

**Clinical trial results:****A Multicenter, Randomized, Double-Blinded, Parallel Group Phase II Study to Evaluate the Safety, Tolerability and Pharmacokinetics of a Second Generation VIR-7831 Material in Non-Hospitalized Participants with Mild to Moderate Coronavirus Disease 2019 (COVID-19)****Summary**

EudraCT number	2021-000724-35
Trial protocol	DE IT ES
Global end of trial date	06 April 2022

Results information

Result version number	v2 (current)
This version publication date	21 April 2023
First version publication date	01 November 2022
Version creation reason	• New data added to full data set EOS Results

Trial information**Trial identification**

Sponsor protocol code	VIR-7831-5006
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04779879
WHO universal trial number (UTN)	-
Other trial identifiers	VIR-7831-5006: 216912

Notes:

Sponsors

Sponsor organisation name	Vir Biotechnology, Inc.
Sponsor organisation address	499 Illinois St , San Francisco , United States, 94158
Public contact	Study Inquiry, Vir Biotechnology, Inc., 415 6545281, clinicaltrials@vir.bio
Scientific contact	Study Inquiry, Vir Biotechnology, Inc., clinicaltrials@vir.bio
Sponsor organisation name	Vir Biotechnology, Inc.
Sponsor organisation address	499 Illinois St , San Francisco , United States, 94158
Public contact	n/a, GlaxoSmithKline (Ireland) Limited, 1415 6545281, na.na@na.com
Scientific contact	n/a, GlaxoSmithKline (Ireland) Limited, 1415 6545281, na.na@na.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
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Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 April 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Safety (Part A): To evaluate the safety and tolerability profile of intravenous (IV) VIR-7831 Generation (Gen2) and IV Gen1

Pharmacodynamics (Part B): To evaluate the virological response of VIR-7831 Gen2 administered IV and via intramuscular (IM) injection in the upper respiratory tract

Protection of trial subjects:

Study participants were closely monitored for the occurrence of infusion reactions. The study intervention was administered in a clinic/study unit where participants were monitored closely for adverse events in the post-infusion period. Subsequent visits for study activities and clinical monitoring were conducted via clinic or home nursing visits (except for Week 16 which was a follow-up by telephone).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 February 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 28
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 3
Country: Number of subjects enrolled	United States: 276
Country: Number of subjects enrolled	Spain: 46
Worldwide total number of subjects	353
EEA total number of subjects	46

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)	337
From 65 to 84 years	16
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Randomized, parallel group study conducted in non-hospitalized participants with mild to moderate Coronavirus Disease 2019 (COVID-19) who received Sotrovimab (VIR-7831) Generation1 (Gen 1) and Gen2.

Pre-assignment

Screening details:

Total of 354 participants (30 participants in Part A, 167 participants in Part B, 157 participants in Part C) were enrolled in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A- Sotrovimab Gen1: 500 mg IV

Arm description:

Participants received Sotrovimab (VIR-7831) Gen1 500 milligrams (mg) intravenous (IV) infusion on Day 1 in Part A.

Arm type	Experimental
Investigational medicinal product name	Sotrovimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sotrovimab was administered as IV infusion

Arm title	Part A- Sotrovimab Gen2: 500 mg IV
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Arm description:

Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part A.

Arm type	Experimental
Investigational medicinal product name	Sotrovimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sotrovimab was administered as IV infusion

Arm title	Part B- Sotrovimab Gen2: 500 mg IV
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Arm description:

Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part B.

Arm type	Experimental
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Investigational medicinal product name	Sotrovimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sotrovimab was administered as IV infusion.

Arm title	Part B- Sotrovimab Gen2: 500 mg IM
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Arm description:

Participants received Sotrovimab (VIR-7831) Gen2 500 mg intramuscular (IM) injection on Day 1 in Part B.

Arm type	Experimental
Investigational medicinal product name	Sotrovimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Sotrovimab was administered as IM administration.

Arm title	Part C- Sotrovimab Gen2: 500 mg IV
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Arm description:

Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part C.

Arm type	Experimental
Investigational medicinal product name	Sotrovimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sotrovimab was administered as IV infusion

Arm title	Part C- Sotrovimab Gen2: 250 mg IM
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Arm description:

Participants received Sotrovimab (VIR-7831) Gen2 250 mg IM injection on Day 1 in Part C.

Arm type	Experimental
Investigational medicinal product name	Sotrovimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Sotrovimab was administered as IM injection

Number of subjects in period 1	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IV
Started	8	22	84
Completed	8	22	84
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Death	-	-	-

Number of subjects in period 1	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM
Started	82	79	78
Completed	81	75	75
Not completed	1	4	3
Consent withdrawn by subject	1	4	2
Death	-	-	1

Baseline characteristics

Reporting groups

Reporting group title	Part A- Sotrovimab Gen1: 500 mg IV
Reporting group description:	
Participants received Sotrovimab (VIR-7831) Gen1 500 milligrams (mg) intravenous (IV) infusion on Day 1 in Part A.	
Reporting group title	Part A- Sotrovimab Gen2: 500 mg IV
Reporting group description:	
Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part A.	
Reporting group title	Part B- Sotrovimab Gen2: 500 mg IV
Reporting group description:	
Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part B.	
Reporting group title	Part B- Sotrovimab Gen2: 500 mg IM
Reporting group description:	
Participants received Sotrovimab (VIR-7831) Gen2 500 mg intramuscular (IM) injection on Day 1 in Part B.	
Reporting group title	Part C- Sotrovimab Gen2: 500 mg IV
Reporting group description:	
Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part C.	
Reporting group title	Part C- Sotrovimab Gen2: 250 mg IM
Reporting group description:	
Participants received Sotrovimab (VIR-7831) Gen2 250 mg IM injection on Day 1 in Part C.	

Reporting group values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IV
Number of subjects	8	22	84
Age categorical			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
<=18 years	0	1	0
19-64 years	8	20	80
>=65 years	0	1	4
Gender categorical			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
Female	5	10	45
Male	3	12	39
Race/ Ethnicity, Customized			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
Black or African American	2	1	4
White - White/Caucasian/European Heritage	6	21	62
White - Arabic/North African Heritage	0	0	5
Asian - East Asian Heritage	0	0	2
Asian - South East Asian Heritage	0	0	11
Asian - Central/South Asian Heritage	0	0	0
American Indian Or Alaska Native	0	0	0

Mixed Asian Race	0	0	0
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Reporting group values	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM
Number of subjects	82	79	78
Age categorical			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
<=18 years	1	0	0
19-64 years	76	77	74
>=65 years	5	2	4
Gender categorical			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
Female	42	39	42
Male	40	40	36
Race/ Ethnicity, Customized			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
Black or African American	1	7	9
White - White/Caucasian/European Heritage	64	66	63
White - Arabic/North African Heritage	0	6	5
Asian - East Asian Heritage	2	0	0
Asian - South East Asian Heritage	13	0	0
Asian - Central/South Asian Heritage	1	0	0
American Indian Or Alaska Native	0	0	1
Mixed Asian Race	1	0	0

Reporting group values	Total		
Number of subjects	353		
Age categorical			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
<=18 years	2		
19-64 years	335		
>=65 years	16		
Gender categorical			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
Female	183		
Male	170		
Race/ Ethnicity, Customized			
Safety Population consisted of all randomized participants who were exposed to study intervention.			
Units: Subjects			
Black or African American	24		
White - White/Caucasian/European Heritage	282		

White - Arabic/North African Heritage	16		
Asian - East Asian Heritage	4		
Asian - South East Asian Heritage	24		
Asian - Central/South Asian Heritage	1		
American Indian Or Alaska Native	1		
Mixed Asian Race	1		

End points

End points reporting groups

Reporting group title	Part A- Sotrovimab Gen1: 500 mg IV
Reporting group description: Participants received Sotrovimab (VIR-7831) Gen1 500 milligrams (mg) intravenous (IV) infusion on Day 1 in Part A.	
Reporting group title	Part A- Sotrovimab Gen2: 500 mg IV
Reporting group description: Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part A.	
Reporting group title	Part B- Sotrovimab Gen2: 500 mg IV
Reporting group description: Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part B.	
Reporting group title	Part B- Sotrovimab Gen2: 500 mg IM
Reporting group description: Participants received Sotrovimab (VIR-7831) Gen2 500 mg intramuscular (IM) injection on Day 1 in Part B.	
Reporting group title	Part C- Sotrovimab Gen2: 500 mg IV
Reporting group description: Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Part C.	
Reporting group title	Part C- Sotrovimab Gen2: 250 mg IM
Reporting group description: Participants received Sotrovimab (VIR-7831) Gen2 250 mg IM injection on Day 1 in Part C.	
Subject analysis set title	Sotrovimab Gen2: 500 mg IV (Parts B and C)
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants received Sotrovimab (VIR-7831) Gen2 500 mg IV infusion on Day 1 in Parts B and C.	

