Clinical trial results:
A Randomized, Double-blind, Placebo-controlled Phase 2a Study to Evaluate a Range of Dose Levels and Vaccination Intervals of Ad26.COV2.S in Healthy Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older and to Evaluate 2 Dose Levels of Ad26.COV2.S in Healthy Adolescents Aged 12 to 17 Years Inclusive

Summary

EudraCT number	2020-002584-63
Trial protocol	DE NL ES Outside EU/EEA
Global end of trial date	09 March 2022

Results information

Result version number	v1 (current)
This version publication date	25 September 2022
First version publication date	25 September 2022

Trial information

Trial identification

Sponsor protocol code	CR108854

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04535453
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Vaccines & Prevention B.V.
Sponsor organisation address	Newtonweg 1, Leiden, Netherlands, 2333 CP
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)	Yes
EMA paediatric investigation plan number(s)	EMEA-002880-PIP01-20
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 March 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 March 2022
Global end of trial reached?	Yes
Global end of trial date	09 March 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the humoral immune response to 3 dose levels (5*10^10 virus particle [vp], 2.5*10^10 vp, 1.25*10^10 vp) of Ad26.COV2.S, administered intramuscularly (IM) as a 2-dose schedule at a 56-day interval, 28 days after Vaccination 2 and to assess the humoral immune response to 2 dose levels (1*10^11 vp and 5*10^10 vp) of Ad26.COV2.S, administered intramuscularly (IM) as a single vaccination, 28 days after Vaccination 1 and to assess the humoral immune response to Ad26.COV2.S at the 5*10^10 vp dose level, administered IM as a 2-dose schedule at a 28-day and at an 84-day interval, 28 days after Vaccination 2 and to assess the safety and reactogenicity of Ad26.COV2.S, administered IM at several dose levels, as a 2-dose or a single-dose schedule.

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	31 August 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 233
Country: Number of subjects enrolled	Spain: 218
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	Netherlands: 152
Worldwide total number of subjects	617
EEA total number of subjects	603

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)	33
Adults (18-64 years)	375
From 65 to 84 years	209
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 635 subjects were enrolled in the study, out of which 617 subjects received treatment. Remaining 18 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	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Arm description:

Adult subjects received 2-dose regimen intramuscular (IM) injection of Ad26.COV2.S vaccine at a dose level of 5*10^10 virus particle (vp) on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

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 intramuscular (IM) injection of Ad26.COV2.S at a dose level of 5*10^10 virus particle (vp) on Days 1 and 57.

Investigational medicinal product name	Ad26.COV2.S 1.25*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 antigen presentation IM injection of Ad26.COV2.S at a dose level of 1.25*10^10 vp at 4 months after second vaccination.

Arm title	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26 1.25*10^10

Arm description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 2.5*10^10 vp on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 1.25*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 antigen presentation IM injection of Ad26.COV2.S at a dose level of 1.25*10^10 vp at 4 months after second vaccination.

Investigational medicinal product name	Ad26.COV2.S 2.5*10^10 vp
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.COV2.S vaccine at dose level of 2.5*10^10 vp on Days 1 and 57.

Arm title	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26 1.25*10^10

Arm description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1.25*10^10 vp on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 1.25*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 antigen presentation IM injection of Ad26.COV2.S at a dose level of 1.25*10^10 vp at 4 months after second vaccination.

Investigational medicinal product name	Ad26.COV2.S 1.25*10^10 vp
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.COV2.S vaccine at dose level of 1.25*10^10 vp on Days 1 and 57.

Arm title	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10

Arm description:

Adult subjects received single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1*10^11 vp on Day 1 and placebo at Day 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

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 single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1*10^11 vp on Day 1.

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 IM injection of placebo matching to Ad26.COV2.S on Day 57.

Investigational medicinal product name	Ad26.COV2.S 1.25*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 antigen presentation IM injection of Ad26.COV2.S at dose level of 1.25*10^10 vp at 4 months after second vaccination.

Arm title	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10

Arm description:

Adult subjects received a single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Day 1 and placebo at Day 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

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 IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Day 1.

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 IM injection of placebo matching to Ad26.COV2.S on Day 57.

Investigational medicinal product name	Ad26.COV2.S 1.25*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 antigen presentation IM injection of Ad26.COV2.S at dose level of 1.25*10^10 vp at 4 months after second vaccination.

Arm title	Group 6: Placebo, Placebo, Placebo, Placebo

Arm description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

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

Dosage and administration details:

Subjects also received a single antigen presentation IM injection of placebo matching to Ad26.COV2.S at 4 months after second vaccination

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 IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 57.

Arm title	Group 7: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Arm description:

Adult subjects received 2 dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Days 1 and 29. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S 1.25*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 antigen presentation IM injection of Ad26.COV2.S at a dose level of 1.25*10^10 vp at 4 months after second 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 IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Days 1 and 29.

Arm title	Group 8: Placebo, Placebo, Placebo

Arm description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 29. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Arm type	Placebo
Investigational medicinal product name	Ad26.COV2.S 1.25*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 antigen presentation IM injection of Ad26.COV2.S at dose level of 1.25*10^10 vp at 4 months after second vaccination.

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 IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 29.

Arm title	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Arm description:

Adult subjects received 2 dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Days 1 and 85. Subjects also received a single antigen presentation injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Arm type	Experimental

Investigational medicinal product name	Ad26.COV2.S 1.25*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 antigen presentation IM injection of Ad26.COV2.S at a dose level of 1.25*10^10 vp at 4 months after second vaccination.

Investigational medicinal product name	Ad26.COV2.S 5x10^10 vp
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.COV2.S vaccine at dose level of 5x10^10 vp on Days 1 and 85.

Arm title	Group 10: Placebo, Placebo, Placebo

Arm description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 85. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

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

Dosage and administration details:

Subjects also received a single antigen presentation IM injection of placebo matching to Ad26.COV2.S at 4 months after second vaccination

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 IM injection of placebo matching to Ad26.COV2.S Placebo on Days 1 and 85.

Arm title	Group A and B Combined: Ad26 2.5*10^10

Arm description:

Adolescent subjects aged 12 to 15 years (Group A) and 16 to 17 years (Group B) received single dose IM injection of Ad26.COV2.S vaccine at a dose of 2.5*10^10 vp on Day 1.

Arm type	Placebo
Investigational medicinal product name	Ad26.COV2.S 2.5*10^10 vp
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received single dose IM injection of Ad26.COV2.S vaccine at a dose level of 2.5*10^10 vp on Day 1

Arm title	Group C: Placebo

Arm description:

Adolescent subjects aged 12 to 17 years received single dose IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1.

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 single dose IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1.

Number of subjects in period 1	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26 1.25*10^10	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26 1.25*10^10
Started	86	81	75
Completed	82	73	70
Not completed	4	8	5
Physician decision	-	-	-
Death	-	1	-
Unspecified	-	-	1
Lost to follow-up	1	1	1
Withdrawal by subject	3	6	3

Number of subjects in period 1	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo, Placebo
Started	74	81	26
Completed	70	75	24
Not completed	4	6	2
Physician decision	1	-	-
Death	-	-	-
Unspecified	-	1	-
Lost to follow-up	-	3	1
Withdrawal by subject	3	2	1

Number of subjects in period 1	Group 7: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 8: Placebo, Placebo, Placebo	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10
Started	56	27	53
Completed	54	25	50
Not completed	2	2	3
Physician decision	-	-	-
Death	-	-	-
Unspecified	1	1	1
Lost to follow-up	-	-	1
Withdrawal by subject	1	1	1

Number of subjects in period 1	Group 10: Placebo, Placebo, Placebo	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo
Started	25	30	3
Completed	23	30	2
Not completed	2	0	1
Physician decision	-	-	-
Death	-	-	-
Unspecified	-	-	-
Lost to follow-up	1	-	-
Withdrawal by subject	1	-	1

Baseline characteristics

Reporting groups

Reporting group title	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen intramuscular (IM) injection of Ad26.COV2.S vaccine at a dose level of 5*10^10 virus particle (vp) on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 2.5*10^10 vp on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1.25*10^10 vp on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10

Reporting group description:

Adult subjects received single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1*10^11 vp on Day 1 and placebo at Day 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10

Reporting group description:

Adult subjects received a single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Day 1 and placebo at Day 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 6: Placebo, Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Reporting group title	Group 7: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2 dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Days 1 and 29. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 8: Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 29. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Reporting group title	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2 dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Days 1 and 85. Subjects also received a single antigen presentation injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 10: Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 85. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Reporting group title	Group A and B Combined: Ad26 2.5*10^10

Reporting group description:

Adolescent subjects aged 12 to 15 years (Group A) and 16 to 17 years (Group B) received single dose IM injection of Ad26.COV2.S vaccine at a dose of 2.5*10^10 vp on Day 1.

Reporting group title	Group C: Placebo

Reporting group description:

Adolescent subjects aged 12 to 17 years received single dose IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1.

Reporting group values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26 1.25*10^10	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26 1.25*10^10
Number of subjects	86	81	75
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	57	48	52
From 65 to 84 years	29	33	23
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	49.1	49.1	49.2
standard deviation	± 18.12	± 19.44	± 17.33
Title for Gender Units: subjects			
Female	26	30	22
Male	60	51	53

Reporting group values	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo, Placebo
Number of subjects	74	81	26
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	48	51	16
From 65 to 84 years	26	30	10
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	50.3	48.6	48.4
standard deviation	± 17.1	± 18.5	± 16.88
Title for Gender Units: subjects			
Female	32	35	13
Male	42	46	13

Reporting group values	Group 7: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 8: Placebo, Placebo, Placebo	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10
Number of subjects	56	27	53

Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	37	17	33
From 65 to 84 years	19	10	20
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	48.8	49.0	48.1
standard deviation	± 17.15	± 17.63	± 18.99
Title for Gender Units: subjects			
Female	14	10	19
Male	42	17	34

Reporting group values	Group 10: Placebo, Placebo, Placebo	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo
Number of subjects	25	30	3
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	30	3
Adults (18-64 years)	16	0	0
From 65 to 84 years	9	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	52.4	16.3	16.3
standard deviation	± 13.63	± 0.47	± 0.58
Title for Gender Units: subjects			
Female	13	20	2
Male	12	10	1

Reporting group values	Total		
Number of subjects	617		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	33		
Adults (18-64 years)	375		
From 65 to 84 years	209		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		
Title for Gender Units: subjects			
Female	236		

Male	381		

End points

End points reporting groups

Reporting group title	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen intramuscular (IM) injection of Ad26.COV2.S vaccine at a dose level of 5*10^10 virus particle (vp) on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 2.5*10^10 vp on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1.25*10^10 vp on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10

Reporting group description:

Adult subjects received single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1*10^11 vp on Day 1 and placebo at Day 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10

Reporting group description:

Adult subjects received a single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Day 1 and placebo at Day 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 6: Placebo, Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Reporting group title	Group 7: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2 dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Days 1 and 29. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 8: Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 29. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Reporting group title	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2 dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Days 1 and 85. Subjects also received a single antigen presentation injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 10: Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 85. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Reporting group title	Group A and B Combined: Ad26 2.5*10^10

Reporting group description:

Adolescent subjects aged 12 to 15 years (Group A) and 16 to 17 years (Group B) received single dose IM injection of Ad26.COV2.S vaccine at a dose of 2.5*10^10 vp on Day 1.

Reporting group title	Group C: Placebo

Reporting group description:

Adolescent subjects aged 12 to 17 years received single dose IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1.

Subject analysis set title	Group 1 and 7 Combined
Subject analysis set type	Safety analysis

Subject analysis set description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at a dose level of 5*10^10 vp on Days 1 and 57 and also received a single antigen presentation IM injection of Ad26.COV2.S at 1.25*10^10 vp at 4 months after second vaccination.

Subject analysis set title	Group 6 and 8 Combined
Subject analysis set type	Safety analysis

Subject analysis set description:

Adult subjects received IM injection of Ad26.COV2.S vaccine matching placebo on Days 1 and 57 and also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Primary: Adults of Groups 1, 2 and 3: Percentage of Subjects With Serological Response to Vaccination as Measured by Virus Neutralization Assay (VNA) Titers at 28 days After Vaccination 2

End point title	Adults of Groups 1, 2 and 3: Percentage of Subjects With Serological Response to Vaccination as Measured by Virus Neutralization Assay (VNA) Titers at 28 days After Vaccination 2[1][2]

End point description:

Percentage of subjects with serological response to vaccination as measured by VNA titers were reported. A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was less than or equal to the lower limit of quantification (<=LLOQ) and the post-baseline sample was greater than (>) LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (greater than or equal to [>=] 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were 50% inhibitory concentration (IC50) of 58 and 12,800, respectively. Per protocol immunogenicity (PPI) population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

28 days after Vaccination 2 (Day 85)

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: Descriptive statistics was done, no inferential statistical analysis was performed.

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	36	36	
Units: Percentage of subjects				
number (confidence interval 95%)	96.8 (83.3 to 99.9)	100.0 (90.3 to 100.0)	88.9 (73.9 to 96.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 1, 2 and 3: Percentage of Subjects With Serological Response to Vaccination as Measured by Spike Binding Antibodies Enzyme-linked Immunosorbent Assay (S-ELISA) at 28 Days After Vaccination 2

End point title	Adults of Groups 1, 2 and 3: Percentage of Subjects With Serological Response to Vaccination as Measured by Spike Binding Antibodies Enzyme-linked Immunosorbent Assay (S-ELISA) at 28 Days After Vaccination 2[3][4]

End point description:

Percentage of subjects with serological response to vaccination as measured by S-ELISA were reported. A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

28 days After Vaccination 2 (Day 85)

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: Descriptive statistics was done, no inferential statistical analysis was performed.

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	67	60	
Units: Percentage of subjects				
number (confidence interval 95%)	100.0 (94.7 to 100.0)	100.0 (94.6 to 100.0)	96.7 (88.5 to 99.6)	

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 1, 2 and 3: Antibody Geometric Mean Titers (GMTs) as Measured by VNA at 28 Days After Vaccination 2

End point title	Adults of Groups 1, 2 and 3: Antibody Geometric Mean Titers (GMTs) as Measured by VNA at 28 Days After Vaccination 2[5][6]

End point description:

Antibody GMTs as measured by VNA at 28 days after Vaccination 2 were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

28 days After Vaccination 2 (Day 85)

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: Descriptive statistics was done, no inferential statistical analysis was performed.

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	36	37	
Units: Titer				
geometric mean (confidence interval 95%)	455 (321 to 645)	490 (376 to 637)	364 (239 to 556)	

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 1, 2 and 3: Antibody Geometric Mean Concentrations (GMCs) as Measured by (S-ELISA) at 28 Days After Vaccination 2

End point title	Adults of Groups 1, 2 and 3: Antibody Geometric Mean Concentrations (GMCs) as Measured by (S-ELISA) at 28 Days After Vaccination 2[7][8]

End point description:

Antibody GMCs as measured by S-ELISA at 28 days after Vaccination 2 were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

28 days After Vaccination 2 (Day 85)

Notes:

[7] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[8] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	71	68	60	
Units: ELISA unit per millilitre (EU/mL)				
geometric mean (confidence interval 95%)	1742 (1400 to 2168)	1563 (1273 to 1918)	1130 (802 to 1593)	

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 4, 5 and 6: Percentage of Subjects With Serological Response to Vaccination as Measured by VNA Titers at 28 days After Vaccination 1

End point title	Adults of Groups 4, 5 and 6: Percentage of Subjects With Serological Response to Vaccination as Measured by VNA Titers at 28 days After Vaccination 1[9][10]

End point description:

Percentage of subjects with serological response to vaccination as measured by VNA titers were reported. A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

28 days After Vaccination 1 (Day 29)

Notes:

[9] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[10] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo, Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	34	14	
Units: Percentage of subjects				
number (confidence interval 95%)	97.3 (85.8 to 99.9)	100.0 (89.7 to 100.0)	0.0 (0.0 to 23.2)	

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 4, 5 and 6: Percentage of Subjects With Serological Response to Vaccination as Measured by S-ELISA at 28 Days After Vaccination 1

End point title	Adults of Groups 4, 5 and 6: Percentage of Subjects With Serological Response to Vaccination as Measured by S-ELISA at 28 Days After Vaccination 1[11][12]

End point description:

Percentage of subjects with serological response to vaccination as measured by S-ELISA were reported. A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

28 days After Vaccination 1 (Day 29)

Notes:

[11] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[12] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo, Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	65	19	
Units: Percentage of subjects				
number (confidence interval 95%)	98.5 (91.7 to 100.0)	95.4 (87.1 to 99.0)	0.0 (0.0 to 17.6)	

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 4, 5 and 6: Antibody GMTs as Measured by VNA at 28 Days After Vaccination 1

End point title	Adults of Groups 4, 5 and 6: Antibody GMTs as Measured by VNA at 28 Days After Vaccination 1[13][14]

End point description:

Antibody GMTs as measured by VNA at 28 days after vaccination 1 were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Here, 99999 signifies that 'Geometric mean' and 'confidence interval' for Group 6 could not be estimated as the analyzed values were below the LLOQ.

End point type	Primary

End point timeframe:

28 days After Vaccination 1 (Day 29)

Notes:

[13] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[14] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo, Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	35	14	
Units: Titer				
geometric mean (confidence interval 95%)	263 (201 to 345)	253 (207 to 308)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 4, 5 and 6: Antibody GMCs as Measured by S-ELISA 28 Days After Vaccination 1

End point title	Adults of Groups 4, 5 and 6: Antibody GMCs as Measured by S-ELISA 28 Days After Vaccination 1[15][16]

End point description:

Antibody GMCs as measured by S-ELISA at 28 days after Vaccination 1 were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Here, 99999 signifies that 'Geometric mean' and 'confidence interval' for Group 6 could not be estimated as the analyzed values were below the LLOQ.

End point type	Primary

End point timeframe:

28 days After Vaccination 1 (Day 29)

Notes:

[15] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[16] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo, Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	65	19	
Units: EU/mL				
geometric mean (confidence interval 95%)	505 (415 to 614)	360 (276 to 471)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 9 and 10: Percentage of Subjects With Serological Response to Vaccination as Measured by VNA Titers 28 days After Vaccination 2

End point title	Adults of Groups 9 and 10: Percentage of Subjects With Serological Response to Vaccination as Measured by VNA Titers 28 days After Vaccination 2[17][18]

End point description:

Percentage of subjects with serological response to vaccination as measured by VNA titers were reported. A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

28 days After Vaccination 2 (Day 113)

Notes:

[17] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[18] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	13		
Units: Percentage of subjects				
number (confidence interval 95%)	100.0 (90.0 to 100.0)	15.4 (1.9 to 45.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 9 and 10: Percentage of Subjects With Serological Response to Vaccination as Measured by S-ELISA at 28 Days After Vaccination 2

End point title	Adults of Groups 9 and 10: Percentage of Subjects With Serological Response to Vaccination as Measured by S-ELISA at 28 Days After Vaccination 2[19][20]

End point description:

Percentage of subjects with serological response to vaccination as measured by S-ELISA were reported. A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

28 days After Vaccination 2 (Day 113)

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: Descriptive statistics was done, no inferential statistical analysis was performed.

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	23		
Units: Percentage of subjects				
number (confidence interval 95%)	100.0 (92.3 to 100.0)	4.3 (0.1 to 21.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 9 and 10: Antibody GMTs as Measured by VNA at 28 Days

After Vaccination 2

End point title	Adults of Groups 9 and 10: Antibody GMTs as Measured by VNA at 28 Days After Vaccination 2[21][22]

End point description:

Antibody GMTs as measured by VNA at 28 days after Vaccination 2 were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Here, 99999 signifies that 'Geometric mean' and 'confidence interval' for Group 10 could not be estimated as the analyzed values were below the LLOQ.

End point type	Primary

End point timeframe:

28 days After Vaccination 2 (Day 113)

Notes:

[21] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[22] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	13		
Units: Titer				
geometric mean (confidence interval 95%)	901 (686 to 1185)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 9 and 10: Antibody GMCs as Measured by S-ELISA at 28 Days After Vaccination 2

End point title	Adults of Groups 9 and 10: Antibody GMCs as Measured by S-ELISA at 28 Days After Vaccination 2[23][24]

End point description:

Antibody GMCs as measured by S-ELISA at 28 days after Vaccination 2 were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Here, 99999 signifies that 'Geometric mean' and 'confidence interval' for Group 10 could not be estimated as the analyzed values were below the LLOQ.

End point type	Primary

End point timeframe:

28 Days After Vaccination 2 (Day 113)

Notes:

[23] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[24] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	23		
Units: EU/mL				
geometric mean (confidence interval 95%)	2391 (1811 to 3156)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Local Adverse Events (AEs) for 7 Days After Vaccination 1

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Local Adverse Events (AEs) for 7 Days After Vaccination 1[25][26]

End point description:

Number of subjects with solicited local AEs at 7 days after vaccination 1 are 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 AEs were pre-defined local (at the injection site) AEs for which subjects were specifically questioned and which were noted by subjects in their e-diary for 7 days after vaccination 1 (day of vaccination and the subsequent 7 days). Solicited local AEs included: injection site pain/tenderness, erythema and swelling at the vaccination site. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

7 days After Vaccination 1 (Day 8)

Notes:

[25] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[26] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	75	74	81
Units: Subjects	27	24	39	42

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	53	25	141	52
Units: Subjects	21	2	75	7

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 1

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Systemic Adverse Events (AEs) for 7 Days After Vaccination 1[27][28]

End point description:

Number of subjects with solicited systemic AEs at 7 days after vaccination 1 are 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. Subjects were instructed on how to note signs and symptoms in their diary on a daily basis for 7 days post-vaccination (Day of vaccination and the subsequent 7 days) for solicited systemic AEs. Solicited systemic AEs included fatigue, headache, myalgia, nausea and fever (body temperature greater than or equal to [>=] 38 degree C). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

7 days After Vaccination 1 (Day 8)

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: Descriptive statistics was done, no inferential statistical analysis was performed.

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	75	74	81
Units: Subjects	35	31	56	50

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	53	25	141	52
Units: Subjects	32	10	84	18

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Local AEs at 7 Days After Vaccination 2

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Local AEs at 7 Days After Vaccination 2[29][30]

End point description:

Number of subjects with solicited local AEs at 7 days after vaccination 2 are 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 AEs were pre-defined local (at the injection site) AEs for which subjects were specifically questioned and which were noted by subjects in their e-diary for 7 days post vaccination 2 (day of vaccination and the subsequent 7 days). Solicited local AEs included: injection site pain/tenderness, erythema and swelling at the vaccination site. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

7 days after Vaccination 2 (Day 64 for Group 1-6; Day 92 for Group 9 and 10)

Notes:

[29] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[30] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	75	74	81
Units: Subjects	33	29	5	4

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	53	25	141	52
Units: Subjects	20	2	63	3

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Systemic AEs at 7 Days After Vaccination 2

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Systemic AEs at 7 Days After Vaccination 2[31][32]

End point description:

Number of subjects with solicited systemic AEs at 7 days after vaccination 2 are 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. Subjects were instructed on how to note signs and symptoms in their diary on a daily basis for 7 days post-vaccination 2 (Day of vaccination 2 and the subsequent 7 days) for solicited systemic AEs. Solicited systemic AEs included fatigue, headache, myalgia, nausea and fever (body temperature greater than or equal to [>=] 38 degree C). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

7 days after Vaccination 2 (Day 64 for Group 1-6; Day 92 for Group 9 and 10)

Notes:

[31] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[32] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	75	74	81
Units: Subjects	32	25	24	20

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	53	25	141	52
Units: Subjects	26	6	81	14

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Unsolicited AEs at 28 Days After Vaccination 1

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Unsolicited AEs at 28 Days After Vaccination 1[33][34]

End point description:

Unsolicited AEs are 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 analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

28 days after Vaccination 1 (Day 29)

Notes:

[33] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[34] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	75	74	81
Units: Subjects	25	15	33	30

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	53	25	141	52
Units: Subjects	8	5	39	9

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Unsolicited AEs at 28 Days After Vaccination 2

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Unsolicited AEs at 28 Days After Vaccination 2[35][36]

End point description:

Unsolicited AEs are 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 analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

28 days After Vaccination 2 (Day 85 for Group 1-6; Day 113 for Group 9 and 10)

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: Descriptive statistics was done, no inferential statistical analysis was performed.

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	75	74	81
Units: Subjects	17	15	16	22

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	53	25	141	52
Units: Subjects	10	4	34	9

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Serious Adverse Events (SAEs)

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Serious Adverse Events (SAEs)[37][38]

End point description:

SAE is any untoward medical occurrence that at any dose may result in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

Up to 1.5 years

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: Descriptive statistics was done, no inferential statistical analysis was performed.

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	75	74	81
Units: Subjects	1	1	1	2

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	53	25	141	52
Units: Subjects	1	0	7	0

Statistical analyses

No statistical analyses for this end point

Primary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Adverse Events of Special Interest (AESIs)

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Adverse Events of Special Interest (AESIs)[39][40]

End point description:

AESIs are significant AEs that are 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, is considered to be an AESI in this study. A suspected TTS case is defined as: Thrombotic events: suspected deep vessel venous or arterial thrombotic events; Thrombocytopenia, defined as platelet count below 150,000/micro liter. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

Up to 1.5 years

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: Descriptive statistics was done, no inferential statistical analysis was performed.

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	26	37	44
Units: Subjects	0	0	0	0

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	19	9	141	52
Units: Subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents: Number of Subjects With Solicited Local AEs at 7 Days After Vaccination 1

End point title	Adolescents: Number of Subjects With Solicited Local AEs at 7 Days After Vaccination 1[41][42]

End point description:

Number of subjects with solicited local AEs at 7 days after vaccination 1 are 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 AEs were pre-defined local (at the injection site) AEs for which subjects were specifically questioned and which were noted by subjects in their e-diary for 7 days post vaccination 1 (day of vaccination and the subsequent 7 days). Solicited local AEs included: injection site pain/tenderness, erythema and swelling at the vaccination site. FAS included all subjects with at least one vaccine administration documented.

End point type	Primary

End point timeframe:

7 Days After Vaccination 1 (Day 8)

Notes:

[41] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[42] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	3		
Units: Subjects	29	1		

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents: Number of Subjects With Solicited Systemic AEs at 7 Days After Vaccination 1

End point title	Adolescents: Number of Subjects With Solicited Systemic AEs at 7 Days After Vaccination 1[43][44]

End point description:

Number of subjects with solicited systemic AEs at 7 days after vaccination 1 are 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. Subjects were instructed on how to note signs and symptoms in their diary on a daily basis for 7 days post-vaccination 1 (Day of vaccination1 and the subsequent 7 days) for solicited systemic AEs. Solicited systemic AEs included fatigue, headache, myalgia, nausea and fever (body temperature greater than or equal to [>=] 38 degree C). FAS included all subjects with at least one vaccine administration documented.

End point type	Primary

End point timeframe:

7 Days After Vaccination 1 (Day 8)

Notes:

[43] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[44] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	3		
Units: Subjects	28	3		

Statistical analyses

No statistical analyses for this end point

Primary: Adolescent Subjects: Number of Subjects With SAEs (inclusive Multisystem Inflammatory Syndrome in Children [MIS-C])

End point title	Adolescent Subjects: Number of Subjects With SAEs (inclusive Multisystem Inflammatory Syndrome in Children [MIS-C])[45][46]

End point description:

SAE is any untoward medical occurrence that at any dose may result in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product. FAS included all subjects with at least one vaccine administration documented. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

up to unblinding date / receipt of a new Covid vaccine (Up to 1.5 years)

Notes:

[45] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[46] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	3		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents: Number of Subjects With Unsolicited AEs at 28 Days After Vaccination 1

End point title	Adolescents: Number of Subjects With Unsolicited AEs at 28 Days After Vaccination 1[47][48]

End point description:

Unsolicited AEs are all AEs for which the subject is not specifically questioned in the subject diary. Full analysis set included all subjects with at least one vaccine administration documented. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

28 Days After Vaccination 1 (Day 29)

Notes:

[47] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[48] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	3		
Units: Subjects	12	2		

Statistical analyses

No statistical analyses for this end point

Primary: Adolescent Subjects: Number of Subjects With AESIs

End point title	Adolescent Subjects: Number of Subjects With AESIs[49][50]

End point description:

AESIs are significant AEs that are 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, is considered to be an AESI in this study. A suspected TTS case is defined as: Thrombotic events: suspected deep vessel venous or arterial thrombotic events; Thrombocytopenia, defined as platelet count below 150,000/micro liter. FAS included all subjects with at least one vaccine administration documented. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Primary

End point timeframe:

up to unblinding date / receipt of a new Covid vaccine (Up to 1.5 years)

Notes:

[49] - 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: Descriptive statistics was done, no inferential statistical analysis was performed.

[50] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	3		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults: Percentage of Subjects With Serological Response to Vaccination as Measured by VNA Titers 7 Days After Antigen Presentation

End point title	Adults: Percentage of Subjects With Serological Response to Vaccination as Measured by VNA Titers 7 Days After Antigen Presentation[51]

End point description:

Percentage of subjects with serological response to vaccination as measured by VNA titers were reported. A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Secondary

End point timeframe:

7 Days After Antigen Presentation (Day 176 for Groups 1-5 ; Day 204 for Group 9)

Notes:

[51] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	33	31	33
Units: Percentage of subjects				
number (confidence interval 95%)	92.0 (74.0 to 99.0)	97.0 (84.2 to 99.9)	83.9 (66.3 to 94.5)	84.8 (68.1 to 94.9)

End point values	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	32		
Units: Percentage of subjects				
number (confidence interval 95%)	96.3 (81.0 to 99.9)	100.0 (89.1 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults: Percentage of Subjects With Serological Response to Vaccination as Measured by S-ELISA 7 Days After Antigen Presentation

End point title	Adults: Percentage of Subjects With Serological Response to Vaccination as Measured by S-ELISA 7 Days After Antigen Presentation[52]

End point description:

Percentage of subjects with serological response to vaccination as measured by S-ELISA were reported.

A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Secondary

End point timeframe:

7 Days After Antigen Presentation (Day 176 for Groups 1-5 ; Day 204 for Group 9)

Notes:

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	62	57	57
Units: Percentage of subjects				
number (confidence interval 95%)	100.0 (94.2 to 100.0)	100.0 (94.2 to 100.0)	96.5 (87.9 to 99.6)	100.0 (93.7 to 100.0)

End point values	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	43		
Units: Percentage of subjects				
number (confidence interval 95%)	91.2 (80.7 to 97.1)	100.0 (91.8 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults: GMTs as Measured by VNA 7 Days After Antigen Presentation

End point title	Adults: GMTs as Measured by VNA 7 Days After Antigen Presentation[53]

End point description:

Antibody GMTs as measured by VNA at 7 days after antigen presentation were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Secondary

End point timeframe:

7 days after antigen presentation (Day 176 for Groups 1-5 ; Day 204 for Group 9)

Notes:

[53] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	33	32	33
Units: Titer				
geometric mean (confidence interval 95%)	318 (207 to 489)	393 (272 to 568)	279 (171 to 457)	275 (182 to 415)

End point values	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	32		
Units: Titer				
geometric mean (confidence interval 95%)	525 (339 to 814)	616 (462 to 822)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adult: Antibody GMCs as Measured by S-ELISA 7 Days After Antigen Presentation

End point title	Adult: Antibody GMCs as Measured by S-ELISA 7 Days After Antigen Presentation[54]

End point description:

Antibody GMCs as measured by S-ELISA 7 days after antigen presentation were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint.

End point type	Secondary

End point timeframe:

7 Days After Antigen Presentation (Day 176 for Groups 1-5 ; Day 176 for Group 7; Day 204 for Group 9)

Notes:

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	63	57	58
Units: EU/mL				
geometric mean (confidence interval 95%)	1146 (904 to 1452)	1179 (933 to 1490)	1038 (730 to 1475)	1024 (721 to 1454)

End point values	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	43		
Units: EU/mL				
geometric mean (confidence interval 95%)	1262 (937 to 1702)	1963 (1514 to 2545)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Local AEs at 7 Days After Antigen Presentation

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Local AEs at 7 Days After Antigen Presentation[55]

End point description:

Number of subjects with solicited local AEs at 7 days after antigen presentation are 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 AEs were pre-defined local (at the injection site) AEs for which subjects were specifically questioned and which were noted by subjects in their e-diary for 7 days after antigen presentation (day of antigen presentation and the subsequent 7 days). Solicited local AEs included: injection site pain/tenderness, erythema and swelling at the vaccination site. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Secondary

End point timeframe:

7 Days After Antigen Presentation (Day 176 for Groups 1-5 ; Day 176 for Group 7; Day 204 for Group 9 and 10)

Notes:

[55] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	74
Units: Subjects	28	29	31	35

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	47	18	127	44
Units: Subjects	16	2	50	1

Statistical analyses

No statistical analyses for this end point

Secondary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Systemic AEs at 7 Days After Antigen Presentation

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Solicited Systemic AEs at 7 Days After Antigen Presentation[56]

End point description:

Number of subjects with solicited systemic AEs at 7 days after antigen presentation are 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. Subjects were instructed on how to note signs and symptoms in their diary on a daily basis for 7 days after antigen presentation (Day of antigen presentation and the subsequent 7 days) for solicited systemic AEs. Solicited systemic AEs included fatigue, headache, myalgia, nausea and fever (body temperature greater than or equal to [>=] 38 degree C). FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Secondary

End point timeframe:

7 Days After Antigen Presentation (Day 176 for Groups 1-5 ; Day 176 for Group 7; Day 204 for Group 9 and 10)

Notes:

[56] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	74
Units: Subjects	30	24	23	28

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	47	18	127	44
Units: Subjects	15	4	51	10

Statistical analyses

No statistical analyses for this end point

Secondary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Unsolicited AEs at 28 Days After Antigen Presentation

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With Unsolicited AEs at 28 Days After Antigen Presentation[57]

End point description:

Unsolicited AEs are all AEs for which the subject is not specifically questioned in the subject diary. Full analysis set included all subjects with at least one vaccine administration documented. Full analysis set included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Secondary

End point timeframe:

28 Days After Antigen Presentation (Day 197 for Groups 1-5; Day 197 for Group 7; Day 225 for Group 9)

Notes:

[57] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	74
Units: Subjects	10	7	6	12

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	47	18	127	44
Units: Subjects	6	4	15	4

Statistical analyses

No statistical analyses for this end point

Secondary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With SAEs After Antigen Presentation

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With SAEs After Antigen Presentation[58]

End point description:

SAE is any untoward medical occurrence that at any dose may result in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Secondary

End point timeframe:

After antigen presentation until end of study (Day 170 up to 1.5 years for Groups 1 to 6, Day 198 up to 1.5 years for Group 9 and 10)

Notes:

[58] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	74
Units: Subjects	0	0	1	0

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	47	18	127	44
Units: Subjects	0	0	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With AESIs After Antigen Presentation

End point title	Adults of Groups 2 to 5, Group 9, 10, Groups (1 and 7 Combined) and Groups (6 and 8 Combined): Number of Subjects With AESIs After Antigen Presentation[59]

End point description:

AESIs are significant AEs that are 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, is considered to be an AESI in this study. A suspected TTS case is defined as: Thrombotic events: suspected deep vessel venous or arterial thrombotic events; Thrombocytopenia, defined as platelet count below 150,000/micro liter. FAS included all subjects with at least one vaccine administration documented. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Subjects from groups 7 and 8 (with vaccination 2 delayed due to pausing rule) were analyzed with groups 1 and 6 in FAS. Hence, Group 7 and 8 are not reported.

End point type	Secondary

End point timeframe:

After antigen presentation until end of study (Day 170 up to 1.5 years for Groups 1 to 6, Day 198 up to 1.5 years for Group 9 and 10)

Notes:

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	68	68	74
Units: Subjects	0	0	0	1

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo	Group 1 and 7 Combined	Group 6 and 8 Combined
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	47	18	127	44
Units: Subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Groups 1 to 6: Percentage of Subjects With Neutralizing Antibody Titers to the Wild-type SARS-CoV-2 Virus Expressing S-protein as Measured by VNA

End point title	Adults Groups 1 to 6: Percentage of Subjects With Neutralizing Antibody Titers to the Wild-type SARS-CoV-2 Virus Expressing S-protein as Measured by VNA[60]

End point description:

Percentage of subjects with neutralizing antibody titers to the wild-type SARS-CoV-2 virus expressing S-protein as measured by VNA were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Here 'n' (number analyzed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated and reported as no subjects were analyzed.

End point type	Secondary

End point timeframe:

Days 197 and 393

Notes:

[60] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	31	29	31
Units: Percentage of subjects				

number (confidence interval 95%)				
Day 197 (n =26, 31, 29, 31, 26, 12)	100.0 (86.8 to 100.0)	100.0 (88.8 to 100.0)	96.6 (82.2 to 99.9)	96.8 (83.3 to 99.9)
Day 393 (n =29, 21, 19, 30, 26, 0)	93.1 (77.2 to 99.2)	95.2 (76.2 to 99.9)	84.2 (60.4 to 96.6)	80.0 (61.4 to 92.3)

End point values	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	12		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 197 (n =26, 31, 29, 31, 26, 12)	80.8 (60.6 to 93.4)	0.0 (0.0 to 26.5)		
Day 393 (n =29, 21, 19, 30, 26, 0)	92.0 (74.0 to 99.0)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Group 9 and 10: Percentage of Subjects With Neutralizing Antibody Titers to the Wild-type SARS-CoV-2 Virus Expressing S-protein as Measured by VNA

End point title	Adults Group 9 and 10: Percentage of Subjects With Neutralizing Antibody Titers to the Wild-type SARS-CoV-2 Virus Expressing S-protein as Measured by VNA[61]

End point description:

Percentage of subjects with neutralizing antibody titers to the wild-type SARS-CoV-2 virus expressing S-protein as measured by VNA were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Here 'n' (number analyzed) signifies number of subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

Days 225 and 421

Notes:

[61] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	10		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 225 (n =29, 10)	100.0 (88.1 to 100.0)	0.0 (0.0 to 30.8)		
Day 421 (n =31, 1)	100.0 (88.8 to 100.0)	0.0 (0.0 to 97.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Groups 1 to 6: Percentage of Subjects With Binding Antibody Titers to SARS-CoV-2 or Individual SARS-CoV-2 Proteins

End point title	Adults Groups 1 to 6: Percentage of Subjects With Binding Antibody Titers to SARS-CoV-2 or Individual SARS-CoV-2 Proteins[62]

End point description:

Percentage of subjects with binding antibody titers to SARS-CoV-2 or individual SARS-CoV-2 proteins were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Here 'n' (number analyzed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated and reported as no subjects were analyzed.

End point type	Secondary

End point timeframe:

Days 197 and 393

Notes:

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	60	55	55
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 197 (n= 62, 60, 55, 55, 56, 16)	100.0 (94.2 to 100.0)	100.0 (94.0 to 100.0)	98.2 (90.3 to 100.0)	100.0 (93.5 to 100.0)
Day 393 (n =63, 33, 28, 51, 51, 0)	100.0 (94.3 to 100.0)	100.0 (89.4 to 100.0)	85.7 (67.3 to 96.0)	92.2 (81.1 to 97.8)

End point values	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	16		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 197 (n= 62, 60, 55, 55, 56, 16)	98.2 (90.4 to 100.0)	0.0 (0.0 to 20.6)		
Day 393 (n =63, 33, 28, 51, 51, 0)	98.0 (89.6 to 100.0)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Groups 9 and 10: Percentage of Subjects With Binding Antibody Titers to SARS-CoV-2 or Individual SARS-CoV-2 Proteins

End point title	Adults Groups 9 and 10: Percentage of Subjects With Binding Antibody Titers to SARS-CoV-2 or Individual SARS-CoV-2 Proteins[63]

End point description:

Percentage of subjects with binding antibody titers to SARS-CoV-2 or individual SARS-CoV-2 proteins were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here N (number of subjects analyzed) signifies subjects evaluated for this endpoint. Here 'n' (number analyzed) signifies number of subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

Days 225 and 421

Notes:

[63] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 10: Placebo, Placebo, Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	14		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 225 (n =37, 14)	100.0 (90.5 to 100.0)	0.0 (0.0 to 23.2)		

Day 421 (n =39, 1)	97.4 (86.5 to 99.9)	0.0 (0.0 to 97.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents: Percentage of Subjects With Serological Response to Vaccination as Measured by VNA Titers 28 Days After Vaccination 1 (Day 29)

End point title	Adolescents: Percentage of Subjects With Serological Response to Vaccination as Measured by VNA Titers 28 Days After Vaccination 1 (Day 29)[64]

End point description:

Percentage of subjects with serological response to vaccination as measured by VNA titers were reported. A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes.

End point type	Secondary

End point timeframe:

28 Days After Vaccination 1 (Day 29)

Notes:

[64] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	3		
Units: Percentage of subjects				
number (confidence interval 95%)	100.0 (87.2 to 100.0)	0.0 (0.0 to 70.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents: Percentage of Subjects With Serological Response to Vaccination as Measured by S-ELISA 28 Days After Vaccination 1 (Day 29)

End point title	Adolescents: Percentage of Subjects With Serological Response to Vaccination as Measured by S-ELISA 28 Days After Vaccination 1 (Day 29)[65]

End point description:

Percentage of subjects with serological response to vaccination as measured by S-ELISA were reported.

A subject was considered a responder if at least one of the following conditions was met: 1) The baseline sample value was <=LLOQ and the post-baseline sample was >LLOQ. 2) The baseline sample value was >LLOQ and the post-baseline sample value represented an at least 4-fold (>= 4-fold) increase from the baseline sample value. The lower limit and upper limit of quantification were IC50 of 58 and 12,800, respectively. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes.

End point type	Secondary

End point timeframe:

28 Days After Vaccination 1 (Day 29)

Notes:

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	3		
Units: Percentage of subjects				
number (confidence interval 95%)	100.0 (86.8 to 100.0)	0.0 (0.0 to 70.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents: Antibody GMTs as Measured by VNA at 28 Days After Vaccination 1 (Day 29)

End point title	Adolescents: Antibody GMTs as Measured by VNA at 28 Days After Vaccination 1 (Day 29)[66]

End point description:

Antibody GMTs as measured by VNA at 28 days after vaccination (Day 29) were reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here, 99999 signifies that 'Geometric mean' and 'confidence interval' for Group C could not be estimated as the analyzed values were below the LLOQ.

End point type	Secondary

End point timeframe:

28 days After Vaccination 1 (Day 29)

Notes:

[66] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	3		
Units: Titer				
geometric mean (confidence interval 95%)	305 (245 to 378)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents: Antibody GMCs as Measured by S-ELISA 28 Days After Vaccination 1

End point title	Adolescents: Antibody GMCs as Measured by S-ELISA 28 Days After Vaccination 1[67]

End point description:

Antibody GMCs as measured by S-ELISA 28 days after vaccination was reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here, 99999 signifies data could not be estimated as the analyzed value were below the LLOQ.

End point type	Secondary

End point timeframe:

28 days After Vaccination 1 (Day 29)

Notes:

[67] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	3		
Units: EU/mL				
geometric mean (confidence interval 95%)	682 (506 to 920)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents: Neutralizing Antibody Titers to the Wild-type SARS-CoV-2 Virus Expressing S Protein as Measured by VNA

End point title	Adolescents: Neutralizing Antibody Titers to the Wild-type SARS-CoV-2 Virus Expressing S Protein as Measured by VNA[68]

End point description:

Neutralizing antibody titers to the Wild-type SARS-CoV-2 virus expressing S protein measured by VNA was reported. PPI population included all randomized and vaccinated subjects for whom immunogenicity data were available excluding subjects with major protocol deviations expected to impact the immunogenicity outcomes. Here 'n' (number analyzed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated as the analyzed value were below the LLOQ.

End point type	Secondary

End point timeframe:

Days 57, 85 and 169

Notes:

[68] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	3		
Units: Titer				
geometric mean (confidence interval 95%)				
Day 57 (n =27, 3)	323 (262 to 399)	99999 (99999 to 99999)		
Day 85 (n =22, 3)	306 (227 to 413)	99999 (99999 to 99999)		
Day 169 (n =15, 0)	342 (219 to 532)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents: Binding Antibody Titers to SARS-CoV-2 or Individual SARS-CoV-2 Proteins as Measured by ELISA

End point title	Adolescents: Binding Antibody Titers to SARS-CoV-2 or Individual SARS-CoV-2 Proteins as Measured by ELISA[69]

End point description:

Binding antibody titers to SARS-CoV-2 or individual SARS-CoV-2 proteins 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 expected to impact the immunogenicity outcomes. Here 'n' (number analyzed) signifies number of subjects evaluable at specified time points. Here, 99999 signifies data could not be estimated as the analyzed value were below the LLOQ.

End point type	Secondary

End point timeframe:

Days 57, 85, 169

Notes:

[69] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	3		
Units: Titer				
geometric mean (confidence interval 95%)				
Day 57 (n =27, 3)	770 (593 to 1000)	99999 (99999 to 99999)		
Day 85 (n =22, 3)	773 (547 to 1093)	99999 (99999 to 99999)		
Day 169 (n =15, 0)	796 (449 to 1411)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 1.5 years

Adverse event reporting additional description:

Subjects from groups 7 and 8 (with vaccination 2 delayed due to study pause) were analyzed with groups 1 and 6 in FAS. However, 1 subject in Groups 7 and 1 subject in group 8 received the second vaccination as scheduled (28 days after first vaccination). Therefore, AEs for these 2 subjects were included in Group 7 and 8 reporting arms.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen intramuscular (IM) injection of Ad26.COV2.S vaccine at a dose level of 5*10^10 virus particle (vp) on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen intramuscular (IM) injection of Ad26.COV2.S vaccine at dose level of 2.5*10^10 vp on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1.5*10^10 vp on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10

Reporting group description:

Adult subjects received single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 1*10^11 vp on Day 1 and placebo at Day 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10

Reporting group description:

Adult subjects received a single dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Day 1 and placebo at Day 57. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 6: Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 57. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Reporting group title	Group 10: Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 85. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S vaccine at 4 months after second vaccination.

Reporting group title	Group 7: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10

vp on Days 1 and 29. Subjects also received a single antigen presentation IM injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group 8: Placebo, Placebo, Placebo

Reporting group description:

Adult subjects received IM injection of placebo matching to Ad26.COV2.S vaccine on Days 1 and 29. Subjects also received a single antigen presentation IM injection with single dose level of placebo matching to Ad26.COV2.S at 4 months after second vaccination.

Reporting group title	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10

Reporting group description:

Adult subjects received 2-dose regimen IM injection of Ad26.COV2.S vaccine at dose level of 5*10^10 vp on Days 1 and 85. Subjects also received a single antigen presentation injection with single dose level of Ad26.COV2.S (1.25*10^10 vp) at 4 months after second vaccination.

Reporting group title	Group A and B Combined: Ad26 2.5*10^10

Reporting group description:

Adolescent subjects aged 12 to 15 years (Group A) and 16 to 17 years (Group B) received single dose IM injection of Ad26.COV2.S vaccine at a dose of 2.5*10^10 vp on Day 1.

Reporting group title	Group C: Placebo

Reporting group description:

Adolescent subjects aged 12 to 17 years received single dose IM injection of placebo matching to Ad26.COV2.S vaccine on Day 1

Serious adverse events	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26 1.25*10^10	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26 1.25*10^10
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 141 (4.96%)	1 / 81 (1.23%)	1 / 75 (1.33%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Myeloid Leukaemia			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
Adenocarcinoma of Colon			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
Lung Adenocarcinoma			
subjects affected / exposed	0 / 141 (0.00%)	0 / 81 (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
Prostate Cancer			

subjects affected / exposed	0 / 141 (0.00%)	0 / 81 (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
Injury, poisoning and procedural complications			
Lower Limb Fracture			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
Nervous system disorders			
Cerebrospinal Fluid Leakage			
subjects affected / exposed	0 / 141 (0.00%)	0 / 81 (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
Ischaemic Stroke			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
Blood and lymphatic system disorders			
Pancytopenia			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 141 (0.00%)	1 / 81 (1.23%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyrexia			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
Hepatobiliary disorders			
Hepatic Cyst			

subjects affected / exposed	0 / 141 (0.00%)	0 / 81 (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
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
Osteoarthritis			
subjects affected / exposed	0 / 141 (0.00%)	0 / 81 (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			
Bacteraemia			
subjects affected / exposed	0 / 141 (0.00%)	0 / 81 (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
Pneumonia			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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
Systemic Candida			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (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

Serious adverse events	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 74 (1.35%)	2 / 81 (2.47%)	0 / 52 (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)			
Acute Myeloid Leukaemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of Colon			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	0 / 74 (0.00%)	1 / 81 (1.23%)	0 / 52 (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
Prostate Cancer			
subjects affected / exposed	1 / 74 (1.35%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Lower Limb Fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
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			
Cerebrospinal Fluid Leakage			
subjects affected / exposed	0 / 74 (0.00%)	1 / 81 (1.23%)	0 / 52 (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
Ischaemic Stroke			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Pancytopenia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
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			
Death			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
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 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic Cyst			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
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			
Haematuria			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
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			
Bacteraemia			

subjects affected / exposed	0 / 74 (0.00%)	1 / 81 (1.23%)	0 / 52 (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
Pneumonia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 10: Placebo, Placebo, Placebo	Group 7: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 8: Placebo, Placebo, Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (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)			
Acute Myeloid Leukaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of Colon			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			

subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
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			
Lower Limb Fracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
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			
Cerebrospinal Fluid Leakage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Pancytopenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
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			
Death			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic Cyst			

subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
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			
Haematuria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo
Total subjects affected by serious adverse events			

subjects affected / exposed	1 / 53 (1.89%)	0 / 30 (0.00%)	0 / 3 (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)			
Acute Myeloid Leukaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of Colon			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
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			
Lower Limb Fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
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			
Cerebrospinal Fluid Leakage			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Pancytopenia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
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			
Death			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
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 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic Cyst			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
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			
Haematuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Bacteraemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Group 1: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 2: Ad26 2.5*10^10, Ad26 2.5*10^10, Ad26 1.25*10^10	Group 3: Ad26 1.25*10^10, Ad26 1.25*10^10, Ad26 1.25*10^10
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 141 (24.82%)	24 / 81 (29.63%)	20 / 75 (26.67%)
Nervous system disorders			
Headache			
subjects affected / exposed	18 / 141 (12.77%)	11 / 81 (13.58%)	8 / 75 (10.67%)
occurrences (all)	18	17	10
General disorders and administration site conditions			
Chills			
subjects affected / exposed	5 / 141 (3.55%)	5 / 81 (6.17%)	1 / 75 (1.33%)
occurrences (all)	6	6	1
Fatigue			
subjects affected / exposed	5 / 141 (3.55%)	5 / 81 (6.17%)	2 / 75 (2.67%)
occurrences (all)	6	7	2
Eye disorders			
Eye Pain			
subjects affected / exposed	0 / 141 (0.00%)	0 / 81 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal Pain			
subjects affected / exposed	1 / 141 (0.71%)	3 / 81 (3.70%)	1 / 75 (1.33%)
occurrences (all)	1	3	1
Reproductive system and breast disorders			
Premenstrual Pain			
subjects affected / exposed	0 / 141 (0.00%)	0 / 81 (0.00%)	0 / 75 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 141 (1.42%)	3 / 81 (3.70%)	2 / 75 (2.67%)
occurrences (all)	2	4	3
Oropharyngeal Pain			
subjects affected / exposed	3 / 141 (2.13%)	3 / 81 (3.70%)	1 / 75 (1.33%)
occurrences (all)	3	3	1
Rhinorrhoea			
subjects affected / exposed	1 / 141 (0.71%)	3 / 81 (3.70%)	5 / 75 (6.67%)
occurrences (all)	1	3	6
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	6 / 141 (4.26%)	2 / 81 (2.47%)	2 / 75 (2.67%)
occurrences (all)	6	2	2
Infections and infestations			
Covid-19			
subjects affected / exposed	3 / 141 (2.13%)	3 / 81 (3.70%)	4 / 75 (5.33%)
occurrences (all)	5	3	5
Herpes Zoster			
subjects affected / exposed	1 / 141 (0.71%)	0 / 81 (0.00%)	0 / 75 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	4 / 141 (2.84%)	1 / 81 (1.23%)	7 / 75 (9.33%)
occurrences (all)	5	1	7

Non-serious adverse events	Group 4: Ad26 1*10^10, Placebo, Ad26 1.25*10^10	Group 5: Ad26 5*10^10, Placebo, Ad26 1.25*10^10	Group 6: Placebo, Placebo, Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 74 (27.03%)	33 / 81 (40.74%)	11 / 52 (21.15%)

Nervous system disorders			
Headache			
subjects affected / exposed	11 / 74 (14.86%)	15 / 81 (18.52%)	7 / 52 (13.46%)
occurrences (all)	14	19	9
General disorders and administration site conditions			
Chills			
subjects affected / exposed	2 / 74 (2.70%)	4 / 81 (4.94%)	1 / 52 (1.92%)
occurrences (all)	2	4	2
Fatigue			
subjects affected / exposed	4 / 74 (5.41%)	1 / 81 (1.23%)	1 / 52 (1.92%)
occurrences (all)	5	1	2
Eye disorders			
Eye Pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 74 (1.35%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Premenstrual Pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 74 (4.05%)	2 / 81 (2.47%)	1 / 52 (1.92%)
occurrences (all)	4	2	1
Oropharyngeal Pain			
subjects affected / exposed	4 / 74 (5.41%)	4 / 81 (4.94%)	1 / 52 (1.92%)
occurrences (all)	5	4	1
Rhinorrhoea			
subjects affected / exposed	4 / 74 (5.41%)	4 / 81 (4.94%)	1 / 52 (1.92%)
occurrences (all)	5	4	1
Musculoskeletal and connective tissue disorders			
Back Pain			

subjects affected / exposed	4 / 74 (5.41%)	5 / 81 (6.17%)	1 / 52 (1.92%)
occurrences (all)	5	5	1
Infections and infestations			
Covid-19			
subjects affected / exposed	0 / 74 (0.00%)	4 / 81 (4.94%)	5 / 52 (9.62%)
occurrences (all)	0	4	5
Herpes Zoster			
subjects affected / exposed	0 / 74 (0.00%)	0 / 81 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 74 (6.76%)	8 / 81 (9.88%)	2 / 52 (3.85%)
occurrences (all)	6	8	3

Non-serious adverse events	Group 10: Placebo, Placebo, Placebo	Group 7: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group 8: Placebo, Placebo, Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 25 (36.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 25 (24.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	9	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	2 / 25 (8.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			

Premenstrual Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Covid-19			
subjects affected / exposed	2 / 25 (8.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Herpes Zoster			
subjects affected / exposed	2 / 25 (8.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Group 9: Ad26 5*10^10, Ad26 5*10^10, Ad26 1.25*10^10	Group A and B Combined: Ad26 2.5*10^10	Group C: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 53 (30.19%)	11 / 30 (36.67%)	2 / 3 (66.67%)
Nervous system disorders			
Headache			
subjects affected / exposed	9 / 53 (16.98%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences (all)	12	0	0
General disorders and administration			

site conditions			
Chills			
subjects affected / exposed	1 / 53 (1.89%)	3 / 30 (10.00%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Fatigue			
subjects affected / exposed	4 / 53 (7.55%)	0 / 30 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	2
Eye disorders			
Eye Pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	3
Reproductive system and breast disorders			
Premenstrual Pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 53 (7.55%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Oropharyngeal Pain			
subjects affected / exposed	3 / 53 (5.66%)	3 / 30 (10.00%)	0 / 3 (0.00%)
occurrences (all)	5	3	0
Rhinorrhoea			
subjects affected / exposed	1 / 53 (1.89%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	2 / 53 (3.77%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Covid-19			

subjects affected / exposed	1 / 53 (1.89%)	7 / 30 (23.33%)	0 / 3 (0.00%)
occurrences (all)	1	8	0
Herpes Zoster			
subjects affected / exposed	0 / 53 (0.00%)	0 / 30 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 53 (3.77%)	2 / 30 (6.67%)	0 / 3 (0.00%)
occurrences (all)	2	2	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 August 2020	This amendment included the following changes: allowing a more flexible window between molecular test for SARS-CoV-2 infection and vaccination and a clarification on the eligibility criteria on blood pressure for subjects greater than or equal to (>=) 65 years of age. In addition, other changes were made for alignment with other study protocols within the program, together with minor editorial changes. The amendments to the protocol were adopted before any study-related procedures had begun.
29 October 2020	This amendment concerned the inclusion of adolescent subjects (aged 12 to 17 years, inclusive) in the study to demonstrate non-inferiority of the immune responses in adolescents (5*10^10 and 2.5*10^10 vp dose levels, 1- and 2-dose regimens) to the immune responses of adults in this study (5*10^10 vp dose levels, 1- and 2-dose regimens). Text was added to clarify the request from authorities after a study pause and to include laboratory tests to assess potential vaccine-induced anti-phospholipid syndrome (APS) and potential vaccine-induced activation of coagulation.
22 December 2020	This amendment included the following changes: Change primary endpoint for adolescents to enzyme-linked immunosorbent assay (ELISA) instead of pseudovirion neutralization assay (psVNA) assay, due to lack of sensitivity of the psVNA, and the high correlation between the wild-type virus neutralization assay (wtVNA) and ELISA assays and high throughput of the ELISA assay; Addition of 2 exploratory endpoints, for in-depth analysis of the binding antibody generated by Ad26.COV2.S and to further confirm the correlation between ELISA and wtVNA at different timepoints; Clarification of exclusion criteria for systemic corticosteroids and investigational drugs; Allowance of unblinding on a subject level in the event that an authorized/licensed COVID-19 vaccine became available prior to the end of the study. Protocol Amendment 3 was never implemented at any of the study sites.
04 March 2021	The amendment included the following changes: Stratification by age of adolescent subjects into 2 groups (16 to 17 years of age, inclusive, and 12 to 15 years of age, inclusive) and the implementation of a staggered age-based approach to collect safety data in the older adolescents (16 to 17 years of age) at 2.5*10^10 vp dose level, prior to proceeding to the younger adolescent cohort and/or to the higher dose level of 5*10^10 vp; Adolescents who were initially assigned to receive a single dose of Ad26.COV2.S at 2.5*10^10 vp, were now to receive 2 doses of Ad26.COV2.S at 2.5*10^10 (56-day interval); Outline of procedures to be followed after Emergency Use Authorization (EUA), or similar program/authorization or approval, or approval in any country for both the Ad26.COV2.S vaccine and protocol Amendment 4 by both health authority and Independent Ethics Committee (IEC)/Institutional Review Board (IRB) where a single dose of Ad26.COV2.S was offered to enrolled subjects who initially received placebo, resulting in de facto unblinding of subjects and investigators.
18 May 2021	This amendment concerned the inclusion of additional safety measures due to reports of AEs following use of the Ad26.COV2.S vaccine under EUA in the United States (US), suggesting an increased risk of thrombosis combined with thrombocytopenia.
21 July 2021	This amendment concerned the adolescent recruitment stop.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
11 October 2020	Sponsor was informed of an SAE in Study VAC31518COV3001 that met a study pausing rule. As a precautionary measure, vaccinations in all studies in the program, including Study VAC31518COV2001, were paused. After Data Safety Monitoring Board (DSMB) review, resumption of study vaccinations was recommended by the DSMB. When the pause in Study VAC31518COV2001 was lifted after Health Authority assessment, all but 2 subjects in Groups 7 and 8 had missed their visit window for Vaccination 2 (Visit 4), rendering it impossible to evaluate the intended 28 day vaccination interval. As the de facto vaccination interval in Groups 7 and 8 matched the vaccination interval in Groups 1 and 6, the data were combined.	04 November 2020
13 April 2021	A safety signal was identified for thrombosis with thrombocytopenia syndrome (TTS) in post marketing data in the USA following EUA. Out of an abundance of caution, the Centers for Disease Control and Prevention (CDC) and FDA had recommended a pause in the use of Ad26.COV.S vaccine. With the recommendation from CDC and FDA, the sponsor decided to voluntarily pause vaccinations in all studies in the program. This study pause did not impact any vaccinations in Study VAC31518COV2001 as Injection 3 (antigen presentation) was completed prior to implementation of the study pause.	15 July 2021

Notes:

Limitations and caveats

None reported