



Clinical trial results:

A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of VX-445/TEZ/IVA Combination Therapy in Subjects With Cystic Fibrosis Who Are 6 Years of Age and Older

Summary

EudraCT number	2019-001827-11
Trial protocol	GB IE
Global end of trial date	24 February 2024

Results information

Result version number	v2 (current)
This version publication date	05 June 2025
First version publication date	07 September 2024
Version creation reason	<ul style="list-style-type: none">New data added to full data setAdded secondary endpoints data

Trial information

Trial identification

Sponsor protocol code	VX19-445-107
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04183790
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Vertex Pharmaceuticals Incorporated
Sponsor organisation address	50 Northern Avenue, Boston, Massachusetts, United States,
Public contact	Medical Monitor, Vertex Pharmaceuticals Incorporated, +1 617-341-6777, medicalinfo@vrtx.com
Scientific contact	Medical Monitor, Vertex Pharmaceuticals Incorporated, +1 617-341-6777, medicalinfo@vrtx.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002324-PIP01-17
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 March 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 February 2024
Global end of trial reached?	Yes
Global end of trial date	24 February 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety and tolerability of elxacaftor (ELX)/tezacaftor (TEZ)/ivacaftor (IVA) in subjects with cystic fibrosis (CF) who are 6 years of age and older

Protection of trial subjects:

The study was conducted in accordance with the ethical principles stated in the Declaration of Helsinki and the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 February 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	45 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Ireland: 5
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Australia: 8
Country: Number of subjects enrolled	United States: 39
Worldwide total number of subjects	64
EEA total number of subjects	5

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)	64
Adolescents (12-17 years)	0

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

Subject disposition

Recruitment

Recruitment details:

The study was conducted in two parts, Part A and Part B. Subjects of both Parts A and B received the same treatment (ELX/TEZ/IVA). Therefore, results were planned to be collected and analysed for the overall population of the study. A total of 64 subjects were enrolled in this study.

Pre-assignment

Screening details:

Subjects who completed Part B of parent study VX18-445-106 (NCT03691779) and did not permanently discontinue study drug in the parent study had the opportunity to enroll in this study.

Period 1

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

Arms

Arm title	ELX/TEZ/IVA
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Arm description:

Subjects greater than or equal to (\geq) 6 years and less than ($<$) 12 years of age and weighing <30 kilograms (kg) received ELX (elexacaftor) 100 milligram (mg) once daily (qd) /TEZ (tezacaftor) 50 mg qd/IVA (ivacaftor) 75 mg every 12 hours (q12h) and those weighing (\geq) 30 kg received ELX 200 mg qd/TEZ 100 mg qd/IVA 150 mg in the treatment period for up to 192 weeks. Subjects \geq 12 years of age received ELX 200 mg qd/TEZ 100 mg qd/IVA 150 mg q12h in the treatment period for up to 192 weeks.

Arm type	Experimental
Investigational medicinal product name	Elexacaftor/Tezacaftor/Ivacaftor
Investigational medicinal product code	VX-445/VX-661/VX-770
Other name	ELX/TEZ/IVA
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received ELX/TEZ/IVA fixed dose combination (FDC) once daily in the morning.

Investigational medicinal product name	Ivacaftor
Investigational medicinal product code	VX-770
Other name	IVA
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received IVA once daily in the evening.

Number of subjects in period 1	ELX/TEZ/IVA
Started	64
Part A completed	60
Rollover to Part B	48
Part B completed	39

Completed	39
Not completed	25
Subjects did not rollover to Part B	12
Adverse event	1
Withdrawal of Consent (not due to AE)	6
Commercial drug is available for subject	6

Baseline characteristics

Reporting groups

Reporting group title	Overall Period
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Reporting group description:

Baseline data was analysed on Full analysis set (FAS) which is defined as all subjects who received at least 1 dose of study drug in this study.

Reporting group values	Overall Period	Total	
Number of subjects	64	64	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	9.3 ± 1.8	-	
Gender categorical Units: Subjects			
Female	39	39	
Male	25	25	
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	56	56	
Not collected per local regulations	8	8	
Race Units: Subjects			
White	55	55	
Asian	0	0	
Not collected per local regulations	8	8	
More than one Race	1	1	

End points

End points reporting groups

Reporting group title	ELX/TEZ/IVA
Reporting group description: Subjects greater than or equal to (\geq) 6 years and less than ($<$) 12 years of age and weighing <30 kilograms (kg) received ELX (elexacaftor) 100 milligram (mg) once daily (qd) /TEZ (tezacaftor) 50 mg qd/IVA (ivacaftor) 75 mg every 12 hours (q12h) and those weighing (\geq) 30 kg received ELX 200 mg qd/TEZ 100 mg qd/IVA 150 mg in the treatment period for up to 192 weeks. Subjects \geq 12 years of age received ELX 200 mg qd/TEZ 100 mg qd/IVA 150 mg q12h in the treatment period for up to 192 weeks.	

Primary: Safety and Tolerability as Assessed by Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Safety and Tolerability as Assessed by Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs) ^[1]
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End point description:

The Open-Label Extension Safety Set (OLE-SS) included all subjects who had received at least 1 dose of study drug in the study.

End point type	Primary
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End point timeframe:

Day 1 up to Week 196

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive statistics were planned. No statistical comparisons were planned for the primary safety endpoint.

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: Subjects				
Subjects with TEAEs	64			
Subjects with SAEs	7			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)

End point title	Absolute Change in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)
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End point description:

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration. Data for this end point was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. Open label Extension Full Analysis Set (OLE FAS) included all enrolled subjects who have received at least 1 dose of study drug in the OLE study. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.

End point type	Secondary
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End point timeframe:
From Baseline up to Week 192

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: percent predicted FEV1				
least squares mean (confidence interval 95%)	9.6 (5.4 to 13.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Sweat Chloride (SwCl)

End point title	Absolute Change in Sweat Chloride (SwCl)
End point description:	Sweat samples were collected using an approved collection device. Data for this end point was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.
End point type	Secondary
End point timeframe:	From Baseline up to Week 192

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	35			
Units: millimole per liter (mmol/L)				
least squares mean (confidence interval 95%)	-57.9 (-63.3 to -52.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain Score

End point title	Absolute Change in Cystic Fibrosis Questionnaire-Revised (CFQ-R) Respiratory Domain Score
End point description:	The CFQ-R is a validated subject-reported outcome measuring health-related quality of life for subjects with cystic fibrosis. Respiratory domain assessed respiratory symptoms, score range: 0-100; higher

scores indicating fewer symptoms and better health-related quality of life. Data for this end point was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.

End point type	Secondary
End point timeframe:	
From Baseline up to Week 192	

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: units on a scale				
least squares mean (confidence interval 95%)	10.0 (6.9 to 13.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Body Mass Index (BMI)

End point title	Absolute Change in Body Mass Index (BMI)
End point description:	
BMI was defined as weight in kilogram (kg) divided by squared height in meters (m ²). Data for this end point was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.	
End point type	Secondary
End point timeframe:	
From Baseline up to Week 192	

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: kg/m ²				
least squares mean (confidence interval 95%)	3.60 (2.98 to 4.23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in BMI-for-age Z-score

End point title	Absolute Change in BMI-for-age Z-score
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End point description:

BMI was defined as weight in kg divided by squared height in meters (m²). The z-score is a statistical measure to describe whether a mean was above or below the standard. A z-score of 0 is equal to the mean and is considered normal. Lower numbers indicate values lower than the mean and higher numbers indicate values higher than the mean. Data for this end point was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.

End point type Secondary

End point timeframe:

From Baseline up to Week 192

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: z-score				
least squares mean (confidence interval 95%)	0.39 (0.19 to 0.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Pulmonary Exacerbations (PEX) for 106/107

End point title Number of Subjects with Pulmonary Exacerbations (PEX) for 106/107

End point description:

Pulmonary exacerbation was defined as the treatment with new or changed antibiotic therapy (intravenous, inhaled, or oral) for greater than or equal to 4 sinopulmonary signs/symptoms. The Cumulative TC Set includes subjects who enrolled and received at least one dose of study drug during the parent study (445-106 Part B) and/or received at least one dose of study drug during this OLE Study. Data for this end point was planned to be collected and analyzed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. Here "Number of subjects analysed" signifies those subjects who were enrolled in this study only and evaluated for this specific end point. Here "n" signifies Cumulative TC set subjects who were evaluable for this endpoint.

End point type Secondary

End point timeframe:

From Baseline up to Week 192

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: Subjects				
n=66	9			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of CF-related Hospitalizations for 106/107

End point title	Number of CF-related Hospitalizations for 106/107
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End point description:

The total number of CF related hospitalization (Planned + Unplanned) events across all subjects were reported. The Cumulative TC Set. Data for this end point was planned to be collected and analyzed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. Here "Number of subjects analysed" signifies those subjects who were enrolled in this study only and evaluated for this specific end point. Here "n" signifies Cumulative TC set subjects who were evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 192

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	64 ^[2]			
Units: hospitalizations				
number (not applicable)				
n=66	5			

Notes:

[2] - 64 subjects enrolled in the 445-107 and 2 subjects from parent study were included for this analysis

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Lung Clearance Index 2.5 (LCI2.5)

End point title	Absolute Change in Lung Clearance Index 2.5 (LCI2.5)
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End point description:

The LCI2.5 index is the number of lung turnovers required to reduce the end tidal inert gas concentration to 1/40th of its starting values and is calculated by dividing the sum of exhaled tidal breaths (cumulative exhaled volume (CEV)) by simultaneously measured functional residual capacity (FRC). An LCI of 7.5 and below is normal; values greater than 7.5 are abnormal. LCI is able to detect abnormalities in lung function earlier than more traditional modalities such as spirometry. Data for this outcome measure was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 192

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: index				
least squares mean (confidence interval 95%)	-2.33 (-2.87 to -1.79)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Weight

End point title	Absolute Change in Weight
End point description:	
Data for this endpoint was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.	
End point type	Secondary
End point timeframe:	
From Baseline up to Week 192	

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: Kilogram (kg)				
least squares mean (confidence interval 95%)	19.9 (18.1 to 21.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Weight-for-age Z-score

End point title	Absolute Change in Weight-for-age Z-score
End point description:	
The z-score is a statistical measure to describe whether a mean was above or below the standard. A z-score of 0 is equal to the mean and is considered normal. Lower numbers indicate values lower than the mean and higher numbers indicate values higher than the mean. Data for this end point was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.	
End point type	Secondary
End point timeframe:	
From Baseline up to Week 192	

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: z-score				
least squares mean (confidence interval 95%)	0.38 (0.20 to 0.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Height

End point title	Absolute Change in Height
End point description:	
Data for this end point was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.	
End point type	Secondary
End point timeframe:	
From Baseline up to Week 192	

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: centimeters (cm)				
least squares mean (confidence interval 95%)	23.1 (21.6 to 24.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Height-for-age Z-score

End point title	Absolute Change in Height-for-age Z-score
End point description:	
The z-score is a statistical measure to describe whether a mean was above or below the standard. A z-score of 0 is equal to the mean and is considered normal. Lower numbers indicate values lower than the mean and higher numbers indicate values higher than the mean. Data for this end point was planned to be collected and analysed for the overall ELX/TEZ/IVA TC arm irrespective of Part A and B separately. OLE FAS. Here "Number of subjects analysed" signifies those subjects who were evaluated for this specific endpoint.	
End point type	Secondary

End point timeframe:
From Baseline up to Week 192

End point values	ELX/TEZ/IVA			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: z-score				
least squares mean (confidence interval 95%)	0.04 (-0.12 to 0.19)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 up to Week 196

Adverse event reporting additional description:

Safety set included all subjects who received at least 1 dose of study drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	ELX/TEZ/IVA
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Reporting group description:

Subjects ≥ 6 years and < 12 years of age and weighing < 30 kg received ELX 100 mg qd /TEZ 50 mg qd/IVA 75 mg q12h and those weighing ≥ 30 kg received ELX 200 mg qd/TEZ 100 mg qd/IVA 150 mg in the treatment period for up to 192 weeks. Subjects ≥ 12 years of age received ELX 200 mg qd/TEZ 100 mg qd/IVA 150 mg q12h in the treatment period for up to 192 weeks

Serious adverse events	ELX/TEZ/IVA		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 64 (10.94%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Haematuria traumatic			
subjects affected / exposed	1 / 64 (1.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Idiopathic intracranial hypertension			
subjects affected / exposed	1 / 64 (1.56%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 64 (1.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Immune system disorders Anaphylactic reaction subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 64 (1.56%) 0 / 1 0 / 0		
Gastrointestinal disorders Constipation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 64 (4.69%) 1 / 3 0 / 0		
Infections and infestations Infective pulmonary exacerbation of cystic fibrosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 64 (3.13%) 0 / 3 0 / 0		

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

Non-serious adverse events	ELX/TEZ/IVA		
Total subjects affected by non-serious adverse events subjects affected / exposed	62 / 64 (96.88%)		
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	6 / 64 (9.38%) 9		
Bacterial test positive subjects affected / exposed occurrences (all)	7 / 64 (10.94%) 12		
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	8 / 64 (12.50%) 8		
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	5 / 64 (7.81%) 7		
Injury, poisoning and procedural complications			

Immunisation reaction subjects affected / exposed occurrences (all)	4 / 64 (6.25%) 4		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	26 / 64 (40.63%) 39		
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all)	28 / 64 (43.75%) 52 10 / 64 (15.63%) 11		
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	5 / 64 (7.81%) 6		
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting	4 / 64 (6.25%) 5 14 / 64 (21.88%) 16 10 / 64 (15.63%) 15 10 / 64 (15.63%) 16 6 / 64 (9.38%) 10		

subjects affected / exposed occurrences (all)	17 / 64 (26.56%) 33		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	40 / 64 (62.50%)		
occurrences (all)	103		
Epistaxis			
subjects affected / exposed	4 / 64 (6.25%)		
occurrences (all)	4		
Nasal congestion			
subjects affected / exposed	23 / 64 (35.94%)		
occurrences (all)	43		
Oropharyngeal pain			
subjects affected / exposed	24 / 64 (37.50%)		
occurrences (all)	43		
Productive cough			
subjects affected / exposed	11 / 64 (17.19%)		
occurrences (all)	23		
Rhinorrhoea			
subjects affected / exposed	21 / 64 (32.81%)		
occurrences (all)	36		
Sinus congestion			
subjects affected / exposed	4 / 64 (6.25%)		
occurrences (all)	9		
Infections and infestations			
COVID-19			
subjects affected / exposed	18 / 64 (28.13%)		
occurrences (all)	21		
Ear infection			
subjects affected / exposed	4 / 64 (6.25%)		
occurrences (all)	4		
Hordeolum			
subjects affected / exposed	9 / 64 (14.06%)		
occurrences (all)	16		
Infective pulmonary exacerbation of cystic fibrosis			

subjects affected / exposed	8 / 64 (12.50%)		
occurrences (all)	8		
Influenza			
subjects affected / exposed	7 / 64 (10.94%)		
occurrences (all)	7		
Nasopharyngitis			
subjects affected / exposed	10 / 64 (15.63%)		
occurrences (all)	22		
Pharyngitis streptococcal			
subjects affected / exposed	5 / 64 (7.81%)		
occurrences (all)	6		
Sinusitis			
subjects affected / exposed	6 / 64 (9.38%)		
occurrences (all)	9		
Upper respiratory tract infection			
subjects affected / exposed	19 / 64 (29.69%)		
occurrences (all)	61		
Viral upper respiratory tract infection			
subjects affected / exposed	7 / 64 (10.94%)		
occurrences (all)	12		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 June 2021	Amended to extend treatment period by adding Part B (additional 96 weeks of treatment duration) and updated monitoring text to include flexibility for remote monitoring.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported