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 Non-Hospitalized Adults with COVID-19.

Summary

EudraCT number	2020-003368-24
Trial protocol	FR GB DE IT PL
Global end of trial date	05 May 2022

Results information

Result version number	v1 (current)
This version publication date	12 May 2023
First version publication date	12 May 2023

Trial information

Trial identification

Sponsor protocol code	MK-4482-002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04575597
WHO universal trial number (UTN)	-
Other trial identifiers	PHRR201209-003186: PHRR, jRCT2031210148: jRCT

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	05 May 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 May 2022
Global end of trial reached?	Yes
Global end of trial date	05 May 2022
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 percentage of participants who are hospitalized and/or die through Day 29.

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	Argentina: 1
Country: Number of subjects enrolled	Brazil: 91
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Chile: 52
Country: Number of subjects enrolled	Colombia: 320
Country: Number of subjects enrolled	Egypt: 2
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Guatemala: 114
Country: Number of subjects enrolled	Israel: 12
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Japan: 8
Country: Number of subjects enrolled	Mexico: 150
Country: Number of subjects enrolled	Philippines: 27
Country: Number of subjects enrolled	Russian Federation: 388
Country: Number of subjects enrolled	South Africa: 184
Country: Number of subjects enrolled	Spain: 20
Country: Number of subjects enrolled	Taiwan: 2
Country: Number of subjects enrolled	Ukraine: 136

Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	United States: 198
Worldwide total number of subjects	1735
EEA total number of subjects	37

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)	1526
From 65 to 84 years	201
85 years and over	8

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were enrolled at 123 study centers in 21 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
Arm title	Part 1: Molnupiravir 200 mg

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:

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

Arm title	Part 1: Molnupiravir 400 mg

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:

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

Arm title	Part 1: Molnupiravir 800 mg

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:

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

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 matching molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Arm title	Part 2: Molnupiravir 800 mg
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:	
800 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Arm title	Part 2: 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 matching molnupiravir administered orally every 12 hours for 5 days (10 doses total)	

Number of subjects in period 1	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg
Started	75	77	76
Treated	74	77	74
Completed	71	74	71
Not completed	4	3	5
Consent withdrawn by subject	2	2	4
Death	-	-	-
Randomized By Mistake Without Study Treatment	-	-	-
Not Recorded	-	-	-
Lost to follow-up	2	1	1

Number of subjects in period 1	Part 1: Placebo	Part 2: Molnupiravir 800 mg	Part 2: Placebo
Started	74	716	717
Treated	74	710	701
Completed	69	675	663
Not completed	5	41	54
Consent withdrawn by subject	2	25	28
Death	1	3	14
Randomized By Mistake Without Study Treatment	-	3	2
Not Recorded	-	-	2
Lost to follow-up	2	10	8

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 title	Part 2: Molnupiravir 800 mg
Reporting group description:	
800 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 2: 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	77	76
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	60	66	59
From 65-84 years	15	11	17
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	49.5	49.2	51.0
standard deviation	± 14.6	± 14.2	± 15.8
Sex: Female, Male Units: Participants			
Female	40	32	41
Male	35	45	35
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	3	1	2
Asian	0	1	0

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	8	6
White	54	52	58
More than one race	13	15	10
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	29	30	23
Not Hispanic or Latino	46	46	51
Unknown or Not Reported	0	1	2
Time from Symptom Onset to Randomization (Part 1)			
Randomization of participants in Part 1 of this study was stratified by the time from symptom onset prior to the day of randomization (≤5 days or >5 days). Analysis population consisted of all randomized participants in Part 1. Per protocol, this stratification factor was applicable to Part 1 of the study only.			
Units: Subjects			
≤5 Days	51	52	52
>5 Days	24	25	24
Not Applicable	0	0	0
At Increased Risk of Severe Illness from Coronavirus Disease (COVID-19) (Part 1)			
Randomization of participants in Part 1 of this study was stratified by whether the participant was at an increased risk of severe illness from COVID-19 (At Increased Risk or Not At Increased Risk). Analysis population consisted of all randomized participants in Part 1. Per protocol, this stratification factor was applicable to Part 1 of the study only.			
Units: Subjects			
At Increased Risk	56	58	57
Not At Increased Risk	19	19	19
Not Applicable	0	0	0
Time from Symptom Onset to Randomization (Part 2)			
Randomization of participants in Part 2 of this study was stratified by the time from symptom onset prior to the day of randomization (≤3 days or >3 days). Analysis population consisted of all randomized participants in Part 2. Per protocol, this stratification factor was applicable to Part 2 of the study only.			
Units: Subjects			
≤ 3 days	0	0	0
> 3 days	0	0	0
Not Applicable	75	77	76

Reporting group values	Part 1: Placebo	Part 2: Molnupiravir 800 mg	Part 2: Placebo
Number of subjects	74	716	717
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	63	643	635
From 65-84 years	11	71	76

85 years and over	0	2	6

Age Continuous Units: years			
arithmetic mean	47.3	44.4	45.3
standard deviation	± 15.2	± 14.6	± 15.0
Sex: Female, Male Units: Participants			
Female	30	384	351
Male	44	332	366
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	5	60	44
Asian	0	26	23
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	40	35
White	52	400	413
More than one race	13	190	202
Unknown or Not Reported	1	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	33	355	356
Not Hispanic or Latino	39	355	358
Unknown or Not Reported	2	6	3
Time from Symptom Onset to Randomization (Part 1)			
Randomization of participants in Part 1 of this study was stratified by the time from symptom onset prior to the day of randomization (≤5 days or >5 days). Analysis population consisted of all randomized participants in Part 1. Per protocol, this stratification factor was applicable to Part 1 of the study only.			
Units: Subjects			
≤5 Days	50	0	0
>5 Days	24	0	0
Not Applicable	0	716	717
At Increased Risk of Severe Illness from Coronavirus Disease (COVID-19) (Part 1)			
Randomization of participants in Part 1 of this study was stratified by whether the participant was at an increased risk of severe illness from COVID-19 (At Increased Risk or Not At Increased Risk). Analysis population consisted of all randomized participants in Part 1. Per protocol, this stratification factor was applicable to Part 1 of the study only.			
Units: Subjects			
At Increased Risk	56	0	0
Not At Increased Risk	18	0	0
Not Applicable	0	716	717
Time from Symptom Onset to Randomization (Part 2)			
Randomization of participants in Part 2 of this study was stratified by the time from symptom onset prior to the day of randomization (≤3 days or >3 days). Analysis population consisted of all randomized participants in Part 2. Per protocol, this stratification factor was applicable to Part 2 of the study only.			
Units: Subjects			
≤ 3 days	0	342	342
> 3 days	0	374	375
Not Applicable	74	0	0

Reporting group values	Total		
Number of subjects	1735		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	1526		
From 65-84 years	201		
85 years and over	8		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Participants			
Female	878		
Male	857		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	115		
Asian	50		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	97		
White	1029		
More than one race	443		
Unknown or Not Reported	1		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	826		
Not Hispanic or Latino	895		
Unknown or Not Reported	14		
Time from Symptom Onset to Randomization (Part 1)			
Randomization of participants in Part 1 of this study was stratified by the time from symptom onset prior to the day of randomization (≤5 days or >5 days). Analysis population consisted of all randomized participants in Part 1. Per protocol, this stratification factor was applicable to Part 1 of the study only.			
Units: Subjects			
≤5 Days	205		
>5 Days	97		
Not Applicable	1433		
At Increased Risk of Severe Illness from Coronavirus Disease (COVID-19) (Part 1)			
Randomization of participants in Part 1 of this study was stratified by whether the participant was at an increased risk of severe illness from COVID-19 (At Increased Risk or Not At Increased Risk). Analysis population consisted of all randomized participants in Part 1. Per protocol, this stratification factor was applicable to Part 1 of the study only.			

Units: Subjects			
At Increased Risk	227		
Not At Increased Risk	75		
Not Applicable	1433		
Time from Symptom Onset to Randomization (Part 2)			
Randomization of participants in Part 2 of this study was stratified by the time from symptom onset prior to the day of randomization (≤3 days or >3 days). Analysis population consisted of all randomized participants in Part 2. Per protocol, this stratification factor was applicable to Part 2 of the study only.			
Units: Subjects			
≤ 3 days	684		
> 3 days	749		
Not Applicable	302		

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)	
Reporting group title	Part 2: Molnupiravir 800 mg
Reporting group description:	
800 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 2: Placebo
Reporting group description:	
Placebo matching molnupiravir administered orally every 12 hours for 5 days (10 doses total)	

Primary: Percentage of Participants Who Were Hospitalized and/or Died Through Day 29 (Primary Pre-specified Analysis)

End point title	Percentage of Participants Who Were Hospitalized and/or Died Through Day 29 (Primary Pre-specified Analysis)

End point description:

The percentage of participants who were hospitalized and/or died through Day 29 is presented. Hospitalization (all cause) is defined as at least 24 hours of acute care in a hospital or similar acute care facility. Death was due to any cause. Any participants with an unknown survival status at Day 29 were treated as failure. The analysis in Part 2 was based on all participants enrolled by the pre-specified futility/early efficacy analysis and was used for demonstration of superiority to placebo for the primary efficacy outcome measure. All randomized participants who received at least one dose of study intervention and were not hospitalized prior to the administration of the first dose of study intervention, and, in Part 2, had reached Day 29 by the time of futility/early efficacy analysis, were analyzed.

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	74	77	74	74
Units: Percentage of Participants				
number (not applicable)	1.4	3.9	4.1	5.4

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	385	377		
Units: Percentage of Participants				
number (not applicable)	7.3	14.1		

Statistical analyses

Statistical analysis title	Number of Participants Who Were Hospitalized/Died
Statistical analysis description:	
Difference in rates % and associated CIs were based on the Miettinen & Nurminen method stratified by randomization strata. Unknown survival status at Day 29 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	other
Parameter estimate	Difference in Rates %
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.2
upper limit	2.5

Statistical analysis title	Number of Participants Who Were Hospitalized/Died
Statistical analysis description:	
Difference in rates % and associated CIs were based on the Miettinen & Nurminen method stratified by randomization strata. Unknown survival status at Day 29 was treated as failure.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Differences in Rates %
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.6
upper limit	6.4

Statistical analysis title	Number of Participants Who Were Hospitalized/Died

Statistical analysis description:

Difference in rates %, associated CIs, and p-value were based on the Miettinen & Nurminen method stratified by randomization strata. Unknown survival status at Day 29 was treated as failure.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	762
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0012
Method	Stratified Miettinen & Nurminen
Parameter estimate	Difference in Rates %
Point estimate	-6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.3
upper limit	-2.4

Statistical analysis title	Number of Participants Who Were Hospitalized/Died

Statistical analysis description:

Difference in rates % and associated CIs were based on the Miettinen & Nurminen method stratified by randomization strata. Unknown survival status at Day 29 was treated as failure.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Rates %
Point estimate	-1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.9
upper limit	6.2

Primary: Number of Participants With an Adverse Event (AE)

End point title	Number of Participants With an Adverse Event (AE)[1]

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 who received at least one dose of study treatment were analyzed.

End point type	Primary

End point timeframe:

Up to 318 days

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: 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	74	77	74	74
Units: Participants	29	24	29	28

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	710	701		
Units: Participants	230	239		

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]

End point description:

The number of participants who discontinued study intervention 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 who received at least one dose of study treatment were analyzed.

End point type	Primary

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	74	77	74	74
Units: Participants	0	0	3	1

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	710	701		
Units: Participants	10	20		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Cough

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Cough

End point description:

Time to sustained resolution or improvement (TSRI) of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (cough) at the time of randomization were analyzed.

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	51	50	53	48
Units: Days				
median (confidence interval 95%)	7.0 (5.0 to 10.0)	6.5 (4.0 to 10.0)	8.0 (6.0 to 11.0)	6.0 (4.0 to 7.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	570	574		
Units: Days				
median (confidence interval 95%)	10.0 (9.0 to 11.0)	10.0 (8.0 to 11.0)		

Statistical analyses

Statistical analysis title	TSRI: Cough

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.13

Statistical analysis title	TSRI: Cough

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1144
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.18

Statistical analysis title	TSRI: Cough

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	1.11

Statistical analysis title	TSRI: Cough

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.08

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Sore Throat

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Sore Throat

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (sore throat) at the time of randomization were analyzed.

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	22	31	28	30
Units: Days				
median (confidence interval 95%)	3.0 (2.0 to 4.0)	3.0 (2.0 to 5.0)	4.5 (3.0 to 8.0)	5.0 (3.0 to 7.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	318	296		
Units: Days				
median (confidence interval 95%)	4.0 (4.0 to 5.0)	5.0 (5.0 to 6.0)		

Statistical analyses

Statistical analysis title	TSRI: Sore Throat

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	2.76

Statistical analysis title	TSRI: Sore Throat

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	614
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.33

Statistical analysis title	TSRI: Sore Throat

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.62

Statistical analysis title	TSRI: Sore Throat

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	2.09

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Nasal Congestion

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Nasal Congestion

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (nasal congestion) at the time of randomization were analyzed.

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	48	41	40	54
Units: Days				
median (confidence interval 95%)	4.0 (3.0 to 6.0)	4.0 (3.0 to 7.0)	8.0 (5.0 to 10.0)	5.0 (4.0 to 6.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	439	429		
Units: Days				
median (confidence interval 95%)	5.0 (4.0 to 6.0)	6.0 (5.0 to 7.0)		

Statistical analyses

Statistical analysis title	TSRI: Nasal Congestion

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.46

Statistical analysis title	TSRI: Nasal Congestion

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo

Number of subjects included in analysis	868
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.23

Statistical analysis title	TSRI: Nasal Congestion

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.07

Statistical analysis title	TSRI: Nasal Congestion

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.79

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-

19 Sign/Symptom - Rhinorrhea

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Rhinorrhea

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (rhinorrhea) at the time of randomization were analyzed.

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	31	30	17	35
Units: Days				
median (confidence interval 95%)	4.0 (2.0 to 6.0)	8.0 (5.0 to 10.0)	9.0 (5.0 to 21.0)	5.0 (3.0 to 6.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	348	347		
Units: Days				
median (confidence interval 95%)	5.0 (4.0 to 6.0)	5.0 (5.0 to 6.0)		

Statistical analyses

Statistical analysis title	TSRI: Rhinorrhoea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	66
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.83

Statistical analysis title	TSRI: Rhinorrhoea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	695
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.18

Statistical analysis title	TSRI: Rhinorrhoea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	0.85

Statistical analysis title	TSRI: Rhinorrhoea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	1.26

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Shortness of Breath or Difficulty Breathing

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Shortness of Breath or Difficulty Breathing

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (shortness of breath or difficulty breathing) at the time of randomization were analyzed.

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	20	25	30	28
Units: Days				
median (confidence interval 95%)	7.0 (4.0 to 22.0)	4.0 (3.0 to 6.0)	9.0 (4.0 to 17.0)	5.0 (4.0 to 12.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	258	260		
Units: Days				
median (confidence interval 95%)	6.0 (6.0 to 8.0)	9.0 (6.0 to 10.0)		

Statistical analyses

Statistical analysis title	TSRI: Shortness of Breath/Difficulty Breathing
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	1.34

Statistical analysis title	TSRI: Shortness of Breath/Difficulty Breathing
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	518
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.37

Statistical analysis title	TSRI: Shortness of Breath/Difficulty Breathing
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	1.42

Statistical analysis title	TSRI: Shortness of Breath/Difficulty Breathing

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron's method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	53
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	2.71

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Muscles or Body Aches

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Muscles or Body Aches

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (muscles or body aches) at the time of randomization were analyzed.

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	49	42	36	47
Units: Days				
median (confidence interval 95%)	5.0 (3.0 to 7.0)	4.0 (3.0 to 4.0)	4.5 (3.0 to 15.0)	4.0 (3.0 to 7.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	460	454		
Units: Days				
median (confidence interval 95%)	4.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)		

Statistical analyses

Statistical analysis title	TSRI: Muscles or Body Aches
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.61

Statistical analysis title	TSRI: Muscles or Body Aches
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	1.23

Statistical analysis title	TSRI: Muscles or Body Aches

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	914
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.16

Statistical analysis title	TSRI: Muscles or Body Aches

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	2.09

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-

19 Sign/Symptom - Fatigue

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Fatigue

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (fatigue) at the time of randomization were analyzed.

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	56	51	56	52
Units: Days				
median (confidence interval 95%)	7.0 (4.0 to 11.0)	5.0 (3.0 to 7.0)	6.0 (4.0 to 11.0)	6.0 (4.0 to 10.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	538	528		
Units: Days				
median (confidence interval 95%)	6.0 (6.0 to 7.0)	7.0 (6.0 to 8.0)		

Statistical analyses

Statistical analysis title	TSRI: Fatigue

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.41

Statistical analysis title	TSRI: Fatigue

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.69

Statistical analysis title	TSRI: Fatigue

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.51

Statistical analysis title	TSRI: Fatigue

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo

Number of subjects included in analysis	1066
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.31

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Feeling Hot or Feverish

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Feeling Hot or Feverish

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (feeling hot or feverish) at the time of randomization were analyzed.

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	27	22	38	32
Units: Days				
median (confidence interval 95%)	4.0 (3.0 to 6.0)	2.0 (2.0 to 3.0)	4.0 (3.0 to 5.0)	3.5 (2.0 to 4.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	386	372		
Units: Days				
median (confidence interval 95%)	3.0 (3.0 to 4.0)	4.0 (3.0 to 4.0)		

Statistical analyses

Statistical analysis title	TSRI: Feeling Hot or Feverish
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.69

Statistical analysis title	TSRI: Feeling Hot or Feverish
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	758
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.21

Statistical analysis title	TSRI: Feeling Hot or Feverish
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.38

Statistical analysis title	TSRI: Feeling Hot or Feverish

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	2

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Chills

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Chills

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (chills) at the time of randomization were analyzed. A value of "9999" indicates the median time to resolution/improvement and confidence interval limits were not reached due to an insufficient number of participants with sustained resolution or improvement after randomization.

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	18	18	23	27
Units: Days				
median (confidence interval 95%)	2.0 (2.0 to 5.0)	2.0 (2.0 to 4.0)	3.0 (2.0 to 3.0)	4.0 (2.0 to 5.0)

End point values	Part 2: Molnupiravir	Part 2: Placebo		

	800 mg			
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	308	279		
Units: Days				
median (confidence interval 95%)	3.0 (2.0 to 3.0)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TSRI: Chills

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	2.76

Statistical analysis title	TSRI: Chills

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	587
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.24

Statistical analysis title	TSRI: Chills

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	2.86

Statistical analysis title	TSRI: Chills

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	3.38

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Headache

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Headache

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (headache) at the time of randomization were analyzed.

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	39	42	35	37
Units: Days				
median (confidence interval 95%)	4.0 (3.0 to 6.0)	4.0 (3.0 to 7.0)	4.0 (3.0 to 10.0)	6.0 (3.0 to 10.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	429		
Units: Days				
median (confidence interval 95%)	5.0 (4.0 to 5.0)	5.0 (5.0 to 6.0)		

Statistical analyses

Statistical analysis title	TSRI: Headache
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	2.2

Statistical analysis title	TSRI: Headache
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo

Number of subjects included in analysis	901
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.18

Statistical analysis title	TSRI: Headache

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	1.65

Statistical analysis title	TSRI: Headache

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	2.31

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-

19 Sign/Symptom - Nausea

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Nausea

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (nausea) at the time of randomization were analyzed.

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	16	17	10	16
Units: Days				
median (confidence interval 95%)	5.0 (2.0 to 8.0)	3.0 (2.0 to 4.0)	6.0 (2.0 to 9.0)	5.0 (2.0 to 9.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	171		
Units: Days				
median (confidence interval 95%)	4.0 (3.0 to 5.0)	4.0 (3.0 to 4.0)		

Statistical analyses

Statistical analysis title	TSRI: Nausea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	1.91

Statistical analysis title	TSRI: Nausea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	347
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.14

Statistical analysis title	TSRI: Nausea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	2.02

Statistical analysis title	TSRI: Nausea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	2.97

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Vomiting

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Vomiting

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (vomiting) at the time of randomization were analyzed. A value of "9999" indicates the median time to resolution/improvement and confidence interval limits were not reached due to an insufficient number of participants with sustained resolution or improvement after randomization.

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	2	2	2	5
Units: Days				
median (confidence interval 95%)	4.0 (2.0 to 6.0)	8.0 (2.0 to 14.0)	5.0 (2.0 to 8.0)	2.0 (2.0 to 4.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	38		
Units: Days				
median (confidence interval 95%)	3.0 (2.0 to 4.0)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TSRI - Vomiting

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.44
upper limit	1.06

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Diarrhea

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Diarrhea

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (diarrhea) at the time of randomization were analyzed.

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	13	19	15	11
Units: Days				
median (confidence interval 95%)	6.0 (2.0 to 13.0)	4.0 (2.0 to 4.0)	3.0 (2.0 to 6.0)	2.0 (2.0 to 3.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	158	166		
Units: Days				
median (confidence interval 95%)	3.0 (3.0 to 4.0)	3.0 (3.0 to 4.0)		

Statistical analyses

Statistical analysis title	TSRI: Diarrhea
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	0.67

Statistical analysis title	TSRI: Diarrhea
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	324
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.36

Statistical analysis title	TSRI: Diarrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	0.79

Statistical analysis title	TSRI: Diarrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	0.83

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Loss of Taste

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Loss of Taste

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (loss of taste) at the time of randomization were analyzed.

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	33	15	18	30
Units: Days				
median (confidence interval 95%)	6.0 (4.0 to 9.0)	6.0 (4.0 to 11.0)	10.0 (4.0 to 19.0)	9.0 (5.0 to 16.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	242	262		
Units: Days				
median (confidence interval 95%)	9.0 (8.0 to 10.0)	10.0 (8.0 to 12.0)		

Statistical analyses

Statistical analysis title	TSRI: Loss of Taste

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	2.23

Statistical analysis title	TSRI: Loss of Taste

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo

Number of subjects included in analysis	504
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.37

Statistical analysis title	TSRI: Loss of Taste
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	1.89

Statistical analysis title	TSRI: Loss of Taste
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	1.8

Secondary: Time to Sustained Resolution or Improvement of Each Targeted COVID-

19 Sign/Symptom - Loss of Smell

End point title	Time to Sustained Resolution or Improvement of Each Targeted COVID-19 Sign/Symptom - Loss of Smell

End point description:

Time to sustained resolution or improvement of the targeted sign/symptom was defined as the number of days from randomization to the first of three consecutive days when resolution or improvement of the targeted sign/symptom was demonstrated and did not worsen by Day 29. The median number of days from randomization to the first day on or before study Day 29 for sustained resolution or improvement is presented. Per protocol, all randomized participants who received at least one dose of study intervention and had the corresponding sign or symptom (loss of smell) at the time of randomization were analyzed.

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	38	29	24	36
Units: Days				
median (confidence interval 95%)	7.0 (6.0 to 9.0)	10.0 (6.0 to 18.0)	12.0 (6.0 to 19.0)	12.0 (7.0 to 16.0)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	318	323		
Units: Days				
median (confidence interval 95%)	10.0 (9.0 to 11.0)	11.0 (9.0 to 14.0)		

Statistical analyses

Statistical analysis title	TSRI: Loss of Smell

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.39

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	2.33

Statistical analysis title	TSRI: Loss of Smell

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.72

Statistical analysis title	TSRI: Loss of Smell

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	641
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	1.43

Statistical analysis title	TSRI: Loss of Smell

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.48

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Cough

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Cough

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (cough) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	68	70	66	67
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	688	672		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Cough

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	133
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	4.23

Statistical analysis title	TP: Cough

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	2.44

Statistical analysis title	TP: Cough

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	135
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.79

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	2.19

Statistical analysis title	TP: Cough

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1360
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.04

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Sore Throat

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Sore Throat

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (sore throat) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	71	72	70	67
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	695	681		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Sore Throat
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	138
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	2.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	6.53

Statistical analysis title	TP: Sore Throat
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1376
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.16

Statistical analysis title	TP: Sore Throat

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	1.84

Statistical analysis title	TP: Sore Throat

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	2.52

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Nasal Congestion

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Nasal Congestion

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (nasal congestion) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	71	71	69	67
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	682	664		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Nasal Congestion

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	138
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	3.32

Statistical analysis title	TP: Nasal Congestion

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo

Number of subjects included in analysis	1346
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1.1

Statistical analysis title	TP: Nasal Congestion

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	2.76

Statistical analysis title	TP: Nasal Congestion

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	138
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	3.74

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom -

Rhinorrhea

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Rhinorrhea

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (rhinorrhea) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	71	72	65	67
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	694	690		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Rhinorrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	138
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.41
upper limit	2.52

Statistical analysis title	TP: Rhinorrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1384
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.17

Statistical analysis title	TP: Rhinorrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	132
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	3

Statistical analysis title	TP: Rhinorrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	1.9

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Shortness of Breath or Difficulty Breathing

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Shortness of Breath or Difficulty Breathing

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (shortness of breath or difficulty breathing) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	69	73	70	68
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	701	681		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Shortness of Breath or Difficulty Breathing
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	1.75

Statistical analysis title	TP: Shortness of Breath or Difficulty Breathing
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1382
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.16

Statistical analysis title	TP: Shortness of Breath or Difficulty Breathing
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	138
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	1.62

Statistical analysis title	TP: Shortness of Breath or Difficulty Breathing

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	1.64

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Muscle or Body Aches

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Muscle or Body Aches

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (muscle or body aches) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	66	71	68	62
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	655	640		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Muscle or Body Aches

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	1.39

Statistical analysis title	TP: Muscle or Body Aches

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	133
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.78

Statistical analysis title	TP: Muscle or Body Aches

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	1.39

Statistical analysis title	TP: Muscle or Body Aches

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1295
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.48

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom -

Fatigue

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Fatigue

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (fatigue) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	64	69	62	60
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	659	637		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Fatigue

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.59

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	1.34

Statistical analysis title	TP: Fatigue

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1296
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.21

Statistical analysis title	TP: Fatigue

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.74

Statistical analysis title	TP: Fatigue

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	1.37

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Feeling Hot or Feverish

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Feeling Hot or Feverish

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (feeling hot or feverish) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	68	71	65	66
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	676	673		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Feeling Hot or Feverish
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	3.02

Statistical analysis title	TP: Feeling Hot or Feverish
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1349
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.11

Statistical analysis title	TP: Feeling Hot or Feverish
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	2.45

Statistical analysis title	TP: Feeling Hot or Feverish

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	2.2

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Chills

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Chills

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (chills) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	68	72	70	66
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	679	676		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Chills

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	2.27

Statistical analysis title	TP: Chills

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo

Number of subjects included in analysis	1355
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.23

Statistical analysis title	TP: Chills

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	1.91

Statistical analysis title	TP: Chills

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	138
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	1

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom -

Headache

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Headache

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (headache) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	69	72	69	67
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	640	640		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Headache

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.58

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	1.2

Statistical analysis title	TP: Headache

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1280
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.19

Statistical analysis title	TP: Headache

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.43
upper limit	1.59

Statistical analysis title	TP: Headache

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	0.95

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Nausea

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Nausea

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (nausea) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	72	73	70	69
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	688	686		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Nausea
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	2.11

Statistical analysis title	TP: Nausea
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	1.34

Statistical analysis title	TP: Nausea
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	2.79

Statistical analysis title	TP: Nausea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1374
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.32

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Vomiting

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Vomiting

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (vomiting) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	72	73	71	69
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	702	692		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Vomiting
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1394
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.25

Statistical analysis title	TP: Vomiting
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	140
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	15.99

Statistical analysis title	TP: Vomiting

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	9999

Statistical analysis title	TP: Vomiting

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates. A value of "999" indicates that the upper limit not reached as no events were recorded.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	141
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	15.54

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom -

Diarrhea

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Diarrhea

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (diarrhea) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	72	73	68	67
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	695	691		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Diarrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	139
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.49

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	3.83

Statistical analysis title	TP: Diarrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1386
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.1

Statistical analysis title	TP: Diarrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	135
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	3.93

Statistical analysis title	TP: Diarrhea

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo

Number of subjects included in analysis	140
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	3.05

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Loss of Taste

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Loss of Taste

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (loss of taste) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	38	56	48	37
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	461	433		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Loss of Taste
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	1.21

Statistical analysis title	TP: Loss of Taste
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	894
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.2

Statistical analysis title	TP: Loss of Taste
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	1.89

Statistical analysis title	TP: Loss of Taste

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	1.36

Secondary: Time to Progression of Each Targeted COVID-19 Sign/Symptom - Loss of Smell

End point title	Time to Progression of Each Targeted COVID-19 Sign/Symptom - Loss of Smell

End point description:

Time to progression (TP) of the targeted sign/symptom was defined as the number of days from randomization to the first of two consecutive days when the targeted sign/symptom was worsened. The median number of days from randomization to the first day on or before study Day 29 for progression/worsening is presented. Per protocol, all randomized participants who received at least one dose of study intervention and reported absent or non-severe symptoms for the targeted sign/symptom (loss of smell) at the time of randomization were analyzed. A value of "9999" indicates that the median time to progression and upper and lower limits not reached due to an insufficient number of participants with progression after randomization.

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	33	42	42	31
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	385	372		
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

Statistical analysis title	TP: Loss of Smell

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	1.33

Statistical analysis title	TP: Loss of Smell

Statistical analysis description:

Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo

Number of subjects included in analysis	757
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.04

Statistical analysis title	TP: Loss of Smell
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	1.48

Statistical analysis title	TP: Loss of Smell
Statistical analysis description:	
Hazard ratio and associated CIs were based on Cox regression model with Efron’s method of tie handling with treatment and randomization stratification factors as covariates.	
Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	2.15

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

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 who received at least one dose of study treatment and have data at the relevant time point were analyzed.

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	74	77	74	74
Units: Participants				
0 (n=72,75,73,70,695,684)	2	0	0	1
1 (n=72,75,73,70,695,684)	2	2	1	1
2 (n=72,75,73,70,695,684)	68	72	66	66
3 (n=72,75,73,70,695,684)	0	0	2	2
4 (n=72,75,73,70,695,684)	0	1	3	0
5 (n=72,75,73,70,695,684)	0	0	1	0
6 (n=72,75,73,70,695,684)	0	0	0	0
7 (n=72,75,73,70,695,684)	0	0	0	0
8 (n=72,75,73,70,695,684)	0	0	0	0
9 (n=72,75,73,70,695,684)	0	0	0	0
10 (n=72,75,73,70,695,684)	0	0	0	0
Missing (n=74,77,74,74,709,699)	2	2	1	4

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	709	699		
Units: Participants				
0 (n=72,75,73,70,695,684)	2	3		
1 (n=72,75,73,70,695,684)	11	13		
2 (n=72,75,73,70,695,684)	655	640		
3 (n=72,75,73,70,695,684)	13	10		
4 (n=72,75,73,70,695,684)	7	4		
5 (n=72,75,73,70,695,684)	4	13		
6 (n=72,75,73,70,695,684)	3	1		
7 (n=72,75,73,70,695,684)	0	0		
8 (n=72,75,73,70,695,684)	0	0		
9 (n=72,75,73,70,695,684)	0	0		
10 (n=72,75,73,70,695,684)	0	0		

Missing (n=74,77,74,74,709,699)	14	15		

Statistical analyses

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 3

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	3.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	15.59

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 3

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1408
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	2.3

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 3

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	1.44

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 3

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.29
upper limit	6.16

Secondary: Odds of a More Favorable Response on WHO 11-point Ordinal Outcomes Score on a Scale on End of Treatment (EOT [Day 5])

End point title	Odds of a More Favorable Response on WHO 11-point Ordinal Outcomes Score on a Scale on End of Treatment (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 who received at least one dose of study treatment and have data at the relevant time point were analyzed.

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	74	77	74	74
Units: Participants				
0 (n=70,75,71,70,697,684)	3	0	2	1
1 (n=70,75,71,70,697,684)	9	5	3	3
2 (n=70,75,71,70,697,684)	58	69	63	65
3 (n=70,75,71,70,697,684)	0	0	0	1
4 (n=70,75,71,70,697,684)	0	0	1	0
5 (n=70,75,71,70,697,684)	0	1	1	0
6 (n=70,75,71,70,697,684)	0	0	0	0
7 (n=70,75,71,70,697,684)	0	0	0	0
8 (n=70,75,71,70,697,684)	0	0	1	0
9 (n=70,75,71,70,697,684)	0	0	0	0
10 (n=70,75,71,70,697,684)	0	0	0	0
Missing (n=74,77,74,74,709,699)	4	2	3	4

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	709	699		
Units: Participants				
0 (n=70,75,71,70,697,684)	11	10		
1 (n=70,75,71,70,697,684)	36	34		
2 (n=70,75,71,70,697,684)	613	593		
3 (n=70,75,71,70,697,684)	14	9		
4 (n=70,75,71,70,697,684)	10	13		
5 (n=70,75,71,70,697,684)	7	21		
6 (n=70,75,71,70,697,684)	5	2		
7 (n=70,75,71,70,697,684)	0	1		
8 (n=70,75,71,70,697,684)	0	1		
9 (n=70,75,71,70,697,684)	1	0		
10 (n=70,75,71,70,697,684)	0	0		
Missing (n=74,77,74,74,709,699)	12	15		

Statistical analyses

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 5

Statistical analysis description:

Odds ratio was on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	3.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.14
upper limit	11.88

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 5

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1408
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	2.39

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 5

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	2.68

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 5

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	3.98

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

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 who received at least one dose of study treatment and have data at the relevant time point were analyzed.

End point type	Secondary

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	74	77	74	74
Units: Participants				
0 (n=70,73,69,69,673,673)	9	11	3	4
1 (n=70,73,69,69,673,673)	15	8	7	13
2 (n=70,73,69,69,673,673)	45	52	56	49
3 (n=70,73,69,69,673,673)	0	0	0	0
4 (n=70,73,69,69,673,673)	0	0	1	2
5 (n=70,73,69,69,673,673)	1	1	1	1
6 (n=70,73,69,69,673,673)	0	1	0	0
7 (n=70,73,69,69,673,673)	0	0	0	0
8 (n=70,73,69,69,673,673)	0	0	1	0
9 (n=70,73,69,69,673,673)	0	0	0	0
10 (n=70,73,69,69,673,673)	0	0	0	0
Missing (n=74,77,74,74,709,699)	4	4	5	5

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	709	699		
Units: Participants				
0 (n=70,73,69,69,673,673)	40	32		
1 (n=70,73,69,69,673,673)	68	81		
2 (n=70,73,69,69,673,673)	519	493		
3 (n=70,73,69,69,673,673)	12	6		
4 (n=70,73,69,69,673,673)	16	23		
5 (n=70,73,69,69,673,673)	11	21		
6 (n=70,73,69,69,673,673)	4	11		
7 (n=70,73,69,69,673,673)	1	2		
8 (n=70,73,69,69,673,673)	2	3		
9 (n=70,73,69,69,673,673)	0	1		
10 (n=70,73,69,69,673,673)	0	0		
Missing (n=74,77,74,74,709,699)	36	26		

Statistical analyses

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 10

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	3.45

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 10

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo

Number of subjects included in analysis	1408
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.14
upper limit	2.2

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 10

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.27
upper limit	1.29

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 10

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	2.33

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 who received at least one dose of study treatment and have data at the relevant time point were analyzed.

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	74	77	74	74
Units: Participants				
0 (n=72,73,70,69,669,667)	20	21	13	11
1 (n=72,73,70,69,669,667)	15	8	9	17
2 (n=72,73,70,69,669,667)	36	43	45	39
3 (n=72,73,70,69,669,667)	0	0	0	0
4 (n=72,73,70,69,669,667)	1	0	1	2
5 (n=72,73,70,69,669,667)	0	0	1	0
6 (n=72,73,70,69,669,667)	0	1	0	0
7 (n=72,73,70,69,669,667)	0	0	0	0
8 (n=72,73,70,69,669,667)	0	0	1	0
9 (n=72,73,70,69,669,667)	0	0	0	0
10 (n=72,73,70,69,669,667)	0	0	0	0
Missing (n=74,77,74,74,709,699)	2	4	4	5

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	709	699		
Units: Participants				
0 (n=72,73,70,69,669,667)	102	94		
1 (n=72,73,70,69,669,667)	110	92		
2 (n=72,73,70,69,669,667)	433	427		
3 (n=72,73,70,69,669,667)	5	6		
4 (n=72,73,70,69,669,667)	11	21		
5 (n=72,73,70,69,669,667)	4	12		
6 (n=72,73,70,69,669,667)	1	6		
7 (n=72,73,70,69,669,667)	1	2		
8 (n=72,73,70,69,669,667)	2	2		
9 (n=72,73,70,69,669,667)	0	0		

10 (n=72,73,70,69,669,667)	0	5		
Missing (n=74,77,74,74,709,699)	40	32		

Statistical analyses

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 15

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	2.73

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 15

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1408
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.03
upper limit	1.78

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 15

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	1.32

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 15

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.94

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

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 who received at least one dose of study treatment and have data at the relevant time point were analyzed.

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	74	77	74	74
Units: Participants				
0 (n=68,72,66,67,645,650)	35	40	39	36
1 (n=68,72,66,67,645,650)	14	13	10	16
2 (n=68,72,66,67,645,650)	19	19	15	14
3 (n=68,72,66,67,645,650)	0	0	0	0
4 (n=68,72,66,67,645,650)	0	0	2	1
5 (n=68,72,66,67,645,650)	0	0	0	0
6 (n=68,72,66,67,645,650)	0	0	0	0
7 (n=68,72,66,67,645,650)	0	0	0	0
8 (n=68,72,66,67,645,650)	0	0	0	0
9 (n=68,72,66,67,645,650)	0	0	0	0
10 (n=68,72,66,67,645,650)	0	0	0	0
Missing (n=74,77,74,74,709,699)	6	5	8	7

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	709	699		
Units: Participants				
0 (n=68,72,66,67,645,650)	312	314		
1 (n=68,72,66,67,645,650)	126	115		
2 (n=68,72,66,67,645,650)	197	198		
3 (n=68,72,66,67,645,650)	1	1		
4 (n=68,72,66,67,645,650)	4	10		
5 (n=68,72,66,67,645,650)	2	2		
6 (n=68,72,66,67,645,650)	0	0		
7 (n=68,72,66,67,645,650)	0	1		
8 (n=68,72,66,67,645,650)	2	0		
9 (n=68,72,66,67,645,650)	0	0		
10 (n=68,72,66,67,645,650)	1	9		
Missing (n=74,77,74,74,709,699)	64	49		

Statistical analyses

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 29

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 200 mg v Part 1: Placebo

Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	1.66

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 29

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1408
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.29

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 29

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 800 mg v Part 1: Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	1.81

Statistical analysis title	WHO 11-point Ordinal Outcomes Score: Day 29

Statistical analysis description:

Odds ratio was based on the proportional odds model with WHO-11 score categories as the response variable. Due to sparse data, the final model includes only treatment as covariate. CIs are based on Wald Chi-Square Test.

Comparison groups	Part 1: Molnupiravir 400 mg v Part 1: Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	1.79

Post-hoc: Percentage of Participants Who Were Hospitalized and/or Died Through Day 29

End point title	Percentage of Participants Who Were Hospitalized and/or Died Through Day 29[3]

End point description:

The percentage of participants who were hospitalized and/or died through Day 29 is presented. Hospitalization (all cause) is defined as at least 24 hours of acute care in a hospital or similar acute care facility. Death was due to any cause. Any participants with an unknown survival status at Day 29 were treated as failure. This analysis was based on all randomized participants in Part 2 who received at least one dose of study treatment, were not hospitalized prior to the administration of the first dose of study intervention, and had reached Day 29 post treatment. All randomized participants in Part 2 who received at least one dose of study intervention and were not hospitalized prior to the administration of the first dose of study intervention were analyzed.

End point type	Post-hoc

End point timeframe:

Up to 29 days

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only applicable to Part 2 of the study.

End point values	Part 2: Molnupiravir 800 mg	Part 2: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	709	699		
Units: Percentage of Participants				
number (not applicable)	6.8	9.7		

Statistical analyses

Statistical analysis title	Number of Participants Who Were Hospitalized/Died

Statistical analysis description:

Difference in rates % and associated CIs were based on the Miettinen & Nurminen method stratified by randomization strata. Unknown survival status at Day 29 was treated as failure.

Comparison groups	Part 2: Molnupiravir 800 mg v Part 2: Placebo
Number of subjects included in analysis	1408
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Rates %
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	-0.1

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to 318 days	
Adverse event reporting additional description:	
The analysis population for All-Cause Mortality included all randomized participants. The safety analysis population included all randomized participants who received at least one dose of study treatment.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.0

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 title	Part 2: Molnupiravir 800 mg
Reporting group description:	
800 mg molnupiravir administered orally every 12 hours for 5 days (10 doses total)	
Reporting group title	Part 2: Placebo
Reporting group description:	
Placebo matching molnupiravir administered orally every 12 hours for 5 days (10 doses total)	

Serious adverse events	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 74 (1.35%)	3 / 77 (3.90%)	4 / 74 (5.41%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to lung			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Shock			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Peripheral vascular disorder			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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			
Oedema peripheral			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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			
Pancreatitis			

subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Cough			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Dyspnoea			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Hiccups			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Hypoxia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Pneumomediastinum			

subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Pneumothorax			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Pulmonary embolism			
subjects affected / exposed	0 / 74 (0.00%)	1 / 77 (1.30%)	0 / 74 (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
Pulmonary hypertension			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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 distress			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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			
Anal abscess			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
COVID-19			

subjects affected / exposed	0 / 74 (0.00%)	1 / 77 (1.30%)	2 / 74 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 74 (1.35%)	2 / 77 (2.60%)	2 / 74 (2.70%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Peritonsillitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	1 / 74 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Septic shock			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			

subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 74 (0.00%)	0 / 77 (0.00%)	0 / 74 (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: Placebo	Part 2: Molnupiravir 800 mg	Part 2: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 74 (6.76%)	51 / 710 (7.18%)	67 / 701 (9.56%)
number of deaths (all causes)	1	4	16
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to lung			

subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Shock			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
Peripheral vascular disorder			
subjects affected / exposed	1 / 74 (1.35%)	0 / 710 (0.00%)	0 / 701 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
General disorders and administration site conditions			
Oedema peripheral			

subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
Gastrointestinal disorders			
Pancreatitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
Thrombosis mesenteric vessel			
subjects affected / exposed	1 / 74 (1.35%)	0 / 710 (0.00%)	0 / 701 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	2 / 701 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cough			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiccups			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypoxia			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
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	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
Pulmonary embolism			
subjects affected / exposed	1 / 74 (1.35%)	1 / 710 (0.14%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 74 (0.00%)	6 / 710 (0.85%)	9 / 701 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Anal abscess			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
COVID-19			
subjects affected / exposed	1 / 74 (1.35%)	37 / 710 (5.21%)	53 / 701 (7.56%)
occurrences causally related to treatment / all	0 / 1	0 / 37	0 / 53
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 9
COVID-19 pneumonia			
subjects affected / exposed	2 / 74 (2.70%)	29 / 710 (4.08%)	43 / 701 (6.13%)
occurrences causally related to treatment / all	0 / 2	0 / 29	0 / 43
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 5
Lung abscess			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
Peritonsillitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 74 (0.00%)	2 / 710 (0.28%)	0 / 701 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	0 / 701 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
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 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia haemophilus			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 74 (0.00%)	3 / 710 (0.42%)	2 / 701 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 710 (0.14%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	1 / 74 (1.35%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 74 (0.00%)	0 / 710 (0.00%)	1 / 701 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Part 1: Molnupiravir 200 mg	Part 1: Molnupiravir 400 mg	Part 1: Molnupiravir 800 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 74 (8.11%)	4 / 77 (5.19%)	5 / 74 (6.76%)
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 74 (4.05%)	2 / 77 (2.60%)	2 / 74 (2.70%)
occurrences (all)	3	2	2
Infections and infestations			
COVID-19			
subjects affected / exposed	3 / 74 (4.05%)	2 / 77 (2.60%)	3 / 74 (4.05%)
occurrences (all)	3	2	3

Non-serious adverse events	Part 1: Placebo	Part 2: Molnupiravir 800 mg	Part 2: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 74 (12.16%)	38 / 710 (5.35%)	38 / 701 (5.42%)
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 74 (5.41%)	16 / 710 (2.25%)	21 / 701 (3.00%)
occurrences (all)	5	17	22
Infections and infestations			
COVID-19			
subjects affected / exposed	5 / 74 (6.76%)	23 / 710 (3.24%)	17 / 701 (2.43%)
occurrences (all)	5	24	17

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 January 2021	AM1: To revise the dose selection process before initiation of Part 2 (Phase 3), update the benefit/risk assessment, clarify the key secondary efficacy objective regarding COVID-19 signs/symptoms, and add a discontinuation criterion.
27 April 2021	AM2: To provide the selected dose and the dose selection rationale for Part 2 (Phase 3) of the study, revise female and male contraception requirements, update the stratification factors, revise entry criteria, and increase the sample size for Part 2 (Phase 3).
17 July 2021	AM3: To clarify that participants can only enroll in this study if they have chosen not to receive a SARS-CoV-2 monoclonal antibody(ies) or SARS-CoV-2 monoclonal antibodies have not been authorized or approved in their country, update the benefit/risk assessment, add new subgroup analyses, and add a description of an unblinded team in the case of a positive efficacy finding noted by the eDMC at interim analysis (IA) 4.
24 August 2021	AM4: To remove the enrollment target of ~50% of Part 2 participants who are >60 years of age and to add a new exploratory objective for detection of infectious virus from nasopharyngeal (NP) swabs.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
02 October 2021	At the recommendation of an independent Data Monitoring Committee and in consultation with the U.S. Food and Drug Administration (FDA), recruitment into the study was stopped early at a planned IA.	-

Notes:

Limitations and caveats

None reported