Clinical trial results:
Evaluation of the Immunogenicity, Safety, and Tolerability of a Single Dose of ABNCoV2 Vaccine in Adult Subjects Previously Vaccinated for SARS-CoV-2: a Phase 3 Trial in Two Parts—Randomized, Double-blind, Active Controlled and Open-label, Single-arm

Summary

EudraCT number	2021-005504-36
Trial protocol	DK BE
Global end of trial date	05 October 2023

Results information

Result version number	v1 (current)
This version publication date	09 March 2025
First version publication date	09 March 2025

Trial information

Trial identification

Sponsor protocol code	ABNCoV2-03

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05329220
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bavarian Nordic A/S
Sponsor organisation address	Philip Heymans Alle 3, Hellerup, Denmark, 2900
Public contact	clinical-mailbox, Bavarian Nordic GmbH, clinical-mailbox@bavarian-nordic.com
Scientific contact	clinical-mailbox, Bavarian Nordic GmbH, clinical-mailbox@bavarian-nordic.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	11 December 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 March 2023
Global end of trial reached?	Yes
Global end of trial date	05 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this phase 3 trial is to assess the non-inferiority, or superiority of vaccination with ABNCoV2 compared to Comirnaty in terms of neutralizing antibodies against the SARS CoV 2 index virus (Wuhan wild type isolate). This objective will be carried out in the randomized, double-blind component (Part A), in Cohort 1 (adult subjects who previously completed primary vaccination only) and Cohort 2 (adult subjects who have received 1 booster vaccination after a primary regimen) simultaneously. If the non-inferiority margin is met, superiority comparison will be carried out in the same cohort with the same type I error level. If for any reason, the minimum sample size of 400 is not met in one cohort, data from that cohort will be summarized descriptively.

Protection of trial subjects:

If an event occurs which fulfills the trial halting rules (see Section 13.3.2 for further details), the DMC will review the event in a timely manner and agree whether to recommend halting or terminating the trial participation of the affected subject(s) and/or the trial as a whole. If the trial as a whole or participation of specific subjects is halted, the DMC also will decide if and when to recommend resuming the trial or subject participation in it.

The events or criteria listed below would trigger a DMC review to determine whether a temporary halting or termination for the trial as a whole is warranted:
1.) A serious AESI or other SAE with an at least reasonable possibility of a causal relationship to the administration of trial vaccine
2.) An unexpected Grade 3 or higher adverse event (e.g., a systemic reaction or lab toxicity) with at least a reasonable possibility of a causal relationship to the administration of trial vaccine
3.) Any case of myocarditis or pericarditis in temporal association to the administration of trial vaccine

The Medical Monitor or safety physician will review cases of Grade 3 or higher adverse events at least weekly. Any issues identified during this review can be brought to the DMC for review.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 August 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 378
Country: Number of subjects enrolled	Denmark: 244
Country: Number of subjects enrolled	United States: 3583
Worldwide total number of subjects	4205
EEA total number of subjects	622

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)	3067
From 65 to 84 years	1138
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

At least 500 subjects were to be enrolled into Part A of this trial, and approximately 3000 subjects were to be enrolled into Part B.

Pre-assignment

Screening details:

Enrollment for Part A and Part B occurred simultaneously and enrollment was based on prior SARS-CoV-2 experience, with Cohort 1 including an authorized primary vaccination regimen; and Cohort 2 including an authorized primary vaccination regimen with a booster vaccination.

Period 1

Period 1 title	Active Trial and 6-month Follow Up (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A Cohort 1 ABNCoV2

Arm description:

Subjects who previously completed primary vaccination 100ug ABNCoV2 by intramuscular injection on Day 1

Arm type	Experimental
Investigational medicinal product name	ABNCoV2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A single dose of 100 ug of ABNCoV2 will be administere. Vials of ABNCoV2 will contain at least 100 ug in 0.5 mL.

Arm title	Part A Cohort 1 Comirnaty

Arm description:

Subjects who previously completed primary vaccination 30ug Comirnaty by intramuscular injection on Day 1

Arm type	Active comparator
Investigational medicinal product name	Comirnaty
Investigational medicinal product code	
Other name	INN-tozinameran, tozinameran/famtozinameran, raxtozinameran, bretovameran
Pharmaceutical forms	Suspension for injection, Suspension for injection in multidose container
Routes of administration	Intramuscular use

Dosage and administration details:

Comirnaty is commercially available and may be a single dose vial containing 1 dose of 0.3 mL containing 30 ug of tozinameran or a multidose vial containing 6 doses of 0.3 mL with each containing 30 ug of tozinameran.