Primary: Part A: Number of Participants With all Adverse Events (AEs) and Serious Adverse Events (SAEs) Through Day 29

End point title	Part A: Number of Participants With all Adverse Events (AEs) and Serious Adverse Events (SAEs) Through Day 29 ^{[1][2]}
End point description: An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. A SAE is defined as any serious adverse event that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, significant medical events that may jeopardize the participant or require medical or surgical intervention to prevent one of the other outcomes listed before. Safety Population consisted of all randomized participants who were exposed to study intervention.	
End point type	Primary
End point timeframe: Up to Day 29	

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: There are no statistical data to report.

[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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants				
All AEs	0	3		
SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Number of Participants With Adverse Events of Special Interest (AESI) Through Day 29

End point title	Part A: Number of Participants With Adverse Events of Special Interest (AESI) Through Day 29 ^[3] ^[4]
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End point description:

An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. AESIs were infusion-related reactions (IRR) including hypersensitivity, events related to antibody-dependent enhancement, and events related to immunogenicity.

Safety Population.

End point type	Primary
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End point timeframe:

Up to Day 29

Notes:

[3] - 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: There are no statistical data to report.

[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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants				
IRR including hypersensitivity	0	0		
Events related to antibody-dependent enhancement	0	0		
Events related to immunogenicity	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Number of Participants With Worst-case Post Baseline Abnormal Electrocardiogram (ECG) Findings Through Day 29

End point title	Part A: Number of Participants With Worst-case Post Baseline Abnormal Electrocardiogram (ECG) Findings Through Day 29 ^[5] ^[6]
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End point description:

Twelve-lead ECGs were recorded with the participant in a semi-supine position after being at rest for at least 10 minutes using an ECG machine. Clinically significant abnormal findings were determined as per clinical judgement by the investigator. Number of participants with worst-case clinically significant and not clinically significant abnormal ECG findings have been presented.

Safety Population.

End point type	Primary
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End point timeframe:

Up to Day 29

Notes:

[5] - 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: There are no statistical data to report.

[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: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants				
Abnormal-Clinically significant	0	0		
Abnormal-Not Clinically significant	6	17		

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Number of Participants With Disease Progression Events (Disease-Related Events) Through Day 29

End point title	Part A: Number of Participants With Disease Progression Events (Disease-Related Events) Through Day 29 ^[7] ^[8]
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End point description:

AEs related to expected progression, signs, or symptoms of COVID-19, unless more severe than expected for the participant's current clinical status and medical history, and considered to be not causally-related to the study agent or study procedures by the Investigator, were reported as a Disease-Related Events (DRE). Safety Population.

End point type	Primary
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End point timeframe:

Up to Day 29

Notes:

[7] - 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: There are no statistical data to report.

[8] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Mean Area Under the Curve (AUC) of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) Viral Load From Day 1 to Day 8 (AUCD1-8)

End point title	Part B: Mean Area Under the Curve (AUC) of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) Viral Load From Day 1 to Day 8 (AUCD1-8) ^[9]
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End point description:

AUC of SARS-CoV-2 viral load was measured by Quantitative reverse transcriptase polymerase chain reaction (qRT-PCR) from Day 1 to Day 8 in nasopharyngeal (NP) swab samples. Analysis was performed using an Analysis of covariance (ANCOVA) model with covariates of treatment and Baseline logarithm (base 10) viral load.

Viral Pharmacodynamic Population consisted of all participants in the Safety Population who had a Baseline (Day 1) quantifiable viral load as assessed using qRT-PCR from NP swabs. Only those participants with data available at the specified time points without missing covariate information were analyzed.

End point type	Primary
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End point timeframe:

Day 1 to Day 8

Notes:

[9] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	65		
Units: Day*log10 copies per (/) milliliter (mL)				
least squares mean (confidence interval 90%)	24.40 (23.53 to 25.31)	25.28 (24.38 to 26.21)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Analysis was performed using an Analysis of covariance (ANCOVA) model with covariates of treatment and Baseline logarithm (base 10) viral load.	
Comparison groups	Part B- Sotrovimab Gen2: 500 mg IV v Part B- Sotrovimab Gen2: 500 mg IM
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.04
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.98
upper limit	1.09

Primary: Part C: Mean AUC of SARS-CoV-2 Viral Load From Day 1 to Day 8 (AUCD1-8)

End point title	Part C: Mean AUC of SARS-CoV-2 Viral Load From Day 1 to Day 8 (AUCD1-8) ^[10]
End point description:	
AUC of SARS-CoV-2 viral load was measured by qRT-PCR from Day 1 to Day 8 in NP swab samples. Analysis was performed using an ANCOVA model with covariates of treatment, and Baseline logarithm (base10) viral load and randomization stratification factor (prior exposure to an authorized or approved SARS-CoV-2 vaccine). Viral Pharmacodynamic Population. Only those participants with data available at the specified time points without missing covariate information were analyzed.	
End point type	Primary
End point timeframe:	
Day 1 to Day 8	

Notes:

[10] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55	62		
Units: Day*log10 copies/mL				

least squares mean (confidence interval 90%)	26.20 (24.68 to 27.81)	26.72 (25.26 to 28.27)		
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Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Analysis was performed using an ANCOVA model with covariates of treatment, and Baseline logarithm (base10) viral load and randomization stratification factor (prior exposure to an authorized or approved SARS-CoV-2 vaccine).	
Comparison groups	Part C- Sotrovimab Gen2: 500 mg IV v Part C- Sotrovimab Gen2: 250 mg IM
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.02
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.94
upper limit	1.11

Secondary: Part A: Number of Participants With Non-Serious AEs Through Week 12

End point title	Part A: Number of Participants With Non-Serious AEs Through Week 12 ^[11]
End point description:	
An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. Adverse events which were not Serious were considered as Non-Serious adverse events. Safety Population.	
End point type	Secondary
End point timeframe:	
Up to Week 12	

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Participants With SAEs Through Week 24

End point title	Part A: Number of Participants With SAEs Through Week 24 ^[12]
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End point description:

A SAE is defined as any serious adverse event that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, significant medical events that may jeopardize the participant or require medical or surgical intervention to prevent one of the other outcomes listed before.

End point type	Secondary
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End point timeframe:

Up to Week 24

Notes:

[12] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Participants With AESI Through Week 24

End point title	Part A: Number of Participants With AESI Through Week 24 ^[13]
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End point description:

An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. AESIs are infusion-related reactions (IRR) including hypersensitivity, events related to antibody-dependent enhancement, and events related to immunogenicity. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 24

Notes:

[13] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants				
IRR including hypersensitivity	0	0		
Events related to antibody-dependent enhancement	0	0		
Events related to immunogenicity	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Participants With Abnormal ECG Findings at Indicated Time Points

End point title	Part A: Number of Participants With Abnormal ECG Findings at Indicated Time Points ^[14]
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End point description:

Twelve-lead ECGs were recorded with the participant in a semi-supine position after being at rest for at least 10 minutes using an ECG machine. Clinically significant abnormal findings were determined as per clinical judgement by the investigator. Number of participants with clinically significant (CS) and not clinically significant (NCS) abnormal ECG findings have been presented.

Safety Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Days 1, 5, 11 and 85 (Week 12)

Notes:

[14] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants				
Day 1: Abnormal-CS, n=7,22	0	0		
Day 1:Abnormal-NCS, n=7,22	4	13		
Day 5: Abnormal-CS, n=7,21	0	0		
Day 5:Abnormal-NCS, n=7,21	5	10		
Day 11: Abnormal-CS, n=8,22	0	0		

Day 11:Abnormal-NCS,n=8,22	5	12		
Day 85 (Week 12): Abnormal-CS, n=8,22	0	0		
Day 85 (Week 12):Abnormal- NCS,n=8,22	6	10		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Participants With Disease Progression Events (Disease-Related Events) Through Week 24

End point title	Part A: Number of Participants With Disease Progression Events (Disease-Related Events) Through Week 24 ^[15]
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End point description:

AEs related to expected progression, signs, or symptoms of COVID-19, unless more severe than expected for the participant's current clinical status and medical history, and considered to be not causally-related to the study agent or study procedures by the Investigator, were reported as a Disease-Related Events (DRE). Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 24

Notes:

[15] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With all AEs and SAEs Through Day 29

End point title	Part B: Number of Participants With all AEs and SAEs Through Day 29 ^[16]
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. A SAE is defined as any serious adverse event that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, significant medical events that may jeopardize the participant or require medical or surgical intervention to prevent one of the other outcomes listed before. Adverse events include both Serious and Other Adverse Events. Safety Population

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[16] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants				
All AEs	8	17		
SAEs	1	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With AESI Through Day 29

End point title	Part B: Number of Participants With AESI Through Day 29 ^[17]
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End point description:

An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. AESIs were infusion/injection-related reactions (IRR) including hypersensitivity; injection site reactions (ISRs); events related to antibody-dependent enhancement; events related to immunogenicity. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[17] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants				
IRR including hypersensitivity	0	1		
Injection site reactions	0	10		
Events related to Antibody-dependent enhancement	0	0		
Events related to immunogenicity	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With Worst-case Post Baseline Abnormal ECG Findings Through Day 29

End point title	Part B: Number of Participants With Worst-case Post Baseline Abnormal ECG Findings Through Day 29 ^[18]
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End point description:

Twelve-lead ECGs were recorded with the participant in a semi-supine position after being at rest for at least 10 minutes using an ECG machine. Clinically significant abnormal findings were determined as per clinical judgement by the investigator. Number of participants with worst-case clinically significant and not clinically significant abnormal ECG findings have been presented. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[18] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants				
Abnormal-Clinically significant	1	1		
Abnormal-Not Clinically significant	43	39		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With Disease Progression Events (Disease-Related Events) Through Day 29

End point title	Part B: Number of Participants With Disease Progression Events (Disease-Related Events) Through Day 29 ^[19]
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End point description:

AEs related to expected progression, signs, or symptoms of COVID-19, unless more severe than expected for the participant's current clinical status and medical history, and considered to be not causally-related to the study agent or study procedures by the Investigator, were reported as a Disease-Related Events (DRE). Safety Population.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[19] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants	0	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With All AEs and SAEs Through Day 29

End point title	Part C: Number of Participants With All AEs and SAEs Through Day 29 ^[20]
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. A SAE is defined as any serious adverse event that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, significant medical events that may jeopardize the participant or require medical or surgical intervention to prevent one of the other outcomes listed before. Adverse events include both Serious and Other Adverse Events. Safety Population

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[20] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants				
All AEs	10	13		
SAEs	1	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With AESI Through Day 29

End point title	Part C: Number of Participants With AESI Through Day 29 ^[21]
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End point description:

An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. AESIs were infusion/injection-related reactions (IRR) including hypersensitivity reactions; injection site reactions (ISRs); events related to antibody-dependent enhancement, and events related to immunogenicity. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[21] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants				
IRR including hypersensitivity	0	0		
Injection site reactions	0	4		
Events related to Antibody-dependent enhancement	0	0		
Events related to immunogenicity	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With Worst-case Post Baseline Abnormal ECG Findings Through Day 29

End point title	Part C: Number of Participants With Worst-case Post Baseline Abnormal ECG Findings Through Day 29 ^[22]
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End point description:

Twelve-lead ECGs were recorded with the participant in a semi-supine position after being at rest for at least 10 minutes using an ECG machine. Clinically significant abnormal findings were determined as per clinical judgement by the investigator. Number of participants with worst-case clinically significant and not clinically significant abnormal ECG findings have been presented. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[22] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants				
Abnormal-Clinically significant	0	0		
Abnormal-Not Clinically significant	38	37		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With Disease Progression Events (Disease-Related Events) Through Day 29

End point title	Part C: Number of Participants With Disease Progression Events (Disease-Related Events) Through Day 29 ^[23]
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End point description:

AEs related to expected progression, signs, or symptoms of COVID-19, unless more severe than expected for the participant's current clinical status and medical history, and considered to be not causally-related to the study agent or study procedures by the Investigator, were reported as a Disease-Related Events (DRE). Safety Population.

End point type	Secondary
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End point timeframe:

Up to Day 29

Notes:

[23] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With Non-Serious AEs Through Week 12

End point title	Part B: Number of Participants With Non-Serious AEs Through Week 12 ^[24]
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 12

Notes:

[24] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants	8	20		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With SAEs Through Week 36

End point title	Part B: Number of Participants With SAEs Through Week 36 ^[25]
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End point description:

A SAE is defined as any serious adverse event that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, significant medical events that may jeopardize the participant or require medical or surgical intervention to prevent one of the other outcomes listed before. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 36

Notes:

[25] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants	1	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With AESI Through Week 36

End point title	Part B: Number of Participants With AESI Through Week 36 ^[26]
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End point description:

An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. AESIs are infusion/injection-related reactions (IRR) including hypersensitivity reactions; injection site reactions (ISRs); events related to antibody-dependent enhancement, and events related to immunogenicity. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 36

Notes:

[26] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants				
IRR including hypersensitivity reaction	0	1		
Injection site reactions	0	10		
Events related to antibody-dependent enhancement	0	0		
Events related to immunogenicity	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With Abnormal ECG Findings at Indicated Time Points

End point title	Part B: Number of Participants With Abnormal ECG Findings at Indicated Time Points ^[27]
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End point description:

Twelve-lead ECGs were recorded with the participant in a semi-supine position after being at rest for at least 10 minutes using an ECG machine. Clinically significant abnormal findings were determined as per clinical judgement by the investigator. Number of participants with clinically significant (CS) and not

clinically significant (NCS) abnormal ECG findings have been presented. Safety Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Days 1, 5, 11 and 85 (Week 12)

Notes:

[27] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants				
Day 1: Abnormal-CS, n=84,82	1	0		
Day 1:Abnormal-NCS, n=84,82	33	31		
Day 5: Abnormal-CS, n=80,78	0	1		
Day 5:Abnormal-NCS, n=80,78	28	24		
Day 11: Abnormal-CS, n=82,78	0	0		
Day 11:Abnormal-NCS,n=82,78	20	24		
Day 85 (Week 12): Abnormal-CS, n=78,79	0	0		
Day 85 (Week 12):Abnormal- NCS,n=78,79	24	20		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With Disease Progression Events Through Week 36

End point title	Part B: Number of Participants With Disease Progression Events Through Week 36 ^[28]
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End point description:

AEs related to expected progression, signs, or symptoms of COVID-19, unless more severe than expected for the participant's current clinical status and medical history, and considered to be not causally-related to the study agent or study procedures by the Investigator, were reported as a Disease-Related Events (DRE). Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 36

Notes:

[28] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	84	82		
Units: Participants	2	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With Non-Serious AEs Through Week 12

End point title	Part C: Number of Participants With Non-Serious AEs Through Week 12 ^[29]
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 12

Notes:

[29] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants	16	16		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With SAEs Through Week 36

End point title	Part C: Number of Participants With SAEs Through Week 36 ^[30]
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End point description:

A SAE is defined as any serious adverse event that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, significant medical events that may jeopardize the participant or require medical or surgical intervention to prevent one of the other outcomes listed before. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 36

Notes:

[30] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants	2	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With AESI Through Week 36

End point title	Part C: Number of Participants With AESI Through Week 36 ^[31]
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End point description:

An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. AESIs are infusion/injection-related reactions (IRR) including hypersensitivity reactions; injection site reactions (ISRs); events related to antibody-dependent enhancement, and events related to immunogenicity. Safety Population.

End point type	Secondary
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End point timeframe:

Up to Week 36

Notes:

[31] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants				
IRR including hypersensitivity	0	0		
Injection site reactions	0	4		
Events related to antibody-dependent enhancement	0	0		
Events related to immunogenicity	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With Abnormal ECG Findings at Indicated Time Points

End point title	Part C: Number of Participants With Abnormal ECG Findings at Indicated Time Points ^[32]
-----------------	--

End point description:

Twelve-lead ECGs were recorded with the participant in a semi-supine position after being at rest for at least 10 minutes using an ECG machine. Clinically significant abnormal findings were determined as per clinical judgement by the investigator. Number of participants with clinically significant (CS) and not clinically significant (NCS) abnormal ECG findings have been presented. Safety Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Days 1, 5, 11 and 85 (Week 12)

Notes:

[32] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants				
Day 1: Abnormal-CS, n=79,78	0	0		
Day 1:Abnormal-NCS, n=79,78	29	28		
Day 5: Abnormal-CS, n=76,74	0	0		
Day 5:Abnormal-NCS, n=76,74	25	23		
Day 11: Abnormal-CS, n=72,76	0	0		
Day 11:Abnormal-NCS,n=72,76	21	23		
Day 85 (Week 12): Abnormal-CS, n=73,77	0	0		
Day 85 (Week 12):Abnormal- NCS,n=73,77	20	23		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Number of Participants With Disease Progression Events Through Week 36

End point title	Part C: Number of Participants With Disease Progression Events Through Week 36 ^[33]
-----------------	--

End point description:

AEs related to expected progression, signs, or symptoms of COVID-19, unless more severe than expected for the participant's current clinical status and medical history, and considered to be not causally-related to the study agent or study procedures by the Investigator, were reported as a Disease-Related Events (DRE). Safety Population.

End point type	Secondary
End point timeframe:	
Up to Week 36	
Notes:	
[33] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.	

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	79	78		
Units: Participants	1	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Change from Baseline in SARS-CoV-2 Saliva and Nasal Mid-Turbinate Viral Load

End point title	Part A: Change from Baseline in SARS-CoV-2 Saliva and Nasal Mid-Turbinate Viral Load ^[34]
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End point description:

SARS-CoV-2 viral load was based on saliva and nasal mid-turbinate swab samples and was measured by qRT-PCR. Baseline log10 viral load was defined as the non-missing assessment taken at Day 1 excluding the NEG and <2.08 results. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value.

Virology Population consisted of all participants in the Safety Population with a central lab confirmed quantifiable nasal mid-turbinate and/or saliva swab at Baseline. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary
End point timeframe:	
Baseline, Days 2, 5, 8, 11, 15, 22 and 29	

Notes:

[34] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	16		
Units: Log10 copies/mL				
arithmetic mean (standard deviation)				
Day 2: Saliva, n=4,11	-0.270 (± 0.4290)	-1.114 (± 0.9201)		
Day 5: Saliva, n=3,11	-0.780 (± 0.3404)	-2.620 (± 1.0199)		

Day 8: Saliva, n=3,11	-0.507 (± 0.5689)	-2.605 (± 1.4982)		
Day 11: Saliva, n=4,10	-1.043 (± 0.5940)	-2.881 (± 1.3963)		
Day 15: Saliva, n=4,11	-0.610 (± 1.3444)	-3.179 (± 1.2132)		
Day 22: Saliva, n=4,11	-1.043 (± 0.5940)	-3.284 (± 1.3210)		
Day 29: Saliva, n=4,11	-1.043 (± 0.5940)	-3.223 (± 1.3123)		
Day 2: Nasal mid-turbinate, n=5,16	-1.252 (± 0.9726)	-1.006 (± 1.2277)		
Day 5: Nasal mid-turbinate, n=4,16	-1.755 (± 1.1230)	-2.111 (± 1.2100)		
Day 8: Nasal mid-turbinate, n=4,16	-1.705 (± 0.7839)	-2.703 (± 1.7842)		
Day 11: Nasal mid-turbinate, n=5,16	-2.810 (± 1.3363)	-2.923 (± 1.5656)		
Day 15: Nasal mid-turbinate, n=5,16	-2.490 (± 1.3243)	-3.445 (± 1.7103)		
Day 22: Nasal mid-turbinate, n=5,16	-2.668 (± 1.2826)	-3.873 (± 1.9434)		
Day 29: Nasal mid-turbinate, n=5,16	-2.810 (± 1.3363)	-3.752 (± 1.8030)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in Viral Load as Measured by qRT-PCR From Nasopharyngeal Swab Samples

End point title	Part B: Change from Baseline in Viral Load as Measured by qRT-PCR From Nasopharyngeal Swab Samples ^[35]
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End point description:

Viral load was based on nasopharyngeal swab samples and was measured by qRT-PCR. Baseline log10 viral load was defined as the non-missing assessment taken at Day 1 excluding the "NEG" and "<2.08" results. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Viral Pharmacodynamic Population consisted of all participants in the Safety Population who had a Baseline (Day 1) quantifiable viral load as assessed using qRT-PCR from NP swabs. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary
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End point timeframe:

Baseline, Days 2, 3, 5, 8, 11, 15, 22 and 29

Notes:

[35] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	68		
Units: Log10 copies/mL				
arithmetic mean (standard deviation)				
Day 2: n=63,68	-1.146 (± 1.1558)	-0.611 (± 1.1518)		
Day 3: n=63,66	-1.438 (± 1.2033)	-1.306 (± 1.3132)		
Day 5: n=62,64	-2.578 (± 1.2480)	-2.352 (± 1.1655)		
Day 8: n=64,64	-3.069 (± 1.4553)	-3.254 (± 1.4193)		
Day 11: n=62,63	-3.522 (± 1.7148)	-3.574 (± 1.4907)		
Day 15: n=62,66	-3.705 (± 1.7443)	-3.733 (± 1.5525)		
Day 22: n=64,66	-3.831 (± 1.7994)	-3.778 (± 1.7476)		
Day 29: n=62,64	-3.933 (± 1.8253)	-3.857 (± 1.7455)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Change from Baseline in Viral Load as Measured by qRT-PCR From Nasopharyngeal Swab Samples

End point title	Part C: Change from Baseline in Viral Load as Measured by qRT-PCR From Nasopharyngeal Swab Samples ^[36]
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End point description:

Viral load was based on nasopharyngeal swab samples and was measured by qRT-PCR. Baseline log10 viral load was defined as the non-missing assessment taken at Day 1 excluding the "NEG" and "<2.08" results. Change from Baseline was calculated by subtracting the Baseline value from the post-dose visit value. Viral Pharmacodynamic Population. Only those participants with data available at the specified time points were analyzed (represented by n=X in the category titles).

End point type	Secondary
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End point timeframe:

Baseline, Days 2, 3, 5, 8, 11, 15, 22 and 29

Notes:

[36] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	66		
Units: Log10 copies per milliliter				

arithmetic mean (standard deviation)				
Day 2: n=59,64	-0.429 (± 1.3835)	-0.519 (± 1.3273)		
Day 3: n=50,57	-0.905 (± 1.5202)	-1.123 (± 1.6172)		
Day 5: n=57,62	-2.076 (± 1.9648)	-1.967 (± 2.0218)		
Day 8: n=55,62	-3.122 (± 1.8234)	-3.180 (± 1.8324)		
Day 11: n=52,61	-3.617 (± 1.6870)	-3.738 (± 1.8168)		
Day 15: n=50,61	-3.719 (± 1.8248)	-3.836 (± 1.8148)		
Day 22: n=55,65	-3.693 (± 1.7647)	-3.956 (± 1.7492)		
Day 29: n=56,63	-3.761 (± 1.8167)	-3.963 (± 1.7189)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Percentage of Participants With Undetectable Viral Load

End point title	Part B: Percentage of Participants With Undetectable Viral
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End point description:

Viral load was measured by qRT-PCR from nasopharyngeal swab samples. Viral load (log10 copies/mL) values recorded as negative were considered as undetectable viral load. Percentage of participants with undetectable viral load have been presented. Percentage values are rounded off. Viral Pharmacodynamic Population. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles).

End point type	Secondary
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End point timeframe:

Days 2, 3, 5, 8, 11, 15, 22 and 29

Notes:

[37] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	68		
Units: Percentage of participants				
number (not applicable)				
Day 2: n=63,68	10	4		
Day 3: n=63,66	11	9		
Day 5: n=62,64	23	27		
Day 8: n=64,64	34	38		
Day 11: n=62,63	58	51		
Day 15: n=62,66	61	73		

Day 22: n=64,66	73	74		
Day 29: n=62,64	81	84		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Percentage of Participants With Undetectable Viral Load

End point title	Part C: Percentage of Participants With Undetectable Viral
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End point description:

Viral load was measured by qRT-PCR from nasopharyngeal swab samples. Viral load (log10 copies/mL) values recorded as negative were considered as undetectable viral load. Percentage of participants with undetectable viral load have been presented. Percentage values are rounded off. Viral Pharmacodynamic Population. Only those participants with data available at the specified time points were analyzed (represented by n= X in the category titles).

End point type	Secondary
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End point timeframe:

Days 2, 3, 5, 8, 11, 15, 22 and 29

Notes:

[38] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	66		
Units: Percentage of participants				
number (not applicable)				
Day 2: n=59,64	10	5		
Day 3: n=50,57	10	14		
Day 5: n=57,62	28	16		
Day 8: n=55,62	42	39		
Day 11: n=52,61	63	72		
Day 15: n=50,61	82	80		
Day 22: n=55,65	80	88		
Day 29: n=56,63	88	86		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Mean AUC of SARS-CoV-2 Viral Load From Day 1 to Day 5 (AUCD1-5)

End point title	Part B: Mean AUC of SARS-CoV-2 Viral Load From Day 1 to Day 5 (AUCD1-5) ^[39]
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End point description:

AUC of SARS-CoV-2 viral load was measured by qRT-PCR from Day 1 to Day 5. Analysis was performed using an ANCOVA model with covariates of treatment and Baseline logarithm (base 10) viral load. Viral Pharmacodynamic Population. Only those participants with data available at the specified time points without missing covariate information were analyzed.

End point type	Secondary
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End point timeframe:

Day 1 to Day 5

Notes:

[39] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	63	65		
Units: Day*Log10 copies/mL				
least squares mean (confidence interval 90%)	16.14 (15.53 to 16.77)	16.97 (16.34 to 17.62)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Analysis was performed using an ANCOVA model with covariates of treatment and Baseline logarithm (base 10) viral load.

Comparison groups	Part B- Sotrovimab Gen2: 500 mg IV v Part B- Sotrovimab Gen2: 500 mg IM
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.05
Confidence interval	
level	90 %
sides	2-sided
lower limit	1
upper limit	1.11

Secondary: Part B: Mean Area Under the Curve (AUC) of SARS-CoV-2 Viral Load From Day 1 to Day 11 (AUCD1-11)

End point title	Part B: Mean Area Under the Curve (AUC) of SARS-CoV-2 Viral Load From Day 1 to Day 11 (AUCD1-11) ^[40]
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End point description:

AUC of SARS-CoV-2 viral load was measured by qRT-PCR from Day 1 to Day 11. Analysis was performed using an ANCOVA model with covariates of treatment and Baseline logarithm (base 10) viral load. Viral Pharmacodynamic Population. Only those participants with data available at the specified time points without missing covariate information were analyzed.

End point type	Secondary
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End point timeframe:

Day 1 to Day 11

Notes:

[40] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	65		
Units: Day*Log10 copies/mL				
least squares mean (confidence interval 90%)	31.69 (30.60 to 32.82)	32.39 (31.28 to 33.53)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Analysis was performed using an ANCOVA model with covariates of treatment and Baseline logarithm (base 10) viral load.

Comparison groups	Part B- Sotrovimab Gen2: 500 mg IV v Part B- Sotrovimab Gen2: 500 mg IM
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.02
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.97
upper limit	1.07

Secondary: Part C: Mean AUC of SARS-CoV-2 Viral Load From Day 1 to Day 5 (AUCD1-5)

End point title	Part C: Mean AUC of SARS-CoV-2 Viral Load From Day 1 to Day 5 (AUCD1-5) ^[41]
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End point description:

AUC of SARS-CoV-2 viral load was measured by qRT-PCR from Day 1 to Day 5. Analysis was performed using an ANCOVA model with covariates of treatment, Baseline logarithm (base 10) viral load and randomization stratification factor (prior exposure to an authorized or approved SARS-CoV-2 vaccine).

Viral Pharmacodynamic Population. Only those participants with data available at the specified time points without missing covariate information were analyzed.

End point type	Secondary
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End point timeframe:

Day 1 to Day 5

Notes:

[41] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	63		
Units: Day*Log10 copies/mL				
least squares mean (confidence interval 90%)	17.42 (16.49 to 18.41)	17.56 (16.66 to 18.51)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Analysis was performed using an ANCOVA model with covariates of treatment, Baseline logarithm (base 10) viral load and randomization stratification factor (prior exposure to an authorized or approved SARS-CoV-2 vaccine).

Comparison groups	Part C- Sotrovimab Gen2: 500 mg IV v Part C- Sotrovimab Gen2: 250 mg IM
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.01
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.93
upper limit	1.09

Secondary: Part C: Mean Area Under the Curve (AUC) of SARS-CoV-2 Viral Load From Day 1 to Day 11 (AUCD1-11)

End point title	Part C: Mean Area Under the Curve (AUC) of SARS-CoV-2 Viral Load From Day 1 to Day 11 (AUCD1-11) ^[42]
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End point description:

AUC of SARS-CoV-2 viral load was measured by qRT-PCR from Day 1 to Day 11. Analysis was performed using an ANCOVA model with covariates of treatment, Baseline logarithm (base 10) viral load and randomization stratification factor (prior exposure to an authorized or approved SARS-CoV-2 vaccine). Viral Pharmacodynamic Population. Only those participants with data available at the specified time points without missing covariate information were analyzed.

End point type	Secondary
End point timeframe:	
Day 1 to Day 11	
Notes:	
[42] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.	

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	62		
Units: Day*Log10 copies/mL				
least squares mean (confidence interval 90%)	33.02 (31.17 to 34.97)	33.63 (31.89 to 35.47)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Analysis was performed using an ANCOVA model with covariates of treatment, Baseline logarithm (base 10) viral load and randomization stratification factor (prior exposure to an authorized or approved SARS-CoV-2 vaccine).	
Comparison groups	Part C- Sotrovimab Gen2: 500 mg IV v Part C- Sotrovimab Gen2: 250 mg IM
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.02
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.94
upper limit	1.1

Secondary: Part B: Percentage of Participants With a Persistently High Viral Load at Day 8

End point title	Part B: Percentage of Participants With a Persistently High Viral Load at Day 8 ^[43]
End point description:	
Percentage of participants with a persistently high viral load were categorized as ≥ 4.1 log10 copies/mL and < 4.1 log10 copies/mL. Percentage of participants with a persistently high viral load at Day 8 was assessed via qRT-PCR in nasopharyngeal swab samples. Percentage of participants with a persistently high viral load at Day 8 has been presented. Percentage values are rounded off. Viral Pharmacodynamic Population. Only those participants with data available at the specified time points were analyzed.	
End point type	Secondary

End point timeframe:

Day 8

Notes:

[43] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV	Part B- Sotrovimab Gen2: 500 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	64		
Units: Percentage of participants				
number (not applicable)				
>=4.1 log 10 copies/mL	17	11		
<4.1 log 10 copies/mL	83	89		

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Percentage of Participants With a Persistently High Viral Load at Day 8

End point title	Part C: Percentage of Participants With a Persistently High Viral Load at Day 8 ^[44]
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End point description:

Percentage of participants with a persistently high viral load were categorized as >=4.1 log10 copies/mL and <4.1 log10 copies/mL. Percentage of participants with a persistently high viral load at Day 8 was assessed via qRT-PCR in nasopharyngeal swab samples. Percentage of participants with a persistently high viral load at Day 8 has been presented. Percentage values are rounded off. Viral Pharmacodynamic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 8

Notes:

[44] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55	62		
Units: Percentage of participants				
number (not applicable)				
>=4.1 log 10 copies/mL	15	13		
<4.1 log 10 copies/mL	85	87		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Maximum Observed Concentration (Cmax) of VIR-7831 after IV administration

End point title	Part A: Maximum Observed Concentration (Cmax) of VIR-7831 after IV administration ^[45]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population consisted of all participants in the Safety Population who had at least 1 non-missing PK assessment (Non-quantifiable [NQ] values were considered as non-missing values). Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[45] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	22		
Units: Microgram per mL				
arithmetic mean (standard deviation)	147.1 (± 48.28)	204.7 (± 77.61)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Cmax of VIR-7831 after IV administration

End point title	Part B: Cmax of VIR-7831 after IV administration ^[46]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[46] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Microgram per mL				
arithmetic mean (standard deviation)	156.5 (± 40.80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Cmax of VIR-7831 after IM administration

End point title	Part B: Cmax of VIR-7831 after IM administration ^[47]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[47] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Microgram per mL				
arithmetic mean (standard deviation)	28.8 (± 15.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Cmax of VIR-7831 after IV administration

End point title	Part C: Cmax of VIR-7831 after IV administration ^[48]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[48] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Microgram per mL				
arithmetic mean (standard deviation)	137.4 (± 32.97)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Cmax of VIR-7831 after IM administration

End point title	Part C: Cmax of VIR-7831 after IM administration ^[49]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[49] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: Microgram per mL				
arithmetic mean (standard deviation)	11.1 (± 5.61)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Concentration at Last Quantifiable Time-point (Clast) of VIR-7831 after IV administration

End point title	Part A: Concentration at Last Quantifiable Time-point (Clast) of VIR-7831 after IV administration ^[50]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[50] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Microgram per mL				
arithmetic mean (standard deviation)	6.9 (± 2.16)	8.1 (± 2.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Clast of VIR-7831 after IV administration

End point title	Part B: Clast of VIR-7831 after IV administration ^[51]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[51] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Microgram per mL				
arithmetic mean (standard deviation)	7.0 (\pm 2.48)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Clast of VIR-7831 after IM administration

End point title	Part B: Clast of VIR-7831 after IM administration ^[52]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[52] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Microgram per mL				
arithmetic mean (standard deviation)	7.9 (\pm 7.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Clast of VIR-7831 after IV administration

End point title	Part C: Clast of VIR-7831 after IV administration ^[53]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[53] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Microgram per mL				
arithmetic mean (standard deviation)	10.5 (± 12.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Clast of VIR-7831 after IM administration

End point title	Part C: Clast of VIR-7831 after IM administration ^[54]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[54] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Microgram per mL				
arithmetic mean (standard deviation)	2.6 (± 1.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Time to Reach Cmax (Tmax) of VIR-7831 after IV administration

End point title	Part A: Time to Reach Cmax (Tmax) of VIR-7831 after IV administration ^[55]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[55] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	22		
Units: Day				
median (full range (min-max))	0.042 (0.04 to 0.38)	0.042 (0.04 to 0.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Tmax of VIR-7831 after IV administration

End point title	Part B: Tmax of VIR-7831 after IV administration ^[56]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[56] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Day				
median (full range (min-max))	0.026 (0.01 to 0.03)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Tmax of VIR-7831 after IM administration

End point title	Part B: Tmax of VIR-7831 after IM administration ^[57]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[57] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day				
median (full range (min-max))	6.878 (3.68 to 56.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Tmax of VIR-7831 after IV administration

End point title	Part C: Tmax of VIR-7831 after IV administration ^[58]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[58] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Day				
median (full range (min-max))	0.014 (0.01 to 0.02)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Tmax of VIR-7831 after IM administration

End point title	Part C: Tmax of VIR-7831 after IM administration ^[59]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[59] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: Day				
median (full range (min-max))	27.866 (13.88 to 56.04)			

Statistical analyses

Secondary: Part A: Time of the Last Quantifiable Concentration (tlast) of VIR-7831 after IV administration

End point title	Part A: Time of the Last Quantifiable Concentration (tlast) of VIR-7831 after IV administration ^[60]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. The time frame is beyond Day 169 as there was one PK sample collected outside of the protocol defined window of +/- 7 days that was included in the analysis (PK sample collected up to Day 169 +/- 12 days).

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[60] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A-Sotrovimab Gen1: 500 mg IV	Part A-Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Day				
median (full range (min-max))	161.333 (160.89 to 174.95)	162.248 (160.70 to 180.15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: tlast of VIR-7831 after IV administration

End point title	Part B: tlast of VIR-7831 after IV administration ^[61]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. The upper value of the full range is outside of the time frame due to the protocol defined time point of Day 169 +/- 7 days.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[61] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day				
median (full range (min-max))	167.715 (160.76 to 175.68)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: tlast of VIR-7831 after IM administration

End point title	Part B: tlast of VIR-7831 after IM administration ^[62]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. The upper value of the full range is outside of the time frame due to the protocol defined time point of Day 169+/-7 days.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[62] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day				
median (full range (min-max))	167.670 (55.68 to 175.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: tlast of VIR-7831 after IV administration

End point title	Part C: tlast of VIR-7831 after IV administration ^[63]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. The time frame is beyond Day 169 as there were a few PK samples collected outside of the protocol defined window of +/- 7 days that were included in the

analysis (PK samples collected up to Day 169 +/- 18 days).

End point type	Secondary
End point timeframe:	
Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)	

Notes:

[63] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Day				
median (full range (min-max))	162.458 (27.79 to 185.75)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: tlast of VIR-7831 after IM administration

End point title	Part C: tlast of VIR-7831 after IM administration ^[64]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. The time frame is beyond Day 169 as there were a few PK samples collected outside of the protocol defined window of +/- 7 days that were included in the analysis (PK samples collected up to Day 169 +/- 18 days).

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[64] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Day				
median (full range (min-max))	168.912 (160.97 to 180.83)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: AUC from Day 1 to 29 (AUCD1-29) of VIR-7831 after IV administration

End point title	Part A: AUC from Day 1 to 29 (AUCD1-29) of VIR-7831 after IV administration ^[65]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29

Notes:

[65] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	1355.2 (± 392.56)	1738.8 (± 308.31)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: AUCD1-29 of VIR-7831 after IV administration

End point title	Part B: AUCD1-29 of VIR-7831 after IV administration ^[66]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29 (+/-2 days)

Notes:

[66] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	1442.9 (\pm 296.96)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: AUCD1-29 of VIR-7831 after IM administration

End point title	Part B: AUCD1-29 of VIR-7831 after IM administration ^[67]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29 (+/-2 days)

Notes:

[67] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	686.9 (\pm 376.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: AUCD1-29 of VIR-7831 after IV administration

End point title	Part C: AUCD1-29 of VIR-7831 after IV administration ^[68]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29 (+/-2 days)

Notes:

[68] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	1405.4 (\pm 528.26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: AUCD1-29 of VIR-7831 after IM administration

End point title	Part C: AUCD1-29 of VIR-7831 after IM administration ^[69]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29 (+/-2 days)

Notes:

[69] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	327.1 (\pm 242.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Area Under the Serum Concentration-time Curve Extrapolated From Zero to Infinity (AUC[0-inf]) of VIR-7831 after IV administration

End point title	Part A: Area Under the Serum Concentration-time Curve Extrapolated From Zero to Infinity (AUC[0-inf]) of VIR-7831 after IV administration ^[70]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[70] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	21		
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	3982.7 (± 1289.19)	5238.4 (± 966.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: AUC(0-inf) of VIR-7831 after IV administration

End point title	Part B: AUC(0-inf) of VIR-7831 after IV administration ^[71]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[71] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	4449.3 (\pm 1123.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: AUC(0-inf) of VIR-7831 after IM administration

End point title	Part B: AUC(0-inf) of VIR-7831 after IM administration ^[72]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[72] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	3194.4 (\pm 1617.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: AUC(0-inf) of VIR-7831 after IV administration

End point title	Part C: AUC(0-inf) of VIR-7831 after IV administration ^[73]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
End point timeframe:	
Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)	
Notes:	
[73] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.	

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	4255.3 (\pm 1369.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: AUC(0-inf) of VIR-7831 after IM administration

End point title	Part C: AUC(0-inf) of VIR-7831 after IM administration ^[74]
End point description:	
Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.	

End point type	Secondary
End point timeframe:	
Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)	
Notes:	
[74] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.	

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	1441.0 (\pm 985.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Area Under the Curve From the Time of Dosing to the Time of the Last Measurable (Positive) Concentration (AUClast) of VIR-7831 after IV administration

End point title	Part A: Area Under the Curve From the Time of Dosing to the Time of the Last Measurable (Positive) Concentration (AUClast) of VIR-7831 after IV administration ^[75]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[75] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	22		
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	3456.5 (± 1086.56)	4528.5 (± 826.89)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: AUClast of VIR-7831 after IV administration

End point title	Part B: AUClast of VIR-7831 after IV administration ^[76]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[76] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	3848.5 (\pm 899.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: AUClast of VIR-7831 after IM administration

End point title	Part B: AUClast of VIR-7831 after IM administration ^[77]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[77] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	2446.5 (\pm 1249.20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: AUClast of VIR-7831 after IV administration

End point title	Part C: AUClast of VIR-7831 after IV administration ^[78]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[78] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	3492.6 (± 1257.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: AUClast of VIR-7831 after IM administration

End point title	Part C: AUClast of VIR-7831 after IM administration ^[79]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[79] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Day*microgram/mL				
arithmetic mean (standard deviation)	1185.8 (± 763.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Percentage of AUC(infinity) Obtained by Extrapolation (%AUCexp) for VIR-7831 after IV administration

End point title	Part A: Percentage of AUC(infinity) Obtained by Extrapolation (%AUCexp) for VIR-7831 after IV administration ^[80]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[80] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	21		
Units: Percentage of AUCexp				
arithmetic mean (standard deviation)	14.9 (± 2.81)	12.6 (± 3.42)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: %AUCexp of VIR-7831 after IV administration

End point title	Part B: %AUCexp of VIR-7831 after IV administration ^[81]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[81] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Percentage of AUCexp				
arithmetic mean (standard deviation)	13.1 (\pm 2.92)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: %AUCexp of VIR-7831 after IM administration

End point title	Part B: %AUCexp of VIR-7831 after IM administration ^[82]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[82] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Percentage of AUCexp				
arithmetic mean (standard deviation)	15.0 (\pm 2.35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: %AUCexp of VIR-7831 after IV administration

End point title	Part C: %AUCexp of VIR-7831 after IV administration ^[83]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[83] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage of AUCexp				
arithmetic mean (standard deviation)	13.6 (± 4.29)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: %AUCexp of VIR-7831 after IM administration

End point title	Part C: %AUCexp of VIR-7831 after IM administration ^[84]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[84] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Percentage of AUCexp				
arithmetic mean (standard deviation)	15.0 (± 2.11)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Terminal Elimination Half-life (t_{1/2}) of VIR-7831 after IV administration

End point title	Part A: Terminal Elimination Half-life (t _{1/2}) of VIR-7831 after IV administration ^[85]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[85] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	21		
Units: Day				
median (full range (min-max))	63.196 (53.98 to 68.09)	55.547 (42.34 to 72.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: t_{1/2} of VIR-7831 after IV administration

End point title	Part B: t _{1/2} of VIR-7831 after IV administration ^[86]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[86] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Day				
median (full range (min-max))	55.735 (47.33 to 66.86)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: t1/2 of VIR-7831 after IM administration

End point title	Part B: t1/2 of VIR-7831 after IM administration ^[87]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[87] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Day				
median (full range (min-max))	59.347 (51.95 to 65.83)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: t1/2 of VIR-7831 after IV administration

End point title	Part C: t1/2 of VIR-7831 after IV administration ^[88]
End point description: Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.	
End point type	Secondary
End point timeframe: Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)	

Notes:

[88] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Day				
median (full range (min-max))	60.938 (42.96 to 70.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: t1/2 of VIR-7831 after IM administration

End point title	Part C: t1/2 of VIR-7831 after IM administration ^[89]
End point description: Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.	
End point type	Secondary
End point timeframe: Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)	

Notes:

[89] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Day				
median (full range (min-max))	61.867 (46.84 to 68.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Apparent Volume of Distribution During the Elimination Phase following intravascular administration (V_z) of VIR-7831

End point title	Part A: Apparent Volume of Distribution During the Elimination Phase following intravascular administration (V _z) of VIR-7831 ^[90]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[90] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	21		
Units: Liter				
arithmetic mean (standard deviation)	12.40 (± 4.625)	7.88 (± 1.374)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: V_z of VIR-7831 after IV administration

End point title	Part B: V _z of VIR-7831 after IV administration ^[91]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[91] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Liter				
arithmetic mean (standard deviation)	9.97 (\pm 2.865)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Apparent Volume of Distribution During the Elimination Phase following extravascular administration (V_z/F) of VIR-7831 after IM administration

End point title	Part B: Apparent Volume of Distribution During the Elimination Phase following extravascular administration (V _z /F) of VIR-7831 after IM administration ^[92]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[92] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Liter				
arithmetic mean (standard deviation)	18.14 (\pm 12.752)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Vz of VIR-7831 after IV administration

End point title	Part C: Vz of VIR-7831 after IV administration ^[93]
End point description: Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.	
End point type	Secondary
End point timeframe: Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)	

Notes:

[93] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Liter				
arithmetic mean (standard deviation)	10.93 (± 3.574)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Vz/F of VIR-7831 after IM administration

End point title	Part C: Vz/F of VIR-7831 after IM administration ^[94]
End point description: Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.	
End point type	Secondary
End point timeframe: Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)	

Notes:

[94] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Liter				
arithmetic mean (standard deviation)	20.24 (±			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Apparent Volume of Distribution at Steady State (Vss) of VIR-7831 after IV administration

End point title	Part A: Apparent Volume of Distribution at Steady State (Vss) of VIR-7831 after IV administration ^[95]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)

Notes:

[95] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	21		
Units: Liter				
arithmetic mean (standard deviation)	11.42 (± 4.110)	7.47 (± 1.232)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Vss of VIR-7831 after IV administration

End point title	Part B: Vss of VIR-7831 after IV administration ^[96]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[96] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Liter				
arithmetic mean (standard deviation)	9.41 (\pm 2.514)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: Vss of VIR-7831 after IV administration

End point title	Part C: Vss of VIR-7831 after IV administration ^[97]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[97] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Liter				
arithmetic mean (standard deviation)	10.61 (\pm 3.973)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Clearance (CL) of VIR-7831 after IV administration

End point title	Part A: Clearance (CL) of VIR-7831 after IV administration ^[98]
End point description: Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.	
End point type	Secondary
End point timeframe: Day 1: Pre-dose, end of infusion and at 1, 2, 6, and 8 hours following end of infusion; Days 2, 5, 8, 15, 29, 43, 57, 85, 141, and 169 (+/-12 days)	

Notes:

[98] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	21		
Units: Milliliter per day				
arithmetic mean (standard deviation)	136.8 (± 42.88)	98.7 (± 18.62)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: CL of VIR-7831 after IV administration

End point title	Part B: CL of VIR-7831 after IV administration ^[99]
End point description: Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.	
End point type	Secondary
End point timeframe: Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)	

Notes:

[99] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Milliliter per day				
arithmetic mean (standard deviation)	120.3 (± 35.96)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Apparent Clearance (CL/F) of VIR-7831 after IM administration

End point title	Part B: Apparent Clearance (CL/F) of VIR-7831 after IM administration ^[100]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-7 days)

Notes:

[100] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Milliliter per day				
arithmetic mean (standard deviation)	216.2 (± 162.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: CL of VIR-7831 after IV administration

End point title	Part C: CL of VIR-7831 after IV administration ^[101]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose, end of infusion; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[101] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 500 mg IV			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Milliliter per day				
arithmetic mean (standard deviation)	130.5 (± 47.83)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part C: CL/F of VIR-7831 after IM administration

End point title	Part C: CL/F of VIR-7831 after IM administration ^[102]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[102] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part C- Sotrovimab Gen2: 250 mg IM			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Milliliter per day				
arithmetic mean (standard deviation)	237.8 (± 125.67)			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized Least Square Geometric Mean Ratio of AUCinf for VIR-

7831 Gen2 Between the Three Dose Levels (250 mg IM in Part C, 500 mg IM in Part B and 500 mg IV in Parts B and C)

End point title	Dose-normalized Least Square Geometric Mean Ratio of AUCinf for VIR-7831 Gen2 Between the Three Dose Levels (250 mg IM in Part C, 500 mg IM in Part B and 500 mg IV in Parts B and C) ^[103]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Dose-normalized least square geometric mean ratio of AUCinf was derived based on collected assessments up to 169 (+/-7 days) for Part B- Sotrovimab Gen2: 500 mg IV arm, and up to 169 (+/-18 days) for Part C- Sotrovimab Gen2: 500 mg IV arm. Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed. Data from Parts B and C is presented in a single outcome to determine the absolute bioavailability (F) based on the loge transformed dose normalized AUCinf for the IV (500 mg), IM (500 mg), and IM (250 mg). Data for 500 mg IV arms with similar dosing strategies across Parts B and C is combined as pre-specified in reporting and analysis plan.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[103] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 250 mg IM	Sotrovimab Gen2: 500 mg IV (Parts B and C)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	8	8	20	
Units: Day*microgram/mL				
least squares mean (confidence interval 90%)	5.52 (4.25 to 7.16)	4.86 (3.75 to 6.30)	8.40 (7.12 to 9.90)	

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Drug bioavailability was analyzed using an ANCOVA model with treatment and weight at Baseline as covariates.

Comparison groups	Part B- Sotrovimab Gen2: 500 mg IM v Sotrovimab Gen2: 500 mg IV (Parts B and C)
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	0.66
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.48
upper limit	0.89

Statistical analysis title	Statistical analysis 2
Statistical analysis description: Drug bioavailability was analyzed using an ANCOVA model with treatment and weight at Baseline as covariates.	
Comparison groups	Part C- Sotrovimab Gen2: 250 mg IM v Sotrovimab Gen2: 500 mg IV (Parts B and C)
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	0.58
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.43
upper limit	0.79

Secondary: Dose-normalized Least Square Geometric Mean Ratio of AUCinf for VIR-7831 Gen2 Between the Two IM Dose Levels (250 mg IM in Part C and 500 mg IM in Part B)

End point title	Dose-normalized Least Square Geometric Mean Ratio of AUCinf for VIR-7831 Gen2 Between the Two IM Dose Levels (250 mg IM in Part C and 500 mg IM in Part B) ^[104]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified data points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[104] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	8		
Units: Day*microgram per milliliter				
least squares mean (confidence interval 90%)	5.56 (3.81 to 8.11)	4.86 (3.33 to 7.09)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Dose proportionality was analyzed using an ANOVA model with treatment (250mg, 500mg) as a covariate, for each parameter of interest.	
Comparison groups	Part B- Sotrovimab Gen2: 500 mg IM v Part C- Sotrovimab Gen2: 250 mg IM
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.14
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.67
upper limit	1.95

Secondary: Dose-normalized Least Square Geometric Mean Ratio of AUClast for VIR-7831 Gen2 Between the Two IM Dose Levels (250 mg IM in Part C and 500 mg IM in Part B)

End point title	Dose-normalized Least Square Geometric Mean Ratio of AUClast for VIR-7831 Gen2 Between the Two IM Dose Levels (250 mg IM in Part C and 500 mg IM in Part B) ^[105]
End point description: Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.	
End point type	Secondary
End point timeframe: Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)	

Notes:

[105] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: Day*microgram per milliliter				
least squares mean (confidence interval 90%)	4.31 (3.21 to 5.77)	4.05 (2.98 to 5.51)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Dose proportionality was analyzed using an ANOVA model with treatment (250mg, 500mg) as a covariate, for each parameter of interest.	
Comparison groups	Part B- Sotrovimab Gen2: 500 mg IM v Part C- Sotrovimab Gen2: 250 mg IM
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.06
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.69
upper limit	1.62

Secondary: Dose-normalized Least Square Geometric Mean Ratio of AUCD1-D29 for VIR-7831 Gen2 Between the Two IM Dose Levels (250 mg IM in Part C and 500 mg IM in Part B)

End point title	Dose-normalized Least Square Geometric Mean Ratio of AUCD1-D29 for VIR-7831 Gen2 Between the Two IM Dose Levels (250 mg IM in Part C and 500 mg IM in Part B) ^[106]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29 (+/-2 days)

Notes:

[106] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: Day*microgram per milliliter				
least squares mean (confidence interval 90%)	1.17 (0.83 to 1.65)	1.06 (0.74 to 1.51)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Dose proportionality was analyzed using an ANOVA model with treatment (250mg, 500mg) as a

covariate, for each parameter of interest.

Comparison groups	Part B- Sotrovimab Gen2: 500 mg IM v Part C- Sotrovimab Gen2: 250 mg IM
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.11
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.68
upper limit	1.82

Secondary: Dose-normalized Least Square Geometric Mean Ratio of Cmax for VIR-7831 Gen2 Between the Two IM Dose Levels (250 mg IM in Part C and 500 mg IM in Part B)

End point title	Dose-normalized Least Square Geometric Mean Ratio of Cmax for VIR-7831 Gen2 Between the Two IM Dose Levels (250 mg IM in Part C and 500 mg IM in Part B) ^[107]
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End point description:

Blood samples were collected at indicated time points for pharmacokinetic analysis of VIR-7831 (Sotrovimab). Pharmacokinetic Population. Only those participants with data available at the specified time points were analyzed.

End point type	Secondary
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End point timeframe:

Day 1: Pre-dose; Days 2, 3, 5, 8, 15, 29, 57, 85, 141, and 169 (+/-18 days)

Notes:

[107] - 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 is only reporting on a subset of the arms that are contained in the Baseline period.

End point values	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 250 mg IM		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: Microgram per milliliter				
least squares mean (confidence interval 90%)	0.05 (0.04 to 0.07)	0.04 (0.03 to 0.06)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Dose proportionality was analyzed using an ANOVA model with treatment (250mg, 500mg) as a covariate, for each parameter of interest.

Comparison groups	Part B- Sotrovimab Gen2: 500 mg IM v Part C- Sotrovimab
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	Gen2: 250 mg IM
Number of subjects included in analysis	18
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Ratio of geometric least squares mean
Point estimate	1.28
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.77
upper limit	2.12

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, non-serious AEs and SAEs were collected up to Week 24 in Part A; and up to Week 36 in Parts B and C of the study

Adverse event reporting additional description:

Safety Population consisted of all randomized participants who were exposed to study intervention.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	Part C- Sotrovimab Gen2: 500 mg IV
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Reporting group description: -	
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Reporting group title	Part A- Sotrovimab Gen1: 500 mg IV
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Reporting group description: -	
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Reporting group title	Part A- Sotrovimab Gen2: 500 mg IV
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Reporting group description: -	
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Reporting group title	Part B- Sotrovimab Gen2: 500 mg IM
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Reporting group description: -	
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Reporting group title	Part C- Sotrovimab Gen2: 250 mg IM
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Reporting group description: -	
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Reporting group title	Part B- Sotrovimab Gen2: 500 mg IV
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Reporting group description: -	
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Serious adverse events	Part C- Sotrovimab Gen2: 500 mg IV	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 79 (2.53%)	0 / 8 (0.00%)	0 / 22 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Incisional hernia			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (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 COVID-19 pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 79 (1.27%) 0 / 1 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 22 (0.00%) 0 / 0 0 / 0
Pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 79 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 22 (0.00%) 0 / 0 0 / 0
Coronavirus pneumonia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 79 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 22 (0.00%) 0 / 0 0 / 0
Metabolism and nutrition disorders Dehydration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 79 (0.00%) 0 / 0 0 / 0	0 / 8 (0.00%) 0 / 0 0 / 0	0 / 22 (0.00%) 0 / 0 0 / 0

Serious adverse events	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 250 mg IM	Part B- Sotrovimab Gen2: 500 mg IV
Total subjects affected by serious adverse events subjects affected / exposed number of deaths (all causes) number of deaths resulting from adverse events	2 / 82 (2.44%) 0	3 / 78 (3.85%) 1	1 / 84 (1.19%) 0
Injury, poisoning and procedural complications Incisional hernia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 82 (0.00%) 0 / 0 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	0 / 84 (0.00%) 0 / 0 0 / 0
Respiratory, thoracic and mediastinal disorders Acute respiratory failure subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 82 (1.22%) 0 / 1 0 / 0	0 / 78 (0.00%) 0 / 0 0 / 0	0 / 84 (0.00%) 0 / 0 0 / 0
Infections and infestations			

COVID-19 pneumonia			
subjects affected / exposed	0 / 82 (0.00%)	3 / 78 (3.85%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (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
Coronavirus pneumonia			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (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

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Part C- Sotrovimab Gen2: 500 mg IV	Part A- Sotrovimab Gen1: 500 mg IV	Part A- Sotrovimab Gen2: 500 mg IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 79 (20.25%)	0 / 8 (0.00%)	6 / 22 (27.27%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Superficial vein thrombosis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			

Injection site pain subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Injection site nodule subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Injection site discomfort subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Feeling abnormal subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Sleep apnoea syndrome subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Anxiety			

subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Conversion disorder			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Investigations			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 79 (2.53%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			

subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Migraine subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	1 / 22 (4.55%) 1
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Motion sickness subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Eye disorders Episcleritis subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Aphthous ulcer subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	0 / 8 (0.00%) 0	0 / 22 (0.00%) 0
Dyspepsia			

subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 79 (2.53%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Uvulitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	2 / 79 (2.53%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	3 / 79 (3.80%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Folliculitis			
subjects affected / exposed	2 / 79 (2.53%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Cellulitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			

subjects affected / exposed	1 / 79 (1.27%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Blister infected			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Helicobacter gastritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Hyperlipasaemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 8 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B- Sotrovimab Gen2: 500 mg IM	Part C- Sotrovimab Gen2: 250 mg IM	Part B- Sotrovimab Gen2: 500 mg IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 82 (24.39%)	16 / 78 (20.51%)	8 / 84 (9.52%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	2 / 82 (2.44%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	10 / 82 (12.20%)	2 / 78 (2.56%)	0 / 84 (0.00%)
occurrences (all)	13	2	0
Injection site nodule			
subjects affected / exposed	1 / 82 (1.22%)	1 / 78 (1.28%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
Injection site discomfort			
subjects affected / exposed	0 / 82 (0.00%)	1 / 78 (1.28%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0

Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 82 (0.00%)	1 / 78 (1.28%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 82 (0.00%)	1 / 78 (1.28%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Conversion disorder			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Investigations			
Brain natriuretic peptide increased			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	1 / 84 (1.19%) 1
Limb injury subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	1 / 84 (1.19%) 2
Restless legs syndrome subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	2 / 84 (2.38%) 2
Headache subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Migraine subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	1 / 78 (1.28%) 3	0 / 84 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	1 / 84 (1.19%) 1
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	1 / 78 (1.28%) 1	0 / 84 (0.00%) 0
Ear and labyrinth disorders Vertigo			

subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1	1 / 78 (1.28%) 1	0 / 84 (0.00%) 0
Motion sickness subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Eye disorders Episcleritis subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	1 / 78 (1.28%) 1	0 / 84 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Aphthous ulcer subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	1 / 84 (1.19%) 1
Dyspepsia subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Paraesthesia oral subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	1 / 84 (1.19%) 1
Nausea subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Uvulitis			

subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Hepatobiliary disorders Hypertransaminasaemia subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Skin and subcutaneous tissue disorders Urticaria subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Alopecia subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1 0 / 82 (0.00%) 0 0 / 82 (0.00%) 0	1 / 78 (1.28%) 1 0 / 78 (0.00%) 0 1 / 78 (1.28%) 1	0 / 84 (0.00%) 0 0 / 84 (0.00%) 0 0 / 84 (0.00%) 0
Renal and urinary disorders Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) Neck pain subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all) Pain in jaw subjects affected / exposed occurrences (all) Arthralgia subjects affected / exposed occurrences (all)	2 / 82 (2.44%) 2 0 / 82 (0.00%) 0 0 / 82 (0.00%) 0 1 / 82 (1.22%) 1 1 / 82 (1.22%) 1	0 / 78 (0.00%) 0 1 / 78 (1.28%) 1 0 / 78 (0.00%) 0 0 / 78 (0.00%) 0 0 / 78 (0.00%) 0	0 / 84 (0.00%) 0 1 / 84 (1.19%) 1 1 / 84 (1.19%) 1 0 / 84 (0.00%) 0 0 / 84 (0.00%) 0

Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 82 (1.22%)	1 / 78 (1.28%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
Folliculitis			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 82 (1.22%)	2 / 78 (2.56%)	0 / 84 (0.00%)
occurrences (all)	1	2	0
Urinary tract infection			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 82 (0.00%)	1 / 78 (1.28%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 82 (0.00%)	1 / 78 (1.28%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	1 / 82 (1.22%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
Acute sinusitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Blister infected			
subjects affected / exposed	0 / 82 (0.00%)	0 / 78 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Helicobacter gastritis			

subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	3 / 78 (3.85%) 3	0 / 84 (0.00%) 0
Metabolism and nutrition disorders			
Dehydration subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	1 / 84 (1.19%) 1
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1	0 / 78 (0.00%) 0	0 / 84 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	1 / 78 (1.28%) 1	0 / 84 (0.00%) 0
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 78 (0.00%) 0	1 / 84 (1.19%) 1
Hyperlipasaemia subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	1 / 78 (1.28%) 1	0 / 84 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 January 2021	Amendment 1: Protocol changes have been made to include nasal mid-turbinate swabs and resistance testing at the request of regulatory agencies.
03 March 2021	Amendment 2: Protocol changes have been made to add a second part (Part B) to this study to assess IM injection of VIR-7831 Gen2 material. The original treatment arms evaluating Gen2 and Gen1 material administered IV is designated Part A. Changes were made throughout the protocol to add information necessary for conducting Part B and to differentiate Part A and Part B procedures. Other changes include: removal of home nursing option for Part A study visits, an additional endpoint for the secondary safety objective for Part A, updates to endpoint wording for Part A, the addition of resistance analyses, updated background information based on new data, and clarifications throughout the protocol
08 April 2021	Amendment 3: Adding measurement of anti-Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) antibody at Baseline and Day 29 to the study procedures to allow for exploratory analysis of immune response. Removing the requirement that at least 15 participants are enrolled in Part A before enrollment in Part B can begin so that Part B can begin without delay
18 May 2021	Amendment 4: Protocol changes have been made to add a third part (Part C) to this study to assess the safety, tolerability, immunogenicity, pharmacokinetics, and viral pharmacodynamics of a 250 milligram (mg) dose of VIR-7831 administered by IM injection. Changes were made throughout the protocol to add information necessary for conducting Part C procedures. Additionally, the post-dose monitoring time for Part B has been reduced to 1 hour after Joint Safety Review Team (JSRT) review on 13 May 2021. Other changes include: moving resistance analysis to an exploratory objective, providing updated data, clarification of inclusion and exclusion criteria, incorporated information from the Germany-specific protocol amendment, and other clarifications throughout the protocol.
29 October 2021	Amendment 5: Expanded the safety follow-up of all active participants through Week 36 (~5 half lives of sotrovimab).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported