



## Clinical trial results:

### A Randomized, Double-blind, Placebo-controlled Phase 1/2a Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26COVS1 in Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2020-001483-28   |
| Trial protocol           | BE               |
| Global end of trial date | 21 February 2023 |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 08 March 2024 |
| First version publication date | 08 March 2024 |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | CR108828 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04436276 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Janssen Vaccines & Prevention B.V.   |
| Sponsor organisation address | Archimedesweg 4-6, Leiden, Netherlands, 2333 CN  |
| Public contact               | Clinical Registry Group, Janssen Vaccines & Prevention B.V.,<br>ClinicalTrialsEU@its.jnj.com |
| Scientific contact           | Clinical Registry Group, Janssen Vaccines & Prevention B.V.,<br>ClinicalTrialsEU@its.jnj.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                       | 21 February 2023 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 21 February 2023 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

Main objective of the study was to assess the safety and reactogenicity of adenovirus type 26 coronavirus-2 virus spike (Ad26.COV2.S) at 2 dose levels,  $5 \times 10^{10}$  virus particles (vp) and  $1 \times 10^{11}$  vp, administered intramuscularly (IM) as a single-dose or 2-dose schedule in healthy adults aged greater than or equal to ( $\geq$ ) 18 to less than or equal to ( $\leq$ ) 55 years and in adults aged  $\geq 65$  years in good health with or without stable underlying conditions.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice (GCP) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

|   |              |
|---|--------------|
| Actual start date of recruitment                          | 16 July 2020 |
| Long term follow-up planned                               | No           |
| Independent data monitoring committee (IDMC) involvement? | No           |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Belgium: 466       |
| Country: Number of subjects enrolled | United States: 610 |
| Worldwide total number of subjects   | 1076               |
| EEA total number of subjects         | 466                |

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)                      | 673 |
| From 65 to 84 years                       | 401 |

|                   |   |
|-------------------|---|
| 85 years and over | 2 |
|-------------------|---|

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 1085 subjects were enrolled in the study, out of which 1076 subjects received treatment. Remaining 9 subjects did not receive any treatment and are excluded from the analyses.

### Period 1

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

### Arms

|                              |  |
|------------------------------|--|
| Are arms mutually exclusive? | Yes  |
| <b>Arm title</b>             | COHORT 1A: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |

Arm description:

Healthy adult subjects aged greater than or equal to ( $\geq$ ) 18 to less than or equal to ( $\leq$ ) 55 received a single intramuscular (IM) injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster vaccination (AHBV) of Ad26.COV2.S at the dose of  $5 \times 10^{10}$   $\geq$  6 months after Vaccination 2.

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental                      |
| Investigational medicinal product name | Ad26.COV2.S $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and an ad hoc booster dose at  $\geq$  6 months after Vaccination 2.

|                  |   |
|------------------|---|
| <b>Arm title</b> | COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10) |
|------------------|---|

Arm description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and matching placebo (PL) on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq$  6 months after Vaccination 2.

|  |                   |
|--|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | Placebo           |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received a single IM injection of placebo matching to Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 57 (Vaccination 2).

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Ad26.COV2.S $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |

|                          |                   |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 and  $\geq 6$  months after Vaccination 2.

|                  |  |
|------------------|--|
| <b>Arm title</b> | COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|------------------|--|

Arm description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq 6$  months after Vaccination 2.

|  |                                    |
|--|------------------------------------|
| Arm type                               | Experimental                       |
| Investigational medicinal product name | Ad26.COV2.S. $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                    |
| Other name                             |                                    |
| Pharmaceutical forms                   | Injection                          |
| Routes of administration               | Intramuscular use                  |

Dosage and administration details:

Subjects received a single ad hoc booster dose of Ad26.COV2.S.  $5 \times 10^{10}$  vp,  $\geq 6$  months after Vaccination 2.

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Ad26.COV2.S $1 \times 10^{11}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2).

|                  |   |
|------------------|---|
| <b>Arm title</b> | COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 5e10) |
|------------------|---|

Arm description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq 6$  months after Vaccination 2.

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental                      |
| Investigational medicinal product name | Ad26.COV2.S $1 \times 10^{11}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1).

|  |                                    |
|--|------------------------------------|
| Investigational medicinal product name | Ad26.COV2.S. $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                    |
| Other name                             |                                    |
| Pharmaceutical forms                   | Injection                          |
| Routes of administration               | Intramuscular use                  |

Dosage and administration details:

Subjects received a single IM injection of ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after Vaccination 2.

|  |         |
|--|---------|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code |         |
| Other name                             |         |

|   |  |
|---|--|
| Pharmaceutical forms  | Injection  |
| Routes of administration  | Intramuscular use                                |
| Dosage and administration details:  |  |
| Subjects received a single IM injection of placebo matching to Ad26.COV2.S $1 \times 10^{11}$ vp on Day 57 (Vaccination 2).   |  |
| <b>Arm title</b>  | COHORT 1A: Placebo, Placebo                      |
| Arm description:  |  |
| Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of $5 \times 10^{10}$ vp Ad26.COV2.S.   |  |
| Arm type  | Experimental                                     |
| Investigational medicinal product name  | Ad26.COV2.S. $5 \times 10^{10}$ vp               |
| Investigational medicinal product code  |  |
| Other name  |  |
| Pharmaceutical forms  | Injection  |
| Routes of administration  | Intramuscular use                                |
| Dosage and administration details:  |  |
| As per protocol amendment 10, after unblinding, enrolled subjects who had initially received only placebo were offered a single dose of $5 \times 10^{10}$ vp Ad26.COV2.S.  |  |
| Investigational medicinal product name  | Placebo  |
| Investigational medicinal product code  |  |
| Other name  |  |
| Pharmaceutical forms  | Injection  |
| Routes of administration  | Intramuscular use                                |
| Dosage and administration details:  |  |
| Subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2).   |  |
| <b>Arm title</b>  | COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
| Arm description:  |  |
| Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $5 \times 10^{10}$ vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of $5 \times 10^{10}$ vp $\geq 6$ months after Vaccination 2.                       |  |
| Arm type  | Experimental                                     |
| Investigational medicinal product name  | Ad26.COV2.S $5 \times 10^{10}$ vp                |
| Investigational medicinal product code  |  |
| Other name  |  |
| Pharmaceutical forms  | Injection  |
| Routes of administration  | Intramuscular use                                |
| Dosage and administration details:  |  |
| Subjects received a single IM injection of Ad26.COV2.S $5 \times 10^{10}$ vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and $\geq 6$ months after Vaccination 2.   |  |
| <b>Arm title</b>  | COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)       |
| Arm description:  |  |
| Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $5 \times 10^{10}$ vp on Day 1 (Vaccination 1) and a matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of $5 \times 10^{10}$ vp $\geq 6$ months after Vaccination 2. |  |
| Arm type  | Experimental                                     |

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

Dosage and administration details:

Subjects received a single IM injection of placebo matching to Ad26.COV2.S 5\*10<sup>10</sup> vp on Day 57 (Vaccination 2).

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Ad26.COV2.S 5*10 <sup>10</sup> vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received a single IM injection of Ad26.COV2.S 5\*10<sup>10</sup> vp on Day 1 and ≥6 months after Vaccination 2.

|                  |  |
|------------------|--|
| <b>Arm title</b> | COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|------------------|--|

Arm description:

Healthy adult subjects aged ≥18 to ≤55 received a single IM injection of Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of 5\*10<sup>10</sup> vp ≥6 months after Vaccination 2.

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental                      |
| Investigational medicinal product name | Ad26.COV2.S 5*10 <sup>10</sup> vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received a single IM injection of Ad26.COV2.S 5\*10<sup>10</sup> vp at ≥ 6 months after Vaccination 2.

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Ad26.COV2.S 1*10 <sup>11</sup> vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received a single IM injection of Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2).

|                  |   |
|------------------|---|
| <b>Arm title</b> | COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 5e10) |
|------------------|---|

Arm description:

Healthy adult subjects aged ≥18 to ≤55 received a single IM injection of Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of 5\*10<sup>10</sup> vp ≥6 months after Vaccination 2.

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental                      |
| Investigational medicinal product name | Ad26.COV2.S 1*10 <sup>11</sup> vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

Dosage and administration details:

Subjects received a single IM injection of Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 1 (Vaccination 1).

|  |                                    |
|--|------------------------------------|
| Investigational medicinal product name | Ad26.COV2.S. 5*10 <sup>10</sup> vp |
| Investigational medicinal product code |                                    |
| Other name                             |                                    |
| Pharmaceutical forms                   | Injection                          |
| Routes of administration               | Intramuscular use                  |

Dosage and administration details:

Subjects received a single IM injection of 5\*10<sup>10</sup> vp Ad26.COV2.S. ≥ 6 months after Vaccination 2.

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

Dosage and administration details:

Subjects received a single IM injection of placebo matching to Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 57 (Vaccination 2).

|                  |                             |
|------------------|-----------------------------|
| <b>Arm title</b> | COHORT 1B: Placebo, Placebo |
|------------------|-----------------------------|

Arm description:

Healthy adult subjects aged ≥18 to ≤55 received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of 5\*10<sup>10</sup> vp Ad26.COV2.S.

|  |                                    |
|--|------------------------------------|
| Arm type                               | Experimental                       |
| Investigational medicinal product name | Ad26.COV2.S. 5*10 <sup>10</sup> vp |
| Investigational medicinal product code |                                    |
| Other name                             |                                    |
| Pharmaceutical forms                   | Injection                          |
| Routes of administration               | Intramuscular use                  |

Dosage and administration details:

As per protocol amendment 10, after unblinding, enrolled subjects who had initially received only placebo were offered a single dose of 5\*10<sup>10</sup> vp Ad26.COV2.S.

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

Dosage and administration details:

Subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2).

|                  |   |
|------------------|---|
| <b>Arm title</b> | COHORT 2A: Ad26 5e10, B: PL(PL/AHBV: Ad26 5e10) |
|------------------|---|

Arm description:

Group 1 and Group 4 healthy adult subjects aged ≥18 to ≤55 received a single IM injection of Ad26.COV2.S 5\*10<sup>10</sup> vp on Day 1 (Vaccination 1) followed by matching placebo at 6 and 12 months as matching Booster (B) 1 and Booster 2 vaccination. As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S. 5\*10<sup>10</sup> vp ≥6 months after Booster 2 Vaccination.

|  |                   |
|--|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | Placebo           |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Subjects received a single IM injection of placebo matching to Ad26.COV2.S 5\*10<sup>10</sup> vp at 6 and 12 months as matching Booster 1 and Booster 2 vaccination.



|  |  |
|--|--|
| Investigational medicinal product name   | Ad26.COV2.S 5*10 <sup>10</sup> vp      |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                              |
| Routes of administration   | Intramuscular use                      |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of Ad26.COV2.S 5*10 <sup>10</sup> vp on Day 1 (Vaccination 1) and ≥6 months after Booster 2 Vaccination.   |  |
| <b>Arm title</b>   | COHORT 2A: Ad26 5e10, B: Ad26 5e10, PL |
| Arm description:   |  |
| Group 2 healthy adult subjects aged ≥18 to ≤55 received a single IM injection of Ad26.COV2.S 5*10 <sup>10</sup> vp on Day 1 (Vaccination 1) followed by first booster vaccination with single IM injection of Ad26.COV2.S 5*10 <sup>10</sup> vp booster 1 at 6 months and a matching placebo at 12 months to match second Booster vaccination. |  |
| Arm type   | Experimental                           |
| Investigational medicinal product name   | Placebo                                |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                              |
| Routes of administration   | Intramuscular use                      |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of placebo matching to Ad26.COV2.S 5*10 <sup>10</sup> vp at 12 months (Booster 2).   |  |
| Investigational medicinal product name   | Ad26.COV2.S 5*10 <sup>10</sup> vp      |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                              |
| Routes of administration   | Intramuscular use                      |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of Ad26.COV2.S 5*10 <sup>10</sup> vp on Day 1 (Vaccination 1) at 6 months (Booster 1).   |  |
| <b>Arm title</b>   | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 |
| Arm description:   |  |
| Group 3 healthy adult subjects aged ≥18 to ≤55 received a single IM injection of Ad26.COV2.S 5*10 <sup>10</sup> vp on Day 1 (Vaccination 1) followed by a matching placebo booster 1 injection after 6 months and Ad26.COV2.S 5*10 <sup>10</sup> vp after 12 months as Booster 2.  |  |
| Arm type   | Experimental                           |
| Investigational medicinal product name   | Placebo                                |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                              |
| Routes of administration   | Intramuscular use                      |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of placebo matching to Ad26.COV2.S 5*10 <sup>10</sup> vp at 6 months (Booster 1).  |  |
| Investigational medicinal product name   | Ad26.COV2.S 5*10 <sup>10</sup> vp      |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                              |
| Routes of administration   | Intramuscular use                      |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of Ad26.COV2.S 5*10 <sup>10</sup> vp on Day 1 (Vaccination 1), 12 months (Booster 2).  |  |
| <b>Arm title</b>   | COHORT 2A: Placebo, B: PL              |

**Arm description:**

Group 5 subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), 6 months (Booster 1) and 12 months (Booster 2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental                      |
| Investigational medicinal product name | Ad26.COV2.S $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

**Dosage and administration details:**

As per protocol amendment 10, after unblinding, enrolled subjects who had initially received only placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

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

**Dosage and administration details:**

Subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), 6 months (Booster 1) and 12 months (Booster 2).

|                  |  |
|------------------|--|
| <b>Arm title</b> | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) |
|------------------|--|

**Arm description:**

Group 1 and 4 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and matching placebo at 6 and 12 months after vaccination 2 as Booster 1 and Booster 2 vaccines. As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after Booster 2 Vaccination.

|  |                   |
|--|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | Placebo           |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

**Dosage and administration details:**

Subjects received a single IM injection of placebo matching to Ad26.COV2.S  $5 \times 10^{10}$  vp at 6 and 12 months after vaccination 2 as Booster 1 and Booster 2 vaccines.

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Ad26.COV2.S $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

**Dosage and administration details:**

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) Day 57 (Vaccination) and  $\geq 6$  months after Booster 2 Vaccination.

|                  |   |
|------------------|---|
| <b>Arm title</b> | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL |
|------------------|---|

**Arm description:**

Group 2 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1), Day 57 (Vaccination 2) and 6 months after Vaccination 2(Booster 1). At 12 months after vaccination 2, subjects received placebo matching to Ad26.COV2.S vaccine (Booster 2).

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

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

**Dosage and administration details:**

Subjects received a single IM injection of placebo matching to Ad26.COV2.S  $5 \times 10^{10}$  vp at 12 months after vaccination 2.

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Ad26.COV2.S $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

**Dosage and administration details:**

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1), Day 57 (Vaccination 2) and 6 months after Vaccination 2 (Booster 1).

|                  |   |
|------------------|---|
| <b>Arm title</b> | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 |
|------------------|---|

**Arm description:**

Group 3 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and matching placebo at 6 months after vaccination 2 as Booster 1 vaccination and Ad26.COV2.S  $5 \times 10^{10}$  vp at 12 months after vaccination 2 as Booster 2 vaccination.

|  |                   |
|--|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | Placebo           |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

**Dosage and administration details:**

Group 3 subjects received a single IM injection of placebo matching to Ad26.COV2.S  $5 \times 10^{10}$  vp at 6 months after vaccination 2 as Booster 1 vaccination.

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Ad26.COV2.S $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

**Dosage and administration details:**

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2), at 12 months after vaccination 2 as Booster 2 vaccination.

|                  |                           |
|------------------|---------------------------|
| <b>Arm title</b> | COHORT 2B: Placebo, B: PL |
|------------------|---------------------------|

**Arm description:**

Group 5 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), Day 57 (Vaccination 2), 8 Month (Booster 1) and 14 months (Booster 2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|  |                                    |
|--|------------------------------------|
| Arm type                               | Experimental                       |
| Investigational medicinal product name | Ad26.COV2.S. $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                    |
| Other name                             |                                    |
| Pharmaceutical forms                   | Injection                          |
| Routes of administration               | Intramuscular use                  |

**Dosage and administration details:**

As per protocol amendment 10, after unblinding, enrolled subjects who had initially received only placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

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

**Dosage and administration details:**

Subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), Day 57 (Vaccination 2), 8 Month (Booster 1) and 14 months (Booster 2).

|                  |   |
|------------------|---|
| <b>Arm title</b> | COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
|------------------|---|

**Arm description:**

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after

|  |                                   |
|--|-----------------------------------|
| Arm type                               | Experimental                      |
| Investigational medicinal product name | Ad26.COV2.S $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

**Dosage and administration details:**

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and  $\geq 6$  months after Vaccination 2.

|                  |  |
|------------------|--|
| <b>Arm title</b> | COHORT 3: Ad26 5e10, PL(AHBV: Ad26 5e10) |
|------------------|--|

**Arm description:**

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after Vaccination 2.

|  |                   |
|--|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | Placebo           |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

**Dosage and administration details:**

Subjects received a single IM injection of placebo matching to Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 57 (Vaccination 2).

|  |                                   |
|--|-----------------------------------|
| Investigational medicinal product name | Ad26.COV2.S $5 \times 10^{10}$ vp |
| Investigational medicinal product code |                                   |
| Other name                             |                                   |
| Pharmaceutical forms                   | Injection                         |
| Routes of administration               | Intramuscular use                 |

**Dosage and administration details:**

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 and  $\geq 6$  months after Vaccination 2.

|                  |   |
|------------------|---|
| <b>Arm title</b> | COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|------------------|---|

**Arm description:**

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after

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

|  |  |
|--|--|
| Investigational medicinal product name   | Ad26.COV2.S. 5*10 <sup>10</sup> vp       |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                                |
| Routes of administration   | Intramuscular use                        |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of Ad26.COV2.S. 5*10 <sup>10</sup> vp at ≥6 months after Vaccination 2.  |  |
| Investigational medicinal product name   | Ad26.COV2.S 1*10 <sup>11</sup> vp        |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                                |
| Routes of administration   | Intramuscular use                        |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of Ad26.COV2.S 1*10 <sup>11</sup> vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2).  |  |
| <b>Arm title</b>   | COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10) |
| Arm description:   |  |
| Adult subjects (with good or stable health) aged ≥65 years received a single IM injection of Ad26.COV2.S 1*10 <sup>11</sup> vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of 5*10 <sup>10</sup> vp Ad26.COV2.S. ≥6 months after Vaccination 2. |  |
| Arm type   | Experimental                             |
| Investigational medicinal product name   | Ad26.COV2.S 1*10 <sup>11</sup>           |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                                |
| Routes of administration   | Intramuscular use                        |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of Ad26.COV2.S 1*10 <sup>11</sup> vp on Day 1 (Vaccination 1).   |  |
| Investigational medicinal product name   | Ad26.COV2.S. 5*10 <sup>10</sup> vp       |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                                |
| Routes of administration   | Intramuscular use                        |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of Ad26.COV2.S. 5*10 <sup>10</sup> vp ≥6 months after Vaccination 2.   |  |
| Investigational medicinal product name   | Placebo                                  |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Injection                                |
| Routes of administration   | Intramuscular use                        |
| Dosage and administration details:   |  |
| Subjects received a single IM injection of placebo matching to Ad26.COV2.S 1*10 <sup>11</sup> vp on Day 57 (Vaccination 2).  |  |
| <b>Arm title</b>   | COHORT 3: Placebo, Placebo               |
| Arm description:   |  |
| Adult subjects (with good or stable health) aged ≥65 years received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of 5*10 <sup>10</sup> vp Ad26.COV2.S.  |  |
| Arm type   | Experimental                             |

|  |                                 |
|--|---------------------------------|
| Investigational medicinal product name   | Ad26.COV2.S. 5*10 <sup>10</sup> |
| Investigational medicinal product code   |                                 |
| Other name   |                                 |
| Pharmaceutical forms   | Injection                       |
| Routes of administration   | Intramuscular use               |
| Dosage and administration details:   |                                 |
| As per protocol amendment 10, after unblinding, enrolled subjects who had initially received only placebo were offered a single dose of 5*10 <sup>10</sup> vp Ad26.COV2.S. |                                 |
| Investigational medicinal product name   | Placebo                         |
| Investigational medicinal product code   |                                 |
| Other name   |                                 |
| Pharmaceutical forms   | Injection                       |
| Routes of administration   | Intramuscular use               |
| Dosage and administration details:   |                                 |
| Subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2).  |                                 |

| Number of subjects in period 1 | COHORT 1A: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) | COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10) | COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|--------------------------------|--|---|--|
| Started                        | 77   | 75  | 75   |
| Completed                      | 48   | 49  | 42   |
| Not completed                  | 29   | 26  | 33   |
| Physician decision             | 1  | -   | 2  |
| Death                          | -  | -   | -  |
| Protocol deviation             | -  | -   | -  |
| Adverse event                  | -  | -   | -  |
| Unspecified                    | 3  | 2   | 5  |
| Lost to follow-up              | -  | 2   | 2  |
| Withdrawal by subject          | 25   | 22  | 24   |

| Number of subjects in period 1 | COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 5e10) | COHORT 1A: Placebo, Placebo | COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
|--------------------------------|---|-----------------------------|--|
| Started                        | 73  | 77                          | 5  |
| Completed                      | 39  | 36                          | 3  |
| Not completed                  | 34  | 41                          | 2  |
| Physician decision             | 1   | -                           | -  |
| Death                          | -   | -                           | -  |
| Protocol deviation             | -   | -                           | -  |
| Adverse event                  | -   | -                           | -  |
| Unspecified                    | 9   | 23                          | 1  |
| Lost to follow-up              | 1   | 4                           | 1  |
| Withdrawal by subject          | 23  | 14                          | -  |

| Number of subjects in period 1 | COHORT 1B: Ad26 5e10, PL(AHBV: Ad26 5e10) | COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: Ad26 1e11) | COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 5e10) |
|--------------------------------|---|--|---|
| Started                        | 5   | 5  | 5   |
| Completed                      | 5   | 4  | 4   |
| Not completed                  | 0   | 1  | 1   |
| Physician decision             | -   | -  | -   |
| Death                          | -   | -  | -   |
| Protocol deviation             | -   | -  | -   |
| Adverse event                  | -   | -  | -   |
| Unspecified                    | -   | -  | -   |
| Lost to follow-up              | -   | -  | 1   |
| Withdrawal by subject          | -   | 1  | -   |

| Number of subjects in period 1 | COHORT 1B: Placebo, Placebo | COHORT 2A: Ad26 5e10, B: PL(PL/AHBV: Ad26 5e10) | COHORT 2A: Ad26 5e10, B: Ad26 5e10, PL |
|--------------------------------|-----------------------------|---|--|
|                                |                             |   |  |
| Started                        | 5                           | 58  | 29                                     |
| Completed                      | 4                           | 33  | 15                                     |
| Not completed                  | 1                           | 25  | 14                                     |
| Physician decision             | -                           | -   | 1                                      |
| Death                          | -                           | -   | -                                      |
| Protocol deviation             | -                           | -   | -                                      |
| Adverse event                  | -                           | -   | -                                      |
| Unspecified                    | -                           | 3   | 1                                      |
| Lost to follow-up              | -                           | 5   | 5                                      |
| Withdrawal by subject          | 1                           | 17  | 7                                      |

| Number of subjects in period 1 | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2A: Placebo, B: PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL(PL/Ad26 5e10) |
|--------------------------------|--|---------------------------|--|
|                                |  |                           |  |
| Started                        | 32                                     | 17                        | 62   |
| Completed                      | 14                                     | 7                         | 31   |
| Not completed                  | 18                                     | 10                        | 31   |
| Physician decision             | 2                                      | -                         | -  |
| Death                          | 1                                      | -                         | 1  |
| Protocol deviation             | -                                      | 1                         | -  |
| Adverse event                  | -                                      | -                         | -  |
| Unspecified                    | 1                                      | 2                         | 3  |
| Lost to follow-up              | 4                                      | 1                         | 7  |
| Withdrawal by subject          | 10                                     | 6                         | 20   |

| Number of subjects in period 1 | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|--------------------------------|---|---|---------------------------|
|                                |   |   |                           |
| Started                        | 30  | 28  | 15                        |

|                       |    |    |    |
|-----------------------|----|----|----|
| Completed             | 16 | 15 | 5  |
| Not completed         | 14 | 13 | 10 |
| Physician decision    | -  | -  | -  |
| Death                 | -  | -  | -  |
| Protocol deviation    | 1  | -  | -  |
| Adverse event         | -  | 1  | -  |
| Unspecified           | -  | -  | 6  |
| Lost to follow-up     | 7  | 1  | -  |
| Withdrawal by subject | 6  | 11 | 4  |

| <b>Number of subjects in period 1</b> | COHORT 3: Ad26<br>5e10, Ad26<br>5e10(AHBV: Ad26 | COHORT 3: Ad26<br>5e10, PL(AHBV:<br>Ad26 5e10) | COHORT 3: Ad26<br>1e11, Ad26<br>1e11(AHBV: Ad26 |
|---------------------------------------|---|--|---|
| Started                               | 81  | 80   | 82  |
| Completed                             | 65  | 53   | 53  |
| Not completed                         | 16  | 27   | 29  |
| Physician decision                    | -   | -  | 1   |
| Death                                 | -   | 2  | -   |
| Protocol deviation                    | -   | -  | -   |
| Adverse event                         | -   | -  | -   |
| Unspecified                           | 1   | -  | 2   |
| Lost to follow-up                     | 1   | 1  | 2   |
| Withdrawal by subject                 | 14  | 24   | 24  |

| <b>Number of subjects in period 1</b> | COHORT 3: Ad26<br>1e11, PL(AHBV:<br>Ad26 5e10) | COHORT 3: Placebo,<br>Placebo |
|---------------------------------------|--|-------------------------------|
| Started                               | 79   | 81                            |
| Completed                             | 57   | 6                             |
| Not completed                         | 22   | 75                            |
| Physician decision                    | 2  | -                             |
| Death                                 | 1  | -                             |
| Protocol deviation                    | -  | -                             |
| Adverse event                         | -  | -                             |
| Unspecified                           | 2  | 60                            |
| Lost to follow-up                     | 1  | 1                             |
| Withdrawal by subject                 | 16   | 14                            |



## Baseline characteristics

### Reporting groups

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 1A: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Healthy adult subjects aged greater than or equal to ( $\geq$ ) 18 to less than or equal to ( $\leq$ ) 55 received a single intramuscular (IM) injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster vaccination (AHBV) of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq$  6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and matching placebo (PL) on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq$  6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq$  6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq$  6 months after Vaccination 2.

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | COHORT 1A: Placebo, Placebo |
|-----------------------|-----------------------------|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq$  6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 1B: Ad26 5e10, PL(AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and a matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq$  6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq$  6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were

offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq 6$  months after Vaccination 2.

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | COHORT 1B: Placebo, Placebo |
|-----------------------|-----------------------------|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2A: Ad26 5e10, B: PL(PL/AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Group 1 and Group 4 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) followed by matching placebo at 6 and 12 months as matching Booster (B) 1 and Booster 2 vaccination. As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S.  $5 \times 10^{10}$  vp  $\geq 6$  months after Booster 2 Vaccination.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2A: Ad26 5e10, B: Ad26 5e10, PL |
|-----------------------|--|

Reporting group description:

Group 2 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) followed by first booster vaccination with single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp booster 1 at 6 months and a matching placebo at 12 months to match second Booster vaccination.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 |
|-----------------------|--|

Reporting group description:

Group 3 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) followed by a matching placebo booster 1 injection after 6 months and Ad26.COV2.S  $5 \times 10^{10}$  vp after 12 months as Booster 2.

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | COHORT 2A: Placebo, B: PL |
|-----------------------|---------------------------|

Reporting group description:

Group 5 subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), 6 months (Booster 1) and 12 months (Booster 2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL(PL/Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Group 1 and 4 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and matching placebo at 6 and 12 months after vaccination 2 as Booster 1 and Booster 2 vaccines. As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after Booster 2 Vaccination.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL |
|-----------------------|---|

Reporting group description:

Group 2 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1), Day 57 (Vaccination 2) and 6 months after Vaccination 2 (Booster 1). At 12 months after vaccination 2, subjects received placebo matching to Ad26.COV2.S vaccine (Booster 2).

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 |
|-----------------------|---|

Reporting group description:

Group 3 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and matching placebo at 6 months after vaccination 2 as Booster 1 vaccination and Ad26.COV2.S  $5 \times 10^{10}$  vp at 12 months after vaccination 2 as Booster 2 vaccination.

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | COHORT 2B: Placebo, B: PL |
|-----------------------|---------------------------|

Reporting group description:

Group 5 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), Day 57 (Vaccination 2), 8 Month (Booster 1) and 14 months (Booster 2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol

15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. ≥6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 3: Ad26 5e10, PL(AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Adult subjects (with good or stable health) aged ≥65 years received a single IM injection of Ad26.COV2.S 5\*10<sup>10</sup> vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. ≥6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Adult subjects (with good or stable health) aged ≥65 years received a single IM injection of Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. ≥6 months after

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Adult subjects (with good or stable health) aged ≥65 years received a single IM injection of Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. ≥6 months after Vaccination 2.

|                       |                            |
|-----------------------|----------------------------|
| Reporting group title | COHORT 3: Placebo, Placebo |
|-----------------------|----------------------------|

Reporting group description:

Adult subjects (with good or stable health) aged ≥65 years received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of 5\*10<sup>10</sup> vp Ad26.COV2.S.

| Reporting group values                      | COHORT 1A: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) | COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10) | COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|---|--|---|--|
| Number of subjects                          | 77   | 75  | 75   |
| Title for AgeCategorical<br>Units: subjects |  |   |  |
| Children (2-11 years)                       | 0  | 0   | 0  |
| Adolescents (12-17 years)                   | 0  | 0   | 0  |
| Adults (18-64 years)                        | 77   | 75  | 75   |
| From 65 to 84 years                         | 0  | 0   | 0  |
| 85 years and over                           | 0  | 0   | 0  |
| Title for AgeContinuous<br>Units: years     |  |   |  |
| arithmetic mean                             | 35.4   | 35.7                                      | 34.5   |
| standard deviation                          | ± 10.11  | ± 9.99                                    | ± 10.59  |
| Title for Gender<br>Units: subjects         |  |   |  |
| Female                                      | 41   | 38  | 38   |
| Male  | 36   | 37  | 37   |

| Reporting group values                      | COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 5e10) | COHORT 1A: Placebo, Placebo | COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
|---|---|-----------------------------|--|
| Number of subjects                          | 73  | 77                          | 5  |
| Title for AgeCategorical<br>Units: subjects |   |                             |  |
| Children (2-11 years)                       | 0   | 0                           | 0  |

|                           |         |        |         |
|---------------------------|---------|--------|---------|
| Adolescents (12-17 years) | 0       | 0      | 0       |
| Adults (18-64 years)      | 73      | 77     | 5       |
| From 65 to 84 years       | 0       | 0      | 0       |
| 85 years and over         | 0       | 0      | 0       |
| Title for AgeContinuous   |         |        |         |
| Units: years              |         |        |         |
| arithmetic mean           | 35.1    | 35     | 43      |
| standard deviation        | ± 10.48 | ± 9.88 | ± 11.45 |
| Title for Gender          |         |        |         |
| Units: subjects           |         |        |         |
| Female                    | 42      | 39     | 1       |
| Male                      | 31      | 38     | 4       |

| Reporting group values    | COHORT 1B: Ad26<br>5e10, PL(AHBV:<br>Ad26 5e10) | COHORT 1B: Ad26<br>1e11, Ad26<br>1e11(AHBV: Ad26 | COHORT 1B: Ad26<br>1e11, PL(AHBV:<br>Ad26 5e10) |
|---------------------------|---|--|---|
| Number of subjects        | 5   | 5  | 5   |
| Title for AgeCategorical  |   |  |   |
| Units: subjects           |   |  |   |
| Children (2-11 years)     | 0   | 0  | 0   |
| Adolescents (12-17 years) | 0   | 0  | 0   |
| Adults (18-64 years)      | 5   | 5  | 5   |
| From 65 to 84 years       | 0   | 0  | 0   |
| 85 years and over         | 0   | 0  | 0   |
| Title for AgeContinuous   |   |  |   |
| Units: years              |   |  |   |
| arithmetic mean           | 44.4  | 29.6   | 41.2  |
| standard deviation        | ± 4.39  | ± 4.34   | ± 5.54  |
| Title for Gender          |   |  |   |
| Units: subjects           |   |  |   |
| Female                    | 4   | 2  | 4   |
| Male                      | 1   | 3  | 1   |

| Reporting group values    | COHORT 1B:<br>Placebo, Placebo | COHORT 2A: Ad26<br>5e10, B:<br>PL(PL/AHBV: Ad26<br>5e10) | COHORT 2A: Ad26<br>5e10, B: Ad26 5e10,<br>PL |
|---------------------------|--------------------------------|--|--|
| Number of subjects        | 5                              | 58   | 29   |
| Title for AgeCategorical  |                                |  |  |
| Units: subjects           |                                |  |  |
| Children (2-11 years)     | 0                              | 0  | 0  |
| Adolescents (12-17 years) | 0                              | 0  | 0  |
| Adults (18-64 years)      | 5                              | 58   | 29   |
| From 65 to 84 years       | 0                              | 0  | 0  |
| 85 years and over         | 0                              | 0  | 0  |
| Title for AgeContinuous   |                                |  |  |
| Units: years              |                                |  |  |
| arithmetic mean           | 40.8                           | 36.8   | 38.1   |
| standard deviation        | ± 11.97                        | ± 9.27   | ± 9.98                                       |
| Title for Gender          |                                |  |  |
| Units: subjects           |                                |  |  |
| Female                    | 3                              | 33   | 15   |
| Male                      | 2                              | 25   | 14   |

| Reporting group values                      | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2A: Placebo, B: PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL(PL/Ad26 5e10) |
|---|--|---------------------------|--|
| Number of subjects                          | 32                                     | 17                        | 62   |
| Title for AgeCategorical<br>Units: subjects |  |                           |  |
| Children (2-11 years)                       | 0                                      | 0                         | 0  |
| Adolescents (12-17 years)                   | 0                                      | 0                         | 0  |
| Adults (18-64 years)                        | 32                                     | 17                        | 62   |
| From 65 to 84 years                         | 0                                      | 0                         | 0  |
| 85 years and over                           | 0                                      | 0                         | 0  |
| Title for AgeContinuous<br>Units: years     |  |                           |  |
| arithmetic mean                             | 39.2                                   | 37.5                      | 37.6   |
| standard deviation                          | ± 10.53                                | ± 10.41                   | ± 9.93   |
| Title for Gender<br>Units: subjects         |  |                           |  |
| Female                                      | 12                                     | 10                        | 23   |
| Male  | 20                                     | 7                         | 39   |

| Reporting group values                      | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|---|---|---|---------------------------|
| Number of subjects                          | 30  | 28  | 15                        |
| Title for AgeCategorical<br>Units: subjects |   |   |                           |
| Children (2-11 years)                       | 0   | 0   | 0                         |
| Adolescents (12-17 years)                   | 0   | 0   | 0                         |
| Adults (18-64 years)                        | 30  | 28  | 15                        |
| From 65 to 84 years                         | 0   | 0   | 0                         |
| 85 years and over                           | 0   | 0   | 0                         |
| Title for AgeContinuous<br>Units: years     |   |   |                           |
| arithmetic mean                             | 38.3  | 36.1  | 37                        |
| standard deviation                          | ± 9.81  | ± 11.48   | ± 9.99                    |
| Title for Gender<br>Units: subjects         |   |   |                           |
| Female                                      | 10  | 15  | 10                        |
| Male  | 20  | 13  | 5                         |

| Reporting group values                      | COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) | COHORT 3: Ad26 5e10, PL(AHBV: Ad26 5e10) | COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|---|---|--|---|
| Number of subjects                          | 81  | 80                                       | 82  |
| Title for AgeCategorical<br>Units: subjects |   |  |   |
| Children (2-11 years)                       | 0   | 0  | 0   |
| Adolescents (12-17 years)                   | 0   | 0  | 0   |
| Adults (18-64 years)                        | 0   | 0  | 0   |
| From 65 to 84 years                         | 81  | 80                                       | 81  |
| 85 years and over                           | 0   | 0  | 1   |

|  |                |                |                |
|--|----------------|----------------|----------------|
| Title for AgeContinuous<br>Units: years<br>arithmetic mean<br>standard deviation | 69.5<br>± 4.24 | 69.8<br>± 3.74 | 69.7<br>± 4.33 |
| Title for Gender<br>Units: subjects  |                |                |                |
| Female   | 40             | 36             | 42             |
| Male   | 41             | 44             | 40             |

| Reporting group values   | COHORT 3: Ad26<br>1e11, PL(AHBV:<br>Ad26 5e10) | COHORT 3: Placebo,<br>Placebo | Total |
|--|--|-------------------------------|-------|
| Number of subjects   | 79   | 81                            | 1076  |
| Title for AgeCategorical<br>Units: subjects                                      |  |                               |       |
| Children (2-11 years)  | 0  | 0                             | 0     |
| Adolescents (12-17 years)  | 0  | 0                             | 0     |
| Adults (18-64 years)   | 0  | 0                             | 673   |
| From 65 to 84 years  | 78   | 81                            | 401   |
| 85 years and over  | 1  | 0                             | 2     |
| Title for AgeContinuous<br>Units: years<br>arithmetic mean<br>standard deviation | 70.3<br>± 4.18                                 | 69.9<br>± 3.73                | -     |
| Title for Gender<br>Units: subjects  |  |                               |       |
| Female   | 40   | 43                            | 541   |
| Male   | 39   | 38                            | 535   |

## End points

### End points reporting groups

|  |  |
|--|--|
| Reporting group title  | COHORT 1A: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
| Reporting group description:<br>Healthy adult subjects aged greater than or equal to ( $\geq$ ) 18 to less than or equal to ( $\leq$ ) 55 received a single intramuscular (IM) injection of Ad26.COV2.S $5 \times 10^{10}$ vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster vaccination (AHBV) of Ad26.COV2.S at the dose of $5 \times 10^{10}$ $\geq$ 6 months after Vaccination 2. |  |
| Reporting group title  | COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)        |
| Reporting group description:<br>Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $5 \times 10^{10}$ vp on Day 1 (Vaccination 1) and matching placebo (PL) on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of $5 \times 10^{10}$ vp $\geq$ 6 months after Vaccination 2.   |  |
| Reporting group title  | COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
| Reporting group description:<br>Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $1 \times 10^{11}$ vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of $5 \times 10^{10}$ vp $\geq$ 6 months after Vaccination 2.  |  |
| Reporting group title  | COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 5e10)        |
| Reporting group description:<br>Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $1 \times 10^{11}$ vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of $5 \times 10^{10}$ vp $\geq$ 6 months after Vaccination 2.  |  |
| Reporting group title  | COHORT 1A: Placebo, Placebo                      |
| Reporting group description:<br>Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of $5 \times 10^{10}$ vp Ad26.COV2.S.  |  |
| Reporting group title  | COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
| Reporting group description:<br>Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $5 \times 10^{10}$ vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of $5 \times 10^{10}$ vp $\geq$ 6 months after Vaccination 2.  |  |
| Reporting group title  | COHORT 1B: Ad26 5e10, PL(AHBV: Ad26 5e10)        |
| Reporting group description:<br>Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $5 \times 10^{10}$ vp on Day 1 (Vaccination 1) and a matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of $5 \times 10^{10}$ vp $\geq$ 6 months after Vaccination 2.  |  |
| Reporting group title  | COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
| Reporting group description:<br>Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $1 \times 10^{11}$ vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S at the dose of $5 \times 10^{10}$ vp $\geq$ 6 months after Vaccination 2.  |  |
| Reporting group title  | COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 5e10)        |
| Reporting group description:<br>Healthy adult subjects aged $\geq 18$ to $\leq 55$ received a single IM injection of Ad26.COV2.S $1 \times 10^{11}$ vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were   |  |

offered a single AHBV of Ad26.COV2.S at the dose of  $5 \times 10^{10}$  vp  $\geq 6$  months after Vaccination 2.

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | COHORT 1B: Placebo, Placebo |
|-----------------------|-----------------------------|

Reporting group description:

Healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2A: Ad26 5e10, B: PL(PL/AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Group 1 and Group 4 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) followed by matching placebo at 6 and 12 months as matching Booster (B) 1 and Booster 2 vaccination. As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single AHBV of Ad26.COV2.S.  $5 \times 10^{10}$  vp  $\geq 6$  months after Booster 2 Vaccination.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2A: Ad26 5e10, B: Ad26 5e10, PL |
|-----------------------|--|

Reporting group description:

Group 2 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) followed by first booster vaccination with single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp booster 1 at 6 months and a matching placebo at 12 months to match second Booster vaccination.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 |
|-----------------------|--|

Reporting group description:

Group 3 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) followed by a matching placebo booster 1 injection after 6 months and Ad26.COV2.S  $5 \times 10^{10}$  vp after 12 months as Booster 2.

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | COHORT 2A: Placebo, B: PL |
|-----------------------|---------------------------|

Reporting group description:

Group 5 subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), 6 months (Booster 1) and 12 months (Booster 2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL(PL/Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Group 1 and 4 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and matching placebo at 6 and 12 months after vaccination 2 as Booster 1 and Booster 2 vaccines. As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after Booster 2 Vaccination.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL |
|-----------------------|---|

Reporting group description:

Group 2 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1), Day 57 (Vaccination 2) and 6 months after Vaccination 2 (Booster 1). At 12 months after vaccination 2, subjects received placebo matching to Ad26.COV2.S vaccine (Booster 2).

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 |
|-----------------------|---|

Reporting group description:

Group 3 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and matching placebo at 6 months after vaccination 2 as Booster 1 vaccination and Ad26.COV2.S  $5 \times 10^{10}$  vp at 12 months after vaccination 2 as Booster 2 vaccination.

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | COHORT 2B: Placebo, B: PL |
|-----------------------|---------------------------|

Reporting group description:

Group 5 healthy adult subjects aged  $\geq 18$  to  $\leq 55$  received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), Day 57 (Vaccination 2), 8 Month (Booster 1) and 14 months (Booster 2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol



15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 3: Ad26 5e10, PL(AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). As per protocol amendment 15, all eligible subjects who had previously received 1 or more doses of any COVID-19 vaccine were offered a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.  $\geq 6$  months after Vaccination 2.

|                       |                            |
|-----------------------|----------------------------|
| Reporting group title | COHORT 3: Placebo, Placebo |
|-----------------------|----------------------------|

Reporting group description:

Adult subjects (with good or stable health) aged  $\geq 65$  years received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). As per protocol amendment 10, after unblinding, enrolled subjects who had initially received placebo were offered a single dose of  $5 \times 10^{10}$  vp Ad26.COV2.S.

### **Primary: Cohort 1a and 1b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen**

|                 |   |
|-----------------|---|
| End point title | Cohort 1a and 1b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen <sup>[1][2]</sup> |
|-----------------|---|

End point description:

Number of Subjects with solicited local AEs for 7 days after vaccination 1 in Cohorts 1a and 1b were reported. An AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). Full analysis set (FAS) included all subjects with at least one vaccine administration documented.

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

End point timeframe:

7 days post-vaccination 1 on Day 1 (Day 8)

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: Only descriptive data was planned to be reported for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                             |  |  |  |  |
|-----------------------------|--|--|--|--|
| <b>End point values</b>     | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 77   | 75   | 75   | 73   |
| Units: Subjects             | 50   | 50   | 57   | 59   |

|                             |                                   |  |  |  |
|-----------------------------|-----------------------------------|--|--|--|
| <b>End point values</b>     | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 77                                | 5  | 5  | 5  |
| Units: Subjects             | 8                                 | 4  | 3  | 5  |

|                             |  |                                   |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| <b>End point values</b>     | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 5  | 5                                 |  |  |
| Units: Subjects             | 4  | 0                                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohorts 1a and 1b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohorts 1a and 1b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen <sup>[3][4]</sup> |
|-----------------|--|

End point description:

Number of Subjects with solicited local AEs for 7 days after vaccination 2 in Cohorts 1a and 1b were reported. An AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint.

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

End point timeframe:

7 days after vaccination 2 on Day 57 (Day 64)

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: Only descriptive data was planned to be reported for this endpoint.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 74   | 74   | 74   | 67   |
| Units: Subjects             | 49   | 5  | 55   | 7  |

| End point values            | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 74                                | 4  | 5  | 5  |
| Units: Subjects             | 2                                 | 4  | 0  | 5  |

| End point values            | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 5  | 5                                 |  |  |
| Units: Subjects             | 1  | 0                                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohorts 1a and 1b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination

|                 |  |
|-----------------|--|
| End point title | Cohorts 1a and 1b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination <sup>[5][6]</sup> |
|-----------------|--|

End point description:

Number of Subjects with solicited local AEs for 7 days after ad hoc booster vaccination in Cohorts 1a and 1b were reported. An AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after ad hoc booster 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: Only descriptive data was planned to be reported for this endpoint.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 6  | 8  | 7  | 7  |
| Units: Subjects             | 5  | 5  | 6  | 5  |

| End point values            | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 0 <sup>[7]</sup>                  | 1  | 2  | 2  |
| Units: Subjects             |                                   | 0  | 1  | 2  |

Notes:

[7] - 0 subjects were available for the analysis as none received ad hoc booster vaccination..

| End point values            | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 0 <sup>[8]</sup>                                   | 0 <sup>[9]</sup>                  |  |  |
| Units: Subjects             |  |                                   |  |  |

Notes:

[8] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[9] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohorts 2a and 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohorts 2a and 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen <sup>[10][11]</sup> |
|-----------------|--|

End point description:

Number of Subjects with solicited local AEs for 7 days after vaccination 1 in Cohorts 2a and 2b were reported. An AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study.

Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented.

|   |         |
|---|---------|
| End point type                              | Primary |
| End point timeframe:                        |         |
| 7 days after Vaccination 1 on Day 1 (Day 8) |         |

Notes:

[10] - 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: Only descriptive data was planned to be reported for this endpoint.

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                             |  |  |  |                              |
|-----------------------------|--|--|--|------------------------------|
| <b>End point values</b>     | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 58   | 29   | 32   | 17                           |
| Units: Subjects             | 48   | 24   | 19   | 4                            |

|                             |   |  |  |                              |
|-----------------------------|---|--|--|------------------------------|
| <b>End point values</b>     | COHORT<br>2B:Ad265e10,<br>Ad26 5e10,<br>B:PL(PL/Ad265<br>e10) | COHORT 2B:<br>Ad26 5e10,<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2B:<br>Ad26 5e10,<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2B:<br>Placebo, B: PL |
| Subject group type          | Reporting group   | Reporting group  | Reporting group  | Reporting group              |
| Number of subjects analysed | 62  | 30   | 28   | 15                           |
| Units: Subjects             | 52  | 23   | 18   | 0                            |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2a: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Booster Vaccination 1

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Booster Vaccination 1 <sup>[12][13]</sup> |
|-----------------|---|

End point description:

Number of Subjects with solicited local AEs for 7 days after booster vaccination 1 in Cohort 2a were reported. An AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

|   |         |
|---|---------|
| End point type  | Primary |
| End point timeframe:                                    |         |
| 7 days after booster vaccination 1 on Day 183 (Day 190) |         |

Notes:

[12] - 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: Only descriptive data was planned to be reported for this endpoint.

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 42   | 19   | 20   | 1                            |
| Units: Subjects             | 6  | 15   | 3  | 0                            |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2a: Number of Subjects With Solicited Local (injection Site) Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination

|                 |  |
|-----------------|--|
| End point title | Cohort 2a: Number of Subjects With Solicited Local (injection Site) Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination <sup>[14][15]</sup> |
|-----------------|--|

End point description:

Number of Subjects with solicited local AEs for 7 days after ad hoc booster vaccination in Cohort 2a were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint.

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

End point timeframe:

7 days after ad hoc booster vaccination

Notes:

[14] - 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: Only descriptive data was planned to be reported for this endpoint.

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 4  | 0 <sup>[16]</sup>                            | 0 <sup>[17]</sup>                            | 0 <sup>[18]</sup>            |
| Units: Subjects             | 1  |  |  |                              |

Notes:

[16] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[17] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[18] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2a: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Booster Vaccination 2

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Booster Vaccination 2 <sup>[19][20]</sup> |
|-----------------|---|

End point description:

Number of Subjects with solicited local AEs for 7 days after booster vaccination 2 in Cohort 2a were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after booster vaccination 2 on Day 366 (Day 373)

Notes:

[19] - 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: Only descriptive data was planned to be reported for this endpoint.

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A: Ad26 5e10, B: PL(PL/AHBV: Ad26 5e10) | COHORT 2A: Ad26 5e10, B: Ad26 5e10, PL | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2A: Placebo, B: PL |
|-----------------------------|---|--|--|---------------------------|
| Subject group type          | Reporting group                                 | Reporting group                        | Reporting group                        | Reporting group           |
| Number of subjects analysed | 19  | 13                                     | 10                                     | 0 <sup>[21]</sup>         |
| Units: Subjects             | 3   | 3                                      | 5                                      |                           |

Notes:

[21] - 0 subjects were available for the analysis as none received booster vaccination 2.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohort 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen <sup>[22][23]</sup> |
|-----------------|--|

End point description:

Number of Subjects with solicited local AEs for 7 days after Vaccination 2 in Cohort 2b were reported. An

AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after Vaccination 2 on Day 57 (Day 64)

Notes:

[22] - 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: Only descriptive data was planned to be reported for this endpoint.

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B: Ad265e10, Ad26 5e10, B: PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                    | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 56   | 29  | 27  | 14                        |
| Units: Subjects             | 42   | 21  | 18  | 3                         |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Booster Vaccination 1

|                 |   |
|-----------------|---|
| End point title | Cohort 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Booster Vaccination 1 <sup>[24][25]</sup> |
|-----------------|---|

End point description:

Number of subjects with solicited local AEs for 7 days after booster vaccination 1 in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after booster vaccination 1 on Day 239 (Day 246)

Notes:

[24] - 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: Only descriptive data was planned to be reported for this endpoint.

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.



| End point values            | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 45   | 21  | 20  | 0 <sup>[26]</sup>         |
| Units: Subjects             | 4  | 15  | 4   |                           |

Notes:

[26] - 0 subjects were available for the analysis as none received booster vaccination 1.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Booster Vaccination 2

|                 |   |
|-----------------|---|
| End point title | Cohort 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Booster Vaccination 2 <sup>[27]</sup> <sup>[28]</sup> |
|-----------------|---|

End point description:

Number of subjects with solicited local AEs for 7 days after booster vaccination 2 in Cohort 2b were reported. An AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after booster vaccination 2 on Day 422 (Day 429)

Notes:

[27] - 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: Only descriptive data was planned to be reported for this endpoint.

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 8  | 3   | 5   | 0 <sup>[29]</sup>         |
| Units: Subjects             | 0  | 1   | 4   |                           |

Notes:

[29] - 0 subjects were available for the analysis as none received booster vaccination 2.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination

|                 |  |
|-----------------|--|
| End point title | Cohort 2b: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination <sup>[30]</sup> <sup>[31]</sup> |
|-----------------|--|

End point description:

Number of subjects with solicited local AEs for 7 days after ad hoc booster vaccination in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, are used to assess the reactogenicity of the study vaccine and are pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after ad hoc booster vaccination

Notes:

[30] - 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: Only descriptive data was planned to be reported for this endpoint.

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B: Ad265e10, Ad26 5e10, B: PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                    | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 7  | 0 <sup>[32]</sup>                                 | 0 <sup>[33]</sup>                                 | 0 <sup>[34]</sup>         |
| Units: Subjects             | 4  |   |   |                           |

Notes:

[32] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[33] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[34] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohorts 1a and 1b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohorts 1a and 1b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen <sup>[35]</sup> <sup>[36]</sup> |
|-----------------|--|

End point description:

Number of subjects with solicited systemic AEs for 7 days after vaccination 1 in Cohorts 1a and 1b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented.

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

End point timeframe:

7 days after vaccination 1 on Day 1 (Day 8)

Notes:

[35] - 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: Only descriptive data was planned to be reported for this endpoint.

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 77   | 75   | 75   | 73   |
| Units: Subjects             | 48   | 52   | 63   | 62   |

| End point values            | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 77                                | 5  | 5  | 5  |
| Units: Subjects             | 17                                | 4  | 3  | 5  |

| End point values            | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 5  | 5                                 |  |  |
| Units: Subjects             | 5  | 4                                 |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 1a and 1b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen

|                 |   |
|-----------------|---|
| End point title | Cohort 1a and 1b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen <sup>[37][38]</sup> |
|-----------------|---|

End point description:

Number of subjects with solicited systemic AEs for 7 days after vaccination 2 in Cohort 1a and 1b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-

vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

|   |         |
|---|---------|
| End point type                                | Primary |
| End point timeframe:                          |         |
| 7 days after Vaccination 2 on Day 57 (Day 64) |         |

Notes:

[37] - 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: Only descriptive data was planned to be reported for this endpoint.

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                             |  |  |  |  |
|-----------------------------|--|--|--|--|
| <b>End point values</b>     | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 74   | 74   | 74   | 67   |
| Units: Subjects             | 43   | 23   | 51   | 19   |

|                             |                                   |  |  |  |
|-----------------------------|-----------------------------------|--|--|--|
| <b>End point values</b>     | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 74                                | 4  | 5  | 5  |
| Units: Subjects             | 15                                | 3  | 2  | 4  |

|                             |  |                                   |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| <b>End point values</b>     | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 5  | 5                                 |  |  |
| Units: Subjects             | 1  | 3                                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 1a and 1b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination

|                 |   |
|-----------------|---|
| End point title | Cohort 1a and 1b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Ad Hoc Booster |
|-----------------|---|

## End point description:

Number of subjects with solicited systemic AEs for 7 days after ad hoc booster vaccination in Cohorts 1a and 1b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

## End point timeframe:

|   |
|---|
| 7 days after ad hoc booster vaccination |
|---|

## Notes:

[39] - 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: Only descriptive data was planned to be reported for this endpoint.

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 6  | 8  | 7  | 7  |
| Units: Subjects             | 5  | 6  | 3  | 4  |

| End point values            | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 0 <sup>[41]</sup>                 | 1  | 2  | 2  |
| Units: Subjects             |                                   | 0  | 2  | 2  |

## Notes:

[41] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

| End point values            | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 0 <sup>[42]</sup>                                  | 0 <sup>[43]</sup>                 |  |  |
| Units: Subjects             |  |                                   |  |  |

## Notes:

[42] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[43] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

**Primary: Cohorts 2a and 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen**

|                 |  |
|-----------------|--|
| End point title | Cohorts 2a and 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen <sup>[44][45]</sup> |
|-----------------|--|

## End point description:

Number of subjects with solicited systemic AEs for 7 days after vaccination 1 in Cohorts 2a and 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented.

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

## End point timeframe:

7 days after Vaccination 1 on Day 1 (Day 8)

## Notes:

[44] - 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: Only descriptive data was planned to be reported for this endpoint.

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 58   | 29   | 32   | 17                           |
| Units: Subjects             | 47   | 23   | 21   | 8                            |

| End point values            | COHORT 2B:<br>Ad26 5e10, B:<br>PL(PL/Ad26 5e10) | COHORT 2B:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2B:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2B:<br>Placebo, B: PL |
|-----------------------------|---|--|--|------------------------------|
| Subject group type          | Reporting group                                 | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 62  | 30   | 28   | 15                           |
| Units: Subjects             | 50  | 23   | 21   | 5                            |

**Statistical analyses**

No statistical analyses for this end point

**Primary: Cohort 2a: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Booster Vaccination 1**

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Booster Vaccination 1 <sup>[46]</sup> |
|-----------------|---|

## End point description:

Number of subjects with solicited systemic AEs for 7 days post booster vaccination 1 in Cohort 2a were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

## End point timeframe:

7 days after booster vaccination 1 on Day 183 (Day 190)

## Notes:

[46] - 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: Only descriptive data was planned to be reported for this endpoint.

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 42   | 19   | 20   | 1                            |
| Units: Subjects             | 14   | 11   | 5  | 0                            |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2a: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Booster Vaccination 2

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Booster Vaccination 2 <sup>[48][49]</sup> |
|-----------------|---|

## End point description:

Number of subjects with solicited systemic AEs for 7 days after booster vaccination 2 in Cohort 2a were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

## End point timeframe:

7 days post booster vaccination 2 on Day 366 (Day 373)

## Notes:

[48] - 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: Only descriptive data was planned to be reported for this endpoint.

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 19   | 13   | 10   | 0 <sup>[50]</sup>            |
| Units: Subjects             | 6  | 2  | 2  |                              |

Notes:

[50] - 0 subjects were available for the analysis as none received booster vaccination 2.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohort 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen <sup>[51][52]</sup> |
|-----------------|--|

End point description:

Number of subjects with solicited systemic AEs for 7 days after vaccination 2 in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint.

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

End point timeframe:

7 days after Vaccination 2 on Day 57 (Day 64)

Notes:

[51] - 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: Only descriptive data was planned to be reported for this endpoint.

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 56   | 29  | 27  | 14                        |
| Units: Subjects             | 40   | 17  | 15  | 6                         |

## Statistical analyses



### Primary: Cohort 2a: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination

|                 |  |
|-----------------|--|
| End point title | Cohort 2a: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination <sup>[53][54]</sup> |
|-----------------|--|

#### End point description:

Number of subjects with solicited systemic AEs for 7 days after ad hoc booster vaccination in Cohort 2a were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

#### End point timeframe:

7 days after ad hoc booster vaccination

#### Notes:

[53] - 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: Only descriptive data was planned to be reported for this endpoint.

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 4  | 0 <sup>[55]</sup>                            | 0 <sup>[56]</sup>                            | 0 <sup>[57]</sup>            |
| Units: Subjects             | 1  |  |  |                              |

#### Notes:

[55] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[56] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[57] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

### Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Booster Vaccination 1

|                 |   |
|-----------------|---|
| End point title | Cohort 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Booster Vaccination 1 <sup>[58][59]</sup> |
|-----------------|---|

#### End point description:

Number of subjects with solicited systemic AEs for 7 days after booster vaccination 1 in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after booster vaccination 1 on Day 239 (Day 246)

Notes:

[58] - 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: Only descriptive data was planned to be reported for this endpoint.

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B: Ad265e10, Ad26 5e10, B: PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                    | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 45   | 21  | 20  | 0 <sup>[60]</sup>         |
| Units: Subjects             | 14   | 13  | 4   |                           |

Notes:

[60] - 0 subjects were available for the analysis as none received booster vaccination1 .

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Booster Vaccination 2

|                 |   |
|-----------------|---|
| End point title | Cohort 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Booster Vaccination 2 <sup>[61]</sup> <sup>[62]</sup> |
|-----------------|---|

End point description:

Number of subjects with solicited systemic AEs for 7 days after booster vaccination 2 in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after booster vaccination 2 on Day 422 (Day 429)

Notes:

[61] - 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: Only descriptive data was planned to be reported for this endpoint.

[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 8  | 3   | 5   | 0 <sup>[63]</sup>         |
| Units: Subjects             | 2  | 2   | 4   |                           |

Notes:

[63] - 0 subjects were available for the analysis as none received booster vaccination 2.

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination

|                 |  |
|-----------------|--|
| End point title | Cohort 2b: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination <sup>[64]</sup> <sup>[65]</sup> |
|-----------------|--|

End point description:

Number of subjects with solicited systemic AEs for 7 days after ad hoc booster vaccination in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after ad hoc booster vaccination

Notes:

[64] - 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: Only descriptive data was planned to be reported for this endpoint.

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 7  | 0 <sup>[66]</sup>                                 | 0 <sup>[67]</sup>                                 | 0 <sup>[68]</sup>         |
| Units: Subjects             | 2  |   |   |                           |

Notes:

[66] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[67] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[68] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

No statistical analyses for this end point

**Primary: Cohort 3: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen**

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen <sup>[69][70]</sup> |
|-----------------|---|

## End point description:

Number of subjects with solicited local AEs for 7 days after vaccination 1 in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, were used to assess the reactogenicity of the study vaccine and were pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented.

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

## End point timeframe:

7 days after vaccination 1 on Day 1 (Day 8)

## Notes:

[69] - 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: Only descriptive data was planned to be reported for this endpoint.

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|---|---|---|---|
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 81  | 80  | 82  | 79  |
| Units: Subjects             | 38  | 30  | 33  | 34  |

| End point values            | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|-----------------------------|----------------------------------|--|--|--|
| Subject group type          | Reporting group                  |  |  |  |
| Number of subjects analysed | 81                               |  |  |  |
| Units: Subjects             | 7                                |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Primary: Cohort 3: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen**

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 1 in the Primary Regimen <sup>[71][72]</sup> |
|-----------------|---|

## End point description:

Number of subjects with solicited systemic AEs for 7 days after vaccination 1 in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic

events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented.

|  |         |
|--|---------|
| End point type                             | Primary |
| End point timeframe:                       |         |
| 7 days post-vaccination 1 on Day 1 (Day 8) |         |

Notes:

[71] - 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: Only descriptive data was planned to be reported for this endpoint.

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|---|---|---|---|
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 81  | 80  | 82  | 79  |
| Units: Subjects             | 39  | 35  | 47  | 42  |

| End point values            | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|-----------------------------|----------------------------------|--|--|--|
| Subject group type          | Reporting group                  |  |  |  |
| Number of subjects analysed | 81                               |  |  |  |
| Units: Subjects             | 20                               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 3: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen <sup>[73][74]</sup> |
|-----------------|---|

End point description:

Number of subjects with solicited local AEs for 7 days after vaccination 2 in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, were used to assess the reactogenicity of the study vaccine and were pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

|  |         |
|--|---------|
| End point type                               | Primary |
| End point timeframe:                         |         |
| 7 days post-vaccination 2 on Day 57 (Day 64) |         |

Notes:

[73] - 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: Only descriptive data was planned to be reported for this endpoint.

[74] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|---|---|---|---|
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 77  | 80  | 80  | 78  |
| Units: Subjects             | 41  | 5   | 51  | 13  |

| End point values            | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|-----------------------------|----------------------------------|--|--|--|
| Subject group type          | Reporting group                  |  |  |  |
| Number of subjects analysed | 79                               |  |  |  |
| Units: Subjects             | 11                               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 3: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 2 in the Primary Regimen <sup>[75][76]</sup> |
|-----------------|---|

End point description:

Number of subjects with solicited systemic AEs for 7 days after vaccination 2 in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 after post-vaccination 2 on Day 57 (Day 64)

Notes:

[75] - 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: Only descriptive data was planned to be reported for this endpoint.

[76] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline

period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|---|---|---|---|
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 77  | 80  | 80  | 78  |
| Units: Subjects             | 33  | 24  | 40  | 24  |

| End point values            | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|-----------------------------|----------------------------------|--|--|--|
| Subject group type          | Reporting group                  |  |  |  |
| Number of subjects analysed | 79                               |  |  |  |
| Units: Subjects             | 24                               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 3: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Solicited Local (Injection Site) Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination <sup>[77]</sup> <sup>[78]</sup> |
|-----------------|---|

End point description:

Number of subjects with solicited local AEs for 7 days after ad hoc booster vaccination in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Solicited local (injection site) AEs that included injection site pain/tenderness, erythema and swelling at the study vaccine injection site, were used to assess the reactogenicity of the study vaccine and were pre-defined local (injection site). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days post Ad hoc booster vaccination

Notes:

[77] - 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: Only descriptive data was planned to be reported for this endpoint.

[78] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|---|---|---|---|
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 11  | 15  | 14  | 9   |
| Units: Subjects             | 5   | 6   | 4   | 5   |

| End point values            | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|-----------------------------|----------------------------------|--|--|--|
| Subject group type          | Reporting group                  |  |  |  |
| Number of subjects analysed | 0 <sup>[79]</sup>                |  |  |  |
| Units: Subjects             |                                  |  |  |  |

Notes:

[79] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohorts 1a and 1b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 1 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohorts 1a and 1b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 1 in the Primary Regimen <sup>[80]</sup> <sup>[81]</sup> |
|-----------------|--|

End point description:

Number of subjects with unsolicited AEs after vaccination 1 in Cohorts 1a and 1b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented.

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

End point timeframe:

28 days after vaccination 1 on Day 1 (Day 29)

Notes:

[80] - 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: Only descriptive data was planned to be reported for this endpoint.

[81] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 77   | 75   | 75   | 73   |
| Units: Subjects             | 11   | 20   | 26   | 24   |



| End point values            | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 77                                | 5  | 5  | 5  |
| Units: Subjects             | 14                                | 2  | 3  | 4  |

| End point values            | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 5  | 5                                 |  |  |
| Units: Subjects             | 4  | 2                                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 3: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Ad Hoc Booster Vaccination <sup>[82]</sup> <sup>[83]</sup> |
|-----------------|---|

End point description:

Number of subjects with solicited systemic AEs for 7 days after ad hoc booster vaccination in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Systemic events included events such as fatigue, headache, nausea, and myalgia, for which subjects were specifically questioned and which will be noted by subjects in their subject diary for 7 days post-vaccination (day of vaccination and the subsequent 7 days). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

7 days after ad hoc booster vaccination on Day 239

Notes:

[82] - 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: Only descriptive data was planned to be reported for this endpoint.

[83] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|---|---|---|---|
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 11  | 15  | 14  | 9   |
| Units: Subjects             | 3   | 7   | 4   | 6   |

| End point values            | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|-----------------------------|----------------------------------|--|--|--|
| Subject group type          | Reporting group                  |  |  |  |
| Number of subjects analysed | 0 <sup>[84]</sup>                |  |  |  |
| Units: Subjects             |                                  |  |  |  |

Notes:

[84] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohorts 1a and 1b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 2 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohorts 1a and 1b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 2 in the Primary Regimen <sup>[85]</sup> <sup>[86]</sup> |
|-----------------|--|

End point description:

Number of subjects with unsolicited AEs after vaccination 2 in Cohorts 1a and 1b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

28 days after vaccination 2 on Day 57 (Day 85)

Notes:

[85] - 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: Only descriptive data was planned to be reported for this endpoint.

[86] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 74   | 74   | 74   | 67   |
| Units: Subjects             | 10   | 4  | 7  | 12   |

| End point values            | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 74                                | 4  | 5  | 5  |
| Units: Subjects             | 6                                 | 2  | 0  | 1  |

| End point values            | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 5  | 5                                 |  |  |
| Units: Subjects             | 0  | 1                                 |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohorts 1a and 1b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Ad Hoc Booster Vaccination

|                 |  |
|-----------------|--|
| End point title | Cohorts 1a and 1b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Ad Hoc Booster Vaccination <sup>[87]</sup> <sup>[88]</sup> |
|-----------------|--|

End point description:

Number of subjects with unsolicited AEs after ad hoc booster vaccination in Cohorts 1a and 1b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

28 days post Ad hoc booster vaccination

Notes:

[87] - 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: Only descriptive data was planned to be reported for this endpoint.

[88] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                             |  |  |  |  |
|-----------------------------|--|--|--|--|
| <b>End point values</b>     | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 6  | 8  | 7  | 7  |
| Units: Subjects             | 0  | 1  | 1  | 0  |

|                             |                                   |  |  |  |
|-----------------------------|-----------------------------------|--|--|--|
| <b>End point values</b>     | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 0 <sup>[89]</sup>                 | 1  | 2  | 2  |
| Units: Subjects             |                                   | 0  | 0  | 0  |

Notes:

[89] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

|                             |  |                                   |  |  |
|-----------------------------|--|-----------------------------------|--|--|
| <b>End point values</b>     | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo |  |  |
| Subject group type          | Reporting group                                    | Reporting group                   |  |  |
| Number of subjects analysed | 0 <sup>[90]</sup>                                  | 0 <sup>[91]</sup>                 |  |  |
| Units: Subjects             |  |                                   |  |  |

Notes:

[90] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[91] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohorts 2a and 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 1 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohorts 2a and 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 1 in the Primary Regimen <sup>[92][93]</sup> |
|-----------------|--|

End point description:

Number of subjects with unsolicited AEs after vaccination 1 in Cohorts 2a and 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented.

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

End point timeframe:

28 days after Vaccination 1 on Day 1 (Day 29)

Notes:

[92] - 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: Only descriptive data was planned to be reported for this endpoint.

[93] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 58   | 29   | 32   | 17                           |
| Units: Subjects             | 15   | 5  | 7  | 5                            |

| End point values            | COHORT<br>2B:Ad265e10,<br>Ad26 5e10,<br>B:PL(PL/Ad265<br>e10) | COHORT 2B:<br>Ad26 5e10,<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2B:<br>Ad26 5e10,<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2B:<br>Placebo, B: PL |
|-----------------------------|---|--|--|------------------------------|
| Subject group type          | Reporting group   | Reporting group  | Reporting group  | Reporting group              |
| Number of subjects analysed | 62  | 30   | 28   | 15                           |
| Units: Subjects             | 11  | 6  | 5  | 2                            |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2a: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Booster Vaccination 1

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Booster Vaccination 1 <sup>[94][95]</sup> |
|-----------------|---|

End point description:

Number of subjects with unsolicited AEs after booster vaccination 1 in Cohort 2a were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint.

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

End point timeframe:

28 days after booster vaccination 1

Notes:

[94] - 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: Only descriptive data was planned to be reported for this endpoint.

[95] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 42   | 19   | 20   | 1                            |
| Units: Subjects             | 2  | 2  | 0  | 0                            |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2a: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Booster Vaccination 2

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Booster Vaccination 2 <sup>[96]</sup> <sup>[97]</sup> |
|-----------------|---|

End point description:

Number of subjects with unsolicited AEs after booster vaccination 2 in Cohort 2a were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

28 days after booster vaccination 2 on Day 366 (Day 394)

Notes:

[96] - 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: Only descriptive data was planned to be reported for this endpoint.

[97] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 19   | 13   | 10   | 0 <sup>[98]</sup>            |
| Units: Subjects             | 2  | 1  | 1  |                              |

Notes:

[98] - 0 subjects were available for the analysis as none received booster vaccination 2.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2a: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Ad Hoc Booster Vaccination

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Ad Hoc Booster Vaccination <sup>[99]</sup> <sup>[100]</sup> |
|-----------------|---|

**End point description:**

Number of subjects with unsolicited AEs after ad hoc booster vaccination in Cohort 2a were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

**End point timeframe:**

28 days after ad hoc booster vaccination

**Notes:**

[99] - 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: Only descriptive data was planned to be reported for this endpoint.

[100] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 4  | 0 <sup>[101]</sup>                           | 0 <sup>[102]</sup>                           | 0 <sup>[103]</sup>           |
| Units: Subjects             | 0  |  |  |                              |

**Notes:**

[101] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[102] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[103] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

**Statistical analyses**

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 2 in the Primary Regimen

|                 |  |
|-----------------|--|
| End point title | Cohort 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 2 in the Primary Regimen <sup>[104][105]</sup> |
|-----------------|--|

**End point description:**

Number of subjects with unsolicited AEs after vaccination 1 in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

**End point timeframe:**

28 days after Vaccination 2 on Day 57 (Day 85)

**Notes:**

[104] - 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: Only descriptive data was planned to be reported for this endpoint.

[105] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 56   | 29  | 27  | 14                        |
| Units: Subjects             | 7  | 4   | 3   | 2                         |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Booster Vaccination 1

|                 |   |
|-----------------|---|
| End point title | Cohort 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Booster Vaccination 1 <sup>[106]</sup> <sup>[107]</sup> |
|-----------------|---|

End point description:

Number of subjects with unsolicited AEs 28 days after booster vaccination 1 in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

28 days after booster vaccination 1 on Day 239 (Day 267)

Notes:

[106] - 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: Only descriptive data was planned to be reported for this endpoint.

[107] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 45   | 21  | 20  | 0 <sup>[108]</sup>        |
| Units: Subjects             | 1  | 4   | 2   |                           |

Notes:

[108] - 0 subjects were available for the analysis as none received booster vaccination 1.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Booster Vaccination 2

|                 |  |
|-----------------|--|
| End point title | Cohort 2b: Number of Subjects With Unsolicited Adverse |
|-----------------|--|



## End point description:

Number of subjects with unsolicited AEs 28 days after booster 2 vaccination in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

## End point timeframe:

28 days after booster vaccination 2 on Day 422 (Day 450)

## Notes:

[109] - 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: Only descriptive data was planned to be reported for this endpoint.

[110] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2B: Ad265e10, Ad26 5e10, B: PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|-----------------------------|--|---|---|---------------------------|
| Subject group type          | Reporting group                                    | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 8  | 3   | 5   | 0 <sup>[111]</sup>        |
| Units: Subjects             | 0  | 0   | 0   |                           |

## Notes:

[111] - 0 subjects were available for the analysis as none received booster vaccination 2.

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Ad Hoc Booster Vaccination

|                 |   |
|-----------------|---|
| End point title | Cohort 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Ad Hoc Booster Vaccination <sup>[112]</sup> [113] |
|-----------------|---|

## End point description:

Number of subjects with unsolicited AEs 28 days after ad hoc booster vaccination in Cohort 2b were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

## End point timeframe:

28 days after ad hoc booster vaccination on Day 604 (Day 632)

## Notes:

[112] - 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: Only descriptive data was planned to be reported for this endpoint.

[113] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                             |  |   |   |                           |
|-----------------------------|--|---|---|---------------------------|
| <b>End point values</b>     | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL(PL/Ad26 5e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
| Subject group type          | Reporting group                                      | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed | 7  | 0 <sup>[114]</sup>                                | 0 <sup>[115]</sup>                                | 0 <sup>[116]</sup>        |
| Units: Subjects             | 0  |   |   |                           |

Notes:

[114] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[115] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[116] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 3: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 1 in the Primary Regimen

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 1 in the Primary Regimen <sup>[117][118]</sup> |
|-----------------|---|

End point description:

Number of subjects with unsolicited AEs 28 days after vaccination 1 in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented.

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

End point timeframe:

28 days after vaccination 1 on Day 1 (Day 29)

Notes:

[117] - 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: Only descriptive data was planned to be reported for this endpoint.

[118] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                             |   |  |   |  |
|-----------------------------|---|--|---|--|
| <b>End point values</b>     | COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) | COHORT 3: Ad26 5e10, PL(AHBV: Ad26 5e10) | COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) | COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10) |
| Subject group type          | Reporting group                                 | Reporting group                          | Reporting group                                 | Reporting group                          |
| Number of subjects analysed | 81  | 80                                       | 82  | 79                                       |
| Units: Subjects             | 16  | 13                                       | 19  | 26                                       |

|                             |                            |  |  |  |
|-----------------------------|----------------------------|--|--|--|
| <b>End point values</b>     | COHORT 3: Placebo, Placebo |  |  |  |
| Subject group type          | Reporting group            |  |  |  |
| Number of subjects analysed | 81                         |  |  |  |
| Units: Subjects             | 16                         |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohort 3: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 2 in the Primary Regimen

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Vaccination 2 in the Primary Regimen <sup>[119][120]</sup> |
|-----------------|---|

End point description:

Number of subjects with unsolicited AEs 28 days after vaccination 2 in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

End point timeframe:

28 days after vaccination 2 on Day 57 (Day 85)

Notes:

[119] - 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: Only descriptive data was planned to be reported for this endpoint.

[120] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|---|---|---|---|
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 77  | 80  | 80  | 78  |
| Units: Subjects             | 11  | 9   | 12  | 12  |

| End point values            | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|-----------------------------|----------------------------------|--|--|--|
| Subject group type          | Reporting group                  |  |  |  |
| Number of subjects analysed | 79                               |  |  |  |
| Units: Subjects             | 9                                |  |  |  |

## Statistical analyses

**Primary: Cohort 3: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Ad Hoc Booster Vaccination**

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Ad Hoc Booster Vaccination <sup>[121][122]</sup> |
|-----------------|---|

## End point description:

Number of subjects with unsolicited AEs 28 days after ad hoc booster vaccination in Cohort 3 were reported. An AE was any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint.

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

## End point timeframe:

28 days after ad hoc booster vaccination on Day 239 (Day 267)

## Notes:

[121] - 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: Only descriptive data was planned to be reported for this endpoint.

[122] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|---|---|---|---|
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 11  | 15  | 14  | 9   |
| Units: Subjects             | 1   | 0   | 3   | 1   |

| End point values            | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|-----------------------------|----------------------------------|--|--|--|
| Subject group type          | Reporting group                  |  |  |  |
| Number of subjects analysed | 0 <sup>[123]</sup>               |  |  |  |
| Units: Subjects             |                                  |  |  |  |

## Notes:

[123] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

**Statistical analyses**

No statistical analyses for this end point

**Primary: Cohorts 1a, 1b and Cohort 3: Number of Subjects With Serious Adverse Events (SAEs)**

|                 |  |
|-----------------|--|
| End point title | Cohorts 1a, 1b and Cohort 3: Number of Subjects With Serious Adverse Events (SAEs) <sup>[124][125]</sup> |
|-----------------|--|

## End point description:

An AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. An SAE is

an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission of any infectious agent via a medicinal product or medically important. FAS included all subjects with at least one vaccine administration documented.

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

End point timeframe:

Day 1 up to 2 years after Vaccination 2 on Day 57 (Day 787)

Notes:

[124] - 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: Only descriptive data was planned to be reported for this endpoint.

[125] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                             |  |  |  |  |
|-----------------------------|--|--|--|--|
| <b>End point values</b>     | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 77   | 75   | 75   | 73   |
| Units: Subjects             | 0  | 1  | 1  | 1  |

|                             |                                   |  |  |  |
|-----------------------------|-----------------------------------|--|--|--|
| <b>End point values</b>     | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 77                                | 5  | 5  | 5  |
| Units: Subjects             | 2                                 | 1  | 0  | 0  |

|                             |  |                                   |   |   |
|-----------------------------|--|-----------------------------------|---|---|
| <b>End point values</b>     | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) |
| Subject group type          | Reporting group                                    | Reporting group                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 5  | 5                                 | 81  | 80  |
| Units: Subjects             | 0  | 0                                 | 3   | 2   |

|                             |   |   |                                  |  |
|-----------------------------|---|---|----------------------------------|--|
| <b>End point values</b>     | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Placebo,<br>Placebo |  |
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group                  |  |
| Number of subjects analysed | 82  | 79  | 81                               |  |

|                 |   |   |   |  |
|-----------------|---|---|---|--|
| Units: Subjects | 2 | 1 | 2 |  |
|-----------------|---|---|---|--|

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohorts 2a and 2b: Number of Subjects With Serious Adverse Events (SAEs)

|                 |  |
|-----------------|--|
| End point title | Cohorts 2a and 2b: Number of Subjects With Serious Adverse Events (SAEs) <sup>[126][127]</sup> |
|-----------------|--|

End point description:

An AE is any untoward medical occurrence in a subject participating in a clinical study that does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. An SAE is an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission of any infectious agent via a medicinal product or medically important. FAS included all subjects with at least one vaccine administration documented.

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

End point timeframe:

Day 1 up to 6 months (up to Day 183 for Cohort 2a; up to Day 239 for Cohort 2b)

Notes:

[126] - 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: Only descriptive data was planned to be reported for this endpoint.

[127] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|-----------------------------|--|--|--|------------------------------|
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 58   | 29   | 32   | 17                           |
| Units: Subjects             | 0  | 0  | 1  | 0                            |

| End point values            | COHORT 2B:<br>Ad26 5e10, B:<br>PL(PL/Ad26 5e10) | COHORT 2B:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2B:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2B:<br>Placebo, B: PL |
|-----------------------------|---|--|--|------------------------------|
| Subject group type          | Reporting group                                 | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 62  | 30   | 28   | 15                           |
| Units: Subjects             | 0   | 1  | 0  | 0                            |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohorts 1a and 1b and Cohort 3: Number of Subjects With Adverse Events of Special Interest (AESIs)

|                 |  |
|-----------------|--|
| End point title | Cohorts 1a and 1b and Cohort 3: Number of Subjects With Adverse Events of Special Interest (AESIs) <sup>[128][129]</sup> |
|-----------------|--|

End point description:

Number of subjects with AESIs was reported. AESIs were significant AEs that were judged to be of special interest because of clinical importance, known or suspected class effects, or based on nonclinical signals. Thrombosis with Thrombocytopenia Syndrome (TTS), a syndrome characterized by a combination of both a thrombotic event and thrombocytopenia, was considered to be an AESI in this study. A suspected TTS case was defined as: Thrombotic events: suspected deep vessel venous or arterial thrombotic events; Thrombocytopenia, defined as platelet count below 150,000/microliter. FAS included all subjects with at least one vaccine administration documented.

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

End point timeframe:

Day 1 up to 2 years after Vaccination 2 on Day 57 (Day 787)

Notes:

[128] - 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: Only descriptive data was planned to be reported for this endpoint.

[129] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values            | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|--|--|--|--|
| Subject group type          | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed | 77   | 75   | 75   | 73   |
| Units: Subjects             | 0  | 0  | 0  | 0  |

| End point values            | COHORT 1A:<br>Placebo,<br>Placebo | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Reporting group                   | Reporting group  | Reporting group                                    | Reporting group  |
| Number of subjects analysed | 77                                | 5  | 5  | 5  |
| Units: Subjects             | 0                                 | 0  | 0  | 0  |

| End point values            | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo,<br>Placebo | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) |
|-----------------------------|--|-----------------------------------|---|---|
| Subject group type          | Reporting group                                    | Reporting group                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed | 5  | 5                                 | 81  | 80  |

|                 |   |   |   |   |
|-----------------|---|---|---|---|
| Units: Subjects | 0 | 0 | 0 | 0 |
|-----------------|---|---|---|---|

|                             |   |   |                                  |  |
|-----------------------------|---|---|----------------------------------|--|
| <b>End point values</b>     | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Placebo,<br>Placebo |  |
| Subject group type          | Reporting group   | Reporting group                                   | Reporting group                  |  |
| Number of subjects analysed | 82  | 79  | 81                               |  |
| Units: Subjects             | 0   | 0   | 0                                |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Cohorts 2a and 2b: Number of Subjects With Adverse Events of Special Interest (AESIs)

|                 |   |
|-----------------|---|
| End point title | Cohorts 2a and 2b: Number of Subjects With Adverse Events of Special Interest (AESIs) <sup>[130][131]</sup> |
|-----------------|---|

End point description:

Number of subjects with AESIs was reported. AESIs were significant AEs that were judged to be of special interest because of clinical importance, known or suspected class effects, or based on nonclinical signals. Thrombosis with Thrombocytopenia Syndrome (TTS), a syndrome characterized by a combination of both a thrombotic event and thrombocytopenia, was considered to be an AESI in this study. A suspected TTS case was defined as: Thrombotic events: suspected deep vessel venous or arterial thrombotic events; Thrombocytopenia, defined as platelet count below 150,000/microliter. FAS included all subjects with at least one vaccine administration documented.

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

End point timeframe:

Day 1 up to 6 months (up to Day 183 for Cohort 2a; up to Day 239 for Cohort 2b)

Notes:

[130] - 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: Only descriptive data was planned to be reported for this endpoint.

[131] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                             |  |  |  |                              |
|-----------------------------|--|--|--|------------------------------|
| <b>End point values</b>     | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
| Subject group type          | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed | 58   | 29   | 32   | 17                           |
| Units: Subjects             | 0  | 0  | 0  | 0                            |

|                         |   |   |   |                              |
|-------------------------|---|---|---|------------------------------|
| <b>End point values</b> | COHORT<br>2B:Ad265e10,<br>Ad26 5e10, B: | COHORT 2B:<br>Ad26 5e10,<br>Ad26 5e10, B: | COHORT 2B:<br>Ad26 5e10,<br>Ad26 5e10, B: | COHORT 2B:<br>Placebo, B: PL |
|-------------------------|---|---|---|------------------------------|



|                             | PL(PL/Ad265e10) | Ad26 5e10, PL   | PL, Ad26 5e10   |                 |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 62              | 30              | 28              | 15              |
| Units: Subjects             | 0               | 0               | 0               | 0               |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohorts 1b: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA)

|                 |  |
|-----------------|--|
| End point title | Cohorts 1b: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA) <sup>[132]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with antibodies binding to SARS-CoV-2 S protein as measured by enzyme-linked immunosorbent assay (ELISA) was reported. Per protocol immunogenicity (PPI) population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluable for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points.

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

End point timeframe:

Days 29 and 71

Notes:

[132] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 1B:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 5e10,<br>PL(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1B:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|----------------------------------|--|--|--|--|
| Subject group type               | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed      | 5  | 5  | 5  | 5  |
| Units: Percentage of subjects    |  |  |  |  |
| number (confidence interval 95%) |  |  |  |  |
| Day 29                           | 80.0 (28.4 to 99.5)  | 100.0 (47.8 to 100.0)                              | 100.0 (47.8 to 100.0)  | 100.0 (47.8 to 100.0)                              |
| Day 71                           | 100.0 (39.8 to 100.0)  | 100.0 (47.8 to 100.0)                              | 100.0 (47.8 to 100.0)  | 100.0 (47.8 to 100.0)                              |

| End point values                 | COHORT 1B:<br>Placebo,<br>Placebo |  |  |  |
|----------------------------------|-----------------------------------|--|--|--|
| Subject group type               | Reporting group                   |  |  |  |
| Number of subjects analysed      | 4                                 |  |  |  |
| Units: Percentage of subjects    |                                   |  |  |  |
| number (confidence interval 95%) |                                   |  |  |  |

|        |                   |  |  |  |
|--------|-------------------|--|--|--|
| Day 29 | 0.0 (0.0 to 60.2) |  |  |  |
| Day 71 | 0.0 (0.0 to 60.2) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Cohort 3: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA)

|                 |  |
|-----------------|--|
| End point title | Cohort 3: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA) <sup>[133]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with antibodies binding to SARS-CoV-2 S protein as measured by enzyme-linked immunosorbent assay (ELISA) was reported. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points.

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

End point timeframe:

Days 15, 29, 87, 100, 114 and 268

Notes:

[133] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|----------------------------------|---|---|---|---|
| Subject group type               | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed      | 72  | 73  | 74  | 75  |
| Units: Percentage of subjects    |   |   |   |   |
| number (confidence interval 95%) |   |   |   |   |
| Day 15 (n =59, 58, 55, 62, 61)   | 78.0 (65.3 to 87.7)   | 72.4 (59.1 to 83.3)                               | 79.6 (66.5 to 89.4)   | 77.4 (65.0 to 87.1)                               |
| Day 29 (n =72, 73, 74, 75, 75)   | 95.8 (88.3 to 99.1)   | 97.2 (90.3 to 99.7)                               | 95.8 (88.3 to 99.1)   | 97.3 (90.7 to 99.7)                               |
| Day 87 (n =67, 67, 66, 71, 69)   | 97.0 (89.6 to 99.6)   | 97.0 (89.5 to 99.6)                               | 96.9 (89.2 to 99.6)   | 98.6 (92.4 to 100.0)                              |
| Day 100 (n =64, 69, 66, 70, 68)  | 98.4 (91.6 to 100.0)  | 97.1 (89.8 to 99.6)                               | 98.4 (91.6 to 100.0)  | 98.6 (92.3 to 100.0)                              |
| Day 114 (n =66, 68, 66, 71, 69)  | 98.5 (91.8 to 100.0)  | 97.0 (89.6 to 99.6)                               | 98.4 (91.6 to 100.0)  | 98.6 (92.4 to 100.0)                              |
| Day 268 (n =60, 56, 55, 57,6)    | 98.3 (91.1 to 100.0)  | 85.5 (73.3 to 93.5)                               | 100.0 (93.3 to 100.0)                                       | 87.7 (76.3 to 94.9)                               |

|                  |                                  |  |  |  |
|------------------|----------------------------------|--|--|--|
| End point values | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|------------------|----------------------------------|--|--|--|

|                                  |                    |  |  |  |
|----------------------------------|--------------------|--|--|--|
| Subject group type               | Reporting group    |  |  |  |
| Number of subjects analysed      | 75                 |  |  |  |
| Units: Percentage of subjects    |                    |  |  |  |
| number (confidence interval 95%) |                    |  |  |  |
| Day 15 (n =59, 58, 55, 62, 61)   | 1.6 (0.0 to 8.8)   |  |  |  |
| Day 29 (n =72, 73, 74, 75, 75)   | 0.0 (0.0 to 4.9)   |  |  |  |
| Day 87 (n =67, 67, 66, 71, 69)   | 1.5 (0.0 to 7.9)   |  |  |  |
| Day 100 (n =64, 69, 66, 70, 68)  | 0.0 (0.0 to 5.4)   |  |  |  |
| Day 114 (n =66, 68, 66, 71, 69)  | 1.5 (0.0 to 7.9)   |  |  |  |
| Day 268 (n =60, 56, 55, 57,6)    | 16.7 (0.4 to 64.1) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1a: Geometric Mean Titers (GMTs) of SARS-CoV-2 Neutralizing Antibodies to the Wild Type Virus Neutralizing Assay (VNA)

|                 |  |
|-----------------|--|
| End point title | Cohort 1a: Geometric Mean Titers (GMTs) of SARS-CoV-2 Neutralizing Antibodies to the Wild Type Virus Neutralizing Assay (VNA) <sup>[134]</sup> |
|-----------------|--|

End point description:

GMTs of SARS-CoV-2 neutralizing antibodies to the Wild-type VNA were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies data could not be estimated as the value was below the LLOQ (58) and "9999" signifies that data could not be estimated as no subjects were available for the analysis. Due to the change in planned analysis, data was not collected and analysed for Cohort 1b and thus no data was reported for this endpoint.

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

End point timeframe:

Days 29, 57, 71, 85, 239, 422

Notes:

[134] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                         | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|--|--|--|--|--|
| Subject group type                       | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed              | 22   | 24   | 24   | 23   |
| Units: Titers                            |  |  |  |  |
| geometric mean (confidence interval 95%) |  |  |  |  |
| Day 29 (n =22, 24 24, 23, 25)            | 233 (170 to 319)   | 224 (158 to 319)                                   | 333 (206 to 537)   | 219 (170 to 282)                                   |
| Day 57 (n =22, 24, 22, 21, 23)           | 310 (232 to 414)   | 284 (220 to 367)                                   | 458 (309 to 677)   | 392 (273 to 563)                                   |

|                                 |                   |                  |                    |                  |
|---------------------------------|-------------------|------------------|--------------------|------------------|
| Day 71 (n =21, 23, 23, 20, 22)  | 862 (666 to 1115) | 294 (229 to 378) | 1189 (845 to 1672) | 414 (310 to 553) |
| Day 85 (n =21, 23, 23, 20, 22)  | 919 (727 to 1161) | 317 (217 to 463) | 1127 (801 to 1587) | 422 (305 to 584) |
| Day 239 (n =21, 21, 20, 20 ,19) | 465 (338 to 641)  | 215 (146 to 317) | 771 (514 to 1154)  | 408 (232 to 716) |
| Day 422 (n =17, 19, 19, 18, 0)  | 328 (202 to 531)  | 235 (132 to 418) | 425 (294 to 613)   | 307 (205 to 460) |

| End point values                         | COHORT 1A:<br>Placebo,<br>Placebo |  |  |  |
|--|-----------------------------------|--|--|--|
| Subject group type                       | Reporting group                   |  |  |  |
| Number of subjects analysed              | 25                                |  |  |  |
| Units: Titers                            |                                   |  |  |  |
| geometric mean (confidence interval 95%) |                                   |  |  |  |
| Day 29 (n =22, 24 24, 23, 25)            | 99999 (99999 to 99999)            |  |  |  |
| Day 57 (n =22, 24, 22, 21, 23)           | 99999 (99999 to 99999)            |  |  |  |
| Day 71 (n =21, 23, 23, 20, 22)           | 99999 (99999 to 99999)            |  |  |  |
| Day 85 (n =21, 23, 23, 20, 22)           | 99999 (99999 to 99999)            |  |  |  |
| Day 239 (n =21, 21, 20, 20 ,19)          | 99999 (99999 to 99999)            |  |  |  |
| Day 422 (n =17, 19, 19, 18, 0)           | 9999 (9999 to 9999)               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2a: Geometric Mean Titers (GMTs) of SARS-CoV-2 Neutralizing Antibodies to the Wild Type Virus Neutralizing Assay (VNA)

|                 |  |
|-----------------|--|
| End point title | Cohort 2a: Geometric Mean Titers (GMTs) of SARS-CoV-2 Neutralizing Antibodies to the Wild Type Virus Neutralizing Assay (VNA) <sup>[135]</sup> |
|-----------------|--|

End point description:

GMTs of SARS-CoV-2 neutralizing antibodies to the Wild-type VNA were reported. PPI population was analyzed. Here N (number of subjects analysed) =subjects evaluated for this endpoint. 'n' (number analysed) =number of subjects evaluable at specified time points. 99999 signifies data could not be estimated as the value was below the LLOQ (58). Here, "99" and "9999" signifies that lower and upper limit of 95% CI could not be estimated because only one subject was analysed. Here, "88888" signifies that data could not be estimated as the data was greater than upper limit of quantification. "99999" signifies that data could not be estimated as no subjects were available for the analysis. Due to the change in planned analysis, data was not collected and analysed for Cohort 2b and thus no data was reported for this endpoint.

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

End point timeframe:

Days 29, 183, 190, 211, 366, 373 and 394

Notes:

[135] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                         | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|--|--|--|--|------------------------------|
| Subject group type                       | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed              | 51   | 23   | 26   | 15                           |
| Units: Titers                            |  |  |  |                              |
| geometric mean (confidence interval 95%) |  |  |  |                              |
| Day 29 (n =51, 23, 26, 15)               | 311 (235 to 411)   | 326 (258 to 411)                             | 369 (251 to 542)                             | 99999 (99999 to 99999)       |
| Day 183 (n =34, 18, 15, 1)               | 241 (179 to 324)   | 379 (214 to 672)                             | 172 (107 to 277)                             | 833 (99 to 9999)             |
| Day 190 (n =32, 16, 13, 1)               | 208 (149 to 290)   | 1576 (976 to 2544)                           | 162 (88 to 301)                              | 961 (99 to 9999)             |
| Day 211 (n =28, 14, 14, 1)               | 216 (150 to 311)   | 2035 (1202 to 3446)                          | 157 (96 to 256)                              | 486 (99 to 9999)             |
| Day 366 (n =21, 13, 6, 0)                | 224 (131 to 383)   | 1137 (661 to 1955)                           | 124 (60 to 258)                              | 9999 (9999 to 9999)          |
| Day 373 (n =17, 11, 4, 0)                | 245 (138 to 435)   | 1248 (566 to 2753)                           | 973 (240 to 3954)                            | 9999 (9999 to 9999)          |
| Day 394 (n =13, 11, 3, 0)                | 297 (152 to 581)   | 1387 (612 to 3143)                           | 3061 (141 to 88888)                          | 9999 (9999 to 9999)          |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Geometric Mean Titers (GMTs) of SARS-CoV-2 Neutralizing Antibodies to the Wild Type Virus Neutralizing Assay (VNA)

|                 |   |
|-----------------|---|
| End point title | Cohort 3: Geometric Mean Titers (GMTs) of SARS-CoV-2 Neutralizing Antibodies to the Wild Type Virus Neutralizing Assay (VNA) <sup>[136]</sup> |
|-----------------|---|

End point description:

GMTs of SARS-CoV-2 neutralizing antibodies to the Wild-type VNA were reported. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated as the value was below the LLOQ (58). Here, "9999" signifies that data could not be estimated as no subjects were available for the analysis.

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

End point timeframe:

Days 15, 29, 87, 100, 114 and 268

Notes:

[136] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                         | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|--|---|---|---|---|
| Subject group type                       | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed              | 23  | 24  | 25  | 23  |
| Units: Titers                            |   |   |   |   |
| geometric mean (confidence interval 95%) |   |   |   |   |
| Day 15 (n =11,10,14,10,10)               | 190 (100 to 360)  | 153 (90 to 261)                                   | 209 (121 to 361)  | 140 (70 to 280)                                   |
| Day 29 (n =23, 24, 25, 23, 22)           | 267 (183 to 389)  | 229 (152 to 346)                                  | 261 (168 to 406)  | 174 (131 to 233)                                  |
| Day 87 (19, 21, 22, 20, 19)              | 224 (134 to 375)  | 165 (114 to 238)                                  | 245 (174 to 346)  | 198 (126 to 309)                                  |
| Day 100 (n =19, 22, 22, 19, 19)          | 878 (521 to 1478)   | 168 (106 to 266)                                  | 574 (367 to 897)  | 178 (97 to 329)                                   |
| Day 114 (n =19, 22, 22, 19, 19)          | 954 (551 to 1652)   | 164 (98 to 273)                                   | 895 (498 to 1609)   | 158 (78 to 319)                                   |
| Day 268 (n =0, 19, 0, 0, 0)              | 9999 (9999 to 9999)   | 114 (65 to 201)                                   | 9999 (9999 to 9999)   | 9999 (9999 to 9999)                               |

| End point values                         | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|--|----------------------------------|--|--|--|
| Subject group type                       | Reporting group                  |  |  |  |
| Number of subjects analysed              | 22                               |  |  |  |
| Units: Titers                            |                                  |  |  |  |
| geometric mean (confidence interval 95%) |                                  |  |  |  |
| Day 15 (n =11,10,14,10,10)               | 99999 (99999 to 99999)           |  |  |  |
| Day 29 (n =23, 24, 25, 23, 22)           | 99999 (99999 to 99999)           |  |  |  |
| Day 87 (19, 21, 22, 20, 19)              | 99999 (99999 to 99999)           |  |  |  |
| Day 100 (n =19, 22, 22, 19, 19)          | 99999 (99999 to 99999)           |  |  |  |
| Day 114 (n =19, 22, 22, 19, 19)          | 99999 (99999 to 99999)           |  |  |  |
| Day 268 (n =0, 19, 0, 0, 0)              | 9999 (9999 to 9999)              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1a: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: Interferon (IFN)g+ or Interleukin 2+ (IL2+) not Helper cell type 2 (TH2)

|                 |  |
|-----------------|--|
| End point title | Cohort 1a: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: Interferon (IFN)g+ or Interleukin 2+ (IL2+) not Helper cell type 2 (TH2) <sup>[137]</sup> |
|-----------------|--|

# End point description:

Percentage of subjects with SARS-Cov2 S Specific CD4+ T-cell Responses for IFNg+ or IL2+ not Helper cell type 2 (TH2) was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Due to the change in planned analysis, data was not collected and analysed for Cohort 1b and thus no data was reported for this endpoint. "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

# End point timeframe:

Baseline, Days 15, 29, 57, 71, 85, 239 and 422

# Notes:

[137] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|----------------------------------|--|--|--|--|
| Subject group type               | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed      | 37   | 39   | 35   | 35   |
| Units: Percentage of subjects    |  |  |  |  |
| number (confidence interval 95%) |  |  |  |  |
| Baseline (n=37, 39, 35, 35, 39)  | 8 (2 to 22)  | 8 (2 to 21)  | 0 (0 to 10)  | 3 (0 to 15)  |
| Day 15 (n =37, 38, 36, 34, 39)   | 76 (59 to 88)  | 76 (60 to 89)                                      | 83 (67 to 94)  | 82 (65 to 93)                                      |
| Day 29 (n =37, 37, 36, 32, 37)   | 73 (56 to 86)  | 70 (53 to 84)                                      | 78 (61 to 90)  | 72 (53 to 86)                                      |
| Day 57 (n =36, 36, 35, 30, 33)   | 75 (58 to 88)  | 53 (35 to 70)                                      | 77 (60 to 90)  | 63 (44 to 80)                                      |
| Day 71 (n =35, 36, 34, 28, 32)   | 63 (45 to 79)  | 47 (30 to 65)                                      | 91 (76 to 98)  | 61 (41 to 79)                                      |
| Day 85 (n =37, 35, 33, 29, 34)   | 68 (50 to 82)  | 46 (29 to 63)                                      | 85 (68 to 95)  | 59 (39 to 76)                                      |
| Day 239 (n =34, 34, 12, 13, 0)   | 47 (30 to 65)  | 47 (30 to 65)                                      | 75 (43 to 95)  | 38 (14 to 68)                                      |
| Day 422 (n =22, 23, 13, 11, 0)   | 27 (11 to 50)  | 43 (23 to 66)                                      | 54 (25 to 81)  | 36 (11 to 69)                                      |

| End point values                 | COHORT 1A:<br>Placebo,<br>Placebo |  |  |  |
|----------------------------------|-----------------------------------|--|--|--|
| Subject group type               | Reporting group                   |  |  |  |
| Number of subjects analysed      | 39                                |  |  |  |
| Units: Percentage of subjects    |                                   |  |  |  |
| number (confidence interval 95%) |                                   |  |  |  |
| Baseline (n=37, 39, 35, 35, 39)  | 0 (0 to 9)                        |  |  |  |
| Day 15 (n =37, 38, 36, 34, 39)   | 8 (2 to 21)                       |  |  |  |
| Day 29 (n =37, 37, 36, 32, 37)   | 19 (8 to 35)                      |  |  |  |
| Day 57 (n =36, 36, 35, 30, 33)   | 12 (3 to 28)                      |  |  |  |
| Day 71 (n =35, 36, 34, 28, 32)   | 16 (5 to 33)                      |  |  |  |
| Day 85 (n =37, 35, 33, 29, 34)   | 12 (3 to 27)                      |  |  |  |
| Day 239 (n =34, 34, 12, 13, 0)   | 99999 (99999<br>to 99999)         |  |  |  |

|                                |                        |  |  |  |
|--------------------------------|------------------------|--|--|--|
| Day 422 (n =22, 23, 13, 11, 0) | 99999 (99999 to 99999) |  |  |  |
|--------------------------------|------------------------|--|--|--|

## Statistical analyses

No statistical analyses for this end point

### Secondary: Cohort 1a: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IL4+ or IL5+ or IL13+ and CD40L+

|                 |  |
|-----------------|--|
| End point title | Cohort 1a: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IL4+ or IL5+ or IL13+ and CD40L+ <sup>[138]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with SARS-Cov2 S Specific CD4+ T-cell responses for IL4+ or IL5+ or IL13+ and CD40L+ was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Due to the change in planned analysis, data was not collected and analysed for Cohort 1b and thus no data was reported for this endpoint. "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

End point timeframe:

Baseline, Day 15, 29, 57, 71, 85, 239 and 422

Notes:

[138] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|----------------------------------|--|--|--|--|
| Subject group type               | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed      | 37   | 39   | 36   | 39   |
| Units: Percentage of Subjects    |  |  |  |  |
| number (confidence interval 95%) |  |  |  |  |
| Baseline (n =37, 39, 35, 39, 39) | 0 (0 to 9)   | 0 (0 to 9)   | 0 (0 to 10)  | 0 (0 to 10)  |
| Day 15 (n =37, 38, 36, 34, 39)   | 0 (0 to 9)   | 3 (0 to 14)  | 0 (0 to 10)  | 0 (0 to 10)  |
| Day 29 (n =37, 37, 36, 32, 37)   | 0 (0 to 9)   | 0 (0 to 9)   | 0 (0 to 10)  | 0 (0 to 11)  |
| Day 57 (n =36, 36, 35, 33, 30)   | 0 (0 to 10)  | 0 (0 to 10)  | 0 (0 to 10)  | 0 (0 to 12)  |
| Day 71 (n =35, 36, 34, 28, 32)   | 0 (0 to 10)  | 0 (0 to 10)  | 0 (0 to 10)  | 4 (0 to 18)  |
| Day 85 (n =37, 35, 33, 29, 34)   | 0 (0 to 9)   | 0 (0 to 10)  | 0 (0 to 11)  | 0 (0 to 12)  |
| Day 239 (n =34, 34, 12, 13, 0)   | 3 (0 to 15)  | 6 (1 to 20)  | 17 (2 to 48)   | 0 (0 to 25)  |
| Day 422 (n =22, 23, 13, 11, 0)   | 5 (0 to 23)  | 4 (0 to 22)  | 0 (0 to 25)  | 9 (0 to 41)  |



|                                  |                                   |  |  |  |
|----------------------------------|-----------------------------------|--|--|--|
| <b>End point values</b>          | COHORT 1A:<br>Placebo,<br>Placebo |  |  |  |
| Subject group type               | Reporting group                   |  |  |  |
| Number of subjects analysed      | 39                                |  |  |  |
| Units: Percentage of Subjects    |                                   |  |  |  |
| number (confidence interval 95%) |                                   |  |  |  |
| Baseline (n =37, 39, 35, 39, 39) | 0 (0 to 9)                        |  |  |  |
| Day 15 (n =37, 38, 36, 34, 39)   | 0 (0 to 9)                        |  |  |  |
| Day 29 (n =37, 37, 36, 32, 37)   | 0 (0 to 9)                        |  |  |  |
| Day 57 (n =36, 36, 35, 33, 30)   | 6 (1 to 20)                       |  |  |  |
| Day 71 (n =35, 36, 34, 28, 32)   | 0 (0 to 11)                       |  |  |  |
| Day 85 (n =37, 35, 33, 29, 34)   | 0 (0 to 10)                       |  |  |  |
| Day 239 (n =34, 34, 12, 13, 0)   | 99999 (99999<br>to 99999)         |  |  |  |
| Day 422 (n =22, 23, 13, 11, 0)   | 99999 (99999<br>to 99999)         |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1a: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA)

|                 |   |
|-----------------|---|
| End point title | Cohort 1a: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA) <sup>[139]</sup> |
|-----------------|---|

End point description:

Percentage of subjects with antibodies binding to SARS-CoV-2 S protein as measured by enzyme-linked immunosorbent assay (ELISA) was reported. Per protocol immunogenicity (PPI) population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points.

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

End point timeframe:

Days 29, 57, 71, 85, 239 and 422

Notes:

[139] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                                  |  |  |  |  |
|----------------------------------|--|--|--|--|
| <b>End point values</b>          | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
| Subject group type               | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed      | 64   | 63   | 67   | 64   |
| Units: Percentage of subjects    |  |  |  |  |
| number (confidence interval 95%) |  |  |  |  |
| Day 29 (n=64, 63, 67, 64, 70)    | 98.4 (91.5 to<br>100.0)                                      | 98.4 (91.5 to<br>100.0)                            | 100.0 (94.6 to<br>100.0)                                     | 98.4 (91.6 to<br>100.0)                            |

|                                 |                       |                       |                       |                       |
|---------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Day 57 (n=65, 64, 66, 61, 66)   | 100.0 (94.4 to 100.0) | 98.4 (91.6 to 100.0)  | 100.0 (94.6 to 100.0) | 96.7 (88.7 to 99.6)   |
| Day 71 (n=62, 59, 64, 56, 61)   | 100.0 (94.1 to 100.0) | 100.0 (93.9 to 100.0) | 100.0 (94.4 to 100.0) | 96.4 (87.7 to 99.6)   |
| Day 85 (n =64, 61, 63, 58, 64 ) | 100.0 (94.3 to 100.0) | 98.4 (91.2 to 100.0)  | 100.0 (94.3 to 100.0) | 96.6 (88.1 to 99.6)   |
| Day 239 (n =61, 59, 56, 52, 49) | 100.0 (94.0 to 100.0) | 98.3 (90.9 to 100.0)  | 100.0 (93.6 to 100.0) | 94.2 (84.1 to 98.8)   |
| Day 422 (n =44, 50, 46, 42, 6)  | 100.0 (91.8 to 100.0) | 92.0 (80.8 to 97.8)   | 100.0 (92.3 to 100.0) | 100.0 (91.6 to 100.0) |

|                                  |                                   |  |  |  |
|----------------------------------|-----------------------------------|--|--|--|
| <b>End point values</b>          | COHORT 1A:<br>Placebo,<br>Placebo |  |  |  |
| Subject group type               | Reporting group                   |  |  |  |
| Number of subjects analysed      | 70                                |  |  |  |
| Units: Percentage of subjects    |                                   |  |  |  |
| number (confidence interval 95%) |                                   |  |  |  |
| Day 29 (n=64, 63, 67, 64, 70)    | 1.4 (0.0 to 7.7)                  |  |  |  |
| Day 57 (n=65, 64, 66, 61, 66)    | 1.5 (0.0 to 8.2)                  |  |  |  |
| Day 71 (n=62, 59, 64, 56, 61)    | 1.6 (0.0 to 8.8)                  |  |  |  |
| Day 85 (n =64, 61, 63, 58, 64 )  | 4.7 (1.0 to 13.1)                 |  |  |  |
| Day 239 (n =61, 59, 56, 52, 49)  | 2.0 (0.1 to 10.9)                 |  |  |  |
| Day 422 (n =44, 50, 46, 42, 6)   | 66.7 (22.3 to 95.7)               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohorts 2a: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: Interferon (IFN)g+ or Interleukin 2+ (IL2+) not Helper cell type 2 (TH2)

|                 |   |
|-----------------|---|
| End point title | Cohorts 2a: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: Interferon (IFN)g+ or Interleukin 2+ (IL2+) not Helper cell type 2 (TH2) <sup>[140]</sup> |
|-----------------|---|

End point description:

Percentage of subjects with SARS-Cov2 S Specific CD4+ T-cell Responses for IFNg+ or IL2+ not Helper cell type 2 (TH2) was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

|                           |           |
|---------------------------|-----------|
| End point type            | Secondary |
| End point timeframe:      |           |
| Baseline, Days 29 and 366 |           |

Notes:

[140] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|----------------------------------|--|--|--|------------------------------|
| Subject group type               | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed      | 11   | 5  | 5  | 3                            |
| Units: Percentage of subjects    |  |  |  |                              |
| number (confidence interval 95%) |  |  |  |                              |
| Baseline (n= 11, 5, 5, 3)        | 9 (0 to 41)  | 20 (1 to 72)                                 | 0 (0 to 52)                                  | 33 (1 to 91)                 |
| Day 29 (n =11, 5, 5, 3)          | 82 (48 to 98)  | 100 (48 to 100.0)                            | 80 (28 to 99)                                | 0 (0 to 71)                  |
| Day 366 (n =9, 5, 3, 0)          | 11 (0 to 48)   | 20 (1 to 72)                                 | 0 (0 to 71)                                  | 99999 (99999 to 99999)       |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohorts 2a: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA)

|                 |  |
|-----------------|--|
| End point title | Cohorts 2a: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA) <sup>[141]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with antibodies binding to SARS-CoV-2 S protein as measured by ELISA was reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated and reported as no subjects were analysed.

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

End point timeframe:

Days 8, 29, 183, 190, 211, 366, 373 and 394

Notes:

[141] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|----------------------------------|--|--|--|------------------------------|
| Subject group type               | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed      | 51   | 23   | 26   | 15                           |
| Units: Percentage of subjects    |  |  |  |                              |
| number (confidence interval 95%) |  |  |  |                              |
| Day 8 (n= 50, 23, 26, 15)        | 6.0 (1.3 to 16.5)  | 0.0 (0.0 to 14.8)                            | 0.0 (0.0 to 13.2)                            | 0.0 (0.0 to 21.8)            |

|                            |                       |                       |                       |                        |
|----------------------------|-----------------------|-----------------------|-----------------------|------------------------|
| Day 29 (n= 51, 23, 26, 15) | 98.0 (89.4 to 99.9)   | 100.0 (85.2 to 100.0) | 100.0 (86.8 to 100.0) | 6.7 (0.2 to 31.9)      |
| Day 183 (n =34, 18, 15, 1) | 97.0 (84.2 to 99.9)   | 100.0 (81.5 to 100.0) | 86.7 (59.5 to 98.3)   | 100.0 (2.5 to 100.0)   |
| Day 190 (n =32, 16, 13, 1) | 96.8 (83.3 to 99.9)   | 100.0 (79.4 to 100.0) | 92.3 (64.0 to 99.8)   | 100.0 (2.5 to 100.0)   |
| Day 211 (n =28, 14, 14, 1) | 100.0 (87.2 to 100.0) | 100.0 (76.8 to 100.0) | 85.7 (57.2 to 98.2)   | 100.0 (2.5 to 100.0)   |
| Day 366 (n= 21, 13, 6, 0)  | 95.2 (76.2 to 99.9)   | 100.0 (75.3 to 100.0) | 83.3 (35.9 to 99.6)   | 99999 (99999 to 99999) |
| Day 373 (n =17, 11, 4, 0)  | 94.1 (71.3 to 99.9)   | 100.0 (71.5 to 100.0) | 100.0 (39.8 to 100.0) | 99999 (99999 to 99999) |
| Day 394 (n =13, 11, 3, 0)  | 92.3 (64.0 to 99.8)   | 100.0 (71.5 to 100.0) | 100.0 (29.2 to 100.0) | 99999 (99999 to 99999) |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Cohort 2b: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IL4+ or IL5+ or IL13+ and CD40L+

|                 |  |
|-----------------|--|
| End point title | Cohort 2b: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IL4+ or IL5+ or IL13+ and CD40L+ <sup>[142]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with SARS-Cov2 S Specific CD4+ T-cell responses for IL4+ or IL5+ or IL13+ and CD40L+ was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

End point timeframe:

Baseline, Days 29, 57, 85 and 422

Notes:

[142] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 2B: Ad265e10, Ad26 5e10, B: PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|----------------------------------|--|---|---|---------------------------|
| Subject group type               | Reporting group                                    | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed      | 12   | 5   | 6   | 2                         |
| Units: Percentage of subjects    |  |   |   |                           |
| number (confidence interval 95%) |  |   |   |                           |
| Baseline (n =12, 5, 6, 2)        | 0 (0 to 26)  | 0 (0 to 52)                                       | 0 (0 to 46)                                       | 0 (0 to 84)               |
| Day 29 (n =11, 5, 6, 2)          | 0 (0 to 28)  | 0 (0 to 52)                                       | 0 (0 to 46)                                       | 0 (0 to 84)               |
| Day 57 (n =12, 5, 5, 2)          | 0 (0 to 26)  | 0 (0 to 52)                                       | 0 (0 to 52)                                       | 0 (0 to 84)               |
| Day 85 (n =10, 5, 6, 2)          | 0 (0 to 31)  | 0 (0 to 52)                                       | 0 (0 to 46)                                       | 0 (0 to 84)               |

|                        |             |             |             |                        |
|------------------------|-------------|-------------|-------------|------------------------|
| Day 422 (n =1,1, 1, 0) | 0 (0 to 98) | 0 (0 to 98) | 0 (0 to 98) | 99999 (99999 to 99999) |
|------------------------|-------------|-------------|-------------|------------------------|

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohorts 2b: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA)

|                 |  |
|-----------------|--|
| End point title | Cohorts 2b: Percentage of Subjects With Antibodies Binding to SARS-CoV-2 S Protein as Measured by Enzyme-linked Immunosorbent Assay (ELISA) <sup>[143]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with antibodies binding to SARS-CoV-2 S protein as measured by ELISA was reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated and reported as no subjects were analysed.

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

End point timeframe:

Days 8, 29, 57, 64, 85, 239, 246, 267 and 422

Notes:

[143] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 2B: Ad265e10, Ad26 5e10, B: PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|----------------------------------|--|---|---|---------------------------|
| Subject group type               | Reporting group                                    | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed      | 51   | 28  | 24  | 12                        |
| Units: Percentage of subjects    |  |   |   |                           |
| number (confidence interval 95%) |  |   |   |                           |
| Day 8 (n =51, 26, 23, 12)        | 0.0 (0.0 to 7.0)                                   | 3.8 (0.1 to 19.6)                                 | 4.5 (0.1 to 22.8)                                 | 0.0 (0.0 to 26.5)         |
| Day 29 (n =49, 28, 24, 12)       | 95.9 (86.0 to 99.5)                                | 96.4 (81.7 to 99.9)                               | 100.0 (84.6 to 100.0)                             | 0.0 (0.0 to 26.5)         |
| Day 57 (n =49, 26, 24, 12)       | 95.8 (85.7 to 99.5)                                | 100.0 (86.8 to 100.0)                             | 100.0 (84.6 to 100.0)                             | 0.0 (0.0 to 26.5)         |
| Day 64 (n =46, 24, 23, 11)       | 100.0 (92.1 to 100.0)                              | 100.0 (85.8 to 100.0)                             | 100.0 (83.9 to 100.0)                             | 0.0 (0.0 to 28.5)         |
| Day 85 (n =46, 26, 21, 11)       | 97.8 (88.2 to 99.9)                                | 100.0 (86.8 to 100.0)                             | 100.0 (82.4 to 100.0)                             | 0.0 (0.0 to 28.5)         |
| Day 239 (n =40, 22, 20, 0)       | 97.4 (86.5 to 99.9)                                | 95.5 (77.2 to 99.9)                               | 94.4 (72.7 to 99.9)                               | 99999 (99999 to 99999)    |
| Day 246 (n =38, 15, 17, 0)       | 97.4 (86.2 to 99.9)                                | 100.0 (78.2 to 100.0)                             | 93.8 (69.8 to 99.8)                               | 99999 (99999 to 99999)    |
| Day 267 (n =37, 18, 18, 0)       | 97.2 (85.5 to 99.9)                                | 100.0 (81.5 to 100.0)                             | 93.8 (69.8 to 99.8)                               | 99999 (99999 to 99999)    |
| Day 422 (n =5, 3, 4, 0)          | 100.0 (47.8 to 100.0)                              | 100.0 (29.2 to 100.0)                             | 100.0 (29.2 to 100.0)                             | 99999 (99999 to 99999)    |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Cohort 1a: Percentage of Subjects With SARS-Cov2 S Specific CD8+ T-cell Responses: IFNg+ or IL2+

|                 |   |
|-----------------|---|
| End point title | Cohort 1a: Percentage of Subjects With SARS-Cov2 S Specific CD8+ T-cell Responses: IFNg+ or IL2+[144] |
|-----------------|---|

End point description:

Percentage of subjects with SARS-Cov2 S Specific CD8+ T-cell Responses for IFNg+ or IL2+ was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis. Due to the change in planned analysis, data was not collected and analysed for Cohort 1b and thus no data was reported for this endpoint.

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

End point timeframe:

Baseline, Days 15, 29, 57, 71, 85, 239 and 422

Notes:

[144] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|----------------------------------|--|--|--|--|
| Subject group type               | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed      | 37   | 39   | 36   | 35   |
| Units: Percentage of subjects    |  |  |  |  |
| number (confidence interval 95%) |  |  |  |  |
| Baseline (n =37, 39, 35, 35, 39) | 0 (0 to 9)   | 3 (0 to 13)  | 0 (0 to 10)  | 3 (0 to 15)  |
| Day 15 (n =37, 38, 36, 34, 39)   | 54 (37 to 71)  | 45 (29 to 62)                                      | 56 (38 to 72)  | 71 (53 to 85)                                      |
| Day 29 (n =37, 37, 36, 32, 37)   | 68 (50 to 82)  | 59 (42 to 75)                                      | 81 (64 to 92)  | 75 (57 to 89)                                      |
| Day 57 (n =36, 36, 35, 30 33)    | 72 (55 to 86)  | 81 (64 to 92)                                      | 89 (73 to 97)  | 83 (65 to 94)                                      |
| Day 71 (n =34, 36, 35, 28, 32)   | 68 (49 to 83)  | 72 (55 to 86)                                      | 86 (70 to 95)  | 79 (59 to 92)                                      |
| Day 85 (n =37, 35, 33, 29, 34)   | 73 (56 to 86)  | 69 (51 to 83)                                      | 88 (72 to 97)  | 83 (64 to 94)                                      |
| Day 239 (n =34, 34, 12, 13, 0)   | 62 (44 to 78)  | 62 (44 to 78)                                      | 92 (62 to 100)   | 85 (55 to 98)                                      |
| Day 422 (n =23, 23, 13, 11, 0)   | 52 (31 to 73)  | 57 (34 to 77)                                      | 77 (46 to 95)  | 82 (48 to 98)                                      |

|                  |            |  |  |  |
|------------------|------------|--|--|--|
| End point values | COHORT 1A: |  |  |  |
|------------------|------------|--|--|--|

|                                  | Placebo,<br>Placebo       |  |  |  |
|----------------------------------|---------------------------|--|--|--|
| Subject group type               | Reporting group           |  |  |  |
| Number of subjects analysed      | 39                        |  |  |  |
| Units: Percentage of subjects    |                           |  |  |  |
| number (confidence interval 95%) |                           |  |  |  |
| Baseline (n =37, 39, 35, 35, 39) | 5 (1 to 17)               |  |  |  |
| Day 15 (n =37, 38, 36, 34, 39)   | 8 (2 to 21)               |  |  |  |
| Day 29 (n =37, 37, 36, 32, 37)   | 3 (0 to 14)               |  |  |  |
| Day 57 (n =36, 36, 35, 30, 33)   | 6 (1 to 20)               |  |  |  |
| Day 71 (n =34, 36, 35, 28, 32)   | 9 (2 to 25)               |  |  |  |
| Day 85 (n =37, 35, 33, 29, 34)   | 9 (2 to 24)               |  |  |  |
| Day 239 (n =34, 34, 12, 13, 0)   | 99999 (99999<br>to 99999) |  |  |  |
| Day 422 (n =23, 23, 13, 11, 0)   | 99999 (99999<br>to 99999) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2a: Percentage of Subjects With SARS-Cov2 S Specific CD8+ T-cell Responses: IFNg+ or IL2+

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Percentage of Subjects With SARS-Cov2 S Specific CD8+ T-cell Responses: IFNg+ or IL2+ <sup>[145]</sup> |
|-----------------|---|

End point description:

Percentage of subjects with SARS-Cov2 S Specific CD8+ T-cell Responses for IFNg+ or IL2+ was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

End point timeframe:

Baseline, Day 29 and 366

Notes:

[145] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|----------------------------------|--|--|--|------------------------------|
| Subject group type               | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed      | 11   | 5  | 5  | 3                            |
| Units: Percentage of subjects    |  |  |  |                              |
| number (confidence interval 95%) |  |  |  |                              |
| Baseline (n =11, 5, 5, 3)        | 0 (0 to 28)  | 0 (0 to 52)                                  | 0 (0 to 52)                                  | 0 (0 to 71)                  |
| Day 29 (n =11,5, 5, 3)           | 91 (59 to 100)   | 100 (48 to 100)                              | 100 (48 to 100)                              | 0 (0 to 71)                  |

|                         |               |               |                 |                        |
|-------------------------|---------------|---------------|-----------------|------------------------|
| Day 366 (n =9, 4, 3, 0) | 78 (40 to 97) | 75 (19 to 99) | 100 (29 to 100) | 99999 (99999 to 99999) |
|-------------------------|---------------|---------------|-----------------|------------------------|

## Statistical analyses

No statistical analyses for this end point

### Secondary: Cohort 3: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IFN g+ or IL2+ not Helper cell type 2 (TH2)

|                 |  |
|-----------------|--|
| End point title | Cohort 3: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IFN g+ or IL2+ not Helper cell type 2 (TH2) <sup>[146]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with SARS-Cov2 S Specific CD4+ T-cell Responses for IFNg+ or IL2+ not Helper cell type 2 (TH2) was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

End point timeframe:

Baseline, Days 15, 29, 87, 100, 114 and 268

Notes:

[146] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|----------------------------------|---|---|---|---|
| Subject group type               | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed      | 37  | 35  | 33  | 40  |
| Units: Percentage of subjects    |   |   |   |   |
| number (confidence interval 95%) |   |   |   |   |
| Baseline (n =37, 35, 33, 40, 35) | 0 (0 to 9)  | 0 (0 to 10)                                       | 3 (0 to 16)   | 0 (0 to 9)  |
| Day 15 (n =38, 35, 33, 39, 35)   | 61 (43 to 76)   | 63 (45 to 79)                                     | 67 (48 to 82)   | 62 (45 to 77)                                     |
| Day 29 (n =38, 36, 34, 41, 35)   | 66 (49 to 80)   | 69 (52 to 84)                                     | 68 (49 to 83)   | 76 (60 to 88)                                     |
| Day 87 (n =31, 27, 23, 33, 26)   | 42 (25 to 61)   | 48 (29 to 68)                                     | 39 (20 to 61)   | 52 (34 to 69)                                     |
| Day 100 (n =33, 33, 27, 36, 30)  | 61 (42 to 77)   | 61 (42 to 77)                                     | 78 (58 to 91)   | 58 (41 to 74)                                     |
| Day 114 (n =34, 32, 29, 36, 29)  | 71 (53 to 85)   | 69 (50 to 84)                                     | 69 (49 to 85)   | 44 (28 to 62)                                     |
| Day 268 (n =29, 26, 10, 14, 0)   | 59 (39 to 76)   | 73 (52 to 88)                                     | 40 (12 to 74)   | 57 (29 to 82)                                     |

|                  |                                  |  |  |  |
|------------------|----------------------------------|--|--|--|
| End point values | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|------------------|----------------------------------|--|--|--|



|                                  |                        |  |  |  |
|----------------------------------|------------------------|--|--|--|
| Subject group type               | Reporting group        |  |  |  |
| Number of subjects analysed      | 35                     |  |  |  |
| Units: Percentage of subjects    |                        |  |  |  |
| number (confidence interval 95%) |                        |  |  |  |
| Baseline (n =37, 35, 33, 40, 35) | 6 (1 to 19)            |  |  |  |
| Day 15 (n =38, 35, 33, 39, 35)   | 6 (1 to 19)            |  |  |  |
| Day 29 (n =38, 36, 34, 41, 35)   | 14 (5 to 30)           |  |  |  |
| Day 87 (n =31, 27, 23, 33, 26)   | 4 (0 to 20)            |  |  |  |
| Day 100 (n =33, 33, 27, 36, 30)  | 3 (0 to 17)            |  |  |  |
| Day 114 (n =34, 32, 29, 36, 29)  | 17 (6 to 36)           |  |  |  |
| Day 268 (n =29, 26, 10, 14, 0)   | 99999 (99999 to 99999) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Cohorts 3: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IL4+ or IL5+ or IL13+ and CD40L+

|                 |  |
|-----------------|--|
| End point title | Cohorts 3: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IL4+ or IL5+ or IL13+ and CD40L+ <sup>[147]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with SARS-Cov2 S Specific CD4+ T-cell responses for IL4+ or IL5+ or IL13+ and CD40L+ was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

End point timeframe:

Baseline, Days 15, 29, 87, 100, 114 and 268

Notes:

[147] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|----------------------------------|---|---|---|---|
| Subject group type               | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed      | 37  | 35  | 33  | 40  |
| Units: Percentage of subjects    |   |   |   |   |
| number (confidence interval 95%) |   |   |   |   |
| Baseline (n =37, 35, 33, 40, 35) | 0 (0 to 9)  | 0 (0 to 10)                                       | 0 (0 to 11)   | 0 (0 to 9)  |
| Day 15 (n =38, 35, 33, 39, 35)   | 0 (0 to 9)  | 0 (0 to 10)                                       | 3 (0 to 16)   | 0 (0 to 9)  |
| Day 29 (n =38, 36, 34, 41, 35)   | 0 (0 to 9)  | 0 (0 to 10)                                       | 0 (0 to 10)   | 0 (0 to 9)  |
| Day 87 (n =31, 27, 23, 33, 26)   | 0 (0 to 11)   | 0 (0 to 13)                                       | 4 (0 to 22)   | 0 (0 to 11)                                       |
| Day 100 (n =33, 33, 27, 36, 30)  | 6 (1 to 20)   | 0 (0 to 11)                                       | 0 (0 to 13)   | 0 (0 to 10)                                       |
| Day 114 (n =34, 32, 29, 36, 29)  | 0 (0 to 10)   | 0 (0 to 11)                                       | 0 (0 to 12)   | 0 (0 to 10)                                       |

|                                |             |             |              |             |
|--------------------------------|-------------|-------------|--------------|-------------|
| Day 268 (n =29, 26, 10, 14, 0) | 7 (1 to 23) | 8 (1 to 25) | 20 (3 to 56) | 7 (0 to 34) |
|--------------------------------|-------------|-------------|--------------|-------------|

|                                  |                                  |  |  |  |
|----------------------------------|----------------------------------|--|--|--|
| <b>End point values</b>          | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
| Subject group type               | Reporting group                  |  |  |  |
| Number of subjects analysed      | 35                               |  |  |  |
| Units: Percentage of subjects    |                                  |  |  |  |
| number (confidence interval 95%) |                                  |  |  |  |
| Baseline (n =37, 35, 33, 40, 35) | 0 (0 to 10)                      |  |  |  |
| Day 15 (n =38, 35, 33, 39, 35)   | 0 (0 to 10)                      |  |  |  |
| Day 29 (n =38, 36, 34, 41, 35)   | 0 (0 to 10)                      |  |  |  |
| Day 87 (n =31, 27, 23, 33, 26)   | 0 (0 to 13)                      |  |  |  |
| Day 100 (n =33, 33, 27, 36, 30)  | 0 (0 to 12)                      |  |  |  |
| Day 114 (n =34, 32, 29, 36, 29)  | 0 (0 to 12)                      |  |  |  |
| Day 268 (n =29, 26, 10, 14, 0)   | 99999 (99999<br>to 99999)        |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Percentage of Subjects With SARS-Cov2 S Specific CD8+ T-cell Responses: IFNg+ or IL2+

|                 |  |
|-----------------|--|
| End point title | Cohort 3: Percentage of Subjects With SARS-Cov2 S Specific CD8+ T-cell Responses: IFNg+ or IL2+ <sup>[148]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with SARS-Cov2 S Specific CD8+ T-cell Responses for IFNg+ or IL2+ was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

End point timeframe:

Baseline, Days 15, 29, 87, 100, 114 and 268

Notes:

[148] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

|                               |   |   |   |   |
|-------------------------------|---|---|---|---|
| <b>End point values</b>       | COHORT 3:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 3:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 3:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
| Subject group type            | Reporting group   | Reporting group                                   | Reporting group   | Reporting group                                   |
| Number of subjects analysed   | 36  | 35  | 33  | 39  |
| Units: Percentage of subjects |   |   |   |   |

| number (confidence interval 95%) |               |               |               |               |
|----------------------------------|---------------|---------------|---------------|---------------|
| Baseline (n =36, 34, 31, 39, 31) | 3 (0 to 15)   | 0 (0 to 10)   | 6 (1 to 21)   | 0 (0 to 9)    |
| Day 15 (n =34, 35, 31, 38, 33)   | 35 (20 to 54) | 23 (10 to 40) | 26 (12 to 45) | 26 (13 to 43) |
| Day 29 (n =36, 35, 33, 39, 33)   | 58 (41 to 74) | 51 (34 to 69) | 52 (34 to 69) | 64 (47 to 79) |
| Day 87 (n =29, 26, 22, 31, 23)   | 59 (39 to 76) | 58 (37 to 77) | 45 (24 to 68) | 71 (52 to 86) |
| Day 100 (n =31, 33, 26, 36, 27)  | 65 (45 to 81) | 52 (34 to 69) | 65 (44 to 83) | 67 (49 to 81) |
| Day 114 (n =32, 32, 26, 34, 26)  | 75 (57 to 89) | 47 (29 to 65) | 62 (41 to 80) | 68 (49 to 83) |
| Day 268 (n =28, 26, 9, 14, 0)    | 57 (37 to 76) | 50 (30 to 70) | 78 (40 to 97) | 71 (42 to 92) |

| End point values                 | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|----------------------------------|----------------------------------|--|--|--|
| Subject group type               | Reporting group                  |  |  |  |
| Number of subjects analysed      | 33                               |  |  |  |
| Units: Percentage of subjets     |                                  |  |  |  |
| number (confidence interval 95%) |                                  |  |  |  |
| Baseline (n =36, 34, 31, 39, 31) | 0 (0 to 11)                      |  |  |  |
| Day 15 (n =34, 35, 31, 38, 33)   | 3 (0 to 16)                      |  |  |  |
| Day 29 (n =36, 35, 33, 39, 33)   | 0 (0 to 11)                      |  |  |  |
| Day 87 (n =29, 26, 22, 31, 23)   | 0 (0 to 15)                      |  |  |  |
| Day 100 (n =31, 33, 26, 36, 27)  | 0 (0 to 13)                      |  |  |  |
| Day 114 (n =32, 32, 26, 34, 26)  | 0 (0 to 13)                      |  |  |  |
| Day 268 (n =28, 26, 9, 14, 0)    | 99999 (99999<br>to 99999)        |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2b: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to ( $\geq$ ) 1 and Less Than ( $<$ ) 1

|                 |   |
|-----------------|---|
| End point title | Cohort 2b: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to ( $\geq$ ) 1 and Less Than ( $<$ ) 1 <sup>[149]</sup> |
|-----------------|---|

End point description:

Percentage of subjects with Th1 (IFN-g OR IL2 NOT TH2) /Th2 (IL4 OR IL5 OR IL13 AND CD40L) ratio  $\geq 1$  and  $< 1$  was reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated and reported as no subjects were analysed.

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

End point timeframe:

Days 29, 57, 85 and 422

Notes:

[149] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                          | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL(PL/Ad26 5e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|---|--|---|---|---------------------------|
| Subject group type                        | Reporting group                                      | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed               | 9  | 4   | 3   | 0 <sup>[150]</sup>        |
| Units: Percentage of subjects             |  |   |   |                           |
| number (confidence interval 95%)          |  |   |   |                           |
| Day 29: Th1/Th2 $\geq 1$ (n =9, 2, 3, 0)  | 100 (66 to 100)                                      | 100 (16 to 100)                                   | 100 (29 to 100)                                   | ( to )                    |
| Day 29: Th1/Th2 $< 1$ (n =9, 2, 3, 0)     | 0 (0 to 34)  | 0 (0 to 84)                                       | 0 (0 to 71)                                       | ( to )                    |
| Day 57: Th1/Th2 $\geq 1$ (n =9, 4, 1, 0)  | 100 (66 to 100)                                      | 100 (40 to 100)                                   | 100 (3 to 100)                                    | ( to )                    |
| Day 57: Th1/Th2 $< 1$ (n =9, 4, 1, 0)     | 0 (0 to 34)  | 0 (0 to 60)                                       | 0 (0 to 98)                                       | ( to )                    |
| Day 85: Th1/Th2 $\geq 1$ (n =6, 4, 3, 0)  | 100 (54 to 100)                                      | 100 (40 to 100)                                   | 100 (29 to 100)                                   | ( to )                    |
| Day 85: Th1/Th2 $< 1$ (n =6, 4, 3, 0)     | 0 (0 to 46)  | 0 (0 to 60)                                       | 0 (0 to 71)                                       | ( to )                    |
| Day 422: Th1/Th2 $\geq 1$ (n =0, 0, 1, 0) | 99999 (99999 to 99999)                               | 99999 (99999 to 99999)                            | 100 (3 to 100)                                    | ( to )                    |
| Day 422: Th1/Th2 $< 1$ (n =0, 0, 1, 0)    | 99999 (99999 to 99999)                               | 99999 (99999 to 99999)                            | 0 (0 to 98)                                       | ( to )                    |

Notes:

[150] - No subjects was available for the analysis at the specified timepoint.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to ( $\geq$ ) 1 and Less Than ( $<$ ) 1

|                 |  |
|-----------------|--|
| End point title | Cohort 3: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to ( $\geq$ ) 1 and Less Than ( $<$ ) 1 <sup>[151]</sup> |
|-----------------|--|

End point description:

Percentage of subjects with Th1 (IFN-g OR IL2 NOT TH2) /Th2 (IL4 OR IL5 OR IL13 AND CD40L) ratio  $\geq 1$  and  $< 1$  was reported. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

End point timeframe:

Days 15, 29, 87, 100, 114 and 268

Notes:

[151] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10) | COHORT 3: Ad26 5e10, PL(AHBV: Ad26 5e10) | COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10) | COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10) |
|----------------------------------|---|--|---|--|
| Subject group type               | Reporting group                                 | Reporting group                          | Reporting group                                 | Reporting group                          |
| Number of subjects analysed      | 25  | 25                                       | 23  | 30                                       |
| Units: Percentage of subjects    |   |  |   |  |
| number (confidence interval 95%) |   |  |   |  |

|   |                 |                 |                 |                 |
|---|-----------------|-----------------|-----------------|-----------------|
| Day 15: Th1/Th2 ratio $\geq 1$ (n =23, 22, 22, 24, 2) | 100 (85 to 100) | 100 (85 to 100) | 100 (85 to 100) | 100 (86 to 100) |
| Day 15: Th1/Th2 ratio $< 1$ (n =23, 22, 22, 24, 2)    | 0 (0 to 15)     | 0 (0 to 15)     | 0 (0 to 15)     | 0 (0 to 14)     |
| Day 29: Th1/Th2 ratio $\geq 1$ (n =25, 25, 23, 30, 4) | 100 (86 to 100) | 100 (86 to 100) | 100 (85 to 100) | 100 (88 to 100) |
| Day 29: Th1/Th2 ratio $< 1$ (n =25, 25, 23, 30, 4)    | 0 (0 to 14)     | 0 (0 to 14)     | 0 (0 to 15)     | 0 (0 to 12)     |
| Day 87: Th1/Th2 ratio $\geq 1$ (n=13,12,9,17,1)       | 100 (75 to 100) | 100 (74 to 100) | 100 (66 to 100) | 100 (80 to 100) |
| Day 87: Th1/Th2 ratio $< 1$ (n=13,12,9,17,1)          | 0 (0 to 25)     | 0 (0 to 26)     | 0 (0 to 34)     | 0 (0 to 20)     |
| Day 100: Th1/Th2 ratio $\geq 1$ (n=20,19,21,21,1)     | 100 (83 to 100) | 100 (82 to 100) | 100 (84 to 100) | 100 (84 to 100) |
| Day 100: Th1/Th2 ratio $< 1$ (n=20,19,21,21,1)        | 0 (0 to 17)     | 0 (0 to 18)     | 0 (0 to 16)     | 0 (0 to 16)     |
| Day 114: Th1/Th2 ratio $\geq 1$ (n=24,20,20,16,5)     | 100 (86 to 100) | 100 (83 to 100) | 100 (83 to 100) | 100 (79 to 100) |
| Day 114: Th1/Th2 ratio $< 1$ (n=24,20,20,16,5)        | 0 (0 to 14)     | 0 (0 to 17)     | 0 (0 to 17)     | 0 (0 to 21)     |
| Day 268: Th1/Th2 ratio $\geq 1$ (n=16,17,4,8,0)       | 100 (79 to 100) | 94 (73 to 100)  | 80 (28 to 99)   | 89 (52 to 100)  |
| Day 268: Th1/Th2 ratio $< 1$ (n=16,17,4,8,0)          | 0 (0 to 21)     | 6 (0 to 27)     | 20 (1 to 72)    | 11 (0 to 48)    |

| End point values                                      | COHORT 3:<br>Placebo,<br>Placebo |  |  |  |
|---|----------------------------------|--|--|--|
| Subject group type                                    | Reporting group                  |  |  |  |
| Number of subjects analysed                           | 4                                |  |  |  |
| Units: Percentage of subjects                         |                                  |  |  |  |
| number (confidence interval 95%)                      |                                  |  |  |  |
| Day 15: Th1/Th2 ratio $\geq 1$ (n =23, 22, 22, 24, 2) | 100 (16 to 100)                  |  |  |  |
| Day 15: Th1/Th2 ratio $< 1$ (n =23, 22, 22, 24, 2)    | 0 (0 to 84)                      |  |  |  |
| Day 29: Th1/Th2 ratio $\geq 1$ (n =25, 25, 23, 30, 4) | 100 (40 to 100)                  |  |  |  |
| Day 29: Th1/Th2 ratio $< 1$ (n =25, 25, 23, 30, 4)    | 0 (0 to 60)                      |  |  |  |
| Day 87: Th1/Th2 ratio $\geq 1$ (n=13,12,9,17,1)       | 100 (3 to 100)                   |  |  |  |
| Day 87: Th1/Th2 ratio $< 1$ (n=13,12,9,17,1)          | 0 (0 to 98)                      |  |  |  |
| Day 100: Th1/Th2 ratio $\geq 1$ (n=20,19,21,21,1)     | 100 (3 to 100)                   |  |  |  |
| Day 100: Th1/Th2 ratio $< 1$ (n=20,19,21,21,1)        | 0 (0 to 98)                      |  |  |  |
| Day 114: Th1/Th2 ratio $\geq 1$ (n=24,20,20,16,5)     | 100 (48 to 100)                  |  |  |  |
| Day 114: Th1/Th2 ratio $< 1$ (n=24,20,20,16,5)        | 0 (0 to 52)                      |  |  |  |
| Day 268: Th1/Th2 ratio $\geq 1$ (n=16,17,4,8,0)       | 99999 (99999 to 99999)           |  |  |  |
| Day 268: Th1/Th2 ratio $< 1$ (n=16,17,4,8,0)          | 99999 (99999 to 99999)           |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Cohort 2b: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: Interferon (IFN)g+ or Interleukin 2+ (IL2+) not Helper cell type 2 (TH2)

|                 |  |
|-----------------|--|
| End point title | Cohort 2b: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: Interferon (IFN)g+ or Interleukin 2+ (IL2+) not Helper cell type 2 (TH2) <sup>[152]</sup> |
|-----------------|--|

#### End point description:

Percentage of subjects with SARS-Cov2 S Specific CD4+ T-cell Responses for IFNg+ or IL2+ not Helper cell type 2 (TH2) was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

#### End point timeframe:

Baseline, Days 15, 29, 57, 85 and 422

#### Notes:

[152] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|----------------------------------|--|---|---|---------------------------|
| Subject group type               | Reporting group                                  | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed      | 12   | 5   | 6   | 2                         |
| Units: Percentage of subjects    |  |   |   |                           |
| number (confidence interval 95%) |  |   |   |                           |
| Baseline (n= 12, 5, 6, 2)        | 25 (5 to 57)                                     | 20 (1 to 72)                                      | 17 (0 to 64)                                      | 0 (0 to 84)               |
| Day 29 (n =11, 5, 6, 2)          | 82 (48 to 98)                                    | 40 (5 to 85)                                      | 67 (22 to 96)                                     | 0 (0 to 84)               |
| Day 57 (n =12, 5, 5, 2)          | 75 (43 to 95)                                    | 80 (28 to 99)                                     | 40 (5 to 85)                                      | 0 (0 to 84)               |
| Day 85 (n =12, 5, 6, 2)          | 60 (26 to 88)                                    | 80 (28 to 99)                                     | 50 (12 to 88)                                     | 0 (0 to 84)               |
| Day 422 (n =1,1,1,0)             | 0 (0 to 98)                                      | 0 (0 to 98)                                       | 100 (3 to 100)                                    | 99999 (99999 to 99999)    |

## Statistical analyses

No statistical analyses for this end point

**Secondary: Cohort 2a: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IL4+ or IL5+ or IL13+ and CD40L+**

|                 |  |
|-----------------|--|
| End point title | Cohort 2a: Percentage of Subjects With SARS-Cov2 S Specific CD4+ T-cell Responses: IL4+ or IL5+ or IL13+ and CD40L+ <sup>[153]</sup> |
|-----------------|--|

## End point description:

Percentage of subjects with SARS-Cov2 S Specific CD4+ T-cell responses for IL4+ or IL5+ or IL13+ and CD40L+ was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

## End point timeframe:

Baseline, Day 29 and 366

## Notes:

[153] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 2A:<br>Ad26 5e10, B:<br>PL(PL/AHBV:<br>Ad26 5e10) | COHORT 2A:<br>Ad26 5e10, B:<br>Ad26 5e10, PL | COHORT 2A:<br>Ad26 5e10, B:<br>PL, Ad26 5e10 | COHORT 2A:<br>Placebo, B: PL |
|----------------------------------|--|--|--|------------------------------|
| Subject group type               | Reporting group  | Reporting group                              | Reporting group                              | Reporting group              |
| Number of subjects analysed      | 11   | 5  | 5  | 3                            |
| Units: Percentage of subjects    |  |  |  |                              |
| number (confidence interval 95%) |  |  |  |                              |
| Baseline (n =11, 5, 5, 3)        | 0 (0 to 28)  | 0 (0 to 52)                                  | 0 (0 to 52)                                  | 0 (0 to 71)                  |
| Day 29 (n =11, 5, 5, 3)          | 0 (0 to 28)  | 0 (0 to 52)                                  | 0 (0 to 52)                                  | 0 (0 to 71)                  |
| Day 366 (n =9, 5, 3, 0)          | 0 (0 to 34)  | 0 (0 to 52)                                  | 0 (0 to 71)                                  | 99999 (99999 to 99999)       |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Cohort 2b: Percentage of Subjects With SARS-Cov2 S Specific CD8+ T-cell Responses: IFNg+ or IL2+**

|                 |   |
|-----------------|---|
| End point title | Cohort 2b: Percentage of Subjects With SARS-Cov2 S Specific CD8+ T-cell Responses: IFNg+ or IL2+ <sup>[154]</sup> |
|-----------------|---|

## End point description:

Percentage of subjects with SARS-Cov2 S Specific CD8+ T-cell Responses for IFNg+ or IL2+ was reported. Cellular immunogenicity was measured by intracellular cytokine staining (ICS), allowing characterization of individual CD4 and CD8 T cell immune responses to vaccination. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, "99999" signifies that data could not be estimated as no subjects were available for the analysis.

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

## End point timeframe:

Baseline, Days 29, 57, 85 and 422

Notes:

[154] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                 | COHORT 2B: Ad265e10, Ad26 5e10, B: PL(PL/Ad265e10) | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2B: Placebo, B: PL |
|----------------------------------|--|---|---|---------------------------|
| Subject group type               | Reporting group                                    | Reporting group                                   | Reporting group                                   | Reporting group           |
| Number of subjects analysed      | 12   | 5   | 6   | 2                         |
| Units: Percentage of subjects    |  |   |   |                           |
| number (confidence interval 95%) |  |   |   |                           |
| Baseline (n =12, 5, 6, 2)        | 8 (0 to 38)  | 20 (1 to 72)                                      | 0 (0 to 46)                                       | 0 (0 to 84)               |
| Day 29 (n =11, 5, 6, 2)          | 82 (48 to 98)                                      | 80 (28 to 99)                                     | 83 (36 to 100)                                    | 0 (0 to 84)               |
| Day 57 (n =12, 5, 5, 2)          | 92 (62 to 100)                                     | 100 (48 to 100)                                   | 80 (28 to 99)                                     | 0 (0 to 84)               |
| Day 85 (n =10, 5, 6, 2)          | 80 (44 to 97)                                      | 100 (48 to 100)                                   | 83 (36 to 100)                                    | 0 (0 to 84)               |
| Day 422 (n =1, 1, 1, 0)          | 100 (3 to 100)                                     | 100 (3 to 100)                                    | 100 (3 to 100)                                    | 99999 (99999 to 99999)    |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1a: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to ( $\geq$ ) 1 and Less Than ( $<$ ) 1

|                 |   |
|-----------------|---|
| End point title | Cohort 1a: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to ( $\geq$ ) 1 and Less Than ( $<$ ) 1 <sup>[155]</sup> |
|-----------------|---|

End point description:

Percentage of subjects with Th1 (IFN-g OR IL2 NOT TH2) /Th2 (IL4 OR IL5 OR IL13 AND CD40L) ratio  $\geq 1$  and  $< 1$  was reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated and reported as no subjects were analysed. Due to the change in planned analysis, data was not collected and analysed for Cohort 1b and thus no data was reported for this endpoint.

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

End point timeframe:

Days 29, 57, 71, 85, 239 and 422

Notes:

[155] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.



| End point values                           | COHORT 1A:<br>Ad26 5e10,<br>Ad26<br>5e10(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 5e10,<br>PL(AHBV: Ad26<br>5e10) | COHORT 1A:<br>Ad26 1e11,<br>Ad26<br>1e11(AHBV:<br>Ad26 5e10) | COHORT 1A:<br>Ad26 1e11,<br>PL(AHBV: Ad26<br>5e10) |
|--|--|--|--|--|
| Subject group type                         | Reporting group  | Reporting group                                    | Reporting group  | Reporting group                                    |
| Number of subjects analysed                | 27   | 29   | 29   | 28   |
| Units: Percentage of subjects              |  |  |  |  |
| number (confidence interval 95%)           |  |  |  |  |
| Day 15: Th1/Th2 >=1 (n =27, 29, 29, 28, 3) | 100 (87 to 100)  | 100 (88 to 100)                                    | 100 (88 to 100)  | 100 (88 to 100)                                    |
| Day 15: Th1/Th2 <1 (n =27, 29, 29, 28, 3)  | 0 (0 to 13)  | 0 (0 to 12)  | 0 (0 to 12)  | 0 (0 to 12)  |
| Day 29: Th1/Th2 >=1 (n =27, 25, 28, 23, 6) | 100 (87 to 100)  | 100 (86 to 100)                                    | 100 (88 to 100)  | 100 (85 to 100)                                    |
| Day 29: Th1/Th2 <1 (n =27, 25, 28, 23, 6)  | 0 (0 to 13)  | 0 (0 to 14)  | 0 (0 to 12)  | 0 (0 to 15)  |
| Day 57: Th1/Th2 >=1 (n =27, 19, 27, 19, 4) | 100 (87 to 100)  | 100 (82 to 100)                                    | 100 (87 to 100)  | 100 (82 to 100)                                    |
| Day 57: Th1/Th2 <1 (n =27, 19, 27, 19, 4)  | 0 (0 to 13)  | 0 (0 to 18)  | 0 (0 to 13)  | 0 (0 to 18)  |
| Day 71: Th1/Th2 >=1 (n =22, 17, 30, 17, 4) | 100 (85 to 100)  | 100 (80 to 100)                                    | 100 (88 to 100)  | 100 (80 to 100)                                    |
| Day 71: Th1/Th2 <1 (n =22, 17, 30, 17, 4)  | 0 (0 to 15)  | 0 (0 to 20)  | 0 (0 to 12)  | 0 (0 to 20)  |
| Day 85: Th1/Th2 >=1 (n =25, 15, 28, 16, 4) | 100 (86 to 100)  | 100 (78 to 100)                                    | 100 (88 to 100)  | 100 (79 to 100)                                    |
| Day 85: Th1/Th2 <1 (n =25, 15, 28, 16, 4)  | 0 (0 to 14)  | 0 (0 to 22)  | 0 (0 to 12)  | 0 (0 to 21)  |
| Day 239: Th1/Th2 >=1 (n =15, 16, 9, 4, 0)  | 100 (78 to 100)  | 100 (79 to 100)                                    | 100 (66 to 100)  | 100 (40 to 100)                                    |
| Day 239: Th1/Th2 <1 (n =15, 16, 9, 4, 0)   | 0 (0 to 22)  | 0 (0 to 21)  | 0 (0 to 34)  | 0 (0 to 60)  |
| Day 422: Th1/Th2 >=1 (n =6, 10, 7, 4, 0)   | 86 (42 to 100)   | 100 (69 to 100)                                    | 100 (59 to 100)  | 100 (40 to 100)                                    |
| Day 422: Th1/Th2 <1 (n =6, 10, 7, 4, 0)    | 14 (0 to 58)   | 0 (0 to 31)  | 0 (0 to 41)  | 0 (0 to 60)  |

| End point values                           | COHORT 1A:<br>Placebo,<br>Placebo |  |  |  |
|--|-----------------------------------|--|--|--|
| Subject group type                         | Reporting group                   |  |  |  |
| Number of subjects analysed                | 6                                 |  |  |  |
| Units: Percentage of subjects              |                                   |  |  |  |
| number (confidence interval 95%)           |                                   |  |  |  |
| Day 15: Th1/Th2 >=1 (n =27, 29, 29, 28, 3) | 100 (29 to 100)                   |  |  |  |
| Day 15: Th1/Th2 <1 (n =27, 29, 29, 28, 3)  | 0 (0 to 71)                       |  |  |  |
| Day 29: Th1/Th2 >=1 (n =27, 25, 28, 23, 6) | 100 (54 to 100)                   |  |  |  |
| Day 29: Th1/Th2 <1 (n =27, 25, 28, 23, 6)  | 0 (0 to 46)                       |  |  |  |
| Day 57: Th1/Th2 >=1 (n =27, 19, 27, 19, 4) | 100 (40 to 100)                   |  |  |  |
| Day 57: Th1/Th2 <1 (n =27, 19, 27, 19, 4)  | 0 (0 to 60)                       |  |  |  |

|   |                        |  |  |  |
|---|------------------------|--|--|--|
| Day 71: Th1/Th2 $\geq 1$ (n =22, 17, 30, 17, 4) | 100 (40 to 100)        |  |  |  |
| Day 71: Th1/Th2 $< 1$ (n =22, 17, 30, 17, 4)    | 0 (0 to 60)            |  |  |  |
| Day 85: Th1/Th2 $\geq 1$ (n =25, 15, 28, 16, 4) | 100 (40 to 100)        |  |  |  |
| Day 85: Th1/Th2 $< 1$ (n =25, 15, 28, 16, 4)    | 0 (0 to 60)            |  |  |  |
| Day 239: Th1/Th2 $\geq 1$ (n =15, 16, 9, 4, 0)  | 99999 (99999 to 99999) |  |  |  |
| Day 239: Th1/Th2 $< 1$ (n =15, 16, 9, 4, 0)     | 99999 (99999 to 99999) |  |  |  |
| Day 422: Th1/Th2 $\geq 1$ (n =6, 10, 7, 4, 0)   | 99999 (99999 to 99999) |  |  |  |
| Day 422: Th1/Th2 $< 1$ (n =6, 10, 7, 4, 0)      | 99999 (99999 to 99999) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Cohort 2a: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to ( $\geq$ ) 1 and Less Than ( $<$ ) 1

|                 |   |
|-----------------|---|
| End point title | Cohort 2a: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to ( $\geq$ ) 1 and Less Than ( $<$ ) 1 <sup>[156]</sup> |
|-----------------|---|

End point description:

Percentage of subjects with Th1 (IFN-g OR IL2 NOT TH2) /Th2 (IL4 OR IL5 OR IL13 AND CD40L) ratio  $\geq 1$  and  $< 1$  was reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expecting to impact the immunogenicity outcomes. Here N (number of subjects analysed) signifies subjects evaluated for this endpoint. Here 'n' (number analysed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated and reported as no subjects were analysed.

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

End point timeframe:

Days 29 and 366

Notes:

[156] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be reported for specified arms only.

| End point values                          | COHORT 2A: Ad26 5e10, B: PL(PL/AHBV: Ad26 5e10) | COHORT 2A: Ad26 5e10, B: Ad26 5e10, PL | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2A: Placebo, B: PL |
|---|---|--|--|---------------------------|
| Subject group type                        | Reporting group                                 | Reporting group                        | Reporting group                        | Reporting group           |
| Number of subjects analysed               | 9   | 4                                      | 4                                      | 0 <sup>[157]</sup>        |
| Units: Percentage of subjects             |   |  |  |                           |
| number (confidence interval 95%)          |   |  |  |                           |
| Day 29: Th1/Th2 $\geq 1$ (n =9, 4, 4, 0)  | 100 (66 to 100)                                 | 100 (40 to 100)                        | 100 (40 to 100)                        | ( to )                    |
| Day 29: Th1/Th2 $< 1$ (n =9, 4, 4, 0)     | 0 (0 to 34)                                     | 0 (0 to 60)                            | 0 (0 to 60)                            | ( to )                    |
| Day 366: Th1/Th2 $\geq 1$ (n =1, 1, 0, 0) | 100 (3 to 100)                                  | 100 (3 to 100)                         | 99999 (99999 to 99999)                 | ( to )                    |

|                                     |             |             |                        |        |
|-------------------------------------|-------------|-------------|------------------------|--------|
| Day 366: Th1/Th2 <1 (n =1, 1, 0, 0) | 0 (0 to 98) | 0 (0 to 98) | 99999 (99999 to 99999) | ( to ) |
|-------------------------------------|-------------|-------------|------------------------|--------|

Notes:

[157] - No subject was available for the analysis at the specified timepoint.

**Statistical analyses**

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Cohorts 1, 2b and 3: From Day 1 up to 787 days; Cohort 2a: Day 1 up to 731 days

Adverse event reporting additional description:

FAS included all subjects with at least one vaccine administration documented.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 25.1 |
|--------------------|------|

### Reporting groups

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | COHORT 1A: Placebo, Placebo |
|-----------------------|-----------------------------|

Reporting group description:

Subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 1A: Ad26 1e11, PL(,AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 1A: Ad26 1e11, Ad26 1e11(,AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 1A: Ad26 5e10, PL(,AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 1A: Ad26 5e10, Ad26 5e10(,AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Subjects received a single intramuscular (IM) injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 1B: Ad26 5e10, Ad26 5e10(,AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2A: Ad26 5e10, B: PL(,PL/AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Group 1 and Group 4 subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and matching placebo at 6 and 12 months as Booster 1 and Booster 2 vaccines. Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Booster 2 Vaccination.

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | COHORT 1B: Placebo, Placebo |
|-----------------------|-----------------------------|

Reporting group description:

Subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). Subjects who had previously received 1 or more doses of any

COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 1B: Ad26 1e11, PL(,AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 1B: Ad26 1e11, Ad26 1e11(,AHBV: Ad26 5e10) |
|-----------------------|---|

Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S  $1 \times 10^{11}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and a matching placebo on Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2A: Ad26 5e10, B: Ad26 5e10, PL |
|-----------------------|--|

Reporting group description:

Group 2 subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp after 6 months (Booster 1) and matching placebo after 12 months (Booster 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Booster 2 Vaccination.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 3: Ad26 5e10, Ad26 5e10(,AHBV: Ad26 5e10) |
|-----------------------|--|

Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | COHORT 2B: Placebo, B: PL |
|-----------------------|---------------------------|

Reporting group description:

Group 5 subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), Day 57 (Vaccination 2), 8 Month (Booster 1) and 14 months (Booster 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Booster 2 vaccination.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 |
|-----------------------|---|

Reporting group description:

Group 3 subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and matching placebo at 6 months after vaccination 2 as Booster 1 vaccination and Ad26.COV2.S  $5 \times 10^{10}$  vp at 12 months after vaccination 2 as Booster 2 vaccination. Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Booster 2 Vaccination.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 |
|-----------------------|--|

Reporting group description:

Group 3 subjects received a single IM injection of Ad26.COV2.S  $5 \times 10^{10}$  vp on Day 1 (Vaccination 1) and a matching placebo injection after 6 months (Booster 1) and Ad26.COV2.S  $5 \times 10^{10}$  vp after 12 months (Booster 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Booster 2 Vaccination.

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | COHORT 2A: Placebo, B: Placebo |
|-----------------------|--------------------------------|

Reporting group description:

Group 5 subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (Vaccination 1), 6 months (Booster 1) and 12 months (Booster 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of  $5 \times 10^{10}$  vp Ad26.COV2.S. 6 months after Booster 2 Vaccination.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL(,PL/AHBV: Ad26 5e10) |
|-----------------------|---|

# Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S 5\*10<sup>10</sup> vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and matching placebo at 6 and 12 months after vaccination 2 as Booster 1 and Booster 2 vaccines. Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. 6 months after Booster 2 Vaccination.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL |
|-----------------------|---|

# Reporting group description:

Group 2 subjects received a single IM injection of Ad26.COV2.S 5\*10<sup>10</sup> vp on Day 1 (Vaccination 1), Day 57 (Vaccination 2) and 6 months after Vaccination 2(Booster 1). At 12 months after vaccination 2, subjects received placebo matching to Ad26.COV2.S vaccine (Booster 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. 6 months after Booster 2 Vaccination.

|                       |  |
|-----------------------|--|
| Reporting group title | COHORT 3: Ad26 1e11, Ad26 1e11(,AHBV: Ad26 5e10) |
|-----------------------|--|

# Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 3: Ad26 5e10, PL(,AHBV: Ad26 5e10) |
|-----------------------|---|

# Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S 5\*10<sup>10</sup> vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |   |
|-----------------------|---|
| Reporting group title | COHORT 3: Ad26 1e11, PL(,AHBV: Ad26 5e10) |
|-----------------------|---|

# Reporting group description:

Subjects received a single IM injection of Ad26.COV2.S 1\*10<sup>11</sup> vp on Day 1 (Vaccination 1) and matching placebo on Day 57 (Vaccination 2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. 6 months after Vaccination 2.

|                       |                            |
|-----------------------|----------------------------|
| Reporting group title | COHORT 3: Placebo, Placebo |
|-----------------------|----------------------------|

# Reporting group description:

Subjects received a single IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1 (vaccination1) and 57 (Vaccination2). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of 5\*10<sup>10</sup> vp Ad26.COV2.S. 6 months after Vaccination 2.

| Serious adverse events  | COHORT 1A:<br>Placebo, Placebo | COHORT 1A: Ad26<br>1e11, PL(,AHBV:<br>Ad26 5e10) | COHORT 1A: Ad26<br>1e11, Ad26<br>1e11(,AHBV: Ad26 |
|---|--------------------------------|--|---|
| Total subjects affected by serious adverse events                   |                                |  |   |
| subjects affected / exposed   | 2 / 77 (2.60%)                 | 1 / 73 (1.37%)                                   | 1 / 75 (1.33%)                                    |
| number of deaths (all causes)                                       | 0                              | 0  | 0   |
| number of deaths resulting from adverse events                      |                                |  |   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                |  |   |
| Breast Cancer Stage Ii  |                                |  |   |
| subjects affected / exposed   | 0 / 77 (0.00%)                 | 0 / 73 (0.00%)                                   | 0 / 75 (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   |
| Surgical and medical procedures                                     |                                |  |   |

|  |                |                |                |
|--|----------------|----------------|----------------|
| Mastectomy   |                |                |                |
| subjects affected / exposed                          | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                |                |                |
| Hanging  |                |                |                |
| subjects affected / exposed                          | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Pyrexia  |                |                |                |
| subjects affected / exposed                          | 0 / 77 (0.00%) | 1 / 73 (1.37%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Immune system disorders                              |                |                |                |
| Anaphylactic Shock                                   |                |                |                |
| subjects affected / exposed                          | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Reproductive system and breast disorders             |                |                |                |
| Uterine Prolapse                                     |                |                |                |
| subjects affected / exposed                          | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                |                |                |
| Asphyxia   |                |                |                |
| subjects affected / exposed                          | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Investigations                                       |                |                |                |
| Blood Pressure Decreased                             |                |                |                |
| subjects affected / exposed                          | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 1 / 75 (1.33%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural complications       |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Craniocerebral Injury                           |                |                |                |
| subjects affected / exposed                     | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Hip Fracture                                    |                |                |                |
| subjects affected / exposed                     | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Procedural Vomiting                             |                |                |                |
| subjects affected / exposed                     | 1 / 77 (1.30%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Procedural Nausea                               |                |                |                |
| subjects affected / exposed                     | 1 / 77 (1.30%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Rib Fracture                                    |                |                |                |
| subjects affected / exposed                     | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Traumatic Fracture                              |                |                |                |
| subjects affected / exposed                     | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Wrist Fracture                                  |                |                |                |
| subjects affected / exposed                     | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Cardiac disorders                               |                |                |                |
| Atrial Fibrillation                             |                |                |                |
| subjects affected / exposed                     | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (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          |
| Coronary Artery Disease                         |                |                |                |



|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed                              | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all          | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all               | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Nervous system disorders</b>                          |                |                |                |
| Multiple Sclerosis                                       |                |                |                |
| subjects affected / exposed                              | 1 / 77 (1.30%) | 0 / 73 (0.00%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all          | 1 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all               | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Ear and labyrinth disorders</b>                       |                |                |                |
| Aural Polyp  |                |                |                |
| subjects affected / exposed                              | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all          | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all               | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Renal and urinary disorders</b>                       |                |                |                |
| Nephrolithiasis  |                |                |                |
| subjects affected / exposed                              | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all          | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all               | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Musculoskeletal and connective tissue disorders</b>   |                |                |                |
| Osteoarthritis   |                |                |                |
| subjects affected / exposed                              | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all          | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all               | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Infections and infestations</b>                       |                |                |                |
| Pneumonia Legionella                                     |                |                |                |
| subjects affected / exposed                              | 0 / 77 (0.00%) | 0 / 73 (0.00%) | 0 / 75 (0.00%) |
| occurrences causally related to treatment / all          | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all               | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Serious adverse events</b>                            |                |                |                |
| COHORT 1A: Ad26 5e10, PL(,AHBV: Ad26 5e10)               |                |                |                |
| COHORT 1A: Ad26 5e10, Ad26 5e10(,AHBV: Ad26 5e10)        |                |                |                |
| COHORT 1B: Ad26 5e10, Ad26 5e10(,AHBV: Ad26 5e10)        |                |                |                |
| <b>Total subjects affected by serious adverse events</b> |                |                |                |
| subjects affected / exposed                              | 1 / 75 (1.33%) | 0 / 77 (0.00%) | 1 / 5 (20.00%) |
| number of deaths (all causes)                            | 0              | 0              | 0              |
| number of deaths resulting from adverse events           |                |                |                |

|   |  |  |   |
|---|--|--|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps)<br>Breast Cancer Stage Ii<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all | 1 / 75 (1.33%)<br><br>0 / 1<br><br>0 / 0 | 0 / 77 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 5 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| Surgical and medical procedures<br>Mastectomy<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all   | 0 / 75 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 77 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 5 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| General disorders and administration site conditions<br>Hanging<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                               | 0 / 75 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 77 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 5 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| Pyrexia<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all   | 0 / 75 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 77 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 5 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| Immune system disorders<br>Anaphylactic Shock<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all   | 0 / 75 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 77 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 5 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| Reproductive system and breast disorders<br>Uterine Prolapse<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                                  | 0 / 75 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 77 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 5 (0.00%)<br><br>0 / 0<br><br>0 / 0 |
| Respiratory, thoracic and mediastinal disorders<br>Asphyxia<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                                   | 0 / 75 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 77 (0.00%)<br><br>0 / 0<br><br>0 / 0 | 0 / 5 (0.00%)<br><br>0 / 0<br><br>0 / 0 |

|   |                |                |               |
|---|----------------|----------------|---------------|
| Investigations                                  |                |                |               |
| Blood Pressure Decreased                        |                |                |               |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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         |
| Injury, poisoning and procedural complications  |                |                |               |
| Craniocerebral Injury                           |                |                |               |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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         |
| Hip Fracture                                    |                |                |               |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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         |
| Procedural Vomiting                             |                |                |               |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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         |
| Procedural Nausea                               |                |                |               |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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         |
| Rib Fracture                                    |                |                |               |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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         |
| Traumatic Fracture                              |                |                |               |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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         |
| Wrist Fracture                                  |                |                |               |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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         |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Cardiac disorders                               |                |                |                |
| Atrial Fibrillation                             |                |                |                |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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          |
| Coronary Artery Disease                         |                |                |                |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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          |
| Nervous system disorders                        |                |                |                |
| Multiple Sclerosis                              |                |                |                |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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          |
| Ear and labyrinth disorders                     |                |                |                |
| Aural Polyp                                     |                |                |                |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (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          |
| Renal and urinary disorders                     |                |                |                |
| Nephrolithiasis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |                |                |                |
| Osteoarthritis                                  |                |                |                |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Pneumonia Legionella                            |                |                |                |
| subjects affected / exposed                     | 0 / 75 (0.00%) | 0 / 77 (0.00%) | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>  | COHORT 2A: Ad26<br>5e10, B:<br>PL(,PL/AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo, Placebo | COHORT 1B: Ad26<br>1e11, PL(,AHBV:<br>Ad26 5e10) |
|--|---|--------------------------------|--|
| Total subjects affected by serious<br>adverse events                   |   |                                |  |
| subjects affected / exposed  | 1 / 58 (1.72%)  | 0 / 5 (0.00%)                  | 0 / 5 (0.00%)                                    |
| number of deaths (all causes)  | 0   | 0                              | 0  |
| number of deaths resulting from<br>adverse events                      |   |                                |  |
| Neoplasms benign, malignant and<br>unspecified (incl cysts and polyps) |   |                                |  |
| Breast Cancer Stage Ii   |   |                                |  |
| subjects affected / exposed  | 0 / 58 (0.00%)  | 0 / 5 (0.00%)                  | 0 / 5 (0.00%)                                    |
| occurrences causally related to<br>treatment / all                     | 0 / 0   | 0 / 0                          | 0 / 0  |
| deaths causally related to<br>treatment / all                          | 0 / 0   | 0 / 0                          | 0 / 0  |
| Surgical and medical procedures  |   |                                |  |
| Mastectomy   |   |                                |  |
| subjects affected / exposed  | 0 / 58 (0.00%)  | 0 / 5 (0.00%)                  | 0 / 5 (0.00%)                                    |
| occurrences causally related to<br>treatment / all                     | 0 / 0   | 0 / 0                          | 0 / 0  |
| deaths causally related to<br>treatment / all                          | 0 / 0   | 0 / 0                          | 0 / 0  |
| General disorders and administration<br>site conditions                |   |                                |  |
| Hanging  |   |                                |  |
| subjects affected / exposed  | 0 / 58 (0.00%)  | 0 / 5 (0.00%)                  | 0 / 5 (0.00%)                                    |
| occurrences causally related to<br>treatment / all                     | 0 / 0   | 0 / 0                          | 0 / 0  |
| deaths causally related to<br>treatment / all                          | 0 / 0   | 0 / 0                          | 0 / 0  |
| Pyrexia  |   |                                |  |
| subjects affected / exposed  | 0 / 58 (0.00%)  | 0 / 5 (0.00%)                  | 0 / 5 (0.00%)                                    |
| occurrences causally related to<br>treatment / all                     | 0 / 0   | 0 / 0                          | 0 / 0  |
| deaths causally related to<br>treatment / all                          | 0 / 0   | 0 / 0                          | 0 / 0  |
| Immune system disorders  |   |                                |  |
| Anaphylactic Shock   |   |                                |  |
| subjects affected / exposed  | 0 / 58 (0.00%)  | 0 / 5 (0.00%)                  | 0 / 5 (0.00%)                                    |
| occurrences causally related to<br>treatment / all                     | 0 / 0   | 0 / 0                          | 0 / 0  |
| deaths causally related to<br>treatment / all                          | 0 / 0   | 0 / 0                          | 0 / 0  |
| Reproductive system and breast<br>disorders                            |   |                                |  |
| Uterine Prolapse   |   |                                |  |

|   |                |               |               |
|---|----------------|---------------|---------------|
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0         |
| Respiratory, thoracic and mediastinal disorders |                |               |               |
| Asphyxia  |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Investigations                                  |                |               |               |
| Blood Pressure Decreased                        |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Injury, poisoning and procedural complications  |                |               |               |
| Craniocerebral Injury                           |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Hip Fracture                                    |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Procedural Vomiting                             |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Procedural Nausea                               |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Rib Fracture                                    |                |               |               |

|   |                |               |               |
|---|----------------|---------------|---------------|
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Traumatic Fracture                              |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Wrist Fracture                                  |                |               |               |
| subjects affected / exposed                     | 1 / 58 (1.72%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Cardiac disorders                               |                |               |               |
| Atrial Fibrillation                             |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Coronary Artery Disease                         |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Nervous system disorders                        |                |               |               |
| Multiple Sclerosis                              |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Ear and labyrinth disorders                     |                |               |               |
| Aural Polyp                                     |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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         |
| Renal and urinary disorders                     |                |               |               |
| Nephrolithiasis                                 |                |               |               |

|   |                |               |               |
|---|----------------|---------------|---------------|
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (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 and connective tissue disorders |                |               |               |
| Osteoarthritis                                  |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0         |
| Infections and infestations                     |                |               |               |
| Pneumonia Legionella                            |                |               |               |
| subjects affected / exposed                     | 0 / 58 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0         | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0         | 0 / 0         |

| <b>Serious adverse events</b>                                       | COHORT 1B: Ad26 1e11, Ad26 1e11(,AHBV: Ad26 | COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10) | COHORT 2A: Ad26 5e10, B: Ad26 5e10, PL |
|---|---|--|--|
| Total subjects affected by serious adverse events                   |   |  |  |
| subjects affected / exposed   | 0 / 5 (0.00%)                               | 0 / 5 (0.00%)                              | 0 / 29 (0.00%)                         |
| number of deaths (all causes)                                       | 0   | 0  | 0                                      |
| number of deaths resulting from adverse events                      |   |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |  |  |
| Breast Cancer Stage Ii  |   |  |  |
| subjects affected / exposed   | 0 / 5 (0.00%)                               | 0 / 5 (0.00%)                              | 0 / 29 (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                                  |
| Surgical and medical procedures                                     |   |  |  |
| Mastectomy  |   |  |  |
| subjects affected / exposed   | 0 / 5 (0.00%)                               | 0 / 5 (0.00%)                              | 0 / 29 (0.00%)                         |
| occurrences causally related to treatment / all                     | 0 / 0                                       | 0 / 0                                      | 0 / 0                                  |
| deaths causally related to treatment / all                          | 0 / 0                                       | 0 / 0                                      | 0 / 0                                  |
| General disorders and administration site conditions                |   |  |  |
| Hanging   |   |  |  |
| subjects affected / exposed   | 0 / 5 (0.00%)                               | 0 / 5 (0.00%)                              | 0 / 29 (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                                  |



|   |               |               |                |
|---|---------------|---------------|----------------|
| Pyrexia   |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Immune system disorders                         |               |               |                |
| Anaphylactic Shock                              |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Reproductive system and breast disorders        |               |               |                |
| Uterine Prolapse                                |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |               |               |                |
| Asphyxia  |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Investigations                                  |               |               |                |
| Blood Pressure Decreased                        |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Injury, poisoning and procedural complications  |               |               |                |
| Craniocerebral Injury                           |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Hip Fracture                                    |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Procedural Vomiting                             |               |               |                |

|   |               |               |                |
|---|---------------|---------------|----------------|
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Procedural Nausea                               |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Rib Fracture                                    |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Traumatic Fracture                              |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Wrist Fracture                                  |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Cardiac disorders                               |               |               |                |
| Atrial Fibrillation                             |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Coronary Artery Disease                         |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Nervous system disorders                        |               |               |                |
| Multiple Sclerosis                              |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Ear and labyrinth disorders                     |               |               |                |

|   |               |               |                |
|---|---------------|---------------|----------------|
| Aural Polyp                                     |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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          |
| Renal and urinary disorders                     |               |               |                |
| Nephrolithiasis                                 |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (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 and connective tissue disorders |               |               |                |
| Osteoarthritis                                  |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |
| Infections and infestations                     |               |               |                |
| Pneumonia Legionella                            |               |               |                |
| subjects affected / exposed                     | 0 / 5 (0.00%) | 0 / 5 (0.00%) | 0 / 29 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0         | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0         | 0 / 0          |

| <b>Serious adverse events</b>                                       | COHORT 3: Ad26 5e10, Ad26 5e10(,AHBV: Ad26 | COHORT 2B: Placebo, B: PL | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL, Ad26 5e10 |
|---|--|---------------------------|---|
| Total subjects affected by serious adverse events                   |  |                           |   |
| subjects affected / exposed   | 3 / 81 (3.70%)                             | 0 / 15 (0.00%)            | 0 / 28 (0.00%)                                    |
| number of deaths (all causes)                                       | 0  | 0                         | 0   |
| number of deaths resulting from adverse events                      |  |                           |   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |                           |   |
| Breast Cancer Stage Ii  |  |                           |   |
| subjects affected / exposed   | 0 / 81 (0.00%)                             | 0 / 15 (0.00%)            | 0 / 28 (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   |
| Surgical and medical procedures                                     |  |                           |   |
| Mastectomy  |  |                           |   |
| subjects affected / exposed   | 0 / 81 (0.00%)                             | 0 / 15 (0.00%)            | 0 / 28 (0.00%)                                    |
| occurrences causally related to treatment / all                     | 0 / 0                                      | 0 / 0                     | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0                                      | 0 / 0                     | 0 / 0   |

|  |                |                |                |
|--|----------------|----------------|----------------|
| General disorders and administration site conditions |                |                |                |
| Hanging  |                |                |                |
| subjects affected / exposed                          | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Pyrexia  |                |                |                |
| subjects affected / exposed                          | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Immune system disorders                              |                |                |                |
| Anaphylactic Shock                                   |                |                |                |
| subjects affected / exposed                          | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Reproductive system and breast disorders             |                |                |                |
| Uterine Prolapse                                     |                |                |                |
| subjects affected / exposed                          | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                |                |                |
| Asphyxia   |                |                |                |
| subjects affected / exposed                          | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Investigations                                       |                |                |                |
| Blood Pressure Decreased                             |                |                |                |
| subjects affected / exposed                          | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Injury, poisoning and procedural complications       |                |                |                |
| Craniocerebral Injury                                |                |                |                |
| subjects affected / exposed                          | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Hip Fracture                                    |                |                |                |
| subjects affected / exposed                     | 1 / 81 (1.23%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Procedural Vomiting                             |                |                |                |
| subjects affected / exposed                     | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Procedural Nausea                               |                |                |                |
| subjects affected / exposed                     | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Rib Fracture                                    |                |                |                |
| subjects affected / exposed                     | 1 / 81 (1.23%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Traumatic Fracture                              |                |                |                |
| subjects affected / exposed                     | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Wrist Fracture                                  |                |                |                |
| subjects affected / exposed                     | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Cardiac disorders                               |                |                |                |
| Atrial Fibrillation                             |                |                |                |
| subjects affected / exposed                     | 1 / 81 (1.23%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Coronary Artery Disease                         |                |                |                |
| subjects affected / exposed                     | 0 / 81 (0.00%) | 0 / 15 (0.00%) | 0 / 28 (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          |
| Nervous system disorders                        |                |                |                |

|   |  |                                |   |
|---|--|--------------------------------|---|
| Multiple Sclerosis  |  |                                |   |
| subjects affected / exposed   | 0 / 81 (0.00%)                         | 0 / 15 (0.00%)                 | 0 / 28 (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   |
| Ear and labyrinth disorders   |  |                                |   |
| Aural Polyp   |  |                                |   |
| subjects affected / exposed   | 0 / 81 (0.00%)                         | 0 / 15 (0.00%)                 | 0 / 28 (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   |
| Renal and urinary disorders   |  |                                |   |
| Nephrolithiasis   |  |                                |   |
| subjects affected / exposed   | 0 / 81 (0.00%)                         | 0 / 15 (0.00%)                 | 0 / 28 (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 and connective tissue disorders                     |  |                                |   |
| Osteoarthritis  |  |                                |   |
| subjects affected / exposed   | 0 / 81 (0.00%)                         | 0 / 15 (0.00%)                 | 0 / 28 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0                                  | 0 / 0                          | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0                                  | 0 / 0                          | 0 / 0   |
| Infections and infestations   |  |                                |   |
| Pneumonia Legionella  |  |                                |   |
| subjects affected / exposed   | 0 / 81 (0.00%)                         | 0 / 15 (0.00%)                 | 0 / 28 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0                                  | 0 / 0                          | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0                                  | 0 / 0                          | 0 / 0   |
| <b>Serious adverse events</b>                                       | COHORT 2A: Ad26 5e10, B: PL, Ad26 5e10 | COHORT 2A: Placebo, B: Placebo | COHORT 2B: Ad26 5e10, Ad26 5e10, B: PL(,PL/AHBV: Ad26 5e10) |
| Total subjects affected by serious adverse events                   |  |                                |   |
| subjects affected / exposed   | 1 / 32 (3.13%)                         | 0 / 17 (0.00%)                 | 1 / 62 (1.61%)  |
| number of deaths (all causes)                                       | 1                                      | 0                              | 1   |
| number of deaths resulting from adverse events                      |  |                                |   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |                                |   |
| Breast Cancer Stage Ii  |  |                                |   |

|  |                |                |                |
|--|----------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (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          |
| Surgical and medical procedures                      |                |                |                |
| Mastectomy   |                |                |                |
| subjects affected / exposed                          | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                |                |                |
| Hanging  |                |                |                |
| subjects affected / exposed                          | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 1 / 62 (1.61%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 1          |
| Pyrexia  |                |                |                |
| subjects affected / exposed                          | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (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          |
| Immune system disorders                              |                |                |                |
| Anaphylactic Shock                                   |                |                |                |
| subjects affected / exposed                          | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (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          |
| Reproductive system and breast disorders             |                |                |                |
| Uterine Prolapse                                     |                |                |                |
| subjects affected / exposed                          | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                |                |                |
| Asphyxia   |                |                |                |
| subjects affected / exposed                          | 1 / 32 (3.13%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 1          | 0 / 0          | 0 / 0          |
| Investigations                                       |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Blood Pressure Decreased<br>subjects affected / exposed | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to<br>treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural<br>complications       |                |                |                |
| Craniocerebral Injury                                   |                |                |                |
| subjects affected / exposed                             | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to<br>treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Hip Fracture  |                |                |                |
| subjects affected / exposed                             | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to<br>treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Procedural Vomiting                                     |                |                |                |
| subjects affected / exposed                             | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to<br>treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Procedural Nausea                                       |                |                |                |
| subjects affected / exposed                             | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to<br>treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Rib Fracture  |                |                |                |
| subjects affected / exposed                             | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to<br>treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Traumatic Fracture                                      |                |                |                |
| subjects affected / exposed                             | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to<br>treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Wrist Fracture  |                |                |                |
| subjects affected / exposed                             | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to<br>treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to<br>treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |



|   |                |                |                |
|---|----------------|----------------|----------------|
| Cardiac disorders                               |                |                |                |
| Atrial Fibrillation                             |                |                |                |
| subjects affected / exposed                     | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (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          |
| Coronary Artery Disease                         |                |                |                |
| subjects affected / exposed                     | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (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          |
| Nervous system disorders                        |                |                |                |
| Multiple Sclerosis                              |                |                |                |
| subjects affected / exposed                     | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (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          |
| Ear and labyrinth disorders                     |                |                |                |
| Aural Polyp                                     |                |                |                |
| subjects affected / exposed                     | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (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          |
| Renal and urinary disorders                     |                |                |                |
| Nephrolithiasis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (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 and connective tissue disorders |                |                |                |
| Osteoarthritis                                  |                |                |                |
| subjects affected / exposed                     | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Pneumonia Legionella                            |                |                |                |
| subjects affected / exposed                     | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                                       | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 3: Ad26 1e11, Ad26 1e11(,AHBV: Ad26 | COHORT 3: Ad26 5e10, PL(,AHBV: Ad26 5e10) |
|---|---|--|---|
| Total subjects affected by serious adverse events                   |   |  |   |
| subjects affected / exposed   | 1 / 30 (3.33%)                                    | 2 / 82 (2.44%)                             | 2 / 80 (2.50%)                            |
| number of deaths (all causes)                                       | 0   | 0  | 2   |
| number of deaths resulting from adverse events                      |   |  |   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |  |   |
| Breast Cancer Stage Ii  |   |  |   |
| subjects affected / exposed   | 0 / 30 (0.00%)                                    | 0 / 82 (0.00%)                             | 0 / 80 (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                                     |
| Surgical and medical procedures                                     |   |  |   |
| Mastectomy  |   |  |   |
| subjects affected / exposed   | 0 / 30 (0.00%)                                    | 0 / 82 (0.00%)                             | 0 / 80 (0.00%)                            |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0                                      | 0 / 0                                     |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0                                      | 0 / 0                                     |
| General disorders and administration site conditions                |   |  |   |
| Hanging   |   |  |   |
| subjects affected / exposed   | 0 / 30 (0.00%)                                    | 0 / 82 (0.00%)                             | 0 / 80 (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                                     |
| Pyrexia   |   |  |   |
| subjects affected / exposed   | 0 / 30 (0.00%)                                    | 0 / 82 (0.00%)                             | 0 / 80 (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                                     |
| Immune system disorders   |   |  |   |
| Anaphylactic Shock  |   |  |   |
| subjects affected / exposed   | 1 / 30 (3.33%)                                    | 0 / 82 (0.00%)                             | 0 / 80 (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                                     |
| Reproductive system and breast disorders                            |   |  |   |
| Uterine Prolapse  |   |  |   |
| subjects affected / exposed   | 1 / 30 (3.33%)                                    | 1 / 82 (1.22%)                             | 0 / 80 (0.00%)                            |
| occurrences causally related to treatment / all                     | 0 / 1   | 0 / 1                                      | 0 / 0                                     |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0                                      | 0 / 0                                     |

|   |                |                |                |
|---|----------------|----------------|----------------|
| Respiratory, thoracic and mediastinal disorders |                |                |                |
| Asphyxia  |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Investigations                                  |                |                |                |
| Blood Pressure Decreased                        |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Injury, poisoning and procedural complications  |                |                |                |
| Craniocerebral Injury                           |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 1 / 80 (1.25%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Hip Fracture                                    |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Procedural Vomiting                             |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Procedural Nausea                               |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Rib Fracture                                    |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Traumatic Fracture                              |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 1 / 80 (1.25%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Wrist Fracture                                  |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Cardiac disorders                               |                |                |                |
| Atrial Fibrillation                             |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Coronary Artery Disease                         |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 1 / 82 (1.22%) | 0 / 80 (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          |
| Nervous system disorders                        |                |                |                |
| Multiple Sclerosis                              |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Ear and labyrinth disorders                     |                |                |                |
| Aural Polyp                                     |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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          |
| Renal and urinary disorders                     |                |                |                |
| Nephrolithiasis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (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 and connective tissue disorders |                |                |                |
| Osteoarthritis                                  |                |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Infections and infestations</b>              |                |                |                |
| Pneumonia Legionella                            |                |                |                |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 1 / 80 (1.25%) |
| 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>  | COHORT 3: Ad26 1e11, PL(,AHBV: Ad26 5e10) | COHORT 3: Placebo, Placebo |  |
| Total subjects affected by serious adverse events                          |   |                            |  |
| subjects affected / exposed  | 1 / 79 (1.27%)                            | 2 / 81 (2.47%)             |  |
| number of deaths (all causes)  | 1   | 0                          |  |
| number of deaths resulting from adverse events                             |   |                            |  |
| <b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b> |   |                            |  |
| Breast Cancer Stage Ii   |   |                            |  |
| subjects affected / exposed  | 0 / 79 (0.00%)                            | 0 / 81 (0.00%)             |  |
| occurrences causally related to treatment / all                            | 0 / 0                                     | 0 / 0                      |  |
| deaths causally related to treatment / all                                 | 0 / 0                                     | 0 / 0                      |  |
| <b>Surgical and medical procedures</b>                                     |   |                            |  |
| Mastectomy   |   |                            |  |
| subjects affected / exposed  | 1 / 79 (1.27%)                            | 0 / 81 (0.00%)             |  |
| occurrences causally related to treatment / all                            | 0 / 1                                     | 0 / 0                      |  |
| deaths causally related to treatment / all                                 | 0 / 0                                     | 0 / 0                      |  |
| <b>General disorders and administration site conditions</b>                |   |                            |  |
| Hanging  |   |                            |  |
| subjects affected / exposed  | 0 / 79 (0.00%)                            | 0 / 81 (0.00%)             |  |
| occurrences causally related to treatment / all                            | 0 / 0                                     | 0 / 0                      |  |
| deaths causally related to treatment / all                                 | 0 / 0                                     | 0 / 0                      |  |
| Pyrexia  |   |                            |  |
| subjects affected / exposed  | 0 / 79 (0.00%)                            | 0 / 81 (0.00%)             |  |
| occurrences causally related to treatment / all                            | 0 / 0                                     | 0 / 0                      |  |
| deaths causally related to treatment / all                                 | 0 / 0                                     | 0 / 0                      |  |
| <b>Immune system disorders</b>   |   |                            |  |

|   |                |                |  |
|---|----------------|----------------|--|
| Anaphylactic Shock                              |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Reproductive system and breast disorders        |                |                |  |
| Uterine Prolapse                                |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Respiratory, thoracic and mediastinal disorders |                |                |  |
| Asphyxia  |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Investigations                                  |                |                |  |
| Blood Pressure Decreased                        |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Injury, poisoning and procedural complications  |                |                |  |
| Craniocerebral Injury                           |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Hip Fracture                                    |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Procedural Vomiting                             |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Procedural Nausea                               |                |                |  |

|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Rib Fracture                                    |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Traumatic Fracture                              |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Wrist Fracture                                  |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Cardiac disorders                               |                |                |  |
| Atrial Fibrillation                             |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Coronary Artery Disease                         |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Nervous system disorders                        |                |                |  |
| Multiple Sclerosis                              |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Ear and labyrinth disorders                     |                |                |  |
| Aural Polyp                                     |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 1 / 81 (1.23%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

|   |                |                |  |
|---|----------------|----------------|--|
| Renal and urinary disorders                     |                |                |  |
| Nephrolithiasis                                 |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Musculoskeletal and connective tissue disorders |                |                |  |
| Osteoarthritis                                  |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 1 / 81 (1.23%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| Infections and infestations                     |                |                |  |
| Pneumonia Legionella                            |                |                |  |
| subjects affected / exposed                     | 0 / 79 (0.00%) | 0 / 81 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

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

| <b>Non-serious adverse events</b>                     | COHORT 1A:<br>Placebo, Placebo | COHORT 1A: Ad26<br>1e11, PL(,AHBV:<br>Ad26 5e10) | COHORT 1A: Ad26<br>1e11, Ad26<br>1e11(,AHBV: Ad26 |
|---|--------------------------------|--|---|
| Total subjects affected by non-serious adverse events |                                |  |   |
| subjects affected / exposed                           | 29 / 77 (37.66%)               | 66 / 73 (90.41%)                                 | 69 / 75 (92.00%)                                  |
| Vascular disorders                                    |                                |  |   |
| Hypertension  |                                |  |   |
| subjects affected / exposed                           | 0 / 77 (0.00%)                 | 1 / 73 (1.37%)                                   | 0 / 75 (0.00%)                                    |
| occurrences (all)                                     | 0                              | 1  | 0   |
| General disorders and administration site conditions  |                                |  |   |
| Chills  |                                |  |   |
| subjects affected / exposed                           | 2 / 77 (2.60%)                 | 11 / 73 (15.07%)                                 | 6 / 75 (8.00%)                                    |
| occurrences (all)                                     | 2                              | 11   | 6   |
| Fatigue   |                                |  |   |
| subjects affected / exposed                           | 5 / 77 (6.49%)                 | 1 / 73 (1.37%)                                   | 1 / 75 (1.33%)                                    |
| occurrences (all)                                     | 6                              | 1  | 1   |
| Fatigue(Solicited)                                    |                                |  |   |
| subjects affected / exposed                           | 17 / 77 (22.08%)               | 53 / 73 (72.60%)                                 | 58 / 75 (77.33%)                                  |
| occurrences (all)                                     | 21                             | 63   | 89  |



|   |                       |                        |                         |
|---|-----------------------|------------------------|-------------------------|
| Injection Site Haemorrhage<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 77 (0.00%)<br>0   | 0 / 73 (0.00%)<br>0    | 0 / 75 (0.00%)<br>0     |
| Pyrexia(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 0 / 77 (0.00%)<br>0   | 28 / 73 (38.36%)<br>29 | 33 / 75 (44.00%)<br>43  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)   | 1 / 77 (1.30%)<br>1   | 0 / 73 (0.00%)<br>0    | 3 / 75 (4.00%)<br>3     |
| Vaccination Site Erythema(Solicited)<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 77 (0.00%)<br>0   | 1 / 73 (1.37%)<br>1    | 3 / 75 (4.00%)<br>4     |
| Vaccination Site Pain(Solicited)<br>subjects affected / exposed<br>occurrences (all)                          | 9 / 77 (11.69%)<br>10 | 60 / 73 (82.19%)<br>66 | 64 / 75 (85.33%)<br>112 |
| Vaccination Site Swelling(Solicited)<br>subjects affected / exposed<br>occurrences (all)                      | 0 / 77 (0.00%)<br>0   | 2 / 73 (2.74%)<br>2    | 4 / 75 (5.33%)<br>5     |
| Reproductive system and breast disorders<br>Uterine Spasm<br>subjects affected / exposed<br>occurrences (all) | 0 / 77 (0.00%)<br>0   | 0 / 73 (0.00%)<br>0    | 0 / 75 (0.00%)<br>0     |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)  | 0 / 77 (0.00%)<br>0   | 1 / 73 (1.37%)<br>1    | 0 / 75 (0.00%)<br>0     |
| Rhinitis Allergic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 77 (0.00%)<br>0   | 0 / 73 (0.00%)<br>0    | 0 / 75 (0.00%)<br>0     |
| Investigations<br>Haemoglobin Decreased<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 77 (0.00%)<br>0   | 0 / 73 (0.00%)<br>0    | 0 / 75 (0.00%)<br>0     |
| Neutrophil Count Decreased<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 77 (0.00%)<br>0   | 0 / 73 (0.00%)<br>0    | 0 / 75 (0.00%)<br>0     |

|  |                  |                  |                  |
|--|------------------|------------------|------------------|
| Injury, poisoning and procedural complications |                  |                  |                  |
| Limb Injury                                    |                  |                  |                  |
| subjects affected / exposed                    | 0 / 77 (0.00%)   | 0 / 73 (0.00%)   | 0 / 75 (0.00%)   |
| occurrences (all)                              | 0                | 0                | 0                |
| Nervous system disorders                       |                  |                  |                  |
| Carpal Tunnel Syndrome                         |                  |                  |                  |
| subjects affected / exposed                    | 0 / 77 (0.00%)   | 0 / 73 (0.00%)   | 0 / 75 (0.00%)   |
| occurrences (all)                              | 0                | 0                | 0                |
| Headache                                       |                  |                  |                  |
| subjects affected / exposed                    | 2 / 77 (2.60%)   | 3 / 73 (4.11%)   | 2 / 75 (2.67%)   |
| occurrences (all)                              | 2                | 3                | 2                |
| Headache(Solicited)                            |                  |                  |                  |
| subjects affected / exposed                    | 14 / 77 (18.18%) | 54 / 73 (73.97%) | 52 / 75 (69.33%) |
| occurrences (all)                              | 19               | 64               | 79               |
| Migraine                                       |                  |                  |                  |
| subjects affected / exposed                    | 1 / 77 (1.30%)   | 0 / 73 (0.00%)   | 0 / 75 (0.00%)   |
| occurrences (all)                              | 1                | 0                | 0                |
| Paraesthesia                                   |                  |                  |                  |
| subjects affected / exposed                    | 0 / 77 (0.00%)   | 0 / 73 (0.00%)   | 0 / 75 (0.00%)   |
| occurrences (all)                              | 0                | 0                | 0                |
| Sinus Headache                                 |                  |                  |                  |
| subjects affected / exposed                    | 0 / 77 (0.00%)   | 0 / 73 (0.00%)   | 0 / 75 (0.00%)   |
| occurrences (all)                              | 0                | 0                | 0                |
| Presyncope                                     |                  |                  |                  |
| subjects affected / exposed                    | 0 / 77 (0.00%)   | 0 / 73 (0.00%)   | 0 / 75 (0.00%)   |
| occurrences (all)                              | 0                | 0                | 0                |
| Blood and lymphatic system disorders           |                  |                  |                  |
| Leukopenia                                     |                  |                  |                  |
| subjects affected / exposed                    | 0 / 77 (0.00%)   | 0 / 73 (0.00%)   | 0 / 75 (0.00%)   |
| occurrences (all)                              | 0                | 0                | 0                |
| Gastrointestinal disorders                     |                  |                  |                  |
| Nausea   |                  |                  |                  |
| subjects affected / exposed                    | 0 / 77 (0.00%)   | 0 / 73 (0.00%)   | 0 / 75 (0.00%)   |
| occurrences (all)                              | 0                | 0                | 0                |
| Nausea(Solicited)                              |                  |                  |                  |

|  |                     |                        |                        |
|--|---------------------|------------------------|------------------------|
| subjects affected / exposed<br>occurrences (all) | 5 / 77 (6.49%)<br>5 | 27 / 73 (36.99%)<br>31 | 25 / 75 (33.33%)<br>29 |
| Skin and subcutaneous tissue disorders           |                     |                        |                        |
| Dermatitis Contact                               |                     |                        |                        |
| subjects affected / exposed                      | 0 / 77 (0.00%)      | 0 / 73 (0.00%)         | 0 / 75 (0.00%)         |
| occurrences (all)                                | 0                   | 0                      | 0                      |
| Hyperhidrosis                                    |                     |                        |                        |
| subjects affected / exposed                      | 0 / 77 (0.00%)      | 0 / 73 (0.00%)         | 1 / 75 (1.33%)         |
| occurrences (all)                                | 0                   | 0                      | 1                      |
| Musculoskeletal and connective tissue disorders  |                     |                        |                        |
| Arthralgia                                       |                     |                        |                        |
| subjects affected / exposed                      | 1 / 77 (1.30%)      | 1 / 73 (1.37%)         | 1 / 75 (1.33%)         |
| occurrences (all)                                | 1                   | 1                      | 1                      |
| Back Pain  |                     |                        |                        |
| subjects affected / exposed                      | 0 / 77 (0.00%)      | 2 / 73 (2.74%)         | 2 / 75 (2.67%)         |
| occurrences (all)                                | 0                   | 2                      | 2                      |
| Myalgia  |                     |                        |                        |
| subjects affected / exposed                      | 0 / 77 (0.00%)      | 0 / 73 (0.00%)         | 0 / 75 (0.00%)         |
| occurrences (all)                                | 0                   | 0                      | 0                      |
| Myalgia(Solicited)                               |                     |                        |                        |
| subjects affected / exposed                      | 4 / 77 (5.19%)      | 48 / 73 (65.75%)       | 52 / 75 (69.33%)       |
| occurrences (all)                                | 4                   | 51                     | 77                     |
| Pain in Extremity                                |                     |                        |                        |
| subjects affected / exposed                      | 0 / 77 (0.00%)      | 1 / 73 (1.37%)         | 0 / 75 (0.00%)         |
| occurrences (all)                                | 0                   | 1                      | 0                      |
| Infections and infestations                      |                     |                        |                        |
| Asymptomatic Bacteriuria                         |                     |                        |                        |
| subjects affected / exposed                      | 0 / 77 (0.00%)      | 0 / 73 (0.00%)         | 0 / 75 (0.00%)         |
| occurrences (all)                                | 0                   | 0                      | 0                      |
| Ear Lobe Infection                               |                     |                        |                        |
| subjects affected / exposed                      | 0 / 77 (0.00%)      | 0 / 73 (0.00%)         | 0 / 75 (0.00%)         |
| occurrences (all)                                | 0                   | 0                      | 0                      |
| Oral Herpes                                      |                     |                        |                        |
| subjects affected / exposed                      | 0 / 77 (0.00%)      | 0 / 73 (0.00%)         | 1 / 75 (1.33%)         |
| occurrences (all)                                | 0                   | 0                      | 1                      |
| Rhinitis   |                     |                        |                        |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 77 (0.00%)<br>0 | 0 / 73 (0.00%)<br>0 | 0 / 75 (0.00%)<br>0 |
| Sinusitis  |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all) | 0 / 77 (0.00%)<br>0 | 0 / 73 (0.00%)<br>0 | 0 / 75 (0.00%)<br>0 |
| Upper Respiratory Tract Infection                |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all) | 0 / 77 (0.00%)<br>0 | 1 / 73 (1.37%)<br>1 | 0 / 75 (0.00%)<br>0 |
| Metabolism and nutrition disorders               |                     |                     |                     |
| Vitamin D Deficiency                             |                     |                     |                     |
| subjects affected / exposed<br>occurrences (all) | 0 / 77 (0.00%)<br>0 | 0 / 73 (0.00%)<br>0 | 0 / 75 (0.00%)<br>0 |

| <b>Non-serious adverse events</b>                        | COHORT 1A: Ad26<br>5e10, PL(,AHBV:<br>Ad26 5e10) | COHORT 1A: Ad26<br>5e10, Ad26<br>5e10(,AHBV: Ad26 | COHORT 1B: Ad26<br>5e10, Ad26<br>5e10(,AHBV: Ad26 |
|--|--|---|---|
| Total subjects affected by non-serious<br>adverse events |  |   |   |
| subjects affected / exposed                              | 64 / 75 (85.33%)                                 | 68 / 77 (88.31%)                                  | 5 / 5 (100.00%)                                   |
| Vascular disorders                                       |  |   |   |
| Hypertension   |  |   |   |
| subjects affected / exposed<br>occurrences (all)         | 0 / 75 (0.00%)<br>0                              | 0 / 77 (0.00%)<br>0                               | 0 / 5 (0.00%)<br>0                                |
| General disorders and administration<br>site conditions  |  |   |   |
| Chills   |  |   |   |
| subjects affected / exposed<br>occurrences (all)         | 3 / 75 (4.00%)<br>3                              | 3 / 77 (3.90%)<br>3                               | 0 / 5 (0.00%)<br>0                                |
| Fatigue  |  |   |   |
| subjects affected / exposed<br>occurrences (all)         | 3 / 75 (4.00%)<br>3                              | 0 / 77 (0.00%)<br>0                               | 0 / 5 (0.00%)<br>0                                |
| Fatigue(Solicited)                                       |  |   |   |
| subjects affected / exposed<br>occurrences (all)         | 41 / 75 (54.67%)<br>52                           | 50 / 77 (64.94%)<br>72                            | 4 / 5 (80.00%)<br>5                               |
| Injection Site Haemorrhage                               |  |   |   |
| subjects affected / exposed<br>occurrences (all)         | 1 / 75 (1.33%)<br>1                              | 0 / 77 (0.00%)<br>0                               | 1 / 5 (20.00%)<br>1                               |
| Pyrexia(Solicited)                                       |  |   |   |
| subjects affected / exposed<br>occurrences (all)         | 14 / 75 (18.67%)<br>14                           | 13 / 77 (16.88%)<br>14                            | 0 / 5 (0.00%)<br>0                                |

|   |                        |                        |                      |
|---|------------------------|------------------------|----------------------|
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)   | 2 / 75 (2.67%)<br>2    | 2 / 77 (2.60%)<br>2    | 0 / 5 (0.00%)<br>0   |
| Vaccination Site Erythema(Solicited)<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 75 (0.00%)<br>0    | 2 / 77 (2.60%)<br>2    | 1 / 5 (20.00%)<br>1  |
| Vaccination Site Pain(Solicited)<br>subjects affected / exposed<br>occurrences (all)                              | 51 / 75 (68.00%)<br>55 | 58 / 77 (75.32%)<br>99 | 5 / 5 (100.00%)<br>8 |
| Vaccination Site Swelling(Solicited)<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 75 (0.00%)<br>0    | 3 / 77 (3.90%)<br>4    | 1 / 5 (20.00%)<br>1  |
| Reproductive system and breast disorders<br>Uterine Spasm<br>subjects affected / exposed<br>occurrences (all)     | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0   |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)      | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0   |
| Rhinitis Allergic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 1 / 5 (20.00%)<br>1  |
| Investigations<br>Haemoglobin Decreased<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0   |
| Neutrophil Count Decreased<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0   |
| Injury, poisoning and procedural complications<br>Limb Injury<br>subjects affected / exposed<br>occurrences (all) | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0   |
| Nervous system disorders  |                        |                        |                      |

|  |                        |                        |                     |
|--|------------------------|------------------------|---------------------|
| Carpal Tunnel Syndrome<br>subjects affected / exposed<br>occurrences (all)                                       | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 1 / 5 (20.00%)<br>1 |
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 0 / 75 (0.00%)<br>0    | 3 / 77 (3.90%)<br>3    | 0 / 5 (0.00%)<br>0  |
| Headache(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 36 / 75 (48.00%)<br>48 | 41 / 77 (53.25%)<br>59 | 2 / 5 (40.00%)<br>3 |
| Migraine<br>subjects affected / exposed<br>occurrences (all)   | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)   | 1 / 75 (1.33%)<br>1    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  |
| Sinus Headache<br>subjects affected / exposed<br>occurrences (all)   | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  |
| Presyncope<br>subjects affected / exposed<br>occurrences (all)   | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  |
| Blood and lymphatic system disorders<br>Leukopenia<br>subjects affected / exposed<br>occurrences (all)           | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  |
| Gastrointestinal disorders<br>Nausea<br>subjects affected / exposed<br>occurrences (all)                         | 1 / 75 (1.33%)<br>1    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  |
| Nausea(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 22 / 75 (29.33%)<br>27 | 19 / 77 (24.68%)<br>22 | 2 / 5 (40.00%)<br>2 |
| Skin and subcutaneous tissue disorders<br>Dermatitis Contact<br>subjects affected / exposed<br>occurrences (all) | 0 / 75 (0.00%)<br>0    | 0 / 77 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  |
| Hyperhidrosis  |                        |                        |                     |

|  |                     |                     |                    |
|--|---------------------|---------------------|--------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 75 (0.00%)<br>0 | 1 / 77 (1.30%)<br>1 | 0 / 5 (0.00%)<br>0 |
| Musculoskeletal and connective tissue disorders  |                     |                     |                    |
| Arthralgia                                       |                     |                     |                    |
| subjects affected / exposed                      | 1 / 75 (1.33%)      | 1 / 77 (1.30%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                | 1                   | 1                   | 0                  |
| Back Pain  |                     |                     |                    |
| subjects affected / exposed                      | 2 / 75 (2.67%)      | 2 / 77 (2.60%)      | 1 / 5 (20.00%)     |
| occurrences (all)                                | 2                   | 4                   | 1                  |
| Myalgia  |                     |                     |                    |
| subjects affected / exposed                      | 1 / 75 (1.33%)      | 0 / 77 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                | 1                   | 0                   | 0                  |
| Myalgia(Solicited)                               |                     |                     |                    |
| subjects affected / exposed                      | 34 / 75 (45.33%)    | 31 / 77 (40.26%)    | 2 / 5 (40.00%)     |
| occurrences (all)                                | 37                  | 48                  | 3                  |
| Pain in Extremity                                |                     |                     |                    |
| subjects affected / exposed                      | 0 / 75 (0.00%)      | 0 / 77 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                  |
| Infections and infestations                      |                     |                     |                    |
| Asymptomatic Bacteriuria                         |                     |                     |                    |
| subjects affected / exposed                      | 0 / 75 (0.00%)      | 0 / 77 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                  |
| Ear Lobe Infection                               |                     |                     |                    |
| subjects affected / exposed                      | 0 / 75 (0.00%)      | 0 / 77 (0.00%)      | 1 / 5 (20.00%)     |
| occurrences (all)                                | 0                   | 0                   | 1                  |
| Oral Herpes                                      |                     |                     |                    |
| subjects affected / exposed                      | 0 / 75 (0.00%)      | 0 / 77 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                  |
| Rhinitis   |                     |                     |                    |
| subjects affected / exposed                      | 0 / 75 (0.00%)      | 0 / 77 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                  |
| Sinusitis  |                     |                     |                    |
| subjects affected / exposed                      | 0 / 75 (0.00%)      | 0 / 77 (0.00%)      | 0 / 5 (0.00%)      |
| occurrences (all)                                | 0                   | 0                   | 0                  |
| Upper Respiratory Tract Infection                |                     |                     |                    |

|  |                     |                     |                     |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)   | 1 / 75 (1.33%)<br>1 | 4 / 77 (5.19%)<br>4 | 1 / 5 (20.00%)<br>1 |
| Metabolism and nutrition disorders<br>Vitamin D Deficiency<br>subjects affected / exposed<br>occurrences (all) | 0 / 75 (0.00%)<br>0 | 0 / 77 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |

| <b>Non-serious adverse events</b>   | COHORT 2A: Ad26<br>5e10, B:<br>PL(,PL/AHBV: Ad26<br>5e10) | COHORT 1B:<br>Placebo, Placebo | COHORT 1B: Ad26<br>1e11, PL(,AHBV:<br>Ad26 5e10) |
|---|---|--------------------------------|--|
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed                               | 53 / 58 (91.38%)  | 5 / 5 (100.00%)                | 5 / 5 (100.00%)                                  |
| Vascular disorders<br>Hypertension<br>subjects affected / exposed<br>occurrences (all)                                | 1 / 58 (1.72%)<br>1                                       | 0 / 5 (0.00%)<br>0             | 0 / 5 (0.00%)<br>0                               |
| General disorders and administration<br>site conditions<br>Chills<br>subjects affected / exposed<br>occurrences (all) | 3 / 58 (5.17%)<br>3                                       | 0 / 5 (0.00%)<br>0             | 3 / 5 (60.00%)<br>3                              |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)   | 2 / 58 (3.45%)<br>2                                       | 0 / 5 (0.00%)<br>0             | 0 / 5 (0.00%)<br>0                               |
| Fatigue(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 37 / 58 (63.79%)<br>37                                    | 4 / 5 (80.00%)<br>6            | 5 / 5 (100.00%)<br>6                             |
| Injection Site Haemorrhage<br>subjects affected / exposed<br>occurrences (all)  | 0 / 58 (0.00%)<br>0                                       | 0 / 5 (0.00%)<br>0             | 0 / 5 (0.00%)<br>0                               |
| Pyrexia(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 15 / 58 (25.86%)<br>15                                    | 0 / 5 (0.00%)<br>0             | 2 / 5 (40.00%)<br>2                              |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 58 (0.00%)<br>0                                       | 0 / 5 (0.00%)<br>0             | 0 / 5 (0.00%)<br>0                               |
| Vaccination Site Erythema(Solicited)  |   |                                |  |



|   |                        |                    |                     |
|---|------------------------|--------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)  | 1 / 58 (1.72%)<br>1    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Vaccination Site Pain(Solicited)<br>subjects affected / exposed<br>occurrences (all)                              | 48 / 58 (82.76%)<br>48 | 0 / 5 (0.00%)<br>0 | 4 / 5 (80.00%)<br>5 |
| Vaccination Site Swelling(Solicited)<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Reproductive system and breast disorders<br>Uterine Spasm<br>subjects affected / exposed<br>occurrences (all)     | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)      | 1 / 58 (1.72%)<br>1    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Rhinitis Allergic<br>subjects affected / exposed<br>occurrences (all)   | 1 / 58 (1.72%)<br>1    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Investigations<br>Haemoglobin Decreased<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Neutrophil Count Decreased<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Injury, poisoning and procedural complications<br>Limb Injury<br>subjects affected / exposed<br>occurrences (all) | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Nervous system disorders<br>Carpal Tunnel Syndrome<br>subjects affected / exposed<br>occurrences (all)            | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0  |
| Headache  |                        |                    |                     |

|  |                        |                     |                      |
|--|------------------------|---------------------|----------------------|
| subjects affected / exposed<br>occurrences (all)   | 3 / 58 (5.17%)<br>3    | 1 / 5 (20.00%)<br>1 | 0 / 5 (0.00%)<br>0   |
| Headache(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 35 / 58 (60.34%)<br>35 | 3 / 5 (60.00%)<br>3 | 5 / 5 (100.00%)<br>5 |
| Migraine<br>subjects affected / exposed<br>occurrences (all)   | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0   |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)   | 1 / 58 (1.72%)<br>1    | 0 / 5 (0.00%)<br>0  | 1 / 5 (20.00%)<br>1  |
| Sinus Headache<br>subjects affected / exposed<br>occurrences (all)   | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0   |
| Presyncope<br>subjects affected / exposed<br>occurrences (all)   | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0   |
| Blood and lymphatic system disorders<br>Leukopenia<br>subjects affected / exposed<br>occurrences (all)           | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0   |
| Gastrointestinal disorders<br>Nausea<br>subjects affected / exposed<br>occurrences (all)                         | 1 / 58 (1.72%)<br>1    | 0 / 5 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0   |
| Nausea(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 19 / 58 (32.76%)<br>19 | 2 / 5 (40.00%)<br>2 | 3 / 5 (60.00%)<br>3  |
| Skin and subcutaneous tissue disorders<br>Dermatitis Contact<br>subjects affected / exposed<br>occurrences (all) | 1 / 58 (1.72%)<br>1    | 1 / 5 (20.00%)<br>1 | 0 / 5 (0.00%)<br>0   |
| Hyperhidrosis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 58 (0.00%)<br>0    | 0 / 5 (0.00%)<br>0  | 2 / 5 (40.00%)<br>2  |
| Musculoskeletal and connective tissue disorders  |                        |                     |                      |

|                                    |                  |                |                 |
|------------------------------------|------------------|----------------|-----------------|
| Arthralgia                         |                  |                |                 |
| subjects affected / exposed        | 0 / 58 (0.00%)   | 0 / 5 (0.00%)  | 2 / 5 (40.00%)  |
| occurrences (all)                  | 0                | 0              | 2               |
| Back Pain                          |                  |                |                 |
| subjects affected / exposed        | 0 / 58 (0.00%)   | 0 / 5 (0.00%)  | 0 / 5 (0.00%)   |
| occurrences (all)                  | 0                | 0              | 0               |
| Myalgia                            |                  |                |                 |
| subjects affected / exposed        | 2 / 58 (3.45%)   | 0 / 5 (0.00%)  | 0 / 5 (0.00%)   |
| occurrences (all)                  | 2                | 0              | 0               |
| Myalgia(Solicited)                 |                  |                |                 |
| subjects affected / exposed        | 34 / 58 (58.62%) | 1 / 5 (20.00%) | 5 / 5 (100.00%) |
| occurrences (all)                  | 34               | 1              | 5               |
| Pain in Extremity                  |                  |                |                 |
| subjects affected / exposed        | 1 / 58 (1.72%)   | 0 / 5 (0.00%)  | 0 / 5 (0.00%)   |
| occurrences (all)                  | 1                | 0              | 0               |
| Infections and infestations        |                  |                |                 |
| Asymptomatic Bacteriuria           |                  |                |                 |
| subjects affected / exposed        | 0 / 58 (0.00%)   | 0 / 5 (0.00%)  | 0 / 5 (0.00%)   |
| occurrences (all)                  | 0                | 0              | 0               |
| Ear Lobe Infection                 |                  |                |                 |
| subjects affected / exposed        | 0 / 58 (0.00%)   | 0 / 5 (0.00%)  | 0 / 5 (0.00%)   |
| occurrences (all)                  | 0                | 0              | 0               |
| Oral Herpes                        |                  |                |                 |
| subjects affected / exposed        | 0 / 58 (0.00%)   | 0 / 5 (0.00%)  | 1 / 5 (20.00%)  |
| occurrences (all)                  | 0                | 0              | 1               |
| Rhinitis                           |                  |                |                 |
| subjects affected / exposed        | 0 / 58 (0.00%)   | 0 / 5 (0.00%)  | 0 / 5 (0.00%)   |
| occurrences (all)                  | 0                | 0              | 0               |
| Sinusitis                          |                  |                |                 |
| subjects affected / exposed        | 0 / 58 (0.00%)   | 0 / 5 (0.00%)  | 0 / 5 (0.00%)   |
| occurrences (all)                  | 0                | 0              | 0               |
| Upper Respiratory Tract Infection  |                  |                |                 |
| subjects affected / exposed        | 0 / 58 (0.00%)   | 1 / 5 (20.00%) | 0 / 5 (0.00%)   |
| occurrences (all)                  | 0                | 1              | 0               |
| Metabolism and nutrition disorders |                  |                |                 |

|   |   |  |  |
|---|---|--|--|
| Vitamin D Deficiency<br>subjects affected / exposed<br>occurrences (all)  | 0 / 58 (0.00%)<br>0                               | 0 / 5 (0.00%)<br>0                               | 0 / 5 (0.00%)<br>0                           |
| <b>Non-serious adverse events</b>   | COHORT 1B: Ad26<br>1e11, Ad26<br>1e11(,AHBV: Ad26 | COHORT 1B: Ad26<br>5e10, PL(,AHBV:<br>Ad26 5e10) | COHORT 2A: Ad26<br>5e10, B: Ad26 5e10,<br>PL |
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed                               | 5 / 5 (100.00%)                                   | 5 / 5 (100.00%)                                  | 27 / 29 (93.10%)                             |
| Vascular disorders<br>Hypertension<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 5 (0.00%)<br>0                                | 0 / 5 (0.00%)<br>0                               | 0 / 29 (0.00%)<br>0                          |
| General disorders and administration<br>site conditions<br>Chills<br>subjects affected / exposed<br>occurrences (all) | 4 / 5 (80.00%)<br>4                               | 0 / 5 (0.00%)<br>0                               | 0 / 29 (0.00%)<br>0                          |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0                                | 0 / 5 (0.00%)<br>0                               | 0 / 29 (0.00%)<br>0                          |
| Fatigue(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 5 / 5 (100.00%)<br>8                              | 3 / 5 (60.00%)<br>4                              | 17 / 29 (58.62%)<br>17                       |
| Injection Site Haemorrhage<br>subjects affected / exposed<br>occurrences (all)  | 0 / 5 (0.00%)<br>0                                | 0 / 5 (0.00%)<br>0                               | 0 / 29 (0.00%)<br>0                          |
| Pyrexia(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 3 / 5 (60.00%)<br>4                               | 0 / 5 (0.00%)<br>0                               | 3 / 29 (10.34%)<br>3                         |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0                                | 0 / 5 (0.00%)<br>0                               | 2 / 29 (6.90%)<br>2                          |
| Vaccination Site Erythema(Solicited)<br>subjects affected / exposed<br>occurrences (all)                              | 0 / 5 (0.00%)<br>0                                | 0 / 5 (0.00%)<br>0                               | 1 / 29 (3.45%)<br>1                          |
| Vaccination Site Pain(Solicited)<br>subjects affected / exposed<br>occurrences (all)                                  | 5 / 5 (100.00%)<br>10                             | 3 / 5 (60.00%)<br>3                              | 23 / 29 (79.31%)<br>23                       |

|   |  |   |  |
|---|--|---|--|
| Vaccination Site Swelling(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 1 / 29 (3.45%)<br>1  |
| Reproductive system and breast disorders<br>Uterine Spasm<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0   | 1 / 5 (20.00%)<br>1   | 0 / 29 (0.00%)<br>0  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)<br><br>Rhinitis Allergic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0                             | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0                            | 0 / 29 (0.00%)<br>0<br><br>0 / 29 (0.00%)<br>0                               |
| Investigations<br>Haemoglobin Decreased<br>subjects affected / exposed<br>occurrences (all)<br><br>Neutrophil Count Decreased<br>subjects affected / exposed<br>occurrences (all)   | 1 / 5 (20.00%)<br>1<br><br>1 / 5 (20.00%)<br>1                           | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0                            | 0 / 29 (0.00%)<br>0<br><br>0 / 29 (0.00%)<br>0                               |
| Injury, poisoning and procedural complications<br>Limb Injury<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0   | 1 / 5 (20.00%)<br>1   | 0 / 29 (0.00%)<br>0  |
| Nervous system disorders<br>Carpal Tunnel Syndrome<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache(Solicited)<br>subjects affected / exposed<br>occurrences (all)<br><br>Migraine | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>5 / 5 (100.00%)<br>9 | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>3 / 5 (60.00%)<br>5 | 0 / 29 (0.00%)<br>0<br><br>1 / 29 (3.45%)<br>1<br><br>16 / 29 (55.17%)<br>16 |

|   |                |                |                 |
|---|----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 1 / 5 (20.00%) | 0 / 29 (0.00%)  |
| occurrences (all)                               | 0              | 1              | 0               |
| Paraesthesia                                    |                |                |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 5 (0.00%)  | 0 / 29 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Sinus Headache                                  |                |                |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 5 (0.00%)  | 0 / 29 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Presyncope                                      |                |                |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 5 (0.00%)  | 2 / 29 (6.90%)  |
| occurrences (all)                               | 0              | 0              | 2               |
| Blood and lymphatic system disorders            |                |                |                 |
| Leukopenia                                      |                |                |                 |
| subjects affected / exposed                     | 1 / 5 (20.00%) | 0 / 5 (0.00%)  | 0 / 29 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0               |
| Gastrointestinal disorders                      |                |                |                 |
| Nausea  |                |                |                 |
| subjects affected / exposed                     | 1 / 5 (20.00%) | 0 / 5 (0.00%)  | 0 / 29 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0               |
| Nausea(Solicited)                               |                |                |                 |
| subjects affected / exposed                     | 3 / 5 (60.00%) | 2 / 5 (40.00%) | 8 / 29 (27.59%) |
| occurrences (all)                               | 3              | 2              | 8               |
| Skin and subcutaneous tissue disorders          |                |                |                 |
| Dermatitis Contact                              |                |                |                 |
| subjects affected / exposed                     | 0 / 5 (0.00%)  | 0 / 5 (0.00%)  | 0 / 29 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0               |
| Hyperhidrosis                                   |                |                |                 |
| subjects affected / exposed                     | 3 / 5 (60.00%) | 0 / 5 (0.00%)  | 0 / 29 (0.00%)  |
| occurrences (all)                               | 3              | 0              | 0               |
| Musculoskeletal and connective tissue disorders |                |                |                 |
| Arthralgia                                      |                |                |                 |
| subjects affected / exposed                     | 1 / 5 (20.00%) | 0 / 5 (0.00%)  | 1 / 29 (3.45%)  |
| occurrences (all)                               | 1              | 0              | 1               |
| Back Pain                                       |                |                |                 |
| subjects affected / exposed                     | 1 / 5 (20.00%) | 0 / 5 (0.00%)  | 0 / 29 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0               |

|  |                      |                     |                        |
|--|----------------------|---------------------|------------------------|
| Myalgia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |
| Myalgia(Solicited)<br>subjects affected / exposed<br>occurrences (all)   | 5 / 5 (100.00%)<br>7 | 3 / 5 (60.00%)<br>3 | 17 / 29 (58.62%)<br>17 |
| Pain in Extremity<br>subjects affected / exposed<br>occurrences (all)  | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |
| Infections and infestations<br>Asymptomatic Bacteriuria<br>subjects affected / exposed<br>occurrences (all)    | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |
| Ear Lobe Infection<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |
| Oral Herpes<br>subjects affected / exposed<br>occurrences (all)  | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |
| Rhinitis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |
| Sinusitis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |
| Upper Respiratory Tract Infection<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |
| Metabolism and nutrition disorders<br>Vitamin D Deficiency<br>subjects affected / exposed<br>occurrences (all) | 0 / 5 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0  | 0 / 29 (0.00%)<br>0    |

|   |  |                              |   |
|---|--|------------------------------|---|
| <b>Non-serious adverse events</b>   | COHORT 3: Ad26<br>5e10, Ad26<br>5e10(,AHBV: Ad26 | COHORT 2B:<br>Placebo, B: PL | COHORT 2B: Ad26<br>5e10, Ad26 5e10, B:<br>PL, Ad26 5e10 |
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed | 63 / 81 (77.78%)                                 | 9 / 15 (60.00%)              | 23 / 28 (82.14%)  |

|  |                  |                 |                  |
|--|------------------|-----------------|------------------|
| Vascular disorders                                   |                  |                 |                  |
| Hypertension   |                  |                 |                  |
| subjects affected / exposed                          | 3 / 81 (3.70%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                                    | 3                | 0               | 0                |
| General disorders and administration site conditions |                  |                 |                  |
| Chills   |                  |                 |                  |
| subjects affected / exposed                          | 1 / 81 (1.23%)   | 0 / 15 (0.00%)  | 1 / 28 (3.57%)   |
| occurrences (all)                                    | 1                | 0               | 1                |
| Fatigue  |                  |                 |                  |
| subjects affected / exposed                          | 1 / 81 (1.23%)   | 1 / 15 (6.67%)  | 1 / 28 (3.57%)   |
| occurrences (all)                                    | 1                | 1               | 4                |
| Fatigue(Solicited)                                   |                  |                 |                  |
| subjects affected / exposed                          | 38 / 81 (46.91%) | 4 / 15 (26.67%) | 19 / 28 (67.86%) |
| occurrences (all)                                    | 49               | 5               | 30               |
| Injection Site Haemorrhage                           |                  |                 |                  |
| subjects affected / exposed                          | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                                    | 0                | 0               | 0                |
| Pyrexia(Solicited)                                   |                  |                 |                  |
| subjects affected / exposed                          | 5 / 81 (6.17%)   | 0 / 15 (0.00%)  | 6 / 28 (21.43%)  |
| occurrences (all)                                    | 5                | 0               | 8                |
| Pyrexia  |                  |                 |                  |
| subjects affected / exposed                          | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                                    | 0                | 0               | 0                |
| Vaccination Site Erythema(Solicited)                 |                  |                 |                  |
| subjects affected / exposed                          | 1 / 81 (1.23%)   | 0 / 15 (0.00%)  | 2 / 28 (7.14%)   |
| occurrences (all)                                    | 1                | 0               | 2                |
| Vaccination Site Pain(Solicited)                     |                  |                 |                  |
| subjects affected / exposed                          | 50 / 81 (61.73%) | 3 / 15 (20.00%) | 20 / 28 (71.43%) |
| occurrences (all)                                    | 79               | 3               | 36               |
| Vaccination Site Swelling(Solicited)                 |                  |                 |                  |
| subjects affected / exposed                          | 2 / 81 (2.47%)   | 0 / 15 (0.00%)  | 1 / 28 (3.57%)   |
| occurrences (all)                                    | 3                | 0               | 2                |
| Reproductive system and breast disorders             |                  |                 |                  |
| Uterine Spasm  |                  |                 |                  |
| subjects affected / exposed                          | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                                    | 0                | 0               | 0                |



|   |                  |                 |                  |
|---|------------------|-----------------|------------------|
| Respiratory, thoracic and mediastinal disorders |                  |                 |                  |
| Cough   |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 1 / 15 (6.67%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 1               | 0                |
| Rhinitis Allergic                               |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Investigations                                  |                  |                 |                  |
| Haemoglobin Decreased                           |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Neutrophil Count Decreased                      |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Injury, poisoning and procedural complications  |                  |                 |                  |
| Limb Injury                                     |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Nervous system disorders                        |                  |                 |                  |
| Carpal Tunnel Syndrome                          |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Headache  |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 1 / 15 (6.67%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 1               | 0                |
| Headache(Solicited)                             |                  |                 |                  |
| subjects affected / exposed                     | 32 / 81 (39.51%) | 7 / 15 (46.67%) | 18 / 28 (64.29%) |
| occurrences (all)                               | 43               | 8               | 29               |
| Migraine  |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Paraesthesia                                    |                  |                 |                  |
| subjects affected / exposed                     | 0 / 81 (0.00%)   | 0 / 15 (0.00%)  | 0 / 28 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Sinus Headache                                  |                  |                 |                  |

|   |                        |                      |                        |
|---|------------------------|----------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)  | 0 / 81 (0.00%)<br>0    | 0 / 15 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0    |
| Presyncope<br>subjects affected / exposed<br>occurrences (all)  | 0 / 81 (0.00%)<br>0    | 0 / 15 (0.00%)<br>0  | 1 / 28 (3.57%)<br>1    |
| Blood and lymphatic system disorders<br>Leukopenia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 81 (0.00%)<br>0    | 0 / 15 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0    |
| Gastrointestinal disorders<br>Nausea<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 81 (0.00%)<br>0    | 0 / 15 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0    |
| Nausea(Solicited)<br>subjects affected / exposed<br>occurrences (all)   | 5 / 81 (6.17%)<br>5    | 2 / 15 (13.33%)<br>3 | 9 / 28 (32.14%)<br>10  |
| Skin and subcutaneous tissue disorders<br>Dermatitis Contact<br>subjects affected / exposed<br>occurrences (all)  | 0 / 81 (0.00%)<br>0    | 0 / 15 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0    |
| Hyperhidrosis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 81 (0.00%)<br>0    | 0 / 15 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0    |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 2 / 81 (2.47%)<br>2    | 0 / 15 (0.00%)<br>0  | 1 / 28 (3.57%)<br>1    |
| Back Pain<br>subjects affected / exposed<br>occurrences (all)   | 0 / 81 (0.00%)<br>0    | 0 / 15 (0.00%)<br>0  | 0 / 28 (0.00%)<br>0    |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 81 (0.00%)<br>0    | 1 / 15 (6.67%)<br>1  | 1 / 28 (3.57%)<br>1    |
| Myalgia(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 26 / 81 (32.10%)<br>34 | 2 / 15 (13.33%)<br>2 | 16 / 28 (57.14%)<br>25 |

|   |                     |                     |                     |
|---|---------------------|---------------------|---------------------|
| Pain in Extremity<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 81 (0.00%)<br>0 | 0 / 15 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 |
| Infections and infestations   |                     |                     |                     |
| Asymptomatic Bacteriuria<br>subjects affected / exposed<br>occurrences (all)          | 0 / 81 (0.00%)<br>0 | 0 / 15 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 |
| Ear Lobe Infection<br>subjects affected / exposed<br>occurrences (all)                | 0 / 81 (0.00%)<br>0 | 0 / 15 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 |
| Oral Herpes<br>subjects affected / exposed<br>occurrences (all)                       | 0 / 81 (0.00%)<br>0 | 0 / 15 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 |
| Rhinitis<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 81 (0.00%)<br>0 | 1 / 15 (6.67%)<br>1 | 0 / 28 (0.00%)<br>0 |
| Sinusitis<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 81 (0.00%)<br>0 | 1 / 15 (6.67%)<br>1 | 0 / 28 (0.00%)<br>0 |
| Upper Respiratory Tract Infection<br>subjects affected / exposed<br>occurrences (all) | 0 / 81 (0.00%)<br>0 | 0 / 15 (0.00%)<br>0 | 0 / 28 (0.00%)<br>0 |
| Metabolism and nutrition disorders  |                     |                     |                     |
| Vitamin D Deficiency<br>subjects affected / exposed<br>occurrences (all)              | 0 / 81 (0.00%)<br>0 | 1 / 15 (6.67%)<br>1 | 0 / 28 (0.00%)<br>0 |

|   |  |                                   |  |
|---|--|-----------------------------------|--|
| <b>Non-serious adverse events</b>   | COHORT 2A: Ad26<br>5e10, B: PL, Ad26<br>5e10 | COHORT 2A:<br>Placebo, B: Placebo | COHORT 2B: Ad26<br>5e10, Ad26 5e10, B:<br>PL(,PL/AHBV: Ad26<br>5e10) |
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed | 27 / 32 (84.38%)                             | 10 / 17 (58.82%)                  | 59 / 62 (95.16%)   |
| Vascular disorders  |  |                                   |  |
| Hypertension<br>subjects affected / exposed<br>occurrences (all)                        | 0 / 32 (0.00%)<br>0                          | 1 / 17 (5.88%)<br>1               | 0 / 62 (0.00%)<br>0  |
| General disorders and administration<br>site conditions                                 |  |                                   |  |

|   |                  |                 |                  |
|---|------------------|-----------------|------------------|
| Chills  |                  |                 |                  |
| subjects affected / exposed                     | 1 / 32 (3.13%)   | 1 / 17 (5.88%)  | 4 / 62 (6.45%)   |
| occurrences (all)                               | 1                | 1               | 4                |
| Fatigue   |                  |                 |                  |
| subjects affected / exposed                     | 0 / 32 (0.00%)   | 2 / 17 (11.76%) | 2 / 62 (3.23%)   |
| occurrences (all)                               | 0                | 2               | 3                |
| Fatigue(Solicited)                              |                  |                 |                  |
| subjects affected / exposed                     | 15 / 32 (46.88%) | 7 / 17 (41.18%) | 43 / 62 (69.35%) |
| occurrences (all)                               | 15               | 7               | 67               |
| Injection Site Haemorrhage                      |                  |                 |                  |
| subjects affected / exposed                     | 0 / 32 (0.00%)   | 0 / 17 (0.00%)  | 0 / 62 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Pyrexia(Solicited)                              |                  |                 |                  |
| subjects affected / exposed                     | 4 / 32 (12.50%)  | 0 / 17 (0.00%)  | 17 / 62 (27.42%) |
| occurrences (all)                               | 4                | 0               | 19               |
| Pyrexia   |                  |                 |                  |
| subjects affected / exposed                     | 0 / 32 (0.00%)   | 0 / 17 (0.00%)  | 1 / 62 (1.61%)   |
| occurrences (all)                               | 0                | 0               | 1                |
| Vaccination Site Erythema(Solicited)            |                  |                 |                  |
| subjects affected / exposed                     | 1 / 32 (3.13%)   | 0 / 17 (0.00%)  | 1 / 62 (1.61%)   |
| occurrences (all)                               | 1                | 0               | 1                |
| Vaccination Site Pain(Solicited)                |                  |                 |                  |
| subjects affected / exposed                     | 19 / 32 (59.38%) | 4 / 17 (23.53%) | 53 / 62 (85.48%) |
| occurrences (all)                               | 19               | 4               | 93               |
| Vaccination Site Swelling(Solicited)            |                  |                 |                  |
| subjects affected / exposed                     | 1 / 32 (3.13%)   | 0 / 17 (0.00%)  | 2 / 62 (3.23%)   |
| occurrences (all)                               | 1                | 0               | 2                |
| Reproductive system and breast disorders        |                  |                 |                  |
| Uterine Spasm                                   |                  |                 |                  |
| subjects affected / exposed                     | 0 / 32 (0.00%)   | 0 / 17 (0.00%)  | 0 / 62 (0.00%)   |
| occurrences (all)                               | 0                | 0               | 0                |
| Respiratory, thoracic and mediastinal disorders |                  |                 |                  |
| Cough   |                  |                 |                  |
| subjects affected / exposed                     | 0 / 32 (0.00%)   | 1 / 17 (5.88%)  | 0 / 62 (0.00%)   |
| occurrences (all)                               | 0                | 1               | 0                |
| Rhinitis Allergic                               |                  |                 |                  |

|  |                        |                      |                        |
|--|------------------------|----------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)                               | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Investigations   |                        |                      |                        |
| Haemoglobin Decreased<br>subjects affected / exposed<br>occurrences (all)      | 1 / 32 (3.13%)<br>1    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Neutrophil Count Decreased<br>subjects affected / exposed<br>occurrences (all) | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Injury, poisoning and procedural complications                                 |                        |                      |                        |
| Limb Injury<br>subjects affected / exposed<br>occurrences (all)                | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Nervous system disorders   |                        |                      |                        |
| Carpal Tunnel Syndrome<br>subjects affected / exposed<br>occurrences (all)     | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Headache<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 32 (0.00%)<br>0    | 1 / 17 (5.88%)<br>1  | 2 / 62 (3.23%)<br>2    |
| Headache(Solicited)<br>subjects affected / exposed<br>occurrences (all)        | 11 / 32 (34.38%)<br>11 | 4 / 17 (23.53%)<br>4 | 43 / 62 (69.35%)<br>69 |
| Migraine<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)               | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Sinus Headache<br>subjects affected / exposed<br>occurrences (all)             | 0 / 32 (0.00%)<br>0    | 1 / 17 (5.88%)<br>1  | 0 / 62 (0.00%)<br>0    |
| Presyncope<br>subjects affected / exposed<br>occurrences (all)                 | 1 / 32 (3.13%)<br>1    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Blood and lymphatic system disorders   |                        |                      |                        |

|   |                        |                      |                        |
|---|------------------------|----------------------|------------------------|
| Leukopenia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Gastrointestinal disorders<br>Nausea<br>subjects affected / exposed<br>occurrences (all)                          | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 1 / 62 (1.61%)<br>1    |
| Nausea(Solicited)<br>subjects affected / exposed<br>occurrences (all)   | 4 / 32 (12.50%)<br>4   | 2 / 17 (11.76%)<br>2 | 22 / 62 (35.48%)<br>27 |
| Skin and subcutaneous tissue disorders<br>Dermatitis Contact<br>subjects affected / exposed<br>occurrences (all)  | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Hyperhidrosis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Back Pain<br>subjects affected / exposed<br>occurrences (all)   | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 32 (0.00%)<br>0    | 0 / 17 (0.00%)<br>0  | 0 / 62 (0.00%)<br>0    |
| Myalgia(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 13 / 32 (40.63%)<br>13 | 4 / 17 (23.53%)<br>4 | 32 / 62 (51.61%)<br>51 |
| Pain in Extremity<br>subjects affected / exposed<br>occurrences (all)   | 0 / 32 (0.00%)<br>0    | 1 / 17 (5.88%)<br>1  | 0 / 62 (0.00%)<br>0    |
| Infections and infestations<br>Asymptomatic Bacteriuria   |                        |                      |                        |

|                                    |                |                |                |
|------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed        | 0 / 32 (0.00%) | 1 / 17 (5.88%) | 0 / 62 (0.00%) |
| occurrences (all)                  | 0              | 1              | 0              |
| Ear Lobe Infection                 |                |                |                |
| subjects affected / exposed        | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Oral Herpes                        |                |                |                |
| subjects affected / exposed        | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Rhinitis                           |                |                |                |
| subjects affected / exposed        | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Sinusitis                          |                |                |                |
| subjects affected / exposed        | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Upper Respiratory Tract Infection  |                |                |                |
| subjects affected / exposed        | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Metabolism and nutrition disorders |                |                |                |
| Vitamin D Deficiency               |                |                |                |
| subjects affected / exposed        | 0 / 32 (0.00%) | 0 / 17 (0.00%) | 0 / 62 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |

| <b>Non-serious adverse events</b>                     | COHORT 2B: Ad26 5e10, Ad26 5e10, B: Ad26 5e10, PL | COHORT 3: Ad26 1e11, Ad26 1e11(,AHBV: Ad26 | COHORT 3: Ad26 5e10, PL(,AHBV: Ad26 5e10) |
|---|---|--|---|
| Total subjects affected by non-serious adverse events |   |  |   |
| subjects affected / exposed                           | 28 / 30 (93.33%)                                  | 69 / 82 (84.15%)                           | 55 / 80 (68.75%)                          |
| Vascular disorders                                    |   |  |   |
| Hypertension  |   |  |   |
| subjects affected / exposed                           | 0 / 30 (0.00%)                                    | 2 / 82 (2.44%)                             | 0 / 80 (0.00%)                            |
| occurrences (all)                                     | 0   | 3  | 0   |
| General disorders and administration site conditions  |   |  |   |
| Chills  |   |  |   |
| subjects affected / exposed                           | 2 / 30 (6.67%)                                    | 6 / 82 (7.32%)                             | 2 / 80 (2.50%)                            |
| occurrences (all)                                     | 2   | 6  | 2   |
| Fatigue   |   |  |   |
| subjects affected / exposed                           | 1 / 30 (3.33%)                                    | 2 / 82 (2.44%)                             | 2 / 80 (2.50%)                            |
| occurrences (all)                                     | 1   | 2  | 2   |

|   |                  |                  |                  |
|---|------------------|------------------|------------------|
| Fatigue(Solicited)                              |                  |                  |                  |
| subjects affected / exposed                     | 15 / 30 (50.00%) | 42 / 82 (51.22%) | 32 / 80 (40.00%) |
| occurrences (all)                               | 26               | 59               | 40               |
| Injection Site Haemorrhage                      |                  |                  |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 1 / 82 (1.22%)   | 1 / 80 (1.25%)   |
| occurrences (all)                               | 0                | 1                | 1                |
| Pyrexia(Solicited)                              |                  |                  |                  |
| subjects affected / exposed                     | 3 / 30 (10.00%)  | 7 / 82 (8.54%)   | 3 / 80 (3.75%)   |
| occurrences (all)                               | 4                | 8                | 3                |
| Pyrexia   |                  |                  |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 82 (0.00%)   | 0 / 80 (0.00%)   |
| occurrences (all)                               | 0                | 0                | 0                |
| Vaccination Site Erythema(Solicited)            |                  |                  |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 1 / 82 (1.22%)   | 2 / 80 (2.50%)   |
| occurrences (all)                               | 0                | 1                | 2                |
| Vaccination Site Pain(Solicited)                |                  |                  |                  |
| subjects affected / exposed                     | 26 / 30 (86.67%) | 55 / 82 (67.07%) | 32 / 80 (40.00%) |
| occurrences (all)                               | 44               | 83               | 34               |
| Vaccination Site Swelling(Solicited)            |                  |                  |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 2 / 82 (2.44%)   | 1 / 80 (1.25%)   |
| occurrences (all)                               | 0                | 2                | 1                |
| Reproductive system and breast disorders        |                  |                  |                  |
| Uterine Spasm                                   |                  |                  |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 82 (0.00%)   | 0 / 80 (0.00%)   |
| occurrences (all)                               | 0                | 0                | 0                |
| Respiratory, thoracic and mediastinal disorders |                  |                  |                  |
| Cough   |                  |                  |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 82 (0.00%)   | 2 / 80 (2.50%)   |
| occurrences (all)                               | 0                | 0                | 2                |
| Rhinitis Allergic                               |                  |                  |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 82 (0.00%)   | 0 / 80 (0.00%)   |
| occurrences (all)                               | 0                | 0                | 0                |
| Investigations                                  |                  |                  |                  |
| Haemoglobin Decreased                           |                  |                  |                  |
| subjects affected / exposed                     | 0 / 30 (0.00%)   | 0 / 82 (0.00%)   | 0 / 80 (0.00%)   |
| occurrences (all)                               | 0                | 0                | 0                |



|   |                        |                        |                        |
|---|------------------------|------------------------|------------------------|
| Neutrophil Count Decreased<br>subjects affected / exposed<br>occurrences (all)                                    | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Injury, poisoning and procedural complications<br>Limb Injury<br>subjects affected / exposed<br>occurrences (all) | 1 / 30 (3.33%)<br>1    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Nervous system disorders<br>Carpal Tunnel Syndrome<br>subjects affected / exposed<br>occurrences (all)            | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Headache<br>subjects affected / exposed<br>occurrences (all)  | 2 / 30 (6.67%)<br>2    | 4 / 82 (4.88%)<br>4    | 1 / 80 (1.25%)<br>1    |
| Headache(Solicited)<br>subjects affected / exposed<br>occurrences (all)   | 23 / 30 (76.67%)<br>30 | 39 / 82 (47.56%)<br>58 | 27 / 80 (33.75%)<br>32 |
| Migraine<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Sinus Headache<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Presyncope<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Blood and lymphatic system disorders<br>Leukopenia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Gastrointestinal disorders<br>Nausea  |                        |                        |                        |

|   |                        |                        |                        |
|---|------------------------|------------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Nausea(Solicited)<br>subjects affected / exposed<br>occurrences (all)   | 8 / 30 (26.67%)<br>10  | 11 / 82 (13.41%)<br>11 | 7 / 80 (8.75%)<br>7    |
| Skin and subcutaneous tissue disorders<br>Dermatitis Contact<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Hyperhidrosis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 0 / 30 (0.00%)<br>0    | 3 / 82 (3.66%)<br>3    | 0 / 80 (0.00%)<br>0    |
| Back Pain<br>subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0    | 3 / 82 (3.66%)<br>3    | 0 / 80 (0.00%)<br>0    |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0    | 1 / 82 (1.22%)<br>1    | 1 / 80 (1.25%)<br>1    |
| Myalgia(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 20 / 30 (66.67%)<br>27 | 35 / 82 (42.68%)<br>39 | 18 / 80 (22.50%)<br>23 |
| Pain in Extremity<br>subjects affected / exposed<br>occurrences (all)   | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 1 / 80 (1.25%)<br>1    |
| Infections and infestations<br>Asymptomatic Bacteriuria<br>subjects affected / exposed<br>occurrences (all)       | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Ear Lobe Infection<br>subjects affected / exposed<br>occurrences (all)  | 0 / 30 (0.00%)<br>0    | 0 / 82 (0.00%)<br>0    | 0 / 80 (0.00%)<br>0    |
| Oral Herpes   |                        |                        |                        |

|                                    |                |                |                |
|------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed        | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Rhinitis                           |                |                |                |
| subjects affected / exposed        | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Sinusitis                          |                |                |                |
| subjects affected / exposed        | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Upper Respiratory Tract Infection  |                |                |                |
| subjects affected / exposed        | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Metabolism and nutrition disorders |                |                |                |
| Vitamin D Deficiency               |                |                |                |
| subjects affected / exposed        | 0 / 30 (0.00%) | 0 / 82 (0.00%) | 0 / 80 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |

| <b>Non-serious adverse events</b>                        | COHORT 3: Ad26<br>1e11, PL(,AHBV:<br>Ad26 5e10) | COHORT 3: Placebo,<br>Placebo |  |
|--|---|-------------------------------|--|
| Total subjects affected by non-serious<br>adverse events |   |                               |  |
| subjects affected / exposed                              | 61 / 79 (77.22%)                                | 42 / 81 (51.85%)              |  |
| Vascular disorders                                       |   |                               |  |
| Hypertension   |   |                               |  |
| subjects affected / exposed                              | 4 / 79 (5.06%)                                  | 1 / 81 (1.23%)                |  |
| occurrences (all)  | 5   | 1                             |  |
| General disorders and administration<br>site conditions  |   |                               |  |
| Chills   |   |                               |  |
| subjects affected / exposed                              | 6 / 79 (7.59%)                                  | 1 / 81 (1.23%)                |  |
| occurrences (all)  | 6   | 1                             |  |
| Fatigue  |   |                               |  |
| subjects affected / exposed                              | 0 / 79 (0.00%)                                  | 1 / 81 (1.23%)                |  |
| occurrences (all)  | 0   | 1                             |  |
| Fatigue(Solicited)                                       |   |                               |  |
| subjects affected / exposed                              | 39 / 79 (49.37%)                                | 22 / 81 (27.16%)              |  |
| occurrences (all)  | 48  | 29                            |  |
| Injection Site Haemorrhage                               |   |                               |  |
| subjects affected / exposed                              | 2 / 79 (2.53%)                                  | 1 / 81 (1.23%)                |  |
| occurrences (all)  | 2   | 1                             |  |

|   |                        |                        |  |
|---|------------------------|------------------------|--|
| Pyrexia(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 7 / 79 (8.86%)<br>7    | 1 / 81 (1.23%)<br>1    |  |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)   | 2 / 79 (2.53%)<br>2    | 0 / 81 (0.00%)<br>0    |  |
| Vaccination Site Erythema(Solicited)<br>subjects affected / exposed<br>occurrences (all)                      | 3 / 79 (3.80%)<br>3    | 0 / 81 (0.00%)<br>0    |  |
| Vaccination Site Pain(Solicited)<br>subjects affected / exposed<br>occurrences (all)                          | 37 / 79 (46.84%)<br>45 | 14 / 81 (17.28%)<br>17 |  |
| Vaccination Site Swelling(Solicited)<br>subjects affected / exposed<br>occurrences (all)                      | 2 / 79 (2.53%)<br>2    | 1 / 81 (1.23%)<br>1    |  |
| Reproductive system and breast disorders<br>Uterine Spasm<br>subjects affected / exposed<br>occurrences (all) | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)  | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Rhinitis Allergic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Investigations<br>Haemoglobin Decreased<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Neutrophil Count Decreased<br>subjects affected / exposed<br>occurrences (all)                                | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Injury, poisoning and procedural complications  |                        |                        |  |

|  |                        |                        |  |
|--|------------------------|------------------------|--|
| Limb Injury<br>subjects affected / exposed<br>occurrences (all)  | 1 / 79 (1.27%)<br>1    | 0 / 81 (0.00%)<br>0    |  |
| Nervous system disorders<br>Carpal Tunnel Syndrome<br>subjects affected / exposed<br>occurrences (all) | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 3 / 79 (3.80%)<br>3    | 1 / 81 (1.23%)<br>1    |  |
| Headache(Solicited)<br>subjects affected / exposed<br>occurrences (all)                                | 28 / 79 (35.44%)<br>41 | 21 / 81 (25.93%)<br>27 |  |
| Migraine<br>subjects affected / exposed<br>occurrences (all)   | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Paraesthesia<br>subjects affected / exposed<br>occurrences (all)                                       | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Sinus Headache<br>subjects affected / exposed<br>occurrences (all)                                     | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Presyncope<br>subjects affected / exposed<br>occurrences (all)   | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Blood and lymphatic system disorders<br>Leukopenia<br>subjects affected / exposed<br>occurrences (all) | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Gastrointestinal disorders<br>Nausea<br>subjects affected / exposed<br>occurrences (all)               | 1 / 79 (1.27%)<br>1    | 0 / 81 (0.00%)<br>0    |  |
| Nausea(Solicited)<br>subjects affected / exposed<br>occurrences (all)                                  | 9 / 79 (11.39%)<br>12  | 11 / 81 (13.58%)<br>11 |  |
| Skin and subcutaneous tissue disorders   |                        |                        |  |

|   |                        |                        |  |
|---|------------------------|------------------------|--|
| Dermatitis Contact<br>subjects affected / exposed<br>occurrences (all)  | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Hyperhidrosis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 2 / 79 (2.53%)<br>2    | 2 / 81 (2.47%)<br>2    |  |
| Back Pain<br>subjects affected / exposed<br>occurrences (all)   | 0 / 79 (0.00%)<br>0    | 2 / 81 (2.47%)<br>2    |  |
| Myalgia<br>subjects affected / exposed<br>occurrences (all)   | 0 / 79 (0.00%)<br>0    | 2 / 81 (2.47%)<br>2    |  |
| Myalgia(Solicited)<br>subjects affected / exposed<br>occurrences (all)  | 27 / 79 (34.18%)<br>31 | 12 / 81 (14.81%)<br>13 |  |
| Pain in Extremity<br>subjects affected / exposed<br>occurrences (all)   | 1 / 79 (1.27%)<br>2    | 0 / 81 (0.00%)<br>0    |  |
| Infections and infestations<br>Asymptomatic Bacteriuria<br>subjects affected / exposed<br>occurrences (all)       | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Ear Lobe Infection<br>subjects affected / exposed<br>occurrences (all)  | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Oral Herpes<br>subjects affected / exposed<br>occurrences (all)   | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Rhinitis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 79 (0.00%)<br>0    | 0 / 81 (0.00%)<br>0    |  |
| Sinusitis   |                        |                        |  |

|  |                     |                     |  |
|--|---------------------|---------------------|--|
| subjects affected / exposed<br>occurrences (all)   | 1 / 79 (1.27%)<br>1 | 1 / 81 (1.23%)<br>1 |  |
| Upper Respiratory Tract Infection<br>subjects affected / exposed<br>occurrences (all)                          | 3 / 79 (3.80%)<br>3 | 1 / 81 (1.23%)<br>1 |  |
| Metabolism and nutrition disorders<br>Vitamin D Deficiency<br>subjects affected / exposed<br>occurrences (all) | 0 / 79 (0.00%)<br>0 | 0 / 81 (0.00%)<br>0 |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment  |
|-----------------|--|
| 29 July 2021    | This amendment was created to add another year of follow-up and its related safety and immunogenicity assessments for Cohorts 1a, 1b and 3 subjects in order to collect additional long-term safety and immunogenicity data for more than one year after second vaccination.   |
| 07 October 2021 | The main purpose of this amendment was to remove planned Ad26.COV2.S booster vaccinations at 24 months after the primary regimen for Cohort 2 subjects, due to the smaller number of subjects remaining than expected, mostly related to severe acute respiratory syndrome (coronavirus-2SARS-CoV-2) infections and receiving authorized/licensed coronavirus disease-2019 (COVID-19) vaccines outside of the study.     |
| 16 August 2022  | The main purpose of this amendment was to remove planned Ad26.COV2.S booster vaccinations at 24 months after the primary regimen for Cohort 2 participants, due to the smaller number of subjects remaining than expected, mostly related to severe acute respiratory syndrome (coronavirus-2SARS-CoV-2) infections and receiving authorized/licensed coronavirus disease-2019 (COVID-19) vaccines outside of the study. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported