



Clinical trial results:

A Phase 2/3, Randomized, Placebo-Controlled, Double-Blind Clinical Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MK-4482 in Hospitalized Adults with COVID-19

Summary

EudraCT number	2020-003367-26
Trial protocol	FR GB SE PL IT
Global end of trial date	11 August 2021

Results information

Result version number	v1
This version publication date	10 August 2022
First version publication date	10 August 2022

Trial information

Trial identification

Sponsor protocol code	MK-4482-001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04575584
WHO universal trial number (UTN)	-
Other trial identifiers	PHRR: PHRR201210-003189, jRCT: jRCT2031200404

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, NJ, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.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 August 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 August 2021
Global end of trial reached?	Yes
Global end of trial date	11 August 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This study aims to evaluate the safety, tolerability and efficacy of molnupiravir (MK-4482) compared to placebo. The primary hypothesis is that molnupiravir is superior to placebo as assessed by the rate of sustained recovery through Day 29.

This study was intended to include two parts: Part 1 was a dose-ranging phase 2 study, and Part 2 was a phase 3 study to evaluate the dose selected in Part 1. However, this study was terminated due to business reasons prior to conducting Part 2. Participants in Part 1 were followed until Month 7.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 October 2020
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	Brazil: 32
Country: Number of subjects enrolled	Chile: 8
Country: Number of subjects enrolled	Colombia: 23
Country: Number of subjects enrolled	France: 15
Country: Number of subjects enrolled	Israel: 15
Country: Number of subjects enrolled	Korea, Republic of: 12
Country: Number of subjects enrolled	Mexico: 23
Country: Number of subjects enrolled	Philippines: 1
Country: Number of subjects enrolled	Poland: 6
Country: Number of subjects enrolled	Russian Federation: 42
Country: Number of subjects enrolled	South Africa: 1
Country: Number of subjects enrolled	Ukraine: 25
Country: Number of subjects enrolled	United Kingdom: 21
Country: Number of subjects enrolled	United States: 46
Country: Number of subjects enrolled	Spain: 34

Worldwide total number of subjects	304
EEA total number of subjects	55

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)	205
From 65 to 84 years	93
85 years and over	6

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were enrolled at 86 study centers in 15 countries.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
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Arm title	Part 1: Molnupiravir 200 mg
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Arm description:

200 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)

Arm type	Experimental
Investigational medicinal product name	Molnupiravir
Investigational medicinal product code	
Other name	MK-4482
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Molnupiravir capsule taken by mouth every 12 hours for 5 days

Arm title	Part 1: Molnupiravir 400 mg
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Arm description:

400 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)

Arm type	Experimental
Investigational medicinal product name	Molnupiravir
Investigational medicinal product code	
Other name	MK-4482
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Molnupiravir capsule taken by mouth every 12 hours for 5 days

Arm title	Part 1: Molnupiravir 800 mg
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Arm description:

800 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)

Arm type	Experimental
Investigational medicinal product name	Molnupiravir
Investigational medicinal product code	
Other name	MK-4482
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Molnupiravir capsule taken by mouth every 12 hours for 5 days

Arm title	Part 1: Placebo
Arm description: Placebo matching molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo capsule matched to molnupiravir taken by mouth every 12 hours for 5 days

Number of subjects in period 1	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg
Started	75	75	76
Treated	73	73	72
Completed	61	60	63
Not completed	14	15	13
Not recorded	-	-	-
Consent withdrawn by subject	7	9	5
Physician decision	-	1	1
Death	6	4	6
Lost to follow-up	1	1	1

Number of subjects in period 1	Part 1: Placebo
Started	78
Treated	75
Completed	70
Not completed	8
Not recorded	1
Consent withdrawn by subject	3
Physician decision	1
Death	2
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	Part 1: Molnupiravir 200 mg
Reporting group description: 200 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 1: Molnupiravir 400 mg
Reporting group description: 400 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 1: Molnupiravir 800 mg
Reporting group description: 800 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 1: Placebo
Reporting group description: Placebo matching molnupiravir administered orally every 12 hours for 5 days (10 doses total)	

Reporting group values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg
Number of subjects	75	75	76
Age categorical Units: participants			
Adults (18-64 years)	51	50	53
From 65-84 years	22	23	23
85 years and over	2	2	0
Age Continuous Units: years			
arithmetic mean	56.9	57.0	56.8
standard deviation	± 14.2	± 14.0	± 13.7
Sex: Female, Male Units: participants			
Female	32	34	32
Male	43	41	44
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	3	1
Asian	10	8	4
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	1	4	6
White	58	52	54
More than one race	6	7	9
Unknown or Not Reported	0	1	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	27	32	28
Not Hispanic or Latino	47	42	46
Unknown or Not Reported	1	1	2

Reporting group values	Part 1: Placebo	Total	
Number of subjects	78	304	

Age categorical Units: participants			
Adults (18-64 years)	51	205	
From 65-84 years	25	93	
85 years and over	2	6	
Age Continuous Units: years			
arithmetic mean	57.1		
standard deviation	± 14.2	-	
Sex: Female, Male Units: participants			
Female	34	132	
Male	44	172	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	6	
Asian	1	23	
Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	7	18	
White	63	227	
More than one race	5	27	
Unknown or Not Reported	0	2	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	27	114	
Not Hispanic or Latino	49	184	
Unknown or Not Reported	2	6	

End points

End points reporting groups

Reporting group title	Part 1: Molnupiravir 200 mg
Reporting group description: 200 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 1: Molnupiravir 400 mg
Reporting group description: 400 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 1: Molnupiravir 800 mg
Reporting group description: 800 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 1: Placebo
Reporting group description: Placebo matching molnupiravir administered orally every 12 hours for 5 days (10 doses total)	

Primary: Time-to-sustained recovery

End point title	Time-to-sustained recovery
End point description: The median time to sustained recovery is reported. Sustained recovery is defined as 1) the participant is alive and not hospitalized; or 2) the participant is alive and medically ready for discharge as determined by the investigator. All randomized participants in Part 1 who received ≥ 1 dose of study drug are included.	
End point type	Primary
End point timeframe: Up to 29 days	

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: days				
median (confidence interval 95%)	9.0 (7.0 to 10.0)	9.0 (8.0 to 10.0)	9.0 (8.0 to 11.0)	9.0 (8.0 to 11.0)

Statistical analyses

Statistical analysis title	Time to Recovery: Molnupiravir 200 mg vs. Placebo
Statistical analysis description: Based on Cox regression model with Efron's method of tie handling.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.562
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.45

Statistical analysis title	Time to Recovery: Molnupiravir 400 mg vs. Placebo
Statistical analysis description: Based on Cox regression model with Efron's method of tie handling.	
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3145
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.65

Statistical analysis title	Time to Recovery: Molnupiravir 800 mg vs. Placebo
Statistical analysis description: Based on Cox regression model with Efron's method of tie handling.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4894
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.47

Primary: Number of participants with an adverse event (AE)

End point title	Number of participants with an adverse event (AE) ^[1]
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End point description:

The number of participants with at least 1 AE is presented. An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. All randomized participants in Part 1 who received ≥ 1 dose of study drug are included.

End point type	Primary
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End point timeframe:

Up to 19 days (during treatment and 14-day follow-up)

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: Per protocol, only descriptive statistics are presented.

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants	40	36	45	46

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants who discontinued study intervention due to an AE

End point title	Number of participants who discontinued study intervention due to an AE ^[2]
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End point description:

The number of participants discontinuing from study treatment due to an AE is presented. An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. All randomized participants in Part 1 who received ≥ 1 dose of study drug are included.

End point type	Primary
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End point timeframe:

Up to 5 days

Notes:

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

Justification: Per protocol, only descriptive statistics are presented.

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with all-cause mortality

End point title	Number of participants with all-cause mortality
End point description: The number of participants with all-cause mortality (ACM) through Day 29 is presented. All-cause mortality is defined as death due to any cause. Any participants with an unknown survival status at Day 29 were imputed as deceased. All randomized participants in Part 1 who received ≥ 1 dose of study drug are included.	
End point type	Secondary
End point timeframe: Up to 29 days	

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants	4	5	4	1

Statistical analyses

Statistical analysis title	ACM: Molnupiravir 200 mg vs. Placebo
Statistical analysis description: Unknown Day 29 survival status was treated as failure.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1642
Method	Miettinen and Nurminen method
Parameter estimate	Mean difference (final values)
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	12.1

Statistical analysis title	ACM: Molnupiravir 800 mg vs. Placebo
Statistical analysis description: Unknown Day 29 survival status was treated as failure.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1594
Method	Miettinen and Nurminen method
Parameter estimate	Mean difference (final values)
Point estimate	4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	12.3

Statistical analysis title	ACM: Molnupiravir 400 mg vs. Placebo
Statistical analysis description: Unknown Day 29 survival status was treated as failure.	
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.09
Method	Miettinen and Nurminen method
Parameter estimate	Mean difference (final values)
Point estimate	5.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	13.9

Secondary: Odds of a more favorable response on Pulmonary ordinal outcome score on Day 3

End point title	Odds of a more favorable response on Pulmonary ordinal outcome score on Day 3
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End point description:

Pulmonary score is a score on an ordinal scale which focuses on respiratory sequelae based on oxygen requirements using 7 mutually exclusive categories. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
End point timeframe:	
Day 3	

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=72,72,72,73)	25	20	21	16
2 (n=72,72,72,73)	2	7	0	7
3 (n=72,72,72,73)	21	20	23	25
4 (n=72,72,72,73)	16	16	19	14
5 (n=72,72,72,73)	7	9	6	10
6 (n=72,72,72,73)	1	0	3	1
7 (n=72,72,72,73)	0	0	0	0
Missing (n=73,73,72,75)	1	1	0	2

Statistical analyses

Statistical analysis title	Pulmonary Day 3: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3623
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	2.35

Statistical analysis title	Pulmonary Day 3: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9313
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.75

Statistical analysis title	Pulmonary Day 3: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5714
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	2.12

Secondary: Odds of a more favorable response on Pulmonary ordinal outcome score on End of Treatment (EOT [Day 5])

End point title	Odds of a more favorable response on Pulmonary ordinal outcome score on End of Treatment (EOT [Day 5])
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End point description:

Pulmonary score is a score on an ordinal scale which focuses on respiratory sequelae based on oxygen requirements using 7 mutually exclusive categories. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
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End point timeframe:

EOT (Day 5)

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=71,68,70,70)	30	22	26	27
2 (n=71,68,70,70)	6	5	4	4
3 (n=71,68,70,70)	17	18	15	16
4 (n=71,68,70,70)	10	14	14	14
5 (n=71,68,70,70)	7	8	8	8
6 (n=71,68,70,70)	1	1	3	1
7 (n=71,68,70,70)	0	0	0	0
Missing (n=73,73,72,75)	2	5	2	5

Statistical analyses

Statistical analysis title	Pulmonary Day 5: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4398
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.3

Statistical analysis title	Pulmonary Day 5: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7069
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.62

Statistical analysis title	Pulmonary Day 5: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6277
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	1.57

Secondary: Odds of a more favorable response on Pulmonary ordinal outcome score on Day 10

End point title	Odds of a more favorable response on Pulmonary ordinal outcome score on Day 10
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End point description:

Pulmonary score is a score on an ordinal scale which focuses on respiratory sequelae based on oxygen requirements using 7 mutually exclusive categories. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
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End point timeframe:

Day 10

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=68,64,67,70)	44	39	33	38
2 (n=68,64,67,70)	4	4	4	5
3 (n=68,64,67,70)	8	8	14	10
4 (n=68,64,67,70)	5	7	8	10
5 (n=68,64,67,70)	4	3	5	4
6 (n=68,64,67,70)	3	0	3	3
7 (n=68,64,67,70)	0	3	0	0
Missing (n=73,73,72,75)	5	9	5	5

Statistical analyses

Statistical analysis title	Pulmonary Day 10: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2422
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	2.85

Statistical analysis title	Pulmonary Day 10: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6052
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.59

Statistical analysis title	Pulmonary Day 10: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4789
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	2.44

Secondary: Odds of a more favorable response on Pulmonary ordinal outcome score on Day 15

End point title	Odds of a more favorable response on Pulmonary ordinal outcome score on Day 15
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End point description:

Pulmonary score is a score on an ordinal scale which focuses on respiratory sequelae based on oxygen requirements using 7 mutually exclusive categories. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
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End point timeframe:

Day 15

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=67,62,68,71)	45	44	41	42
2 (n=67,62,68,71)	7	2	2	5
3 (n=67,62,68,71)	6	6	14	10
4 (n=67,62,68,71)	3	5	3	6
5 (n=67,62,68,71)	2	1	0	4
6 (n=67,62,68,71)	4	1	7	3
7 (n=67,62,68,71)	0	3	1	1
Missing (n=73,73,72,75)	6	11	4	4

Statistical analyses

Statistical analysis title	Pulmonary Day 15: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2644
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	2.88

Statistical analysis title	Pulmonary Day 15: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2184
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	3.14

Statistical analysis title	Pulmonary Day 15: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9771
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.94

Secondary: Odds of a more favorable response on Pulmonary ordinal outcome score on Day 29

End point title	Odds of a more favorable response on Pulmonary ordinal outcome score on Day 29
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End point description:

Pulmonary score is a score on an ordinal scale which focuses on respiratory sequelae based on oxygen requirements using 7 mutually exclusive categories. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
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End point timeframe:

Day 29

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=63,59,69,69)	46	47	47	49
2 (n=63,59,69,69)	2	2	2	5
3 (n=63,59,69,69)	4	5	9	7
4 (n=63,59,69,69)	5	1	3	5
5 (n=63,59,69,69)	0	0	0	0
6 (n=63,59,69,69)	2	0	5	2
7 (n=63,59,69,69)	4	4	3	1
Missing (n=73,73,72,75)	10	14	3	6

Statistical analyses

Statistical analysis title	Pulmonary Day 29: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9945
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	2.06

Statistical analysis title	Pulmonary Day 15: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3227
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	3.37

Statistical analysis title	Pulmonary Day 15: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.52
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	1.61

Secondary: Odds of a more favorable response on Pulmonary+ ordinal outcome score on Day 3

End point title	Odds of a more favorable response on Pulmonary+ ordinal outcome score on Day 3
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End point description:

Pulmonary+ score is a score on an ordinal scale which is a 7-category assessment that captures the range of disease severity in hospitalized participants, including coagulation-related complications and respiratory dysfunction. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory

sequae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
End point timeframe:	
Day 3	

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=72,72,72,73)	25	20	21	16
2 (n=72,72,72,73)	2	7	0	7
3 (n=72,72,72,73)	20	20	23	25
4 (n=72,72,72,73)	16	16	19	14
5 (n=72,72,72,73)	7	9	6	10
6 (n=72,72,72,73)	2	0	3	1
7 (n=72,72,72,73)	0	0	0	0
Missing (n=73,73,72,75)	1	1	0	2

Statistical analyses

Statistical analysis title	Pulmonary+ Day 3: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4472
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.25

Statistical analysis title	Pulmonary+ Day 3: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5714
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	2.12

Statistical analysis title	Pulmonary+ Day 3: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9313
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.75

Secondary: Odds of a more favorable response on Pulmonary+ ordinal outcome score on EOT (Day 5)

End point title	Odds of a more favorable response on Pulmonary+ ordinal outcome score on EOT (Day 5)
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End point description:

Pulmonary+ score is a score on an ordinal scale which is a 7-category assessment that captures the range of disease severity in hospitalized participants, including coagulation-related complications and respiratory dysfunction. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
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End point timeframe:

EOT (Day 5)

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=71,68,70,70)	30	22	26	27
2 (n=71,68,70,70)	6	5	4	4
3 (n=71,68,70,70)	16	18	15	16
4 (n=71,68,70,70)	10	14	14	14
5 (n=71,68,70,70)	7	8	8	8
6 (n=71,68,70,70)	2	1	3	1
7 (n=71,68,70,70)	0	0	0	0
Missing (n=73,73,72,75)	2	5	2	5

Statistical analyses

Statistical analysis title	Pulmonary+ Day 5: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5222
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	2.21

Statistical analysis title	Pulmonary+ Day 5: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6277
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	1.57

Statistical analysis title	Pulmonary+ Day 5: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7069
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.62

Secondary: Odds of a more favorable response on Pulmonary+ ordinal outcome score on Day 10

End point title	Odds of a more favorable response on Pulmonary+ ordinal outcome score on Day 10
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End point description:

Pulmonary+ score is a score on an ordinal scale which is a 7-category assessment that captures the range of disease severity in hospitalized participants, including coagulation-related complications and respiratory dysfunction. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
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End point timeframe:

Day 10

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=68,64,67,70)	44	39	33	38
2 (n=68,64,67,70)	4	4	4	5
3 (n=68,64,67,70)	8	8	14	10
4 (n=68,64,67,70)	4	7	8	10
5 (n=68,64,67,70)	4	3	4	4
6 (n=68,64,67,70)	4	0	4	3
7 (n=68,64,67,70)	0	3	0	0
Missing (n=73,73,72,75)	5	9	5	5

Statistical analyses

Statistical analysis title	Pulmonary+ Day 10: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2627
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	2.8

Statistical analysis title	Pulmonary+ Day 10: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4789
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	2.44

Statistical analysis title	Pulmonary+ Day 10: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5938
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.58

Secondary: Odds of a more favorable response on Pulmonary+ ordinal outcome score on Day 15

End point title	Odds of a more favorable response on Pulmonary+ ordinal outcome score on Day 15
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End point description:

Pulmonary+ score is a score on an ordinal scale which is a 7-category assessment that captures the range of disease severity in hospitalized participants, including coagulation-related complications and respiratory dysfunction. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
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End point timeframe:

Day 15

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=67,62,68,71)	45	44	41	42
2 (n=67,62,68,71)	7	2	2	5
3 (n=67,62,68,71)	6	6	14	10
4 (n=67,62,68,71)	3	5	3	6
5 (n=67,62,68,71)	2	1	0	4
6 (n=67,62,68,71)	4	1	7	3
7 (n=67,62,68,71)	0	3	1	1
Missing (n=73,73,72,75)	6	11	4	4

Statistical analyses

Statistical analysis title	Pulmonary+ Day 15: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2644
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	2.88

Statistical analysis title	Pulmonary+ Day 15: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9771
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.94

Statistical analysis title	Pulmonary+ Day 15: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2184
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	3.14

Secondary: Odds of a more favorable response on Pulmonary+ ordinal outcome score on Day 29

End point title	Odds of a more favorable response on Pulmonary+ ordinal outcome score on Day 29
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End point description:

Pulmonary+ score is a score on an ordinal scale which is a 7-category assessment that captures the range of disease severity in hospitalized participants, including coagulation-related complications and respiratory dysfunction. The score ranges from 1 ("can independently undertake personal usual activities with minimal or no symptoms") to 7 ("death") with a higher score indicating more severe respiratory sequelae. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data available at the relevant time point are included.

End point type	Secondary
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End point timeframe:

Day 29

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
1 (n=63,59,69,69)	46	47	47	49
2 (n=63,59,69,69)	2	2	2	5
3 (n=63,59,69,69)	4	5	9	7
4 (n=63,59,69,69)	5	1	3	5
5 (n=63,59,69,69)	0	0	0	0
6 (n=63,59,69,69)	2	0	5	2
7 (n=63,59,69,69)	4	4	3	1
Missing (n=63,59,69,69)	10	14	3	6

Statistical analyses

Statistical analysis title	Pulmonary+ Day 29: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9445
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	2.06

Statistical analysis title	Pulmonary+ Day 29: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3227
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	3.37

Statistical analysis title	Pulmonary+ Day 29: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.52
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	1.61

Secondary: Odds of a more favorable response in the clinical risk of mortality category from the National Early Warning Score (NEWS)

End point title	Odds of a more favorable response in the clinical risk of mortality category from the National Early Warning Score (NEWS)
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End point description:

NEWS (Royal College of Physicians, 2012) assesses a participant's degree of illness as assessed by clinical risk prediction categories based on a set of vital sign measurements. There are 7 physiological parameters: respiration rate, oxygen saturation, supplemental oxygen, systolic blood pressure, pulse

rate, level of consciousness, and temperature. A score of 0 to 3 was allocated to each parameter except supplemental oxygen use (score of 0 [no] or 1 [yes]) and level of consciousness (score of 0 or 3 with 0 = normal health condition and 3 = worst health condition). All scores were summed to get an aggregate score. Aggregate NEWS score ranged from 0 to 19, with higher scores meaning more severity/higher risk: low risk (score 0 to 4); low to medium risk (score of 3 in any individual parameter); medium risk (score 5 to 6); high risk (score 7 to 19). All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data at the relevant time point are included.

End point type	Secondary
End point timeframe:	
EOT (Day 5)	

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
Low (n=70,64,69,69)	57	45	52	55
Medium (n=70,64,69,69)	8	8	9	11
High (n=70,64,69,69)	5	11	8	3
Missing (n=70,64,69,69)	3	9	3	6

Statistical analyses

Statistical analysis title	NEWS: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8732
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	2.47

Statistical analysis title	NEWS: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4326
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	1.61

Statistical analysis title	NEWS: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1277
Method	Wald Chi-square
Parameter estimate	Odds ratio (OR)
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	1.19

Secondary: Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on Day 3

End point title	Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on Day 3
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End point description:

The World Health Organization (WHO) outcome scale is an 11-point ordinal score that categorizes clinical progression. Score ranges from 0 ("uninfected") to 10 ("dead") with higher score indicating clinical progression. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data at the relevant time point are included.

End point type	Secondary
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End point timeframe:

Day 3

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
0 (n=73,73,72,75)	0	0	0	0
1 (n=73,73,72,75)	0	0	0	0
2 (n=73,73,72,75)	1	1	0	2
3 (n=73,73,72,75)	1	0	0	1
4 (n=73,73,72,75)	27	27	21	24
5 (n=73,73,72,75)	36	36	42	37
6 (n=73,73,72,75)	7	9	6	10
7 (n=73,73,72,75)	0	0	0	0
8 (n=73,73,72,75)	0	0	2	0
9 (n=73,73,72,75)	1	0	1	1
10 (n=73,73,72,75)	0	0	0	0
Missing (n=73,73,72,75)	0	0	0	0

Statistical analyses

Statistical analysis title	WHO Day 3: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.683
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	2.88

Statistical analysis title	WHO Day 3: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	2.39

Statistical analysis title	WHO Day 3: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8244
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	2.2

Secondary: Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on EOT (Day 5)

End point title	Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on EOT (Day 5)
End point description:	
The World Health Organization (WHO) outcome scale is an 11-point ordinal score that categorizes clinical progression. Score ranges from 0 ("uninfected") to 10 ("dead") with higher score indicating clinical progression. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data at the relevant time point are included.	
End point type	Secondary
End point timeframe:	
EOT (Day 5)	

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
0 (n=71,68,70,72)	2	0	1	0
1 (n=71,68,70,72)	2	1	1	2
2 (n=71,68,70,72)	3	5	0	9
3 (n=71,68,70,72)	0	2	2	1
4 (n=71,68,70,72)	29	20	27	25

5 (n=71,68,70,72)	27	31	28	26
6 (n=71,68,70,72)	7	8	8	8
7 (n=71,68,70,72)	0	0	0	0
8 (n=71,68,70,72)	1	1	1	0
9 (n=71,68,70,72)	0	0	2	1
10 (n=71,68,70,72)	0	0	0	0
Missing (n=71,68,70,72)	2	5	2	3

Statistical analyses

Statistical analysis title	WHO Day 5: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5022
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	1.64

Statistical analysis title	WHO Day 5: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0991
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.24
upper limit	1.13

Statistical analysis title	WHO Day 5: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5204
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	1.64

Secondary: Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on Day 10

End point title	Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on Day 10
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End point description:

The World Health Organization (WHO) outcome scale is an 11-point ordinal score that categorizes clinical progression. Score ranges from 0 ("uninfected") to 10 ("dead") with higher score indicating clinical progression. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data at the relevant time point are included.

End point type	Secondary
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End point timeframe:

Day 10

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
0 (n=68,64,67,69)	3	4	2	3
1 (n=68,64,67,69)	10	7	7	7
2 (n=68,64,67,69)	26	19	22	21
3 (n=68,64,67,69)	3	4	7	8
4 (n=68,64,67,69)	8	16	7	13
5 (n=68,64,67,69)	11	9	14	11
6 (n=68,64,67,69)	4	2	5	3
7 (n=68,64,67,69)	0	0	1	0
8 (n=68,64,67,69)	2	0	0	3
9 (n=68,64,67,69)	1	0	2	0
10 (n=68,64,67,69)	0	3	0	0
Missing (n=68,64,67,69)	5	9	5	6

Statistical analyses

Statistical analysis title	WHO Day 10: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6346
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	2.29

Statistical analysis title	WHO Day 10: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8879
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.84

Statistical analysis title	WHO Day 10: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7596
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.75

Secondary: Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on Day 15

End point title	Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on Day 15
End point description: The World Health Organization (WHO) outcome scale is an 11-point ordinal score that categorizes clinical progression. Score ranges from 0 ("uninfected") to 10 ("dead") with higher score indicating clinical progression. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data at the relevant time point are included.	
End point type	Secondary
End point timeframe: Day 15	

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
0 (n=67,61,68,70)	10	8	10	8
1 (n=67,61,68,70)	12	12	9	11
2 (n=67,61,68,70)	25	25	27	27
3 (n=67,61,68,70)	7	5	4	8
4 (n=67,61,68,70)	4	3	3	5
5 (n=67,61,68,70)	4	4	7	4
6 (n=67,61,68,70)	2	0	0	3
7 (n=67,61,68,70)	0	0	2	1
8 (n=67,61,68,70)	3	0	1	0
9 (n=67,61,68,70)	0	1	4	2
10 (n=67,61,68,70)	0	3	1	1
Missing (n=67,61,68,70)	6	12	4	5

Statistical analyses

Statistical analysis title	WHO Day 15: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6002
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.24

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	2.82

Statistical analysis title	WHO Day 15: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.622
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.78

Statistical analysis title	WHO Day 15: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4733
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	1.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	3.21

Secondary: Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on Day 29

End point title	Odds of a more favorable response on WHO 11-point ordinal outcomes score on a scale on Day 29
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End point description:

The World Health Organization (WHO) outcome scale is an 11-point ordinal score that categorizes clinical progression. Score ranges from 0 ("uninfected") to 10 ("dead") with higher score indicating clinical progression. The number of participants at each score category is presented. All randomized participants in Part 1 who received ≥ 1 dose of study drug and have data at the relevant time point are

included.

End point type	Secondary
End point timeframe:	
Day 29	

End point values	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73	73	72	75
Units: participants				
0 (n=63,59,68,69)	25	17	29	22
1 (n=63,59,68,69)	4	13	7	9
2 (n=63,59,68,69)	24	21	17	24
3 (n=63,59,68,69)	3	2	7	7
4 (n=63,59,68,69)	0	2	0	0
5 (n=63,59,68,69)	1	0	0	4
6 (n=63,59,68,69)	0	0	0	0
7 (n=63,59,68,69)	0	0	2	0
8 (n=63,59,68,69)	2	0	2	2
9 (n=63,59,68,69)	0	0	1	0
10 (n=63,59,68,69)	4	4	3	1
Missing (n=63,59,68,69)	10	14	4	6

Statistical analyses

Statistical analysis title	WHO Day 29: Molnupiravir 200 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7871
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	2.6

Statistical analysis title	WHO Day 29: Molnupiravir 400 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9598
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	3.06

Statistical analysis title	WHO Day 29: Molnupiravir 800 mg vs. Placebo
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.667
Method	Wald Chi-Square
Parameter estimate	Odds ratio (OR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	2.31

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 7 months

Adverse event reporting additional description:

All randomized participants are included in the all-cause mortality assessment; only confirmed (no imputed) deaths are reported.

All participants who received ≥ 1 dose of study treatment are included in the assessment of serious adverse events (SAEs) and nonserious AEs.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	Part 1: Molnupiravir 200 mg
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Reporting group description:

200 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)

Reporting group title	Part 1: Molnupiravir 800 mg
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Reporting group description:

800 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)

Reporting group title	Part 1: Placebo
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Reporting group description:

Placebo matching molnupiravir administered orally every 12 hours for 5 days (10 doses total)

Reporting group title	Part 1: Molnupiravir 400 mg
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Reporting group description:

400 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)

Serious adverse events	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 73 (15.07%)	13 / 72 (18.06%)	12 / 75 (16.00%)
number of deaths (all causes)	6	7	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Physical deconditioning			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 73 (1.37%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute respiratory failure			
subjects affected / exposed	3 / 73 (4.11%)	2 / 72 (2.78%)	2 / 75 (2.67%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Asthma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumothorax spontaneous			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory acidosis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	3 / 73 (4.11%)	3 / 72 (4.17%)	3 / 75 (4.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Haemorrhoids			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 73 (1.37%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Gouty arthritis			

subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	2 / 73 (2.74%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	7 / 73 (9.59%)	5 / 72 (6.94%)	6 / 75 (8.00%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 73 (0.00%)	3 / 72 (4.17%)	5 / 75 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Peritonitis bacterial			
subjects affected / exposed	1 / 73 (1.37%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 73 (0.00%)	2 / 72 (2.78%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Septic shock			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			

subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 73 (1.37%)	2 / 72 (2.78%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 73 (0.00%)	1 / 72 (1.39%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 72 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: Molnupiravir 400 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 73 (12.33%)		
number of deaths (all causes)	4		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions			
Physical deconditioning			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pneumothorax spontaneous subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory acidosis subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory failure subjects affected / exposed	4 / 73 (5.48%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Investigations			
Haemoglobin decreased subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transaminases increased subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac arrest subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Supraventricular tachycardia subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Haemorrhoids			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Gouty arthritis			

subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	4 / 73 (5.48%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Peritonitis bacterial			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary sepsis			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Urinary tract infection enterococcal			

subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 73 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lactic acidosis			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	1 / 73 (1.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 800 mg	Part 1: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 73 (15.07%)	7 / 72 (9.72%)	13 / 75 (17.33%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 73 (5.48%)	7 / 72 (9.72%)	8 / 75 (10.67%)
occurrences (all)	4	7	8
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 73 (4.11%)	5 / 72 (6.94%)	3 / 75 (4.00%)
occurrences (all)	3	6	3
Gastrointestinal disorders			

Constipation subjects affected / exposed occurrences (all)	5 / 73 (6.85%) 5	0 / 72 (0.00%) 0	5 / 75 (6.67%) 5
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	4 / 73 (5.48%) 4	0 / 72 (0.00%) 0	1 / 75 (1.33%) 1

Non-serious adverse events	Part 1: Molnupiravir 400 mg		
Total subjects affected by non-serious adverse events subjects affected / exposed	11 / 73 (15.07%)		
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all) Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	5 / 73 (6.85%) 5 5 / 73 (6.85%) 5		
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all)	2 / 73 (2.74%) 2		
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	5 / 73 (6.85%) 5		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 December 2020	AM1: To revise the dose selection process before initiation of Part 2 (Phase 3), update the benefit/risk assessment, clarify the primary efficacy endpoint definition, and add a new inclusion criterion and discontinuation criterion.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
11 August 2021	This study was terminated early for business reasons.	-

Notes:

Limitations and caveats

None reported