30 ug will be administered intramuscularly.

Arm title	Part A Cohort 2 ABNCoV2

Arm description:

Subjects who previously completed primary vaccination plus 1 booster 100ug ABNCoV2 by intramuscular injection on Day 1

Arm type	Experimental
Investigational medicinal product name	ABNCoV2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A single dose of 100 ug of ABNCoV2 will be administere. Vials of ABNCoV2 will contain at least 100 ug in 0.5 mL.

Arm title	Part A Cohort 2 Comirnaty

Arm description:

Subjects who previously completed primary vaccination plus 1 booster 30ug Comirnaty by intramuscular injection on Day 1

Arm type	Active comparator
Investigational medicinal product name	Comirnaty
Investigational medicinal product code	
Other name	INN-tozinameran, tozinameran/famtozinameran, raxtozinameran, bretovameran
Pharmaceutical forms	Suspension for injection, Suspension for injection in multidose container
Routes of administration	Intramuscular use

Dosage and administration details:

Comirnaty is commercially available and may be a single dose vial containing 1 dose of 0.3 mL containing 30 ug of tozinameran or a multidose vial containing 6 doses of 0.3 mL with each containing 30 ug of tozinameran.

30 ug will be administered intramuscularly.

Arm title	Part B Cohort 1 ABNCoV2

Arm description:

Subjects who previously completed primary vaccination 100ug ABNCoV2 by intramuscular injection on Day 1

Arm type	Experimental
Investigational medicinal product name	ABNCoV2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A single dose of 100 ug of ABNCoV2 will be administere. Vials of ABNCoV2 will contain at least 100 ug in 0.5 mL.

Arm title	Part B Cohort 2 ABNCoV2

Arm description:

Subjects who previously completed primary vaccination plus 1 booster 100ug ABNCoV2 by intramuscular injection on Day 1

Arm type	Experimental
Investigational medicinal product name	ABNCoV2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A single dose of 100 ug of ABNCoV2 will be administere. Vials of ABNCoV2 will contain at least 100 ug in 0.5 mL.

Number of subjects in period 1	Part A Cohort 1 ABNCoV2	Part A Cohort 1 Comirnaty	Part A Cohort 2 ABNCoV2
Started	34	34	277
Completed	34	33	272
Not completed	0	1	5
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	-	-	1
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Moved out of country	-	-	1
Out of town for extended period	-	-	-
Sponsor Decision	-	-	-
Lost to follow-up	-	1	2
Refused to attend final visits, various reasons	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part A Cohort 2 Comirnaty	Part B Cohort 1 ABNCoV2	Part B Cohort 2 ABNCoV2
Started	277	1438	2145
Completed	273	1285	2009
Not completed	4	153	136
Adverse event, serious fatal	1	-	1
Consent withdrawn by subject	1	34	35
Physician decision	-	2	2
Adverse event, non-fatal	-	2	1
Moved out of country	-	-	-
Out of town for extended period	-	1	-
Sponsor Decision	-	-	1
Lost to follow-up	2	113	89
Refused to attend final visits, various reasons	-	-	6
Protocol deviation	-	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Part A Cohort 1 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination 100ug ABNCoV2 by intramuscular injection on Day 1	

Reporting group title	Part A Cohort 1 Comirnaty
Reporting group description:	
Subjects who previously completed primary vaccination 30ug Comirnaty by intramuscular injection on Day 1	
Reporting group title	Part A Cohort 2 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 100ug ABNCoV2 by intramuscular injection on Day 1	
Reporting group title	Part A Cohort 2 Comirnaty
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 30ug Comirnaty by intramuscular injection on Day 1	
Reporting group title	Part B Cohort 1 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination 100ug ABNCoV2 by intramuscular injection on Day 1	
Reporting group title	Part B Cohort 2 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 100ug ABNCoV2 by intramuscular injection on Day 1	

Reporting group values	Part A Cohort 1 ABNCoV2	Part A Cohort 1 Comirnaty	Part A Cohort 2 ABNCoV2
Number of subjects	34	34	277
Age categorical Units: Subjects			
Adults (18-64 years)	34	34	247
From 65-84 years	0	0	30
Age continuous Units: years			
arithmetic mean	34.4	32.2	42.8
standard deviation	± 13.44	± 11.67	± 16.4
Gender categorical Units: Subjects			
Female	15	12	133
Male	19	22	144
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	2
Not Hispanic or Latino	34	33	274
Unknown or Not Reported	0	0	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0

Asian	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	33	34	272
More than one race	0	0	0
Unknown or Not Reported	1	0	3
Region of Enrollment Units: Subjects			
Belgium	24	26	161
United States	0	0	0
Denmark	10	8	116

Reporting group values	Part A Cohort 2 Comirnaty	Part B Cohort 1 ABNCoV2	Part B Cohort 2 ABNCoV2
Number of subjects	277	1438	2145
Age categorical Units: Subjects			
Adults (18-64 years)	249	1147	1356
From 65-84 years	28	291	789
Age continuous Units: years			
arithmetic mean	41.8	48.2	54.5
standard deviation	± 15.91	± 15.6	± 15.73
Gender categorical Units: Subjects			
Female	135	813	1210
Male	142	625	935
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	623	593
Not Hispanic or Latino	274	795	1523
Unknown or Not Reported	0	20	29
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	6	17
Asian	1	27	59
Native Hawaiian or Other Pacific Islander	0	0	3
Black or African American	1	439	469
White	273	911	1521
More than one race	1	14	28
Unknown or Not Reported	1	41	48
Region of Enrollment Units: Subjects			
Belgium	167	0	0
United States	0	1438	2145
Denmark	110	0	0

Reporting group values	Total		
Number of subjects	4205		

Age categorical Units: Subjects			
Adults (18-64 years)	3067		
From 65-84 years	1138		
Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	2318		
Male	1887		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1222		
Not Hispanic or Latino	2933		
Unknown or Not Reported	50		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	23		
Asian	89		
Native Hawaiian or Other Pacific Islander	3		
Black or African American	909		
White	3044		
More than one race	43		
Unknown or Not Reported	94		
Region of Enrollment Units: Subjects			
Belgium	378		
United States	3583		
Denmark	244		

End points

End points reporting groups

Reporting group title	Part A Cohort 1 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination 100ug ABNCoV2 by intramuscular injection on Day 1	

Reporting group title	Part A Cohort 1 Comirnaty
Reporting group description:	
Subjects who previously completed primary vaccination 30ug Comirnaty by intramuscular injection on Day 1	

Reporting group title	Part A Cohort 2 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 100ug ABNCoV2 by intramuscular injection on Day 1	

Reporting group title	Part A Cohort 2 Comirnaty
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 30ug Comirnaty by intramuscular injection on Day 1	

Reporting group title	Part B Cohort 1 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination 100ug ABNCoV2 by intramuscular injection on Day 1	

Reporting group title	Part B Cohort 2 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 100ug ABNCoV2 by intramuscular injection on Day 1	

Primary: Neutralizing Antibody Titers Against the SARS-CoV-2 Index Virus (Wuhan Wild Type Isolate) at 2 Weeks After Trial Vaccination [Time Frame: 2 weeks after the single trial vaccination occurring on Day 1]

End point title	Neutralizing Antibody Titers Against the SARS-CoV-2 Index Virus (Wuhan Wild Type Isolate) at 2 Weeks After Trial Vaccination [Time Frame: 2 weeks after the single trial vaccination occurring on Day 1][1]
End point description:	
The primary endpoint was SARS-CoV-2 index virus (Wuhan wild type isolate) neutralizing antibodies assessed at 2 weeks after trial vaccination, for subjects in the Immunogenicity Analysis Sets in Part A Cohort 1 (adult subjects who previously completed primary vaccination at least 3 months prior to the screening visit) and Part A Cohort 2 (adult subjects who have completed primary vaccination and have received 1 booster vaccination).	
End point type	Primary
End point timeframe:	
2 weeks after the single trial vaccination occurring on Day 1	

Notes:

[1] - 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: Analyses were performed only on the groups included in Part A Cohort 1 and 2 of the protocol. Part B of the trial was open-label ABNCoV2 for Safety Analyses only, as there was no comparator.

End point values	Part A Cohort 1 ABNCoV2	Part A Cohort 1 Comirnaty	Part A Cohort 2 ABNCoV2	Part A Cohort 2 Comirnaty
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	33	267	261
Units: titer				
geometric mean (confidence interval 95%)	1018.1 (621.1 to 1669)	1060.6 (708.2 to 1588.3)	1259 (1125.3 to 1408.4)	1619.6 (1485.9 to 1765.4)

Statistical analyses

Statistical analysis title	Non-Inferiority Test of Part A Cohort 1

Statistical analysis description:

Formal hypothesis testing was performed due to having at least 400 evaluable subjects with primary endpoint data available at baseline and at 2 weeks after trial vaccination. The null hypothesis is that ABNCoV2 is inferior to Comirnaty and will be rejected if the ratio of the GMTs for ABNCoV2 versus Comirnaty is within the non-inferiority margin of 0.67; that is, the lower bound of the 2-sided 97.5% CI of the GMT ratio is >=0.67.

Comparison groups	Part A Cohort 1 ABNCoV2 v Part A Cohort 1 Comirnaty
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
P-value	= 0.635 [3]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	0.89
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.5
upper limit	1.57

Notes:

[2] - The success criterion for the null hypothesis that ABNCoV2 is inferior to Comirnaty will be rejected if the ratio of the GMTs for ABNCoV2 versus Comirnaty is within the non-inferiority margin of 0.67; that is, the lower bound of the 2-sided 97.5% CI of the GMT ratio is >=0.67.

[3] - P-value corresponds to Cohort 1 ABNCoV2 comparison to Cohort 1 Comirnaty

Statistical analysis title	Non-Inferiority Test of Part A Cohort 2

Statistical analysis description:

Formal hypothesis testing was performed due to having at least 400 evaluable subjects with primary endpoint data available at baseline and at 2 weeks after trial vaccination. The null hypothesis is that ABNCoV2 is inferior to Comirnaty and will be rejected if the ratio of the GMTs for ABNCoV2 versus Comirnaty is within the non-inferiority margin of 0.67; that is, the lower bound of the 2-sided 97.5% CI of the GMT ratio is >=0.67.

Comparison groups	Part A Cohort 2 ABNCoV2 v Part A Cohort 2 Comirnaty

Number of subjects included in analysis	528
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
P-value	= 0.0002 [5]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	0.8
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.7
upper limit	0.92

Notes:

[4] - The success criterion for the null hypothesis that ABNCoV2 is inferior to Comirnaty will be rejected if the ratio of the GMTs for ABNCoV2 versus Comirnaty is within the non-inferiority margin of 0.67; that is, the lower bound of the 2-sided 97.5% CI of the GMT ratio is >=0.67.

[5] - P-value corresponds to Cohort 2 ABNCoV2 comparison to Cohort 2 Comirnaty

Secondary: Neutralizing Antibody Titers Against the SARS-CoV-2 Variants of Concern (Omicron Variant BA.4/BA.5) at 2 Weeks After Trial Vaccination

End point title	Neutralizing Antibody Titers Against the SARS-CoV-2 Variants of Concern (Omicron Variant BA.4/BA.5) at 2 Weeks After Trial Vaccination[6]

End point description:

The secondary endpoint was SARS-CoV-2 variants of concern (Omicron Variant BA.4/BA.5) pseudovirus neutralizing antibodies assessed at 2 weeks after trial vaccination, for subjects in the Immunogenicity Analysis Sets in Part A Cohort 1 (adult subjects who previously completed primary vaccination at least 3 months prior to the screening visit) and Part A Cohort 2 (adult subjects who have completed primary vaccination and have received 1 booster vaccination.

End point type	Secondary

End point timeframe:

2 weeks after the single trial vaccination occurring on Day 1

Notes:

[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: Analyses were performed only on the groups included in Part A Cohort 2 of the protocol as the others did not meet the sample size requirement to be included. Part B of the trial was open-label ABNCoV2 for Safety Analyses only, as there was no comparator.

End point values	Part A Cohort 1 ABNCoV2	Part A Cohort 1 Comirnaty	Part A Cohort 2 ABNCoV2	Part A Cohort 2 Comirnaty
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	0[8]	265	260
Units: titre				
geometric mean (confidence interval 95%)	(to)	(to)	17112.6 (14775.8 to 19818.9)	23506.3 (20794.5 to 26571.7)

Notes:

[7] - Due to not meeting the primary objective criteria, Part A Cohort 1 was not analyzed.

[8] - Due to not meeting the primary objective criteria, Part A Cohort 1 was not analyzed.

Statistical analyses

Statistical analysis title	Non-Inferiority Test of Part A Cohort 2 BA.4/BA.5

Statistical analysis description:

Formal hypothesis testing was performed due to meeting the primary endpoint success criterion in

Cohort 2. The null hypothesis is that ABNCoV2 is inferior to Comirnaty and will be rejected if the ratio of the GMTs for ABNCoV2 versus Comirnaty is within the non-inferiority margin of 0.67; that is, the lower bound of the 2-sided 97.5% CI of the GMT ratio is >=0.67.

Comparison groups	Part A Cohort 2 ABNCoV2 v Part A Cohort 2 Comirnaty
Number of subjects included in analysis	525
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
P-value	= 0.0008 [10]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	0.76
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.64
upper limit	0.91

Notes:

[9] - The success criterion for the null hypothesis that ABNCoV2 is inferior to Comirnaty will be rejected if the ratio of the GMTs for ABNCoV2 versus Comirnaty is within the non-inferiority margin of 0.67; that is, the lower bound of the 2-sided 97.5% CI of the GMT ratio is >=0.67.

[10] - P-value corresponds to Cohort 2 ABNCoV2 comparison to Cohort 2 Comirnaty for Omicron variant BA.4/BA.5

Secondary: Neutralizing Antibody Titers Against the SARS-CoV-2 Variants of Concern (Omicron Variant XBB.1.5) at 2 Weeks After Trial Vaccination

End point title	Neutralizing Antibody Titers Against the SARS-CoV-2 Variants of Concern (Omicron Variant XBB.1.5) at 2 Weeks After Trial Vaccination[11]

End point description:

The secondary endpoint was SARS-CoV-2 variants of concern (Omicron Variant XBB.1.5) virus neutralizing antibodies assessed at 2 weeks after trial vaccination, for subjects in the Immunogenicity Analysis Sets in Part A Cohort 1 (adult subjects who previously completed primary vaccination at least 3 months prior to the screening visit) and Part A Cohort 2 (adult subjects who have completed primary vaccination and have received 1 booster vaccination.

End point type	Secondary

End point timeframe:

2 weeks after the single trial vaccination occurring on Day 1

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: Analyses were performed only on the groups included in Part A Cohort 2 of the protocol as the others did not meet the sample size requirement to be included. Part B of the trial was open-label ABNCoV2 for Safety Analyses only, as there was no comparator.

End point values	Part A Cohort 2 ABNCoV2	Part A Cohort 2 Comirnaty		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	265	260		
Units: titre				
geometric mean (confidence interval 95%)	54.7 (48.9 to 61.3)	81.3 (73.1 to 90.4)		

Statistical analyses

Statistical analysis title	Non-Inferiority Test of Part A Cohort 2 XBB.1.5

Statistical analysis description:

Formal hypothesis testing was performed due to meeting the primary endpoint success criterion in Cohort 2. The null hypothesis is that ABNCoV2 is inferior to Comirnaty and will be rejected if the ratio of the GMTs for ABNCoV2 versus Comirnaty is within the non-inferiority margin of 0.67; that is, the lower bound of the 2-sided 97.5% CI of the GMT ratio is >=0.67.

Comparison groups	Part A Cohort 2 ABNCoV2 v Part A Cohort 2 Comirnaty
Number of subjects included in analysis	525
Analysis specification	Pre-specified
Analysis type	non-inferiority[12]
P-value	< 0.0001 [13]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	0.69
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.59
upper limit	0.81

Notes:

[12] - The success criterion for the null hypothesis that ABNCoV2 is inferior to Comirnaty will be rejected if the ratio of the GMTs for ABNCoV2 versus Comirnaty is within the non-inferiority margin of 0.67; that is, the lower bound of the 2-sided 97.5% CI of the GMT ratio is >=0.67.

[13] - P-value corresponds to Cohort 2 ABNCoV2 comparison to Cohort 2 Comirnaty for Omicron Variant XBB.1.5.

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall trial from vaccination through final follow-up visit at Day 182	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups	
Reporting group title	Part A Cohort 1 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination 100ug ABNCoV2 by subcutaneous injection on Day 1	
Reporting group title	Part A Cohort 1 Comirnaty
Reporting group description:	
Subjects who previously completed primary vaccination 30ug Comirnaty by subcutaneous injection on Day 1	
Reporting group title	Part A Cohort 2 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 100ug ABNCoV2 by subcutaneous injection on Day 1	
Reporting group title	Part A Cohort 2 Comirnaty
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 30ug Comirnaty by subcutaneous injection on Day 1	
Reporting group title	Part B Cohort 1 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination 100ug ABNCoV2 by subcutaneous injection on Day 1	
Reporting group title	Part B Cohort 2 ABNCoV2
Reporting group description:	
Subjects who previously completed primary vaccination plus 1 booster 100ug ABNCoV2 by subcutaneous injection on Day 1	

Serious adverse events	Part A Cohort 1 ABNCoV2	Part A Cohort 1 Comirnaty	Part A Cohort 2 ABNCoV2
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	3 / 277 (1.08%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Brain cancer metastatic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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 cancer metastatic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell carcinoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Arterial occlusive disease			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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			
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic organ prolapse			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 277 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Delirium tremens			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Major depression			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 277 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Astrovirus test positive			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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			
Cervical vertebral fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Joint dislocation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury cervical			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound necrosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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			
Cerebral infarction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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			
Anaemia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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 loss anaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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			
Cholecystitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Diabetic foot			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive nephropathy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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			
Intervertebral disc degeneration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal stenosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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			
Abdominal wall abscess			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 277 (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
Arthritis bacterial			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 277 (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
Diverticulitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic inflammatory disease			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 277 (0.00%)
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	Part A Cohort 2 Comirnaty	Part B Cohort 1 ABNCoV2	Part B Cohort 2 ABNCoV2
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 277 (2.53%)	23 / 1438 (1.60%)	49 / 2145 (2.28%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain cancer metastatic			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Breast cancer metastatic			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Lung cancer metastatic			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lung neoplasm malignant			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	2 / 2145 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell carcinoma			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Vascular disorders			
Arterial occlusive disease			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			

subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic organ prolapse			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			

subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Bipolar disorder			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Completed suicide			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	0 / 2145 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium tremens			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Depression			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Major depression			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	0 / 2145 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Astrovirus test positive			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Cervical vertebral fracture			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Femur fracture			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	1 / 277 (0.36%)	0 / 1438 (0.00%)	0 / 2145 (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
Hip fracture			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Spinal cord injury cervical			

subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Subdural haematoma			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound necrosis			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 277 (0.00%)	2 / 1438 (0.14%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	3 / 2145 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 277 (0.36%)	0 / 1438 (0.00%)	0 / 2145 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			

subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	2 / 2145 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 277 (0.36%)	0 / 1438 (0.00%)	0 / 2145 (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
Myocarditis			
subjects affected / exposed	1 / 277 (0.36%)	0 / 1438 (0.00%)	0 / 2145 (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			
Cerebral infarction			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 277 (0.00%)	2 / 1438 (0.14%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			

subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 277 (0.36%)	2 / 1438 (0.14%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 277 (0.36%)	0 / 1438 (0.00%)	0 / 2145 (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			
Anaemia			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Rash maculo-papular			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			

subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive nephropathy			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc degeneration			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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			
Abdominal wall abscess			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis bacterial			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	2 / 2145 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	0 / 2145 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	1 / 277 (0.36%)	0 / 1438 (0.00%)	0 / 2145 (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
Large intestine infection			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Pelvic inflammatory disease			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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
Perirectal abscess			

subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	0 / 2145 (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 / 277 (0.00%)	0 / 1438 (0.00%)	2 / 2145 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 277 (0.00%)	1 / 1438 (0.07%)	2 / 2145 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	3 / 2145 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	1 / 277 (0.36%)	2 / 1438 (0.14%)	3 / 2145 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 277 (0.00%)	0 / 1438 (0.00%)	1 / 2145 (0.05%)
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: 5 %

Non-serious adverse events	Part A Cohort 1 ABNCoV2	Part A Cohort 1 Comirnaty	Part A Cohort 2 ABNCoV2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 34 (17.65%)	4 / 34 (11.76%)	40 / 277 (14.44%)
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 34 (8.82%)	1 / 34 (2.94%)	11 / 277 (3.97%)
occurrences (all)	3	1	11
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	17 / 277 (6.14%)
occurrences (all)	1	1	17
Nasopharyngitis			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	15 / 277 (5.42%)
occurrences (all)	2	0	15
Pharyngitis			
subjects affected / exposed	1 / 34 (2.94%)	2 / 34 (5.88%)	2 / 277 (0.72%)
occurrences (all)	1	2	2

Non-serious adverse events	Part A Cohort 2 Comirnaty	Part B Cohort 1 ABNCoV2	Part B Cohort 2 ABNCoV2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 277 (16.97%)	36 / 1438 (2.50%)	125 / 2145 (5.83%)
Nervous system disorders			
Headache			
subjects affected / exposed	10 / 277 (3.61%)	11 / 1438 (0.76%)	16 / 2145 (0.75%)
occurrences (all)	10	11	17
Infections and infestations			
COVID-19			
subjects affected / exposed	14 / 277 (5.05%)	36 / 1438 (2.50%)	125 / 2145 (5.83%)
occurrences (all)	14	36	125
Nasopharyngitis			
subjects affected / exposed	21 / 277 (7.58%)	5 / 1438 (0.35%)	13 / 2145 (0.61%)
occurrences (all)	21	5	13
Pharyngitis			
subjects affected / exposed	3 / 277 (1.08%)	3 / 1438 (0.21%)	5 / 2145 (0.23%)
occurrences (all)	3	3	5

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 April 2022	The protocol Edition 2.0 has been created to implement and incorporate administrative and clerical revisions and to add demographics collection at the screening visit within the schedule of events.
01 June 2022	The protocol Edition 3.0 was created to implement a title change and major design changes to the previous edition. Extensive changes included: The addition of the two-part trial design; Separation of Cohort 1 and 2 based on previous vaccination schedule; Comparator vaccine sourcing changed from routine access to blinded trial vaccine; Randomization ratio changed from 3:1 to 1:1; Part B Component including immunogenicity subset; Non-inferiority testing to be completed simultaneously in both cohorts in Part A; Comparison between Part A and Part B added; Homologous primary vaccination cohort removed; Prior booster vaccination amount limited to 1; Inclusion criteria for prior vaccination changed from 6 months to 3 months; Exclusion limited to COVID-19 infection in last 3 months (reduced from 6 months); Trial population to include 1000 subjects ≥65 years of age; Trial schedule: Visit 1 and day of vaccination combined (no need to allow time for routine access); Safety data updated to be consistent with Topline Interim Clinical Study Report; T-cell data added to phase 2 results in Background section; Gate-keeping approach to multiplicity described; Seropositivity (≥2-fold and ≥4-fold increase) added as supportive analyses; Unblinding process added; COVID-19 resulting in critical illness added to severe COVID-19 as cases to be reviewed by DMC; Regions limited to Denmark, Belgium, US; Editorial updates.
09 June 2022	The protocol Edition 4.0 has been created to implement changes to the previous edition. These changes include: Removal of ECG during screening; Addition of text indicating an ECG may be performed as needed during an unscheduled visit.
14 June 2022	The protocol Edition 5.0 has been created to implement and incorporate administrative and clerical revisions.
28 July 2022	The protocol Edition 6.0 has been created to implement and incorporate changes as requested by the US FDA. These changes include: Additional clerical text about timing of safety follow-up; Addition of reporting for medically attended adverse events; Details around shipping and storage of the comparator product; Addition of an ECG at baseline; Collection of Adverse events of Special interest; Updates to the DMC stopping rules.

15 February 2023	The protocol Edition 7.0 has been created to implement and incorporate revisions as requested by EMA. These changes include: Clarification on the timing of the previous vaccination schedule or vaccination plus booster schedule; Specification on the number of sites in each country; New exclusion criteria; Sample collection for nucleocapsid protein antibody testing; Transition of responsibilities; Study completion definition added; Clarity for solicited AE collection; Methods for secondary endpoint adjustments for multiplicity further specified; Addition of prior vaccination regimen as a subgroup analysis; Time of analysis and reporting.
23 June 2023	The protocol Edition 8.0 has been created to implement changes related to the analysis of nucleocapsid protein results.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported