 0       | 0              | 0              |
| Not completed                         | 14      | 22             | 10             |
| Adverse Event                         | -       | 1              | 1              |
| Discontinuation by Sponsor            | 14      | 21             | 9              |

## Baseline characteristics

### Reporting groups

|  |                |
|--|----------------|
| Reporting group title  | Control        |
| Reporting group description:<br>Routine childhood vaccines (InfanrixHexa, Meningitec, Prevenar and Rotarix) according to local practice. |                |
| Reporting group title  | rLP2086 20 mcg |
| Reporting group description:<br>rLP2086 20 mcg vaccine along with routine childhood vaccines according to local practice.                |                |
| Reporting group title  | rLP2086 60 mcg |
| Reporting group description:<br>rLP2086 60 mcg vaccine along with routine childhood vaccines according to local practice.                |                |

| Reporting group values             | Control | rLP2086 20 mcg | rLP2086 60 mcg |
|------------------------------------|---------|----------------|----------------|
| Number of subjects                 | 14      | 22             | 10             |
| Age categorical<br>Units: Subjects |         |                |                |

|  |                 |               |                 |
|--|-----------------|---------------|-----------------|
| Age continuous<br>Units: days<br>arithmetic mean<br>standard deviation | 63.6<br>± 11.57 | 64<br>± 10.02 | 71.6<br>± 11.35 |
| Gender categorical<br>Units: Subjects                                  |                 |               |                 |
| Female   | 6               | 12            | 4               |
| Male   | 8               | 10            | 6               |

| Reporting group values             | Total |  |  |
|------------------------------------|-------|--|--|
| Number of subjects                 | 46    |  |  |
| Age categorical<br>Units: Subjects |       |  |  |

|  |    |  |  |
|--|----|--|--|
| Age continuous<br>Units: days<br>arithmetic mean<br>standard deviation | -  |  |  |
| Gender categorical<br>Units: Subjects                                  |    |  |  |
| Female   | 22 |  |  |
| Male   | 24 |  |  |

## End points

### End points reporting groups

|  |                |
|--|----------------|
| Reporting group title  | Control        |
| Reporting group description:<br>Routine childhood vaccines (InfanrixHexa, Meningitec, Prevenar and Rotarix) according to local practice. |                |
| Reporting group title  | rLP2086 20 mcg |
| Reporting group description:<br>rLP2086 20 mcg vaccine along with routine childhood vaccines according to local practice.                |                |
| Reporting group title  | rLP2086 60 mcg |
| Reporting group description:<br>rLP2086 60 mcg vaccine along with routine childhood vaccines according to local practice.                |                |

### Primary: Percentage of Subjects Achieving at Least 1:4 rLP2086-specific Serum Bactericidal Assay (SBA) Titer to 1 Subfamily A Strain and 1 Subfamily B Strain

|  |   |
|--|---|
| End point title  | Percentage of Subjects Achieving at Least 1:4 rLP2086-specific Serum Bactericidal Assay (SBA) Titer to 1 Subfamily A Strain and 1 Subfamily B Strain <sup>[1]</sup> |
| End point description:<br>Percentage of Subjects Achieving at Least 1:4 rLP2086-specific SBA Titer to 1 Subfamily A Strain and 1 Subfamily B Strain. Results were not reported, as no immunogenicity data was collected due to study termination prior to first post vaccination blood draw. |   |
| End point type   | Primary   |
| End point timeframe:<br>1 month after Dose 3   |   |

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: No statistical analyses was done since no descriptive data was collected due to early study termination.

| End point values              | Control          | rLP2086 20 mcg   | rLP2086 60 mcg   |  |
|-------------------------------|------------------|------------------|------------------|--|
| Subject group type            | Reporting group  | Reporting group  | Reporting group  |  |
| Number of subjects analysed   | 0 <sup>[2]</sup> | 0 <sup>[3]</sup> | 0 <sup>[4]</sup> |  |
| Units: percentage of subjects |                  |                  |                  |  |
| number (not applicable)       |                  |                  |                  |  |

Notes:

[2] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[3] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[4] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects With at Least One Adverse Event (AE)

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects With at Least One Adverse Event (AE) <sup>[5]</sup> |
|-----------------|--|



End point description:

The Safety population included all subjects who have received at least 1 dose of the investigational vaccine.

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

End point timeframe:

From signing of informed consent form to completion of study (up to 2 years)

Notes:

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

Justification: No statistical analysis have been specified as descriptive statistic was planned.

| End point values              | Control         | rLP2086 20 mcg  | rLP2086 60 mcg  |  |
|-------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type            | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed   | 14              | 22              | 10              |  |
| Units: percentage of subjects |                 |                 |                 |  |
| number (not applicable)       | 21.4            | 31.8            | 20              |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Serum Bactericidal Assay (SBA) Geometric Mean Titers (GMTs) for 1 Subfamily A Strain and 1 Subfamily B Strain

|                 |   |
|-----------------|---|
| End point title | Serum Bactericidal Assay (SBA) Geometric Mean Titers (GMTs) for 1 Subfamily A Strain and 1 Subfamily B Strain |
|-----------------|---|

End point description:

Results were not reported, as no immunogenicity data was collected due to study termination prior to first post vaccination blood draw.

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

End point timeframe:

1 month after Dose 2, Dose 3; before Dose 4

| End point values                         | Control          | rLP2086 20 mcg   | rLP2086 60 mcg   |  |
|--|------------------|------------------|------------------|--|
| Subject group type                       | Reporting group  | Reporting group  | Reporting group  |  |
| Number of subjects analysed              | 0 <sup>[6]</sup> | 0 <sup>[7]</sup> | 0 <sup>[8]</sup> |  |
| Units: titer                             |                  |                  |                  |  |
| geometric mean (confidence interval 95%) | ( to )           | ( to )           | ( to )           |  |

Notes:

[6] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[7] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[8] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

## Statistical analyses

No statistical analyses for this end point

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**Secondary: Percentage of Subjects Achieving at Least 1:4, 1:8, 1:16, 1:32, 1:64, 1:128 rLP2086-specific SBA Titer to 1 Subfamily A Strain and 1 Subfamily B Strain**

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|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects Achieving at Least 1:4, 1:8, 1:16, 1:32, 1:64, 1:128 rLP2086-specific SBA Titer to 1 Subfamily A Strain and 1 Subfamily B Strain |
|-----------------|---|

End point description:

Results were not reported, as no immunogenicity data was collected due to study termination prior to first post vaccination blood draw.

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

End point timeframe:

1 month after Dose 2, Dose 3; before Dose 4

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| End point values              | Control          | rLP2086 20 mcg    | rLP2086 60 mcg    |  |
|-------------------------------|------------------|-------------------|-------------------|--|
| Subject group type            | Reporting group  | Reporting group   | Reporting group   |  |
| Number of subjects analysed   | 0 <sup>[9]</sup> | 0 <sup>[10]</sup> | 0 <sup>[11]</sup> |  |
| Units: percentage of subjects |                  |                   |                   |  |
| number (not applicable)       |                  |                   |                   |  |

Notes:

[9] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[10] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[11] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

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**Statistical analyses**

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No statistical analyses for this end point

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**Other pre-specified: Percentage of Subjects Achieving Response  $\geq$  1:4 for Additional Meningococcal Serogroup B (MnB) Test Strain-specific SBA Titer**

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|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Achieving Response $\geq$ 1:4 for Additional Meningococcal Serogroup B (MnB) Test Strain-specific SBA Titer |
|-----------------|--|

End point description:

Results were not reported, as no immunogenicity data was collected due to study termination prior to first post vaccination blood draw.

|                |                     |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

1 month after Dose 2, Dose 3; before Dose 4; 1, 6, 12, 18, 24, 36, 48 months after Dose 4

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| End point values              | Control           | rLP2086 20 mcg    | rLP2086 60 mcg    |  |
|-------------------------------|-------------------|-------------------|-------------------|--|
| Subject group type            | Reporting group   | Reporting group   | Reporting group   |  |
| Number of subjects analysed   | 0 <sup>[12]</sup> | 0 <sup>[13]</sup> | 0 <sup>[14]</sup> |  |
| Units: percentage of subjects |                   |                   |                   |  |
| number (not applicable)       |                   |                   |                   |  |

Notes:

[12] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[13] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[14] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

## Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Subjects Achieving SBA Titer Levels $\geq 1:4$ , $\geq 1:8$ , $\geq 1:16$ , $\geq 1:32$ , $\geq 1:64$ and $\geq 1:128$ for Additional MnB Test Strains

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects Achieving SBA Titer Levels $\geq 1:4$ , $\geq 1:8$ , $\geq 1:16$ , $\geq 1:32$ , $\geq 1:64$ and $\geq 1:128$ for Additional MnB Test Strains |
|-----------------|--|

End point description:

Results were not reported, as no immunogenicity data was collected due to study termination prior to first post vaccination blood draw.

|                |                     |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

1 month after Dose 2, Dose 3; before Dose 4; 1, 6, 12, 18, 24, 36, 48 months after Dose 4

| End point values              | Control           | rLP2086 20 mcg    | rLP2086 60 mcg    |  |
|-------------------------------|-------------------|-------------------|-------------------|--|
| Subject group type            | Reporting group   | Reporting group   | Reporting group   |  |
| Number of subjects analysed   | 0 <sup>[15]</sup> | 0 <sup>[16]</sup> | 0 <sup>[17]</sup> |  |
| Units: percentage of subjects |                   |                   |                   |  |
| number (not applicable)       |                   |                   |                   |  |

Notes:

[15] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[16] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[17] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

## Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Serum Bactericidal Assay (SBA) Geometric Mean Titers (GMTs) for Additional MnB Test Strains

|                 |   |
|-----------------|---|
| End point title | Serum Bactericidal Assay (SBA) Geometric Mean Titers (GMTs) for Additional MnB Test Strains |
|-----------------|---|

End point description:

Results were not reported, as no immunogenicity data was collected due to study termination prior to first post vaccination blood draw.

|   |                     |
|---|---------------------|
| End point type  | Other pre-specified |
| End point timeframe:  |                     |
| 1 month after Dose 2, Dose 3; before Dose 4; 1, 6, 12, 18, 24, 36, 48 months after Dose 4 |                     |

| End point values                         | Control           | rLP2086 20 mcg    | rLP2086 60 mcg    |  |
|--|-------------------|-------------------|-------------------|--|
| Subject group type                       | Reporting group   | Reporting group   | Reporting group   |  |
| Number of subjects analysed              | 0 <sup>[18]</sup> | 0 <sup>[19]</sup> | 0 <sup>[20]</sup> |  |
| Units: titer                             |                   |                   |                   |  |
| geometric mean (confidence interval 95%) | ( to )            | ( to )            | ( to )            |  |

Notes:

[18] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[19] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

[20] - Immunogenicity data was not collected as study was terminated prior to first scheduled blood draw.

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From signing of informed consent form till study termination

Adverse event reporting additional description:

Version was not captured, here 0.0 is mentioned for dictionary version.

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

### Dictionary used

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

|                    |     |
|--------------------|-----|
| Dictionary version | 0.0 |
|--------------------|-----|

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | Control |
|-----------------------|---------|

Reporting group description:

Routine childhood vaccines (InfanrixHexa, Meningitec, Prevenar and Rotarix) according to local practice.

|                       |                |
|-----------------------|----------------|
| Reporting group title | rLP2086 20 mcg |
|-----------------------|----------------|

Reporting group description:

rLP2086 20 mcg vaccine along with routine childhood vaccines according to local practice.

|                       |                |
|-----------------------|----------------|
| Reporting group title | rLP2086 60 mcg |
|-----------------------|----------------|

Reporting group description:

rLP2086 60 mcg vaccine along with routine childhood vaccines according to local practice.

| Serious adverse events                            | Control        | rLP2086 20 mcg  | rLP2086 60 mcg  |
|---|----------------|-----------------|-----------------|
| Total subjects affected by serious adverse events |                |                 |                 |
| subjects affected / exposed                       | 0 / 14 (0.00%) | 4 / 22 (18.18%) | 1 / 10 (10.00%) |
| number of deaths (all causes)                     | 0              | 0               | 0               |
| number of deaths resulting from adverse events    | 0              | 0               | 0               |
| Infections and infestations                       |                |                 |                 |
| Bronchitis  |                |                 |                 |
| subjects affected / exposed                       | 0 / 14 (0.00%) | 1 / 22 (4.55%)  | 0 / 10 (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           |
| Meningitis aseptic                                |                |                 |                 |
| subjects affected / exposed                       | 0 / 14 (0.00%) | 0 / 22 (0.00%)  | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all   | 0 / 0          | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all        | 0 / 0          | 0 / 0           | 0 / 0           |
| Respiratory syncytial virus bronchiolitis         |                |                 |                 |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 14 (0.00%) | 1 / 22 (4.55%) | 0 / 10 (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          |
| Urinary tract infection                         |                |                |                |
| subjects affected / exposed                     | 0 / 14 (0.00%) | 2 / 22 (9.09%) | 0 / 10 (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          |
| Viral infection                                 |                |                |                |
| subjects affected / exposed                     | 0 / 14 (0.00%) | 1 / 22 (4.55%) | 0 / 10 (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          |

Frequency threshold for reporting non-serious adverse events: 0 %

| <b>Non-serious adverse events</b>                     | Control         | rLP2086 20 mcg  | rLP2086 60 mcg  |
|---|-----------------|-----------------|-----------------|
| Total subjects affected by non-serious adverse events |                 |                 |                 |
| subjects affected / exposed                           | 3 / 14 (21.43%) | 4 / 22 (18.18%) | 2 / 10 (20.00%) |
| Eye disorders   |                 |                 |                 |
| Conjunctivitis  |                 |                 |                 |
| subjects affected / exposed                           | 1 / 14 (7.14%)  | 0 / 22 (0.00%)  | 0 / 10 (0.00%)  |
| occurrences (all)                                     | 1               | 0               | 0               |
| Gastrointestinal disorders                            |                 |                 |                 |
| Gastroesophageal reflux disease                       |                 |                 |                 |
| subjects affected / exposed                           | 0 / 14 (0.00%)  | 1 / 22 (4.55%)  | 1 / 10 (10.00%) |
| occurrences (all)                                     | 0               | 1               | 1               |
| Respiratory, thoracic and mediastinal disorders       |                 |                 |                 |
| Asthma  |                 |                 |                 |
| subjects affected / exposed                           | 1 / 14 (7.14%)  | 0 / 22 (0.00%)  | 0 / 10 (0.00%)  |
| occurrences (all)                                     | 1               | 0               | 0               |
| Skin and subcutaneous tissue disorders                |                 |                 |                 |
| Dermatitis  |                 |                 |                 |
| subjects affected / exposed                           | 1 / 14 (7.14%)  | 0 / 22 (0.00%)  | 0 / 10 (0.00%)  |
| occurrences (all)                                     | 1               | 0               | 0               |
| Rash  |                 |                 |                 |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 14 (0.00%)<br>0 | 1 / 22 (4.55%)<br>1 | 0 / 10 (0.00%)<br>0 |
| Infections and infestations                      |                     |                     |                     |
| Gastroenteritis                                  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 14 (0.00%)      | 1 / 22 (4.55%)      | 0 / 10 (0.00%)      |
| occurrences (all)                                | 0                   | 1                   | 0                   |
| Nasopharyngitis                                  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 14 (0.00%)      | 0 / 22 (0.00%)      | 1 / 10 (10.00%)     |
| occurrences (all)                                | 0                   | 0                   | 1                   |
| Respiratory tract infection                      |                     |                     |                     |
| subjects affected / exposed                      | 1 / 14 (7.14%)      | 1 / 22 (4.55%)      | 0 / 10 (0.00%)      |
| occurrences (all)                                | 1                   | 1                   | 0                   |
| Respiratory tract infection viral                |                     |                     |                     |
| subjects affected / exposed                      | 1 / 14 (7.14%)      | 0 / 22 (0.00%)      | 0 / 10 (0.00%)      |
| occurrences (all)                                | 1                   | 0                   | 0                   |
| Viral infection                                  |                     |                     |                     |
| subjects affected / exposed                      | 0 / 14 (0.00%)      | 1 / 22 (4.55%)      | 0 / 10 (0.00%)      |
| occurrences (all)                                | 0                   | 1                   | 0                   |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

|   |
|---|
| Immunogenicity results were not reported because the study was terminated due to the reactogenicity profile of the vaccine in infants prior to the first scheduled post-vaccination blood draw and no immunogenicity data were collected. |
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Notes: