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., ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Vaccines & Prevention B.V., 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*10^10 virus particles (vp) and 1*10^11 vp, administered intramuscularly (IM) as a single-dose or 2-dose schedule in healthy adults aged greater than or equal to (>=) 18 to less than or equal to (<=) 55 years and in adults aged >=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
Arm title	COHORT 1A: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)

Arm description:

Healthy adult subjects aged greater than or equal to (>=) 18 to less than or equal to (<=) 55 received a single intramuscular (IM) injection of Ad26.COV2.S 5*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*10^10 >=6 months after Vaccination 2.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and an ad hoc booster dose at >= 6 months after Vaccination 2.

Arm title	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)

Arm description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=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*10^10 vp on Day 57 (Vaccination 2).

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 and >=6 months after Vaccination 2.

Arm title	COHORT 1A: 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*10^11 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*10^10 vp >=6 months after Vaccination 2.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S. 5*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*10^10 vp, >=6 months after Vaccination 2.

Investigational medicinal product name	Ad26.COV2.S 1*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*10^11 vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2).

Arm title	COHORT 1A: 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*10^11 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*10^10 vp >=6 months after Vaccination 2.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 1*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*10^11 vp on Day 1 (Vaccination 1).

Investigational medicinal product name	Ad26.COV2.S. 5*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*10^10 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*10^11 vp on Day 57 (Vaccination 2).

Arm title	COHORT 1A: 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*10^10 vp Ad26.COV2.S.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S. 5*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 offerred a single dose of 5*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).

Arm title	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)

Arm description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=6 months after Vaccination 2.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and >=6 months after Vaccination 2.

Arm title	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)

Arm description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=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*10^10 vp on Day 57 (Vaccination 2).

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 and >=6 months after Vaccination 2.

Arm title	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*10^11 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*10^10 vp >=6 months after Vaccination 2.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp at >= 6 months after Vaccination 2.

Investigational medicinal product name	Ad26.COV2.S 1*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*10^11 vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2).

Arm title	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*10^11 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*10^10 vp >=6 months after Vaccination 2.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 1*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*10^11 vp on Day 1 (Vaccination 1).

Investigational medicinal product name	Ad26.COV2.S. 5*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 5*10^10 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*10^11 vp on Day 57 (Vaccination 2).

Arm title	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*10^10 vp Ad26.COV2.S.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S. 5*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 offerred a single dose of 5*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).

Arm title	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*10^10 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*10^10 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*10^10 vp at 6 and 12 months as matching Booster 1 and Booster 2 vaccination.

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1) and >=6 months after Booster 2 Vaccination.

Arm title	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*10^10 vp on Day 1 (Vaccination 1) followed by first booster vaccination with single IM injection of Ad26.COV2.S 5*10^10 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*10^10 vp at 12 months (Booster 2).

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1) at 6 months (Booster 1).

Arm title	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*10^10 vp on Day 1 (Vaccination 1) followed by a matching placebo booster 1 injection after 6 months and Ad26.COV2.S 5*10^10 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*10^10 vp at 6 months (Booster 1).

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1), 12 months (Booster 2).

Arm title	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*10^10 vp Ad26.COV2.S.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 5*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*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).

Arm title	COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10)

Arm description:

Group 1 and 4 healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp Ad26.COV2.S. >=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*10^10 vp at 6 and 12 months after vaccination 2 as Booster 1 and Booster 2 vaccines.

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1) Day 57 (Vaccination) and >=6 months after Booster 2 Vaccination.

Arm title	COHORT 2B: Ad26 5e10, 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*10^10 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*10^10 vp at 12 months after vaccination 2.

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1), Day 57 (Vaccination 2) and 6 months after Vaccination 2 (Booster 1).

Arm title	COHORT 2B: Ad26 5e10, 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*10^10 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*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*10^10 vp at 6 months after vaccination 2 as Booster 1 vaccination.

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2), at 12 months after vaccination 2 as Booster 2 vaccination.

Arm title	COHORT 2B: Placebo, B: PL

Arm description:

Group 5 healthy adult subjects aged >=18 to <=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*10^10 vp Ad26.COV2.S.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S. 5*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*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).

Arm title	COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)

Arm description:

Adult subjects (with good or stable health) aged >=65 years received a single IM injection of Ad26.COV2.S 5*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*10^10 vp Ad26.COV2.S. >=6 months after

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2) and >=6 months after Vaccination 2.

Arm title	COHORT 3: Ad26 5e10, 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 5*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*10^10 vp Ad26.COV2.S. >=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*10^10 vp on Day 57 (Vaccination 2).

Investigational medicinal product name	Ad26.COV2.S 5*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*10^10 vp on Day 1 and >=6 months after Vaccination 2.

Arm title	COHORT 3: Ad26 1e11, Ad26 1e11(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*10^11 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*10^10 vp Ad26.COV2.S. >=6 months after

Arm type	Experimental

Investigational medicinal product name	Ad26.COV2.S. 5*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*10^10 vp at >=6 months after Vaccination 2.

Investigational medicinal product name	Ad26.COV2.S 1*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*10^11 vp on Day 1 (Vaccination 1) and Day 57 (Vaccination 2).

Arm title	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*10^11 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*10^10 vp Ad26.COV2.S. >=6 months after Vaccination 2.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 1*10^11
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*10^11 vp on Day 1 (Vaccination 1).

Investigational medicinal product name	Ad26.COV2.S. 5*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*10^10 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*10^11 vp on Day 57 (Vaccination 2).

Arm title	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*10^10 vp Ad26.COV2.S.

Arm type	Experimental

Investigational medicinal product name	Ad26.COV2.S. 5*10^10
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*10^10 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).

Number of subjects in period 1	COHORT 1A: Ad26 5e10, Ad26 5e10(AHBV: Ad26	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26
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
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	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:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10)
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

Number of subjects in period 1	COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26	COHORT 3: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 3: Ad26 1e11, Ad26 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

Number of subjects in period 1	COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 3: Placebo, 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 (>=) 18 to less than or equal to (<=) 55 received a single intramuscular (IM) injection of Ad26.COV2.S 5*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*10^10 >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 1*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 1*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*10^10 vp >=6 months after Vaccination 2.

Reporting group title	COHORT 1A: Placebo, Placebo

Reporting group 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*10^10 vp Ad26.COV2.S.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 1*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 1*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*10^10 vp >=6 months after Vaccination 2.

Reporting group title	COHORT 1B: Placebo, Placebo

Reporting group 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*10^10 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 >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=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 >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*10^10 vp on Day 1 (Vaccination 1) followed by first booster vaccination with single IM injection of Ad26.COV2.S 5*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 >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*10^10 vp on Day 1 (Vaccination 1) followed by a matching placebo booster 1 injection after 6 months and Ad26.COV2.S 5*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*10^10 vp Ad26.COV2.S.

Reporting group title	COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10)

Reporting group description:

Group 1 and 4 healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 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 healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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 >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*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 >=18 to <=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*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 >=65 years received a single IM injection of Ad26.COV2.S 5*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*10^10 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*10^10 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*10^10 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*10^11 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*10^10 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*10^11 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*10^10 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*10^10 vp Ad26.COV2.S.

Reporting group values	COHORT 1A: Ad26 5e10, Ad26 5e10(AHBV: Ad26	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26
Number of subjects	77	75	75
Title for AgeCategorical			
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			
Units: years			
arithmetic mean	35.4	35.7	34.5
standard deviation	± 10.11	± 9.99	± 10.59
Title for Gender			
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
Number of subjects	73	77	5
Title for AgeCategorical			
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 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: Ad26	COHORT 1B: Ad26 1e11, PL(AHBV: 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: Placebo, Placebo	COHORT 2A: Ad26 5e10, B: PL(PL/AHBV: Ad26 5e10)	COHORT 2A: Ad26 5e10, B: Ad26 5e10, 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:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10)
Number of subjects	32	17	62
Title for AgeCategorical			
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			
Units: years			
arithmetic mean	39.2	37.5	37.6
standard deviation	± 10.53	± 10.41	± 9.93
Title for Gender			
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			
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			
Units: years			
arithmetic mean	38.3	36.1	37
standard deviation	± 9.81	± 11.48	± 9.99
Title for Gender			
Units: subjects			
Female	10	15	10
Male	20	13	5

Reporting group values	COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26	COHORT 3: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26
Number of subjects	81	80	82
Title for AgeCategorical			
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			
Units: years			
arithmetic mean	69.5	69.8	69.7
standard deviation	± 4.24	± 3.74	± 4.33
Title for Gender			
Units: subjects			
Female	40	36	42
Male	41	44	40

Reporting group values	COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 3: Placebo, Placebo	Total
Number of subjects	79	81	1076
Title for AgeCategorical			
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			
Units: years			
arithmetic mean	70.3	69.9	
standard deviation	± 4.18	± 3.73	-
Title for Gender			
Units: subjects			
Female	40	43	541
Male	39	38	535

End points 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 (>=) 18 to less than or equal to (<=) 55 received a single intramuscular (IM) injection of Ad26.COV2.S 5*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*10^10 >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 1*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 1*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*10^10 vp >=6 months after Vaccination 2.

Reporting group title	COHORT 1A: Placebo, Placebo

Reporting group 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*10^10 vp Ad26.COV2.S.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 1*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*10^10 vp >=6 months after Vaccination 2.

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

Reporting group description:

Healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 1*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*10^10 vp >=6 months after Vaccination 2.

Reporting group title	COHORT 1B: Placebo, Placebo

Reporting group 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*10^10 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 >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 vp >=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 >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*10^10 vp on Day 1 (Vaccination 1) followed by first booster vaccination with single IM injection of Ad26.COV2.S 5*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 >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*10^10 vp on Day 1 (Vaccination 1) followed by a matching placebo booster 1 injection after 6 months and Ad26.COV2.S 5*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*10^10 vp Ad26.COV2.S.

Reporting group title	COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265e10)

Reporting group description:

Group 1 and 4 healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*10^10 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 healthy adult subjects aged >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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 >=18 to <=55 received a single IM injection of Ad26.COV2.S 5*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*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 >=18 to <=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*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 >=65 years received a single IM injection of Ad26.COV2.S 5*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*10^10 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*10^10 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*10^10 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*10^11 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*10^10 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*10^11 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*10^10 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*10^10 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[1][2]

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.

End point 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)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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

End point values	COHORT 1A: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: 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

End point values	COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, 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[3][4]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: 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: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, 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[5][6]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	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: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[8]	0[9]		
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[10][11]

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.

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	58	29	32	17
Units: Subjects	48	24	19	4

End point values	COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265 e10)	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	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[12][13]

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: 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	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[14][15]

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: 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	4	0[16]	0[17]	0[18]
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[19][20]

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[21]
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[22][23]

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[24][25]

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[26]
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[27][28]

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[29]
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[30][31]

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[32]	0[33]	0[34]
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[35][36]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: 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: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, 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[37][38]

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.

End point 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)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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

End point values	COHORT 1A: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: 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

End point values	COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, 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

	Vaccination[39][40]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[41]	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: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[42]	0[43]		
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

No statistical analyses for this end point

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[44][45]

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: 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	58	29	32	17
Units: Subjects	47	23	21	8

End point values	COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265 e10)	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	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[46]

	[47]

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: 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	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[48][49]

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: 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[50]
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[51][52]

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/Ad265 e10)	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

No statistical analyses for this end point

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[53][54]

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: 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	4	0[55]	0[56]	0[57]
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[58][59]

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/Ad265 e10)	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[60]
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[61][62]

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[63]
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[64][65]

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[66]	0[67]	0[68]
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[69][70]

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: 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	38	30	33	34

End point values	COHORT 3: Placebo, 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[71][72]

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: 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	39	35	47	42

End point values	COHORT 3: Placebo, 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[73][74]

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: 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	77	80	80	78
Units: Subjects	41	5	51	13

End point values	COHORT 3: Placebo, 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[75][76]

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: 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	77	80	80	78
Units: Subjects	33	24	40	24

End point values	COHORT 3: Placebo, 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[77][78]

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: 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	11	15	14	9
Units: Subjects	5	6	4	5

End point values	COHORT 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	0[79]			
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[80][81]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: 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: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, 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[82][83]

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: 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	11	15	14	9
Units: Subjects	3	7	4	6

End point values	COHORT 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	0[84]			
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[85][86]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: 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: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, 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[87][88]

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.

End point 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)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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

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

Notes:

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

End point values	COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[90]	0[91]		
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[92][93]

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: 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	58	29	32	17
Units: Subjects	15	5	7	5

End point values	COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265 e10)	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	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[94][95]

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: 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	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[96][97]

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: 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[98]
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[99][100]

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: 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	4	0[101]	0[102]	0[103]
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[104][105]

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/Ad265 e10)	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[106][107]

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/Ad265 e10)	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[108]
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 Ad Hoc Booster Vaccination

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

	Events (AEs) for 28 Days After Ad Hoc Booster

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:

[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/Ad265 e10)	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[111]	0[112]	0[113]
Units: Subjects	0			

Notes:

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

[112] - 0 subjects were available for the analysis as none received ad hoc booster vaccination.

[113] - 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 Booster Vaccination 2

End point title	Cohort 2b: Number of Subjects With Unsolicited Adverse Events (AEs) for 28 Days After Booster Vaccination 2[114][115]

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:

[114] - 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.

[115] - 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[116]
Units: Subjects	0	0	0	

Notes:

[116] - 0 subjects were available for the analysis as none received booster vaccination 2.

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[117][118]

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.

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	81	80	82	79
Units: Subjects	16	13	19	26

End point values	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 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[119][120]

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:

[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: 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	11	15	14	9
Units: Subjects	1	0	3	1

End point values	COHORT 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	0[121]			
Units: Subjects				

Notes:

[121] - 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 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[122][123]

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:

[122] - 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.

[123] - 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	77	80	80	78
Units: Subjects	11	9	12	12

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

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)[124][125]

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.

End point 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)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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

End point values	COHORT 1A: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: 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

End point values	COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, Placebo	COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 3: Ad26 5e10, PL(AHBV: Ad26 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

End point values	COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 3: Placebo, 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)[126][127]

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: 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	58	29	32	17
Units: Subjects	0	0	1	0

End point values	COHORT 2B:Ad265e10, Ad26 5e10, B:PL(PL/Ad265 e10)	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	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)[128][129]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, Placebo	COHORT 1B: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: 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: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 1B: Placebo, Placebo	COHORT 3: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 3: Ad26 5e10, PL(AHBV: Ad26 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

End point values	COHORT 3: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 3: Ad26 1e11, PL(AHBV: Ad26 5e10)	COHORT 3: Placebo, 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)[130][131]

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.

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	58	29	32	17
Units: Subjects	0	0	0	0

End point values	COHORT 2B:Ad265e10, Ad26 5e10, B:	COHORT 2B: Ad26 5e10, Ad26 5e10, B:	COHORT 2B: Ad26 5e10, Ad26 5e10, B:	COHORT 2B: 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)[132]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1B: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1B: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Percentage of subjects				
number (confidence interval 95%)				

Day 29 Day 71	0.0 (0.0 to 60.2) 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)[133]

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: 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	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: Placebo, 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)[134]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, 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)[135]

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. "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 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: 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	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)[136]

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: 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	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: Placebo, 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)[137]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, 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 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+[138]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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)

End point values	COHORT 1A: Placebo, 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 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 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)[139]

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.

End point 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)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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 100.0)	98.4 (91.5 to 100.0)	100.0 (94.6 to 100.0)	98.4 (91.6 to 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)

End point values	COHORT 1A: Placebo, 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 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)[140]

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:

[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: 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	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: 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)[141]

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:

[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: 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	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: 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+[142]

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/Ad265 e10)	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)[143]

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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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, 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 to 99999)			
Day 422 (n =23, 23, 13, 11, 0)	99999 (99999 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+[145]

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: 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	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)[146]

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: 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	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: Placebo, 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+[147]

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: 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	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)

End point values	COHORT 3: Placebo, 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 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+[148]

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.

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	36	35	33	39
Units: Percentage of subjets				

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: Placebo, 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 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 (>=) 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 (>=) 1 and Less Than (<) 1[149]

End point description:

Percentage of subjects with Th1 (IFN-g OR IL2 NOT TH2) /Th2 (IL4 OR IL5 OR IL13 AND CD40L) ratio >=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: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	9	4	3	0[150]
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 29: Th1/Th2 >=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 >=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 >=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 >=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 (>=) 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 (>=) 1 and Less Than (<) 1[151]

End point description:

Percentage of subjects with Th1 (IFN-g OR IL2 NOT TH2) /Th2 (IL4 OR IL5 OR IL13 AND CD40L) ratio >=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 >=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 >=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 >=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 >=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 >=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 >=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: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 15: Th1/Th2 ratio >=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 >=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 >=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 >=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 >=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 >=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)[152]

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/Ad265 e10)	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 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+[153]

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:

[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 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 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+[154]

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:

[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 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	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 1a: Percentage of Subjects With T helper cell 1/T Helper Cell 2 Ratio (Th1/Th2) Greater Than or Equal to (>=) 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 (>=) 1 and Less Than (<) 1[155]

End point description:

Percentage of subjects with Th1 (IFN-g OR IL2 NOT TH2) /Th2 (IL4 OR IL5 OR IL13 AND CD40L) ratio >=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: Ad26 5e10, Ad26 5e10(AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, PL(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 1e11(AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, PL(AHBV: Ad26 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: Placebo, 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 >=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 >=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 >=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 >=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 (>=) 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 (>=) 1 and Less Than (<) 1[156]

End point description:

Percentage of subjects with Th1 (IFN-g OR IL2 NOT TH2) /Th2 (IL4 OR IL5 OR IL13 AND CD40L) ratio >=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[157]
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 29: Th1/Th2 >=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 >=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*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*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*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*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*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*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*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*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*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*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*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*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*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*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*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*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*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*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*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*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*10^10 vp on Day 1 (Vaccination 1) and single IM injection of Ad26.COV2.S 5*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*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*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*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*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*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*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*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*10^10 vp on Day 1 (Vaccination 1) and a matching placebo injection after 6 months (Booster 1) and Ad26.COV2.S 5*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*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*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*10^10 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. Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of 5*10^10 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*10^10 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). Subjects who had previously received 1 or more doses of any COVID-19 vaccine received a single ad hoc booster dose of 5*10^10 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*10^11 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*10^10 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*10^10 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*10^10 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*10^11 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*10^10 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*10^10 vp Ad26.COV2.S. 6 months after Vaccination 2.

Serious adverse events	COHORT 1A: Placebo, Placebo	COHORT 1A: Ad26 1e11, PL(,AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 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
Nervous system disorders			
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
Ear and labyrinth disorders			
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
Renal and urinary disorders			
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
Musculoskeletal and connective tissue disorders			
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
Infections and infestations			
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

Serious adverse events	COHORT 1A: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, Ad26 5e10(,AHBV: Ad26	COHORT 1B: Ad26 5e10, Ad26 5e10(,AHBV: Ad26
Total subjects affected by serious adverse events			
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)			
Breast Cancer Stage Ii			
subjects affected / exposed	1 / 75 (1.33%)	0 / 77 (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
Surgical and medical procedures			
Mastectomy			
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
General disorders and administration site conditions			
Hanging			
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
Pyrexia			
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
Immune system disorders			
Anaphylactic Shock			
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
Reproductive system and breast disorders			
Uterine Prolapse			
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
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
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

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

Serious adverse events	COHORT 2A: Ad26 5e10, B: PL(,PL/AHBV: Ad26 5e10)	COHORT 1B: Placebo, Placebo	COHORT 1B: Ad26 1e11, PL(,AHBV: Ad26 5e10)
Total subjects affected by serious 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 adverse events			
Neoplasms benign, malignant and 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 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 / 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
General disorders and administration site conditions			
Hanging			
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
Pyrexia			
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
Immune system disorders			
Anaphylactic Shock			
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
Reproductive system and breast 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

Serious adverse events	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

Serious adverse events	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

Serious adverse events	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			
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
Injury, poisoning and procedural complications			
Craniocerebral Injury			
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
Hip Fracture			
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
Procedural Vomiting			
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
Procedural Nausea			
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
Rib Fracture			
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
Traumatic Fracture			
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
Wrist Fracture			
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

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

Serious adverse events	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
Infections and infestations			
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

Serious adverse events	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			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
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	
Surgical and medical procedures			
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	
General disorders and administration site conditions			
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	
Immune system disorders			

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 %

Non-serious adverse events	COHORT 1A: Placebo, Placebo	COHORT 1A: Ad26 1e11, PL(,AHBV: Ad26 5e10)	COHORT 1A: Ad26 1e11, Ad26 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			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
Pyrexia(Solicited)			
subjects affected / exposed	0 / 77 (0.00%)	28 / 73 (38.36%)	33 / 75 (44.00%)
occurrences (all)	0	29	43
Pyrexia			
subjects affected / exposed	1 / 77 (1.30%)	0 / 73 (0.00%)	3 / 75 (4.00%)
occurrences (all)	1	0	3
Vaccination Site Erythema(Solicited)			
subjects affected / exposed	0 / 77 (0.00%)	1 / 73 (1.37%)	3 / 75 (4.00%)
occurrences (all)	0	1	4
Vaccination Site Pain(Solicited)			
subjects affected / exposed	9 / 77 (11.69%)	60 / 73 (82.19%)	64 / 75 (85.33%)
occurrences (all)	10	66	112
Vaccination Site Swelling(Solicited)			
subjects affected / exposed	0 / 77 (0.00%)	2 / 73 (2.74%)	4 / 75 (5.33%)
occurrences (all)	0	2	5
Reproductive system and breast disorders			
Uterine Spasm			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 77 (0.00%)	1 / 73 (1.37%)	0 / 75 (0.00%)
occurrences (all)	0	1	0
Rhinitis Allergic			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
Investigations			
Haemoglobin Decreased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	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	5 / 77 (6.49%)	27 / 73 (36.99%)	25 / 75 (33.33%)
occurrences (all)	5	31	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	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 77 (0.00%)	1 / 73 (1.37%)	0 / 75 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 77 (0.00%)	0 / 73 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	COHORT 1A: Ad26 5e10, PL(,AHBV: Ad26 5e10)	COHORT 1A: Ad26 5e10, Ad26 5e10(,AHBV: Ad26	COHORT 1B: Ad26 5e10, Ad26 5e10(,AHBV: Ad26
Total subjects affected by non-serious adverse events			
subjects affected / exposed	64 / 75 (85.33%)	68 / 77 (88.31%)	5 / 5 (100.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	3 / 75 (4.00%)	3 / 77 (3.90%)	0 / 5 (0.00%)
occurrences (all)	3	3	0
Fatigue			
subjects affected / exposed	3 / 75 (4.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Fatigue(Solicited)			
subjects affected / exposed	41 / 75 (54.67%)	50 / 77 (64.94%)	4 / 5 (80.00%)
occurrences (all)	52	72	5
Injection Site Haemorrhage			
subjects affected / exposed	1 / 75 (1.33%)	0 / 77 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Pyrexia(Solicited)			
subjects affected / exposed	14 / 75 (18.67%)	13 / 77 (16.88%)	0 / 5 (0.00%)
occurrences (all)	14	14	0

Pyrexia			
subjects affected / exposed	2 / 75 (2.67%)	2 / 77 (2.60%)	0 / 5 (0.00%)
occurrences (all)	2	2	0
Vaccination Site Erythema(Solicited)			
subjects affected / exposed	0 / 75 (0.00%)	2 / 77 (2.60%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Vaccination Site Pain(Solicited)			
subjects affected / exposed	51 / 75 (68.00%)	58 / 77 (75.32%)	5 / 5 (100.00%)
occurrences (all)	55	99	8
Vaccination Site Swelling(Solicited)			
subjects affected / exposed	0 / 75 (0.00%)	3 / 77 (3.90%)	1 / 5 (20.00%)
occurrences (all)	0	4	1
Reproductive system and breast disorders			
Uterine Spasm			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Investigations			
Haemoglobin Decreased			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb Injury			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 75 (0.00%)	3 / 77 (3.90%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Headache(Solicited)			
subjects affected / exposed	36 / 75 (48.00%)	41 / 77 (53.25%)	2 / 5 (40.00%)
occurrences (all)	48	59	3
Migraine			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 75 (1.33%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Sinus Headache			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 75 (1.33%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Nausea(Solicited)			
subjects affected / exposed	22 / 75 (29.33%)	19 / 77 (24.68%)	2 / 5 (40.00%)
occurrences (all)	27	22	2
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			

subjects affected / exposed	0 / 75 (0.00%)	1 / 77 (1.30%)	0 / 5 (0.00%)
occurrences (all)	0	1	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	1 / 75 (1.33%)	4 / 77 (5.19%)	1 / 5 (20.00%)
occurrences (all)	1	4	1
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 75 (0.00%)	0 / 77 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	COHORT 2A: Ad26 5e10, B: PL(,PL/AHBV: Ad26 5e10)	COHORT 1B: Placebo, Placebo	COHORT 1B: Ad26 1e11, PL(,AHBV: Ad26 5e10)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 58 (91.38%)	5 / 5 (100.00%)	5 / 5 (100.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 58 (1.72%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	3 / 58 (5.17%)	0 / 5 (0.00%)	3 / 5 (60.00%)
occurrences (all)	3	0	3
Fatigue			
subjects affected / exposed	2 / 58 (3.45%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Fatigue(Solicited)			
subjects affected / exposed	37 / 58 (63.79%)	4 / 5 (80.00%)	5 / 5 (100.00%)
occurrences (all)	37	6	6
Injection Site Haemorrhage			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia(Solicited)			
subjects affected / exposed	15 / 58 (25.86%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	15	0	2
Pyrexia			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaccination Site Erythema(Solicited)			

subjects affected / exposed	1 / 58 (1.72%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vaccination Site Pain(Solicited)			
subjects affected / exposed	48 / 58 (82.76%)	0 / 5 (0.00%)	4 / 5 (80.00%)
occurrences (all)	48	0	5
Vaccination Site Swelling(Solicited)			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Uterine Spasm			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 58 (1.72%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Rhinitis Allergic			
subjects affected / exposed	1 / 58 (1.72%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Investigations			
Haemoglobin Decreased			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb Injury			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	3 / 58 (5.17%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	3	1	0
Headache(Solicited)			
subjects affected / exposed	35 / 58 (60.34%)	3 / 5 (60.00%)	5 / 5 (100.00%)
occurrences (all)	35	3	5
Migraine			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Sinus Headache			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 58 (1.72%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Nausea(Solicited)			
subjects affected / exposed	19 / 58 (32.76%)	2 / 5 (40.00%)	3 / 5 (60.00%)
occurrences (all)	19	2	3
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed	1 / 58 (1.72%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	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			
subjects affected / exposed	0 / 58 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	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 non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	5 / 5 (100.00%)	27 / 29 (93.10%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	4 / 5 (80.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	4	0	0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Fatigue(Solicited)			
subjects affected / exposed	5 / 5 (100.00%)	3 / 5 (60.00%)	17 / 29 (58.62%)
occurrences (all)	8	4	17
Injection Site Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Pyrexia(Solicited)			
subjects affected / exposed	3 / 5 (60.00%)	0 / 5 (0.00%)	3 / 29 (10.34%)
occurrences (all)	4	0	3
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Vaccination Site Erythema(Solicited)			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Vaccination Site Pain(Solicited)			
subjects affected / exposed	5 / 5 (100.00%)	3 / 5 (60.00%)	23 / 29 (79.31%)
occurrences (all)	10	3	23

Vaccination Site Swelling(Solicited)			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Uterine Spasm			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Investigations			
Haemoglobin Decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Neutrophil Count Decreased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Limb Injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Headache(Solicited)			
subjects affected / exposed	5 / 5 (100.00%)	3 / 5 (60.00%)	16 / 29 (55.17%)
occurrences (all)	9	5	16
Migraine			

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			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Myalgia(Solicited)			
subjects affected / exposed	5 / 5 (100.00%)	3 / 5 (60.00%)	17 / 29 (58.62%)
occurrences (all)	7	3	17
Pain in Extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Ear Lobe Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Oral Herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	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 non-serious adverse events			
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	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Nausea(Solicited)			
subjects affected / exposed	5 / 81 (6.17%)	2 / 15 (13.33%)	9 / 28 (32.14%)
occurrences (all)	5	3	10
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 81 (2.47%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	2	0	1
Back Pain			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 81 (0.00%)	1 / 15 (6.67%)	1 / 28 (3.57%)
occurrences (all)	0	1	1
Myalgia(Solicited)			
subjects affected / exposed	26 / 81 (32.10%)	2 / 15 (13.33%)	16 / 28 (57.14%)
occurrences (all)	34	2	25

Pain in Extremity			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Ear Lobe Infection			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Oral Herpes			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 81 (0.00%)	1 / 15 (6.67%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 81 (0.00%)	1 / 15 (6.67%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 81 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 81 (0.00%)	1 / 15 (6.67%)	0 / 28 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	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 non-serious adverse events			
subjects affected / exposed	27 / 32 (84.38%)	10 / 17 (58.82%)	59 / 62 (95.16%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
General disorders and administration 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	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Investigations			
Haemoglobin Decreased			
subjects affected / exposed	1 / 32 (3.13%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb Injury			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)	2 / 62 (3.23%)
occurrences (all)	0	1	2
Headache(Solicited)			
subjects affected / exposed	11 / 32 (34.38%)	4 / 17 (23.53%)	43 / 62 (69.35%)
occurrences (all)	11	4	69
Migraine			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Sinus Headache			
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	1 / 32 (3.13%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			

Leukopenia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Nausea(Solicited)			
subjects affected / exposed	4 / 32 (12.50%)	2 / 17 (11.76%)	22 / 62 (35.48%)
occurrences (all)	4	2	27
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 17 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Myalgia(Solicited)			
subjects affected / exposed	13 / 32 (40.63%)	4 / 17 (23.53%)	32 / 62 (51.61%)
occurrences (all)	13	4	51
Pain in Extremity			
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
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

Non-serious adverse events	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			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb Injury			
subjects affected / exposed	1 / 30 (3.33%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 30 (6.67%)	4 / 82 (4.88%)	1 / 80 (1.25%)
occurrences (all)	2	4	1
Headache(Solicited)			
subjects affected / exposed	23 / 30 (76.67%)	39 / 82 (47.56%)	27 / 80 (33.75%)
occurrences (all)	30	58	32
Migraine			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Sinus Headache			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			

subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nausea(Solicited)			
subjects affected / exposed	8 / 30 (26.67%)	11 / 82 (13.41%)	7 / 80 (8.75%)
occurrences (all)	10	11	7
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 30 (0.00%)	3 / 82 (3.66%)	0 / 80 (0.00%)
occurrences (all)	0	3	0
Back Pain			
subjects affected / exposed	0 / 30 (0.00%)	3 / 82 (3.66%)	0 / 80 (0.00%)
occurrences (all)	0	3	0
Myalgia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 82 (1.22%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Myalgia(Solicited)			
subjects affected / exposed	20 / 30 (66.67%)	35 / 82 (42.68%)	18 / 80 (22.50%)
occurrences (all)	27	39	23
Pain in Extremity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ear Lobe Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 82 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	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

Non-serious adverse events	COHORT 3: Ad26 1e11, PL(,AHBV: Ad26 5e10)	COHORT 3: Placebo, Placebo	
Total subjects affected by non-serious 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 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) subjects affected / exposed occurrences (all)	7 / 79 (8.86%) 7	1 / 81 (1.23%) 1	
Pyrexia subjects affected / exposed occurrences (all)	2 / 79 (2.53%) 2	0 / 81 (0.00%) 0	
Vaccination Site Erythema(Solicited) subjects affected / exposed occurrences (all)	3 / 79 (3.80%) 3	0 / 81 (0.00%) 0	
Vaccination Site Pain(Solicited) subjects affected / exposed occurrences (all)	37 / 79 (46.84%) 45	14 / 81 (17.28%) 17	
Vaccination Site Swelling(Solicited) subjects affected / exposed occurrences (all)	2 / 79 (2.53%) 2	1 / 81 (1.23%) 1	
Reproductive system and breast disorders Uterine Spasm subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 81 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 81 (0.00%) 0	
Rhinitis Allergic subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 81 (0.00%) 0	
Investigations Haemoglobin Decreased subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 81 (0.00%) 0	
Neutrophil Count Decreased subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 81 (0.00%) 0	
Injury, poisoning and procedural complications			

Limb Injury			
subjects affected / exposed	1 / 79 (1.27%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	3 / 79 (3.80%)	1 / 81 (1.23%)	
occurrences (all)	3	1	
Headache(Solicited)			
subjects affected / exposed	28 / 79 (35.44%)	21 / 81 (25.93%)	
occurrences (all)	41	27	
Migraine			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Sinus Headache			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 79 (1.27%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
Nausea(Solicited)			
subjects affected / exposed	9 / 79 (11.39%)	11 / 81 (13.58%)	
occurrences (all)	12	11	
Skin and subcutaneous tissue disorders			

Dermatitis Contact			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 79 (2.53%)	2 / 81 (2.47%)	
occurrences (all)	2	2	
Back Pain			
subjects affected / exposed	0 / 79 (0.00%)	2 / 81 (2.47%)	
occurrences (all)	0	2	
Myalgia			
subjects affected / exposed	0 / 79 (0.00%)	2 / 81 (2.47%)	
occurrences (all)	0	2	
Myalgia(Solicited)			
subjects affected / exposed	27 / 79 (34.18%)	12 / 81 (14.81%)	
occurrences (all)	31	13	
Pain in Extremity			
subjects affected / exposed	1 / 79 (1.27%)	0 / 81 (0.00%)	
occurrences (all)	2	0	
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Ear Lobe Infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Oral Herpes			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Sinusitis			

subjects affected / exposed	1 / 79 (1.27%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 79 (3.80%)	1 / 81 (1.23%)	
occurrences (all)	3	1	
Metabolism and nutrition disorders			
Vitamin D Deficiency			
subjects affected / exposed	0 / 79 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	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:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported