Clinical trial results:
A phase 2b, open-label, multi-center, extension study to evaluate the safety and immunogenicity of a revaccination dose of the RSVPreF3 older adults (OA) investigational vaccine administered intramuscularly 18 months post-Dose 2 in adults 60 years and older who participated in the RSV OA=ADJ-002 study

Summary

EudraCT number	2020-000692-21
Trial protocol	BE
Global end of trial date	25 October 2021

Results information

Result version number	v1 (current)
This version publication date	18 June 2022
First version publication date	18 June 2022

Trial information

Trial identification

Sponsor protocol code	213569

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04657198
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GSKClinicalSupportHD@gsk.com, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 March 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To evaluate the safety and reactogenicity following intramuscular (IM) administration of RSVPreF3 OA investigational vaccine up to 1 month post-Dose 3, for all participants.
- To evaluate the humoral immune response following IM administration of RSVPreF3 OA investigational vaccine up to 1 month post-Dose 3, for participants vaccinated with 2 doses of RSVPreF3 OA investigational vaccine in the parent study.

Protection of trial subjects:

The subjects were observed closely for at least 30 minutes following the administration of the vaccines, with appropriate medical treatment readily available in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 60
Country: Number of subjects enrolled	Belgium: 66
Worldwide total number of subjects	126
EEA total number of subjects	66

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	46
From 65 to 84 years	80

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

From a total of 126 participants enrolled in this study, 4 participants were withdrawn before vaccination. 122 participants received the study vaccination.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	High Dose_AS01E Group

Arm description:

Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.

Arm type	Experimental
Investigational medicinal product name	RSVPreF3 OA investigational vaccine (GSK3844766A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5 mL dose of investigational vaccine administered intramuscularly in the deltoid region of the non-dominant arm, at Day 1 (18 months post-Dose 2 in the RSV OA=ADJ-002 parent study).

Arm title	Low Dose_AS01E Group

Arm description:

Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.

Arm type	Experimental
Investigational medicinal product name	RSVPreF3 OA investigational vaccine (GSK3844766A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5 mL dose of investigational vaccine administered intramuscularly in the deltoid region of the non-dominant arm, at Day 1 (18 months post-Dose 2 in the RSV OA=ADJ-002 parent study).

Arm title	Medium Dose_AS01E Group

Arm description:

Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.

Arm type	Experimental

Investigational medicinal product name	RSVPreF3 OA investigational vaccine (GSK3844766A)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One 0.5 mL dose of investigational vaccine administered intramuscularly in the deltoid region of the non-dominant arm, at Day 1 (18 months post-Dose 2 in the RSV OA=ADJ-002 parent study).

Number of subjects in period 1[1]	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group
Started	40	39	43
Completed	39	39	43
Not completed	1	0	0
CONSENT WITHDRAWAL, NOT DUE TO A (S)AE	1	-	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: From a total of 126 participants enrolled in this study, 4 participants were withdrawn before vaccination. 122 participants received the study vaccination.

Baseline characteristics

Reporting groups	
Reporting group title	High Dose_AS01E Group
Reporting group description:	
Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.	
Reporting group title	Low Dose_AS01E Group
Reporting group description:	
Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.	
Reporting group title	Medium Dose_AS01E Group
Reporting group description:	
Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.	

Reporting group values	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group
Number of subjects	40	39	43
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 68.3 ± 5.4	 69.1 ± 5.3	 66.6 ± 5.6
Sex: Female, Male Units: Participants			
Female	27	21	24
Male	13	18	19
Race/Ethnicity, Customized Units: Subjects			
American Indian Or Alaska Native	1	0	0
Black Or African American	1	2	1
White	38	37	42

Reporting group values	Total		
Number of subjects	122		
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 -	 	
Sex: Female, Male Units: Participants			
Female	72		

Male	50		

Race/Ethnicity, Customized Units: Subjects			
American Indian Or Alaska Native	1		
Black Or African American	4		
White	117		

End points

End points reporting groups

Reporting group title	High Dose_AS01E Group
Reporting group description:	
Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.	
Reporting group title	Low Dose_AS01E Group
Reporting group description:	
Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) low dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.	
Reporting group title	Medium Dose_AS01E Group
Reporting group description:	
Participants received 1 dose of the RSV Vaccine (GSK3844766A) high dose adjuvanted with AS01E in the current study after having received 2 doses of the RSV Vaccine (GSK3844766A) medium dose adjuvanted with AS01E in the RSV OA=ADJ-002 (NCT03814590) parent study.	

Primary: Number of participants with any solicited administration site adverse events (AEs)

End point title	Number of participants with any solicited administration site adverse events (AEs)[1]
End point description:	
Assessed solicited administration site AEs are erythema, pain and swelling. Any pain is defined as any pain regardless of intensity grade. Any injection site erythema/swelling is scored with a diameter larger than (>) 20 millimeters (mm). The analysis was performed on the Exposed Set that included all participants who received the study intervention dose.	
End point type	Primary
End point timeframe:	
During the 4-day follow-up period post-vaccination (i.e. on the day of vaccination [Day 1] and 3 subsequent days)	

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: The scope of this endpoint analysis was descriptive. Therefore, no statistical analyses apply to this endpoint.

End point values	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	39	43	
Units: Participants				
Any erythema	1	6	5	
Any pain	21	23	26	
Any swelling	0	2	4	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any solicited systemic AEs

End point title	Number of participants with any solicited systemic AEs[2]

End point description:

Assessed solicited systemic AE is fever (any temperature greater than or equal to 38.0 °C – the preferred location for measuring temperature being the oral cavity). Any is defined as occurrence of the symptom regardless of intensity grade or relation to study. The analysis was performed on the Exposed Set that included all participants who received the study intervention dose.

End point type	Primary

End point timeframe:

During the 4-day follow-up period post-vaccination (i.e. on the day of vaccination [Day 1] and 3 subsequent days)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this endpoint analysis was descriptive. Therefore, no statistical analyses apply to this endpoint.

End point values	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	39	43	
Units: Participants				
Any fever	1	1	4	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs

End point title	Number of participants with any unsolicited AEs[3]

End point description:

An unsolicited AE is any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited AE. Any is defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to study vaccination. The analysis was performed on the Exposed Set that included all participants who received the study intervention dose.

End point type	Primary

End point timeframe:

During the 30-day follow-up period post-vaccination (i.e., on the day of vaccination [Day 1] and 29 subsequent days)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this endpoint analysis was descriptive. Therefore, no statistical analyses apply to this endpoint.

End point values	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	39	43	
Units: Participants	5	11	12	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any Serious Adverse Events (SAEs) up to 30 days post-vaccination

End point title	Number of participants with any Serious Adverse Events (SAEs) up to 30 days post-vaccination[4]

End point description:

An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity. Any is defined as any occurrence of SAE regardless of intensity grade or relation to study vaccination. The analysis was performed on the Exposed Set that included all participants who received the study intervention dose.

End point type	Primary

End point timeframe:

From Day 1 up to 30 days post-vaccination (Day 31)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this endpoint analysis was descriptive. Therefore, no statistical analyses apply to this endpoint.

End point values	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	39	43	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any potential immune-mediated diseases (pIMDs) up to 30 days post-vaccination

End point title	Number of participants with any potential immune-mediated diseases (pIMDs) up to 30 days post-vaccination[5]

End point description:

pIMDs are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune etiology. Any is defined as the occurrence of any pIMD regardless of intensity grade or relation to study vaccination. The analysis was performed on the Exposed Set that included all participants who received the study intervention dose.

End point type	Primary

End point timeframe:

From Day 1 up to 30 days post-vaccination (Day 31)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this endpoint analysis was descriptive. Therefore, no statistical analyses apply to this endpoint.

End point values	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	39	43	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Humoral immune response in terms of neutralizing antibody titers against Respiratory Syncytial Virus (RSV)-serotype A

End point title	Humoral immune response in terms of neutralizing antibody titers against Respiratory Syncytial Virus (RSV)-serotype A[6][7]

End point description:

Serological assays for the determination of functional antibodies against RSV-A are performed by neutralization assay. Anti RSV-A neutralizing antibody titers are given as Geometric Mean Titers (GMTs) and expressed as Estimated Dose: serum dilution giving a 60% reduction of the signal compared to a control without serum (ED60). The analysis was performed on the Per Protocol Set (that included participants who received the study intervention dose and have post-vaccination data, minus participants with protocol deviations that led to exclusion), for the High Dose_AS01E Group only (as per protocol).

End point type	Primary

End point timeframe:

At 30 days post-vaccination (Day 31)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this endpoint analysis was descriptive. Therefore, no statistical analyses apply to this endpoint.
[7] - 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: The analysis was performed on the Per Protocol Set, for the High Dose_Adjuvanted Group only, which included participants who received the study intervention dose and have post-vaccination data, minus participants with protocol deviations that led to exclusion.

End point values	High Dose_AS01E Group			
Subject group type	Reporting group			
Number of subjects analysed	34			
Units: Titers				
geometric mean (confidence interval 95%)	4394.9 (3191.3 to 6052.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Humoral immune response in terms of neutralizing antibody titers against RSV-serotype B

End point title	Humoral immune response in terms of neutralizing antibody titers against RSV-serotype B[8][9]

End point description:

Serological assays for the determination of functional antibodies against RSV-B are performed by neutralization assay. Anti RSV-B neutralizing antibody titers are given as GMTs and expressed as ED60. The analysis was performed on the Per Protocol Set (that included participants who received the study intervention dose and have post-vaccination data, minus participants with protocol deviations that led to exclusion), for the High Dose_AS01E Group only (as per protocol).

End point type	Primary

End point timeframe:

At 30 days post-vaccination (Day 31)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this endpoint analysis was descriptive. Therefore, no statistical analyses apply to this endpoint.
[9] - 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: The analysis was performed on the Per Protocol Set, for the High Dose_Adjuvanted Group only, which included participants who received the study intervention dose and have post-vaccination data, minus participants with protocol deviations that led to exclusion.

End point values	High Dose_AS01E Group			
Subject group type	Reporting group			
Number of subjects analysed	34			
Units: Titers				
geometric mean (confidence interval 95%)	6094.3 (4476.8 to 8296.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Humoral immune response in terms of RSVPreF3-specific Immunoglobulin G (IgG) antibody concentrations

End point title	Humoral immune response in terms of RSVPreF3-specific Immunoglobulin G (IgG) antibody concentrations[10]

End point description:

The detection and the quantification of total IgG antibodies directed against RSVPreF3 in human serum

samples were based on an indirect Enzyme-Linked Immunosorbent Assay (ELISA). Anti RSVPreF3 antibody concentration is given in geometric mean concentration (GMC) and is expressed in ELISA Laboratory Units per milliliter (ELU/mL). The analysis was performed on the Per Protocol Set (that included participants who received the study intervention dose and have post-vaccination data, minus participants with protocol deviations that led to exclusion), for the High Dose_AS01E Group only (as per protocol).

End point type	Secondary

End point timeframe:

At 30 days post-vaccination (Day 31)

Notes:

[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: The analysis was performed on the Per Protocol Set, for the High Dose_Adjuvanted Group only, which included participants who received the study intervention dose and have post-vaccination data, minus participants with protocol deviations that led to exclusion.

End point values	High Dose_AS01E Group			
Subject group type	Reporting group			
Number of subjects analysed	34			
Units: ELU/mL				
geometric mean (confidence interval 95%)	46276.5 (36821.3 to 58159.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of RSVPreF3-specific cluster of differentiation 4+ (CD4+) T-cells identified as expressing at least two markers

End point title	Frequency of RSVPreF3-specific cluster of differentiation 4+ (CD4+) T-cells identified as expressing at least two markers[11]

End point description:

Among markers expressed are interleukin-2 (IL2), cluster of 40 ligand (CD40L), tumour necrosis factor alpha (TNF α) and interferon gamma (IFN γ), in vitro upon stimulation with RSVPreF3 peptide preparations. The analysis was performed on the Per Protocol Set (that included participants who received the study intervention dose and have post-vaccination data, minus participants with protocol deviations that led to exclusion), for the High Dose_AS01E Group only (as per protocol).

End point type	Secondary

End point timeframe:

At 30 days post-vaccination (Day 31)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was performed on the Per Protocol Set, for the High Dose_Adjuvanted Group only, which included participants who received the study intervention dose and have post-vaccination data, minus participants with protocol deviations that led to exclusion.

End point values	High Dose_AS01E Group			
Subject group type	Reporting group			
Number of subjects analysed	31			
Units: cells per million CD4+ T Cells				
median (inter-quartile range (Q1-Q3))	1601 (1174 to 2541)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any SAEs, up the end of follow-up study period (Month 6)

End point title	Number of participants with any SAEs, up the end of follow-up study period (Month 6)

End point description:

An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity. The analysis was performed on the Exposed Set that included all participants who received the study intervention dose.

End point type	Secondary

End point timeframe:

From Day 1 up to the end of follow-up period (Month 6)

End point values	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	39	43	
Units: Participants	1	1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants reporting pIMDs up to the end of follow-up study period (Month 6)

End point title	Number of participants reporting pIMDs up to the end of follow-up study period (Month 6)

End point description:

pIMDs are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune etiology. The analysis was performed on the Exposed Set that included all participants who received the study intervention dose.

End point type	Secondary

End point timeframe:

From Day 1 up to the end of follow-up period (Month 6)

End point values	High Dose_AS01E Group	Low Dose_AS01E Group	Medium Dose_AS01E Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	39	43	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected during the 4-day follow-up period after vaccination. Unsolicited AEs were collected during the 30-day follow-up period after vaccination. SAEs were collected throughout the study period (from Day 1 to Month 6).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	High Dose_Adjuvanted Group

Reporting group description:

Participants received high formulation dose of RSVPreF3 OA interventional vaccine (adjuvanted with AS01E) after having received 2 adjuvanted AS01E high formulation doses of RSVPreF3 OA interventional vaccine in the RSV OA=ADJ-002 (NCT03814590-EudraCT:2018-000849-38) parent study.

Reporting group title	Medium Dose_Adjuvanted Group

Reporting group description:

Participants received high formulation dose of RSVPreF3 OA interventional vaccine (adjuvanted with AS01E) after having received 2 adjuvanted AS01E medium formulation doses of RSVPreF3 OA interventional vaccine in the RSV OA=ADJ-002 (NCT03814590-EudraCT:2018-000849-38) parent study.

Reporting group title	Low Dose_Adjuvanted Group

Reporting group description:

Participants received high formulation dose of RSVPreF3 OA interventional vaccine (adjuvanted with AS01E) after having received 2 adjuvanted AS01E low formulation doses of RSVPreF3 OA interventional vaccine in the RSV OA=ADJ-002 (NCT03814590-EudraCT:2018-000849-38) parent study.

Serious adverse events	High Dose_Adjuvanted Group	Medium Dose_Adjuvanted Group	Low Dose_Adjuvanted Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 40 (2.50%)	2 / 43 (4.65%)	1 / 39 (2.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	0 / 39 (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
Injury, poisoning and procedural complications			
Limb traumatic amputation			

subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (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
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (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
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	High Dose_Adjuvanted Group	Medium Dose_Adjuvanted Group	Low Dose_Adjuvanted Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 40 (55.00%)	29 / 43 (67.44%)	25 / 39 (64.10%)
Investigations			
High density lipoprotein decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Transferrin saturation decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Vascular disorders			
Peripheral coldness			
subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 40 (2.50%)	1 / 43 (2.33%)	4 / 39 (10.26%)
occurrences (all)	1	1	5
Paraesthesia			

subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	21 / 40 (52.50%)	26 / 43 (60.47%)	23 / 39 (58.97%)
occurrences (all)	21	26	23
Injection site erythema			
subjects affected / exposed	1 / 40 (2.50%)	5 / 43 (11.63%)	6 / 39 (15.38%)
occurrences (all)	1	5	6
Injection site swelling			
subjects affected / exposed	0 / 40 (0.00%)	4 / 43 (9.30%)	2 / 39 (5.13%)
occurrences (all)	0	4	2
Pyrexia			
subjects affected / exposed	1 / 40 (2.50%)	4 / 43 (9.30%)	1 / 39 (2.56%)
occurrences (all)	2	4	1
Fatigue			
subjects affected / exposed	1 / 40 (2.50%)	3 / 43 (6.98%)	1 / 39 (2.56%)
occurrences (all)	1	3	1
Chills			
subjects affected / exposed	0 / 40 (0.00%)	2 / 43 (4.65%)	2 / 39 (5.13%)
occurrences (all)	0	2	2
Malaise			
subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Influenza like illness			
subjects affected / exposed	0 / 40 (0.00%)	2 / 43 (4.65%)	2 / 39 (5.13%)
occurrences (all)	0	2	2
Chest pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Injection site warmth			

subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Axillary pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Glossitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Increased upper airway secretion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Sebaceous adenitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Dry skin			

subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Intervertebral disc degeneration			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Arthralgia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Oral herpes			
subjects affected / exposed	1 / 40 (2.50%)	1 / 43 (2.33%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 43 (2.33%)	0 / 39 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 November 2020	The protocol is amended to address the comments from the United States Food and Drug Administration (US FDA). Specifically, instructions to delay enrolment or vaccination of participants with symptoms suggestive of Coronavirus Disease 2019 (COVID-19) infection or with known COVID-19 positive contacts have been updated. In addition, the requirement to obtain written approval from the Sponsor for a participant to receive a vaccine as part of mass vaccination for an unforeseen public health threat (e.g., pandemic) if the vaccine to be used according to the local governmental recommendations has been amended. Other changes have been made to align the protocol with the parent RSV OA=ADJ-002 study and other phase 3 studies in the project.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported