Clinical trial results:
A Randomized, Double-blind, Placebo-controlled, Multicenter, Proof-of-Concept, Phase IIa Study of MP1032 Plus Standard of Care vs Standard of Care in the Treatment of Hospitalized Patients With Moderate to Severe COVID-19

Summary

EudraCT number	2021-000344-21
Trial protocol	FR HU ES BG IT RO
Global end of trial date	05 September 2022

Results information

Result version number	v1 (current)
This version publication date	10 May 2023
First version publication date	10 May 2023

Trial information

Trial identification

Sponsor protocol code	MP1032-CT05

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04932941
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MetrioPharm AG
Sponsor organisation address	Europaallee 41, Zurich, Switzerland, 8004
Public contact	Clinical Trials Group, MetrioPharm Deutschland GmbH, +49 30 338439502, info@metriopharm.com
Scientific contact	Clinical Trials Group, MetrioPharm Deutschland GmbH, +49 30 338439502, info@metriopharm.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 September 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 September 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to measure the effect of MP1032 plus standard of care (SoC) versus placebo plus SoC on Day 14 on disease progression in patients with moderate to severe coronavirus disease 2019 (COVID-19).

Protection of trial subjects:

This study was conducted in accordance with the accepted version of the Declaration of Helsinki and/or all relevant federal regulations as set forth in Parts 50, 56, 312, Subpart D, of Title 21 of the US Code of Federal Regulations; EU 536/2014, Annex 1, D, 17 (a); in compliance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use good clinical practice (GCP) guidelines, and according to the appropriate regulatory requirements in the countries where the study was conducted. An independent data monitoring committee (IDMC) was established which reviewed unblinded data on a regular basis and gave recommendations on the study continuation. In addition, criteria that might have warranted the discontinuation of an individual subject from study or even the termination of the whole study were in place.

Background therapy:

All subjects received standard of care.

Evidence for comparator: -

Actual start date of recruitment	19 October 2021
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	Romania: 39
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	Bulgaria: 57
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Hungary: 24
Country: Number of subjects enrolled	Italy: 2
Worldwide total number of subjects	132
EEA total number of subjects	132

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)	70
From 65 to 84 years	61
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 20 sites in 6 countries from 19 October 2021 to 05 September 2022. Subjects were randomized in the 2:1 ratio to treatment groups using an Interactive Web Response System (IWRS).

Pre-assignment

Screening details:

A total of 134 subjects were screened, of which 132 subjects were randomized to either the MP1032 plus standard of care (SoC) or the placebo plus SoC group.

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, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	MP1032 300 mg + SoC

Arm description:

Subjects received MP1032, 300 milligrams (mg) hard gelatin capsules orally, twice daily (BID) with hospital selected SoC procedure for 28 days.

Arm type	Experimental
Investigational medicinal product name	MP1032
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects received MP1032 300 mg hard gelatin capsules orally.

Arm title	Placebo + SoC

Arm description:

Subjects received placebo matched to MP1032 hard gelatin capsules orally, BID with hospital selected SoC procedure for 28 days.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo, matched to MP1032 hard gelatin capsules orally.

Number of subjects in period 1	MP1032 300 mg + SoC	Placebo + SoC
Started	87	45
Completed	73	38
Not completed	14	7
Consent withdrawn by subject	7	4
Unspecified	4	2
Lost to follow-up	3	1

Baseline characteristics

Reporting groups	
Reporting group title	MP1032 300 mg + SoC
Reporting group description:	
Subjects received MP1032, 300 milligrams (mg) hard gelatin capsules orally, twice daily (BID) with hospital selected SoC procedure for 28 days.	
Reporting group title	Placebo + SoC
Reporting group description:	
Subjects received placebo matched to MP1032 hard gelatin capsules orally, BID with hospital selected SoC procedure for 28 days.	

Reporting group values	MP1032 300 mg + SoC	Placebo + SoC	Total
Number of subjects	87	45	132
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	59.6	62.3	
standard deviation	± 13.83	± 14.15	-
Gender categorical Units: Subjects			
Female	36	19	55
Male	51	26	77
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	1	6
Not Hispanic or Latino	79	44	123
Unknown or Not Reported	3	0	3
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	87	45	132

End points

End points reporting groups

Reporting group title	MP1032 300 mg + SoC
Reporting group description:	
Subjects received MP1032, 300 milligrams (mg) hard gelatin capsules orally, twice daily (BID) with hospital selected SoC procedure for 28 days.	
Reporting group title	Placebo + SoC
Reporting group description:	
Subjects received placebo matched to MP1032 hard gelatin capsules orally, BID with hospital selected SoC procedure for 28 days.	

Primary: Percentage of Subjects With Disease Progression Using National Institute of Allergy and Infectious Diseases (NIAID) 8-point Ordinal Scale at Day 14

End point title	Percentage of Subjects With Disease Progression Using National Institute of Allergy and Infectious Diseases (NIAID) 8-point Ordinal Scale at Day 14
End point description:	
Disease progression was defined as the percentage of subjects who were not alive or who had respiratory failure (RF). RF was defined as subjects who had a score of 2, 3 or 4 on the NIAID 8-point ordinal scale: NIAID scale is an assessment of clinical status on a given study day and was defined as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or ECMO; 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care; 6) Hospitalized, not requiring supplemental oxygen-no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities. Total score range was 1 to 8 where, higher score=improvement in clinical status. Intention-to-Treat (ITT) Population. "Number of subjects analysed" signifies who were evaluable for this endpoint.	
End point type	Primary
End point timeframe:	
At Day 14	

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	43		
Units: Percentage of subjects				
number (confidence interval 95%)	9.8 (4.307 to 18.321)	11.6 (3.885 to 25.083)		

Statistical analyses

Statistical analysis title	MP1032 300 mg + SoC Versus Placebo + SoC
Comparison groups	MP1032 300 mg + SoC v Placebo + SoC

Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.962
Method	Mantel-Haenszel
Parameter estimate	Common risk difference
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.634
upper limit	11.081

Secondary: Percentage of Subjects With Disease Progression Using NIAID 8-point Ordinal Scale at Day 28

End point title	Percentage of Subjects With Disease Progression Using NIAID 8-point Ordinal Scale at Day 28

End point description:

Disease progression was defined as the percentage of subjects who were not alive or who had RF. RF was defined as subjects who had a score of 2, 3 or 4 on the NIAID 8-point ordinal scale: NIAID scale is an assessment of clinical status on a given study day and was defined as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or ECMO; 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care; 6) Hospitalized, not requiring supplemental oxygen-no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities. Total score range was 1 to 8 where, higher score indicates improvement in clinical status. ITT Population. Here "number of subjects analysed" signifies subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At Day 28

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	41		
Units: Percentage of subjects				
number (confidence interval 95%)	2.5 (0.308 to 8.848)	2.4 (0.062 to 12.855)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Disease Resolution at Day 28

End point title	Percentage of Subjects With Disease Resolution at Day 28

End point description:

Disease resolution was defined as participants who were alive and had a score of 6, 7, or 8 on the NIAID 8-point ordinal scale. The NIAID scale is an assessment of clinical status on a given study day and was

defined as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or ECMO; 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise); 6) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities. The total score range was 1 to 8 where, higher score indicates improvement in the clinical status. Intention-to-Treat (ITT) Population. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At Day 28

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	41		
Units: Percentage of subjects				
number (confidence interval 95%)	97.5 (91.152 to 99.692)	97.6 (87.145 to 99.938)		

Statistical analyses

No statistical analyses for this end point

Secondary: All-cause Mortality Rate up to Day 28

End point title	All-cause Mortality Rate up to Day 28

End point description:

All-cause Mortality Rate was the percentage of subjects in each treatment group who died at Day 28. The ITT Set corresponded with the randomized set and included all randomized subjects, irrespective of any deviation from the protocol or premature discontinuation from the study drug or withdrawal from study. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Up to Day 28

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	42		
Units: Percentage of participants				
number (confidence interval 95%)	2.4 (0.297 to 8.534)	2.4 (0.060 to 12.566)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Status Score Related to COVID-19 According to the NIAID 8-point Ordinal Scale at Day 28

End point title	Change From Baseline in Clinical Status Score Related to COVID-19 According to the NIAID 8-point Ordinal Scale at Day 28

End point description:

The NIAID 8-point Ordinal Scale is an assessment of the clinical status on a given study day and the scale was defined as follows: 1=Death, 2=Hospitalized, on invasive ventilation (mechanical ventilator and/or ECMO), 3=Hospitalized, on non-invasive ventilation or high-flow oxygen devices, 4=Hospitalized, requiring supplemental oxygen, 5=Hospitalized, not requiring supplemental oxygen, but requiring ongoing medical care (COVID-19 related or otherwise), 6=Hospitalized, not requiring supplemental oxygen and no longer requires ongoing medical care (used if hospitalization was extended for infection-control reasons), 7=Not hospitalized, limitation on activities, and/or requiring home oxygen, 8=Not hospitalized, no limitations on activities. The total score range was 1 to 8 where, higher score indicates improvement in the clinical status. The change from baseline in NIAID clinical status score related to COVID-19 at Day 28 were reported. ITT Population.

End point type	Secondary

End point timeframe:

Baseline, Day 28

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	45		
Units: Score on a scale				
least squares mean (standard error)	3.542 (± 0.130)	3.612 (± 0.174)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Disease Resolution at Day 14

End point title	Percentage of Subjects With Disease Resolution at Day 14

End point description:

Disease resolution was defined as participants who were alive and had a score of 6, 7, or 8 on the NIAID 8-point ordinal scale. The NIAID scale is an assessment of clinical status on a given study day and was defined as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or ECMO; 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise); 6) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities. The total score range was 1 to 8 where, higher score indicates improvement in the clinical status. ITT Population.

End point type	Secondary

End point timeframe:

At Day 14

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	43		
Units: Percentage of subjects				
number (confidence interval 95%)	84.1 (74.417 to 91.280)	72.1 (56.331 to 84.671)		

Statistical analyses

No statistical analyses for this end point

Secondary: All-cause Mortality Rate up to Day 14 and Day 60

End point title	All-cause Mortality Rate up to Day 14 and Day 60

End point description:

The percentage of subjects who died by Day 14 and Day 60 were reported. The ITT Set corresponded with the randomized set and included all randomized participants, irrespective of any deviation from the protocol or premature discontinuation from the study drug or withdrawal from study. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint and, "n" signifies subjects who were evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Up to Day 14 and Day 60

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	43		
Units: Percentage of participants				
number (confidence interval 95%)				
Day 14 (n=83,43)	1.2 (0.030 to 6.531)	2.3 (0.059 to 12.289)		
Day 60 (n=80,41)	3.8 (0.780 to 10.570)	4.9 (0.596 to 16.533)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Status Score Related to COVID-19 According to the NIAID 8-point Ordinal Scale at Day 14

End point title	Change From Baseline in Clinical Status Score Related to COVID-19 According to the NIAID 8-point Ordinal Scale at Day

	14

End point description:

The NIAID scale is an assessment of clinical status on a given study day and was defined as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or ECMO; 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care; 6) Hospitalized, not requiring supplemental oxygen-no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities. Here, higher score indicates improvement in clinical status. The change from baseline in NIAID clinical status score by Visit Days were reported. ITT Population. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Day 14

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	43		
Units: Score on a scale				
least squares mean (standard error)	2.987 (± 0.174)	2.543 (± 0.242)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Required Invasive Ventilation (Mechanical Ventilator and/ ECMO), or Who Died at Day 14 and Day 28

End point title	Percentage of Subjects Who Required Invasive Ventilation (Mechanical Ventilator and/ ECMO), or Who Died at Day 14 and Day 28

End point description:

Percentage of subjects who required invasive mechanical ventilation/ECMO or who died by Day 14 and Day 28 were reported. The ITT Set corresponded with the randomized set and included all randomized subjects, irrespective of any deviation from the protocol or premature discontinuation from the study drug or withdrawal from study. Here, "number of subjects analyzed" signifies subjects who were evaluable for this endpoint and "n" signifies to number of subjects who were evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

At Day 14 and Day 28

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	43		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 14 (n=82,43)	1.2 (0.031 to 6.608)	2.3 (0.059 to 12.289)		
Day 28 (n=79,41)	2.5 (0.308 to 8.848)	2.4 (0.062 to 12.855)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Status Score of the NIAID 8-point Ordinal Scale at Each Visit

End point title	Change From Baseline in Clinical Status Score of the NIAID 8-point Ordinal Scale at Each Visit

End point description:

The NIAID scale is an assessment of clinical status on a given study day and was defined as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or ECMO; 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise); 6) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities. The total score range was 1 to 8 where, higher score indicates improvement in the clinical status. ITT Population. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint and "n" signifies number of subjects who were evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline up to Day 60

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	86	44		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Day 2 (n=86,44)	0.1 (± 0.42)	0.0 (± 0.21)		
Day 3 (n=85,44)	0.2 (± 0.73)	0.1 (± 0.46)		
Day 4 (n=85,44)	0.2 (± 0.83)	0.2 (± 0.53)		
Day 5 (n=84,44)	0.4 (± 0.88)	0.3 (± 0.70)		
Day 6 (n=81,44)	0.6 (± 1.01)	0.4 (± 0.76)		
Day 7 (n=83,43)	1.2 (± 1.44)	1.0 (± 1.34)		
Day 8 (n=76,43)	1.6 (± 1.60)	1.6 (± 1.75)		
Day 9 (n=75,39)	2.0 (± 1.70)	1.7 (± 1.77)		
Day 10 (n=74,38)	2.2 (± 1.69)	1.7 (± 1.83)		
Day 11 (n=73,38)	2.3 (± 1.65)	1.9 (± 1.82)		
Day 12 (n=70,37)	2.5 (± 1.66)	1.9 (± 1.82)		

Day 13 (n=68,34)	2.7 (± 1.64)	2.2 (± 1.71)		
Day 14 (n=82,43)	3.0 (± 1.47)	2.6 (± 1.72)		
Day 28 (n=78,40)	3.7 (± 0.89)	3.7 (± 0.51)		
Day 60 (n=74,38)	3.7 (± 1.01)	3.8 (± 0.49)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to (First) Improvement of at Least 1 Category on the NIAID 8-point Ordinal Scale

End point title	Time to (First) Improvement of at Least 1 Category on the NIAID 8-point Ordinal Scale

End point description:

The NIAID scale is an assessment of clinical status on a given study day and is defined as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or ECMO; 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care; 6) Hospitalized, not requiring supplemental oxygen-no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities. Subjects who did not improve at least 1 category on the NIAID scale or died before Day 28 were censored at Day 28. The total score range was 1 to 8 where, higher score indicates improvement in the clinical status. ITT Population. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline up to Day 28

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	81	40		
Units: Days				
median (confidence interval 95%)	7 (7.000 to 8.000)	7 (6.000 to 8.000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Odds Ratio for Subjects With Clinical Status Improvement From Baseline on the NIAID 8-point Ordinal Scale at Day 14 and Day 28

End point title	Odds Ratio for Subjects With Clinical Status Improvement From Baseline on the NIAID 8-point Ordinal Scale at Day 14 and Day 28

End point description:

The NIAID scale is an assessment of clinical status on a given study day and is defined as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or ECMO; 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care; 6) Hospitalized, not requiring

supplemental oxygen-no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities. Higher score = improvement in clinical status. The odds ratio at Day 14 and Day 28 was analyzed using a logistic regression with consideration of the 2 stratification factors. ITT Population. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint and and "n" signifies subjects who were evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Day 14 and Day 28

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	43		
Units: Odds Ratio				
number (not applicable)				
Day 14 (n=82,43)	1.476	1.0		
Day 28 (n=78,40)	0.000	1.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Discharge by Day 28 and Day 60

End point title	Time to Discharge by Day 28 and Day 60

End point description:

Time to discharge i.e., the total duration of subject hospitalization from baseline to discharge at Day 28 and Day 60 was reported. ITT Population. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint and "n" signifies number of subjects evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Day 28 and Day 60

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	83	42		
Units: Days				
median (confidence interval 95%)				
Day 28 (n=82,41)	9 (8.000 to 10.000)	10 (8.000 to 13.000)		
Day 60 (n=83,42)	9 (8.000 to 10.000)	10 (8.000 to 13.000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Were Alive and Tested Negative for COVID-19 at Day 14, Day 28, and Day 60

End point title	Percentage of Subjects Who Were Alive and Tested Negative for COVID-19 at Day 14, Day 28, and Day 60

End point description:

Percentage of subjects who are alive and tested negative for COVID-19 at Day 14, Day 28, and Day 60 were reported. ITT Population. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint and "n" signifies number of subjects evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

At Day 14, Day 28 and Day 60

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	76	39		
Units: Percentage of subjects				
number (confidence interval 95%)				
Day 14 (n=76,39)	67.1 (55.374 to 77.457)	66.7 (49.783 to 80.912)		
Day 28 (n=69,38)	91.3 (82.028 to 96.742)	92.1 (78.623 to 98.341)		
Day 60 (n=67,31)	95.5 (87.467 to 99.067)	93.5 (78.578 to 99.209)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs) and Serious TEAEs

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs) and Serious TEAEs

End point description:

An Adverse Event (AE) was any symptom, physical sign, syndrome, or disease that either emerges during the study or, if present at screening, worsens during the study, regardless of the suspected cause of the event. TEAE was defined as any adverse event which starts or worsens at any time after initiation of study drug until the end of the follow-up period at Day 60. An SAE was any untoward medical occurrence that at any dose met one, more of the following criteria: results in death, life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent, significant disability/incapacity, a congenital abnormality/birth defect, an important medical event. Number of participants with TEAEs and Serious TEAEs were reported. The Safety Set included all randomized participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Day 1 up to Day 60

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	86	45		
Units: Subjects				
Subjects with TEAEs	46	26		
Subjects with Serious TEAEs	5	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Change in Vital Sign

End point title	Number of Subjects With Clinically Significant Change in Vital Sign

End point description:

Vital sign parameters included of systolic and diastolic blood pressure, heart rate, respiration rate, oxygen saturation (SpO2), and body temperature. Any clinically significant change in vital signs were judged by the investigator. Number of subjects with clinically significant change in vital sign values were reported. The Safety Set included all randomized subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Day 1 up to Day 60

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	86	45		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Abnormalities in Physical Examinations

End point title	Number of Subjects With Clinically Significant Abnormalities in Physical Examinations

End point description:

Physical examination included examination of Body System (BS) which included respiratory, cardiovascular, dermatological, neurological, and gastrointestinal system. Any clinically significant abnormalities in physical examination were judged by the investigator. Number of subjects with clinically significant abnormalities in physical examinations findings were reported. The Safety Set included all

randomized subjects who received at least 1 dose of study drug. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint and "n" signifies subjects who were evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Day 1 up to Day 60

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	86	45		
Units: Subjects				
BS: Abdomen-Baseline(n=86,45)	0	1		
BS: Abdomen-Day 8(n=6,3)	0	1		
BS: Cardiovascular-Baseline(n=86,45)	4	2		
BS: Cardiovascular-Day 8(n=5,4)	0	1		
BS: Cardiovascular-Day 14(n=6,2)	2	0		
BS: Head,Eyes,Ears,Nose,Throat-Baseline(n=86,45)	8	7		
BS: Head,Eyes,Ears,Nose,Throat-Day 8(n=21,9)	0	2		
BS: Head,Eyes,Ears,Nose,Throat-Day 14(n=10,7)	0	2		
BS: Neurologic-Baseline(n=85,45)	0	1		
BS: Neurologic-Day 14(n=3,1)	0	1		
BS: Other-Baseline(n=16,8)	14	8		
BS: Other-Day 8(n=8,7)	1	2		
BS: Other-Day 14(n=7,4)	0	1		
BS: Respiratory-Baseline(n=86,45)	38	22		
BS: Respiratory-Day 8(n=45,22)	4	2		
BS: Respiratory-Day 14(n=28,11)	0	1		
BS: Dermatologic-Baseline(n=85,45)	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Abnormalities in Clinical Laboratory Results

End point title	Number of Subjects With Clinically Significant Abnormalities in Clinical Laboratory Results

End point description:

Clinical laboratory tests included biochemistry, hematology and urinalysis. Any clinically significant abnormalities in clinical laboratory results were judged by the investigator. Number of subjects with clinically significant abnormalities in laboratory results were reported. The Safety Set included all randomized participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Day 1 up to Day 60

End point values	MP1032 300 mg + SoC	Placebo + SoC		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	86	45		
Units: Subjects	23	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) of MP1032

End point title	Maximum Observed Plasma Concentration (Cmax) of MP1032[1]

End point description:

Cmax of MP1032 in plasma were reported. Geometric mean and geometric coefficient of variation percent (CV%) was reported. The Pharmacokinetic (PK) Analysis Set included all the subjects who were administered active study drug and had at least 1 post-dose evaluable plasma concentration after Day 1 dose. Here, "n" signifies subjects who were evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Pre-dose, 0.16, 0.33, 0.5, 1, 2, 8 and 24 hours post-dose at Day 1 and Day 7

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Pharmacokinetic Parameters were planned to be analysed for the test arm (subjects who received active study drug) only.

End point values	MP1032 300 mg + SoC			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: nanogram per milliliter (ng/ml)				
geometric mean (geometric coefficient of variation)				
Day 1 (n=4)	284.15 (± 170.38)			
Day 7 (n=3)	279.29 (± 37.85)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve From Time Zero to Last Non-zero Concentration (AUC0-t) of MP1032

End point title	Area Under the Plasma Concentration-time Curve From Time Zero to Last Non-zero Concentration (AUC0-t) of MP1032[2]

End point description:

AUC0-t of MP1032 in plasma were reported. Geometric mean and geometric coefficient of variation percent (CV%) was reported. The PK Analysis Set included all the subjects who were administered active study drug and had at least 1 post-dose evaluable plasma concentration after Day 1 dose. Here, "n" signifies subjects who were evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Pre-dose, 0.16, 0.33, 0.5, 1, 2, 8 and 24 hours post-dose at Day 1 and Day 7

Notes:

[2] - 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: Pharmacokinetic Parameters were planned to be analysed for the test arm (subjects who received active study drug) only.

End point values	MP1032 300 mg + SoC			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: hour per nanogram per milliliter				
geometric mean (geometric coefficient of variation)				
Day 1 (n=4) Day 7 (n=3)	350.40 (± 42.87) 251.24 (± 28.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Elimination Rate Constant (Kel) of MP1032

End point title	Apparent Elimination Rate Constant (Kel) of MP1032[3]

End point description:

Kel was calculated using negative of the estimated slope of the linear regression of the ln-transformed plasma concentration versus time profile in the terminal elimination phase. Kel of MP1032 in plasma were reported. The PK Analysis Set included all the subjects who were administered active study drug and had at least 1 post-dose evaluable plasma concentration after Day 1 dose.

End point type	Secondary

End point timeframe:

Pre-dose, 0.16, 0.33, 0.5, 1, 2, 8 and 24 hours post-dose at Day 1

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: Pharmacokinetic Parameters were planned to be analysed for the test arm (subjects who received active study drug) only.

End point values	MP1032 300 mg + SoC			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: per hour				
arithmetic mean (standard deviation)	0.7162 (± 0.8851)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Body Clearance (CL/F) of MP1032

End point title	Apparent Body Clearance (CL/F) of MP1032[4]

End point description:

Cl/F was estimated as Dose/AUC0-inf. CL/F of MP1032 in plasma was reported. The PK Analysis Set included all the subjects who were administered active study drug and had at least 1 post-dose evaluable plasma concentration after Day 1 dose. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Pre-dose, 0.16, 0.33, 0.5, 1, 2, 8 and 24 hours post-dose at Day 1

Notes:

[4] - 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: Pharmacokinetic Parameters were planned to be analysed for the test arm (subjects who received active study drug) only.

End point values	MP1032 300 mg + SoC			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: liter per hour				
geometric mean (geometric coefficient of variation)	625.05 (± 26.09)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Volume of Distribution (Vz/F) of MP1032

End point title	Apparent Volume of Distribution (Vz/F) of MP1032[5]

End point description:

Vz/F was estimated as Dose/(Kel x AUC0-inf). Vz/F of MP1032 in plasma was reported. The PK Analysis Set included all the subjects who were administered active study drug and had at least 1 post-dose evaluable plasma concentration after Day 1 dose. Here, "number of subjects analysed" signifies subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Pre-dose, 0.16, 0.33, 0.5, 1, 2, 8 and 24 hours post-dose at Day 1

Notes:

[5] - 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: Pharmacokinetic Parameters were planned to be analysed for the test arm (subjects who received active study drug) only.

End point values	MP1032 300 mg + SoC			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Liter				
geometric mean (geometric coefficient of variation)	1494.56 (± 130.81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration Prior to the Next Dose (Ctrough) of MP1032

End point title	Plasma Concentration Prior to the Next Dose (Ctrough) of MP1032[6]

End point description:

Ctrough of MP1032 in plasma was reported. The PK Analysis Set included all the subjects who were administered active study drug and had at least 1 post-dose evaluable plasma concentration after Day 1 dose. Here, "n" signifies subjects who were evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Pre-dose concentration (Day 2, Day 7, and Day 8)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic Parameters were planned to be analysed for the test arm (subjects who received active study drug) only.

End point values	MP1032 300 mg + SoC			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: ng/ml				
arithmetic mean (standard deviation)				
Day 2 (n=4)	9.74 (± 11.27)			
Day 7 (n=4)	60.79 (± 121.59)			
Day 8 (n=3)	66.67 (± 115.48)			

Statistical analyses

No statistical analyses for this end point

Secondary: Average Observed Plasma Concentration at Steady State of MP1032

End point title	Average Observed Plasma Concentration at Steady State of MP1032[7]

End point description:

Average observed plasma concentration at steady state of MP1032 was reported. The PK Analysis Set included all the subjects who were administered active study drug and had at least 1 post-dose evaluable plasma concentration after Day 1 dose. Here, "n" signifies subjects who were evaluable at

specified timepoints and '99999' indicates that at 8 hours geomean and CV% data was not estimated due to below limit of quantification (BLOQ).

End point type	Secondary

End point timeframe:

Pre-dose, 0.16, 0.33, 0.5, 1, 2, 8 and 24 hours post-dose at Day 1 and Day 7

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Pharmacokinetic Parameters were planned to be analysed for the test arm (subjects who received active study drug) only.

End point values	MP1032 300 mg + SoC			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: ng/ml				
geometric mean (geometric coefficient of variation)				
Day 1: pre-dose (n=4)	0 (± 0)			
Day 1: 0.16 hours post-dose (n=4)	175.7 (± 322.8)			
Day 1: 0.33 hours post-dose (n=4)	200.1 (± 84.6)			
Day 1: 0.5 hours post-dose (n=4)	140.4 (± 55.3)			
Day 1: 1 hour post-dose (n=4)	64.39 (± 34.5)			
Day 1: 2 hours post-dose (n=4)	28.55 (± 145.5)			
Day 1: 8 hours post-dose (n=4)	15.48 (± 29.7)			
Day 1: 24 hours post-dose (n=4)	19.45 (± 7.5)			
Day 7: pre-dose (n=4)	243.2 (± 0)			
Day 7: 0.16 hours post-dose (n=3)	187.3 (± 53.3)			
Day 7: 0.33 hours post-dose (n=3)	281.5 (± 55.4)			
Day 7: 0.5 hours post-dose (n=3)	178.8 (± 41.1)			
Day 7: 1 hour post-dose (n=3)	94.42 (± 117.8)			
Day 7: 2 hours post-dose (n=3)	79.55 (± 155.0)			
Day 7: 8 hours post-dose (n=3)	99999 (± 99999)			
Day 7: 24 hours post-dose (n=3)	200.0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Baseline up to Day 60	
Adverse event reporting additional description:	
Reported adverse events (AEs) are treatment-emergent AEs that developed, worsened, or became serious during the treatment period (time from the first dose of study treatments up to 60 days). Serious and Other AEs were collected for safety population.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups	
Reporting group title	MP1032 300 mg + SoC
Reporting group description:	
Subjects received MP1032 300 mg hard gelatin capsules orally, BID with hospital selected SoC procedure for 28 days.	
Reporting group title	Placebo + SoC
Reporting group description:	
Subjects received placebo matched to MP1032 hard gelatin capsules orally, BID with hospital selected SoC procedure for 28 days.	

Serious adverse events	MP1032 300 mg + SoC	Placebo + SoC	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 86 (5.81%)	3 / 45 (6.67%)	
number of deaths (all causes)	3	2	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			

subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	3 / 86 (3.49%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 86 (0.00%)	2 / 45 (4.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	MP1032 300 mg + SoC	Placebo + SoC	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	46 / 86 (53.49%)	26 / 45 (57.78%)	
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	1 / 86 (1.16%)	1 / 45 (2.22%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Chest discomfort			

subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Chest pain			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	2 / 86 (2.33%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	2 / 86 (2.33%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Dyspnoea			
subjects affected / exposed	1 / 86 (1.16%)	1 / 45 (2.22%)	
occurrences (all)	1	1	
Epistaxis			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Respiratory failure			
subjects affected / exposed	2 / 86 (2.33%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Psychiatric disorders			
Emotional disorder			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Investigations			
Activated partial thromboplastin time shortened			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	

Alanine aminotransferase increased				
subjects affected / exposed	7 / 86 (8.14%)	6 / 45 (13.33%)		
occurrences (all)	7	6		
Aspartate aminotransferase increased				
subjects affected / exposed	2 / 86 (2.33%)	2 / 45 (4.44%)		
occurrences (all)	2	2		
Blood alkaline phosphatase increased				
subjects affected / exposed	2 / 86 (2.33%)	0 / 45 (0.00%)		
occurrences (all)	2	0		
Blood bilirubin increased				
subjects affected / exposed	2 / 86 (2.33%)	0 / 45 (0.00%)		
occurrences (all)	2	0		
Blood creatinine increased				
subjects affected / exposed	0 / 86 (0.00%)	2 / 45 (4.44%)		
occurrences (all)	0	2		
Blood glucose increased				
subjects affected / exposed	1 / 86 (1.16%)	3 / 45 (6.67%)		
occurrences (all)	1	3		
Blood pressure increased				
subjects affected / exposed	2 / 86 (2.33%)	1 / 45 (2.22%)		
occurrences (all)	2	1		
Blood pressure systolic increased				
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)		
occurrences (all)	0	1		
Blood triglycerides increased				
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)		
occurrences (all)	1	0		
Gamma-glutamyltransferase increased				
subjects affected / exposed	4 / 86 (4.65%)	2 / 45 (4.44%)		
occurrences (all)	4	2		
Intestinal transit time increased				
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)		
occurrences (all)	1	0		
Transaminases increased				

subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Bradycardia			
subjects affected / exposed	4 / 86 (4.65%)	2 / 45 (4.44%)	
occurrences (all)	4	2	
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Tremor			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Blood disorder			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Leukocytosis			
subjects affected / exposed	3 / 86 (3.49%)	1 / 45 (2.22%)	
occurrences (all)	3	1	
Neutrophilia			
subjects affected / exposed	2 / 86 (2.33%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Thrombocytosis			
subjects affected / exposed	2 / 86 (2.33%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Ear and labyrinth disorders			

Tinnitus			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	1 / 86 (1.16%)	1 / 45 (2.22%)	
occurrences (all)	1	1	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Ulcerative keratitis			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Abdominal pain			
subjects affected / exposed	1 / 86 (1.16%)	2 / 45 (4.44%)	
occurrences (all)	1	2	
Constipation			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	5 / 86 (5.81%)	0 / 45 (0.00%)	
occurrences (all)	5	0	
Dry mouth			
subjects affected / exposed	2 / 86 (2.33%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Dyspepsia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Dysphagia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Food poisoning			

subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	2 / 86 (2.33%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Vomiting			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Hepatobiliary disorders			
Hepatic cytolysis			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Hepatitis toxic			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Hand dermatitis			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Haematuria			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			

Bronchitis bacterial			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
COVID-19			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Clostridium difficile colitis			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Clostridium difficile infection			
subjects affected / exposed	2 / 86 (2.33%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Conjunctivitis			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
HIV infection			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Hepatic infection			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Infection			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Oral candidiasis			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Oral herpes			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	1 / 86 (1.16%)	0 / 45 (0.00%)	
occurrences (all)	1	0	

Toxic shock syndrome			
subjects affected / exposed	2 / 86 (2.33%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Urinary tract infection			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Fluid overload			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Hypercholesterolaemia			
subjects affected / exposed	3 / 86 (3.49%)	2 / 45 (4.44%)	
occurrences (all)	3	2	
Hyperglycaemia			
subjects affected / exposed	3 / 86 (3.49%)	4 / 45 (8.89%)	
occurrences (all)	3	4	
Hyperkalaemia			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Hypertriglyceridaemia			
subjects affected / exposed	9 / 86 (10.47%)	4 / 45 (8.89%)	
occurrences (all)	9	4	
Hypoglycaemia			
subjects affected / exposed	1 / 86 (1.16%)	1 / 45 (2.22%)	
occurrences (all)	1	1	
Hypokalaemia			
subjects affected / exposed	2 / 86 (2.33%)	0 / 45 (0.00%)	
occurrences (all)	2	0	
Hypophosphataemia			
subjects affected / exposed	2 / 86 (2.33%)	1 / 45 (2.22%)	
occurrences (all)	2	1	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 86 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported