



## Clinical trial results:

**A Phase II, randomised, observer-blind, controlled, multi-country study to assess the safety, reactogenicity and immunogenicity of a single intramuscular dose of different formulations of GlaxoSmithKline (GSK) Biologicals' investigational RSV vaccine (GSK3003891A), in healthy women aged 18 to 45 years**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2014-002688-14 |
| Trial protocol           | CZ DE          |
| Global end of trial date | 21 June 2016   |

### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1           |
| This version publication date  | 29 June 2017 |
| First version publication date | 29 June 2017 |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 201510 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT02360475 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

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

Notes:

### Paediatric regulatory details

|                                                                      |    |
|----------------------------------------------------------------------|----|
| Is trial part of an agreed paediatric investigation plan (PIP)       | 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                       | 08 November 2016 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 02 July 2015     |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 21 June 2016     |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the reactogenicity and the safety of a single intramuscular dose of the investigational RSV vaccines, in healthy, non-pregnant women, during the first 30 days after vaccination.

To evaluate the functional antibody titres induced by a single intramuscular dose of the investigational RSV vaccines, in healthy, non-pregnant women, 30 days after vaccination.

Protection of trial subjects:

The body temperature of the subject was determined prior to study vaccination. If a subject had fever on the day of planned vaccination, the vaccination visit was rescheduled. All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications. Subjects were followed for one year following administration of the study vaccine.

Background therapy: -

Evidence for comparator: -

|                                                           |               |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment                          | 20 March 2015 |
| 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 | Czech Republic: 125 |
| Country: Number of subjects enrolled | Germany: 126        |
| Country: Number of subjects enrolled | Australia: 125      |
| Country: Number of subjects enrolled | United States: 131  |
| Worldwide total number of subjects   | 507                 |
| EEA total number of subjects         | 251                 |

Notes:

### Subjects enrolled per age group

|                                           |   |
|-------------------------------------------|---|
| In utero                                  | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days)                      | 0 |
| Infants and toddlers (28 days-23 months)  | 0 |

|                           |     |
|---------------------------|-----|
| Children (2-11 years)     | 0   |
| Adolescents (12-17 years) | 0   |
| Adults (18-64 years)      | 507 |
| From 65 to 84 years       | 0   |
| 85 years and over         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

A total of 507 subjects were screened, but only 500 subjects received vaccination.

### Pre-assignment

Screening details:

NA

### Period 1

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

Blinding implementation details:

Given the different appearance and presentation of the investigational RSV vaccines, and Boostrix, double blinding was not possible and data was collected in an observer-blind manner: during the course of the study, the vaccine recipient and those responsible for the evaluation of any study endpoint were unaware of which vaccine was administered.

### Arms

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

|                  |                                     |
|------------------|-------------------------------------|
| <b>Arm title</b> | GSK3003891A 30 Non-adjuvanted Group |
|------------------|-------------------------------------|

Arm description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of the non-adjuvanted 30 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                                        |                                                |
|----------------------------------------|------------------------------------------------|
| Arm type                               | Experimental                                   |
| Investigational medicinal product name | GSK3003891A non-adjuvanted 30 µg PreF          |
| Investigational medicinal product code |                                                |
| Other name                             |                                                |
| Pharmaceutical forms                   | Powder and solution for solution for injection |
| Routes of administration               | Intramuscular use                              |

Dosage and administration details:

Subjects received a single dose of GSK3003891A non-adjuvanted 30 µg PreF vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                  |                                     |
|------------------|-------------------------------------|
| <b>Arm title</b> | GSK3003891A 60 Non-adjuvanted Group |
|------------------|-------------------------------------|

Arm description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of non-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                                        |                                                |
|----------------------------------------|------------------------------------------------|
| Arm type                               | Experimental                                   |
| Investigational medicinal product name | GSK3003891A 60 PreF Group                      |
| Investigational medicinal product code |                                                |
| Other name                             |                                                |
| Pharmaceutical forms                   | Powder and solution for solution for injection |
| Routes of administration               | Intramuscular use                              |

Dosage and administration details:

Subjects received a single dose of GSK3003891A non-adjuvanted 60 µg PreF vaccine, intramuscularly in the deltoid region of the non-dominant arm, at Day 0.

|                  |                                 |
|------------------|---------------------------------|
| <b>Arm title</b> | GSK3003891A 60 Adjuvanted Group |
|------------------|---------------------------------|

**Arm description:**

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of aluminium-adsorbed 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                                        |                              |
|----------------------------------------|------------------------------|
| Arm type                               | Experimental                 |
| Investigational medicinal product name | GSK3003891A 60 PreF-AI Group |
| Investigational medicinal product code |                              |
| Other name                             |                              |
| Pharmaceutical forms                   | Solution for injection       |
| Routes of administration               | Intramuscular use            |

**Dosage and administration details:**

Subjects received a single dose of RSV GSK3003891A aluminium-adsorbed 60 µg Pref vaccine, intramuscularly in the deltoid region of the non-dominant arm, at Day 0.

|                  |                |
|------------------|----------------|
| <b>Arm title</b> | Boostrix Group |
|------------------|----------------|

**Arm description:**

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of Boostrix™ vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                                        |                          |
|----------------------------------------|--------------------------|
| Arm type                               | Active comparator        |
| Investigational medicinal product name | Boostrix™                |
| Investigational medicinal product code |                          |
| Other name                             | dTpa/Tdap                |
| Pharmaceutical forms                   | Suspension for injection |
| Routes of administration               | Intramuscular use        |

**Dosage and administration details:**

Subjects received a single dose of Boostrix™ vaccine, intramuscularly in the deltoid region of the non-dominant arm, at Day 0.

| <b>Number of subjects in period 1<sup>[1]</sup></b> | GSK3003891A 30 Non-adsorbed Group | GSK3003891A 60 Non-adsorbed Group | GSK3003891A 60 Adjuvanted Group |
|-----------------------------------------------------|-----------------------------------|-----------------------------------|---------------------------------|
| Started                                             | 126                               | 124                               | 125                             |
| Completed                                           | 122                               | 111                               | 117                             |
| Not completed                                       | 4                                 | 13                                | 8                               |
| Consent withdrawn by subject                        | -                                 | 1                                 | 2                               |
| Migrated/moved from study area                      | -                                 | -                                 | -                               |
| Lost to follow-up                                   | 4                                 | 12                                | 6                               |

| <b>Number of subjects in period 1<sup>[1]</sup></b> | Boostrix Group |
|-----------------------------------------------------|----------------|
| Started                                             | 125            |
| Completed                                           | 120            |
| Not completed                                       | 5              |
| Consent withdrawn by subject                        | -              |
| Migrated/moved from study area                      | 1              |
| Lost to follow-up                                   | 4              |

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Notes:

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

Justification: A total of 507 subjects were screened, but only 500 subjects received vaccination.

## Baseline characteristics

### Reporting groups

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | GSK3003891A 30 Non-adjuvanted Group |
|-----------------------|-------------------------------------|

Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of the non-adjuvanted 30 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | GSK3003891A 60 Non-adjuvanted Group |
|-----------------------|-------------------------------------|

Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of non-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | GSK3003891A 60 Adjuvanted Group |
|-----------------------|---------------------------------|

Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of aluminium-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                       |                |
|-----------------------|----------------|
| Reporting group title | Boostrix Group |
|-----------------------|----------------|

Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of Boostrix™ vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

| Reporting group values                                                                                                                                                                                                                                    | GSK3003891A 30 Non-adjuvanted Group | GSK3003891A 60 Non-adjuvanted Group | GSK3003891A 60 Adjuvanted Group |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------|---------------------------------|
| Number of subjects                                                                                                                                                                                                                                        | 126                                 | 124                                 | 125                             |
| Age categorical<br>Units: Subjects                                                                                                                                                                                                                        |                                     |                                     |                                 |
| In utero<br>Preterm newborn infants (gestational age < 37 wks)<br>Newborns (0-27 days)<br>Infants and toddlers (28 days-23 months)<br>Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over |                                     |                                     |                                 |
| Age continuous<br>Units: years                                                                                                                                                                                                                            |                                     |                                     |                                 |
| arithmetic mean                                                                                                                                                                                                                                           | 29.2                                | 29.5                                | 29.1                            |
| standard deviation                                                                                                                                                                                                                                        | ± 7.5                               | ± 8.2                               | ± 7.4                           |
| Gender categorical<br>Units: Subjects                                                                                                                                                                                                                     |                                     |                                     |                                 |
| Female                                                                                                                                                                                                                                                    | 126                                 | 124                                 | 125                             |
| Male                                                                                                                                                                                                                                                      | 0                                   | 0                                   | 0                               |

| Reporting group values | Boostrix Group | Total |  |
|------------------------|----------------|-------|--|
| Number of subjects     | 125            | 500   |  |

|                                                       |       |     |  |
|-------------------------------------------------------|-------|-----|--|
| Age categorical<br>Units: Subjects                    |       |     |  |
| In utero                                              |       | 0   |  |
| Preterm newborn infants<br>(gestational age < 37 wks) |       | 0   |  |
| Newborns (0-27 days)                                  |       | 0   |  |
| Infants and toddlers (28 days-23<br>months)           |       | 0   |  |
| Children (2-11 years)                                 |       | 0   |  |
| Adolescents (12-17 years)                             |       | 0   |  |
| Adults (18-64 years)                                  |       | 0   |  |
| From 65-84 years                                      |       | 0   |  |
| 85 years and over                                     |       | 0   |  |
| Age continuous<br>Units: years                        |       |     |  |
| arithmetic mean                                       | 29.2  |     |  |
| standard deviation                                    | ± 7.9 | -   |  |
| Gender categorical<br>Units: Subjects                 |       |     |  |
| Female                                                | 125   | 500 |  |
| Male                                                  | 0     | 0   |  |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                                  |                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                            | GSK3003891A 30 Non-adjuvanted Group |
| Reporting group description:<br>Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of the non-adjuvanted 30 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.   |                                     |
| Reporting group title                                                                                                                                                                                                                                                                                            | GSK3003891A 60 Non-adjuvanted Group |
| Reporting group description:<br>Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of non-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.       |                                     |
| Reporting group title                                                                                                                                                                                                                                                                                            | GSK3003891A 60 Adjuvanted Group     |
| Reporting group description:<br>Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of aluminium-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0. |                                     |
| Reporting group title                                                                                                                                                                                                                                                                                            | Boostrix Group                      |
| Reporting group description:<br>Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of Boostrix™ vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.                                              |                                     |

### Primary: Number of subjects with solicited local symptoms

|                                                                                                                                                                                                                                                                                                                                                  |                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                  | Number of subjects with solicited local symptoms <sup>[1]</sup> |
| End point description:<br>Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = Significant pain at rest, pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling with a maximum diameter greater than 100 millimeters (mm). |                                                                 |
| End point type                                                                                                                                                                                                                                                                                                                                   | Primary                                                         |
| End point timeframe:<br>During the 7-day (Days 0-6) post-vaccination period                                                                                                                                                                                                                                                                      |                                                                 |
| Notes:<br>[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.<br>Justification: The scope of this primary end point was descriptive, no statistical hypothesis test was performed.                                               |                                                                 |

| End point values            | GSK3003891A 30 Non-adjuvanted Group | GSK3003891A 60 Non-adjuvanted Group | GSK3003891A 60 Adjuvanted Group | Boostrix Group  |
|-----------------------------|-------------------------------------|-------------------------------------|---------------------------------|-----------------|
| Subject group type          | Reporting group                     | Reporting group                     | Reporting group                 | Reporting group |
| Number of subjects analysed | 124                                 | 119                                 | 124                             | 124             |
| Units: Subjects             |                                     |                                     |                                 |                 |
| Any Pain                    | 62                                  | 68                                  | 104                             | 104             |
| Grade 3 Pain                | 1                                   | 2                                   | 9                               | 3               |
| Any Redness                 | 6                                   | 3                                   | 8                               | 6               |
| Grade 3 Redness             | 0                                   | 0                                   | 0                               | 0               |
| Any Swelling                | 7                                   | 6                                   | 12                              | 5               |
| Grade 3 Swelling            | 0                                   | 0                                   | 0                               | 0               |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with solicited general symptoms

|                 |                                                                   |
|-----------------|-------------------------------------------------------------------|
| End point title | Number of subjects with solicited general symptoms <sup>[2]</sup> |
|-----------------|-------------------------------------------------------------------|

End point description:

Assessed solicited general symptoms (symp.) were headache, fever [defined as oral temperature (temp.) equal to or above 37.5 degrees Celsius (°C)], fatigue, gastrointestinal (Gastro.) symptoms [nausea, vomiting, diarrhoea and/or abdominal pain]. Any = occurrence of the symptom regardless of intensity grade and relationship. Grade 3 (G3) symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.5 °C. Related = symptom assessed by the investigator as related to the vaccination.

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

End point timeframe:

During the 7-day (Days 0-6) post-vaccination period

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: The scope of this primary end point was descriptive, no statistical hypothesis test was performed.

| End point values            | GSK3003891A<br>30 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Adjuvanted<br>Group | Boostrix Group  |
|-----------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------|-----------------|
| Subject group type          | Reporting group                               | Reporting group                               | Reporting group                       | Reporting group |
| Number of subjects analysed | 124                                           | 119                                           | 124                                   | 124             |
| Units: Subjects             |                                               |                                               |                                       |                 |
| Any Fatigue                 | 53                                            | 50                                            | 56                                    | 45              |
| G3 Fatigue                  | 8                                             | 1                                             | 4                                     | 2               |
| Related Fatigue             | 44                                            | 41                                            | 50                                    | 39              |
| Any Gastro. symp.           | 16                                            | 19                                            | 23                                    | 20              |
| G3 Gastro. symp.            | 1                                             | 2                                             | 1                                     | 0               |
| Related Gastro. symp.       | 9                                             | 14                                            | 21                                    | 17              |
| Any Headache                | 47                                            | 44                                            | 53                                    | 39              |
| G3 Headache                 | 3                                             | 2                                             | 5                                     | 3               |
| Related Headache            | 37                                            | 33                                            | 39                                    | 33              |
| Any Temp.                   | 7                                             | 9                                             | 12                                    | 7               |
| G3 Temp.                    | 0                                             | 0                                             | 0                                     | 0               |
| Related Temp.               | 5                                             | 8                                             | 11                                    | 6               |

## Statistical analyses

No statistical analyses for this end point

**Primary: Number of subjects with unsolicited adverse events (AEs)**

|                 |                                                                         |
|-----------------|-------------------------------------------------------------------------|
| End point title | Number of subjects with unsolicited adverse events (AEs) <sup>[3]</sup> |
|-----------------|-------------------------------------------------------------------------|

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. "Any" was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

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

End point timeframe:

During the 30-Day (Days 0-29) post-vaccination period

Notes:

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

Justification: The scope of this primary end point was descriptive, no statistical hypothesis test was performed.

| End point values            | GSK3003891A<br>30 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Adjuvanted<br>Group | Boostrix Group  |
|-----------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------|-----------------|
| Subject group type          | Reporting group                               | Reporting group                               | Reporting group                       | Reporting group |
| Number of subjects analysed | 126                                           | 124                                           | 125                                   | 125             |
| Units: Subjects             |                                               |                                               |                                       |                 |
| Any AE(s)                   | 35                                            | 38                                            | 34                                    | 37              |

**Statistical analyses**

No statistical analyses for this end point

**Primary: Number of subjects with serious adverse events (SAEs)**

|                 |                                                                      |
|-----------------|----------------------------------------------------------------------|
| End point title | Number of subjects with serious adverse events (SAEs) <sup>[4]</sup> |
|-----------------|----------------------------------------------------------------------|

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

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

End point timeframe:

From vaccination at Day 0, up to Day 30 post-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: The scope of this primary end point was descriptive, no statistical hypothesis test was performed.

| End point values            | GSK3003891A<br>30 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Adjuvanted<br>Group | Boostrix Group  |
|-----------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------|-----------------|
| Subject group type          | Reporting group                               | Reporting group                               | Reporting group                       | Reporting group |
| Number of subjects analysed | 126                                           | 124                                           | 125                                   | 125             |
| Units: Subjects             |                                               |                                               |                                       |                 |
| Any SAE(s)                  | 1                                             | 1                                             | 0                                     | 0               |

## Statistical analyses

No statistical analyses for this end point

### Primary: Titres of RSV-A neutralizing antibodies

|                 |                                                        |
|-----------------|--------------------------------------------------------|
| End point title | Titres of RSV-A neutralizing antibodies <sup>[5]</sup> |
|-----------------|--------------------------------------------------------|

End point description:

RSV-A neutralizing antibody titres, expressed as Geometric Mean Titres (GMTs). Seropositive subjects were defined as subjects whose antibody titre was greater than or equal to ( $\geq$ ) the cut-off 8 serum dilution that induced 60 % inhibition in plaque forming units (ED60).

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

End point timeframe:

At Day 0 pre-vaccination

Notes:

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

Justification: The scope of this primary end point was descriptive, no statistical hypothesis test was performed.

| End point values                            | GSK3003891A<br>30 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Adjuvanted<br>Group | Boostrix Group            |
|---------------------------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------|---------------------------|
| Subject group type                          | Reporting group                               | Reporting group                               | Reporting group                       | Reporting group           |
| Number of subjects analysed                 | 117                                           | 117                                           | 118                                   | 118                       |
| Units: Titers                               |                                               |                                               |                                       |                           |
| geometric mean (confidence interval<br>95%) |                                               |                                               |                                       |                           |
| anti-RSV A neutralizing antibodies          | 397.1 (330.7<br>to 476.7)                     | 326.3 (277.1<br>to 384.4)                     | 444.2 (370.4<br>to 532.6)             | 423.7 (360.2<br>to 498.4) |

## Statistical analyses

No statistical analyses for this end point

### Primary: Titres of RSV-A neutralizing antibodies

|                 |                                                        |
|-----------------|--------------------------------------------------------|
| End point title | Titres of RSV-A neutralizing antibodies <sup>[6]</sup> |
|-----------------|--------------------------------------------------------|

End point description:

RSV-A neutralizing antibody titres, expressed as Geometric Mean Titres (GMTs). Seropositive subjects were defined as subjects whose antibody titre was greater than or equal to ( $\geq$ ) the cut-off 8 serum dilution that induced 60 % inhibition in plaque forming units (ED60).

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

End point timeframe:

At Day 30 post-vaccination

Notes:

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

Justification: The scope of this primary end point was descriptive, no statistical hypothesis test was performed.

| End point values                         | GSK3003891A<br>30 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Adjuvanted<br>Group | Boostrix Group         |
|------------------------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------|------------------------|
| Subject group type                       | Reporting group                               | Reporting group                               | Reporting group                       | Reporting group        |
| Number of subjects analysed              | 117                                           | 117                                           | 118                                   | 118                    |
| Units: Titers                            |                                               |                                               |                                       |                        |
| geometric mean (confidence interval 95%) |                                               |                                               |                                       |                        |
| anti-RSV A neutralizing antibodies       | 1237 (1094.8 to 1397.6)                       | 1278.7 (1141.6 to 1432.2)                     | 1442.5 (1287.4 to 1616.2)             | 387.1 (328.4 to 456.3) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Titres of RSV-A neutralizing antibodies

|                        |                                                                                                                                                                                                              |
|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title        | Titres of RSV-A neutralizing antibodies                                                                                                                                                                      |
| End point description: | RSV-A neutralizing antibody titres, expressed as Geometric Mean Titres (GMTs), were greater than or equal to ( $\geq$ ) the cut-off 8 serum dilution inducing 60% inhibition in plaque forming units (ED60). |
| End point type         | Secondary                                                                                                                                                                                                    |
| End point timeframe:   | At Day 60 (D60) and 90 (D90) post-vaccination                                                                                                                                                                |

| End point values                         | GSK3003891A<br>30 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Adjuvanted<br>Group | Boostrix Group         |
|------------------------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------|------------------------|
| Subject group type                       | Reporting group                               | Reporting group                               | Reporting group                       | Reporting group        |
| Number of subjects analysed              | 112                                           | 111                                           | 110                                   | 111                    |
| Units: Titers                            |                                               |                                               |                                       |                        |
| geometric mean (confidence interval 95%) |                                               |                                               |                                       |                        |
| anti-RSV A, D60 [N=109;111;108;111]      | 947.2 (832.9 to 1077.1)                       | 882.9 (781.9 to 996.9)                        | 1055.7 (926.1 to 1203.4)              | 358.8 (297.8 to 432.3) |
| anti-RSV A, D90 [N=112;111;110;111]      | 837.7 (738.9 to 949.7)                        | 774.5 (682.6 to 878.7)                        | 897.5 (782.8 to 1029.2)               | 358.3 (291.9 to 439.9) |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Concentrations of Palivizumab competing antibodies (PCA)

|                 |                                                          |
|-----------------|----------------------------------------------------------|
| End point title | Concentrations of Palivizumab competing antibodies (PCA) |
|-----------------|----------------------------------------------------------|

End point description:

Palivizumab competing antibody concentrations, expressed as Geometric Mean Concentrations (GMCs), were greater than or equal to 3.34 micrograms per millilitre (µg/mL).

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

End point timeframe:

At Day 0 (D0) pre-vaccination, Day 30 (D30), Day 60 (D60) and Day 90 (D90) post-vaccination

| End point values                            | GSK3003891A<br>30 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Adjuvanted<br>Group | Boostrix Group   |
|---------------------------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------|------------------|
| Subject group type                          | Reporting group                               | Reporting group                               | Reporting group                       | Reporting group  |
| Number of subjects analysed                 | 115                                           | 111                                           | 116                                   | 111              |
| Units: µg/mL                                |                                               |                                               |                                       |                  |
| geometric mean (confidence interval<br>95%) |                                               |                                               |                                       |                  |
| anti-PCA, D0 [N=110;107;105;110]            | 5.4 (4.7 to 6.3)                              | 5.2 (4.4 to 6)                                | 4.6 (4 to 5.4)                        | 5.7 (4.8 to 6.7) |
| anti-PCA, D30 [N=115;116;116;109]           | 79.9 (72.1 to<br>88.6)                        | 88.6 (79.9 to<br>98.2)                        | 97.2 (89.1 to<br>105.9)               | 6.1 (5.3 to 7.1) |
| anti-PCA,D60 [N=109;111;108;111]            | 65.9 (57.8 to<br>75.1)                        | 68.4 (61.5 to<br>75.9)                        | 74.1 (66.6 to<br>82.3)                | 5.8 (5 to 6.7)   |
| anti-PCA, D90 [N=112;111;110;109]           | 60.4 (54 to<br>67.6)                          | 62.5 (56.7 to<br>68.9)                        | 66.1 (59.9 to<br>73)                  | 7.5 (6.6 to 8.6) |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with SAEs

|                 |                              |
|-----------------|------------------------------|
| End point title | Number of subjects with SAEs |
|-----------------|------------------------------|

End point description:

SAEs assessed include medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

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

End point timeframe:

Up to study end at Day 360

| <b>End point values</b>     | GSK3003891A<br>30 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Non-<br>adjuvanted<br>Group | GSK3003891A<br>60 Adjuvanted<br>Group | Boostrix Group  |
|-----------------------------|-----------------------------------------------|-----------------------------------------------|---------------------------------------|-----------------|
| Subject group type          | Reporting group                               | Reporting group                               | Reporting group                       | Reporting group |
| Number of subjects analysed | 126                                           | 124                                           | 125                                   | 125             |
| Units: Subjects             |                                               |                                               |                                       |                 |
| Any SAE(s)                  | 3                                             | 3                                             | 6                                     | 2               |

### Statistical analyses

---

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited and Unsolicited AEs: within the 30-day (Days 0-29) post-vaccination period; SAEs: from Day 0 up to study end at Day 360.

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

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 19.0   |

### Reporting groups

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | GSK3003891A 30 Non-adjuvanted Group |
|-----------------------|-------------------------------------|

Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of the non-adjuvanted 30 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | GSK3003891A 60 Non-adjuvanted Group |
|-----------------------|-------------------------------------|

Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of non-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | GSK3003891A 60 Adjuvanted Group |
|-----------------------|---------------------------------|

Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of aluminium-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

|                       |                |
|-----------------------|----------------|
| Reporting group title | Boostrix Group |
|-----------------------|----------------|

Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of Boostrix™ vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

| Serious adverse events                            | GSK3003891A 30 Non-adjuvanted Group | GSK3003891A 60 Non-adjuvanted Group | GSK3003891A 60 Adjuvanted Group |
|---------------------------------------------------|-------------------------------------|-------------------------------------|---------------------------------|
| Total subjects affected by serious adverse events |                                     |                                     |                                 |
| subjects affected / exposed                       | 3 / 126 (2.38%)                     | 3 / 124 (2.42%)                     | 6 / 125 (4.80%)                 |
| number of deaths (all causes)                     | 0                                   | 0                                   | 0                               |
| number of deaths resulting from adverse events    |                                     |                                     |                                 |
| Injury, poisoning and procedural complications    |                                     |                                     |                                 |
| Multiple injuries                                 |                                     |                                     |                                 |
| subjects affected / exposed                       | 0 / 126 (0.00%)                     | 0 / 124 (0.00%)                     | 0 / 125 (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                           |
| Musculoskeletal injury                            |                                     |                                     |                                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 126 (0.00%) | 1 / 124 (0.81%) | 0 / 125 (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           |
| Fibula fracture                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 0 / 124 (0.00%) | 1 / 125 (0.80%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Incisional hernia                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 0 / 124 (0.00%) | 1 / 125 (0.80%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Tibia fracture                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 0 / 124 (0.00%) | 1 / 125 (0.80%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Nervous system disorders                        |                 |                 |                 |
| Transient ischaemic attack                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 1 / 124 (0.81%) | 0 / 125 (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           |
| Pregnancy, puerperium and perinatal conditions  |                 |                 |                 |
| Abortion spontaneous                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 1 / 124 (0.81%) | 1 / 125 (0.80%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrointestinal disorders                      |                 |                 |                 |
| Colitis                                         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 0 / 124 (0.00%) | 1 / 125 (0.80%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Umbilical hernia                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 0 / 124 (0.00%) | 1 / 125 (0.80%) |
| 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, thoracic and mediastinal disorders |                 |                 |                 |
| Asthma                                          |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 0 / 124 (0.00%) | 1 / 125 (0.80%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Obliterative bronchiolitis                      |                 |                 |                 |
| subjects affected / exposed                     | 1 / 126 (0.79%) | 0 / 124 (0.00%) | 0 / 125 (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           |
| Psychiatric disorders                           |                 |                 |                 |
| Suicide attempt                                 |                 |                 |                 |
| subjects affected / exposed                     | 1 / 126 (0.79%) | 0 / 124 (0.00%) | 0 / 125 (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           |
| Musculoskeletal and connective tissue disorders |                 |                 |                 |
| Jaw cyst                                        |                 |                 |                 |
| subjects affected / exposed                     | 1 / 126 (0.79%) | 0 / 124 (0.00%) | 0 / 125 (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                     |                 |                 |                 |
| Pneumonia bacterial                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 0 / 124 (0.00%) | 0 / 125 (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           |
| Erysipelas                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 126 (0.00%) | 0 / 124 (0.00%) | 1 / 125 (0.80%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|                                                   |                 |  |  |
|---------------------------------------------------|-----------------|--|--|
| <b>Serious adverse events</b>                     | Boostrix Group  |  |  |
| Total subjects affected by serious adverse events |                 |  |  |
| subjects affected / exposed                       | 2 / 125 (1.60%) |  |  |
| number of deaths (all causes)                     | 0               |  |  |
| number of deaths resulting from adverse events    |                 |  |  |

|                                                 |                 |  |  |
|-------------------------------------------------|-----------------|--|--|
| Injury, poisoning and procedural complications  |                 |  |  |
| Multiple injuries                               |                 |  |  |
| subjects affected / exposed                     | 1 / 125 (0.80%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Musculoskeletal injury                          |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Fibula fracture                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Incisional hernia                               |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Tibia fracture                                  |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Nervous system disorders                        |                 |  |  |
| Transient ischaemic attack                      |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pregnancy, puerperium and perinatal conditions  |                 |  |  |
| Abortion spontaneous                            |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastrointestinal disorders                      |                 |  |  |
| Colitis                                         |                 |  |  |

|                                                 |                 |  |  |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Umbilical hernia                                |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Respiratory, thoracic and mediastinal disorders |                 |  |  |
| Asthma                                          |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Obliterative bronchiolitis                      |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Psychiatric disorders                           |                 |  |  |
| Suicide attempt                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Musculoskeletal and connective tissue disorders |                 |  |  |
| Jaw cyst                                        |                 |  |  |
| subjects affected / exposed                     | 0 / 125 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Infections and infestations                     |                 |  |  |
| Pneumonia bacterial                             |                 |  |  |
| subjects affected / exposed                     | 1 / 125 (0.80%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Erysipelas                                      |                 |  |  |

|                                                 |                 |  |  |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed                     | 0 / 125 (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>                     | GSK3003891A 30<br>Non-adjuvanted<br>Group | GSK3003891A 60<br>Non-adjuvanted<br>Group | GSK3003891A 60<br>Adjuvanted Group |
|-------------------------------------------------------|-------------------------------------------|-------------------------------------------|------------------------------------|
| Total subjects affected by non-serious adverse events |                                           |                                           |                                    |
| subjects affected / exposed                           | 93 / 126 (73.81%)                         | 88 / 124 (70.97%)                         | 112 / 125 (89.60%)                 |
| Nervous system disorders                              |                                           |                                           |                                    |
| Headache                                              |                                           |                                           |                                    |
| subjects affected / exposed                           | 49 / 126 (38.89%)                         | 45 / 124 (36.29%)                         | 56 / 125 (44.80%)                  |
| occurrences (all)                                     | 49                                        | 45                                        | 56                                 |
| General disorders and administration site conditions  |                                           |                                           |                                    |
| Fatigue                                               |                                           |                                           |                                    |
| subjects affected / exposed                           | 53 / 126 (42.06%)                         | 50 / 124 (40.32%)                         | 56 / 125 (44.80%)                  |
| occurrences (all)                                     | 53                                        | 50                                        | 56                                 |
| Pain                                                  |                                           |                                           |                                    |
| subjects affected / exposed                           | 62 / 126 (49.21%)                         | 68 / 124 (54.84%)                         | 104 / 125 (83.20%)                 |
| occurrences (all)                                     | 62                                        | 68                                        | 104                                |
| Pyrexia                                               |                                           |                                           |                                    |
| subjects affected / exposed                           | 7 / 126 (5.56%)                           | 10 / 124 (8.06%)                          | 12 / 125 (9.60%)                   |
| occurrences (all)                                     | 7                                         | 10                                        | 12                                 |
| Swelling                                              |                                           |                                           |                                    |
| subjects affected / exposed                           | 7 / 126 (5.56%)                           | 6 / 124 (4.84%)                           | 12 / 125 (9.60%)                   |
| occurrences (all)                                     | 7                                         | 6                                         | 12                                 |
| Gastrointestinal disorders                            |                                           |                                           |                                    |
| Gastrointestinal disorder                             |                                           |                                           |                                    |
| subjects affected / exposed                           | 16 / 126 (12.70%)                         | 19 / 124 (15.32%)                         | 23 / 125 (18.40%)                  |
| occurrences (all)                                     | 16                                        | 19                                        | 23                                 |
| Skin and subcutaneous tissue disorders                |                                           |                                           |                                    |
| Erythema                                              |                                           |                                           |                                    |
| subjects affected / exposed                           | 6 / 126 (4.76%)                           | 3 / 124 (2.42%)                           | 8 / 125 (6.40%)                    |
| occurrences (all)                                     | 6                                         | 3                                         | 8                                  |
| Infections and infestations                           |                                           |                                           |                                    |

|                                                                                       |                      |                      |                      |
|---------------------------------------------------------------------------------------|----------------------|----------------------|----------------------|
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 2 / 126 (1.59%)<br>2 | 7 / 124 (5.65%)<br>7 | 3 / 125 (2.40%)<br>3 |
|---------------------------------------------------------------------------------------|----------------------|----------------------|----------------------|

|                                                                                                                                                                                                                                                                                                                            |                                                                                                                  |  |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--|--|
| <b>Non-serious adverse events</b>                                                                                                                                                                                                                                                                                          | Boostrix Group                                                                                                   |  |  |
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed                                                                                                                                                                                                                                       | 109 / 125 (87.20%)                                                                                               |  |  |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                   | 41 / 125 (32.80%)<br>41                                                                                          |  |  |
| General disorders and administration site conditions<br>Fatigue<br>subjects affected / exposed<br>occurrences (all)<br><br>Pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Pyrexia<br>subjects affected / exposed<br>occurrences (all)<br><br>Swelling<br>subjects affected / exposed<br>occurrences (all) | 45 / 125 (36.00%)<br>45<br><br>104 / 125 (83.20%)<br>104<br><br>8 / 125 (6.40%)<br>8<br><br>5 / 125 (4.00%)<br>5 |  |  |
| Gastrointestinal disorders<br>Gastrointestinal disorder<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                | 20 / 125 (16.00%)<br>20                                                                                          |  |  |
| Skin and subcutaneous tissue disorders<br>Erythema<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                     | 6 / 125 (4.80%)<br>6                                                                                             |  |  |
| Infections and infestations<br>Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                       | 6 / 125 (4.80%)<br>6                                                                                             |  |  |



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 20 February 2015 | <p>Following US Food and Drug Administration (FDA) feedback on the RSV F-020 (201510) protocol, the following changes were implemented:</p> <p>Addition of a one-year safety phone call to collect information about any serious adverse events (SAEs) and pregnancies that may have occurred between Visit 4 (Day 90) and the Phone contact (Day 360).</p> <p>Section 8.1.4 has been updated to clarify that clinical safety laboratory testing is not required per protocol unless the investigator believes it is warranted. Any abnormal laboratory findings (e.g. clinical chemistry, haematology, urinalysis) or other abnormal assessments that are judged by the investigator to be clinically significant will be recorded as AE or SAE if they meet the definition of an AE or SAE.</p> <p>In addition, the list of contributing authors was updated.</p> |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported